wcg™ velos

eResearch User Guide

Version 13.0

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1 About This Guide

This document presents the following topics:

- An overview of Velos eResearch
- Login and System Navigation
- Personalizing the Velos eResearch experience by changing account settings and utilizing customizable features
- Creating foundational account elements such as organizations, groups, users, quick links, and account forms
- Managing studies, study status and study team members
- Submit study or site documents for WCG IRB Review
- Creating foundational study elements in the library such as events, calendars, fields, and forms
- Managing patient enrollment, statuses, and demographic information
- Analysis and management of study finances
- Pulling reports using Report Central and the Ad-Hoc Query tool (AHQ)
- Utilization of the Dashboard

Note:
1. Depending on your specific permissions, some functions described in this guide may not appear in your user interface. If you see a functionality that you believe you should have access to, please contact your system administrator for assistance.
2. eResearch is 21 CFR Compliant.

1.1 Who Should Use It?

This guide is intended for system users tasked with functionalities associated with system administration, patient management, and financial responsibilities who need to create foundational account elements, review study, patient, financial and system data, and maintain the system.

This guide assumes users have a knowledge of managing patient data, clinical trial management systems, and clinical trial regulatory requirements.

2 General Information – Getting Started

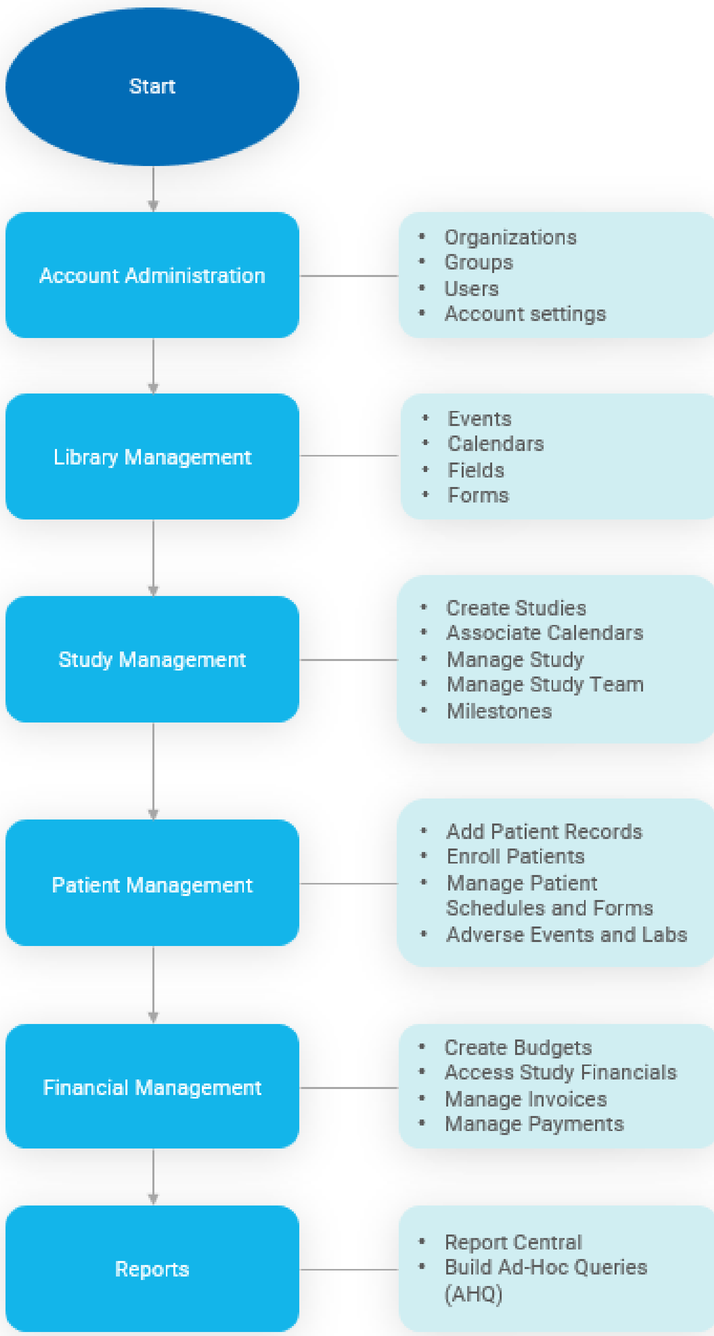
Velos eResearch is a software system to manage clinical trials, also known as a Clinical Trial Management System (CTMS).

This guide will cover system functionalities in both the Velos eResearch Enterprise and Velos eResearch eXpress versions. Some functionalities may not be available based on your system.

eResearch Enterprise	eResearch eXpress
In the Enterprise version, CTMS functionality is available including Study Management, Patient Management, Adverse Event tracking, Labs, Forms, Calendars, Financial Management, Reporting and Ad-Hoc Queries. Additional functionality available includes: eSample, eCompliance, Networks, Participant Portal, and WCG IRB.	The eResearch eXpress platform provides CTMS functionality which includes Study Management, Patient Management, Forms, Calendars, Financial Management, Reporting and Ad-Hoc Queries along with defined user permissions.

2.1 Recommended System Configuration Workflow

The following diagram presents the recommended workflow for initial configuration, and identifies the high-level tasks associated with each step.



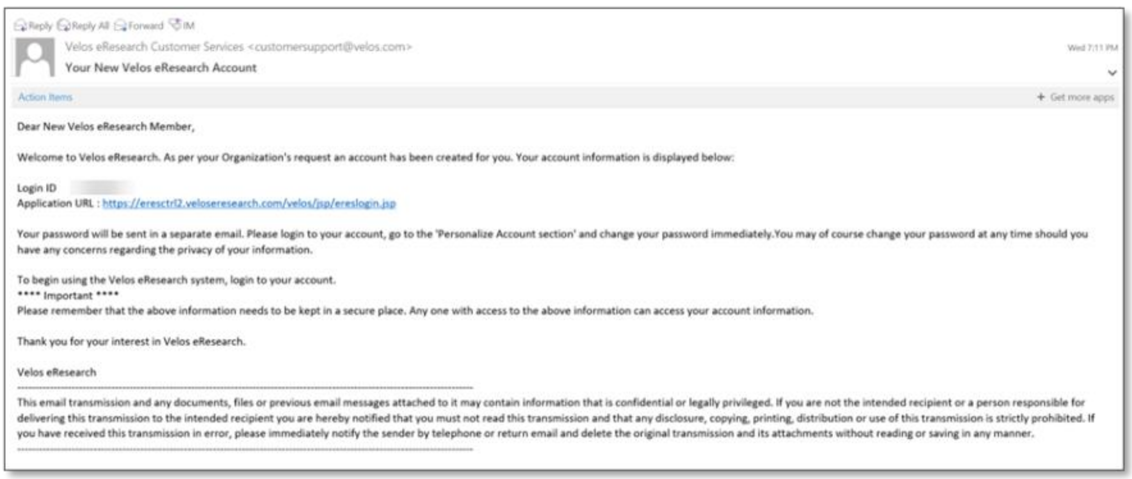
2.2 System Access

The Velos Implementation Team will provide the initial access to the System Admin who then will create and manage user accounts. For more information on how to add users to Velos eResearch see the Users section.

> **Note:** This section is not applicable to users with Single Sign On (SSO) access to eResearch.

After a user account has been created, users will receive two welcome emails.

The first email contains the user's Username (Login ID) and Application URL.



Reply Reply All Forward IM

Velos eResearch Customer Services <customersupport@velos.com>

Wed 7:11 PM

Your New Velos eResearch Account

Action Items

+ Get more apps

Dear New Velos eResearch Member,

Welcome to Velos eResearch. As per your Organization's request an account has been created for you. Your account information is displayed below:

Login ID
Application URL : https://eresctrl2.veloseresearch.com/velos/jsp/ereslogin.jsp

Your password will be sent in a separate email. Please login to your account, go to the 'Personalize Account section' and change your password immediately.You may of course change your password at any time should you have any concerns regarding the privacy of your information.

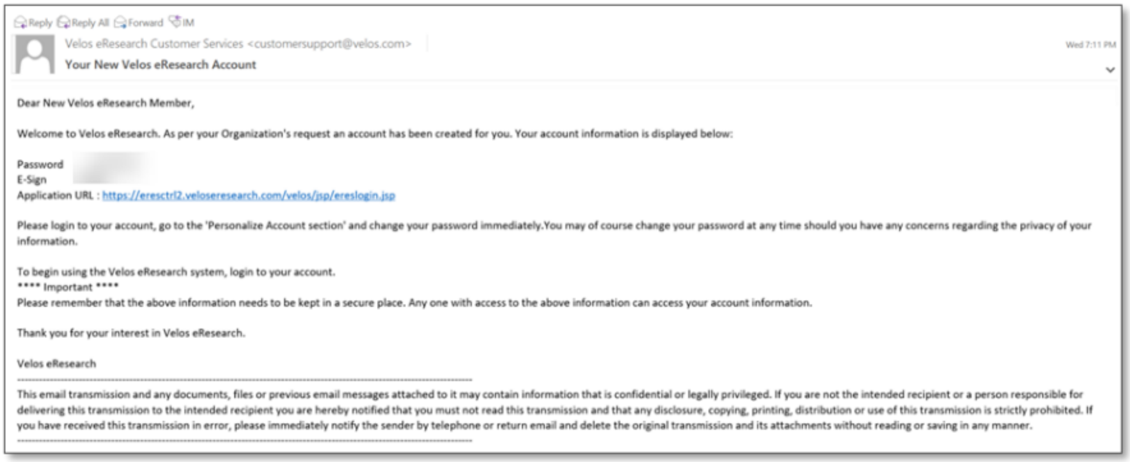
To begin using the Velos eResearch system, login to your account.
**** Important ****
Please remember that the above information needs to be kept in a secure place. Any one with access to the above information can access your account information.

Thank you for your interest in Velos eResearch.

Velos eResearch

This email transmission and any documents, files or previous email messages attached to it may contain information that is confidential or legally privileged. If you are not the intended recipient or a person responsible for delivering this transmission to the intended recipient you are hereby notified that you must not read this transmission and that any disclosure, copying, printing, distribution or use of this transmission is strictly prohibited. If you have received this transmission in error, please immediately notify the sender by telephone or return email and delete the original transmission and its attachments without reading or saving in any manner.

The second email contains the user's Password, e-Signature, and Application URL.


Reply Reply All Forward IM

Velos eResearch Customer Services <customersupport@velos.com>

Wed 7:11 PM

Your New Velos eResearch Account

Dear New Velos eResearch Member,

Welcome to Velos eResearch. As per your Organization's request an account has been created for you. Your account information is displayed below:

Password
E-Sign
Application URL : https://eresctrl2.veloseresearch.com/velos/jsp/ereslogin.jsp

Please login to your account, go to the 'Personalize Account section' and change your password immediately.You may of course change your password at any time should you have any concerns regarding the privacy of your information.

To begin using the Velos eResearch system, login to your account.
**** Important ****
Please remember that the above information needs to be kept in a secure place. Any one with access to the above information can access your account information.

Thank you for your interest in Velos eResearch.

Velos eResearch

This email transmission and any documents, files or previous email messages attached to it may contain information that is confidential or legally privileged. If you are not the intended recipient or a person responsible for delivering this transmission to the intended recipient you are hereby notified that you must not read this transmission and that any disclosure, copying, printing, distribution or use of this transmission is strictly prohibited. If you have received this transmission in error, please immediately notify the sender by telephone or return email and delete the original transmission and its attachments without reading or saving in any manner.

Note: A user's e-Signature is a unique 4 to 8-digit code that is used to save pages throughout Velos eResearch Enterprise and Velos eResearch eXpress.

2.2.1 Logging In / Logging Out

To log into the system users will need their username and password, as defined by their welcome emails. If you have not received your welcome emails and require access, contact your system administrator for more information.

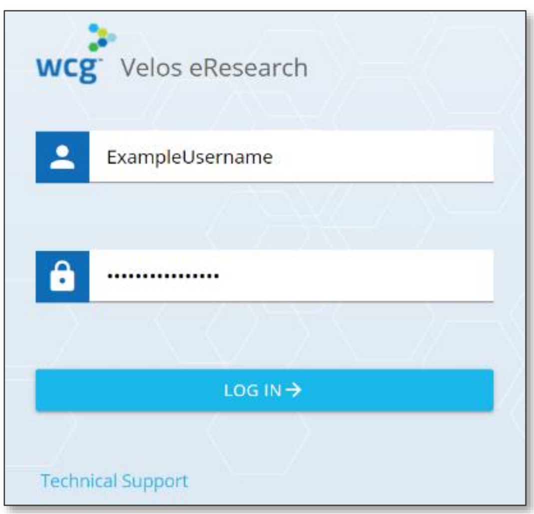
2.2.1.1 Logging In

After receiving login credentials via emails, users can log in to Velos eResearch. For more information about the welcome emails, see the System Access section. For information on how to change your password, see Password / e-Signature.

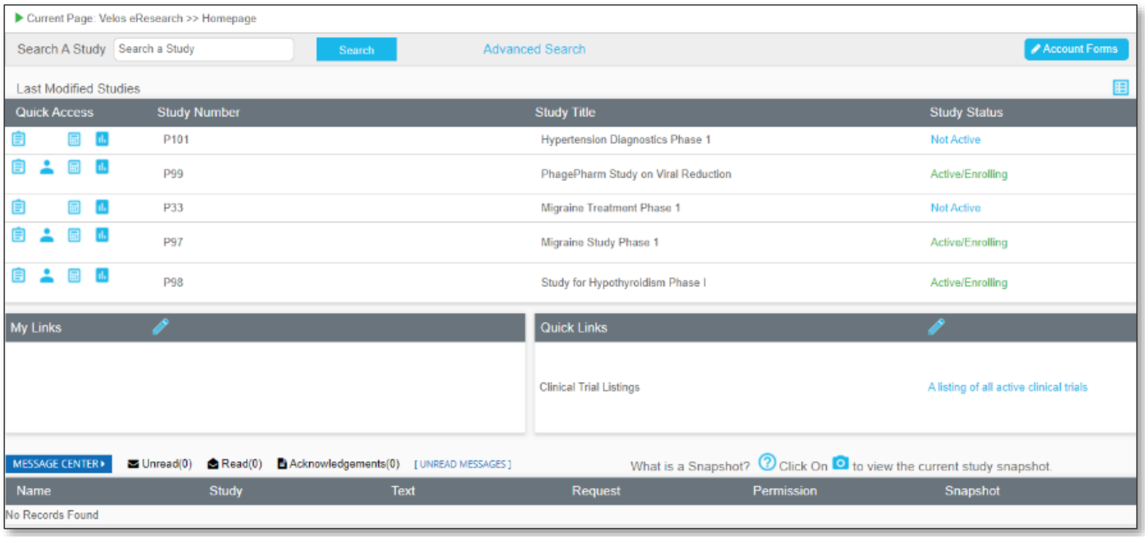
To log in to Velos eResearch:

1. Using a system-supported browser, open the Velos eResearch login page by clicking the application URL found in either of your welcome emails. The Velos eResearch login page will display:

2. Enter the username and password found in your two welcome emails, and click **LOG IN**.



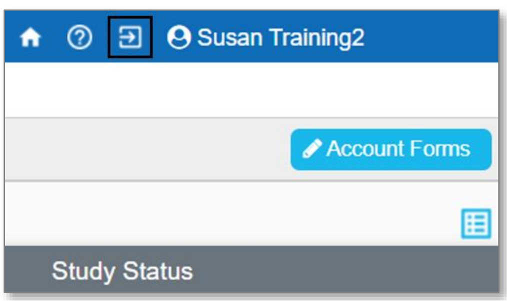
The default homepage displays.



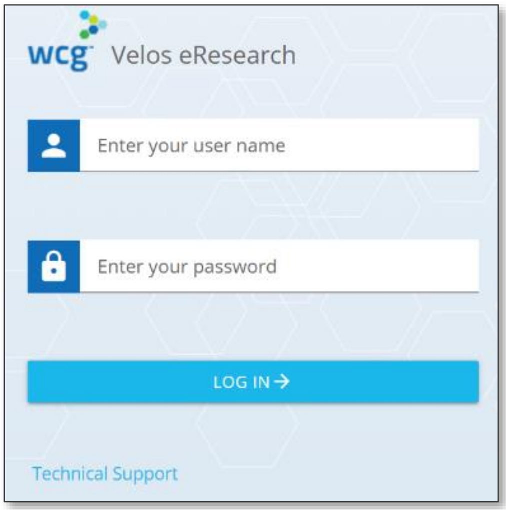
2.2.1.2 Logging Out

To log out of Velos eResearch:

1. Click **Logout** button on the top navigation bar within Velos eResearch.



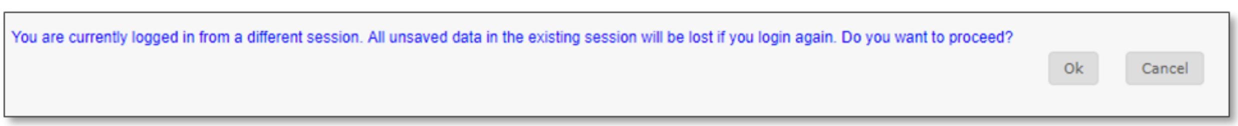
2. After clicking the Logout button, the user's active session will end, and the Velos eResearch login page displays:



Warning: If the browser window is closed instead of using Logout, your active session will persist, and you may lose any unsaved information that you were working on prior to closing the browser. Review the Terminate an Active Session section to learn more about terminating an active session.

2.2.2 Terminate an Active Session

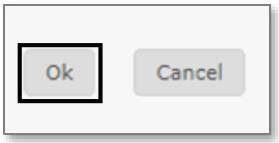
If a user loses internet connection unexpectedly, or closes the browser window without logging out properly, their session remains active until the automatic logout time is reached (default automatic logout time is 15 minutes). If a user attempts to log into Velos eResearch when their session is still active, a warning message will appear as shown below:



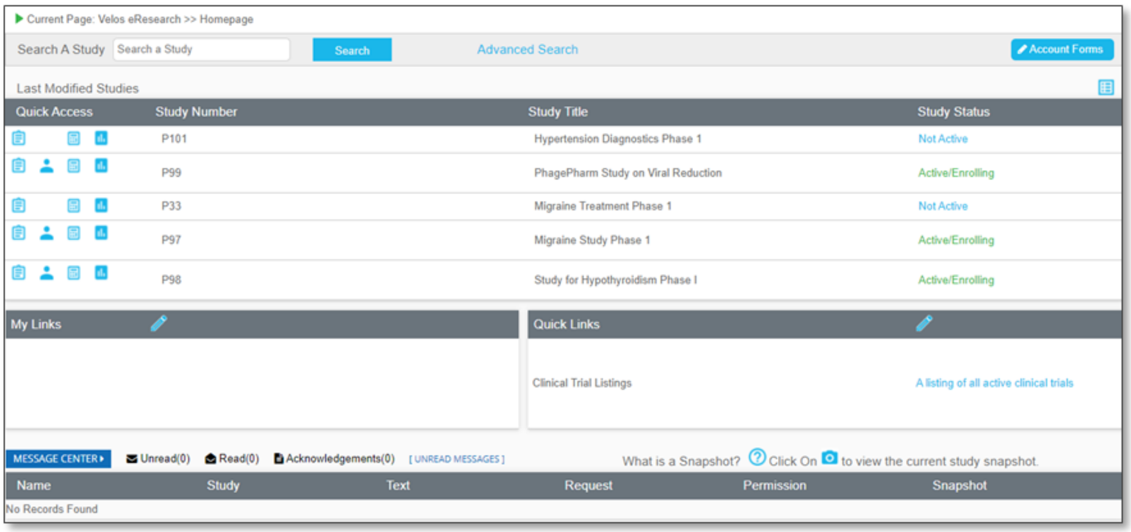
Note: Velos eResearch does not allow concurrent sessions.

To terminate an active session:

1. Click **OK** on the left side of the warning message.

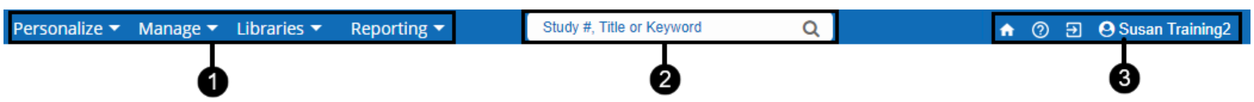


After clicking OK, a new active session will begin, and the homepage will display:



3 System Navigation

Navigation throughout the Velos eResearch application will vary, depending on the task, your specific permissions, and the page you are viewing. Information on navigating within specific pages will be discussed in each functional section of this user guide. However, there are some consistent, basic elements of the application located at the top of the page that you can use to navigate the system, regardless of which page you are using. Review the following diagram below to understand the basic elements of system navigation:



1. **Navigation menus**: Allows you to navigate to core system pages which include Personalize, Manage, Libraries, or Reporting menus.
2. **System Search Bar**: Allows you to search for a Study that the user logged into the system has access to by using the Study Number, Study Title, and Keywords defined on the study Summary / Study Details page.
3. Home, User Guide, and Logout buttons:

Icon	Name	Description
	**Home**	Takes you to your default homepage as defined on the Settings page. See the Personalize section for more information about setting a default homepage.
	**User Manual**	Displays the most recent system user guide for your reference in a new tab.
	**Logout**	Securely logs you out of the system.

Note: When using the search bar, Velos eResearch will only return data that the searching user has access to. For information on user access rights, see the Groups section or Appendix E – Permission Types and Appendix F – Study Role Permissions.

4 Personalize

Velos eResearch provides the user the ability to modify their account information and personalize their experience in the application through the use of the Personalize menu. This menu provides access to the following pages, as described in the subsequent user guide sections:

- My Profile
- My Links
- Settings
- Password/e-Sign

4.1 My Profile

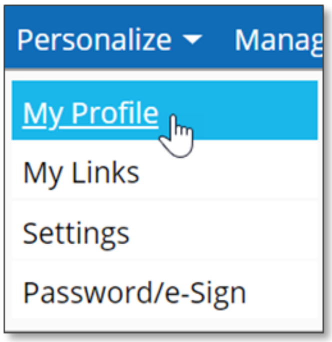
The My Profile page provides a means to change basic account information such as an address, phone number, email address, and research involvement details. This information can be changed at any time from this screen, requiring only a valid e-Signature.

Note: To ensure access rights are granted appropriately in eResearch, it is not recommended to make changes to "My Profile", unless instructed by your system administrator.

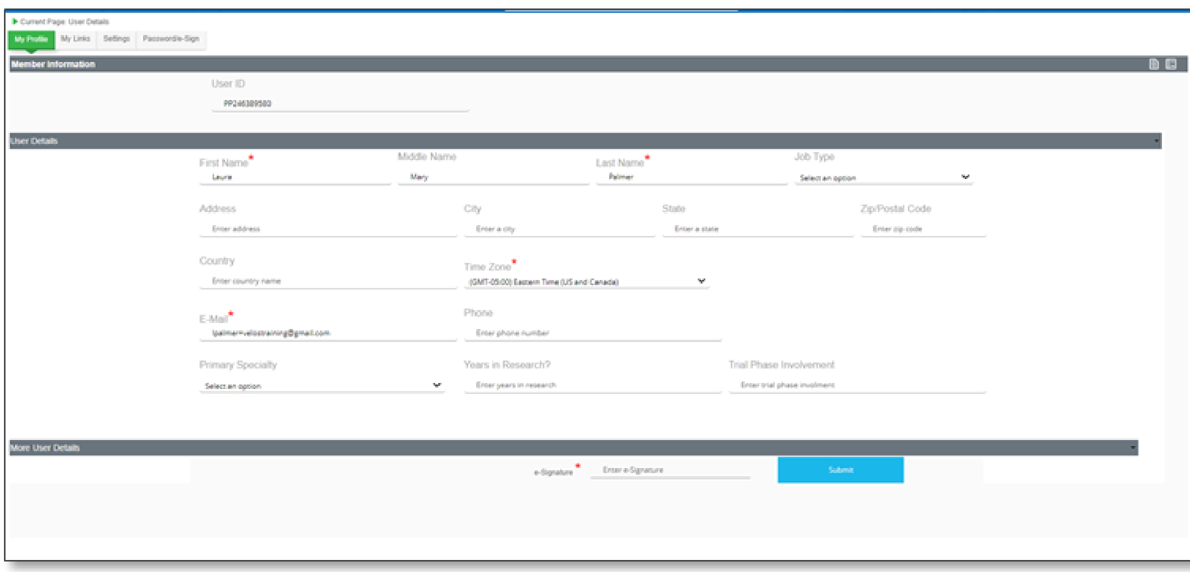
Warning: Adding a Specialty on My Profile will prevent users from seeing patients and studies.

To change details on the My Profile screen:

1. Click the **Personalize** menu in the upper-left hand corner of the screen and select **My Profile**.



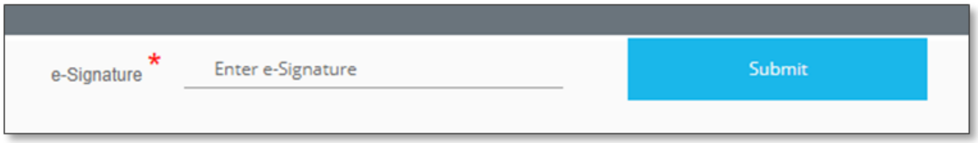
The My Profile page displays:



2. Add or enter information as needed.

Note: A red asterisk denotes a mandatory field.

3. Enter your e-Signature (see the System Access section for information about obtaining your initial e-Signature from your Welcome email) in the field at the bottom of the page and click **Submit** to confirm.



4.2 My Links

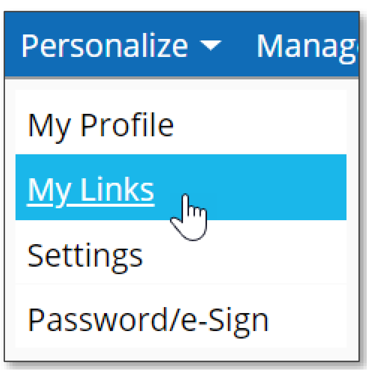
It is possible to include links to external pages within Velos eResearch as a resource, if needed. If added, links will be displayed on the default Homepage within the My Links section. The My Links page allows users to add, modify and delete links. Links added here are only viewable to the end user who created the link.

4.2.1 Add Links

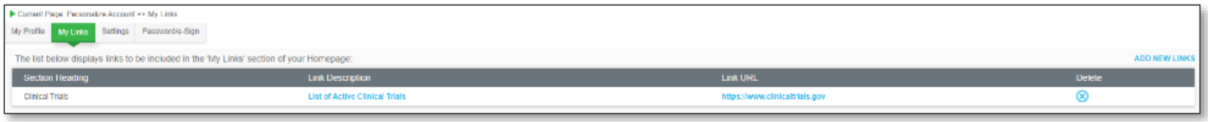
Users can add links to the My Links section of their default homepage using the Personalize menu.

To add new links to the My Links section of the default homepage:

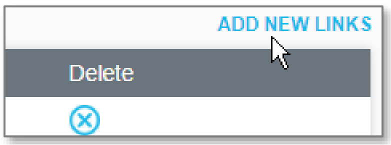
1. Click the **Personalize** menu in the upper-left hand corner of the screen and select **My Links**.



The My Links page displays:



2. Add new links by clicking **Add News Links** on the right side of the screen.



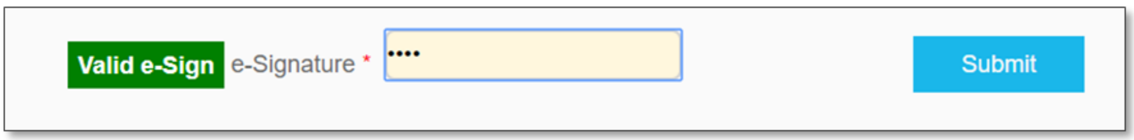
The Enter Link Details page displays:

3. Enter the required information into the available fields including Section Heading, URL, and Description details. The description entered here will be the active link visible on the user's homepage within the My Links gadget.

Note: Section headings organize your links by grouping them together under the same description. If you would like multiple URLs to display under the same section heading, enter the same section heading text for each entry. Ensure that any documents you add to an existing heading uses the same spelling and punctuation that was used in the existing section heading.

Warning: When entering a URL, it must contain either http:// or https:// for the links to work properly. Failing to do so will result in broken, unusable links.

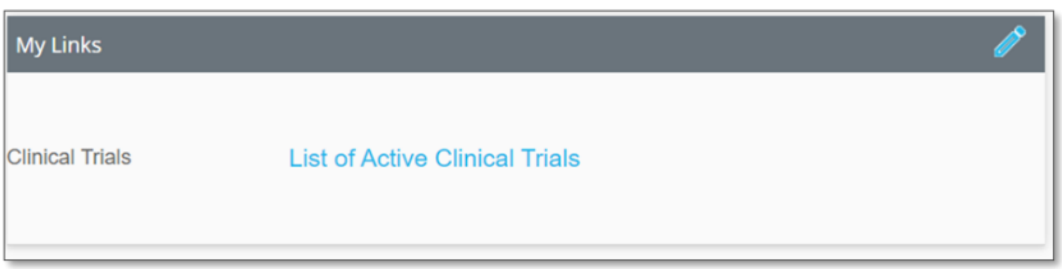
4. To save the new links, enter your e-Signature and click **Submit** to confirm.



The new links have been added and now display within the My Links section of the default Homepage and on the My Links page.

My Links page view:

Default Homepage view:

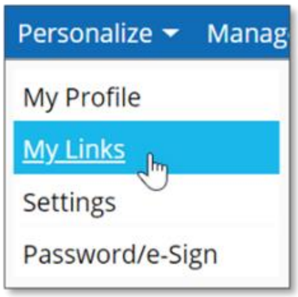


4.2.2 Modify Links

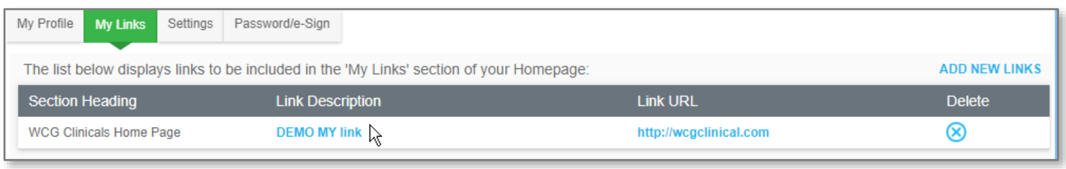
Users can modify links that already exist on the My Links section of their homepage using the Personalize menu.

To modify existing links:

1. Navigate to the My Links page by clicking the **Personalize** menu in the upper-left hand corner of the screen and selecting **My Links**.

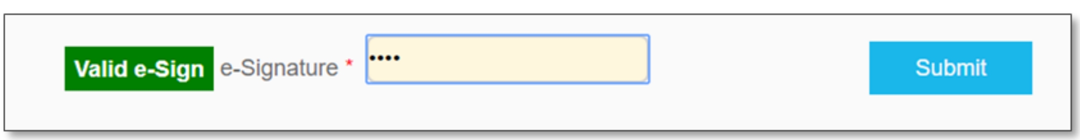


2. Click the link within the **Link Description** column of the entry you would like to modify.



The Enter Link Details page displays:

3. Update the required information, enter your e-Signature, and click **Submit** to confirm.



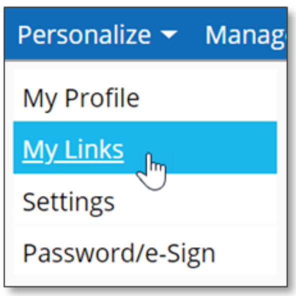
The updates now display on the My Links page and within the My Links section of the Homepage.

4.2.3 Delete Links

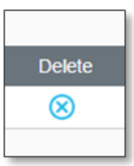
Users can remove links that already exist on the My Links section of their homepage using the Personalize menu.

To delete existing links:

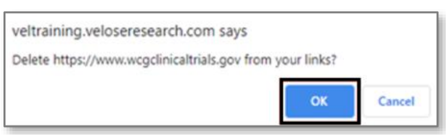
1. Navigate to the My Links page by clicking the **Personalize** menu in the upper-left hand corner of the screen and selecting **My Links**.



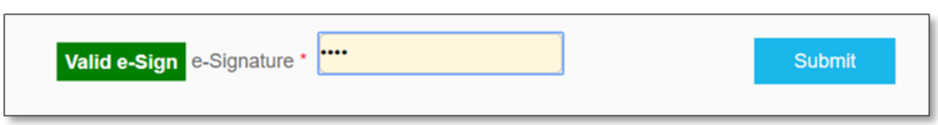
2. Click the **Delete** button in the Delete column next to the link you would like to delete.



3. Click **OK** to confirm, in the pop-up message.



4. To confirm the deletion, enter your e-Signature and click **Submit** to confirm.



After clicking Submit, the link is permanently removed from the system.

4.3 Settings

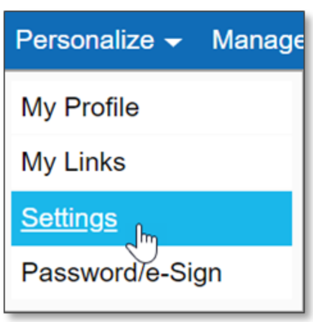
Within Velos eResearch, users have the option to specify the automatic logout time for their account, and to select their default landing page. The **Automatic Logout Time** feature protects the privacy and security of the user's account by logging them out automatically after a period of inactivity.

Note:
1. Users can change their automatic logout time if not restricted.
2. Logout time is displayed in minutes and can range in time from 15-300 minutes.
3. Settings changed on the Settings page affect only your account.

In addition, each user has the option to define the default landing page for their functional role. For example, a finance user may prefer to have the Budgets page as their default landing page instead of My Homepage.

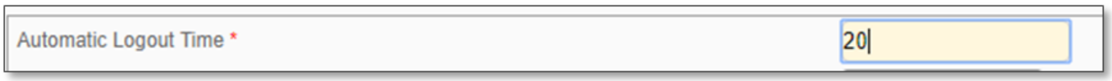
To access the Settings page:

1. Click on the **Personalize** menu and select **Settings**.



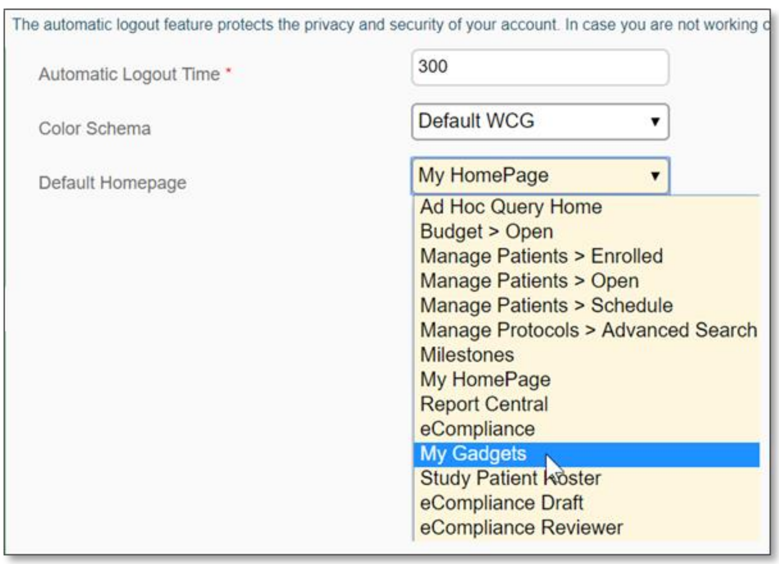
The Settings page displays:

2. Change the automatic logout time for your account by replacing the value (in minutes) in the **Automatic Logout Time** field.

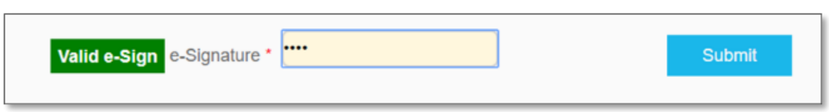


-OR-

If you would like to only, or also, change the default landing page for your account, select the appropriate option from the **Default Homepage** dropdown menu. For more information on Homepage options, refer to Homepage Options.



3. After making the desired changes, enter your e-Signature and click **Submit** to confirm.



The account setting changes have been saved.

Note: For any account setting changes to take effect, you must first log out and log back into Velos eResearch.

4.3.1 Homepage Options

There are many homepage options to select from. My Homepage is the system default option. “My Gadgets” is a homepage frequently used by financial personnel. For system users who primarily work with patient records, the “Study Patient Roster” homepage is frequently used.

Review the table below for more information about each Homepage.

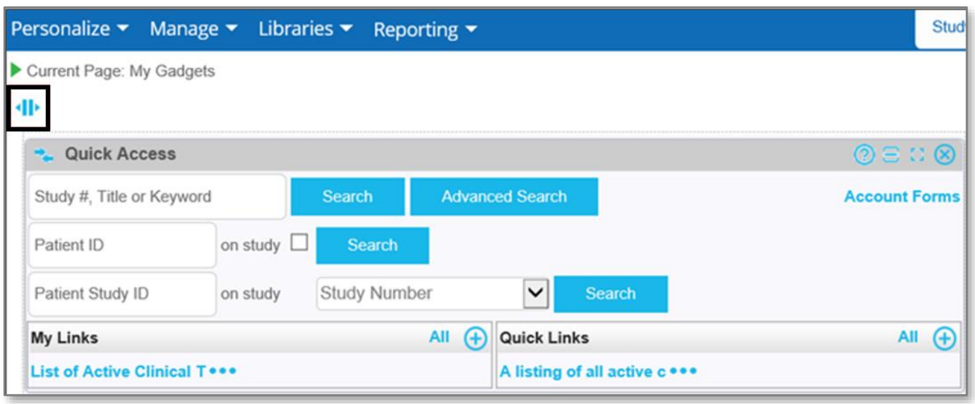
Homepage Name	System Users Primary Role	Landing Page	For Use Refer To:
Ad Hoc Query Home	Ad-hoc Queries Utilization	Ad-hoc Queries	Ad-hoc Queries (AHQ)
Budget> Open	Budget Management	Budget Browser	Browser Budgets
Manage Patients > Enrolled	Patient Management - Enrollment	Manage Patients - Enrolled Tab	Enrolled Patients Tab
Manage Patients > Open	Patient Management	Manage Patients – Patient Search Tab	Patient Search
Manage Patients > Schedule	Patient Management - Scheduling	Manage Patients – Schedule Tab	Schedule Patients Tab
Manage Protocols >Advanced Search	Study Management	Manage Protocols - Advanced Search	Studies
Milestones	Financials Management	Financials Browser	Access Study Financials
My HomePage	All Roles	Default Homepage	N/A
Report Central	Reporting	Report Central	Report Central
My Gadgets	Financial Management	My Gadgets	Customize the “My Gadgets” Homepage
Study Patient Roster	Study Patient Management	Study Patient Roster	Study Patient Roster Homepage

4.3.2 Customize the "My Gadgets" Homepage

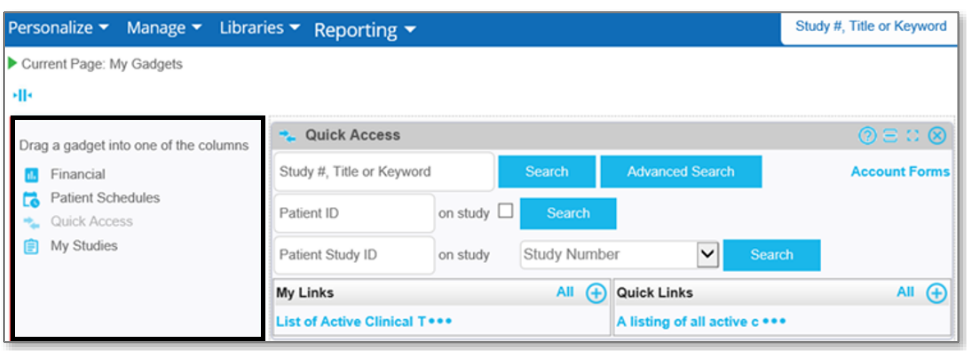
The My Gadgets homepage is a fully customizable landing page that allows users to view their own snapshot of important system, patient, and financial information each time they log in. For most users, the My Gadgets page is the recommended account homepage. For more information on how to change the default landing page for your account, see Settings.

To add gadgets to the My Gadgets homepage:

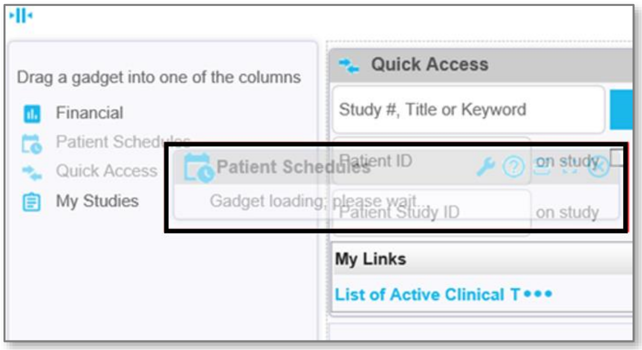
1. Click on the **Expand** button on the left side of the page.



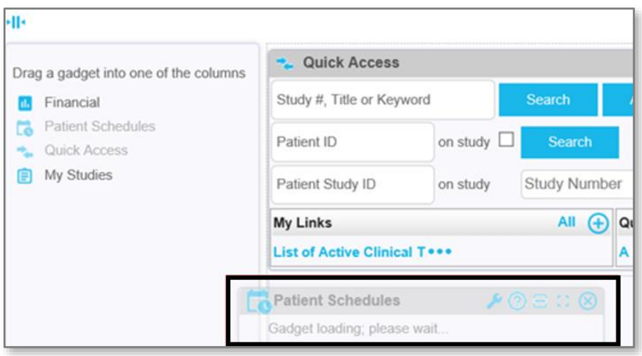
The gadgets panel expands and displays gadgets that are available for use:



2. Move your mouse cursor over any of the available gadgets that have not already been added to your My Gadgets page, and click your mouse, hold the button in, and drag it out of the gadgets panel.

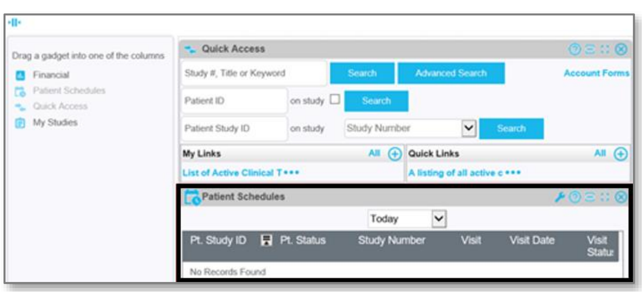


3. Drop the gadget into an available block on the My Gadgets page by releasing the mouse button when it is positioned where you would like it to display.



Note: Available blocks are indicated by light blue blocks that appear as the gadget hovers over different sections of the page.

The gadget displays and loads relevant data that is available to the user.

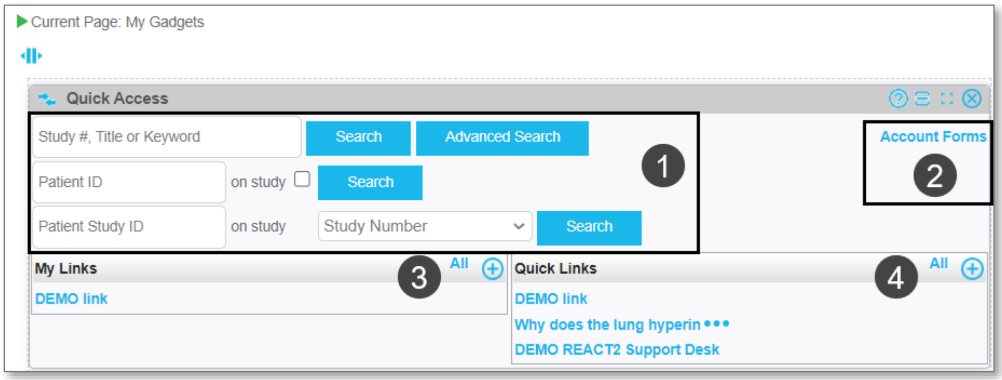


To modify/adjust gadget settings, use one of the available gadget options in the upper-right corner of the gadget as follows:

Gadget Icon	Gadget Name	Description
	Change gadget settings	Allows you to fine-tune each widget to display different values, date ranges and other information as needed.
	More information	Displays more information about the function of the widget.
	Minimize/Restore	Clicking the Minimize button will allow you to collapse the gadget into a static information bar or restore it to its original state. This can be useful if you have multiple gadgets and need more space to view a different gadget temporarily.
	Expand/Shrink	Clicking the Expand/Shrink button will allow you expand the gadget to the width of the page or restore it to its original state. This can be useful if there is a lot of data in a widget, and the increased size will allow you to read the data more clearly.
	Remove Gadget	Clicking the Remove button will allow you to remove the gadget from your My Gadgets page.

4.3.2.1 "My Gadgets" Quick Access Container

The Quick Access container of the "My Gadgets" homepage may be used for searching for a study or patient, accessing account forms, and viewing, deleting, or adding My Links or Quick Links.

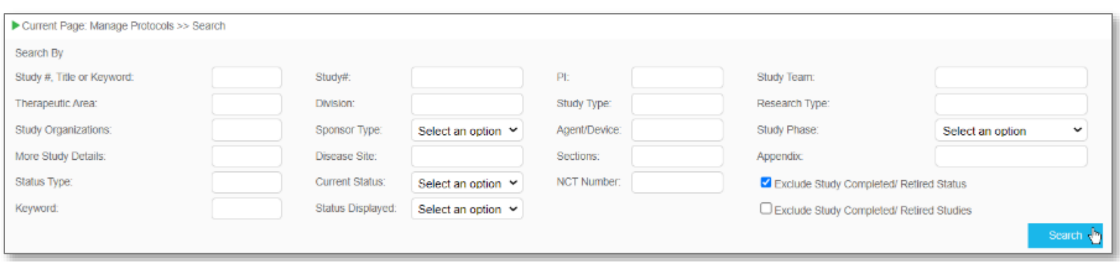


1. **Search Area**:
   a. *Row 1*: Enter either a study number, title, or keyword, then click **Search** to locate a study.

The study Quick Access information will appear in a new page.

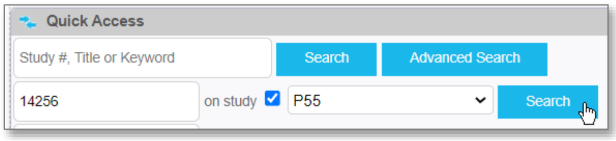
-OR-

Advanced Search: Click **Advanced Search** to access advanced searching field options. Enter field criteria, then click **Search** to locate a study.



-OR-

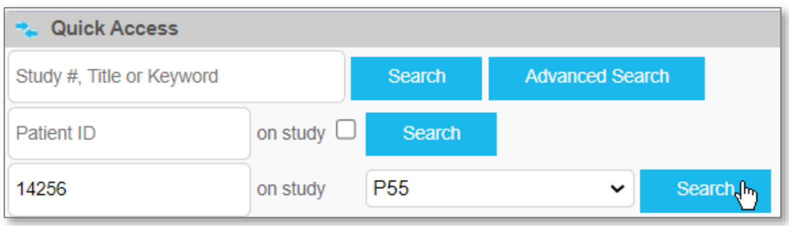
Row 2: Enter a **Patient ID** to locate a specific patient record. Check the checkbox if the patient is on a study and then enter the **Study Number**, if applicable. Then click **Search**.



The Patient Search page will appear, or, if a Study Number was selected, the Study Patients page will appear for the study with the associated Patient Study ID information.

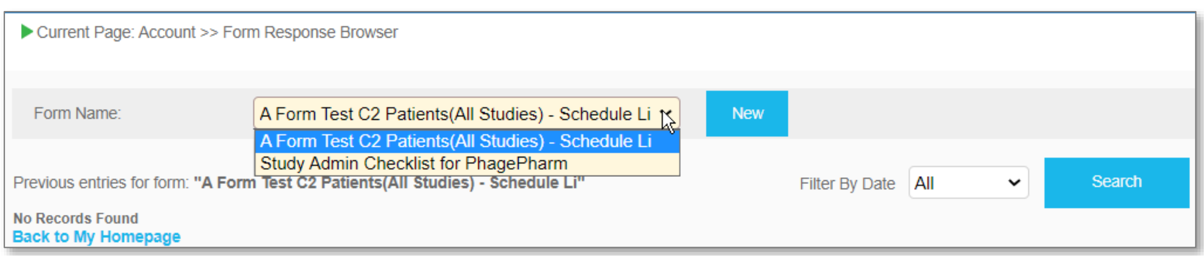
-OR-

Row 3: Enter a **Patient Study ID** and select the Study Number from the dropdown in which the patient is associated to. Then click **Search**.

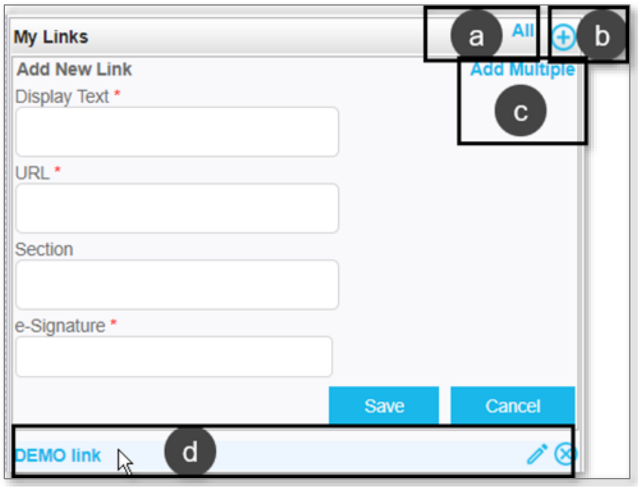


The Study Patients page will appear for the study selected.

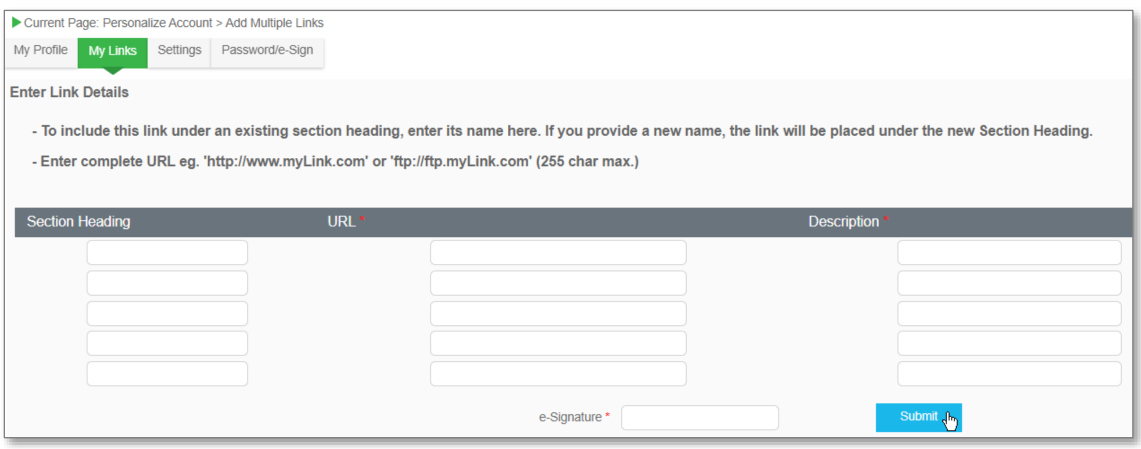
2. **Account Forms**: Click Account Forms to access the Form Response Browser. Click **New** to complete a selected Account form from the dropdown. Any completed forms will appear in a table below the Search area.



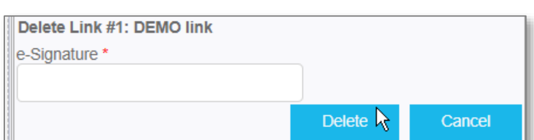
3. **My Links**:



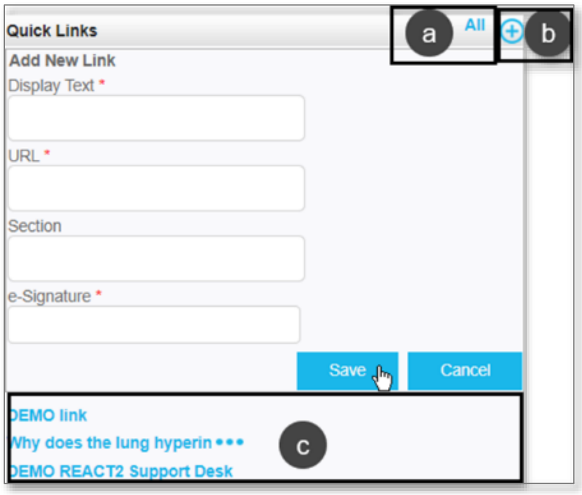
a. *All*: Click **All** to access the My Links page for adding, editing, or deleting My Links.
b. *Add*: Click **Add New Link** to add a link by completing the new fields, then click **Save**.
c. *Add Multiple*: Click **Add Multiple** to access the Add Multiple Links page. Complete required fields then enter your e-Signature and click **Submit** to add.



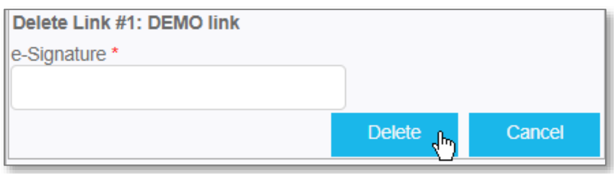
d. *My Link*: Hover over a link name. Click a link name to access the link. Or, click **Edit** to view completed fields. Or, click **Delete** then enter your -e-Signature and click **Delete** to delete.



4. **Quick Links**:

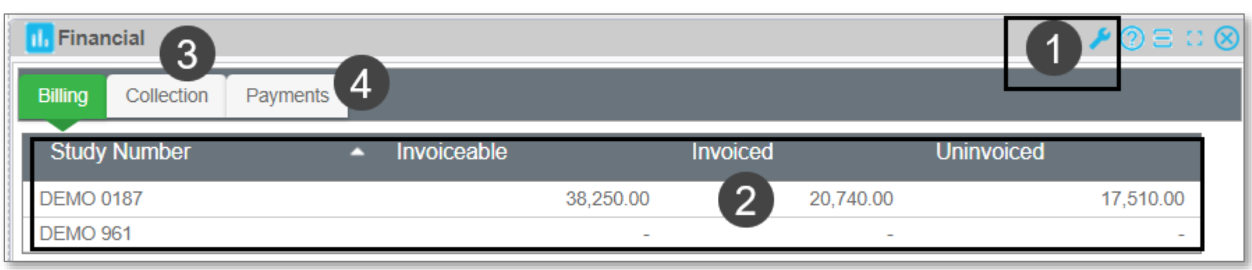


a. *All*: Click **All** to access the Account Links page for adding, modifying, or deleting Quick Links.
b. *Add*: Click Add New Link to add a link by completing the new fields, then click Save.
c. *Quick Link*: Hover over a link name. Click a link name to access the link. Or, click Edit to view completed fields. Or, click Delete then enter your e-Signature and click Delete to delete.



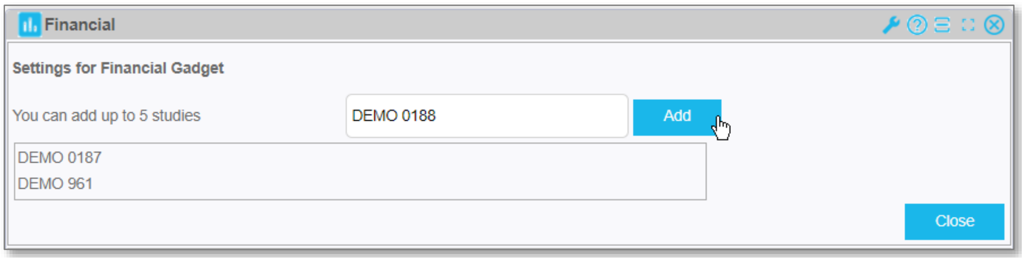
4.3.2.2 "My Gadgets" Financial Container

The Financial container of the "My Gadgets" page may be used for adding new studies to the list and reviewing and exporting Billing, Collection, and Payments information.



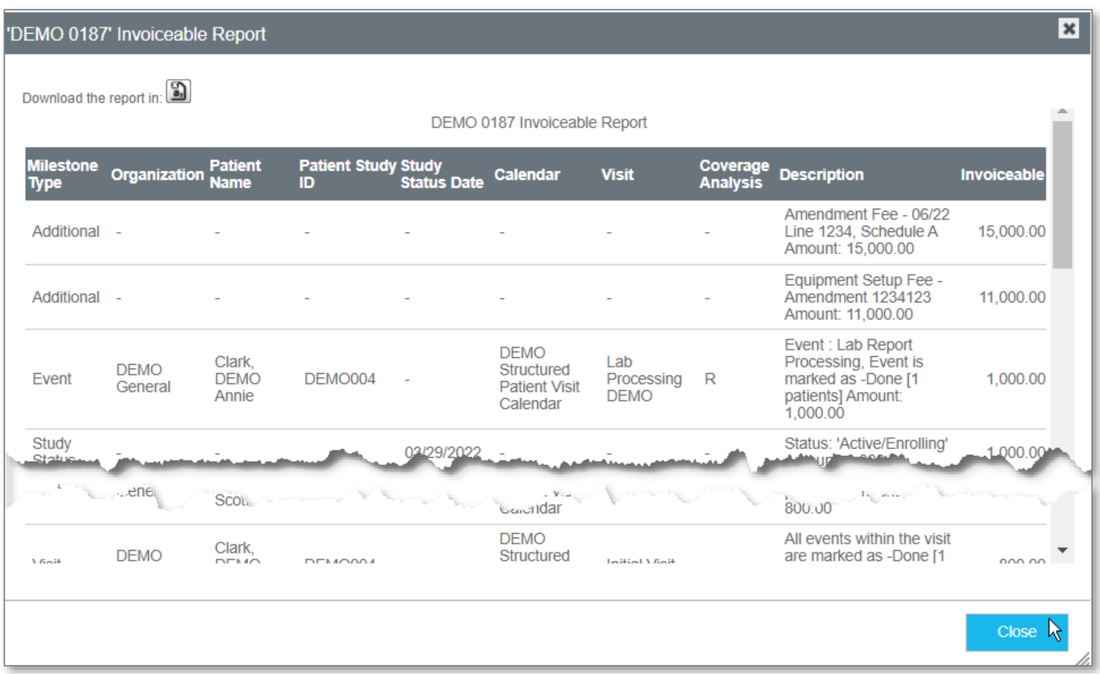
- Selected studies are sorted by Study Number

1. **Configure Settings**: Click **Configure Settings**, then select a study and click **Add** to add the study to the list. Click **Close** to close the Configure Settings area.



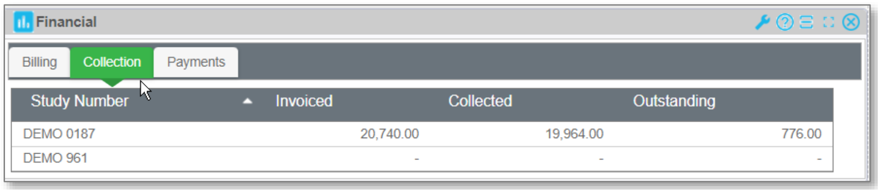
- Five studies maximum may be selected.

2. **Billing**: From the default billing tab, hover over the Study Number to view additional information, or click a financial amount in any column to view a breakdown of the amount. Click **Close** to close the pop-up.

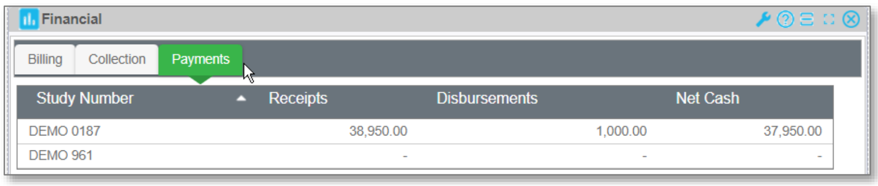


- The CSV Format button may be clicked to download the information

3. **Collection**: Click **Collection** to perform the same functions as in the Billing tab.

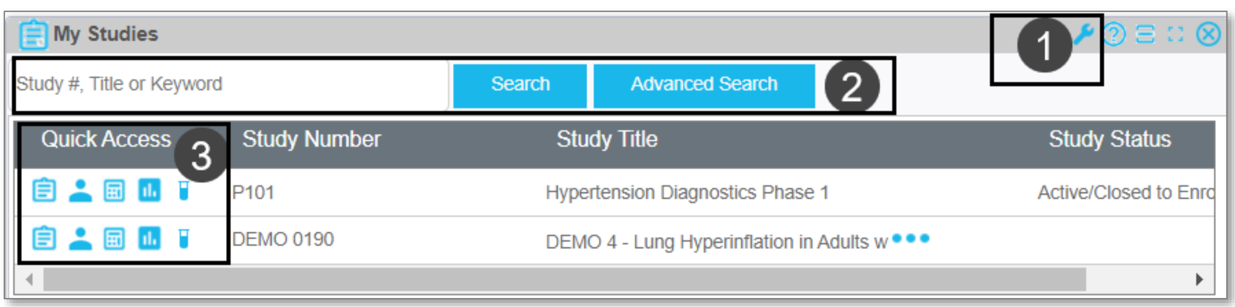


4. **Payments**: Click **Payments** to perform the same functions as in the Billing tab.

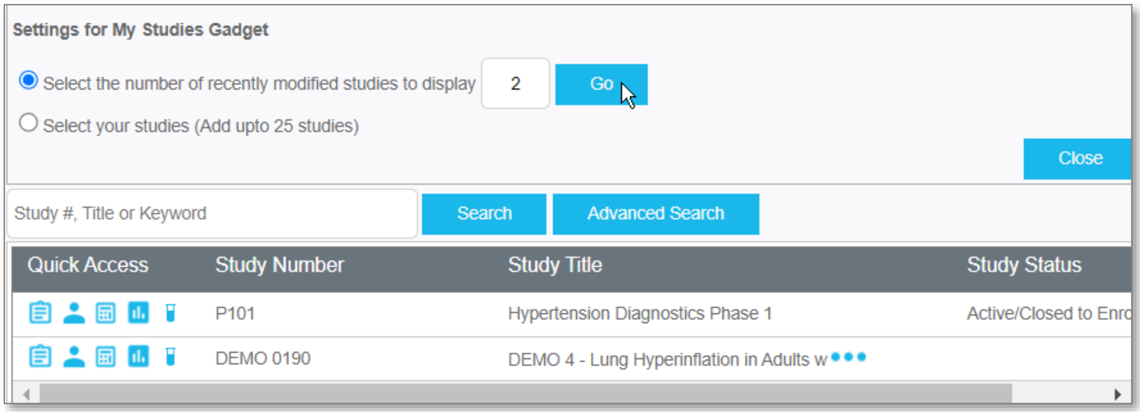


4.3.2.3 "My Gadgets" My Studies Container

The My Studies container of the "My Gadgets" page may be used for selecting the studies to display in the table, searching for a study in the table, and for using Quick Access for study, patient, or financial information for a study.



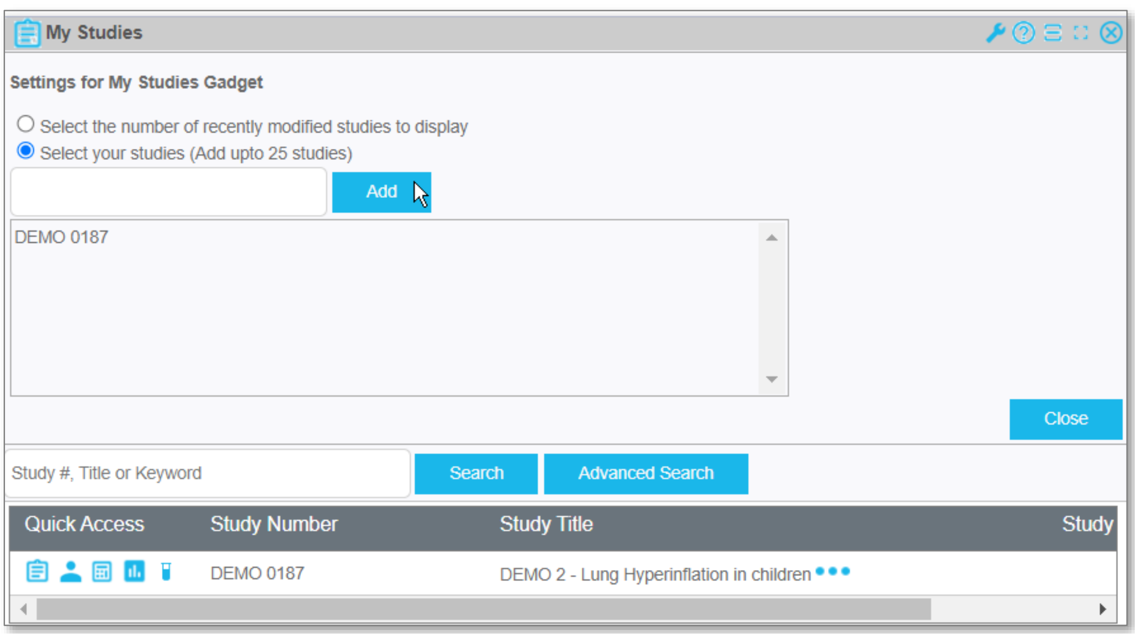
1. **Configure Settings**: Click Configure Settings. New fields will appear.
    a. *First radio button*: Select how many of the most recently modified studies will display in the table, by entering a number, then click **Go**. The most recently modified studies will appear in the table below the Search area.



- 25 studies maximum may be added

-OR-

Second radio button: Select the specific study or studies to display by selecting in the search field and then click **Add**. The selection(s) will appear in a list below and in the Quick Access table. Click **Close** to close the Configure Settings area.

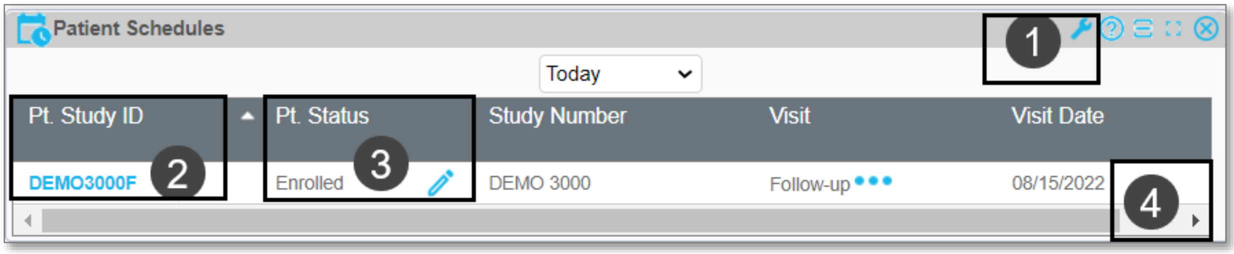


- 25 studies maximum may be selected

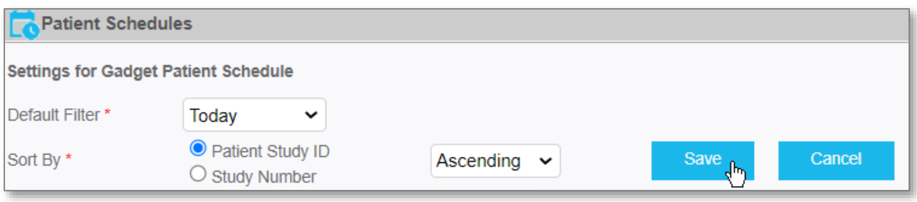
2. **Search**: Enter either a study number, title, or keyword in the first row, then click **Search** to locate a study. The study Quick Access information will appear in a new page. Or, click **Advanced Search** to access advanced searching field options. For more information, refer to "My Gadgets" Quick Access Container.
3. **Quick Access**: Click any of the quick access buttons to access the specific area for the study information including Study Management (Study Administration button), Patient Management (Patient Management – Enrolled Patients button), Budgets (Budgets button), and Milestones (Financial Summary button).

4.3.2.4 "My Gadgets" Patient Schedules Container

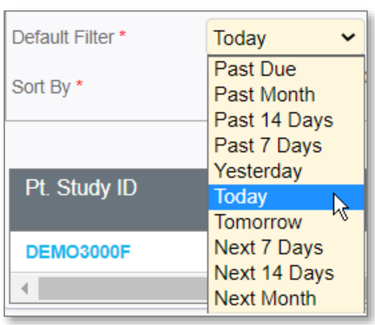
The Patient Schedules container of the "My Gadgets" page may be used for selecting patient study records for viewing in a table to further access the Patient Study ID record or edit a Patient Status.



1. **Configure Settings**: Click **Configure Settings** to open the Settings for Gadget Patient Schedule area.

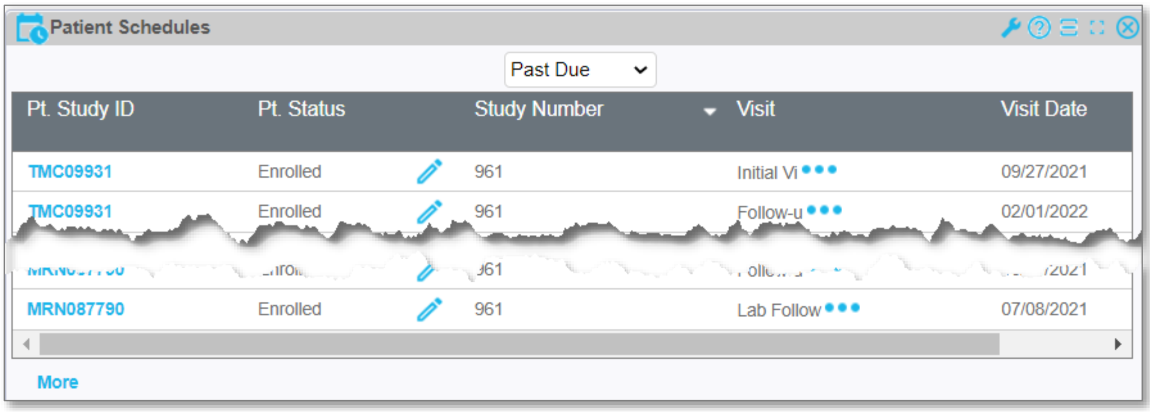


   a. Click the Default Filter dropdown and make a selection from the options listed.

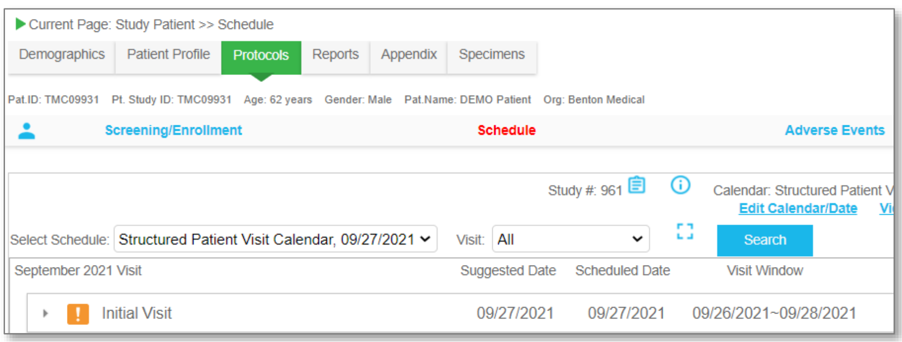


   b. Select the Sort By as either **Patient Study ID** or **Study Number,** by selecting the appropriate radio button.

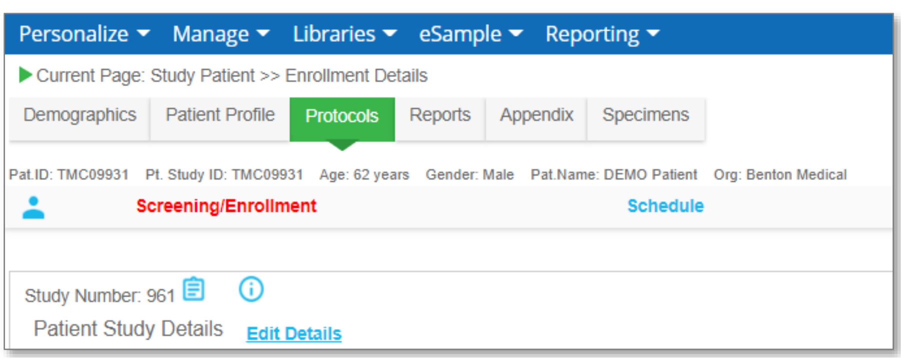
c. Select either **Ascending** or **Descending** from the dropdown, then click **Save**.
The data selected will appear in the table and the selected header will be sortable as either ascending or descending direction.



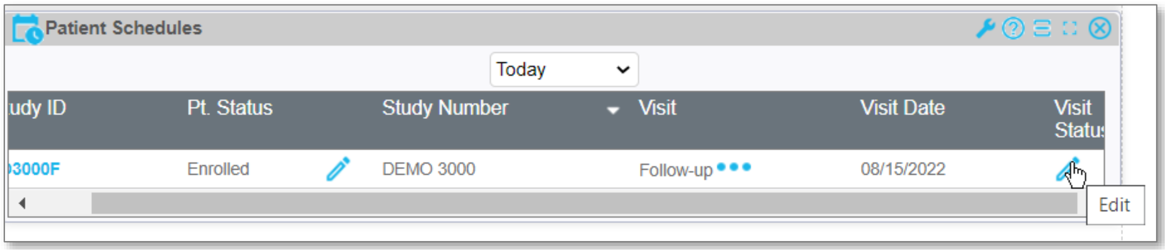
2. **Pt Study ID**: Click a Patient Study ID to access the Protocols tab > Schedule page for the patient on the study.



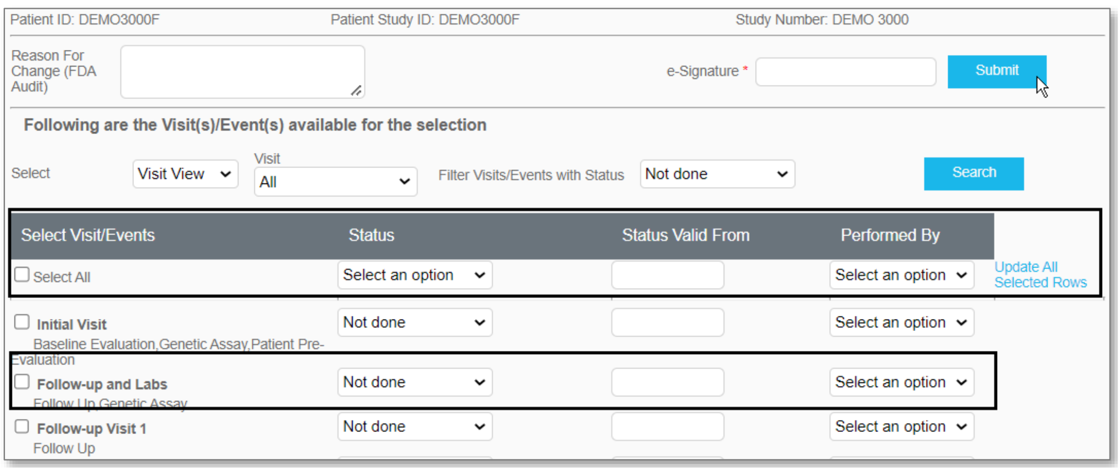
3. **Edit Pt Status**: Click **Edit** for a Patient Status to access the Protocols tab > Screening/Enrollment page for a patient on the study.



4. **Edit Visit Status**: Scroll to the far right of the table, then click **Edit** for a specific patient's Visit Status.



   a. In the pop-up, either use the power bar to Select All visit/events, select a status and a status valid from date, and who performed the action, then click **Update All Selected Rows**.



   -OR-

   Individually, check a visit or event checkbox, select a status, select a status valid from date, and select a performed by dropdown option.

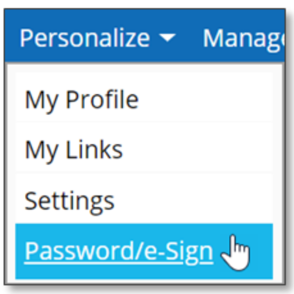
   b. Enter your e-Signature and click **Submit**.

4.4 Password / e-Signature

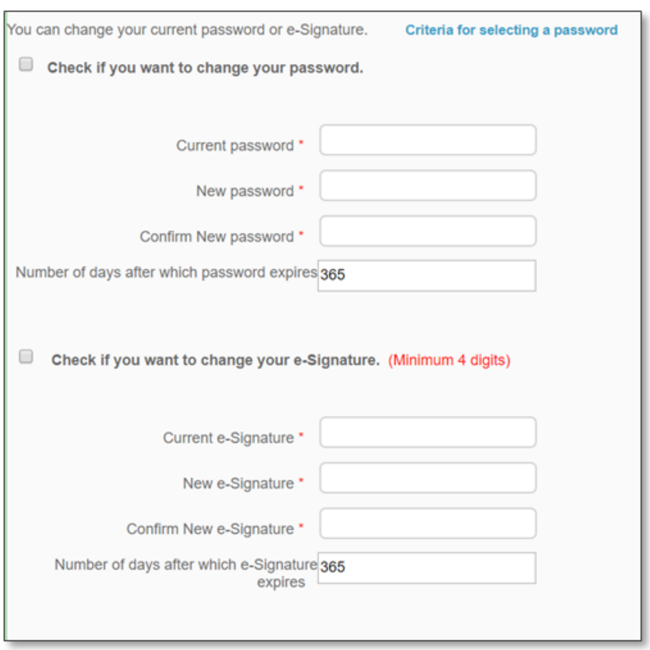
Your password and e-Signature are integral security features of Velos eResearch. Your password is used to securely log into the Velos eResearch application. Your e-Signature is a secure key unique to your account, which is required to finalize virtually any data change or action within the application. For security reasons or preference, it may be necessary to change your password or e-Signature on occasion. Velos eResearch offers the ability to change both your password and e-Signature using the Personalize menu.

To change your password:

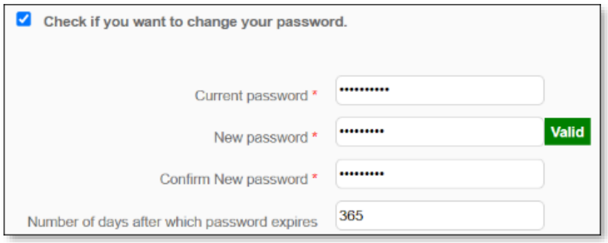
1. Click on the **Personalize** menu and select **Password/e-Sign**.



The Password/e-Signature page will display:



2. To change your password, check the “Check if you want to change your password.” box and type your current and new password into the required fields.



Note: Note that a minimum of 8 characters are required for a valid password.

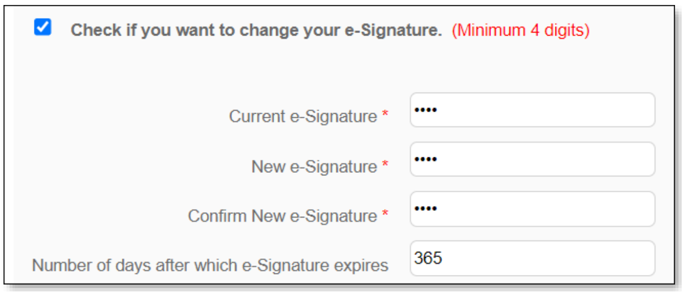
Criteria for choosing a valid password:

- Do not reuse password from last 10 passwords.
- Password must contain at least three out of four given below characters sets:
  - English upper case (A through Z).
  - English lower case (a through z).
  - Numeral (0 through 9).
  - Special character (e.g., () ` ~ ! @ # $ % ^ & * - + = | \ { } [ ] : ; ” ’ < > , . ? /)
- Password and username may never be the same.
- More than 2 consecutive same characters are not allowed.
- Spaces are not permitted.

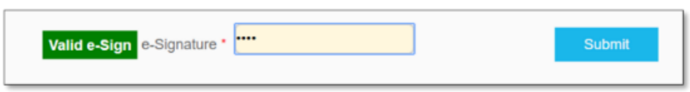
-OR-

If you want to simultaneously, or separately change your e-Signature, check the “Check if you want to change your e-Signature” box and enter your current and new e-Signature into the required fields.

Note: A minimum of 4 digits is required for a valid e-Signature.



3. After adding your new password and/or e-Signature, enter your current e-Signature and click **Submit** to confirm.



Your new password and/or e-Signature have been updated successfully.

Note: You must log out of the system for your new password to take effect. A new e-Signature will take effect immediately after you click Submit.

5 Account Administration

The foundation of a Velos eResearch account begins with the configuration of the account management settings. One of the most critical steps you take in configuring and managing your eResearch environment is mapping out organizations, groups, and other user permissions that define the user experience. Consider, for example, that each user account, patient record, and study must be linked to an organization. Further the organization that each of these elements is tied to controls what studies and patients the end user sees in your environment. Therefore, considering how many organizations, if there are any hierarchical relationships, or instances of multi-organizational access is a foundational, and essential step to take before implementation, if possible.

Also important are groups and other configured permissions, as users must also belong to at least one group, and the sum of their group and other configured permissions are what dictate the totality of their system-level permissions, and therefore, what data they can see, create and manipulate.

Note:

1. Thoughtful, forward-thinking design of organizations and groups is key to successful eResearch implementations and workflow design.
2. If Networks is an option in your version of eResearch, please refer to Networks, for more information.

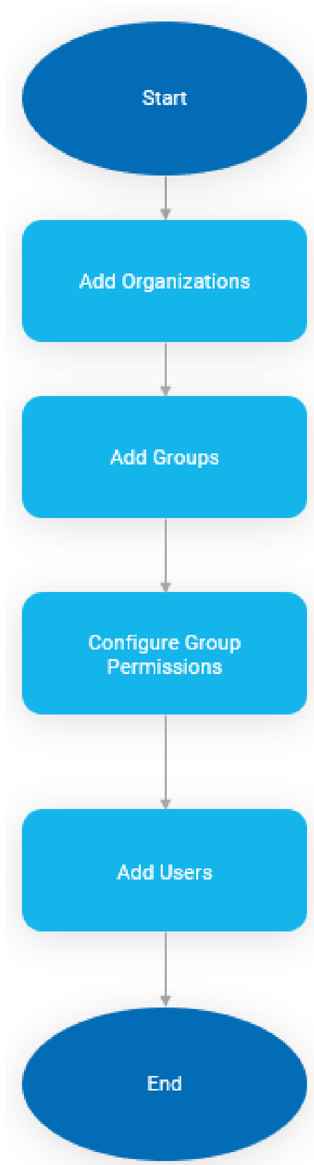
Warning:

1. Organizations and Groups must be created prior to creating additional user accounts, as each user must be associated with an organization and group.
2. This topic is for site administrators or super users. Most end-users will not have access to the Manage Account module and the menu option will not display on the menu bar.

Account management includes creating and maintaining the following elements:

- Organizations
- Groups
- Users
- Quick Links
- Manage Account – Form Management

5.1 Process Overview



5.2 Organizations

The first step in setting up the Velos eResearch system is to establish organizations. Organizations are a foundational unit within Velos eResearch that represent an entity (Institution, Affiliate, Department, etc.). Studies, users, and patients must be associated to at least one organization. Permissioned users can add or edit organizations. There are four types of organizations as described in the table below.

Type	Examples
Hospital	General Hospital
Laboratory	Kinder Laboratories
Site	Dr. John's Private Practice, School of Pharmacy at WCG University
Department	Oncology, Pediatrics, Hematology

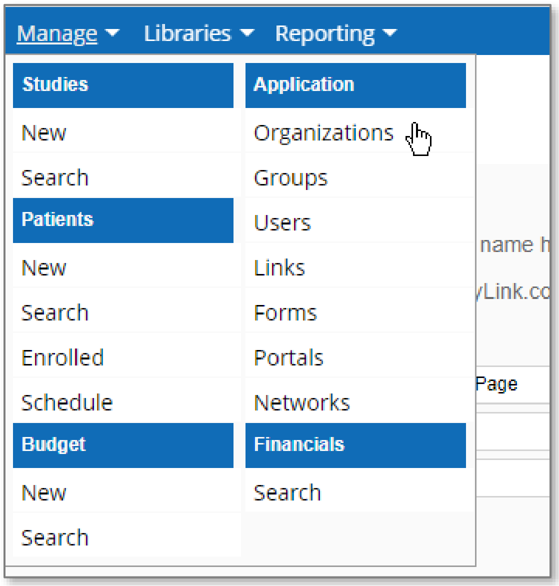
Enterprise Only: The Site of Service Type is Enterprise Only.

5.2.1 Add an Organization

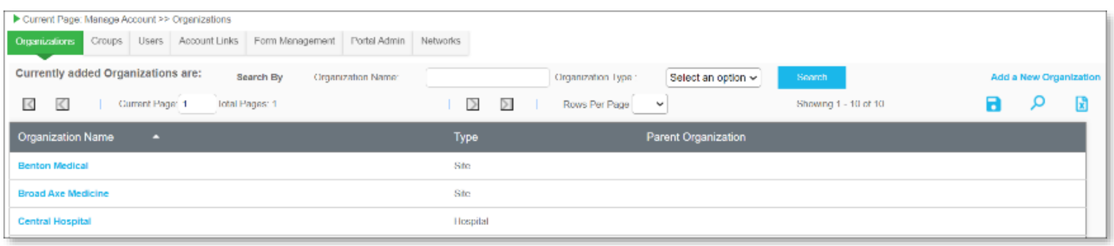
Permissioned users can add organizations using the Organizations page.

To add a new organization:

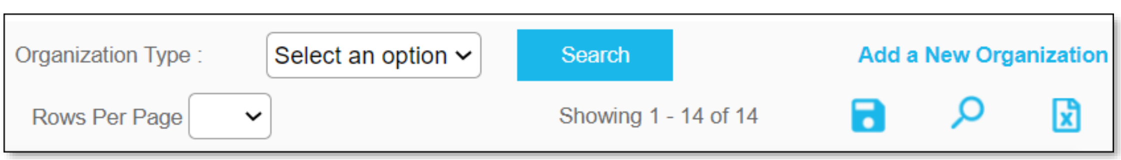
1. Click the **Manage** menu tab on the upper left of the screen and select **Organizations** under the "Application" heading.



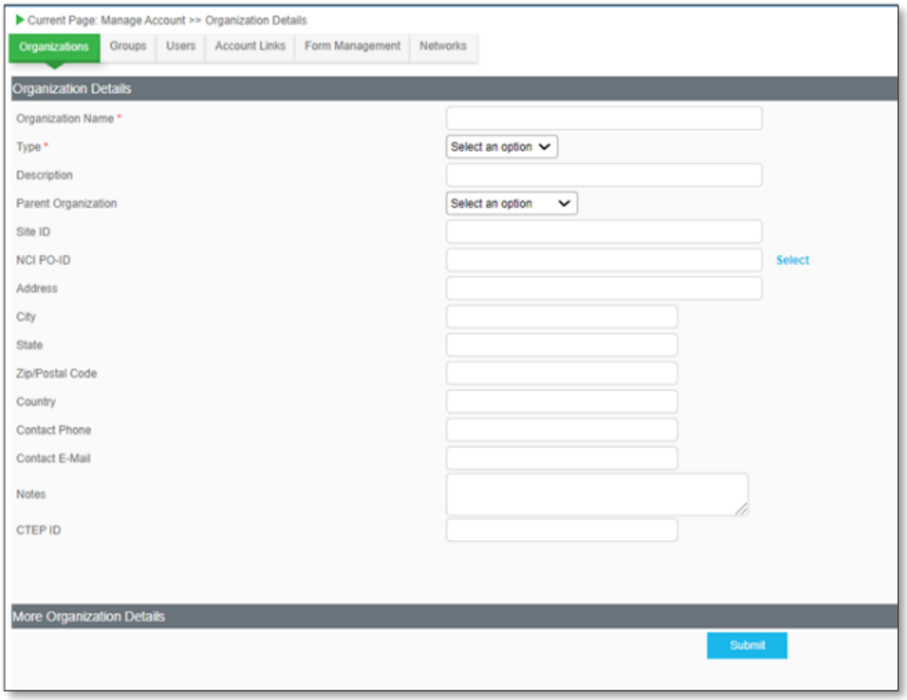
The Organizations page will display:



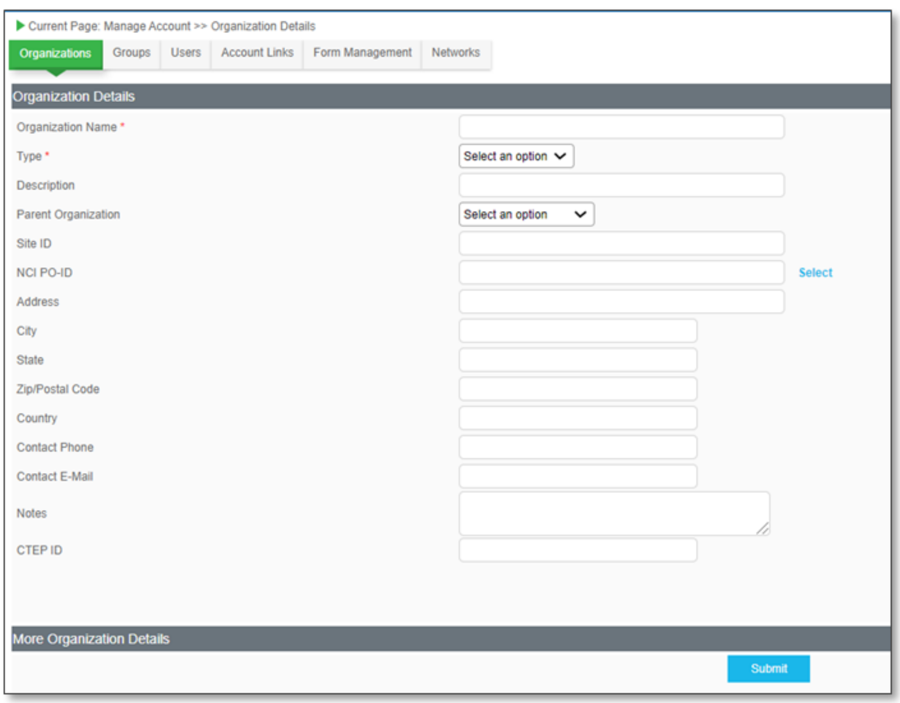
2. Click **Add a New Organization**.



The Organization Details page will display:



3. Fill in the required fields as indicated by an asterisk, and any additional information as needed in the available fields. Click **Submit** to save your entry.



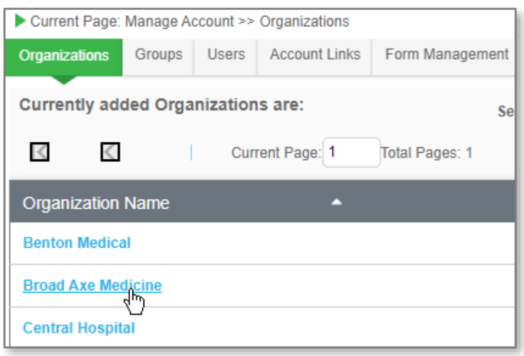
Note: You can add a "Parent Organization", which associates the organization as a subordinate member of another organization, creating a child-parent relationship throughout Velos eResearch.

5.2.2 Edit an Organization

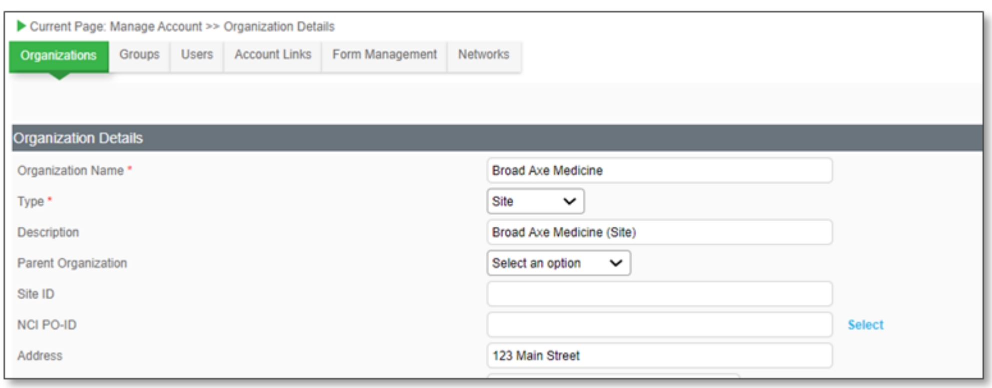
Permissioned users can make changes to information associated with an organization from the Organization page.

To edit an organization:

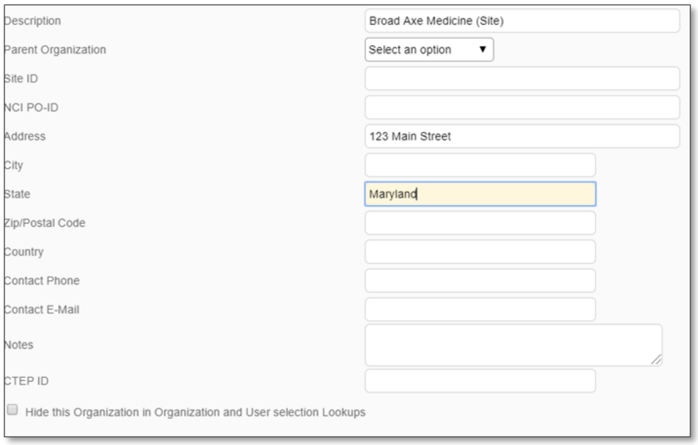
1. Navigate to the **Organizations** page and click directly on the name of the organization you would like to edit.



The Organization Details page will display:



2. Add or edit information as needed and click **Submit** to save your updates.



- Check the checkbox for the ‘Hide this Organization in Organization and User selection Lookups’ when the Organization is to no longer be used. Organizations cannot be deleted.

The updates to the organization are saved.

5.3 Groups

Groups define access permissions for users within Velos eResearch. Groups are used to control permissions for a defined set of users by permission types. Within each permission type, a permission can be defined as the ability to create a new element, edit an element, or simply read an element. If a group is not given permission to any of these functions for a permission type, any sections or UI elements related to this permission type will not be visible to users assigned to that group. For more information on permission types, see Appendix E – Permission Types.

Permissioned users can add, edit and delete groups, define the super-user group and add users to groups.

eResearch Enterprise comes with one default group, which is for Administration users, while eResearch eXpress comes with four default groups: Admin, Management, Finance, and Patient Management.

Note: It is recommended that users not change the access rights within the default groups. Best practice would be to create a new Group containing the required permissions and types for each and document within the Description field the purpose for the group.

5.3.1 Add a Group and Assign Users to a Group

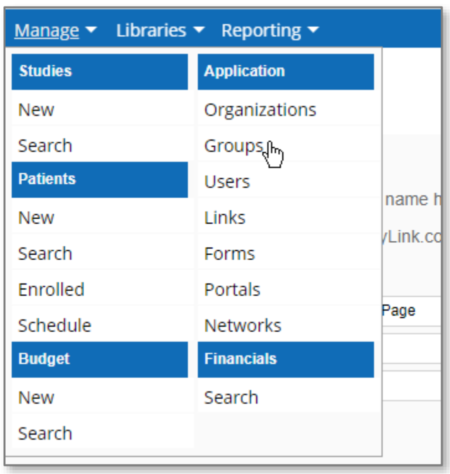
There are two methods to add groups using the Group Management page:

- **Add Multiple Groups** – Add up to five groups simultaneously.
- **Add a New Group** – Add one group at a time.

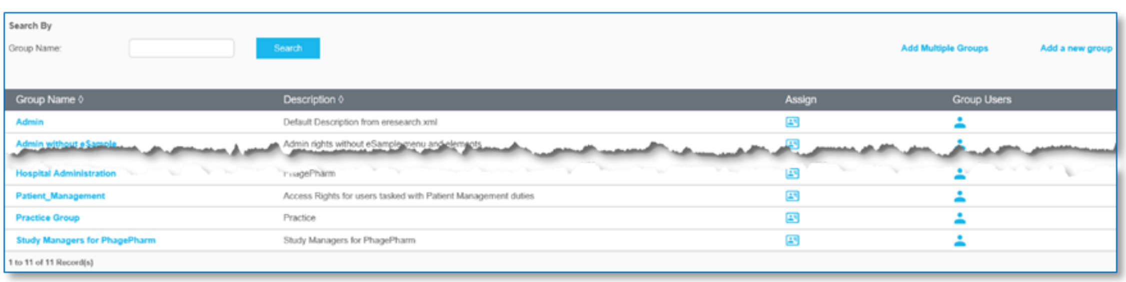
Additionally, users can be assigned to a group from the group users button.

To add a group:

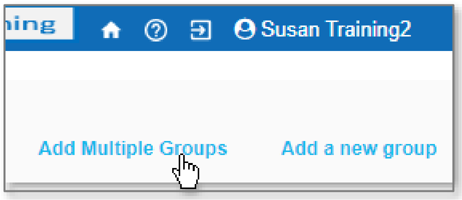
1. Click the **Manage** menu in the upper-left hand corner of the screen and select **Groups** under the "Application" heading.



The Groups management page displays:

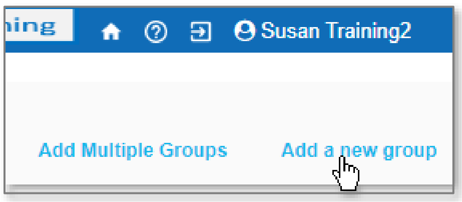


2. Click **Add Multiple Groups** to add multiple groups at once.

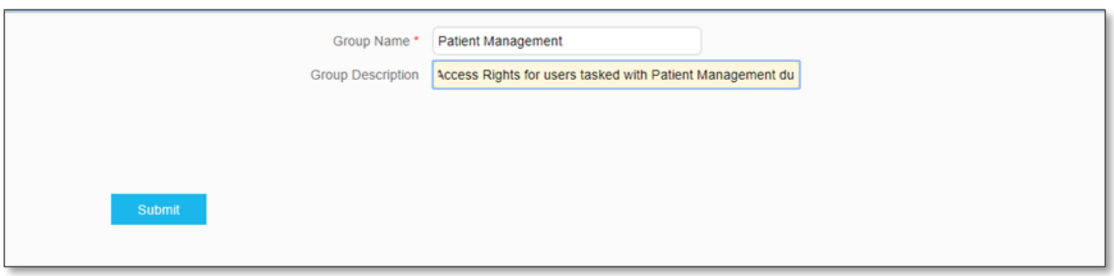


-OR-

Click **Add a New Group** located on the right side of the page.

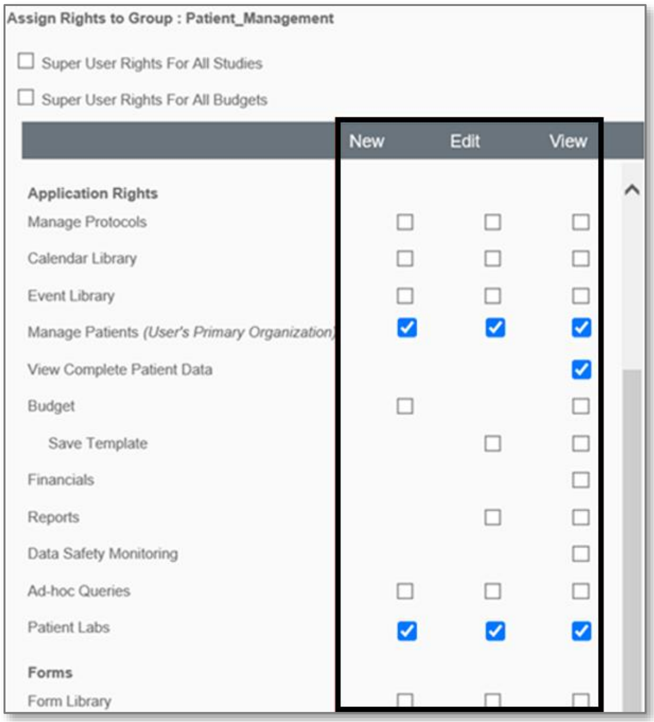


3. Enter a group name and description into the available fields and click **Submit** to save your new group.



Note: It is recommended that you provide a brief description of the type of permissions each group has in the Group Description field.

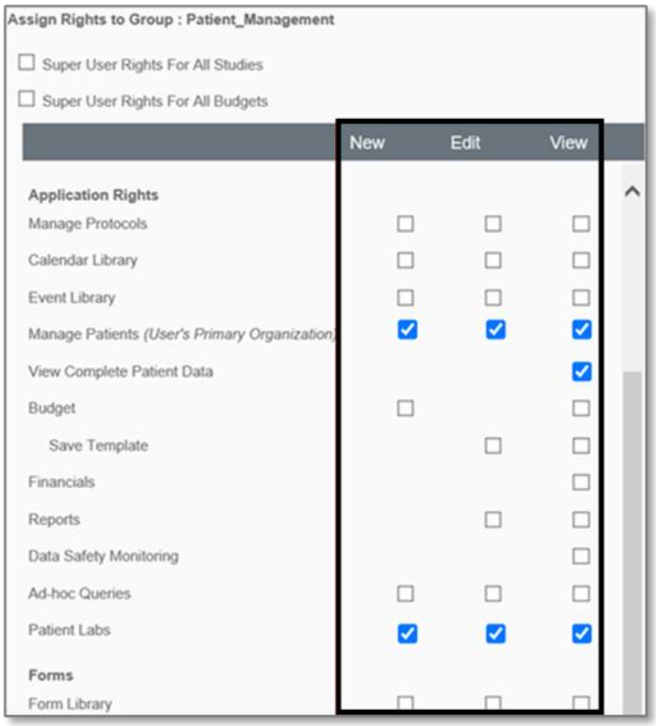
The new group is added to the Group Management page and the Assign Rights to a Group page displays:



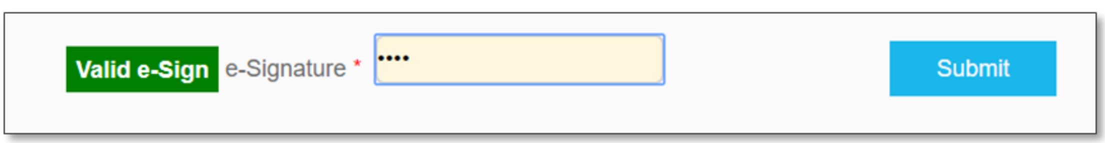
Note:

1. At the top of this page there is a checkbox to apply Super User Rights. Checking this box will give users the assigned rights across all studies.
2. By default, all groups have no rights assigned upon creation. If you skip this step, you must return later to define the group rights, or the group will not have access to any system functionality.

4. Select the **New** (create), **Edit**, and **View** permissions for each permission type as needed for this group.

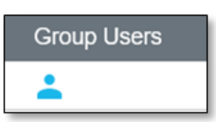


5. After the permissions have been defined, enter your e-Signature and click **Submit** to confirm.

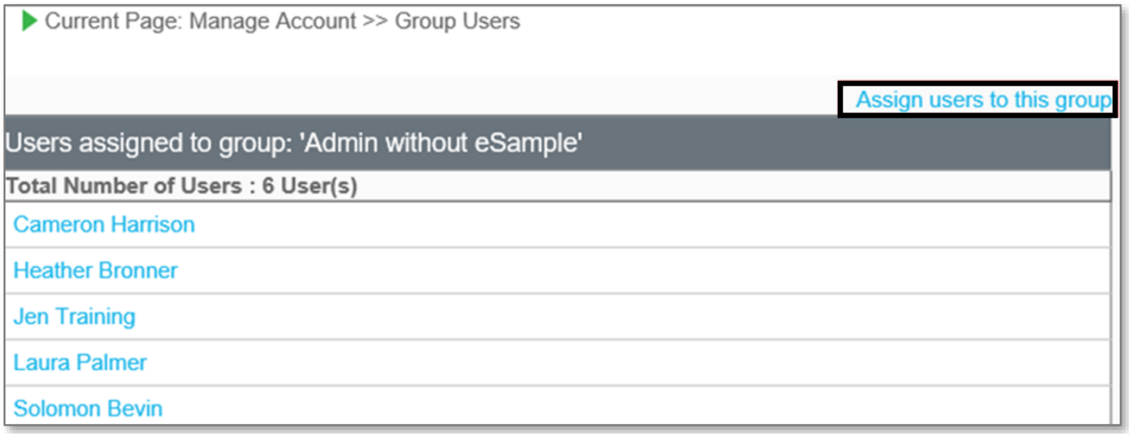


–OR-

6. To assign users to a group from the Group Management page, click the **Group User** button for a specific Group.

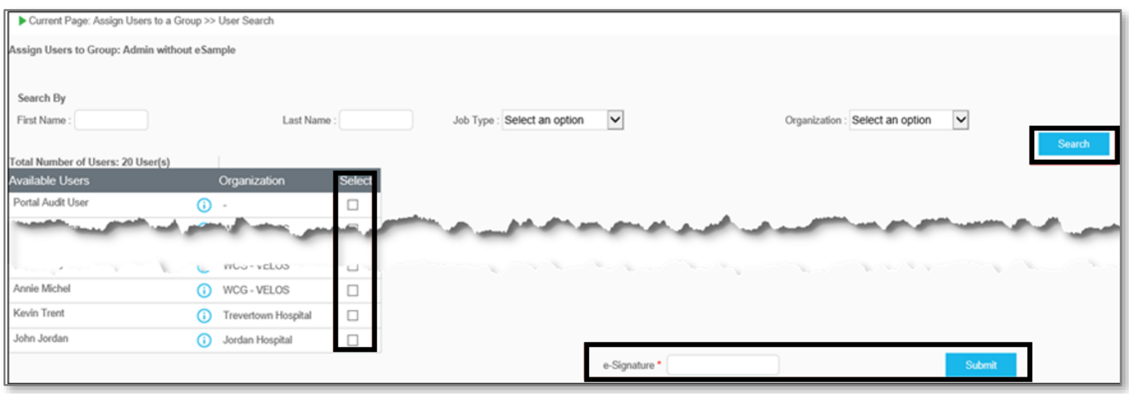


7. Click **Assign users to this group**.



- Clicking on an existing user in the Group Users page will access that user's User Details. For more information on User Details see Edit Users.

8. After searching the list as needed and clicking **Search**, check checkboxes for a user or users to add to the group, and then enter your e-Signature and click **Submit** to confirm.



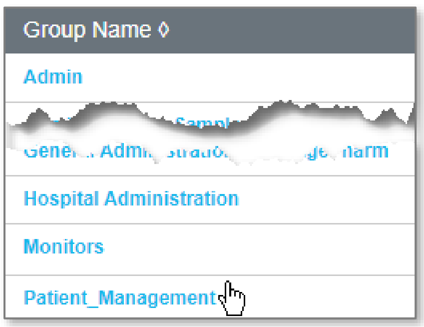
The user or users will now be added to the Group Users page.

5.3.2 Edit a Group

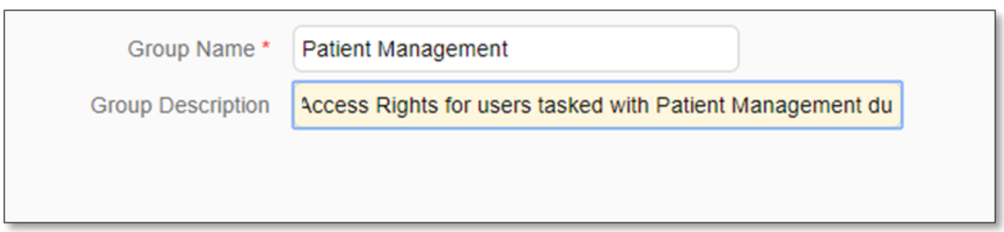
Permissioned users can edit group permissions for existing groups by using the edit functionality.

To edit an existing group:

1. From the Group Management page, click directly on the name of the group in the **Group Name** column.



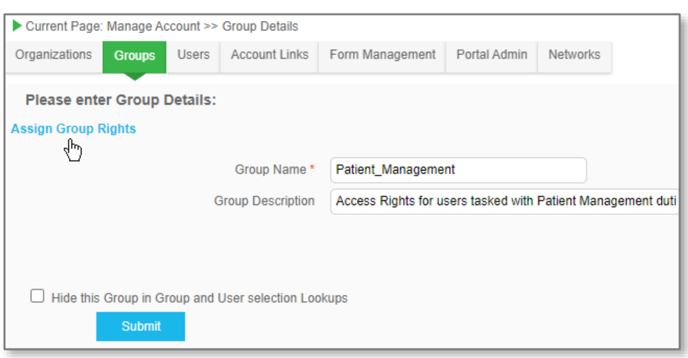
The Group Details page displays:



2. Change the **Group Name** and/or **Group Description** using the available fields and click **Submit**.

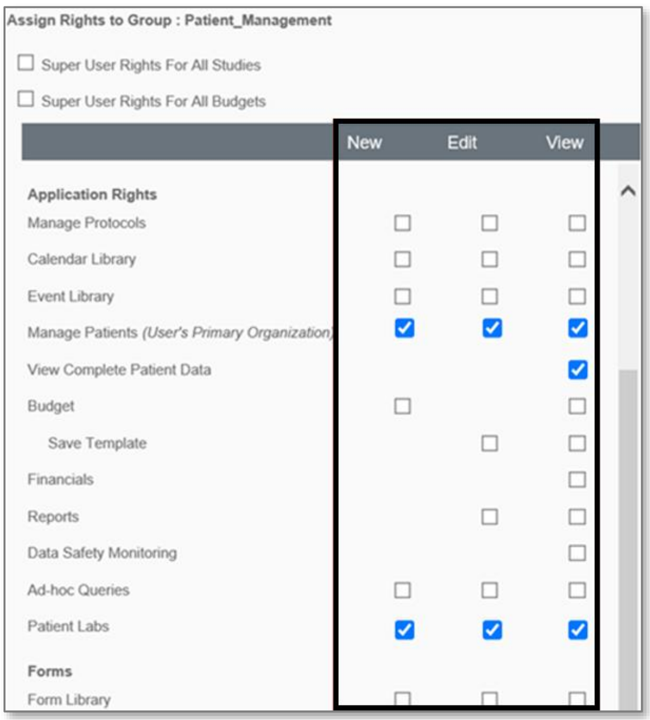
   -OR-

   If you would like to change group permissions, click **Assign Group Rights**.

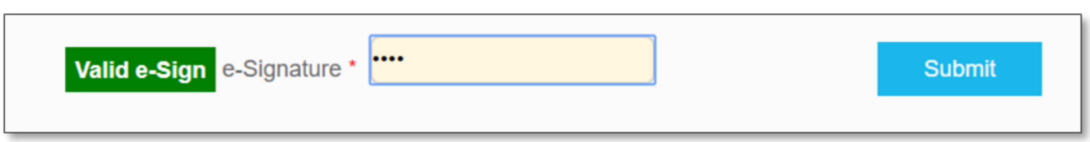


- Alternatively, to access the Access Group Rights page directly from the Groups page, click on an **Assign** button for the specific Group Name.

3. On the Assign Rights to a Group page, make the necessary changes by selecting or deselecting the appropriate checkboxes next to the permission types.



4. After the permissions have been defined, enter your e-Signature and click **Submit** to confirm.



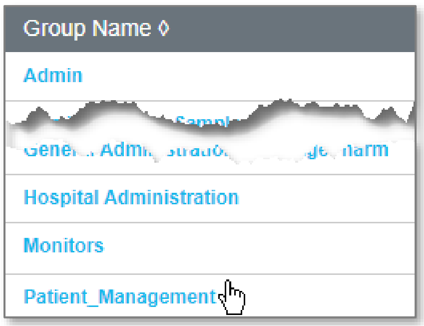
5.3.3 Hide Group

Groups within eResearch cannot be deleted once created, although, permissioned users may prevent the group from appearing during lookup.

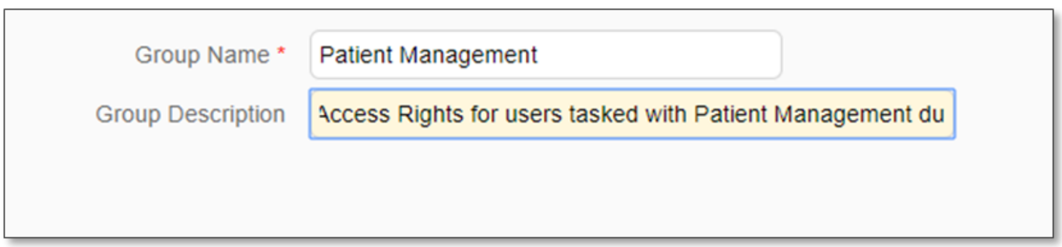
Note: Groups within eResearch cannot be deleted once created. It is possible to hide groups, so they do not appear in lookups.

To Hide a Group:

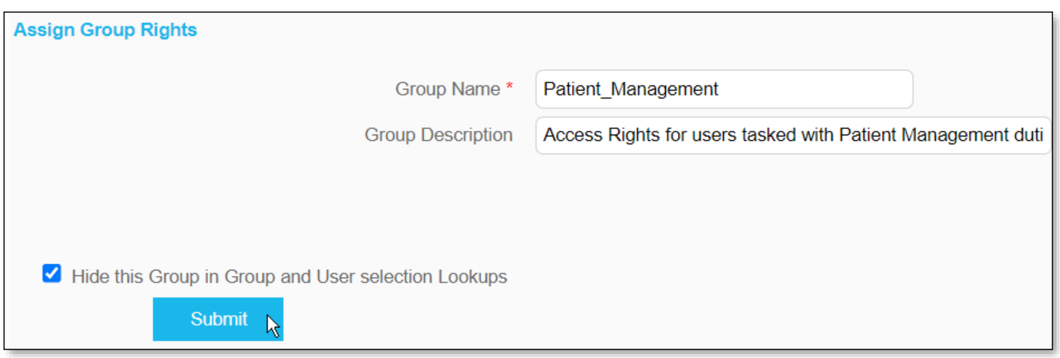
1. From the Groups tab, select the **Group Name** for the desired group to hide.



The Group Details page displays:



2. Click the checkbox for “Hide this Group in Group and User selection lookups” and click **Submit**.



5.3.4 Define and Edit Super User Rights for a Group

Super users are users with the highest level of permissions and access rights in the system. Typical types of users with super user roles would be system administrators.

Within Velos eResearch, there are two categories of Super User permissions:

- super users for all studies
- super users for all budgets

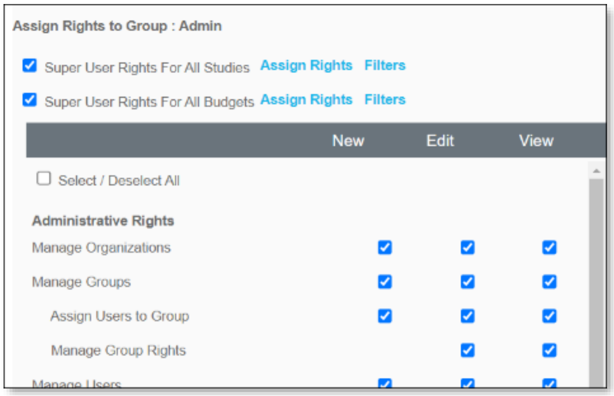
These access rights allow you to access studies or budgets without being specifically permissioned at the study team level.

Note: If you have both super user rights and study team access, the more local permission will supersede the broader permission (in other words, if you have a conflicting permission at the study team level, the study team level differences will trump the super user ones, but only for that study.)

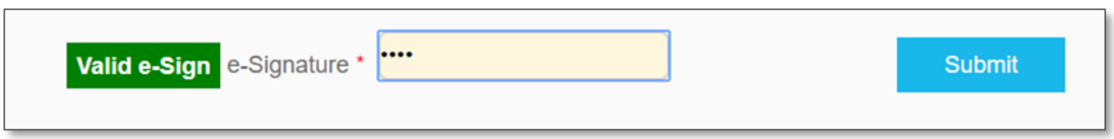
Super User Permission Type	Description
Super Users Rights for All Studies	Allows a group of users to have the defined rights across all studies in the categories of Study Administration, Patient Management and Study Form Management.
Super Users Rights for All Budgets	Allows a group of users to have the access to all budget information and defined system financial rights regardless of study involvement across all studies

To define Super User rights to a group:

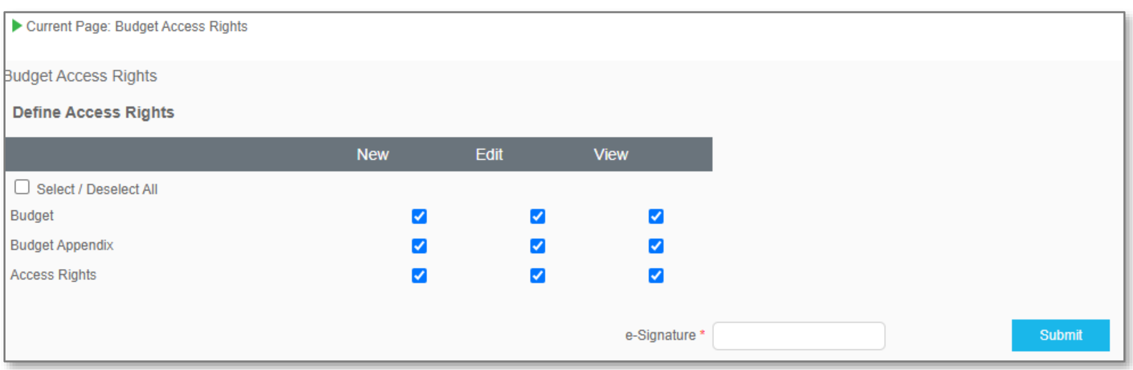
1. Navigate to the Assign Rights to a Group page, as described in Edit a Group, and select one or both of the available super user options at the top of the page.



2. Enter your e-Signature and click **Submit** to confirm.

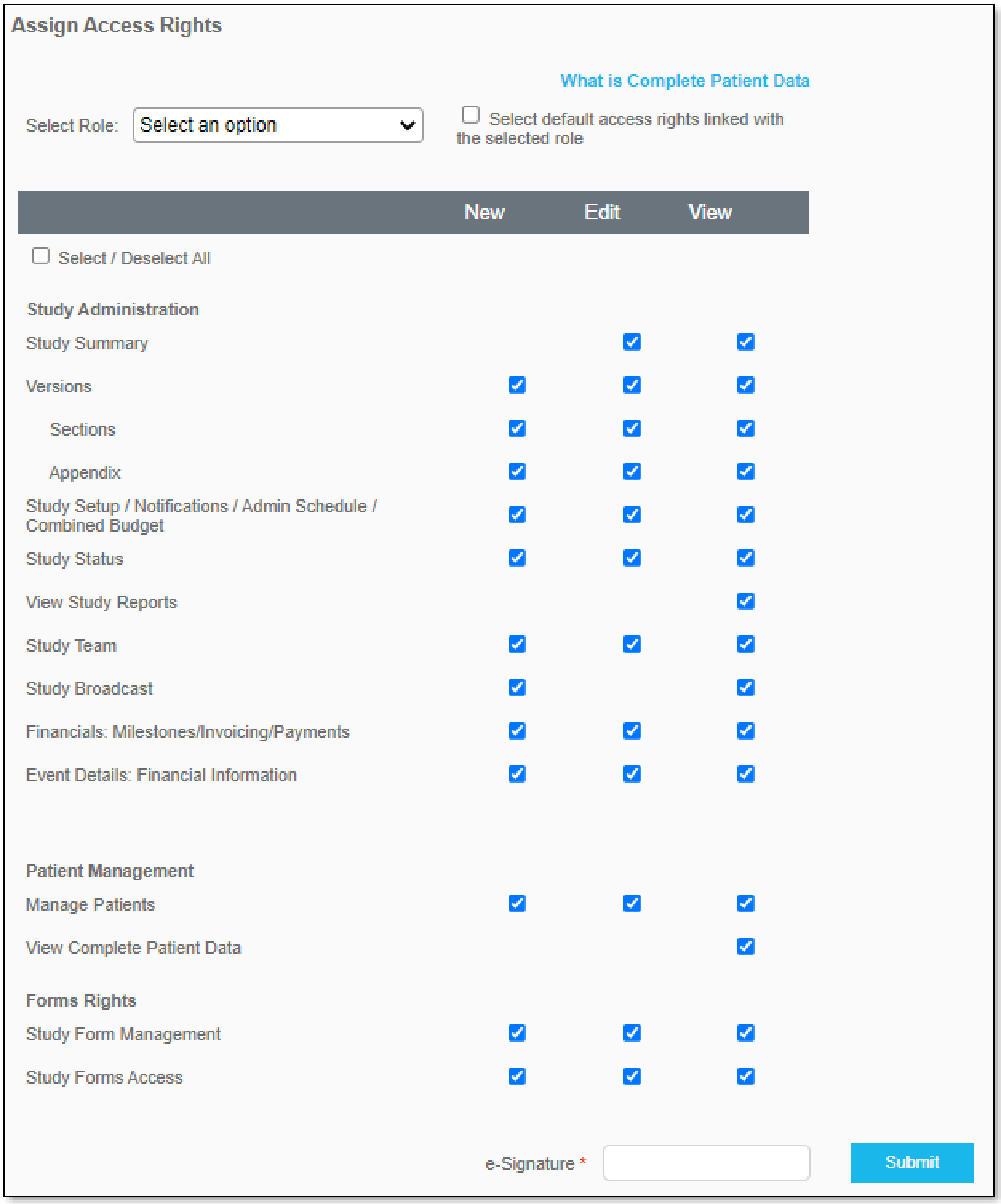


3. If you selected the Super User Rights for All Budgets only, or both selections, then you will arrive on the Budget Access Rights page. Uncheck checkboxes as needed, then enter your e-Signature and click **Submit** to confirm changes.



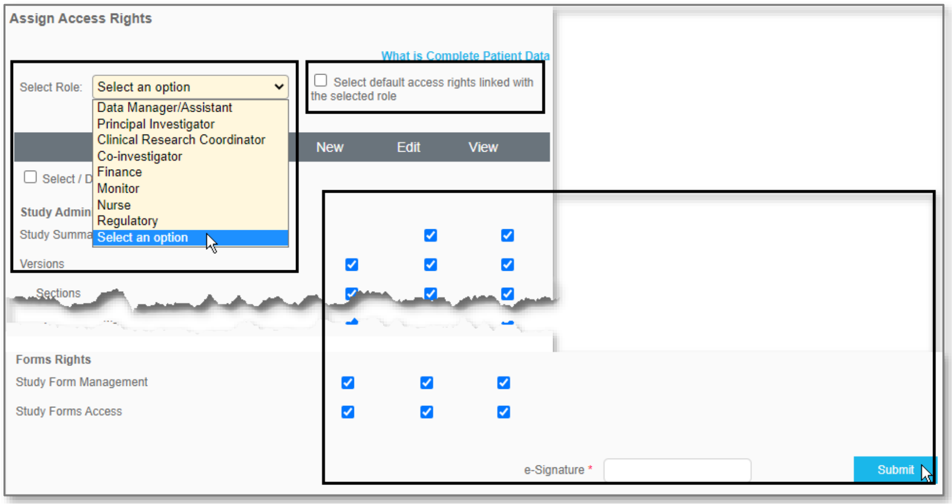
-OR-

If you selected Super User Rights for All Studies only, you will be returned to the Groups page. Click on the **Group Name**, then click **Assign Group Rights**, and then click the **Assign Rights** link to access the following screen.



- The above process is also how you access the All Studies' Assign Access Rights page if you selected both Super User Rights selections.

a. Select the **Role** from the dropdown, if needed. Check the checkbox to the right of the role, if you would like default access rights applied to the selected role, or leave it unchecked. Uncheck checkboxes as needed below the header. Then enter your e-Signature and click **Submit** to confirm changes.



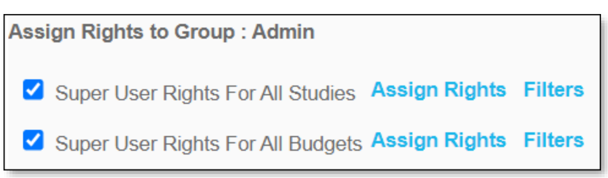
- If the blue link titled "What is Complete Patient Data" is clicked in the system, a new screen appears with information on the fields that will be viewable or hidden depending on whether the user has access to view complete patient information or not. Click the link in the system to view field details or refer to Patient Management in the Study Role Permissions Appendix. Refer to information on Complete Patient Data in Application Rights, for more information.

5.3.4.1 Refining Super User Rights for All Studies

Super User rights can be refined by using Filters. These filters can be defined for specific Therapeutic Areas, Divisions, and/or Disease Sites. Using these filters can refine access for Super Users to view limited data as refined.

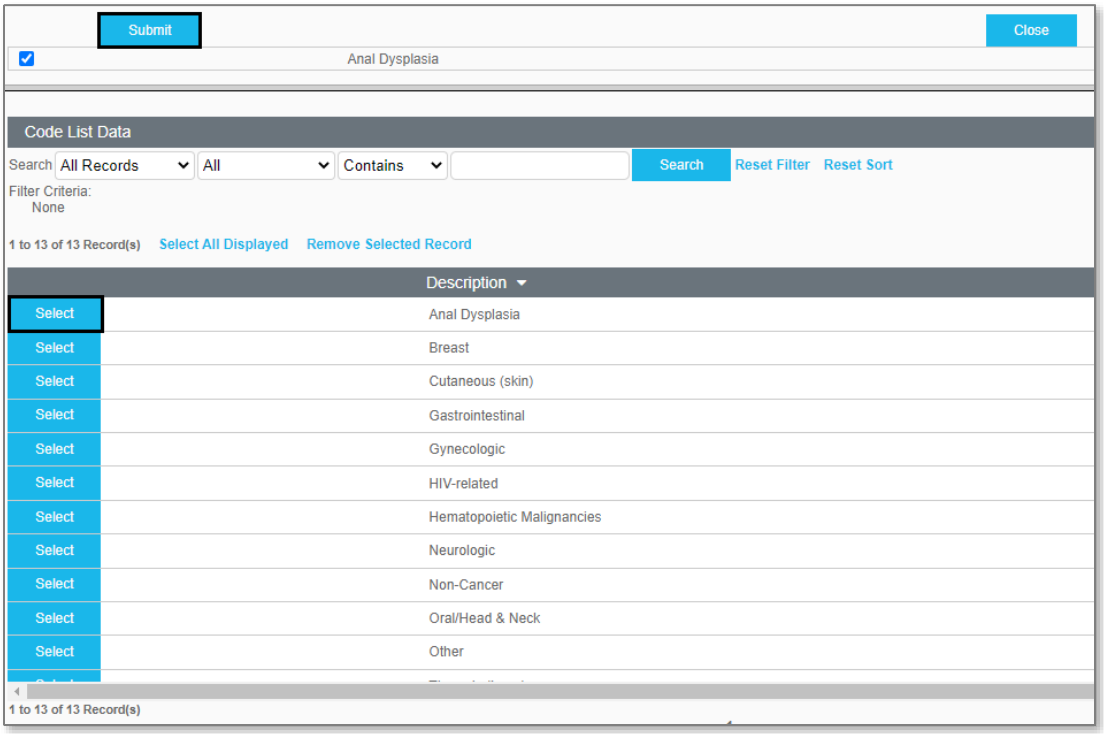
To add a filter to a Super User Rights for All Studies, from the Assign Rights to Group page:

1. Click **Filters** to the right of Super User Rights For All Studies.

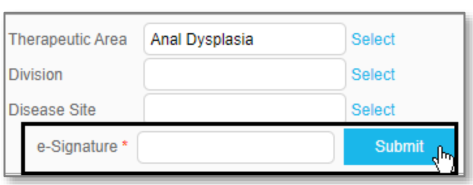


The following pop-up displays:

2. Click **Select**, for each area to include in the filter, and then click **Submit**.



The filter(s) selected will appear in the text field.



3. Enter your e-Signature and click **Submit** to confirm.

Note: Adding a filter to super-user rights will restrict the super-user rights to specific Therapeutic Area(s), Division(s), or Disease Site(s) as defined.

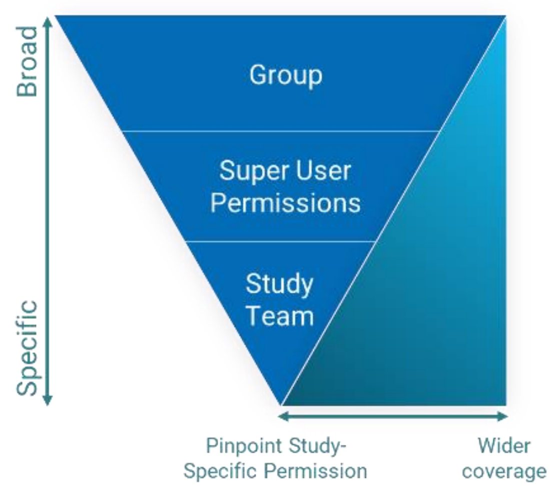
5.4 Understanding Permissions

Understanding how each element that defines a user's permissions, how specific permissions can be limited, and how they interact with one another is critical to ensure operational success in eResearch. Therefore, it is important to take a look at why one might want to layer permissions and how conflicting permissions are resolved by eResearch.

Some specific permissions, such as "Manage Patients" can be found in more than one area. For example, "Manage Patients" access can be provided at the group, super user, or study team level.

If a user were to have Super User Permissions to only "view" patient records, but View, Edit and New permission at the study team level, which definition would prevail? The answer is that the more "local" permission would take precedence over the broader permission.

In this example, the user would be able to only view patient records throughout the system on all other studies, but on the study where they were given a study team role with New, Edit and View permissions, they would be able to create new patient records, and edit and view existing patient records.

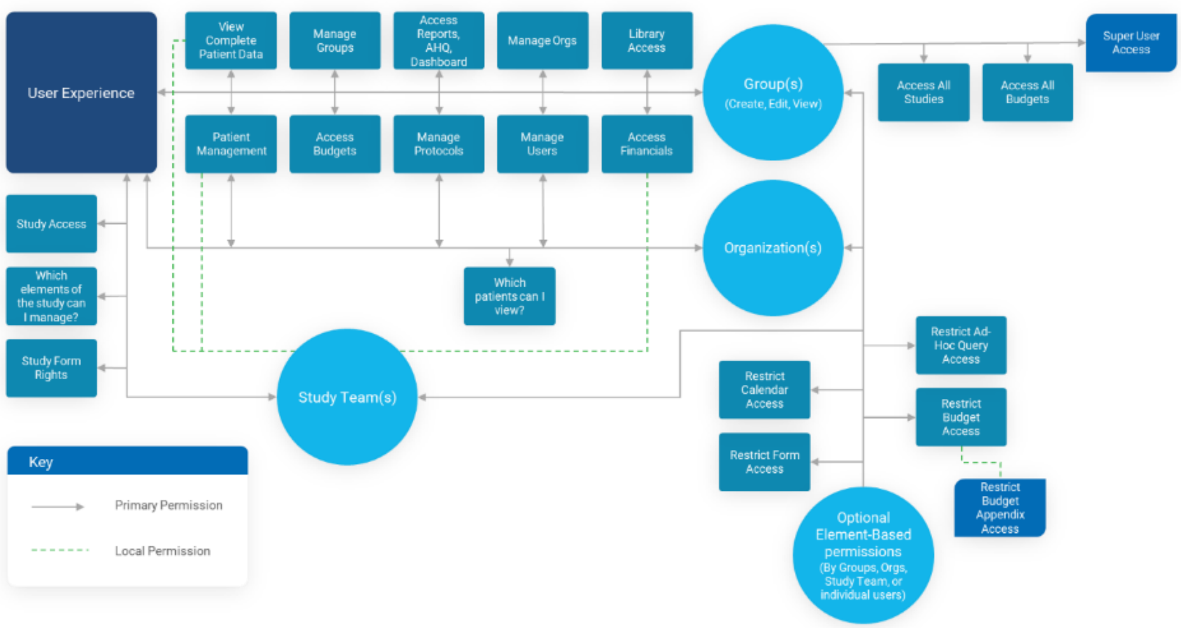


If layering a permission this way, think of the Super User permissions as giving that user very broad access across the system, unless contradicted locally, by a specific permission, in this case, a study team role permission.

5.4.1 User Experience Map

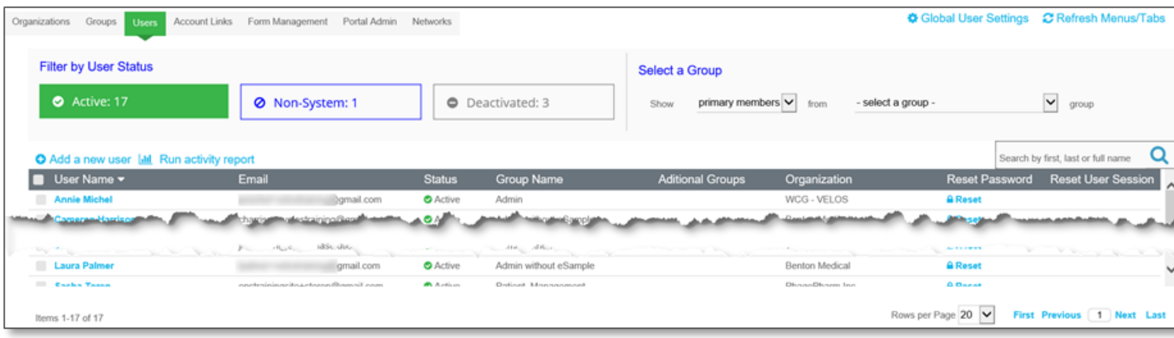
This section provides a map with the purpose of illustrating the complexity of how permissions configured throughout the system and organizations work behind the scenes to create the user's experience, highlighting the importance of carefully planning out your use of groups, organizations and other permissions, as they are all interconnected, and each decision can have downstream effects on other areas of the system.

Warning: It is highly recommended to consult with your Velos implementation partner to map out your organizations and groups before building out your first studies.



5.5 Users

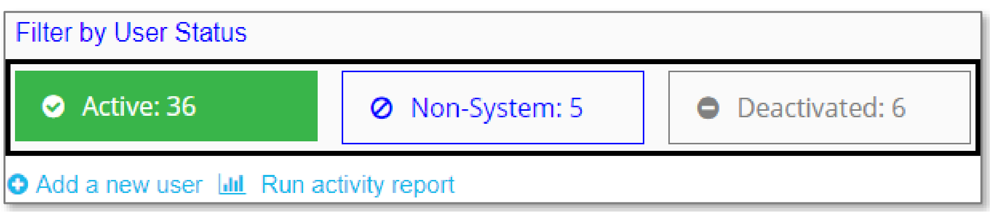
After groups and organizations have been added to the Velos eResearch system, users can be added. Active users perform all of the study, patient, budgetary, financial and reporting functions that are available within the system. Permissioned users can search, add, edit, and delete users. Account administrators can also adjust default account settings for all users, email users, reset passwords, and run a basic account activity report. Active system users are displayed on the Active Account Users page, sorted by the users' permission group.



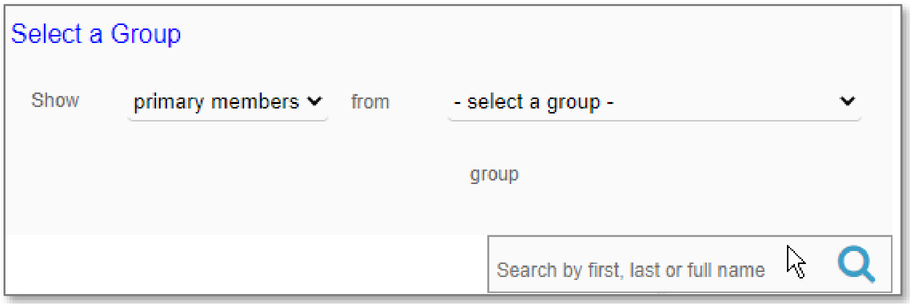
5.5.1 Search Users

From the Users tab, permissioned users can Search for Users.

1. Users should first filter by User Status. Active is the Default User Status Filter.



2. Then users can search by entering first, last, or full name into the search field and then click the magnifying lens or press enter.



Note: If a user is not found using the Active filter, search again using either the Non-System or Deactivated Filters. The Search function does not work across all three filter options.

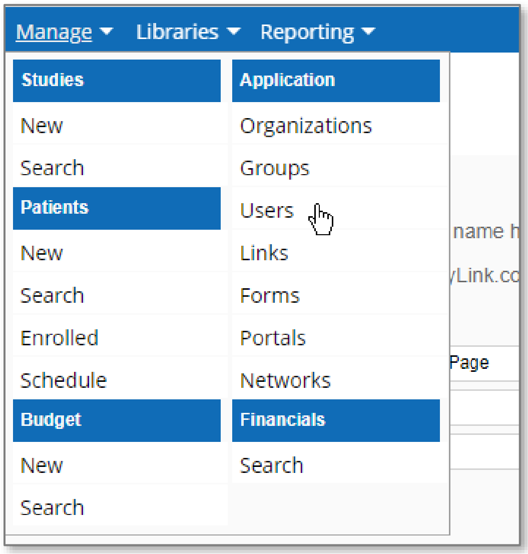
5.5.2 Add Active Users

Permissioned users can add new users to the system from the Active Account Users page.

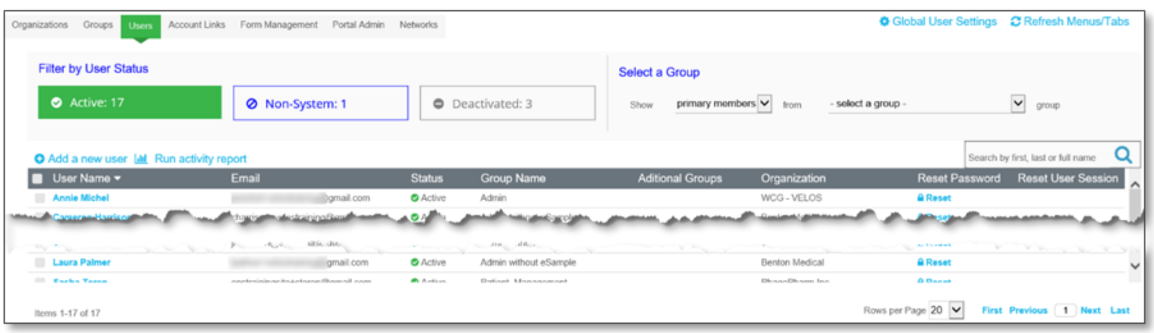
Note: Prior to adding users, confirm they do not already exist in the system by searching. Refer to Search Users. The system will not allow you to proceed, if trying to submit a username which is already in the system. If trying to submit an email that already exists in the system, a warning message will appear.

To add new Active users:

1. Click the **Manage** menu in the upper-left hand corner of the screen and select **Users** under the "Application" heading.

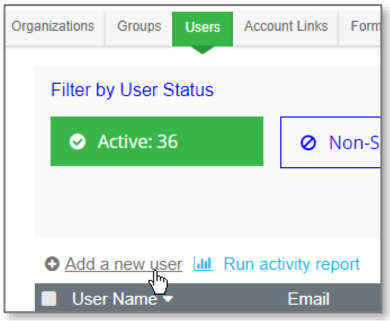


The Active Account Users page displays:

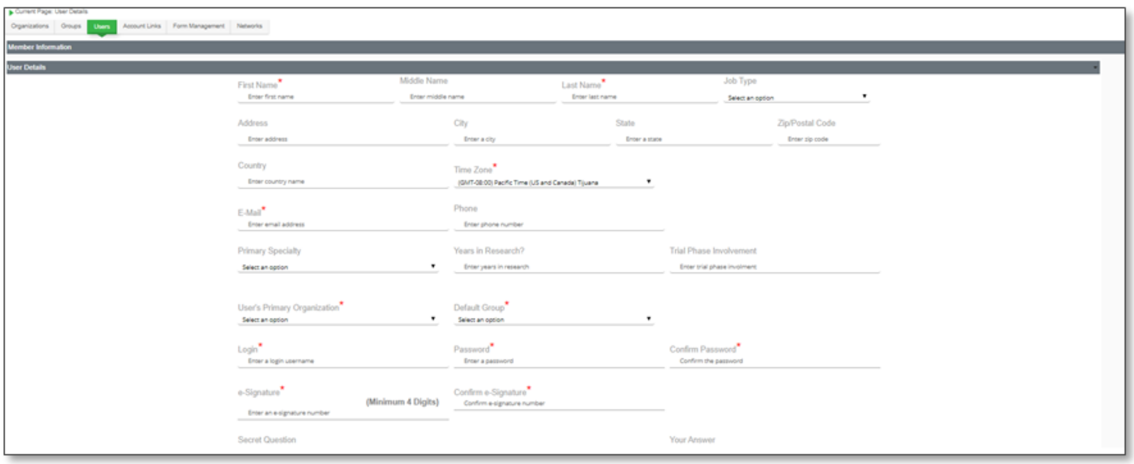


Note: Below is the process for adding an Active user to the system. An Active user will actively work in the system to add, edit, and/or view data. Continue to Non-System Users and Deactivated Users to learn more about these types of users.

2. Click **Add a new user**.



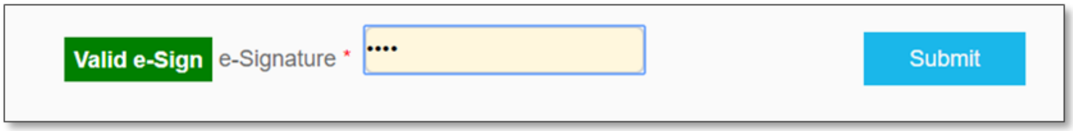
The User Details page displays:



3. Enter information as required into the available fields into the User Details section. All required fields are marked by an asterisk.

Note:
1. Additional optional fields will be available in eResearch Enterprise, such as “Middle Name
2. “Primary Specialty” field should not be completed for a user in the users detail section. It is intended to provide an additional level of access security that cannot be changed.
3. For information regarding Password and e-Signature requirements, see the Password / e-Signature section.

4. Once all user details have been entered, enter your e-Signature and click **Submit** to confirm.



Note: Once a user has been created, eResearch will automatically send two system generated welcome emails, providing the new user with login credentials.

5.5.2.1 Non-System Users

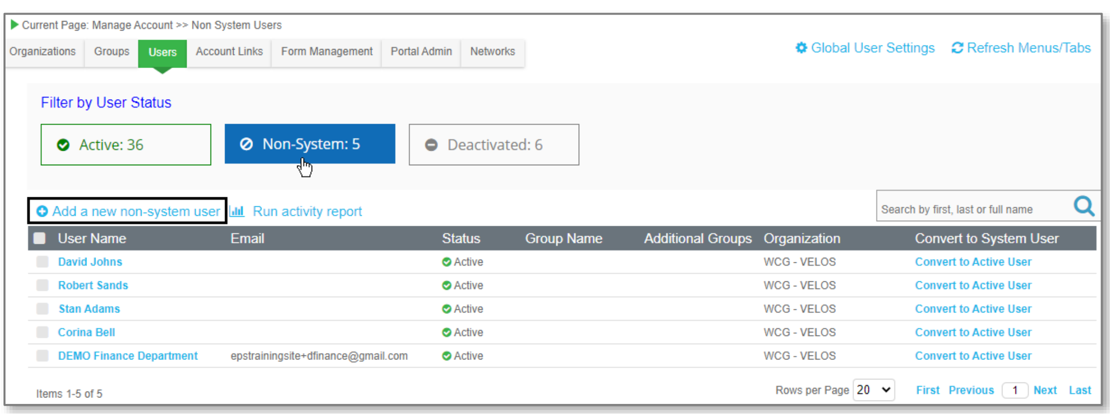
Non-System Users are those persons with roles such as external Principle Investigators, Sponsor Contacts, Nurses, and Doctors, who do not physically use the eResearch system but are involved in the management of patients and either:

- Need the data they record noted in the system by a secondary source who is an Active user
- They require notifications from the system to be sent to them

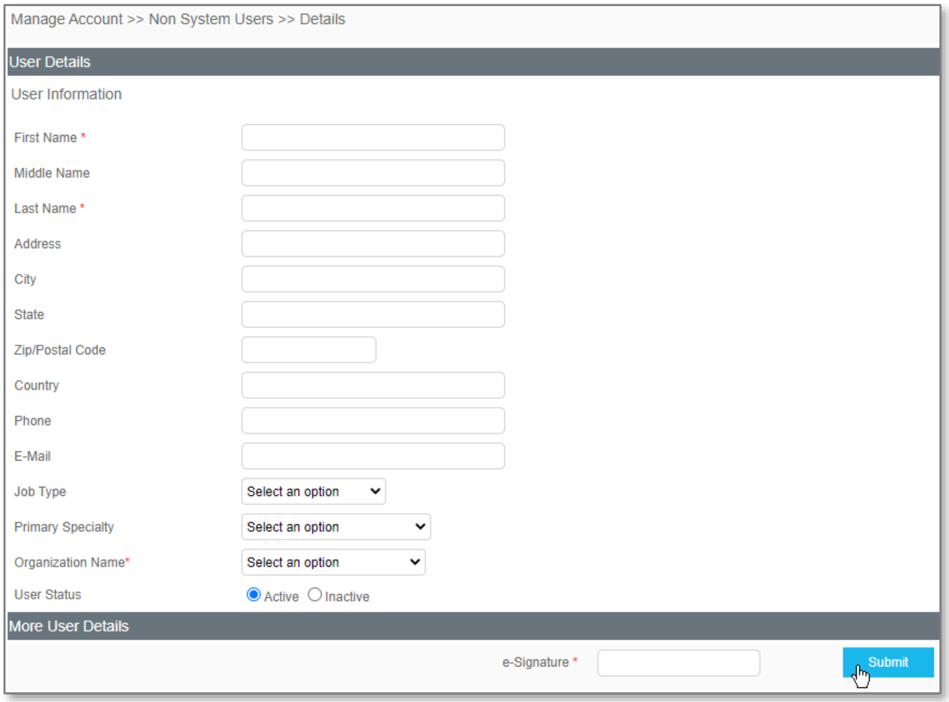
Note:
1. Non-system users may be deleted using the Power Bar.
2. Non-system users may be converted to active users, if needed, after they are initially added in the system by clicking the Convert to Active User link.
3. After a non-system user is converted into an active user, they cannot become a non-system user again. The active user account may only be deactivated.

To add new Non-System users:

1. Click **Non-System** and then click **Add a new non-system user**.



2. At minimum, complete the required information, as noted by asterisks, then enter your **e-Signature** and click **Submit**.

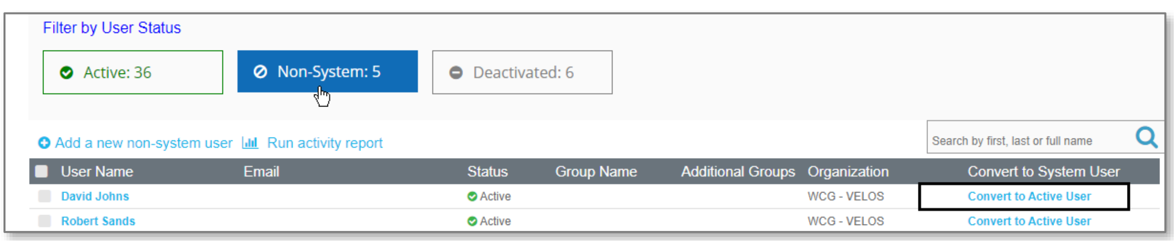


- In order for email notifications to be received, the E-Mail field must be completed.

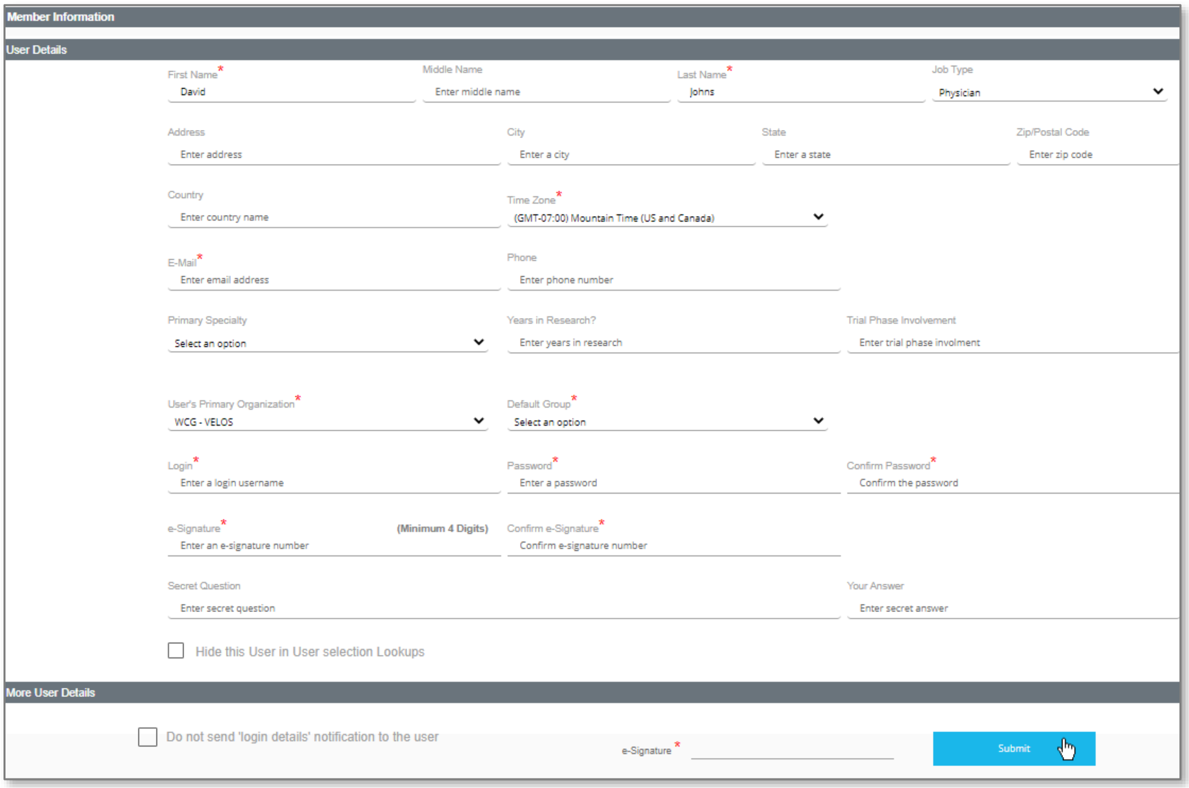
The new Non-System user may now receive system-generated notifications and the user can be recorded as the primary source for documentation by an Active user.

To upgrade the Non-System user to an Active user:

1. Click the **Convert to Active User Link** in the row for the Non-System user.



2. Update, adding at minimum required User Details, then enter your e-Signature and click **Submit**.



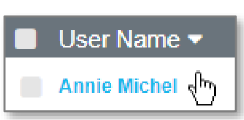
The Non-System User will now be located in the Active users list and will receive emailed login credentials in order to access the system.

5.5.3 Edit Users

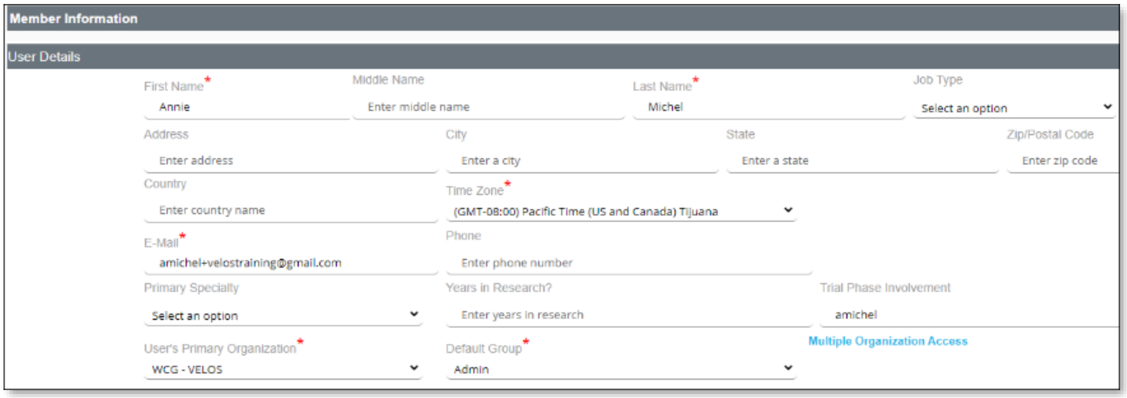
Permissioned Active users can edit system users' account details, password, and e-Signature as necessary. Non-System users do not have access to the system, but an Active user may edit their User Details.

To edit a user:

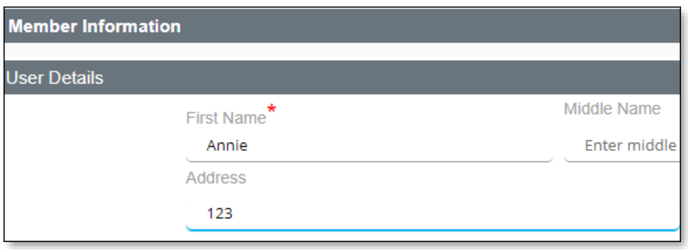
1. Click on the user's name as found in the **User Name** column.



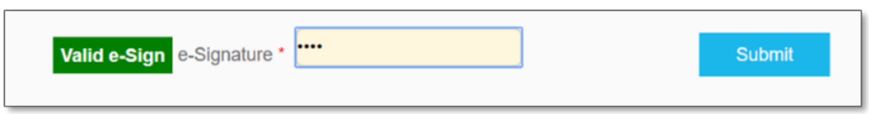
The User Details page displays:



2. Enter any missing or updated information into the available fields as necessary.



3. Once all user details have been entered, enter your e-Signature and click **Submit** to confirm.

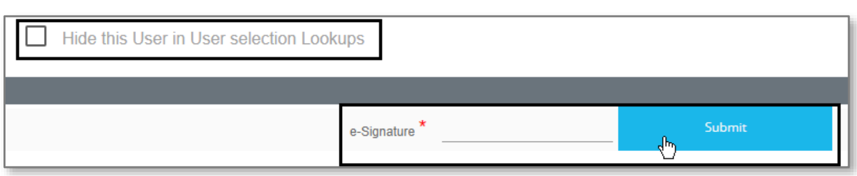


5.5.3.1 Hide User in Selection Lookups

After adding a user, a user's system login details can be withheld or hidden in a selection Lookup when editing a user's User Details page.

To hide a user from the selection Lookup, after accessing the User Details page:

1. Check the now visible **Hide this User in User selection Lookups** checkbox, enter e-Signature, and click **Submit** to confirm.



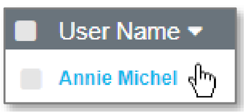
5.5.4 Add Existing Users to a Group

Permissioned users can add existing users to a group depending on their specific tasks and responsibilities within Velos eResearch. Adding users to a group defines their permissions for study, budget, and patient tasks, and can vary based on the settings established when the group was created.

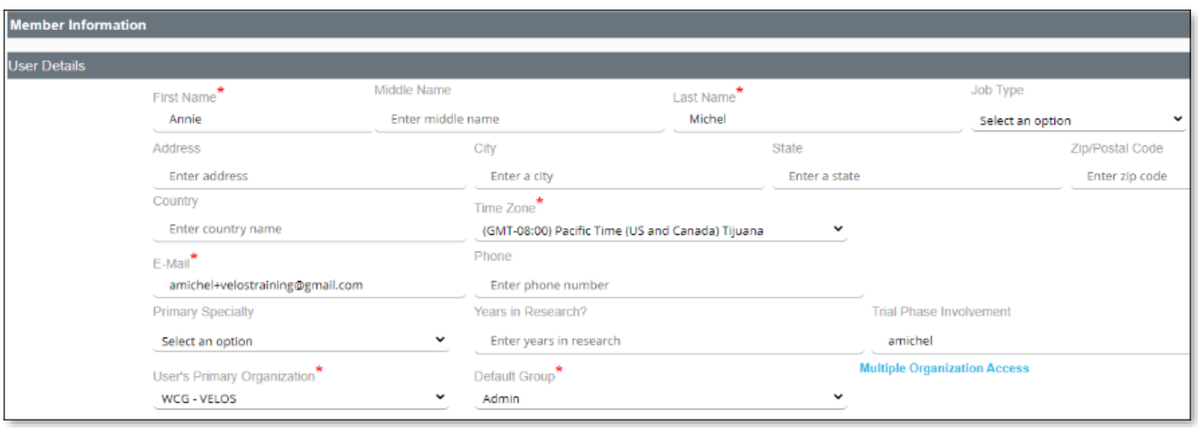
Note: Non-System and Deactivated users cannot be added or deleted from groups.

To add a user to a group:

1. From the Users tab, select the appropriate **User Name** to add to a group.

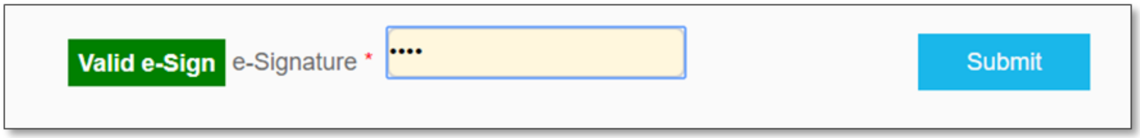


The **User Details** page displays:



2. Use the **Default Group** dropdown menu to select the desired group to assign the user to.

3. Once group details have been entered, enter your e-Signature, and click **Submit** to confirm.



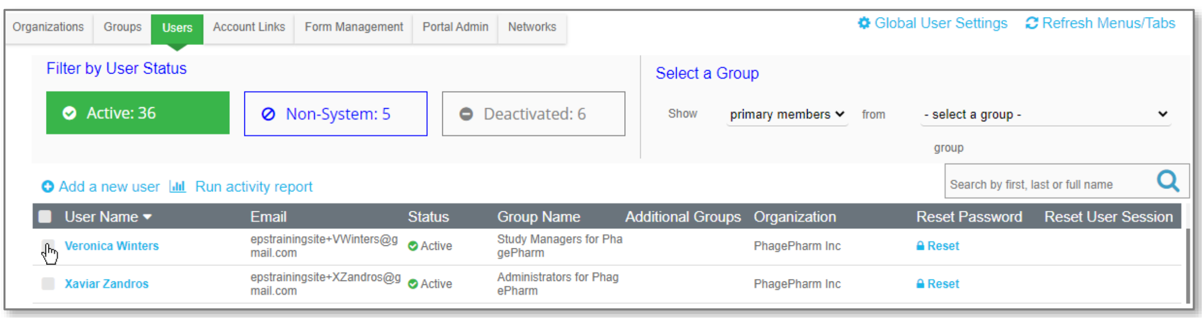
5.5.5 Deleting Users from a Group

Permissioned users can remove users from a permission group from the Active Account Users page.

Warning: Consult your internal processes prior to deleting users from a group before proceeding.

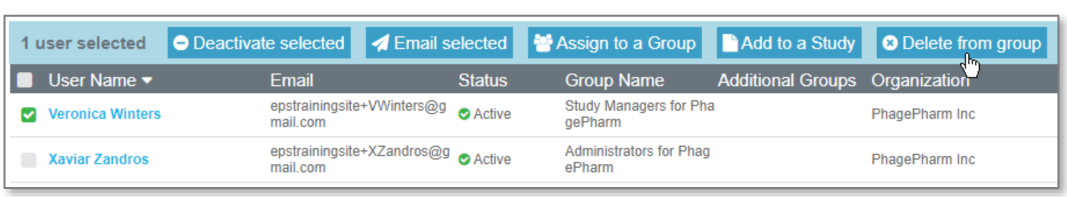
To remove a user:

1. From the Users tab page, check a checkbox for a specific user.

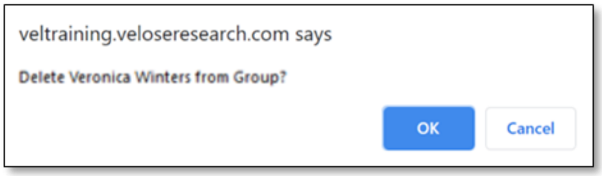


Note: Users must exist in at least one group. You cannot remove a user from their default group. A user's account cannot be deleted but may be deactivated. See Deactivate Users for more information about disabling user accounts.

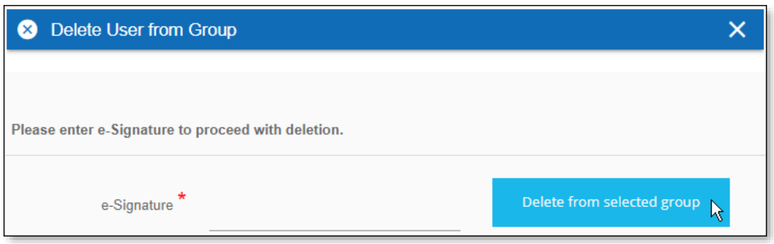
2. Click the now visible header button **Delete from group**.



3. Click **OK** in the first pop-up window.



4. Enter e-Signature and click **Delete from selected group** in the following pop-up window.



The user has been deleted from this group successfully.

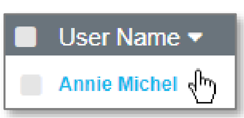
5.5.6 Deactivate Users

In addition to removing users from groups, permissioned users can deactivate users, effectively preventing them from logging into the application from the Active Account Users page.

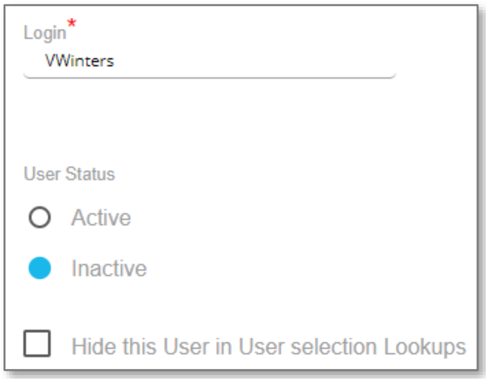
Note: Both Active and Non-System users may be deactivated following the steps below.

To deactivate active users:

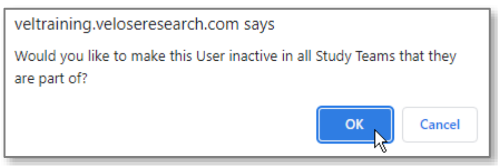
1. Navigate to the Active Account Users page, and click on the name for the appropriate user within the **User Name** column.



2. The user details page displays. At the bottom of the page, select **Inactive** in the **User Status** field.

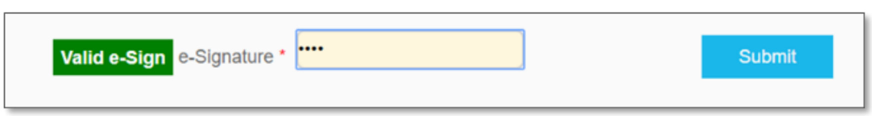


3. A notification displays, asking you to confirm user deactivation from ALL Study Team rosters. Click **OK** to proceed or click **Cancel** to deactivate the user in the system only.



Warning: Clicking OK above deactivates a user from all Study Team rosters. To deactivate a user's access to the system, but still allow a user to appear in a Study Team's roster(s), click Cancel and then enter e-Signature and Submit.

4. Enter your e-Signature and click **Submit** to confirm.

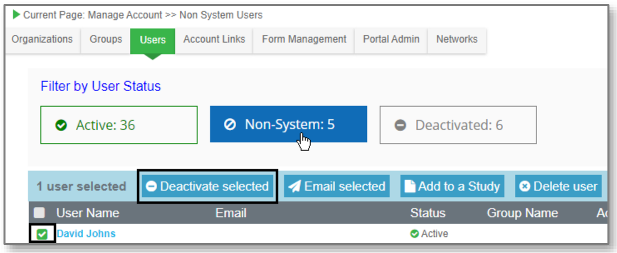


The user is deactivated.

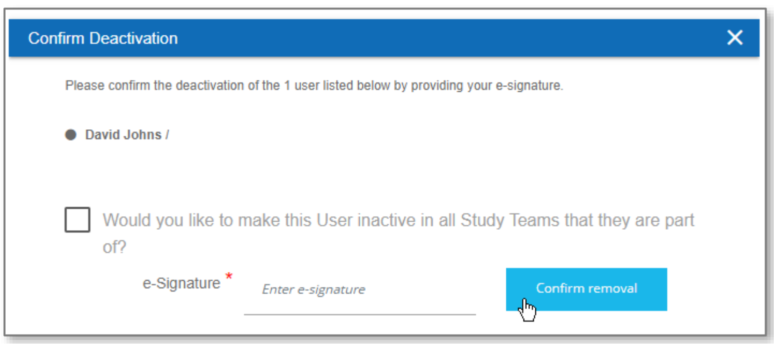
Note: You may view and reactivate any deactivated users by searching the Deactivated users list on the Active Account Users page

To deactivate Non-System users:

1. Check the User Name checkbox in the **Non-System** group and then click **Deactivate** selected.



2. Check the checkbox to make inactive in all Study Teams, if needed, then enter your e-Signature and click **Confirm removal**.



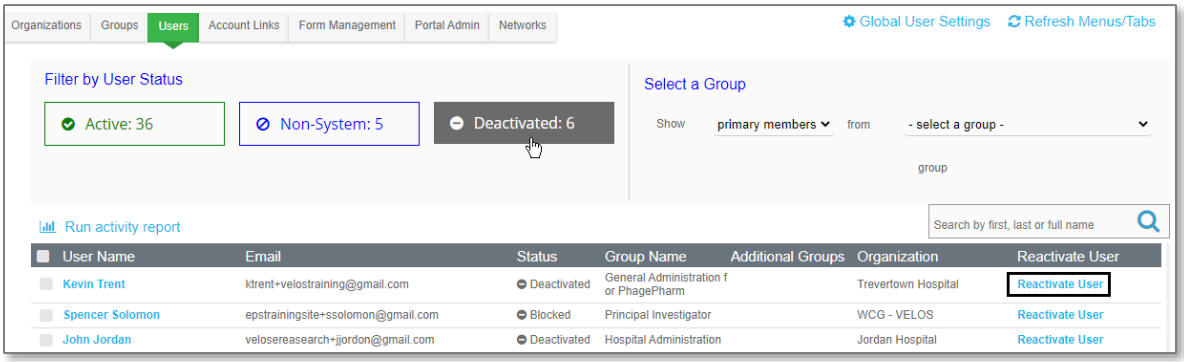
The user is now deativated and can be found in the Deactivated user group.

5.5.6.1 Reactivating Deactivated or Blocked User Accounts

Deactivated or blocked user accounts may have accounts restored to Active status. Deactivated users have been set to the status of “inactive” by a permissioned user (usually an admin) for the purpose of locking their account while still preserving ta log of their activities in eResearch. Blocked users are locked out of the system by exceeding the allowed number of login attempts with incorrect credentials.

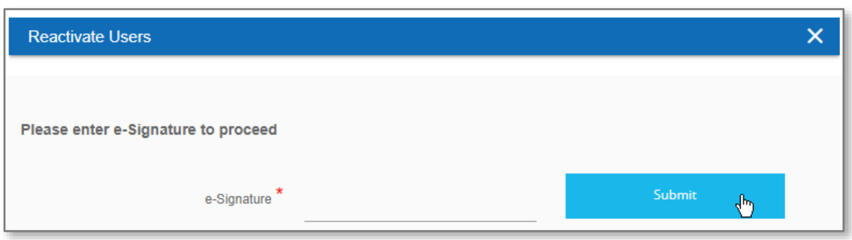
To activate a Deactivated user:

1. Click the **Deactivated** button, then click the **Reactivate User** link in the row for the user.

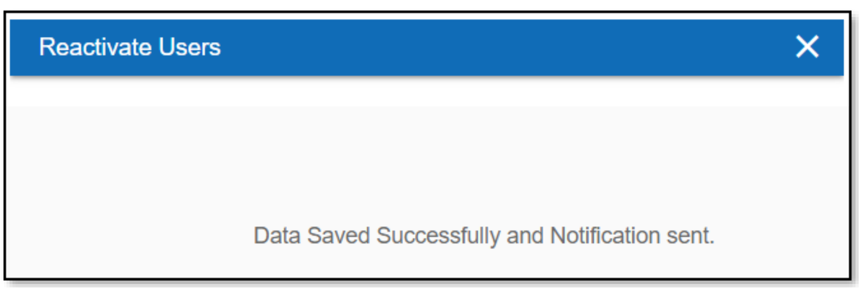


A pop-up will appear.

2. Enter your e-Signature and click **Submit** to confirm.



The following note will appear in the pop-up.



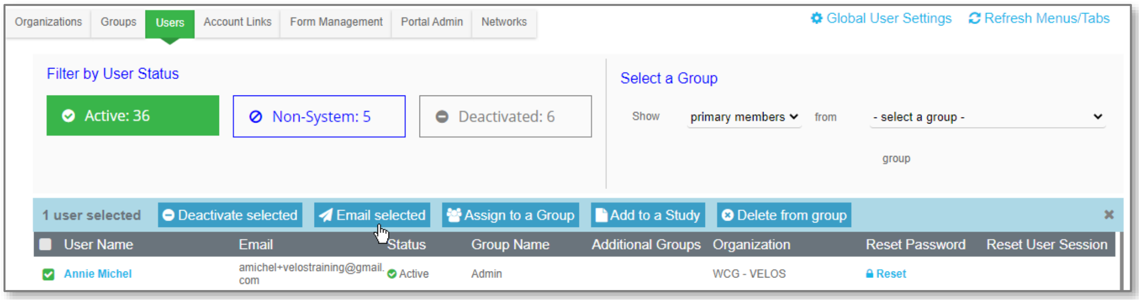
The Deactivated user is now an Active user and will receive emailed login credentials in order to access the system.

5.5.7 Email Users

Permissioned users can email users from the system using the Active, Non-System, or Deactivated Account Users pages.

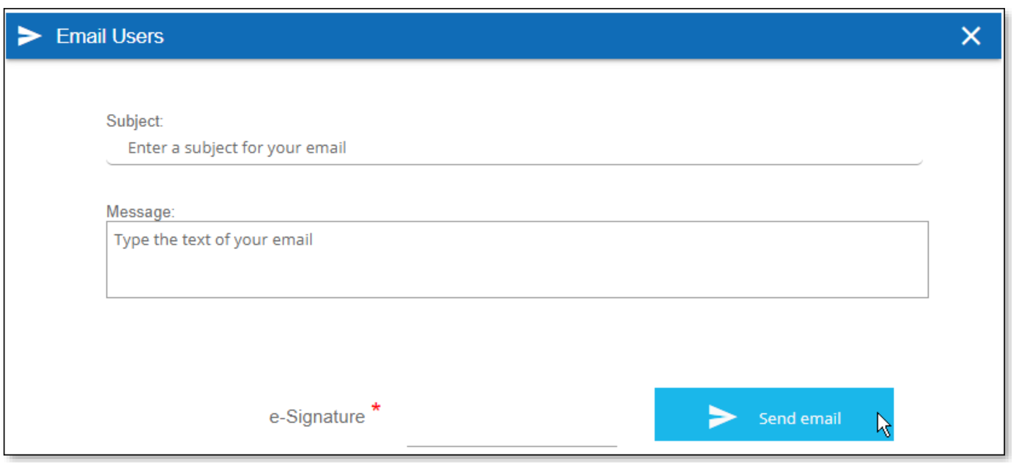
To email users:

1. Navigate to the Active, Non-System, or Deactivated Account Users page, and select the desired user or users by checking one or more checkboxes.



2. Click **Email selected**, now visible.

   The Email Users page displays:



3. Enter the **Subject** and body of your **Message** into the available fields.

Note: When creating an email, ensure that you have checked with your institutional policy compliance department regarding recipient verbiage.

4. Enter your e-Signature and click **Send email** to confirm.

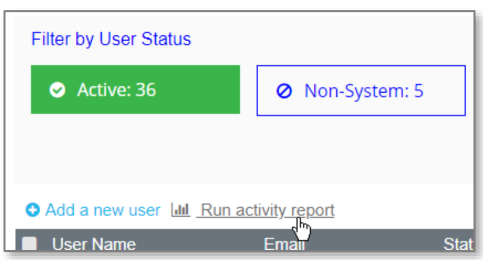
The email is sent successfully.

5.5.8 Run a User Activity Report

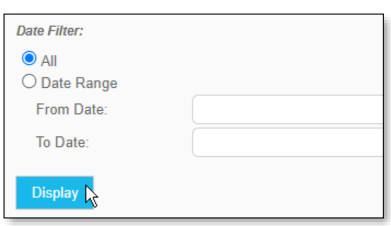
Permissioned users can run a basic User Activity Report using the Active Account Users page. The User Activity Report displays the following information: group name, user name, login count (total logins), total login duration, average login duration, date last logged in, and accessed from (IP Address).

To run a User Activity Report:

1. Navigate to the Active Account Users page and click **Run activity report**.



The Date Filter page opens in a new window.

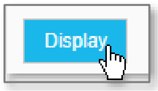


2. Select the option **All**.

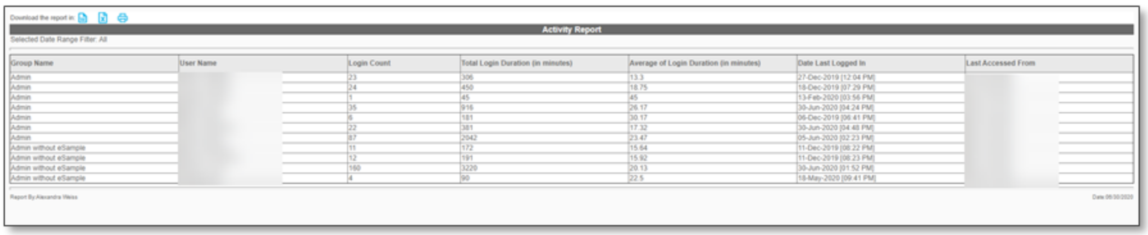
   -OR-

Select the option **Date Range**, and define the **From Date** and **To Date** to generate a more specific report.

3. Click **Display**.



The activity report displays:



Download the report in:

Activity Report

Selected Date Range Filter: All

Group Name	User Name	Login Count	Total Login Duration (in minutes)	Average of Login Duration (in minutes)	Date Last Logged In	Last Accessed From
Admin		23	306	13.3	27-Dec-2019 [12:04 PM]	
Admin		24	450	18.75	18-Dec-2019 [07:29 PM]	
Admin		1	45	45	13-Feb-2020 [03:56 PM]	
Admin		35	916	26.17	30-Jun-2020 [04:24 PM]	
Admin		6	181	30.17	06-Dec-2019 [06:41 PM]	
Admin		22	381	17.32	30-Jun-2020 [04:48 PM]	
Admin		87	2042	23.47	05-Jun-2020 [02:23 PM]	
Admin without eSample		11	172	15.64	11-Dec-2019 [08:22 PM]	
Admin without eSample		12	191	15.92	11-Dec-2019 [08:23 PM]	
Admin without eSample		160	3220	20.13	30-Jun-2020 [01:52 PM]	
Admin without eSample		4	90	22.5	18-May-2020 [09:41 PM]	

Report By:Alexandra Weiss

Date:06/30/2020

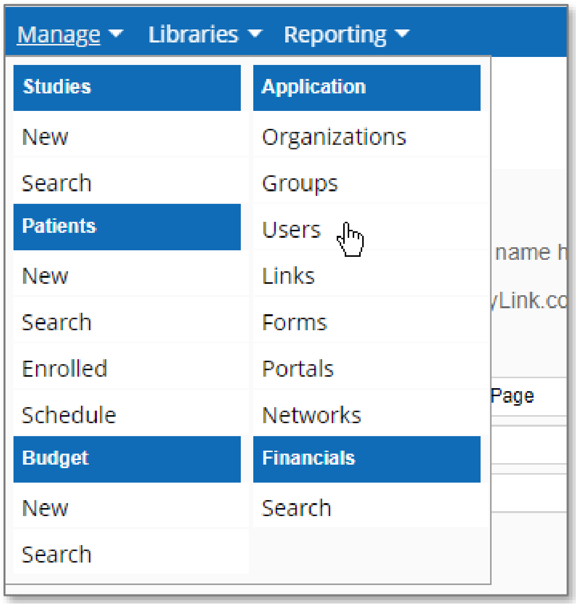
5.5.9 Global User Settings / Account Settings

Within Velos eResearch, system administrators have the option to specify the default automatic logout time for all accounts and Time Zones for users. The Automatic Logout Time feature protects the privacy and security of a user's account by logging them out automatically after a period of inactivity.

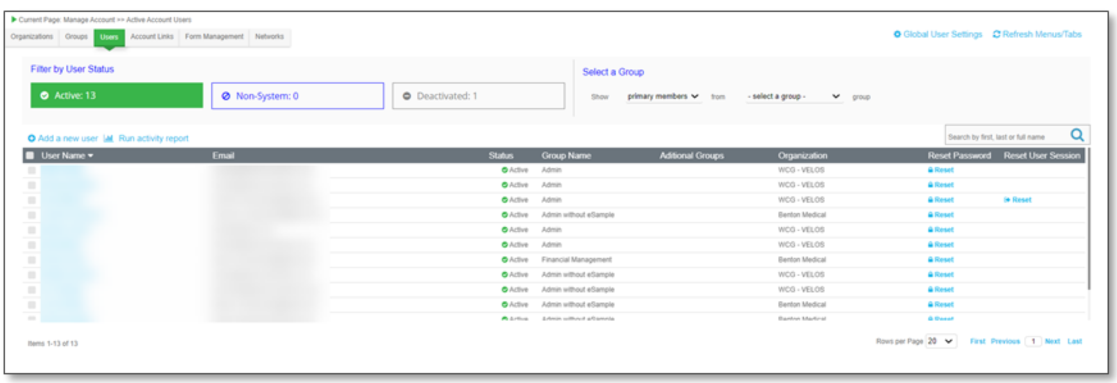
> **Note:** Settings changed on the Global User Settings / Account Settings page establishes the default settings for all user accounts. To learn more about changing the settings for your own account, see Settings.

To access the Global User Settings / Account Settings page:

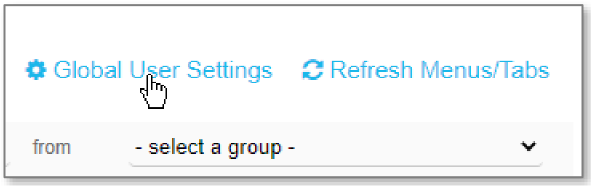
1. Click the **Manage** menu in the upper-left hand corner of the screen and select **Users** under the "Application" heading.



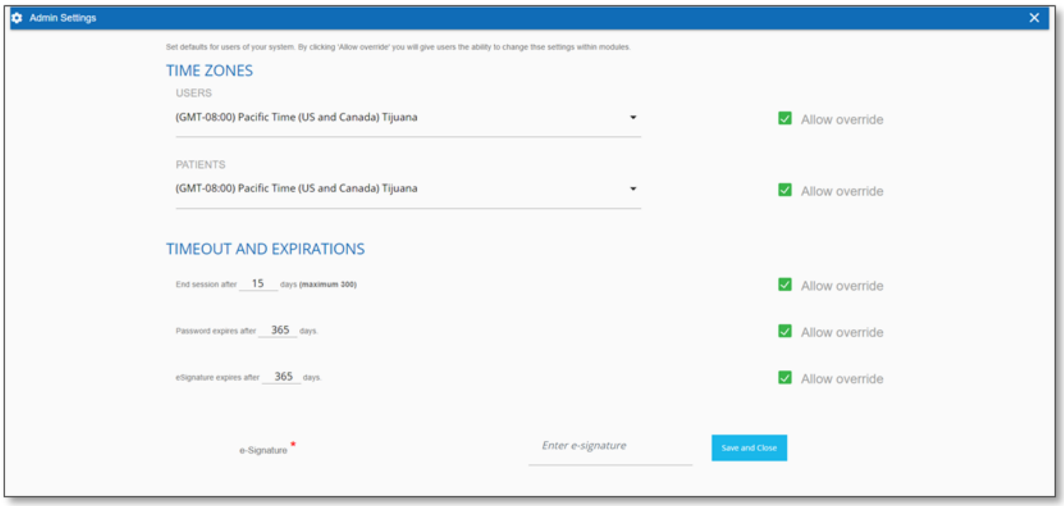
The Users page displays:



2. Click **Global User Settings** on the upper-right hand side of the screen.



The Admin Settings page opens in a new window:



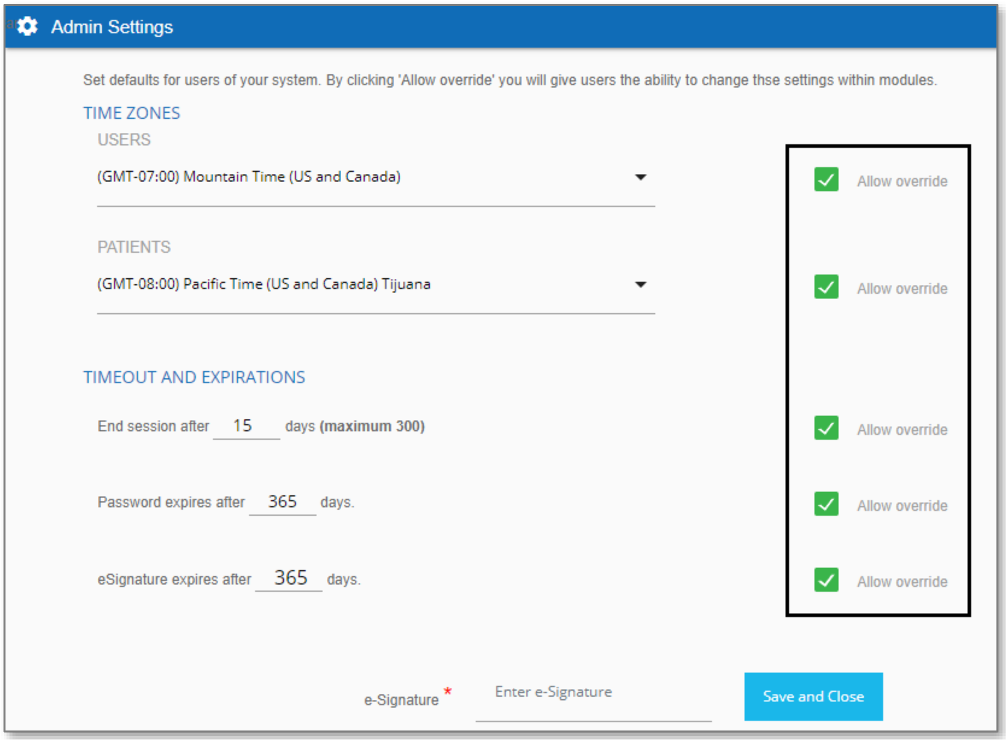
The following settings can be adjusted on this page. All values will be the default setting for user accounts.

- **Default User Time Zone** – Default time zone for all users.
- **Default Patient Time Zone** – Default time zone for all patients.
- **Default Automatic Logout Time** – Default automatic logout time.
- **Default Number of days after which the password expires** – Default days until users must reset their passwords.
- **Default Number of days after which the e-Signature expires** – Default days until users must reset their e-Signatures.

Note: Users can adjust these settings using the Settings page if the “Allow override” Can be Overridden? checkbox is checked for a setting.

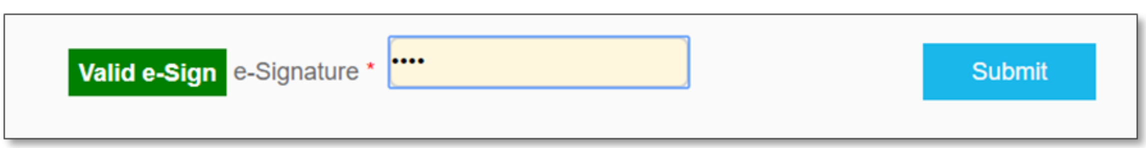
To adjust the default settings on the Admin Settings page:

1. Enter or select the desired values into each available field, checking the **Allow override** box for any settings that you would like users to be able to change.



Note: The value entered into the Default Automatic Logout Time field cannot exceed 300 minutes.

2. After making the desired changes, enter your e-Signature and click **Submit** to confirm.



The account setting changes have been saved.

5.6 Quick Links

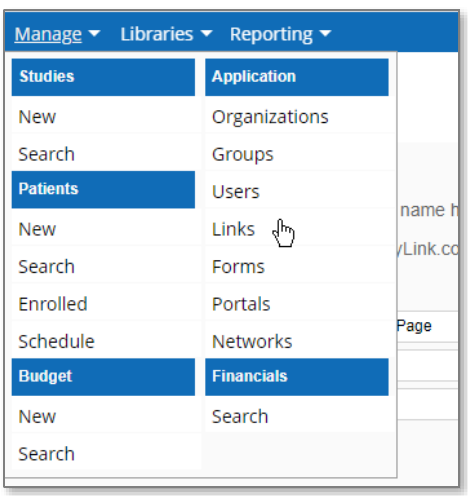
For convenience, or as part of your standard operating procedures, you may want to include links to external pages within Velos eResearch as a resource for all users. These links are displayed on the Default Homepage within the Quick Links section. Quick Links can be accessed by all users in the system. The Account Links page allows permissioned users to add, modify and delete links that are visible to all account users in the Quick Links section.

Note: To learn about My Links, which are configured by and only visible to individual users, see My Links.

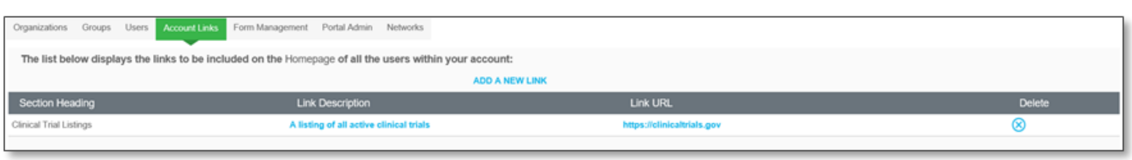
5.6.1 Add Quick Links

To add new account-level links to the Quick Links section of the Default Homepage:

1. Click the **Manage** menu in the upper-left hand corner of the screen and select **Links** under the "Application" heading.

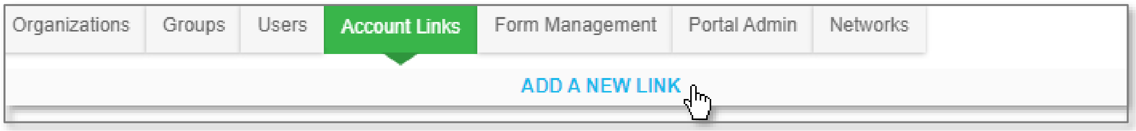


The Account Links page displays:



- The view above is if there is an existing link in the system.

2. Add new links by clicking **ADD A NEW LINK** on the left-hand side of the screen, for an initial link, or if there are existing links the ADD A NEW LINK will be located in the middle of the screen.

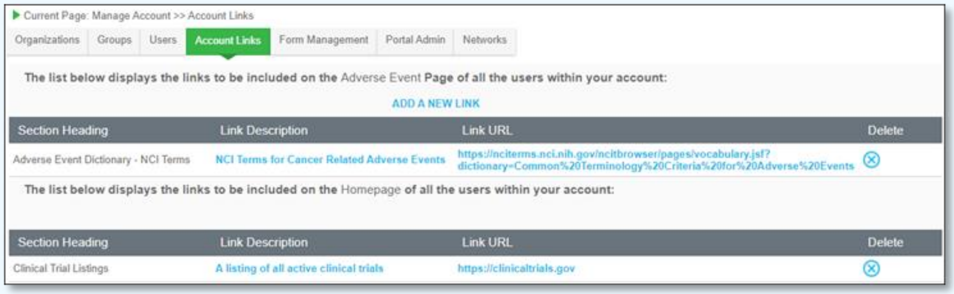


The Enter Link Details page displays:

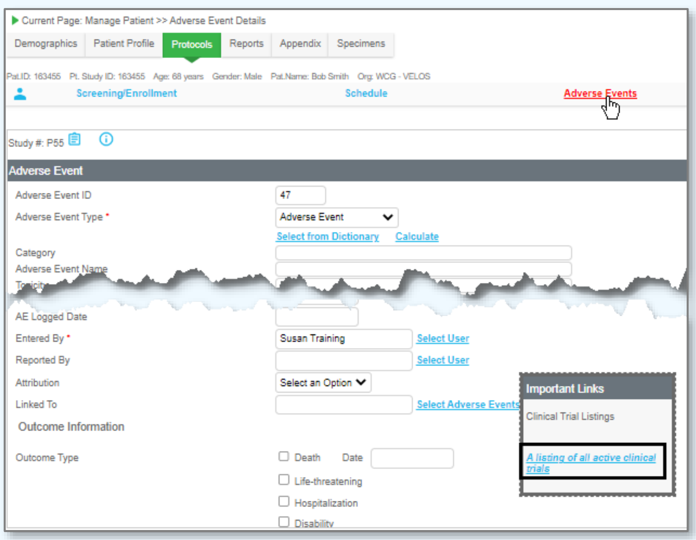
3. Enter the required information into the available fields including **Section Heading**, **URL**, and **Description** details. Also, select the appropriate **Link Type** of General or Adverse Event from the dropdown.

General Account Links appear on the Homepage in the Quick Links section

Enterprise Only: General Type and Adverse Event Type of Account Links will appear as two separate headings in the Account Links page. If the AE option is selected, the link displays on the Manage Patient Adverse Event Details page.



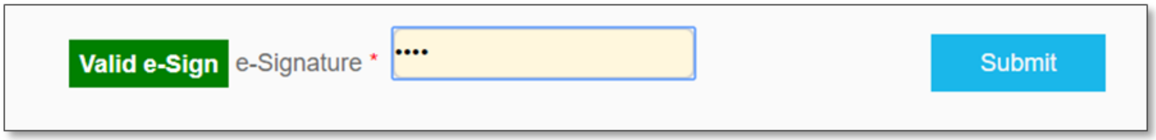
Enterprise Only: When adding Adverse Events, all AE Details pages for all patients in all studies will have a clickable AE link.



Note: Section headings organize your links by grouping them together under the same description. If you would like multiple URLs to display under the same section heading, enter the same section heading text for each entry. Ensure that any links you add to an existing heading uses the same spelling and punctuation that was used in the existing section heading.

Warning: When entering a URL, it must contain either http:// or https:// for the links to work properly. Failing to do so will result in broken, unusable links.

4. To save the new links, enter your e-Signature and click **Submit** to confirm.

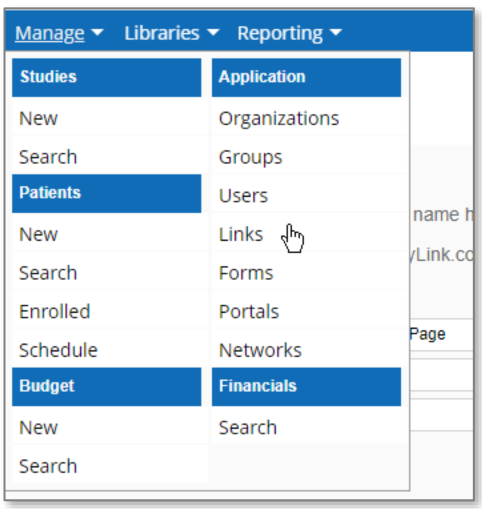


The new links have been added and now display within the Quick Links section of your Homepage and on the Account Links page.

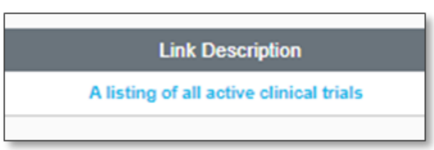
5.6.2 Modify Quick Links

To modify existing links:

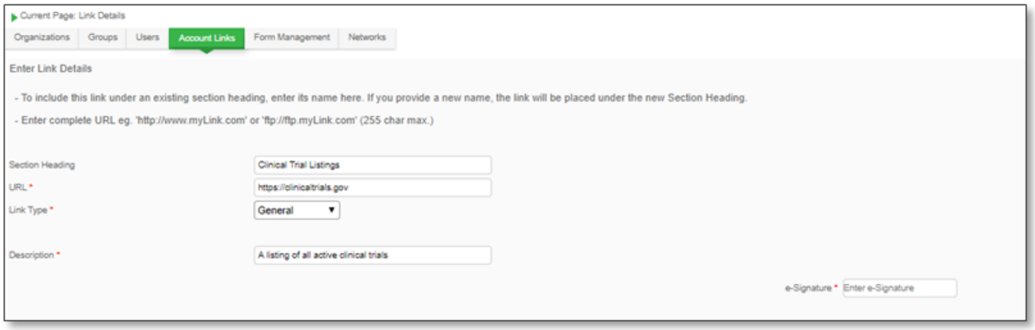
1. Navigate to the Account Links page by clicking the **Manage** menu in the upper-left hand corner of the screen and selecting **Links** under the "Application" heading.



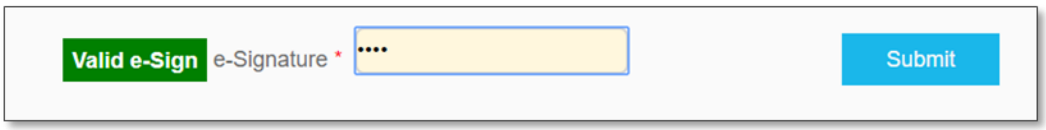
2. Click the link within the **Link Description** column of the entry that you would like to modify.



The Enter Link Details page displays:

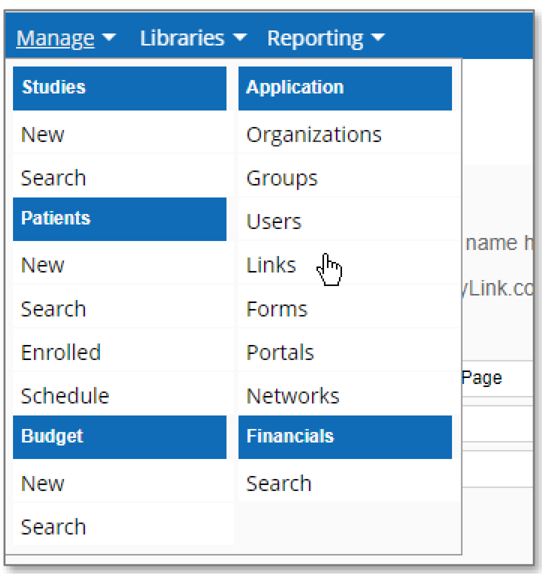


3. Update the required information, enter your e-Signature and click **Submit** to confirm.

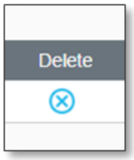


5.6.3 Delete Links

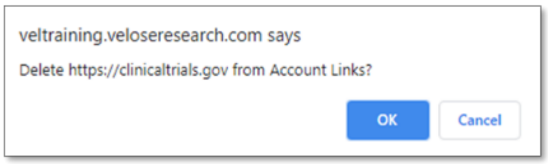
1. Navigate to the Account Links page by selecting **Manage** in the navigation menu and **Links** under the “Application” heading.



2. Click the **Delete** button in the Delete column next to the link you would like to delete



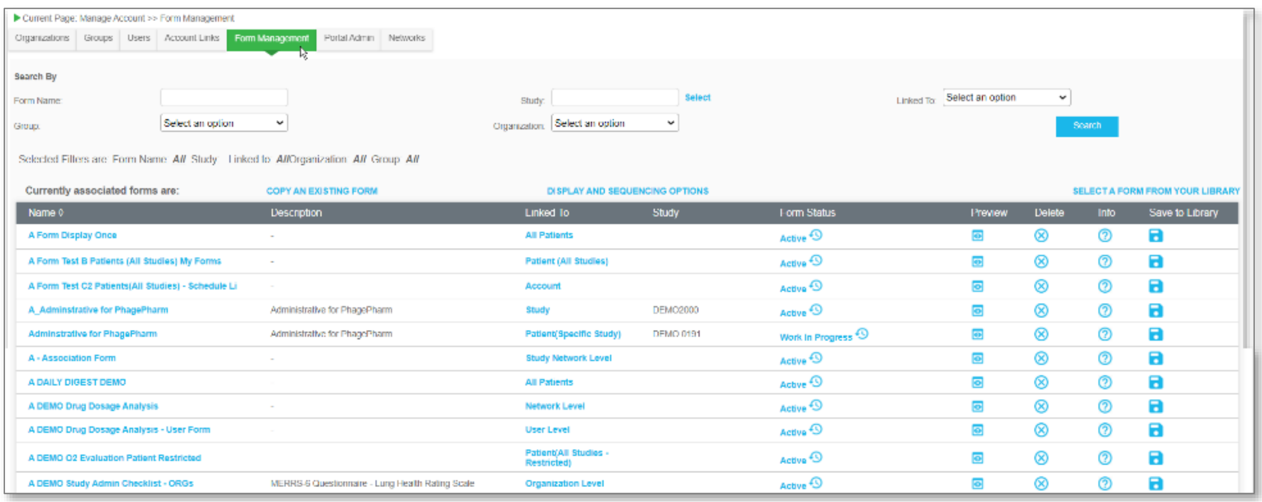
3. After clicking **OK** in the pop-up, to confirm the deletion, enter your e-Signature in the field on the new page that opens, and click **Submit** to confirm.



After clicking **Submit**, the link is permanently removed from the system.

5.7 Manage Account - Form Management

Within Velos eResearch, permissioned users can associate forms from the library using the Form Management page or can copy existing forms. For more information, refer to Add a Form. The Form Management page allows for deletion of forms, if not actively used, saving linked forms back to the library, and changing a linked forms status. Linking forms here provides associated forms to be accessed in various areas of the system, for other purposes. When a form is linked to a specific study, the study number will appear in the Study column.



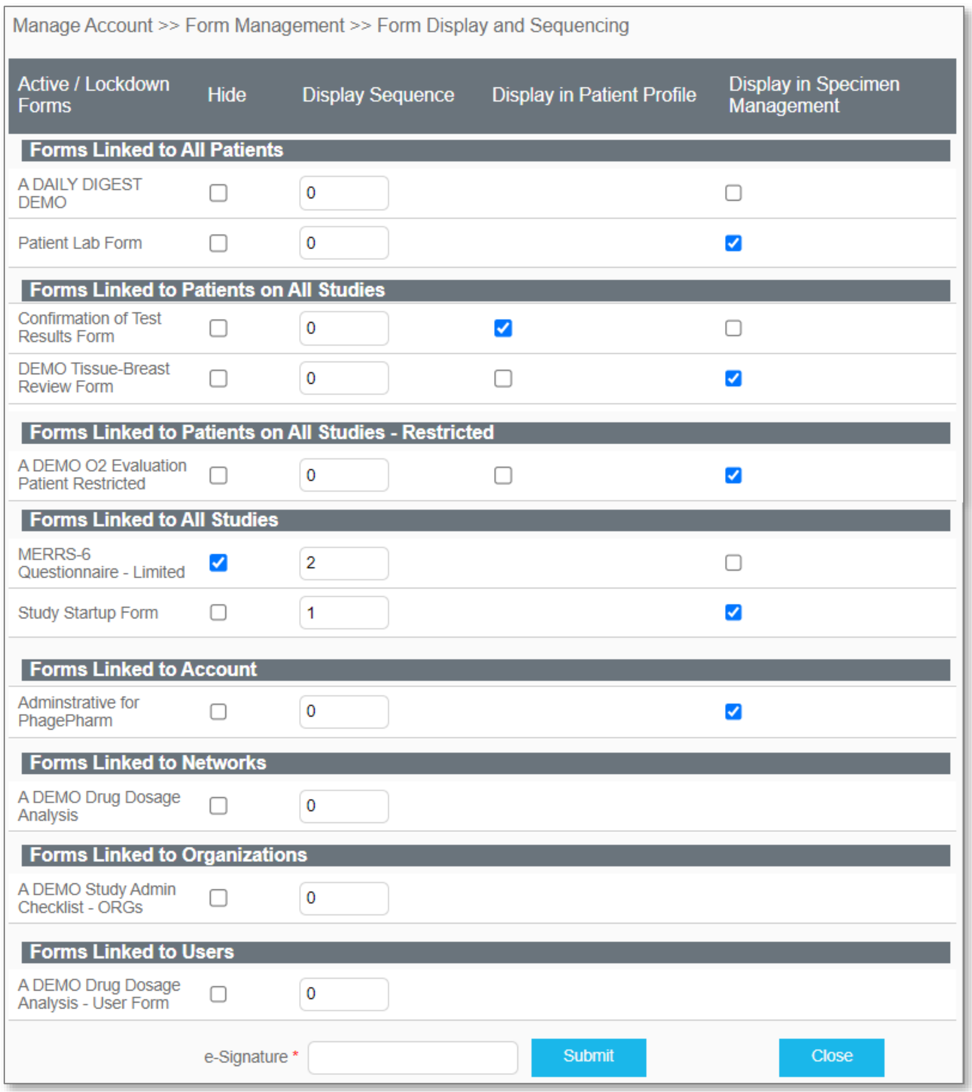
Navigation Bar Links:

- A *Name* of the form may be clicked to view the form details. For more information on changing details in a linked form, refer to Modify a Form and Form Statuses.
- A *Linked To* link may be clicked to view the option selected as well as Characteristics and Filters selected. Refer to Add a Form for more information. Refer to Linked Forms in Account Management for more information on the different Linked To selections.
- A *Form Status* may be changed. For more details, refer to Modify a Form and Form Statuses.
- Preview can be clicked to see a preview of a form
- Delete may clicked if a form is to be deleted. For more information, refer to Delete a Form.
- Info can be hovered over to view creation and modified by information for a form
- Save to Library can be clicked to save the form to the library, if desired, by assigning a Form Category in the pop-up, then e-Sign and Submit

Refer to Display and Sequencing Options for more information on the functions of this page.

5.7.1 Display and Sequencing Options

Utilizing the Display and Sequencing Options page allows for forms in active status to be hidden from view in a dropdown list, to be organized in a dropdown list by sequencing, to display applicable linked types in patient profiles, and to display applicable linked types in specimen management for use in eSample. **Refer to the eSample User Guide for more information about this module.**



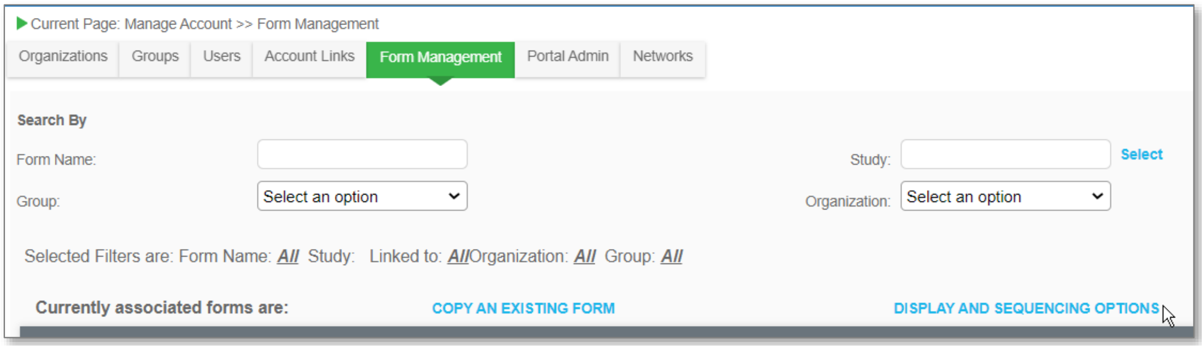
Manage Account >> Form Management >> Form Display and Sequencing

Active / Lockdown Forms	Hide	Display Sequence	Display in Patient Profile	Display in Specimen Management
Forms Linked to All Patients				
A DAILY DIGEST DEMO	☐	0		☐
Patient Lab Form	☐	0		☑
Forms Linked to Patients on All Studies				
Confirmation of Test Results Form	☐	0	☑	☐
DEMO Tissue-Breast Review Form	☐	0	☐	☑
Forms Linked to Patients on All Studies - Restricted				
A DEMO O2 Evaluation Patient Restricted	☐	0	☐	☑
Forms Linked to All Studies				
MERRS-6 Questionnaire - Limited	☑	2		☐
Study Startup Form	☐	1		☑
Forms Linked to Account				
Adminstrative for PhagePharm	☐	0		☑
Forms Linked to Networks				
A DEMO Drug Dosage Analysis	☐	0		
Forms Linked to Organizations				
A DEMO Study Admin Checklist - ORGs	☐	0		
Forms Linked to Users				
A DEMO Drug Dosage Analysis - User Form	☐	0		

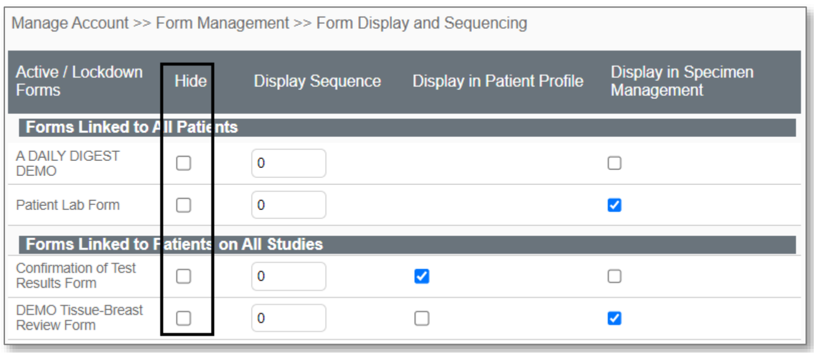
e-Signature * Submit Close

To manage display and sequencing options, from the Form Management page:

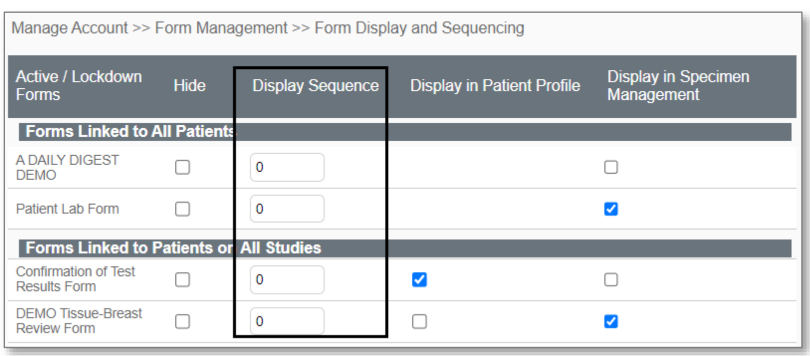
1. Click **DISPLAY AND SEQUENCING OPTIONS**.



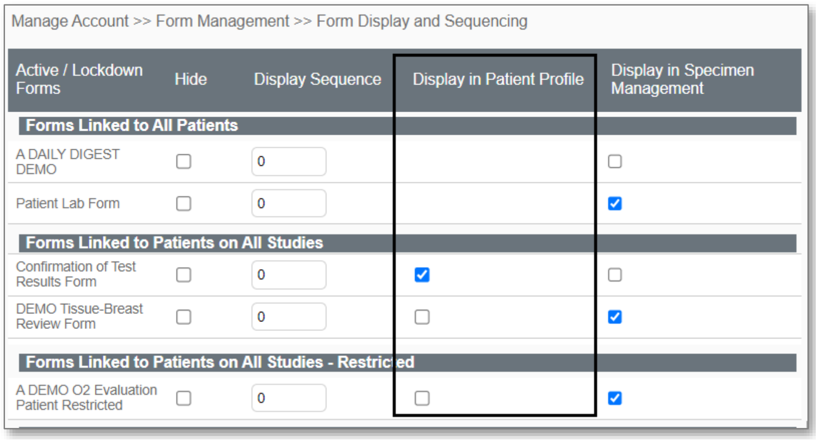
2. If a form is to be hidden from selection in a dropdown, click the applicable Hide checkbox.



3. If there is more than one form in a Forms Linked In category, enter numbers into the Display Sequence fields to re-order in chronological order in the system dropdowns, as desired.

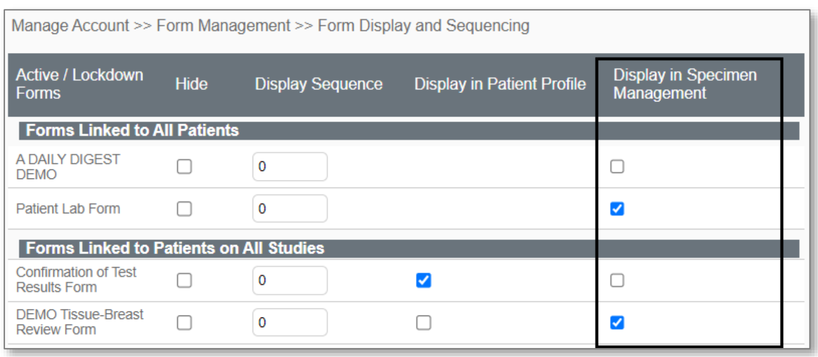


4. For Forms Linked to Patients on All Studies and -Restricted, check checkboxes to display the forms in Patient Profiles for all patients on all studies, as needed.



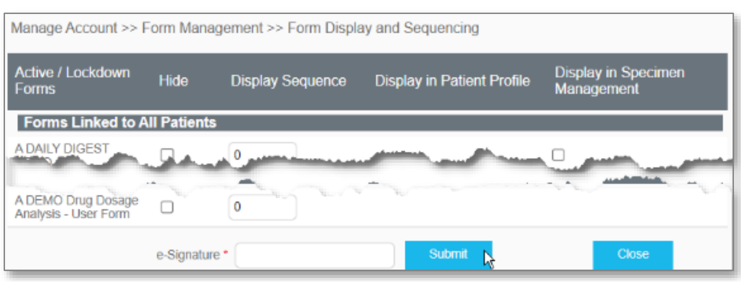
- For more information on where these selected forms appear, refer to Linked Forms in Account Management

5. *eSample Only*: For those forms that are required for eSample, check the checkboxes in the Display in Specimen Management Area and the forms will appear in all Specimens Forms pages.



- For more information on where these selected forms appear, refer to Linked Forms in Account Management

6. When the form is complete, enter your e-Signature and click **Submit**.



5.7.2 Linked Forms in Account Management

Account Form Management allows an administrator to link forms using many options. Depending on the Linked To option selected, the form will appear in specific system locations for use.

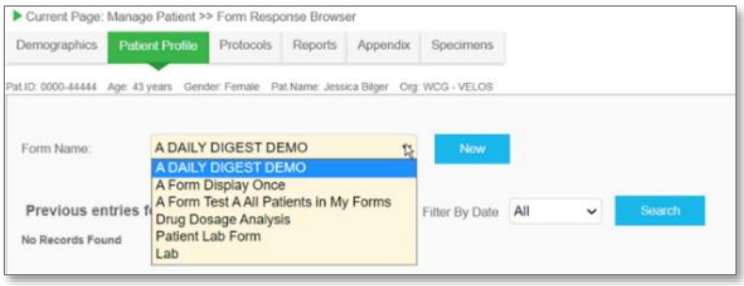
The table below shows where the forms will initially appear when linked in the Form Management page. View additional details on the following pages, for more information.

Linked To Selection	Where the Form Appears in the System When Initially Linked
Patient Level (all)	All Patient Profile tabs
Account Level	Account Forms on Homepage
Study Level (all)	All Studies' Study Management > Forms tabs
Patient Level (All Studies)	All Study Patient > Protocols tab > Forms pages
Patient Level (All Studies – Restricted)	[This kind of form response for Patients will be displayed only in the study where they are created not in all studies]
User Level	All User Details > Forms pages
Organization Level	All Organization Details > Forms pages
Network Level	All Network > Forms pages for each Organization
Study Network Level	All Studies with Networks added in the Study Management > Study Network tab > Forms pages for each Organization
Specific Study Level	Only the specific study selected- Study Management > Forms tab
Specific Study Patient Level	For all patients on a specific study only – Study Patient > Protocols tab > Forms link

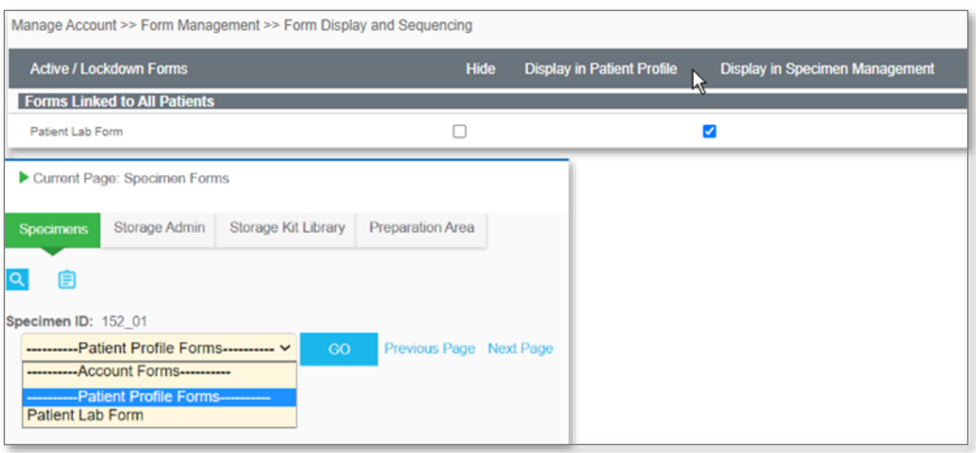
ADDITIONAL DETAILS FOR LINKED FORMS:

Patient Level (all)

- Appears in the Form Management table as Linked To: All Patients
- When a form is linked in the Form Management page using this selection, all patients will have the form appear in their Patient Profile tabs

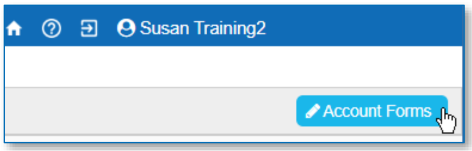


- *Participant Portal Only*: Forms using this selection may also appear in the location above after completion in the Participant Portal
- *eSample Only*: The form selection may also be checked for selection in the Form Display and Sequencing page in which it will appear in Specimen Forms under Patient Profile Forms

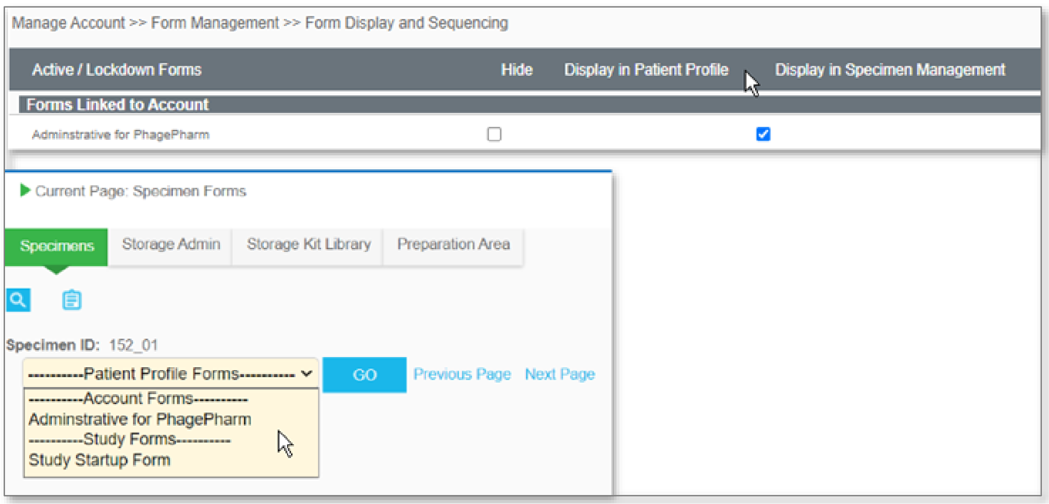


Account Level

- When a form is linked in the Form Management page using this selection, the form will appear in the Account Forms page from the Homepage link

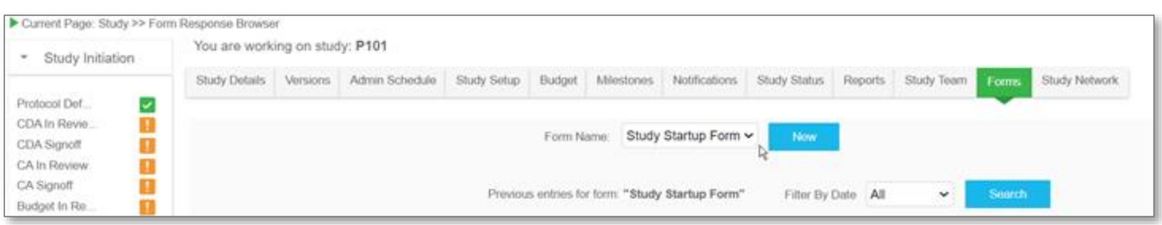


- *eSample Only*: The form selection may be checked for selection in the Form Display and Sequencing page in which it will appear in Specimen Forms under Account Forms

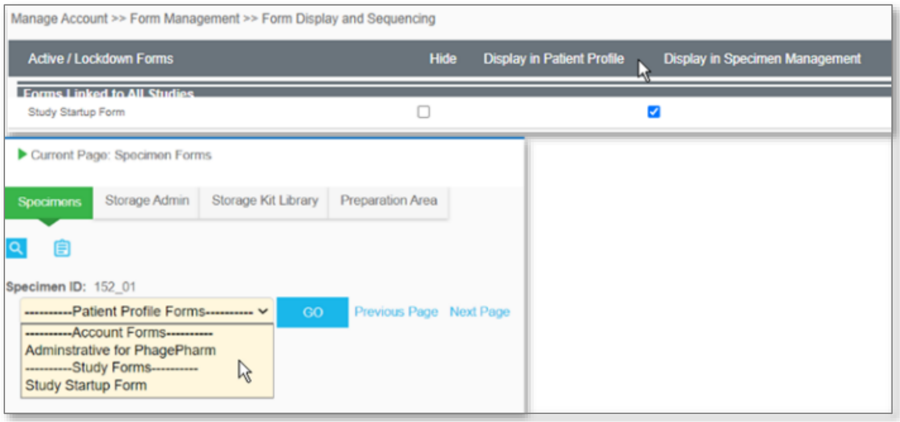


Study Level (all)

- Appears in the Form Management table as Linked To: All Studies
- When a form is linked in the Form Management page using this selection, all studies will have the form appear in the Forms tab

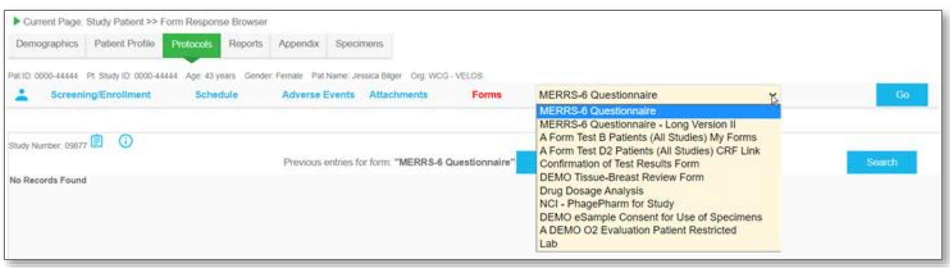


- *eSample Only*: The form selection may also be checked for selection in the Form Display and Sequencing page in which it will appear in the Specimen Forms under Study Forms

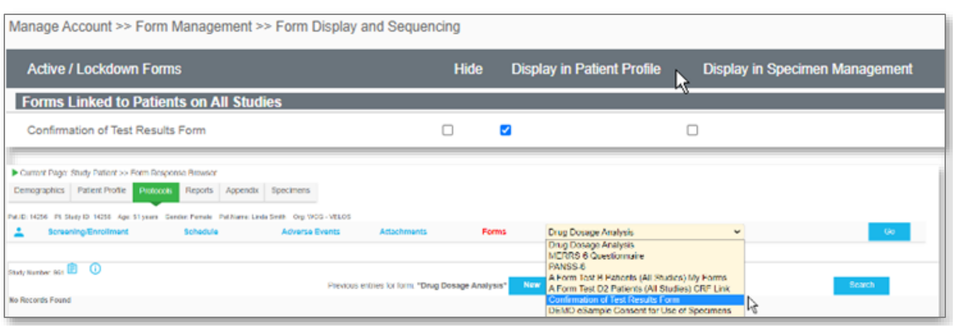


Patient Level (All Studies)

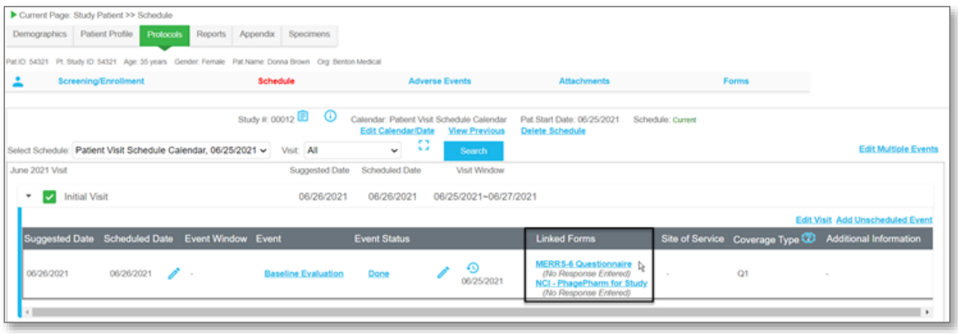
- When a form is linked in the Form Management page using this selection, all patients for all studies will have the form appear in their Protocols Forms pages



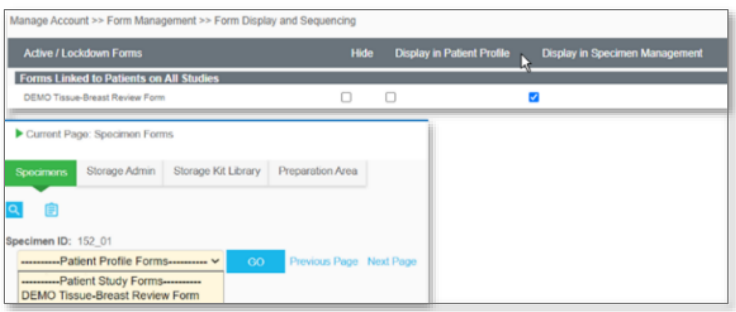
- *Display in Patient Profile Option*: The form selection may also be checked for selection in the Form Display and Sequencing page, under Display in Patient Profile, in which it will appear in the same location as above



- *Participant Portal Only*: Forms using this selection may also appear in the location above after completion in the Participant Portal
- *CRF Event Tab*: This selected form type may also be associated to an event or events in the CRF Details tab. The form(s) would then appear for all patients for that study in the Study Patient's Protocols tab, after clicking the Schedule link, as Linked Forms

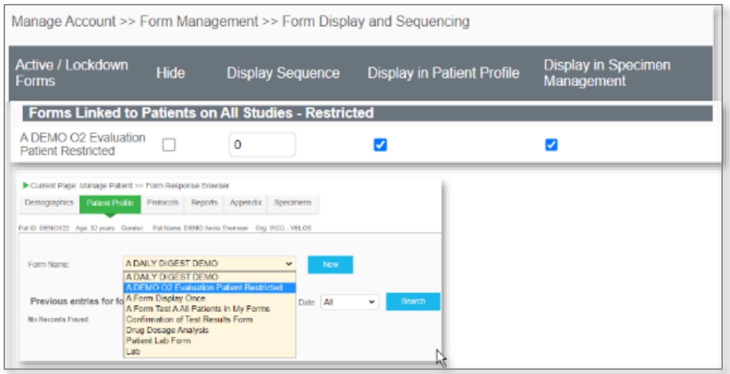


- *eSample Only*: The form selection may also be checked for selection in the Form Display and Sequencing page in which it will appear in Specimen Forms under Study Forms

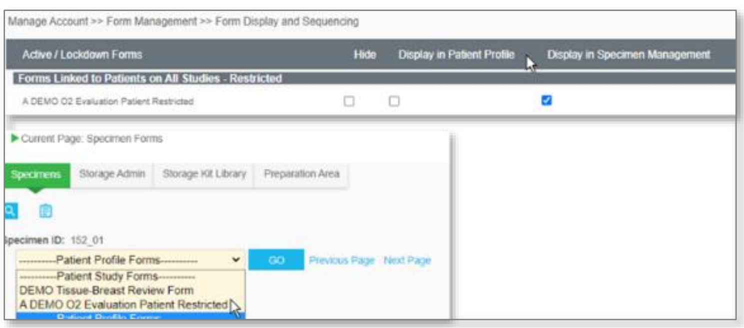


Patient Level (All Studies – Restricted)

- *Display in Patient Profile Option*: The form selection may also be checked for selection in the Form Display and Sequencing page, under Display in Patient Profile, in which it will appear in all patients' Patient Profile pages

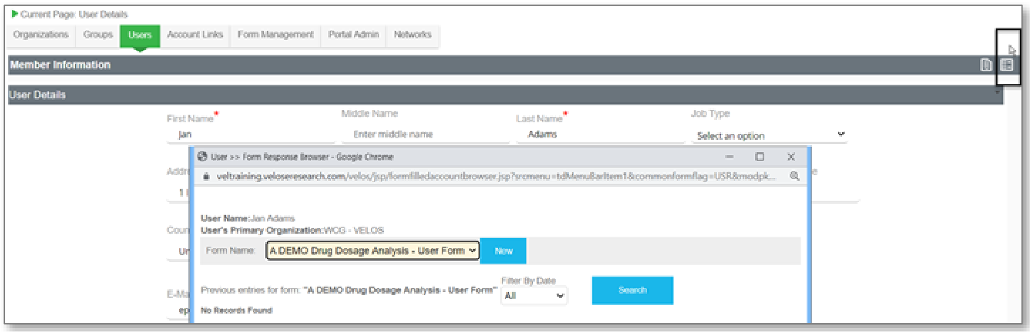


- *eSample Only*: The form selection may be checked for selection in the Form Display and Sequencing page in which it will appear in Specimen Forms under Patient Study Forms



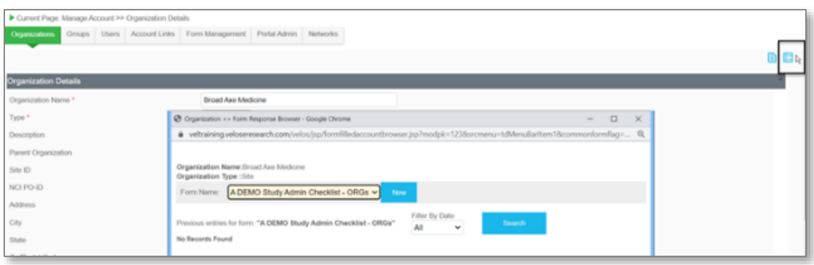
User Level

- When a form is linked in the Form Management page using this selection, all users of the system will have the form appear in the User Details Forms page



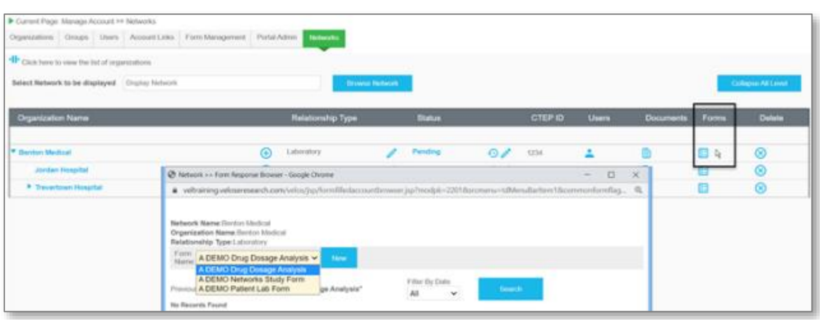
Organization Level

- When a form is linked in the Form Management page using this selection, the form will appear for all organizations in their Organization Details Forms page



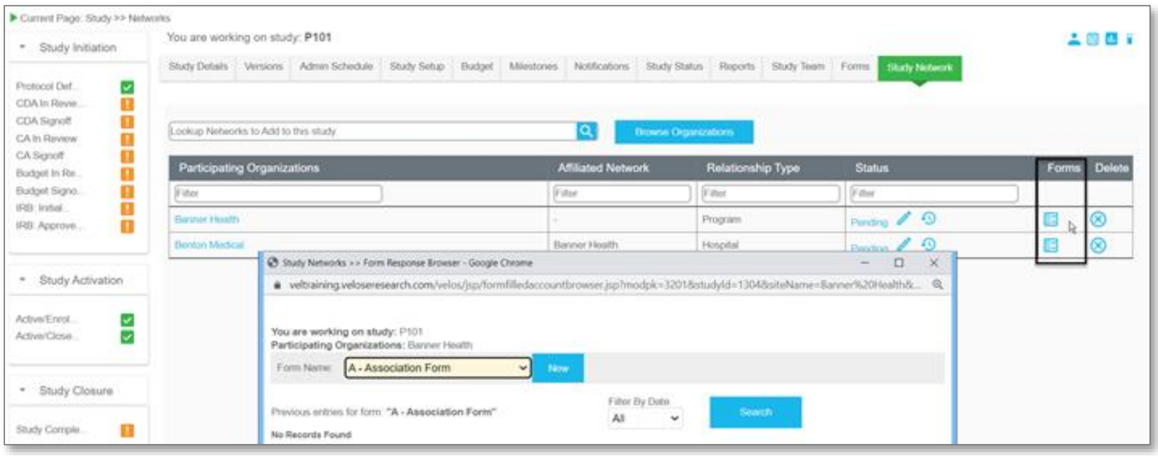
Network Level

- *Networks Only*: When a form is linked in the Form Management page using this selection, the form will appear for all organizations in the Network Forms page



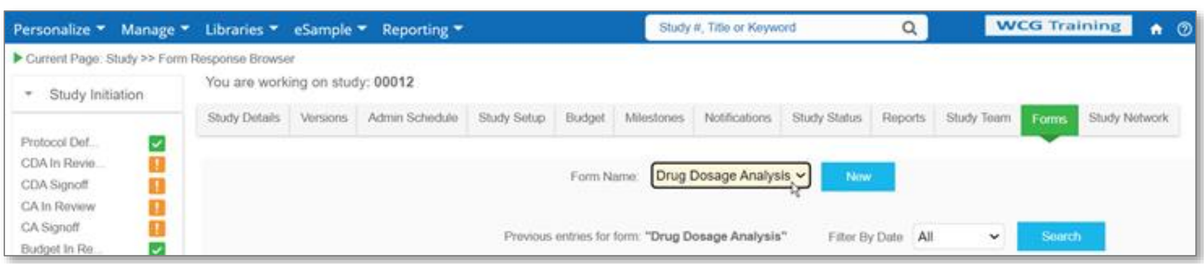
Study Network Level

- *Networks Only*: When a form is linked in the Form Management page using this selection, the form will appear for all organizations in a study with associated networks in the Study Network tab from the Forms button

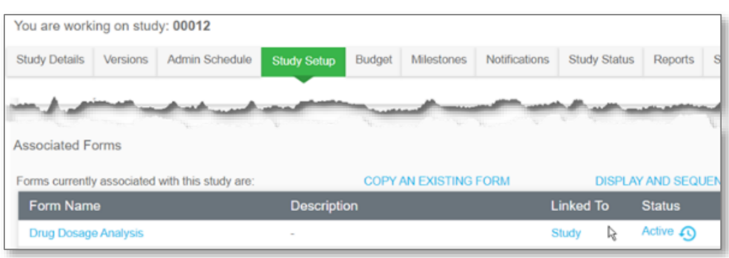


Specific Study Level

- Appear in the Form Management table as Linked To: Study; Study: Study #
- When a form is linked in the Form Management page using this selection, the form will appear only for the specific study selected in the Forms tab



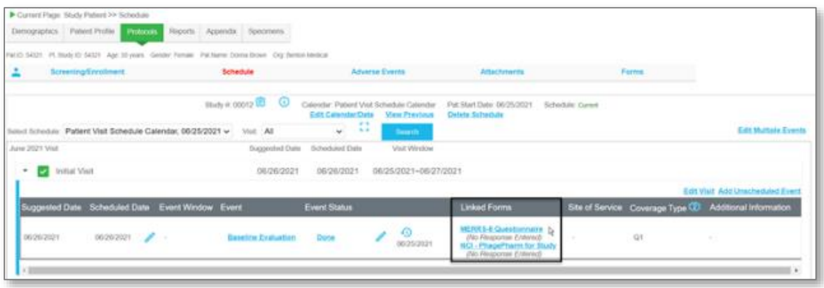
- **NOTE:** When a study form is associated in the Study Setup tab for a study, it will appear in the Form Management page



Specific Study Patient Level

- Appear in the Form Management table as Linked To: Patient (Specific Study); Study: Study #
- When a form is linked in the Form Management page using this selection, the form will appear for all patients on a specific study only in their Study Patient' Protocols tab Forms page

- *CRF Event Tab*: This selected form type may also be associated to an event or events in the CRF Details tab. The form(s) would then appear for patients for that study in the Study Patient's Protocols tab after clicking the Schedule link, as Linked Forms



- **NOTE:** When a patient form is associated in the Study Setup tab for a study, it will appear in the Form Management page

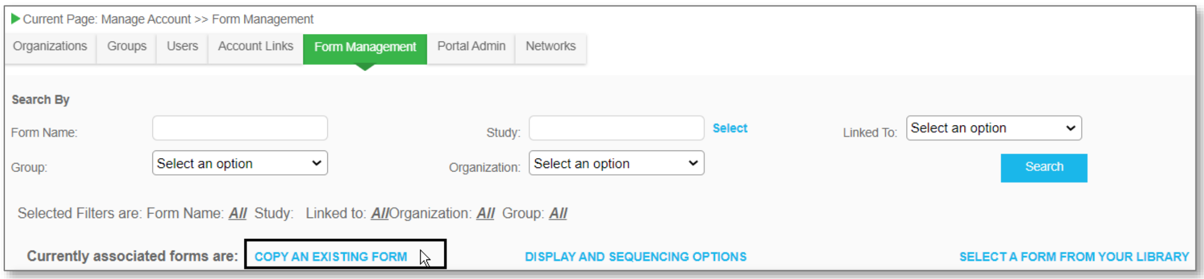
To learn more about creating forms and library management, see Forms Management within the Library Management section of this user guide.

5.7.3 Add a Form

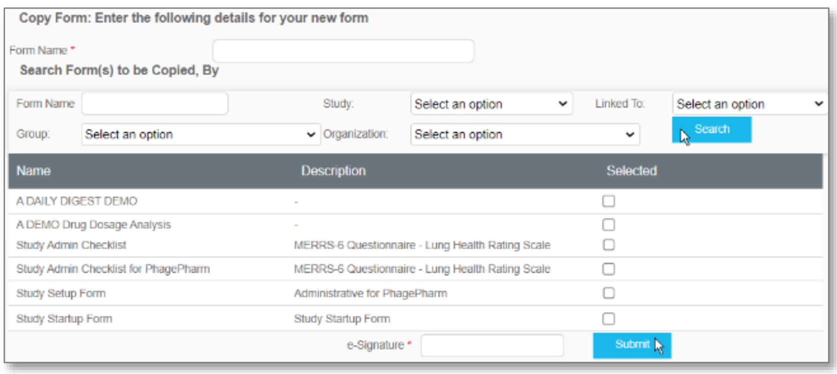
Permissioned users may add a form using one of two options: Copy an existing form and Select a form from your Library.

To add a new form, from the Form Management page:

1. Click **COPY AN EXISITING FORM**.



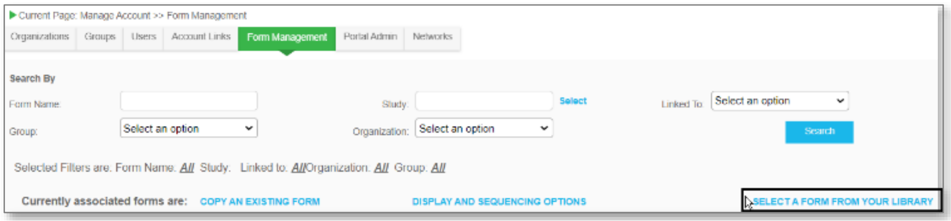
   a. Use search fields, if needed to narrow options, then click **Search**.



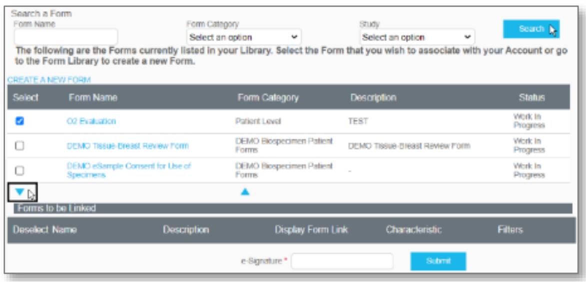
   b. Enter a new form name into the **Form Name** field, check a checkbox in the Selected column for the form to be copied, then enter your e-Signature and click **Submit**.
      The form will now appear in the Form Management table in Work in Progress status and will require modificaton to update information. All copied forms start Linked To: Account Level. For more information on modifying, refer to Modify a Form and Form Statuses.

-OR-

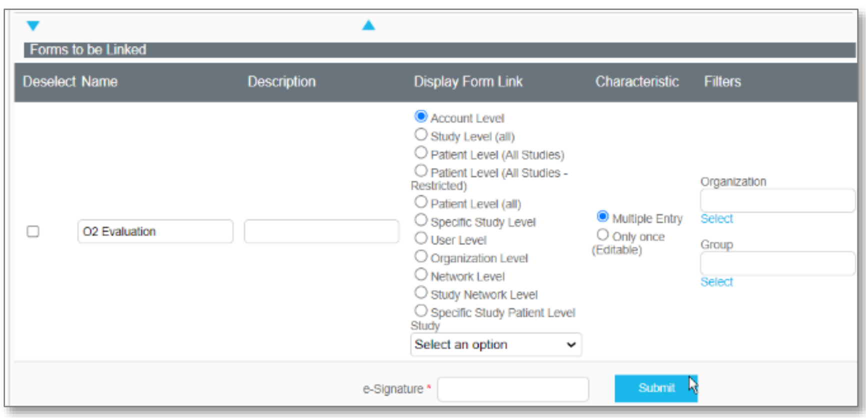
Click SELECT A FORM FROM YOUR LIBRARY.



a. Use Search fields, if needed to narrow options, then click **Search**.



b. Check a checkbox in the Select column to select a form to copy, then click the down arrow. The form selected will appear in the Forms to be Linked area of the page.



- The up arrow may be clicked, after checking the checkbox in the Deselect column, to remove a form from selection
- Revise the Name and / or Description, as needed
- Select the appropriate Display Form Link option. For Specific Study Level and Specific Study Patient Level selections only, select a Study from the options after clicking **Select an option**. For more information, refer to Linked Forms in Account Management.

- For Characteristic radio button options, select either **Multiple Entry** (to allow for creation of multiple form entries) or **Only Once (Editable)** (to allow for the form to be completed only once but may be edited by permissioned users)
- For Filters, to limit who can view the form, click **Select** and then select only the organization(s) and / or group(s) that will be permitted to view the form for completion in the system

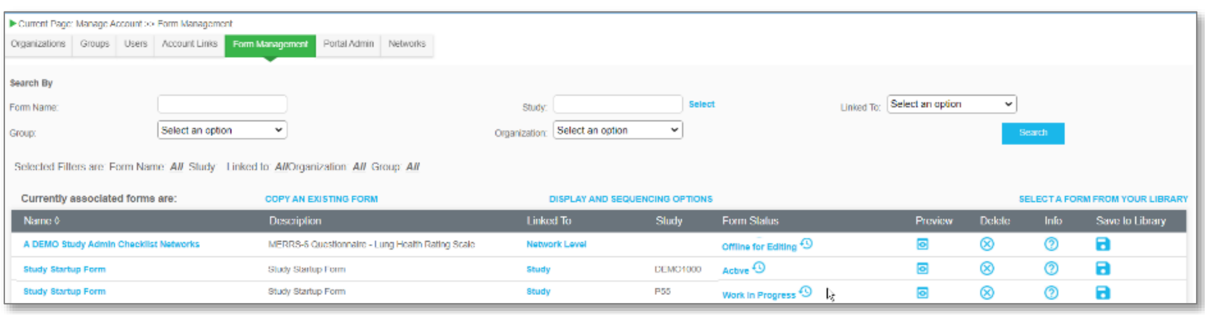
c. When the field entries are completed, enter your e-Signature and click **Submit**.
The form will appear in the Form Management table in Work in Progress status and will require modificaton to update information. For more information, refer to Modify a Form and Form Statuses.

5.7.4 Modify a Form and Form Statuses

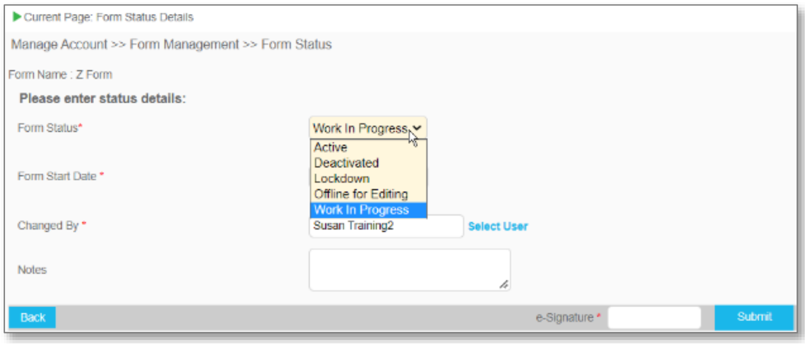
Permissioned users may be permitted to modify the title of a form, change its Linked To selection, and change the form's status. When modifying a form at the account level, only the account-level instance of the form is being modified and not the original study-level or library versions of the form.

To change a form's status, from the Form Management Page:

1. Click the Form Status for a form.

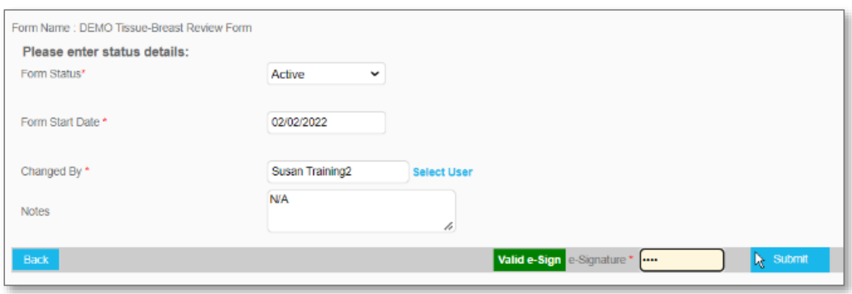


2. The Form Status Details page will appear.

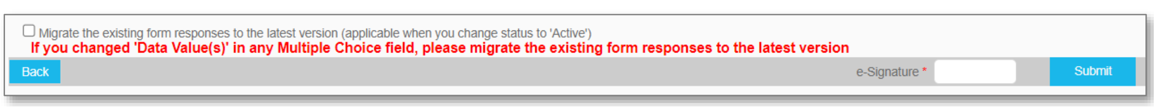


- Forms in Work in Progress (WIP) may only be changed to Active or Deactivated
- Forms in Active status may only be changed to Offline for Editing, Deactivated or Lockdown
- Forms in Offline for Editing may only be changed to Active or Work in Progress
- Forms in Lockdown may only be changed to Active
- Forms in Deactivated status cannot be changed
    - Deactivated may be is used in place of deleting when there are associated completed forms

3. After changing the form's status, select a Form Start Date, use **Select User** to change the Changed By field, if needed, optionally enter notes, then enter your e-Signature and click **Submit**.



    a. If changing the status from Offline for Editing to Active or WIP, an additional checkbox will appear. Check if applicable before submitting. [Refer to image below for details.]



The Form Status will update in the Form Management page as selected.

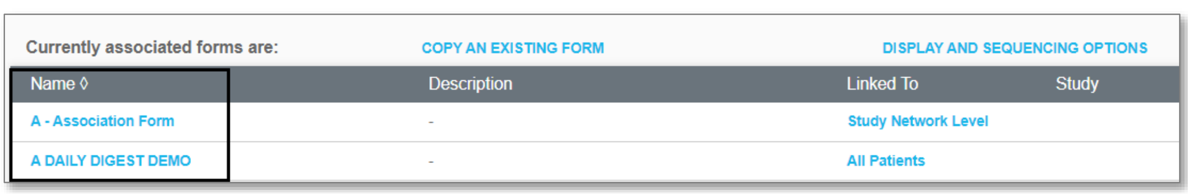
Form information updates, in the *Name* or *Linked To* fields, are restricted by form status. See the table below for details.

Form Status	Field	What May Be Changed
Work in Progress	Name	All fields
	Linked To	Any Linked To selection, unless was added at the study level in Study Setup ▪ If added as Linked To: Study in Study Setup, the Linked To option will allow for changing to a Patient option All Characteristic and Filters Fields
Active	Name	Only the checkbox for Mandatory e-Signature
	Linked To	Only response private checkbox and Select options in Characteristic and Filters Fields Only
Lockdown	Name	Only the checkbox for Mandatory e-Signature
	Linked To	Only response private checkbox and Select options in Characteristic and Filters Fields Only
Offline for Editing	Name	The checkbox for Mandatory e-Signature A new checkbox for changed data values (see details in steps below)
	Linked To	Only response private checkbox and Select options in Characteristic and Filters Fields Only

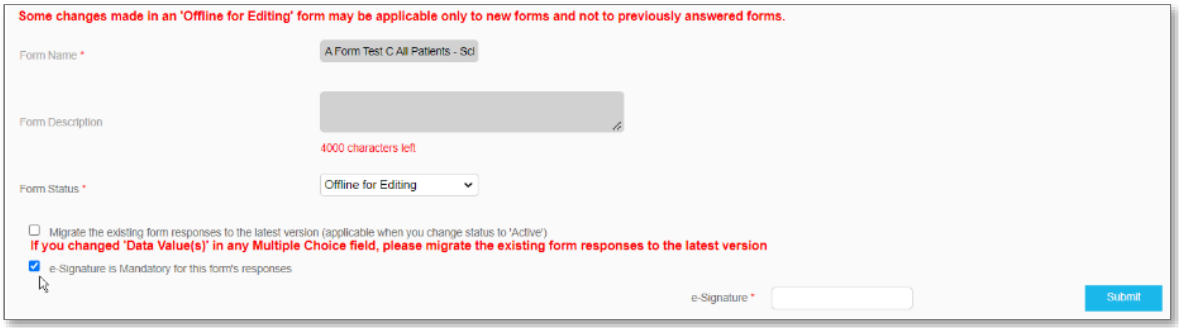
Note: For Deactivated form status, changes are not permitted.

To update the *Name* field information, from the Form Management page:

1. Click a name in the Name column.



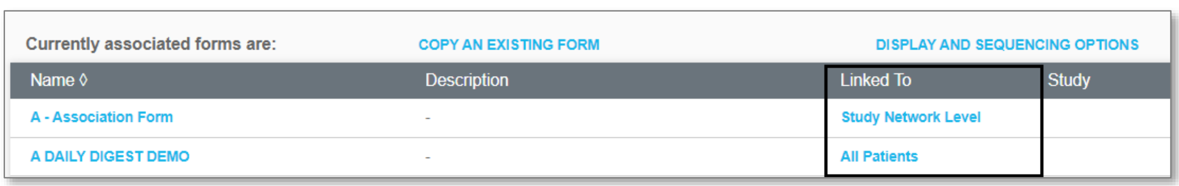
2. For all but WIP status, there will be a new check box to check to include a mandatory e-Signature when completing a form. Check the checkbox, if needed.



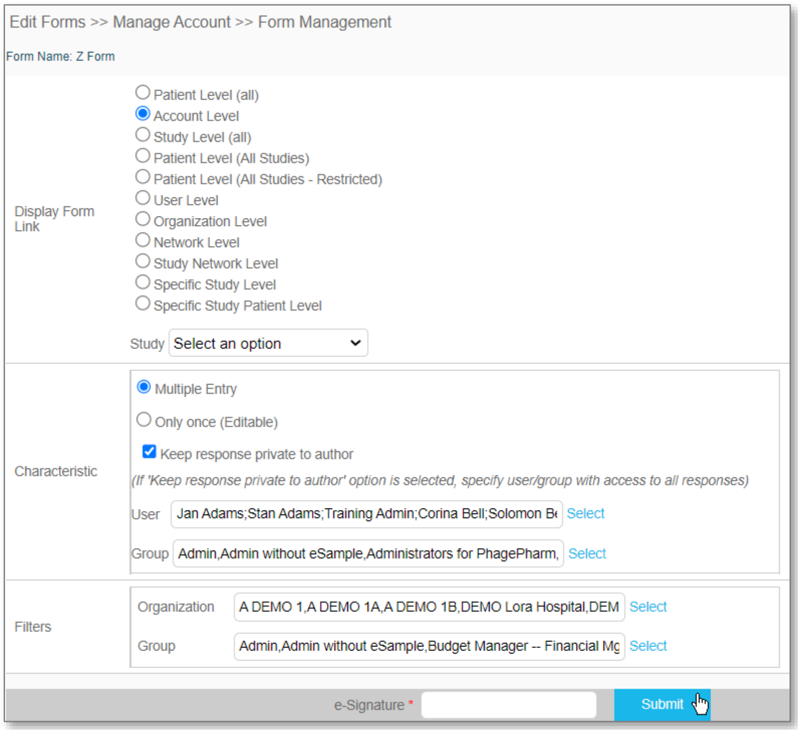
3. For Offline for Editing status only, the red sentences in the image above will appear along with a new check box to allow for migrating existing form responses to the latest version of the form, after changing to Active status. Check this checkbox if applicable.
4. For WIP status only, the Form Name and Form Description may be changed prior to submitting.
5. After making any changes to the form Name area, enter your e-Signature and click **Submit**. Changes have been saved.

To update the *Linked To* information, from the Form Management page:

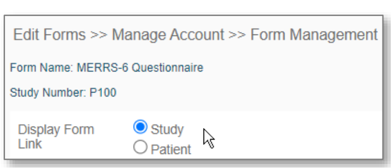
1. Click a selection in the Linked To column.



2. For all statuses, the Filters area for selecting organizations and groups may be updated by clicking **Select** and selecting applicable options, as needed.



3. For all statuses, in the Characteristic area, new fields appear. These are used for keeping the response private to author and then allowing selection of users and groups. To allow this new characteristic, first check the checkbox for *Keep responses private to author*, then click **Select** and select the applicable option(s) for User(s) and / or Group(s).
   a. For WIP Status, the option of *Multiple Entry* or *Only once (Editable)* may also be updated.
4. For WIP status, for *Linked To* options, the Linked To selection may be changed, unless the form was initially added in the Study Startup tab for a study.
   a. For *Linked To*: Study, added in the Study Startup tab, a new radio button selection will allow for changing *Display Form Link* from Study to Patient.



5. After the *Linked To* information is updated, enter your e-Signature and click **Submit**. Changes have been saved.

5.7.5 Delete a Form

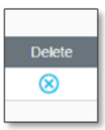
Permissioned users may wish to delete a form. If deleting an account form that was pulled from the forms library, it does not delete the form in the library, only the account form. For more information about the forms library, see Forms Management.

Warning: If using Participant Portals, use caution when deleting a patient linked form as participants will no longer be able to view the form linked in a portal after deletion.

Note: Forms may be deleted regardless of the Form Status, however, a form cannot be deleted if it has from response(s) added.

To delete a form, from the Form Management page:

1. Click **Delete** for a form to be deleted.

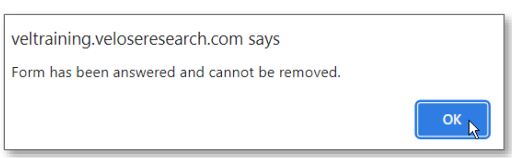


2. A warning notification will display. Click **OK** to delete the account form.

After clicking OK, the account form is deleted.

-OR-

If the form has been used and contains answers, a warning will appear and deleting will not be permitted.



a. Click **OK** to close the pop-up.

5.8 Networks

Velos eResearch Enterprise offers an add-on module that allows organizations to be tied together by larger associations, known in eResearch as “Networks”. The Network tool allows permissioned users, with the Network module enabled, to create networks of organizations that have a shared relationship, for informational purposes only. This can be used to improve system organization and can specifically be used to associate a network to a study instead of individually adding organization associations. Additionally, study network forms may be completed.

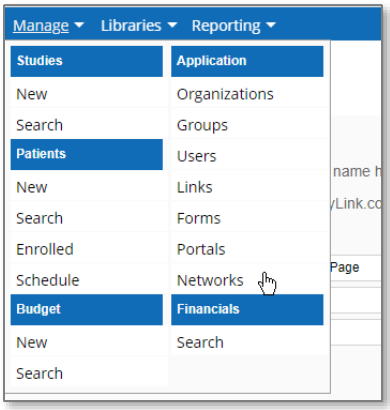
For example, the organizations “General Hospital”, “Evangelical Hospital” and “Central Hospital” may be part of a larger, common association known as “Mercy Healthcare”. In this example, “Mercy Healthcare” would be entered into Velos as a Network, and “General Hospital”, “Evangelical Hospital” and “Central Hospital” would all be entered as Organizations, tied together by the Network “Mercy Healthcare”. For more information about Organizations, see Organizations. Using the Network tool, permissioned users can create, view, and edit network associations.

Enterprise Only: Networks are an optional add-on module for the Enterprise version.

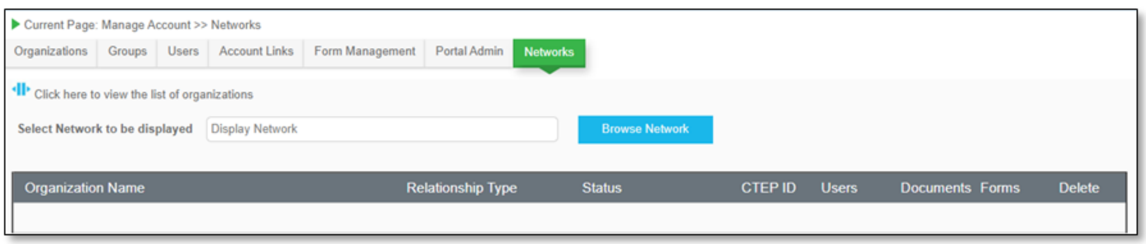
Warning: Networks only apply to organizations with “Active” status. If you would like to remove a network or network association, the organization network status must be set to “Pending”and must not be associated to any study networks. Only permissioned Administrators may delete organizations and their networks.

To access networks:

1. Click the **Manage** menu and select **Networks**.



The Networks page displays:



5.8.1 Create Networks

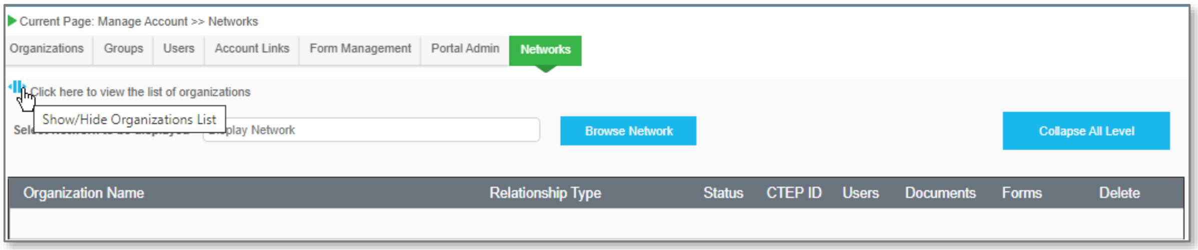
Permissioned users can create network associations using the Network tool in Velos eResearch Enterprise.

Note: Organizations must be added prior to creating a network. To learn more about organizations, see Organizations.

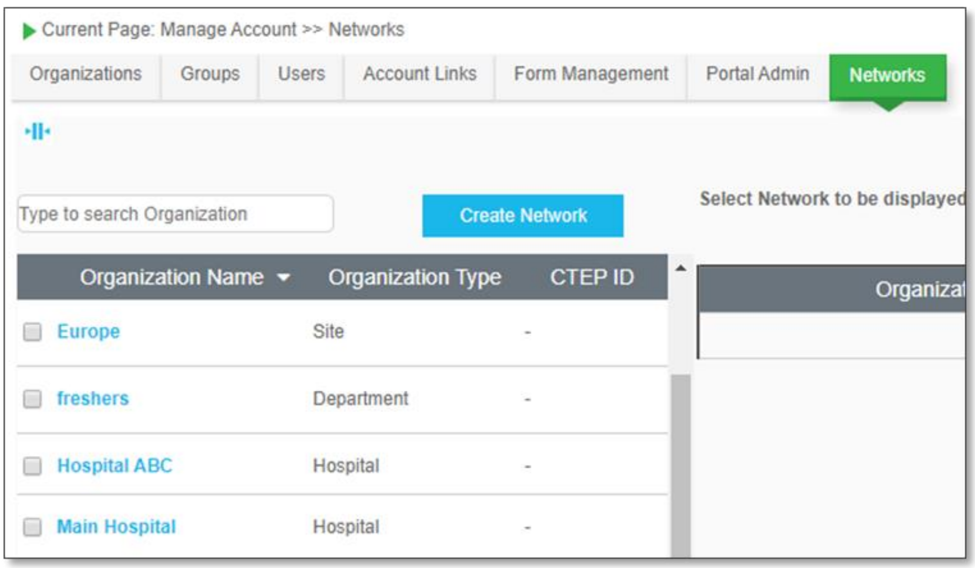
Warning: Networks only apply to organizations with "Active" status. If you would like to remove a network or network association, the organization network status must be set to "Pending"and must not be associated to any study networks. Only permissioned Administrators may delete organizations and their networks.

To create a new network:

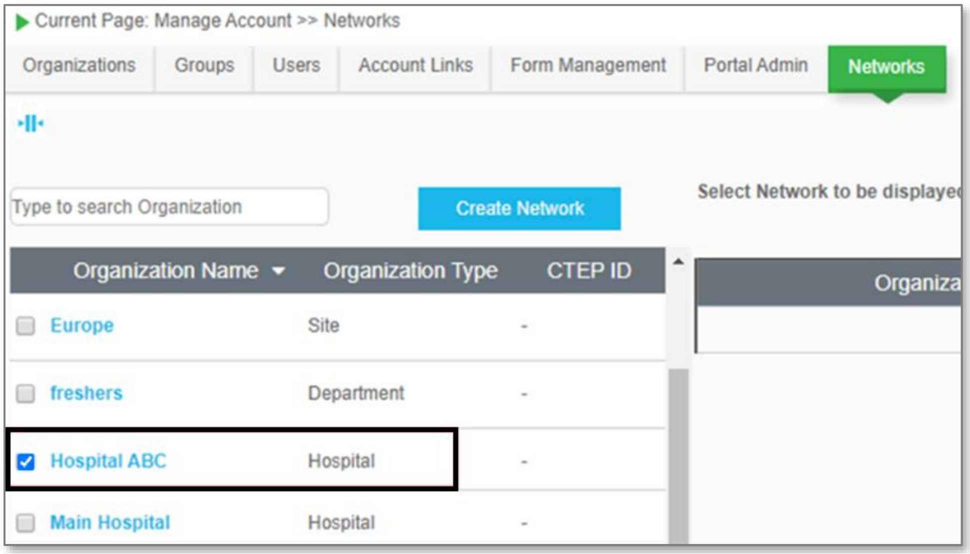
1. Navigate to the network page and click **Show/Hide** next to the "Click here to view the list of organizations" text.



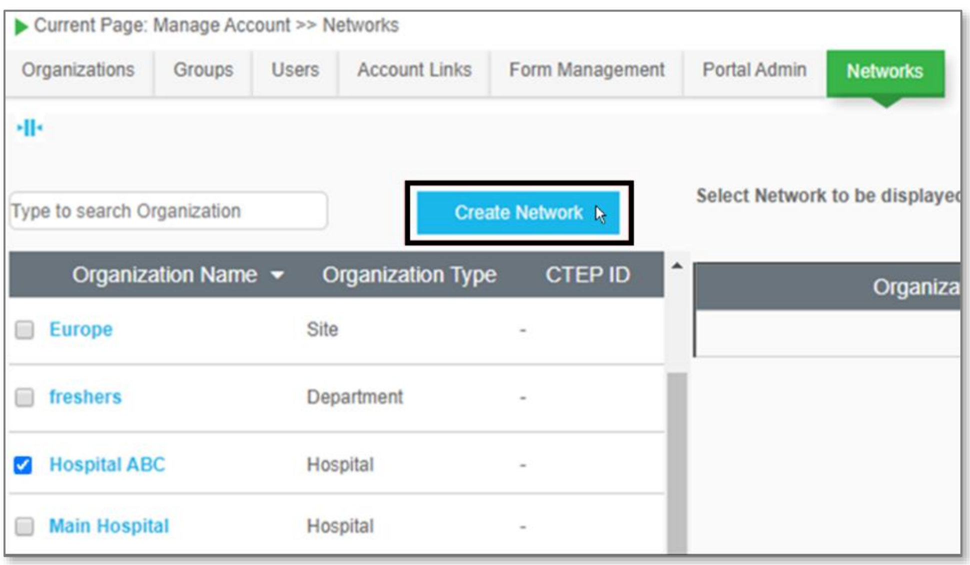
A list of all configured organizations displays on the left side of the screen:



2. Select the organization that you would like to be the Network (parent) by clicking the checkbox next to its name.

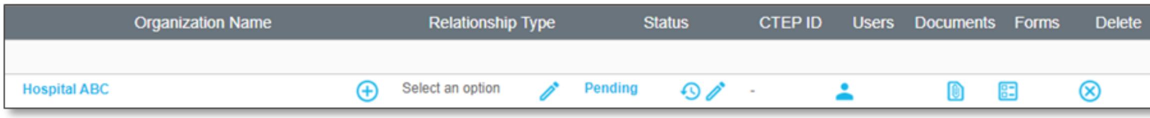


3. After the organization has been selected, click **Create Network**.



Note: The network (parent) must be created as an organization first, and then designated as a network. An organization can only be a parent network one time.

The new network has been created and displays on the right side of the screen:

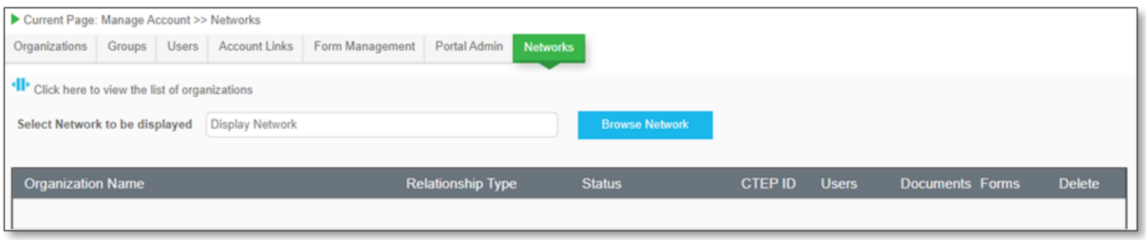


5.8.1.1 Add Child Organizations

After networks are created, the organizations that comprise the network must be added.

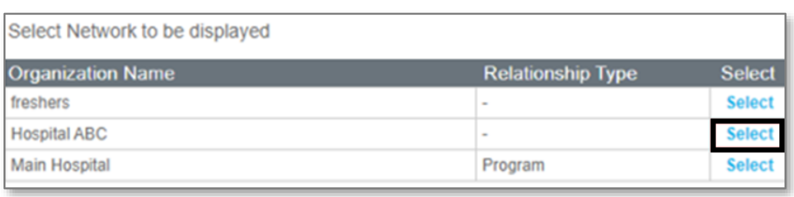
To add a child organization to a network:

1. Navigate to the **Networks** tab and click **Browse Network**.

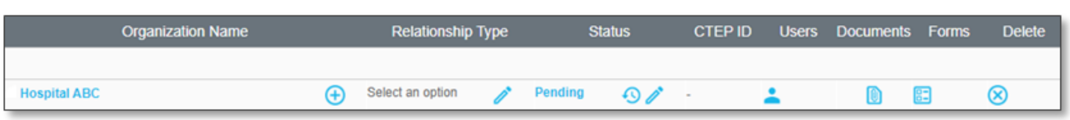


Note: Networks may also be selected by typing the name of the network into the **Select Network to be displayed** field and selecting the appropriate network option from the search results.

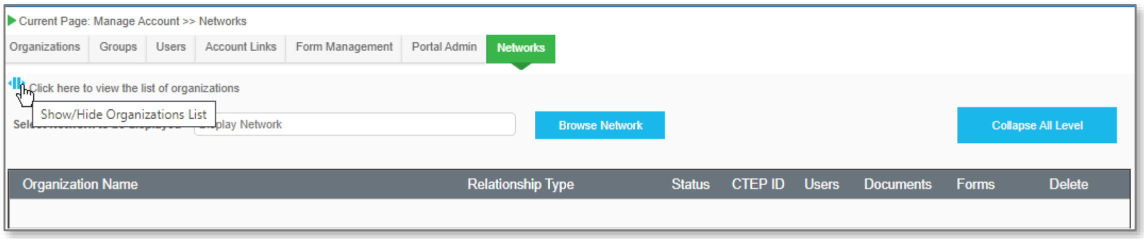
2. The list of available networks display. Select a network by clicking **Select** on the right side of the entry.



The network displays:



3. If not already done, click **Show/Hide** next to the "Click here to view the list of organizations" text to view all available organizations.

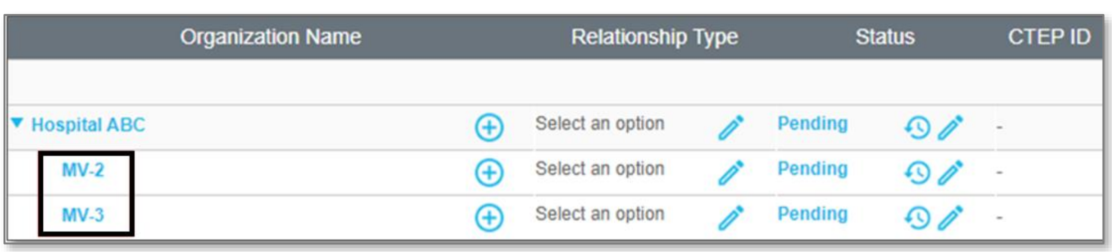


4. Select the organization(s) to be added to the network by clicking the checkboxes next to their name.

5. Next, click **Add Child to the Site** next to the network name.

- Adding organizations in this way, child hierarchies of multiple levels can be created

The child organizations are added to the network:

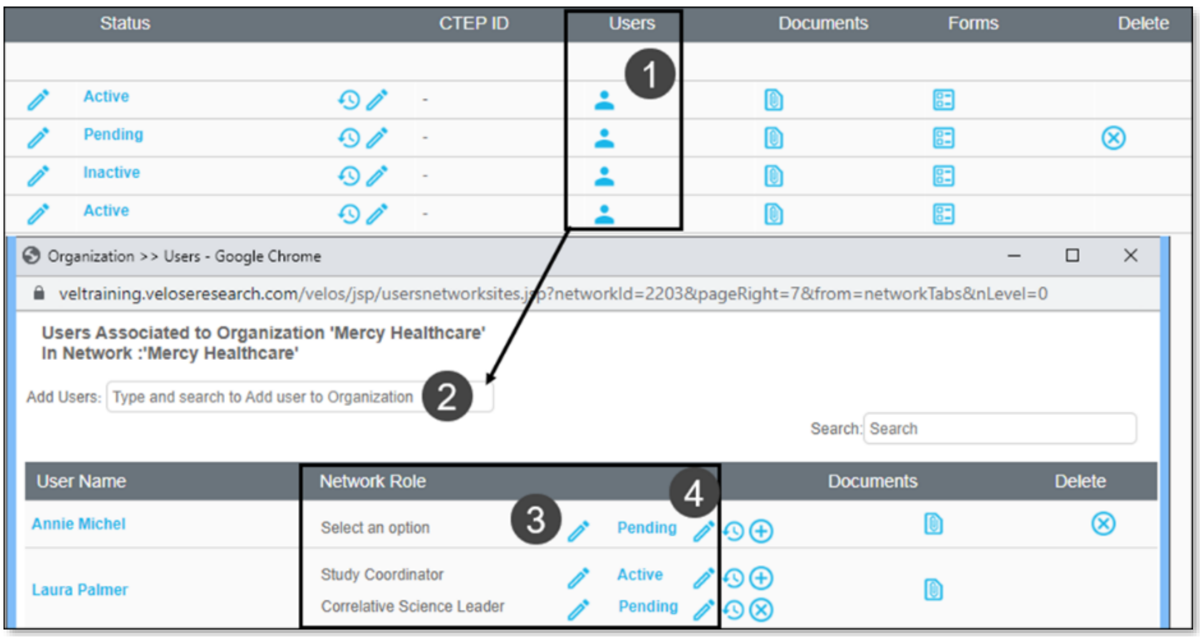


5.8.1.2 Adding Users along with their Documents and Links

After networks are created, users may be added with network roles for each organization. Each user may have more than one network role assigned. Each user may have documents and links associated here at either or both the network level and / or user level.

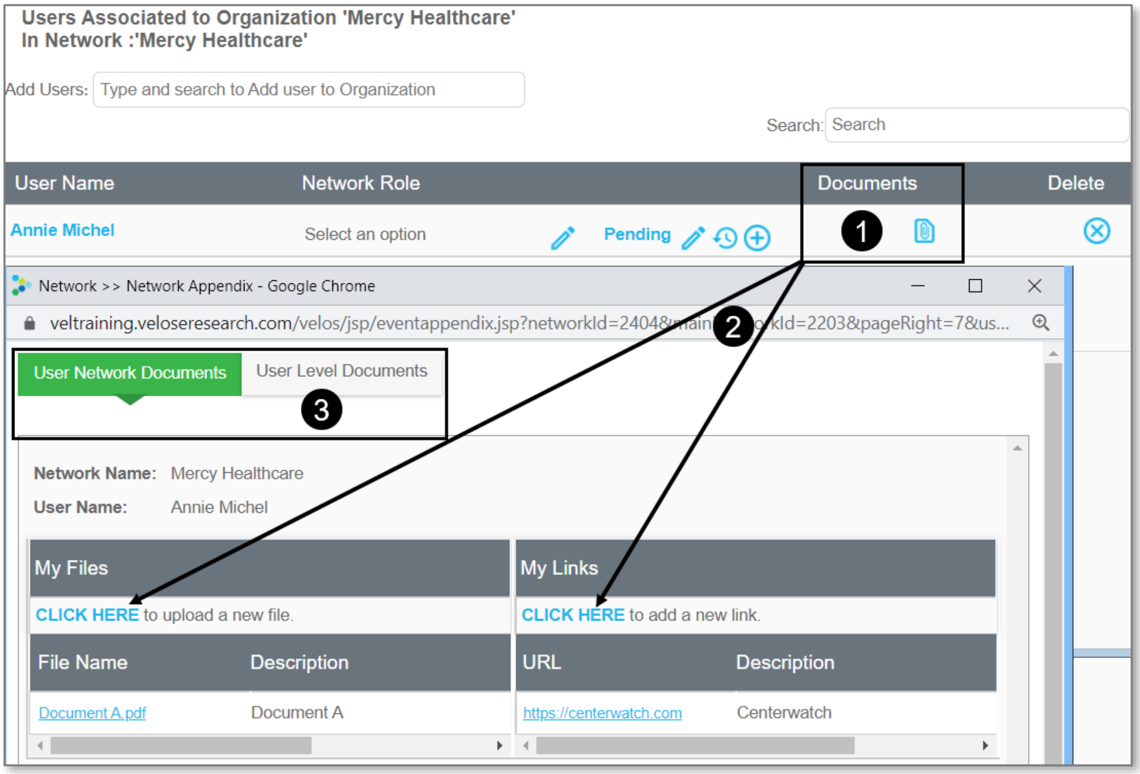
> **Note:** Network user roles do not provide access to studies and are for informational purposes only.

To add a network user with network user role(s) and role status(es), to an organization:

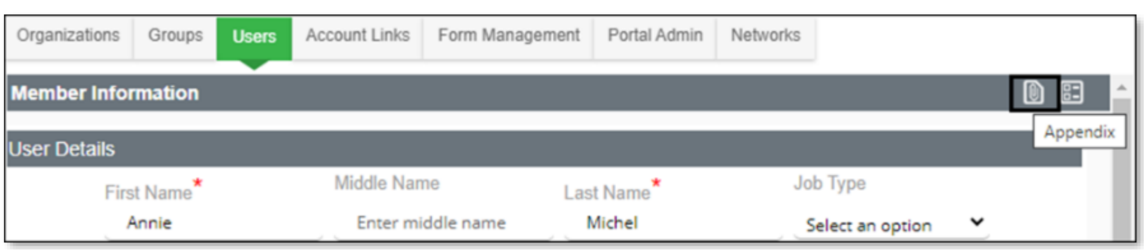


1. Click **Users** for a specific organization.
2. Search for a user's name in the Add Users field and click an option to select.
3. Use the role **Edit** to update or select a user's network role, from the dropdown options.
   a. Click the plus sign to add additional roles for a user, as needed.
4. Use the status **Edit** to select a status for the network user role, from the dropdown options.

To add user documents and links:



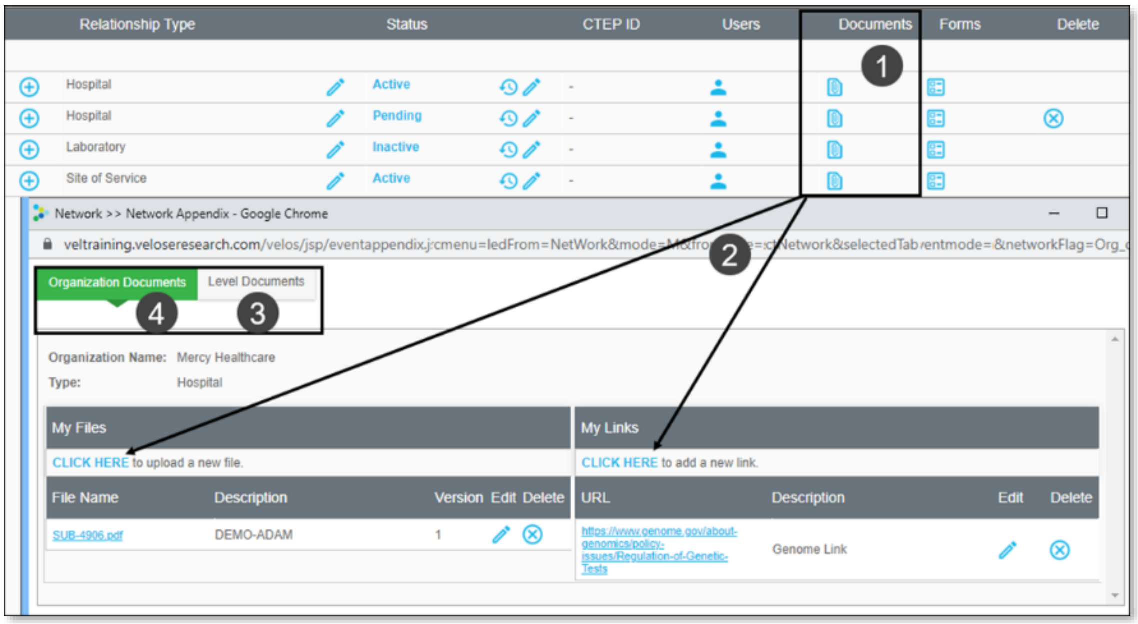
1. Click **Documents** for a specific user.
2. Click **CLICK HERE** in either My Files or My Links to upload a document or associate a link and submit. File names and URLs will appear in the tables below for documents and links.
   - Files and links associated in the default User Network Documents tab will only appear in this location
3. Click **User Level Documents** and associate files and links, as needed, as above.
   - Files and links associated in this tab will not only be located here but will also appear in the **Appendix** page for the specific user identified in the User Details page.



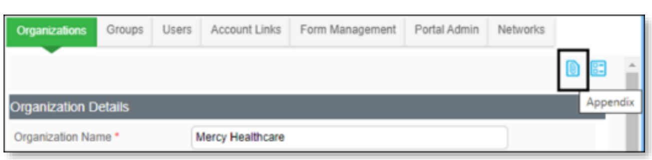
5.8.1.3 Adding Organizational Network Documents and Links

After networks are created, documents and links may be added to each organization in the network. These documents and links may be associated at either or both the network level and / or the organizational level.

To add documents and links:



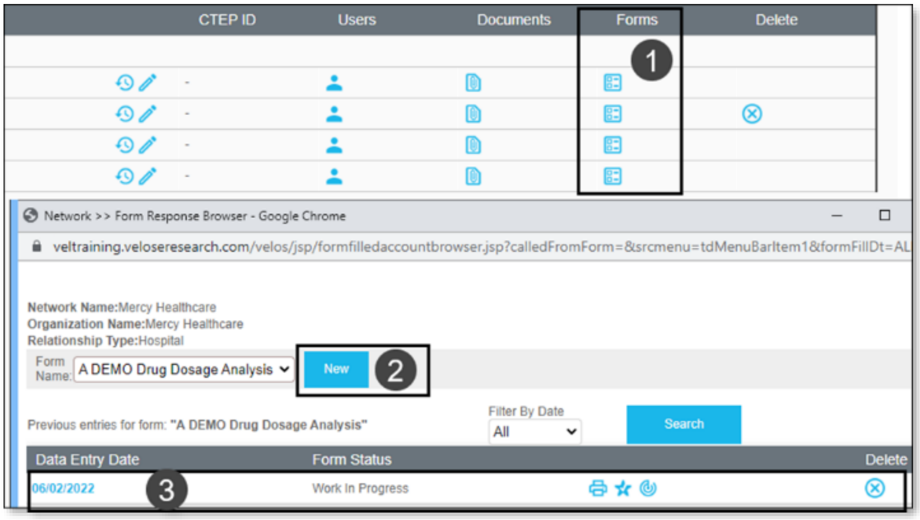
1. Click **Documents** for an organization.
2. Click **CLICK HERE** for My Files or My Links and upload a document or associate a link, as needed, and submit. File names and URLs will appear in the tables below for documents and links.
3. Click **Level Documents** to add files and links in the same manner as the default Organization Documents tab.
   - Files and links associated in the Level Documents tab will only appear in this location
4. Files and links associated in the default Organization Documents tab will not only appear here but will also appear in the **Appendix** page accessed from the Organization Details page.



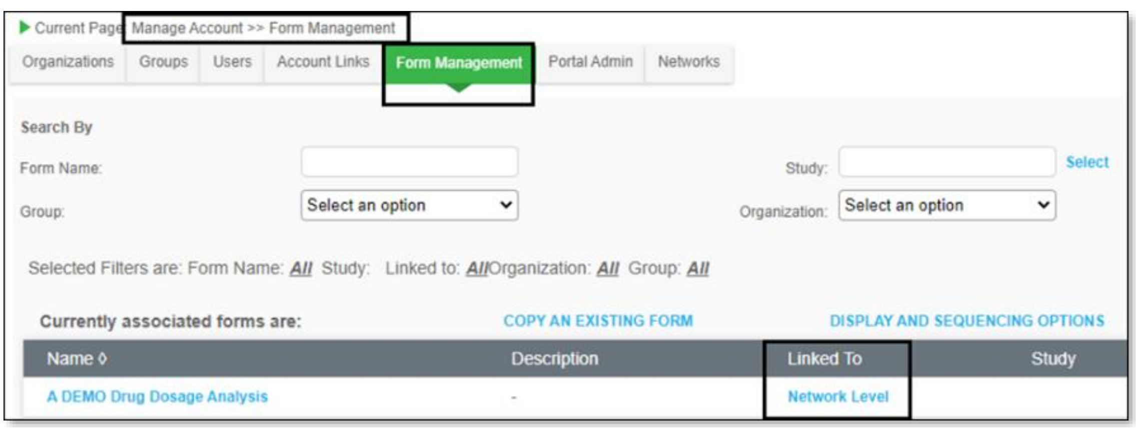
5.8.1.4 Adding Organizational Network Forms

After networks are created, organization associated forms may be completed, reviewed, printed, and edited. These forms must be assigned as Linked to Network Level in the Manage > Forms area.

To complete or access a completed form for an organization in a network:



1. Click **Forms** for a specific Organization.
2. Click **New** to complete and submit a new form.
   - For a form to appear in the Form Name dropdown, the form must be Linked to Network Level in the Form Management page



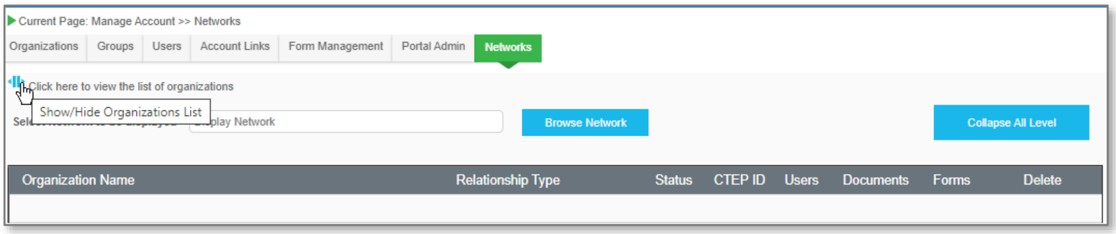
3. Click the **Data Entry Date** link to review a completed form. Additionally, there are links to print, view history, or delete the form, if needed, as permissioned.

5.8.2 Modify Network Details

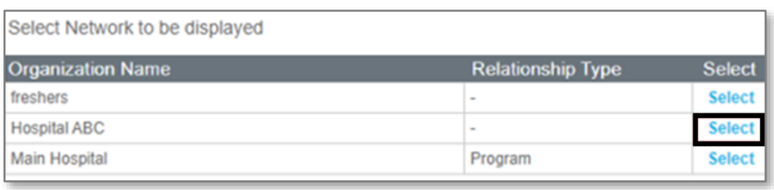
Permissioned users can modify relationships, edit documents and forms, and generally edit the organization-network relationships.

To modify network details:

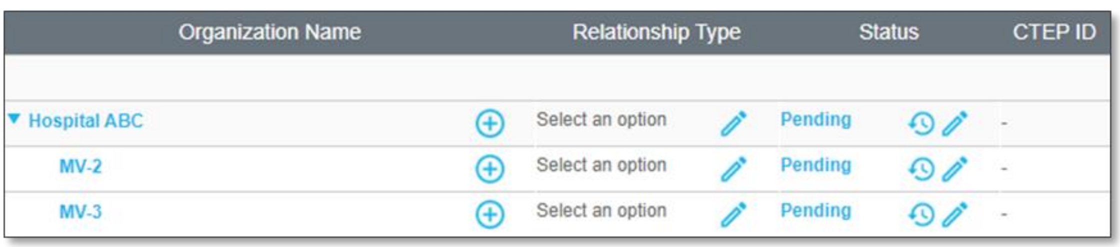
1. Navigate to the **Networks** tab and click **Browse Network**.



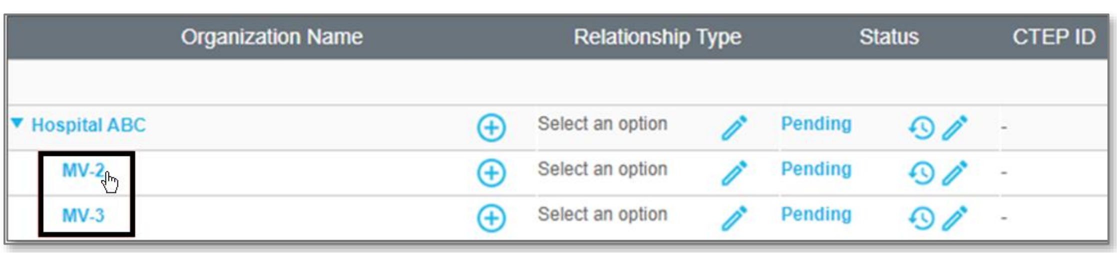
2. The list of available networks display. Select a network by clicking **Select** on the right side of the entry.



The network displays along with any child organizations:

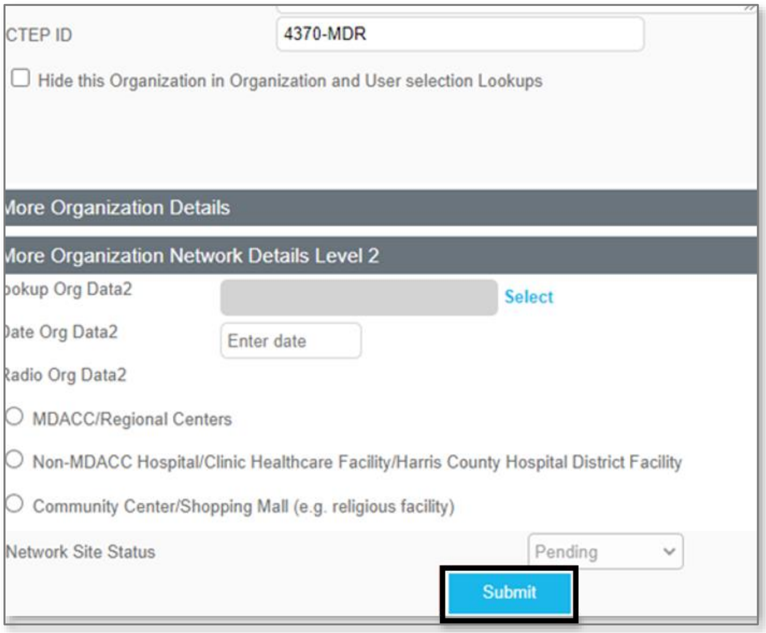


3. Click on the **Organization Name** link to modify details about the organization, including CTEP ID.

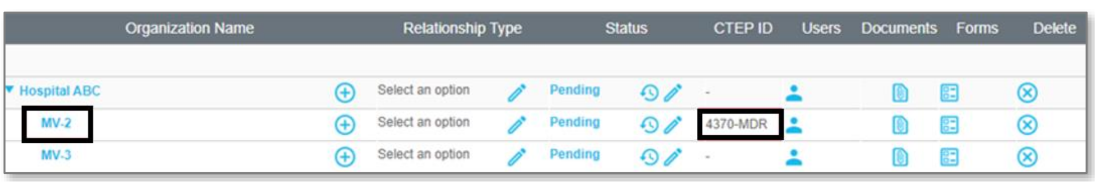


Note: Clicking the Network Organization name will also allow for editing details.

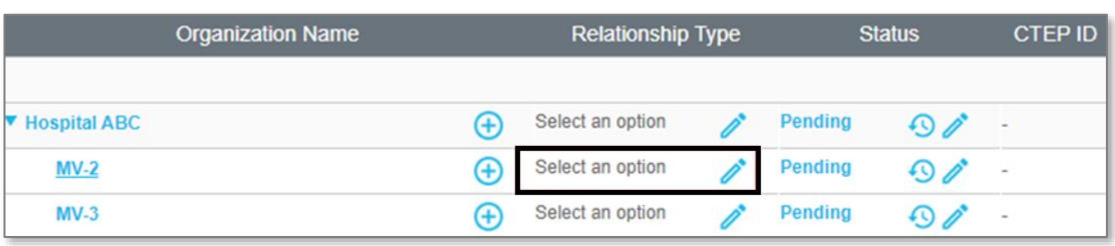
4. A new window displays, allowing you to modify organization details. Apply your changes and click **Submit** to confirm.



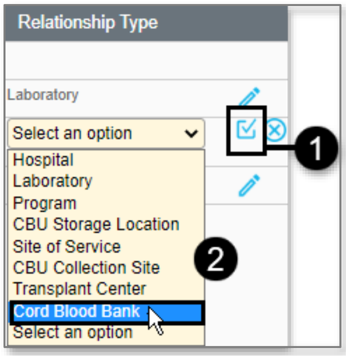
The organization information is updated. If the organization name or CTEP ID is changed, that information will automatically update in the network association table:



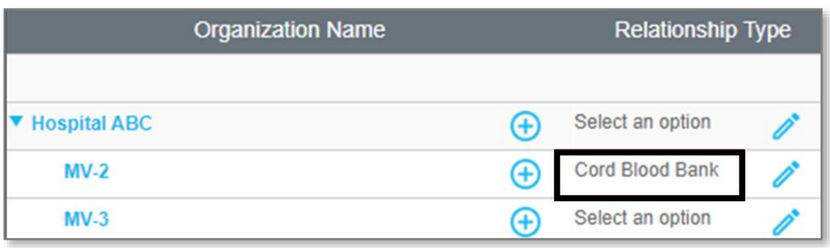
5. To modify the relationship type, click **Edit** in the Relationship Type column.



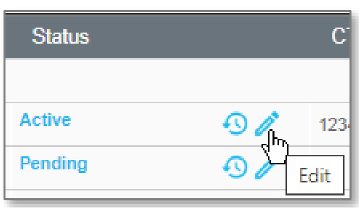
6. A dropdown menu displays. (1) Select the appropriate relationship option, and then (2) click the checkmark to confirm.



The relationship type is updated in the network association table:



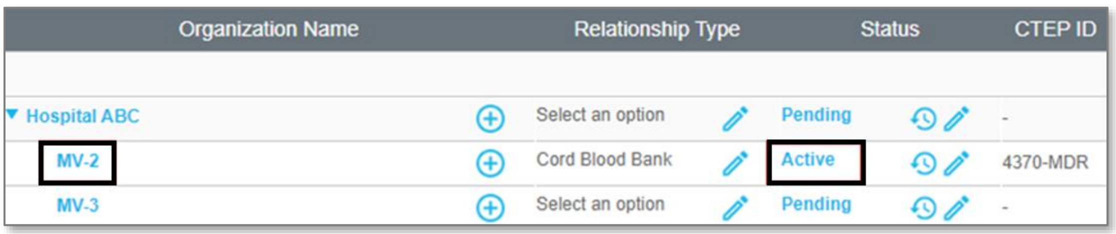
7. To modify the network status, click **Edit** in the Status column.



Note: By default, all network organizations, including the parent in the Network will be in a status of "Pending" when created. Network organizations with a status of "Pending" can be deleted from the Network, by permissioned Administrators only. In order to delete an organization, it must be changed to Pending status and all study network associations must no longer exist.

8. The status details page opens in a new window. Set the **Status** and the status **Date**. Enter your e-Signature and click **Submit** to confirm.

The updated status displays:



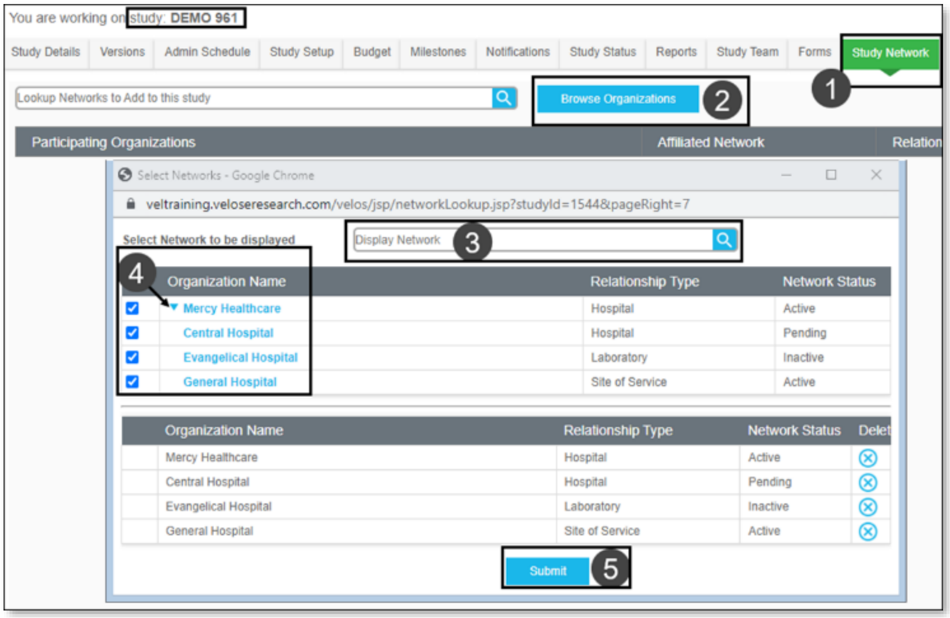
Note: You can also view network status history for an organization by clicking the History button in the status column.

5.8.3 Study Network Association

One of the key benefits to using the Network tool in Velos eResearch Enterprise, is creating study network associations. Study network associations provide an informational way for study team members to view networks associated to a study. Study network forms may be completed for associated network organizations.

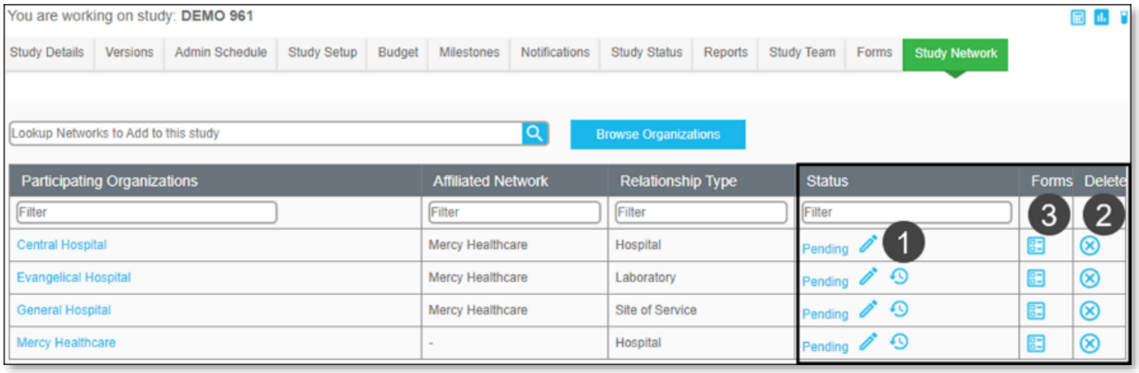
Note: To see the Study Network tab, the "View" access permission for Manage Organization must be enabled within the user's Group rights.

To create a study network association, after accessing the study:

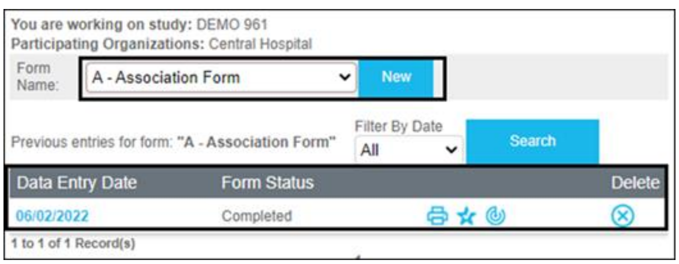


1. Click the **Study Network** tab.
2. Click **Browse Organizations**.
3. Search for the parent organization / network name in the Display Network field and click the appropriate name from the options provided.
4. Click the down arrow to the left of the parent Organization Name, to view the additional organizations associated to the Network, and check all checkboxes for the organizations which will be associated to the study.
5. Click **Submit**.

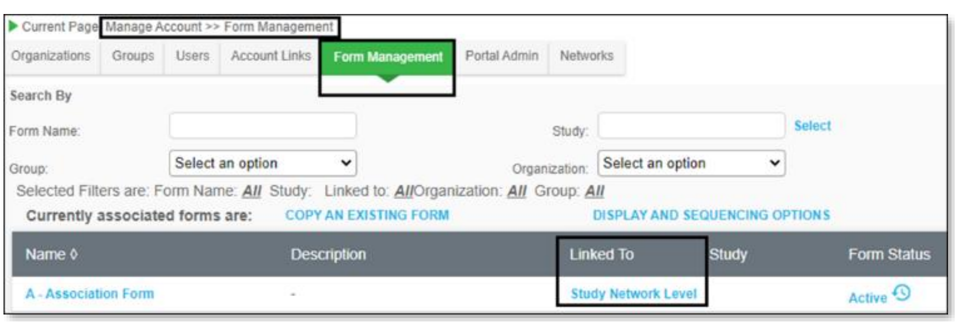
To manage study network associations and add forms for a specific organization:



1. Click **Edit** to change the status of an Organization's association, from the dropdown, as needed.
2. Permissioned Administrators may click **Delete**, to delete an organization from the study association, when the organization is in Pending status only.
3. Click **Forms** to access forms for an organization in the study associated network.



   a. Select a form from the Form Name dropdown and click **New** to create a new form.
   b. Click the Data Entry Date to review a completed form, or use additional links to print, view a history for the form, or delete the form, as needed, and as permissioned.
   - For a form to appear in the Form Name dropdown, the form must be Linked to Study Network Level in the Form Management page



6 Library Management

The Library within Velos eResearch is a central repository for saved templates of Calendars, Events, Forms and Fields. The Library is therefore a powerful tool that provides permissioned users the ability to reuse standard items that are deployed across studies. This section of the Velos eResearch user guide addresses the creation and management of the four types of Libraries available within Velos eResearch:

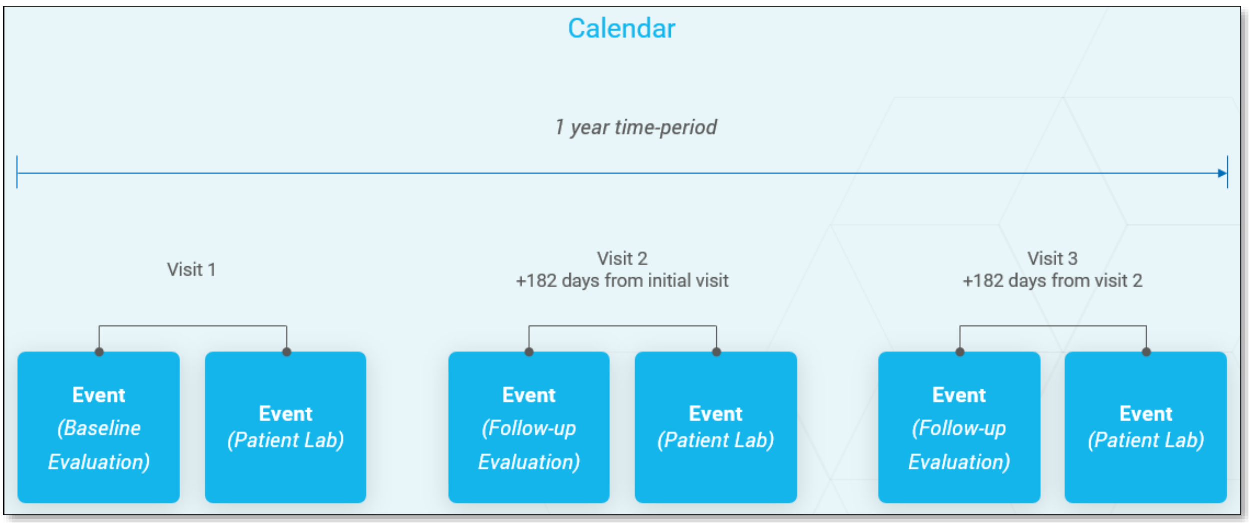
Library	Description
Events	This library is used to create events, which are specific, billable or actionable items that are used to build/define calendars, and then are stored as templates. See Charge Masters for more information.
Calendars	This library is used to create calendars, which are a time-defined set of events that can be applied to various functions within Velos eResearch, and then are stored as templates.
Fields	This library is used to house fields commonly used in forms. By creating and storing fields in the field library, it allows users to select fields to build a form.
Forms	This library is used to create form templates and store them. Form templates can be associated to an account, study, study patient, or patient level, and other levels depending on your configuration. After a template has been associated, it can be modified, if needed.

- See Calendar Management to learn how to work with events and calendars
- See Forms Management to learn how to work with fields and forms

Note:
1. Charge Masters may be provided to WCG Velos for populating the library with existing library items. A default / blank charge master will be available if one is not provided.
2. When a library element, such as a calendar, event, form, or field is used, the system creates a separate copy of that item, leaving the original template intact, regardless of any changes made to the applied copy.
3. In order to maintain consistency and control of library templates, it is highly recommended to define the processes for user responsibility regarding library management.
4. Charge Masters may be provided to WCG Velos for populating the library with existing library items. A default / blank charge master will be available if one is not provided.

6.1 Calendar Management

Calendars are a time-defined set of events that can be applied to various functions within Velos eResearch. Before a calendar can be completed, the corresponding events must be drawn from the event library and visits must be created. For more information on events, see the Event Library. Permissioned users can create calendars, calendar categories, add events, manage visits, customize the event-visit grid, and assign coverage codes to each event type. Please see the diagram below, illustrating a simple example of the Calendar/Event/Visit relationship.



6.1.1 Event Library

Events are billable or actionable activities that act as the building blocks for Calendars. Events can range from anything that is actionable or has a cost implication, such as procedures, evaluations, labs, or questionnaires. Permissioned users can create new events and event categories, customize event notifications, add costs and expected resource hours, link files and URLs, and add CRF information to each event in Velos eResearch. When you create an event in the Event Library, you are creating a template for use and modification across calendars. Once a calendar has been created and the event fields are updated with relevant information, the templates stored in the event library remain unchanged.

6.1.1.1 Charge Masters

Many customers provide Velos with their institution's charge masters. These charge masters are then uploaded to the Event Library by the WCG Velos team. Each charge master represents an Event Library, and each item in the charge master becomes a unique event in the library.

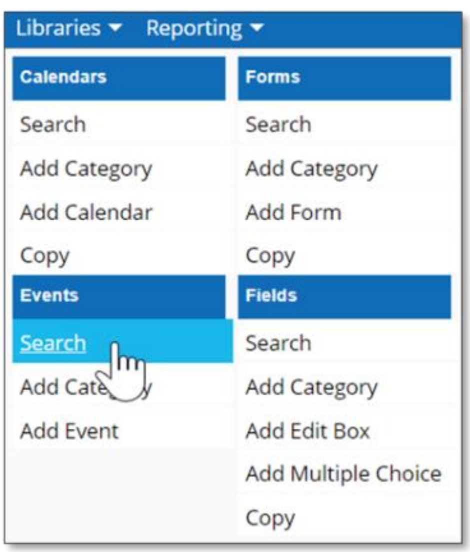
6.1.1.2 Search the Events Library

Before adding a new event, you should search the Event Library to see if there is a similar event or if the event already exists. If there is a similar event, you could save time by copying that event and making minor modifications instead of building one from the start. To learn more about copying an event, see Copy an Event.

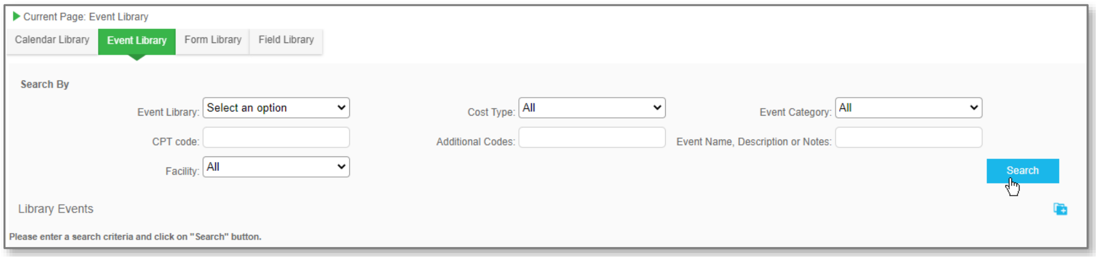
Note: Ensure you have selected the correct event library when searching for a specific event.

To search the events library:

1. Click the **Libraries** menu in the upper-left hand corner of the screen and select **Search** under the heading "Events".



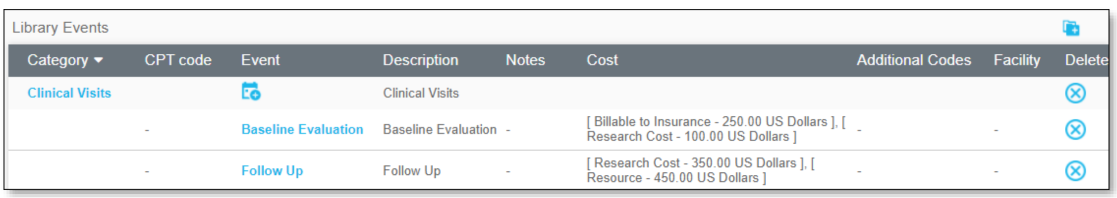
The Event Library displays:



2. Enter your search criteria in the available fields within the **Search By** section of the page and click **Search**.

Note: At a minimum, you must select an option from a charge master from the Event Library dropdown field before clicking Search. If you attempt to search with the Event Library field in the default "Select an Option" state, the search attempt will fail.

The search results display at the bottom of the page in the Library Events section:


Library Events

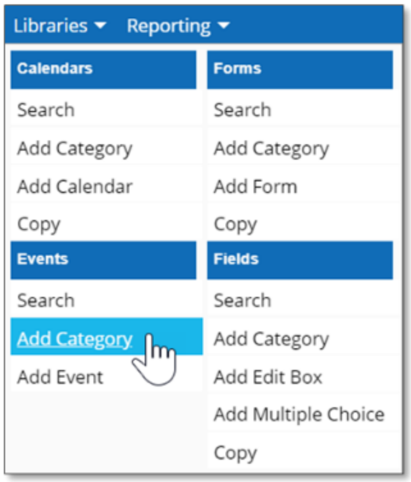
Category	CPT code	Event	Description	Notes	Cost	Additional Codes	Facility	Delete
Clinical Visits			Clinical Visits					
	-	Baseline Evaluation	Baseline Evaluation	-	[Billable to Insurance - 250.00 US Dollars], [Research Cost - 100.00 US Dollars]	-	-	
	-	Follow Up	Follow Up	-	[Research Cost - 350.00 US Dollars], [Resource - 450.00 US Dollars]	-	-	

6.1.1.3 Add an Event Category

Within each charge master, events can be organized by category. For example, you may organize your events by "patient questionnaires", "patient labs or tests", and "evaluations". Before creating an event, at least one event category must first be established.

To add an event category:

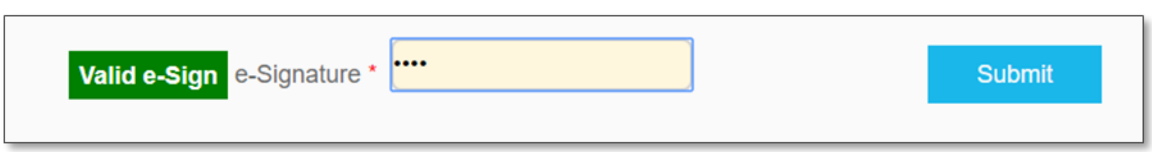
1. Click the **Libraries** menu in the upper-left hand corner of the screen and select **Add Category** under the heading Events.



The Event Category screen displays:

2. Enter the required information in the available fields.

3. After filling in the required information, enter your e-Signature and click **Submit** to confirm.



6.1.1.4 Add and Manage Events

In Velos eResearch, events are fundamental to the creation of study and administrative calendars. Events also drive financial elements such as visit and event milestones, and budgets. Depending on your organization's initial setup, events may already be pre-populated in one or more Charge Masters as provided by your organization. For more information on charge masters, see Charge Masters. Regardless if your organization has provided events in a charge master or not, permissioned users will have the ability to add and manage events in Velos eResearch.

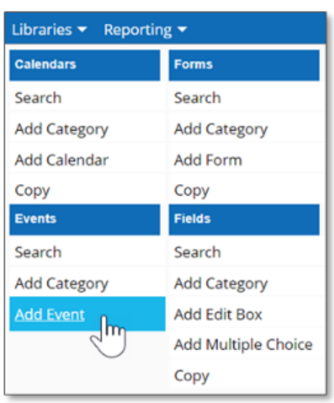
> **Note:** It is recommended that some event settings be left undefined until they are associated with a study. These steps are marked with a warning information box throughout this section and include the Message, Resource, and CRF Details tabs, as well as the following fields in the Event Details screen: Event Duration, Event Window, Site of Service, Facility, and Coverage Type.

6.1.1.4.1 Add an Event

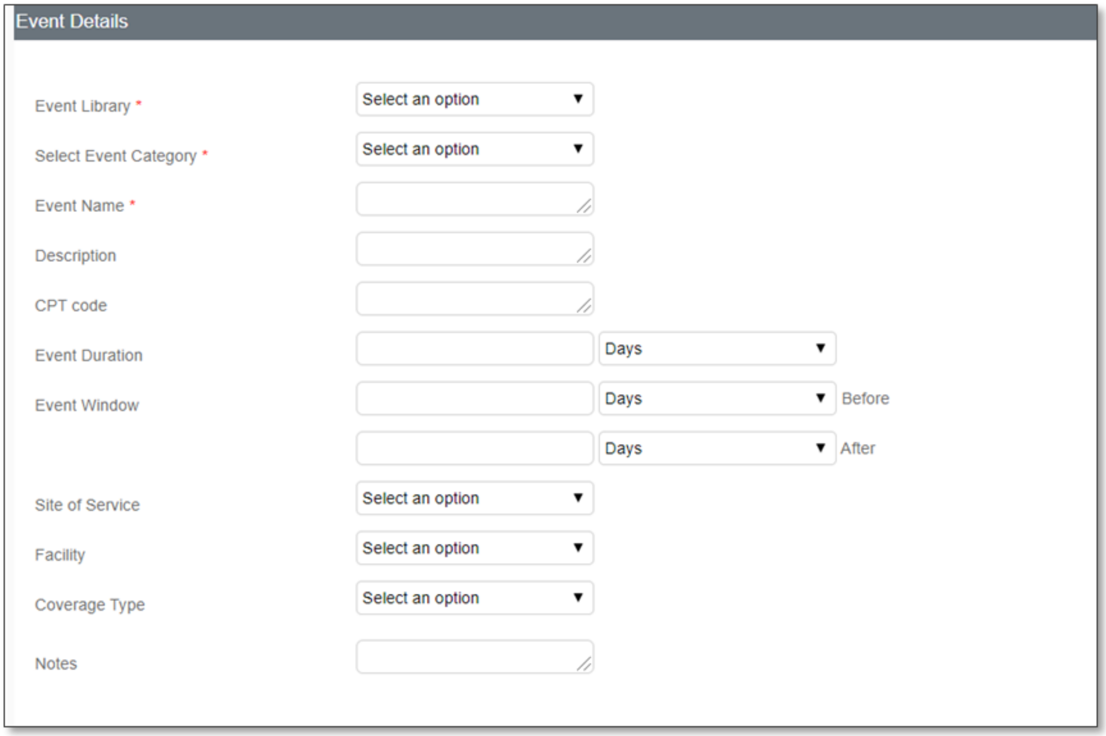
If a required study event does not already exist in the Event Library, permissioned users can add new events using the Libraries menu.

To add a new event:

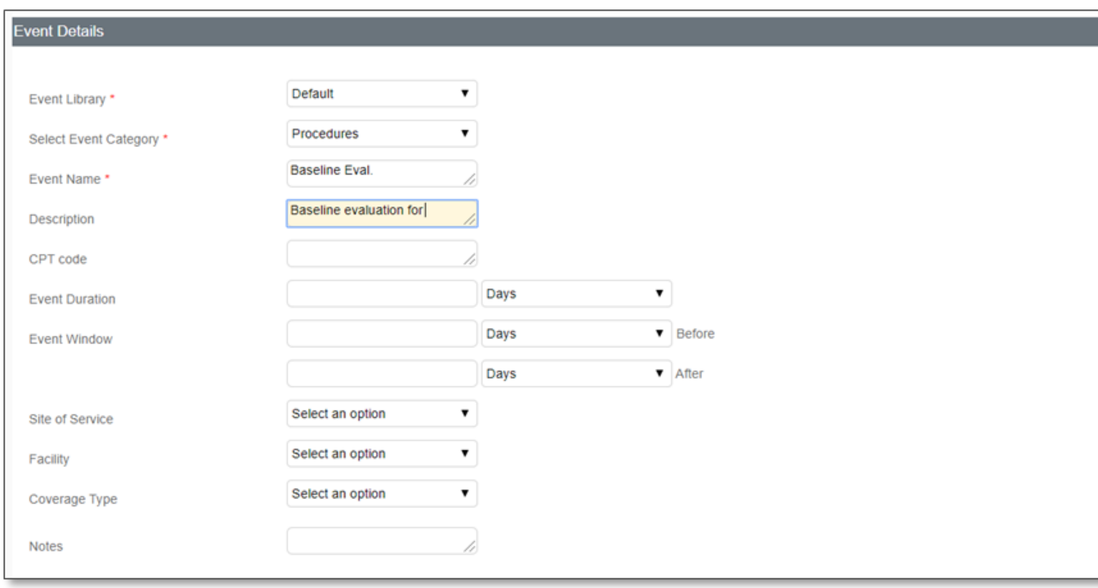
1. Click the **Libraries** menu in the upper-left hand corner of the screen and select **Add Event** under the heading "Events".



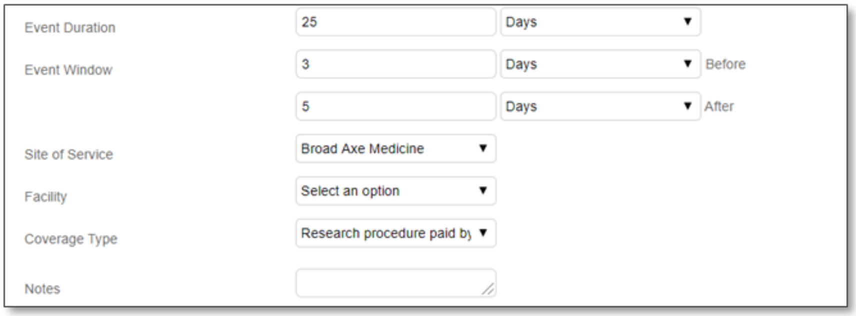
The Event Details screen displays:



2. Enter category and description information into the available fields at the top of the page.



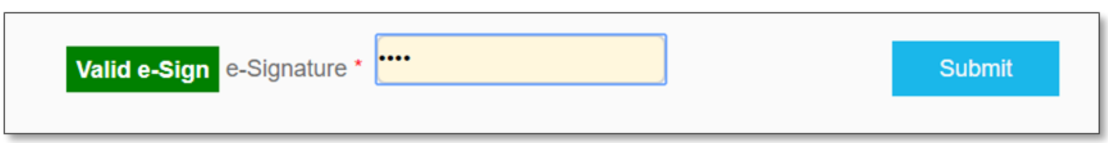
3. Continuing down the page, enter event timing, Site of Service, Facility, and Coverage Type information into the remaining fields if required*. See the table below for a short description of the event timing fields.



Category	Description
Event Duration	The amount of time in days or weeks that the event takes to complete.
Event Window (Before)	The amount of time in hours, days, weeks or months **before** the scheduled event that this event can be completed.
Event Window (After)	The amount of time in hours, days, weeks or months **after** the scheduled event that this event can be completed.

Warning: For events in the library, it is highly recommended to skip step 3, leaving the fields as open fields. These details are typically study-specific and can be defined when a calendar with this event is associated to a study. See Study Management for more information about adding events to a study.

4. After filling in the required information, enter your e-Signature and click **Submit** to confirm.



Note: Before proceeding to the other event configuration tabs, you must first enter the required information on the Event Details page and create the new event by clicking Submit. If you proceed to other tabs before saving the information on the Event Details page, the other tabs will be disabled, and your progress on the Event Details page will be lost.

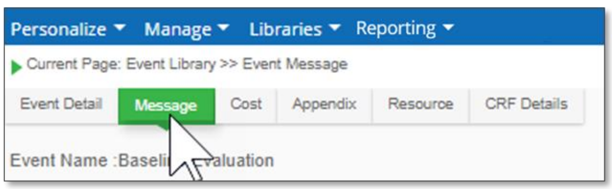
6.1.1.4.2 Event Message

Velos eResearch provides the ability to generate event auto-notifications for patients and system users using the Message tab within an event.

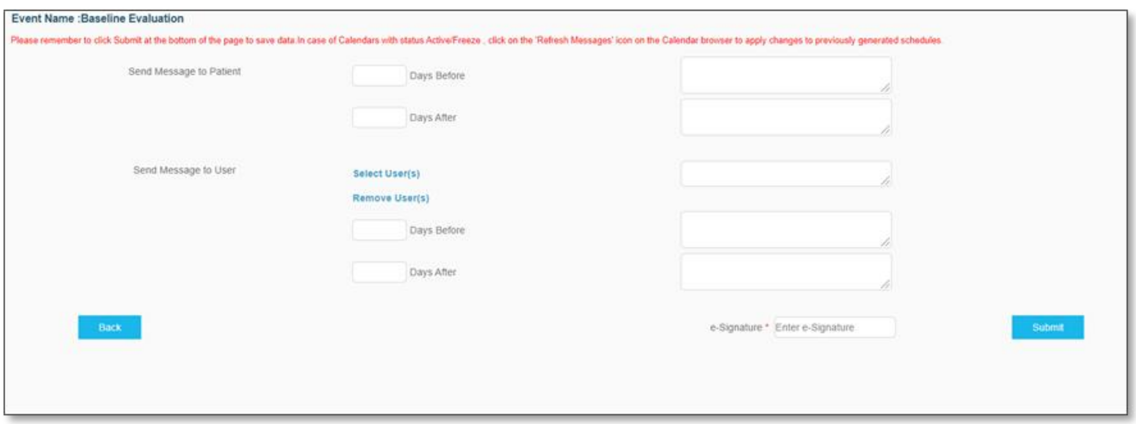
Warning: For events in the library, it is highly recommended to leave Messages undefined. These details are typically study-specific and can be defined when a calendar with this event is associated to a study. See Study Management for more information about adding events to a study.

To add an event message:

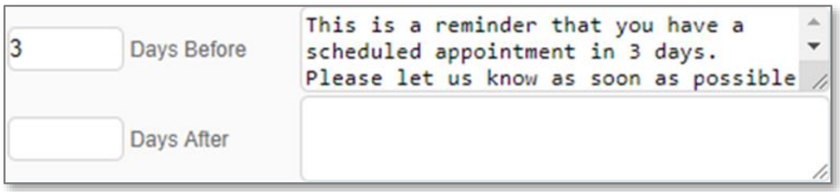
1. Navigate to a specific event through the Event Library and click the **Message** tab.



The Event Message page displays:



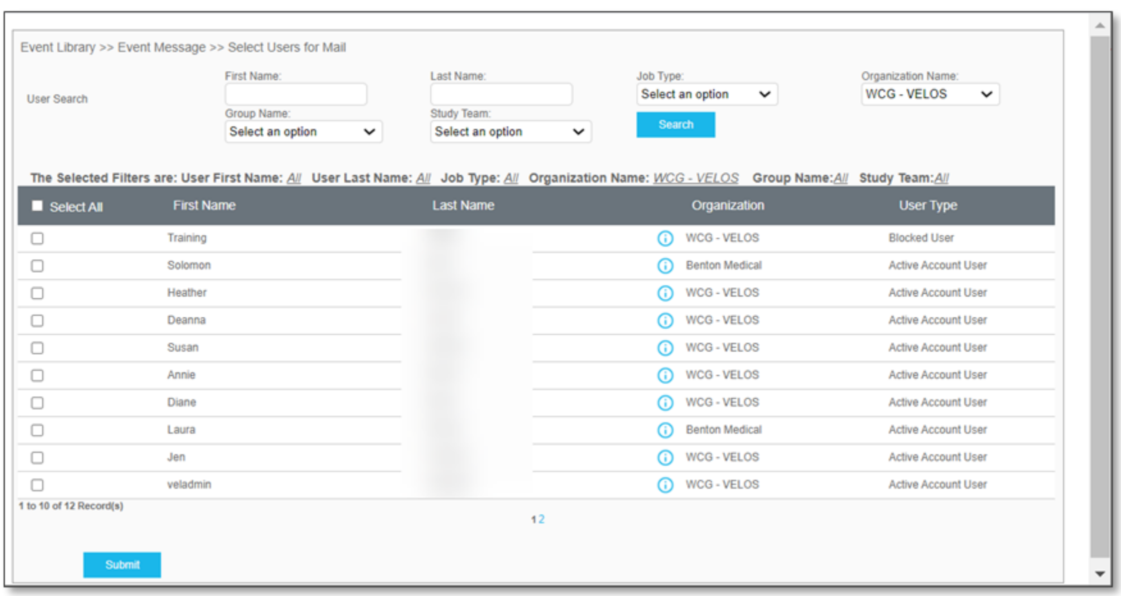
2. If you want to send a notification to patients, enter the number of days before and/or after the scheduled event that you would like a notification to be sent to the patient within the **Send Message to Patient** section. For each field that is used, enter the notification text in the available field to the right.



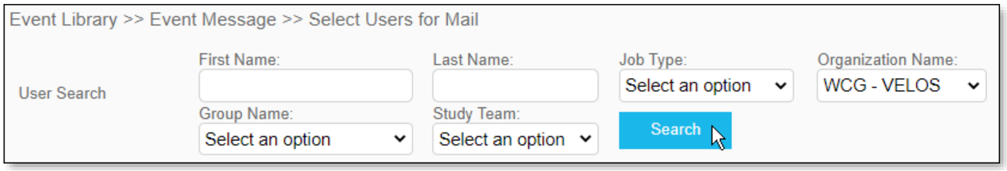
Note: Patient messages are sent using the patient email address established under the patient profile in Demographics. A message will only be sent if the patient has the specific event in their calendar.

3. If you want to send a notification to system users, first, select the target users by clicking **Select Users**.

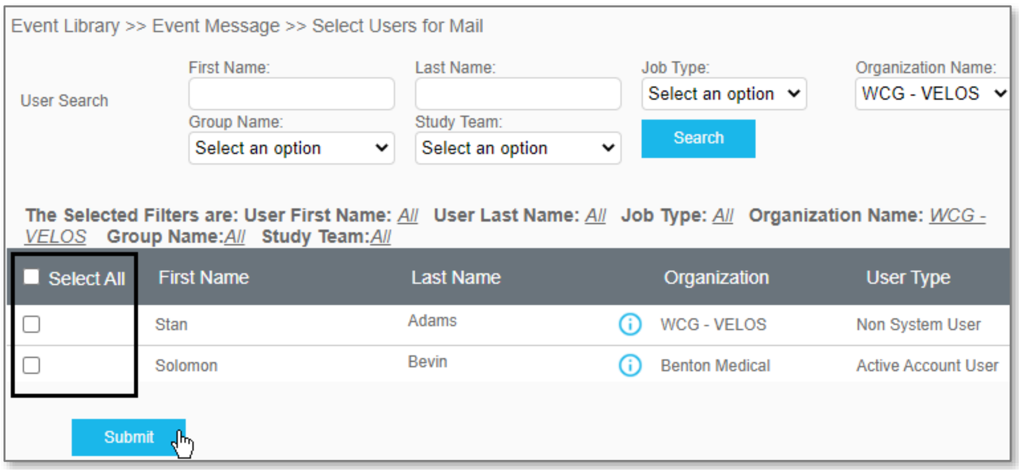
The Select Users for Mail page displays in a new window:



4. Search for target users using the **User Search** menu fields and click **Search**.

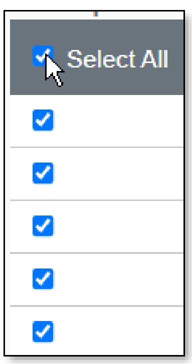


5. Then click on the checkbox next to the individual(s) you would like to receive your notification(s).

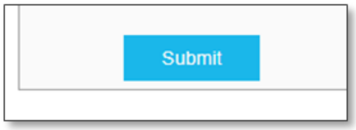


-OR-

Click on the checkbox next to **Select All** to select all displayed users.

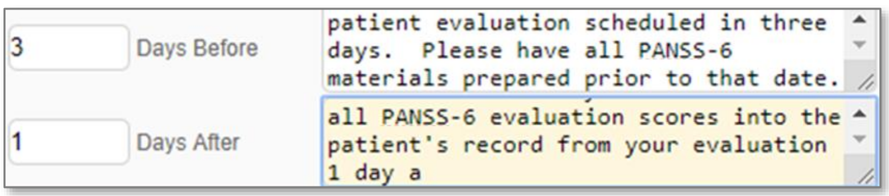


6. Click **Submit** to add the selected users to the notification.



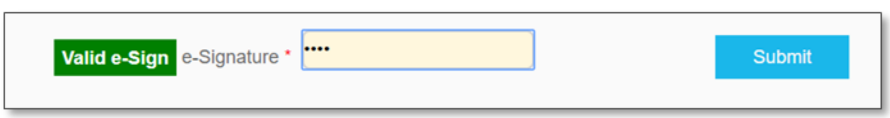
The selected user(s) display in the Select User(s) field. Click **Remove User(s)** to remove users from this field as needed.

7. Enter the number of days before and/or after the scheduled event that you would like a notification to be sent to the system user within the **Send Message to User** section. For each field that is used, enter the notification text in the available field to the right.



Note: Some special characters are not allowed to be used in the message fields. The system will warn you when you try to submit your changes if your message contains an invalid character. Refer to Appendix D – Special Character Behaviors / Reserved Words.

8. Enter your e-Signature and click **Submit** to confirm.



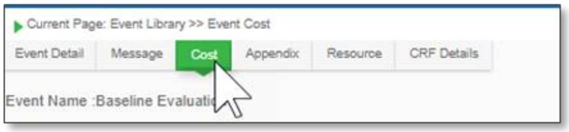
The event messages have been saved.

6.1.1.4.3 Event Cost

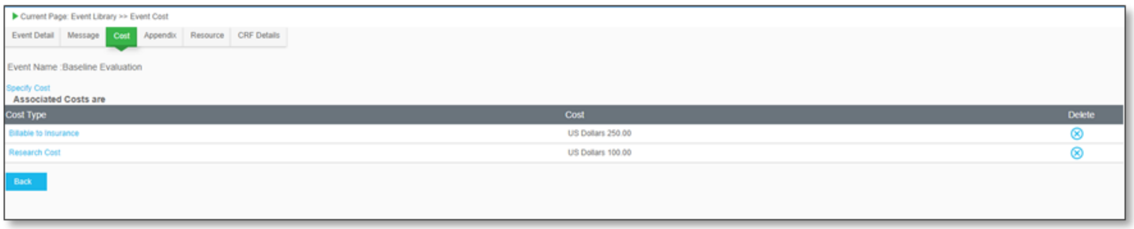
Velos eResearch provides the ability to allocate event costs using the Cost tab within an event.

To access the Event Cost page:

1. Navigate to a specific event through the Event Library and click the **Cost** tab.



The Event Cost page displays:



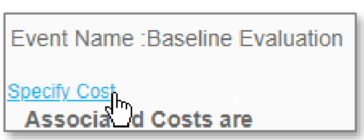
6.1.1.4.3.1 Add an Event Cost

Permissioned users can add cost line items to an event using the Cost tab of an event.

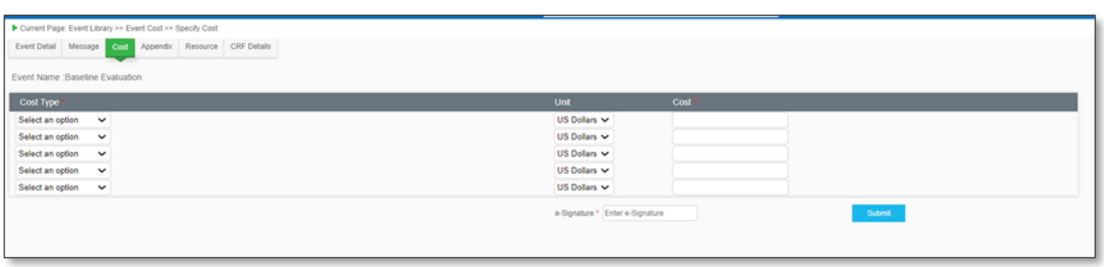
Warning: Enter static costs during Library management that will be carried across all studies, otherwise add the costs at the study level as outlined in Financial Management.

To add an event cost:

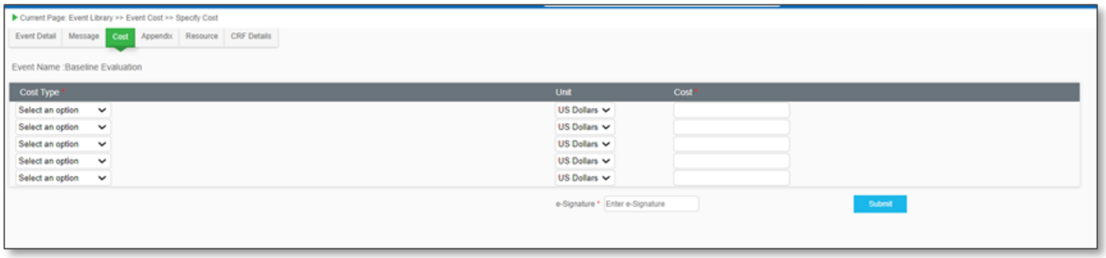
1. Navigate to the Event Cost page of an event and click **Specify Cost** to add a cost line item to this event.



The **Cost Details** page displays:



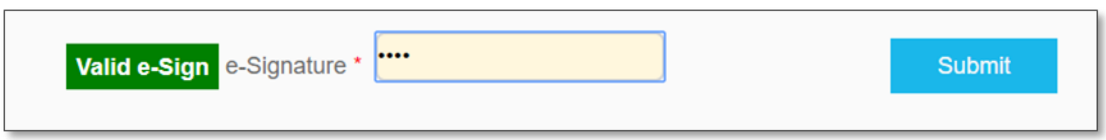
2. Select a **Cost Type**, the currency unit, and then enter the amount (numerical value) in the **Cost** column.



eXpress Only: Cost line items entered in eXpress must use US Dollars as the unit type.

Note: It is recommended that you add one cost at a time to ensure accurate line-item descriptions and costs pull through when a calendar budget is created.

3. Enter your e-Signature and click **Submit** to confirm.

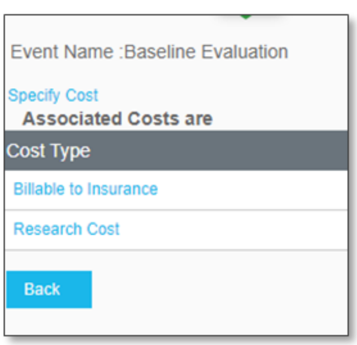


6.1.1.4.3.2 Edit an Event Cost

Permissioned users can edit cost line items to an event using the Cost tab of an event.

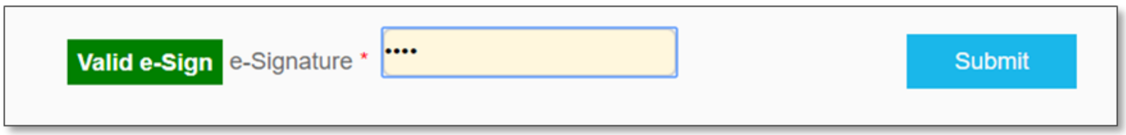
To edit an event cost:

1. Navigate to the Event Cost page and click directly on the **Cost Type** for the line item you would like to edit.



2. The Cost Details page displays. Make required changes as needed, to the cost type, currency, or amount.

3. Enter your e-Signature and click **Submit** to confirm.



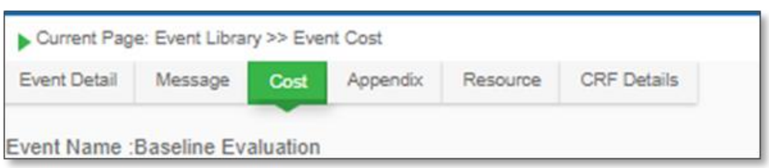
The event cost(s) have been updated, and now display on the Event Cost page.

6.1.1.4.3.3 Delete an Event Cost

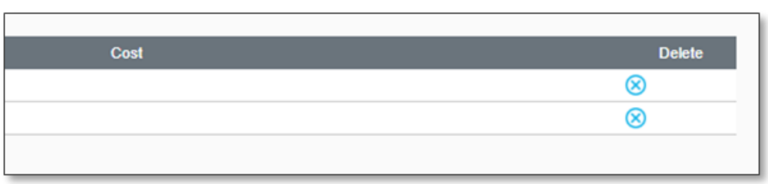
Permissioned users can delete cost line items to an event using the Cost tab of an event.

To delete an event cost:

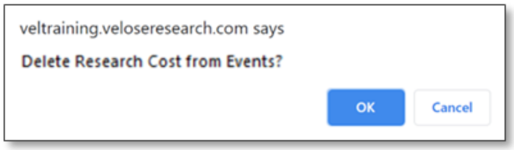
1. Navigate to a specific event through the Event Library and click the **Cost** tab.



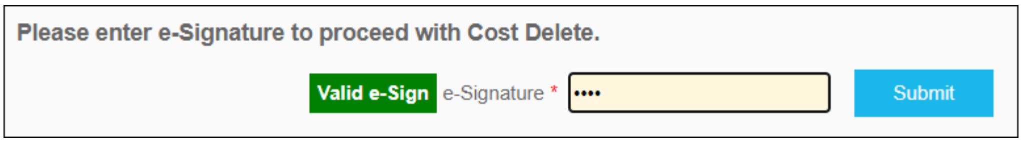
2. Click on the **Delete** button located at the right side of the page for the line item that you would like to delete.



3. A notification displays asking you to confirm if you would like to delete the cost line item. Click **OK** to delete the line item.



4. Enter your e-Signature and click **Submit** to confirm



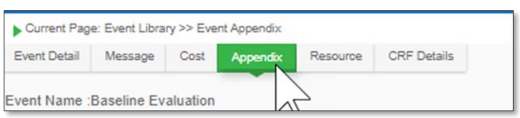
The line that was deleted has been removed from the Event Cost page.

6.1.1.4.4 Event Appendix

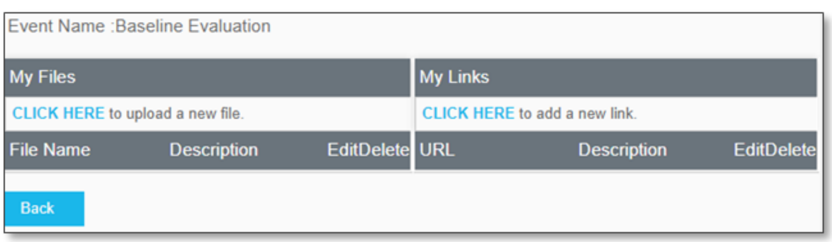
Velos eResearch provides the ability to add reference materials to an event using the Appendix tab within an event. Permissioned users can add, delete and edit files and links within the appendix.

To access the Event Appendix:

1. Navigate to a specific event through the Event Library and click the **Appendix** tab.



The Event Appendix page displays:



6.1.1.4.4.1 Add a File to the Event Appendix

Permissioned users can add a file or link to an event using the Appendix tab of an event.

To add event reference materials to the event appendix:

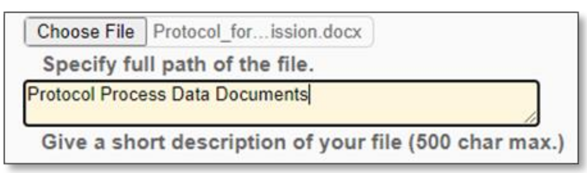
1. From the Event Appendix page, click **CLICK HERE** within the My Files section to add a file to this event.

   The Event File Details page displays:

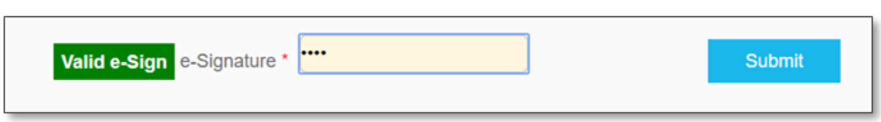
   

2. Click **Choose File** to select a file to attach to the event.
3. Select the file using the file picker and click **Open**.
4. The filename displays next to **Choose File**. Enter a short description of the file in the description field below.

Note: The description you enter is the value that will be displayed on the event for end-users. Please ensure you use a description that properly describes the file.

5. Enter your e-Signature and click **Submit** to confirm.

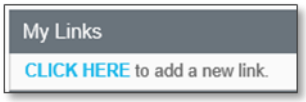
   

6.1.1.4.4.2 Add a Link to the Event Appendix

Permissioned users can add a file or link to an event using the Appendix tab of an event.

To add a link to the Event Appendix:

1. Click **CLICK HERE** within the My Links section.

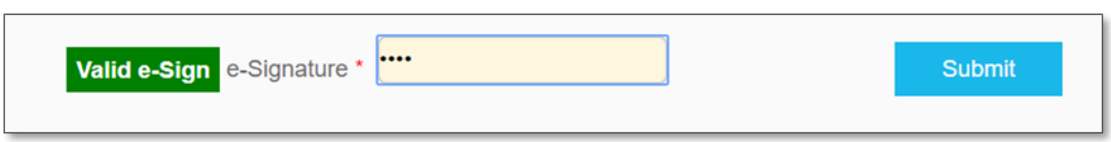


The Event Link Details page displays:

2. Enter the link URL and a description into the available fields.

Warning: When entering a URL, it must contain either http:// or https:// for the links to work properly. Failing to do so will result in broken, unusable links.

3. Enter your e-Signature and click **Submit** to confirm.



6.1.1.4.4.3 Edit a File or Link

Permissioned users can edit a file or link associated with an event using the Appendix tab of an event.

To edit a file or link:

1. Click the **Edit** button in the Edit column of either the My Files or My Links sections on the Event Appendix page.

2. If you are editing a file, the Event File Details page displays. Make changes to the file or the description, enter your e-Signature, and click **Submit** to confirm.

-OR-

If you are editing a link, the Event Link Details page displays. Make changes to the link or the description, enter your e-Signature and click **Submit** to confirm

The event file or event link changes are saved.

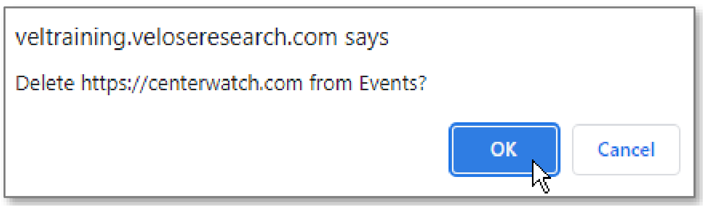
6.1.1.4.4.4 Delete a File or Link

Permissioned users can remove a file or link from an event using the Appendix tab of an event.

To delete a file or link:

1. Click the **Delete** button under the Delete column with either the My files or My Links sections on the Event Appendix page.

2. A notification displays asking you to confirm if you would like to delete the file or link. Click **OK** to delete the file.



3. Enter e-Signature in next page and click **Submit** to confirm.

The file or link that was deleted has been removed from the Event Appendix page.

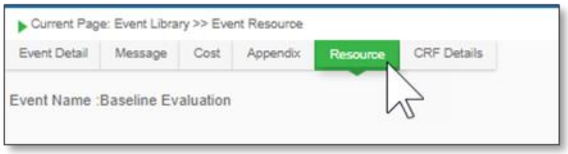
6.1.1.4.5 Event Resources

Velos eResearch allows permissioned users to add personnel resource information for study roles and/or specific system users to an event. Personnel resource information can be notes about each user role's participation in this event and expected resource time investment to complete an event.

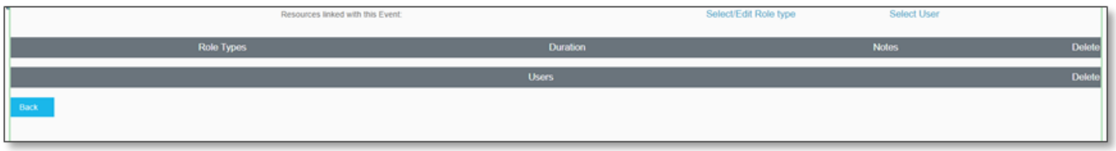
Warning: For events in the library, it is highly recommended to leave Resources undefined. These details are typically study-specific and can be defined when a calendar with this event is associated to a study. See Study Management for more information about adding events to a study.

To access the Event Resources page:

1. Navigate to a specific event through the Event Library and click the **Resource** tab.



The Event Resources page displays:

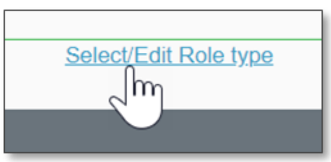


6.1.1.4.5.1 Add resource information or system users to an event

Permissioned users can add resource information to an event using the **Resource** tab of an event.

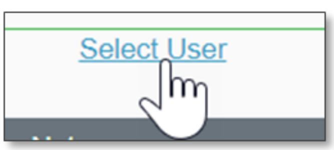
To add resource or user information to an event:

1. To add resource information, click **Select/Edit Role Type** on the Event Resources page.

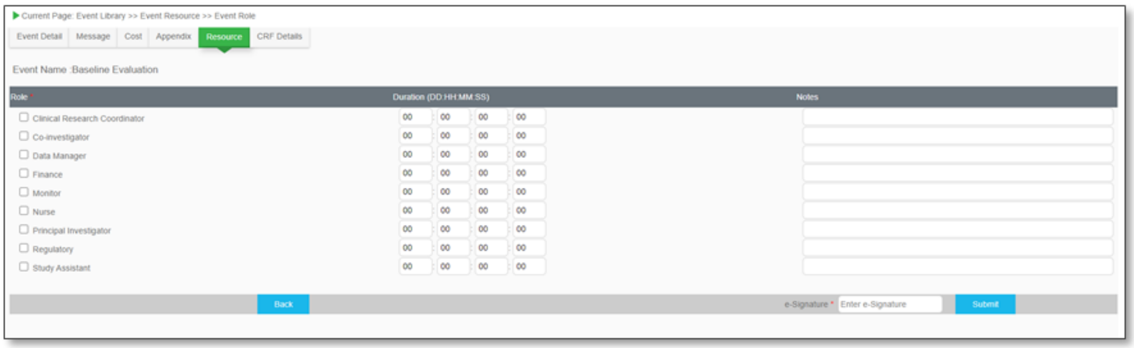


-OR-

To add a specific user to the event, click **Select User** on the Event Resources page.

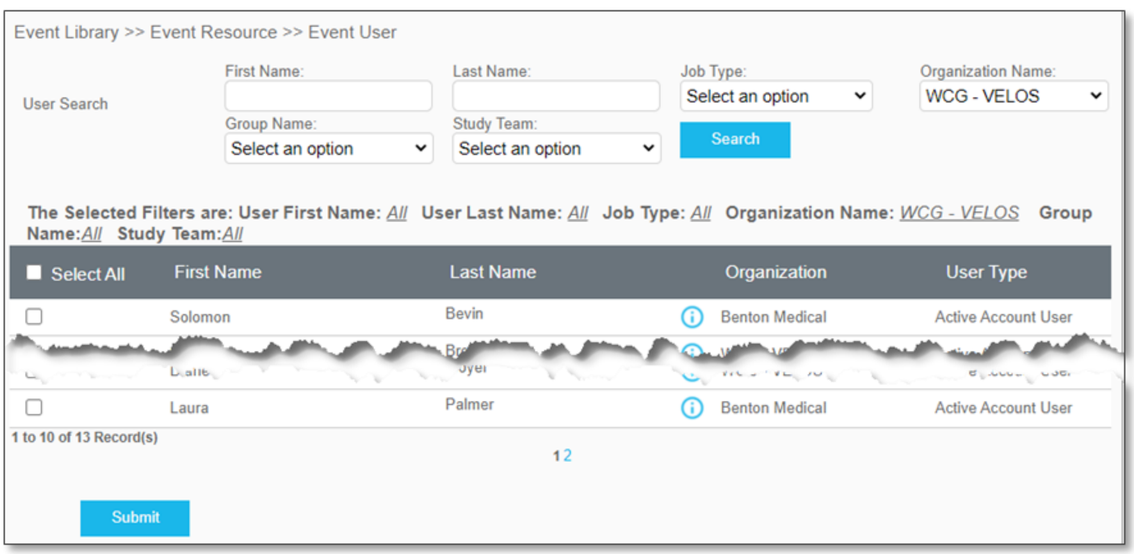


2. If you are adding resource information, the resource information page displays. Select each study role you would like to add by clicking on the checkbox next to the role name. For each role, add in estimated time that each role will need to perform their duties in the Duration column, in days, hours, minutes, and seconds. Finally, add a description, as needed, in the Notes column.

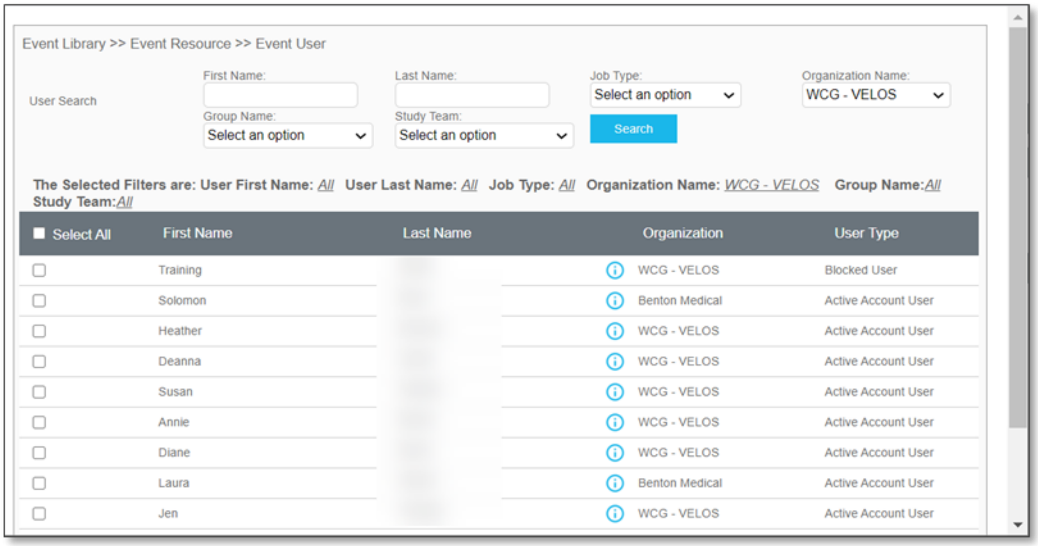


-OR-

If you are adding a specific user to the event by clicking Select User, the Event User selection page opens in a new window. Search for target users using the **User Search** fields and click **Search**.

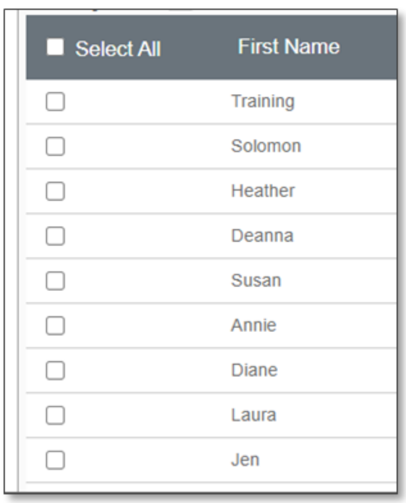


a. Then click on the checkbox next to the individual(s) you would like to receive your notification(s).



-OR-

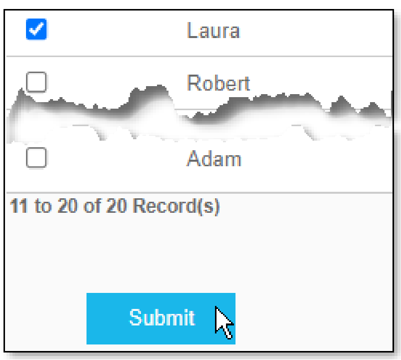
Click on the checkbox next to **Select All** to select all displayed users.



Note: Note that the default roles available vary between the Velos eResearch Enterprise and eXpress versions. See the table below for more information.

Enterprise Study Roles	eXpress Study Roles
Clinical Research Coordinator	Coordinator
Data Manager	Data Manager
Principal Investigator	Principal Investigator
Study Assistant	Study Assistant
Co-investigator	Sub Investigator
Nurse	N/A
Finance	N/A
Regulatory	N/A
Monitor	N/A

3. Once you have entered resource information to be added to the event, click **Submit** to confirm.



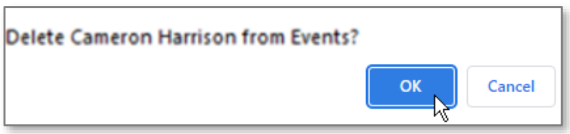
6.1.1.4.5.2 Remove a resource

Permissioned users can remove resource information or system users from an event using the Resource tab of an event.

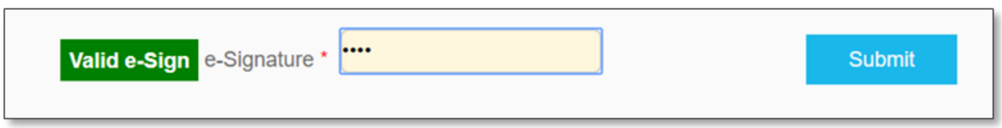
To remove a resource:

1. Click on the **Delete** button located at the right side of the Event Resources page for the line item that you would like to delete.

2. A notification displays asking you to confirm if you would like to delete the resource line item. Click **OK** to delete the line item.



3. Enter your e-Signature and click **Submit** to confirm.



The line item has been removed from the Event Resource page.

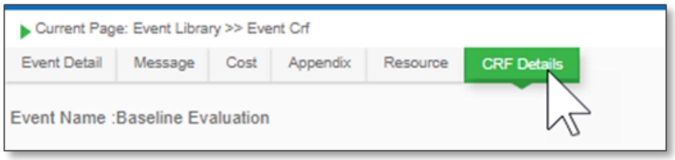
6.1.1.4.6 Event CRF Details

Velos eResearch provides the ability to add Case Report Form (CRF) information to an event. Permissioned users can add, edit, and delete CRF reference information and forms on the Event CRF page.

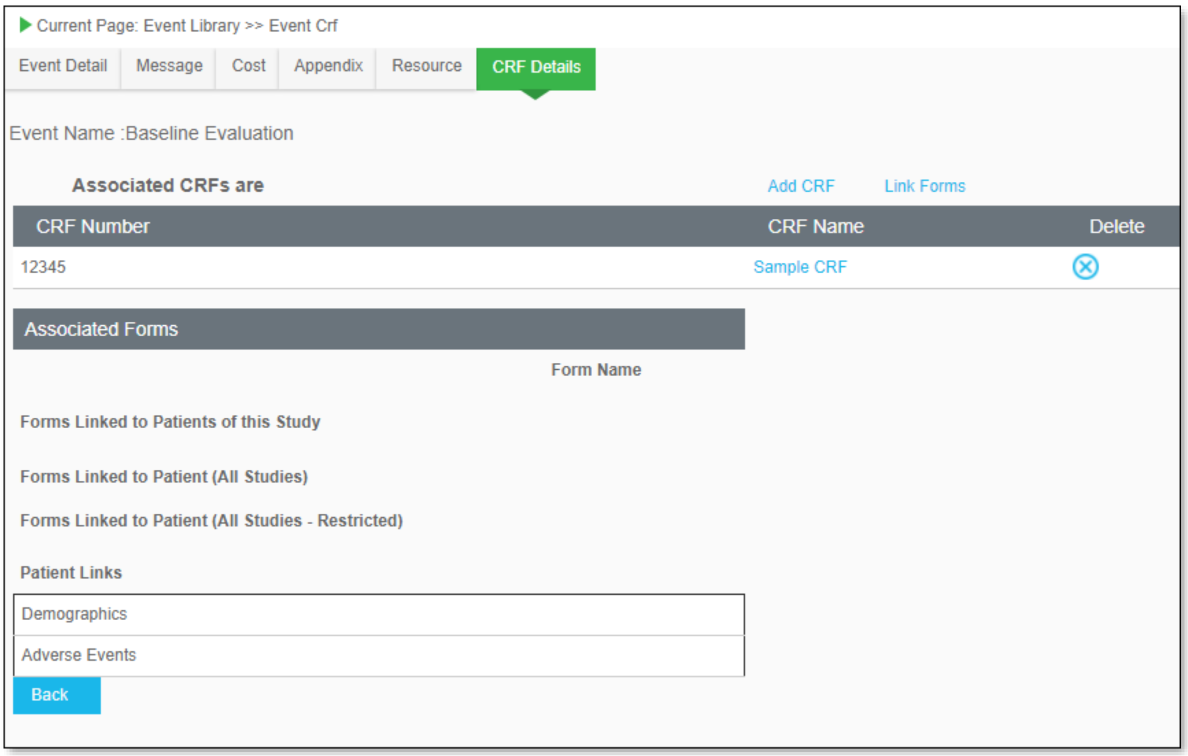
Warning: For events in the library, it is highly recommended to leave CRF Details undefined. These details are typically study-specific and can be defined when a calendar with this event is associated to a study. See Study Management for more information about adding events to a study.

To load the Event CRF page:

1. Navigate to a specific event through the Event Library, and click the **CRF Details** tab.



The Event CRF page displays:



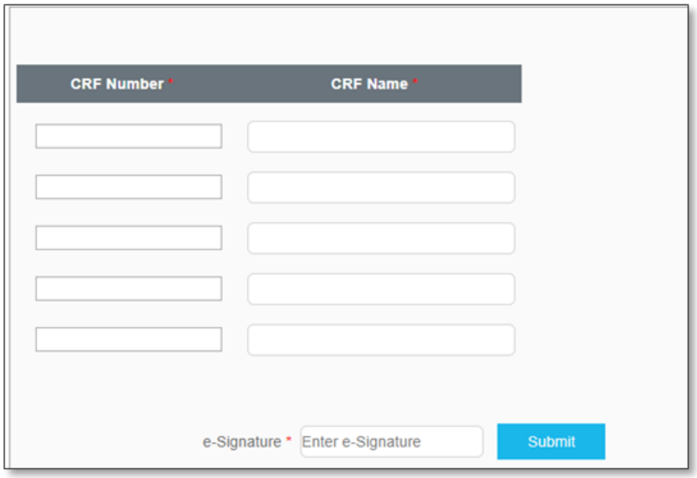
6.1.1.4.6.1 Add CRF reference information

Permissioned users can add a CRF number and name to an event on the Event CRF tab of an event.

To add CRF information:

1. From the Event CRF page, click **Add CRF**.

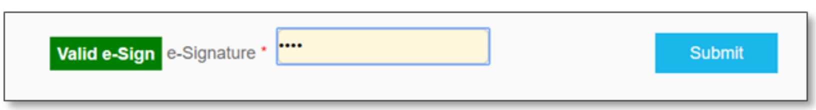
The CRF Information entry page displays in a new window:



2. Enter the **CRF Number** and **CRF Name** in the available fields.

Note: This page provides up to five rows for adding CRF entries at one time. If you need to add more than five line items to this event, add your first five line items, then repeat the process above by clicking on the Add CRF link on the Event CRF page to add more line items.

3. Enter your e-Signature and click **Submit** to confirm.



6.1.1.4.6.2 Link Forms and Patient Links

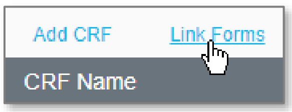
Permissioned users can link forms or labs to an event on the Event CRF tab of an event. Linking a form or lab to an event creates an easy link and reminder to the user completing the event in the system to fill out a form, or the results of a patient lab. The forms need not be only CRFs, any pre-visit/post-visit or general questionnaires for the participant may be linked. To learn more about forms in Velos eResearch, see Forms Management.

eXpress Only: Labs are not available in Velos eResearch eXpress.

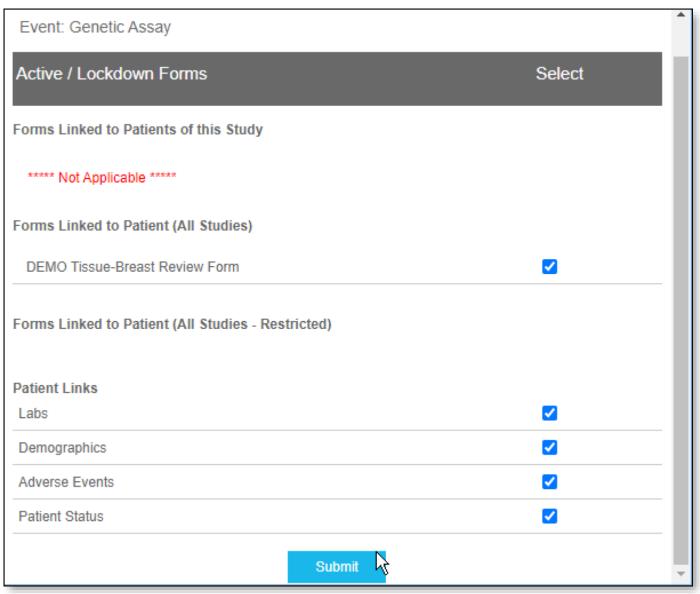
Warning: If using Participant Portals, use caution when unchecking a linked form in the CRF tab for a calendar as the participants will no longer be able to view the linked form in a portal.

To link form, adverse event, or lab pages:

1. From the Event CRF page, click **Link Forms**.



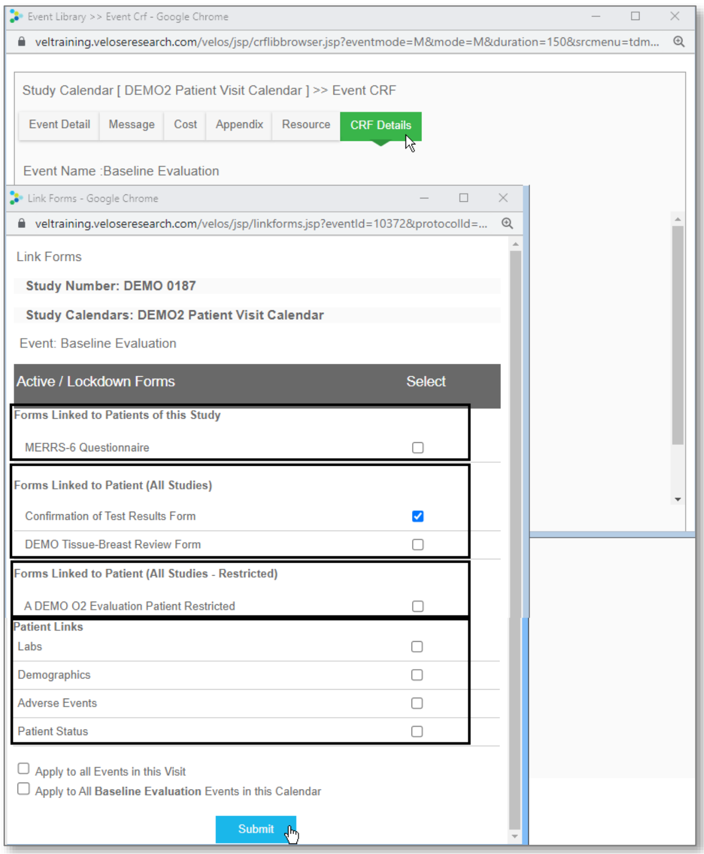
The Link Forms page displays in a new window:



2. Check checkboxes in the forms area(s), as applicable, for the available form(s) you would like associated to this event. For the Patient Links section, in order to access Adverse Events or Labs from a patient's schedule, ensure these checkboxes are checked, as needed.
3. Click **Submit**.

The patient form(s) selected will display on the Event CRF page within one of four patient form categories:

- Forms Linked to Patients of this Study
- Forms Linked to Patient (All Studies)
- Forms Linked to Patient (All Studies – Restricted)
- Patient Links – includes linking to Adverse Events



Note: The category that a patient form falls into depends on the way the form was configured in the library. In Enterprise, labs will always be listed as patient links. To learn more about form configuration see Forms Management.

6.1.1.4.6.3 Edit and Deleting CRF Information or Forms

At times, it may be necessary to edit or delete the CRF information or forms linked to an event. The ability to edit or delete both CRF information and forms is provided to permissioned users on the Event CRF page.

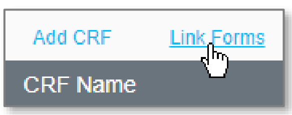
To edit CRF information or forms:

1. Navigate to the Event CRF page, and directly click the name of the CRF in the **CRF Name** column to edit CRF Information on an event.

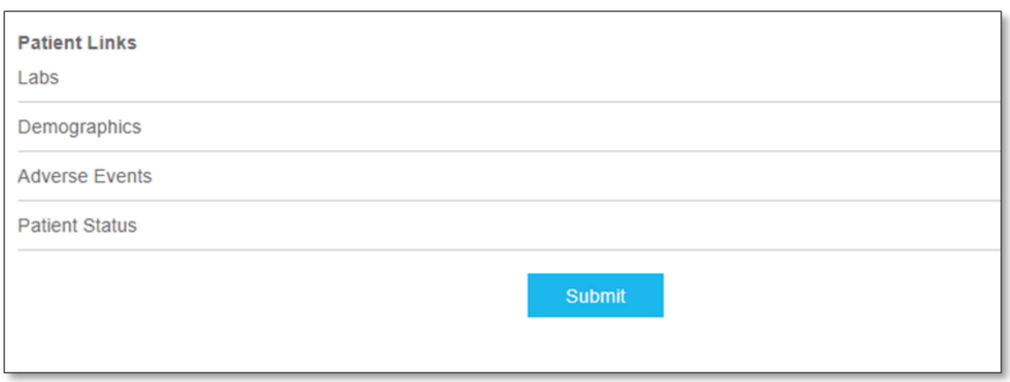
The CRF Details page displays:

-OR-

Click **Link Forms** to edit the linked forms for this event.



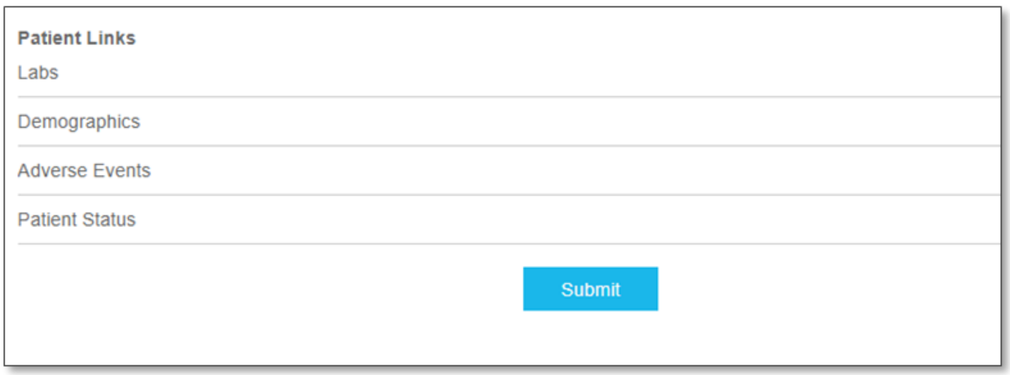
The Link Forms page opens in a new window.



2. If you are editing CRF information, update the CRF Number and/or CRF Name in the available fields as needed, enter your e-Signature and click **Submit** to confirm.

-OR-

If you are editing Linked Forms, check the checkbox next to the forms you would like to add or remove from this event and click **Submit**.

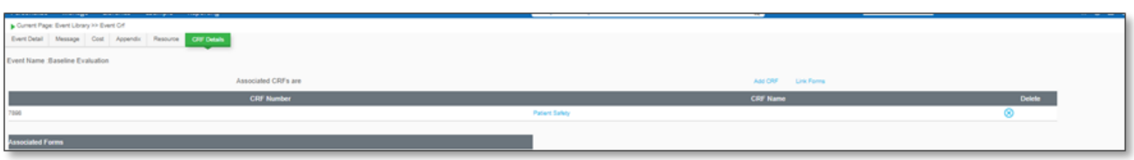


The CRF information is updated.

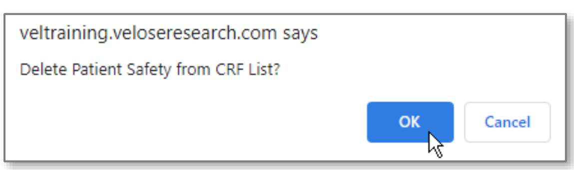
-OR-

To delete CRF information:

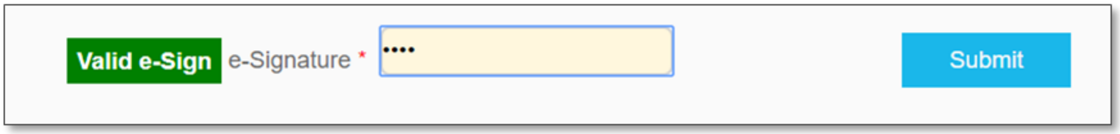
1. From the Event CRF page (CRF Details tab). Click on the **Delete** button located at the right side of the page for the line item that you would like to delete.



2. A notification displays asking you to confirm deletion. Click **OK** to delete.



3. Enter your e-Signature and click **Submit** to confirm.



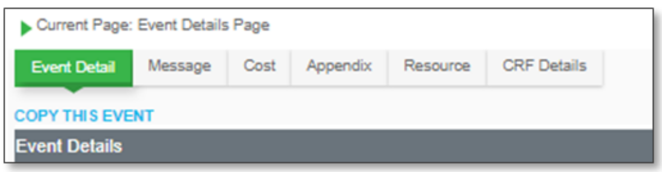
The selected line item has been removed from the Event CRF page.

6.1.1.5 Copy an Event

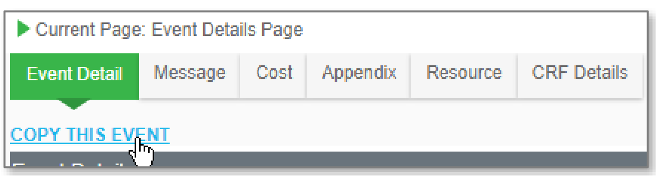
Velos eResearch offers a means to copy an existing event and make modifications to the copy using the Copy This Event link on the Event Details page of an event.

To copy an existing event:

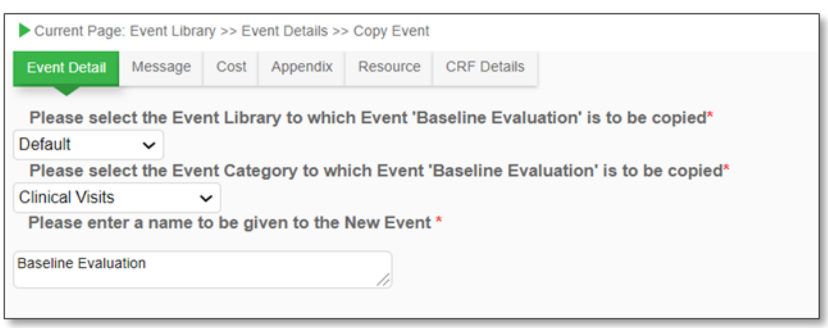
1. Navigate to an event and click on the **Event Detail** tab (default tab).



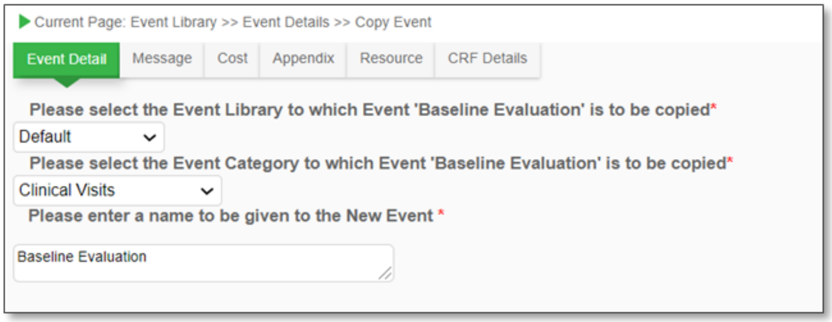
2. Click **Copy This Event** in the upper-left hand corner of the screen.



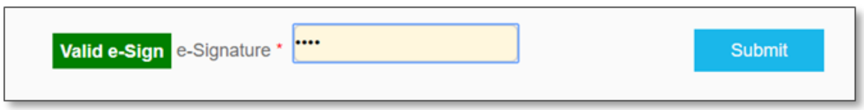
The Copy Details page displays:



3. Make edits to the Event Library (Charge Master), Event Category, and/or Event Name as needed.



4. Enter your e-Signature and click **Submit** to confirm.



The selected event has been copied to the Event Library and category that was selected in step 3.

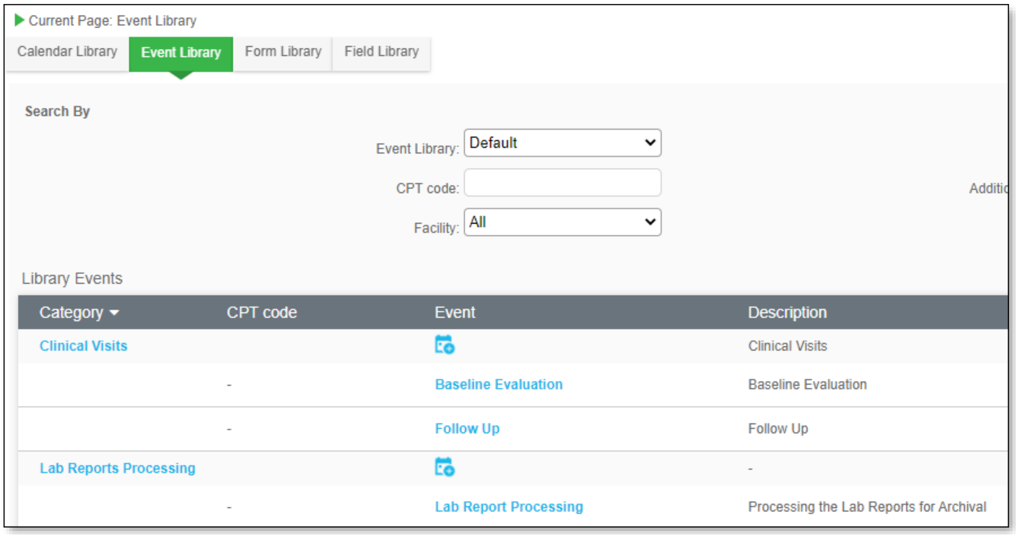
6.1.1.6 Remove an Event

Permissioned users can remove events from the Event Library as needed. Before removing an event from a calendar that has been associated with a study, ensure that it is not being actively used.

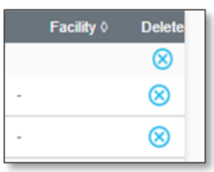
Note: Events cannot be removed from calendars associated with a study with an Active status.

To remove an event:

1. Navigate to the Events Library, and search for the target event. For more information about searching the Event Library, see Search the Events Library.

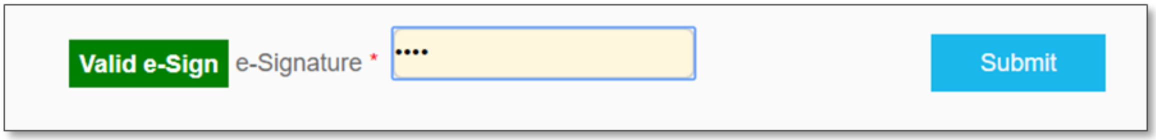


2. Click on the **Delete** button located at the right side of the page for the event that you would like to delete.



3. A notification displays asking you to confirm if you would like to delete the event. Click **OK** to delete the event.

4. Enter your e-Signature and click **Submit** to confirm.



The event is deleted from the **Event Library**.

6.1.2 Calendar Library

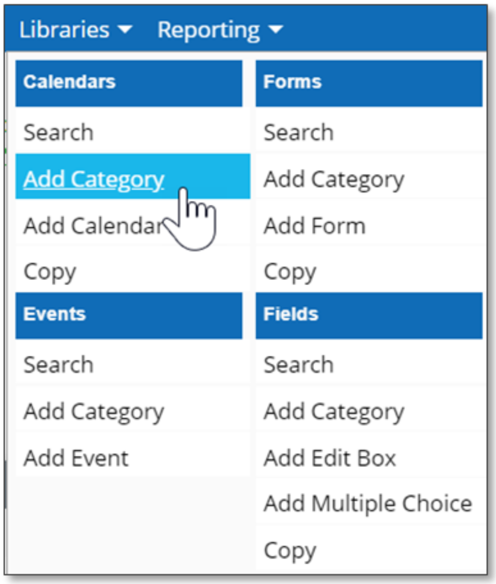
Calendars are a time-defined set of visits and events that can be applied to various functions within Velos eResearch. Calendars establish patient visit and administrative action timing, costs, event/visit matrices, and other important information related to the study calendar. As with the Event Library, when you create a Calendar in the Calendar Library, you are creating a template to use and modify across studies. Altering the copy of the Calendar added directly to a study will not affect the template stored in the library.

6.1.2.1 Add a Calendar Category

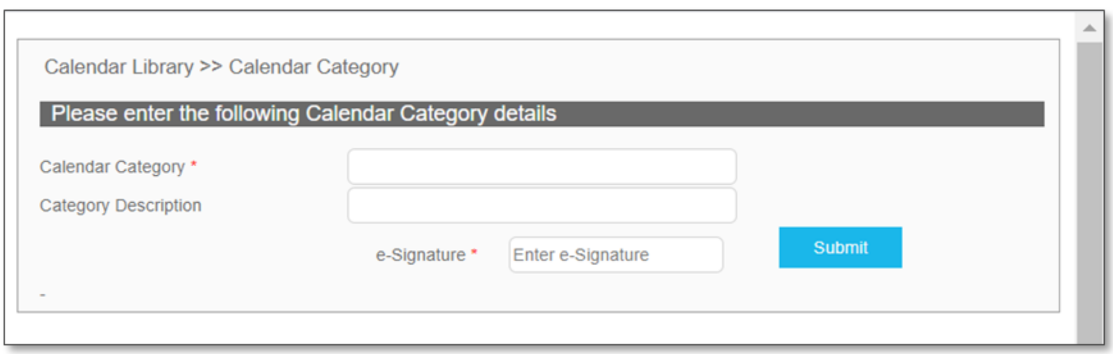
Within Velos eResearch, calendars can be organized by category. Before creating a calendar, at least one calendar category must first be established. For example, you may organize your calendars by specific study patient visit schedules, by indication category, or any way that makes the most sense for your processes.

To add a calendar category:

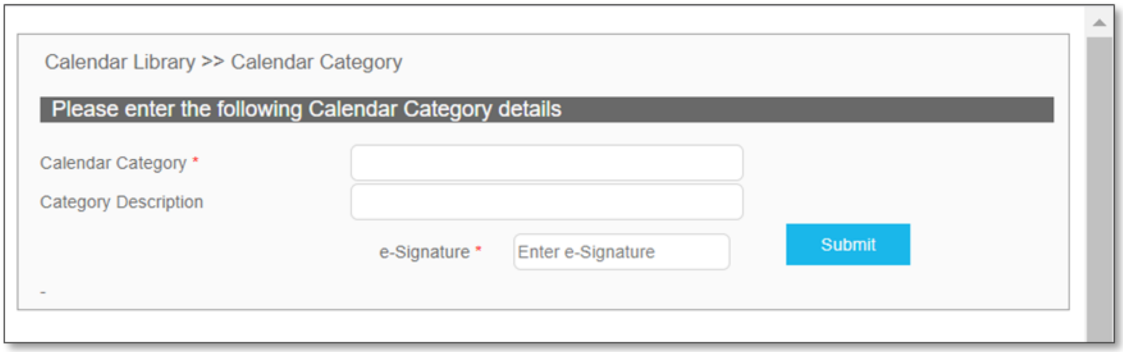
1. Click the **Libraries** menu in the upper-left hand corner of the screen and select **Add Category** under the heading "Calendars".



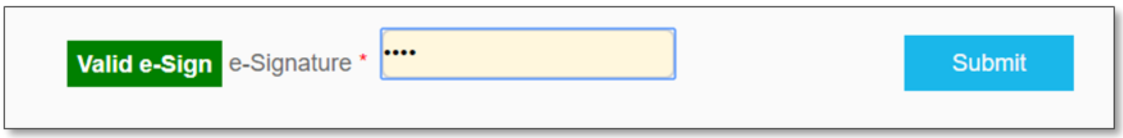
A new window opens, displaying the Calendar Category page:



2. Enter the category name and description in the available fields.



3. After filling in the required information, enter your e-Signature and click **Submit** to confirm.



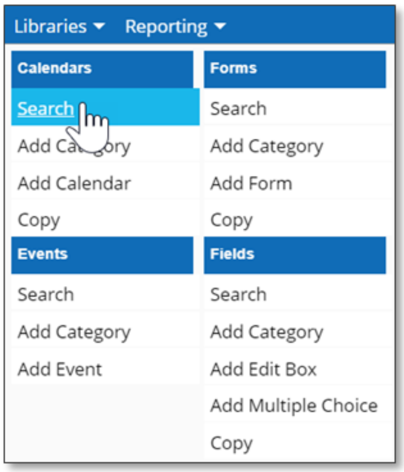
The calendar category has been saved.

6.1.2.2 Search the Calendar Library

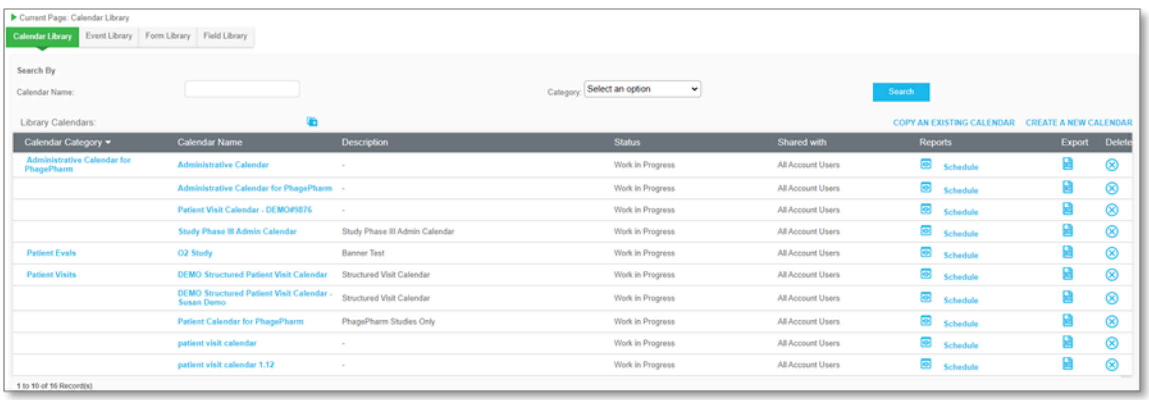
Before adding a new calendar, you should search the calendar library to see if there is a similar calendar or the calendar already exists. If there is a similar calendar, you could save time by copying a calendar and making minor modifications instead of building one from the start. To learn more about copying a calendar, see Copy a Calendar.

To search the calendar library:

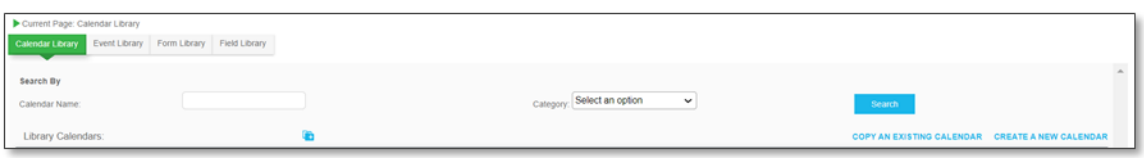
1. Click the **Libraries** menu in the upper-left hand corner of the screen and select **Search** under the heading Calendars.



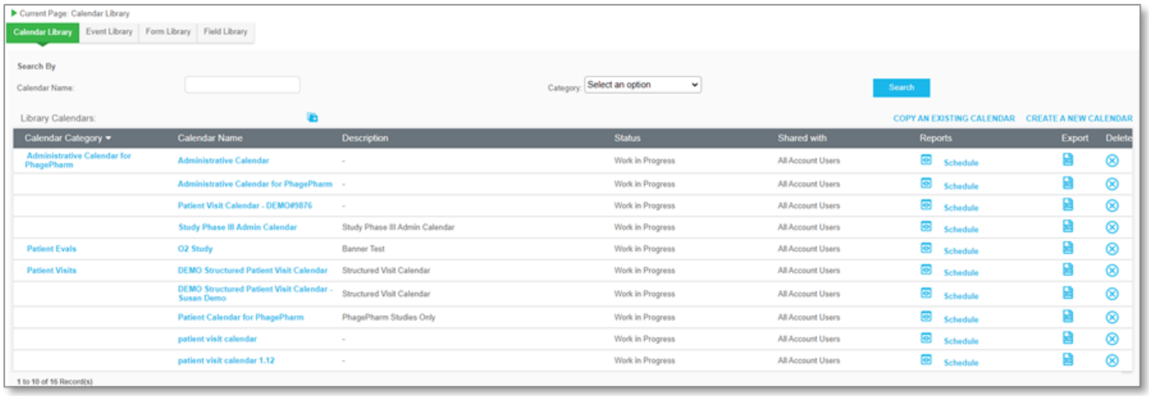
The Calendar Library displays:



2. Enter your search criteria in the available fields within the **Search By** section of the page, and click **Search**.



The search results display at the bottom of the page in the Library Calendars section:



6.1.2.3 Add and Manage Calendars

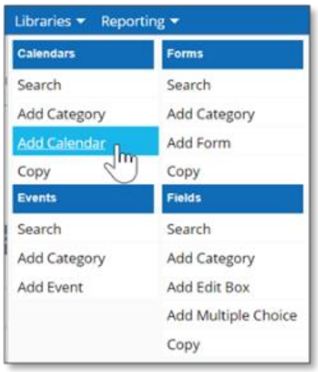
In this section, there are instructions on how to manage and add calendars. Calendars are a time-defined set of events that can be applied to studies to drive study requirements. Before creating calendars, events should be established in the Event Library. See Event Library for more information about adding events.

Note: It is recommended that some calendar settings be left undefined until they are associated with a study. These steps are marked with a warning information box throughout this section. It is also recommended to use Calendar Library to design reusable calendar templates. Always build Study specific calendars while working on a study in the Study Set up tab.

6.1.2.3.1 Add a Calendar

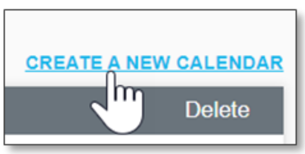
To add a calendar:

1. Click the **Libraries** menu in the upper-left hand corner of the screen and select **Add Calendar** under the heading “Calendars”.

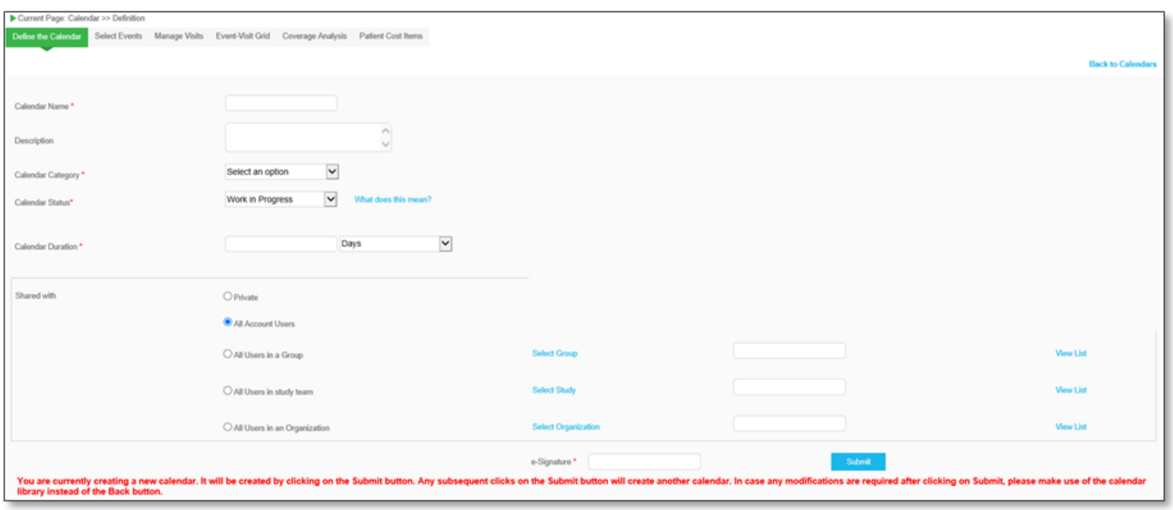


-OR-

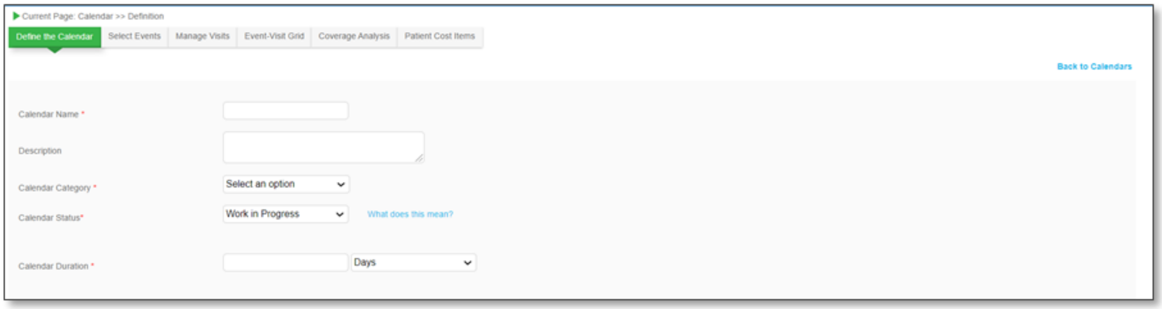
Navigate to the Calendar Library page and click **Create a New Calendar** on the left side of the page.



The Calendar Definition page displays:



2. Start defining the calendar by entering the name, description, category, status, and duration in the available fields.



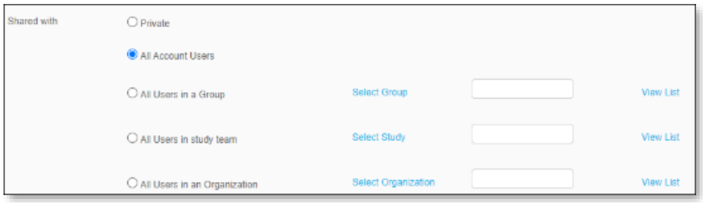
See the table below for more information about Calendar Statuses:

Status	Description
Work in Progress	The calendar is being created or can undergo modifications. Patient schedules cannot be generated while the calendar is in this mode.
Freeze	Once the calendar is set to Freeze no further modifications can be made. To make modifications, the protocol calendar will need to be copied and saved under another name. Modifications can then be made to that protocol calendar as long as it is in Work in Progress mode.
Active*	Once the calendar is made Active, patient schedules can be generated. However, no further modifications can be made to the calendar unless the status is changed to Offline for Editing.
Deactivated*	If a calendar is no longer in use, it can be deactivated. It will still show up in the calendar browser as a Deactivated calendar but will not be available to generate patient schedules. Once deactivated, it cannot be reactivated again.
Offline for Editing*	Once the calendar is made Active, the calendar can only undergo certain modifications if its status is changed to Offline for Editing.

Note: *These statuses are only available after a calendar has been associated with a study. They can be set from the Admin Schedule or Study Setup tabs within a study. For more information about using calendars in studies, see Study Management.

Warning: It is highly recommended to leave the status set to "Work in Progress" for all library calendars. If a calendar is changed to the status "Freeze", the calendar is permanently locked down, and no further changes can be made (including status).

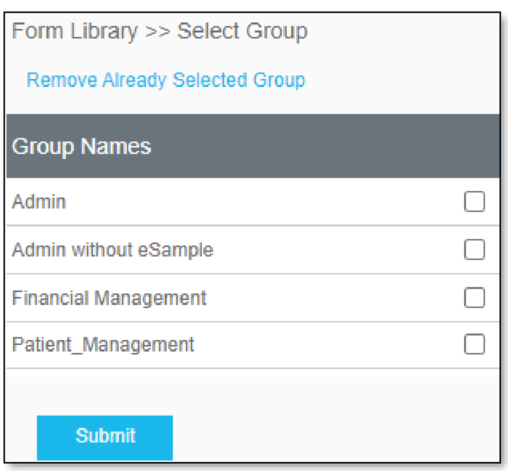
3. Define how the calendar should be shared.



See the table below for definitions of each share category:

Category	Definition
Private	Hidden from all users in the system.
All Account Users	Available to all system users.
All Users in a Group	Available to all system users in a group. For more information about groups, see Groups.
All Users in a Study Team	Available to all system users in a study. For more information about studies, see Study Management.
All Users in an Organization	Available to all system users in an organization. For more information about organizations, see Organizations.

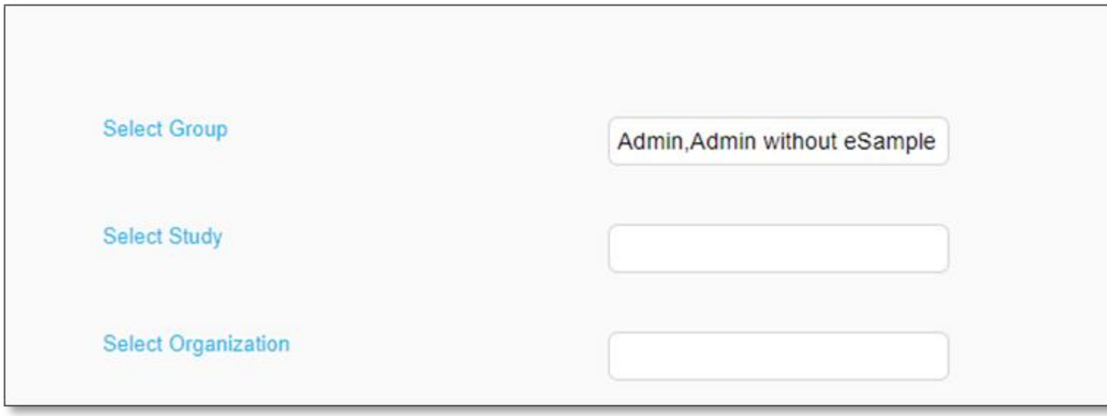
4. If you select the option **All Users in a Group**, click **Select Group**, and select a group or multiple groups using the selection window that displays. Click **Submit**.



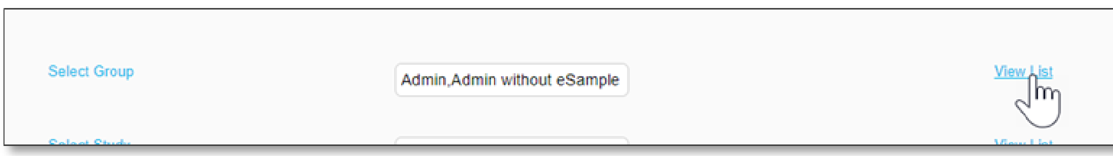
-OR-

If you select the options **All Users in a Study Team** or **All Users in an Organization**, follow the same steps above by clicking either the **Select Study** or **Select Organization** links.

The groups, studies or organizations you selected will display in the corresponding field:



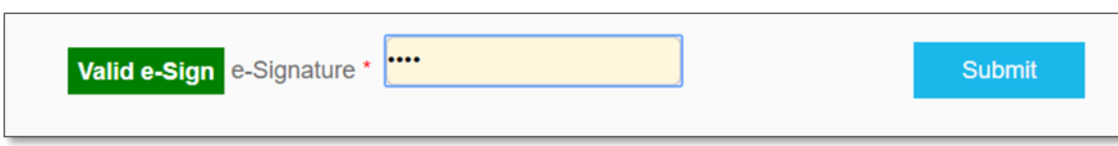
5. Click **View List** to view all users who will have access to the calendar based on your group, study, or organization selections.



The list of users, organized by group, study, or organization display in a new window:

Warning: If you share this calendar with a group, user, or organization to which you do not belong, you will not be able to see the calendar in the calendar library after you have saved it and leave the calendar creation page.

6. After filling in the required information, enter your e-Signature and click **Submit** to confirm.



The calendar has been saved. See the Manage Calendar Events section to continue the calendar configuration process.

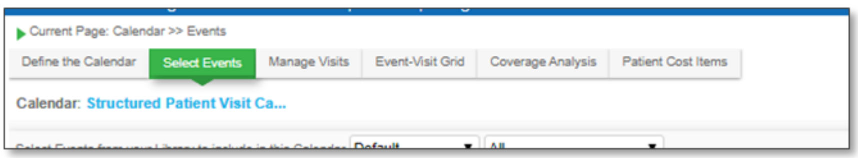
> **Note:** When making changes to each tab during calendar configuration, it is important to note that changes made in subsequent tabs will not change previously configured tabs in a right-to-left sequence. Configuring tabs in a left-to-right sequence will cascade changes made to the next tab. For example, if you make a change to the Event-Visit Grid, those changes will flow into the Coverage Analysis tab, but changing the Coverage Analysis tab will not affect the Event-Visit Grid.

6.1.2.3.2 Manage Calendar Events

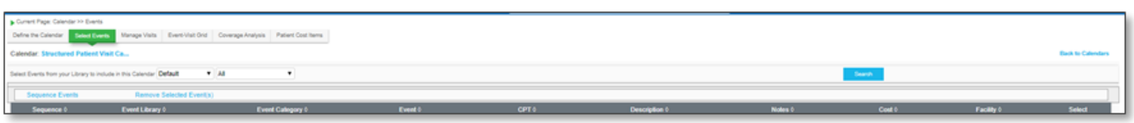
Events are foundational elements of calendars. Permissioned users can add, sequence, or delete events added to a calendar.

To access the Calendar Events page:

1. Navigate to a specific calendar in the calendar library, and click the **Select Events** tab.



The Calendar Events page displays:

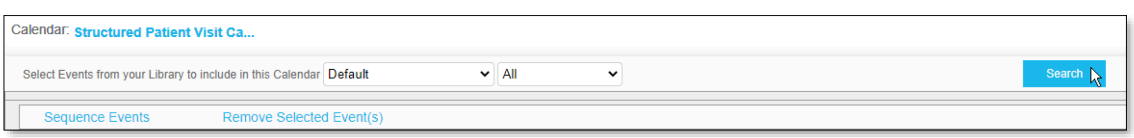


6.1.2.3.2.1 Add Calendar Events

Permissioned users can add events to a calendar using the Select Events tab of a calendar.

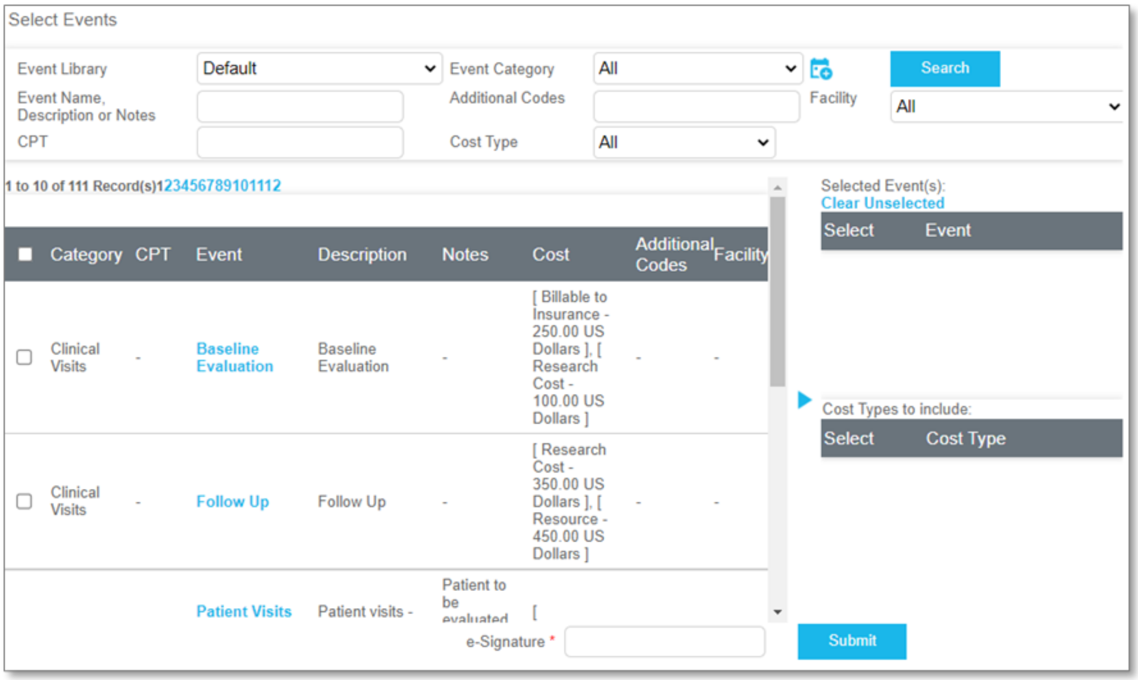
To add calendar events:

1. Navigate to the Calendar Events page and search the events library for the event you would like to add to this calendar and click **Search**.



Note: If you do not select an event library (charge master) before searching, your search results will fail. To learn more about charge masters see Charge Masters.

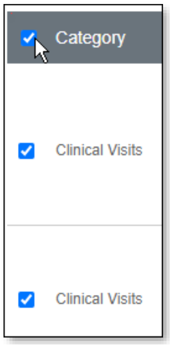
The search results display in a new window:



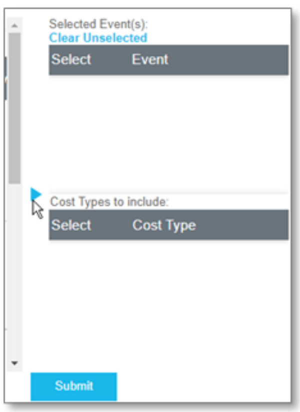
2. Select the individual events that you would like to add to the calendar by clicking on the checkbox next to the event.

-OR-

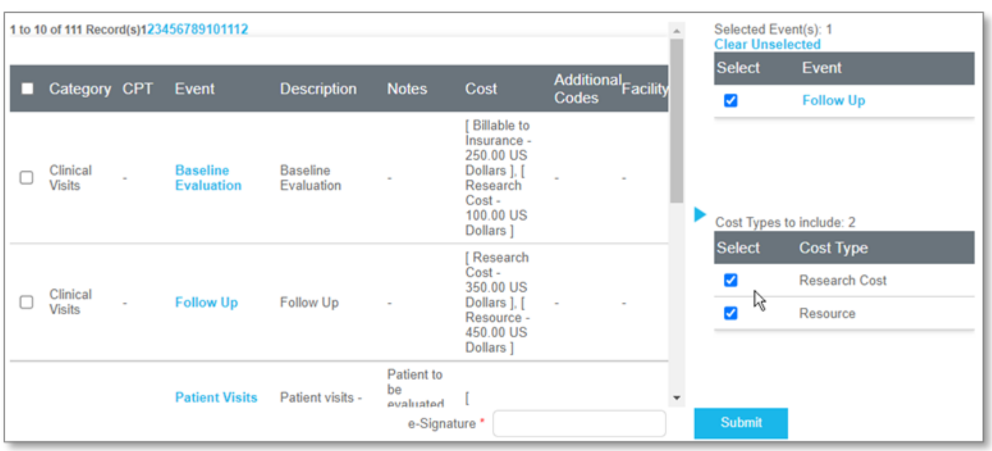
Select all events displayed by clicking the checkbox at the top of the search results section in the column **Select**.



3. Click the **Transfer** button to add these events to the calendar.

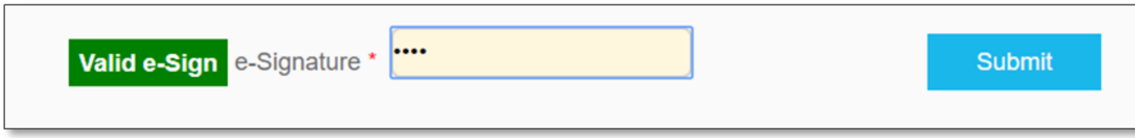


The event(s) display in the Selected Event(s) section of the search results page:



a. If all costs are to be included, leave the checkmarks checked in the Cost Types to include area, otherwise, uncheck the checkboxes in the Select column which do not apply.

4. Enter your e-Signature and click **Submit** to confirm.



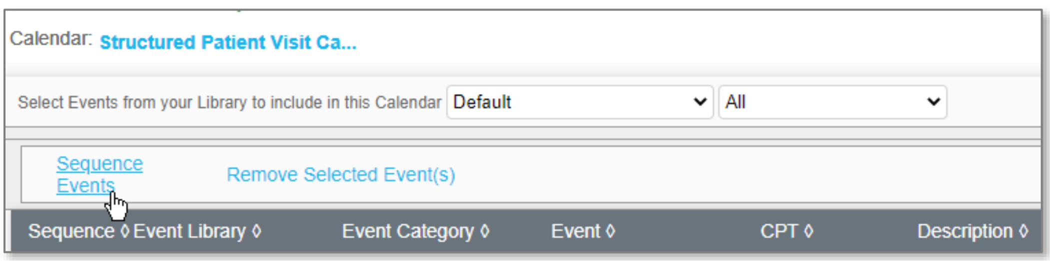
6.1.2.3.2.2 Sequence Events

Permissioned users have the ability to change the order of events on the Select Events tab by using the Sequence Events link.

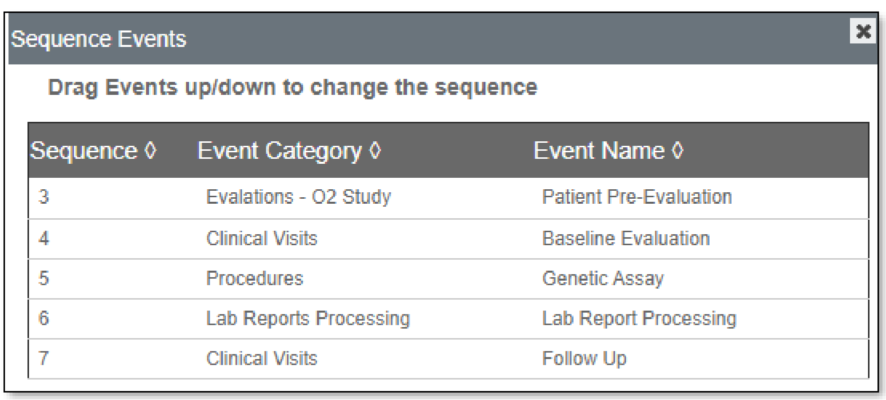
Note: The sequencing function only works if events have already been added to the calendar. See Add Calendar Events for more information about adding events.

To change the sequence of events:

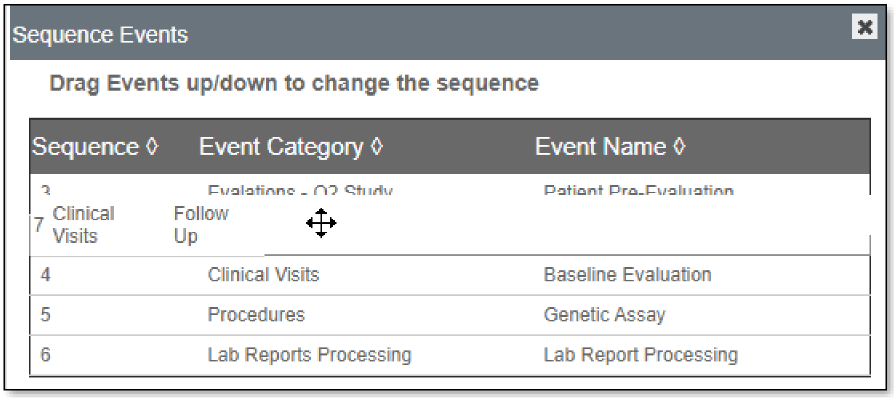
1. Navigate to the Calendar Events page and click **Sequence Events**.



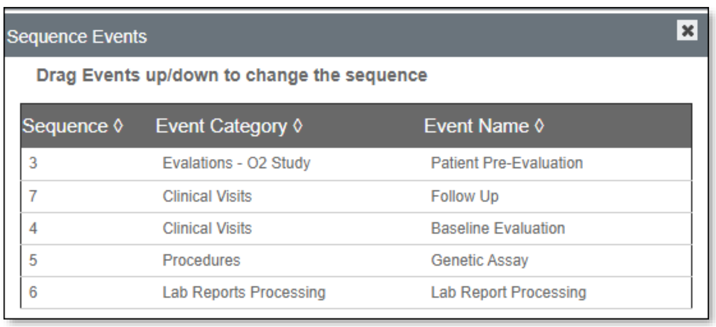
The sequencing panel opens in a new window:



2. Left click on the event you would like to reorder and hold the mouse button while moving it to the position you would like it to be. Release the mouse button to place the event in the new position.



The event sequence now reflects the changes you have made:



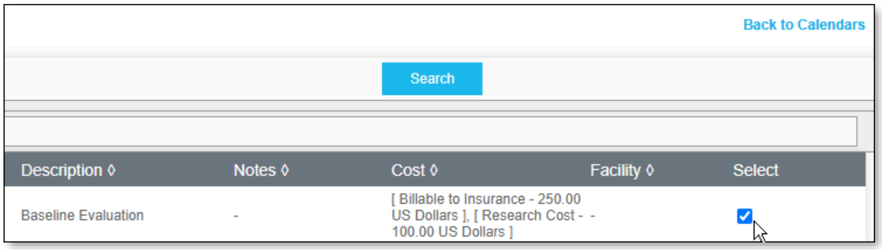
3. Click **Save** to confirm the changes.

6.1.2.3.2.3 Remove Calendar Events

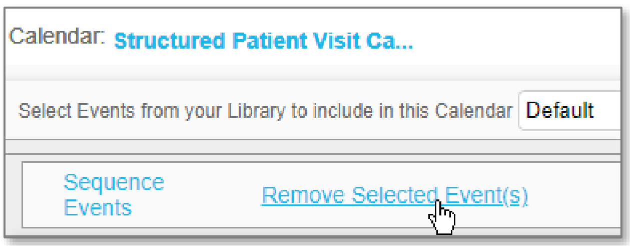
Permissioned users have the ability to remove events from the calendar from the Select Events tab by using the Remove Selected Event(s) link.

To remove events:

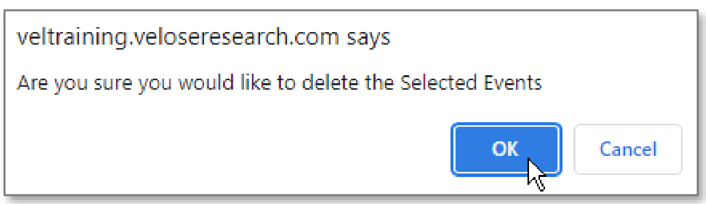
1. Navigate to the Calendar Events page and select the event(s) you would like to remove by clicking on the checkbox in the **Select** column.



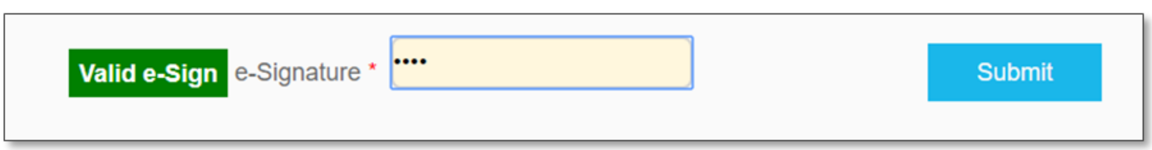
2. Click Remove Selected Event(s).



3. A notification displays, asking you to confirm that you would like to remove the event. Click **OK** to confirm.



4. Enter your e-Signature and click **Submit** to confirm.



The event is removed from the calendar.

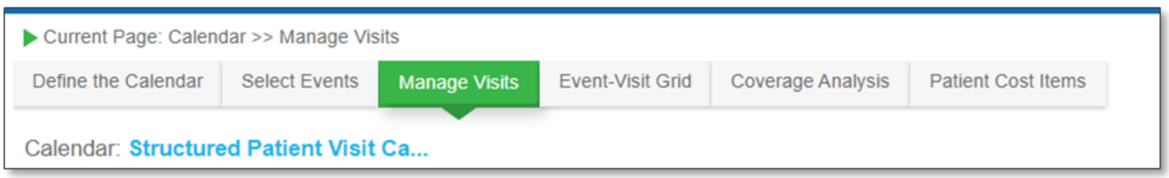
6.1.2.3.3 Manage Visits

In parallel to events, visits are also foundational elements of calendars. Visits create a schedule for when events should take place within the time parameters established by the calendar. Permissioned users can add, modify, or delete visits.

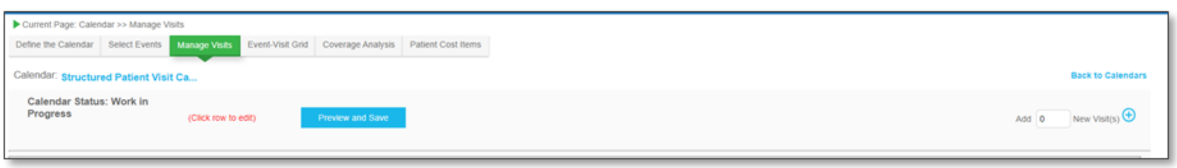
> **Warning:** For events in the library, it is highly recommended to leave Manage Visits undefined. These details are typically study-specific and can be defined when a calendar is associated to a study. See Study Management for more information about adding calendars to a study.

To access the Manage Visits page:

1. Navigate to a specific calendar in the calendar library, and click the **Manage Visits** tab.



The Manage Visits page displays:

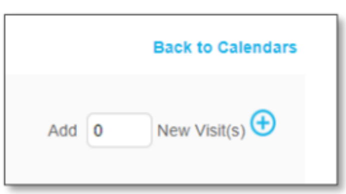


6.1.2.3.3.1 Add New Visits

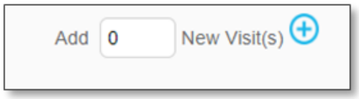
Permissioned users can add visits to a calendar using the Manage Visits tab of a calendar.

To add visits:

1. Navigate to the Manage Visits page and enter the number of new visits you would like to add to this calendar.



2. Click the **Add Visits** button.



6.1.2.3.3.2 Configure Visits

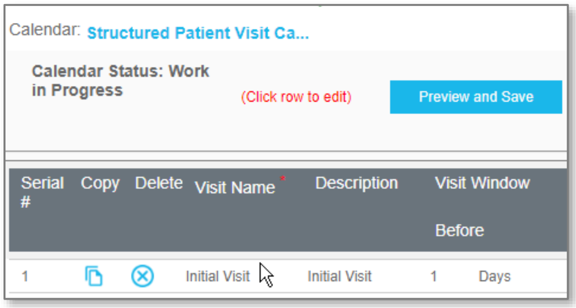
Permissioned users can configure the timing of visits associated with a calendar using the Manage Visits tab of a calendar.

Visits can be configured as per the following type of time points Using each type of time point has a different implication when assigning visits to a calendar:

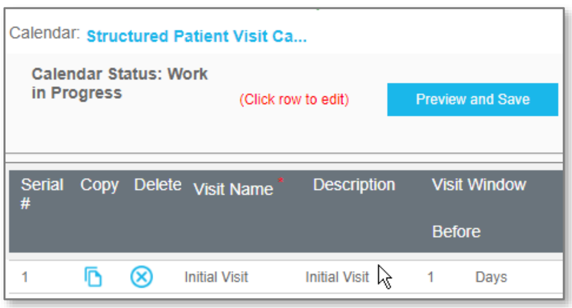
Time Point Type	Description
No Time Point Defined	No Time Point Defined would be selected for visits with no specific dates or dependencies. This may be used when a visit is not mandatory for all patients or when only some patients have certain visits due to treatments.
Fixed Time Point	A fixed time point is a fixed time period in which the visit will occur based on the date on which the calendar starts. For example, a visit needs to occur exactly 25 days after the date in which the calendar starts, or 2 months after the date in which the calendar starts.
Dependent Time Point	A dependent time point visit is a visit that occurs at a determined period of time. These visits are calculated based on a previous selected time point. For example, a dependent visit could be assigned to occur one week after the Baseline Visit. The specific date for this dependent visit will not be finalized until the Baseline visit is completed.

To configure a visit:

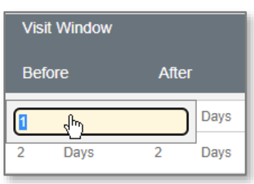
1. Navigate to the Manage Visits page.
2. Click the field under the **Visit Name** column header to add or edit a visit name.



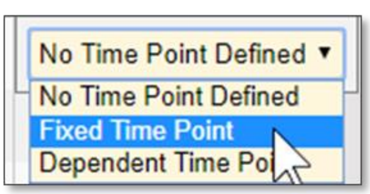
3. Click the field under the **Description** column header to add or edit a visit description.



4. Click the fields under the **Before** and **After** column headers within the **Visit Window** section to add or edit the acceptable time before or after a visit is scheduled to conduct the associated event procedures. See Event-Visit Grid to learn more about setting up the Event Visit Grid.

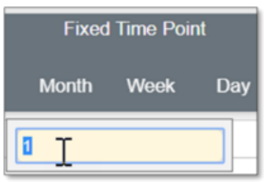


5. Click the field under the **Time Point Type** column header to define this visit as being at a fixed time point (**Fixed Time Point**), or dependent on another visit (**Dependent Time Point**).



Note: If you need to select Dependent Time Point for any visits, click the **Preview and Save** button before proceeding to the next step. If the first visit (row) is set as Fixed Time Point, the Dependent Time Point can be specified for subsequent visits and "Previous Visit" should be selected for the Visit Name. These selections can be done before saving.

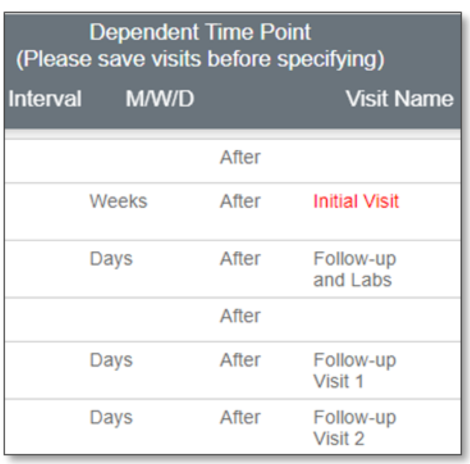
6. If you selected **Fixed Time Point** in step 5, click the fields under the **Month**, **Day** and **Week** column headers as needed to add or edit the visit timing.



-OR-

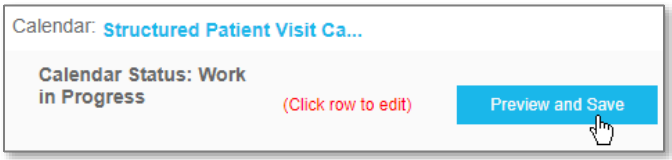
If you selected **Dependent Time Point** in step 5, click the fields under the **Interval** (the number of days, weeks, or months), **M/W/D** (define if the interval is in days, weeks or months), and **Visit Name** columns to add or edit the visit timing and the visit that this visit is dependent upon for scheduling. Within the Visit Name column, select one of the options:

- **Initial Visit** – Visit date calculated based on the initial visit.
- **Visit Not Listed** – Visit date based on an unlisted visit.
- **First Visit** – Visit date calculated based on the first visit in the list.
- **Previous Visit** – Visit date calculated based on the previous visit in the list.

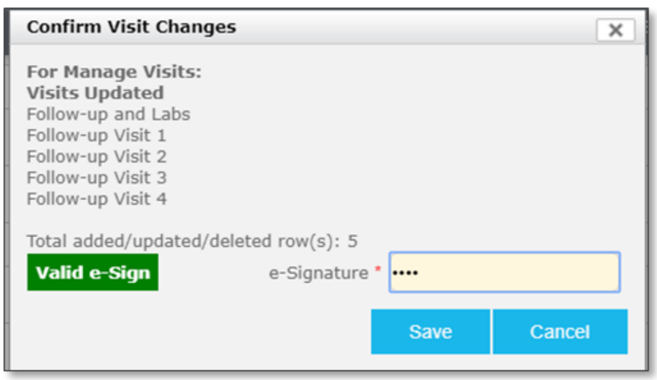


Warning: You must have established your initial visit before you can conditionally link visits to previous visit, initial visit, or first visit.

7. Click Preview and Save.



8. A notification displays in a new window with all recent changes being saved displayed. Enter your e-Signature and click **Save** to save the changes to the calendar.



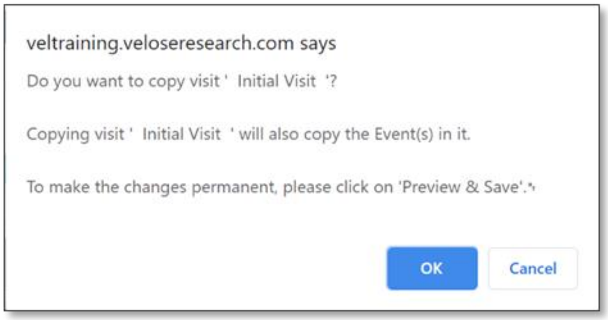
6.1.2.3.3.3 Copy and Delete Visits

Permissioned users can copy and remove visits from a calendar using the Manage Visits tab of a calendar.

To copy visits:

1. Navigate to the Manage Visits page and click the **Copy** button next to the visit you would like to duplicate.

2. A notification displays asking you to confirm that you would like to copy the visit. Click **OK** to proceed.

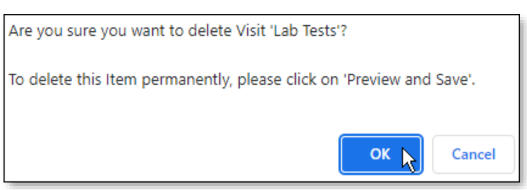


Warning: If you navigate away from this page before clicking **Preview and Save**, all changes to the duplicated visit will be lost.

To delete visits:

1. Navigate to the Manage Visits page and click the **Delete** button next to the visit you would like to delete.

2. A notification panel displays, asking you to confirm that you would like to remove the visit. Click **OK** to confirm.

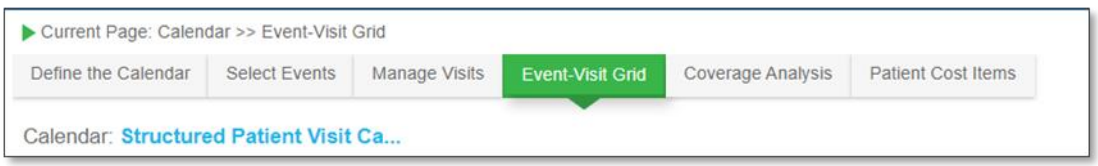


6.1.2.3.4 Event-Visit Grid

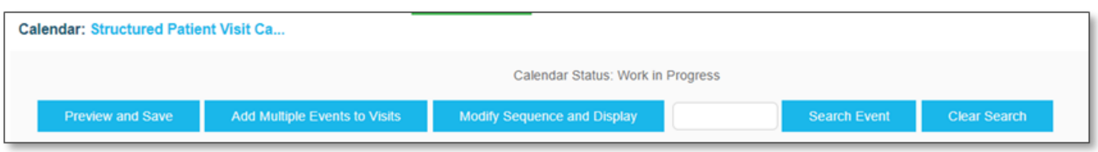
The Event-Visit Grid combines events and visits into a matrix to create a detailed schedule that explains both when a visit should occur, but also which events should take place during those visits. For more information about events, see Event Library. For more information about adding events and visits to calendars, see Manage Calendar Events, and Manage Visits.

Warning: For calendars in the library, it is highly recommended to leave Event-Visit Grid undefined. These details are typically study-specific and can be defined when a calendar is associated to a study. See Study Management for more information about adding calendars to a study.

To access the Event-Visit Grid page: Navigate to a specific calendar in the calendar library, and click the **Event-Visit Grid** tab.



The Event-Visit Grid page displays:



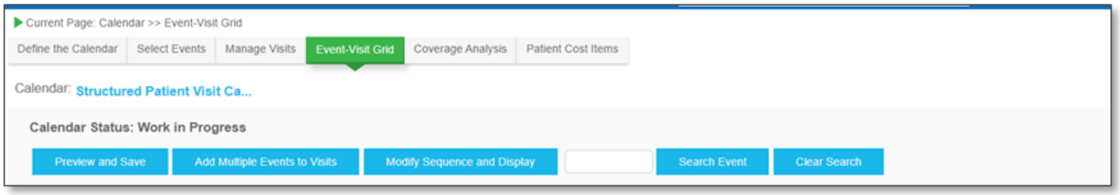
Note: The Event-Visit Grid page should display events in the Event column and Visits across the top of the table. If the page is missing events, please see Manage Calendar Events. If the page is missing visits, please see Manage Visits for more information.

6.1.2.3.4.1 Configure the Event-Visit Grid

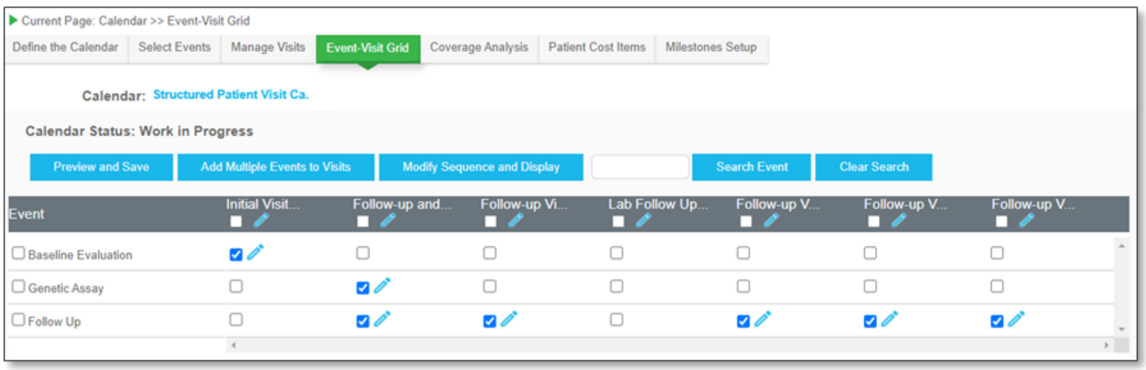
Permissioned users have the ability to define which events occur during each calendar visit on the Event-Visit Grid by using the checkboxes in the grid.

To configure the event-visit grid:

1. Navigate to the Event-Visit Grid of a calendar.

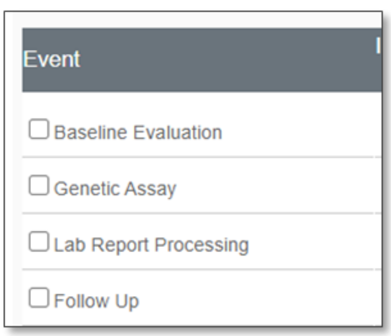


2. Click on the checkbox at the convergence point in the grid to indicate which visits you would like each event to take place.



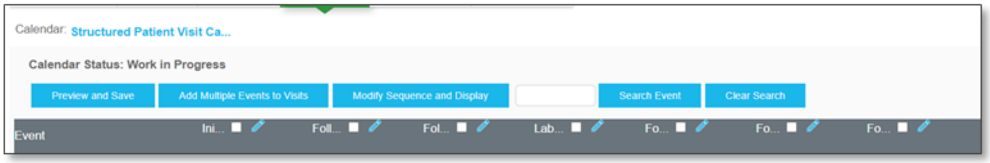
-OR-

Click the checkbox to the left of the event in the **Event** column to apply this event to all visits.

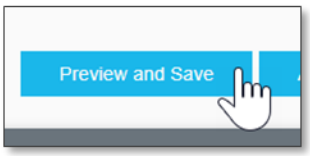


-OR-

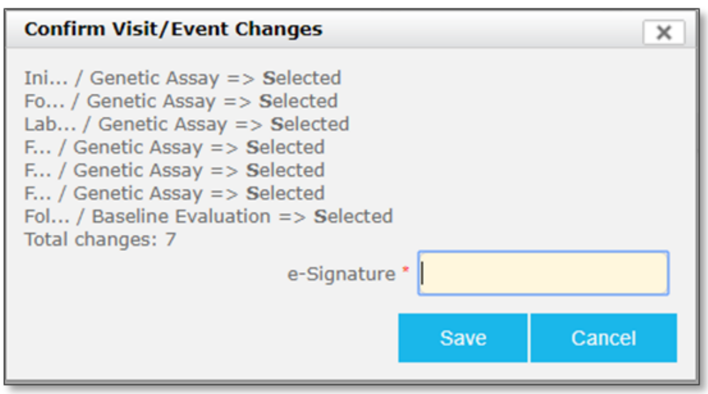
Click the checkbox to the left of the pencil symbol in the header of a visit if you would like to apply all events to one visit.



3. Click Preview and Save.



4. A notification displays asking you to confirm the changes you made. Enter your e-Signature and click **Save** to proceed.



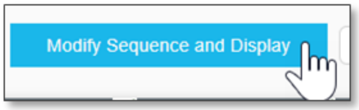
The changes have been saved.

6.1.2.3.4.2 Modify Sequence and Display

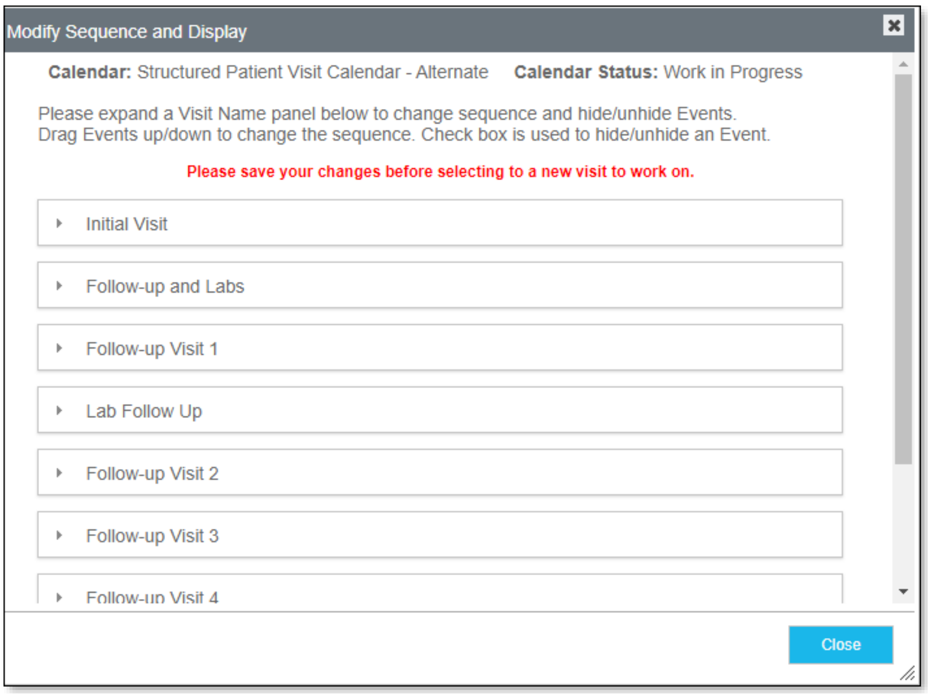
Permissioned users have the ability to change the order of events on the Event-Visit Grid tab by using the Modify Sequence and Display button. This sequence of events will define the order and sequencing of events in a visit when patient schedules are generated.

To change the sequence:

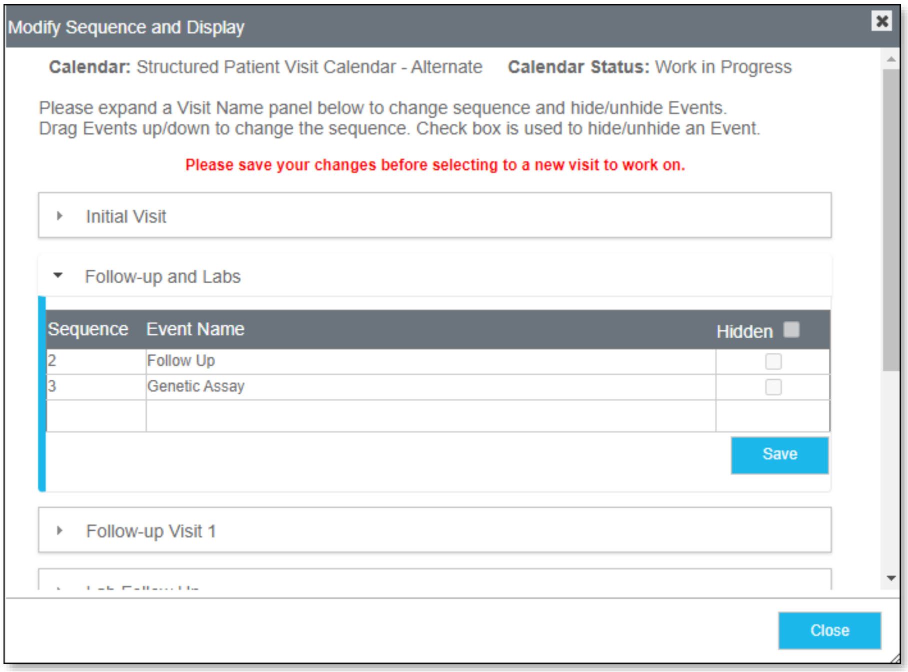
1. Navigate to the Event-Visit Grid page and click **Modify Sequence and Display**.



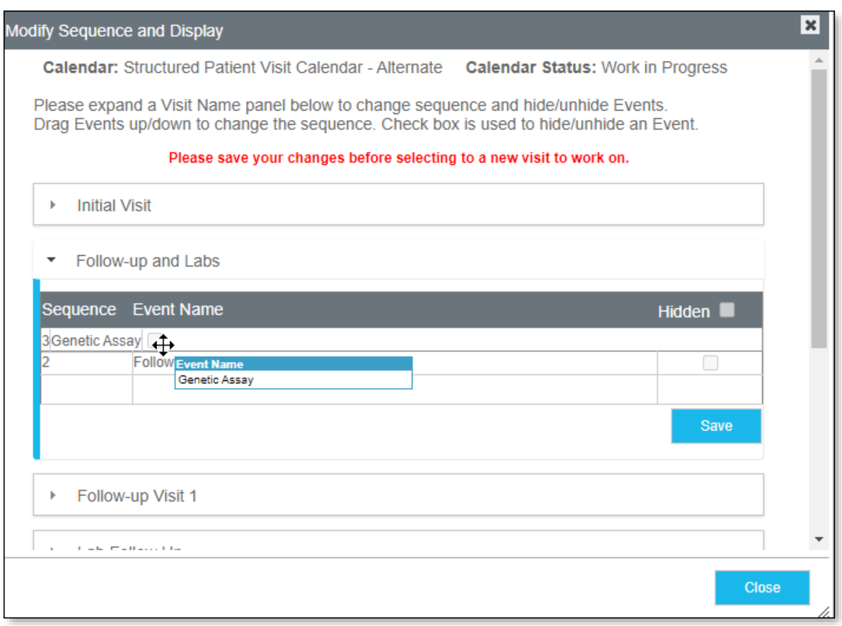
The sequencing panel opens in a new window:



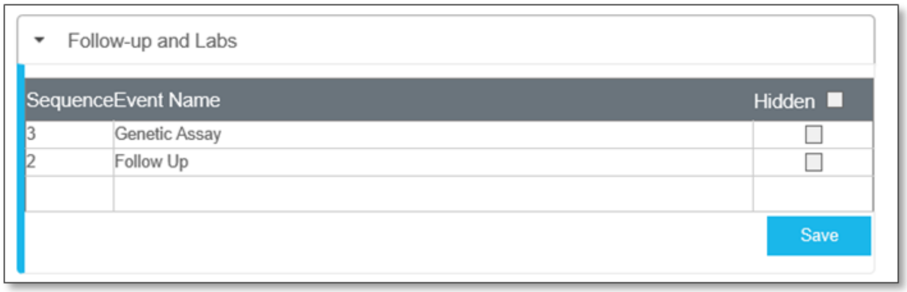
2. Click on the visit that you would like to edit to expand the menu and make the events within visible.



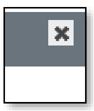
3. Left click on the event you would like to reorder and hold the mouse button while moving it to the position you would like it to be. Release the mouse button to place the event in the new position.



The event sequence now reflects the changes you have made:



4. Click **Save** to confirm the changes.
5. Click the **Close** button to return focus to the Event-Visit Grid page.

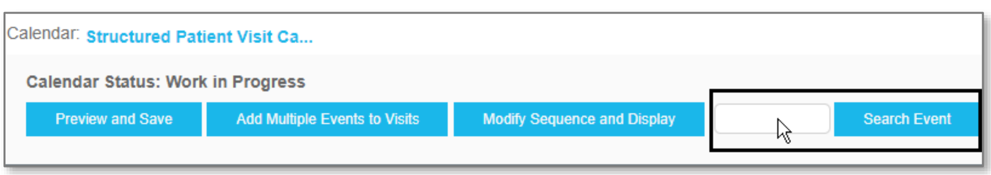


6.1.2.3.4.3 Search Event

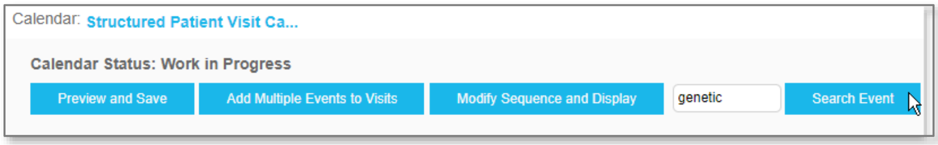
The Event-Visit Grid page provides permissioned users the ability to search the event-visit grid for specific events. This is helpful if you have added a significant number of events to the calendar and need to use the filter to find a specific event in a timely fashion.

To search the event-visit grid for a specific event:

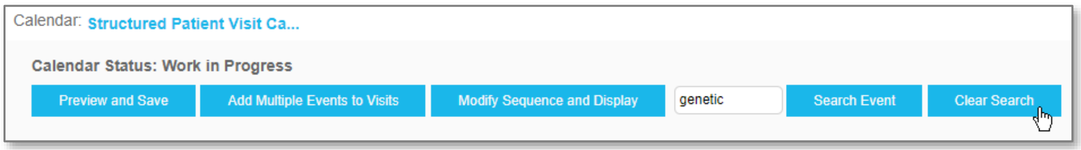
1. Navigate to the Event-Visit Grid of a calendar.
2. Enter your search criteria in the search field at the top of the page and click **Search Event**.



The Event-Visit Grid will filter the events displayed in the grid based on your search criteria:



3. Click **Clear Search** to remove the filter and return to the default view.

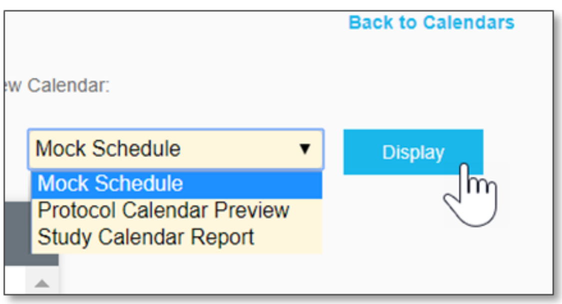


6.1.2.3.4.4 Display Schedule

After the calendar events, visits, and event-visit grid are configured, permissioned users have the ability to pull a mock schedule, protocol calendar, and study calendar report on the Event-Visit Grid.

To display a schedule, protocol calendar, or study calendar report:

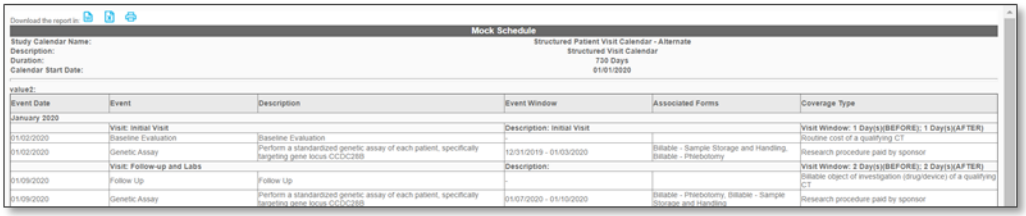
1. Navigate to the Event-Visit Grid page and select one of the options from the drop-down menu on the right-hand side of the screen and click **Display**.



The targeted report will display in a new window or tab.

Note: Please see examples and short descriptions of each report type below.

Mock Schedule – Creates a mock patient schedule assuming study start on the 1st day of the year.



Download the report in:

Mock Schedule

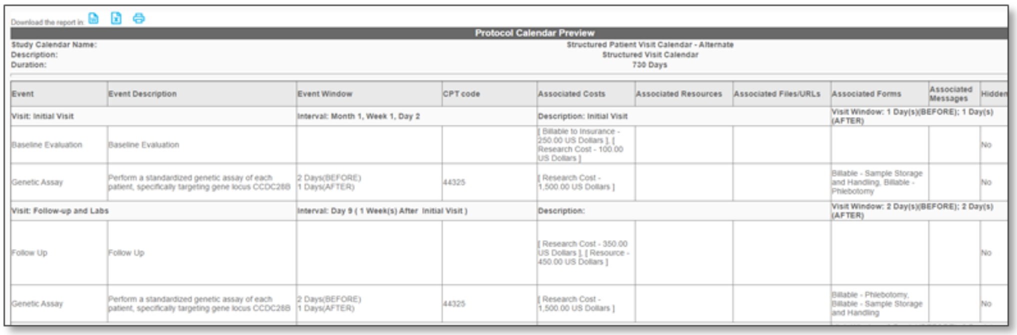
Study Calendar Name:	Structured Patient Visit Calendar - Alternate
Description:	Structured Visit Calendar
Duration:	730 Days
Calendar Start Date:	01/01/2020

value2:

Event Date	Event	Description	Event Window	Associated Forms	Coverage Type
January 2020					
	Visit: Initial Visit		Description: Initial Visit		Visit Window: 1 Day(s)(BEFORE); 1 Day(s)(AFTER)
01/02/2020	Baseline Evaluation	Baseline Evaluation	-		Routine cost of a qualifying CT
01/02/2020	Genetic Assay	Perform a standardized genetic assay of each patient, specifically targeting gene locus CCDC28B	12/31/2019 - 01/03/2020	Billable - Sample Storage and Handling, Billable - Phlebotomy	Research procedure paid by sponsor
	Visit: Follow-up and Labs		Description:		Visit Window: 2 Day(s)(BEFORE); 2 Day(s)(AFTER)
01/09/2020	Follow Up	Follow Up	-		Billable object of investigation (drug/device) of a qualifying CT
01/09/2020	Genetic Assay	Perform a standardized genetic assay of each patient, specifically targeting gene locus CCDC28B	01/07/2020 - 01/10/2020	Billable - Phlebotomy, Billable - Sample Storage and Handling	Research procedure paid by sponsor

Note: The mock schedule is not a real schedule. Scheduled can be pulled from the study calendar once a calendar is associated with a study. For more information about associating calendars with a study, see Study Management.

Protocol Calendar Preview – Displays an overview of the visits, events, costs, and other important study information about this calendar.



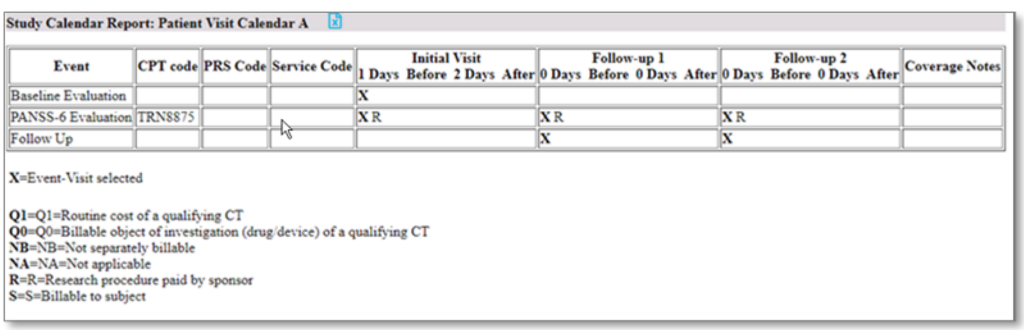
Download the report in:

Protocol Calendar Preview

Study Calendar Name:	Structured Patient Visit Calendar - Alternate
Description:	Structured Visit Calendar
Duration:	730 Days

Event	Event Description	Event Window	CPT code	Associated Costs	Associated Resources	Associated Files/URLs	Associated Forms	Associated Messages	Hidden
Visit: Initial Visit		Interval: Month 1, Week 1, Day 2		Description: Initial Visit			Visit Window: 1 Day(s)(BEFORE); 1 Day(s)(AFTER)		
Baseline Evaluation	Baseline Evaluation			[Billable to Insurance - 250.00 US Dollars], [Research Cost - 100.00 US Dollars]					No
Genetic Assay	Perform a standardized genetic assay of each patient, specifically targeting gene locus CCDC28B	2 Days(BEFORE) 1 Days(AFTER)	44325	[Research Cost - 1,500.00 US Dollars]			Billable - Sample Storage and Handling, Billable - Phlebotomy		No
Visit: Follow-up and Labs		Interval: Day 9 (1 Week(s) After Initial Visit)		Description:			Visit Window: 2 Day(s)(BEFORE); 2 Day(s)(AFTER)		
Follow Up	Follow Up			[Research Cost - 350.00 US Dollars], [Resource - 450.00 US Dollars]					No
Genetic Assay	Perform a standardized genetic assay of each patient, specifically targeting gene locus CCDC28B	2 Days(BEFORE) 1 Days(AFTER)	44325	[Research Cost - 1,500.00 US Dollars]			Billable - Phlebotomy, Billable - Sample Storage and Handling		No

Study Calendar Report – Provides a report of the event-visit grid combined with coverage analysis. For more information on coverage analysis, see Coverage Analysis.



Study Calendar Report: Patient Visit Calendar A

Event	CPT code	PRS Code	Service Code	Initial Visit 1 Days Before 2 Days After	Follow-up 1 0 Days Before 0 Days After	Follow-up 2 0 Days Before 0 Days After	Coverage Notes
Baseline Evaluation				X			
PANSS-6 Evaluation	TRN8875			X R	X R	X R	
Follow Up					X	X	

X=Event-Visit selected

Q1=Q1=Routine cost of a qualifying CT
Q0=Q0=Billable object of investigation (drug/device) of a qualifying CT
NB=NB=Not separately billable
NA=NA=Not applicable
R=R=Research procedure paid by sponsor
S=S=Billable to subject

6.1.2.3.5 Coverage Analysis

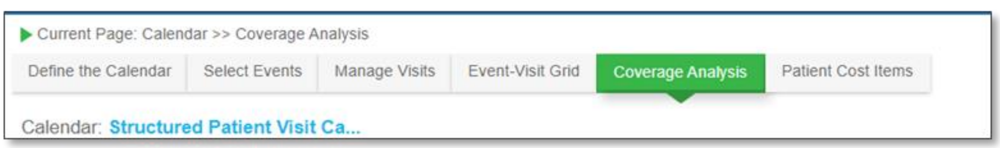
The Coverage Analysis page provides permissioned users the ability to code coverage types to events. The table below provides a description of the available coverage codes and their meaning:

Coverage Code	Description
Q1	Routine cost of a qualifying clinical trial.
Q0	Billable object of investigation (drug/device) of a qualifying clinical trial.
NB	Not separately billable.
NA	Not applicable.
R	Research procedure paid by sponsor
S	Billable to subject

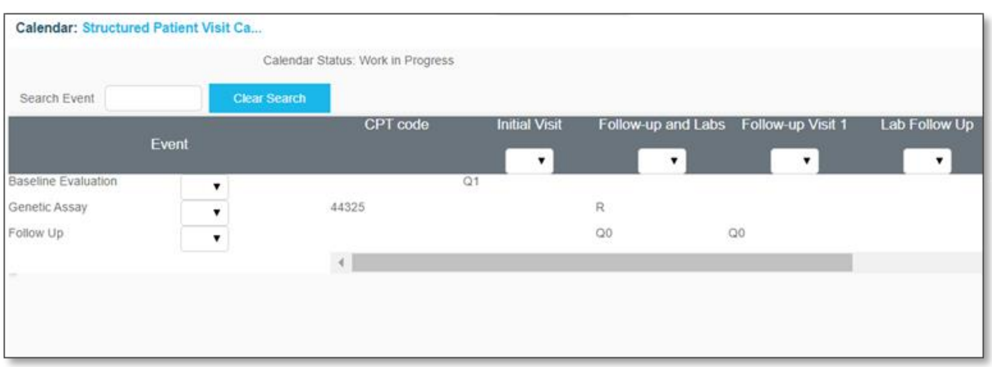
Warning: For calendars in the library, it is highly recommended to leave Coverage Analysis undefined. These details are typically study-specific and can be defined when a calendar is associated to a study. See Study Management for more information about adding calendars to a study.

To access the Coverage Analysis page:

1. Navigate to a specific calendar in the calendar library, and click the **Coverage Analysis** tab.



The Coverage Analysis page displays:



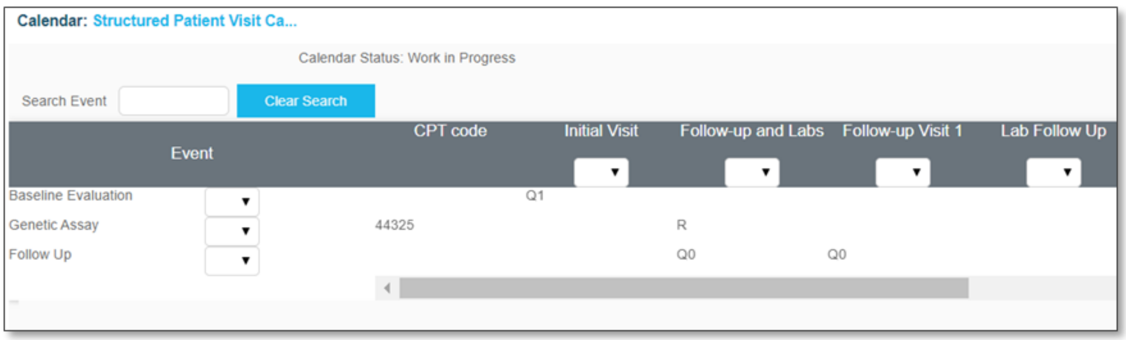
Note: If the page is missing events, please see Manage Calendar Events. If the page is missing visits, please see Manage Visits for more information.

6.1.2.3.5.1 Configure the Coverage Analysis

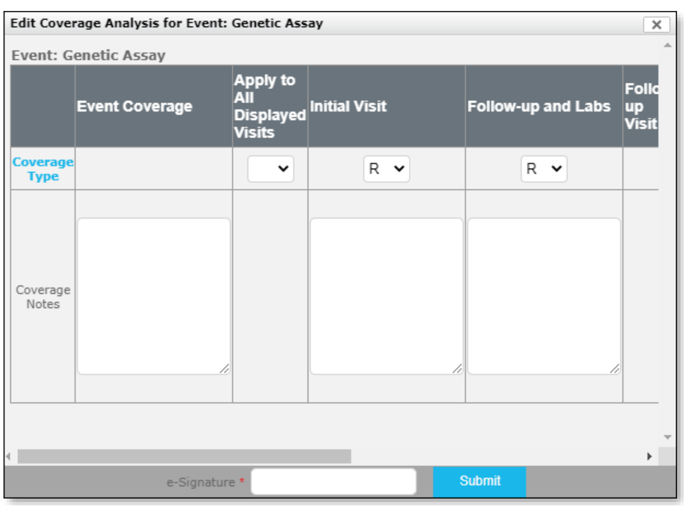
Permissioned users can configure the Coverage Analysis page by applying coverage codes to each event within an event-visit grid.

To configure the Coverage Analysis page:

1. Navigate to the Coverage Analysis page of a calendar.

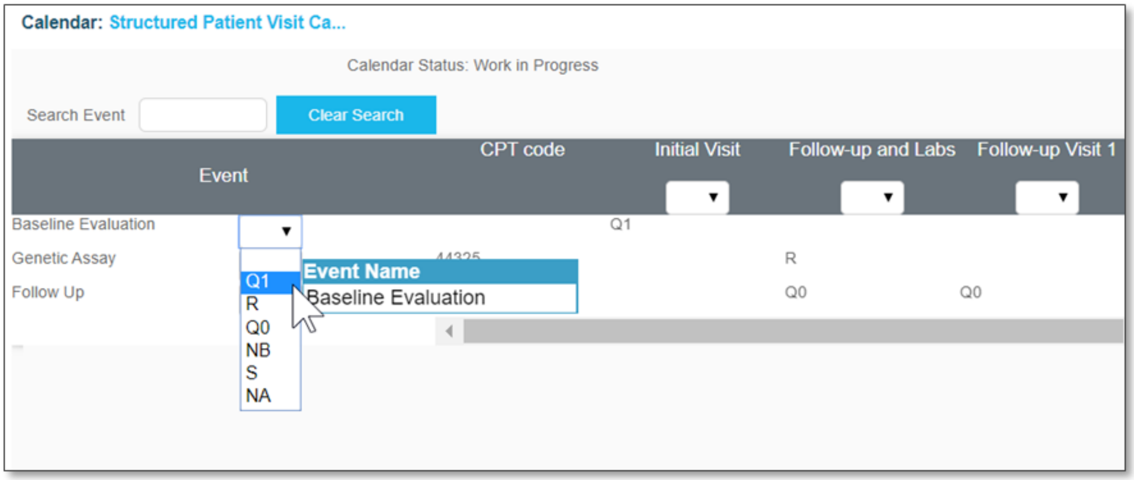


2. Click directly on any grid square at the convergence of an event and a visit and select a coverage code from the window that displays.



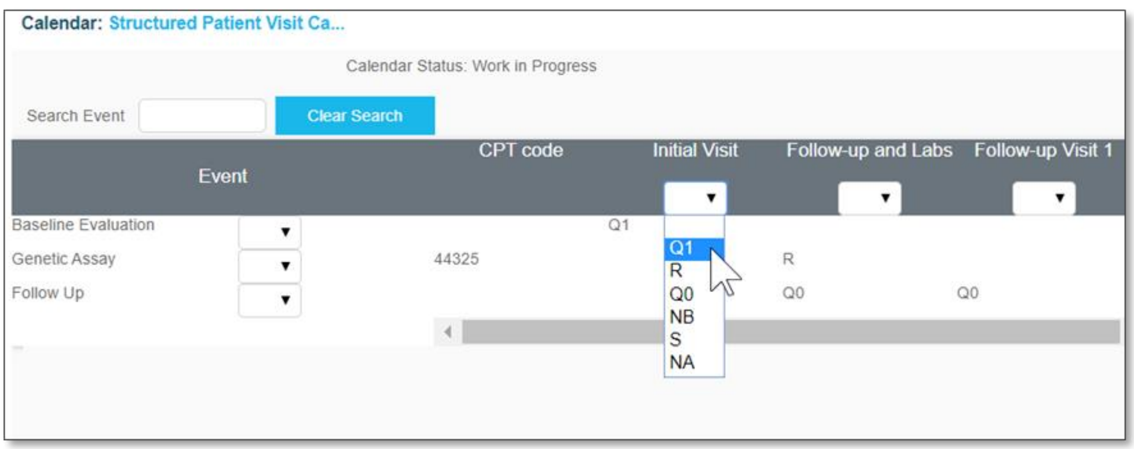
-OR-

Click on the drop-down menu to the right of the event in the **Event** column to apply this code to each instance of this event across all visits.

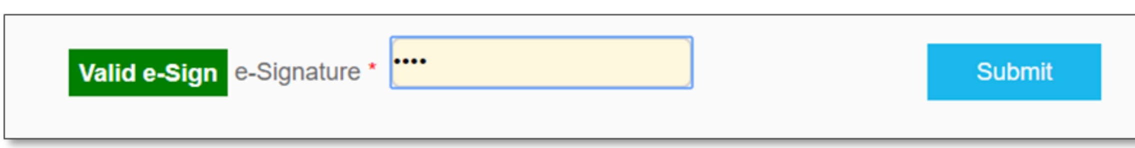


-OR-

Click the drop-down menu to the right of the visit name if you would like to apply one code to all events in one visit.

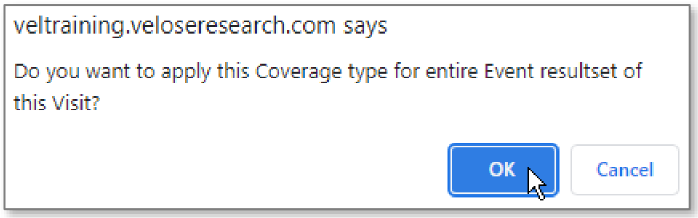


3. Enter your e-Signature and click **Submit** to confirm if you changed the coverage code by clicking directly on any event-visit intersection.



-OR-

Click **OK** on the notification that displays if you used the visit or event drop-down menus to apply a coverage code to multiple points.



The coverage codes have been updated.

Note: Ensure that any events that have an X next to a visit have been applied coverage codes. This will make certain that the coverage type for each event is clear.

6.1.2.3.5.2 Export Coverage Analysis

Velos eResearch provides a means to export the coverage analysis for any calendar. Permissioned users can export to either a printable page (for clearer printing), a Microsoft Word document, or a Microsoft Excel spreadsheet.

To export the coverage analysis of a calendar:

1. Navigate to the Coverage Analysis page of a calendar.
2. Click directly on one of the Export to: buttons located on the right side of the Coverage Analysis page.

Icon	Name	Description
	Print	Opens the page in a more printable version.
	Export to Excel	Exports the coverage analysis to a Microsoft Excel spreadsheet.
	Export to Word	Exports the coverage analysis to a Microsoft Word document.

6.1.2.3.6 Patient Cost Items

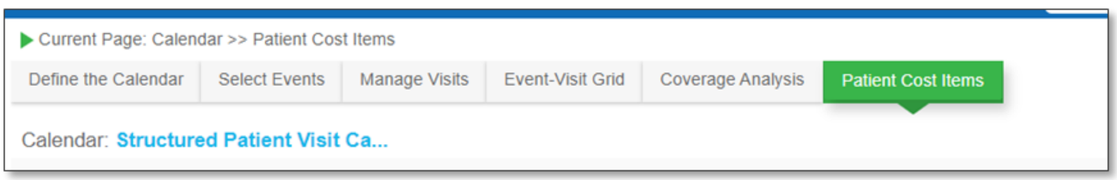
The Velos eResearch Enterprise version provides a means to define patient costs for specific calendar visits. This information will then cascade into the calendar budget template during financial management setup.

Enterprise Only: The Patient Cost Items functionality is only available in the Velos eResearch Enterprise platform.

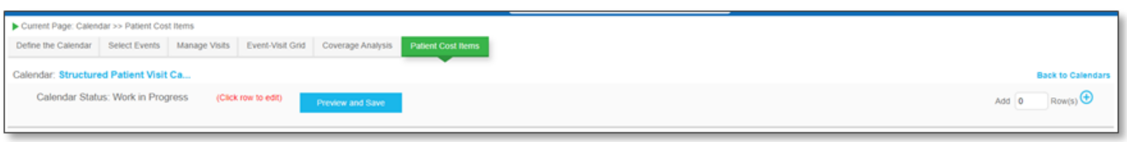
Warning: For calendars in the library, it is highly recommended to leave Patient Cost Items tab undefined. These details are typically study-specific and can be defined when a calendar is associated to a study. See Study Management for more information about adding calendars to a study.

To access the Patient Cost Items page:

1. Navigate to a specific calendar in the calendar library, and click the **Patient Cost Items** tab.



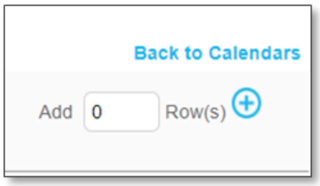
The Patient Cost Items page displays:



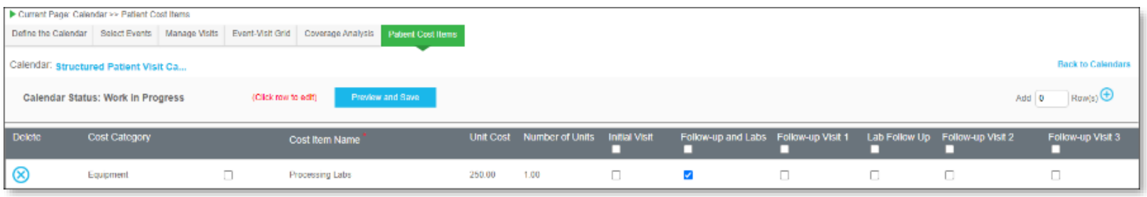
6.1.2.3.6.1 Add Patient Cost Items

To add patient cost items:

1. Navigate to the Patient Cost Items page and enter the number of new items you would like to add to this calendar by entering a number in the rows field and clicking the **Add** button.

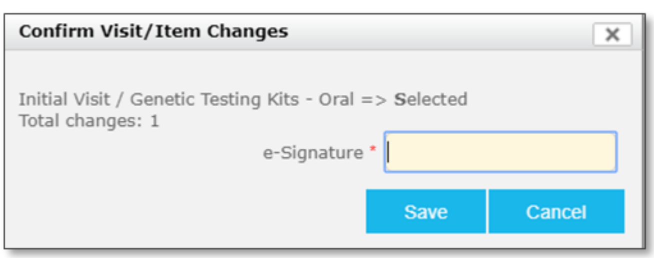


The new patient cost item entries are now displayed:



2. Configure each cost item by defining the cost category, entering a name, the unit cost, the number of units, and to which visits the cost item should be associated.
3. Click Preview and Save.

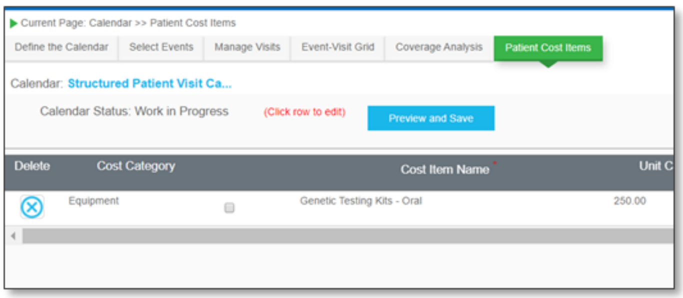
4. A notification displays in a new window with all recent changes being saved displayed. Enter your e-Signature and click **Save** to save the changes to the cost item.



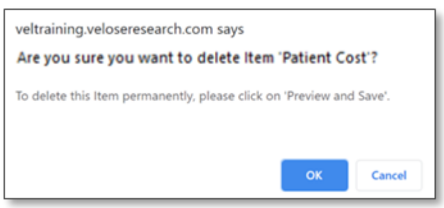
6.1.2.3.6.2 Remove Patient Cost Items

To remove patient cost items:

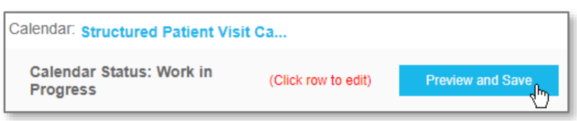
1. Navigate to the **Patient Cost Items** page and click the **Delete** button next to the item you would like to delete.



2. A notification panel displays, asking you to confirm that you would like to remove the item. Click **OK** to confirm.



3. Click Preview and Save.



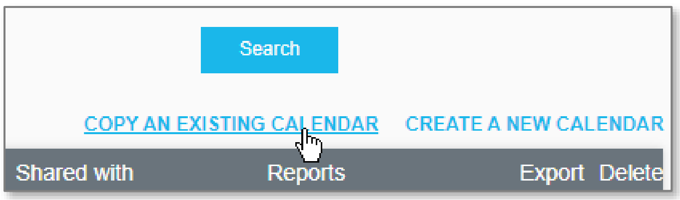
4. A notification displays in a new window with all recent changes being saved displayed. Enter your e-Signature and click **Save** to permanently remove the cost item.

6.1.2.4 Copy a Calendar

Velos eResearch offers a means to copy an existing calendar and make modifications to the copy using the Copy an Existing Calendar link on the Calendar Library page, or the Copy button within the Libraries menu.

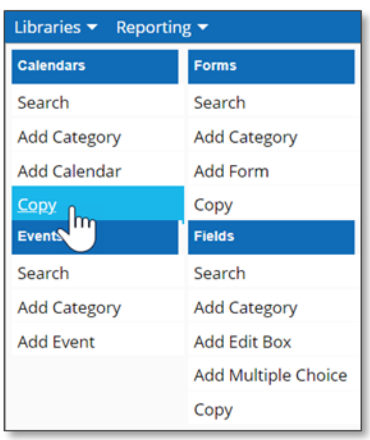
To copy an existing calendar:

1. Navigate to the calendar library and click **Copy an Existing Calendar** in the upper-left hand corner of the screen.

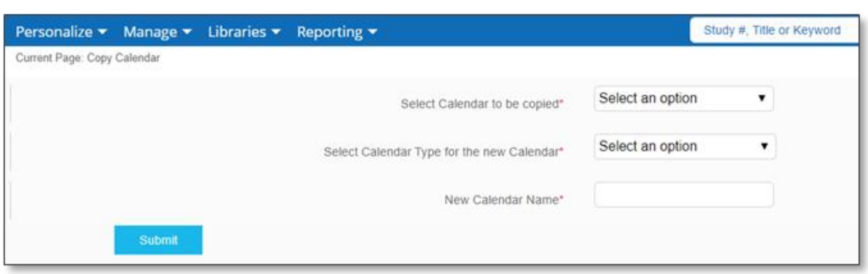


-OR-

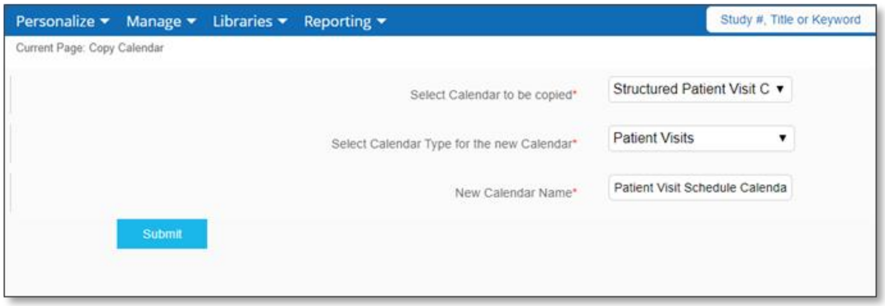
Click the **Libraries** menu in the upper-left hand corner of the screen, and select **Copy** under the heading Calendars.



The Copy Calendar page displays:



2. Select the calendar to be copied and the calendar type for the new calendar, enter a unique calendar name, and then click **Submit** to confirm.



The selected calendar has been copied to the calendar library, and may need to be configured further, as needed. For more information on how to manage calendars see Add and Manage Calendars.

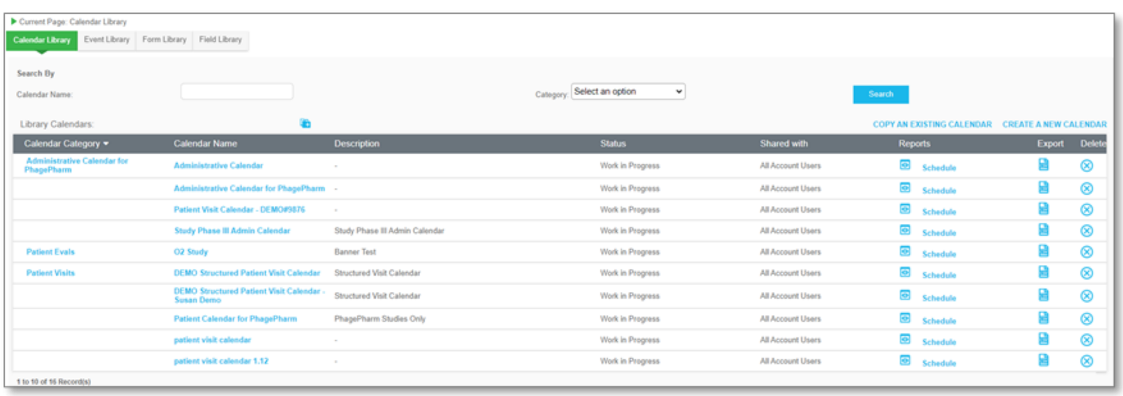
6.1.2.5 Remove a Calendar

Permissioned users can remove calendars from the Calendar Library as needed.

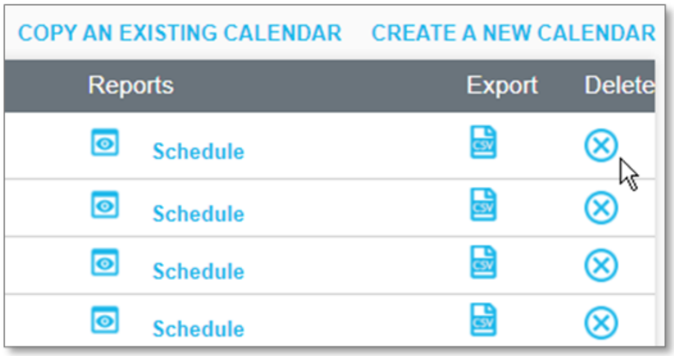
> **Note:** Removing a calendar template from the library that has already been associated with one or more studies will not affect the study calendars in use. It will only remove the template from the library.

To remove a calendar:

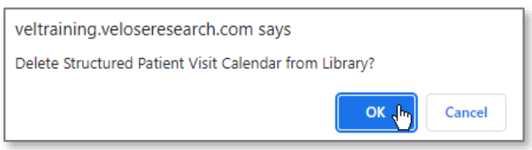
1. Navigate to the Calendar Library, and search for the target calendar. For more information about searching the Calendar Library, see Search the Calendar Library.



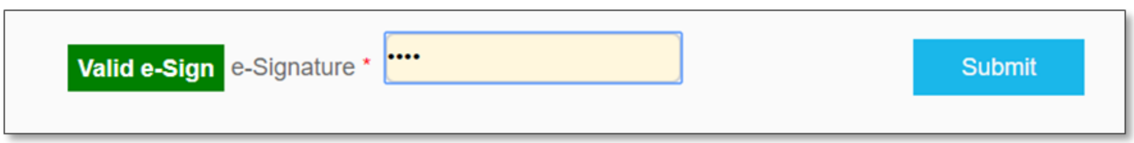
2. Click the **Delete** button located at the right side of the page for the calendar that you would like to delete.



3. A notification displays asking you to confirm if you would like to delete the calendar. Click **OK** to delete the calendar.



4. Enter your e-Signature and click **Submit** to confirm.



The calendar is deleted from the **Calendar Library**.

6.2 Forms Management

Forms are data-entry points for key study, patient, and administrative functions. Additionally, forms can be designed to capture extra information that is not already entered into the system in an organized matter. Before creating forms, however, fields must be established. Forms are essentially an organized collection of fields. Fields are the granular points of data entry, such as text fields and multiple-choice fields.

See the diagram below for a visual representation of the basic relationship forms and fields share:

In Velos eResearch Enterprise, study monitors and/or anyone with study monitoring responsibilities can review and comment on form response findings using the Dashboard tool. This can be used to ensure data integrity, and that procedures are being followed for form response on a study.

Enterprise Only:	The Dashboard tool is only available in the Velos eResearch Enterprise platform.

6.2.1 Field Library

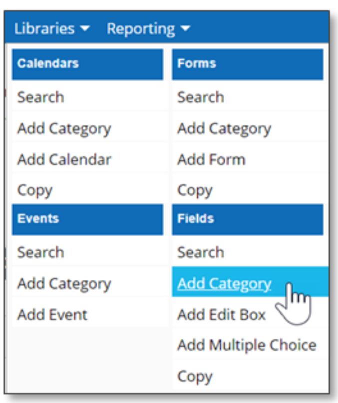
Fields are the granular points of data entry, such as text fields and multiple-choice fields that make up forms. Before creating forms, it is necessary to first create fields. As with the other libraries in Velos eResearch, when you create a field in the Field Library, you are creating a template for use and modification across forms. Altering the copy of the field added directly to a form will not affect the template stored in the library.

6.2.1.1 Add a Field Category

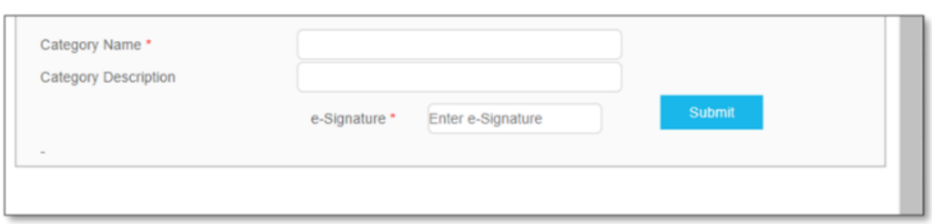
Within Velos eResearch, fields can be organized by category. Before creating a field, at least one field category must first be established. For example, you may organize your fields by specific types of data to be collected such as Date Fields, Demographics, or Medical History.

To add a field category:

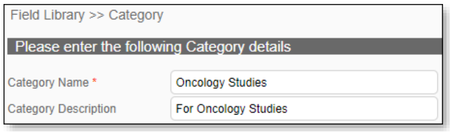
1. Click the **Libraries** menu in the upper-left hand corner of the screen and select **Add Category** under the heading "Fields".



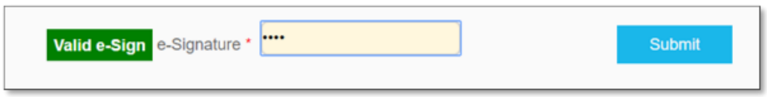
A new window opens, displaying the Field Category page:



2. Enter the **Category Name** and **Description** in the available fields.



3. After filling in the required information, enter your e-Signature and click **Submit** to confirm.



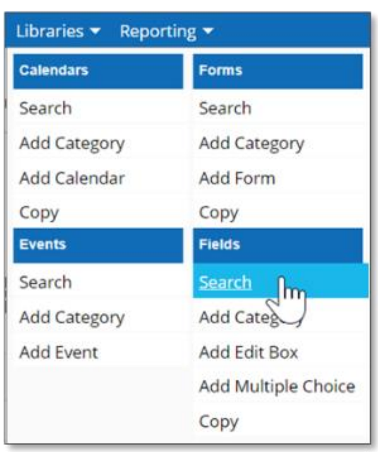
The field category has been saved.

6.2.1.2 Search the Field Library

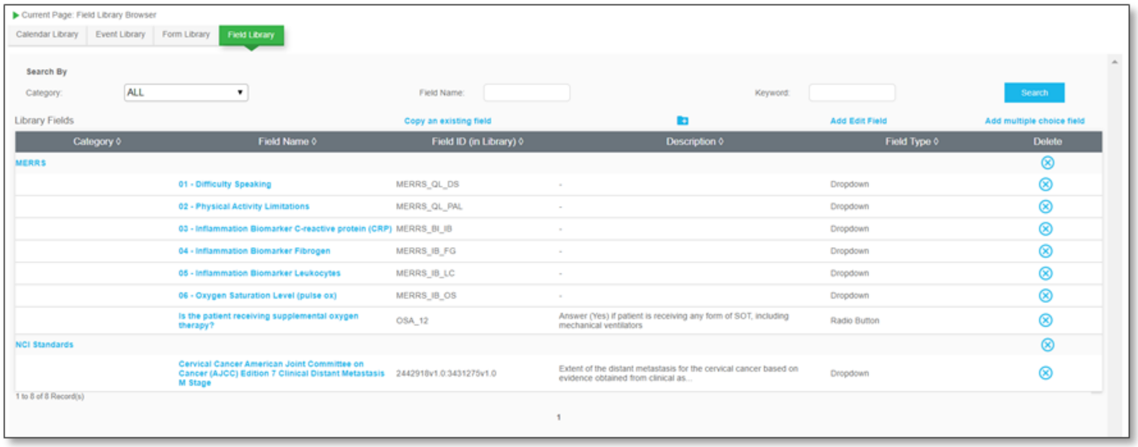
Before adding a new field, you should search the field library to see if there is a similar field or the field already exists. If there is a similar field, you could save time by copying a field and making minor modifications instead of building one from the start. To learn more about copying a field, see Copy a Field.

To search the field library:

1. Click the **Libraries** menu in the upper-left hand corner of the screen and select **Search** under the heading “Fields”.

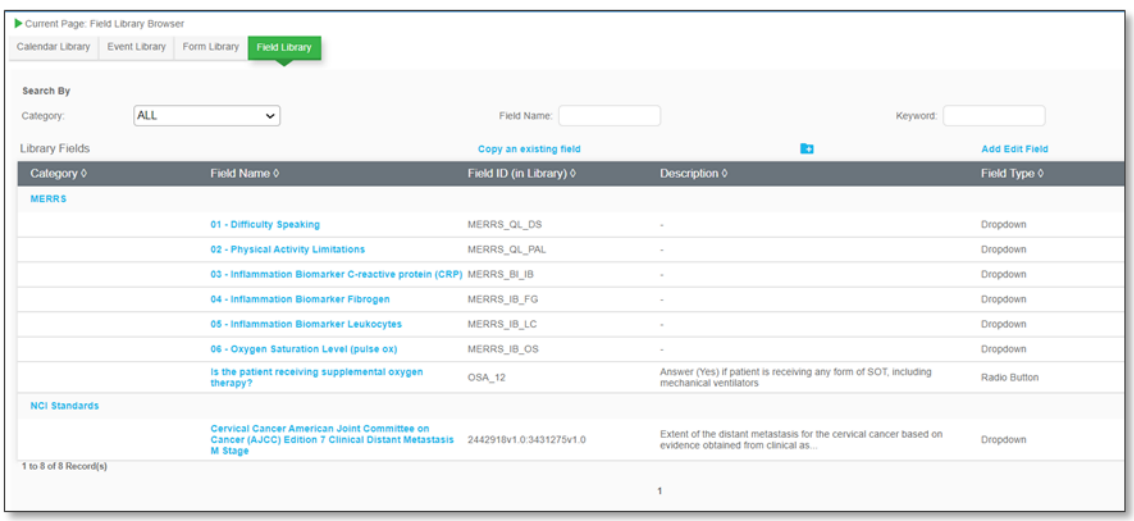


The Field Library displays:



2. Enter your search criteria in the available fields within the **Search By** section of the page and click **Search**.

The search results display at the bottom of the page in the Library Fields section:



6.2.1.3 Add and Manage Fields

Two types of fields can be created within the Field Library: Edit Fields and Multi Choice Fields. Each field has sub-types that determines how data is entered. Two additional field types, Lookup and Comment Fields, can only be created directly within a form, and not in the Field Library.

See the table below for detailed descriptions of each type of field and sub-type.

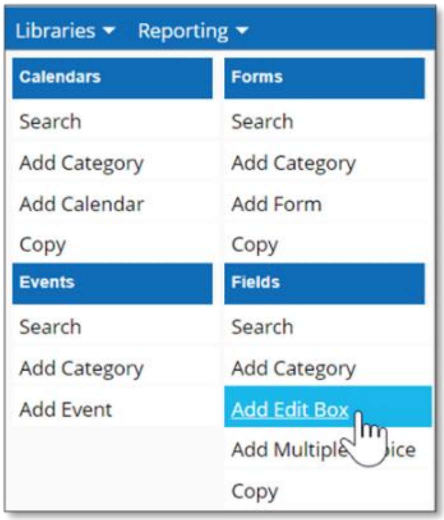
Field Type	Sub-type	Description
Edit Field	**Text**	Field that accepts alpha-numeric characters.
	Number	Field that accepts numbers only.
	Date	Field that only allows specific dates to be entered.
Multi Choice	**Drop-down**	Creates a drop-down menu with selection options.
	Checkbox	Creates a multiple-choice question that allows users to check multiple answers using checkboxes.
	Radio Button	Creates a multiple-choice question that allows users to select one of a selection of responses using radio buttons.

6.2.1.3.1 Add an Edit Field

Edit fields are open fields that allow end-users to enter data into the form. Depending on the sub-type of edit field, it may be text, numerical, or date data. See Add and Manage Fields for more information on subtypes. If a required edit field does not already exist in the Field Library, permissioned users can add new edit fields using the Libraries menu.

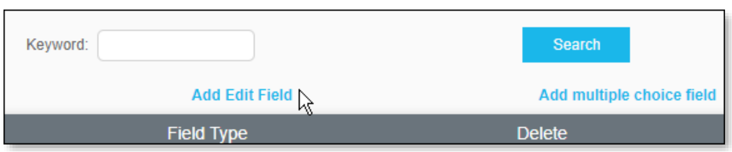
To add a new edit field:

1. Click the **Libraries** menu in the upper-left hand corner of the screen and select the **Add Edit Box** under the heading “Fields”.

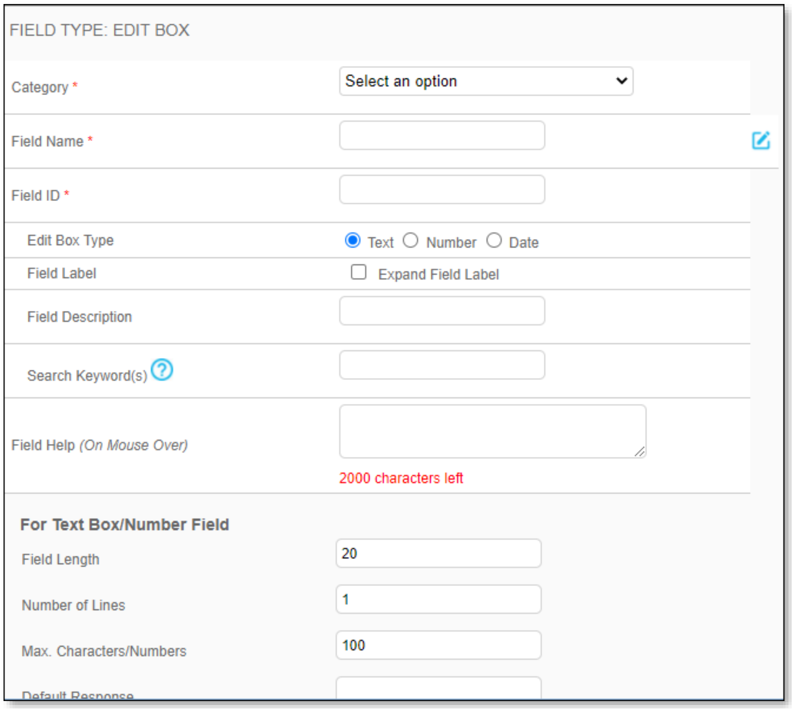


-OR-

From the Field Library page, click **Add Edit Field** on the right side of the screen.



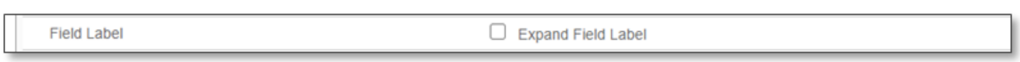
The Edit Box editor displays in a new window:



2. Select the field category, name, a unique ID, and Edit Box Type. See **[Add and Manage Fields]** for more information about edit box types.

Note: Field ID values cannot contain any spaces and must be unique.

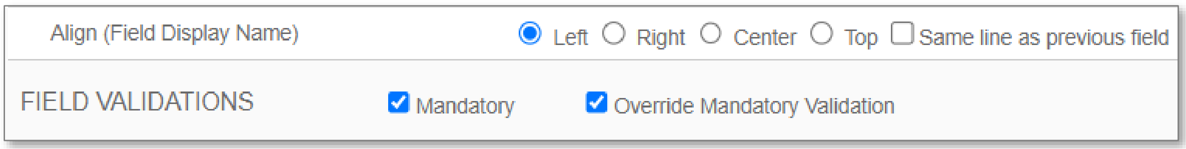
3. Continue down the page. Determine if the field label should expand automatically based on its contents by selecting or skipping the **Expand Field Label** checkbox.



4. Continue down the page. Enter a **Field Description**, **Search Keywords**, and **Field Help** message. The field help message displays a notification when the user hovers their mouse over the field.

Note: Search keywords aid user searches by associating these keywords with the field to improve search results in the Field Library. Separate keywords by a comma.

5. For edit fields on forms, the next two fields will appear. They do not appear in edit fields added to the library. For the Align field, select Left, Right, Center, or Top for the alignment of the field name to be displayed. Check the checkbox if the field name should be on the same line as the previous field.



6. For FIELD VALIDATIONS: check the Mandatory checkbox, if the field is mandatory to be completed, or, check both the Mandatory and Override Mandatory Validation checkboxes if the field is mandatory to be completed but may be initially skipped.
   - If the Override checkbox is checked, but the Mandatory checkbox is not checked, a warning pop-up will appear not allowing for submission of the field entry
   - There are times when a user may not have the mandatory data when filling out the form. The override box will allow the user to submit the form, but the user will be prompted for a reason why the data is not entered in the mandatory field.
   - A field with both options checked will appear with both a red and a grey asterisk

   - If any validation has 'override' field checked, the system will generate a query for data management activities

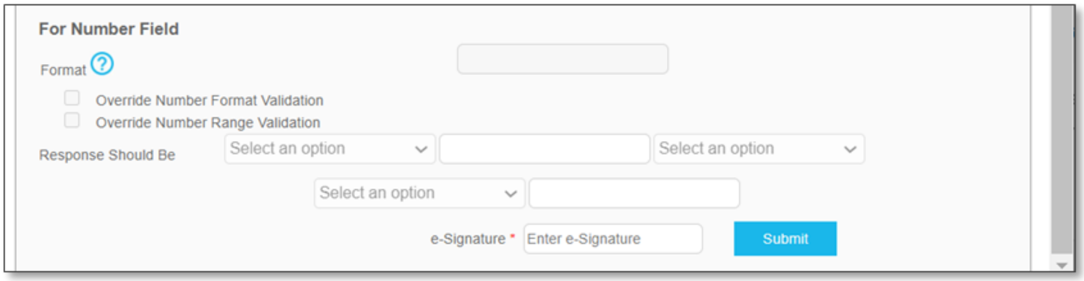
7. Continue down the page. If required, enter field length, number of lines, max characters allowed and a default response in the available fields. The default response auto-populates a value in the field.

Note: Field length determines how wide the field is relative to characters that can fit in the field. Number of lines determines how many lines the field occupies, and Max Characters/Numbers determines the maximum number of characters that can be entered into the field.

8. If the edit field is a date sub-type, make the appropriate selections in the **For Date Field** section.

Note: The available options in For Date Field allow you to constrain the data to past dates (Date cannot be a future date), allow custom date formats (Override Date Validation), and to default the field value to the current date (Default date to current date).

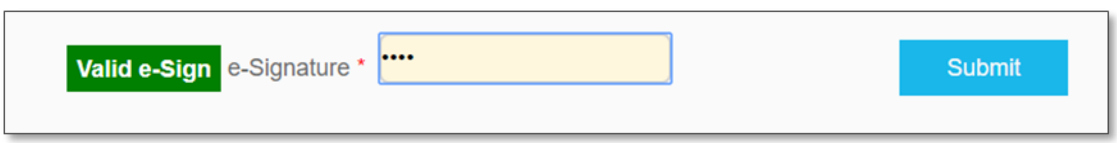
9. If the edit field is a number sub-type, make the appropriate selections in the **For Number Field** section. This section allows you to constrain the format, override validation and number ranges (this is best configured when adding a field to a form), and to set number range parameters.



Note:

1. The For Number Field section allows you to determine format by using "#" to represent a number and "." to represent a decimal. This will constrain the format of the number entered by users.
2. Check the checkbox next to *Override Number Format Validation* to allow the data entry user to enter the number they need to, regardless of the format, and provide a reason if the format is different than what was specified.
3. Check the checkbox next *to Override Number Range Validation* to allow the data entry user to enter the number they need to, regardless of the range, and provide a reason if the range is different than what was specified. A query will be generated for data management activities

Enter your e-Signature and click **Submit** to confirm.



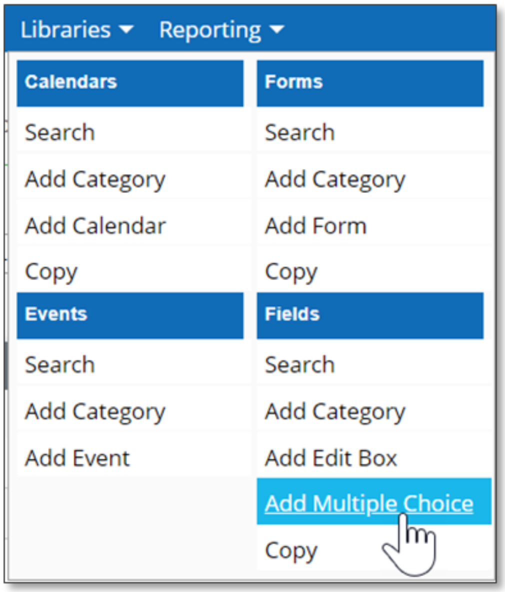
The field is saved in the field library.

6.2.1.3.2 Add a Multi Choice Field

Multi Choice fields are multiple choice fields that allow end-users to enter data into the form by selecting from a pre-determined set of responses. Depending on the sub-type of multi choice field, the response(s) may be gathered using checkboxes, a drop-down menu, or radio buttons. See Add and Manage Fields for more information on subtypes. If a required multi choice field does not already exist in the **Field Library**, permissioned users can add new fields using the Libraries menu.

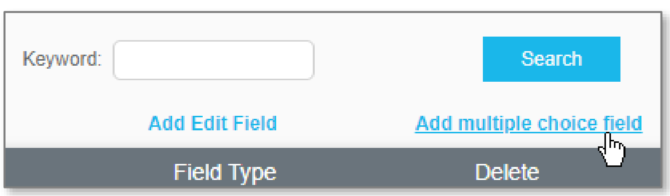
To add a new multi choice field:

1. Click the **Libraries** menu in the upper-left hand corner of the screen and select the **Add Multiple Choice** Box under the heading "Fields".

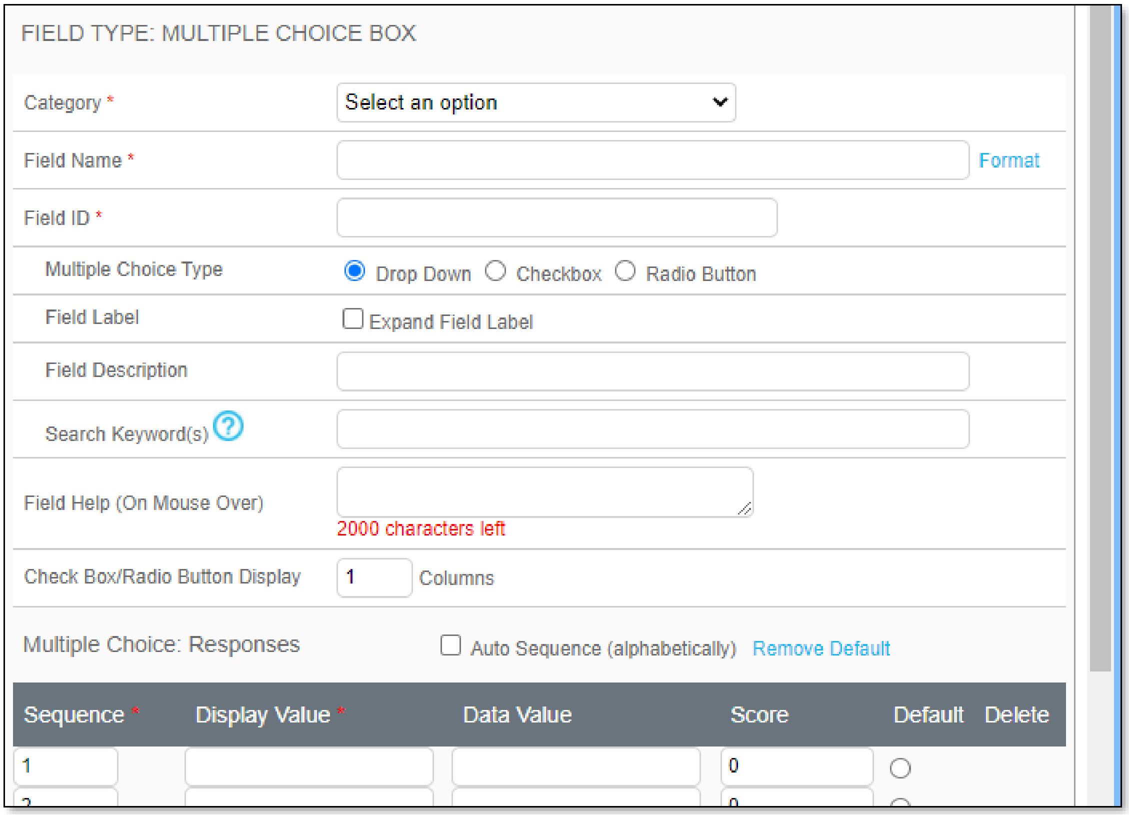


-OR-

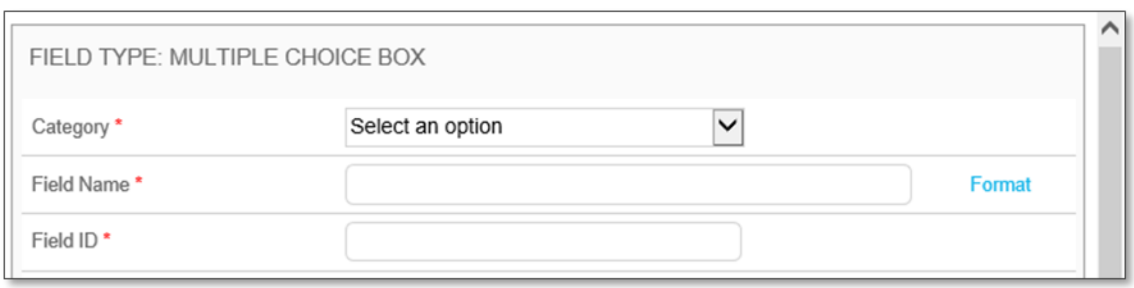
From the Field Library page, click **Add multiple choice field** on the right side of the screen.



The Multiple Choice Box editor displays in a new window:



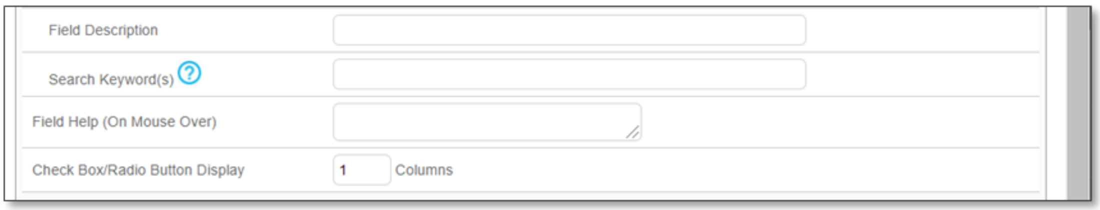
2. Select the field category, name, a unique ID, and Multi Choice type. See the Add and Manage Fields section for more information about Multi Choice types.



Note: Velos eResearch provides a means to apply formatting to the field name. To do so, click the Format link to the right of the Field Name field. The formatting options include bold, italics, underline, change of font style, size and color, setting text alignment, and more.

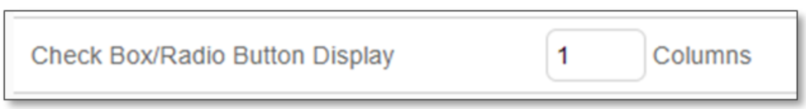
3. Continue down the page. Determine if the field label should be expanded by selecting or skipping the **Expand Field Label** checkbox.

4. Continue down the page. Enter a **Field Description**, **Search Keywords**, and **Field Help** message. The field help message displays a notification when the user places their mouse over the field.

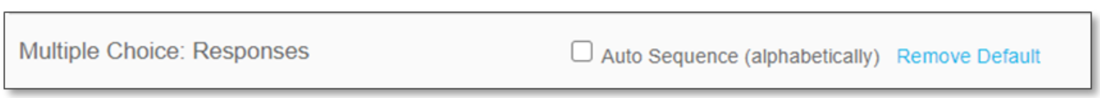


Note: Search keywords aid user searches by associating these keywords with the field to improve search results in the Field Library. Separate keywords by a comma.

5. Continue down the page. If required, modify the number of columns that checkboxes or radio buttons occupy. This does not apply to the drop-down subtype of multiple-choice field.

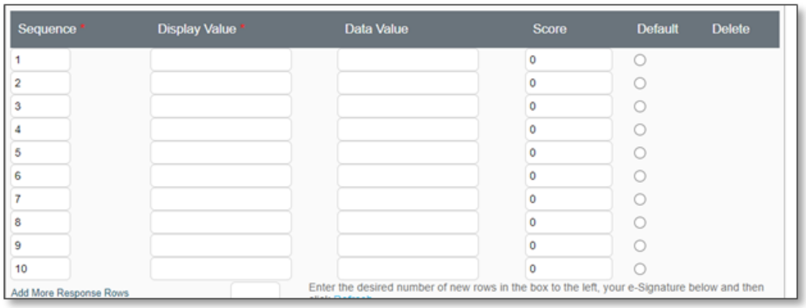


6. Continue down the page. If required, enable auto sequencing by response label.



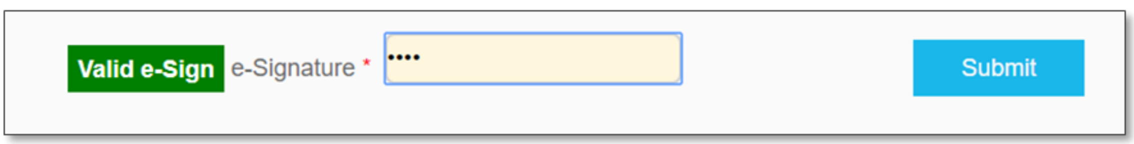
Note: The auto sequence feature sequences the responses alphabetically.

7. Continue down the page. Add the response values in the available fields. Edit **Sequence** (order) of the responses using the Sequence column on the left. You can optionally select a default value for the field by clicking the radio button on the right next to the target value.



Note: 1. If you require more than 10 rows for responses in this field, enter the number of additional rows in the Add More Response Rows field and click the Refresh link.
2. Display value text should not exceed 250 characters or have apostrophes.

8. Enter your e-Signature and click **Submit** to confirm.



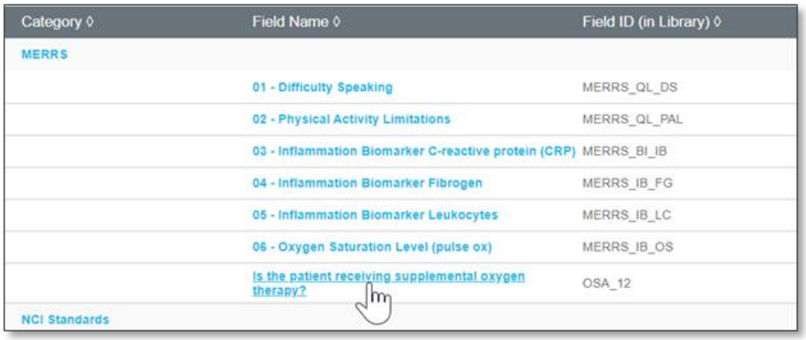
The field is saved in the field library.

6.2.1.3.3 Edit a field

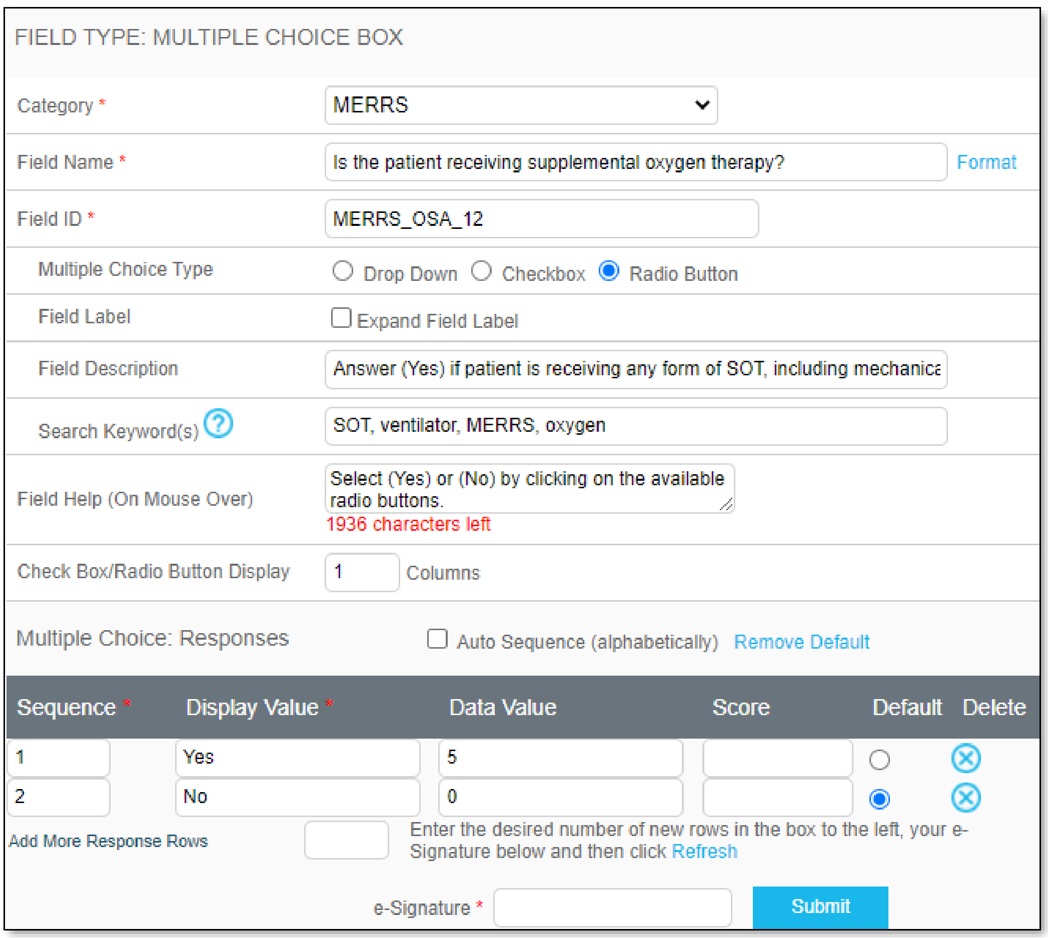
Permissioned users have the ability to edit fields within the Field Library page.

To edit a field in the field library:

1. Navigate to the Field Library page and click directly on the **Field Name** link to modify a field.

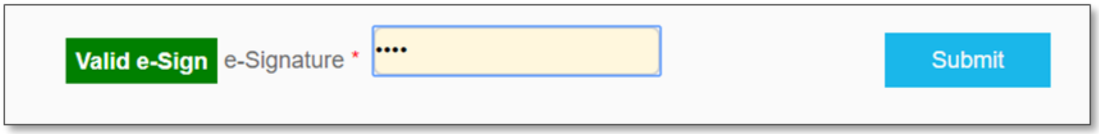


The Field Type page displays in a new window:



2. Make changes to the available fields as required.

3. Enter your e-Signature and click **Submit** to confirm.

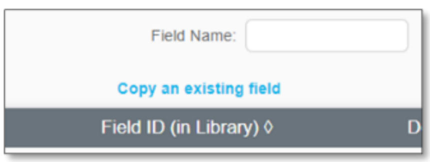


6.2.1.4 Copy a Field

Velos eResearch offers a means to copy an existing field and make modifications to the copy using the Copy an Existing Field link on the Field Library page, or the Copy button within the Libraries menu.

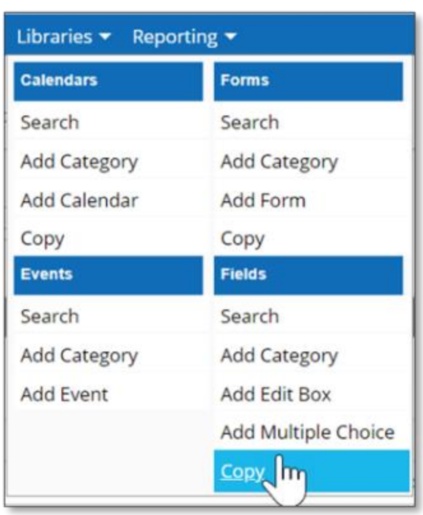
To copy an existing field:

1. Navigate to the field library and click on **Copy an Existing Field** in the upper-left hand corner of the screen.

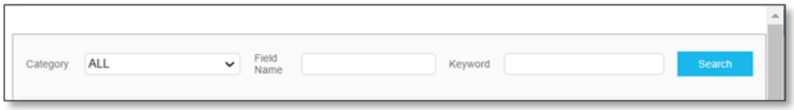


-OR-

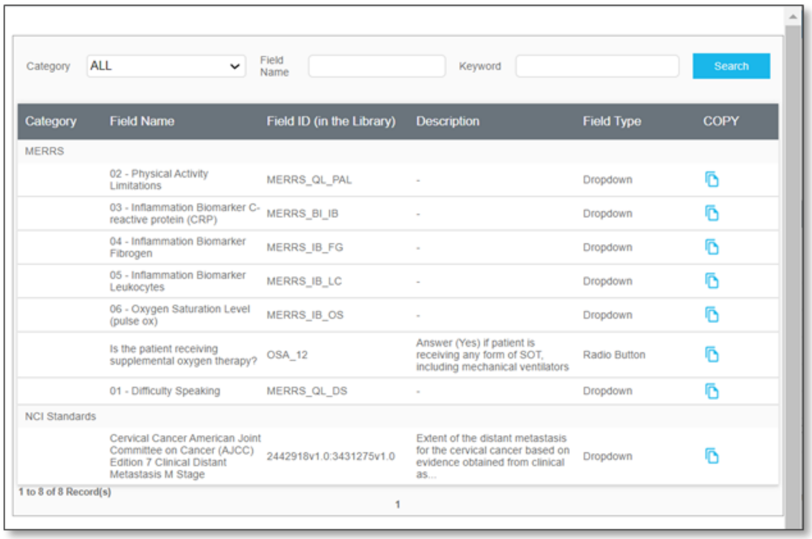
Click the **Libraries** menu in the upper-left hand corner of the screen, and select **Copy** under the heading "Fields".



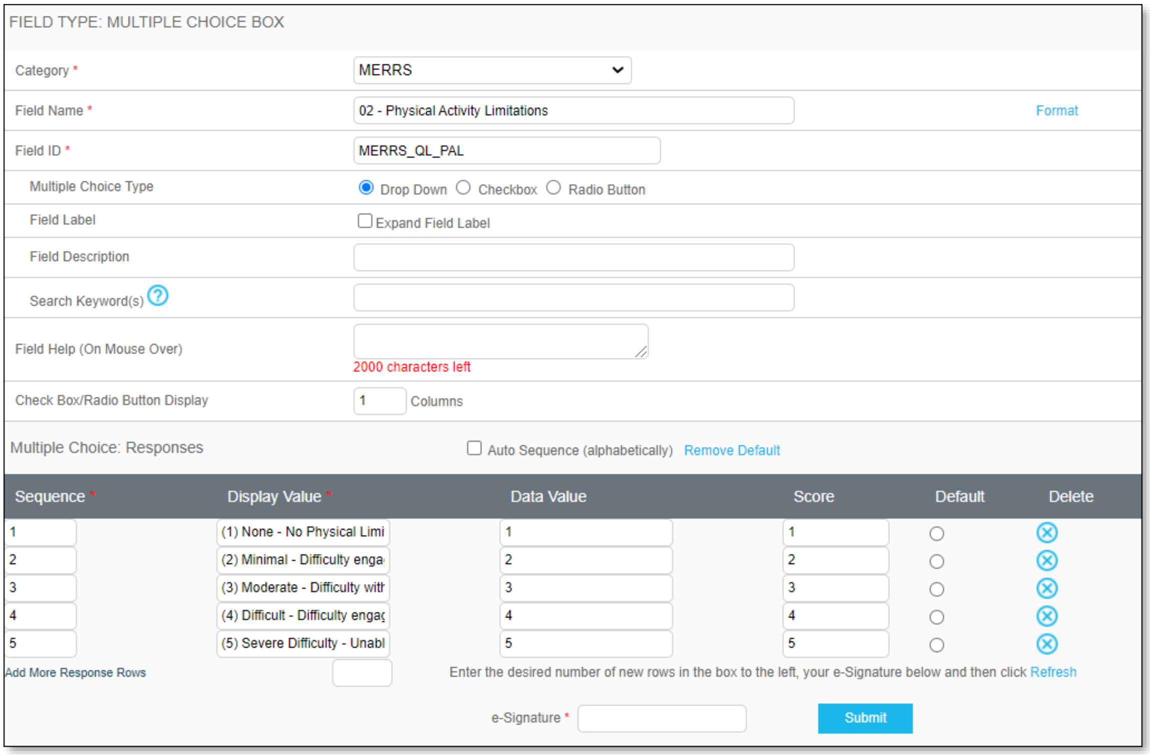
The Copy Field page displays:



2. Click the **Copy** button on the right side of the Copy Field page.



3. The Edit Field page displays. Configure the copied field as needed, enter your e-Signature, and click **Submit** to confirm. For more information about configuring fields, see the Field Library.

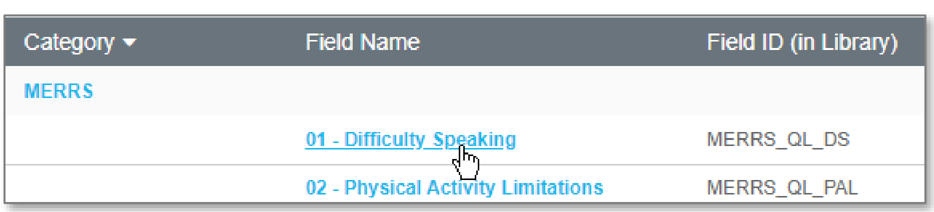


6.2.1.5 Remove a Field

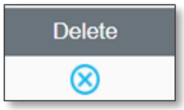
Permissioned users can remove fields from the Field Library as needed. Before removing a field, ensure it is not currently being used in an active study form.

To remove a field:

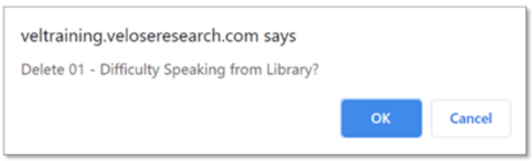
1. Navigate to the Field Library, and search for the target field. For more information about searching the Field Library, see the Search the Field Library section.



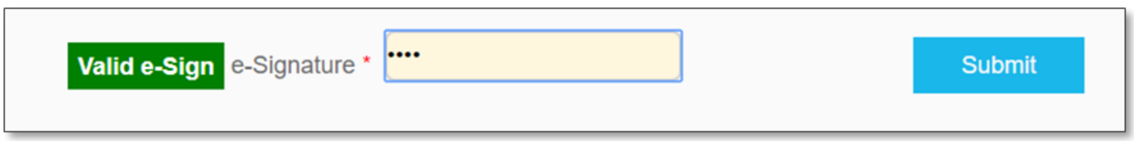
2. Click on the **Delete** button located at the right side of the page for the field that you would like to delete.



3. A notification displays asking you to confirm if you would like to delete the field. Click **OK** to delete the field.



4. Enter your e-Signature and click **Submit** to confirm.



The field is deleted from the **Field Library**.

6.2.2 Form Library

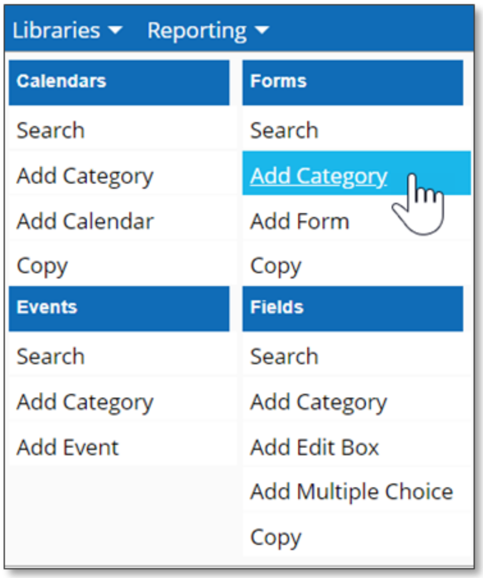
Forms are the fundamental data collection tool in Velos eResearch. In order to create a form, it is necessary to first create fields. See the Field Library for more information on creating library fields. As with the other libraries in Velos eResearch, when you create a form in the Form Library, you are creating a template for use and modification across forms. Altering the copy of the field added directly to a form will not affect the template stored in the library.

6.2.2.1 Add a Form Category

Within Velos eResearch, forms can be organized by category. Before creating a form, at least one form category must first be established. For example, you may organize your forms by specific types of data to be collected such as Patient Intake, Medical History, or Protocol-Specific forms.

To add a form category:

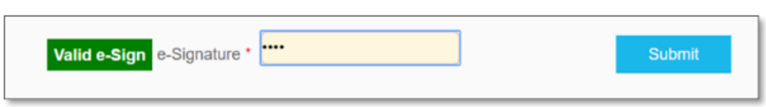
1. Click the **Libraries** menu in the upper-left hand corner of the screen and select **Add Category** under the heading "Forms".



A new window opens, displaying the Form Category page:

2. Enter the **Form Category** name and **Category Description** in the available forms.

3. After filling in the required information, enter your e-Signature and click **Submit** to confirm.



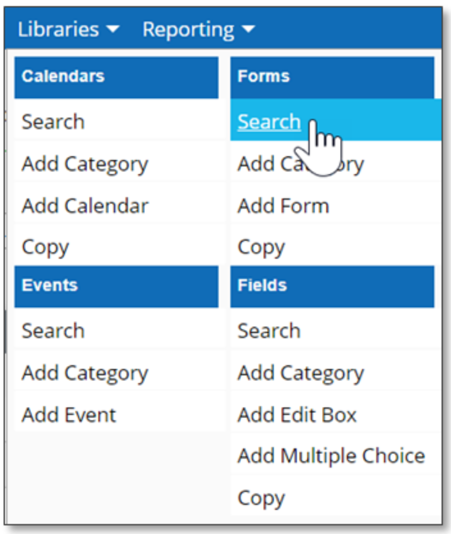
The form category has been saved.

6.2.2.2 Search the Form Library

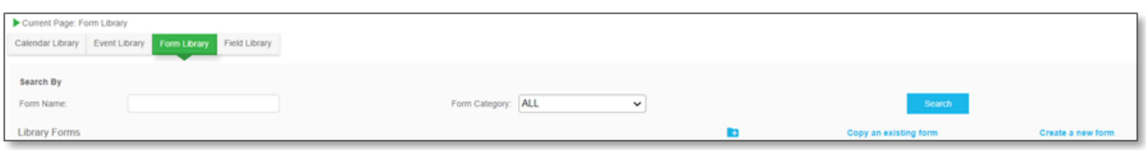
Before adding a new form, you should search the form library to see if there is a similar form or if the same form already exists. If there is a similar form, you could save time by copying a form and making minor modifications instead of building one from the start. To learn more about copying a form, see Copy a Form.

To search the form library:

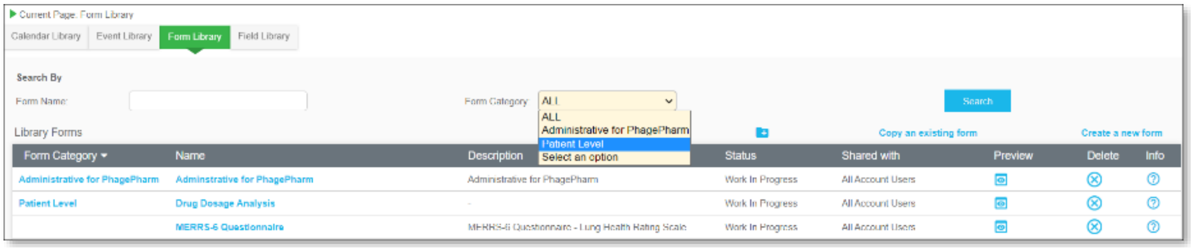
1. Click the **Libraries** menu in the upper-left hand corner of the screen and select **Search** under the heading Forms.



The Form Library displays:



2. Enter your search criteria in the available forms within the **Search By** section of the page, and click **Search**.



The search results display at the bottom of the page in the Library Forms section.

6.2.2.3 Add and Manage Forms

In Velos eResearch, forms are fundamental to the collection of study and patient information. Before creating forms, fields and form categories must be established. For more information on fields and form categories see the Field Library, and how to Add a Form Category. Permissioned users will have the ability to add and manage forms in Velos eResearch.

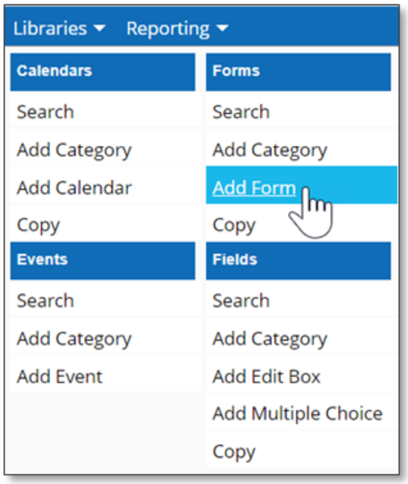
> **Note:** It is recommended that some form settings be left undefined until they are associated with a study. These steps are marked with a warning information box throughout this section.

6.2.2.3.1 Add a Form

If a required study form does not already exist in the Form Library, permissioned users can add new forms using the Libraries menu.

To add a new form:

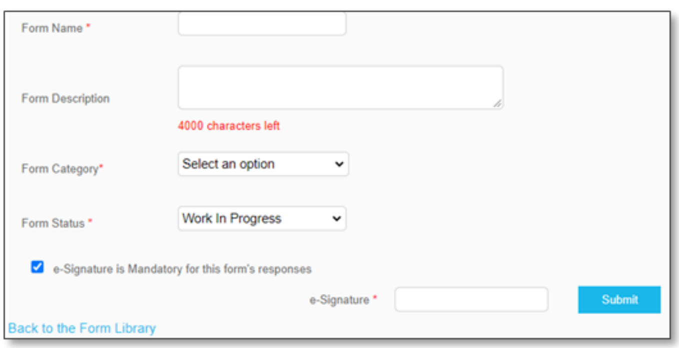
1. Click the **Libraries** menu in the upper-left hand corner of the screen and select **Add Form** under the heading “Forms”.



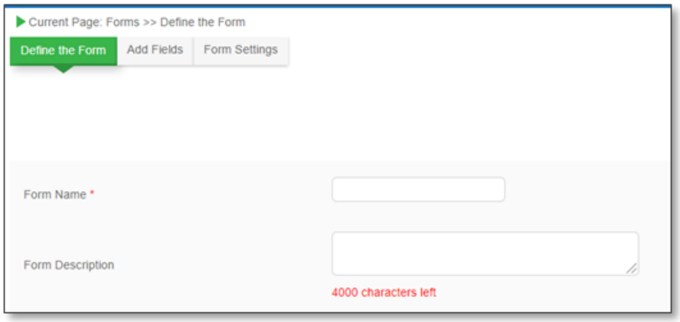
-OR-

From the Form Library page, click **Create a New Form** on the right side of the screen.

The Define the Form screen displays:

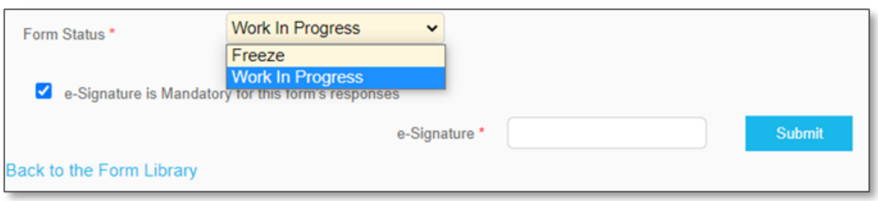


2. Enter the form name and description in the available fields.



3. Select the form category from the drop-down menu. See Add a Form Category for more information about categories.

4. Select the form status. See the table below for a short description of both form statuses.



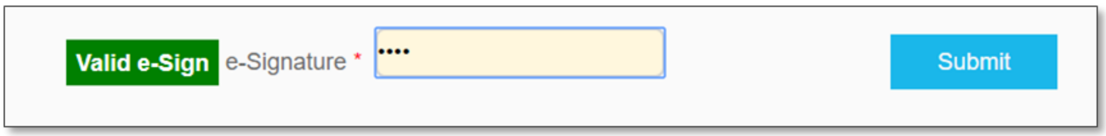
Category	Description
Work in Progress	Edits can be made to the fields under each of the form tabs.
Freeze	Does not allow any changes to the form template.

Warning: It is highly recommended to leave the status set to "Work in Progress" for all library forms. If a form is changed to the status "Freeze", the form is permanently locked down, and no further changes can be made (including status).

Note: The option e-Signature is Mandatory for this form's responses does not take effect during previews in the form library. Address this option when the form has been associated at the account, study, or patient level.

Warning: Before proceeding to the other form configuration tabs, you must first enter the required information on the Define the Form page and create the new form by clicking Submit. If you proceed to other tabs before saving the information on the Define the Form page, the other tabs will be disabled, and your progress on the Define the Form page will be lost.

5. After filling in the required information, enter your e-Signature and click **Submit** to confirm.



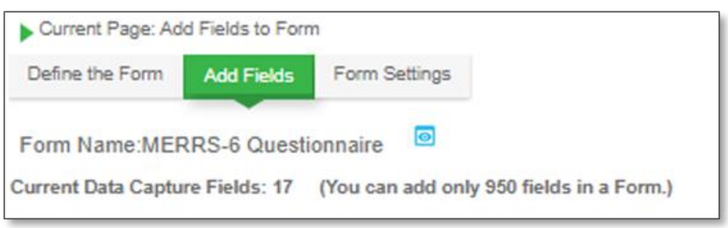
The form has been created.

6.2.2.3.2 Add Fields

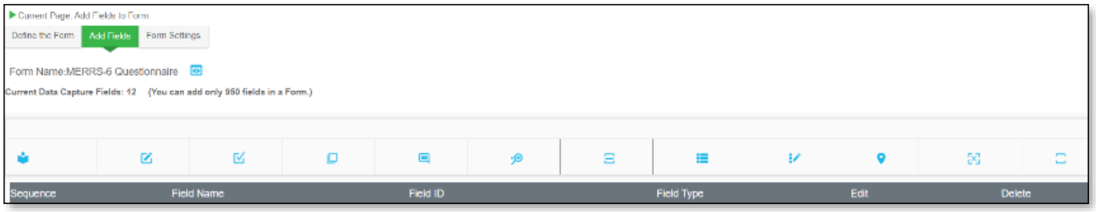
The second, and most crucial step in configuring a new form is to add fields. Fields are the building blocks of your form; the specific data-collection points. Permissioned users have the ability to add, edit, and delete fields from a form. For more information about creating fields see Add and Manage Fields.

To access the Add Fields page:

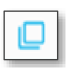
1. Navigate to the **Add Fields** tab of a form.



The Add Fields page displays:



2. Add fields and formatting to your form using the available field and form controls. See the table below for a detailed description of each button:

Icon	Name	Description
	**Field Library**	Select a field from the field library.
	**Edit Box**	Creates an Edit Box field.
	**Multi Choice**	Creates a multiple-choice field.
	**Copy Field**	Copies a field already in your form.
	**Comments**	Allows users to insert a statement, such as instructions for completing the form. The comment should be specific to the form and not study-specific.
	**Lookup**	Inserts a lookup link within the form. The lookup link allows users to pull data from other pages or forms within Velos eResearch, including selected fields from Ad-hoc Queries.
	**Line Break**	Inserts a horizontal line within the form.
	**New Section**	Creates a new section of your form.
	**Edit Section**	Allows a user to edit a description or the sequence of a section.
	**Form Metadata**	Displays the form fields and their field characteristics.

Icon	Name	Description
	**Delete Multiple**	Allows users to delete multiple elements of a form at the same time.
	**Space Break**	Inserts a space break within the form.

Note:
1. Using the New Section field option, the Repeat Fields field is useful if the form is capturing similar information, i.e. a medication log. If the Field should appear in the form three times, the Field will repeat two times, so the number entered is a "2".
2. Using the New Section field option, in the Format field selecting “Tabular” will display the fields within the section horizontally across the page. Keep the default "Non-Tabular" to display the fields with the section in a column format.

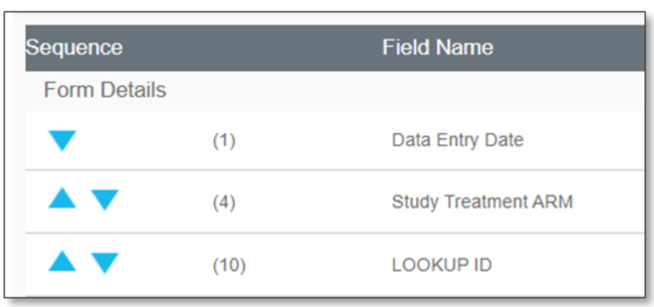
Warning: Fields created directly within a form cannot be used in other forms. If a field could be reused in the future in another form, it is recommended that all fields are created in the Field Library.

6.2.2.3.2.1 Change the Order of a Form Element

Permissioned users have the ability to change the order of form elements on the Add Fields page by using the Modify Sequence buttons.

To change the sequence:

1. Navigate to the Add Fields page and click the **Modify Sequence** button(s) to move elements up and down within a section.

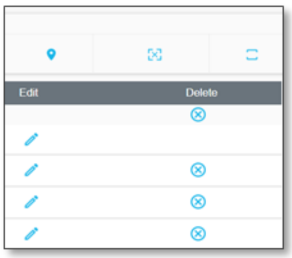


6.2.2.3.2.2 Edit a Form Element

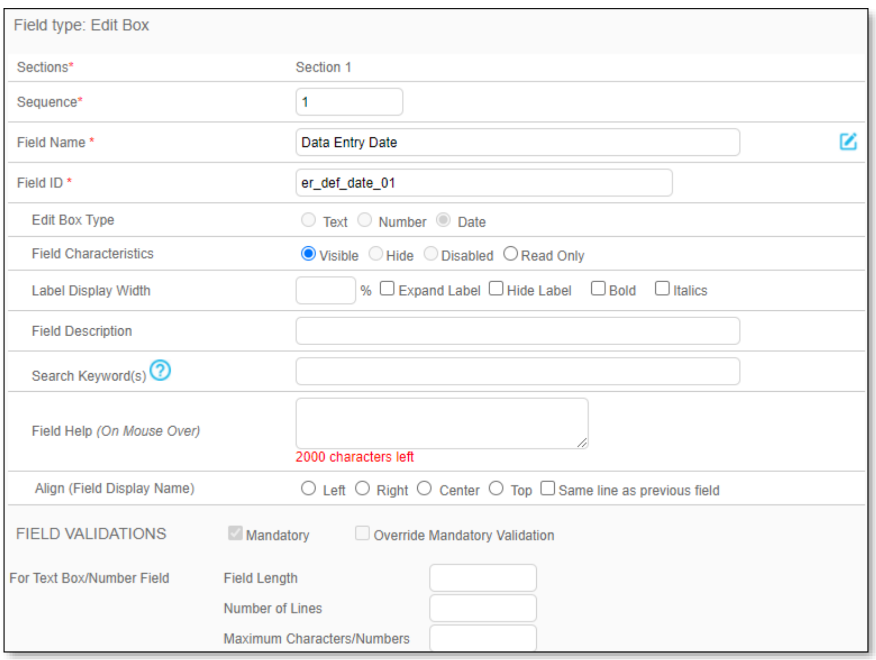
Permissioned users have the ability to edit some form elements on the Add Fields page by using the Edit button.

To edit a form element:

1. Navigate to the Add Fields page and click the **Edit** button to modify a form element.

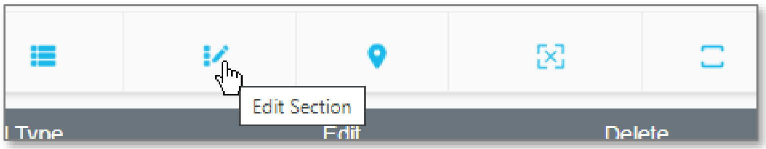


The element's edit page displays in a new window:

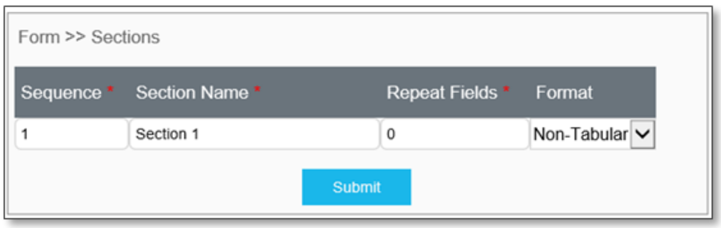


-OR-

Click the **Edit Section** button to edit a section.



The Section opens for editing.



Note: The specific edit page will vary, depending on the element you are editing. For example, the edit page varies greatly between a field and a structural element like a line break.

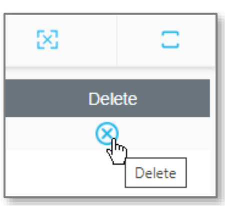
2. Make the necessary changes in the available fields and click Submit to confirm.

6.2.2.3.2.3 Delete a Form Element

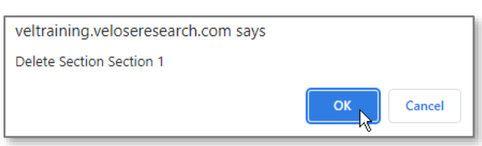
Permissioned users have the ability to delete form elements and sections on the Add Fields page by using the Delete button.

To delete a form element or section:

1. Navigate to the Add Fields page and click the **Delete** button to remove elements or sections.



2. A notification displays asking you to confirm the deletion. Click **OK** to proceed.

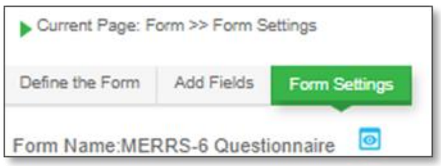


6.2.2.3.3 Form Settings

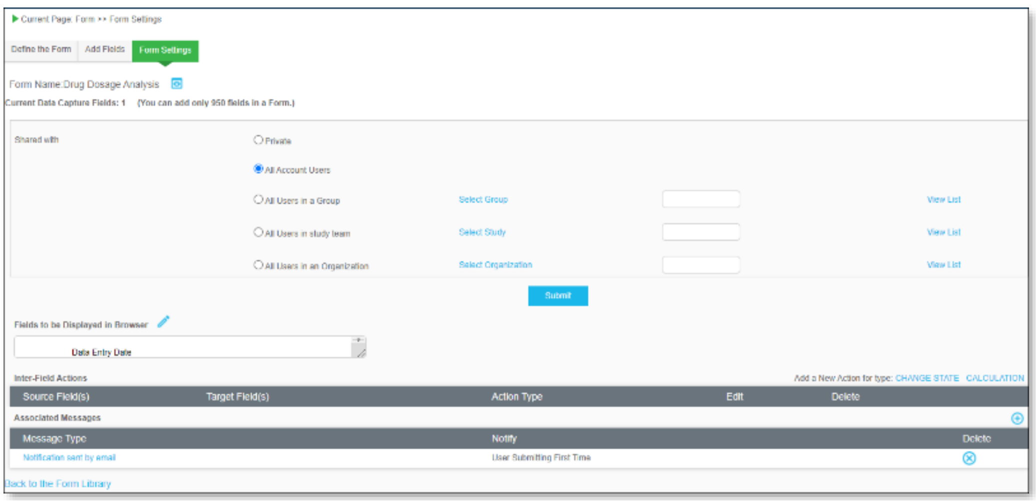
The third step in creating a new form is to configure the form settings. Form settings allows you to share the form with the whole account, an organization, a group, or specific users. In addition, field settings and calculations can be setup on this page.

To configure the form settings:

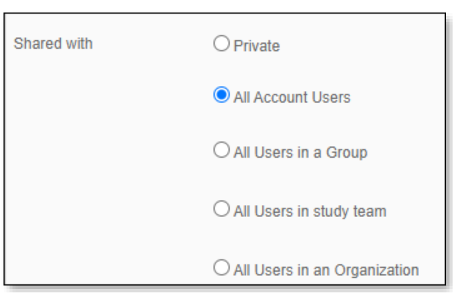
1. Navigate to the **Form Settings** tab of a specific form.



The Form Settings page displays:



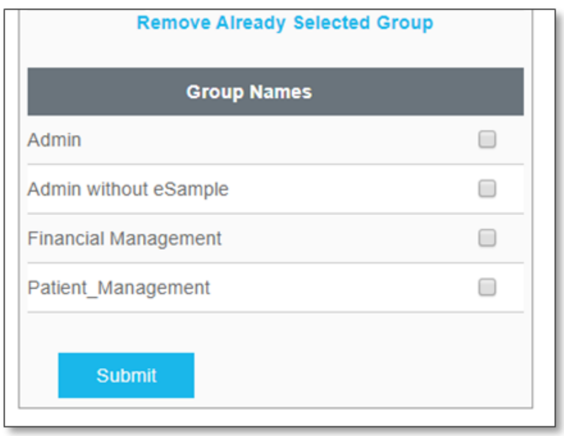
2. Define how the form should be shared.



See the table below for definitions of each share category:

Category	Definition
Private	Hidden from all users in the system.
All Account Users	Available to all system users.
All Users in a Group	Available to all system users in a group. For more information about groups, see Groups.
All Users in a Study Team	Available to all system users in a study. For more information about studies, see Study Management.
All Users in an Organization	Available to all system users in an organization. For more information about organizations, see Organizations.

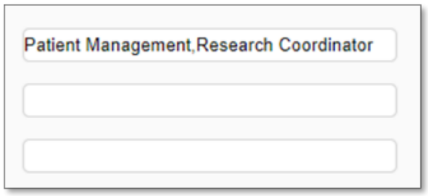
3. If you select the option **All Users in a Group**, click the **Select Group** link, and select a group or multiple groups using the selection window that displays. Click **Submit**.



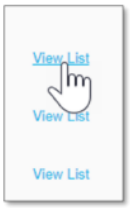
-OR-

If you select the options **All Users in a Study Team** or **All Users in an Organization**, follow the same steps above by clicking either the **Select Study** or **Select Organization** links.

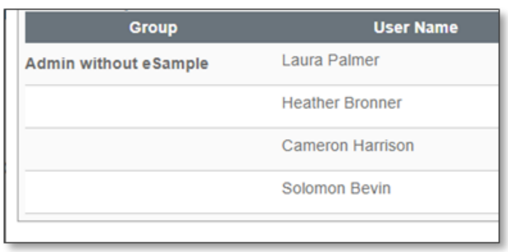
The groups, studies or organizations you selected will display in the corresponding field:



4. Click **View List** to view all users who will have access to the calendar based on your group, study or organization selections.



The list of users, organized by group, study, or organization display in a new window:



Group	User Name
Admin without eSample	Laura Palmer
	Heather Bronner
	Cameron Harrison
	Solomon Bevin

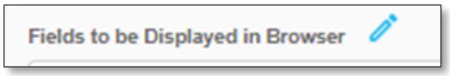
Warning: If you share this form with a group, user, or organization to which you do not belong, you will not be able to see the form in the form library after you have saved it and leave the form creation page.

6.2.2.3.3.1 Fields to be Displayed in Browser

The Fields to be Displayed in Browser feature applies to the Form Response Browser pages and allows permissioned users to determine which fields are displayed in the browser to the end user.

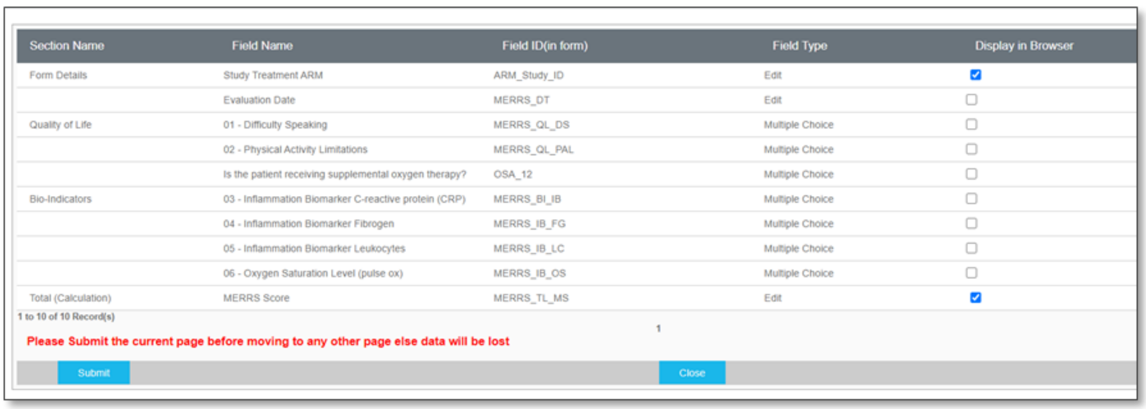
To define which fields are displayed in the browser:

1. Navigate to the Form Settings tab of a form and continue down the page to the Fields to be Displayed in Browser section. Click the **Edit** button.



Note: The Data Entry Date, Form Status, and Study Number (only for study patient linked forms) are default fields displayed in the browser.

The Fields to be Displayed in Browser editor opens in a new window:



Section Name	Field Name	Field ID(in form)	Field Type	Display in Browser
Form Details	Study Treatment ARM	ARM_Study_ID	Edit	☑
	Evaluation Date	MERRS_DT	Edit	☐
Quality of Life	01 - Difficulty Speaking	MERRS_QL_DS	Multiple Choice	☐
	02 - Physical Activity Limitations	MERRS_QL_PAL	Multiple Choice	☐
	Is the patient receiving supplemental oxygen therapy?	OSA_12	Multiple Choice	☐
Bio-Indicators	03 - Inflammation Biomarker C-reactive protein (CRP)	MERRS_BI_IB	Multiple Choice	☐
	04 - Inflammation Biomarker Fibrogen	MERRS_IB_FG	Multiple Choice	☐
	05 - Inflammation Biomarker Leukocytes	MERRS_IB_LC	Multiple Choice	☐
	06 - Oxygen Saturation Level (pulse ox)	MERRS_IB_OS	Multiple Choice	☐
Total (Calculation)	MERRS Score	MERRS_TL_MS	Edit	☑

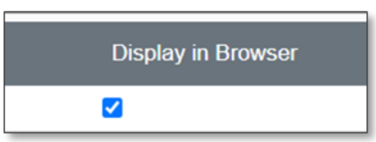
1 to 10 of 10 Record(s)

1

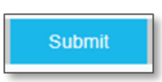
Please Submit the current page before moving to any other page else data will be lost

Submit Close

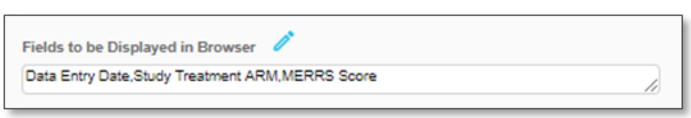
2. Select the fields you would like to display in the browser by clicking the checkbox next to the field(s) in the **Display in Browser** column.



3. Click **Submit** to close the window after the changes are saved.



The new fields that will display in the browser are listed in the field directly below the **Fields to be Displayed in Browser** section:

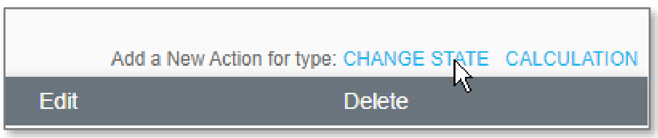


6.2.2.3.3.2 Inter-Field Actions

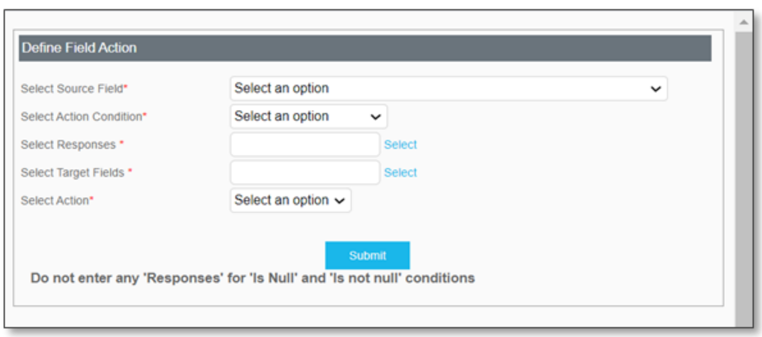
Velos eResearch allows permissioned users to configure more advanced form functionality using the Inter-Field Actions section of the Form Settings page. Within this section, you can create field dependencies and calculations.

To configure inter-field actions:

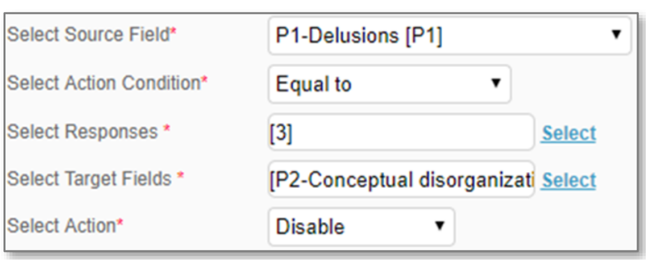
1. Navigate to the **Form Settings** tab of a form and continue down the page to the Inter-Field Actions section. Click **CHANGE STATE**.



   The Define Field Action page displays in a new window:

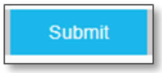


2. Select a Source Field, Action Condition, Responses, Target Field and Action.

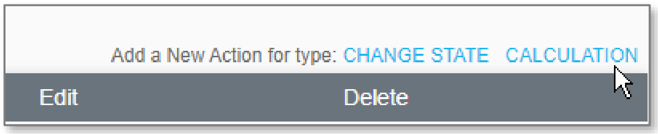


   - Using the example in the image above, the field action logic will function as described by the conditional statement below:
     - If the value of field P1-Delusions is Equal to 3, then the field P2-Conceptual Disorganization will be disabled.

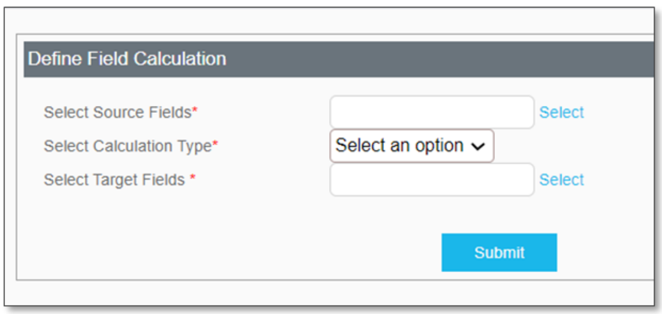
3. Click **Submit** to confirm.



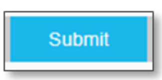
4. Click CALCULATION.



The **Define Field Calculation** page displays in a new window:



5. Select the Source Fields, Calculation Type, and Target Fields.
6. Click **Submit** to confirm.



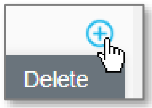
6.2.2.3.3.3 Associated Messages

Velos eResearch allows permissioned users to configure customized messages that are linked to forms.

Note: It is advised to only associate a message after the form has been associated to a patient or study so the form may be used as a more generic template.

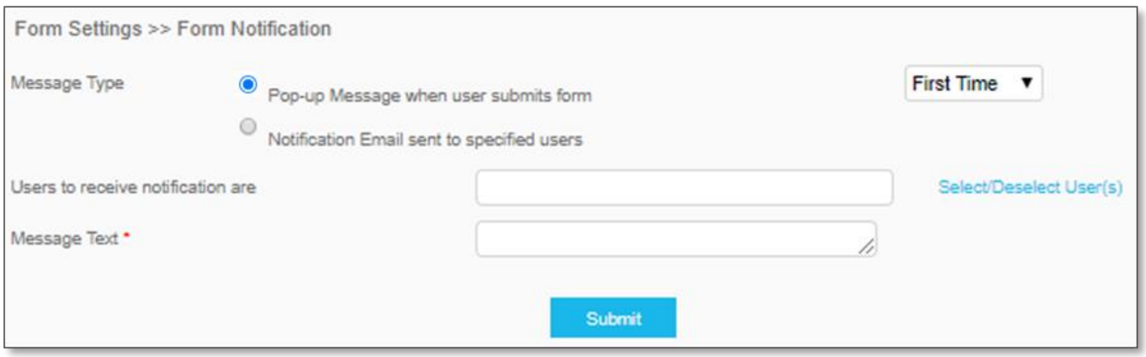
To link messages to forms:

1. Navigate to the Form Settings tab of a form and continue down the page to the Associated Messages section. Click the **New Messages** button.

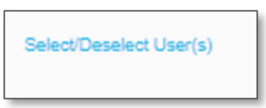


The Form Notification page displays in a new window.

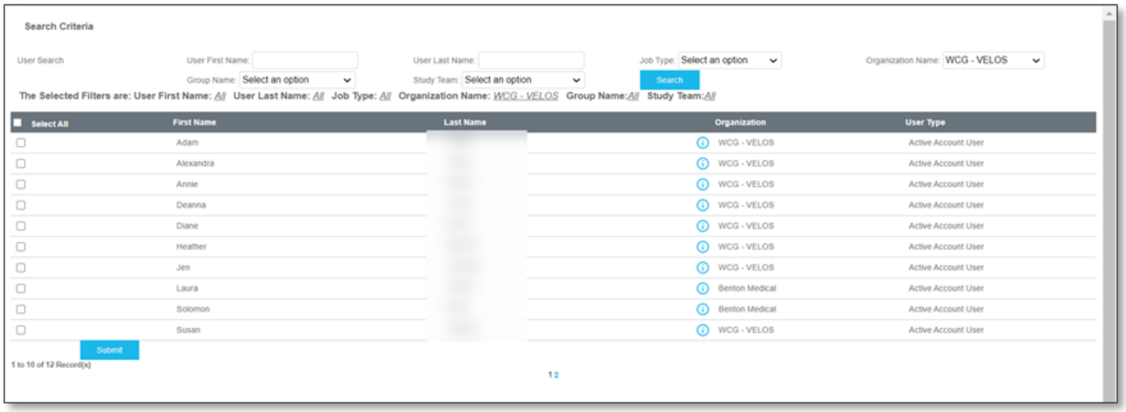
2. Select the **Message Type**, and frequency.



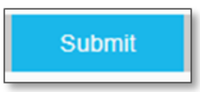
3. If you select the option to send a Notification Email in step 2, select the users to receive notifications by clicking **Select/Deselect User(s)**.



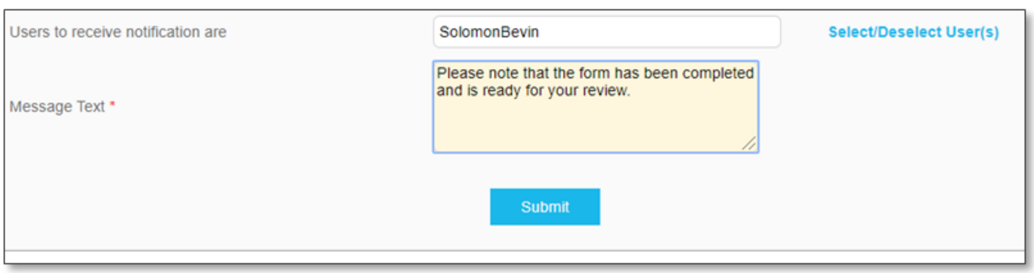
4. Add users by clicking the checkbox next to their name.



5. Click **Submit**.



6. Finally, enter your message text in the available field and click **Submit** to confirm.

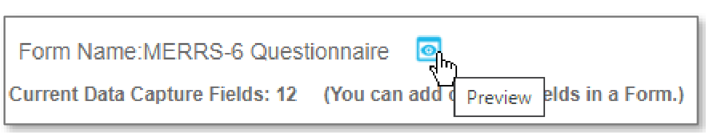


6.2.2.3.3.4 Preview the Form

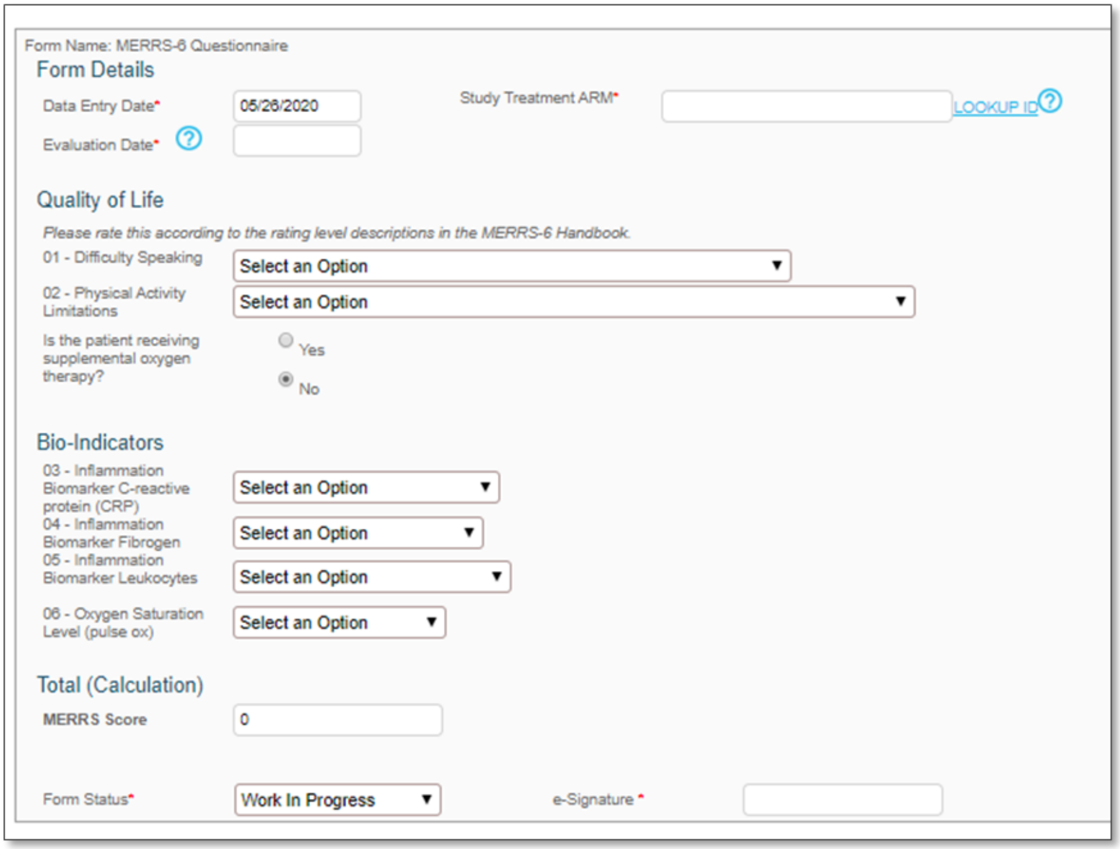
At any point during the configuration of a form, permissioned users can preview the result of the form as end-users would see it by clicking the preview button at the top of any of the form configuration tabs.

To preview a form:

1. Navigate to any configuration tab of a form (Define the Form, Add Fields, or Form Settings).
2. Click the preview button located at the top of the page.



The form preview displays in a new window.



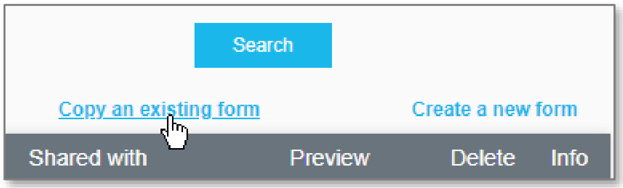
Note: This is only a preview of the form. Permissioned users can interact with the elements of the form to test its functionality and construction, but responses will not be stored in the system.

6.2.2.4 Copy a Form

Velos eResearch offers a means to copy existing forms and make modifications to the copy using the Copy an Existing Form link on the Form Library page, or the Copy button within the Libraries menu.

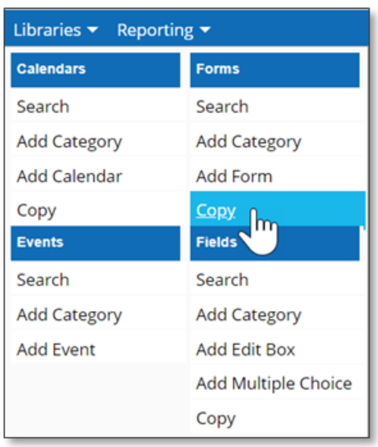
To copy an existing form:

1. Navigate to the form library and click **Copy an existing form** in the upper-left hand corner of the screen.

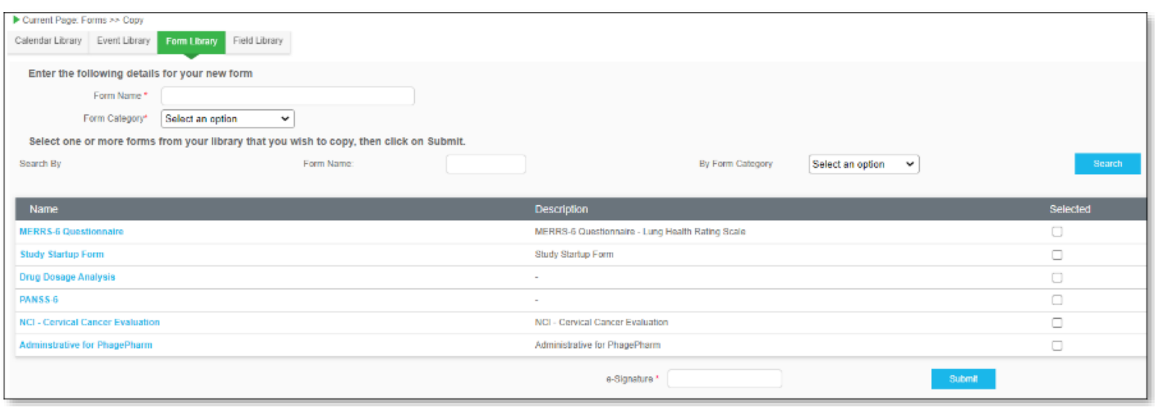


-OR-

Click the **Libraries** menu in the upper-left hand corner of the screen, and select **Copy** under the heading "Forms".

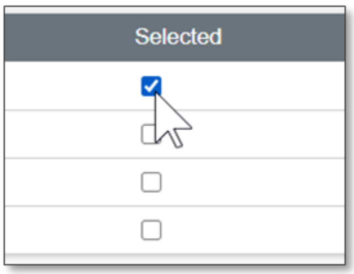


The Copy Form page displays:



2. Enter the form name and select a form category at the top of the Copy Form page, then click **Search**. For more information about form categories, see how to Add a Form Category.

3. Select the existing form that you would like to copy by clicking the checkbox on the right side of the Copy Form page next to the corresponding form, enter your e-Signature and click **Submit** to confirm. For more information about configuring forms, see Forms Management.

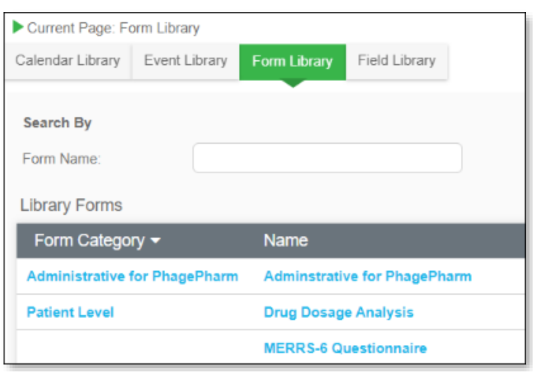


6.2.2.5 Remove a Form

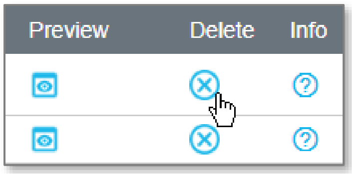
Permissioned users can remove forms from the Form Library as needed.

To remove a form:

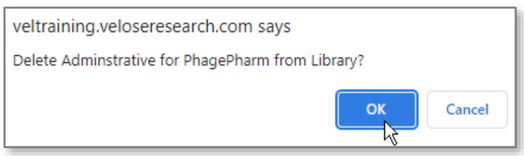
1. Navigate to the Form Library, and search for the target form. For more information about searching the Form Library, see Search the Form Library.



2. Click the **Delete** button located at the right side of the page for the form that you would like to delete.



3. A notification displays asking you to confirm if you would like to delete the form. Click **OK** to delete the form.



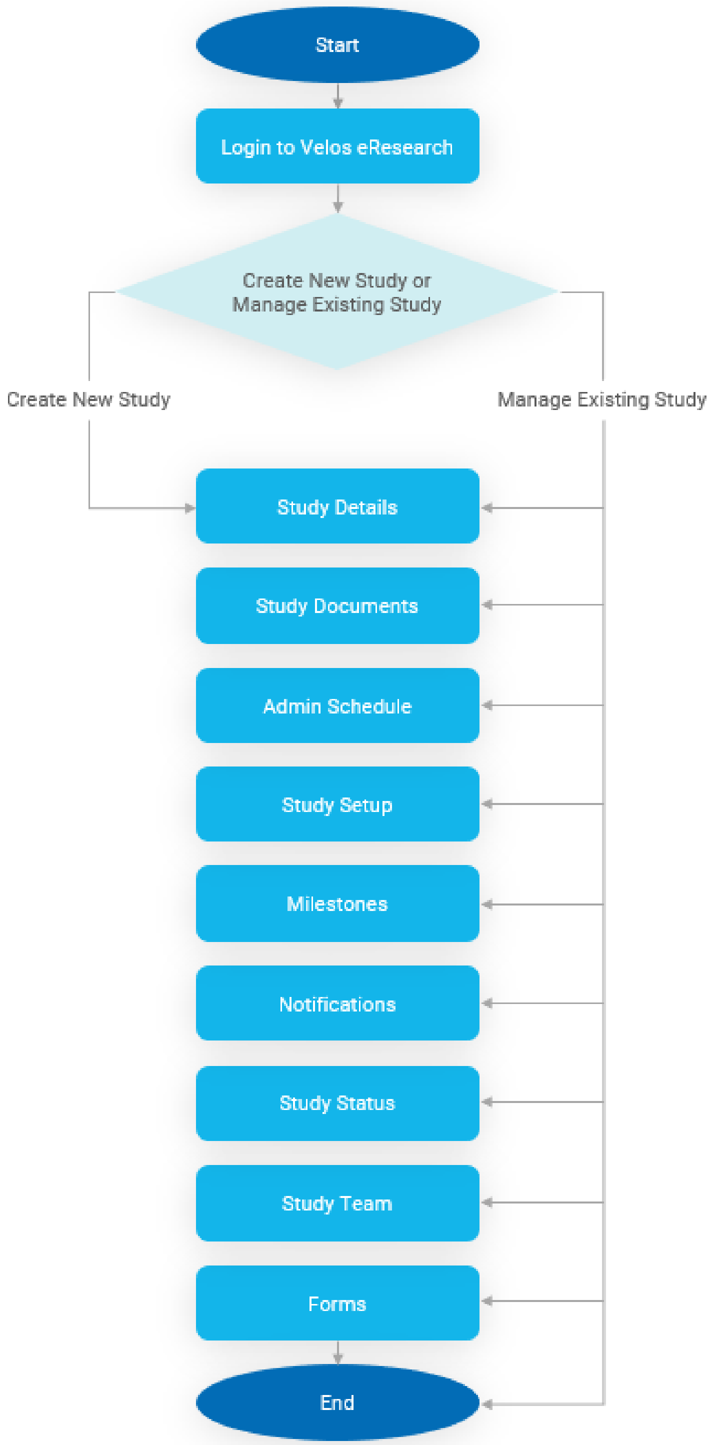
The form is deleted from the Form Library.

7 Study Management

Users with duties of study administration should be permissioned with the abilities and functionalities associated with Study Management. (See Appendix E – Permission Types and/or Appendix F – Study Role Permissions, for more information.) These include, but are not limited to, adding new studies, editing information for existing studies, adding study documents, editing versions, generating Study Patient IDs, creating and managing Milestones. Study Management additionally includes defining the study status, managing associated reports, managing Study Team Members, and, associating and managing forms. These features are integral to Study Management. The following section describes how to utilize the Study Management functions within eResearch Enterprise and eResearch eXpress.

Note: If Networks is an option in your version of eResearch, please refer to Networks, for more information.

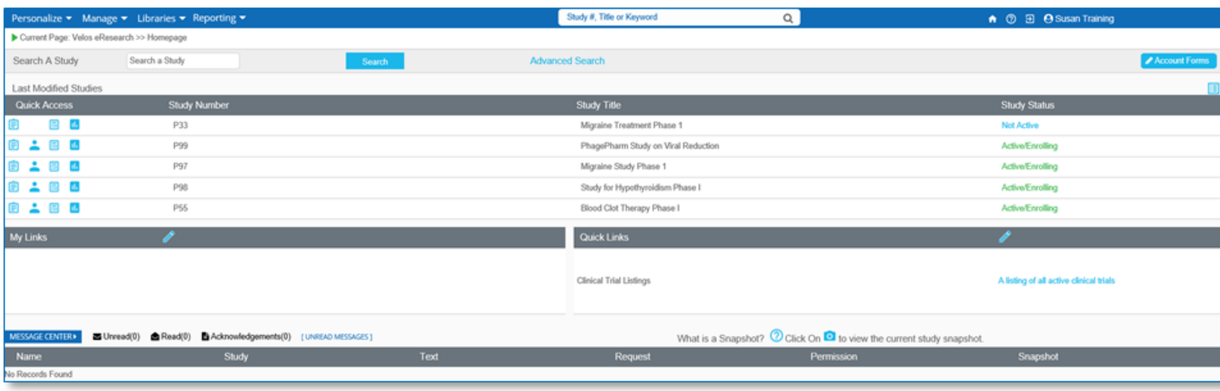
7.1 Process Overview



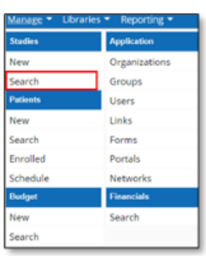
7.2 Studies

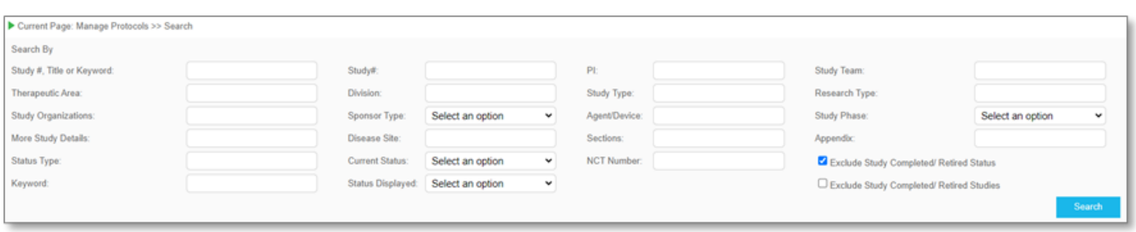
In this section, users will learn how to create new studies and manage an existing study. Once a study is selected, users may then proceed to view and edit Study Details, manage Study Documents associated with a specific study, manage the admin schedule for a study, set up study specific information such as settings for patient information, manage study Milestones, change Study Statuses, manage Study Reports, edit Study Teams, and associate or edit Forms.

Recently modified studies will appear on the user's Homepage or users may search, using the search bars, for a specific study based on various fields.



- Click **Advanced Search** in the image above or click **Search** under "Studies" in the **Manage** dropdown, to access a detailed Search page for a study.





> **Note:** The appearance of the homepage may be changed by a user. The image above is the default homepage. For information on how to customize or change the homepage, see Settings.

7.2.1 Add a New Study

Users who have the approved access to perform the duties of Study Administration, will be able to add and manage studies in the system.

This section will show how to manually add a new study.

In the Enterprise version only, in the Study Details Tab, the following additional fields are supplied:

- The Study Summary Section:
  - Principal Investigator was a major author/initiator of this study?
  - FDA Regulated Study
  - Disease Site
  - Specific Sites
  - Sample Size
  - Estimated Begin Date
  - Study Scope
  - Study Type
  - Linked to (A Study in Enterprise)
  - Blinding Randomization
  - Contact
  - Keywords (allows permissioned users to associate keywords for study searches)
  - NIH Grant Information
  - CTRP Reportable
- The entire More Study Details Section including fields:
  - IRB Number
  - Other Number

- Short Protocol Name
- Specify Name for Other Number

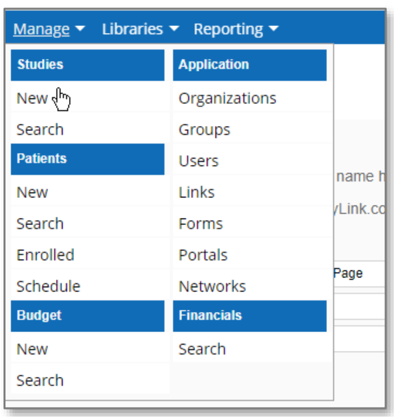
Note: The More Study Details Section is where any custom requested fields would be added.

Additional information/rules for completing the fields in the Study Details Tab:

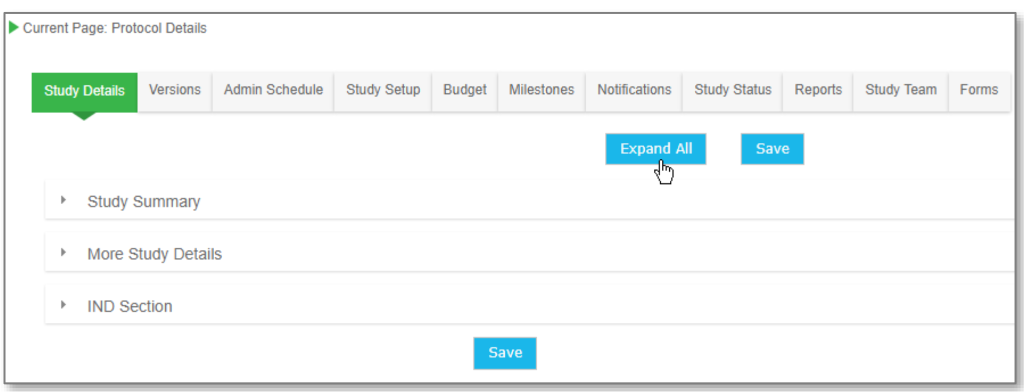
- Fields marked with a red asterisk (*) are mandatory fields for entry
- NCT must be listed before the 8-digit number
- The Division field is required in order to select the correct Therapeutic Area

To add a new study:

1. From the homepage, go to the menu tabs at the top of the page. Select **Manage** and under the "Studies" heading, click **New**.

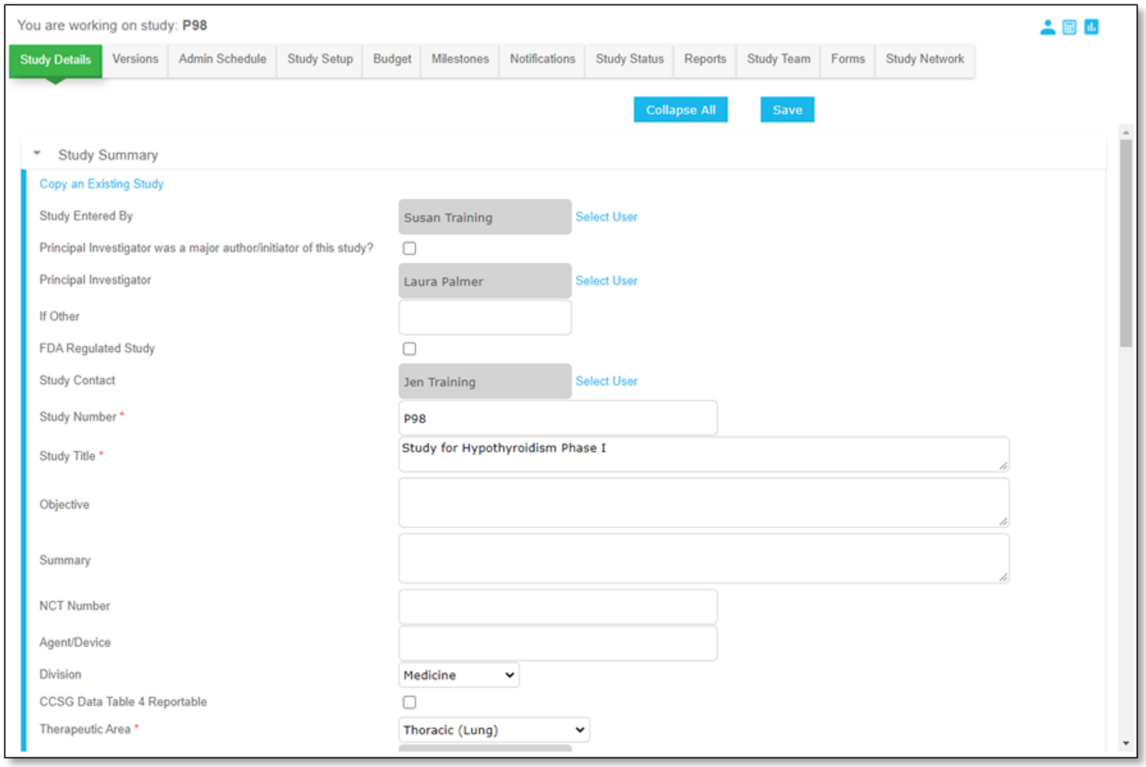


The Study Details page displays:



- Only the Enterprise version will view a More Study Details dropdown section

2. Click the **Expand All** button to view all sections.



3. Enter the required and necessary information into the available fields.

Note:
1. Fields marked with a red asterisk (*) are mandatory fields for entry.
2. It is recommended to leave the radio button for “Do you want information in this section to be available to the public?” as No, until it is confirmed it can be made available for public viewing.

4. Scroll down to the bottom of the page and click **Save**.

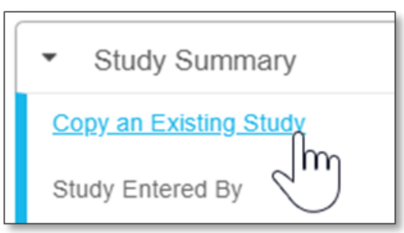
The page refreshes and the study is saved.

7.2.2 Copy an Existing Study

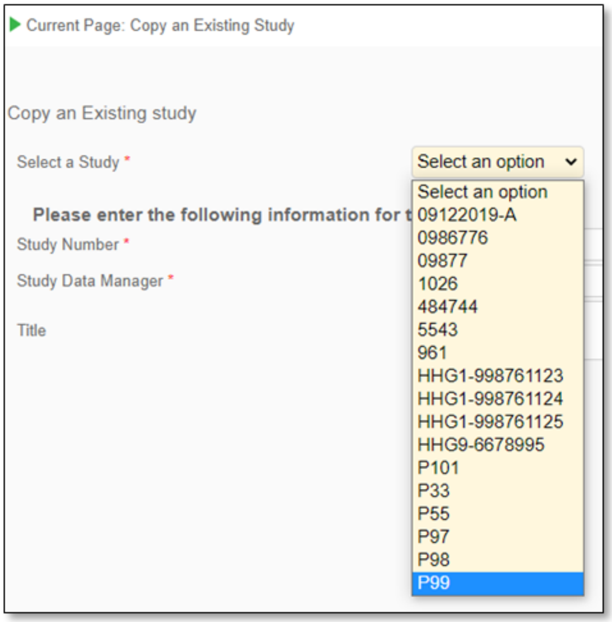
Users with Study Management duties will have the ability to copy an existing study. Users may want to copy a study to use as a template for another study. Copying an existing study allows users to additionally copy all templates associated to a study, such as Patient Calendars, Admin Calendars, Study Treatment Arms, Associated Forms, Study Status, Study Team, and Study Dictionaries/Settings.

To copy an existing study:

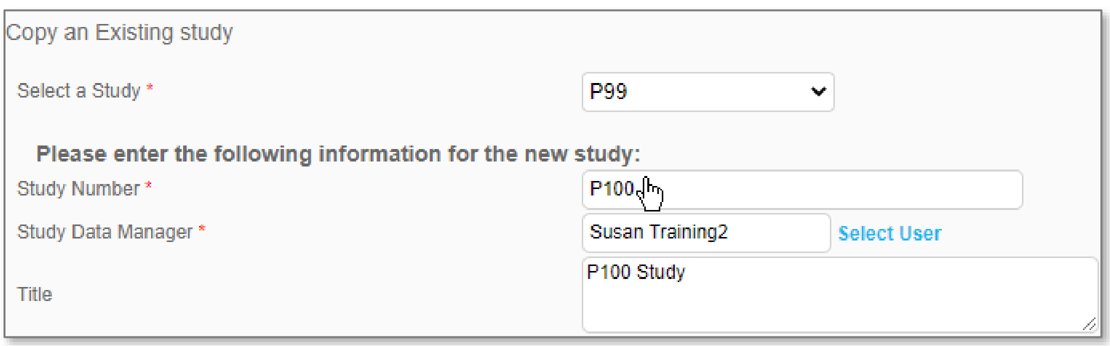
1. From the Study Details tab of a selected study, or after navigating to a New Study page, **Copy an Existing Study**" beneath the Study Summary dropdown.



2. Select the Study from the **Select a Study** dropdown menu.

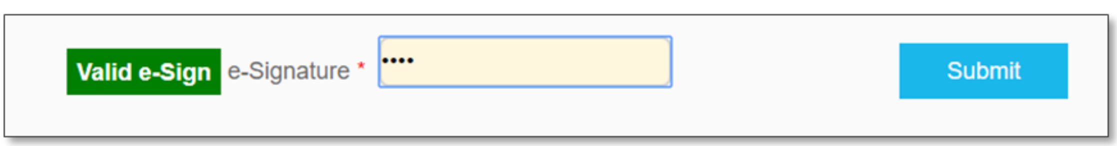


3. Add the new **Study Number**.



- The **Study Data Manager** field auto-populates but may be changed by clicking the **Select User** link and selecting a different user

4. Enter your e-Signature and click **Submit** to confirm.



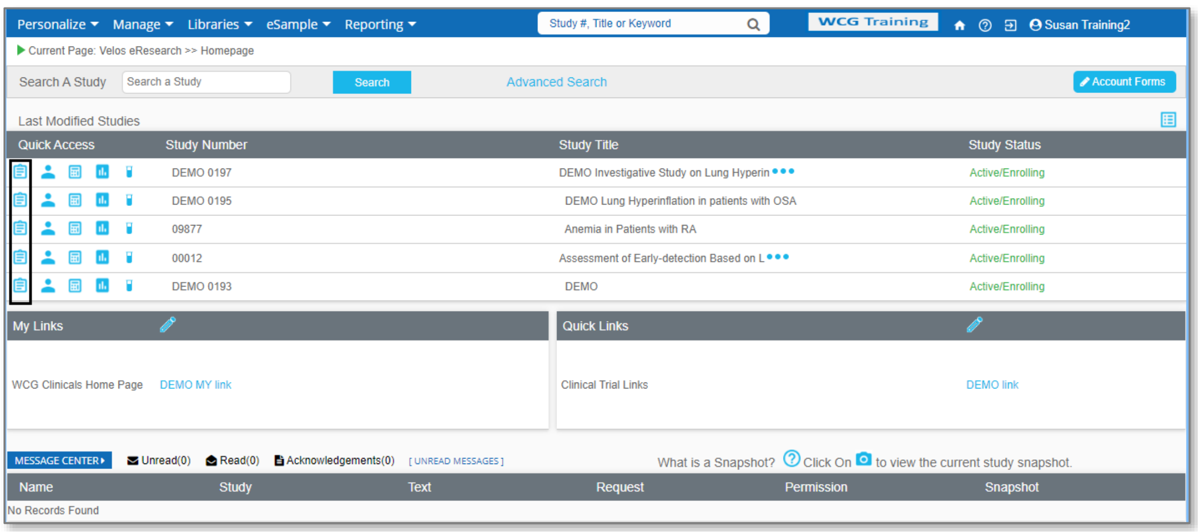
A copy of the Study is created.

7.2.3 Manage an Existing Study

This section will explain the multiple features associated with how to manage an existing Study such as Study Details, Documents, Schedules, Milestones, Notifications, Study Status, Reports, Study Team Members associated with a Study, and Forms. Users can view an existing study from the Velos eResearch default homepage, or search for an existing study in any of the search pages.

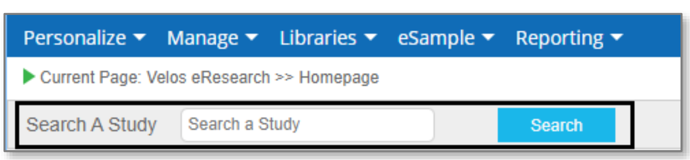
To manage an existing study:

1. Select a study from the Homepage using the appropriate clipboard **Study Administration** button, as shown below:

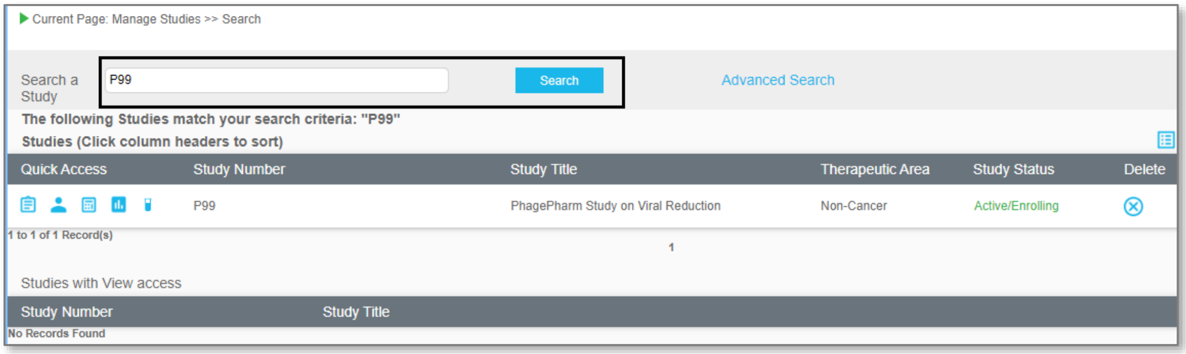


-OR-

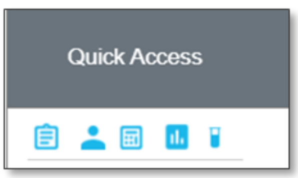
Search for a specific study by using the search field and click **Search**.



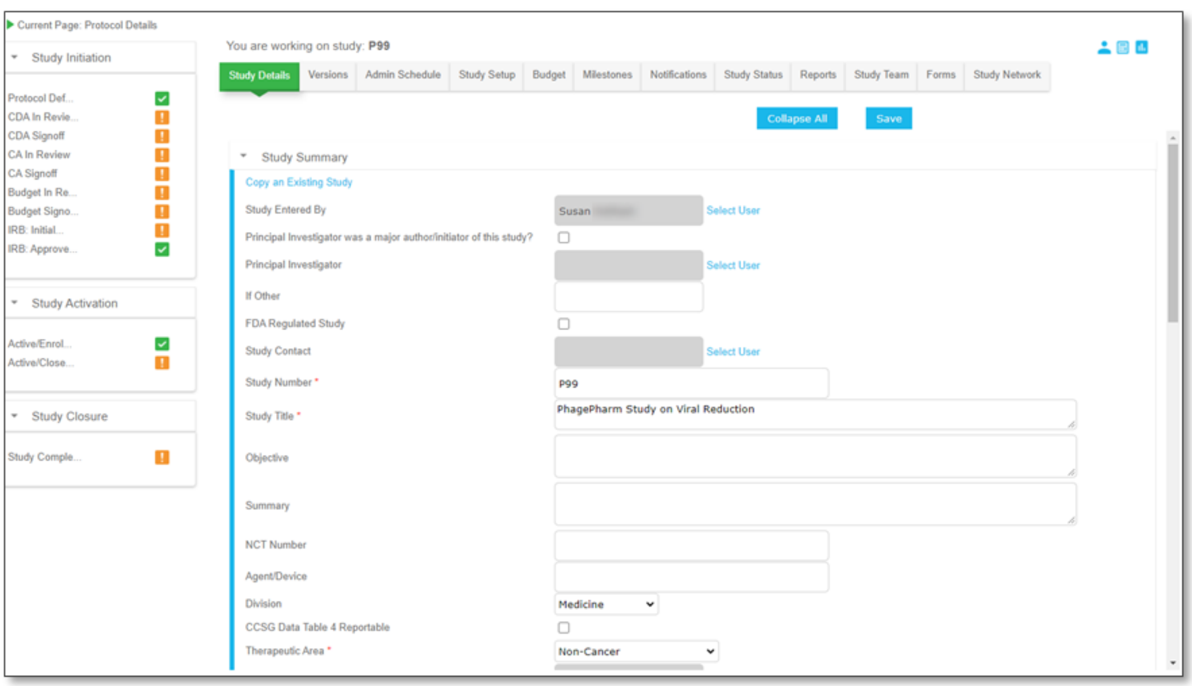
Studies that meet the search criteria and that are viewable to the logged in user will display within the Search page:



2. From the Search results, click the clipboard **Study Administration** button for the study that you wish to view.

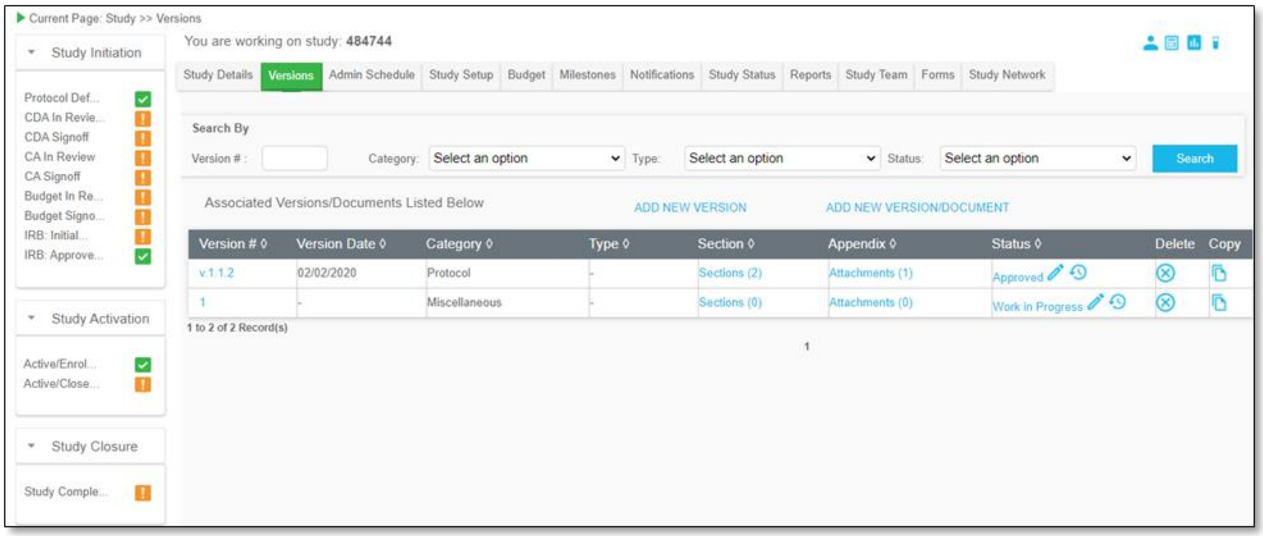


Users are taken to the Study Summary / Study Details page.



7.3 Versions/ Attachments Tab

Study documents are located under the Versions or Attachments tab. Here permissioned users may add a new version of an existing document through the Add New Version/Document link, for example, if a protocol is updated but you wish to keep records of previous versions. Documents will display on the tab and users may narrow the document list displayed by using the Search functionality. This section will cover how to add and edit Study Documents for an existing study.



Note: Depending on your configuration, the name of the Version tab may be titled the Attachments tab.

7.3.1 Add New Version or New Study Documents

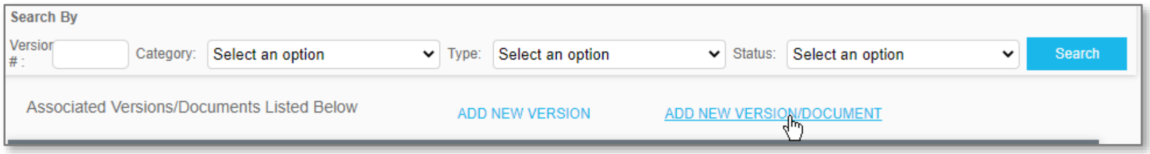
This section will cover how permissioned users may add a new version of an existing document type or add a new study document type to an existing study.

Note:

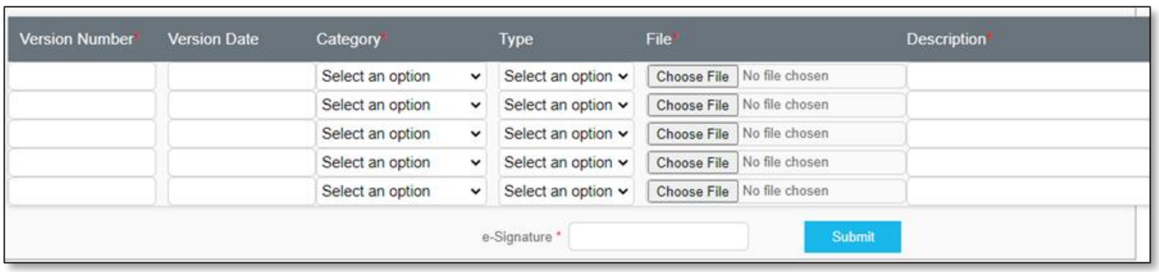
1. The following special characters are allowed when uploading an attachment: @ # $ % ^ & ( ) _ =+; } { [] , . ` ~ , however, if trying to use a single quote, ‘, the system will provide a warning message that single quotes are not allowed.
2. Only PDF, Word, Excel, PowerPoint, .zip files, and text formats are accepted in the system as Documents.

To Add a New Study Document or a New Version of an existing document Type:

1. From the Versions tab, select **Add New Version/Document** (Enterprise version) or **Add New Document** (eXpress version).

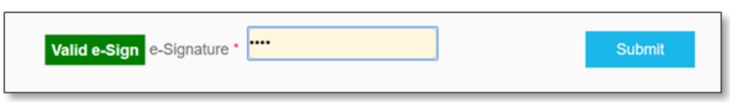


The Add New Version/Document window opens:



Note:
1. If the document type being uploaded is a new version of an existing document type, enter the next subsequent Version Number for the selected document Type.
2. Version Numbers may be alpha-numeric.
3. Multiple documents can be uploaded at once by adding each new document as a line item.

2. Enter e-Signature and click **Submit** to confirm.



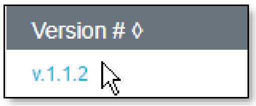
7.3.2 Manage Existing Documents

The Versions tab lists all available versions of uploaded documents. From this tab, there are several options for managing versions and documents including: Editing a Version, Updating Attachments, Updating the Status, and Deleting a Document.

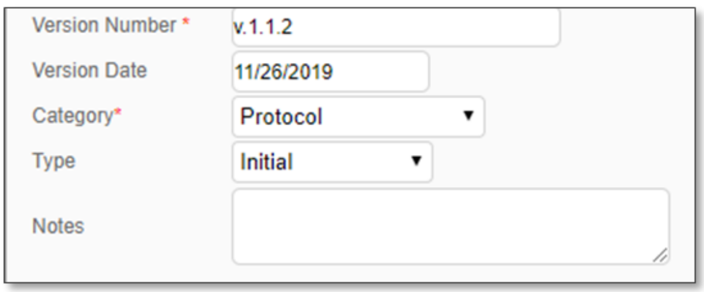
7.3.2.1 Editing a Version

To edit a version:

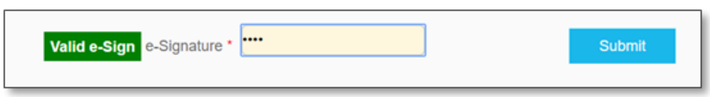
1. Select the **Version number** link for the desired document to modify.



The Document Details window opens:



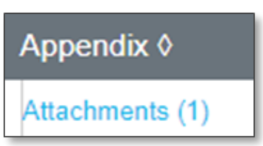
2. Modify or enter information as needed and **Submit** changes with your e-Signature to confirm.



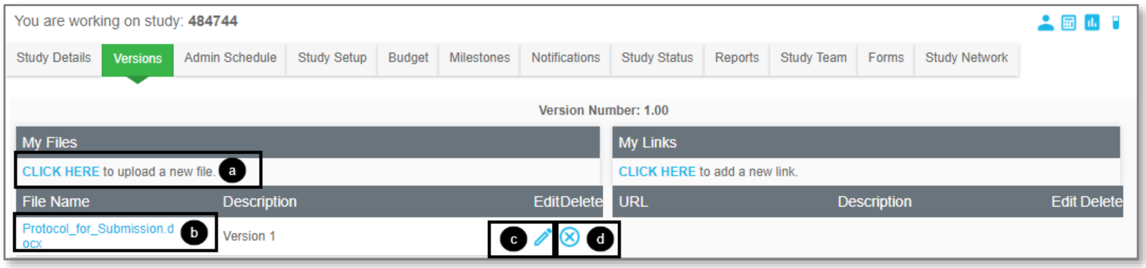
7.3.2.2 Adding, Downloading, Editing or Deleting an Attachment

To add, download, edit, or delete and Attachment:

1. Select **Attachments** for the desired document under the Appendix column.



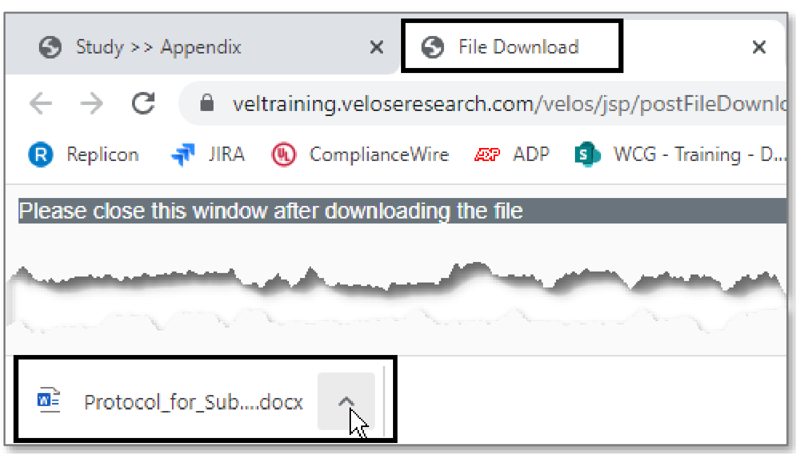
The Study Document Appendix page appears.



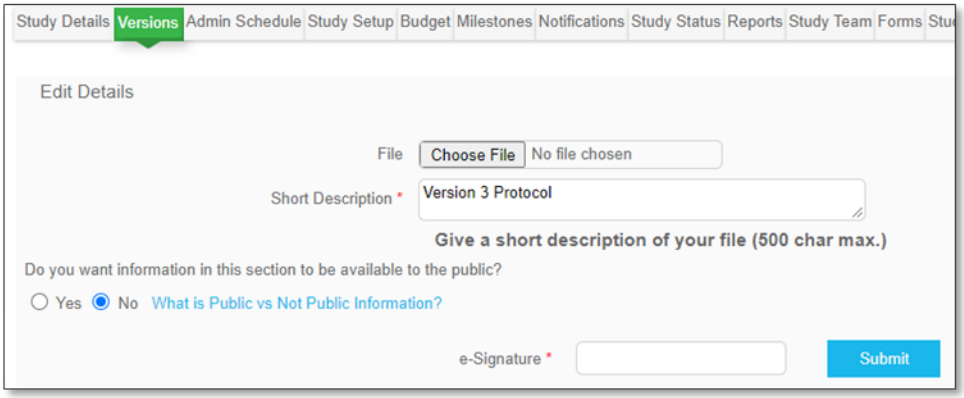
a. To add a new attachment, click the **Click Here** link.

i. Enter required information, select the appropriate radio button regarding making the attachment public information, then enter e-Signature and click **Submit** to confirm.

b. To download an existing attachment, click the **File Name** and the attachment will appear at the bottom of the screen to download. Close the new File Download window when done viewing the document.

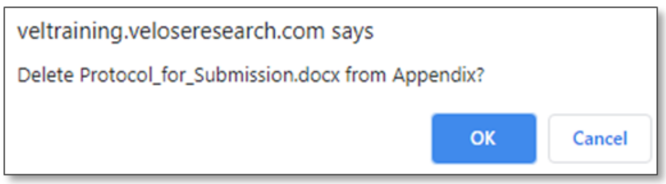


c. To edit an existing attachment's information, click the **Edit** button.



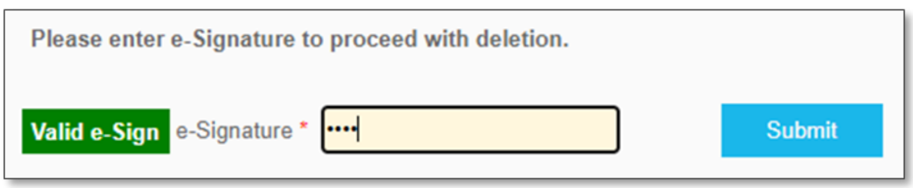
i. Update information as needed, enter e-Signature and click **Submit** to confirm.

d. To delete the existing attachment, click the **Delete** button.



i. Click **OK**.

ii. Enter e-Signature and click **Submit** to confirm.



Note: Users may also add, edit, or delete links from this page as well.

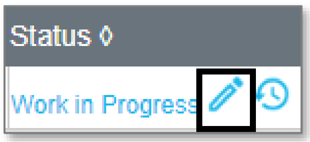
7.3.2.3 Editing a Document Status

By default, all new documents added to the Versions tab of a study will be in the Work in Progress status. Changing the status of a document is important for a number of reasons – it can be used to indicate expired or incorrect historical versions of a document, it can indicate that a document is not yet completed, that a document is ready for IRB submission, or that it has been approved. This section details how to change the status of any document.

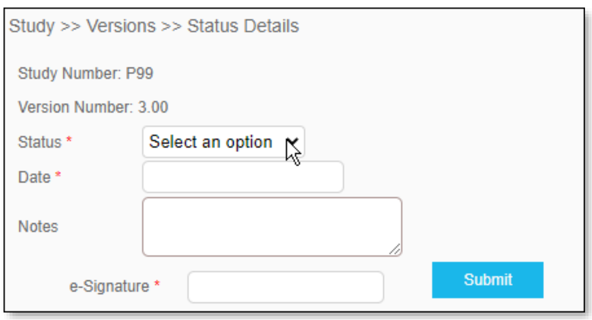
> **Note:** To submit a document for IRB review using the WCG IRB tab, the document(s) must first be in the Freeze status. For more information about the WCG IRB tab, see the WCG IRB Tab.

To change the status of an existing document:

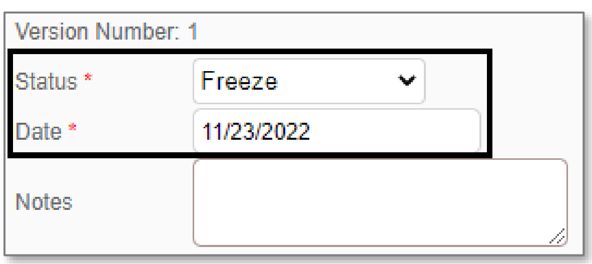
1. Click the **Edit** button next to the existing status of the target document.



The Status Details page opens in a new window:



2. Select a new status and effective date for that status, then enter your eSignature and click Submit to confirm.



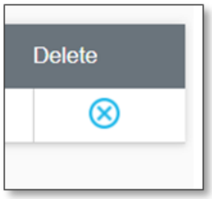
7.3.2.4 Deleting Documents

This section will cover how to delete Document attachments for an existing study. For best practice, only delete documents which were added in error.

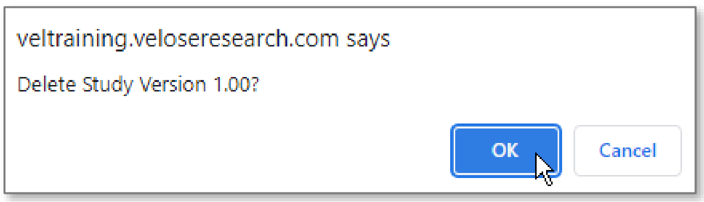
> **Warning:** If using Participant Portal, shared documents cannot be deleted.

To delete a document:

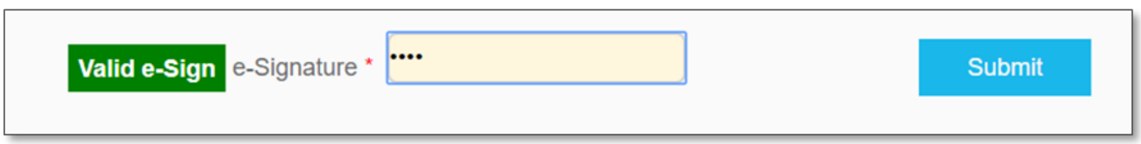
1. Select the **Delete** button to delete the desired document.



2. Click **OK** to confirm deletion of the version.



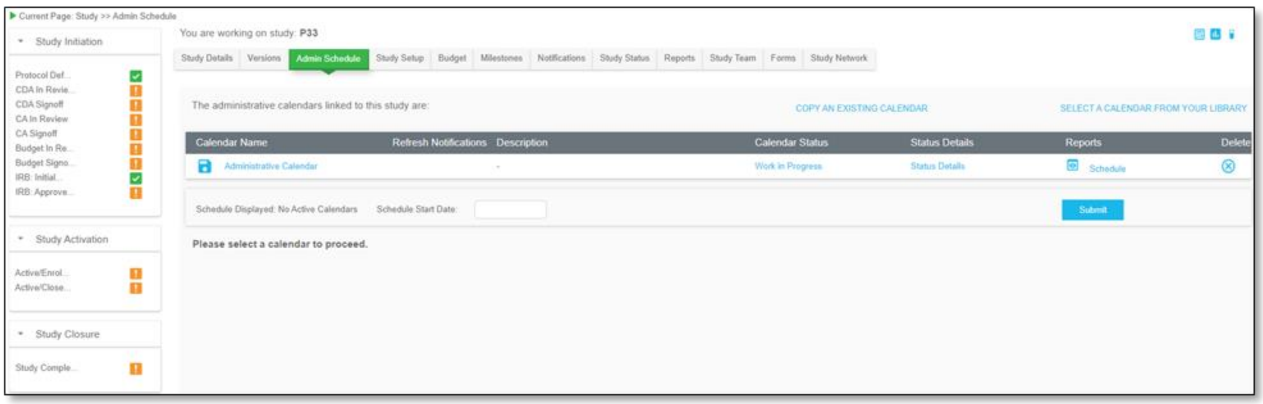
3. Enter your e-Signature and click **Submit** to confirm.



Note: At least one version of a document must remain in the system, or when trying to remove the last existing version, users will receive an error message preventing the version deletion.

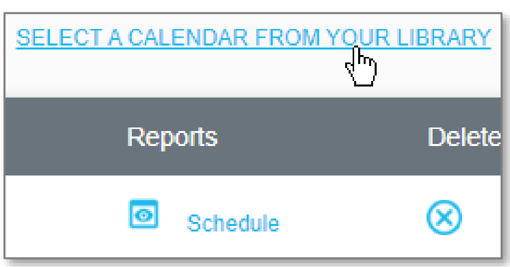
7.4 Admin Schedule Tab

Within the Admin Schedule tab, users may associate and generate administrative calendars to a specific study to manage Administrative Calendar events. For information on how to create calendars to associate with a study, see Calendar Management. The main features of the Admin Schedule tab are the ability to select a calendar from your library to associate with a study or copy an existing calendar that pre-exists within the selected study.

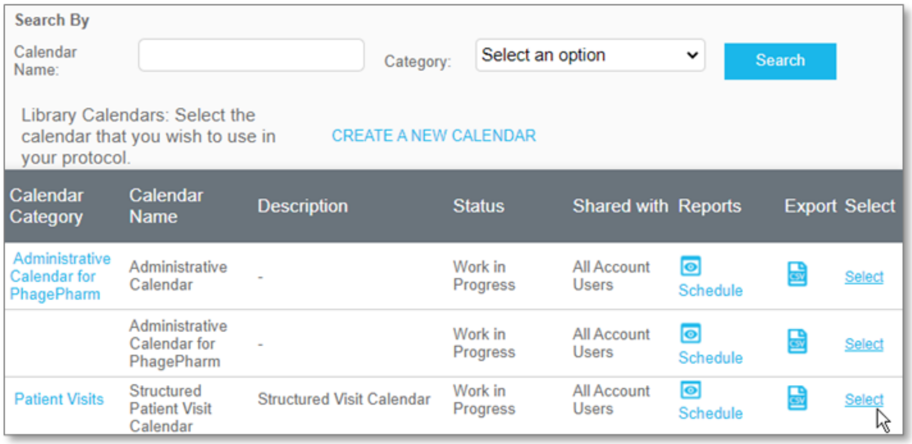


To associate a calendar with a study:

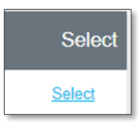
1. From the Admin Schedule page, click **Select a Calendar From Your Library** on the right side of the page.



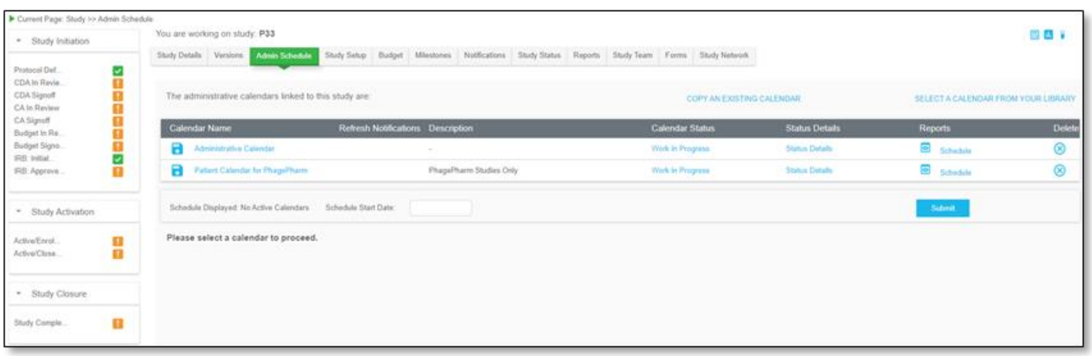
The Calendar Library window displays:



2. To associate one of the calendars listed, select the desired calendar by clicking **Select** for the calendar.



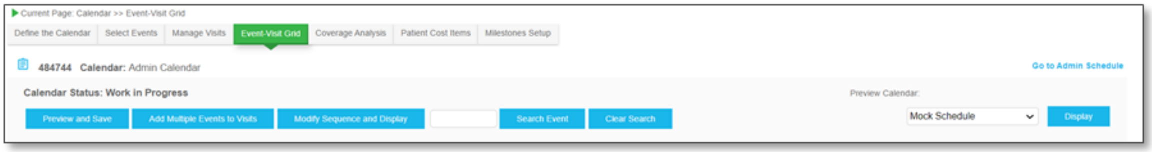
The selected calendar will display on the Admin Schedule page:



- The calendar associated with the study can be managed by clicking the **Calendar Name**. For more information on managing calendar events and visits, see Calendar Management.

Note:
1. Changes made to the calendar will only affect the calendar for this study, not the calendar template itself stored within the library. See Calendar Management for more information on how to modify calendars within the Calendar Library.
2. The calendar should be renamed once changes are made so that the calendar is study specific.

The Event-Visit Grid displays:



- From here, the calendar can be customized for the study. The below tabs provide options to update items such as the calendar name status. Existing events can be modified and/or add new events added. Visit information as well as coverage analysis information may be updated as well.

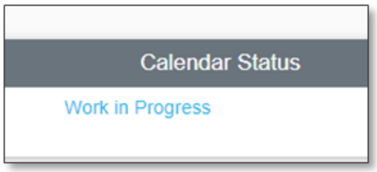
Tab Name	Description
Define the Calendar	Edit Calendar Name, Add a Calendar Description, Select a Calendar Category, Set a Calendar Status, and Set a Calendar Duration. For information on how this tab functions, see Add and Manage Calendars.
Select Events	Sequence Events, remove Selected Events, and Select Events from Libraries to include in this Calendar. For information on how this tab functions, see Manage Calendar Events.
Manage Visits	Add New Visits and Manage Existing Visits. For information on how this tab functions, see Manage Visits.
Event Visit Grid	Add Multiple Events to Visits, Modify Sequence and Display, Search for an Events, and Preview Calendar. For information on how this tab functions, see Event-Visit Grid.
Coverage Analysis	Specify Event, CPT Code, and Coverage Type based on Coverage Type Legend, and Exporting. For information on how this tab functions, see Coverage Analysis.
Patient Cost Items	Enterprise has an additional tab that allows users to define Patient Cost Items.
Milestones Setup	Enterprise has an additional tab that allows permissioned users to define Milestones for the Study Calendar on the Milestone Setup tab of a selected Study Calendar.

7.4.1 Admin Schedule Calendar Status

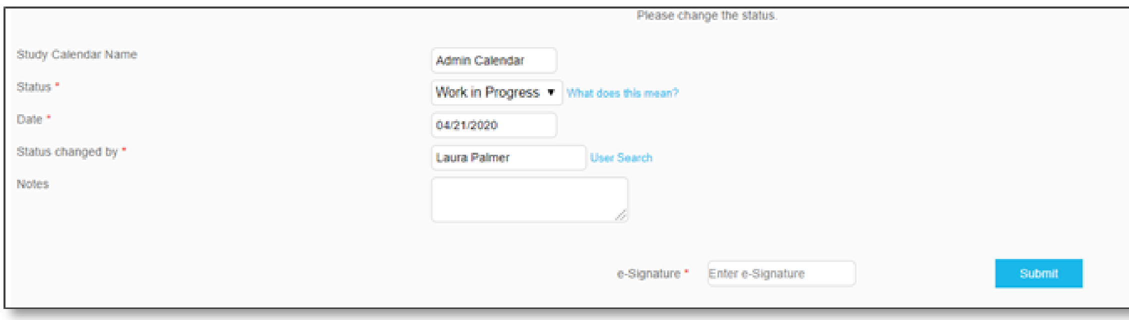
The default calendar status once associated to the study is “Work in Progress”. This status allows users to customize the calendar as needed. In order to generate an Admin Schedule, the calendar Status must be set to “Active”.

To change a calendar status on the Admin Schedule tab:

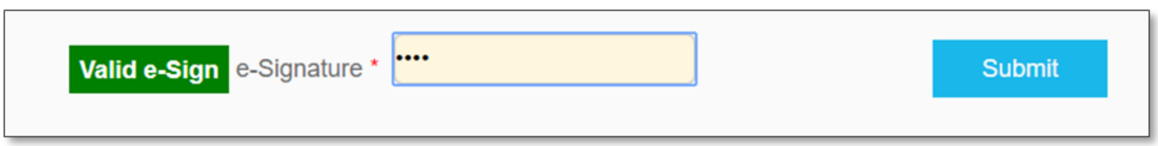
1. From the Admin Schedule tab, select the **Calendar Status** to modify for the desired calendar.



2. The Calendar Status page displays where users can modify the status as needed using the dropdown menus.



3. Enter your e-Signature and click **Submit** to confirm.



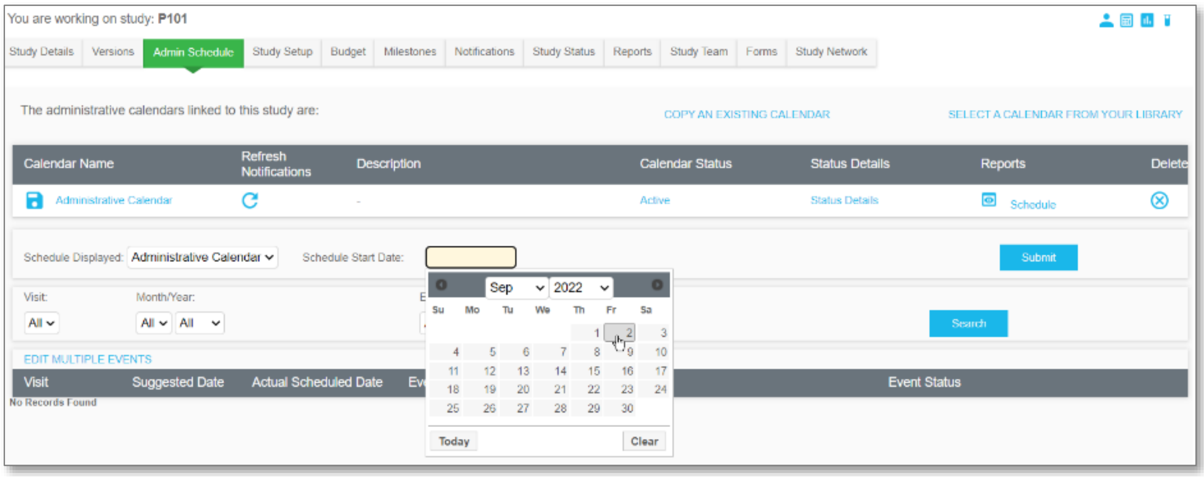
Note: Calendars listed under Admin Schedule do not have the ability to be taken off-line for editing. If a change is needed, the active calendar should be copied, edited, and then saved as an active calendar. The outdated calendar should then be deactivated.

7.4.2 Generate an Admin Schedule

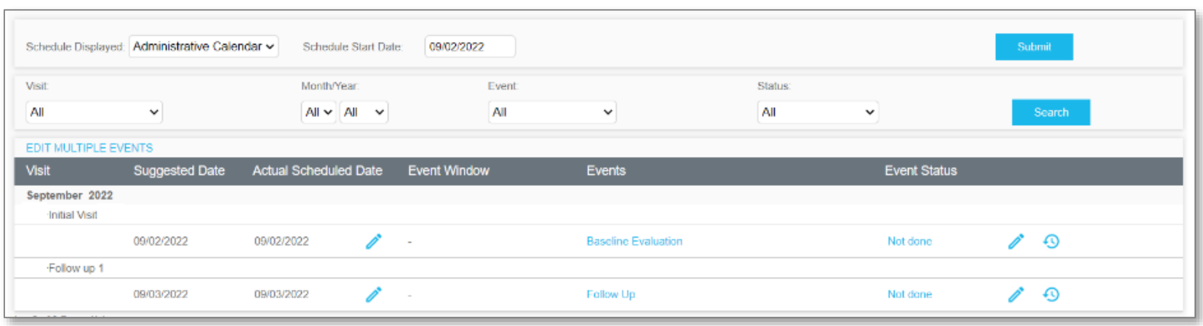
After a calendar is selected for an Admin schedule, the schedule needs to be generated.

To generate an Admin schedule:

1. Navigate to the Admin Schedule tab for a specific study with at least one Admin Calendar added and in active status.



2. Click the field for Schedule a Start date, select a date from the date picker, then click **Submit**. The schedule appears in a table below.

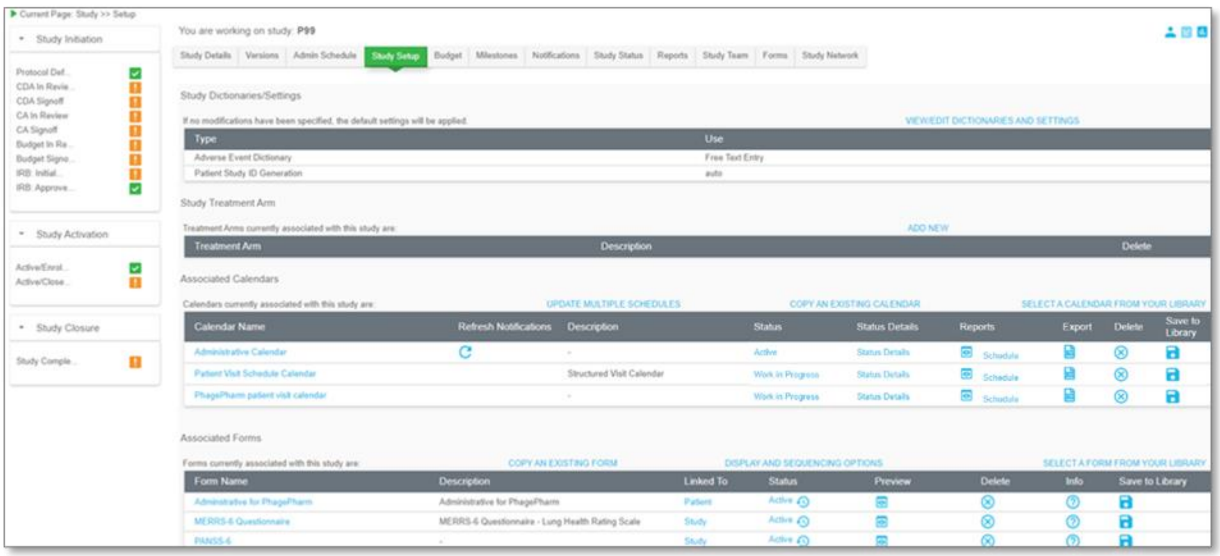


- For information on how to edit and complete the visit and event information in the table above, refer to Change Schedule Dates and Modify an Event Status for a Schedule.
- If editing of the calendar is needed, change the Calendar Status field to Offline for Editing, then make changes, before changing the Calendar Status back to Active.

7.5 Study Setup Tab

This tab allows the study team user to define and/or modify:

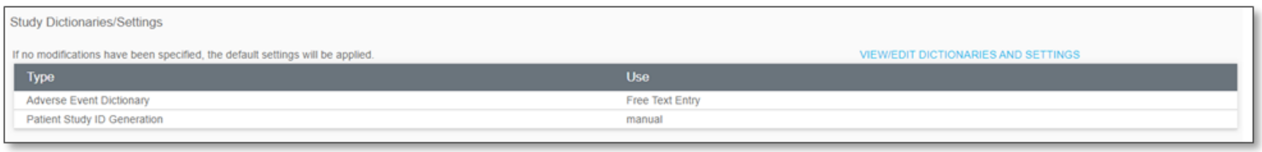
- **Study Dictionaries/Settings**: Define and modify the Adverse Event Dictionary and Patient Study ID Generation
- **Study Treatment Arm**: Define and associate any treatment arms that are appropriate for the selected study
- **Associated Calendars**: Associate Calendars from the Calendar Library
- **Associated Forms**: Associate Forms and define as Study or Patient centric



7.5.1 Study Dictionaries/Settings

Within the Study Dictionaries/Settings permissioned users can define and modify the Adverse Event Dictionary and the how Patient Study IDs will be generated.

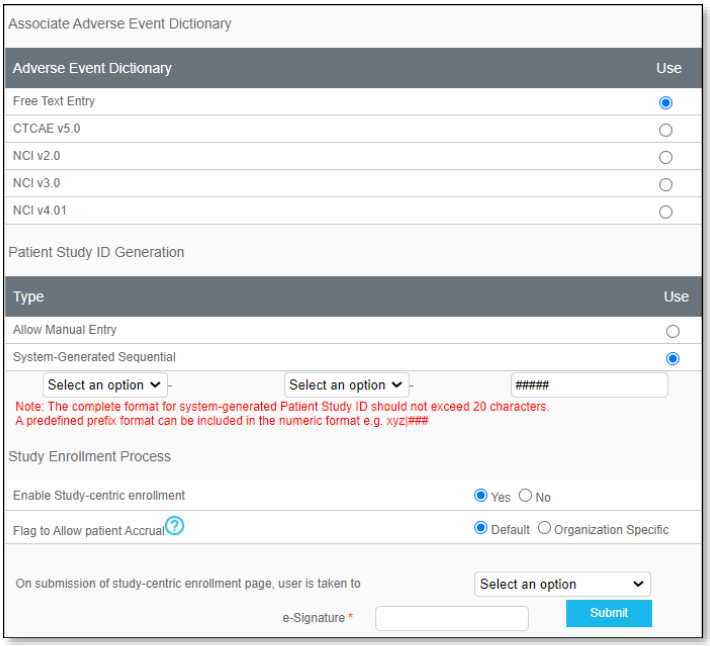
Enterprise Only: The Adverse Event Dictionary is an eResearch Enterprise only feature.



To define Study Dictionaries/Settings:

1. From the Study Setup tab, select the **View/Edit Dictionaries** and Settings link.

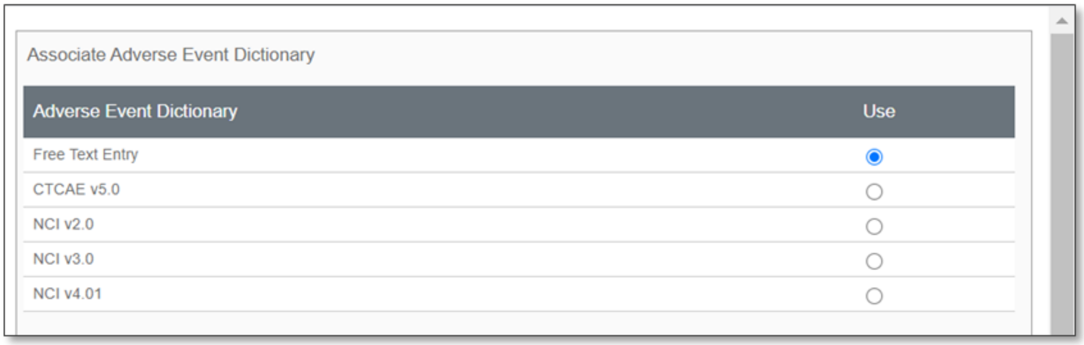
A Dictionaries and Settings window will display.



Options	Description
Adverse Event Calendar	Users may define by selecting a radio button for the appropriate dictionary for the study. [Enterprise Version only]
Patient Study ID Generation	Users may define if the Patient Study ID Generation will Allow Manual Entry or be System-Generated Sequential. ▪ If System-Generated Sequential was selected, the format may be further defined by selecting from the two dropdowns as either Study or Site ID, and the default hash tags may be increased or decreased in number, if needed. For example, a system-generated patient study ID may appear in the format as Study-Site ID-###.
Enable Study-centric Enrollment	Users may keep the default No, or, if changed to Yes, study-centric enrollment will be permitted, and the Add New Patient button will be functional in the Enrollment tab for patient management. ▪ For Yes, the *Select an option* dropdown may be clicked and a patient location or form may be selected as the landing page a user will be taken to after adding a new patient from the Enrollment tab.
Flag to Allow Patient Accrual	Users may keep the Default option to Flag to Allow for patient Accrual or they may select the radio button to change the option to Organization Specific. Hover over the question mark to view more information.

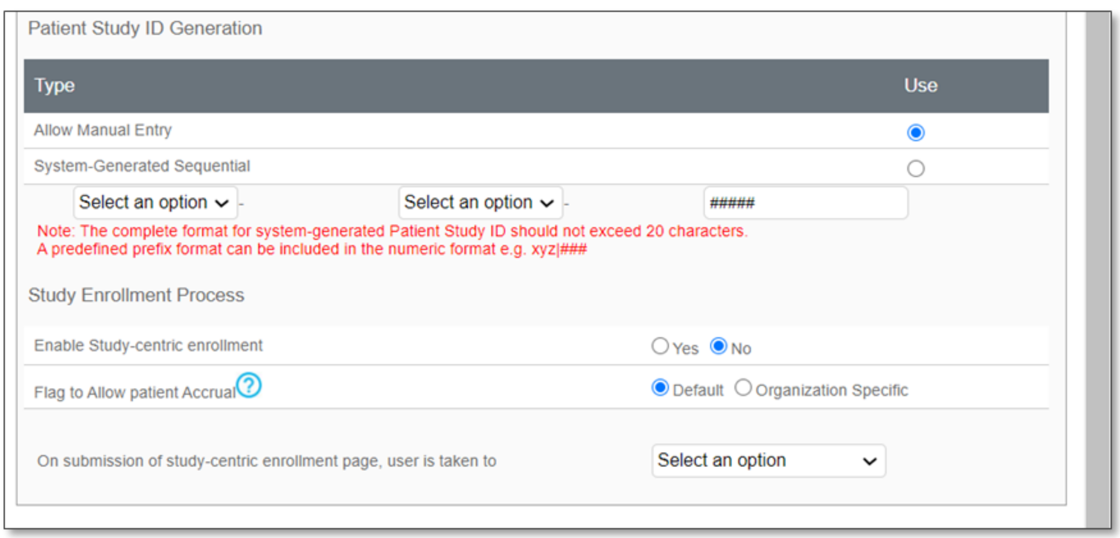
7.5.1.1 Associating the Adverse Event Dictionary (Enterprise version only)

To associate the Adverse Event dictionary to be used for the study, check the appropriate radio button.



7.5.1.2 Patient Study ID Generation

Velos eResearch provides two options for the generation of Patient IDs: Manual creation or system generated sequential. If the system generated option is selected, the format for Patient IDs must also be defined.



Patient Study ID Generation Type	Description
Allow Manual Entry	This option allows permissioned users to set the Patient Study IDs to be defined manually by Patient Management tasked users.
System-Generated Sequential	This option allows permissioned users to set the Patient Study IDs to be automatically generated sequentially by the system upon patient record creation.

Note: Numbers entered in the ##### field represent the length of the number. When determining the length keep in mind the number of patients planned for enrollment. For example, if 1,000 or more patients will be enrolled into the study, indicate four #### instead of three ###.

7.5.1.3 Study Enrollment Process

The Study Enrollment process has the following options:

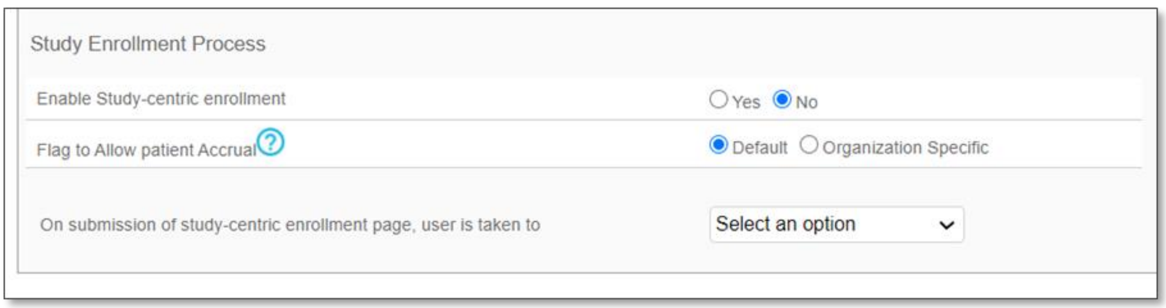
Field Name	Description
Enable Study-centric Enrollment	This option registers to a new patient and associates them to a study through a one step process and allows for the study team to determine which form or page the user is directed to after the patient is registered in the system. The Patient Study ID will be the Patient ID when registering the patient and defaults to “No” if one does not already exist. Click the “Yes” radio button to allow this type of enrollment.
Flag to Allow Patient Accrual	This option allows users to select Default or Organization Specific. The “Organization Specific” option determines when patients can be associated to a study based on whether a study has Active/Enrolling status, or Active/Closed status. Select “Organization Specific" when the ability to accrue a patient is specific to the status at the organization the patient will be/is associated to. The Default option allows for: ▪ 'Active/ Enrolling' equivalent study status entered for any Organization ALLOWS patient accrual by ANY Organization in the Study Team ▪ ‘Closed to Accrual' equivalent study status entered for any Organization STOPS patient accrual by ANY of the Organizations in the Study Team ▪ ‘Temporary Suspension’ entered for any Organization STOPS patient accrual by ANY of the Organizations in the Study Team ▪ 'Permanent Closure' equivalent study status entered for any Organization STOPS patient accrual by ANY one of the Organizations in the Study Team

Field Name	Description
On submission of study-centric enrollment page, user is taken to	Select the appropriate option if the user should be directed to a specific page.

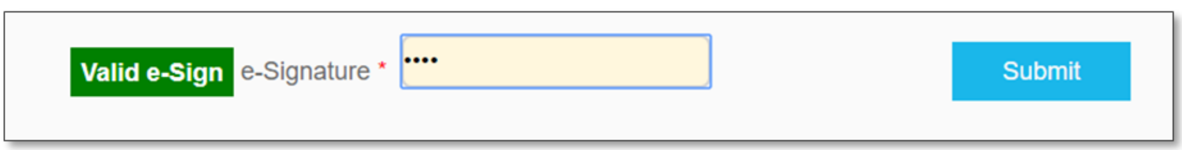
Warning: Most customers do not enable study-centric enrollment as it may result in duplicate patients. Use this function with care. This option should not be used if there is an ADT (Admissions, Discharges, and Transfers) interface.

To set the study enrollment information:

1. Select the appropriate settings for your study in the Study Enrollment Process section.



2. Enter your e-Signature and click **Submit** to confirm.

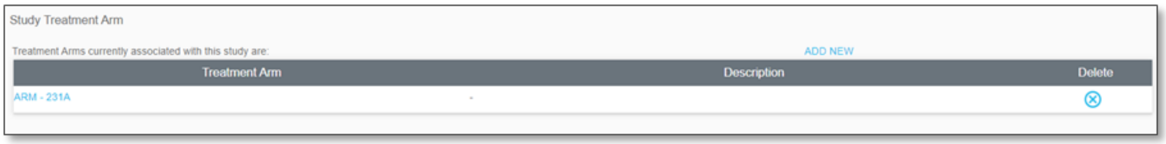


7.5.2 Study Treatment Arms

The Study Treatment Arm section allows the study team user to define the treatment arms for the study. When a patient is linked to a study, a treatment arm for the patient can be specified.

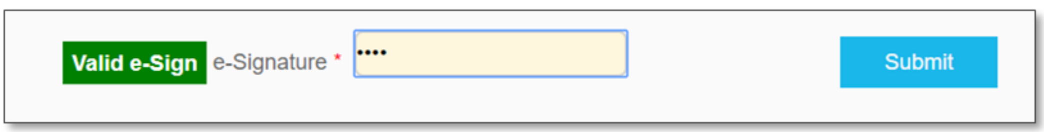
To manage treatment arms:

1. From the Study Treatment Arm section click **Add New**.



The Study Treatment Arm window displays:

2. In the **Name** field, enter a name for the treatment arm. In the **Description** field, enter a description of the treatment arm being created. Fields marked with an asterisk are required.
3. To save changes, enter your e-Signature and click **Submit** to confirm.



7.5.3 Associated Calendars

In the Study Setup tab, Calendar templates from the Calendar Library can be associated to one or more studies. When a Calendar template is associated, it can be modified as needed for the study. Any changes made at the study level will not impact the template in the Calendar Library.

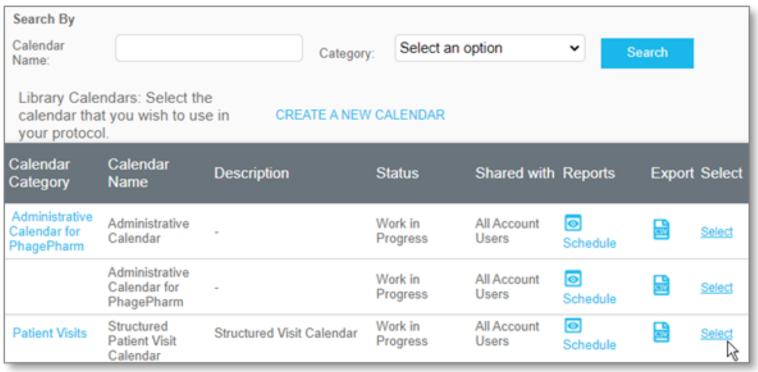
7.5.3.1 Associate a Calendar to a Study

Before a calendar can be associated to a study, a template must exist in the Calendar Library. For information on the creating Calendar templates, see Calendar Management.

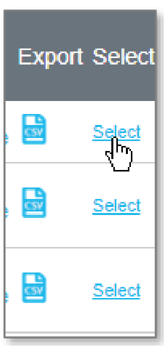
To associate a calendar to a study:

1. Navigate to the Associated Calendars section and click **Select A Calendar From Your Library**.

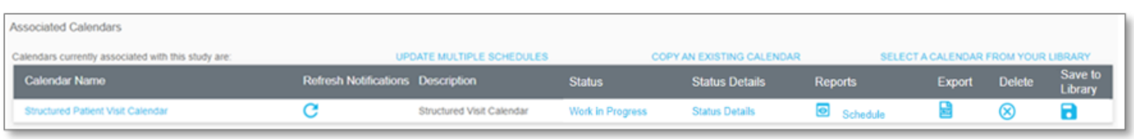
2. The Calendar Library window opens with available calendars to associate to your study.



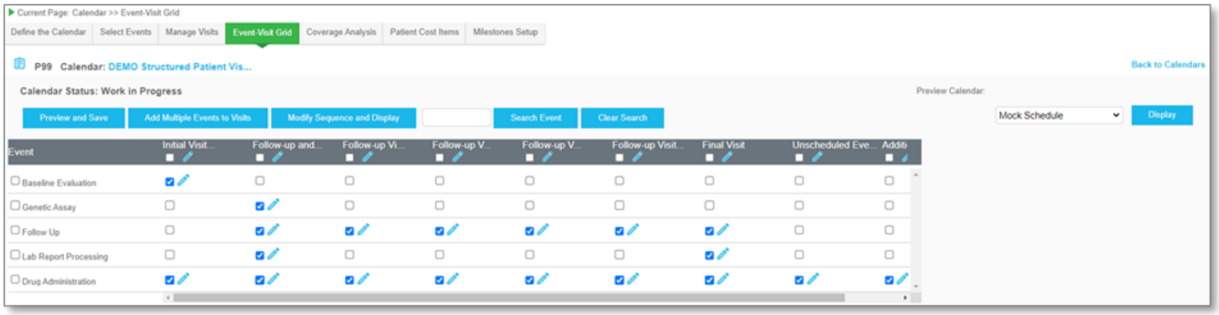
3. Click **Select** to select the appropriate calendar to associate to your study.



The Study Setup page refreshes and the newly associated calendar displays:

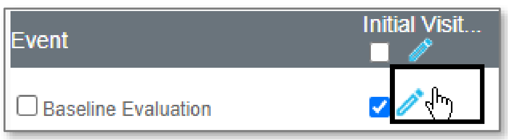


Clicking on the **Calendar name** allows users to modify the calendar event and visit tabs:

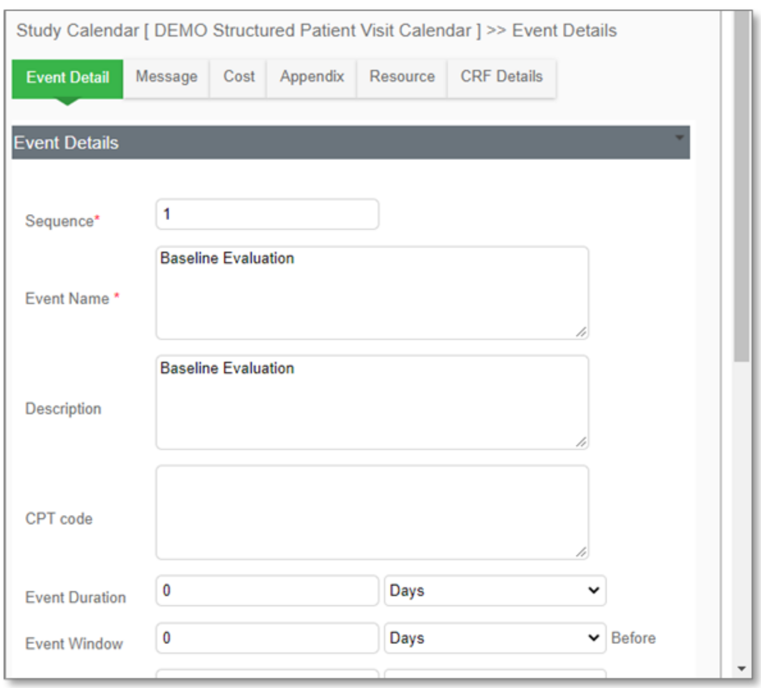


- Here, users can modify visits and/or add events and associated costs to customize the calendar for the study. Changes made here will not impact the template in the Calendar Library.

4. To access a specific Event Details page, from the Calendar click an **Edit** button.



The Event Details page opens.



View the table below for links to other sections that provide information on how to update the tabs in the Event Details page.

Tab Name	Section Link for More Information
Event Details	Add an Event
Message	Event Message
Cost	Event Cost
Appendix	Event Appendix
Resource	Event Resources
CRF Details	Event CRF Details

Note: Changes may only be made to a calendar when the status is Work in Progress or Offline for Editing.

7.5.3.2 Managing a Calendar Budget

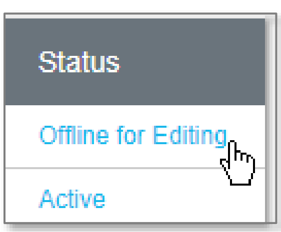
After customizing the calendar for a study, a budget template can be associated to the calendar to manage study financials. Budget templates are explained in detail in Financial Management.

7.5.3.3 Modify a Calendar Status

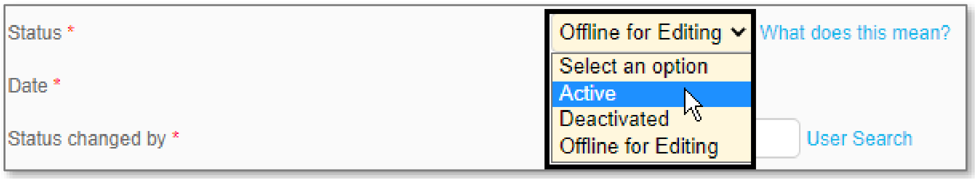
When a calendar is associated to a study, the default status is “Work In Progress”. The “Offline for Editing” status is used when a calendar is active, and edits are needed.

To activate a study calendar:

1. Click the **Status** for the calendar that you wish to activate.

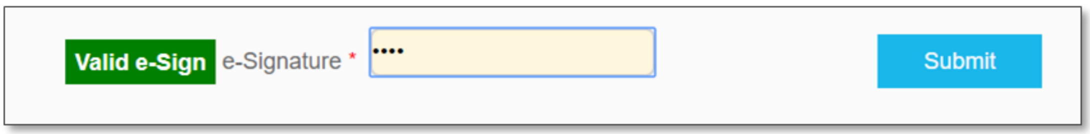


2. Using the **Status** dropdown menu, change the status to **Active** to activate the calendar.



Note: Ensure all aspects of a calendar are updated /configured (including budgets) before activating and enrolling patients.

3. Enter your e-Signature and click **Submit** to confirm.



The calendar status is saved.

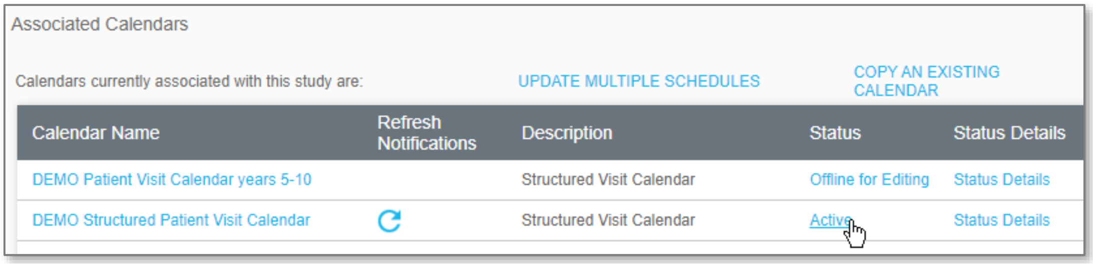
7.5.3.4 Modify an Active Calendar

This section will instruct how to take an Active Calendar and change it to the Offline for Editing status.

Note: After a calendar is edited, a user has the option to save the calendar back to the library as a new template by clicking **Save to Library**, completing the pop-up, and submitting.

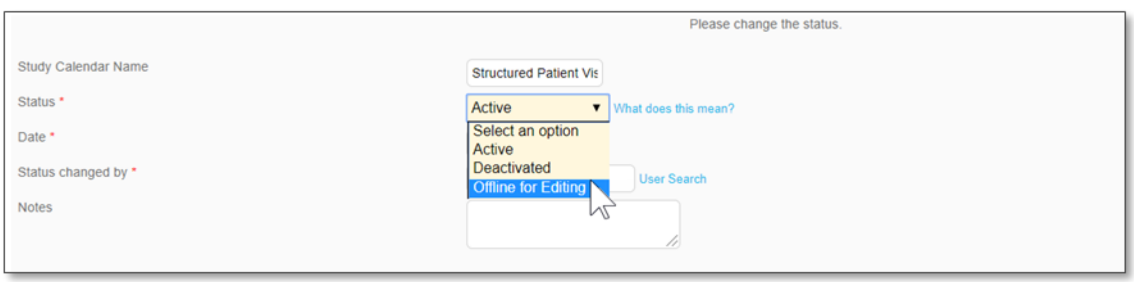
To make a Calendar Offline for Editing:

1. From the Study Setup tab, navigate to the active calendar that you would like to modify and click the **Status**.

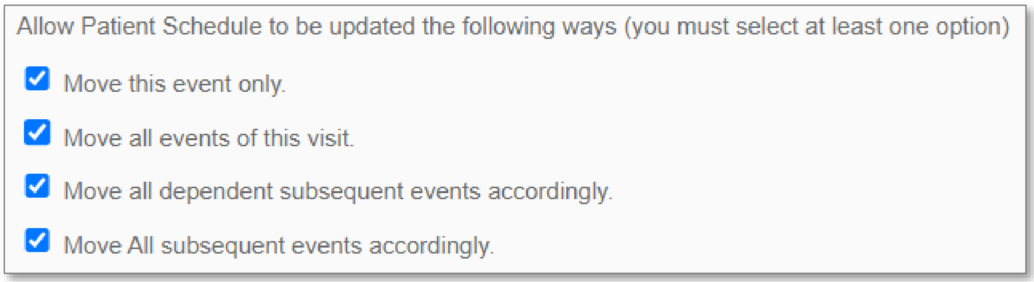


The status page displays:

2. Using the dropdown options, select the **Offline for Editing** status.

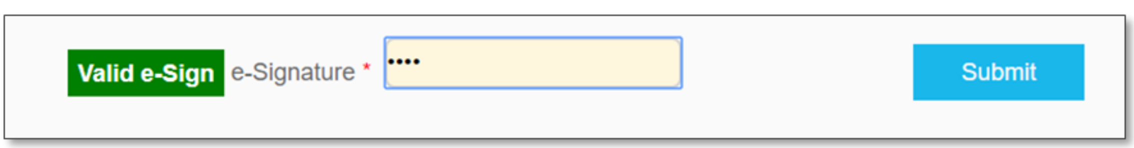


3. Additionally, the checkboxes below may be modified, as needed, by checking the appropriate checkboxes. The selected options give study team members/ study coordinators the selected abilities to change a schedule.



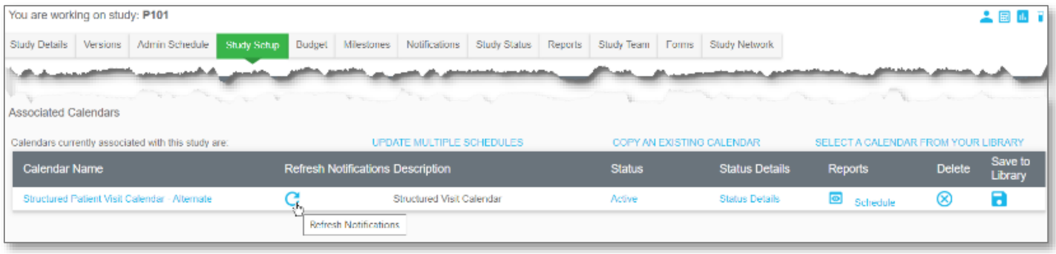
- Only selections made will appear in patient schedules when a user is updating event dates
- The first checkbox option allows only the specific event to be moved. This option may be needed if only a specific event requires moving in a visit, perhaps due to a piece of equipment not being available that day or at that location.
- The second checkbox option allows the entire visit and events to be moved. This option may be needed if perhaps a patient cannot make the visit or the visit needs to be scheduled due to unforeseen circumstances.
- The third checkbox option allows not only the event to be moved but all event that are dependent on that event to occur to be moved accordingly. This option may be needed if perhaps a visit has one event that is being moved by a great amount of time and the other visits and events all need to occur a specific amount of time after their suggested dates.
- The fourth checkbox option allows for not only all dependent visits to be moved but also visits that are not dependent on the event to be moved. This option may be needed if perhaps a visit needs to be moved by a great amount of time, such as half a year, and there are not only dependent events but an event such as one that occurs at a half year point and that date also needs to be moved by half a year.

4. Enter your e-Signature and click **Submit** to confirm.



5. Revise the calendar, visits and events as needed. For more information, refer to Calendar Management.

6. After all updates have been made, as needed, follow steps 1 to 4 above to save the calendar as Active.
7. If a notification associated to an event has been updated, click **Refresh Notifications** for a calendar to initiate sending out the new / modified notification(s).



- Changes made to Notifications for an active calendar are not automatically applied to existing generated schedules. Clicking Refresh Notifications allows for all existing schedules and future schedules to use the modified notification(s).

7.5.3.5 Update Multiple Schedules

The Update Multiple Schedules function provides options for all patients' schedules associated to a specific calendar to be simultaneously updated. There are times when a modification to a protocol requires a change to the calendar that could affect many patients. This feature allows you to generate, discontinue, or update the event status for a calendar for multiple patient schedules at one time.

Note: Calendars must be in Active status to appear for selection in all four options. Calendars in Work in Progress or Offline for Editing status will not appear for selection.

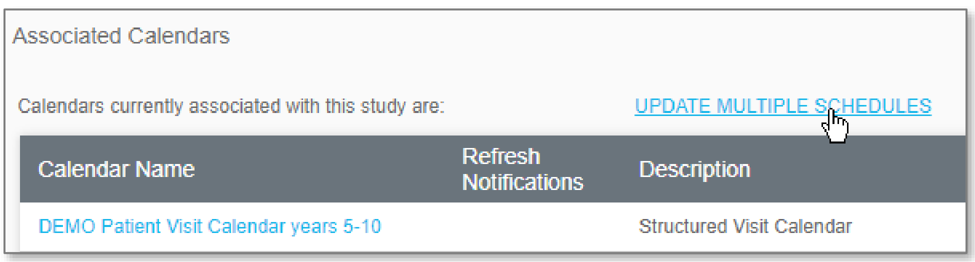
There are four actions in which multiple schedules can be updated at one time.

Update Option Name	Description / Example of Use
Discontinue schedules for all patients assigned to a calendar	May discontinue schedules for all patients and optionally start a new schedule for all patients on the original calendar
	Use when a calendar has become obsolete for all patients and optionally add a new calendar for those patients
	May update all event statuses, from or before a specific date, to a specific status for a discontinued calendar for all patients

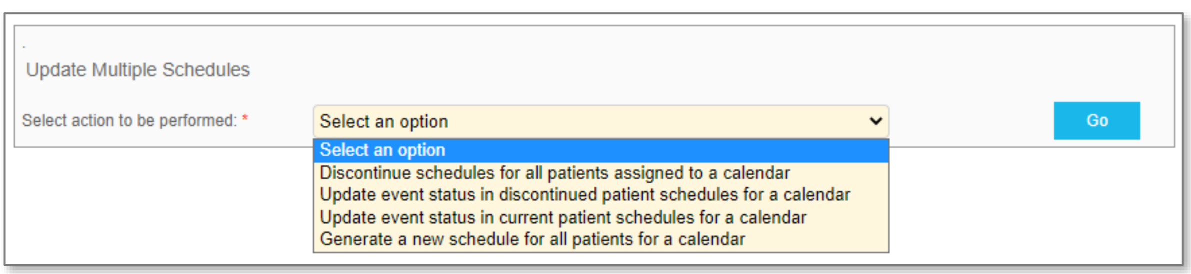
Update Option Name	Description / Example of Use
Update event status in discontinued patient schedules for a calendar	Use when patients had calendars discontinued and the status for all events require an update from or before a specific date
Update event status in current patient schedules for a calendar	May update all event statuses, from or before a specific date, to a specific status for a current schedule for all patients on that calendar
	Use when a group of events, from or before a specific date, need to be marked as a specific status in a current schedule for all patient schedules
Generate a new schedule for all patients for a calendar	May generate a new schedule for all patients assigned to a calendar, from or before a specific date
	Use to generate a new schedule for multiple patients who are new to the specific calendar, from or before a specific date

To update multiple schedules:

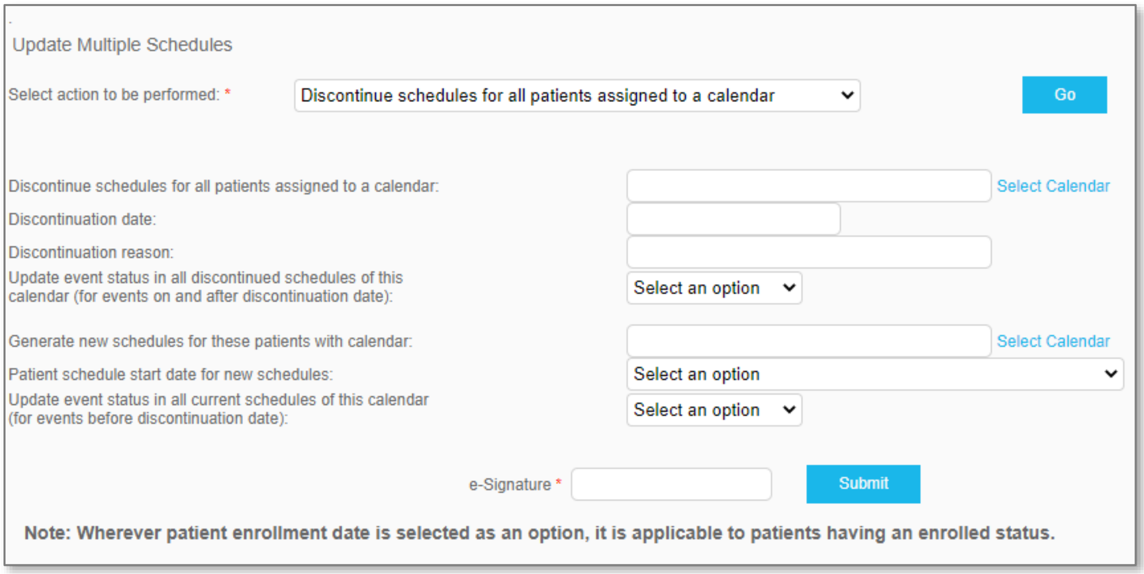
1. From the study Setup tab, click **UPDATE MULTIPLE SCHEDULES**.



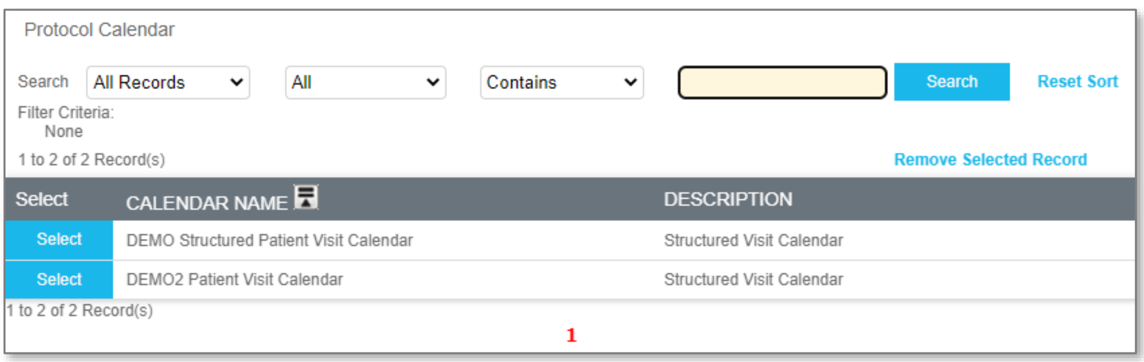
2. In the pop-up, click the **Select an option** dropdown to access actions to be performed.



a. Select **Discontinue schedules for all patients assigned to a calendar**, to perform that action, then click **Go**.



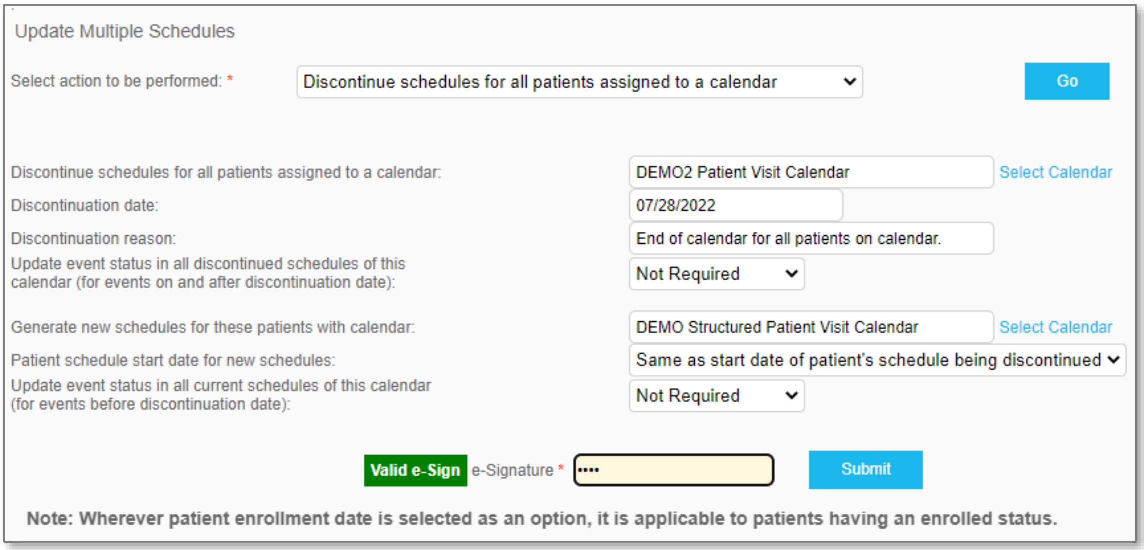
i. Click **Select Calendar** and then click **Select** in the pop-up for the appropriate calendar(s).



ii. Use a date picker to select the Discontinuation Date; enter an appropriate Discontinuation reason; Update event status in all discontinued schedules, as per options in dropdown; and then select the new calendar to Generate new schedules from after clicking **Select Calendar**.

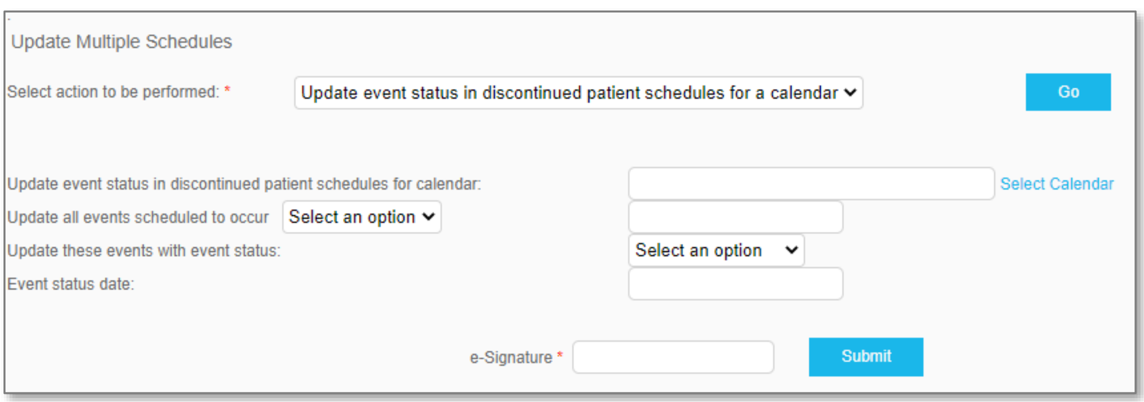
iii. For the Patient schedule start date for new schedules select either *Same as start date of patient's schedule being discontinued* or *Same as patient's enrollment date*.

iv. Select the Update event status in all current schedules, as per the dropdown options, enter your e-Signature, then click **Submit**.



v. All patients on the discontinued calendar(s) will have the schedule(s) end and the new schedule begin.

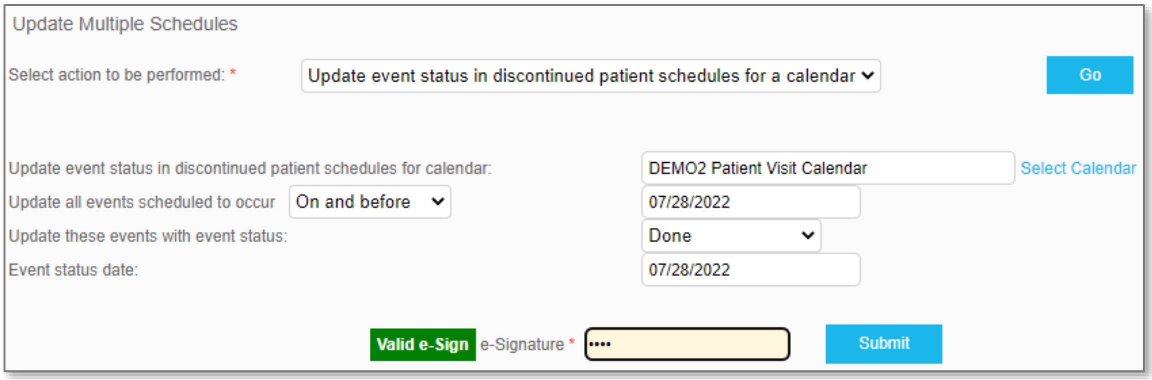
b. Select **Update event status in discontinued patient schedules for a calendar**, to perform that action, then click **Go**.



i. Click **Select Calendar** to select a calendar to Update event status in discontinued patient schedules.

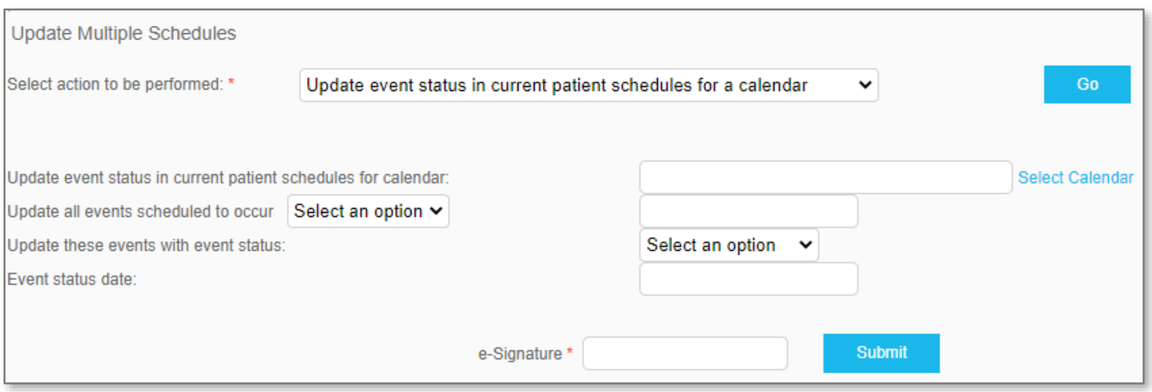
ii. For the *Update all events scheduled to occur* dropdown select from: Before, On and before, After, or On and after, then use the Date Picker to select a date.

iii. Use the Date Picker to select an Event status date, enter your e-Signature, then click **Submit**.



All patient schedules associated with the selected calendar(s) will now have event statuses updated as per selections made.

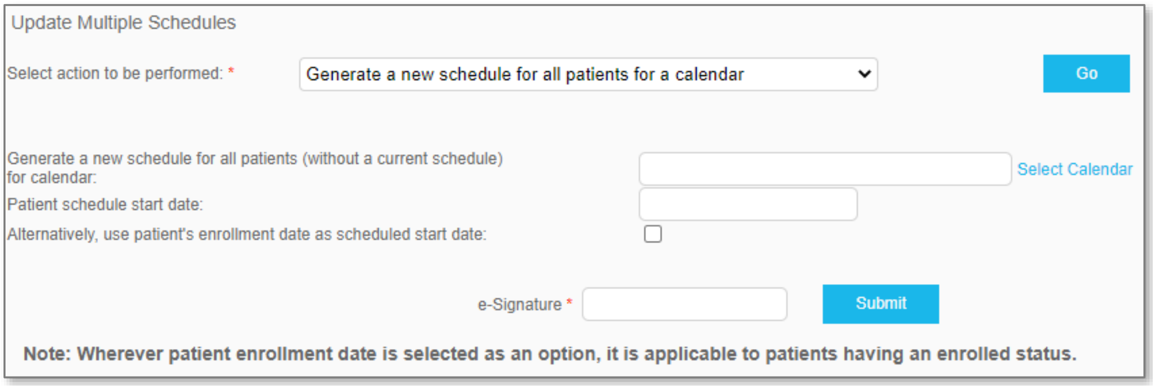
c. Select **Update event status in current patient schedules for a calendar**, to perform that action, then click **Go**.



i. Make selections using the same steps as above for *Update event status in discontinued patient schedules for a calendar*.

After submitting, all patient schedules associated to the current calendar selected will have the events status(es) updated as per selections made.

d. Select **Generate a new schedule for all patients for a calendar**, to perform that action, then click **Go**.



i. Click **Select Calendar** to select a calendar to *Generate a new schedule for all patients (without a current schedule)*.

ii. Use the Date Picker to select a Patient schedule start date.
-OR-
Check the checkbox for Alternatively, use patient's enrollment date as scheduled start date, if applicable.

iii. Enter your e-Signature, then click **Submit**.

All patients without a current schedule will have a new schedule generated for the calendar selected as per the start date selected.

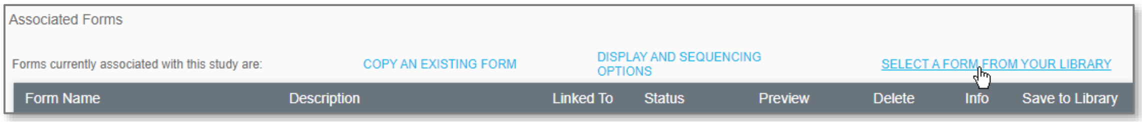
7.5.4 Associated Forms

This section explains how a study team user can add study-specific forms from the Forms Library, modify forms, and activate the form.

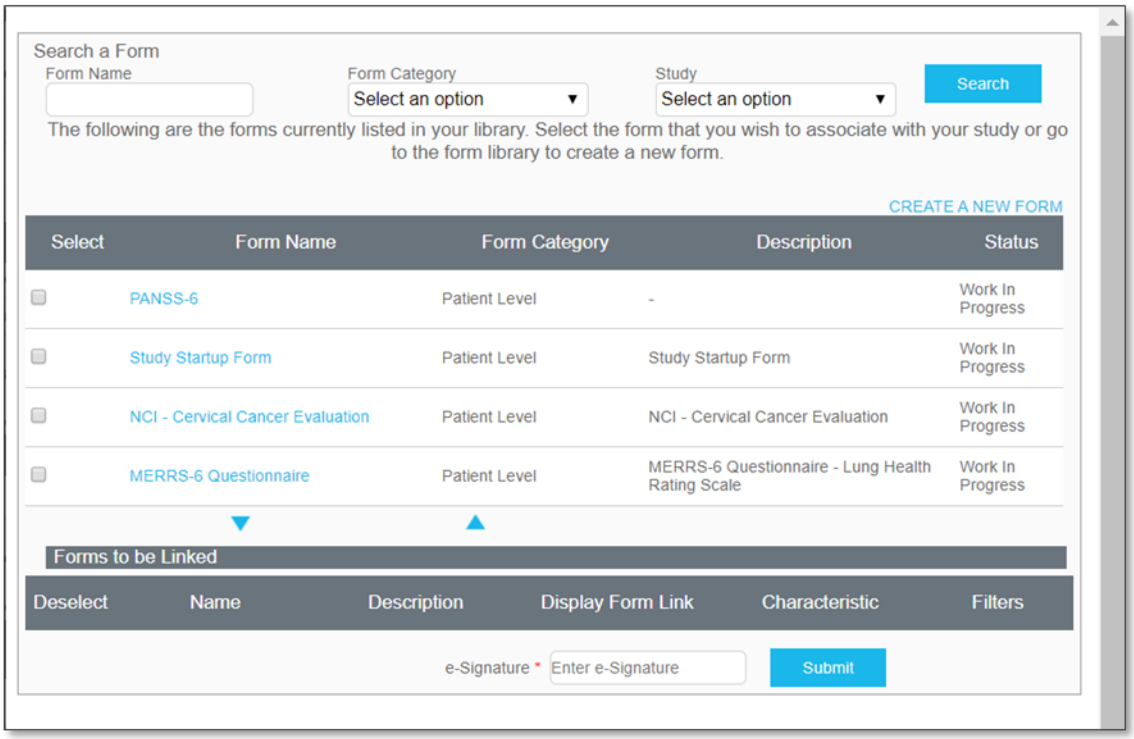
Forms added will be required to be associated to either the Study level or Patient level. Study Forms once associated and activated can be later managed on the Study Forms tab. Patient Forms once associated and activated can be managed on a patient level.

To Add a Form:

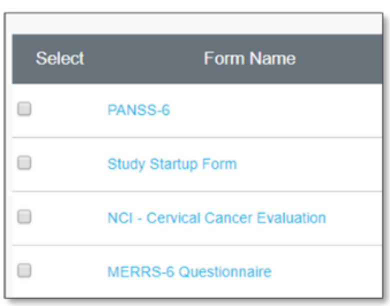
1. Navigate to the Associated Forms section and click **Select a Form from Your Library**.



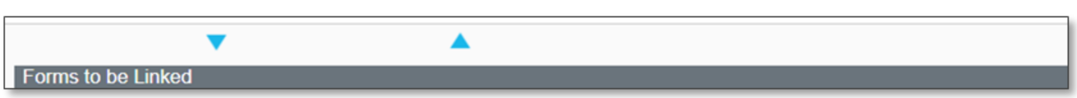
The Add Forms window will display:



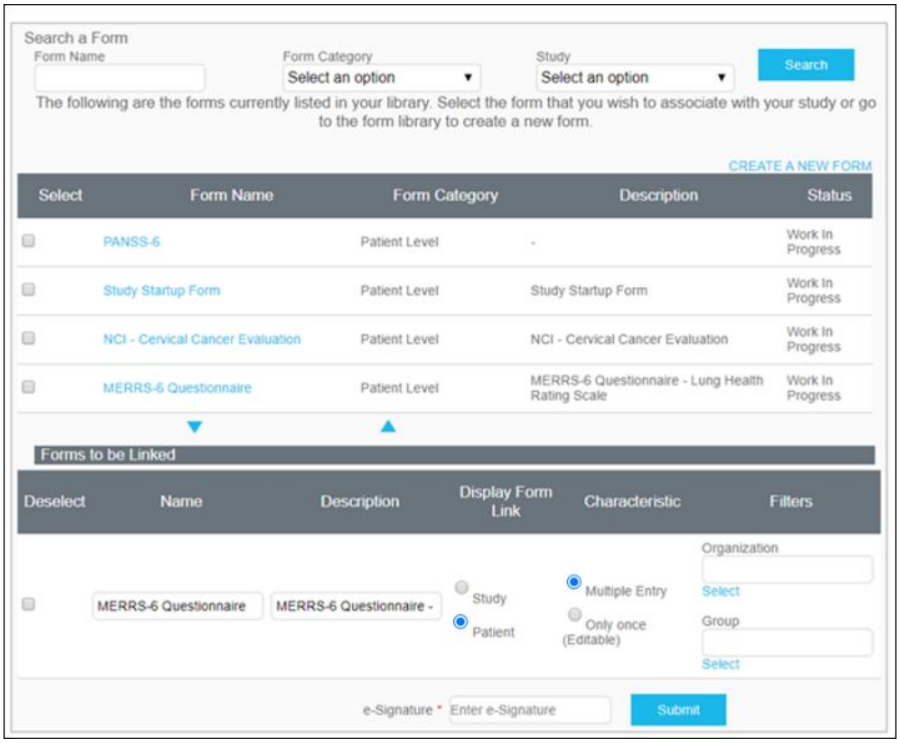
2. Click the checkbox next to the appropriate form to associate.



3. Click the **down arrow** button to add the selected form(s) to the Forms to be Linked section.



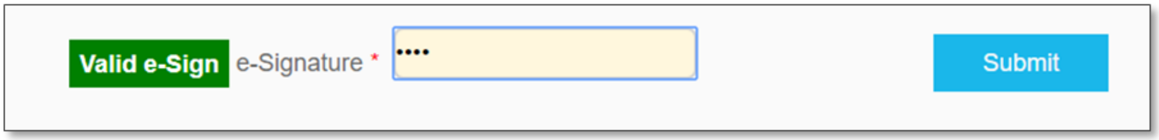
4. Define how the form is to be associated using the following columns in the **Forms to be Linked** section of the page:



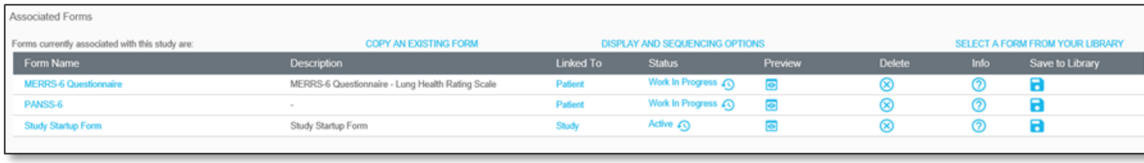
Column	Column Description
Name	Users may edit the form name for the form being associated with the study.
Description	Users may edit a description of the form being linked to the study.
Display Form Link	Users may select whether the Study or Patient page should link the form.
Characteristic	Users may select whether the formed being linked will be a Multiple Entry or Once (but Editable).
Filters	Users may select an Organization or Group to filter the form being linked.

Note: Multiple Entry means that form will have multiple entries of different datasets. Once (but Editable) means that there will be only one dataset submitted for this form (one time), but the user can edit that single entry at any time. If edited, the Audit Trail report for the response displays all changes made to the original response.

5. Enter your e-Signature and click **Submit** to confirm.



The Associated Forms will now be listed under the Associated Forms section on the Study Setup page:

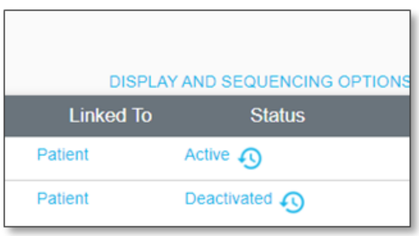


7.5.4.1 To Change a Form Status

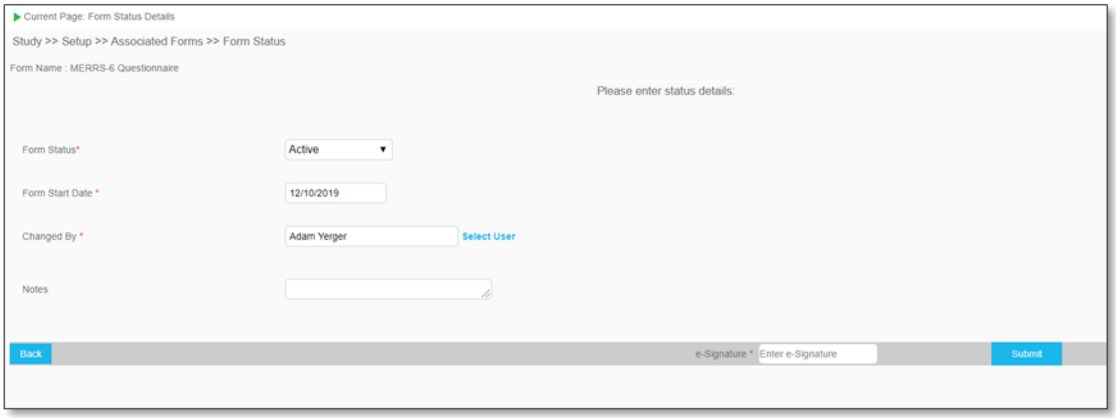
Once a form has been associated on a Study or Patient level, the form status must be "Active" before it can be used.

To change a form status:

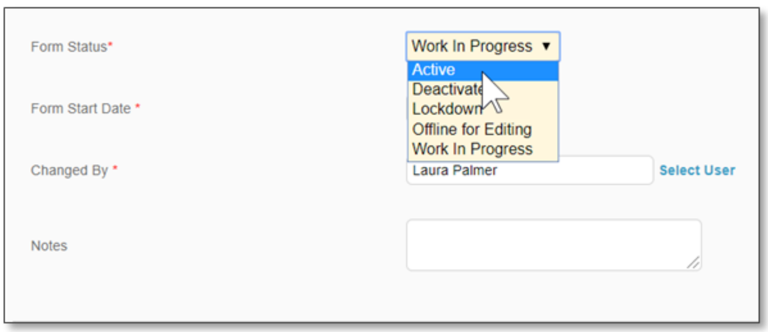
1. Click the **Status** link for the desired form.



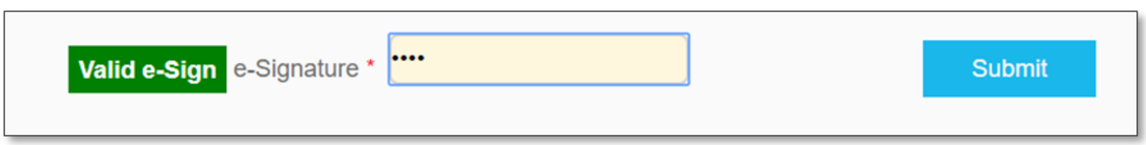
The Form Status page displays:



2. Use the dropdown menu to set the appropriate status.

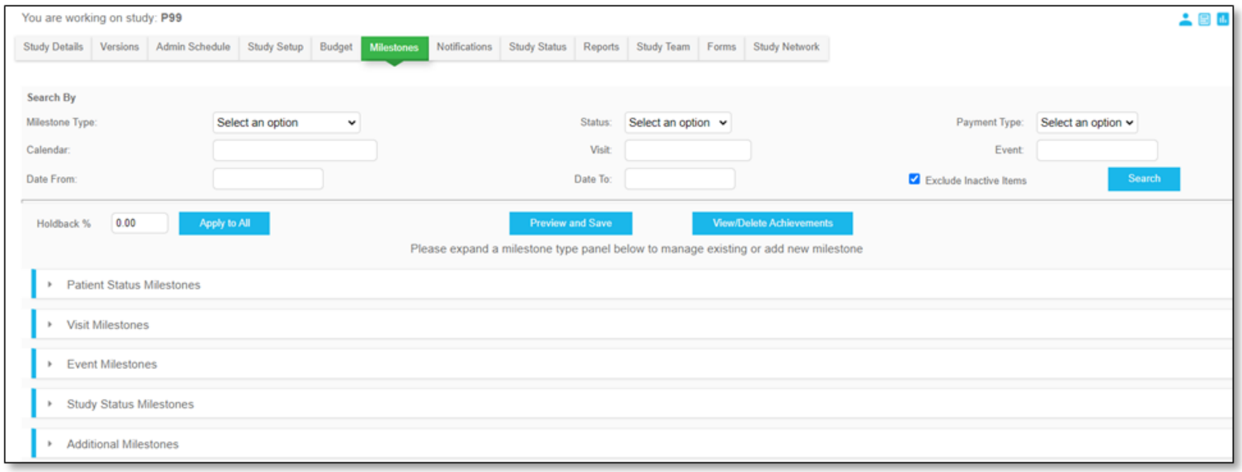


3. Enter your e-Signature and click **Submit** to confirm.



7.6 Study Milestones Tab

The Milestone tab allows the study team user to create and manage Milestones. There are five Milestone Types: Patient Status, Visit, Event, Study Status, and Additional Milestones. For additional information about Milestones, Budgets and Financials, see Financial Management.



When adding milestones, all mandatory fields are indicated by an asterisk and are defined below.

Note: If there is study calendar with a budget, create the initial Visit and Event milestones from the Manage Budget tab.

Milestone Section	Column Name	Description	Example
Patient Status	**Patient Count**	Specify the number of the patients that should be tracked. This column does not apply to the "Study Status" milestone type.	If a sponsor pays for every fifth patient screened, enter "5". When every fifth patient on the study has the screen status added, a milestone will be achieved.
	Patient Status	Specify the desired patient status that should be tracked.	N/A
	Milestone Status	Specify the "Active" status when the milestone should be turned on or select "Inactive" if a Milestone no longer applies.	N/A

Milestone Section	Column Name	Description	Example
Visit	**Calendar**	Select the study calendar from which you want to derive the visit milestones.	N/A
	Visit	Specify the visit name for the milestone.	N/A
	Milestone Rule	Select the logic that determines when the visit is considered complete.	Options include: "**All events within the visit are marked as-**", "**At least one event is marked as-**", and "**On Scheduled Date**".
	Event Status	Dependent on Milestone Rule field. This completes the logic selected in the previous field. This field is left blank if "On Scheduled Date" is selected in previous field.	Options include: "**Not Done**", "**Not Required**", "**Done**", "**To be rescheduled**", and "**Suspended**".
	Milestone Status	Specify the "Active" status when the milestone should be turned on or select "Inactive" if a Milestone no longer applies.	N/A
Event	**Calendar**	Select the study calendar from which you want to derive the event milestones.	N/A
	Visit	Specify the visit name for the milestone.	N/A
	Event	Specify the specific event associated with the calendar visit for this milestone.	N/A
	Milestone Rule	Select the logic that determines when the event is considered complete.	Options include: "**All events within the visit are marked as-**", "**At least one event is marked as-**", and "**On Scheduled Date**".
	Event Status	Dependent on Milestone Rule field. This completes the logic selected in the previous field. This field is left blank if "On Scheduled Date" is selected in previous field.	Options include: "**Not Done**", "**Not Required**", "**Done**", "**To be rescheduled**", and "**Suspended**".

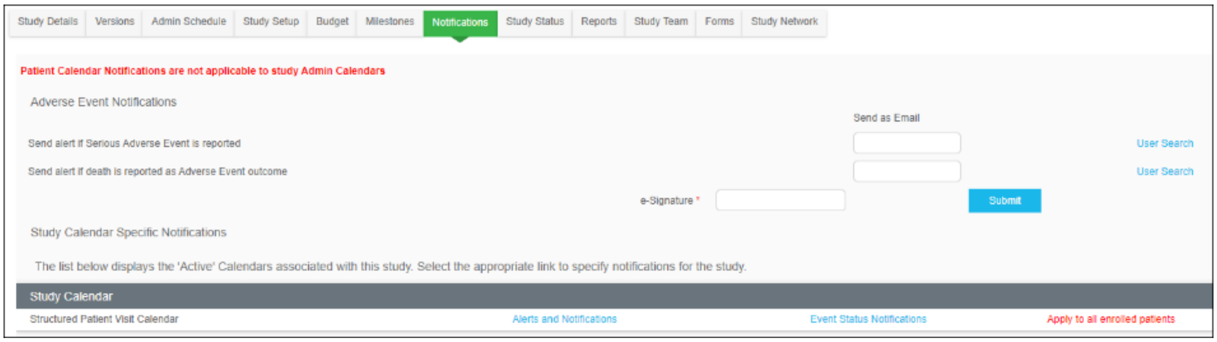
Milestone Section	Column Name	Description	Example
	Milestone Status	Specify the “Active” status when the milestone should be turned on or select “Inactive” if a Milestone no longer applies.	N/A
Study Status	**Study Status**	Specify the study status that must be achieved for the milestone to be considered complete.	e.g. – “**Active/Enrolling**”, “**IRB: Approved**”, etc.
	Milestone Status	Specify the “Active” status when the milestone should be turned on or select “Inactive” if a Milestone no longer applies.	N/A
Additional	**Milestone Description**	Enter a description of the milestone.	Any activity that needs to be invoiced but the activity does not have a specific time point, e.g. – “**Startup Fees**” “**Contract Renewal**”, “**Custom Recruitment/Retention Milestone**”, etc.
	Milestone Status	Specify the “Active” status when the milestone should be turned on or select “Inactive” if a Milestone no longer applies.	N/A

7.6.1 Add Milestones

For instructions on how to Add Milestones, see Milestones.

7.7 Notifications Tab

The Notifications tab allows users to define and set Notifications for a specific Study. In addition to Alerts or Event Status Notifications, users of the Enterprise version may set Notifications for Adverse Events Reported.



A Study Calendar must be associated to a Study prior to the Notifications being set up and must have an “Active” status. For each Study Calendar associated, users may select to set notifications through the following links:

- Alerts and Notifications
- Event Status Notifications

For instructions on how to associate a calendar to a study and activate a calendar, see Study Setup Tab.

Note:
1. Calendar Notifications are not applicable to Study Admin Calendars.
2. After patients have been enrolled to a study and assigned a schedule from the calendar, if changes are made to Notifications, the changes will automatically take affect for any new patients enrolled. To apply the notification changes to patients already enrolled to the Study, click a red ‘Apply to all enrolled patients’ link.

7.7.1 Adverse Event Notifications

Within the Notifications tab, permissioned users may send alerts:

- If **Serious Adverse Event** are reported
- If **Death** is reported as an Adverse Event Outcome

To assign a user as a recipient to either type of Adverse Event Notification:

1. Click **User Search** and select a desired user.

2. Select the user by checking the checkbox to send an Adverse Event Notification to and then click **Submit** to confirm.

Note: To ensure only the relevant users have been selected to receive notifications, confirm the correct users have been selected before clicking on submit.

Enterprise Only: This functionality is only available in the Enterprise version of Velos eResearch.

7.7.2 Alerts and Notifications

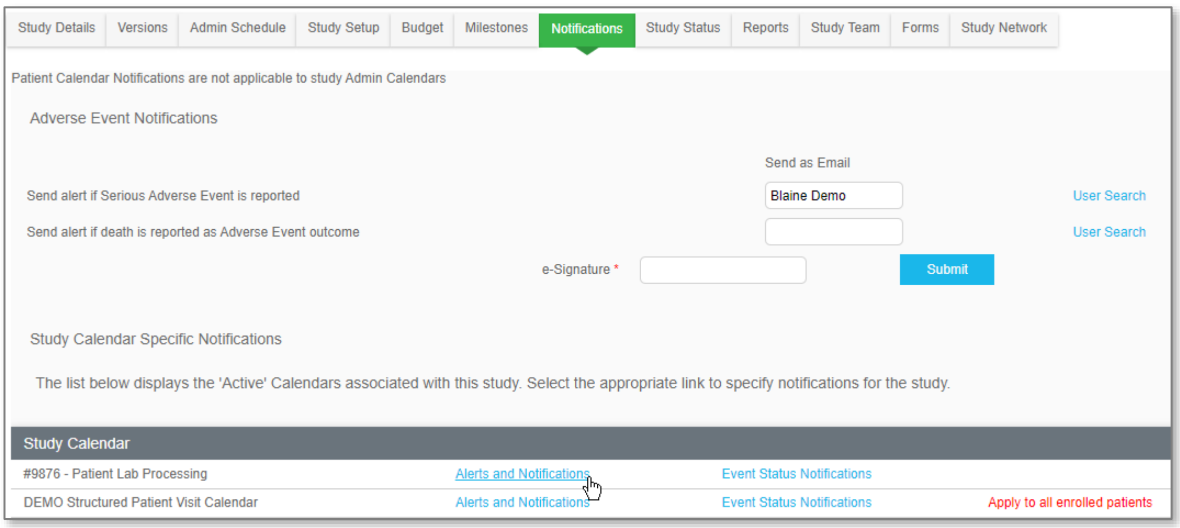
Alerts and Notifications can be set up for Study Calendar events to send an email or text message advising the user when an event has occurred. A calendar must have an “Active” Status in order to set up these alerts and notifications.

> **Note:** Network firewalls may restrict the use of notifications at your location. Please contact your local administrator for more information on the types of notifications you can receive.

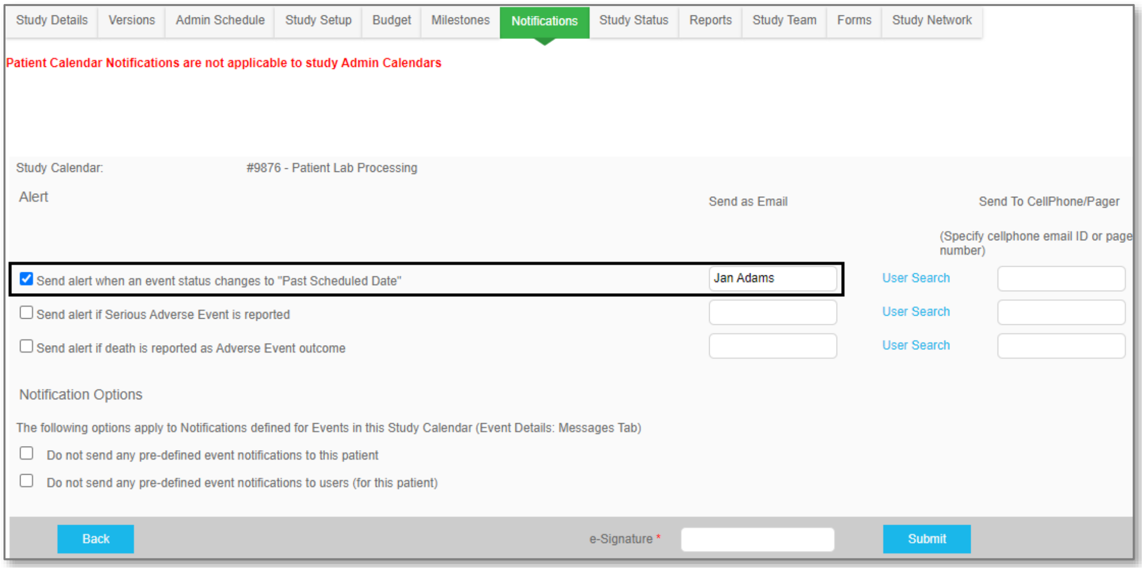
> **Enterprise Only:** The Serious Adverse Event options are only available in the Enterprise version of Velos eResearch.

To create Alerts and Notifications:

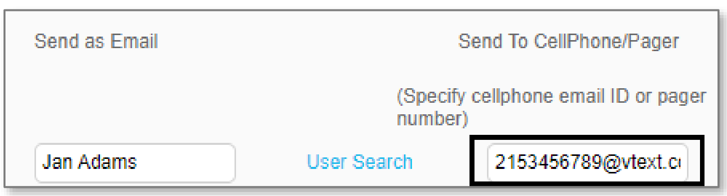
1. Click **Alerts and Notifications** associated with the appropriate study calendar.



2. Check the appropriate checkbox(es) and select a system user to receive the notification by clicking the **User Search.**



3. Additionally, if a user has a cell phone for text messaging alerts, the cell phone can be entered into the box to the right of the User Search link.

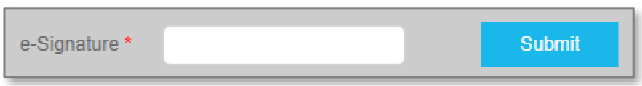


Below is a list of the most common mobile providers and the format used to send text messages:

Mobile Provider	Text Message Format
AT&T	10digitphonenumber@txt.att.net
Carolina West Wireless	10digit10digitnumber@cwwsms.com
Cellular One	10digitphonenumber@mobile.celloneusa.com
Illinois Valley Cellular	10digitphonenumber@ivctext.com
Inland Cellular Telephone	10digitphonenumber@inlandlink.com
Sprint	10digitphonenumber@messaging.sprintpcs.com
T-Mobile	10digitphonenumber@tmomail.net

Mobile Provider	Text Message Format
US Cellular	10digitphonenumber@email.uscc.net
Sprint	10digitphonenumber@messaging.sprintpcs.com
T-Mobile	10digitphonenumber@tmomail.net
US Cellular	10digitphonenumber@email.uscc.net
Verizon	10digitphonenumber@vtext.com
Virgin Mobile	10digitphonenumber@vmobl.com

4. When finished adding users for alerts, enter your e-Signature and click **Submit** to confirm.

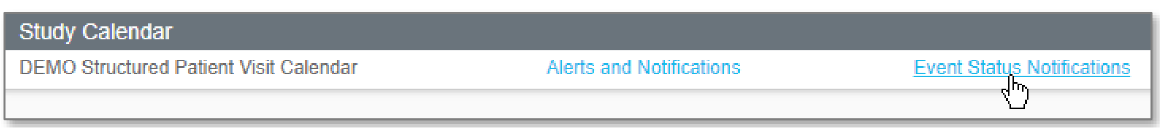


7.7.3 Event Status Notifications

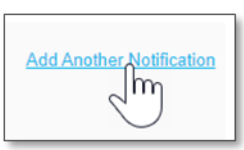
Event Status Notifications are notifications which can be sent when a Status of a Study or Calendar has changed.

To create Event Status Notifications:

1. Click **Event Status Notifications** associated with the appropriate Study Calendar.



2. The Alerts and Notifications page displays. Click **Add Another Notification**.



3. The Alert Notification page will display. Enter information for the Notification, including a user to **Send Message To**, the **When Event Status Changed To** option, and the **For Event** option.

4. Enter your e-Signature and select either **Submit** to save changes, or, **Submit and Add Another**, to add another notification setting.

7.8 Study Status Tab

The Study Status tab allows for the tracking of study activities in the different categories. Some of these categories are:

- Study Activity
- Reports
- Budget
- Contract
- IRB

Display Browser Logic:

For the pages of My HomePage, Gadgets>Quick Access, and Manage Protocols>Search, Study Status displays on the browser when:

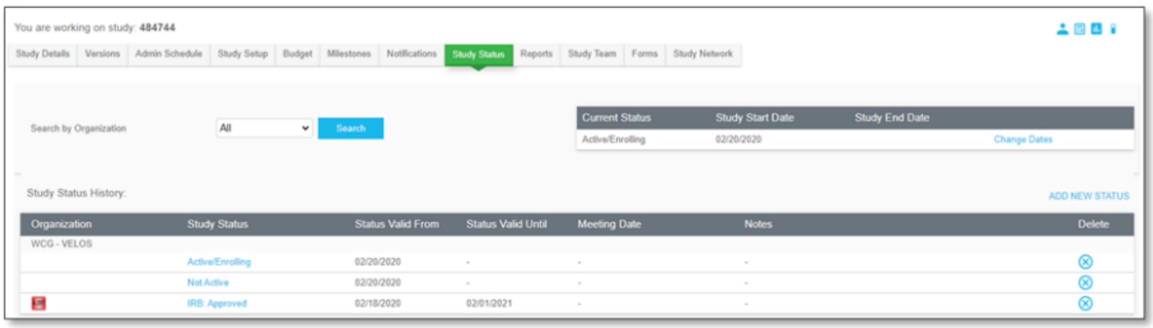
- The status is flagged to display in the browser

AND

- The Current Status checkbox is checked for the status for the default study organization

OR

- The status was the most recent one added of the statuses flagged to display in the browser and a non-flagged status has the Current Status checkbox checked for the default study organization



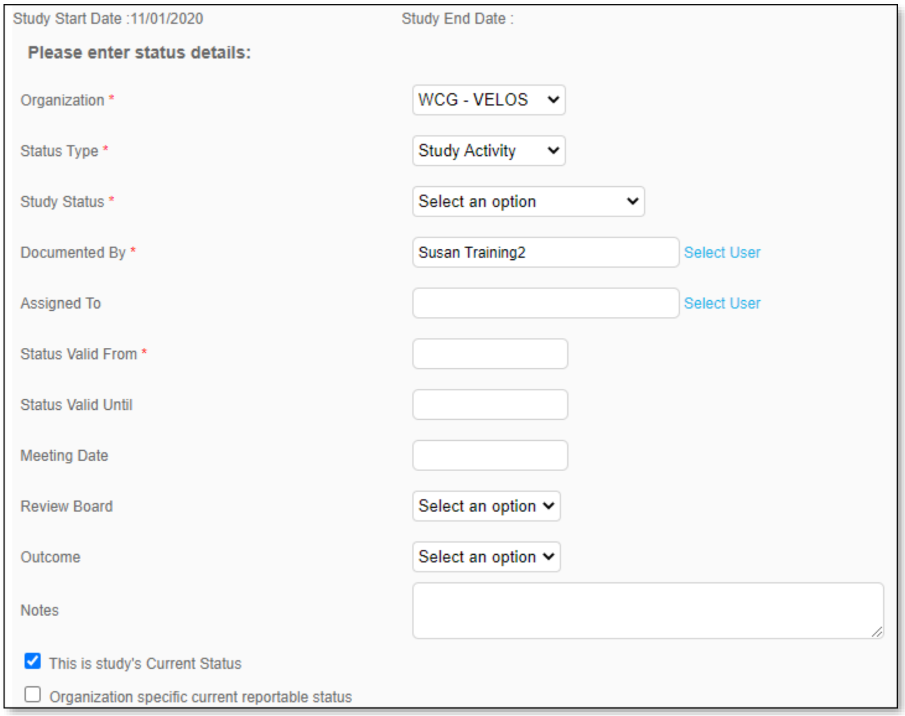
Note:

1. Any status can be identified as the study's Current Status. This is meant to be used for Ad-Hoc Query reporting purposes. When a new Study Status is added, the option to indicate the Status as the "Study's Current Status" is marked by default.
2. It is best practice to maintain the study status as it affects the availability of certain system functions. For example, patients cannot be added to a study unless the status is set to Active/Enrolling.
3. It is best to leave the "Study's Current Status" box unchecked, for new study statuses, once a study is made Active until it is Closed.

To change the status of an existing study:

1. From the Study Status tab of a selected study, select **Add New Status**.

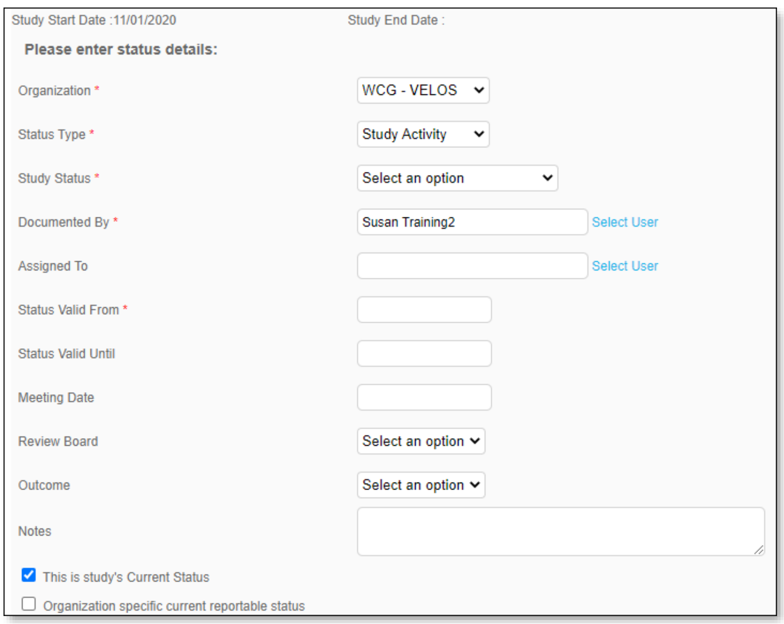
The Study Status Details page displays. Here, users may edit the Study Status information as needed. See the table below for more information about each study status field.



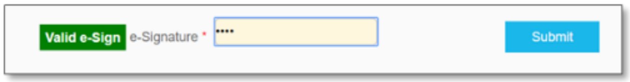
Field Name	Description
Organization	Designates the associated organization.
Status Type	The type of status for the study.
Study Status	The study status being documented. The specific values vary based on Status Type. Some of the Study Statuses will impact certain report types as follows: ▪ Active/Closed to Enrollment: This status is linked to reports and will prevent patients being associated to the study if the Flag to All Patient Accrual field is set. ▪ IRB Approved: This status is linked to reports and the IRB Approval Indicator Status flag. ▪ Not Active: This study status is the default status for new studies and is linked to reports. Study Completed/Retired: This study status is linked to reports and prevents patients being associated to the study.
Documented By	Used to select the user who documented the study information.

Field Name	Description
Assigned To	Used to select the user that is responsible for monitoring this study status.
Status Valid From	Required date for which the Study Status is valid from.
Status Valid Until	End Date for Study Status.
Notes	Notes on the Study Status.
This is study's Current Status	Checked by default. This will set the study status for the applicable status type to this study status.
Organization specific current reportable status	Used to report the current status for the designated organization.

2. Using the dropdown menus and text fields, define the **Study Status** as appropriate.



3. Enter your e-Signature and click **Submit** to confirm.



The study status details are saved.

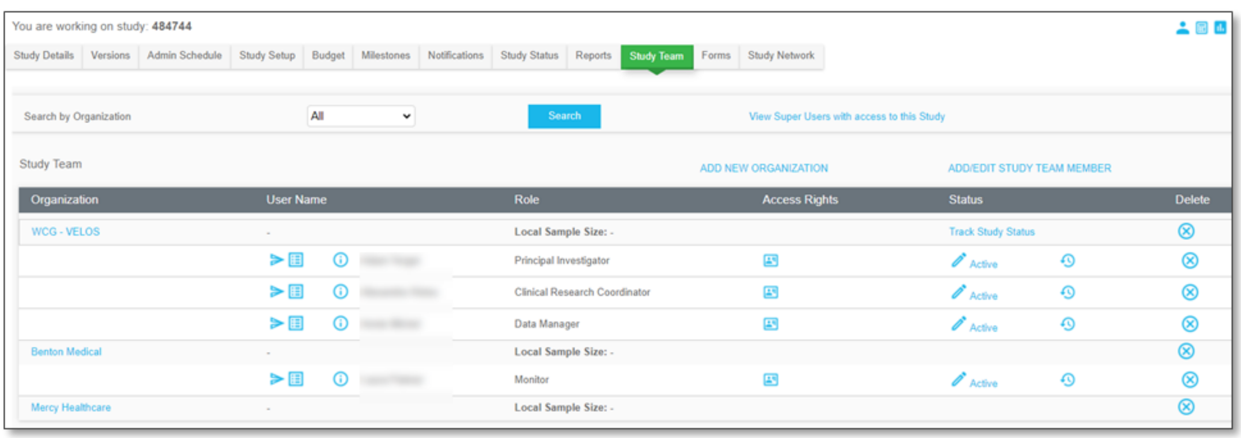
7.9 Reports Tab

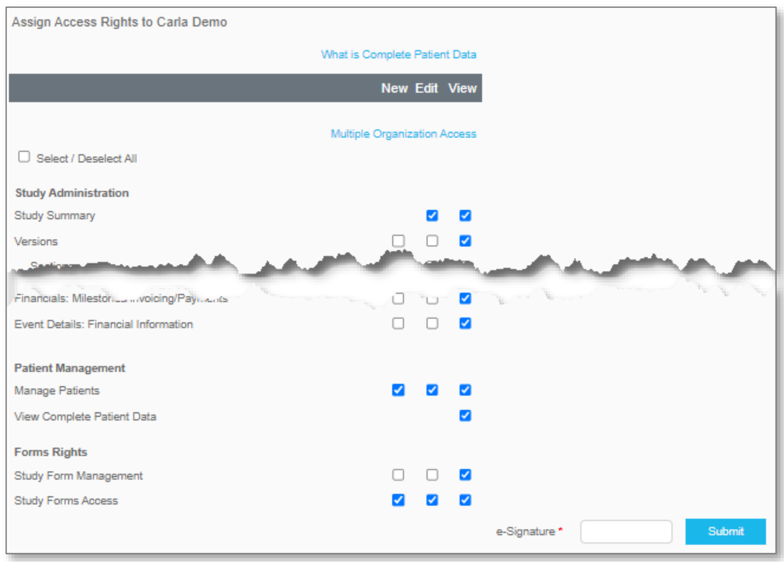
The reports section lists the standard study related reports available. Reports generated here are specific to the study that users have selected and/or are currently navigating. Within the Reports tab, there are sorting and filtering options available for each report selected. For detailed information on Reporting, see Reports, Ad-hoc Queries & Dashboard.

7.10 Study Team Tab

The Study Team tab allows the permissioned user to manage the study team for a study. Here they can assign Study Team Members to the study, manage their rights and their study status.

Below, the functions available on the Study Team screen are defined.

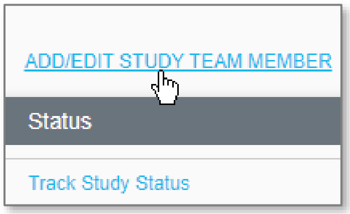


Icon	Name	Description
	**Users Details**	Opens the **User Details** page, where basic user information can be edited.
	**More Information**	Opens the **More Study Team Details** page.
	**More Information**	Opens the **More Study Team Details** page. This will be blank if the More User Details section on the User Details page does not have any fields.
	**Assign Rights**	Opens the **Assign Access Rights** page, where study-specific access rights can be defined. 
	**Edit**	Used to **Edit** the status of **Study Team** users.
	**History**	Provides an audit trail of user status history within the study.
	**Delete**	Removes the user from the study.

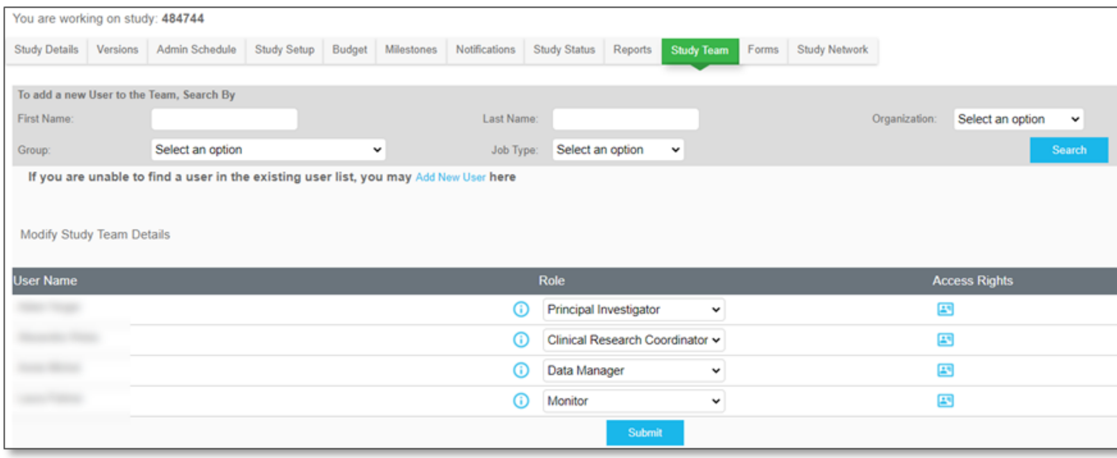
7.10.1 Add a New Study Team Member

To add a new study team member:

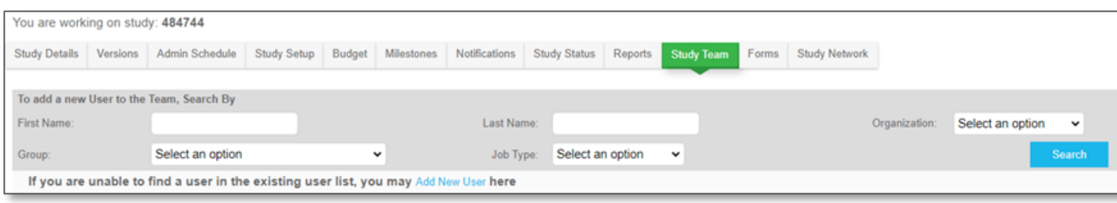
1. Click **Add/Edit Study Team Member**.



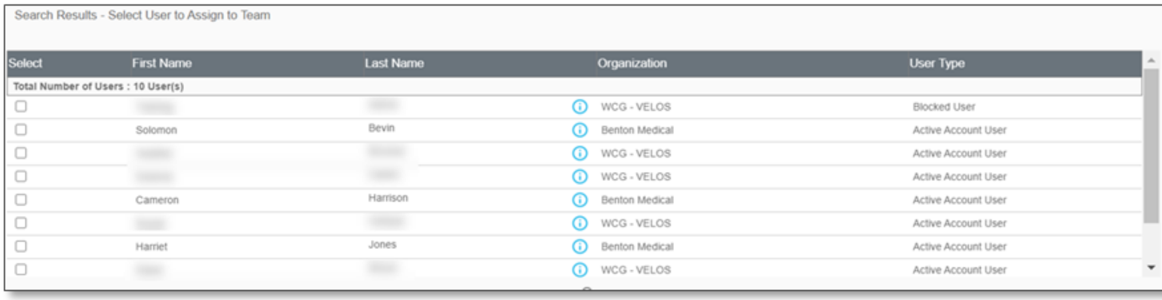
The Study Team Details page opens:



2. Using the Search Bar, **Search** for a user to add to a study.

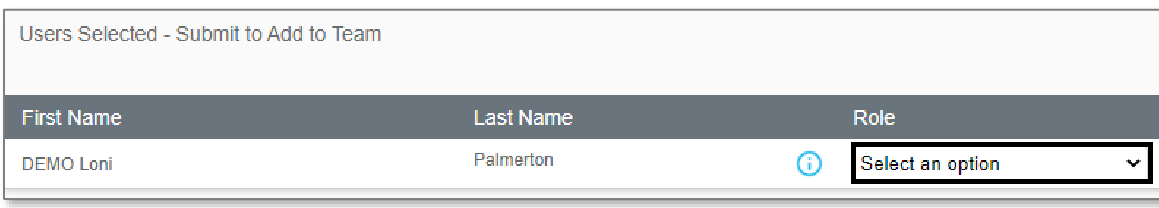


Users meeting the search criteria display:



3. Click the checkbox next to the desired user to add to the study.

4. Select the appropriate **Role** for the selected user and click **Submit** to confirm.



The user is saved to the study team.

Note: If you do not have the appropriate Organization, permissioned users may use the Add New Organization link to add a new organization and associate users to that Organization. If users need access to data in multiple organizations, they will need to be added to each organization.

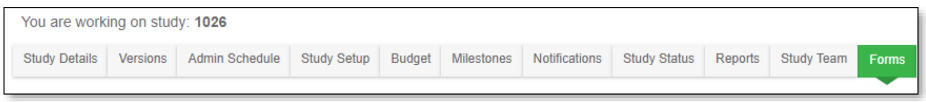
7.11 Forms Tab

Forms associated to studies are linked to either the “Study” or “Patient”. Forms linked to “Study” are used to capture study-specific data that is not collected in one of the standard Study Administration tabs. For Study Forms, responses are completed from this tab.

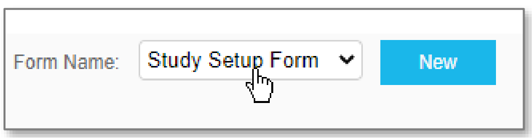
> **Note:** Only Forms associated as “Study” level forms on the Study Setup page and Account level forms will display on the Forms tab of a selected Study.

To complete a study form:

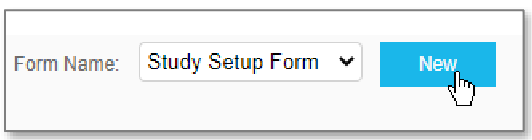
1. Click on the **Forms** tab:



2. Use the dropdown menu to select the desired study **Form Name**.



3. Once a form is selected, click **New** to open the form.



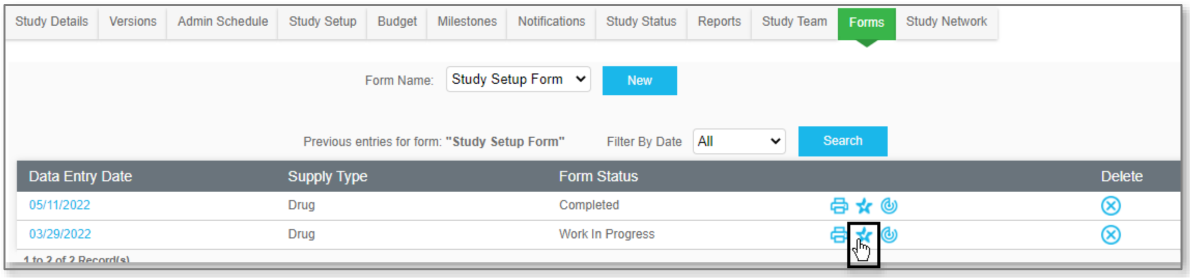
4. After filling out the form, enter your e-Signature and click **Submit** to confirm.

7.11.1 Forms Tab Audit Trail

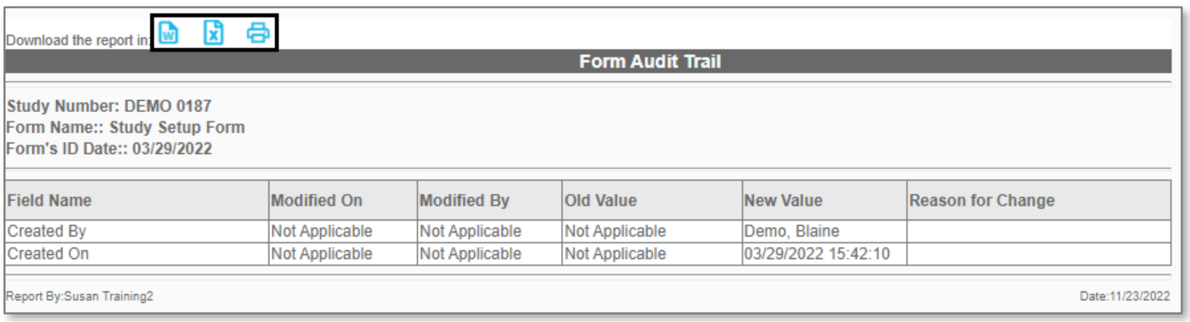
When a Form has been updated, a record is created which can be viewed in an audit trail.

To view an audit trail for a Form:

1. Click the **Star** button representing the Audit Trail.



The Form Audit Trail page opens in a new page.



Download the report in

Form Audit Trail

Study Number: DEMO 0187
Form Name:: Study Setup Form
Form's ID Date:: 03/29/2022

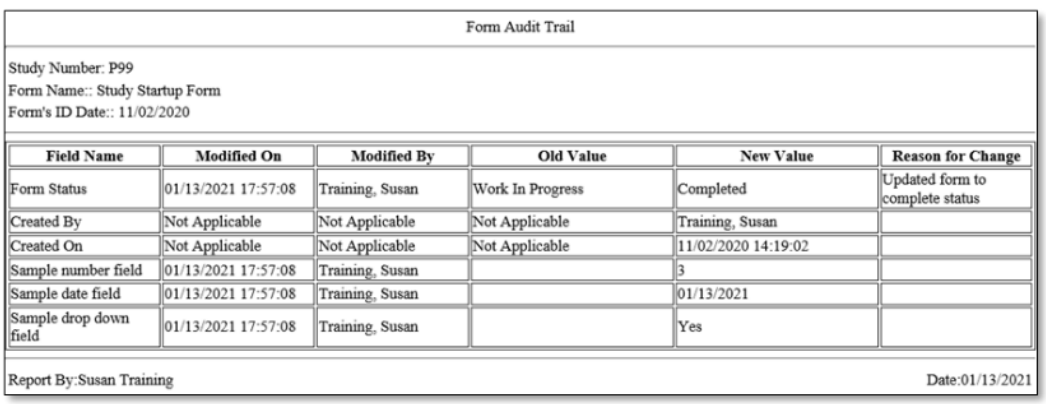
Field Name	Modified On	Modified By	Old Value	New Value	Reason for Change
Created By	Not Applicable	Not Applicable	Not Applicable	Demo, Blaine	
Created On	Not Applicable	Not Applicable	Not Applicable	03/29/2022 15:42:10	

Report By:Susan Training2 Date:11/23/2022

2. To export in Word or as an Excel file, click a **Word** or **Excel** button at the top of the form.

   -OR-

   To create a printer friendly format, click the **Printer** button.



Form Audit Trail

Study Number: P99
Form Name:: Study Startup Form
Form's ID Date:: 11/02/2020

Field Name	Modified On	Modified By	Old Value	New Value	Reason for Change
Form Status	01/13/2021 17:57:08	Training, Susan	Work In Progress	Completed	Updated form to complete status
Created By	Not Applicable	Not Applicable	Not Applicable	Training, Susan	
Created On	Not Applicable	Not Applicable	Not Applicable	11/02/2020 14:19:02	
Sample number field	01/13/2021 17:57:08	Training, Susan		3	
Sample date field	01/13/2021 17:57:08	Training, Susan		01/13/2021	
Sample drop down field	01/13/2021 17:57:08	Training, Susan		Yes	

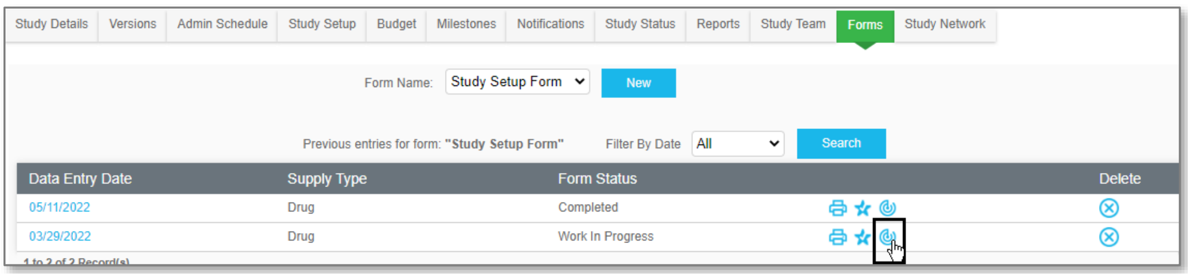
Report By:Susan Training Date:01/13/2021

7.11.2 Forms Tab Track Changes

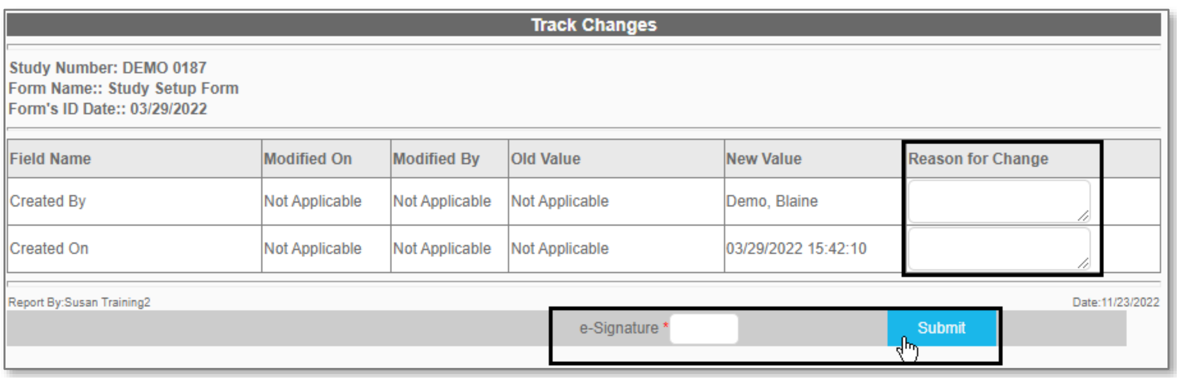
When a Form has been updated, track changes are created. Reasons for change can be added to the Track Changes page.

To view track changes for a specific form:

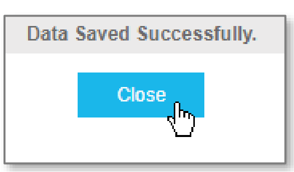
1. Click the **Track Changes** button.



The Track Changes page opens in a new page.



2. Enter a reason for making a change per line item, as needed, into the Reason for Change field, enter e-Signature, and click **Submit** to confirm.
3. Click **Close** to close the page and return to the portal.



The next time the Track Changes page is accessed, the reason(s) added will appear.

7.12 WCG IRB Tab

The WCG IRB tab is a feature available for both WCG Velos eResearch Enterprise and WCG Velos eResearch eXpress that enables study teams to directly submit study documentation to the WCG's IRB for approval. The WCG IRB tab streamlines the process of submitting documentation to WCG's IRB to perform ethical review of the submitted documents.

Note:
1. The WCG IRB functionality is an optional add-on module, and therefore must be configured and turned on by the Velos team. For more information about this functionality, please contact Velos Support.
2. When WCG IRB is added, the Documents tab in Study Management will automatically change its name to Attachments. Contact Velos Support if the tab name requires revision.

Before using the WCG IRB tab, the following items must be completed:

- Define a Principal Investigator for the study on the Study Details tab
- Enter the Sponsor Protocol Number in the Sponsor Protocol Number field of the Study Details tab
- Add all documents that need to be submitted for IRB review to the Versions tab and place them in the Freeze status

Note: Documents submitted to the WCG IRB tab must be in the status of Freeze in order to submit. Refer to Mange an Existing Study for details on required fields to complete.

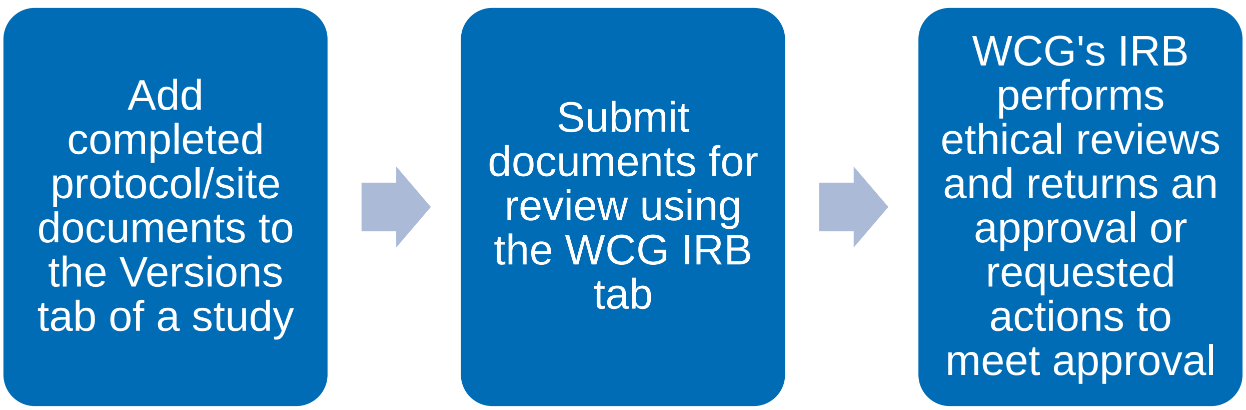
- "IRB" permission must be granted at the Study Team level to generate new submissions, edit existing submissions and/or view submissions (for more information about study team permissions, see the Study Team Tab and Appendix F – Study Role Permissions

Note: For more information about completing the prerequisite actions described above, see the Studies and the Versions Tab.

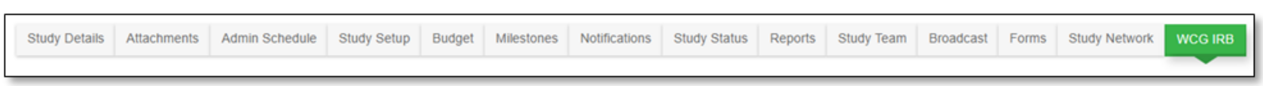
The process workflow begins by adding your protocol / site documents to the Versions tab within a study in WCG Velos eResearch. After adding your completed documents to the study, they then need to be placed in the Freeze status to enable them to be transmitted to the WCG IRB. Once the version has a Freeze status, documents can be submitted.

Warning: If you do not place your documents in the freeze status, they will not be available to submit to WCG IRB for review and/or approval.

Once the documents are added, they can be transmitted via the WCG IRB tab within that study. As individual submissions are processed, their status will be updated to reflect their most recent processing state each time the study management>WCG IRB page is loaded. A high-level overview of this process is displayed below:



When this feature is enabled, an additional tab, WCG IRB displays on the Study Management page:



7.12.1 Submit Documents for WCG IRB Review

This section outlines the process for submitting protocol / site documents for approval using the WCG IRB tab within a study.

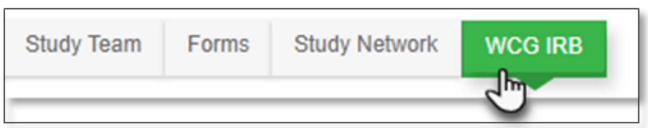
Warning: Submissions must follow all requirements for WCG's IRB, which includes downloading the necessary "Smart Forms" from the WCG IRB website and including those in the submission. Failure to submit the necessary documents will result in delays in IRB review of the submission.

To submit a document to the WCG IRB for review:

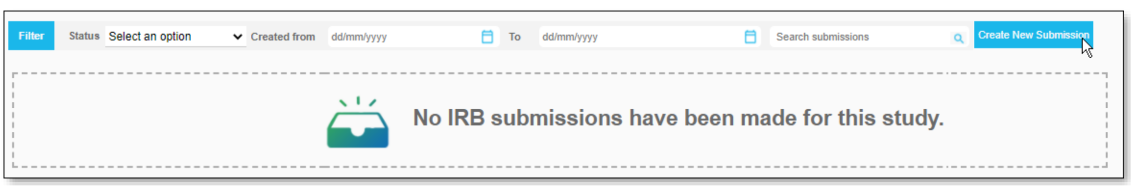
1. Navigate to the Versions tab of the target study and ensure that the documents intended for submission have been added and placed in the Freeze status.

Version #	Category	Type	Appendix	Attachment Status	Delete
1.00	Informed Consent	Initial	Attachments (1)	Freeze	-
1.00	Investigator Brochure	Modified	Attachments (1)	Freeze	-
1.00	Protocol	-	Attachments (1)	Freeze	-

2. Click on the **WCG IRB** tab.

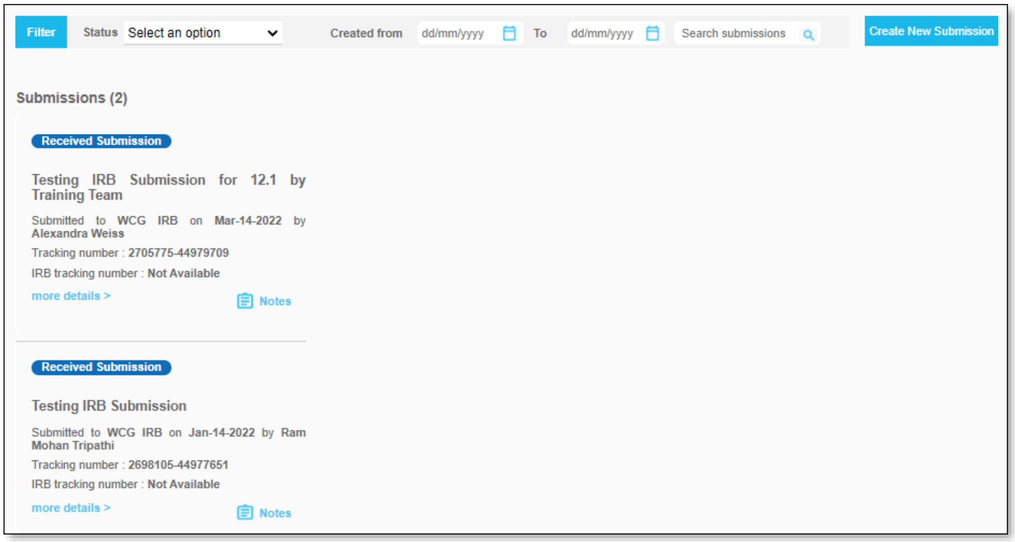


The WCG IRB page loads. A message stating, "No IRB submissions have been made for this study" will display if no submissions have been made.

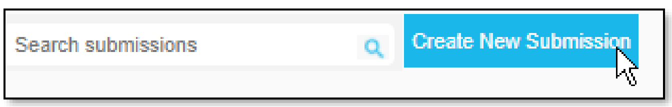


- OR -

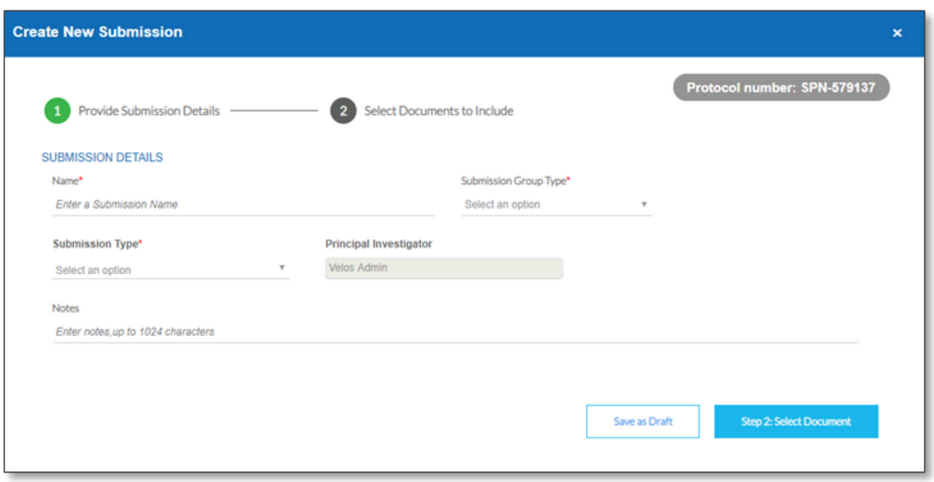
If previous submissions have been made, the submissions will display on the left side of the screen:



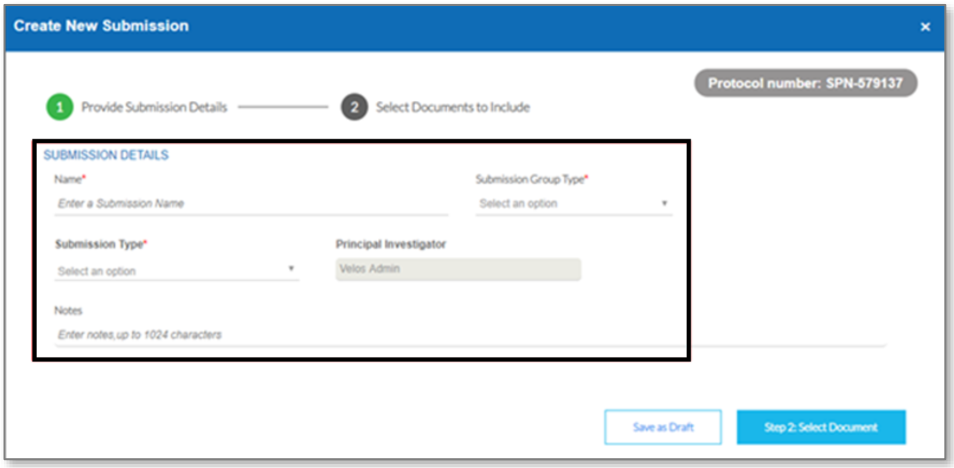
3. Click **Create New Submission** on the right side of the screen.



The Create New Submissions window displays:



4. Provide the submission details by completing the **Name**, **Submission Group Type**, **Submission Type**, and **Notes** fields. The Principal Investigator field is auto-populated based on the information entered into the Study Summary / Study Details tab.



The following table displays each Submission Group Type and the Submission Types available within each:

Submission Group Type	Available Submission Type
New Study	Initial Review
	Initial Review – CPU Services
New PI Submission	Initial Review
	Initial Review – CPU Services
Existing Site Submission	Change in Research
	Change in Research – CPU Services
	Change in Investigator
	Closure Report
	Consent Form
	Contact Information Update
	Continuing Review Report Form
	DSMB and New Scientific Evaluations
	Dear Investigator Letter

Submission Group Type	Available Submission Type
	Drug Brochure
	FDA Inspection Information or Medical Board Action
	HUD Submission
	IND Safety Report
	Promptly Reportable Information
	Recruitment or Supplemental Documents
	Translations
Existing Study Submission	Change in Research
	Change in Research – CPU Services
	Consent Form
	Contact Information Update
	Continuing Review Report Form
	DSMB and New Scientific Evaluations
	Dear Investigator Letter
	Drug Brochure
	HUD Submission
	IND Safety Report
	Other Materials
	Promptly Reportable Information
	Protocol Amendment or Clarification
	Recruitment or Supplemental Documents
	Translations

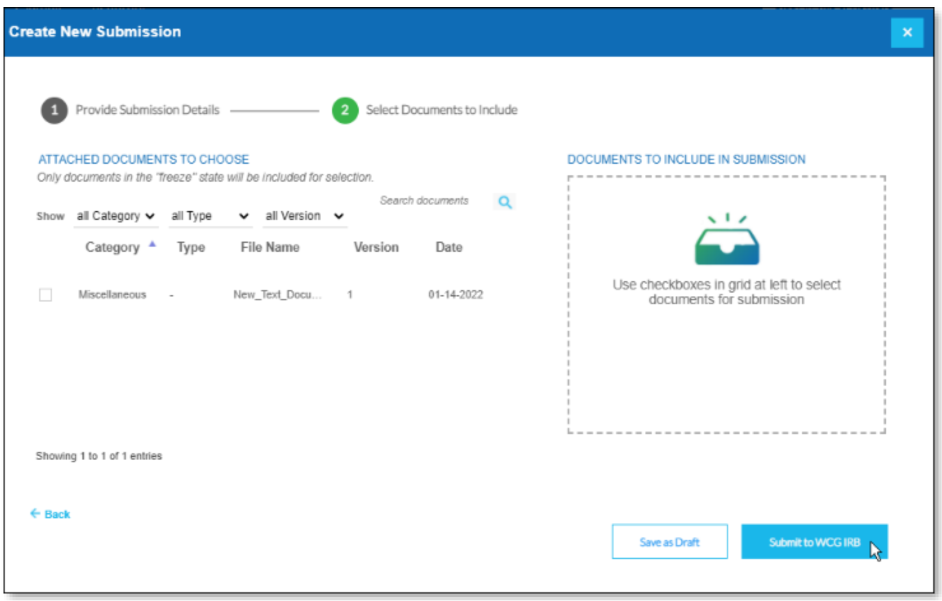
5. After the applicable information has been entered, click **Step 2: Select Document** to continue.

- OR –

Click **Save as Draft** to save this submission as a draft that you can return to later to complete.

Note: If you click **Save as Draft** in step 5 above, the Create New Submission window will close, and you may restart this process at step 4 by clicking on the draft submission in the WCG IRB tab.

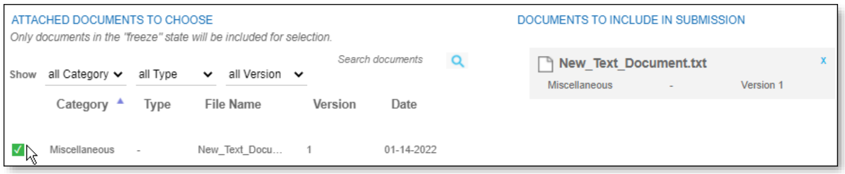
After clicking the Step 2: Select Document button, the document selection screen displays:



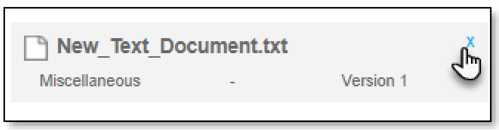
Note: Documents must first be added to the Versions tab and placed in the "Freeze" status to be available for submissions using the WCG IRB tab.

Warning: Submissions must follow all requirements for WCG's IRB, which includes downloading the necessary "Smart Forms" from the WCG IRB website and including those in the submission. Failure to submit the necessary documents will result in delays in IRB review of the submission.

6. Click the checkbox next to each available document that you would like to include in this submission. For each document you select, an information card will display on the right that corresponds to that document.

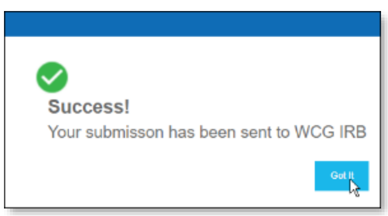


7. To remove documents from the submission, click the **X** button in the upper-right corner of the document information card in the Documents to include in Submission section.



8. After selecting the required documents, click **Submit to WCG IRB** to submit these documents for IRB review.

   a. Click **Got it** in the pop-up to close.

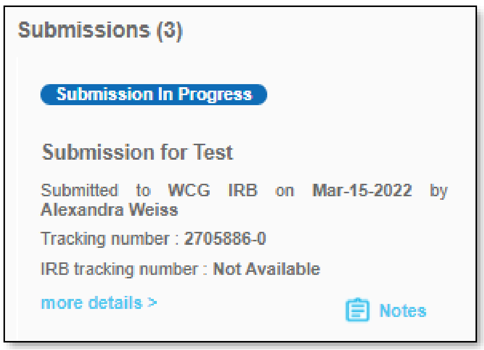


-OR-

Click **Save as Draft** to save this submission as a draft that you can return to later to complete.

Note: If you click Save as Draft in step 8 above, the Create New Submission window will close, and you may restart this process at step 6 by clicking on the draft submission in the WCG IRB tab.

After finalizing the submission for WCG IRB review, the new submission once received, will display in an information card on the left side of the WCG IRB tab.



Warning: There is a short delay after you finalize your submission before it is received by the IRB. While your submission is awaiting transmission to the IRB database, a status of "Unsubmitted" will display. Once transmission has been completed, this status will change to "Transmitted".

Note: For more information on submission statuses and the information cards displayed on this page, see the Review Submissions section.

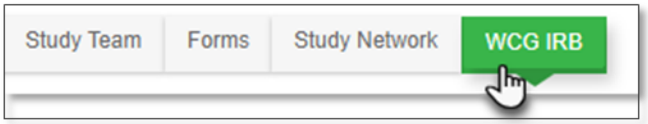
7.12.2 Review Submissions

The following section describes how to check the status of a submission using the WCG IRB tab of a Study.

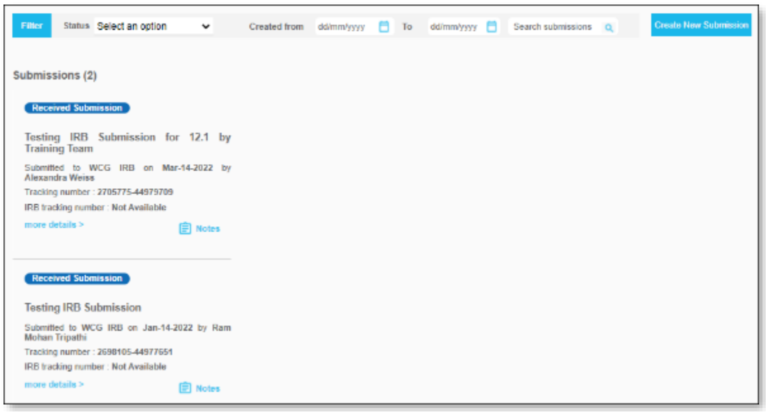
Warning: Changes in status for a submission will refresh each time you load a study's WCG IRB tab. Therefore, you must open / refresh the WCG IRB tab of a study for any changes in WCG IRB review status to be pulled into WCG Velos eResearch.

To review a submission:

1. Click on the **WCG IRB** tab of a study.

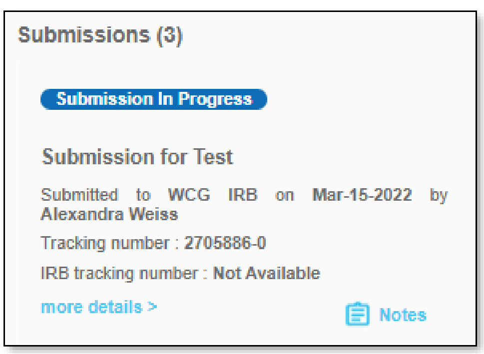


The WCG IRB page displays. All submissions (including draft submissions) display on the left side of the page in information cards.

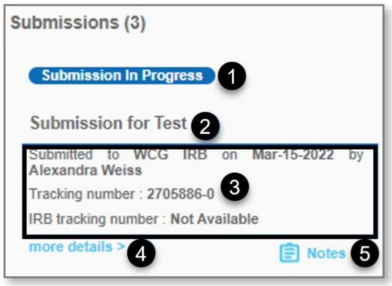


Note: You can filter the submission results using the Status or Created from fields at the top of this page. You can also search for a specific submission by typing a partial or complete search term into the Search Submissions field.

2. Locate a specific submission information card to see its current status.



Review the following diagram to learn more about the information available in the submission information cards:



1. **Submission Status** – Displays the current submission status. Review the table below for more information about each status' meaning.
2. **Submission Name** – Displays the name given to this submission.
3. **Submission Details** – Displays important submission details including submission date, tracking number, IRB tracking number, and any notes added to the submission.
4. **More Details Link** – Click the more details > link to display the Submission Type, Submission Group Type, view Submission Documents and applicable Outcome Documents, as defined when the submission was made.
5. **Notes** – Hover over to view notes that were entered upon submissions.

Status	Description
Draft	This submission is a draft, which means it has been started, but not submitted. Clicking on a submission information card with this status allows you to continue the submission process as described in the Submit Documents for WCG IRB Review section.
Unsubmitted	The submission process in WCG Velos eResearch was completed, but this submission is in queue, waiting to be transferred to the IRB database.
Transmitted	The submission results have been successfully transmitted from the WCG IRB database back to the Velos eResearch database.
Received	The submission has been successfully received by the IRB team, and is in the process of being added to the review queue.
Received Submission	Formal confirmation of receipt by the IRB.
Processing	The submission is being processed in preparation for panel review.
Reviewing	Submission is currently being reviewed by the IRB panel.

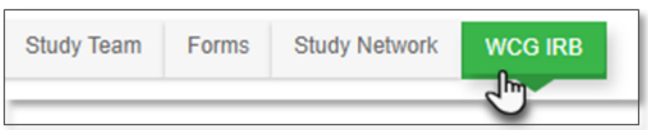
Status	Description
Post-Panel Processing	The submission is currently in Post-Panel Review processing or awaiting a signature for finalization.
Completed	IRB Review is complete. Outcome documents may be attached to this submission for your records. See Download Submitted and Outcome Documents for more information.

7.12.3 Download Submitted and Outcome Documents

All documents that were added to a submission, in addition to any outcome documents that were sent back by the WCG IRB after review can be downloaded using the WCG IRB tab.

To download submission and outcome documents:

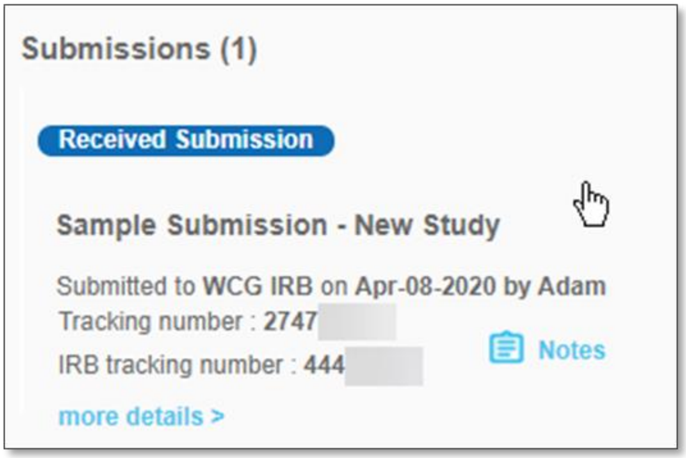
1. Click the **WCG IRB** tab of a study.



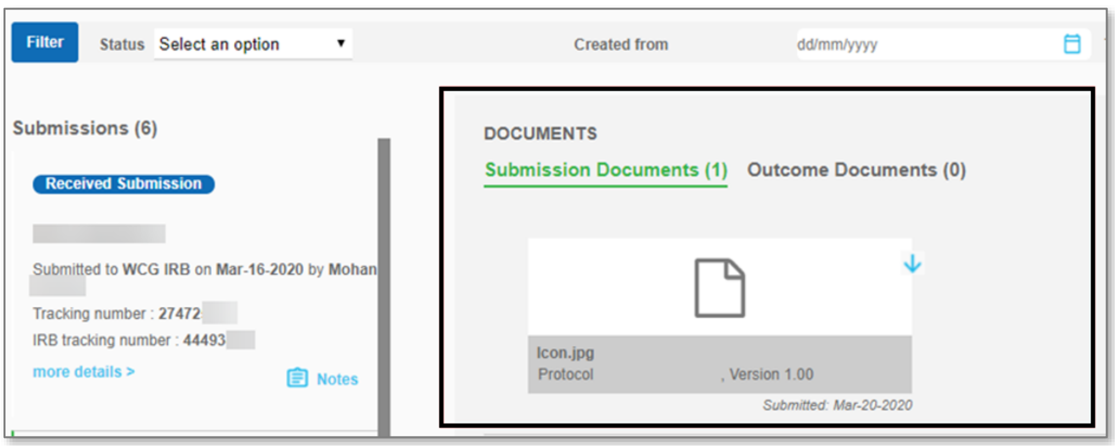
The WCG IRB page displays. All submissions (including draft submissions) display on the left side of the page in information cards.

Note: You can filter the submission results using the Status or Created from fields at the top of this page. You can also search for a specific submission by typing a partial or complete search term into the Search Submissions field.

2. Locate the target submission information card and click to select.



After clicking on a submission information card, the Documents panel displays on the right side of the page:

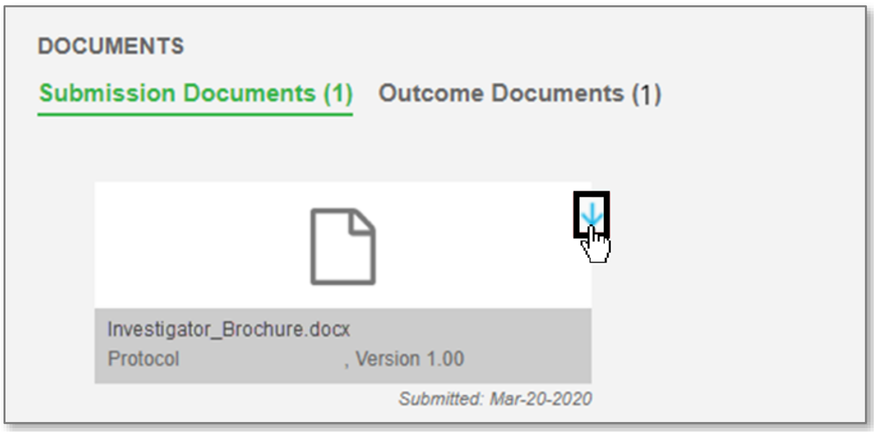


3. Click **Submission Documents** to view all submitted documents.

-OR-

Click **Outcome Documents** to view all outcome documents received from the WCG IRB.

4. After clicking either the Submission Documents or Outcome Documents link, you can download any attached document by clicking the **Download** button on the document information card.



8 Patient Management

Velos eResearch is a patient-centric system, meaning a patient has one system record and can have one or multiple study records within the system. A patient study record is created when a patient is associated to a study. The Patient Management module allows Study Team Members to add patients and associate them to a study. Within the module, a user can update patient demographics, monitor study statuses from screening to off-study, and manage patient schedules.

Study-centric:

- In Study Management > Study Setup, in the Study Dictionaries /Settings area, the radio button selection of *Yes* for Enable Study-centric enrollment must be selected
- Allows for creating and enrolling the patient at the same time
- Patient has to be linked to at least one study but can be linked to multiple studies later
- A new patient is added and associated with the study by completing the Study Centric Enrollment page
- After submitting the enrollment page, the user can be directed to a specific page

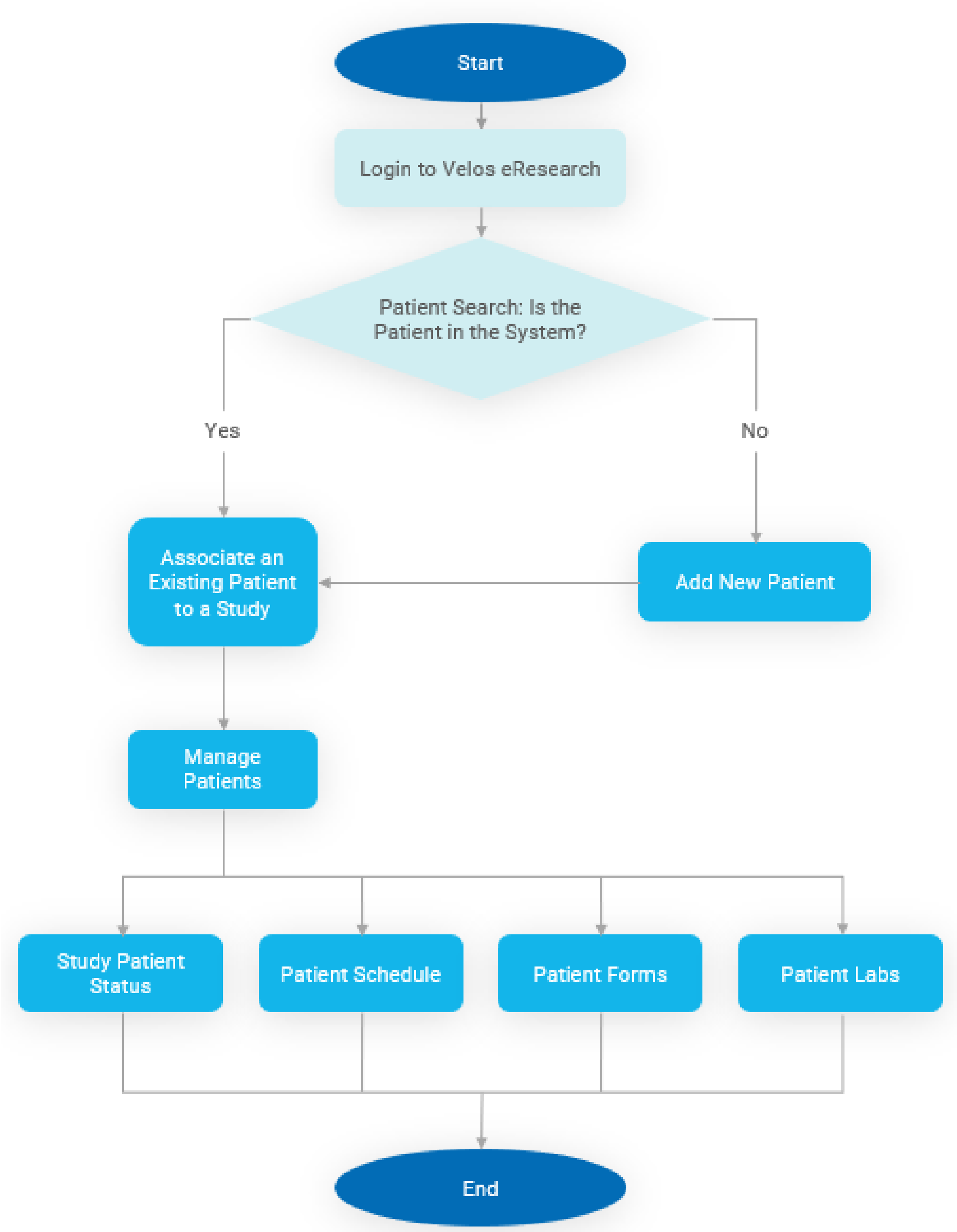
Velos eResearch has built in triggers to prevent patient enrollment to a study until the necessary criteria is met such as proper status, screening, etc.

There are two routes for managing patients in the system:

- Using the default / standard Homepage
- Using the Study Patient Roster

Note: If a user's role is only for managing study patients, it is recommended to set the Default Homepage to the Study Patient Roster, otherwise, if managing multiple functionalities, it is recommended to use the Default Homepage. For information on how to change your default homepage, see the Personalize section.

8.1 Patient Management Process Overview

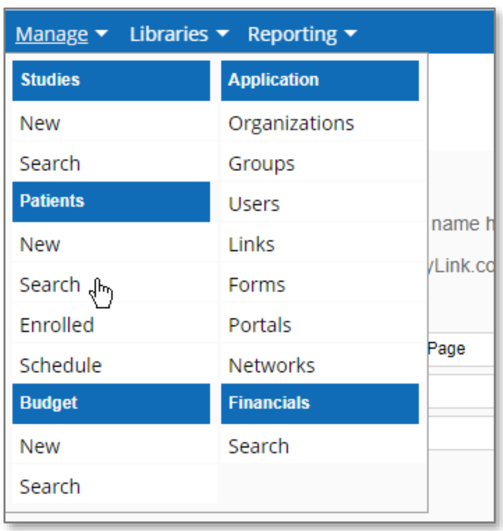


8.2 Patient Search

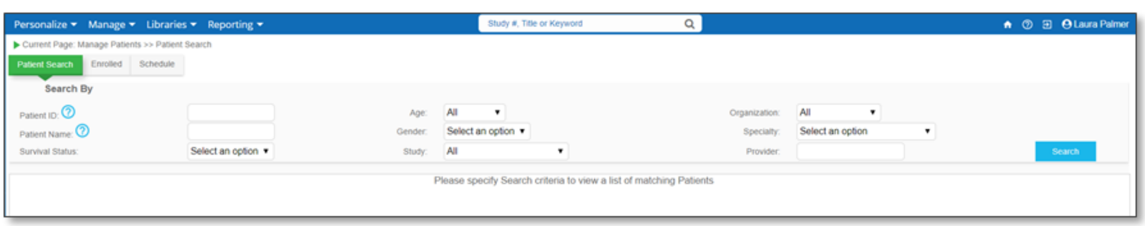
Prior to adding a Patient Record to the system, it is crucial to search for the patient to prevent duplicates. A patient in eResearch will have one patient record but may be associated to multiple studies.

To search for a patient via the default homepage:

1. From the Homepage, navigate to the "Patients" section under the **Manage** tab and click **Search** link.



The Patient Search page displays:

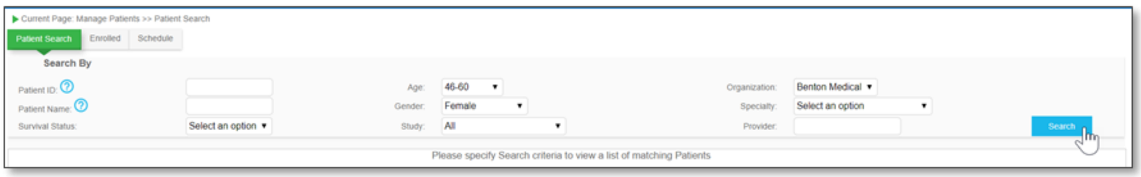


Users may use the search options to filter patients existing within the system. Filtering options include:

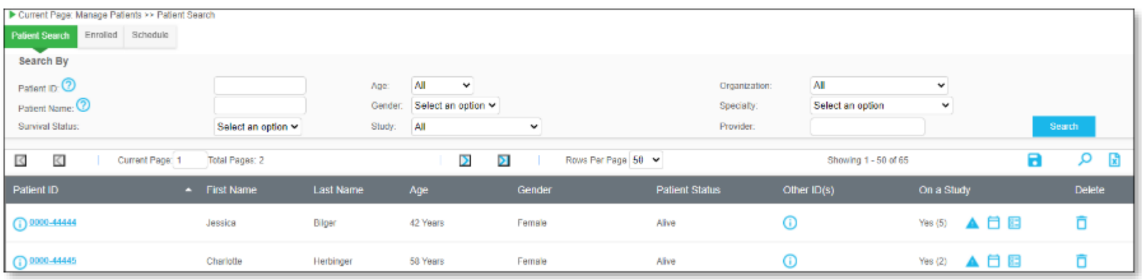
- Patient ID
- Patient Name
- Survival Status

- Age
- Gender
- Study
- Organization
- Specialty
- Provider

2. Enter the desired information to filter the search results by and click **Search** to search for any patients matching the search criteria.



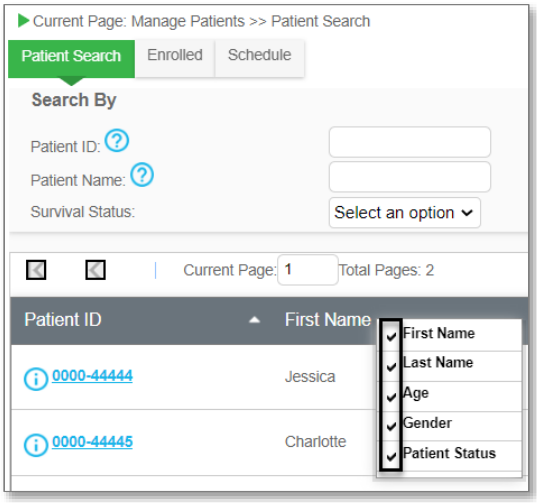
The search results display:



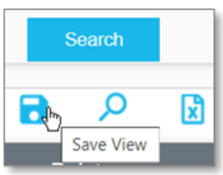
Note: The Organizations populated in the Organization dropdown will be based on the user's Organization access(es).

3. Proceed as appropriate based on search results to Manage an Existing Patient or Add a New Patient record.

4. To hide any columns from view, right click the header and uncheck applicable header name(s).



5. The column(s) selected will be hidden. Right click the header again and check to unhide, when needed.
   - Navigating away from the page will remove the selections, unless the view is saved



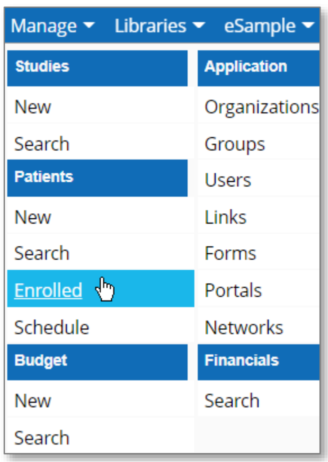
     - Click **Save View**, to save the column selections to only view the specific columns upon returning to the Patient Search tab
   - Hiding applies to all three tabs: Patient Search, Enrolled, and Schedule
   - Capability is available for hiding columns. When using, the columns will still appear in an exported Excel table.

8.3 Enrolled Tab

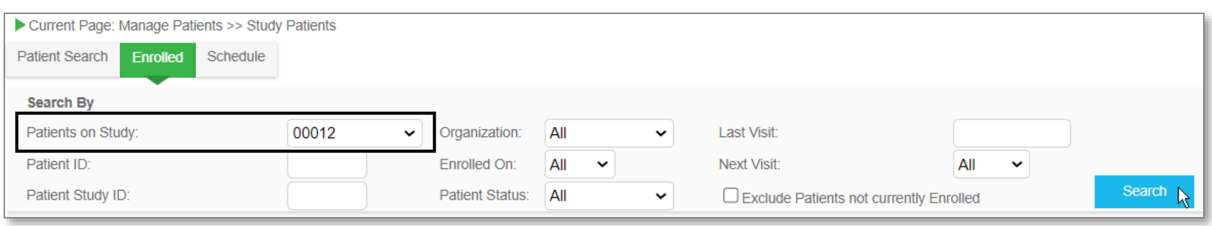
When first landing on the enrolled patients tab, the Patients on Study field will default to the first alphanumerical study in the list. Data in the table will show the patients associated with the selected study. The search results will display the patient's most recent and current statuses. New patients may be added to the selected study. Additionally, the enrolled patient's Visit Status may be updated, and a patient study record may be accessed for other system functionalities.

To access and then update data in the Enrolled tab, for patients on a study:

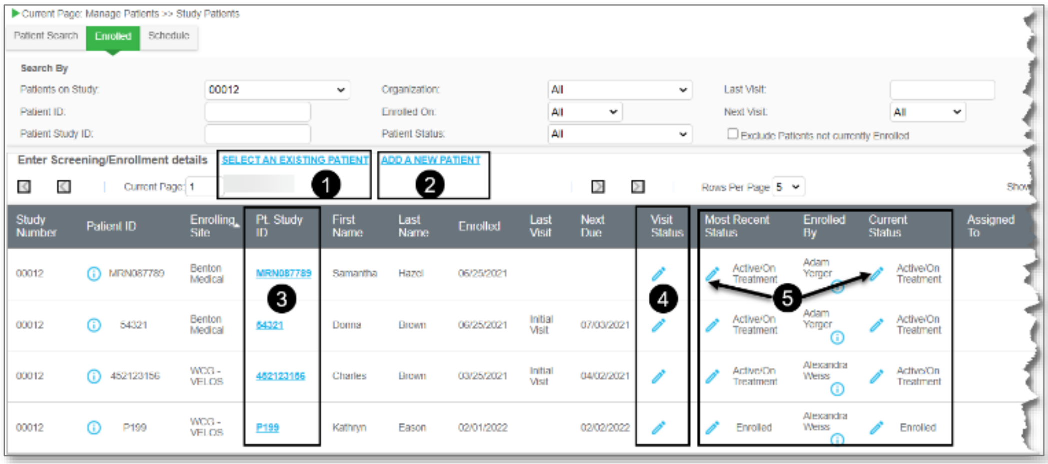
1. Click **Manage** > **Enrolled** (Patients).



2. From the default landing page, click **Patients on Study** dropdown and select a different study, if needed. Then click **Search**.

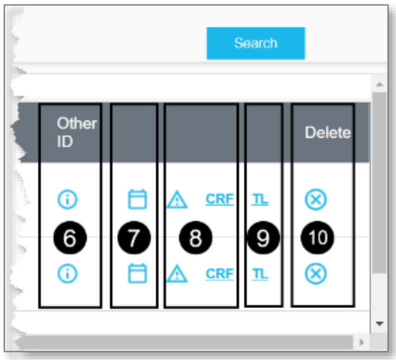


For features available on the Enrolled tab, refer to the diagram and steps below:



Number	Feature Name	Description
1	Select An Exisitng Patient	Used to access a Patient ID search page. Complete the applicable fields, then click **Search**, to view a single study patient record.
2	Add A New Patient	Used to add a new patient to the study. Complete the required fields at minimum, select **Enrolled** in the Status dropdown, then e-Sign and **Submit.**
3	Pt. Study ID Link	Used to access the Schedule page for a patient study record. Click the link in the Pt. Study column. For more information, refer to Patient Schedules.
4	Edit Visit Status	Used to change the date for a selected visit(s) / event(s) for a specific study patient record. Search fields to filter, select checkboxes for applicable visti(s) and / or event(s). select the appropriate Status field(s) from the dropdown(s), add Status Valid From Date(s), e-Sign and **Submit**.
5	Edit Most Recent OR Current Status	Used to access the study patient record's Screening / Enrollment page. Click **Edit** in either the Most Recent Status or Current Status cloumn. For more information, refer to Screening/Enrollment.

For additional features on the far right of the Enrolled tab, refer to the diagram and steps below.



Number	Feature Name	Description
6	View	Used to view a table showing Site Name and ID for other study patient associated records for the selected patient. Click **View** in the Other ID column for a specific patient record.
7	Calendars	Used to view a printable and downloadable specific patient schedule for the current and upcoming month. Click **Calendars** to view the patient specific calendar in a new window.
8	Adverse Event OR CRF	Used to view a printable and downloadable list of adverse events or CRFs for a specific patient. Click **Adverse Events** or **CRF** to view the patient specific Patient Event/CRF page in a new window. Note: Adverse Events are not applicable to eResearch eXpress.
9	Patient Timeline Report (TL)	Used to view a printable and downloadable patient timeline of patient events. Click **Patient Timeline Report (TL)** to view the patient specific Patient Timeline Report in a new window.
10	Delete	Used to delete a study patient record, if permissioned. Click **Delete**, click **OK** in the pop-up, e-Sign and click **Submit** to confirm.

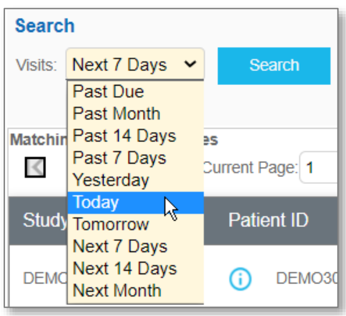
Warning: Once a study patient record is deleted, the action cannot be undone. Delete with caution.

8.4 Schedule Tab

The patient schedule tab defaults to schedules on today's current date. All studies' visits will be viewed, as per the selection made in the Visits dropdown for those studies that your organization(s)/ study team access allows.

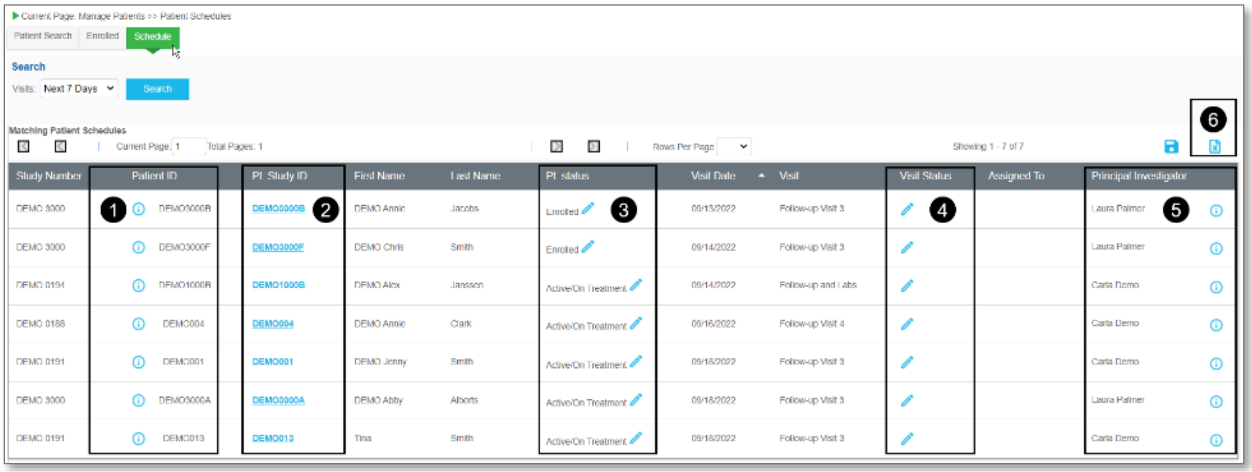
Using the Schedule tab may assist in planning for current and upcoming patient visits or when personnel may be out of office and another user will need to perform their duties. This is a good option for a default homepage for study coordinators.

Schedule information can be searched by past, current, and future dates, as per the selections below.



After selecting from the Visits dropdown and clicking **Search**, the applicable data will appear in a table. Continue to the next page for more information.

View the diagram below for details on the functionalities of the Schedule page.



Number	Feature Name	Description
1	Information – Patient ID	Used to access the Demographics page for a patient record. Click the i in the Patient ID column for a specific study patient record. For more information, refer to Manage Patient Demographics.
2	Pt. Study ID	Used to access the Schedule page for a study patient record. Click a link in the Pt. Study ID column for a specific study patient record. For more information, refer to Patient Schedules.
3	Edit – Pt. Status	Used to access the Screening/Enrollment page for a study patient record. Click **Edit** in the Pt. status column for a specific study patient record. For more information, refer to Screening/Enrollment.
4	Edit – Visit Status	Used to change the date for selected visit(s) / event(s) for a specific study patient record. Click **Edit** in the Visit Status column, in the pop-up, use the Search fields to filter, then select checkboxes for the applicable visit(s) and / or event(s). Select the appropriate Status field dropdown(s), add Status Valid From date(s), e-Sign, and then click **Submit**.
5	Information – Principal Investigator	Used to view a PIs email address. Hover over the **i** in the Principal Investigator column for a specific study patient record.
6	Export to Excel	Used to download a spreadsheet of the table data. Click **Export to Excel** for a specific study patient record.

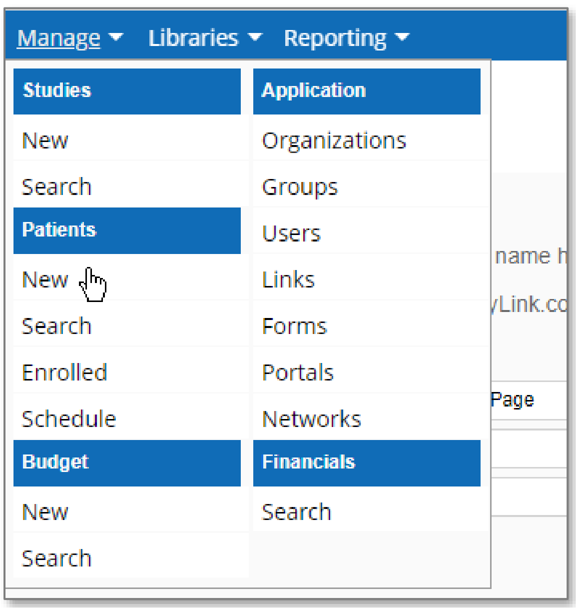
8.5 Add a New Patient

This section will cover how to Add a New Patient to the eResearch database and/or study. It is important to search for a patient prior to adding a new patient to prevent creating duplicate patient entries. For information on how to complete a Patient Search, see Patient Search.

Note: If your environment has an ADT (EHR Demographic) interface, your process for adding a new patient may be different. Check with your administrator.

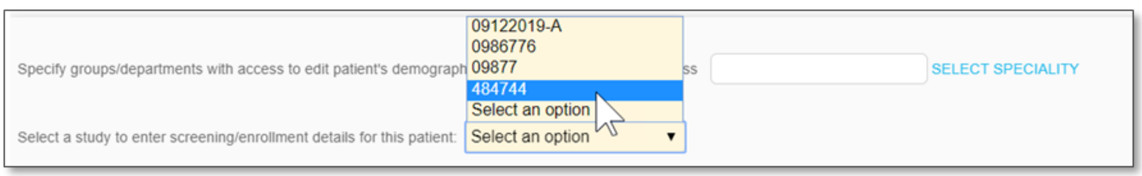
To add a new patient from the default homepage:

1. Navigate to the **Manage** tab. Under "Patients", click **New**.



The New Patient: Patient Details page displays:

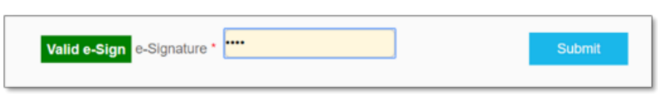
2. Enter patient specific information in the fields ensuring to enter data into all required fields. If the patient is associated with a study that is already set up, select the study from the dropdown to open screening/enrollment information upon saving the patient record.



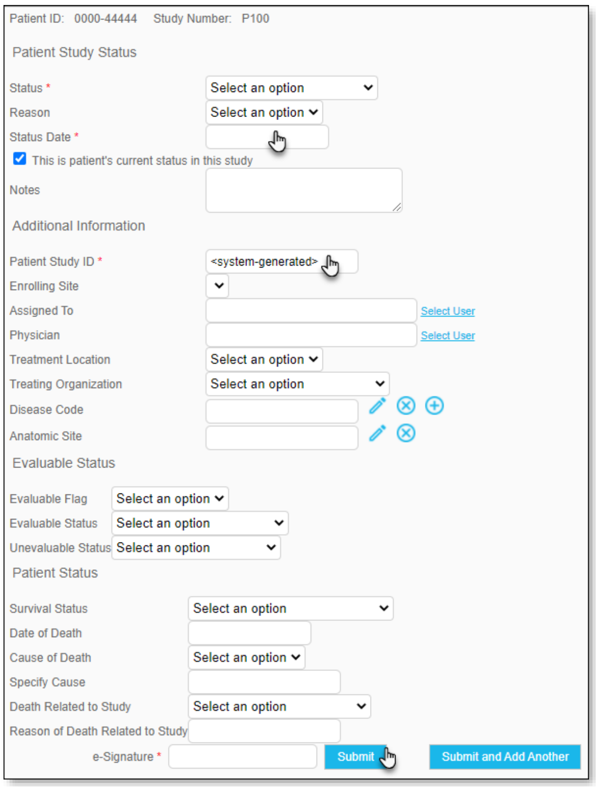
Warning: It is NOT recommended to use the Select Specialty option on this page as it prevents user access to the patient record.

Note: If a Patient with the same information already exists in the system, a warning will display but it is recommended and best practice to search for a patient properly before adding a patient record to the system.

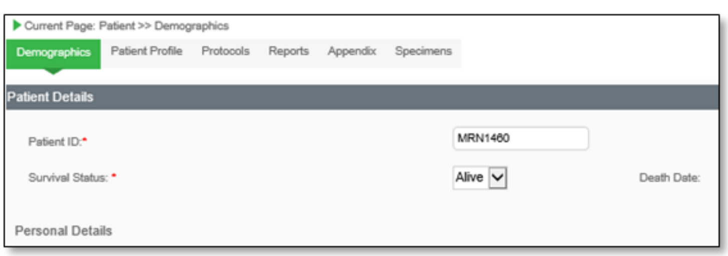
3. Enter the appropriate information and enter your e-Signature and click **Submit** to confirm.



4. If you selected a study to associate the patient to in step 2, the Patient Study Status page will display in a new window. Select a **Status** and **Status Date**.
   - If the **Patient Study ID** was selected to be automatically generated, then leave as is.
   - Or, if the **Patient Study ID** was set to manual generation, then it will be a copy of the Patient ID, which can then be revised as needed, to be study specific.



5. Then enter e-Signature and click **Submit** to confirm.
   -OR-
   If you did not select a study, the Patient Demographics page displays after saving the patient record.



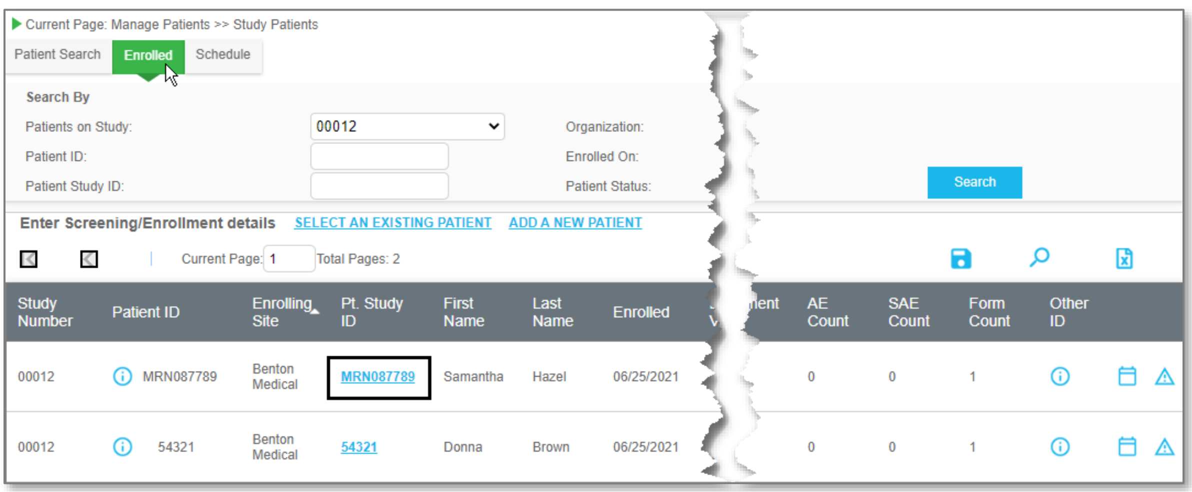
8.6 Manage an Existing Patient

This section will explain how to Manage an Existing Patient the default system homepage. Managing an Existing Patient includes the functionalities associated with Patient Demographics, Screening/Enrollment, and Modifying information of Enrolled Patients.

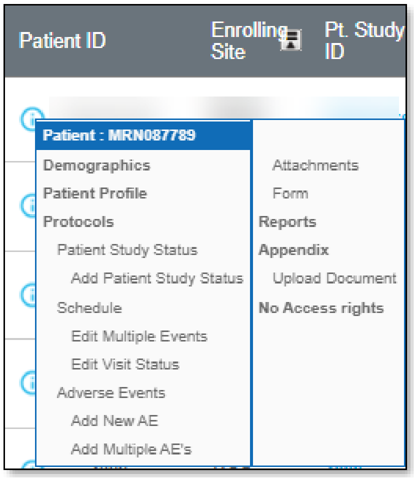
To manage an Existing Patient:

1. From the Patient Search page, users may search for a specific patient using the search filters or may view all patients by leaving filters blank and clicking **Search**.

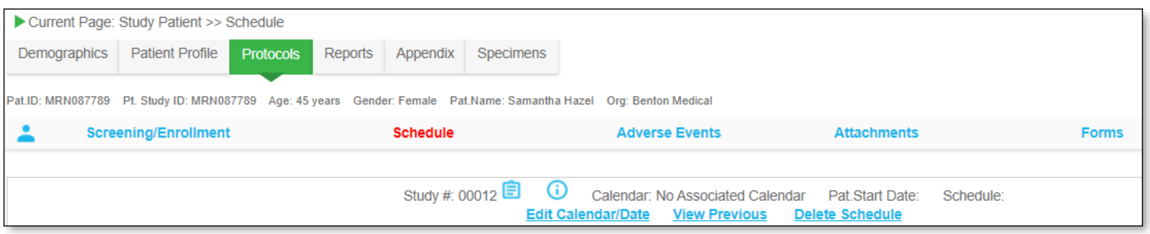
2. Patients that meet the search criteria will display on the screen below. A Patient Overview will be available. To view Enrolled Study Patients, click the **Enrolled** tab. Click the **Patient Study ID** link for the desired patient to examine.



a. Or, first right click on the **i** in a Patient ID column, while on the Enrolled tab, to view a quick access panel, and then click **Protocols** or a different desired page, as needed.

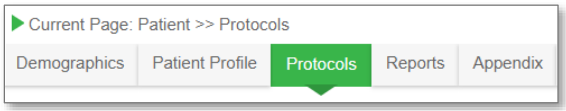


The Patient Protocols page displays for the selected patient.



8.6.1 Patient Record Tabs

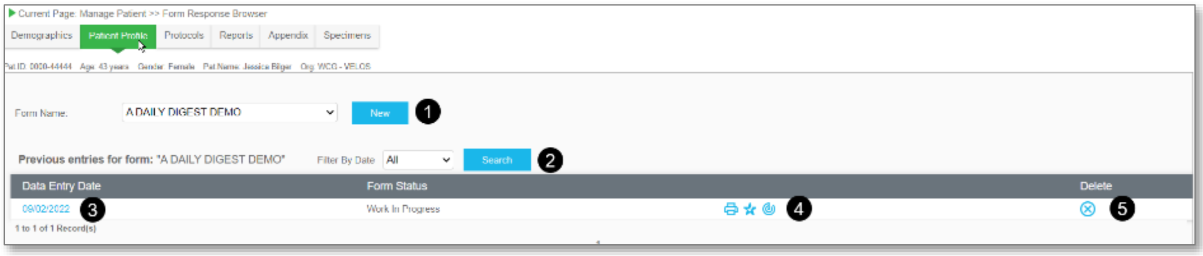
After the patient record is added, there are five tabs created for the record. After searching for a patient, the default landing page will be the Protocols tab.



Tab Name	Description
Demographics	Used to access and update patient information, as permissioned. For more information, refer to Manage Patient Demographics.
Patient Profile	Used for creating, viewing, and editing patient forms not specific to a study. [See this section for more information.]
Protocols	Used for accessing or adding a study to a patient record, for creating a patient study record. [See this section for more information.]
Reports	Used for generating patient reports specific to the patient. For more information, refer to Report Central.
Appendix	Used for adding files and links to a specific patient record. For more information on how to add files and links, refer to Adding, Downloading, Editing, or Deleting an Attachment.

To use the Patient Profile tab:

1. Click **Patient Profile** for a patient record.



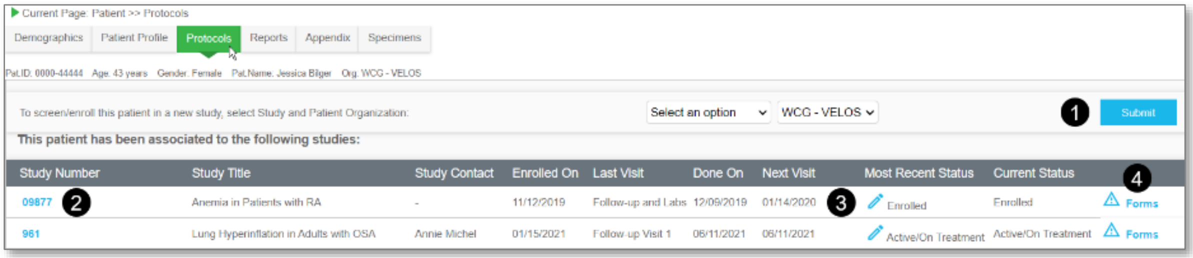
For additional Patient Profile tab features, refer to the table below:

Number	Feature Name	Description
1	New - Form	Used to create a new patient form response. Click the dropdown to select a Form Name, then click **Go**. Complete the form and submit. The completed form will appear as a line item in the table.
2	Search	Used to locate a specific form or forms. Select a Filter By Date from the dropdown, then click **Search**.
3	Edit Form	Used to access a form to update or review. Click a Data Entry Date link. Submit any changes to save.
4	Print / Audit / Track Changes	Print is used to print the completed form. Click **Print**, then click **Print** again in the pop-up. -OR- Audit is used to view, print or export an audit trail in Word or Excel format. Click **Audit** to open a new page to access features. -OR- Track Changes is used to add reasons for a change to a completed form. Click **Track Changes**, click a line item's Reason for Change field and enter a reason for the change, e-Sign, and then click **Submit**.
5	Delete	Used to delete a form response. Click **Delete**.

Warning: Once a form response is deleted, the action cannot be undone. Delete with caution.

To use the Protocols tab:

1. Click **Protocols** for a patient record.



For additional Protocols tab features, refer to the table below:

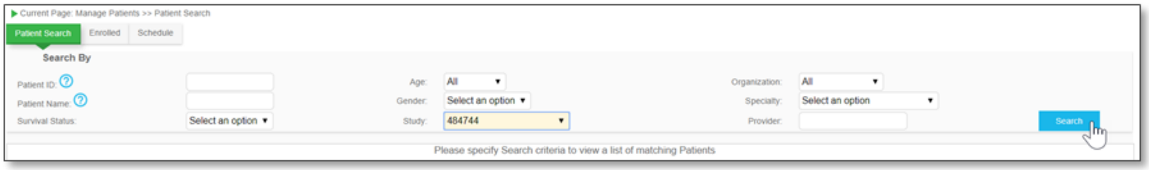
Number	Feature Name	Description
1	Screen/ Enroll a Patient to a Study	Used to screen or enroll a patient to a study. Click **Select an option**, click a study from the dropdown list, then click **Submit**. A new pop-up will appear. Follow the steps in Add an Existing Patient to a Study.
2	Access Study Number	Used to access the patient's study specific Protocol. Click a Study Number to view the default Schedule tab. For more information, refer to Patient Schedules.
3	Edit – Most Recent Status	Used to access the patient's study specific Protocol. Click **Edit** for a line item to view the default Screening/Enrollment tab. For more information, refer to Screening/Enrollment.
4	Forms	Used to access the patient's study specific Protocol. Click **Forms** for a line item to view the Forms tab. For more information, refer to Patient Forms and Labs.

8.6.2 Manage Patient Demographics

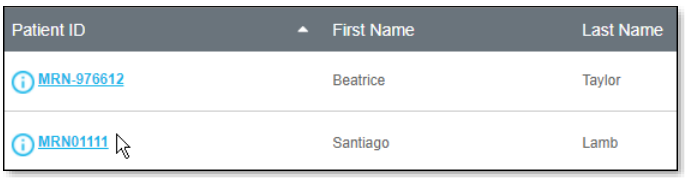
In addition to Patient Details, various patient demographic details can be stored in Velos eResearch. This information can be helpful when enrolling patients in studies that are specific to areas, such as: age, gender, race, or ethnicity. While this information is not required by the system when adding patients to the system, it is important to document for enrollment purposes.

To manage patient demographics:

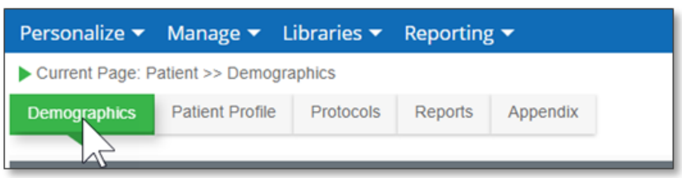
1. Navigate to the Patient Search page. **Search** for a patient as appropriate.



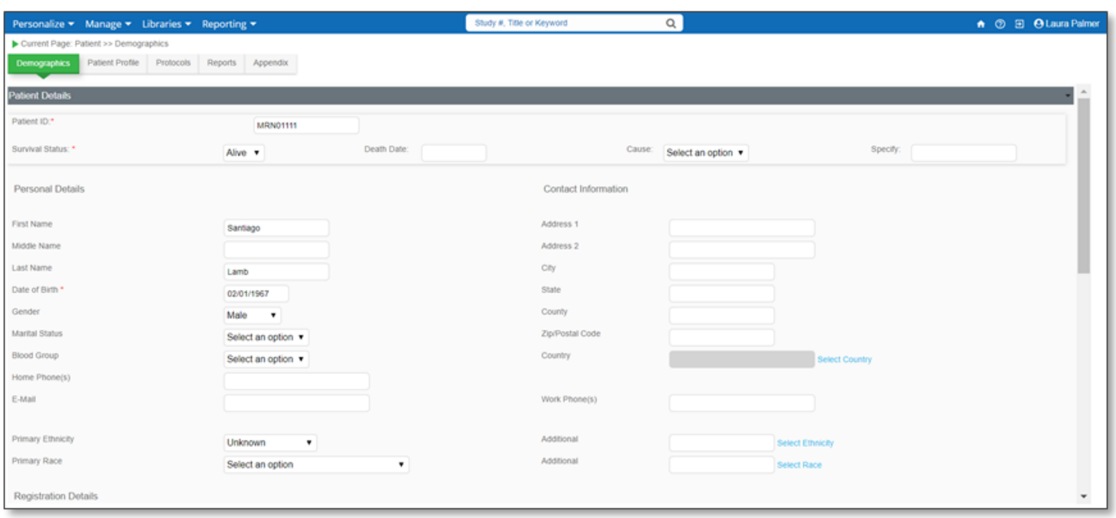
2. Select the **Patient ID** link for the appropriate patient to manage.



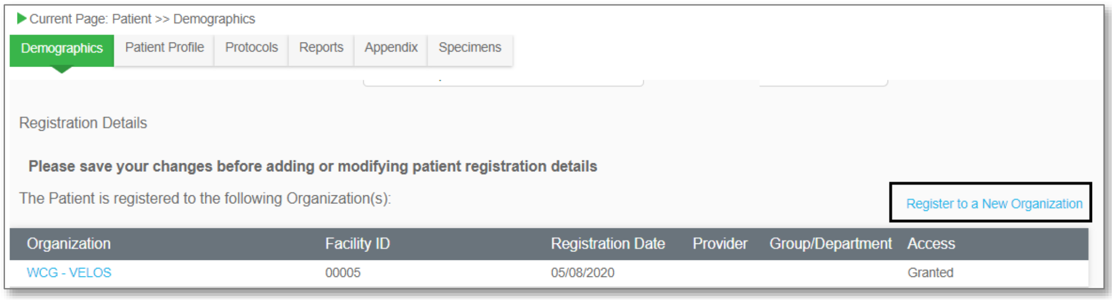
3. The Protocols tab will open. Select the **Demographics** tab.



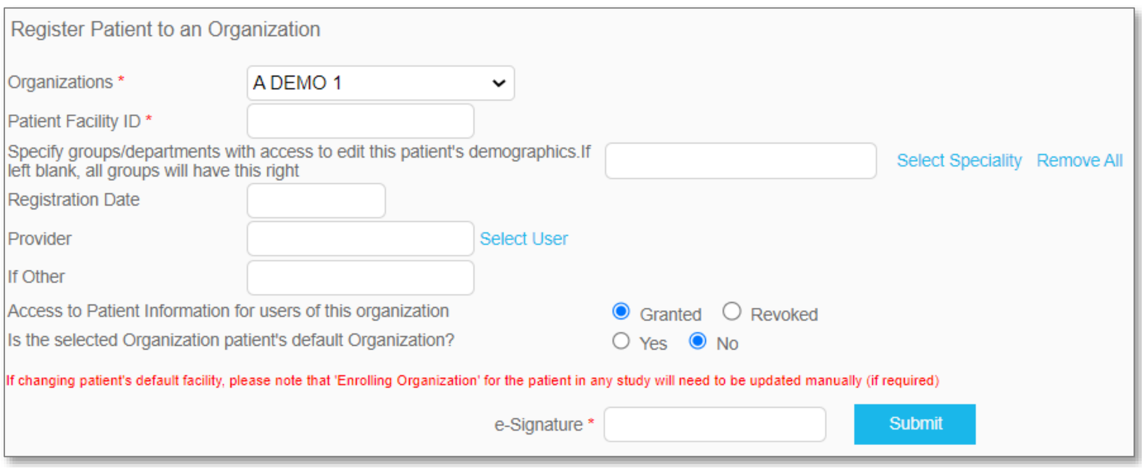
4. The Demographics tab displays. Here, users may specify patient information as needed within the Patient Details page.



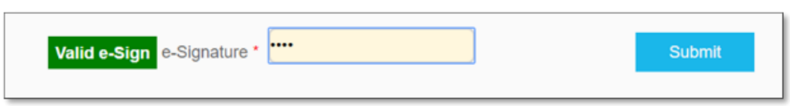
5. To register the patient to multiple organizations, click **Register to a New Organization** in the Registration Details area, if needed.



- By selecting the 'Revoked' radio button, the organization's users may be allowed to track registration details for the patient, but users will not be permitted to view the patient's record



6. Enter your e-Signature and click **Submit** to confirm.

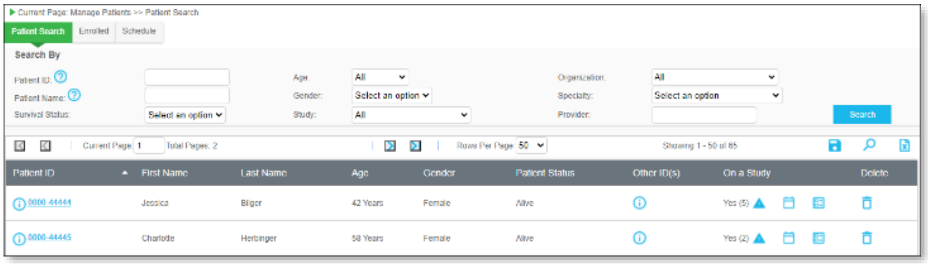


8.6.3 Add an Existing Patient to a Study

Every patient has a system or database record and typically, study records. While a patient may be in the system, it does not mean they are associated to a study unless specified when creating the initial patient record. This section will cover how to add an existing patient to a study.

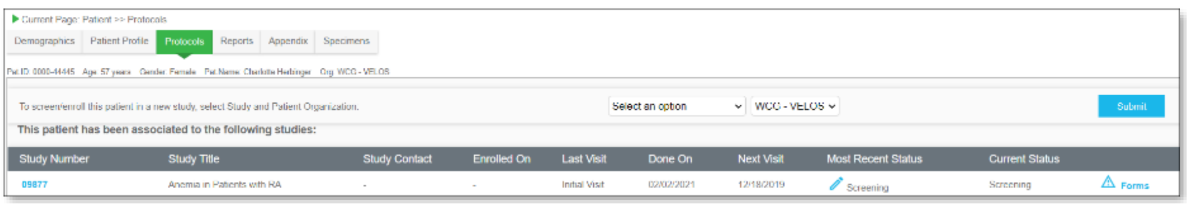
To add an existing patient to a study:

1. **Search** for the appropriate patient.

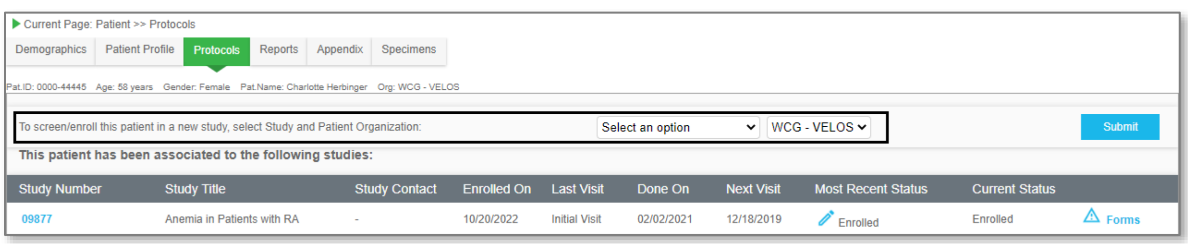


2. Select the **Patient ID** for the desired patient.

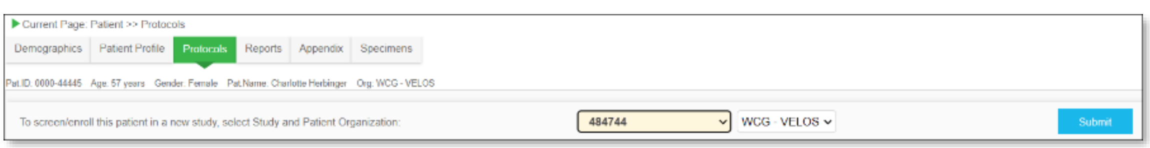
The Patient Protocols page displays:



3. Use the dropdown field to select a study to associate with the patient.

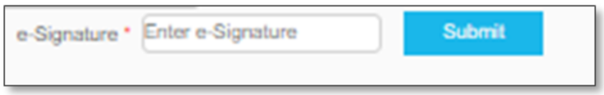


4. Click **Submit**.



The Patient Study Status screen opens:

5. Define the patient study status fields as appropriate and enter your e-Signature and **Submit** to confirm.



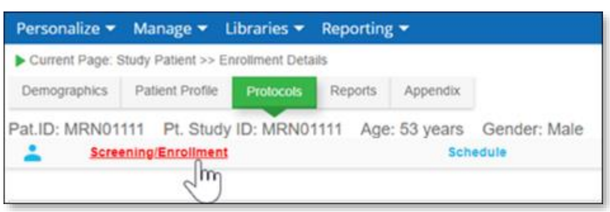
- If both the Enrolled and Active statuses need to be entered on the same day, first add the Enrolled status and the date enrolled and then click **Submit and Add Another** to set to the additional status

8.6.4 Screening/Enrollment

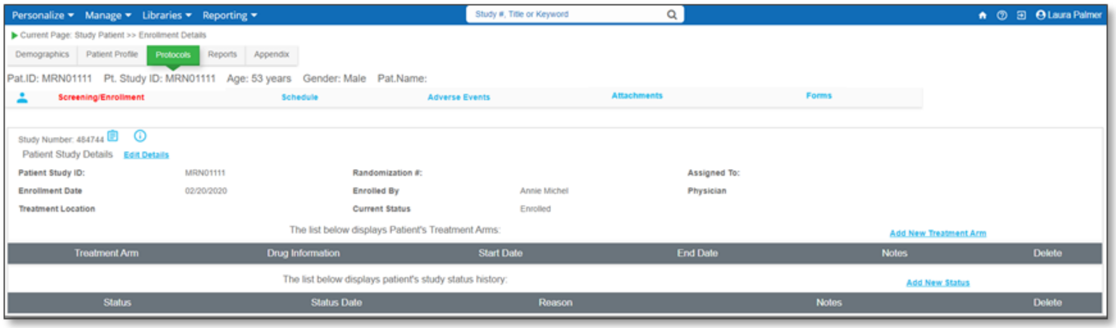
This section will explain the Screening and Enrollment features within the Velos eResearch system and will begin from the Protocols tab. Screening determines the eligibility of a patient for a study. If a patient is eligible, they may be enrolled in that study, or more than one if appropriate.

To manage patient screening/enrollment:

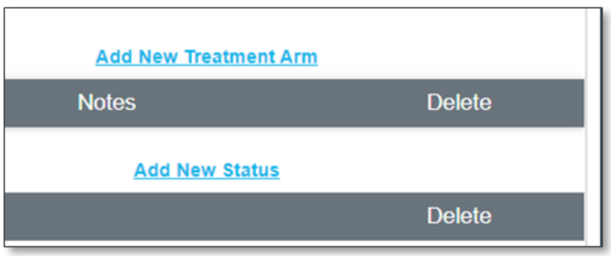
1. From the Protocols tab, click **Screening/Enrollment**.



The Study Patient Enrollment Details tab displays:



Here permissioned users can **Add New Treatment Arm** or **Add New Status** for the selected patient.



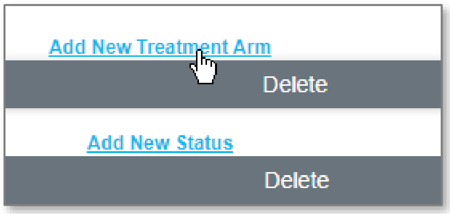
Note: The Add New Treatment Arm provides a Treatment Arm lookup that will search Treatment Arms associated to studies via the Study Setup tab.

8.6.4.1 Add New Treatment Arm

Clicking the link to Add New Treatment Arm allows permissioned users to enter Treatment Arm details through this page from the Treatment Arms listed on the Study Setup page for the selected study. For information on how to associate a Treatment Arm to a study, see Study Treatment Arms.

To Add a New Treatment Arm:

1. From the Screening/Enrollment page, click **Add New Treatment Arm**.

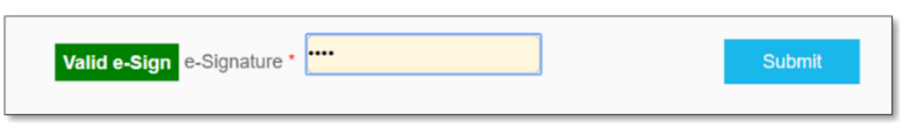


The Patient's Treatment Arm window opens:

2. Using the dropdown option and text fields, define the Patient's Treatment Arm to be associated.

Note: Treatment Arms available in the dropdown field are related to Treatment Arms associated on the Study Setup page.

3. Enter your e-Signature and click **Submit** to confirm.

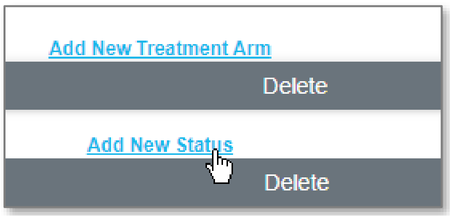


8.6.4.2 Add New Status

On the Screening/Enrollment page of the Protocols tab, permissioned users may update and save Patient Statuses. For information on how to navigate to this point, see Screening/Enrollment.

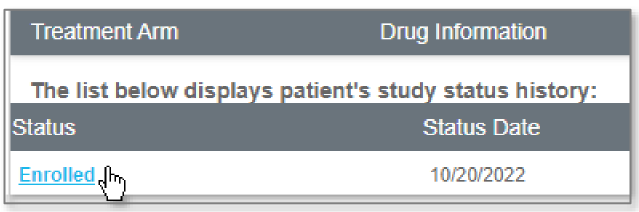
To add a new patient status:

1. From the Screening/Enrollment page, click **Add New Status**.

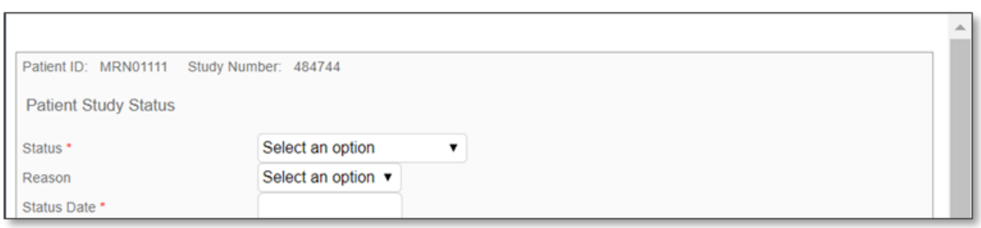


   -OR-

   Edit an existing status by clicking the **Status** link.



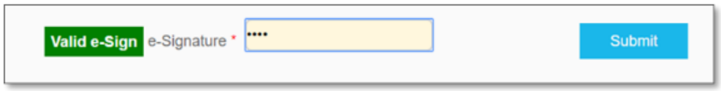
2. a new status or managing an existing status will both take users to the Patient Study Status window. Here, users must set a **Status** from the dropdown options and set the date that the status is valid from.



Some patient statuses have certain behaviors that change patient management functionalities. For patient status information, see below:

Status Name	Description
Active/On-Treatment	This status indicates that the patient is currently actively associated to the study or on treatment.
Enrolled	This status indicates that the patient associated to this status is enrolled to a study. The "Patient is not yet enrolled" screen display message will appear until this status has been added and the enrollment details section becomes available to define when this status has been selected.
In Follow-up	This status indicates that the patient is in follow-up status. Some reasons for using this status include disease progression or survival only statuses.
Informed Consent Signed	This status indicates that the patient's informed consent has been signed. Once selected, this status will display the informed consent details section for more information to be added. Some reasons for using this status include initial patient status or to document re-consent.
Lockdown	This status indicates that the patient's progress on the study is in lockdown. This status prevents the documenting user from editing or adding information in regard to the Patient Schedule, Adverse Events, and Patient Forms.
Off Study	This status indicates that the patient has been removed from the study. Some reasons for using this status include but are not limited to: an adverse event, alternative therapy, complete response per protocol, consent withdrawn after treatment started, consent withdrawn before treatment started, disease progression after treatment started, lost to f/u, noncompliance, other, other complicating condition, patient died, physician discretion, sponsor termination, or study complete.
Off Treatment	This status indicates that the patient is off treatment currently. Some reasons for using this status include but are not limited to: an adverse event, alternative therapy, complete response per protocol, consent withdrawn after treatment started, consent withdrawn before treatment started, disease progression after treatment started, lost to f/u, noncompliance, other, other complicating condition, patient died, physician discretion, sponsor termination, or treatment complete.
Screen Failure	This status indicates that the patient was a screening failure.
Screening	This status indicates that the patient is in screening. Selecting this status will cause screening details to display for more information.

3. Enter information as appropriate and then enter your e-Signature. Click **Submit** to confirm.



8.6.4.3 Updating Statuses for Deceased Participant

Throughout the lifecycle of a study, permissioned users will need to update and modify patient statuses periodically. When a patient is deceased, not only should it be indicated in their system record, but their status needs to be changed on each study they were enrolled in so that their visits are cancelled by setting the patient study status to 'Off-Study' with a reason of 'death' and by including a date. This will ensure the patient cannot be added to other studies going forward. Update remaining visits, or edit multiple visits, to the status of "not required".

8.6.5 Patient Schedules

Patient Schedules manage patient study activity, patient events, visits, and milestones for financial records. This assists in keeping track of patient visit schedules and visit records. Users can Edit Multiple Events, Edit Visits and Add Unscheduled Events from the Protocol tab. Patient Schedules are created based on the Calendars associated to a Study. See the Calendar Library for more information on the Calendar Library. See how to Associate a Calendar to a Study for information on associating a Calendar to a Study.

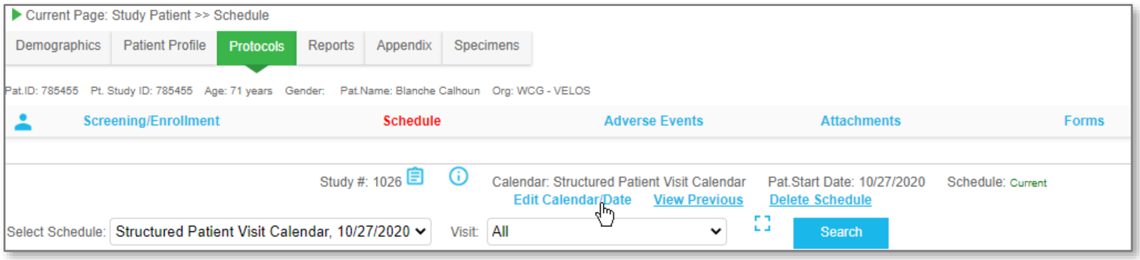
8.6.5.1 Generate a Study Patient Schedule

Once a patient is associated to a study and a calendar is associated to a study, a patient Schedule can be generated based on the events and visits with that calendar. The instructions for this section begin on the Patient Protocols tab. For information on how to get to this point, see Patient Schedules.

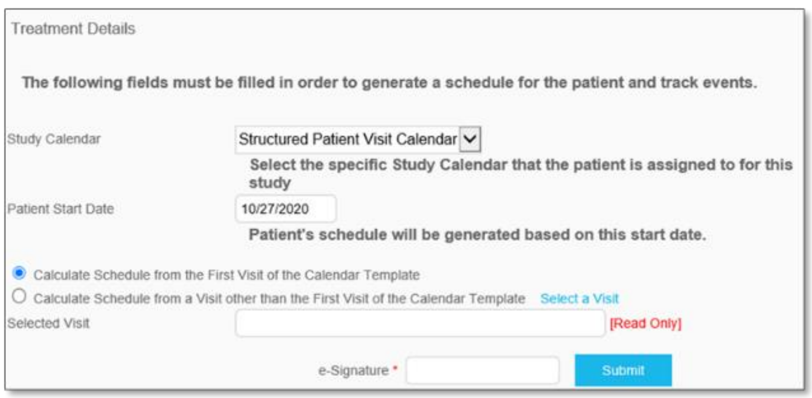
Note: Ensure the Calendar in the study is set to active.

To generate a patient schedule:

1. Click a user's **Study ID Number** then navigate to the **Protocols** tab. Click **Schedule** and click **Edit Calendar/Date**.



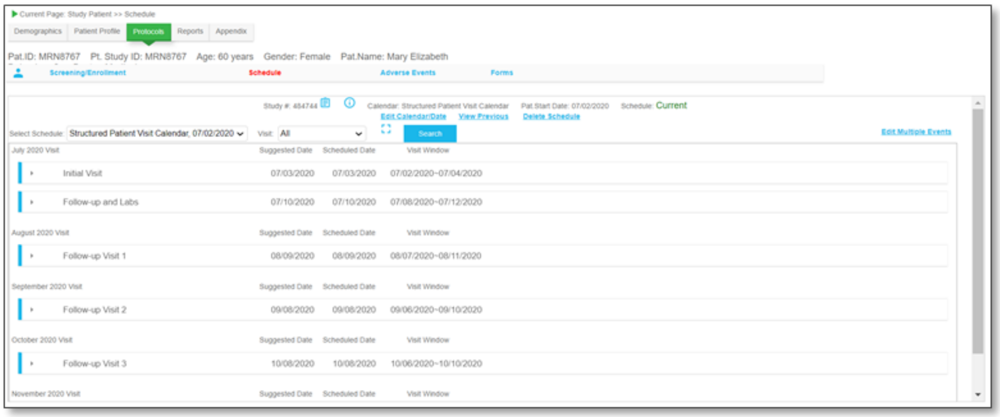
2. The Patient Protocol Details window will display. Select the appropriate calendar from the **Select Calendar** field. Enter a date in the **Patient Start Date** field. Enter your e-Signature and click **Submit** to confirm.



- If selecting the default radio button "Calculate Schedule from the First Visit of the Calendar Template", the 'First Visit' is the first visit that does not have a negative interval. For example, if the first three visits have negative intervals: Day -14, Day -7, and Day -1 and the Fourth visit has a positive interval: Day 5, then the Fourth Visit is considered the 'First Visit'. The start date will be Day 1 (09/08/22) and the fourth visit will be calculated from that date. The Schedule Date for the fourth visit would be 09/12/22.
- If selecting the radio button "Calculate Schedule from a Visit other than the First Visit of the Calendar Template", then click **Select A Visit**. For example, if a calendar has 3 visits – V1(Day1), V2(Day8), V3(Day15) and V3 was selected to generate the schedule with 09/01/2022 as the selected start date, then in the generated schedule V1 and V2 will not be listed. The first visit displayed on the schedule is V3. The actual schedule date for V3 will be

09/15/2022. Even though V3 was selected as the first visit for the schedule, because the schedule dates will be generated off the first visit in the Calendar template, in this case V1.

The Patient visit schedule generates and displays:



8.6.5.2 Change Schedule Dates

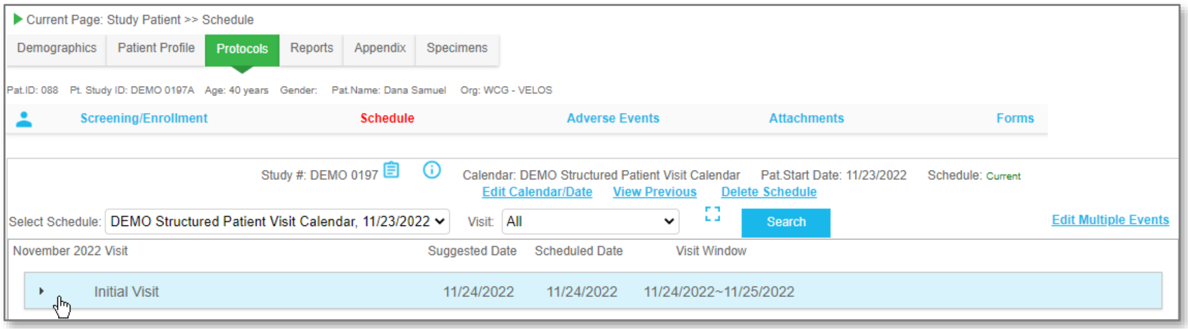
From a created schedule, users may wish to modify scheduled dates associated with a patient. This section will instruct how to change an event date for a patient. For instructions on how to get to this point, see Patient Schedules.

When viewing the patient's schedule there are two Scheduled Date columns: 'Suggested Date' and 'Scheduled Date'.

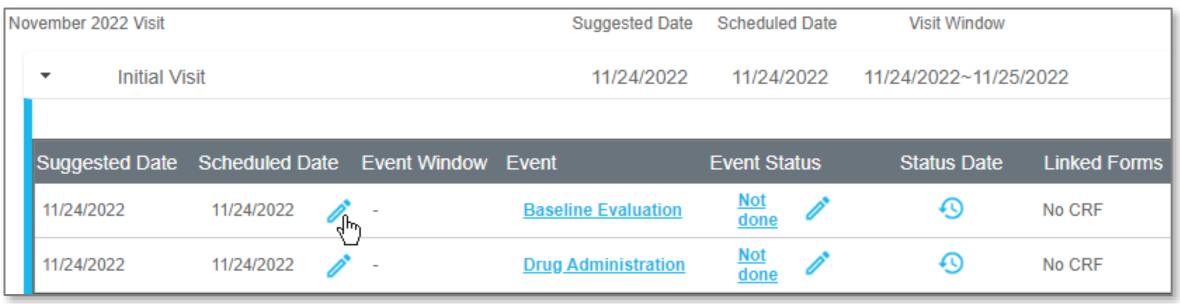
- Suggested Dates displays the date based on the Visit Intervals and the Start Date which is generated automatically by the system.
- Scheduled Date is the date that the Event gets scheduled (if changed by the Study Coordinator). By default, the Scheduled Date is the same as the Suggested Date of the event.

To change a patient's scheduled event dates:

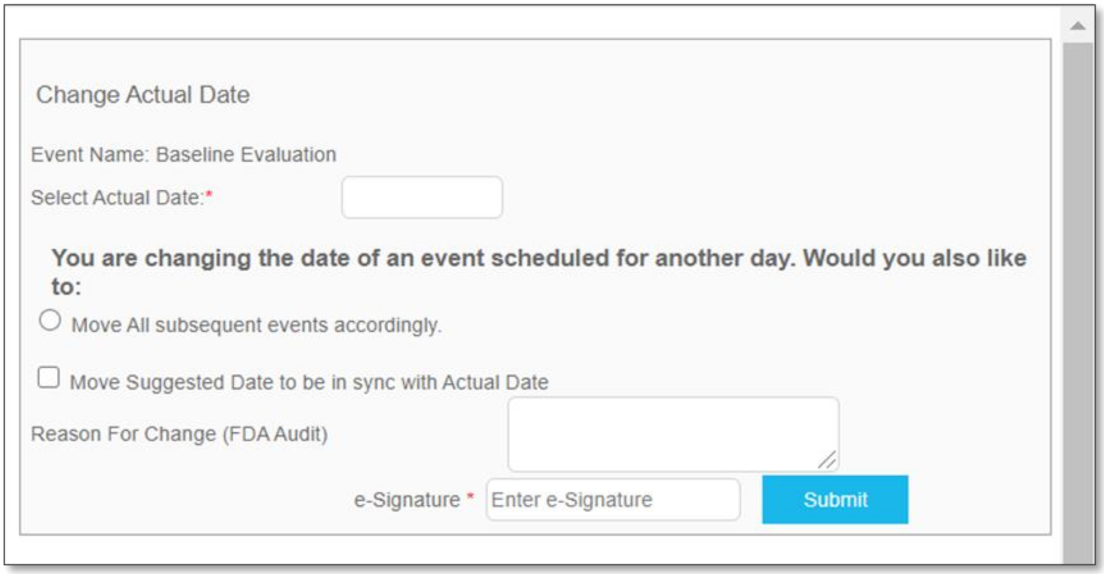
1. From the Manage Patient Schedule page, click the **arrow** button to display the events under the selected visit.



2. The visit section expands with events listed below. Click the **Edit** button under the **Scheduled Date** column for the appropriate event.



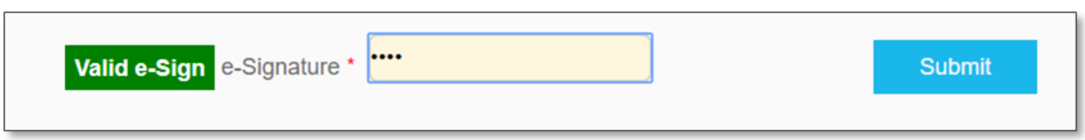
The Change Actual Date window displays:



Note:

1. The Select Actual Date field can be entered manually without using the Date Picker. To do this, the pop-up screen may need to be maximized.
2. Different radio button options appear based on what was selected in the Define tab for a calendar. For more information, refer to Modify an Active Calendar.
3. Check the checkbox for Move Suggested Date to be in sync with Actual Date, if an entire visit is being moved, or as needed.

3. Modify fields as necessary. Enter your e-Signature and click **Submit** to confirm



8.6.5.3 Modify an Event Status for a Schedule

When the status of an event has changed, it is important to update in the system. For example, when a visit or lab is completed for a patient, it should be updated. This section will instruct how to modify the events status on the patient study schedule.

Users may select between three options to modify an event or multiple event statuses:

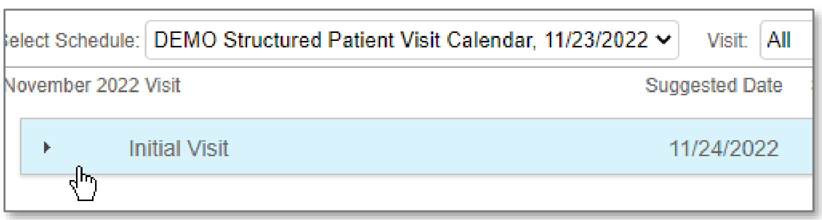
Options	Refer To:
Edit a Single Event Status	Edit a Single Event
Edit Multiple Events in a Single Visit	Edit Visit
Edit Multiple Event Statuses in Different Visits	Edit Multiple Events

8.6.5.3.1 Edit a Single Event

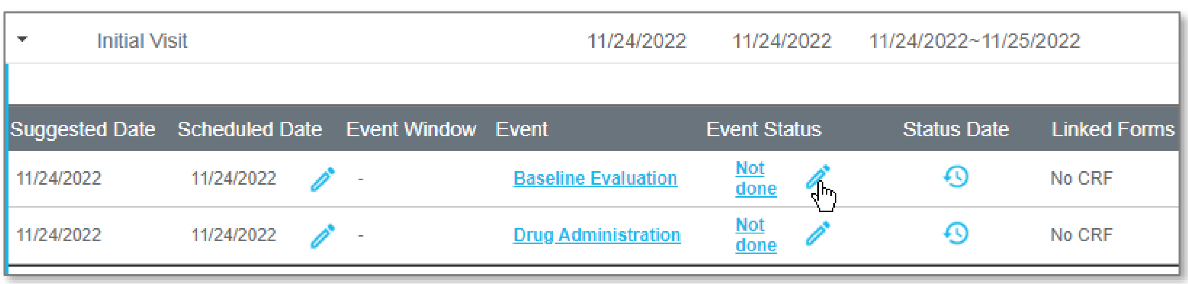
This section will instruct how users may edit a single event.

To edit a single event:

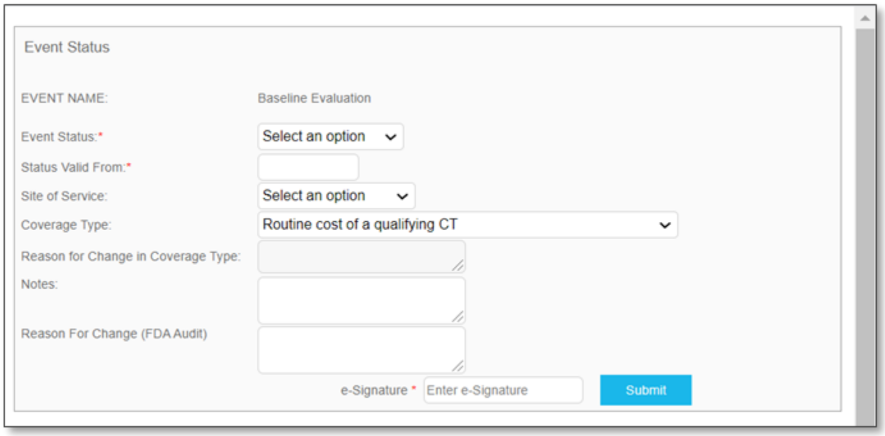
1. From the Manage Patient Schedule page, use the **arrow** buttons to display the events under the desired Visit.



2. The Visit section will expand, listing all associated events. Click the **Edit** button for the appropriate event under the **Event Status** column.

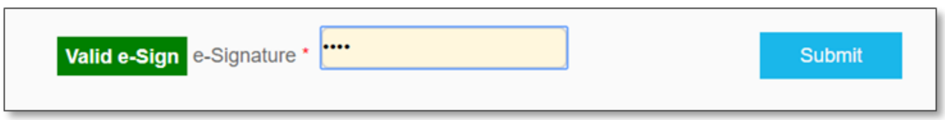


3. The Event Status window displays. Here, users may change the **Event Status**, set the **Status Valid From** date, choose a **Site of Service**, **Coverage Type**, and add **Notes**.



Note: Changes made to coverage type must be made at the calendar event level, not at the patient level to ensure correct billing.

4. Edit information as appropriate. Enter your e-Signature and click **Submit** to confirm.



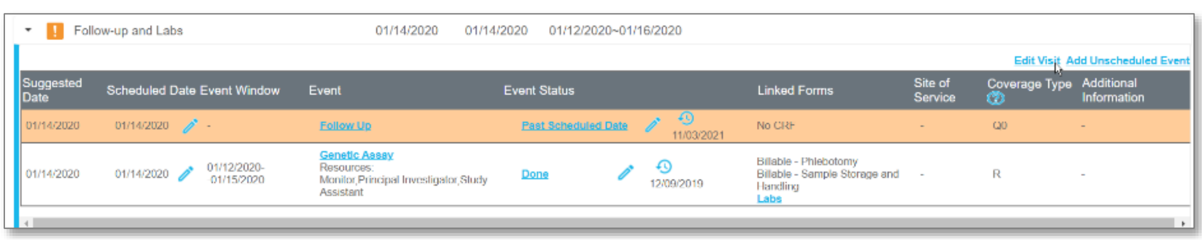
The Manage Patient Schedule page will display with the saved changes.

8.6.5.3.2 Edit Visit

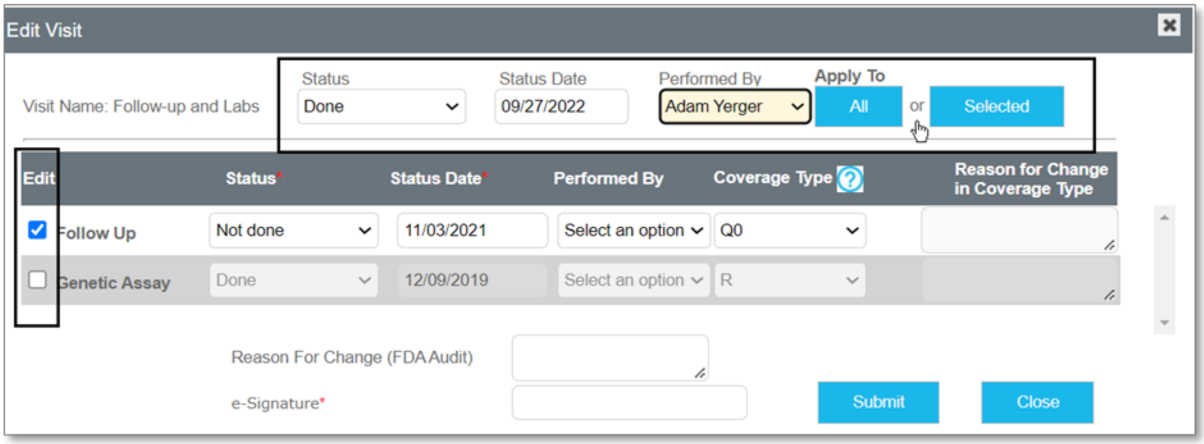
User may edit a visit to update all or some events in the visit at one time.

To edit a visit:

1. From the Patient Protocols tab and the Schedule page, click **Edit Visit** above a specific visit.



2. In the Edit Visit pop-up, use the Power Bar in the top row to select a Status from the dropdown, and a Status Date, and optionally select a Performed By Option.

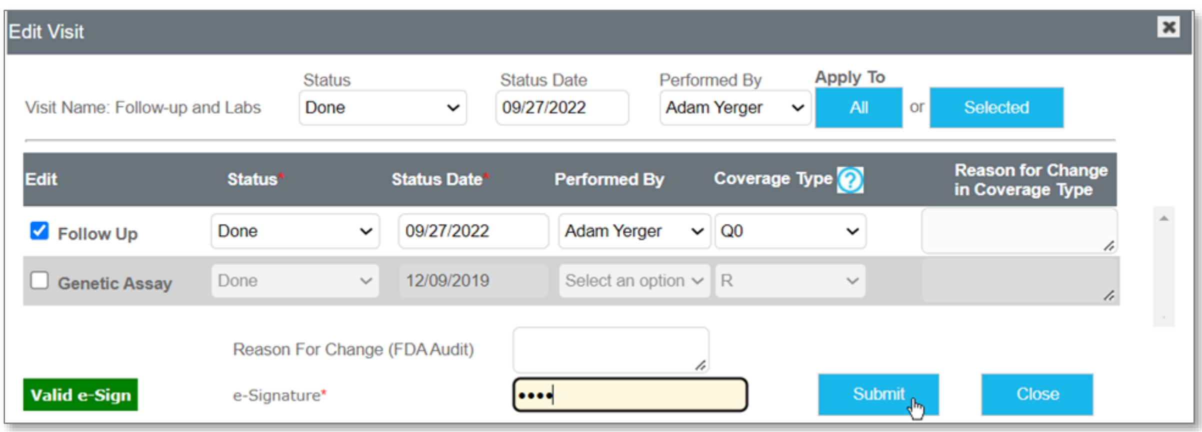


3. Click **ALL**.

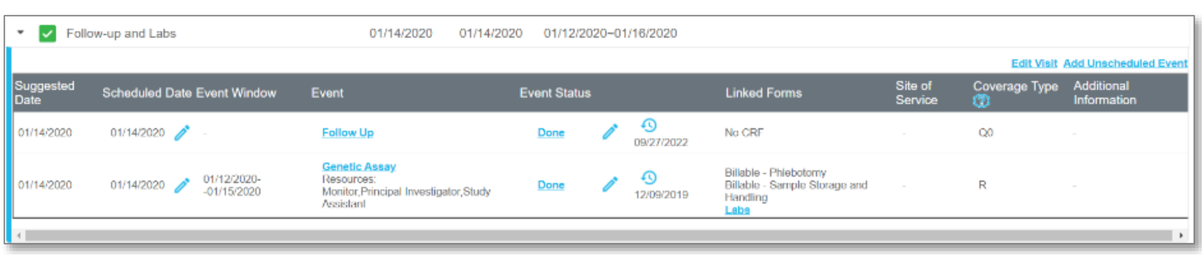
   -OR-

   If not updating all events, add checkmarks in the Edit column for the applicable events to be updated simultaneously, then click **Selected**.

4. After the data populates in the table, enter your e-Signature and click **Submit**.



The data will be updated for the visit's events as selected.



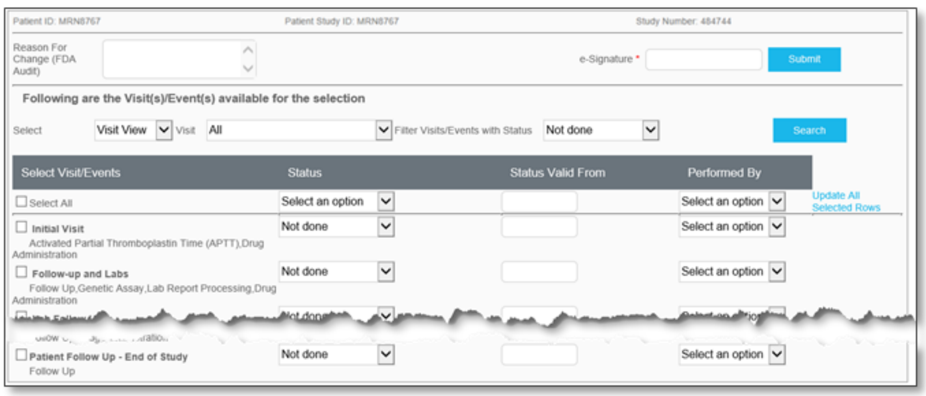
8.6.5.3.3 **Edit Multiple Events**

Users may also update multiple events at one time. This feature will allow the updating of multiple events with the same status and information.

To edit multiple events:

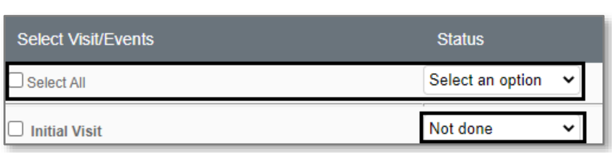
1. From the Patient Protocols tab and the Schedule page, click **Edit Multiple Events**.

2. The Edit Multiple Visits window displays. Here, users may use fields to update all or select events with the same **Status**, **Status Valid From** date, and select the **Performed By** user.



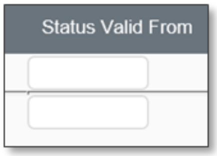
Note: When editing multiple visits, the visit view is useful when all events for a single visit have the same status and date. If not, the event view should be used for editing. Visit View is usually used if a user is behind in data entry. Using Visit View allows for updating multiple Visits from one window.

3. Select the appropriate option under the **Status** field for each visit and/or event.



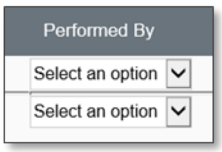
- The top field showing **Select an option** is for when checking the checkbox for **Select All** and the selection will apply to all Visit/Events at one time

4. Select the appropriate date for the **Status Valid From** field for each visit and/or event.



- The top field entry will apply to all Visit/Events when checking the **Select All** checkbox

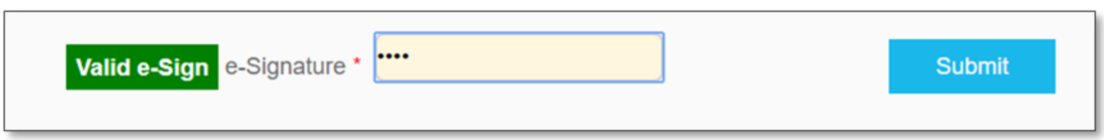
5. Select the appropriate user from the dropdown for the **Performed By** field for each visit and/or event.



- The top field selection will apply to all Visit/Events when checking the **Select All** checkbox

Note: Using the checkboxes will select individual Visits/Events, while using All will apply changes to all.

6. Make changes as necessary and enter your e-Signature and click **Submit** to confirm.

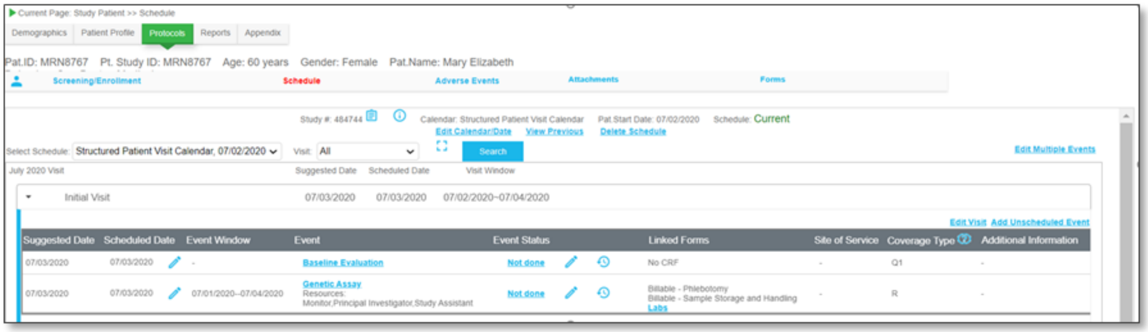


8.6.5.3.4 Add Unscheduled Events

When a patient schedule is generated, permissioned users have the ability to add an unscheduled event to a visit.

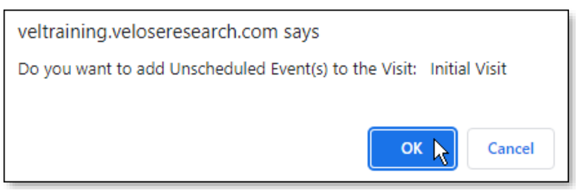
To add an unscheduled event:

1. From a patient schedule / calendar, select the desired visit to expand.

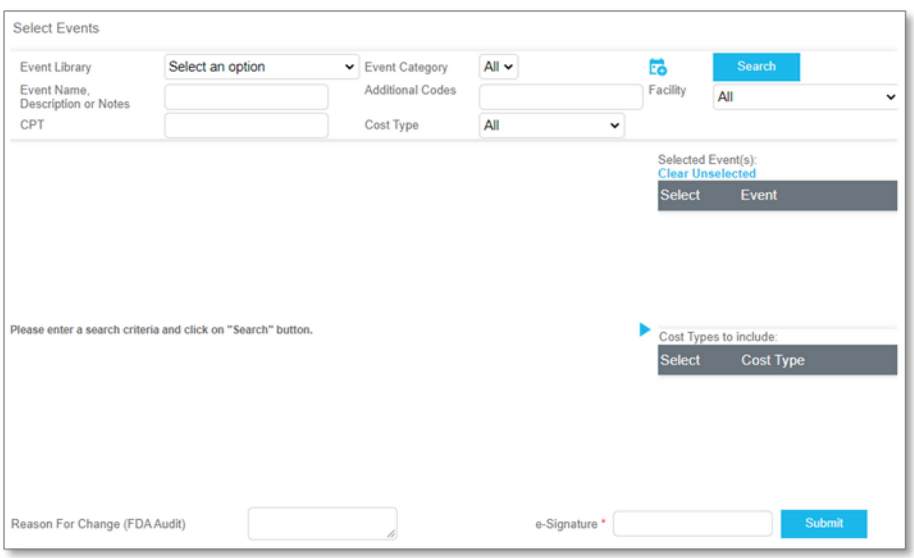


2. Click Add Unscheduled Event.

3. A window asking to confirm the visit to add an unscheduled event to opens. Click **OK**.

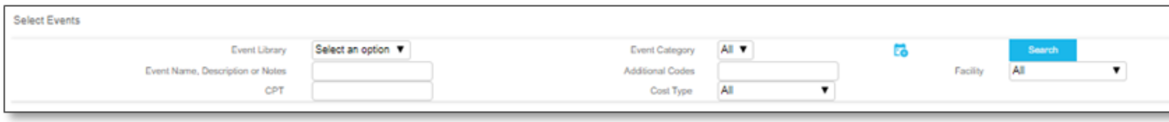


The Select events window opens:

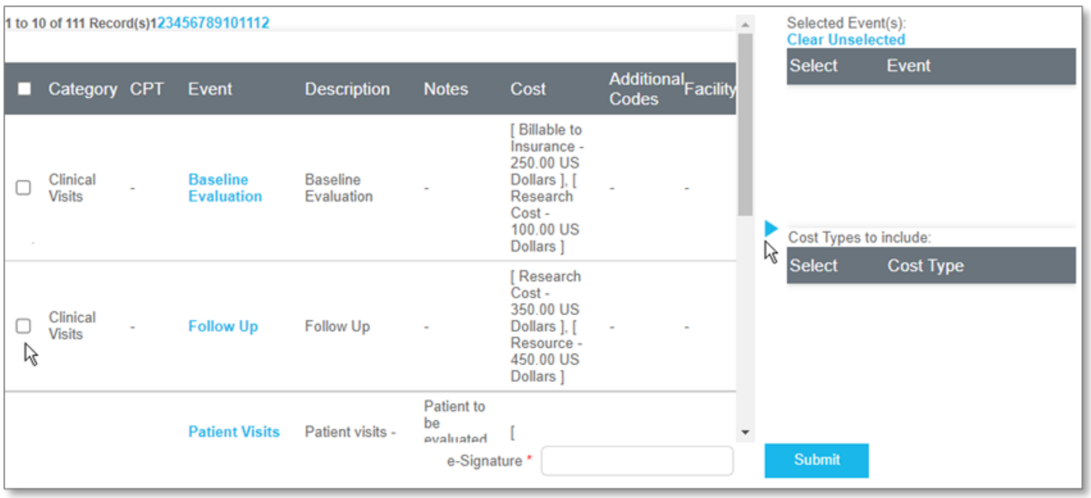


Note: If the pop-up window does not appear, ensure the pop-up blockers is turned off for the eResearch application.

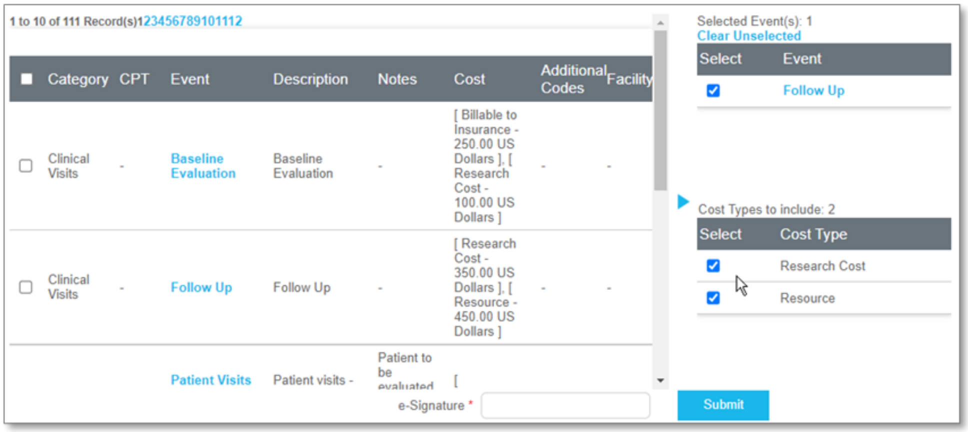
4. **Search** for the desired event.



5. Select the appropriate and desired event(s) and click **Transfer** to move the event(s) to the Selected Event(s)column.



6. Once the desired event(s) are selected, either keep the default Cost Types all selected or uncheck checkmarks in the Selected Event(s) column for costs that should not be included then, enter your e-Signature and click **Submit** to confirm.

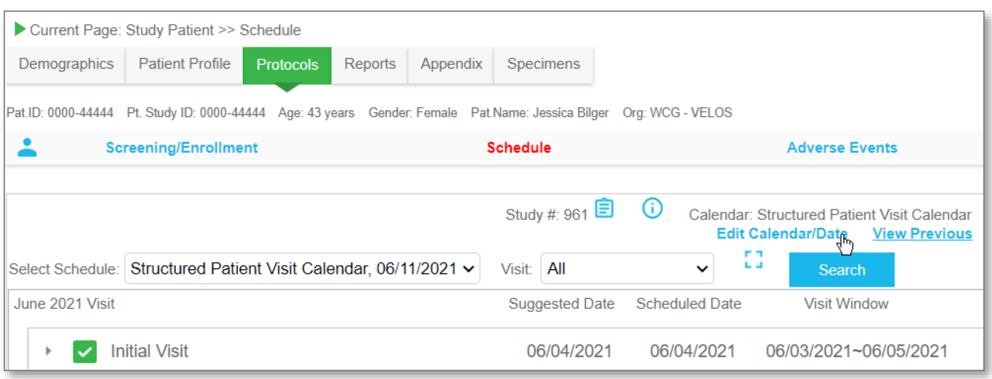


8.6.5.3.5 Discontinuing Schedules

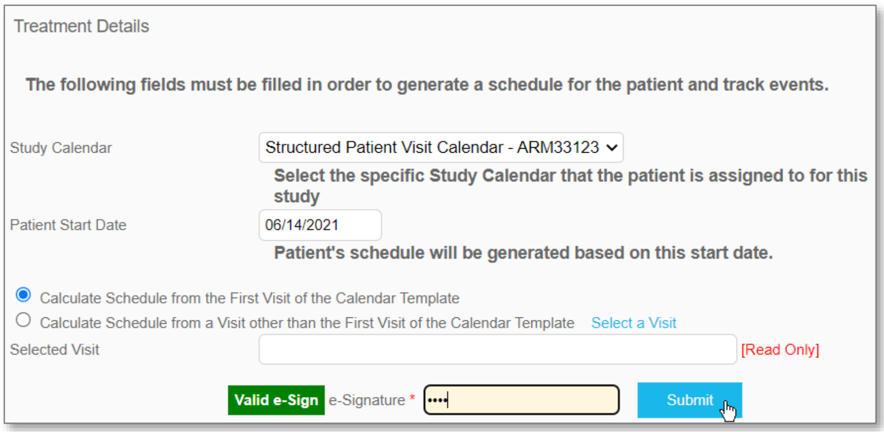
Schedules may be discontinued to start using a new schedule starting on a specific date. This may be desired if using multiple schedules for different arms of a protocol. The new schedule will be marked as the Current Schedule. A user can return to the discontinued schedule and utilize to complete visits and events until the start date of the new schedule.

To discontinue a patient schedule for a specific study patient record:

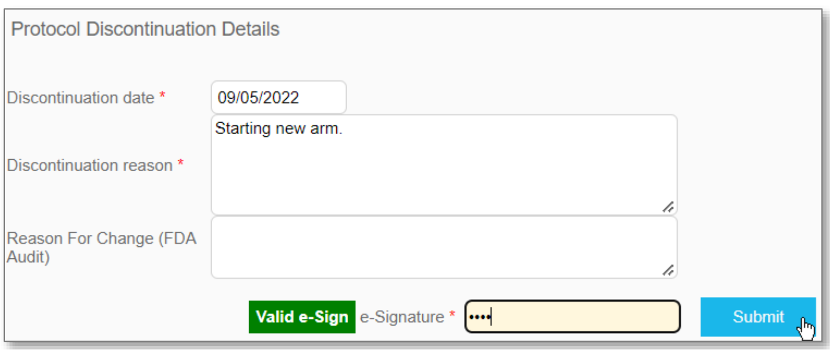
1. From the Protocols >Schedule tab, click Edit Calendar/Date.



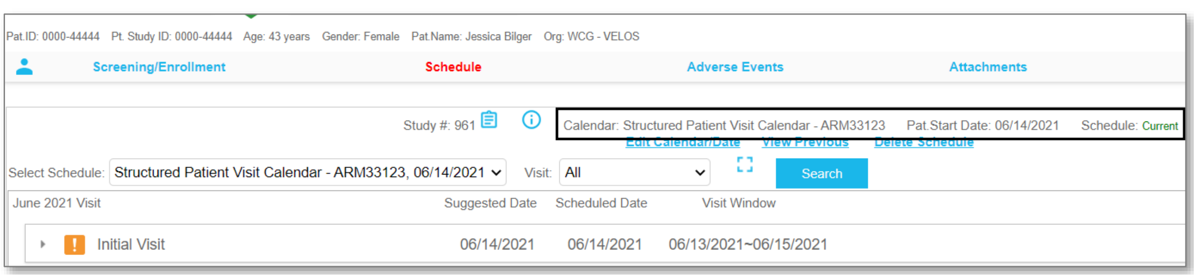
2. In the Treatment Details pop-up, select the new Study Calendar from the dropdown, select the Patient Start Date from the date picker, select the appropriate radio button option (selecting a visit if needed for options two), enter your e-Signature, then click **Submit**.



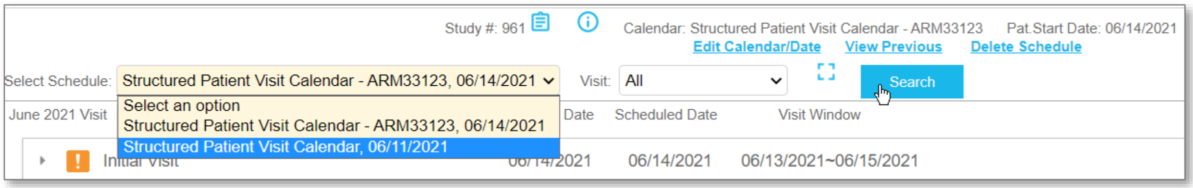
3. In the pop-up, select the Discontinuation Date from the date picker, enter a Discontinuation reason in the blank field, enter your e-Signature, then click **Submit**.



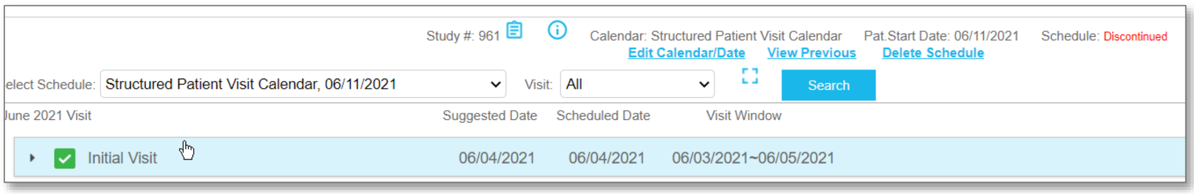
The new schedule will appear as current.



4. If the prior schedule has not yet ended, select the applicable schedule from the Select Schedule dropdown, then click **Search**.



5. The discontinued schedule may be viewed or edited as needed.



8.6.6 Adverse Events

Patient Adverse Events (AE's) can be documented through the Protocol tab and on the Adverse Events page. To manage the Adverse Event dictionary, see the Studies.

Enterprise Only: Adverse Events are only found within eResearch Enterprise.

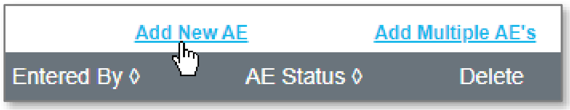
8.6.6.1 Add New AE

The instructions for this section will cover how to upload a single Adverse Event. For information on how to navigate to this screen, see Manage an Existing Patient. For information on how to Add Multiple Adverse Events, see Add Multiple AE's.

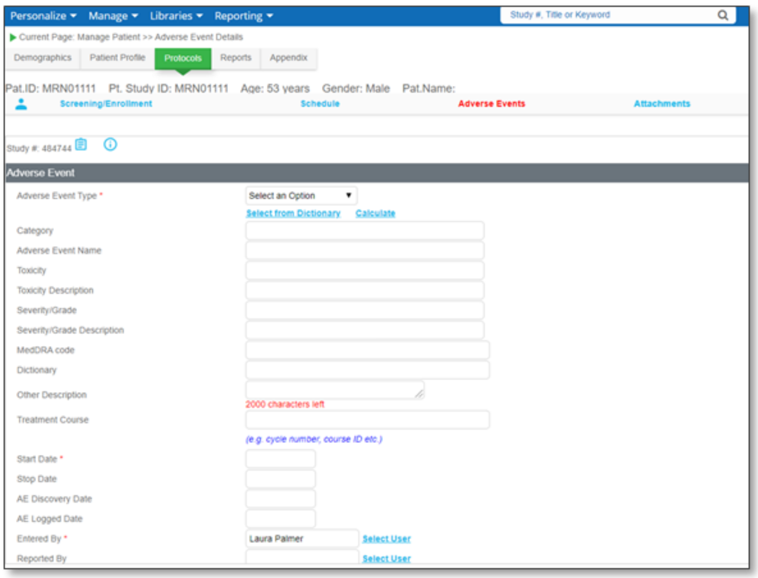
Note: Adverse Event details may vary based on what was selected for defining an Adverse Event via the Study Setup tab.

To add a New Adverse Event:

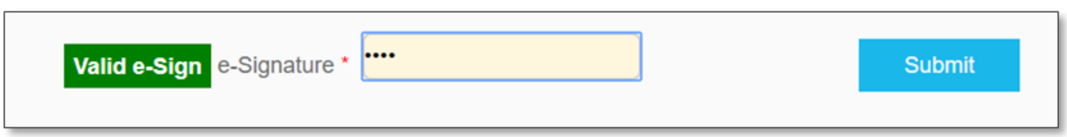
1. From the Adverse Event page, select **Add New AE**.



The Adverse Event page displays:



2. Enter in information as appropriate to define the Adverse Event, enter your e-Signature and click **Submit** to confirm.

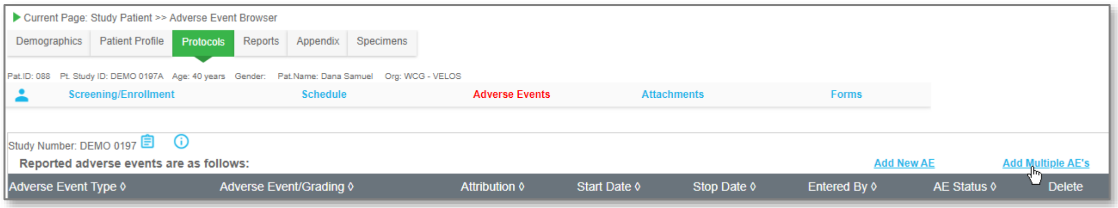


8.6.6.2 Add Multiple AE's

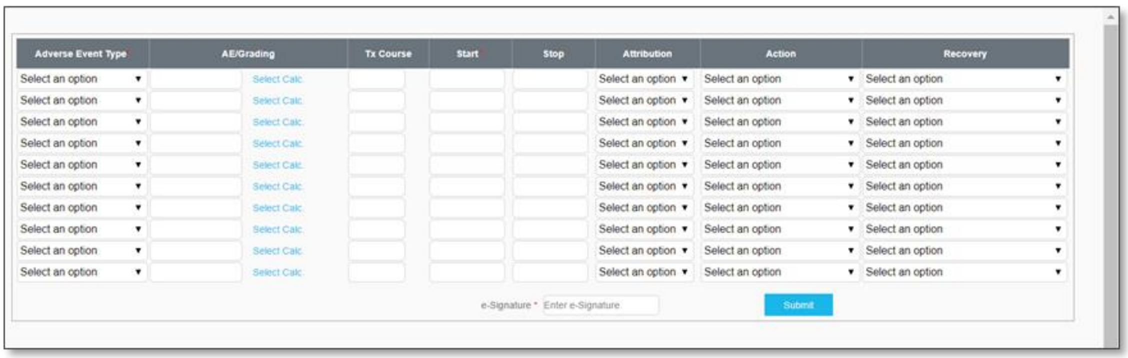
This section will cover how to add multiple adverse events at once. For information on how to get to this point, see Manage an Existing Patient. For instructions on how to get to add a single adverse event, see Add New AE. Dictionaries selected in Study Setup in study management determine the options for AE forms, including the option for NCI CTC dictionaries. For more information, refer to Associating the Adverse Event Dictionary.

To add multiple adverse events:

1. From the Adverse Events page of the Protocols tab, click **Add Multiple AE's**.



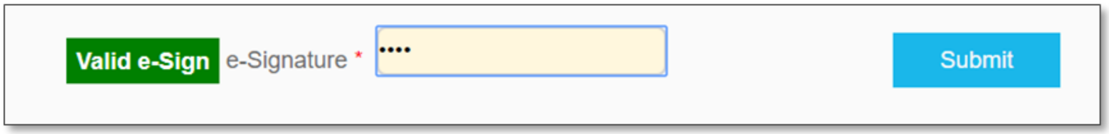
The Multiple Adverse Events window opens:



The available fields are described in detail below:

Field	Description
Adverse Event Type	Dropdown field to select either Adverse Event or Serious Adverse Event.
AE/Grading	Select the severity/grade using the Select Link and the Calendar*. *If no Adverse Event Dictionary is associated with the study, a popup will appear notifying the user.
Tx Course	Define as appropriate.
Start*	Enter the start date of the Adverse Event.
Stop	Enter the stop date, if appropriate.
Attribution	Dropdown field to select from the available options: Definite, Probable, Possible, Unlikely, Not related, Unknown.
Action	Select the appropriate option from the dropdown menu options: None, Dose Modification, Counteractive Medication, Medical/ Surgical Intervention.
Recovery	Select the appropriate field from the dropdown menu options: Recovered/ resolved without Sequelae, Recovered / resolved with Sequelae, Recovering / resolving, Intervention for AE Continues, Not recovered / Not resolved, Other.

2. Define the fields as appropriate, enter your e-Signature, and click **Submit** to confirm.



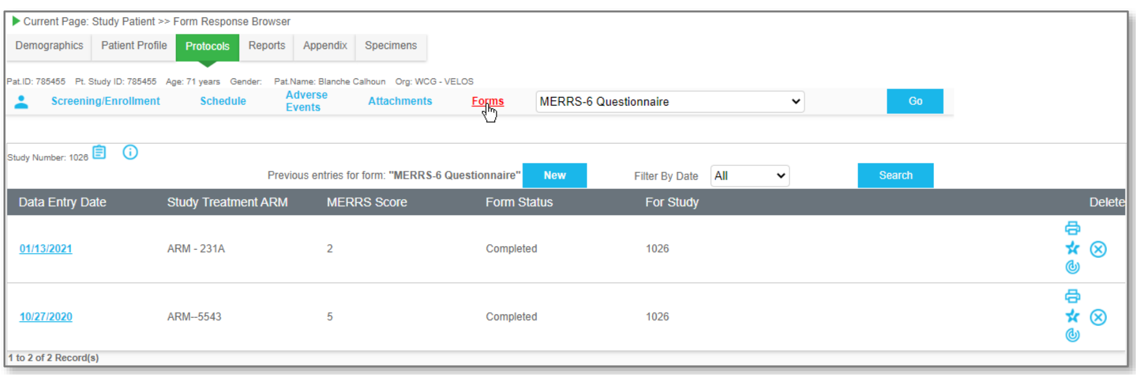
8.7 Patient Forms and Labs

Patient Forms are used to track study patient data, such as Patient Form Responses. Patient Forms include, but are not limited to, Patient Medical History documents, Patient Emergency Contact Forms, etc. In order to use a Form for a Study, the form must first have to be set up within the system. The Study must have an "Active" status, or the equivalent of "Active" and the form must be associated to a study. Additionally, the Form must be set to "Patient" when selecting either Study or Patient association. For information on how to associate a patient form, please refer to Associated Forms. For information on creating a form in the Form Library, see Forms Management.

Enterprise Only: Labs are an Enterprise only feature in eResearch.

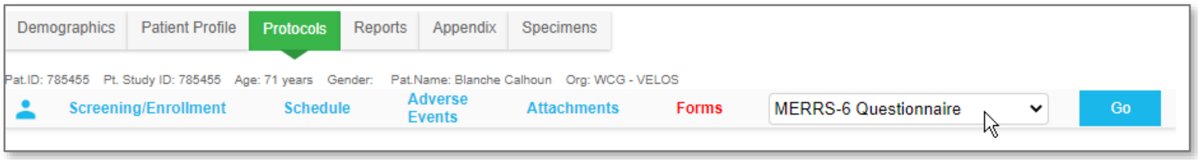
To add a form response:

1. From the Protocols tab, select **Forms**.



The Study Patient Form Response page displays.

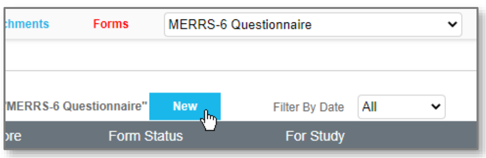
2. Using the dropdown menu, select the appropriate associated form to record a patient response.



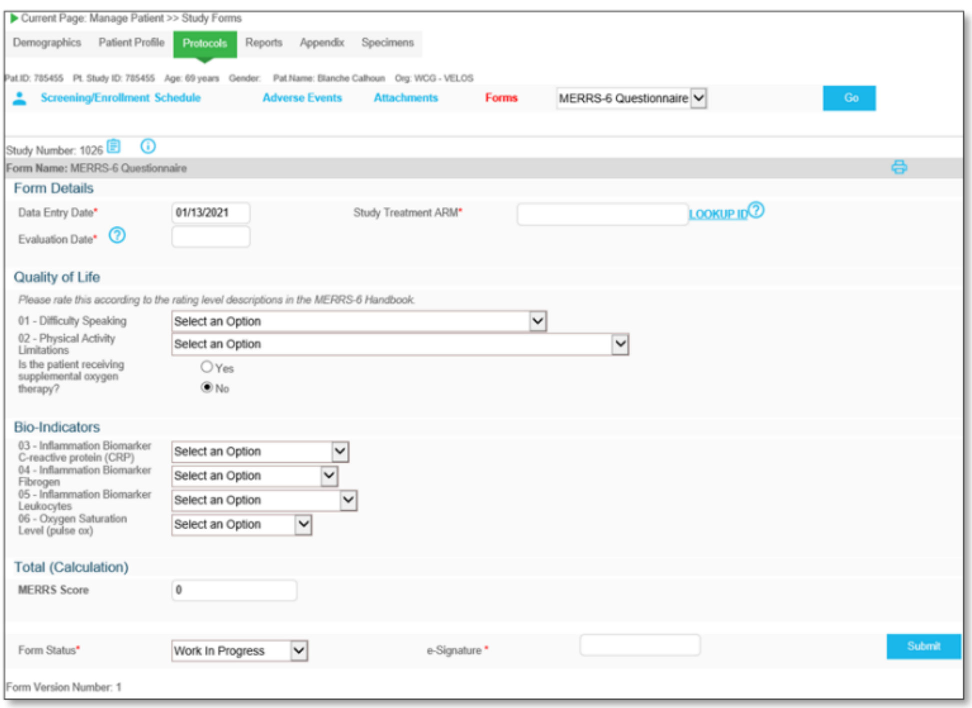
Note: Forms that appear within the Form dropdown field are Active Patient Forms associated via the Study Setup tab.

Warning: Do not click Go at this point in the process, click New, to see a new form. Clicking Go takes you to view already existing form responses, if there are any.

3. Click **New**.

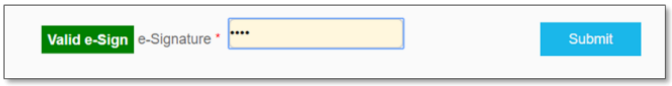


The Manage Patient Study Forms page displays. (The below image is a sample form.)



Note: The form that displays will be the selected form that was associated to the study on the Study Setup tab from the Form Library. For some studies, form options may include forms added at the Account level.

4. Complete the form, enter your e-Signature, and click **Submit** to confirm.

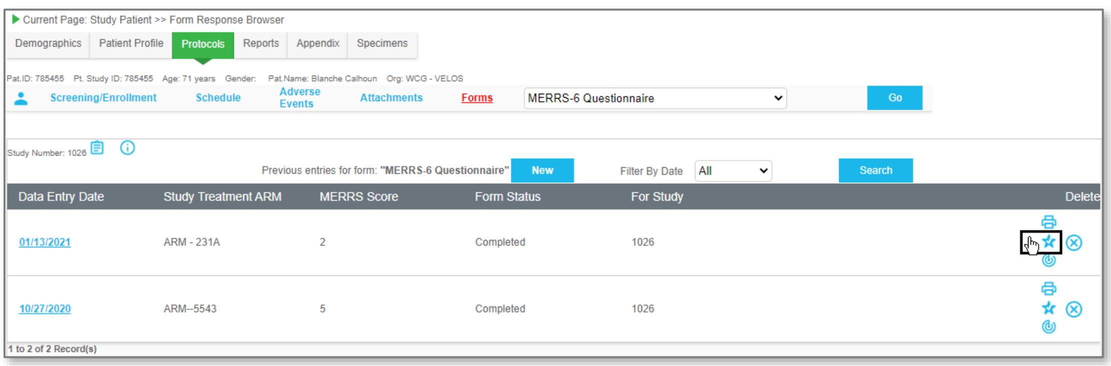


8.7.1 Patient Forms Audit Trail

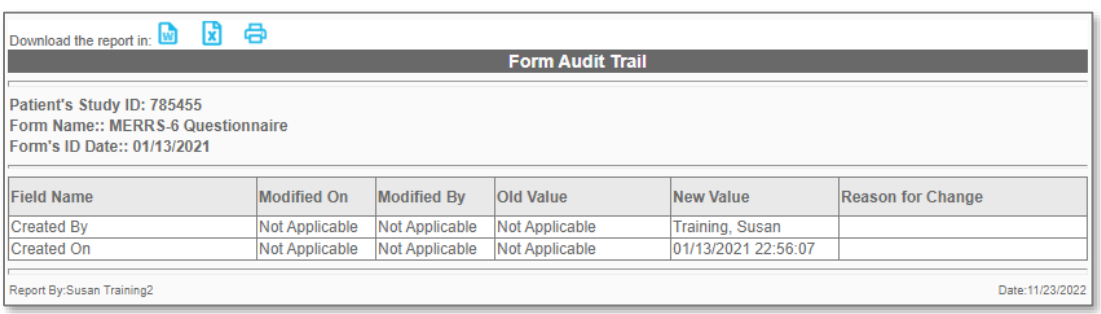
When a Form has been updated, a record is created which can be viewed in an audit trail.

To view an audit trail for a Form:

1. Click the **Star** button representing the Audit Trail.



The Form Audit Trail page opens in a new page.



Download the report in:

Form Audit Trail

Patient's Study ID: 785455
Form Name:: MERRS-6 Questionnaire
Form's ID Date:: 01/13/2021

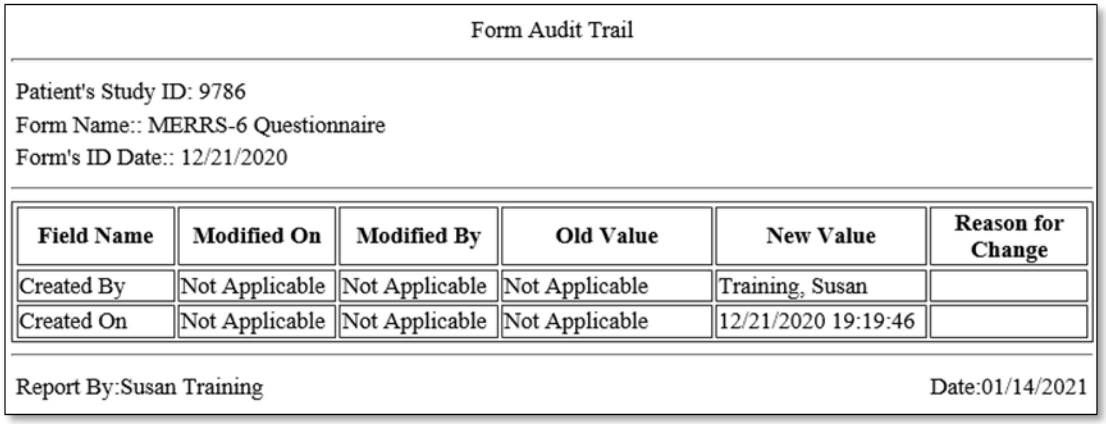
Field Name	Modified On	Modified By	Old Value	New Value	Reason for Change
Created By	Not Applicable	Not Applicable	Not Applicable	Training, Susan	
Created On	Not Applicable	Not Applicable	Not Applicable	01/13/2021 22:56:07	

Report By:Susan Training2 Date:11/23/2022

2. To export in Word or as an Excel file, click a **Word** or **Excel** button at the top of the form.

   -OR-

To create a printer friendly format, click the **Printer** button.



Form Audit Trail

Patient's Study ID: 9786
Form Name:: MERRS-6 Questionnaire
Form's ID Date:: 12/21/2020

Field Name	Modified On	Modified By	Old Value	New Value	Reason for Change
Created By	Not Applicable	Not Applicable	Not Applicable	Training, Susan	
Created On	Not Applicable	Not Applicable	Not Applicable	12/21/2020 19:19:46	

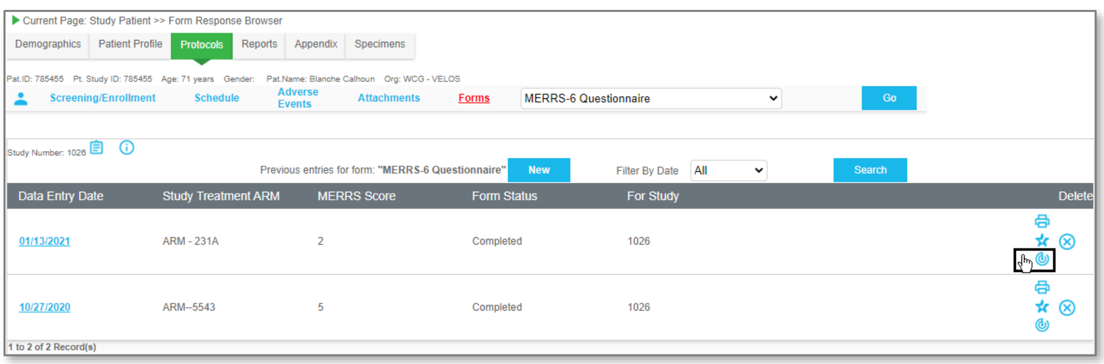
Report By:Susan Training   Date:01/14/2021

8.7.2 Patient Forms Track Changes

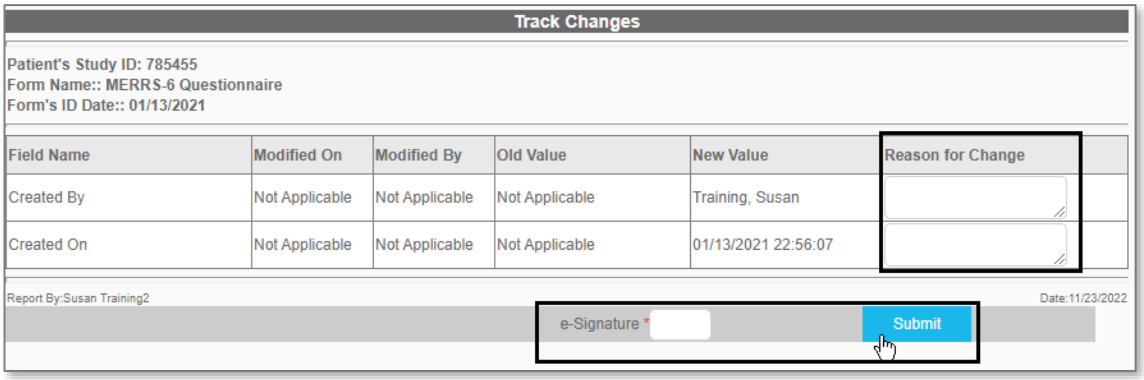
When a Form has been updated, track changes are created. Reasons for change can be added to the Track Changes page.

To view track changes for a specific form:

1. Click the **Track Changes** button.



The Track Changes page opens in a new page.


Track Changes

Patient's Study ID: 785455
Form Name:: MERRS-6 Questionnaire
Form's ID Date:: 01/13/2021

Field Name	Modified On	Modified By	Old Value	New Value	Reason for Change
Created By	Not Applicable	Not Applicable	Not Applicable	Training, Susan	
Created On	Not Applicable	Not Applicable	Not Applicable	01/13/2021 22:56:07	

Report By:Susan Training2

Date:11/23/2022

e-Signature *

Submit

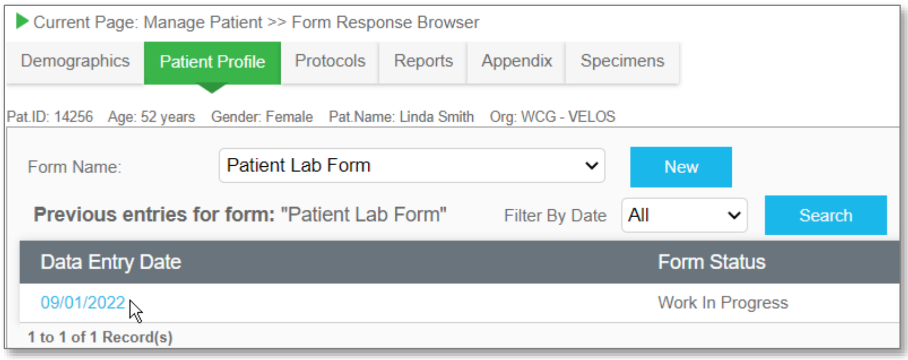
2. Enter a reason for making a change per line item, as needed, into the **Reason for Change** field, enter e-Signature, and click **Submit** to confirm.
   - The next time the Track Changes page is accessed, the reason(s) added will appear.

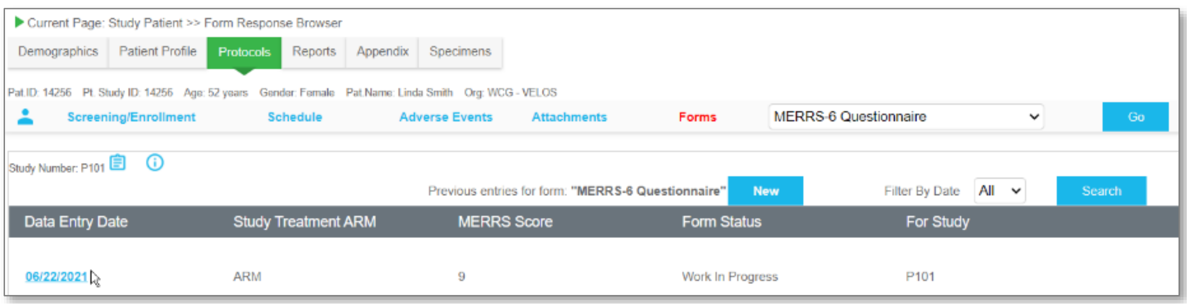
8.7.3 Patient Form Queries

Whether a patient form is completed from the Patient Profile tab or the Forms page of the Protocols tab, for a specific study, the completed form may be opened and reviewed, and queries may be added. A created query will appear in the forms queries page as well as in the Dashboard and may have a response recorded from either location. For more information on the Dashboard, refer to Dashboard.

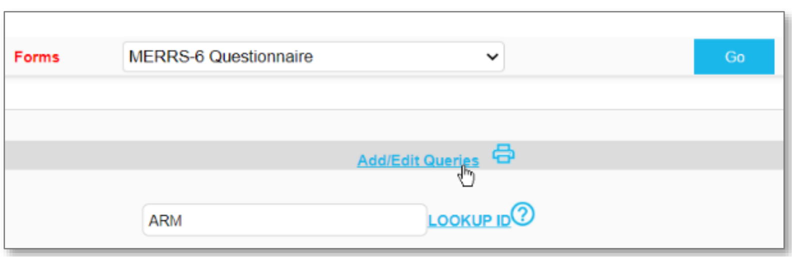
To create and respond to a form query in a patient record:

1. Navigate to a completed form from either the Patient Profile tab, or the Forms page for a study from the Protocols tab.

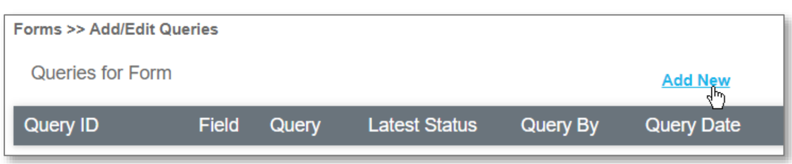




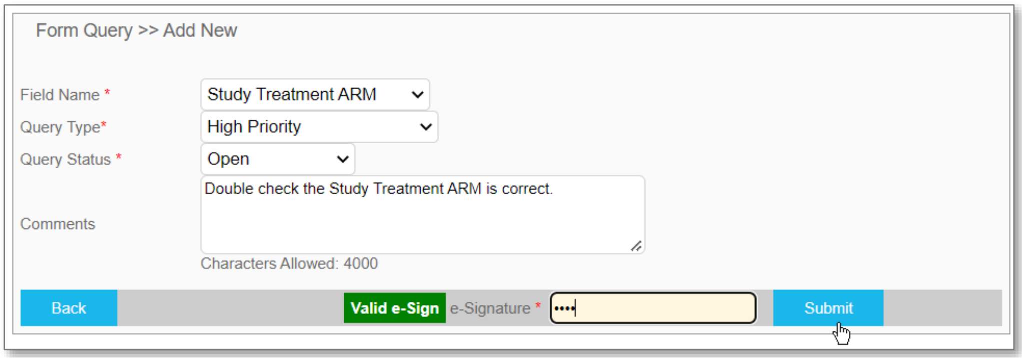
2. Click a Data Entry date.
3. In the upper right of the completed form, click **Add/Edit Queries**.



4. Click **Add New** in the pop-up window.

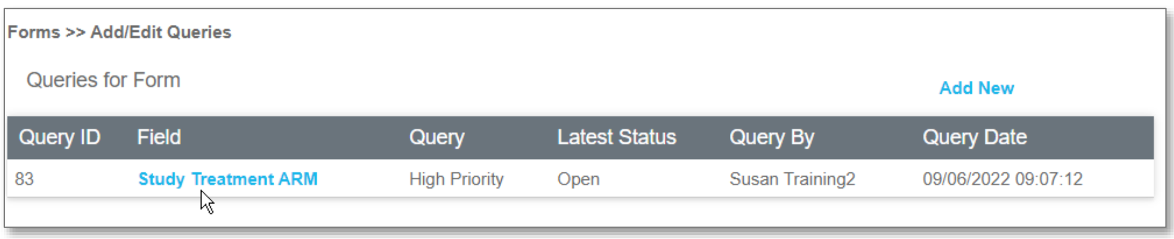


5. Select a Field Name, Query Type, and Query Status from the dropdown. Optionally, add Comments.

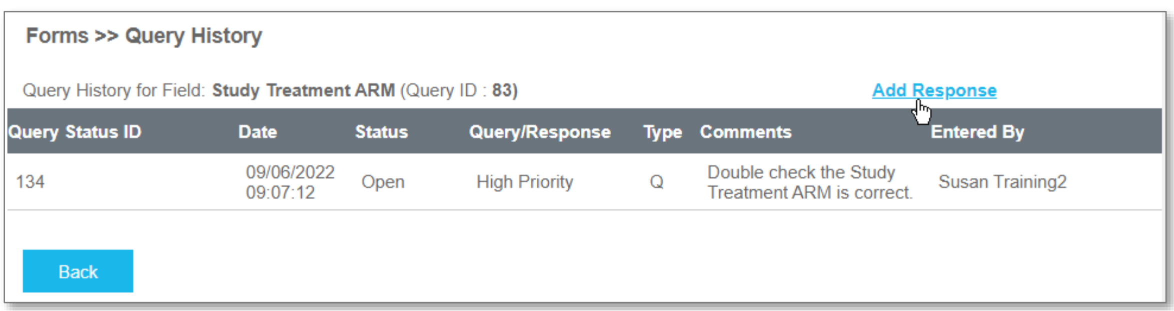


6. Enter your e-Signature and click **Submit**.

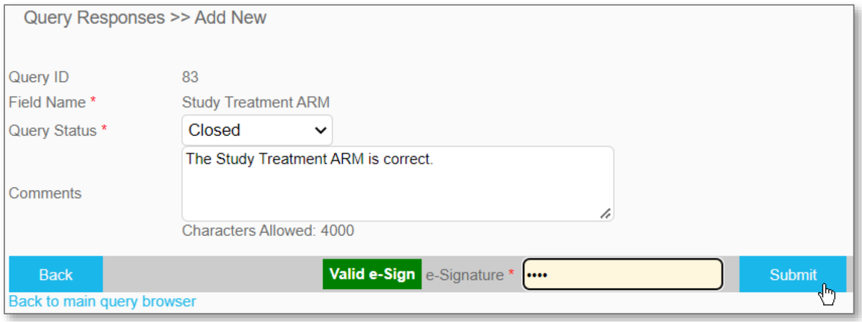
   The query will be added to the form.



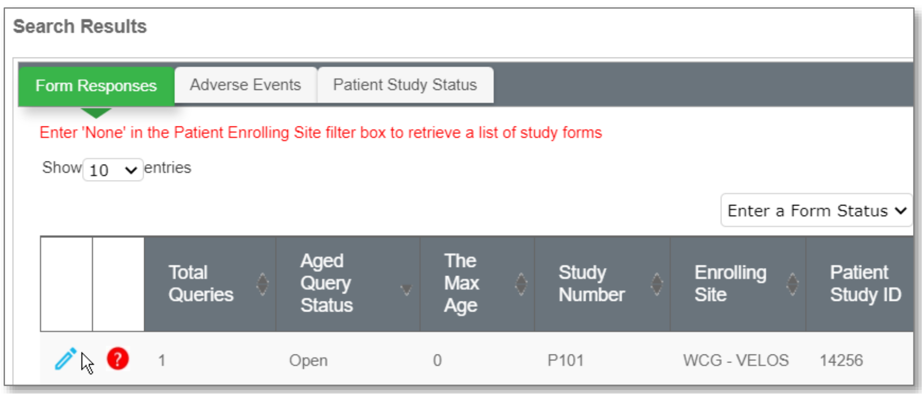
7. To view the query or to add a response, click the Field name in the query pop-up.
8. Click **Add Response**, to add a response, as needed.



a. Select a Query Status from the dropdown, optionally add Comments, then e-Sign, and **Submit**.



9. Alternatively, queries can be added, viewed, and responded to from the Dashboard. For more information, refer to the Dashboard.



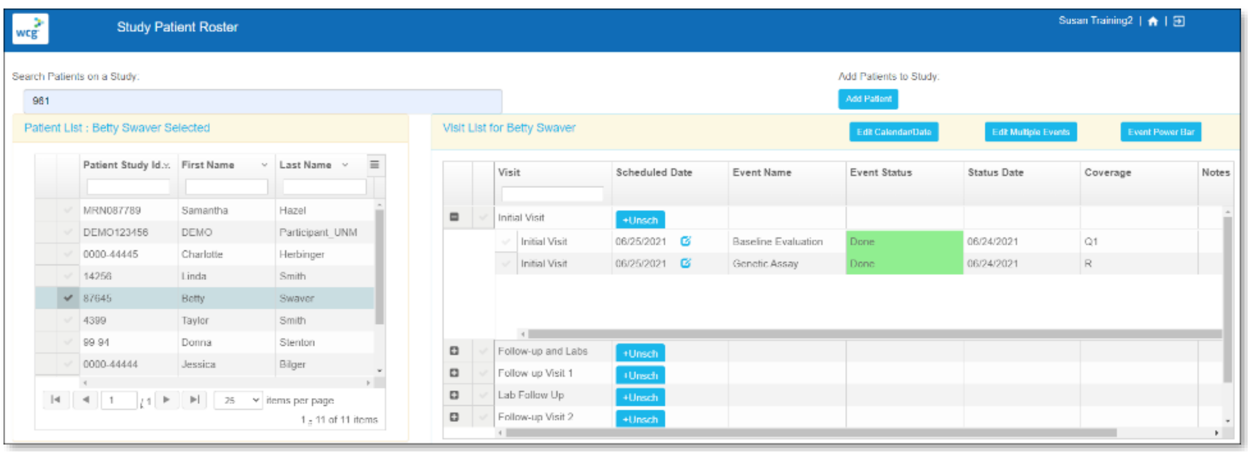
8.8 Study Patient Roster Homepage

If your role is strictly Managing Study Patient Data, it is recommended that your system homepage be set to the Study Patient Roster. To set this as your homepage, refer to Settings. Using the Study Patient Roster homepage can be beneficial as it provides a one-page roster for functionalities related just to study patients and their schedules. This one-page view allows users to view and manage patient schedules, switch selected patients for management, and add or link patients to a Study.

8.8.1 Navigating the Study Patient Roster Homepage

From the Study Patient Roster homepage, permissioned users can search for a study and patients, add patients, edit the calendar/dates, edit single visit data vs. updating multiple events, and change a patient's status. To update multiple events at one time, there is an event power bar that can be used in order to save time rather than updating each event in a visit individually. Familiarize yourself with the diagram and table below to learn more about navigation on the Study Patient Roster homepage.

Note: Study Patient Roster homepage must be the default homepage to view the following functionalities.

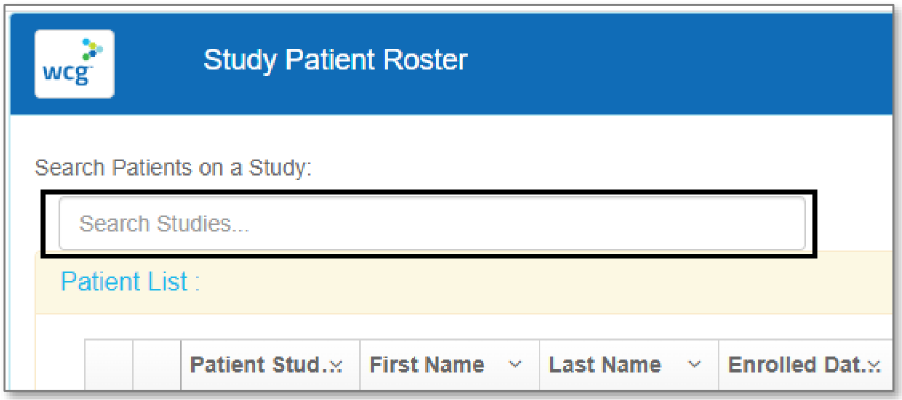


8.8.2 Search Patients

This section will show how users may search for patients via the Study Patient Roster homepage.

To search for patients:

1. From the Study Patient Roster page, enter the study number and select the appropriate study from the provided options that meet the search criteria.

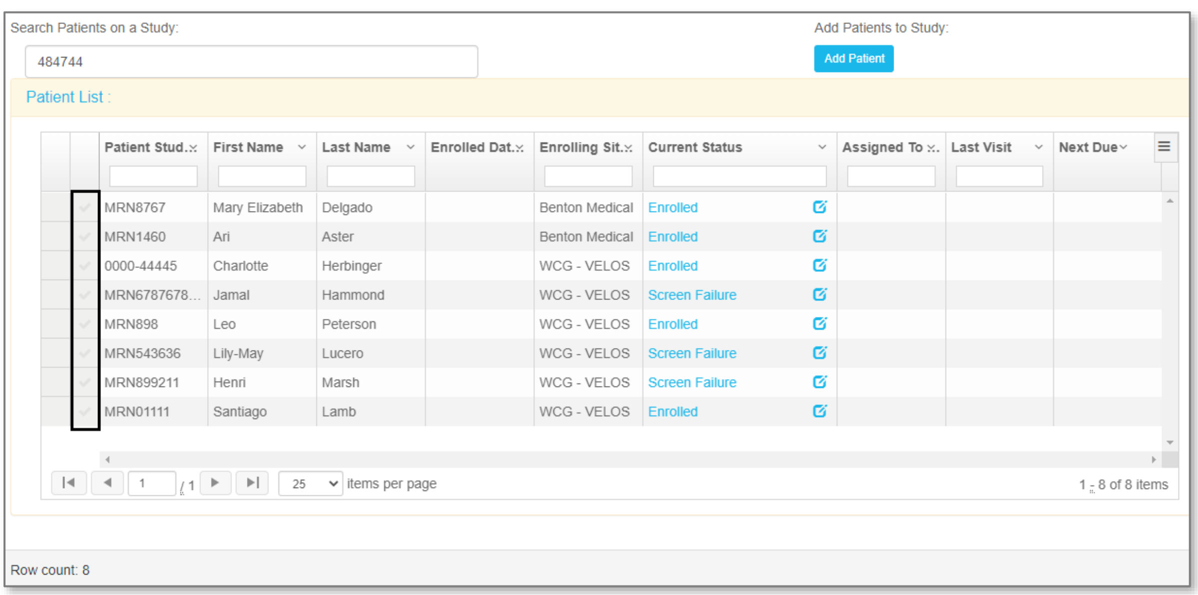


Note: The study search must be in the form of the Study Number.

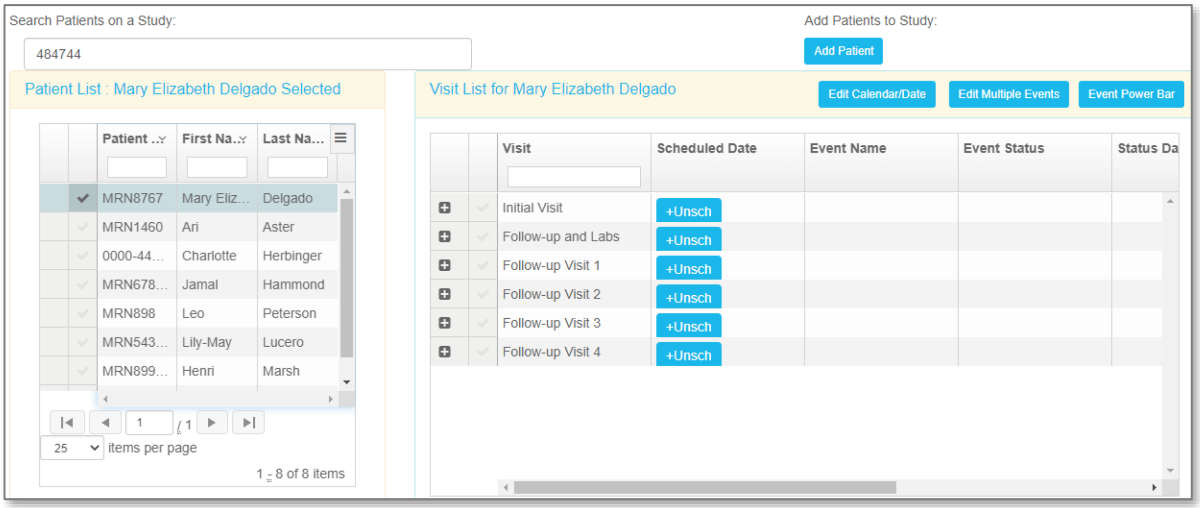
- The patients associated to that study will display in rows. Users can further filter the search results by using the open fields below each table heading.

a. If no patients are associated to a study continue to Add a New Patient.

2. From the search results, users may select the desired patient using the checkboxes next to the patient name and Patient Study ID.



The Visit List for the selected Patient will display:

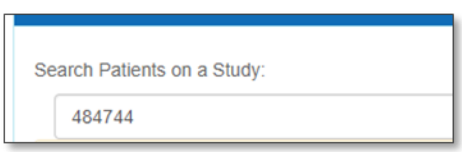


8.8.3 Add a New Patient

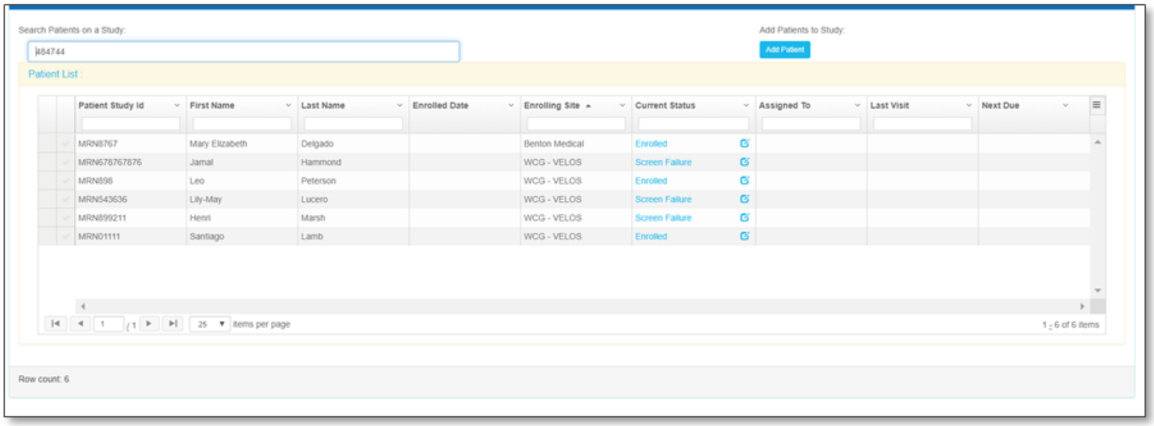
This section will cover how users may add a new patient via the Study Patient Roster homepage. It is important to add patients after searching for patients in the system to ensure there are no system patient duplicates. New Patients can be added once a study has been searched. For instructions on how to complete a successful patient search, see the Patient Search.

To add a new patient using the Study Patient Roster homepage:

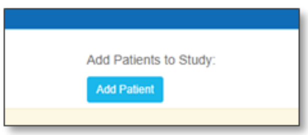
1. Search for a study using the **Search Patients on Study** field. Partial searches of at least two numbers can be used in this field.



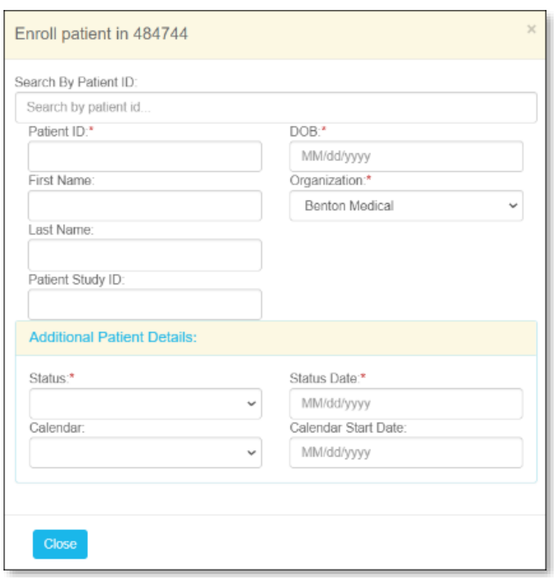
After searching and selecting a study, a list of already-associated patients will display, if any exist. An Add Patient button will also appear on the right side of the screen:



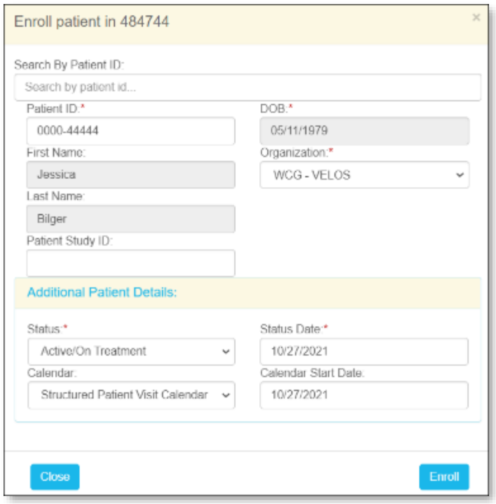
2. If a patient does not already exist within the study Patient List, click **Add Patient**.



The Enroll Patient page displays:



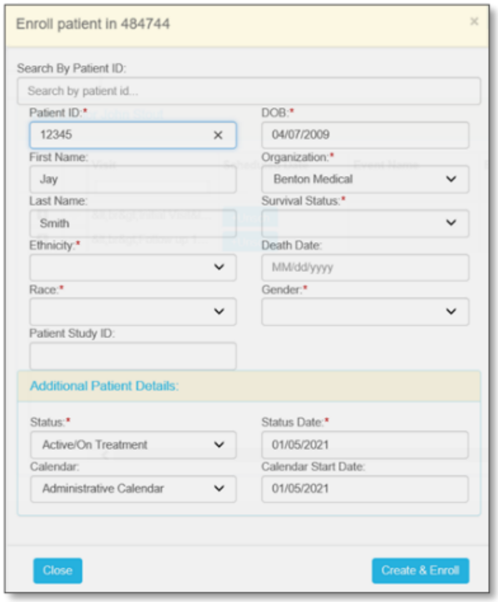
3. If adding a new patient that is already in the system to this study, first **Search By Patient ID,** select that user, complete details, and click **Enroll**.



Note: If an existing patient record is found by using the Search by Patient ID field, the record will auto-populate the additional fields in the top half of the screen.

-OR-

Define details as appropriate for a new user not in the system and click **Create & Enroll** to add to the study.

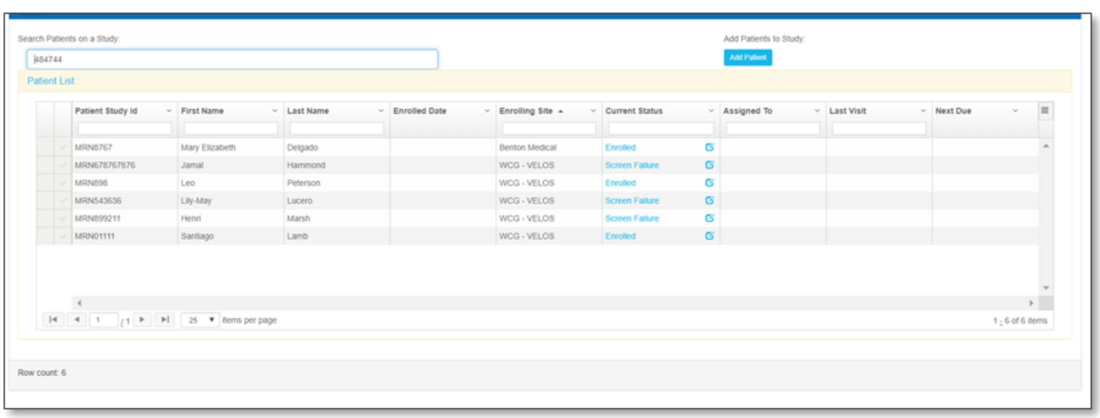


8.8.4 Update Patient Status

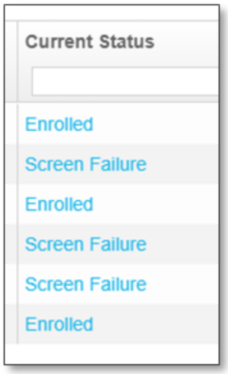
This section will cover how to change a patient status from the Study Patient Roster.

To update a patient status:

1. From the Study Patient Roster homepage, select a study through the Search Field.



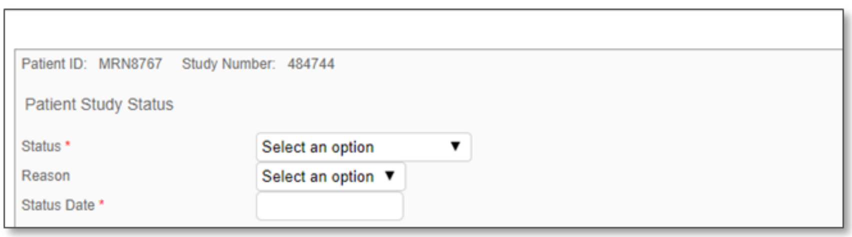
2. Search for the patient to change the status. Click the link for the **Current Status**.



-OR-

Click the **Edit** button, to edit any details associated to the patient's current status.

The Patient Study Status window displays:

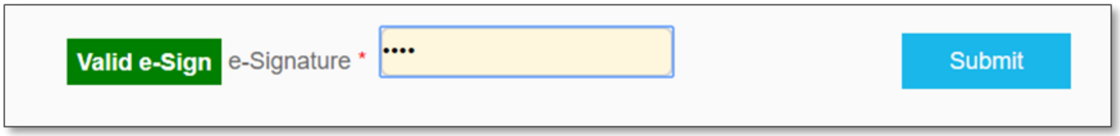


Patient information may be edited within this window for the following:

Section Name	Field Name	Field Description
Patient Study Status	**Status**	Patient Status may be set in this field from the dropdown menu. Options include Active/On Treatment, Completed Study, Died, Enrolled, In Follow-Up, Informed Consent Signed, Inpatient, Off Study, Off Treatment, Prescreening, Screen Failure, Screening, or Terminated – noncompliance.
	Reason	This field will only display options if the following Statuses were selected in Patient Study Status: In Follow-Up, Off Study, or Off Treatment.
	Status Date	Date Status is valid from.

Section Name	Field Name	Field Description
Additional Information	**Patient Study ID**	This is the Patient's Study ID number, usually in the form of the MRN number.
	Enrolling Site	Site the Study Patient is Enrolled to.
	Assigned To	Select a User to Assign the Study Patient to.
	Physician	Select a User to Assign the Study Patient to.
	Treatment Location	Select a location from the dropdown menu for the Treatment Location.
	Treating Organization	Select an Organization from the dropdown menu.
	Disease Code	Add, Edit, or Delete a Disease Code.
	Anatomic Site	Edit or Delete an Anatomic Site.
Evaluable Status	**Evaluable Flag**	Select an option from the dropdown menu.
	Evaluable Status	Evaluable Status options to select from the dropdown menu based on previously selected fields.
	Unevaluable Status	Unevaluable Status options to select from the dropdown menu based on previously selected fields.
Patient Status	**Survival Status**	Patient Survival Status options from the dropdown menu.
	Date of Death	Patient Date of Death from Calendar.
	Cause of Death	Cause of Death options from dropdown menu.
	Specify Cause	Specify Cause of Death if "Other" is selected in Cause of Death field.
	Death Related to Study	Select whether the death of the Patient was related to the Study.
	Reason of Death Related to Study	State the reason of the death being related to the study.

3. Enter information as needed to Update Patient Status. Enter your e-Signature and click **Submit** to confirm.

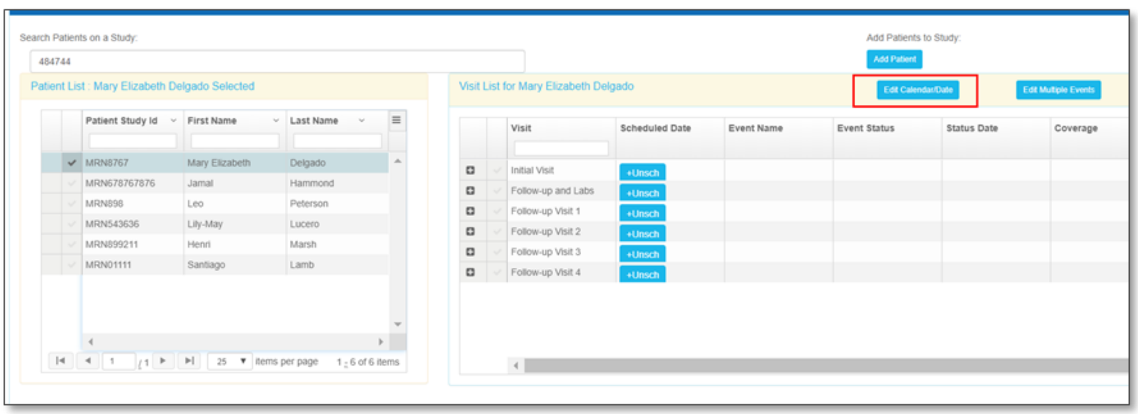


8.8.5 Patient Schedule

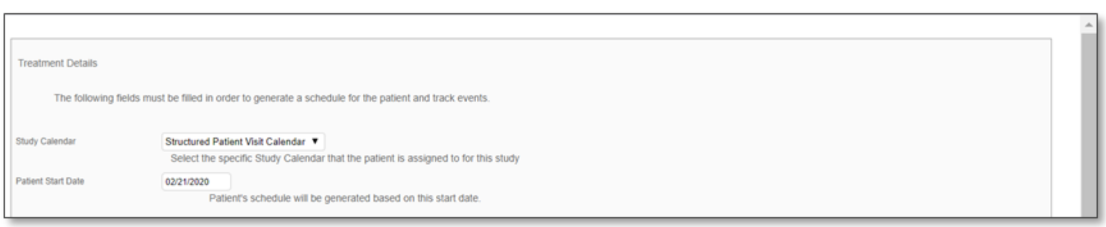
If a Patient has a schedule associated to them, it will appear in the Visit List. The Patient Schedule is organized by Visits.

To generate a patient visit schedule:

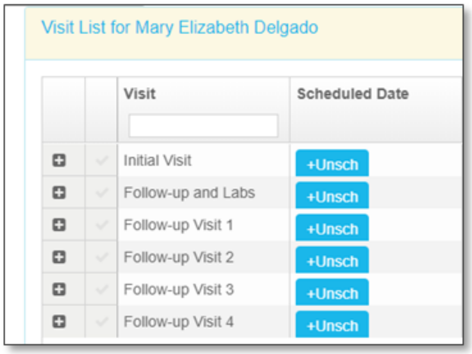
1. If a patient does not have a schedule associated with them already, select the patient, by clicking in the Checkbox to the left of the Patient Study ID. In the Visit List, click **Edit Calendar/Date**.



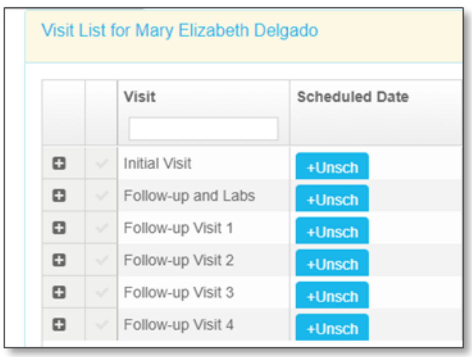
2. The Treatment Details page displays. Select the study calendar, patient start date, and how you would like the schedule to be calculated. Enter your e-Signature and click **Submit** to confirm.



The patient's visits display:

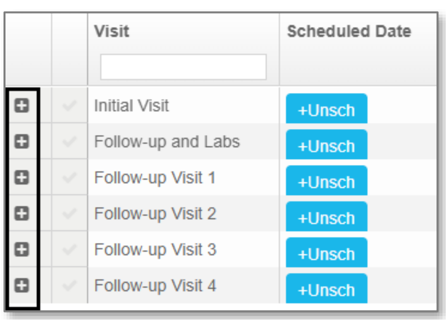


3. Click **+Unsch** to add an event to the visit or schedule an unscheduled event.



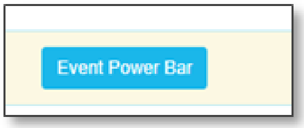
-OR-

Click the **Plus** button to expand the visit and view or edit the scheduled dates and/or event status of each visit event.

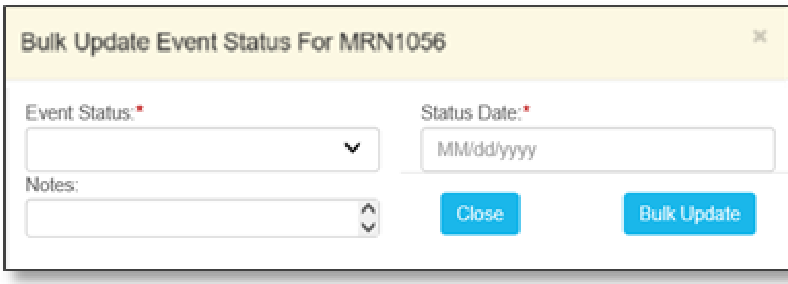


–OR-

The Event Power Bar may be selected to bulk update events. For this example, click **Event Power Bar**.



The Bulk Update Event Status for the selected Study will display:



Note: An event must first be associated to a study for this function.

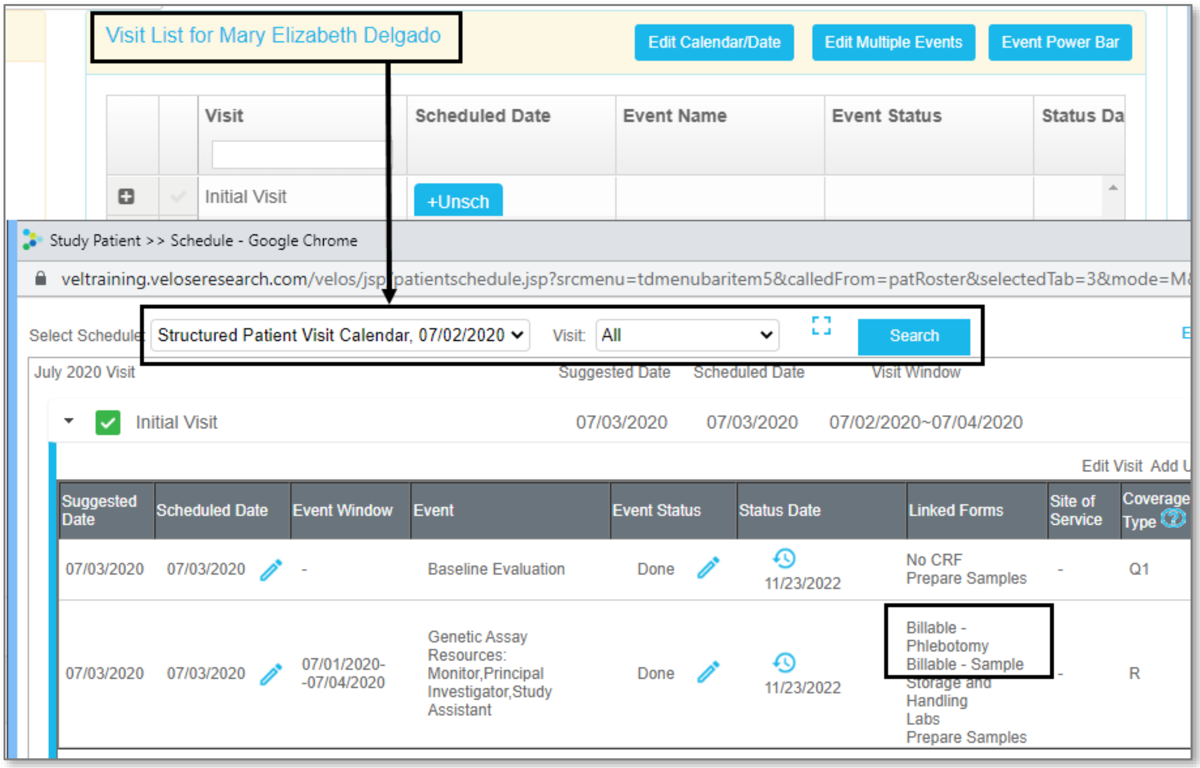
8.8.6 View Linked Forms and Adverse Events in Schedules

After accessing a study patient's calendar, the Visit List for that patient will become available to view additional schedules. From this page, all calendars can be viewed and the Linked Forms, including Adverse Events, become accessible for viewing.

To learn how to link forms and adverse events as an Admin, refer to Link Forms and Patient Links.

To view a linked form for a specific patient selected for a study:

1. Click the blue link above the current scheduled titled **Visit List for [Name of Patient]**.



2. Select the calendar to view from the **Select Schedule** dropdown and click **Search**, selecting a specific visit in the **Visit** dropdown as needed.
3. In the Linked Form column, for an Event, click the linked form or adverse event to view more information.
   - Clicking a form will allow for a Form Response pop-up to be viewed, however, clicking an adverse event will take the user to the adverse event page and the user will need to return to the Study Patient Roster Homepage to return to the specific study patient record.

9 Financial Management

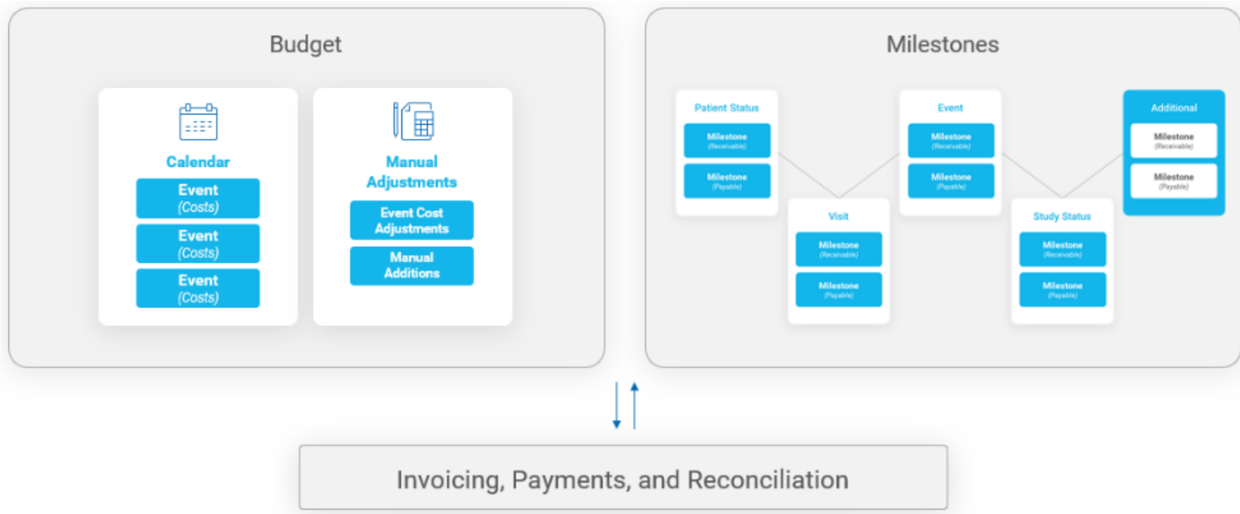
The Financial Management module is a powerful tool that allows you to achieve the following:

- Build Budgets for high-level study cost tracking or negotiation
- Track receivable and payable items using Milestones (also known as “financial achievement triggers”)
- Generate invoices
- Track sent and received payments
- Reconcile payments against milestones or invoices

Within Financial Management, there are three core components that work together to manage a study’s financial tasks:

- Budgets
- Milestones (financial achievement triggers)
- Invoicing, Payments, and Reconciliation

The following graphic illustrates the relationship between budgets, milestones (financial achievement triggers), invoicing, payments, and reconciliation.

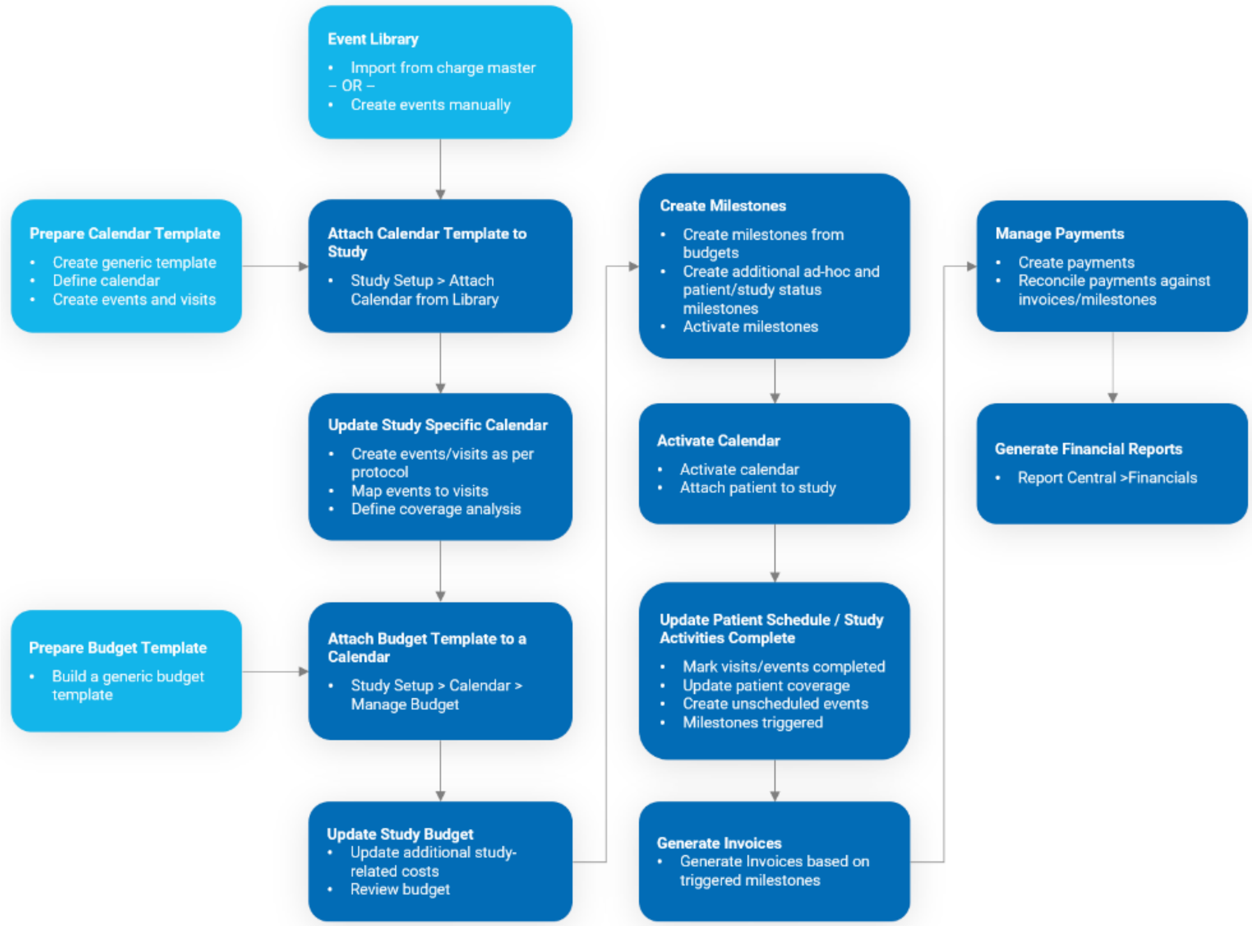


This section will cover the Financial Management recommended process, and detail how permissioned users can create and modify a budget or budget template, configure and manage milestones, prepare invoices, enter payments, and reconcile those payments against invoices and milestones.

For more information about:

- **Budgets**, see Budgets
- **Milestones**, see Milestones
- **Invoices**, see Manage Invoices
- **Payments**, see Manage Payments
- **Financial Reports**, see Report Central

9.1 Recommended Process Overview Flowchart



9.2 Financial Management Setup

The first step in the recommended process of financial management setup is to ensure that all of your requisite financial data is in place. For example, ensuing that your event costs and cost types, Calendar settings, patient cost items and coverage analysis grid have been configured with all the required financial information for your study. You can learn more about configuring study-specific calendars and events with financial information by reviewing the Associated Calendars section, or library calendars and events by reviewing the Calendar Management section.

Once your requisite financial data is in place, you will want to create a new budget with the goal of using that budget to estimate study costs, generate visit and event milestones, and potentially for use in contract negotiations. The recommended type of budget is a calendar budget template as they are dynamic and pull financial data directly from your study calendar(s), however, you can create different types of budgets to align with your study needs. See Budget Types to learn more about each type.

Note: It is not recommended to associate a calendar with a Browser Budget as any associated calendar modifications will not update in the browser budget. The user would need to remove the calendar and re-associate it to the browser budget to see the calendar changes in the budget.

If a budget template type is created, that budget should then be associated with a calendar, and any necessary modifications and adjustments should be made to the costs. This can be done manually or via the Bulk Edit Tool. From there, milestones (financial achievement triggers) need to be configured to define what should be paid, to whom, and how that payment milestone is achieved.

- See Budgets, for more information about budget configuration and types
- See Milestones, for more information about milestone configuration and types

Before getting started, it is extremely important to understand that budgets and milestones build upon the information established in the foundational elements created in other modules of Velos eResearch, such as calendars, studies, and patient management. Financial Management cannot function properly without all of the foundational elements being in place first. It is also recommended that all stakeholders involved in these key areas have, at a minimum, a high-level understanding of financial management to ensure the accuracy of study financial records and processes.

Note: Calendars are the driving force behind Financial Management, in that they are the source of most cost information for budgets. In addition, they define patient schedules and may be used to generate Visit and Event milestones.

Warning: Prior to setting up budgets and milestones, ensure that study calendars are fully configured.

To learn more about these foundational elements, refer to the following sections of the user guide:

- **Calendars, Events, Visits** – see Calendar Management
- **Studies** – see Study Management
- **Patient Enrollment / Patient Status Updates** – see Patient Management

9.2.1 Budgets

There are three types of budgets available for use within Velos eResearch: Calendar budgets, Browser budgets, and Combined budgets. Budgets provide a cost projection and do not dynamically update the estimations from the calendar / event costs of running your trial. However, it is useful to create budgets as they provide a framework to estimate overall costs and to generate event and visit milestones.

9.2.1.1 Budget Types

In Velos eResearch, there are three core budget types: Calendar, Browser, and Combined budgets. See the tables below for a brief description of each type, their recommended uses, and in which Velos eResearch versions they can be found.

Budget Type	Description	Recommended Use	Enterprise	eXpress
Calendar Budget	Designed to dynamically link directly with a study calendar. In order to create a budget from a study calendar, a budget template must first be created, and then the budget template should be associated to the study calendar. Event / Visit costs, cost and coverage types, and patient cost items will then automatically flow into the budget from the calendar.	Used to dynamically track study costs by study calendar.	X	X **Note**: Patient Cost Items are not available in eXpress.
Browser Budget	Created as an independent budget useful for estimating costs for a potential study during concept phases. In contrast to Calendar Budgets, Browser Budgets may be associated to multiple calendar templates from the library, as well as specific study calendars and may include Admin calendars from the Admin Schedule tab. Before a Browser Budget can be linked to any study calendars, however, a study must first be linked to the budget. Once that has been done, all study calendars will be available to associate to the Browser Budget for inclusion in the record. Study browser budgets do not utilize study or Admin calendars.	Tracking of Event, Personnel, Miscellaneous, and Visit costs across all or select study calendars simultaneously. **Note**: This budget type captures budget data at a point-in-time and does not dynamically update.	X	X

Budget Type	Description	Recommended Use	Enterprise	eXpress
Combined	Study-level budget based on study calendars with a common status of Active or Work in Progress only and a budget template for one study. Accessed via the **Study > Budget tab.**	May be useful when combining study calendar budgets (i.e. two study calendars for Treatment Arm 1 & 2) into one. **Note**: This budget type captures budget data at a point-in-time and does not dynamically update.	X	N/A

The following table provides a more detailed overview of features associated with each budget type:

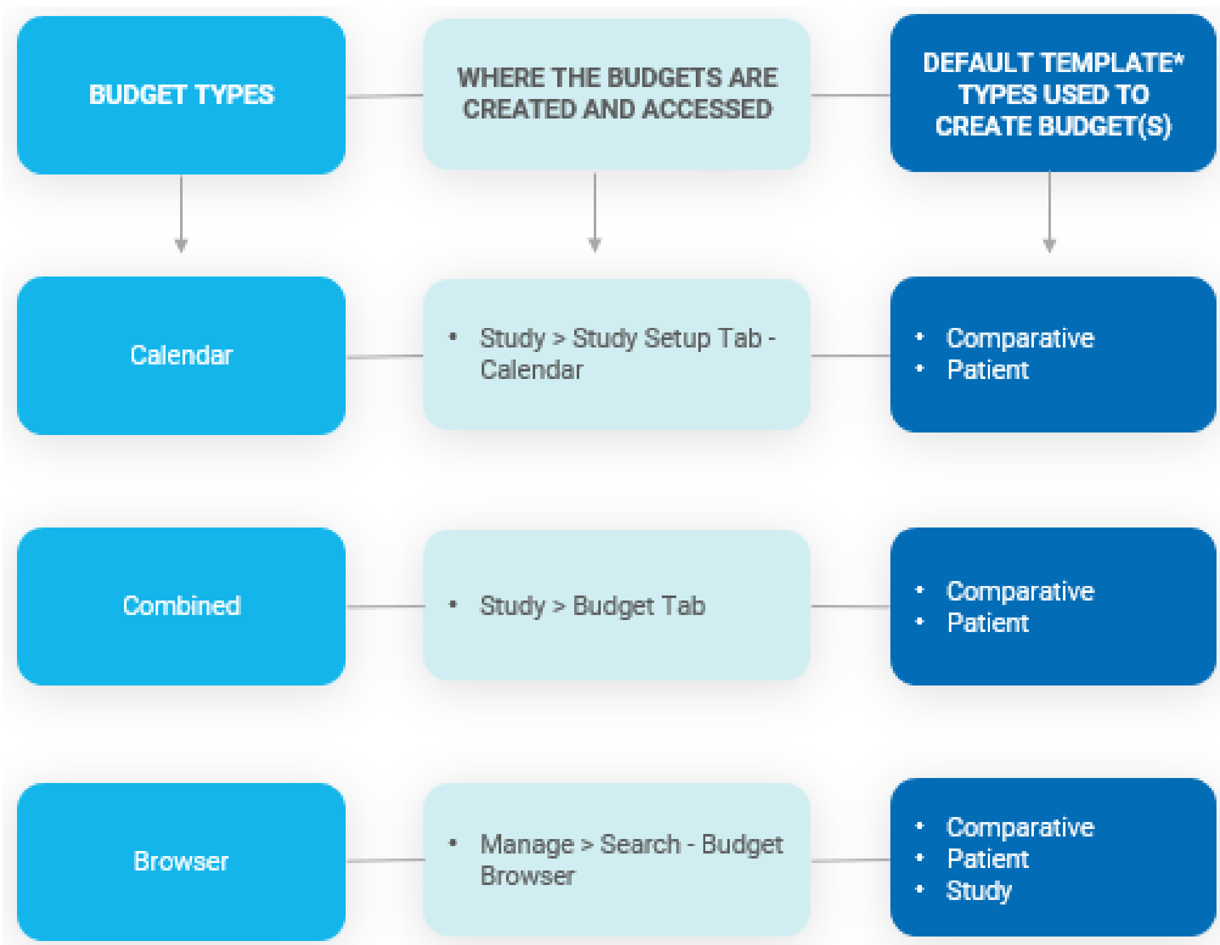
Features	Calendar Budget	Browser Budget*	Combined
Visits and events listed on the Event-Visit Grid page are added to the budget as sections and line items with the specified event cost listed on the Event Details page. The unit cost for calendar line items (events) can be modified. If modified, the cost Is not applied to the event cost on the Event Detail page. If an event has multiple costs associated with it, the budget will generate repeat line items for each event cost.	X	X	X
Used when creating visit and event milestones from the budget for all visits and/or events.	X	X	X
Used to view the milestone rules created from the budget from the Study Milestone page.	X	X	X
Line Items can be added to Calendar sections (Visits).	N/A	X	X
Multiple study calendars can be associated to the budget.	N/A	X	X
Budget has two calendar views: combined or individual. Combined view displays the total budget for all associated calendars. Individual view displays the total budget for the specified view.	N/A	X	X
The budget amount is carried over when visit and event milestones are created.	X	N/A	N/A
Individual budget for each study calendar that has a calendar budget template associated.	X	N/A	N/A
When the event cost is modified from the Event-Visit Grid page, the budget line item is dynamically updated.	X	N/A	N/A
The Manage Milestone tab from the Calendar Design Wizard displays the visit and event milestone rules created from the study budget.	X	N/A	N/A
One or multiple library calendar templates and/or study calendars can be associated to the budget.	N/A	X	N/A
Items on the Patient Cost Items page from the Calendar Design Wizard are listed as budget line items.	X	X	N/A

* Information for the Browser Budget column applies only to Comparative and Patient type templates used for browser budgets and not to Study templates, as they are unique.

Enterprise Only: Combined budgets are not available in Velos eResearch eXpress.

9.2.1.1.1 Budget Types and Template Types Diagram

The three budget types are initially created and accessed from different locations. The study template type is only ever used as a browser budget. See the diagram below for an overview of where the budget types are created and accessed and what default template types may be used in creation of the budget type.



*Default comparative, patient, and study template types may be used to create custom template types which then may be used for budgets.

9.2.1.1.2 System Budget Template Types

System budget templates are default templates that define the format of your budget. This is a required configuration for any budget type that you create, therefore it is important to understand the characteristics of each.

System Budget Template	Description
Patient	Standard budget template. Displays cost fields by default for both personnel, and Miscellaneous categories, and can be used as a calendar budget template to view costs on a per-patient basis. See a Patient Template Type Example. **This template is typically used for investigator-initiated studies.**
Comparative	The Comparative budget system template contains the same defaults as the Patient system budget template but has two additional columns: **Sponsor** and **Variance**. These columns are used to enter the amount a Sponsor pays for a given cost item, and the difference between your cost, and the amount the Sponsor pays on a per patient basis or in total. See a Comparative Template Type Example. **This template is typically used for sponsored studies.**
Study	The Study budget system template is visually very different from both the patient and comparative budget types and can be used to estimate high level study costs. This budget system template cannot be used for calendar budget templates or combined budgets and is best used in a browser budget type. See a Study Template Type Example.

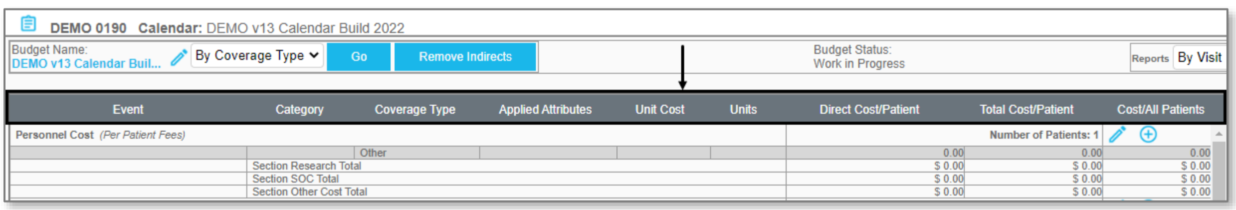
As noted in the table above, both the Patient and Comparative system budget templates have default sections that can be used to specify personnel cost and miscellaneous cost items. For a Calendar Budget Template, the default sections may be removed if needed, as the budget will pull the majority of its financial information directly from the associated calendar.

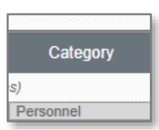
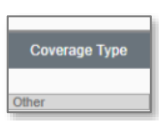
9.2.1.1.2.1 Patient Template Type Example

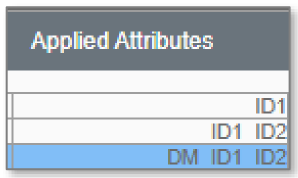
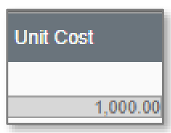
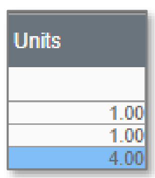
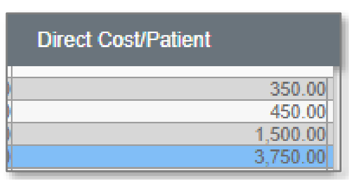
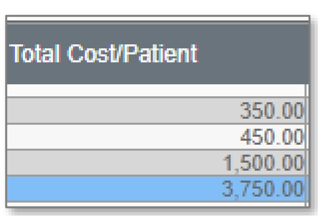
In this section, we see an example of a Patient Template Type and key elements. For a definition of each template type, see the System Budget Template Types section.

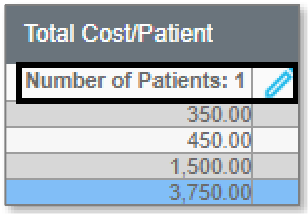
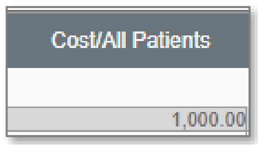
> **Note:** Both the Patient and Comparative template types display financial information as per-patient fees. These are also the only types of System Budget Templates that can be used in combined budgets, or as a calendar budget template.

Patient template type budgets organize line items by section, with each section containing line items with their own cost, cost category and coverage type. Patient template type budgets also display costs with the ability to include per patient modifiers (costs * number of patients). See the image and table below to learn more about each column and its description.



Column Name	Visual	Description
Event		Displays specific budget line items' names within sections. Line items and sections can be created manually, or if part of a budget that is linked to a calendar, lists each visit as a section and each event or patient cost item as a line item.
Category		Displays the cost category of each line item. Can be manually changed within the budget, or if part of a budget that is linked to a calendar, lists the inherited category from each calendar event or patient cost item.
Coverage Type		Displays the coverage type of each line item. Can be manually changed within the budget, or if part of a budget that is linked to a calendar, lists the inherited coverage type from each calendar event or patient cost item.

Column Name	Visual	Description
Applied Attributes		Displays any calculated attributes set for that line item in this budget. • **ID1** = Indirect 1 • **ID2** = Indirect 2 • **DM** = Discount / Markup **Indirect 1** is added to the ***Total Cost/Patient*** column total. **Indirect 2** is added to the ***Total Cost/Patient*** column total. **Discount / Markup** applies either a discount or markup to the ***Direct Cost/Patient*** depending on how it was configured within Calculation Attributes.
Unit Cost		Displays the cost of each line item. Can be manually changed within the budget, or if part of a budget that is linked to a calendar, lists the inherited cost from each calendar event or patient cost item.
Units		Displays the number of units for that line item. Acts as a direct cost multiplier. Units can be manually adjusted, or if part of a budget that is linked to a calendar, lists the inherited number of units for patient cost items only.
Direct Cost/Patient		Displays the direct cost per patient. This total includes any applied discounts or markups.
Total Cost/Patient		Displays the total cost per patient. This total includes indirect 1 and indirect 2 calculations.

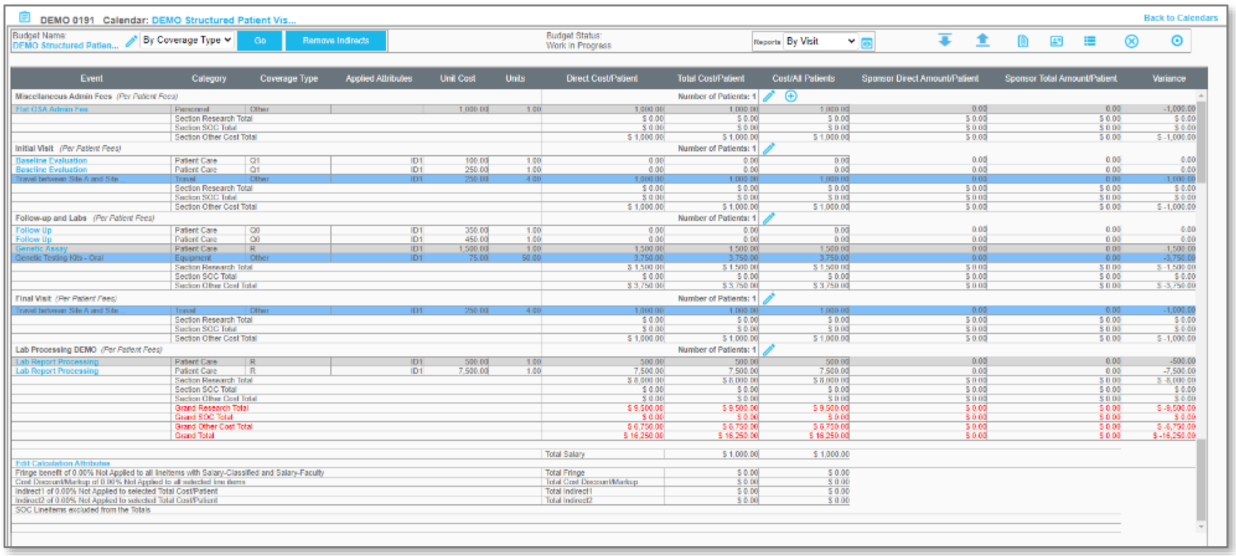
Column Name	Visual	Description
*Number of Patients		The **Number of Patients** toggle displays beneath the ***Total Cost/Patient*** column and can be modified by clicking the edit line item button. The number of patients can be applied to each line item manually. If applied, acts as a line item multiplier in the ***Cost/All Patients*** column.
Cost/All Patients		Displays the cost for all patients by line item.

**Number of Patients* is a sub-control within the Total Cost/Patient column and only exists on Comparative and Patient template types.*

Note: Data in both Comparative and Patient budget template types can also be manually updated more efficiently Using the Bulk Edit Tool for Budgets.

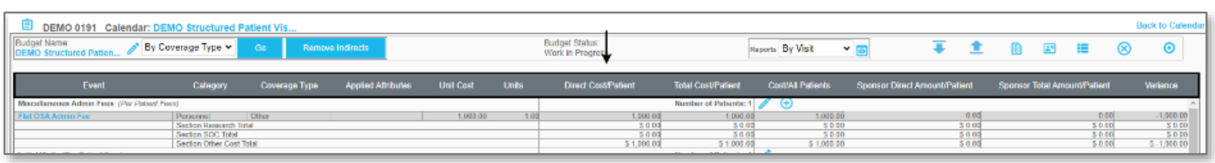
9.2.1.1.2.2 Comparative Template Type Example

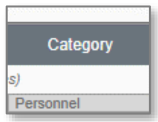
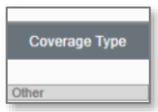
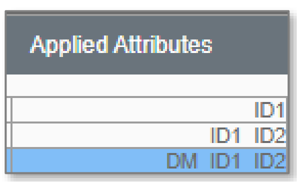
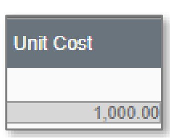
In this section, we see an example of a Comparative Template Type and key elements. For a definition of each template type, see the System Budget Template Types section.

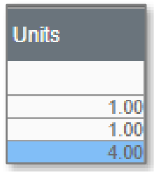
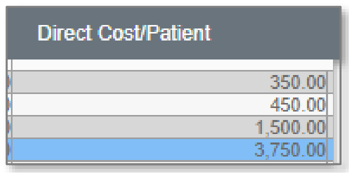
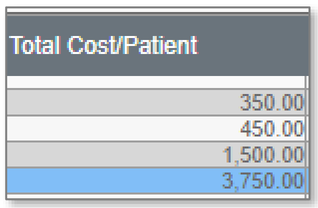
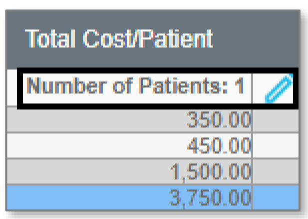
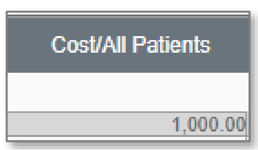
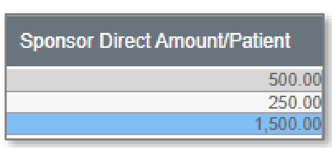


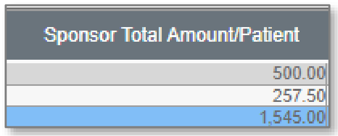
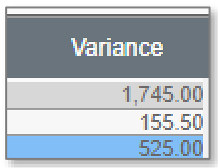
> **Note:** Both the Patient and Comparative template types can display input financial information as per patient fees. These are also the only types of System Budget Templates that can be used in combined budgets, or as a calendar budget template.

Comparative template type budgets display the same information as patient template types but additionally include the Sponsor Direct Amount/Patient, Sponsor Total Amount/Patient and Variance columns. See the image and table below to learn more about each column and its description.



Column Name	Visual	Description
Event		Displays specific budget line items' names within sections. Line items and sections can be created manually, or if part of a budget that is linked to a calendar, lists each visit as a section and each event or patient cost item as a line item.
Category		Displays the cost category of each line item. Can be manually changed within the budget, or if part of a budget that is linked to a calendar, lists the inherited category from each calendar event or patient cost item.
Coverage Type		Displays the coverage type of each line item. Can be manually changed within the budget, or if part of a budget that is linked to a calendar, lists the inherited coverage type from each calendar event or patient cost item.
Applied Attributes		Displays any calculated attributes set for that line item in this budget. • **ID1** = Indirect 1 • **ID2** = Indirect 2 • **DM** = Discount / Markup **Indirect 1** is added to the ***Total Cost/Patient*** column total. **Indirect 2** is added to either the ***Total Cost/Patient*** column total, or the ***Sponsor Total Cost/Patient*** column depending on how it was configured within Calculation Attributes. **Discount / Markup** applies either a discount or markup to the ***Direct Cost/Patient*** depending on how it was configured within Calculation Attributes.
Unit Cost		Displays the cost of each line item. Can be manually changed within the budget, or if part of a budget that is linked to a calendar, lists the inherited cost from each calendar event or patient cost item.

Column Name	Visual	Description
Units		Displays the number of units for that line item. Acts as a direct cost multiplier. Units can be manually adjusted, or if part of a budget that is linked to a calendar, lists the inherited number of units for patient cost items only.
Direct Cost/Patient		Displays the direct cost per patient. This total includes any applied discounts or markups.
Total Cost/Patient		Displays the total cost per patient. This total includes indirect 1 calculations and indirect 2 calculations if configured for this column.
***Number of Patients**		The **Number of Patients** toggle displays beneath the ***Total Cost/Patient*** column and can be modified by clicking the edit line item button. The number of patients can be applied to each line item manually. If applied, acts as a line item multiplier in the ***Cost/All Patients*** column.
Cost/All Patients		Displays the cost for all patients by line item.
Sponsor Direct Amount/Patient		Displays the sponsor amount by line item. This total can only be manually added to each line item and is used to calculate variance between sponsor compensation and your overall study/event costs in the ***Variance*** column.

Column Name	Visual	Description
Sponsor Total Amount/Patient		Displays the sponsor total by line item. This is a combination of your Sponsor Direct Amount/Patient, and Indirect 2 calculations if applied. Like ***Sponsor Direct Amount/Patient*** this amount is used to calculate variance between sponsor compensation and your overall study/event costs in the ***Variance*** column.
Variance		Displays the difference between ***Sponsor Total Amount/Patient*** and ***Cost/All Patients*** totals. Can display positive or negative amounts. (***Sponsor Total Amount/Patient – Cost/All Patients = Variance***)

Number of Patients *is a sub-control within the Total Cost/Patient column and only exists on Comparative and Patient template types.*

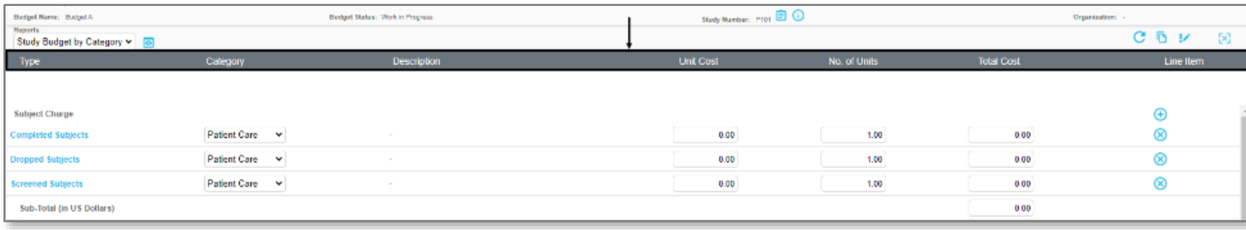
Note: Data in both Comparative and Patient budget template types can also be manually updated more efficiently Using the Bulk Edit Tool for Budgets.

9.2.1.1.2.3 Study Template Type Example

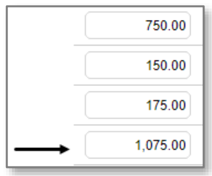
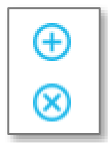
In this section, we see an example of a Study Template Type and key elements. For a definition of each template type, see the System Budget Template Types section.

Note: Values in a Study Template Type can only be expressed in US Dollars.

Study templates can only be used as a browser budget and are more customizable than Comparative or Patient budgets with the specific purpose of capturing study costs not included in calendars. See the image and table below to learn more about each column and its description.



Column Name	Visual	Description
Type	Subject Charge Completed Subjects Dropped Subjects Screened Subjects Sub-Total (in US Dollars)	Displays specific budget line items' names within sections and provides the line heading for the section subtotal in the Sub-Total (in US Dollars). Line items and sections are created manually. To edit a line item, click on the name in this column.
Category	Patient Care Contractual	Displays the cost category of each line item. Can be manually changed within the budget by making a selection from the dropdown menu.
Description	-Base cost per site -cost per study -	Displays a description of each line item. Can be manually changed for each line item. If left blank, this column will display a hyphen and a blank space.
Unit Cost	250.00 75.00 175.00	Displays the unit cost for each line item. Works with ***Number of Units*** value to calculate ***Total Cost***. Can be manually added for each line item by entering the amount in the provided fields.
Number of Units	3.00 2.00 1.00	Displays the total unit count for each line item. Works as a multiplier with ***Unit Cost*** value to calculate ***Total Cost***. Can be manually added for each line item by entering the amount in the provided fields.

Column Name	Visual	Description
Total Cost		Displays the total cost by line item. Calculated after clicking the submit button once Unit Costs and Number of Units values are in place. Also displays the section sub-total in the last field in this column.
Line Item		Contains both the Add New and Delete buttons. • **Add New** – Use this button to add a new line item in this section. • **Delete** – Use this button to remove the corresponding line item.

9.2.1.2 Calendar Budget Templates

Calendar Budget Templates are needed to generate calendar budgets for study calendars. It's important to understand that calendar budget templates differ from System Budget Template types. Whereas System Budget Template types can be thought of as the formatting of a budget (how it appears, and what data columns are available), a Calendar Budget Template is a manually created budget that is converted into a template that is then attached to a calendar.

The calendar budget template must be associated to a Study Calendar to generate a meaningful budget. Additional Calendar Budget templates can be created for new requirements or items not covered in existing templates, but the recommendation is to create a template that can be used for multiple studies that can then be edited.

Note: One calendar budget template may be associated to multiple study calendars, but each study calendar can only have one calendar budget template association.

To create a Calendar Budget Template for a calendar, a budget must be created first from either a patient or comparative system budget template. See the section System Budget Template Types for more information.

It is recommended that two calendar budget templates be created if conducting both Investigator Initiated Studies and Sponsored Studies at your institution.

- **Investigator Initiated Studies:** To create a study calendar budget template, the Patient System Budget Template should be used
- **Sponsored Studies:** To create a calendar budget template, the Comparative Budget System Template should be used

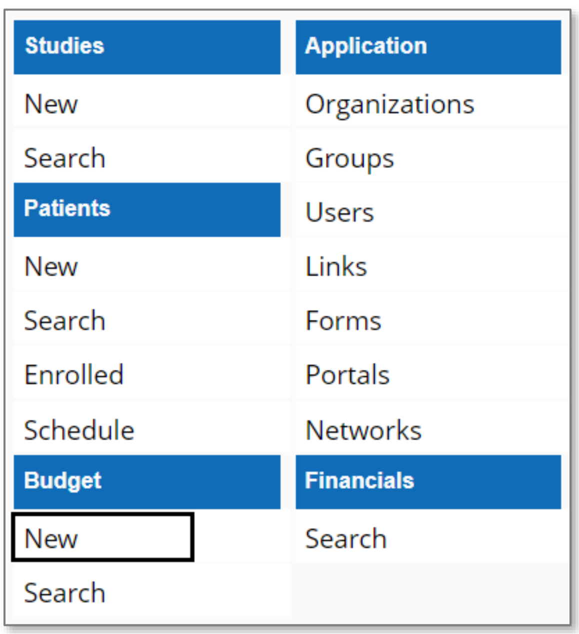
9.2.1.2.1 Create a Budget Template

This section will cover how to create a customized **Budget Template** to be used with Studies. For more information about Calendar Budgets, please refer to Budgets.

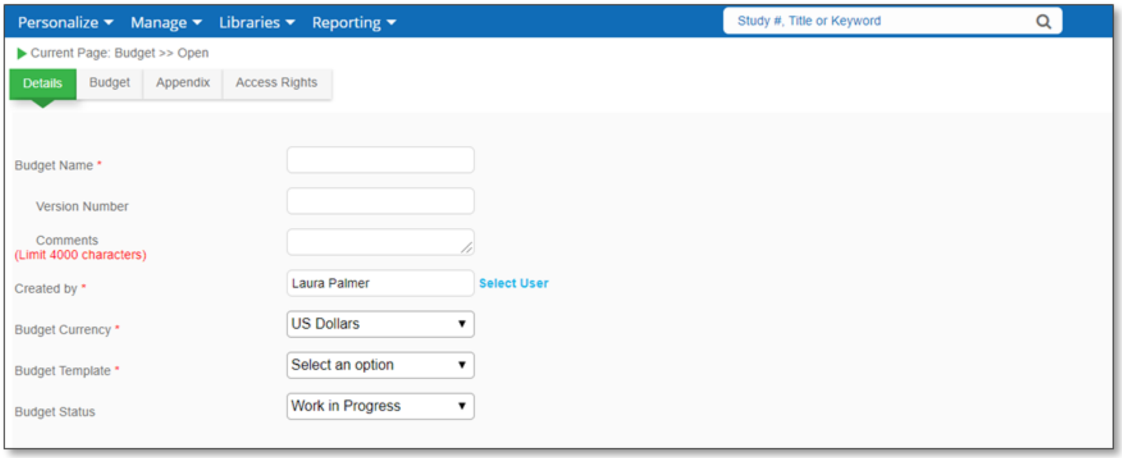
Note:
1. Once a calendar budget template is created it may be reused and this step may be skipped.
2. When creating a Calendar Budget Template, it is recommended that users delete the default Personnel and Miscellaneous sections.

To create a Budget Template:

1. From the Homepage, select the **Manage** tab. Click **New** under "Budget".



The Budget Details page displays. Here, users may enter information regarding: **Budget Name**, **Version Number**, **Comments**, (user) **Created by**, **Budget Template**, and **Budget Status**.

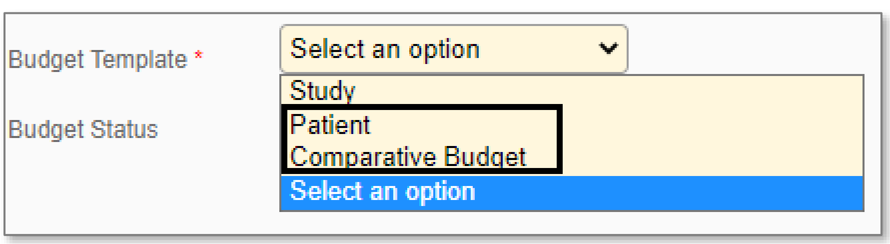


Warning: When creating a budget template that will be used for various studies the "Associate Budget to the following Study" dropdown field should not be used.

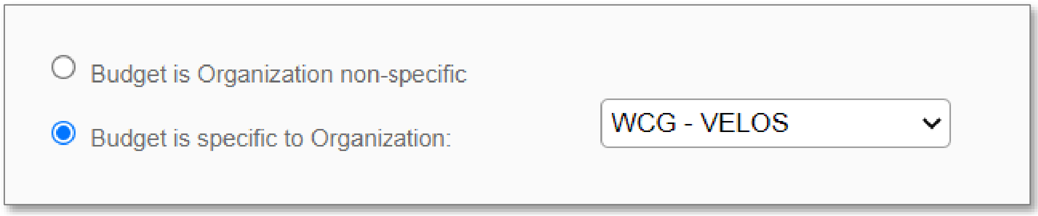
Enterprise Only: The Budget Currency field is only customizable in the Enterprise version.

Note: For sponsored studies, it is recommended that users select the Comparative budget system template, as it has the additional Amount and Variance columns used to compare site costs vs. sponsor payment amount. See System Budget Template Types to learn more.

2. Select either one of the **Patient** or **Comparative** System Budget Template Types in the Budget Template field.

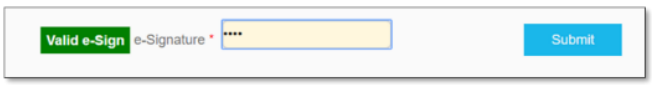


3. Define if all organizations or only a specific organization should have access to this budget template.

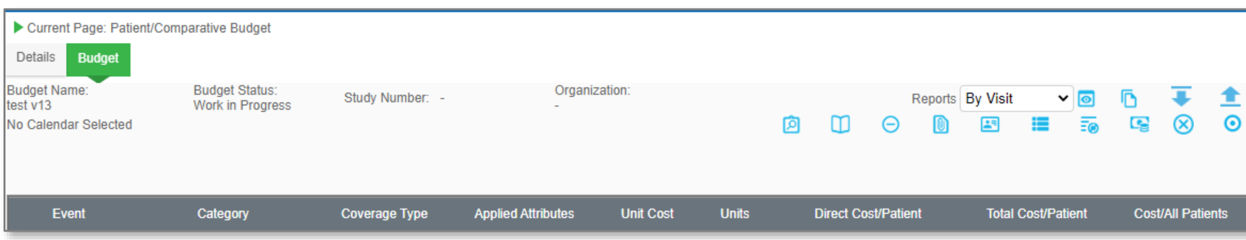


- Associating a budget to an Organization allows the creator to make copies for different sites as well as for sharing with all members of that Organization

4. Enter your e-Signature and click **Submit** to confirm.

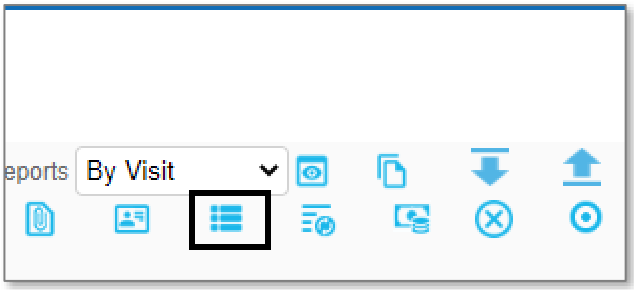


The Patient/Comparative Budget screen displays:

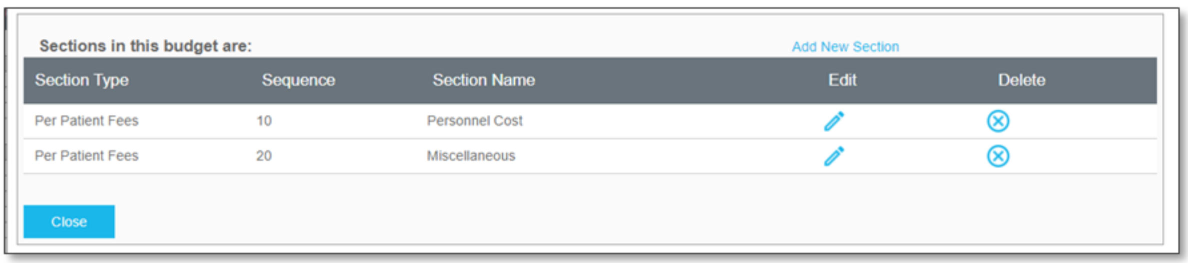


Note: You may want to keep the default Miscellaneous or Personnel Cost sections, and/or add custom sections to create your standard template. However, keep in mind that you are making a template that should be usable across multiple studies. Study-specific budget sections and line items can be added later once a budget template is associated with a study calendar if the sections are only required for one or a few studies.

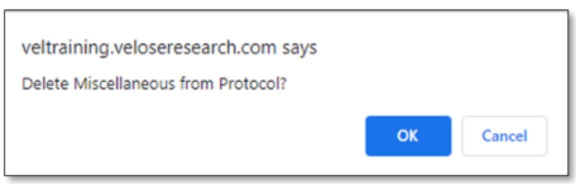
5. If you would like to add custom sections or remove the default Miscellaneous or Personnel Cost sections, click the **Sections** button. If you would like to keep the default sections, skip to Step 8**.**



6. Delete a default section by clicking the **Delete Button**.



7. Click **OK** in the confirmation pop-up.

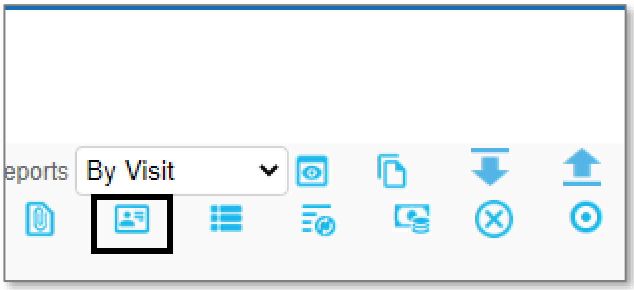


8. Enter your e-Signature and click **Submit** to confirm.

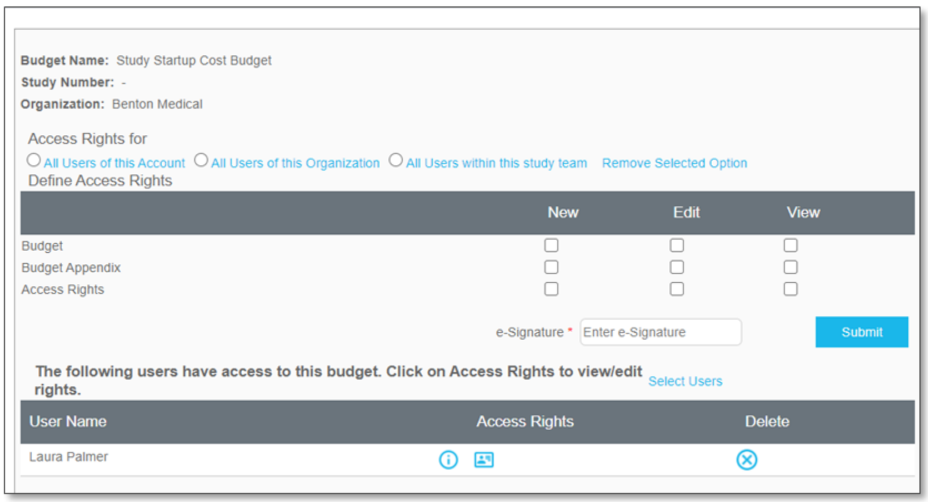
   a. Repeat to step 8 above for each section type, as needed, or click **Close**.

9. Click **Close** to close the pop-up when finished deleting or modifying default sections, as needed.

10. Click the **Access Rights** button.



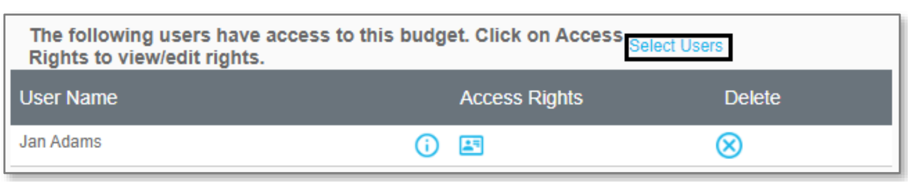
11. Assign access to **All Users of this Account** and check all of the boxes within the "Define Access Rights" area.



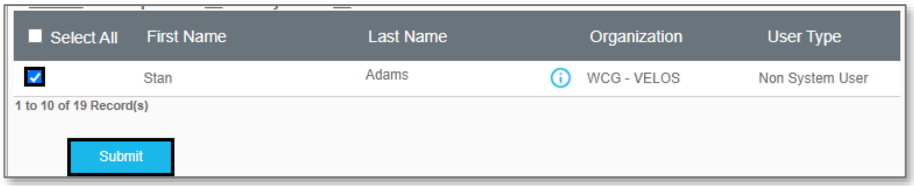
a. Then add your e-Signature and click **Submit** to confirm.

-OR-

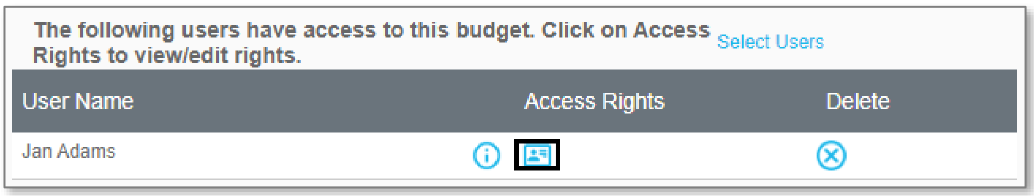
To assign individual users, click **Select Users.**



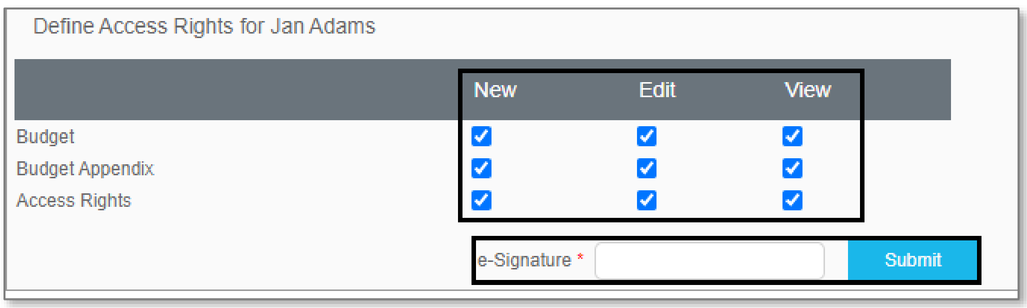
a. Check the checkbox for the appropriate new users and click **Submit**.



b. Click the **Access Rights** button for each new user.

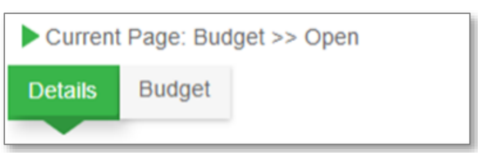


c. Check applicable checkboxes to assign rights, enter your e-Signature, and click **Submit** to confirm.



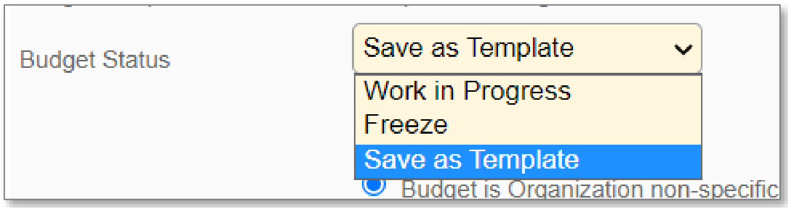
d. To close the Access Rights pop-up window, click the **X**.

12. Once rights have been assigned to users for the Budget as appropriate, navigate to the Details tab.

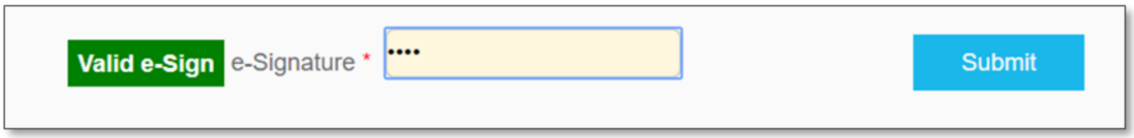


Warning: Once a budget is saved as a budget template, you can no longer alter the budget on the Budget tab until it is associated with a calendar. If budget changes are needed, you can replace the budget by making a copy of the template from the **Budget** tab, making the necessary changes, and deleting the original budget version.

13. Click the **Details** tab and select **Save as Template** from the dropdown options of **Budget Status**.



14. Enter your e-Signature and click **Submit** to confirm.

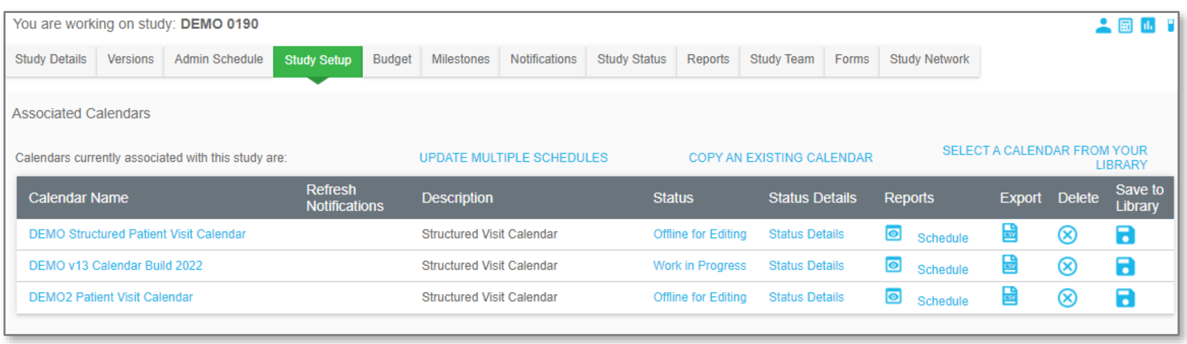


9.2.1.3 Associate a Comparative or Patient Budget Template to a Calendar

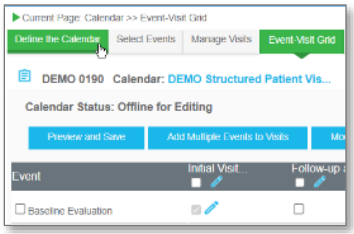
Comparative and patient budget template types, in Save as Template status only, may be associated to a study calendar and then modified. For more information on how to modify a budget after association, refer to Modify a Comparative or Patient Calendar Budget.

To associate a comparative or patient budget template to a calendar:

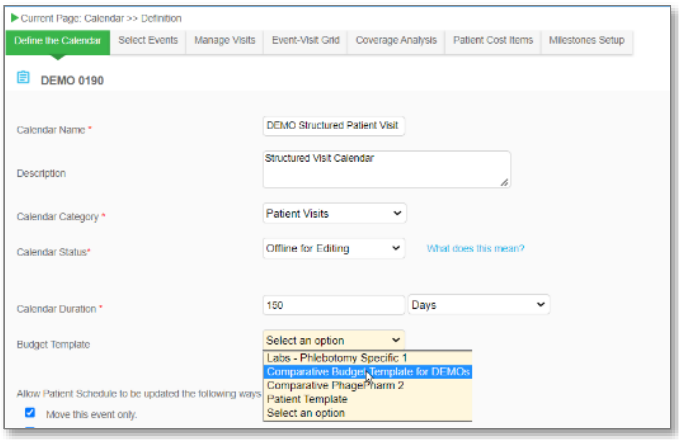
1. Locate the applicable calendar in the **Study Setup** tab of a study, ensuring it is in Work in Progress or Offline for Editing status, then click the Calendar Name.



2. Click **Define the Calendar**.

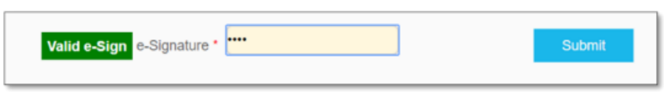


3. Select a Budget Template from the dropdown options.

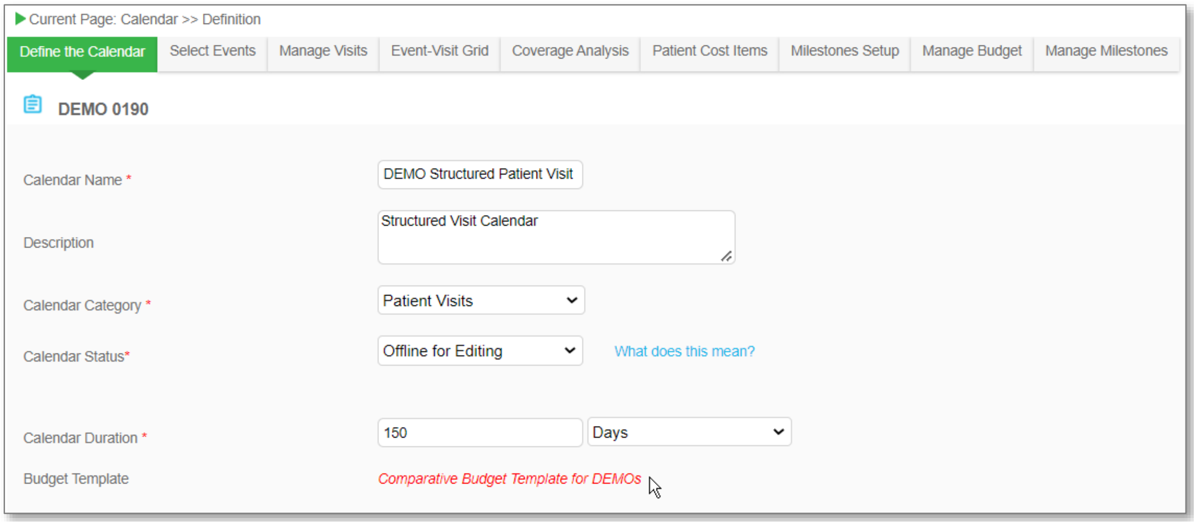


- Only those comparative or patient template types in Save as Template status will appear for selection

4. Enter your e-Signature and click **Submit** to confirm.



Two new tabs will appear: Manage Budget and Manage Milestones. The Budget Template selected will not be editable.



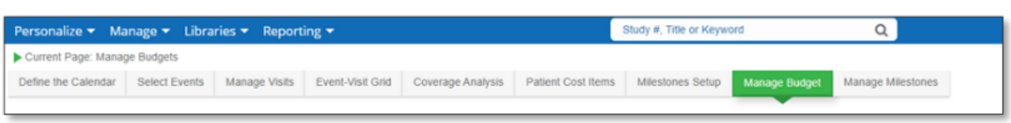
- For information on how to delete the associated budget template, if needed, refer to Deleting a Budget

9.2.1.3.1 Modify a Comparative or Patient Calendar Budget

In Velos eResearch, permissioned users can modify comparative and patient calendar budgets after they have been associated to a calendar. When visits are added to the calendar, the budget gets updated automatically. Most sections and line items will inherit the majority of the necessary financial information from the calendar via the visit and event details. Some elements such as Sponsor Amount and Calculation Attributes can only be applied manually to a Comparative or Patient Calendar budget.

To modify a comparative or patient calendar budget attached to a study calendar:

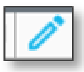
1. Navigate to the budget page of a study calendar by clicking on the study calendar name on the **Study Setup** page of a study, and selecting the **Manage Budget** tab. See Study Management for more information about the Study Setup page.



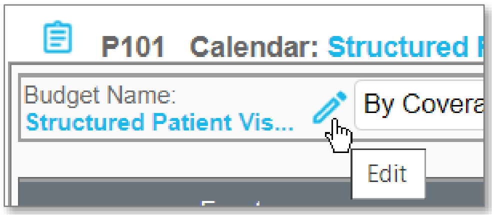
The Manage Budgets page displays.

> **Note:** Review Patient Template Type Example or Comparative Template Type Example for more information about these system budget template types.

From this page, most modifications can be made by clicking one of the available buttons as described by their icons in the table below:

Icon	Name	Description
	**Edit**	Used to make important adjustments to various elements of a budget, including line items, budget name, and number of patients. Using this link for line items allows the user to edit costs, apply indirects and a discount/markup, and add a sponsor amount in comparative budgets.
	**Add New Line Item**	Used to create new line items.
	**Download Budget**	Used to download a budget as a CSV file. See Using the Bulk Edit tool for Budgets for more information.
	**Upload Budget**	Used to bulk upload a budget from the downloaded CSV file. Can be used to make bulk updates to a budget. See Using the Bulk Edit tool for Budgets for more information.
	**Sections**	Add, Delete, or Edit budget sections. * Sections pulled in from a calendar cannot be edited or deleted
	**Exclude Multiple**	Used to turn off repeating line items by section.
	**Milestones**	Used to create both Visit and Event milestones from associated calendar events.
	**Access Rights**	Used to define access to the budget, budget appendix, or general access at the organization level. Access can also be defined for specific users.
	**Display Report**	Used to display a report that may be exported, after making a selection in the Reports dropdown field.
	**Appendix**	Used to add reference materials to the budget. Can add both files and URLs (links). For information how to use the Appendix, refer to Adding, Downloading, Editing or Deleting an Attachment.

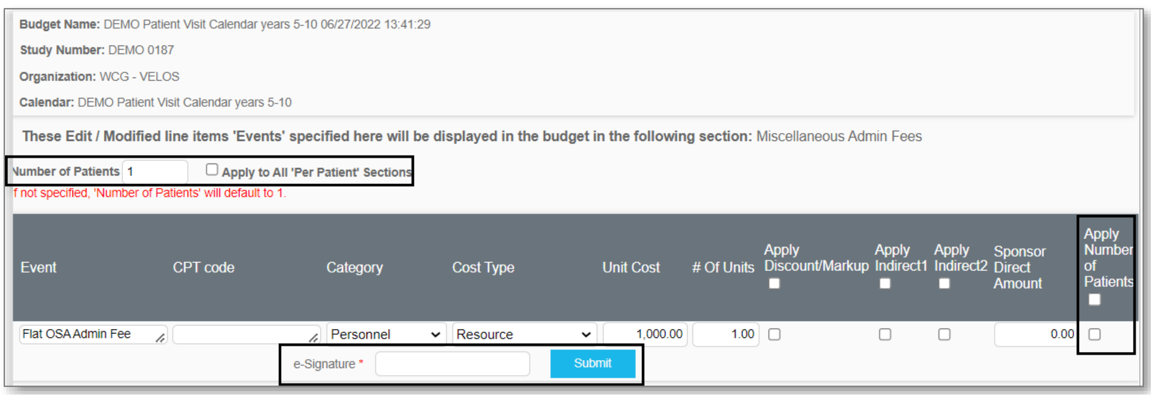
2. Click **Edit**, to change the calendar budget name, if needed.



   a. In the pop-up, change the budget name, e-Sign, and click **Submit**.

3. ***EDIT SECTION LINE ITEMS ICON***: Click **Edit Section Line Items**, to edit information for a section and to adjust fee calculations, as needed.

   a. Update Category, Cost Type, Unit Costs, and # of Units fields as needed. Check applicable checkboxes for the Event section to Apply Discount/Markup, Apply Indirect1, ApplyIndirect2, and / or to apply the Sponsor Direct Amount, as needed.



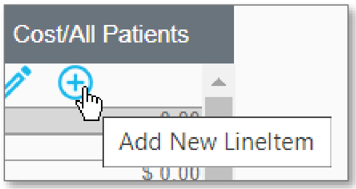
   - Event and CPT Code fields are not updatable in default calendar budgets

   b. To update applicable patient data, enter a number in the **Number of Patients** field. Check *the Apply to All 'Per Patient' Sections*, if applicable. Additionally, to apply to the section immediately, check the applicable checkbox(es) in the Apply Number of Patients column.

Note: See System Budget Template Types for more information about each field.

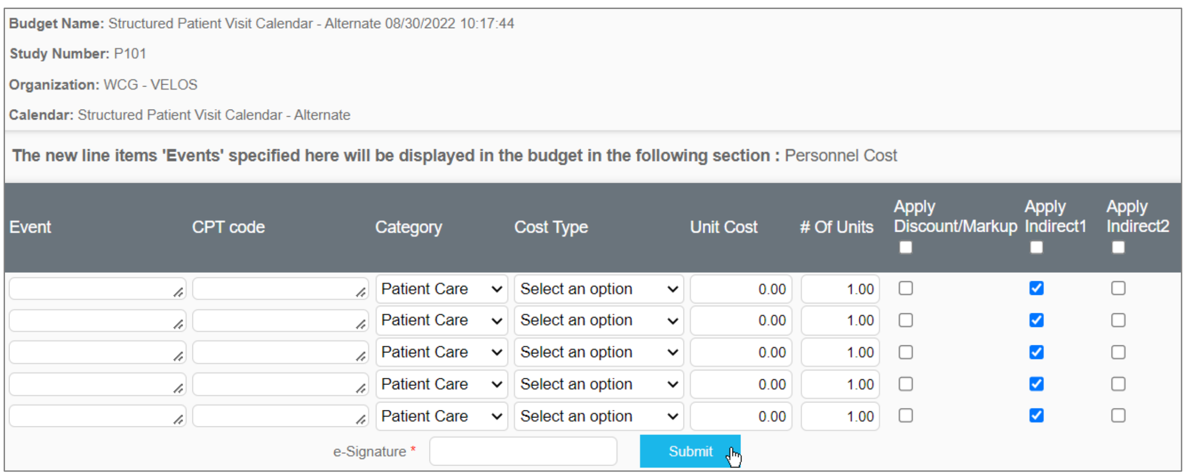
   c. Enter your e-Signature then click **Submit**.

4. ***ADD NEW LineItem ICON***: Click Add New LineItem, if needed.



Note: On Comparative and Patient System Budget Templates that are linked to a calendar, the Add New LineItem button is only available for sections that were created manually (not inherited from the calendar).

A pop-up appears for adding new line items to a section.


Budget Name: Structured Patient Visit Calendar - Alternate 08/30/2022 10:17:44

Study Number: P101

Organization: WCG - VELOS

Calendar: Structured Patient Visit Calendar - Alternate

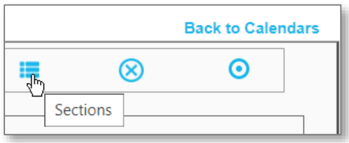
The new line items 'Events' specified here will be displayed in the budget in the following section : Personnel Cost

Event	CPT code	Category	Cost Type	Unit Cost	# Of Units	Apply Discount/Markup	Apply Indirect1	Apply Indirect2
		Patient Care	Select an option	0.00	1.00	☐	☑	☐
		Patient Care	Select an option	0.00	1.00	☐	☑	☐
		Patient Care	Select an option	0.00	1.00	☐	☑	☐
		Patient Care	Select an option	0.00	1.00	☐	☑	☐
		Patient Care	Select an option	0.00	1.00	☐	☑	☐

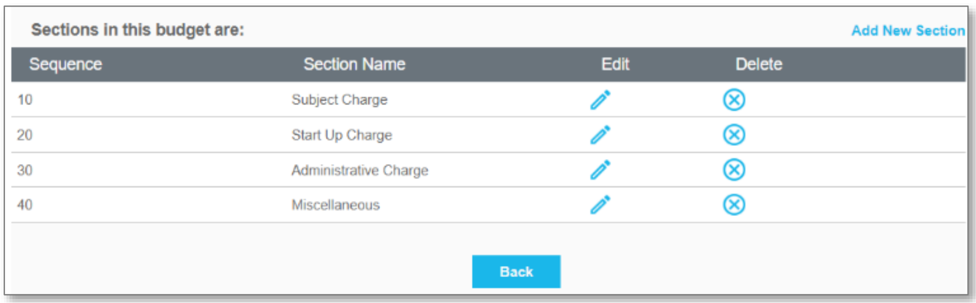
e-Signature * Submit

a. Create an Event name at minimum, complete the rest of the table fields as needed, e-Sign, then click **Submit**, to add up to five new line items for the section selected.

5. ***SECTIONS ICON***: Click Sections.



The Sections appear.

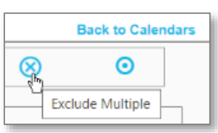


- Click **Edit** to edit the section name or sequence of the section, as needed, e-Sign, and **Submit**
- Click **Delete** to delete the section, as needed. Then click **OK** in the pop-up, e-Sign, **Submit**.

Note: Sections inherited from a linked calendar cannot be deleted here. To remove or add sections generated by a calendar, you need to add/modify the visits on the Visits tab of the linked calendar.

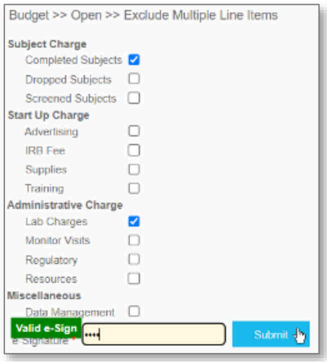
- Click **Add New Section**, select the Section Type (Per Patient Fee or One Time Fees), enter the Sequence and Section Name, e-Sign, and **Submit**, if needed

6. ***EXCLUDE MULTIPLE ICON***: Click Exclude Multiple, if needed.



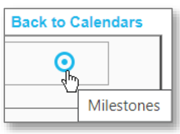
Warning: Delete with extreme caution. Once a line item is deleted, it cannot be added back in from this page. This may cause a difference in your projected versus final budgets.

a. Check applicable checkboxes, e-Sign, then click **Submit**.

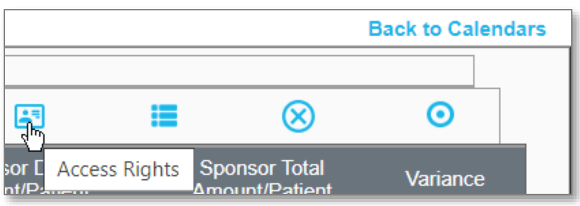


The selected line items no longer appear in the budget.

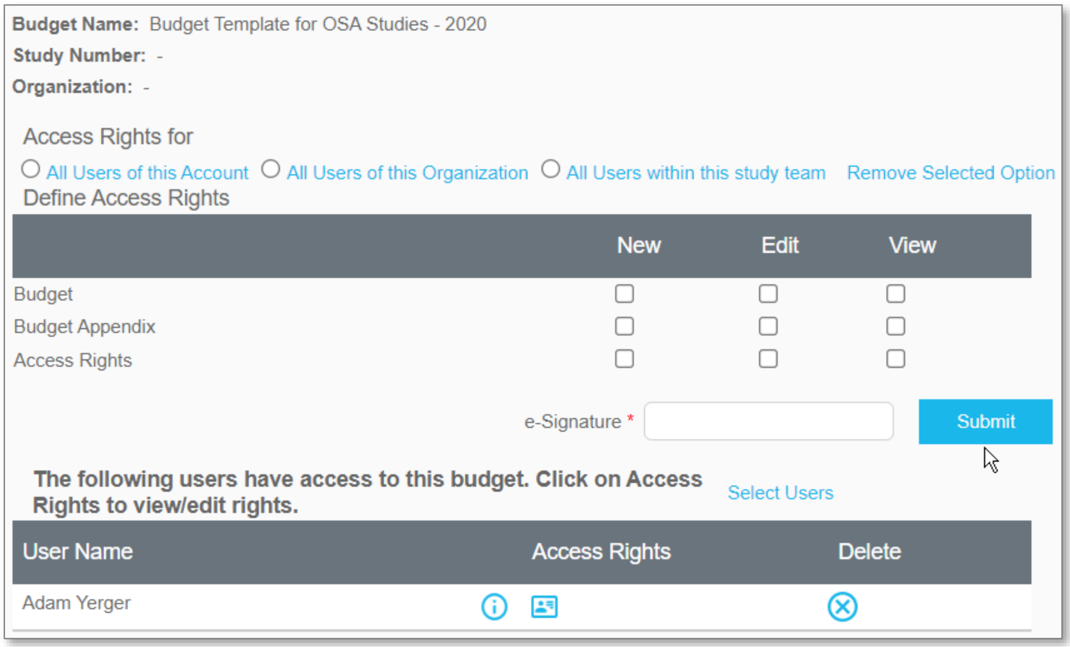
7. ***MILESTONES ICON***: Click Milestones to generate Additional, Visit, or Event milestones from a budget. See Generating Milestones from a Budget for more information about this process.



8. ***ACCESS RIGHTS ICON***: Click Access Rights, to modify or create new access rights.

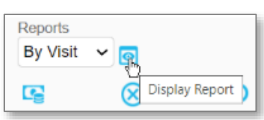


A pop-up appears.



- Select an ‘Access Rights for’ radio button if applicable, check checkboxes for New, Edit, and View, as needed, then e-Sign, and click **Submit**
- Click **Remove Selected Option**, e-Sign, and click **Submit**, to remove the selections, if needed
- Click **Select Users** and select specific users to create specific access rights
  - Click **Access Rights** to define the specific user’s access rights in a new screen, by checking checkboxes, then e-Sign, and click **Submit**
  - The specific users may be deleted from the table by clicking **Delete**, then e-Sign, and click **Submit**

9. ***DISPLAY REPORT ICON***: Use this dropdown to select one of three exportable budget reports. See Exporting Budget-Specific Reports for more information.



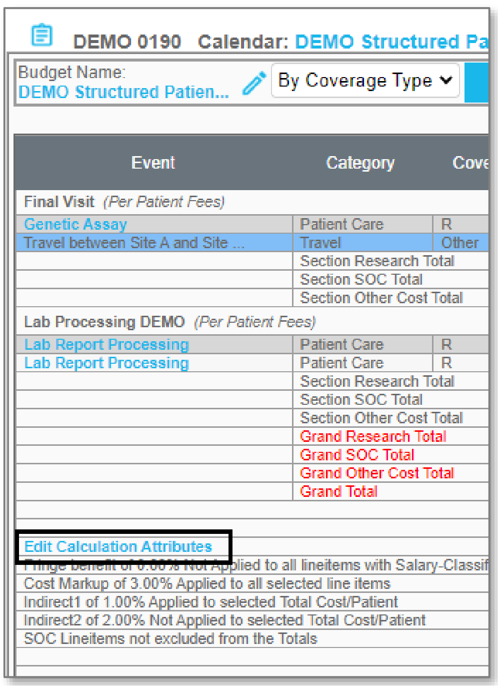
9.2.1.3.2 Edit Calculation Attributes (Indirects, Fringe, Discounts, and Markups)

Permissioned users can add dynamic calculations, such as Indirect Costs, Fringe benefits, Discounts, and Markups to a budget by using the Edit Calculations Attributes link on the budget page. The Edit Calculations Attributes link is located in the lower left portion of a comparative or patient budget, located right after the last line item.

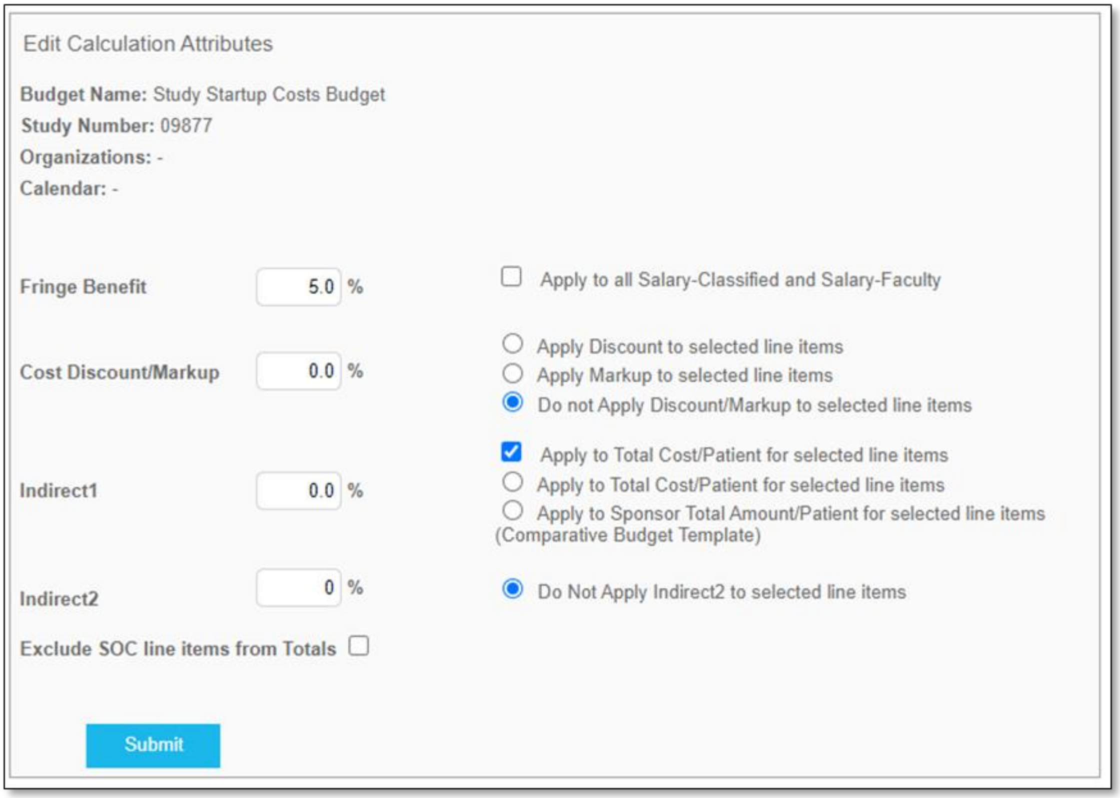
> **Note:** If your budget contains a large number of line items, it may be necessary to scroll to the bottom of the budget to access the link.

To edit a budget's calculation attributes:

1. Scroll to the bottom of the table and click **Edit Calculation Attributes**.



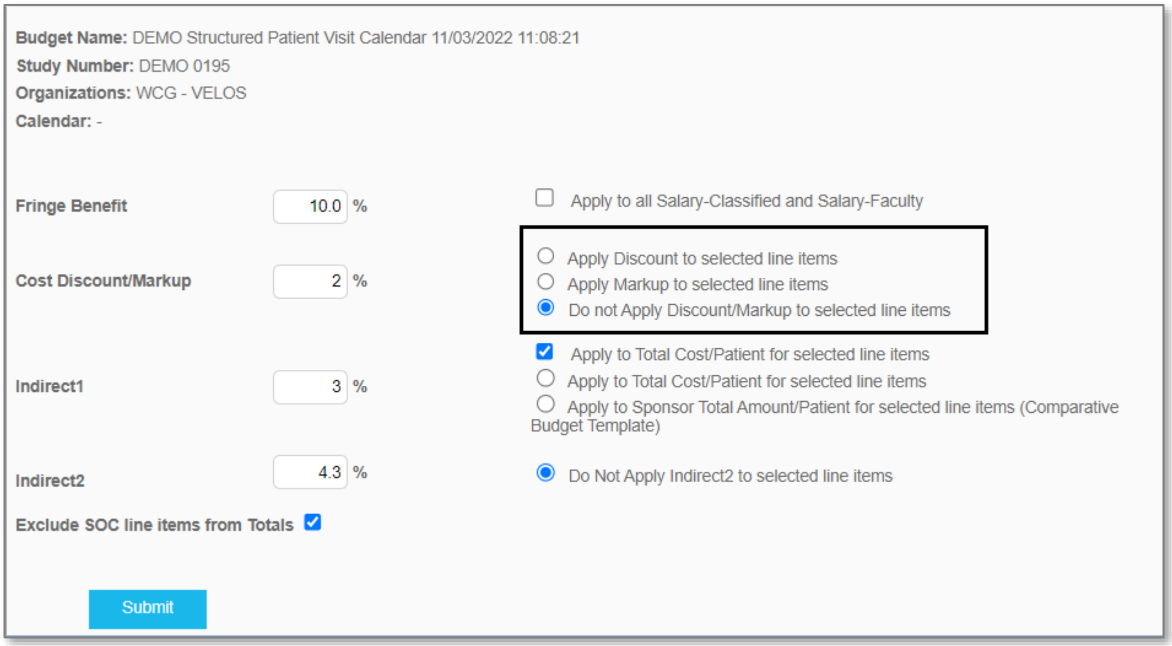
The **Edit Calculation Attributes** page opens in a new window:



2. Make any changes needed to the **Fringe Benefit** percentage field by typing the percentage value into the open field.

Note:
1. To view the applied fringe benefit, the Budget View must be Cost Type and the Category “personnel”.
2. Any changes made to the fringe benefit will apply only to this specific budget.

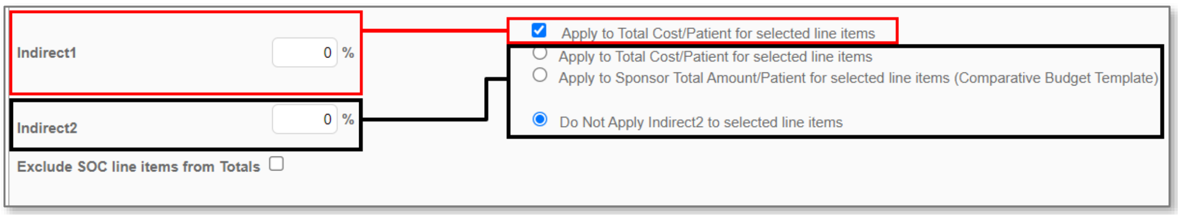
3. Next, make adjustments as necessary to the **Cost Discount / Markup** percentage field and select either the option **Apply Discount to selected line items**, or **Apply Markup to selected line items**, to indicate if this percentage is a markup or discount.



Warning: You can only apply a discount or a markup to any given budget. There is no way to apply both calculations simultaneously.

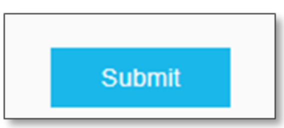
Note: If you need to remove all indirect modifiers from the budget, Click the **Remove Indirects** button, then click **OK** to confirm. To add indirects back, check the indirect 1 or indirect 2 box on the target line items.

4. Finally, make adjustments as necessary to the **Indirects** percentage fields to indicate if indirects should be applied to designated line items. Line items that have the **Apply Indirects** checkbox ticked using the Edit Section Line Items button are designated for application of the indirect calculation. For Indirect1, there is the option to apply to Total Cost/Patient or turn the calculation off. For Indirect2, there is the option to apply to Total Cost/Patient, Sponsor Total Amount/Patient, or turn the calculation off.



Note:
1. Indirects, Discounts and Markups are applied or removed by clicking on the Edit Section Line Items button, as described in the Patient Template Type Example and Comparative Template Type Example sections.
2. Indirect1 and Indirect2 should be applied separately as Indirect2 behavior can depend on the budget type.
3. You can also optionally exclude any line items classified with the Coverage Analysis type “Standard of Care” from the budget by clicking the **Exclude SOC line items from totals** checkbox. This applies to cost type - Standard of Care or Coverage type that is configured to designate 'Standard of Care'.

5. After configuring all necessary calculations to the Edit Calculation Attributes page, click **Submit** to confirm to apply the calculations to the budget.



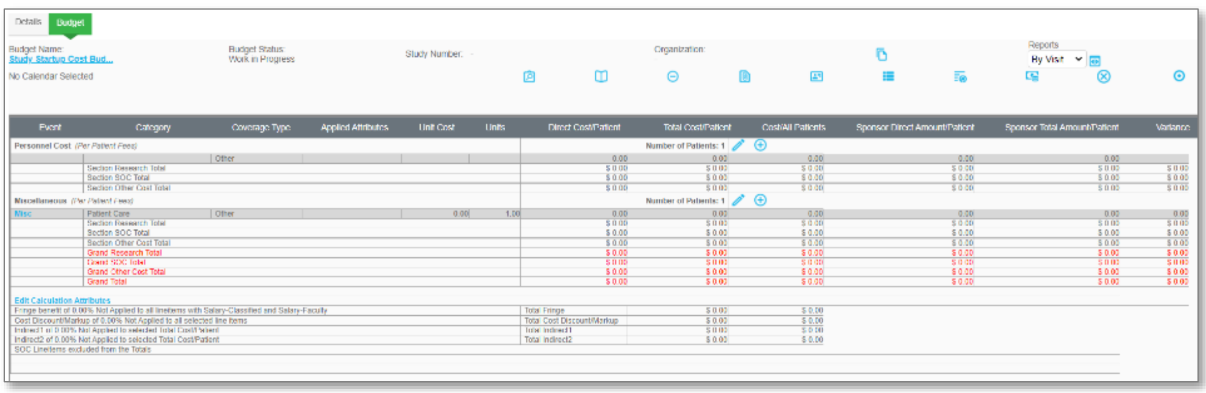
Note: See the examples described in the Patient Template Type Example and Comparative Template Type Example sections for more information on how these are applied.

9.2.1.4 Browser Budgets

Browser budgets are any budgets that are created directly from the Budget Browser page, as accessed from Manage > Search (Budget). They do not include any of the budgets in the status of 'Save as Template' or any of the additional budgets available when checking the checkbox for 'Default Calendar Budgets'. They do not include combined budgets specific to a study. Browser budgets may use comparative, patient, or System Budget Template Types.

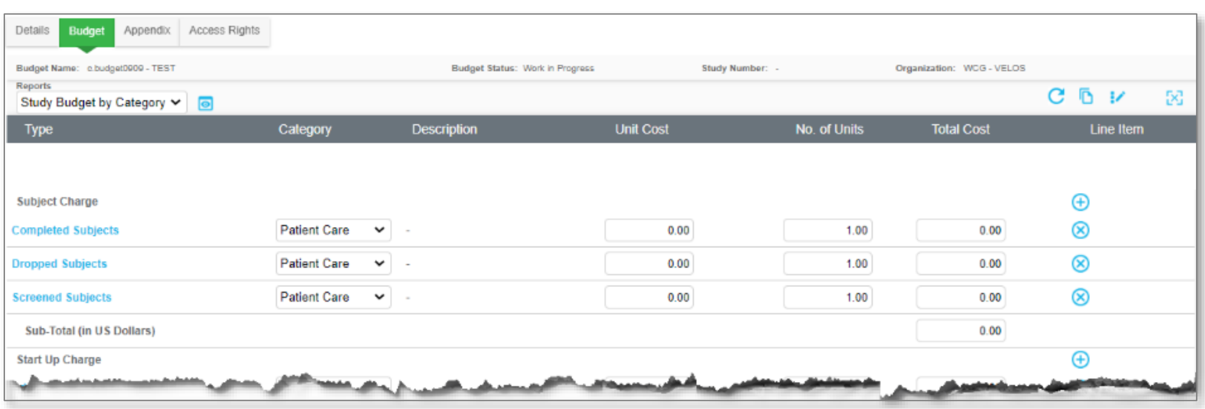
Comparative and patient templates, which are in 'Work in Progress' status, may be used as browser budgets from the Budget Browser page. For more information, refer to Modify a Comparative or Patient Browser Budget.

Comparative Browser Budget Example:



Study browser budgets have a very different appearance. For more information, refer to Modify a Study Browser Budget.

Study Browser Budget Example:

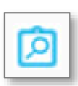


9.2.1.4.1 Modify a Comparative or Patient Browser Budget

Comparative or patient templates, not in' Save as Template' status, may be used as browser budgets for forecasting future costs. There are icons for these types of browser budgets that can also be found in a calendar budget. For information on using the icons also found in calendar budgets, refer to Modify a Comparative or Patient Calendar Budget. For information on the Edit Calculations Attributes button, refer to Edit Calculation Attributes (Indirects, Fringe, Discounts, and Markups).

Note: Review Patient Template Type Example or Comparative Template Type Example for more information about these system budget template types.

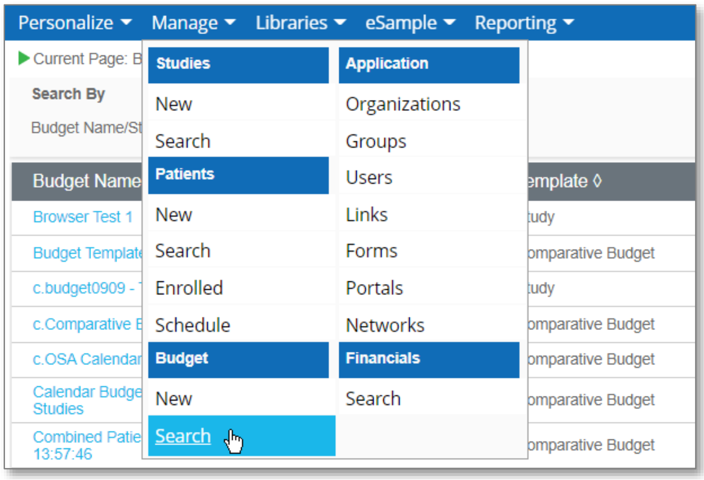
In addition to the calendar budget icons explained in the Associate a Comparative or Patient Budget Template to a Calendar section, comparative and patient browser budgets contain the following icons:

Icon	Name	Description
	**Library Calendar(s)**	Used to select library calendars to link to the budget.
	**Study Calendar(s)**	Used to select study calendars to link to the budget.
	**Delete Calendar(s)**	Used to disassociate one or more calendars from the budget.
	**Repeating Line Items**	Create line items that repeat in all sections, in the one-time fees' sections, or in the per patient fees sections.
	**Personnel Costs**	Used to create personnel costs. Only available after selecting a specific calendar.
	**Copy Budget**	Used to create a copy of the budget.

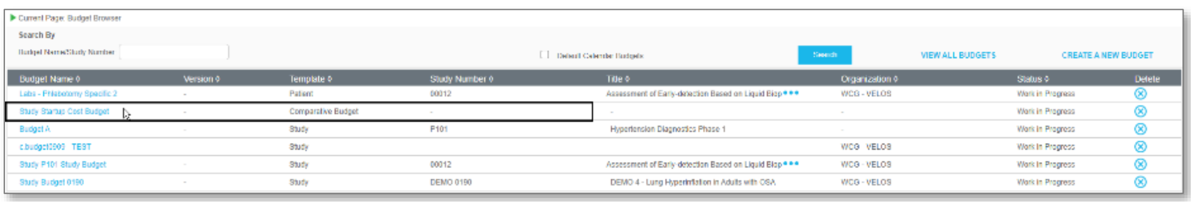
Note: See Using the Bulk Edit tool for Budgets for more information about bulk updating a comparative or patient browser budget.

To update a comparative or patient browser budget:

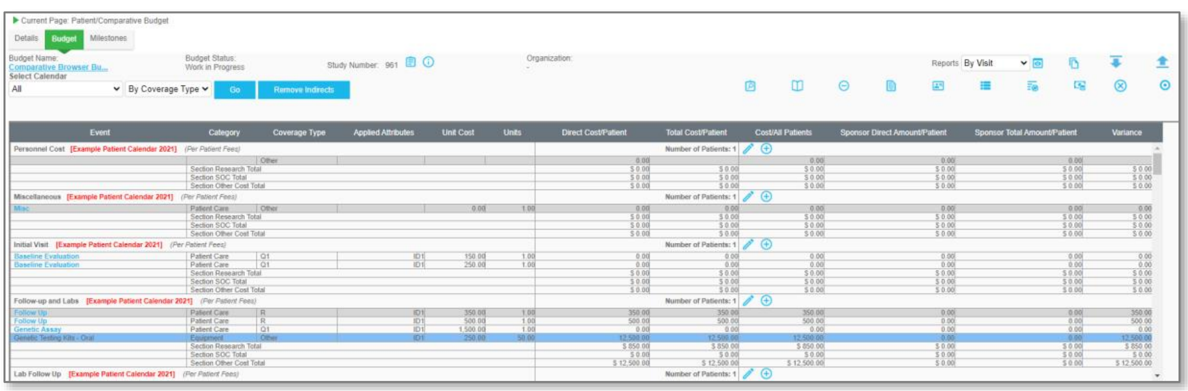
1. Click **Manage** > **Search** under Budget to access the Budget Browser page.



2. Click the budget name, for a budget identified as either a patient or a comparative template type, in the Template column, that is in 'Work in Progress' status.

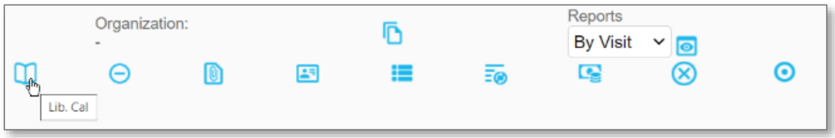


3. The browser budget for either a comparative or patient template type will appear.

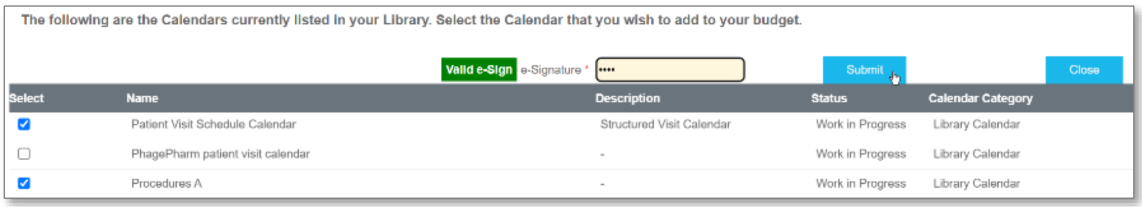


4. Update, as needed, for icons described in Modify a Comparative or Patient Calendar Budget or functional areas described in System Budget Template Types.

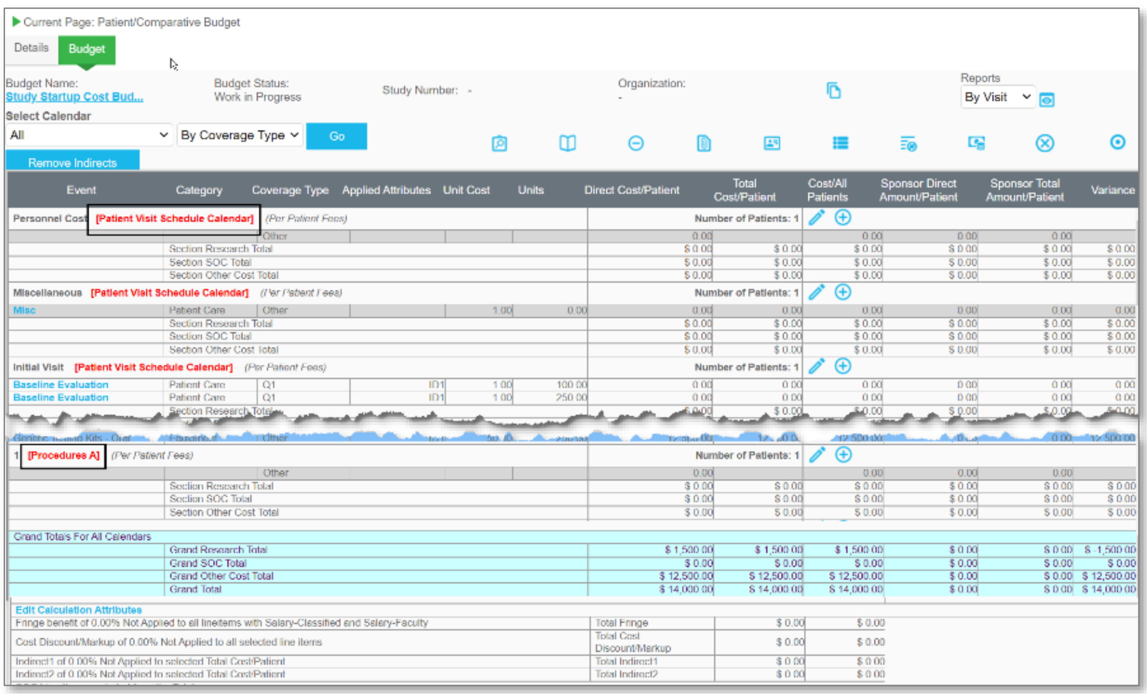
5. ***LIBRARY CALENDARS ICON***: If needed, Library Calendars may be added. Click **Lib. Cal.**



a. In the pop-up, check checkboxes for the applicable library calendar(s) to add, e-Sign, and click **Submit**.

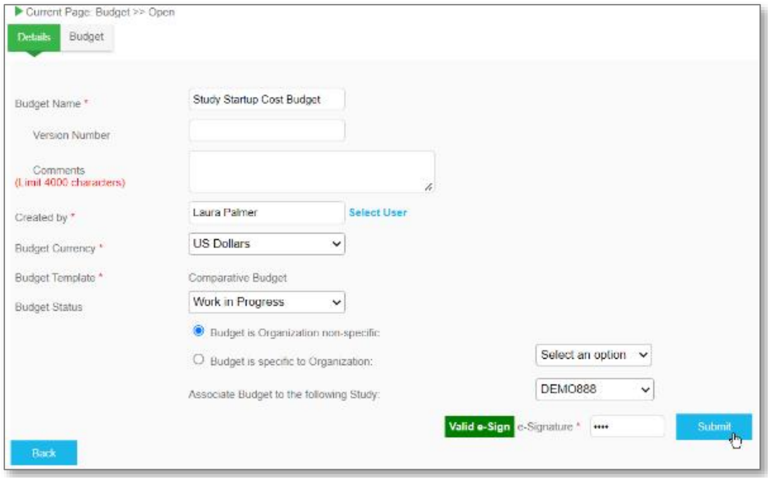


The new library calendar(s) will be added to the browser budget. Each Event section of the calendar will appear with the associated calendar name colored red.

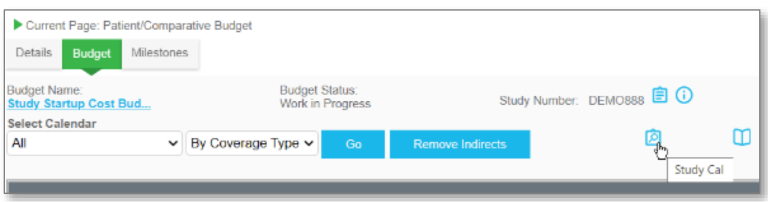


6. ***STUDY CALENDARS ICON***: If needed, Study Calendars may be added. First click **Details** to associate the browser budget to a study.

   a. Select the applicable study in the dropdown for the 'Associate Budget to the following Study' field, e-Sign, and click **Submit**.



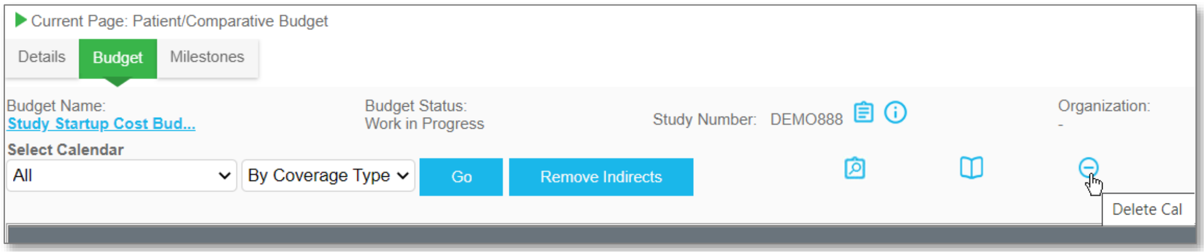
   b. The Budget tab now appears. Click **Study Cal**.



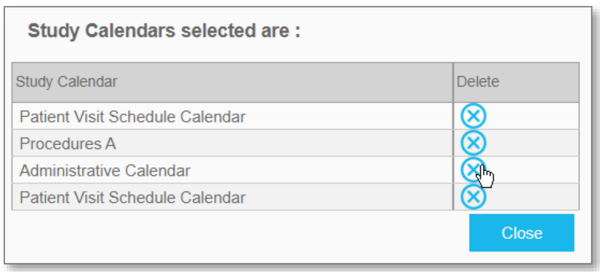
   c. In the pop-up, check the checkbox(es) for the applicable study calendar(s), e-Sign, and click **Submit**.

   - Study calendars added in browser budgets may be in' Work in Progress', 'Active', or 'Offline for Editing' status, and may be study calendars or admin calendars
   - As with adding library calendars, the study calendars will appear in the Budget tab with each Event section showing the name of the calendar colored red

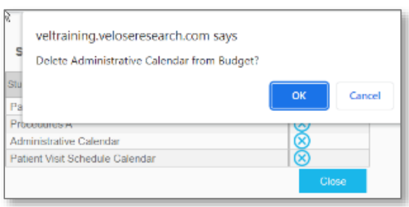
7. ***DELETE CALENDARS ICON***: If needed, added calendars may be deleted. Click **Delete Cal**.



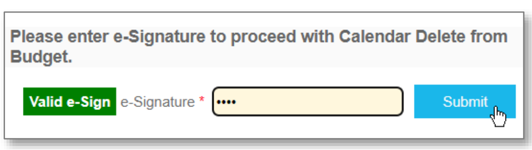
a. Click **Delete** for the applicable calendar.



b. Click **OK** to confirm deletion.



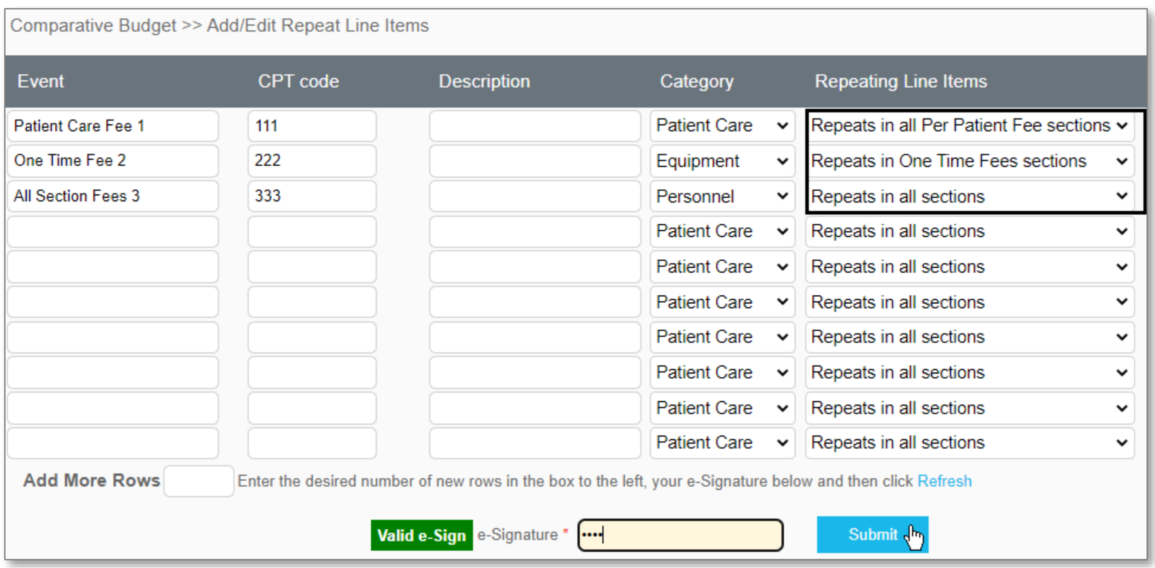
c. Enter your e-Signature and click **Submit** to confirm.



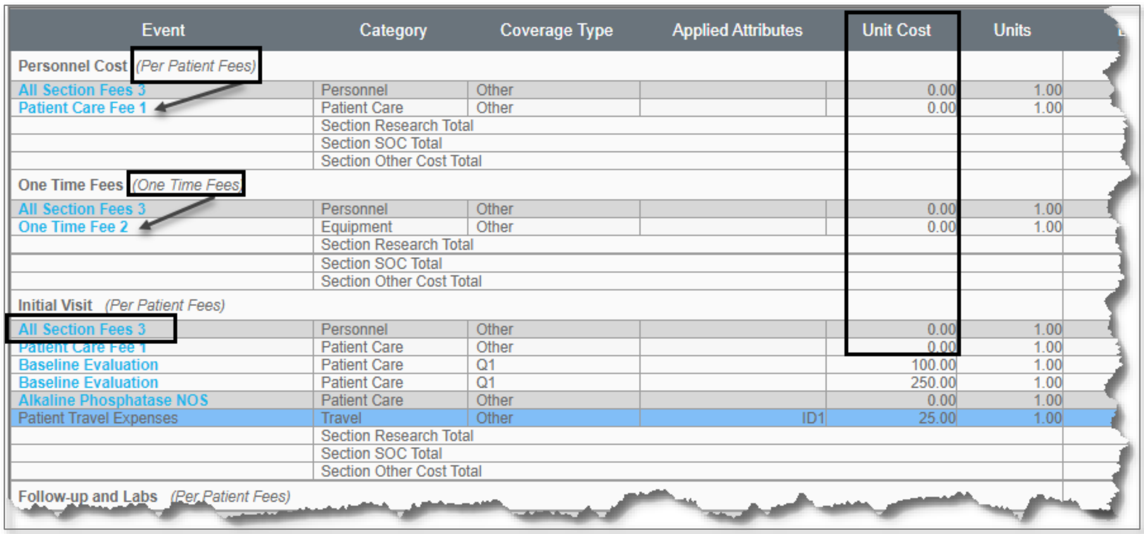
All sections of the calendar and costs will be deleted from the Budget tab.

8. ***REPEATING LINE ITEMS ICON***: If line items are needed for all sections, one-time fees' sections, or in the per patient fees' sections, they can be added at one time. Select a calendar from the Select Calendar dropdown and click **Go**, if prompted, and then click **Repeating Line Items**.

a. Enter an Event name, and optionally enter a CPT Code and / or Description. Select a Category from the dropdown options. Select either **Repeats in all Per Patient Fee sections**, **Repeats in One Time Fees sections**, or **Repeats in all sections** in the Repeating Line Items dropdown. Enter your e-Signature and click **Submit**.

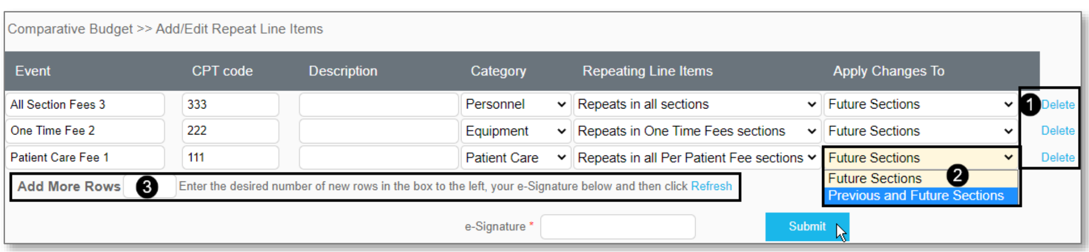


The One Time Fees line items will only appear in the One Time Fees section(s), the Per Patient Fees will only appear in the Per Patient Fees section(s), and the all sections selection will appear as line items in all sections.



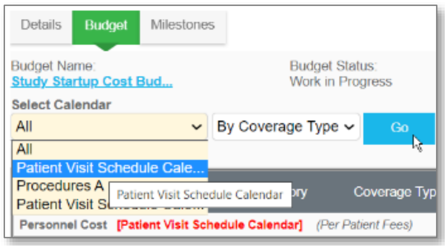
- The Unit Costs will be 0.00 for all new line items and each section will require editing to add in specific costs

b. After adding line items, after clicking **Repeating Line Items** again, there are three options for additional functionality.

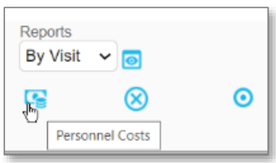


1. Click **Delete**, for a line item, to delete the Event from the applicable sections, then enter your e-Signature and click **Submit**.
2. Change the Apply Changes To dropdown option to **Previous and Future Sections**, in order to update information for the line item in all applicable sections which are existing, and for those new sections in the future. Enter your e-Signature and click **Submit**.
3. As the additional blank lines have been deleted, more lines may be added by entering a number in Add More Rows field. Then click **Refresh**, add data into the new line item(s), then enter your e-Signature and click **Submit**.

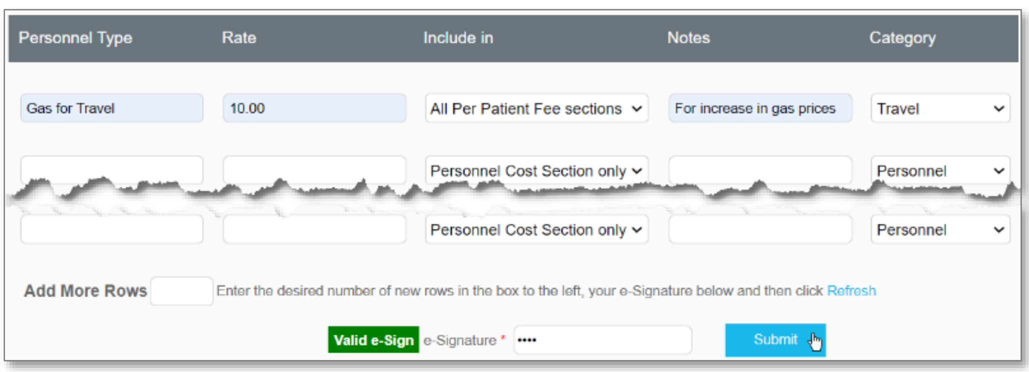
9. ***PERSONNEL COSTS ICON***: If personnel costs are needed to be added, or individual calendars are to be viewed, a specific calendar must be selected. Click the applicable calendar from the Select Calendar dropdown, then click **Go**.



a. Click **Personnel Costs** to add up to ten personnel costs simultaneously.

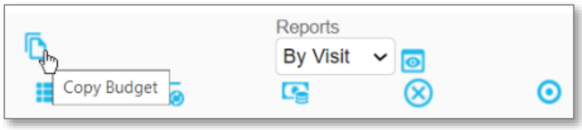


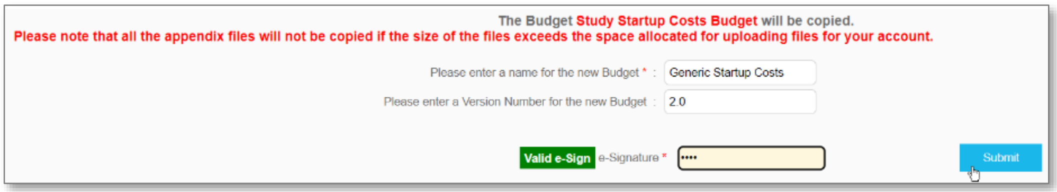
b. Enter and select applicable information, e-Sign, and click **Submit**.



- For the 'Include In' field, if selecting **Personnel Cost Section** only, then the cost will only appear in that section; if selecting **All Per Patient Fee sections**, then the cost will appear in all Per Patient Fee sections; or, if selecting **All Sections**, then the fee will appear in all sections
- If requiring more than ten rows, or returning to the Personnel Costs page after submitting, add more rows by entering the number of rows into the Add More Rows field, e -Sign, then click **Refresh.** Complete information, e-Sign, then click **Submit**.
- Alternately, when returning to the Personnel Costs page, click **Delete** to delete a cost, then e-Sign and click **Submit** to confirm, if needed

10. ***COPY BUDGET ICON***: If the budget created is something that would be beneficial to use later, or referred to as a new version, it may be copied. Click **Copy Budget**.





The copied version is now located in the Budget Browser page.

Note: For all other icon and button functionality not noted in this section, for more information, refer to Modify a Comparative or Patient Calendar Budget, or Edit Calculation Attributes (Indirects, Fringe, Discounts, and Markups).

9.2.1.4.2 Modify a Study Browser Budget

Study browser budgets may be used to analyze study costs for forecasting. The study type of budget template may only be associated to a study from the Budget Browser. A new study template must be created for use each time and must be kept in the 'Work in Progress' status. For information on how to create a budget template, refer to Create a Budget Template.

Note: See Study Template Type Example for more information about using this type of budget.

Study Budgets can document general distribution plans for various types of costs incurred while managing a Study.

Default Sections for new Study Budgets include the following, including their default line items:

- Subject Costs – Screened Subjects, Dropped Subjects, Completed Subjects
- Start Up Fees – IRB Fee, Advertising, Supplies, Training
- Administrative Charge – Regulatory, Resources, Monitor Visits, Lab Charges
- Miscellaneous – Data Management

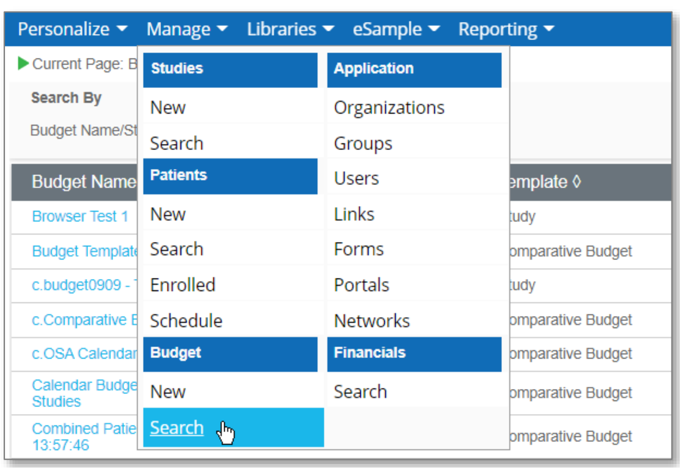
The Line Items can be customized by Category, Unit Cost, and Number of Units. Each Section displays a Sub-Total and the Total of All Costs at the bottom of the Budget page. Indirect Costs can be specified as a percentage of the Total Costs.

In addition to the Add New Line Item and Display Report calendar budget icons, and the Copy Budget icon in the comparative and patient browser budgets, a study browser budget contains the following icons:

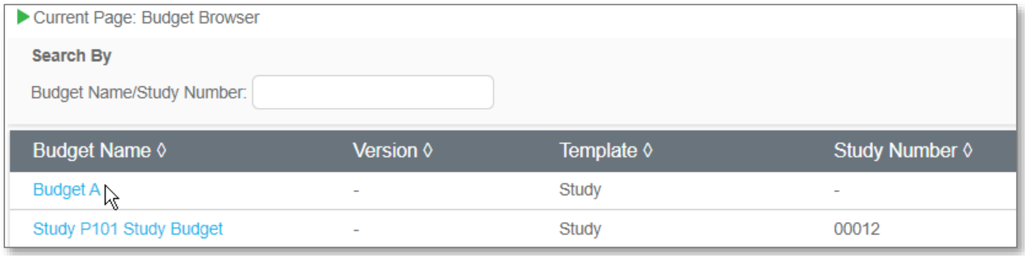
Icon	Name	Description
	**Edit Sections**	Used for editing section names, sequencing of sections, and deleting. For more information, refer to the Sections Icon information in Modify a Comparative or Patient Calendar Budget, which has the same functionalities.
	**Delete Multiple**	Used for excluding line items in sections. For more information, refer to the Exclude Multiple Icon information in Modify a Comparative or Patient Calendar Budget, which has the same functionalities.
	**Refresh Calculations**	Used for refreshing calculations after modifying fields.

To modify a study browser budget:

1. Click **Manage** > **Search** under Budget to access the Budget Browser page.

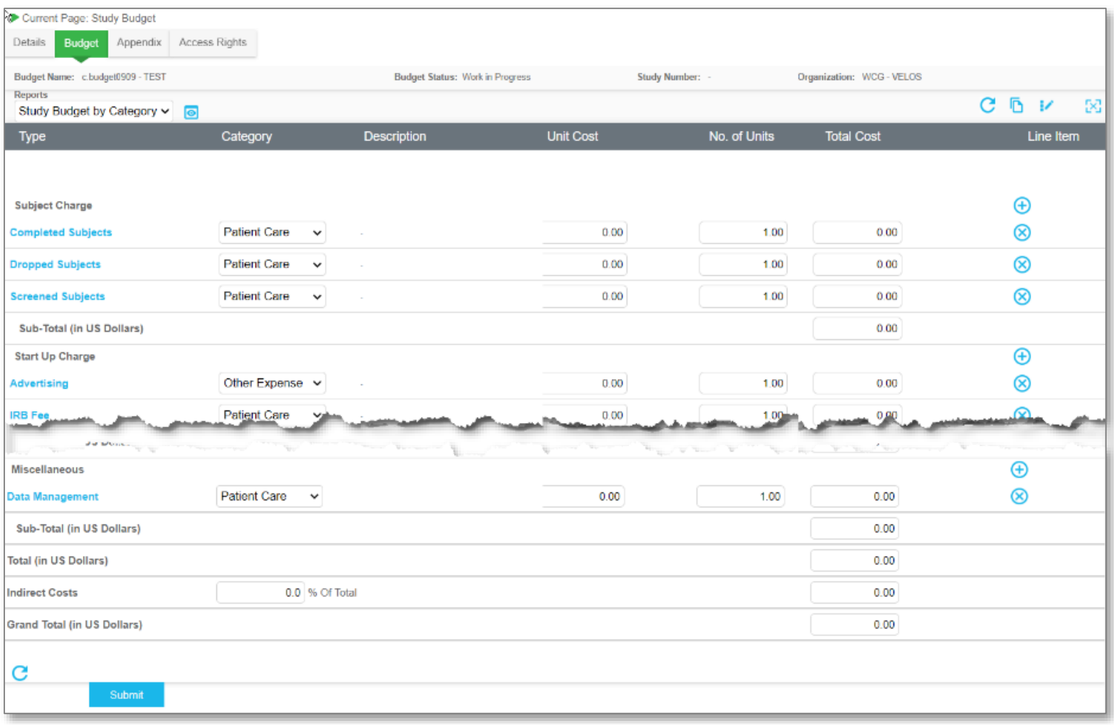


2. Locate the study budget and click the budget name.

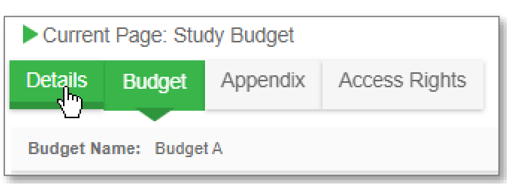


- Study budgets show Study in the Template column
- A study budget not used for a study will have a dash in place of Study Number
- Study budgets in a Save as Template status are not usable for browser budgets

The Study Budget page appears.



3. If not already associated to a study, click **Details** to associate to a study, if needed, otherwise, skip to step 4.

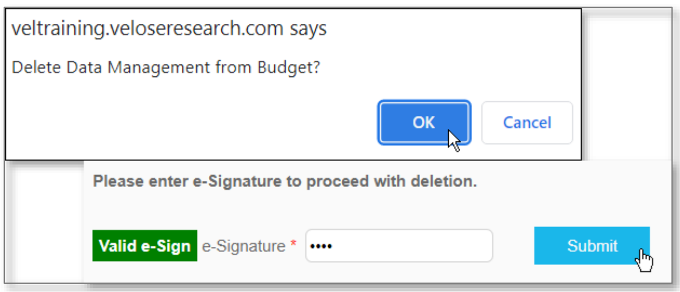


a. Select an option from the dropdown in the field 'Associate Budget to the following Study'.

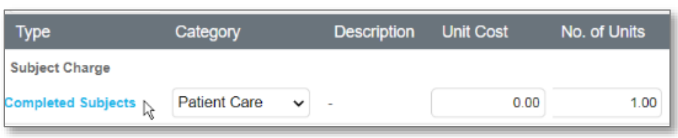
b. Enter your e-Signature and click **Submit** to confirm.

4. To use the Add New Line Item, Edit Sections, or Delete Multiple icons, refer to Modify a Comparative or Patient Calendar Budget.

5. Click **Delete**, to remove line items, if not needed. Then click **OK** in the pop-up, e-Sign, and **Submit**.

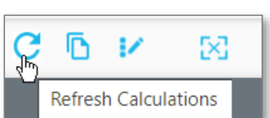


6. Click a link in the Type column to update the name of a line item and its' description, if needed, per line item.



7. Click the Category dropdown and select a different option, if needed, per line item.
8. Modify the Unit Cost and /or No. of Units fields, per line item, as needed.
9. Modify the Indirect Costs field, if needed.

10. Click **Refresh Calculations**, to refresh the Total Cost column calculations after updating any other cost fields.

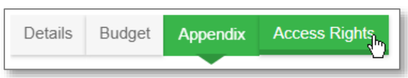


- Icon is also located to the left of the Submit button

11. Click **Submit**, to save all changes to the budget.
12. For more information on the use of the Display Report icon, refer to Modify a Comparative or Patient Calendar Budget.
13. For more information on the use of the Copy Budget icon, refer to Modify a Comparative or Patient Browser Budget.

Warning: Ensure Submit is clicked to save all changes on the Budget page before navigating to any other system tabs or areas.

14. Click **Appendix** to add files and links. For more information, refer to Adding, Downloading, Editing or Deleting an Attachment.



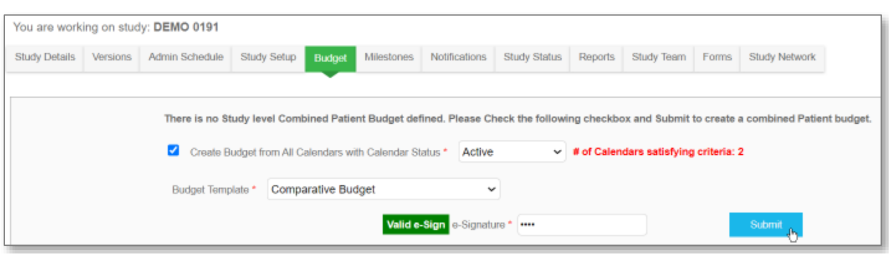
15. Click **Access Rights** to adjust budget access rights. For more information, refer to Modify a Comparative or Patient Calendar Budget.

9.2.1.5 Create a Combined Budget

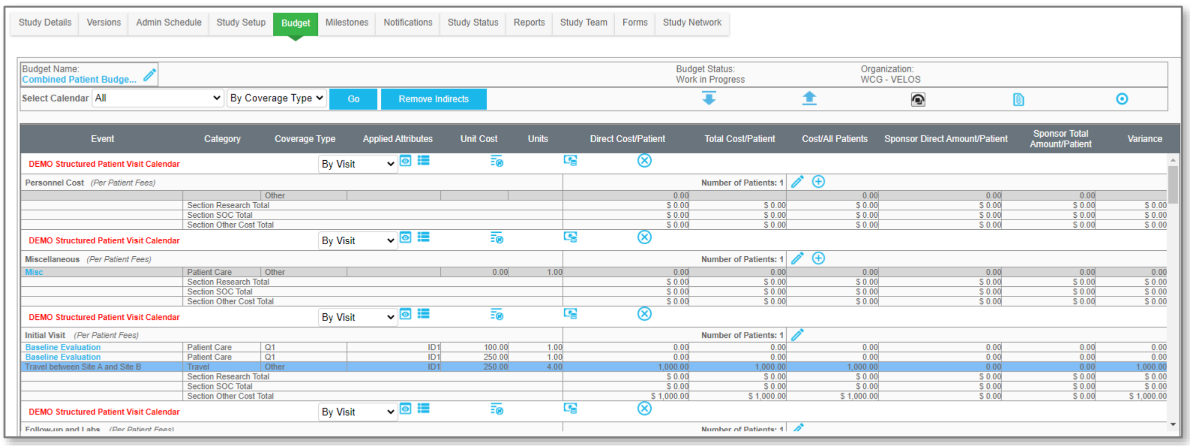
Calendars may be combined to create a combined view of more than one study calendar budgets. The calendars must all either be in Work in Progress or Active status only. All calendar types must be either Patient or Comparative. This view is not dynamic and will only show a single point in time for the data presented. If a combined budget needs to be created again, the original will need to be deleted. For more information on deleting a combined budget, refer to Deleting a Budget.

To create a combined study budget:

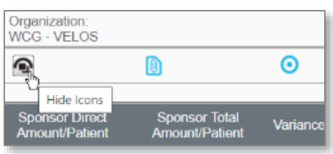
1. Locate a study and click **Budget** in the Study Management area.



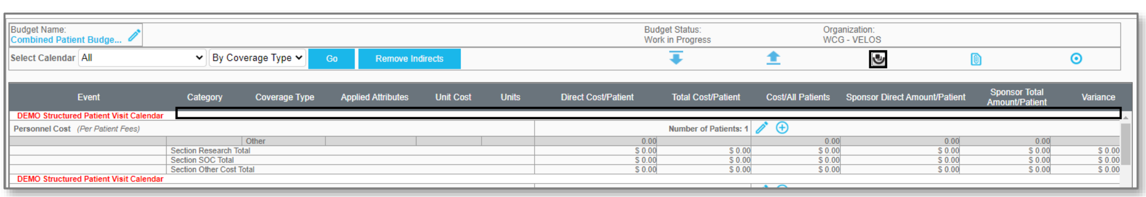
2. Select either Active or Work in Progress from the dropdown and check the checkbox to the far left of the status field.
    - As the type of status is selected, the number of calendars satisfying the criteria will show
3. Select the Budget Template field type from the dropdown, e-Sign, and **Submit**.
    - The options are comparative or patient
4. The combined study budget will appear.



5. To hide icons above each calendar section, click **Hide Icons**, if needed.



   a. To view the icons again, click **Hide Icons** a second time.



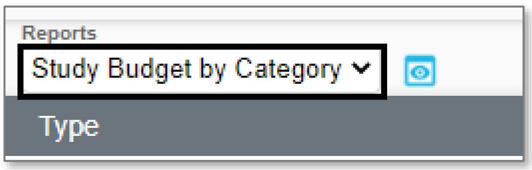
Note: For all other icon and button functionality not noted in this section, please refer to Modify a Comparative or Patient Calendar Budget or Modify a Comparative or Patient Browser Budget, for more information.

9.2.1.6 Exporting Budget-Specific Reports

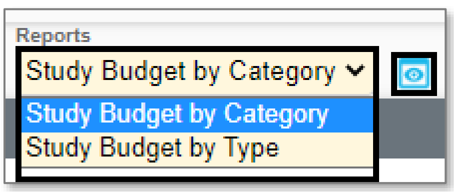
All budgets provide a means to export data directly from the budget page for archival, compliance, or offline sharing purposes. Each budget-specific report can only be accessed via the budgets page and will only pull data for that specific budget where it is pulled from.

To access and export a budget-specific report:

1. Navigate to any budget and click on the dropdown menu under the Reports heading.



2. Select the budget-specific report you would like to export and click the **Display Report** (eye icon) button.



Note: The specific reports available vary depending upon which budget type you are viewing.

3. Once the report displays, the report can exported as an Excel file, Word file, or opened in a printer-friendly format by clicking on the associated icons.

There are three distinct budget-specific reports associated with Comparative and Patient Budget Template Types:

- By Visit
- Calendar Grid
- Overview

There are two distinct budget-specific reports associated with the Study Budget Template type:

- Study Budget by Category
- Study Budget by Type

Review the sections below for examples of each type of report.

9.2.1.6.1 By Visit (Comparative / Patient Budgets)

The **By Visit** report is available only on Comparative or Patient type budgets. This report displays your budget data in a summarized format organized by visit/section. Calculation attributes information is summarized at the top of the report. See a report example below:

Download the report in:

By Visit

Budget Name:	DEMO Structured Patient Visit Calendar 08/30/2022 11:16:31
Budget Version:	1
Study Number:	DEMO 0190
Study Title:	DEMO 4 - Lung Hyperinflation in Adults with OSA
Study Calendar:	DEMO Structured Patient Visit Calendar
Organization:	WCG - VELOS
Applied Attributes:	ID1 = "1"%, ID2 = "2"%

Event	CPT code	Additional Codes	Category	Coverage Type	Applied Attributes	Unit Cost	Units	Direct Cost/Patient	Total Cost/Patient	Cost/All Patients	Sponsor Direct Amount/Patient	Sponsor Total Amount/Patient	Variance
		Personnel Cost *(Per Patient Fees)*							**Number of Patients: 1**				
Admin Fee			Personnel	Other	ID1	250.00	1.00	250.00	252.50	252.50	10.00	10.00	-242.50
			Section Research Total					$ 0.00	$ 0.00	$ 0.00	$ 0.00	$ 0.00	$ 0.00
			Section SOC Total					$ 0.00	$ 0.00	$ 0.00	$ 0.00	$ 0.00	$ 0.00
			Section Other Cost Total					$ 250.00	$ 252.50	$ 252.50	$ 10.00	$ 10.00	$ -242.50
		Initial Visit *(Per Patient Fees)*							**Number of Patients: 2**				
Baseline Evaluation			Patient Care	Q1	ID1	100.00	1.00	100.00	101.00	202.00	10.00	10.00	-91.00
Baseline Evaluation			Patient Care	Q1	DM	250.00	1.00	257.50	257.50	515.00	20.00	20.00	-237.50
Lab Report Processing			Patient Care	Other	ID1 ID2	500.00	1.00	500.00	505.00	1,010.00	0.00	0.00	-505.00
Lab Report Processing			Patient Care	Other	ID1	7,500.00	1.00	7,500.00	7,575.00	15,150.00	0.00	0.00	-7,575.00
Travel between Site A and Site B			Travel	Other	ID1	250.00	4.00	1,000.00	1,010.00	2,020.00	10.00	10.00	-1,000.00
test			Personnel	Other	ID1	5.00	1.00	5.00	5.05	10.10	0.00	0.00	-5.05
			Section Research Total					$ 0.00	$ 0.00	$ 0.00	$ 0.00	$ 0.00	$ 0.00
			Section SOC Total					$ 357.50	$ 358.50	$ 717.00	$ 30.00	$ 30.00	$ -328.50
			Section Other Cost Total					$ 9,005.00	$ 9,095.05	$ 18,190.10	$ 10.00	$ 10.00	$ -9,085.05
		Follow-up and Labs *(Per Patient Fees)*							**Number of Patients: 1**				
Follow Up			Patient Care	Q0	ID1	350.00	1.00	350.00	353.50	353.50	10.00	10.00	-343.50
Follow Up			Patient Care	Q0	ID1	450.00	1.00	450.00	454.50	454.50	10.00	10.00	-444.50
Genetic Assay	44325		Patient Care	R	ID1	1,500.00	1.00	1,500.00	1,515.00	1,515.00	10.00	10.00	-1,505.00
Genetic Testing Kits - Oral			Equipment	Other	ID1	75.00	50.00	3,750.00	3,787.50	3,787.50	10.00	10.00	-3,777.50
			Section Research Total					$ 1,500.00	$ 1,515.00	$ 1,515.00	$ 10.00	$ 10.00	$ -1,505.00
			Section SOC Total					$ 800.00	$ 808.00	$ 808.00	$ 20.00	$ 20.00	$ -788.00
			Section Other Cost Total					$ 3,750.00	$ 3,787.50	$ 3,787.50	$ 10.00	$ 10.00	$ -3,777.50
		Follow-up Visit 1 *(Per Patient Fees)*							**Number of Patients: 1**				
Follow Up			Patient Care	Q0	ID1	350.00	1.00	350.00	353.50	353.50	10.00	10.00	-343.50
Follow Up			Patient Care	Q0	ID1	450.00	1.00	450.00	454.50	454.50	10.00	10.00	-444.50
			Section Research Total					$ 0.00	$ 0.00	$ 0.00	$ 0.00	$ 0.00	$ 0.00
			Section SOC Total					$ 800.00	$ 808.00	$ 808.00	$ 20.00	$ 20.00	$ -788.00
			Section Other Cost Total					$ 0.00	$ 0.00	$ 0.00	$ 0.00	$ 0.00	$ 0.00
		test *(Per Patient Fees)*							**Number of Patients: 1**				
Genetic Assay	44325		Patient Care	R	ID1	1,500.00	1.00	1,500.00	1,515.00	1,515.00	0.00	0.00	-1,515.00
Baseline Evaluation			Patient Care	Other	ID1	100.00	1.00	100.00	101.00	101.00	0.00	0.00	-101.00
Baseline Evaluation			Patient Care	Other	ID1	250.00	1.00	250.00	252.50	252.50	0.00	0.00	-252.50
			Section Research Total					$ 1,500.00	$ 1,515.00	$ 1,515.00	$ 0.00	$ 0.00	$ -1,515.00
			Section SOC Total					$ 0.00	$ 0.00	$ 0.00	$ 0.00	$ 0.00	$ 0.00
			Section Other Cost Total					$ 350.00	$ 353.50	$ 353.50	$ 0.00	$ 0.00	$ -353.50
		Follow-up Visit 3 *(Per Patient Fees)*							**Number of Patients: 1**				
Follow Up			Patient Care	Q0	ID1	350.00	1.00	350.00	353.50	353.50	10.00	10.00	-343.50
Follow Up			Patient Care	Q0	ID1	450.00	1.00	450.00	454.50	454.50	10.00	10.00	-444.50
			Section Research Total					$ 0.00	$ 0.00	$ 0.00	$ 0.00	$ 0.00	$ 0.00
			Section SOC Total					$ 800.00	$ 808.00	$ 808.00	$ 20.00	$ 20.00	$ -788.00
			Section Other Cost Total					$ 0.00	$ 0.00	$ 0.00	$ 0.00	$ 0.00	$ 0.00
		Follow-up Visit 4 *(Per Patient Fees)*							**Number of Patients: 1**				
Genetic Assay	44325		Patient Care	R	ID1	1,500.00	1.00	1,500.00	1,515.00	1,515.00	0.00	0.00	-1,515.00
Travel between Site A and Site B			Travel	Other	ID1	250.00	4.00	1,000.00	1,010.00	1,010.00	10.00	10.00	-1,000.00
			Section Research Total					$ 1,500.00	$ 1,515.00	$ 1,515.00	$ 0.00	$ 0.00	$ -1,515.00
			Section SOC Total					$ 0.00	$ 0.00	$ 0.00	$ 0.00	$ 0.00	$ 0.00
			Section Other Cost Total					$ 1,000.00	$ 1,010.00	$ 1,010.00	$ 10.00	$ 10.00	$ -1,000.00
		Lab Processing DEMO *(Per Patient Fees)*							**Number of Patients: 1**				
Lab Report Processing			Patient Care	R	ID1	500.00	1.00	500.00	505.00	505.00	10.00	10.00	-495.00
Lab Report Processing			Patient Care	R	ID1	7,500.00	1.00	7,500.00	7,575.00	7,575.00	10.00	10.00	-7,565.00
			Section Research Total					$ 8,000.00	$ 8,080.00	$ 8,080.00	$ 20.00	$ 20.00	$ -8,060.00
			Section SOC Total					$ 0.00	$ 0.00	$ 0.00	$ 0.00	$ 0.00	$ 0.00
			Section Other Cost Total					$ 0.00	$ 0.00	$ 0.00	$ 0.00	$ 0.00	$ 0.00
			Grand Research Total					$ 12,500.00	$ 12,625.00	$ 12,625.00	$ 30.00	$ 30.00	$ -12,595.00
			Grand SOC Total					$ 4,357.50	$ 4,398.50	$ 4,757.00	$ 130.00	$ 130.00	$ -4,268.50
			Grand Other Cost Total					$ 14,355.00	$ 14,498.55	$ 23,593.60	$ 40.00	$ 40.00	$ -14,458.55
			Grand Total					$ 31,212.50	$ 31,522.05	$ 40,975.60	$ 200.00	$ 200.00	$ -31,322.05

	Total Salary	$ 257.55	$ 262.60
Fringe benefit of 0.00% Not Applied to all lineitems with Salary-Classified and Salary-Faculty	Total Fringe	$ 0.00	$ 0.00
Cost Markup of 3.00% Applied to all selected line items	Total Cost Markup	$ 7.50	$ 15.00
Indirect1 of 1.00% Applied to selected Total Cost/Patient	Total Indirect1	$ 309.55	$ 400.60
Indirect2 of 2.00% Not Applied to selected Total Cost/Patient	Total Indirect2	$ 0.00	$ 0.00
SOC Lineitems not excluded from the Totals			

9.2.1.6.2 Calendar Grid (Comparative / Patient Budgets)

The **Calendar Grid** report is available only on Comparative or Patient type budgets in the "By Cost Type" view. This report displays your budget data in an event-visit matrix. Calculation attributes information is summarized at the top of the report, and personnel /calculation totals are displayed in tables at the bottom of the page. All **excluded** standard of care items are marked with "SOC". See a report example below:

> **Note:** The Calendar Grid report is only available in the "By Cost Type" view of the budget.

Download the report in:

Calendar Grid

Budget Name:	DEMO Structured Patient Visit Calendar 11/03/2022 11:08:21
Budget Version:	1
Study Number:	DEMO 0195
Study Title:	DEMO Lung Hyperinflation in patients with OSA
PI:	Carla Demo
Study Calendar:	DEMO Structured Patient Visit Calendar
Organization:	WCG - VELOS
Applied Attributes:	ID1 = "10"%, ID2 = "0"%

Events	CPT Code	Initial Visit (1 patients)	Follow-up and Labs (1 patients)	Follow-up Visit 1 (1 patients)	Follow-up Visit 2 (1 patients)	Follow-up Visit 3 (1 patients)	Follow-up Visit 4 (1 patients)	Final Visit (1 patients)	Unscheduled Events (1 patients)	Additional / Optional Visit (1 patients)	Total Cost/Patient
Baseline Evaluation		350.00									350.00
Genetic Assay	44325		1,500.00								1,500.00
Follow Up			800.00	800.00	800.00	800.00	800.00	800.00			4,800.00
Lab Report Processing			8,000.00					8,000.00			16,000.00
Drug Administration		SOC	500.00	500.00	500.00	500.00	500.00	500.00	700.00	500.00	4,200.00
Genetic Testing Kits - Oral			3,750.00								3,750.00
Travel between Site A and Site B		1,000.00						1,000.00			2,000.00
PPE		60.00		60.00	60.00	60.00	60.00	60.00			360.00
Direct Cost/Patient		1,410.00	14,550.00	1,360.00	1,360.00	1,360.00	1,360.00	10,360.00	700.00	500.00	
Total Cost (Per Patient) (Inclusive of Calculation Attributes listed below)		1,551.00	16,005.00	1,496.00	1,496.00	1,496.00	1,496.00	11,396.00	770.00	550.00	36,256.00
Total (All Patients) (Inclusive of Calculation Attributes listed below)		1,551.00	16,005.00	1,496.00	1,496.00	1,496.00	1,496.00	11,396.00	770.00	550.00	36,256.00
Sponsor Direct Amount (Total By Visit)		0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	
Sponsor Total Amount (Total By Visit)		0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	

One time Sections

Personnel Cost (1 patients)	Cost	Total (Inclusive of Calculation Attributes listed below)
Admin Fee	250.00	275.00
Total:	250.00	275.00
Sponsor Direct Amount Total:		100.00
Sponsor Total Amount Total:		100.00

Attributes			Total Cost/Patient	Cost/All Patients
Fringe benefit of 10.00% Not to all lineitems with Personnel category		Total Fringe	0.00	0.00
Cost Discount/Markup of 5.00% Not Applied to all selected line items		Total Cost Discount/Markup	0.00	0.00
Indirect1 of 10.00% Applied to selected Total Cost/Patient		Total Indirect1	3,321.00	3,321.00
Indirect2 of 0.00% Not Applied to selected Total Cost/Patient		Total Indirect2	0.00	0.00
SOC Lineitems excluded from the Totals				

Legends				
SOC	Standard of Care			

9.2.1.6.3 Overview (Comparative / Patient Budgets)

The **Overview** report is available only on Comparative or Patient type budgets. This report displays only section totals and grand totals from your budget. Calculation attributes information is summarized at the top of the report. See a report example below:

Download the report in:

Overview

Budget Name:	DEMO Structured Patient Visit Calendar 08/30/2022 11:16:31
Budget Version:	1
Study Number:	DEMO 0190
Study Title:	DEMO 4 - Lung Hyperinflation in Adults with OSA
Study Calendar:	DEMO Structured Patient Visit Calendar
Organization:	WCG - VELOS
Applied Attributes:	ID1 = "1"%, ID2 = "2"%

Section	Type	Direct Cost/Patient	Total Cost/Patient	Cost/All Patients	Sponsor Direct Amount/Patient	Sponsor Total Amount/Patient	Variance
Personnel Cost							
	Section Research Total	$ 0.00	$ 0.00	$ 0.00	$ 0.00	$ 0.00	$ 0.00
	Section SOC Total	$ 0.00	$ 0.00	$ 0.00	$ 0.00	$ 0.00	$ 0.00
	Section Other Cost Total	$ 250.00	$ 252.50	$ 252.50	$ 10.00	$ 10.00	$ -242.50
Initial Visit							
	Section Research Total	$ 0.00	$ 0.00	$ 0.00	$ 0.00	$ 0.00	$ 0.00
	Section SOC Total	$ 0.00	$ 0.00	$ 0.00	$ 30.00	$ 30.00	$ 30.00
	Section Other Cost Total	$ 9,005.00	$ 9,095.05	$ 18,190.10	$ 10.00	$ 10.00	$ -18,180.10
Follow-up and Labs							
	Section Research Total	$ 1,500.00	$ 1,515.00	$ 1,515.00	$ 10.00	$ 10.00	$ -1,505.00
	Section SOC Total	$ 0.00	$ 0.00	$ 0.00	$ 20.00	$ 20.00	$ 20.00
	Section Other Cost Total	$ 3,750.00	$ 3,787.50	$ 3,787.50	$ 10.00	$ 10.00	$ -3,777.50
Follow-up Visit 1							
	Section Research Total	$ 0.00	$ 0.00	$ 0.00	$ 0.00	$ 0.00	$ 0.00
	Section SOC Total	$ 0.00	$ 0.00	$ 0.00	$ 20.00	$ 20.00	$ 20.00
	Section Other Cost Total	$ 0.00	$ 0.00	$ 0.00	$ 0.00	$ 0.00	$ 0.00
Follow-up Visit 2							
	Section Research Total	$ 0.00	$ 0.00	$ 0.00	$ 0.00	$ 0.00	$ 0.00
	Section SOC Total	$ 0.00	$ 0.00	$ 0.00	$ 20.00	$ 20.00	$ 20.00
	Section Other Cost Total	$ 0.00	$ 0.00	$ 0.00	$ 0.00	$ 0.00	$ 0.00
Follow-up Visit 3							
	Section Research Total	$ 0.00	$ 0.00	$ 0.00	$ 0.00	$ 0.00	$ 0.00
	Section SOC Total	$ 0.00	$ 0.00	$ 0.00	$ 20.00	$ 20.00	$ 20.00
	Section Other Cost Total	$ 0.00	$ 0.00	$ 0.00	$ 0.00	$ 0.00	$ 0.00
Follow-up Visit 4							
	Section Research Total	$ 0.00	$ 0.00	$ 0.00	$ 0.00	$ 0.00	$ 0.00
	Section SOC Total	$ 0.00	$ 0.00	$ 0.00	$ 20.00	$ 20.00	$ 20.00
	Section Other Cost Total	$ 0.00	$ 0.00	$ 0.00	$ 0.00	$ 0.00	$ 0.00
Final Visit							
	Section Research Total	$ 1,500.00	$ 1,515.00	$ 1,515.00	$ 0.00	$ 0.00	$ -1,515.00
	Section SOC Total	$ 0.00	$ 0.00	$ 0.00	$ 0.00	$ 0.00	$ 0.00
	Section Other Cost Total	$ 1,000.00	$ 1,010.00	$ 1,010.00	$ 10.00	$ 10.00	$ -1,000.00
Lab Processing DEMO							
	Section Research Total	$ 8,000.00	$ 8,080.00	$ 8,080.00	$ 20.00	$ 20.00	$ -8,060.00
	Section SOC Total	$ 0.00	$ 0.00	$ 0.00	$ 0.00	$ 0.00	$ 0.00
	Section Other Cost Total	$ 0.00	$ 0.00	$ 0.00	$ 0.00	$ 0.00	$ 0.00
Grand Totals							
	Grand Research Total	$ 12,500.00	$ 12,625.00	$ 12,625.00	$ 30.00	$ 30.00	$ -12,595.00
	Grand SOC Total	$ 0.00	$ 0.00	$ 0.00	$ 130.00	$ 130.00	$ 130.00
	Grand Other Cost Total	$ 14,355.00	$ 14,498.55	$ 23,593.60	$ 40.00	$ 40.00	$ -23,553.60
	Grand Total	$ 26,855.00	$ 27,123.55	$ 36,218.60	$ 200.00	$ 200.00	$ -36,018.60

9.2.1.6.4 Study Budget by Category (Study Budgets)

The **Study Budget by Category** report is available only on Study type budgets. This report displays budget financial data by section. Budget information such as name, version, description, study number, study title and organization is displayed at the top of the page. See a report example below:

Download the report in:

Study Budget by Category

Budget Name:	Budget A
Budget Version:	
Budget Description:	
Study Number:	P101
Study Title:	Hypertension Diagnostics Phase 1
Organization:	

Category	Section	Type	Description	Unit Cost	Number of Units	Total Cost
Contractual						
	Subject Charge	Dropped Subjects	-cost per study	75.00	2	150.00
					Sub Total	$ 150.00
Other Expense						
	Subject Charge	Screened Subjects		175.00	1	175.00
					Sub Total	$ 175.00
Patient Care						
	Start Up Charge	Advertising		5,000.00	2	10,000.00
	Miscellaneous	Data Management		0.00	1	0.00
	Start Up Charge	Training		1,500.00	5	7,500.00
	Administrative Charge	Regulatory		0.00	1	0.00
	Administrative Charge	Resources		0.00	1	0.00
	Administrative Charge	Monitor Visits		0.00	1	0.00
	Administrative Charge	Lab Charges		0.00	1	0.00
	Start Up Charge	IRB Fee		15,000.00	1	15,000.00
	Subject Charge	Completed Subjects	-Base cost per site	250.00	3	750.00
	Start Up Charge	Supplies		190.00	35	6,650.00
					Sub Total	$ 39,900.00
					Total	$ 40,225.00
					Indirects of 0.00% applied to Total	$ 0.00
					Grand Total	$ 40,225.00

9.2.1.6.5 Study Budget by Type (Study Budgets)

The **Study Budget by Type** report is available only on Study type budgets. This report displays budget financial data by budget section. Budget information such as name, version, description, study number, study title and organization is displayed at the top of the page. See a report example below:

Download the report in:

Study Budget by Type

Budget Name:	Budget A
Budget Version:	
Budget Description:	
Study Number:	P101
Study Title:	Hypertension Diagnostics Phase 1
Organization:	

Section	Type	Category	Description	Unit Cost	Number of Units	Total Cost
Subject Charge						
	Dropped Subjects	Contractual	-cost per study	75.00	2	150.00
	Screened Subjects	Other Expense		175.00	1	175.00
	Completed Subjects	Patient Care	-Base cost per site	250.00	3	750.00
					Sub Total	$ 1,075.00
Start Up Charge						
	Advertising	Patient Care		5,000.00	2	10,000.00
	IRB Fee	Patient Care		15,000.00	1	15,000.00
	Supplies	Patient Care		190.00	35	6,650.00
	Training	Patient Care		1,500.00	5	7,500.00
					Sub Total	$ 39,150.00
Administrative Charge						
	Regulatory	Patient Care		0.00	1	0.00
	Resources	Patient Care		0.00	1	0.00
	Monitor Visits	Patient Care		0.00	1	0.00
	Lab Charges	Patient Care		0.00	1	0.00
					Sub Total	$ 0.00
Miscellaneous						
	Data Management	Patient Care		0.00	1	0.00
					Sub Total	$ 0.00
					Total	$ 40,225.00
					Indirects of 0.00% applied to Total	$ 0.00
					Grand Total	$ 40,225.00

9.2.1.7 Generating Milestones from a Budget

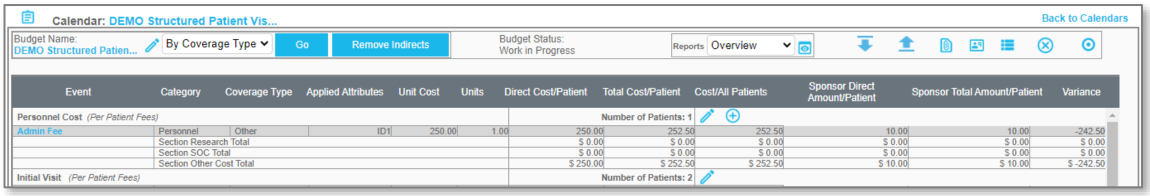
One of the methods available to generate meaningful milestones for your study is by using the Milestones tool on any Comparative or Patient type budget. Using this tool, you can create Additional, Visit, or Event type milestones. The advantage to generating milestones from your budget is twofold:

- Allows you to create multiple milestones in one step
- Allows you to automatically inherit event/visit attributes including costs or sponsor amount totals (comparative type only) from your budget as your milestone amount, to save time

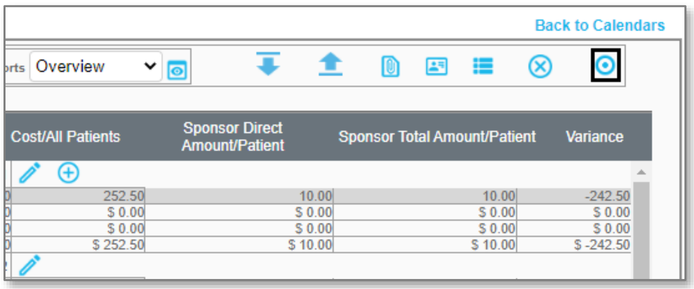
Note: To learn more about creating milestones manually from within the Financial Summary or Milestones tab of the Study Management page, see the Milestones section.

To access the budget milestones tool to generate milestones from your budget:

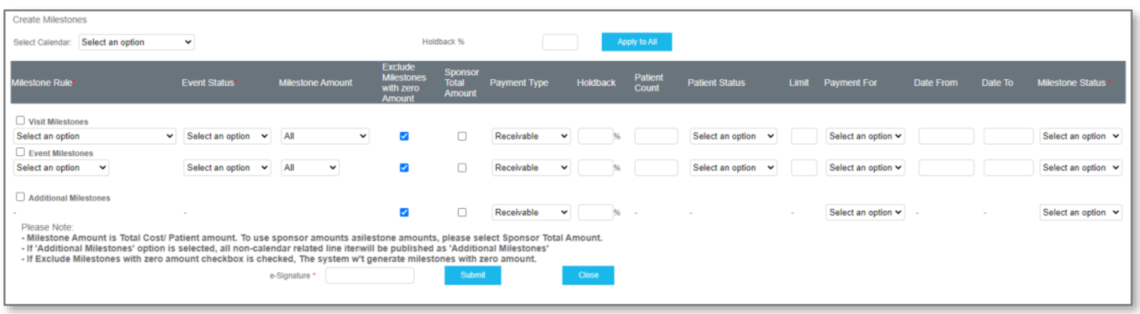
1. Open the target comparative or patient budget.



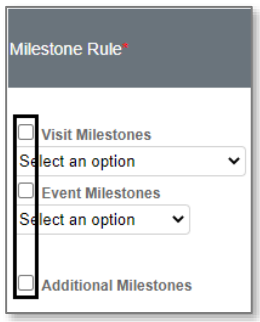
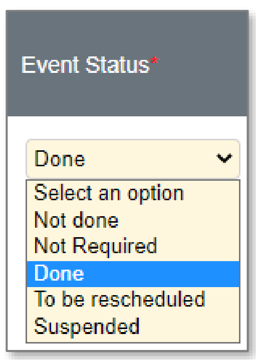
2. Click the **Milestones** button.

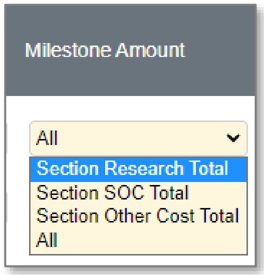
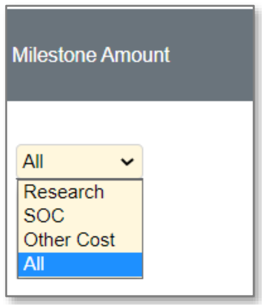
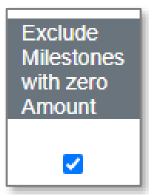
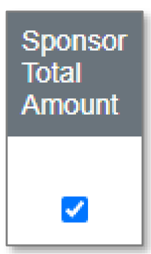
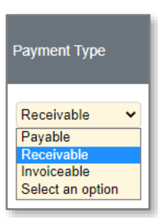


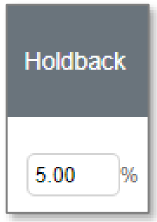
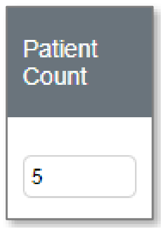
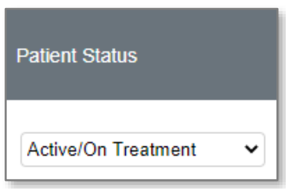
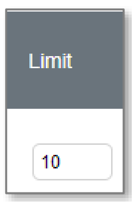
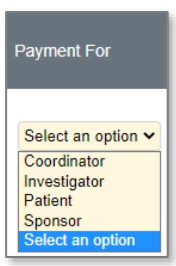
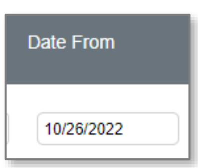
The Create Milestones window displays:

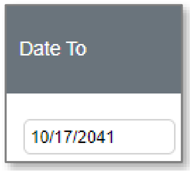
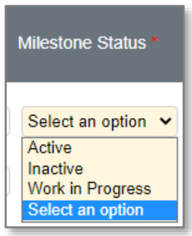


Review the following table to learn more about how to generate each type of milestone from your budget:

Column Name	Visual	Description
Milestone Rule		For visit and event type milestones, this lists the condition under which the generated milestones will be considered achieved. Milestone Rules are not applicable to Additional milestones. *e.g. – "All events within the visit are marked as"*
Milestone Type Toggle		Checkbox(es) that must be checked to generate that type of milestone before clicking **Submit**.
Event Status		The trigger event status that completes the condition established under ***Milestone Rule.*** e.g. - *All events within the visit are marked as **"DONE"***

Column Name	Visual	Description
Milestone Amount	 	Establishes which sections totals from your budget should be used to generate the milestone value. For Visit Milestones - options are: ▪ Section Research Total ▪ Section SOC (standard of care) Total ▪ Section Other Cost Total ▪ All For Event Milestones - options are: ▪ Research ▪ SOC (Standard of Care) ▪ Other Cost ▪ All
Exclude Milestones with Zero Amount		**For Visit Milestones** – Selecting this checkbox will exclude section totals that have a value of 0 from milestone generation. **For Event Milestones** – Selecting this checkbox will exclude line items that have a value of 0 from milestone generation.
Sponsor Total Amount		Selecting this checkbox will use the Sponsor Total Amount as the value of the generated milestones instead of the Total Cost/ Patient value. ***This option is only applicable to Comparative type budgets.***
Payment Type		Determines the type of payment as a result of the milestone achievement. Options include: ▪ Payable ▪ Receivable ▪ Invoiceable

Column Name	Visual	Description
Holdback		Amount of the milestone that should be held back as a separate billable amount. Defined as a percentage of the milestone amount.
Patient Count		The number of patient achievements required for this rule before it counts as 1 achievement.
Patient Status		The patient status that required for this milestone to be considered achieved.
Limit		The maximum number of achievements that can be logged from this milestone. If left blank, an unlimited amount of achievements can be logged against this milestone rule.
Payment For		Flags the recipient of the payment. Default options include: ▪ Coordinator ▪ Investigator ▪ Patient ▪ Sponsor
Date From		Status date that the target achievement defined in the Event Status field must be, at a **minimum**, to be counted as an achievement. Any event status achievements **before** this date will not be a milestone achievement for this rule. If left blank, there are no restrictions.

Column Name	Visual	Description
Date To		Status date that the target achievement defined in the Event Status field must be, at a **maximum,** to be counted as an achievement. Any event status achievements **after** this date will not be a milestone achievement for this rule. If left blank, there are no restrictions.
Milestone Status		The state of the milestone. Will not begin logging achievements per milestone rules until it is marked as Active. Options include: ▪ Active ▪ Inactive ▪ Work in Progress

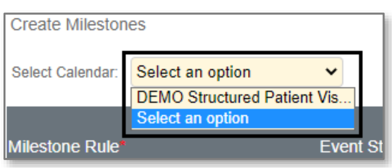
9.2.1.7.1 Generating Additional Milestones from a Budget

The Create Milestones window allows you to create Additional milestones from any manually created line items in your budget.

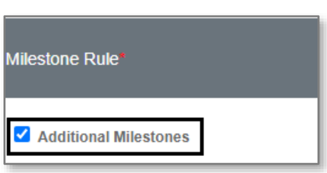
Note: Unless you create manual sections and line items on a Calendar Budget Template, this function may not apply.

To generate additional milestones from a budget:

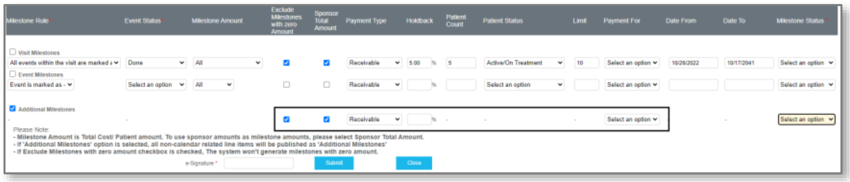
1. From the Create Milestones window of a budget, Select a calendar from the dropdown menu.



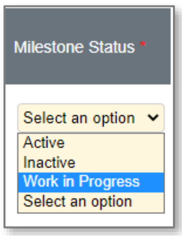
2. Select the checkbox next to Additional Milestones in the Milestone Rule column.



3. Configure the rest of the milestone rule as needed. See Generating Milestones from a Budget for more information about each field.



4. Select a status for the milestones to be set as after generation.



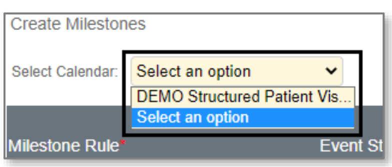
5. Enter your e-Signature and click **Submit**.

9.2.1.7.2 Generating Visit or Event Milestones from a Budget

The Create Milestones window allows you to create Visit milestones from your budget sections, and Event milestones from your budget line items.

To generate visit or event milestones from a budget:

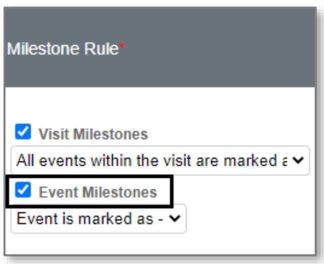
1. From the Create Milestones window of a budget, select a calendar from the Select calendar dropdown menu.



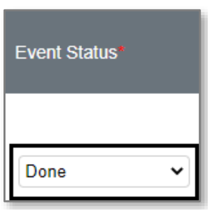
2. Select the checkbox next to Visit Milestones in the Milestone Rule column to generate visit milestones.

-OR-

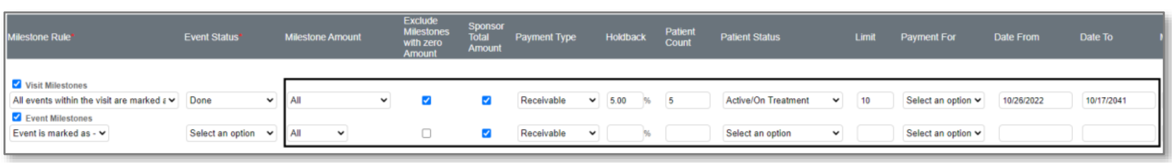
Select the checkbox next to Event Milestones in the Milestone Rule column to generate event milestones.



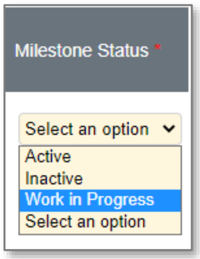
3. Select an Event Status.



4. Configure the rest of the milestone rule as needed. See Generating Milestones from a Budget for more information about each field.



5. Select a status for the milestones to be set as after generation.



6. Enter your e-Signature and click **Submit**.

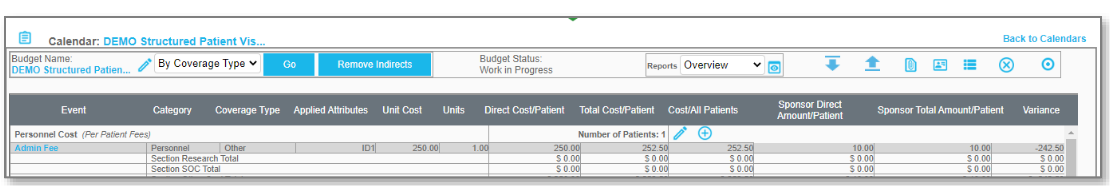
Note: When using the Milestones button, using the Sponsor amount instead of the Total Cost allows providers to bill the payer the "agreed upon" sponsor amount as the milestone amount. If the Sponsor Amount box is not checked in the Create Milestones window, the milestones are set to the Total Cost/Patient amount indicated in the comparative budget.

9.2.1.8 Using the Bulk Edit Tool for Budgets

A faster way to make changes to your budget(s) can be accomplished by using the Bulk Edit Tool for budgets. This tool is available for Comparative and Patient type budgets used as Calendar Budgets, Combined Budgets, or Browser Budgets. The process involves downloading a CSV file from the budget page, making your updates to the Unit Cost, Unit, or Sponsor Direct Amount fields, saving the file and then using the upload tool to import the changes back into eResearch.

To access the bulk edit tool for budgets:

1. Open any combined, browser or calendar budget using the Comparative or Patient template type.



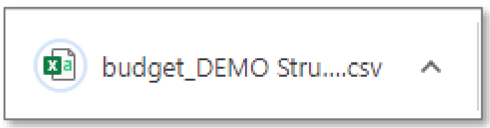
9.2.1.8.1 Download Budget File

The first step in the process of performing a budget bulk upload is to download the bulk upload file from your budget.

To download the bulk upload file:

1. Click the **Download Budget** button.

A CSV version of the file downloads.



Note: Each budget file is unique to the budget you initiated the download from. Ensure you are updating the correct file before performing the upload.

9.2.1.8.2 Updating the Budget File

After downloading the budget bulk upload file from a specific budget and opening it, users can update the Units, Unit Cost and Sponsor Direct Amount per Patient (Comparative budgets only) fields.

To update the budget file:

1. Open the csv file for this budget.

Budget Name	DEMO Structured Patient Visit Calendar 08302022 111631								
Calendar Name	LineItemID	Section	Event	CPT Code	Category	Cost Type	Unit Cost	Units	Sponsor Direct Amount Per Patient
DEMO Structured Patient Visit Calendar	6080	Personnel Cost	Admin Fee		Personnel	Billable to Site	250	1	10
DEMO Structured Patient Visit Calendar	6081	Initial Visit	Baseline Evaluation		Patient Care	Billable to Insurance	250	1	10
DEMO Structured Patient Visit Calendar	6082	Initial Visit	Baseline Evaluation		Patient Care	Research Cost	100	1	10
DEMO Structured Patient Visit Calendar	6083	Initial Visit	Alkaline Phosphatase NOS		Patient Care	Research Cost	0	1	10
DEMO Structured Patient Visit Calendar	6084	Initial Visit	Albumin - Blood		Patient Care	Research Cost	0	1	10
DEMO Structured Patient Visit Calendar	6099	Initial Visit	Travel between Site A and Site B		Travel	Research Cost	250	4	10
DEMO Structured Patient Visit Calendar	7164	Initial Visit	test		Personnel	Research Cost	5	1	0
DEMO Structured Patient Visit Calendar	7165	Initial Visit	Lab Report Processing		Patient Care	Research Cost	7500	1	0
DEMO Structured Patient Visit Calendar	7166	Initial Visit	Lab Report Processing		Patient Care	Supplies	500	1	0
DEMO Structured Patient Visit Calendar	6085	Follow-up and Labs	Follow Up		Patient Care	Research Cost	350	1	10
DEMO Structured Patient Visit Calendar	6086	Follow-up and Labs	Follow Up		Patient Care	Resource	450	1	10
DEMO Structured Patient Visit Calendar	6087	Follow-up and Labs	Genetic Assay	44325	Patient Care	Research Cost	1500	1	10
DEMO Structured Patient Visit Calendar	6098	Follow-up and Labs	Genetic Testing Kits - Oral		Equipment	Research Cost	75	50	10
DEMO Structured Patient Visit Calendar	6088	Follow-up Visit 1	Follow Up		Patient Care	Research Cost	350	1	10
DEMO Structured Patient Visit Calendar	6089	Follow-up Visit 1	Follow Up		Patient Care	Resource	450	1	10
DEMO Structured Patient Visit Calendar	6090	Follow-up Visit 2	Follow Up		Patient Care	Research Cost	350	1	10
DEMO Structured Patient Visit Calendar	6091	Follow-up Visit 2	Follow Up		Patient Care	Resource	450	1	10
DEMO Structured Patient Visit Calendar	7168	test	Genetic Assay	44325	Patient Care	Research Cost	1500	1	0
DEMO Structured Patient Visit Calendar	7169	test	Baseline Evaluation		Patient Care	Billable to Insurance	250	1	0
DEMO Structured Patient Visit Calendar	7170	test	Baseline Evaluation		Patient Care	Research Cost	100	1	0
DEMO Structured Patient Visit Calendar	6092	Follow-up Visit 3	Follow Up		Patient Care	Research Cost	350	1	10
DEMO Structured Patient Visit Calendar	6093	Follow-up Visit 3	Follow Up		Patient Care	Resource	450	1	10
DEMO Structured Patient Visit Calendar	6094	Follow-up Visit 4	Follow Up		Patient Care	Research Cost	350	1	10
DEMO Structured Patient Visit Calendar	6095	Follow-up Visit 4	Follow Up		Patient Care	Resource	450	1	10
DEMO Structured Patient Visit Calendar	6100	Final Visit	Travel between Site A and Site B		Travel	Research Cost	250	4	10
DEMO Structured Patient Visit Calendar	7167	Final Visit	Genetic Assay	44325	Patient Care	Research Cost	1500	1	0
DEMO Structured Patient Visit Calendar	6096	Lab Processing DEMO	Lab Report Processing		Patient Care	Research Cost	7500	1	10
DEMO Structured Patient Visit Calendar	6097	Lab Processing DEMO	Lab Report Processing		Patient Care	Supplies	500	1	10

2. Modify only the Unit Cost, Units, and Sponsor Direct Amount Per Patient fields as needed.

Budget Name	DEMO Structured Patient Visit Calendar 08302022 111631								
Calendar Name	LineItemID	Section	Event	CPT Code	Category	Cost Type	Unit Cost	Units	Sponsor Direct Amount Per Patient
DEMO Structured Patient Visit Calendar	6080	Personnel Cost	Admin Fee		Personnel	Billable to Site	250	1	10
DEMO Structured Patient Visit Calendar	6081	Initial Visit	Baseline Evaluation		Patient Care	Billable to Insurance	250	1	10
DEMO Structured Patient Visit Calendar	6082	Initial Visit	Baseline Evaluation		Patient Care	Research Cost	100	1	10
DEMO Structured Patient Visit Calendar	6083	Initial Visit	Alkaline Phosphatase NOS		Patient Care	Research Cost	0	1	10
DEMO Structured Patient Visit Calendar	6084	Initial Visit	Albumin - Blood		Patient Care	Research Cost	0	1	10
DEMO Structured Patient Visit Calendar	6099	Initial Visit	Travel between Site A and Site B		Travel	Research Cost	250	4	10

Keep the following validation rules in mind:

- Commas are not accepted
- A single decimal may be used per field (e.g. – 10000.0)
- Up to two decimal places may be used (e.g – 199.99)
- If Sponsor Direct Amount Per Patient is left blank, it will leave the previous value intact in the budget after upload
- Do not edit the LineItem ID field, or eResearch will not accept the bulk upload file

3. Save and close the CSV file.

9.2.1.8.3 **Uploading the Budget File**

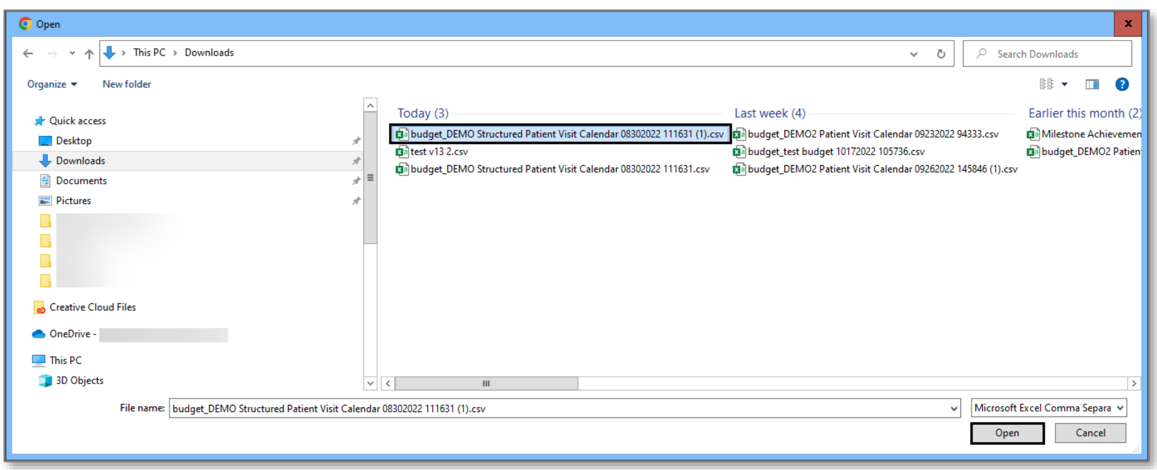
The last step in the process of performing a budget bulk upload is to upload the finalized bulk upload file from your budget.

> **Note:**
> 1. Users must have edit permissions for that budget to perform the bulk upload process
> 2. Budgets in the “Freeze” or “Save as Template” style cannot accept bulk uploads

To upload the bulk upload file:

1. Click the **Upload Budget** button.

2. Navigate to the finalized bulk upload file for this specific budget using the file picker and click **Open**.



> **Note:** You can only use a bulk upload file that was downloaded from the specific budget you are uploading the bulk upload file into.

After uploading the bulk upload file, the system will notify you if the upload has been successful.

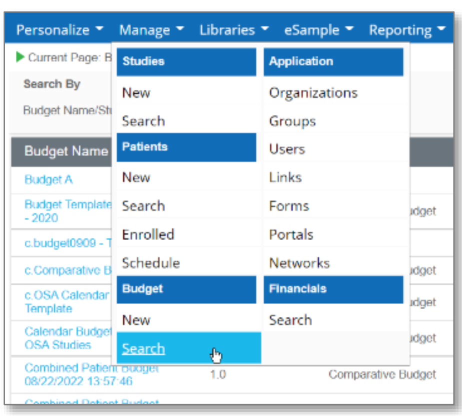
Note: If there is an issue with your upload file, eResearch will notify you that there was an error, and provide insight into what may have gone wrong in the system notification description.

9.2.1.9 Deleting a Budget

When a budget needs to be removed from a study calendar, or a study's combined budget, template, or browser budget needs to be removed, all deletions must occur starting at the Budget Browser page. If a study calendar has a budget that has actively been used, it will not permit deletion.

To delete a budget:

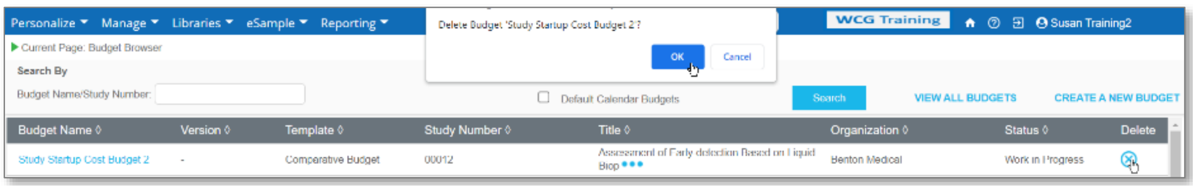
1. Click **Manage** > **Search** (Budget).



2. For combined study budgets and calendar budgets, first check the checkbox for Default Calendar Budgets, then click **Search**.

- For browser budgets of any template type, and for any template in Save as Template status, these budgets will appear on the landing page of the Budget Browser

3. Click **Delete** to delete, then click **OK** in the pop-up.



4. Enter your e-Signature, then click **Submit** to confirm.

9.2.2 Milestones

Milestones are one of the key components of Financial Management in Velos eResearch. Whereas budgets create a framework to estimate study costs based on calendars and custom items, Milestones can be thought of as “financial achievement triggers”. When the condition for a milestone rule is met, an achieve milestone is triggered as an item that can be invoiced.

Milestones can be triggered based on changes in study status, patient status, visits or events that are marked as complete, or as an additional miscellaneous fee. The type of milestone determines how it is triggered.

See the table below for a detailed description of each milestone type and their configuration options:

Milestone Section	Column Name	Description	Example
ALL	**Payment Type**	Determines the type of payment as a result of the milestone achievement. Options include: ▪ Payable ▪ Receivable ▪ Invoiceable	N/A
	Amount	The value of each milestone achievement generated by this milestone rule.	N/A
	Holdback	Amount of the milestone that should be held back as a separate billable amount. Defined as a percentage of the milestone amount.	
	Payment For	Flags the recipient of the payment. Default options include: ▪ Coordinator ▪ Investigator ▪ Patient ▪ Sponsor	
	Milestone Status	The state of the milestone. Will not begin logging achievements per milestone rules until it is marked as Active. Options include: ▪ Active ▪ Inactive ▪ Work in Progress	N/A
All "Status" Milestone Types (Patient, Study, Visit, Event)	**Limit**	The maximum number of achievements that can be logged from this milestone. If left blank, an unlimited amount of achievements can be logged against this milestone rule.	

Milestone Section	Column Name	Description	Example
	Date From	Status date that the target achievement defined in the Event Status field must be, at a **minimum,** to be counted as an achievement. Any event status achievements **before** this date will not be a milestone achievement for this rule. If left blank, there are no restrictions.	If a rule was set to the date of 10-Oct-2022, no trigger statuses (e.g. patient status, event status, visit status, etc.) with status dates **before** 10-Oct-2022 will count as an achievement for this milestone.
	Date To	Status date that the target achievement defined in the Event Status field must be, at a **maximum,** to be counted as an achievement. Any event status achievements **after** this date will not be a milestone achievement for this rule. If left blank, there are no restrictions.	If a rule was set to the future date of 10-Oct-2024, no trigger statuses (e.g. patient status, event status, visit status, etc.) with status dates **after** 10-Oct-2024 will count as an achievement for this milestone.
Patient Status	**Patient Count**	Specify the number of the patients that should be tracked. This column does not apply to the "Study Status" milestone type.	If a sponsor pays for every fifth patient screened, enter "5". When every fifth patient on the study has the screen status added, a milestone will be achieved.
	Patient Status	Specify the desired patient status that should be tracked.	N/A
	Milestone Status	Specify the "Active" status when the milestone should be turned on or select "Inactive" if a Milestone no longer applies.	N/A
Visit	**Calendar**	Select the study calendar from which you want to derive the visit milestones.	N/A
	Visit	Specify the visit name for the milestone.	N/A

Milestone Section	Column Name	Description	Example
	Milestone Rule	Select the logic that determines when the visit is considered complete.	Options include: "**All events within the visit are marked as-**", "**At least one event is marked as-**", and "**On Scheduled Date**".
	Event Status	Dependent on Milestone Rule field. This completes the logic selected in the previous field. This field is left blank if "On Scheduled Date" is selected in previous field.	Options include: "**Not Done**", "**Not Required**", "**Done**", "**To be rescheduled**", and "**Suspended**".
	Milestone Status	Specify the "Active" status when the milestone should be turned on or select "Inactive" if a Milestone no longer applies.	N/A
Event	**Calendar**	Select the study calendar from which you want to derive the event milestones.	N/A
	Visit	Specify the visit name for the milestone.	N/A
	Event	Specify the specific event associated with the calendar visit for this milestone.	N/A
	Milestone Rule	Select the logic that determines when the event is considered complete.	Options include: "**All events within the visit are marked as-**", "**At least one event is marked as-**", and "**On Scheduled Date**".
	Event Status	Dependent on Milestone Rule field. This completes the logic selected in the previous field. This field is left blank if "On Scheduled Date" is selected in previous field.	Options include: "**Not Done**", "**Not Required**", "**Done**", "**To be rescheduled**", and "**Suspended**".
	Milestone Status	Specify the "Active" status when the milestone should be turned on or select "Inactive" if a Milestone no longer applies.	N/A

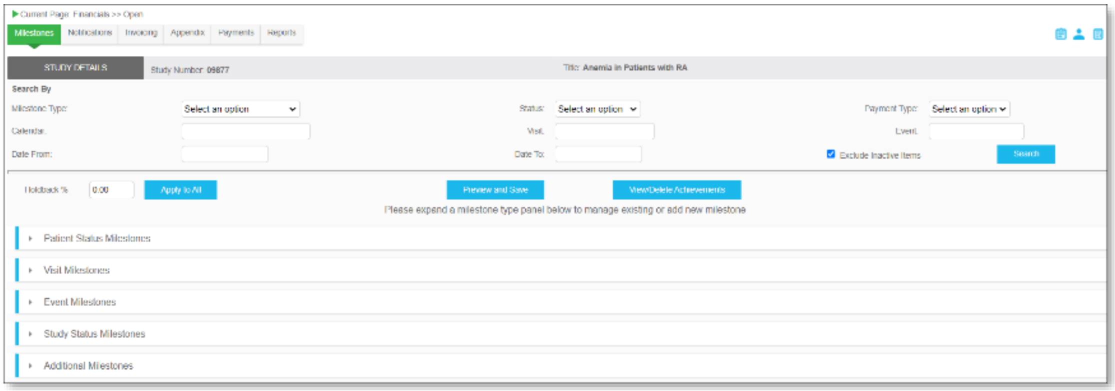
Milestone Section	Column Name	Description	Example
Study Status	**Study Status**	Specify the study status that must be achieved for the milestone to be considered complete.	e.g. – "**Active/Enrolling**", "**IRB: Approved**", etc.
	Milestone Status	Specify the "Active" status when the milestone should be turned on or select "Inactive" if a Milestone no longer applies.	N/A
Additional	**Milestone Achieved Date**	Indicates the calendar date that this additional milestone was achieved.	N/A
	Milestone Description	Enter a description of the milestone.	e.g. – "**Contract Renewal**", "**Custom Recruitment/Retention Milestone**", etc.
	Milestone Status	Specify the "Active" status when the milestone should be turned on or select "Inactive" if a Milestone no longer applies.	N/A

Note:

1. All required fields are indicated by a red asterisk in the system
2. An Additional milestone is considered "achieved" when the additional milestone rule status is "Active" and available to be invoiced
3. When a Milestone Payment Type is set to Payable, the Holdback field is locked at 0.00%
4. Milestones may also be added to Admin Schedules following the same steps as described in this section. However, if the calendar's status is Active, modifications cannot be made
5. Milestone achievement dates can be modified using the View/Delete Achieved Milestones page

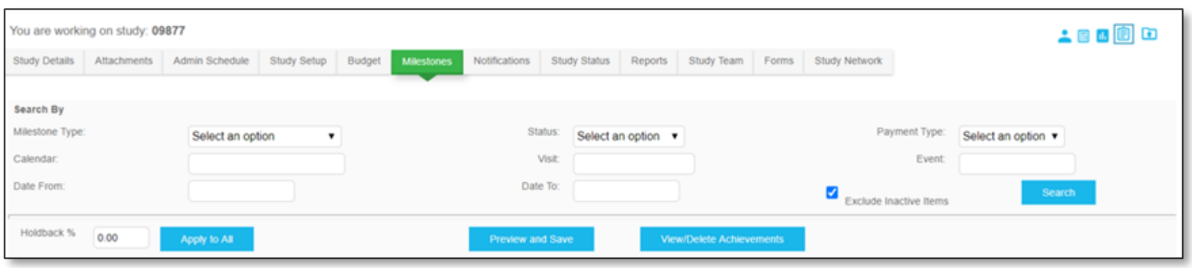
To manage a milestone:

1. From the study management page, or default homepage, click the **Financial Summary** button, and select the **Milestones** tab.

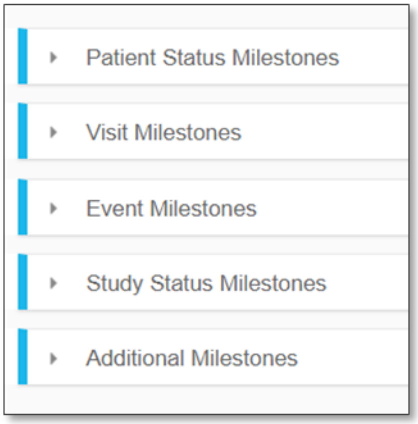
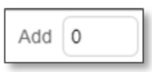
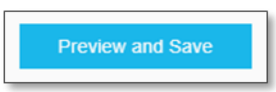


-OR-

From the Study page, navigate to the **Milestone** tab.

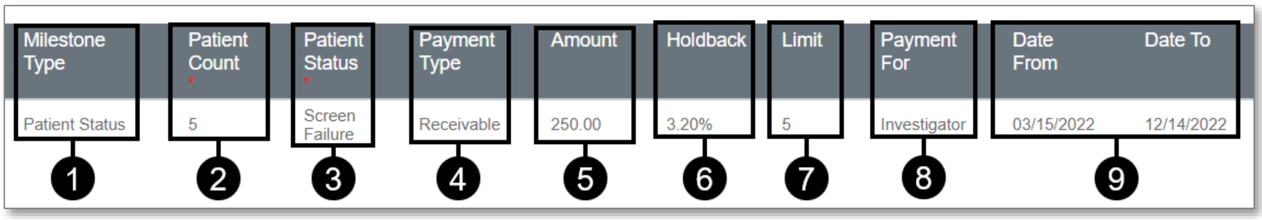


Here, users will have accessibility to various functionalities:

Icon	Name	Description
	**Accordion Dropdown Menus**	Use the Dropdown Menu button to expand or close a section of the Milestones tab (not applicable to the budget milestones page).
	**Add field**	Use the Add field to specify the number of rows to be added for a milestone type.
	**Plus**	Use the Plus button to add the rows from the Add field.
	**Preview and Save**	Use the Preview and Save button to confirm any changes made to milestones. If you do not click the Preview and Save button, you will lose your changes.

9.2.2.1 Example Milestone

Below is an example of a patient status milestone. This is only one example of the many possible milestone configurations but can serve as a reference for how one might construct a milestone based on protocol/contract requirements.

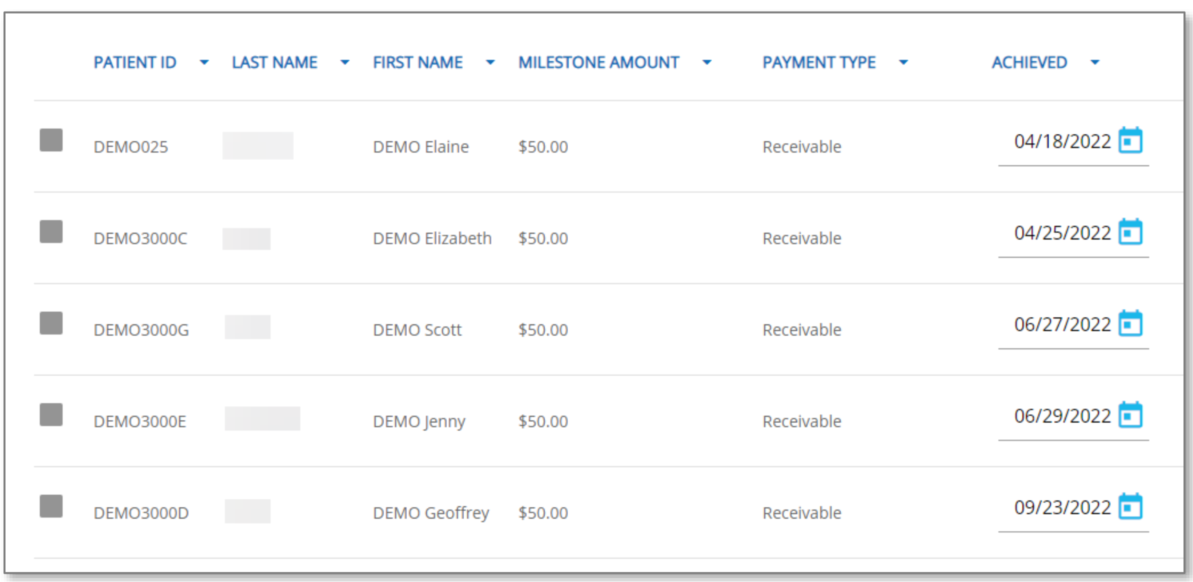


Ref #	Element	Description	Example
1	**Milestone Type**: Patient Status	Indicates the type of milestone being configured.	This example is a **Patient Status** type milestone, so it listens for changes in status for patients on this study to the target status (see **Patient Status** below)
2	**Patient Count**: 5	Indicates the total number of patients that are needed to meet the status conditions set in this milestone to equal **1 financial achievement** on the study. Any milestone that has a patient count > 1, might also be referred to as a “compound” milestone rule.	In this milestone example, 5 patients must be associated with the configured target status (see **Patient Status** below) on this study to equal 1 financial achievement
3	**Patient Status**: Screen Failure	Indicates the target status for this milestone.	In this milestone example, a patient must be assigned the patient study status of “Screen Failure” to meet this condition of this milestone

Ref #	Element	Description	Example
4	**Payment Type**: Receivable	Indicates the type of financial achievement line item generated by this milestone. Default options include: Invoiceable, Payable, or Receivable.	In this example, each financial achievement realized by the conditions of this milestone will be **receivable** line items.
5	**Payment Amount**: 250.00	Indicates the amount that each financial achievement generated by this milestone is worth.	In this example, each financial achievement realized by the conditions of this milestone will be worth $250.00
6	**Holdback**: 3.20%	Indicates the holdback amount of the Payment Amount to be separated as a holdback line item. Holdback is always a percentage of **Payment Amount.**	In this example, each financial achievement realized by the conditions of this milestone will have a holdback amount of 3.20% of the total payment amount.
7	**Limit**: 5	Sets a limit on the number of financial achievements that this milestone rule can generate. If this field is left blank, this milestone rule has no limits on the number of financial achievements it can generate.	In this example, this milestone rule can generate no more than 5 achievements.
8	**Payment For**: Investigator	Informational tag used to indicate who should receive the payments as the result of financial achievements generated by this milestone rule. Default options include: Investigator, Coordinator, Sponsor, and Patient.	In this example, the payments are for the investigator.

Ref #	Element	Description	Example
9	**Date Range:** 03/15/2022 – 12/14/2022	The **Date From** and **Date To** fields can be used independently or together to define date ranges that this milestone will monitor for status changes.	In this example, only patient status changes that occurred between the dates of 03/15/2022 – 12/14/2022 can be counted towards a financial achievement. If they fall outside of that range, but otherwise match the remaining criteria, they will be ignored.

As noted above, the configuration of the milestone above requires 5 patients who have screen failed on this study and meet the rest of the requirements of the milestone to equal 1 financial achievement. Below is an example of how this would look on a study where this milestone was achieved from the View/Delete Achievements tool.



Note: It's possible to change the achievement date of any milestone achievement from this page if not used in an invoice or reconciliation. See View/Delete Achievements for more information.

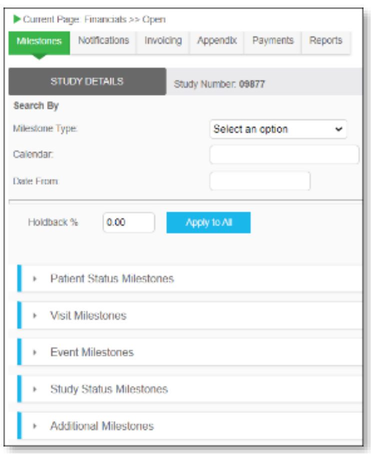
9.2.2.2 Add Milestones

This section will instruct users on how to add a milestone.

Note: It is possible to make modifications or add milestones using the milestones tab of a calendar linked to a budget, the milestones button on a budget, on the milestones tab of the study management page, or on the milestones tab of the financial summary page of any study.

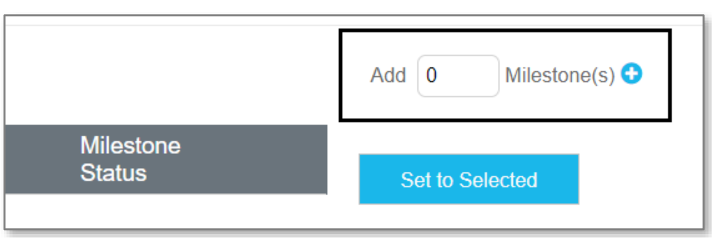
To add a milestone:

1. From the **Milestone** tab, use the **arrows** to expand the milestone section that you wish to add to.



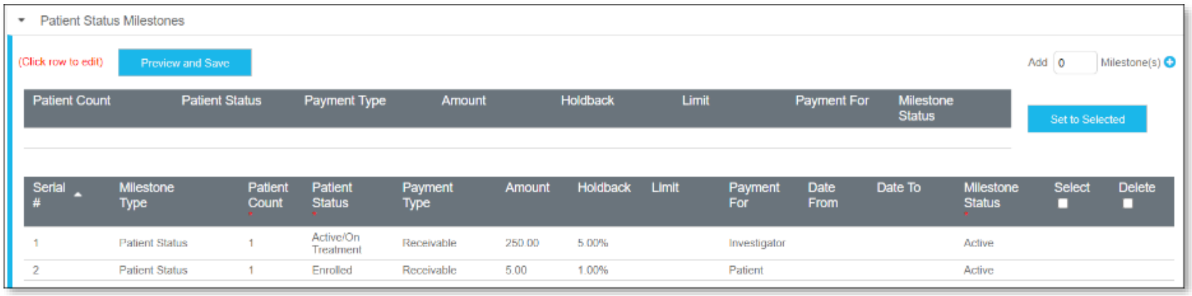
Note: Event and Visit milestones should be created through the calendar budget if you want the amounts / sponsor amounts to be carried over from the budget.

2. Add the desired number of milestone fields by using the **Add** field and the plus button.



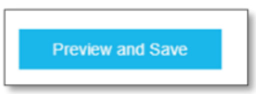
Note: Each row represents a unique milestone rule.

3. The input number of milestone rows will display. Use the fields to enter information as needed.

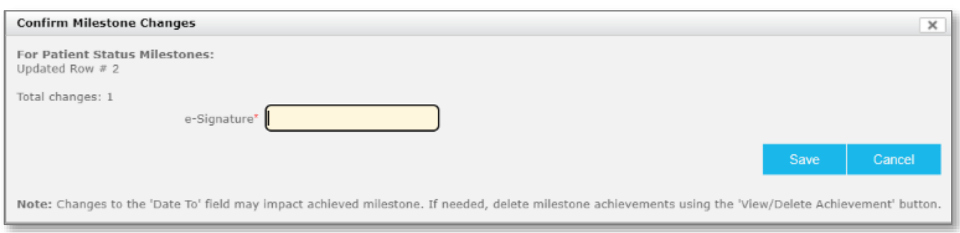


Note: For more information about milestone configuration options see Milestones, or if you want to review an example, see Example Milestone.

4. Click **Preview and Save** to save changes.



5. A notification displays asking you to confirm the milestone changes. Enter your e-Signature and click **Save** to confirm.



The milestone(s) are now created.

9.2.2.3 Updating Milestones

Milestone rules can be modified as needed from one of two screens –the milestones tab of a study on the study management page, or the milestones tab on the financial summary page. Milestone achievement dates can also be modified from the View/Delete Achieved Milestones page of these tabs as well. This section will begin from the Milestones tab of a study but note that modifying a milestone in any one of the two locations follows the same steps.

To modify a milestone:

1. From the **Milestone** tab, select the milestone that needs to be modified.

Serial #	Milestone Type	Patient Count	Patient Status	Payment Type	Amount	Holdback	Limit	Payment For	Date From	Date To	Milestone Status	Select	Delete
1	Patient Status	1	Enrolled	Receivable	550.00	5.00%	200				Active		
2	Patient Status	5	Screen Failure	Receivable	250.00	0.00%	3				Active	☐	☐

2. Modify the fields as needed.

Warning: The milestone fields: Calendar, Visit, Event Status, Patient Count, or Patient Status can only be modified in specific circumstances. The items listed can be modified if the milestone status is set to “work in progress”. If the milestone status is “active”, it can be changed to “work in progress” only if there are no achievements for the milestone.

3. Click Preview and Save.

Preview and Save

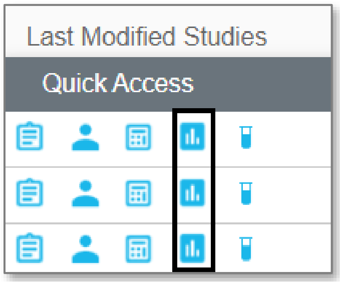
4. A notification displays asking you to confirm the milestone changes. Enter your e-Signature and click **Save** to confirm.

Note: Use the bullseye icon in budgets as an easy way to create calendar level milestones.

9.3 Access Study Financials

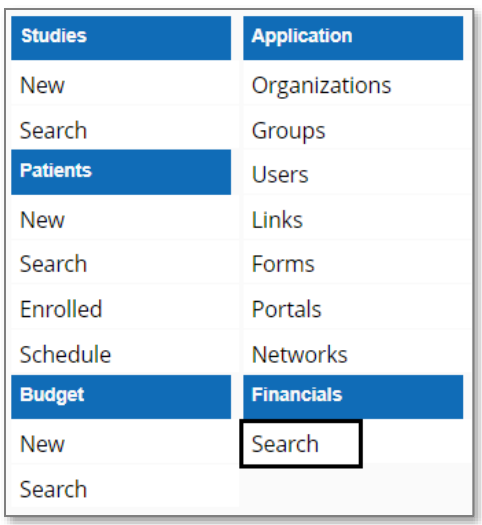
Once milestones have been created, the next steps in the financial management process are to generate invoices, record payments, and then reconcile those payments against either milestones or an invoice. Before that can happen, however, the milestone conditions created must first be achieved. Depending on the milestone type, this could happen instantly, or may require some time until the milestone conditions are achieved. To learn how to view milestones that have been achieved, and can be invoiced, see View/Delete Achieved Milestones for more information.

In Velos eResearch, invoicing and payment management can be accessed using the financial management module. For quick navigation, users can use the **Financial Summary** button to navigate to the financial page for a study.

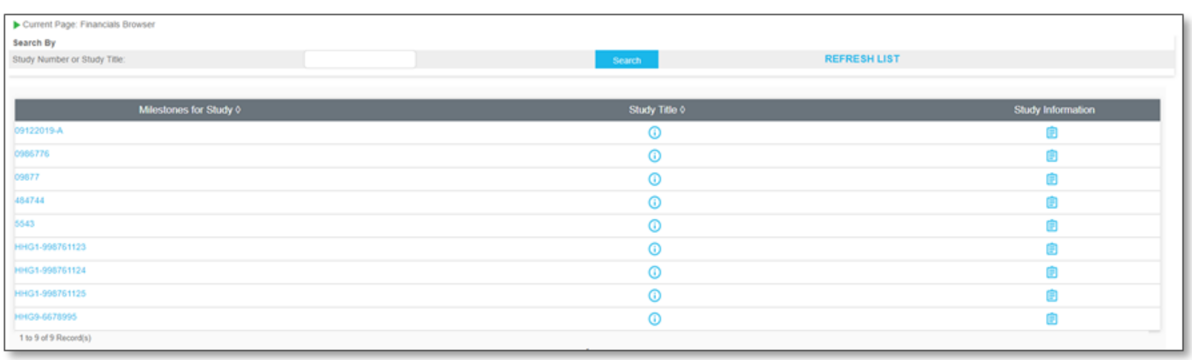


To access the Financials Module page:

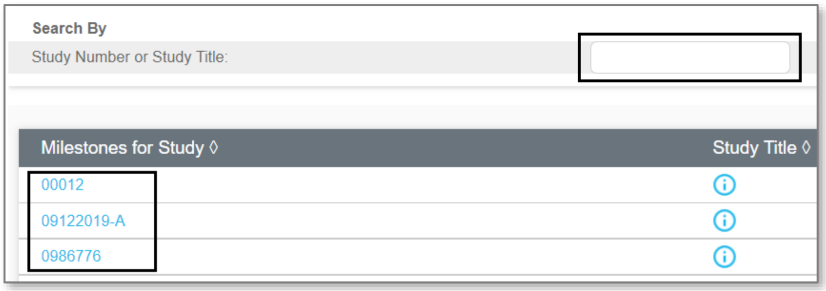
1. From the Homepage, navigate to **Search** under **Manage** and “Financials”.



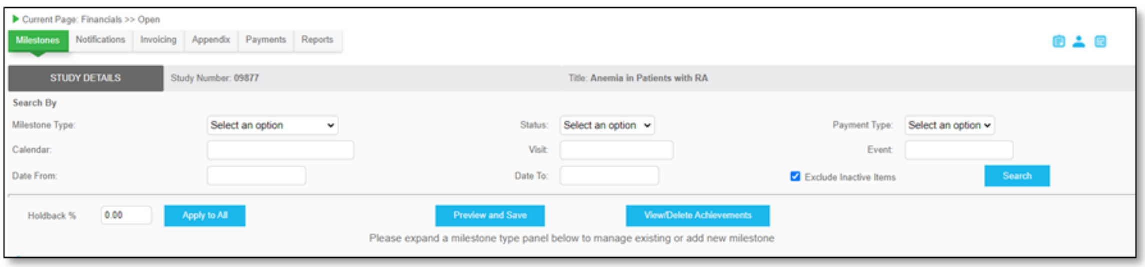
The Financials Browser page displays with a list of Studies.



2. Search using the search field and click the **Search** button, to limit the study numbers in the Milestones for Study column, and/or click the appropriate study number.

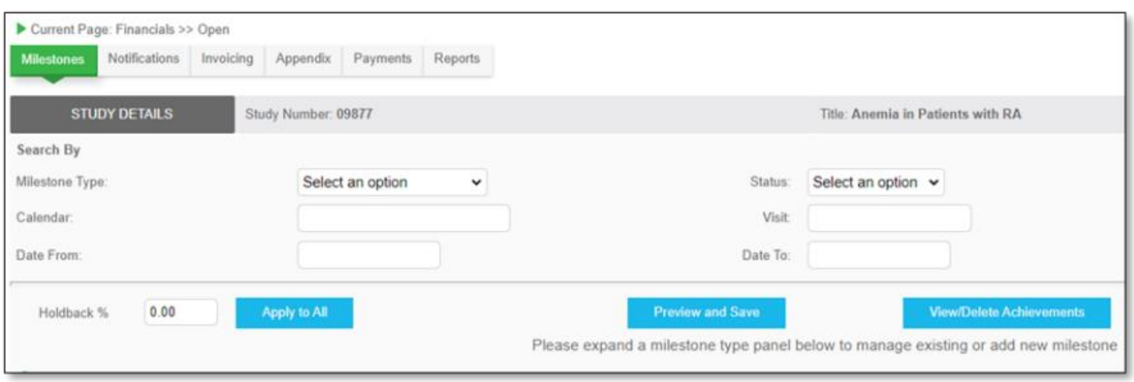


The Financials page displays:



9.3.1 Milestones

The milestones tab on the Financial Summary page displays all study milestones and allows users to view and edit achieved milestones for that study.



Note: This page is one of two places in the system where all milestones for a study can be managed.

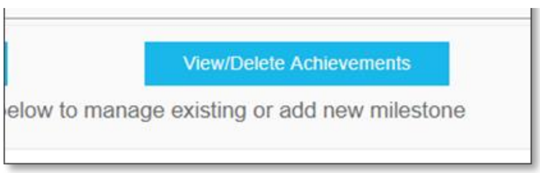
For more information about managing milestones, see Milestones.

9.3.1.1 View/Delete Achieved Milestones

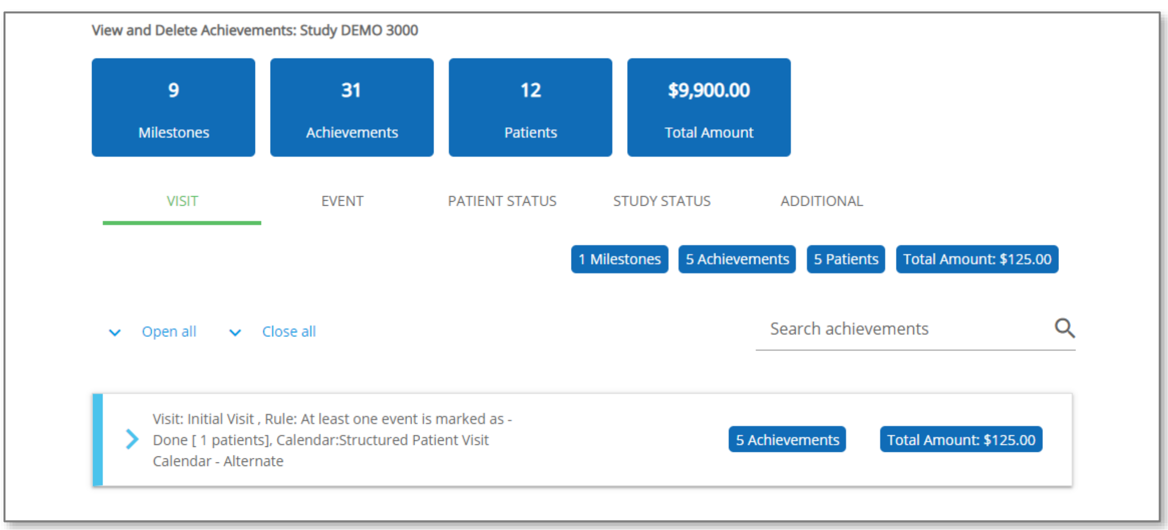
Achieved milestones for a study can be viewed and deleted from the Financial Summary page, on the Milestones tab, or from the Study Management page, on the Milestones tab in Velos eResearch. If an achievement is not part of an invoice or reconciled against a payment, the achievement date may also be modified from this page. See Modifying Achievement Dates for more information.

To view and delete Milestone Achievements:

1. From the Financial Summary page, Milestones tab, click **View/Delete Achievements**.



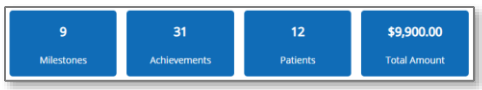
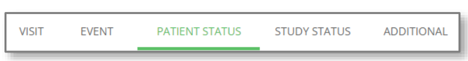
2. The View/Delete Achievements page displays with tabs to each type of Achievement. Click the tab for the appropriate milestone type to view and manage achievements.

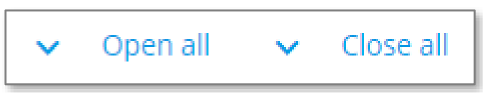
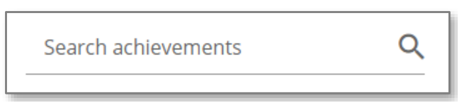


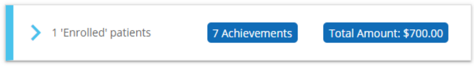
Warning: Achievements that have been included in an invoice, have been reconciled directly (connected to a payment), or are part of a compound milestone cannot be deleted.

Note: Achieved milestones can also be viewed for your records by pulling the Milestone Achievement Log (All) report as described in Report Central.

View the table below to learn more about the View/Delete Achievements page:

Element	Visual	Description
Summary		Summarizes key financial achievement data for this study. Includes the following data points: ▪ **Milestones:** Total Milestone Rules ▪ **Achievements:** Number of achievements recorded against all milestone rules ▪ **Patients:** Number of patients involved in achievements ▪ **Total Amount:** Value of all achievements for this study
Milestone Selector		Used to select and manage milestone rules by type of milestone. Defaults to Visit milestones.

Element	Visual	Description
Milestone Type Summary		Summarizes key financial achievement data for the selected milestone type only for this study. Includes the following data points: ▪ **Milestones:** Total Milestone Rules of this type ▪ **Achievements:** Number of achievements recorded against all milestone rules of this type ▪ **Patients:** Number of patients involved in achievements for milestone rules of this type ▪ **Total Amount:** Value of all achievements for this milestone type
Open all / Close all Toggles		Used to open or collapse all Milestone Rule Categories to display each achievement or close them all simultaneously for that milestone type.
Search Achievements Field		Used to search all milestone rules under a milestone type for a specific keyword or other search criteria such as Study Patient ID.

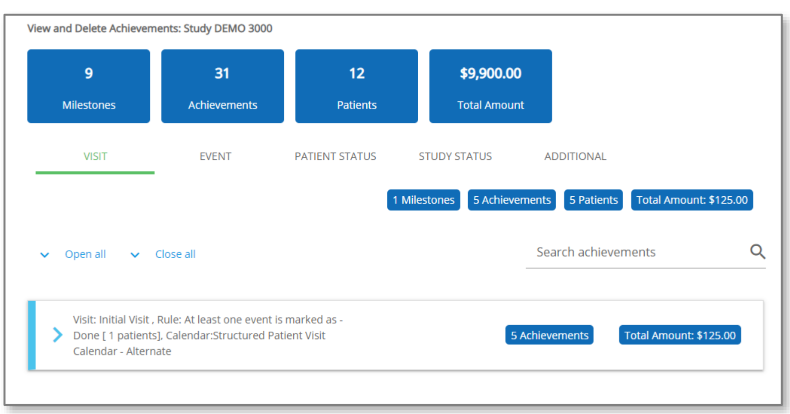
Element	Visual	Description
Milestone Rule Category		Each study milestone rule is self-contained within a category that summarizes the key status or description of the milestone. Click on the arrow to expand this category and view all individual achievements. The category header contains the following financial data points: ▪ **Achievements:** Number of achievements recorded against this milestone rule ▪ **Total Amount:** Value of all achievements for this milestone rule

9.3.1.1.1 Modifying Achievement Dates

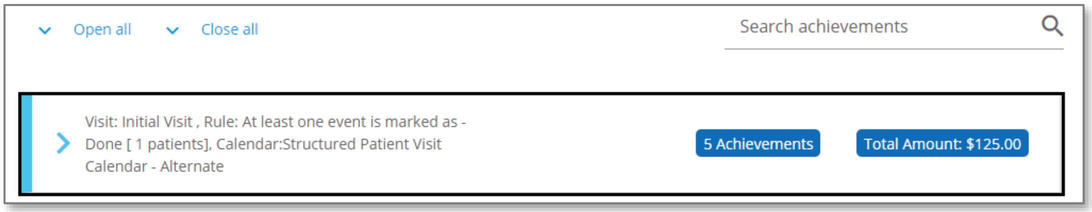
eResearch gives you the ability to modify achievement dates for all milestone types, with the exception of achievements that have been added to an invoice, have been reconciled against a payment record, or are part of a compound achievement (any achievement where the Patient Count in the milestone rule is required to be >1). Achievement dates can be modified using the View/Delete Achieved Milestones window on any study.

To modify milestone achievement dates:

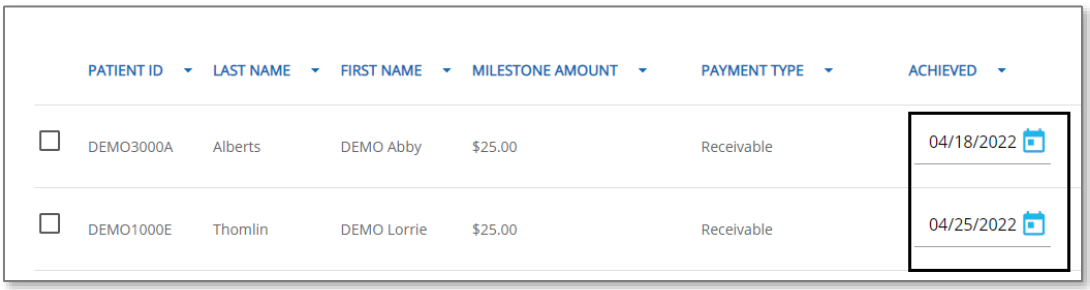
1. Open the View/Delete Achieved Milestones window from the milestones tab of any study.



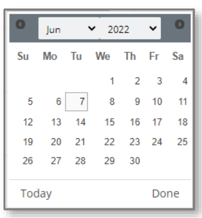
2. Select the milestone type and expand the milestone rule category to reveal the individual achievements logged for that rule.



3. Locate the achievement you would like to modify and click the Achievement Date field.



4. Select a new achievement date from the date picker.



The milestone achievement date is now changed to the new date.

Note: If an achievement date is light grey and not selectable, this indicates you cannot modify the achievement date for this item. Reasons an achievement date cannot be modified are if this achievement is part of an invoice, reconciled against a payment record, or part of a compound milestone rule (e.g. Patient count must be >1 to equal 1 achievement).

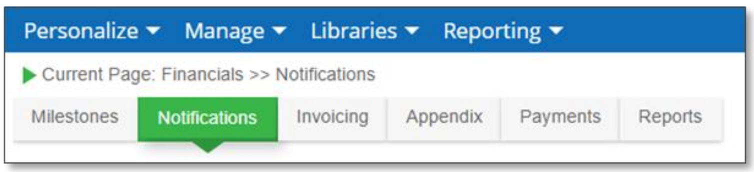
9.3.2 Manage Milestone Notifications

Notifications are configured through the Notifications tab of the Financial Summary page. The Notifications page will display all milestones created from the Manage Budget, Manage Milestones, and Study Milestone pages and can be used to notify any associated user(s) when a financial achievement is generated by that milestone. This section will cover how to configure notifications when a milestone has been achieved. Milestones are described in further detail in Milestones.

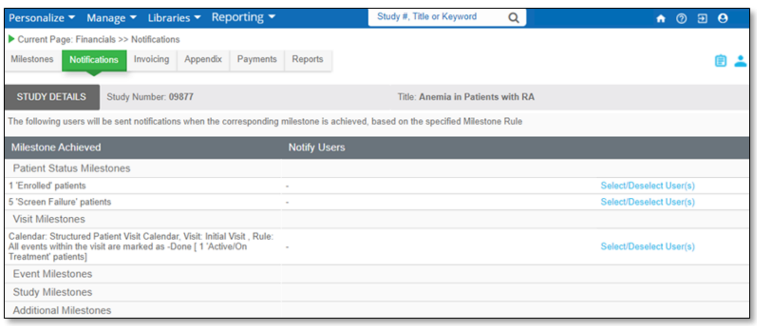
> **Note:** Milestone rules must be configured prior to configuring any milestone achievement notifications.

To setup achieved milestone notifications:

1. From the Financial Summary page, select the **Notifications** tab.

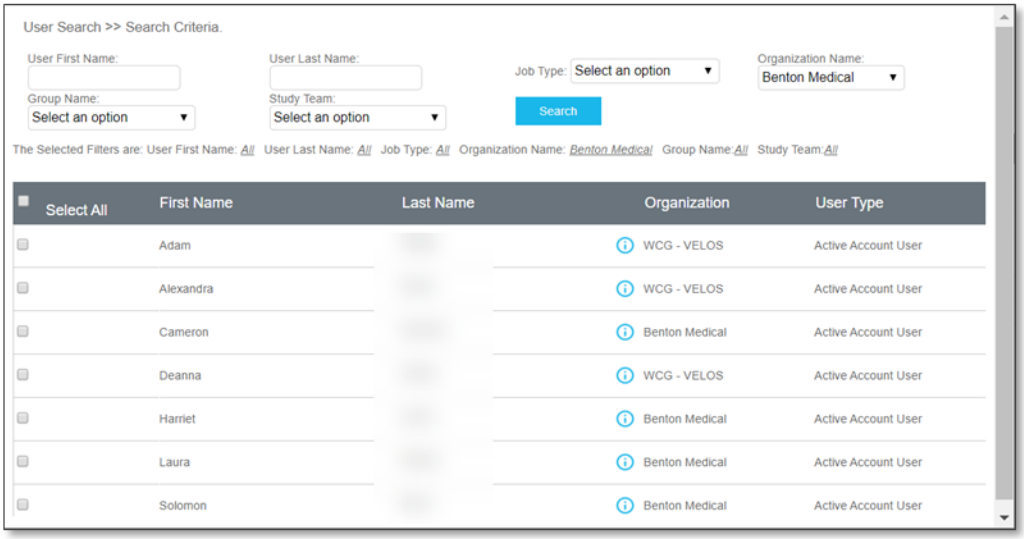


The Notifications page displays.

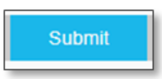


2. Locate the milestone that you'd like to configure for notifications and click **Select/Deselect User(s)**.

3. The User Search window will display. Select the appropriate user by clicking the corresponding checkboxes.



4. Click **Submit** to confirm.



Note: Users designated for a milestone notification will only receive a notification when that milestone has been achieved.

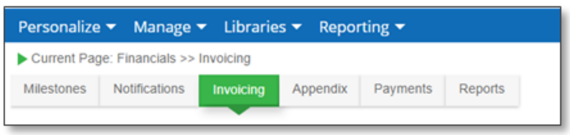
9.3.3 Manage Invoices

Invoices can be created based on how many milestones have been achieved for a study, and how much is to be invoiced. Achieved milestones can only be invoiced if the milestone rules have payment types of 'Receivable" or "Invoiceable”. Auditable comments can be added at the study level of the invoices tab using the “Quick Notes” tool, and for individual invoices using the “Internal Comment” tool. See the Add and Review Invoice Internal Comments section for more information on adding and reviewing invoice comments. After invoices are generated, they can be edited, including removing individual line items.

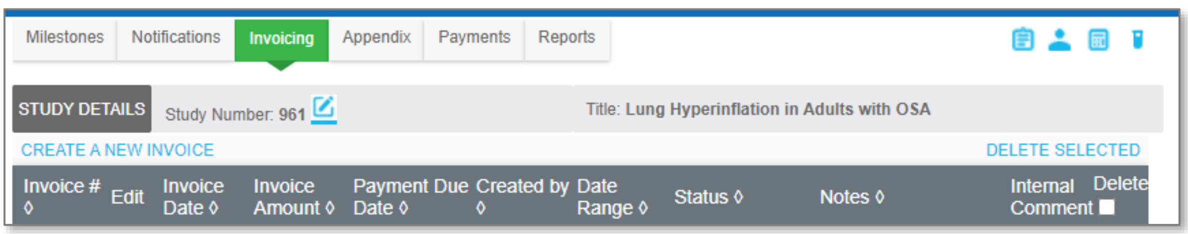
Note: Any holdback amounts specified in an achieved milestone will be listed as a separate invoiceable line item when generating an invoice. Holdbacks are a portion of the payment that is held back and not typically paid out until certain stipulations are met.

To navigate to the Invoice page:

1. From the Financial Open Milestone page, select the **Invoicing** tab.



The Invoicing page displays:

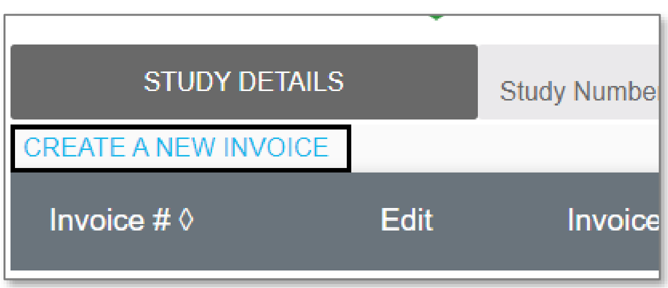


9.3.3.1 Create an Invoice

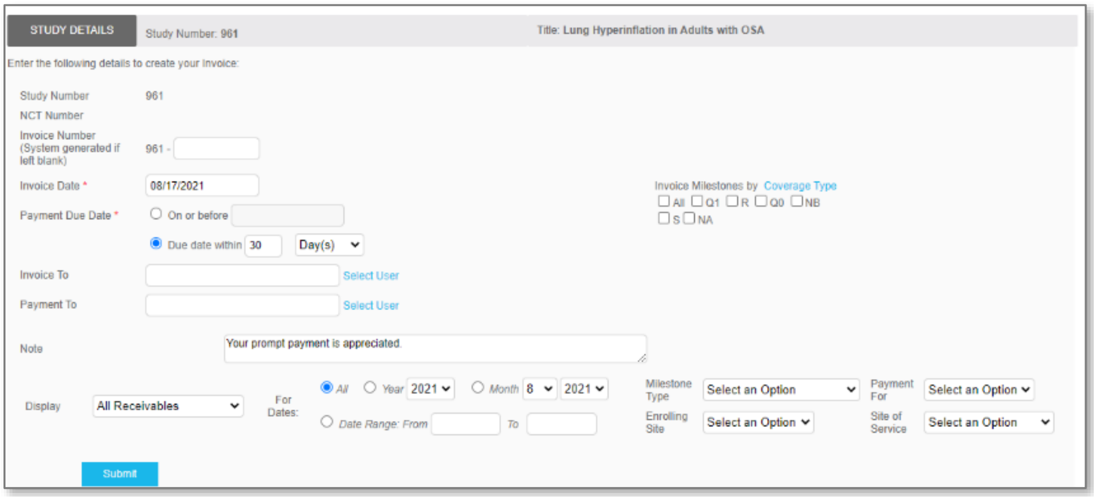
Permissioned users can create new invoices using the Invoicing page.

To create an invoice:

1. From the Invoicing tab, select **Create a New Invoice**.



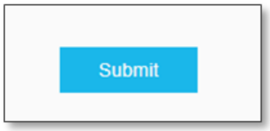
The Invoice Creation page displays:



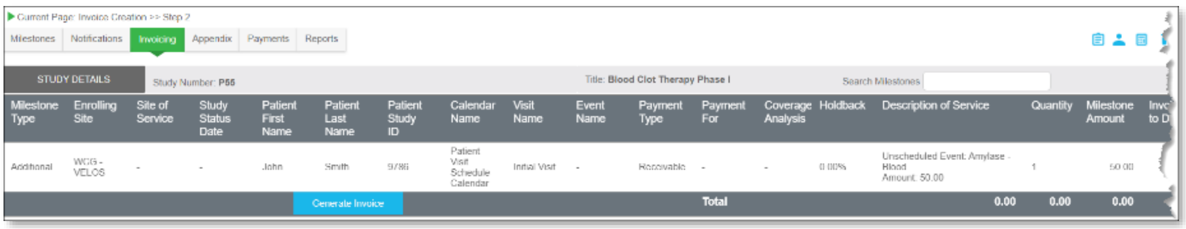
Fields available on this screen are defined below.

Field	Description
Invoice Number	Enter an invoice number. Will be system generated if left blank.
Invoice Date	Enter the date for the invoice.
Payment Due Date	Use the calendar picker to specify the date the payment is due.
Invoice To	Click the Select User link to associate a user for the invoice.
Payment To	Click the Select User link to associate a user for the payment.
Note	Enter notes as necessary, if notes should appear with the invoice.
Display	Select the appropriate options for which the receivables should display. Options include: All Receivables, Uninvoiced Receivables, Invoicables, Uninvoiced Invoicables.
For Dates	Select a timeframe for which receivables should display.
Milestone Type	Display by milestone type. Options include: Patient Status, Visit, Event, Study Status, and Additional.
Enrolling Site	Display by enrolling site.
Payment for	Display by payment for field. Options include: Investigator, Coordinator, Patient, Sponsor.
Site of Service	Display by site of service.
Invoice Milestones by Coverage Type	Select a type for which receivables should display.

2. After filling out information in the available fields to meet your specific invoicing needs, click **Submit** to confirm.

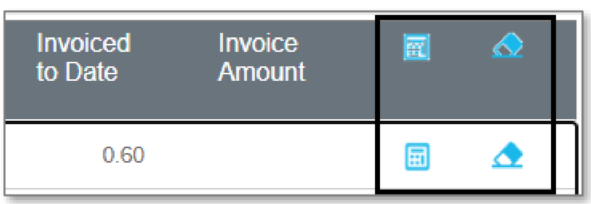


The **Invoicing** page will refresh to display the newly created invoice:



Note: You may search for milestones using any information contained in the table by using the Search Milestones field.

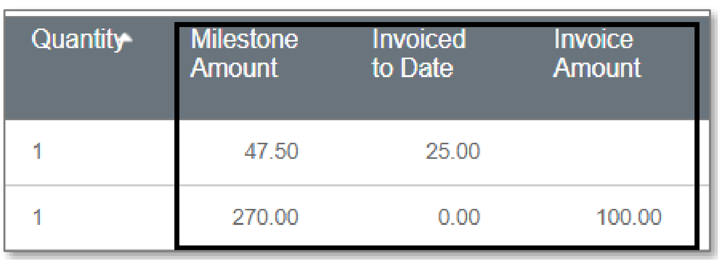
There are two functionalities used to calculate the amount to be invoiced, **Calculate** and **Erase**:



View the table below to learn more about how calculate, erase, and search milestones work:

Name	Description
Calculate	*Power Bar*: Click **Calculate** to insert the amount for all the milestones displayed. This button adds the amount listed under the Milestone Amount column for each milestone. *Row*: Click **Calculate** to insert the amount for one line item. The invoice amount(s) cannot be greater than the milestone amount.
Erase	*Power Bar*: Click **Erase** to clear all invoice amounts displayed. *Row*: Click Erase to clear the invoice amount displayed for one line item.
Search Milestones	Enter a letter or word into the Search Milestones field to filter by Milestone Type

3. Enter the amount to be invoiced by using the **Calculate** button to invoice the full invoiceable amount or click directly in the Invoice Amount field to enter a custom amount to be invoiced. Note that as you enter values in the Invoice Amount column, a total is calculated at the bottom. This will be the total invoice amount.



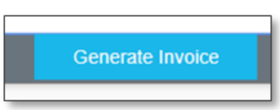
Quantity	Milestone Amount	Invoiced to Date	Invoice Amount
1	47.50	25.00	
1	270.00	0.00	100.00

Note: Only achieved milestones with an Invoice amount will be listed on the invoice.

Warning: The Invoice Amount cannot be greater than the Milestone amount but can be less.

Note: Each invoiceable line item may be invoiced partially. The system will keep track of invoices that have been paid via the reconciliation process and update the "Invoiced to Date" amount column accordingly. This ensures you cannot ever exceed the Milestone amount as defined by the milestone.

4. Click **Generate Invoice** once all desired invoice amounts have been assigned.



5. The Print Invoice window will display. Users may export the invoice, print using the appropriate buttons, or close the window.

Warning: If your browser's pop-up blocker is enabled, it may prevent the window from automatically opening. Either allow this website to open pop-ups or click on the invoice number in the Invoices table to open the Print Invoice window.

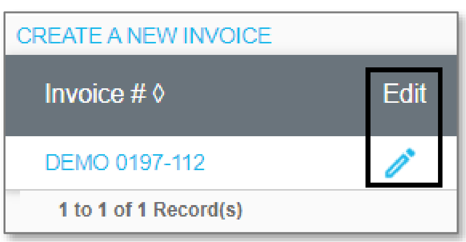
Note:
1. Any items added to a generated invoice will not be considered "Invoiced" until they have been reconciled via payments. See Manage Payments to learn more.
2. There are three views available once the invoice generates: Velos Invoice (using your logo), Invoice by milestone type, and Invoice by patient. Select the invoice template that best suits your needs and export it for invoicing.

9.3.3.2 Edit an Invoice

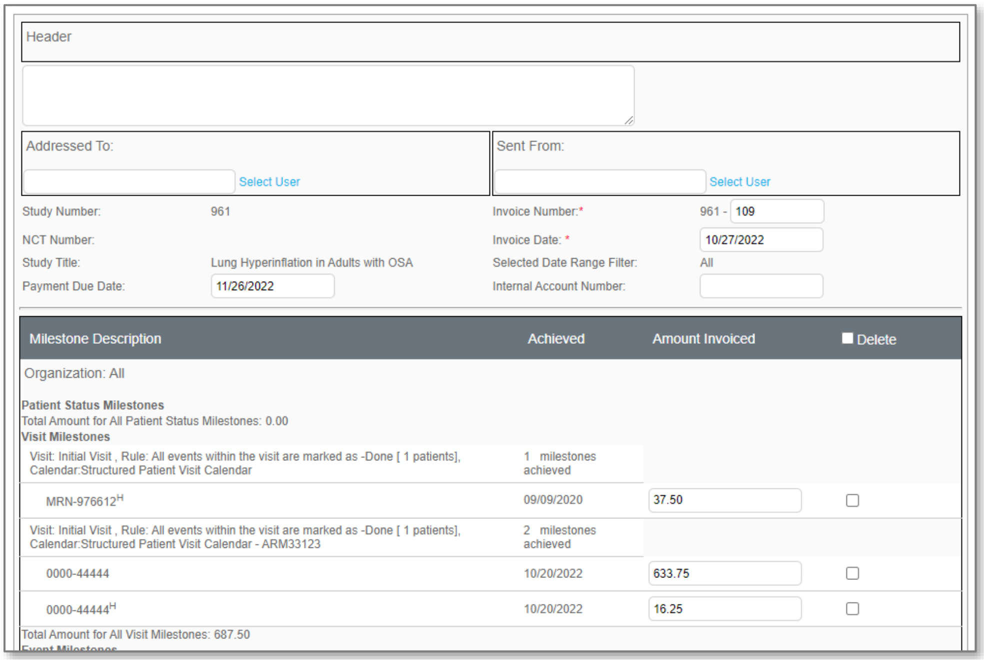
Created invoices can be edited to reflect updated activities, amounts, patient data, and dates of service. It's also possible to remove specific line items from an invoice from this page.

To edit an invoice:

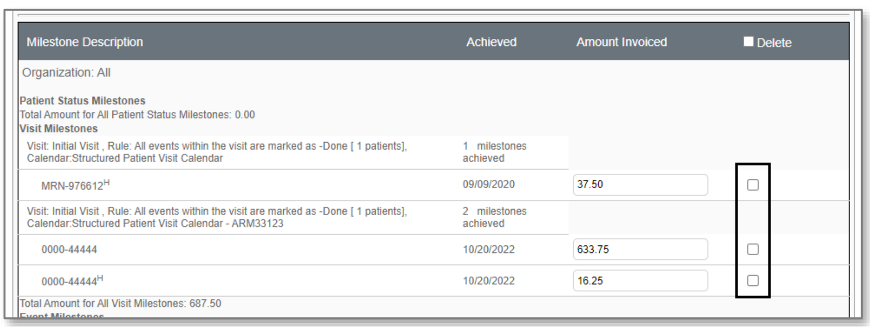
1. From the Invoicing page, click the **Edit** button for the desired invoice.



2. The window to modify an invoice will open. Update information as appropriate.

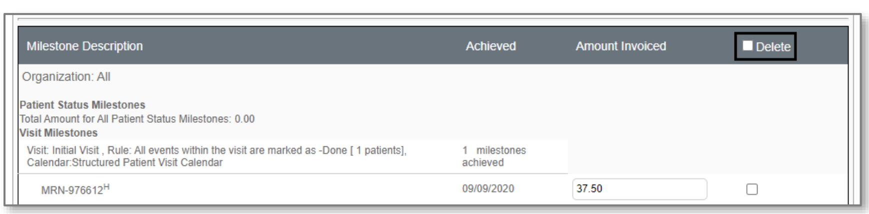


3. To remove a specific line item, select the checkbox next to the item.



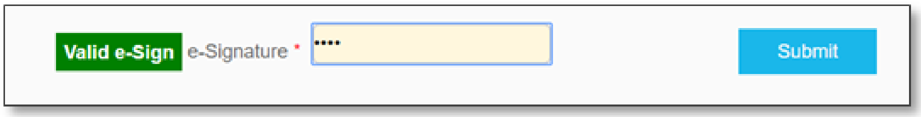
-OR-

To remove all line items, select the **Delete** checkbox.



Note: If removing all line items, or you remove the last line item in an invoice, the invoice will be automatically deleted.

4. Enter your e-Signature and click **Submit** to confirm.



Note: You cannot delete any line items that have already been reconciled against a payment record.

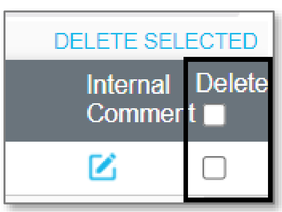
9.3.3.3 Delete an Invoice

Users may wish to delete an invoice that is not necessary. This section will cover how to delete an invoice.

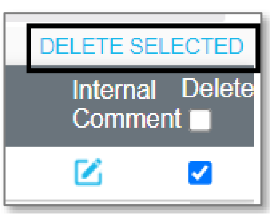
Note: Deleting an invoice will remove it from the system permanently.

To delete an Invoice:

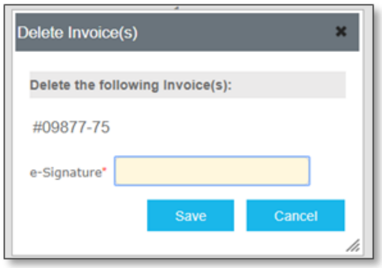
1. From the Invoicing page, select the checkbox next to the invoice that you wish to delete.



2. Click **Delete Selected** to delete the selected invoice.



3. A window confirming deletion pops up. Enter your e-Signature and click **Save** to confirm.

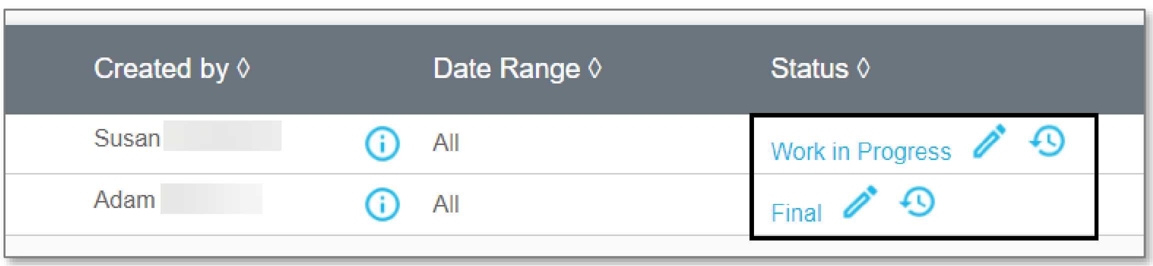


9.3.3.4 Manage Invoice Status

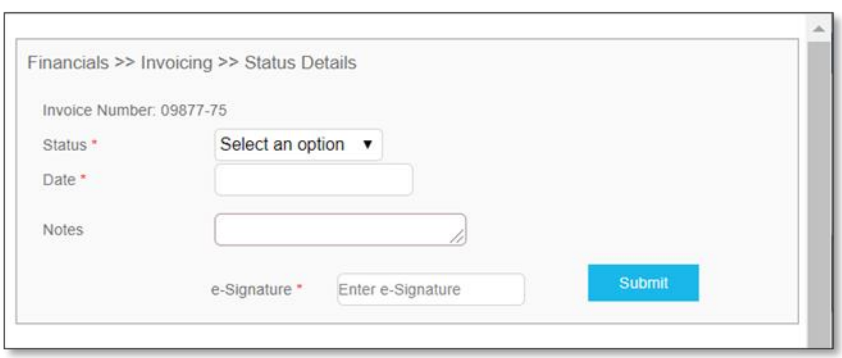
The default Invoice Status is "Work in Progress". This section will cover how to change the Invoice status. There are two invoice status options: "Work in Progress" or "Final".

To manage an invoice status:

1. From the Invoicing page, click the **Edit** button for the status you wish to modify.

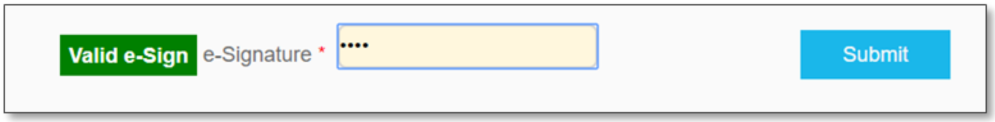


2. The Status Details page displays. Edit the status as appropriate.



Note: A status date must be entered.

3. Enter your e-Signature and click **Submit** to confirm.



9.3.3.5 Add and Review Invoice Internal Comments

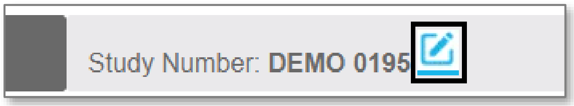
Velos eResearch provides the ability to add auditable comments to the invoicing tab of a study. Comments can be added at the study level of the invoices tab using the “Quick Notes” tool, and for individual invoices using the “Internal Comment” tool. Comments are sequential, meaning that multiple comments can be added over time, and reviewed when clicking on the “Quick Notes” tool or appropriate “Internal Comment” tool. Each note contains the following information:

- Author
- Quick Note/Internal Comment creation timestamp (date and time of creation)
- Quick Note/ Internal Comment text

Note:
1. Quick Notes/Internal Comments text fields are limited to 4000 characters per entry.
2. Users cannot edit or delete comments once they have been created. Note that Quick Notes/Internal Comments display is sorted in descending (oldest to newest) order.

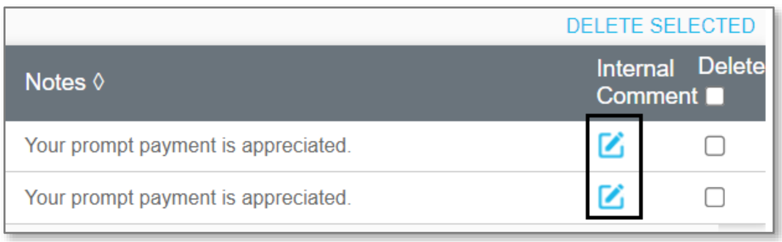
To add a Quick Note/ Internal Comment:

1. From the Invoicing page, to add a Quick Note click the add comment icon next to the study number at the top of the page.



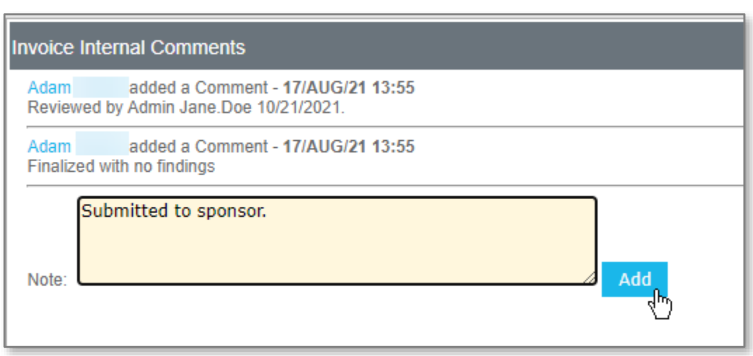
-OR-

To add an Internal Comment, click the add comment icon next to the target invoice in the Internal Comment column.

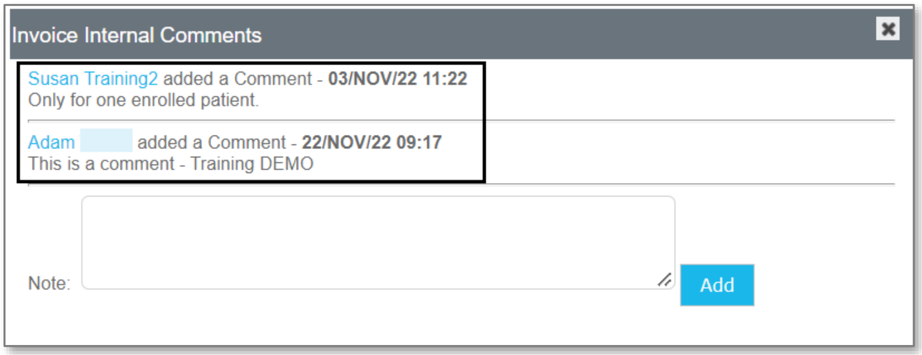


The Quick Note/ Internal Comments modal will display. From here, you can review any existing comments:

2. Enter your Quick Note/Internal Comment text in the note field and click **Add**.



The Quick Note / Internal Comment is added. If existing notes were already present, the display will sort them in descending order (oldest to newest):



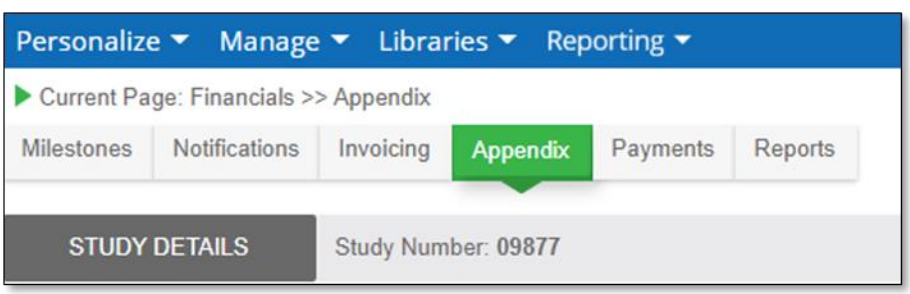
Note: The information contained within Quick Notes / Internal Comments is auditable by custom report or by contacting Velos Support.

9.3.4 Appendix

Velos eResearch provides the ability to add reference materials to a study's Financial Summary page using the Appendix tab. Permissioned users can add, delete, and edit files and links within the appendix.

To access the Financial Summary Appendix:

1. Navigate to the Financial Summary page of a specific study and click the **Appendix** tab.



The Appendix page displays:

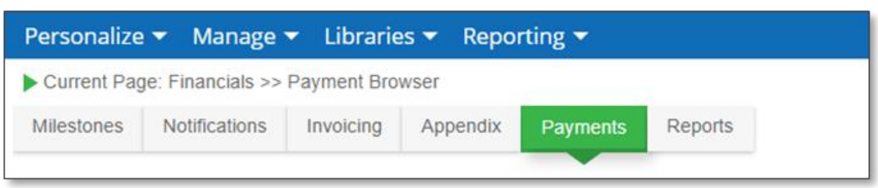
Note: The steps required to add, delete, and edit the files and links in the Financial Summary appendix are the same as modifying the Event Appendix. See the Event Appendix for the steps required to add and modify files and links to the Financial Summary appendix.

9.3.5 Manage Payments

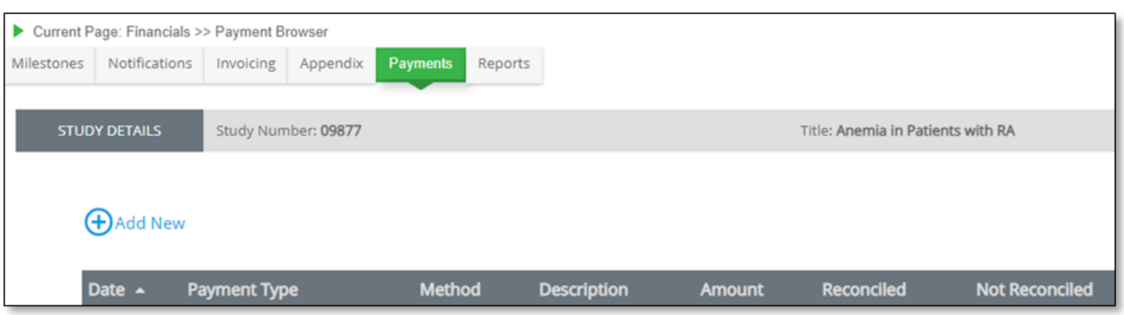
In the Velos eResearch system, payments are managed from the Financials Module. Payments can be reconciled with invoices and for achieved Milestones with "receivable" or "payable" payment types. Payments should be managed to keep a record of Payments made, Payments received, and their respective amounts.

To navigate to the Payments page:

1. From the Financial Summary page, select the **Payments** tab.



The Payments page displays:

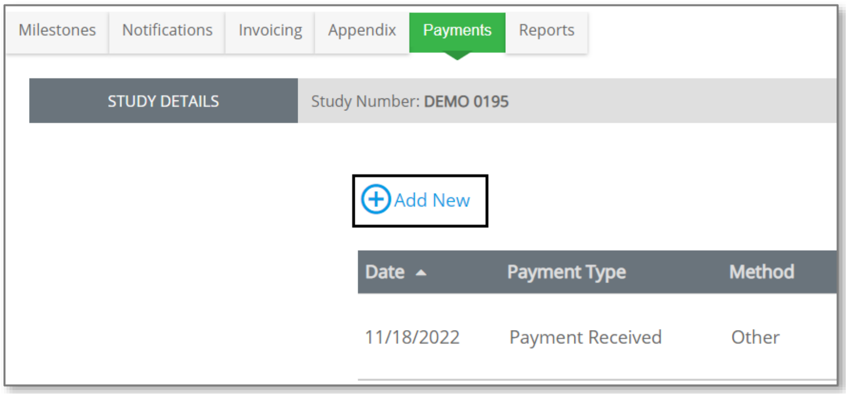


9.3.5.1 Record a Payment

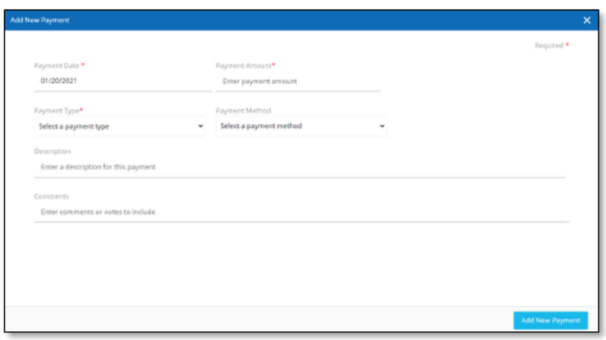
This section will cover how to record a payment.

To record a payment:

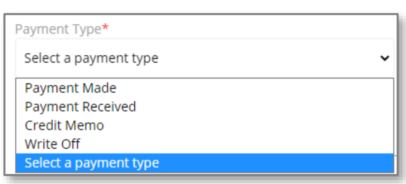
1. From the Financial Payment Browser, select **Add New**.



2. The Add New Payment window will open.

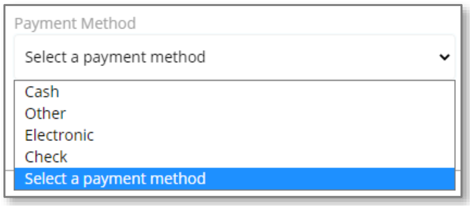


3. Enter required information into the fields for **Payment Date** and **Payment Amount**. For **Payment Type**, select Payment Made, Payment Received, Credit Memo, or Write Off.



Note: If the Payment Type of Payment Made is selected, you can only reconcile against Milestones, but if Payment Received is selected, you will have the option to reconcile against either Milestones or Invoices.

4. Optionally, include the **Payment Method** by selecting Cash, Electronic, Cheque, or Other.



Note: Information such as a Check # or other billing information that you might need to recall later can be entered into either the Description or Comments field. This information can then be recalled later by pulling the report "Payment Records (ALL)" from Report Central. See the Report Central for more information.

5. Click **Add New Payment** to save the payment information.

9.3.5.2 Reconcile a Payment

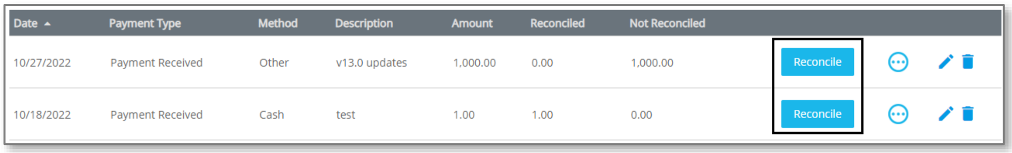
In the Velos eResearch system, payments can be reconciled either to invoices or milestones for Payments Received Payment Types or to Milestones only for Payment Made Payment Types. The instructions below cover how to reconcile a payment for both Payment Types.

9.3.5.2.1 Reconcile by Milestone

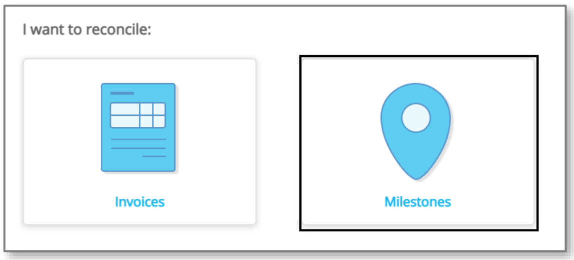
The reconcile tool allows users to reconcile payment records directly against milestone achievements. This can be beneficial if a payment is sent automatically without an invoice, or as an estimated payment.

To reconcile a payment with a milestone:

1. From the Payments page, click **Reconcile** for the appropriate payment.

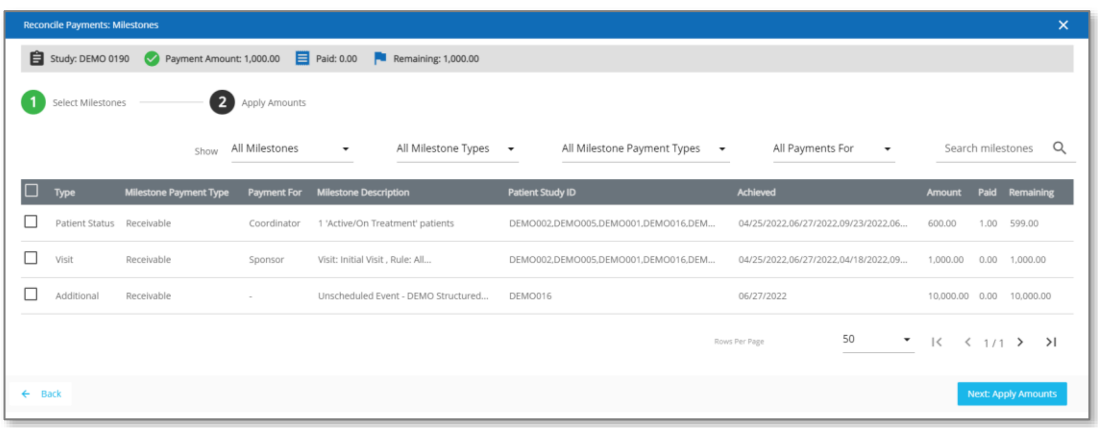


For a Payment Received Payment Type, the Reconcile Payments window appears.

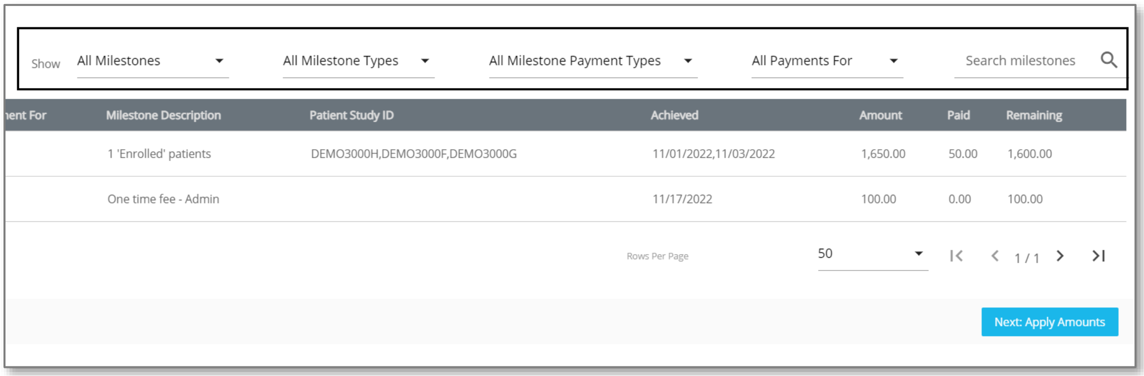


   a. Click the **Milestones** button.

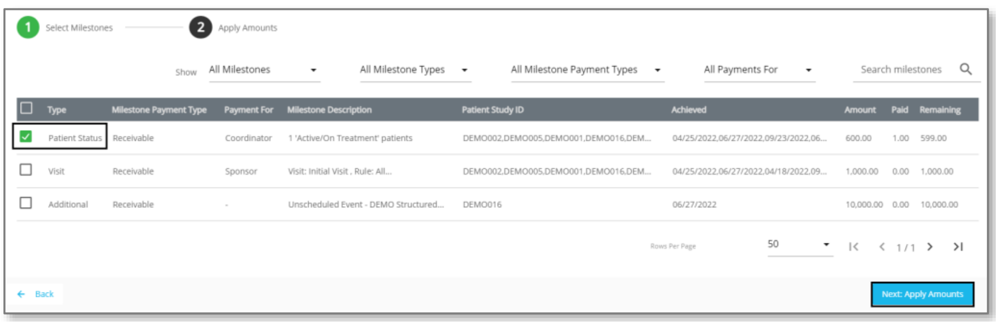
   The Reconcile Payments: Milestones Step 1 Select Milestones window displays, after clicking the Milestones button for a Payment Received Payment Type or after clicking the Reconcile button for the Payment Made Payment Type.



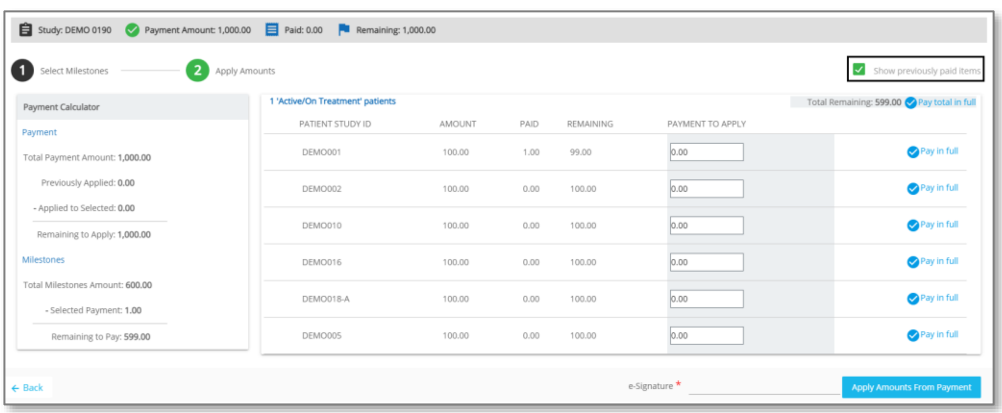
2. If there are multiple Milestones, filter using the dropdowns by Milestones, Milestone Types, Milestone Payment Types, and/or All Payments For, and/or enter a word into the search and click the magnifying glass, as needed.



3. Check the checkbox for the desired Milestone Type, then click **Next: Apply Amounts**.

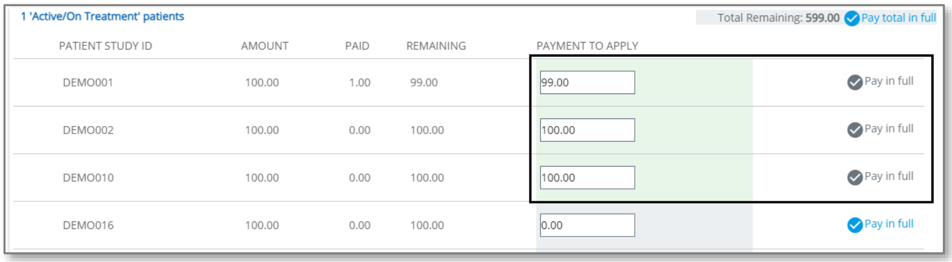


The Step 2 Apply Amounts step displays.

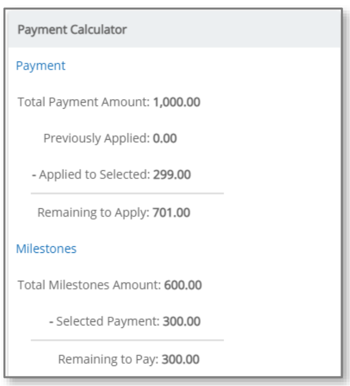


a. Uncheck the **Show previously paid items** checkbox if you do not want to view paid items in this view, if applicable.

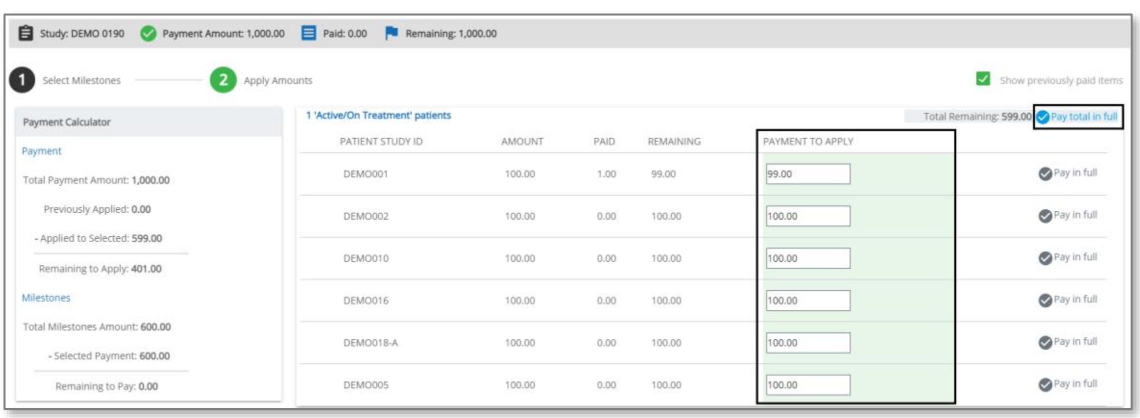
4. In the **Payment To Apply** column, enter individual amounts that should be paid to each line item.



a. Calculations of Payment: Applied to Selected and Remaining to Apply and Milestones: Selected Payments and Remaining to Pay will be shown in the Payment Calendar as amounts are credited to each line item from the Total Payment Amount. See the following example for entries made above.



b. Alternatively, to pay each line in full, click the **Pay in Full** link to the right of the line item.
-OR-
If the full Total Payment Amount is to be used to pay the Total Remaining item costs, and the costs are to be paid simultaneously, then click **Pay total in full**.



Note:
1. The funds from the Total Payment Amount will be used for each line item paying from the top line entry down to the last line entry in which there are available funds. This may leave unpaid line items and/or the last line item may be partially paid.
2. If there is an excess of funds left after applying all amounts, then there will be funds left in the Remaining to Apply section of the Payment Calendar and in the Not Reconciled column on the Study Details page.

5. After Payment to Apply line items are entered, as needed, enter e-Signature and click **Apply Amounts From Payment**.

The Study Details page will show the amount reconciled in the Reconciled column (added to any previously reconciled amount) and any remaining amount to use for reconciling in the Not Reconciled Column.

Date	Payment Type	Method	Description	Amount	Reconciled	Not Reconciled	
10/27/2022	Payment Received	Other	v13.0 updates	1,000.00	99.00	901.00	Reconcile
10/18/2022	Payment Received	Cash	test	1.00	1.00	0.00	Reconcile

9.3.5.2.2 Reconcile by Invoice

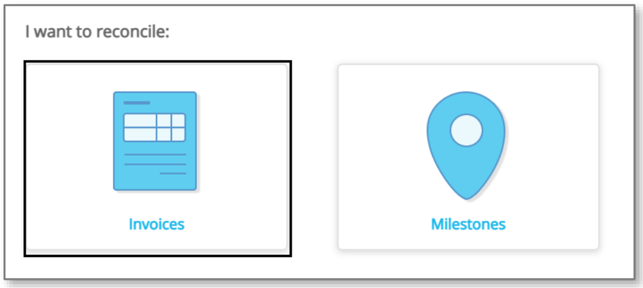
The reconcile tool allows users to reconcile payment records directly against milestone achievements. Depending on your specific processes, this method can be easier to track and is generally more efficient than reconciliation by milestone.

To reconcile a payment by Invoice:

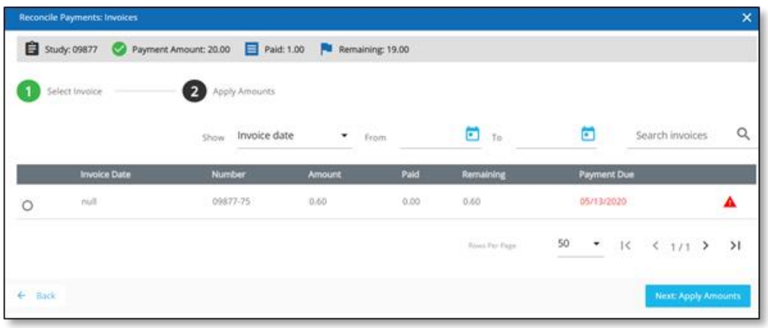
1. From the Payments page, click **Reconcile** for the appropriate Payment Received Payment Type.

Date	Payment Type	Method	Description	Amount	Reconciled	Not Reconciled	
10/27/2022	Payment Received	Other	v13.0 updates	1,000.00	0.00	1,000.00	Reconcile
10/18/2022	Payment Received	Cash	test	1.00	1.00	0.00	Reconcile

2. In the new Reconcile Payments Window, click the **Invoices** button.

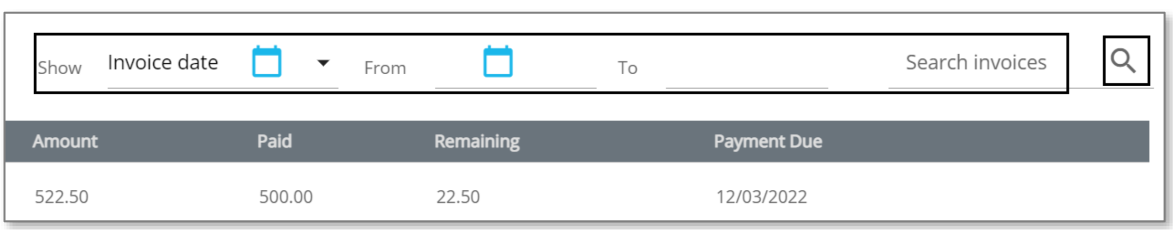


The Reconcile Payments: Invoices Step 1 Select Invoice window appears.

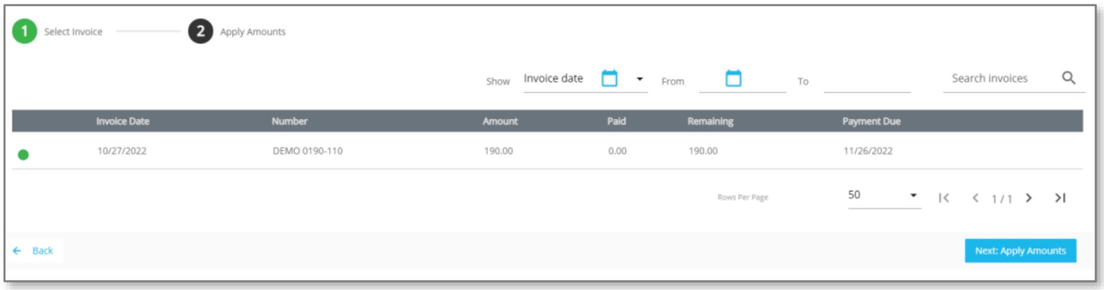


- If the payment date is past due, the date will be red and there will be a red exclamation mark icon

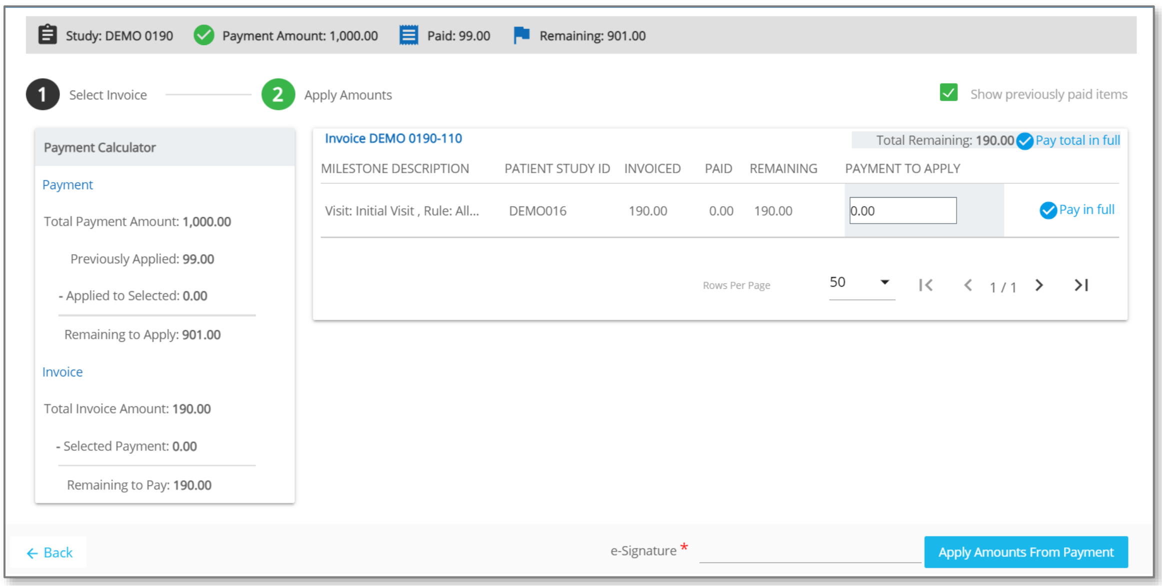
3. If there are multiple Invoices, use the Search function by filtering by **Invoice date** or **Payment date** and/or using **From** and/or **To** calendar selections, and/or enter a word into the search field and click the magnifying glass, as needed.



4. Choose the appropriate Invoice by selecting a radio button and click **Next: Apply Amounts**.

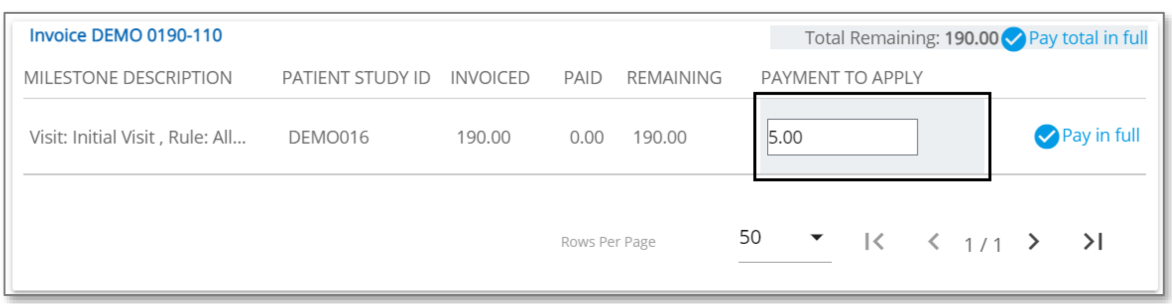


The Step 2 Apply Amounts step is viewed.

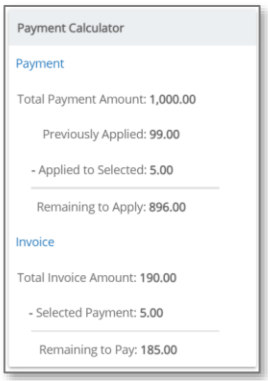


   a. Uncheck the **Show previously paid items** checkbox if you do not want to view paid items in this view, if applicable.

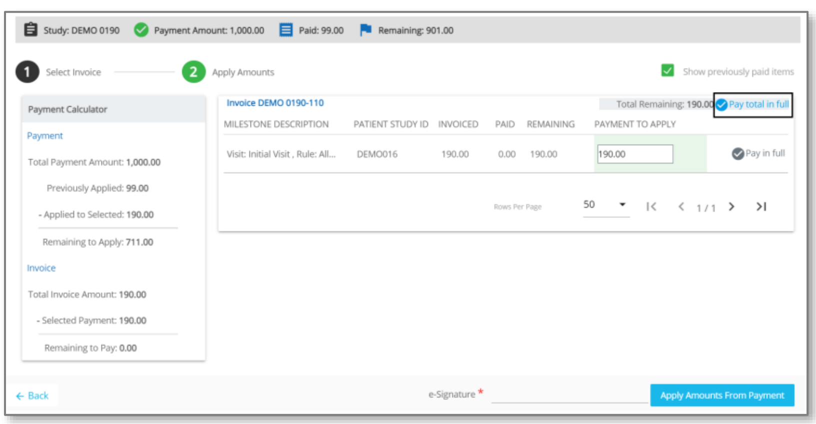
5. In the **Payment To Apply** column, enter an amount to be paid.



a. Calculations of Payment: Applied to Selected and Remaining to Apply and Invoice: Selected Payment and Remaining to Pay will be shown in the Payment Calendar as an amount is credited from the Total Payment Amount.



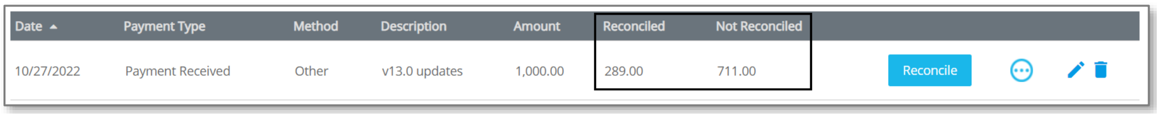
b. Alternatively, to the full line item, click the **Pay in Full** link to the right of the line item.
-OR-
If the full Total Payment Amount is to be used to pay the Total Remaining item cost, then click **Pay total in full**.



Note:
1. The total funds from the Total Payment Amount will be used towards the Payment To Apply column in its entirety. This may leave a partially paid field.
2. If there is an excess of funds left after paying total in full, then there will be funds left in the Remaining to Apply section of the Payment Calendar and in the Not Reconciled column on the Study Details page.

6. After "**Payment To Apply**" line items are entered, as needed, enter e-Signature and click **Apply Amounts From Payment**.

The Study Details page will show the amount reconciled (added to any previously reconciled amount) in the Reconciled column and any remaining amount to use for reconciling in the Not Reconciled column.

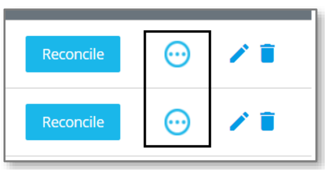


9.3.5.3 Reconcile Details

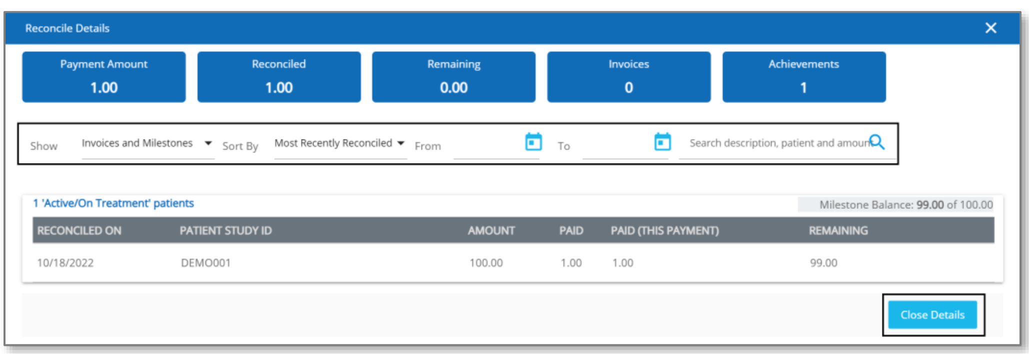
From the Payments page, Reconcile Details can be viewed.

To view details for a reconciled payment:

1. Click a Reconcile Details button.



The Reconcile Details screen appears.



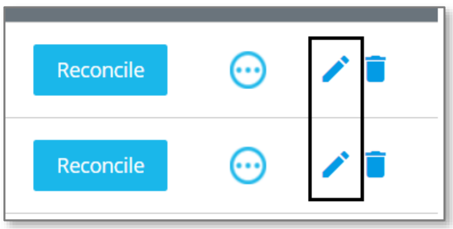
2. Filter as needed using the dropdowns, calendar filters, and searching tool to find a specific record.
3. Click **Close Details** when viewing is complete.

9.3.5.4 Edit Payment Record

From the Payments page, payment records can be edited.

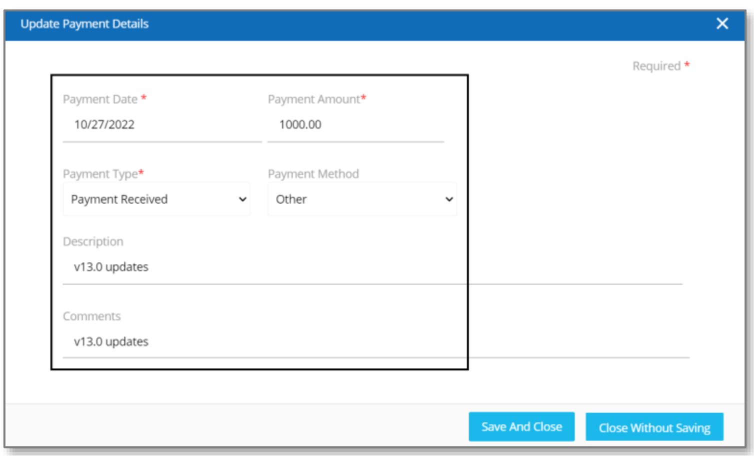
To edit an existing payment record:

1. Click an **Edit** button.



Note: Double check payment details and make adjustments as needed before editing.

The Update Payment Details screen appears.



2. Change payment details fields as needed and click **Save And Close**.

   -OR-

   Do not make any changes and click **Close Without Saving**.

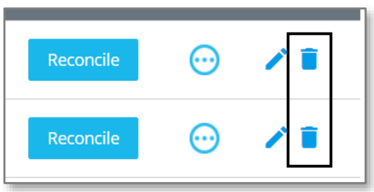
9.3.5.5 Delete a Payment Record

From the Payments page, payment records can be deleted.

Warning: The record will be removed when deleting, ensure the record is to be deleted before deleting for accurate records. Deleting records may occur in such cases as when applying an incorrect payment.

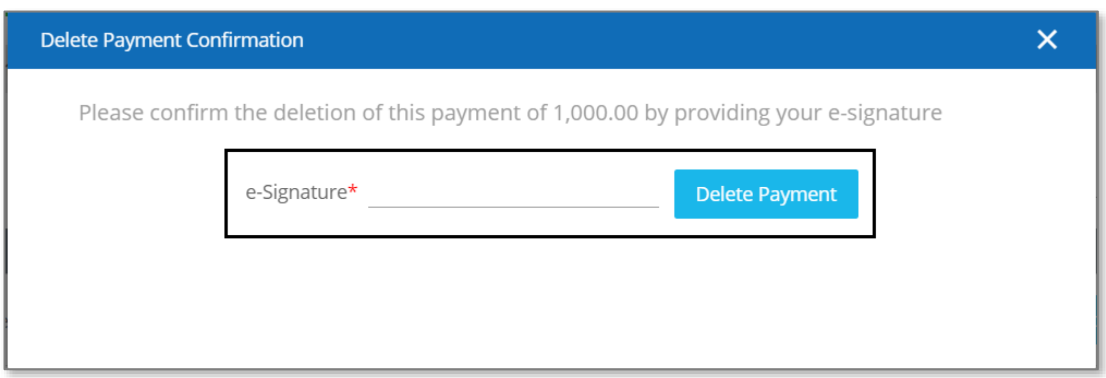
To delete a record:

1. Click the **Delete** button.



A Delete Payment Confirmation pop-up will appear.

2. To confirm deletion, enter e-Signature and click **Delete Payment**.



10 Reports, Ad-hoc Queries & Dashboard

Once studies are running in your system and data is being captured, one of the most important tasks will be to extract data for use in compliance, budgets, and research management requirements. To accomplish this task, Velos eResearch offers a variety of out-of-the-box reports in Report Central, and for more advanced reporting jobs, an Ad-Hoc Query tool.

- See Report Central for more information about the types of reports offered in Velos eResearch.
- See Ad-Hoc Queries (AHQ) to learn how to build and manage custom reports using Ad-Hoc Queries.

In addition to pulling reports and creating Ad-hoc Queries, Velos eResearch Enterprise offers the ability for Data Monitors and users with data monitoring responsibilities to review form entries, provide feedback, and resolve any flagged issues.

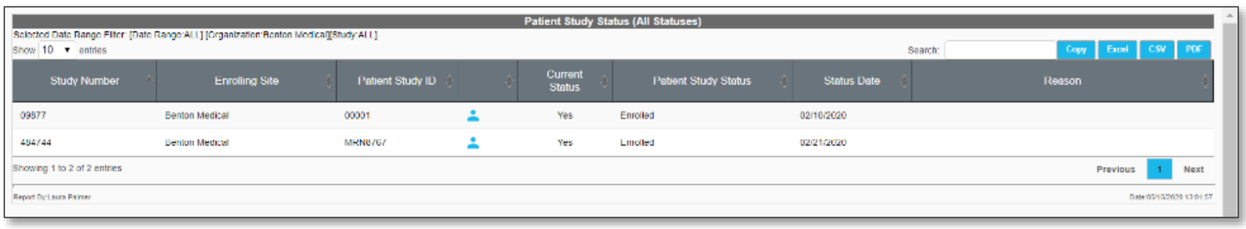
- For more information about forms, see Forms Management
- For more information about the Dashboard tool, see Dashboard

Enterprise Only:	The Dashboard tool is only available in the Enterprise version of eResearch. Additionally, some reports may only be available in Enterprise.

10.1 Report Central

Reporting is available in Report Central to assist users with oversight and monitoring of day-to-day operational activities. The reports provide account, regulatory, financial, patient, and study information. Report Central can be accessed by using the Reporting tab. In addition, some specific reports can be accessed directly from their functional areas (e.g. Patient reports for specific individuals can be accessed from the patient management page or financials).

For each category of report, there is a set of search criteria available that allows permissioned users to filter the reporting results.



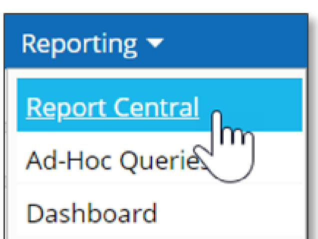
Note: The Reports available in this module pull data from the standard eResearch fields. Ad-Hoc Queries are used to generate reports on data entered into forms. For any custom fields added to eResearch a custom report would need to be designed to report on that data.

10.1.1 Access and Run Reports

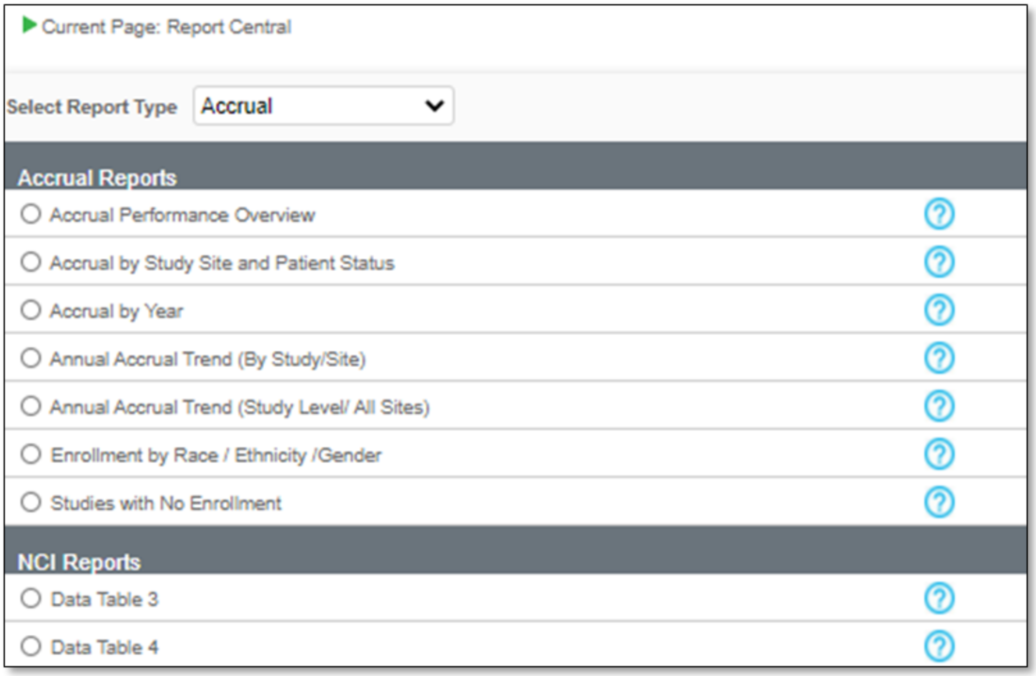
Velos eResearch allows permissioned users to pull data from a variety of pre-determined reports. See Report Types to learn more about the various reports available within Velos eResearch.

To access and run reports from Report Central:

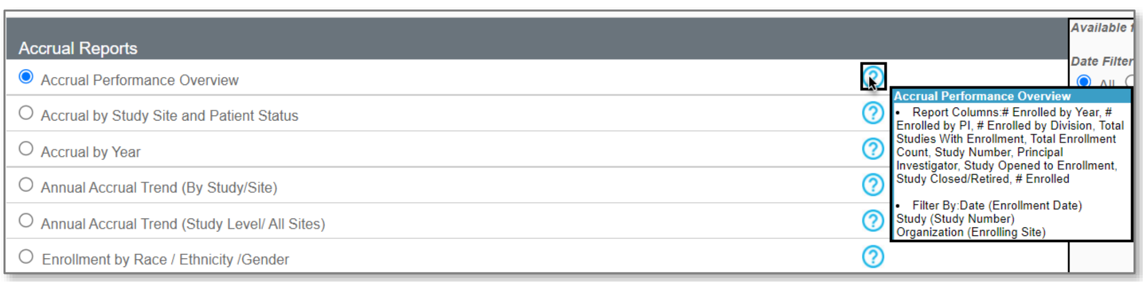
1. Click the **Reporting** menu and select **Report Central**.



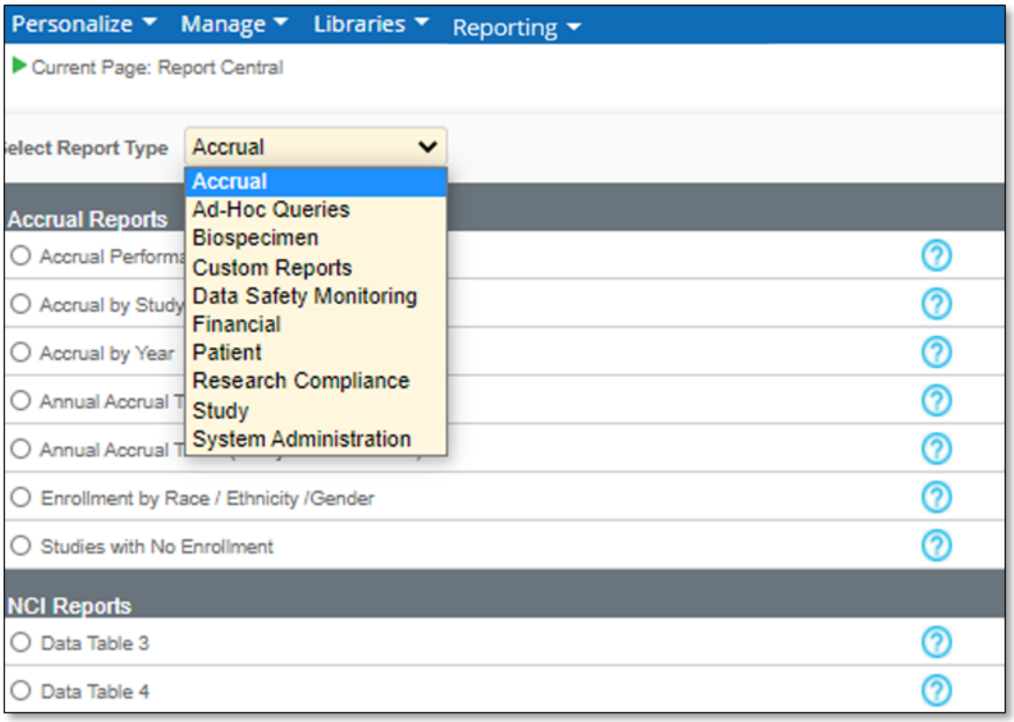
The Report Central page displays:



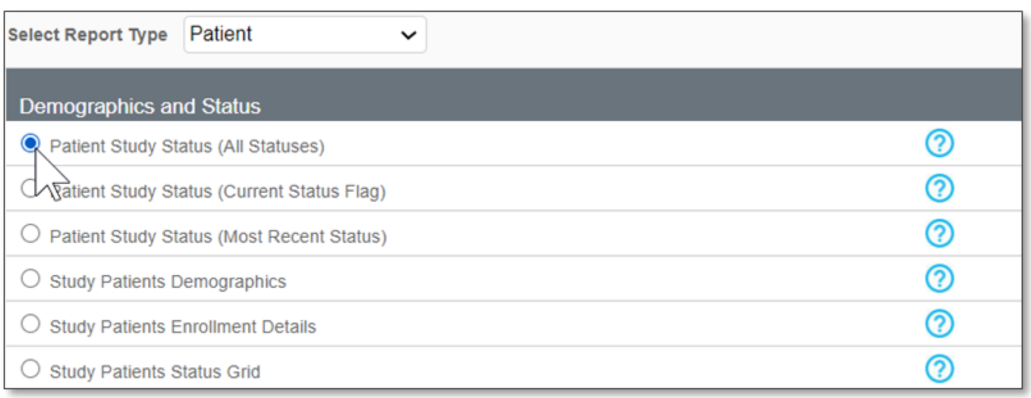
- When hovering over the question mark icon, the available columns and filters for a report are displayed. See example below.



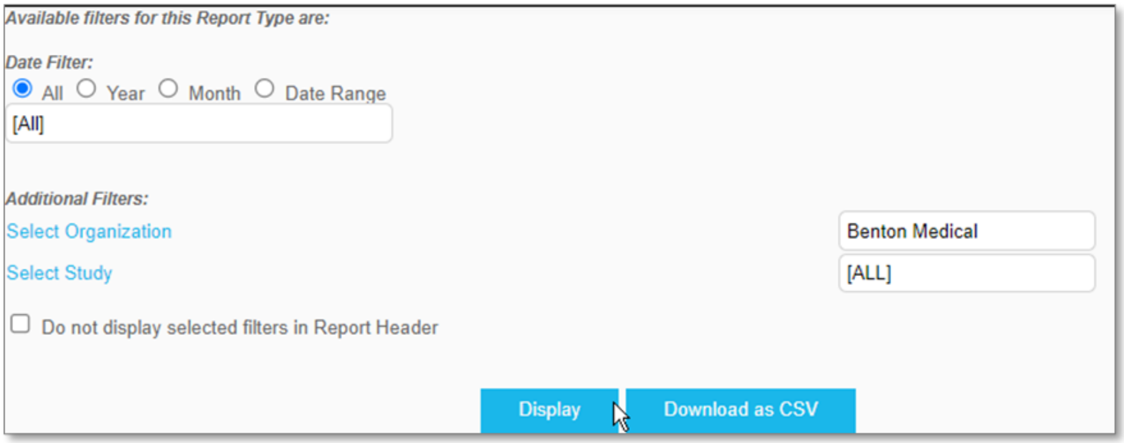
2. **Select Report Type** from the dropdown menu. See Report Types for more information about report types.



3. Select the specific report by clicking the radio button next to the report name.



4. Apply filters as needed. See Filtering Options for more information about report filtering.



5. Click **Display** and the report will display in a new tab or window.

   -OR-

   Click **Download as CSV** to download a CSV version without viewing in a new window .

10.1.2 Export and Print a Report

Velos eResearch provides a means to export any reports within Report Central. The specific options to export a report vary, depending on the report that was selected. The options fall into two general categories as shown in the tables below.

Note: The specific export options for each report may vary. In some cases, for example, a user may only have the option to print the report.

To export a report from Report Central:

1. Generate a report from Report Central. For more information about how to run a report, see Access and Run Reports.
2. **Option 1**: Click on one of the labeled buttons at the top of the report to perform the described export functions.

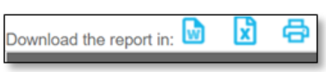
Icon	Name	Description
	**Copy to Clipboard**	Copies the report data to your clipboard for easy "pasting" into a document or spreadsheet.
	**Export to CSV**	Exports the report to a Comma-separated values (CSV) delimited text file.
	**Export to Excel**	Exports the report to a Microsoft Excel spreadsheet.
	**Export to PDF**	Exports the report to an Adobe PDF document.

-OR-

Option 2: Click directly on one of the Download the report in **Export to**: buttons located at the top of the report page.

Note: The exporting option button appearance will vary depending on the type of report you have pulled.

Example of Download the report in: button view.



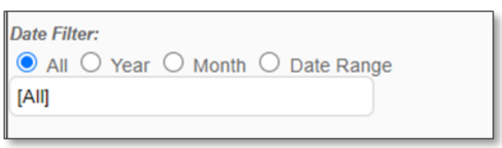
Icon	Name	Description
	**Export to Word**	Exports the report to a Microsoft Word document.
	**Export to Excel**	Exports the report to a Microsoft Excel spreadsheet.
	**Print**	Opens a print-optimized version of the report.

10.1.3 Filtering Options

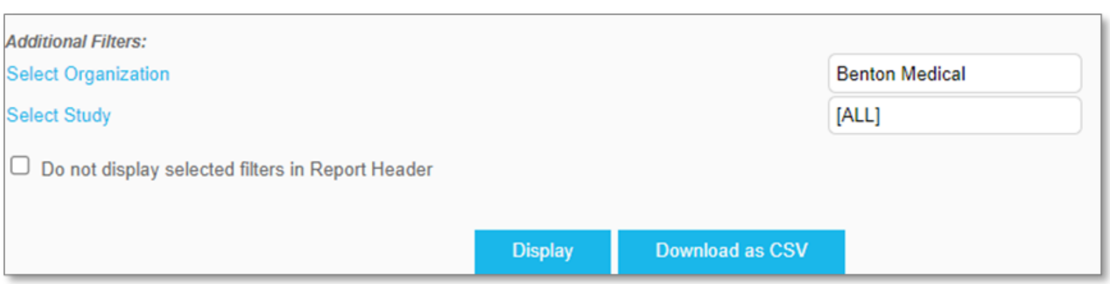
Within Report Center, filtering options are displayed on the right side of the page. The available options that display depend on the specific report and report type that is chosen.

To filter a report:

1. Navigate to the Report Center. Select a report type and report.
2. Within the **Date Filter** area of the page define the date restrictions for the report, as needed:



3. Within the **Additional Filters** area of the page, define other filter criteria as needed. You may also choose not to display the filter selections at the top of the report page by clicking the checkbox at the bottom of the Additional Filters area.



Note: Depending on the specific report you choose, different filters may display. Common options include, but are not limited to, Study, Organization, and User.

4. Click **Display** to view the report in a new window.

-OR-

Click **Download as CSV** to download a CSV version without viewing in a new window.

10.1.4 Report Types

The following sections describe each available report, report category, and in which version(s) of Velos eResearch they are available. For more information about how to access Report Central, see Access and Run Reports.

10.1.4.1 Accrual Reports

Accrual reports display patient recruitment statistics.

Recommended Primary User: Study Coordinator

Benefits / Uses:

- Displays enrollment information in the aggregate
- Can be used to identify enrollment trends and issues
- Only report category that allows you to see aggregated demographic information

Available Reports:

The following reports are available within the Accrual Reports library.

Report Name	Report Description	Report Date Filter Field	Enterprise	eXpress
Accrual Performance Overview	This report presents a graphical representation of study enrollment by year, by PI and by Division. The report also provides details for each study including when the study opened for enrollment and the number of patients enrolled. This report can be generated to show this data for all studies and selected organizations for a designated time period.	**Enrollment Date, Study Number, Enrollment Site**	X	X
Accrual by Study Site and Patient Status	This report provides information on patient status by study. The report will show date of first patient enrollment and include # of screened patients, screen failures, # of patients enrolled, # off treatment, # in follow-up and the # off the study. This report can be generated to show this data for all studies and selected organizations for a designated time period.	**Date, Study Number, Study Site**	X	X
Accrual by Year	This report provides information on patient enrollment yearly data for studies, PI details and therapeutic area. This report can be generated to show this data for all studies and selected organizations.	**Date, Study Number, Enrolling Site**	X	X
Annual Accrual Trend (By Study/Site)	Displays the total of number of accrual by site (organization) for each month per the specified filters.	**Enrollment Date, Study Number, Enrolling Site**	X	X
Annual Accrual Trend (Study Level/All Sites)	Displays the total of number of accrual for all study sites (organization) for each month per the specified filters.	**Enrollment Date, Study Number, Enrolling Site**	X	X

Report Name	Report Description	Report Date Filter Field	Enterprise	eXpress
Enrollment by Race/ Ethnicity /Gender	Displays study accruals by race, ethnicity, and gender per the specified filters.	**Enrollment Date, Study Number, Enrolling Site**	X	X
Studies with No Enrollment	Displays active studies with no enrollment.	**Study Number**	X	X
NCI Data Table 3	Report design based on NCI CCSG (Cancer Center Support Guidelines) data guide. It draws data from the fields as defined on a study's "Summary" tab. Only the Date Range filter applies.	**Enrollment Date, Reporting Organization, Enrolling Organization, Treating Organization**	X	N/A
NCI Data Table 4	Report design based on NCI CCSG (Cancer Center Support Guidelines) data guide. It displays the Disease Site and accrual data for a study. To pull the accruals by Disease Site, it looks at the value as defined in the Disease Site field on a study's "Summary" tab. Only the Date Range filter applies.	**Enrollment Date, Study Type, Reporting Organization, Research Type**	X	N/A

Note: For study or patient data to be included in either the NCI Data Table 3 or 4 reports, the checkbox for the field "CCSG Data Table 4 Reportable" needs to be checked on the study details tab of a study. For more information about this field and the Study Details tab, see Manage an Existing Study.

10.1.4.2 Biospecimen Reports

Biospecimen reports display storage, inventory and sample information using the eSample module.

Refer to the eSample User Guide for more information about this module.

Recommended Primary User(s): Study Coordinator

Benefits / Uses:

- Displays Inventory, Storage and Specimen reports
- Works exclusively with the eSample module

Enterprise Only: eSample is an optional add-on module for Velos eResearch Enterprise.

Available Reports:

The following reports are available within the Biospecimen library.

Report Name	Report Description	Report Date Filter Field	Enterprise	eXpress
Specimen Storage Association	Displays specimen storage association information.	**Date, Study, Storage, Organization**	X	N/A
Storage Capacity Discrepancy	Displays storage capacity available versus storage capacity used.	**Date, Storage**	X	N/A
Storage Status Discrepancy By Child Storage Status	Displays storage capacity available versus storage capacity used, organized by child storage status.	**Date, Storage**	X	N/A
Storage Summary	Summary of cataloged storage.	**Date, Storage**	X	N/A
Storage Trail & Occupancy	Displays a simple audit trail of storage use.	**Date, Storage**	X	N/A
Depleted Specimens	Displays specimens that have been depleted from processing.	**Date, Study, Organization**	X	N/A
Specimen Listing	Displays all catalogued specimens.	**Date, Study, Organization**	X	N/A
Specimen Listing with Calendar	Displays a list of specimen samples collected on a study with a calendar name.	**Date, Study, Organization**	X	N/A

Report Name	Report Description	Report Date Filter Field	Enterprise	eXpress
Specimen Processing History	Displays a history of all specimen processing.	**Date, Study, Organization**	X	N/A
Specimen Provider Association	Displays the association between specimens and providers.	**Date, Study, Organization**	X	N/A
Specimen Status History	Displays an audit trail of specimen statuses.	**Date, Study, Organization**	X	N/A
Specimen Trail (Non Study Specimens)	Displays an audit trail of non-study specimens.	**Date, Organization**	X	N/A
Specimen Trail (Study Specimens)	Displays an audit trail of study associated specimens.	**Date, Study, Organization**	X	N/A
Specimens by Patient	Displays the association between specimens and the patient from which they were collected.	**Date, Study, Organization**	X	N/A
Specimens by Study	Displays the association between specimens and the studies for which they were collected.	**Date, Study, Organization**	X	N/A

10.1.4.3 Custom Reports

Custom reports are built for specific client needs by the Velos eResearch team, and then deployed to the Custom Reports group within Report Central.

Benefits / Uses:

- Displays custom reports

Enterprise Only: Custom reports are only available in the Enterprise version of Velos eResearch.

10.1.4.4 Data Safety Monitoring Reports

The Data Safety Monitoring report type displays a study specific Study Enrollment by Race/Gender report for use by safety monitors and data managers.

Recommended Primary User(s): Monitors, Data Managers

Benefits / Uses:

- Displays information useful for data safety monitoring

Enterprise Only: Data Safety Monitoring reports are only available in the Enterprise version of Velos eResearch.

Available Reports:

The following report is available within the Data Safety Monitoring library.

Report Name	Report Description	Report Date Filter Field	Enterprise	eXpress
Study Enrollment by Race/Gender (Per Study)	Displays study accruals by race, ethnicity, and gender per the specified study.	**Enrollment Date, Study Number**	X	N/A

10.1.4.5 Financial Reports

Financial reports display accounting, invoicing, and budgeting information.

Recommended Primary User(s): Financial Manager, Account Administrator

Benefits / Uses:

- Displays financial records and information
- Can be used to audit invoice records
- Can be used to identify payment records
- Can be used to predict future costs and/or income based on, personnel, calendar budgets and coverage. To learn more about calendars in Velos eResearch, see Calendar Management.

Note: Additional Milestones are only displayed in the Additional Milestones report.

Available Reports:

The following reports are available within the Financial Reports library.

Report Name	Report Description	Report Date Filter Field	Enterprise	eXpress
Account Payable (By Milestone)	Displays achieved payable milestones with milestone, invoice, and reconciled details per the specified filters.	**Milestone Achieved Date, Study Number**	X	X
Account Receivable (By Milestone)	Displays achieved receivable milestones with milestone, invoice, and reconciled details per the specified filters.	**Milestone Achieved Date, Study Number**	X	X
Account Receivable (By Study)	Displays the overall milestone amount, holdback %, invoice amount, amount not invoiced, reconciled amount, and outstanding amount for achieved receivable milestones by study per the specified filters.	**Date, Study Number**	X	X
Additional Milestones	Displays the overall milestone amount, holdback %, invoice amount, amount not invoiced, reconciled amount, and outstanding amount for additional milestones by study per the specified filters.	**Date, Study Number**	X	X
Invoice Records (All)	Displays invoice details with reconciled paid amount and remaining balance per the specified filters.	**Invoice Date, Study Number**	X	X
Invoices – Aging Report	Displays invoice details with reconciled paid amount and amount overdue per the specified filters.	**Invoice Date, Study Number**	X	X

Report Name	Report Description	Report Date Filter Field	Enterprise	eXpress
Milestone Achievement Log (All)	Displays achieved milestone types with milestone details per the specified filters. The report has a column that lists the Financial Summary button for each milestone. The button displays the Financial > Open window for the study.	**Milestone Achieved Date, Study Number**	X	X
Payment Records (All)	Displays all payment type details per the specified filters.	**Payment Date, Study Number, Payment Type, Payment Mode**	X	X
Payments Made with Reconciliation	Displays the payments for the "made" type with amount reconciled details per the specified filters.	**Payment Date, Study Number**	X	X
Payments Received with Reconciliation	Displays the payments for the "received" type with amount reconciled details per the specified filters.	**Payment Date, Study Number**	X	X
Research Ticket Items (Per Patient)	Report listing the protocol specific events, CPT codes and charges by patient for a study.	**Date of Service Study Number, Patient ID**	X	N/A
Research Ticket Items (Per Study)	Report listing the protocol specific events, CPT codes and charges by patient for a study. **Note**: Data filter for Patient ID not available in this report.	**Date of Service Study Number**	X	N/A
Routine Care Events (Per Patient)	Report listing routine care events, CPT codes and charges by patient for a study.	**Date of Service, Study Number, Patient ID**	X	N/A
Routine Care Events (Per Study)	Report listing routine care events, CPT codes and charges by patient for a study. **Note**: Data filter for Patient ID not available in this report.	**Date of Service, Study Number**	X	N/A

Report Name	Report Description	Report Date Filter Field	Enterprise	eXpress
Budget Personnel Items	Displays budget personnel line item details per specified filters.	**Study Number**	X	X
Calendar Budget and Coverage (Active – Per Study)	Displays budget sections and line items with the cost details for active calendars per the specified filters.	**Study Number**	X	X
Calendar Budget and Coverage (WIP – Per Study)	Displays budget sections and line items with the cost details for work in progress calendars per the specified filters.	**Study Number**	X	X
Milestone Forecast Details	This report shows forecasted patient milestone details by study and provides the milestone description, type, and scheduled milestone date. This report can be generated to show this data for a selected study or studies, organization(s) user(s), division(s), therapeutic area(s), patient(s) and/or research type over a designated time period or for all data in the system.	**Date, Study Number, Organization, User, Division, Therapeutic Area, Patient, Research Type, Sponsor**	X	X
Milestone Forecast by Intervals	This report shows the number of forecasted milestones and amount by study for a specified date range. This report can be generated to show this data for a selected study or studies, user(s), division(s), therapeutic area(s), patient(s) and/or research type over a designated time period or for all data in the system.	**Date, Study Number, User, Division, Therapeutic Area, Research Type, Sponsor**	X	X

10.1.4.6 Patient Reports

Patient reports display patient status, schedule, and treatment ARM information.

Recommended Primary User(s): Study Manager, Principal Investigator

Benefits / Uses:

- Displays patient records and information
- Can be used to audit patient statuses and enrollment details
- Can be used to audit events completed, and events that were completed out of the specified window.
- Can be used to plan staff schedules vs patient schedules. To learn more about calendars in Velos eResearch, see Calendar Management.

Available Reports:

The following reports are available within the Patient Reports library.

Report Name	Report Description	Report Date Filter Field	Enterprise	eXpress
Patient Study Status (All Statuses)	Displays all patient study statuses for patient per specified filters.	**Patient Status Date, Enrolling Site Organization, Study Number**	X	X
Patient Study Status (Current Status Flag)	Displays the patient study status that has the current status flag checked per specified filters.	**Patient Status Date, Enrolling Site Organization, Study Number**	X	X
Patient Study Status (Most Recent Status)	Displays the patient study status with the most recent "status date" per specified filters.	**Patient Status Date, Enrolling Site Organization, Study Number**	X	X
Study Patients Demographics	Displays the patient demographic details per the specified filters.	**Enrollment Date, Enrolling Site Organization, Study Number**	X	X

Report Name	Report Description	Report Date Filter Field	Enterprise	eXpress
Study Patients Enrollment Details	Displays the patient enrollment status details per the specified filters.	**Enrollment Date, Enrolling Site Organization, Study Number**	X	X
Study Patients Status Grid	Displays the patient status grid with pre-defined statuses per the specified filters.	**Date, Enrolling Site Organization, Study Number**	X	X
Adverse Event Log	Displays adverse events by study per the specified filters.	**"Adverse Event" Start Date, Enrolling Site Organization, Study Number**	X	N/A
Adverse Event Overview (Per Study)	Displays graphs and tables for adverse event grades and types per the specified filters.	**"Adverse Event" Start Date, Enrolling Site Organization, Study Number**	X	N/A
Adverse Event Summary by Arm (Per Study)	Displays the grades by arm for serious adverse event and adverse events per the specified filters.	**"Adverse Event" Start Date, Enrolling Site Organization, Study Number**	X	N/A
Adverse Event Tracking (Per Study)	Displays type, attribution, and other attributions for study adverse events by organization per the specified filters.	**"Adverse Event" Start Date, Study Number**	X	N/A
Patient Current Schedule – Missed Events	Displays the missed events and lists the number of days past the scheduled date per the specified filters.	**"Event" Schedule Date, Enrolling Site Organization, Study Number**	X	X
Patient Current Schedule – Upcoming Events	Displays the upcoming events and list the number of days until it occurs based on the scheduled date per the specified filters.	**"Event" Schedule Date, Enrolling Site Organization, Study Number**	X	X
Patient Events Done Out of Window	Displays the events that were done outside the window per specified filters.	**"Event" Status Date, Enrolling Site Organization, Study Number**	X	X

Report Name	Report Description	Report Date Filter Field	Enterprise	eXpress
Patient Schedule (Current Schedule)	Displays all visits and events for the patient's current schedule per specified filters.	**"Event" Schedule Date, Enrolling Site Organization, Study Number**	X	X
Patient Schedule (Discontinued Schedule)	Displays events with the "not done" status for a discontinued schedule by patient per the specified filters.	**"Event" Schedule Date, Enrolling Site Organization, Study Number**	X	X
Patient Treatment ARM Log	Displays the patient treatment arms per the specified filters.	**"Treatment Arm" Start Date, Enrolling Site Organization, Study Number**	X	X
Study Form Response Query Count	Displays the forms that have query (s) with a count for each query status per the specified filters.	**Query Status Date, Enrolling Site Organization, Study Number**	X	N/A
Study Form Response Query Details	Displays the query details for each query per the specified filters.	**Query Status Date, Enrolling Site Organization, Study Number**	X	N/A
Study Patient Form Tracking	Displays patients with form responses and lists a count by form response status per the specified filters.	**Created On / Last Modified Date, Enrolling Site Organization, Study Number**	X	N/A
Patient Timeline (Per Study Patient)	Displays a chronological list of data entered for a patient per the specified filters.	**Data Entry Date, Enrolling Site Organization, Study Number**	X	X
Patient Visit Calendar (Per Study Patient)	Displays a patient schedule in a calendar format per the specified filters.	**"Event" Schedule Date, Enrolling Site Organization, Study Number**	X	X

10.1.4.7 Research Compliance Reports

Research Compliance reports display IRB submission and approval information.

Recommended Primary User(s): Study Coordinator

Benefits / Uses:

- Displays history of IRB submissions and approvals

Enterprise Only: Research Compliance reports are only available in the Enterprise version of Velos eResearch for use with the eCompliance module.

Available Reports:

The following reports are available within the Research Compliance Reports library:

Report Name	Report Description	Report Date Filter Field	Enterprise	eXpress
IRB Continuing Review	Displays IRB review information for studies per the specified filters.	**Date, Study**	X	N/A
IRB Protocol History	Displays an audit trail of IRB statuses for studies per the specified filters.	**Date, Study**	X	N/A
Study Submission History (All)	Displays an audit trail of IRB submissions per the specified filters.	**Date, Study**	X	N/A
Study Submission History (Current)	Displays all current IRB statuses per the specified filters.	**Date, Study**	X	N/A

10.1.4.8 Study Reports

Study reports display study information such as study status, admin schedule, and study visit calendars. Some study statuses are connected to specific report types. For a complete list, see Study Status Tab for more details study statuses connected to possible reports.

Recommended Primary User(s): Study Manager, Principal Investigator, Account Administrator

Benefits / Uses:

- Displays study records and information
- Can be used to audit study statuses and enrollment details
- Can be used to understand resource efforts required for past and future events
- Can be used to plan staff schedules vs admin schedules. To learn more about calendars in Velos eResearch, see Calendar Management.

Available Reports:

The following reports are available within the Study Reports library.

Report Name	Report Description	Report Date Filter Field	Enterprise	eXpress
Active Studies (by Current Status Flag)	Displays the studies with the "Active/Enrolling" or equivalent status marked as the current study status per the specified filters.	**Study Status Date, Enrolling Site Organization, Study Number**	X	X
Active Studies (by Timeframe)	Displays active studies per the specified filters.	**Date, Study Site Organization, Study Number, Division, Therapeutic Area, User- Principal Investigator**	X	X
Admin Schedule Event List	Displays study admin calendar details per the specified filters.	**"Event" Schedule Date, Study Number**	X	X
All Studies List	Displays all studies with details from the Study Summary page per the specified filters.	**Study Number**	X	X

Report Name	Report Description	Report Date Filter Field	Enterprise	eXpress
IRB Approval Expiration	Displays studies with an IRB approved status per the specified filters.	**Status Valid From Date, Study Site Organization, Study Number**	X	X
Resource Effort (Completed Events)	Displays patients with events that have a Role Type duration specified and the event status is done per the specified filters.	**“Event” Schedule Date, Organization, Study Number**	X	X
Resource Effort (Not Completed Events)	Displays patients with events that have a Role Type duration specified and are not done per the specified filters.	**“Event” Schedule Date, Organization, Study Number**	X	X
Study Status Key Metrics	Displays key study status dates and number of days to achieve the key study status per the specified filters.	**Study Number**	X	X
Study Status List (All)	Displays all study statuses per the specified filters.	**Study Status Date, Study Site Organization, Study Number**	X	X
Study Status List (Current)	Displays a study’s current status per the specified filters.	**Study Status Date, Study Site Organization, Study Number**	X	X
Study Summary Information	Displays data form the Study Summary page per the specified filters.	**Date, Study Number, Division, Therapeutic Area**	X	X
Study Summary Timeline	Displays studies most recent IRB approval, Open for Enrollment, Closed to Accrual, and Completed/Retired status per the specified filters.	**Date, Study Number, Division, Therapeutic Area**	X	X

Report Name	Report Description	Report Date Filter Field	Enterprise	eXpress
Study Team Members	Displays Study Team Members contact information and status per specified filters.	**Date, Study Number**	X	X
Study Status and Accrual Overview (Per Study)	Displays a bar graph and table by study statuses.	**Date, Study Number**	X	X
Study Visit Calendar (Per Study)	Displays study schedule in a calendar format listing all patients per the specified filters.	**"Event" Schedule Date**	X	X

10.1.4.9 System Administration Reports

System Administration reports display system data such as account users, access logs, and audit trails.

Recommended Primary User(s): Account Administrator

Benefits / Uses:

- Displays patient records and information
- Can be used to audit patient statuses and enrollment details
- A useful tool to ensure compliance and security at the account level

Available Reports:

The following reports are available within the **Administration Reports** library:

Report Name	Report Description	Report Date Filter Field	Enterprise	eXpress
All Account Users	Displays account user name, organization, specialty, group, phone number, email, and account status.	**Date**	X	X
Audit Trail	Displays the modification by module with study number, patient ID, modified on date, user, field, old value, and new value.	**Created On / Last Modified Date**	X	X

Report Name	Report Description	Report Date Filter Field	Enterprise	eXpress
Report Access Audit Log	Displays report access by module, format, when report was downloaded, user access data, and IP address.	**Date**	X	X
User Profile and Access	Displays a user's contact information, access rights, and notifications per the specified filters.	**Date, User**	X	X

10.2 Ad-hoc Queries (AHQ)

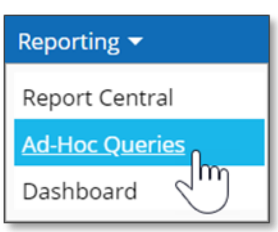
Ad-Hoc Queries (AHQ) allow permissioned users to create custom reports from:

- Key Velos eResearch datasets (e.g. – Study Status, patient demographics, etc.)
- User-created forms (forms created in Velos eResearch). See Forms Management for more information about forms.
- Defined form fields (Fields that are used in forms). See Field Library for more information about fields.

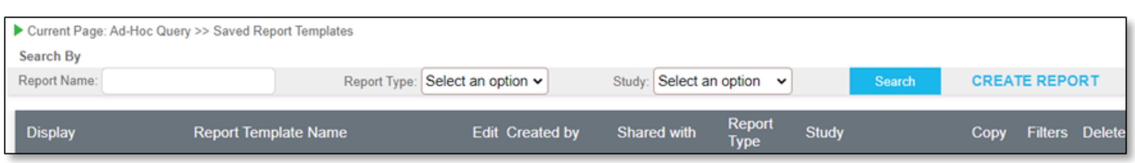
Note: An AHQ report displays raw data. AHQ do not have the functionality to perform calculations within the report.

To access the AHQ browser:

1. Click the **Reporting** menu and select **Ad-Hoc Queries**.



The Ad-hoc Queries browser displays:



Note: Report Templates can be sorted by clicking on a table header one time to sort descending, again to sort ascending, and again to remove the sort.

10.2.1 Create a New AHQ

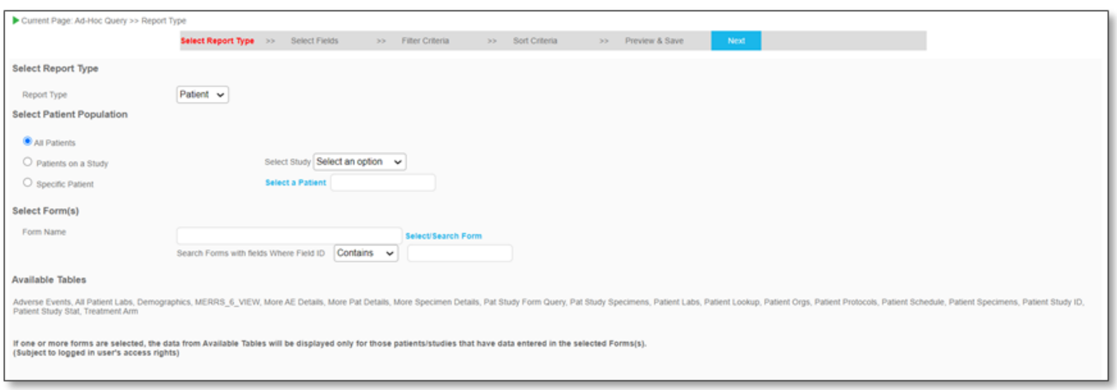
If a required Ad-hoc Query does not already exist in the Ad-hoc Queries browser, permissioned users can create new ad-hoc queries using the Reporting menu. Users can select from one of three report types when creating an Ad-Hoc Query:

- Study
- Patient
- Account

To create a new AHQ:

1. Navigate to the Ad-hoc Queries browser and click **Create Report** on the right side of the screen.

The Select Report Type page displays:



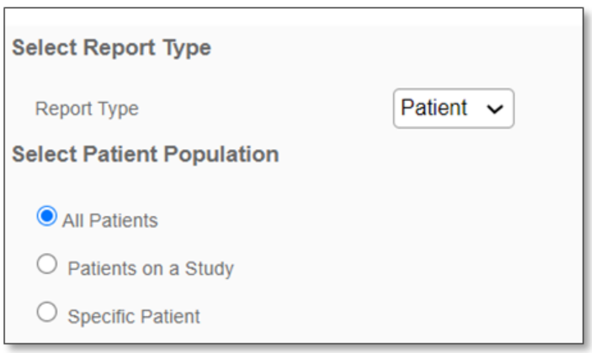
10.2.1.1 Select Report Type

There are three report types that can be selected when creating an Ad-hoc query, Study, Patient, and Account. Depending on which report type you select, the report will have access to different sets of data.

Report Category	Description	Radio Button - Additional Selection
Study	Pulls data associated with studies. (e.g. budgets, milestones achieved, study arms, etc.)	All Studies Specific Study- Select Study
Patient	Pulls data associated with patients. (e.g. Demographics, patient form data, etc.)	All Patients Patients on a Study- Select Study Specific Patient- Select Patient
Account	Pulls data associated with the entire account. (e.g. usage audit, groups, organizations, etc.)	N/A

To define the report:

1. Select the report type from the **Report Type** dropdown menu as either Study, Patient or Account.

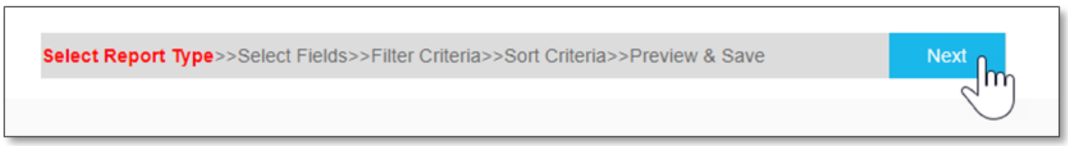


2. Click an applicable radio button to select a specific selection for the Report Type. [Refer to table above.]

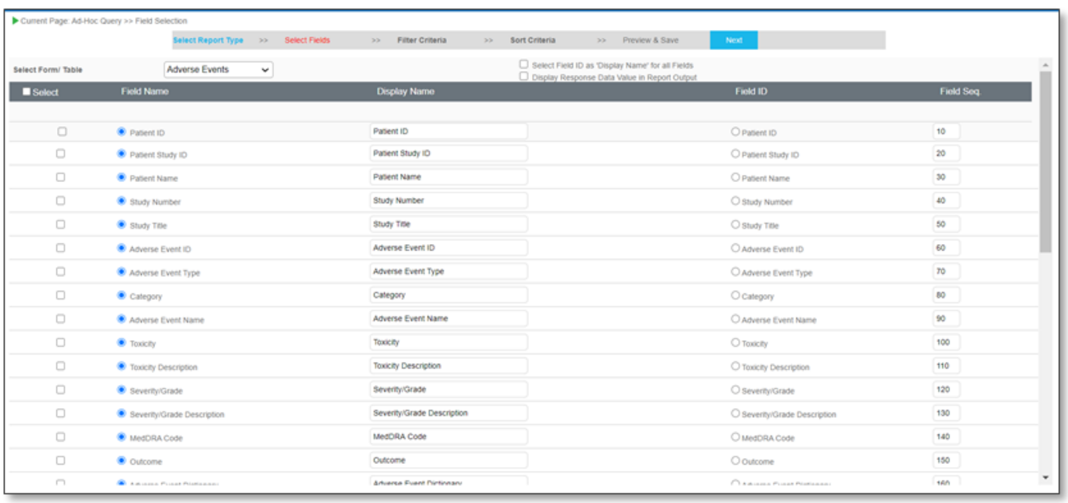
3. Continuing down the page, select the forms that you would like to base this report on, if any.

> **Note:** You can further refine your report criteria by asking the report query to search forms with specific field IDs, using the option below the form search field.

4. Click **Next** to continue.



The Select Fields page displays:

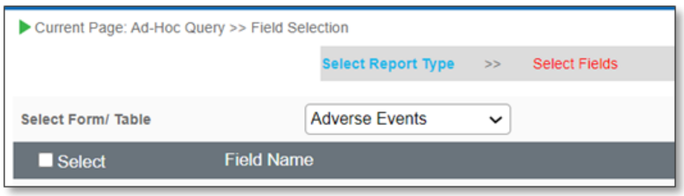


10.2.1.2 Select Fields

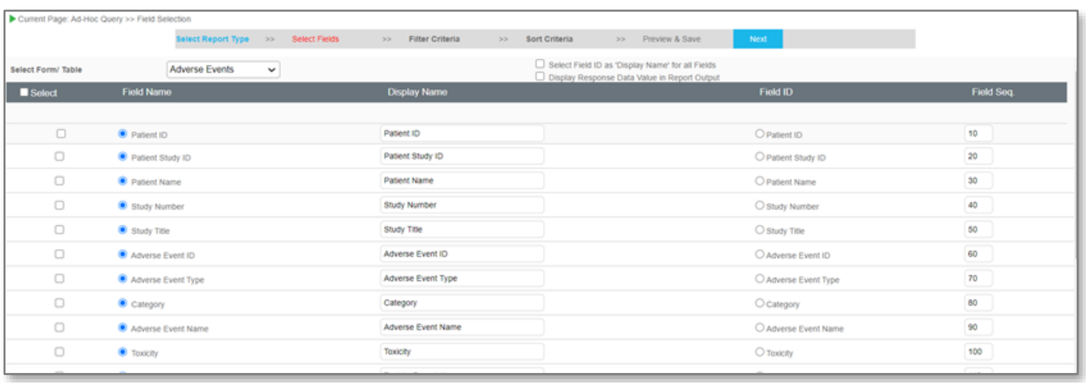
Next, define the specific fields that will be used feed the report data output.

To select fields for a report:

1. Choose a Form or Table to derive fields for selection by clicking on the dropdown menu next to **Select Form/Table**.



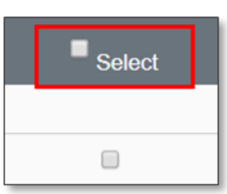
2. Select the specific field(s) you would like to be included in the report, if any, by clicking the checkbox next to the field(s) in the **Select** column. Any fields from the form you selected in the previous step will display at the bottom of this page, organized by form section.



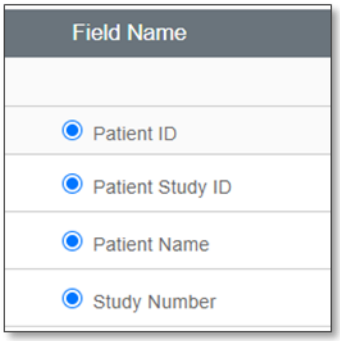
Note: The Field Seq column is used for sequencing the Field Names in the report. The smallest sequential number will be the first column shown in the report.

-OR-

Select the all available fields by clicking the checkbox next to **Select** in the Select column.

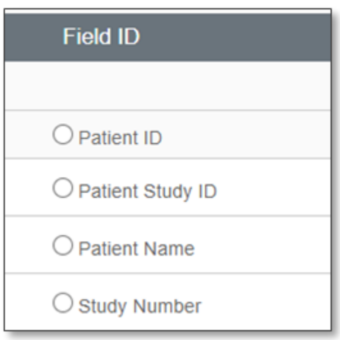


3. If you would like the **Field Name** value to display in the report for a field, click the radio button next to the field name.

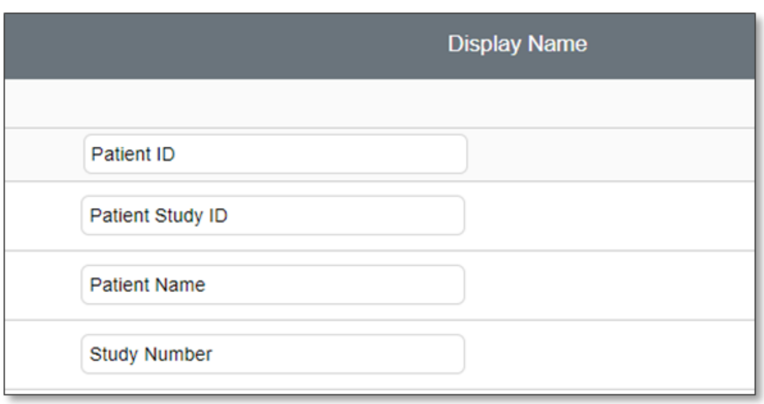


-OR-

If you would like the **Field ID** value to display in the report for a field, click the radio button next to the Field ID.

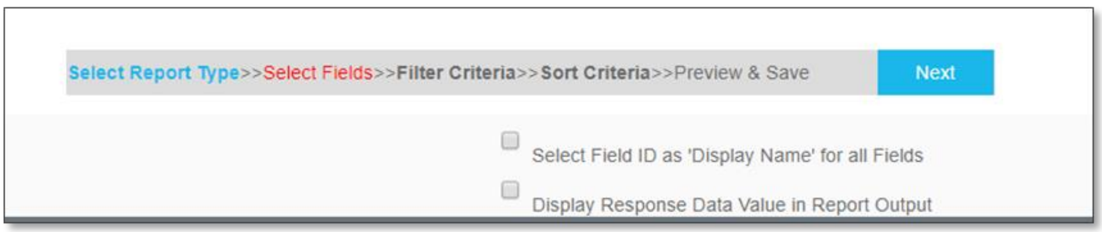


4. If you would like to customize the **Display Name** for the field, modify the text in the Display Name field. By default, the Display Name will always match the Field Name.

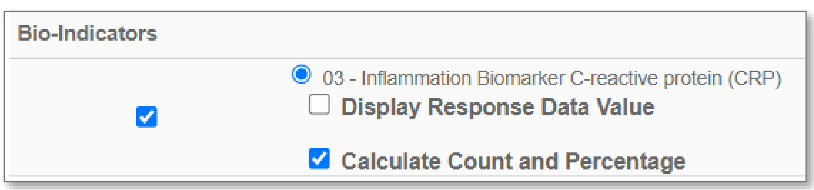


5. If desired, you may determine if you would like the Field ID to display in the report for all fields in lieu of the field name in the Display Name section of the report by clicking the checkbox at the top of the screen.

6. If desired, you may also determine if you would like to display the specific response data value in the report by clicking the checkbox at the top of the screen.



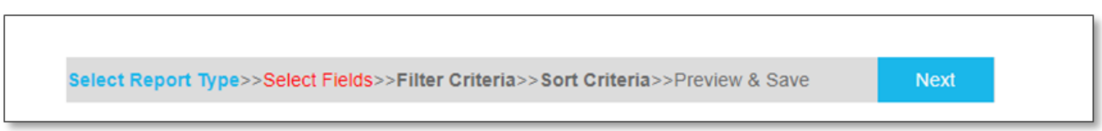
   a. Additionally, instead of checking the checkbox above to display *all* fields with the ability to show display response values, check an individual field's checkbox for Display Response Data Value for only the specific field.



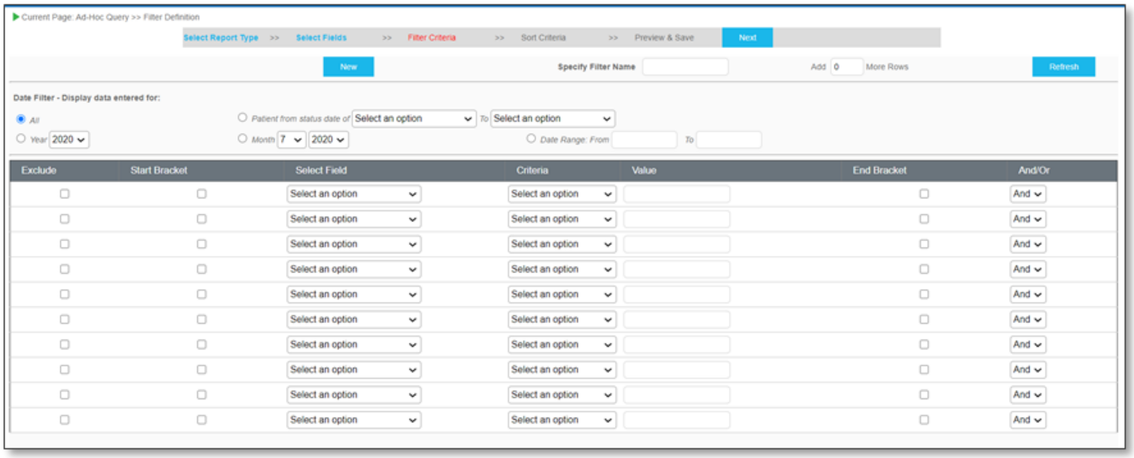
   -OR-

   b. Select the checkbox for Calculate Count and Percentage.
      - This option will summarize the data at the top of the report after creation

7. Click **Next** to continue.



The Filter Criteria page displays:



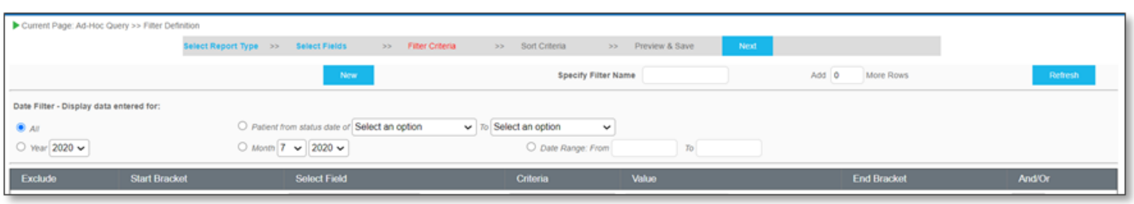
10.2.1.3 Select Filter Criteria

Next, define the filter criteria that will be used restrict and define the data that displays in the report.

Note: Filters cannot be deleted from this page. Refer to View and Delete Filters applied to an AHQ for more information.

To define the filter criteria:

1. Select the **Date Filter** criteria, and data-based filters by selecting the options within the fields at the bottom of the page. Selecting the **Exclude** checkbox removes the information filtered from the report.



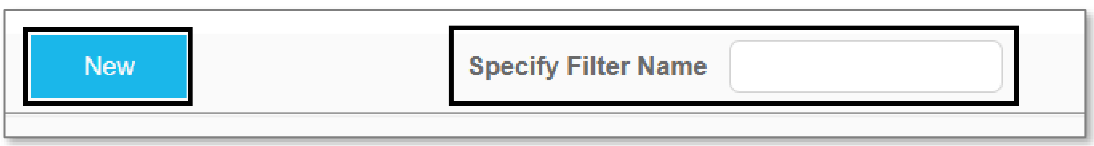
- Selecting Exclude does not mean to include all data excluding the specified criteria

Note:

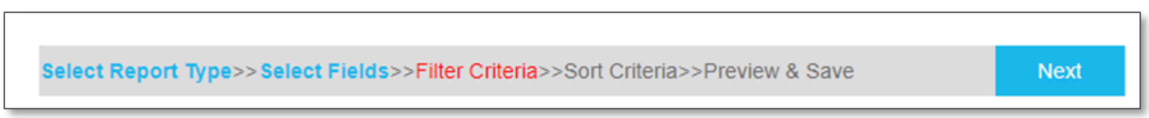
2. Use the Start Bracket and End Bracket to create conditional filters. The Start Bracket indicates the beginning of the filter definition, and the End Bracket indicates the end of the filter definition. In most cases brackets are not needed but an additional option.
3. Selecting "And" means the filter should match all of the criteria in this row and the next.
4. Selecting "Or" means the filter should match any of the criteria in this row and the next.

2. If you need to add additional filter logic rows, enter the number of new rows you need in the **Add More Rows** field and click **Refresh**.

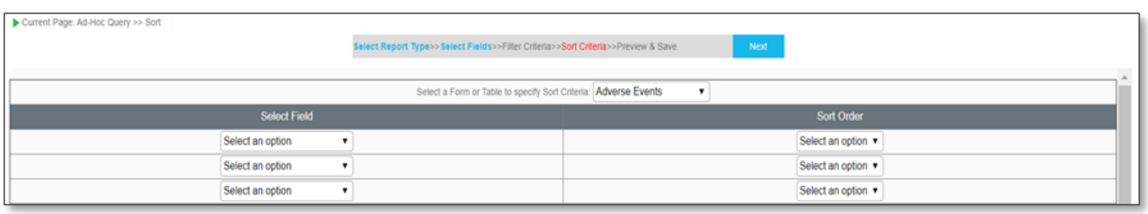
3. Enter a name for the filter in the **Specify Filter Name** field and click **New**.



4. Click **Next** to continue.



The Sort Criteria page displays:

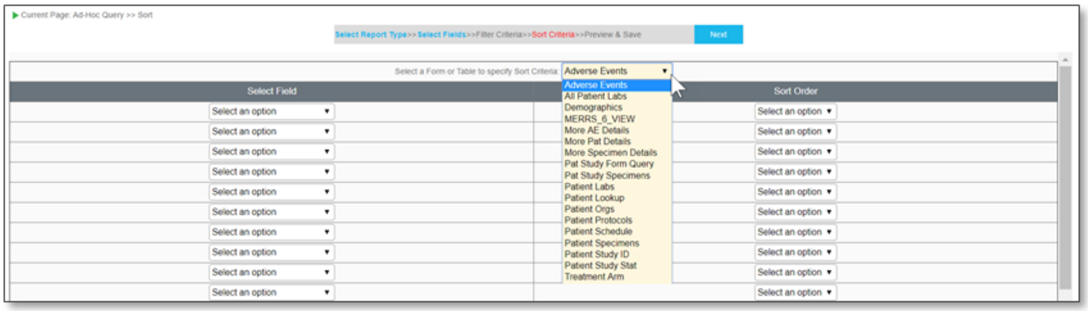


10.2.1.4 Define Sort Criteria

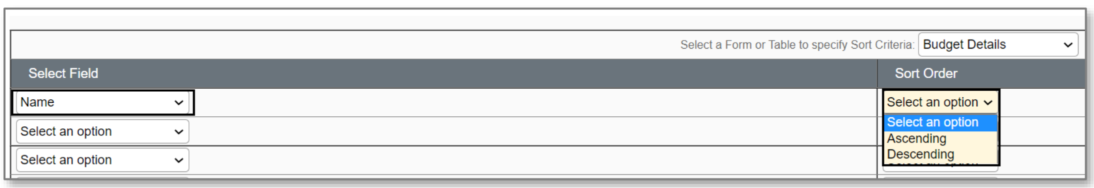
Next, define the sort criteria that will be used to determine the order in which the data is displayed in the report for a selected header.

To define the sort criteria:

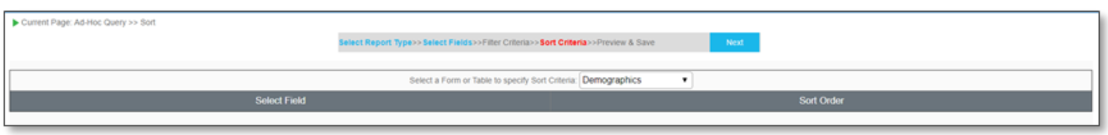
1. Select a form or table to specify the sort criteria by selecting an option within the dropdown menu at the top of the page.



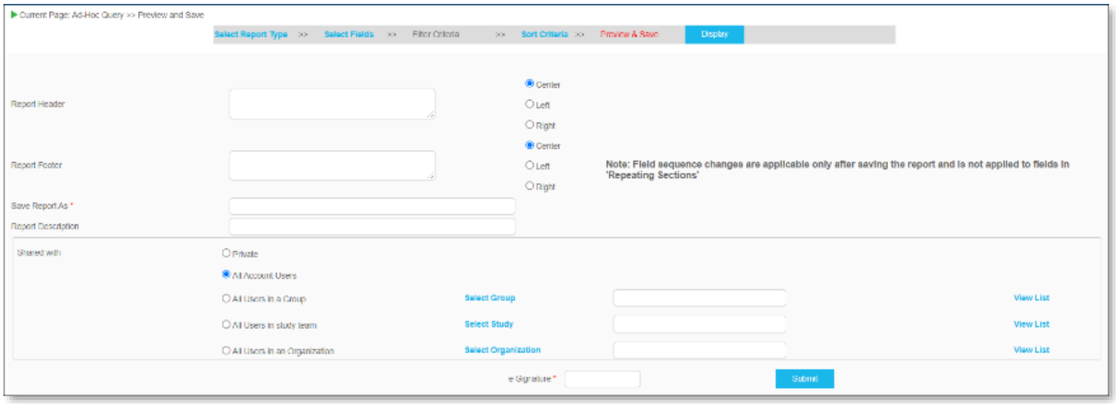
2. Select a data field within the **Select Field** column and determine if the data should be sorted in an **Ascending** or **Descending** order in the **Sort Order** column.



3. Click **Next** to continue.



The Preview & Save page displays:



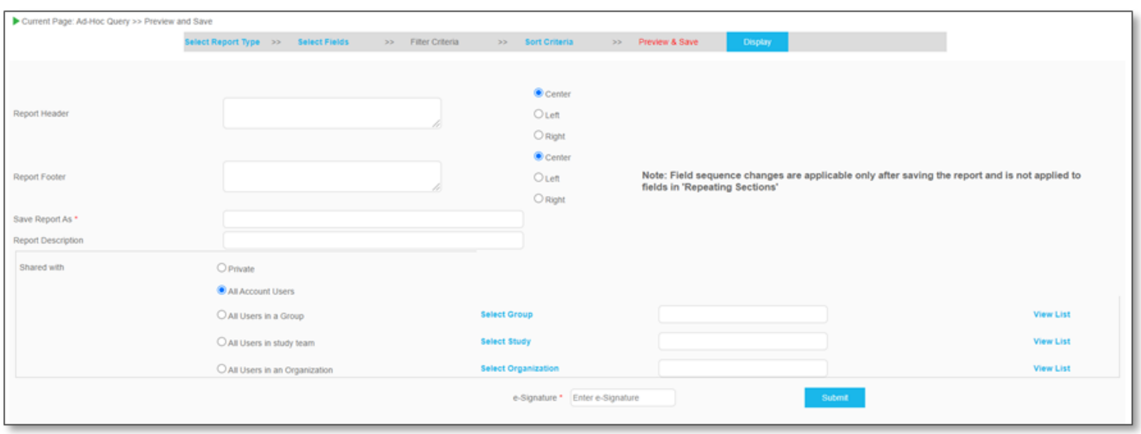
10.2.1.5 Preview & Save

Finally, enter the report filename, header/footer, and sharing details. After establishing these settings, and saving the report, you can preview the report.

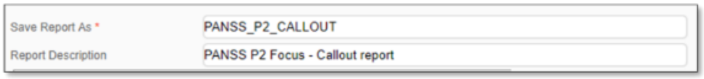
Note: Reports can be previewed without entering data in the last step for Ad-Hoc Queries, if the user intends to only preview the report and exit without saving.

To preview and save the report:

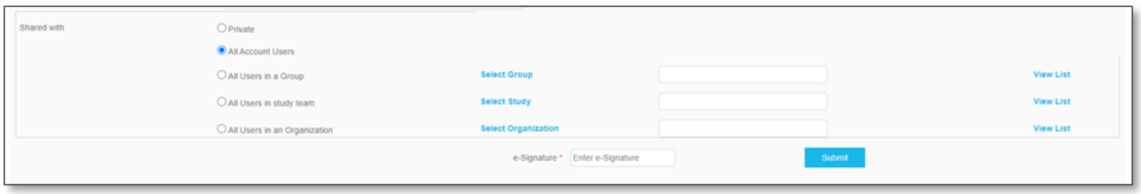
1. Enter the **Report Header** and **Report Footer** text, and their alignment using the available fields.



2. Enter the filename that the report will output as, and a description of the report. The description will be how the report displays in the Ad-hoc queries browser.



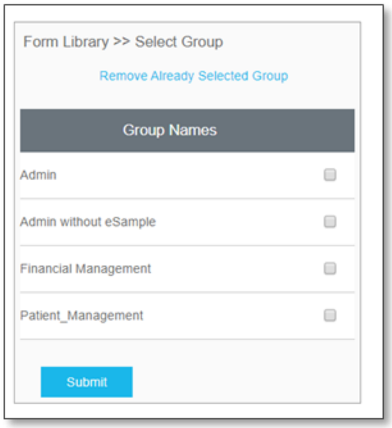
3. Define how the report should be shared. Use the table below as a guide.



See the table below for definitions of each share category:

Category	Definition
Private	Hidden from all users in the system.
All Account Users	Available to all system users with access to the Ad-hoc Query tool. However, if the user does not have access to the defined study, patient, or form for the report, then no data will display when the user runs the report.
All Users in a Group	Available to all system users in a group. For more information about groups, see Groups.
All Users in a Study Team	Available to all system users in a study. For more information about studies, see Study Management.
All Users in an Organization	Available to all system users in an organization. For more information about organizations, see Organizations.

4. If you select the option **All Users in a Group**, click the **Select Group** link, and select a group or multiple groups using the selection window that displays. Click **Submit**.



-OR-

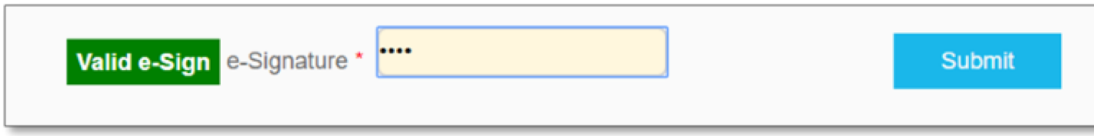
If you select the options **All Users in a Study Team** or **All Users in an Organization**, follow the same steps above by clicking either the **Select Study** or **Select Organization** links.

5. Click **View List** to view all users who will have access to the report based on your group, study or organization selections.

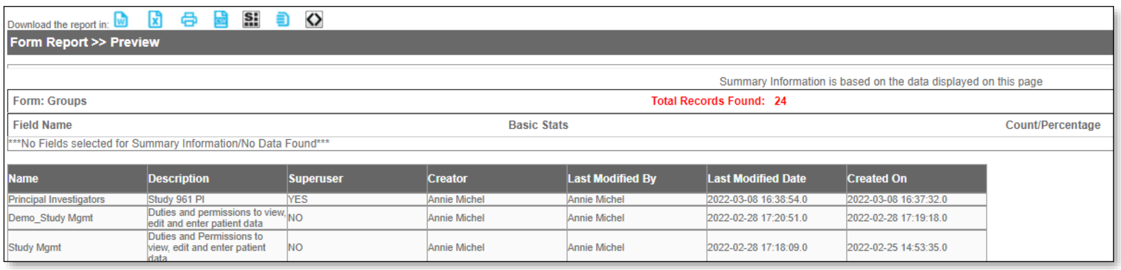
Warning: If you share this report with a group, user, or organization to which you do not belong, you will not be able to see the report in the Ad-hoc Queries browser after you have saved it and leave the AHQ creation page.

6. To preview the report, click **Display**.

7. After filling in the required information, enter your e-Signature and click **Submit** to confirm.



The report displays in a new window or tab:

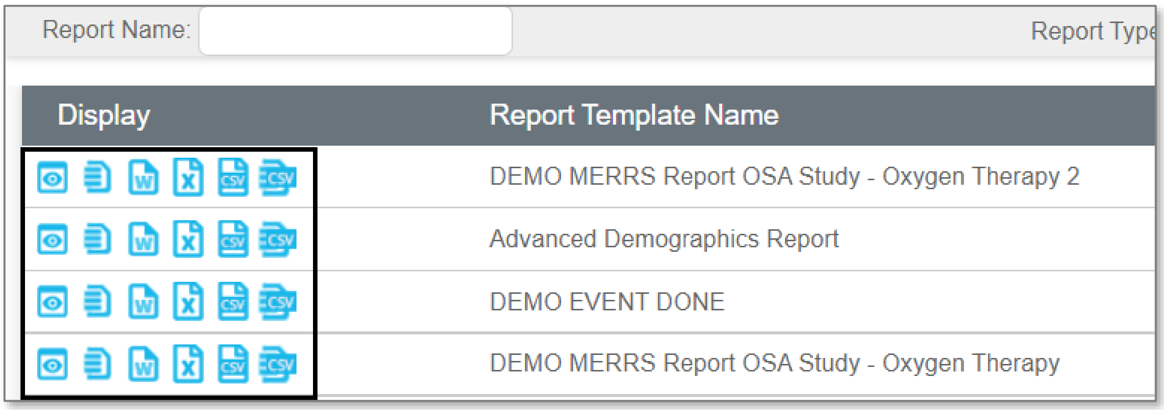


10.2.2 Display and Export an AHQ

From the Ad-hoc Queries browser you can display or export any reports available to you based on share or security settings. Permissioned users can display the report in normal or linear format, export to a Microsoft Word document, or a Microsoft Excel spreadsheet. When the Display Report icon is clicked the most up-to-date data will be displayed. There is no need to create a new Ad-Hoc Query when the most current data needs to be viewed.

To display or export a report from the Ad-hoc Queries browser:

1. Navigate to the Ad-hoc Queries browser.
2. Click directly on one of the display buttons located in the display column of the specific Ad-hoc Query.



Icon	Name	Description
	Display Report	Displays the report results.
	Display Report in Linear Format	Displays the report results in a linear format.
	Export to Word	Exports the report to a Microsoft Word document.
	Export to Excel	Exports the report to a Microsoft Excel spreadsheet.
	Export to CSV CSV Format	Exports to a CSV Format spreadsheet.
	Export to CSV CSV Linear Format	Exports to a CSV Linear Format spreadsheet.
	SAS Export	Exports an SAS readable database file. **Note**: This export type is only accessible by first clicking on **Display Report**.

10.2.3 Modify an Existing AHQ

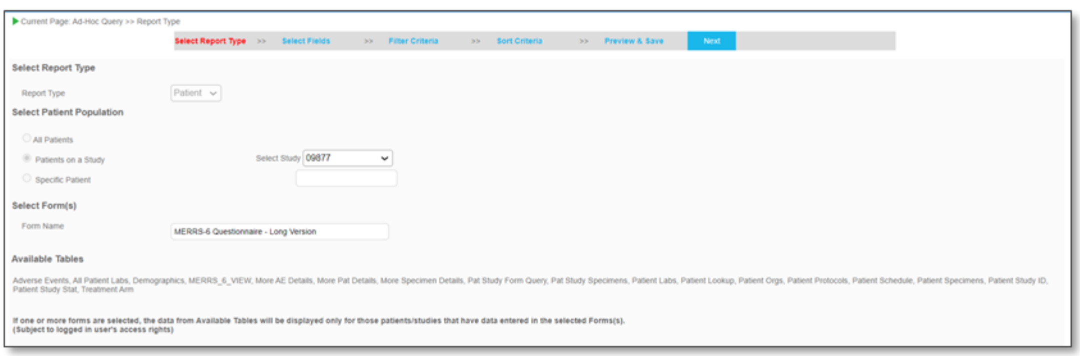
From the Ad-hoc Queries browser you can modify any reports available to you based on share or security settings.

Note: The Report Type, Study, Group, and Patient Population attributes cannot be modified.

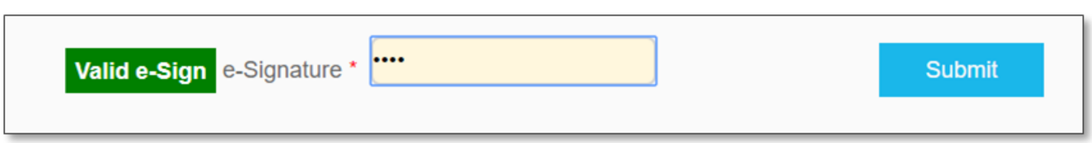
To modify an existing ad-hoc query:

1. Navigate to the Ad-hoc Queries browser.
2. Click directly on the **Edit** button located in the Edit column of the specific Ad-hoc Query.

The Select Report Type page displays:



3. Edit report fields and parameters as described in Create a New AHQ.
4. After modifying the required settings and/or information, enter your e-Signature and click **Submit** to confirm to save the report on the Preview & Save page.

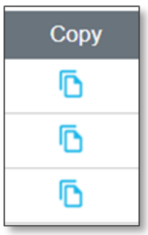


10.2.4 Copy an Existing AHQ

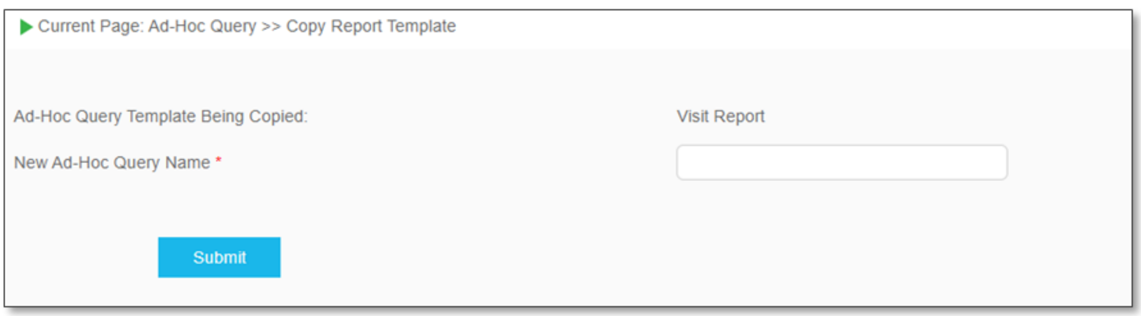
From the Ad-hoc Queries browser you can copy any reports available to you based on share or security settings.

To copy an existing ad-hoc query:

1. Navigate to the Ad-hoc Queries browser.
2. Click directly on the **Copy** button located in the Copy column of the specific Ad-hoc Query.



3. A new page displays, asking you to enter a **New Ad-Hoc Query Name** for the copied report. Enter a new name into the available field and click **Submit** to confirm.



The new report displays in the Ad-hoc Queries browser.

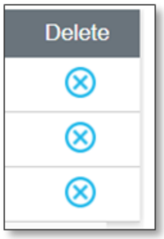
Note: After copying a report, you will most likely want to make modifications to the copy. See Modify an Existing AHQ for more information on how to modify an AHQ.

10.2.5 Delete an AHQ

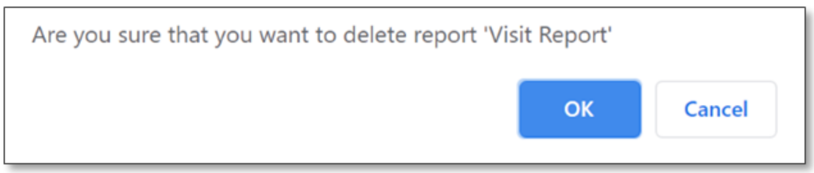
From the Ad-hoc Queries browser you can delete any reports available to you based on share or security settings.

To delete an existing ad-hoc query:

1. Navigate to the Ad-hoc Queries browser.
2. Click directly on the **Delete** button located in the Delete column of the specific Ad-hoc Query.



3. A notification displays, asking you to confirm the deletion. Click **OK** to proceed.



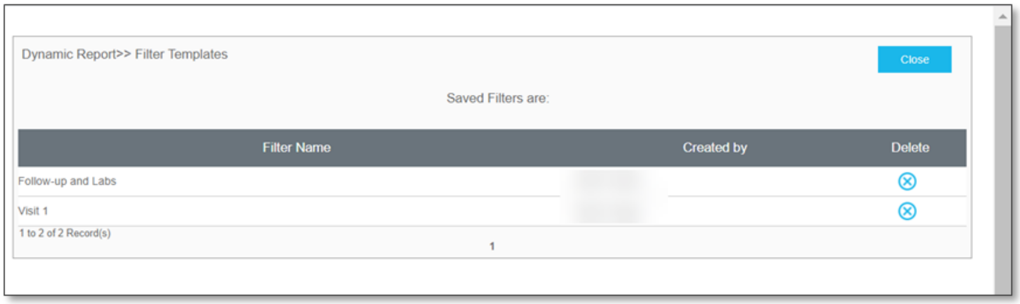
10.2.6 View and Delete Filters applied to an AHQ

From the Ad-hoc Queries browser you can view filters applied to reports available to you. The specific reports you see in the Ad-hoc Queries browser are based on the established share or security settings in your system.

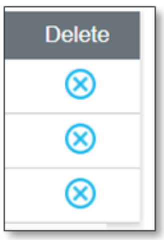
To view and delete filters applied to an existing ad-hoc query:

1. Navigate to the Ad-hoc Queries browser.
2. Click directly on the **Filter** button located in the Filters column of the specific Ad-hoc Query.

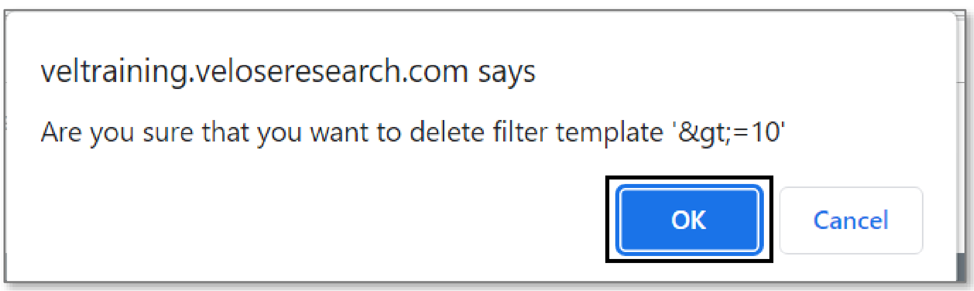
The applied filters display in a new window.



3. Click directly on the **Delete** button located in the Delete column of the specific filter.



4. A notification displays, asking you to confirm the deletion. Click **OK** to proceed.



The filter has been removed from the Ad-hoc Query.

10.3 Dashboard

Velos eResearch Enterprise provides a means to monitor and perform data management activities for a study using the Dashboard tool. The Dashboard tool allows permissioned users to monitor key data in the following three areas:

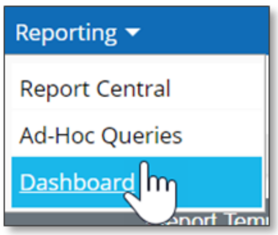
- Form entries
- Adverse events
- Patient study status

The Dashboard tool allows permissioned users to review data entries, open queries on specific data-entry fields, correct data, and resolve open queries.

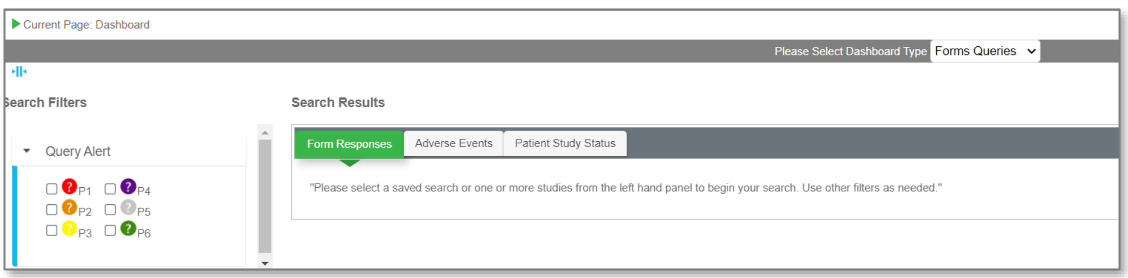
Enterprise Only: The Dashboard tool is only available in the Enterprise version of eResearch.

To access the Dashboard tool:

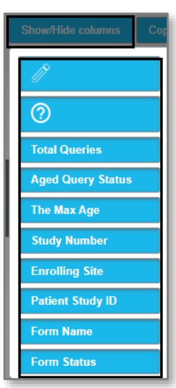
1. Click the **Reporting** menu and select **Dashboard**.



The Dashboard tool displays:



   a. If you do not see all columns shown in the above image, or if you wish to add or remove columns in your view, click **Show/Hide Columns**.



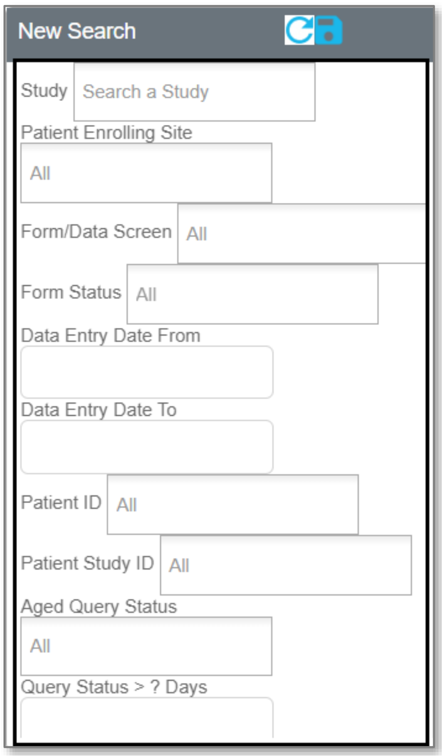
   b. Then click each applicable header name in the dropdown to add or remove headers from the table as needed.

10.3.1 Search Results Panel

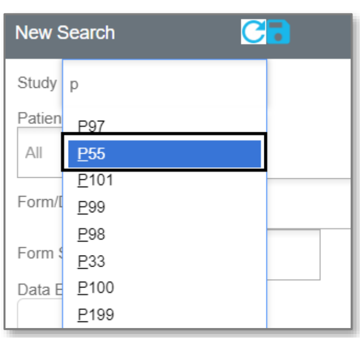
The Dashboard tool allows permissioned users to access Form Responses, Adverse Events, and Patient Study Status information by study. Before reviewing any data, however, one must first perform a study search.

To perform a dashboard study search:

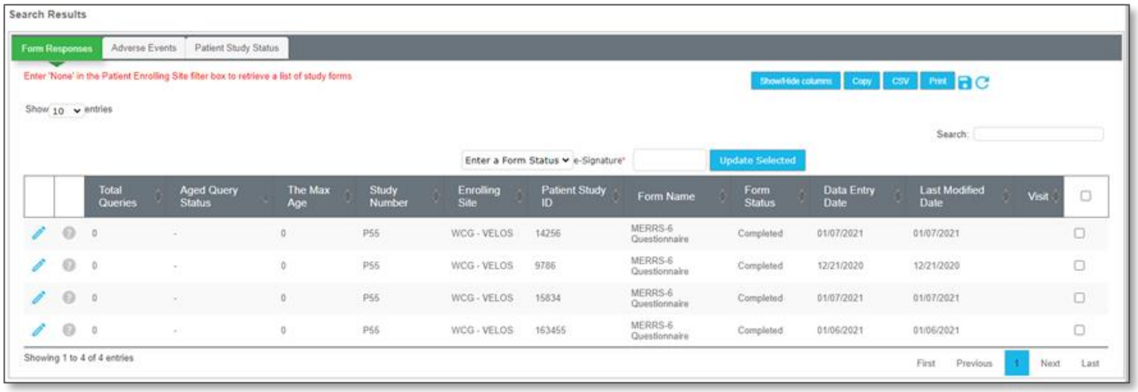
1. Locate the “New Search” panel in the lower left corner of the screen.



2. Enter your search criteria in the **Study** field. A partial search will display results as well.



3. When the study you are searching for appears in the drop-down menu, click that option.



After selecting your study, all form response, adverse event, and patient study status items will display (if available) in the search results panel, under each respective tab.

See the following sections to learn how to access and review data entries from each functional area of the Dashboard tool:

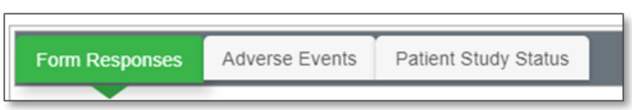
- Access Form Responses
- Access Reported Adverse Events
- Access Patient Study Status
- Reset or Save Searches

10.3.1.1 Access Form Responses:

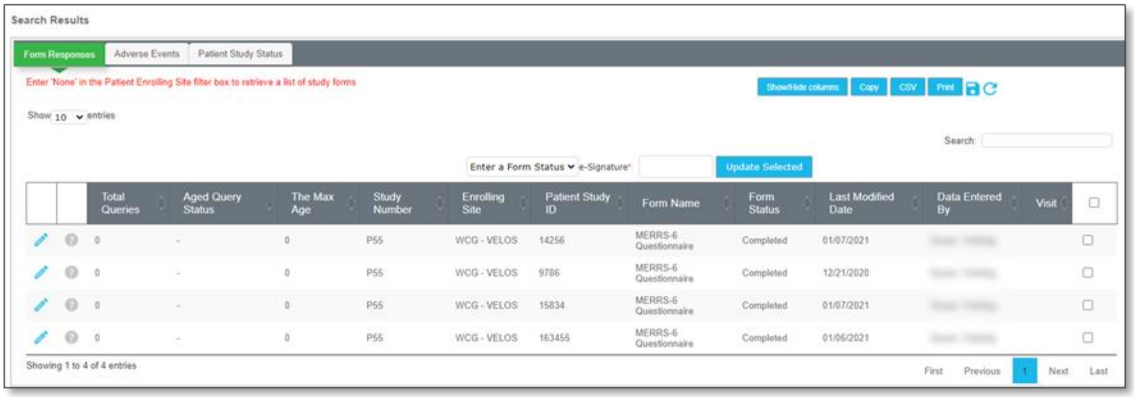
Permissioned users can access form responses by study using the Dashboard tool.

To access form responses:

1. After performing a valid study search, click the **Form Responses** tab in the Search Results panel.



The list of available form responses displays.



Each entry displays the following information:

- **Total Queries**: Displays the total number of queries associated with this form response.
- **Aged Query Status**: Displays the status of the oldest query associated with this form.
- **The Max Age**: Displays the age (in days) of the oldest query associated with this form.
- **Study Number**: Displays the study number that the form response was collected through.
- **Enrolling Site**: Displays the site that enrolled the patient associated with this form response.
    - For Form response View, provide the filter details for different types of forms. For Ex: Select 'None' in Patient enrolling site to view Study forms and select Organization name in Patient enrolling site to view Study patient form responses.
- **Patient Study ID**: The patient study ID of the patient associated with this form response.
- **Form Name**: Name of the form used to generate this form response.
- **Form Status**: Current status of the form used to generate this form response.
- **Data Entry Date**: Initial date that form response was entered.
- **Last Modified Date**: Displays a time stamp indicating the last time this form response was modified.
- **Data Entered By**: Displays the user for who entered the data.
- **Visit:** Displays the visit (if any) associated with the form used to generate this response.

Note:

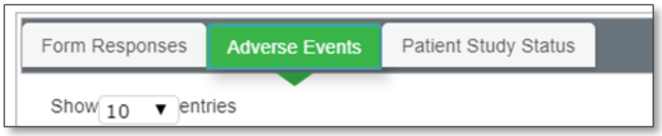
1. Additional fields may be available in the Show/Hide columns button dropdown options.
2. Clicking the Edit button allows permissioned users to revise data or generate queries for the associated entry. Proceed to Response View to learn more about revising data and managing queries.

10.3.1.2 Access Reported Adverse Events:

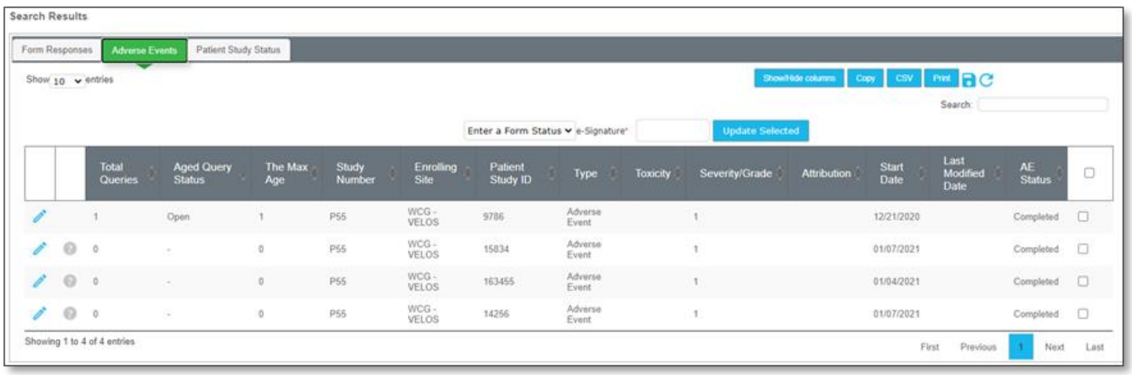
Permissioned users can access all recorded Adverse Events by study using the Dashboard tool.

To access reported adverse events:

1. After performing a valid study search, click the **Adverse Events** tab in the Search Results panel.



The list of available adverse event entries displays:



Each entry displays the following information:

- **Total Queries**: Displays the total number of queries associated with this adverse event.
- **Aged Query Status**: Displays the status of the oldest query associated with this adverse event.
- **The Max Age**: Displays the age (in days) of the oldest query associated with this adverse event.
- **Study Number**: Displays the study number that the adverse event was reported through.
- **Enrolling Site**: Displays the site that enrolled the patient associated with this adverse event.
- **Patient Study ID**: The patient study ID of the patient associated with this adverse event.
- **Type**: Displays either "Adverse Event" or "Serious Adverse Event".
- **Toxicity**: Displays the toxicity (if any) associated with this adverse event.
- **Severity/Grade**: Displays the severity grade for this adverse event.
- **Attribution**: Displays the attribution value (if any) associated with this adverse event.

- **Start Date**: Displays the date that the adverse event was reported to have begun.
- **Last Modified Date**: Displays a time stamp indicating the last time this adverse event was modified.
- **AE Status**: Displays the current status of this adverse event.

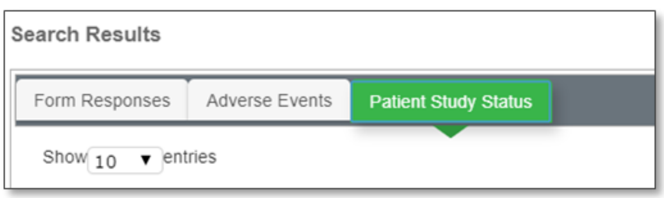
> **Note:** 1. Additional fields may be available in the Show/Hide columns button dropdown options.
> 2. Clicking the Edit button allows permissioned users to revise data or generate queries for the associated entry. Proceed to Response View to learn more about revising data and managing queries.

10.3.1.3 Access Patient Study Status:

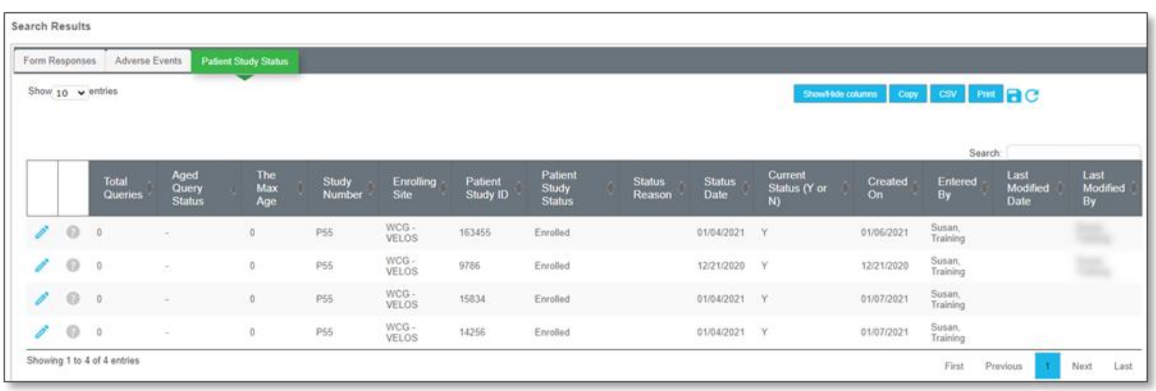
Permissioned users can access Patient Study Statuses using the Dashboard tool.

To access patient study statuses:

1. After performing a valid study search, click the **Patient Study Status** tab in the Search Results panel.



The list of available patient study status entries displays:



Each entry displays the following information:

- **Total Queries**: Displays the total number of queries associated with this form response.
- **Aged Query Status**: Displays the status of the oldest query associated with this form.
- **The Max Age**: Displays the age (in days) of the oldest query associated with this form.
- **Study Number**: Displays the study number that the form response was collected through.
- **Enrolling Site**: Displays the site that enrolled the patient associated with this form response.
- **Patient Study ID**: The patient study ID of the patient associated with this form response.
- **Patient Study Status**: Displays the patient study status that generated this entry.
- **Status Reason**: Displays the provided reason (if any) that the status was changed.
- **Status Date**: Displays the effective date of the status.
- **Current Status (Y or N)**: Displays a Y or N value to indicate if this entry is the patient's current status.
- **Created on**: Displays the date that the status was created.
- **Entered By**: Displays the name of the system user who entered/changed the patient study status.
- **Last Modified Date**: Displays a time stamp indicating the last time the patient status was modified.
- **Last Modified By**: Displays name of user who last modified the Patient Study Status data.

Note: Clicking the Edit button allows permissioned users to revise data or generate queries for the associated entry. Proceed to the Response View to learn more about revising data and managing queries.

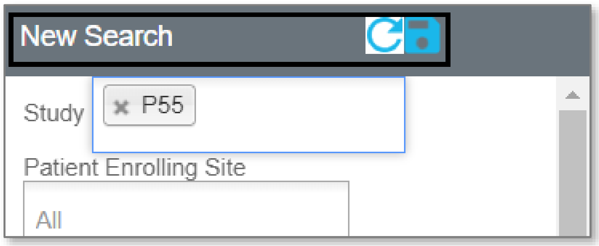
10.3.1.4 Reset or Save Searches

After searching a search can be reset. Also, it is possible to save time and maintain consistency by saving study searches using the Dashboard tool. To save a search, permissioned users must first perform a study search, as described in Search Results Panel.

Note: Saved searches are unique to each dashboard functional area. In other words, there will be a different collection of saved searches each for Form Responses, Adverse Events, and Patient Study Status.

To reset a search within the Dashboard tool:

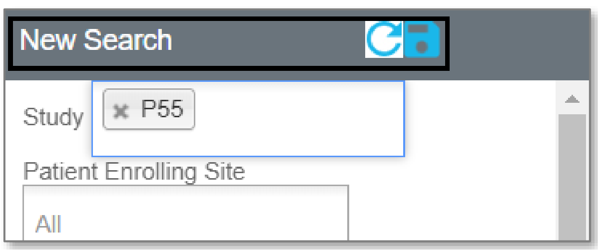
1. Search for a study in the New Search panel.



2. Click the **Reset** button in the New Search panel, to reset and start again.

To save a search within the Dashboard tool:

1. Search for a study in the New Search panel.

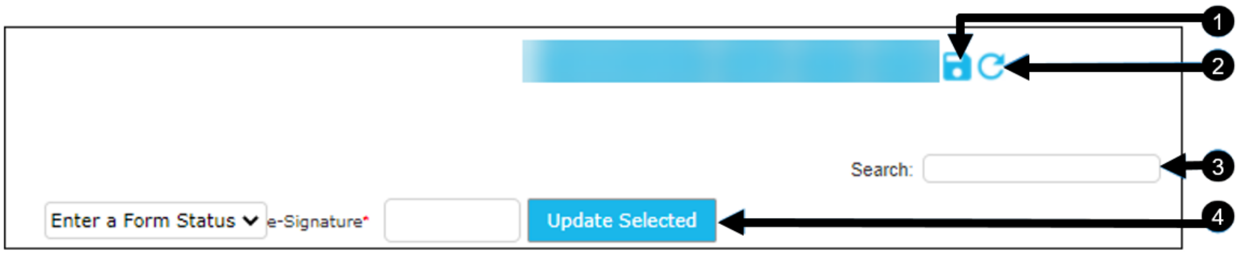


2. Click the **Save** button in the New Search panel.

3. Enter a search name in the **SAVE AS** field and click **Save**.

10.3.1.5 Save View, View Refresh, View Search, and Update Selected Options

Additionally, Dashboard users may save a view for a study, refresh the data, search for data in a view, or update selected data by form status.



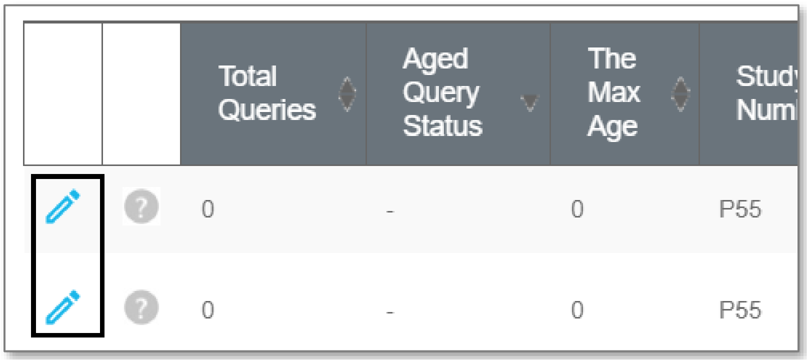
1. **Save View**: To save the view, click this button. When returning to view the specific study, the view saved is what will appear, including the specific tab shown when the view is saved. Also, if navigating away from the page and returning, the saved view is what will first appear, however, navigating to other tabs will show blank data and a study will need to be searched for in the Results Panel.
2. View **Refresh**: After applying a search to the view or sorting a header, click this button to refresh the data to the original view for the tab being viewed.
3. View **Search**: To search in a view, enter data into a Search field and the table for that view will update automatically. Click the x next to the search in order to remove the search or move to another tab and the search will be removed. Applying a search to one tab will not apply it to the other tabs.
4. **Update Selected**: If available, select a Form Status from the dropdown, after checking the checkboxes for appropriate rows, enter your e-Signature and click **Update Selected**, to update all checked Queries in the Form Responses tab or the Adverse Events tab to the selected Form Status. This does not apply to the Patient Study Status tab.

10.3.2 Response View

The Response View screen of the Dashboard tool allows permissioned users to view, edit, or open queries for selected form responses, adverse event entries, and patient study statuses. The Response View screen allows safety data monitors, data managers, or users tasked with data oversight a means to review, and as needed, call out incorrect, inconsistent, or otherwise questionable entries that need to be corrected.

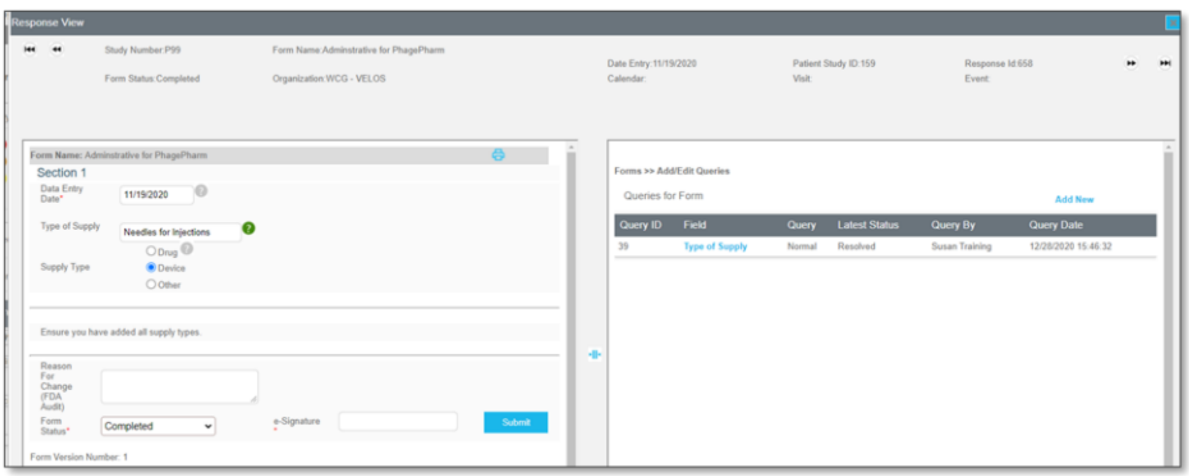
To open the Response View for a selected form response, adverse event entry, or patient study status:

1. Click the **Edit** button in the first column of any form response, adverse event, or patient study status entry.



Note: For more information about accessing the form response, adverse event or patient study status tabs, see Search Results Panel.

The Response View displays:



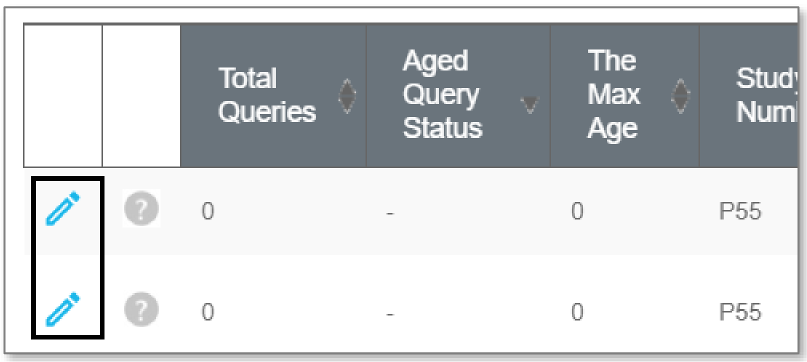
- The response view for each entry type (form responses, adverse events, and patient study status) displays two panels. The first panel is the original form, adverse event, or patient study status page. The second panel is the queries panel, which displays any queries that have been opened for this entry.

10.3.2.1 Revise Data

Depending on your specific processes, you may be required to both monitor data integrity and make the necessary corrections. In Velos eResearch Enterprise, the Dashboard tool allows you to do both, most notably, making virtually any data change necessary to the original form entry in an efficient manner. Data revision from the Dashboard tool can only be done in the Response View. For more information about how to access the response view, see Response View.

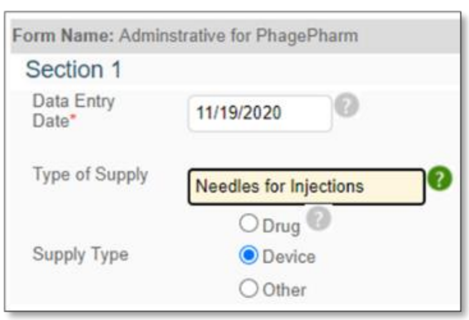
To revise data:

1. Navigate to the response view of any form response, adverse event, or patient study entry by clicking **Edit** button.

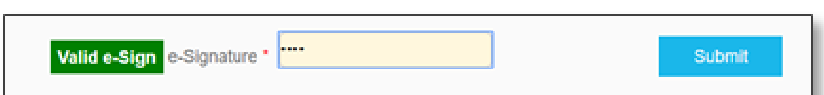


The response view displays. The entry details as they were entered originally display on the left side of the response view page.

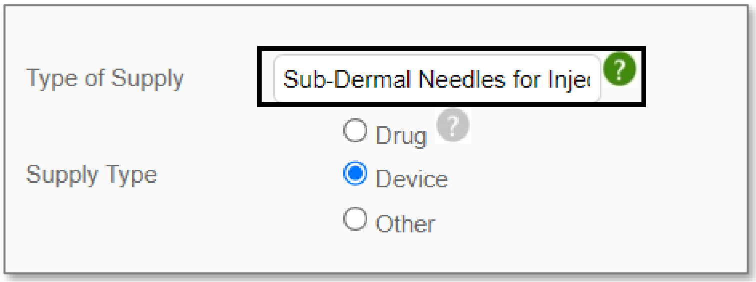
2. Revise any data entry field as required.



3. Enter your e-Signature and click **Submit** to confirm.



The data revision is saved and the corrected entry is now displayed:

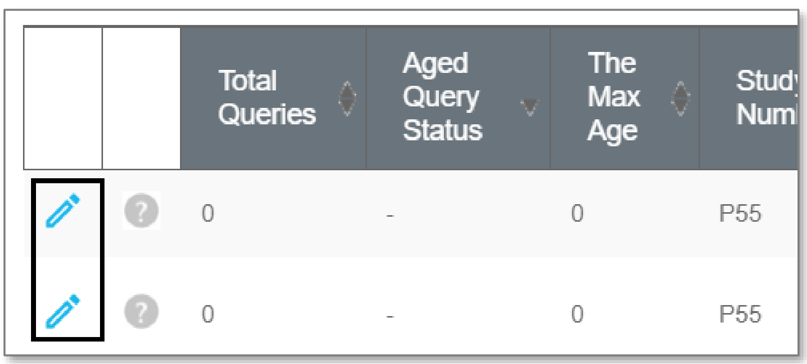


10.3.2.2 Queries

Queries allow permissioned users to document questions they have about any form response, adverse event, or patient study status entry. The Dashboard tool provides the ability to make and resolve query threads. Queries are tied to a specific field within an entry, meaning that any given dashboard entry could have multiple queries opened at any time.

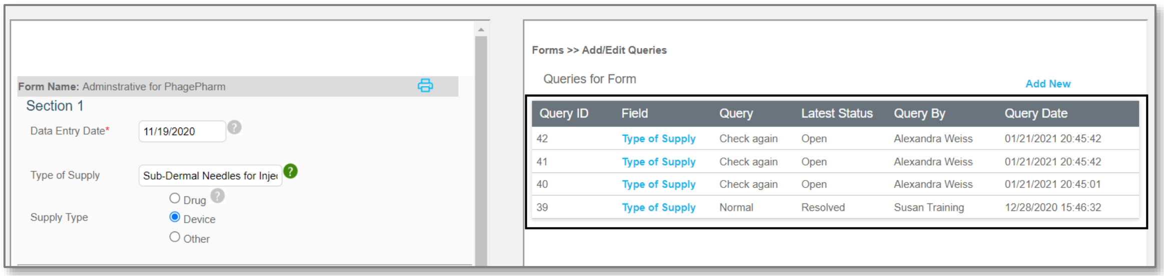
To view queries:

1. Navigate to the response view of any form response, adverse event, or patient study entry, by clicking the **Edit** button.



- This example looks at the response view of a form response

The response view displays. Any queries associated with this entry display on the right side of the Response View page.



10.3.2.2.1 Add a New Query

Permissioned users can create new queries for data entries using the Dashboard tool.

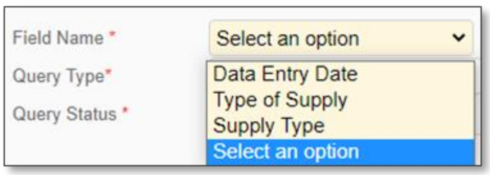
Warning: Queries cannot be deleted once they have been added.

To add a new query:

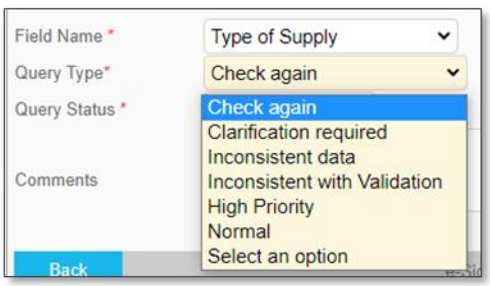
1. Navigate to the response view of any form response, adverse event, or patient study entry and click **Add New** in the Queries panel.

After clicking Add New, the Queries panel refreshes to display the new query entry form:

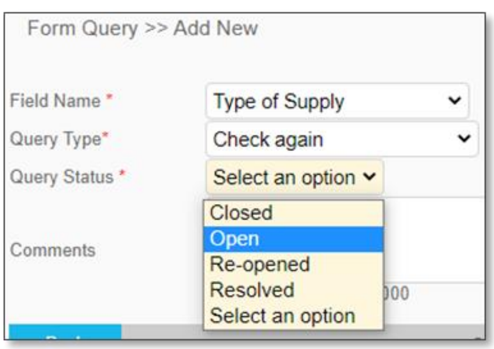
2. Choose the target field for the query using the **Field Name** dropdown menu.



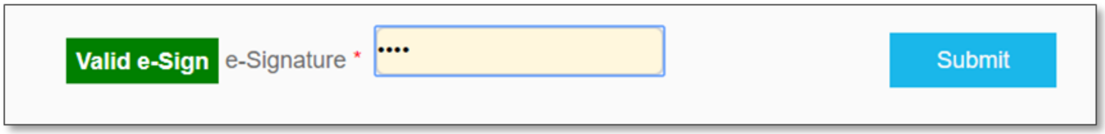
3. Enter the rationale for the query using the **Query Type** dropdown menu.



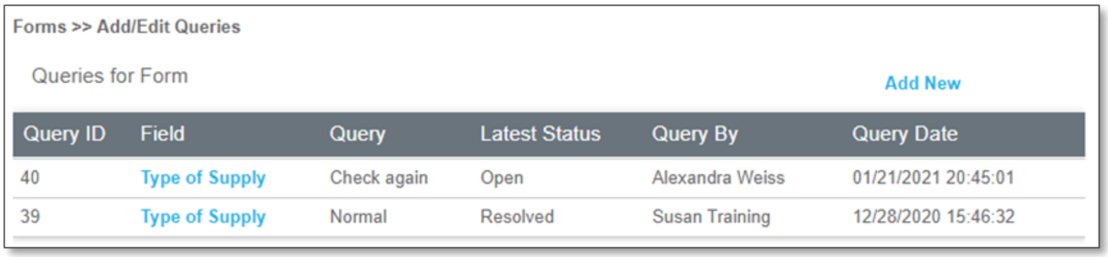
4. Select a status for the query and enter any comments as needed using the **Query Status** and **Comments** fields.



5. Enter your eSignature and click **Submit** to confirm to create a new query for this entry.



The query displays in the query field for this entry:



Forms >> Add/Edit Queries

Queries for Form

Add New

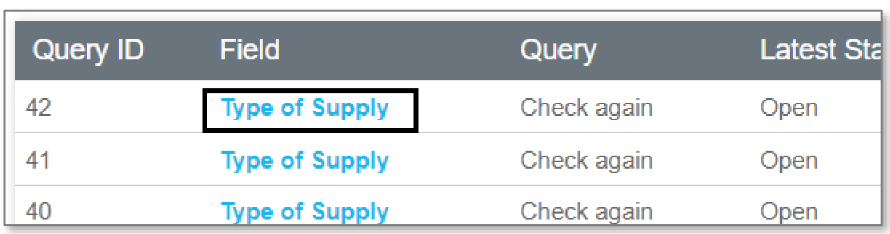
Query ID	Field	Query	Latest Status	Query By	Query Date
40	Type of Supply	Check again	Open	Alexandra Weiss	01/21/2021 20:45:01
39	Type of Supply	Normal	Resolved	Susan Training	12/28/2020 15:46:32

10.3.2.2.2 Respond to a Query

Permissioned users can respond to existing queries using the Dashboard tool.

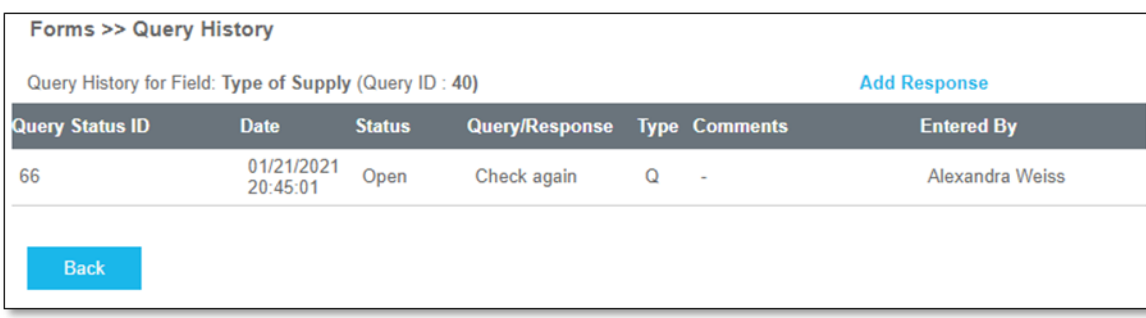
To respond to a query:

1. Navigate to the response view of any form response, adverse event, or patient study entry and click the **Field Name** link for the target query entry in the Queries panel.



Query ID	Field	Query	Latest Sta
42	Type of Supply	Check again	Open
41	Type of Supply	Check again	Open
40	Type of Supply	Check again	Open

After clicking the Field Name link, the Queries panel refreshes to display the query history form:



Forms >> Query History

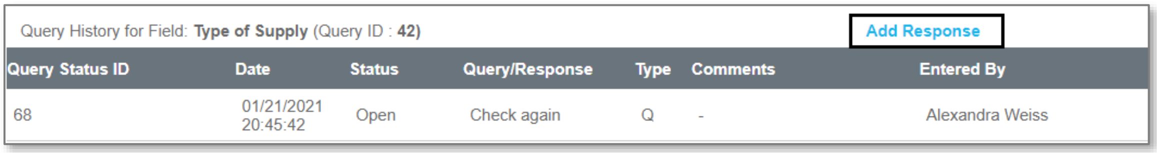
Query History for Field: **Type of Supply** (Query ID : **40**)

Add Response

Query Status ID	Date	Status	Query/Response	Type	Comments	Entered By
66	01/21/2021 20:45:01	Open	Check again	Q	-	Alexandra Weiss

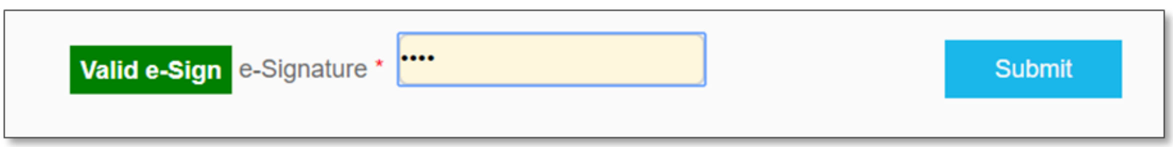
Back

2. Click the **Add Response** link.



Select a new **Query Status** and add any **Comments** to the query as part of the response or resolution to the initial query.

3. Enter your eSignature and click **Submit** to confirm.



The query response displays in the query history for this entry with the type “R”.

10.3.3 Export

Velos eResearch provides a means to export the Dashboard form responses, adverse events, and patient study status search results.

To export the search results from the Dashboard tool:

1. Perform a valid study search for any form responses, adverse events, or patient study status.
2. Click on one of the labeled buttons at the top of the search results to perform the described export functions.

Icon	Name	Description
	**Copy to Clipboard**	Copies the search results data to your clipboard for easy “pasting” into a document or spreadsheet.
	**Export to CSV**	Exports the report to a Comma-separated values (CSV) delimited text file.
	**Print**	Opens the print console to print the results.

11 CTRP Reporting

The CTRP (Clinical Trial Reporting Program) option supports the requirements of the National Cancer Institute (NCI) Clinical Trial Reporting Program. Once a study is designated as "CTRP Reportable" on the Study Summary/ Details page, drafts can be created that capture current study data for NCI submissions.

All trial sponsored or otherwise financially supported by NCI are CTRP Reportable. For instance, NCI expects all interventional clinical trials, however sponsored, that are conducted in NCI-designated Cancer Centers, to be registered (with the exception below). Thus, trials that NCI-designated Cancer Centers report as interventional trials in the Cancer Center Summary 4 Report to NCI are expected to be reported through CTRP. Both industry-sponsored and investigator-initiated trials conducted at NCI-designated Cancer Centers should be registered.
Exception: Trials that are reviewed and monitored by NCI CTEP and DCP PIOs need not be registered through the CTRP website, as the information will be transferred within NCI. This exception applies to all CTEP trials submitted via the Clinical Data Update System (CDUS), including all Cooperative Group trials, and all early phase trials submitted to the Clinical Trial Monitoring Service operated by Theradex.

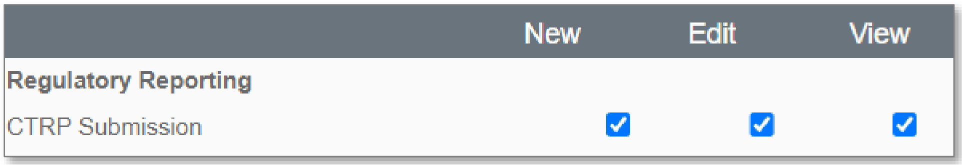
To use this feature, ensure the following:

- CTRP access rights are selected
- A study is designated as CTRP Reportable

Note: Depending on your eResearch configuration, you may have either a Study Summary or a Study Details tab as well as either an Attachments or a Versions tab for all studies. If you have a Study Details tab and you need to add IND/IDE information, ensure you have requested for this dropdown option to be added to the Study Details page through eResearch Support.

11.1 CTRP Access Rights

Users must have CTRP access rights options checked in their default user group to access CTRP features.

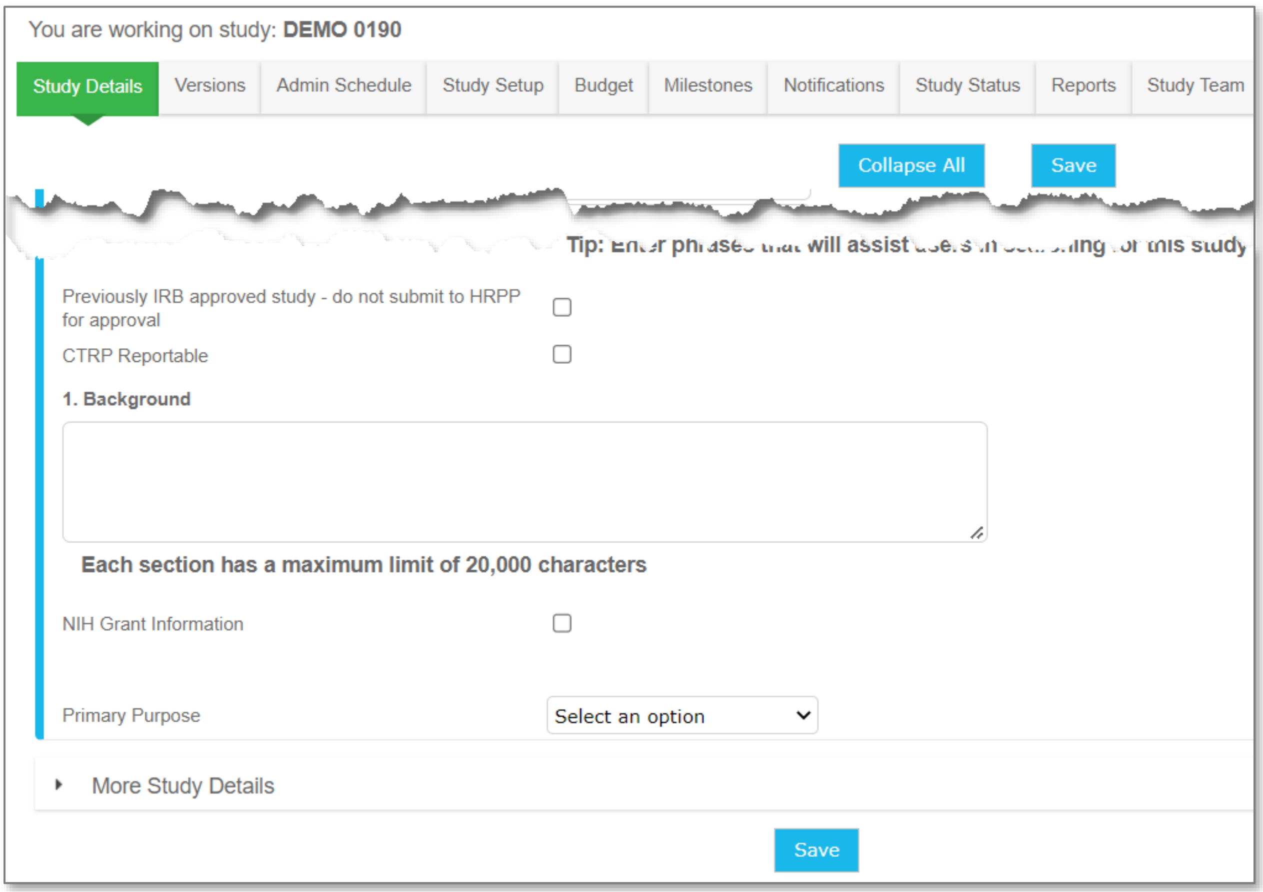


CTRP access rights include:

Access Right	Description
New	Allows users to create new drafts, view existing drafts, validate drafts and download saved drafts.
Edit	Allows users to view and edit existing drafts and validate drafts.
View	Allows users to see existing drafts and validation reports.

11.2 Designating a Study with CTRP Reportable Data

Designating a study as CTRP Reportable will allow for extraction of submission data by the National Cancer Institute (NCI). Additional information may also be added such as IDE/INE data and NIH Grant information. Documents for submission should also be added to the Attachments/ Versions tab.



When creating the CTRP Reportable study, users should provide as much of the optional details as possible in the Study Summary / Details tab.

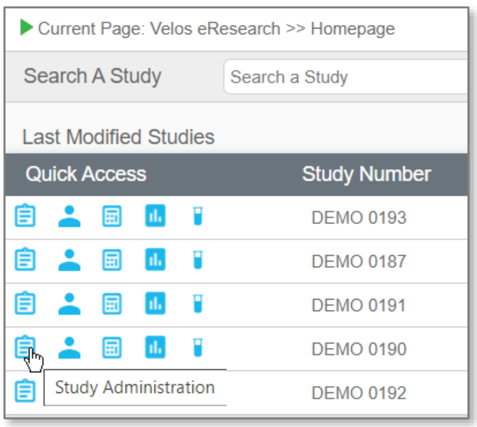
Note: Some information in the Study Summary / Details tab is not required upon initial creation of a study in Velos eResearch, but it may be required later when a user validates a draft submission.

11.2.1 Identify the Research Type and Assign CTRP Reportable

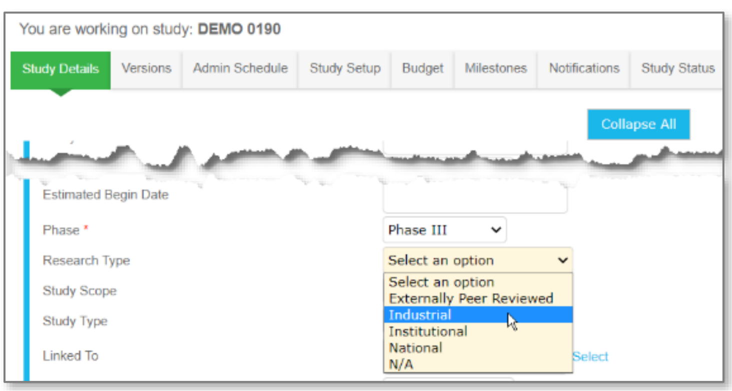
The Research Type field, in the Study Summary/ Details page for a CTRP Reportable study, must have an option selected in order to be permitted to create a CTRP draft. (Refer to Create a CTRP Trial Registration Draft for more information.) Selecting the CTRP Reportable option allows for study data to be captured according to the reporting requirements of the National Cancer Institute (NCI).

To assign a study's Research Type and assign CTRP Reporting:

1. Click **Study Administration** for the selected study from the Homepage or from search results.

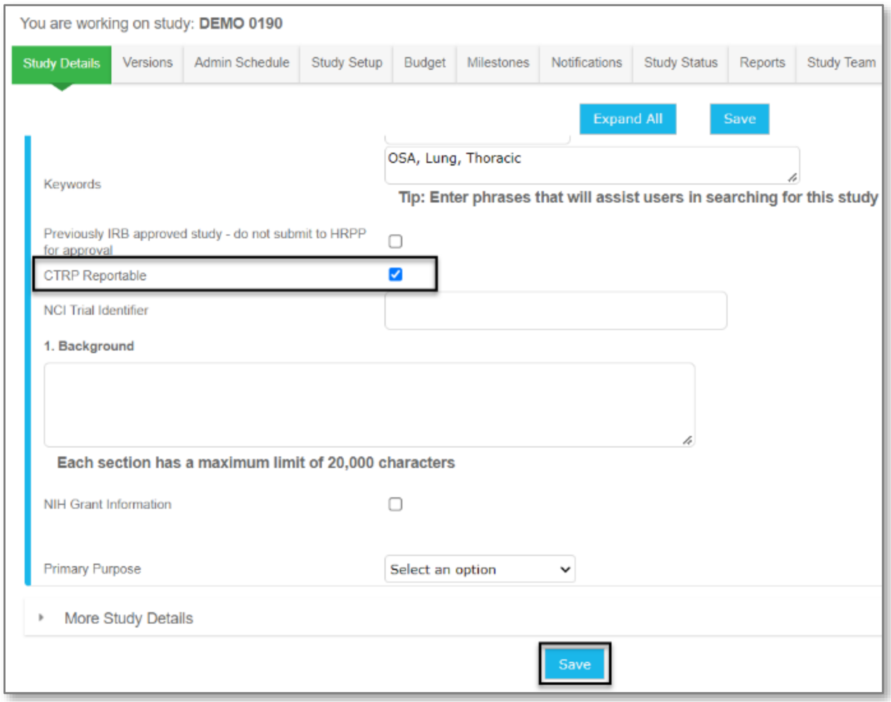


2. In the Study Summary/ Details page, select an option from the Research Type dropdown.



- All options that are not Industrial are considered in the category of non-industrial
- As per your configurations, the Research Type filed may have a different name, for example, Study Source

3. Scroll down and check the checkbox for CTRP Reportable, then click **Save**.



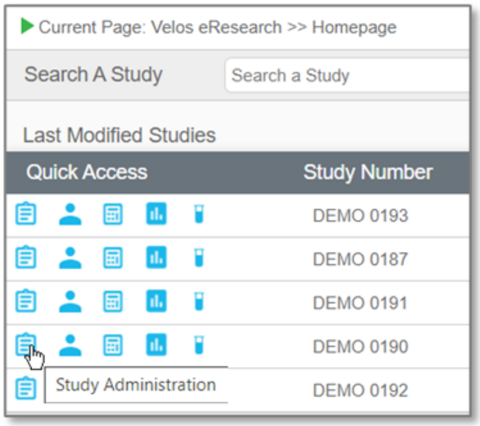
11.2.2 Specify the IND/IDE Information

If a study involves an investigational new drug or device, the Study Summary/ Details page will be used to specify any IND/IDE Information.

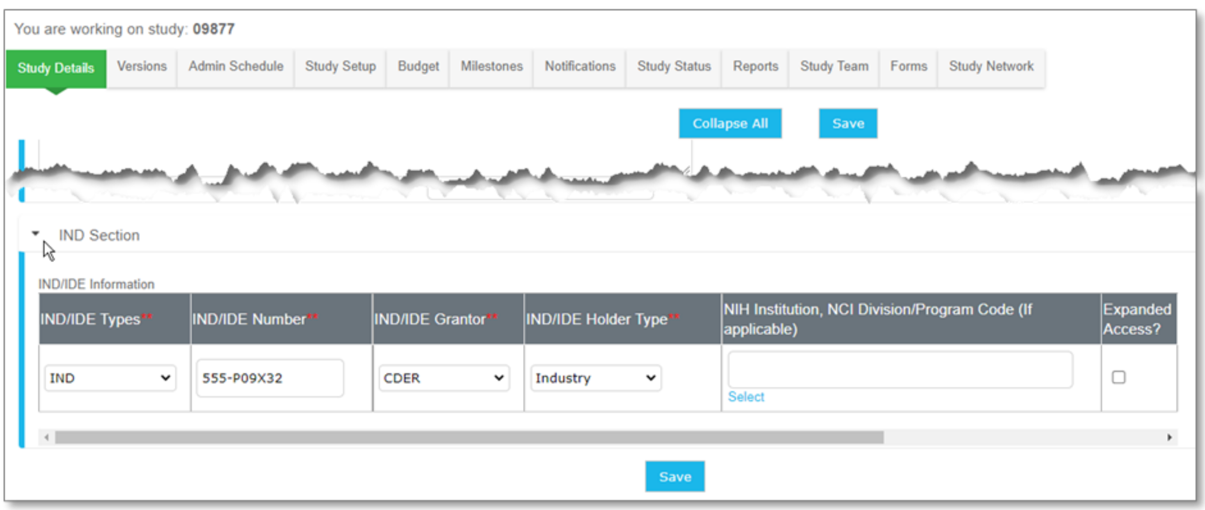
Note: Depending on your eResearch configuration, you may have either a Study Summary or a Study Details tab for all studies. If you have a Study Details tab and you need to add IND/IDE information, ensure you have requested for this dropdown option to be added to the Study Details page through eResearch Support.

To assign a study's IND/IDE Information:

1. Click **Study Administration** for the selected study from the Homepage or from search results.

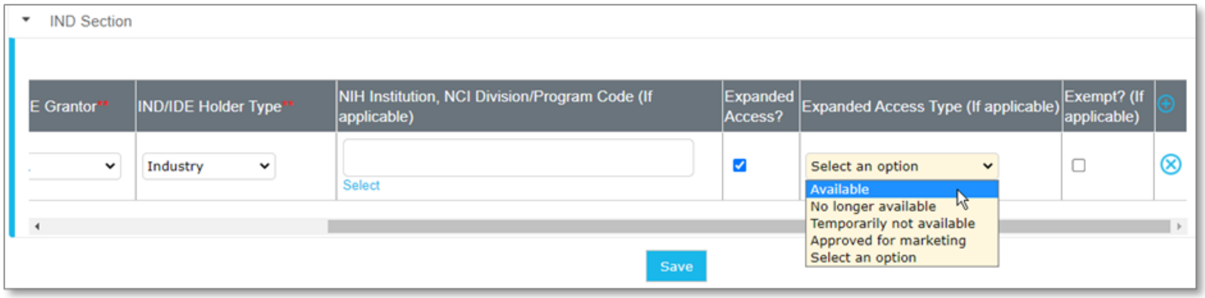


2. In the Study Summary/ Details page, click the IND Section dropdown arrow.



3. Select the IND/IDE Types option from the dropdown, enter an IND/IDE Number, select an IND/IDE Grantor (CDER or CBER) and IND//IDE Holder Type from the dropdowns, if not pre-populated.
4. Optionally enter an NIH Institution/ NCI Division/Program Code, click the **Select** link to select the applicable data.
5. Scroll the bar at the bottom of the table to the far right.

6. If needed, check the Expanded Access checkbox, then select an Expanded Access Type from the new dropdown available.



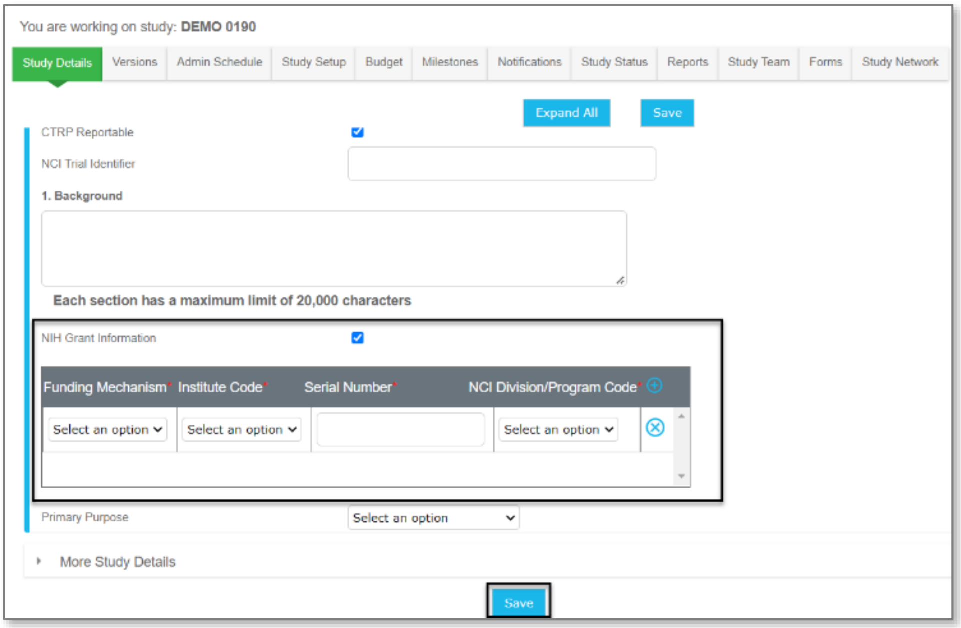
7. If the study should be exempt, then check the Exempt checkbox.
8. Optionally, a row may be added by clicking **Add**, or deleted by clicking **Delete** and then **OK** in the subsequent pop-up box.

11.2.2.1 Specify NIH Grant Information

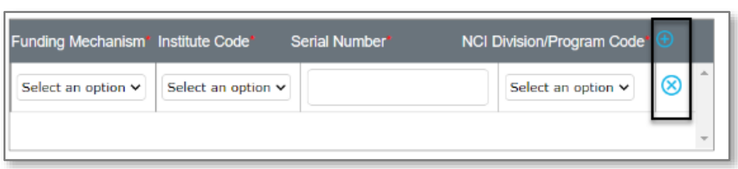
If a study has any National Institutes of Health (NIH) funding, the Study Summary/ Details page will be used to specify the NIH Grant Information so that it can be included with a submission. This only applicable to NIH related studies.

To add NIH Grant information, from the Study Summary/ Details page of a study:

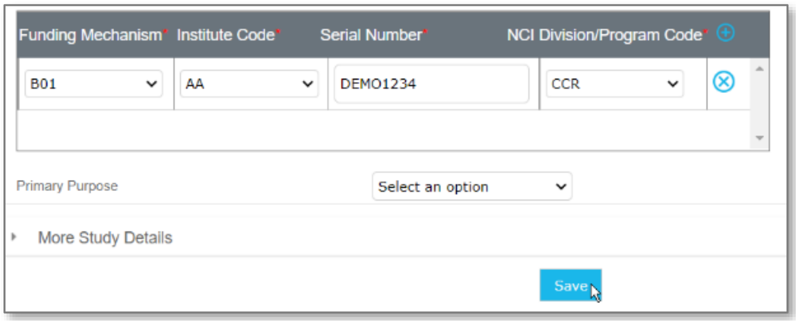
1. Check the checkbox for NIH Grant Information.



2. In the new NIH Grant Information table, select a Funding Mechanism, Institute Code, and an NCI Division/Program Code from the dropdown options, and enter a study-specific Serial number.
   a. Additional rows can be added by clicking **Plus**. A row of information can be deleted by clicking **Delete** and then clicking **OK** in the resulting pop-up.



3. When the table is complete, click **Save**.

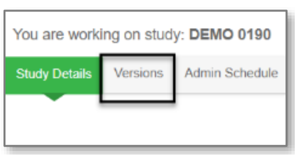


11.2.3 Attach New Documents to the Study

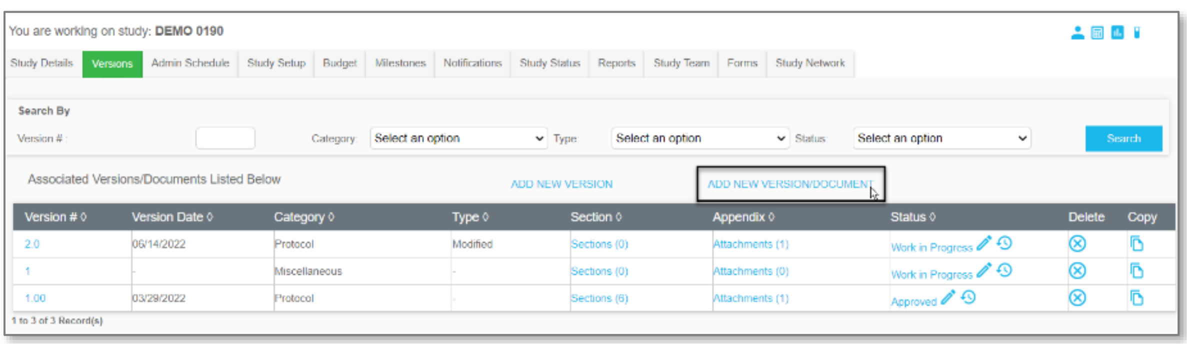
In the Versions / Attachments tab, CTRP supporting documents may be uploaded. These documents may be required for validating drafts. (Refer to Run Validation for more information.) Only upload batch upload files compatible with the CTRP website for Subject Accrual Data.

To attach a new CTRP document, from the Study Summary/ Details page of a study:

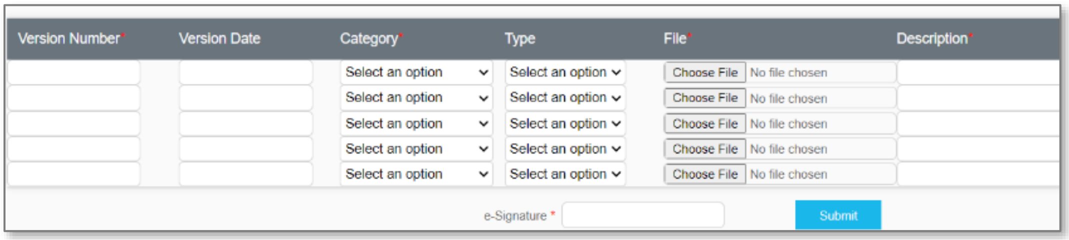
1. Click the Attachments or Versions tab.



2. Click ADD NEW VERSION/DOCUMENT.

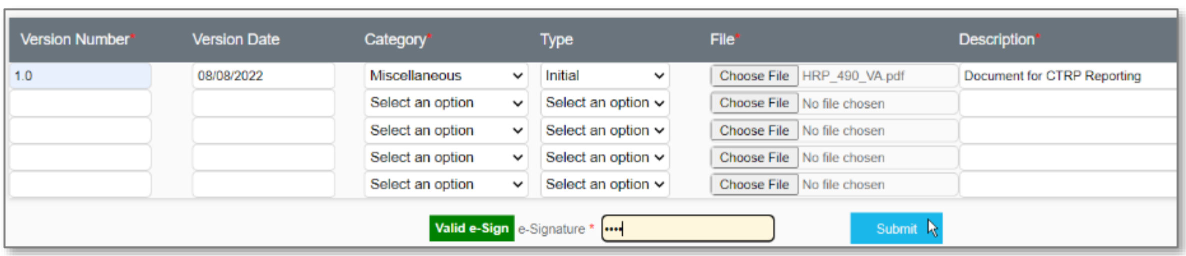


A pop-up window will appear.



- In the Version Number column, enter the document version number
- In the Version Date column, optionally enter a date for the version of the document
- In the Category column, select the appropriate category from the dropdown menu
- In the Type column, optionally select the document type from the dropdown menu
- In the File column, click **Choose File**, then browse for the appropriate file and select
- In the Description column, enter a brief description of the document

3. When all document are added, as needed, enter your e-Signature and click **Submit**.



11.3 Create a CTRP Trial Registration Draft

After a CTRP Reportable Study has been created, a trial registration draft can be created which will capture reportable information from the study. This information should be reviewed and used as part of the submission to NCI. For an “On-Hold” or “Rejected” NCI status, a trial registration draft can be reverted to “Work In Progress”. The system will track the history of the trial registration draft statuses and NCI Trial Processing Statuses.

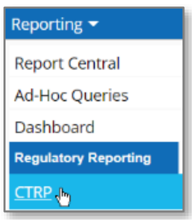
Note: Trial registration drafts may vary slightly depending on the Research Type that was selected.

11.3.1 Locate Study and Create a Trial Registration Draft

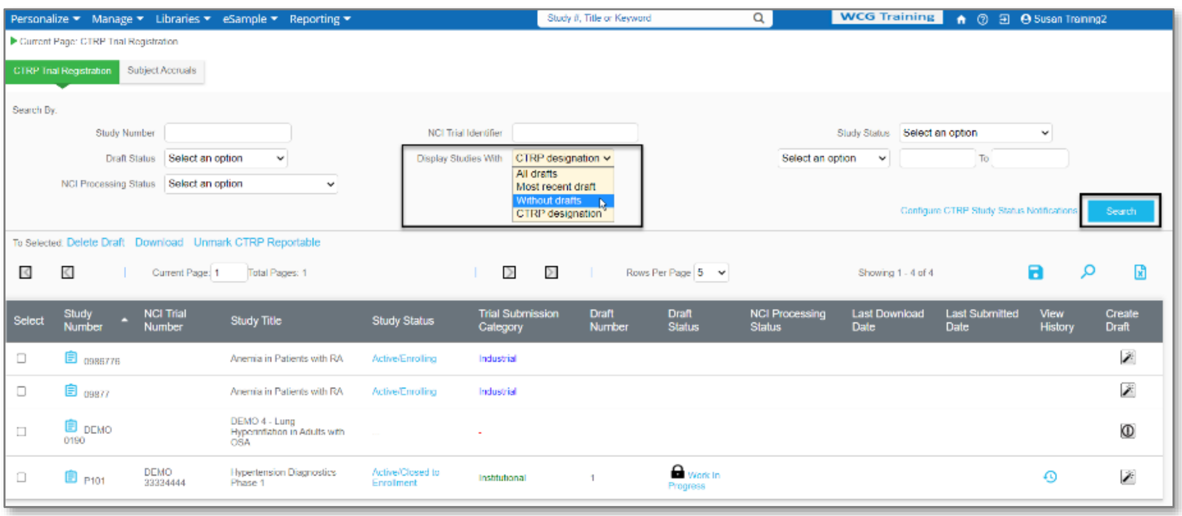
All CTRP Reportable studies can be viewed from the CTRP Reporting option. When a draft is first being created, the study should be searched for by displaying studies without drafts.

To locate a CTRP study and create a draft:

1. From the Navigation menu, click **Reporting** > **CTRP**.

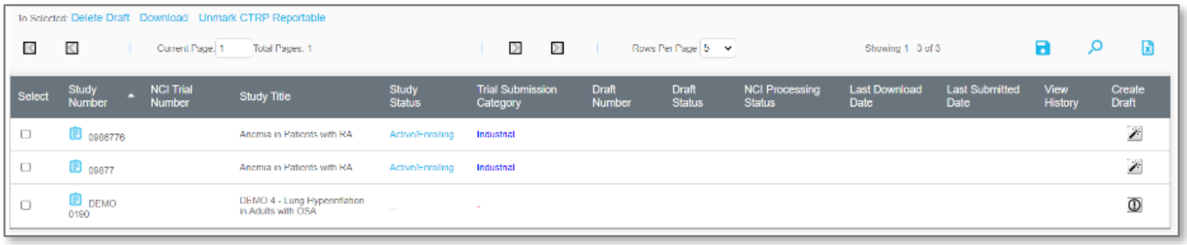


The CTRP Trial Registration page will appear.

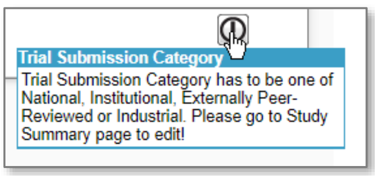


2. Click **Without drafts** in the *Display Studies With* dropdown, then click **Search**.

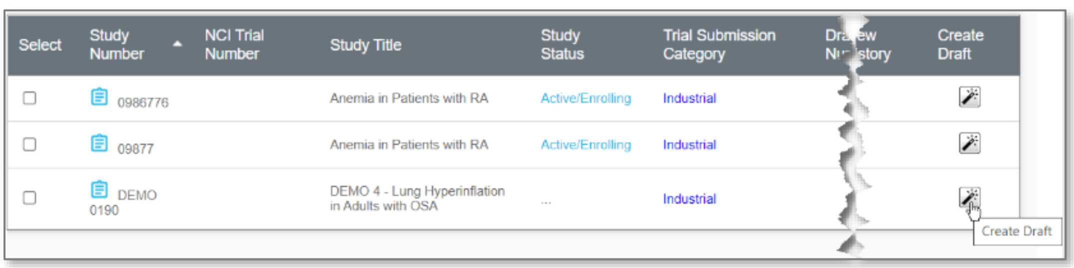
Only the CTRP Reportable studies without drafts will appear in the table.



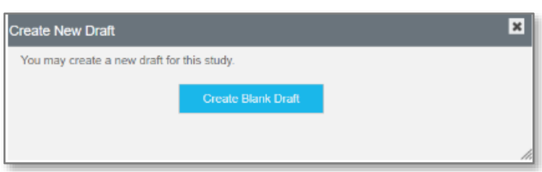
- If there is an exclamation mark in the Create Draft column for the specific study, the Research Type field is missing data. Click the study icon to the left of the Study Number to update the Study Summary/ Details page Research Type field prior to continuing.



3. Click **Create Draft** for the study needing a CTRP trial registration draft.

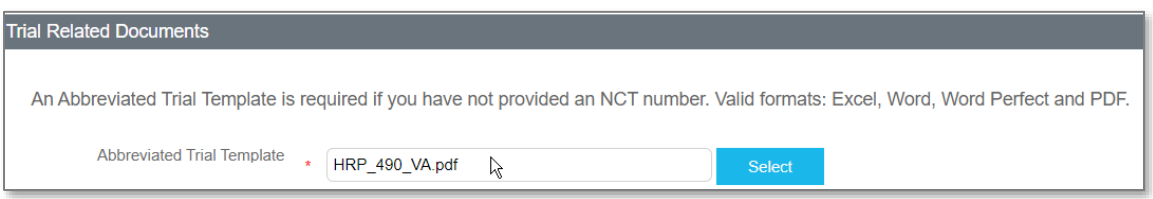


4. In the pop-up, click **Create Blank Draft**.

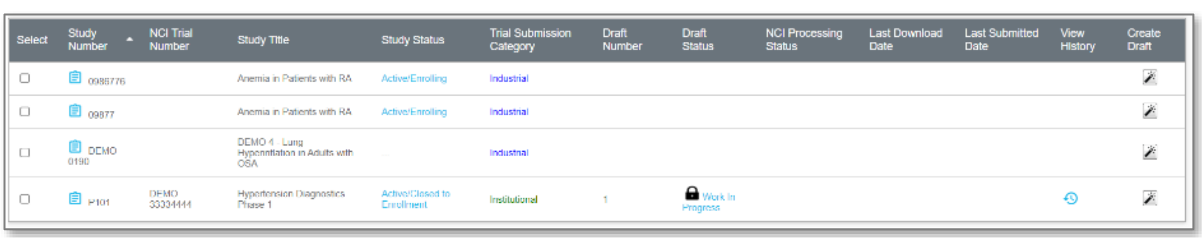


5. Review the data in the CTRP Draft for accuracy and update as needed.

- Data required will vary depending on the template selected as per the Trial Submission Category in CTRP (from the selection made in the Research Type field for the study)
- At minimum, ensure all required fields with red asterisks have entries
- Use **Select** to select the applicable information for such fields as Trial Owner, Organization IDs, and/ or Site PI ID, as applicable
    - If there are two Select options, the first will be for pulling data from a global list, whereas the second Select option will pull from the data you have added to your system. If using the second option, ensure that the address and phone number for the user or organization is populated in the specific User or Organization's pages.
- Ensure the Trial Related Documents are selected, as applicable, which were previously uploaded in the Attachments / Version tab for the study



6. The draft is now in Work in Progress status on the CTRP Trial Registration page and is ready for validation.



Select	Study Number	NCI Trial Number	Study Title	Study Status	Trial Submission Category	Draft Number	Draft Status	NCI Processing Status	Last Download Date	Last Submitted Date	View History	Create Draft
	0986776		Anemia in Patients with RA	Active/Enrolling	Industrial							
	09877		Anemia in Patients with RA	Active/Enrolling	Industrial							
	DEMO 0190		DEMO 4 - Lung Hyperinflation in Adults with OSA		Industrial							
	P101	DEMO 33334444	Hypertension Diagnostics Phase 1	Active/Closed to Enrollment	Institutional	1	Work In Progress					

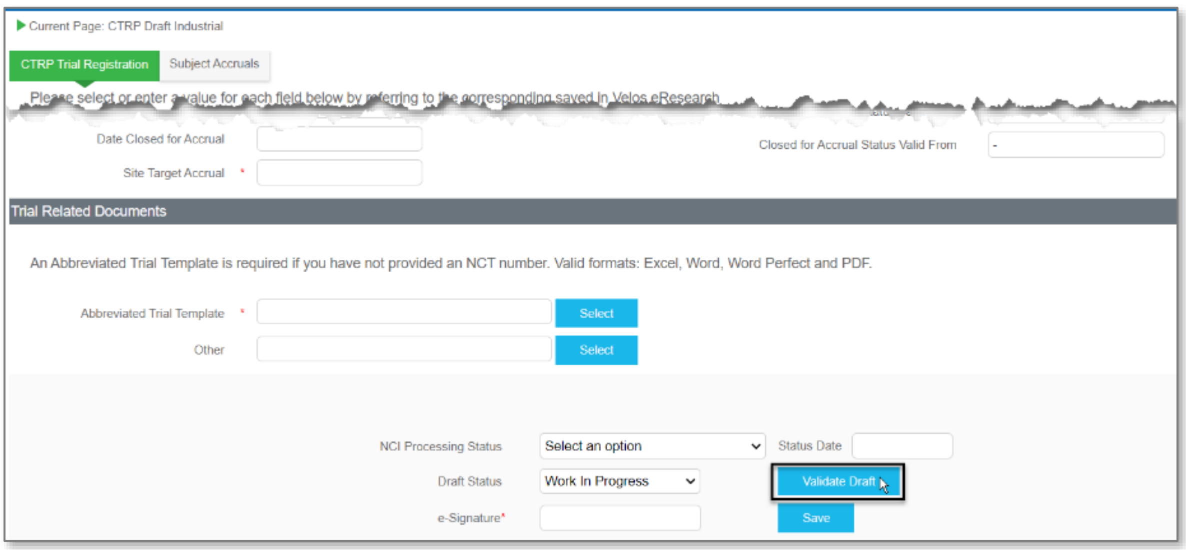
7. Continue to Run Validation for next steps.

11.4 Run Validation

Once a trial registration draft is created, the information will require validation to ensure there are no errors. Velos eResearch has automated this validation process so that the system checks the report and immediately notifies users of any errors. Preferably, a user should validate the draft prior to navigating away from the CTRP Draft page, however, the draft will still be accessible for validation from the CTRP Trial Registration page by clicking the Work In Progress link in the Draft Status column.

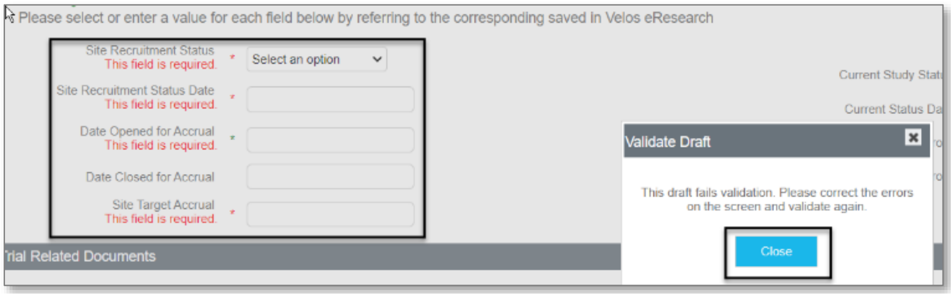
To validate the draft, from the CTRP Draft page:

1. Scroll to the bottom of the page then click **Validate Draft**.



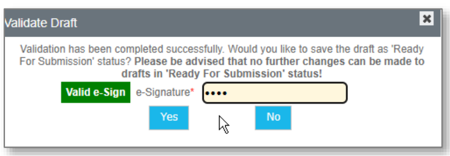
2. The resulting pop-up will indicate if the validation was successful or not.

3. If the draft fails validation, click **Close**, make necessary changes, and click **Validate Draft** again until successful.



Note: You may need to enter some of the missing information in other areas of the system. For example, if selecting a PI that does not have an address listed in their User Details page, the validation may fail. You would then need to return to the PI's User Details page, add an address, and then select the PI again.

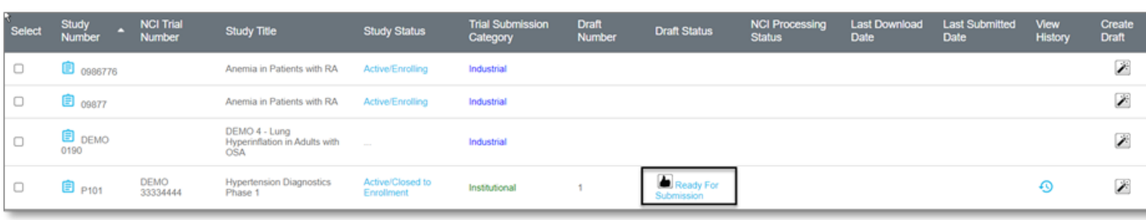
4. Once the validation is successful, enter your e-Signature.



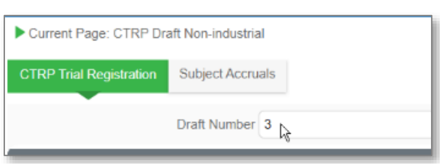
5. Click **No**, to keep the draft in Work in Progress draft status.

   -OR-

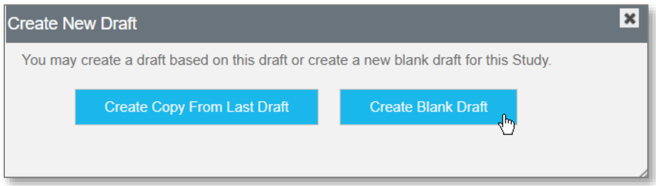
6. Click **Yes**, to push the draft to Ready For Submission draft status.



- By clicking **Ready for Submission**, the draft can be accessed. Most data will be locked and grey in color, however the draft may be updated and re-validated. Each time a validation occurs, the Draft Number field will update.



a. If updates to the draft are needed, click **Create Draft** in the CTRP Trial Registration page.



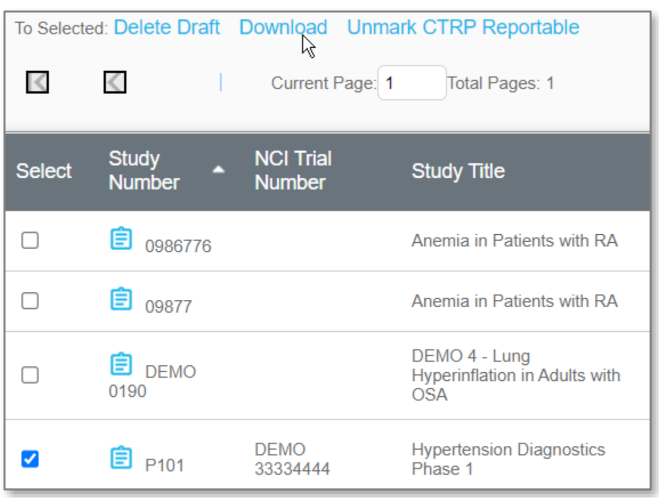
b. In the pop-up, the **Create Blank Draft** option will remove most data, including required data, and will require a new validation, whereas the **Create Copy From Last Draft** option will keep all data and will require validation to again push the draft to Ready for Submission draft status.

11.5 Download the Draft, Save Locally and Submit

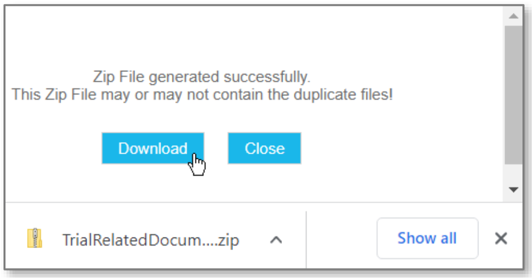
Once the trial registration draft is saved as 'Ready For Submission' it may be downloaded and saved locally to manually submit via email to NCI.

To download a draft, from the CTRP Trial Registration page:

1. Check the checkbox for the applicable draft to download, then click **Download**.

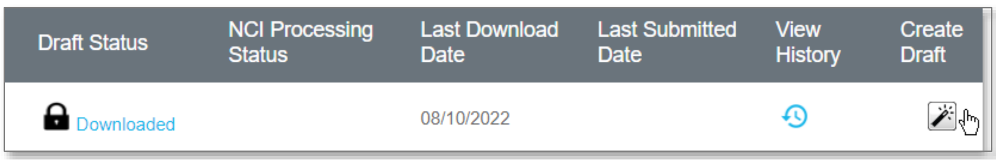


2. In the pop-up, click **Download** then download and save locally.



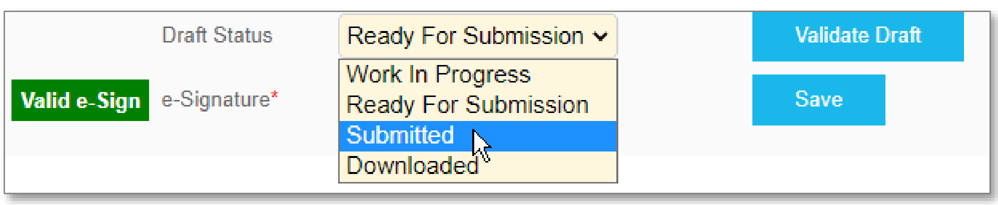
3. Click **Close** to close the pop-up window.

   The submission will show Downloaded draft status.



   - The draft may be updated and revalidated by clicking **Create Draft**, if needed
   - Each time the submission is downloaded, the Last Downloaded Date field will populate with the current date

4. Submit the NCI submission via email as per your company's policies.
5. Return to the draft by clicking **Downloaded** in the Draft Status column, scroll to the bottom of the draft, click **Submitted** in the Draft Status dropdown, enter your e-Signature, and then click **Save**.



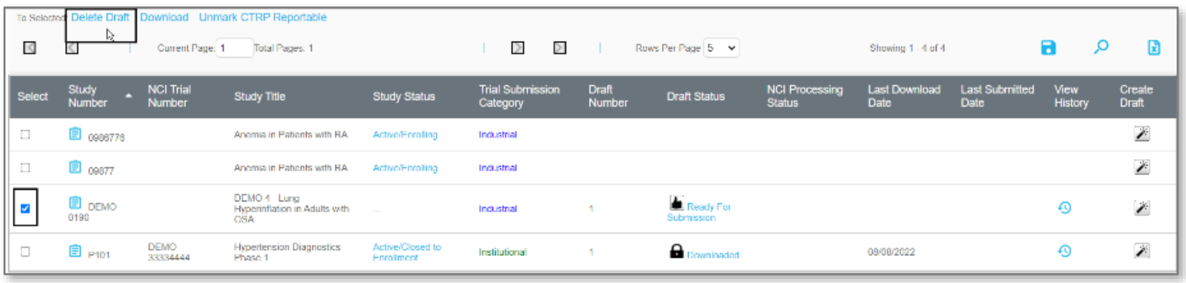
6. Follow the Run Validation steps, if requested. For more information, refer to Run Validation.
7. Continue to Manage NCI Processing Status, to update NCI processing statuses as they occur.

11.6 Delete a Trial Registration Draft

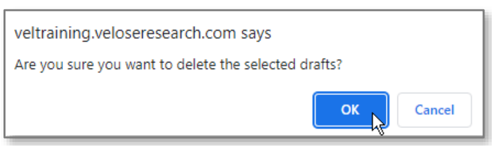
Permissioned users may delete a trial registration draft. Only drafts may be deleted. A CTRP reportable study with a draft will have a Draft Status of either Ready for Submission or Downloaded. If there is no draft, the Draft Status will be blank, and the system will show an error message when trying to perform deletion of the draft.

To delete a draft from the CTRP Trial Registration page:

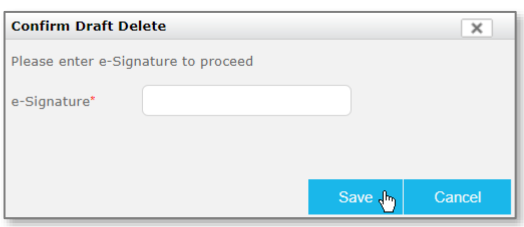
1. Check the Select checkbox for the applicable Study Number entry, then click **Download Draft**.



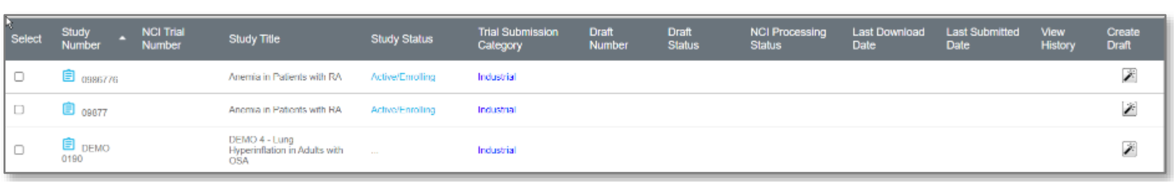
2. Click **OK** to confirm deletion.



3. Enter your e-Signature and click **Save** in the pop-up.



4. The status in the Draft Status column will be removed and **Create Draft** can be performed again.



11.7 Subject Accrual Reporting

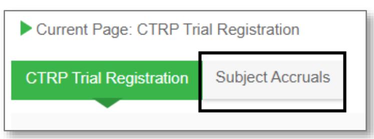
The Subject Accruals tab allows for downloading patient accrual data if a study has been submitted to NCI and has an NCI trial identifier. For qualified studies, validation will be run after a user enters the cutoff date. Studies that fail the validation can be downloaded but will not meet NCI CTRP requirements, and as such may not be accepted.

Possible requirements:

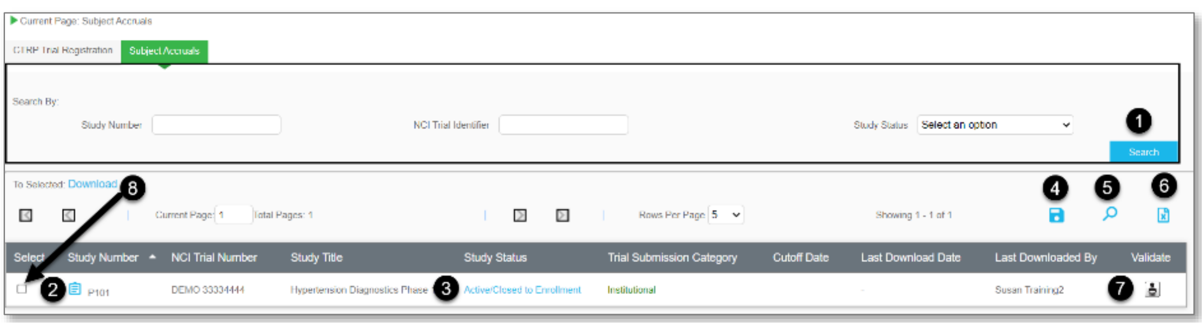
- Race of Patient: If this is required, update in the patient's Demographics page
- Disease Code: If this is required, update in the patient's study Protocol > Screening /Enrollment page using the Edit Details link
- NCI PO-ID: If this is required, go to the patient's Demographics page and view the organization they are associated with. Then go to the Organization's page and update the NCI PO-ID field.

To manage Subject Accruals in CTRP, from the CTRP Trial Registration page:

1. Click the Subject Accruals tab.



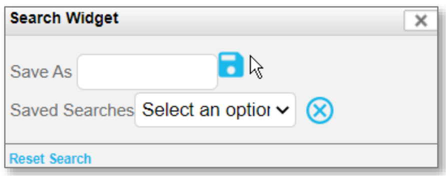
All studies with patients, part of the CTRP Trials, will be listed.



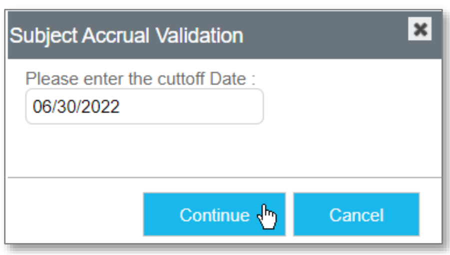
The following functions may be performed on this page:

1. Enter search criteria and click **Search** to further filter results.
2. Click **Study Management** to access the Study Summary/ Details page for the study.
3. Click Study Status to access the Study Status tab for the study.

4. Click **Save View**, to save the view.
5. Click **Save(d) Search** to access the Search Widget.

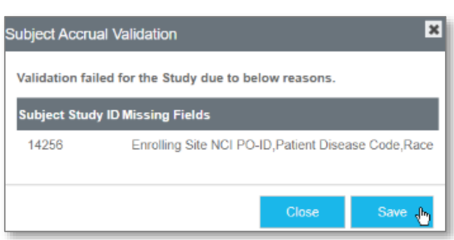


   a. Enter a name into the Save As field and click **Save Search**.
   b. To access the saved search, return to this pop-up and make a selection from the **Select an option** dropdown. Note that clicking **Delete** allows for deletion of the selection.
6. Click **Export to Excel** to export an Excel Spreadsheet of the view. The spreadsheet will open automatically after clicking.
7. Click **Validate** to validate the data.

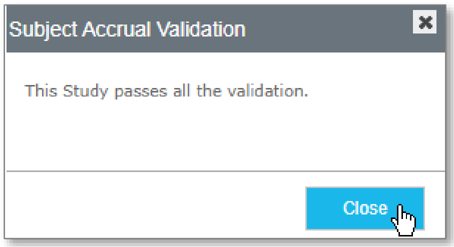


   a. Select the cutoff date then click **Continue**.
   - In the next pop-up, the validation will show as passing or failed.
   - If a patient linked with a study with 'Enrolled' status, and the status date falls on or below the 'Cut Off' date, AND in the case the NCI criteria is not satisfied, then the system will display an error message; otherwise the system will display a validation successful message.

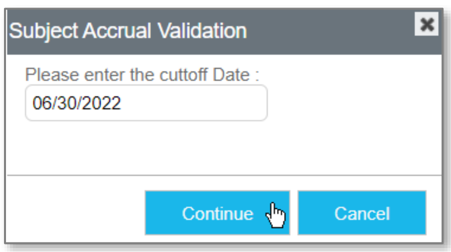
   b. If failed, click **Close** and make corrections before clicking Validate again otherwise click **Save** and a download of the failure message will become accessible.



c. If validation passes, click **Close**.

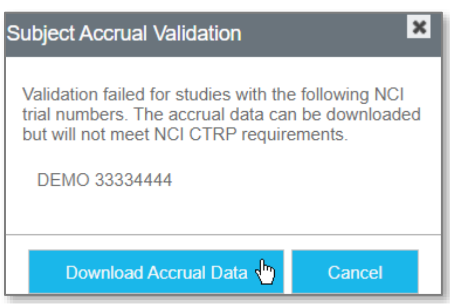


8. Check a checkbox in the Select column, then click **Download** to download the subject accruals for a study.



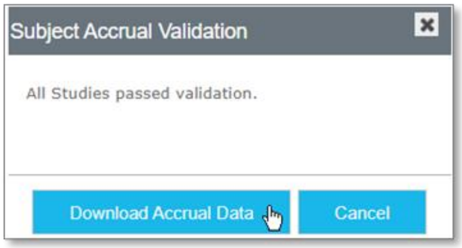
a. Enter the subject accrual date into the pop-up and click **Continue**.

b. If the validation fails, a warning note will appear. The data may still be downloaded by clicking **Download Accrual Data** and then opening the downloaded file folder with text file.



-OR-

If the validation passes, the following pop-up will be observed. Click **Download Accrual Data** to view the data by opening the downloaded file folder with text file.



- See the example below of a validated text file for subject accruals.

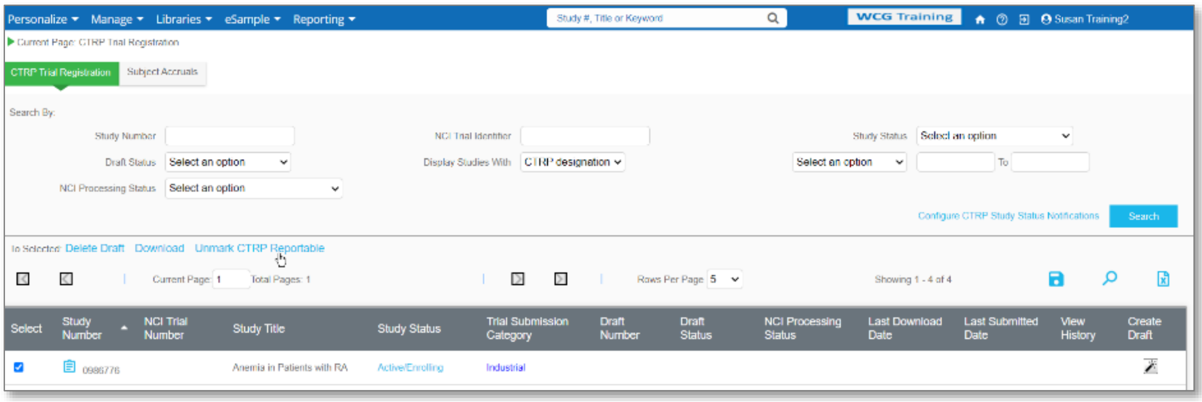
```
COLLECTIONS,887766,,,,,,,,,
PATIENTS,887766,1-004,,,198505,"Female","Not Reported",,20170512,,557,,,,,,,,,,10,,
PATIENTS,887766,1-005,,,198005,"Female","Non-Hispanic",,20170512,,557,,,,,,,,,,10.01,,
PATIENTS,887766,1-003,,,199005,"Female","Hispanic or Latino",,20170512,,557,,,,,,,,,,10.94,,
PATIENTS,887766,1-007,,,198505,"Female","Hispanic or Latino",,20170512,,557,,,,,,,,,,10.04,,
PATIENTS,887766,1-002,,,198509,"Female","Hispanic or Latino",,20170403,,557,,,,,,,,,,104,,
PATIENTS,887766,1-006,,,199005,"Female","Unknown",,20170512,,557,,,,,,,,,,10.01,,
PATIENTS,887766,1-001,94538,"US - United States",198104,"Female","Non-Hispanic",,20170403,,557,,,,,,,,,,11.03,,
PATIENT_RACES,887766,1-004,"Not Reported"
PATIENT_RACES,887766,1-005,"White"
PATIENT_RACES,887766,1-003,"Asian"
PATIENT_RACES,887766,1-007,"American Indian or Alaska Native"
PATIENT_RACES,887766,1-002,"White"
PATIENT_RACES,887766,1-006,"Unknown"
PATIENT_RACES,887766,1-001,"Asian"
```

11.8 Unmark CTRP Reportable Study

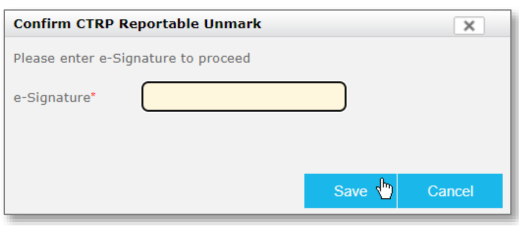
If a study was incorrectly identified as CTRP Reportable, the study can be removed from the CTRP Trial Registration page, only if the study in CTRP does not have a draft. If the study has a draft, the draft would need to be deleted first before unmarking for CTRP Reportable.

To unmark (remove) a study as CTRP reportable from the CTRP Trial Registration page:

1. Check a checkbox in the Select column for the appropriate study, then click **Unmark CTRP Reportable**.



2. In the pop-up, enter your e-Signature and click **Save**.



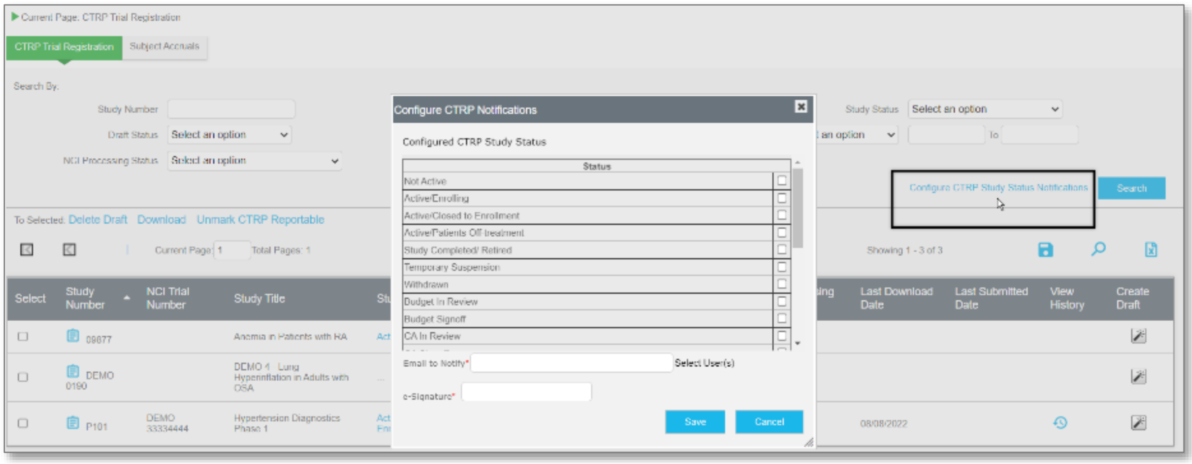
3. The study will no longer appear in the CTRP Trial Registration page.

11.9 Configure CTRP Study Status Notifications

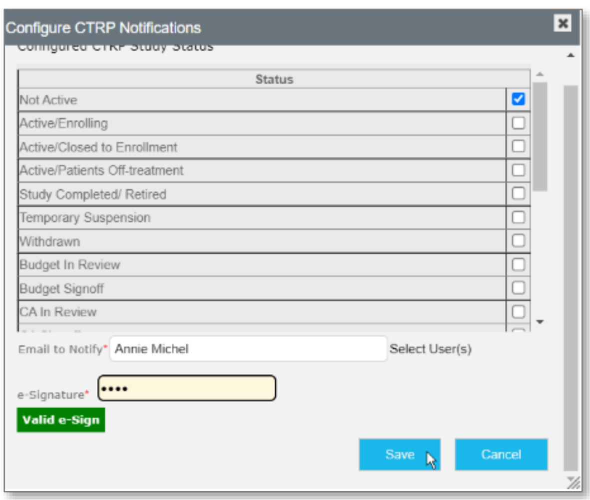
When CTRP reportable study statuses change, users may receive notifications of the change in status from the system.

To assign users to receive study status change notifications, from the CTRP Trial Registration page:

1. Click Configure CTRP Study Status Notifications.



2. In the pop-up, check one or more study status checkboxes, then click **Select User(s)** and select one or more users to receive study status notifications for the selected status(es), then click **Save**.



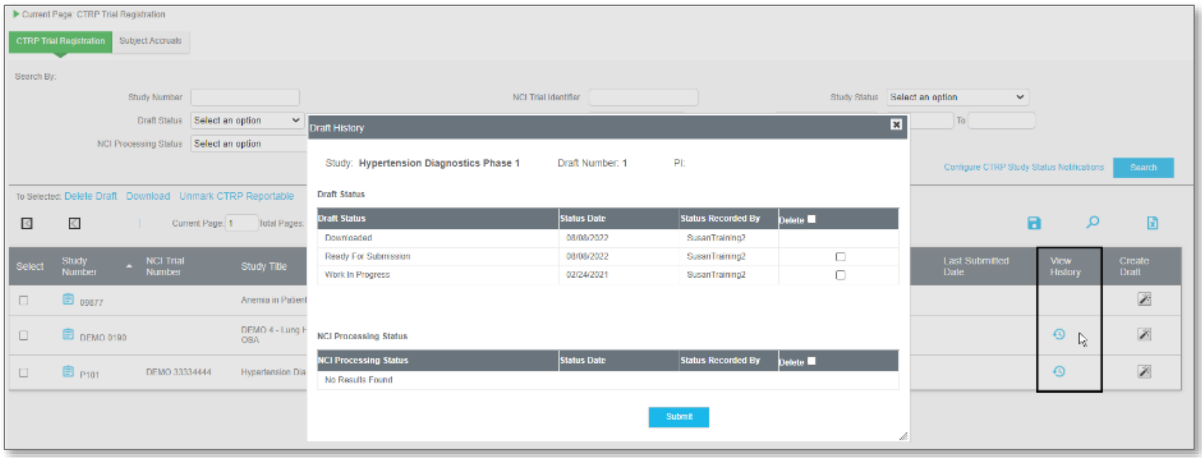
3. When a selected status is changed, the user(s) will receive a change in status email notification.

11.10 View History of CTRP Reportable Draft

History of CTRP reportable drafts may be viewed. Draft statuses and NCI processing status in the history may also be deleted.

To view a draft history from the CTRP Trial Registration page:

1. Click **View History**, for a specific study number.



2. If deletion of a draft status or an NCI processing status is required, check the appropriate checkbox, then click **Submit**.

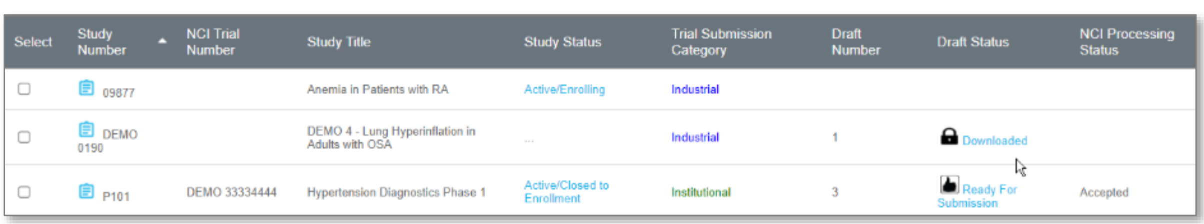
Warning: Do not use deletion of draft status or NCI processing status unless required to do so as this data will no longer be available in the draft history.

11.11 Manage NCI Processing Status

After manually submitting the submission to NCI, the NCI Processing Status may be updated in the system.

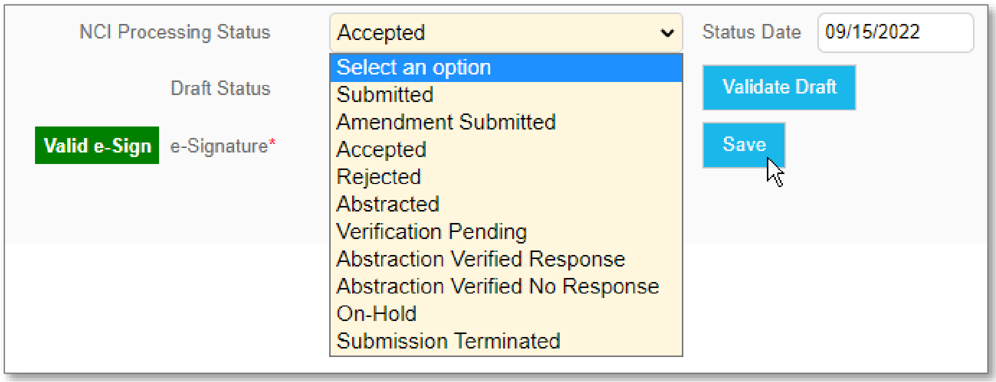
To update NCI Processing Statuses, from the CTRP Trial Registration page:

1. Click either **Ready for Submission** or **Downloaded** in the Draft Status column.

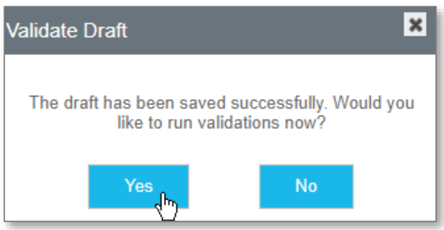


Select	Study Number	NCI Trial Number	Study Title	Study Status	Trial Submission Category	Draft Number	Draft Status	NCI Processing Status
	09877		Anemia in Patients with RA	Active/Enrolling	Industrial			
	DEMO 0190		DEMO 4 - Lung Hyperinflation in Adults with OSA	...	Industrial	1	Downloaded	
	P101	DEMO 33334444	Hypertension Diagnostics Phase 1	Active/Closed to Enrollment	Institutional	3	Ready For Submission	Accepted

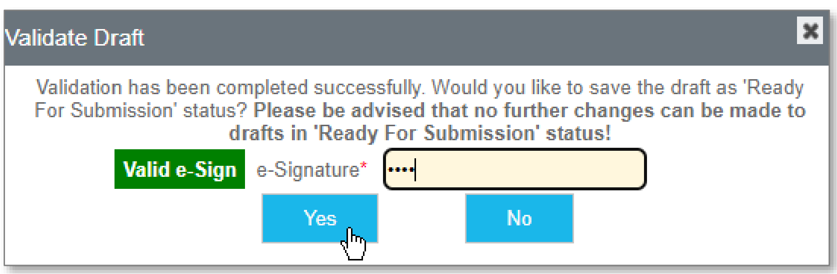
2. Scroll to the bottom of the submitted draft, click the appropriate NCI Processing Status in the dropdown, select a Status Date from the date picker, enter your e-Signature, and then click **Save**.



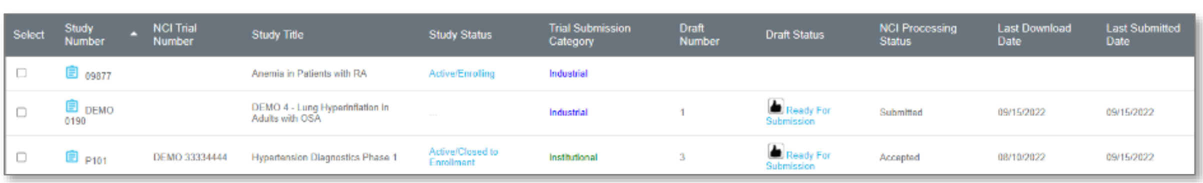
3. Click **Yes** in the subsequent pop-up.



4. Enter your e-Signature and click **Yes**.



5. To view the NCI Processing Status update for the submission, click **Reporting** > **CTRP**.



Select	Study Number	NCI Trial Number	Study Title	Study Status	Trial Submission Category	Draft Number	Draft Status	NCI Processing Status	Last Download Date	Last Submitted Date
☐	09877		Anemia in Patients with RA	Active/Enrolling	Industrial					
☐	DEMO 0190		DEMO 4 - Lung Hyperinflation In Adults with OSA	...	Industrial	1	Ready For Submission	Submitted	09/15/2022	09/15/2022
☐	P101	DEMO 33334444	Hypertension Diagnostics Phase 1	Active/Closed to Enrollment	Institutional	3	Ready For Submission	Accepted	08/10/2022	09/15/2022

- Submissions with NCI Processing Status dates added that last showed Downloaded Draft Status will now appear as Ready for Submission status in the Draft Status column

6. Continue to update the NCI Processing Status until fully approved.

12 Support

Technical support is provided to users of the Velos eResearch system. There are several ways for a user to access this support.

Note: For support with using Velos eResearch, please contact your internal eResearch Support Team or Administrator. If needed, they can contact WCG Velos Support on your behalf.

13 Appendix A – Technical Information

13.1 Revision History

Version	Section	Description of Changes
1	N/A, first version	1. N/A, first version
2	All Sections as Applicable	1. Incorporation of both Enterprise and eXpress functionality.
3	All Sections as Applicable	1. Update for new 11.2 UI and add-ons.
4	All Sections as Applicable	1. Update for 11.2.1 UI

Version	Section	Description of Changes
5	Throughout as listed:	1. User Guide content updated to incorporate Version 11.3 new software functionalities including:
	Throughout	2. Throughout sections the Manage dropdown images have been updated.
	General Information>Getting Started	3. Added table information of new additional functionalities.
	Deleting Users from a Group	4. Removed steps for removed Delete column buttons and replaced with new steps.
	Studies	5. Added Advanced Search information.
	Add a New Study	6. Added Enterprise Only details and notes due to deleting the no longer applicable section previously titled Study Summary/Study Details Tab.
	Copy an Existing Study	7. Updated to include both paths to access for copying an existing study link.
	Versions Tab	8. Updated title and associated references to the tab throughout document as this is now the only tab name for both core Enterprise and eXpress versions, changing the title from Attachments/Versions/Study Documents Tab.
	Versions Tab	9. Updated title and directions as this is only Versions tab in both core Enterprise and eXpress versions. Updated to Versions Tab throughout document.
	Adding, Downloading, Editing, or Deleting an Attachment	10. Changed title and added details on how to perform each function from the Appendix page.
	Associate a Calendar to a Study	11. Added steps for editing events in this section.
	Study Status Tab	12. Added information on Display Browser Logic.

5	Forms Audit Trail and Forms Tab Track Changes	13. Added new sections.
	Screening/ Enrollment and Sub-Sections, Add Unscheduled Events, Edit Multiple Events, Add New AE, Add Multiple AEs, and Patient Forms and Labs	14. Updated Images for new Attachments Link.
	Edit Multiple Events	15. Added Steps and updated images for additional Performed By column.
	WCG IRB and sub-sections	16. Updated to WCG's IRB references as there is now only one WCG IRB.
	Add a New Patient	17. Add a New Patient: Added a note and instructions instructing the user on two ways to add a new patient using the Enroll button versus using the Create & Enroll button.
	Patient Forms Audit Trail and Patient Schedule	18. Added new sections.
	Create a Budget Template	19. Added steps for assigning access rights for an individual user.
	Manage Payments and Sub-Sections	20. New tabs in the header for the table.
	Record a Payment and Reconcile a Payment	21. New steps for the new Payment Type options of Payment Made versus Payment Received.
	Reconcile Details, Edit Reconciliation Record, and Delete a Payment Record	22. Added new sections for new icons.
	Financial Reports	23. Added new table rows for new Report Names.
	Preview & Save	24. Revised steps to click Display to preview before clicking Submit for an AHQ AND updated image for new CSV icon export option.
	Display and Export an AHQ	25. Updated image and tables for new CSV Format and new CSV Linear Format icons for export options.
	Dashboard and Sub-Sections	26. Added information on Hide/Show columns button for adding and removing table headers in the Search Results table.
	Reset or Save Searches	27. Added "Reset or" to title and steps for using the Reset icon in the New Search area.
	Adding, Downloading, Editing, or Deleting an Attachment	28. Changed title and added details on how to perform each function from the Appendix page.

Version	Section	Description of Changes
	Associate a Calendar to a Study	29. Added steps for editing events in this section.
	Appendix A – System Icons	30. New Section.
	eSample Reports	31. Added section.
	Portal Design and Options	32. Updated title name and made all option sub-sections into this section.
	Throughout all sections	33. Minor user interface updates to images have been made including changing of colors for buttons, dropdowns, icons, and other updates which do not affect process steps.
6	Throughout as listed:	1. User Guide content updated to incorporate Version 11.3.1 new software functionalities including:
	Appendix A	2. Moved Revision History and Supported Workstations to be Appendix A and all Appendices became the next letter.
	Appendix C	3. Added as a new Appendix for Special Character Behaviors and moved all Appendices to the next letter
	Manage Invoices	4. Updated user interface controls to allow adding Quick Notes at the study level, and internal comments on individual invoices. Both controls are located on a study's invoices tab.
	Create Invoices	5. Updated filters and fields when searching for and adding achieved milestones to an invoice.
	Add and review invoicing comments	6. New sub-section under Manage Invoices.

7	Throughout as listed: Settings Organizations Define and Edit Super User Rights for a Group Non-System Users Deactivated Users Add Quick Links Configure Visits Manage an Existing Patient to a Study View Linked Forms and Adverse Events in Schedule Add Milestones Add Quick Notes to Invoicing for a Study Create an Invoice Accrual Reports Biospecimen Reports Financial Reports Ad-Hoc Queries Save View, View Refresh, View Search, and Update Selected Options Application Rights Patient Management (in Study Role Permissions) eSample Appendix – throughout See description	1. User Guide content updated to incorporate Version 12.0 new software functionalities including: 2. Added a note about Logout time. 3. Updated the Organization Types as per default options. 4. Updated for the Assign Rights steps and information for "What is Complete Patient Data". 5. New section. 6. New section. 7. Added examples for General and Adverse Event Type of Account links. 8. Added Time Point Type description table. 9. Updated images for new Most Recent Status and Current Status columns. 10. New section. 11. Updated images for moved Payment Type column and added note about 0% Holdback for Payables. 12. New section. 13. Updated images to show Step 2 and new Site of Service and Event Name columns. 14. Added three new reports to the table. 15. Added one new report to the table. 16. Added two new reports to the table. 17. Added a note for new sorting options. 18. New section. 19. Added information on Complete Patient Data. 20. Added information on Complete Patient Data. 21. Updated images for a new Export link, a More Specimen Details field in the Search, a new Scan Multiple button, a new column header titled Storage Name, and a Child Specimens PowerBar including the Set and Clear Location buttons. 22. Moved Specimen Inventory Management after Storage Admin, changed name to include Management, and split Preparing a Sample with a Storage Kit to remain after Storage Kit Library

Version	Section	Description of Changes
	Create a Storage Kit	23. Added Disposition field in table.
	Add Multiple Storage Units	24. Added information on the new Storage naming Style dropdown.
	Child Storage Units, Edit Child Storage Units, and Search and View in Grid View	25. New sections.
	Specimen Details Overview	26. Added a note about the new See Patient Schedule link in a Patient's Specimens tab next to the Visit/Event field.
	Create Specimen and Edit a Specimen	27. Updated images for the new Age at Time of Collection field.
	Child Specimens	28. New section.
	Bulk Upload of Specimens	29. New section.
	Update Specimen Status	30. Added warning about Clear Location button.
	Associate Specimen to a Parent Specimen	31. Added image to show updated fields of Collected Amount and Current Amount.
	Export Specimens	32. New section.
	Scan Multiple Option	33. New section.
	Participant Login Details	34. Updated images and process for new Change Patient Password checkbox.
	eCompliance and Acronyms	35. New appendices.

Version	Section	Description of Changes
8	Entire user guide	1. Converted to new template.
	eSample Appendix	2. Removed to a free-standing user guide.
	Participant Portal Appendix	3. Removed to a free-standing user guide.
	eCompliance Appendix	4. Removed to a free-standing user guide.
	Networks Appendix	5. Moved after Form Management in Account Management.
	Throughout UG	6. Updated images for UI changes and updated verbiage for any links to reference. to new free-standing user guides.
	Revision History	7. Updated this table to change from Author to Section.
	About This Guide	8. Added topic bullet point.
	Deleting Users from a Group	9. Button name change in image and text.
	Email Users	10. Button name change in image and text.
	Delete a Form	11. Added note with an image.
	Submit Documents for WCG IRB Review	12. Added Success pop-up and step.
	Review Submission	13. Add #5 Notes description.
	Create a New AHQ	14. Updated image with new SAS Export button.
	Display and Export an AHQ	15. Added SAS Export to table and description.
	Account Management and Study Management	16. Added note to reference Networks section for users with Networks access.
	Account Administration	17. Added note and revised most information.
	Understanding Permissions	18. New section.
	User Experience Map	19. New section.
	Financial Management, including sub-sections from Recommended Process Overview Flowchart down to and including Updating Milestones	20. Revised approximately 20% of information and images for clarity.
	System Budget Template Types	21. New section.
	Example Milestone	22. New section.
	Appendix A – Revision History and Supported Workstations	23. Updated Supported Workstation Requirements
	Appendix C – System Icons	24. Added SAS Export icon.

9	Settings Homepage Options Add an Organization Non-System Users Deactivated Users and Reactivating their Accounts Deleting Users from a Group Manage Account – Form Management Display and Sequencing Options Linked Forms in Account Management Add a Form Modify a Form and Form Statuses Delete a Form Networks Create Networks Study Network Association Adding Users along with their Documents and Links Adding Organizational Network Documents and Links Adding Organizational Network Forms Modify Network Details Study Network Associations Search the Calendar Library Add Calendar Events Remove a Calendar Link Forms and Patient Links Add an Edit Field Add a Multi Choice Field Add Fields Versions/Attachments Tab Admin Schedule Tab Generate an Admin Schedule Study Setup tab Associate a Calendar to a Study Study Dictionaries/Settings Study Enrollment Process	Added note #3. New section. Added to note. Added notes #1 and #3. Revised title. Added to note. Revised title and complete revision for more details. New section. New section. Major revisions for more details. Revised title and complete revision for more details. Major revisions for more details. Minor revisions to first paragraph. Revised warning. Complete revisions for accuracy. New section. New section. New section. Revised second note and removed step 9 for creating a new section. Revised for new steps. New Export column images. New Cost Types to include option with new events. New Export column. Revised information on adding labs and Adverse Events to patient schedules. Added steps 5 and 6 and notes 2 and 3. Added to first note and added #2 note. Added to Lookup description and note. Revised Title. New Export column. New section. New Export column in Associated Calendars section. New Export column. Added/ updated bullet points. Added to description for Flag to Allow Patient Accrual.

Modify an Active Calendar	Added first note; added steps 3 and 7.
Update Multiple Schedules	New section.
Associated Forms	Revised note.
Notifications Tab	Added #2 to note.
Study Status Tab	Added #1 and #3 to note.
Study Enrollment Process	Updated Flag to Allow Patient Accrual information
Patient Management	Added information to first paragraphs.
Patient Search	Added steps 4 and 5 and note.
Enrolled Tab	New section.
Schedule Tab	New section.
Patient Record Tabs	New section.
Manage Patient Demographics	Added step 5.
Generate a Study Patient Schedule	Added bullet points to step 2.
Change Schedule Date	Added second paragraph and note #3.
Edit Visit	New section.
Add Unscheduled Events	New Cost Type option for new events.
Discontinuing Schedules	New section.
Patient Form Queries	New section.
Financial Management Setup	Added additional workflow information for clarity and accuracy.
Budgets	Revised Patient Cost Item note verbiage for clarity.
Budget Types and Template Types Diagram	Moved section below Budget Types to improve section structure.
System Budget Template Types	Moved section below Budget Types to improve section structure. Added links to template type example sections.
Patient Template Type Example	New Section.
Comparative Template Type Example	New Section.
Study Template Type Example	New Section.
Calendar Budget Templates	Added additional information for clarity and accuracy. Added links to new template example sections.
Create A Budget Template	Added bullet to step 2.
Create a Budget Template	Added missing Budget Template Step Updated screenshots to include new icons/functionality. Added additional information for clarity and accuracy.
Associate a Comparative or Patient Budget Template to a Calendar	New Section.

Modify a Comparative or Patient Calendar Budget	Revised title and removed basic template examples and linked to the more robust new template example sections. Added table descriptions / images for new Download and Upload budget functions. Added additional information for clarity and accuracy.
Modify a Comparative or Patient Browser Budget	New Section.
Edit Calculation Attributes (Indirects, Fringe, Discounts, and Markups)	Added additional information for clarity and accuracy. Updated screenshots. Removed template graphic and descriptions and redirected with note to new budget template sections.
Browser Budgets	New Section.
Modify a Study Browser Budget	New Section.
Create a Combined Budget	New Section.
Exporting Budget-Specific Reports	New Section.
By Visit	
Calendar Grid	New Section.
Overview	New Section.
Study Budget by Category	New Section.
Study Budget by Type	New Section.
Generating Milestones from a Budget	New Section.
Generating Additional Milestones from a Budget	New Section.
Generating Visit or Event Milestones from a Budget	New Section.
Using the Bulk Edit tool for Budgets	New Section.
Download Budget File	New Section.
Updating the Budget File	New Section.
Uploading the Budget File	New Section.
Deleting a Budget	New Section.
Milestones	Added first note. Added new ALL and All “Status” Milestone Types (Patient, Study, Visit, Event) sections to description table. Added new Milestone Achieved Date field to description table.
Example Milestone	Updated screenshot to reflect new UI changes.

Version	Section	Description of Changes
		Added note about updating achievement dates.
	Updating Milestones	Added new information about updating milestone achievement dates.
	View/Delete Achieved Milestones	Added new information about updating milestone achievement dates. Updated screenshots. Added View/Delete Achievements UI description table.
	Modifying Achievement Dates	New Section.
	Manage Invoices	Added new information about deleting line items from invoices.
	Create an Invoice	Updated table on erase / delete and added search milestones information.
	Edit an Invoice	Added new information about deleting line items from invoices. Updated screenshots to reflect new UI changes.
	Record a Payment	Added screenshots and references to reflect new Credit Memo and Write Off Payment types. Updated screenshots to reflect new UI changes.
	Reconcile by Milestone	New Section.
	Reconcile by Invoice	New Section.
	Reconcile Details	Updated screenshots to reflect new UI changes.
	Edit Payment Record	Updated Section Title. Changed references from "Reconciliation Record" to "Payment Record". Updated screenshots.
	Delete a Payment Record	Updated screenshots.
	Access and Run Reports	New Download as CSV button.
	Filtering Options	New Download as CSV button.
	Select Fields	Added steps a and b to step 6.
	Select Filter Criteria	Added bullet to step 1; added #2 and #3 to second note.
	Preview & Save	Added bullet to step 1.
	Display and Export an AHQ	Added to first paragraph.
	CTRP Reporting and all sub-sections	New section and all new sub-sections.
	Minimum Workstation Requirements	Internet Explorer is no longer supported, and Microsoft Edge is now a supported browser.

13.2 Related Software

Software	Version
Velos eResearch	13.0

13.3 Minimum Workstation Requirements

Browser	Version	Screen Resolutions
Google Chrome	104	1280x1024 1360x768
Firefox	104	
Edge	104	

14 Appendix B – Acronyms

The following table lists the acronyms used in this user guide along with what the acronyms stand for.

Acronym	Acronym Spelled Out
ADT	Admissions, Discharges, and Transfers
AE	Adverse Event
AHQ	Ad-Hoc Query/ Queries
CPU	Clinical Pharmacology Unit
CPT	Current Procedural Terminology
CRF	Case Report Form
CSV	Comma-separated Values
CTEP ID	Cancer Therapy Evaluation Program Identification
CTMS	Clinical Trial Management System
CTRP	Clinical Trial Reporting Program
DSMB	Data Safety Monitoring Board
EHR	Electronic Health Records
FDA	Food and Drug Administration
HUD	Humanitarian Use Device
IND/IDE	Investigational New Drug / Investigational Device Exemption
IRB	Independent or Institutional Review Board
LLN	Lower Limit of Normal
NCT	National Clinical Trial number
NIH	National Institutes of Health
PDF	Portable Document Format
PI	Principal Investigator
Pt	Patient

Acronym	Acronym Spelled Out
SAE	Severe Adverse Event
SOC	Standard of Care
SSO	Single Sign On
Tx	Therapy
UI	User Interface
ULN	Upper Limit of Normal
URL	Uniform Resource Locator
WIP	Work in Progress

15 Appendix C – System Icons

Icon	Name	Icon	Name	Icon	Name
	Access Rights		Delete Selected		Last Page
	Action Small		Delete Trash		Less
	Add		Design Portal		Library
	Add New Event		Disable Format		Line
	Appendix		Down		List Expand
	Audit		Edit		Milestone
	Box		Edit Section		More
	Budget		Email		More Info
	Calendar		Erase		Navigation Next
	Cart		eSample		Org
	Choice		Excel		Patient
	Clear		Financial Gadget		Personnel Cost
	Clip		Form		Preview Linear
	Comments		Form Link		Printer
	Copy		Help		Refresh
	Create		History		Repeating Line Items
	Delete		Icon Clip		SAS Export

Icon	Name	Icon	Name	Icon	Name
	Save		Schedule		Space Break
	Unexpected Event		Section		Study Patients
	Up		Setting		Study Search
	User		Snapshot		Submissions
	View		Sort Descending		Track Changes
	Word		Edit Achieved Milestone Date		

16 Appendix D – Special Character Behaviors / Reserved Words

When entering special characters on specific pages in the portal, some special characters may be saved while others may not be saved. Please see the following guidance below.

The use of the word ‘alert’ (in any case) when completing fields in the database or when naming any objects (form fields, ad-hoc query names, report names, etc.) will result in that word being removed.

Special characters allowed and NOT allowed in the Study Module:

<table>
<tr><th>Page Name/ Title</th><th>Field Name(s)</th><th>Allowed</th><th>Common Special Characters NOT Allowed</th></tr>
<tr><td rowspan="3">Study >> Summary</td><td>Study Number</td><td>~ ! @ # $ % ^ & * ( ) _ + ` - = { } |: > ? [ ] \ ; . /</td><td>Single quote ('), double quote ("), less than sign (<), Comma sign (,)</td></tr>
<tr><td>Title, Objective, Summary</td><td>~ ! @ # $ % ^ & * ( ) _ + ` - = { } | : < > ? [ ] \ ; ' , . /</td><td>Double quote (")</td></tr>
<tr><td>Principal Investigator (If Other), Agent/Device, Sponsor Name(if Other), Sponsor ID, Contact, Other Information, Keywords</td><td>~ ! @ # $ % ^ & * ( ) _ + ` - = { } | : < > ? [ ] \ ; , . /</td><td>Single quote ('), double quote (")</td></tr>
<tr><td>Study >> Summary>>More Study Details</td><td>All Text Fields</td><td>~ ! @ # $ % ^ & * ( ) _ + ` - = { } | : < > ? [ ] \ ; , . /</td><td>Single quote ('), double quote (")</td></tr>
<tr><td>Study >> Version>>Add New Version</td><td>Version Number, Notes</td><td>~ ! @ # $ % ^ & * ( ) _ + ` - = { } | : < > ? [ ] \ ; , . /</td><td>Single quote ('), double quote (")</td></tr>
<tr><td>Study >> Version>>Add New Version/Document</td><td>Version Number, Description</td><td>~ ! @ # $ % ^ & * ( ) _ + ` - = { } | : < > ? [ ] \ ; , . /</td><td>Single quote ('), double quote (")</td></tr>
<tr><td>Study >> Study Setup>>Study Treatment Arm>>Add New</td><td>Name, Description, Drug Information</td><td>~ ! @ # $ % ^ & * ( ) _ + ` - = { } | : < > ? [ ] \ ; , . /</td><td>Single quote ('), double quote (")</td></tr>
</table>

Page Name/ Title	Field Name(s)	Allowed	Common Special Characters NOT Allowed
Study >> Study Status>>Add New Status	Notes	~ ! @ # $ % ^ & * ( ) _ + ` - = { } | : < > ? [ ] \ ; , . /	Single quote ('), double quote (")
Study>>Study Team>>Add/Edit Study Team Member	First Name, Last Name	~ ! @ # $ % ^ & * ( ) _ + ` - = { } | : < > ? [ ] \ ; , . /	Single quote ('), double quote (")

Special characters allowed and NOT allowed in the Patient Module:

Page Name/ Title	Field Name(s)	Allowed	Common Special Characters NOT Allowed
Manage Patient >> Demographics	Patient ID	~ ! @ # $ ^ & * ( ) _ + ` - = { } | : < > ? [ ] ; . /	Single quote ('), double quote ("), percent (%), backslash (\), Comma sign (,)
	First Name	~ ! @ # $ % ^ & * ( ) _ + ` - = { } | : < > ? [ ] ; , . /	Single quote ('), backslash (\), double quote (")
	Middle Name	~ ! @ # $ % ^ & * ( ) _ + ` - = { } | : < > ? [ ] \ ; , . /	Single quote ('), double quote (")
	Last Name	~ ! @ # $ % ^ & * ( ) _ + ` - = { } | : < > ? [ ] ; , . /	Single quote ('), backslash (\), double quote (")
	Address1, Adress2, City, State, Country, Zip/Postal Code, Home Phone(s), Work Phone(s), E-Mail, SSN, Specify	~! @ # $ % ^ & * ( ) _ + ` - = { } | : < > ? [ ] \ ; , . /	Single quote ('), double quote (")
	Notes	~! @ # $ % ^ & * ( ) _ + ` - = { } | : < > ? [ ] \ ; , . /"	Single quote (')
	Reason For Change (FDA Audit)	~! @ # $ % ^ & * ( ) _ + ` - = { } | : < > ? [ ] \ ; , . /	Single quote ('), double quote (")
Manage Patient>> Demographics>> Register to a new organization	Patient Facility ID	~! @ # $ ^ & * ( ) _ + ` - = { } | : < > ? [ ] \ ; , . /	Single quote ('), double quote ("), percent (%)
	Provider (If Other)	~! @ # $ % ^ & * ( ) _ + ` - = { } | : < > ? [ ] \ ; , . /	Single quote ('), double quote (")
Manage Patient >> Demographics>>More Patient Details	All Text Field	~! @ # $ % ^ & * ( ) _ + ` - = { } | : < > ? [ ] \ ; , . /	Single quote ('), double quote (")
Patient >> Appendix>>Add new URL	URL, Short Description	~! @ # $ % ^ & * ( ) _ + ` - = { } | : < > ? [ ] \ ; , . /	Single quote ('), double quote (")

Page Name/ Title	Field Name(s)	Allowed	Common Special Characters NOT Allowed
Patient >> Appendix>>Upload Document	Short Description	~! @ # $ % ^ & * ( ) _ + ` - = { } | : < > ? [ ] \ ; , . /	Single quote ('), double quote (")
Patient>>Enrolled	Patient Study ID	~! @ # $ ^ & * ( ) _ + ` - = { } | : < > ? [ ] ; , . /	Percentage(%), Backslash(\), Single quote ('), double quote (")
	First Name, Last Name	~! @ # $ % ^ & * ( ) _ + ` - = { } | : < > ? [ ] ; , . /	Backslash(\), Single quote ('), double quote (")

Special characters allowed and NOT allowed in the Library Module:

Page Name/ Title	Field Name(s)	Allowed	Common Special Characters NOT Allowed
Field Library Browser>>Field type edit box	Field Name	~! @ # $ % ^ & * ( ) _ + ` - = { } | : < > ? [ ] \ ; , . /	Single quote ('), double quote (")
	Field ID	~ ! @ $ ^ * ( ) _ + ` - = { } | : < > ? [ ] \ ; , . /	Percent (%), ampersand (&), hash (#), single quote ('), double quote (")
	Field Description	~! @ # $ % ^ & * ( ) _ + ` - = { } | : < > ? [ ] \ ; , . /	Single quote ('), double quote (")
	Search Keyword	~ @ & _ + ` - = { } | : < > [ ] \ ; , . /	Single quote ('),percent (%), asterisk (*), caret (^),exclamation(!), question(?), brackets (), hash (#),dollar ($)
	Field Help	~ ! @ # $ % ^ & * ( ) _ + ` - = | : < > ? [ ] ; , . /	Backslash (\), single quote ('),double quote ("),curly brackets({})
Field Library Browser>>Multiple choice box	Field Name	~! @ # $ % ^ & * ( ) _ + ` - = { } | : < > ? [ ] \ ; , . /	Single quote ('), double quote (")
	Field ID	~ ! @ $ ^ * ( ) _ + ` - = { } | : < > ? [ ] \ ; , . /	Percent (%), ampersand (&), hash (#), single quote ('), double quote (")
	Field Description	~! @ # $ % ^ & * ( ) _ + ` - = { } | : < > ? [ ] \ ; , . /	Single quote ('), double quote (")
	Search Keyword	~ @ & _ + ` - = { } | : < > [ ] \ ; , . /	Single quote ('),percent (%), asterisk (*), caret (^),exclamation(!), question(?), brackets (), hash (#),dollar ($)

<table>
<tr><th>Page Name/ Title</th><th>Field Name(s)</th><th>Allowed</th><th>Common Special Characters NOT Allowed</th></tr>
<tr><td rowspan="2"></td><td>Field Help</td><td>~ ! @ # $ % ^ & * ( ) _ + ` - = | : < > ? [ ] ; , . /</td><td>Backslash (\), single quote ('),double quote ("),curly brackets({})</td></tr>
<tr><td>Display Value, Data Value</td><td>~! @ # $ % ^ & * ( ) _ + ` - = { } | : < > ? [ ] \ ; , . /</td><td>Single quote ('), double quote (")</td></tr>
<tr><td rowspan="2">Library Calendar >>Define the calendar</td><td>Calendar Name</td><td>~! @ # $ % ^ & * ( ) _ + ` - = { } | : ? [ ] ; , . /</td><td>Less than sign(<), Greater than sign(>), Backslash (\), Single quote ('), double quote (")</td></tr>
<tr><td>Calendar Description</td><td>~! @ # $ % ^ & * ( ) _ + ` - = { } | : < > ? [ ] \ ; , . /</td><td>Single quote ('), double quote (")</td></tr>
<tr><td>Library>>Calendar >>Copy</td><td>New Calendar Name</td><td>~! @ # $ % ^ & * ( ) _ + ` - = { } | : ? [ ] ; , .</td><td>Backslash(\), Single quote ('), double quote ("), Less than sign(<), Greater than sign(>), Forward slash(/)</td></tr>
<tr><td>Protocol Calendar>> Visit Definition</td><td>Visit Name, Description</td><td>~ ! @ # $ % ^ & * ( ) _ + ` - = { } | : " < > ? [ ] \ ; ' , . /</td><td>N/A</td></tr>
<tr><td>Event Library>> Event Category</td><td>Event Category Name, Description, Event Name, CPT Code, Notes</td><td>~! @ # $ % ^ & * ( ) _ + ` - = { } | : < > ? [ ] \ ; , . /</td><td>Single quote ('), double quote (")</td></tr>
<tr><td rowspan="2">Event Library>> Event Category</td><td>Event Category Name</td><td>~! @ # $ % ^ & * ( ) _ + ` - = { } | : < > ? [ ] \ ; , . /</td><td>Single quote ('), double quote (")</td></tr>
<tr><td>Event Category Description</td><td>~! @ # $ % ^ & * ( ) _ + ` - = { } | : < > ? [ ] \ ; , . /</td><td>Single quote ('), double quote (")</td></tr>
<tr><td>Event Library >> Event Message</td><td>Send Message to Patient, Send Message to User</td><td>~! @ # $ % ^ & * ( ) _ + ` - = { } | : < > ? [ ] \ ; , . /</td><td>Single quote ('), double quote (")</td></tr>
<tr><td>Event Library >> Event Appendix>>Link URL</td><td>URL, Short Description</td><td>~! @ # $ % ^ & * ( ) _ + ` - = { } | : < > ? [ ] \ ; , . /</td><td>Single quote ('), double quote (")</td></tr>
<tr><td>Event Library >> Event Appendix>>Upload Document</td><td>Short Description</td><td>~! @ # $ % ^ & * ( ) _ + ` - = { } | : < > ? [ ] \ ; , . /</td><td>Single quote ('), double quote (")</td></tr>
<tr><td>Event Library >> Event Resource>>Select/Edit Role Type</td><td>Notes</td><td>~! @ # $ % ^ & * ( ) _ + ` - = { } | : < > ? [ ] \ ; , . /</td><td>Single quote ('), double quote (")</td></tr>
<tr><td>Event Library >> Event Crf>>Add CRF</td><td>CRF Number, CRF Name</td><td>~! @ # $ % ^ & * ( ) _ + ` - = { } | : < > ? [ ] \ ; , . /</td><td>Single quote ('), double quote (")</td></tr>
</table>

Special characters allowed and NOT allowed in the Forms Module:

Page Name/ Title	Field Name(s)	Allowed	Common Special Characters NOT Allowed
Forms >> Define the Form	Form Name	~ ! @ # $ % ^ & * ( ) _ + ` - = { } | : ? [ ] ; , .	Single quote ('), backslash (\), double quote ("), less than sign (<), greater than sign (<), forward slash(/)
	Form Description	~ ! @ # $ % ^ & * ( ) _ + ` - = { } | : < > ? [ ] \ ; ' , . /	Double quote (")
Forms>>Add Fields>>Edit Box	Field Name	~! @ # $ % ^ & * ( ) _ + ` - = { } | : < > ? [ ] \ ; , . /	Single quote ('), double quote (")
	Field ID	~! @ $ ^ * ( ) _ + ` - = { } | : < > ? [ ] \ ; , . /	Percentage(%), And(&), Pound(#), Single quote ('), double quote (")
	Field Description	~! @ # $ % ^ & * ( ) _ + ` - = { } | : < > ? [ ] \ ; , . /	Single quote ('), double quote (")
	Search Keyword(s)	~ @ & _ + ` - = { } | : < > [ ] \ ; , . /	Single quote ('), double quote ("), Percentage(%), Asterisk(*), Caret(^), Exclamation(!), Question mark(?), Parentheses bracket(()), Pound(#), Dollar($)
	Field Help (On mouse over	~! @ # $ % ^ & * ( ) _ + ` - = | : < > ? [ ] ; , . /	Single quote ('), double quote ("), Backslash(\), Braces({})
Forms>>Add Fields>>Multi Choice	Field Name	~! @ # $ % ^ & * ( ) _ + ` - = { } | : < > ? [ ] \ ; , . /	Single quote ('), double quote (")
	Field ID	~! @ $ ^ * ( ) _ + ` - = { } | : < > ? [ ] \ ; , . /	Percentage(%), And(&), Pound(#), Single quote ('), double quote (")
	Field Description	~! @ # $ % ^ & * ( ) _ + ` - = { } | : < > ? [ ] \ ; , . /	Single quote ('), double quote (")
	Search Keyword(s)	~ @ & _ + ` - = { } | : < > [ ] \ ; , . /	Single quote ('), double quote ("), Percentage(%), Asterisk(*), Caret(^), Exclamation(!), Question mark(?), Parentheses bracket(()), Pound(#), Dollar($)
	Field Help (On mouse over	~! @ # $ % ^ & * ( ) _ + ` - = | : < > ? [ ] ; , . /	Single quote ('), double quote ("), Backslash(\), Braces({})
Forms>>Add Fields>>Comments	Text	~ ! @ # $ % ^ & * ( ) _ + ` - = { } | : " < > ? [ ] \ ; ' , . /	N/A
Forms>>Add Fields>>New Section	Section Name	~ ! @ # $ % ^ & * ( ) _ + ` - = { } | : " < > ? [ ] \ ; ' , . /	N/A

Special characters allowed and NOT allowed in the Manage Account Module:

<table>
<tr><th>Page Name/ Title</th><th>Field Name(s)</th><th>Allowed</th><th>Common Special Characters NOT Allowed</th></tr>
<tr><td>Manage Account >> Organization Details</td><td>ALL Fields</td><td>~ ! @ # $ % ^ & * ( ) _ + ` -
= { } | : " < > ? [ ] \ ; ' , . /</td><td>N/A</td></tr>
<tr><td>Manage Account >> Group Details</td><td>Group Name, Group Description</td><td>~ ! @ # $ % ^ & * ( ) _ + ` -
= { } | : " < > ? [ ] \ ; ' , . /</td><td>N/A</td></tr>
<tr><td>Manage Account >> Groups>>Add Multiple Groups</td><td>Group Name, Group Description</td><td>~ ! @ # $ % ^ & * ( ) _ + ` -
= { } | : " < > ? [ ] \ ; ' , . /</td><td>N/A</td></tr>
<tr><td>Manage Account>>User Details</td><td>F/N, L/N, Address, City, State, Country, E-Mail, # Years in Research?, Trial Phase Involvement, Secret Question, Your Answer</td><td>~ ! @ # $ % ^ & * ( ) _ + ` -
= { } | : < > ? [ ] \ ; ' , /</td><td>Double quote (")</td></tr>
<tr><td>Manage Account >> Active Account Users</td><td>By First Name, Last Name</td><td>~ ! @ # $ % ^ & * ( ) _ + ` -
= { } | : < > ? [ ] \ ; ' , /</td><td>Double quote (")</td></tr>
<tr><td>Manage Account>>User >>EmailUsers</td><td>Subject, Message Text</td><td>~ ! @ # $ % ^ & * ( ) _ + ` -
= { } | : < > ? [ ] \ ; ' , /</td><td>Double quote (")</td></tr>
<tr><td>Manage Account>>Account Links>>Add a new link</td><td>Section Heading, URL, Description</td><td>~! @ # $ % ^ & * ( ) _ + ` -
= { } | : < > ? [ ] \ ; , . /</td><td>Single quote ('), double quote (")</td></tr>
<tr><td>Portal Admin</td><td>Portal Name, Description</td><td>~ ! @ # $ % ^ & * ( ) _ + ` -
= { } | : < > ? [ ] \ ; , /</td><td>Single quote ('), double quote (")</td></tr>
</table>

Special characters allowed and NOT allowed in the Budget Module:

<table>
<tr><th>Page Name/ Title</th><th>Field Name(s)</th><th>Allowed</th><th>Common Special Characters NOT Allowed</th></tr>
<tr><td>Manage>>Budget >>New>>Details</td><td>Budget Name, Accounts(CFS), Comments</td><td>~ ! @ # $ % ^ & * ( ) _ + `
- = { } | : < > ? [ ] \ ; , /</td><td>Single quote ('), double quote (")</td></tr>
<tr><td>Manage>>Budget >>New>>Budget</td><td>Section Name, Notes</td><td>~ ! @ # $ % ^ & * ( ) _ + `
- = { } | : < > ? [ ] \ ; , /</td><td>Single quote ('), double quote (")</td></tr>
<tr><td>Manage>>Budget >>New>>Appendix>>Add new URL</td><td>URL, Short Description</td><td>~ ! @ # $ % ^ & * ( ) _ + `
- = { } | : < > ? [ ] \ ; , /</td><td>Single quote ('), double quote (")</td></tr>
</table>

Page Name/ Title	Field Name(s)	Allowed	Common Special Characters NOT Allowed
Manage>>Budget >>New>>Appendix>>Upload document	Short Description	~ ! @ # $ % ^ & * ( ) _ + ` - = { } | : < > ? [ ] \ ; , /	Single quote ('), double quote (")
Budget >> Add/Edit Line Items	Type	~ ! @ # $ % ^ & * ( ) _ + ` - = { } | : < > ? [ ] \ ; , /	Single quote ('), double quote (")

Special characters allowed and NOT allowed in the Milestone Module:

Page Name/ Title	Field Name(s)	Allowed	Common Special Characters NOT Allowed
Milestone >> Payment Browser	Description, Comments	~ ! @ # $ % ^ & * ( ) _ + ` - = { } | : " < > ? [ ] \ ; ' , . /	N/A
Milestone >>Appendix>> Add new URL	URL	~ ! @ # $ % ^ & * ( ) _ + ` - = { } | : < > ? [ ] \ ; , /	Single quote ('), double quote (")
	Short Description	~ ! @ # $ % ^ & * ( ) _ + ` - = { } | : < > ? [ ] \ ; , /	Single quote ('), double quote (")
Milestone >>Appendix	Short Description	~ ! @ # $ % ^ & * ( ) _ + ` - = { } | : < > ? [ ] \ ; , /	Single quote ('), double quote (")

Special characters allowed and NOT allowed in the Ad-Hoc Query Module:

Page Name/ Title	Field Names	Allowed	Common Special Characters NOT Allowed
Ad-Hoc Query >> Report Type	Report Header, Report Footer, Save Report As, Report Description	~ ! @ # $ % ^ & * ( ) _ + ` - = { } | : < > ? [ ] \ ; , /	Single quote ('), double quote (")

Special characters allowed and NOT allowed in the eSample Module:

<table>
<tr><th>Page Name/ Title</th><th>Field Names</th><th>Allowed</th><th>Common Special Characters NOT Allowed</th></tr>
<tr><td>eSample>> Specimens >> Add new</td><td>Alternate ID, Description, Notes, Field1</td><td>~ ! @ # $ % ^ & * ( ) _ + ` - = { } | : < > ? [ ] \ ; , /</td><td>Single quote ('), double quote (")</td></tr>
<tr><td>eSample>> Specimens>> Storage Admin>> Add New</td><td>Storage Name, Alternate ID, Notes, Status Notes</td><td>~ ! @ # $ % ^ & * ( ) _ + ` - = { } | : < > ? [ ] \ ; , /</td><td>Single quote ('), double quote (")</td></tr>
<tr><td>eSample>> Specimens>> Storage Admin>> Add Multiple</td><td>ID, Storage Name, Alternate ID</td><td>~ ! @ # $ % ^ & * ( ) _ + ` - = { } | : < > ? [ ] \ ; , /</td><td>Single quote ('), double quote (")</td></tr>
<tr><td>eSample>> Specimens>> Storage kit library>> Add new kit</td><td>Storage Kit Name, Name, Notes</td><td>~ ! @ # $ % ^ & * ( ) _ + ` - = { } | : < > ? [ ] \ ; , /</td><td>Single quote ('), double quote (")</td></tr>
</table>

Special characters allowed and NOT allowed in the eCompliance Module:

<table>
<tr><th>Page Name/ Title</th><th>Field Name</th><th>Allowed</th><th>Common Special Characters NOT Allowed</th></tr>
<tr><td rowspan="2">Research Compliance >> New Application >> Initial Details</td><td>Title</td><td>~ ! @ # $ % ^ & * ( ) _ + ` - = { } | : < > ? [ ] \ ; , / '</td><td>double quote (")</td></tr>
<tr><td>Study Number</td><td>~ ! @ # $ % ^ & * ( ) _ + ` - = { } | : > ? [ ] \ ; , /</td><td>Less than(<), Single quote ('), double quote (")</td></tr>
</table>

Special characters allowed and NOT allowed in the CTRP Module:

<table>
<tr><th>Page Name/ Title</th><th>All Fields</th><th>Allowed</th><th>Common Special Characters NOT Allowed</th></tr>
<tr><td>CTRP Trial Registration>>CTRP Draft Non-industrial</td><td>ALL Fields</td><td>~ ! @ # $ % ^ & * ( ) _ + ` - = { } | : " < > ? [ ] \ ; ' , . /</td><td>N/A</td></tr>
<tr><td>CTRP Trial Registration>>CTRP Draft Industrial</td><td>ALL Fields</td><td>~ ! @ # $ % ^ & * ( ) _ + ` - = { } | : " < > ? [ ] \ ; ' , . /</td><td>N/A</td></tr>
</table>

17 Appendix E– Permission Types

This section covers group permissions. Review the tables below, organized by permission type, for all permissions that can be applied to groups in Velos eResearch.

17.1 Administrative Rights

Access Rights	New	Edit	View
Manage Organizations	Create New Organizations	Edit Organization Details	View the Organization Details
Manage Groups	Create New Groups	Edit Group Details	View the Group Details
Assign Users to a Group	Add New Users to a Group	Remove Users from a Group	View the Users Assigned to the Group
Manage Group Rights	N/A	Edit Existing Rights for a Group	View the Group Rights
Manage users	Add New Users	Edit User Details	View User Details
Manage Account Links	Add New Account Links	Edit Account Links	View Account Links
Portal Admin	Create New Portals	Edit Portal Details	View Portal Details

17.2 Application Rights

Access Rights	New	Edit	View
Manage Protocols	Create New Studies	Edit Study Details	View Study Administrative Tabs
Calendar Library	Create New Calendars within the Library	Edit Calendar Details within the Library	View Calendars within the Library
Event Library	Create New Events within the Library	Edit Event Details within the Library	View Events within the Library
Manage Patients(*User's Primary Organization*)	Create New Patients	Edit Patient Details	View Patient Information
View Complete Patient Data	N/A	N/A	See Patient PHI information (if not checked, ***** asterisks are listed instead)^
Budget	Create New Budgets	N/A	View Budgets
Save Template	N/A	Save a Budget as a Template	View Budget Templates
Financials	N/A	N/A	View Financials
Reports	N/A	Export a Report from Report Central	View a Report from Report Central
Data Safety Monitoring	N/A	N/A	View Accrual type report
Ad-hoc Queries (AHQ)	Create New AHQ Reports	Edit Existing AHQ Reports and Delete Filters and/or Reports	View the AHQ Reports
Patient Labs	Create New Lab Data	Edit Existing Lab Data	View Existing Lab Data

^The permission View Complete Patient Data is both an application level (group) permission, as well as a study-level (study team) permission, which can affect a user's ability to see complete patient data in the View/Delete Achievements or Study Patient Roster areas, depending on the specific setup. The following scenarios describe how varying combinations of these permissions affect the user experience:

Patient Demographic data and study level dependencies in View/Delete Achievements:

- In cases where "View Complete Patient Data" is checked at the application level (group), users within the group can view complete patient (demographic) data, unless revoked at a study level
- In cases where "View Complete Patient Data" is unchecked at the application level (group), users within the group cannot view complete patient (demographic) data, unless added at a study level

Patient Demographic data and study level dependencies in the Patient Study Roster view (for a patient enrolled in more than 1 study):

- The study level access rights for "View Complete Patient Data" must be checked for all studies in order for a user to view complete patient (demographic) data across all studies.
- Unchecking the "View Complete Patient data" for any study, will revoke access to patient demographic data across all studies, for that patient for a user.

17.3 Forms Rights

Access Rights	New	Edit	View
Form Library	Create New Forms in the Form Library	Edit existing forms with the “Work in Progress” status, and only ready-only view for forms with the “Freeze” status in the Form Library	View forms in the Form Library
Filed Library	Create new fields in the Field Library	Edit existing fields in the Field Library	View fields in the Field Library
Account Form Management	Associate forms to Account, Studies, and/or Patients	Edit the form characteristics and access to the associated forms for forms with the “Work in Progress” status	View the forms under Form Management

Access Rights	New	Edit	View
Account Forms Access	Create new form response for forms linked to the Account Level	Edit existing form responses for forms linked to the Account Level	View the form and form responses for forms linked to the Account level
All Study Forms Access	Create new form response for forms linked to the Study Level	Edit existing form responses for forms linked to the Study Level	View the form and form responses for forms linked to the Study level
All Patient Forms Access	Create new form response for forms linked to the Patient Level	Edit existing form responses for forms linked to the Patient Level	View the form and form responses for forms linked to the Patient level

17.4 Inventory Management

Access Rights	New	Edit	View
Manage Storages	Create new storage unites and kits in the Biospecimen Management module	Edit existing storage units and kits in the Biospecimen Management module	View existing storage unite and kits in the Biospecimen Management module
Manage Specimens	Create new specimens in the Biospecimen Management module	Edit existing specimens in the Biospecimen Management module	View existing specimens in the Biospecimen Management module

17.5 Regulatory Reporting

Access Rights	New	Edit	View
CTRP Submission	Create new draft reports	Edit existing draft reports	View drafts, download saved drafts. And validate reports

17.6 Dashboard

Access Rights	New	Edit	View
Dashboard	N/A	N/A	View the dashboards

18 Appendix F – Study Role Permissions

This section covers study permissions. Review the tables below, organized by permission type, for all permissions that can be applied to users associated to a study in Velos eResearch.

18.1 Study Administration

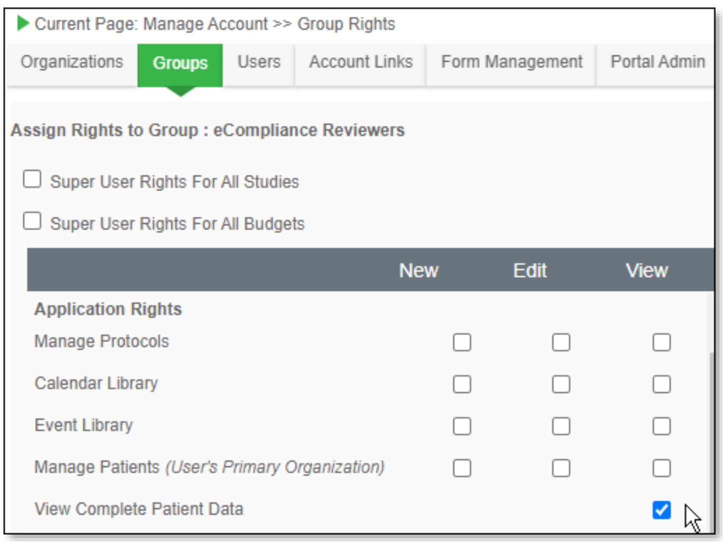
Access Rights	New	Edit	View
Study Summary	N/A	Modify existing Study data	View Study data
Versions	Create new Versions	Modify existing Versions data	View Versions data
Sections	Create new Sections	Modify existing Sections data	View Sections data
Appendix	Upload new documents and add new URLs	Modify existing Appendix data	View Appendix data
Study Setup/ Notifications/ Admin Schedule/ Combined Budget*	Add new settings, add new Event Status notifications, a calendar to the Admin Schedule tab, and a combined budget **For users to add a calendar from the Calendar Library, their group must have Viewing rights for the calendar library.**	Modify existing settings, notification, patient/admin calendars and forms	View existing settings, notification, patient/admin calendars and forms
Study Status	Add new statuses	Modify existing Study Statuses	View the Study Statuses
View Study Reports	N/A	N/A	View the study reports

Access Rights	New	Edit	View
Study Team	Add new Study Team Members and define access rights	Modify existing Study Team Members and define access rights	View Study Team Members
Study Broadcast	Add new study notifications	N/A	View study notifications
Financials: Milestones/ Invoicing/ Payments	Add milestones, invoices, appendix, and payments under the Financial Summary tab	Modify milestones, invoices, appendix, and payments under the Financial Summary tab	View the Financial Summary tab. **To view milestones, view access must be provided at the group level.**
Event Details: Financial Information	Add a new cost to an event for a study calendar	Modify the event details for an event on a study calendar When this right is provided, the Edit and View rights must be provided for **Study Setup / Notifications / Admin Schedule / Combined Budget** as well	View the event details to an event for a study calendar When this right is provided, the View right must be provided for **Study Setup / Notifications / Admin Schedule / Combined Budget** as well
WCG IRB	Add a new submission on the WCG IRB tab	Modify drafts, download outcome documents	View submissions and submission statuses

18.2 Patient Management

Access Rights	New	Edit	View
Manage Patients	Enroll patients to the study	Modify existing patient study data	View patient study data
View Complete Patient Data	N/A	N/A	*View the forms linked to the study (patient or study form) When this right is provided, the View right must be provided for **Study Setup / Notifications / Admin Schedule / Combined Budget** as well

*What is Complete Patient Data / Information?



This is an additional security feature provided for the Velos eResearch user. While defining user access rights, you may specify if that specific study team member should be able to view patient identifiable fields or not. 'Complete Patient Information' includes certain pre-determined data fields that, if hidden from the viewer, would make it impossible to identify the patient unless they are aware of the patient identification code. Although some, or all, of these fields are captured while registering a patient to the system, the user who does not have access rights to view these fields will not be able to do so.

The following fields will be *hidden* from a user who *does not have access* to view 'Complete Patient Information':

- First Name
- Middle Name
- Last Name
- Date of Birth
- SSN
- Registration Date
- Address
- City
- State
- Zip/Postal Code
- Country
- Phone Number
- Email
- Age

If a user *does not have access* to 'Complete Patient Information' *but has still been given the right to manage patients, he/she will be able to view* the following patient information:

- Patient ID
- Gender
- Marital Status
- Blood Group
- Ethnicity
- Organization to which the patient is registered
- Registered by
- Status (Active/ Inactive)
- Employment
- Education
- Study Enrollment details/Patient Schedule/Patient Reports - without any patient identifiable fields

18.3 Forms Rights

Access Rights	New	Edit	View
Study Form Management	Select forms from the library	Modify forms linked to the study or patients on the study	View the forms linked to the study (Patient or Study forms) When this right is provided, the View right must be provided for **Study Setup / Notifications / Admin Schedule / Combined Budget** as well
Study Forms Access	Create a new form response	Modify a new form response	View the study form (Patient or Study forms) listed under its respective form response browser and exiting form responses