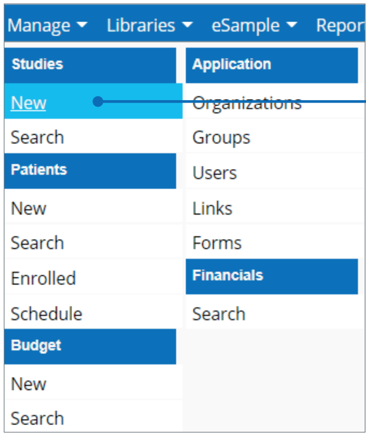
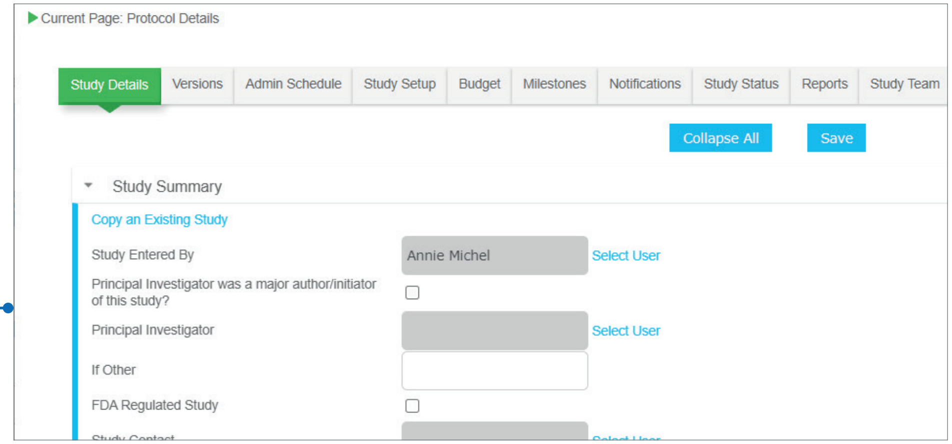
Study Management



Create a New Study

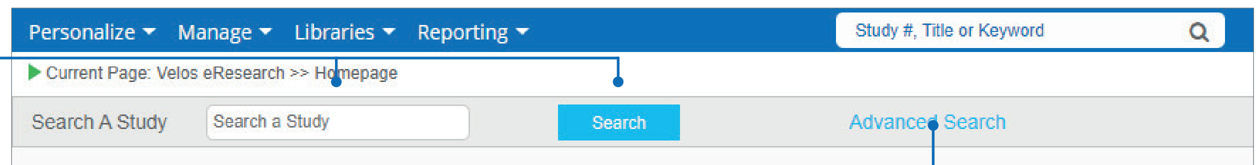
From the **Manage** dropdown, select **New** under the "Studies" heading.

The **Study Details/Summary** page displays. Enter fields as appropriate to define the study, at minimum, mandatory fields identified with red asterisks must be completed.

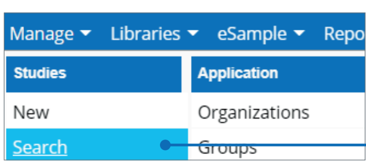


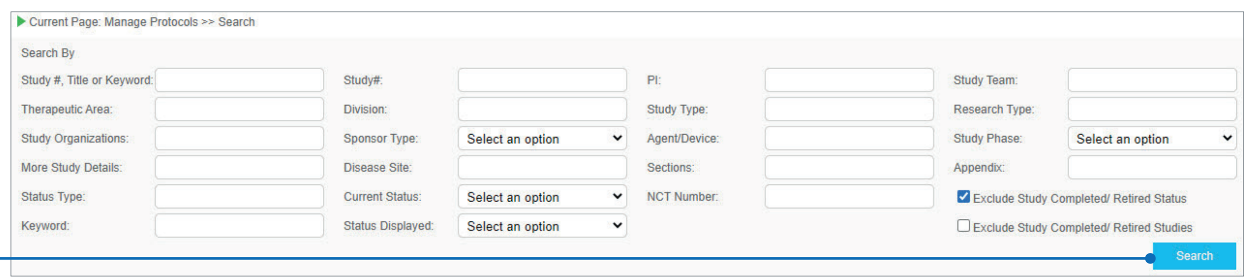
Navigate to an Existing Study

From the default homepage, enter search criteria then click the **Search** button.

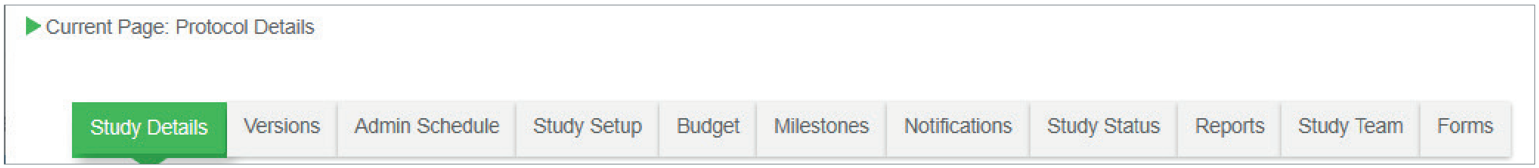


For more precise searching, click the **Advanced Search** link, or from the **Manage** dropdown, select **Search** under the "Studies" heading. It is recommended users search by entering a study number or part of a study title. Users have the ability to search for a study using Study Keywords if any were associated to the study during study creation.





Study Management Navigation Tabs



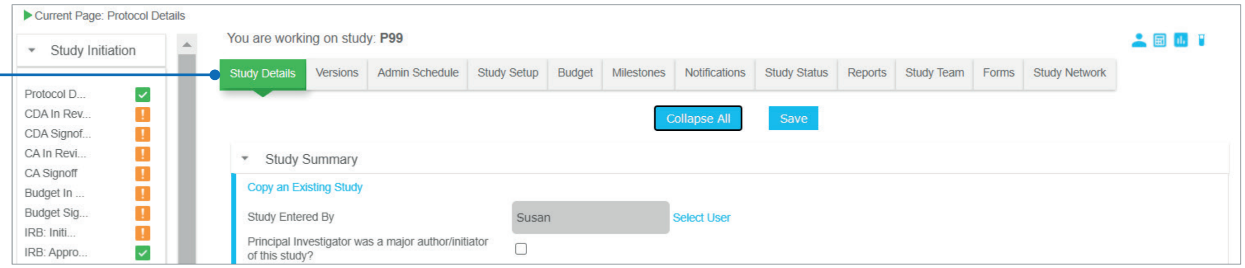
Once a study exists, the following tabs allow for Study Management:

- **Study Details/Summary** – Specify the study information, definition, details, design, and sponsor information.
- **Versions/Attachments** – Houses study documents such as correspondences, Investigator brochures, or any other documents a study team member may need to reference.
- **Admin Schedule** – Track administrative study related activities (IRB renewals, sponsor submissions, etc.)
- **Study Setup** – Allows the study team to specify the study treatment arms, select an adverse event dictionary, configure study settings, add study or patient forms, and associate calendars to generate patient schedules.
- **Budget** – Used to create a study level combined patient budget. Refer to the Financial Management Quick Reference Guide for preferred steps for adding and managing budgets.
- **Milestones** – Manage milestone rules to track completed activities for invoicing such as patient events.
- **Notifications** – There are two types of study notifications: "Alerts and Notifications" for Adverse and Serious Adverse Events and "Event Status Notifications" for patient visit calendars.
- **Study Status** – The Study Status tab lists statuses related to study activities, budgets, review boards, etc.
- **Reports** – 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.
- **Study Team** – Study Team members can be added, have their role and access rights changed, and status updated.
- **Forms** – Forms linked to "Study" are used to capture study-specific data that is not collected in one of the standard study administration tabs.

Study Summary and Versions

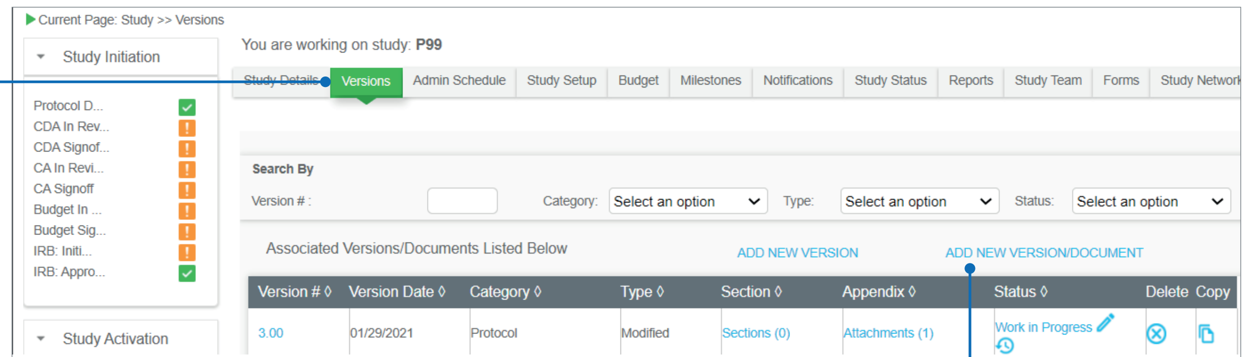
Study Details

The **Study Details/Summary** tab is used to specify the study information, definition, details, design, and sponsor information.



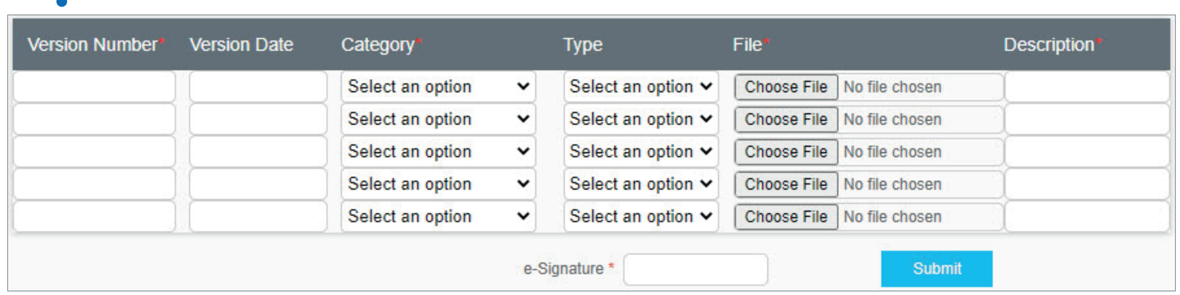
Add New Study Documents

The **Versions/Attachments** tab is used to house study documents such as correspondences, Investigator brochures, or any other documents a study team member may need to reference.



Users can select to edit an existing Document by selecting the desired version, or **Add New Version** of a document. To add a new document, click the link **Add New Document**.

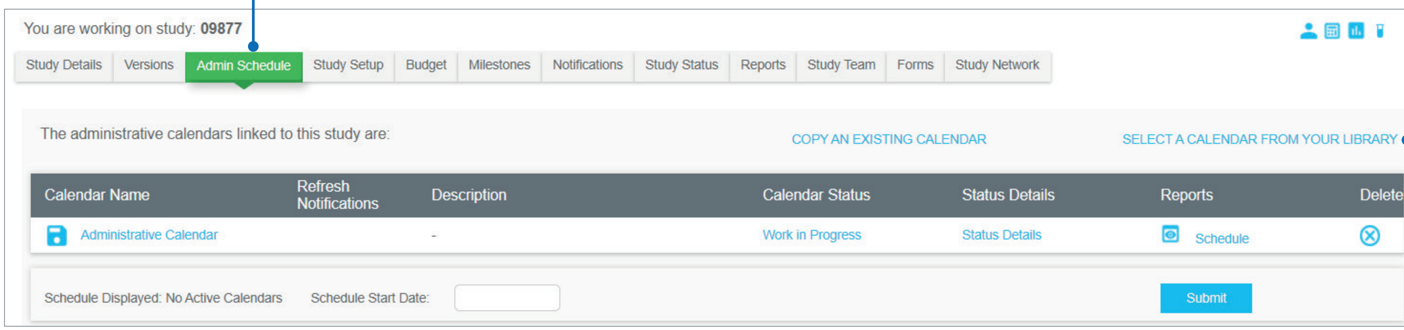
A window to enter or modify Version Number, Version Date, Category, Type, File, and document Description opens. If multiple documents should be listed under the same version, the Version Number, Version Date, Category, and Type columns need the same information for each document name to be associated with the same version.



Note: Depending on a client's configurations, the Study Details tab may be renamed as the Summary tab and the Versions tab may be renamed as the Attachments tab.

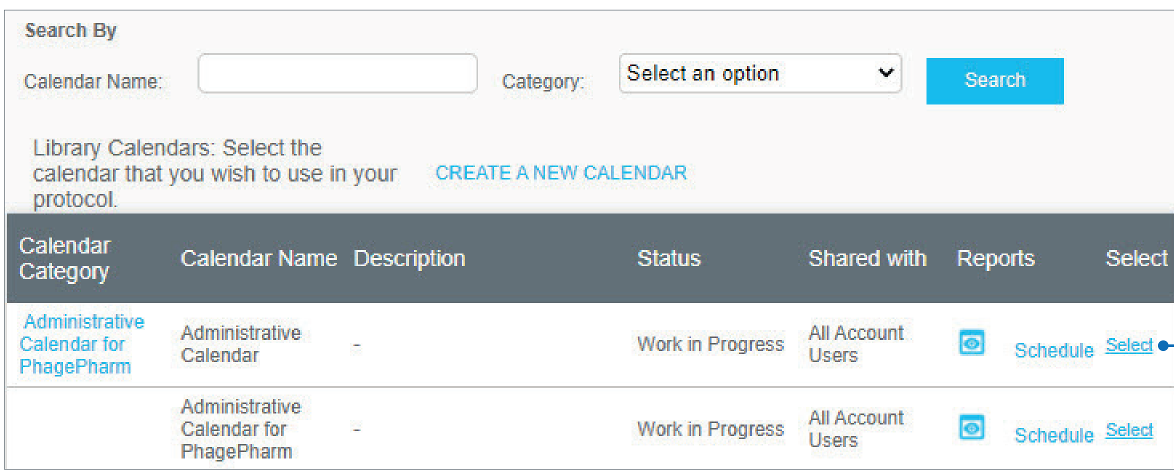
Admin Schedule

The **Admin Schedule** tab is used to associate and link administrative calendars to a specific study. A calendar must first exist in the Calendar Library before associating it to a study. Admin schedules are used to build a study-level administrative calendar containing events and visits much like a patient visit calendar, however, admin schedules are strictly used to track important dates and events for administrative tasks for the study team only.



Associate a Calendar

From the Admin Schedule tab, click select **Select A Calendar From Your Library**.

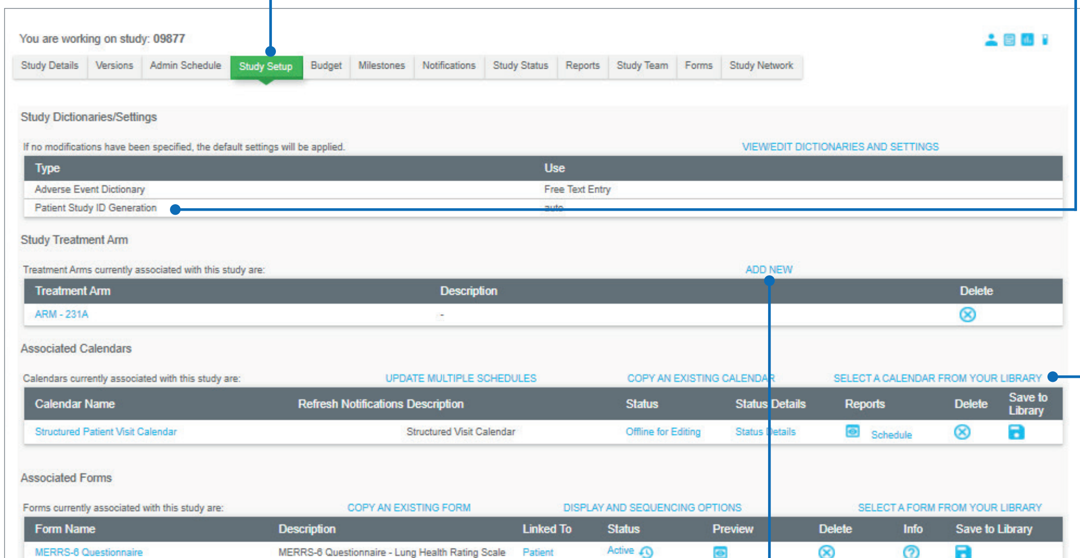


The Calendar Library window opens where users can select a calendar by clicking **Select**.

Study Setup

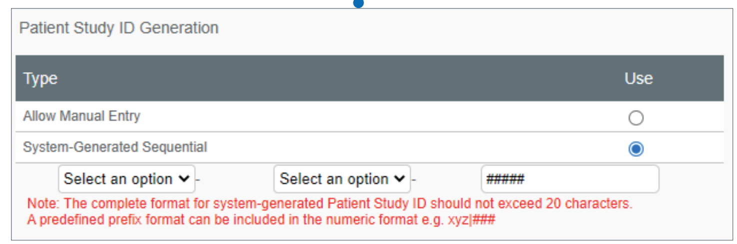
Study Setup

The **Study Setup** tab is used for patient study ID generation, study enrollment, and to manage treatment arms.



Patient Study ID Generation

Enter and modify information as needed. For Velos eResearch eXpress, it is not recommended that users select the System-Generated option for patient study ID.



Associated Calendars

Select **Select a Calendar from Your Library** to associate a Calendar from the Calendar Library. Calendars here can be modified by selecting the Calendar Name and will allow budgets to be associated to the selected calendar.

Note: To update an active calendar, you must first change the calendar status to 'Offline for Editing' and then back to 'Active' once the updates have been made.

Study Treatment Arms

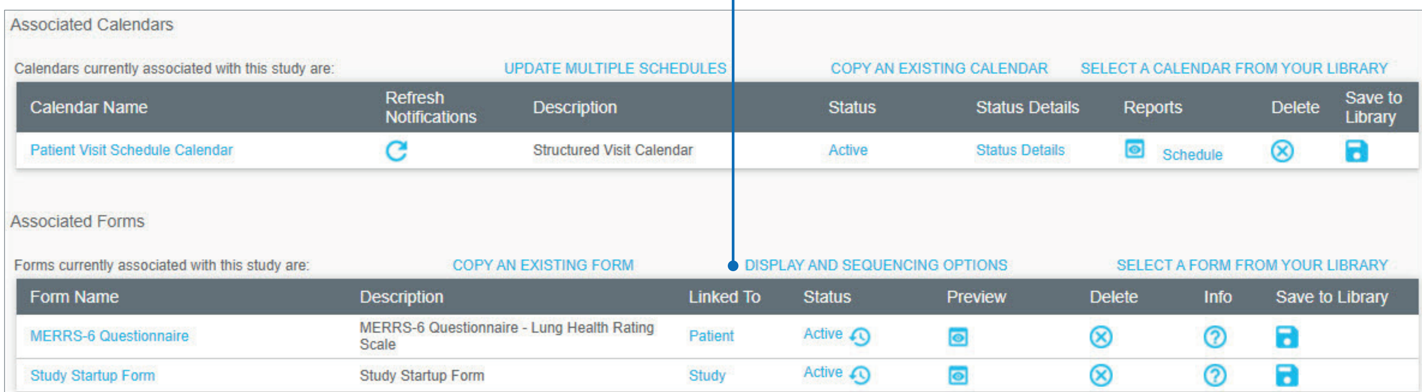
Select **Add New** to add a new Study Treatment Arm or select the Treatment Arm name to manage an existing treatment arm.

The Treatment Arm window opens. Enter information into the Name, Description, and Drug Information fields as needed.

Study Setup *(continued)*

Link Forms

The **Linked To** column allows users to Link a Form to a Study or a Patient. Study forms will appear on the Forms tab, whereas patient forms will appear during Patient Management.



Manage Forms

From the **Study Setup** tab, forms can be managed by selecting an existing form under **Form Name**, or associate a Form by clicking **Select a Form from Your Library**.

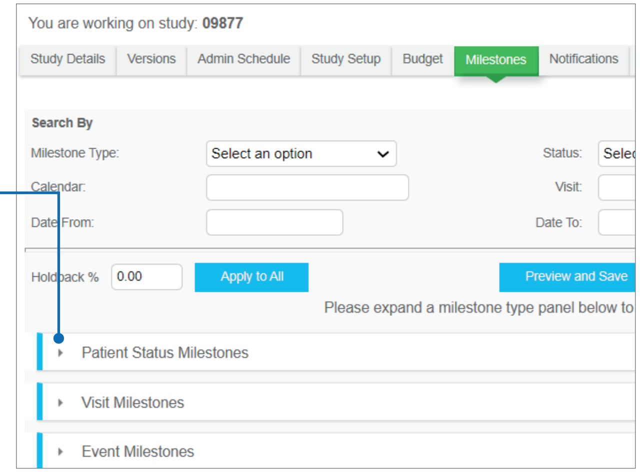
Milestones

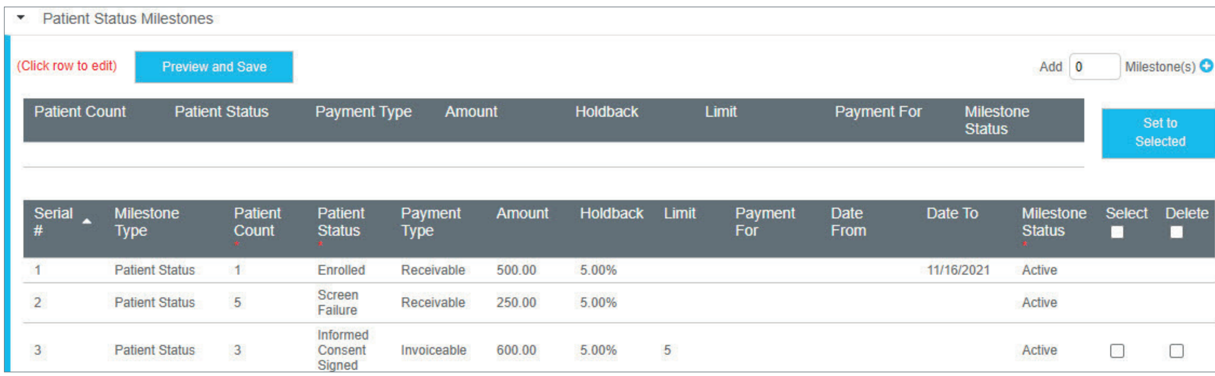
Milestone Types

There are five milestone types that users can manage: Patient Status, Visit, Event, Study Status, and Additional Milestones.

Add Milestones

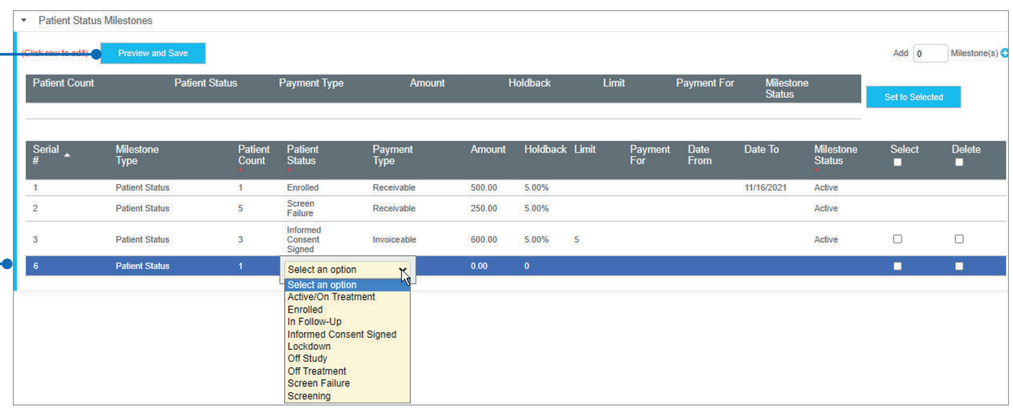
From the **Milestones** tab, select the arrows for the milestone type you wish to manage.



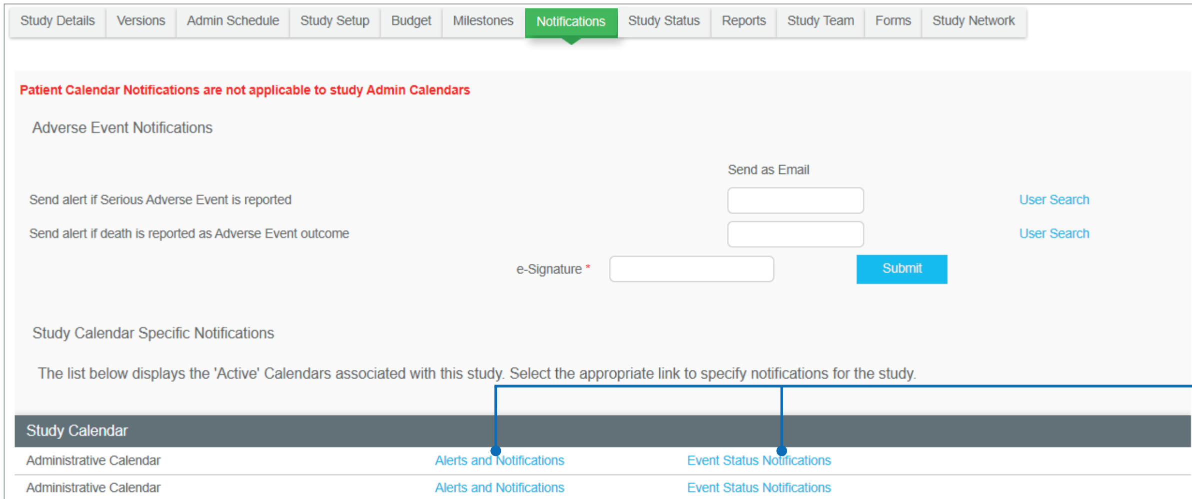


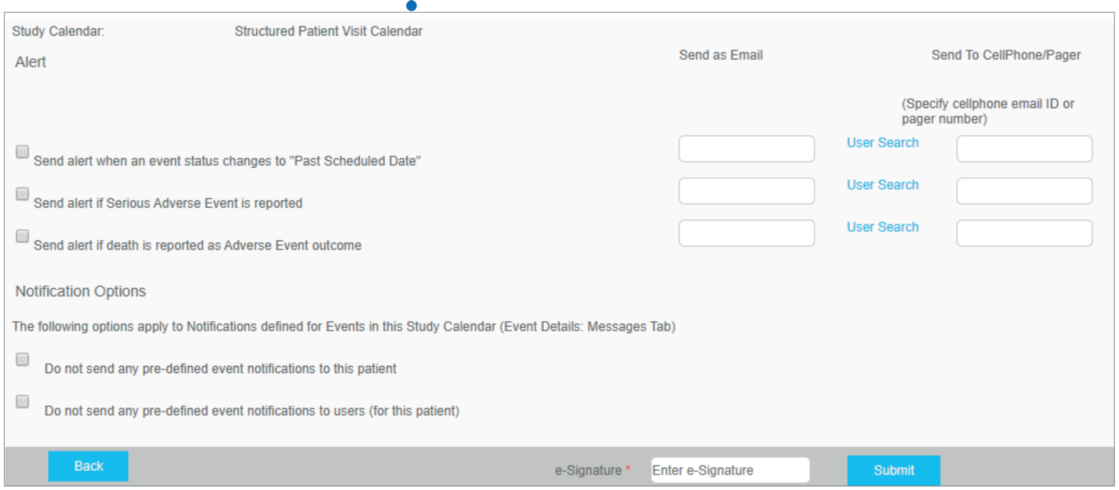
Use the **Add Milestone(s)** field to add as many rows as needed to create milestone rules. Rows are added per Milestone type.

For the added rows, define the milestone rule and then click **Preview and Save** to create rules for the Milestone type.



Notifications





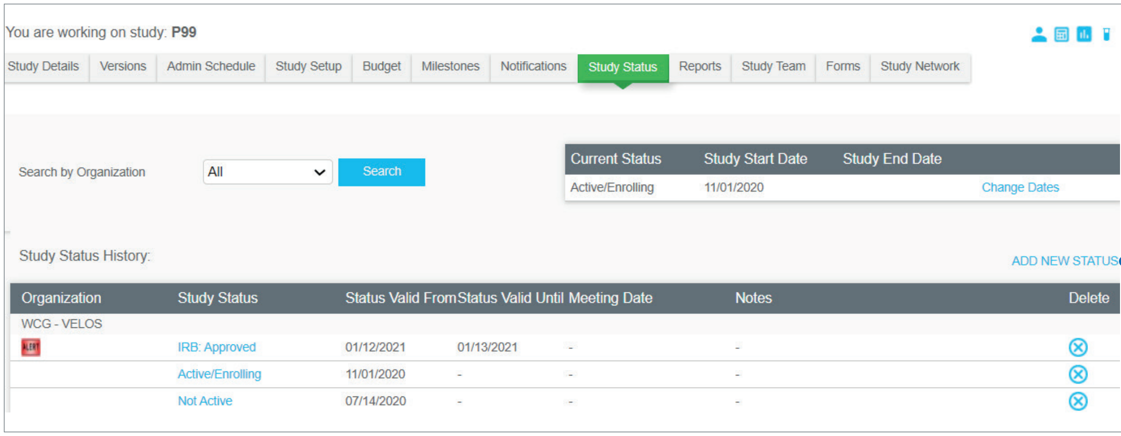
Define Notifications

From the **Notifications** tab, click the link for **Alerts and Notifications** or **Event Status Notifications** to define the notifications. Notifications can be set to notify users associated to a study by phone or email depending on what alert notifications you set.

Define the Notifications as appropriate.

Note: A patient calendar needs to be associated under Study Setup and set to active. This does not apply to Admin calendars.

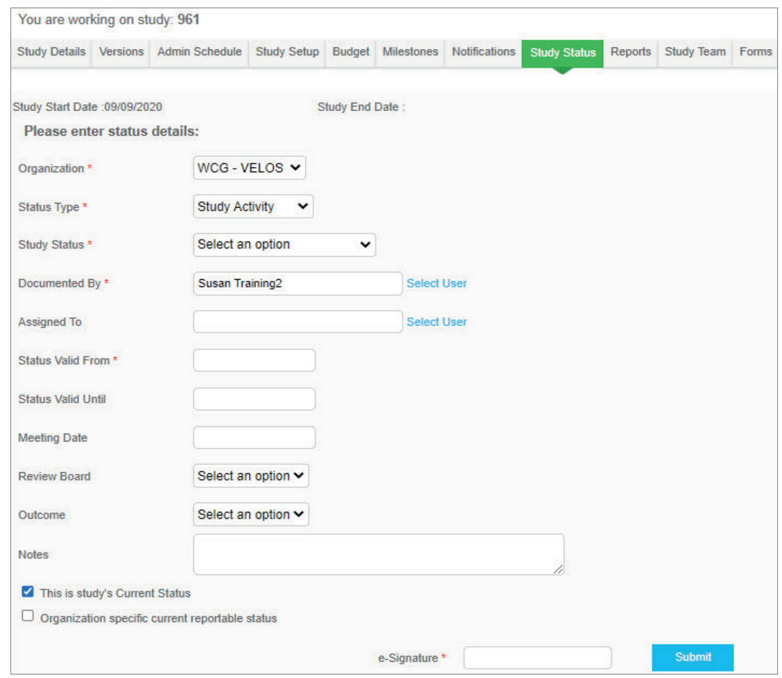
Study Status



Add a Study Status

From the **Study Status** tab, select the **Add New Status** link.

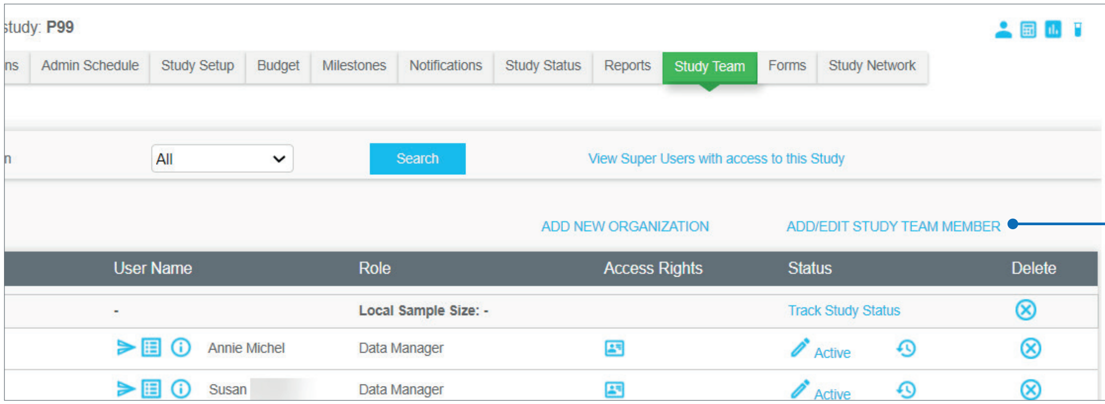
The Study Status Details page displays where users can define fields as appropriate.



Study Enrollment Statuses

Active/Enrolling	This status is the study start date and allows patients to be associated to the study.
IRB Approved	When the status is entered, along with providing a Status Valid Until date, an Indicator Icon displays in the Organization column and this indicator will change to a red alert when the IRB approval expires. Hovering over the indicator shows the number of days until IRB Expiration.
Study Retired/Completed	This status is the study end date and prevents patients to be associated to the study.

Study Team

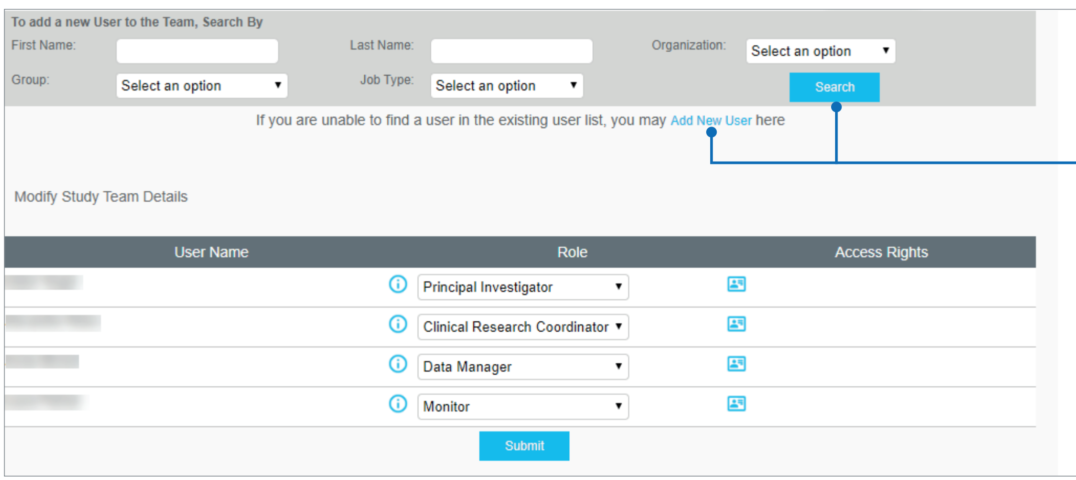


Study Team

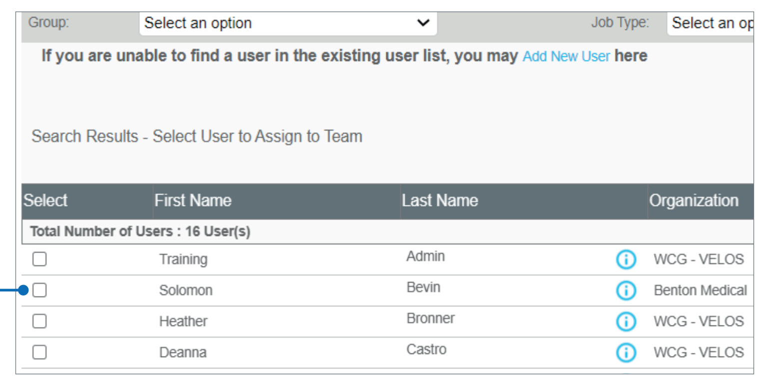
The **Study Team** tab allows users to update and modify the Study Team roles, permissions, access, and user status.

Add or Edit a Study Team Member

Select the **Add/Edit Study Team Member** link.



Search for a Study Team user using the **Search** fields or select **Add New User**.



Check the **Select** checkbox for the person to be to be added to the study team and specify the role or modify the role for an existing person.