

Study Management

Manage ▾	Libraries ▾	eSample ▾	Report
Studies	Application		
New	Organizations		
Search	Groups		
Patients	Users		
New	Links		
Search	Forms		
Enrolled	Financials		
Schedule	Search		
Budget			
New			
Search			

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.

Current Page: Protocol Details

Study Details Versions Admin Schedule Study Setup Budget Milestones Notifications Study Status Reports Study Team

Collapse All Save

Study Summary

Copy an Existing Study

Study Entered By Annie Michel [Select User](#)

Principal Investigator was a major author/initiator of this study? ☐

Principal Investigator [Select User](#)

If Other

FDA Regulated Study ☐

Study Contact [Select User](#)

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.

Personalize ▾ Manage ▾ Libraries ▾ Reporting ▾

Study #, Title or Keyword

Current Page: Velos eResearch >> Homepage

Search A Study Search [Advanced Search](#)

Manage ▾	Libraries ▾	eSample ▾	Repo
Studies	Application		
New	Organizations		
Search	Groups		

Current Page: Manage Protocols >> Search

Search By

Study #, Title or Keyword: Study#: PI: Study Team:

Therapeutic Area: Division: Study Type: Research Type:

Study Organizations: Sponsor Type: Agent/Device: Study Phase:

More Study Details: Disease Site: Sections: Appendix:

Status Type: Current Status: NCT Number:

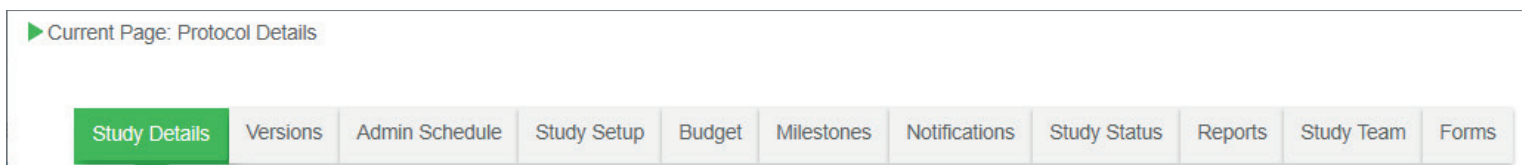
Keyword: Status Displayed:

☒ Exclude Study Completed/ Retired Status

☐ Exclude Study Completed/ Retired Studies

Search

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.

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.

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**.

Admin Schedule

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.

You are working on study: 09877

Study Details Versions **Admin Schedule** Study Setup Budget Milestones Notifications Study Status Reports Study Team Forms Study Network

The administrative calendars linked to this study are:

[COPY AN EXISTING CALENDAR](#) [SELECT A CALENDAR FROM YOUR LIBRARY](#)

Calendar Name	Refresh Notifications	Description	Calendar Status	Status Details	Reports	Delete
Administrative Calendar		-	Work in Progress	Status Details	Schedule	

Schedule Displayed: No Active Calendars Schedule Start Date: [Submit](#)

Associate a Calendar

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

Search By

Calendar Name: Category: [Select an option](#) [Search](#)

Library Calendars: Select the calendar that you wish to use in your protocol. [CREATE A NEW CALENDAR](#)

Calendar Category	Calendar Name	Description	Status	Shared with	Reports	Select
Administrative Calendar for PhagePharm	Administrative Calendar	-	Work in Progress	All Account Users	Schedule	Select
	Administrative Calendar for PhagePharm	-	Work in Progress	All Account Users	Schedule	Select

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.

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.

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 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.





Associated Calendars

Calendars currently associated with this study are:

UPDATE MULTIPLE SCHEDULES

COPY AN EXISTING CALENDAR

SELECT A CALENDAR FROM YOUR LIBRARY

Calendar Name	Refresh Notifications	Description	Status	Status Details	Reports	Delete	Save to Library
Patient Visit Schedule Calendar		Structured Visit Calendar	Active	Status Details	 Schedule		











Associated Forms

Forms currently associated with this study are:

COPY AN EXISTING FORM

DISPLAY AND SEQUENCING OPTIONS

SELECT A FORM FROM YOUR LIBRARY

Form Name	Description	Linked To	Status	Preview	Delete	Info	Save to Library
MERRS-6 Questionnaire	MERRS-6 Questionnaire - Lung Health Rating Scale	Patient	Active 				
Study Startup Form	Study Startup Form	Study	Active 				

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.

▼ Patient Status Milestones

(Click row to edit)

Preview and Save

Add0Milestone(s)

Set to Selected

Patient Count	Patient Status	Payment Type	Amount	Holdback	Limit	Payment For	Milestone Status						
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	500.00	5.00%				11/16/2021	Active		
2	Patient Status	5	Screen Failure	Receivable	250.00	5.00%					Active		
3	Patient Status	3	Informed Consent Signed	Invoiceable	600.00	5.00%	5				Active	<input type="checkbox"/>	<input type="checkbox"/>

You are working on study: 09877

Study Details | Versions | Admin Schedule | Study Setup | Budget | **Milestones** | Notifications

Search By

Milestone Type: Status:

Calendar:

Date From: Date To:

Holdback % [Apply to All](#) [Preview and Save](#)

Please expand a milestone type panel below to

- ▶ Patient Status Milestones
- ▶ Visit Milestones
- ▶ Event Milestones

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.

▼ Patient Status Milestones

Click row to edit

Preview and Save

Add 0 Milestone(s)

Set to Selected

Patient Count	Patient Status	Payment Type	Amount	Holdback	Limit	Payment For	Milestone Status						
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	500.00	5.00%				11/16/2021	Active		
2	Patient Status	5	Screen Failure	Receivable	250.00	5.00%					Active		
3	Patient Status	3	Informed Consent Signed	Invoiceable	600.00	5.00%	5				Active	<input type="checkbox"/>	<input type="checkbox"/>
6	Patient Status	1	Select an option		0.00	0						<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>

Select an option

Select an option

Active/On Treatment

Enrolled

In Follow-Up

Informed Consent Signed

Lockdown

Off Study

Off Treatment

Screen Failure

Screening

Notifications

Study Details Versions Admin Schedule Study Setup Budget Milestones **Notifications** Study Status Reports Study Team Forms Study Network

Patient Calendar Notifications are not applicable to study Admin Calendars

Adverse Event Notifications

Send alert if Serious Adverse Event is reported [User Search](#)

Send alert if death is reported as Adverse Event outcome [User Search](#)

e-Signature *

Study Calendar Specific Notifications

The list below displays the 'Active' Calendars associated with this study. Select the appropriate link to specify notifications for the study.

Study Calendar		
Administrative Calendar	Alerts and Notifications	Event Status Notifications
Administrative Calendar	Alerts and Notifications	Event Status Notifications

Study Calendar: Structured Patient Visit Calendar

Alert

Send as Email

Send To CellPhone/Pager
(Specify cellphone email ID or pager number)

☐ Send alert when an event status changes to "Past Scheduled Date" [User Search](#)

☐ Send alert if Serious Adverse Event is reported [User Search](#)

☐ Send alert if death is reported as Adverse Event outcome [User Search](#)

Notification Options

The following options apply to Notifications defined for Events in this Study Calendar (Event Details: Messages Tab)

☐ Do not send any pre-defined event notifications to this patient

☐ Do not send any pre-defined event notifications to users (for this patient)

e-Signature *

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

You are working on study: **P99**

Study Details | Versions | Admin Schedule | Study Setup | Budget | Milestones | Notifications | **Study Status** | Reports | Study Team | Forms | Study Network

Search by Organization: All Search

Current Status	Study Start Date	Study End Date
Active/Enrolling	11/01/2020	Change Dates

[ADD NEW STATUS](#)

Study Status History:

Organization	Study Status	Status Valid From	Status Valid Until	Meeting Date	Notes	Delete
WCG - VELOS	IRB: Approved	01/12/2021	01/13/2021	-	-	
	Active/Enrolling	11/01/2020	-	-	-	
	Not Active	07/14/2020	-	-	-	

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.

You are working on study: **961**

Study Details | Versions | Admin Schedule | Study Setup | Budget | Milestones | Notifications | **Study Status** | Reports | Study Team | Forms

Study Start Date : 09/09/2020 Study End Date :

Please enter status details:

Organization * WCG - VELOS

Status Type * Study Activity

Study Status * Select an option

Documented By * Susan Training2 [Select User](#)

Assigned To [Select User](#)

Status Valid From *

Status Valid Until

Meeting Date

Review Board Select an option

Outcome Select an option

Notes

☒ This is study's Current Status
☐ Organization specific current reportable status

e-Signature * Submit

Study Team

Study: P99

ns Admin Schedule Study Setup Budget Milestones Notifications Study Status Reports **Study Team** Forms Study Network

All View Super Users with access to this Study

[ADD NEW ORGANIZATION](#) [ADD/EDIT STUDY TEAM MEMBER](#)

User Name	Role	Access Rights	Status	Delete
-	Local Sample Size: -		Track Study Status	<input type="button" value="X"/>
Annie Michel	Data Manager		Active	<input type="button" value="X"/>
Susan	Data Manager		Active	<input type="button" value="X"/>

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.

To add a new User to the Team, Search By

First Name: Last Name: Organization:

Group: Job Type:

If you are unable to find a user in the existing user list, you may [Add New User](#) here

Modify Study Team Details

User Name	Role	Access Rights
	Principal Investigator	
	Clinical Research Coordinator	
	Data Manager	
	Monitor	

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

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

Group: Job Type:

If you are unable to find a user in the existing user list, you may [Add New User](#) here

Search Results - Select User to Assign to Team

Select	First Name	Last Name	Organization
Total Number of Users : 16 User(s)			
<input type="checkbox"/>	Training	Admin	WCG - VELOS
<input type="checkbox"/>	Solomon	Bevin	Benton Medical
<input type="checkbox"/>	Heather	Bronner	WCG - VELOS
<input type="checkbox"/>	Deanna	Castro	WCG - VELOS