

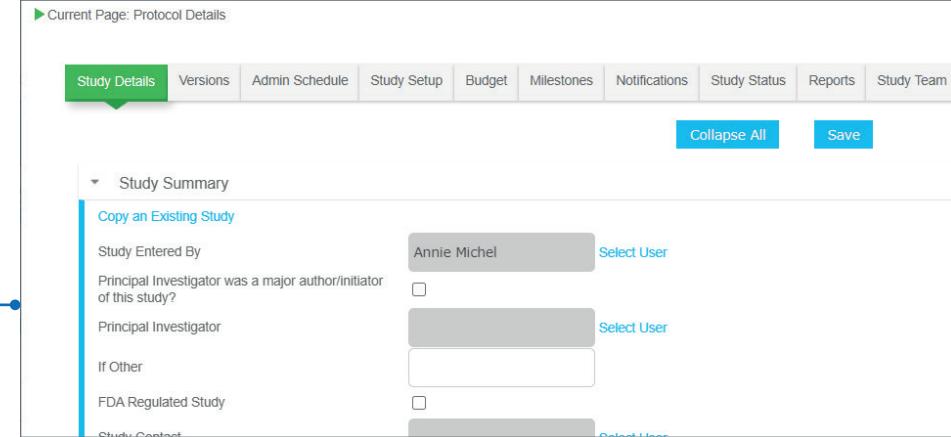
Manage ▾ Libraries ▾ eSample ▾ Reports

Studies	Application
New	Organizations
Search	Groups
<b>Patients</b>	Users
New	Links
Search	Forms
Enrolled	Financials
Schedule	Search
<b>Budget</b>	
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.



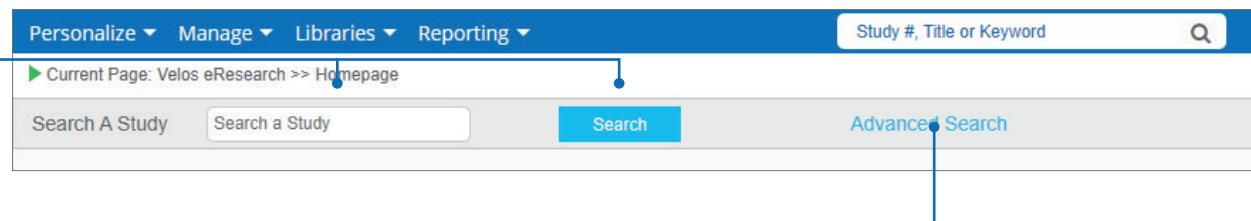
► Current Page: Protocol Details

Study Details	Versions	Admin Schedule	Study Setup	Budget	Milestones	Notifications	Study Status	Reports	Study Team
<b>Study Summary</b>									
<a href="#">Copy an Existing Study</a>									
Study Entered By	Annie Michel	<a href="#">Select User</a>							
Principal Investigator was a major author/initiator of this study?	<input type="checkbox"/>								
Principal Investigator		<a href="#">Select User</a>							
If Other									
FDA Regulated Study	<input type="checkbox"/>								
Study Contact		<a href="#">Select User</a>							

## Navigate to an Existing Study

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

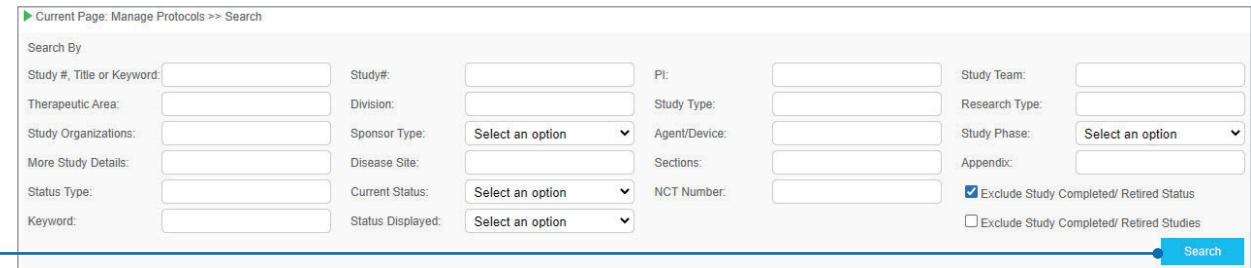
For more precise searching, click the **Advanced Search** link, or from the **Manage** dropdown, select **Search** under the "Studies" heading. It is recommended users search by entering a study number or part of a study title. Users have the ability to search for a study using Study Keywords if any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



Personalize ▾ Manage ▾ Libraries ▾ Reporting ▾

► Current Page: Velos eResearch >> Homepage

Study #, Title or Keyword			
<a href="#">Search A Study</a>	<a href="#">Search a Study</a>	<a href="#">Search</a>	<a href="#">Advanced Search</a>



► 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:	<input checked="" type="checkbox"/> Exclude Study Completed/ Retired Status
Keyword:	Status Displayed:		<input type="checkbox"/> Exclude Study Completed/ Retired Studies

## Study Management Navigation Tabs

▶ Current Page: Protocol Details

[Study Details](#) [Versions](#) [Admin Schedule](#) [Study Setup](#) [Budget](#) [Milestones](#) [Notifications](#) [Study Status](#) [Reports](#) [Study Team](#) [Forms](#)

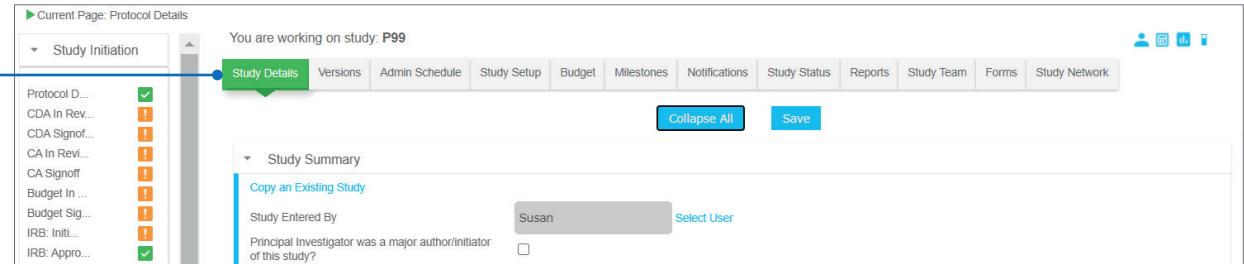
Once a study exists, the following tabs allow for Study Management:

- **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

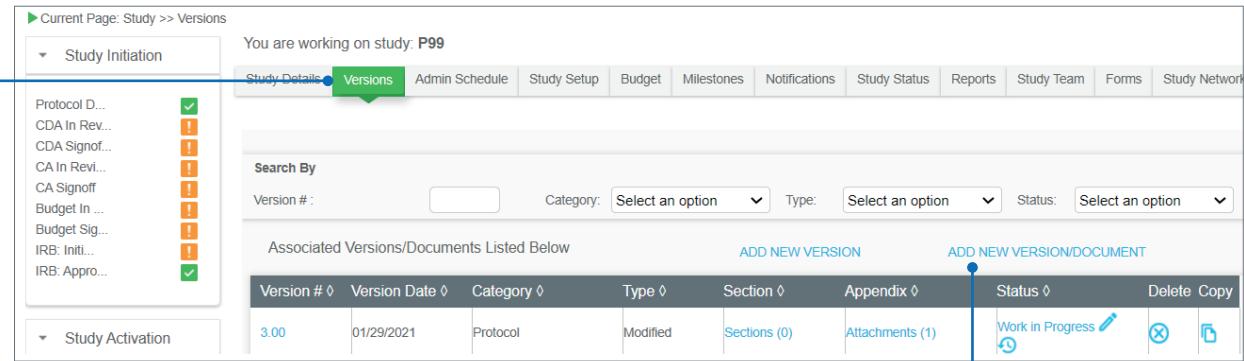
### Study Details

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



### Add New Study Documents

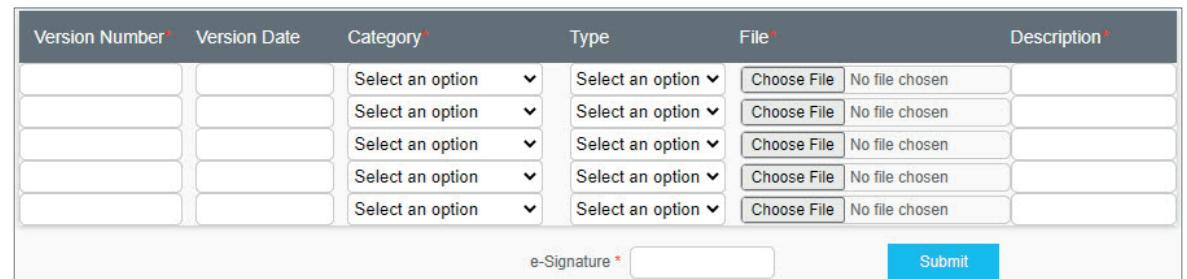
The **Versions/Attachments** tab is used to house study documents such as correspondences, Investigator brochures, or any other documents a study team member may need to reference.



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

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.

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

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**.

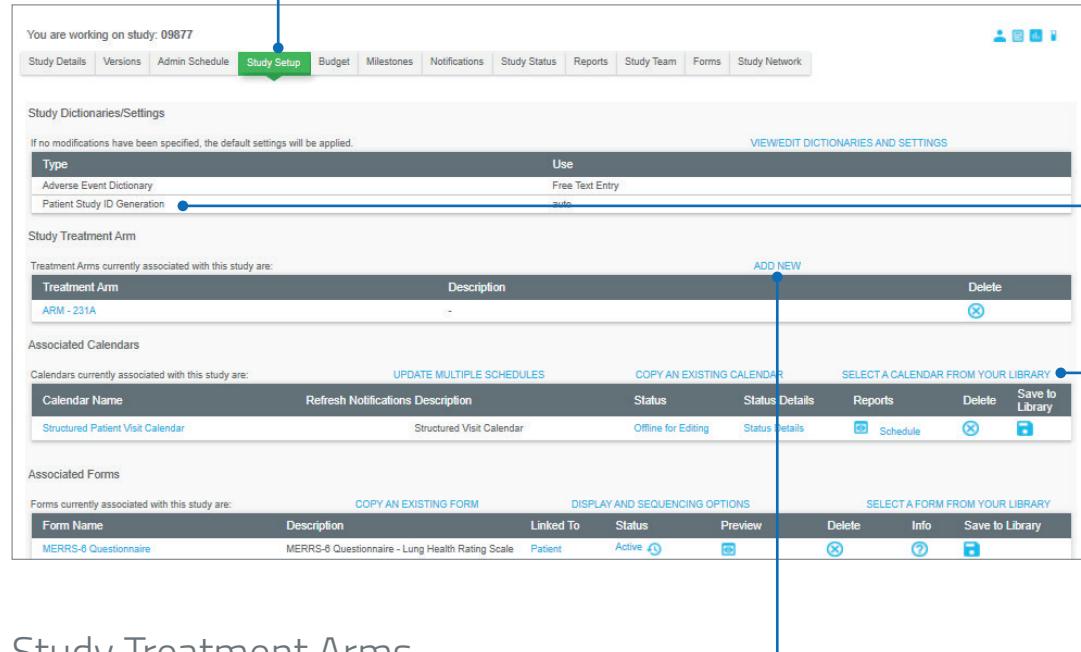
Search By	Category	Search				
Calendar Name: <input type="text"/>	Select an option					
Library Calendars: Select the calendar that you wish to use in your protocol. <a href="#">CREATE A NEW CALENDAR</a>						
Calendar Category	Calendar Name	Description	Status	Shared with	Reports	Select
Administrative Calendar for PhagePharm	Administrative Calendar	-	Work in Progress	All Account Users	Schedule	<a href="#">Select</a>
	Administrative Calendar for PhagePharm	-	Work in Progress	All Account Users	Schedule	<a href="#">Select</a>

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



## Study Setup

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



You are working on study: 09877

**Study Setup** (highlighted)

Study Dictionaries/Settings

If no modifications have been specified, the default settings will be applied.

Type	Use
Adverse Event Dictionary	Free Text Entry
Patient Study ID Generation	auto

**Study Treatment Arm**

Treatment Arms currently associated with this study are:

Treatment Arm	Description	ADD NEW	Delete
ARM - 231A			

**Associated Calendars**

Calendars currently associated with this study are:

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

**Associated Forms**

Forms currently associated with this study are:

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

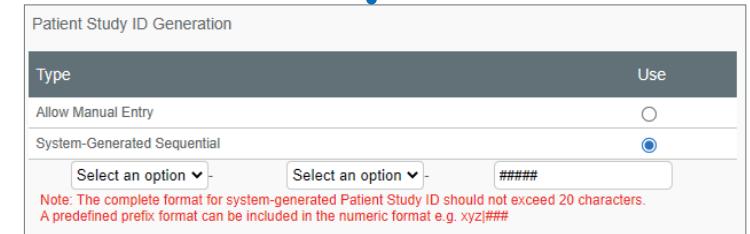
## Study Treatment Arms

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.



Patient Study ID Generation

**Type**

Allow Manual Entry

System-Generated Sequential

Select an option  Select an option  #####

Note: The complete format for system-generated Patient Study ID should not exceed 20 characters. A predefined prefix format can be included in the numeric format e.g. xyz|###

## 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.*



Treatment Arm

Name\*

Description

Drug Information

e-Signature\*

Submit

## 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:								
Calendar Name	Refresh Notifications	Description	Status	Status Details	Reports	Delete	Save to Library	
Patient Visit Schedule Calendar		Structured Visit Calendar	Active	<a href="#">Status Details</a>	 Schedule			
Associated Forms								
Forms currently associated with this study are:			<a href="#">COPY AN EXISTING FORM</a>		<a href="#">DISPLAY AND SEQUENCING OPTIONS</a>		<a href="#">SELECT A FORM FROM YOUR LIBRARY</a>	
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.

(Click row to edit) Preview and Save

										Add <input type="button" value="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 <input type="checkbox"/>	Delete <input type="checkbox"/>	
1	Patient Status	1	Enrolled	Receivable	500.00	5.00%				11/16/2021	Active	<input type="checkbox"/>	<input type="checkbox"/>	
2	Patient Status	5	Screen Failure	Receivable	250.00	5.00%					Active	<input type="checkbox"/>	<input type="checkbox"/>	
3	Patient Status	3	Informed Consent Signed	Invoiceable	600.00	5.00%	5				Active	<input type="checkbox"/>	<input type="checkbox"/>	

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

### Add Milestones

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

You are working on study: 09877

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

**Search By**

Milestone Type:

Calendar:

Date From:

Date To:

Holdback %:   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.

(Click row to edit) Preview and Save

Milestone(s) 

**Patient Status Milestones**



- Active/On Treatment
- Enrolled
- In Follow-Up
- Informed Consent Signed
- Lockdown
- Off Study
- On 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

Send alert if death is reported as Adverse Event outcome

Send as Email   
User Search

e-Signature \*  **Submit**

**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	Alerts and Notifications	Event Status Notifications
Administrative Calendar	<a href="#">Alerts and Notifications</a>	<a href="#">Event Status Notifications</a>
Administrative Calendar	<a href="#">Alerts and Notifications</a>	<a href="#">Event Status Notifications</a>

**Study Calendar:** Structured Patient Visit Calendar

**Alert**

Send alert when an event status changes to "Past Scheduled Date"  
 Send alert if Serious Adverse Event is reported  
 Send alert if death is reported as Adverse Event outcome

Send as Email   
Send To CellPhone/Pager   
(Specify cellphone email ID or pager number)  
User Search   
User Search   
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)

**Back** **e-Signature \*** **Enter e-Signature** **Submit**

## 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.*



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	<a href="#">Change Dates</a>

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 NEW 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.

You are working on study: 961

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

Please enter status details:

Organization *	<input type="text" value="WCG - VELOS"/>
Status Type *	<input type="text" value="Study Activity"/>
Study Status *	<input type="text" value="Select an option"/>
Documented By *	<input type="text" value="Susan Training2"/> <a href="#">Select User</a>
Assigned To	<input type="text"/> <a href="#">Select User</a>
Status Valid From *	<input type="text"/>
Status Valid Until	<input type="text"/>
Meeting Date	<input type="text"/>
Review Board	<input type="text" value="Select an option"/>
Outcome	<input type="text" value="Select an option"/>
Notes	<input type="text"/>

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

e-Signature \*  [Submit](#)

## Study Enrollment Statuses

<b>Active/Enrolling</b>	This status is the study start date and allows patients to be associated to the study.
<b>IRB Approved</b>	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.
<b>Study Retired/Completed</b>	This status is the study end date and prevents patients to be associated to the study.



study: P99

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

Search 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	
  Annie Michel	Data Manager		Active 	
  Susan	Data Manager		Active 	

To add a new User to the Team, Search By

First Name:  Last Name:  Organization:  Select an option

Group:  Job Type:  Search

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 	

Submit

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.

## 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**.

Group:  Job Type:  Select an option

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