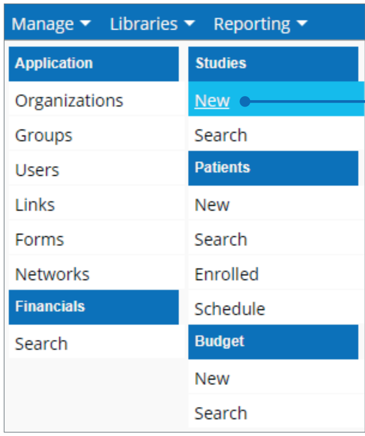
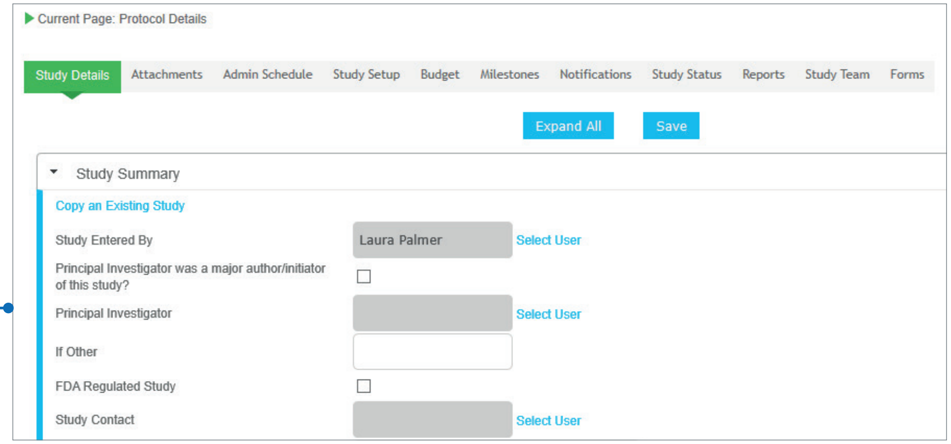
Study Management



Create a New Study

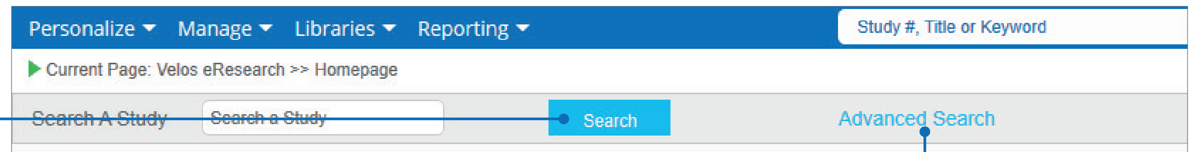
From the **Manage** tab, select **New** under the "Studies" heading.

The **Summary** page displays. Enter fields as appropriate to define the study.

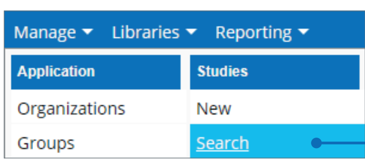


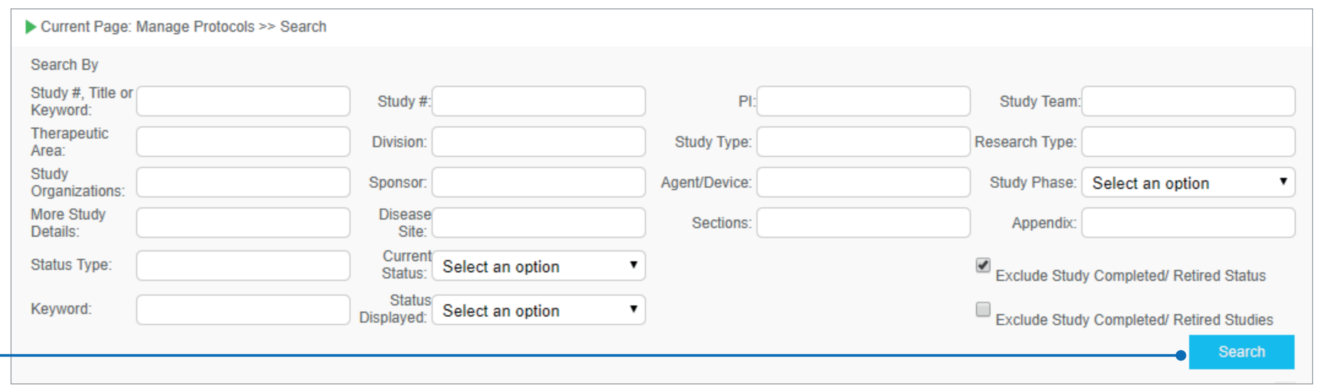
Navigate to an Existing Study

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

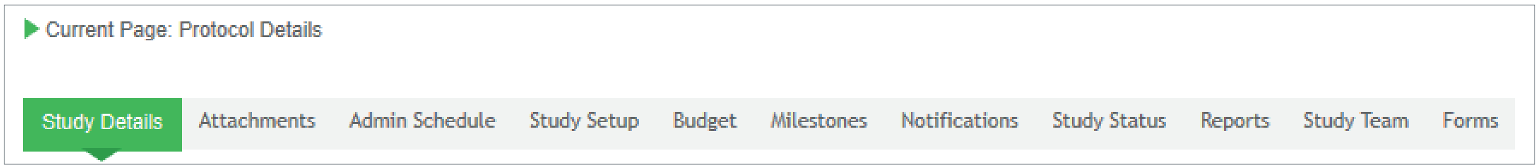


From more precise searching, click the **ADVANCED SEARCH** link, or from the **Manage** tab, select **Search** under the "Studies" heading. It is recommended users search by entering a study number or part of a study title. Users have the ability to search for a study using Study Keywords if any were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





Study Management Navigation Tabs



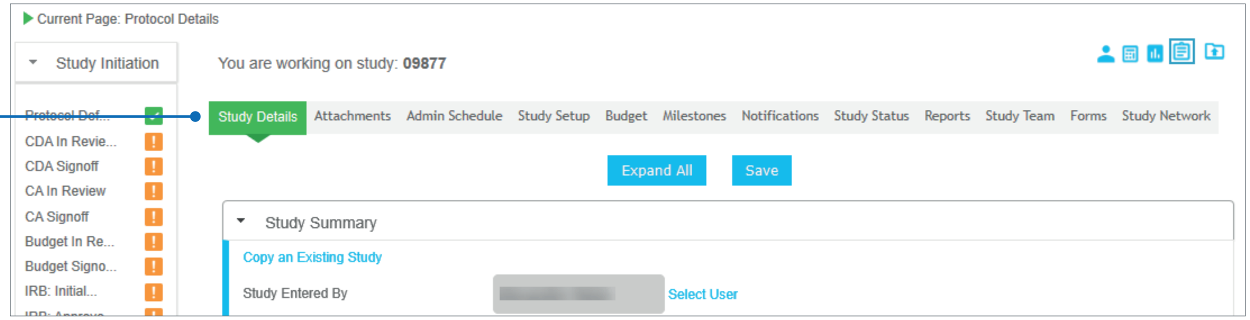
Once a study exists, the following tabs allow for Study Management:

- **Summary** – Specify the study information, definition, details, design, and sponsor information.
- **Versions** – Houses study documents such as correspondences, Investigator brochures, or any other documents a study team member may need to reference.
- **Admin Schedule** – Track study related activities (IRB renewals, sponsor submissions, etc.)
- **Study Setup** – Allows the study team to specify the study treatment arms and associate calendars to generate patient schedules.
- **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" and "Event Status Notifications".
- **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

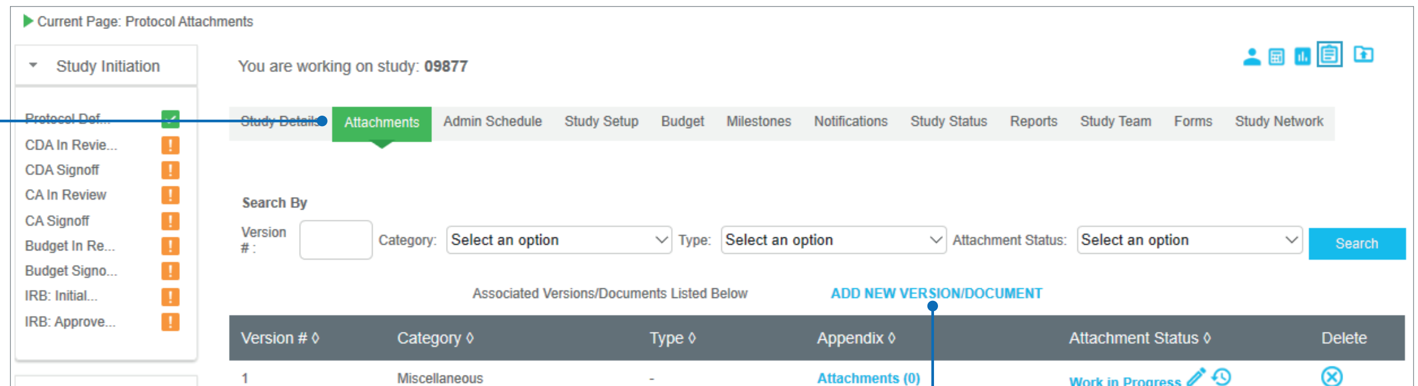
Study Summary

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



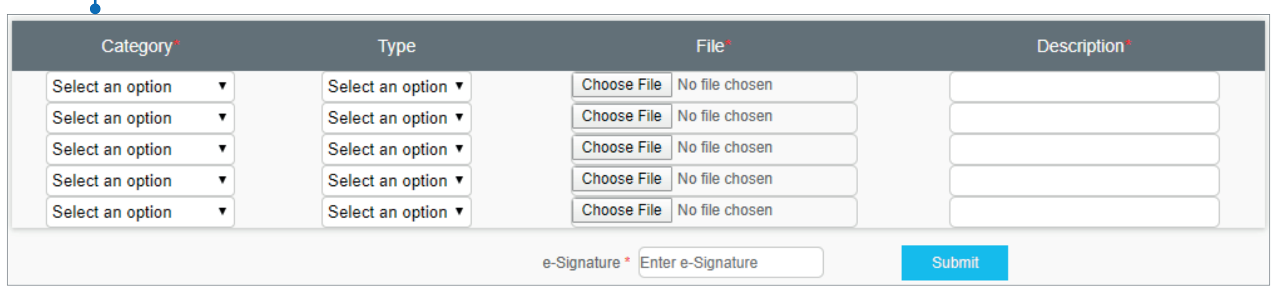
Add New Study Versions/Documents

The **Study 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**.

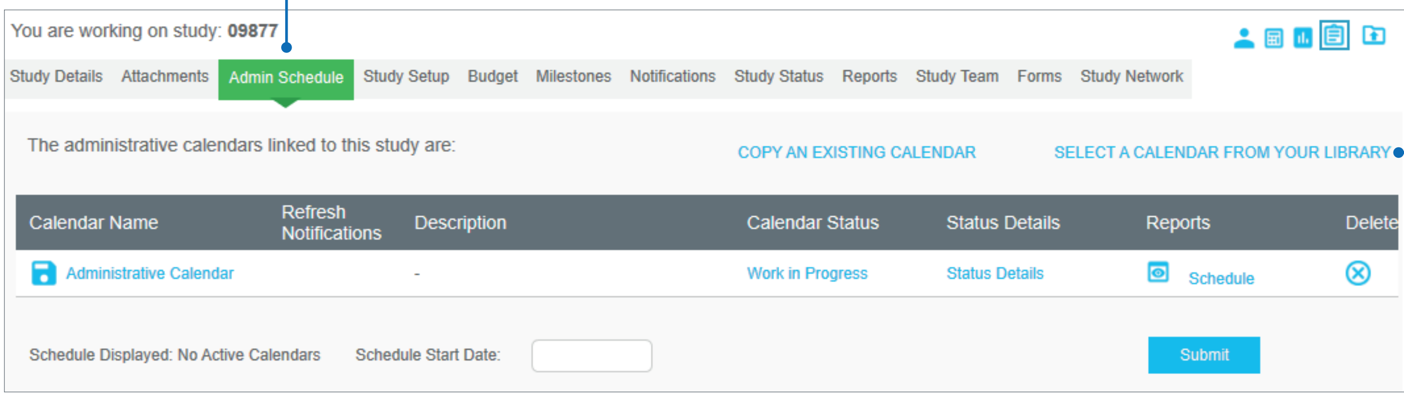
A window to enter or modify Version Number, Version Date, Category, Type, File, and document Description opens. If multiple documents should be listed under the same version, the Version Number, Version Date, Category, and Type columns need the same information for each document name to be associated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



Admin Schedule

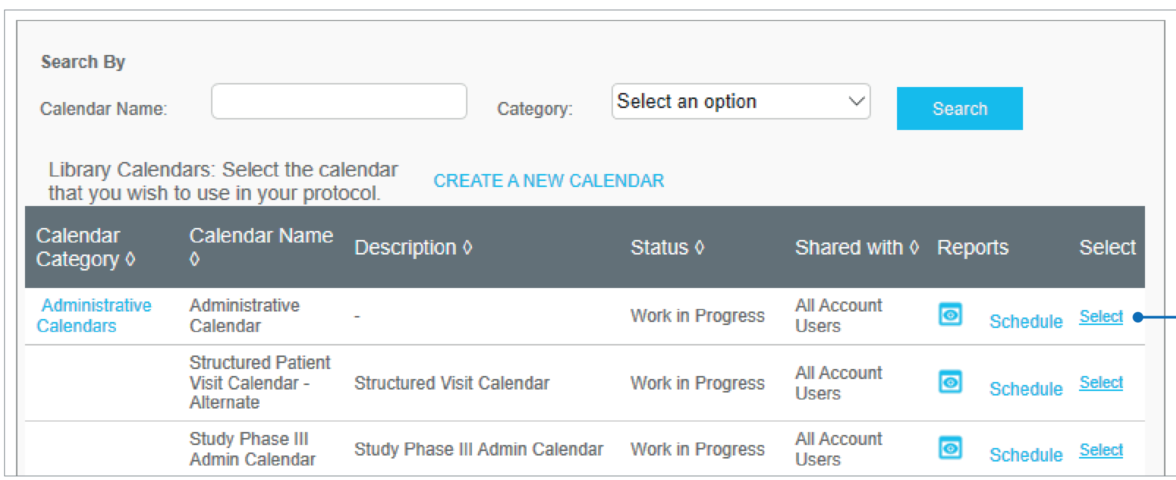
Admin Schedule

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.



Associate a Calendar

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

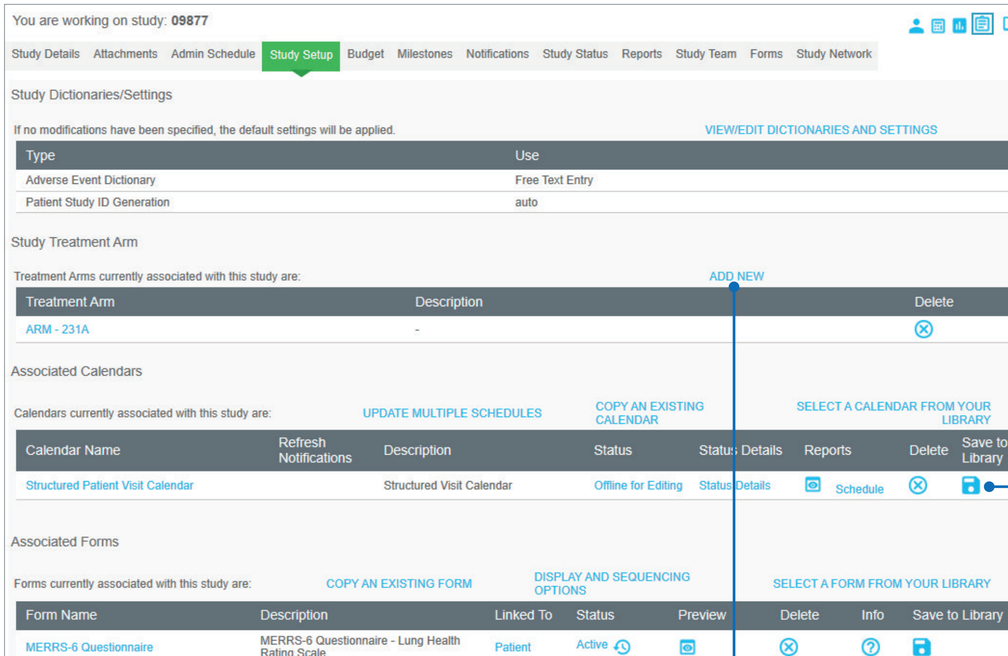


The Calendar Library window opens where users can select a Calendar by clicking **Select**.

Study Setup

Study Setup

The **Study Setup** tab is used for Patient Study ID Generation, Study Enrollment, and to Manage Treatment Arms.



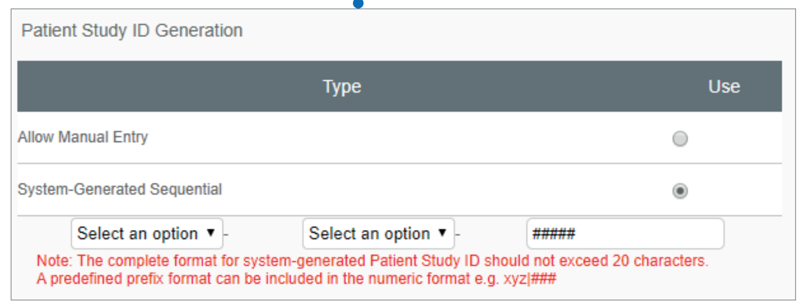
Study Treatment Arms

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 as appropriate such as the Name, Description, and Drug Information.

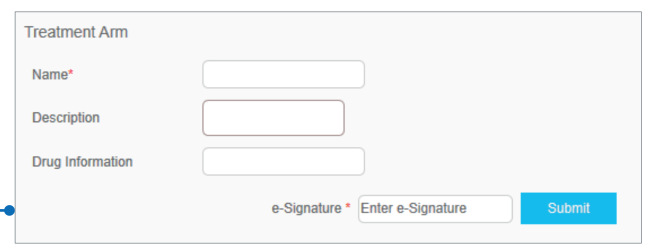
Patient Study ID Generation

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



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.



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
Structured Patient Visit Calendar		Structured Visit Calendar	Offline for Editing	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				
MERRS-6 Questionnaire - Long Version	MERRS-6 Questionnaire - Lung Health Rating Scale	Patient	Deactivated				
MERRS-6 Questionnaire - Long Version II	MERRS-6 Questionnaire - Lung Health Rating Scale	Patient	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**.

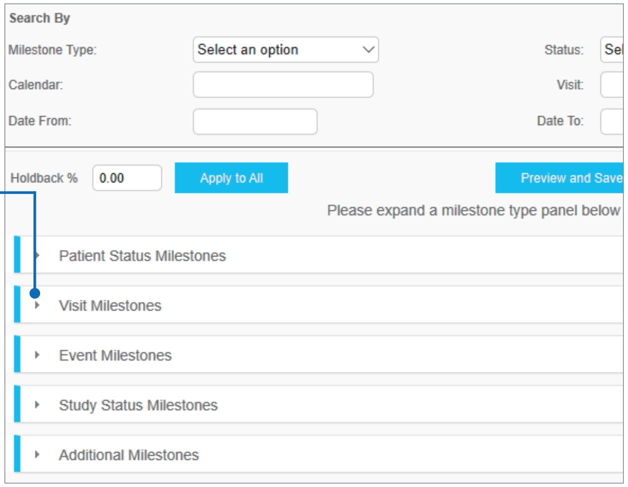
Milestones

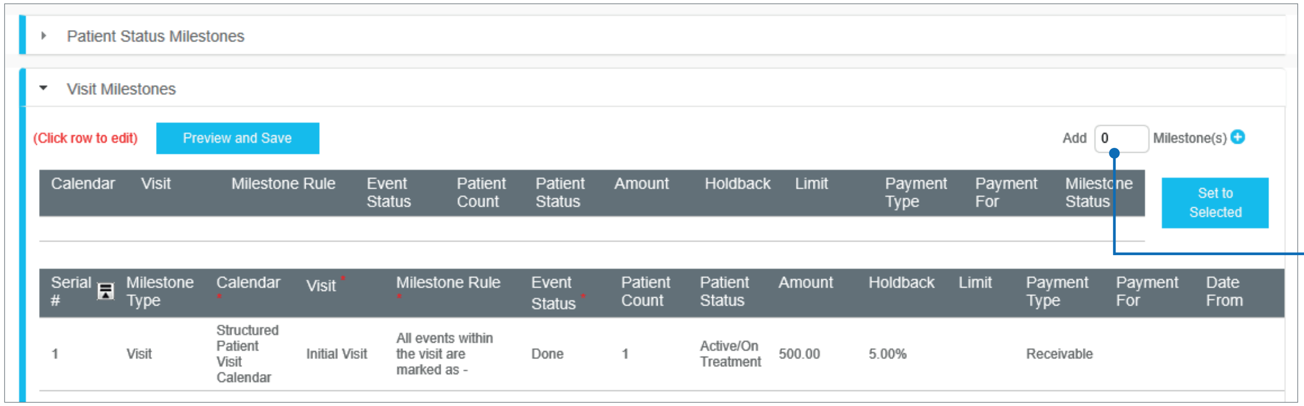
Milestone Types

There are five milestone types that uses can manage: Visits, Events, Study Status, Patient, Status, and Additional Milestones.

Add Milestones

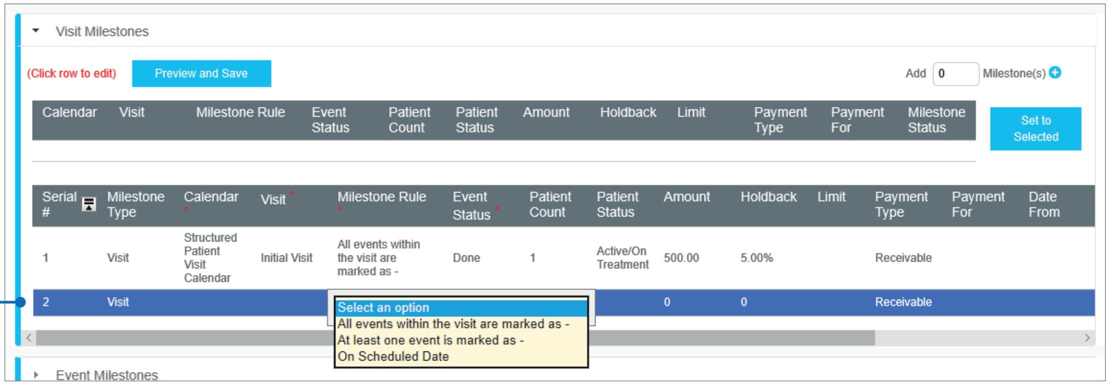
From the Milestone tab, select the arrows for the milestone type you wish to manage.



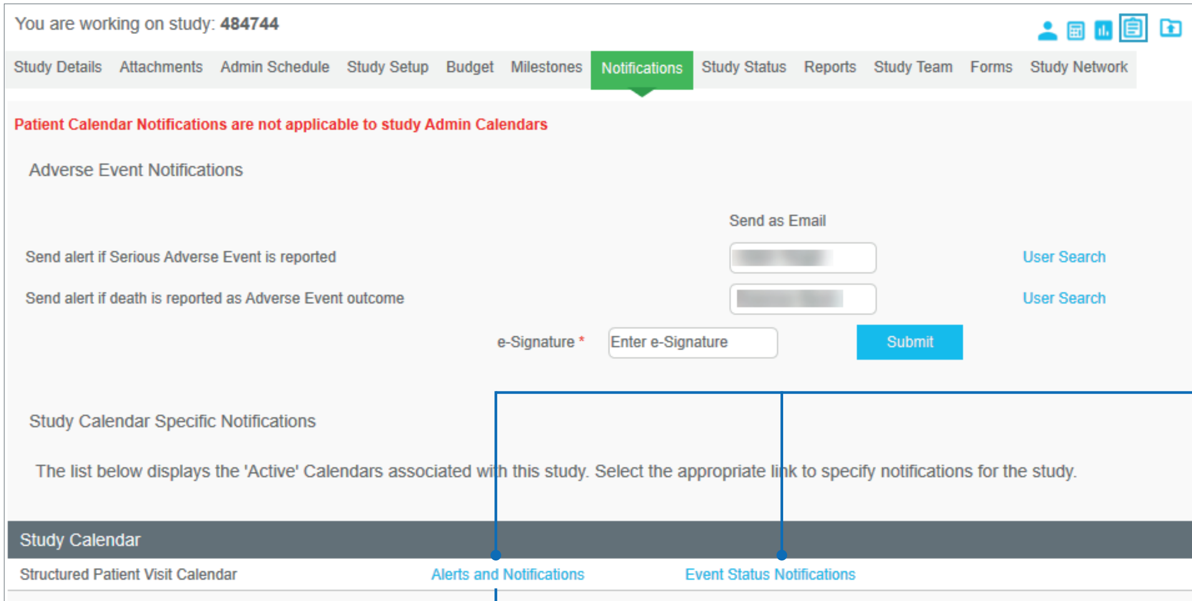


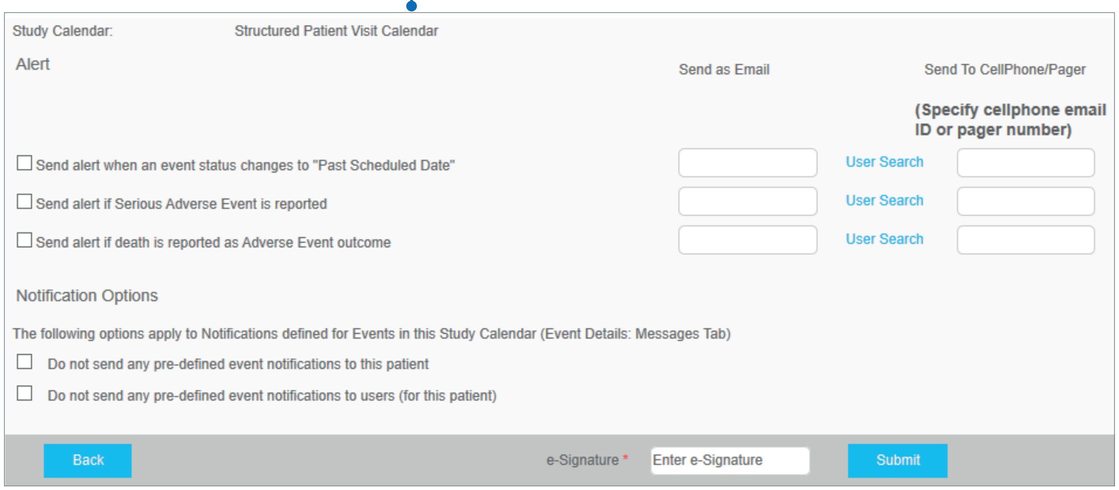
Use the Add Milestones Field to add as many rows as needed to create Milestone Rules. Rows are added per Milestone Type.

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



Notifications





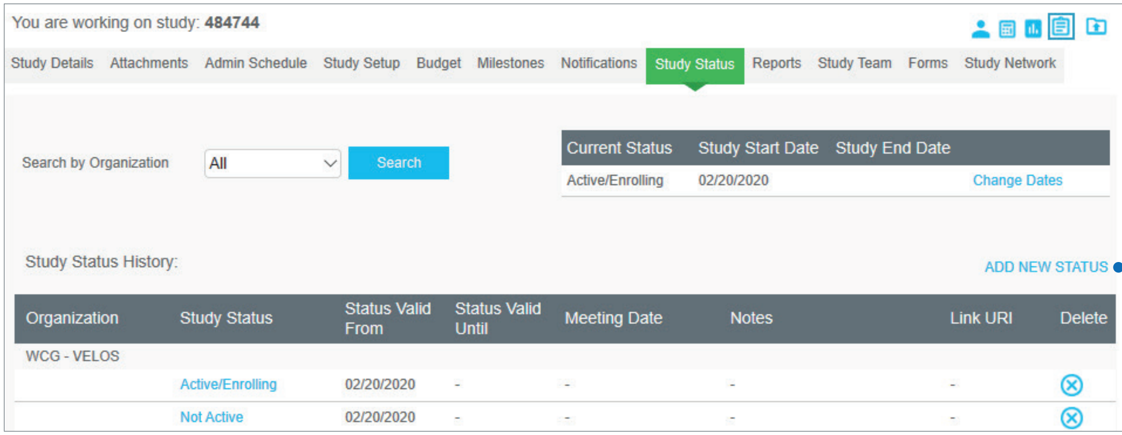
Define Notifications

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.

Note: a patient calendar needs to be associated under Study Setup and does not apply to Admin calendars.

Define the Notifications as appropriate.

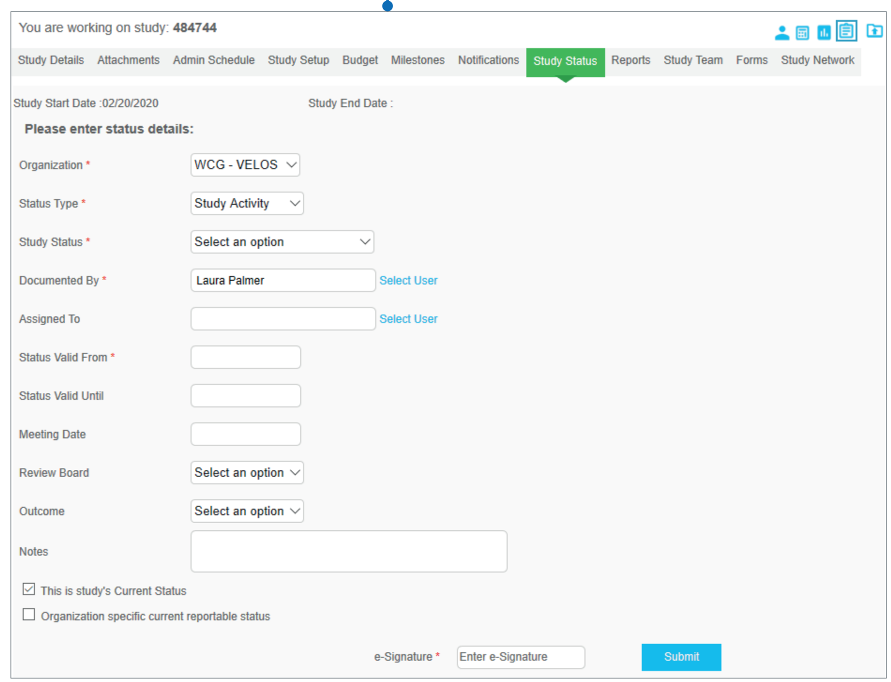
Study Status



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.



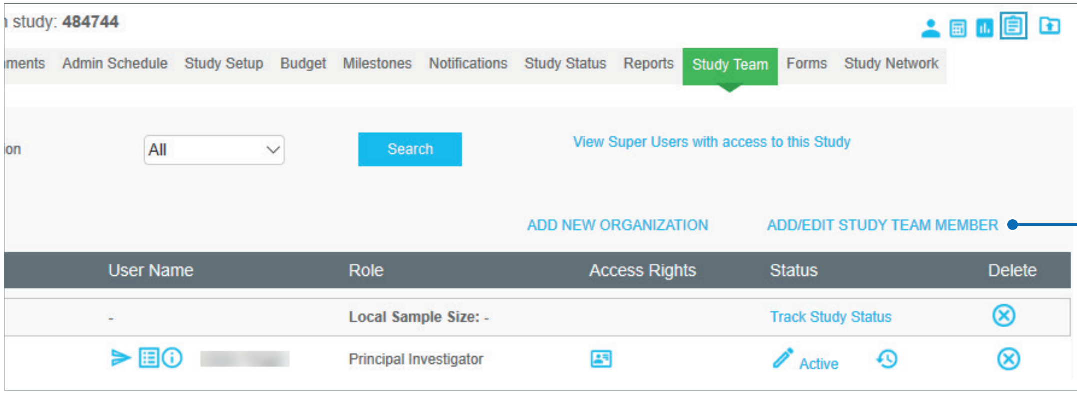
Study Enrollment Statuses

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 an Indicator icon displays. The indicator is color coded and list 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

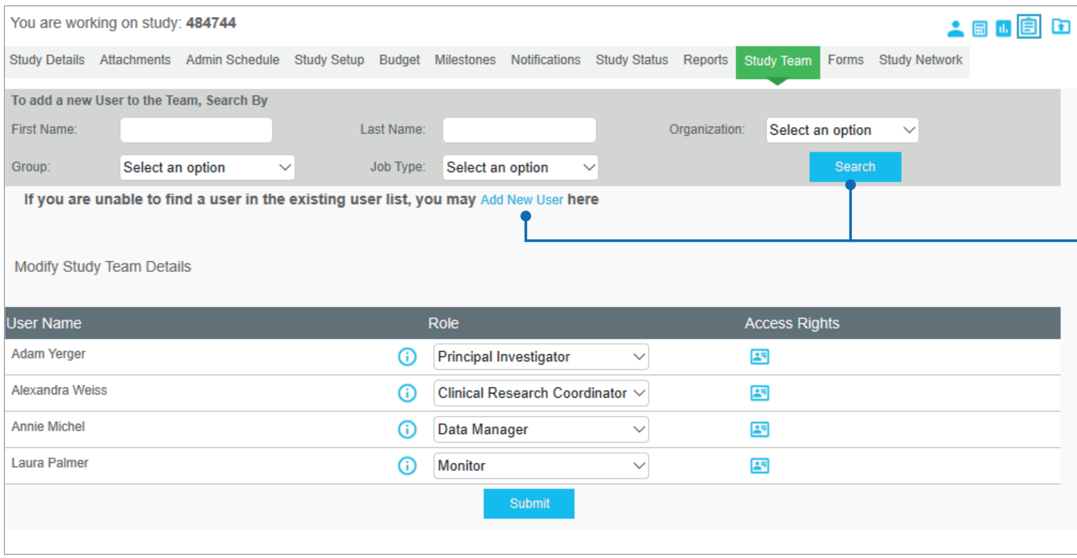
Study Team

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

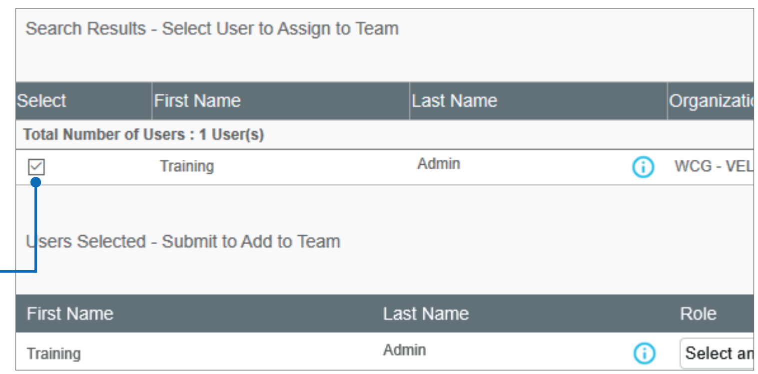


Add or Edit a Study Team Member

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 modified the role for an existing person.