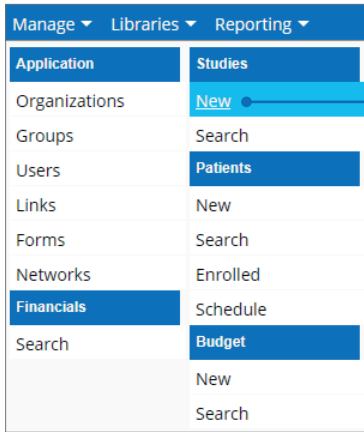


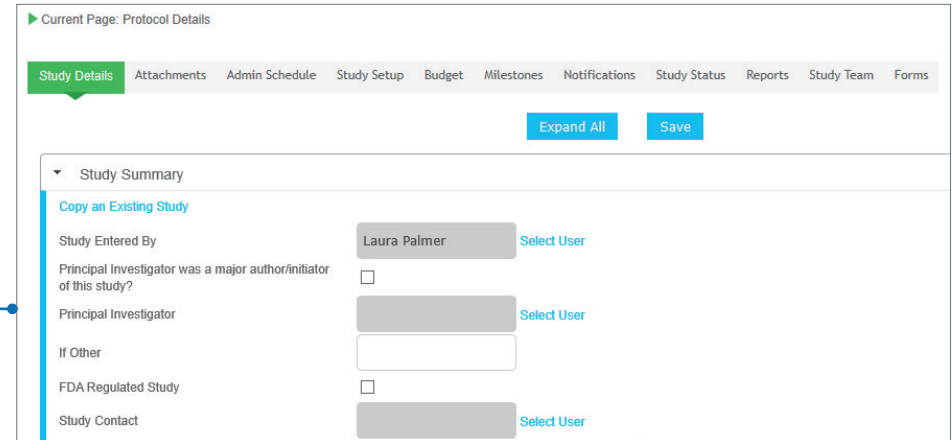
Study Management



Create a New Study

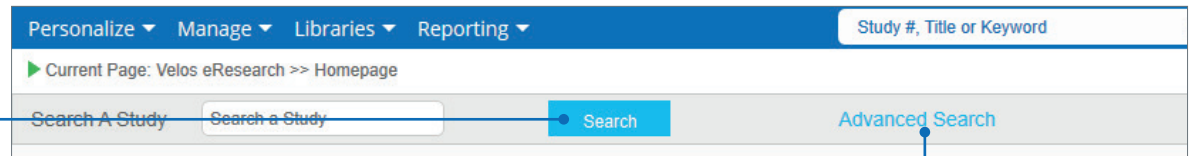
From the **Manage** tab, select **New** under the “Studies” heading.

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

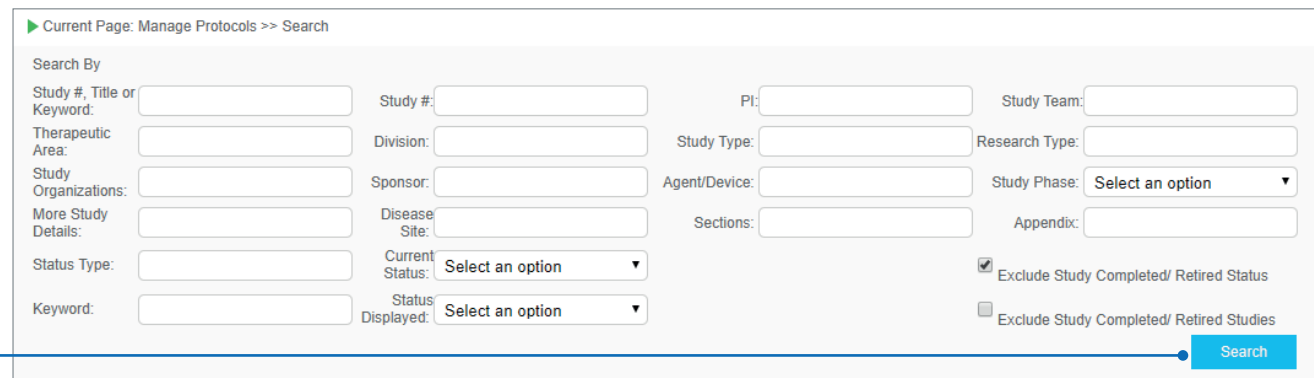
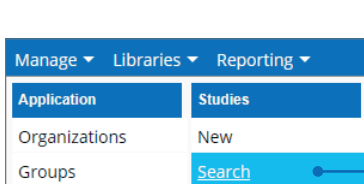


Navigate to an Existing Study

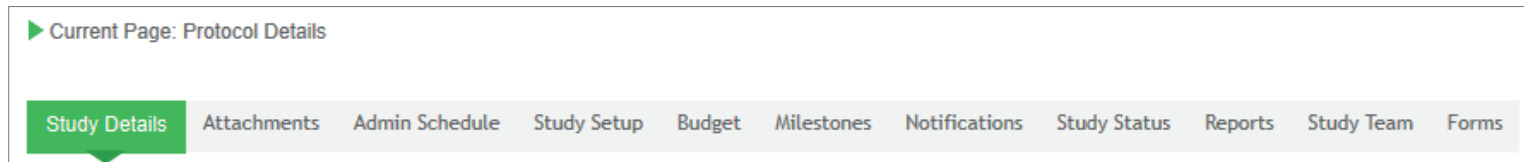
From the default homepage, enter search criteria then click the **Search** button.



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



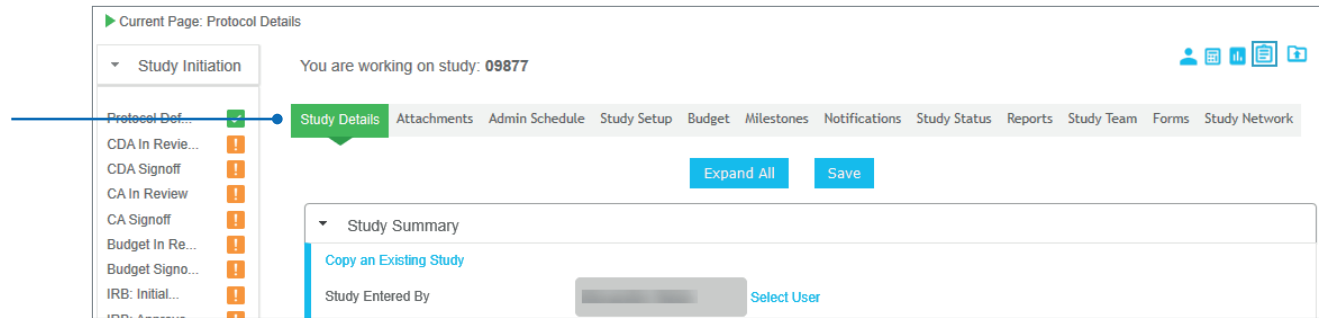
Once a study exists, the following tabs allow for Study Management:

- **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

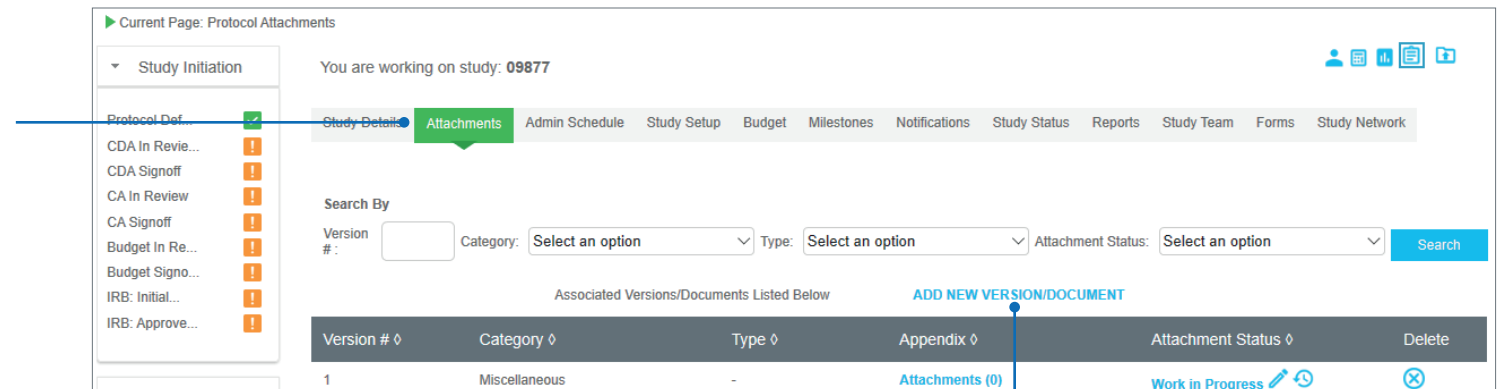
Study Summary

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



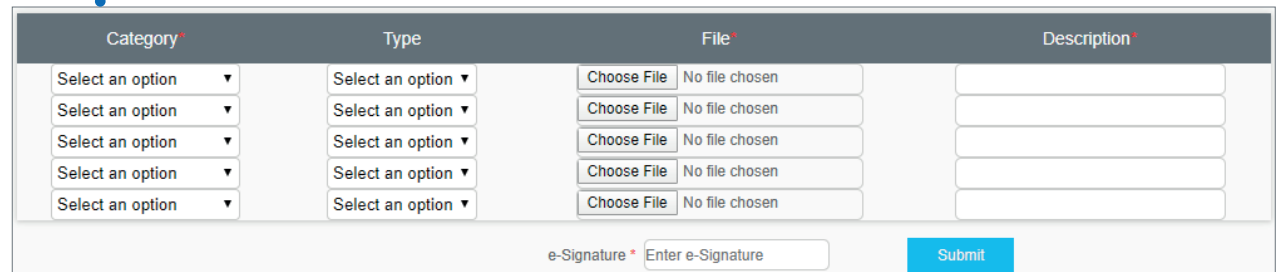
Add New Study Versions/Documents

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.



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.

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.

You are working on study: **09877**

Study Details | Attachments | **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, 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 Calendars	Administrative Calendar	-	Work in Progress	All Account Users	Schedule	Select
	Structured Patient Visit Calendar - Alternate	Structured Visit Calendar	Work in Progress	All Account Users	Schedule	Select
	Study Phase III Admin Calendar	Study Phase III Admin Calendar	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.

The screenshot shows the 'Study Setup' interface for study 09877. It includes a navigation bar with tabs like Study Details, Attachments, Admin Schedule, Study Setup (active), Budget, Milestones, Notifications, Study Status, Reports, Study Team, Forms, and Study Network. The main content area is divided into several sections:

- Study Dictionaries/Settings:** A table with columns 'Type' and 'Use'. It lists 'Adverse Event Dictionary' (Free Text Entry) and 'Patient Study ID Generation' (auto). A link 'VIEW/EDIT DICTIONARIES AND SETTINGS' is present.
- Study Treatment Arm:** A section with an 'ADD NEW' button and a table of treatment arms. One arm is listed: 'ARM - 231A'.
- Associated Calendars:** A section with buttons for 'UPDATE MULTIPLE SCHEDULES', 'COPY AN EXISTING CALENDAR', and 'SELECT A CALENDAR FROM YOUR LIBRARY'. Below is a table with columns: Calendar Name, Refresh Notifications, Description, Status, Status Details, Reports, Delete, and Save to Library. One calendar is listed: 'Structured Patient Visit Calendar'.
- Associated Forms:** A section with buttons for 'COPY AN EXISTING FORM', 'DISPLAY AND SEQUENCING OPTIONS', and 'SELECT A FORM FROM YOUR LIBRARY'. Below is a table with columns: Form Name, Description, Linked To, Status, Preview, Delete, Info, and Save to Library. One form is listed: 'MERRS-6 Questionnaire'.

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.

The 'Patient Study ID Generation' window shows two radio button options: 'Allow Manual Entry' (unselected) and 'System-Generated Sequential' (selected). Below these are two dropdown menus labeled 'Select an option' and a text input field containing '#####'. A red note states: '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.

The 'Treatment Arm' form contains the following fields and controls:

- Name*:** A required text input field.
- Description:** A text input field.
- Drug Information:** A text input field.
- e-Signature*:** A required field with a text input labeled 'Enter e-Signature' and a blue 'Submit' button.

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 can be managed: 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.

Search By

Milestone Type: Status:

Calendar:

Date From: Date To:

Holdback %

Please expand a milestone type panel below

- Patient Status Milestones
- Visit Milestones
- Event Milestones
- Study Status Milestones
- Additional Milestones

▼ Patient Status Milestones

▼ Visit Milestones

(Click row to edit)

Add Milestone(s)

Calendar	Visit	Milestone Rule	Event Status	Patient Count	Patient Status	Amount	Holdback	Limit	Payment Type	Payment For	Milestone Status
1	Visit	Structured Patient Visit Calendar	Initial Visit	All events within the visit are marked as -	Done	1	Active/On Treatment	500.00	5.00%		Receivable

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.

▼ Visit Milestones

(Click row to edit)

Add Milestone(s)

Calendar	Visit	Milestone Rule	Event Status	Patient Count	Patient Status	Amount	Holdback	Limit	Payment Type	Payment For	Milestone Status
1	Visit	Structured Patient Visit Calendar	Initial Visit	All events within the visit are marked as -	Done	1	Active/On Treatment	500.00	5.00%		Receivable
2	Visit							0	0		Receivable

Select an option
All events within the visit are marked as -
At least one event is marked as -
On Scheduled Date

▼ Event Milestones

Notifications

You are working on study: **484744**

Study Details Attachments 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
Structured Patient Visit Calendar Alerts and Notifications Event Status 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.

Study Calendar: Structured Patient Visit Calendar

Alert	Send as Email	Send To CellPhone/Pager (Specify cellphone email ID or pager number)
<input type="checkbox"/> Send alert when an event status changes to "Past Scheduled Date"	<input type="text"/>	<input type="text"/> User Search
<input type="checkbox"/> Send alert if Serious Adverse Event is reported	<input type="text"/>	<input type="text"/> User Search
<input type="checkbox"/> Send alert if death is reported as Adverse Event outcome	<input type="text"/>	<input type="text"/> 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 the Notifications as appropriate.

Study Status

You are working on study: **484744**

Study Details Attachments 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	02/20/2020	Change Dates

Study Status History: ADD NEW STATUS

Organization	Study Status	Status Valid From	Status Valid Until	Meeting Date	Notes	Link URI	Delete
WCG - VELOS	Active/Enrolling	02/20/2020	-	-	-	-	
	Not Active	02/20/2020	-	-	-	-	

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 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.

You are working on study: **484744**

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

Study Start Date : 02/20/2020 Study End Date :

Please enter status details:

Organization * WCG - VELOS

Status Type * Study Activity

Study Status * Select an option

Documented By * Laura Palmer 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: 484744

Study Team

ADD/EDIT STUDY TEAM MEMBER

User Name	Role	Access Rights	Status	Delete
-	Local Sample Size: -		Track Study Status	⊗
Principal Investigator			Active	⊗

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.

You are working on study: 484744

Study Team

To add a new User to the Team, Search By

First Name: [] Last Name: [] Organization: Select an option

Group: Select an option Job Type: Select an option [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
Adam Yerger	Principal Investigator	
Alexandra Weiss	Clinical Research Coordinator	
Annie Michel	Data Manager	
Laura Palmer	Monitor	

Submit

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

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

Search Results - Select User to Assign to Team

Select	First Name	Last Name	Organization
Total Number of Users : 1 User(s)			
<input checked="" type="checkbox"/>	Training	Admin	WCG - VEL

Users Selected - Submit to Add to Team

First Name	Last Name	Role
Training	Admin	Select an