Work Instruction Study Startup

Velos - eResearch 9.2

Version: 2.0, 04/29/2015
Revision History

<table>
<thead>
<tr>
<th>Version/Amendment #</th>
<th>Version Date</th>
<th>Description</th>
<th>Completed By</th>
</tr>
</thead>
<tbody>
<tr>
<td>Version 0.1</td>
<td>04/03/2014</td>
<td>Initial Draft Document</td>
<td>Jason R. Bates, MBA</td>
</tr>
<tr>
<td>Version 0.2</td>
<td>08/01/2014</td>
<td>Updates to Initial Draft, creation of “Study Setup” Process</td>
<td>Jason R. Bates, MBA</td>
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<tr>
<td>Version 0.3</td>
<td>09/09/2014</td>
<td>Updates for Suggested Additions</td>
<td>Jason R. Bates, MBA</td>
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<tr>
<td>Version 0.4</td>
<td>09/15/2014</td>
<td>Creation of Role/action format</td>
<td>Lissa Persson</td>
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<tr>
<td>Version 1.0</td>
<td>11/18/2014</td>
<td>Finalize Document</td>
<td>Pamela Sabrsula</td>
</tr>
<tr>
<td>Version 1.1</td>
<td>02/18/2015</td>
<td>Cancer Center Review</td>
<td>Kim Markosfeld /Kayla Jackson</td>
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<td>Version 1.2</td>
<td>03/09/2015</td>
<td>Updating and accepting changes</td>
<td>Lissa Persson</td>
</tr>
<tr>
<td>Version 2.0</td>
<td>04/29/2015</td>
<td>Finalize Document</td>
<td>Pamela Sabrsula</td>
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Documentation of Change History:


Version 0.3, 09/09/2014: Addition of requested sections with regards to Purpose, Responsibilities, Entry or Prerequisite and Exit criteria.


Version 1.1, 02/18/2015: Updated for Cancer Center

Version 1.2, 03/09/2015: Reviewing and accepting changes; updating where necessary.

Version 2.0, 04/29/2015: Final revisions to finalize document
Work Instruction Study Startup

PURPOSE
The purpose of this work instruction is to walk users through the process of completing the Study Startup process after a Research Study has been created and registered within Velos eResearch.

RESPONSIBILITY
The designated Study Entry Team will have primary responsibilities for this work instruction. This team may include multiple departments and job roles as defined by area specific work flows.

These responsibilities are defined in Appendix: A – Roles and Responsibilities

ENTRY/PREREQUISITE CRITERIA
Prior to performing the tasks described in this work instruction, the following must be completed:
- The Study Summary Page within eResearch has been fully completed.

REFERENCE DOCUMENTS
The latest revision of the following documents may be used as reference points throughout these work instructions:
- Common Application Research Application – Step 1 Intent to Conduct Research
- Common Application Research Application – Step 2 Institutional
- Common Application Research Application – Step 2 UTHSCSA Continuation IRB Application
- Study Protocol documents containing the “Protocol Schedule of Events” or “Protocol Visit Breakdown”
- Study Clinical Trial Agreement (CTA), Notice of Grant Award (NOGA) or other Funding Agreement
- Budget

WORK INSTRUCTIONS

<table>
<thead>
<tr>
<th>Role/Function</th>
<th>Description of Action</th>
</tr>
</thead>
</table>
| Study Entry Team Navigate to Study Setup | 1. Log into eResearch  
2. Click the MANAGE button from the toolbar and select SEARCH under the STUDIES option  
3. From the list of studies that appears, locate the desired study and click the Clipboard icon for quick access to the Study >> Summary Page  
4. Click on the Study Setup tab |

[NOTE: Enter the study number in the “Search a Study” text field, then click SEARCH to quickly locate the desired study.]
Refer to the following screenshot when completing Initial Study Setup Tasks

Study Dictionaries/Settings

<table>
<thead>
<tr>
<th>Study Dictionaries/Settings</th>
<th>VIEW/EDIT DICTIONARIES AND SETTINGS</th>
</tr>
</thead>
<tbody>
<tr>
<td>Study</td>
<td>Type</td>
</tr>
<tr>
<td>Adverse Event Dictionary</td>
<td>Free Text Entry</td>
</tr>
</tbody>
</table>

Study Treatment Arms

Add New

<table>
<thead>
<tr>
<th>Treatment Arms currently associated with this study</th>
<th>Description</th>
<th>Unselect</th>
</tr>
</thead>
</table>

Associated Calendars

<table>
<thead>
<tr>
<th>Calendar Name</th>
<th>Refresh Notifications</th>
<th>Description</th>
<th>Status</th>
<th>Status Details</th>
<th>Reports</th>
<th>Delete</th>
<th>Delete to Library</th>
</tr>
</thead>
</table>

Associated Forms

<table>
<thead>
<tr>
<th>Event Name</th>
<th>Description</th>
<th>Linked To</th>
<th>Status</th>
<th>Preview</th>
<th>Delete</th>
<th>Info</th>
<th>Save to Library</th>
</tr>
</thead>
</table>

Study Entry Team

Define initial settings for the Study

1. From the Study Setup tab, click the VIEW/EDIT DICTIONARIES AND SETTINGS

2. Associate Adverse Event Dictionary (OPTIONAL)
   An adverse event dictionary is a predefined set of acceptable Adverse Events terms applicable to a given study. Select radio button next to the dictionary you would like to use.

   [ NOTE: If left blank, the selection will default to “Free Text Entry” which allows the user to enter text into the field.

3. Patient Study ID Generation (OPTIONAL)
   Specify if the Study will manually generate a patient’s Study ID by selecting the “Allow Manual Entry” radio button or select the “System-Generated Sequential” radio button which allows the system to auto-generate a patient study ID.

   [ NOTE: If allowing the system to generate the study patient ID, you may define the format using the drop-down options.

4. Study Enrollment Process (MANDATORY)
   a. “Enable Study-centric enrollment” – ensure the NO radio button is selected.
   b. “Flag to Allow patient Accrual” – ensure the DEFAULT radio button is selected.
   c. No selection is needed for the “On submission of study-centric enrollment page, user is taken to.”

5. ENTER your e-SIGNATURE and click the SUBMIT button to save your selections.
**Study Entry Team**

### Define Treatment Arms for the Study

1. Click the **ADD NEW** link to open the Study Treatment Arm window.
2. ENTER the following information:
   a. **Name** *(REQUIRED FIELD)* – Enter the name of the Treatment Arm as specified in the “Study Protocol Summary” or “Treatment Selection and Assignment” sections of the Study Protocol.
   b. **Description** – Enter the description of the Treatment Arm as it is documented in the Study Protocol.
   c. **Drug Information** – Enter the drug information that is also specified in the Study Protocol.
3. ENTER your e-SIGNATURE and click the **SUBMIT** button to save your selections.

   ![When you have properly saved a Treatment Arm, it will be listed under the Study Treatment Arm section of the Study Setup.](image)

Refer to the following screenshot when Assigning a Calendar to the Study

![Library Calendars: Select the calendar that you wish to use in your protocol.](image)

### Study Entry Team

#### Associate a Calendar with a Study

1. From the **Study Setup** tab, click the **SELECT A CALENDAR FROM YOUR LIBRARY**.
2. From the list of “Calendar Templates” that appears,
   a. **SELECT** the template that is best to associate with the given study by clicking on the **Select** hyperlink (last column towards the right); OR
   b. Create a new calendar by clicking on the **CREATE A NEW CALENDAR** hyperlink at the top right corner of the Library Calendars page.

   ![NOTE: User access rights will limit the view and selection of Template Calendars.](image)
### Define the Study Calendar

1. From the **Study Setup** tab, click the **Calendar Name**, selected in the previous section, which now appears as a hyperlink in the Calendar Name column.

2. From the Calendar Definition page (**Define the Calendar** tab), ENTER the following information:
   - **Calendar Name** (REQUIRED FIELD) - SPECIFY a meaningful name. The name should be Study Specific using the Protocol number or identifier and any additional study specific designation for the calendar (i.e. Study, Sub-Study, Screening Randomization). Consider adding protocol version to Calendar name in case the Calendar must be amended later.
     
     For Cancer Studies – Calendar name to include Sponsor Name, CTMS Number, Treatment Arm (if applicable). (e.g., Sponsor #14-2070 Arm A)
   - **Description** – SPECIFY a meaningful description and specify VERSIONING information based on Protocol version (i.e. “Version 1, dated mm/dd/yyyy” or “Version 1, Amendment 2 dated mm/dd/yyyy”) AND/OR Clinical Trial Agreement amendment.
   - **Calendar Category** (REQUIRED FIELD) – SELECT the appropriate value from the drop down value which the system uses for searching and designation purposes.
   - **Calendar Status** (REQUIRED FIELD) – SELECT “Work In Progress” from the list of drop down values. ([Calendar Status Definitions](#))
   - **Calendar Duration** (REQUIRED FIELD) – Using the “Protocol Schedule of Events Timeline” found in the Study Protocol, specify the entire length of participation a Study patient may be on a Study.

   
   | Time of visit (weeks) | -10 | -8 | -7 | -6 | -5 | -4 | -3 | -2 | -1 | 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 | 11 | 12 | 13 | 14 | 15 | 16 | 17 | 18 | >3 days | >30 days |
   |-----------------------|-----|----|----|----|----|----|----|----|----|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
   |                      |     |    |    |    |    |    |    |    |    |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |

   - **Budget Template** (OMIT THIS FIELD) - This field will be defined during budget creation

5. ENTER your e-SIGNATURE and click the **SUBMIT** button to save your selections.

   **NOTE:** Study Calendars should be kept in the “Work In Progress” state as long as possible. Once a calendar is switched to an “Active” status, there are limits to what a user may modify. Please refer to the **DEFINITIONS** section at the end of this document for additional statuses.
Refer to the following screenshot when Adding Events to a Calendar

![Select Events](image)

**Add \Delete Events to the Study Calendar**

1. CLICK on the **Select Events** tab, to view the “Calendar Events” page.
2. **ADD** or **DELETE** events from the Calendar as needed.

**Add Existing Events**

a. Using the drop down lists, SELECT an Event Library to search for an event, then click the SEARCH button.
   i. The Library should be specific to the parent organization of the Study or the location which the procedure will be completed (i.e. HSC, UT Med, UHS or IDD).

b. From the list of Events that appears, select and event by MARKING THE CHECKBOX that appears in the first column.

c. Click the **RIGHT ARROW** button to move the Event to the SELECTION list that appears on the right

d. REVIEW the selection list that has been created.

e. ENTER your e-SIGNATURE and click the **SUBMIT** button to save your selections.

**Search for Existing Events**

a. Using the drop down lists, select an Event Library and click the SEARCH button.

b. From the Select Events form that appears, a user may refine their search by specifying any combination of the following fields:
   i. Event Category
Add /Delete Events to the Study Calendar (cont.)

<p>| | |</p>
<table>
<thead>
<tr>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>ii.</td>
<td>Event Name, Description or Notes</td>
</tr>
<tr>
<td>iii.</td>
<td>Additional Codes</td>
</tr>
<tr>
<td>iv.</td>
<td>Facility Name</td>
</tr>
<tr>
<td>v.</td>
<td>CPT</td>
</tr>
<tr>
<td>vi.</td>
<td>Cost Type</td>
</tr>
</tbody>
</table>

c. Click the SEARCH button

- NOTE: Each Event Library must be searched individually. Search all libraries prior to proceeding to add new.

Add New Events

- ALWAYS SEARCH for Events by key words, prior to requesting new events

a. After determining that an Event does not exist in any of the Event Libraries, submit a request to add the Event to CTMS-Support@uthscsa.edu. Include as much description about the event as possible in the request.

Delete Events (from Calendar ONLY)

a. While on the “Calendar Events” page, MARK THE CHECKBOX in the last column of the event you wish to delete.

b. Click the Remove Selected Event(s) link and acknowledge the warning that appears to delete the selected Events.

- NOTE: Events cannot be deleted after a Calendar has been marked as “ACTIVE”; however, Events can be “Hidden”.

Refer to the following screenshot when Defining Study Calendar Visits and Defining Time Points

![Screenshot of Study Calendar Visits and Time Points](image_url)

Study Entry Team

Manage Visits: Define Study Calendar Visits

1. SELECT the Manage Visits tab
2. ADD, COPY or DELETE visits as needed.

- NOTE: Depending on the calendar associated with the study, visits may already exist. Should visits already exist, modify the visits as necessary to match the study protocol.

Add Visits to the calendar

a. REFERENCE the “Protocol Schedule of Events” or “Protocol Version 2.0, 04/29/2015”
Manage Visits: Define Study Calendar Visits (cont.)

- Visit Breakdown” to help determine how many visits are needed.
- ADD Visits to the calendar by entering the number of visits needed in the available field and clicking the Add button.

Add [ ] New Visit(s) 

- NOTE: Users are limited to adding 20 visit rows at a time.

- ENTER a Visit Name for each visit row.
  - Visit naming should be in accordance to the Protocol Schedule of Events
  - The following naming conventions are recommended:
    - Visit 1, Visit 2, Visit 3...
    - Visit 1, Visit 1a, Visit 1b, Visit 2, Visit 2a, Visit 2b
    - Screening, C1D1, C1D2....

- ENTER a Description for each visit row
  - The visit description should be used to provide detailed information about the visit
  - The following naming conventions are recommended:
    - Screening (Week -10, +7 days)
    - Randomization (Week 0)
    - Treatment Period (Week 18, ±3 days)

- SAVE the information you have entered by clicking the “Preview and Save” button

Copy an Existing Visit

- Copy an existing visit by clicking the Copy button.
- SAVE your row copy by clicking the “Preview and Save” button

- NOTE: All Events associated with the visit will also be copied.

Delete Visits from the calendar

- DELETE a visit from the calendar clicking the Delete button.
- SAVE your deletion by clicking the “Preview and Save” button.

- NOTE: All Events associated with the visit will also be deleted.
### Define Study Visit Windows

**Visit Windows** allow the user to record the timeframe in which a patient visit must occur as specified in the “Protocol Schedule of Events”.

1. **SELECT** the Manage Visits tab
2. **DETERMINE** the timeframe in which each visit must occur. “The visit can occur ___ (Days/Wks/Mths/Yrs) BEFORE the scheduled visit date OR up to ____ (Days/Wks/Mths/Yrs) AFTER the scheduled visit date”.
3. **DEFINE** the Visit Window for each visit using the fields in the BEFORE and AFTER columns.
   a. **ENTER** the number which will correspond to the unit of time.
   b. **SPECIFY** the unit of time (Days, Weeks, Months, Years) in the dropdown.

4. **SAVE** the information you have entered by clicking the “Preview and Save” button.

### Defining Visit Time Points

**Visit Time Points** outline when a visit should occur on the Visit calendar schedule. A Visit Time Point can be defined as a **Fixed Time Point** or a **Dependent Time Point**. Once a user has defined the Visit Time Points, eResearch will automatically create a calculated study timeline. This calculated timeline will calculate suggested scheduled visit dates on a patient calendar as a patient is enrolled in a study.

1. **SELECT** the Manage Visits tab.
2. **REFERENCE** the “Protocol Schedule of Events” to determine when visits should occur.
   a. **DETERMINE** all visits that are **Fixed Time Points**.
      i. Visits such as “Day 0” or “Day 1”... can be considered Fixed Time Points.
      ii. Any visits that must occur on a specific day should be listed as a Fixed Time Point.
   b. **DETERMINE** all visits that are **Dependent Time Points**.
      i. Visits with a dependency on the timing of another visit, such as “1 week after visit 1”... are considered Dependent Time Point.

   **NOTE:** Fixed Time Points must be defined in the system prior to entering Dependent Time Points.
Defining Visit Time Points (cont.)

3. LOCATE the row that contains the Visit Name that is considered a Fixed Time Point and SELECT “Fixed Time Point” from the Time Point Type column drop down field.
   a. As the selection for Fixed Time Point is made, the cells relevant to Dependent Time Points will remain unavailable in that row.
4. In the same row, ENTER a number in the appropriate Month, Week and/or Day cell.
   a. Depending on the cell in which the number was entered, it means the Month, week and/or day of the calendar’s start date.
   b. Entering “1” under the Day cell would be interpreted scheduling the visit for the first day of the calendar.
5. REPEAT steps 3-4 for any additional Fixed Time Points visits that may exist. If no other Fixed Time Points exist, proceed to next step.
6. SAVE the information you have entered by clicking the “Preview and Save” button.
7. LOCATE the row that contains the Visit Name that is considered a Dependent Time Point and SELECT “Dependent Time Point” from the Time Point Type column drop down field.
   a. As the selection for Dependent Time Point is made, the cells relevant to Fixed Time Points will remain unavailable in that row.
8. Using the Interval, M/W/D and Visit Name drop down fields, specify the Dependent Time Point details.

Example

“Visit 2 occurs 15 (Months/Weeks Days) AFTER Visit 1”

   a. ENTER a number in the Interval cell which will represent the number of Months, Weeks or Days.
   b. SELECT a unit of time in the M/W/D drop down.
   c. SELECT the Visit Name from the drop down that the current visit row is dependent on.

   TIP: If the Visit Name is not available in the drop down, select “Visit Not Listed” and SAVE the entry. You MUST update the Visit Name when the dependent visit has been saved.
9. SAVE the information you have entered by clicking the “Preview and Save” button.
10. REVIEW all visit time points ensuring a Calculated Time Point has been calculated. (The Calculated Time Point will display “No Interval” if its time point has not been defined).

NOTE: The Time Point Type cannot be edited in existing visit
### Defining Visit Time Points (cont.)

After a Calendar had been made **ACTIVE**; however new visits that have been added to the calendar can be edited.

- **NOTE 2:** Visit time points cannot exceed the **Calendar Duration** established on the “Define the Calendar” tab. Ensure the **Calendar Duration** is set correctly, if you are unable to save a time point.

### Study Entry Team

**Manage Event-Visit Grid**

1. **SELECT** the **Event-Visit Grid** tab
2. **ADD** Events to the Visits and **EDIT** as needed.

### Add an event to ALL Visits

- **a.** **MARK** the CHECKBOX to the LEFT of the Event name to add the event to all visits.
- **b.** **SAVE** the information you have entered by clicking the **“Preview and Save”** button

### Add an event to a specific Visit

- **a.** If necessary, use the SCROLL BARS to navigate through out the grid to locate the appropriate checkbox that applies to the visit.
  
  - **TIP:** HOVER over the CHECKBOX to see a description of the corresponding event.
- **b.** **MARK** the CHECKBOX which corresponds to the visit.
- **c.** **SAVE** the information you have entered by clicking the **“Preview and Save”** button

### Add multiple events to multiple Visits

- **a.** CLICK on the **“Add Multiple Events to Visits”** button
- **b.** **MARK** the CHECKBOX of all events you wish to add from the left window panel.
- **c.** **MARK** the CHECKBOX of the visits you wish to add the events to in the right window panel.
- **d.** CLICK the **SUBMIT** button to add the specified events to the specified visits.

### Edit Event

- **a.** CLICK on the **Edit** button located next to the event checkboxes of the event you wish to modify.
  
  - **NOTE:** The **EDIT** button will only become available after the event has been saved to the Visit using the **“Preview and Save”** button
- **b.** From the **Event Details form** that appears, edit Event details
**Work Instruction Study Startup**

<table>
<thead>
<tr>
<th>Manage Event-Visit Grid (cont.)</th>
</tr>
</thead>
<tbody>
<tr>
<td>as necessary. The following Event details may be modified:</td>
</tr>
<tr>
<td>i. Event Name</td>
</tr>
<tr>
<td>ii. Description</td>
</tr>
<tr>
<td>iii. CPT code</td>
</tr>
<tr>
<td>iv. Event Duration</td>
</tr>
<tr>
<td>v. Site of Service</td>
</tr>
<tr>
<td>vi. Facility</td>
</tr>
<tr>
<td>vii. Coverage Type</td>
</tr>
<tr>
<td>viii. Cost (CLICK on the <strong>Cost Tab</strong>)</td>
</tr>
<tr>
<td>ix. Quantity (Frequency) (CLICK on the <strong>More Details</strong> icon)</td>
</tr>
<tr>
<td>c. MARK the appropriate CHECKBOX to SPECIFY how the Event modifications should be applied</td>
</tr>
<tr>
<td>i. “Apply to all Events in this Visit”</td>
</tr>
<tr>
<td>ii. “Apply to all &lt;Event Name&gt; Events in this Calendar”</td>
</tr>
<tr>
<td>d. ENTER your e-Signature and click the <strong>SUBMIT</strong> button to commit changes to the system.</td>
</tr>
<tr>
<td>NOTE: Changes to Event Name and Description will not be applied to other events when you select “Apply to all Events in this Visit”</td>
</tr>
</tbody>
</table>

3. REVIEW all changes you have made in the Event-Visit Grid.  
   a. SAVE all information once more by clicking the **Preview and Save** button

<table>
<thead>
<tr>
<th>Study Entry Team</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Manage Patient Cost Items</strong></td>
</tr>
<tr>
<td>Patient Cost Items allow the user to track visit level costs that are not associated with the study, for budgeting purposes. These costs can be categorized as personnel, travel, supplies etc.</td>
</tr>
<tr>
<td>NOTE: Patient Cost Items are only pulled into the Budget when using the Comparative Budget</td>
</tr>
</tbody>
</table>

1. SELECT the **Patient Cost Items** tab  
2. **ADD, EDIT or DELETE** Patient Cost Items as necessary.

**Add a Patient Cost Item**  
1. ADD a Patient Cost Item by entering the number of rows needed in the available field and clicking the **Add** button.

   ![Add Row(s)](image)

   **NOTE:** Users are limited to adding 20 rows at a time.
**Manage Patient Cost Items (cont.)**

<table>
<thead>
<tr>
<th>Step</th>
<th>Action</th>
</tr>
</thead>
<tbody>
<tr>
<td>b.</td>
<td>SELECT a <strong>Cost Category</strong> from the available drop down field.</td>
</tr>
<tr>
<td>c.</td>
<td>ENTER a <strong>Cost Item Name, Unit Cost and Number of Units</strong> in the appropriate cells.</td>
</tr>
<tr>
<td>d.</td>
<td>SPECIFY which visit(s) the <strong>Patient Cost Item</strong> can be applied to by MARKING the appropriate CHECKBOX.</td>
</tr>
<tr>
<td>e.</td>
<td>SAVE the information you have entered by clicking the “<strong>Preview and Save</strong>” button.</td>
</tr>
</tbody>
</table>

**Edit a Patient Cost Item**

<table>
<thead>
<tr>
<th>Step</th>
<th>Action</th>
</tr>
</thead>
<tbody>
<tr>
<td>a.</td>
<td>CLICK within a cell to edit data as needed.</td>
</tr>
<tr>
<td>b.</td>
<td>SAVE your modification by clicking the “<strong>Preview and Save</strong>” button.</td>
</tr>
</tbody>
</table>

**Delete a Patient Cost Item**

<table>
<thead>
<tr>
<th>Step</th>
<th>Action</th>
</tr>
</thead>
<tbody>
<tr>
<td>a.</td>
<td>DELETE a Patient Cost Item by clicking the Delete button.</td>
</tr>
<tr>
<td>b.</td>
<td>SAVE your deletion by clicking the “<strong>Preview and Save</strong>” button.</td>
</tr>
</tbody>
</table>

**NOTE 1:** If a budget has already been created using the calendar and Patient Cost Items are added to that budget, you will need to delete the budget from the calendar and then add it again to include the NEWLY ADDED or MODIFIED Patient Cost Items.

**NOTE 2:** To **DELETE a BUDGET** that is associated with a calendar, click on **MANAGE>>BUDGET>>SEARCH.** MARK the “Default Calendar Budgets” checkbox box near the top of the screen. **ENTER** the CTMS number of the associated budget in the “**Budget Name/Study Number**” field, then click the **SEARCH** button. Click the Delete **button** to delete the appropriate budget.

---

**Study Entry Team**

**Associate Forms to the Study**

**NOTE:** Most commonly used **FORMS** are automatically associated to each Study. This task refers to any Study Specific form that may be required for the Study in addition to the most commonly used FORMS.

1. From the **Study Setup** tab, click the **SELECT A FORM FROM YOUR LIBRARY**
2. From the list of available Forms that appears, MARK the CHECKBOX that appears next to the Form to be associated to the Study.
   a. Use the **UP** and **DOWN** buttons to move the selected FORM to the “**Forms to be Linked**” section of the form.
   b. **SELECT** “Study” or “Patient” from the Display Form Link column to indicate whether the form will display Study or Patient data.
   c. **SELECT** the “Multiple Entry” or “Only Once (Editable)” from the Characteristic column to indicate how the user
Associate Forms to the Study (cont.)

will enter data on the form.

NOTE: The Audit Trail Report will track changes made to forms that are Only Once/single entry forms.

d. SELECT an Organization, Group (or both) to indicate which users shall be granted access to the form.

NOTE: This may be used only rarely. If an Organization or Group are specified, the Form may not be accessible by the Study Team unless each member is a part of the Group designated.

3. ENTER your e-Signature and click the SUBMIT button.

EXIT CRITERIA:

Upon completion of this work instruction, the study calendar has been defined with visits and events. The study calendar is ready for Coverage Analysis.

Appendix A: ROLES & RESPONSIBILITIES

<table>
<thead>
<tr>
<th>RACI Chart</th>
<th>Study Entry Team</th>
<th>Research Team</th>
</tr>
</thead>
<tbody>
<tr>
<td>STUDY STARTUP</td>
<td>Principal Investigator</td>
<td>Research Team</td>
</tr>
<tr>
<td>-Define Initial Study Settings</td>
<td>R,A</td>
<td>C</td>
</tr>
<tr>
<td>-Adverse Event Dictionaries</td>
<td>R,A</td>
<td>C</td>
</tr>
<tr>
<td>-Patient Study ID Generation</td>
<td>R,A</td>
<td>C</td>
</tr>
<tr>
<td>-Study Enrollment Process</td>
<td>R,A</td>
<td>C</td>
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<tr>
<td>-Define Study Treatment Arms</td>
<td>R,A</td>
<td>C</td>
</tr>
<tr>
<td>-Assoicate Forms to Study</td>
<td>R,A</td>
<td>C</td>
</tr>
<tr>
<td>-Calendar Set up</td>
<td>R,A</td>
<td>C</td>
</tr>
<tr>
<td>-Associate a Calendar with a Study</td>
<td>R,A</td>
<td>C</td>
</tr>
<tr>
<td>-Define the Study Calendar</td>
<td>R,A</td>
<td>C</td>
</tr>
<tr>
<td>-Select Events for Study Calendar</td>
<td>R,A</td>
<td>C</td>
</tr>
<tr>
<td>-Define Study Calendar Visits</td>
<td>R,A</td>
<td>C</td>
</tr>
<tr>
<td>-Define Study Visit Windows</td>
<td>R,A</td>
<td>C</td>
</tr>
<tr>
<td>-Define Study Time Points</td>
<td>R,A</td>
<td>C</td>
</tr>
<tr>
<td>-Manage Event-Visit Grid</td>
<td>R,A</td>
<td>C</td>
</tr>
<tr>
<td>-Manage Patient Cost Items</td>
<td>R,A</td>
<td>C</td>
</tr>
<tr>
<td>-Associate Forms to the Study</td>
<td>R,A</td>
<td>C</td>
</tr>
</tbody>
</table>

R = Responsible party
A = Accountable party
C = Consulting party
I = Party to be kept informed

Appendix B: DEFINITIONS

Calendar Status:

Work in Progress: Protocol calendar is being created or can undergo modifications. Patient schedules cannot be generated while calendar currently set to this status.

Active: Once a protocol calendar status is changed to “Active,” patient schedules can be generated.
**Offline for Editing:** Once the protocol calendar is made “Active,” the calendar can undergo certain modifications if the status is currently set to this status.

**Reactivated:** Once the protocol calendar is set to “Reactivated,” patient schedules can be generated. However no further modifications can be made to the calendar unless status is changed to “Offline for Editing.”

**Deactivated:** If a protocol calendar is no longer in use, the status is set to “Deactivated”. It will still show up in the “Protocol Calendar” browser as a “Deactivated Calendar,” but will not be available to generate patient schedules. Once “Deactivated,” it CANNOT be “Reactivated” again.

**Freeze:** Once the protocol calendar status is set to “Freeze,” the calendar can be associated to a study. However no further modifications can be made to the calendar. To make modifications, the protocol calendar will need to be COPIED and SAVED under a DIFFERENT NAME. Modifications can then be made to that protocol calendar as long as it is in “Work in Progress” status mode.

END OF DOCUMENT