Data Entry Manual

Data Entry process

Step 1: OpenClinica login

Log on to the OpenClinica with authorized user name and password (figure 1).

Figure 1: OpenClinica Login page

> Note: Reset password
>
> For security purposes, user needs reset the password when the user tries to log in for the first time. The password must be at least eight characters long.

Step 2.1: Add New Subject from Subject Matrix

It leads to the home page after successful log in. On top of the Home page, it displays the study name and the site name. In the Subject Matrix, click “Add New Subject” link to add a new subject (figure 2). Subject can also be added from the Tasks menu (see section2.2).

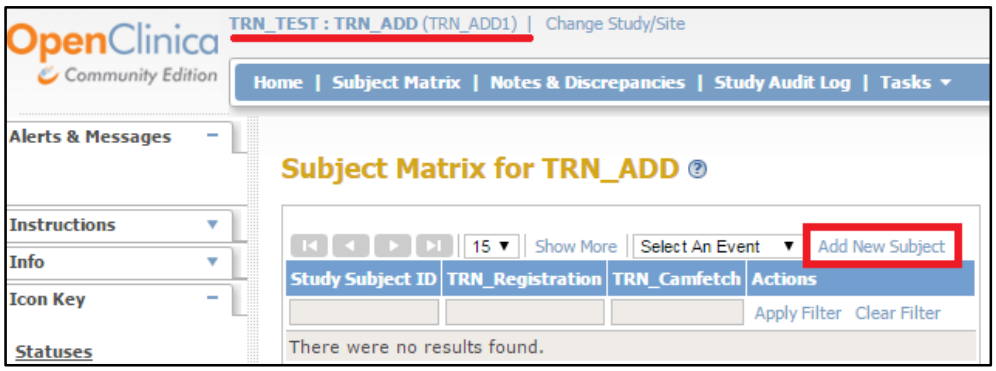

Figure 2: Subject Matrix

Subject information

Complete the information on the page (figure 3) as described in the following. Some of the information might be optional for the study; an asterisk (*) indicates a required field.

- Enter the Study Subject ID
- Enter the Enrolment Date in the specified format, or click the calendar icon to select it.
- Select the Sex.
- Enter the Date of Birth in the specified format, or click the calendar to select it.
- Select the first Study Event for the drop-down list.
- Enter the Start Date for the Event, or click the calendar icon to select it.
- Click “Add” to add the Subject to the Study.

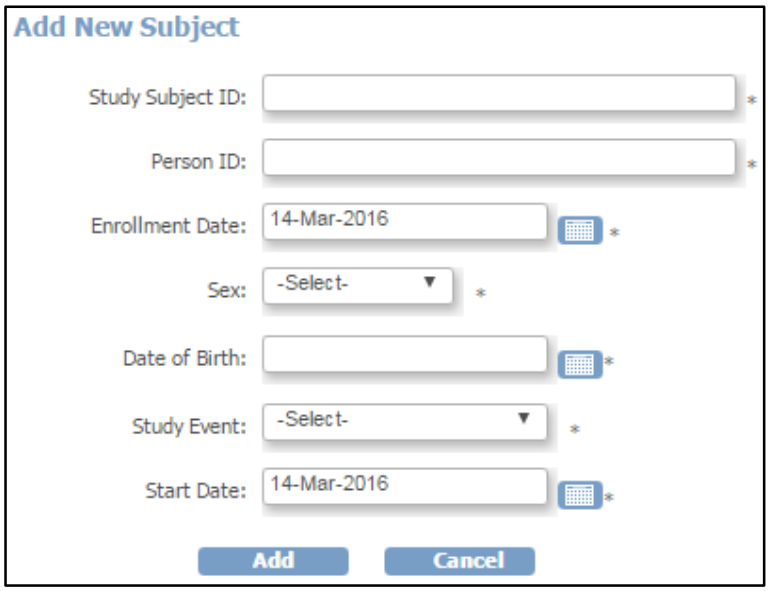

Figure 3: Add New Subject

Step 2.2: Add Subject from Tasks Menu

Adding Subject from Tasks Menu allows the user to add more than one Subject, schedule one or more Events for the added Subjects (figure 4).

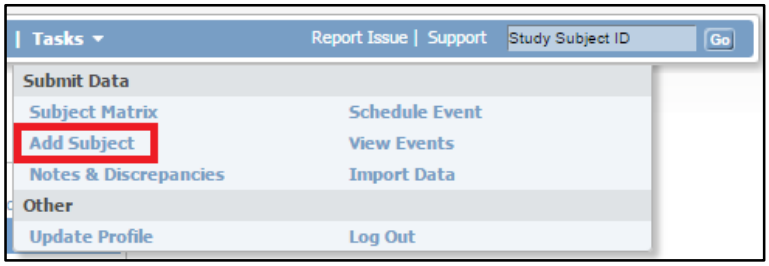

Figure 4: Add Subject from Tasks Menu

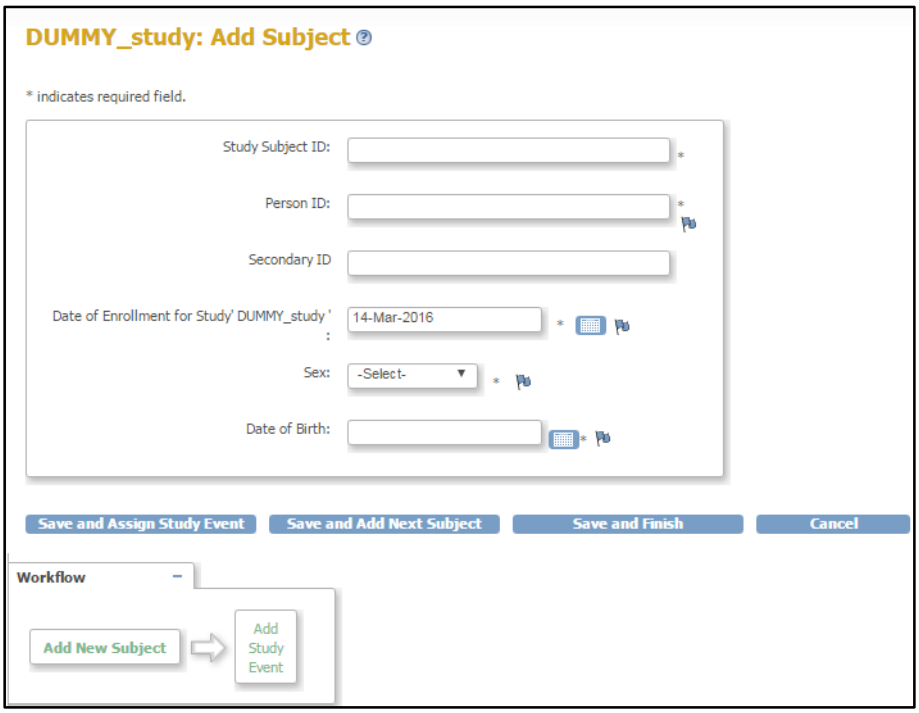

Figure 5: Add Subject

Or the user can click "Add Subject" from the top tasks bar (see below), and it will also lead to the Add Subject page (figure 5)

Note: Secondary ID (optional)

Secondary ID is the Family ID. If the study is recruiting as part of the 100,000 Genomes Project then Family ID from Genomics England must be used.

Step 3: Entering Data into a CRF

CRF Status: There are four main CRF statuses (figure 6).

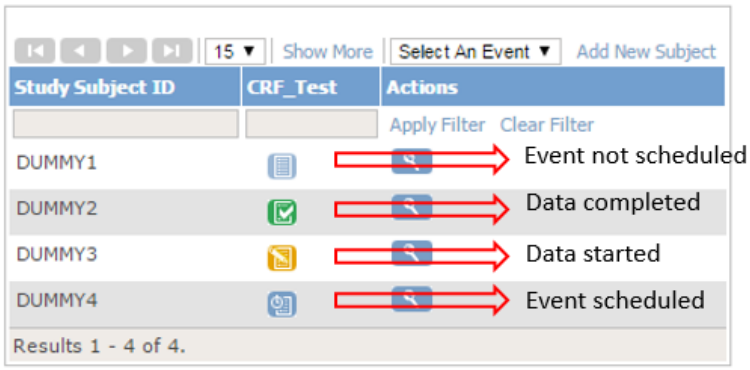

Figure 6: CRF status

In the Subject Matrix, find the subject and Event you want to complete the CRF for, then click the icon in the cell for that Event, and click View/Enter Data (figure 7).

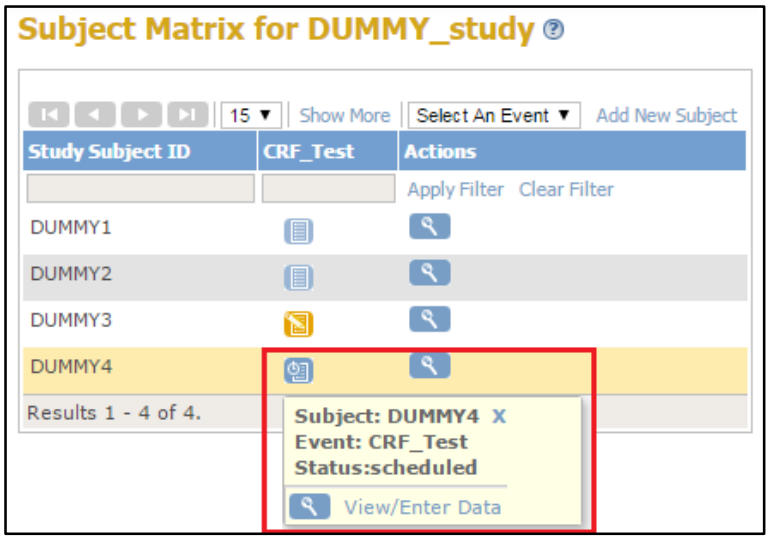

Figure 7: Scheduled Event

Schedule the Event if it is not scheduled (figure 8).

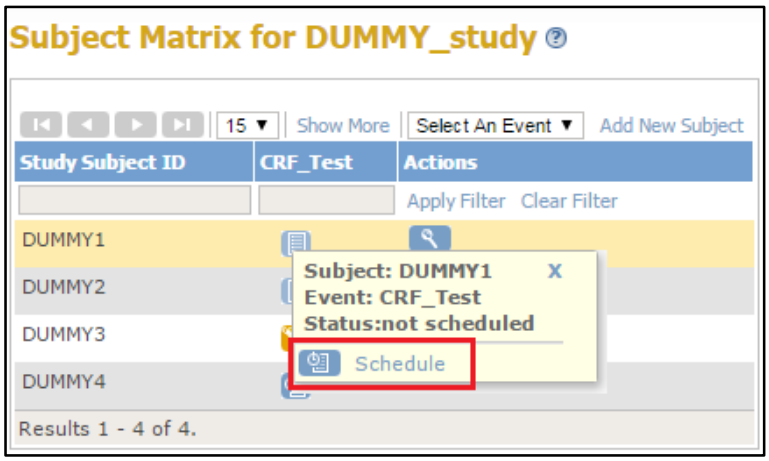

Figure 8: Unscheduled Event

The Enter or Validate Data for CRFs page opens (figure 9). The page reports the Event information followed by a table of all CRFs in the Event.

If there is more than one version of the CRF available for the Site or Study, select the one you want from the drop-down list in the version column (figure 9).

To enter data for a CRF, Click the Enter Data icon in the Actions column for that CRF (figure 9).

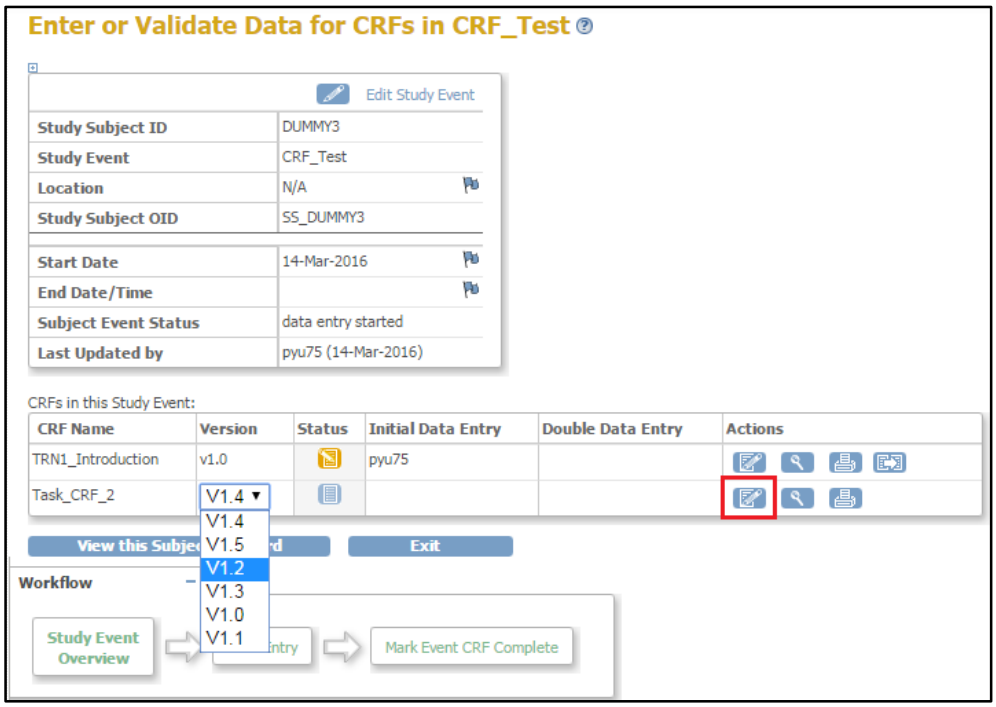

Figure 9: Enter or Validate Data for CRFs

The CRF opens, showing the first section. Start the Data entry (figure 10).

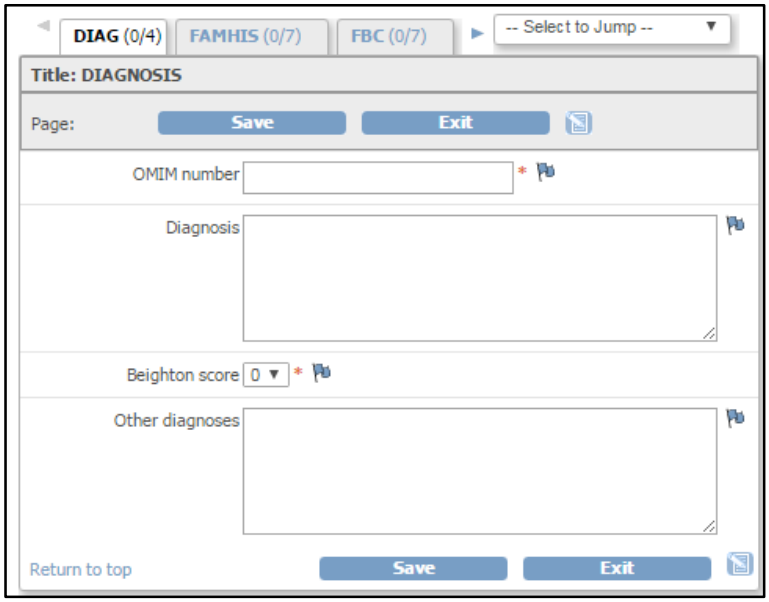

Figure 10: CRF (first section)

The user needs to complete all Sections in the CRF, saving each Section as completes it, and mark CRF completed at the end of the last section of the CRF (figure 11).

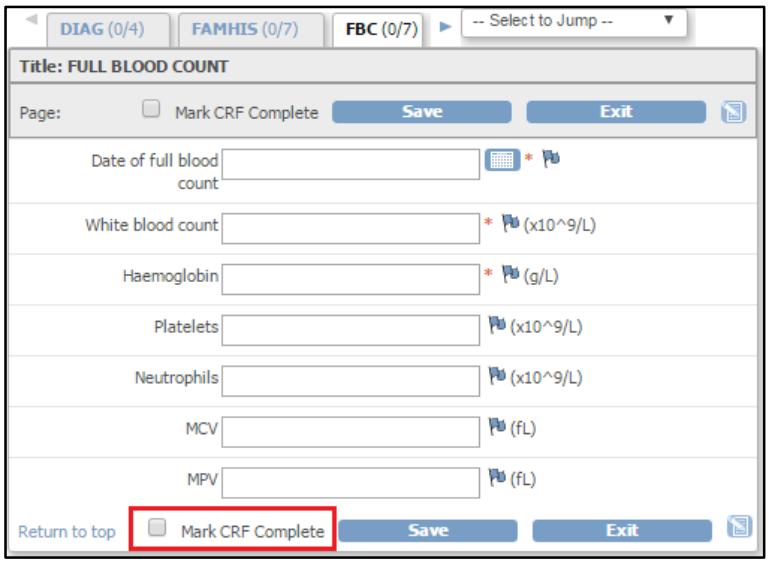

Figure 11: CRF (last section)

Note: Double Data Entry

- After a user completes entering the initial CRF data, a different user can perform the double entry.
- The user who initially enters the data can also perform the double entry but must wait at least twelve hours after the initial data entry to perform the double entry.

Notes and Discrepancies

The OpenClinica Notes and Discrepancies provides a means for users to document, communicate, and manage issues about data in a clinical trial. The user can generate a Discrepancy note during data entry by clicking the Add Discrepancy Note icon " " next to the item.

Discrepancy Notes can be created automatically by OpenClinica, or by users.

Automatically-Created Discrepancy Notes

OpenClinica can automatically generate a Discrepancy Note as part of an Edit Check or data validation:

- When a CRF is marked complete and the user makes a change to an Item in it, OpenClinica automatically creates a Reason for Change Discrepancy Note for the user to fill out.
- When the user enters data into a CRF, if the user does not provide a value for a required field and click Save, OpenClinica prompts the user to provide a value. The user must either provide the missed value or click the flag next to the item to create a "Missing data in a required field" Discrepancy Note.

User-Created Discrepancy Notes

The user can generate a Note in OpenClinca during data entry or when reviewing a CRF, as follows:

1. When viewing or entering data for a CRF Item, click the Add Discrepancy Note icon next to the Item. The Add Discrepancy Note window opens for that Item (figure 12).
2. In the Add Discrepancy Note window, complete the fields.

a. Complete the Description and Detailed Note fields.

b. Select the Type from the drop-down list. The list includes only the appropriate options. If the user accessed the Discrepancy Note by viewing rather than editing, the user can only select the Query Type.

c. Select the Status for the Discrepancy Note from the drop-down list. The list includes only the appropriate options.

d. For a Query Note Type, select from the Assign to User drop-down list the user recommended to take the next step for the Note; note that OpenClinica will not prevent other users from taking the next action for the Note. To send an email to the assigned person, select the Email Assigned User checkbox. The user cannot assign other Types of Discrepancy Notes when creating the Note.

3. Click Submit.
   A message replaces the contents of the window, indicating the Note was created. The window then closes automatically.
4. In the CRF page, the flag icon for the Item is no longer blue, but instead is a colour that reflects the status of the Discrepancy Note.

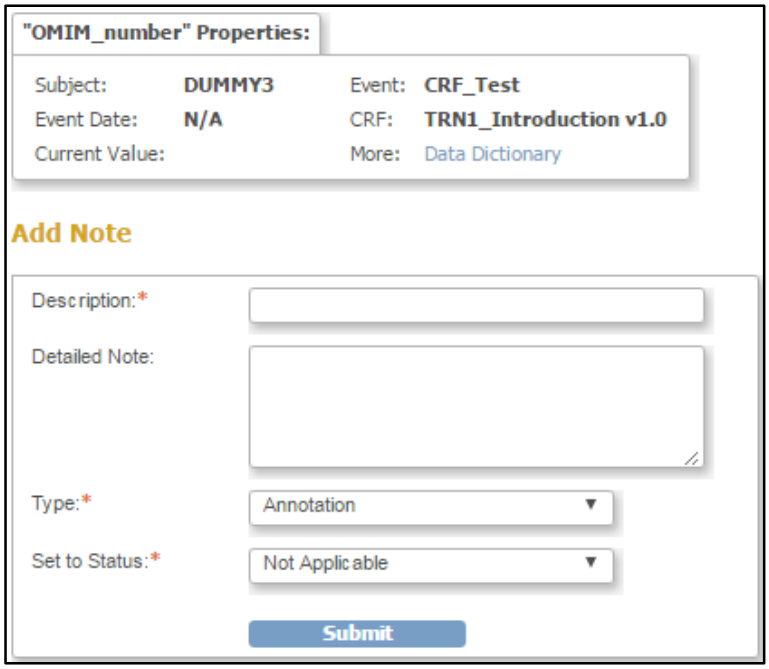

Figure 12: Discrepancy Note