Subject Forms Data Entry

As you have seen, subject calendars define subject visits with events and associate forms. When a subject visit has been marked as **Occurred**, OnCore uses the visit's scheduled procedures to determine which forms need to be filled out. OnCore provides an easy way for you to see the list of forms that need to be completed.

To Do Forms

1. If you are on the Subject Console, click the **Forms By Status** vertical tab. (If you are not on the Subject Console, go to the Subjects → CRA Console, enter your protocol number, and select your subject from the Accrual vertical tab. Then click the Forms By Status tab.)

   The **Forms By Status** tab has a number of horizontal tabs:

   - **Queried Forms –** Forms that have been monitored for accuracy - and in doing so, a question is being asked regarding the data entry.
   - **To Do Forms** - Forms where data entry has not been started for visits that have Occurred.
   - **Active Forms** - Forms where data entry has been started, but not yet completed.
   - **Completed Forms** - Forms that have been completed.
   - **Planned Forms** - Forms for a visit that has not yet been marked as Occurred (or Missed or N/A), but the planned visit date is in the past. No actions can be performed with planned forms. This list is for informational purposes only.
   - **Forms Summary** - A table of information about this subject's Forms.

2. Click the **To Do Forms** horizontal tab.

   On the **To Do Forms** tab, the Subject Forms Details table is displayed. The Visit column shows the names of the visits on the subject's calendar. The Procedure column shows the procedure that was done during that visit. The Form No. column contains hyperlinks to screens where data gathered during the procedure may be entered into an eCRF.

   If a procedure was marked as **Missed** or **Not Applicable**, its form does not appear in this table.

Form Data Entry

3. Click the **Physical Exam** form for the **Baseline** visit.

   The **Subject Form Update** screen displays. Note the upper right corner of the table – it displays the form's status as **Started**.

   The table in the top portion of the page displays information from the **Subject Visit Update** page. You can use the **Edit** hyperlink to modify this information. After clicking the **Edit** hyperlink, you can change the **Visit Date** that defaulted in from the **Procedure Date**, or can mark the form as **Missed** or **Not Applicable** by checking the corresponding checkbox. If you change any of this information, you should then click the **Save** hyperlink. If you mark the form as **Missed** or **Not Applicable**, you should not continue to enter data on it. These two checkboxes indicate that the form was not filled out even though the procedure happened during the visit. (Otherwise, the procedure would have been marked as missed or not applicable and the form would not be available.)

The lower portion of the page is where you enter lab results.

In the left (vertical tab) column, the uppermost tabs are links to all forms for this visit. You can quickly jump among the forms by clicking the tab for the form on the left side. Doing this for a form that has not been started (is on the To Do Forms tab) will activate the form and mark it as **Started**.

4. In the form table, enter data for various **Body Systems**.

5. Click the **Save** button at the upper right of the form table.

   When you save the form, the page refreshes and displays the form in view-only mode. The upper right corner of the upper table still displays the form's status as **Started**. You can return to an edit mode by clicking on the **Edit** button.

   You can jump back to the various horizontal tabs of the **Forms By Status** tab by clicking on the **Subject To Do Forms**, **Subject Active Forms**, and **Subject Completed Forms** tabs on the left side. You can also jump to the **Forms By Visit** and **Calendar** tabs in the Subject Console, and to the **CRA Console**.

6. Click the **Subject Active Forms** vertical tab.

   Because your form has been started, it is no longer "To Do". It is now in the "Active" list. However, other forms for the visit are still on the To Do list.

7. Click the Physical Exam **Form No.** hyperlink to return to the **Subject Form Update** page.

   You may enter additional data at this point. When you have finished entering data, you must save it and **Complete** the form.

8. Click the Complete hyperlink at the upper right.

   Note the upper right corner of the upper table – your form's status is **Completed**.

   When a form is **Completed**, it appears in the **DM Console** for a Data Monitor to check (if that's in your workflow). The Data Monitor can validate the form's data or can query it when she has questions. If a form was completed in error, the Completed status may be undone by clicking the **Undo Completed** hyperlink that replaces the **Complete** hyperlink.

Data Entry - Tabular Forms

Some forms have a different method of entering data. Tabular forms and their data-entering characteristics were discussed in the Forms Administration section. Please review if necessary.

9. Return to the **To Do Forms** list.

   There are different ways to navigate to it!

10. Select the **Adverse Events** form for the first available visit.

This is a **Tabular** form. A Tabular form allows collection of multiple rows of data for a set of fields. This is the only form type that has an "Add" block:

Tabular forms are used when there is a need to capture multiple occurrences (rows) of data. In the current example, it may be necessary to record multiple tumors during a visit.

11. Enter data into the fields of the **Add** block. Be sure to enter a Date Measured (or possibly Date of Evaluation) that matches (or is a few days after) the Visit Date!

    When you have completed entering data into the Add block fields, click the **Add** button.

    Note that one row has been added to the table beneath the Add block.

12. Enter another row of data into the fields of the Add block, and click the **Add** button.

    Note that there are now two rows of data recorded for this procedure on this visit.

13. Click the **Complete** hyperlink at the upper right to complete the form.

    For each row you create on this form and other forms, you have the ability to enter a free-text note.

14. Click the **Notes** hyperlink to the right side of the first row in the table.

    A window will pop up with a Notes field where you can enter a note about the row. This is often used to explain data that is outside the norm.

15. After entering a free-text note, click the **Add** button to save the note.

    After the note has been entered, the **Notes** hyperlink will display a superscript exclamation point (**!**) to indicate there are notes.

Additional Forms

There are times when a procedure is performed multiple times on a visit and multiple forms need to be completed. Although the calendar can indicate that the procedure happens multiple times, multiple instances of the forms are not automatically created.

16. Navigate to the **Completed Forms** list.

17. Click the Physical Exam **Form No.** hyperlink to return to the **Subject Form Update** page.

    On this page, you can create additional forms for the visit. The visit description is shown in the header by the form status.

18. Click the **Additional Forms** tab.

    A window pops up with a list of the forms for the visit. You can add another instance of the form for the visit by clicking on its hyperlink.

19. Click the **Physical Exam Form No.** hyperlink.

A second instance of the form will be added to the vertical tab list with an **(A1)** indicator after the form number. This means it is the first additional form. The data entry for this form is independent of the other physical exam form.

Multiple instances of additional forms can be created. The additional form indicator's number will increment for each, i.e., **(A2)**, **(A3)**, etc.

Deleting Forms

If a form was activated in error and needs to be deleted, or needs to be deleted in order to delete the subject visit, you can delete it from the **Active Forms** tab.

20. Navigate to the **Active Forms** list.
21. Check the **Delete?** checkbox for the additional physical exam form you just created and click the **Submit** button.

The form is deleted and returns to the **To Do Forms** tab. Only forms in the **Started** status (those on the **Active Forms** tab) can be deleted. When a form and its additional form(s) are on the Active Forms tab at the same time, only the highest instance of the additional forms can be deleted. The forms need to be deleted in the reverse order of how they were created.

Forms By Visit

22. If you are on the Subject Console, click the **Forms By Visit** vertical tab. (If you are not on the Subject Console, go to the Subjects → CRA Console, enter your protocol number, and select your subject from the Accrual vertical tab. Then click the Forms By Visit tab.)

This is another way to view a subject's forms. The most recently verified visit will be selected by default in the Visit dropdown in the upper right corner. The table displays all forms for the visit, regardless of their status. In comparison, the **Forms By Status** tab displays all forms of the same status, regardless of their visits. Other visits may be selected from the dropdown list, and there is an **All** option to see all forms for all verified visits. This tab is a different view and organization of the subject's forms for additional flexibility.

Clicking on the **Form No.** hyperlink will jump you into the form's data entry page in the same manner as described for the **Forms By Status** tab.