Subject Management in Forte EDC

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Registering Subjects to Protocols

Subjects in Forte EDC must be registered to a protocol and to a specific study site. A released calendar version is required before subjects can be added. This chapter assumes that a protocol and calendar have already been built and the calendar has been deployed.

For more information about building protocols and calendars in Forte EDC, consult the Protocol Setup guide or the Forte EDC Learning Portal.

Add a subject to a protocol

1. Since EDC is linked to OnCore, the subjects will already exist. Provided that the calendar has been deployed, subjects will become available in EDC as soon as they are on study in OnCore.

Enter data in ongoing forms

Remember that ongoing forms are not associated with a specific visit or timepoint, so data can be entered into ongoing forms at any time.

1. Click the **Subject Number** of the person you just enrolled.

2. In the Ongoing Forms section, click the name of the form for which you wish to enter data.

Here is an example of the Concomitant Medications form:
IMPORTANT

You must Apply the data to the table, and then click Save Form to capture data in a multi-row grid form like this example.

3. In the breadcrumb trail, click the **Subject Number** to return to your subject record.
Visit Management

After you have added a subject to the protocol, you can begin your data entry. The Visits table displays the visits within each of the segments that have been added to the subject’s calendar, along with the visit date and status. In the Visit Name column, each entry is a link to the details for the corresponding visit.

Protocol Subject Summary Page

1. In the Visit Name column, click Screening.
2. In the Details section, click **Edit**.

3. Enter a value for Visit Date, such as **29/03/18**.
   
   You can use the format DD/MM/YYYY, DD/MM/YY, DD MMM YY, or DD MMM YYYY.
   
   You can also use date shortcuts such as t (today’s date), w-1 (one week ago), mb (beginning of the month) and others.

4. Enter a Visit Time.

5. Click **Save**.
   
   If any forms were associated with this visit in the calendar, they now appear in the Forms section. You will learn more about entering data in subject forms in the next section.

6. Click **Data Entry Complete** to change the visit status to Complete.

   **NOTE:** You can also change the visit status to Missed or Not Applicable.

   - **Missed**
     Indicates that the subject should have completed the visit but did not. None of the forms for the visit will appear in the subject’s calendar.

   - **Not Applicable**
     Indicates that the subject was not required to complete the visit. None of the forms for the visit will appear in the subject’s calendar.

   - **Data Entry Complete**
     Indicates that the visit occurred by entering the Visit Date. After the visit is saved, the forms for the visit appear in the subject’s calendar.
What if I don’t see the visit I’m looking for?

The visits that appear automatically are those in the Primary segment for the protocol. To add scheduled visits to the subject’s calendar, select the appropriate segment from the drop-down and click **Create**. If the segment has been set up as repeating or open ended, you will be able to add it to the subject’s calendar multiple times.

How do I document that a subject came in for an additional/unscheduled visit?

To add an Additional Visit to the subject’s calendar, click **+ Additional Visit**. Enter the **Visit Date** and specify the segment in which the visit belongs. Click **Create**.

If a visit is outside a planned visit tolerance (or missed or delayed for some other reason) can I recalculate planned visits going forward?

Yes, if the protocol is set up to allow for recalculation. If it is, you’ll see a **Reset Planned Visit Dates?** field on the Visit Details page:

- Set the value to None to keep the current planned date visits.
- Set the value to Current Segment to update only planned dates on the selected segments.
- Set the value to All Visits to update all planned dates going forward on all segments.
Managing Forms

After you have indicated that the visit occurred by saving the Visit Date, the Forms table appears and provides a link to all of the forms for the selected visit. You can navigate through the subject’s calendar using the left navigation pane.

Select a form from the Visit Details page

Ongoing forms are available in the left pane in addition to the forms related to the subject visit.
**Form Status Options**

After you have selected a visit form, you have three options for Form Status:

<table>
<thead>
<tr>
<th>Status</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Missed</td>
<td>Indicates that the form should have been completed but was not. This inactivates all the fields on the form and clears previously entered data.</td>
</tr>
<tr>
<td>Not Applicable</td>
<td>Indicates that the form was not required for this subject. This inactivates all the fields on the form and clears previously entered data.</td>
</tr>
<tr>
<td>Data Entry</td>
<td>Indicates that the form was completed after all relevant data has been entered and saved.</td>
</tr>
</tbody>
</table>

**What if I need an additional form?**

To document data related to an additional procedure, click **+ Add a Form**. This button also allows you to add forms to an Additional Visit.
Good to know: Conditional form badge

If a form was created because of conditional form constraints, it appears with a "C" badge next to it in the following places: the Forms table in subject visits and subject forms, the left pane when viewing a subject, and in Subject Forms.

Hovering over the badge displays the source visit, timepoint (if relevant), form name, and section. If the conditional form was created from a multi-row grid or lab section, the row number also appears in the hover text. The name of the source form is a link that opens the form.

Subject Form Data Entry

Forte EDC forms can contain multiple sections and fields of various types. Required fields are indicated by a red asterisk. Most forms require that you enter data in the
applicable fields and click **Save**, while some will require you to click **Apply** first and then **Save**.

*eCRF Data Entry: sample Previous and Concomitant Medications form*
When you make changes to the data after the form is saved, Forte EDC requires that you enter a reason for the change. These changes are tracked in the audit trail for the form, which is visible via the History tab in the Form Status table.

**Form Status table**

<table>
<thead>
<tr>
<th>Status</th>
<th>User</th>
<th>Changes</th>
<th>Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>Audit Details</td>
<td>Megan Syverson</td>
<td>1 update</td>
<td>30 Dec 2014 18:55:57 GMT-06:00</td>
</tr>
<tr>
<td>Audit Details</td>
<td>Megan Syverson</td>
<td>8 creates</td>
<td>30 Dec 2014 18:55:58 GMT-06:00</td>
</tr>
<tr>
<td>Data Entry Complete</td>
<td>Megan Syverson</td>
<td></td>
<td>30 Dec 2014 18:55:13 GMT-06:00</td>
</tr>
</tbody>
</table>

**Enter data in an eCRF**

1. In the Forms table, click any form available for the relevant visit.

2. Enter data in all required fields.

3. Click Save Form.

**NOTE:** In multi-row grid forms, remember to click Apply and then Save.

4. Click **Data Entry Complete** to change the form status to Complete.

5. Navigate to other forms associated with the visit in the left pane.

6. Enter any data, click **Save Form** and then click **Data Entry Complete** for each.
Add notes to a form

You can add notes to eCRFs to clarify data to prevent queries. Within a form, notes can be added at the form, section, and field level.

1. Open any form for your subject’s visit.

2. Click the button at the top of the form.
   The first 0 indicates that there are no Notes on this form.

3. Enter a new note for the Data Manager, such as “Pt forgot to fast.”

4. Click Save, then click Close.
   The button now indicates that one note is present on this form.

Why would I add a Note to a form?

You can add notes to eCRFs to clarify data in an effort to prevent queries. Within a form, notes can be added at the form, section, and field level. To add a note to a field in a list or matrix section, click the field name. To add a note to a field in a grid or lab section, click the blue [+ ] next to the field. To add a note at the form or section level (in multi-section forms), click the blue Form or Section button.
Data Verification and Review

(Data Manager and/or Coordinator)

After the Protocol Coordinator has marked a visit or form as Data Entry Complete, you can verify (CRA) and review (DM) the data. To find visits and forms that require verification and review, use the filters on the Subject Forms page.

1. Navigate to Menu > Subject Forms.

2. Use the Protocol, Study Site, and Subject filters on the left to find your subject’s forms.
   
   Only forms with a status of Data Entry Complete will appear in this activity.

3. In the Verification Status filter, select Needed.
   
   You can also search for a form in the top Search bar.
4. Click the form link for a form that needs verification.

5. Use the Previous and Next links in the left navigation pane to move through the filtered list.

6. At the top of the form, click **Verified** (CRA) or **Review Complete** (DM).
If the data is as expected, you can change the Visit or Form Status:

- **Verified** or **Verification Not Applicable (CRA)** - After the visit/form has been source document verified, you can mark it as Verified. If the form does not require source document verification, you can mark it as Verification Not Applicable. You can perform this task before or after the Data Manager performs review. Any changes made to the data will prompt the Verified or Verification Not Applicable status to be undone.

- **Review Complete (DM)** - After the visit/form data has been reviewed, you can mark it as Review Complete. You can perform this task before or after the CRA performs verification. Any changes made to the data will prompt the Review Complete status to be undone.
Optional: Change the status of multiple visits/forms simultaneously

Use the Ready For filter on the Subject Forms page to find all visits and forms that are ready for a certain status.

Select the checkboxes for the appropriate visits and forms or select the checkbox in the header of the far-right column to select all visits and forms on the current page. Then, click Submit Status.
Query Management

If data discrepancies are present for the visit or form, you can open a query. Queries can be added after the Protocol Coordinator marks a Visit or Form as Data Entry Complete. The workflow is as follows:

- Data Manager or CRA opens the query.
- Protocol Coordinator responds to the query.
- Data Manager or CRA closes the query.

Queries on the Visit Date or Visit Time level

![Image of Visit Date and Visit Time details]

Name: Screening
Planned Visit Date: 01 Jan 2014
Visit Date: 01 Jan 2014
Visit Time: 14:20
If you have a question about data entered on a form, you can query a specific value, a row on the form, a whole section of the form, or the entire form. If you need clarification on data entered across several forms, you can also add a query to the visit. An icon with a count appears next to each field to which queries have been added. A count of Visit, Form, and Section level queries is included in the Visit Details, Form, and Section buttons. The count shows the number of Open, Responded, and Closed queries at each level.

**Open a new query**

1. Within the subject visit or form, determine where to place the query.

2. Bring up the Notes/Queries dialog:
   - For field-level queries, click the **field name** (list or matrix section) or the **blue + icon** (grid or lab section).
   - For form-level or section-level queries, click the **Form** or **Section** button.
3. Enter the query text, such as “Value appears to be out of range”

4. Click Save.

5. Click Close to return to the visit or form.

What if I need to make a change to my query?

Until the query has been responded to, you can click the Edit link to make changes to the query text or the Close link to close queries that were added in error.

How will I know that the Protocol Coordinator has responded to the query?

Use the Subject Forms page to navigate to visits and forms with responded queries. Simply select a Protocol and Study Site/Subject (if applicable), and click the Responded Queries option in the Data Entry Status filter group. Use the Form, Protocol, Subject Number, and Visit links to navigate to the appropriate record. You can also see a list of visits and forms with responded queries on the Home page.

How can I tell what the Protocol Coordinator changed on the Visit or CRF?

Click the History button in the Visit or Form Statuses table to see all changes to the data.
After the Protocol Coordinator makes any necessary changes to the data and responds to the query, you must review and close the query. If the query response is not sufficient, you can add a new query using the **New Query** button.
Close a query

1. Within the subject visit or form, bring up the Notes/Queries dialog:
   - For field-level queries, click the field name (list or matrix section) or the blue + icon (grid or lab section).
   - For form- or section-level queries, click the Form or Section button.

2. Review the query response.

3. If the query response is sufficient, click Close.

4. Click Close to return to the visit or form.

Lock and Freeze Visits and CRFs

After visits and forms have been Reviewed and Verified (or marked as Verification Not Applicable), you can change the visit/form status to Locked. This prevents the Protocol Coordinator from making additional changes to the data. If changes need to be made, you can undo the Locked status.

After you have locked the visit/form, the Principal Investigator (PI) must approve it. After the PI has approved the visit/form, you can change the status to Frozen in preparation for your final data extract. If changes are needed after the form is Frozen, a user with the Undo Freeze in Production role must undo that status. The DM or PI can then undo the Approved status, allowing the DM to unlock the form for editing.
Find Visits and CRFs that Need Approval

Visits and forms are locked by the Data Manager to prevent additional changes to data. After that step is complete, you can approve and electronically sign them.

Use the CRF Approvals section on the Home Page or the Ready for Approval filter on the Subject Forms page to find visits and CRFs that need your approval.

**Option A:**

1. On the Home Page, select a **Protocol** and **Study Site** (if applicable) in the CRF Approvals section.
2. Click **Search**.

**Option B:**

1. Click the Subject Forms menu.
2. Select the Protocol, Study Site, and Subject filters, if needed.
3. Select Approval in the Ready For filter.

Both options take you to the list of visits and forms that meet the Ready for Approval criteria in Subject Forms. Within the Subject Forms page, you can search for a form name in the top Search bar.
Use the **Form**, **Protocol**, **Subject Number**, and **Visit** links to navigate to the appropriate record. Then, use the **Previous** and **Next** links in the left navigation pane to move through the filtered list.

**Subject Forms Filter Navigation**
Approve Visits and CRFs

If the data is as expected, you can change the Visit or Form Status to Approved.

1. After you’ve confirmed that the data is accurate, click Approved in the Form Status table.

2. Enter your username and personal identification number (PIN) in the CRF Approval window.
   
   If you have already approved other visits/forms during the current login session, you’ll just need to enter your PIN.

3. Click Approve.
   
   If the data is not as expected, contact the Data Manager to unlock the form and the Protocol Coordinator to make the necessary changes.
Optional: Approve multiple visits/forms simultaneously

Use the Ready For Approval filter on the Subject Forms page to find all visits and forms that are ready for Approval.

Select the checkboxes for the appropriate visits and forms or select the checkbox in the far right column header to select all visits and forms on the current page. Then, click Submit Status. The CRF Approval window appears, allowing you to review the number of items you are approving. Enter your username and PIN and click Approve.
Set Your PIN

To electronically sign visits/forms, you must use your username and a personal identification number (PIN).

1. Choose the User Profile menu item from the user menu.

2. On the User Profile page, click Set PIN.

3. In the confirmation window, click Confirm to receive an email to set your PIN.

4. Open the email you receive and click the Set Pin link.

5. On the Set PIN page, enter the numbers you want to use for your PIN. Use the requirements listed on the right of the screen as a guideline for choosing your PIN.

If you haven’t set your PIN before you are ready to approve a visit/form, you can also start the PIN-setting process from the approval window by clicking Set PIN.

What do I do if I forget my PIN?

You can reset your pin from either of two locations:

- The User Profile (where the Set PIN button appears)
- The approval window (start the PIN reset process by clicking the Forgot your PIN? link)


Run Reports

Several standard reports are available via the Reports menu.

- Under the Reports menu item, you can run custom reports set up by your organization.
- Under the Standard Reports menu item, you can run reports that are included in Forte EDC.

Click the name link for the report you want to run and specify the parameters for the report. For more information, see the Reports page on the Learning Portal.

Run a standard report

1. Navigate to Menu > Reports > Standard Reports.

2. Choose a report by clicking the report name.
   - Example: Click Visit Report

3. Enter the following parameters:
   - From Date: leave as default (should be today’s date)
   - To Date: m+1
   - Protocol: select a protocol

4. In the Format field, choose XLSX.

5. Click Run.

6. When the Outcome is Completed in the Queued Tasks window, click View Output.
### Sample output in XLSX format:

<table>
<thead>
<tr>
<th></th>
<th>A</th>
<th>B</th>
<th>C</th>
<th>D</th>
<th>E</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Visit Report</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>2</td>
<td>Report Run Date: 06 Apr 2018</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>3</td>
<td>From Date: 06 Apr 2018</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>4</td>
<td>To Date: 06 May 2018</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>5</td>
<td>Protocol</td>
<td>Site</td>
<td>Subject Number</td>
<td>Visit Name</td>
<td>Planned Dates</td>
</tr>
<tr>
<td>6</td>
<td>JDS Protocol</td>
<td>Great Hospital</td>
<td>200</td>
<td>Primary - Baseline</td>
<td>29 Mar 2018 - 26 Apr 2018</td>
</tr>
</tbody>
</table>

### Sample output in HTML format:

```html
Form Status by Site and Subject  
Report run date: 23 Apr 2014  
Protocol: CARD0815; Site: All; Subject: All

<table>
<thead>
<tr>
<th>Site</th>
<th>Subject</th>
<th>In Progress</th>
<th>Entry Complete</th>
<th>Verified</th>
<th>Reviewed</th>
<th>Locked</th>
<th>Approved</th>
<th>Frozen</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>Great Hospital</td>
<td>1011</td>
<td>10</td>
<td>20.0</td>
<td>1</td>
<td>1.0</td>
<td>1.0</td>
<td>0</td>
<td>0</td>
<td>0.0</td>
</tr>
<tr>
<td>Great Hospital</td>
<td>1012</td>
<td>0</td>
<td>0.0</td>
<td>0</td>
<td>0.0</td>
<td>0.0</td>
<td>0</td>
<td>0</td>
<td>0.0</td>
</tr>
<tr>
<td>Great Hospital</td>
<td>1013</td>
<td>10</td>
<td>17.0</td>
<td>1</td>
<td>1.0</td>
<td>1.0</td>
<td>1</td>
<td>0</td>
<td>1.0</td>
</tr>
<tr>
<td>Great Hospital</td>
<td>1014</td>
<td>14</td>
<td>24.0</td>
<td>0</td>
<td>0.0</td>
<td>0.0</td>
<td>0</td>
<td>0</td>
<td>0.0</td>
</tr>
<tr>
<td>Great Hospital</td>
<td>1015</td>
<td>27</td>
<td>47.0</td>
<td>2</td>
<td>3.0</td>
<td>3.0</td>
<td>1</td>
<td>0</td>
<td>0.0</td>
</tr>
<tr>
<td>Great Hospital</td>
<td>1016</td>
<td>17</td>
<td>29.0</td>
<td>0</td>
<td>0.0</td>
<td>0.0</td>
<td>0</td>
<td>0</td>
<td>0.0</td>
</tr>
<tr>
<td>Great Hospital</td>
<td>1099</td>
<td>0</td>
<td>0.0</td>
<td>0</td>
<td>0.0</td>
<td>0.0</td>
<td>0</td>
<td>0</td>
<td>0.0</td>
</tr>
<tr>
<td>Great Hospital</td>
<td>Sub Total</td>
<td>84</td>
<td>29.0</td>
<td>1.0</td>
<td>0.0</td>
<td>0.0</td>
<td>0</td>
<td>0</td>
<td>0.0</td>
</tr>
<tr>
<td>Grand Total</td>
<td>84</td>
<td>29.0</td>
<td>1.0</td>
<td>4</td>
<td>0.0</td>
<td>0.0</td>
<td>0</td>
<td>0</td>
<td>0.0</td>
</tr>
</tbody>
</table>
```
Subject Data Set Export

The Data Set Export feature allows you to export data in Excel or SAS file formats for either a single subject or all subjects on a protocol. A separate file is generated for each selected form.

1. Navigate to Menu > Data Export.

2. Choose a protocol.

3. Use the checkboxes to select the forms you want to export to Excel.
   - Use the filters on the left to limit the data by Study Site, Subject, or Status.

4. In the Data Export Options section, indicate how you want the data to appear:
   - **Column Headers**: Use Descriptions
   - **Option Lists**: Descriptions
   - **Format**: Excel
   - **Lab Exams as Columns**: No

5. Click Export.

6. When the Outcome is Completed in the Queued Tasks window, click View Output.
Data Set Export

Select the forms for which you wish to export data sets.

<table>
<thead>
<tr>
<th>Form Name</th>
<th>Instance Count</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Adverse Events_Severity Scale V1</td>
<td>1</td>
<td></td>
</tr>
<tr>
<td>Body Measurements_Standard V1</td>
<td>0</td>
<td></td>
</tr>
<tr>
<td>Concomitant Medications V1</td>
<td>1</td>
<td></td>
</tr>
<tr>
<td>Demographics_US V1</td>
<td>1</td>
<td></td>
</tr>
<tr>
<td>ECG_Central V1</td>
<td>0</td>
<td></td>
</tr>
<tr>
<td>Eligibility V1</td>
<td>1</td>
<td></td>
</tr>
<tr>
<td>Informed Consent V1</td>
<td>1</td>
<td></td>
</tr>
<tr>
<td>Labs_Central V1</td>
<td>0</td>
<td></td>
</tr>
<tr>
<td>PK Blood Draw V1</td>
<td>0</td>
<td></td>
</tr>
<tr>
<td>Physical Examination V1</td>
<td>0</td>
<td></td>
</tr>
<tr>
<td>Pregnancy Test V1</td>
<td>1</td>
<td></td>
</tr>
<tr>
<td>Study Completion / Discontinuation V1</td>
<td>0</td>
<td></td>
</tr>
<tr>
<td>Treatment Admin - Data and Time only V1</td>
<td>0</td>
<td></td>
</tr>
<tr>
<td>Usage Specific Labs with Normal Ranges V1</td>
<td>0</td>
<td></td>
</tr>
<tr>
<td>Vital Signs with DateTime V1</td>
<td>0</td>
<td></td>
</tr>
</tbody>
</table>

Data Export Options

- Column Headers: Use Descriptions, Use Variable Names, Exclude Headers
- Option Lists: Codes, Descriptions
- Format: Excel, SAS
- Lab Exams as Columns: Yes, No

Export
What are the other choices in the Data Set Export?

In the Column Headers field, choose **Use Descriptions** to show field names, **Use Variable Names** to show the field variable names, or **Exclude Headers** to not include a header row at all.

In the Option Lists field, select whether you want to see the list **Codes** or their item **Descriptions** in the export.

You can choose either **Excel** or **SAS** for the Format.

In the Lab Exams as Columns field, selecting **Yes** transposes the lab section items into columns and the first value of each row in the lab section appears in the report. Selecting **No** shows each field in the lab section as its own column, with a row present for each row in the section.
**Subject Casebook Export**

PC  PI  DM  CRA

The Subject Casebook Export feature allows you to view all the visit and form data for a single subject.

1. Navigate to Menu > Data Export.

2. Click any protocol.

3. Click **Subject Casebook Export** in the left panel.

4. Select a subject from the drop-down menu.
   Queries, Notes and Audit History are included by default. To exclude them, select the checkbox.

5. Click Export Casebook.

6. When the Outcome is Completed in the Queued Tasks window, click **View Output**.

When you see a number next to your name, you have a new completed Queued Task to review.