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The focus of this training section is on subjects. In OnCore, a *subject* is a person who is participating in a protocol, who is considering participating, or who is being evaluated for their eligibility to participate. Each subject record in OnCore represents one patient (one person) who is registered to a protocol. A person might have several subject records in OnCore if they are participating on more than one study or if they register to a study multiple times.

Some information in OnCore is stored at the *patient* level; this information is the same throughout OnCore, no matter what protocol you are looking at. The patient information includes the MRN, demographics, address, emergency contact information, expiration date, and other optional identifiers such as the patient’s driver’s license number. If this information is updated anywhere in OnCore, it is reflected in all subject records for that patient.

Other information in OnCore is stored at the *subject* level; this information is specific to the person’s enrollment on a particular study. The subject information includes the sequence number, consent dates and versions, eligibility criteria, study site, treatment and follow-up start dates, and visit details. When this data is entered or updated in a subject record, it does not change any other subject records.
The Subject and CRA Consoles

There are two consoles used in subject management: the Subject Console and the CRA Console.

- **Subject Console**: This console allows you to view subject information within the context of a protocol. The console provides access to a subject’s demographic information, the protocols the subject is associated with, what consent forms the subject has signed, their eligibility status, etc.

- **CRA Console**: This console is designed to provide subject information at a protocol level. When a protocol is selected in the CRA Console, it displays the subjects who have been accrued, which subject forms have been completed and are yet to be completed, a list of serious adverse events (SAEs), visits outside of tolerance, and other subject deviations in this protocol. The CRA Console also indicates which subjects need to review and accept a more recent version of the consent form.

The CRA Console provides a summary of subject information, including each subject’s study site, sequence number, treatment arm, and current status.

Use the CRA Console to find a subject record, then click the Patient MRN to open that subject’s record.
IMPORTANT

Always start in the CRA Console and open a protocol. Then click any patient MRN to open a subject’s individual record. The CRA Console provides a summary of subject information, including each subject’s current status, study site, treatment arm assignment, and sequence number. The summary of information visible in the CRA Console > Accrual tab will help you open the correct subject record. If you start in the Subject Console without being in the context of a protocol, you must know the patient’s full MRN in order to open their record.

The RR superscript indicates that this subject needs to review and accept a newer version of the consent form.
Registering Subjects

The first task is to create a new subject. Subjects must be associated with a protocol.

Find an existing patient record

1. Navigate to Subjects > CRA Console.

2. In the Select Protocol field, select the protocol to which you wish to register a subject.

3. Click the Register Subject tab.

   The Register Subject page allows you to search for existing subjects or add a new patient. Note that you are still working within the context of the protocol; a subject can't be entered into OnCore without a protocol association.

4. In the Study Site field, choose the location where the subject is to be enrolled. This is a find-as-you-type field that allows you to choose among the study sites participating in this protocol at your institution.

5. When entering a new subject, first check to see whether they have already been entered into OnCore, in order to avoid duplicate subject entries. In the Find
Subject section on the left, enter the subject’s last name and birth date (if known) in the Last Name and Birth Date fields respectively and click Find.

The Results table shows all subjects matching the search criteria. Subject MRN is displayed as a link; clicking this link populates the fields on the Register Subject page with the selected subject’s data.

Create a new patient

If the patient does not yet exist in OnCore, you must create a new patient record. The new patient will be enrolled on a protocol, and a subject record will be generated.

1. On the Register Subject page, click Create New.

2. In the Study Site field, select where the patient will be enrolled.

3. Enter the following into the Subject Details section:
   - Subject MRN
   - Last Name
   - Birth Date
   - First Name
   - Gender
   - Ethnicity
   - Race
4. Click **Add** to register the new subject to the protocol.

The **Subject Console** page opens on the Demographics tab. Note that the subject demographic information you entered appears on the page.
Update subject demographics

Subject demographic information is updated on the Subject Console > Demographics tab. Clicking Update allows you to make changes to a subject’s demographic and contact information.

- **Subject Contact Information**
  This section is where you record contact information, such as address, phone number, and email address, and the patient’s emergency contacts.

- **Additional Subject Identifiers**
  This section lists identifiers for the patient other than the MRN. Information in the Identifier Type field is selected from a pre-defined list (a reference list); free text can be entered in both the Identifier and Identifier Owner fields. An example of an additional subject identifier is a Hospital ID from another system or a driver’s license number; these identifiers are patient-level IDs because they remain the same no matter which protocol subject record you are looking at.
Managing Subjects

Subjects in OnCore can progress through several statuses during the course of the protocol. The vertical tabs in the Subject Console (Consent, Eligibility, On Study, Treatment, Follow-Up) allow you to record this status information.

Enter subject consent

Since you have already selected a subject, the Subject Console header displays the protocol, protocol status, subject MRN, and subject name. Note that the subject does not yet have a subject status. The next steps will show you how to update the subject’s status to Consented.

1. Select the Consent vertical tab.
   The Existing Consents section will list signed consent forms for this subject. Since this is a new registration, the message “No Subject Consent Found” appears in the Consents section because no consent forms have yet been signed.

2. Click Update.

3. In the Signed Date field, enter the date on which the consent was signed and then click Select Consents.
   A list of available consents opens, showing consent forms for the subject that have been approved at the subject’s study site and added at the protocol level via PC Console > Reviews > IRB record, or if an affiliate study site, via the Institution > [institution] > Consent Forms tab.
4. For the relevant consent, select **Accepted** and then click **Save**.

The consent form information appears along with the subject’s signed date. Note that the Subject Status field at the top of the page has been updated to CONSENTED.

The Other Consent Status table records comments related to consent information, consents being refused or waived or withdrawn, and reconsents when a minor subject has reached the legal age.

5. Click **Close**.

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**Determine a subject’s eligibility**

Confirming a subject's eligibility is *not* required by OnCore prior to placing that subject On Study, but it is generally done. To confirm a subject’s eligibility, use the following procedure:

1. Navigate to Subject Console > Eligibility.

   The Eligibility tab is used in one of two ways, depending on how the protocol was set up:
   
   - To record the subject’s eligibility status and the date of that status
• To supply the answers to a predefined eligibility questionnaire that helps users to determine the subject’s eligibility status. This questionnaire is defined per protocol in the PC Console > Eligibility tab.

2. If the protocol has an Eligibility questionnaire, click **Update** to record the subject’s responses.

3. Click **Submit** when you are done answering the questions.
   Note that the Subject Status has been changed to **ELIGIBLE**.

4. Click **Close**.

5. To simply record a subject’s eligibility status, fill in the Version Date, **Verified By** (name of the physician who determined that the subject was eligible), **Status Date** (date that the physician signed the eligibility questionnaire), and **Eligibility Status** fields.

6. Click **Submit**.

7. If the subject is not eligible, select a reason from the **Reason Not Eligible** field.
Answer the questionnaire so that the subject is eligible to participate

If the protocol does not have a questionnaire, select the appropriate Eligibility Status and enter the Status Date
Place a subject on study

When a subject has a recorded consent and a status of Eligible, the next step is to place them On Study.

1. Navigate to Subjects > Subject Console > On Study and click Update.

   At the top right of the page is the Sequence No., a number unique to each subject within the protocol. The sequence number can be manually entered, or may be automatically assigned by OnCore.

   One of the most important fields is On Study Date. The presence of this date is what OnCore uses to determine subject accrual to the protocol. Enter the On Study Date.

2. Make selections in the Disease Site and Histology fields (or Primary and Secondary Diagnosis fields for non-Oncology studies).

3. Click Submit.

   Note that the Subject Status has been changed to ON STUDY, and a Sequence Number has been assigned.
IMPORTANT

The Transferred Date field indicates the subject was first enrolled on the protocol at another institution and was transferred to the current study site. The Transferred Date field will prevent the subject from counting as an accrual for the current study site because, presumably, the subject was already counted as an accrual for their initial institution.
Add subject staff

The Subject Staff section on the Subject Console > On Study page holds information about the treatment staff assigned to the subject.

1. Enter the staff information, including your own, by using the dropdown menus. If you start typing a name, it should show up.

2. Click Add.
   
   This subject and this subject’s visits will now appear in My Console and in the Subjects widget on your home screen, if configured to show your subject assignments.

3. Click Team to create subject staff assignments from the Protocol Staff list.

Place a subject on treatment

In the Subject Console, the Treatment tab allows you to select the protocol arm assigned to the subject. You can also enter additional dates used in subject visit scheduling.

1. Select the Treatment tab and then click Add.

2. Enter the relevant treatment information.

3. Click Save.
   
   Notice that the Subject Status in the upper right of the page changed to ON TREATMENT.
As you’ve been doing these steps, visits have been “activating” on the subject’s calendar. The planned dates for the visits in the calendar are relative to the dates entered for each individual subject.

This subject was put on Arm A on 8/19/2016, so that is the day she started treatment.

Her status will be ON TREATMENT while she is on any arm.

This subject was transferred from Arm A to Arm B on 10/21/2016, but her status is still ON TREATMENT.
<table>
<thead>
<tr>
<th>Seq No</th>
<th>Name</th>
<th>Start Date</th>
<th>Unit</th>
<th>No of Repetition(s)</th>
<th>Visit(s)</th>
<th>Duration</th>
<th>Exclude Weekend</th>
<th>Arms</th>
</tr>
</thead>
<tbody>
<tr>
<td>5</td>
<td>Screening</td>
<td>Consent Signed</td>
<td>Day</td>
<td>1</td>
<td>1</td>
<td>1</td>
<td></td>
<td></td>
</tr>
<tr>
<td>10</td>
<td>On Treatment</td>
<td>On Treatment</td>
<td>Day</td>
<td>4</td>
<td></td>
<td>28</td>
<td></td>
<td>ArmA, ArmB</td>
</tr>
<tr>
<td>15</td>
<td>Arm A Treatment</td>
<td>On Arm</td>
<td>Day</td>
<td>4</td>
<td></td>
<td>28</td>
<td></td>
<td>ArmA</td>
</tr>
<tr>
<td>20</td>
<td>Arm B Treatment</td>
<td>On Arm</td>
<td>Day</td>
<td>6, 10, 15, 20, 25, 30, 40, 50</td>
<td></td>
<td>50</td>
<td></td>
<td>ArmB, ArmC</td>
</tr>
<tr>
<td>25</td>
<td>Arm C Treatment</td>
<td>On Arm</td>
<td>Day</td>
<td>6</td>
<td></td>
<td>21</td>
<td></td>
<td>ArmC</td>
</tr>
</tbody>
</table>

Segment 10 will only be triggered once, when a subject is assigned to his *first* treatment arm and his status changes to On Treatment.

Segments 15, 20, and 25 will trigger each time a subject is assigned to (or switches to) any arm, even if it’s not his first arm assignment.
Enter Off Treatment, On Follow Up, and Off Study statuses

Additional subject statuses are available after On Treatment, including Off Treatment, On Follow Up, and Off Study. These statuses can also be triggers for visits in the subject calendar. If the protocol doesn’t have a follow-up portion, the On Follow Up status isn’t required.

The following instructions show you how to enter these statuses.

1. Click the Follow-Up tab and then click Update (if necessary).

2. In the Off Treatment Date field, type the relevant date.

3. Choose the appropriate Off Treatment Reason and then click Submit.

   The subject status is now OFF TREATMENT. You can see this in the Subject Console header.

4. If the subject is on Follow Up, type the relevant date into the Follow-Up Start Date field and click Submit.
Note that the Subject Status has changed to ON FOLLOW UP. If you are using a protocol calendar, treatment visits with Planned Dates after the Follow-Up Start Date will no longer be available to be checked in.

There are additional fields in the Subject Follow-Up Update section, some related to tracking follow-ups without a calendar and others related to the last known status of the subject. The Expired Date field appears here in addition to being on the Demographics tab.

5. If the subject is off study, enter the relevant Off Study Date and click Submit.

Note that the Subject Status has changed to OFF STUDY. The status of OFF STUDY is the final status for the subject.

Serious Adverse Events (SAEs) and Deviations

The SAEs tab in the Subject Console can track any serious adverse events associated with a subject. SAEs must be entered at the subject level; however, SAEs can be
viewed across all subjects at the protocol level in the CRA Console and other safety monitoring tools and reports, such as the DSMC Console and the Protocol SAE Report.

Create an SAE with minimum detail, for sponsor invoicing

1. Navigate to Subjects > Subject Console > SAEs tab and click New.

2. In the Subject SAE Update section, enter information into required fields listed below:
   - Event Date
   - Reported Date
   - Outcome

3. Click Submit.

   A unique Event Number is assigned to the SAE. This number appears at the top of the page.

   This SAE will now appear as an invoiceable item in the Financials Console if the Parameters tab is configured appropriately (if SAEs are invoiceable to the sponsor). This is the minimum amount of detail required to create an SAE in OnCore.

4. In this scenario, the SAE details are documented in the sponsor’s EDC. Link this SAE record to the detailed record entered in the sponsor’s system:

   In the Additional SAE Identifiers section, choose Sponsor in the Identifier Type field, enter the sponsor’s Identifier value, and then click Add.

   This SAE can be invoiced to the sponsor, and anyone viewing this SAE record in OnCore will know which SAE record in the sponsor’s EDC system contains additional details.

Add adverse event details for safety monitoring

At a high-level, SAE data for a protocol is aggregated and can be reviewed in the DSMC Console (Data Safety and Monitoring Committee Console) if additional details
are provided, such as the category, attribution, and grade. In the Adverse Event Details section in the middle of the page, enter the following information:

- Course Start
- Category
- AE Detail
- Grade/Severity
- Unexpected
- DLT
- Action
- Attribution to relevant drug

5. Click Add (in the middle of the page). The details you enter appear in the table. In the Adverse Events Details section in the middle of the page, you can also document a category using the Select Detail link:

6. Enter a Course Start date.

7. Click the Select Detail… link.
8. SAEs can be locked when you are finished to prevent edits to all but the Tracking Details section. Click **Complete and Lock**.

9. Click **Close**. You can view this subject’s SAEs in the **Subject Console > SAE** tab.

If SAE details are entered in OnCore in the Subject Console, then an aggregate view of all SAEs as well as the worst grade SAEs can be seen in Reviews > DSMC Console:
Create a subject deviation

A deviation is a variance from the approved protocol procedures. Deviations specific to an individual subject are entered via the Subject Console > Deviations tab.

1. Navigate to the Subject Console > Deviations tab.
   
The table at the top of the page shows the subject’s deviations. The bottom table shows any visits with a visit date outside of the planned date’s tolerance. This table is for informational purposes, and you can use it as a guide for entering deviations if needed.

2. Click New to create a deviation.
   
The Date Discovered and Reported By fields default to the current date and user, but they can be changed. When entering deviation data, the required fields are marked with an asterisk.

3. Enter the following:
• Date Discovered
• Reported By: the default is your name
• Deviation Date
• Category
• Description of Deviation
• Action Taken
• Report to IRB?

4. Click Submit to create the deviation.

Other information can be entered to record when it should be reported to the IRB, the date it was reported, and the date it was reported to the sponsor.

5. Click the Deviations vertical tab to see the updated page.

The Delete link allows you to delete a deviation record entered in error.

Document monitor visits

Subject staff can now alert financial staff when monitor events have taken place and are ready for inclusion on an invoice to the sponsor by documenting a financial event in the CRA Console.

1. To add a financial event, navigate to the CRA Console > Financial Events tab and click Update.

2. Select the event from the drop-down list for the Financial Event field. The events that appear in the drop-down list are configured by the financial analysts in the Financials Console.

3. Add any comments. Comments entered here are visible for the financial team in the Financials Console.

4. Click Add to submit the event.
After an event is submitted, it appears on the Financials Console > Invoiceable Items tab in the Protocol Items section. A ? icon appears in the Triggering Event column for events with comments, and financial staff can hover over the icon to view the comments.