Subject Administration

Subject Administration

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 to register participants and add information about their studies:

- **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.

Study Site	Subject Id	Last Name	First Name	Seq No.	Arm	Level	Status	Status Date	Ver	Last Visit	Last Visit Date	Select
Carolinas Medical Center	BR4927819	Ausbrook	Lonn				CONSENTED	08/18/2015	2			☐
South Clinic	PG86163C5RR	Bailey	Wayne	CAR-11	1		ON TREATMENT	02/06/2015	3	D1	02/06/2015	☐
East Clinic	PL17760WD	Charters	Robert	CAR-14	1		ON FOLLOW UP	08/01/2015	3	D30	08/30/2015	☐
Carolinas - West Clinic	CLB12356	CLBL	CLBF						4			☐
Carolinas - South Clinic	CLBTester	CLBL	CLBF						4			☐
East Clinic	CLB1234	CLBLN1	CLBFN1						4			☐
East Clinic	EH63785RT	Fawell	John	CAR-8	1		ON FOLLOW UP	01/31/2015	4	Y2	01/30/2017	☐
South Clinic	VG801418Y	Feraca		CAR-18	1		ON FOLLOW UP	11/10/2019	2	D30	12/09/2019	☐
East Clinic	IB648187K	Filiberto	Anita				ON FOLLOW UP	03/18/2015	3	Y4	03/17/2019	☐
North Clinic	ER71653DD	Garton	Ken	CAR-1			TREATMENT	02/07/2015	3	D1	02/07/2015	☐

CRA Console header details:
- Protocol No.: CAR0815
- Library: Cardiology
- PI: Wallenstone, Ben
- Sponsor: Bayer Healthcare Pharmaceuticals, Inc.
- Protocol Target Accrual: 50
- Accrual To Date: 20
- Protocol Status: OPEN TO ACCRUAL
- RC Total Accrual Goal (Upper): 60
- IRB Expiration: 09/27/2020
- Short Title: Pre-hospital Administration of Thrombolytic Therapy With Urgent Culprit Artery Revascularization

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

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 to open their record.

CRA Console   **?**

Protocol No.: CAR0815	Library: Cardiology	PI: Wallenstone, Ben	Sponsor: Bayer Healthcare Pharmaceuticals, Inc.
Protocol Target Accrual: 50	Accrual To Date: 20	Protocol Status: OPEN TO ACCRUAL
RC Total Accrual Goal (Upper): 60		IRB Expiration: 09/27/2020

Short Title: Pre-hospital Administration of Thrombolytic Therapy With Urgent Culprit Artery Revascularization

Select Protocol
CAR0815 ▾

Select Subject
▾

Accrual

Forms by Status (Queried) »

Protocol Calendar

Monitoring Visits

Financial Events

SAEs

Deviations

FAQs

Register Subject

Accrual Details

Page Size 10 ▾

All ▾

< Page 1 ▾ of 4 > >>

The RR superscript indicates that this subject needs to review and accept a newer version of the consent form.

Study Site	Subject Id	Last						Ver	Last Visit	Last Visit Date	Select
Carolinas Medical Center	BR4927819	...sbrook					5	2			☐
South Clinic	PG8616305 RR	Bailey	Wayne	CAR-11	1	ON TREATMENT	02/06/2015	3	D1	02/06/2015	☐
East Clinic	PL17760WD	Charters	Robert	CAR-14	1	ON FOLLOW UP	08/01/2015	3	D30	08/30/2015	☐
Carolinas - West Clinic	CLB12356	CLBL	CLBF					4			☐
Carolinas - South Clinic	CLBTester	CLBL	CLBF					4			☐
East Clinic	CLB1234	CLBLN1	CLBFN1					4			☐
East Clinic	EH63785RT	Fawell	John	CAR-8	1	ON FOLLOW UP	01/31/2015	4	Y2	01/30/2017	☐
South Clinic	VG801418Y	Feraca	Roland	CAR-18	1	ON FOLLOW UP	11/10/2019	2	D30	12/09/2019	☐
East Clinic	IB648187K	Filiberto	Anita	CAR-10	2	ON FOLLOW UP	03/18/2015	3	Y4	03/17/2019	☐
North Clinic	ER71653DD	Garton	Ken	CAR-1	1	ON TREATMENT	02/07/2015	3	D1	02/07/2015	☐

Switch Calendar Versions   1 (Protocol v01/05/2015) ▾   Replace Versions

Select All | None

Accrual

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 **Menu > Subjects > CRA Console**.

2.   In the **Select Protocol** field, select your protocol: **PROT-*your initials***.

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 your protocol; a subject can't be entered into OnCore without a protocol association.

4.   In the Study Site field, choose **The Research Institute**.

This field indicates the location where the subject is 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 (or an institution with which you are affiliated). Emory does not provide promission to create a new subject.

5.   When a patient has an MRN, but you cannot pull the patient up in OnCore, complete an **ADT REFRESH in EPIC to push the patient MRN. Into OnCore!**

6.   Research Coordinator logs into **Hyperspace**, click the Patient Station Button on the toolbar.

7.   **Search for the patient** - enter the patient's Name/MRN and/or Birth Date.

8.   Once the patient chart opens, click **Resend Msg button** on the Patient Station Activity.

9.   *Resend Msg*: Sends msg to OnCore to refresh the patient in OnCore.

10. Go back into *OnCore* and look up the subject again, and he/she should be there.

11. If the patient truly does not have an MRN, you will have to complete a "Request for MRN" that can only be processed by OCR Data Integrity & Integration team.

12. The form can be located by clicking on the link and scrolling to the OnCore Tab: MRN Request Form.

13. Enter **Smith** in the Last Name field, then 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.

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. This information can be stored in OnCore, or it can be stored in another electronic registration system.

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.

Consented → Eligible → On Study → On Treatment → Off Treatment → On Follow Up → Off Study

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. In the next procedure, you will set the subject's status as having consented to the protocol.
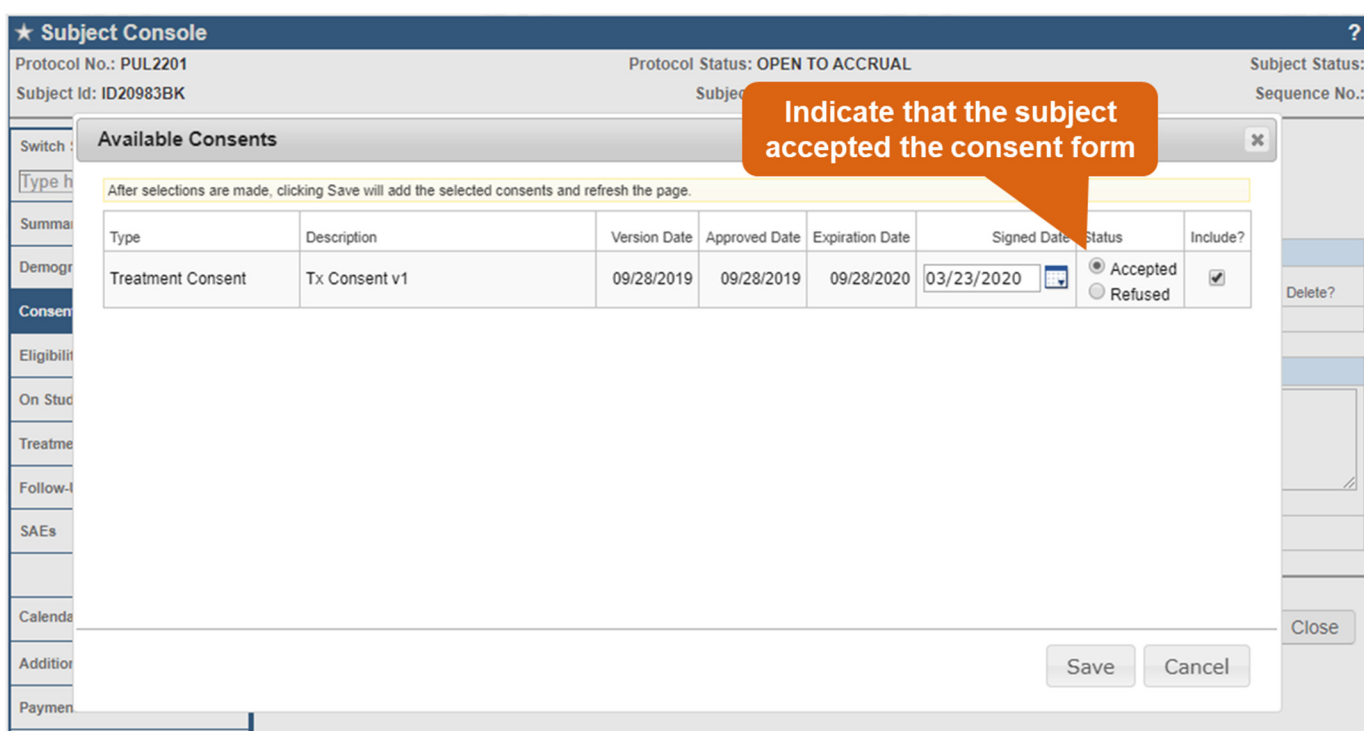
1. Navigate to the **Subject Console > Consent** tab.

    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 **w-20** 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 via the PC Console.

4. For the Treatment Consent v1, 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 re-consents when a minor subject has reached the legal age.

NOTE: You will not be able to consent a subject if a protocol has the status of Closed to Accrual or Suspended, unless the Signed Date for the consent falls within the time period of when the protocol has the status of Open to Accrual.

5. Click **Close**.
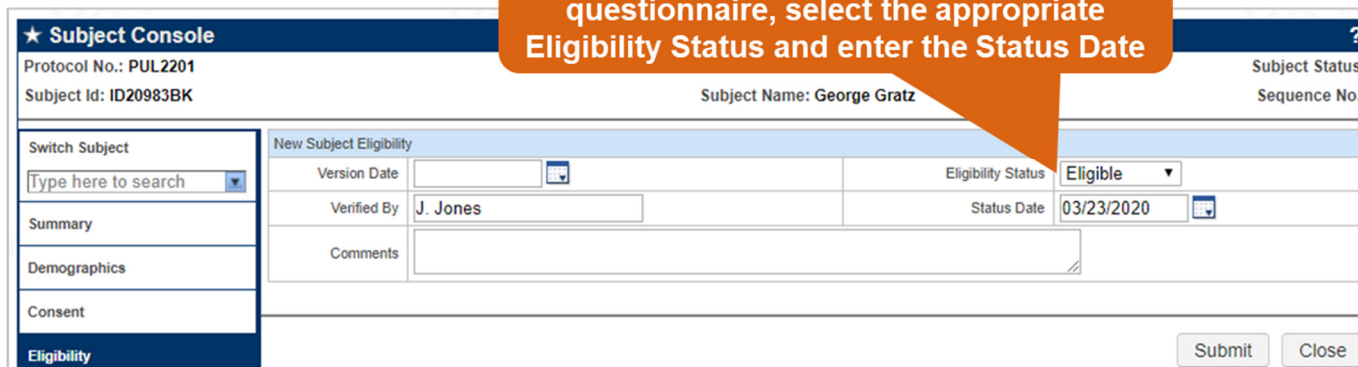
Determine a subject's eligibility

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 the protocol setup:

- 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. <u>Emory OnCore will not use eligibility questionnaires.</u>

2.   Enter the following:

- **Verified By**: *your initials*
- **Status Date**: w-18

3.   Click **Submit**.

The Subject Status has been changed to Eligible.

NOTE: When deeming a subject eligible, in situations when the protocol is in a suspended status, a warning message appears, but the eligibility status date can still be entered. Additionally, an eligibility status date can only be added when the subject has already consented or when the date entered falls within the time period when the protocol is Open to Accrual.

4.   Click **Close**.

Place a subject on study

Our subject has a recorded consent and a status of Eligible. The next step is to place our subject 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.

   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.

2. Enter an On Study Date of **w-16**.

3. Enterprise does not utilize the **Primary** and **Secondary Diagnosis** fields

4. Click **Submit**.

   Note that the Subject Status has 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.

5. The **Additional Protocol Subject Identifiers** section is optional and contains identifiers for the subject applicable only to this protocol. Enter the following and then click **Add**.

   - **Identifier Type**: Drug Kit ID
   - **Identifier**: AP09.30

The On Study Date counts the subject as an accrual for this protocol

Subject On Study Update

Sequence No.	SDC101	On Study Date (MM/DD/YYYY)	12/16/2019
Primary Diagnosis	Chronic pharyngitis		
Secondary Diagnosis	Deviated nasal septum		
Diagnosis Date			
ZIP at Registration			
Study Site	RI - North Clinic	Transferred Date (MM/DD/YYYY)	
Comments			

Additional Protocol Subject Identifiers

Identifier Type	Identifier	
		Add Cancel
Drug Kit ID	JS801.42	Edit

The Additional Protocol Subject Identifiers are only relevant for this study

(a patient might hve more than one Drug Kit ID if he is in enrolled on multiple protocols)

Add subject staff

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

6. Enter the following staff information from the drop-down lists attached to each field:

   - **Role**: Treating Physician
   - **Staff Name**: *choose any staff name in the Training environment.*

7. 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.

8. 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. Navigate to the **Subject Console > Treatment** tab.

2. Click **Add**.

3. Enter the following information:

   - **Arm:** Arm A
   - **On Arm Date**: w-15
   - **On Treatment Date**: w-15

4. Click **Save**.

   Notice that the Subject Status in the upper right of the page changed to On Treatment.

The two screenshots above show the Subject Console for Mary Mifflin (Patient MRN: hdm12920), Protocol No.: PUL3309.

First screenshot callout: This subject was put on Arm A on 10/09/2019, so that is the day she started treatment. Her status will be On Treatment while she is on *any* arm

Second screenshot callout: This subject was transferred from Arm A to Arm B on 1/13/20220, but her status is still On Treatment

As you have 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.

NOTE: In the screen shot above, the subject went On Arm *twice* (on Arm A, then on Arm B), but only On Treatment *once*.

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.

The following instructions show you how to enter these statuses as an exercise, but you will remove the statuses in the final step in order to avoid problems with the subject calendar.

1. Navigate to the **Subject Console > Follow-Up** tab.

2. Click **Update** (if necessary).

3. In the **Off Treatment Date** field, type **w-5**

4. Choose any **Off Treatment Reason** and then click **Submit**.

    The subject status is now Off Treatment. You can see this in the Subject Console header.

5. In the **Follow-Up Start Date** field, type **w-4** 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.
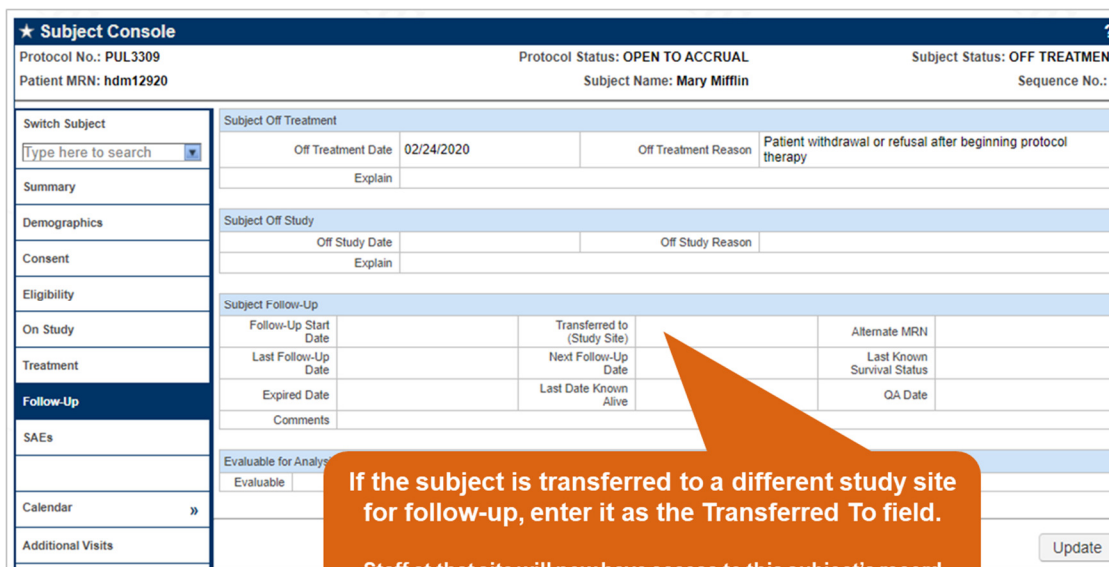
There are additional fields in the Subject Follow-Up Update section, some related to tracking follow-ups without a calendar and others related to the last known status of the subject. The Expired Date field appears here in addition to being on the Demographics tab.

6.   Enter an **Off Study Date** of **t-20** 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. You do not want your subject to be Off Study at this point, however.

7.   Remove the **Off Treatment Date**, **Off Study Date**, and **Follow-Up Start Date** and any Reasons you have entered. Then click **Submit**.

Note that the Subject Status has returned to On Treatment.

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

If your staff are already tracking SAE details in the sponsor's EDC system, asking them to document the same details in OnCore would be redundant. But if you want to use the OnCore Financials tools to invoice sponsors for SAEs, consider asking your staff to document the minimum information (three required fields) about SAEs.

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

2. In the **Subject SAE Update** section, enter the following information in the required fields listed below:

   - **Event Date**: w-3
   - **Reported Date**: w-2
   - **Outcome**: Recovering/Resolving

3. Click **Submit**.

   A unique Event Number is assigned to the SAE and 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.

   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:

4. In the Additional SAE Identifiers section, choose **Sponsor** in the Identifier Type field, enter an Identifier value of **ASCEN16-100-57**, 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.

Create a detailed SAE for an investigator-initiated protocol

For IITs that are not required to enter SAE details in a different system, staff might decide to use the SAE tab in the Subject Console to track *detailed* information about subjects' adverse events on a protocol. In this example, you will create an SAE with more information (toxicity, category, grade, etc.), which can be reviewed in tools like the DSMC Console or by running OnCore's safety monitoring reports.

5. If you still have an SAE record open, click **Close**.

6. In the Subject Console > SAEs tab, click **New**.

7. Enter the following information in the Subject SAE Update section (at the top):

    - **Event Date**: t-6 (six days ago)
    - **Event End Date**: t-4 (four days ago)
    - **Reported Date**: t (today)
    - **Reported By**: enter your name
    - **Event Narrative**: Subject presented to ED with severe chest pain and SOB. Hospitalized 48hrs due to severe emesis, elevated HR.
    - **Protocol Attribution**: Possible
    - **Outcome**: Recovered/Resolved without Sequelae
    - **SAE Classification**: Inpatient hospitalization or prolongation of existing hospitalization (for > 24 hours)

8. Click **Submit** to save the basic SAE information.

Add SAE 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 this example, the subject experienced chest pain (a common side effect for this drug) but also severe vomiting, which is *not* an expected outcome. Fortunately, the subject recovered without any lasting side effects or conditions and did not have to interrupt treatment.

9. In the Adverse Event Details section in the middle of the page, enter the following information:

   - **Course Start**: t-6
   - **Category**: Musculoskeletal and connective tissue disorders
   - **AE Detail**: Chest wall pain
   - **Grade/Severity**: 3
   - **Unexpected**: No
   - **DLT**: No
   - **Action**: None
   - **Attribution** to **Nebivolol** (or Investigational Tx): Probable

10. 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, document a second category using the **Select Detail** link:

11. Enter a Course Start of **t-6**.

12. Click the **Select Detail...** link.

Enter the Course Start, then click the Select Detail… link

13. Type "**vomit**" in the search field, then select the row for Vomiting – Gastrointestinal disorders – Grade/Severity 4 – Life-threatening consequences; urgent intervention indicated and click **Select**.

Search for a keyword, then select the row that accurately describes the subject's adverse events

Select an item from the list below

vomit

AE Description ▲	Code	AE Category	Grade/Severity	Grade Description
Pancreatitis	10033645	Gastrointestinal disorders	3	Severe pain; vomiting; medical intervention indicated (e.g., analgesia, nutritional support)
Rectal ulcer	10038080	Gastrointestinal disorders	2	Symptomatic; altered GI function (e.g., altered dietary habits, vomiting, diarrhea)
Vomiting	10047700	Gastrointestinal disorders	1	Intervention not indicated
Vomiting	10047700	Gastrointestinal disorders	2	Outpatient IV hydration; medical intervention indicated
Vomiting	10047700	Gastrointestinal disorders	3	Tube feeding, TPN, or hospitalization indicated
Vomiting	10047700	Gastrointestinal disorders	4	Life-threatening consequences
Vomiting	10047700	Gastrointestinal disorders	5	Death

Select   Cancel

14. Enter the following additional required details:

- Unexpected: Yes
- **DLT**: No
- **Action**: None
- Attribution to Nebivolol: Unlikely

15. Click **Add** (in the middle of the page). Two rows now appear in the AE Details table.

16. SAEs can be locked when you are finished to prevent edits to all but the Tracking Details section. Click **Complete and Lock**.

17. You alerted the IRB of the unexpected grade 3 SAE right away – enter **t** (today) in the **Notified IRB** Action Date field and then click **Submit**.

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

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**: keep the default (the current day)
      - **Reported By**: keep the default (your user name)
      - **Deviation Date**: w-1
      - **Category:** Treatment
      - **Description of Deviation:** Did not draw enough blood for Lipid Panel
      - **Action Taken:** Lipid Panel performed at next visit
      - **Report to IRB?** Not Applicable

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**.
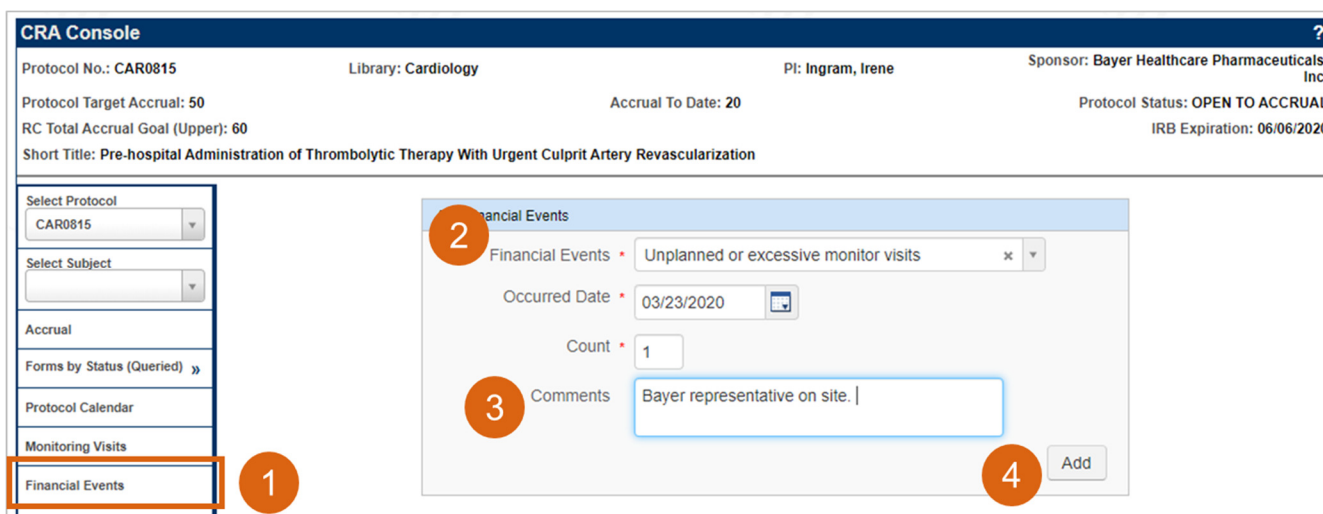
2. Select the event from the drop-down list for the Financial Event field.

    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.

5.

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

Demographic information entered

new subject
(no status)

Consent forms presented and explained

CONSENTED
Subject understands and agrees to the details in any consent form

CONSENT WAIVED
Subject does not need to consent for this study

CONSENT REFUSED
Subject declines to sign the consent form ✖

Eligibility assessed by research team

ELIGIBLE
Subject has been evaluated and meets all criteria

ELIGIBLE (O)
Subject has been evaluated and does not meet criteria precisely, but PI has granted an exception for *each* eligibility item missed

NOT ELIGIBLE
Subject has been evaluated but does not meet all criteria ✖

Study in progress

ON STUDY
CRC has entered an On Study Date

ON TREATMENT
Subject is enrolled on an Arm and the CRC has entered an On Treatment Date

NOTE: Entering an On Arm Date does not change the subject's status

WITHDRAWN
At some point after being presented with a consent form, the subject changes their mind and no longer consents to treatment and withdraws from the study

This status is only available if a subject has accepted or refused at least one consent form ✖

Study concluded

OFF TREATMENT
CRC has entered an Off Treatment Date

Subject will receive no additional treatment for this study

Subject is off all Arms

ON FOLLOW UP
CRC has entered a Follow Up Start Date

Overrides OFF TREATMENT

OFF STUDY
CRC has entered an Off Study Date

Overrides ON FOLLOW UP and OFF TREATMENT ✖

EXPIRED
Subject is no longer alive (may or may not be related to treatment or procedures received during the study) ✖