

Serious Adverse Events

Serious Adverse Events (SAEs) must be entered at the Subject level via the **Subject Console** → **SAEs** tab. Currently, you have no SAEs recorded for your subject.

1. If you are in the **Subject Console**, click the **SAEs** vertical tab. (If you are not on the Subject Console, go to the **Subjects** → **CRA Console** menu item, enter your protocol number, and select your subject from the **Accrual** vertical tab. Then click the **SAEs** tab.)
2. Click the **New** button to create an SAE.

You are presented with a screen full of data entry fields. (The ? help icon in the upper right corner can be of great use here.) In this upper section, the fields with an asterisk are required before submitting.

3. Enter the following:

Event Date: 04/01/2012

Reported Date: 04/04/2012

Protocol Attribution: Possible

Outcome: Recovering/Resolving

The **Event Date** has to be on or after the **Consent Date** for the subject.

The **SAE Classification** is not required by OnCore but is required by Yale. To fill in this area click the **Select** button, you are presented with a list defined in Reference Codes. Select **Hospitalization**.

The **Toxicity** area is not required by OnCore but is required by Yale. If you decide to fill in this area, you will need to supply all the asterisked fields, then click the **Add** button. You may provide multiple entries.

The **Tracking Details** table is where you can record the dissemination of information regarding the SAE.

4. Click the **Submit** button.

Once the SAE is correctly submitted, an **Event Number** will be assigned. This is a unique number for the SAE, and displays at the top of the upper table.

The **Additional SAE Identifiers** table can be used to record other identifiers for the SAE, such as a number assigned by the IRB. An **Identifier Type** can be selected from a pre-defined list, and the **Identifier** and **Identifier Owner** can be entered as free-text before clicking the **Add** hyperlink.

SAEs can be locked when you are finished entering them using the **Complete and Lock** button. After it has been locked, you will still be able to update the **Tracking Details** section of the SAE and will be able to create a follow-up SAE.

5. Click the **Complete and Lock** button.

6. Select the **SAEs** vertical tab.

Now that you have created an SAE, the tab displays a table with your entry. The table lists the protocol Arm that the subject is on.

7. Click on the SAE's **Event No.** hyperlink to return to the SAE.

At the bottom of the page is the **Create Follow-Up** button. This button will create a follow-up SAE, copying most of the SAE information you've supplied and will allow you to make modifications (usually the change in Outcome).

8. Click the **Create Follow-Up** button.

A follow-up SAE is created and a new **Event No.** is assigned to it. The Event No. of the 'parent' SAE displays next to it in parentheses. The **Follow-Up Number** is shown toward the right side of the small header band.

9. Enter the following:

Reported Date: 04/10/2012

Outcome: Intervention for AE Continues

10. Click the **Submit** button.

11. Click on the **SAEs** vertical tab.

Note the Event Numbering of the SAE and its parent.

The follow-up SAE has a **Delete** hyperlink to the right side, but its parent does not. When SAEs are to be deleted, they have to be deleted in the reverse order of when they were created so a hole isn't left in the sequence.