

Subject Calendars

OnCore Calendars and Calendar Activation

Your protocol has a calendar that defines a schedule of **visits** (when a subject is to be seen) and what treatment will be done during each visit.

Because subjects accrue to the protocol at different times, the protocol schedule cannot contain “hard” dates like “March 15”. Instead, schedules are based upon subject **milestone dates** like the subject’s Consent Signed and On Study date. Offsets from these dates (e.g. “the tenth day after the subject goes On Study”) are used to determine the “hard” date of a subject’s visit.

In the last session, you created a Subject and placed them on the protocol. When you entered a number of subject milestone dates, you **activated** their calendar. OnCore has now generated a personalized treatment schedule for the subject.

Viewing the Subject Calendar

To see the subject’s calendar, you need to go to the **Calendar** tab of the **Subject Console**.

1. If you are not on the Subject Console, navigate there via the **Subjects** → **CRA Console** or **Subjects** → **Subject Console** menu link. Once you are viewing your subject in the Subject Console, select the **Calendar** tab.

You should see something similar to this:

Protocol Calendar		Show Items	Hide Items	Charge Master Version:1 (01/01/1990)							
Procedure Toggle Full Screen	Forms	Treatment									
		Arm A : Treatment + Angiographic and IVUS sub studies				Arm B : Treatment + Angiographic sub study					
		Screening (Pre-treatment) 1@1Days	Procedure Arm A 1:3@1Days			Screening (Pre-treatment) 1@1Days	Procedure Arm B 1:3@1Days				
		D1	Pre-Procedure (within 24 hr)	Procedure	Post-Procedure	D1	Pre-Procedure (within 24 hr)	Procedure	Post-Procedure		
Research Activities [Demographics, Eligibility Review-Inclusion Exclusion Criteria, Informed Consent, Medical History]		R				R					
Research Activities [Concomitant Medication Assessment, Toxicity and Adverse Event Assessment]				R	R			R	R		
Research Activities											

In the **first column**, each row following “Visit Date” displays the name of a Lab, Panel, or Procedure.

The **second column** displays the names of the eCRFs (Forms) that will be used to capture data from the corresponding Lab, Panel, or Procedure.

The **Planned Date row** displays the subject's scheduled visit dates. Hovering the mouse cursor over the date in the Planned Date row will show which day of the week it is (and the visit tolerances if they were entered).

Below each **visit date**, an **R, S, or NA** indicates which Labs, Panels, and Procedures are scheduled for that date. An **S** will show if the visit is indicated as **Standard of Care** in the **Financials Console**. If the procedure is supposed to happen multiple times on a visit, there may be a number in front of the indicator to show how many times it should happen, like **2R**.

Below the calendar are **Footnotes** if added to a specific procedure or procedure visit.

The **Calendar** tab has two horizontal tabs: **Calendar** and **Orphaned Visits**. The **Calendar** horizontal tab is the default and is where the screenshot comes from. The **Orphaned Visits** horizontal tab shows visits that were on one version of the subject's calendar, but aren't showing anymore for some reason, perhaps because the schedule changed and they were removed from the newer calendar version.

Verifying Subject Visits – Visit Dates

The hyperlinks above each visit date ([Screening](#), [Pre-Procedure](#), etc.) are links to pages where you enter visit information. This is called **verifying** the visit.

2. Select the first visit hyperlink.

The **Subject Visit Update** page is displayed. The first field on the page is the **Visit Date**, and the data in this field defaults to the planned date shown on the calendar. You may change this date as necessary.

The box next to the Visit Date shows the **Visit Status**. By default, the status is **Planned**, but not yet **Occurred**.

3. Verify the visit by selecting the **Occurred** radio button. Verify all procedures occurred as planned then click the **Submit and Close** button to return to the Subject Calendar.

On the Subject Calendar the **Visit Status** shows **Occurred** and the **Visit Date** displays.

That was the simplest of Visit verifications. As you saw on the Subject Visits Update page, there are a number of data entry fields to deal with Subject Visits.

4. Select the next visit hyperlink.
5. The Subject missed the entire visit. Verify the visit by selecting the **Missed** radio button. Click the **Submit and Close** button to return to the Subject Calendar.

For missed visits, the Subject Calendar displays the Visit Status and Visit Date in red.

Take note of the visit dates for the missed visit and a few subsequent visits.

6. Select the missed visit hyperlink again.
7. Mark the visit as **Occurred** (which resets the date to the default).

8. Edit the Visit Date, changing it to **two days later** (2/22/2011).
9. In the **Reset Calendar?** field, select **All Visits**.
10. Click the **Submit and Close** button to return to the Subject Calendar.

The Subject Calendar shows the Visit Status as **Occurred** and displays the Visit Date you supplied. Note that all subsequent dates have been reset to two days after their previous values.

Verifying Subject Visits – Visit Details

11. Select the last visit hyperlink again.

Most fields in the top half of the display collect details about the visit, and are self-explanatory. The **Submitted Date** is the date the data has been submitted to the Sponsor. Entering a **Locked Date** means no more changes should be performed on the data (this is not enforced – you can change data on this page later). **Collection Location** is the location of correlative specimen collection for this visit.

The **Procedures** table lists the Labs, Panels, and Procedures that have been scheduled for the Visit. Each procedure has a set of data entry fields:

- **Procedure Date** - Enter a date only if it is different than the Visit Date above.
- **SOC** - If the procedure is standard-of-care (as defined in the Financials portion of OnCore), this will be pre-checked. Changing the state of this checkbox has Financial implications. There is a security privilege that controls access to this checkbox.
- **SOC Modifier** - Indicates whether the SOC procedure is Q1, Q0, or Unknown.
- **Missed** - Check if procedure was missed during the visit.
- **Missed Count** - You can have the calendar schedule a procedure to happen multiple times during a visit. If some of those procedures were missed, indicate how many.
- **N/A** - Check if procedure was not applicable for this visit.
- **Location** – If the procedure can be performed at different locations, this indicates which location was used. This field is only available when the Cost Center configuration is enabled.

Unless they are marked as **Missed** or **N/A**, it is assumed that if the visit has occurred, the procedures have been performed.

Verifying Subject Visits – Additional Procedures

If a procedure is done during the visit that is not part of the calendar, the **Additional Procedures** button can be used to record it. When the button is clicked, a popup window displays with multiple horizontal tabs.

The **Protocol Procedures** tab lists the Labs, Panels, and Procedures that have been assigned to the protocol, along with their associated forms. Use the checkboxes and the **Submit** button to add these events and forms to the visit record.

The **All Charge Master Procedures/Labs** tab lists all events in your protocol's library. Use the checkboxes and the **Submit** button to add one of these events to the visit record. No form will be associated with these events.

The remaining tabs provide ways to search for and select events from your protocol's library. Use checkboxes and the **Submit** button to add one of these events to the visit record. No form will be associated with these events.

12. Click the **Additional Procedures** button.
13. Select the checkbox for a procedure on that visit, and click the **Submit** button.
14. In the popup box, enter a **Reason for adding**. Click the **OK** button to return to the Subject Visit Update page.

The new procedure is listed in the bottom table.

If data has been recorded in a visit in error, the Delete button on the Subject Visit Update page can be used to delete the visit. Visits with activated electronic case report forms (eCRFs) cannot be deleted until the forms have been deleted.

15. Click the **Submit and Close** button to return to the Subject Calendar.

The calendar has a **Summary** button at the top. It is a way to shorten the number of visits showing. This may be useful when there are a lot of visits and you would have to scroll to the right to see the first unverified visits. When clicked, it will show the most recently verified visit and a number of unverified visits. Your view will be narrowed to show only the most relevant visits. The total number of visits shown is a configuration setting. In summary mode, there is a **Full Calendar** button that will return you to the full calendar view.