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Subject Calendars and Visits

Using Subject Calendars

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

Because subjects join the clinical trial at different times, the protocol schedule cannot contain specific dates such as 6/9/2017. Instead, schedules are based upon *milestone* dates, such as the subject’s Consent Signed date and On Study date. Offsets from these dates (such as “the tenth day after the subject goes On Study”) are used to determine the specific date of each subject visit.

View the subject calendar

To view the subject’s calendar, navigate to **Subject Console > Calendar**.

If you are not in the Subject Console, navigate to Subjects > CRA Console and select your subject from the Accrual tab. Once the subject record opens in the Subject Console, click the Calendar tab.

The Subject Console opens on the Calendar tab:
Procedure column
In the first column, each row following Visit Date displays the name of a lab, panel, or procedure.

Planned Date row
This row displays the subject’s scheduled visit dates. Hovering your cursor over the date in this row reveals the day of the week (and any visit tolerances).

Visit Dates
Listed below each visit date are the labs, panels, and procedures scheduled for that date, indicated by an X. If the procedure is supposed to take place multiple times on a visit, there is a number inserted before the X, indicating the number of times the procedure will take place (such as 2X).
Entering Subject Data and Tracking Visits

Verifying a visit involves submitting visit information, which consequently updates the status of the visit. A visit will have one of four statuses: Planned, Occurred, Missed, and N/A.

Mark a visit Occurred

The links shown immediately above each visit date (Screening, C1D1, etc.) are links to pages where you can enter visit information to verify the visit.

1. Click the relevant visit link.
   
The Subject Visit Update page opens. The first field on this page is the Visit Date. By default, the date in this field is the Planned date shown on the calendar. You can change this date as necessary.
   
   Next to the Visit Date is the Visit Status box. By default, Planned is selected.

2. Select Occurred in the Visit Status box.

3. Click Submit And Close to return to the subject calendar.
   
   On the subject calendar, the Visit Status is Occurred and the Visit Date field has been entered.

Mark a visit Missed

1. Click the relevant visit link.

2. Select the Missed button in the Visit Status box.

3. Click Submit And Close.
   
   On the subject calendar, the Visit Status and Visit Date appear in red because the visit is missed.
Delete a visit

1. Click the relevant visit link.

2. At the bottom of the subject visit page, click **Delete**.

3. Click **OK** to confirm.

   Deleting a visit removes all visit information and returns the visit to a Planned status.

   This can be helpful if a visit was recently checked in on calendar V1 but should be deleted and re-checked in on calendar V2.

   **NOTE:** A visit cannot be deleted if there are forms associated with the visit or if the visit has been added to an invoice.
Mark a visit Occurred but not on the planned date

Research visits might occur earlier or later than the planned date calculated by OnCore based on the subject’s milestone dates.

1. Click the relevant visit link in the subject’s calendar.

2. Select Occurred in the Visit Status box.

3. In the Visit Date field, input the new date.

4. Click Submit to create the visit and stay in the visit update page.
   
   If the date violates the allowed tolerance, a window will appear to let you know. If you entered the wrong date by accident, click Cancel to return to the Subject Visit Update page and edit the Visit Date. If you confirm the date, OnCore will automatically create a Visit Outside Tolerance deviation.

5. Click OK in the window to confirm the actual date of the visit.

Adjust future visit dates

When a visit does not occur on its planned date, you might need to adjust future visit dates so that the subject’s treatment schedule is back on track.
1. In the **Reset Calendar?** field, select **All Visits**.

2. Click **Submit And Close**.

The subject calendar opens, showing the Visit Status as Occurred and displaying the Visit Date that you entered. Note that all subsequent planned dates have been adjusted to two days after their previous values.

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**If one visit occurs off-schedule, use the Reset Calendar? field to adjust future visit planned dates**
Document missed and N/A procedures

Staff can document additional details about the procedures and labs that were scheduled (expected to happen) during each visit.

1. Click the relevant visit link.

2. Select **Occurred** in the Visit Status box.
   
   Review the list of procedures and labs expected during this visit:

   ![Screen capture of Subject Visit Update](image)

   If any of these scheduled (expected) procedures did not happen during this visit, mark them Missed or N/A

3. Select the **Missed** checkbox for the procedure that did not occur.

4. Enter a **Reason** that the procedure was missed.

5. Select the **N/A** checkbox if any other procedure is no longer applicable.

6. Enter a **Reason**, such as “No visible lesions.”
You will be prompted to enter a Reason for each missed and N/A procedure in every visit. Adding details here is helpful for the post-award invoicing team, who must decide whether these missed procedures will affect sponsor invoicing.

7. Click Submit to create the visit and stay in the Subject Visit Update page.

IMPORTANT

The labs, panels, and procedures listed in the Subject Visit Update page will inherit the Visit Date as their Procedure Date. Unless they are marked as Missed or N/A, it is assumed that if the visit has occurred, the procedures have been performed on that Visit Date, unless a different Procedure Date is entered.
Document additional (unscheduled) procedures

Sometimes during a research visit, additional procedures that are not part of the standard schedule of events are performed based on the physician’s judgement.

1. Click **Additional Procedures** at the bottom of the Subject Visit Update page.
   
   If you don’t see the Additional Procedures button, select a **Visit Status** of **Occurred** and click **Submit** to create the visit. Additional procedures can only be added to a visit that has been checked in.

2. In the window that appears, select the checkbox for the relevant procedure.

3. Click **Submit** in the window.

4. Enter a **Reason** for the additional procedure.

5. Click **Submit** to save the changes to the visit.
Enter visit comments

Text entered in the Clinical Comments field can be seen in the subject’s calendar view. The clinical research coordinator who checks in the visit can leave notes for other staff members.

1. Enter Clinical Comments for the visit.

2. Click Submit and Close to return to the subject’s calendar.

Mark a visit as Planned

If a subject knows they must reschedule their next visit, you can update the planned date of a future visit without checking it in. Visits can’t be checked in with a future visit date.

1. Click the relevant visit link.

2. Choose Planned in the Visit Status field.

3. Change the Visit Date.

4. Click Submit and Close.
Review changes to the subject’s calendar view

Some of the details entered for each visit are visible in the subject calendar; some details are only visible from the Subject Visit Update page:

![Calendar Image]

Hover over the (C) to view the Clinical Comment

View each visit’s status, planned date, and actual date

Missed and additional procedures do not update in the subject calendar view

The subject calendar view will always show the expected (scheduled) procedures and labs, according to the protocol calendar. **When procedures are marked as Missed, N/A, or added as additional procedures, those details are not reflected in the subject calendar view.**

You can see each visit’s status, the Planned Date for each visit, and the actual Visit Date for each occurred visit in the subject calendar.

Clinical comments are visible by hovering over the (C) indicator for the visit.

In addition, hovering over the Planned Date will show you the day of the week and the +/- tolerances for that visit, in case the subject asks to reschedule an upcoming visit.
<table>
<thead>
<tr>
<th>Procedure</th>
<th>Forms</th>
<th>Treatment</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>Baseline 1@1Days</td>
</tr>
<tr>
<td></td>
<td></td>
<td>1</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Screening</td>
</tr>
<tr>
<td>Planned Date</td>
<td></td>
<td>Planned Date: 07/14/2016</td>
</tr>
<tr>
<td>Visit Status</td>
<td></td>
<td>07/14/2016</td>
</tr>
<tr>
<td>Visit Date</td>
<td></td>
<td>07/14/2016</td>
</tr>
<tr>
<td>Adverse Events</td>
<td>Adverse Events V1</td>
<td>07/14/2016</td>
</tr>
<tr>
<td>Physical Exam</td>
<td>Physical Exam V1</td>
<td>07/14/2016</td>
</tr>
<tr>
<td>Blood Chemistries</td>
<td>Blood Chemistries V1</td>
<td>07/14/2016</td>
</tr>
</tbody>
</table>

Hover your cursor over any Planned Date to see the day of the week and the visit tolerance.
Use the Calendar Summary view

When a subject calendar extends for dozens of visits, it can be hard to scroll to the relevant upcoming visits. Staff who open a subject’s calendar will always see the first visits in the calendar, which eventually will all be past occurred visits.

1. Above the subject calendar, click the **Summary** button.

   The subject’s calendar is reduced to just 10 visits; the one most recently occurred visit, and the next nine scheduled visits.

   ![Calendar Summary View](image)

   Summary View will show the most recent occurred visit, plus several upcoming planned visits

   You can still check in visits while using the Summary view. When you return to this subject’s calendar, you will still see the one most recent visit and the next nine scheduled visits.

   This setting is user-specific; if you navigate to a different subject record or an entirely different protocol, you will remain in Summary view.

2. Above the subject’s calendar, click **Full Calendar** to exit the summary view.
Document an additional (unscheduled) visit

Subjects participating on clinical trials might require additional unscheduled visits during the study. Examples of additional visits include:

- Repeat inconclusive or incomplete tests or procedures from the previous visit
- Perform scans that must occur on a strict schedule

Additional visits are not visible in the subject calendar. Instead, they are documented in the Additional Visits tab of the Subject Console.

1. Navigate to the Subject Console > Additional Visits tab.
2. Click New.
3. Enter the relevant date in the Visit Date field.
4. Enter a short description of the visit in the Visit Description field.
   (Procedures can’t be added to the visit until it’s checked in.)
5. Click Submit to create the visit record.
6. Click the Additional Procedures button.
7. In the window that appears, select the relevant procedures.
8. Click Submit.
9. In the Reason field, enter the reason for this additional visit and then click OK.
10. Click Submit and Close.
A summary of the subject’s additional visits can be viewed in the Subject Console > Additional Visits tab:

These visits are not inserted into or visible in the subject calendar, but the added procedures can be invoiced to the sponsor in the Financials Console, if appropriate.
Beyond the Basics: More Subject Visit Information

There are many additional fields in the Subject Visit Update page that can be used to document more information about the visit. Many of these fields are part of the financials workflow for sponsor invoicing.

Check in a visit with Charge Master events linked

When building a budget, the financials team will often link the calendar procedures to Charge Master events with specific codes and negotiated rates. In these visits, each linked event can be marked as Missed or N/A individually.
Choose from a list of procedure alternatives

The financials team might also link multiple events to one procedure and ask the staff to choose the appropriate event when the subject visit is checked in.

In this example, staff must choose the level of complexity of the physical exam that was performed during the subject visit:

In this example, staff must indicate which Imaging procedure was performed:

The choices in this drop-down field are Charge Master events configured as Procedure Alternatives in the Financials Console.
Choose a location for an event

If your OnCore environment has cost centers enabled, each Charge Master event linked to a calendar procedure can be performed at one or more locations. The locations available in the Subject Visit Update page are the cost centers allowed for that event, which are configured in the Financials Console.

If Cost Centers are enabled, you might have to choose a Location for some procedures or labs.
View orphaned visits from a previous calendar version

You might have noticed that there is a second horizontal tab in the Subject Console > Calendar page, labeled Orphaned Visits. These visits are from a previous calendar version and are not associated with any visits on the subject’s current calendar version.

Most of the time, when modifications are made to a new calendar version, OnCore can upgrade a subject from calendar V1 to V2 and map the subject’s occurred visits to visits on calendar V2. If that’s the case, then the visits will appear in the main Calendar tab with the future (expected) visits, all in the same view.

Orphaned visits were checked in on calendar V1 but do not have an association with any visit on calendar V2, so they can’t be viewed on the main calendar. But the visits are retained so that the comments, procedures, and eCRF data are not lost.