Subject – Status, Calendar, Visits and Other Events

Subject Statuses

Consent
Eligible
Not Eligible
On Study
On Treatment
Off Treatment
On Follow-Up
Off Study
Withdrawn
Expired

Viewing Protocol Calendar

Viewing Subject Calendar

Entering Subject Visits

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SAE’s
Subject – Status, Calendar, Visits and Other Events

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.

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.
**Subject – Status, Calendar, Visits and Other Events**

**Subject Statuses**

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. These statuses triggers visit segment in the subject calendar.
Subject understands and agrees to the details in the consent form.

Steps:
1. Navigate to Subjects-> CRA Console
2. Select a Protocol
3. Click on the Research ID
4. Click Consent
5. Click Update
6. Click Select Consents
7. Enter Signed Date
8. Select Status
9. Click Save
Subject – Status, Calendar, Visits and Other Events

10. Click Close

Coordinators are required to upload signed ICF and HIPAA forms for registered patients. Sponsor payments will not be processed if missing forms are not in OnCore. It is essential a timely upload of documents to avoid payments delay.

11. Click Documents/Info -> Attachments
12. Click Add

13. Select Document Type from the drop-down (HIPAA or Signed Treatment Consent or Signed Treatment Reconsent)
14. Click on File (select file to upload; ICF and HIPAA can either be a combined file or separate)
15. Enter Version Date
16. Click Add

17. Repeat 5-9 to upload additional file
 Eligible

Subject has been evaluated and meets all criteria (Screening).

Steps:
1. Navigate to Subjects-> CRA Console
2. Select a Protocol
3. Click on the Research ID
4. Click Eligibility
5. Click Update
6. Select Eligibility Status from the drop-down
7. Enter Status Date
8. Click Submit
9. Click Close
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Subject has been evaluated and does not meet all criteria (Screening). However, some studies allow subject to re-screen after a screen failure. When ready to re-screen, register the patient using the same ResearchID but different Sequence No. Make sure to upload the new signed ICF and HIPAA to the corresponding record.

Steps:
1. Navigate to Subjects-> CRA Console

2. Select a Protocol
3. Click on the Research ID

4. Click Eligibility
5. Click Update

6. Select Eligibility Status from the drop-down
7. Enter Status Date
8. Click Submit
9. Click Close
Subject – Status, Calendar, Visits and Other Events

Subject has a recorded Consent and a status of Eligible.

Steps:
1. Navigate to Subjects-> CRA Console

2. Select a Protocol
3. Click on the Research ID

4. Click On Study
5. Click Update

6. Enter Sequence No (Subject protocol no from sponsor or IVRS)
7. Enter On Study Date
8. Click Submit
9. Click Close
Subject – Status, Calendar, Visits and Other Events

**On Treatment**

Subject has been enrolled on an Arm and will begin Treatment.

**Steps:**
1. Navigate to Subjects-> CRA Console
2. Select a Protocol
3. Click on the Research ID
4. Click Treatment
5. Click Add
6. Select Arm from the drop-down
7. Enter On Arm Date
8. Enter On Treatment Date
9. Click Save

When a patient is assigned to a specific Arm and switches to another Arm at a later point.

10. Click Edit
11. Enter Off Arm Date
12. Click Save
13. Click Add
14. Select Arm from the drop-down
15. Enter On Arm Date
16. Enter On Treatment Date
17. Click Save
Subject – Status, Calendar, Visits and Other Events

**Off Treatment**

Subject will receive no additional Arm Treatment.

**Steps:**

1. Navigate to Subjects-> CRA Console

![CRA Console Screenshot]

2. Select a Protocol
3. Click on the Research ID

![Account Details Screenshot]

4. Click Follow-Up
5. Click Update

![Update Screenshot]

6. Enter Off Treatment Date
7. Click Submit
8. Click Close

![Submit and Close Screenshot]
Subject – Status, Calendar, Visits and Other Events

On Follow Up

Subject will receive Follow-Up and all Arm Treatment complete.

Steps:
1. Navigate to Subjects-> CRA Console

2. Select a Protocol
3. Click on the Research ID

4. Click Follow-Up
5. Click Update

6. Enter Follow-up Start Date
7. Click Submit
8. Click Close
Subject – Status, Calendar, Visits and Other Events

Off Study

Subject completed all visits and no longer in the study.

Steps:
1. Navigate to Subjects-> CRA Console
2. Select a Protocol
3. Click on the Research ID
4. Click Follow-Up
5. Click Update
6. Enter Off Study Date
7. Click Submit
8. Click Close
At some point after being presented with a consent form, the subject changes his/her mind and no longer consents to treatment and withdraws from the study.

Steps:
1. Navigate to Subjects-> CRA Console
2. Select a Protocol
3. Click on the Research ID
4. Click Consent
5. Click Update
6. Select Status from the drop-down
7. Enter Status Date
8. Click Submit
9. Click Close
Expired

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

Steps:
1. Navigate to Subjects-> CRA Console
2. Select a Protocol
3. Click on the Research ID
4. Click Follow-Up
5. Click Update
6. Enter Expired Date
7. Click Submit
8. Click Close
Subject – Status, Calendar, Visits and Other Events

Viewing Protocol Calendar

A protocol calendar will display ALL visit schedule, expected procedures as well as the billing designations. It is typically built in segments triggered by date entered in the Subject Console.

- Screening/Pre-Treatment – consent signed date
- Treatment – treatment arm, on/off arm date, on/off treatment date
- Off Study – off treatment date, off study date
- Follow-up – follow-up start date

Steps:
1. Navigate to Subjects-> CRA Console
2. Select a Protocol
3. Click Protocol Calendar
Subject – Status, Calendar, Visits and Other Events

Viewing Subject Calendar

Subject calendar defines a schedule of visits and what procedures will be performed based on the Treatment Arm the subject is assigned.

Steps:
1. Navigate to Subjects-> CRA Console
2. Select a Protocol
3. Click on the Research ID
4. Click Calendar -> Calendar

Subjects transferred from one Treatment Arm to another Treatment Arm will have multiple calendar treatment. To view calendar based on the treatment arm.

5. From the subject calendar, scroll down and select the treatment arm calendar to view
Subject – Status, Calendar, Visits and Other Events

**Entering Subject Visits**

Verifying a visit involves submitting visit information, which consequently updates the status of the visit.

**Steps:**
1. Navigate to Subjects-> CRA Console

   ![CRA Console Menu](image)

   - **Select Protocol**
   - **Click on the Research ID**

   ![Protocol Selection](image)

2. Select a Protocol
3. Click on the Research ID

4. Click on Calendar -> Calendar
5. Click on Visit hyperlink

![Calendar View](image)
Subject – Status, Calendar, Visits and Other Events

6. Enter Visit Date
7. Select Occurred
8. Enter Procedure Date (if it’s different than the Visit Date)
9. Mark procedure as Missed or NA (if necessary)
10. Select the procedure occurred if there are different types available (if necessary)
11. Click Submit and Close
**Subject – Status, Calendar, Visits and Other Events**

**Entering Additional (unscheduled) Procedures**

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

**Steps:**

1. Navigate to Subjects-> CRA Console

2. Select a Protocol

3. Click on the Research ID

4. Click on Calendar -> Calendar

5. Click on Visit hyperlink

6. Enter Visit Date

7. Select Occurred

8. Click Submit
9. Click Additional Procedures  
10. Select Procedure to add  
11. Click Submit  

12. Enter Reason for adding  
13. Click OK  

14. Click Submit and Close
Deleting Visit

Deleting a visit removes all information and returns the visit to a Planned status. A visit cannot be deleted if the visit has been added to an Invoice.

Steps:
1. Navigate to Subjects-> CRA Console
2. Select a Protocol
3. Click on the Research ID
4. Click on Calendar -> Calendar
5. Click on Visit hyperlink (wish to delete)
6. Click Delete
7. Click OK
Subject – Status, Calendar, Visits and Other Events

Adding Additional (unscheduled) Visit

Subjects participating on clinical trials might require additional unscheduled visits during the study. Additional visits are not visible in the subject calendar.

Steps:
1. Navigate to Subjects-> CRA Console
2. Select a Protocol
3. Click on the Research ID
4. Click on Additional Visits
5. Click New
6. Enter Visit Date
7. Enter Visit Description
8. Click Submit
9. Click Additional Procedures
10. Select Procedure to add
11. Click Submit

12. Enter Reason for adding
13. Click OK

14. Click Submit and Close
Subject – Status, Calendar, Visits and Other Events

Switch Calendar Version

New calendar version is created during amendments or changes need to be made to an existing version due to some errors or missing information. Subjects are not automatically upgraded to a new calendar version, and subjects are not required to be upgraded. Depending on the protocol amendment, the schedule of events might change for new subjects enrolled on the study, but existing subjects might be allowed to continue treatment and finish on their original schedule.

Steps:
1. Navigate to Subjects-> CRA Console

2. Select a Protocol
3. Click on the Research ID
4. Click on Calendar
5. Scroll all down the page
6. Select the calendar version to switch
Subject – Status, Calendar, Visits and Other Events

7. Click Replace Version

8. Click Orphaned Visits
   These visits are from a previous calendar version and are not associated with any visits on the subject’s current calendar version. These may be due to the change of visit name or the visit is no longer valid on the current calendar. These visits are retained under the Orphaned Visits and can’t be viewed on the main calendar.
Subject – Status, Calendar, Visits and Other Events

Protocol Financial Events (Fees)

Add Protocol-Related Events that occurred like “Office Monitoring Visit”, “Remote Monitoring Visit”, “Protocol Amendment Re-Consent Fee”, and “IND Safety Reporting Fee”. Once an event is added, it will create an Invoiceable Item to invoice sponsor.

Steps:
1. Navigate to Subjects-> CRA Console

   ![Image of CRA console]

2. Select a Protocol No
3. Click on Financial Events
4. Click Update

   ![Image of financial events update]

5. Select Financial Event from the drop down
6. Enter Occurred Date
7. Enter Count (multiple instances can be created at the same time)
8. Enter Comments (if needed) – for “Protocol Amendment Re-Consent Fee”, please enter subject Seq No
9. Click Add

   ![Image of adding financial events]

10. Click Close
SAE’s

SAEs entered will create an Invoiceable Item to invoice sponsor.

Steps:
1. Navigate to Subjects-> CRA Console
2. Select a Protocol
3. Click on the Research ID
4. Click on SAEs
5. Click New
6. Enter Event Date
7. Enter Reported Date
8. Select Outcome from drop down
9. Click Submit
10. Click Close