

Managing Subject Calendar Versions

Study calendars allow tracking of subject visits using the subject status dates to plan expected study visits. OCTA develops calendars during study activation using protocol documents including schedule of assessments. OnCore identifies the protocol version of a calendar in several places, using the format:

V1 (V4.0; 08/18/21)
 V[Calendar Version] ([Protocol version + date])

New subjects are automatically added to the most recent calendar version. Subsequent calendar versions may be developed to incorporate protocol amendments. These are released after amended coverage analysis is finalized and contract is executed. Subject calendar versions are managed by the study team and should be updated as new calendar versions are released.

Viewing subject calendar version

Current Subject Calendar Version can be seen from CRA Console > Accrual under “Ver” on the Accrual Details table, or from Subject Console > Calendar next to “Current Subject Calendar Version.”

CRA Console > Accrual Details

| Study Site | Subject MRN | Last Name | First Name | Seq. No. | Arm | Level | Status | Status Date | Ver | Last Visit | Last Visit Date | Select |
|--|-------------------------|-----------|------------|----------|------|-------|--------------|-------------|-----|------------|-----------------|--------------------------|
| University of California San Francisco | RHN5400 | Mouse | Minnie | 001 | ArmA | | ON TREATMENT | 05/10/2022 | 3 | C3D1 | 07/05/2022 | <input type="checkbox"/> |

Subject Console > Calendar

| Screening | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | Follow Up |
|--------------|------------|------------|------------|------------|------------|------------|------------|------------|-----------|
| Planned Date | 04/26/2022 | 05/10/2022 | 06/07/2022 | 07/05/2022 | 08/02/2022 | 08/30/2022 | 09/27/2022 | 10/25/2022 | M3 M6 M |
| Visit Status | Occurred | Occurred | Missed | Occurred | | | | | |
| Visit Date | 04/26/2022 | 05/10/2022 | 06/07/2022 | 07/05/2022 | | | | | |

Migrating subjects to new calendar version

The calendar version can be changed from CRA Console > Accrual by checking the select box for subjects to-be-updated, choosing the newer version in the “Switch Calendar Versions” dropdown list, and clicking the “Replace Versions” button. Please be aware: **this change cannot be undone!**

Switch Calendar Versions 1 (V1.1; 10/13/21) ▾ Replace Versions

Steps to migrate subject calendars from CRA Console:

1. Check “Select” checkboxes for subjects to migrate
2. Select from “Switch Calendar Versions” dropdown box the calendar version to migrate
3. Click “Replace Versions” and confirm

Accrual Details

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| Study Site | Subject MRN | Last Name | First Name | Seq. No. | Arm | Level | Status | Status Date | Ver. | Last Visit | Last Visit Date | Select |
|--|---------------------------|-----------|------------|----------|-----|-------|----------|-------------|------|------------|-----------------|-------------------------------------|
| University of California San Francisco | TESTTRAIN | TESTTRAIN | TEST | 59944 | | | ON STUDY | 06/02/2022 | 1 | | | <input checked="" type="checkbox"/> |

Switch Calendar Versions 2 (V2.0; 05/21/22) ▾ Replace Versions Select All | None

Another method for updating individual subject calendar versions is to choose the newer version from the “Switch Version” dropdown list on the Subject Console > Calendar page. A preview of the newer version will be displayed and clicking “Replace Version” will confirm the change.

Switch Version 2 (V2.0; 05/21/22) ▾ Replace Version

Steps to migrate subject calendars from Subject Console > Calendar page:

1. On bottom left of page, select from “Switch Version” dropdown the calendar version to migrate
2. Page will load with a preview of the newer version
3. Click “Replace Version” button.

Calendar Orphaned Visits

Freeze Panes Summary Manage Optional Segments

Current Subject Calendar Version - V1

| Procedure | Forms | Treatment | | | |
|--------------------------------------|--|--------------------|---------------------------|----------------------|--------------------|
| | | Enrollment 1@1Days | Treatment 5 Cycles @7Days | | |
| Toggle Full Screen | | 1 | 2 | 3 | 4 |
| | | D1 | C1D1 | C2D1 | C3 |
| Planned Date | | 12/04/2021 | 12/04/2021 | 12/11/2021 | 12/ |
| Visit Status | | | Occurred | | |
| Visit Date | | | 12/04/2021 | | |
| (Central) Biopsy Tissue ¹ | Adverse Event Report (CRE 97) V4 | | X | X | X |
| CRC with Differential | | | | | |
| Calendar Footnotes | | | | | |
| 1. test foot note | | | | | |

Switch Version 1 (V1.0; 07/21/2021) ▾ [Printable Subject Cal](#)

Calendar Orphaned Visits

Freeze Panes Summary Manage Optional Segments

Current Subject Calendar Version - V1

| Procedure | Forms | Treatment | | | |
|--------------------------------------|--|--------------------|----------------------------|----------------------|--------------------|
| | | Enrollment 1@1Days | Treatment 5 Cycles @14Days | | |
| Toggle Full Screen | | 1 | 2 | 3 | 4 |
| | | D1 | C1D1 | C2D1 | C3 |
| Planned Date | | | 12/04/2021 | 12/18/2021 | 01 |
| Visit Status | | | | | |
| Visit Date | | | | | |
| (Central) Biopsy Tissue ¹ | Adverse Event Report (CRE 97) V4 | | X | X | X |
| CRC with Differential | | | | | |
| Calendar Footnotes | | | | | |
| 1. test foot note | | | | | |

Switch Version 2 (V2.0; 05/21/22) ▾ Replace Version [Printable Subject Cal](#)

Orphaned Visits

When a visit has been removed from the new version of a calendar, migrating subjects to the new version result in Orphaned Visits. Access these under Subject Console > Calendar > Orphaned Visits.

The screenshot shows the 'Subject Console' for protocol ZZ-AMI and subject TESTTRAIN. The 'Orphaned Visits' tab is highlighted with a red box. The main content area displays a table for 'Current Subject Calendar Version - V2' with columns for Procedure, Forms, Treatment, and Follow Up. The 'Treatment' section includes a table with columns for Enrollment, Treatment cycles, and Follow-up visits.

| Procedure | Forms | Treatment | | | | | Follow Up | | |
|--------------------------------------|--|--------------------|----------------------------|------------|------------|------------|------------|----|----|
| | | Enrollment 1@1Days | Treatment 5 Cycles @14Days | | | Followup | | | |
| | | 1 | 2 (C) | 3 (C) | 4 | 5 | 6 | 1 | 2 |
| | | D1 | C1D1 | C2D1 | C3D1 | C4D1 | C5D1 | W1 | W2 |
| Planned Date | | 01/01/2022 | 01/01/2022 | 01/15/2022 | 01/29/2022 | 02/12/2022 | 02/26/2022 | | |
| Visit Status | | Occurred | N/A | N/A | | | | | |
| Visit Date | | 01/01/2022 | 01/01/2022 | 01/15/2022 | | | | | |
| (Central) Biopsy Tissue ¹ | Adverse Event Report (CRF 97) V4 | | X | X | X | X | X | | |
| CBC with Differential | | X | X | X | X | X | X | X | X |

The Orphaned Visits page shows any occurred visit belonging to an earlier calendar version that was removed during subject calendar migration. The page displays the visit and its original calendar version.

The screenshot shows the 'Orphaned Visits' table in the Subject Console. The 'Calendar Version' column is highlighted with a red box. The table lists visits C1D1 and C2D1, both with a status of 'Occurred' and a calendar version of '1'.

| Visit | Phase | Segment | Visit Date | Visit Status | Calendar Version |
|-------|-----------|-----------|------------|--------------|------------------|
| C1D1 | Treatment | Treatment | 01/03/2022 | Occurred | 1 |
| C2D1 | Treatment | Treatment | 01/10/2022 | Occurred | 1 |

Clicking into a visit brings up the Subject Visit Update page, the detailed calendar version - including the protocol version - can be seen on the top right corner of the Visit Detail section.

The screenshot shows the 'Subject Visit Update' page for visit C1D1. The 'Version: V1 (12/04/2021)' is highlighted with a red box. The page includes fields for Visit Date (01/03/2022), Visit Status (Planned, Occurred, Missed), and Visit Description.