OnCore System Guideline

Clinical Calendar Review

Prepared for: OnCore Version 2023R3.4

Revision Number: 1.2

Version Date: April 30th, 2025

Overview:

This document was prepared to guide clinical teams tasked with building, reviewing, and providing feedback on clinical calendars in OnCore. In general, this is to have all visits and procedures accurately represented in the calendar.

Calendar and PC Console

The specifications console has a dependent relationship with the PC Console. Once a protocol has been created and the treatment information has been entered, the specification can now be saved to the protocol and treatment arms are now visible in the treatment sequences.

Specifications Landing Page

- Protocol Specifications vs. Specification Templates
  - Specification Templates – where all templates live. Templates are a shell of the calendar.
    - Use a template to save to a protocol & edit further
  - Protocol Specifications – where all calendars attached to a protocol live.
    - Once a template is selected, users will select "Save As" and use the drop-down menu under 'Attach _____ Specification to Protocol' to select which protocol to save the template to and select 'Save'.
    - If you get an error notification that the template already exists, re-name the template to save to a protocol

Visit Specifications

To navigate to the Study Specifications, select the Specifications from the Forms/Calendars section in the 'Menu' drop down:

- Visit specifications define when the protocol visits will take place.
  - It is recommended for non-cancer studies to use enumerated visits
- The subject visit schedule defines when procedures will be performed.
- When building a calendar you will need to select 'Start Dates', which are triggered by varying subject milestones.

Anchor Date (Calendar Build)	Subject Statuses that Activate Visits	Subject Statuses that Lock Visits
Treatment		
Consent Signed	Consented	Off Study
On Study	On Study	Off Study
On Arm	On Arm	Off Arm, Off Treatment, Off Study, On Follow Up
On Treatment	On Treatment	Off Arm, Off Treatment, Off Study, On Follow Up
Off Arm	Off Arm	
Off Treatment	Off Treatment	Off Study, On Follow Up
Off Study	Off Study	
End of Previous	Follows whatever status came before	
Follow Up		
On Study	On Study	Off Study, Date of Progression*
On Follow up	On Follow Up	Off Study, Date of Progression*
Date of Progression	Date of Progression	Off Study

Calendar Procedures

- The OnCore Procedure names should represent what is shown in the protocol schedule of events to indicate the corresponding assessment.
- A Consent Procedure should **always** be included.
- If a procedure isn't available in the find-as-you-type search bar on the 'Add Procedures' pop-up, type the entire procedure name, click outside of the text box, and select 'Add' to the right.
- **Helpful hint:** when previewing a calendar, only enter one procedure that occurs at every visit. Each visit will be displayed in the calendar's preview, and staff can ensure that the dates line up with what is outlined in the protocol.
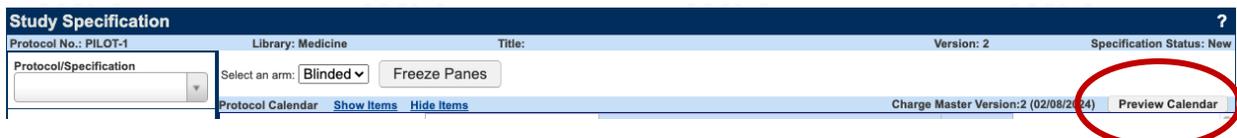
- **As Needed Procedures:** this functionality should not be used, but if a procedure is indicated as needed in the protocol, note this as a footnote.
- **Tolerances:** will only be defined as days, regardless of the time unit selected in the treatment segments

Additional / Unscheduled Visits

Additional & unscheduled visits will mostly be managed in the Subject Console, however you can set yourself up for success for these visits in the Specifications Console.

- If a protocol lays out the details of an unscheduled visit, ensure you are adding each of the procedures listed for that visit.
  - If these procedures are not required at the visits on the calendar but are necessary for unscheduled visits, do not schedule these at other visits. Use a footnote to indicate
- You can also create an 'Unscheduled Visit' procedure. Again, this will not be scheduled to other visits.
  - Communicate with the Coverage Analyst and Budgeting teams to include the billing items the unscheduled visit will need to account for.

Calendar Footnotes

- Footnotes can be added and assigned to the calendar multiple ways.
  - Calendar Footnotes section found in the lower portion of the Calendar tab
    - Use the Add button to enter new footnotes
    - Schedule footnotes on the overall visit here
  - Users can also add footnotes by selecting the linked procedure name and using the Footnotes section in the lower portion of the 'Procedure Details' page and using the 'Select Footnotes' button
    - This will open a pop-up where users can enter footnotes and assign them to this procedure
    - Once the footnote is assigned to the procedure, users can select the 'Visits' button to the right of the footnote to assign to the footnotes to specific visit(s)

Calendar Versions

- Each new calendar version will require a new budget version as well
- Subjects move to new budgets automatically
- Registered subjects move to new calendars manually, new subjects will be automatically placed onto the newest calendar version
  - Individual subjects can be updated to the new version in the subject console
  - Groups of subjects can be placed on the new calendar in the accrual tab of the CRA console