Reviewing a Clinical Calendar in OnCore

The clinical calendar should accurately reflect all visits and procedures, mirroring the study protocol calendar, or schedule of events (SOE), as closely as possible. While reviewing the study protocol calendar, please be sure to reference the Calendar Build Notes, as you go through the following steps:

1. To locate your protocol calendar, click on Menu > Protocols > PC Console
2. After navigating to the **PC Console**, enter in your protocol number in the **Select Protocol** field (this is a find-as-you-type field). You can also enter in additional protocol identifiers, such as IRB number, sponsor number, etc.

3. Once you have located your protocol, click on the name of the protocol. This will bring you to the **PC Console > Main > Protocol Details** for your particular protocol.
4. Once you have landed on the **PC Console > Main > Protocol Details** page, click on the **Treatment** tab on the left-hand side of the screen. This will bring you to a screen similar to the one below, with the **Protocol Arms** defined. Please make sure that the arms are correct and labeled according to the names delineated in the protocol.

![PC Console](image)

**IMPORTANT**: Please reference the **Calendar Build Notes** when verifying that the Protocol Arms are correct. Sometimes additional “utility arms” are built, enabling the calendar to function appropriately. You may see additional “arms” listed here that are not defined in the protocol.

- “Utility arms” are created, as needed, to accommodate unique treatment segments that require On Arm and/or On Treatment milestones to become actionable.
- If the protocol involves blinding, you will only see one arm called BLD.

5. After verifying that the Protocol Arms are correct, navigate to the **Protocol Calendar** by clicking on the **Protocol Calendar** tab on the left-hand side of the screen.
6. After clicking on the **Protocol Calendar** tab, you will be directed to the protocol calendar, similar to the screen below.

- If the calendar is the same for every arm, your screen will be white, like the one above.

- If the calendar differs between arms (different procedures, different time points, etc.), you will see white and gray, separating the calendars by arm, like below:

Note: the default view for the Protocol Calendar is for **All Arms** to be displayed at once. This may make the calendar look different, as OnCore may group segments next to each other, but if you view the calendar by arm, it should look correct.
7. Look across the top of the calendar at the **Treatment Visits**. It indicates which arms apply to each segment and the duration of each segment.

8. Next, look across the top of the calendar at the **Follow Up** visits. Again, these may be separated out by arm, or all arms may share the same follow-up schedule.

- Verify that the treatment visits are correct for each arm, that all treatment visits are included, and that each segment has the appropriate duration.

- Verify that the follow-up visits are correct for each arm, that all follow-up visits are included, and that each segment has the appropriate duration.
9. Next, look at the **Procedures** along the left-hand side of the calendar.

Please compare the Protocol Calendar/SOE to the Calendar built in OnCore:

**Procedures:**

- Verify that all procedures are accounted for and named appropriately, keeping in mind that some procedures may have been added (they were listed in the body of the protocol, but not the protocol calendar), or some procedures may have been split into separate procedures (e.g. Height/Weight procedure may be split into 2 separate procedures: Height, Weight).

  **The Calendar Build Notes will delineate any discrepancies between the procedures listed in the protocol calendar and those found in the clinical calendar built into OnCore. Please refer to that document while reviewing the calendar***

**Visits:** all visit names are listed across the top of the calendar.

- Verify that the visit names are correct (column headers) and that all visits are built according to the protocol calendar.
- Verify that all required procedures within a visit are correct, and that they are listed for the appropriate amount of occurrences; i.e. number of times a procedure occurs during each visit (e.g., five times is denoted with a ‘5R’)

  **Note:** The letter “R” indicates charge designation and will be reviewed and/or changed by CRSO Coverage Analysts once coverage analysis has been performed on the protocol.

**Important:** Study teams must ensure EVERY procedure and/or lab for EVERY visit on EVERY arm is accurate.
Footnotes: all footnotes are listed at the bottom of the calendar and are visible to all Arms.

- Verify that all of the footnotes listed in the protocol calendar are accurately represented on the clinical calendar built into OnCore, keeping in mind that additional footnotes may have been added, some special symbol footnotes may have been changed to a different character (OnCore does not support special symbols), and/or some footnotes may have been re-named (e.g. if a protocol has multiple calendars and/or multiple footnote ‘1’s.)

***The Calendar Build Notes will delineate any discrepancies between the footnotes listed in the protocol calendar and those found in the clinical calendar built into OnCore. Please refer to that document while reviewing the calendar***

NOTE: Footnotes can be placed on procedures, visits, a specific procedure on a specific visit, or the overall calendar (see image below):

The order of procedures and footnotes can be customized as needed, please contact the CRSO Calendar Builders if you would like any changes.

The OnCore calendar is not intended to take the place of the study protocol and other study documents for the conduct of the study.

The study protocol document should ALWAYS be the source of truth.
10. Calendar Communication & Feedback Responsibilities

**CRSO Calendar Builders**
CRSO calendar builders will be responsible for notifying and/or requesting guidance from the study team if any of the following issues arise (note: this list is not all inclusive):

- Discrepancies between the schedule of events and protocol text
- Discrepancies within the protocol text
- Discrepancies between the protocol and the consent form
- Ambiguous labs or procedures
- The use of utility arms in building the OnCore calendar
- Protocol version dates
- For multi-stage trials, in what aspects of the trial the University of Kentucky is/will participate

CRSO calendar builders will build the Treatment Arms in the PC Console and the Protocol Calendar, making any adjustments, as necessary, for the life of the protocol. A Calendar Build document will accompany each build, describing the steps taken to create the calendar.

**Clinical Study Team/Calendar Reviewer**
The Study Team and/or Calendar Reviewer will be responsible for:

- Providing the most up to date information regarding protocols, versions, treatment arms, etc.
- Reviewing the calendar (after calendar build is complete)
- Communicating with the CRSO calendar builder(s) regarding any discrepancies, feedback, questions, requests, etc.

11. **If you have questions/feedback/requests** for a particular protocol, procedure, visit, footnote, etc., please do the following:

- Make note of the procedure, visit, footnote, etc. and what contradicts the protocol calendar or schedule of events.
- The more details you provide, the easier and faster it will be for the CRSO calendar builder(s) to respond and complete your request.
- Please direct all questions/feedback/requests by EMAIL: [CTMS.support@uky.edu](mailto:CTMS.support@uky.edu)