

OnCore System Guideline

Clinical Calendar Building: Strategies for Yale

Prepared For: Calendar Builders assisting in OnCore Calendar Builds

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The URL for OnCore is <https://oncore.ynhh.org>

For more information about OnCore please visit the project website at <http://oncore.yale.edu>

Protocol Treatment Arms PC Console> Treatment>> Details tab

- **Arms:** name the arms according to the names given in the protocol.
- “Utility Arms” may need to be added to accommodate unique treatment segments that require an On- Arm milestone to activate. Naming of Utility Arms should clearly identify the treatment segment.
- **Drugs:** for non-cancer trials, free text the drug name in the arm description. For cancer trials, choose a drug from the drop-down list. If the drug is not available, email oncology.support@yale.edu and ask for the drug to be added to the Reference List.
- **Modalities, Devices and Levels:** are not required be may be entered

Double-blind studies:

If OnCore is used to randomize subjects as indicated in the calendar build request, add arms without identifying treatment (Arm A, Arm B, Arm I, Arm II etc.); otherwise, create only one arm and name it ‘Double Blind’ or ‘DB’.

- Double-blinded studies that are created with only one arm; for cancer trials, builder will choose a study drug and “Placebo” (if appropriate) from the drop-down list
- Double-blinded studies that are created with multiple arms for randomization; do not add drug in the arm description or choose from the drop-down list

Specifications

- You may create and save your own calendar template (by using “save as”) if you prefer, or start with any template in the system, however, be careful not to alter or delete existing templates.

Treatment Visits

- When building treatment segments try to minimize the amounts of start dates that segments are tied to as it confuses the study teams.
- Name treatment segments to match protocol schema/schedule of events as closely as practical.
- Cycles are typically oncology specific study designs while Visits are typically used for non- oncology calendars. Use Visits or Cycles as most appropriate to the calendar you are building.
- For open ended calendars, display sufficient cycles to display the longest cycling procedure at a minimum. Note that footnotes, renamed visits, and visit tolerances can only be entered on displayed visits and a new release of the calendar is required for those subjects that go beyond the displayed visits to incorporate these features. For this reason, err on the side of displaying too many cycles.
- “End Of Previous” can only be tied to one segment start date. Multiple End Of Previous can be used but must all be tied to the same segment start date.
- When a treatment segment's Start Date is specified as Consent Signed, On Study, Off Treatment, or Off Study, the Optional checkbox appears. When the Optional checkbox is selected, the segment is not required for all subjects and does not appear automatically in the subject calendar.
- After segments are marked as optional, they must remain optional in all subsequent calendar versions.
- Note that End of Previous segments cannot follow optional segments.
- Use the preview calendar function with a single procedure put onto all anticipated visits to check the visit specifications before proceeding with adding all procedures. You will be glad that you did.
- Follow-up treatment segments should not be linked to On-Study, only on Follow-Up start date except for scenarios where there are multiple follow-up schedules with visits required "from the date of randomization" and from "last dose"; make sure duration begin is populated correctly.
- EOT treatment segments should never be linked to On-Study, On-Arm, or On-Treatment start date, except for scenarios where the EOT visit is created utilizing "End of Previous" to "On Treatment" for subjects who can continue "On Treatment" visits to complete the remaining scheduled visits post treatment discontinuation visit.
- Do not add negative sign (-) in the Visit - Tolerances section. Adding a - to that field creates a double negative that OnCore doesn't know how to handle and causes this bug.

Calendar Procedures

- Match Procedure text as close as is practical to the text in the protocol schema/schedule of events. The Charge Master and the Calendar are decoupled which allows free text entries for procedures into OnCore. Every procedure entered onto a calendar will become part of a pick list in the type to search field in the Procedure Add screen. If available text exists clearly indicating the exact procedure, use that text even if it is not the exact text on the schema. For example, if the schema says “12-lead Electrocardiogram” and you find “12 lead EKG” the procedure is clearly identified with this variation of text and it can be used.
- Do not reference specific drugs (put name in footnotes)
- Do not include parentheses in procedures
- Do not copy and paste procedures from protocol, it adds special characters and creates erroneous values
- For laboratory tests, typically panels are assigned and then items not included in the panels are added separately. Common panels include CBC, Urinalysis, and CMP. Currently available active panels:
 1. BKR - Basic Metabolic Panel
 2. BKR - Electrolyte Panel
 3. BKR - Comprehensive Metabolic Panel
 4. BKR - Lipid Panel
 5. BKR - Hepatic Function Panel
 6. BKR - Urinalysis
 7. BKR - CBC Complete with Platelets and Differential
- Do **not** use “clinical chemistry”, “clinical hematology” or other generic labs that are available in OnCore.
- **Central Labs** - use names that include “Central” if available, otherwise use “Blood Draw for Central Lab” and footnote the correct lab.
- **Local Labs** - almost all other lab tests can be found under **Beaker Labs** and **BKR Panels**. Always use **Beaker Labs** as a procedure then search the lab items. For **BKR Panels**, choose from list above. You can search for existing values under Admin > Other Admin > **Labs and Panels**.
- Always include a Consent Procedure.
- Order the calendar procedures to follow the order on the protocol schema as closely as possible.
- Procedures clearly included in the text of the protocol but not included on the protocol schema should be included on the OnCore calendar.
- Include a research sample collection and processing procedure if specimens are collected and processed for submission to a central lab. Sometimes these are not included on the protocol schema and may be either embedded in the text of the protocol, include in a protocol appendix, or in a separate lab manual. Pick generic/abbreviated procedures. Here are some examples:
 - Vital signs
 - Physical exam – separate abbreviated / complete
 - Informed Consent
 - Questionnaire (use acronym if possible)
 - Medical History
 - Demographics
 - ECOG
 - Blood Draw for PK
 - Survival Follow Up
 - PRO Assessment
- To aid in CA designations for oncology protocols, break out CT/MRI of chest, abdomen and pelvis as separate calendar procedures.

Calendar Visits

- Rename visit to correspond to visit names on protocol schema. Avoid having baseline, treatment day one, off treatment day, and first follow-up day all being D1 on the calendar.
- Baseline tolerances can be added if consistent for baseline procedures. Note that if baseline begins at consent signed date (they almost all do) and the baseline period is Day -21 to Day -1, the visit tolerance is +21 days.
- Add visit tolerances to treatment segments and follow-up segments if consistent for procedures within the segment.

Calendar Footnotes

- All footnotes in the protocol need not be entered onto the OnCore Calendar. The OnCore calendar is not intended to take the place of the protocol and other study documents for the conduct of the study.
- Enter visit footnotes, procedure footnotes, and visit specific procedure footnotes as appropriate. Feel free to move a footnote off of a procedure and to a specific visit if that makes more sense.
- Footnotes indicating whether or not a procedure is done are typically included. For example, a study may include subjects with different cancer indications and some tests may only be done for subject with a specific type of cancer (PSA for prostate cancer only).
- Footnotes providing additional details regarding a procedure are typically included. For example, the footnote may define a long or ambiguous acronym.
- Footnotes defining visit schedules for a procedure that are redundant with a completed calendar need not be included.
- Entering “As Needed” is sufficient for the most common tests that may or may not be done, such as a pregnancy test for WOCBP.

Calendar Feedback

- The clinical teams will require feedback or may provide input into the clinical calendars regarding the following issues. The list is not all inclusive:
 - Discrepancies between the schema and protocol text.
 - Discrepancies within the protocol text.
 - Discrepancies between the protocol and the consent form
 - The use of utility arms in building the OnCore calendar
- The calendar builder is not responsible for ensuring no discrepancies exist in the documentation provided, however, must provide feedback if noted during the building process to ensure the calendar reflects what the clinics are doing.
- The persons completing the financials console may request change to the calendar build, if required and will also need to be updated to procedure and visit changes made after the budgeting process has been started.