

OnCore System Guideline

Clinical Calendar Review

Prepared For: OnCore Version 2020R2
Revision Number: 6
Revision Date: September 1, 2020

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

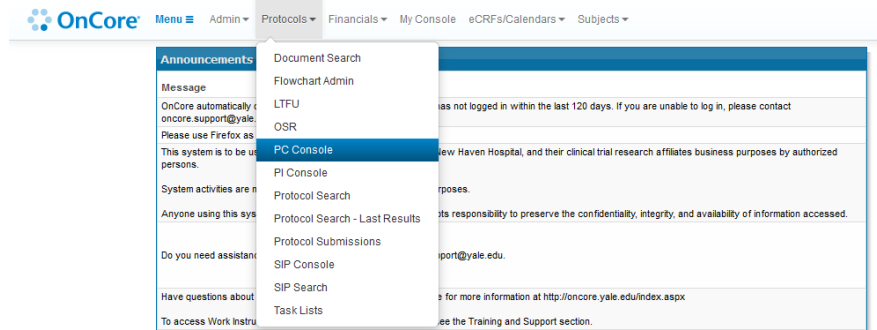
For more information about OnCore please visit the project website at <http://OnCore.yale.edu>



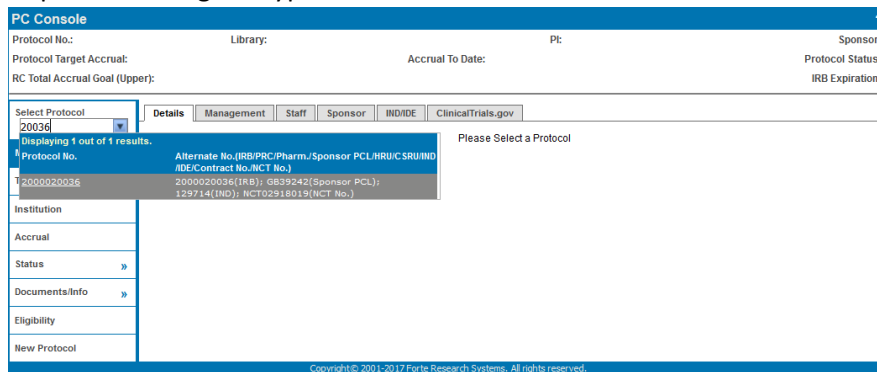
OnCore Guideline – Clinical Calendar Review

This document has been prepared to provide guidance to clinical teams who have been asked to review and provide feedback on clinical calendars that have been built in OnCore. In general, the aim is to have all visits and procedures accurately represented in the calendar.

The first step in the calendar review process is to locate the protocol through the PC Console. From the toolbar drop-down menus select PC Console:



Then find the protocol using the type to search field:



The following areas may be checked or provide useful information for review an OnCore Calendar as part of a quality assurance check prior to release for use:

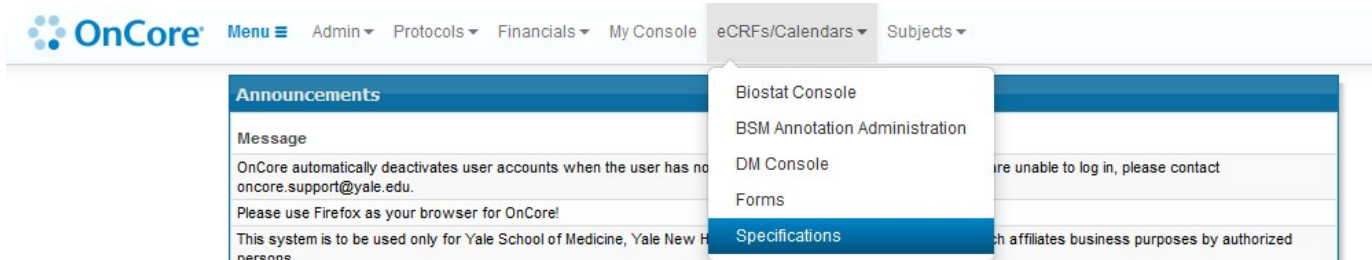
Protocol Arms

- Ensure arms have been properly defined in the PC Console> Treatment> Details tab. The arms should be named according to the names given in the protocol. Modalities/Drugs/Devices and Levels typically are not entered at this point of the review, but may be entered for dose escalation studies specifically needing these defined.
- If arms differ only in which drug(s) are being administered, only one calendar may have been built. If the calendars between two arms have only trivial differences (eg, one procedure is not done during follow-up for one arm) this may be addressed by adding a footnote to the calendar rather than building two calendars.

- If it is a double-blind study, there should be one arm called Double Blind (DB).
- At the protocol level OnCore will “bookend” each and every treatment arm with the baseline and follow-up visits. This may look odd, but at the subject level only one arm will display at any one time

Visit Specifications

To navigate to the Study Specifications, select Specifications from the eCRF/Calendars drop-down:



- Visit specifications define when the protocol visits will take place. You *may* see cycles for repeating segments of time that go on for an indefinite duration (open ended), such as “until last patient last visit occurs” on a calendar for any type of protocol.
- For open ended calendars, sufficient cycles will be displayed to accommodate the longest cycling procedure, at a minimum. **Footnotes, custom visit names, and visit tolerances can only be entered on displayed visits** and a new calendar is required for subjects that go beyond the displayed visits to incorporate these features. For this reason, generally, about a year should minimally display.
- Open ended segments in OnCore will automatically add new visits as the displayed visits are checked-in as having occurred

Calendar Procedures

- The OnCore Procedure names should match closely enough to the text in the protocol schema/schedule of events to clearly indicate the corresponding assessment.
- A Consent Procedure should always be included
- 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. **Let the calendar builder know if this is not how labs are to be ordered for the protocol.** The complete list of panels currently available are:

- BKR CBC Complete with Platelets and Differential
- BKR Basic Metabolic panel
- BKR Electrolyte panel
- BKR Comprehensive metabolic panel
- BKR Lipid panel
- BKR Hepatic function panel
- BKR Urinalysis

OnCore Guideline – Clinical Calendar Review

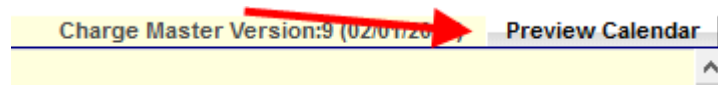
- Almost all other lab tests will be included as items under the heading of **Beaker Labs**.
- Procedures clearly included in the text of the protocol but not included on the protocol schema should be included on the OnCore calendar.
- A research sample collection and processing procedure should be included if specimens are collected and processed for submission to a central lab.

Calendar Visits

- Visit names should be clear
- Visit tolerances will be programmed into the visits. These can be viewed by clicking on the blue hyperlink for the visit segment above the visit names. This is also the place where default visit names may have been changed.

Treatment Segment		- Tolerances	+ Tolerances
Double-Blind Treatment Period		<input type="text"/>	<input type="text"/>
Default Visit Description	New Visit Description	Visit - Tolerances	Visit + Tolerances
W1	<input type="text" value="Randomization"/>	<input type="text" value="5"/>	<input type="text" value="5"/>
W3	<input type="text"/>	<input type="text" value="3"/>	<input type="text" value="3"/>
W5	<input type="text"/>	<input type="text" value="5"/>	<input type="text" value="5"/>
W9	<input type="text"/>	<input type="text" value="5"/>	<input type="text" value="5"/>
W13	<input type="text"/>	<input type="text" value="5"/>	<input type="text" value="5"/>

Visit dates should populate as expected. This can be tested using the Preview Calendar button located towards the top right of the calendar screen.



Enter the dates for the defined treatment segments. If there are multiple arms, each arm must be tested individually.

Preview Parameters	
Arm	BLD
Consent Signed Date	<input type="text" value="01/01/2017"/>
On Study Date	<input type="text" value="01/01/2017"/>
On Treatment Date	<input type="text" value="01/15/2017"/>
Off Treatment Date	<input type="text" value="07/15/2017"/>
On Follow Up Date	<input type="text" value="07/17/2017"/>
Off Study Date	<input type="text" value="11/17/2017"/>
<input type="button" value="Preview"/> <input type="button" value="Close"/>	

OnCore Guideline – Clinical Calendar Review

Dates will display under the visit names. Pay close attention to dates as they transition between calendar segments.

Protocol Calendar [Show Items](#) [Hide Items](#) Charge Master Version:9 (02/01/2016) [Preview Calendar](#)

Preview: Arm BLD (Consent Signed Date:01/01/2017) (Off Study Date:11/05/2017) (On Treatment Date:01/15/2017) (Off Treatment Date:07/20/2017) (On Study Date:01/05/2017)
(On Follow Up Date:08/01/2017)

Procedure	Forms	Treatment	Screen	Run-In Visit	Double-Blind Treatment Period	Week 4	Week 6	Week 10	Week 14	Week 18	Week 22	Week 26	Week 30	34	38	42
Toggle Full Screen	1@21Days	1@2Weeks	1,3,5,9,13,17,21,25,29,33,37,41,45,49,53@53Weeks													
	-3	0	Randomization													
	01/01/2017	01/05/2017	01/15/2017	01/29/2017	02/12/2017	03/12/2017	04/09/2017	05/07/2017	06/04/2017	07/02/2017	07/30/2017	08/27/2017	09/24/2017	10/22/2017		

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.
- 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.

Standard of Care versus Research Charges

- The calendar will be marked with as S1 or S0 for Standard of Care (SOC) procedures and R for Research procedures. Research procedures may be billed to an industry sponsor, grant, or to the department. Procedures that are not billed are designated as Research by default.
- SOC vs. R designations should be consistent on the OnCore calendar with the Financial Considerations in the Informed Consent Form, Contract, and/or Clinical Trial Agreement.

Calendar Feedback

- The calendar builders should notify the clinical teams and solicit guidance regarding the following issues. The 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