

Description: Each study calendar in OnCore may use different milestones to open up calendar segments; the design of the calendar is typically based on a combination of the protocol table of events, the budget, and the way in which the sponsor will be invoiced for visits and other study activities.

Study coordinators should take the time to familiarize themselves with each protocol calendar prior to consenting the first subject to that particular protocol in OnCore.

Audience: Study team members who are responsible for recording study visits in OnCore.

STUDY CALENDAR SEGMENTS

The study calendar is composed of visits and events. To understand how these were set up in a calendar, you need to understand calendar **segments**.

Segments are “chunks” of time that have a **Start Date** based on a subject **Milestone Date**. Visits are scheduled within segments. There are two types of segments – treatment segments and follow-up segments. Each segment must have a trigger or milestone date that indicates the beginning of the segment (the only exception is an “End of Previous” segment, which is triggered when the milestone date is entered for the previous segment).

Segments are collections of visits that are triggered or activated at the same time. For example, a subject’s treatment visits might be triggered by the subject status changing to **On Study** or **On Treatment**, at which point the treatment-related visits can be checked in. If the subject does not yet have a status of **On Follow Up**, then their follow-up visits are not activated and cannot yet be checked in.

treatment segments====>	Baseline	On Treatment Arm A, Arm B		Maintenance Arm A Only	Off Treatment		In-Clinic Follow Up	Annual Follow Up
	Within 14 days of signing consent	6 cycles x 28 days All visits +/- 1 day		3 cycles x 14 days immediately after treatment	2 weeks following disease progression		only after ox prog, then every 6M for 2 years	(by phone) Y3, Y4, Y5, Y6
	Screening	Day 1	Day 15		W1 DX Prog	W2 DX Prog		
Adverse Events	X	X					X	X
Physical Exam	X					X		
Blood Chemistries: Amylase, LDH, Sodium, Uric Acid		2X	2X	2X	2X		2X	
Lipid Panel: Cholesterol, HDL, LDL, Triglycerides		X	X	X	X		X	
Study Drug Administration		X		This calendar requires 6 segments				
Imaging (MRI)			X					
Tumor Biopsy			X					
Survival Status	X							X

IDENTIFY START DATE TRIGGERS

Subject Milestone Dates are selected as the **Start Date** for each calendar segment. A calendar segment **Start Date** trigger can be one of the following:

- Consent Signed
- On Study
- On Arm
- On Treatment
- Off Treatment
- Off Arm
- Off Study
- On Follow Up
- End Of Previous (simply allows one segment to follow another segment)
- Date of Progression (only available for oncology protocols)

1. Navigate to **Menu > eCRFs/Calendars > Specifications.**
2. If you are not still in your protocol, type **your protocol identifier** in the **Select Protocol** field
3. Click on the **Treatment Visits** vertical tab.
4. You will see the **Start Date** triggers for your study.

Treatment									
Seq. No.	Name	Start Date	Unit	No. of Repetition	Visit(s)	Duration	Exclude Weekend	Arms	
10	Baseline	Consent Signed	Day		1				
20	On Treatment	On Treatment	Day	6		28		ArmA, ArmB	
30	Maintenance	End Of Previous	Day	3		15		ArmA	
40	Off Treatment	Off Treatment	Week		1:2		2		

Follow-Up										
Seq. No.	Name	Start Date	Unit	Visit(s)	Duration	Duration Begin	Duration End	Interval	Starting Number	Arms
50	In-clinic Follow-Up	On Follow Up	Month			6	24	6		
60	Annual Follow Up	On Follow Up	Year	3:6	6					

SUBJECT MILESTONE DATES

How does a milestone date get entered in order to trigger a calendar segment? Once you register a subject to the study, there will be OnCore pages that have fields for you to enter these dates as each subject reaches those milestones:

- **Consent Signed Date** - Entered on **Subject Console > Consent** page

Subject Console: Protocol No.: OCR16360, Subject MRN: E993450, Subject Name: JOHNNIE J DOE, Subject Status: OPEN TO ACCRUAL, Sequence No.: [blank].

Available Consents: Signed Date [] Select Consents

Existing Consents: No Subject Consent Found

- **On Study Date** – Entered on **Subject Console > On Study** page

Subject Console: Protocol No.: OCR33677, Subject MRN: E0000024, Subject Name: Taika Zed, Subject Status: OPEN TO ACCRUAL, Sequence No.: [blank].

On Study Date: []

- a. **On Arm Date** Entered on **Subject Console > On Treatment** page
- b. **On Treatment Date** - Entered on **Subject Console > On Treatment** page
- c. **Off Arm Date** - Entered on **Subject Console > On Treatment** page

Subject Console: Protocol No.: OCR16360, Subject MRN: E993450, Subject Name: JOHNNIE J DOE, Subject Status: ON STUDY, Sequence No.: [blank].

On Arm Date [a] On Treatment Date [b] Off Arm Date [c] Save Cancel

- a. **Off Treatment Date** - Entered on **Subject Console > Follow Up** page
- b. **Follow-Up Start Date** - Entered on **Subject Console > Follow Up** page
- c. **Off Study Date** - Entered on **Subject Console > Follow Up** page

The screenshot shows the 'Subject Console' for protocol OCR16360 and subject JOHNNIE J DOE. It features three update sections: 'Subject Off Treatment Update' with an 'Off Treatment Date' field (labeled 'a'), 'Subject Off Study Update' with an 'Off Study Date' field (labeled 'c'), and 'Subject Follow-Up Update' with a 'Follow-Up Start Date' field (labeled 'b'). Other fields include 'Off Treatment Reason', 'Off Study Reason', 'Transferred to (Study Site)', 'Next Follow-Up Date', 'Last Date Known Alive', 'QA Date', 'Alternate MRN', and 'Last Known Survival Status'. A left sidebar contains navigation tabs like Summary, Demographics, Consent, Eligibility, On Study, Treatment, Follow-Up, and SAEs.

- **Date of Progression** (only available for oncology protocols) – Entered on **Subject Console > Follow Up** page.

IMPORTANT!



In some scenarios visits must be checked in within a calendar segment before entering the next subject milestone date. For example, entering an Off Treatment date before completing all the visits in the On Treatment segment are checked in will result in the remaining visits becoming inactive and unavailable to be checked in.

NEED HELP?

If you would like to meet with OnCore Support and/or the Calendar Team to walk through your study, do not hesitate to [Request a Consult](#).

If you have any questions or concerns about your calendar, contact us via OnCore-Support@ahc.ufl.edu or Oncore-Calendars@ahc.ufl.edu.