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.

<table>
<thead>
<tr>
<th>Treatment segments</th>
<th>Baseline</th>
<th>On Treatment</th>
<th>Maintenance</th>
<th>Off Treatment</th>
<th>In-Clinic Follow Up</th>
<th>Annual Follow Up</th>
</tr>
</thead>
<tbody>
<tr>
<td>Within 14 days of signing consent</td>
<td>6 cycles x 28 days All visits +/- 1 day</td>
<td>2 doses x 14 day immediately after treatment</td>
<td>2 weeks following disease progression</td>
<td>W1 DX Entry</td>
<td>W2 DX Entry</td>
<td>Date of Progression (only available for oncology protocols)</td>
</tr>
</tbody>
</table>

- Adverse Events
- Physical Exam
- Blood Chemistries: Amylase, LDH, Sodium, Uric Acid
- Lipid Panel: Cholesterol, HDL, LDL, Triglycerides
- Study Drug Administration
- Imaging (MRI)
- Tumor Biopsy
- Survival Status

This calendar requires 6 segments

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.

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

- **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**.