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Protocol Calendars

In OnCore, the calendar describes when a subject will have research-related visits, what procedures and labs will be performed at each visit, and what data will be recorded in eCRFs. There are three different types of calendar-related records in OnCore:

### Specification Templates
- Not attached to a specific protocol (so there are no arms)
- Often is blank; sometimes templates include common procedures or visits
- Based on Milestone dates (Consent Signed, Day 5, Month 6…)

### Protocol Specifications (Protocol Calendars)
- Attached to one protocol
- Must include all procedures and visits
- Protocol arms can have different schedules
- Based on Milestone dates (Consent Signed, Day 5, Month 6…)
- Must be Released

### Subject Calendars
- A copy of the Protocol Calendar for one subject
- Subject milestones trigger specific visit dates ("Day 5" becomes June 18th)

This chapter covers specification templates and protocol calendars.
Before Building a Calendar in OnCore

Before creating any segments or procedures, spend some time analyzing the protocol’s schedule of events. Thinking about how to translate a study calendar into OnCore will save you time fixing and rebuilding your calendar in the future.

Specifically, review the protocol documents and the schedule of events provided by the sponsor or PI to determine:

- How many segments you need to create
- What subject status will “trigger” each segment (the Start Date)
- Which segments will be built with cycles vs. enumerated (specific) visits

As an example, consider the following simple calendar:

<table>
<thead>
<tr>
<th>Form / Status</th>
<th>Baseline</th>
<th>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>Adverse Events</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Physical Exam</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Blood Chemistries</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Lipid Panel</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Treatment Administration</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Imaging</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Lesion Biopsy</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Survival Status</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

In the next sections, you will analyze this calendar and make a plan for the segments and visits needed to recreate this schedule of events in OnCore.
**Identify segments**

The calendar is composed of visits and events. To understand how these are added to a calendar, the first step is to understand treatment segments.

**Segments** are “chunks” of time that begin on a subject status 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 start date that indicates the beginning of the 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></th>
<th>Baseline</th>
<th>Treatment arms A, B</th>
<th>Maintenance arm A only</th>
<th>Off Treatment</th>
<th>In-clinic follow up</th>
<th>Annual follow up</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Screening</td>
<td>Day 1</td>
<td>Day 15</td>
<td>Day 1</td>
<td>W1 Dx Prg</td>
<td>W2 Dx Prg</td>
</tr>
<tr>
<td>Adverse Events</td>
<td>X</td>
<td>X</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Physical Exam</td>
<td>X</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Blood Chemistries</td>
<td>X</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Lipid Panel</td>
<td>X</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Treatment Administration</td>
<td>X</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Imaging</td>
<td>X</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Lesion Biopsy</td>
<td>X</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Survival Status</td>
<td>X</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

*This calendar requires 6 segments*
Choose appropriate “triggers” (Start Dates)

Subject statuses are selected as the Start Date for each calendar segment. Each segment is activated by one of the following triggers:

- 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)

<table>
<thead>
<tr>
<th>Triggers</th>
<th>Baseline</th>
<th>Treatment arms A, B</th>
<th>Maintenance arm A only</th>
<th>Off Treatment</th>
<th>In-clinic follow up</th>
<th>Annual follow up</th>
</tr>
</thead>
<tbody>
<tr>
<td>Adverse Events</td>
<td>Screening</td>
<td>Day 1</td>
<td>Day 15</td>
<td>Day 1</td>
<td>W1 Dx Prg</td>
<td>W2 Dx Prg</td>
</tr>
<tr>
<td>Physical Exam</td>
<td>PE-01 V1</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>(by phone)</td>
</tr>
<tr>
<td>Blood Chemistries</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Y3, Y4, Y5, Y6</td>
</tr>
<tr>
<td>Lipid Panel</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Treatment Administration</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Imaging</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Lesion Biopsy</td>
<td>DA-MD001 V1</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Survival Status</td>
<td>SS-001 V1</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

- Consent Signed
- End of Previous
- On Study
- On Arm
- Off Treatment
- Off Treatment
- On Follow Up (both segments)
Use cycles or enumerated visits

Each calendar segment in OnCore will be created using a cycle-based pattern of visits or by listing out the specific enumerated visits that should occur during the segment.

In this example, the Treatment segment comprises eight visits that are scheduled in a cycle-based pattern – each subject will have a visit on day 1 and day 15 of each cycle:

In this example, the specific visits needed in the calendar are enumerated:

The visits in this segment are defined in cycles

The visits in this calendar are scheduled on Day 1, Day 30, Day 90, and Day 365 (specific enumerated visits with no pattern)
Creating a Protocol Specification in OnCore

To create a protocol calendar, you must begin with a protocol specification. When you navigate to the eCRFs/Calendars > Specifications menu in OnCore, you see two types of specifications: specification templates and protocol specifications.

Specification templates define a set of visits or procedures common to many protocols and are used as the starting point for a protocol specification. A protocol specification is associated with a specific protocol and is where you define all visits, procedures, and forms included in the protocol calendar.

Open an existing specification template

1. Navigate to Forms/Calendars > Specifications.
   The first time you navigate to this menu item, OnCore opens the Specification Templates tab.
   **NOTE:** If you navigate to this menu item after selecting a protocol elsewhere in OnCore, you will be directed to the specification associated with your protocol instead.

   Specification templates are listed in a table with the columns Specification No., Library, Title, Description, and Status. A template status can be New, Complete, or Released (not editable). Templates of any status can be used as the basis for other templates or protocol specifications.

2. Click the relevant specification template based on your library. If your protocol is in the Oncology Library, this will be SPEC-Temp.

3. Click the Save As tab.
   The top section of the page allows you to save your specification template as a new template (creating a copy of your template). The bottom half of the page allows you to create a protocol-specific specification based on your template.
   **NOTE:** Each section of the page has its own Save button, which saves changes only in the corresponding section.
4. In the Attach Specification to Protocol section, use the **Protocol** field to select your protocol.

   **NOTE:** The **Protocol** find-as-you-type field searches only those protocols in the same library as the selected specification.

5. Click the corresponding **Save** button (on the bottom half of the page).

   A copy of the template has now been saved to your protocol. Verify this by finding your protocol title in the page header.
6. Click the **Specifications** tab.

You are returned to the Specifications menu with the Protocol Specifications tab highlighted. The table lists all protocol specifications in OnCore, identified by their Protocol No. For protocol specifications with multiple versions, the Protocol Title column lists all version numbers as links.

7. Locate your new protocol specification in the list. Note that it is shown as Version 1, with a Status of New. It can now be edited.
Components of a Calendar

A treatment segment can be a simple duration of time (for example, 30 days), or it can be durations of time that repeat (for example, four sets of 28 days). Repeating “chunks” of time are called cycles (for example, four cycles of 28 days). If a segment is built with specific visits (for example, day 1, day 8, and day 30), they are called enumerated visits.

Within a segment, subject visit dates are defined. Examples of visit date definitions are

- “the first and fifth day of the segment”
- “the first, tenth, and eighteenth day of each cycle”

Because treatment segments are anchored to subject statuses, planned visit dates are calculated based on dates entered in subject status fields.

There are two vertical tabs used to create the final calendar:

**Treatment Visits tab:** This tab allows you to define segments. There are two horizontal tabs within the Treatment Visits vertical tab.

- **(Pre-Treatment) Treatment tab**
  This tab is used to define treatment segments encompassing the time from Consent Signed to End of Treatment.

- **Follow-Up tab**
  This tab is used to define treatment segments that begin after subject treatment.

**Calendar tab:** This tab allows you to define the events (labs, panels, and procedures) that will be performed, the visits the events correspond to, and the forms that will capture the data for these events

When you define treatment segments on the Treatment Visits tab, you will use the following attributes:
<table>
<thead>
<tr>
<th>Segment Attribute</th>
<th>Purpose</th>
</tr>
</thead>
<tbody>
<tr>
<td>Seq. No</td>
<td>Each segment must be given a number. A calendar can consist of multiple segments, and the sequence numbers assist in determining their order.</td>
</tr>
<tr>
<td>Name</td>
<td>Giving a segment a name makes a calendar easier to understand.</td>
</tr>
<tr>
<td>Start Date</td>
<td>The subject status date when this segment begins.</td>
</tr>
<tr>
<td>Time Unit</td>
<td>Is the segment defined as a number of Days, Weeks, Months, or Years?</td>
</tr>
<tr>
<td>No. Of Repetition(s)</td>
<td>When a segment defines cycles, this is the number of cycles. If the segment is a duration of time (not cycles), this field is left blank.</td>
</tr>
<tr>
<td>Visit(s)</td>
<td>When a segment defines a duration of time with enumerated visits (not cycles), these are the scheduled occurrences for subject visits. <strong>NOTE:</strong> You will either enter data for No. Of Repetition(s) or Visit(s), not both.</td>
</tr>
<tr>
<td>Duration</td>
<td>When a segment defines a duration of time with enumerated visits, this field indicates the total segment duration. When a segment defines cycles, this field indicates the duration of each cycle.</td>
</tr>
<tr>
<td></td>
<td>The duration of visit-based segments must be greater than or equal to the last visit in the segment. (For example, if visits are scheduled on day 1, day 8, and day 30, then the Duration must be 30 days or greater.)</td>
</tr>
<tr>
<td>Exclude Weekend</td>
<td>When visits defined for this segment fall on a weekend, selecting this checkbox moves the visit to the following Monday. Subsequent visits are also shifted by the same number of days.</td>
</tr>
</tbody>
</table>
What is the Description/Notes tab used for?

The Description/Notes tab allows you to add a brief description (20 characters) as well as additional explanatory notes (4000 characters) about the version of the calendar. The Description appears in the CRA and Subject Consoles when selecting the calendar version to which to upgrade the subject. The Description also appears in PC Console > Institution when institution-specific calendar version functionality is in use.
## Sample calendar

<table>
<thead>
<tr>
<th></th>
<th>Baseline</th>
<th>Treatment arms A, B</th>
<th>Maintenance arm A only</th>
<th>Off Treatment</th>
<th>In-clinic follow up</th>
<th>Annual follow up</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>6 cycles x 28 days all visits +/- 1 day</td>
<td>3 cycles x 14 days imn. after Tx</td>
<td>2 weeks following disease progression</td>
<td>6M after dx prog, then every 6M for first 2 years</td>
<td>(by phone) Y3, Y4, Y5, Y6</td>
</tr>
<tr>
<td>Within 14 days of signing consent</td>
<td>Screening</td>
<td>Day 1</td>
<td>Day 15</td>
<td>Day 1</td>
<td>W1 Dx Prog</td>
<td>W2 Dx Prog</td>
</tr>
<tr>
<td>Forms</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Adverse Events</td>
<td>Adverse Events V1</td>
<td>X</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Physical Exam</td>
<td>PE-001 V1</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>X</td>
</tr>
<tr>
<td>Blood Chemistries</td>
<td>Blood Chemistries V1</td>
<td>2X</td>
<td>2X</td>
<td>2X</td>
<td>2X</td>
<td></td>
</tr>
<tr>
<td>Amylase, LDH, Sodium, Uric Acid</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Lipid Panel</td>
<td>LE-CBO001 V1</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>2X</td>
</tr>
<tr>
<td>Cholesterol, HDL, LDL, Triglycerides</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Treatment Administration</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Imaging</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>X</td>
</tr>
<tr>
<td>Lesion Biopsy</td>
<td>DA-MD001 V1</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>X</td>
</tr>
<tr>
<td>Survival Status</td>
<td>SS-001 V1</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

### Questions

- **How many segments** are needed for this calendar?
- **What trigger should be used as the Start Date for the Baseline segment?**
- **Which segments will use cycles?**
- **Which will use enumerated visits?**
- **What subject status(es) might be appropriate as the Start Date for the Treatment segment?**
Creating Treatment Segments

Protocol specifications are designed using trigger dates, rather than actual dates. Visits are based upon offsets from these statuses, such as “the day the subject starts on the study” or “the first and fifth days of treatment.”

The protocol calendar is a blueprint for the subject calendar. As each subject’s status dates are recorded in the Subject Console, the subject calendar is automatically generated using actual dates.

Create a treatment segment with a single visit

The sample calendar shows a Baseline segment, consisting of a single visit called Screening. The calendar indicates that the visit must be within 14 days of the date the subject signs the informed consent form. The following instructions show how to create the Baseline segment.

The following instructions assume that you have a practice protocol available in the Test environment and that a simple specification template has been applied to it.

1. From the Forms/Calendars > Specifications > Protocol Specifications tab, click the link for your protocol specification.
   
   The Study Specification opens on the Treatment Visits tab. If any treatment segments were defined for your specification, they would be listed in the Treatment table.

2. Click Update.
   
   The Treatment Visits tab now shows two horizontal tabs, with the (Pre-Treatment) Treatment tab selected. The Add Segment section allows you to add new treatment segments, which will appear in the Treatment table below as they are created.
3. Verify that one segment in the Treatment section already exists with the following details (if the details don’t match, you can edit them in the calendar):
   - **Sequence No:** 10
   - **Name:** Baseline
   - **Start Date:** Consent Signed
   - **Time Unit:** Day

4. Verify that a second segment exists in the Follow-Up section with these details:
   - **Sequence No:** 50
   - **Name:** On Follow Up
   - **Unit:** Month
   - **Visits:** 6, 12, 18, 24

   If the segments above do not exist yet, you can add them after following the steps below to learn how to create Treatment and Follow-Up segments. If they do exist but need to be edited, you will be able to do so (including removing unwanted segments).

5. Before you enter data into the second row, you must identify whether the segment is a *cycling* segment (consisting of a schedule of visits that repeat at least once) or an *enumerated segment* (consisting of one or more visit dates that do not repeat). Since the Baseline segment in the sample calendar (page 14) consists of a single non-repeating visit, it can be scheduled as an enumerated segment. Therefore, you will enter data into the **Visit(s)** and **Duration** fields (leaving the **No. Of Repetitions** field blank).

**NOTE:** The Arms column does not show a value for the segment you created. Segments with a Start Date of Consent Signed, On Study, Off Treatment, and Off Study *always* apply to all subjects on all arms. Other segments (starting with On Arm, On Treatment, End of Previous, and Off Arm) can be defined as arm-specific, depending on the requirements of your protocol.

**Good to know**

It's a good idea to leave gaps between your sequence numbers (such as 10, 20, 30, 40) in case you need to insert additional segments in subsequent calendar versions. Sequence numbers are only visible to the calendar builder.
Create a cycle-based treatment segment

In the sample calendar, the Treatment segment consists of six cycles of 28 days, with visits on days 1 and 15 of each cycle. To begin, you will create a cycling segment by defining a Number of Repetitions (6) and a Duration (28 days).

**IMPORTANT:** Before building a calendar segment in OnCore, you must identify whether the segment is a cycling segment (consisting of a schedule of visits that repeat at least once) or an enumerated segment (consisting of one or more visit dates that do not repeat). Use the Number of Repetitions field when creating a cycle-based segment and use the Visits field when creating an enumerated segment. You cannot use both fields in the same segment.

1. In the **Add Segment** section, enter the following values:
   - **Sequence No:** 20
   - **Name:** Treatment (if you’re using the Oncology template, you will already have an “On study” segment here; the details will need to be changed, however)
   - **Start Date:** On Treatment
   - **Time Unit:** Day
   - **No. Of Repetition(s):** 6
   - **Duration:** 28
   - **Exclude Weekend:** leave unselected
   - **Open Ended:** leave unselected

2. At the bottom right of the **Add Segment** section, click **Add**.

   In the Arm column of the Treatment table, you can see that this segment has been applied to both Arm A and Arm B. When the segment is created, all arms are automatically selected.

**NOTE:**

If a specification is created before treatment arms have been defined in the PC Console, the Arms column shows a blue dash. After arms are defined, click the dash to select the appropriate arms.
Where do I define the visits in a cycling segment?

You have defined this Treatment segment as a 28-day period of time that repeats six times. Note that there was no place to indicate that visits occur on days 1 and 15 of the cycle. Cycle-based segments differ from one-time segments in that you do not define cycle visits on the Treatment Visits tab. Instead, you will define the day 1 and day 15 visits later, when you schedule the calendar procedures.
Create a segment with a Start Date of End of Previous

On the sample calendar, the Maintenance segment is also cycle-based, but it is triggered by the end of something (Treatment) rather than the start of something. This scenario is handled by using the Start Date called End of Previous. End of Previous is the only Start Date option that is triggered by another part of the calendar rather than a subject status date.

1. In the Add Segment section, enter the following values:
   - **Sequence No:** 30
   - **Name:** Maintenance
   - **Start Date:** End Of Previous
   - **Time Unit:** Day
   - **No. Of Repetition(s):** 3
   - **Duration:** 14
   - **Exclude Weekend:** leave unselected
   - **Starting Number:** leave blank

2. At the bottom right of the Add Segment section, click Add.

3. The sample calendar indicates that the Maintenance segment applies only to Arm A. Since all arms are selected by default, we'll need to disassociate Arm B from this segment. In the Treatment table, in the row for Seq. No. 30, click the ArmA, ArmB link.

4. Clear the checkbox associated with ArmB and then click Submit.
   - The link in the Arms column now shows ArmA.

You have defined the Maintenance segment so that it begins on the day following the final day of the Treatment segment. In this case, that would be after six repetitions of 28, or 168 days after the subject's On Treatment Date.
Create a segment with multiple visits

The sample calendar indicates that after subjects are off treatment they need to come in for a week 1 and a week 2 visit. Because the visit schedule is calculated in weeks, the Time Unit field will be set to Weeks in this segment.

1. In the Add Segment section, enter:

- **Sequence No.**: 40
- **Name**: Off Treatment
- **Start Date**: Off Treatment
- **Time Unit**: Week
- **Visit(s)**: 1,2 (defines visits on week 1 and week 2 of the segment)
- **Duration**: 2 (indicating that the segment spans a period of two weeks)
- **Exclude Weekend**: leave unselected

**NOTE**: Segments with a Time Unit of Week only allow you to schedule a single visit on the first day of the week. If you need multiple visits within a week, you must use a Time Unit of Day.

2. At the bottom right of the Add Segment section, click Add.

After adding the Off Treatment segment, you will see the following schedule in the Treatment table:
NOTE: Although you defined the visits in the Off Treatment segment as “1,2”, OnCore saved them as a range using a colon (1:2). OnCore gives you the flexibility to list sequential visits either as a comma-separated list (1,2,3,4,5) or as a range (1:5). If you enter a comma-separated list of sequential visits, it will be shown as a range when the list is saved.

Create follow-up segments

The sample calendar shows two types of follow-up visits: in-clinic every six months for the first two years, and then by phone annually after that. This is represented in OnCore by two follow-up segments.

Follow-up segments are created on the Treatment Visits > Follow-Up tab. Follow-up segments can be an offset of the subject’s On Study or On Follow Up date. The following instructions detail how to set up two follow-up segments with a Start Date of On Follow Up.

Adding a follow-up segment is similar to adding a treatment segment, except when defining cycles. Whereas treatment segments use a single Duration field to define the length of time between the Start Date and the end of the segment, follow-up segments use three fields to define cycles: Duration Begin, Duration End, and Interval. The following instructions demonstrate how these fields work together to create the follow-up segments on the sample calendar.

1. Click the Follow-Up horizontal tab.
   One follow-up segment already exists because it was in the specification template that you copied to create this calendar.

2. In the Add Segment section, enter:
   - Seq. No: 60
   - Name: Annual Follow Up
   - Start Date: On Follow Up
   - Time Unit: Year
   - Duration Begin: 3 (indicating that the first visit in this segment will be year 3)
3. At the bottom right of the **Add Segment** section, click **Add**.

4. Click **Close**. You will see the following:

<table>
<thead>
<tr>
<th>Seq. No</th>
<th>Name</th>
<th>Start Date</th>
<th>Unit</th>
<th>No. of Repetition(s)</th>
<th>Visit(s)</th>
<th>Duration</th>
<th>Exclude Weekend</th>
<th>Arms</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>10</td>
<td>Baseline</td>
<td>Consent Signed</td>
<td>Day</td>
<td>1</td>
<td>1</td>
<td>1</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>20</td>
<td>Treatment</td>
<td>On Treatment</td>
<td>Day</td>
<td>6</td>
<td>28</td>
<td></td>
<td></td>
<td>Arms A, Arms B</td>
<td></td>
</tr>
<tr>
<td>30</td>
<td>Maintenance</td>
<td>End Of Previous</td>
<td>Day</td>
<td>3</td>
<td>14</td>
<td></td>
<td></td>
<td>Arms A</td>
<td></td>
</tr>
<tr>
<td>40</td>
<td>Off Treatment</td>
<td>Off Treatment</td>
<td>Week</td>
<td>12</td>
<td>2</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**IMPORTANT**

Segments within the calendar should not overlap, meaning the same visit should not exist in multiple segments. Since the In-Clinic Follow Up segment goes through year 2 (month 24), the Annual Follow Up will begin at year 3.

You now have six segments defining blocks of time where subject visits can occur. In the Baseline segment, you have already indicated that a visit occurs on the first day of the segment. In the Off Treatment segment, visits occur on the first day of weeks 1 and 2 of the segment. For the other cycle-based segments, the visit days have yet to be determined.

The next step is to define the labs, panels, and procedures that will be conducted on this protocol. These are defined on the **Study Specification > Calendar** tab.
Adding Procedures to the Calendar

You have defined the general structure (segments) for your protocol calendar. Now you will add the events (labs, panels, and procedures) that will be performed during subject visits.

Add events to the calendar

1. If you have left your protocol specification, navigate to Forms/Calendars > Specifications > Protocol Specifications, and select the practice protocol you were working on.

2. Click the Calendar tab.

Even though you’ve defined the segments for the calendar, they don’t appear on the Calendar tab yet. To see the calendar start to take shape, you need to add the procedures listed on the sample calendar.

3. Some procedures may already exist on your calendar. If you’re using the Oncology specification, these would be:
   - Informed Consent
   - ECOG performance status
   - History & physical, weight, PS

If you use a blank template, no procedures will be listed automatically.
4. On the lower right of the page, click **Add Procedures**.

A window opens, displaying a find-as-you-type **Clinical Procedure** field. You have the option of selecting an existing procedure or adding a new free-text procedure.

5. In the **Clinical Procedure** field, start typing the name of the procedure to see a list of potential matches. After selecting each procedure, click **Add**.

- Blood Chemistry
- Lipid Profile
- Treatment Administration
- Adverse Events
- Imaging
- Lesion Biopsy
- Survival Status
6. After you have added each procedure, click **Submit**.

The newly added procedures appear as links in the Procedure column of the protocol calendar. (The names won’t match exactly with what is shown in the image below, but it should look similar.)

<table>
<thead>
<tr>
<th>Protocol Calendar</th>
<th>Show Items</th>
<th>Hide Items</th>
</tr>
</thead>
<tbody>
<tr>
<td>Procedure</td>
<td></td>
<td>Forms</td>
</tr>
<tr>
<td>Toggle Full Screen</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Adverse Events</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Physical Exam</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Blood Chemistries</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Lipid Panel</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Treatment Admin</td>
<td>tration</td>
<td></td>
</tr>
<tr>
<td>Imaging</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Lesion Biopsy</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Survival Status</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
Scheduling Procedures

Now that you’ve identified which procedures will be done throughout the course of the study, you can associate them with specific visits.

Schedule procedures on specific visits

The following instructions explain how to schedule the Survival Status procedure from the sample calendar. Survival Status must be assessed on both the Screening and Annual Follow Up visits.

1. In the Procedure column, click **Survival Status**.
   The Procedure Details: Survival Status page opens, where you can schedule the procedure.

2. On the right side of the **Schedules** section, click **Visits/Schedules**.
   A window opens with two horizontal tabs:
   - **Visits**
     Allows you to schedule the procedure on *enumerated visits* (visits you defined on the Treatment Visits tab as part of a non-cycling segment) and on visits associated with Follow-Up segments
   - **Treatment Schedules**
     Used to schedule the procedure on a specified schedule within a cycle-based segment

3. Since the Survival Status procedure occurs in non-cycling segments, remain on the Visits tab. Select the **Annual Follow Up** checkbox, which automatically selects all of the visits (years 3, 4, 5, and 6) within the segment.

4. Click **Submit** and then click **Close** to return to the Procedure Details page.
   The visits you selected are listed in the Schedules section. Note that the Treatment and Follow Up schedules are separated by a horizontal rule.
Schedule procedures on cycle-based visits

According to the sample calendar, Adverse Events should be assessed at the Screening visit, on day 1 of each treatment cycle, and at each of the follow-up visits. You will use the method you just learned to schedule the procedure for Screening and follow-up and learn a new method for scheduling on day 1 of each cycle.

1. In the Procedure column, click **Adverse Events**.
   The Procedure Details: Adverse Events page appears where we can schedule the procedure.

2. Click **Visits/Schedules**. Remain on the **Visits** tab and select the following:
   - In the **Baseline** segment, select **D1**.
   - Select the **In-Clinic Follow Up** segment (to select all visits)
   - Select the **Annual Follow Up** segment (to select all visits).

   **NOTE:** Since you built the Annual Follow Up segment using Duration Begin, Duration End, and Interval, procedures are scheduled to all visits within the segment or no visits within the segment (all or nothing). Alternatively, procedures can be scheduled on the M6, M12, M18, and M24 visits independently because that segment is built with enumerated visits.

3. Click **Submit** to save your work.
4. Click **Treatment Schedules** to schedule the procedure on the cycle-based visits.

The Treatment Schedules tab allows you to create patterns for scheduling procedures to cycle-based treatment segments. The Cycles drop-down allows you to select the cycles that are included in each pattern.

<table>
<thead>
<tr>
<th>Cycles</th>
<th>Indicates that the procedure applies to:</th>
</tr>
</thead>
<tbody>
<tr>
<td>All</td>
<td>All cycles</td>
</tr>
<tr>
<td>Even</td>
<td>Every even-numbered cycle</td>
</tr>
<tr>
<td>Odd</td>
<td>Every odd-numbered cycle</td>
</tr>
<tr>
<td>From</td>
<td>Every cycle from a specified number onward; a field appears to specify the number. (For example, when the segment includes five cycles, selecting “From 3” indicates that the procedure applies to cycles 3, 4, and 5.)</td>
</tr>
<tr>
<td>Cycles</td>
<td>Only specified cycles; a field appears to specify the numbers. (For example, “Cycles 2, 3” indicates that the procedure applies only to cycles 2 and 3.)</td>
</tr>
<tr>
<td>Every</td>
<td>Every x number of cycles; two fields appear to indicate the starting cycle and interval. (For example, “Every 2 cycles from Cycle 3” indicates that the procedure applies to cycles 3, 5, 7, etc.)</td>
</tr>
</tbody>
</table>

The other fields in the Treatment Schedules tab change depending on the value selected for the Cycles field.
5. Since the Adverse Events assessment needs to happen on day 1 of all six treatment cycles, select the following:
   - **Cycles**: All
   - **Days**: 1 (*indicates that the procedure occurs on day 1 of each cycle*)

6. Click **Add**.
   The schedule you created appears in the table. You can apply this schedule to the selected procedure. It will also be available for selection when you schedule other procedures.

7. Select the checkbox associated with the schedule you created and then click **Submit**. Click **Close** to return to the Procedure Details page.

8. Next, use the same process to schedule the Treatment Administration procedure on day 1 of each treatment cycle. Click the **Treatment Administration** link.

9. Click **Visits/Schedules** and then the **Treatment Schedules** horizontal tab.

10. The treatment schedule that you defined for the Adverse Events procedure is already listed in the Schedules table. Since the Treatment Administration uses the same schedule, simply select the checkbox for the **All Cycles Visit 1** schedule and click **Submit** and then **Close**.

11. On the **Procedure Details** page, click **Close** to return to the Calendar tab.
    The Treatment Administration procedure is now scheduled for the same visits as the Adverse Events procedure.
Continue to schedule the remaining procedures.

1. In the **Calendar** tab, click **Blood Chemistry** to open the Lab Details page.

2. Click **Visits/Schedules**. On the **Visits** tab, select the following and then click **Submit**:
   - In the **Off Treatment** segment, select **W1**
   - Select **In-Clinic Follow Up** to include all visits in the segment

3. Click the **Treatment Schedules** tab to schedule the procedure on days 1 and 15 of each treatment cycle.

   You have already created a pattern for “All Cycles Day 1,” but you also need to schedule the Blood Chemistry to “All Cycles Day 15.” If you create this pattern for the Blood Chemistry lab, you can re-use it when scheduling other procedures (such as Lesion Biopsy and Imaging).

4. For the Blood Chemistry lab, create the following pattern in the **Add Schedule** section of the Treatment Schedules tab and then click **Add**:
   - **Cycles**: All
   - **Days**: 15

   The schedule you created appears in the table, below the existing schedule “All Cycles Day 1.” You can apply either or both of these schedules to the Blood Chemistries procedure.

5. Select the checkboxes for both patterns (**All Cycles Day 1** and **All Cycles Day 15**) and then click **Submit**.

6. Because the Blood Chemistry lab is also used in the Maintenance segment, you need to create another new schedule that accounts for those visits. In the **Add Schedule** section, select the following and then click **Add**.
   - **Segment**: Maintenance
   - **Cycles**: All
   - **Days**: 1
7. The schedule you just created appears in the table, but it is not yet selected for the lab. Select the checkbox that corresponds with the Maintenance segment, click Submit, and then click Close.

8. You’ll notice that the Treatment portion of the calendar is now divided into two distinct sections: a gray section for Arm A and an olive-colored section for Arm B. Arms with different schedules are color-coded to help you distinguish between them. If the schedule is identical for all treatment arms, OnCore saves space on the page by consolidating the calendar.

NOTE: OnCore offers two features to make calendars easier to view:
- The Freeze Panes button anchors the Procedure column, allowing you to scroll to the right while maintaining the procedure list as a reference.
- At the top right corner of the Calendar tab, the Arm drop-down gives you the option to view each arm of the calendar separately.
<table>
<thead>
<tr>
<th>Procedure</th>
<th>Treatment</th>
<th>Arm A: Arm A - drug plus inhibitor</th>
<th>Arm B: Arm B - drug only</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>1st 10 Days</td>
<td>6 Cycles @21 Days</td>
<td>Maintenance</td>
</tr>
<tr>
<td></td>
<td>C1D1 C1D15</td>
<td>C2D1 C2D15</td>
<td>C3D1 C3D15</td>
</tr>
<tr>
<td></td>
<td>R R R R R R</td>
<td>R R R R R R</td>
<td>R R R R R R</td>
</tr>
<tr>
<td>Adverse Events</td>
<td>Physical Exam</td>
<td>Blood Chemistries</td>
<td>Amylase, LDH</td>
</tr>
<tr>
<td>R</td>
<td>R</td>
<td>R</td>
<td>R</td>
</tr>
</tbody>
</table>

Arm A and Arm B are now color-coded because their schedules are no longer identical.

Use Freeze Panes to keep the procedure names visible.
Indicate that a procedure/lab occurs twice in a visit

On the sample calendar (page 14), the Blood Chemistry procedure is indicated with a 2X, meaning that it should be performed *twice* during each visit.

1. Click the **Blood Chemistry** lab procedure on the calendar.

2. On the Blood Chemistry page, click the **Details** button.

3. In the window that appears, all scheduled visits are listed. In the **No. of Occurrences** column, enter 2 for every visit and then click **Submit**.

4. On the **Procedure Details** page, click **Close** to return to the Calendar tab. You can see that the calendar grid now indicates that the Blood Chemistry procedure occurs twice on each visit for which it is scheduled.

5. Follow the steps used to schedule the Blood Chemistry lab to schedule the **Lipid Panel**. (In the sample calendar, the schedules are identical.)

6. Click **Close** on the **Procedure Details** page to return to the Calendar tab and confirm that your panel has been scheduled correctly.
Schedule multiple procedures simultaneously

Since both procedures (Imaging and Lesion Biopsy) have the same schedule, you can schedule them simultaneously:

1. Make sure that Freeze Panes is turned off.

2. Click to the right of the Imaging link. (Do not click directly on the link.) The procedure will appear highlighted in blue.

3. Hold the CTRL key and click to the right of the Lesion Biopsy link. This procedure will also appear highlighted in blue.

4. With both procedures highlighted in blue, click the Visits/Schedules button at the bottom of the calendar.

5. Open the Treatment Schedules horizontal tab.

6. Select the checkbox that corresponds to the All Cycles Day 15 schedule.

7. Click Submit and then Close.
Both procedures received the same schedule and now appear on the calendar on day 15 of all treatment cycles.
Customizing Procedure Order, Visit Names, and Visit Tolerances

There are several features within OnCore calendars that make them easier for staff to use.

Reorder procedures

If you add more items to the calendar, you might want to change the order of the procedures to match the list of procedures in the protocol document.

1. Click the blank space to the right of the Physical Exam procedure.
   The background color of the row will change to blue.

2. Use the Up button below the calendar to move Physical Exam above Adverse Events.

3. Use the same method to update any other procedures.

4. Click Save Order to preserve the changes.

   NOTE: If you navigate away from this page without clicking the Save Order button, your re-ordering will be lost and you will have to do it again.
**Update visit names and set visit tolerances**

The names that OnCore assigns to visits might not be what you want to appear on the calendar. For example, the visits in the Baseline and Off Treatment segments are both named D1. OnCore allows you to change these visit names. You can also indicate the allowable date range for each visit. The following instructions show you how to rename these visits and set visit tolerances.

1. On the **Protocol Specification > Calendar** tab, click the **Baseline** segment. 
   A window opens, with each visit in the treatment segment listed.

2. Enter the following:
   - **New Visit Description**: Screening
   - **Visit - Tolerances**: 0
   - **Visit + Tolerances**: 14

3. Click **Submit**.
   Notice that the D1 visit description on the calendar has changed to Screening. This description will also be used on subject calendars. The visit tolerance information can be seen from subject calendars.

4. Click **Treatment** segment.
   Since all of the visits can happen within +/- 1 day of their Planned Date, you can use the segment-level tolerances at the top of the window.

5. Enter the following:
   - **- Tolerances**: 1
   - **+ Tolerances**: 1
6. Click **Submit**.

You can see that your visits have been renamed. The visit tolerances you set will be enforced when clinical staff users check in subject visits; any visits that are given an Occurred date outside of the tolerance will automatically generate a visit outside tolerance record, which can prompt users to create a subject deviation if necessary.

**Click the segment name to change visit descriptions and set +/- tolerances**

![Table of visit descriptions and tolerances]

<table>
<thead>
<tr>
<th>Procedure</th>
<th>Forms</th>
<th>Treatment (1@1 Days)</th>
<th>Treatment (6 Cycles @28 Days)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Adverse Events</td>
<td>Adverse Events V1</td>
<td>R</td>
<td>R</td>
</tr>
<tr>
<td>Physical Exam</td>
<td>PE-001 V1</td>
<td>R</td>
<td>R</td>
</tr>
<tr>
<td>Blood Chemistries</td>
<td>Blood Chemistries V1</td>
<td>R</td>
<td>R</td>
</tr>
<tr>
<td>Amylase, LDH, Sodium; Uric Acid</td>
<td></td>
<td>R</td>
<td>R</td>
</tr>
<tr>
<td>Lipid Panel</td>
<td></td>
<td>R</td>
<td>R</td>
</tr>
<tr>
<td>Treatment</td>
<td></td>
<td>R</td>
<td>R</td>
</tr>
<tr>
<td>Administration</td>
<td></td>
<td>R</td>
<td>R</td>
</tr>
<tr>
<td>Imaging</td>
<td></td>
<td>R</td>
<td>R</td>
</tr>
<tr>
<td>Lesion Biopsy</td>
<td>DA-MD001 V1</td>
<td>R</td>
<td>R</td>
</tr>
<tr>
<td>Survival Status</td>
<td>SS-001 V1</td>
<td>R</td>
<td>R</td>
</tr>
</tbody>
</table>
Adding Footnotes

Footnotes can be added to three areas on a calendar:

- Procedures
- Visits
- Visit procedures (that is, on a procedure during a specific visit)

Footnotes allow you to provide additional information or instructions to the study team, located on the visit or procedure to which the information applies.

Add a footnote to a procedure

1. On the Protocol Specification > Calendar tab, click the Imaging procedure.
2. In the Foot Notes section, click Select Footnotes.
3. In the Index field, enter A.
4. In the Foot Note field, type: Conducted via MRI, CT Scan, or Ultrasound.
5. Click Add.
6. Select the corresponding Select? checkbox and click Submit.
   The footnote appears in the Foot Notes table on the Procedure Details page.
7. Click Close.
   The footnote appears at the bottom of the Specifications page, and its index appears next to the procedure.
Add a footnote to a visit

1. On the Protocol Specification > Calendar tab, click Add at the upper right of the Calendar Foot Notes section at the bottom of the page.
   
   All visits are shown in a table, allowing you to select the visits to which the footnotes should apply.

2. In the Index field, enter B.

3. In the Foot Note field, type: **Must occur within 28 days of Screening visit.**

4. Select the checkboxes for the C1D1 visits in the Treatment segment for ArmA and ArmB.

5. Click Submit.
   
The footnote appears at the bottom of the Specifications page, and its index appears next to both C1D1 visit names in the Treatment segments.

Add a footnote to a visit procedure

1. To add a footnote to a particular procedure on a particular visit, create the footnote using steps 1, 2, 3, and 5 in the section above. (Supply your own Index and Foot Note.)
   
   Your footnote will appear at the bottom of the Specifications page.

2. Click the **Lesion Biopsy** procedure.
   
   On the procedure’s Procedure Details page, the footnote can be selected using the Select Footnotes button. After the footnote has been selected for the procedure, it will appear in the Foot Notes table with a Visits link at the far right.

3. Click **Visits**.

4. Select checkboxes for the visits of your choice and click **Submit**.

5. Click **Close**.
Footnotes can be added to (A) a procedure, (B) a visit, (C) a specific procedure on a specific visit, or (D) the overall calendar.

The footnote appears at the bottom of the Specifications page, and its index appears next to the selected visit for the selected procedure.
Releasing a Protocol Calendar

To use the schedule of visits that you have created, you must release the protocol specification to make it available as a finalized protocol calendar. Remember that protocol specifications are considered calendars-in-progress; it is the finalized protocol calendar that generates the customized subject calendars. Before you release the protocol specification, it’s a good idea to do a final check of the visits, procedures, and schedules.

Preview the calendar

OnCore’s calendar preview feature allows you to double-check the visit structure using example subject status dates.

1. Click the Preview Calendar button in the upper right corner of the Calendar tab.

2. Select Arm A.

3. Enter the following status dates:
   - Consent Signed Date: m - 5
   - On Treatment Date: m - 4
   - Off Treatment Date: m + 2
   - On Follow Up Date: m + 4

4. Click Preview.
   Planned Dates are generated for each of the Arm A visits.

5. Click the red X to remove the example status dates.
Manage the calendar status

The calendar is currently in the New status, as indicated in the top right corner of the header. As long as the calendar is New, it can be modified in Forms/Calendars > Specifications and is not available for subjects. To indicate that it is ready for use, you must complete and release it:

1. Navigate to your protocol specification page (Forms/Calendars > Specifications tab > select your specification).

2. Click the Complete button.
   
   A specification with a status of Complete should not be edited. It is a way to indicate that the calendar is ready to be reviewed by someone else.
   
   NOTE: Signoff buttons will likely appear. (For Oncology protocols, those signoffs are the Coverage Analysis Signoff, Budget Signoff, and Coordinator Signoff.) These must be applied by users with the appropriate permissions until the Release button appears.

3. Click any Signoff buttons and then click the Release button.

   After a specification is released, it can be used by a protocol. Once released, it will be used to generate subject calendars based on each subject’s status dates.

You’ve successfully created a protocol calendar. When subjects are accrued to a protocol that uses this protocol specification, a calendar will be created for them based upon your work.