



*The*  
**UNIVERSITY**  
*of* **VERMONT**



**OnCore**™

OnCore System Guideline  
Subject Management

Prepared for: OnCore Version 2023R3.4

Revision Number: 2

Revision Date: October 22, 2025

Overview ..... 2

Accrual Tab ..... 2

Protocol Calendar..... 2

Monitoring Visits ..... 2

Financial Events..... 3

SAEs ..... 3

Deviations..... 4

FAQs..... 4

Registering a Subject..... 4

## Overview

The CRA Console offers an overview of similar information for all subjects within a protocol. Users can view subject information from a protocol perspective through various tabs. Access the CRA console from the Subjects menu.

## Accrual Tab

This tab is a high-level overview of subjects registered to the selected protocol.

- Select the MRN of a patient to go directly to their Subject Console.
- Use the checkboxes in the “Select” column to switch calendar versions if there is an update to the calendar.

## Protocol Calendar

Here you will see a read-only view of the protocol calendar with all arms included.

## Monitoring Visits

Coordinators can mark multiple visits as monitored on this tab, rather than individually in the Subject Console.

- To search for completed monitor visit(s) to mark as monitored enter a **From Date** and a **Thru Date** and select Refresh.
- The visits that populate include the visits that have not been marked as ‘Monitored’, UNLESS you select the ‘Include Monitored’ checkbox.
- **Monitored?** & **CRF Submitted?** - Use these columns to select dates that the visit has been monitored / CRF has been submitted using the **Monitored Date** or **CRF Submitted** date entry fields.

## OnCore System Guideline – Subject Management

**CRA Console**

Protocol No.: REFRESHERTRAINING    Library: Medicine    PI: Riley, Michelle    Sponsor: Acadia Pharmaceuticals, Inc.  
 Protocol Target Accrual: 50    Accrual To Date: 4    Protocol Status: OPEN TO ACCRUAL  
 RC Total Accrual Goal (Upper): 50    IRB Expiration:  
 Short Title: RTG

Select Protocol: REFRESHERTRAINING  
 Select Subject: [Dropdown]  
 Visit Type: [Dropdown]    From Date: 01/01/2025    Thru Date: 05/15/2025    Include Monitored?     Clear    Refresh

MRN	Seq No.	Visit Date	Phase	Cycle	Day	Visit Description	Monitored Date	CRF Submitted Date	Monitored?	CRF Submitted?
0006663983		01/15/2025	Treatment		D1	D1	01/20/2025		<input type="checkbox"/>	<input type="checkbox"/>
0006663983		01/30/2025	Treatment		D1	D1	02/01/2025		<input type="checkbox"/>	<input type="checkbox"/>
0006663983		02/06/2025	Treatment		D46	D46	02/01/2025		<input type="checkbox"/>	<input type="checkbox"/>
0010001651		03/01/2025	Treatment		D1	D1			<input type="checkbox"/>	<input type="checkbox"/>
0015598469		03/20/2025	Treatment		D1	D1			<input type="checkbox"/>	<input type="checkbox"/>
0123456789		03/20/2025	Treatment		D1	D1			<input type="checkbox"/>	<input type="checkbox"/>
0123456789		03/27/2025	Treatment		D1	D1			<input type="checkbox"/>	<input type="checkbox"/>

Mark All As Monitored    Mark All As Submitted    Unselect All

Monitored Date: [Date Picker]    CRF Submitted Date: [Date Picker]    Submit

ADVARRA © 2025 Advarra, Inc.

## Financial Events

Coordinators can mark the financial items as occurred for any financial items that have been assigned to the trigger type ‘CRA Console’.

### Add Financial Events section

**Add Financial Events**

Financial Events \* [Dropdown]  
 Occurred Date \* [Date Picker]  
 Count \* 1  
 Comments [Text Area]    Add

Occurred Date ↓	Event	Protocol Related Comments	Submitted By	Comments	Delete?
No events submitted					
0 Total Records					

Submit    Close

- **Financial Events** – items available here are pulled from the Protocol Related tab of the Financials Console **ONLY IF** items have been assigned the correct trigger type (CRA Console).
- **Occurred Date** – verify the date the financial item occurred
- **Count** – how many times this event occurred. If the financial item is listed as a ‘Variable’ the count can be increased up to 99.

## SAEs

Any SAEs entered at the subject level can be viewed here.

- Use the hyperlink of the event number to open a pop-up allowing users to review the details of the SAE.
- Two options:
  - Subject SAE: downloads a file of the subjects SAE
  - SAE Report: downloads a report of the SAE

### Deviations

All deviations entered in the Subject Console > Deviations page can be viewed here.

- Select the Deviation Date link to view the deviation details. Use the Subject Deviation link to download a report of the deviation.
- All out of visit window deviations are automatically added here when a visit is recorded as out of window.

### FAQs

FAQs entered in the PC Console are available to view here.

### Registering a Subject

#### Register Subject Tab

- Select the Register Subject tab on the left vertical tab list.
- Enter the subject information in the 'Find Subject' field to pull the subject information from Epic.
  - The minimum information required when entering a subject is the **Study Site** and the **MRN**.
  - Once this information is entered, use the "Find" function to pull all related subjects. To filter the search, use additional information (last name and birthday) to refine the subject search and select the correct participant.
- Subjects cannot be added anonymously as this disrupts billing.
- Select the subject and click 'Add', this will take you to the Subject Console Demographics tab.

#### Legacy Studies:

## OnCore System Guideline – Subject Management

When enrolling patients, ensure they are moved all the way through to their current status to ensure there are no differences in Epic.