OnCore System Guideline

Subject Management

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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.

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

- **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:

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