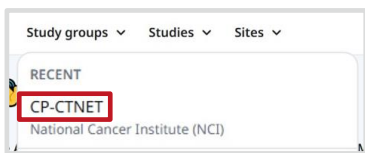## Accessing and Adding a *CP-CTNet Protocol Deviation Notification* eCRF in Medidata Rave

The *CP-CTNet Protocol Deviation Notification* eCRF is available at the patient (participant) level in Medidata Rave (see QKREFGD13 *Accessing Medidata Rave* for more information about accessing Medidata Rave). This section shows the process that accruing LAO and AO staff follow to access and add a new *CP-CTNet Protocol Deviation Notification* eCRF for a participant.
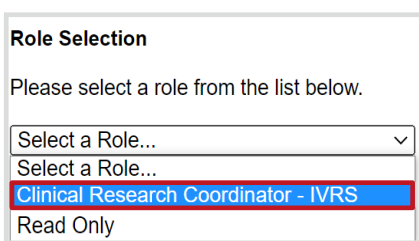
1. Select **CP-CTNET** from the *Study groups* dropdown at the top of the Medidata homepage.
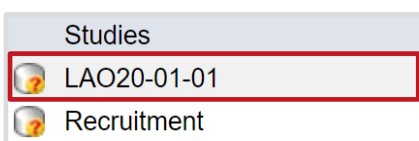
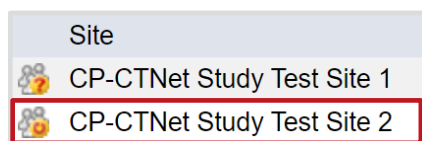2. Select **Rave EDC** under the CP-CTNET container.

3. Select the **Clinical Research Coordinator - IVRS** role from the *Role Selection* dropdown. If only one role is assigned, this dropdown is not displayed. Proceed to step 4.
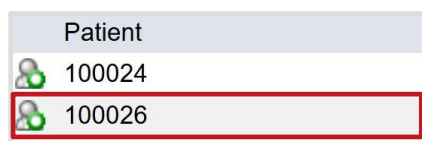
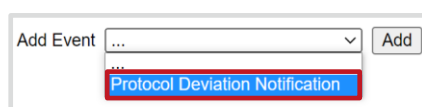4. Select the **protocol number** from the *Studies* list.

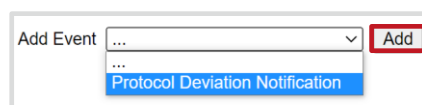5. Select the **site name** from the *Site* list.

6. Select the **Participant ID** from the *Patient* list.
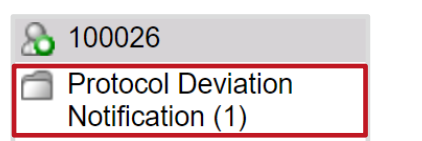
7. Select **Protocol Deviation Notification** from the *Add Event* dropdown on the bottom of the *Patient* page.

8. Click the **Add** button.

9. Click the **Protocol Deviation Notification (1)** folder on the left of the *Patient* page.

Reporting Protocol Deviations with the *CP-CTNet Protocol Deviation Notification* eCRF

The first section of the *CP-CTNet Protocol Deviation Notification* eCRF is used by accruing LAOs and AOs to report protocol deviations that occur at their site in Medidata Rave. The relevant fields are highlighted below.

Protocol Information
➢ Provide the protocol number and agent name(s).

Protocol Deviation Information
➢ Describe the PD and identify the relevant protocol section.

Initial Protocol Deviation Grade
➢ Assign an initial PD grade.

Site Investigator Review
➢ Confirm the site investigator's review.

Protocol Deviation Date
➢ Provide the date the PD occurred.

Protocol Deviation Categorization
➢ Select the appropriate category and subcategory for the PD.

Corrective and Preventative Action
➢ Describe any CAPA taken to address the PD.

Name
➢ Add your name.

Responding to Queries on the *CP-CTNet Protocol Deviation Notification* eCRF

After a protocol deviation is reported, the study's LAO Administrative Team reviews the protocol deviation, followed by the study's DCP Medical Monitor (MM) or Nurse Consultant (NC). Queries may be added to the eCRF during either review, and the reporting site must respond to any queries within 14 calendar days. A sample query and associated response is shown below.

Query, Marking Group, and Date
➢ The query text, marking group that placed the query (e.g., LAO, DMACC Data Manager (DM)), and date the query was placed are included here.
➢ **Note:** DMACC DMs send queries on behalf of the DCP MM/NC. This is indicated in the query text.

Reason for Editing the Field
➢ If the original entry needs to be edited, select the reason for editing the field from the dropdown.

Immediate Corrective Action(s) Taken [500]: ❓

? What is the Site Investigator's plan of action to ensure participant safety? Note: Query sent by a DMACC DM on behalf of the DCP MM. Opened To Site from DM (31 Jan 2025)

↻ Updated the plan of action.

Per Query Resolution ▾

Entered concomitant medication into the concomitant medication form at week 8 and updated the concomitant medication form at week 4. The site investigator will order follow-up blood tests, monitor the participant for AEs/SAEs, check for discontinuation of concomitant medication, and notify DCP of any updates.

Query Response
➢ Provide a brief response to the query in the available field.

Save the Query Response
➢ Save the eCRF once all updates are made in response to the query.

Save | Cancel

Edit Original Field
➢ Update the original entry in response to the query (as needed).

Acknowledging the DCP MM/NC Review on the *CP-CTNet Protocol Deviation Notification* eCRF

The fourth section of the *CP-CTNet Protocol Deviation Notification* eCRF allows the accruing LAO or AO to confirm their site investigator's acknowledgement of the DCP MM/NC review, as per institutional policy. The relevant field and functions are highlighted below.

Site Investigator Acknowledgment
➢ Confirm that the site investigator has acknowledged the DCP MM/NC review.

For Site Use Only:
By checking this box, I confirm that the site investigator has acknowledged the MM/NC review: ☐ ✅

Pencil Icon
➢ Click the *Pencil* icon to edit the field and provide a response.

For Site Use Only:
By checking this box, I confirm that the site investigator has acknowledged the MM/NC review: New Information ▾ ☑ ✅

Reason for Editing the Field
➢ Select *New Information* as the reason for editing the field.

Site Investigator Acknowledgment
➢ Click to place a checkmark in the box to confirm that the site investigator has acknowledged the DCP MM/NC review.

Save the Acknowledgement
➢ Save the eCRF after editing the final question.

Save | Cancel

CP-CTNetDMACC
Cancer Prevention Clinical Trials Network
Data Management, Auditing, and Coordinating Center