Add

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





Read Only

Studies

LAO20-01-01

Recruitment

- **Role Selection** Please select a role from the list below. Select a Role... ~ Select a Role.. Clinical Research Coordinator - IVRS
- button. 9 Click the Protocol

8. Click the Add

5. Select the site

Site list.

6. Select the

name from the

Participant ID from

the Patient list.

Deviation

Deviation Notification (1) folder on the left of the Patient page.

- CP-CTNet Study Test Site 1 CP-CTNet Study Test Site 2
- Patient 100024

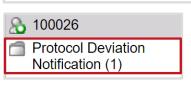
100026

Add Event

Site

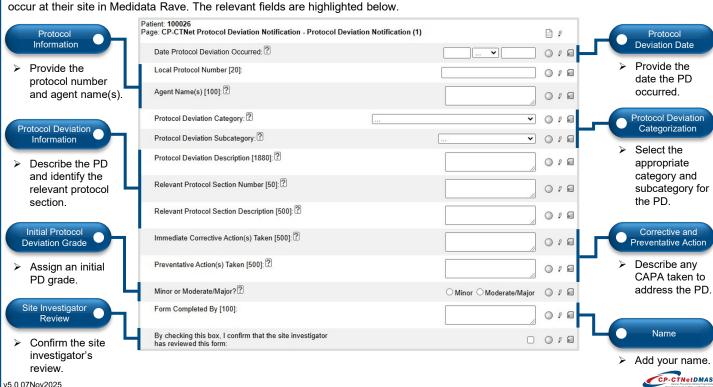
- 7. Select Protocol **Notification** from the Add Event dropdown on the bottom of the Patient page.
- Add Event ✓ Add Protocol Deviation Notification

Protocol Deviation Notification



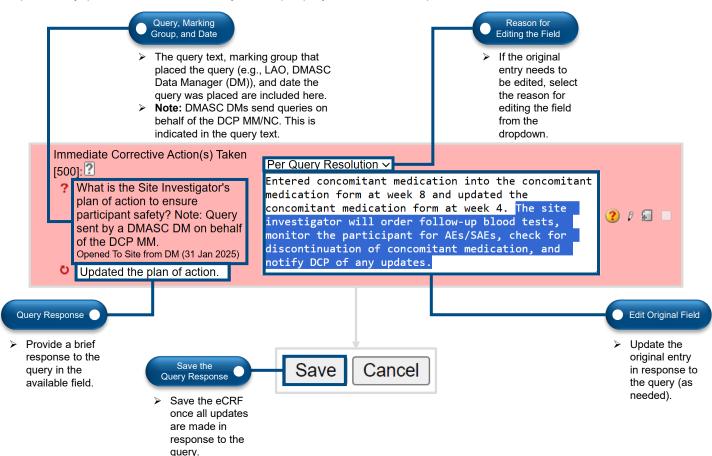
Reporting Protocol Deviations with the CP-CTNet Protocol Deviation Notification eCRF

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.



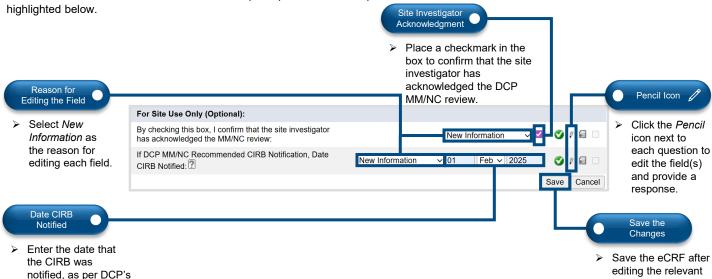
Responding to Queries on the CP-CTNet Protocol Deviation Notification eCRF

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.



For Site Use Only (Optional) Section of 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. This section also allows the accruing LAO or AO to indicate the date that the Central Institutional Review Board (CIRB) was notified, as per DCP's recommendation. The relevant fields and functions are



recommendation.

question(s).

CP-CTNetDMASC