

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]: ?

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.

Edit Original Field

- Update the original entry in response to the query (as needed).

Save **Cancel**

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.

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**