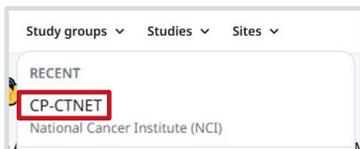


CP-CTNet QKREFGD06 Protocol Deviation Review for LAOs

Accessing 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 the LAO Administrative Team follows to access the eCRF for a participant.

1. Select **CP-CTNET** from the *Study groups* dropdown at the top of the Medidata homepage.



5. Select **Patient** from the *Find* dropdown on the *Study* page.



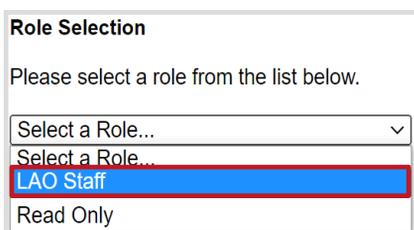
2. Select **Rave EDC** under the CP-CTNET container.



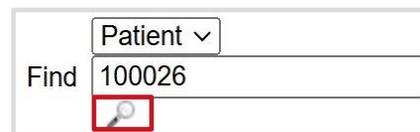
6. Enter the **Participant ID** into the *Find* field.



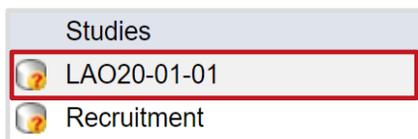
3. Select the **LAO Staff** role from the *Role Selection* dropdown. If only one role is assigned, this dropdown is not displayed. Proceed to step 4.



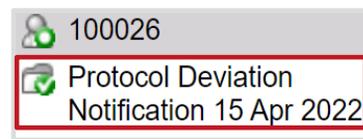
7. Click the **magnifying glass** icon to search by the entered Participant ID.



4. Select the **protocol number** from the *Studies* list.



8. Click the **Protocol Deviation Notification** folder on the left of the *Patient* page.



For LAO Administrative Team Use Only Section on the CP-CTNet Protocol Deviation Notification eCRF

The second section of the CP-CTNet Protocol Deviation Notification eCRF is used by the LAO Administrative Team to complete their review of protocol deviations reported by their accruing LAOs and AOs. Once an accruing LAO or AO reports a protocol deviation and saves the eCRF, Medidata Rave sends the LAO Administrative Team an automatic email indicating that there is a protocol deviation ready for review. The relevant fields of the *For LAO Administrative Team Use Only* section are highlighted below.

CIRB Notification

- Was the CIRB notified (if required)?

For LAO Administrative Team Use Only:

CIRB notified? (for CIRB-approved studies): ?

Does LAO review require queries?

LAO review complete: ?

LAO Queries Based on Review

- Indicate if queries are required based on your review.

LAO Review Complete

- Indicate that the review is now complete.

Pencil Icon

- Click the *Pencil* icon next to each field to provide a response.

CP-CTNet QKREFGD06 Protocol Deviation Review for LAOs

Using the Add Marking Icon to Open a Query on the CP-CTNet Protocol Deviation Notification eCRF

When conducting the review, the LAO Administrative Team clicks the *Add Marking* icon next to the field that they would like to query. Accruing LAOs and AOs address the query as part of their typical data management activities in Medidata Rave. A sample question and response completed by an accruing LAO or AO is provided below with its associated *Add Marking* icon.

Protocol Deviation Description [200]: ?

Use of exclusionary concomitant medication (St. John's wort) reported at week 4 visit but was not entered in Rave until week 8 visit when it was re-reported by the participant.

Add Marking Icon

- Click the *Add Marking* icon to open a query on the adjacent field.

Sample Response

- Sample response entered by an accruing LAO or AO describing a reported protocol deviation.

Components of an Open Query on the CP-CTNet Protocol Deviation Notification eCRF

After adding a query to a specific field on the *CP-CTNet Protocol Deviation Notification eCRF*, the LAO Administrative Team adds the query text and ensures that the default settings are applied before saving the eCRF. This section outlines the components of a newly opened query.

Protocol Deviation Description [200]: ?

Open Query ▾ Site from LAO ▾

What is the drug category for St. John's wort?

require response

Use of exclusionary concomitant medication (St. John's wort) reported at week 4 visit but was not entered in Rave until week 8 visit when it was re-reported by the participant.

Action Type

- Ensure that the *Open Query* action type is selected.

Marking Group

- Ensure that the *Site from LAO* marking group is selected.

Require Response

- Ensure that *require response* is checked.

Query Text

- Enter the text of the query in this field.

Closing a Query on the CP-CTNet Protocol Deviation Notification eCRF

After the accruing LAO or AO responds to the query on the *CP-CTNet Protocol Deviation Notification eCRF*, the LAO Administrative Team must log into Medidata Rave to review the query response, re-query or close the query, and complete their review. All queries must be closed before the LAO Administrative Team completes their review. This section shows a query with a response from an accruing LAO or AO.

Protocol Deviation Description [200]: ?

? What is the drug category for St. John's wort?
Opened To Site from LAO (05 Aug 2022)

CYP3A4 inducer - Added drug category.

...
...
Close Query
Re-Query

Use of exclusionary concomitant medication (St. John's wort, CYP3A4 inducer) reported at week 4 visit but was not entered in Rave until week 8 visit when it was re-reported by the participant.

Query Response

- The text of the query response from the accruing LAO or AO.

Query Action

- Select from the *Query Action* dropdown to re-query or close the query.

Updated Field

- Any updates to the field are included here.

Delta Symbol

- A small yellow delta symbol indicates that the response has changed.

Status Icon

- Click the status icon to access the audit trail and view the change history for the field.

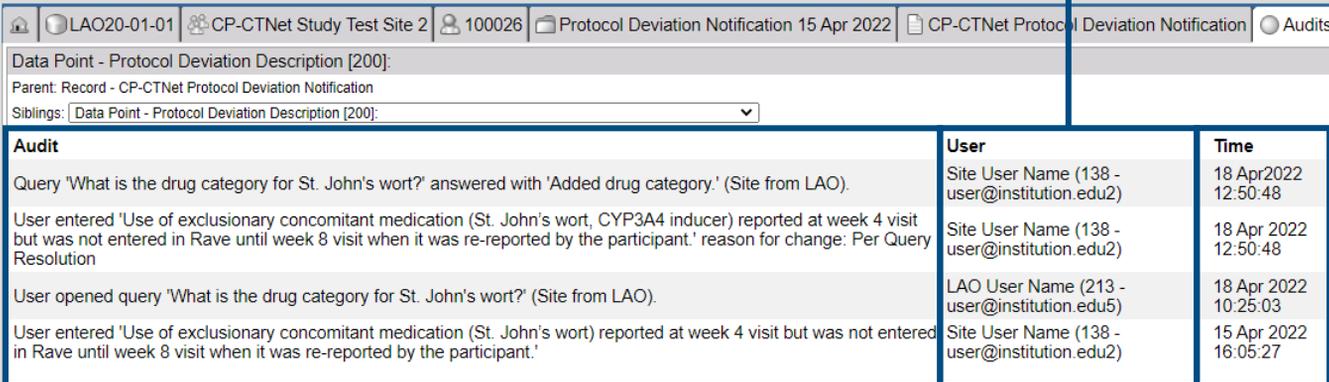
CP-CTNet QKREFGD06 Protocol Deviation Review for LAOs

Audit Trail for a Field on the CP-CTNet Protocol Deviation Notification eCRF

The LAO Administrative Team may click the status icon next to a field to access the audit trail and view the change history for the field. Once the status icon is clicked, an *Audits* tab opens within Medidata Rave. The *Audits* tab displays the original data entered by the LAO or AO and any subsequent changes made to the field. Each update is timestamped and highlights the user that updated the field. This section shows a sample *Audits* tab for the *Protocol Deviation Description* field.

User Column

- Displays the user that updated the field.



Audit	User	Time
Query "What is the drug category for St. John's wort?" answered with 'Added drug category.' (Site from LAO).	Site User Name (138 - user@institution.edu2)	18 Apr 2022 12:50:48
User entered 'Use of exclusionary concomitant medication (St. John's wort, CYP3A4 inducer) reported at week 4 visit but was not entered in Rave until week 8 visit when it was re-reported by the participant.' reason for change: Per Query Resolution	Site User Name (138 - user@institution.edu2)	18 Apr 2022 12:50:48
User opened query 'What is the drug category for St. John's wort?' (Site from LAO).	LAO User Name (213 - user@institution.edu5)	18 Apr 2022 10:25:03
User entered 'Use of exclusionary concomitant medication (St. John's wort) reported at week 4 visit but was not entered in Rave until week 8 visit when it was re-reported by the participant.'	Site User Name (138 - user@institution.edu2)	15 Apr 2022 16:05:27

Audit Column

- Displays the specific change that was made to the field.

Time Column

- Displays the date and time that each update was made to the field.

Completing the LAO Review on the CP-CTNet Protocol Deviation Notification eCRF

After all queries have been addressed on the *CP-CTNet Protocol Deviation Notification* eCRF, the LAO Administrative Team completes the *For LAO Administrative Team Use Only* section before completing their review. **Note:** The “Does LAO review require queries?” question must be answered with a *No* response and the “LAO review complete” question must be checked before the LAO Administrative Team completes and saves their review. This section shows an example of a completed *For LAO Administrative Team Use Only* section.

LAO Queries Based on Review

- Ensure that a *No* response is provided for the LAO queries question.

For LAO Administrative Team Use Only:

CIRB notified? (for CIRB-approved studies): Yes No

Does LAO review require queries? Yes No

LAO review complete:

Save the eCRF

- Save the eCRF after completing all questions in this section.

LAO Review Complete

- Ensure that a checkmark is added to indicate that the review is now complete.