

## Overview

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Cancer Prevention Clinical Trials Network (CP-CTNet) accruing Lead Academic Organizations (LAOs) and Affiliated Organizations (AOs) are responsible for entering data in Medidata Rave within 14 calendar days of a scheduled visit and resolving queries in Medidata Rave within 14 calendar days of issuance.

Data entered in Medidata Rave are queried in three ways:

1. Pre-programmed edit checks for data entered in non-expected fields, data missing from expected fields, etc. These queries display as *To Site from System* queries upon saving the electronic Case Report Form (eCRF).
2. Manual query entry by LAOs for source data discrepancies detected during source data verification. These queries display as *To Site from LAO* queries. See SOP 03-03 *LAO Oversight Activities* for more information.
3. Manual query entry by Data Management, Auditing, and Statistical Center (DMASC) Data Managers (DMs) for incorrect or discrepant data detected during routine data review. These queries display as *To Site from DM* queries.
  - 3.1. DMASC DMs also enter Minimum Data Set (MDS) report queries and Division of Cancer Prevention (DCP) Medical Monitor (MM)/Nurse Consultant (NC) protocol deviation queries.
    - MDS report queries are prefaced with *MDS REPORT QUERY*: and contain the exact wording from the MDS report query spreadsheet received from the Protocol Information Office (PIO).
    - DCP MM/NC protocol deviation queries are prefaced with *DCP MM/NC QUERY*: and contain the exact wording from the DCP MM/NC's request.

Accruing LAOs and AOs should regularly log into Medidata Rave to review and resolve outstanding queries, correct nonconformant data, and address overdue data. LAOs, accruing LAOs, and AOs can view outstanding queries, nonconformant data, and overdue data in Medidata Rave at any time.

This quick reference guide provides accruing LAOs and AOs with key information to support the implementation of routine data management activities in Medidata Rave.

**Note:** Medidata Rave is updated periodically by Medidata Solutions Inc. These updates may impact the user interface. This quick reference guide includes screenshots of Medidata Rave, but users may notice minor differences between the screenshots and the current version of Medidata Rave. Please reach out to [Documentation\\_CP-CTNet@frontierscience.org](mailto:Documentation_CP-CTNet@frontierscience.org) with any questions about the screenshots included in this quick reference guide.

## Routine Data Management Tools in Medidata Rave

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Accruing LAOs and AOs can use the Task Summary for each study to identify outstanding queries, nonconformant data, and overdue data. They should set priorities for addressing the tasks (e.g., the queries that have been outstanding the longest, the queries that are the simplest to resolve, the overdue data that are the simplest to enter, etc.).

To access a task within the Task Summary for a study:

1. Log into [Medidata](#) and select **CP-CTNET** from the *Study groups* dropdown at the top of the Medidata homepage.

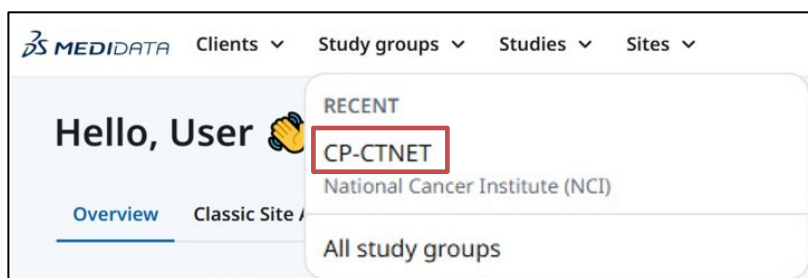


Figure 1: Study groups dropdown at the top of the Medidata homepage.

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



Figure 2: EDC under the CP-CTNET container.

3. Select the **Clinical Research Coordinator - IVRS** role from the *Role Selection* dropdown and click the **Continue** button. If only one role is assigned, this dropdown is not displayed. Proceed to step 4.

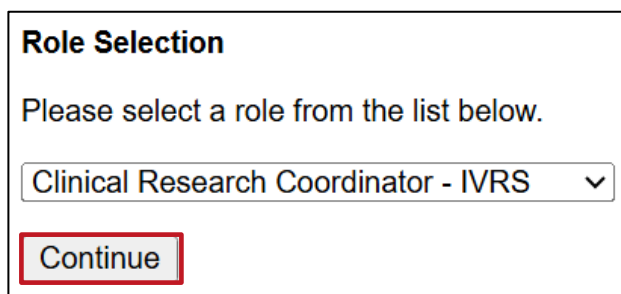


Figure 3: Role Selection dropdown and Continue button.

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

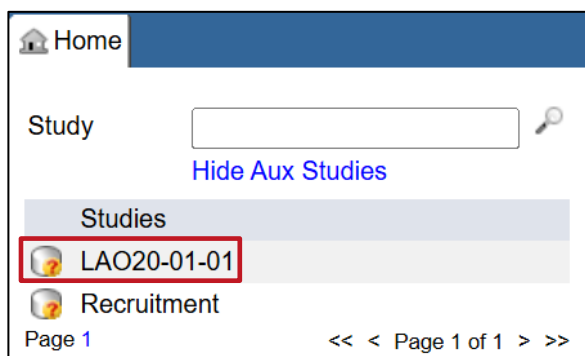
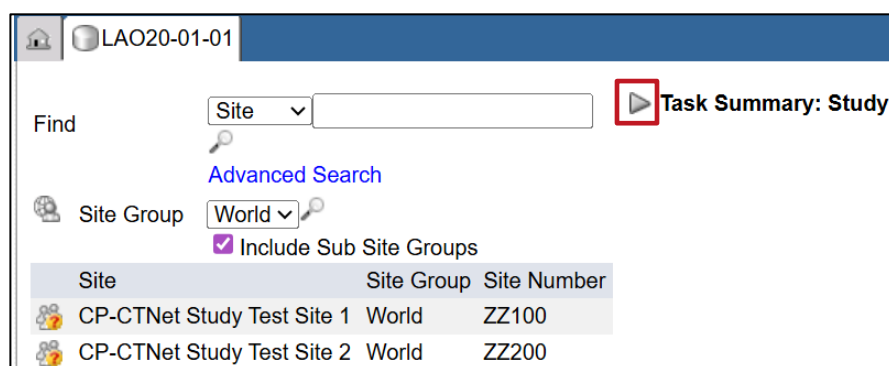


Figure 4: Studies list.

5. Click the **arrow** next to the *Task Summary: Study* heading.

**Note:** LAOs have access to all the sites that they are overseeing for the selected study, so they can see the Task Summary: Study. However, accruing LAOs and AOs only have access to their own site for the selected study, so they can only see the Task Summary: Site (proceed to step 8).



Find  Site  **Task Summary: Study**

[Advanced Search](#)

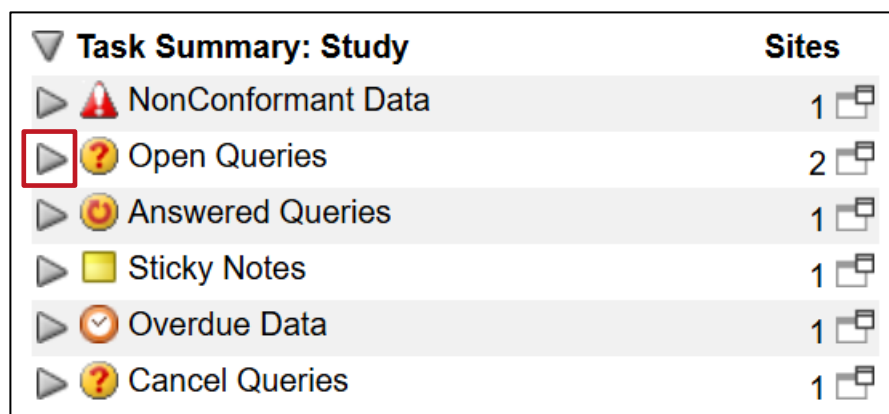
Site Group  World

☒ Include Sub Site Groups

| Site                       | Site Group | Site Number |
|----------------------------|------------|-------------|
| CP-CTNet Study Test Site 1 | World      | ZZ100       |
| CP-CTNet Study Test Site 2 | World      | ZZ200       |

Figure 5: Task Summary: Study heading.

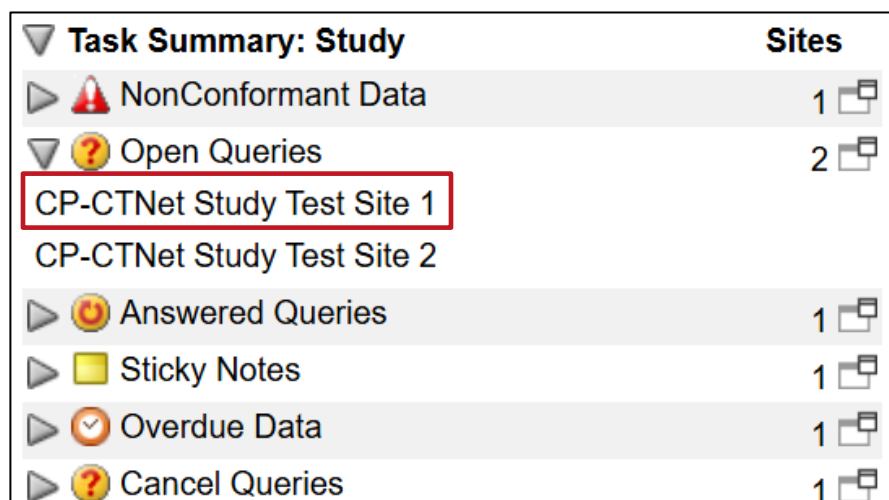
6. Click the **arrow** next to the relevant task to display the Site(s) associated with the task.



| Task Summary: Study | Sites |
|---------------------|-------|
| NonConformant Data  | 1     |
| Open Queries        | 2     |
| Answered Queries    | 1     |
| Sticky Notes        | 1     |
| Overdue Data        | 1     |
| Cancel Queries      | 1     |

Figure 6: Task Summary: Study tasks.

7. Click the relevant site name to see a list of Patient(s) associated with the task.



| Task Summary: Study        | Sites |
|----------------------------|-------|
| NonConformant Data         | 1     |
| Open Queries               | 2     |
| CP-CTNet Study Test Site 1 |       |
| CP-CTNet Study Test Site 2 |       |
| Answered Queries           | 1     |
| Sticky Notes               | 1     |
| Overdue Data               | 1     |
| Cancel Queries             | 1     |

Figure 7: Sites with the Open Queries task in the Task Summary: Study.

8. Click the relevant Participant ID (PID) to see a list of the eCRFs associated with the task.

**Note:** If you proceeded directly to this step at step 5, you will need to click the **arrow** next to the relevant task to display the Patient(s) associated with the task, and then click the relevant PID to see a list of the eCRFs associated with the task.

| ▼ Task Summary: Site   |  | Patients |
|------------------------|--|----------|
| ▶ ⚠ NonConformant Data |  | 1        |
| ▼ ? Open Queries       |  | 2        |
| 100034                 |  |          |
| 100708                 |  |          |
| ▶ 🔥 Answered Queries   |  | 1        |
| ▶ 📝 Sticky Notes       |  | 1        |
| ▶ ⌚ Overdue Data       |  | 5        |
| ▶ ? Cancel Queries     |  | 1        |

Figure 8: PIDs with the Open Queries task in the Task Summary: Site.

9. Click the relevant eCRF to navigate to the eCRF that contains the task.

| ▼ Task Summary: Patient                                                                 |  | Pages |
|-----------------------------------------------------------------------------------------|--|-------|
| ▶ ⚠ NonConformant Data                                                                  |  | 0     |
| ▼ ? Open Queries                                                                        |  | 1     |
| Protocol Deviation Notification 17 May 2026-CP-CTNet<br>Protocol Deviation Notification |  |       |
| ▶ 🔥 Answered Queries                                                                    |  | 0     |
| ▶ 📝 Sticky Notes                                                                        |  | 0     |
| ▶ ⌚ Overdue Data                                                                        |  | 0     |
| ▶ ? Cancel Queries                                                                      |  | 1     |

Figure 9: eCRF with the Open Query task in the Task Summary: Patient.

In addition, accruing LAOs and AOs can use the 360 Query Management Dashboard to view an up-to-date, detailed summary of a study's open, answered, and closed queries over time. They can also use the Page Status v2.0 report to view counts of overdue data as well as open and answered queries at various levels of detail. See QKREFGD01 *Medidata Rave Reports* and USRMAN03 *Rave Reports Resource Guide for the CP-CTNet Project* for more information.

**Note:** Nonconformant data are grouped with queries in the 360 Query Management Dashboard and the Page Status v2.0 report.

## Responding to Queries

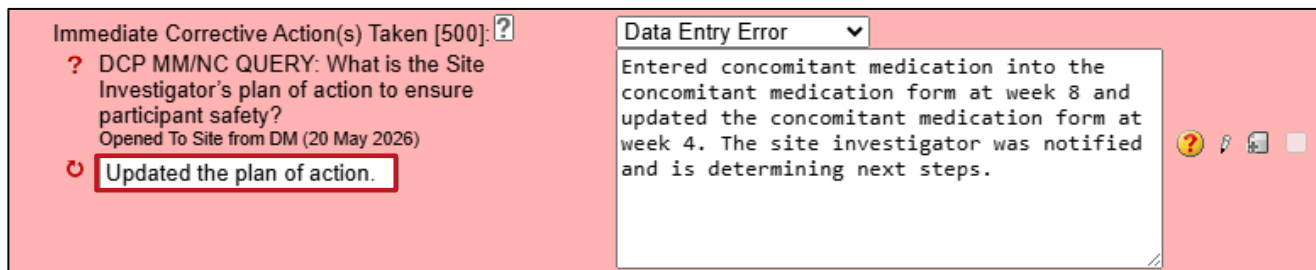
All queries in Medidata Rave can be viewed as soon as they are issued, so queries should be addressed in as real time as possible. DMASC also sends monthly query reports to the LAOs which outline all open queries per study and accruing LAO and AO. Accruing LAOs and AOs should not wait until they receive the monthly query reports from their LAOs to address queries. See REFGD03 *CP-CTNet Master Data Management Plan for LAOs, Accruing LAOs, and AOs* for more information.

Outstanding queries on Medidata Rave eCRFs are highlighted in red or pink and marked with a yellow, circular icon with a red question mark. After evaluating the query and consulting the relevant source data, accruing LAOs and

AOs should respond to a query by either correcting the data and providing the reason for the correction, or by providing a reason why the data are accurate and do not need correction. **In either case, accruing LAOs and AOs must respond to the query in the comment field below the query. Only updating the data in Medidata Rave is not sufficient.**

To respond to a query:

1. Provide a brief response in the comment field below the query.



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

? DCP MM/NC QUERY: What is the Site Investigator's plan of action to ensure participant safety?  
Opened To Site from DM (20 May 2026)

Updated the plan of action.

Data Entry Error

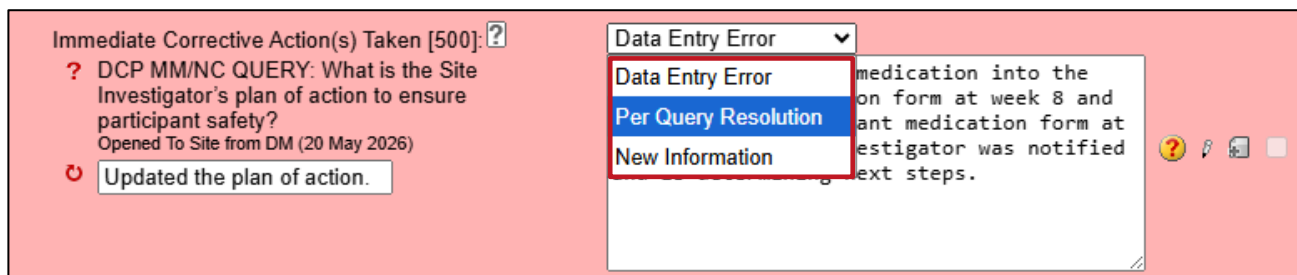
Entered concomitant medication into the concomitant medication form at week 8 and updated the concomitant medication form at week 4. The site investigator was notified and is determining next steps.

Figure 10: An open query with a response in the comment field below the query.

2. If the original entry needs to be edited:

- 2.1. Select the reason for editing the field from the dropdown. The reasons for editing the field include:

- **Data Entry Error:** Select this reason if the field is being edited to correct an error made when originally keying the data.
- **Per Query Resolution:** Select this reason if the field is being edited in response to a *To Site from System*, *To Site from LAO*, or *To Site from DM* query.
- **New Information:** Select this reason if the field is being edited to include information that was not available when the data were originally keyed.



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

? DCP MM/NC QUERY: What is the Site Investigator's plan of action to ensure participant safety?  
Opened To Site from DM (20 May 2026)

Updated the plan of action.

Data Entry Error

Data Entry Error

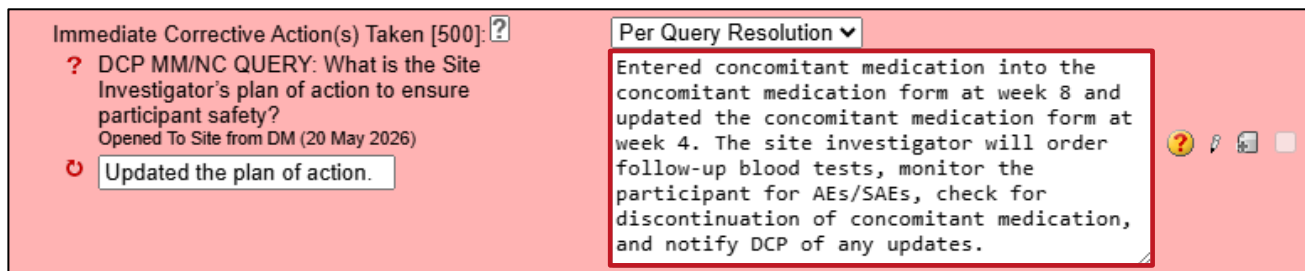
Per Query Resolution

New Information

medication into the on form at week 8 and ant medication form at estigator was notified next steps.

Figure 11: An open query with the reason for editing dropdown displayed.

- 2.2. Edit the field.



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

? DCP MM/NC QUERY: What is the Site Investigator's plan of action to ensure participant safety?  
Opened To Site from DM (20 May 2026)

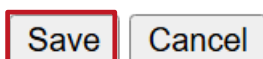
Updated the plan of action.

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.

Figure 12: An open query with an edited field.

3. Click the **Save** button at the bottom of the eCRF to save the eCRF once all updates are made in response to the query.



**Figure 13: The Save and Cancel buttons at the bottom of an eCRF.**

- The query response has been saved and is ready for review. A small yellow delta symbol is added next to the data to indicate that the originally keyed data have been changed.

|                                                                                                                                                                                                                       |                                                                                                                                                                                                                                                                                                                        |                                                                                                                                                                                                                                                                                                                                                 |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Immediate Corrective Action(s) Taken [500]:<br>? DCP MM/NC QUERY: What is the Site Investigator's plan of action to ensure participant safety?<br>Opened To Site from DM (20 May 2026)<br>Updated the plan of action. | 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. |     |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|

**Figure 14: An open query that has been responded to and is ready for review.**

## Correcting Nonconformant Data

Medidata Rave marks fields as nonconformant when data are entered in a format that the field is not designated to accept. Fields with nonconformant data are highlighted in red or pink and marked with a red, triangular icon with a white exclamation point. There are some cases where nonconformant data may be allowed based on what is reported in the relevant source data (e.g., the participant answered an integer question on a questionnaire with a decimal). In these cases, please reach out to the DMASC Data Management team (via [DataManagement\\_CP-CTNet@frontierscience.org](mailto:DataManagement_CP-CTNet@frontierscience.org)) for further instruction. Otherwise, nonconformant data should be corrected in Medidata Rave. Accruing LAOs and AOs should first determine why the data are nonconformant. Common reasons include data that:

- Are out of range:** Data that are out of the acceptable range designated for the field (e.g., entering a future date when only a current or past date is acceptable, entering a participant age that is younger or older than the age range specified by the protocol, entering a participant's weight in pounds when the field has been designated to record weight in kilograms, etc.).
- Are entered in an incorrect format:** Data that do not match the expected format designated for the field (e.g., entering alphabetical characters in numeric fields, entering decimals in integer fields, etc.).
- Exceed the character limit:** Data that exceed the maximum character length designated for the field. Character limits are listed in bracketed text next to each free text field (e.g., Comments [200] for an alphabetical field or Pulse Rate [nnn] for a numeric field).

| Medication #                                                                                                                | Medication [200] | Dose [nnnnnn.nnnn]                                                                                                                       | Dose Units | Route       | Frequency | Reason [200]                           | Start Date ? | Continuing | Stop Date ? |                                                                                                                                                                                                                                                                                                                                                         |
|-----------------------------------------------------------------------------------------------------------------------------|------------------|------------------------------------------------------------------------------------------------------------------------------------------|------------|-------------|-----------|----------------------------------------|--------------|------------|-------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| 1                                                                                                                           | Atorvastatin     | <div style="border: 1px solid #ccc; padding: 2px;">Data Entry Error</div> <div style="border: 1px solid #ccc; padding: 2px;">25,00</div> | mg         | Oral and IV | AM and PM | High LDL cholesterol and triglycerides | 01 Jul 2026  | Yes        |             |     |
| <b>Dose [nnnnnn.nnnn]:</b><br>? Data entered is non-conformant. Please correct.<br>Opened To Site from System (27 Jul 2026) |                  |                                                                                                                                          |            |             |           |                                        |              |            |             |                                                                                                                                                                                                                                                                                                                                                         |

**Figure 15: A field with nonconformant data.**

To correct nonconformant data:

- Select the reason for editing the field from the dropdown (e.g., Data Entry Error).  
**Note:** A comment field does not display for nonconformant fields as it does for queries.



| Medication<br># Reported<br>Date | Medication<br>[200] | Dose [nnnnnn.nnnn]                                                                                                                         | Dose<br>Units | Route             | Frequency    | Reason [200]                                    | Start<br>Date?    | Continuing | Stop<br>Date? |                                                                                                                                                                                                                                                                                                                                                 |
|----------------------------------|---------------------|--------------------------------------------------------------------------------------------------------------------------------------------|---------------|-------------------|--------------|-------------------------------------------------|-------------------|------------|---------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| 27 Jul<br>2026                   | Atorvastatin        | <div style="border: 1px solid red; padding: 2px;">Data Entry Error<br/>Data Entry Error<br/>Per Query Resolution<br/>New Information</div> | mg            | Oral<br>and<br>IV | AM and<br>PM | High LDL<br>cholesterol<br>and<br>triglycerides | 01<br>Jul<br>2026 | Yes        |               |     |

**Dose [nnnnnn.nnnn]:**  
 Data entered is non-conformant. Please correct.  
 Opened To Site from System (27 Jul 2026)

Figure 16: A field with nonconformant data with the reason for editing dropdown displayed.

- Correct the nonconformant data.

| Medication<br># Reported<br>Date | Medication<br>[200] | Dose [nnnnnn.nnnn]                                                                 | Dose<br>Units | Route             | Frequency    | Reason [200]                                    | Start<br>Date?    | Continuing | Stop<br>Date? |                                                                                                                                                                                                                                                                                                                                                 |
|----------------------------------|---------------------|------------------------------------------------------------------------------------|---------------|-------------------|--------------|-------------------------------------------------|-------------------|------------|---------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| 1<br>27 Jul<br>2026              | Atorvastatin        | <div style="border: 1px solid red; padding: 2px;">Data Entry Error<br/>25.00</div> | mg            | Oral<br>and<br>IV | AM and<br>PM | High LDL<br>cholesterol<br>and<br>triglycerides | 01<br>Jul<br>2026 | Yes        |               |     |

**Dose [nnnnnn.nnnn]:**  
 Data entered is non-conformant. Please correct.  
 Opened To Site from System (27 Jul 2026)

Figure 17: A field with nonconformant data that has been corrected.

- Click the **Save** button at the bottom of the eCRF to save the eCRF once all updates are made in response to the nonconformant data.

Save

Cancel

Figure 18: The Save and Cancel buttons at the bottom of an eCRF.

- The nonconformant data have been corrected and saved. A small yellow delta symbol is added next to the data to indicate that the originally keyed data have been changed.

| # | Medication<br>Reported<br>Date | Medication<br>[200] | Dose [nnnnnn.nnnn]                                                                        | Dose<br>Units | Route             | Frequency    | Reason [200]                                    | Start<br>Date?    | Continuing | Stop<br>Date? |                                                                                                                                                                                                                                                                                                                                                         |
|---|--------------------------------|---------------------|-------------------------------------------------------------------------------------------|---------------|-------------------|--------------|-------------------------------------------------|-------------------|------------|---------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| 1 | 27 Jul<br>2026                 | Atorvastatin        | 25.00  | mg            | Oral<br>and<br>IV | AM and<br>PM | High LDL<br>cholesterol<br>and<br>triglycerides | 01<br>Jul<br>2026 | Yes        |               |     |

Figure 19: A field with nonconformant data that has been corrected and saved.

## Keying Overdue Data

In Medidata Rave, overdue data refers to expected eCRFs that have not been keyed by their target entry dates as per the timelines or windows specified in the protocol. Overdue data are marked with an analog clock icon.

To key overdue data:

- Navigate to the eCRF with overdue data. After consulting the relevant source data, key the overdue data.  
**Note:** This may include keying the data pertaining to the visit/assessment/procedure, or indicating that the visit/assessment/procedure did not occur.

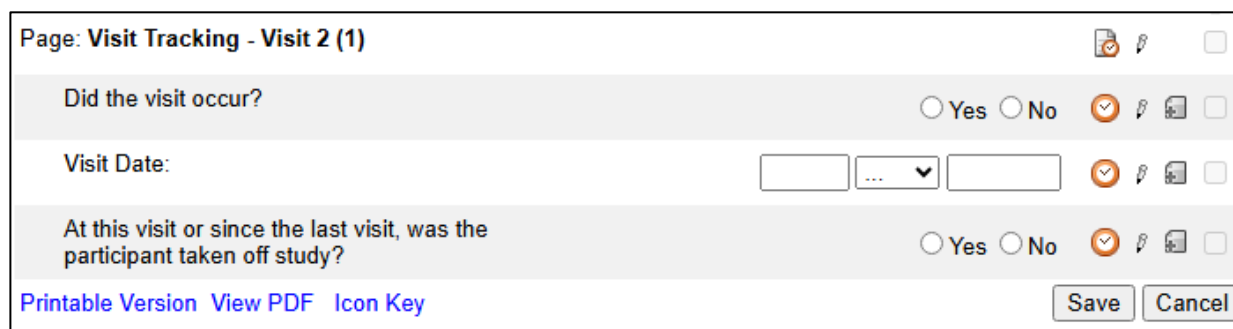


Figure 20: An eCRF with overdue data.

- Click the **Save** button at the bottom of the eCRF to save the eCRF once all updates are made in response to the overdue data.

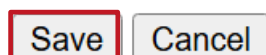


Figure 21: The Save and Cancel buttons at the bottom of an eCRF.

## Who to Contact

For any questions or comments regarding this quick reference guide, please contact the DMASC Data Management team by email at [DataManagement\\_CP-CTNet@frontierscience.org](mailto:DataManagement_CP-CTNet@frontierscience.org).

## References

**Note:** All CP-CTNet standard operating procedures (SOPs) are included in the [CP-CTNet Manual of Standard Operating Procedures \(M-SOP\)](#), which is available on the [CP-CTNet DMASC public website](#).

| Resource                                                              | ID        | Location                          |
|-----------------------------------------------------------------------|-----------|-----------------------------------|
| CP-CTNet Master Data Management Plan for LAOs, Accruing LAOs, and AOs | REFGD03   | <a href="#">Program Resources</a> |
| Lead Academic Organization Oversight Activities                       | SOP 03-03 | <a href="#">Program Resources</a> |
| Medidata Rave Reports                                                 | QKREFGD01 | <a href="#">Program Resources</a> |
| Rave Reports Resource Guide for the CP-CTNet Project                  | USRMAN03  | <a href="#">Program Resources</a> |