

Protocol Deviation Reporting System

Presented by the Data Management Center

What is the system for?

- The Protocol Deviation Reporting System (PDRS) is for reporting protocol deviations for all or multiple participants for a study.
- The PDRS was created in response to protocol deviations caused by the COVID-19 pandemic.
- In addition to reporting protocol deviations, the system also allows you to review previously entered deviations.
- The PDRS is **NOT** for reporting individual participant level deviations. These deviations should continue to be reported per network or study guidelines.
- Deviations should be reported either through the PDRS or the eCRF. Do **NOT** enter a deviation through the eCRF if you are using the PDRS.

Accessing the PDRS

- The PDRS can be found on the Portal under the Site Support category.

Links and Applications Listed by Category

Show Most Recently Used Items

Calculators	Case Report Forms
Age Calculator Week Calculator	Forms Management Utility
Site Support	Study Specific
Computer Account Report Medidata Rave Resources <u>Protocol Deviation Reporting System</u>	A5001 Calendar A5128 Report A5300B Protocol Deviations A5302 Co-Enrollment Reports A5322 Participant Calendar A5359 Protocol Deviations



Home Screen

- When you first access the program, you will see a table of previously reported deviations for your affiliated site(s). Scroll to the right to see the “View” button, which can be clicked to show detailed information about the deviation. You may also “Update” or “Delete” a previously entered deviation.
- All columns can be sorted in ascending or descending order.
- Click “Report Deviation” to report a deviation.

Protocol Deviation Reporting System

The below table displays previously reported deviations. All columns can be sorted in ascending or descending order. Click the **View** button on the right to display full information about a deviation.

Click the **Report Deviation** button to report a deviation.

This utility should only be used to report deviations that apply to multiple studies or multiple participants enrolled on a study. Individual participant level deviations should continue to be reported per network or study guidelines.

Report Deviation 

Site	Study	Patid	Site Awareness Date	Start Date	End Date	Report Date ▼	Summary	 Scroll to the right to access the "View" button
		All	20-Apr-2020	12-Apr-2020	27-Apr-2020	27-Apr-2020	Does not meet criteria	

Required fields

- All required fields are marked with a red *
- The deviation end date is not required.
- The orange text reminds you to **ONLY** use the system for all or multiple participants.

Protocol Deviation Reporting System

This utility should only be used to report deviations that apply to multiple studies or multiple participants enrolled on a study. Individual participant level deviations should continue to be reported per network or study guidelines.

* Required field

* Site:

* Study:

Does this deviation apply to all participants on study at this site? Yes No

* Site awareness date: dd-Mmm-yyyy

* Deviation start date: dd-Mmm-yyyy

Deviation end date: dd-Mmm-yyyy

* Has or will this deviation be reported to local IRB/EC? Yes No

* Is this deviation a result of the COVID-19 pandemic? Yes No

* Type of deviation: ⓘ

Selecting all or multiple participants

- You may report deviations for only one site at a time.
- If you select multiple studies, the deviation entered will apply to all active participants for the selected studies.
- If you are entering deviations for a single study, you may select “No” and then multi-select patids for the participants affected.

*** Required field**

* Site:

* Study:

Does this deviation apply to all participants on study at this site? Yes No 

Patid:

Entering further deviation information

- Only one 'Type of deviation' may be selected. If there are multiple types of deviations to report, they must be reported separately.
- The brief summary has a 200 character limit; the description can be up to 5700 characters.

* Type of deviation: Select one of the following

* Brief summary of deviation: 200 characters maximum

* Deviation description: 5700 characters remaining (5700 maximum)

Submit Cancel

If you have multiple types of deviations, they must be reported separately

- Did not meet eligibility criteria
- Failure to follow trial randomization or blinding procedures
- Study product management deviation
- Study product dispensing error
- Conduct of non-protocol procedure
- Breach of confidentiality
- Physical assessment deviation
- Lab assessment deviation
- Use of non-IRB/EC-approved materials

Types of deviations

- Did not meet eligibility criteria
- Failure to follow trial randomization or blinding procedures
- Study product management deviation
- Study product dispensing error
- Conduct of non-protocol procedure
- Breach of confidentiality
- Missed visit trend
- Assessment deviation
- Physical assessment deviation
- Lab assessment deviation
- Use of non-IRB/EC-approved materials
- Informed assent/consent process deviation
- Delegation of duties deviation
- IRB, ethics or regulatory review deviation
- Use of disallowed medication or device
- Blood volume maximum exceeded
- Specimen handling deviation
- AE/SAE/EAE reporting deviation
- Other

Scenario #1

- All participants at the site miss all visits between 15 March and 30 April due to COVID-19 related lockdowns.
- This deviation should be reported using the new PDRS, selecting the “Missed visit trend” deviation type.

Scenario #2

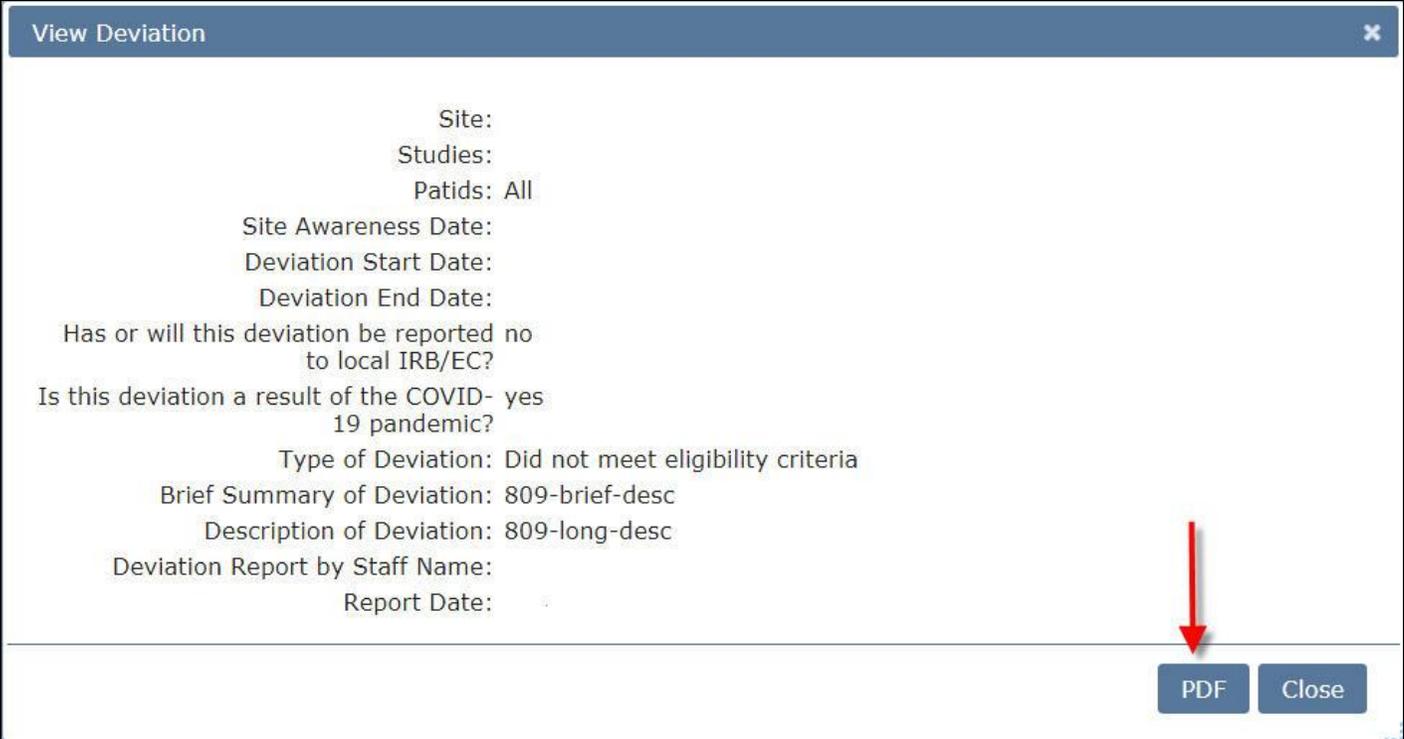
- All participant visits are conducted virtually (e.g., by telephone) starting 15 March due to COVID-19 related lockdowns. No laboratory or physical evaluations are performed.
- The missed evaluations should be reported as a protocol deviation using the new PDRS, selecting the “Assessment deviation” deviation type.
- The end date would initially be left blank to indicate an ongoing scenario. Once in-person participant visits resume, the PDM should be contacted to update the deviation end date in the PDRS.

Updating and deleting a deviation

- Clicking “Update” brings up the information previously entered on the deviation. You may update information from this screen. You will be required to enter a reason in the dropdown.
- Clicking “Delete” brings up a dialogue box asking you to confirm that you wish to delete the deviation. Click Delete again to confirm deletion, or Cancel to exit without making changes. You must select a reason for the deletion from the dropdown box.

Printing a deviation

- A previously entered deviation can be printed by clicking the “View” button on the first screen. Then, click the PDF button.



The screenshot shows a window titled "View Deviation" with a close button (X) in the top right corner. The window contains the following text:

Site:
Studies:
Patids: All
Site Awareness Date:
Deviation Start Date:
Deviation End Date:
Has or will this deviation be reported no
to local IRB/EC?
Is this deviation a result of the COVID-19
pandemic? yes
Type of Deviation: Did not meet eligibility criteria
Brief Summary of Deviation: 809-brief-desc
Description of Deviation: 809-long-desc
Deviation Report by Staff Name:
Report Date:

At the bottom right of the window, there are two buttons: "PDF" and "Close". A red arrow points down to the "PDF" button.

How far back am I required to report mass deviations?

- Mass deviations should be reported back to 15 March.