Protocol Deviation Reporting System

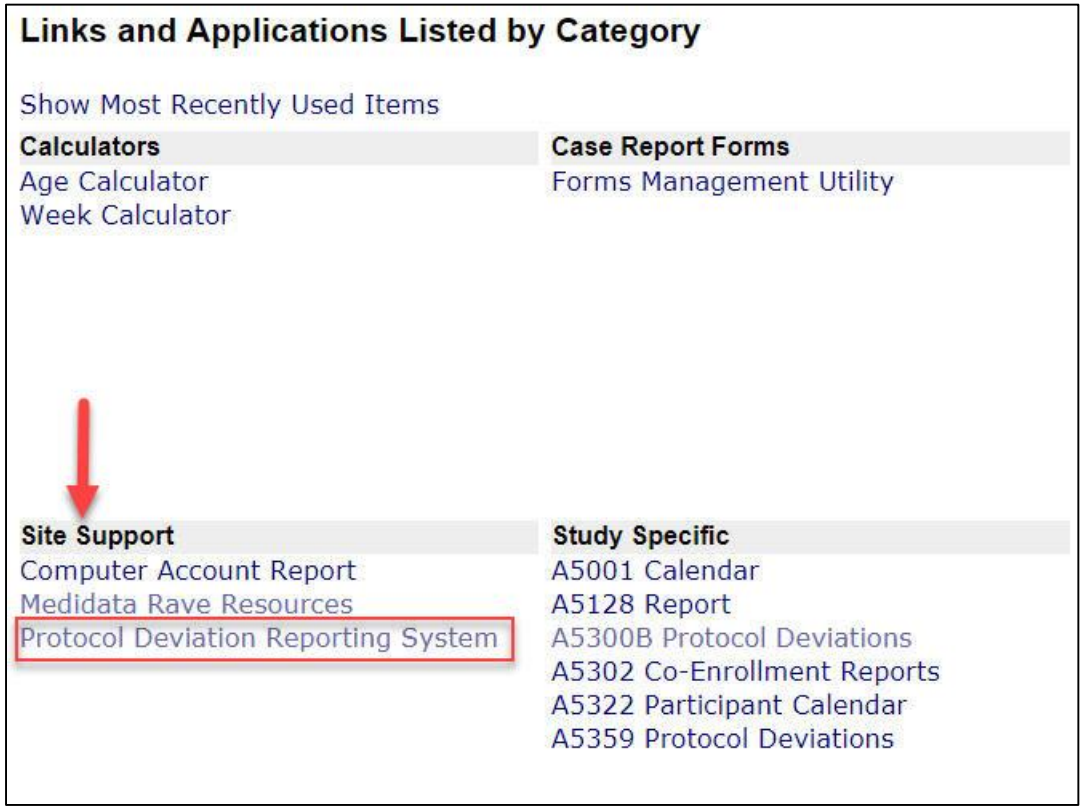
Presented by the Data Management Center

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.



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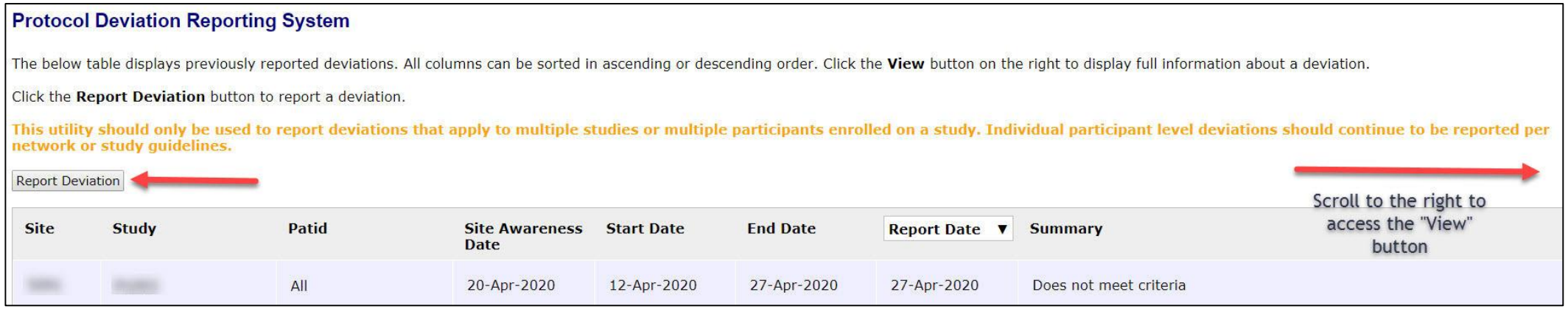
Home Screen

- 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.



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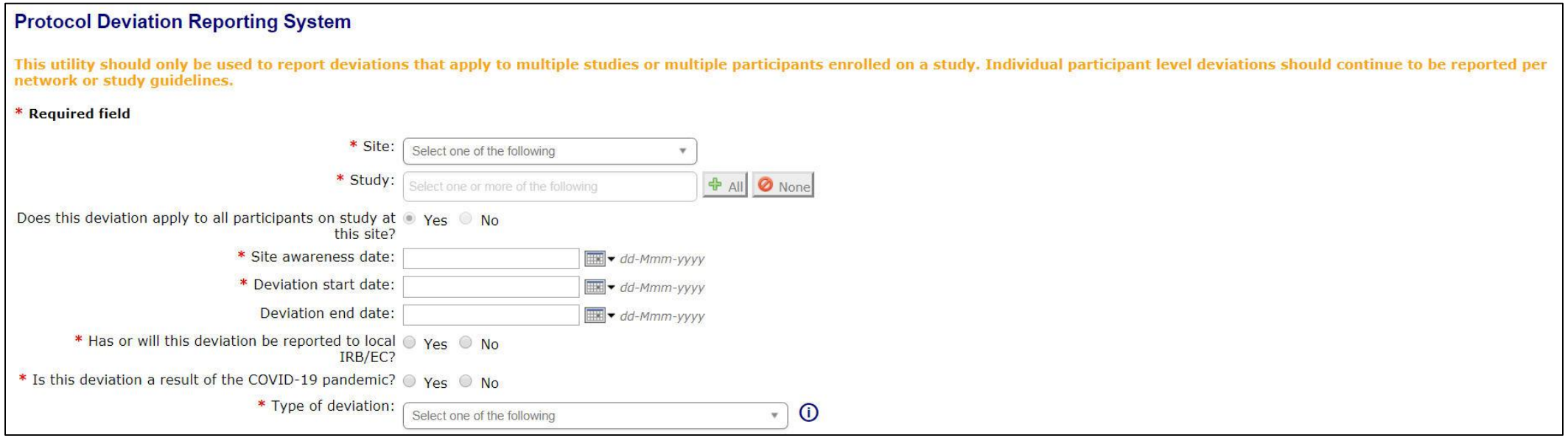
Required fields

- 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.



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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.

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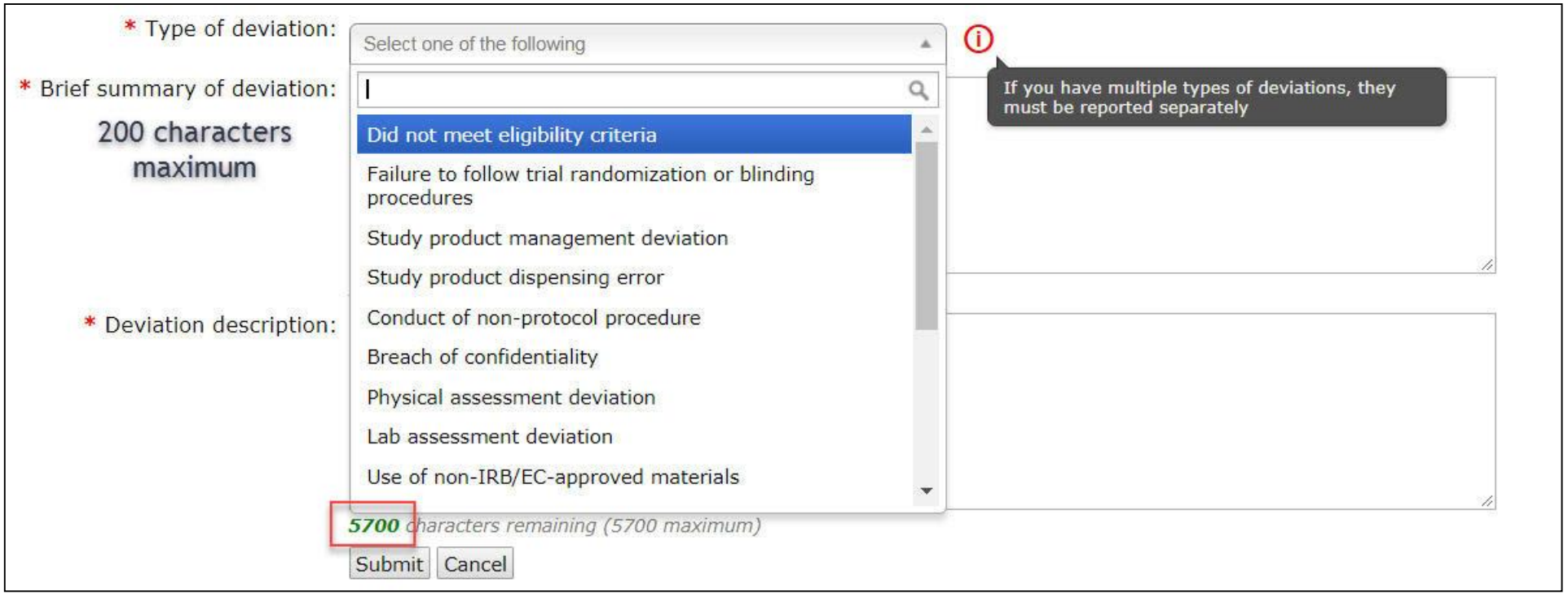
Entering further deviation information

- 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.



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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.

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How far back am I required to report mass deviations?

- Mass deviations should be reported back to 15 March.