Protocol Deviation Tracking System (PDTS) User Guide

August 2022

VERSION 1.1.0

Office of Information Technology

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Introduction

The Protocol Deviation Tracking System (PDTS) is an application that allows the user to record protocol deviations (minor and major). Protocol deviations are defined by the NIH human research protection program below:

- Deviation: Any change, divergence, or departure from the IRB-approved research protocol.
- Major: Deviation from the IRB-approved protocol that have, or may have the potential to, negatively impact, the rights, welfare or safety of the subject, or to substantially negatively impact the scientific integrity or validity of the study.
- Minor: A Deviation that does not have the potential to negatively impact the rights, safety, or welfare of subjects or others, or the scientific integrity or validity of the study.

For CCR-held INDs/IDEs, the PDTS also tracks non-adherences which is defined as any noncompliance with the clinical trial protocol, GCP, or protocol-specified procedural requirements. PDTS allows non-adherence events that are not deviations (e.g., issues related to Informed Consent) to be entered but not as a deviation so they will not be reported in the Continuing Review report. This is done by having some fields be optional – see table in the entering a deviation section of the manual.

The user interface (UI) is a Web Application compatible with Google Chrome, Microsoft Edge, Mozilla Firefox, and Apple Safari. It has been developed by the Office of Information Technology, CCR, NCI, NIH, that also supports and updates the system.

Getting to PDTS

To access PDTS, open your preferred Web Browser and enter https://pdts.ccr.cancer.gov in the URL bar. PDTS is only accessible while connected to the NIH network.

Login

Users are prompted to login by entering a Username and Password (NIH username and password).

Protocol Deviation Tracking System   ? Help

Login

NIH Username *

jaddap2

NIH Password *

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Login

WARNING NOTICE

This warning banner provides privacy and security notices consistent with applicable federal laws, directives, and other federal guidance for accessing this Government system, which includes (1) this computer network, (2) all computers connected to this network, and (3) all devices and storage media attached to this network or to a computer on this network.

This system is provided for Government-authorized use only.

Unauthorized or improper use of this system is prohibited and may result in disciplinary action and/or civil and criminal penalties.

FIGURE 1 - LOGIN SCREEN

You can click on eye icon in password field to view entered password. If you are not able login or receive an error message, please contact support team using one of the ways shown below

Help

Help button is located at the right top part before Login/Logout button on every page. Click on it to see the Help page which lists User Manual link, and Frequently Asked Questions (FAQs) along with an option to create support ticket. See help section for more details.

Home Page

After entering a valid Username and Password, the system will redirect you to the home page. The tiles on the home page will enable the user to access different sections based on the user's privileges. The tiles that appear in the figure below belong to a System Admin. Other users will not be able to see all sections.

The home page consists of 4 sections

- Side Navigation Bar
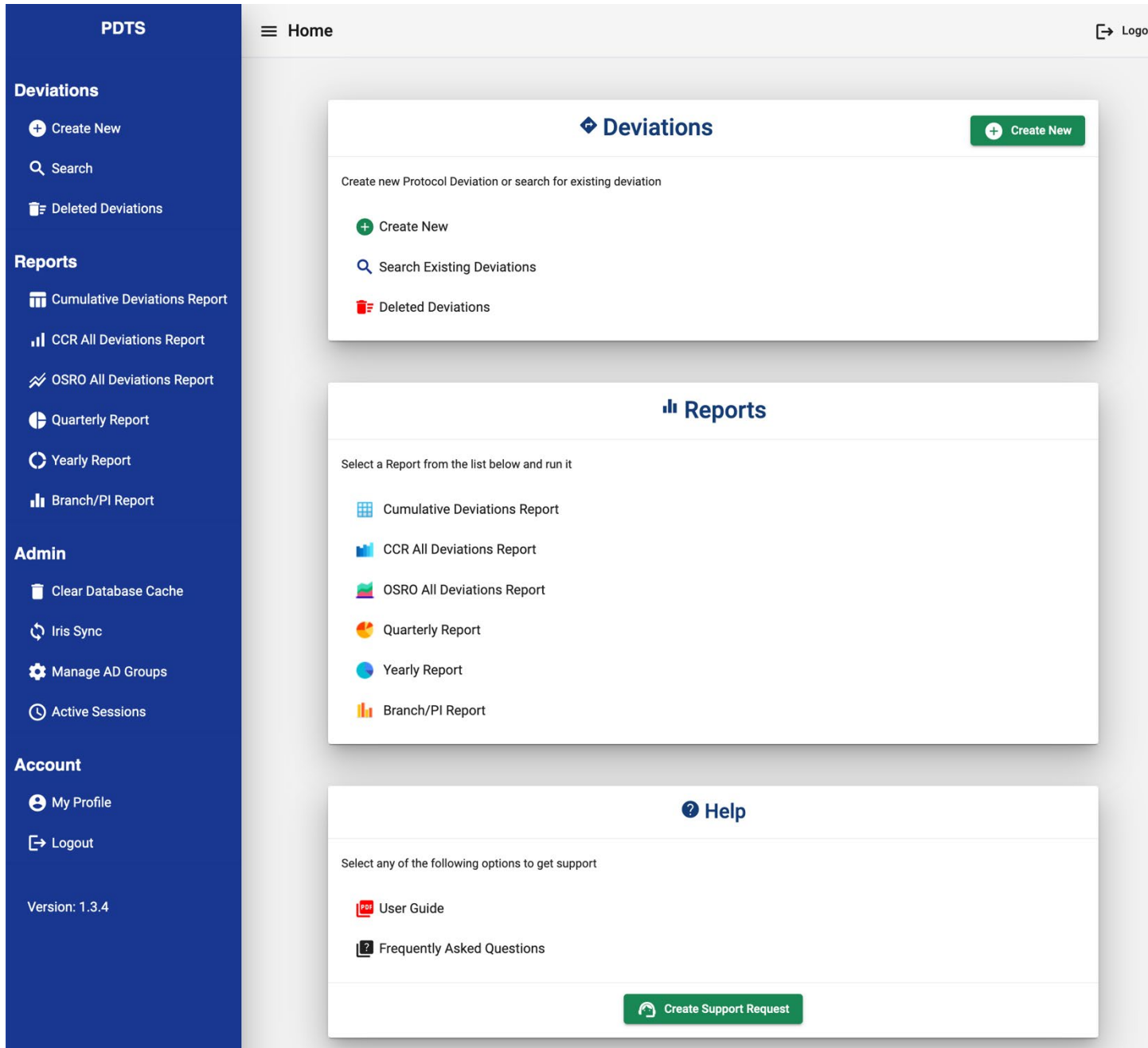- Header
- Deviations Tile
- Reports Tile
- Help Tile

**FIGURE 3 - HOME PAGE**

Side Navigation Bar

The side navigation bar present in all pages provides quicker navigation between pages. You can minimize the side bar by clicking on menu or hamburger icon on left side of header

Header

The header present in all pages contains Menu button, Breadcrumbs section and Login/Logout button.

- Menu button – Menu button allows you to Show/Hide side navigation bar
- Breadcrumbs - Breadcrumbs give you orientation and show you exactly where you are on a website. With breadcrumbs, if you've reached a page you don't want to be on, you can easily find your way back or go back a step or two and start over.
- Login button – Login button shown if you are not already logged in
- Logout button – Logout button shown when you are logged in and clicking on it will initiate logout process and redirects to Login page
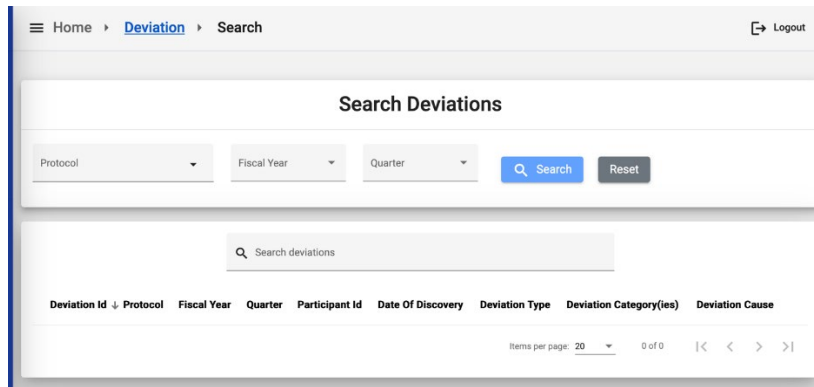
Deviations Tile

Deviation's tile shows links to create new deviation, search existing deviations and see deleted deviations

Reports Tile

Reports tile shows links to of reports present in the system

Help Tile

Help tile shows links to User Manual link, and Frequently Asked Questions (FAQs) along with an option to create support ticket

Entering a Deviation

Create Deviation

To create a new deviation select Create New Deviation tab in Deviation's tile.

Chose the protocol from the list

The branch, PI and type of protocol will be auto populated.

Fill out all required fields and then submit the deviation.

The following table is a list of the fields and descriptions:

Field Name	Description
Protocol*	Use the pick list to select the protocol. Start typing in the protocol number to narrow the list.
PI Branch	Derived field
Type of Protocol	Derived field. Will be either observational or interventional
PI	Derived field
Participant ID[1]	Use the subject's unique study ID. Should be the same as what is being used for CRF data collection.
Date of Occurrence	Date the deviation occurred. The field will pre-populate to current date.
Date of Discovery*	Date when the deviation was discovered.
Discovered By*	Select from pick list: Monitor/Auditor or Research Team
Description[1]	Describe the deviation. Justify the selected deviation category and cause in the deviation description
Type of Deviation[1]	Select either Major or Minor
Deviation Category [1, 2, 4, 5, 6,7]	Select all that apply from the following list: • Non-lab study procedure/assessment conducted out of timeframe • Laboratory procedure conducted out of timeframe • Non-lab study procedure/assessment not done • Laboratory procedure not done • Study visit out of timeframe

	- Study visit not done - Participant failure to return diary - Eligibility - Study drug administration - Study drug accountability - Sample loss or unanticipated destruction - Expedited event reported to Sponsor or IRB outside of timeframe - Expedited event not reported to Sponsor or IRB - Informed consent - Site over-enrollment - Study drug storage - Prohibited Concomitant medication/measure used - Other, please specify reason
Deviation Causes [1, 2, 3,7]	Select all that apply from the following list: - Study Team - Non-Study Team Staff Member (use for NIH staff) - Participant - Weather/Travel Issues - Sponsor/CRO - COVID-19 pandemic - Non-NIH staff - Other, please specify reason

* Mandatory Field

[1] Optional in the PDTS to report the events that are non-adherence and don't meet the definition of a protocol deviation for CCR held IND/IDE studies. To report those events, leave the field blank and fill out Sponsor Required Information section only. This field will be mandatory for a deviation for CCR held IND/IDE studies.

[2] If the deviation with the same category/cause occurred with a participant at different dates, make a separate entry for each case.

[3] If the cause of deviation is the outside provider's decision/oversight, please select *Non-NIH Staff* as a deviation cause.

[4] If visit was not done per protocol or done out of time frame, submit one deviation for the event, not multiple deviations for every missed/delayed procedure.

[5] If the visit/procedure was not done per protocol or done out of time frame allowed due to AE/ SAE, select the *Study Team* and not a *Participant* as a cause, since it is the PI's decision to deviate from the protocol schedule.

[6] If the blood for the labs was collected per protocol, but appropriate tests weren't done due to technical issues, select *Sample loss or unanticipated destruction* option for deviation cause.

[7] If the deviation with the same category/cause occurred with multiple participants on the same protocol, make a separate entry for each case.

CCR-held IND/IDE protocols

The Office of Sponsor and Regulatory Oversight (OSRO) also tracks issues of non-compliance with GCP. If the protocol is a CCR-held IND/IDE study, an additional mandatory Sponsor Required Information section will need to be completed.

The following table is a list of the fields and descriptions for this section:

Field Name	Description
Report Date	Current date. This will always be the day your start the deviation and is prepopulated.
Completed By	Prepopulated since NIH log in is required to access the database.
Non-Adherence Category*	Select from the following pick list: • Lab specimen related • Protocol procedure or assessment • Study product related • Treatment dose administration • Treatment Schedule
Non-Adherence Reason*	Select from the following pick list: • Equipment failure • Laboratory error • Other, added to description • Pharmacy error • PI/Team decision • Staff member error
Date of Non-Adherence*	Enter the date the non-adherence occurred.
Date of IRB Report, if required	Enter date the non-adherence event was reported to the IRB via a REF in iRIS, if applicable per HRPP Policy 801.
Description of the Non-Adherence*	Describe the non-adherence in detail.
Non-Adherence Action*	Describe the action(s) taken to resolve or avoid non-adherence recurrence.

Did non-adherence result in AE or SAE?	Select "yes" or "no". Automatic default set to No
Did non-adherence result in subject withdrawal?	Select "yes" or "no". Automatic default set to No
Did or could non-adherence affect product stability?	Select "yes" or "no". Automatic default set to No
* Mandatory field	

The Office of Education and Compliance receives an email notification when deviation is submitted into the PDTS. The deviation will be reviewed. If any clarifications are needed, a member from the OEC, will contact the submitter. If minor changes need to be done in PDTS, OEC team will do after verification with the team.

Search/Update Existing Deviations

To search an existing deviation, use Search Deviations tab in Deviation's tile. Choose the protocol from the list. The search can be narrowed by fiscal year or/and quarter.

After the deviation pops up, you can delete or update the entry.

Deleted Deviation

To search the deleted deviation, use Deleted deviations tab in Deviation's tile.

Choose the protocol from the list and search. You can only view the deleted deviations. There is no option to retrieve them.
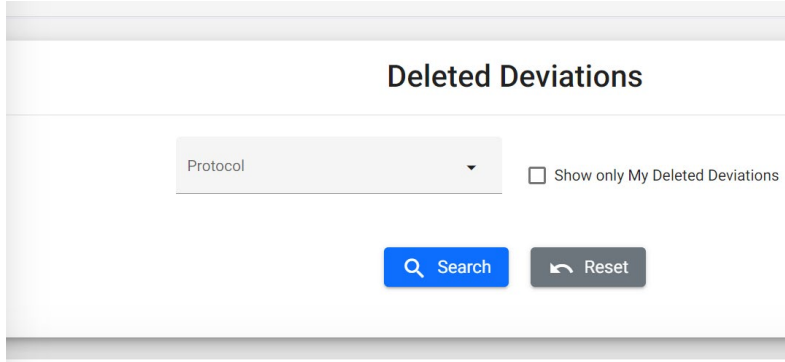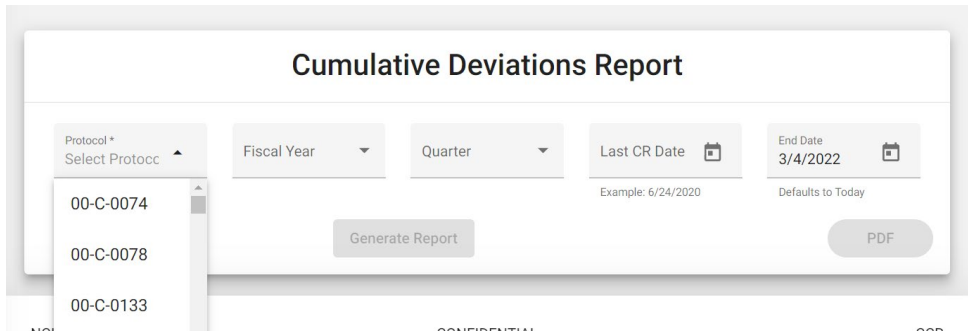
Reports

Cumulative Deviations Report

Use Cumulative Deviations Report to get a number of submitted deviations both total and by category/cause.

Choose the protocol number. The search can be narrowed by fiscal year, quarter and last CR date. Please leave those fields blank if you want to see all submitted deviations for the protocol. After report is submitted it can be transferred into PDF format.

CCR All Deviations Report

Use CCR All Deviations Report to get the deviations with all submitted details, description.

Choose the protocol number. The search can be narrowed by fiscal year, quarter and start date. Please leave those fields blank if you want to see all submitted deviations for the protocol. After report is submitted it can be transferred into PDF and Excel format.

OSRO All Deviations Report

Use OSRO All Deviations Report to the non-adherence report with all submitted details, description. Choose the protocol number. The search can be narrowed by fiscal year, quarter and start date. Please leave those fields blank if you want to see all submitted non-adherences for the protocol. After report is submitted it can be transferred into PDF and Excel format.

Quarterly, Yearly and Branch/PI reports are used for the Office of Education and Compliance purposes.

Help

Help button is located at the right top part before Login/Logout button on every page. Click on it to see the Help page which lists User Manual link, and Frequently Asked Questions (FAQs) along with an option to create support ticket.

User Guide

User Manual hosted on CCR wiki page and clicking on the User Guide link redirects you to that page.

Frequently Asked Questions

The Frequently Asked Questions (FAQs) page lists commonly asked questions from the users. See the below image for reference

Create Support Ticket

If the Frequently Asked Questions page does not have an answer for your question and you want to contact support team, click **Create Support Request** button. It will open a pop-up window in which you need provide issue details. Your information is automatically populated if you already logged in and provide below

- Issue Summary
- Issue Detailed Description
- Attachments (optional)

See below image for reference