

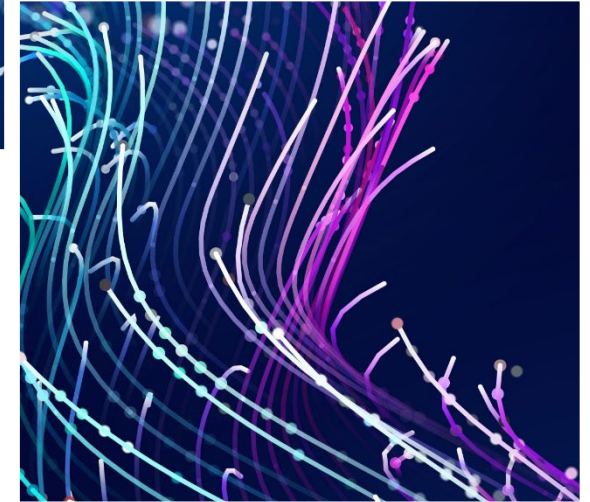


Insider Client Training Session: Protocol Deviations

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February 6, 2025

Thanks for joining. We will
be starting shortly.



Agenda

1

Overview of
Protocol
Deviations

2

Configuration of
Global and
Study-level
PDAPs

Protocol Deviation Assessment
Plans

3

Using Protocol
Deviations in
Data Central

4

Questions





Protocol Deviations Overview



Overview of Protocol Deviations

Protocol Deviations within illuminate:

- Provides a centralized location for all Protocol Deviations within a study
 - ★ Standards, Data, Action all in one platform
- Enables you to then categorize and organize them to easily identify trends
- Understanding the trends can then help to reduce PDs going forward
- Accessed from Data Central



Global vs Study-level PDAPS

Configuration is required before Protocol Deviations can be used

Global Protocol Deviation Assessment Plans

- Requires the Global PDAP Configure privilege
- Accessed from:
9-dot icon > Metadata Management > Protocol Deviation Assessment Plan
- Can import a list of PDAPs or manually enter them
- Global PDAPs can be associated to studies

Study-level Protocol Deviation Assessment Plans

- Study settings must have Protocol Deviations turned on
- Requires the Data Central and Study Configure privileges
- Accessed from within Data Central Configuration
- Can add Global PDAPs or import or manually add study specific PDAPs

After the PDAPs have been configured, Protocol Deviations are viewed / managed from within Data Central.



Protocol Deviations in Data Central

After configuration...

Protocol Deviations Breakdown

42 Total Deviations

30 Subject
6 Site
2 Country
4 Study

Important/ Non-Important

21 Non-Important
21 Important

Top Categories

8 Investigator
7 Administrative
5 Protocol

Review Progress

12/41

Review Status

18 Unreviewed
12 Reviewed
11 Re-review

Status	Description	Standard Category	Standard Description	Importance Classification	Code	PD Type	Subject	Site	Identified Date	Start Date	End Date	Category	Classification	Importance	ID
8 Reviewed	Subject had a PK sample drawn, ...	Safety	Adverse Event Reporting	No	NCMP-01	Subject	0001-001	Mansfield Hospital	2023-04-04	2018-12-18	2018-12-24	Trial Procedures	Non-Important	No	PD-22
2 Unreviewed	Subject did not complete study fi...	Administrative	Missed Visit	Yes	ADMIN-01	Subject	0002-001	Uniklinik Tuebingen	2020-01-21		1900-01-01	Trial Procedures	Important	Yes	PD-01
2 Reviewed	Subject did not complete QoL as...	Administrative	Missed Visit							2021-03-03	1900-01-01	Trial Procedures	Non-Important	No	PD-14
1 Reviewed	Subject did not complete QoL as...	Regulatory	Failure to Report							2021-03-03	1900-01-01	Trial Procedures	Non-Important	No	PD-14
1 Reviewed	Subject enrolled in incorrect trial ...	Regulatory	Failure to Report							2021-11-03	2021-11-03	Trial Procedures	Important	Yes	PD-14
Unreviewed	Lab result missing: Protein, CK, F...	Regulatory	Failure to Report							2019-07-29	2019-08-15	Trial Procedures	Non-Important	No	PD-11
1 Reviewed	Required on-study laboratory test...	Investigator	Improper Dosing							1900-01-01	1900-01-01	Trial Procedures	Non-Important	No	PD-21
1 Canceled	Improper dosing amount admini...	Investigator	Improper Dosing							1900-01-01	1900-01-01	Study Intervention (Study Treatm...	Non-Important	No	PD-01
3 Re-review	Lab result missing: Protein, CK, F...	Administrative	Missed Visit							2019-08-01	2019-08-08	Lab Assessments	Non-Important	No	PD-11
2 Re-review	Lab result missing: Protein, CK, F...	Data Integrity	Informed Consent							2019-08-16		Lab Assessments	Non-Important	No	PD-11
2 Reviewed	Lab result missing: Protein, CK, F...	Data Integrity	Informed Consent							2019-08-20		Lab Assessments	Non-Important	No	PD-11
Re-review	Improper dosing amount admini...	Investigator	Improper Dosing							2014-06-19	2014-06-30	Study Intervention (Study Treatm...	Non-Important	No	CTMS
Unreviewed	Subject administered incorrect st...	Investigator	Improper Dosing							2017-06-29	2017-07-04	Study Intervention (Study Treatm...	Important	Yes	CTMS
Unreviewed	Subject's withdrawn consent not ...	Regulatory	Failure to Report							2019-10-25	2019-10-30	Safety Reporting	Non-Important	No	CTMS
2 Unreviewed	Test	Safety	Adverse Event Reporting							2024-06-18	2024-06-20				
Unreviewed	No PDAP														
2 Reviewed	Recruitment criteria were widened.	Documentation	Protocol Deviation Log	No	DOC-01	Study			2024-06-11	2024-04-15					
Reviewed	temperature excursion not adequ...	Protocol	Non-compliance	Yes	PTCL-01	Site		Alabama	2024-07-09	2024-07-04	2024-07-06				
Unreviewed	Test	Documentation	Protocol Deviation Log	No	DOC-01	Country			2024-07-16						
Unreviewed	Improper IC	Protocol	Non-compliance	Yes	PTCL-01	Study			2024-07-17						

Privileges for using Protocol Deviations:

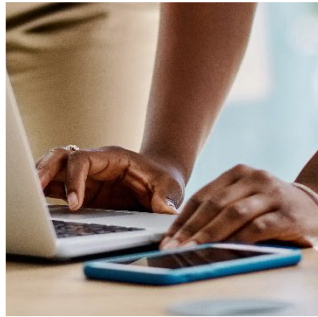
- Protocol Deviation Edit, or
- Protocol Deviation View
- Data Central

All users of Protocol Deviations can add comments.





Let's take a look...



Thank you

