CDISC Protocol Deviation Sub-Team SDTMIG 4.0 Updates and Open Topics

Éanna Kiely Associate Director, Statistical Programming, Data Standards & Governance
Alexion, AstraZeneca Rare Disease
14MAY2025

Meet the Speaker

Éanna Kiely

Title: Associate Director, Statistical Programming – Data Standards & Governance

Organization: Alexion, AstraZeneca Rare Disease

In Alexion Éanna Kiely is the lead of the SDTM standards team, co-lead of the E2E Standards Governance Team and member of the Standards team for ADaM, CRF and Laboratory Data.

He is also a volunteer on the CDISC SDTM team including the co-lead of the Protocol Deviations team.

He is an author on CDASHIG 2.0, SDTMIG 3.3, 3.4 and draft 4.0 and a trainer in CDASH and SDTM.

Disclaimer and Disclosures

- *The views and opinions expressed in this presentation are those of the author(s) and do not necessarily reflect the official policy or position of CDISC or Alexion AstraZeneca Rare Disease.*

- *The author has no real or apparent conflicts of interest to report.*

Agenda

1. Heterogeneity of Protocol Deviation Classification (/Categorization/Severity) Assessments in Industry
2. FDA PD Guidance
3. SDTMIG 4.0 Updates
   - DVCLASI (Classification of Protocol Deviation) Variable
4. Industry, Regulatory and ICH Approaches to PD Classifications
5. PD Management in Define.xml and BIMO and SITEID/INVID

Survey of Protocol Deviation Classification Mapping Approaches

DVCAT	7	47%
SUPPDV	4	27%
DVSEV	3	20%
Not Needed	1	7%

IMPORTANT/ NON-IMPORTANT	5	38%
Major/Minor	3	23%
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#	Organization	Variable	CT	Comment	PD Sub-Team
1	Alexion (AstraZeneca Rare Disease)	DVCAT	IMPORTANT, NON-IMPORTANT	DVSEV is used if Major and Minor are reported. They trigger CRA workflows. Both Important/Non-Important and Major/Minor have been used in the same study.	Y
2	AstraZeneca	DVCAT	Important, Non-Important		
3	Roche	DVCAT	Major, Minor	CDISC Advisory Committee (CAC) member supports DVSEV	
4	J&J	DVCAT	Major, Minor		
5	Galapagos	DVCAT	MAJOR-MINOR		Y
6	Bayer	DVCAT		CAC member supports DVSEV	Y
7	UCB	DVCAT			Y
8	Eli Lilly	DVSEV		CAC member supports DVSEV	
9	AbbVie	DVSEV		CAC member supports DVSEV	
10	GSK	SUPPDV			
11	Fortrea	SUPPDV - Criticality	Important, Non-Important	CAC member supports DVSEV	
12	Novo Nordisk	SUPPDV DEVTYPE	PD Imp, PD Non imp		
13	Astellas	SUPPDV.DVCLAS (Deviation Classification)	IMPORTANT/NON-IMPORTANT		Y
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FDA PD Guidance

- The FDA released the ***Protocol Deviations for Clinical Investigations of Drugs, Biological Products, and Devices Guidance for Industry*** (2024-12-30) for Public Consultation.
  - Comments due: 28FEB2025 – Comments were extended but not closed.
- The FDA PD Guidance clarifies the use of Important Protocol Deviations as their preferred term vs Major, Critical or Significant and stating that these terms are synonymous.
  - ! Does not provide a term for Non-Important.
- The FDA requested sponsors to provide an assessment of Importance in a variable in the parent DV domain.

CDISC PD sub-team presented the draft SDTMIG 4.0 including DVCLASI (Classification of Protocol Deviation) to the FDA in November 2024 and industry feedback on ICH Guidance

FDA PD Guidance: Importance Variable

Does this mean a new variable like DVCLASI (Classification of Protocol Deviation) or a dedicated variable e.g. DVCAT?

89 **III. DISCUSSION**

184 **B. Roles and Responsibilities in Monitoring, Mitigating, and Reporting Protocol**

185 **Deviations**

218 *2. Role of the Sponsor in Evaluating, Mitigating, and Reporting Protocol Deviations*

246 Sponsors should also report all protocol deviations in the Study Data Tabulation

247 Model Protocol Deviation (DV) domain, which will assist FDA in confirming whether protocol

248 deviations had a significant impact on data quality. Sponsors should include a variable in the

249 DV domain that provides the sponsor's determination of whether the protocol deviation was

250 important.

A comment was sent to the FDA requesting clarification and that an update be added to the TCG PD section after the final PD Guidance

FDA Comment 1: DV Variable for Classification

- In lines 248 to 250 it states that "*a variable in the DV domain that provides the sponsor's determination of whether the protocol deviation was important.*". Is it acceptable for a sponsor to use an existing SDTM variable e.g. DVCAT (Category for Protocol Deviation) or should a new variable specific to the purpose of "*determination of whether the protocol deviation was important*" be used e.g. DVCLASI (Classification of Protocol Deviation) as proposed in draft SDTMIG 4.0.

PD sub-team assumes any existing variable can be used e.g. DVCAT, DVSEV

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These sponsors will need to move the classification variable to the parent domain and potentially lose DVCAT and DVSCAT and any CT present in them.

FDA Comment 4: SDTM DV Guidance mentioned in FDA sdTCG

- When the final PD Guidance is published by the FDA is it possible to update the FDA Study Data Technical Conformance Guide (sdTCG) section 4.1.1.3 DV Domain (Protocol Deviations) with the relevant updates for the DV domain or a reference the FDA PD Guidance.
- Having the FDA PD Guidance in or referenced from the sdTCG will support sponsors in adhering to the guidance.

Draft SDTMIG 4.0 section 6.2.7 Protocol Deviation (DV)

Assumptions 3 describes the new DVCLASI (Classification of Protocol Deviation) variable

3. Classification: DVCLASI can be used to classify protocol deviations based on criteria including their ability to significantly affect the completeness, accuracy, and/or reliability of the study data or that might significantly affect a subject's rights, safety, or well-being (see E3 Q&As (R1) 2012, Section 3.7[2]). Sponsor controlled terminology for DVCLASI could include pairs of terms of IMPORTANT and NON-IMPORTANT or MAJOR and MINOR etc.

STUDYID	DOMAIN	USUBJID	DVSEQ	DVTERM	DVDECOD	DVCAT	DVCLASI
ABC123	DV	123101	1	IVRS PROCESS DEVIATION - NO DOSE CALL PERFORMED.	TREATMENT DEVIATION	STUDY INTERVENTION	NON-IMPORTANT
ABC123	DV	123103	1	DRUG XXX ADMINISTERED DURING STUDY TREATMENT PERIOD	EXCLUDED CONCOMITANT MEDICATION	PROHIBITED CONCOMITANT INTERVENTION	IMPORTANT
ABC123	DV	123103	2	VISIT 3 DOSE <15 MG	TREATMENT DEVIATION	STUDY INTERVENTION	IMPORTANT
ABC123	DV	123104	1	TOOK ASPIRIN	PROHIBITED MEDS	PROHIBITED CONCOMITANT INTERVENTION	IMPORTANT

Draft SDTMIG 4.0 section 6.2.7 Protocol Deviation (DV)

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Order	Variable Name	Variable Label	Codelist	Role	Variable Group	CDISC Notes	Notes	Examples	Core
12	DVCLASI	Classification of Protocol Deviation		Qualifier	Event Impact Variable Group	A classification of protocol deviations based on the potential impact to the completeness, accuracy, and/or reliability of the study data, or to a subject's rights, safety, or well-being. (ICH E3 Q&As (R1))	See DV Assumption 3.	"IMPORTANT"/ "NON-IMPORTANT"; "MAJOR"/ "MINOR"; "CRITICAL"/ "NON-CRITICAL".	Perm

STUDYID	DOMAIN	USUBJID	DVSEQ	DVTERM	DVDECOD	DVCAT	DVCLASI
ABC123						STUDY INTERVENTION	NON-IMPORTANT
ABC123						OHIBITED CONCOMITANT INTERVENTION	IMPORTANT
ABC123						STUDY INTERVENTION	IMPORTANT
ABC123	DV	123104	1	TOOK ASPIRIN	PROHIBITED MEDS	PROHIBITED CONCOMITANT INTERVENTION	IMPORTANT

The PD sub-team did not set CT for the DVCLASI variable since there was no clear regulatory/ICH Guidance

FDA PD Guidance: Controlled Terminology Recommendations – Important Only

CDISC Submission	CDISC Synonym(s)
DVCLASI	Classification for Protocol Deviation
IMPORTANT	Major, Critical, Significant

89 **III. DISCUSSION**

91 **A. Protocol Deviations**

116 1. *Important Protocol Deviations*

118 As noted above, in this guidance an important protocol deviation is a subset of protocol
119 deviations that might significantly affect the completeness, accuracy, and/or reliability of the
120 study data or that might significantly affect a subject's rights, safety, or well-being. While other
121 terms such as major, critical, and significant have sometimes been used to classify such protocol
122 deviations, FDA recommends using *important* to encompass all these terms.

Could this form the basis for a SDTM CT for DVCLASI?

FDA PD Guidance: Controlled Terminology Recommendations – Non-Important Undefined

CDISC Submission	CDISC Synonym(s)
DVCLASI	Classification for Protocol Deviation
IMPORTANT	Major, Critical, Significant
NON-IMPORTANT	Minor, Noncritical, Non-Significant

89 **III. DISCUSSION**

91 **A. Protocol Deviations**

175 2. All Other Protocol Deviations

176 All other protocol deviations that do not meet the definition of an important protocol deviation

177 may encompass the commonly used terms minor, noncritical, and non-significant deviations.

Is there sufficient ICH and regulatory guidance available for CDISC to propose CT?

Should CDISC propose a SDTM CT for DVCLASI with only Important or also add Non-Important?

Request the FDA to add "Non-Important" based on BIMO TCG 3.1 Appendix 3 Table B

Variable Index	Variable Name	Variable Label	Notes or Description
28	NOIMPDEV	Number of Non-Important Protocol Deviations	Total number of protocol deviations, excluding important protocol deviations, at a given site by treatment arm for subjects in the SAFPOP. A protocol deviation is any change, divergence, or departure from the study design or procedures defined in the protocol or associated investigational plans that is not implemented or intended as a systematic change.

FDA BIMO Guidance

FDA BIMO mentions Important and Non-Important PDs

Bioresearch Monitoring Technical Conformance Guide v3.1 2024-10 references the ICH E3 R1 Q&A

125 **7. Protocol Deviations**

126

127 This by-subject, by-clinical site listing should include all protocol deviations. The listing should

128 include a description of the deviation and identify whether the sponsor considered the deviation

129 to be an important or non-important protocol deviation.[5]

[5] See ICH guidance for industry E3 Structure and Content of Clinical Study Reports — Questions and Answers (R1) (January 2013).

APPENDIX 3: CLINICAL SITE DATA ELEMENTS SUMMARY LISTING

Table B: Clinical Site Data Elements Summary Listing

Variable Index	Variable Name	Variable Label	Type	Controlled Terms or Format
27	IMPDEV	Number of Important Protocol Deviations	Num	Integer
28	NOIMPDEV	Number of Non-Important Protocol Deviations	Num	Integer

ICH E6 R3: Good Clinical Practice Updates Are In Line With the FDA PD Guidance

- ICH E6 (Good Clinical Practice) R3 (2025-01-06)

2.5 Compliance with Protocol

2.5.3 The investigator should document all protocol deviations. In addition to those identified by the investigator themselves, protocol deviations relevant to their trial participants and their conduct of the trial may be communicated to them by the sponsor (see section 3.11.4.5.1(b)). In either case, the investigator should review the deviations, and for those deviations deemed important, the investigator should explain the deviation and implement appropriate measures to prevent a recurrence, where applicable (see section 3.9.3).

3.9 Sponsor Oversight

3.9.3 The sponsor should determine necessary trial-specific criteria for classifying protocol deviations as important. Important protocol deviations are a subset of protocol deviations that may significantly impact the completeness, accuracy and/or reliability of the trial data or that may significantly affect a participant's rights, safety or wellbeing.

ICH E6 R3 aligns with the FDA PD Guidance

ICH PD Terminology Protocol Violation vs Deviation

- ICH E9 - Statistical Principles for Clinical Trials

1.1 Background and Purpose

For example, protocol violations and exclusion of subjects from analysis based upon knowledge of subject outcomes are possible sources of bias that may affect the accurate assessment of t

ICH E9 appears to use protocol violation more but is significantly older with R1 from 1998-02-05

3.6 Data Capture and Proce

It should focus on the data necessary to implement the planned analysis, including the context information (such as timing assessment relative to dosing) necessary to confirm protocol compliance or identify important protocol deviations.

ICH PD Terminology Protocol Violation vs Deviation

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ICH E9 appears to use protocol violation more but is significantly older with R1 from 1998-02-05

ICH E9 R1 Addendum on Estimands

A.1. PURPOSE AND SCOPE

…to explore the impact of protocol violations and deviations can be addressed in a way that is less bia

ICH E9 Addendum appears to use protocol violation in the place of Important Protocol Deviation and is from 2019-11-20

Other Regulatory Documents Related to Important PDs: EMA Serious Breaches

The EMA discuss the concept of Important protocol deviations and serious breaches in "**Guideline for the notification of serious breaches of Regulation (EU) No 536/2014 or the clinical trial protocol** (2023-06-23 EMA/698382/2021)"

5.1. What needs to be reported

Deviations from clinical trial protocols, good clinical practice (GCP) and/or European or national legislation may occur in clinical trials and where these are considered important, as defined by the ICH E3 guideline on the structure and content of clinical study reports, they should be described in the clinical study report (CSR). It is important to underline that an important deviation as defined in the ICH guideline E3 questions and answers (R1) is not equivalent to the definition of a serious breach and therefore an important deviation is not necessarily also a serious breach and vice versa. Nevertheless, all serious breaches should be included in the corresponding clinical study report.

Industry Groups: TransCelerate Statements on PD Terminology Synonyms

- The TransCelerate PD Guidance in section 3.2 and Appendix 2 states:

Preferred Term	Definition	Equivalent Terms / Examples
Important	Term used to classify protocol deviations.	Major Critical Significant
Non-Important	Term used to classify protocol deviations.	Minor

- TransCelerate bases this on the ICH E3 R1 Q&A (2012-07-06)

ICH E3 R1 Q&A (2012-07-06) – Important Deviations

E3 Implementation Working Group ICH E3 Guideline: Structure and Content of Clinical Study Reports Questions & Answers (R1) (2012-07-06) Q&A: 3. TERMINOLOGY 7 (2012-06)

Questions	Answers
Section 10.2 of the ICH E3 Guideline requests an accounting of important protocol deviations. However, the flowchart in Annex IVa of E3 (Subject Disposition) recommends that data be provided on the number of subjects withdrawn from the study due to “protocol violations.” Neither the term “protocol deviations” nor “protocol violations” has been previously defined by ICH. What is the distinction between a protocol deviation, important protocol deviation, and a protocol violation? Can these terms be clarified? Additionally, does the Guideline allow sponsors’ flexibility in defining what constitutes an important protocol deviation for a trial?	A protocol deviation is any change, divergence, or departure from the study design or procedures defined in the protocol. Important protocol deviations are a subset of protocol deviations that may significantly impact the completeness, accuracy, and/or reliability of the study data or that may significantly affect a subject's rights, safety, or well-being. For example, important protocol deviations may include enrolling subjects in violation of key eligibility criteria designed to ensure a specific subject population or failing to collect data necessary to interpret primary endpoints, as this may compromise the scientific value of the trial. Protocol violation and important protocol deviation are sometimes used interchangeably to refer to a significant departure from protocol requirements. The word “violation” may also have other meanings in a regulatory context. However, in Annex IVa, Subject Disposition of the ICH E3 Guideline, the term protocol violation was intended to mean only a change, divergence, or departure from the study requirements, whether by the subject or investigator, that resulted in a subject’s withdrawal from study participation. (Whether such subjects should be included in the study analysis is a separate question.) To avoid confusion over terminology, sponsors are encouraged to replace the phrase “protocol violation” in Annex IVa with “protocol deviation”, as shown in the example flowchart below. Sponsors may also choose to use another descriptor, provided that that the information presented is generally consistent with the definition of protocol violation provided above. The E3 Guideline provides examples of the types of deviations that are generally considered important protocol deviations and that should be described in Section 10.2 and included in the listing in Appendix 16.2.2. The definition of important protocol deviations for a particular trial is determined in part by study design, the critical procedures, study data, subject protections described in the protocol, and the planned analyses of study data. In keeping with the flexibility of the Guideline, sponsors may amend or add to the examples of important deviations provided in E3 in consideration of a trial’s requirements. Substantial additions or changes should be clearly described for the reviewer.

ICH E3 R1 Q&A (2012-07-06) – Important Deviations

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ICH E3 R1 Q&A and now E6 R3 define Important Protocol Deviations

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Should CDISC propose a SDTM CT for DVCLASI with only Important or also add Non-Important?

The ICH and multiple regulators appear to use Important for PDs consistently with Non-Important appearing to be the natural opposite

FDA Comment 3: DVCLASI Controlled terminology Non-Important Undefined

- In lines 176 and 177 its states that the sponsor can choose the term to describe "*All other protocol deviations that do not meet the definition of an important protocol deviation may encompass the commonly used terms minor, noncritical, and non-significant deviations.*".
- Is it possible for the FDA PD guidance to be updated to align the FDA BIMO TCG 3.1 Appendix 3 Table B where the variable 28 NOIMPDEV (Number of Non-Important Protocol Deviations) uses the term Non-Important?
- This also aligns with the TransCelerate Protocol Deviations Guidance (2020-08-10) section 3.2.
- If it is not possible for the FDA to the single term of "Non-Important" is it possible to add "Non-Important" to the list of examples. Some organizations can read non-binding recommendations from the FDA as Normative and change their processes based on them.

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A new DVCLASI CT will impact a number of sponsors

Draft SDTMIG 4.0 section 6.2.7 Protocol Deviation (DV) Internal Review

Assumptions 4 provides example CT for DVCAT separating it from DVDECOD which summarizes the DVTERM

4. DVCAT (DV categorization) is for which category a protocol deviation is related to (e. g. INFORMED CONSENT, STUDY INTERVENTION, PROHIBITED CONCOMITANT INTERVENTION).

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ABC123	DV	123104	1	TOOK ASPIRIN	PROHIBITED MEDS	PROHIBITED CONCOMITANT INTERVENTION	IMPORTANT

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PD Sub-team categories based on the TransCelerate PD Guidance

Category
Informed Consent
Inclusion/ Exclusion
Study Intervention
Prohibited Concomitant Medication
Safety Reporting
Trial Procedures
Discontinuation

STUDYID	DOMAIN	USUBJID	DVSEQ	DVTERM	DVDECOD	DVCAT	DVCLASI
ABC123	DV	123101	1	IVRS PROCESS DEVIATION - NO DOSE CALL PERFORMED.	TREATMENT DEVIATION	STUDY INTERVENTION	NON-IMPORTANT
ABC123	DV	123103	1	DRUG XXX ADMINISTERED DURING STUDY TREATMENT PERIOD	EXCLUDED CONCOMITANT MEDICATION	PROHIBITED CONCOMITANT INTERVENTION	IMPORTANT
ABC123	DV	123103	2	VISIT 3 DOSE <15 MG	TREATMENT DEVIATION	STUDY INTERVENTION	IMPORTANT
ABC123	DV	123104	1	TOOK ASPIRIN	PROHIBITED MEDS	PROHIBITED CONCOMITANT INTERVENTION	IMPORTANT

Draft SDTMIG 4.0 section 6.2.7 Protocol Deviation (DV) Internal Review

Assumptions 4 provides example CT for DVCAT separating it from DVDECOD which summarizes the DVTERM

4. DVCAT (DV categorization) is for which category a protocol deviation is related to (e. g. INFORMED CONSENT, STUDY INTERVENTION, PROHIBITED CONCOMITANT INTERVENTION).

PD Sub-team categories based on the TransCelerate PD Guidance

Category
Informed Consent
Inclusion/ Exclusion
Study Intervention
Prohibited Concomitant Medication
Safety Reporting
Trial Procedures
Discontinuation

TransCelerate PD Guidance based on ICH E3

STUDYID	DOMAIN	USUBJID	DVSEQ	DVTERM	DVDECOD	DVCAT	DVCLASI
ABC123	DV	123101	1	IVRS PROCESS DEVIATION - NO DOSE CALL PERFORMED.	TREATMENT DEVIATION	STUDY INTERVENTION	NON-IMPORTANT
ABC123	DV	123103	1	DRUG XXX ADMINISTERED DURING STUDY TREATMENT PERIOD	EXCLUDED CONCOMITANT MEDICATION	PROHIBITED CONCOMITANT INTERVENTION	IMPORTANT
ABC123	DV	123103	2	VISIT 3 DOSE <15 MG	TREATMENT DEVIATION	STUDY INTERVENTION	IMPORTANT
ABC123	DV	123104	1	TOOK ASPIRIN	PROHIBITED MEDS	PROHIBITED CONCOMITANT INTERVENTION	IMPORTANT

FDA PD Guidance § III.A.1		**Impact the protection of trial participants and the assessment of safety**
Trial Procedures	1	Failure to conduct study procedures designed to assess participant safety or failure to adequately monitor participants; for example, (1) failure to collect important laboratory assessments for monitoring safety issues or (2) failure to administer the study product according to specifications in the protocol
Prohibited Concomitant Medication	2	Administration of concomitant treatment prohibited by the study protocol that may increase risks to participants (e.g., drug-drug interactions) and/or impact interpretation of a device's safety and efficacy
Informed Consent	3	Failure to obtain informed consent or meet other applicable requirements under FDA regulations for the protection of human subjects11 under 21 CFR part 50
Trial Procedures: Privacy	4	Failure to protect a participant's identifiable private protected health information
Discontinuation	5	Failure to withdraw investigational product administration from trial participants who meet withdrawal criteria
Study Intervention	6	Administration of the wrong treatment or incorrect dose to trial participants or implantation of an incorrect device
Trial Procedures: Randomization	7	Failure to adhere to the protocol-specified randomization scheme
		May reduce the reliability of conclusions on effectiveness
Inclusion/Exclusion	8	Enrollment of a trial participant in violation of key eligibility criteria designed to ensure a specific participant population
Trial Procedures	9	Failure to collect data to evaluate important study endpoints (e.g., primary or secondary endpoints)
Trial Procedures: Unblinding	10	Premature unblinding of a trial participant's treatment allocation for reasons other than those specified in the study protocol

FDA PD Guidance § III.A.1		**Impact the protection of trial participants and the assessment of safety**
Trial Procedures	1	Failure to conduct study procedures designed to assess participant safety or failure to adequately monitor participants; for example, (1) failure to collect important laboratory assessments for monitoring safety issues or (2) failure to administer the study product according to specifications in the protocol
Prohibited Concomitant Medication	2	Administration of concomitant treatment prohibited by the study protocol that may increase risks to participants (e.g., drug-drug interactions) and/or impact interpretation of a device's safety and efficacy
Informed Consent	3	Failure to obtain informed consent or meet other applicable requirements under FDA regulations for the protection of human subjects11 under 21 CFR part 50
Trial Procedures: Privacy	4	Failure to protect a participant's identifiable private protected health information
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Trial Procedures: Randomization	7	Failure to adhere to the protocol-specified randomization scheme
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The FDA proposed new categories

FDA PD Guidance § III.A.1		**Impact the protection of trial participants and the assessment of safety**
Trial Procedures	1	Failure to conduct study procedures designed to assess participant safety or failure to adequately monitor participants; for example, (1) failure to collect important laboratory assessments for monitoring safety issues or (2) failure to administer the study product according to specifications in the protocol
Prohibited Concomitant Medication	2	Administration of concomitant treatment prohibited by the st risks to participants (e.g., drug-drug interactions) and/or impa safety an
Informed Consent	3	Failure to other applicable requirements under FDA regulations for the pr er 21 CFR part 50
Trial Procedures: Privacy	4	Failure to private protected health information
Discontinuation	5	Failure to administration from trial participants who meet withdraw
Study Intervention	6	Administ ncorrect dose to tr f an incorr
Trial Procedures: Randomization	7	Failure to andomization scheme
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Trial Procedures	9	Failure to collect data to evaluate important study endpoints (e.g., primary or secondary endpoints)
Trial Procedures: Unblinding	10	Premature unblinding of a trial participant's treatment allocation for reasons other than those specified in the study protocol

EMA Serious Breach Categories

1. IMP
2. Temperature monitoring
3. IRT issues
4. Potential fraud
5. Source data
6. Emergency unblinding
7. Sample processing
8. Protocol compliance
9. SAE reporting
10. Consent
11. Access to data
12. Randomisation/ stratification errors
13. DSMB/DMC

The EMA proposed new categories

The FDA proposed new categories

PD Sub-Team Categories and CT Codetable

DVCAT	DVDECOD	Comments
STUDY INTERVENTION	PARTICIPANT RECEIVED ~~WAS ADMINISTERED~~ THE WRONG STUDY TREATMENT	Taken from TransCelerate Protocol Deviation Guidance
STUDY INTERVENTION	TREATMENT KIT NUMBER USED NOT CORRESPONDING TO THE PLANNED ONE	Came from a team member as a part of her company's DV library What would be DVTERM then?
STUDY INTERVENTION	PARTICIPANT RECEIVED ~~WAS ADMINISTERED~~ THE INCORRECT DOSAGE REGIMEN ~~DOSE UNIT~~ OR/AND ROUTE OF ADMINISTRATION FOR STUDY TREATMENT ~~AND/OR INACCURATE FREQUENCY OF ADMINISTRATION OR EXPIRED PRODUCT~~	Taken from TransCelerate Protocol Deviation Guidance
STUDY INTERVENTION	PARTICIPANT RECEIVED THE INCORRECT DOSAGE REGIMEN OR/AND ROUTE OF ADMINISTRATION FOR BACKGROUND MEDICATION/RESCUE MEDICATION	Maybe to use "REQUIRED MEDICATION" instead?

PD Sub-Team Categories and CT Codetable

DVCAT	DVDECOD	Comments
STUDY INTERVENTION	PARTICIPANT RECEIVED ~~WAS ADMINISTERED~~ THE WRONG STUDY TREATMENT	Taken from TransCelerate Protocol Deviation Guidance
STUDY INTERVENTION	TREATMENT KIT NUMBER USED NOT CORRESPONDING TO THE PLANNED ONE	Came from a team member as a part of her company's DV library
STUDY INTERVENTION	PARTICIPANT RECEIVED ~~WAS ADMI~~ DOSAGE REGIMEN ~~DOSE UNIT~~ OR/ ADMINISTRATION FOR STUDY TREATMENT ~~AND/OR INACCURATE FREQUENCY OF ADMINISTRATION OR EXPIRED PRODUCT~~	
STUDY INTERVENTION	PARTICIPANT RECEIVED THE INCORRECT DOSAGE REGIMEN OR/AND ROUTE OF ADMINISTRATION FOR BACKGROUND MEDICATION/RESCUE MEDICATION	Maybe to use "REQUIRED MEDICATION" instead?

The PD sub-team categories could be updated with FDA and EMA content before being published as a CDISC CT codetable

FDA PD Guidance: Submit All PDs

Organizations that only report Important PDs may need to update their processes for the FDA

89 **III. DISCUSSION**

184 B. Roles and Responsibilities in Monitoring, Mitigating, and Reporting Protocol

185 **Deviations**

218 *2. Role of the Sponsor in Evaluating, Mitigating, and Reporting Protocol Deviations*

246 Sponsors should also report all protocol deviations in the Study Data Tabulation

247 Model Protocol Deviation (DV) domain, which will assist FDA in confirming whether protocol

248 deviations had a significant impact on data quality. Sponsors should include a variable in the

249 DV domain that provides the sponsor's determination of whether the protocol deviation was

250 important.

Survey of Protocol Deviation Classification Mapping Approaches

DVCAT	7	47%
SUPPDV	4	27%
DVSEV	3	20%
Not Needed	1	7%

IMPORTANT/ NON-IMPORTANT	5	38%
Major/Minor	3	23%
Both	1	8%
IMPORTANT only	1	8%
No answer		23%

#	Organization	Variable	CT	Comment	PD Sub-Team
1	Alexion (AstraZeneca Rare Disease)	DVCAT	IMPORTANT, NON-IMPORTANT	DVSEV is used if Major and Minor are reported. They trigger CRA workflows. Both Important/Non-Important and Major/Minor have been used in the same study.	Y
2	AstraZeneca	DVCAT	Important, Non-Important		
3	Roche	DVCAT	Major, Minor	CDISC Advisory Committee (CAC) member supports DVSEV	
4	J&J	DVCAT	Major, Minor		
5	Galapagos	DVCAT	MAJOR-MINOR		Y
6	Bayer	DVCAT		CAC member supports DVSEV	Y
7	UCB	DVCAT			
8	Eli Lilly	DVSEV			
9	AbbVie	DVSEV			
10	GSK	SUPPDV			
11	Fortrea	SUPPDV - Criticality	Important, Non-Important		
12	Novo Nordisk	SUPPDV DEVTYPE	PD Imp, PD Non imp		
13	Astellas	SUPPDV.DVCLAS (Deviation Classification)	IMPORTANT/NON-IMPORTANT		Y
14	Chiesi Farmaceutici	None	IMPORTANT	Only reports IMPORTANT in SDTM therefore no variable is needed	Y

Organizations that only report Important PDs may need to update their processes for the FDA

FDA Comment 3: Reporting All PDs vs Important Only

- In Line246 to 248 , it states that "*Sponsors should also report all protocol deviations in the Study Data Tabulation Model Protocol Deviation (DV) domain, which will assist FDA in confirming whether protocol deviations had a significant impact on data quality.*". Does this new recommendation require all studies to include non-important PD in SDTM DV domain? In the FDA BIMO TCG 3.1 section I.A major (i.e., pivotal) studies are required. A number of sponsor organization in the CDISC Protocol Deviation Sub-Team do not currently report all PDs in the DV domain only those assessed as Important. This recommendation would have a large impact on these organizations.
- Does the FDA also recommend to include Non-Important PDs in ADaM or is this a sponsor decision?

FDA PD Guidance: Non-SDTM Recommendations - Protocol

89 **III. DISCUSSION**

91 **A. Protocol Deviations**

116 1. *Important Protocol Deviations*

136 It may be helpful for a protocol to define important protocol deviations and provide examples of

137 what constitutes such for the particular study. The following is a non-exhaustive list of protocol

138 deviations considered to be important by FDA due to the impact on the protection of trial

139 participants and the assessment of safety:

If new IPDs are identified should a protocol amendment take place?

In the recently published ICH E6 R3 it does not appear to state that Important PDs should be in the Protocol.
Neither are PDs in the TransCelerate CPT (v10)

FDA PD Guidance: Non-SDTM Recommendations - SAEs and SUSARs

The FDA recommends sponsors to include PDs that contributed to SUSARs/SAEs.

89 **III. DISCUSSION**

184 **B. Roles and Responsibilities in Monitoring, Mitigating, and Reporting Protocol**

185 **Deviations**

218 2. Role of the Sponsor in Evaluating, Mitigating, and Reporting Protocol Deviations

254 …sponsors must report serious and

255 unexpected suspected adverse reactions for drug products under 21 CFR 312.32; serious adverse

256 events under 21 CFR 320.31(d)(3) for IND-exempt bioavailability/bioequivalence studies; and

257 unanticipated adverse device effects under 21 CFR 812.150 (b)(1). Sponsors should note in such

258 mandatory reports when protocol deviations contributed to the occurrence of these events (e.g., a

259 safety laboratory test to monitor for a potential drug safety event was not collected, and the

260 safety event subsequently occurred and was serious).

The recommendation does not appear in Safety Reporting Requirements for INDs (Investigational New Drug Applications) and BA/BE (Bioavailability/Bioequivalence) Studies (2012-12). Could be useful information for Safety Teams.

FDA Comment 5: Protocol Referenced Documents

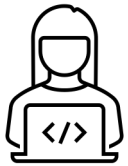
- An additional comment is provided by the CDISC Protocol Deviation Sub-Team in addition to the comments sent in m7o-nnsp-xeg5.
- In footnote 2 "*In this guidance, the term protocol encompasses both written protocols and their related plans and procedures (e.g., monitoring plan, statistical analysis plan).*" please consider updating the "*related plans and procedures*" examples that are provided in the brackets from "*(e.g. monitoring plan, statistical analysis plan)*" to other examples like "*(e.g. laboratory manual, pharmacy manual, eCOA/IRT guidance documents)*".
- The CDISC Protocol Deviation sub-team's recommendation is that Monitoring Plans and the SAP do not further describe activities for the site to perform to support the protocol but describe actions that the sponsor performs e.g. the SAP describes the analysis of trial data.
- The pharmacy manual can include information on the management of IMP temperature excursions by the site which can be included as Important (or Non-Important) protocol deviations. A deviation from the monitoring plan e.g. the CRA did not perform 100% Source Data Verification as required would not lead to a protocol deviation but a separate quality issue possibly managed by a sponsor/CRO CAPA.

In TransCelerate PD Process Guide section 3.1.3: *The event is related to the protocol or documents referenced in the protocol (e.g., laboratory manual)*

PD Management in Define.xml and BIMO and SITEID/INVID

- Define.xml Origin Type and Source
- BIMO Site Transfer Counts
- Organization Level SITEIDs and INVIDs

DV Define.xml Origin Type and Source



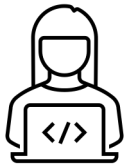
Fully outsourced CRO

If Protocol Deviations are entered by a fully outsourced CRO CRA the Origin Type could be Collected and the Source could be Vendor.

Protocol Deviations (DV) [STDTMIG 4.0] Location: dv.xpt

Variable	Label / Description	Type	Role	Length or Display Format	Controlled Terms or ISO Format	Origin / Source / Method / Comment
DVTERM	Protocol Deviation Term	text	Topic	200		Collected (Source: Vendor)

DV Define.xml Origin Type and Source



Fully outsourced CRO

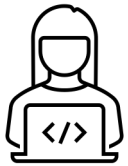
Sponsor CRA Employee

If Protocol Deviations are entered by a sponsor CRA the Origin Type could be Collected and the Source could be Sponsor.

Protocol Deviations (DV) [STDTMIG 4.0] Location: dv.xpt

Variable	Label / Description	Type	Role	Length or Display Format	Controlled Terms or ISO Format	Origin / Source / Method / Comment
DVTERM	Protocol Deviation Term	text	Topic	200		Collected (Source: Vendor)
DVTERM	Protocol Deviation Term	text	Topic	200		Collected (Source: Sponsor)

DV Define.xml Origin Type and Source



Fully outsourced CRO

Sponsor CRA Employee

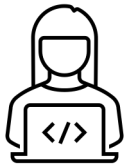
Functional Service Provider (FSP) CRA working on internal team

If Protocol Deviations are entered by a Functional Service Providers (FSPs) CRA working on an internal team the Origin Type could be Collected and the Source could be Sponsor.

Protocol Deviations (DV) [STDTMIG 4.0] Location: dv.xpt

Variable	Label / Description	Type	Role	Length or Display Format	Controlled Terms or ISO Format	Origin / Source / Method / Comment
DVTERM	Protocol Deviation Term	text	Topic	200		Collected (Source: Vendor)
DVTERM	Protocol Deviation Term	text	Topic	200		Collected (Source: Sponsor)

DV Define.xml Origin Type and Source



Fully outsourced CRO

Sponsor CRA Employee

Functional Service Provider (FSP) CRA working on internal team

If both internal and external CRAs are creating Protocol Deviations more than one origin is needed. This is acceptable according to the Define.xml Specification 2.1 section 5.3.12.3

rotocol Deviations (DV) [STDTMIG 4.0]

Location: dv.xpt

Variable	Label / Description	Type	Role	Length or Display Format	Controlled Terms or ISO Format	Origin / Source / Method / Comment
VTERM	Protocol Deviation Term	text	Topic	200		Collected (Source: Vendor)
VTERM	Protocol Deviation Term	text	Topic	200		Collected (Source: Sponsor)
VTERM	Protocol Deviation Term	text	Topic	200		Collected (Source: Sponsor) Collected (Source: Vendor)

5.3.12.3 def:Origin Element

Element Name	def:Origin
Element XPath(s)	/ODM/Study/MetaDataVersion/ItemDef/def:Origin
Element Textual Value	None
Usage	• Cardinality: Zero or more ○ Multiple def:Origins may be provided when there are multiple sources for a single Variable but no way to construct a ValueList that clearly identifies the cases where each def:Origin applies.

Where Statements for PD Origins Could Be Complex

USUBJID	DVTERM	DVCAT
ALXN-RD-01001	IP INFUSION RATE FASTER THAN PROTOCOL	NON-IMPORTANT
ALXN-RD-01001	INCORRECT IP DOSE ADMINISTERED.	IMPORTANT

CRANAM	CRAORGTP
JANE DOE	SPONSOR
JOHN DOE	CRO

Variable	Label
CRANAME	CRA Name
CRAORGTP	CRA Organization Type

New Non-Standard Variables could be used

Where Statements for PD Origins Could Be Complex

USUBJID	DVTERM	DVCAT
ALXN-RD-01001	IP INFUSION RATE FASTER THAN PROTOCOL	NON-IMPORTANT
ALXN-RD-01001	INCORRECT IP DOSE ADMINISTERED.	IMPORTANT

CRANAM	CRAORGTP
JANE DOE	SPONSOR
JOHN DOE	CRO

Variable	Label
CRANAME	CRA Name
CRAORGTP	CRA Organization Type

Could DVPARTY be used?

New Non-Standard Variables could be used

USUBJID	DVTERM	DVCAT	DVPARTY
ALXN-RD-01001	IP INFUSION RATE FASTER THAN PROTOCOL	NON-IMPORTANT	SPONSOR CRA

Class	Variable Name	Variable Label	Description
Events	--PARTY	Accountable Party	Party accountable for the transferable object (e.g., device, specimen) as a result of the activity performed in the associated --TERM variable. The party could be an individual (e.g., subject), an organization (e.g., sponsor), or a location that is a proxy for an individual or organization (e.g., site). It is usually a somewhat general term that is further identified in the --PRTYID variable.

Where Statements for PD Origins Could Be Complex

USUBJID	DVTERM	DVCAT
ALXN-RD-01001	IP INFUSION RATE FASTER THAN PROTOCOL	NON-IMPORTANT
ALXN-RD-01001	INCORRECT IP DOSE ADMINISTERED.	IMPORTANT

CRANAM	CRAORGTP
JANE DOE	SPONSOR
JOHN DOE	CRO

Variable	Label
CRANAME	CRA Name
CRAORGTP	CRA Organization Type

Could DVPARTY be used?

New Non-Standard Variables could be used

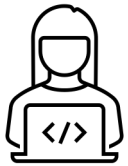
USUBJID	DVTERM	DVCAT	DVPARTY
ALXN-RD-01001	IP INFUSION RATE FASTER THAN PROTOCOL	NON-IMPORTANT	SPONSOR CRA

USUBJID	DVTERM	DVCAT	DVEVAL
ALXN-RD-01001	IP INFUSION RATE FASTER THAN PROTOCOL	NON-IMPORTANT	SPONSOR CRA

Could DVEVAL be repurposed to capture the information?

Class	Variable Name	Variable Label	Description
Events	--PARTY	Accountable Party	Party accountable for the transferable object (e.g., device, specimen) as a result of the activity performed in the associated --TERM variable. The party could be an individual (e.g., subject), an organization (e.g., sponsor), or a location that is a proxy for an individual or organization (e.g., site). It is usually a somewhat general term that is further identified in the --PRTYID variable.
Findings	--EVAL	Evaluator	Role of the person who provided the evaluation. Used only for results that are subjective (e.g., assigned by a person or a group). Examples: "ADJUDICATION COMMITTEE", "INDEPENDENT ASSESSOR", "RADIOLOGIST".

DV Define.xml Origin Type and Source



Fully outsourced CRO

Sponsor CRA Employee

Functional Service Provider (FSP) CRA working on internal team

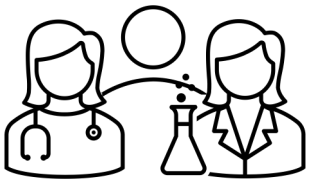
A comment could also clarify the process around how PDs are entered and reviewed if there are challenges entering multiple Origins in Define.xml generating software.

Protocol Deviations (DV) [STDTMIG 4.0] Location: dv.xpt

Variable	Label / Description	Type	Role	Length or Display Format	Controlled Terms or ISO Format	Origin / Source / Method / Comment
DVTERM	Protocol Deviation Term	text	Topic	200		Collected (Source: Vendor)
DVTERM	Protocol Deviation Term	text	Topic	200		Collected (Source: Sponsor)
DVTERM	Protocol Deviation Term	text	Topic	200		Collected (Source: Sponsor) Collected (Source: Vendor)
DVTERM	Protocol Deviation Term	text	Topic	200		Collected (Source: Vendor) Protocol Deviations (PDs) were entered by the CRO's CRA. During the PD Classification and Review Meeting the Sponsor Clinical Opperations team modified PDs.

Go to the top of the Define-XML document

section



Clinical Trial Team

Considerations for the BIMO clinsite Dataset

Bioresearch Monitoring Technical Conformance Guide v3.1 2024-10

174 **III. SUMMARY-LEVEL CLINICAL SITE DATASET**

176 **A. Organization of the Site-Level Dataset**

178 A single summary-level clinical site dataset that contains data from all major (i.e., pivotal)
179 studies used to support safety and efficacy in the application, including studies with different
180 treatment indications, should be provided.

182 For each major (i.e., pivotal) study used to support safety and efficacy, data by clinical site and
183 treatment arm for the safety population (SAFPOP) and primary efficacy population (EFFPOP)
184 should be provided.

PHUSE has produced the BIMO Data Reviewers Guide to support BIMO submissions

BIMO Counts and Site Transfers

- Screening failures PDs should not be counted
- Only PDs from the SAFPOP
- Site transfers patient's PDs should be applied to the appropriate site based on DVSTDTC (and DVENDTC if applicable)
- Pooled PDs should be split out and counted individually

Variable Index	Variable Name	Variable Label	Type	Controlled Terms or Format	Notes or Description	Sample Value
27	IMPDEV	Number of Important Protocol Deviations	Num	Integer	Total number of important protocol deviations at a given site by treatment arm for subjects in the SAFPOP. A protocol deviation is any change, divergence, or departure from the study design or procedures defined in the protocol or associated investigational plans that is not implemented or intended as a systematic change. This value should include multiple deviations per subject and all major deviation types. Important deviations are those deviations that might significantly affect the completeness, accuracy, and/or reliability of the study data or that might significantly affect a subject's rights, safety, or well-being.	2
28	NOIMPDEV	Number of Non-Important Protocol Deviations	Num	Integer	Total number of protocol deviations, excluding important protocol deviations, at a given site by treatment arm for subjects in the SAFPOP. A protocol deviation is any change, divergence, or departure from the study design or procedures defined in the protocol or associated investigational plans that is not implemented or intended as a systematic change.	98

Site Transfers

- Participants site changes can be recorded in the DS according to the CDISC Knowledge Base Article referencing the CDISC Guidance for Ongoing Studies Disrupted by COVID-19 Pandemic Version 1.0
- Participant below changed from site 002 (DM.SITEID) to 001 (DM.SITEID1). One NIPD occurred before the transfer and two IPDs after the transfer.

USUBJID	DVTERM	DVCAT	DVCLASI	DVSTDTC
1001	SUBJECT MISSED VISIT 8	TRIAL PROCEDURES	NON-IMPORTANT	2020-02-01
1001	A SUBJECT TOOK IMP THAT HAD EXPIRED	INVESTIGATIONAL PRO…	IMPORTANT	2020-02-06
1001	ADMINISTRATION OF PROHIBITED CONC..	PROHIBITED CONCOM…	IMPORTANT	2020-03-13

DOMAIN	USUBJID	DSSEQ	DSTERM	DSDECOD	DSCAT	DSEPCHGI	DSPARTY	DSPARTYID	DSSTDTC
DS	1001	3	Subject moved and was transferred to a site in Florida	TRANSFERRED	OTHER EVENT		SITE	001	2/3/20

STUDYID	TITLE	SPONSOR	SITEID	ARM	COHORT	SAFPOP	EFFPOP	SCREEN	IMPDEV	NOIMPDEV
ABC-123	Double blind…	DrugCo, Inc.	001	Active	-	26	54	61	1	4
ABC-123	Double blind…	DrugCo, Inc.	002	Active	-	23	44	54	2	9

Site Transfers

- Participants site changes can be recorded in the DS according to the CDISC Knowledge Base Article referencing the CDISC Guidance for Ongoing Studies Disrupted by COVID-19 Pandemic Version 1.0
- Participant below changed from site 002 (DM.SITEID) to 001 (DM.SITEID1). One NIPD occurred before the transfer and two IPDs after the transfer.

Occurred in site 002 – No change

USUBJID	DVTERM	DVCAT	DVCLASI	DVSTDTC
1001	SUBJECT MISSED VISIT 8	TRIAL PROCEDURES	NON-IMPORTANT	2020-02-01
1001	A SUBJECT TOOK IMP THAT HAD EXPIRED	INVESTIGATIONAL PRO…	IMPORTANT	2020-02-06
1001	ADMINISTRATION OF PROHIBITED CONC..	PROHIBITED CONCOM…	IMPORTANT	2020-03-13

Occurred in site 001 – Add 2 IPDs

DOMAIN	USUBJID	DSSEQ	DSTERM	DSDECOD	DSCAT	DSEPCHGI	DSPARTY	DSPARTYID	DSSTDTC
DS	1001	3	Subject moved and was transferred to a site in Florida	TRANSFERRED	OTHER EVENT		SITE	001	2/3/20

STUDYID	TITLE	SPONSOR	SITEID	ARM	COHORT	SAFPOP	EFFPOP	SCREEN	IMPDEV	NOIMPDEV
ABC-123	Double blind…	DrugCo, Inc.	001	Active	-	26	54	61	1 +2	4
ABC-123	Double blind…	DrugCo, Inc.	002	Active	-	23	44	54	2 -2	9

Site Transfers

- Participants site changes can be recorded in the DS according to the CDISC Knowledge Base Article referencing the CDISC Guidance for Ongoing Studies Disrupted by COVID-19 Pandemic Version 1.0
- Participant below changed from site 002 (DM.SITEID) to 001 (DM.SITEID1). One NIPD occurred before the transfer and two IPDs after the transfer.

Occurred in site 002 – No change

USUBJID	DVTERM	DVCAT	DVCLASI	DVSTDTC
1001	SUBJECT MISSED VISIT 8	TRIAL PROCEDURES	NON-IMPORTANT	2020-02-01
1001	A SUBJECT TOOK IMP THAT HAD EXPIRED	INVESTIGATIONAL PRO…	IMPORTANT	2020-02-06
1001	ADMINISTRATION OF PROHIBITED CONC..	PROHIBITED CONCOM…	IMPORTANT	2020-03-13

Occurred in site 001 – Add 2 IPDs

DOMAIN	USUBJID	DSSEQ	DSTERM	DSDECOD	DSCAT	DSEPCHGI	DSPARTY	DSPARTYID	DSSTDTC
DS	1001	3	Subject moved and was transferred to a site in Florida	TRANSFERRED	OTHER EVENT		SITE	001	2/3/20

STUDYID	TITLE	SPONSOR	SITEID	ARM	COHORT	SAFPOP	EFFPOP	SCREEN	IMPDEV	NOIMPDEV
ABC-123	Double blind…	DrugCo, Inc.	001	Active	-	26	54	61	3	4
ABC-123	Double blind…	DrugCo, Inc.	002	Active	-	23	44	54	0	9

Site Transfers

- Participants site changes can be recorded in the DS according to the CDISC Knowledge Base Article referencing the CDISC Guidance for Ongoing Studies Disrupted by COVID-19 Pandemic Version 1.0
- Participant below changed from site 002 (DM.SITEID) to 001 (DM.SITEID1). One NIPD occurred before the transfer and two IPDs after the transfer.

Occurred in site 002 – No change

USUBJID	DVTERM	DVCAT	DVCLASI	DVSTDTC
1001	SUBJECT MISSED VISIT 8	TRIAL PROCEDURES	NON-IMPORTANT	2020-02-01
1001	A SUBJECT TOOK IMP THAT HAD EXPIRED	INVESTIGATIONAL PRO…	IMPORTANT	2020-02-06
1001	ADMINISTRATION OF PROHIBITED CONC..	PROHIBITED CONCOM…	IMPORTANT	2020-03-13

Occurred in site 001 – Add 2 IPDs

DOMAIN	USUBJID	DSSEQ	DSTERM	DSDECOD	DSCAT	DSEPCHGI	DSPARTY	DSPARTYID	DSSTDTC
DS				ANSFERRED	OTHER EVENT		SITE	001	2/3/20

Creating the BIMO counts in ADDV allows additional variables to be added to support effective counts e.g. SAFFL, EFFPFL and SITEIDA (Actual Site ID) etc.

ST					COHORT	SAFPOP	EFFPOP	SCREEN	IMPDEV	NOIMPDEV
AB					-	26	54	61	3	4
ABC-123	Double blind…	DrugCo, Inc.	002	Active	-	23	44	54	0	9

FDA PD Guidance: PD Levels: Participant, Site, Study

89 **III. DISCUSSION**

91 **A. Protocol Deviations**

97. …Additionally, deviations may occur at the

98. participant level (e.g., missed scheduled visit, inclusion of a participant not meeting eligibility

99. criteria, failure to conduct a protocol-specified procedure during a visit), at the site level (e.g.,

100. storage of investigational products outside of protocol-required temperature range), or at the

101. study level (e.g., premature unblinding of treatment assignments).

PD sub-team does not agree with Site, Country, Region, Study Level PD due to complexities of management see 2022 PD Sub-Team presentation for further discussion

SITEID Reduces the Records to 9 with no POOLDEF

STUDYID	DOMAIN	USUBJID	SITEID	DVSEQ	DVSPID	DVTERM	DVDECOD	DVCAT	DVCLASN
PD01	DV		3001	1	PD001	OPTIONAL INFORMED CONSENT NOT OBTAINED FOR GENE EXPRESSION PROFILE (DNA EXTRACTION)	INFORMED CONSENT	INFORMED CONSENT	IMPORTANT
PD01	DV		3002	2	PD001	OPTIONAL INFORMED CONSENT NOT OBTAINED FOR GENE EXPRESSION PROFILE (DNA EXTRACTION)	INFORMED CONSENT	INFORMED CONSENT	IMPORTANT

Tracking Sites by SITEID

- If SITEID is set at an organization level it can be reused across studies to give trends of issues per site.
- Listings and dashboards can be produced to give a better overview of quality issues at sites overtime.

SITEID	INVNAM	COUNTRY
001	GAFFEY	IRL
002	SMITH	USA
003	FORGERON	CHE
004	FERRARI	ITA

Tracking Sites by SITEID

- If SITEID is set at an organization level it can be reused across studies to give trends of issues per site.
- Listings and dashboards can be produced to give a better overview of quality issues at sites overtime.

SITEID	INVNAM	COUNTRY
5351	GAFFEY	IRL
0215	SMITH	USA
1882	FORGERON	CHE
2685	FERRARI	ITA

Tracking Sites and Investigator by SITEID and INVID

- If SITEID is set at an organization level it can be reused across studies to give trends of issues per site.
- Listings and dashboards can be produced to give a better overview of quality issues at sites overtime.

SITEID	INVID	INVNAM	COUNTRY
9631	0001	GAFFEY	IRL
8666	0002	SMITH	USA
0755	0003	FORGERON	CHE
4283	0004	FERRARI	ITA

- This process could also be repeated for the investigators enabling investigators to be tracked across sites if they change site.

Tracking Sites and Investigator by SITEID and INVID

- If SITEID is set at an organization level it can be reused across studies to give trends of issues per site.
- Listings and dashboards can be produced to give a better overview of quality issues at sites overtime.

SITEID	INVID	INVNAM	COUNTRY
9631	5533	GAFFEY	IRL
8666	6707	SMITH	USA
0755	8735	FORGERON	CHE
4283	6717	FERRARI	ITA

- This process could also be repeated for the investigators enabling investigators to be tracked across sites if they change site.

Tracking Sites and Investigator by SITEID and INVID

- If SITEID is set at an organization level it can be reused across studies to give trends of issues per site.
- Listings and dashboards can be produced to give a better overview of quality issues at sites overtime.

SITEID	INVID	INVNAM	COUNTRY
9631	8735	FORGERON	IRL
8666	6707	SMITH	USA
0755	5533	GAFFEY	CHE
4283	6717	FERRARI	ITA

- This process could also be repeated for the investigators enabling investigators to be tracked across sites if they change site.

Next Steps

- PD sub-team to development of controlled terminology for
  - DVCLASI
  - DVCAT (and DVSCAT?)
    - Codetable

- Review and provide comments through the SDTMIG 4.0 Public Review 13th August to the 14th October
- Reach out with questions and feedback
- Volunteer for the PD Sub-team

Thank You!

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and the PD Sub-team

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and the CAC and Reviewers!!!

Thank You!

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