DMPK

Bioanalysis & Biomarkers
Development Germany

Introduction to CDISC for the Bioanalyst

Workshop Generic Data Transfer Agreement

Dr. Martina Wein

Boehringer Ingelheim

What is CDISC?

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CDISC = Clinical Data Interchange Standards Consortium

- CDISC is a global, open, multidisciplinary, **non-profit organization** that has **established standards to support the acquisition, exchange, submission** and archive of **clinical research data** and metadata.
- The CDISC mission is to develop and **support global, platform-independent data standards** that enable information system interoperability to improve medical research and related areas of healthcare.
- CDISC standards are **vendor-neutral, platform-independent and freely available** via the CDISC website.

  (Mission statement from www.cdisc.org)

- CDISC was formed in 1997 (2000) and is based in Austin, Texas

Relevant Standards for Bioanalysts

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SDTM: Study Data Tabulation Model for clinical trials

- Recommended for FDA regulatory submissions since 2004
- Submissions of trials with a start date after 17 Dec 2016 are expected to conform to this format
- STDMIG: STDM Implementation Guide (version 3.2, 18 Aug 2015)

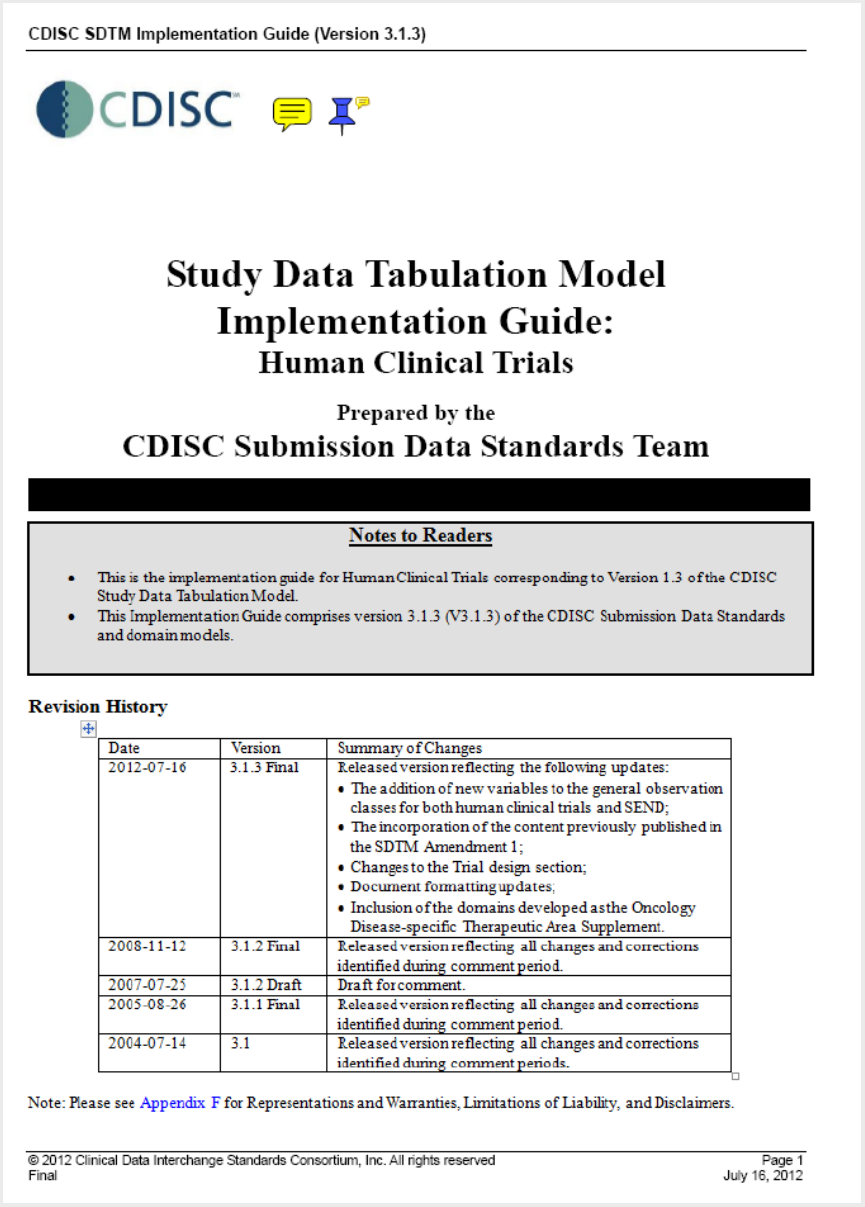
SEND: Standard for Exchange of Non-clinical Data

- Accepted in 2011
- Submissions of studies with a start date after Dec 2016 have to conform to this format
- SENDIG: SEND Implementation Guide (version 3.0, 19 May 2011, version 3.1 posted for review)

SDTM Implementation Guide

- 298 pages
- available on www.cdisc.org / standards
- version 3.1.3 and 3.2 available

- Provides specifications, defines domains and variables, and offers examples with study data



CDISC SDTM Implementation Guide (Version 3.1.3)

CDISC

Study Data Tabulation Model Implementation Guide:
Human Clinical Trials

Prepared by the
CDISC Submission Data Standards Team

Notes to Readers

- This is the implementation guide for Human Clinical Trials corresponding to Version 1.3 of the CDISC Study Data Tabulation Model.
- This Implementation Guide comprises version 3.1.3 (V3.1.3) of the CDISC Submission Data Standards and domain models.

Revision History

Date	Version	Summary of Changes
2012-07-16	3.1.3 Final	Released version reflecting the following updates: • The addition of new variables to the general observation classes for both human clinical trials and SEND; • The incorporation of the content previously published in the SDTM Amendment 1; • Changes to the Trial design section; • Document formatting updates; • Inclusion of the domains developed as the Oncology Disease-specific Therapeutic Area Supplement.
2008-11-12	3.1.2 Final	Released version reflecting all changes and corrections identified during comment period.
2007-07-25	3.1.2 Draft	Draft for comment.
2005-08-26	3.1.1 Final	Released version reflecting all changes and corrections identified during comment period.
2004-07-14	3.1	Released version reflecting all changes and corrections identified during comment periods.

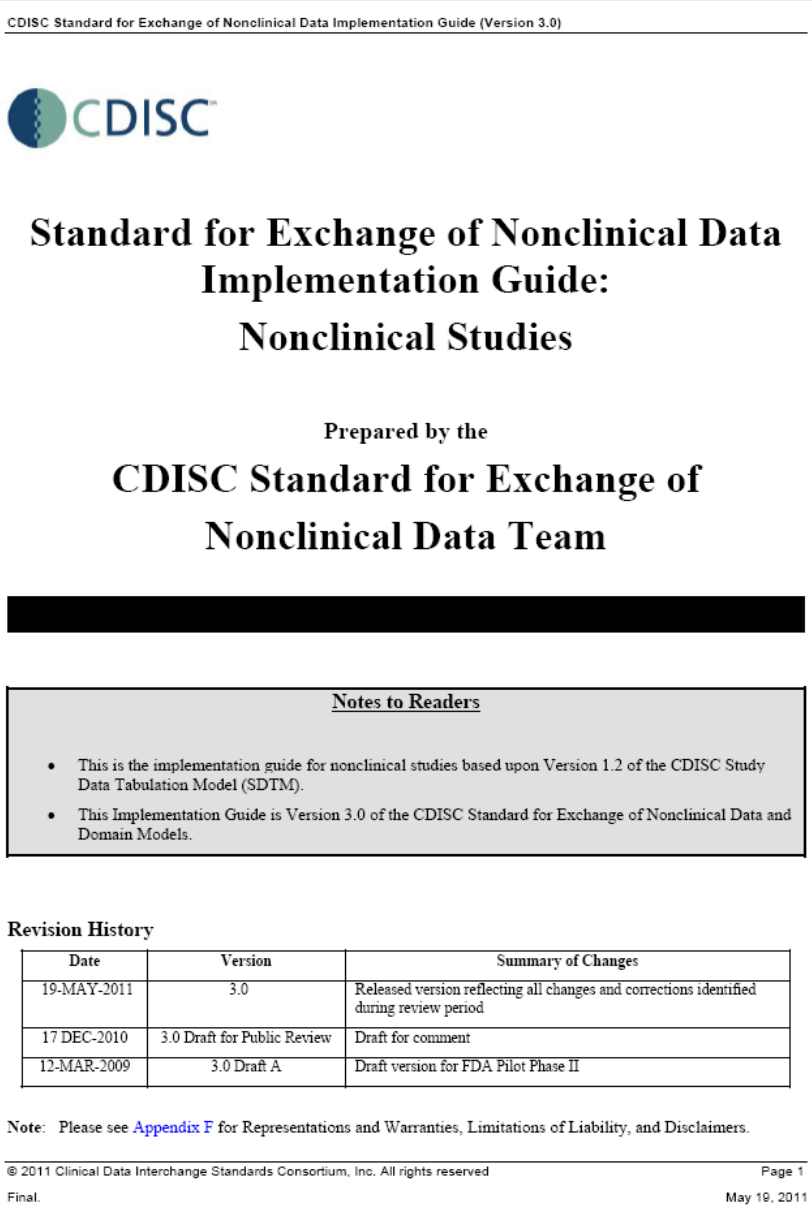
Note: Please see Appendix F for Representations and Warranties, Limitations of Liability, and Disclaimers.

SEND Implementation Guide

- 256 pages
- available on www.cdisc.org / standards
- Version 3.0 released in 2011
- Version 3.1 draft was available for review

- Provides specifications, defines domains and variables, and offers examples with study data

- In scope:
  Single and repeat toxicity studies
  Carcinogenicity studies
- SENDIG Repro to be released



CDISC Standard for Exchange of Nonclinical Data Implementation Guide (Version 3.0)

CDISC

Standard for Exchange of Nonclinical Data Implementation Guide:
Nonclinical Studies

Prepared by the
CDISC Standard for Exchange of Nonclinical Data Team

Notes to Readers

- This is the implementation guide for nonclinical studies based upon Version 1.2 of the CDISC Study Data Tabulation Model (SDTM).
- This Implementation Guide is Version 3.0 of the CDISC Standard for Exchange of Nonclinical Data and Domain Models.

Revision History

Date	Version	Summary of Changes
19-MAY-2011	3.0	Released version reflecting all changes and corrections identified during review period
17 DEC-2010	3.0 Draft for Public Review	Draft for comment
12-MAR-2009	3.0 Draft A	Draft version for FDA Pilot Phase II

Note: Please see Appendix F for Representations and Warranties, Limitations of Liability, and Disclaimers.

Why standards

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- Using a common language improves efficiency
- Facilitates data sharing
- Enables more efficient data review
- Automated tools can be used for data extraction, analysis, or evaluation
- Data mining across studies is possible

SDTM Standard Domain Models

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CDISC SDTM Implementation Guide (Version 3.1.2)

2.5 THE SDTM STANDARD DOMAIN MODELS

The following standard domains with their respective domain codes have been defined or referenced by the CDISC SDS Team in this document. Note that other domain models may be posted separately for comment after this publication.

Special-Purpose Domains (defined in Section 5):

- Demographics — DM
- Comments — CO
- Subject Elements — SE
- Subject Visits — SV

Interventions General Observation Class (defined in Section 6.1):

- Concomitant Medications — CM
- Exposure — EX
- Substance Use — SU

Events General Observation Class (defined in Section 6.2):

- Adverse Events — AE
- Disposition — DS
- Medical History — MH
- Protocol Deviations — DV
- Clinical Events — CE

Findings General Observation Class (defined in Section 6.3):

- ECG Test Results — EG
- Inclusion/Exclusion Criterion Not Met — IE
- Laboratory Test Results — LB
- Physical Examination — PE
- Questionnaires — QS
- Subject Characteristics — SC
- Vital Signs — VS
- Drug Accountability — DA
- Microbiology Specimen — MB
- Microbiology Susceptibility Test — MS
- PK Concentrations — PC
- PK Parameters —PP

Findings About (defined in Section 6.4)

- Findings About — FA

Trial Design Domains (defined in Section 7):

- Trial Arms — TA
- Trial Elements — TE
- Trial Visits — TV
- Trial Inclusion/Exclusion Criteria — TI
- Trial Summary — TS

Relationship Datasets (defined in Section 8):

- Supplemental Qualifiers — SUPPQUAL or multiple SUPP-- datasets
- Related Records — RELREC

SDTM and SEND Standard Domain Models

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CDISC SDTM Implementation Guide (Version 3.1.2)

2.5 THE SDTM STANDARD

The following standard domains with their re
Team in this document. Note that other doma

Special-Purpose Domains (defined in Sect

- Demographics — DM
- Subject Elements — SE

Interventions General Observation Class (

- Concomitant Medications — CM
- Substance Use — SU

Events General Observation Class (define

- Adverse Events — AE
- Medical History — MH
- Clinical Events — CE

Findings General Observation Class (defi

- ECG Test Results — EG
- Laboratory Test Results — LB
- Questionnaires — QS
- Vital Signs — VS
- Microbiology Specimen — MB
- PK Concentrations — PC

Findings About (defined in Section 6.4)

- Findings About — FA

Trial Design Domains (defined in Section

- Trial Arms — TA
- Trial Visits — TV
- Trial Summary — TS

Relationship Datasets (defined in Section

- Supplemental Qualifiers — SUPPQ multiple SUPP-- datasets

CDISC Standard for Exchange of Nonclinical Data Implementation Guide (Version 3.0)

2.3 THE SENDIG STANDARD DOMAIN MODELS

The following standard domains with their respective domain codes have been defined or referenced by the CDISC SEND Team in this document.

Special-Purpose Domains (Section 5)

- Demographics – DM
- Subject Elements – SE
- Comments – CO

Interventions General Observation Class (Section 6.1)

- Exposure – EX

Events General Observation Class (Section 6.2)

- Disposition – DS

Findings General Observation Class (Section 6.3)

- Body Weights – BW
- Body Weight Gains – BG
- Clinical Observations – CL
- Death Diagnosis – DD
- Food and Water Consumption – FW
- Laboratory Test Results – LB
- Macroscopic Findings – MA
- Microscopic Findings – MI
- Organ Measurements – OM
- Palpable Masses – PM
- Pharmacokinetics Concentrations – PC
- Pharmacokinetics Parameters – PP
- Subject Characteristics – SC
- Tumor Findings – TF
- Vital Signs – VS
- ECG Test Results – EG

Trial Design Domains (Section 7)

- Trial Elements – TE
- Trial Arms – TA
- Trial Sets – TX
- Trial Summary – TS

Relationship Datasets (Section 8)

- Supplemental Qualifiers – SUPP-- datasets
- Related Records – RELREC
- Pooling – POOLDEF

General Information on Variables

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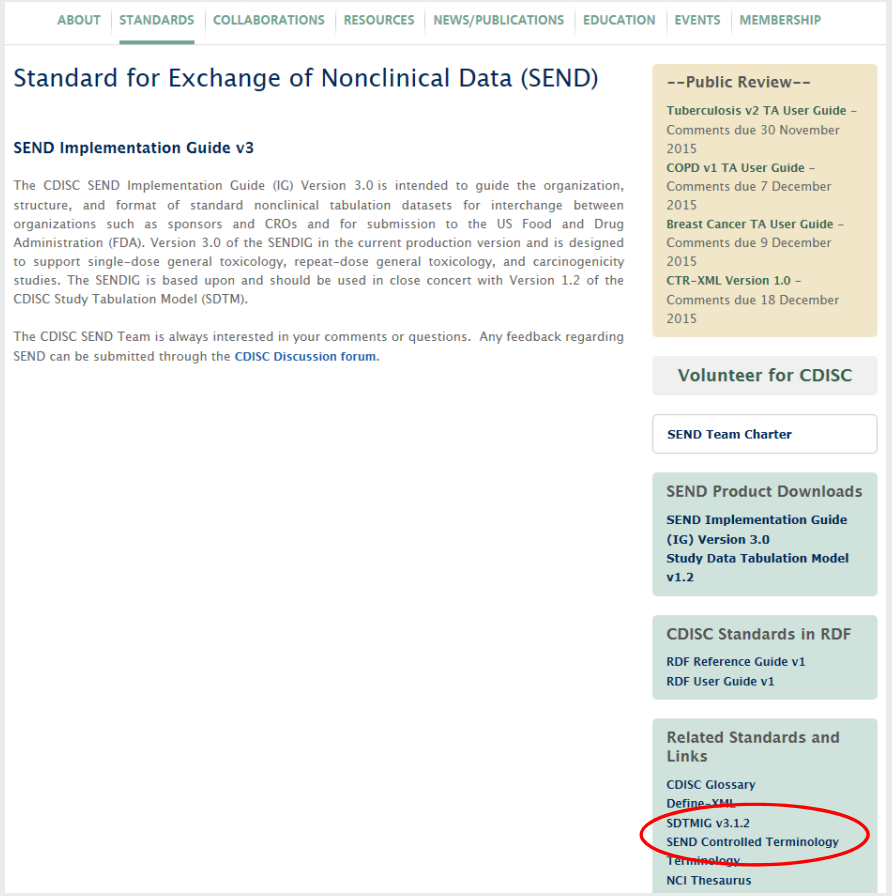
- **Variable Name**
- **Variable Label:** Describes the meaning of the variable
- **Type:** Character or numeric
- **Controlled terminology:** Indicates whether codelists or certain formats are to be used
- **Three categories of variables are available:**
  - Requested (Req) - variable must be included and cannot be null
  - Expected (Exp) – column for this variable must be included, but may contain some null values
  - Permissible (Per) – variable should be included if data was collected or derived, columns which only contain null values might be omitted

Controlled terminology

Code list is available on:

- www.cdisc.org for SEND



- National Cancer Institute web page (www.cancer.gov > Research > R&D Resources > Terminology Resources > CDISC Terminology

Codelist – Example for Specimen Condition

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SDTM Terminology.xls [Schreibgeschützt] [Kompatibilitätsmodus]

	A	B	C	D	E	F	G
1	Code	Codelist Code	Codelist Extensible (Yes/No)	Codelist Name	CDISC Submission Value	CDISC Synonym(s)	CDISC Definition
9479	C78733		Yes	Specimen Condition	SPECCOND	Specimen Condition	The physical state or quality of a biological specimen.
9480	C78725	C78733		Specimen Condition	AUTOLYZED		A specimen that has undergone autolysis, or self-digestion by the specimen's own digestive enzymes. (NCI)
9481	C78723	C78733		Specimen Condition	CALCIFIED	Calcified Specimen	A specimen that has undergone calcification. (NCI)
9482	C78724	C78733		Specimen Condition	CLOTTED	Clotted Specimen	A specimen that has become coagulated. (NCI)
9483	C68768	C78733		Specimen Condition	CONTAMINATED		The presence of any substance or organism that makes a preparation impure. (NCI)
9484	C84516	C78733		Specimen Condition	DRIED	Dried Specimen	A specimen that has become dessicated or dehydrated.
9485	C84517	C78733		Specimen Condition	FRESH	Fresh Specimen	A specimen that is analyzed in the state that it was collected.
9486	C70717	C78733		Specimen Condition	FROZEN	Frozen Specimen	A specimen that has been subjected to and immobilized by severe cold. (NCI)
9487	C70720	C78733		Specimen Condition	HEMOLYZED	Hemolysis in Specimen	A specimen that has undergone the destruction of red blood cells followed by the release of the hemoglobin. (NCI)
9488	C98744	C78733		Specimen Condition	ICTERIC	Icteric Specimen	A specimen that exhibits a yellowish pigmentation due to jaundice. (NCI)
9489	C70715	C78733		Specimen Condition	LIPEMIC	Lipemic Specimen	A specimen that consists of or contains excessive amounts of fat and fatty substances. (NCI)
9490	C19597	C78733		Specimen Condition	PARAFFIN-EMBEDDED	Paraffin Block; Paraffin-Embedded Specimen	A specimen that has been fixed and preserved in paraffin.
9491	C70718	C78733		Specimen Condition	REFRIGERATED	Refrigerated Specimen	A specimen that has been kept or preserved at a low temperature in a refrigerator. (NCI)
9492	C70719	C78733		Specimen Condition	ROOM TEMPERATURE	Ambient Temperature; Specimen at Room Temperature	A specimen that has been subjected to and adjusted to the average ambient temperature of a room, usually considered to be around 20 degrees C (68 degrees F). (NCI)

Codelist - Units

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A	B	C	D	E	F
Code	**Codelist Code**	**Codelist Extensible (Yes/No)**	**Codelist Name**	**CDISC Submission Value**	**CDISC Synonym(s)**
C68887	C71620		Unit	fmol/L	Femtomole per Liter
C64572	C71620		Unit	mg/L	Gram per Cubic Meter; Microgram per Milliliter; Milligram per Liter; g/m3; mcg/mL; mg/L; ng/uL; ug/mL
C64387	C71620		Unit	mmol/L	Micromole per Milliliter; Millimole per Liter; Mole per Cubic Meter; mcmol/mL; mmol/L; mol/m3; nmol/uL; umol/mL
C67327	C71620		Unit	ng/L	Microgram per Cubic Meter; ng/L; pg/mL; ug/m3
C67432	C71620		Unit	nmol/L	Nanomole per Liter; pmol/mL
C85597	C71620		Unit	pg/L	fg/mL; pg/L
C67434	C71620		Unit	pmol/L	Femtomole per Milliliter; Picomole per Liter; fmol/mL
C67306	C71620		Unit	ug/L	Microgram per Liter; Milligram per Cubic Meter; Nanogram per Milliliter; mcg/L; mg/m3; ng/mL; ug/L
C48508	C71620		Unit	umol/L	Micromole per Liter

Timetable - FDA Standards Catalog

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FDA Data Standards Catalog v4.4 (08-17-2015) - Supported and Required Standards

Use	Data Exchange Standard	Exchange Format	Standards Development Organization (SDO)	Supported Version	Implementation Guide Version	FDA Center(s)	Date Support Begins (MM/DD/YYYY)	Date Support Ends (MM/DD/YYYY)	Date Requirement Begins (MM/DD/YYYY)	Re
Clinical study datasets	Study Data Tabulation Model (SDTM)	XPT	Interchange Standards Consortium (CDISC)	1.4	3.2	CDER, CBER	17.08.2015		03/15/2018 [1] 03/15/2019 [2]	
Clinical study datasets	SDTM	XPT	CDISC	1.3	3.1.3	CDER, CBER	12.01.2012		12/17/2016 [1] 12/17/2017 [2]	
Clinical study datasets	SDTM	XPT	CDISC	1.2	Version 3.1.2 Amendment 1	CDER, CBER	08.07.2013		12/17/2016 [1] 12/17/2017 [2]	
Clinical study datasets	SDTM	XPT	CDISC	1.2	3.1.2	CDER, CBER	30.10.2009		12/17/2016 [1] 12/17/2017 [2]	
Clinical study datasets	SDTM	XPT	CDISC	1.1	3.1.1	CDER, CBER	Ongoing	01.28.2015		
Clinical study datasets	Analysis Data Model (ADaM)	XPT	CDISC	2.1	1.0	CDER, CBER	Ongoing		12/17/2016 [1] 12/17/2017 [2]	
Animal study datasets	Standard for Exchange of Nonclinical Data (SEND)	XPT	CDISC	1.2	3.0	CDER	06.13.2011		12/17/2016 [1] 12/17/2017 [2]	

Notes:

[1] For NDAs, ANDAs, and certain BLAs. See section II.A of the Providing Regulatory Submissions In Electronic Format — Standardized Study Data guidance document

[2] For certain INDs. See section II.A of the Providing Regulatory Submissions In Electronic Format — Standardized Study Data guidance document

Guidance for Industry: Providing Regulatory Submissions In Electronic Format – Standardized Study Data

Requested Variables (SEND and SDTM)

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Variable Name	Variable Label	Type	Controlled Term, Codelist or Format
STUDYID	Study Identifier	Char	
DOMAIN	Domain Abbreviation	Char	PC
USUBJID	Unique Subject Identifier	Char	
PCSEQ	Sequence Number	Num	
PCTESTCD	Test Short Name*	Char	
PCTEST	Test Name	Char	
PCSPEC	Specimen Material	Char	(SPEC)

* Analyte – short form
- Cannot be longer than 8 characters, nor can it start with a number (e.g., “1TEST” is not valid).
- Cannot contain characters other than letters, numbers, or underscores.
- Examples: ASA, VOL, SPG

Expected variables (SEND)

Boehringer Ingelheim

Variable Name	Variable Label	Type	Controlled Term, Codelist or Format
PCORRES	Original Result	Char	
PCORRESU	Unit of the Original Result	Char	(PKUNIT)
PCSTRESC	Standardized Result in Character Format	Char	
PCSTRESN	Standardized Result in Numeric Format	Num	
PCSTRESU	Unit of the Standardized Result	Char	(PKUNIT)
PCBLFL	Baseline Flag	Char	(NY)
PCLLOQ	Lower Limit Of Quantification	Num	
PCDTC	Date/Time of Specimen Collection	Char	ISO 8601
VISITDY (PCNOMDY)	Nominal Study Day for Reporting Purposes	Num	
PCRFTDTC	Date/Time of Reference Point	Char	ISO 8601

Expected variables (SEND)

Boehringer Ingelheim

Variable Name	Variable Label	Type	Controlled Term, Codelist or Format
PCORRES	Original Result	Char	
PCORRESU	Unit of the Original Result	Char	(PKUNIT)
PCSTRESC	Standardized Result in Character Format	Char	
PCSTRESN	Standardized Result in Numeric Format	Num	
PCSTRESU	Unit of the Standardized Result	Char	(PKUNIT)
PCBLFL	Baseline Flag	Char	(NY)
PCLLOQ	Lower Limit Of Quantification	Num	
PCDTC	Date/Time of Specimen Collection	Char	ISO 8601
VISITDY (PCNOMDY)	Nominal Study Day for Reporting Purposes	Num	
PCRFTDTC	Date/Time of Reference Point	Char	ISO 8601

Result of the measurement or finding as originally received or collected.
E.g. 12.5; 2050; <1.00

Expected variables (SEND)

Boehringer Ingelheim

Variable Name	Variable Label	Type	Controlled Term, Codelist or Format
PCORRES	Original Result	Char	
PCORRESU	Unit of the Original Result	Char	(PKUNIT)
PCSTRESC	Standardized Result in Character Format	Char	
PCSTRESN	Standardized Result in Numeric Format	Num	
PCSTRESU	Unit of the Standardized Result	Char	(PKUNIT)
PCBLFL	Baseline Flag	Char	(NY)
PCLLOQ	Lower Limit Of Quantification	Num	
PCDTC	Date/Time of Specimen Collection	Char	ISO 8601
VISITDY (PCNOMDY)	Nominal Study Day for Reporting Purposes	Num	
PCRFTDTC	Date/Time of Reference Point	Char	ISO 8601

Result value from PCORRES in a standard format
E.g. 12.5; 2050; <1.00

Expected variables (SEND)

Boehringer Ingelheim

Variable Name	Variable Label	Type	Controlled Term, Codelist or Format
PCORRES	Original Result	Char	
PCORRESU	Unit of the Original Result	Char	(PKUNIT)
PCSTRESC	Standardized Result in Character Format	Char	
PCSTRESN	Standardized Result in Numeric Format	Num	
PCSTRESU	Unit of the Standardized Result	Char	(PKUNIT)
PCBLFL	Baseline Flag	Char	(NY)
PCLLOQ	Lower Limit Of Quantification	Num	
PCDTC	Date/Time of Specimen Collection	Char	ISO 8601
VISITDY (PCNOMDY)	Nominal Study Day for Reporting Purposes	Num	
PCRFTDTC	Date/Time of Reference Point	Char	ISO 8601

Result value from PCORRES in a standard format
E.g. 12.5; 2050 but null if <1.00

Expected variables (SEND)

Boehringer Ingelheim

Variable Name	Variable Label	Type	Controlled Term, Codelist or Format
PCORRES	Original Result	Char	
PCORRESU	Unit of the Original Result	Char	(PKUNIT)
PCSTRESC	Standardized Result in Character Format	Char	
PCSTRESN	Standardized Result in Numeric Format	Num	
PCSTRESU	Unit of the Standardized Result	Char	(PKUNIT)
PCBLFL	Baseline Flag	Char	(NY)
PCLLOQ	Lower Limit Of Quantification	Num	
PCDTC	Date/Time of Specimen Collection	Char	ISO 8601
VISITDY (PCNOMDY)	Nominal Study Day for Reporting Purposes	Num	
PCRFTDTC	Date/Time of Reference Point	Char	ISO 8601

A baseline indicator may be used to calculate differences or changes from baseline.
For PK usually not applicable.

Expected variables

Boehringer Ingelheim

Variable Name	Variable Label	Type	Controlled Term, Codelist or Format
PCORRES	Original Result	Char	
PCORRESU	Unit of the Original Result	Char	(PKUNIT)
PCSTRESC	Standardized Result in Character Format	Char	
PCSTRESN	Standardized Result in Numeric Format	Num	
PCSTRESU	Unit of the Standardized Result	Char	(PKUNIT)
PCBLFL	Baseline Flag	Char	null (NY)
PCLLOQ	Lower Limit Of Quantification	Num	
PCDTC	Date/Time of Specimen Collection	Char	ISO 8601
VISITDY (PCNOMDY)	Nominal Study Day for Reporting Purposes	Num	
PCRFTDTC	Date/Time of Reference Point	Char	ISO 8601

ISO 8601: YYYY-MM-DDThh:mm:ss.

Expected variables (SEND)

Boehringer Ingelheim

Variable Name	Variable Label	Type	Controlled Term, Codelist or Format
PCORRES	Original Result	Char	
PCORRESU	Unit of the Original Result	Char	(PKUNIT)
PCSTRESC	Standardized Result in Character Format	Char	
PCSTRESN	Standardized Result in Numeric Format	Num	
PCSTRESU	Unit of the Standardized Result	Char	(PKUNIT)
PCBLFL	Baseline Flag	Char	null (NY)
PCLLOQ	Lower Limit Of Quantification	Num	
PCDTC	Date/Time of Specimen Collection	Char	ISO 8601
VISITDY (PCNOMDY)	Nominal Study Day for Reporting Purposes	Num	
PCRFTDTC	Date/Time of Reference Point	Char	ISO 8601

Study Day relative to first dose: 23:55 after first dose is Day 1, 24:00 after first dose is Day 2

Expected variables (SEND)

Boehringer Ingelheim

Variable Name	Variable Label	Type	Controlled Term, Codelist or Format
PCORRES	Original Result	Char	
PCORRESU	Unit of the Original Result	Char	(PKUNIT)
PCSTRESC	Standardized Result in Character Format	Char	
PCSTRESN	Standardized Result in Numeric Format	Num	
PCSTRESU	Unit of the Standardized Result	Char	(PKUNIT)
PCBLFL	Baseline Flag	Char	null (NY)
PCLLOQ	Lower Limit Of Quantification	Num	
PCDTC	Date/Time of Specimen Collection	Char	ISO 8601
VISITDY (PCNOMDY)	Nominal Study Day for Reporting Purposes	Num	
PCRFTDTC	Date/Time of Reference Point	Char	ISO 8601

Date/time of the reference time point described by PCTPTREF.
PCTPTREF is the most recent dose

Expected variables (SDTM)

Boehringer Ingelheim

Variable Name	Variable Label	Type	Controlled Term, Codelist or Format
PCORRES	Original Result	Char	
PCORRESU	Unit of the Original Result	Char	(PKUNIT)
PCSTRESC	Standardized Result in Character Format	Char	
PCSTRESN	Standardized Result in Numeric Format	Num	
PCSTRESU	Unit of the Standardized Result	Char	(PKUNIT)
PCNAM	Vendor Name	Char	
PCBLFL	Baseline Flag	Char	null (NY)
PCLLOQ	Lower Limit Of Quantification	Num	
VISITNUM	Visit Number	Num	
PCDTC	Date/Time of Specimen Collection	Char	ISO 8601

Permissible Variables (SEND)

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Variable Name	Variable Label	Type	Comment
POOLID	Pool Identifier	Char	Assign a single result to multiple subjects
PCGRPID	Group Identifier	Char	Related records within a subject
PCREFID	Sample Identifier	Char	
PCSPID	Sponsor Identifier	Char	
PCCAT	Test Category	Char	ANALYTE or SPECIMEN PROPERTY
PCSCAT	Test Subcategory	Char	
PCSTAT	Completion Status	Char	null or ND
PCREASND	Reason Not Done	Char	
PCNAM	Vendor Name	Char	Lab Name
PCSPCCND	Specimen Condition	Char	(Codelist exists)
PCMETHOD	Method of Test	Char	e.g. LC-MS (Codelist exists)
PCFAST	Fasting Status	Char	(NY)

Permissible Variables (SEND)

Boehringer Ingelheim

Variable Name	Variable Label	Type	Comment
PCDRVFL	Derived Flag	Char	(NY)
PCEXCLFL	Exclusion Flag	Char	(NY)
PCREASEX	Reason for Exclusion	Char	Reason for exclusion from PK evaluation
PCENDTC	End Date/Time of Specimen Collection	Char	ISO 8601
PCDY	Study Day of Specimen Collection	Num	Relative to first dose (variable in DM domain)
PCENDY	Study Day of End of Specimen Collection	Num	
PCTPT	Planned Time Point Name	Char	e.g. predose, 1H30MIN
PCTPTNUM	Planned Time Point Number	Num	

Permissible variables (SEND)

Boehringer Ingelheim

Variable Name	Variable Label	Type	Comment
PCELTM	Planned Elapsed Time from Time Point Ref	Char	ISO 8601
PCTPTREF	Time Point Reference	Char	Most recent dose, e.g. Day 14 Dose
PCEVLINT	Evaluation Interval	Char	ISO 8601

Permissible variables (SDTM)

Boehringer Ingelheim

Variable Name	Variable Label	Type	Comment
PCGRPID	Group Identifier		Related records within or between domains
PCREFID	Reference Identifier		
PCSPID	Sponsor Identifier	Char	
PCCAT	Test Category		ANALYTE or SPECIMEN PROPERTY
PCSCAT	Test Subcategory		
PCSTAT	Completion Status	Char	null or ND
PCREASND	Reason Not Done	Char	
PCSPCCND	Specimen Condition	Char	
PCMETHOD	Method of Test	Char	e.g. LC-MS (codelist exists)
PCFAST	Fasting Status	Char	(NY)
PCDRVFL	Derived Flag	Char	(NY)
PCULOQ	Upper Limit of Quant.	Num	
VISIT	Visit Name	Char	

Permissible variables (SDTM)

Boehringer Ingelheim

Variable Name	Variable Label	Type	Comment
VISITDY	Planned Study Day of Visit	Num	
PCENDTC	End Date/Time of Specimen Collection	Char	ISO 8601
PCDY	Study Day of Specimen Collection	Num	Relative to first dose (variable in DM domain)
PCTPT	Planned Time Point Name	Char	e.g. predose, 1H30MIN
PCTPTNUM	Planned Time Point Number	Num	
PCELTM	Planned Elapsed Time from Time Point Ref	Char	ISO 8601
PCTPTREF	Time Point Reference	Char	Most recent dose, e.g. Day 14 Dose
PCRFTDTC	Date/Time of Reference Point	Char	ISO 8601
PCEVLINT	Evaluation Interval	Char	ISO 8601

Variables which are not originally in the bioanalytical focus

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- PCEXCLFL (Exclusion Flag) – generated during TK evaluation
- PCREASEX (Reason for Exclusion)
- PCDTC (Date/Time of Specimen Collection) – actual time
- PCENDTC (End Date/Time of Specimen Collection) – actual time
- PCDY (Study Day of Specimen Collection) – relative to RFSTDTC from DM domain
- PCENDY (Study Day of End of Specimen Collection) – relative to RFSTDTC
- PCRFTDTC (Date/Time of Reference Point) – actual time of most recent dose

  - **Get information in electronic format**
  - **Merge data from other sources**
  - **Consider dependencies already in the protocol**
  - **Levels and phases do not exist in SEND or SDTM**

Data Transfer Agreements

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- **Define file format**
- **Define all variables which should be included**
  - ➢ full data set: the sponsor need to provide the missing information!
  - ➢ only typical bioanalytical data: implement a process in-house to complete the data set
- **Specify the order of variables and the names of the variables**
  - ➢ Data should be provided in the order as specified in the Implementation Guides
  - ➢ However, if data warehouses are used to collect data, other orders might be applicable and the names could differ
- **Provide codelists**

Thank You For Your Attention

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