

Applying the SDTM for Non-Clinical Data



Setting the
Global Standard
for Clinical Data

**CLINICAL DATA INTERCHANGE
STANDARDS CONSORTIUM**

Fred Wood
February 1, 2005

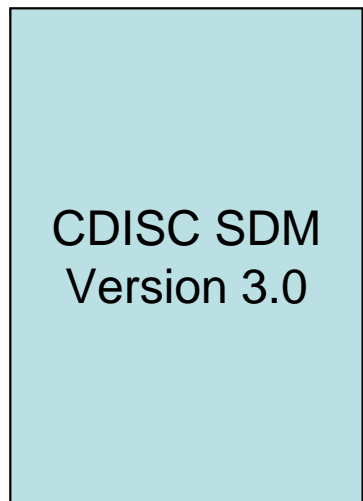
Outline

- SEND Overview and Evolution
- Comparison of Clinical and Nonclinical Domains
- SEND Domain Basics: variables Roles and Metadata
- Use of SDTM variables for PK Studies: Comparison of Clinical and Nonclinical Data

Standards for the Exchange of Non-clinical Data

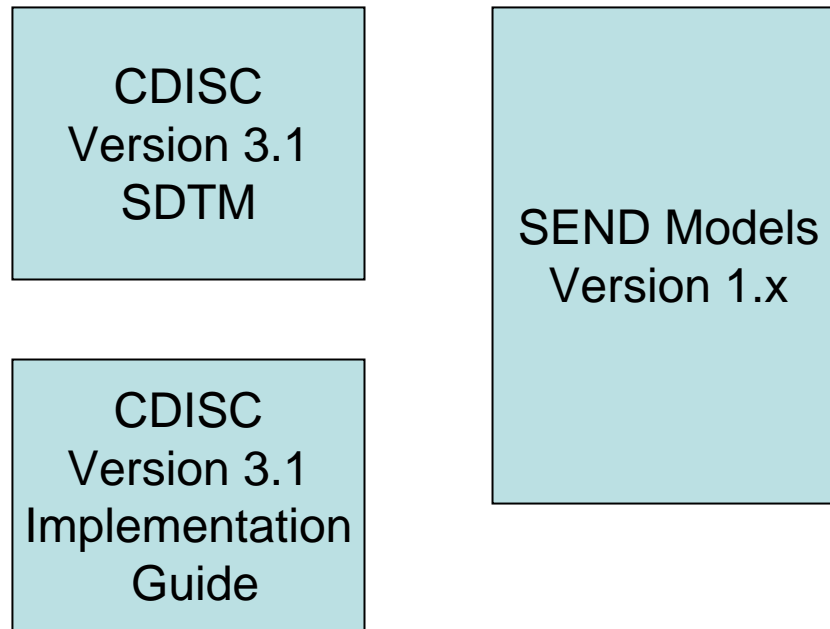
- SEND 2.0 based upon CDISC SDS V3.1, modified for submission of animal study data; toxicology data
 - Has been in development and pilot since 2002
- SEND model is included in the SDTM core model, which will be referenced in FDA Guidance
- SEND has a separate Implementation Guide
- The SEND consortium is now a CDISC team

CDISC, SEND, and the SDTM 2002

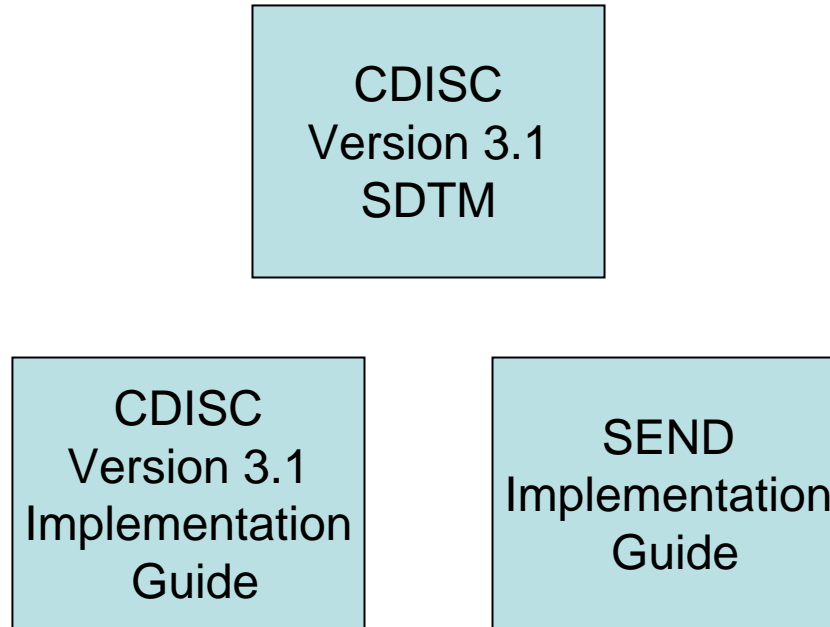


The SEND Models have been prepared to guide the organization, structure, and format for non-clinical data submitted to the FDA. The focus of the SEND Consortium has been on data collected from animal toxicology studies. The SEND models are intended to facilitate transfer of nonclinical data from sponsor to the FDA and subsequent loading into the FDA repository.

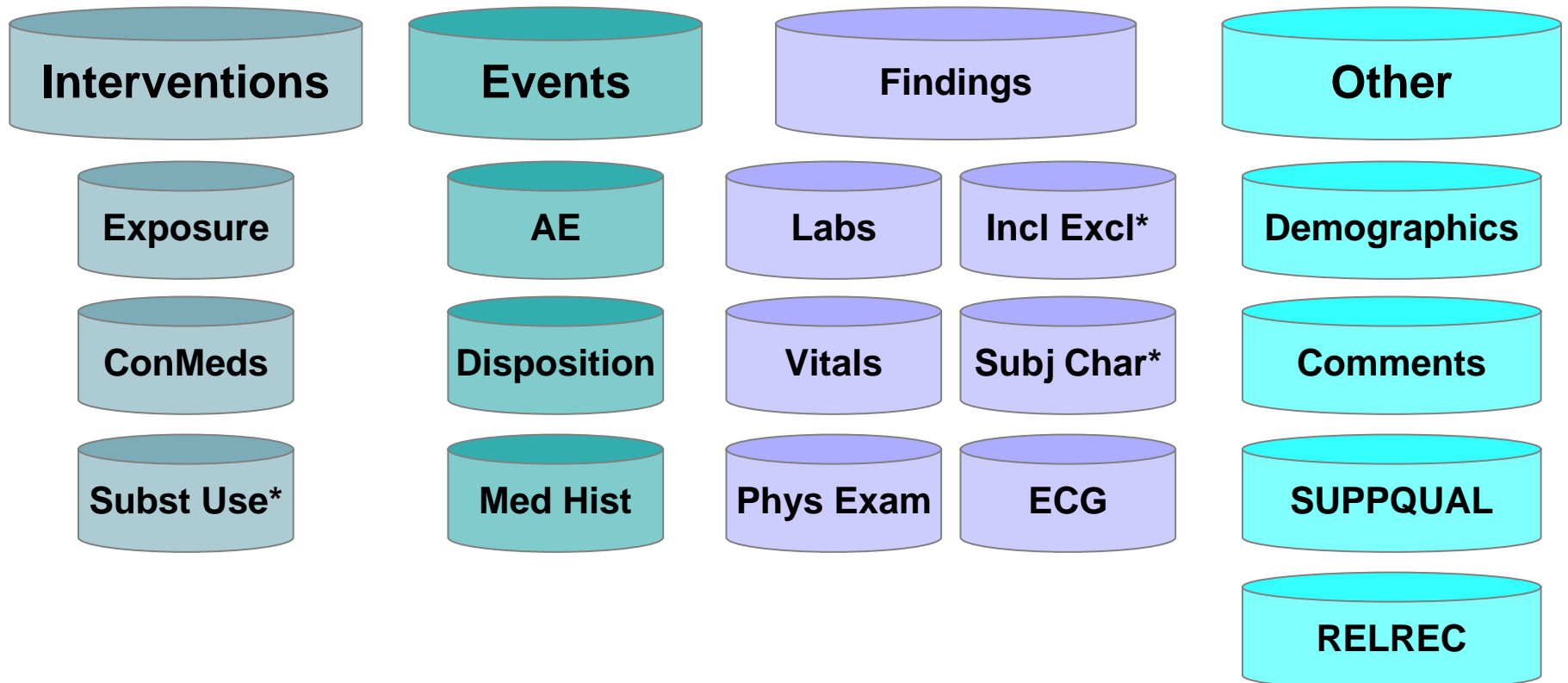
CDISC, SEND, and the SDTM Early 2004



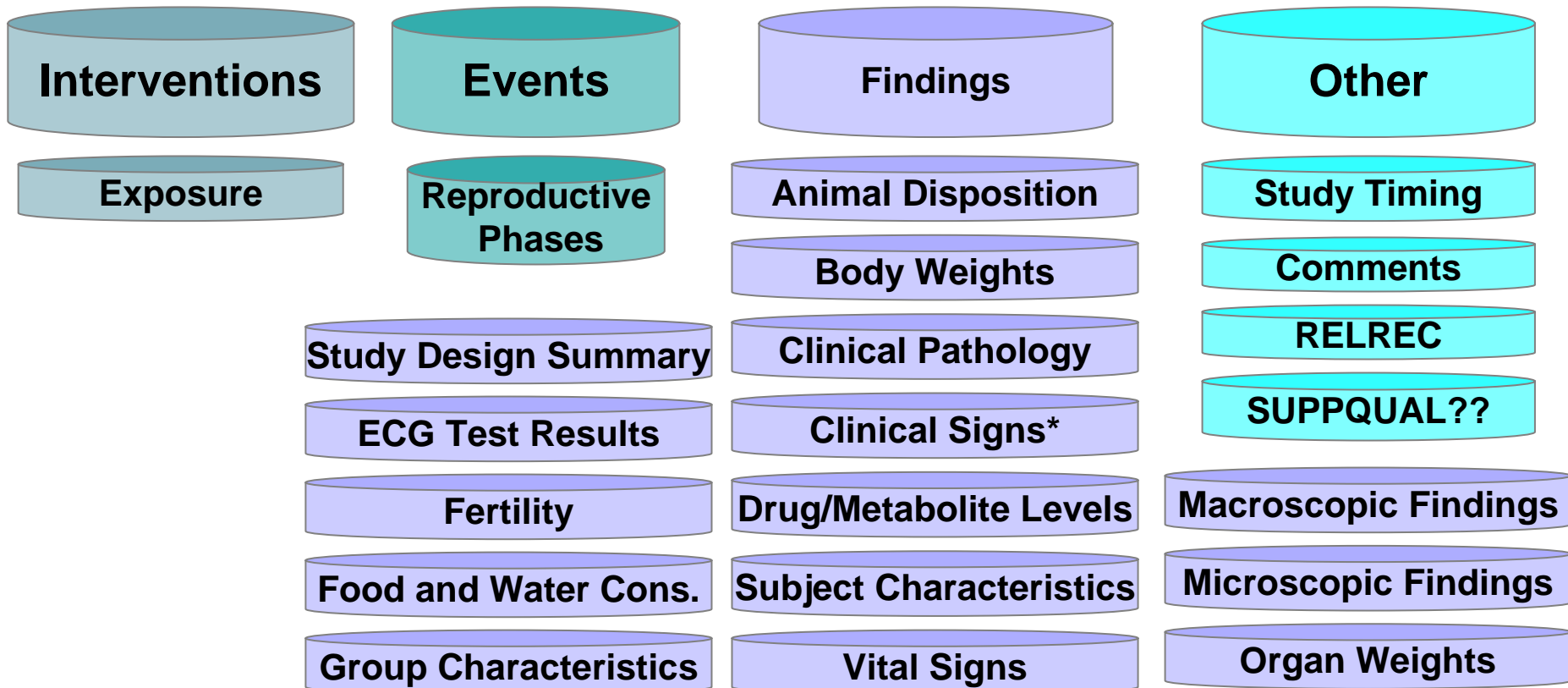
CDISC, SEND, and the SDTM Late 2004



Fitting Clinical Domains into SDTM Observation Classes



Fitting Nonclinical Domains into SDTM Observation Classes



Body Weights Domain (Findings)

Variable Name	Variable Label	Type	Controlled Terms or Format	Origin	Role	Usage Notes
STUDYID	Study Identifier	Char			Identifier	Unique identifier for a study within the submission.
USUBJID	Animal Identifier	Char			Identifier	Animal identifier.
DOMAIN	Domain	Char*	BW		Identifier	Two-character code for the domain most relevant to the observation.
BWSEQ	Sequence Number	Num			Identifier	Sequence number given to ensure uniqueness within a dataset for an animal. Can be used to join related records.
BWGRPID	Group ID	Char			Identifier	Used to link together a block of related records for an animal in a single domain. This is not the treatment group number.
BWTESTCD	Test Short Name	Char*	BW, BWGAIN		Topic	The topic variable of the domain.
BWTEST	Test Name	Char*	Body Weight, Body Weight Gain		Qualifier	Represents the name of the measurement.
BWORRES	Body Weight	Char			Qualifier	This field should contain all results, whether numeric or character.
BWORRESU	Units for Body	Char*			Qualifier	Unit for BWORRES (e.g., g, kg).

The Variable Name (SEND) which identifies the variable.

A descriptive Variable Label (up to 40 characters) that describes each variable in the dataset.

The data Type (e.g., Char, Num) of the variable, which can be a character or a number.

Any Controlled Terms or Format (e.g., BW, BWGAIN) associated with the variable.

The Origin (e.g., BW, BWGAIN) of each variable.

The Role of the variable (e.g., Identifier, Topic, Qualifier) describes how the variable is used.

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BWSTRESC	Character Result/Finding in Std Format	Char			Qualifier	Contains the result value for all findings, copied or derived from BWORRES or BWSTRESN in a standard format or standard units.

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Body Weights Domain (Findings)

Variable Name	Variable Label	Type	Controlled Terms or Format	Origin	Role	Usage Notes
BWSTRESN	Numeric Result/Finding in Std Units	Num			Qualifier	Used for continuous or numeric results or findings in standard format; copied in numeric format from BWORRES. BWSTRESN should store all numeric test results or findings.
BWSTRESU	Standard Units	Char*			Qualifier	Standardized unit used for BWSTRESC or BWSTRESN.
BWBLFL	Baseline Flag	Char*	Y or Null (blank)		Qualifier	Indicator used to identify a baseline value. Should be Y or Null (blank).
BWDTC	Date/Time Animal Weighed	Char			Timing	This is the date and time of collection of the observation.
BWSTAT	Finding Status	Char*	NOT DONE		Qualifier	Used to indicate a missing finding. Should be Null (blank) if a result exists in ORRES.
BWREASND	Reason Not Done	Char			Qualifier	Describes why a finding is missing. Used in conjunction with STAT when value is NOT DONE.

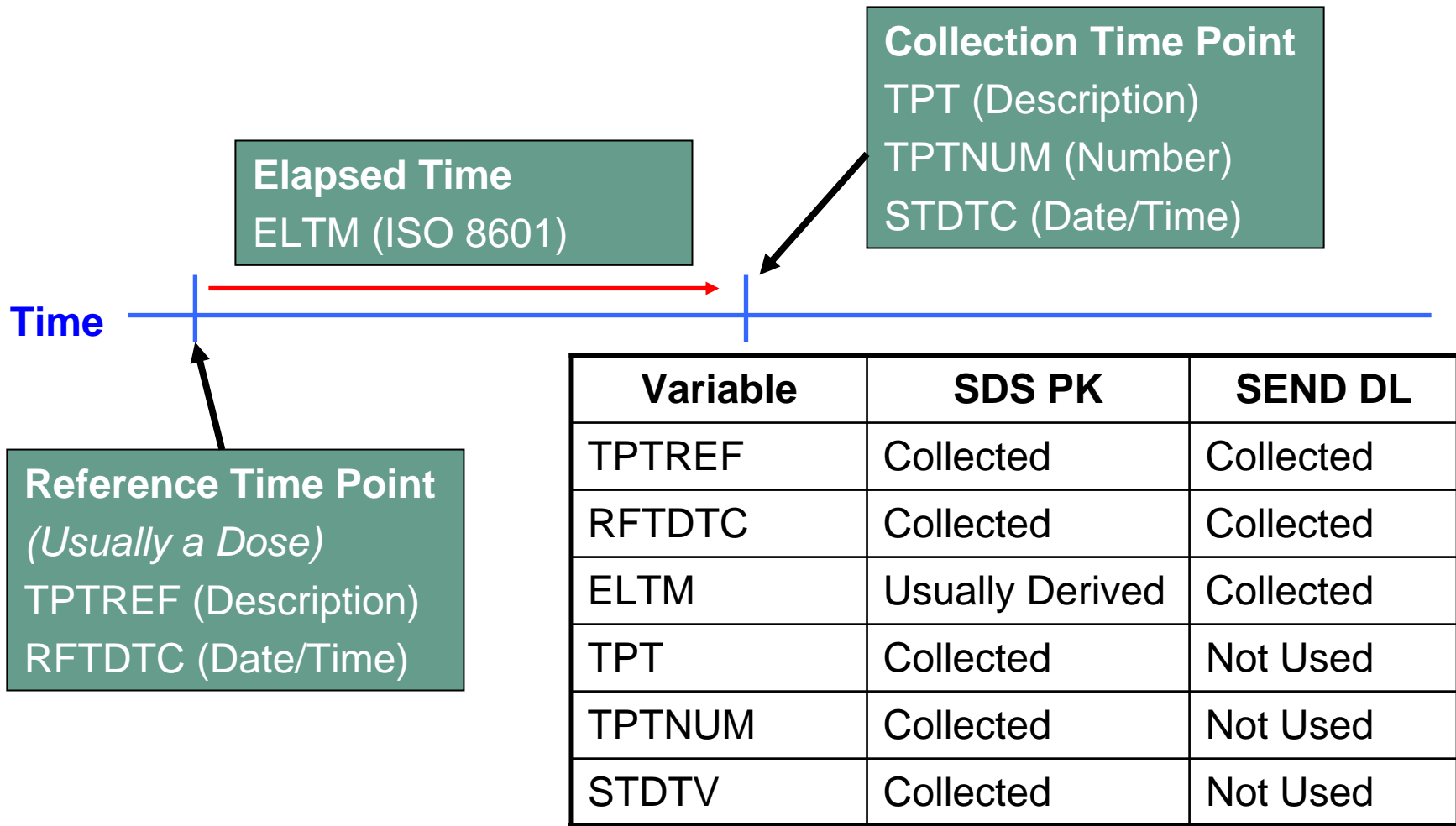
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Example Rows of Body Weight Dataset

STUDYID	USUBJID	DOMAIN	BWTEST CD	BWTEST	BWORRES	BWORRESU	BWBLFL	BWDTC
ABC001	1501	BW	BW	Body Weight	195	g	Y	2004-01-04
ABC001	1501	BW	BW	Body Weight	226	g		2004-01-08
ABC001	1501	BW	BW	Body Weight	258	g		2004-01-12
ABC001	1501	BW	BW	Body Weight	282	g		2004-01-15
ABC001	1501	BW	BW	Body Weight	306	g		2004-02-18

PK/Drug-Level Data



Example Rows of Drug Levels Dataset

STUDYID	USUBJID	DOMAIN	DLTEST	DLSPEC	DLELTM	DLORRES	DLORRESU	DLTPREF
ABC001	1501	DL	Drug A	SERUM	P15M	5.6	ng/mL	1 st Dose
ABC001	1501	DL	Drug A	SERUM	P30M	14.8	ng/mL	1 st Dose
ABC001	1501	DL	Drug A	SERUM	P1H	31.5	ng/mL	1 st Dose
ABC001	1501	DL	Drug A	SERUM	P2H	63.7	ng/mL	1 st Dose
ABC001	1501	DL	Drug A	SERUM	P4H	105.0	ng/mL	1 st Dose
ABC001	1501	DL	Drug A	LIVER	P4H	100	ng/g	1 st Dose

Summary

- SDTM standards were successfully applied to nonclinical data.
- Although PK and DL data are very similar, the data that are collected are different.
- The SDTM is sufficiently flexible to handle such differences.
- The SDTM can be used as a format for a wide variety of data.