

SEND (and SDTM) Implementation Guide Web-Based EASY Search Tool

Nonclinical Working Group

Summary

The SEND and SDTM implementation guides (IGs) are fact-dense documents which can be time consuming to navigate, and intimidating to all but frequent readers.

A web site was developed, to allow rapid browsing and searching of the IG domains.

This new tool serves the dual purpose of being immediately useful to SEND and SDTM implementers and is a practical example of the use of RDFs.

Methods

The PhUSE/CSS Emerging Technologies group created a Semantic data model/Resource Description Framework (RDF) of the IGs and their underlying data models. These are available in OWL and TTL format from:

<https://github.com/phuse-org/rdf.cdisc.org>

CDSIC together with NCI make available the CDISC SEND and CDISC SDTM Controlled Terminology in RDF OWL format from:

<http://evs.nci.nih.gov/ftp1/CDISC/SEND/>

These OWL and TTL files are read using the Java libraries of the JENA project for RDF and use SPARQL calls to query the models (<https://jena.apache.org/>).

A Java servlet based program combines these into an easy to use, publicly accessible web site.

Figures

- Starting page
- List of SDTM Domains – with links to details
- List of SEND Domains – with links to details
- Definition of a domain with links to controlled terminology
- Controlled terminology descriptions
- Result of searching for a term across domains

Conclusions and Recommendations

This web site was relatively easy to create, taking advantage of standard libraries that read the RDF data in OWL and TTL format.

This web site allows SEND and SDTM implementers a quick way of finding needed information in the standards. This is just one example of usage of these models.

The benefit of the implementation guides and controlled terminologies being available in RDF format is that they open these standards to a wide potential of software tools.

Screens of the SEND and SDTM Search Tool Web Site

Domains defined in SDTM Semantic Description

List of domains available.

Click on domain code to see full domain description.

Domain code	Label	Assumption	Structure
AE	Adverse Events	The Adverse Events dataset includes clinical data describing "any untoward medical occurrence in a patient or clinical investigation subject administered a pharmaceutical product and which does not necessarily have to have a causal relationship with this treatment" (ICH E2A). In consultation with regulatory authorities, sponsors may extend or limit the scope of adverse event collection (e.g., collecting pre-treatment events related to trial conduct, not collecting events that are assessed as efficacy endpoints). The events included in the AE dataset should be consistent with the protocol requirements. Adverse events may be captured either as free text or via a pre-specified list of terms.	One record per adverse event per subject
CE	Clinical Events	The intent of the domain model is to capture clinical events of interest that would not be classified as adverse events. The data may be data about episodes of symptoms of the disease under study (often known as signs and symptoms), or about events that do not constitute adverse events in themselves, though they might lead to the identification of an adverse event. For example, in a study of an investigational treatment for migraine headaches, migraine headaches may not be considered to be adverse events per protocol. The occurrence of migraines or associated signs and symptoms might be reported in CE. Other studies might track the occurrence of efficacy endpoints. For example, in a study of an agent for prevention of ischemic stroke, all occurrences of death might be captured as clinical events and assessed as endpoint criteria. Note that other information about events might be reported in other datasets. For example, the event might be reported in AE and death would also be a reason for discontinuation in DS.	One record per event per subject

Domains defined in SEND Semantic Description

List of domains available.

Click on domain code to see full domain description.

Domain code	Label	Assumption	Structure
BG	Body Weight Gains	Body weight gain is the actual difference between two body weight measurements for any given interval for a subject. This is most commonly shown as the difference between two consecutive body weight measurements.	One record per test per interval per subject
BW	Body Weights	The Body Weight domain captures body weights collected for subjects during the study and at the end of the study (terminal body weights).	One record per test per observation time per subject
CL	Clinical Observations	The Clinical Observations domain captures clinical sign information in addition to ophthalmology, physical examination, and dermal examination collected during in-life while executing the study.	One record per finding per observation time per subject or pool
CO	Comments	The Comments special-purpose domain provides a free-text comments related to data in one or more domains. Comments are generally not responses to specific questions; they consist of voluntary, free-text, or unsolicited observations.	
DD	Death Diagnosis	The Death Diagnosis domain captures the diagnosis of a subject.	
DM	Demographics		
DS	Disposition	a. The disposition dataset provides a record for the disposition of a subject throughout the study. One record will be created for each subject, whether it ultimately died or was removed from the study.	
EG	ECG Test Results	The ECG Test Results domain captures electrocardiogram parameters.	

Description of Domain in SEND IG

Domain: EX

Assumptions						
Exposure						
a. The Exposure Domain Model records the details of a subject's administered dose of protocol-specified study treatment. Study treatment may be any intervention that is prospectively defined as a test material within a study, and is typically, but not always, administered to the subject. Examples include, but are not limited to, placebo, active comparators, and investigational products. Only protocol-specified treatments should be included in this domain.						
b. This domain should contain one record per constant dosing interval per subject. A constant dosing interval is sponsor-defined and represents a specific period of time during which an animal was treated with a specific lot at a constant dose level. For example, for a study with once-a-week administration of a standard dose for 6 weeks, the administered dose may be represented with a single record per subject spanning the entire treatment phase. Alternatively, a separate entry can be made for each treatment administration and any deviations in treatment that occur. For this example there could be up to six records (one for each weekly administration).						
a. The variables --PRESPEC, --OCCUR, --STAT, and --REASND from the Interventions general observation class would not generally be used in the EX domain because EX should only contain treatments received.						
b. Other additional Qualifiers (not previously mentioned) from the SDTM Interventions Class may be added to this domain.						
Name	Label	Description	Control Terminology	Compliance	Type	Role
STUDYID	Study Identifier	Unique identifier for a study.		RequiredVariable	Character	IdentifierVariable
DOMAIN	Domain Abbreviation	Two-character abbreviation for the domain.	EX	RequiredVariable	Character	IdentifierVariable

Description of CT List

Controlled Terminology List: (ROUTE)

Code	CTLList	Definition	Description	Extensible?
C66729	ROUTE	The course by which a substance was administered in order to reach the site of action in the body.	CDISC SDTM Route of Administration Terminology	true

Name	Code	Definition	nci Preferred Term
AURICULAR (OTIC)	C38192	Administration to or by way of the ear. (FDA)	Auricular Route of Administration
BUCCAL	C38193	Administration directed toward the cheek, generally from within the mouth. (FDA)	Buccal Route of Administration
CONJUNCTIVAL	C38194	Administration to the conjunctiva, the delicate membrane that lines the eyelids and covers the exposed surface of the eyeball. (FDA)	Conjunctival Route of Administration
CUTANEOUS	C38675	Administration to the skin. (FDA)	Cutaneous Route of Administration
DENTAL	C38197	Administration to a tooth or teeth. (FDA)	
DIETARY	C78373	Administration by way of food stuff.	
ELECTRO-OSMOSIS	C38633	Administration of through the diffusive substance through a membrane in an electric field. (FDA)	
ENDOCERVICAL	C38205	Administration within the canal of the uterus. Synonymous with the term intracervical. (FDA)	
ENDOSINUSIAL	C38206	Administration within the nasal sinus. (FDA)	
ENDOTRACHEAL	C38208	Administration directly into the trachea. Synonymous with the term intratracheal.	

Domain Elements in SEND IG containing the search term: STDTC

Domain	Name	Label	Description	Control Terminology	Compliance	Type	Role
BG	BGDY	Study Day Animal Weighed	Study day of the start of the weight interval, in integer days. The algorithm for calculations must be relative to the sponsor-defined RFSTDTC variable in the Demographics (DM) domain.		PermissibleVariable	Numeric	TimingVariable
BG	BGENDY	Study Day of End of Weight Interval	Study day of the end of the weight interval, in integer days. The algorithm for calculations must be relative to the sponsor-defined RFSTDTC variable in the Demographics (DM) domain.		PermissibleVariable	Numeric	TimingVariable
BW	BWDY	Study Day Animal Weighed	Study day of body weight collection, in integer days. The algorithm for calculations must be relative to the sponsor-defined RFSTDTC variable in the Demographics (DM) domain.		PermissibleVariable	Numeric	TimingVariable
CL	CLDY	Study Day of Observation	Study day of the clinical observation, in integer days. The algorithm for calculations must be relative to the sponsor-defined RFSTDTC variable in the Demographics (DM) domain.		PermissibleVariable	Numeric	TimingVariable

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Note: The opinions expressed in this poster are those of the authors and do not necessarily represent the opinions of their respective companies