Introducing the CDASH eCRF Project + CDISC Standards for Animal Rule Studies

Alana St. Clair, Project Manager, CDISC
Dan Crawford, Senior Director, Vault CDMS Strategy, Veeva Systems
Jon Neville, Sr. Standards Developer, CDISC

Tuesday, 21 JUL 2020
11:00 – 12:30 EDT

Today’s Agenda

1. Housekeeping
2. Presenter Introductions
3. Feature Presentations
4. Question & Answer Session
5. Upcoming Learning Opportunities + Resources

Housekeeping

Housekeeping

- You will remain on **mute** for the entirety of the call
- There will be a Q&A after all of the presentations are finished
- Audio issues? Shut down and restart the GoToWebinar app
- The slides from the presentation and a recording of this webinar will be available in the Members Only section of the CDISC website
  - To access – make sure that you create a login for the CDISC website if you haven't already
  - If you are employed by a CDISC member organization, please ensure you use your employer-issued email address with your employer's domain name, so we can verify membership for the purpose of applying discounts to purchasing event tickets, online courses, and more!

Content Disclaimer

- The purpose of this webinar is to provide examples of implementation and should not be considered official recommendations by CDISC unless otherwise stated in the presentation.
- This webinar is not an authorized CDISC course, is not developed or delivered under CDISC Operating Procedures, and should not replace a published standard. Please refer to the latest published standards for the most authoritative implementation information.

Our Presenters

- Alana St. Clair, Project Manager, CDISC
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The CDASH eCRF Library Project

Presented by:

Alana St. Clair
Project Manager, CDISC

Dan Crawford
Senior Director CDMS Strategy, Veeva Systems

Agenda

1. What is the CDASH eCRF Library Project?
2. Purpose
3. Approach
4. ODM Component
5. Status and Delivery Plan

What is the CDASH eCRF Library Project?

CDASH

Version	Related
CDASHIG v2.1	CDASH Model v1.1
CDASHIG v2.0	CDASH Model v1.0
CDASH Serious Adverse Event (SAE) Supplement v1.0	SDTM v1.3 SDTM v1.3 and SDTMIG v3.1.3 CDASH v1.1

What is the CDASH eCRF Library Project?

- Supplement to the CDASHIG
- Machine-readable, visual representations of case report form (CRF) layout
- Project scope - CDASHIG v2.1
- The team is using the Data Acquisition Designer offered by Formedix to create the CRFs for this project.

Purpose

Ready-to-use CRFs

- “Out-of-the-box” solution for new users
- Meets the basic needs for many users, but also customizable
- Great for those new to CDASH

Align with CDISC 360

- End-to-end automation

Project Approach

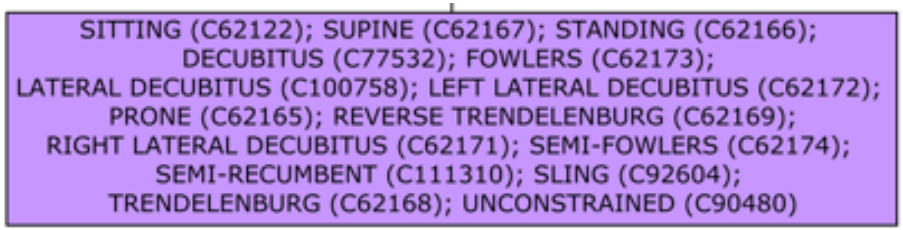
Process

- ODM-XML file of the CDASHIG v2.1 metadata was loaded into Formedix
- Review domain metadata in the Wiki, use the 80/20 rule
- Make necessary updates in Formedix
- Review CRF visualizations
- Create initial CRF package for posting

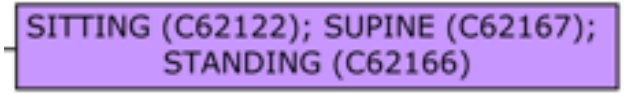
Review CRF Metadata in the Wiki - 80/20 Rule

- Include variable/field on CRF?
- Question text or prompt?
- Parse CT codelist
- Documented decisions in “Decision Record”

From not very useful



To more useful



Review CRF Visualization

Form AE - Adverse Events			
1 AE - Adverse Events			
1.1	Were any adverse events experienced?	○ [N] No ○ [Y] Yes	***AEYN***
1.2	What is the adverse event term?		***AETERM***
1.3	Start Date (DD-MMM-YYYY)	_____	***AESTDAT***
1.4	Ongoing (as of [the study-specific time point or period])	○ [N] No ○ [Y] Yes	***AEONGO***
1.5	End Date (DD-MMM-YYYY)	_____	***AEENDAT***
1.6	Severity	○ [MILD] Mild ○ [MODERATE] Moderate ○ [SEVERE] Severe	***AESEV***

Create CRF Package for Posting

- Excel metadata table
- PDF with CDASH annotations
- ODM-XML File
- HTML rendering via XSL
- “Decision record" to outline project approach and any decisions made during CRF review

ODM Component

Operational Data Model (ODM)

- Vendor-neutral, platform-independent, data exchange standard

- Language of choice for representing CRF content in many electronic data capture (EDC) systems

eCRF Project and ODM Now

- Implementation examples are based on the CDASHIG v2.1, ODM v1.3 and extensions.

- ODM has intentionally omitted presentation metadata.

eCRF Project and ODM in the Future

- Looking to add ‘implementation’ metadata (dropdown list, form location, etc.)

- The ODM format for the eCRF project may be upgraded with the next ODM version.

Status and Delivery Plan

Status and Delivery Plan

- Completed work: DM, VS, CM, IE, AE, PE, DS, MH, EC
- Planned work: Q3 2020 – First CRF package complete
- Publicly available on the CDISC Website and through Formedix, with a subscription

Thank you to the team!

- Dan Crawford – Team Lead
- Dawn Kaminski – Team Lead
- Jorge Torres Borrero – Team Lead
- Nikki Flores
- Carolyn Famatiga-Fay
- Erica Gonzales
- Fred Bermont
- Rebecca Lynch
- Venkata Maguluri
- Tisanna Shelton
- Kevin Gao
- Swarupa Sudini
- Yogesh Gupta
- Anoop Galhotra
- Mike Ward

CDISC Standards for Animal Rule Studies

CDISC Webinar
21 July 2020

Presented by Jon Neville
Senior Standards Developer, CDISC

Agenda

1. Background on FDA Animal Rule including drugs approved under this law and the need for standards
2. The Animal Rule standards development project
3. Impact on SEND and SDTM

Background

Shortly after September 11, 2001

- September-November 2001, a highly sophisticated powdered form of *B. anthracis* (anthrax) was spread via the U.S. Mail in a bioterrorism attack that resulted in 22 infected individuals
- 5 infected individuals died
- Standard of care at the time: Ciprofloxacin
  - Generally well-tolerated, but not in all individuals
  - Other drugs are sometimes used in support: doxycycline, procaine penicillin G
  - Options were limited; production of Ciprofloxacin had to be increased

Anthrax treatment and prevention, 2020

- Two additional drugs, and one vaccine and one biologic are now approved for use in the U.S. for treating/preventing anthrax
  - raxibacumab injection and obiltoxaximab injection for treatment
  - Anthrax vaccine (Biothrax)
  - Anthrax immune globulin (Anthrasil)

How were these drugs approved?

Human clinical trials are not ethical

The Animal Rule

In 2002, FDA amended its regulations to allow for the approval of drugs and biological products intended to treat or prevent conditions caused by exposure to chemical, biological, radiological or nuclear (CBRN) agents using **animal models** when human efficacy studies are not ethical and field trials are not feasible

This change to the regulations is commonly referred to as the "*Animal Rule*"

21 CFR 314.600-650 for drugs and
21 CFR 601.90-95 for biological products

Animal Rule

- Efficacy is established based on adequate and well-controlled studies in **animal models** of the human disease or condition of interest “when the results of those animal studies establish that the drug product [or the biological product] is reasonably likely to produce clinical benefit in humans.”
- Safety is evaluated under the preexisting requirements for drugs and biological products

21 CFR 314.610(a) for drugs and 21 CFR 601.91(a) for biological products

CDER drugs approved under the Animal Rule (11)

PROPRIETARY NAME	ESTABLISHED NAME OR PROPER NAME WITH DOSAGE FORM	INDICATION	ORIGINAL APPLICANT	APPLICATION NUMBER	APPROVAL DATE
PYRIDOSTIGMINE BROMIDE	pyridostigmine bromide tablet (30mg)	For prophylaxis against the lethal effects of soman nerve agent poisoning	US Army	NDA 20414	2/5/2003
CYANOKIT	hydroxocobalamin injection, powder, lyophilized, for solution	For the treatment of known or suspected cyanide poisoning	EMD Pharmaceuticals, Inc.	NDA 22041	12/15/2006
LEVAQUIN	levofloxacin tablet, levofloxacin injection, levofloxacin oral solution	For treatment of plague, including pneumonic and septicemic plague, due to *Yersinia pestis* (*Y. pestis*) and prophylaxis for plague in adults and pediatric patients, 6 months of age and older	Janssen Pharmaceuticals, Inc.	NDA 20634/S-061 NDA 20635/S-067 NDA 21721/S-028	4/27/2012
RAXIBACUMAB	raxibacumab injection	For the treatment of adult and pediatric patients with inhalational anthrax due to *Bacillus anthracis* in combination with appropriate antibacterial drugs; also indicated for prophylaxis of inhalational anthrax when alternative therapies are not available or are not appropriate	Human Genome Sciences, Inc.	BLA 125349	12/14/2012
CIPRO CIPRO IV	ciprofloxacin hydrochloride tablet, ciprofloxacin hydrochloride oral suspension ciprofloxacin for intravenous infusion	For treatment of plague, including pneumonic and septicemic plague, due to *Yersinia pestis* (*Y. pestis*) and prophylaxis for plague in adults and pediatric patients from birth to 17 years of age	Bayer Healthcare Pharmaceuticals, Inc.	NDA 19537/S-083 NDA 20780/S-041 NDA 19847/S-055 NDA 19857/S-063	2/2/2015
NEUPOGEN	filgrastim injection	To increase survival in patients acutely exposed to myelosuppressive doses of radiation (Hematopoietic Syndrome of Acute Radiation Syndrome)	Amgen Inc.	BLA 103353/S-5183	3/30/2015
AVELOX AVELOX IV	moxifloxacin hydrochloride tablet, moxifloxacin injection	For adult patients for the treatment of plague, including pneumonic and septicemic plague, due to susceptible isolates of *Yersinia pestis* and prophylaxis of plague in adult patients	Bayer Healthcare Pharmaceuticals, Inc.	NDA 21085/S-060 NDA 21277/S-056	5/8/2015

CDER drug approvals, continued

PROPRIETARY NAME	ESTABLISHED NAME OR PROPER NAME WITH DOSAGE FORM	INDICATION	ORIGINAL APPLICANT	APPLICATION NUMBER	APPROVAL DATE
NEULASTA	pegfilgrastim injection	To increase survival in patients acutely exposed to myelosuppressive doses of radiation (Hematopoietic Subsyndrome of Acute Radiation Syndrome)	Amgen Inc.	BLA 125031/S-180	11/13/2015
ANTHIM	obiltoxaximab injection	Indicated in adult and pediatric patients for treatment of inhalational anthrax due to *B. anthracis* in combination with appropriate antibacterial drugs and, for prophylaxis of inhalational anthrax when alternative therapies are not available or are not appropriate	Elusys Therapeutics, Inc.	BLA 125509	3/18/2016
LEUKINE	sargramostim (solution) injection sargramostim (lyophilized powder) for injection	To increase survival in adult and pediatric patients from birth to 17 years of age acutely exposed to myelosuppressive doses of radiation (Hematopoietic Syndrome of Acute Radiation Syndrome [H-ARS])	Sanofi-Aventis	BLA 103362/S-5240	3/29/2018
TPOXX	tecovirimat monohydrate capsule	For the treatment of human smallpox disease in adults and pediatric patients weighing at least 13 kg	SIGA Technologies, Inc.	NDA 208627	7/13/2018

CBER biologic approvals (3)

CBER has approved three products under the Animal Rule (see bulleted list below). For more information on these CBER approvals, see CBER's Biologics Products & Establishments webpage, available at: https://www.fda.gov/BiologicsBloodVaccines/ucm121134.htm.

- BAT (Botulism Antitoxin Heptavalent (A, B, C, D, E, F, G) – (Equine) [injection]) for the treatment of symptomatic botulism following documented or suspected exposure to botulinum neurotoxin serotypes A, B, C, D, E, F, or G in adults and pediatric patients
- Anthrasil (Anthrax Immune Globulin Intravenous (Human)) for the treatment of inhalational anthrax in adult and pediatric patients in combination with appropriate antibacterial drugs
- BioThrax (Anthrax Vaccine Adsorbed [injection]) for post-exposure prophylaxis of disease following suspected or confirmed *Bacillus anthracis* exposure, when administered in conjunction with recommended antibacterial drugs

FDA call for proposals- Develop standards for AR Studies

Counter-Terrorism and Emergency Coordination Staff (CTECS)

"Provides consultation on the development and availability of safe, effective, and quality medical countermeasures (MCMs) for chemical, biological, radiological and nuclear (CBRN) threats and emerging infectious diseases."

In 2017, CDISC and Critical Path Institute were awarded a grant to develop CDISC standards for studies of MCMs conducted under the animal rule.

AR Standards Development Project

Definitions

- **Challenge agent-** a chemical, biological, radiological or nuclear (CBRN) agent that is designed to cause injury, given deliberately to an animal subject

- **Medical Countermeasure (MCM) –** an agent that is designed to mitigate or treat the damage caused by CBRN agents

Exposure to challenge agents may be viewed as the indication for which MCMs are developed and approved for marketing

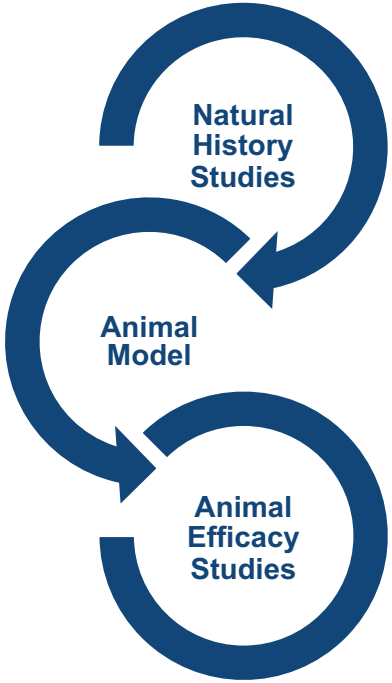
Standards Development

- Prior to this IG, no standard existed for the submission of data from these studies.
- CDISC worked with C-Path and the FDA (CTECS) to develop standards.
- The result is an implementation guide based upon the SENDIG, referred to as the SENDIG-AR.

Deliverables and Requirements

- An Animal Rule implementation guide that meets the needs of the FDA for the identified and anticipated use cases for Animal Rule studies, including:
  - Applicability to each of the categories of challenge agents identified in the funding opportunity
  - Representation of the characterization and attributes of medical countermeasures
  - Representation of regulatory demographic information
- Changes to SDTM represented in SDTM v1.8
- Any new rules, variables, assumptions, and data modeling approaches specified meet the needs of the CDISC user community and do not conflict with existing rules and principles of SDTM and the SEND.
- Guidelines specified in CDISC Operating Procedure 001 (CDISC-COP-001), Standards Development are followed [5]

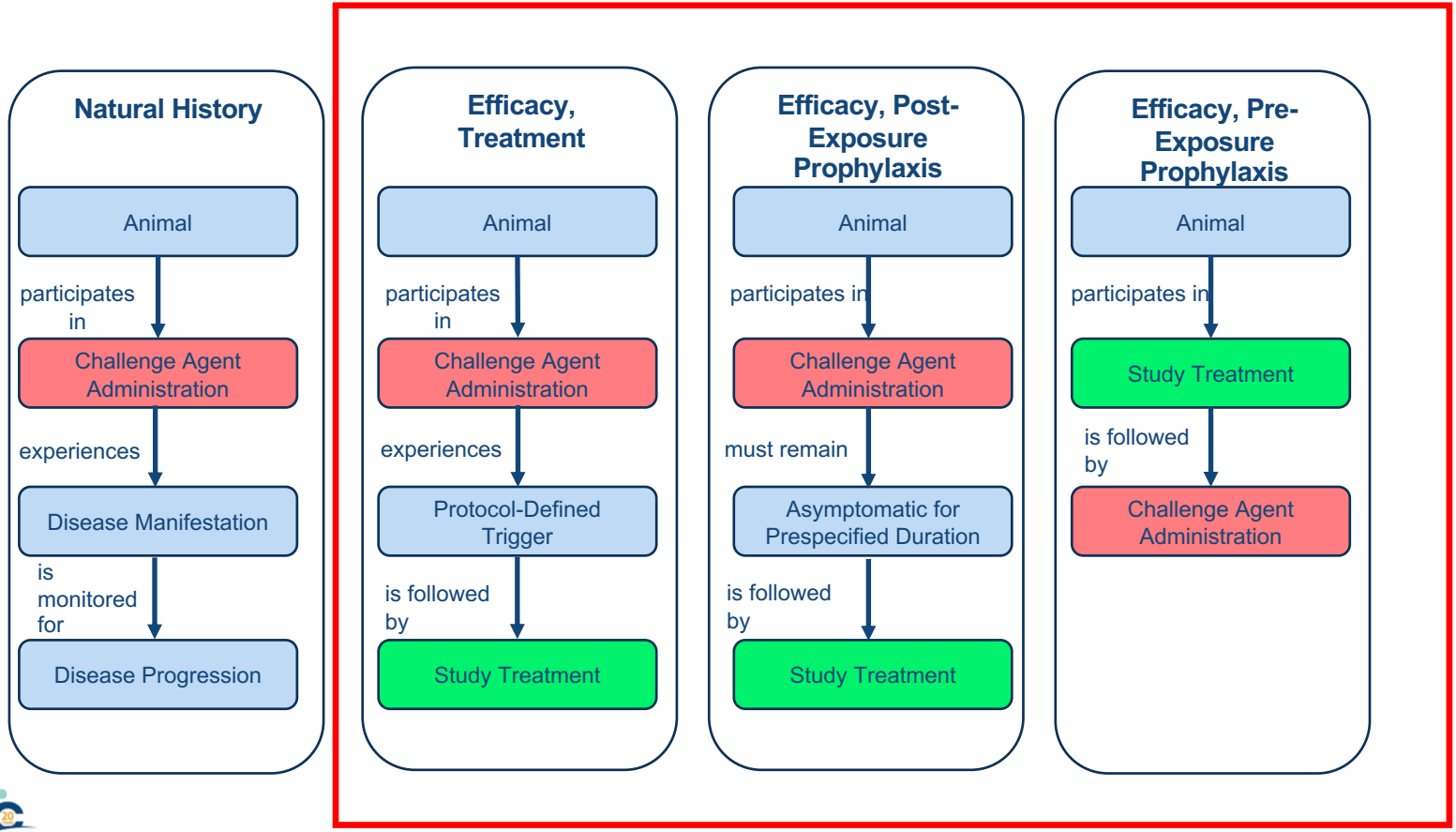
Animal rule study types: Natural History Studies



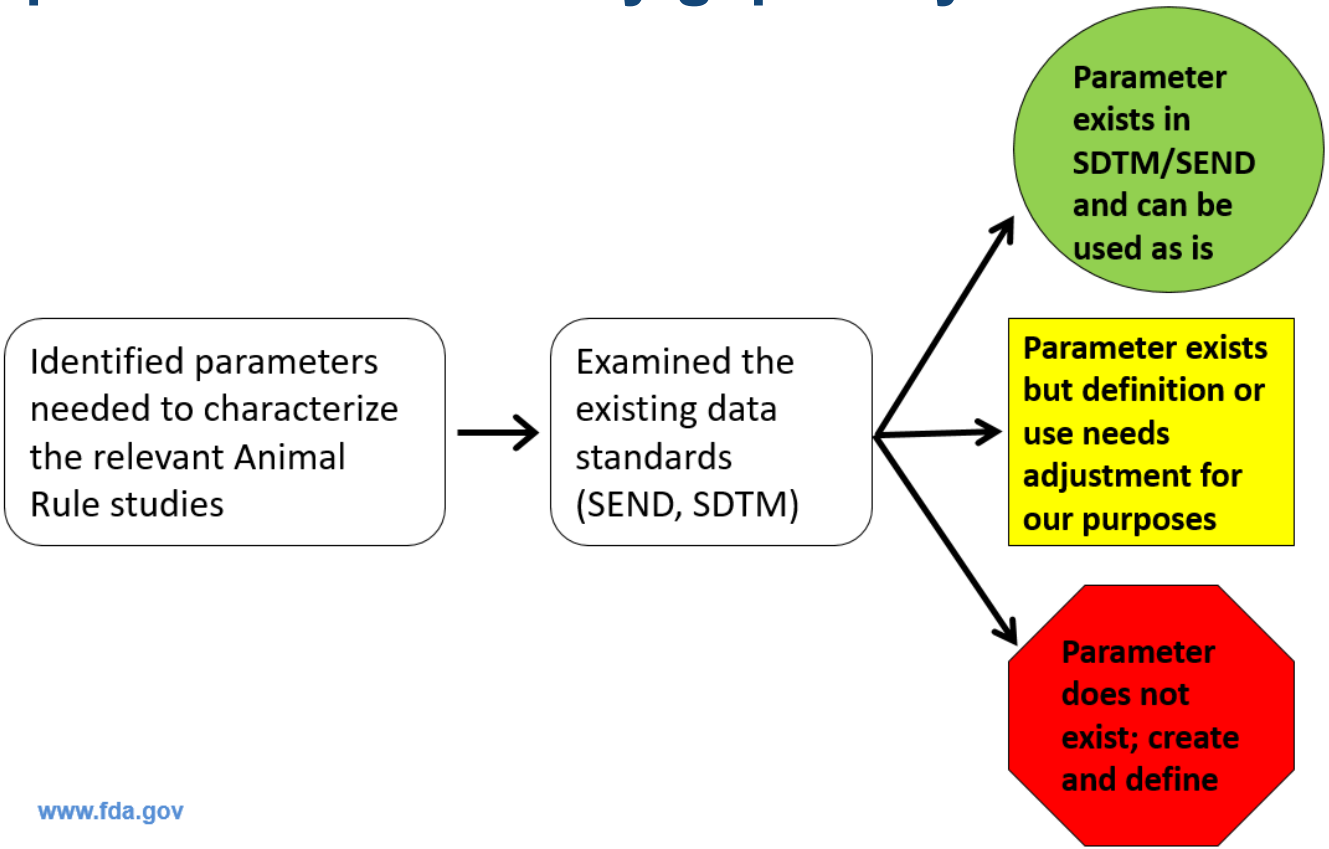
Studies in which animals are exposed to a challenge agent and monitored to gain an understanding of the development and progression of the resulting disease or condition, including parameters such as manifestations (e.g., signs, clinical and pathological features, laboratory parameters, extent of organ involvement, morbidity, and outcome), the time from exposure to manifestation onset, time course and order of manifestation progression, and severity

From FDA's guidance *Product Development Under the Animal Rule* – Appendix C

Types of Efficacy Studies



Development was driven by gap analysis



www.fda.gov

The Approach

- Begin with SENDIG v3.1 domains.
  - Do not duplicate material in the SENDIG v3.1.
  - Represent only significant changes in this IG.
- Include clinical domains from the SDTMIG v3.2 as needed.
- Create new domains as needed.
- Create new SDTM variables as needed. Include these in the accompanying version of the SDTM (V1.8).
- Develop/expand controlled terminology.
- Publish SENDIG-AR

Organization of the SENDIG-AR

- Introduction
- New Domains Introduced in this Document
- New Variables Introduced in this Document
  - Interventions Variables
  - Findings Variables
  - Timing Variables
- Updates to Demographics
- Domains Based upon the General Observation Classes
  - Interventions
    - Concomitant/Prior Medications (CM)
    - Exposure (EX)
    - Procedure Agents (AG)
    - Procedures (PR)
    - Integrated Intervention Examples
- Domains Based upon the General Observation Classes (cont'd)
  - Events
    - Medical History (MH)
  - Findings
    - Microbiology Specimen (MB)
    - Subject Characteristics (SC)
  - Findings About Events or Interventions
- Updates to Trial Design
  - Trial Sets
  - Trial Summary
  - Challenge Agent Characterization (AC)
- Additional Changes to Existing Domains
- Appendices

Impact on SDTM and SEND

Domain Comparison: Nonclinical vs. Clinical

Nonclinical Only (SENDIG v3.1)

Findings
- Body Weights
- Clinical Observations
- Food and Water Consumption
- Macroscopic Findings
- Microscopic Findings
- Palpable Masses
- Organ Measurements
- Tumor Findings

Trial Design
- Trial Sets

Relationships
- POOLDEF

Clinical Only (SDTMIG v3.3)

Interventions
- Concomitant Medications
- Exposure as Collected
- Meal Data
- Procedure Agents
- Procedures
- Substance Use

Events
- Adverse Events
- Clinical Events
- Deviations
- Healthcare Encounters
- Medical History

Findings
- Disease Response and Clin Classification
- Drug Accountability
- Functional Tests
- Immunogenicity Specimen Assessments
- Inclusion/Exclusion Criteria Not Met
- Microbiology Specimen
- Microbiology Susceptibility
- Musculoskeletal System Findings
- Morphology
- Nervous System Findings
- Ophthalmic Examinations
- Physical Exam
- Questionnaires
- Reproductive System Findings
- Subject Status
- Skin Response
- Tumor/Lesion Identification
- Tumor/Lesion Results
- Urinary System Findings
- Findings About Subclass

Trial Design
- Trial Visits
- Trial Inclusion/Exclusion
- Trial Disease Milestones

Relationships
- RELSUB

Special Purpose
- Subject Visits
- Subject Disease Milestones

Domains introduced to SEND for Animal Rule IG

Code	Domain Name	Purpose in Animal Rule Studies	Status
AG	**Procedure Agents**	For representing the challenge agent administration	From SDTMIG
CM	**Concomitant Medications**	For medications given as supportive care, and for prior medications	From SDTMIG
FA	**Findings About**	For exposure conditions of the challenge agent administration	From SDTMIG
MB	**Microbiology Specimen**	One use case so far: detection of ova and parasites in stool samples	From SDTMIG
MH	**Medical History**	Same as in human studies; first use in SEND	From SDTMIG
PR	**Procedures**	Biopsies; Holter monitor	From SDTMIG
AC	**Challenge Agent Characterization**	Defines parameters/characteristics of the CBRN agents used in AR studies	New Domain

Challenge Agent Characterization (AC)

Domain Specification

Variable Name	Variable Label
STUDYID	Study Identifier
DOMAIN	Domain Abbreviation
ACSEQ	Sequence Number
ACGRPID	Group ID
ACPARMCD	Challenge Agent Parameter Short Name
ACPARM	Challenge Agent Parameter
ACVAL	Parameter Value
ACVALU	Parameter Units
ACVALNF	Parameter Null Flavor
ACVALCD	Parameter Value Code
ACVCDREF	Name of the Reference Terminology
ACVCDVER	Version of the Reference Terminology

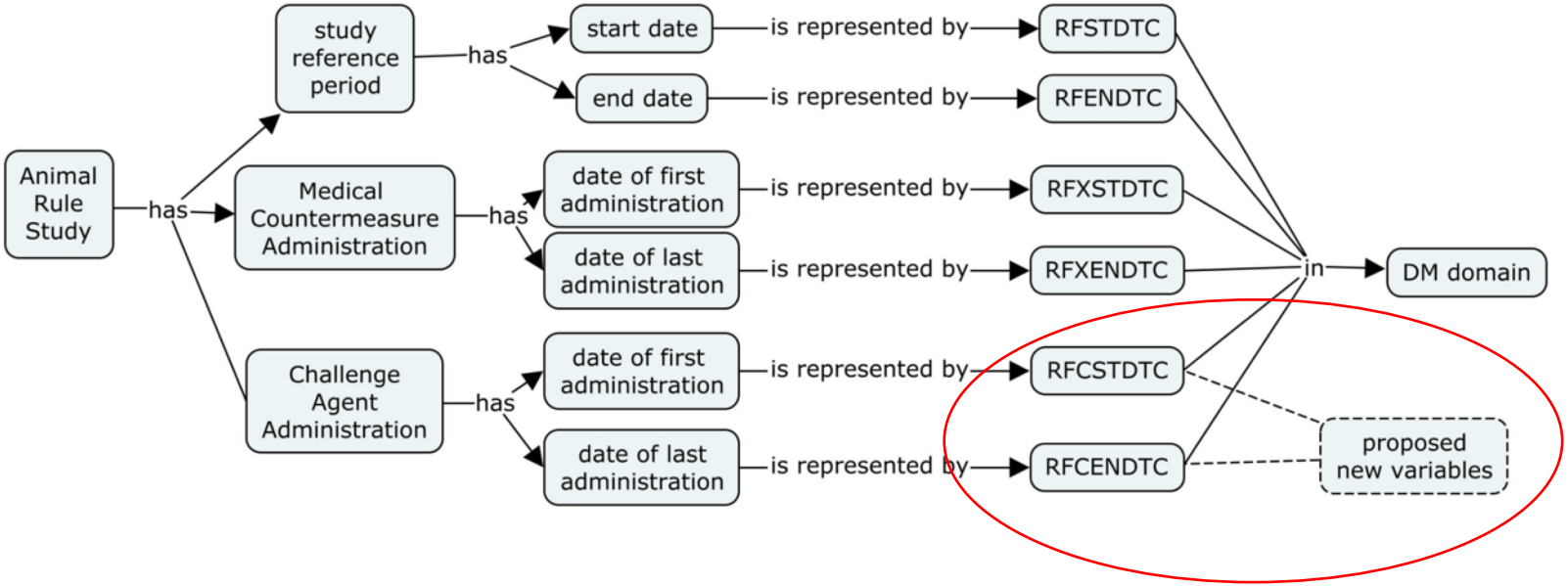
Challenge Agent Parameters (1)

Challenge Agent Type	Parameter Code	Parameter	Controlled Terms, Codelist, or Format
All	CAGTCAT	Challenge Agent Category	(CAGTCAT)
All	CAGTSUPA	Challenge Agent Supplier Address	Free text
All	CAGTSUPN	Challenge Agent Supplier Name	Free text
All	MCCATIND	Multiple Challenge Agent Category Ind	(NY)
All	MCSCTIND	Multiple Challenge Agent Same Cat Ind	(NY)
Biological	BAMTIDCD	Batch or Lot Number	Free text
Biological	BWBPSIND	Bio Ag Work Bank/Primary Stock Char Ind	(NY)
Biological	BABIOVRN	Biological Agent Biovar Name	Free text
Biological	BACAT	Biological Agent Category	(BACAT)
Biological	BACHRIND	Biological Agent Characterized Indicator	(NY)
Biological	BACOAIND	Biological Agent CoA Indicator	(NY)
Biological	BAENGIND	Biological Agent Engineered Indicator	(NY)
Biological	BAGENETN	Biological Agent Genetic Character	Free text
Biological	BAGENSPC	Biological Agent Genus and Species	(MICROORG)
Biological	BAMTIDCD	Biological Agent Material Ident Code	Free text
Biological	BANSIND	Biological Agent Nucleotide Sequence Ind	(NY)
Biological	BANSLOC	Biological Agent Nucleotide Sequence Loc	Free text
Biological	BASEROVN	Biological Agent Serovar Name	Free text
Biological	BASTRNN	Biological Agent Strain Name	Free text

Challenge Agent Parameters (2)

Challenge Agent Type	Parameter Code	Parameter	Controlled Terms, Codelist, or Format
Chemical	CHAGCAS	Chemical Agent CAS Number	Structured text
Chemical	CACOAIND	Chemical Agent CoA Indicator	(NY)
Chemical	CHAGMCAS	Chemical Agent Metabolite CAS Number	Structured text
Chemical	CHAGMNAM	Chemical Agent Metabolite Name	Free text
Chemical	CHAGMF	Chemical Agent Molecular Formula	Use standard representation
Chemical	CHAGMW	Chemical Agent Molecular Weight	Numeric
Chemical	CHAGNAM	Chemical Agent Name	Standard names
Chemical	CHAGPURT	Chemical Agent Purity	Numeric
Rad/Nuc	RNAISBS	Rad/Nuc Agent Irrad Source Beam Strength	Numeric in keV
Rad/Nuc	RNAMFIND	Rad/Nuc Agent Mixed Field Indicator	(NY)
Rad/Nuc	RNARADSN	Rad/Nuc Agent Radioisotope Species Name	Standard text
Rad/Nuc	RNASRC	Rad/Nuc Agent Source	(RNASRC)
Rad/Nuc	RNAIOTYP	Rad/Nuc Ionizing Radiation Type	(RNAIOTYP)

Impact on existing standards: New Demography variables required



New SDTM Demographics Variables

Variable Name	Variable Label	Type	Controlled Terms, Codelist, or Format	Role	Core
RFCSTDTC	Date/Time of First Challenge Agent Admin	Char	ISO 8601	Record Qualifier	Exp
RFCENDTC	Date/Time of Last Challenge Agent Admin	Char	ISO 8601	Record Qualifier	Exp

New SDTM Timing Variables

Variable Name	Variable Label	Type	CDISC Notes
--XDY	Day of Obs Relative to Exposure	Num	The actual study day of an intervention, event, or finding, derived relative to the first exposure to any protocol-specified treatment.
--XSTDY	Start Day of Obs Relative to Exposure	Num	The actual study day of the start of an intervention or event, derived relative to the first exposure to any protocol-specified treatment.
--XENDY	End Day of Obs Relative to Exposure	Num	The actual study day of the end of an intervention, event, or finding, derived relative to the first exposure to any protocol-specified treatment.
--CHDY	Day of Obs Rel to Challenge Agent	Num	The actual study day of an intervention, event, or finding, derived relative to the first exposure to the challenge agent that induces the condition that the investigational treatment is intended to counteract.
--CHSTDY	Start Day of Obs Rel to Challenge Agent	Num	The actual study day of the start of an intervention or event derived relative to the first exposure to the challenge agent that induces the condition that the investigational treatment is intended to counteract.
--CHENDY	End Day of Obs Rel to Challenge Agent	Num	The actual study day of the end of an intervention, event, or finding derived relative to the first exposure to the challenge agent that induces the condition that the investigational treatment is intended to counteract.

New SDTM Interventions Variables

Variable Name	Variable Label	Type	Controlled Terms, Codelist, or Format	Role
--TDOSD	Toxic/Physiologic Dose Descr	Char		Record Qualifier
--FTDOSD	Factor for Toxic/Physiologic Dose Descr	Num		Variable Qualifier of --TDOSD
--RSTIND	Restraint Indicator	Char	(NY)	Record Qualifier
--RSTMOD	Restraint Mode	Char		Record Qualifier

New SDTM Findings Variables

Variable Name	Variable Label	Type	Controlled Terms, Codelist, or Format	Role
--RSTIND	Restraint Indicator	Char	(NY)	Record Qualifier
--RSTMOD	Restraint Mode	Char		Record Qualifier

Updates to Trial Design

- New Challenge Agent Characterization Domain
- New Parameters for Trial Summary
- New Parameters for Trial Sets or Trial Summary

Trial Sets

- Allows for the subdivision of Arms, using different parameters
- There should be no planned parameters of interest that could further subdivide a Trial Set
- Every subject is in a Set, describe in DM.SETCD
- Permits additional information about an Arm or a Set to be represented in a structured way.

New Parameters for Trial Sets and Trial Summary

- SEND uses the same codelist for Trial Sets and Trial Summary.
- Parameters can be represented at the highest level.
- The following slides show parameters that are trial specific, and parameters that may apply at either the trial or the Set level.

Additional Parameters to Be Included in Trial Summary *

TSPARM	TSPARMCD
Final Report Indicator	FRIND
Medical Countermeasure Sub-Type	MCSTYP
Medical Countermeasure Type	MCTYP
FDA Qualified Animal Model Indicator	AMQPIND
Study Type	SSTYP

** In addition to those that are designated "Should Include" in the SENDIG v3.1*

Additional Parameters to Be Included in Trial Sets or Trial Summary *

TXPARM	TXPARMCD
Antimicrobial Acidified/Chlor H20 Ind	AACHIND
Species	SPECIES
Specific Pathogen Free Indicator	SPFIND
Pathogen Exclusion	PATHEX
Pathogen Exclusion Verification Method	PATHEXVM
Strain/Substrain	STRAIN
Strain Type	STRNTYP
Telemetered Indicator	TELMIND
Genetically Modified Organism Indicator	GMOIND
Age Estimation Method	AGESMETH
Percent Bone Marrow Shielded	To Be Determined
Challenge Agent Dose Frequency	CADFREQ
Challenge Agent Dose	CADOSE
Challenge Agent Dose Units	CADOSU
Challenge Agent Multiple Route Indicator	CAMRTIND
Challenge Agent Exposure Rate	To Be Determined

TXPARM	TXPARMCD
Toxic/Physiologic Dose Descr	TDOSD
Factor for Toxic/Physiologic Dose Descr	FTDOSD
Genetically Modified Organism Indicator	GMOIND
Irradiation Field	IRRADFLD
Previous Research Experience Indicator	PRVRSIND
Pharmacokinetic Analysis Indicator	PKANIND
Telemetered Indicator	TELMIND
Targeted Onset of Development	TGONSET
Targeted Organ System	TGORGSYS
Treatment Dosing Frequency	TRTFREQ
Treatment Rate	TRTRATE

** In addition to those that are designated "Should Include" in the SENDIG v3.1*

SDTM v1.8

SDTM v1.8 serves as the model for animal rule studies (to be used in conjunction with SENDIG v3.1)

Significant changes from previous version:

- Section 5.1.3, Challenge Agent Characterization Dataset
  - Table 5.1.3.1, Challenge Agent Characterization Dataset

  New variables have been added to the following tables:
- Table 2.2.1.1 Interventions—Topic and Qualifier Variables
- Table 2.2.3.1 Findings—Topic and Qualifier Variables
- Table 2.2.5.1 Timing Variables for all classes
- Table 2.2.6.1 Subject Demographics Domain Variables

Team Members

Name	Organization
Fred Wood, Team Lead	Data Standards Consulting Group (TalentMine)
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Craig Zwickl	Independent
Christy Kubin	MPI Research
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Jerry Davis
Valérie Jimenez

Thank You!

Special thanks to **Fred Wood** and **Lou Ann Kramer** who shouldered the heaviest weight of the work on this project

Additionally, Fred contributed some of the slides shown in this presentation

Audience Questions

How will we be notified of the CRF library release?

Audience Questions

Can I still join the CRF library team?

Upcoming Learning Opportunities

Events Coming Your Way Soon!

- 2020 China Virtual Interchange
  - Only Two Weeks Away!
    - 5 Aug: 8:30-17:00* (English Sessions)
    - 6-7 Aug: 8:30-12:3*0 (Mandarin Sessions)
  - CDE and FDA Presenters
  - Virtual Networking with Presenters and Sponsors

*Times listed in China Standard Time

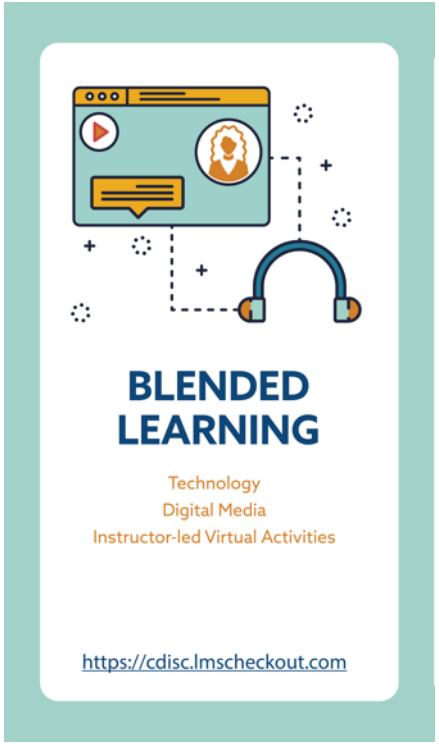
- 2020 US Virtual Interchange
  - Registration Now Open!
  - Presenter, Sponsor and Exhibitor Opportunities Available**
  - Launching NEW Enhanced Virtual Conference Platform
    - 1:1 Virtual Netowrking
    - F2F Online and On-screen Meetings
    - 3D Exhibitor Experience

**Abstract Submissions Due 24 July

https://www.cdisc.org/events/interchanges

NEW Blended Learning from CDISC

- Self-paced online training combined with remote instructor-led Q&A
  - Developed by standards experts
  - CDISC authorized instructors
  - Currently in English, Japanese, and Mandarin
  - Four global time zones
  - **Introductory Offer – Additional 25% Off!**



Now available!

NEW Blended Learning

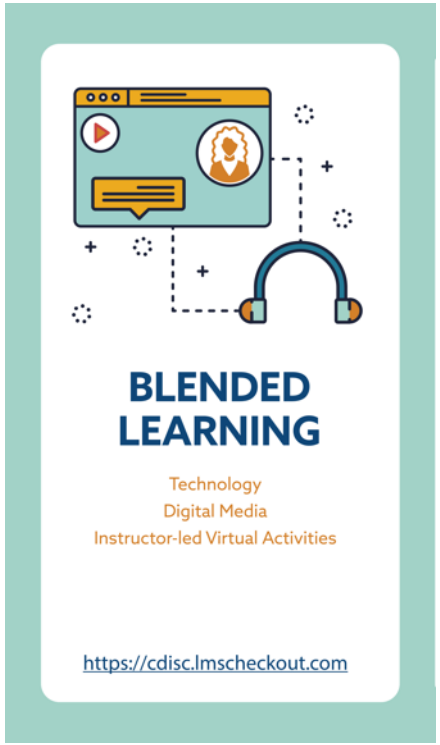
- Sessions starting soon!

SDTM Blended Learning*			
	Start Date	Live Q&A	Language
Americas	5 AUG – 9 SEP	Weekly	English
Europe	25 AUG – 29 SEP	Weekly	English
Japan	4 AUG – 8 SEP	Weekly	Japanese
China	3 – 29 SEP	Weekly	Mandarin

*Includes 19 modules & weekly Q&A sessions

CDASH Blended Learning**			
	Start Date	Live Q&A	Language
Americas	5 – 19 AUG	Weekly	English
Europe	1 – 15 SEP	Weekly	English
Japan	4 – 18 AUG	Weekly	Japanese
China	3 – 17 SEP	Weekly	Mandarin

**Includes eight modules & weekly Q&A sessions



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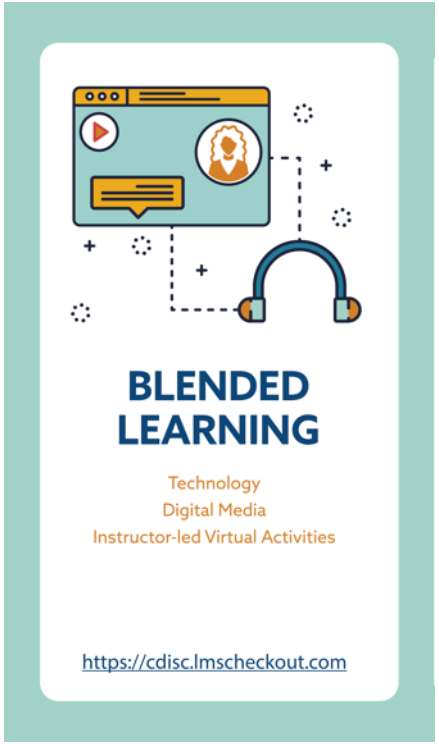


Now available!

2020 Webinars

Date	Webinar Title
28 JUL	Leveraging Clinical Research Data Standards in Academia: What's in it for Me?
13 OCT 2020	Controlled Terminology Updates for Q4

Visit https://www.cdisc.org/events/education/webinars for information on additional Public Training events.

Join CDISC for a Virtual

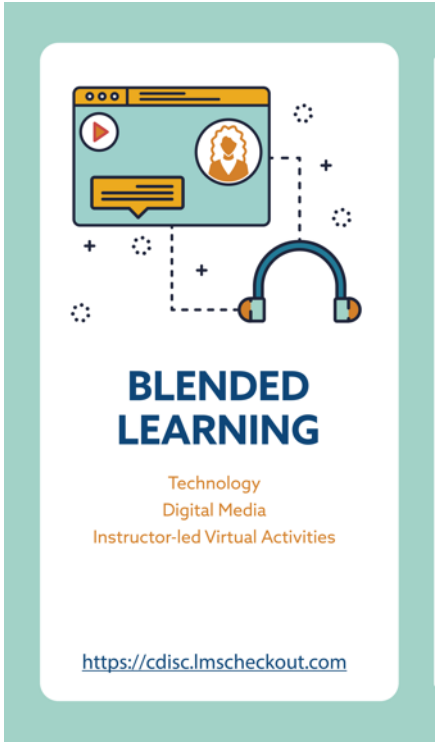
CDISC for Newcomers (Virtual)

New to **CDISC Standards**? Attend our workshop geared to getting you started with standards to amplify the full potential of data, drive operational efficiencies and expedite the regulatory review process. The workshop goes over examples of the standards, along with how to build them into the process of writing a protocol, collecting and tabulating data, and using the data in analysis. The CDISC **Data Exchange standards** are reviewed and the **CDISC Library** is discussed.

The workshop also identifies standards strategies that can make the clinical research process more efficient and offers a high-level introduction into the current regulatory requirements for submissions.

- **Agenda**:
- Topic 1: What is CDISC?
- Topic 2: Why Are Standards Needed?
- Topic 3: Overview of Regulatory Requirements
- Topic 4: Overview of CDISC Models
- Topic 5: CDISC Connects Research Globally
- Topic 6: Therapeutic Area User Guides
- Topic 7: Data Exchange Standards
- Topic 8: Implementing CDISC Standards
- Topic 9: CDISC Library
- Topic 10: How Does CDISC Work?

Date and Time:
29 JUL – Asia/Tokyo
5 AUG – Europe/Brussels



Thank You!

Questions, comments, concerns? Email bklinke@cdisc.org

Don’t forget to fill out the feedback survey!