The SEND Implementation Guide for Animal Rule (SENDIG-AR) Public Review

Presented by Fred Wood

5 Mar. 2019

Panelists

Fred Wood

Vice President, Consulting Services

Data Standards Consulting Group

A Division of TalentMine

Panelist

Fred Wood

Vice President, Consulting Services at TalentMine

Fred leads the Data Standards Consulting Group, and is an SDTM and SEND Implementation Advisor. He has been active in leading the development of CDISC standards since 1999. He is a founding member of the SDS Team (1999), the SEND Team (2002), and the Medical Devices Team (2007), and has led or co-led these for many years; he currently serves on the Leadership Teams of all three. Fred previously worked at Procter & Gamble Pharmaceuticals, Octagon Research Solutions, and Accenture, managing and consulting on data standards.

Fred has been the technical lead for the team that developed the SENDIG-AR.

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Housekeeping

- You will remain on mute for the entirety of the call
- Submit questions via ‘Questions’ section of toolbar
- A short marketing presentation on upcoming CDISC learning opportunities will follow Q&A portion; will answer additional incoming questions that come in

Submitting Questions

- If you have a question for a specific panelist, please indicate the panelist's name at the beginning of the question
  - Examples:
    - Sam: 'Question'
    - Anthony: 'Question'
- If your question is not for any specific panelist, submit it without a name and we will delegate the question to the appropriate panelist.
  - Examples:
    - General: 'Question'
    - 'Question'

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Content Disclaimer

The purpose of this webinar is to provide examples of implementation and should not be considered official recommendations by the standards development teams or CDISC unless otherwise stated in the presentation.

This webinar is not considered to be an authorized CDISC course, is not developed or delivered under CDISC procedures, and should not replace a published CDISC IG or UG. Please refer to the latest published standards documents for the most authoritative implementation information.

The SEND Implementation Guide for Animal Rule (SENDIG-AR) Public Review

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5 Mar. 2019

Agenda

- Animal Rule Background
- Development of the SENDIG-AR
- Organization of the SENDIG-AR

The Animal Rule Background

- The regulations commonly referred to as the Animal Rule (AR) provide a regulatory mechanism for the approval of drugs and licensure of biological product when human efficacy studies are not ethical or feasible.
- Applies only to products developed to ameliorate or prevent serious or life-threatening conditions caused by chemical, biological, radiological, or nuclear substances.
- Human clinical trials are still required to evaluate the safety of the product, and for determining the appropriate human dose(s).
- Applies only if the product cannot be approved for the proposed indication using another regulatory pathway.

Animal Rule Guidance

- CDER and CBER published a general, overarching Animal Rule guidance in 2015 entitled *Product Development Under the Animal Rule*
- CDER has published three indication-specific Animal Rule guidances:
  - Anthrax
  - Smallpox (Variola Virus) Infection
  - Internal Radioactive Contamination—Development of Decorporation Agents

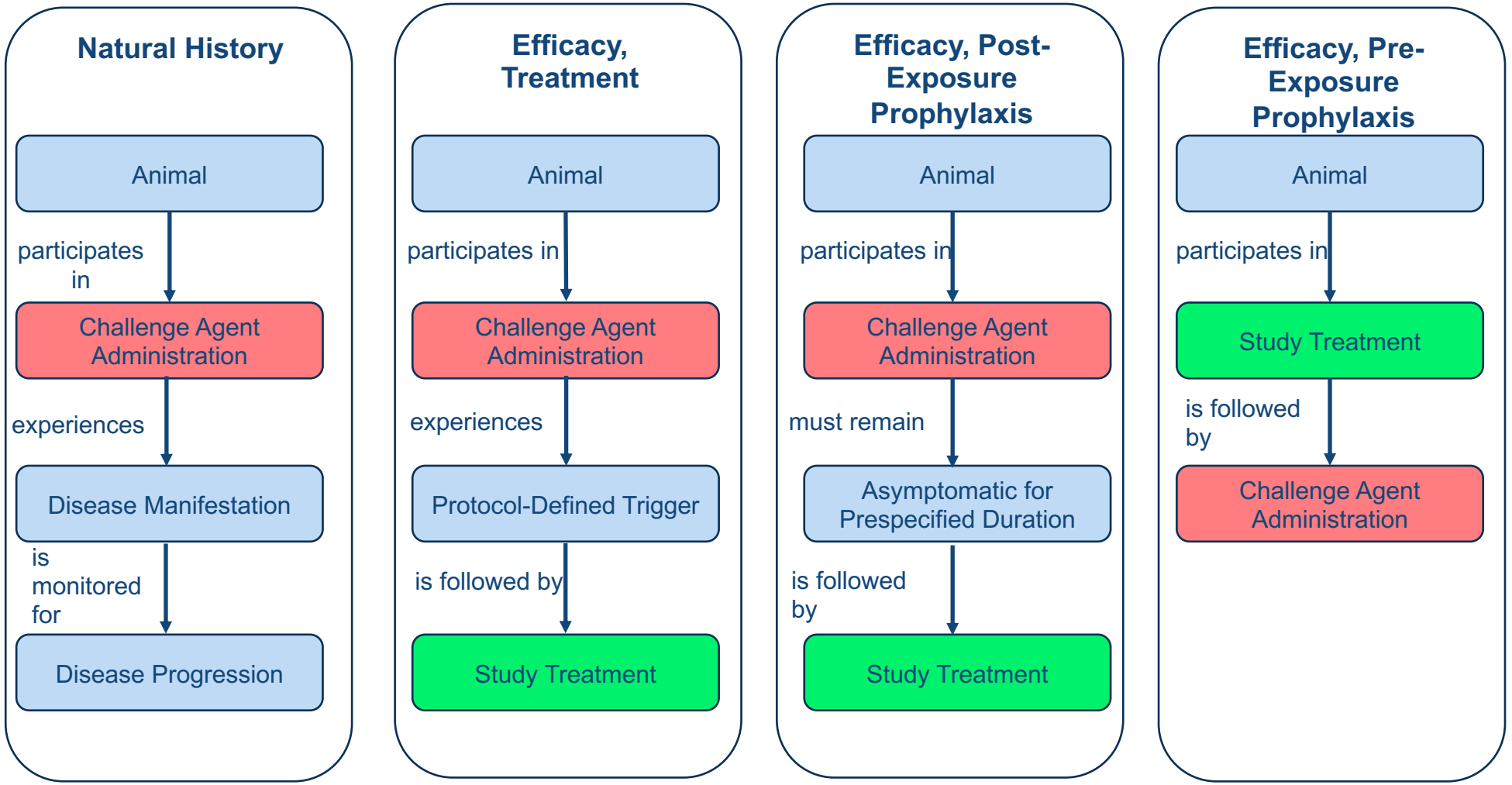
Examples Diseases/Conditions for which Products Have Been Developed Under the AR

- Inhalational anthrax
- Smallpox
- Botulism
- Pneumonic and septicemic plague

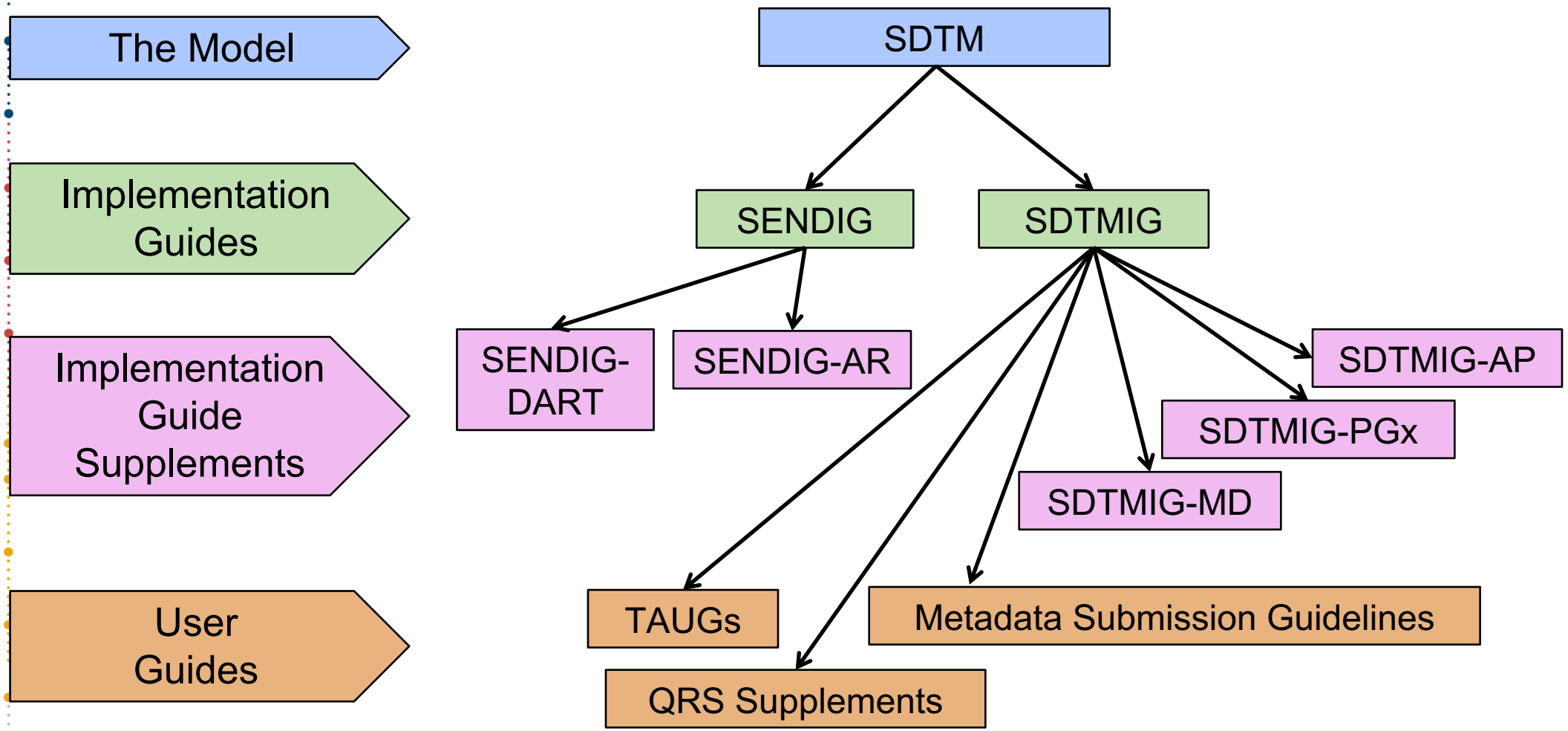
Definitions Used

- A *challenge agent* is the substance used to cause the disease or condition in animal studies.
- A *medical countermeasure (MCM)* is the study treatment.

Types of Studies



The Study Data Tabulation Model and Implementation Guides



Standards Development

- Until now, no standard exists for the submission of data from these studies.
- CDISC has been working 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.

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 any clinical domains from the SDTMIG v3.2.
- Create new domains as needed.
- Create new SDTM variables as needed. These are represented in the SDTM v1.8, out for review at the same time as this IG.
- Develop/expand controlled terminology.

Notice Regarding Controlled Terminology

- Much of the controlled terminology (CT) shown in the SENDIG-AR and this presentation is under development. Users should always refer to the latest published CDISC SEND CT prior to creating submission datasets.
- The proposed CT for the SENDIG-AR domains is summarized separately. The link to this is referenced in Section 1.1 of the SENDIG-AR.

Domain Comparison: Nonclinical vs. Clinical (1)

Both (SDTMIG v3.3 and SENDIG v3.1)	
Interventions • Exposure **Events** • Disposition **Findings** • Cardiovascular System Findings • Death Diagnosis and Details • ECG Test Results • Laboratory Test Results • Microscopic Findings • PK Concentrations • PK Parameters • Respiratory System Findings • Subject Characteristics • Vital Signs	**Special Purpose** • Demographics • Comments • Subject Elements **Trial Design** • Trial Elements • Trial Arms • Trial Summary **Relationships** • SUPPQUAL • RELREC

Domain Comparison: Nonclinical vs. Clinical (2)

Nonclinical Only (SENDIG v3.1)	Clinical Only (SDTMIG v3.3)	
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	**Interventions** • Concomitant Medications • Exposure as Collected • Meal Data • Procedure Agents • Procedures • Substance Use **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 **Trial Design** • Trial Visits • Trial Inclusion/Exclusion • Trial Disease Milestones	**Events** • Adverse Events • Clinical Events • Deviations • Healthcare Encounters • Medical History **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 **Relationships** • RELSUB **Special Purpose** • Subject Visits • Subject Disease Milestones

SDTMIG Domains Added

Domain Code	Domain
AG	Procedure Agents
CM	Concomitant Medications
FA--	Findings About
MB	Microbiology Specimen
MH	Medical History
PR	Procedures

- Domain specifications, adapted from the SDTMIG, with variables removed or added as needed.
- Assumptions revised as applicable.
- Examples relevant for AR studies.

Findings About (FA)

The SDTMIG describes five use cases; for this implementation guide, however, only two use cases are relevant, and have examples represented:

1. Data or observations that have different timing from an associated Event or Intervention as a whole.
   - Measurements of the aerosol containing the challenge agent have a timing different from that of the exposure period. The aerosol characteristics are represented in the faag.xpt file.

2. Data or observations about an Event or Intervention that have Qualifiers of their own that can be represented in Findings variables (e.g., results, units).
   - Results of the aerosol measurements (faag.xpt) and the infusion rate (faex.xpt) contain results and units. When these are represented in Findings About, the numeric value and the units can be represented on the same record.

New Study References: 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	BIOLOGICAL; CHEMICAL; RADIOLOGICAL/NUCLEAR
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	BACTERIA; VIRUS; FUNGUS
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	RADIOISOTOPE; LINEAR ACCELERATOR; RESEARCH X-RAY IRRADIATOR; NUCLEAR REACTOR; BOOSTER SYNCHROTRON
Rad/Nuc	RNAIOTYP	Rad/Nuc Ionizing Radiation Type	ALPHA PARTICLES; BETA PARTICLES; GAMMA RAY; X-RAY; NEUTRON; HIGH LINEAR ENERGY TRANSFER

Integrated Interventions Examples (1)

Six examples, each with data from one study showing the following domains:

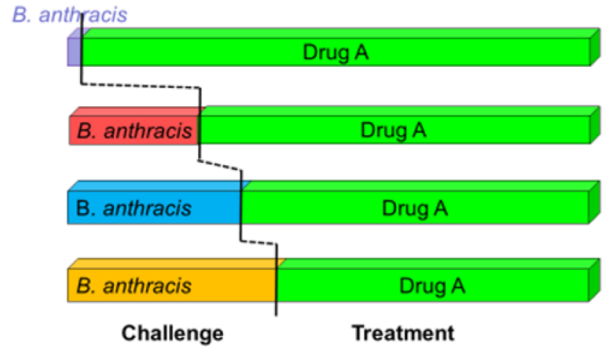
- Trial Elements (TE)
- Trial Arms (TA)
- Trial Sets (TX)
- Demographics (DM)
- Exposure (EX)
- Procedure Agents (AG)
- Subject Elements (SE)

Integrated Interventions Examples (2)

1. Post-Exposure Treatment: Study Treatment Given at Various Times after Exposure to *Bacillus anthracis*
2. Post-Exposure Treatment: Study Treatment Given when Bacteremia Observed after *Bacillus anthracis* Exposure
3. Pre-Exposure Prophylaxis: Study Treatment Given Two Days Prior to Exposure to *Bacillus anthracis*
4. Post-Exposure Treatment: Single or Combined Therapy of Drug B and Drug A (Antimicrobial) after *Bacillus anthracis* Exposure
5. Post-Exposure Treatment: Various Doses of The Study Treatment Given after Radiation
6. Post-Exposure Treatment: Study Treatment Given after Various Doses of Radiation.

Integrated Interventions Examples (3)

ARM	ARMCD
TRT1MIN	1
TRT12HR	2
TRT24HR	3
TRT36HR	4



ARM	ARMCD	Challenge	Treatment
PLACEBO	1	B. anthracis	Placebo
20MGKG	2	B. anthracis	Drug B 20
40MGKG	3	B. anthracis	Drug B 40

ARM	ARMCD	Treatment	Challenge
Placebo	1	Placebo	B.anthracis
Drug C 10 mg/kg	2	Drug C 10	B.anthracis
Drug C 20 mg/kg	3	Drug C 20	B.anthracis
Drug C 40 mg/kg	4	Drug C 40	B.anthracis

ARM	ARMCD	Challenge	Treatment
Placebo	1	B.anthracis	Placebo
Drug A	2	B.anthracis	Drug A
Drug A + Drug B	3	B.anthracis	Drug A + Drug B

ARM	ARMCD	Challenge	Treatment
0 mg/kg	1	Radiation	Placebo
50 mg/kg	2	Radiation	50 mg/kg Drug Z
100 mg/kg	3	Radiation	100 mg/kg Drug Z
200 mg/kg	4	Radiation	200 mg/kg Drug Z

ARM	ARMCD	Radiation	Treatment
Radiation 0.05 Gy/min	1	Radiation 0.05 Gy/min	Drug Z
Radiation 0.10 Gy/min	2	Radiation 0.10 Gy/min	Drug Z
Radiation 0.15 Gy/min	3	Radiation 0.15 Gy/min	Drug Z
Radiation 0.20 Gy/min	4	Radiation 0.20 Gy/min	Drug Z

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
- Each subject must be assigned to one and only one Trial Set in DM
- Also allows for multiple Arms to be “grouped” together (using SPGRPCD)

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.

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*

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*

New SDTM Variables

New Variables for Demographics (Table 2.2.6.1)

Variable Name	Variable Label	Type	Controlled Terms, Codelist, or Format	Role	CDISC Notes	Core
RFCSTDTC	Date/Time of First Challenge Agent Admin	Char	ISO 8601	Record Qualifier	The start date or date and time of the first date of exposure to any protocol-specified challenge agent, represented in a standardized character format. For use in Animal Rule (AR) studies only. Equal to the earliest value of AGSTDTC for the challenge agent.	Exp
RFCENDTC	Date/Time of Last Challenge Agent Admin	Char	ISO 8601	Record Qualifier	The end date or date and time of the last date of exposure to any protocol-specified challenge agent, represented in a standardized character format. For use in AR studies only. Equal to the latest value of AGENDTC for the challenge agent.	Exp

New SDTM Variables

New Variables for the Interventions General Observation Class (Table 2.2.1.1)

Variable Name	Variable Label	Type	Controlled Terms, Codelist, or Format	Role	CDISC Notes	Core
--TDOSD	Toxic/Physiologic Dose Descr	Char		Record Qualifier	A description of a statistically derived estimate of a dose with a certain toxicological or physiologic effect in a population, based on data from a dose-response study. Examples: LD50, ED90	Exp
--FTDOSD	Factor for Toxic/Physiologic Dose Descr	Num		Variable Qualifier of --TDOSD	The quantity given for the multiplier of the Toxicologic/Physiologic Dose Descriptor. Example: XX times LD50, where XX is a number.	
--RSTIND	Restraint Indicator	Char	(NY)	Record Qualifier	An indicator as to whether the subject was restrained during the intervention period.	
--RSTMOD	Restraint Mode	Char		Record Qualifier	A description of whether the restraint was physical or chemical.	Exp

New SDTM Variables

New Variables for the Findings General Observation Class (Table 2.2.3.1)

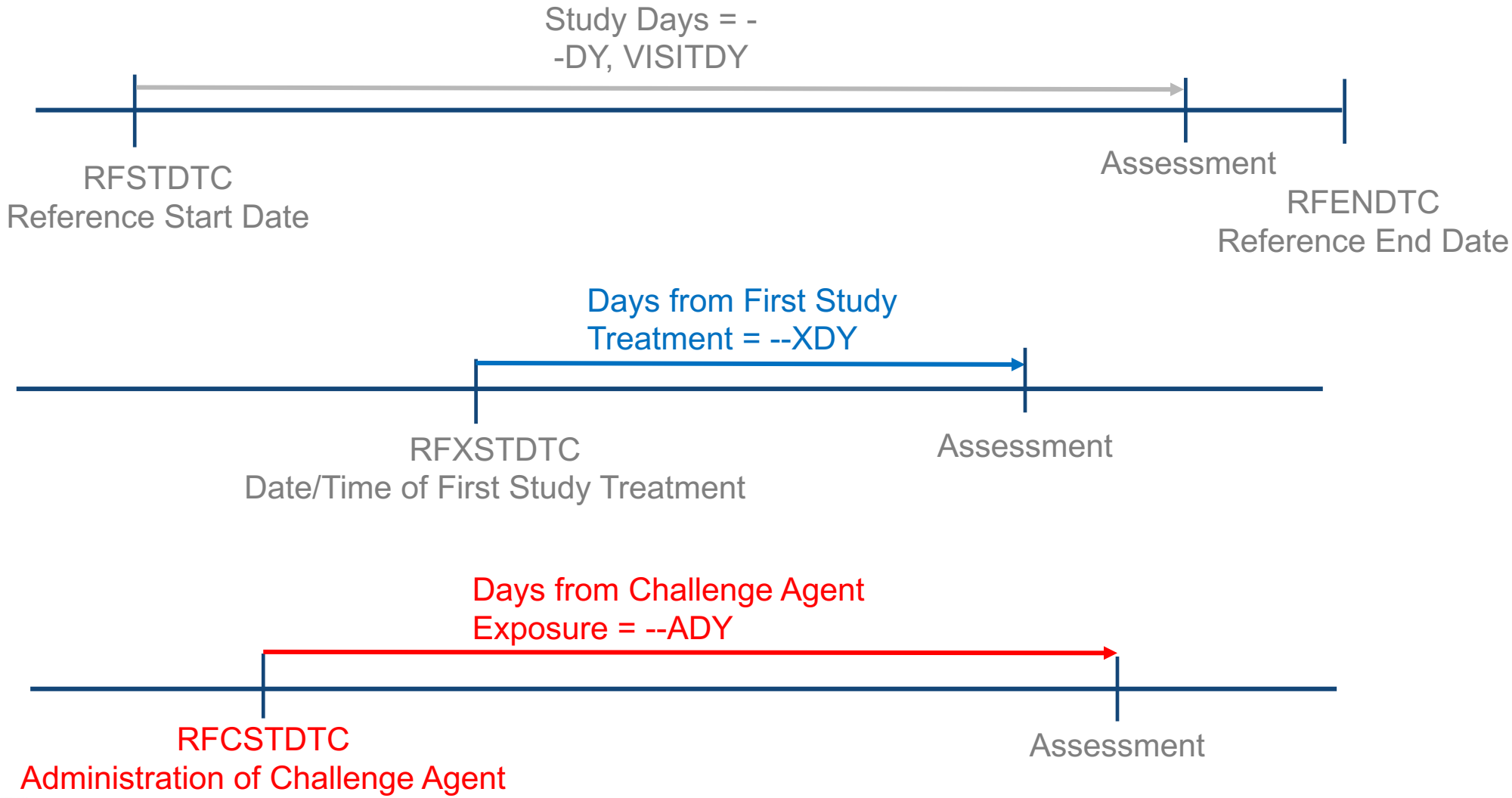
Variable Name	Variable Label	Type	Controlled Terms, Codelist, or Format	Role	CDISC Notes	Core
--RSTIND	Restraint Indicator	Char	(NY)	Record Qualifier	An indication as to whether the subject was restrained during the observation period.	
--RSTMOD	Restraint Mode	Char		Record Qualifier	A description of whether the restraint was physical or chemical.	Exp

New SDTM Variables

New Timing Variables for the General Observation Classes (Table 2.2.5.1)

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. Expressed in integer days relative to RFXSTDTC in DM.
--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. Expressed in integer days relative to e RFXSTDTC in DM.
--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. Expressed in integer days relative to RFXSTDTC in DM.
--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. Expressed in integer days relative to RFCSTDTC in DM.
--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. Expressed in integer days relative to RFCSTDTC in DM.
--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. Expressed in integer days relative to RFCSTDTC in DM.

Timing Variables Diagram



Known Issues (Section 1.6)

- Infusion rate and units may be considered as a future standard variables, but is being represented in Findings About in this implementation guide.
- Example (partial representation of variables):

ex.xpt

STUDYID	DOMAIN	USUBJID	EXSEQ	EXSPID	EXTRT	EXDOSE	EXDOSU	EXDOSFRM	EXROUTE
ABC002	EX	ABC002001	2	321	Drug B	40	mg/kg	SOLUTION	INTRAVENOUS

faex.xpt

STUDYID	DOMAIN	USUBJID	FASEQ	FASPID	FATESTCD	FATEST	FAOBJ	FAORRES	FAORRESU	FASTRESC	FASTRESN	FASTRESU
ABC002	FA	ABC002001	6	321	INFUSR	Infusion Rate	Drug B	10	mL/kg/min	10	10	mL/kg/min

relrec.xpt

STUDYID	RDOMAIN	USUBJID	IDVAR	IDVARVAL	RELTYPE	RELID
ABC002	EX		EXSPID		ONE	1
ABC002	FAEX		FASPID		ONE	1

Changes to Existing Domains

Domain	Variable Name	Variable Label	Change Type	Version	Change Wording/Text
MA, MI	MASPID, MISPID	Mass Identifier	CDISC Notes	Existing, SENDIG v3.1	Mass identifier such as MASS 1 or MASS A. Used when the mass was discovered during the in-life phase or during pathology and was assigned a mass identifier. The mass identification should be unique within the subject, regardless of mass location.
				Revised for SENDIG-AR	Mass **or lesion** identifier such as MASS 1 or MASS A. Used when the mass or lesion was discovered during the in-life phase or during pathology and was assigned a mass identifier. The mass **or lesion** identification should be unique within the subject, regardless of mass or lesion location.
MA, MA, DD	MAEVAL, MAEVAL, DDEVAL	Evaluator	Core	Existing, SENDIG v3.1	Perm
				Revised for SENDIG-AR	Exp
DM	RFXSTDTC	Date/Time of First Study Treatment	Core	Existing, SENDIG v3.1	Perm
				Revised for SENDIG-AR	Exp
DM	RFXENDTC	Date/Time of Last Study Treatment	Core	Existing, SENDIG v3.1	Perm
				Revised for SENDIG-AR	Exp

Organization of the SENDIG-AR

How to Create Comments from the Wiki

Demonstration

Instructions for Reviewers: Adding comments to JIRA from the Wiki

1. Select the text to which you wish to attach the comment. After a moment, a small contextual menu should appear. If the text you have selected is not unique on the page, or contains any links or images, the JIRA Connector will be unable to find the right place to automatically insert the issue upon creation. In most cases, five words of plain text should be enough to ensure a unique text string, but this is not guaranteed.
2. Depending on your browser, the JIRA Connector may also experience difficulties if the content to which you wish to add the issue is mirrored from another page. Reviewers are recommended to enter comments on the content's source page whenever feasible.
3. Within the contextual menu, click on the icon that looks like an X. This will trigger an abbreviated Create Issue form. If you get a notice that "Atlassian JIRA needs your permission to connect to Confluence" instead, click on "Allow", and then "Allow" again. When you are returned to the page in the Wiki, the Create Issue form should be open.
4. Choose "Animal Rule" in the drop-down menu on the top left for Project, if it is not already chosen.
5. Choose "Review Comments" in the drop-down menu on the top right for Issue Type (if it is not already chosen).
6. Fill out the form and click the "Create" button in the bottom left corner of the form to submit your comment as an issue. In case of technical difficulties, please make sure to provide a brief description of the context of your comment, so the team can address it properly.
7. The page should automatically update with your comment inserted in place. If you get a notice that the issue "has been created, but there is a problem in adding it to the page," you can click on the key in the notice to open the issue just created in JIRA, and then insert it into the page manually.

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Instructions for Reviewers: Adding comments from within JIRA

- Go to the "Animal Rule" project in JIRA at: https://jira.cdisc.org/projects/ARPROJECT
- Keeping JIRA open in a separate window to capture comments is easier than navigating back and forth between the Wiki and JIRA.
- Click on the "Create" button in the top menu to bring up the Create Issue form.
- Make sure the project is set to "Animal Rule" and the issue type is set to "Review Comments".
- Fill out the form.
  - In the **Summary** field, describe the content to which the comment applies.
  - Enter your comment, and any additional details, in the **Description** field. To help the team address your comment properly, be thorough.
- Click the "Create" button in the bottom right corner of the form to submit.

Questions from the Audience

- For people who are less familiar with SEND and SDTM, are there trainings or online resources to learn more about how to use these standards?

Questions from the Audience

- How do we know which parameters need to be filled out?

Questions from the Audience

- Although these standards are developed for the Animal Rule, could these standards be used for other types of animal efficacy studies?

Questions from the Audience

- Animal studies usually consider Day 0 to be the first day of the study, but we note that these standards are using Day 1 as the first day of a study. Can you please clarify?

Questions from the Audience

- In support of SEND-AR new variables have been introduced to SDTM 1.8 (in DM and general timing variables). However, these have been flagged as "Not to be used with human clinical trials."
  - What is the reason for this?
  - These variables would be useful in "Human Viral Challenge" studies where a subject is challenged with a virus (e.g. RSV or HRV) and then treated. Analysis can be based on timing relative to either challenge of treatment start date (i.e. RFXSTDTC or RFCSTDTC). These new variables would aid in a consistent approach in mapping data.

CDISC Education: Upcoming Learning Opportunities

Bernard Klinke

UPCOMING NORTH AMERICA PUBLIC COURSES

Location	Dates	Courses Offered:	Discount period ends:	Host
Boston, MA	25-29 Mar 2019	SDTM, CDASH, Define-XML, ADaM	24 Dec 2018	VITA DATA SCIENCES a division of SOFTWORLD
Bridgewater, NJ	20-24 May 2019	SEND, SDTM, Define-XML, CDASH, ADaM	18 Feb 2019	janssen PHARMACEUTICAL COMPANIES OF Johnson & Johnson
Seattle, WA	3-7 Jun 2019	SDTM, CDASH, ADaM	4 Mar 2019	Axio PARTNERS IN RESEARCH
Gaithersburg, MD	9-13 Sep 2018	SDTM, CDASH, Define-XML, ADaM	10 Jun 2019	MedImmune A member of the AstraZeneca Group

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Additional public training events in Chicago, Bay Area, Durham, and San Diego to be published soon.

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UPCOMING EUROPE PUBLIC COURSES

Location	Dates	Courses Offered:	Discount period ends	Host
Amsterdam, Netherlands	6-10 May 2019	SDTM, SDTM-MD, SEND, ADaM, Define-XML, ODM, Controlled Terminology, CDASH, CDISC for Newcomers	TBD	cdisc
Frankfurt, Germany	3-7 Jun 2019	SDTM, CDASH, ADaM, Define-XML	4 Mar 2019	HMS Analytical Software
Brussels, Belgium	9-13 Sep. 2019	CDASH, SDTM, Define-XML, ADaM Primer + Theory & Application	6 Jun. 2019	Business & Decision Life Sciences
Paris, France	7-11 Oct. 2019	CDASH, SDTM, Define-XML, ADaM Primer + Theory & Application	8 Jul. 2019	SERVIER
Visit cdisc.org/public-courses for information on other CDISC Public Training events.				

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UPCOMING ASIA PUBLIC COURSES

Location	Dates	Courses Offered	Discount period ends:	Host
Osaka, Japan	3-7 Jun 2019	SDTM, CDASH, ADaM, Define-XML	3 Mar 2019	Croit
Tokyo, Japan	2-6 Sep 2019	SDTM, CDASH, ADaM, Define-XML	2 Jun 2019	Croit
Visit cdisc.org/public-courses for information on other CDISC Public Training events.				Croit

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Upcoming Webinars

Date	Webinar Title
21 Feb	CDISC SHARE 2.0 Launch
1 Mar	CDISC Public Webinar: SENDIG-AR Public Review
18 Apr	CDISC Public Webinar: ADaMIG v1.2 & ADaM Integration
25 Apr	CDISC Public Webinar: Membership Benefits and Innovations Project

Learn more at https://www.cdisc.org/events/education/webinars.

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  - Is delivered by an instructor qualified by the standards team
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Q&A

Audio difficulties – please email **bklinke@cdisc.org**