Standardization Roadmap

Project Scope

Need/Challenge

Need ID 0030. Currently, the SEND standard allows for the submission of general tox and carc studies in electronic standardized format. However, there are additional study types that are generally received that have not been standardized. There is a need to develop a strategy on how to plan, maximize, and transform standardization efforts. This plan should take into account resources, complexity, timeline and new approaches and technologies. Data gaps have been identified for many assessments, including Safety Pharm, Repro, Genetox, hERG, Animal Rule/MCM, Receptor Screen, and Device combination. Additionally, drug metadata can be better utilized so that, for example, Lot and Impurity information can be linked to study data, class, structure. Study Metadata represents another challenge. Information on protocol-related info + deviations, regulatory interpretation, sponsor interpretation, and regulatory information can be structured and linked so that information for a single study or across studies is more accessible.

Vision

Availability of useful electronic meta- and study data to enable more effective and efficient review of nonclinical data by both industry and regulatory reviewers. Data should be accessible to further investigate class effects and address regulatory science questions.

Deliverable	Link
Poster CSS 2015	SDTM customized to nonclinical data using a streamlined process.pdf
How to build a custom domain resource	How to build a custom domain resource
Ocular Irritation Custom Domain	Ocular Irritation Custom Domain
Micronucleus Custom Domain	Micronucleus Custom Domain
Motor Activity Custom Domain	Motor Activity Custom Domain
Poster CSS 2014	How to Design a SDTM Custom Domain for Nonclinical Data.pptx
e-Paper	"The Roadmap for Nonclinical Data Standards and Elements to Improve Data Access"
Poster CSS 2013	Priorities in Nonclinical Data CSS2013.ppt

Plans

Milestones

Identified Projects/Pilots/Activities

March 2014 - March 2015
Further development of "How to Design a Custom Domain" Resource

1. Validate using modeled data
2. Create step-by-step instructions (numeric)
3. Use Cases for instructions
4. Conformance rules

March 2013 - March 2014

1. "How to Design a Custom Domain"
2. Finish e-paper: Priorities in Nonclinical Data and Elements to Improve Data Utility

March 2012 - March 2013

1. Communication of the CDISC SEND team roadmap/goals
2. Identify elements that belong on the road map, including study types that need standardization and study metadata that enhance data utility.
3. Prioritize the elements from above and stratify them as projects for the immediate future versus longer term goals.
4. A directory of knowledge on current standardization initiatives

Tasks

Accomplished

1. Designed a framework for Custom Domains creation
2. Posted e-Paper which

a) Identifies priorities in nonclinical study types and elements that enhance data utility, and b) Provides considerations for standards implementation and optimization

Communication of the CDISC SEND team roadmap/goals (via Advance Hub)

Planned

1. Document current standardization efforts for nonclinical studies. (Advance Hub)
2. Identify information gaps or challenges in current data (study types, exchange methods, standards, etc. Also consider integration with CMC and Clinical
3. Characterize a view of optimal access to data
4. Project: "Standards Facilitation"

March 2012 to March 2013
1 month

- Convey CDISC SEND team roadmap/goals
- Set up system for workgroup communications and forum on the Advance Hub

4 month

- Identify study types that need standardization and elements that enhance data utility (i.e. tagging). Identify roadblocks.

7 month

- Distribute survey to industry about priorities in nonclinical data"

9 month

- Construct roadmap that prioritizes the standardization efforts and elements that integrate the data

March 2013 to March 2014
3 month

- Finish e-paper

5 month

- Characterize open forum, communication plan

7 month

- Characterize test space, and testing process

9 month

- Pilot run of test space with model (CNS model already established)

11 month

- Report on pilot

Deliverables

March 2014 - March 2015

- Poster: SDTM can be customized to different types of nonclinical data using a streamlined decision-making process
- How to Design a Custom Domain resource

March 2013 - March 2014

- Poster: How to Design a SDTM Custom Domain for Nonclinical Data
- e-paper containing nonclinical data prioritization
- Directory of standardization initiatives

March 2012 - March 2013

- Graphical representation of roadmap for standardization priorities -
- Presented poster, "Priorities in Nonclinical Data" at PHUSE 2013 meeting

Participation Needs

A vast number of stakeholders will be impacted by the transformation and implementation of data standards. As the impact will be broad, we need representation from people with diverse backgrounds to join and actively participate in this group. A broad representation from the pharmaceutical industry, contract research organisations, software vendors and other stakeholders in data standardisation and eventually regulatory submissions will ensure the most complete and robust picture for the industry and the regulators to align to going forward.

- Participants may have backgrounds which include (but are not limited to)
  - Pharmacologists/Toxicologists
  - Pathologists
  - Pharmacokineticists
  - Informatics and database specialists
  - Those with experience in data standardization
  - Those implementing data standards

Member Commitment

- Teleconferences will require active participation for approximately 1 hour every two weeks. Our open forum needs your creative and innovative ideas.
- Projects will require time and effort outside of general teleconferences. Time commitments will vary but are likely to take several hours per month.
- Ongoing email/phone correspondences and additions to the Wiki are essential to developing these projects.
- Members contribute to Wiki content, meeting proceedings, and presentations that result from the group's effort.

Project Members
Gitte Frausing, Data Standards Decisions (co-lead), gfrausing@datastandardsdecisions.com Bob Dorsam, FDA (co-lead), robert.dorsam@fda.hhs.gov Lynda Sands, GlaxoSmithKline Debra Oetzman, Covance Anisa Scott, SAS Institute, Inc. Donna Danduone, Instem Kathy Powers, Pfizer Frederic Mura, PDS Kristi Johnson, PointCross Lou Ann Kramer, Eli Lilly Sarah Obbers, Janssen Research & Development

Former Project Members
Deborah Sholtes, FDA Alain Nanzer, Roche Jerker Ringstrom, SixSteps AB Geoff Mann, SAS Institute John Anderson, Novo Nordisk Natalia Smeljanski, Merck Rick Thompson, Janssen Research & Development

Meeting Minutes
2012
2013
2014

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