CDISC Public Webinar – Standards Updates and Additions

13 OCT 2016
Agenda

• Ebola TA Public Review
  ▪ Rhonda Facile, MS, Vice President, Standards Development
  ▪ Maura Kush, CDISC Specialist and Data Standards Consultant, Pharmastat
  ▪ Shannon Labout CCDM, Vice President of Education, CDISC
  ▪ Bess LeRoy, Metadata Engineer, CDISC
  ▪ Jon Neville, PSM, Program Director, Data Standards and Management
  ▪ Diane Wold, Senior Director, Standards Development and Modeling, CDISC

• Malaria TA Public Review
  ▪ Lesley Workman, Scientific Coordinator, Division of Clinical Pharmacology, University of Cape Town
  ▪ Bess LeRoy, Metadata Engineer, CDISC
  ▪ Alana St. Clair, Associate Project Manager, CDISC
  ▪ Jon Neville, PSM, Program Director, Data Standards and Management
  ▪ Diane Wold, Senior Director, Standards Development and Modeling, CDISC
  ▪ Rhonda Facile, MS, Vice President, Standards Development
Question & Answer

• ‘Panelist’: Question
OR
• ‘Presentation’: Question

Examples:

Maura: Where can I find the Ebola TA Guide?
Malaria Team: Are there known issues with the Malaria TA analysis section?
EVD Therapeutic Area User Guide

Maura Kush
EVD Project Co-Lead

Panelists: Bess LeRoy, Diane Wold, Jon Neville, Shannon Labout
Agenda

- Background on project and participants
- Scope and gap analysis
- Additional requirements
- Known issues and focus of public review
- Public review dates
Background

• Sense of urgency during the Ebola outbreak
• Collaboration with the Oxford University Clinical Research Unit (OUCRU) in Vietnam
• Needed to address certain challenges of EVD studies
  ▪ Outbreak setting
  ▪ Many different stakeholders, all with different use cases and research goals
• Led to a gap analysis and a narrowed scope with more focused development
EVD TAUG Scope

• Majority based on data elements from WHO CORE case report form (CRF),
  ▪ Includes some epidemiological and vaccination data
  ▪ Does not include pediatric or survivor data, or vaccine trials as a whole
  ▪ Does not include ADaM

• Describes how to represent the most common data for Ebola studies
EVD TAUG Documentation

- SDTM v1.4
- SDTMIG v3.2
- SDTMIG – AP
- Controlled Terminology
- CDASH v1.1
- Influenza v2.0, Tuberculosis v2.0, Malaria v1.0
Ebola Table of Contents

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1.3 Known Issues

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4.4 Reproductive Findings
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Threshold Cycle CDASH CRF and SDTM Examples

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Sponsors are responsible for understanding and implementing CDISC Controlled Terminology where applicable.
Viral Identification

- Historically viral identification shown in LB
- This has changed, and this guide has examples that show it in MB where MBTSTDTL='IDENTIFICATION'

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New Domain

• ER (Environmental Risk Factors)
  - Out for review with SDTM v3.3 Batch 3
  - Events observation class domain for data collected on potential exposures to, or diseases by way of environmental contact or through participation in activities associated with risk
Known Issues

• Non Standard Variables (NSV) - proposed changes
• Signs and symptoms in Findings About (FA)
• Personally identifying information in Subject Characteristics (SC)
• Controlled Terminology is not final
• NHOID=‘Zaire Ebola Virus’ - provides enough detail without an OI domain
• Measured/Estimated Weight
Public Review

• Public Review comments due: 4 November 2016

• Public review is a key part of the standards development process.

We look forward to getting your feedback!
DEVELOPING A DATA STANDARD FOR UNCOMPLICATED MALARIA

Clinical Data Interchange Standards Consortium (CDISC)
WorldWide Antimalarial Resistance Network (WWARN)

• WWARN collaboration
• 13 October, 2016
www.wwarn.org
Twitter: @WWARN
Topics

• Project Scope - Alana
• Project Background - Lesley
• New Domains and Examples - Bess
• Known issues - Bess
• Public review
Malaria Standards Development Project Scope

• Describe how to represent the most common data for uncomplicated malaria studies
  ▪ Deliverables: CDISC Therapeutic Area User Guide, concept maps, CDASH compliant CRF, SDTM examples and controlled terminology

• Based on data elements from WWARN case report form (CRF)
  ▪ Includes examples for parasite genotyping, combination therapy, dosing with food and post dose vomiting, among others
  ▪ Includes an analysis considerations section
Project Mission:

To support efficient, scientifically valid generation and reporting of clinical malaria data to streamline antimalarial development, regulatory submission and post-marketing research, as well as enable data sharing, comparison and aggregation.

Aim:

Consensus-based development of a single, freely available data standard to ensure the consistent use of existing CDISC standards, and to facilitate alignment and development of new standards for the electronic acquisition, exchange, submission and archiving of clinical malaria data collection, analysis and reporting.

Scope (Year 1):

- Uncomplicated falciparum malaria
- Uncomplicated vivax malaria

Preventive treatment (e.g SMC, IPT, MDA), Induced Blood Stage Malaria (Human Challenge Studies), severe malaria to follow, as needed
Role of WWARN

- Facilitate the development of a CDISC data standard for malaria.
- Enable data sharing
- Conduct pooled data analyses to quantify effects
- Provide the (long-term) storage infrastructure and maintaining of the antimalarial data repository / archive
The role of stakeholders

Current Stakeholders include:
- CDISC, C-PATH
- WWARN members
- WHO GMP / TDR
- BMGF
- GHT, LSTM,
- Pharma:
  - GlaxoSmithKline
  - Medicines for Malaria Venture
  - Merck
  - Novartis
  - Sanofi
  - Shin Poon
  - Sigma Tau
  - Takeda
  - UCB

Review draft data standards

Share relevant experience:
- Recent CRF templates / Database Structures / Statistical Analysis Plans
- Identification of critical issues in regulatory submissions.
CDASH CRF and SDTM Examples
New Domain #1

- ER – Environmental Risk Factors

### Household Characteristics (ER)

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- **Has the Malaria Control Program performed Indoor Residual Insecticide Spraying (IRS) of your home in the last 12 months?**
  - **EHTERM=** indoor residual insecticide spraying

- **Did you sleep under an insecticide treated bed-net last night?**
  - **ERTERM=** Sleep under an insecticide treated bed-net

### Table

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Row 1: Shows that subject ABC-001’s household had indoor residual insecticide spraying within the last 12 months (EREVLINT).
Row 2: Shows that subject ABC-001 slept under an insecticide treated bed-net last night (EREVINTX). MAL-112 - Getting issue details... STATUS er.xpt
New Domain #2

- SI – Site Summary

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Known Issues

• Representation of combination therapy data
  ▪ We show an example using a combination of EC and EX as a possible solution. This is different from the modeling strategy used in the TAUG-TB (example using a combination of EX and FA).

• Use of --EVINTX for representation of timing around food intake and post dose vomiting
  ▪ There is disagreement regarding whether or not this is an appropriate use of –EVINTX.
30-Day Public Review

• Public Review dates:
  ▪ October 6 – November 6

• Public review is a *key* part of the standards development process.

*We look forward to getting your feedback!*
Q&A
CDISC Online Education & Event Updates

John Ezzell, CDISC
# Upcoming Webinars

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<td>Dr. Lauren Becnel, CDISC</td>
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*Webinar details and registration at [www.cdisc.org/webinars](http://www.cdisc.org/webinars)*
Standard currently out for review

- **Terminology Call for Public Review Package 28**
  Comments Due by: October 7, 2016

- **Draft Content SDTMIG v3.3 Batch 3 Now Available for Public Review**
  Comments Due by: October 21, 2016

- **New Draft Ebola v1 Now Available for Public Review**
  Comments Due by: November 4, 2016
# UPCOMING NORTH AMERICA PUBLIC COURSES

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Visit [cdisc.org/public-courses](http://cdisc.org/public-courses) for information on other CDISC Public Training events.
# UPCOMING EUROPE PUBLIC COURSES

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Visit [cdisc.org/public-courses](http://cdisc.org/public-courses) for information on other CDISC Public Training events.
CDISC Online Training Production Update

- Just Released
  - ADaM Module 4 Online Training
  - Mini-Training: Ensuring USUBJID is Unique for an Individual in an Application

Drag and Drop Exercise: Required, Conditionally Required and Permissible ADSL Variables
Instructions: Drag the Required, Conditionally Required and Permissible variables into the correct barrels. When you are complete, click the “Submit” button to check your answers.

Online Courses in Development

- TA Alzheimer's
- TA QT Studies
- TA Vaccines
- TA Prostate Cancer
- TA Rheumatoid Arthritis
- TA Pain
- ADaM Modules 5-8
- CT Module 1 & 2
- Define-XML
Any more questions?

Thank you for attending this webinar.

CDISC’s vision is to:
Inform Patient Care & Safety Through Higher Quality Medical Research
CDISC Members Drive Global Standards

Thank you for your support!

Learn CDISC from CDISC!