

# CDISC Public Webinar – Standards Updates and Additions

26 Mar 2015



**Strength** *through Collaboration*

# Agenda

- Controlled Terminology, Batch 21 (Publication Release) and Batch 22 (Public Review)
  - Bernice Yost, CDISC
- CDISC Medical Devices Standards
  - Kit Howard, CDSIC
- Quarterly Technical Update
  - Wayne Kubick, CDISC
- CDISC Education and Events Updates\*
  - John Ezzell, CDISC

*\*After Q&A session & time permitting*

# Question & Answer

- 'Presenter': Question

OR

- 'Presentation': Question

Examples:

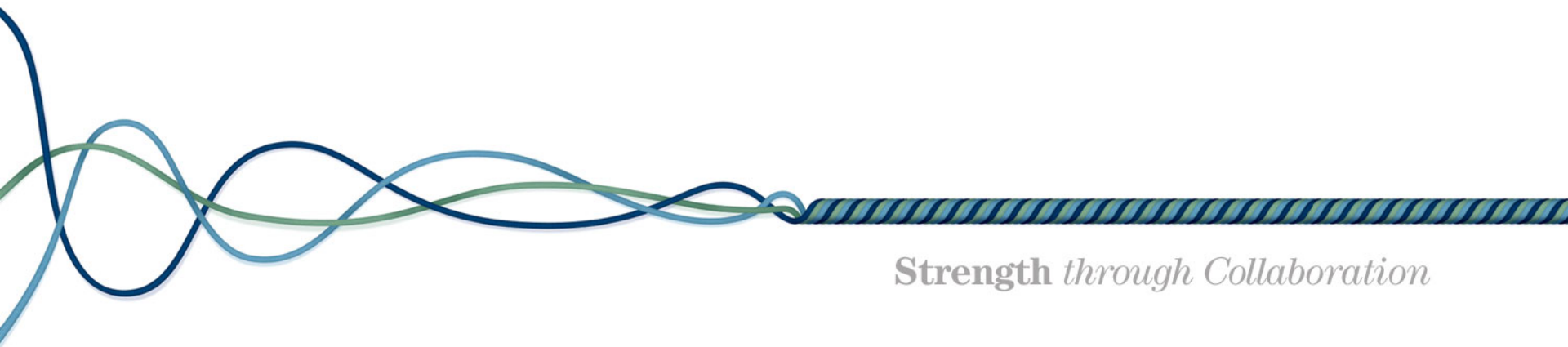
Bernice: When will Batch 21 be published?

OR

CDISC: When can we start registering for the  
Interchange?

# CDISC CONTROLLED TERMINOLOGY

Presented by Bernice F. Yost



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# Controlled Terminology Agenda

- Package 21 Publication Release (27 Mar 2015)
  - What's new
  - What's changed
- Package 22 Public Review (24 Mar 2015 to 24 Apr 2015)
  - What's new
  - What's changed

# Controlled Terminology Publication Schedule

Package Number	Team Cutoff (requests must be received at least two months before this date)	Public Review Start Date (1 wk from Team Cutoff)	Public Review Closed Date (4 wks)	Final Changes to NCI EVS (4 wks)	Publication Date (6 wks)	Codelists to be Included			
18	3/14/2014	3/21/2014	4/18/2014	5/16/2014	6/27/2014	CV	Device	ECG	General
18						Lab	PK	QS	SEND
18						Unit	Virology		
19	6/13/2014	6/20/2014	7/18/2014	8/15/2014	9/26/2014	CV	Device	ECG	General
19						Lab	Oncology	PK	QS
19						SEND	Spectype Speccond	Unit	Virology
20	9/5/2014	9/12/2014	10/10/2014	11/7/2014	12/19/2014	CV	Device	ECG	General
20						Lab	Oncology	PK	QS
20						SEND	Spectype Speccond	Unit	Virology
21	12/12/2014	12/19/2014	1/23/2015	2/13/2015	3/27/2015				
21									
21									
22	3/13/2015	3/20/2015	4/17/2015	5/15/2015	6/26/2015				

# **Controlled Terminology Package 21 Publication Release**

# Controlled Terminology Package 21 Publication Release

- COA Terminology Team
  - New COA Instruments
    - Questionnaire
      - Chronic Respiratory Questionnaire Self-Administered Standardized Format (CRQ-SAS)
        - » First Administration Version
        - » Follow-up Administration Version
    - Functional Test
      - Brief Assessment of Cognition in Schizophrenia (BACS)
    - Clinical Classification
      - Body-Mass Index, Airflow Obstruction, Dyspnea, and Exercise Capacity Index (BODE)
      - Child-Pugh Classification (CHILD-PUGH)
      - Model for End Stage Liver Disease (MELD)
      - Negative Symptoms Assessment-16 (NSA-16)
      - Acute Physiology and Chronic Health Evaluation II (APACHE II)



# Controlled Terminology

## Package 21 Publication Release

- Device Terminology Team
  - New Term Added to Existing Codelist
    - Device Properties Test Name/Test Code
    - Device Identifier Short Name/Long name

# Controlled Terminology Package 21 Publication Release

- ECG Terminology Team
  - New Codelist
    - Holter ECG Test Name/Test Code
    - Holter ECG Results
  - New Term Added to Existing Codelist
    - ECG Test Code/Test Name
    - ECG Result

# Controlled Terminology

## Package 21 Publication Release

- General Terminology Team:
  - New Term Added to Existing Codelist
    - Anatomical Location
    - Control Type
    - Method
    - Morphology Test Code/Test Name
    - Ophthalmic Exam Test Code/Test Name
    - Relationship to Subject
    - Reproductive System Findings Test Code/Test Name
    - Respiratory Test Code/Test Name
    - Trial Type

# Controlled Terminology Package 21 Publication Release

- Lab Terminology Team (*Laboratory Test Codelists*)
  - Submission Value Change
    - Laboratory Test Name Codelist
      - Platelet Derived Growth Factor Isoform AB
      - **Platelet Derived Growth Factor IsoformAB**
        - » The length of the test name was one character too long. It should not be longer than 40 characters.
  - New Term Added to Existing Codelist
    - Laboratory Test Code/Test Name

# Controlled Terminology

## Package 21 Publication Release

- Lab Terminology Team (*Specimen Type/Specimen Condition Codelists*)
  - Submission Value Change
    - Specimen Condition Codelist
      - AUTOLIZED
      - **AUTOLYZED**
  - New Term Added to Existing Codelist
    - Specimen Type

# Controlled Terminology

## Package 21 Publication Release

- Lab Terminology Team (*Unit Codelist*)
  - Term Removed
    - Unit Codelist
      - CCID 50
      - EID 50
      - log10 CCID 50
      - log10 EID 50
      - log10 TCID 50
        - » CCID50, TCID50, EID50 alone are not valid units of measure.
      - mEq/g Creatinine
      - mg/g Creatinine
      - mmol/g Creatinine
      - mmol/mol Creatinine
      - U/g Creatinine
      - U/g HGB
      - cells/kg
      - cells/uL
        - » Team decision: this information is reflected in the lab test, it does not need to be in the unit.

# Controlled Terminology Package 21 Publication Release

- Lab Terminology Team (*Unit Codelist continued*)
  - New Term Added to Existing Codelist
    - Unit Codelist

# Controlled Terminology Package 21 Publication Release

- Oncology Terminology Team
  - Term Removed
    - Tumor Response Result Codelist
      - UPD (Unequivocal Progression)
        - » The scope of the RSSTRESC codelist is expanding to include all currently relevant and accepted responses for various oncology criteria and the following principle was followed during the expansion effort: Each individual response is meant to convey the general use of the term (non-tumor specific) and will be defined in the general sense. The specific details on the requirements for each response within a criteria used in a clinical study reside in the criteria to be applied and within the protocol.
        - » It was agreed, after review of many criteria during the expansion effort, that progressive disease is unequivocal progressive disease and PD is the appropriate RSSTRESC submission value. Unequivocal progressive disease has been added as a synonym of PD. If the status of the response is open to question then PD would not be recorded as the RSSTRESC submission value.
        - » At the time it was added, UPD was included to support a specific RECIST 1.1 table for subjects with non-target disease only and was to apply only to the Non-target response (RSTESTCD=NTRGRES) component of the overall response. Following the principle above, PD is the appropriate RSSTRESC submission value. The use of the word 'unequivocal' in the RECIST table was likely included to make the point that for subjects with non-target disease only, the overall response can be based on unequivocal progression of the non-targets only. In addition, the definition of UPD in the CT, contains the statement “even in the presence of SD or PR in target disease” which contradicts the intended use case.



# Controlled Terminology

## Package 21 Publication Release

- PK Terminology Team
  - Submission Value Change
    - PK Parameters/PK Parameters Code
      - Midpoint of Collection Interval (MIDPTLST)
        - » Midpoint of Interval of Last Nonzero ER (ERTLST)
      - Time of Max Excretion Rate (ERTMAX)
        - » Midpoint of Interval of Maximum ER (ERTMAX)
      - MRT Infinity Obs (MRTIFO)
        - » MRT Intravasc Infinity Obs (MRTIVIFO)
      - MRT Infinity Pred (MRTIFP)
        - » MRT Intravasc Infinity Pred (MRTIVIFP)
      - MRT to Last Nonzero Conc (MRTLST)
        - » MRT Intravasc to Last Nonzero Conc (MRT Intravasc to Last Nonzero Conc)

# Controlled Terminology

## Package 21 Publication Release

- PK Terminology Team continued
  - Term Removed
    - PK Parameter Units of Measure Codelist
      - uL
        - » Our std base units for volume are mL and L.
      - L/umol/day
      - L/umol/h
      - L/umol/min
      - L/mmol/day
      - L/mmol/h
      - L/mmol/min
      - L/mol
      - L/mol/day
      - L/mol/h
      - L/mol/min
      - L/ng/day
      - L/ng/h
      - L/ng/min
      - L/nmol/day
      - L/nmol/h
      - L/nmol/min
      - L/pg/day
      - L/pg/h
      - L/pg/min
      - mL/mol/day
      - mL/mol/h
      - mL/mol/min
    - » We limit the units of dose to micrograms and/or milligrams.

# Controlled Terminology Package 21 Publication Release

- PK Terminology Team continued
  - New Term Added to Existing Codelist
    - PK Parameters Code/PK Parameters
    - PK Parameter Units of Measure

# Controlled Terminology Package 21 Publication Release

- SEND Terminology Team
  - New Term Added to Existing Codelist
    - Specimen

# Controlled Terminology Package 21 Publication Release

- Virology Terminology Team
  - Submission Value Change
    - Viral Resistance Findings Test Name/Test Code
      - IC50 Treatment Result (IC50T)
        - » IC50 Subject Result (IC50S)
      - IC95 Treatment Result (IC95T)
        - » IC95 Subject Result (IC95S)

# Controlled Terminology

## Package 21 Publication Release

- Virology Terminology Team continued
  - New Codelist
    - Microbiology Test Code/Test Name
    - Immunogenicity Specimen Assessments Test Code/Test Name
    - Anti-Viral Outcome of Treatment
  - New Term Added to Existing Codelist
    - Microorganism

# **Controlled Terminology Package 22 Public Review**

# Controlled Terminology Package 22 Public Review

- Cardiovascular Terminology Team
  - New Term Added to Existing Codelist
    - Cardiovascular Test Code/Test Name



# Controlled Terminology Package 22 Public Review

- General Terminology Team
  - Submission Value Change
    - Subject Characteristic Test Code/Test Name Codelist

CDISC Test Code	CDISC Test Name	CDISC Definition
<del>EDLEVEL</del> EDUYRNUM	<del>Education Level</del> Number of Years of Education	<del>Years of education that a person has completed.</del> The number of years of education that a person has completed.

# Controlled Terminology

## Package 22 Public Review

- General Terminology Team continued
  - Term Removed
    - Vital Signs Test Code/Test Name Codelist

CDISC Test Code	CDISC Test Name	CDISC Definition
BODYFAT	Adipose Tissue	A specialized form of connective tissue consisting primarily of adipocytes (fat cells), surrounded by a meshwork of collagen fibers. (NCI)
BODYFATM	Body Fat Measurement	A measurement of the total fat mass within the subject's body.

# Controlled Terminology Package 22 Public Review

- General Terminology Team continued
  - New Codelist
    - COPD Findings About Test Code/Test Name

# Controlled Terminology

## Package 22 Public Review

- General Terminology Team continued:
  - New Term Added to Existing Codelist
    - Anatomical Location
    - Respiratory Test Code/Test Name
    - Vital Signs Test Code/Vital Signs Test Name
    - Skin Response Test Code/Test Name
    - Reproductive System Findings Test Code/Test Name
    - Subject Characteristic Test Code/Test Name
    - Method
    - Morphology Test Code/Test Name
    - Ophthalmic Exam Test Code/Test Name

# Controlled Terminology Package 22 Public Review

- Lab Terminology Team (*Laboratory Test Codelists*)
  - New Term Added to Existing Codelist
    - Laboratory Test Code/Test Name

# Controlled Terminology Package 22 Public Review

- Lab Terminology Team (*Unit Codelist*)
  - New Term Added to Existing Codelist
    - Unit Codelist

# Controlled Terminology

## Package 22 Public Review

- PK Terminology Team
  - Submission Value Change
    - PK Parameters Code/PK Parameters Codelist

PK Parameters Code	PK Parameters	CDISC Definition
ARAUC	Accumulation Ratio AUC Accumulation Ratio AUCTAU	The area under the curve (AUCTAU) at steady state divided by the area under the curve over the initial dosing interval. The area under the curve (AUCTAU) at steady state divided by the area under the curve (AUCTAU) over the initial dosing interval.

# Controlled Terminology Package 22 Public Review

- PK Terminology Team continued
  - New Term Added to Existing Codelist
    - Pharmacokinetic Parameters Name/Code



# Controlled Terminology Package 22 Public Review

- SEND Terminology Team
  - New Term Added to Existing Codelist
    - Strain/Substrain
    - Specimen

# Controlled Terminology Package 22 Public Review

- Virology Terminology Team
  - New Term Added to Existing Codelist
    - Microorganism

# CDISC Medical Device Standards v2.0

CDISC Medical Device Leadership Team

*Presenter: Kit Howard*

CDISC Public Webinar Series, 26Mar2015



**Strength** *through Collaboration*

# Agenda

## State of CDISC's Medical Device Standards

- Version 1.0
- Version 2.0

## Context

- Regulatory
- Industry
- Healthcare

## Next Steps in Development and Distribution

# Current Medical Device IG v1.0

Published December 2012

Descriptions of drug/device differences

7 device domains

- DE, DI, DO, DU, DX, DT, DR
- How device domains relate to each other

3 new variables

- --ACNDEV, --PARTY, --PRTYID

Instructions implementation including cross-domain examples

New terminology

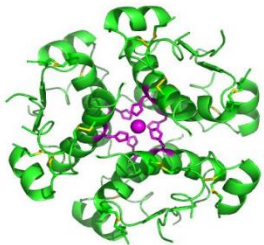
# CDISC Therapy Area Standards Using Device Domains

National Institutes of Health/Department of Health



Asthma

**Asthma**



**Diabetes**

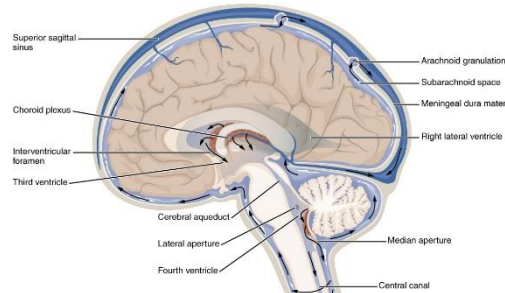
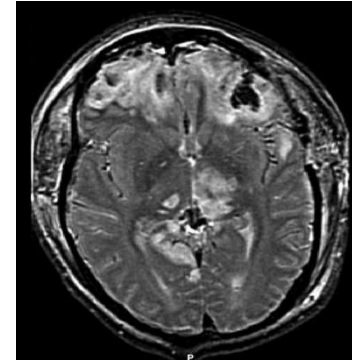
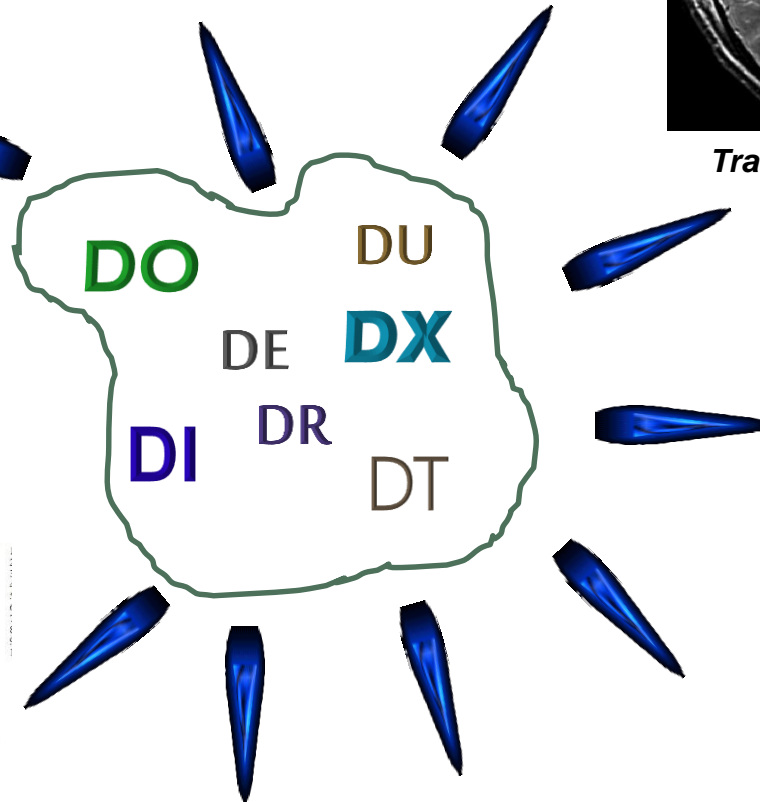


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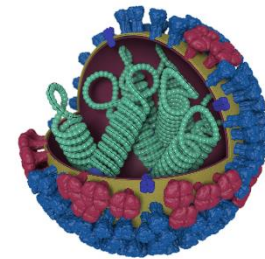
**Alzheimer's**



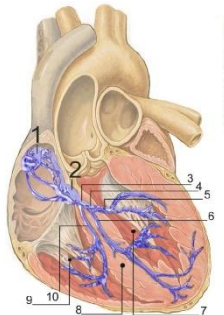
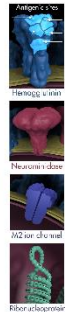
**Traumatic Brain Injury**



AN INFLUENZA VIRUS



**Influenza**



# New for Medical Device IG v2.0

CDASH for the 7 existing domains

Possibly ADaM model - ADDL

Models for *in vitro* diagnostics run and sample domains

Resolutions to numerous modeling issues

- How to relate components to devices and track them together or separately
- How to link several devices to a single AE for relationship and action taken

Integrated examples across domains and standards

- CDASH, SDTM, possibly ADaM

Expected public review 3Q2015

# Agenda

## State of CDISC's Medical Device Standards

- Version 1.0
- Version 2.0

## Context

- Regulatory
- Industry
- Healthcare

## Next Steps in Development and Distribution



CDRH Senior management open to discussing CDISC standards implementation

CDISC Invited to participate in MDEpiNet, public/private project to improve/standardize device data ecosystem

# MDUFA IV negotiations beginning - use of CDISC standards will be discussed\*



The screenshot shows the FDA website's 'Medical Devices' section. The main heading is 'Medical Device User Fee Amendments 2012 (MDUFA III)', which is crossed out with a red diagonal line and the text '2018 MDUFA IV' is written in red. The page includes a sidebar with links to 'Overview of Medical Device Regulation', 'MDUFA III', 'MDUFA III Fees', 'MDUFA III Guidance Documents', 'MDUFA III Meetings', and 'MDUFA III FR Notices'. The main content area discusses the 2012 amendments and the device user fees. A 'Resources for You' section lists '2015 Medical Device User Fees'. A 'Contact FDA' section provides contact information for the DICE office. The top of the page features the FDA logo, navigation links, and a search bar.

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Home | Food | Drugs | Medical Devices | Radiation-Emitting Products | Vaccines, Blood & Biologics | Animal & Veterinary | Cosmetics | Tobacco Products

## Medical Devices

Home > Medical Devices > Device Advice: Comprehensive Regulatory Assistance > Overview of Medical Device Regulation > MDUFA III

### Medical Device User Fee Amendments 2012 (MDUFA III)

**2018 MDUFA IV**

[CDRH Industry: Get e-mail updates](#)

The Food and Drug Administration Safety and Innovation Act (Public Law 112-144) includes the Medical Device User Fee Amendments of 2012, or MDUFA III. MDUFA III will take effect on October 1, 2012 and will sunset in five years on October 1, 2017.

Device user fees were first established by Congress in 2002. Medical device companies pay fees to FDA when they register their establishment and list their devices with the agency, whenever they submit an application or a notification to market a new medical device in the U.S. and for certain other types of submissions.

Ultimately, MDUFA III represents a commitment between the U.S. medical device industry and the FDA to increase the efficiency of regulatory processes in order to reduce the time it takes to bring safe and effective medical devices to the U.S. market.

MDUFA III is the result of more than a year of public input negotiations.

**Device Advice: Comprehensive Regulatory Assistance**

- Overview of Medical Device Regulation
- MDUFA III**
- MDUFA III Fees
- MDUFA III Guidance Documents
- MDUFA III Meetings
- MDUFA III FR Notices

**Resources for You**

- 2015 Medical Device User Fees

**Contact FDA**

1-800-638-2041  
301-796-7100  
Fax: 301-847-8149  
[DICE@fda.hhs.gov](mailto:DICE@fda.hhs.gov)

CDRH-Division of Industry and Consumer Education (DICE)  
Office of Communication and Education  
Center for Devices and Radiological Health  
Food and Drug Administration  
10903 New Hampshire Avenue  
WO66-4621  
Silver Spring, MD 20993

\*may or may not end up in MDUFA IV

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# Co-authored a poster at PhUSE with Rajesh Nair, CDRH Stats Reviewer



## HOW CAN CDISC HELP CDRH?



### Abstract

*CDRH, FDA's center for medical devices, receives data in regulatory submissions in many structures and formats.*

*Regulatory mandates imposed by MDUFA III on CDRH also require ever decreasing time for reviews as numbers of covered submissions increase. Together, these result in challenges that can significantly delay reviews.*

*CDISC's standards cover much of the clinical data in device submissions, including device-centric data (SDTMIG-MD).*

*CDISC standards have been mandated for CDER submissions, and while devices have many*

### CDRH: Current Situation

- Over 100 PMAs and 510(k) marketing applications containing clinical data received per year
- MDUFA III: establishes rigorous premarket review performance goals with steady increase in percentage of submissions for which review will be completed within the specified review time goals
- Applications are typically an e-copy (PDF of paper copy), often with no subject- or device-level data
- When data are submitted, any format is accepted (i.e., no data standardization)
- Lack of standards significantly slows review process and ability to deal with late-breaking issues

### CDISC *Data* Standards Include...

- CDASH: Data capture (CRF), begin by collecting data in standard structure
- SDTM: Regulatory submission of subject- and device-level data (tabulations)
- ADaM: Statistical analysis datasets
- Controlled Terminology: code lists
- Define-xml: comprehensive metadata for each study dataset and variable

### CDISC *Device* Standards Include...

- Device Identifiers: Supports UDI/GUDID
- Device Properties: Unchanging, e.g., composition, coil type, size
- Device-in-Use: Settings used with device, e.g., magnetic field strength
- Device Tracking: Location and disposition of device; flexible granularity
- Device Events: What happens to the device, e.g., malfunctions, calibrations

*Based on a paper presented by Dr. Nair at the CDISC 2014 International Interchange. Available at <http://www.phuse.eu/CSS-Presentations2015.aspx>, Poster #16.*

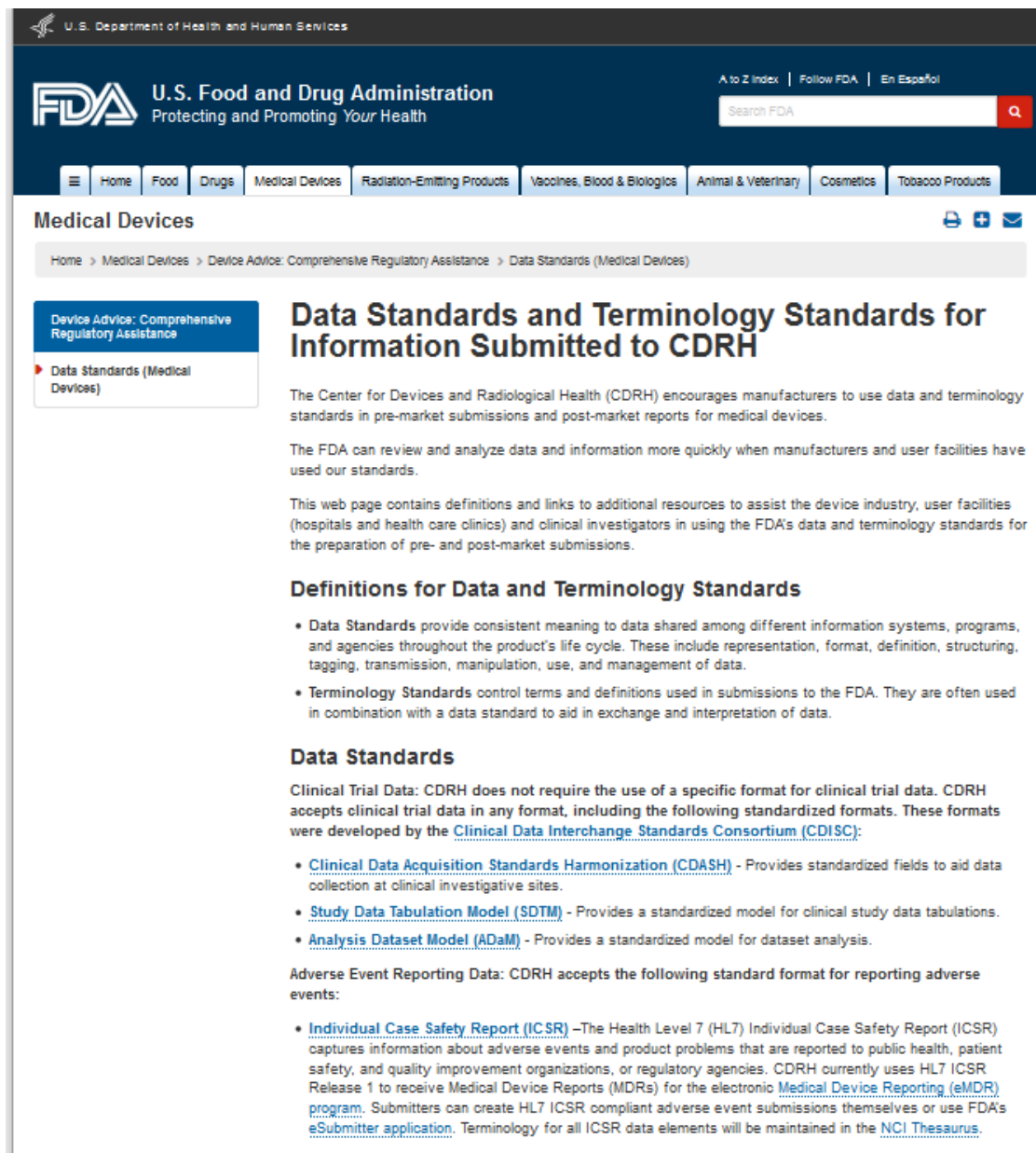


# Some of the CDISC-facilitated solutions

<table><tr><td>Protocol Deviations</td></tr><tr><td><u>Issue</u></td></tr><tr><td>▶ Hard to identify, determine impact</td></tr><tr><td><u>CDRH Reviewer Requests</u></td></tr><tr><td>▶ Summary tables by type of deviation (major/minor)</td></tr><tr><td>▶ Protocol deviations by investigational site</td></tr><tr><td><u>CDISC Solution</u></td></tr><tr><td>▶ SDTM: designed to facilitate summary table production;</td></tr><tr><td>▶ CDASH: defines deviation data capture, including narratives; facilitates categorization</td></tr></table>	Protocol Deviations	<u>Issue</u>	▶ Hard to identify, determine impact	<u>CDRH Reviewer Requests</u>	▶ Summary tables by type of deviation (major/minor)	▶ Protocol deviations by investigational site	<u>CDISC Solution</u>	▶ SDTM: designed to facilitate summary table production;	▶ CDASH: defines deviation data capture, including narratives; facilitates categorization	<table><tr><td>Missing data</td></tr><tr><td><u>Issue</u></td></tr><tr><td>▶ May impact validity of conclusions, choice of statistical model</td></tr><tr><td><u>CDRH Reviewer Requests</u></td></tr><tr><td>▶ Show why and when data are missing (missed visits, value not recorded, etc.)</td></tr><tr><td>▶ No undisclosed data omissions; justify all data omissions</td></tr><tr><td>▶ Clearly note all imputed data</td></tr><tr><td><u>CDISC Solution</u></td></tr><tr><td>▶ SDTM and ADaM define-xml:</td></tr><tr><td>▶ ▶ Origin of each variable is defined as collected, derived or imputed</td></tr><tr><td>▶ Algorithms for all derivations and</td></tr></table>	Missing data	<u>Issue</u>	▶ May impact validity of conclusions, choice of statistical model	<u>CDRH Reviewer Requests</u>	▶ Show why and when data are missing (missed visits, value not recorded, etc.)	▶ No undisclosed data omissions; justify all data omissions	▶ Clearly note all imputed data	<u>CDISC Solution</u>	▶ SDTM and ADaM define-xml:	▶ ▶ Origin of each variable is defined as collected, derived or imputed	▶ Algorithms for all derivations and	<table><tr><td>Patient Accountability</td></tr><tr><td><u>Issue</u></td></tr><tr><td>▶ Hard to determine accountability for all subjects</td></tr><tr><td><u>CDRH Reviewer Request</u></td></tr><tr><td>▶ Provide patient accountability charts with discussions of missing data</td></tr><tr><td><u>CDISC Solution</u></td></tr><tr><td>▶ CDASH and SDTM: Subject Disposition domain captures status of each subject at each defined time point, which can be used to produce accountability charts; see also “Missing Data” box</td></tr></table>	Patient Accountability	<u>Issue</u>	▶ Hard to determine accountability for all subjects	<u>CDRH Reviewer Request</u>	▶ Provide patient accountability charts with discussions of missing data	<u>CDISC Solution</u>	▶ CDASH and SDTM: Subject Disposition domain captures status of each subject at each defined time point, which can be used to produce accountability charts; see also “Missing Data” box	<table><tr><td>Missing coding tools</td></tr><tr><td><u>Issue</u></td></tr><tr><td>▶ Hard to identify, determine impact</td></tr></table>	Missing coding tools	<u>Issue</u>	▶ Hard to identify, determine impact	<table><tr><td>Missing Data Issues</td></tr><tr><td><u>CDRH Reviewer Requests</u></td></tr><tr><td>▶ Include electronic datasets in PMA submission</td></tr><tr><td>▶ Adverse Event listings for medical reviewers</td></tr><tr><td>▶ Study endpoints analysis dataset(s) and raw data to minimize complicated manipulations and merges required to validate results</td></tr><tr><td>▶ Analysis datasets to support key effectiveness/safety analyses</td></tr><tr><td>▶ Include basic demographic variables and important covariates in analysis datasets</td></tr><tr><td>▶ Define/README file for datasets and program files</td></tr><tr><td>▶ Document datasets and code sufficiently</td></tr><tr><td><u>CDISC Solution</u></td></tr><tr><td>▶ SDTM and ADaM provide subject- and device-level tabulation and analysis datasets</td></tr><tr><td>▶ Data transmitted in SAS</td></tr></table>	Missing Data Issues	<u>CDRH Reviewer Requests</u>	▶ Include electronic datasets in PMA submission	▶ Adverse Event listings for medical reviewers	▶ Study endpoints analysis dataset(s) and raw data to minimize complicated manipulations and merges required to validate results	▶ Analysis datasets to support key effectiveness/safety analyses	▶ Include basic demographic variables and important covariates in analysis datasets	▶ Define/README file for datasets and program files	▶ Document datasets and code sufficiently	<u>CDISC Solution</u>	▶ SDTM and ADaM provide subject- and device-level tabulation and analysis datasets	▶ Data transmitted in SAS
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▶ Analysis datasets to support key effectiveness/safety analyses																																														
▶ Include basic demographic variables and important covariates in analysis datasets																																														
▶ Define/README file for datasets and program files																																														
▶ Document datasets and code sufficiently																																														
<u>CDISC Solution</u>																																														
▶ SDTM and ADaM provide subject- and device-level tabulation and analysis datasets																																														
▶ Data transmitted in SAS																																														

Based on a paper presented by Dr. Nair at the CDISC 2014 International Interchange. Available at <http://www.phuse.eu/CSS-Presentations2015.aspx>, Poster #16.

# CDRH Lists CDISC Standards as accepted



The screenshot shows the FDA's website for Medical Devices. The header includes the FDA logo, the text 'U.S. Food and Drug Administration Protecting and Promoting Your Health', and a search bar. A navigation menu lists various FDA categories. The main content area is titled 'Medical Devices' and contains a breadcrumb trail: 'Home > Medical Devices > Device Advice: Comprehensive Regulatory Assistance > Data Standards (Medical Devices)'. A sidebar on the left lists 'Device Advice: Comprehensive Regulatory Assistance' and 'Data Standards (Medical Devices)'. The main heading is 'Data Standards and Terminology Standards for Information Submitted to CDRH'. The text explains that the Center for Devices and Radiological Health (CDRH) encourages manufacturers to use data and terminology standards in pre-market submissions and post-market reports. It states that the FDA can review and analyze data more quickly when manufacturers and user facilities have used their standards. The page also contains definitions for Data Standards and Terminology Standards, and lists specific standards accepted by CDRH, including Clinical Trial Data, Clinical Data Acquisition Standards Harmonization (CDASH), Study Data Tabulation Model (SDTM), Analysis Dataset Model (ADaM), and Adverse Event Reporting Data. It also mentions the Individual Case Safety Report (ICSR) and the Medical Device Reporting (eMDR) program.

U.S. Department of Health and Human Services

**FDA** U.S. Food and Drug Administration  
Protecting and Promoting Your Health

A to Z Index | Follow FDA | En Español

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Home Food Drugs Medical Devices Radiation-Emitting Products Vaccines, Blood & Biologics Animal & Veterinary Cosmetics Tobacco Products

**Medical Devices**

Home > Medical Devices > Device Advice: Comprehensive Regulatory Assistance > Data Standards (Medical Devices)

Device Advice: Comprehensive Regulatory Assistance

Data Standards (Medical Devices)

## Data Standards and Terminology Standards for Information Submitted to CDRH

The Center for Devices and Radiological Health (CDRH) encourages manufacturers to use data and terminology standards in pre-market submissions and post-market reports for medical devices.

The FDA can review and analyze data and information more quickly when manufacturers and user facilities have used our standards.

This web page contains definitions and links to additional resources to assist the device industry, user facilities (hospitals and health care clinics) and clinical investigators in using the FDA's data and terminology standards for the preparation of pre- and post-market submissions.

### Definitions for Data and Terminology Standards

- **Data Standards** provide consistent meaning to data shared among different information systems, programs, and agencies throughout the product's life cycle. These include representation, format, definition, structuring, tagging, transmission, manipulation, use, and management of data.
- **Terminology Standards** control terms and definitions used in submissions to the FDA. They are often used in combination with a data standard to aid in exchange and interpretation of data.

### Data Standards

Clinical Trial Data: CDRH does not require the use of a specific format for clinical trial data. CDRH accepts clinical trial data in any format, including the following standardized formats. These formats were developed by the [Clinical Data Interchange Standards Consortium \(CDISC\)](#):

- [Clinical Data Acquisition Standards Harmonization \(CDASH\)](#) - Provides standardized fields to aid data collection at clinical investigative sites.
- [Study Data Tabulation Model \(SDTM\)](#) - Provides a standardized model for clinical study data tabulations.
- [Analysis Dataset Model \(ADaM\)](#) - Provides a standardized model for dataset analysis.

Adverse Event Reporting Data: CDRH accepts the following standard format for reporting adverse events:

- **Individual Case Safety Report (ICSR)** -The Health Level 7 (HL7) Individual Case Safety Report (ICSR) captures information about adverse events and product problems that are reported to public health, patient safety, and quality improvement organizations, or regulatory agencies. CDRH currently uses HL7 ICSR Release 1 to receive Medical Device Reports (MDRs) for the electronic [Medical Device Reporting \(eMDR\)](#) program. Submitters can create HL7 ICSR compliant adverse event submissions themselves or use FDA's [eSubmitter application](#). Terminology for all ICSR data elements will be maintained in the [NCI Thesaurus](#).



---

# Guidance for Industry

## Providing Regulatory Submissions in Electronic Format — Standardized Study Data

### *DRAFT GUIDANCE*

This guidance document is being distributed for comment purposes only.

Comments and suggestions regarding this draft document should be submitted within 60 days of publication in the *Federal Register* of the notice announcing the availability of the draft guidance. Submit comments to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. All comments should be identified with the docket number listed in the notice of availability that publishes in the *Federal Register*.

For questions regarding this draft document contact (CDER) Kieu Pham at 301-796-1616, (CBER) Office of Communication, Outreach and Development (OCOD) at 301-827-1800 or 1-800-835-4709, or (CDRH) Terrie Reed at 301-796-6130.

U.S. Department of Health and Human Services  
Food and Drug Administration  
Center for Drug Evaluation and Research (CDER)  
Center for Biologics Evaluation and Research (CBER)  
Center for Devices and Radiological Health (CDRH)



February 2012  
Electronic Submissions

# Standards Progression?

NDA, BLA, ANDA

PDUFA III

Encouraged  
electronic  
submissions

PDUFA IV

Encouraged  
CDISC

PDUFA V

Required  
CDISC  
(2016)

MDUFA III

Required  
e-copies

MDUFA IV

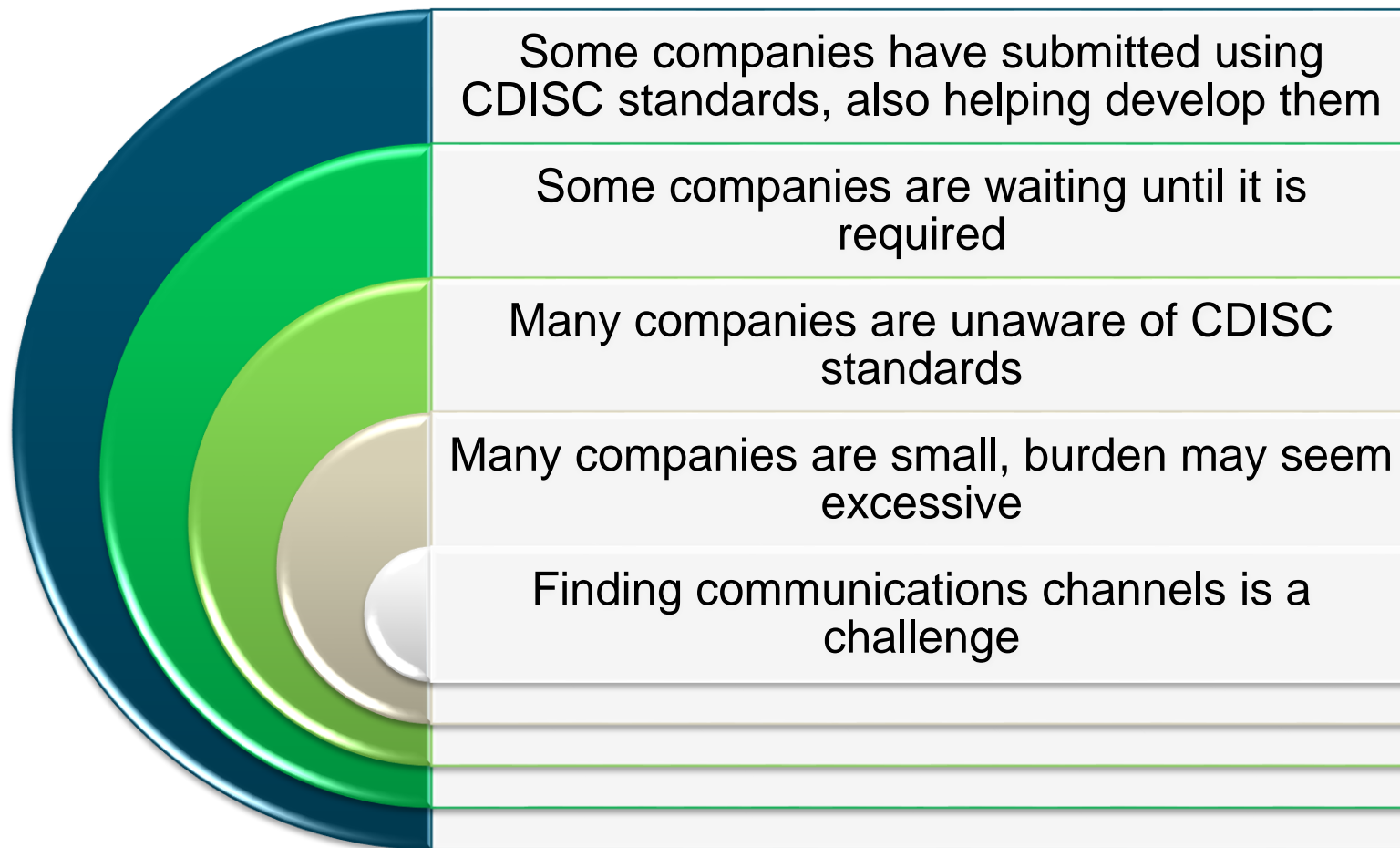
*Encourage  
CDISC???*

MDUFA V

*Require  
CDISC???*

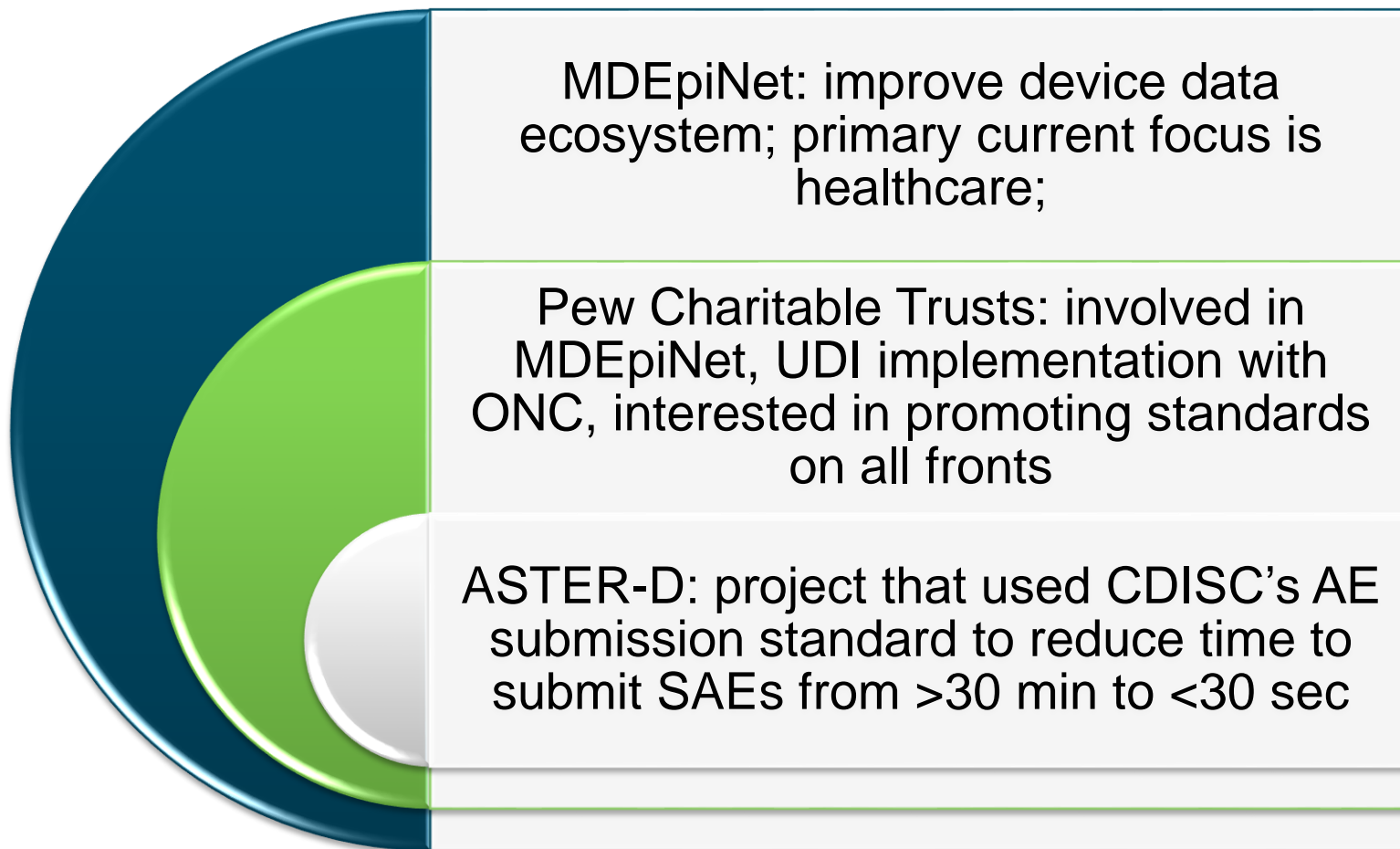
PMA, 510(k), ???

# Industry Context





# Healthcare Context



# Agenda

## State of CDISC's Medical Device Standards

- Version 1.0
- Version 2.0

## Context

- Regulatory
- Industry
- Healthcare

## Next Steps in Development and Distribution

# Next Steps

Complete sections for Medical Devices IG v2.0, Public review

- CDASH, ADaM
- IVD
- Device/components and multiple devices/AE
- Integrated examples

Increase awareness in device industry, encourage additional companies to adopt

Partner with Pew, others, to ensure research is part of medical device data ecosystem

Influence adoption of CDISC standards at CDRH

Meet training needs for multiple audiences



**Strength *through* collaboration.**

# CDISC Standards Update

## March 2015

Wayne R. Kubick  
CDISC CTO  
[wkubick@cdisc.org](mailto:wkubick@cdisc.org)



**Strength** *through Collaboration*

# Keeping Up with CDISC Standards



ABOUT STANDARDS CO  
ABOUT STANDARDS COLLABORATIONS RESOURCES NEWS/PUBLICATIONS EDUCATION EVENT

Foundational

Therapeutic Areas

Healthcare Link

Semantics

SHARE

Technical Plan Updates

## Technical Plan Updates

### CDISC Technical Update – Recent and Upcoming Accomplishments February 2015

#### Therapeutic Areas:

- ✦ An updated CFAST pipeline showing planned projects in 2015-2016 has been posted on the CFAST page.
- ✦ The CFAST TAUG for CFAST TAUG for Schizophrenia, is now scheduled to be posted for public comment in February.
- ✦ Coming next is the new Draft CFAST TAUG for Dyslipidemia, which should be posted for public comment in March.

#### Foundational Standards:

- ✦ The ADaM Analysis Results Metadata Specification for Define-XML v2 is now available for use.
- ✦ The CDISC Standards in RDF Reference Guide, prepared by the PhUSE CSS Semantic Technology group, is still open for comment until 20 February.
- ✦ Next up is the draft ADaM Data Structure for Integration (ADSL), due to be posted for comment in February
- ✦ The SEND Developmental and Reproductive Toxicology is being readied for public comment in March.
- ✦ The final ADaM Occurrence data structure is also due to be posted in March.

#### SHARE:

- ✦ The first release of electronic metadata for ADaM v2.1 is now available for download.
- ✦ CDASH v1.1 to SDTMIG v3.1.2 mapping metadata is now available for download.
- ✦ The first package of electronic metadata for a CFAST TAUG is now under review and should be posted in March.

The CDISC **Technical Plan P** upcoming CDISC planned p milestones are not expected have previously completed p projects presented as task b the comment period and th provisional or final standard. task bar as well.

Because projects in progre: availability of our volunteers)

#### Technical Plan Project:

- [Technical Plan Project Sch](#)

#### Monthly Technical Updates:

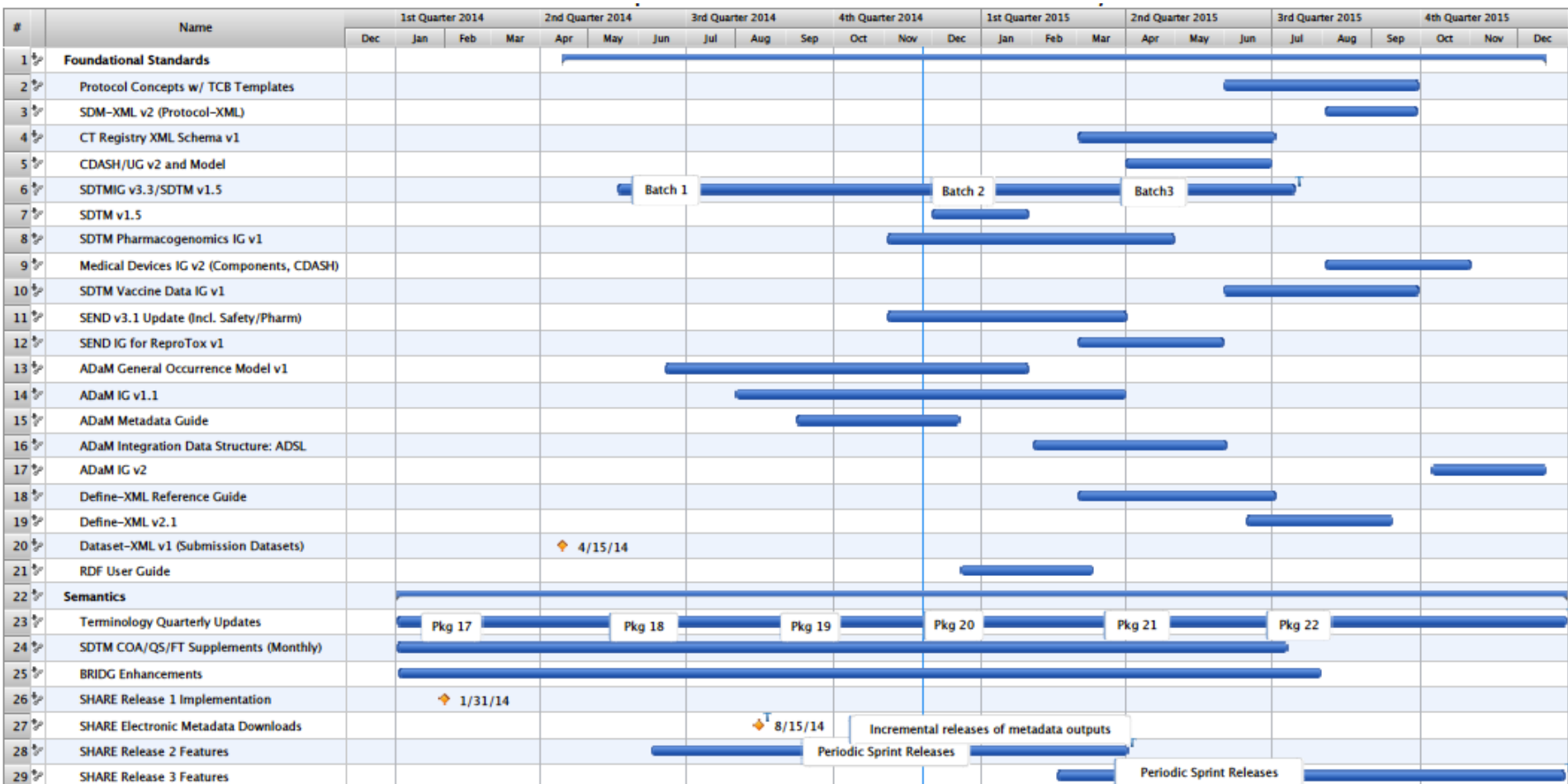
- [March 2015 Technical Up](#)
- [February 2015 Technical I](#)
- [January 2015 Technical U](#)

## What's New

Now Available: ADaM v1.3 Vali



# 2014 CDISC Technical Plan



# 2015 CDISC Technical Plan

Team	Project	Description	Reqs Date	State	Target Date
Foundational Content Standards					
PRG	Protocol Concepts	Protocol Concepts V1.0 spreadsheet release for review and collaboration with <u>TransCelerate</u> Common Protocol Template (concept mapping to Template)		Draft	Q2
CDASH	CDASHIG v2	CDASH Model, new domains (PR, HO, SR, DD, MI, MO, RP, PC, PP, FA, QS)		Draft	Q4
SDTM	SDTM v1.5	New variables, domain-specific variable class, disease milestones, new special purpose domains to support SEND, <u>PGx</u> , Human Clinical Trials.		Draft	Q2
SDS	SDTMIG v3.3	<p>New Intervention domains: Procedure Agents (AG) and Meal (ML)</p> <p>New Physiology Findings domains: Respiratory (RE) Nervous System (NV) Ophthalmology (OE), Urinary (UR), Cardiovascular (CV)</p> <p>Broadening TU, TR, and RS domains to handle non-tumor lesions</p> <p>Use of "Non-Standard Variables" in parent domains rather than as supplemental qualifiers</p> <p>Disease Milestones</p>		Final	Q3



# Progress Update – Foundational Standards

Foundatio

PLA

## Foundational Products Released in 2014-2015:

- Dataset-XML v1 Final
- SDTMIG 3.3 Batch 1 (7 draft domains)
- SDTMIG 3.3 Batch 2 (Milestones, 2 Domains)
- Pharmacogenomics SDTMIG v1 Draft
- SEND v3.1 Draft
- ADaM Occurrence Data Structure v1 Draft
- ADaM IG v1.1 Draft
- ADaM Results Metadata Spec for Define-XML
- ADaM v1.3 Validation Checks
- CDISC in RDF Reference Guide (PhUSE)
- Periodic Terminology (P22) and COA Packages
- Updated COP001 and Process Docs

Solution

## Upcoming Major New Drafts for Comment:

- ADaM Data Structure for Integration (ADSL)
- SEND DART
- SDTMIG Batch 3, SDTM v1.5
- Protocol Concepts
- CTReg XML Schema
- Define-XML IG, v2.1

Semant

Therapeutic Area	Coordinating Organizations/ Project Manager	Proposal Approval Date	Stage 0 Scoping & Planning	Stage 1 Concept Modeling	Stage 2 Standards Development	Stage 3a Internal Review	*Stage 3b Public Review	*Stage 3c **Projected Publication	Notes
Traumatic Brain Injury v1	CDISC Rhonda Facile	O							Internal review goal: March
Chronic Hepatitis C Virus v1	TCB John Owen	N							Publication goal: Mar 27
Schizophrenia v1	CDISC/DCRI Amy Palmer	N							Public Review: Feb 25 - Mar 27
Breast Cancer v1	TCB John Owen	N							Internal Review goal: Mar 6
Dyslipidemia v1	TCB John Glover	D							Public Webinar: Mar 9 Public Review goal: Mar 13
COPD v1	TCB John Glover	N							Internal Review goal: mid-April
ADaM Supplement to Diabetes v1	TCB Rachael Zirkle								Internal Review goal: Mar 6
Diabetic Kidney Disease v1	TCB Rachael Zirkle	M							Working on scoping and concept list, Charter?
Tuberculosis v2	C-Path Laura Butte	D							Finalizing scope, working on stage 1 concurrently
Rheumatoid Arthritis v1	TCB Trisha Simpson	J							Starting weekly meeting soon, received FDA requirements
CV Imaging v1	CDISC/DCRI Amy Palmer	D							Received draft data elements, finalizing scope
Virology v2	C-Path Laura Butte	F							Submitted charter

### TAUGs released in 2014-2015:

- Multiple Sclerosis
- Diabetes
- Cardiovascular
- Influenza
- QT Studies
- *Schizophrenia*
- *Dyslipidemia*

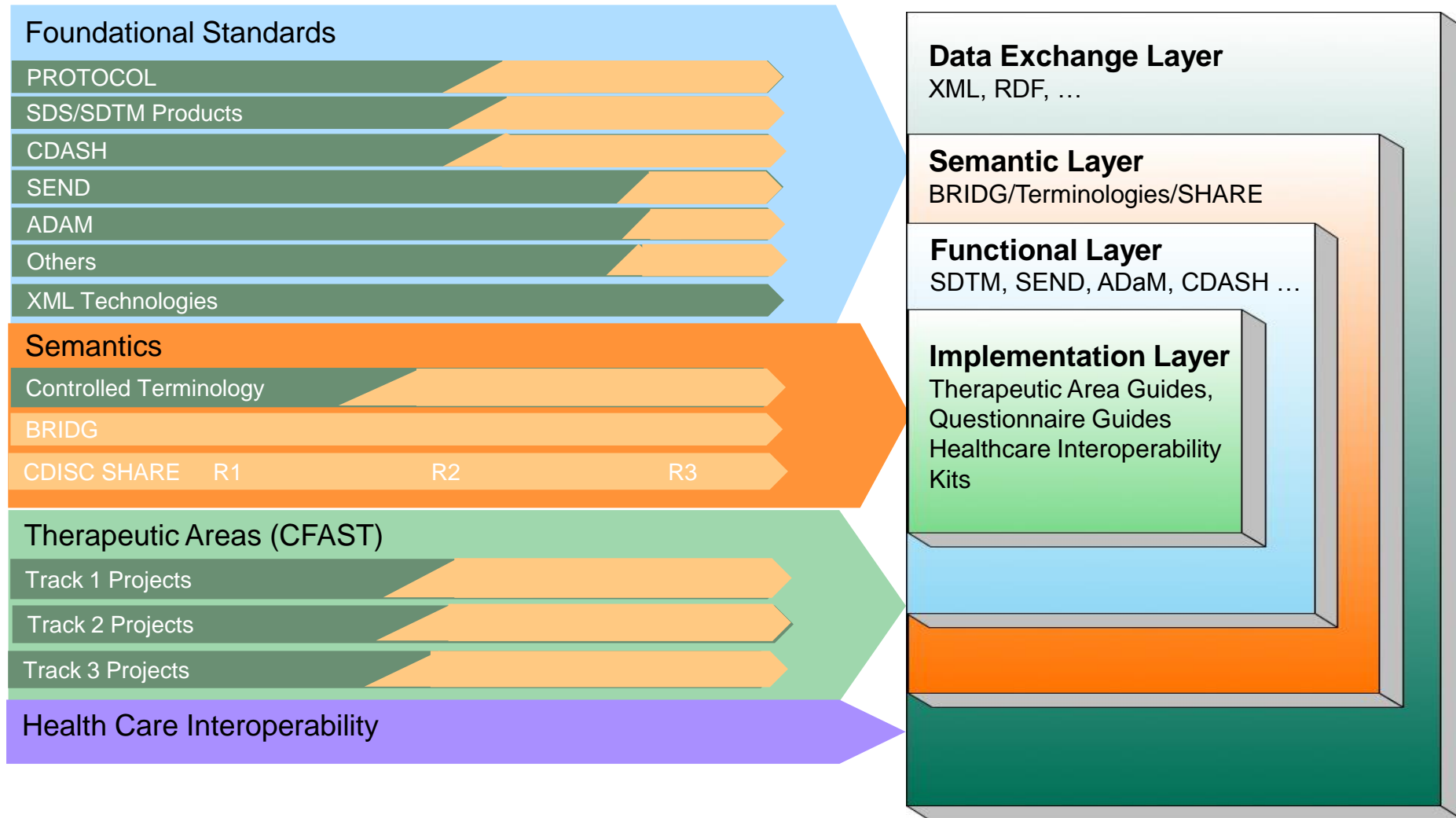
### Upcoming:

- Chronic Hep-C
- *Diabetes ADaM Supplement*
- *Traumatic Brain Injury*

Key |  Stage completed |  Stage ongoing | All months reflect when stage is, or is projected to be, completed.

\*The Stage3b concludes at the end of the 30-day review period and Stage 3c concludes when all tasks have been completed and the standard is publically available.  
\*\* Specific projected publication dates to be added to the notes section at the conclusion of Stage 3b.

# CDISC Technical Roadmap - 2014



The Roadmap depicts evolution from siloed standards to an integrated stack based on BRIDG and SHARE

# 2015 Standards Development Priorities

- Improve transparency
  - Share requirements and plans in advance; invite feedback
  - Make it easier for global participants to get more involved
- Agile standards development processes
  - Expand use of collaboration tools to work more efficiently
  - Smaller teams, with scrum and sprints, all coordinated through SHARE and JIRA
  - Get content into SHARE early – as soon as its stable
  - Rollout SHARE collaborative curation initiative – to rapidly expand and expedite filling gaps in content
  - Engage a second class of Fellows
- Focus and Execution
  - Do what's necessary so industry and regulatory authorities get what they need when they need it to better realize the benefits of CDISC standards



**Strength *through* collaboration.**

# Question and Answer Session



# CDISC Education & Events Announcements

John Ezzell, CDISC, Manager of Education Products



**Strength** *through Collaboration*

# Standards currently out for review

- TA CFAST TAUG for Schizophrenia
  - Visit <http://www.cdisc.org/standards/dataexchange> for more information.
  - Deadline for Comments: 27 Mar 2015
- TA CFAST TAUG for Dyslipidemia
  - Visit <http://www.cdisc.org/standards/dataexchange> for more information.
  - Deadline for Comments: 20 Apr 2015

Click [here](#) to submit your comments.



# Upcoming USA Public Course Events

Location	Dates	Courses Offered	Registration Deadline	Discounts?	Host
Audubon, PA	18-22 May 2015	SDTM, CDASH, ADaM	18 Apr 2015	<i>Expired</i>	 <b>BIOCLINICA</b> Global clinical trial solutions. Real-world results.
Minneapolis, MN	23-26 June 2015	SDTM for Med. Devices, CDASH, CT	23 May 2015	<i>Expired</i>	 <b>MedNet</b> Solutions
Durham, NC	27-31 July 2015	SDTM, ADaM		31 Mar 2015	 <b>Duke Clinical Research Institute</b> DUKE UNIVERSITY MEDICAL CENTER
Gaithersburg, MD	1-4 Sep 2015	SDTM, CDASH, ADaM		24 April 2015	 <b>MedImmune</b>
International Interchange, Chicago, IL	9-13 Nov 2015	TBD			 <b>CDISC</b>

*Registration deadline indicates online deadline. Offline registration deadlines for each event can be found [here](#). Additional 2015 public training events can be found @ <http://cdisc.org/public-courses>.*

# Upcoming Europe Public Course Events

Location	Dates	Courses Offered	Registration Deadline	Discounts?	Host
Europe Interchange in Basel, Switzerland	4-8 May 2015	FDA Review, CDASH, ODM, CT, Healthcare Link, Dataset-XML, Define-XML, SDTM, SDTM for Med. Devices, SEND, ADaM	20 April 2015	Early Bird Discount Available until 23 Feb 2015	
Eschborn (Frankfurt), Germany	28-31 Jul 2015	SDTM, CDASH, ADaM	14 June 2015	28 Feb 2015	
Brussels, Belgium	7-10 Sep 2015	SDTM, CDASH, ADaM		31 Mar 2015	

*Registration deadline indicates online deadline. Offline registration deadlines for each event can be found [here](#). Additional 2015 public training events can be found @ <http://cdisc.org/public-courses>.*

# Upcoming Asia Public Course Events

Location	Dates	Courses Offered	Registration Deadline	Discounts?	Host
Beijing, China	12-15 May 2015	SDTM, CDASH, ODM, Dataset-XML, Define-XML, ADaM	24 Apr 2015	13 Mar 2015	
Shanghai, China	18-21 May 2015	SDTM, CDASH, ODM, Dataset-XML, Define-XML, ADaM	24 Apr 2015	13 Mar 2015	
Japan Interchange	22-26 Jun 2015	SDTM, CDASH, ODM, Dataset-XML, Define-XML, ADaM	<i>Registration to open soon</i>		

*Registration deadline indicates online deadline. Offline registration deadlines for each event can be found [here](#). Additional 2015 public training events can be found @ <http://cdisc.org/public-courses>.*

# CDISC In-House Education

- Below courses readily available for 'in-house' training:

- ADaM
- BRIDG Deep Dive
- CDASH
- SDTM
- SDTM for Medical Devices
- SEND
- *Others pending availability*



The screenshot shows a web browser window with the address bar displaying [www.cdisc.org/private-courses](http://www.cdisc.org/private-courses). A green arrow points to the address bar. The left sidebar contains a list of navigation links: Partner Events & User Group Events, CDISC-Authorized Education, CDISC Authorized Instructors, CDISC Course Descriptions, **Private (In-House) Courses**, CDISC Event Archives, and CDISC Education. The main content area features the text: "CDISC-authorized education courses are only available if the CDISC logo is your assurance that the education courses are provided by individuals who have passed a rigorous qualification process." Below this text is a link titled "CDISC Private (In-House) Courses" with a green button that says "CLICK HERE! To request CDISC In-House Training". A green arrow points to this button.

- For more information visit our [website](#) or submit request [here](#).

# Online Training

- SDTM, CDASH, BRIDG, ADaM, and Therapeutic Area modules available on CDISC Training Campus (<http://CDISC.trainingcampus.net>)
- Bundle packages available for SDTM, CDASH, and BRIDG modules
- *All members should contact [training@cdisc.org](mailto:training@cdisc.org) to retrieve company-specific discount code.*



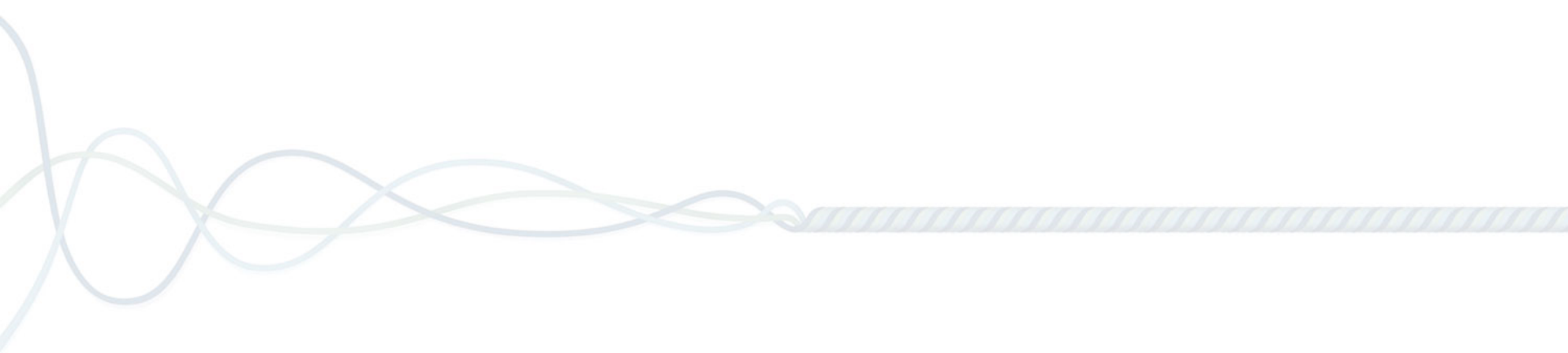
# Next Members-Only Webinar

- **Topic**: Associated Persons Domains
- **Date/Time**: 23 Apr 2015, 10:00-11:30 AM CST
- **Speakers**:
  - Alyssa Wittle, Theorem Clinical
- Register [here](#).

*Webinar details also at [www.cdisc.org/webinars](http://www.cdisc.org/webinars)*

# **CDISC Members Drive Global Standards**

## **Thank you for your support!**



*Any more questions?*

*Thank you for attending this webinar.*

**CDISC's vision is to:  
Inform Patient Care & Safety Through Higher Quality Medical Research**



**Strength** *through collaboration.*