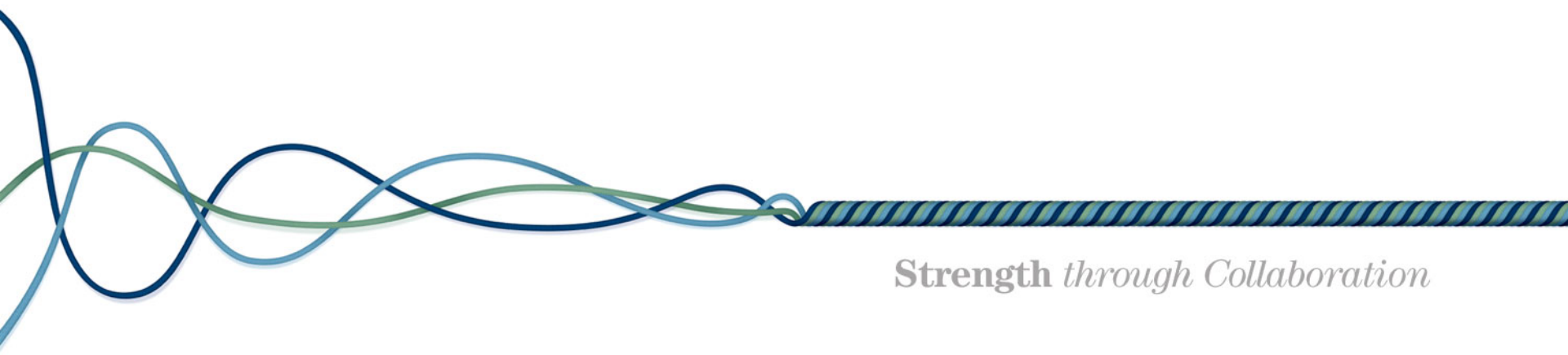
CDISC Public Webinar – Standards Updates and Additions

26 Mar 2015



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:

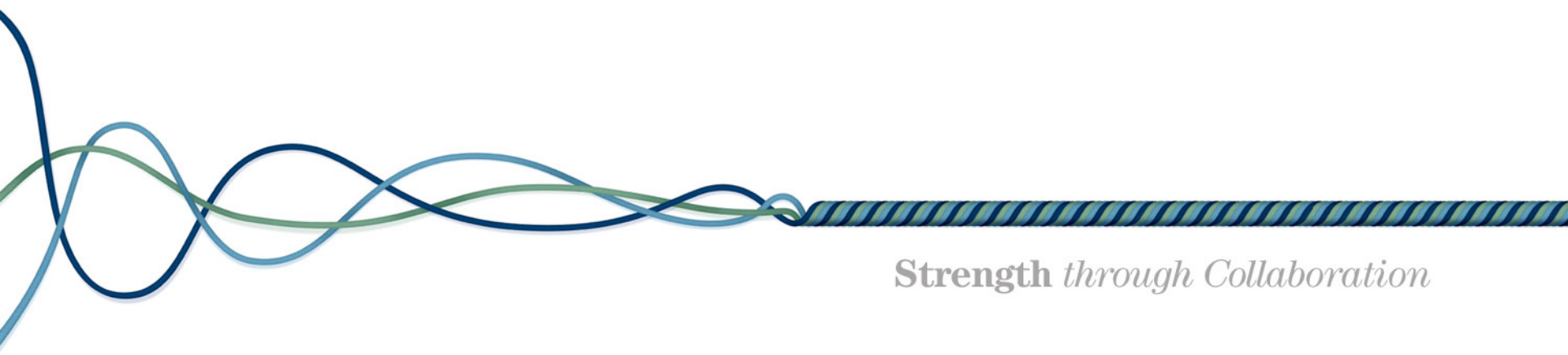
Bernice: When will Batch 21 be published?

OR

CDISC: When can we start registering for the Interchange?

CDISC CONTROLLED TERMINOLOGY

Presented by Bernice F. Yost



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=NTRGRESP) 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
~~EDLEVEL~~ EDUYRNUM	~~Education Level~~ Number of Years of Education	~~Years of education that a person has completed.~~ 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

CDISC Therapy Area Standards Using Device Domains

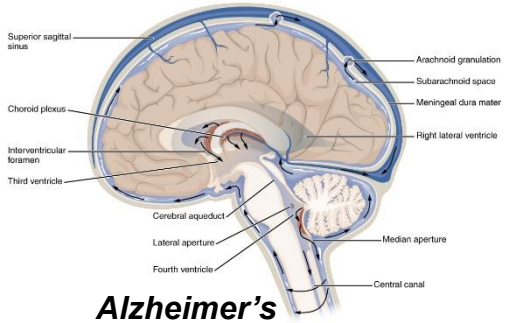
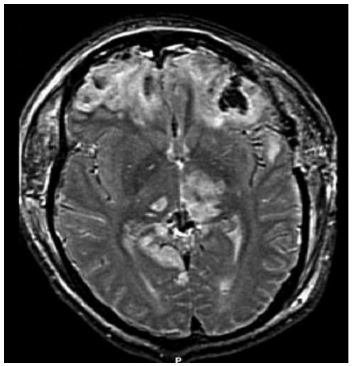
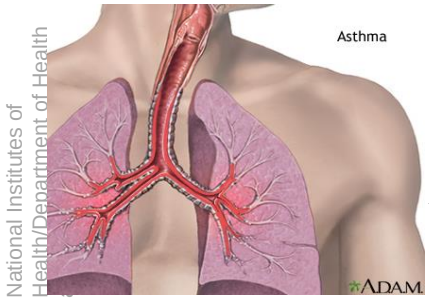


Image: CSF

Alzheimer's

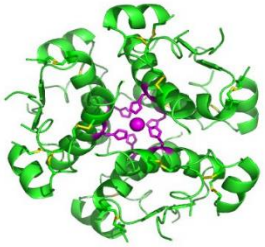


Traumatic Brain Injury

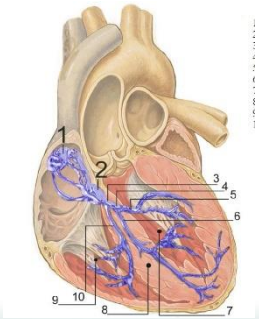


National Institutes of Health/Department of Health

Asthma

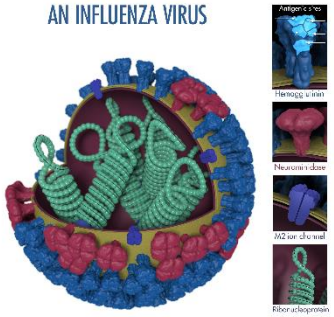


Diabetes



QT Cardiac

DO DU DE DX DR DI DT



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

Regulatory Context

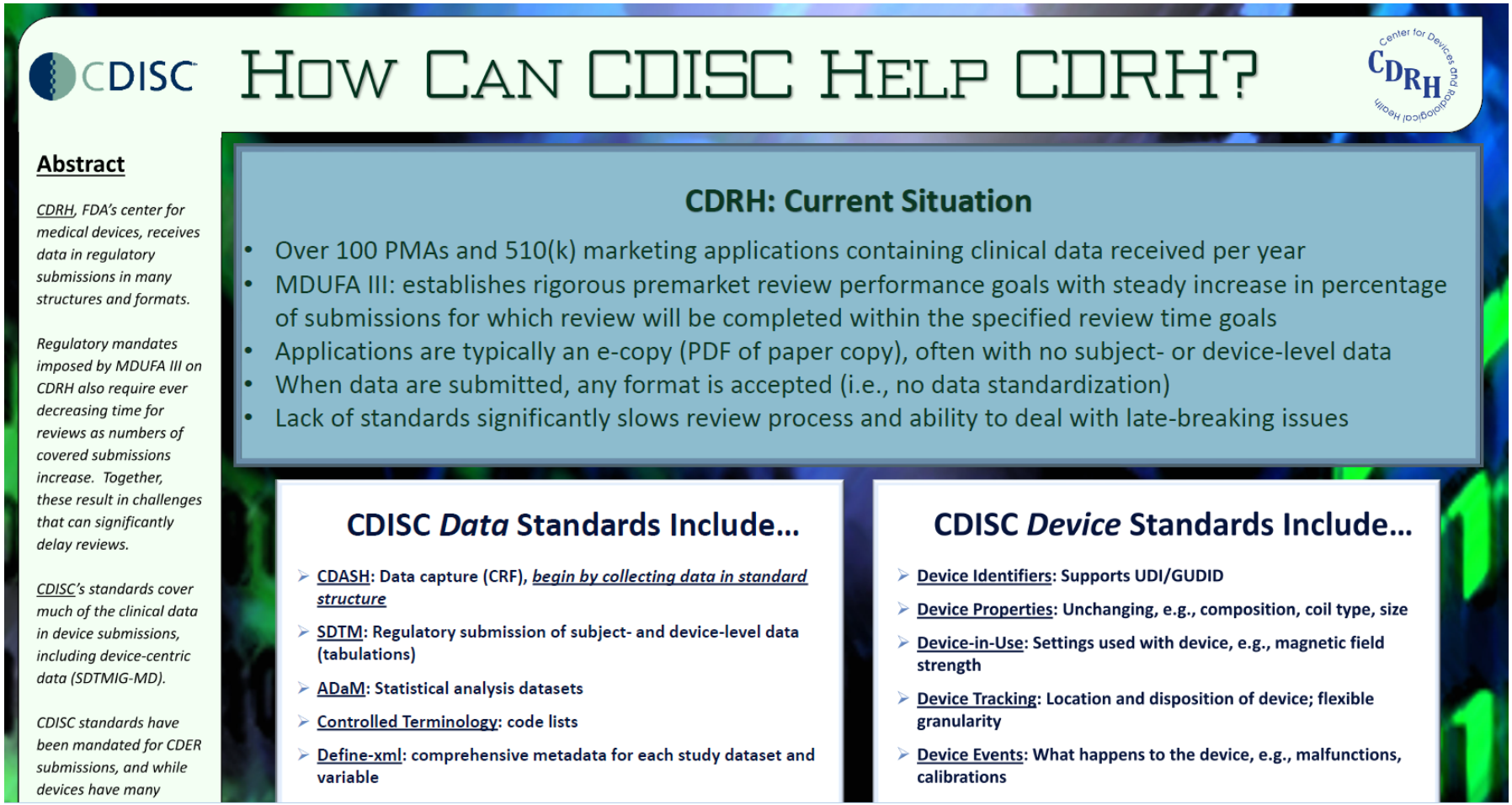
CDRH Senior management open to discussing CDISC standards implementation

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*

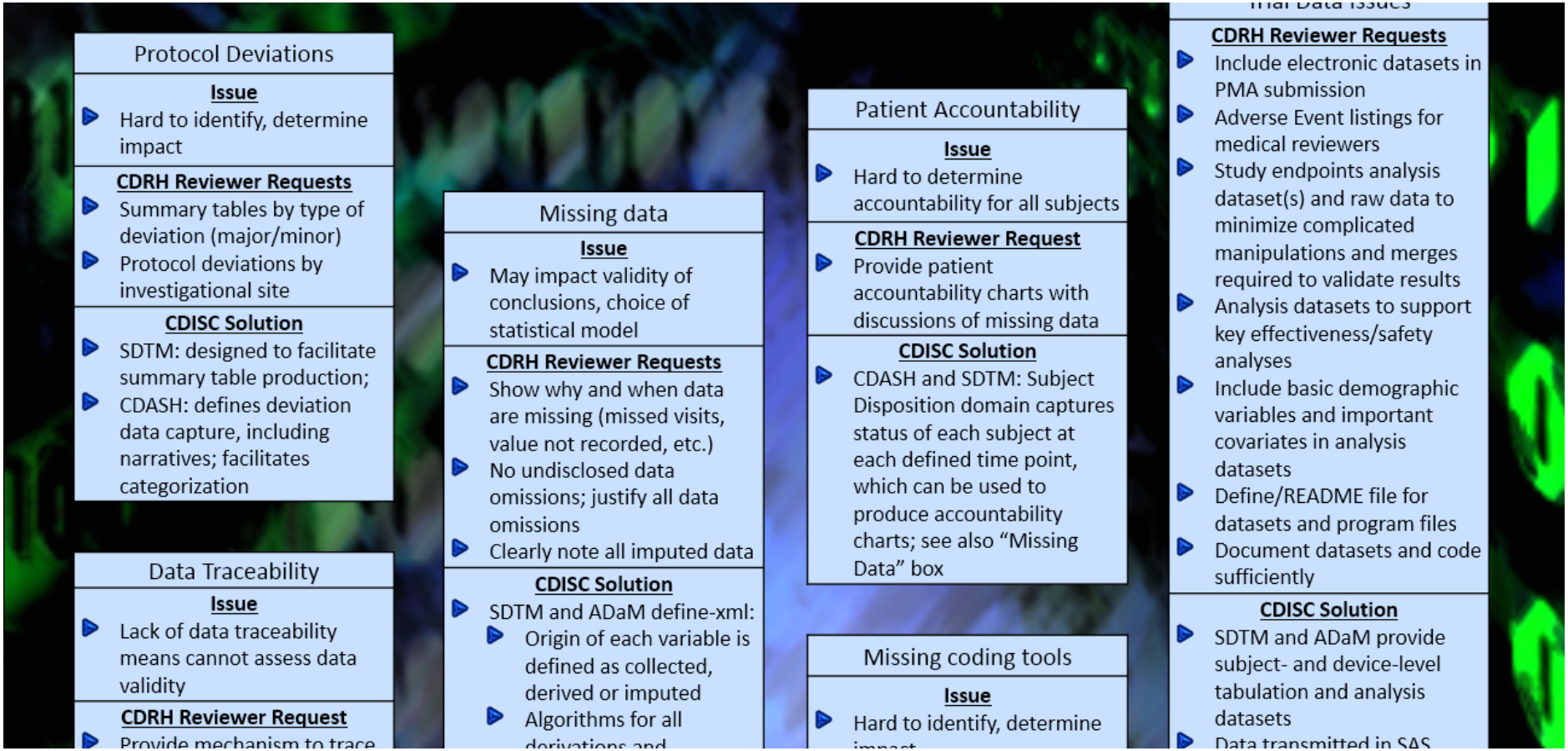
*may or may not end up in MDUFA IV

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



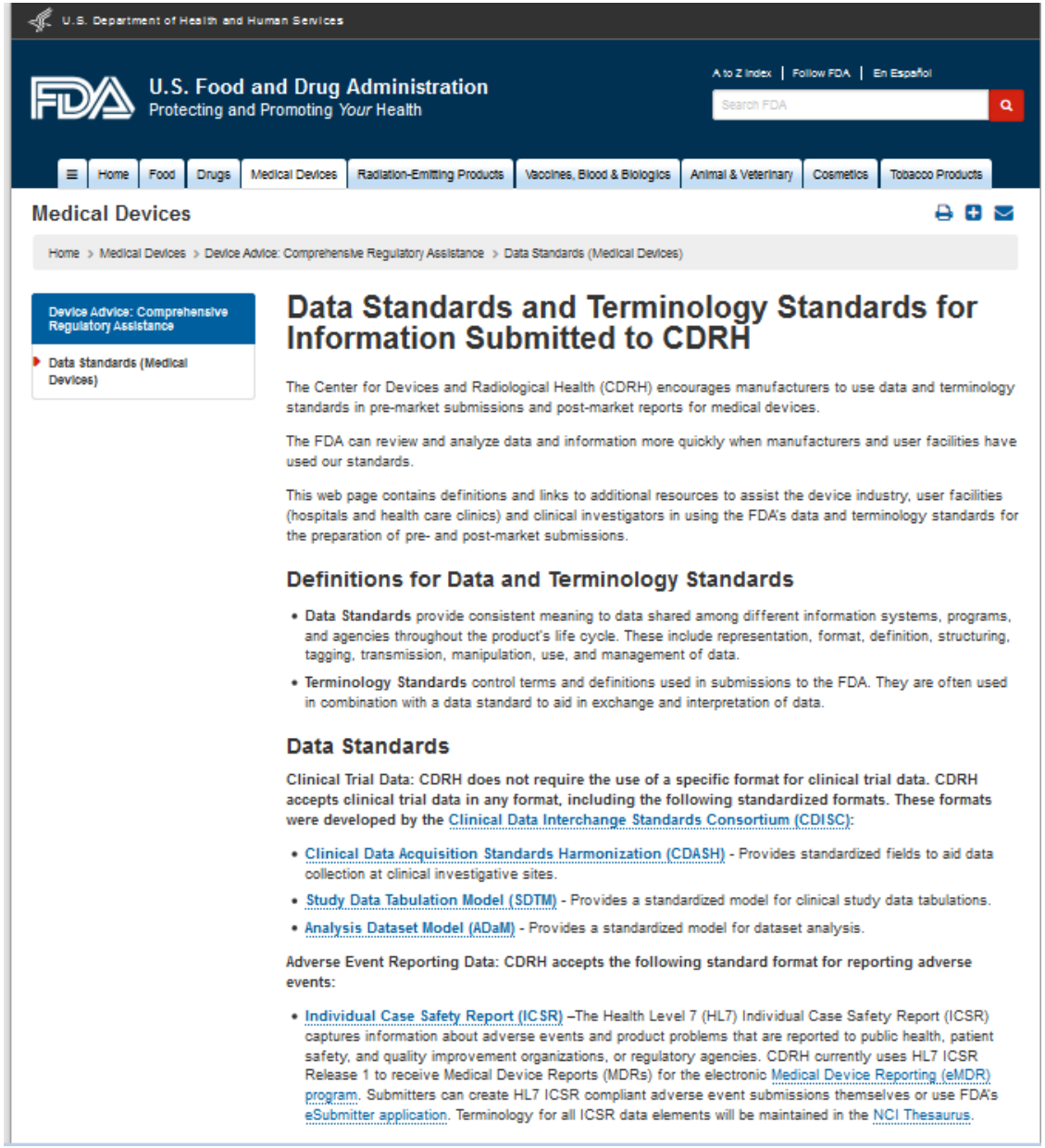
Based on a paper presented by Dr. Nair at the CDISC 2014 International Interchange. Available at http://www.phuse.eu/CSS-Presentations2015.aspx, Poster #16.

Some of the CDISC-facilitated solutions



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



U.S. Department of Health and Human Services

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

A to Z Index | Follow FDA | En Español

Search FDA

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.

CDRH originally an author

Guidance for Industry

Providing Regulatory Submissions in Electronic Format — Standardized Study Data

DRAFT GUIDANCE

This guidance document is being distributed for comment purposes only.

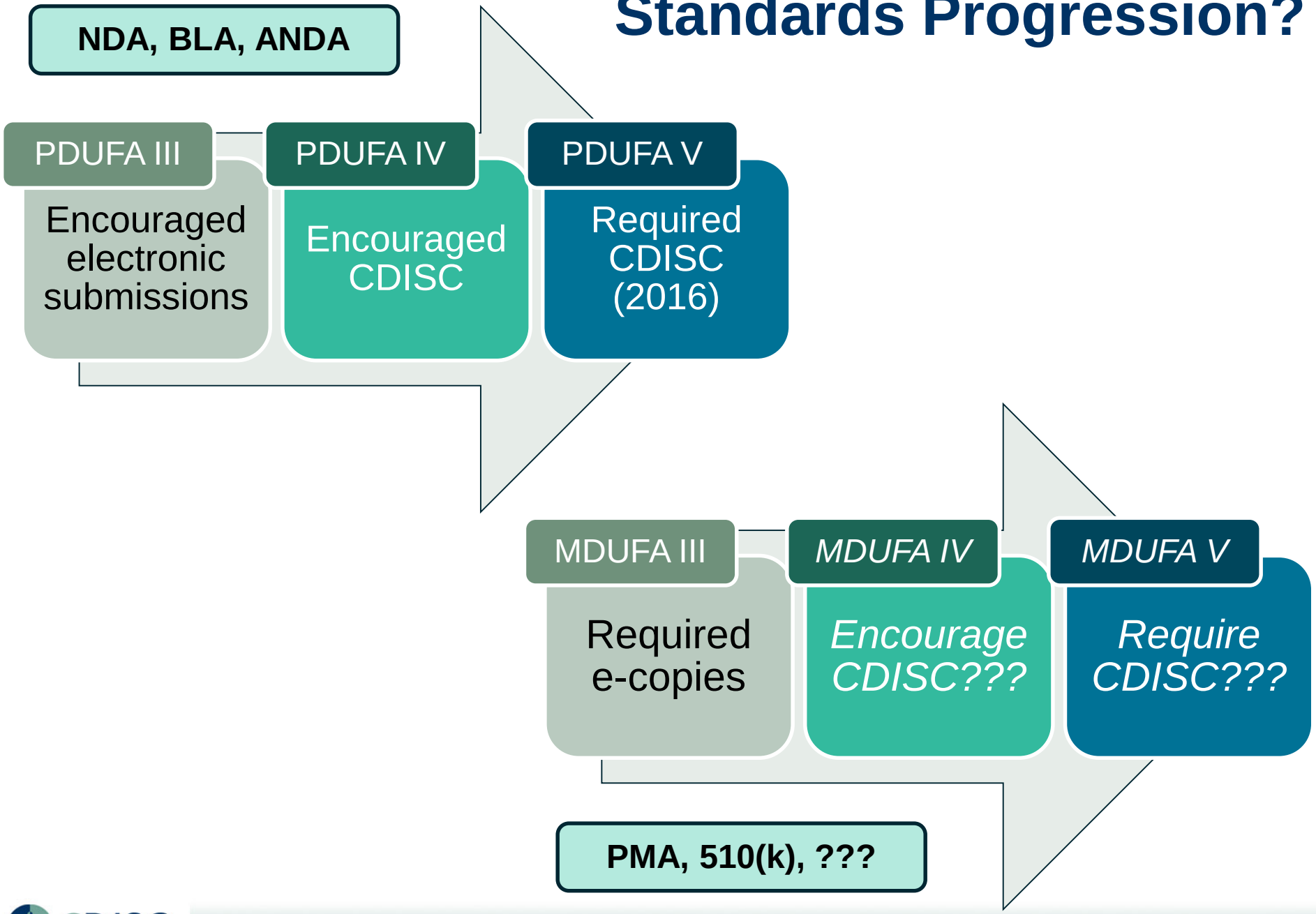
Comments and suggestions regarding this draft document should be submitted within 60 days of publication in the *Federal Register* of the notice announcing the availability of the draft guidance. Submit comments to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers 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.

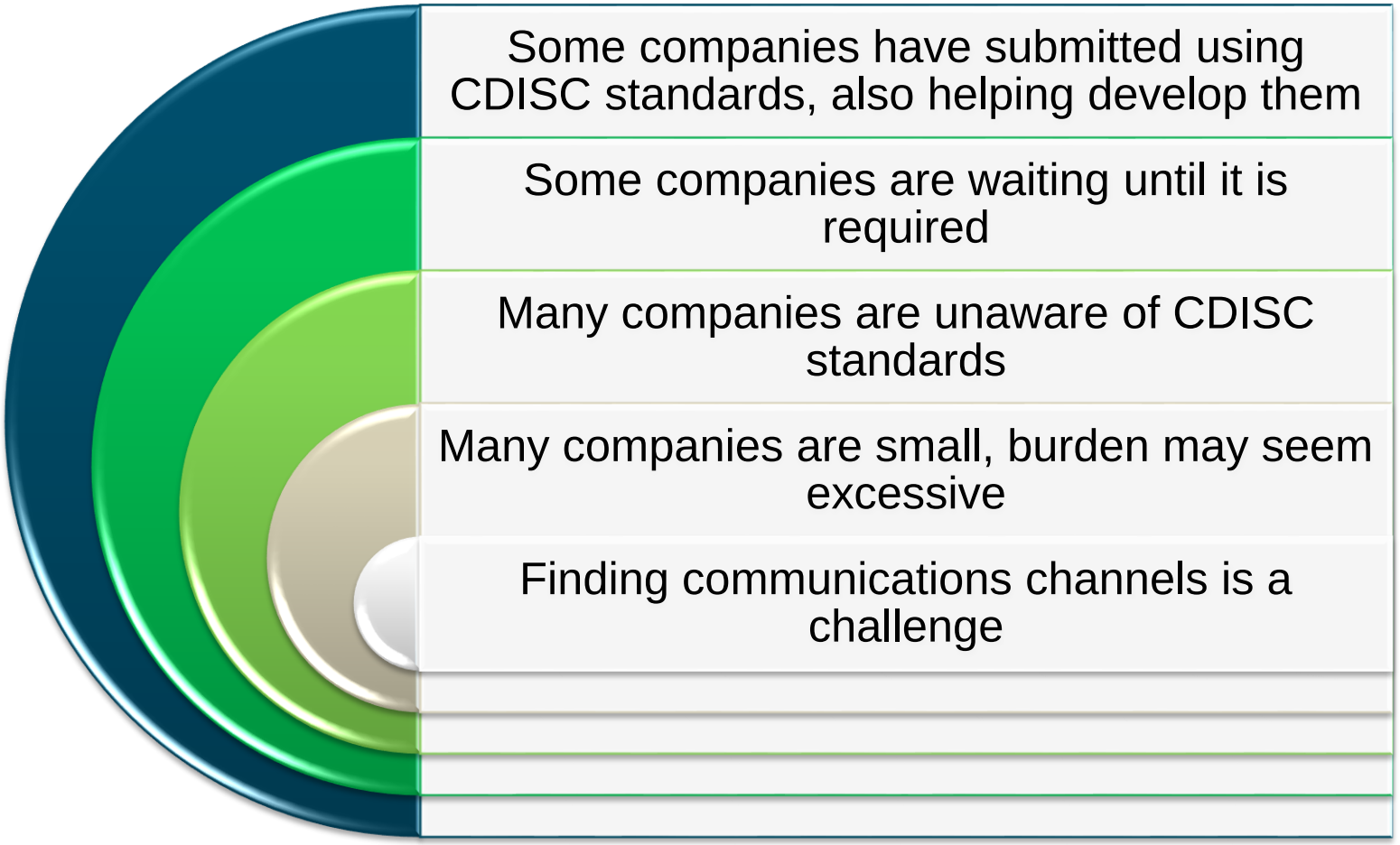
U.S. Department of Health and Human Services
Food and Drug Administration
Center for Drug Evaluation and Research (CDER)
Center for Biologics Evaluation and Research (CBER)
Center for Devices and Radiological Health (CDRH)

February 2012
Electronic Submissions

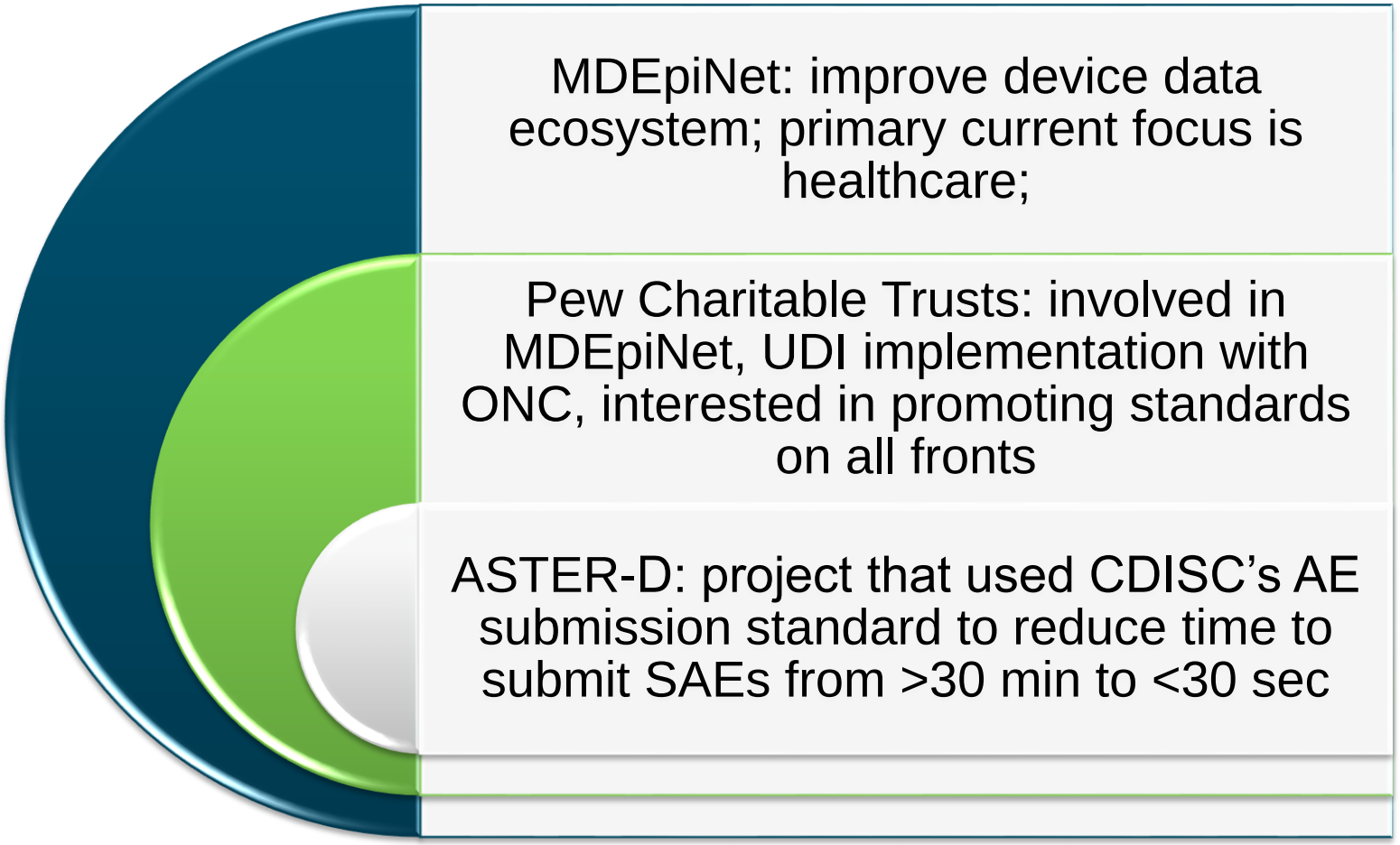
Standards Progression?



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

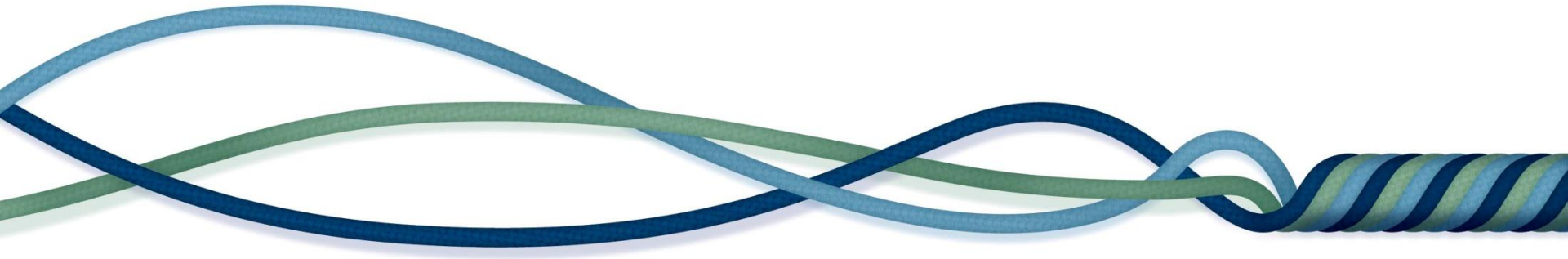
- CDASH, ADaM
- IVD
- Device/components and multiple devices/AE
- Integrated examples

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

Strength *through Collaboration*

Keeping Up with CDISC Standards

CDISC Home

CDISC Strength Through Collaboration

Search...

ABOUT | STANDARDS | CO

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

- Foundational
- Therapeutic Areas
- Healthcare Link
- Semantics
- SHARE
- Technical Plan Updat

What's New

Now Available: ADaM v1.3 Vali

Technical Plan Updates

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 progres
availability of our volunteers)

Technical Plan Project:

- **Technical Plan Project Sch**

Monthly Technical Updates:

- **March 2015 Technical Up**
- **February 2015 Technical**
- **January 2015 Technical U**

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.

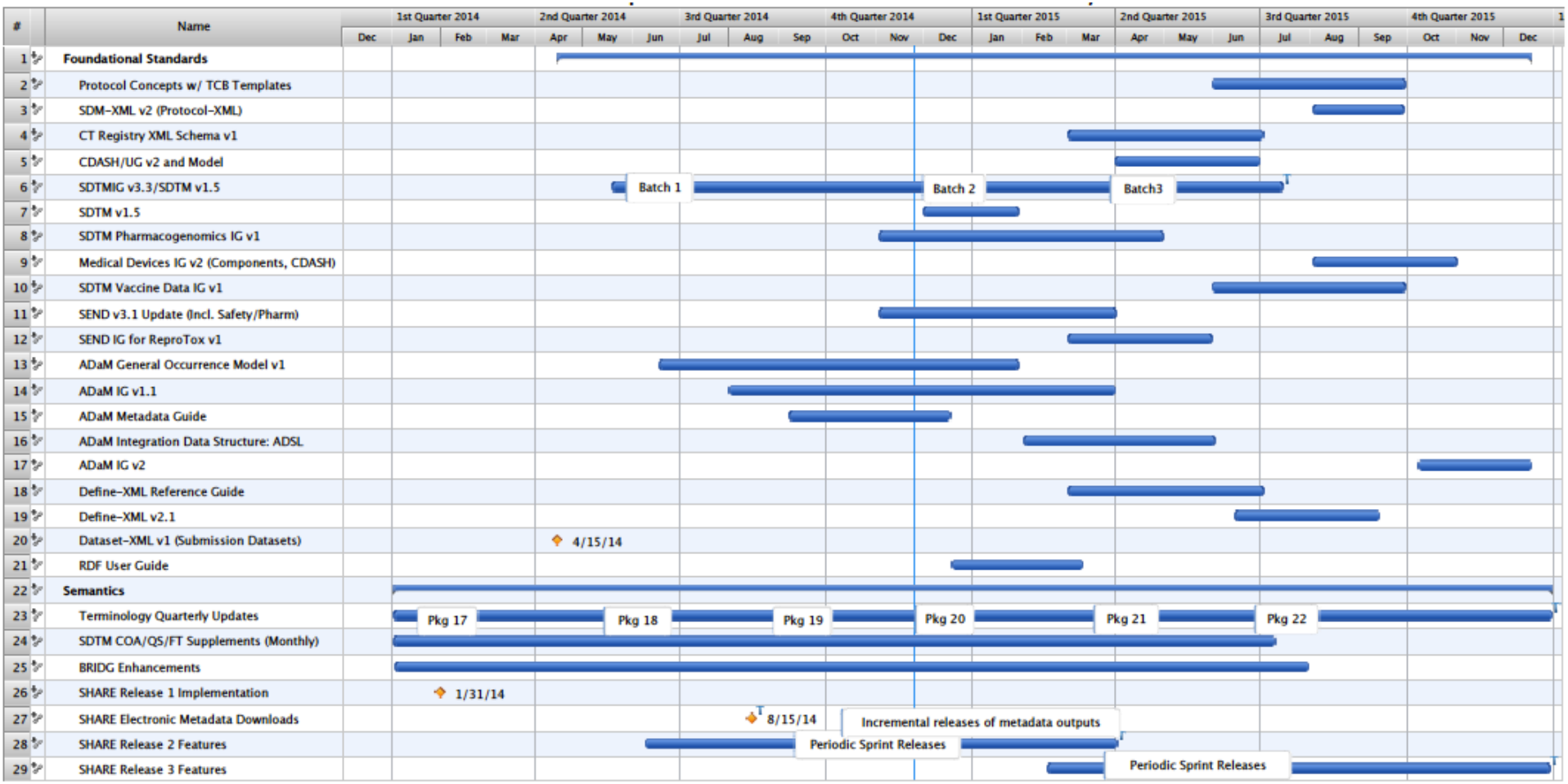
Foundational Standards:

- 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.

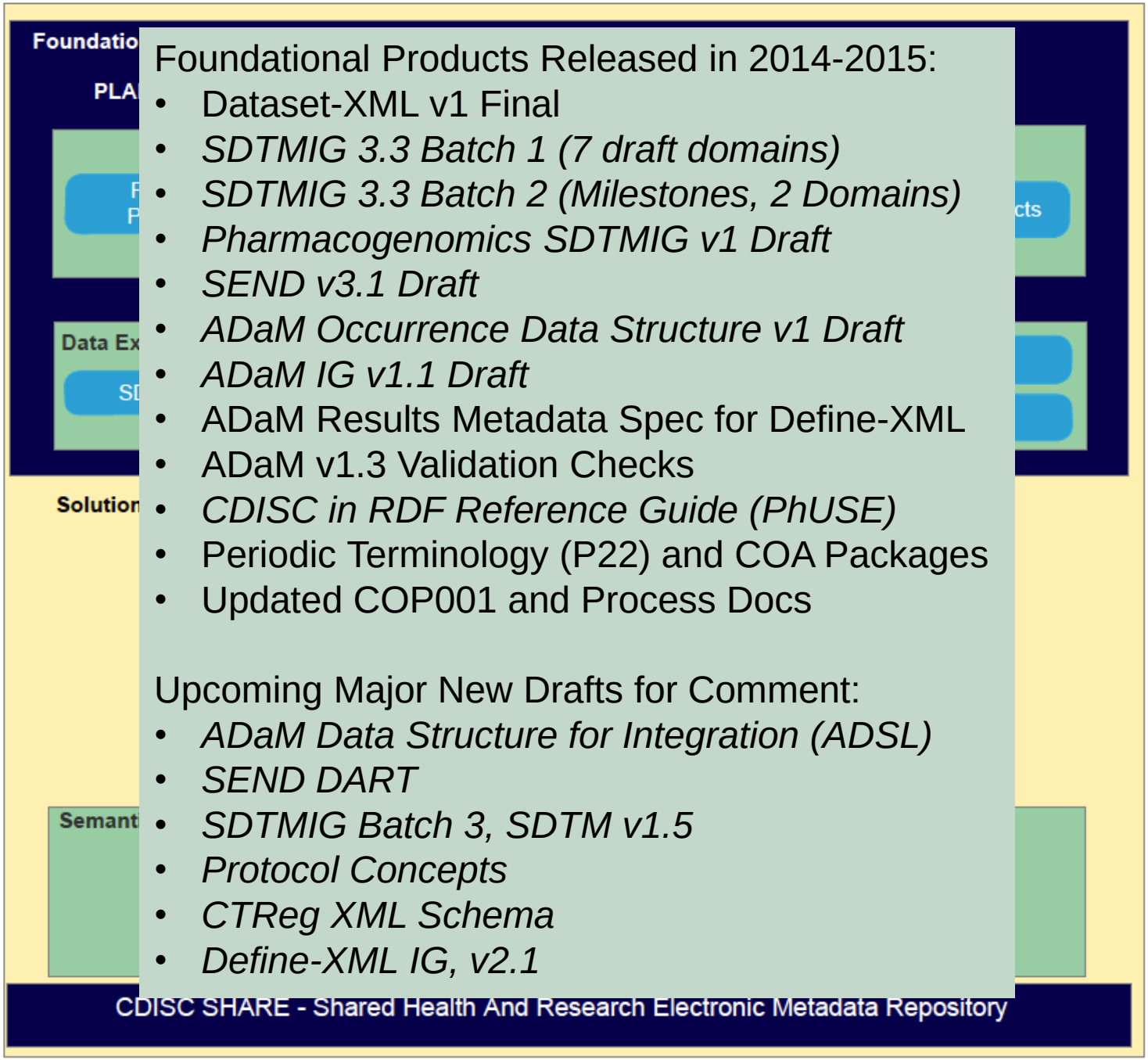
2014 CDISC Technical Plan



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 TransCelerate 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, PGx, Human Clinical Trials.		Draft	Q2
SDS	SDTMIG v3.3	New Intervention domains: Procedure Agents (AG) and Meal (ML) New Physiology Findings domains: Respiratory (RE) Nervous System (NV) Ophthalmology (OE), Urinary (UR), Cardiovascular (CV) Broadening TU, TR, and RS domains to handle non-tumor lesions Use of "Non-Standard Variables" in parent domains rather than as supplemental qualifiers Disease Milestones		Final	Q3

Progress Update – Foundational Standards



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

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*

Program Overview – March 2015
Approved Therapeutic Area Standards Projects

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	Fe							Submitted charter

TAUGs released in 2014-2015:

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

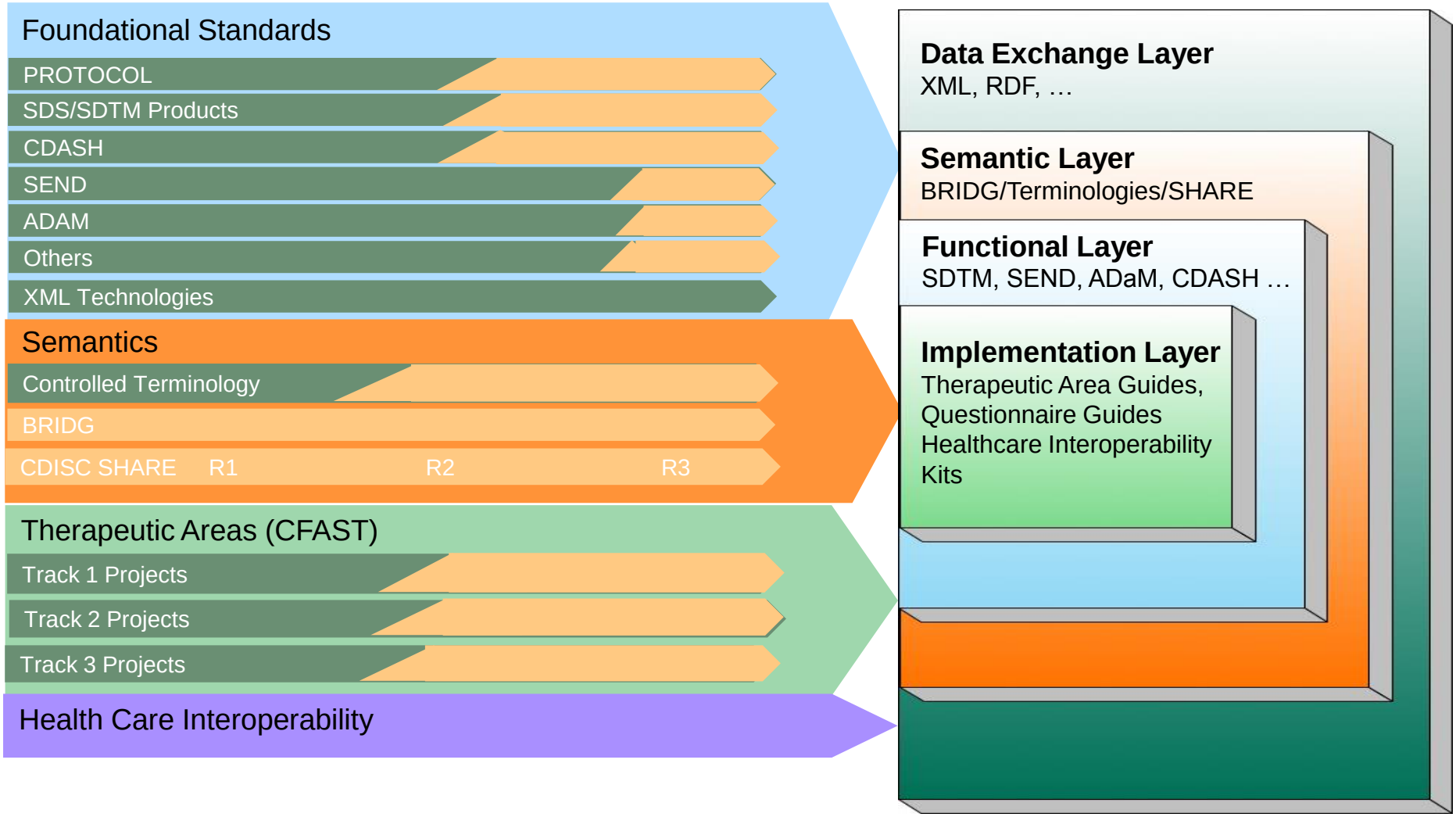
Upcoming:

- 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.

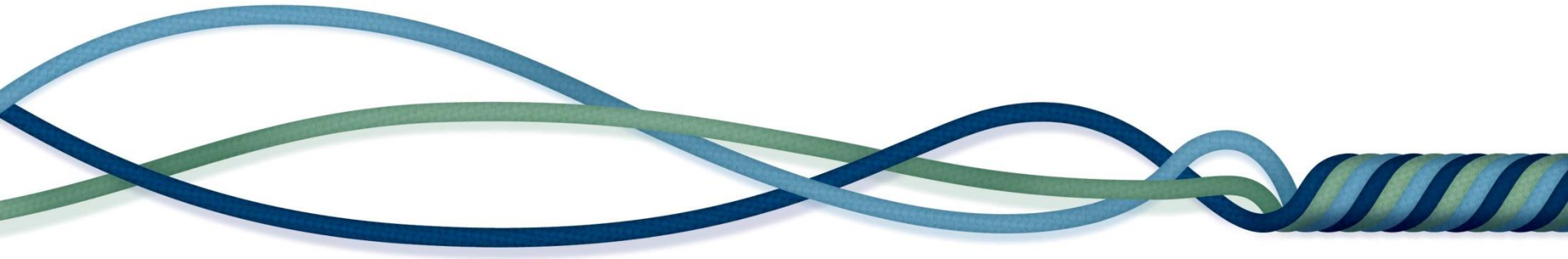
CDISC Technical Roadmap - 2014



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

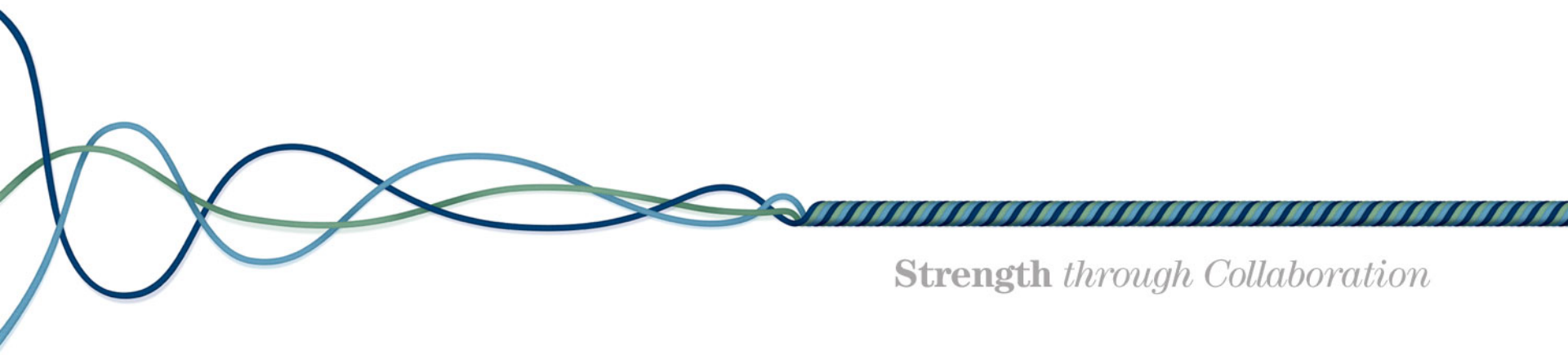


Strength *through collaboration.*

Question and Answer Session

CDISC Education & Events Announcements

John Ezzell, CDISC, Manager of Education Products



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	*Expired*	BIOCLINICA Global clinical trial solutions. Real-world results.
Minneapolis, MN	23-26 June 2015	SDTM for Med. Devices, CDASH, CT	23 May 2015	*Expired*	MedNet Solutions
Durham, NC	27-31 July 2015	SDTM, ADaM		31 Mar 2015	Duke Clinical Research Institute, Duke University Medical Center
Gaithersburg, MD	1-4 Sep 2015	SDTM, CDASH, ADaM		24 April 2015	MedImmune
International Interchange, Chicago, IL	9-13 Nov 2015	TBD			CDISC

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	CDISC
Eschborn (Frankfurt), Germany	28-31 Jul 2015	SDTM, CDASH, ADaM	14 June 2015	28 Feb 2015	ACCOVION
Brussels, Belgium	7-10 Sep 2015	SDTM, CDASH, ADaM		31 Mar 2015	Business & Decision Life Sciences

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	PPD
Shanghai, China	18-21 May 2015	SDTM, CDASH, ODM, Dataset-XML, Define-XML, ADaM	24 Apr 2015	13 Mar 2015	gsk GlaxoSmithKline 葛兰素史克
Japan Interchange	22-26 Jun 2015	SDTM, CDASH, ODM, Dataset-XML, Define-XML, ADaM	*Registration to open soon*		CDISC

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*

- 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 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

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