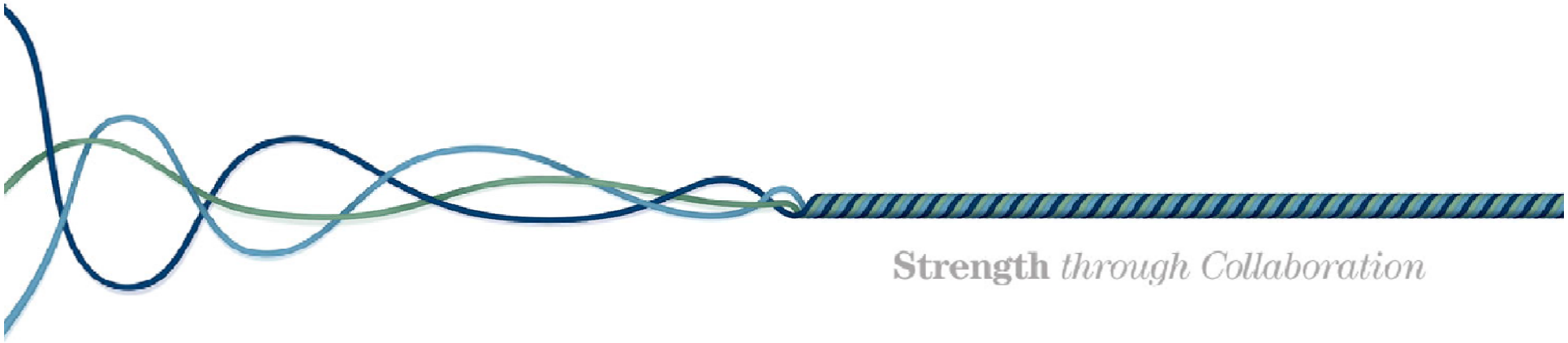
CDISC Selected Topics and Update from the E3C

Mark Lambrecht, E3C member

Director, SAS Health and Life Sciences Global Practice



What is CDISC?

Clinical Data Interchange Standards Consortium

- Founded in 1997 (all volunteers); incorporated in 2000 as a non-profit charitable organization
- Today ~ 400 member organizations of all types
- **Global Standards Development Organization (SDO) developing global consensus-based standards focusing on Clinical Research**
- Collaborate with other SDOs (e.g. ISO, HL7, IHE)
- **2016: Required by U.S. FDA and Japan's PMDA**
- CDISC Standards
  - Enable innovation
  - Support all types of research from protocol through analysis and reporting
  - Significantly streamline research processes and enable data sharing/aggregation
  - Include links to healthcare through EHRs/eSource

CDISC Develops Global Standards

CFAST & Therapeutic Area Partnerships

CDISC collaborates with many organizations to develop Therapeutic Area (TA) standards for multiple disease areas through the Coalition for Accelerating Standards and Therapies (CFAST) initiative, as well as other partnerships.

Regulatory Collaborations

CDISC works closely with regulators around the world to ensure that CDISC standards will 1) streamline research from protocol/study design and trial registration through analysis and reporting; 2) facilitate the eSubmission review process; 3) ensure that clinical research is high quality; and 4) support the approvals of safe and efficacious medicines for patients.

Regulators also contribute to TA standards development

Individual collaborations also part of JIC

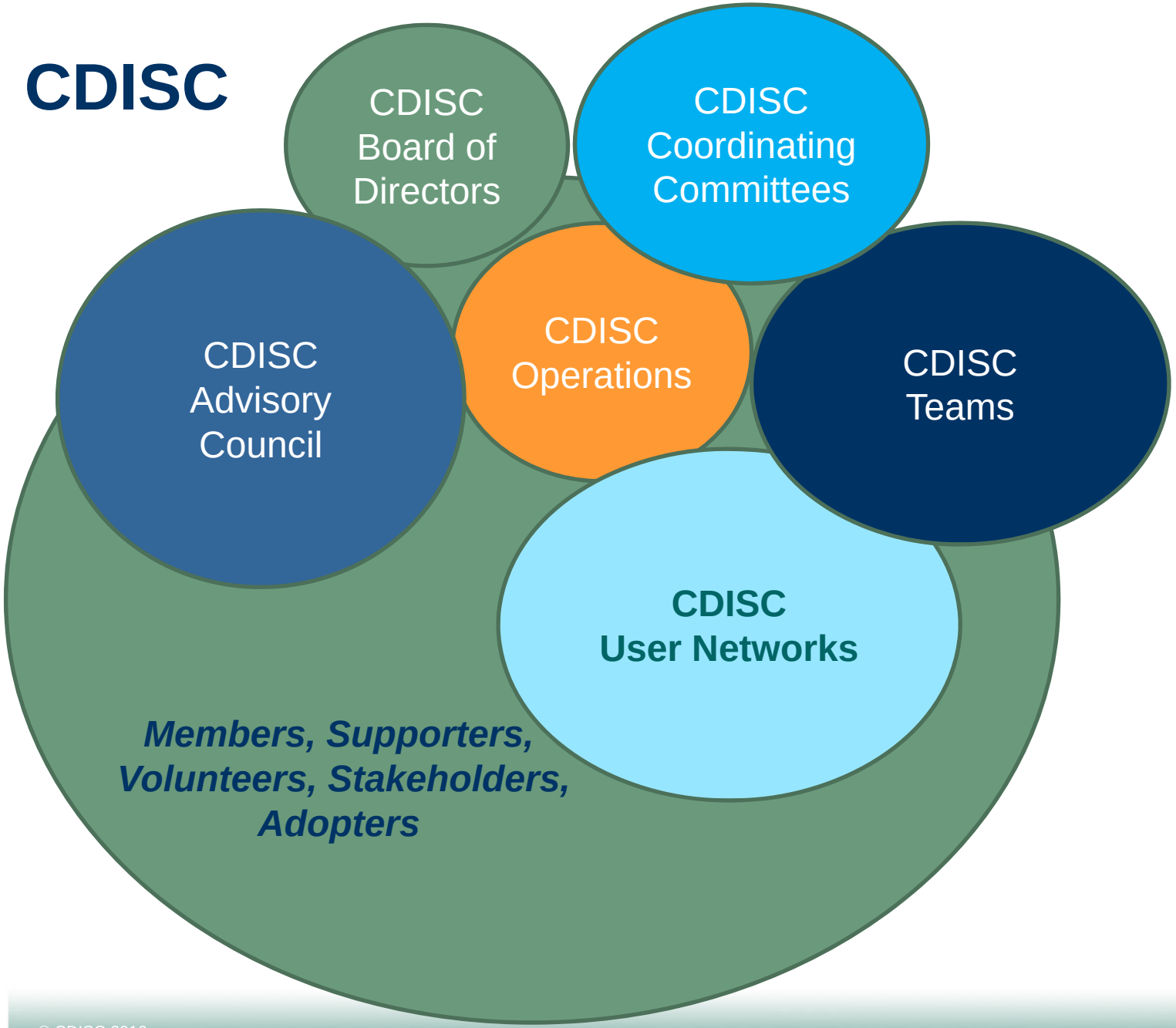
Joint Initiative Council (JIC)

Standards Development Organizations (SDO) Collaborations

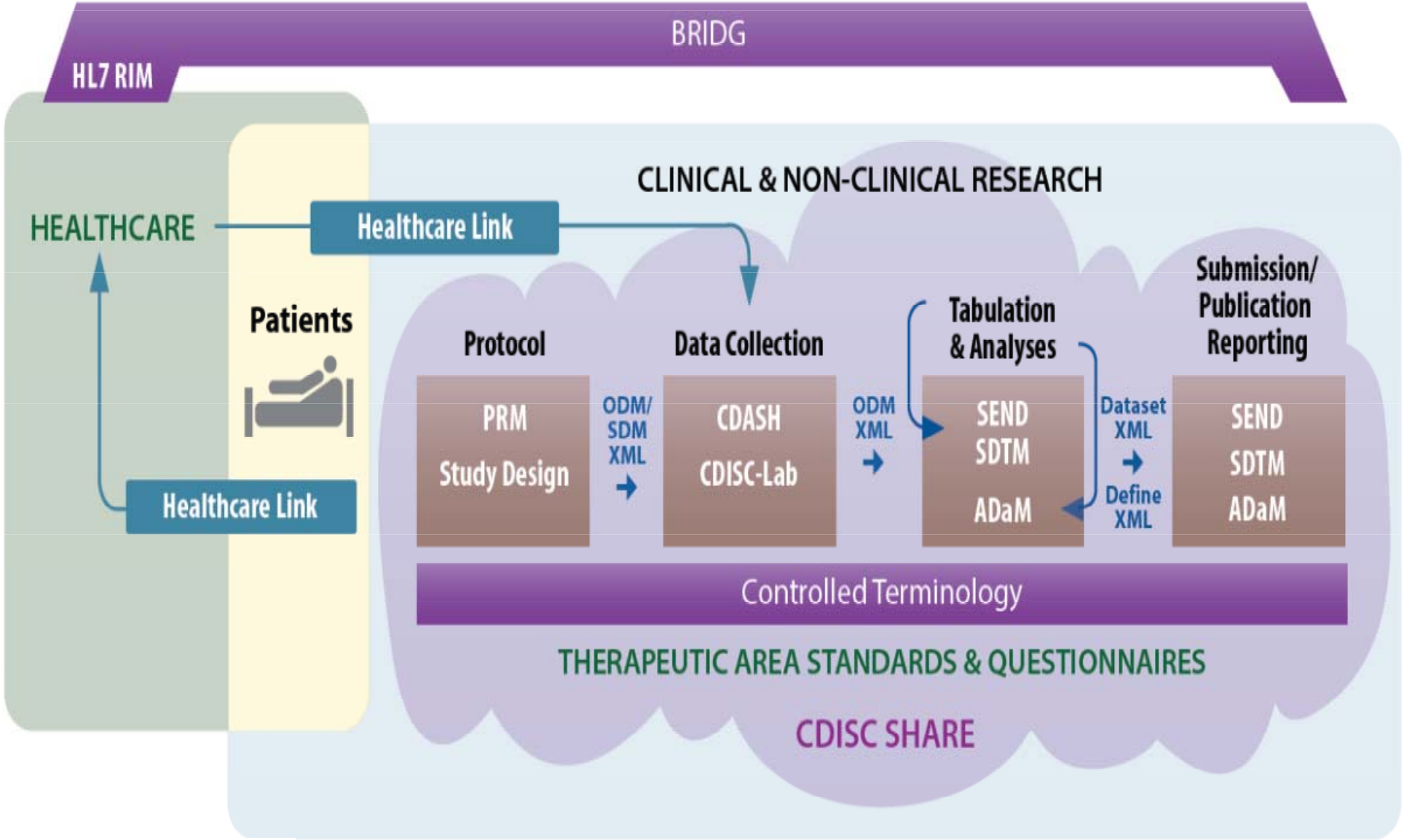
CDISC collaborates with other SDOs to develop standards that are synergistic to support a learning health system based upon high quality research.

CDISC and PhUSE partner to further the mission of each organization collectively, with CDISC focusing on the development of global, platform-independent data standards, and PhUSE focusing on the implementation and use of the CDISC standards. The two organizations work to combine efforts on key initiatives around end-to-end standards, TA standards, and semantics, strengthening an interdependent process.

CDISC



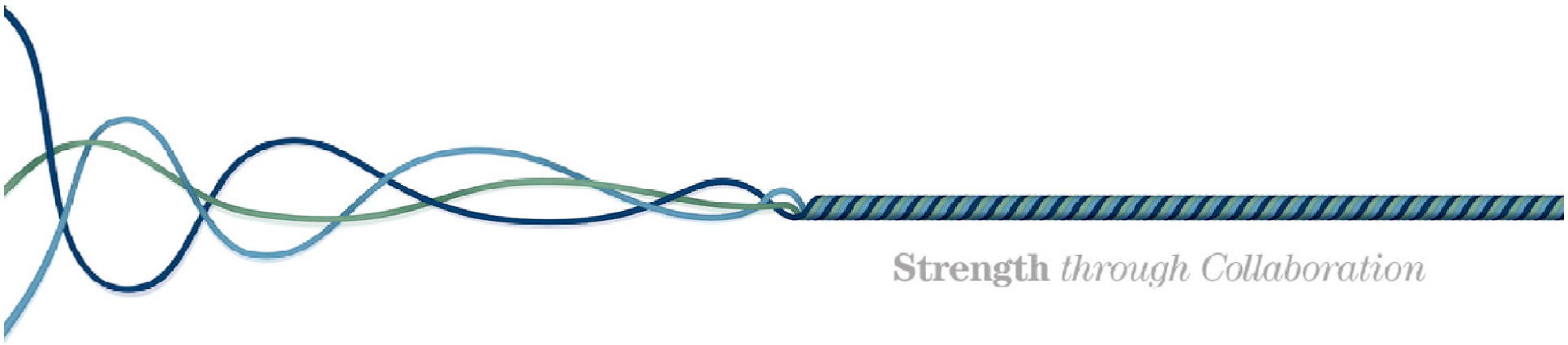
Achieving Interoperability



CDISC

Foundational Standards | Data Exchange | Semantics

European CDISC Coordinating Committee: The 17th Year!



Current E3C Members

- **Chair**
  - Peter van Reusel, Innovion, Belgium
- **Vice-Chair**
  - Jörg Dillert, Oracle, Germany
- **Full Members**
  - Andrea Rauch, Boehringer-Ingelheim, Germany
  - Mark Lambrecht, SAS, Belgium
  - Sofia Inari Castella, Novo Nordisk, Denmark
  - Angelo Tinazzi, Cytel, Switzerland
  - Jozef Aerts, Univ.Appl.Sci. FH Joanneum
  - Stéphane Auger, Danone, France
- **CDISC E3C Liaison**
  - Bron Kisler, CDISC, US
  - Paul Houston, CDISC, UK
- **CDISC Board Member**
  - Stephen Pyke, GSK, UK
- **CDISC funded Support**
  - Diana Harakeh, CDISC
  - Dominik Ruisinger, EuroInterchange Organization & Meetings logistics

E3C Charter

- Purpose
  - Yearly action plan, aligned with CDISC Strategic Goals
  - Organize & Promote CDISC Interchanges for Europe
  - Liaise with regulatory authorities on behalf of CDISC
  - Assess regional CDISC training needs
  - Assist in the creation & coordination of European User Networks
  - Communicate activities
- Composed of volunteers
  - Sponsors
  - CRO
  - Vendors
  - Academia
  - …
- Election process

Annual Meetings

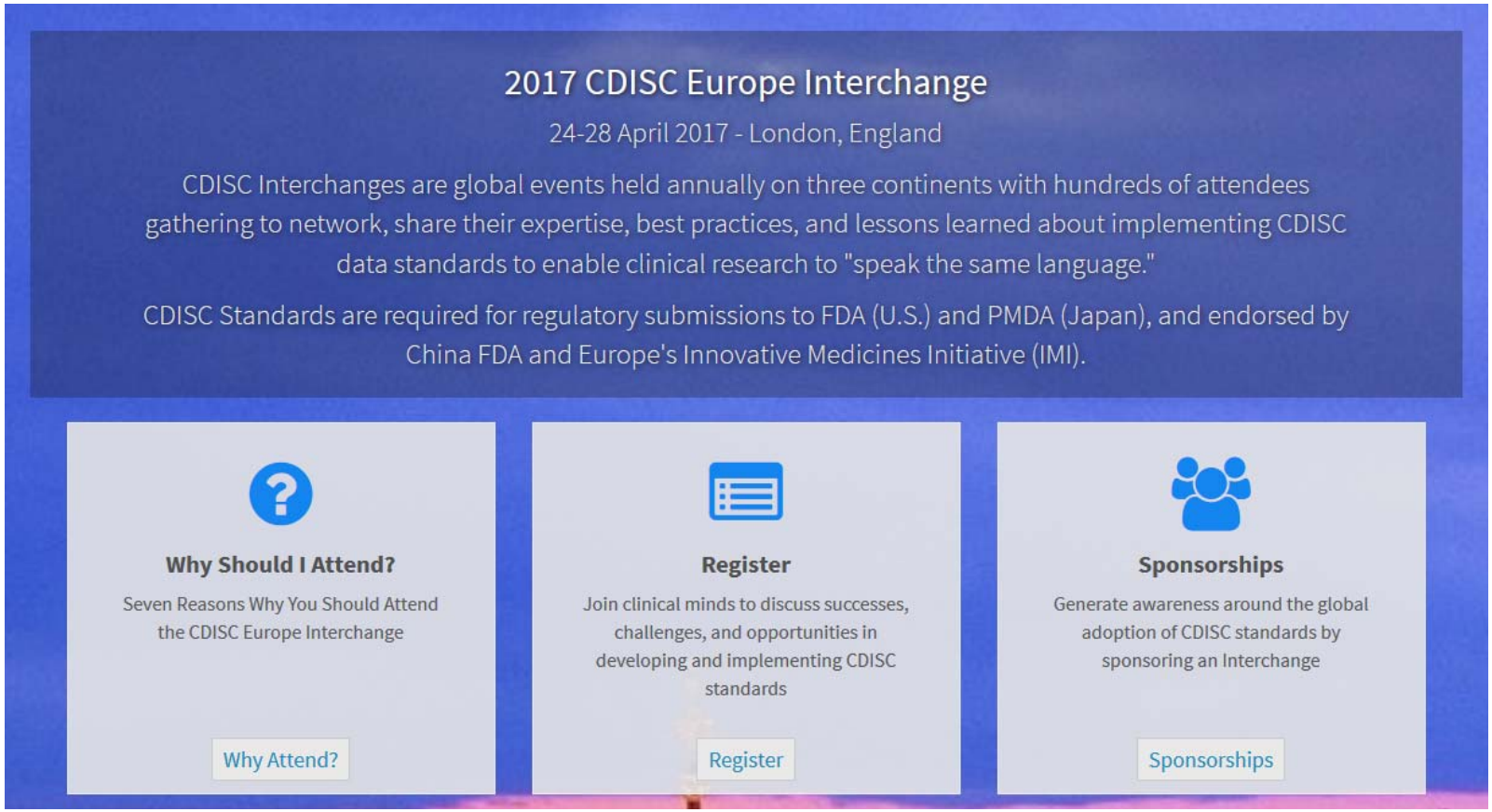
Workshops ★

- Frankfurt 2002
- Dublin 2003

Interchanges ★

- Brussels 2004
- Paris 2005
- Berlin 2006
- Montreux 2007
- Copenhagen 2008
- Budapest 2009
- London 2010
- Brussels 2011
- Stockholm 2012
- Frankfurt 2013
- Paris, 2014
- Basel, 2015
- Vienna, 2016

https://www.cdisc.org/events/interchanges/2017-europe-interchange



HOME / EVENTS / INTERCHANGE / 2017 EUROPE INTERCHANGE / 2017 EUROPE INTERCHANGE

2017 Europe Interchange

Program subject to change without notice.

Wednesday, April 26, 2017

Session 1: Opening Plenary

Peter Van Reusel, CDISC E3C Chair

09:00 - 11:00

- Welcome Address
  Peter Van Reusel, CDISC E3C Chair
- Opening Keynote Address: Raising the Standard for Global Collaboration in Emerging Infection
  Dr. Laura Merson, Oxford University Clinical Research Unit
- State of CDISC Union
  Dr. Rebecca Kush, CDISC
- Future of CDISC
  Dr. Nicole Harmon, CDISC
- The State of CDISC Standards
  Barrie Nelson, CDISC

Innovative Medicines Initiative

- Public-private initiative
  - European Union (EU)
  - European Federation of Pharmaceutical Industry and Associations (EFPIA)
- Supports collaborative research projects to boost pharmaceutical innovations
- 2 Billion € budget
- Memorandum of understanding with CDISC
  - CDISC and IMI have similar visions and goals
  - MOU establishes collaboration framework
  - IMI defaults the use of CDISC standards on all IMI research projects !

Innovative Medicine Initiative (IMI)

EHR4CR

Electronic Health Records for Clinical Research

HOME CONSORTIUM WORKPLAN

Website under construction

HOME

The EHR4CR (Electronic Health Records for Clinical Research) project aims to design and demonstrate a scalable and cost-effective approach to interoperability between Electronic Health Record systems (EHRs) and Clinical Research through multiple but unified initiatives across different therapeutic areas, with varying local and national stakeholders and across several countries under various legal frameworks. This unified approach will be made possible by both an EHR4CR business model and an EHR4CR platform.

Working closely with the EFPIA partners, the consortium will confirm priority clinical trials scenarios, such as patient recruitment, to be addressed and the requirements for these scenarios. The present gap between EHR systems and clinical research systems to deliver these scenarios will be analysed, which will direct the business model and the platform design.

The EHR4CR platform will:

- enable trial eligibility and recruitment criteria to be expressed in ways that permit searching for relevant patients across distributed EHR systems, and initiate participation requests confidentially via the patients' authorized clinicians;
- support the feasibility, exploration, design and execution of clinical studies and long-term surveillance of populations;
- provide harmonised access to multiple heterogeneous and distributed clinical (EHR) systems and

SUPPORTED BY

The EHR4CR project is funded by the IMI Programme.

imi

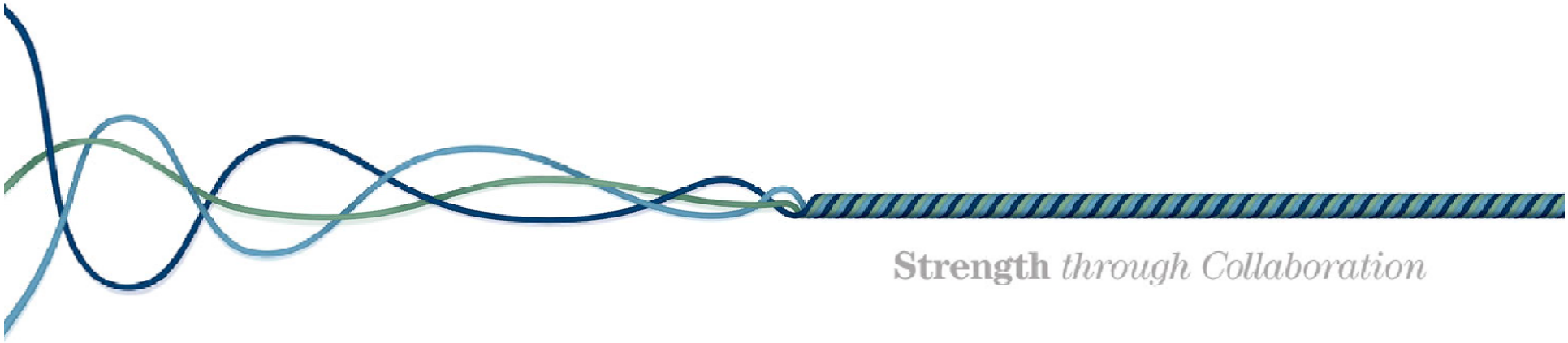
The Innovative Medicines Initiative (IMI) is a unique public-private partnership designed by the European Commission and European Federation of Pharmaceutical Industries and Associations (EFPIA). It is a pan-European collaboration that brings together large biopharmaceutical companies, small- and medium-sized enterprises (SMEs), patient organisations, academia, hospitals and public authorities. The initaive aims to accelerate the discovery and

EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

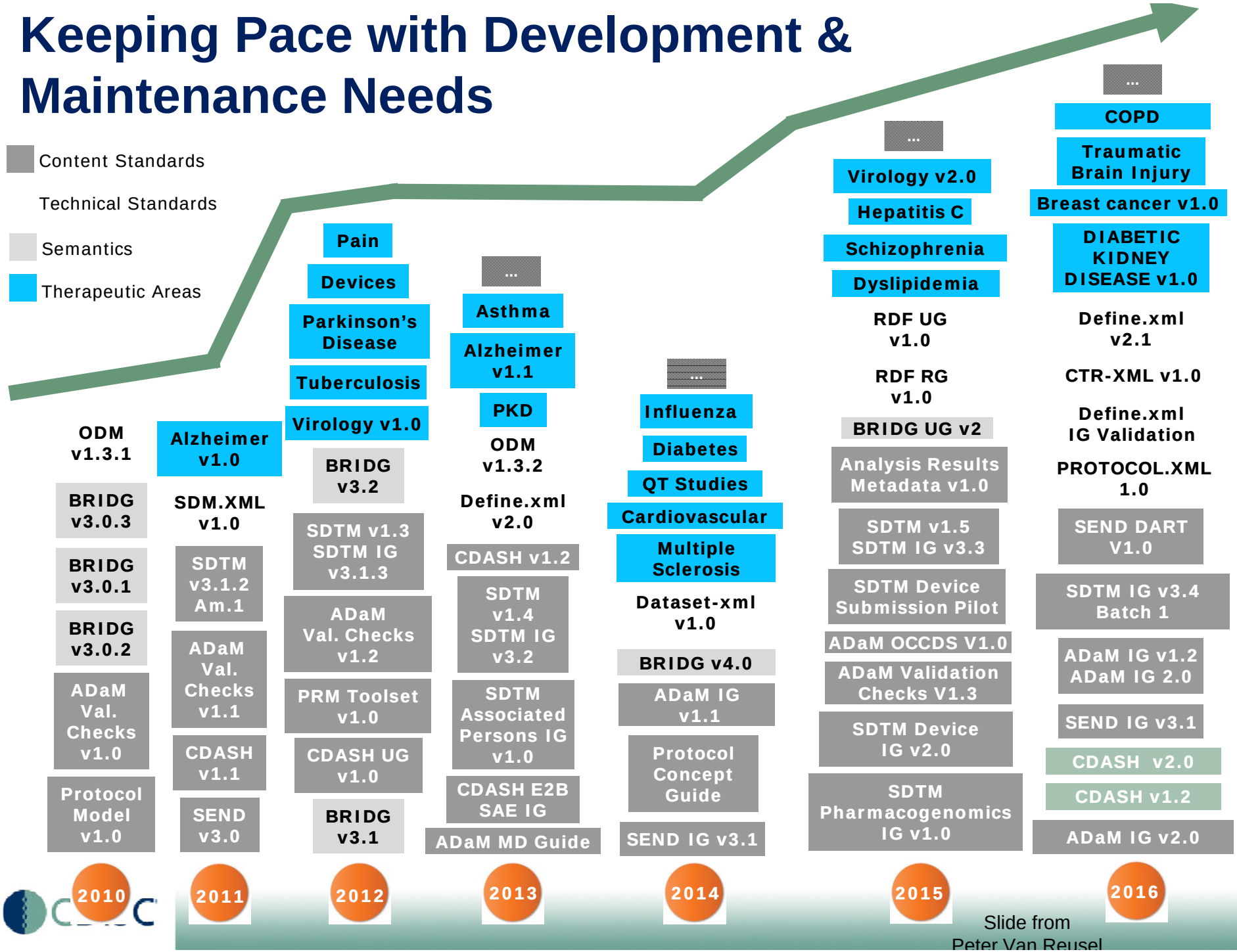
- Project Scope
  - Clinical reports & data from all clinical studies in Europe

- Timelines
  - Jan 2013 – Apr 2013 : Advisory Groups
    - Patient Confidentiality
    - Clinical Data Formats
    - Rules of engagement
    - Good Analysis Practice
    - Legal Aspects
  - June 2013 : Draft Agency Policy
  - Nov 2013 : Final Agency Policy
  - Jan 2014 : Policy comes into force

Future of CDISC Standards: Technical Roadmap



Keeping Pace with Development & Maintenance Needs



Slide from Peter Van Reusel

Foundational CDISC Standards
Focus on Governance, Controlled Terminology Process, Version Control and Validation Rules

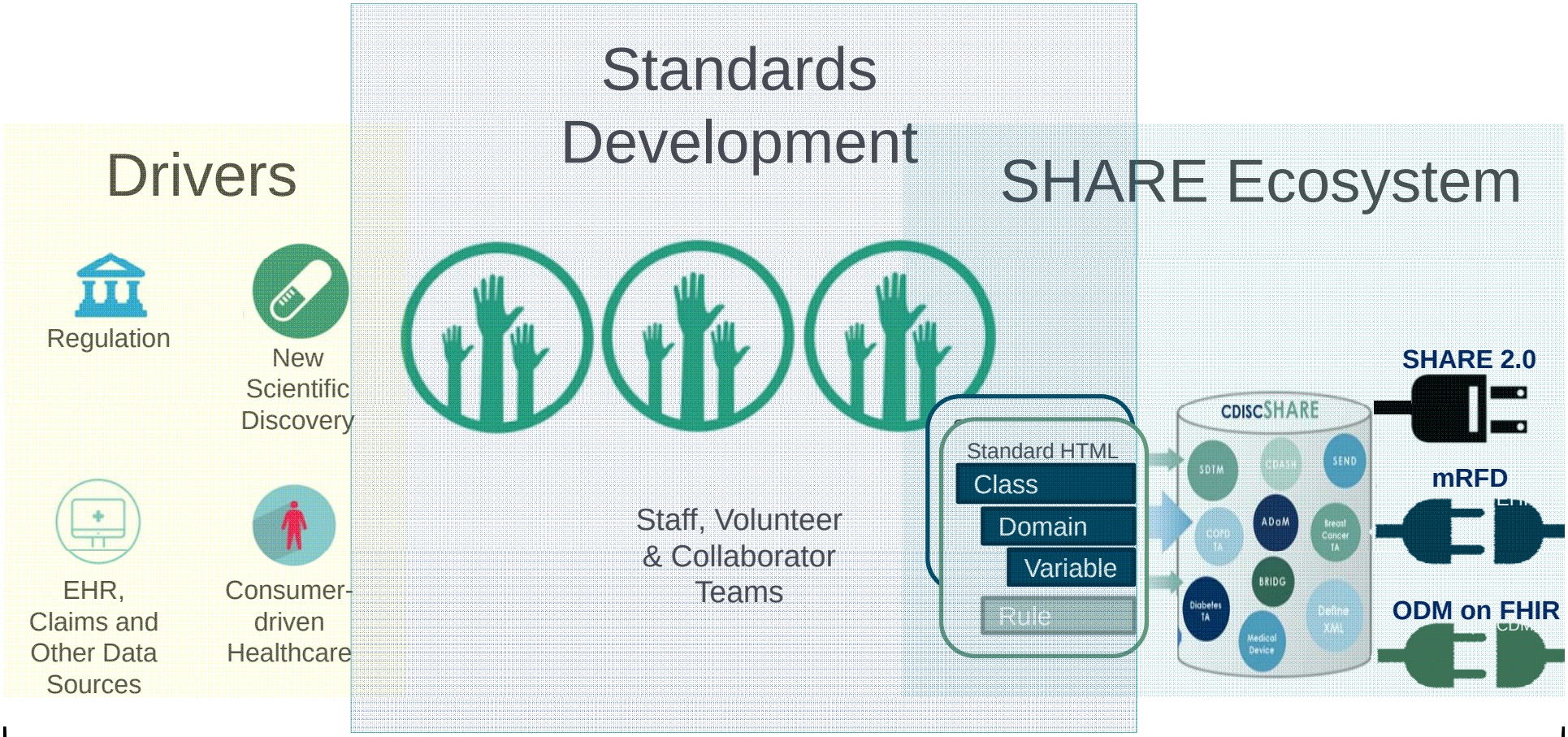
Coalition For Accelerating Standards and Therapies (CFAST)
Continue to develop Therapeutic Area (TA) Standards to support Beginning to End Automation with SHARE-generated TA Standards

Adoption
Education, Survey and Implementation Calls, SHARE Roll-out, IntraChanges, Interchanges, CFAST TA Standards Workshops, New Messaging & Publications

Healthcare Link
Launch eSource Stakeholders Group and projects to provide direct links between healthcare and research

Shared Health and Research Electronic Library (SHARE)
Support "Beginning to End" Automation and use of Standards in Therapeutic Areas, Support Healthcare Link and eSource Projects, ***Demonstrate and Publish on Value of SHARE***

Compatible data standards to enable automation and streamlining of the entire research process to dramatically reduce costs and speed the development of therapies for patients



Foundational Standards-Based Therapeutic Area Extensions

Cross-cutting Topic Guides for Solutions across Standards

Automation of Trial Registration & eSubmissions

Standardized EHR & PRO Research

Beginning-to-End Therapeutic Area Extensions (CDASH, SDTM, ADaM, CT)

CDISC

CDISC Strategic Goals 2015-2017

#1 Promote and support the continued global adoption of harmonized data standards throughout the clinical research lifecycle by engaging regulatory agencies, research sponsors, academia and other stakeholders through education, advocacy and collaboration.

#2 Implement clinical research standards that are complementary to standards in the broader healthcare ecosystem and thus add value for clinical researchers, healthcare providers and patients.

#3 Leverage the Shared Health And Research Electronic Library (SHARE) and other tools to further expedite the development and facilitate the implementation of harmonized standards for clinical research.

- Approved by the CDISC Board of Directors, February 2015

2017 Goals

- *Strategic Goal 1: Promote and support the continued global adoption of harmonized data standards throughout the clinical research lifecycle by engaging regulatory agencies, research sponsors, academia and other stakeholders through education, advocacy and collaboration.*

- Seek to harmonize with other stakeholders protocol models from CDISC, FDA/NIH, and TransCelerate Biopharma
    - Harmonization with ClinicalTrials.gov, WHO ITCR nodes, EudraCT
- Gather key stakeholders to provide scoping, guidance and rules for inclusion of medical semantics in regulatory submissions (Afternoon session)
- Seek to align or harmonize CDISC pharmacogenomics standards with those from HL7, GA4GH and other stakeholders
- Develop plan to partner with PhUSE for implementation support
- Extend CT collaboration with NCI EVS

2017 Goals (2)

Strategic Goal 2: Implement clinical research standards that are complementary to standards in the broader healthcare ecosystem and thus add value for clinical researchers, healthcare providers and patients.

- Establish a strategic approach to use and development of standards to improve data exchange between healthcare delivery and healthcare research (and the Learning Healthcare System) via Healthcare Link
- Leverage the eSource Stakeholders Group to develop effective standards approaches to use of healthcare data electronic sources in clinical research with emphasis on EHRs, mobile, wearables, and clinical data warehouses
- Highlight effective eSource solutions via real-world projects involving a broad range of stakeholders (sponsors, research sites, EHR/EDC vendors)
- Collaborate & provide leadership in the HL7 Biomedical Research & Regulation WG
- Participate in PCOR TF One Source project

2017 Goals (3)

- *Strategic Goal 3: Leverage the Shared Health And Research Electronic Library (SHARE) and other tools to further expedite the development and facilitate the implementation of harmonized standards for clinical research.*

- Relevant technological goals plus…
- Continue to seek support to make SHARE free & open
- Assess NCI EVS' new metadata repository solution
- Understand diverse community needs for enhancement planning, including those from reviewers

Conformance Rules

- First set of SDTM Conformance rules just published
  - SDTMIG v3.2 Conformance Rules v1.0
- ADaM team reviewing and refining rules for ADaMIG v1.0
- SHARE will eventually house all conformance rules.
  - SHARE model updated to accommodate rules
  - Standard templates in development for rules teams to use
- Should the SHARE Repository house any Regulator defined business rules in additional to CDISC developed rules?
  - One central repository for all rules
- Future State: Conformance rule release strategy
  - Release together with an IG or UG as a package with CT also
- Formal acceptance of rules through ISO/CASCO

Cross Team Interactions

- Historically CDISC Foundational Standards teams set their own goals and worked independently
- Going forward Foundational Standards teams work together more closely *(Focus of the 3/16 IntraChange)*
  - Annual team goals aligned and support the CDISC Roadmap
  - Project priorities are based on the CDISC Roadmap
  - Greater use of collaboration tools (Wiki, Jira, SHARE ecosystem
  - Teams work together on Cross Team Collaborations, e.g.
    - Multiple Disposition Events per Epoch
    - Immunohistochemistry (IHC) Project
  - Standards will be brought into alignment
    - E.g. CDASHIG is currently a version behind SDTMIG
    - Organize IGs around Normative content

Questionnaires, Ratings & Scales (QRS)

- The QRS team work semi-autonomously to develop terminology and standardized values for qualifier, timing and result variables to populate the SDTM QS Domain
- The QRS team develop a document called a QRS supplement for each Questionnaire, Rating or Scale
- Developed under COP-017 available on the website
  - https://www.cdisc.org/about/bylaws
- QRS releases are similar to Controlled Terminology in that they are not aligned with a specific SDTMIG version
- Updates to the QRS process now separate out Questionnaires, Functional Tests and Clinical Classifications (3 distinct SDTM domains)
  - COP-017 will be updated to reflect this change
  - Decision required on whether to apply this change retrospectively

Cross Cutting Projects

- Projects to address a specific issue, or topic, that has implications for two or more of the CDISC standards
- Projects approved by stakeholders prior to initiation
- Project teams made up of representatives from each of the interested/effected teams
- Requirements for a solution developed with interests of each standard considered
- Solution will be holistic and will ensure that the standards/models can accommodate the solution without unnecessary rework later
- Solution may be published as a standalone document that augments foundational standard IGs

Standards Development Plan 2017: Cross Cutting Projects

Topic	Teams Involved	Description
Adjudication	SDTM, ADaM, CDASH	Representation of results supplied by adjudication committees. Complex data flow, since adjudication committee decisions are collected data, but may be based on analyses of data collected at the site.
Imaging	SDTM, CDASH, ADaM, SHARE, SEND*	Imaging domain, category? Consolidation of examples? Explaining representation of methods? User guide or topic guide. DICOM-NCI Imaging project. BRIDG adaptions just made. BK to ask JE to join TLC. Inform Ed Helton, involve Jordan Li.
Class level metadata	SDTM, CDASH, ADaM, SHARE, SEND, XML Tech*	Separating metadata at the model, class, and domain levels. Develop an easy-to-reference format with less redundancy (e.g., repetition of class-level metadata in every domain in the class)
Biomedical Concepts	SDTM, CDASH, ADaM, CT, SHARE	Create reusable models and metadata describing biomedical Develop way to represent BCs in SHARE. Develop process for curating, approving, maintaining. procedures, observations and other activities.
Rules into SHARE	SDTM, CDASH, ADaM, SHARE, XML, SEND	Create central metadata-driven definitions of rules and provide SHARE tools for consistent rule capture & management. Develop representation to store in SHARE. Reorganize text of IGs so that their relationship to rules is clear, less duplicatative. Rules governance team
Example Library	SDTM, CDASH, ADaM, SHARE, SEND	Create central metadata-driven tools for the development and reuse of CDISC normative and informative content. Develop processes for curating and maintaining examples. Identify tags useful for locating examples.
Site Audit Data	SDTM, ADaM	Take PhUSE recommendations and develop SDTM/ADaM components for delivery of sitei audit information for BIMO

Standards Development Plan 2017: Therapeutic Area Extensions

- Prostate Cancer v1
- Colorectal Cancer v1
- Vaccines v1
- Duchenne Muscular Dystrophy v1
- Nutrition v1
- Post Traumatic Stress Disorder v1
- Huntington's Disease v1
- QRS Supplements
- Updates:
  - Group 2 TAUGs: Diabetes v1.1 Dyslipidemia v1.1, QT Studies v1.1, COPD, v1.1
  - Group 3: Alzheimer's v2.1, Hepatitis C v1.1, MS v1.1, TBI v1.1

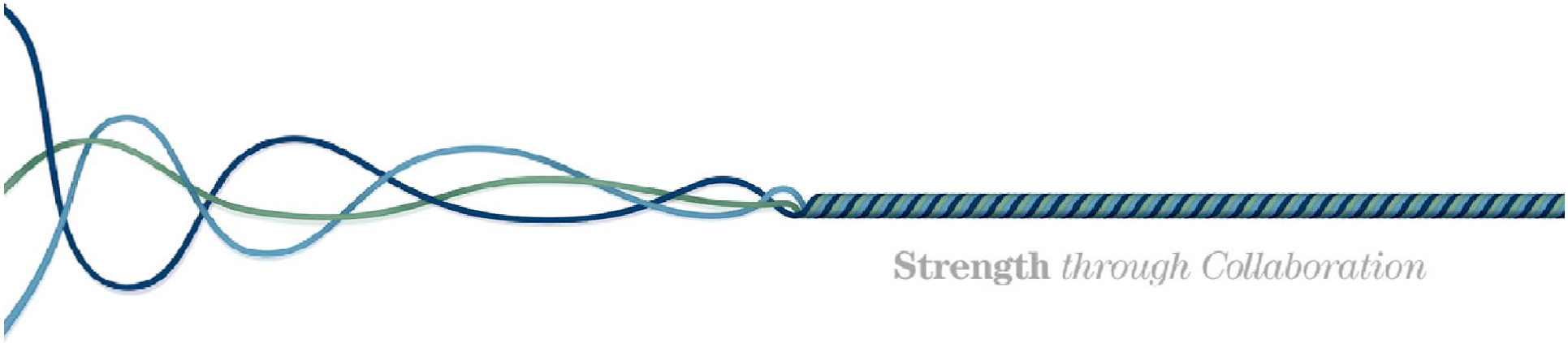
Path to Requiring TA Extensions

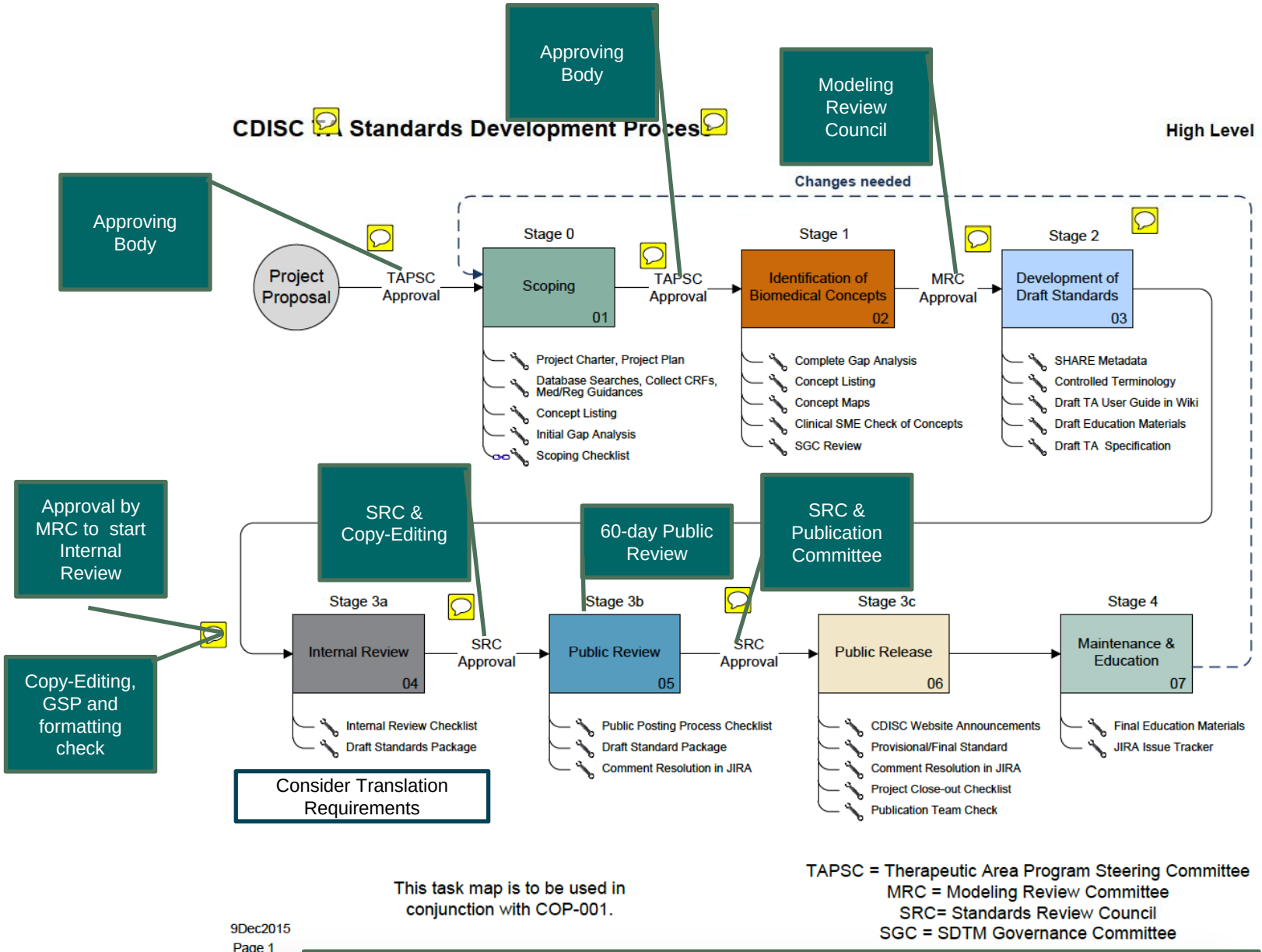
- TA Extensions currently referenced within the Technical Conformance Guide:
  - 5.2.1 Chronic Hepatitis C
  - 5.2.2 Dyslipidemia
  - 5.2.3 Diabetes
  - 5.2.4 QT Studies
  - 5.2.5 Tuberculosis

- What is the path to TA requirement?
- How should we communicate this to the community?

- STUDY DATA TECHNICAL CONFORMANCE GUIDE, Technical Specifications Document, November 2016. http://www.fda.gov/downloads/ForIndustry/DataStandards/StudyDataStandards/UCM384744.pdf

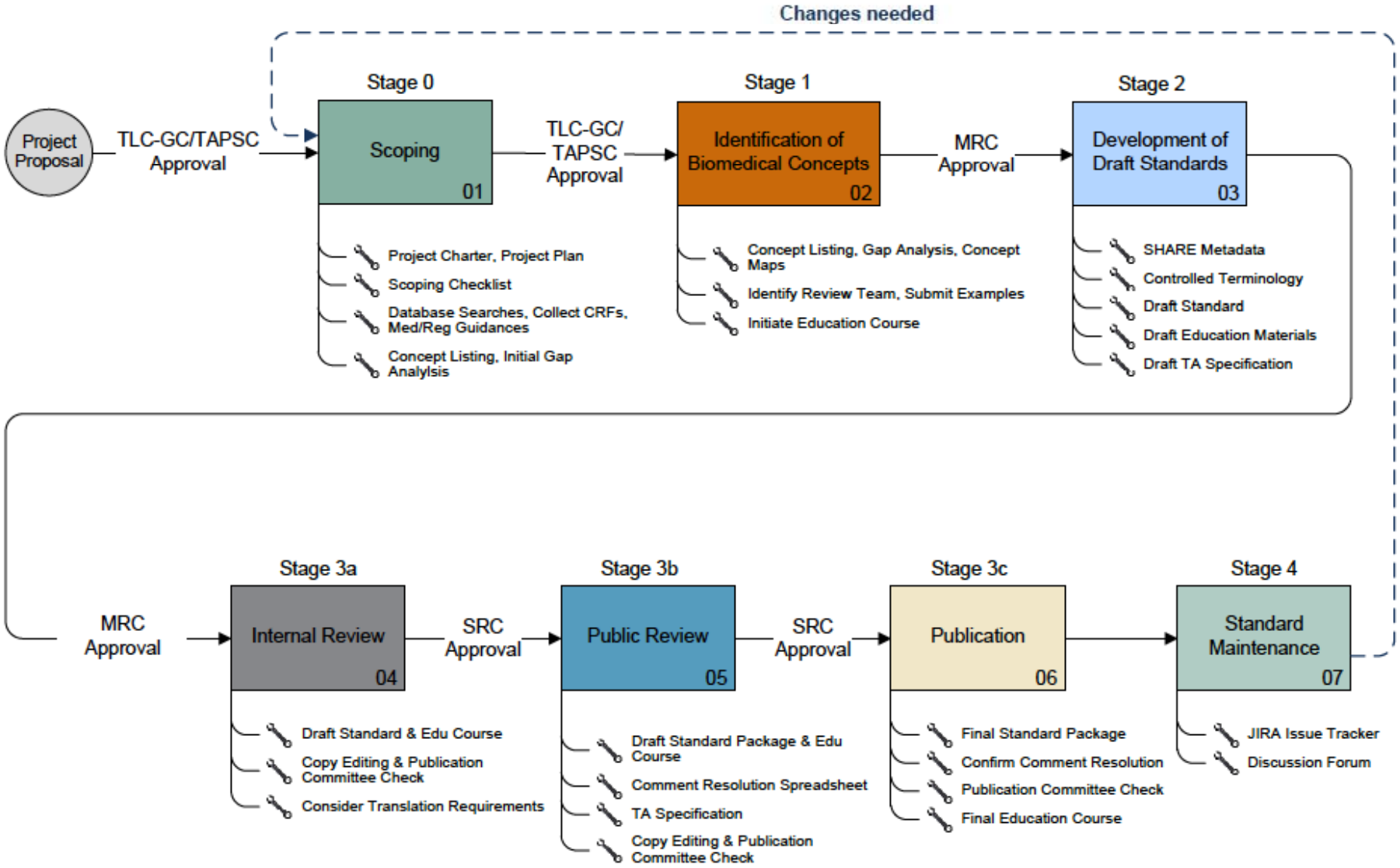
Future Development of CDISC Standards




CDISC Standards Development Process
High Level
Approving Body
Modeling Review Council
Approving Body
Changes needed
Project Proposal
TAPSC Approval
Stage 0
Scoping
01
TAPSC Approval
Stage 1
Identification of Biomedical Concepts
02
MRC Approval
Stage 2
Development of Draft Standards
03
Project Charter, Project Plan
Database Searches, Collect CRFs, Med/Reg Guidances
Concept Listing
Initial Gap Analysis
Scoping Checklist
Complete Gap Analysis
Concept Listing
Concept Maps
Clinical SME Check of Concepts
SGC Review
SHARE Metadata
Controlled Terminology
Draft TA User Guide in Wiki
Draft Education Materials
Draft TA Specification
Approval by MRC to start Internal Review
SRC & Copy-Editing
60-day Public Review
SRC & Publication Committee
Copy-Editing, GSP and formatting check
Stage 3a
Internal Review
04
SRC Approval
Stage 3b
Public Review
05
SRC Approval
Stage 3c
Public Release
06
Stage 4
Maintenance & Education
07
Internal Review Checklist
Draft Standards Package
Public Posting Process Checklist
Draft Standard Package
Comment Resolution in JIRA
CDISC Website Announcements
Provisional/Final Standard
Comment Resolution in JIRA
Project Close-out Checklist
Publication Team Check
Final Education Materials
JIRA Issue Tracker
Consider Translation Requirements
This task map is to be used in conjunction with COP-001.
TAPSC = Therapeutic Area Program Steering Committee
MRC = Modeling Review Committee
SRC= Standards Review Council
SGC = SDTM Governance Committee
9Dec2015
Page 1
TLC-GC or TAPSC – Technical Leadership Team – Governance Committee or TA Steering Committee
MCT- SR - Modeling Consultation Team - Super Reviewers
Modeling Forum

CDISC Standards Development Process

High Level



This task map is to be used in conjunction with the Standards Development Process Guideline.

Governance Body = TLC-GC or TAPSC
MRC = Modeling Review Council
SRC= Standards Review Council

Summary of Changes to Standards Development Process

- MRC Reviews
  - Stage 1 – approval of modeling to proceed to Development of Draft Standards
  - Stage 2 – approval to proceed to Internal Review
- SRC Reviews
  - Final draft TAUG prior to Public Review
  - Comments & resolutions (xls) prior to publication
- Extension of Public Review
  - extended from 30 to 60 days
- Escalation is managed by MRC

Modeling Review Council

Deliverables

The MRC will perform four types of review:

- ***Modeling strategy approval*** - Each team will be asked to describe each concept, domain placement, and a general modeling strategy employed. They will also be asked to identify any new domains, variables, or modeling that may be controversial (e.g., combination therapy, pre-specified findings, etc.). This will ensure that the team is on the right track from the beginning.
- ***Consultation*** – A team can sign up to get technical advice on concept maps as well as CDASH, SDTM, and ADaM examples.
- ***Example approval*** – Review of the final examples that have been developed prior to internal review to make sure that they are consistent with the decisions that have been made based on the approved modeling strategy and previous consultations.
- ***Escalation*** - Review and consensus on modeling issues that have been escalated for resolution from CDISC teams.
- ***Key decision making*** – Delphi method being applied to allow for all opinions to be heard and considered. FDA representation is desired.

Modeling Review Council (MRC)

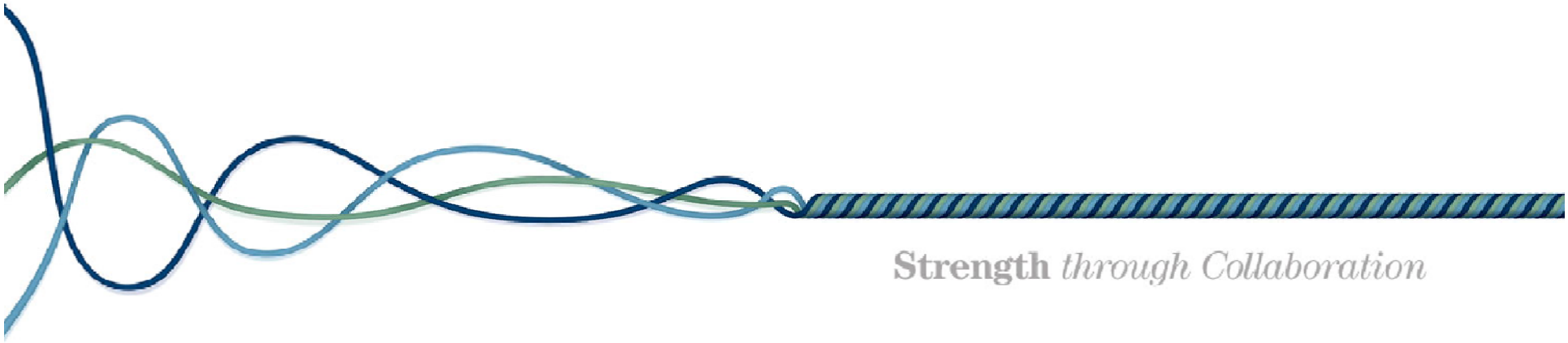
- Membership:
  - Permanent members from ADaM, SDS, CDASH, CT, SHARE, SEND
  - Rotating members, invited by topic
  - Ideally would include an FDA SME

- Responsibilities
  - Commits to 4-6 hours per month of CDISC work
  - Must confirm they have time for CDISC activities

CDISC Review Councils

Modeling Review Council (MRC)	Standards Review Council (SRC)
Provide early input on technical approaches (Concept Maps, CDASH, SDTM, ADaM, Controlled Terminology, XML Tech)	Review packages of documents/standards after internal review and prior to public review to ensure harmonization with existing standards
Review and approval of packages of documents/standards prior to internal review to ensure harmonization with existing standards	Ensure that all public review comments have been appropriately addressed
Review modeling issues that have been escalated for resolution from internal CDISC teams	

Enhancing CDISC”s Support for Medical Terminologies in Regulatory Submissions



LOINC and SNOMED CT

- Pending regulatory requirements
- Many questions regarding scope in the community
- Clear guidance for the community will improve quality of submissions

LOINC Dimensions

Part	Description
Component	Analyte - The substance or entity being measured or observed.
Property	The characteristic or attribute of the analyte.
Time	The interval of time over which an observation was made.
System	Specimen - The specimen or thing upon which the observation was made.
Scale	How the observation value is quantified or expressed: quantitative, ordinal, nominal.
Method	Assay Method - high-level classification of how the observation was made. Only needed when the technique affects the clinical interpretation of the results.

CDISC Variables Mappings to LOINC Dimensions

Part	What is this in CDISC standards
Component	LBTEST/CD + others
Property	Does not exist yet
Time	MULTIPLE: Various Timing Variables
System	SPEC+LOC
Scale	Does not exist yet
Method	METHOD + other things

CDISC's Approach to LOINC

- Perform business analysis
- Reuse wherever possible clinical laboratories' internal LOINC-to-CDISC mappings & lessons learned
- Compile analysis and mappings and collaborate with partners (e.g., Regenstrief, NLM, NCI EVS, FDA)
- Identify resources of support
- Tackle any challenges with stakeholder-based team
- Generate recommendations for enhanced LOINC incorporation in CDISC submissions
- Revise and repeat process for SNOMED CT

Progress: LOINC Initial Assessment

Findings for HEMBC Analysis

- CDISC lacks variables for Time and Property
- Component:
  - Duplications, use of “Other” and occasional units, findings, methods, and assay details contained therein
- System
  - Rules for handling LOINCs where either specimen type and anatomic location included
- Method
  - pH values pre-coordinated (CDISC separates)
  - Scale names and timings can be pre-coordinated

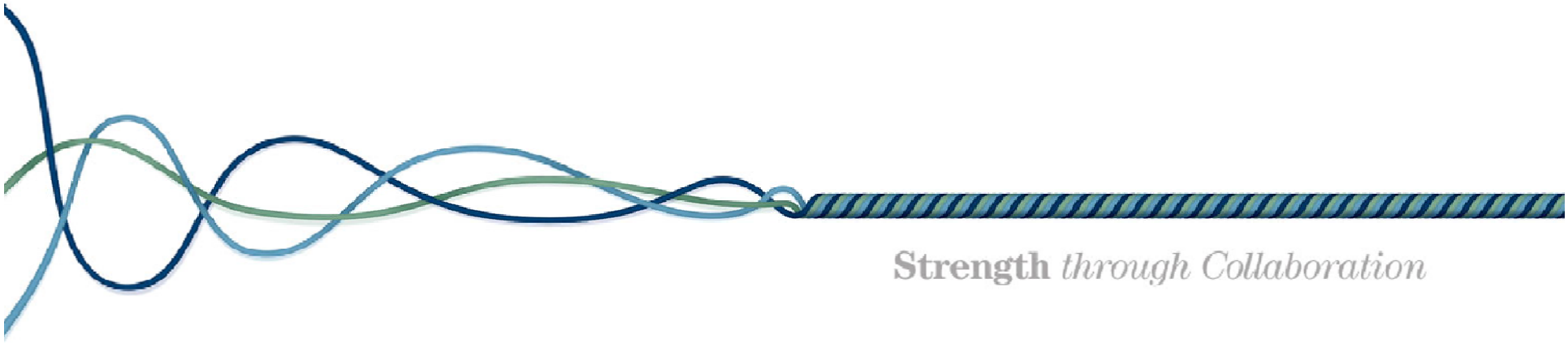
Recommended Next Steps

- Discussion in next session on drivers, scope, early wins, stakeholders
- Convene a small task force to review these findings
- Task Force should draft an initial assessment document containing solutions or guidelines
  - May need to iterate with smaller team
- Hold meetings with community stakeholders to hear their use cases, if any
  - Update document
- Assessment document may contain suggested changes to CDISC and LOINC
  - It should recommend “stop gap” solutions until those changes are released

CDISC's Approach to SNOMED CT

- Revise process from LOINC
  - Assess alignment and synonym linkages between SNOMED CT for indications and CDISC TA semantics
  - Determine appropriate stakeholder partners (e.g., SNOMED CT, NLM, NCI EVS, FDA)
- Generate recommendations for enhanced SNOMED CT incorporation in CDISC submissions

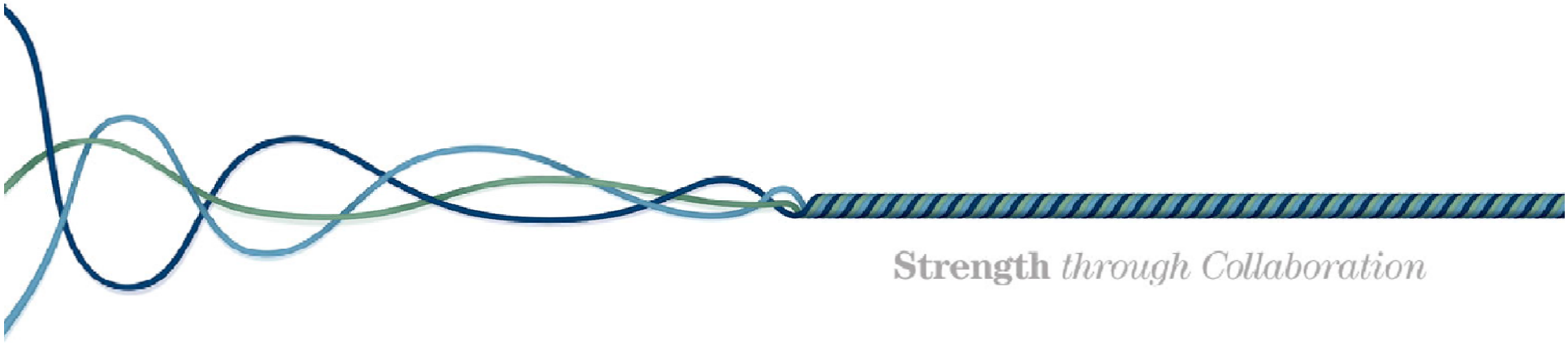
Discussion: Defining Medical Terminology Pilot Project



NIH-FDA pilot project to harmonize and/or identify gaps across *value sets* for the same purpose

- LOINC Next Steps Proposal
- Scope & boundaries
- Early wins vs long-term goals
- Stakeholders & leads
- Meeting structure

Discussion: Harmonizing Value Sets Pilot Project



NIH-FDA pilot project to harmonize and/or identify gaps across *value sets* for the same purpose

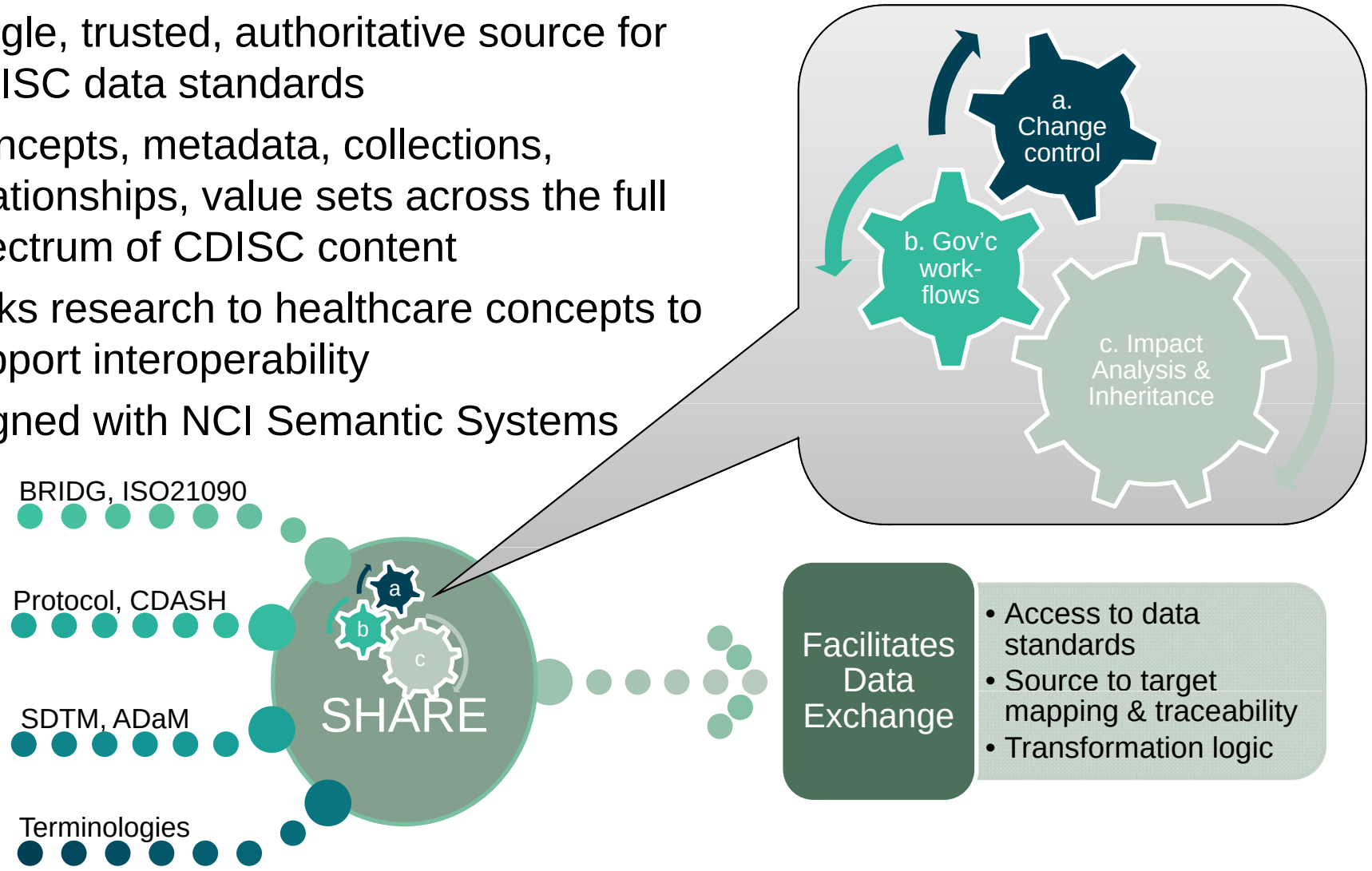
- This topic needs further definition; it would seem to include various levels of potential harmonization that could be discussed and approached collaboratively.
  - Harmonizing common or popular models (e.g. PCORI Common Data Model, ODHSI/OMOP, Sentinel, BRIDG)
  - “Datasets” (e.g. CDASH, Argonaut’s core dataset, CDEs and NCI ‘valid value]\ sets’)
  - Terminologies (e.g. terminology lists for CDISC TA standards)
  - Metadata repositories (NIH CDE repository, NCI caDSR, SHARE)
- Scope, definition and stakeholder identification required

SHARE

CDISC SHARE

SHARED HEALTH AND CLINICAL RESEARCH ELECTRONIC LIBRARY

- Single, trusted, authoritative source for CDISC data standards
- Concepts, metadata, collections, relationships, value sets across the full spectrum of CDISC content
- Links research to healthcare concepts to support interoperability
- Aligned with NCI Semantic Systems



Adapted from Source by Sue Dubman, Sanofi-Aventis

SHARE

- SHARE is CDISC's metadata repository along with supporting tools
- The first priority for SHARE was loading existing standards
- CDISC development teams are benefitting from SHARE
  - Consistency checking, version comparisons
  - Cataloging domains, supplemental qualifiers, examples
- Will be the repository for biomedical concept metadata

Impact on implementers

- Today
  - Extrapolate for data not in implementation guides
  - Connect up separate standards
  - Figure out how to pull together the right structural and terminology elements
- Future
  - Standards cover more content
  - TA user guides and biomedical concept metadata integrate across standards
  - Download machine-readable, immediately useable standards

CDISC *Strength Through Collaboration*

Search...

ABOUT | STANDARDS | COLLABORATIONS | RESOURCES | NEWS/PUBLICATIONS | EDUCATION | EVENTS | MEMBERSHIP | MEMBERS ONLY

CDISC SHARE

What is SHARE?

CDISC SHARE, a cornerstone of the CDISC technical roadmap, is a global electronic repository for developing, integrating and accessing CDISC metadata standards in electronic format. SHARE is envisioned to help users find, understand and use rich metadata and controlled terminologies relevant to clinical studies more efficiently and consistently, and to improve integration and traceability of clinical data from protocol through analysis.

SHARE Team Still Accepting Volunteers

The SHARE Team is accepting new volunteers to our growing list of participants. There are a number of sub-teams that are either underway or planning to start in the near future. A current **list of sub-**

--Public Review--

ADaM Integration-IADSL v1 Draft
Comments due 10 July 2015

CDISC eSHARE Downloads Now Available for Platinum Members!

If your organization is a Platinum member, please sign in with your organization's email address.

Volunteer for CDISC

SHARE Related Downloads / Links

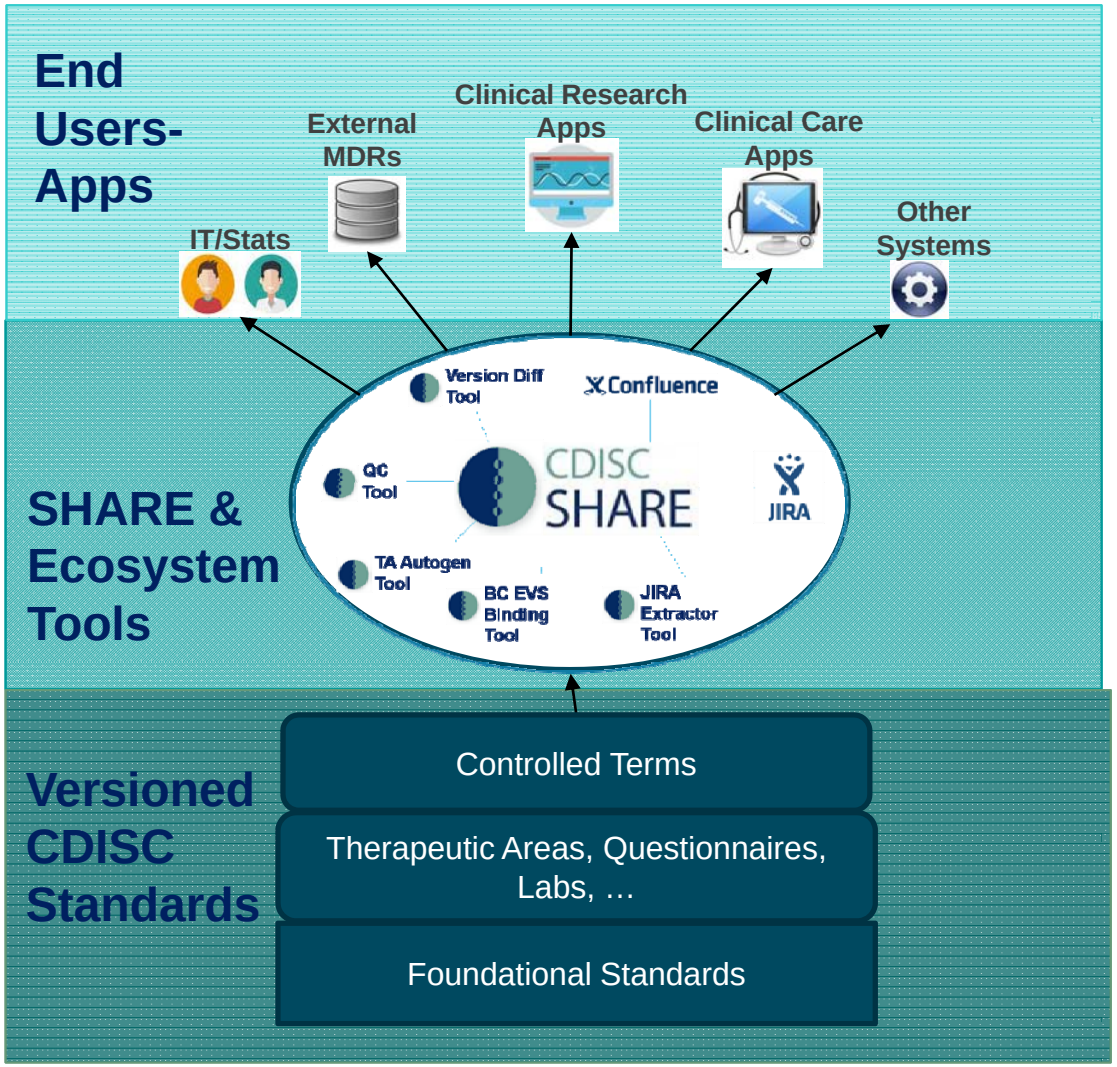
eSHARE Content Catalog
Subscribe to SHARE_News
Volunteer for SHARE
SHARE on CDISC Wiki
CDISC SHARE Video
SHARE Requirements (pdf)
2013 International Interchange SHARE Presentation (pdf)

What is SHARE?

A global, accessible electronic library, which through advanced technology, enables precise and standardised data element definitions that can be used in applications and studies to improve biomedical research and its link with healthcare

http://www.youtube.com/watch?v=gCyVdvgVpY8&feature=youtu.be

CDISC Shared Health and Research Electronic Library

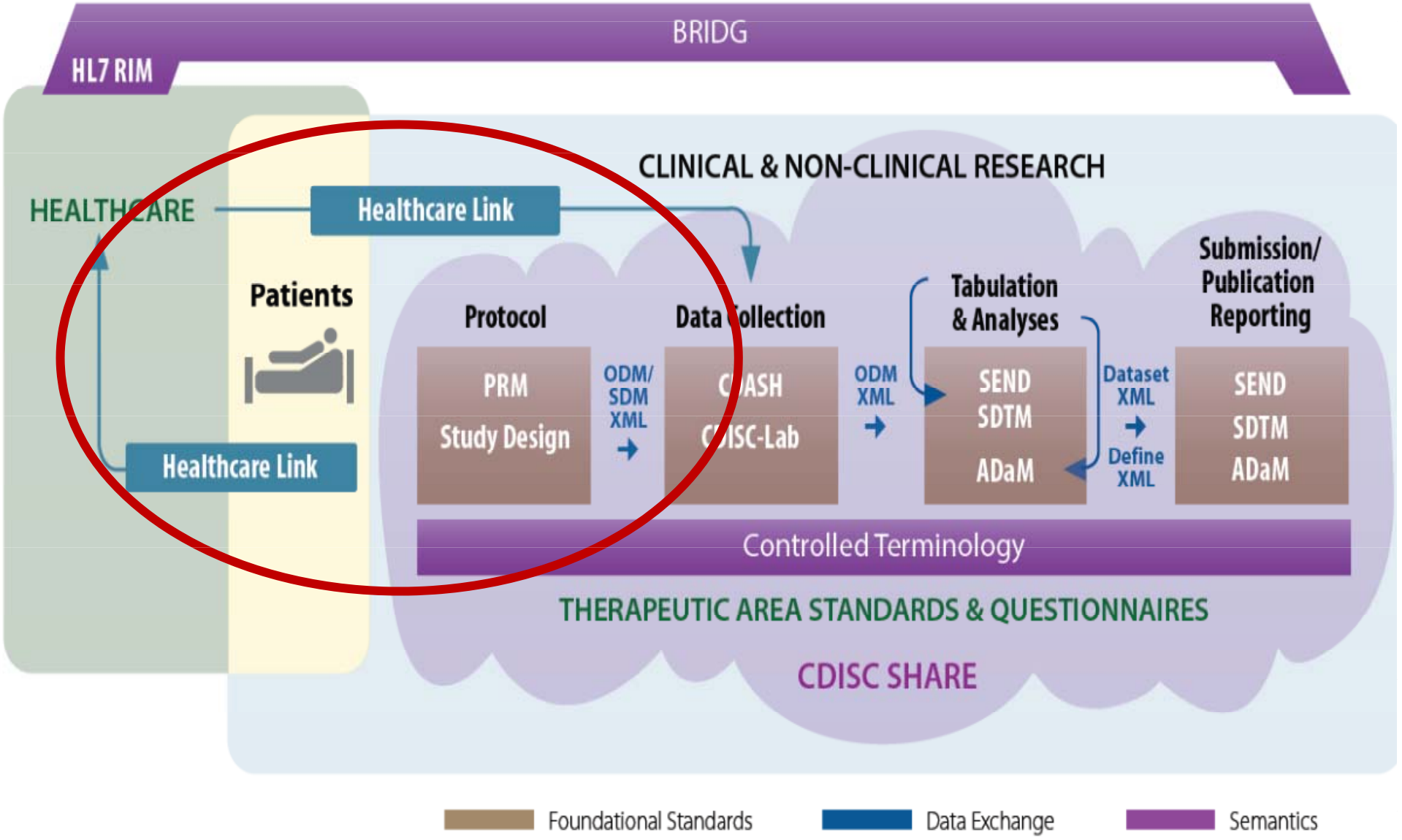


SHARE provides immediate access to *curated, computable CDISC Standards* to:

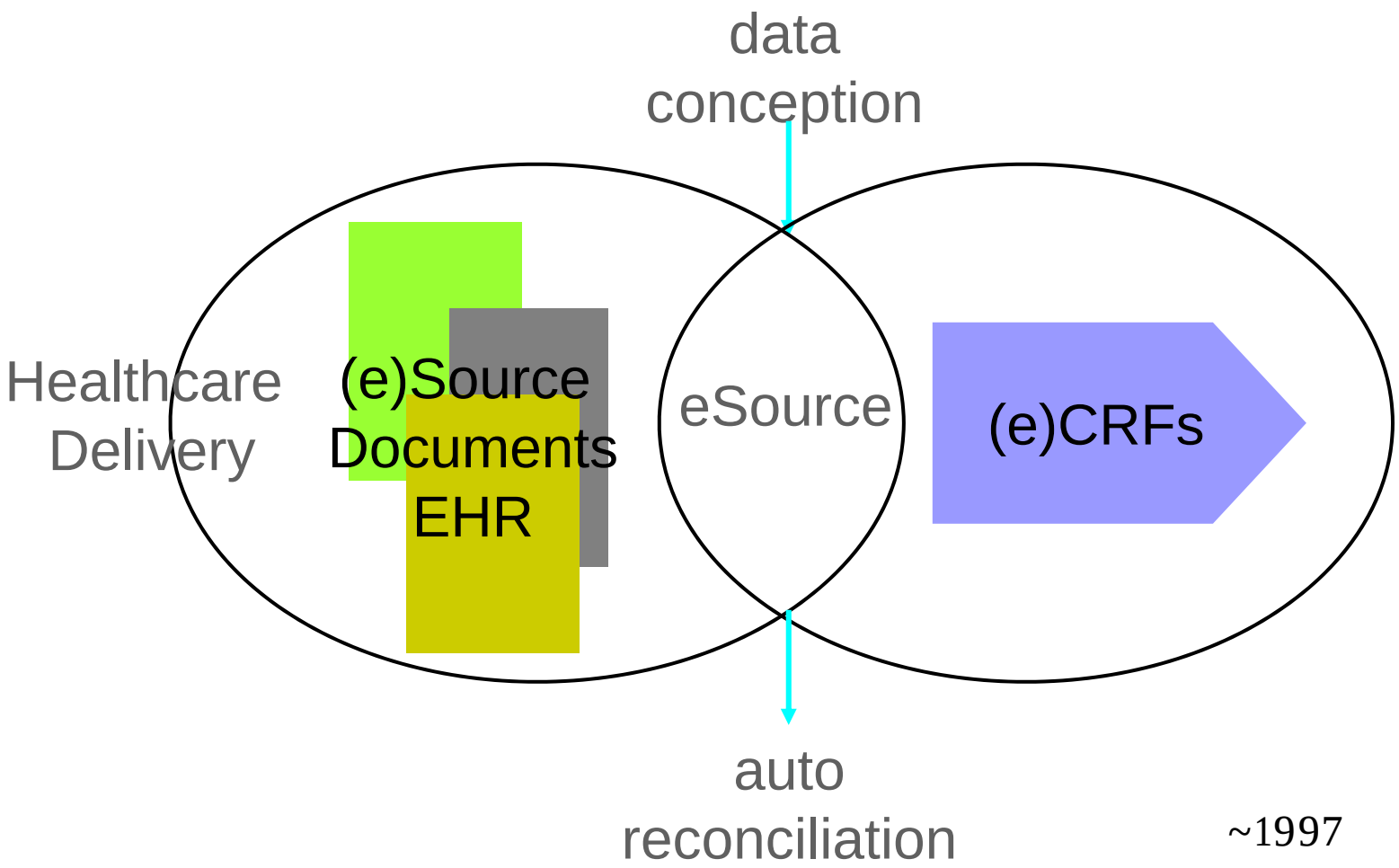
- Implement standards in real time and/or as 'packages'
- Enable exchange of health research data
- Reduce costs through increased automation
- Comply with eSubmission requirements for FDA, PMDA

Healthcare Link

Achieving Interoperability



Goal: Optimize the Process



~1997

eSource Data Interchange (eSDI)

- **Purpose:** FDA initiative to facilitate the use of electronic technology in the context of existing regulations for the collection of eSource data in clinical research
- eSource: collecting data electronically initially (e.g., eDiaries, ePRO, EDC, EHRs)
- Overarching Goals of eSource:
  - Make it easier for physicians to conduct clinical research
  - Collect data only once in an industry standard format for multiple downstream uses, and thereby
  - Improve data quality and patient safety
- eSDI Document:
  - Developed by multidisciplinaryteam
  - 12 requirements for eSource (based on predicate rules)
  - Formed basis for Retrieve Form for Data Capture (RFD) IHE Integration Profile
  - Available at www.cdisc.org/eSDI-document

EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

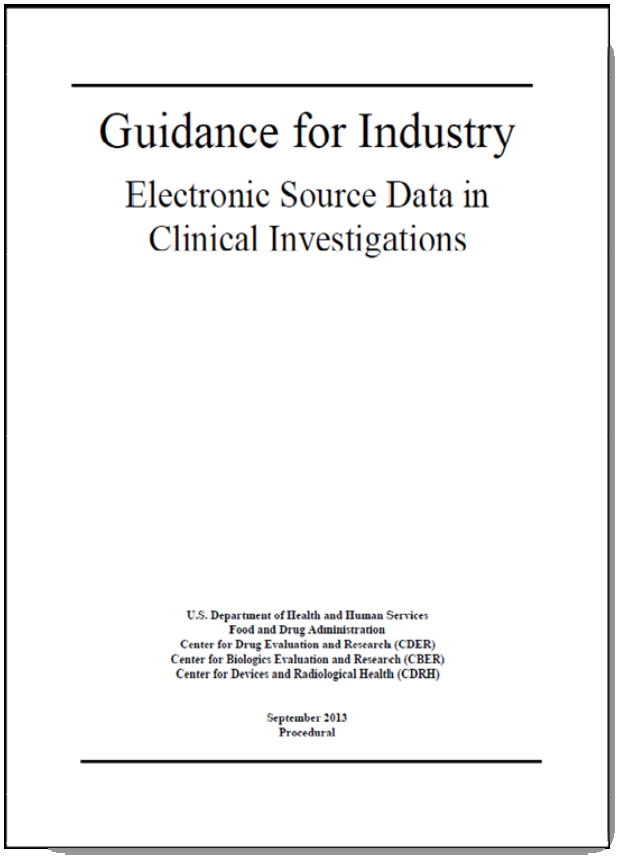
09 June 2010
EMA/INS/GCP/454280/2010
GCP Inspectors Working Group (GCP IWG)
Date for coming into effect 01 August 2010

Reflection paper on expectations for electronic source data and data transcribed to electronic data collection tools in clinical trials

References

2. CDISC (Clinical Data Interchange Standards Consortium) Clinical Research **Glossary Version 8.0**, DECEMBER 2009
http://www.cdisc.org/stuff/contentmgr/files/0/be650811feb46f381f0af41ca40ade2e/misc/cdisc_2009_glossary.pdf.

3. **CDISC e-source standard requirements-CDISC** (Clinical Data Interchange Standards Consortium) Version 1.0 20 November 2006.

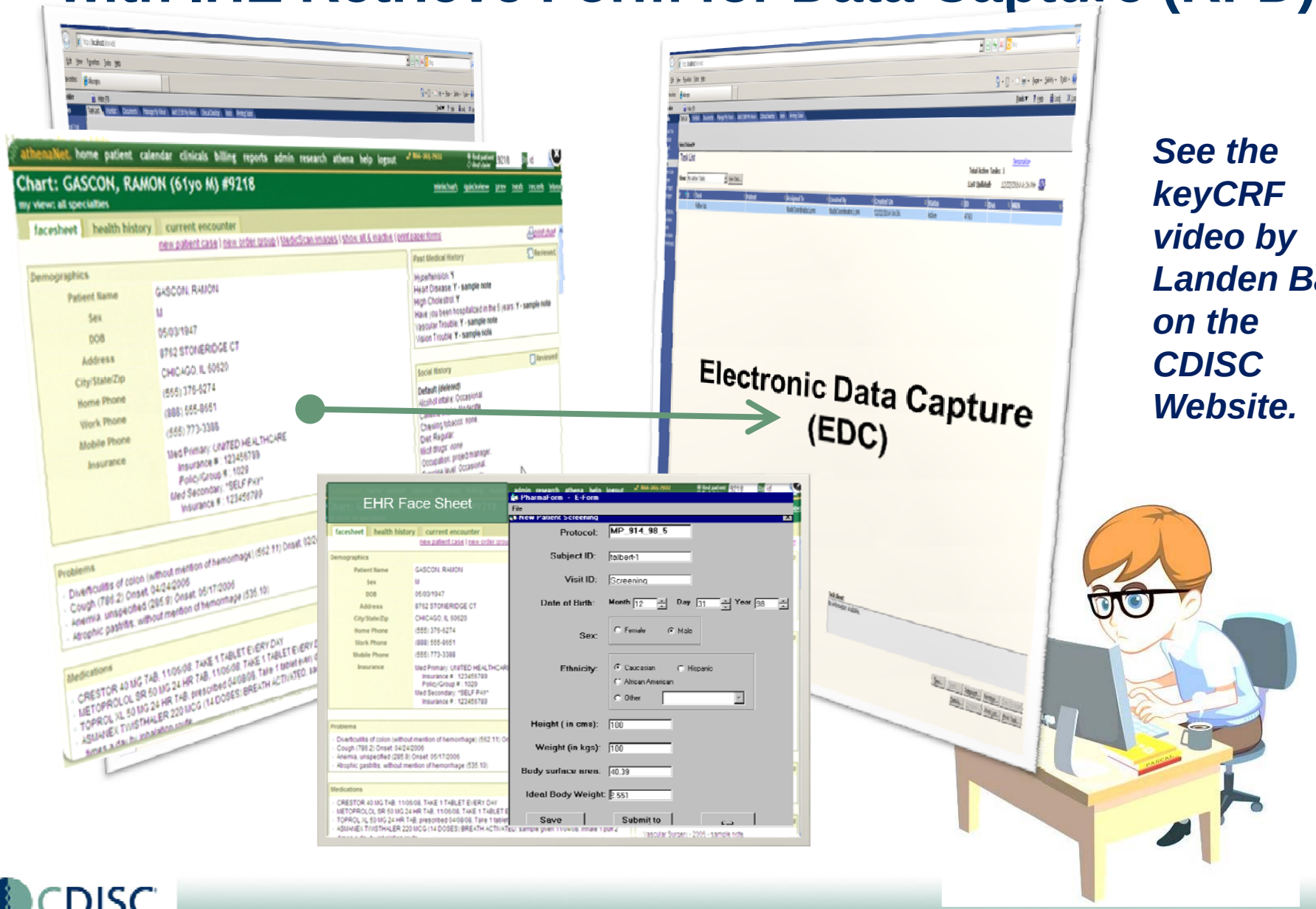

Guidance for Industry

Electronic Source Data in Clinical Investigations

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)

September 2013
Procedural

EHR to Electronic Data Capture (CDASH) with IHE Retrieve Form for Data Capture (RFD)



See the keyCRF video by Landen Bain on the CDISC Website.

CDISC

ASTER (AE Reporting from EHRs)

30 Ambulatory care physicians at Harvard and Brigham and Women's

with Pfizer, CDISC, CRIX

Nov 08 – Jun 09, > 200 Reports Sent to FDA

Physician Reporting:

*91% of participating physicians had submitted no ADE reports in the prior year

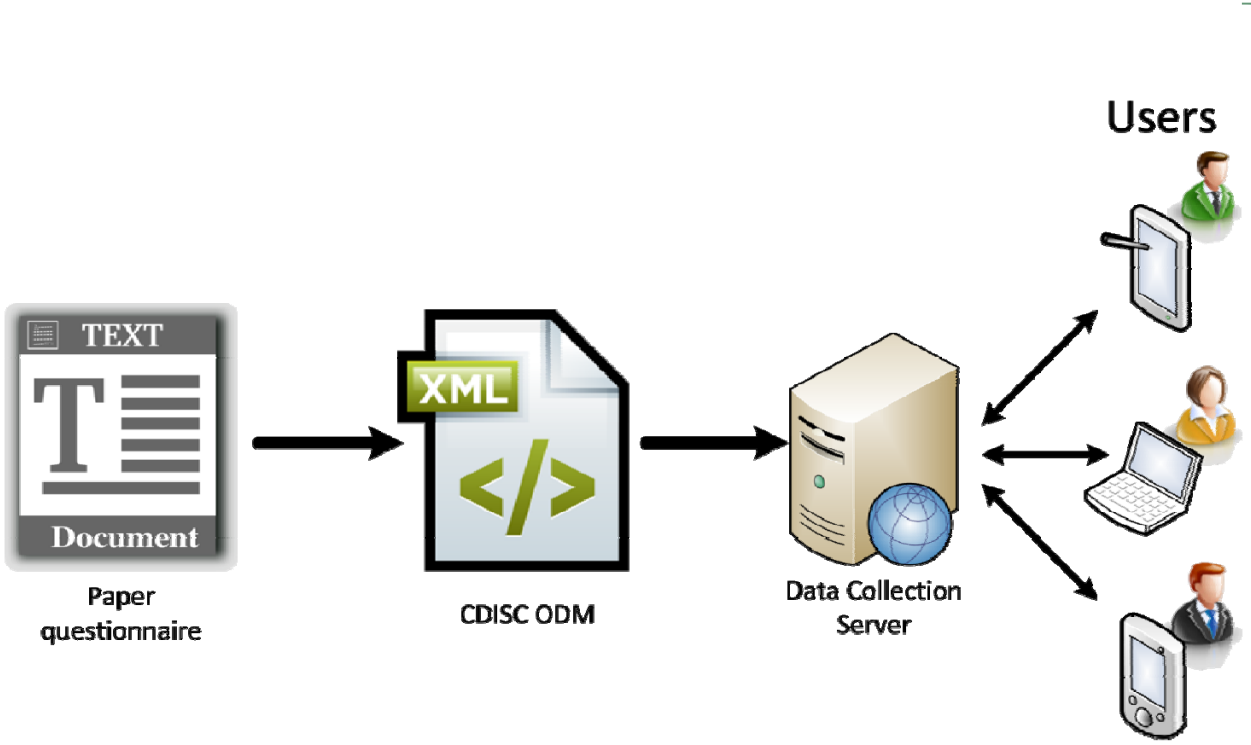
**During the study, participants reported an average of approximately 5 reports in a 3 month time period*

*All participants reported at least 1 AD

* Process: *Time to report decreased from ~35 min to* ***< 1 min***

Source: Michael Ibara, Pfizer

Patient-centered eSource Data Collection



CDISC ODM Extension Enables eSource Data Collection from Patients Via Smart Phones or Tablets

- CDISC ODM extended with GUI elements
- When an ODM is created, the QuestionType attribute is added to every ItemDef object in ODM
- Platform-agnostic, rendered appropriately for each device

Source: Brendan Delaney, TRANSFoRm, EU

Closing Thoughts

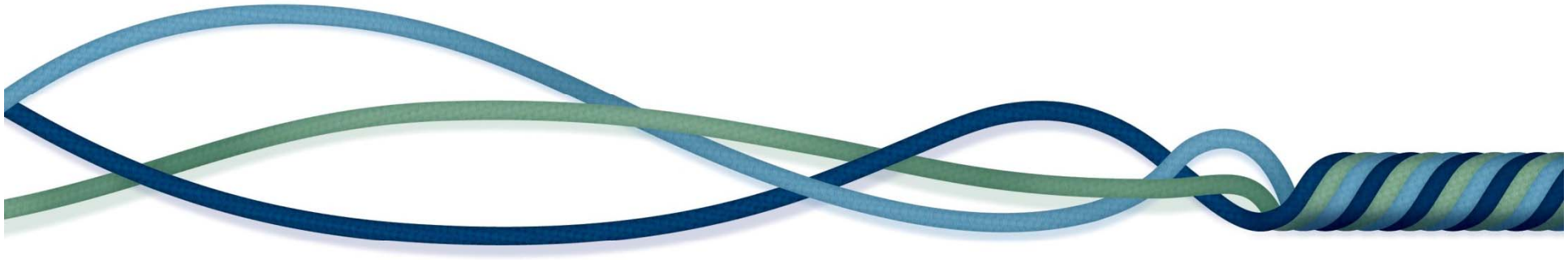
Strength through Collaboration

CDISC provides a common clinical data language that allows us to share and compare data.

With more minds around the challenges, problems get solved faster and the pursuit of cures is accelerated.

CDISC has a new 2-day **Beginning to End** course for investigators, project leads, monitors, CRCs and others who want to learn more about the CDISC standards.

Learn more about our Educational opportunities at: www.cdisc.org/Education and cdisc.trainingcampus.net or contact us at training@cdisc.org



Strength *through collaboration.*