CLINICAL DATA INTERCHANGE STANDARDS CONSORTIUM

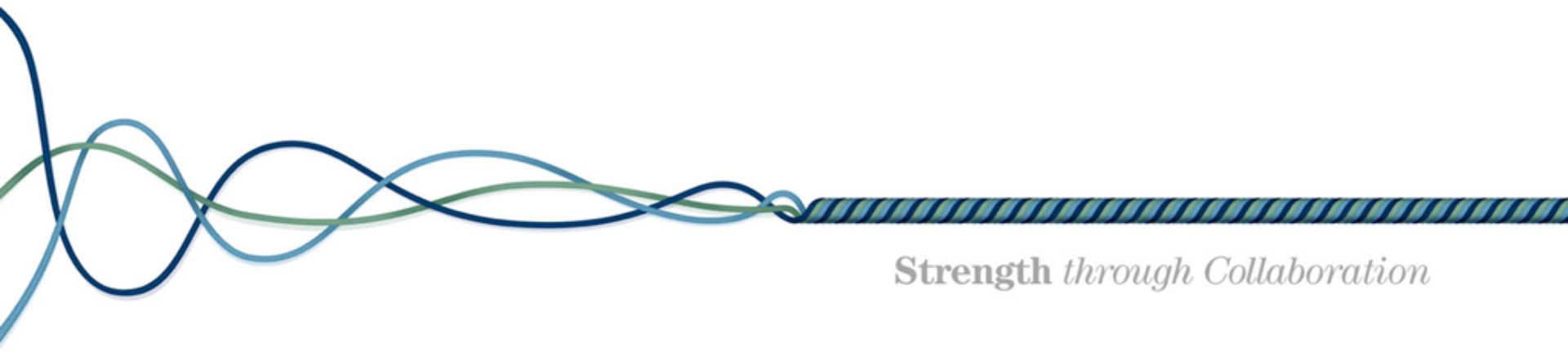
The CDISC vision is to inform patient care & safety through higher quality medical research.

Strength *through Collaboration*

CDISC UK Network face to face – Reading

Paul Houston,
CDISC Head of European Operations

CDISC Update and European Activity



"Perfect as the wing of a bird may be, it will never enable the bird to fly , if unsupported by the air. Facts are the air of science. Without them a man of science can never rise."

Ivan Pavlov, 1904

COLLABORATE

Strength *through Collaboration*

CDISC

About Our Global Organization

"Never doubt that a small group of thoughtful, committed citizens can change the world. Indeed, it is the only thing that ever has."
–Margaret Mead

CDISC Board of Directors: The CDISC Board of Directors is made up of ~ 12 members, each serving a three-year term. Elections are held annually for vacant seats and new members begin their terms on 1 January. The role of the Board of Directors is to focus on financial stability and responsibility and the strategic direction of the CDISC organization.

CDISC Advisory Council: The CDISC Advisory Council (CAC) is comprised of a representative from each CDISC Platinum Member organization. The CAC supports the CDISC Strategic Goals, participates in fund-raising, and works to enhance the organization's public image. There are CAC representatives on 3 Board Committees (Financial Oversight, Strategy and Technical Advisory) and the CAC Leader is an ex-officio member of the CDISC Board.

CDISC Coordinating Committees: CDISC Coordinating Committees support global CDISC initiatives within specific regions of the world and provide regional feedback to the central CDISC organization. CDISC 3Cs help to strengthen relationships with international and local entities as well as organizations in their respective regions.

CDISC Technical Leadership Committee: The Technical Leadership Committee is composed of CDISC Team Leaders. Their primary responsibility is to ensure that the CDISC Teams are working toward achieving the CDISC Strategic and Operational Goals.

CDISC Teams: CDISC teams are composed of hundreds of volunteers from around the globe who develop, use and maintain the CDISC standards.

CDISC User Networks: CDISC User Networks enable face-to-face interactions in specific regions or languages. They are self-formed groups that encourage the adoption and understanding of the usefulness and value of CDISC standards.

CDISC Members, Stakeholders, Supporters, Adopters and Volunteers: It would not be possible to develop the CDISC standards and demonstrate their value without the incredible support we have had from this increasingly large group of amazing individuals and organizations.

For more information about CDISC bylaws, policies, charters, operating procedures and related information, please visit the CDISC website: cdisc.org/mission-and-principles.

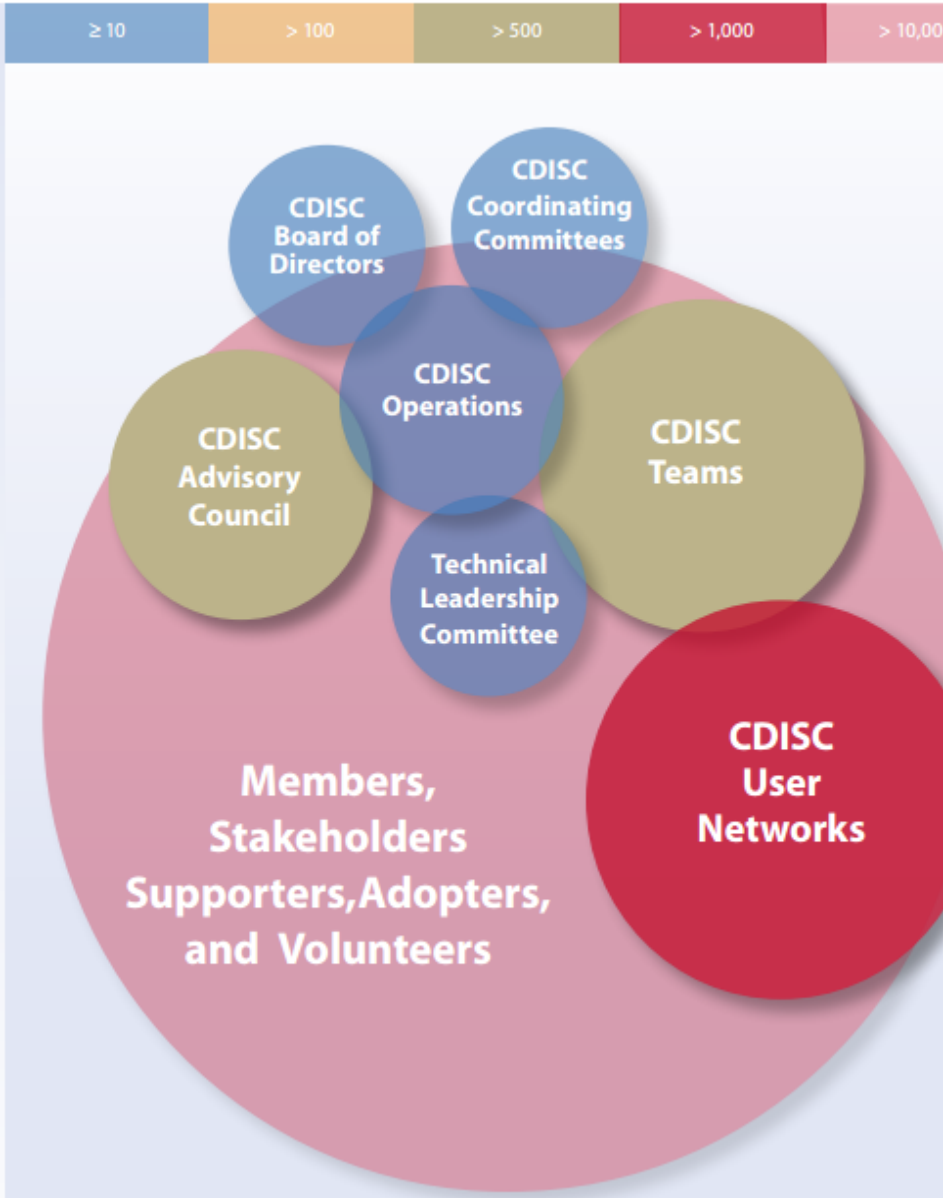


Diagram above illustrates the relationship between and different sizes of the varied groups that represent CDISC

CDISC Operations Leadership

Rebecca Kush, PhD
CDISC President and CEO

Wayne Kubick, MBA
Chief Technical Officer

Bron Kisler
Vice President of Strategic Alliances

Nicole Harmon, PhD
Executive Director

Sam Hume, MS
Vice President of SHARE Technology and Services

Rhonda Facile, MS, MBA
Vice President of Standards Development

Shannon Labout, CCDM
Vice President of Education

Landen Bain, Liaison to Healthcare

Julie Chason, SHARE Metadata Curator

Anthony Chow, SHARE Metadata Curator

Joe Ben Clark, Software Application Support Specialist

Rene Dahlheimer, Metadata Developer

Robert Dempsey, Terminology Specialist

Julie Evans, Sr. Director, Technical Services

John Ezzell, Manager of Education Products

Diana Harakeh, Director, International Development

Paul Houston, Head of European Projects, CDISC Europe Foundation

Kit Howard, Director, Education

Steve Kopko, CDISC Subject Matter Expert

Sheila Leaman, Director, Global CDISC Relations

Amy Palmer, Sr. Project Manager, Standards Development

Jyoti Pillay, Sr. Accountant

Sara Shafer, Communications and Events Specialist

Alana St. Clair, Associate Project Manager

Andrea Vadakin, Director, Communications and Public Relations

Ann White, Manager, Member Relations

Shirley Williams, VP of Finance and Administration

Diane Wold, Sr. Director, Standards Development and Modeling

Kaci Wood, Administrative Specialist

Bernice Yost, Manager, Standards Development

Saad Yousef, Manager, Education Services

CDISC Values and Principals

- Core value – Foster…CDISC community is altruistic and contributing to the advancement of healthcare.
- Catalyze global collaboration to maximise sharing of information, mimimize duplication of effort and foster the evolution of a global learning healthcare system.
- Enable regulatory submissions that allow for flexibility in scientific content and are easily interpreted, understood and navigated by regulatory reviewers.
- A culture of giving…consistent individual and business principles, balanced work/life , excellence & respect

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.

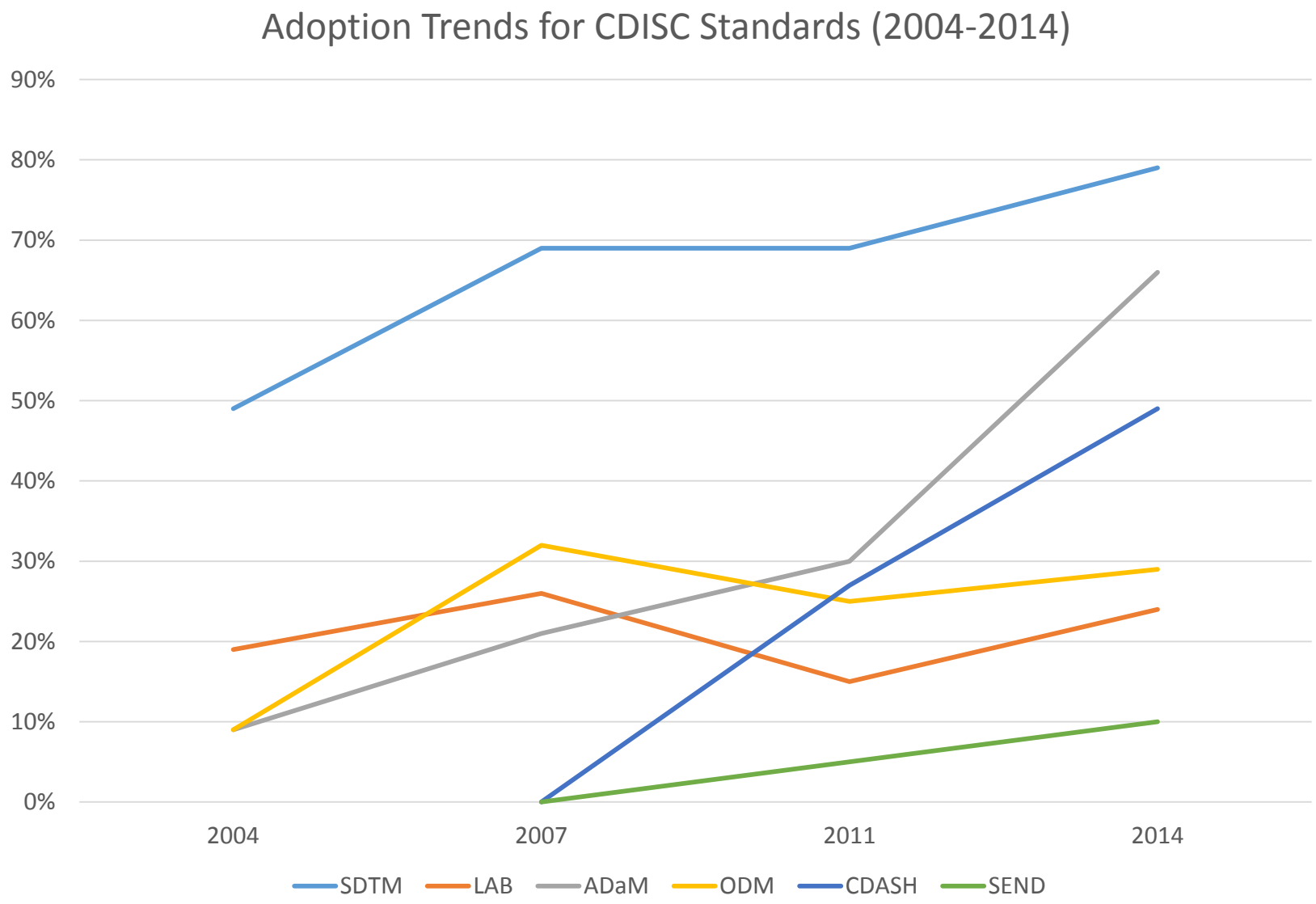
Published Standards

Therapeutic Area	Scoping	Modeling	Development	Internal Review	Public Review	Published
Alzheimer's Disease v2	Jan	Mar	Jun	Sep		*Dec, 2013*
Asthma v1	Jan	Mar	Jun	Jul		*Nov, 2013*
Multiple Sclerosis v1	May	Oct	Nov	Jan	April	*May, 2014*
CV Endpoints v1	Jul	Sep	Nov	Feb	May	*Oct ,2014*
Diabetes v1	May	Aug	Dec	Apr		*Sep, 2014*
Influenza v1	May	July	Aug	Sep	Oct	*Nov,2014*
QT Studies v1	Oct	Feb	Mar	Jul	Sep	*Dec, 2014*
Chronic Hepatitis C Virus v1	Feb	Apr	Jul	Nov	Jan	*May, 2015*
Schizophrenia v1	May	July	Aug	Dec	Mar	*Q215*
Dyslipidemia v1	May	Sep	Dec			*Q215*
Breast Cancer v1	Aug	Dec	Jan			*Q315*
Diabetes ADaM Supplement	NA	NA	Jan			*Q215*
Traumatic Brain Injury v1	Dec	Jan	Feb	Apr	Jun	*Q315*
COPD v1	Aug	Dec	Apr	Jun		*Q315*
Virology v2	Mar	Apr	May	Jun		*Q315*
Tuberculosis v2	Apr	Jun	Aug			*Q116*
Diabetic Kidney Disease v1	May	Jun				*Q116*
Rheumatoid Arthritis v1	May	Jun				*Q116*
CV Imaging v1	May					*Q216*
Prostate Cancer v1	May					*Q216*

2 in 2013

5 in 2014

1 Published, 7 more planned for 2015



2014 Data from recent Tufts CSDD Survey

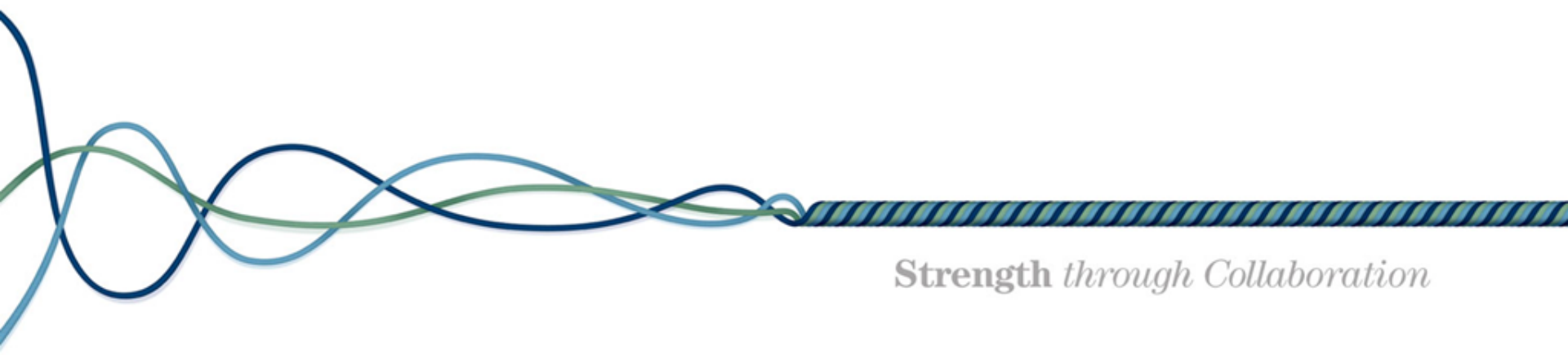
My interests here today and beyond

- Pre-competive data sharing initiatives
- Efficiency gains statistics for using standards
- Sponsors for the CTR&R initiative
- Deepen and create collaborative networks and opportunities (CDISC UK Network, new opportunities)….
- Extend the use of CDISC for researchers, governments, etc

Please contact phouston@cdisc.org

CEF (CDISC European Foundation)

European Activity and Projects



IMI Consortia and CEF

- EHR4CR

  Electronic Health Records for Clinical Research http://www.ehr4cr.eu is in its fourth year and CDISC is contributing to the semantic interoperability and pilot work packages to ensure reuse of data from Electronic Health Record systems for Clinical Research.

- BioVacSafe

  Biomarkers for Enhanced Vaccine ImmunoSafety http://www.biovacsafe.eu is entering its third year. The goal of BioVacSafe is to develop cutting edge tools to speed up and improve the testing and monitoring of vaccine safety. CDISC is working closely with Charité University (Germany), University of Surrey (UK), and global vaccine manufacturers on a data standards package and a Vaccine standard.

- eTRIKS

  European Translational Information & Knowledge Management Services http://www.etriks.org is now in its second year. CDISC is leading the data standards work package with Roche. Building upon the open source tranSMART system, eTRIKS will provide a sustainable Knowledge Management Platform and Service to support Private/Public Translational Research (TR) across IMI, bringing curated data together from key IMI project consortia.

eTRIKS Partner Consortium

10 Pharma

6 Partners

eTRIKS (Oct 2012 – Sept 2017)

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IMI Projects engaging eTRIKS

Oncology
- Colon
- Prostate
- Breast
- Lung

Safety
- Multiple Sclerosis
- Vaccine Preventable Diseases e.g. flu

Inflammation
- Severe Asthma
- Rheumatoid Arthritis

Infection
- Tuberculosis

eTRIKS highlights

1. IMI2 – SGGs to cascade down WP3 recommendations – needs to build on what eTRIKS WP3 does. (CDISC will be at the core for clinical data). BRIDG will be an underlying model and PGX to connect some clinical and genomic data.
2. Standards starter Pack v1. end of March 2015. To be included with IMI's Data Management Plan.
3. Meta Data Registry – mappings of meta data for all standards. External collaboration with SHARE and NCBO MDR work – Cedar project.

Suggested architecture of the full proposal

The Applicants are expected to suggest architecture for the full proposal to set up the platform that addresses the scope and the expected impact of this CSA, as well as incorporating and complementing the industry consortium contribution.

The consortium will be expected to keep informed the European Commission of the activities of the CSA, in particular the responsible unit of DG Health & Food Safety.

The successful applicant consortium will be expected to adhere to the following principles, if inappropriate please provide rationale in the short proposal:

1) Disseminate scientific publications and research data on the basis of open access. Collection, processing and generation of research data is to follow documented data management procedures (see "Guidelines on Open Access to Scientific Publications and Research Data in Horizon 2020" and "Guidelines on Data Management in Horizon 2020 "). In order to ensure adherence to the legislation concerning protection of personal data, controlled access digital repositories and data governance will need to be established.

2) Use well-established data format and content standards in order to ensure interoperability to quality standards. Preferably existing standards should be adopted. Should no such standards exist, consideration should be given to adapt or develop novel standards in collaboration with a data standards organization (e.g. CDISC).

eTRIKS

efpia

Platform and services for data staging, exploration, and use in translational research

eTRIKS Standards Starter Pack

The use of standards increases the value of your dataset as they make it easier to load you data into knowledge management platforms and makes your data easily comparable to other datasets that have used the same standards.

The eTRIKS Standards Starter Pack Standards Guidelines will be enhanced and extended as the project develops.

Standards Starter Pack Standards Guidelines 1.3.5

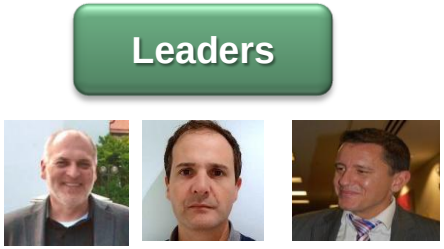
eTRIKS consortium

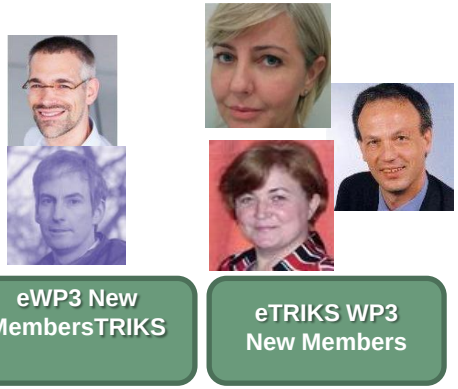
BioSci Consulting (Collaboration Management)

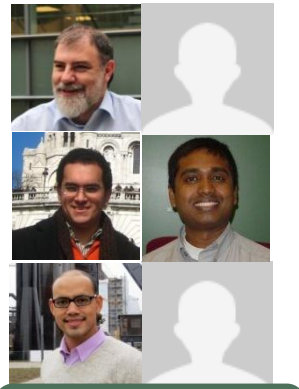
Work Package	WP Leads
Platform Service Delivery	CNRS/JPNV
Platform Development	Imperial/Sanofi/ Pfizer
Standards Research and Coordination	Roche/IDBS/Merck KGaA/ CDISC
Analytics Research & Content Curation	Luxembourg/Sanofi
Governance and Business Model	AstraZeneca/BioSci Consulting
Community Engagement & Outreach	Janssen/BioSci Consulting
Ethics for eTRIKS platform data	GSK/CNRS/Bayer/ Sanofi

- public–private partnership funded within the European Commission's Innovative Medicines Initiative (IMI)

eTRIKS Standardization Activities







Leaders

eWP3 New MembersTRIKS

eTRIKS WP3 New Members

eTRIKS RT meeting, Berlin

Proposal for eTRIKS Metadata Registry

Starter Pack Release 1

Request to access U-biopred Eclipse data

eTRIKS XWP meeting, Oxford

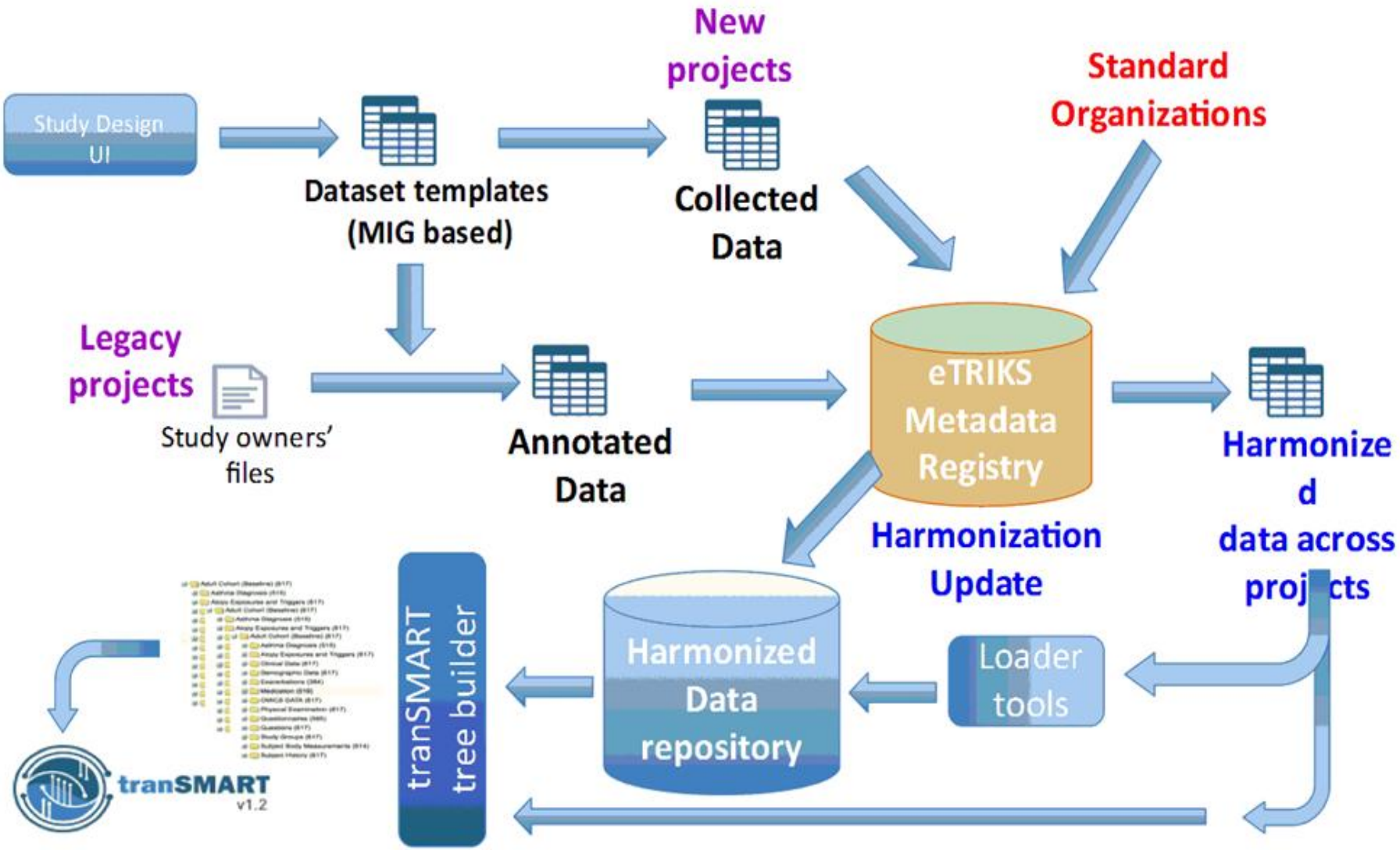
eTRIKS annual meeting, Barcelona

WP3 Proposals & Roadmap

WP3 deliverables: D3.2; D3.3; D3.4; D3.5; D3.8

Feb.2014 | July 2014 | Oct.2014 | Jan.2015 | Feb.2015 | March 2015

eTRIKS MetaData Registry Needs



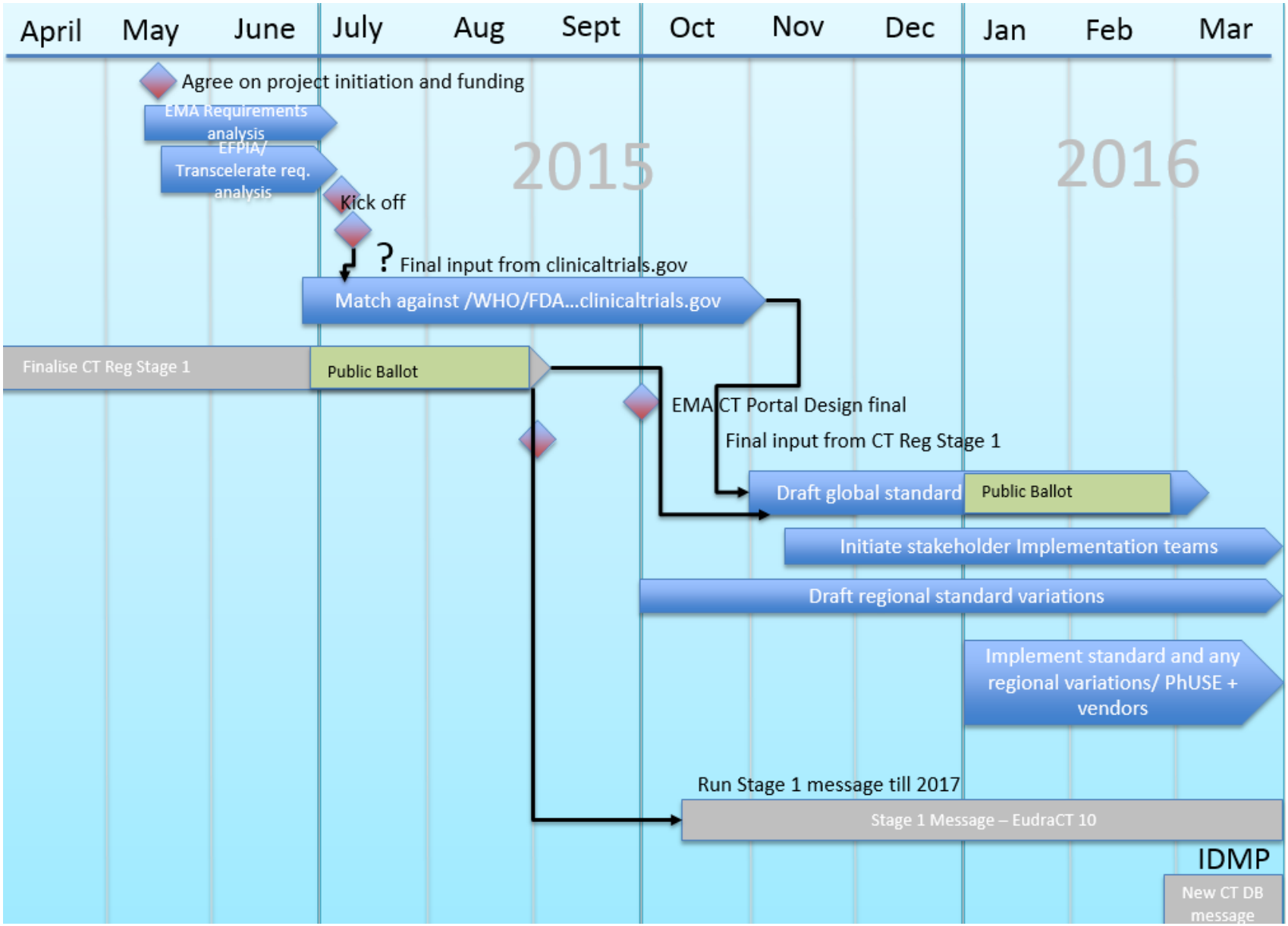
MIG(*) Minimal Information Guidelines

Clinical Trial Registration & Results

- Develop a draft standard, specification and XML-Schema to cover Clinical Trial Registrations of Study Designs to:Based on CDISC ODM 1.3.2

- Extended with the existing SDM-XML 1.0 (Study Design Model in XML)
- For very specific Eudra-CT content, incorporation of two Eudra-CT XML-Schemas

Clinical Trial Registration & Results



Other European Activity

- Talks with EMA on CTReg phase 1 and phase 2 – CTReg & Results (AdAM) and TA areas. Looking towards Patient Level Data standards wit phase 2.
- COMET initiative Core Competency Sets for TAs
- Recruitment – John Owen (Therapeutic Area Standards), Dorina Bratfalean (Data Management expert), Sue Smith (PA to CEF)
- Looking for case study and project with GA4GH to prove standards with API and MOU for consistency with BRIDG and template team.
- Collaboration with other SDO's and research organisatons, EBI, HL7, ISO, GA4GH, etc.

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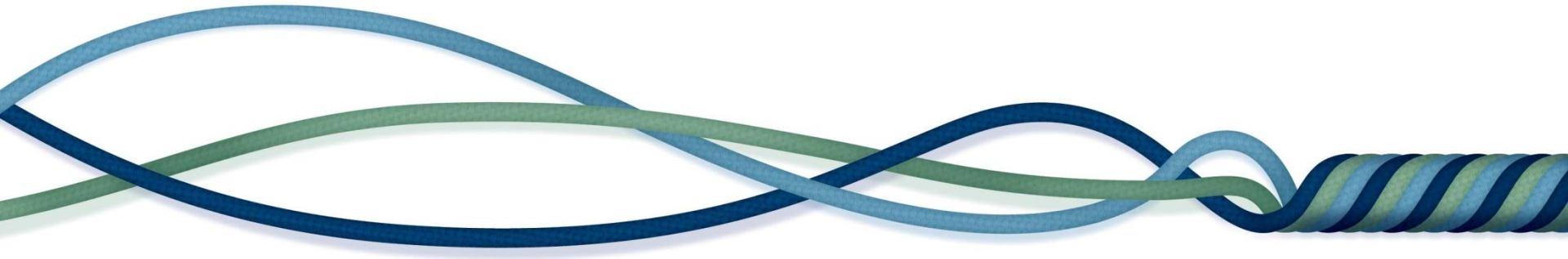

Strength *through collaboration.*