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

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.

“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

Diagram above illustrates the relationship between and different sizes of the varied groups that represent CDISC.
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, minimize 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.
<table>
<thead>
<tr>
<th>Therapeutic Area</th>
<th>Scoping</th>
<th>Modeling</th>
<th>Development</th>
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</table>
Adoption Trends for CDISC Standards (2004-2014)

2014 Data from recent Tufts CSDD Survey
My interests here today and beyond

- Pre-competitive 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](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](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](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
AstraZeneca  Roche  Johnson & Johnson  Bayer
Sanofi  GSK  Novo Nordisk  Pfizer
Lilly  Merck Serono

6 Partners
Imperial College London  CNRS  CON2P3  eisbm  idbs  mi.im
BioSci Consulting

eTRIKS (Oct 2012 – Sept 2017)
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 and IDBS. 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.

IMI Projects engaging eTRIKS

Oncology
- Colon  Prostate  Breast  Lung

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

Inflammation
- Severe Asthma  Rheumatoid Arthritis

RA-Map

Infection
- Tuberculosis

ND4BB
### 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.


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 Standards Starter Pack

The use of standards increases the value of your dataset as they make it easier to load your 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

<table>
<thead>
<tr>
<th>Work Package</th>
<th>WP Leads</th>
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<tbody>
<tr>
<td>Platform Service Delivery</td>
<td>CNRS/JPNV</td>
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<tr>
<td>Platform Development</td>
<td>Imperial/Sanofi/Pfizer</td>
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<td>Standards Research and Coordination</td>
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<td>Luxembourg/Sanofi</td>
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<td>Governance and Business Model</td>
<td>AstraZeneca/BioSci Consulting</td>
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<td>Community Engagement &amp; Outreach</td>
<td>Janssen/BioSci Consulting</td>
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<tr>
<td>Ethics for eTRIKS platform data</td>
<td>GSK/CNRS/Bayer/Sanofi</td>
</tr>
</tbody>
</table>

- Public–private partnership funded within the European Commission’s Innovative Medicines Initiative (IMI)
eTRIKS Standardization Activities

- Feb. 2014: eWP3 New Members
  - eTRIKS New Members
  - eTRIKS RT meeting, Berlin

- July 2014: eTRIKS WP3
  - Proposal for eTRIKS Metadata Registry
  - Starter Pack Release 1

- Oct. 2014: eTRIKS XWP meeting, Oxford
  - Request to access U-biopred Eclipse data

- Jan. 2015: eTRIKS annual meeting, Barcelona
  - WP3 Proposals & Roadmap

- Feb. 2015: WP3 deliverables: D3.2; D3.3; D3.4; D3.5; D3.8

- March 2015: eTRIKS annual meeting, Barcelona
  - WP3 Proposals & Roadmap
eTRIKS MetaData Registry Needs

Study Design UI →

Dataset templates (MIG based) →

New projects →

Collected Data →

Standard Organizations →

Legacy projects

Study owners’ files →

Annotated Data →

eTRIKS Metadata Registry →

Harmonization Update →

Harmonized data across projects →

tranSMART tree builder →

Harmonized Data repository →

Loader tools

MIG(*) Minimal Information Guidelines

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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

- Agree on project initiation and funding
- EMA requirements analysis
- Draft global standard
- Draft regional standard variations
- Run Stage 1 message till 2017
- Implement standard and any regional variations/PhUSE + vendors

2015

- Kick off
- Final input from clinicaltrials.gov
- EMA/CT Portal Design final
- Public Ballot

2016

Finalise CT Reg Stage 1

IDMP

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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 with 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 organisations, EBI, HL7, ISO, GA4GH, etc.
Strength through collaboration.