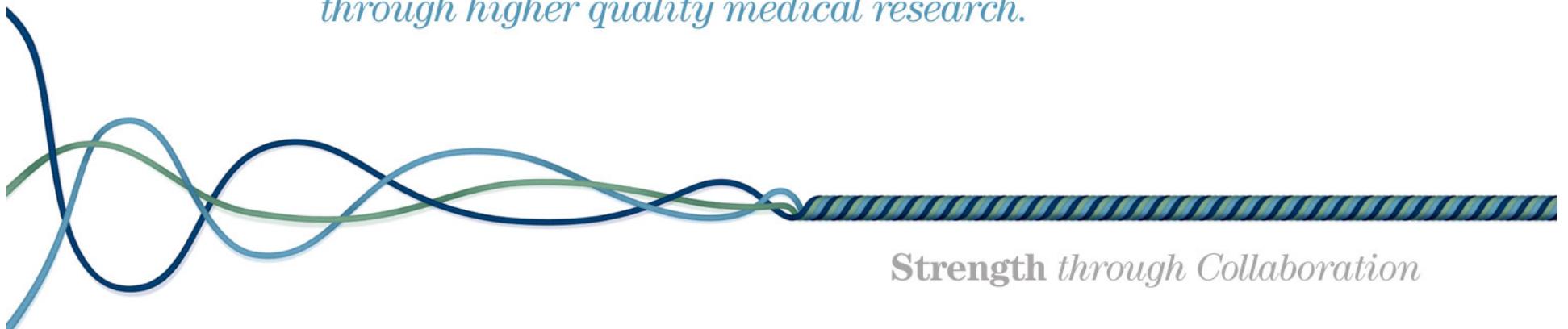




**CDISC®**

CLINICAL DATA INTERCHANGE STANDARDS CONSORTIUM

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



*Strength through Collaboration*

*"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

# 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.

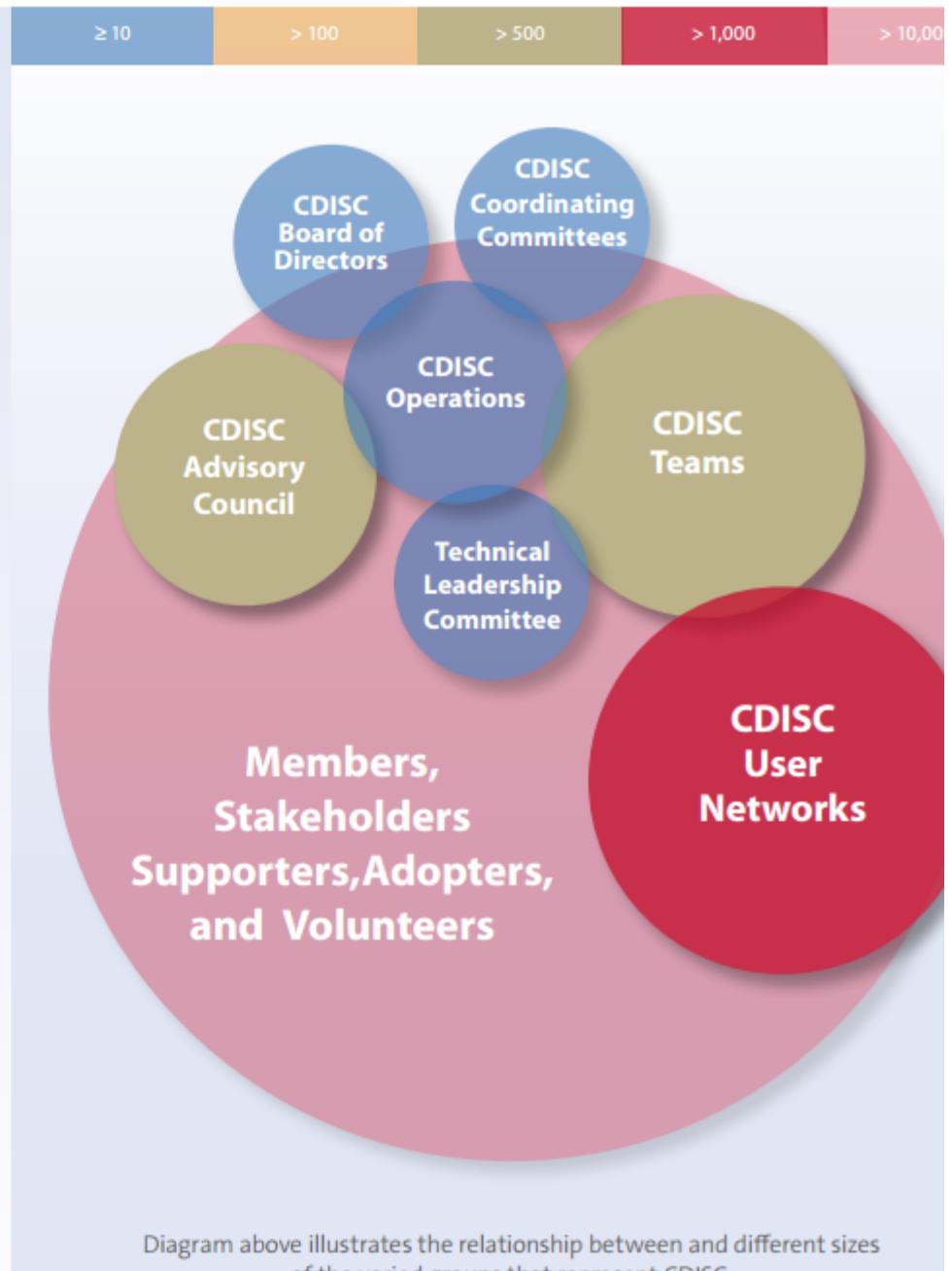
**CDISC Teams:** CDISC teams are composed of hundreds of volunteers from around the globe who develop, use and maintain the CDISC standards.

**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.

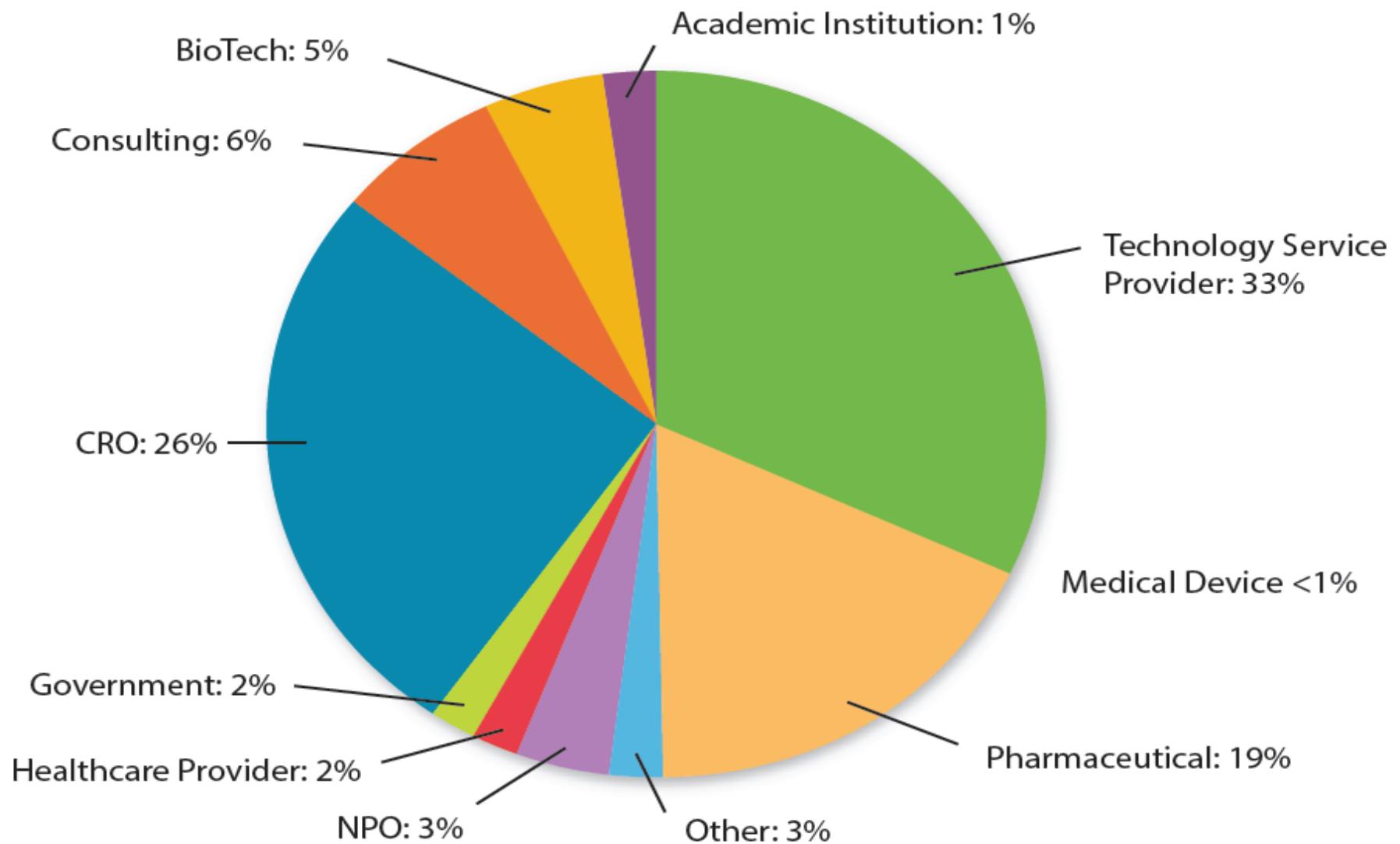
**CDISC Members, Stakeholders, Supporters, Adopters and Volunteers:** It would not be possible to develop the CDISC standards and demonstrate their value without the incredible support we have had from this increasingly large group of amazing individuals and organizations.

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



## Members by Industry



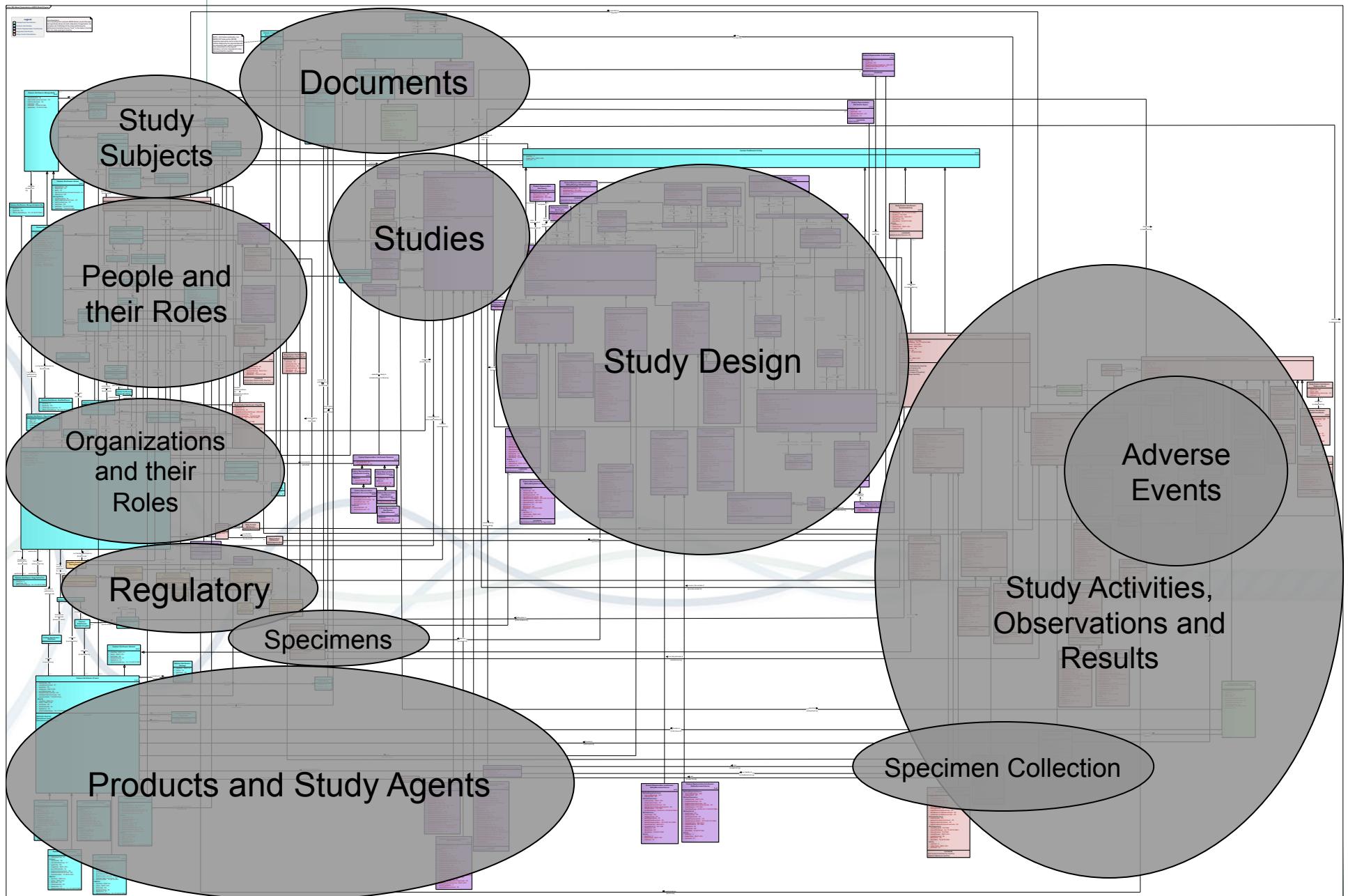


*Strength through Collaboration*



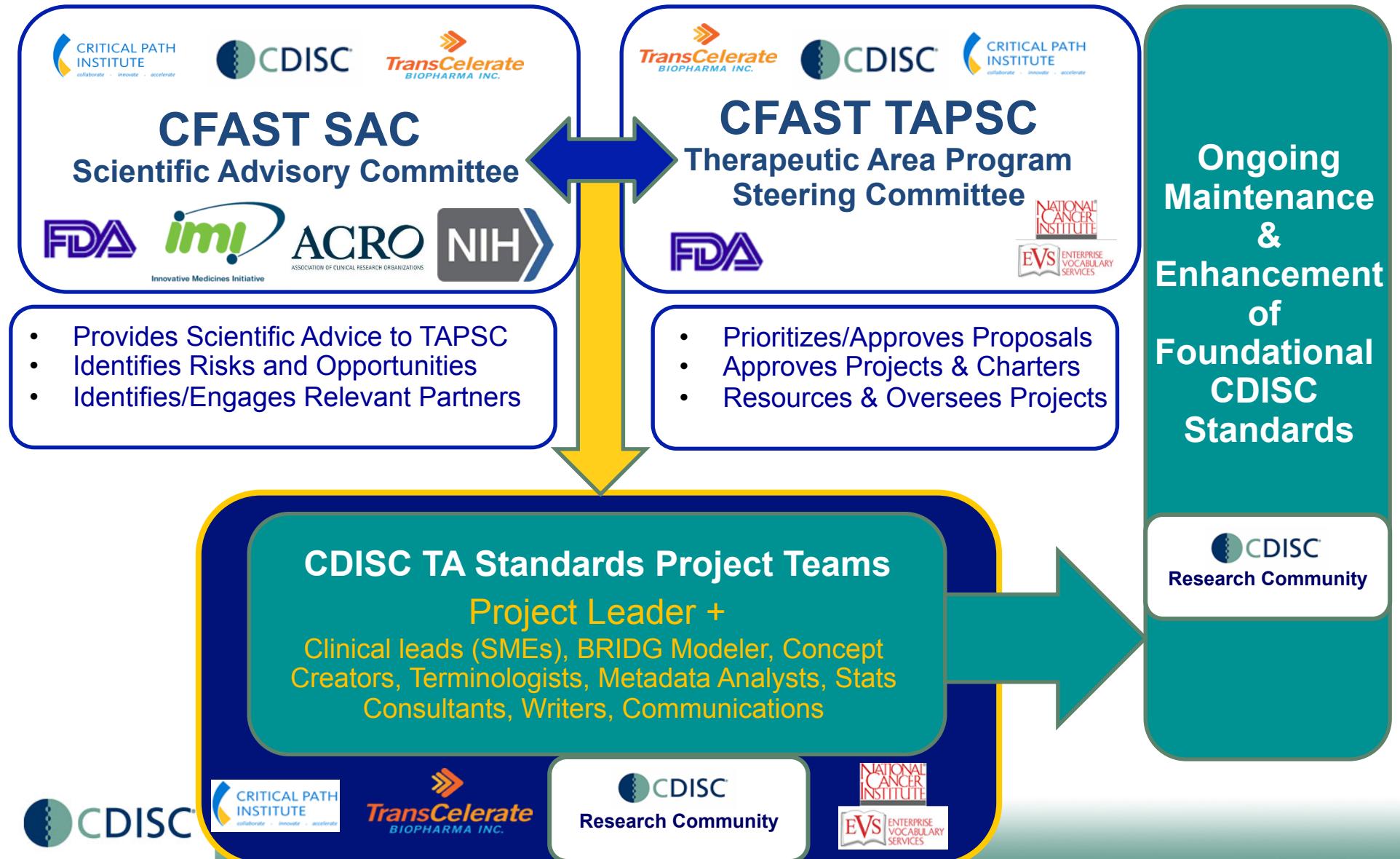
- ▶ **BRIDG Purpose:**  
A collaborative effort to produce a shared view of the dynamic and static semantics that collectively define a shared domain-of-interest.  
Harmonizes CDISC Standards and links to HL7 RIM.
- ▶ **Domain-of-interest/scope:**  
Protocol-driven research and its associated regulatory artifacts.
- ▶ **Stakeholders:**  
   
- ▶ **Governing body:**
  - ▶ BRIDG Steering Committee
  - ▶ BRIDG passed the ISO Draft International Standard Ballot (7 January 2015); soon to be a Final International Standard.

# Layer 2: UML-Based BRIDG Model





# CFAST Therapeutic Area Standards Governance





# CFAST Collaborations & Governance

## CFAST SAC Scientific Advisory Committee



Innovative Medicines Initiative

- Provides Scientific Advice to TAPSC
- Identifies Risks and Opportunities
- Identifies/Engages Relevant Partners

## CFAST TAPSC Therapeutic Area Program Steering Committee



- Prioritizes/Approves Proposals
- Approves Projects & Charters
- Resources & Oversees Projects

# How Important is Metadata?

Event	Time	D	S	F
Begin	9/23/99 02:01:00	121,900,000	12,300	143.878
End	9/23/99 02:17:23		9,840	

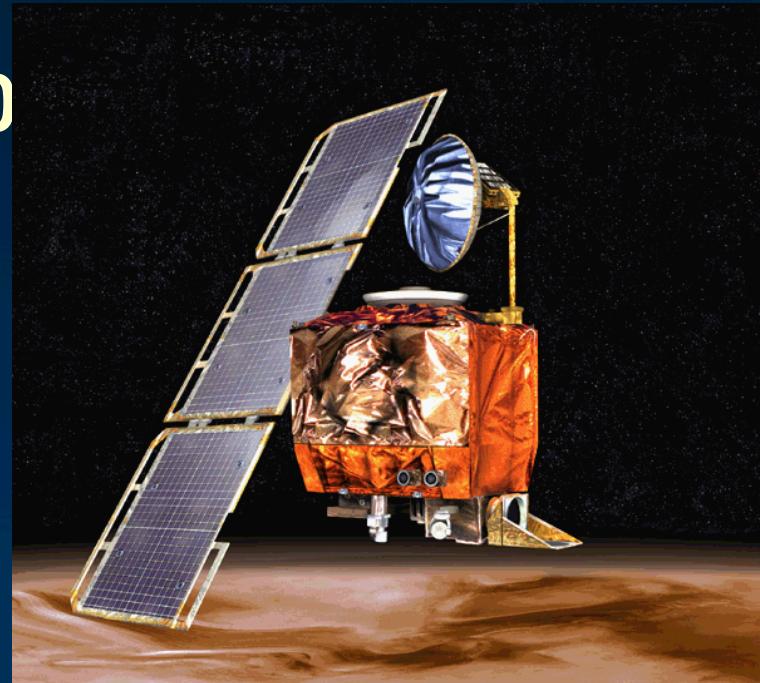
Event	Time	D	S	F
Start	19990923 05:01:00	196,200,000	5.5	640
Finish	19990923 05:17:23		4.4	

Slide developed by David Christiansen, DrPH

# In this case \$125,000,000 Mars Climate Orbiter

Scientists expected data in SI Units (International Standards);  
By mistake, they received data in Imperial Units...

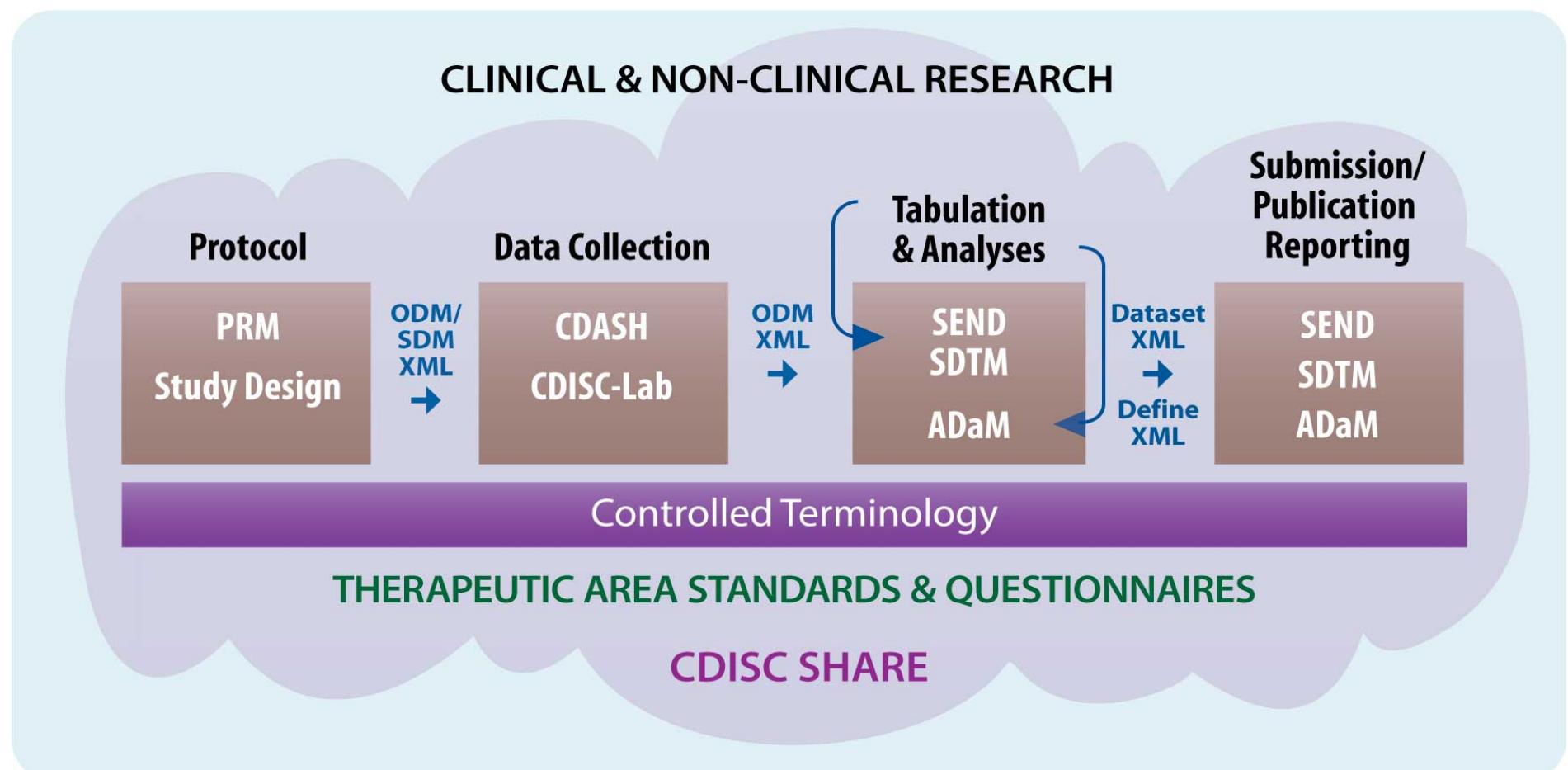
*The Orbiter crashed.*



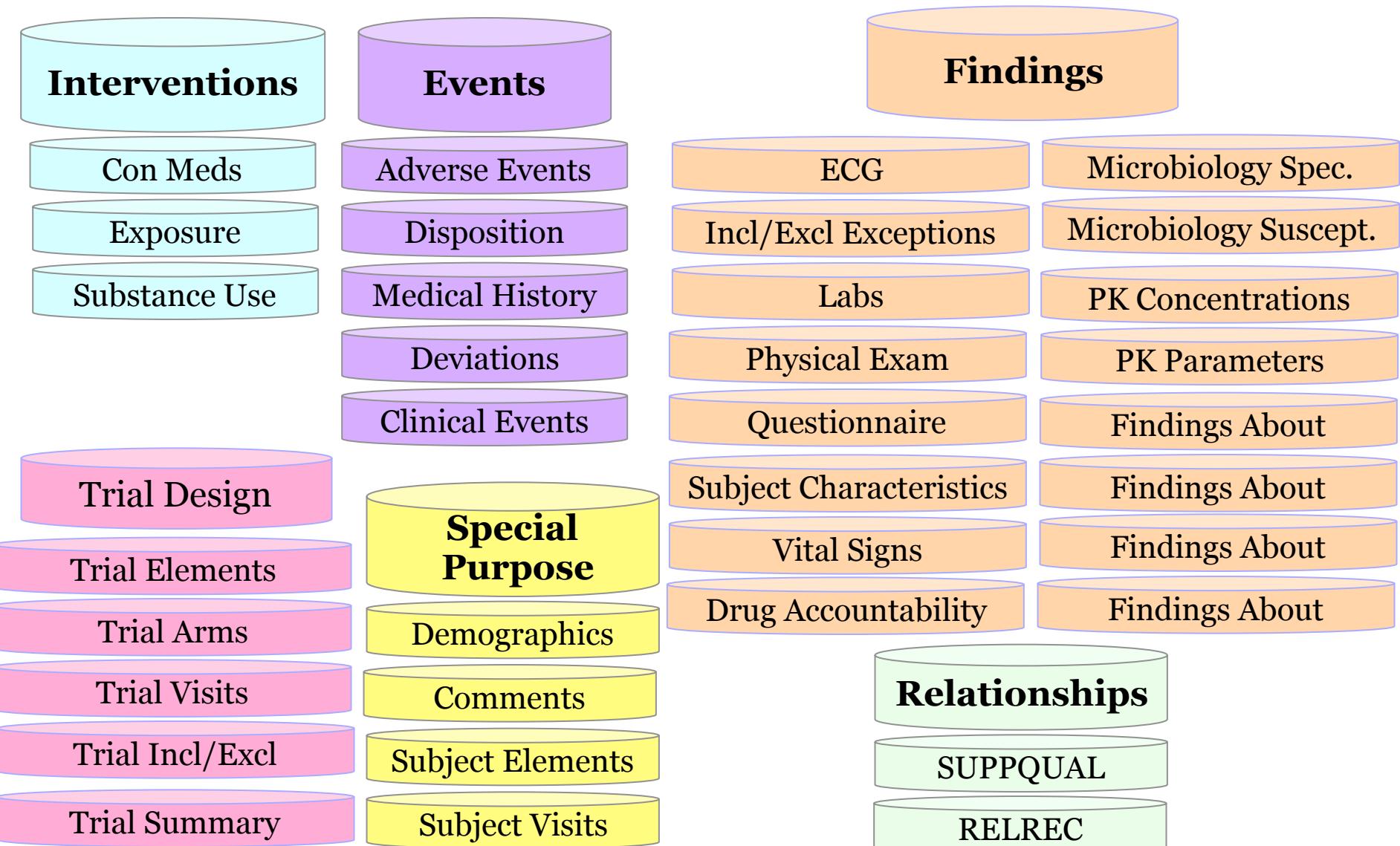
Mars Orbit Insertion Burn	M/D/Y HH:MM:SS PDT (Earth Receive Time, 10 min. 49 sec. Delay)	Distance (miles)	Speed (miles/hr)	Force (Pounds)
Begin	9/23/99 02:01:00	121,900,000	12,300	143.878
End	9/23/99 02:17:23		9,840	
Mars Orbit Insertion Burn	YYYYMMDD EDT (Earth Receive Time, 10 min. 49 sec. Delay)	Distance (km)	Speed (km/sec)	Force (Newtons)
Start	19990923 05:01:00	196,200,000	5.5	640
Finish	19990923 05:17:23		4.4	

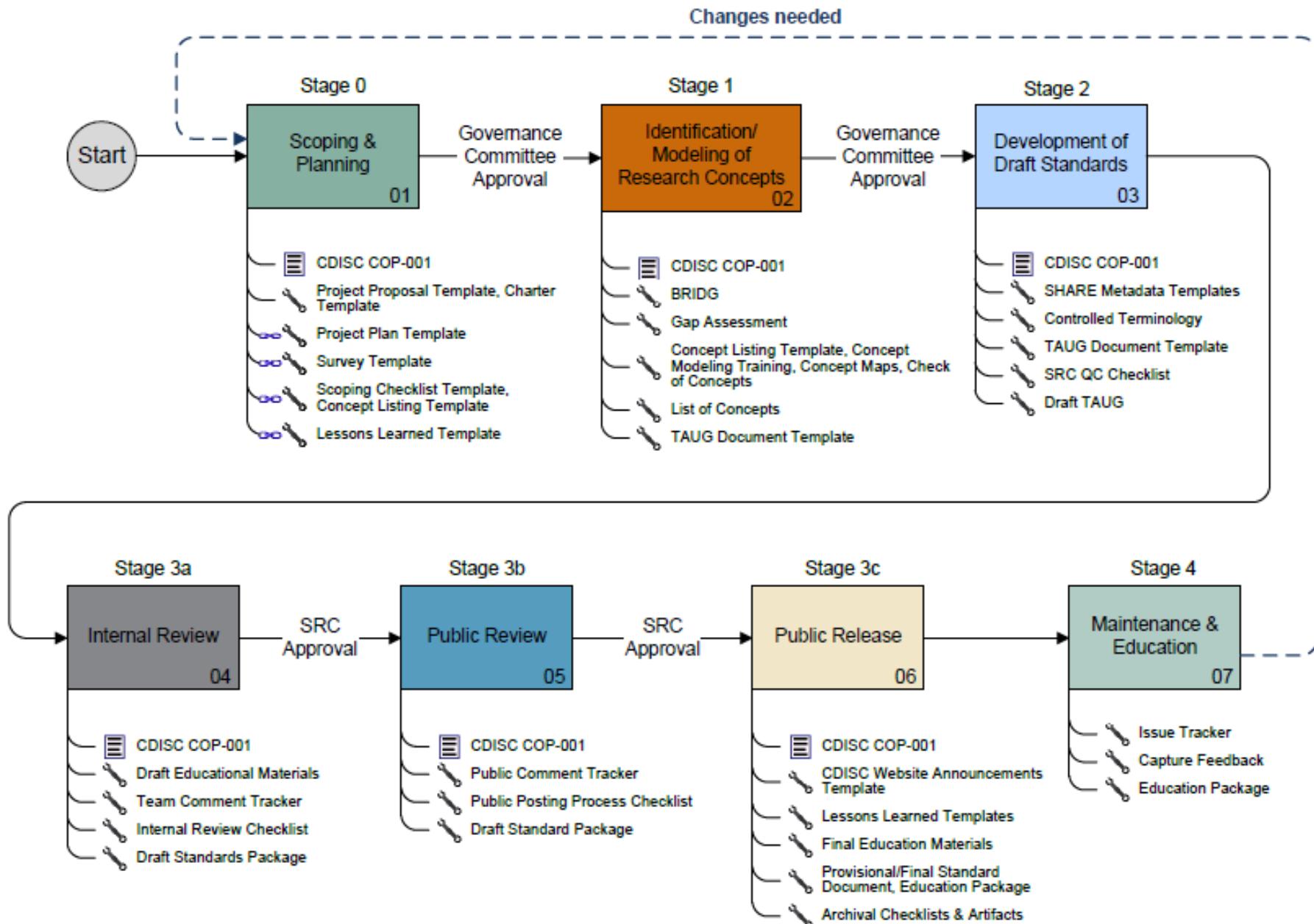
# Achieving Interoperability

BRIDG



# SDTMIG Standard Domains – v3.1.3





# CDISC Projects

- \* Protocol, CTR and BRIDG
- \* CFAST and SHARE
- \* IMI Projects
- \* Healthcare Link

*(in addition to foundational standards)*



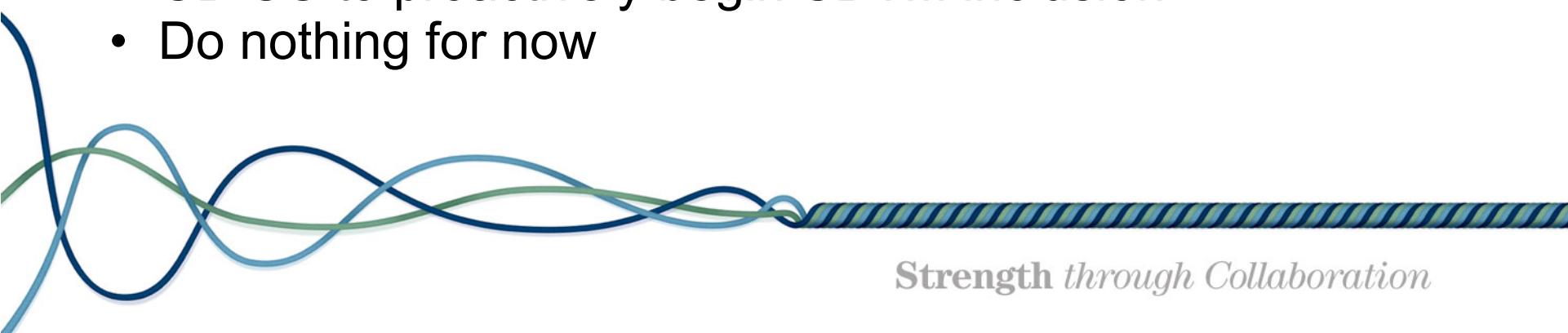
Global electronic repository for developing, integrating and accessing CDISC standards metadata in electronic format.

SHARE should dramatically improve the quality, accessibility, reusability and integration across CDISC standards and controlled terminologies, and improve interoperability with healthcare.

***SHARE is a requirement for standards-based automation, which is key to ROI from standards implementation.***

# Where will IDMP requirements come from?

- FDA mandating IDMP inclusion in CDISC datasets
- EMA to implement IDMP in their CT Application
- CDISC to extend CTR in CTR&R to include EMA requirements
- Sponsors of clinical Trials to request IDMP compliance in SDTM
- CDISC to proactively begin SDTM inclusion
- Do nothing for now



*Strength through Collaboration*

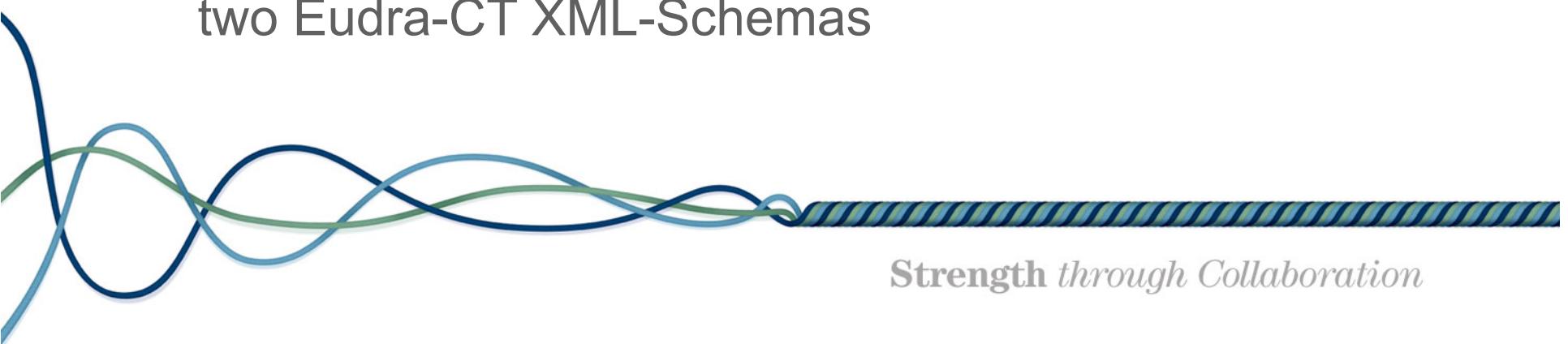
- EMA CTA already has a large set of data elements related to products and substances. So an XML placeholder for these has been left in the ODM CTR
- EMA will be reviewing their current model to be fully IDMP compliant in the future – 1 year after implementation
- IDMP model includes classes and links from Trial Registration to Investigational Medicinal Product to Substance.
- labeling, and manufacturing information is currently not covered by CDISC



*Strength through Collaboration*

# Clinical Trial Registration

- 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



# Goal of the project

- Develop a draft standard, specification and XML-Schema to cover Clinical Trial Registrations of Study Designs to:
  - ClinicalTrials.gov
  - Eudra-CT
- And obeys the 20 base requirements of the WHO
- Trial results is out of scope

EMA						
EudraCT Field	EudraCT Dictionary Field Name or Term	WHO TRDS Element or Term	Section	Data Element or Term	XML Parent Element	XML Child Element
<b>Trial Identification</b>						
1.1	Application MS	TRDS-11 for EEA trials			ctr:RecruitmentCountry	CountryCode
1.1	Application NCA					
2	EudraCT number	TRDS-01-TIN TRDS-01-PR = EudraCT	1	Secondary ID Secondary ID Issuing Organization Secondary ID Type = EudraCT Number	ctr:Registration ctr:Registration ctr:Registration	RegistrationID RegistrationAutho Type = primary
3	Full title	TRDS-10	1	Official Title	ctr:StudyNameLocalizations	odm:TranslatedTe
3.1	Lay person title	TRDS-09 TRDS-21	1 5	Brief Title Detailed Description	ctr:PublicTitle ctr:StudyDetailedDescription	odm:TranslatedTe odm:TranslatedTe
3.2	Abbreviated title	TRDS-10-TA	1	Acronym	ctr:BriefTitle	odm:TranslatedTe
4.1	Sponsor protocol code	TRDS-03-SIN for protocol number	1	Organization's Unique Protocol Id	odm:Protocol	ctr:ProtocolId
4.2	Sponsor protocol version				odm:Protocol	ctr:ProtocolVersio
4.3	Sponsor protocol version date				odm:Protocol	ctr:ProtocolVersio
4.4	Sponsor Protocol change date				odm:Protocol	ctr:ProtocolVersio
5.1	ISRCTN number	TRDS-03-SIN TRDS-03-IA = ISRCTN	1	Secondary ID Secondary ID Issuing Organization Secondary ID Type = Registry Identifier	ctr:Registration ctr:Registration ctr:Registration	RegistrationID RegistrationAutho Type = primary
5.2	US NCT number	TRDS-03-SIN TRDS-03-IA = NCT		ClinicalTrials.gov registry number	ctr:Registration	RegistrationID RegistrationAutho
5.3	WHO UTRN	TRDS-03-SIN TRDS-03-IA = UTN	1	Secondary ID Secondary ID Issuing Organization Secondary ID Type = Registry Identifier	ctr:Registration ctr:Registration ctr:Registration	RegistrationID RegistrationAutho Type = universal
5.4	Other Identifier Name	TRDS-03-IA			ctr:Registration	RegistrationAutho
5.4	Other Identifier	TRDS-03-SIN	1	Secondary ID Secondary ID Issuing Organization	ctr:Registration	RegistrationID Type
6	Is resubmission		1	Secondary ID Type		
6	Resubmission letter					
7	Trial part of a PIP					
8	PIP Decision number					
<b>Sponsor Identification</b>		TRDS-05 for first sponsor TRDS-06 for other sponsors			ctr:PrimarySponsor ctr:SecondarySponsor	OrganizationOID OrganizationOID
1	Sponsor Identification Details					
1.1	Sponsor Organisation	TRDS-03-IA for protocol number	3	Sponsor	ctr:Organization odm:User	Name odm:Organization
1.2	Sponsor Contact					
1.2.1	Sponsor Contact Given name				odm:User	odm:FirstName
1.2.2	Sponsor Contact Middle name					
1.2.3	Sponsor Contact Family Name				odm:User	odm:LastName
1.3	Sponsor Address				ctr:Organization odm:User	odm:Address odm:Address
1.3.1	Sponsor Street Address				odm:Address	odm:StreetName
1.3.2	Sponsor Town/City				odm:Address	odm:City
1.3.3	Sponsor Post Code				odm:Address	odm:PostalCode

# Schema components

- Based on CDISC ODM 1.3.2
- Extended with the existing SDM-XML 1.0 (Study Design Model in XML)
  - Especially for Trial Parameters (sdm:Parameter)
- Additional elements for common CT.gov-EudraCT-WHO content, not already covered by ODM
- For very specific Eudra-CT content, incorporation of two Eudra-CT XML-Schemas

# Testing of the XML-Schema

- Fitness of XML-Schema was tested by automated generation of Java classes (“beans”), and by automated generation of GUI elements

The screenshot shows the CDASH (Clinical Data Analysis SHell) application. The top menu bar includes File, CDASH, Edit, Add, Validate, View, Options, and Help. Below the menu is a toolbar with icons for folder, file, and other operations. A navigation bar contains tabs for Global Study Variables, Basic Study Definitions, Study Metadata, Authorities, medicinal\_product\_information, population\_information, Item Definitions, Codelists, Imputation Methods, Presentations, Conditions, Method Definitions, Recruitment (which is highlighted in yellow), Interventions, OutcomeMeasures, Includes, Protocol/Trial Design, Study Event Definitions, and Form Definitions. A search icon is located on the far left of the toolbar. A modal dialog box titled "Extra information for: Recruitment" is open, showing a table with columns for Country and CurrentStatus. The CurrentStatus column has a dropdown menu open, displaying options: Pending, Pending, Recruiting, Suspended, Complete, and Other. The CDISC logo is visible in the bottom left corner of the application window.

Country	CurrentStatus	RecruitmentStartDate	RecruitmentEndDate	EstimatedRecruitmentDu...
[empty]	Pending			
[empty]	Pending			
[empty]	Recruiting			
[empty]	Suspended			
[empty]	Complete			
[empty]	Other			

CDISC

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23

# What can it be used for?

- Software vendors can develop software that provides a “develop once, submit multiple” solution, i.e.
- One software tool for generating CTR submissions to as well ClinicalTrials.gov as to Eudra-CT as to WHO etc...
- Starting from scratch or from an existing Study Design in ODM

## Current status of CTR

- Internal review by the CTR team completed
- Internal review by the XML-Tech team completed.
- public review October 15-Dec15
- Publish Jan 2016

# Next Up – CTR&Results

- to match up the current and ongoing development of requirements of regulatory bodies and registries of the world. All will be invited and all SDOs will be consulted to define the best supporting standards to use
- Further drive to harmonise the inputs that government and industry systems use to register clinical trials. Ensure that industry can update as many registries around the world with the touch of a button with core information sets that are consistent and that are using data that is globally compliant to international standards and legislation.

# The Challenges for CTR2

- Usual international collaboration
- Political backdrop to clinical trial data availability
- Evolving requirements of NIH and EMA
- Different legislative procedures and environments

