CDISC Evolution

CJUG SDTM Meeting

Thursday, September 7, 2017

Clinical Data Interchange Standards Consortium (CDISC)

- >435 organizational members
- Community consensus standards development for clinical & translational research
- Ongoing global research support in the Americas, Europe, Japan, China, India, Korea and other regions
  - Standards downloaded in 90+ countries

www.cdisc.org

CDISC Evolution

- Redefining CDISC Standards Products
- Piloting Final Release Eligibility
- Updated COP-001 Standards Development
- More Transparency into Standards Development and Documentation
- NEW COP-019 Volunteer Engagement
- Volunteer Training

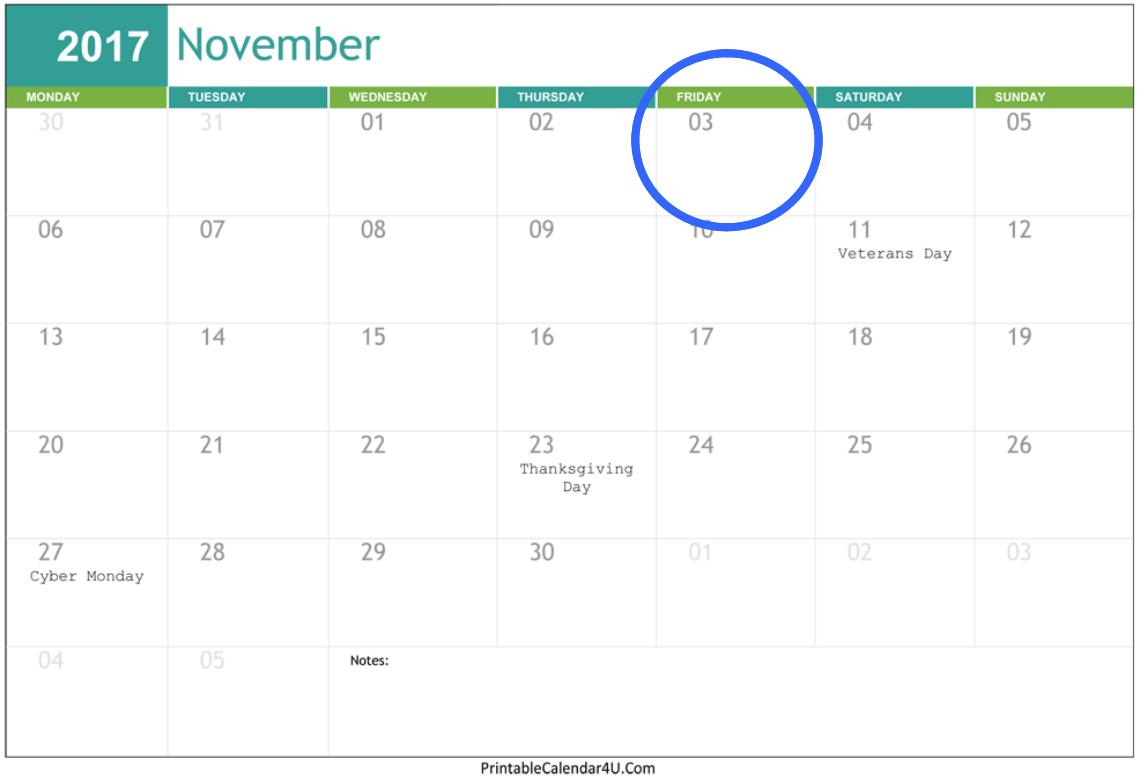
Redefining CDISC Standards Products

Evolution of what makes a CDISC product?

- Historically: PDF
  - Not readily discoverable through web searches
  - Not machine-readable
    - Implementers have to hand-extract content, which is error-prone
  - Asynchronous development (CT, training, SHARE metadata) created incomplete standards and challenges for implementers
- Evolving:
  - New file formats (e.g., HTML)
  - Fully-reviewed and governed standard per CDISC Operating Procedures (CT, conformance rules)
  - Metadata in CDISC SHARE
  - Education learning outcomes defined

Piloting Final Release Eligibility

Predicable Product Release Schedules



- Teams define work packages with CDISC
  - May be quick, 1 year releases or take 3-5 years
- **Annual 1st Friday in November** Final Foundational Standards Release
  - *Eligible* standards products only
  - Every standard will not have an update each year
- Continue **Quarterly** CT releases and **Ad hoc** TA User Guide releases
  - TA Status may initially be Provisional

Annual November Final Standards Release Day Eligibility

- Readiness Eligibility criteria:
  - All Development, Public Review, Updates completed and QCd
    - Standard, CT and conformance rules
  - Metadata in SHARE ready to export
  - Learning outcomes developed with Education and approved by team
- Foundational standard products that meet these criteria by a defined cut-off date (e.g., August 31) each year **will be eligible** for publication as Final on the Annual Release Day

What about CT and TAUGs?

- CT will continue to publish quarterly
- TAs that are fully represented in final, published foundational standards will have their status changed from Provisional to Final on Annual Release Day
- Miss the cut-off dates? No problem!
  - Release complete product as Provisional when it is ready
  - Change status to Final the next November

2017 Transition Period
Publish What We Have Started

Standard	Current status
CDASH Model v1.0 and CDASHIG v2.0	Very close to publication; estimated 2-3 weeks
SDTMIG v3.3	Publication estimated Q3 or early Q4, depending on volunteer availability
SDTMIG Disposition Events	Will be incorporated into SDTMIG v3.3
Define-XML v2.1	Publication estimated Q4
BRIDG v5.0	Comments being addressed
SDTM 1.6 & Final SENDIG-DART	Comments being addressed
SEND Confirmed Endpoints document	Comments being addressed
TAUG Updates Group 1	Publication estimated for Influenza v1.1, Virology v2.1 and Asthma v1.1 late July or early August
TAUG Duchenne Muscular Dystrophy	Publication estimated in September
TAUG Vaccines	Publication estimated in September

Providing More Visibility Into What's Coming Next

- Working on a method to publish information on website and/or Wiki about which standards are
  - In Development
  - Coming out soon for public review
  - Slated for publication during annual release
- Other transparency projects include
  - List of all draft and published domains and where to find them
  - Relationships between standards documents (e.g., SDTM V1.4 + SDTMIG V3.2, CDASH V1.1 + SDTMIG V3.1.2)
  - "Why is this TAUG provisional?"

New and Updated Policies and Procedures

COP-001 Standards Development

COP-019 Volunteer Engagement

Where to find CDISC Policies / COPs

www.cdisc.org/about/bylaws

COP-001 Standards Development

- Based on original COP-001, but expanded with more details and governance
  - Planning and scoping
  - Development, governance and escalation
  - Required review cycles
  - Education and SHARE deliverables
- Defines status
  - Draft
  - Provisional
  - Final
- Modeling governance will occur earlier in the process (New Global Governance Group - GGG)

Early Modeling Governance

- Current governance teams (SGC, CGC, SRC…) will collaborate on modeling decisions through a new joint Global Governance Group
- Representatives from each foundational team will “sign off” on the decision on behalf of their team
- This will allow us to
  - harmonize and align modeling decisions across standards before internal review
  - get to public review more quickly once a standards document is drafted
- There will still be an approval step at the end, but will be more focused on the publication of a well formatted, high quality document.

COP-019 Volunteer Engagement

- Establishes expectations for volunteer participants
- CDISC will:
  - accept applications and connect new volunteers with the respective teams
  - Provide initial volunteer training
- Team leadership will:
  - Provide meeting information
  - Help CDISC determine active participation
- Succession planning for team leadership
- Volunteers should actively, productively contribute
- Volunteers should collaborate respectfully
  Tracking volunteer hours (legal requirement)

Volunteer Monthly Hours Tracking

More On Volunteer Hours Tracking

- Internal purpose: So we know how much time we spend on each project
  - Make sure we're focusing on the right priorities
  - Ensure teams are appropriately staffed
  - Identify need for additional support
  - Improve planning accuracy
- External purpose: reporting to stakeholders
  - Being able to communicate to the CDISC community the importance of volunteers and volunteer work
  - Complying with legal requirements: reporting volunteer work in our Form 990
- Longer term: being able to formally recognize individual volunteer engagement

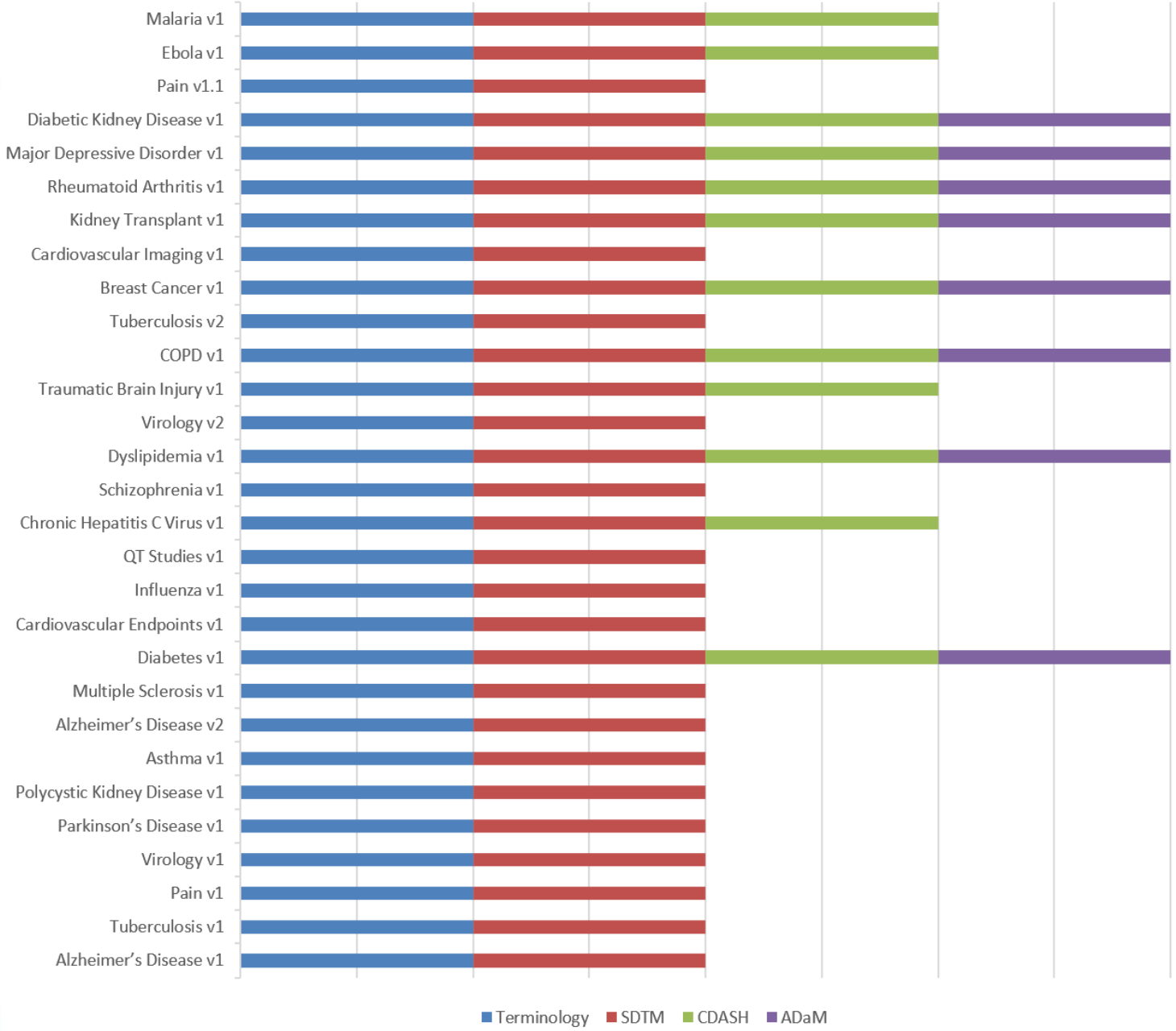
Evolving the Development Process

- CDISC staff will provide project management support for foundational teams
- Foundational teams are documenting development principles
- Escalation process will allow us to move past impasse
- Cross-team modeling governance will occur earlier in the process
  - Global Governance Group (GGG)

Therapeutic Area (TA) & Indication Standards

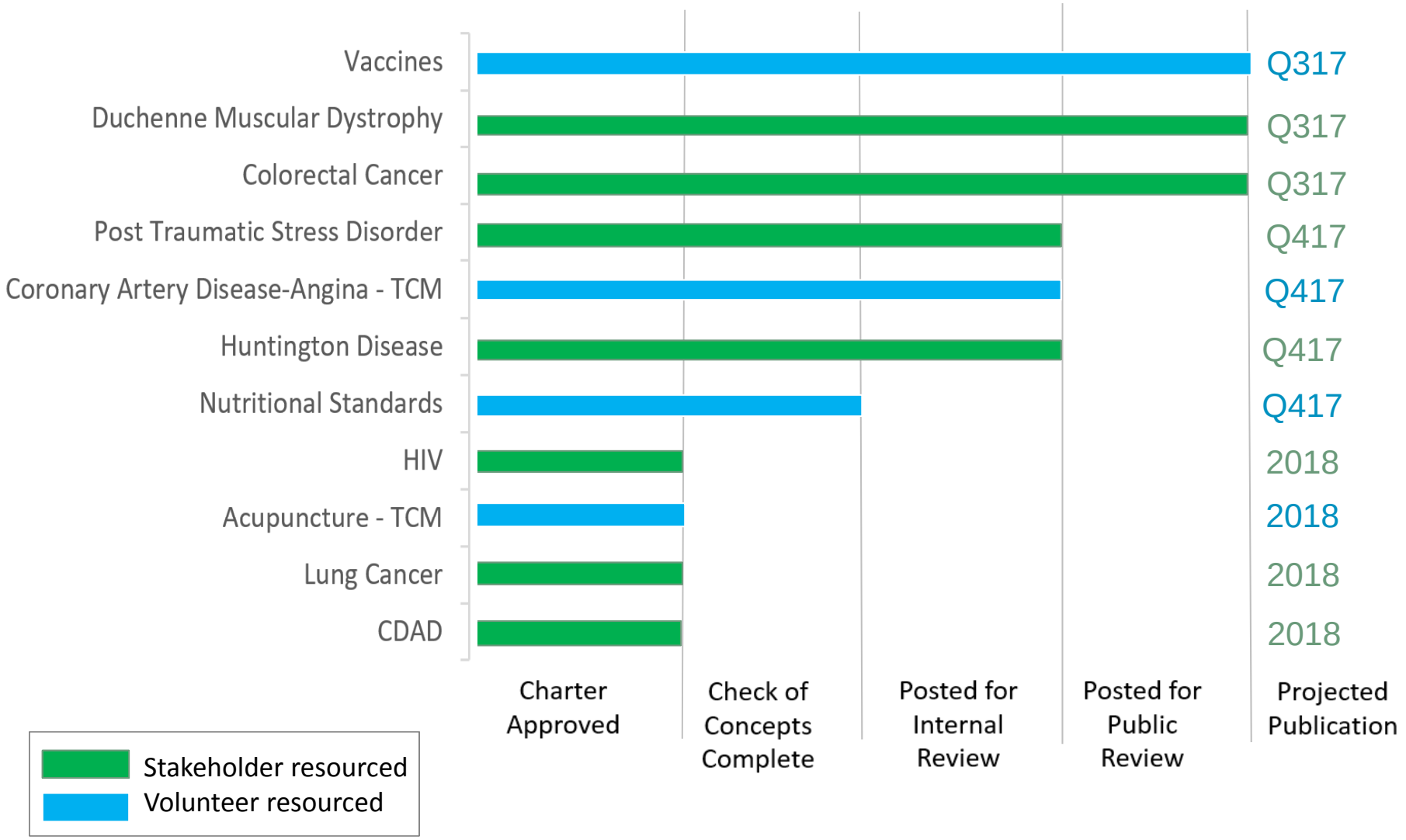
TAs Extend Foundational Standards

2016



2011

Therapeutic Area Current Projects



TA-Specific Extensions Include

Oncology	Infectious Diseases	Mental & Behavioral Disorders	CV	Neurology	Chronic Respiratory Diseases	Auto-immune Diseases	Endocrinology	Other
Breast Cancer v1	Tuberculosis v1 Tuberculosis v2, *Gates*	Schizophrenia *FDA*	Dyslipidemia v1	Parkinson's Disease v1	Asthma v1	Rheumatoid Arthritis v1	Polycystic Disease v1 University of Rochester	Pain v1 *University of Rochester*
Prostate Cancer v1 FDA	Influenza v1	Alzheimer's v1, v2	CV Endpoints v1 *FDA*	Multiple Sclerosis v1 *MS Society*	COPD v1		Diabetes v1	*Solid Organ (Kidney Transplant) v1* FDA
Colorectal Cancer v1 FDA	Hepatitis C, v1 *FDA*	Parkinson's v1	CV Imaging v1	**Duchenne Muscular Dystrophy v1**			Diabetic Kidney Disease v1	
Lung Cancer v1 FDA	Virology v1, v2 *FDA*	Traumatic Brain Injury v1 *One Mind*	QT Studies v1	**Huntington's Disease v1**				
	Malaria v1 Gates / WWARN	Major Depressive Disorder v1 FDA		***Parkinson's v2***				
	Ebola v1	Post Traumatic Stress Disorder v1 Cohen Veterans Bioscience						
	Vaccines v1	Bi-Polar v1						
	HIV v1 **NIAID & FDA**	General Anxiety Disorder v1						
	CDAD **FDA**							
4	*9*	*8*	4	5	2	1	3	2

Bold - ongoing
Planned

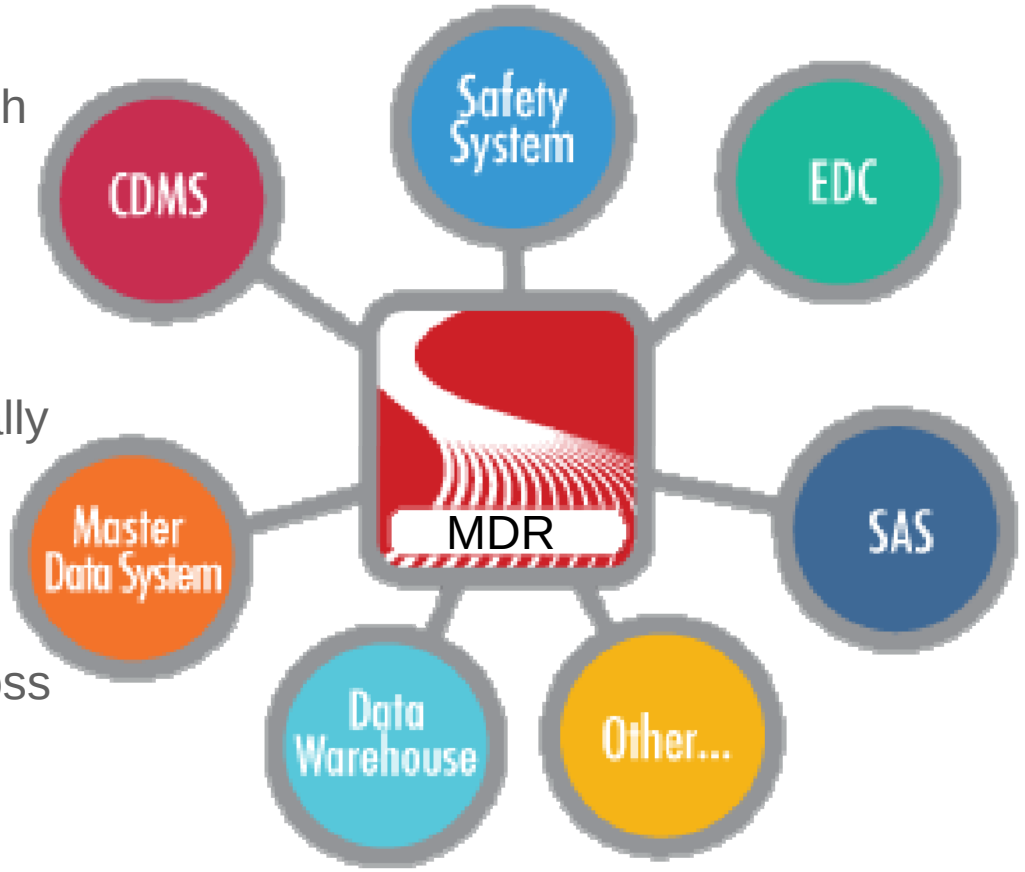
SHARE

Supporting Standards Development and Implementation

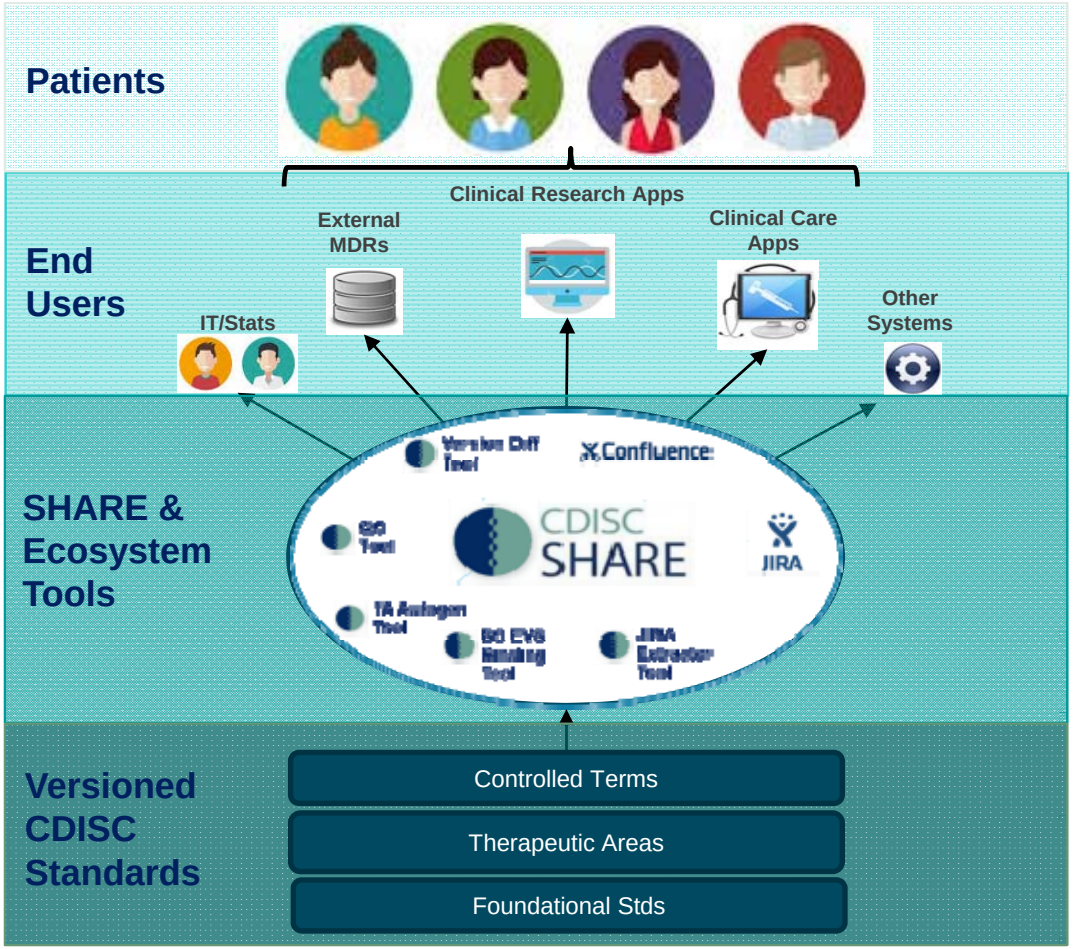
Typical Research Organization's MDR

Benefits

- Deploy the same metadata through multiple electronic systems
- Define common data via shared metadata in multiple systems, traceability
- Synchronize metadata automatically across multiple systems
- Version control
- Multiple language/dialect support
- Consistency & quality of data across systems
- Facilitated interoperability & data aggregation/reporting
- Up-front investment, downstream savings

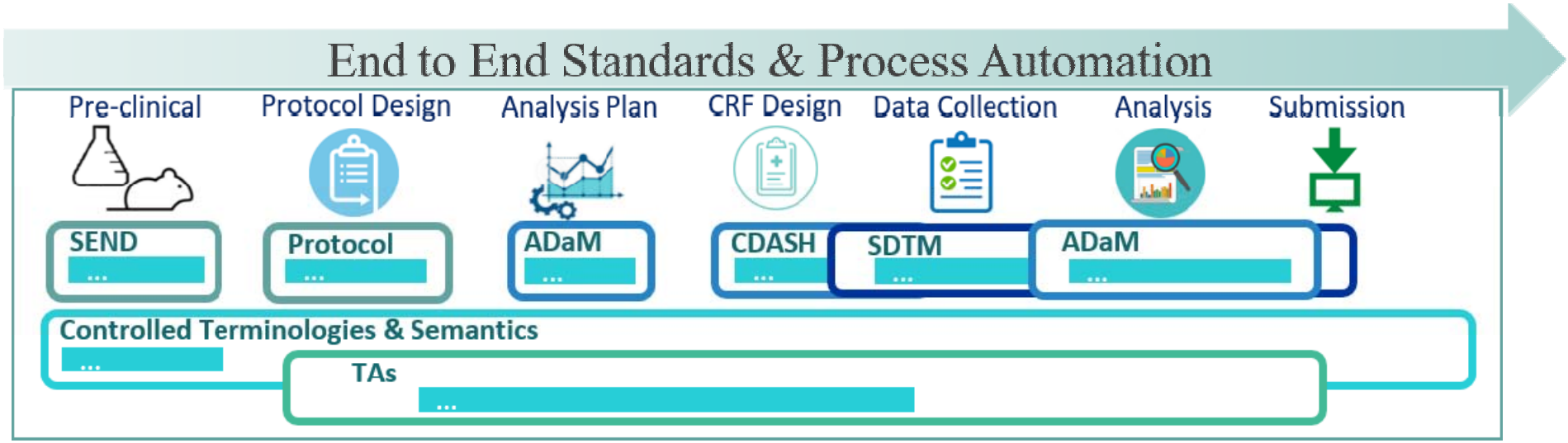


CDISC SHARE MDR



Benefits of SHARE

- Support reuse and management of standards
- Meaningfully exchange health research data
- Over time, reduce costs
- Maintain compliance of data submission to FDA, PMDA



Moving Toward Biomedical Concept-Driven, Linked-Data Standards

MH=Medical History FA=Findings About

Medical History of Parkinson's Disease (PD)

[Study Name/ID pre-filled] Site Name: _____

Subject ID: _____

Date Medical History Taken: ____/_____/20_____ (mm dd yyyy) MHDTC

1	Year of First Symptoms as confirmed by history obtained by the physician? ____ QNAM=MHOSDTC in SUPPMH QLABEL= Onset of Symptoms
2	Year of Initial Diagnosis? _____ MHCAT=PRIMARY DIAGNOSIS MHTERM=Parkinson's Disease
3	Diagnostic Features/Criteria (as evident on clinical assessment of the patient): MHCAT=PARKINSON'S DISEASE MHSCAT=DIAGNOSTIC CRITERIA MHPR 4-6 Hz Rest Tremor: MHTERM ☐ Present ☐ Absen Bradykinesia: ☐ Present ☐ Absen Rigidity: ☐ Present ☐ Absen Asymmetric Onset: ☐ Present ☐ Absen Substantial Response to Dopaminergic Therapy: ☐ Present ☐ Absen
4	Degree of Certainty of Diagnosis of PD: FACAT= MEDICAL HISTORY ☐ 90-100% Certain FAOBJ= PARKINSON'S DISEASE ☐ 50-89% Certain FAORRES when FATESTCD=DEG ☐ 10-49% Certain ☐ 0-9% Certain FAORRES for FAT Other important diagnostic alternative(s) (give reason):_____
5	Initial Motor Symptoms, i.e., as described by the patient (please check all that ap MHCAT=PARKINSON'S DISEASE MHSCAT=INITIAL MOTOR SYMPTOM MHTERM MHPRESP=Y MHOCCUR=Y/N ☐ Tremor (including internal tremor) ☐ Stiffness ☐ Change in facial expression ☐ Disturbances of dexterity ☐ Micrographia

PD Version 1.1

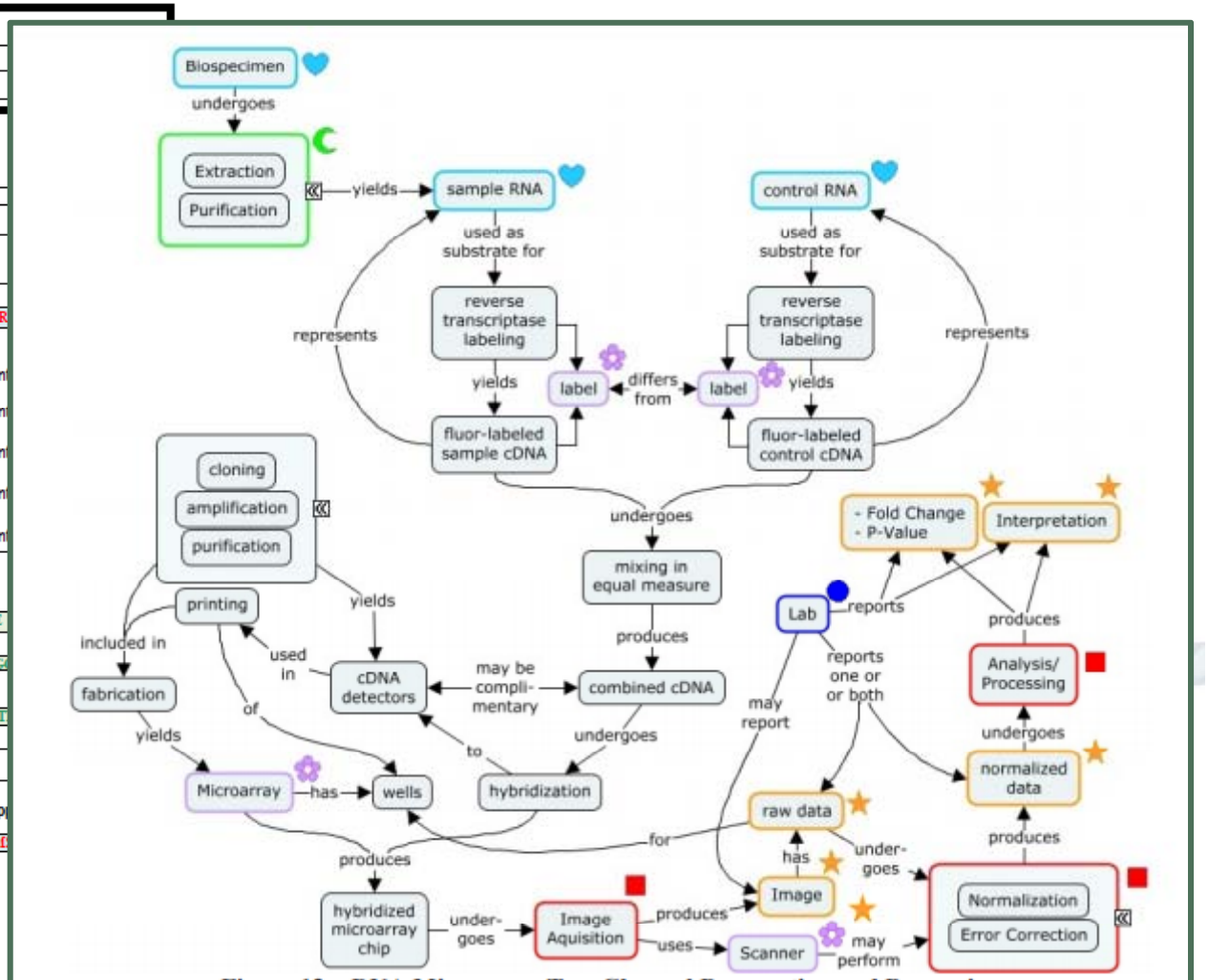
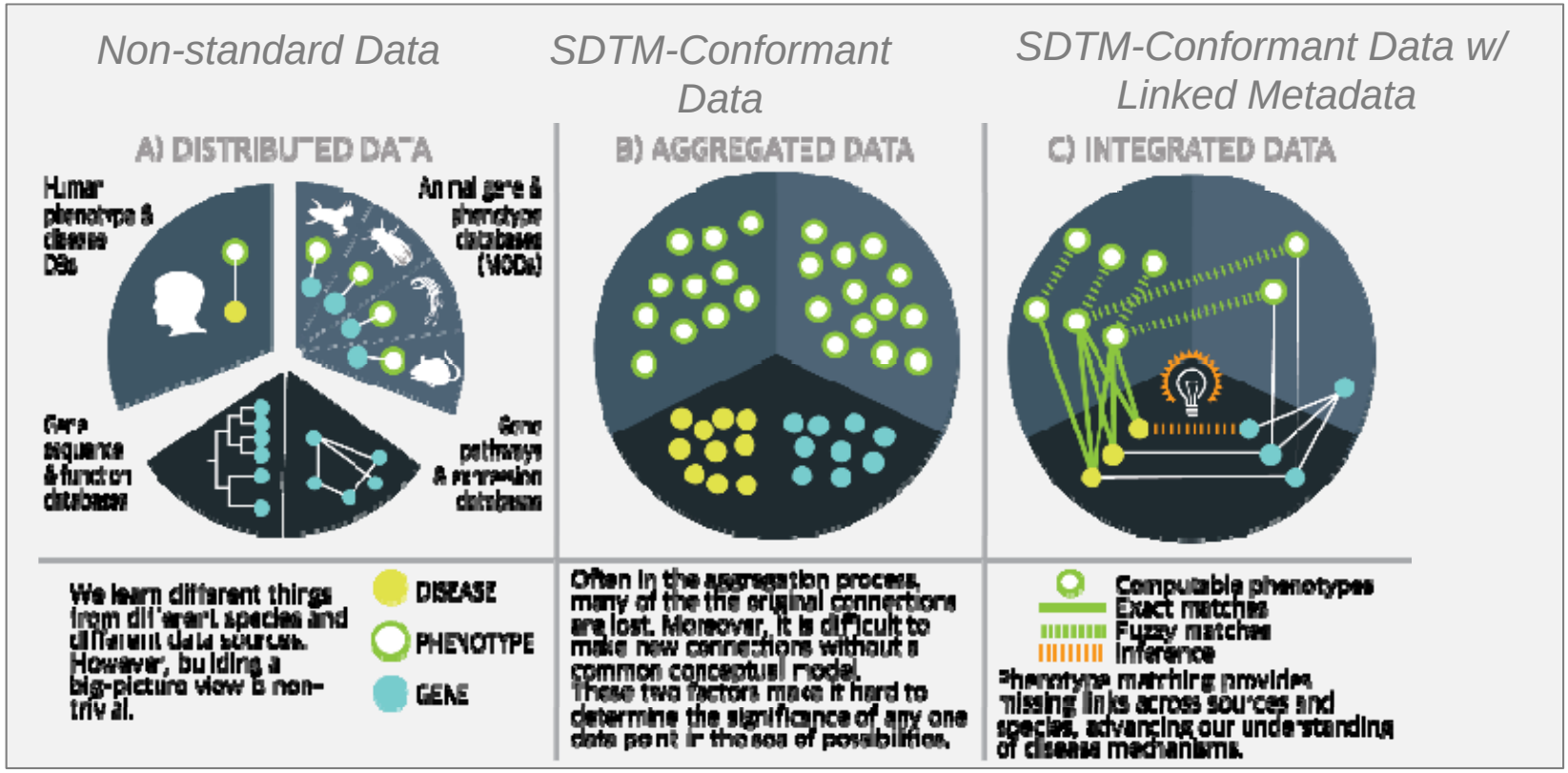


Figure 12: cDNA Microarray Two Channel Preparation and Processing

Modeling of microarray preparation is based upon protocols outlined by the National Human Genome Research Institute (NHGRI) at: http://research.nhgri.nih.gov/microarray/protocols.html. Methodologies may vary.

Biomedical Concepts & Ontologies Can Drive Big Data Analyses



From Haendel, M. http://www.scidatacon.org/2016/sessions/14/paper/315/

Volunteer Training

Volunteer Training

- Setting clear expectations through a review of policies and procedures that apply to volunteers
  - 001 Ethics and Conflict of Interest Policy
  - 003 Intellectual Property Policy
  - COP-001 Standards Development
  - COP-005 Education
  - COP-019 Volunteer Engagement (NEW)
- Asking all volunteers to complete and document training by Q4

What's in all these changes for you?

- We are listening to our community
- We are responding and evolving
- You are AWESOME and we want to honor you by
  - Producing and supporting quality standards
  - Providing more support to teams and leadership
  - Providing more transparency and predictability for implementers
- Small changes can have big impacts

We hope ALL of you will come along with us for this next stage in the CDISC Evolution

Upcoming Events

SAVE THE DATE

https://www.cdisc.org/events/interchanges

SAVE THE DATE

SAVE THE DATE

CDISC Membership

Europe CDISC Members

aCROnordic	Actelion Pharmaceuticals Ltd	AdClin	Almirall, S.A.
Assero Limited	Assign Data Management and Biostatistics GmbH	AstraZeneca AB	ATLANSTAT
Atlant Clinical Ltd.	AXIODIS	Basilea Pharmaceutica International Ltd.	Bayer Pharma AG
Bioforum Ltd.	bioskin GmbH	BioStata ApS	Biotrial Biometrics
Blueclinical, Ltd.	Beohringer Ingelheim Pharmaceuticals	Business & Decisions Life Sciences	Capish Nordic AB
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CROSS Metrics SA	CRS Clinical Research Serivces Mannheim GmbH	CTEP (RealWorldEDC) Ltd	Danone Nutricia Research
Data MATRIX, Ltd.	Data Standards Decisions Aps	DATAMAP GmbH	Ennov Clinical
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Europe CDISC Members

GSK	H. Lundbeck A/S	Hands-on GmbH	Helsinn Healthcare SA
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Europe CDISC Members

PHASTAR	Philip Morris Products SA	Plus-Project	Profil Institut fuer Stoffwechselfforschung
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Quotient Clinical	Quretec, Ltd	RCTs	Robertson Centre for Biostatistics
S-cude ApS	SAM GmbH	SanaClis s.r.o	Sanofi
SGS	Shire Pharmaceuticals, Inc.	Signifikans Aps	Simbec Research Ltd
SyMetric	Syne qua non Ltd	TELEMEDICINE TECHNOLOGIES S.A.S	TFS
TMF – Technology, Methods and Infrastructure for Networked Medical Research	Trium Analysis Online GmbH	UCG Biosciences, Inc.	University of Luxembourg
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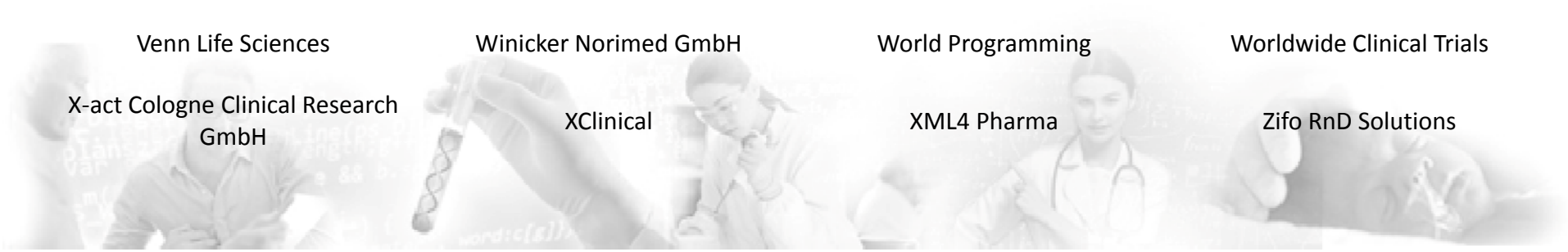
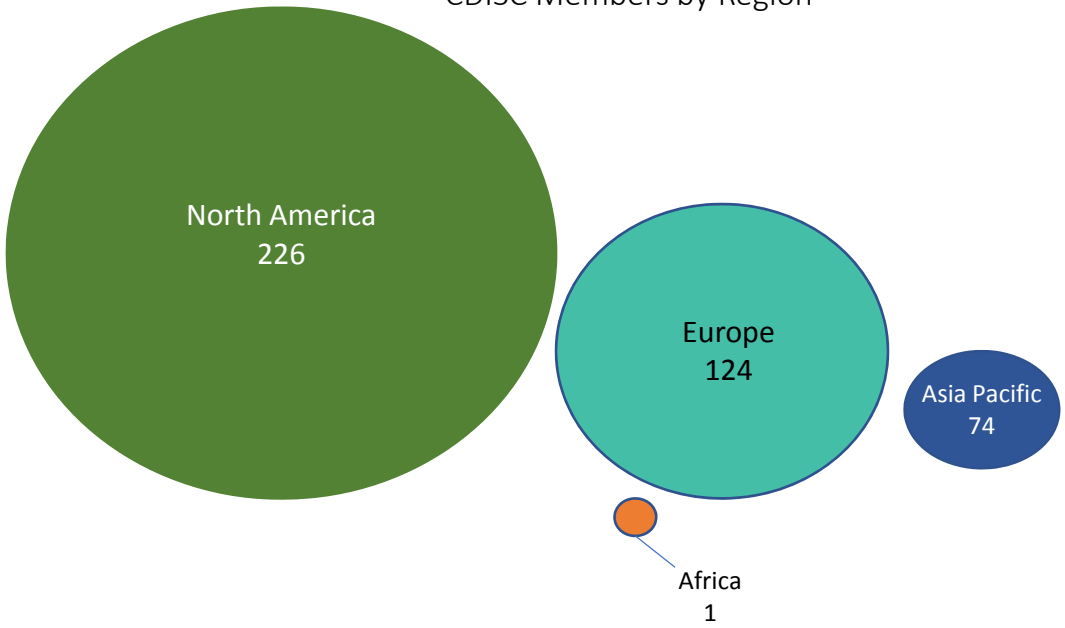
Venn Life Sciences	Winicker Norimed GmbH	World Programming	Worldwide Clinical Trials
X-act Cologne Clinical Research GmbH	XClinical	XML4 Pharma	Zifo RnD Solutions



Our Members

CDISC Members by Region



Thank you to Our Members in Europe

Out of a total of 425 CDISC members –

124 members (29.2%) are from Europe!

MEMBERHIP

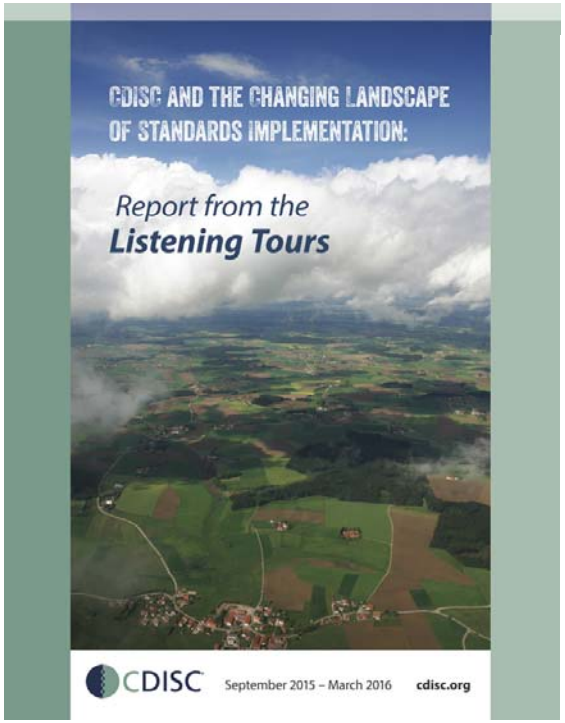
A Part of CDISC

Join Now!

membership@cdisc.org

CDISC LISTENS to OUR MEMBERS and CONTRIBUTING COMMUNITY

- Listening Tours – Published White Paper
- CDISC Advisory Council (CAC)
- SHARE Survey
- 2016 Strategy Session with FDA Commissioner
- and global input
- LOINC Survey
- Member Survey coming soon…
- Blue Ribbon Commission coming soon…



2017 CDISC New, Additional Member Benefits

Platinum Members:

Gold Members:

Check Out the New, Improved CDISC Website!

36% increase in page views*

Top Page Views:

#1 CDISC Homepage

#2 Study Data Tabulation Model (SDTM)

#3 Controlled Terminology

#4 Analysis Data Model (ADaM)

#5 Standards Landing Page

*Sept 2016 – Apr 2017 vs. same time frame year prior

CDISC Website

Traffic by Country:

#1 United States

#2 India

#3 Japan

#4 United Kingdom

#5 Germany

#6 France

#7 China

#8 Canada

#9 Switzerland

#10 Russia

CDISC is more than standards…

…it is passionate people working together to *advance research*

Questions?

Thank you!

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