Fund Once, Reuse Often: Making Clinical Data Reusable by Design with Standards in Mind

Housekeeping

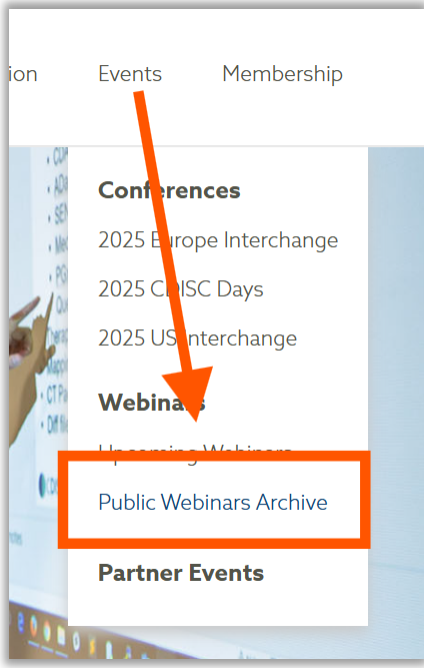
You will remain on **mute**

Audio Issues?

First, close & restart your Teams App, check your local internet connection strength

Submit questions at any time via the Q&A section on your Teams app

A **recording of this webinar** and a PDF of the slides will be available in the Public Webinar Archive on the CDISC website.



Speakers

Chris Decker, President & CEO, CDISC

Aaron Mann, CEO, Clinical Research Data Sharing Alliance (CRDSA)

Meredith Zozus, PhD, FACMI, Professor and Division Chief, Director of Clinical Research Informatics, UT Health San Antonio

Alex Cheng, PhD, Assistant Professor, Department of Biomedical Informatics, Vanderbilt University (REDCap)

Frank Rockhold, PhD, Professor of Biostatistics and Bioinformatics, Duke University School of Medicine

Agenda

1. CDISC Introduction & Vision
2. Spotlight: Clinical Research Data Sharing Alliance (CRDSA)
3. Spotlight: REDCap Enabling Academic Research
4. Panel: Academic Leaders Designing "Shareable from Day One" Studies

Introduction To CDISC

Global, nonprofit standards development organization (SDO)

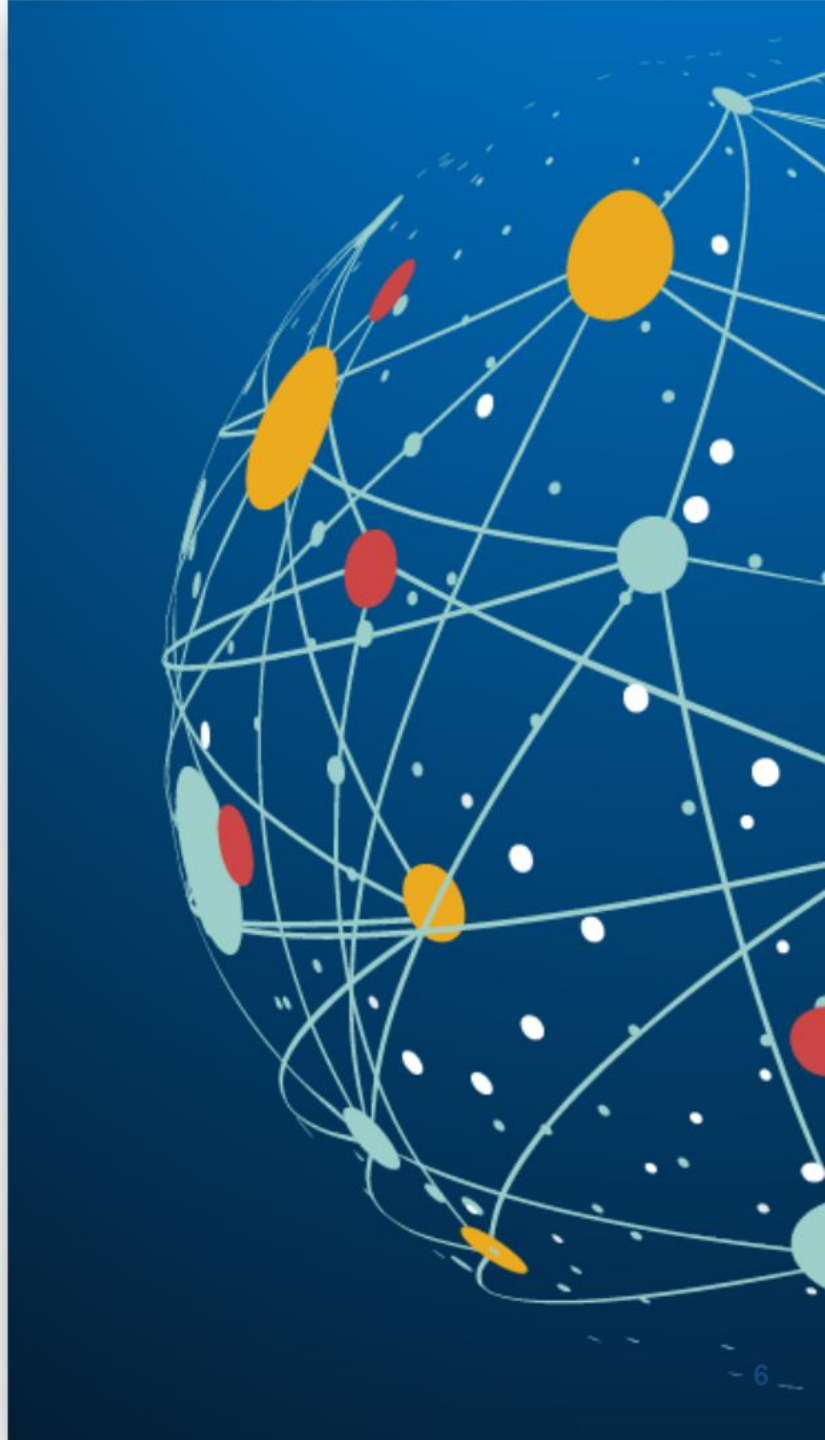
- 501(c)(3) non-profit
- Founded by volunteers in 1997

For consensus-based, research data standards development

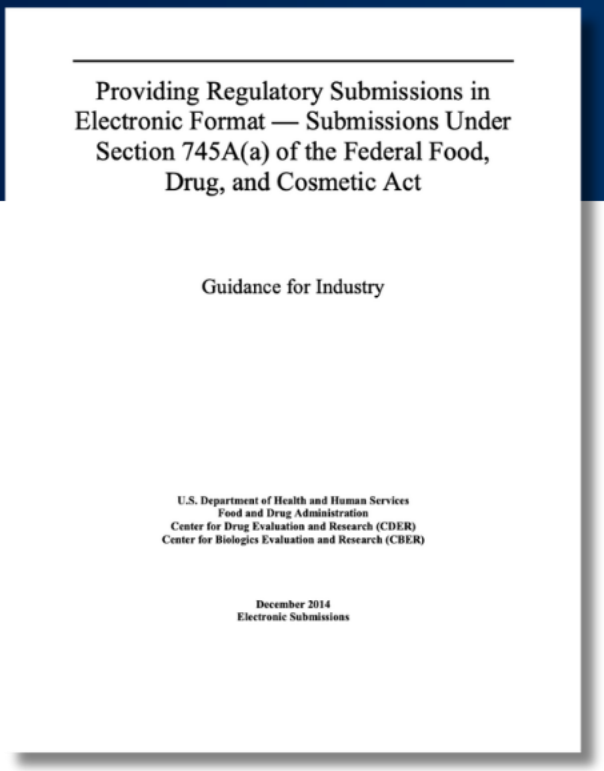
- Established, documented development process
- Required by regulators and embedded in sponsors

With a Vision to…

- *amplify data's Impact to advance research by creating* ***connected standards*** *across the* ***study information lifecycle*** *to enable accessible, interoperable, and reusable data for more* ***meaningful and effective research***



CDISC Standards and Global Regulation



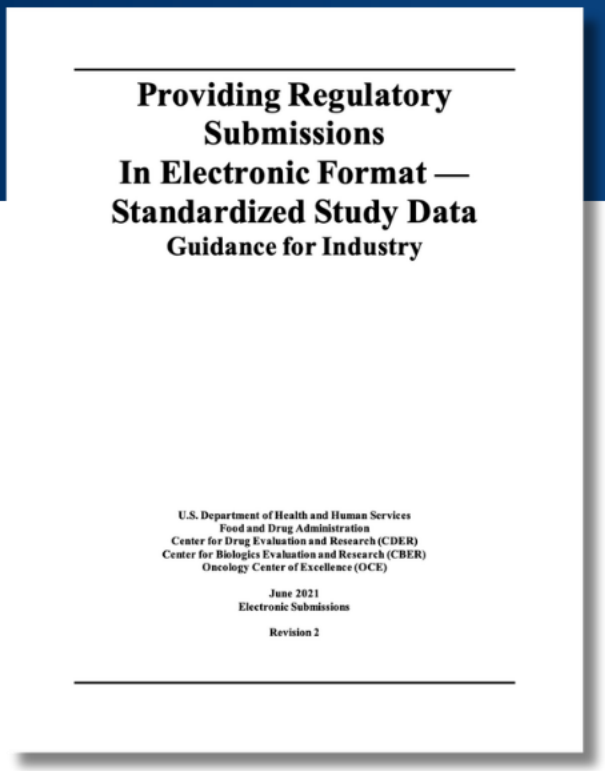
Providing Regulatory Submissions in Electronic Format — Submissions Under Section 745A(a) of the Federal Food, Drug, and Cosmetic Act

Guidance for Industry

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)

December 2014
Electronic Submissions

https://www.fda.gov/media/88120/download



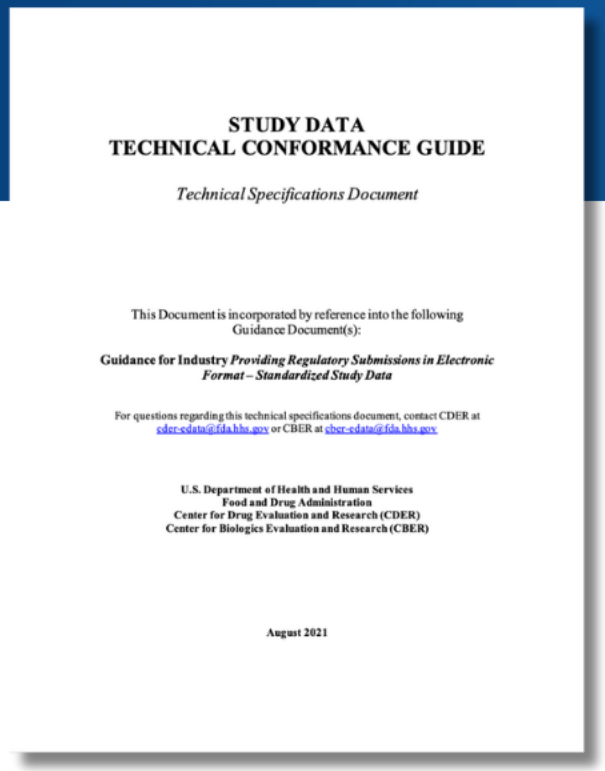
Providing Regulatory Submissions In Electronic Format — Standardized Study Data
Guidance for Industry

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)
Oncology Center of Excellence (OCE)

June 2021
Electronic Submissions

Revision 2

https://www.fda.gov/media/82716/download



STUDY DATA TECHNICAL CONFORMANCE GUIDE

Technical Specifications Document

This Document is incorporated by reference into the following Guidance Document(s):

Guidance for Industry *Providing Regulatory Submissions in Electronic Format – Standardized Study Data*

For questions regarding this technical specifications document, contact CDER at sder-edata@fda.hhs.gov or CBER at cber-edata@fda.hhs.gov

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)

August 2021

https://www.fda.gov/media/147233/download

https://www.pmda.go.jp/english/review-services/reviews/0002.html

***CDISC Standards** are **required** for submission to USA FDA and Japan PMDA, can be used for patient-level data submission to EU EMA, and are **recognized** by China NMPA and Korea MFDS*

U.S. FOOD & DRUG ADMINISTRATION

PMDA 独立行政法人 医薬品医療機器総合機構 Pharmaceuticals and Medical Devices Agency

EMA EUROPEAN MEDICINES AGENCY

NATIONAL MEDICAL PRODUCTS ADMINISTRATION 国家药品监督管理局

KOREA MFDS

Therapeutic Area Partnerships

Autoimmune/Respiratory

CRITICAL PATH INSTITUTE
collaborate · innovate · accelerate

Cardiovascular

American Heart Association

Endocrine/Gastro

THE LEONA M. AND HARRY B. HELMSLEY CHARITABLE TRUST

PKD FOUNDATION
Polycystic Kidney Disease

Infectious

IDDO
INFECTIOUS DISEASES DATA OBSERVATORY

WORLDWIDE ANTIMALARIAL RESISTANCE NETWORK
WWARN

Interoperability Platforms/Repositories

REDCap
Research Electronic Data Capture

Vivli

CRDSA
Clinical Research Data Sharing Alliance
crdsalliance.org

Mental Health

HEROIC HONORABLE DEDICATED DUTY SERVICE BRAVE READY COMMITMENT COURAGEOUS SELFLESS INTEGRITY VALIANT
MISSION PATRIOTIC RESPECT ALWAYS COUNTRY SEMPER DEFEND
Cohen Veterans Bioscience

ONE MIND

cdisc

Neuro

CRITICAL PATH INSTITUTE
collaborate · innovate · accelerate

UsAgainst Alzheimer's

CHDI FOUNDATION

ADNI
Alzheimer's Disease Neuroimaging Initiative

Alzheimer's Drug Discovery Foundation

ALZHEIMER'S ASSOCIATION

THE MICHAEL J. FOX FOUNDATION FOR PARKINSON'S RESEARCH

MS National Multiple Sclerosis Society

NIH National Institute of Neurological Disorders and Stroke

Oncology

PANCREATIC CANCER ACTION NETWORK
PanCAN
WORKING TOGETHER FOR A CURE

NIH NATIONAL CANCER INSTITUTE
Enterprise Vocabulary Services

Pediatric

conect 4children
COLLABORATIVE NETWORK FOR EUROPEAN CLINICAL TRIALS FOR CHILDREN

Rare

NORD
National Organization for Rare Disorders

CDISC Vision and Value of Connected Information

Five Year Vision: CDISC 2030

By end of 2030, all CDISC standards are digital, linked, and easily consumable by users and systems.

- Digital, connected standards create the trusted foundation required for scalable automation and responsible AI.
- Digital standards empower experts across the clinical research ecosystem, reducing manual burden, increasing transparency, and enabling better, faster decisions for patients

Digital

Structured, machine-readable standards that reduce manual effort

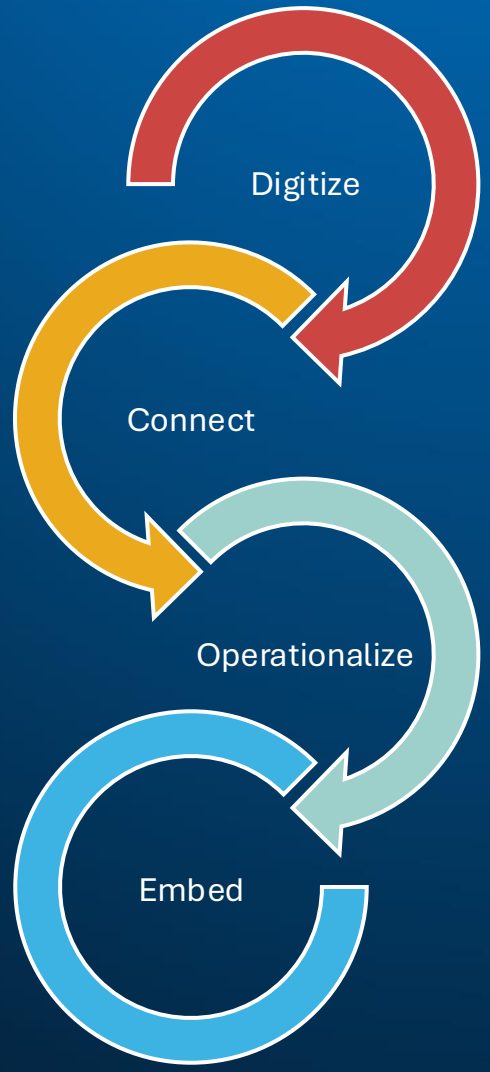
Linked

Unified semantic backbone that provides clarity and context

Accessible

Embedded in workflows to support informed, confident decisions

Path to 2030

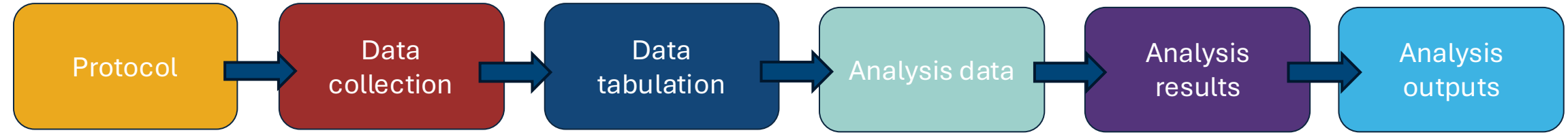


Value Of A Connected World

Transition standards use from necessary requirement to valuable enabler through connected and ready to use implementable standards.

Patients	Easier access to trials, better engagement in those trials, and faster life saving products to market
Researchers	Reduce barrier to entry and cost for standards through ready to use implementable standards & open-source tools
Sponsors	Protocol driven research automating the metadata & data pipeline reducing time to study results & increasing quality
Regulators	Reduced variability & clickable traceability from analysis to the collected data increasing confidence in decisions
Technologists	Provide machine readable and interoperable inputs and outputs for easier adoption by software solutions

Using Digital Assets to Enable Seamless Data Flow



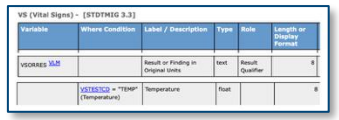
Conceptual Biomedical Concepts (BC)

Schedule of Activities

BC CRF Implementation

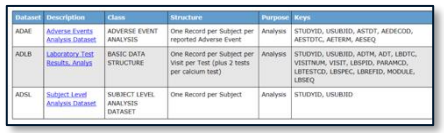
eCRF

BC SDTM Implementation



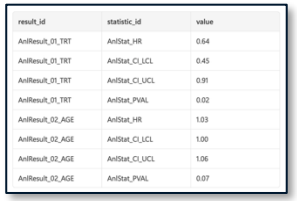
- *SDTM Define.XML*
- *Mapping Specifications*

Analysis Concepts



- *ADaM Define.XML*
- *Mapping Specifications*

Analysis Results Metadata



Analysis Results Dataset

Therapeutic Area Users Guides (TAUGs)

Standardizing Therapeutic Knowledge Across Research

CDISC TAUGs bridge foundational data standards and disease-specific research

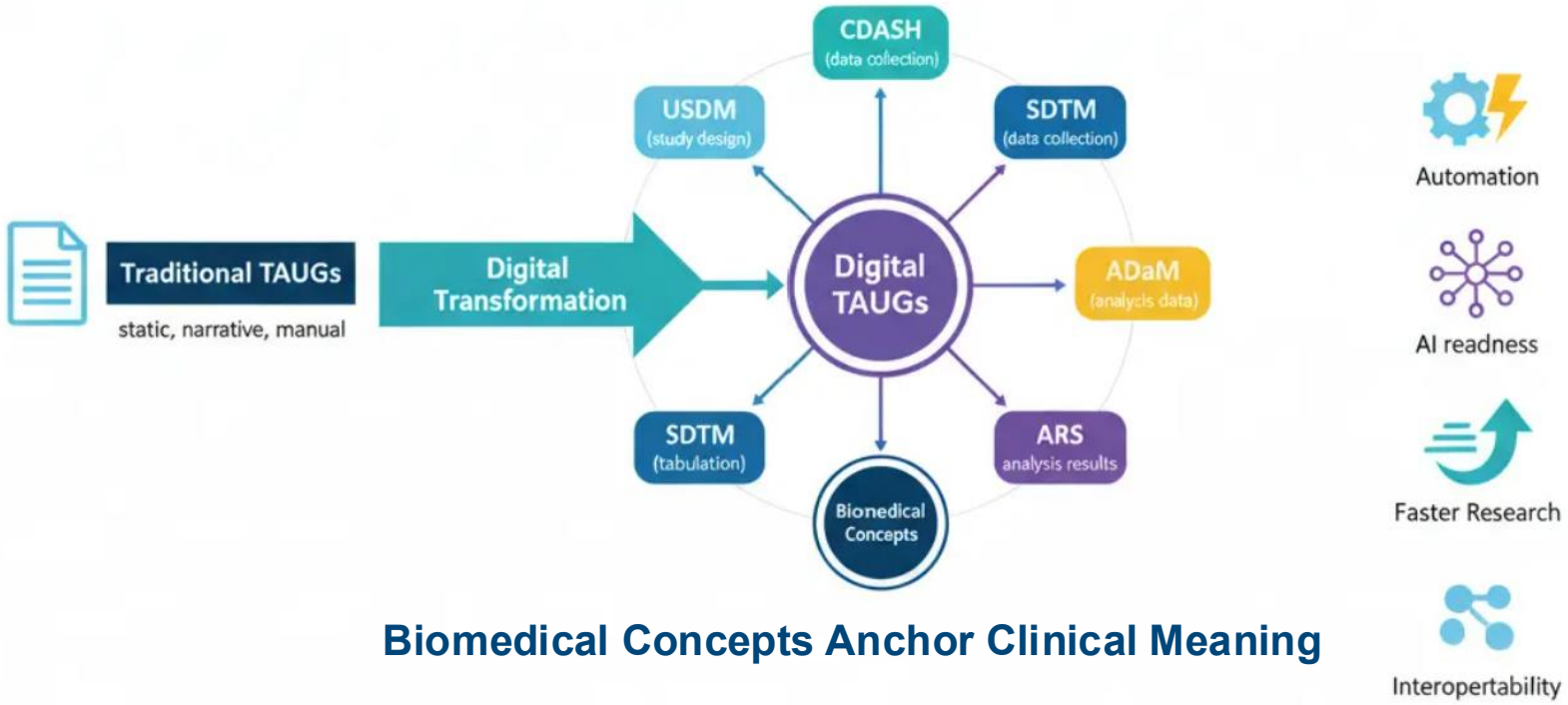
Data Consistency: Ensure data consistency from clinical data collection through data tabulation and analysis across 45+ disease areas

Built with global collaboration: Pharmaceutical companies, regulators, and disease experts jointly partner on TAUGs

Used worldwide: TAUGs inform regulatory submissions, accelerate data sharing, and enable cross-study comparisons.

Rich, validated reference content: TAUGs capture disease-specific metadata, examples, and CDISC standard mappings.

Transforming Therapeutic Knowledge into Digital Intelligence



Biomedical Concepts Anchor Clinical Meaning

Funding digital TAUGs shifts research dollars from manual data wrangling to faster answers, higher-quality evidence, and greater patient impact.

Digitizing TAUGs connects the full research lifecycle:
Using Biomedical Concepts and linked metadata (CDISC 360i model), Digital TAUGs connect protocol design, data collection, tabulation, analysis, and results

Enables automation and AI:
Machine-readable standards allow systems to automatically configure data flow, analyses, and study artifacts.

FAIR and future-proof:
Digital TAUGs enable Findable, Accessible, Interoperable, and Reusable content for automated research and meta-analysis.

Accelerates discovery:
Reduces time and cost from study design to results, supporting faster progress in therapeutic innovation

Thank You!

Spotlight: Clinical Research Data Sharing Alliance (CRDSA)

Delivering collaborative solutions

CRDSA

AMGEN

AstraZeneca

Genentech
A Member of the Roche Group

Roche

Takeda

CRITICAL PATH INSTITUTE

Duke Clinical Research Institute

HDRUK
Health Data Research UK

Global Alliance for Genomics & Health
Collaborate. Innovate. Accelerate.

Flinders University

THE MICHAEL J. FOX FOUNDATION FOR PARKINSON'S RESEARCH

THE UNIVERSITY OF CHICAGO
PEDIATRIC CANCER DATA COMMONS

DATA FOR THE COMMON GOOD

PISTOIA ALLIANCE

Project Data Sphere

Vivli
CENTER FOR GLOBAL CLINICAL RESEARCH DATA

Real Life Sciences

d-wise
An Instem Company

PRIVACY ANALYTICS
an IQVIA company

atorus
Your Complete Data Solution

Collaborating Organizations

imi innovative medicines initiative
FACILITATE

phuse

Global Alliance for Genomics & Health
Collaborate. Innovate. Accelerate.

The problem

CRDSA

Data Contributors

Industry

Pharma A

Pharma B

Pharma C

Academic

Institution 1

Institution 2

Institution 3

Data Platforms

CRITICAL PATH INSTITUTE

Vivli
CENTER FOR GLOBAL CLINICAL RESEARCH DATA

HDRUK
Health Data Research UK

innovative health initiative

ClinicalStudy DataRequest.com

Project Data Sphere

DataCelerate

THE FORUM
For Collaborative Research℠

THE UNIVERSITY OF CHICAGO
PEDIATRIC CANCER DATA COMMONS

Roche

NOVARTIS

AstraZeneca

AMGEN

and many more…

Researchers

DM_extended_template_40_subjects_sample

TRIAL	SUBJID	SEX	RACE	AGE	AGEU	ETHNIC	COUNTRY	SITEID	STUDYID	USUBJID	ARMCD	ARM	BRTHDTC	RFSTDTC	RFENDTC	DOMAIN
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rd_subj_NCT00554229	120	1	99			1	Brazil	3071	D4320C00014	D4320C00014-120.0						DM
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Sample from 8 oncology trials, pre-harmonization

✓ Findable

✗ Interoperable

✓ Accessible

✗ Reusable

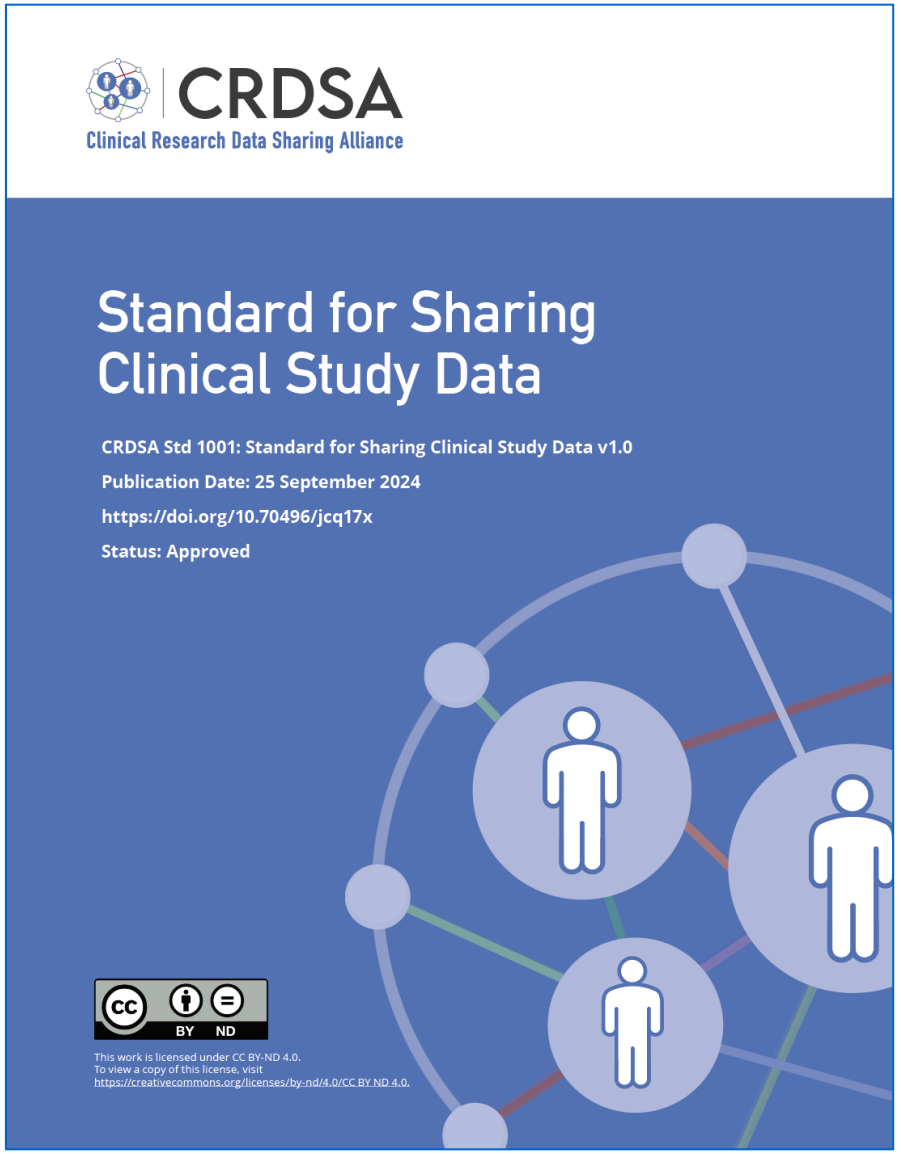
Standard for Sharing Clinical Study Data

- CRDSA Std 1001: Standard for Sharing Clinical Study Data (approved and published September 2024)

2.1 DATASETS

2.1.1 SDTM and ADaM formats

Anonymized raw datasets and analysis-ready datasets from interventional clinical trials **are to be shared in Study Data Tabulation Model (SDTM)** [5] and Analysis Data Model (ADaM) [6] data schema, respectively, because these models provide a standardized way to organize and structure clinical trial data. Doing so helps enable consistency across different studies, making it easier to compare and combine data from various sources.



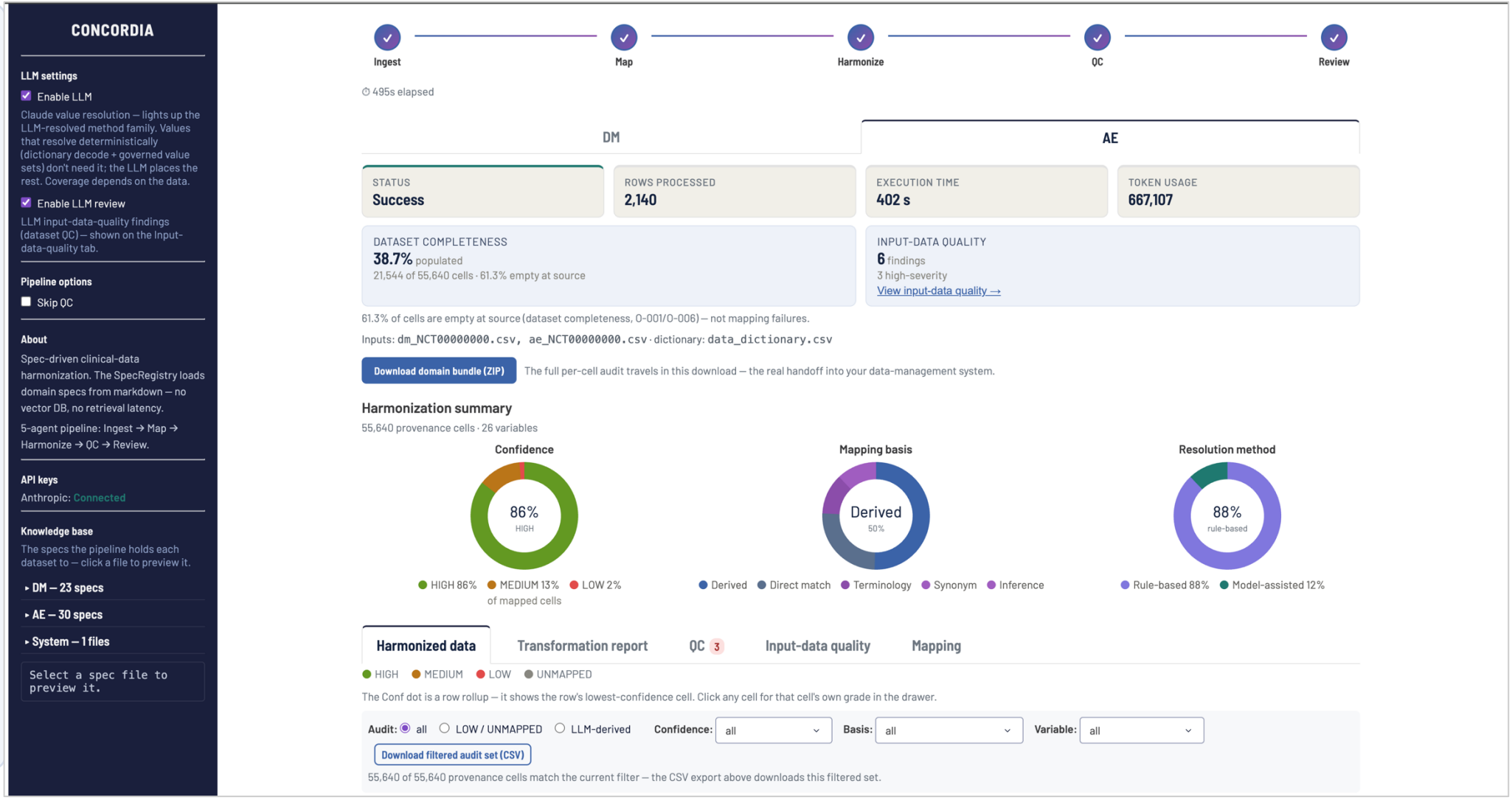
Doesn’t AI solve all this?

Project Concordia: harmonization-as-infrastructure

CRDSA

Output:

- Per-domain status
- Confidence, mapping basis, and resolution method
- Transformation report (variable level)
- Cell-level provenance & audit trail
- source data quality findings
- downloadable bundle with the all reports inc. full per-cell audit



Dataset comparison (LLM off – Python deterministic)

CONCORDIA · CLINICAL-DATA HARMONIZATION

Harmonization Quality Report RUBRIC V1.2

An on-demand quality assessment of a Concordia release, specification set, or update.

EVALUATION TARGET	RUN MODE	RUBRIC VERSION	BLOCKING ISSUES
Active dev tree	Keyless (deterministic core)	v1.2	None — 0 hard failures

TRIGGERED BY	RUN COMPLETED	DATASETS	DOMAINS EVALUATED
Local CLI (manual) · SYNTHTRIAL_01	2026-06-24 01:12 UTC	follows SDTM structure	DM, AE

QUALITY PROFILE — PER PILLAR (NATIVE 0–100)

Decompose & routing	75
Structural conformance POST-PROCESSING	99
Value accuracy	84
Provenance & lineage	99

TOTAL QUALITY SCORE **714 / 800**

SCORES BY DOMAIN — THIS RUN (KEYLESS (DETERMINISTIC CORE)) · RUBRIC V1.2

QUALITY PILLAR	DM	AE	AGGREGATE
Decompose & routing	75	75	150
Structural conformance POST-PROCESSING	98	100	198
Value accuracy	82	87	169
Provenance & lineage	100	97	197
Total (sum of points)	**355**	**359**	**714**
Max at today's bar	400	400	800

CONCORDIA · CLINICAL-DATA HARMONIZATION

Harmonization Quality Report RUBRIC V1.2

An on-demand quality assessment of a Concordia release, specification set, or update.

EVALUATION TARGET	RUN MODE	RUBRIC VERSION	BLOCKING ISSUES
Active dev tree	Keyless (deterministic core)	v1.2	None — 0 hard failures

TRIGGERED BY	RUN COMPLETED	DATASETS	DOMAINS EVALUATED
Local CLI (manual) · ACAD_STRESS_01	2026-06-24 01:13 UTC	no standard applied	DM, AE

QUALITY PROFILE — PER PILLAR (NATIVE 0–100)

Decompose & routing	50
Structural conformance POST-PROCESSING	96
Value accuracy	54
Provenance & lineage	99

TOTAL QUALITY SCORE **599 / 800**

SCORES BY DOMAIN — THIS RUN (KEYLESS (DETERMINISTIC CORE)) · RUBRIC V1.2

QUALITY PILLAR	DM	AE	AGGREGATE
Decompose & routing	50	50	100
Structural conformance POST-PROCESSING	93	100	193
Value accuracy	47	61	108
Provenance & lineage	98	99	197
Total (sum of points)	**289**	**310**	**599**
Max at today's bar	400	400	800

Dataset comparison (LLM on – Opus 4.8)

CRDSA

CONCORDIA · CLINICAL-DATA HARMONIZATION

Harmonization Quality Report RUBRIC V1.2

An on-demand quality assessment of a Concordia release, specification set, or update.

EVALUATION TARGET	RUN MODE	RUBRIC VERSION	BLOCKING ISSUES
Active dev tree	With LLM (full pipeline)	v1.2	None — 0 hard failures
TRIGGERED BY	**RUN COMPLETED**	**DATASETS**	**DOMAINS EVALUATED**
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QUALITY PROFILE — PER PILLAR (NATIVE 0–100)

Decompose & routing	75
Structural conformance POST-PROCESSING	99
Value accuracy	91
Provenance & lineage	98

TOTAL QUALITY SCORE **727 / 800**

SCORES BY DOMAIN — THIS RUN (WITH LLM (FULL PIPELINE)) · RUBRIC V1.2

QUALITY PILLAR	DM	AE	AGGREGATE	Δ ON–OFF
Decompose & routing	75	75	150	+0.0
Structural conformance POST-PROCESSING	98	100	198	+0.0
Value accuracy	84	98	183	+14.0
Provenance & lineage	100	97	197	-0.6
Total (sum of points)	**357**	**370**	**727**	**+13.4**
Max at today's bar	400	400	800	

CONCORDIA · CLINICAL-DATA HARMONIZATION

Harmonization Quality Report RUBRIC V1.2

An on-demand quality assessment of a Concordia release, specification set, or update.

EVALUATION TARGET	RUN MODE	RUBRIC VERSION	BLOCKING ISSUES
Active dev tree	With LLM (full pipeline)	v1.2	None — 0 hard failures
TRIGGERED BY	**RUN COMPLETED**	**DATASETS**	**DOMAINS EVALUATED**
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QUALITY PROFILE — PER PILLAR (NATIVE 0–100)

Decompose & routing	50
Structural conformance POST-PROCESSING	96
Value accuracy	57
Provenance & lineage	99

TOTAL QUALITY SCORE **604 / 800**

SCORES BY DOMAIN — THIS RUN (WITH LLM (FULL PIPELINE)) · RUBRIC V1.2

QUALITY PILLAR	DM	AE	AGGREGATE	Δ ON–OFF
Decompose & routing	50	50	100	+0.0
Structural conformance POST-PROCESSING	93	100	193	+0.0
Value accuracy	53	61	114	+5.2
Provenance & lineage	98	99	197	+0.0
Total (sum of points)	**294**	**310**	**604**	**+5.2**
Max at today's bar	400	400	800	

Spotlight: REDCap Enabling Academic Research

Panel Discussion

Final Panel Questions

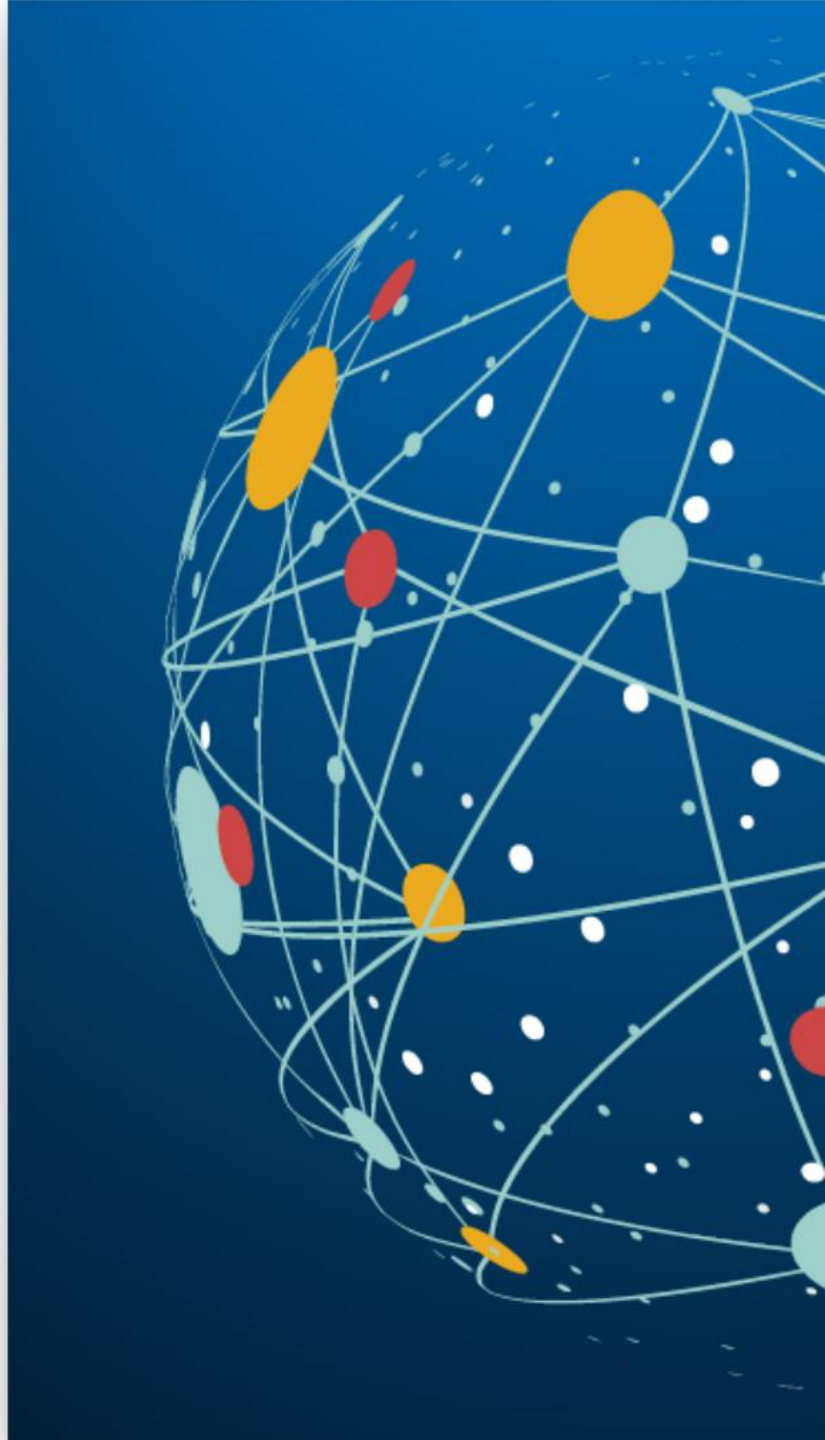
- Please provide a little bit of your background and describe your thoughts on the value of standards in research? (Frank, Meredith)
- If you could correct one common misunderstanding about CDISC or standards in general in academic research, what would it be? (Alex, Meredith)
- Over the last two years, I've often heard the quote 'If we have AI we don't need standards'. Can you provide your thoughts on this comment and how AI and standards fit together? (Frank, Alex)
- What internal roles are essential for successful implementation of standards in an academic setting? (Alex, Meredith)
- What is one thing every academic researcher should do differently to improve their next trial? (Frank, Alex, Meredith, Aaron)

Call to Action

Trainings for Academia and Non-Profits

- **CDISC for Newcomers (Virtual)**
- **Designing TRUE Research in partnership with the Learning Health Community On-Demand Bundle**
- **CDASH in Action On-Demand Bundle**
- **SDTM in Action On-Demand Bundle**
- **Understanding USDM** Virtual 24 - 26 June 2026 | 9:00am - 12:00pm EDT
- **SDTM Theory and Application** Virtual 26 June 2026 | 9:00am - 12:30pm EDT
- **ADaM Core Theory and Application** Virtual 10 July 2026 | 9:00am-12:00pm EDT
- **Define XML** Virtual 14 - 16 July 2026 | 9:00am-12:00pm EDT (15:00 - 18:00 CET)

Free On-Demand Trainings | CDISC For Academic Researchers



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Join CDISC's Academic and Non-Profit Member Community to collaborate, connect and advance clinical research standards together.

Harvard University, University of Alabama at Birmingham, Vanderbilt University Medical Center (VUMC), Wakayama Medical University Hospital, Korea Institute of Toxicology, Massachusetts General Hospital, Memorial Sloan Kettering Cancer Center, Seoul National University Hospital

Partner with CDISC to Ensure You Multiply the Impact of Your Investment in Research & Accelerate Progress

Fund and participate collaborative working groups developing disease-specific Digital TAUGs for more meaningful and efficient research

Engage with CDISC training for academic research teams to accelerate adoption and use

Sponsor harmonization pilots to educate and enable researchers

Grants – Incentivize CDISC-ready data as a condition of funding

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Thank You!