A Shared Language for Clinical Research

MULTI-REGIONAL CLINICAL TRIALS
THE MRCT CENTER OF BRIGHAM AND WOMEN'S HOSPITAL and HARVARD

cdisc SCDM

How technical organizations are embracing plain language and implementing the MRCT Center Clinical Research Glossary

Thursday, May 8, 2025
10 - 11 AM ET

Learn more at www.mrctcenter.org

Disclaimer

The opinions contained are those of the authors and are not intended to represent the position of Brigham and Women's Hospital, Harvard University, or any other entity.

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We are committed to autonomy in our research and to transparency in our relationships. The MRCT Center—and its directors—retain responsibility and final control of the content of any products, results, and deliverables.

Session Overview

- Welcome
- Overview of Patient Centricity, Health Literacy, and Clinical Research
- Patient Centricity and Data Sciences with SCDM
- Patient Centricity and the Data Standards Landscape with CDISC
- Discussion and Q&A
- Final Thoughts and Wrap-up

Welcome!

Sylvia Baedorf Kassis
MRCT Center

Erin Muhlbradt
NCI EVS [c]

Rebecca Baker
CDISC

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2025 Chair, SCDM

Claudine Moore
Editor in Chief, JSCDM

Patient Centricity, Health Literacy, and Clinical Research Data

The MRCT Center:
A Focus on Participant Understanding Benefits Everyone

About Us

MRCT Center is an applied policy center focused on addressing the conduct, oversight, ethics and regulatory environment for clinical trials around the world.

www.mrctcenter.org

Our Vision

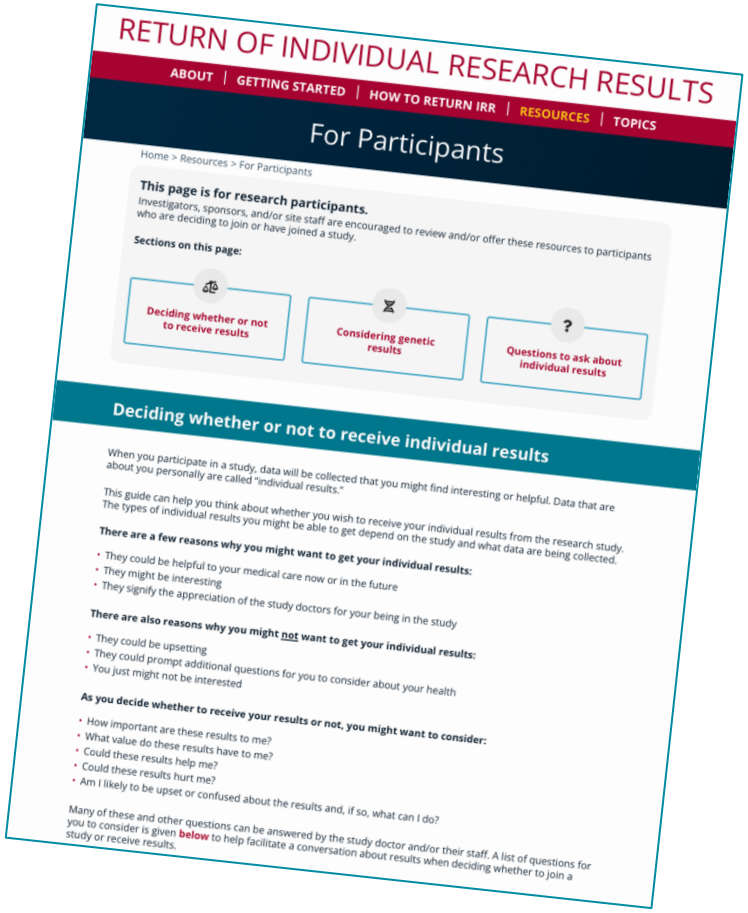
Improve the integrity, safety, and rigor of clinical trials around the world.

Our Community

We engage diverse stakeholders to define emerging issues in global clinical trials and to create and implement ethical, actionable, and practical solutions.

The MRCT Center offers….

Foundational information for participants…

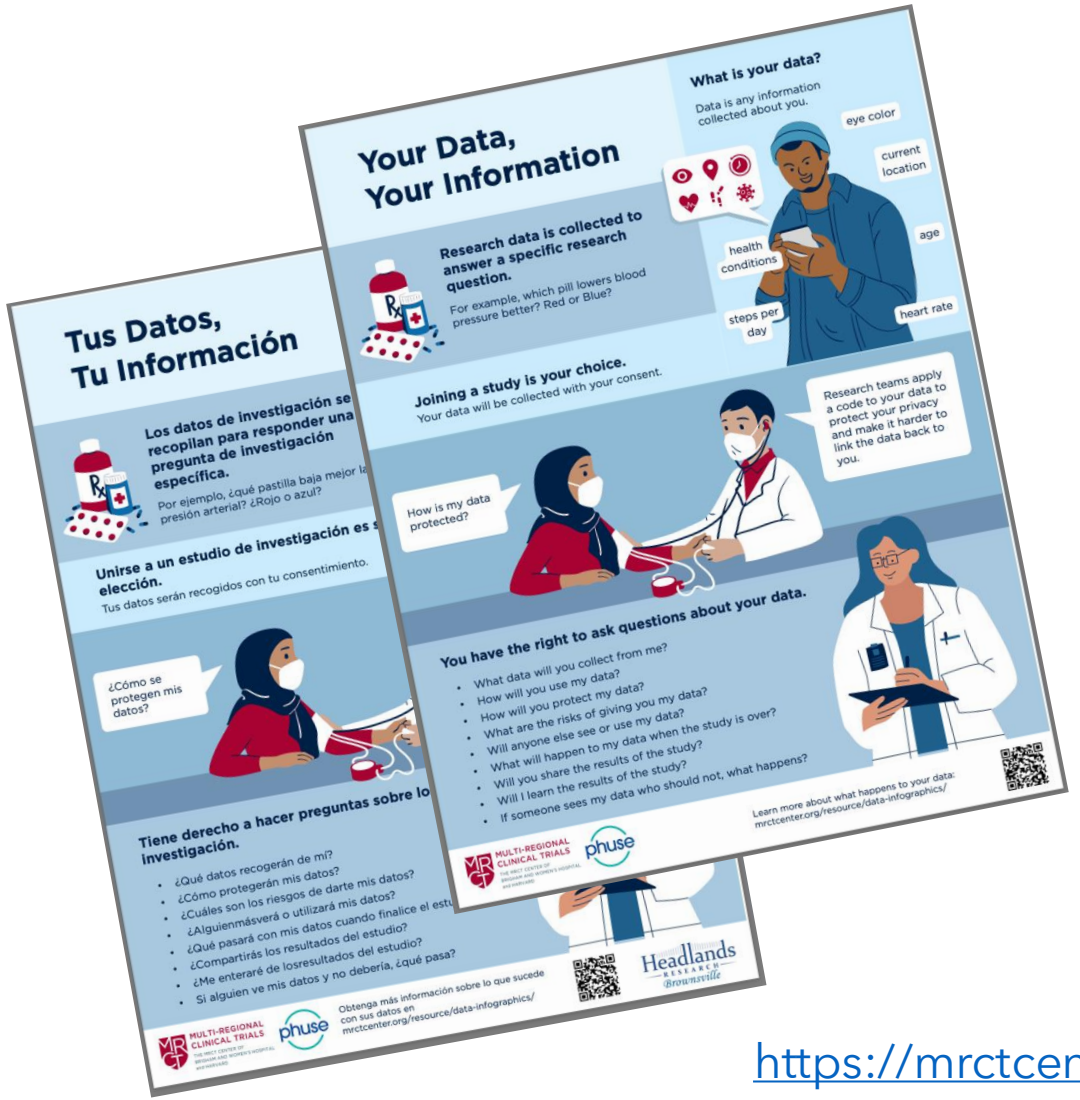


…with an extra focus on special populations…

… and topics.

More at: https://mrctcenter.org/project/resources-for-patients-and-participants/

New in 2025 – Data Literacy Infographics



English

- **Infographic #1:** 'Your Data, Your Information'
- **Infographic #2:** *'What Happens to Data During a Research Study?'*
- **Infographic #3:** *'What Happens to Data After a Research Study?'*
- **Infographic #4**: '*What is a Data Repository?*'
- **Infographic #5**: '*What Happens to Data if You Leave a Research Study?'*

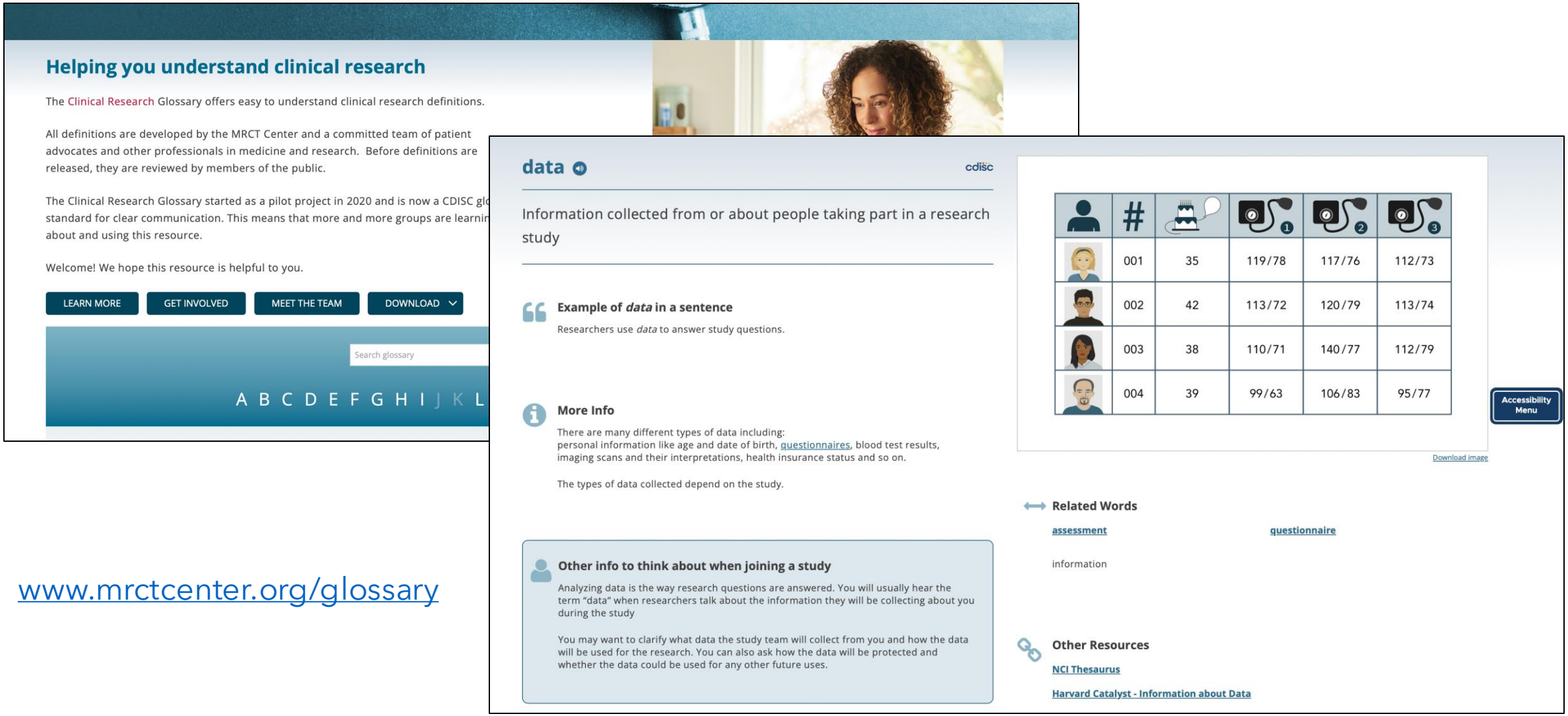
Spanish

- **Infographic #1:** 'Tus Datos, Tu Información'
- **Infographic #2:** ¿Qué Sucede Con Los Datos Durante un Estudio de Investigación?
- **Infographic #3:** *¿Qué Sucede Con Los Datos Después de un Estudio de Investigación?*

  Infographic #4: ¿Qué es un Repositorio de Datos?
- **Infographic #5**: ¿Qué pasa con los datos si te retiras de un studio de Investigación?

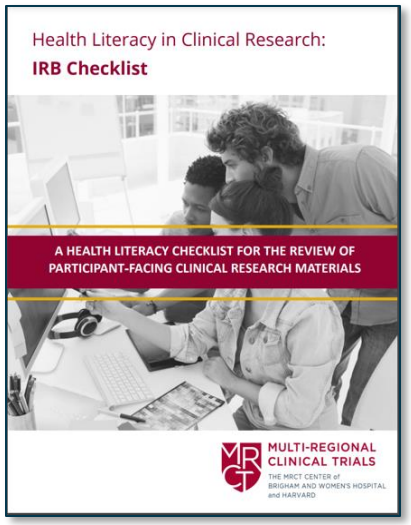
https://mrctcenter.org/resource/data-infographics/

MRCT Center Clinical Research Glossary



www.mrctcenter.org/glossary

2013 - 2017

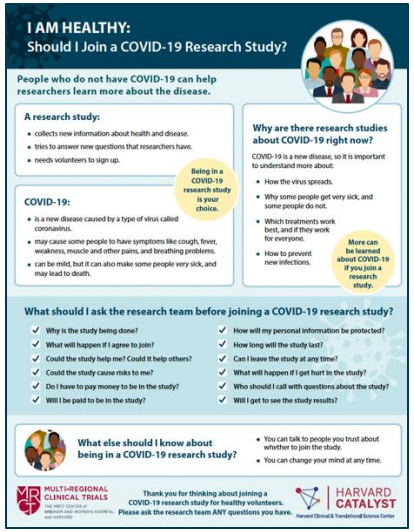


2019

Glossary Pilot Project

2018 - 2019

2020



2021

V 1.0

2022

2023

2024

V 2.0

SCDM

Clinical Research Glossary Expansion Efforts

Baedorf Kassis S, White S, & Bierer B. (2022). Developing a consensus-driven, plain-language clinical research glossary for study participants and the clinical research community. *Journal of Clinical and Translational Science,* 1-20. doi:10.1017/cts.2022.12

Health Literacy (and its connection to data)

Organizational health literacy

The degree to which organizations **equitably enable individuals** to find, understand, and use information and services to inform health-related decisions and actions for themselves and others

Personal health literacy

The degree to which individuals have the ability to find, understand, and **use information and services** to inform health-related **decisions and actions** for themselves and others

From: https://odphp.health.gov/healthypeople/priority-areas/health-literacy-healthy-people-2030

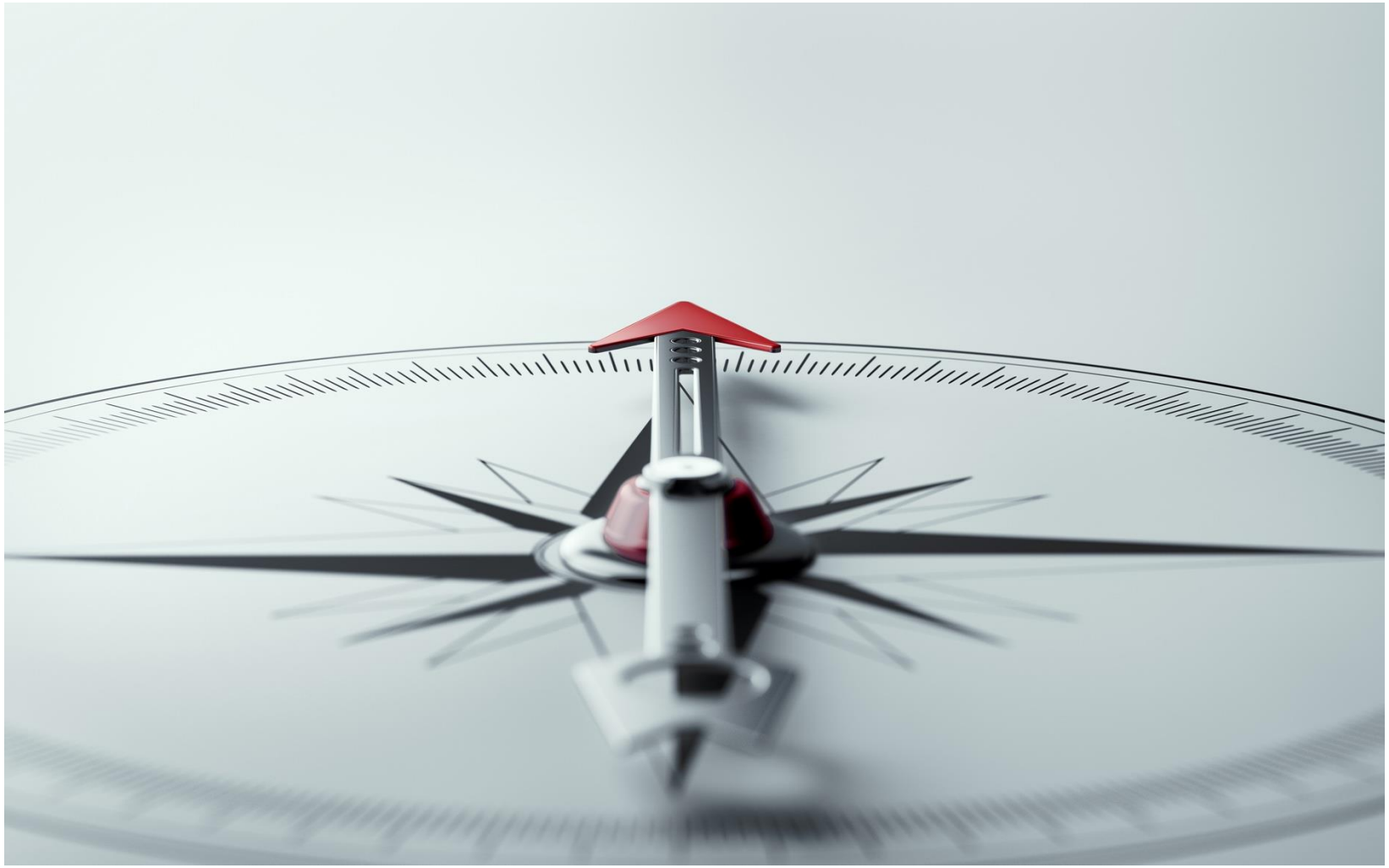
Patient Centricity Benefits Everyone

Individual Patients, Participants, and Care Partners

The Public

Clinical Research Professionals

Health and Research Organizations



Patient Centricity and the Data Sciences

Who We Are

Non-Profit Global Professional Organization founded in 1994

- Membership spanning Academia, Sponsor, CRO, Regulatory and Technology Providers
- Serving Clinical Data Management and Research Professionals
- Setting the stage for Data Management and framing the future
- Research, Education and Certification
- Conferences and Networking

Our Vision:

To lead the clinical data science industry for a healthier world.

Our mission:

- **Accelerate the development** of preventative and curative medical interventions by leading the clinical data science profession.
- **Prepare our industry and professionals** for the evolution of the management of health data through education, best practices and certification programs.
- **Engage and partner** with policy makers, regulators, patient organizations and other key stakeholders for a healthier world.

In 2024, we consolidated our strategic plan and established ourselves as leaders in the industry

Bridging the skills gap

- CDM Competency Framework
- CDA Certification Program
- Conferences with a global reach
- Promoting lifelong professional learning with more than 15 Webinars in 2024
- Strategic investments in talent and technological capabilities in education

Expanding through partnerships

- Regulatory Council through PPP with FDA
- Expanded Corporate Partnership Program
- Expansion into CDM/CDS regions of growth
- Collaboration with MRCT Center

Influencing through leadership

- JSCDM quarterly publications, including GCDMP chapters
- Career journey: Insights into the CCDA and CCDS roles through on-demand, free webinars
- Updates from the industry: 15 podcast episodes

SCDM

CDM Industry Competency Framework

Risk-Based CDM (RB-CDM)

Quality by Design (QbD)
Controlling risks by building with the end in mind; Proactive planning

RB-study execution: Risk controls
Risk assessment; Quality checks & mitigation

RBQM
Incorporate QbD, Quality Controls and Continuous Quality Improvement; Use of RACT as a Risk Evaluation Tool

Soft Skills Inc. Leadership & Executive Skills

CDS-driven business models
CDS-based organization/ business structure

Change management
Skills to effectively implement change; Transition planning from CDM to CDS

People/Team development
High performing teams; Career development

Critical & strategic thinking
Skills to effectively analyze information plan according to objectives

Crisis management
Maintaining business continuity during a significant event

Clinical Trial Operations

Patient-driven development & inclusion
Patient/Site-driven development; For example: DCT, patient-centric designs

Emerging study execution
Patient/Site-driven development; For example: DCT, patient-centric designs

Trial design & logistics
Understanding study objectives and site/sample logistics

Protocol design, feasibility & review
Understanding protocol objectives and endpoints and how to review with a CDS eye/how to contribute to draft protocol design

Clinical Data Competencies & Cross-Functional Interactions

Good Clinical Data Management Practices (GCDMP)
Chapter topics/updates

CDM-role evolution
CDM to CDS

Partnership governance & oversight
Vendor management/governance

Stakeholder identification and management
Relationship building/interaction

Cross-functional collaboration
Relationship building/interaction

Regulations & Standards

CDISC, FHIR, HL7

Global Regulatory Guidelines
For example: ICG-GCP

Country/Regional – specific regulations
For example: HGRAC China, GDPR

AI & Cognitive Tech

AI-driven technology platform
AI-driven DM workbenches

AI rb-SDLC
Risk-based approach to AI development life cycle

Generative AI
For example: Chat GPT, GPT 4.0

Data curation & insights generation
Spotfire, Power BI, visualization tools

Technology & Data Platforms

Data collection platforms
For example ECOA, EDC

Site eSource
EHR, Telemedicine, Home Care, DCT

Patient-tailored technology
For example: wearables, BYOD

SCDM: Driving Change to Address Industry Challenges

Lead

Leverage innovation and thought leadership to identify industry needs and develop best practices / standards to adapt.

Influence

Utilize partnerships of value, interactions with regulators and policy makers to work together providing industry expertise.

Transform

Drive the CDM to CDS evolution and identify future needs.

Provide education and certification keeping skills in line with industry changes.

Grow

Leveraging global CDMs/CDSs footprint to expand knowledge and industry expertise driving leadership, influence and transformation

Professional growth through education and certification.

Our Vision for 2030

THE INDUSTRY

Clinical Research 2.0

The line between clinical research and healthcare will continue to blur, driven by the increased use of real-world data (RWD) and the adoption of innovative study designs, reshaping how clinical data is collected, analyzed, and utilized for improved patient outcomes.

End-2End Data Flow

The integration of metadata beyond MDR, digital protocol-driven data flows (USDM – ICH M11), and seamless integration of source data (ETL to ELT) alongside real-world data (RWD) will redefine clinical data management, enabling scalable audit trails and maximizing the value of data for more accurate and efficient patient care.

Patient's Choice

The patient voice will shape the future of clinical trials, with patient data return reducing site burden through decentralized trial activities. Multi-source data streams and improved data quality will drive more efficient, patient-centered research.

Intelligent Technologies

Continuous technology advancements will enable AI-assisted data flow and transformations, augmenting clinical data management with new roles like data curators and prediction modelers. 'Human in the loop' integration and AI/ML best practices will ensure ethical and efficient clinical trial solutions

SCDM's ROLE

Opportunities & Considerations

- Education Strategy Transformation CDM to CDS
- Collaborations/Partnerships of Value
- Global Influence

Evolution & Growth: certifications, roles, technology

CCDA, CCDM, CCDS…is there another?

Evolve Competency Framework toward CD

- Evolution of ROLES

AI is changing landscape of roles

Clinical Data Manager & Central Monitor Role Blending

Lower reliance on site Monitors for Data Review and technology management.

- Evolution of TECHNOLOGIES

End of SAS and Data of Analytics as we know it (Used for exploration NOT issue identification<n)

The rise of Natural Language Interaction & Programming (~ "Prompt Engineering")

What is JSCDM?

- Scholarly publication that began in 2020
- Open-access; Member of the Directory of Open Access Journals (DOAJ)
- Peer-reviewed
- Focus: Publishing the science and operations behind data collection and use in clinical studies
- Complies with International Committee of Medical Journal Editors (ICJME) recommendations
- In collaboration with CDISC
- Contains links to the Multi-Regional Clinical Trials (MRCT) Plain Language Medical Glossary

Journal of the Society for Clinical Data Management

JSCDM
Journal of the Society for Clinical Data Management

Journal of the Society for Clinical Data Management

- Where is JSCDM viewed?
- Accessed by 180 Countries
- Top 10 Countries by View

Country	Views
United States	130302
China	56504
India	17368
Germany	11318
Japan	7758
United Kingdom	6900
Canada	6679
Ireland	6404
Russian Federation	4493
Singapore	3467

Journal of the Society for Clinical Data Management

- Who's citing us?
- 14 Published JSCDM articles have been cited 30 times across 16 Journals

Journal Name	# times JSCDM article cited
Clinical and Translational Science	6
JMIR Formative Research	5
JMIR Medical Informatics	3
Journal of the Society for Clinical Data Management	2
npj Digital Medicine	2
Therapeutic Innovation & Regulatory Science	2
Discover Health Systems	1
Journal of Medical Systems	1
Journal of Biomedical Informatics	1
BMC Medical Research Methodology	1
Data	1
Nuklearmedizin - NuclearMedicine	1
Heliyon	1
Contemporary Clinical Trials	1
BMJ Health & Care Informatics Online	1
JMIR Research Protocols	1

Search

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SCDM Glossary

MRCT Glossary

Glossary

The Good Clinical Data Management Practices adopt the ICH definitions for terms defined within the ICH guidelines. Unless otherwise noted, these definitions were taken from ICH E6.1 (ASQ) in a definition indicates the American Society for Quality as a source.

In addition, where available, technical definitions include a link to patient-friendly, plain language definitions. These easy-to-understand definitions, and the accompanying information and graphics, have been developed by an engaged multi-stakeholder workgroup of the Multi-Regional Clinical Trials Center of Brigham and Women's Hospital and Harvard (MRCT Center). Learn more about the MRCT Center and their Clinical Research Glossary here.

Go to:

A B C D E F G H I J

https://www.jscdm.org/

Thank you

Patient Centricity and the Data Standards Landscape

The Clinical Data Interchange Standards Consortium (CDISC): Together, we can do so much more

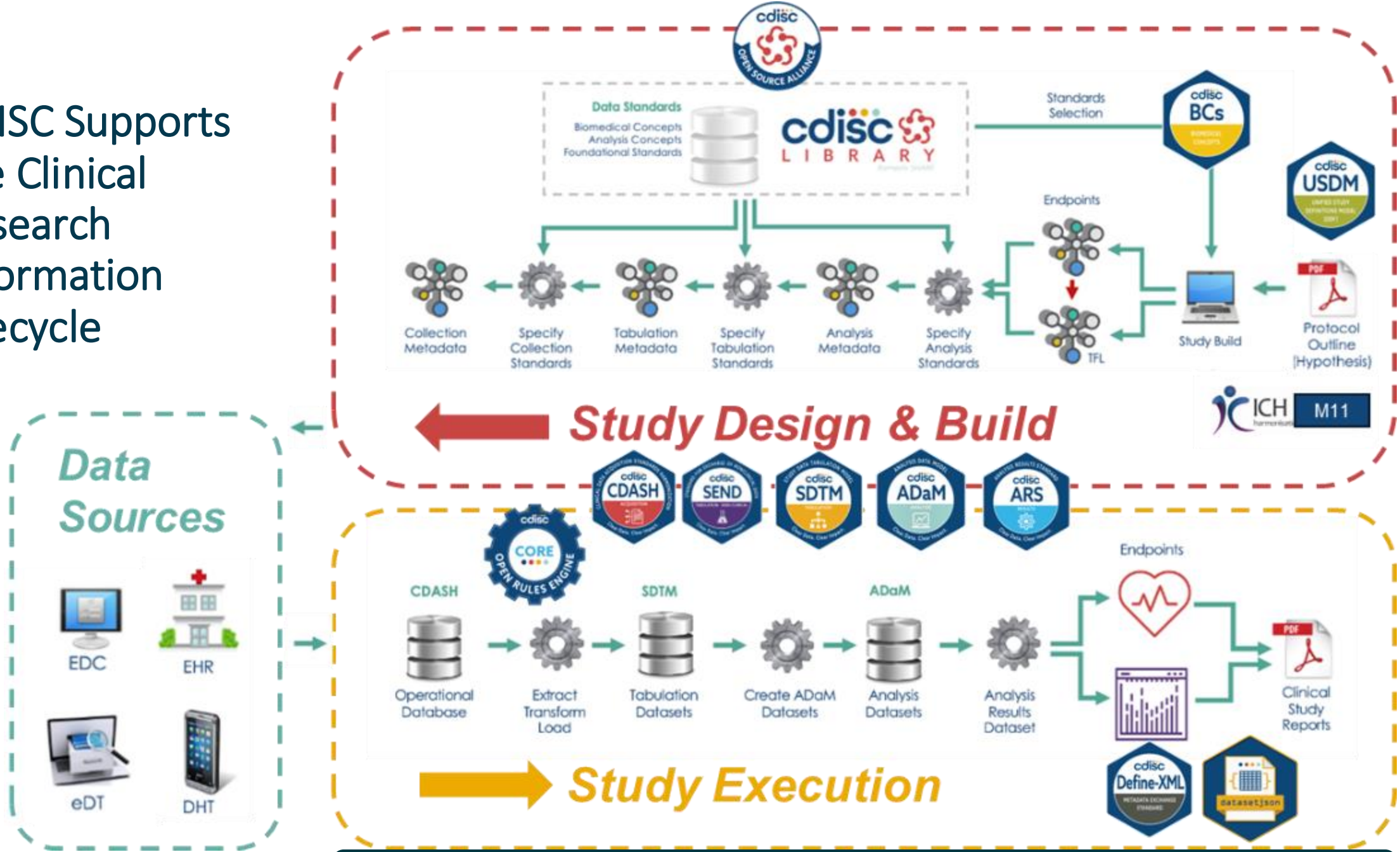
CDISC Standards

- Consensus-based standards development nonprofit founded in 2000
- Standards for clinical, non-clinical and translational research
- Standards are freely available at www.cdisc.org
- IP Policy ensures open standards
- Ongoing global research support in the Americas, Europe, Japan, China, India, Korea and other regions
- Standards downloaded in 90+ countries

Alliances and Partnerships Landscape

cdisc

CDISC Supports the Clinical Research Information Lifecycle



NCI EVS Controlled Terminology and Glossary

NCI EVS Partnership

CDISC and EVS have been working closely together for more than 20 years.

- EVS provides dedicated terminology experts, subject matter experts, and management resources.
- CDISC provides subject matter experts, data model experts, and a large review community.

EVS is responsible for CDISC controlled terminology development, harmonization, publication and maintenance.

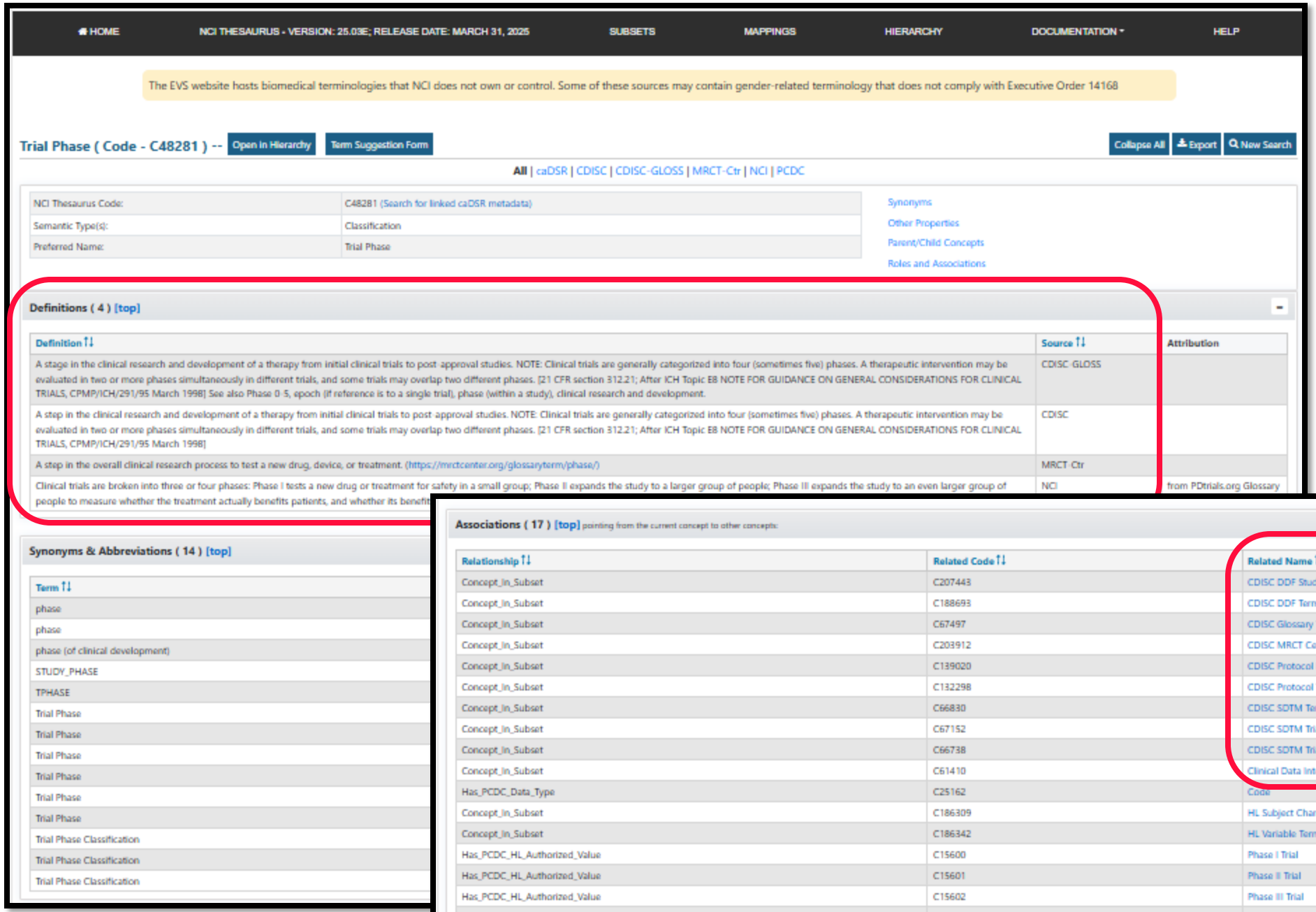
EVS provides established terminology infrastructure and standard operating procedures.

>60,000 CDISC terms are coded and tagged in NCI Thesaurus (NCIt)

- Required by FDA and PMDA
- Preferred NMPA and Recommended by EMA

CDISC terminology standards average >50,000 downloads/month in more than 60 countries.

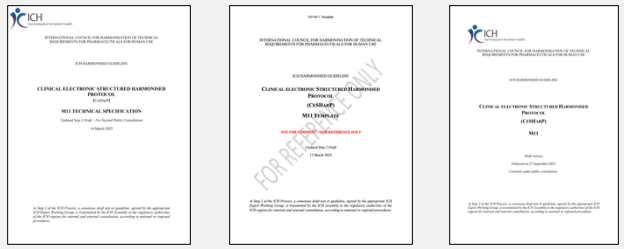
- Publications: DDF (USDM), SEND, CDASH, SDTM, ADaM, Define-XML, TMF, MRCT, CDISC Glossary
  - (Coming Soon: ICH M11 Protocol)
- Formats: .xls, .txt, .html, .odm-xml, .OWL/RDF, .pdf
- Changes files (from previous release) + Changes Program
- All files stored on NCI Ftp and archived files are made available.
- FREE Terminology Access:
  - NCI website*
  - CDISC website*
  - CDISC Library metadata repository
  - EVS Explore Browser*
  - EVS REST API
  - MRCT Glossary website


HOME
NCI THESAURUS - VERSION: 25.03E; RELEASE DATE: MARCH 31, 2025
SUBSETS
MAPPINGS
HIERARCHY
DOCUMENTATION
HELP
The EVS website hosts biomedical terminologies that NCI does not own or control. Some of these sources may contain gender-related terminology that does not comply with Executive Order 14168
Trial Phase (Code - C48281) --
Open in Hierarchy
Term Suggestion Form
Collapse All
Export
New Search
All | caDSR | CDISC | CDISC-GLOSS | MRCT-Ctr | NCI | PCDC
NCI Thesaurus Code: C48281 (Search for linked caDSR metadata)
Semantic Type(s): Classification
Preferred Name: Trial Phase
Synonyms
Other Properties
Parent/Child Concepts
Roles and Associations
Definitions (4) [top]
Definition
Source
Attribution
A stage in the clinical research and development of a therapy from initial clinical trials to post-approval studies. NOTE: Clinical trials are generally categorized into four (sometimes five) phases. A therapeutic intervention may be evaluated in two or more phases simultaneously in different trials, and some trials may overlap two different phases. [21 CFR section 312.21; After ICH Topic E8 NOTE FOR GUIDANCE ON GENERAL CONSIDERATIONS FOR CLINICAL TRIALS, CPMP/ICH/291/95 March 1998] See also Phase 0-5, epoch (if reference is to a single trial), phase (within a study), clinical research and development.
CDISC GLOSS
A step in the clinical research and development of a therapy from initial clinical trials to post-approval studies. NOTE: Clinical trials are generally categorized into four (sometimes five) phases. A therapeutic intervention may be evaluated in two or more phases simultaneously in different trials, and some trials may overlap two different phases. [21 CFR section 312.21; After ICH Topic E8 NOTE FOR GUIDANCE ON GENERAL CONSIDERATIONS FOR CLINICAL TRIALS, CPMP/ICH/291/95 March 1998]
CDISC
A step in the overall clinical research process to test a new drug, device, or treatment. (https://mrctcenter.org/glossaryterm/phase/)
MRCT Ctr
Clinical trials are broken into three or four phases: Phase I tests a new drug or treatment for safety in a small group; Phase II expands the study to a larger group of people; Phase III expands the study to an even larger group of
NCI
from PDtrials.org Glossary
Synonyms & Abbreviations (14) [top]
Term
phase
phase
phase (of clinical development)
STUDY_PHASE
TPHASE
Trial Phase
Trial Phase
Trial Phase
Trial Phase
Trial Phase
Trial Phase
Trial Phase Classification
Trial Phase Classification
Trial Phase Classification
Associations (17) [top] pointing from the current concept to other concepts:
Relationship
Related Code
Related Name
Concept_In_Subset C207443 CDISC DDF Study Version Attribute Terminology
Concept_In_Subset C188693 CDISC DDF Terminology
Concept_In_Subset C67497 CDISC Glossary Terminology
Concept_In_Subset C203912 CDISC MRCT Center Clinical Research Glossary
Concept_In_Subset C139020 CDISC Protocol Entities Clinical Trial Attribute Terminology
Concept_In_Subset C132298 CDISC Protocol Terminology
Concept_In_Subset C66830 CDISC SDTM Terminology
Concept_In_Subset C67152 CDISC SDTM Trial Summary Parameter Long Name Terminology
Concept_In_Subset C66738 CDISC SDTM Trial Summary Parameter Short Name Terminology
Concept_In_Subset C61410 Clinical Data Interchange Standards Consortium Terminology
Has_PCDC_Data_Type C25162 Code
Concept_In_Subset C186309 HL Subject Characteristics Table
Concept_In_Subset C186342 HL Variable Terminology
Has_PCDC_HL_Authorized_Value C15600 Phase I Trial
Has_PCDC_HL_Authorized_Value C15601 Phase II Trial
Has_PCDC_HL_Authorized_Value C15602 Phase III Trial
Has_PCDC_HL_Authorized_Value C15303 Pilot Study

New CDISC Initiatives

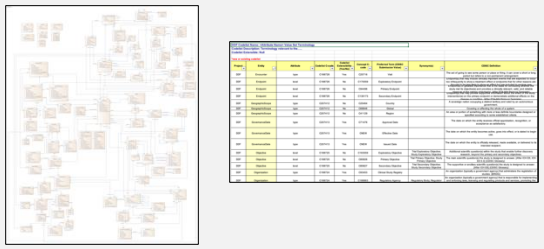
ICH M11 and CDISC USDM

ICH M11



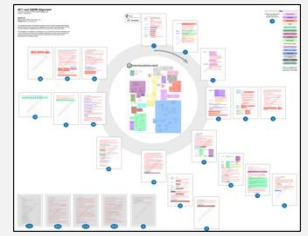
- M11 is a Working Group within ICH
- The WG has produced three documents:
  - A guideline (general overview)
  - A protocol document template specification
  - An associated technical specification detailing content within the template (e.g. CT)
- The focus is on the protocol document, the human readable view

CDISC USDM



- Unified Study Definitions Model
- A logical model with associated CT
- Designed to provide industry and academia with a consistent way to digitize study designs
- Supports interventional (incl complex design) and observational study designs
- Provides support for protocol document templates
- Provides support for precise definition of the study design including detailed SoAs

Digital Protocol



- USDM fully supports the M11 and other templates
- M11 documents can be digitized and held within the USDM format
- ICH M11 and USDM share common controlled terms
- USDM and M11 combined provides a complete electronic digital protocol solution

360i: Next Step to Realizing Standards Driven Research

Intelligent protocol-driven research to improve patient outcomes

Science & Innovation

Study Design & Conduct

Study Analysis & Review

Standards Driven Automation

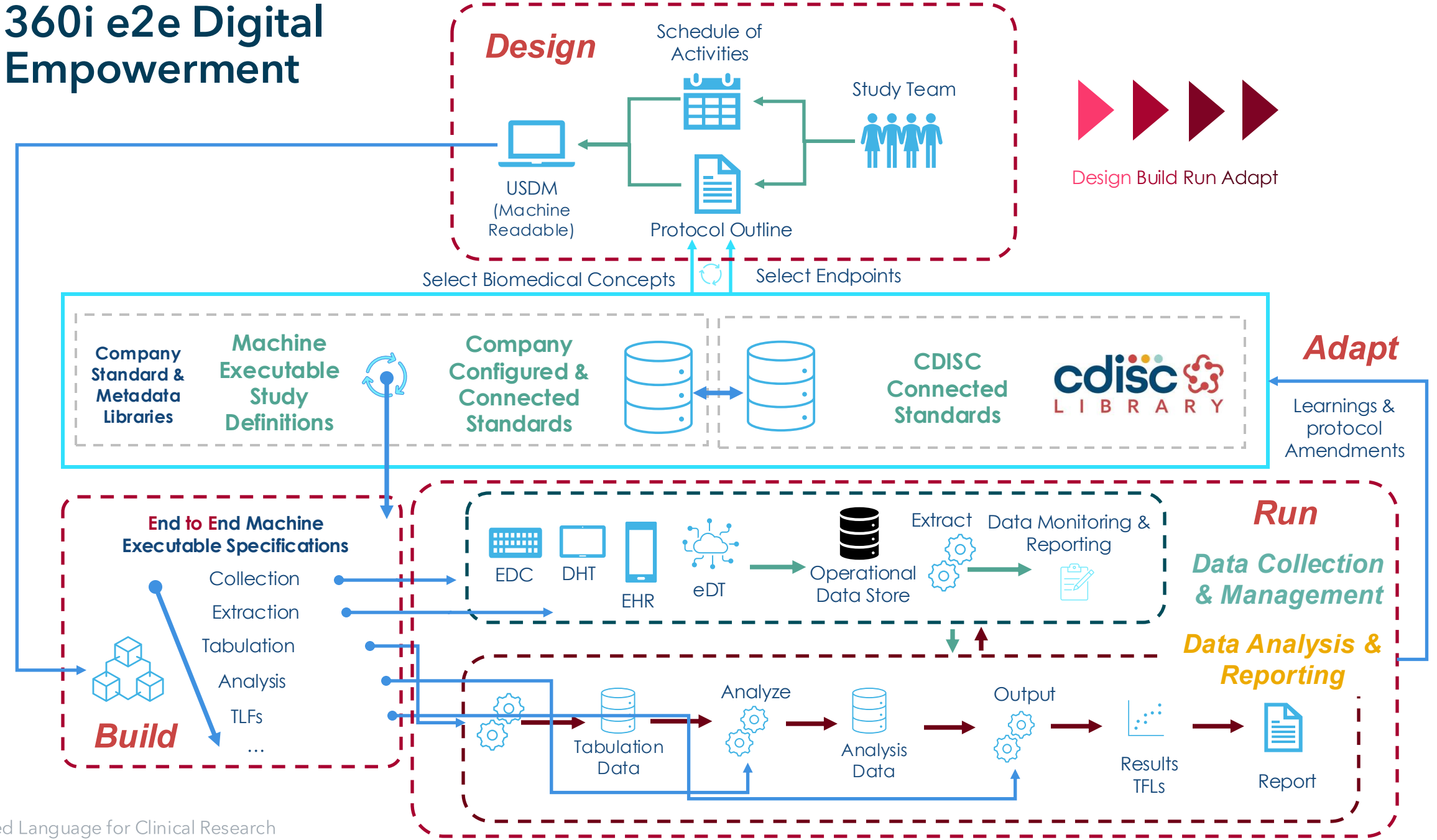
Well-defined scientific concepts

With a connected data life cycle

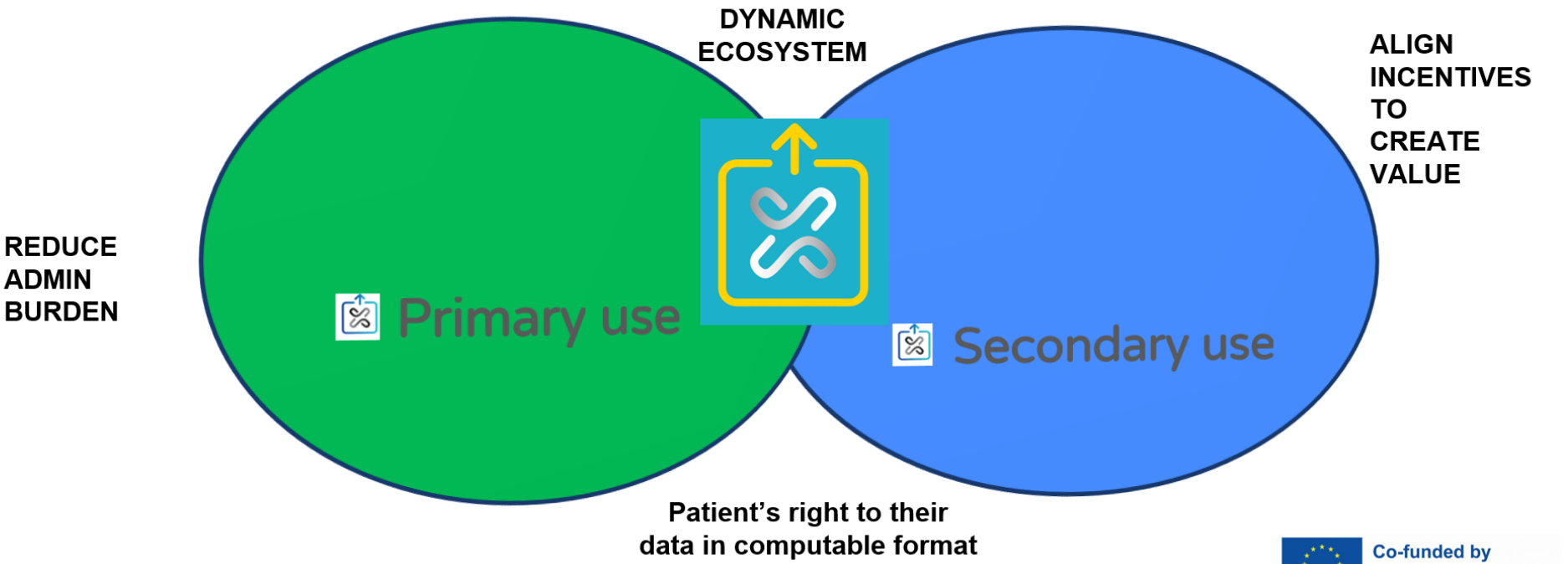
For traceable, interactive, and AI driven results

Courtesy of CDISC 360i team

360i e2e Digital Empowerment



PRIMARY & SECONDARY USE are not (Totally) SEPARATE WORLDS



Courtesy of xShare IHI Consortium

Co-funded by the European Union

Digital Protocol (USDM)

Open study enrollment

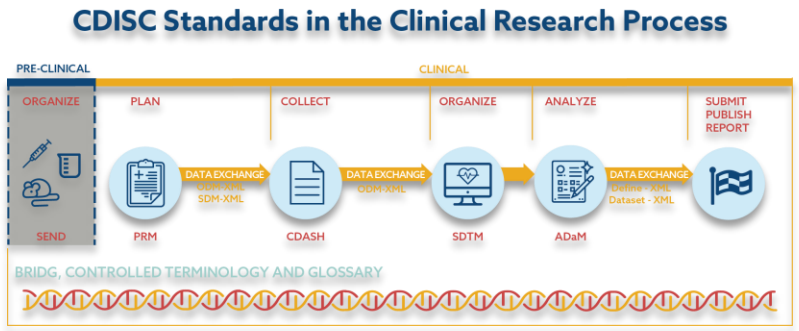
Study participation (study schedule of activities)

Patient community w patient facing activities enabled by MRCT glossary

Study Data Collection informed by Data Management Best Practices (SCDM)

Share
EHR Xchange Format

SCDM



Not a comprehensive view of all CDISC initiatives

MULTI-REGIONAL CLINICAL TRIALS
THE MRCT CENTER of BRIGHAM AND WOMEN'S HOSPITAL and HARVARD

Clinical Research Glossary

Image from Stock photos

Value Of A Connected World

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

Patients	Data that is easier to extract and understand making it more accessible to patients
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
Researchers	Reduce barrier to entry and cost for standards through ready to use implementable standards & open source tools
Technologists	Provide machine readable and interoperable inputs and outputs for easier adoption by software solutions

Courtesy of CDISC 360i team

CDISC – Patient Centricity & Data Standards

The vision for the future

Together we can do so much more

Thank you

Discussion and Q&A

Upcoming Clinical Research Glossary Webinar

Join the MRCT Center on **June 24 from 12 – 1 PM ET** to learn how to participate in the annual **Public Review**—an essential step in making these plain language clinical research definitions a global standard.

Your involvement ensures the Clinical Research Glossary remains accurate, inclusive, and effective for informed decision-making in clinical research.

Register here:
https://lp.constantcontactpages.com/ev/reg/4dmwmwf

Representation in Research

- Underrepresented Populations in General
- Disabled populations/People with disabilities
- Global populations/People living outside the US
- Financially challenged and underinsured populations
- LGBTQIA+ populations
- Limited English Proficiency (LEP) populations
- Resources for IRB/HRPP members

https://mrctcenter.org/project/representation-in-research/

Many thanks again!