WHEN CLINICAL RESEARCH IS DONE IN SILOS, WE CAN’T HARVEST CURES.
THERE’S A PROBLEM WE NEED TO TALK ABOUT

Clinical research data are collected in a hodgepodge of formats that won’t allow it to talk. This practice of “siloed research” is a disease in itself, leading to redundancies, dead ends and the loss of valuable time and billions of dollars.

CDISC IS THE SOLUTION.

WHAT IS CDISC?

Unlocking cures is our life’s work. At CDISC, we enable clinical research to work smarter by allowing data to speak the same language.

CDISC is a 501(c)3 global, non-profit charitable organization that develops data standards to streamline clinical research and enable connections to healthcare, empowering the valuable information offered by patients participating in research studies around the world.

Standards Development

Drivers

- Regulation
- New scientific discovery
- EHR, claims and other data sources
- Consumer-driven healthcare

CDISC Team & Volunteers

SHARE Ecosystem

CDISC Standards are required for regulatory submissions to FDA (U.S.) and PMDA (Japan), endorsed by China FDA, and requested for use by the European Innovative Medicines Initiative (IMI).

BENEFITS OF IMPLEMENTING CDISC STANDARDS

- Fostered efficiency
- Enhanced innovation
- Facilitated data sharing
- Increased predictability
- Complete traceability
- Improved data quality
- Reduced costs
- Streamlined processes
CDISC Foundational Standards are the basis of the complete suite of standards, enhancing the quality, efficiency and cost effectiveness of clinical research processes from beginning to end.

CDISC Standards in the Clinical Research Process

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THERAPEUTIC AREA STANDARDS

CDISC Therapeutic Area (TA) Standards extend the Foundational Standards to represent data that pertains to specific disease areas. CDISC has developed TA standards for the following disease areas with more in the pipeline annually:

- Alzheimer’s
- Asthma
- Breast Cancer
- COPD
- Cardiovascular
- CDAD
- Colorectal Cancer
- Diabetes
- Diabetic Kidney Disease
- Duchenne MD
- Dyslipidemia
- Ebola
- Hepatitis C
- HIV
- Influenza
- Kidney Transplant
- Lung Cancer
- Malaria
- Major Depressive Disorder
- Multiple Sclerosis
- Nutritional Standards
- Pain
- Parkinson’s
- Polycystic Kidney Disease
- Prostate Cancer
- QT Studies
- Rheumatoid Arthritis
- Schizophrenia
- Traumatic Brain Injury
- Tuberculosis
- Vaccines
- Virology

HEALTHCARE LINK

The Healthcare Link initiative focuses on creating standards and methods that link healthcare delivery and clinical research by leveraging electronic source data (eSource) from mobile devices, wearables, and other real-time sources.
**SHARE**

Shared Health and Research Electronic library (SHARE) is our metadata repository that provides computer-readable versions of CDISC standards to improve collecting, aggregating and analyzing standardized data from early design to end analysis. CDISC is the only Standards Development Organization to free standards from PDF and deliver them electronically.

**MADE POSSIBLE THROUGH SHARE**

- Electronic versions of all CDISC standards & guidelines
- Controlled Terminologies
- Explore variables reused in multiple standards
- Standards Interconnection
- Diff Files for rapid impact analysis
- CRFs mapped to CDISC Standards
- Standards Version Management

**SHARE API**

The SHARE Application Programming Interface (API) enables other metadata repositories and software tools access to SHARE content, facilitating the implementation of CDISC standards, and further automating clinical research processes.
Although all the information presented was new to me, it was explained in enough detail to easily understand. The exercises were very useful to apply all that was learned and helped me conceptualize how I would practically use AdA,M.

The instructor explained clearly and got to the point of SDTM, not only spec and IG but also FDA/PMDA regulations.

The instructor was quite knowledgeable about CDASH topics and was able to relay all information in a friendly and interesting manner. It provided an insight on how to begin standardization of CRFs.

Your training dollars support the ongoing development of global standards to foster smarter research to unlock cures.
CDISC standards and related innovations would not be possible without the dedicated volunteer efforts and financial assistance of our member organizations. Our members’ support ensures that CDISC standards remain open and free, and that they are sustainable into the future. We sincerely appreciate the continuing support and advocacy of our members.

MEMBERSHIP BENEFITS

- Significant Discounts on Training and Events
- Exclusive Access to SHARE and SHARE API
- Free Monthly Members-Only Mini Training Sessions
- Participation in the CDISC Engagement Trail
- Postings on the CDISC Job Board

EVENTS

Join CDISC at one of our global events! CDISC Interchanges offer attendees the opportunity to learn best practices in standards implementation and to network with industry colleagues.
CDISC collaborates with a variety of organizations to develop Therapeutic Area standards for multiple disease areas through the CFAST initiative.

CDISC works closely with regulators around the world to ensure our standards:
- Streamline research from beginning to end
- Facilitate the eSubmission review process
- Foster high-quality clinical research
- Support the approvals of safe and effective medicines for patients

CDISC and PhUSE partner to further the mission of each organization, with CDISC focusing on developing global, platform-independent data standards, and PhUSE focusing on implementing CDISC standards. The two organizations combine efforts on key initiatives around end-to-end standards and semantics, strengthening an interdependent process.

3Cs participate in a variety of initiatives and activities throughout Europe, China, Japan, and Asia-Pacific to enrich our global presence in local regions.

CDISC collaborates with fellow SDOs to develop standards that are synergistic to facilitate workflow from patient care to medical research, enabling a learning health system.
HOW CAN I HELP UNLOCK CURES?

You are key to this effort. Please consider becoming an CDISC Unlock Cures Champion. Your partnership will enable developing clinical research data standards that streamline research, making it possible to develop better, faster therapies for patients around the globe. When we reach our goal of 100% standards adoption, our job will be done. Until then, thanks for your help in getting us there.

GET INVOLVED WITH CDISC.

BECOME A MEMBER  VOLUNTEER  SPONSOR  DONATE

FIND OUT MORE:
CDISC.ORG
UNLOCKCURES.ORG