Data Standardisation Strategy Stakeholder Workshop

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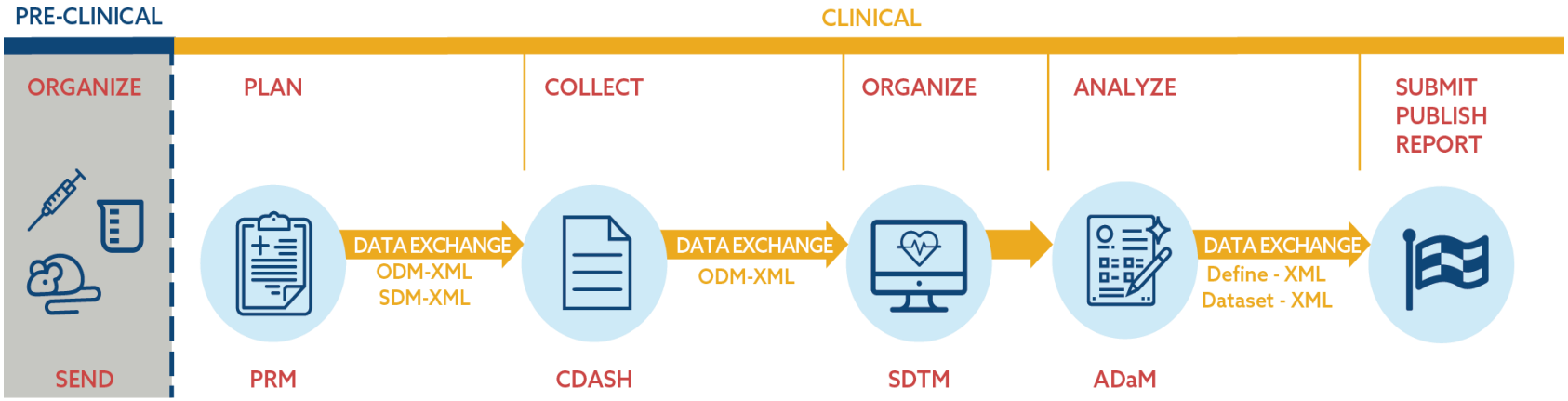
***Mission**: To develop and support global, platform-independent data standards that enable information system interoperability to improve medical research and related areas of healthcare*

- Global Non-profit Standards Development Organization
- 20 Years of Regulatory Clinical Data Standards Development and Implementation
- Consensus-based standards development
- Experienced Leadership Team and Dedicated Staff of 40+ Professionals and SMEs
- Volunteer Network of 1000+ Industry Experts
- 500+ Member Organizations
- Widely Adopted and Freely Available Clinical Research Data Standards
- Mature Standard Governance Processes
- Innovative Open-Source Technology for Standards Library and Metadata Management
- Evolved in a wide range of emerging Industry Initiatives and Projects
- Collaborative Ecosystem of Relationships and Partnerships
  - Members, Regulators, Patient Foundations, Academia, SDOs and Industry

CDISC Standards in the Clinical Research Process



TAUGS

BRIDG, CONTROLLED TERMINOLOGY AND GLOSSARY

Alliances and Collaborations

phuse

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

Additional Collaborations

- Academic Institutions
- Accumulus Synergy
- BioPharmaceutical Statistics Leaders Consortium
- Clinical Data Privacy Consortium
- ImproveCareNow
- Learning Health Community
- Oxford University
- Phuse
- Pharmaceutical Data Standards Leaders
- Vivli

Regulatory Agency Collaboration

Trusted and required by the United States FDA and Japan's PMDA, CDISC streamlines the review process and expedites approval times for more efficient and effective clinical research. CDISC Standards are also recommended by China's NMPA for clinical data submissions.

Requiring standardized data enables regulators to modernize the review process with a more consistent use of analysis tools to better view drug data and highlight areas of concern.

By standardizing raw data, interoperability and reusability across studies is increased and reproducibility and traceability is maximized.

Ensuring all data submitted by pharmaceutical companies is standardized reaffirms the data that is reviewed is safe and effective. As CDISC continues the quest for global awareness and adoption of standards, with your help, we can find ever-better ways to create a shared language that increases visibility into data and brings better, safer drugs to patients more quickly.

Patient Foundations Collaboration

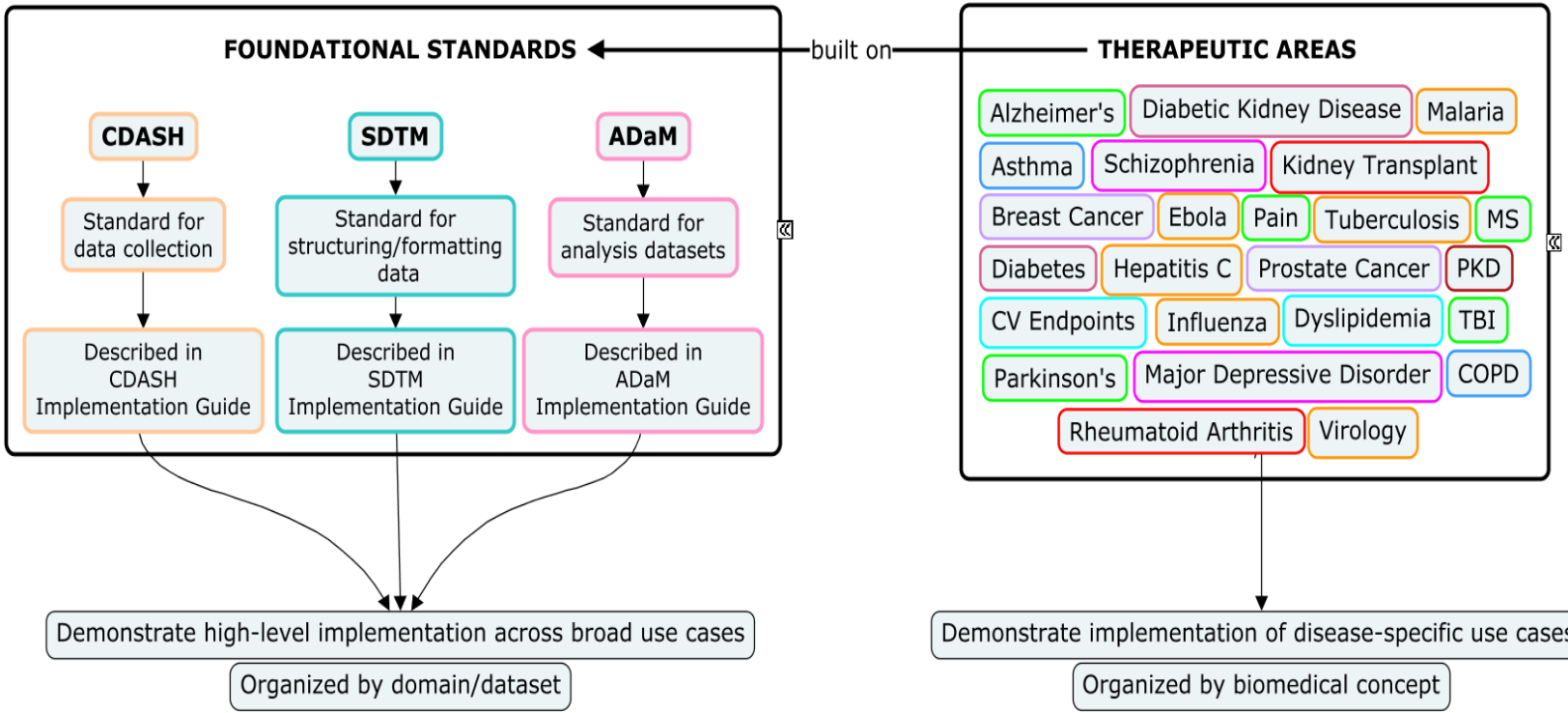
From Alzheimer's to kidney disease to malaria to Covid and beyond, CDISC standards have helped drive critical breakthroughs in treating diseases. For decades, we have worked hand-in-hand with our community of expert volunteers, member organizations, and non-profit partners around the world, developing standards that help mission-focused foundations and patient-centered organization achieve their goals of data standardization and sharing.

CDISC has worked with C-Path Consortia, Transcelerate Biopharma, MS Society, One Mind, Gates Foundation, WWARN, CHDI, DCRI, Cohen Veterans Bioscience, The Helmsley Charitable Trust, Pancreatic Cancer Action Network, and others to enable global researchers to efficiently aggregate and analyze data across studies so they can find the hidden connections that make a difference in the lives of the patients.

By working collaboratively with patient foundations and organizations, CDISC has created over 45 Therapeutic Area User Guides (TAUG) that provide the best practices and documentation on how to use the CDISC Standards from collection to analysis in specific disease treatment areas.

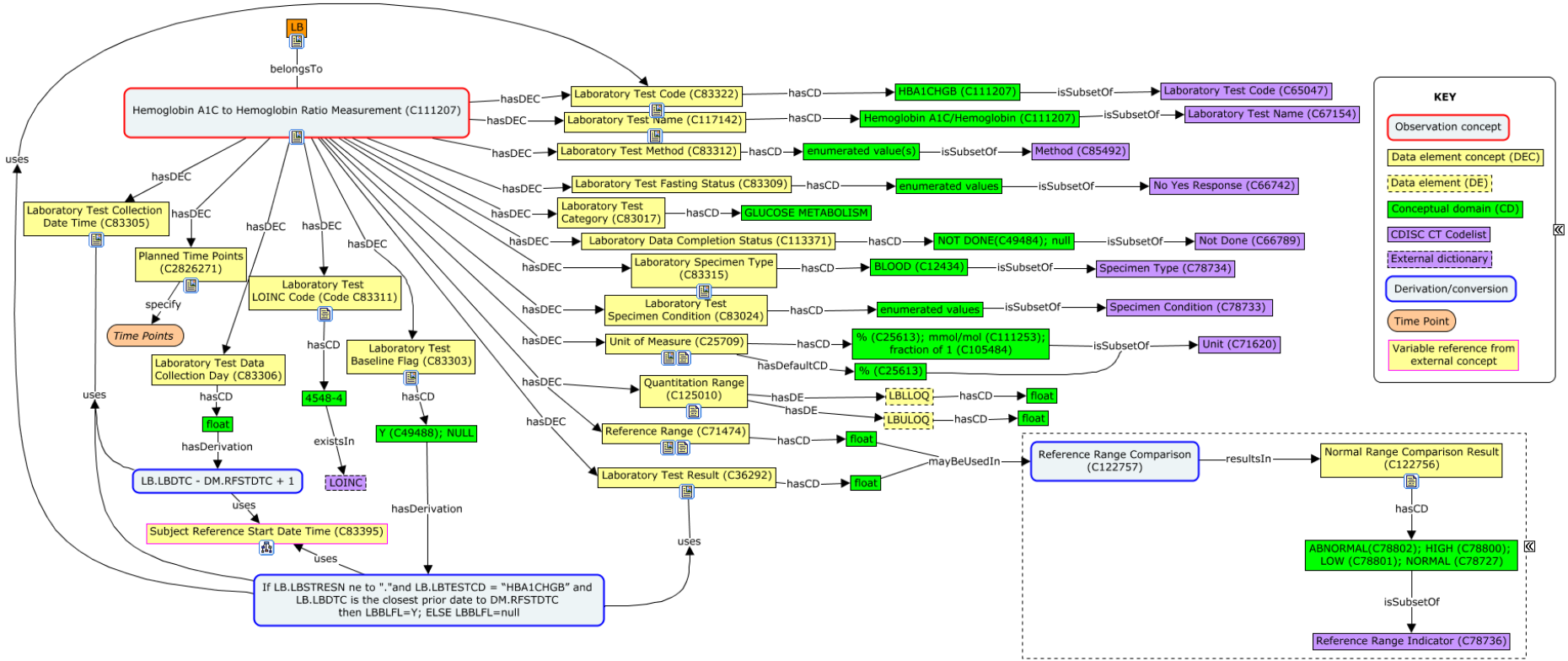
TAUGs provide disease-specific data standards, implementation examples, standardization of applicable Questionnaires, Ratings and Scales, and extended controlled terminologies that allows for the creation of standardized data for scientific data sharing and RWD harmonization and analysis.

CDISC Standards



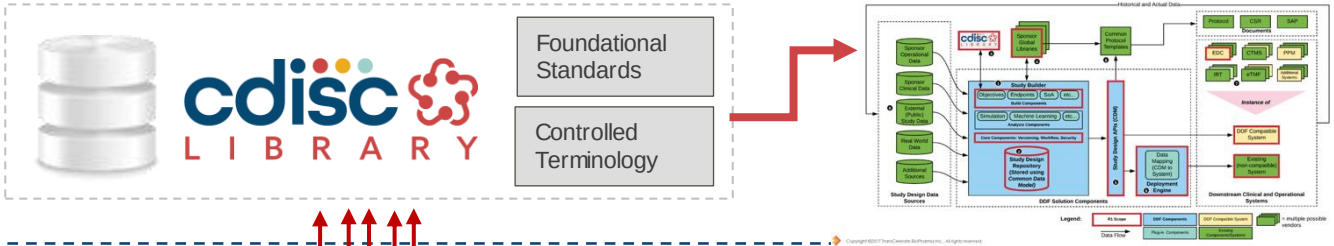
*The full list of foundational and therapeutic area standards are available at https://www.cdisc.org/standards

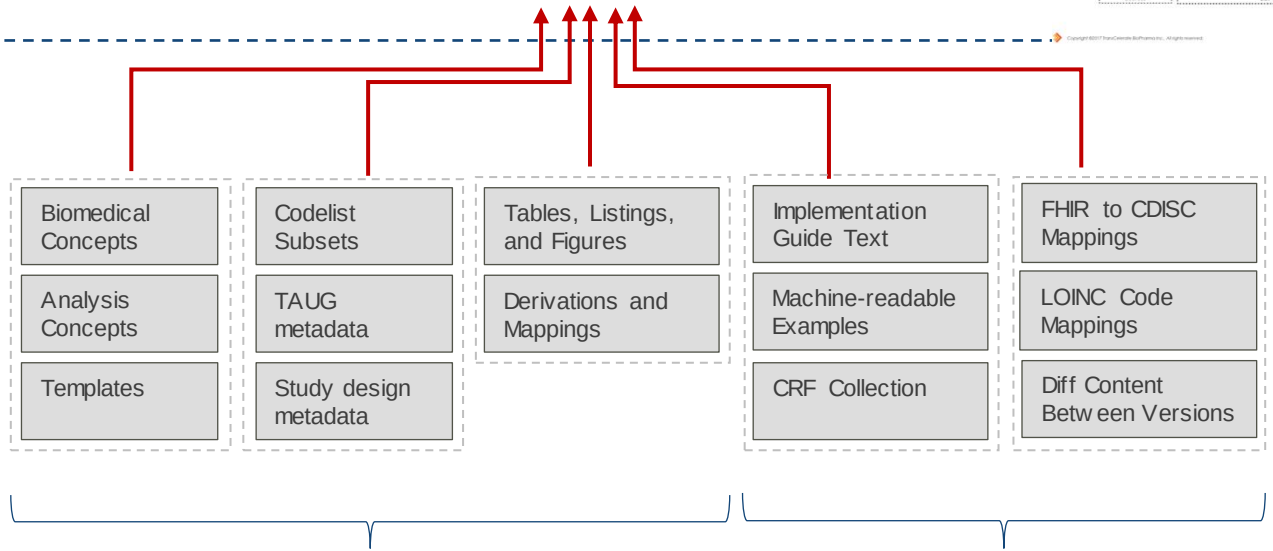
Biomedical Concept



CDISC Library

Connect with Digital Data Processes through Open-API





CDISC Standards

Informative Content

Strategic projects ongoing and looking forward

- eCRF Portal and Validated Instruments - QRS Portal
- Analysis Results Standard
- Safety User Guide
- CDISC Biomedical Concepts
- CDISC Library – expansion of content and functionality
- COSA – CDISC Open-Source Alliance
- Machine readable and executable Conformance Rules
- Digital Data Flow Standards
- TAUGs, QRS, Digital Biomarkers
- Standards of the Standards – Standards governance beyond just clinical data elements