



2024

CDISC JAPAN
INTERCHANGE

TOKYO

12-13 JUNE: CONFERENCE & EXPO | 10-11 JUNE: TRAININGS

CDISC Technical Landscape

Anthony Chow, CDISC



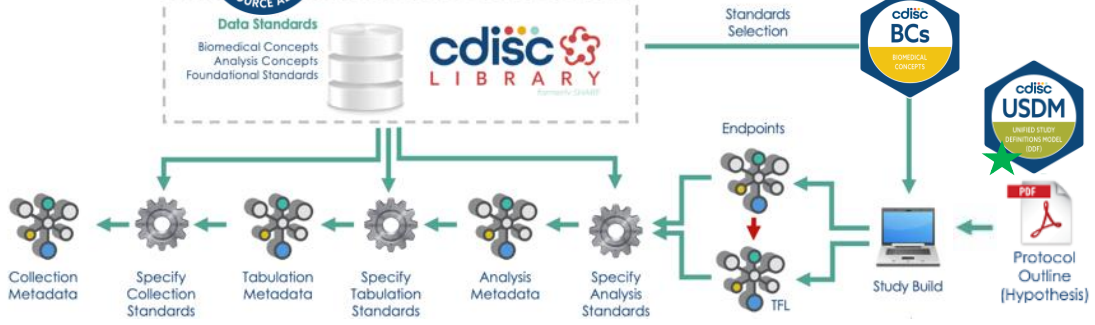
Meet the Speaker

Anthony Chow

Title: Executive Director, Data Science

Organization: CDISC

Anthony Chow is a multi-faceted professional with a proven track record in developing international standards, implementing software, managing projects, and providing consultancy. His professional experience spans multiple industries over the 30 years of his career. He earned a degree in Computer Science and is currently pursuing his master's in healthcare informatics. Anthony frequents professional conferences, volunteers, gives workshops, and presents on contemporary topics. In his free time, he enjoys nature photography and cooking for friends and family.



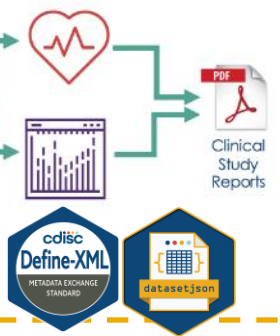
Study Design & Build




Data Sources



Study Execution



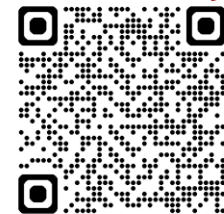


Collaborate to
innovate through
standards-based
automation.

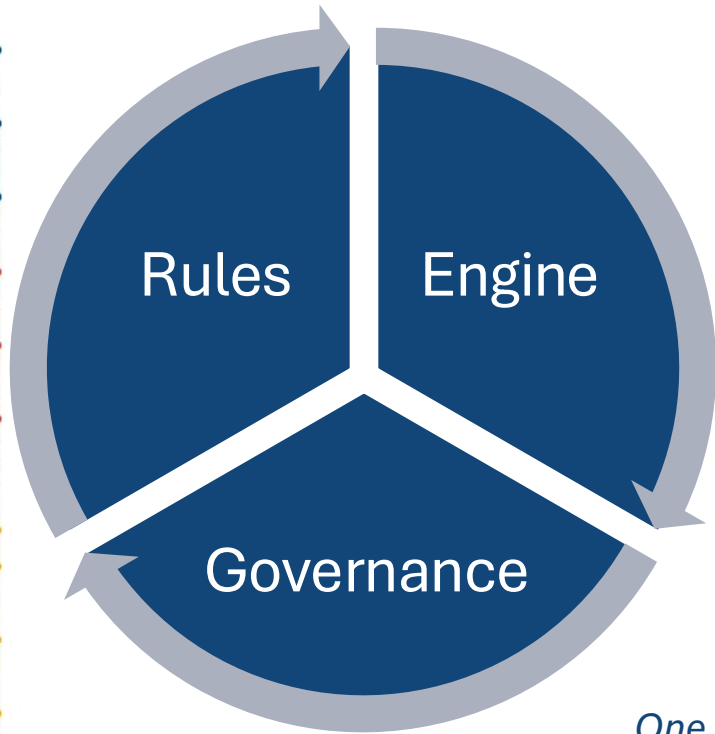
CDISC Open-Source Alliance (COSA)



- Recent and upcoming activities
- Hackathons
- Workshops
- Quarterly COSA Spotlight Webinars



What is CORE?



CDISC Open-Source Rules
Engine (CORE)



- **Rules:** Complete set of aligned, open and unambiguous machine-readable conformance rules for each standard including CDISC, Regulatory, and Industry needs
- **Governance:** Well-defined governance model for the evaluation, development, and publication of rules from all stakeholders
- **Engine:** Open-source rules engine available for testing and community use

One set of aligned and transparent conformance rules used across regulatory, sponsors, and vendors along with central curation and governance of the rules



CDISC Open-Source Rules Engine (CORE)



- Latest and upcoming release of CORE Command Line Interface (CLI)
- Expanded support for Digital Data Flow (DDF) rules
- Statistical computing environment (SCE) integrations
- FDA Research Collaborative Agreement (RCA)
- Coming soon: CORE certifications

GitHub repo



CDISC's Data Exchange Framework



Logical Data Model

The UML class diagram (normative) as well as SQL Data Dictionary, Entity Relationship Diagram and example JSON output (informative)



Application Programming Interface (API) Specification

The API definition (normative) in JSON and HTML forms



CDISC Controlled Terminology

The controlled terminology (normative) developed for the project and published quarterly in the CDISC Library.



JSON

The API returns a JSON payload by default. Examples provided as JSON files. The API may also support XML and other media types.



Biomedical Concepts

Semantics that work across standards, including RWD, coupled with dataset specializations that provide pre-configured standards.



Dataset-JSON



- A dataset exchange standard for exchanging tabular data leveraging JSON designed to meet the regulatory submission needs and eliminate the limitations of legacy formats
- Version 1.1 under development to enhance from findings noted during the Regulatory Submissions Pilot with FDA
- Specification and API
- Virtual hackathon for tooling

Project team wiki





oak Data Transformation Engine



- R package {sdtm.oak} that is an open-source software solution to transform raw data into SDTM using a set of predefined syntax and algorithms.
- CDISC: Transformation logic between CDASH data collection scenarios and SDTM
- Data mapping rules between CDASH and SDTM to be accessible through CDISC Library

GitHub repo





Analysis Result Standards (ARS)



- A structured model, developed using LinkML, that represents the complexity of all analysis result components accurately
- Key Results: Logical data model and a User Guide
- Draft REST API specification
- Agile Scrum
- Hackathon
- Practical examples in GitHub


GitHub repo





Biomedical Concepts



- Concepts that define relationships between variables, associated terminology code lists, and linkages across standards
- 300 concepts curated
- Prebuilt with SDTM domains, variables, code lists, values, relationships, definitions
- Undergoing Public Review
- DDF  USDM CDASH  oak SDTM

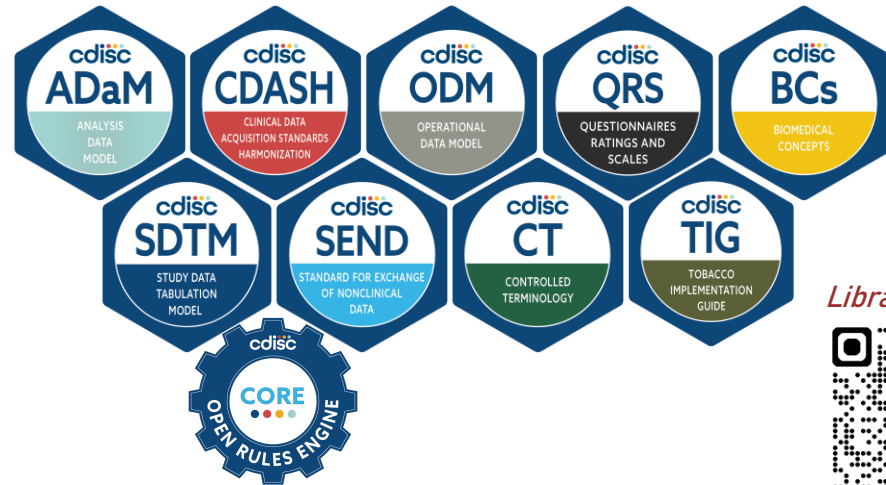
GitHub repo



CDISC Library



- Data Standards Browser accessible using cdiscID
- Library API is the simplest way to automate the retrieval of CDISC standards



Library Browser





Stay
Engaged



Collaborate &
Innovate



Transform



Thank You!

cdisc