OSB Workshop

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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.

CDISC Data Exchange Framework Examples

- Digital Data Flow
- CDISC Library
- CORE
- Biomedical Concepts
- Dataset Specializations
- OAK SDTM Transformations
- Dataset-JSON
- Analysis Results Standard
- ODM v2.0
- TMF
- M11

ODM v2.0 Data Exchange Standard

- Currently working on Dataset-JSON v1.1 and an API specification
- Next, working on ODM v2.0 supplements, including JSON schemas, ODM API specification, ODMPath, Compressed and streaming ODM
- ODM vendor extension library

Study Setup	Integration	Data Exchange	End-to-end Standards
• Study Design Model	• Enhanced semantics	• Dataset-JSON	• Biomedical Concepts
• Flexible metadata beyond CRFs	• RWD / HL7 FHIR support	• JSON support	• Enhanced MethodDef
• Matrix forms	• Data Queries	• REST API*	• Traceability enhancements

CDISC Open-Source Alliance (COSA)

Community Driven Development

Supports and promotes open-source software projects that create tools for implementing or developing CDISC standards to drive innovation in the CDISC community

cdisc

https://cosa.cdisc.org

Elements of the CDISC Strategy

A glimpse into the updated CDISC strategy and roadmap

Value to our Community: Expand and Connect

Expand, Connect, and Digitize our Standards

Embrace and adopt digital study design

Defining digital study design information up front (enter once, use many times) leveraged downstream will significantly increase automation, improve quality of the data, and accelerate delivery of results

Expand and connect our standards across the end-to-end clinical research information lifecycle

Connecting our standards and closing the gaps allows automation of the study information workflow allowing people to spend less time on transcription and more time on the science while having more confidence in the results

Define clear pipeline for integration of new data sources (e.g. DHTs, RWD)

Real world information is challenging to standardize up front, so it's critical CDISC helps ease the path to integrating the data ensuring lineage and traceability are represented in a standard way and the data quality meets or exceeds expectations

Value to our Community: Enable and Automate

Reduce Variability, Enable Interoperability, and Increase Automation

Develop implementation ready standards

Delivering standards that are ready to use and producer/ consumer centric simplifies standards management and adoption while reducing variability between studies

Create open-source technology enabled standards

Embracing technology integrated as part of standards is required to automate the research data lifecycle and realize the full value of standards

Establish and manage a conformance framework

Delivering a conformance framework as part of the standards will significantly increase data quality while reducing variability

Thank You!

Questions?

Interested in volunteering for Dataset-JSON v1.1?

https://www.cdisc.org/volunteer/form

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