CDISC Technical Landscape and Roadmap

Presented by Charles Shadle, Head of Data Science, CDISC

Meet the Speaker

Charles Shadle

Title: Head of Data Science

Organization: CDISC

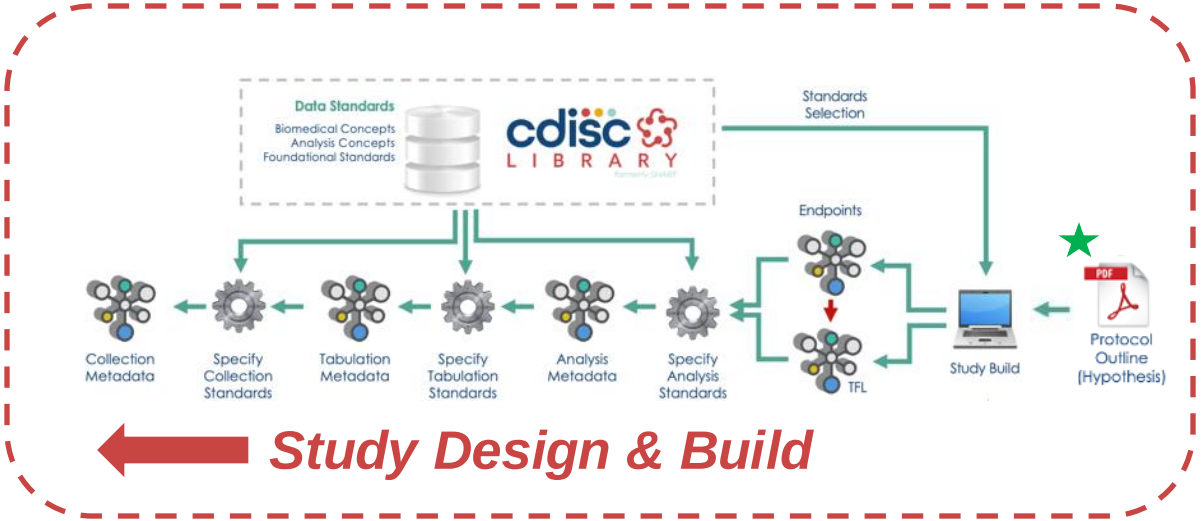
Charels Shadle is an experienced data science leader with a focus on advancing data standards and automation in the regulated biopharma industry. He has played a pivotal role in developing innovative processes for clinical data management, enhancing reproducibility, interoperability, and efficiency across the clinical lifecycle. With expertise in regulated environments, Charles has contributed to industry-wide efforts, enabling seamless data integration from protocol design to regulatory submission.

Agenda

1. 360 POC
2. Building Foundational 360 Capabilities
3. 360 Implementation

360 POC

CDISC 360


Data Standards
Biomedical Concepts
Analysis Concepts
Foundational Standards
cdisc LIBRARY
Standards Selection
Endpoints
Collection Metadata
Specify Collection Standards
Tabulation Metadata
Specify Tabulation Standards
Analysis Metadata
Specify Analysis Standards
TFL
Study Build
PDF
Protocol Outline (Hypothesis)
Study Design & Build

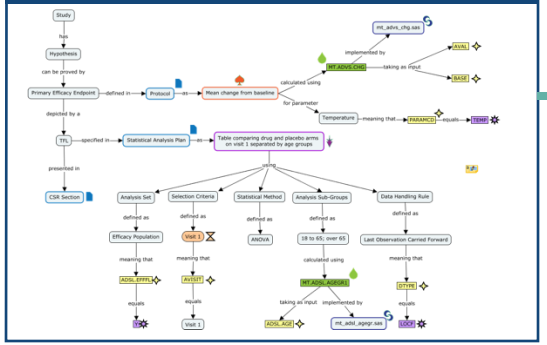

Data Sources
EDC
EHR
eDT
DHT


CDASH
SDTM
ADaM
Endpoints
Operational Database
Extract Transform Load
Tabulation Datasets
Create ADaM Datasets
Analysis Datasets
Analysis Results Dataset
PDF
Clinical Study Reports
Study Execution


abbvie
Allergan
AMGEN
AstraZeneca
Bayer HealthCare
BeiGene
Biogen
BIOMARIN
C&R RESEARCH
Celgene
Cytel
STATISTICAL SOFTWARE & SERVICES
Deloitte.
dMed 绵脉
FDA
formedix
frontier science foundation
GILEAD
Inductive Quotient
Research . Bigdata . Analytics
Johnson & Johnson
Lilly
Mel Consulting
MERCK
Microsoft
novo nordisk
ORACLE
Otsuka
Pfizer
PharmaStat
PINNACLE 21
POINT CROSS
S-CUBED
SANOFI
sas
Syneos Health
TALENT MINE
VITA DATA SCIENCES
a division of SOFTWORLD
xclinical
Clinical Solutions Group

CDISC 360 Workstreams

Workstream 1 - *ENHANCE STANDARDS*



Create concepts in knowledge graphs

Workstream 2 - *PUBLISH STANDARDS*

Load into library

Biomedical Concepts
Analysis Concepts
Foundational Standards

cdisc LIBRARY
formerly SHARE

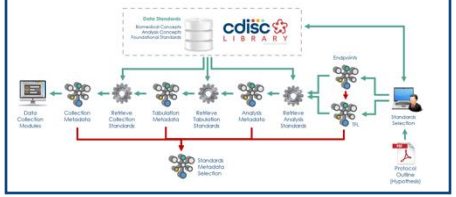
API

Extend API's

Transform concepts in machine readable form

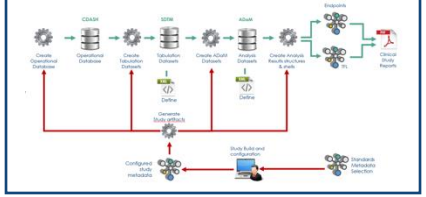
Study Library

Workstream 4 - *DEFINE*



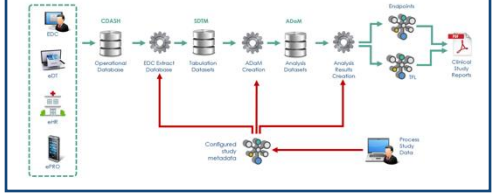
Identify and select standards specification (Use Case 1)

Workstream 5 - *BUILD*



Configure study specification and create artifacts (Use Case 2)

Workstream 6 - *EXECUTE*



Automatically process and transform data (Use Case 3)

CDISC 360 Whitepaper

Building Foundational 360 Capabilities

To build a foundation for 360 Implementation

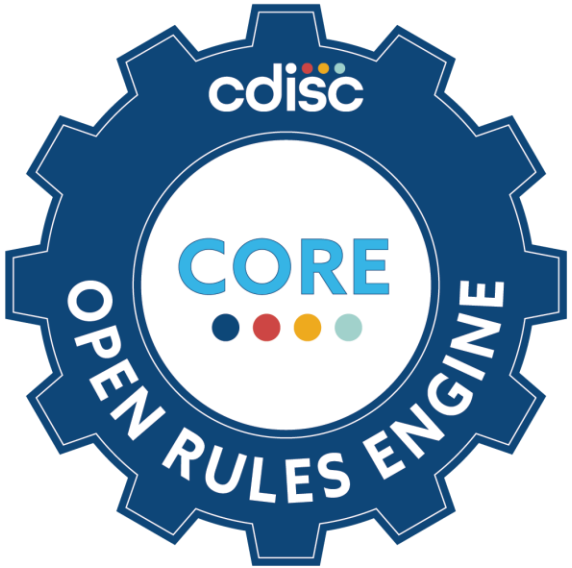
- We needed
  1. Collaboration …we can't do it all
  2. Conformance ….for automation, data must conform to the standards
  3. Defined relationships …between variables, associated terminology code lists, and linkages across standards
  4. Transformation…of raw data to SDTM
  5. Dataset exchange standard ….that would eliminate the limitations of legacy formats
  6. Analysis results standardization …to facilitate automation, reproducibility, reusability, and traceability of analysis results data.
  7. Digitized Accessibility…. to access all tools and allow easier integration and collaboration

1. Collaboration
CDISC Open-Source Alliance (COSA)

- Open-Source Software
- Hackathons
- Workshops
- Quarterly COSA Spotlight Webinars

COSA directory

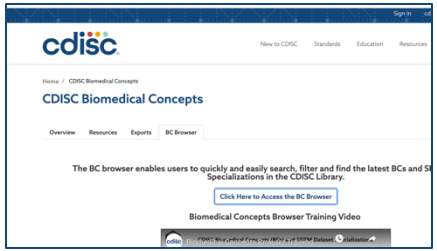
2. Conformance
CDISC Open Rules Engine (CORE)



- CDISC Open Rules needed an application that could check datasets for conformance -> CORE
- CORE v0.8.4 Released
- Expanded support for Digital Data Flow (DDF) rules
- Statistical computing environment (SCE) integrations
- FDA Research Collaborative Agreement (RCA)
- CORE certifications

GitHub repo

3. Defined relationships
Biomedical Concepts



cdisc BCs BIOMEDICAL CONCEPTS

- Concepts that define relationships between variables, associated terminology code lists, and linkages across standards
- 320 concepts curated
- Prebuilt with SDTM domains, variables, code lists, values, relationships, definitions
- DDF CDASH SDTM

USDM oak

- Publishing more in December!

GitHub repo

4. Transformation sdtm.oak

- 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

5. Dataset exchange standard
Dataset-JSON v1.1

- 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 (enhancements from findings noted during the Regulatory Submissions Pilot with FDA)has completed public review.
- Specification and API
- Virtual hackathon for a Viewer

Project team wiki

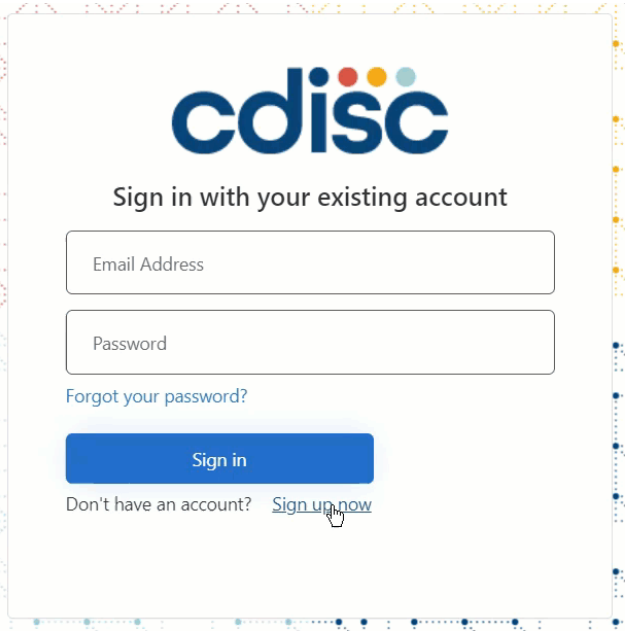
6. Analysis Standardization
Analysis Result Standards (ARS)

- 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

7. Digitized Accessibility CDISC Library



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

Library Browser

360 Implementation

What's Changed since the CDISC 360 POC?

New standards:

- DDF USDM
- Analysis Results Standard
- Biomedical Concepts and Dataset Specializations
- OAK SDTM Transformations
- Dataset-JSON for dataset exchange
- Open conformance rules

New software tools:

- Open Study Builder
- TLF Designer
- Admiral
- CORE
- OAK
- Dataset-JSON conversion tools
- Other COSA tools
- Other Pharmaverse tools

These lists are examples and not intended to be comprehensive

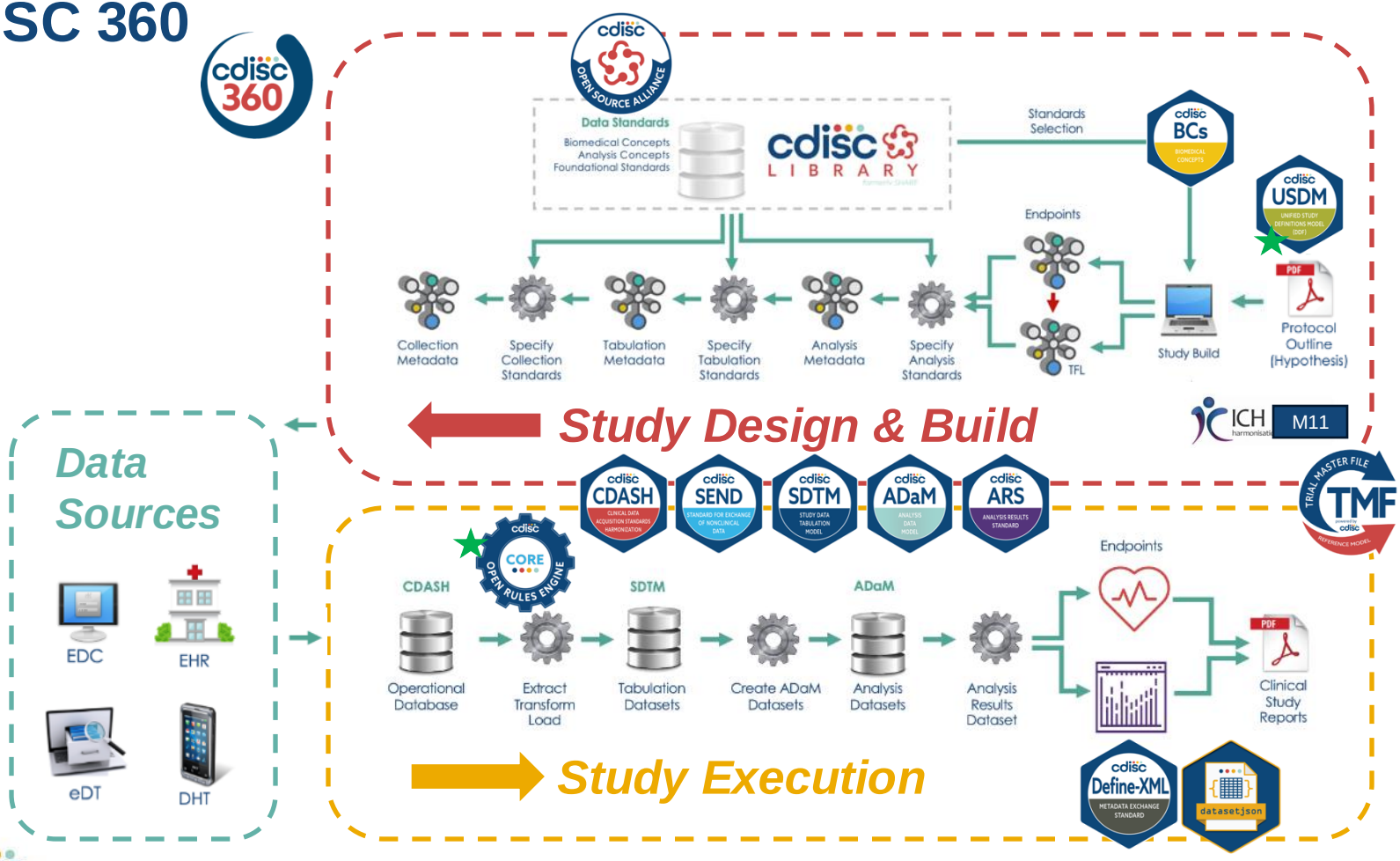
Software Tools*

Study Design	Data Collection	SDTM	ADaM	Define-XML	ARS
Open Study Builder	odmlib	OAK	Admiral	OpenCST	TLF Designer**
Study Definitions Workbench	ODM XML Stylesheet	Dataset-JSON Tools	Dataset-JSON Tools	defineR	JMP Clinical**
BC Browser		CORE	carver	odmlib	cards
DDF SDR		Smart Dataset Viewer		Define XSL Stylesheet	gtsummary

* Examples listed – not a comprehensive listing

** Open-source components expected to be available

CDISC 360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datasetjson

360i End State

360i has published a complete preconfigured study package with all the components defined in metadata from study design to submission, test data for the study, and software to execute the study data pipeline to generate analysis results

360i – Moving from Proof of Concept to Implementation

Register Now!

Thank You!