Introduction to OpenStudyBuilder

COSA Spotlight webinar  30 March 2022
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Background and vision

- **Background** – today characterised by
  - Lots of IT systems and tools
  - Numerous manual steps which consume time and resources ... and introduce errors
  - Costly system maintenance and integrations

- **Vision** – tomorrow characterised by
  - IT that enable seamless interoperability and cross-functional end-to-end collaboration
  - Driven by concept based data standards
  - Sustainable model for maintenance and integrations
Project scope

- **Establish a study builder solution**
  - To support the study specification process using concept based data standards *from* protocol development and CRF design *to* creation of submission datasets, analyses, reporting and public disclosure of study information
  - To promote seamless, cross-functional collaboration during study milestones and processes
  - To be able to close the legacy MDR solution
  - To be an active player in the industry transformation towards using concept based data standards for study specification and end-to-end digital data flow by collaborating externally with CDISC, TransCelerate DDF, vendors and peers as part of open source initiatives to avoid an NN custom solution
Why open source

• Avoiding a v2 custom solution
  • Solution based on industry standards
  • By driving this as an collaborative open source solution
• Benefit from collaborations
• Benefit from future tools and extensions
We are building an OpenStudyBuilder and MDR solution based on the CDISC 360 POC

Future State - with Concept-based Standards:
Study Specification in a CDISC 360 Study Builder App

Key features in the Study Designer App

- **Library**
  - Import definitions from external libraries.
  - Manage sponsor defined selections and definitions.

- **Define**
  - Identifiers and a general set of trial summary parameters for the study

- **Design**
  - Study design parameters as well as defining study arms, elements, epochs and visits

- **Select**
  - Search and select concept-based standards and define schedule of activities and assessments

- **Build**
  - Generate study specification artefacts that support automation of study setup and execution

https://www.cdisc.org/cdisc-360
What is the OpenStudyBuilder ...

- The OpenStudyBuilder is a new approach to working with studies that will promote end-to-end consistency and flow of study specification information
- **OpenStudyBuilder application** (web-based user interface)
- **Clinical Metadata Repository (MDR)** (central repository for all study specification data)
- **API layer** (allowing interoperability with other applications)
The OpenStudyBuilder includes

• A **Studies** part for specification of studies, including disease area and study type, objectives and endpoints, population and eligibility criteria, study compounds and other interventions, study design, arms and visits, schedule of activities and associated procedure and assessment instructions

• A **Library** part for maintenance of terminology standards (incl. CDISC controlled terminology, relevant parts of external dictionaries for medical terms, pharmacological classes, units, a detailed compound library, a granulated library of activity terms) as well as syntax templates for cross-study and cross-project harmonisation

• An underlying **knowledge database** enabling complex queries and visualisations for aggregation of information and showing how things are connected end-to-end
To apply concept-based data standards end-to-end

• From protocol preparation through study conduct to reporting and submission of applications to health authorities
  • and with reference to externally-compliant concept-based data standards and terminology

• Ensuring build-in compliance, and enabling more automation, efficient reuse across studies and projects, and aggregation of study specification details for insights
Vision

Design centrally for multiple purposes

SDTM: study data tabulation model,
ADAM: analysis data model,
TFL: tables, figures and listings,
EDC: electronic data capturing
**Process outline**

- **CTMS**
- **SmartChart**
- **StudyBuilder**
  - **Protocol outline**
  - **Refine protocol**
  - **CRF specification**
  - **Benefit/Risk**
  - **Build Protocol**
  - **Data for trial supplies**
  - **Build SAP**
  - **SDTM datasets**
  - **ADaM/TFL builder**
  - **Export to CTR**
  - **Data for pharmaCM**

**StudyBuilder**
- Study identifiers & registries
- Study status
- Study type
- Study title
- Benefit-risk table
- Study population & criteria
- Study arms and periods
- Study interventions incl compounds
- Study objectives and endpoints
- List of assessments
- Assessment instructions
- Schedule of activities

**Roles**
- Medical specialist
- Pharmacology scientist
- Statistician
- Global safety
- Programmer
- Data manager
- Trial manager
- Trial supplies responsible
- Medical writer
- Disclosure specialist
- Standards developer

**Process**
- Develop and maintain code lists and templates in clinical MDR
- Protocol outline
- SmartChart
- CTMS
- StudyBuilder
  - Protocol outline
  - Refine protocol
  - CRF specification
  - Benefit/Risk
  - Build Protocol
  - Data for trial supplies
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**Legal**
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**Technical**
- Introduction to StudyBuilder

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Core capabilities for a standards based OpenStudyBuilder

Industry and sponsor standards

• CDISC and Sponsor defined controlled terminologies
• Subset of external dictionary terms
• Concept based standards (Biomedical Concepts)
• Syntax templates for standardising descriptions referring to terms
• Full versioning and audit trail on data element level
• Role based access and workflows

Study definition repository

• Select and define the study specification using concept based data standards
• All related to versioned library elements
• Version control and audit trail
• Integrations for up- and down stream usage
Introduction to StudyBuilder

Protocol Process

Overview of protocol elements:

The process map provides links to where you specify each element:

- **SELECT STUDE**
- **ADD STUDY**
- **STUDY DESIGN**
- **STUDY POPULATION**
- **SWISS & PREVIEW**
- **ACTIVATE & REVIEW**

- **Study Population** includes criteria
- **Inclusion Criteria**
- **Exclusion Criteria**
- **Randomization Criteria**
- **Dosing Criteria**
- **Withdrawal Criteria**
- **Other Criteria**

Protocol Elements (COSA SDTM):

<table>
<thead>
<tr>
<th>Element</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Dosing</td>
<td>Dosing protocol is specified in a single strength, using a single strength in a single strength. Inclusion criteria for dosing are specified in a single strength, using a single strength in a single strength.</td>
</tr>
<tr>
<td>Flowchart</td>
<td>Flowchart is specified in a single strength, using a single strength in a single strength. Inclusion criteria for flowchart are specified in a single strength, using a single strength in a single strength.</td>
</tr>
<tr>
<td>Study Design</td>
<td>Study Design is specified in a single strength, using a single strength in a single strength. Inclusion criteria for Study Design are specified in a single strength, using a single strength in a single strength.</td>
</tr>
</tbody>
</table>

Additional elements, such as SDTM, ODM, ADaM.
OpenStudyBuilder Conceptual Architecture

OpenStudyBuilder system and integrations

Foundational components – all can be shared under COSA

CDISC Library

CDISC Concepts Library
API
CDISC Data Model

Standards Management
Integrated into the OpenStudyBuilder App as the Library module

CDISC Standards Management Tools

CDISC Library Repository

Other Libraries / Dictionaries

X Repository

OpenStudyBuilder Documentation
Online documentation portal

OpenStudyBuilder App
Web app

Protocol Metadata add-in
Structured content

Up-stream integrations
ODM-XML
Integration Service

Study Metadata

Clinical MDR

Industry Standards

Sponsor Standards

Study Definitions

Core Components: Linked graph data model (Neo4j), Versioning, Workflow, Security

Open Study Builder API

CDISC Data Model

SDTM Study Design
Define.xml

Down-stream integrations

SCE with SAS & R

Explore data

FAIR based

Add-on components
- some can be shared under COSA
OpenStudyBuilder next steps

- We will release a non-GCP MVP internally at Novo Nordisk in Q3 2022
- We plan a GCP release later
- We intend to share the project as an open source project under COSA in Q3 2022
  - [https://cosa.cdisc.org/directory/openStudyBuilder](https://cosa.cdisc.org/directory/openStudyBuilder)
  - Currently only containing a project description
- We seek to actively collaborate with CDISC, TransCelerate DDF, peers and vendors
- Join us at [COSA OpenStudyBuilder Workshop](https://cosa.cdisc.org/directory/openStudyBuilder) Breakout Session Selection | CDISC