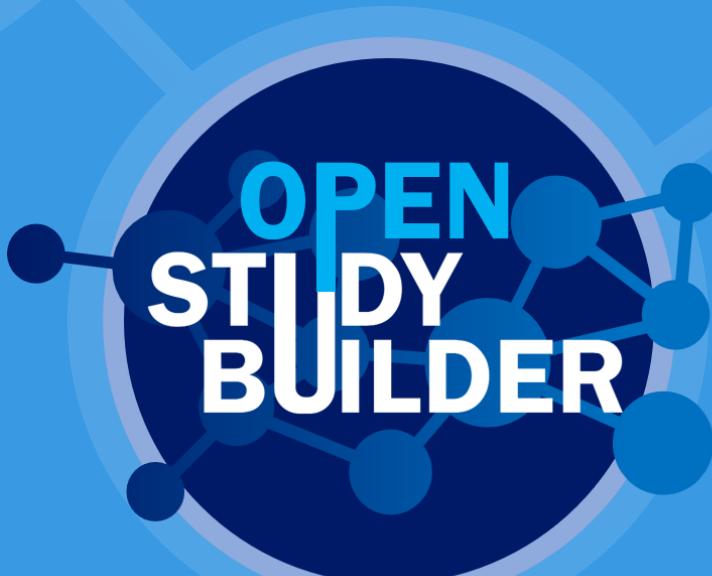


OpenStudyBuilder Hub (OSB-Hub)

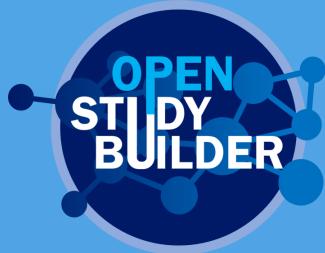
OSB-Trail-ControlledTerminology

Innovating Through Community Collaboration
July 2024

Katja
Pascal
Panikos



Agenda



Introduction

- OpenStudyBuilder
- OSB-Hub
- OSB-Trails

OSB-Trail-ControlledTerminology



What is the OpenStudyBuilder?

A Metadata Data and Study Definition Repository

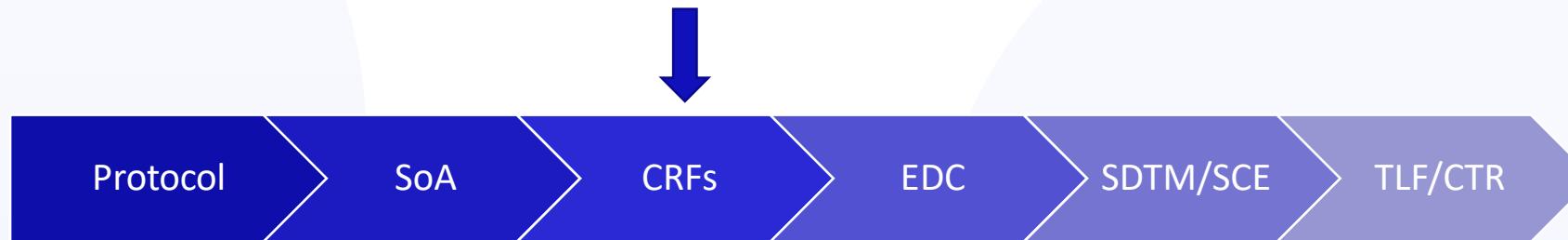
End-to-end automation from structured protocol to submission deliverables using concept-based standards



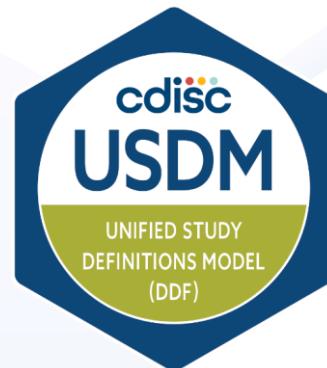
MDR & SDR



Goal of Open Study Builder



Aligned to:



COSA Collaboration Team





OSB Hub

Mission and Vision:

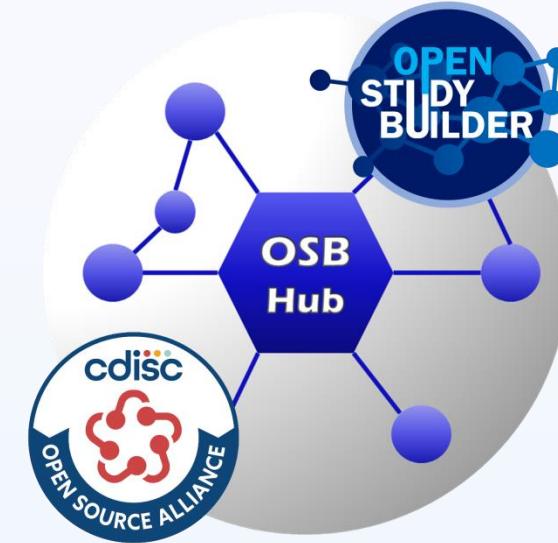
Support the utilization and enhancement of the OpenStudyBuilder open-source tool.

Core Objectives:

Collect feedback, run focused projects, drive innovation through community engagement.

Participants:

Everybody is invited!



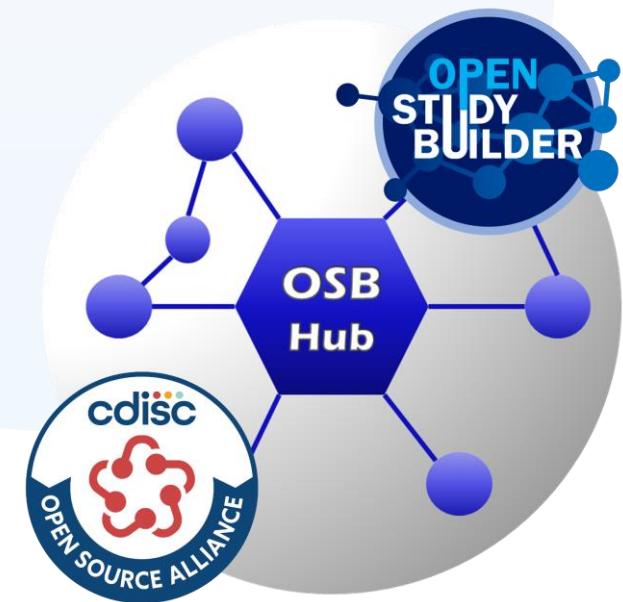
Purpose of OSB Hub

- COSA Community
 - List, add and discuss use-cases
 - Feedback & community interest
 - Prioritise use-cases of interest
 - Manage and run focus projects
 - Utilization and enhancement of the OpenStudyBuilder

😊 Join us on Slack: [Invite](#)

💡 Feedback on Use-Cases: [Discussions](#)

📋 Checkout Information: [Wiki](#)



Participate in OSB Hub

■ Rate & Join Discussions

Discussions

- UC1: Defining Enterprise Meta - Controlled Terminology, Dictionaries and Unit of Measure**
KatjaGlassConsulting started 2 hours ago in Use-Cases
- UC2: Defining Enterprise Meta - Clinical Standards**
KatjaGlassConsulting started 2 hours ago in Use-Cases
- UC3: Defining clinical study meta data**
KatjaGlassConsulting started 2 hours ago in Use-Cases
- UC4: Integration with data collection systems**
KatjaGlassConsulting started 2 hours ago in Use-Cases
- UC5: Enabling transformation through Code Generation**
KatjaGlassConsulting started 2 hours ago in Use-Cases
- UC6: Enabling Document generation**
KatjaGlassConsulting started 2 hours ago in Use-Cases
- UC7: Impact Analysis and Orchestrating**
KatjaGlassConsulting started 2 hours ago in Use-Cases

This Use-Case is about the definition of enterprise data for controlled terminology, dictionaries and unit of measure. Please join the discussions to include ideas, suggestions and consideration related to this use case. Additionally leave a rating if you think the use-case or addition is relevant for prioritization.

We consider following sub use cases:

- UC1.1: Controlled Terminology
- UC1.2: Dictionaries
- UC1.3: Unit of Measure

Upvote (1) Smile (1) Thumbs Up (1) Thumbs Down Surprised Happy Angry Heart Rocket Speaker

Add a comment

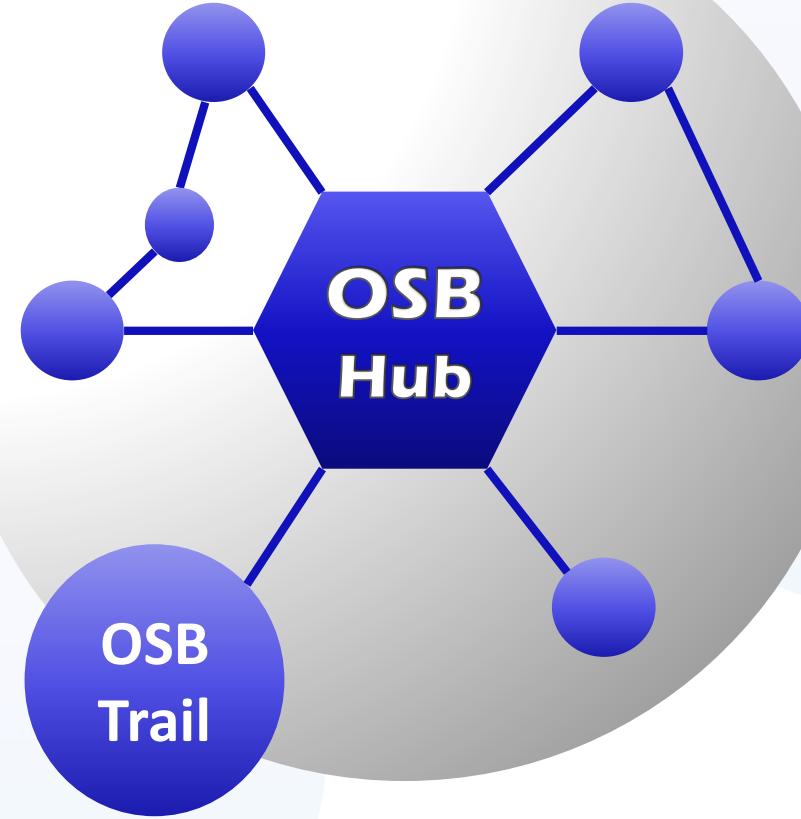
Write
Preview

Add your comment here...

Markdown is supported
Paste, drop, or click to add files

Close discussion
Comment

OSB Trails – Focus Projects



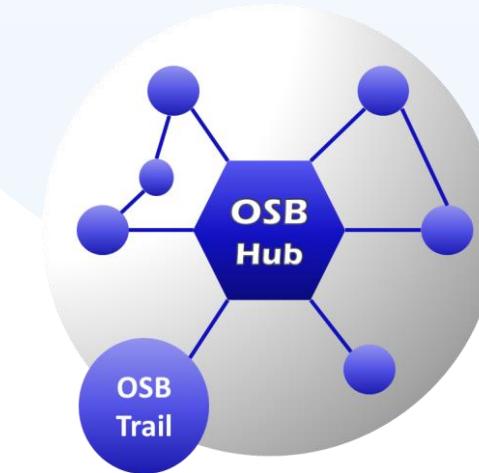
OSB Trails – Focus Projects

Work as a community on:

- Enhanced documentation
- Best practices
- Additional requirements
- Supporting tools
- Concepts for integrations
- ...

Community powered Use Cases:

- Together, we'll chart the course for our upcoming trails.



OSB-Trail-ControlledTerminology

CT Catalogues ?

All ADAM CT CDASH CT COA CT DDF CT DEFINE-XML CT GLOSSARY CT PROT

Select rows

Search Q Search with terms Operator or Delete

+ Download Print Import

Library	Sponsor preferred name	Template parameter	Code list status
CDISC	Category of Questionnaire	No	Final
CDISC	Relationship to Subject		
CDISC	Q5-Alzheimer's Disease Assessment Scale - Cognitive Disturbance Version		

VisitType (CTCodelist_000002) - TIMELB / Terms listing

Library	Sponsor name	Order	Name status	Name date	Concept ID	Code submission value	Name submission value
Sponsor	Early discontinuation		Final	Apr 22, 2024, 1:10 PM	CTTerm_000190	EARLY DISCON VISIT TYPE	EARLY DISCON VISIT TYPE
Sponsor	End of treatment		Final	Apr 22, 2024, 1:10 PM	CTTerm_000170	EOTRT VISIT TYPE	EOTRT VISIT TYPE
Sponsor	End of trial		Final	Apr 22, 2024, 1:10 PM	CTTerm_000173	EOTRIAL VISIT TYPE	EOTRIAL VISIT TYPE
Sponsor	Follow-up		Final	Apr 22, 2024, 1:10 PM	CTTerm_000172	FU VISIT TYPE	FU VISIT TYPE



OSB-Trail-ControlledTerminology

CDISC & Sponsor Standards

- How to seamlessly integrate with new CDISC CT versions?
- How to load or create sponsor terminology?
- What kind of additional attributes can I apply?
- What would I need additionally?
- How to use this downstream?
- How to deal with different versions?





OSB-Trail-ControlledTerminology

OSB-Trail-ControlledTerminology:

Timeline	July 2024 – December 2024
Outcome	Documentation & best practices Supporting script(s) / tool(s) Additional requirements
Collaboration	Support documentation Join discussion and requirement collection Review documentation Create specifications & requirements Implement supporting tool, e.g. Excel interface / importer/exporter

OSB-Trail-ControlledTerminology

OSB-Trail-ControlledTerminology:

Timeline	Content
July - August	<p>Feedback & Planning phase</p> <ul style="list-style-type: none">➤ Struggles➤ Information Gaps➤ Improvement Ideas / Add-ons
September - December	<p>Action phase – work on items</p> <ul style="list-style-type: none">➤ Documentation & best practices➤ Supporting script(s) / tool(s)➤ Additional requirements

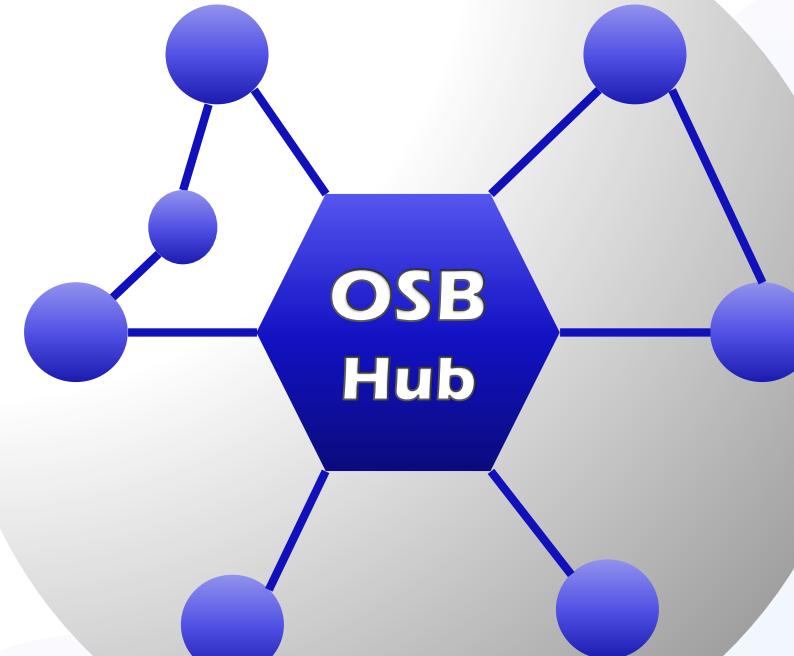
OSB-Trail-ControlledTerminology



OSB-Trail-ControlledTerminology

- Struggles
 - ...
 - Information Gaps
 - ...
 - Improvement Ideas / Add-ons
 - ...
-

<https://github.com/cdisc-org/osb-hub/wiki>



We need YOUR
Feedback!



OSB-Trail-ControlledTerminology





OSB-Trail-ControlledTerminology

- What is controlled terminology?
 - Where is it applied
 - Differentiation from initiatives (ICH M11, USDM, FHIR)
 - How to get CDISC CT
 - Via update script
 - Link to available documentation
-



OSB-Trail-ControlledTerminology

- How to get updates
 - Via update script
- How to extend CDISC CT
 - E.g. unit codelists
 - Via script -> better documentation
 - Via GUI
 - https://gitlab.com/Novo-Nordisk/nn-external-collaboration/nn-cvp-rdit/openstudybuilder-collaboration-group/OpenStudyBuilder/-/tree/main/mdr-standards-import?ref_type=heads

OSB-Trail-ControlledTerminology

- What is explained good/bad
 - Initially what is explained where
 - What is with the USDM CT?
 - Differs from CDISC CT?
 - Differences in spreadsheet
 - It might be valuable to have linkage as additional attributes
 - USDM CT package
-

OSB-Trail-ControlledTerminology

- Study level usage of CT version
 - Question upgrading & stability for studies
 - Additional documentation required
 - Different scenarios (upgrade / don't)
 - For Protocols
 - For SDTM / ADAM mapping
 - Bulk upload support
-