

OpenStudyBuilder DDF Connect-a-thon

Integration to Protocol and SDTM Study Design datasets
Connectathon Category: Supplemental Data and Standards

30th September



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What is the OpenStudyBuilder ...

The OpenStudyBuilder is the new approach to study specification that will:

- Ensure a higher degree of end-to-end consistency
- Have built-in compliance with external and internal standards
- Facilitate more automation and content reuse

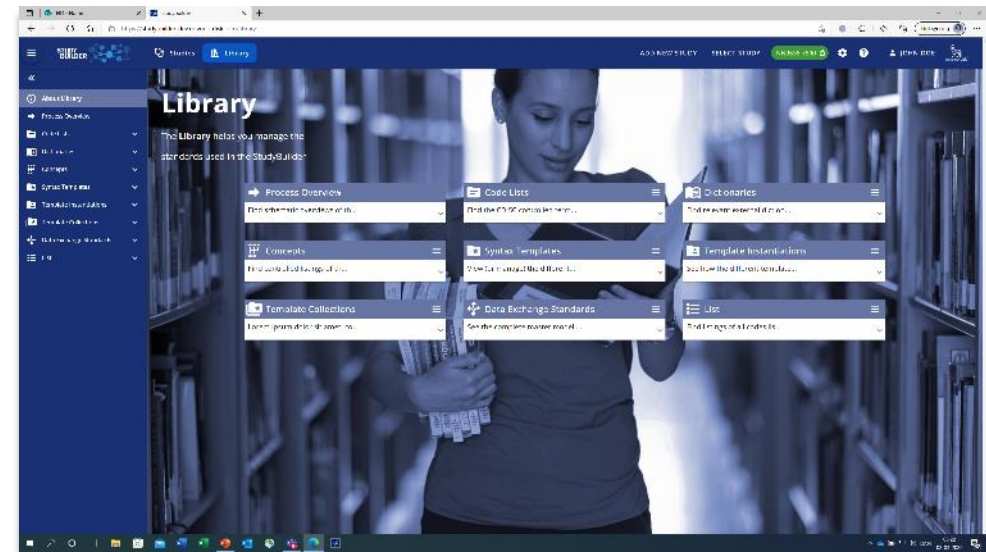
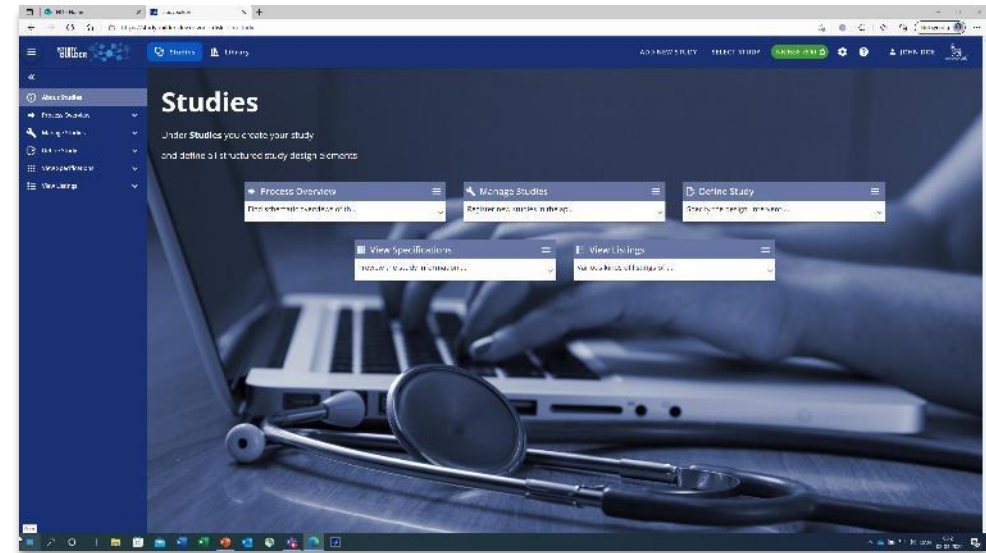
The OpenStudyBuilder comprises three elements:

- **Clinical Metadata Repository (clinical MDR)**
(central repository for all study specification data)
- **OpenStudyBuilder application**
(web-based user interface)
- **API layer**
(allowing interoperability with other applications)
(DDF API Adaptor – enabling DDF SDR Compatibility)



The StudyBuilder includes:

- A **Studies** part for specification of studies (incl. 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)



Demo Library Part

The screenshot shows the 'Library' section of the StudyBuilder application. The top navigation bar includes 'STUDY BUILDER', 'Studies', and 'Library' (highlighted). It also contains 'ADD NEW STUDY', 'SELECT STUDY', a study ID 'CDISC DEV-0001', and a user profile 'MT (MIKKEL TRAUN)'. The left sidebar lists navigation options: 'About Library', 'Process Overview', 'Code Lists', 'Dictionaries', 'Concepts', 'Syntax Templates', 'Template Instantiations', 'Template Collections', 'Data Exchange Standards', and 'List'. The main content area features a large 'Library' heading and a descriptive text: 'The Library helps you manage the standards used in the StudyBuilder'. Below this, there is a grid of nine interactive cards, each representing a library category with an icon, title, and a brief description.

Category	Description
Process Overview	Find schematic overviews of th...
Code Lists	Find the CDISC controlled term...
Dictionaries	Find relevant external diction...
Concepts	Find controlled listings of th...
Syntax Templates	View (or manage) the different...
Template Instantiations	See how the different template...
Template Collections	Lorem ipsum dolor sit amet, co...
Data Exchange Standards	See the complete master model ...
List	Find listings of all codes lis...

Demo SDTM Study Design datasets

The screenshot displays the 'STUDY BUILDER' application interface. The top navigation bar includes 'Studies' and 'Library' tabs, along with buttons for 'ADD NEW STUDY', 'SELECT STUDY', and a lock icon for 'CDISC DEV-0001'. The user 'JOHN DOE' is logged in. The left sidebar shows a navigation menu with 'View Specifications' selected. The main content area is titled 'SDTM Specifications' and shows a table of study design datasets for 'CDISC DEV-0001'.

Navigation: Studies / View Specifications / SDTM Study Design Datasets

SDTM Specifications ⓘ

Trial Arm | Trial Elements | Trial Visits | Trial Inclusion/Exclusion Criteria | Trial Disease Assessments | Trial Summary

Select rows

Filtering currently not activated

Study Identifier	Domain Abbreviation	Planned Arm Code	Description of Planned Arm	Planned Order of Element within Arm
CDISC DEV-0001	TA	A	OLAPARIB_ADDON	1
CDISC DEV-0001	TA	A	OLAPARIB_ADDON	2
CDISC DEV-0001	TA	A	OLAPARIB_ADDON	3
CDISC DEV-0001	TA	A	OLAPARIB_ADDON	4
CDISC DEV-0001	TA	A	OLAPARIB_ADDON	5
CDISC DEV-0001	TA	B	NEW1_ADDON	1
CDISC DEV-0001	TA	B	NEW1_ADDON	2

Rows per page: 10 | 1-10 of 10

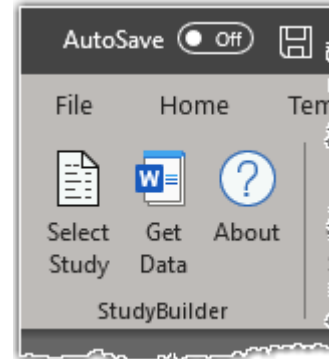
Demo of the Word add-in - design



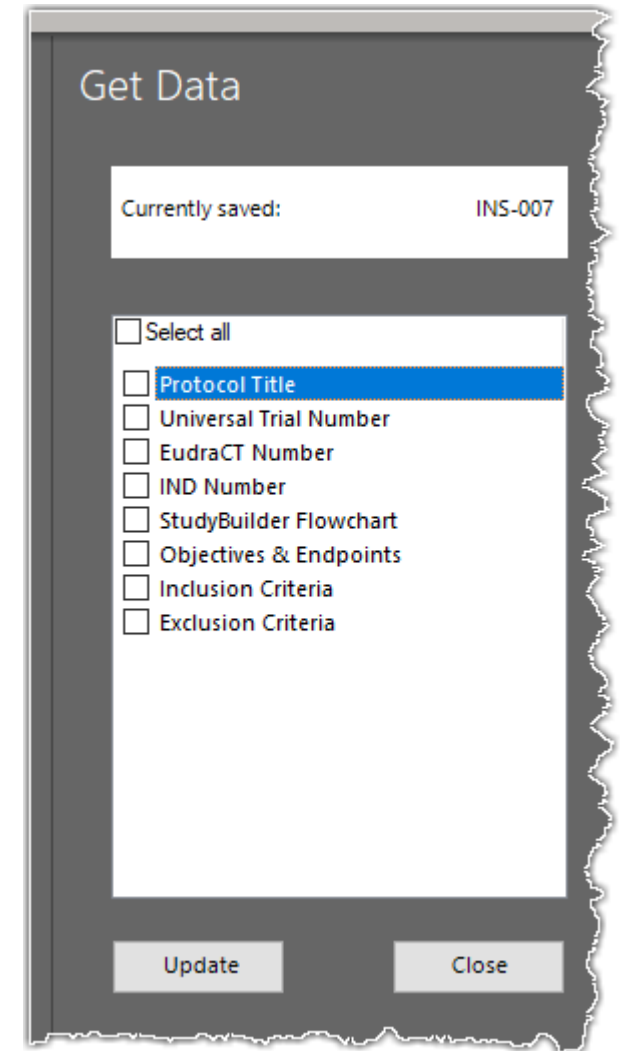
StudyBuilder ribbon (Word add-in)

✓ One-way
connection

- ✓ Code recognizes the document type
- ✓ User-friendly ribbon and 'fly-out' in Word
- ✓ Styles ensure proper formatting in Word



Protocol



Integration to Protocol and SDTM Study Design datasets

Connectathon Category: Supplemental Data and Standards

- ✓ **Managing industry and sponsor standards**
- ✓ **Supporting down-stream usage**

Watch also the other videos:

- OpenStudyBuilder as a DDF compatible SDR solution
- OpenStudyBuilder and EDC Integrations

Visit our GitLab site for more information:

<https://novo-nordisk.gitlab.io/nn-public/openstudybuilder/project-description/>



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