Introduction

CDISC 360°

TransCelerate Digital Data Flow

OpenStudyBuilder
Open-Source by Novo Nordisk
Introduction

The OpenStudyBuilder comprises three elements:

- **Clinical Metadata Repository (clinical MDR) & Study Definition Repository (SDR)**
  (graph database, 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)
Introduction

The OpenStudyBuilder 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)
OpenStudyBuilder will also be DDF Compatible
The OpenStudyBuilder is an open-source project for clinical study specifications. This tool is a new approach for working with studies that once fully implemented will drive end-to-end consistency and more efficient processes - all the way from protocol development and CRF design - to creation of datasets, analysis, reporting, submission to health authorities and public disclosure of study information.
Links

• Project Homepage: https://openstudybuilder.com/
• YouTube Demonstration (30’): https://youtu.be/dL5CY0BwFEs
• GitLab (Solution, Description): https://gitlab.com/Novo-Nordisk/nn-public/openstudybuilder
• Slack: https://join.slack.com/t/openstudybuilder/shared_invite/zt-19mtauzic-Jvrhtmy7hGstgy1vB1Wsw
• E-Mail: openstudybuilder@gmail.com

Sandbox:

• Mail openstudybuilder@neotechnology.com – Subject “Request Sandbox access”
• Note: when add/modify/delete, you mail might be exposed in the version history
Getting along

• **Support**
  • Documentation
  • OpenStudyBuilder Q&A sessions
  • Slack & Mail
  • Commercial support options of vendors

• **Share**
  • Documentation, Feedback, Ideas
  • Enhancements, connected tools
  • Biomedical Concepts discussions & additions
  • Remark: no direct contribution in repository
OpenStudyBuilder – What's in?

What do I get?

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**Application**
- Including example data

**API**

**DB Browser**

**Neo4j database**
- Including example data

**Scripts**

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**Documentation**
- Project Homepage
- Tool documentation
- GitLab documentation
  - Database design
  - Architecture design
  - Instructions

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*available in sandbox, can be installed on other environments
Sandbox

• **OpenStudyBuilder App**
  https://openstudybuilder.northeurope.cloudapp.azure.com/

• **Documentation**
  https://openstudybuilder.northeurope.cloudapp.azure.com/doc/

• **NeoDash**
  https://openstudybuilder.northeurope.cloudapp.azure.com/neodash/

• *(DB Browser)*
  https://openstudybuilder.northeurope.cloudapp.azure.com/browser/

• *(Bloom)*
  https://openstudybuilder.northeurope.cloudapp.azure.com/bloom/
Questions!
SDR Use Cases

Protocol Automation

➢ Word Add-In open-source release planned by Novo Nordisk
SDR Use Cases

Within OpenStudyBuilder Universe

Plugin Extension
Stand-alone tools

MDR / SDR (with API)
Industry Standards
Sponsor Standards
Study Definitions

Tools
Scripts