

What is the OpenStudyBuilder?

The OpenStudyBuilder is an open-source metadata and study definition repository for more efficient and consistent management of studies and standards, from protocol development to study reporting.

The solution uses modern graph technology to support FAIR data, traceability, and automation. The Library area allows for the management of standards and dictionaries including CDISC, sponsor and protocol standards. The Study area enables the management of study metadata including the utilization of biomedical concepts enabling automated data flows. Linking activities in the protocol enables data specifications which can be used to define the study structure (define.xml), CRF definitions, and for EDC automation. Finally, the API provides a powerful, standardized interface for integrations.

The OpenStudyBuilder is an implementation of the Digital Data Flow supporting the USDM representation, protocols in ICH M11 format and enabling the end-to-end flow.

Furthermore, the OpenStudyBuilder is part of the CDISC Open Source Alliance (COSA) and the CDISC 360i project which focus on implementing the full end-to-end process.

Deployment & Public Sandbox

It is possible to run the full system in a local environment or on any of the major cloud platforms. Additionally, a public sandbox is available where people can register simply via mail (openstudybuilder@neotechnology.com) to test the open-source solution without the need to install anything.

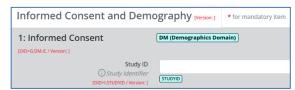


Components

OpenStudyBuilder – Library. The library is available to manage controlled terminology, dictionaries, syntax templates, biomedical concepts as activities, standard CRFs and more.

The OpenStudyBuilder also supports protocol standards. The syntax templates use textual descriptions with semantic context, enabling, for example, cross-trial search and comparison of endpoints and objectives in logical ways.

The CRF design features are supported in the library and are intended to manage a CRF library for various purposes including aCRFs and to drive EDC setup either through ODM.xml standard or API utilization.



OpenStudyBuilder – Study Definition. In the study part of the application users can create and manage study information. Protocol information is entered and maintained, including the generation of the schedule of activities for the protocol and for data collection.



Along with the metadata, the SDTM Study Design Datasets content is generated for reuse.



Documentation. Extensive tool documentation and an additional project homepage are available along with the source repository, which holds technical descriptions and installation instructions.

Integrations (API). All actions performed in the application are executed through API calls. There are numerous available API endpoints, providing comprehensive integration support, including USDM, ODM, and other standard format exports.

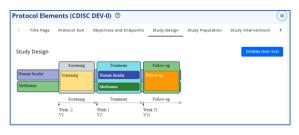
Dashboards & Tools. Additional tools, such as the Neo4j browser and dashboards are available to provide additional insights. Biomedical concepts, the history of controlled terminology or data models can be explored!



Word Add-In. As one integration, a Word Add-In is available as open-source. With this new ribbon, it is possible to connect to an OpenStudyBuilder instance to create and update protocol elements for a study directly in a Word document.

Study Structure

Next to the Schedule of Activities, core features define the Study Structure such as arms, branches, cohorts, epochs, elements, and visits which can be displayed in the Design Matrix. The core benefit is utilization of biomedical concepts, linking various standards together. This enables significant automation opportunities in downstream processes like setting up the Protocol in Word, perform EDC setup, deliver Trial Domain datasets, as well as supporting dataset creation.



Collaborate, Innovate, Integrate

The OpenStudyBuilder is designed to accelerate collaboration and streamline integrations. Our API-first approach and adherence to industry standards (USDM, M11, CDISC) make it easy to connect with other systems. You can be a part of this evolution:

- Become part of our community!
- Join our collaborative projects (OSB-Hub & 360i)!
- Share ideas, feedback and more on Slack!
- Build integrations and develop new extensions to enrich and enable the digital data flow!

priving change for generations



Status

Novo Nordisk is committed to revolutionizing the clinical trial process with end-to-end automation committing to open-source with this project. We apply protocol metadata in production to automate our structured protocol parts. We are now focusing on enabling more metadata utilization to replace a legacy system. Alongside this, we focus on CRF standardization

Additionally, we are enhancing our open-source strategy to enable partners to contribute and coown the solution.

and EDC automation.

