

OPEN STUDY BUILDER



Open-Source MDR & SDR



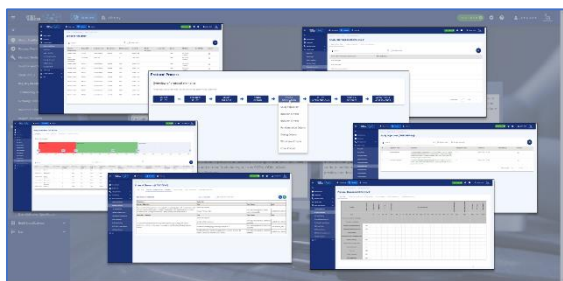
What is the OpenStudyBuilder?

The OpenStudyBuilder is a new open-source tool for more efficient and consistent management of studies, from protocol development to study reporting. The solution uses modern graph technology to support FAIR data, traceability, and automation. The Library area allows for management of standards and dictionaries. The Study area can be seen as Study Definition Repository and allows for managing study-related metadata content. Finally, the API provides a powerful, standardized interface, supporting TransCelerate DDF.

Overall, the OpenStudyBuilder aims to improve study management through standardization, reuse, and automation. As part of the CDISC Open Source Alliance (COSA) we foster collaboration through open-source.

Local Install or Sandbox

It is possible to run the full system on a local desktop environment or on an individual cloud subscription on any of the main cloud providers. Furthermore, there is a sandbox environment available where people can register to play around with the open-source solution without needing to install anything.



Components

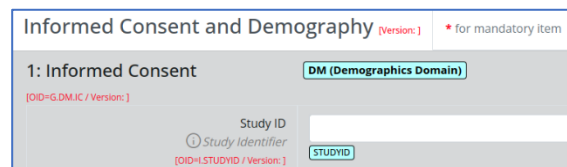
OpenStudyBuilder – Library. The library is available to manage standards, dictionaries and syntax templates.

Codelists can be browsed, e.g., to see differences for CDISC versions. But also sponsor codelists can be managed. Dictionaries and

units – including conversions are supported as well.

The syntax templates are an excellent way to have textual descriptions with a semantically context assigned. This enables for example a much better cross-trial search for and comparison of endpoints and objectives.

The CRF design features are currently supported in the library: definition of CRF standards, export and visualizations like the annotated CRF.



OpenStudyBuilder – Study Definition. In the study part of the application users can create and manage study information. All protocol information is managed, which enables for example the generation of the protocol flowchart (schedule of activities) and the SDTM Study Design Datasets generation.

Study epoch	Screening	Treatment										Follow-up		
Visit short name	V1	V2	V3	V4	V5	V6	V7	V8	V9	V10D1	V11D1	V12	V12A	V13
Study day	-14	1	8	15	22	29	36	43	57	113	171	183	213	
Visit window (days)	-13/+0	±0	±1	±1	±1	±1	±1	±1	±1	±0	±0	±1	±0	+0/+35
SUBJECT RELATED INFORMATION														
General														
Randomisation		X												
End of Study														X
Physical Examination - early ph1	X													
Body Measurements	X	X	X	X	X	X	X	X	X			X		X
Eligibility Criteria	X													
EFFICACY														
Laboratory Assessments														
Glucose Metabolism	X	X	X	X	X	X	X	X	X			X	X	X

Documentation. Documentation explaining the tool is included, but you can also access the projects homepage with many additional guides and other information.

OpenStudyBuilder - API. The APIs are an integral part of the design. All actions from the application are performed through the API interface. This allows any tool and script for any kind of automation. Integrations will no longer be an issue.

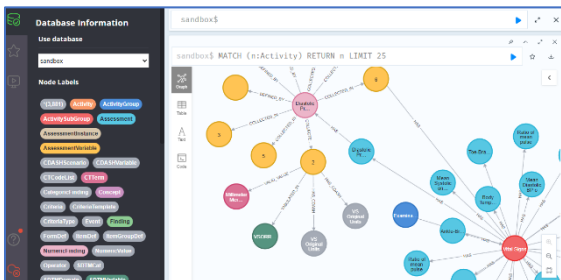
The swagger documentation is available to document and easily execute all available API endpoints.

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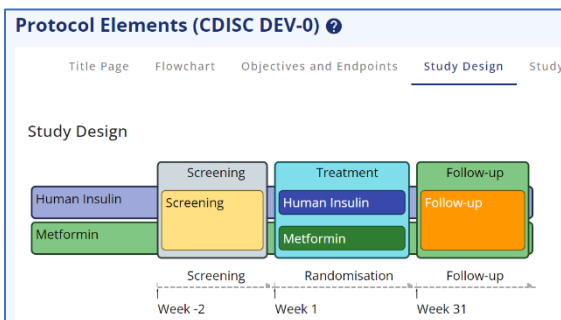


Browsing Neo4j. Tools are available to browse the database. With “Neo dashboard” any kind of dashboards can be created. Additionally, a browser and the tool “bloom” is available to browse the graph database and concepts.



Study Structure

One main feature is the Study Structure, which allows for management of study components such as arms, branches, cohorts, epochs, elements, and visits. The Design Matrix tab provides an overview of all these components, where colours can be added for the study design in the protocol elements. The Study Structure metadata can be used in other systems and documents, such as the Protocol, CRF, and SDTM generation easily through the API interface.



A very important aspect is the handling of study visits. We include four visit types: scheduled, unscheduled, non-visit, and special visits. Scheduled visits are planned visits as specified in the protocol. Unscheduled visits are technical placeholders for events that occur outside of planned visits. Non-visit is a placeholder for data that are not visit related and finally special visits are other visits without specific timing but related to data collection.

Collaboration

An important goal of the OpenStudyBuilder is to allow for next level collaboration. Let's not only share ideas and discuss processes but share concepts and tools as well! For example, the following contributions are very welcome:

- Join discussion and user group
- Feature and bug reporting
- Documentation, training, explanations
- Code contribution directly/through vendors
- Additional components standalone or under this project's umbrella
- Connecting tools

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Status

Novo Nordisk as project owner is working on the end-to-end automation for the complete clinical trial process. We are starting at the front, so currently the study definition for protocol and Trial Summary datasets are supported. The CRF design is working at the standards level and will be made available on study-level later. The codelist management is also finalized. The development continues non-stop with new features introduced via global pharma initiatives like DDF and the COSMoS project from CDISC. We share this as open-source project and are looking for collaborations.

