Introduction to OpenStudyBuilder

USDM Compatible SDR solution

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OpenStudyBuilder – a next generation end-to-end clinical data standards and study specification solution, enabling clinical study data solutions to use linked metadata for higher degree of automation, limiting manual document driven work processes,
enabling a Digital Data Flow approach.

What's in?

Today

OpenStudyBuilder is used to ...

- **manage** structured study protocol elements, enabling downstream support (Word Protocol, ICH M11, USDM 4.0, Trial Registration, pre-define.xml)
- **manage** industry standards with extensions and enrichments, including protocol standards
- **manage** the CRF library

Tomorrow

OpenStudyBuilder will additionally be used to ...

- **use** the CRF library to drive EDC automation
- **manage** mapping specification, enabling automated data transformation

The Future

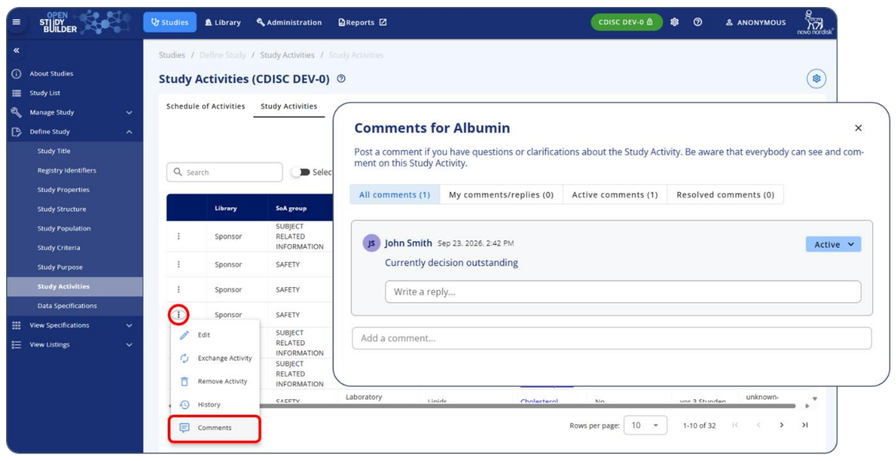
OpenStudyBuilder will furthermore evolve to ...

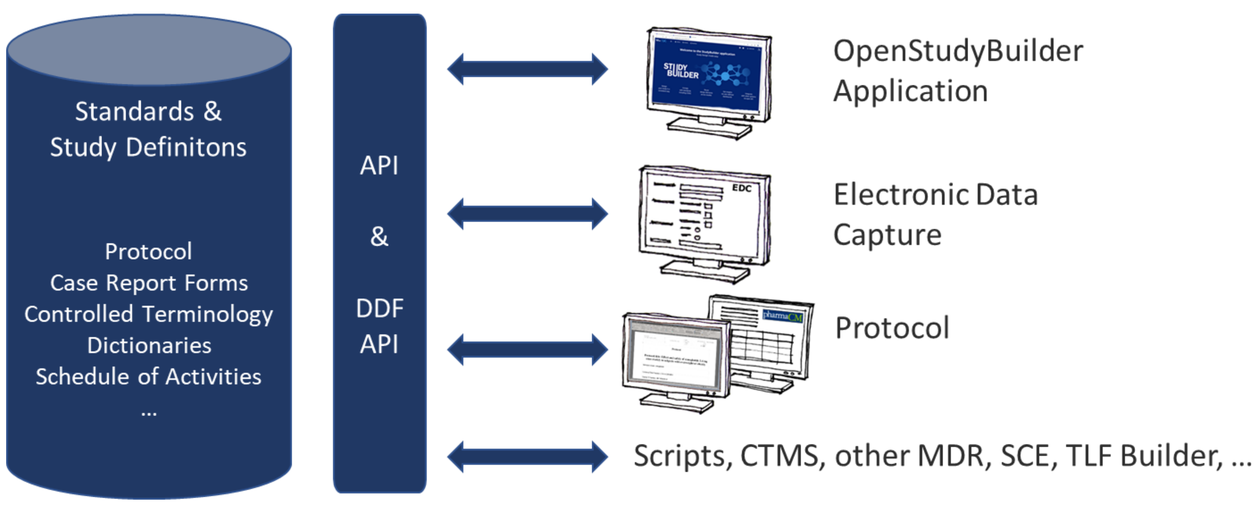
- **a plug-and-play ecosystem** where modular functionalities integrate seamlessly with other solutions through standards-driven data flows



What's new

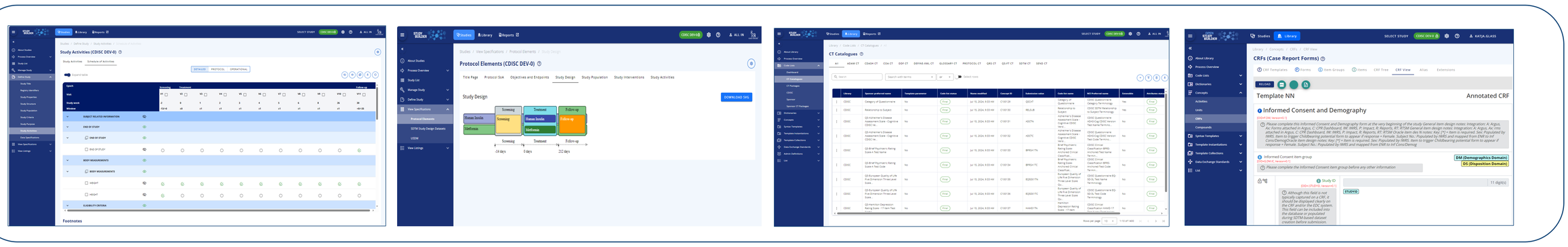
- **USDM 4.0 export:** study design, endpoints, populations, criteria, biomedical concepts and SoA
- **Complete Trial Summary:** all TS parameters, including sponsor-defined ones
- **Comments on study activities:** discuss questions where they arise
- **Your own look:** themes for your corporate design





Connectivity to Systems

- Full connectivity to any kind of systems through APIs
- Maintenance of standards, like CRFs standardization and utilization in downstream EDC system
- Protocol harmonization through standards



Open Source

- OpenStudyBuilder is shared as open source under COSA by Novo, now developed together with industry partners
- Collaborate with TransCelerate as a Digital Data Flow (DDF) compatible solution
- Collaborate with CDISC, e.g. for Biomedical Concept Development & Enhancements

https://www.cdisc.org/ddf | https://openstudybuilder.com | https://transcelerate.github.io/ddf-home/