

OpenStudyBuilder

Introduction to the Open Source
Metadata Repository

French CDISC User Group, Tours - France

2023-06-15 / Nicolas de SAINT JORRE

- 01 – OpenStudyBuilder as a COSA project
- 02 – Metadata Repository
- 03 – Demonstration
- 04 – Conclusion

Agenda

OPEN STUDY BUILDER



01 – OpenStudyBuilder as a COSA project



01- CDISC Open Source Alliance

The CDISC Open-Source Alliance (COSA) supports, promotes, and sometimes sponsors open-source software projects that create tools for implementing or developing CDISC standards to drive innovation in the CDISC community.

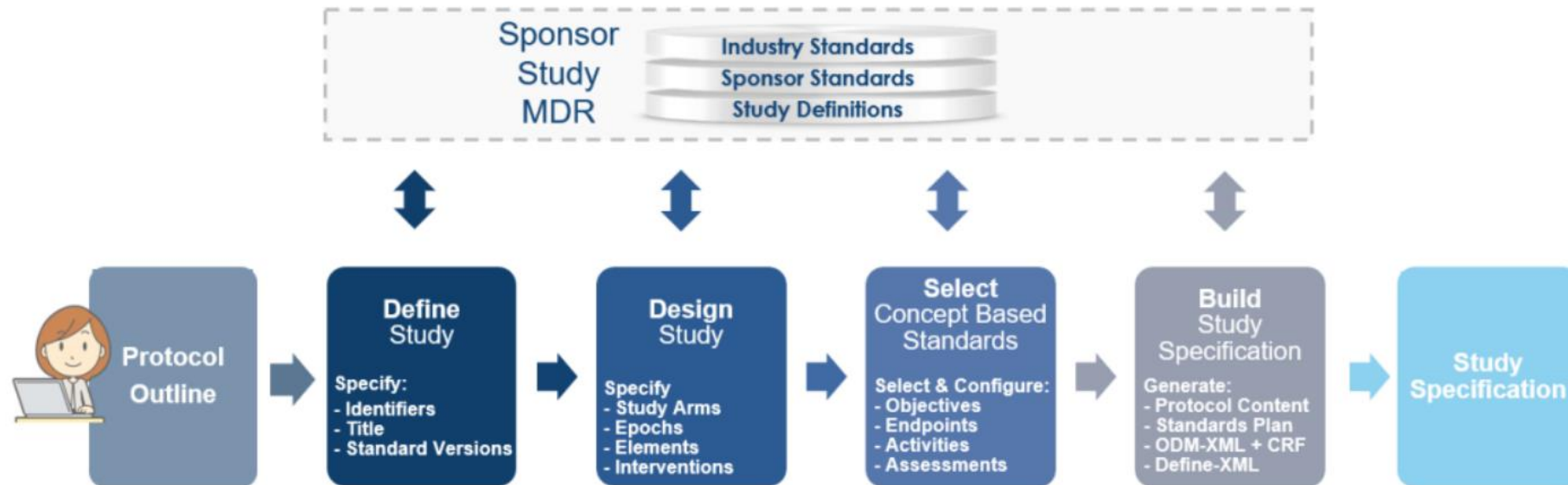
- OpenStudyBuilder is an open-source project for clinical study specifications
- [LinkedIn Newsletter](#)
- Project Homepage: <https://openstudybuilder.com/>
 - Information, Guides, References, Events
- Demonstration Video ([YouTube](#))
- [GitLab Source Code](#)
- Slack ([invite Link](#))
- E-Mail: openstudybuilder@gmail.com
- Public Sandbox:
- Mail openstudybuilder@neotechnology.com – Subject “Request Sandbox access”
- ***Note: when add/modify/delete, you mail might be exposed in the version history***

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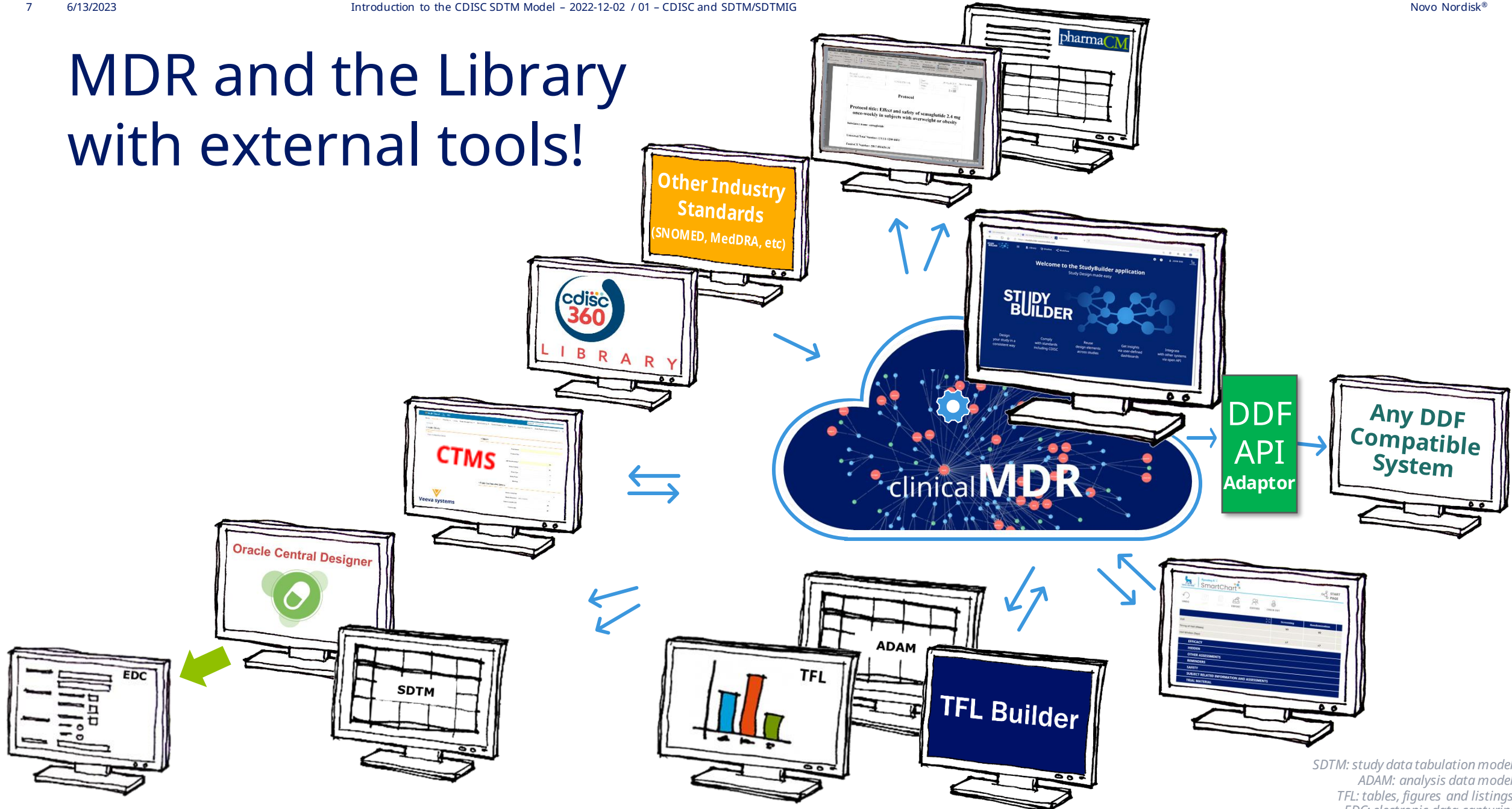


02 – MetaData Repository

Metadata Repository... As MDR



MDR and the Library with external tools!



SDTM: study data tabulation model,
 ADAM: analysis data model,
 TFL: tables, figures and listings,
 EDC: electronic data capturing

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03 – Demonstration

Welcome to the StudyBuilder application

Study Specification made easy

OPEN STUDY BUILDER

Epoch	Visit	Day	Window	Screening	Treatment	Follow-up				
V1	V2	V3	V4	V5	V6	V7	V8	V9	V10	V11
1	8	15	22	29	36	43	57	183	213	0/+35
-14	±0	-1/+1	-1/+1	-1/+1	-1/+1	-1/+1	-1/+1	-1/+1	-1/+1	-1/+1
-13/+0										

Build
your study in a
consistent way

Comply
with standards
including CDISC

Reuse
specification elements
across studies

Get insights
via user-defined
dashboards

Integrate
with other systems
via open API

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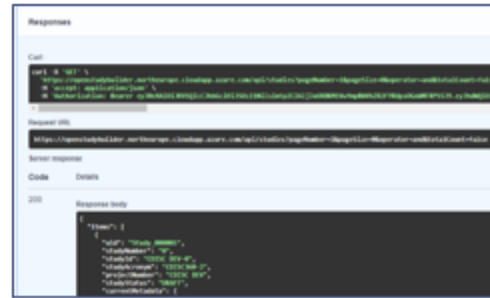
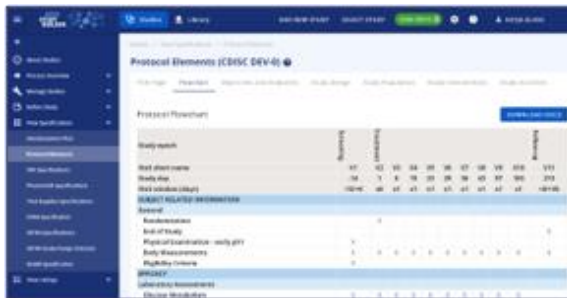


04 – Conclusion

More after this presentation!

See Slide #4

- How to get the “software”?
 - Local / Server installation from the source code
 - In the Sandbox environment
 - Via a dedicated hosted instance managed by Neo4j (\$\$)
- What do I get?
 - Application + API + Neo4j database + NeoDash dashboards + Documentation portal



Thank you!

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