

OpenStudyBuilder

Introduction to the Open Source
Metadata Repository

French CDISC User Group, Tours - France

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- 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.

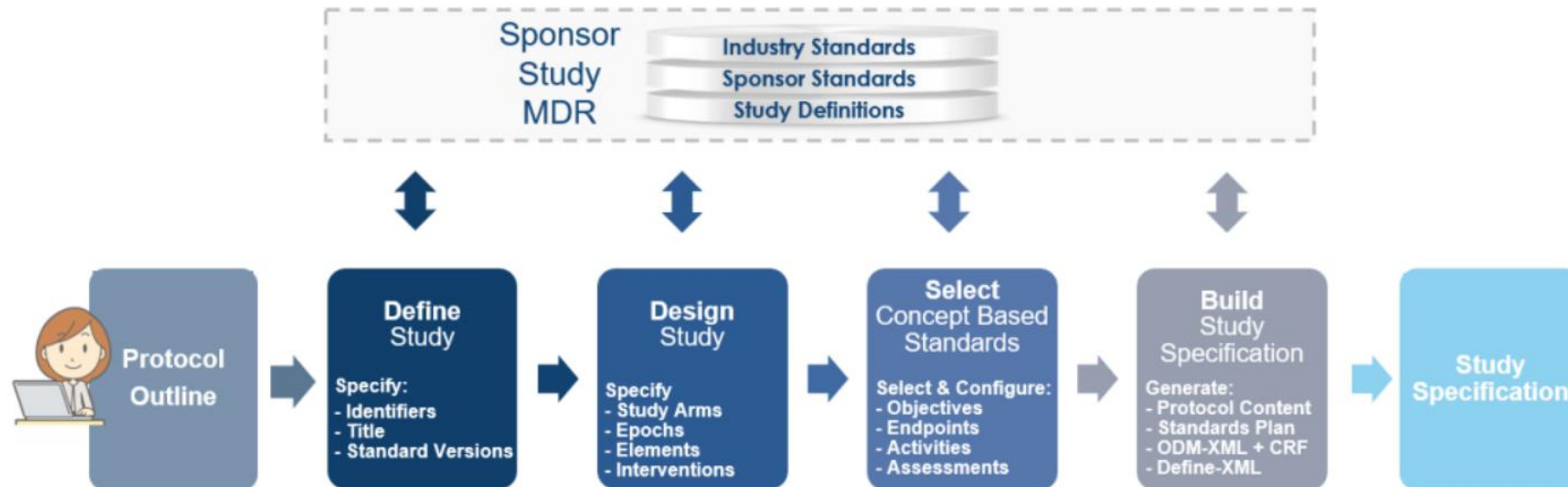
- OpenStudyBuilder is an open-source project for clinical study specifications
- [LinkedIn Newsletter](#)
- Project
Homepage: <https://openstudybuilder.com/>
 - Information, Guides, References, Events
- Demonstration Video ([YouTube](#))
- [GitLab Source Code](#)
- Slack ([invite Link](#))
- E-Mail: 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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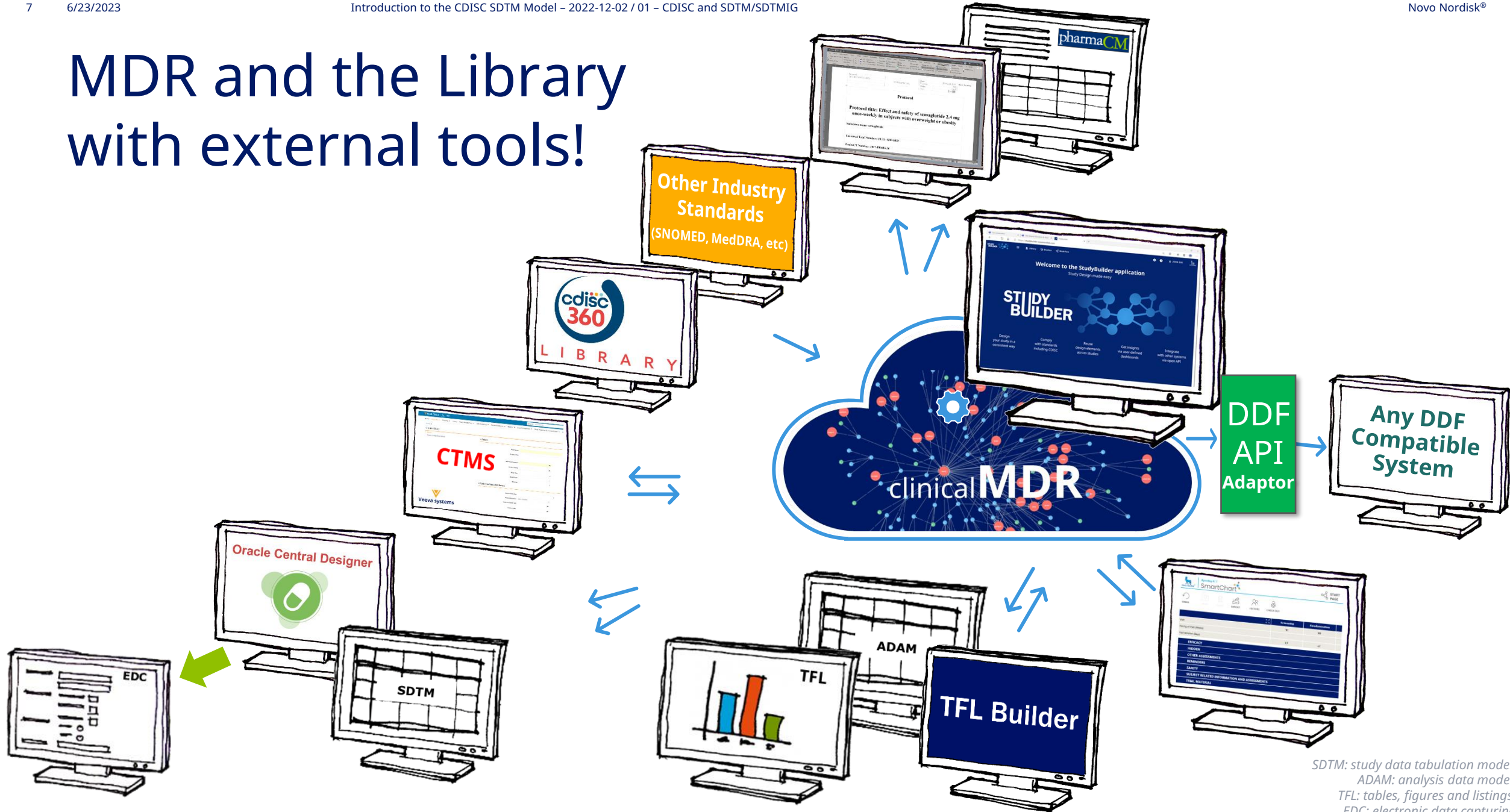


02 – MetaData Repository

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

Study Activities (CDISC DEV-0)

List of Study Activities | Detailed Flowchart | Protocol Flowchart | Activity Instructions

Expand table | Collapse table | Hide flowchart groups

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

Activities

- SUBJECT RELATED INFORMATION
- General
 - Randomisation
 - Randomized
 - End of Study
 - End of Study
 - Body Measurements

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

Thank you!

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