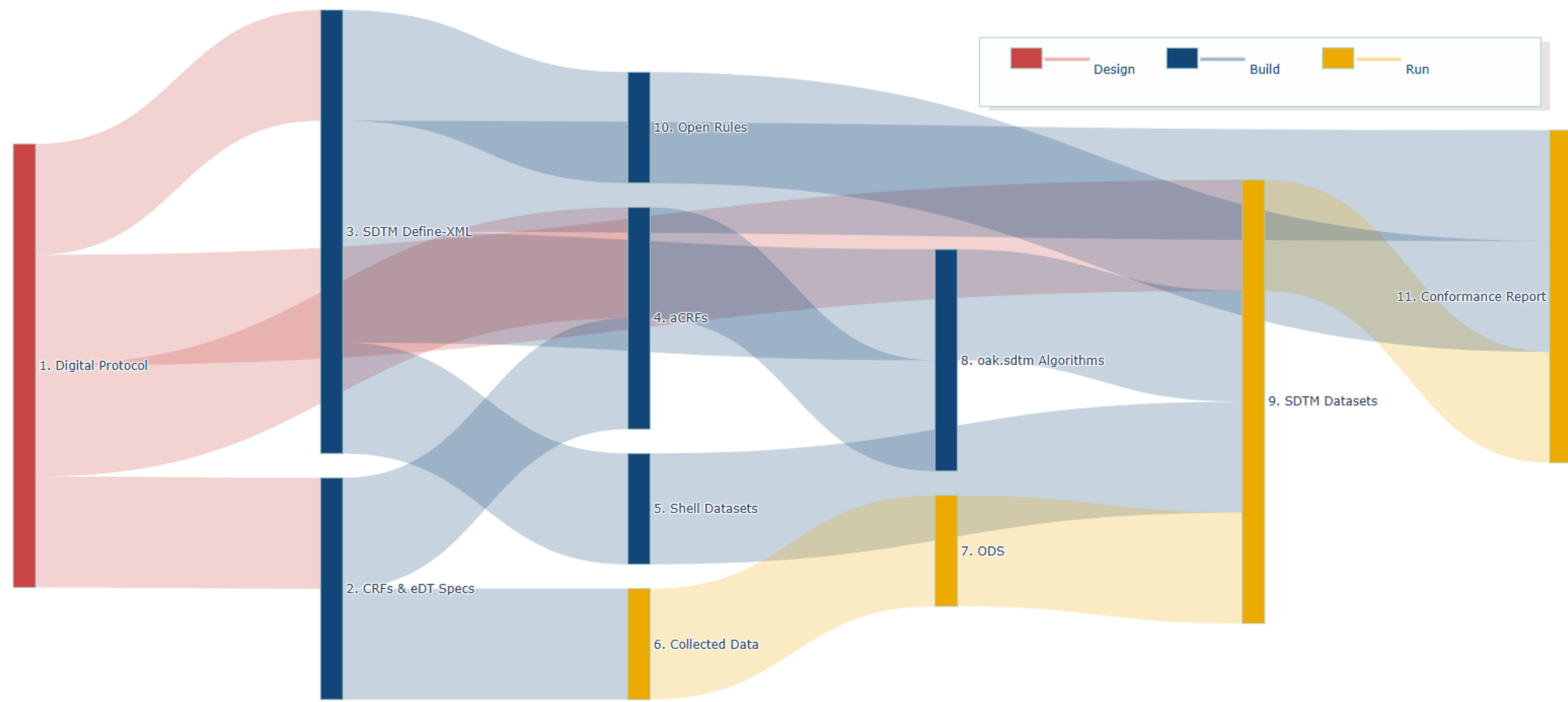


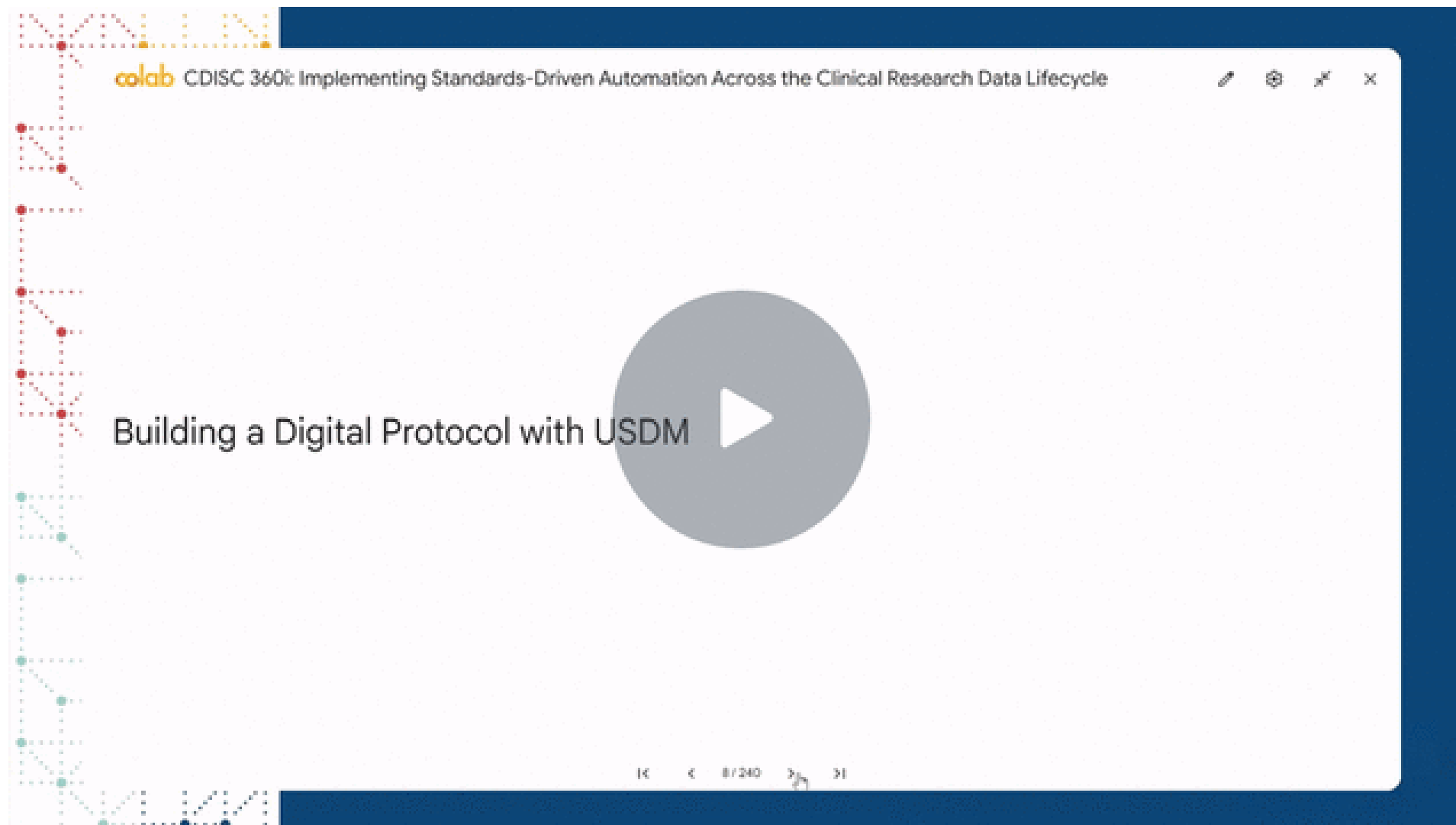
CDISC 360i in Action

Demonstrating the Shift to Fully Digital Standards

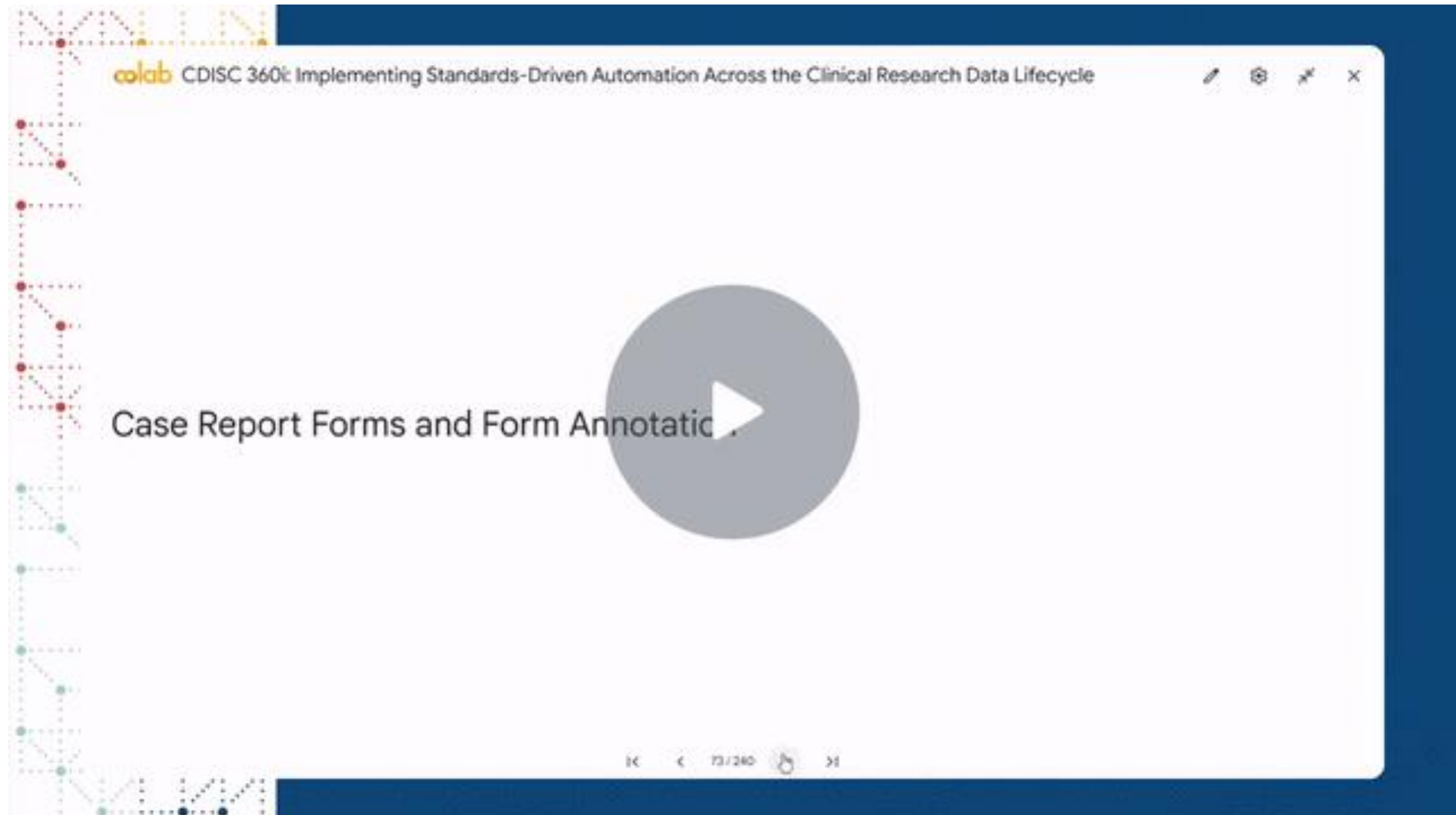




Digital Protocol



CRFs & aCRFs

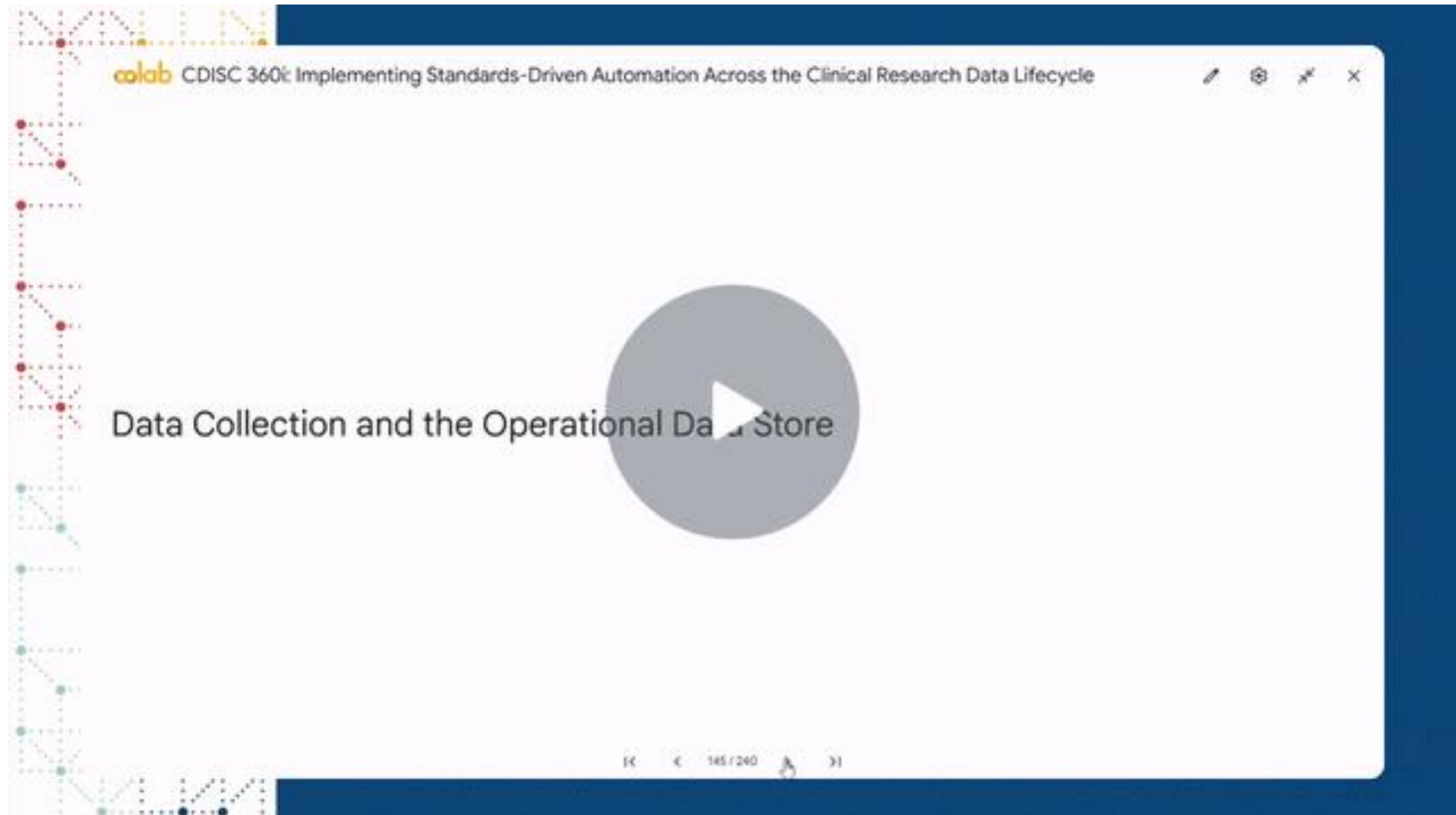


SDTM Resources

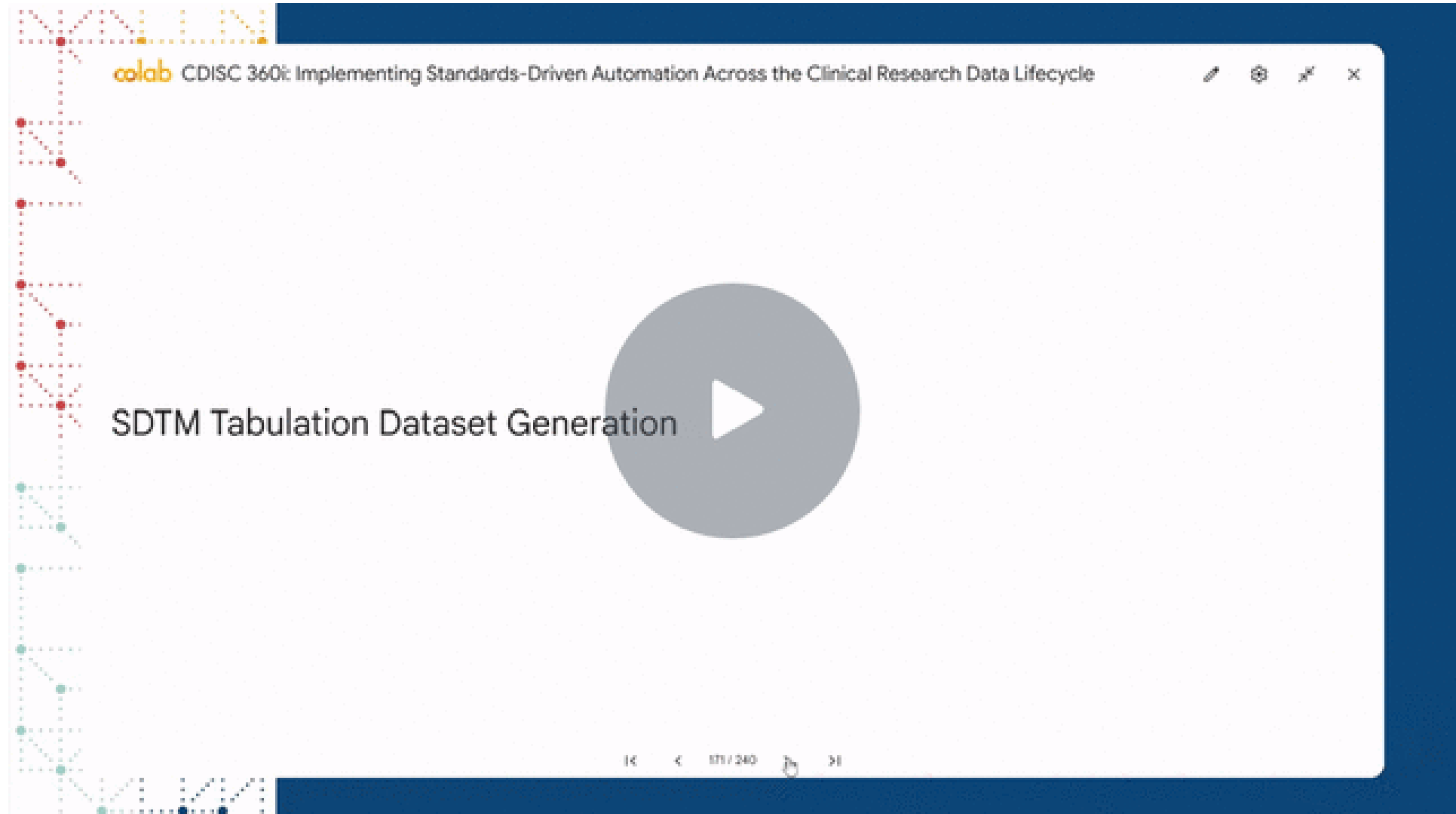
Define-xml, Shell Datasets, & Trial Design Domains



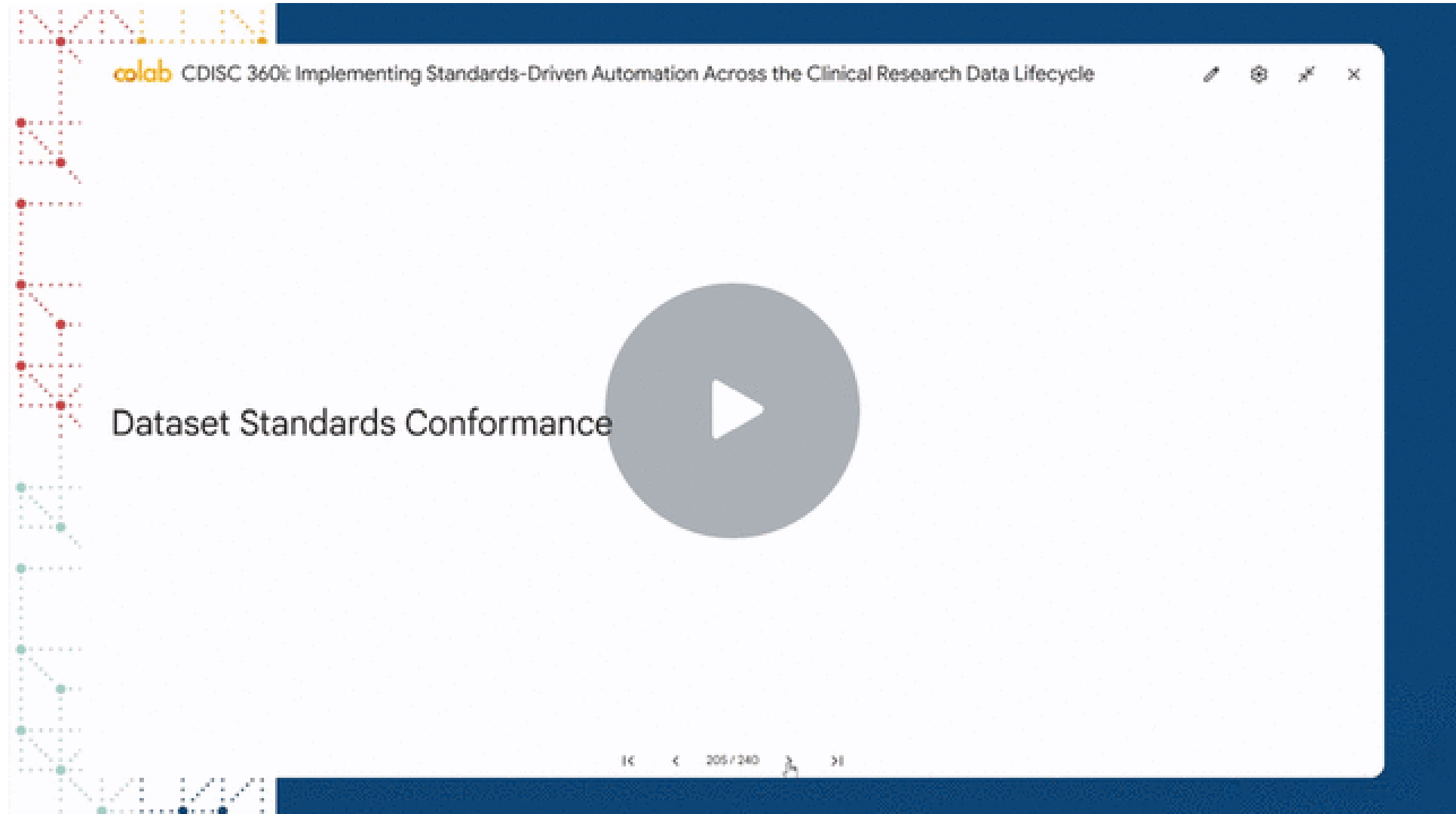
Data Collection & ODS



SDTM Datasets



360i Conformance



GitHub Repositories Used in the Demo

Purpose	Location
Study Definition Workbench	https://github.com/data4knowledge/study_definitions_workbench
Open Study Builder	https://gitlab.com/Novo-Nordisk/nn-public/openstudybuilder/OpenStudyBuilder-Solution
Study USDM documents	https://github.com/cdisc-org/360i/tree/main/data/protocol/LZZT/usdm
USDM validation utility	https://github.com/pendingintent/cdisc-json-validation
CDISC CORE Rules Engine	https://github.com/cdisc-org/cdisc-rules-engine
CRF creation	https://github.com/lexjansen/cdisc360i-pocs
Trial Design Dataset creation	https://github.com/pendingintent/cdisc-usdm-utils
Define-XML template creation	https://github.com/dostiep/360i
Define-XML creation	https://github.com/swhume/template2define
Raw subject data	https://github.com/alidootson/UpdatedCDISCPilotData/tree/main/UpdatedCDISCPilotData/CDASH

Using GitHub

The GitHub repositories used in the demo are public and use open-source libraries

The process for using these libraries is consistent:

- Fork the original public repository into personal GitHub repository
- Create new branch in personal GitHub repository
- Edit code to meet individual requirements, add features or fix issues
- Commit changes to personal branch
- If proposing change to parent (original) branch to share with wider community:
 - Raise a Pull Request with original repository owner
 - Original repository owner will review the Pull Request and work with requestor to evaluate and test Pull Request
 - Merge new code in Pull Request with original parent branch

Accessing the 360i Notebook

The notebook displayed during this demonstration can be found here:

<https://github.com/cdisc-org/cdisc-360i-notebooks>

- The repository is under continued development; follow repository for latest releases
- There are multiple notebooks
- Raise any issues encountered while using notebooks
- To contribute to the CDISC project:
 - Fork the repo and create a new branch
 - Once changes are made and tested, raise a Pull Request