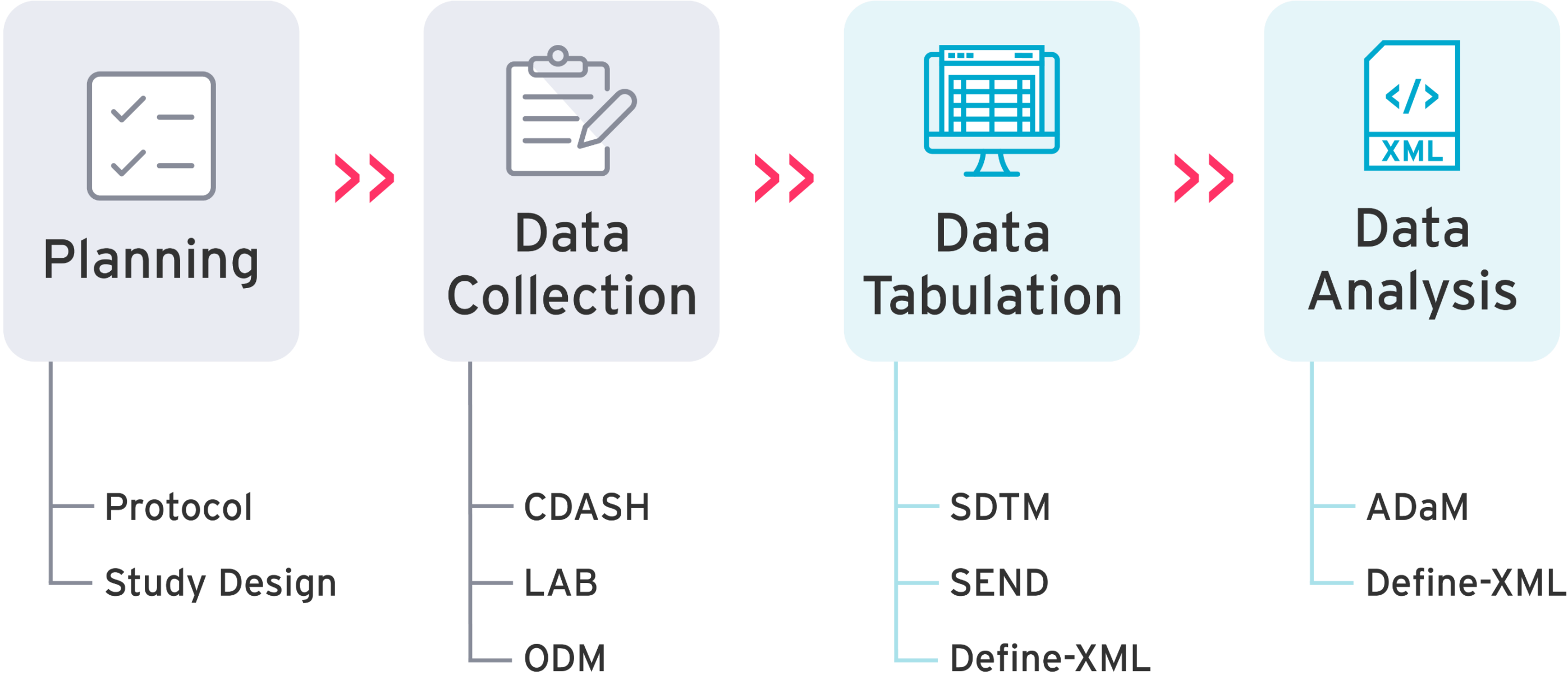


Best practice for successful adoption and implementation of CDISC data standards

Gilbert Hunter | Customer Success Manager



CDISC standards



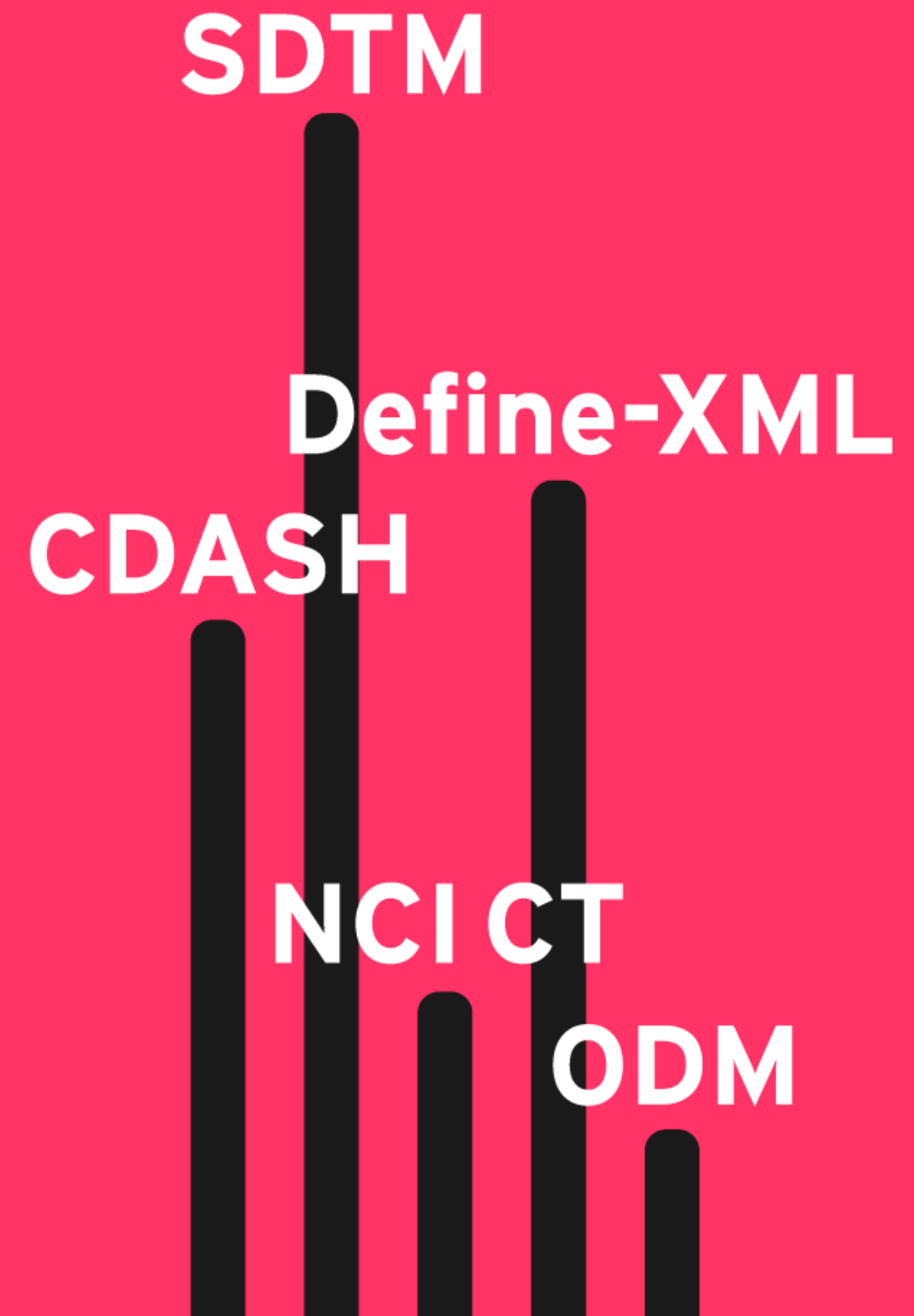
NCI Terminology

NCI Terminology



The need for data standards

cdisc



Getting started

- Time must be invested upfront!
- Lack of CDISC knowledge
- Difficulty interpreting standards
- Culture shock and buy-in
- Defining consistent standards across your organization
- Governance – establishing processes and workflows to manage standards



Get everyone on board!



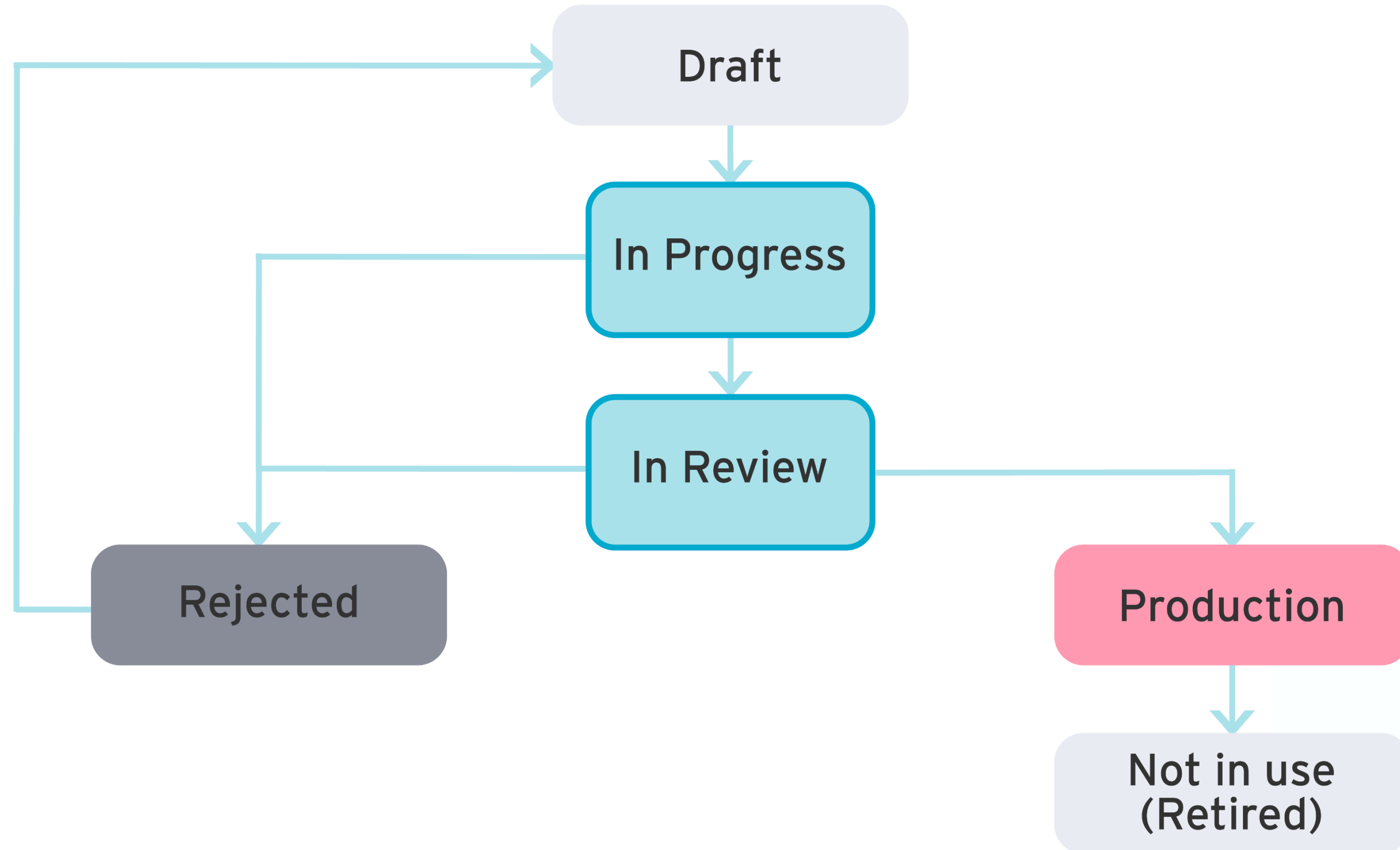
Design with SDTM in mind... not just a submission standard!

- Design eCRFs that align with SDTM and NCI Controlled Terminology (CT)
- Design target SDTM datasets and map to raw datasets upfront
- Ensure required submission data is collected
- Only collect required data

= AVOID SUBMISSION DELAYS & SEE DATA EARLIER!



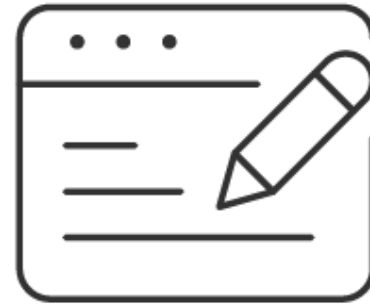
Establish an approvals process



Establish an approved metadata content library



FORMS



ANNOTATIONS



TERMINOLOGIES



DATASETS



MAPPINGS

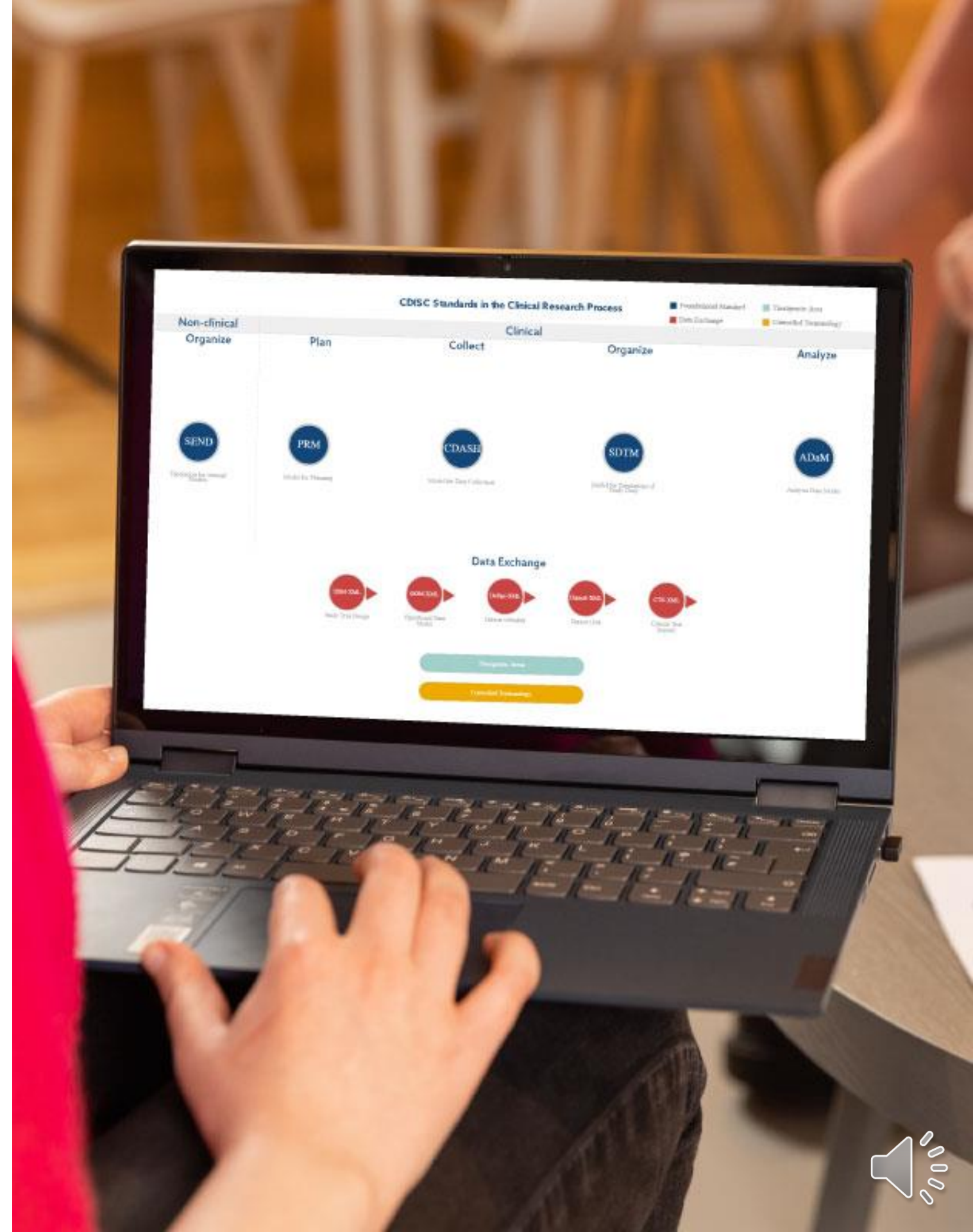


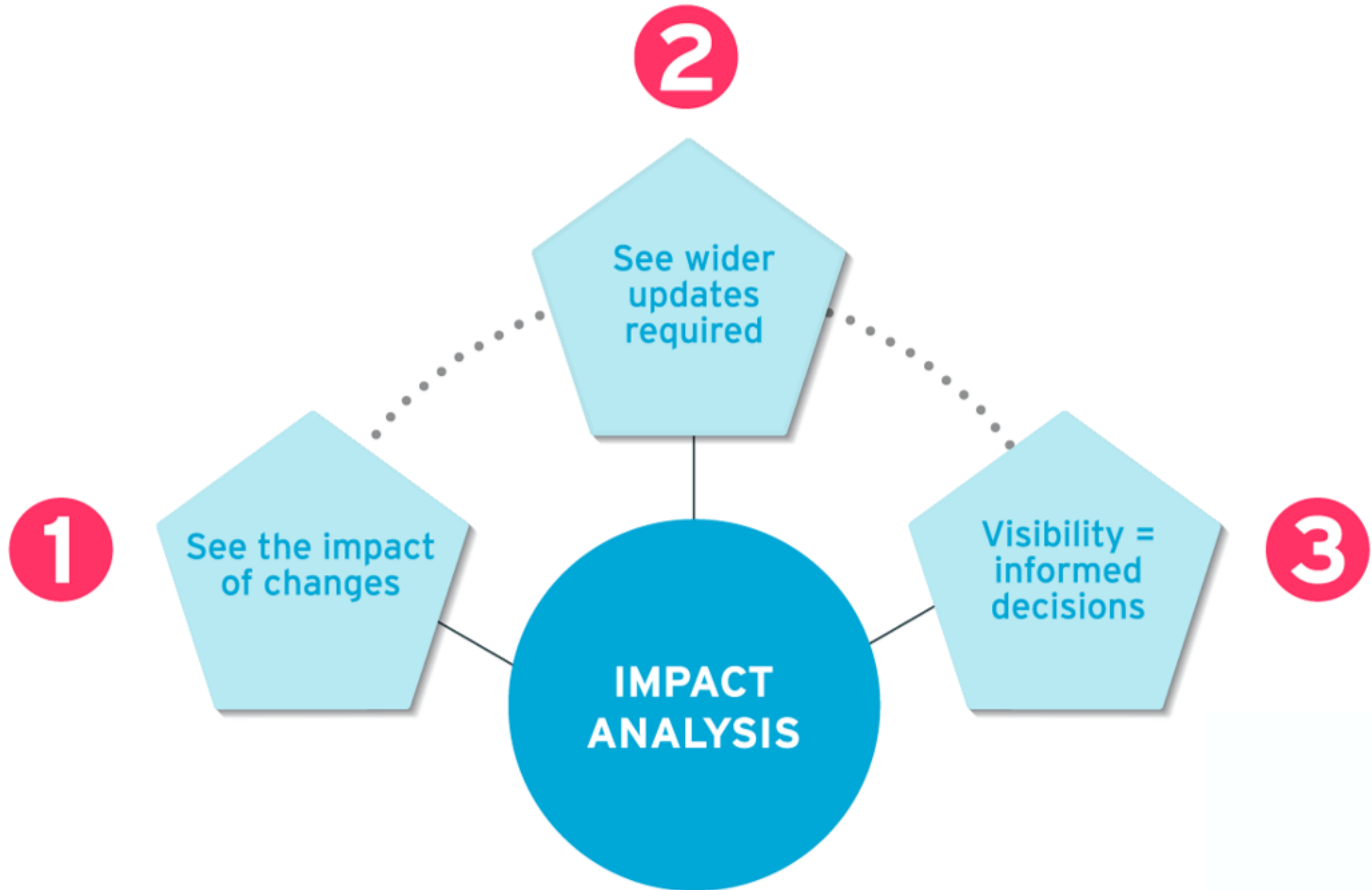
FILES



Ensure consistency

- ✓ Define rules for how your standards should be used in studies
- ✓ Review the compliance of your studies to your standards





Benefits of implementing CDISC data standards

Efficiencies

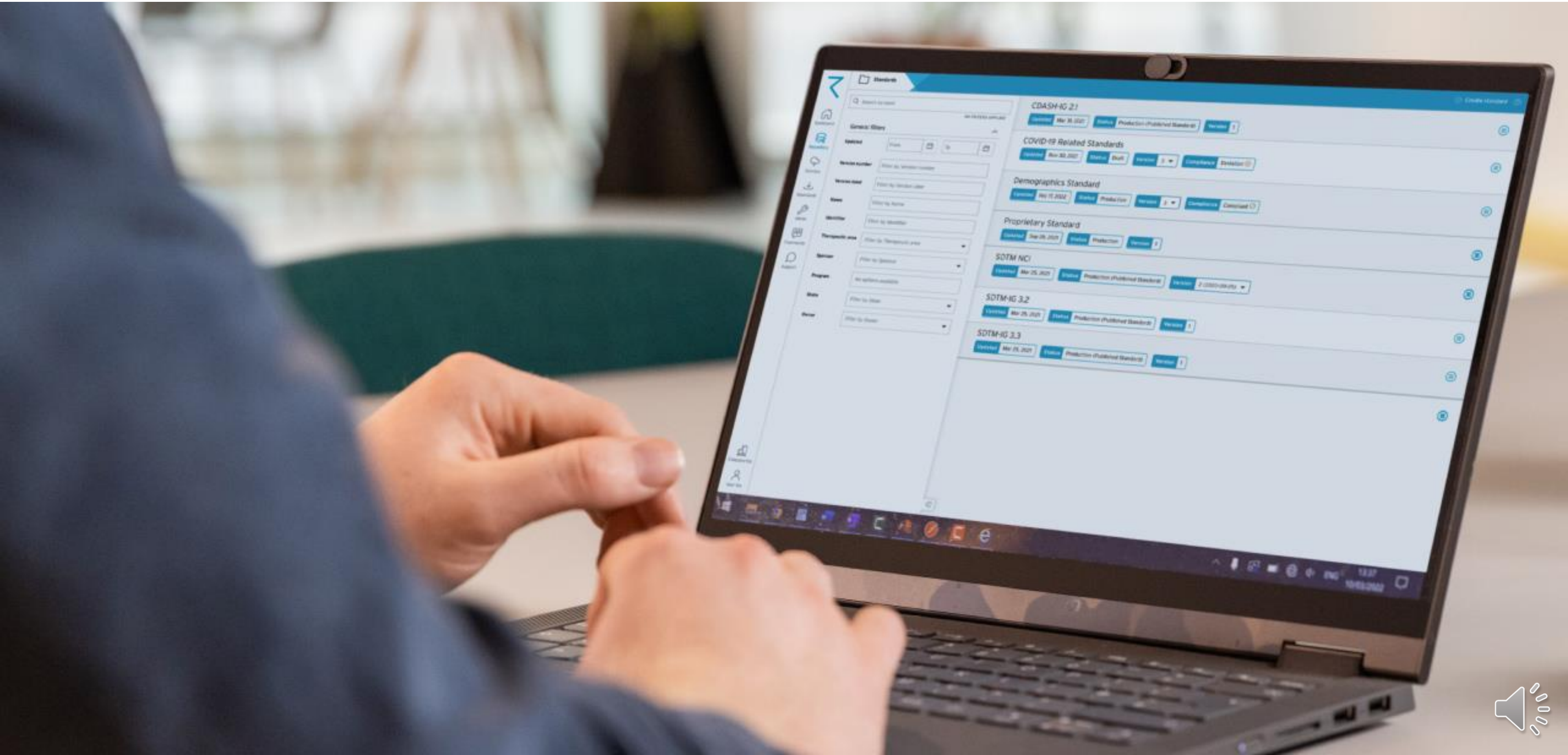
Quality

Consistency

Governance



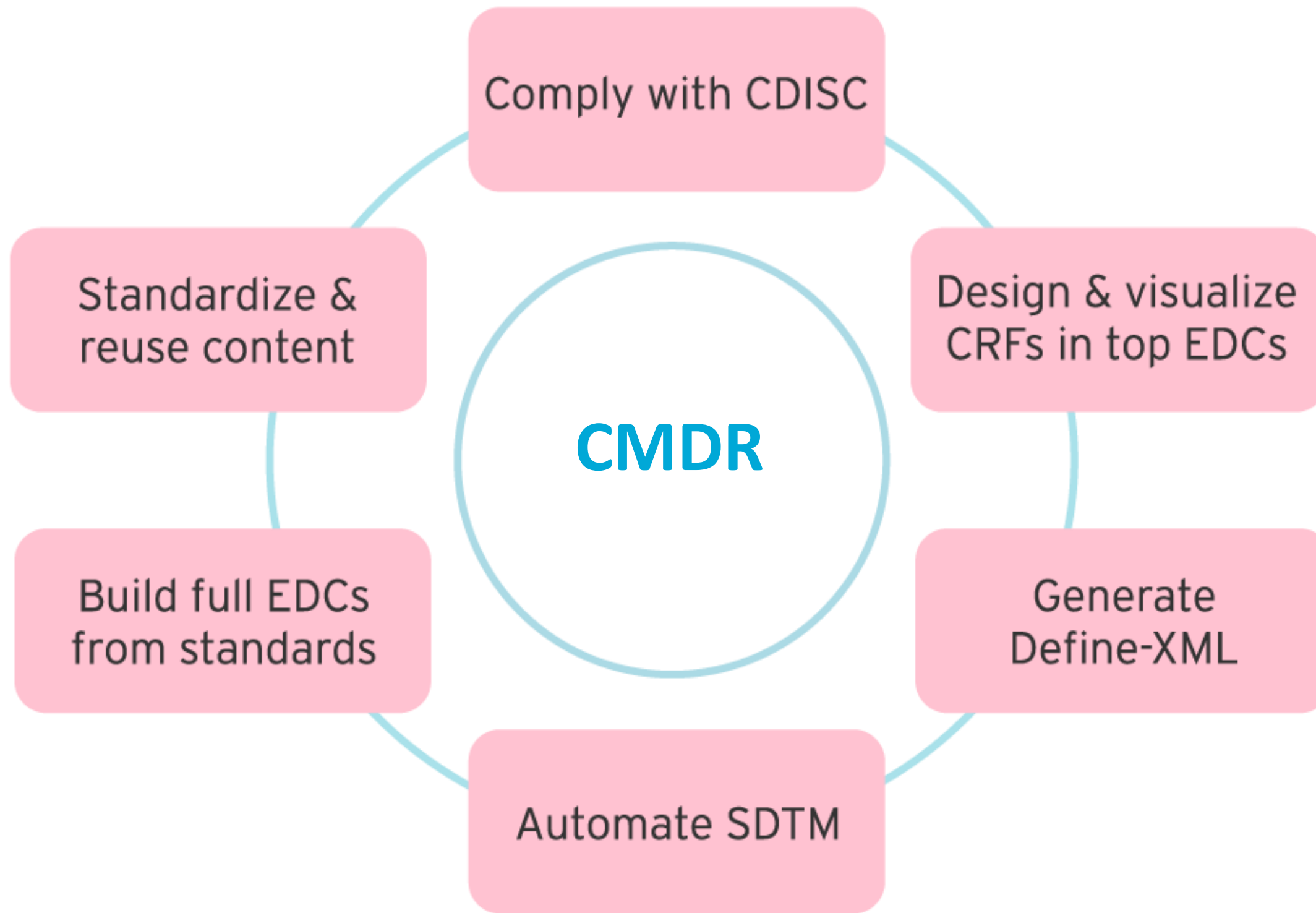
Software tools can help!



Your platform must...

- ✓ Have a content library for standards and enable reuse
- ✓ Have built-in CDISC templates
- ✓ Enable alignment with SDTM from eCRF design
- ✓ Facilitate an approvals process
- ✓ Enable change management
- ✓ Provide impact analysis







How pharma are impacted by standards



Challenges

- Where to start?
- Governance and integration
- Organizational challenges
- Gaps



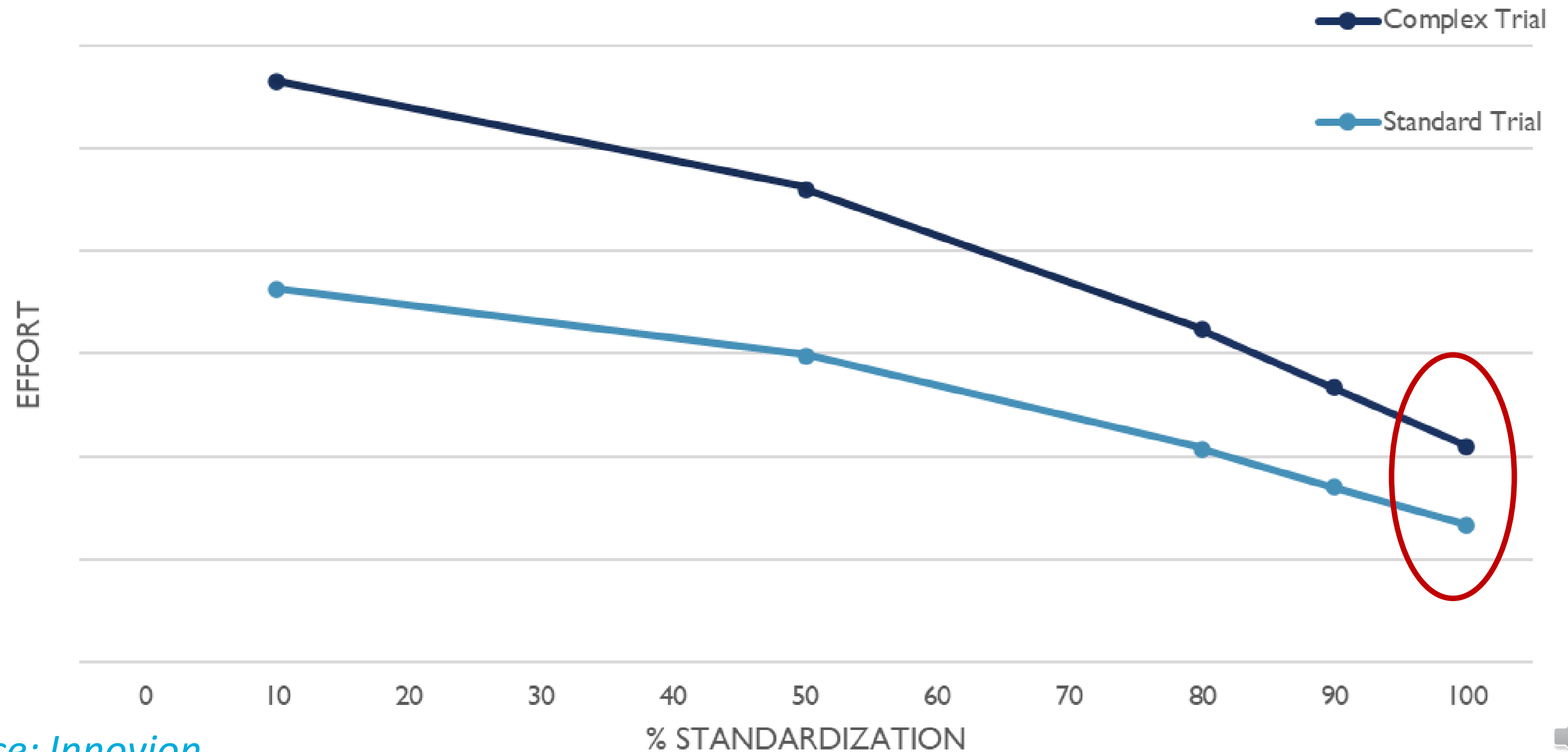


Benefits

- ✓ Regulatory compliance
- ✓ Understand clinical trial data fast
- ✓ Increase useful clinical data
- ✓ Enhance interoperability



Impact of Standardization on trial setup effort





How academia is adopting and leveraging CDISC standards



BEFORE

- ☹️ No alignment with CDISC and NCI CT.
- ☹️ No governance between standards and studies.
- ☹️ Minimal reuse of standards.



AFTER

- 😊 Imported EDC content into CMDR
- 😊 Developed new standards - reviewed and approved with ryze visualizations
- 😊 Standards can now be reused!
- 😊 Can now design & build EDC studies from CMDR!





BEFORE

- ☹️ No standards
- ☹️ No alignment with CDASH or SDTM
- ☹️ Future trials & grants in jeopardy





AFTER

- 😊 Created CDASH compliant CRFs
- 😊 Built datasets in line with SDTM
- 😊 Mapped CRFs & datasets to SDTM domains and NCI CT
- 😊 Push to establish standards library and use CMDR



Conclusions

- ✓ Teamwork!
- ✓ Build from the end
- ✓ Establish governance
- ✓ Software can help!



To find out more visit formedix.com or stop by booth #20 for a demo 😊

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