

How a Clinical Metadata Repository facilitates compliance with industry standards and expedites metadata storage, sharing, analysis and submission times.

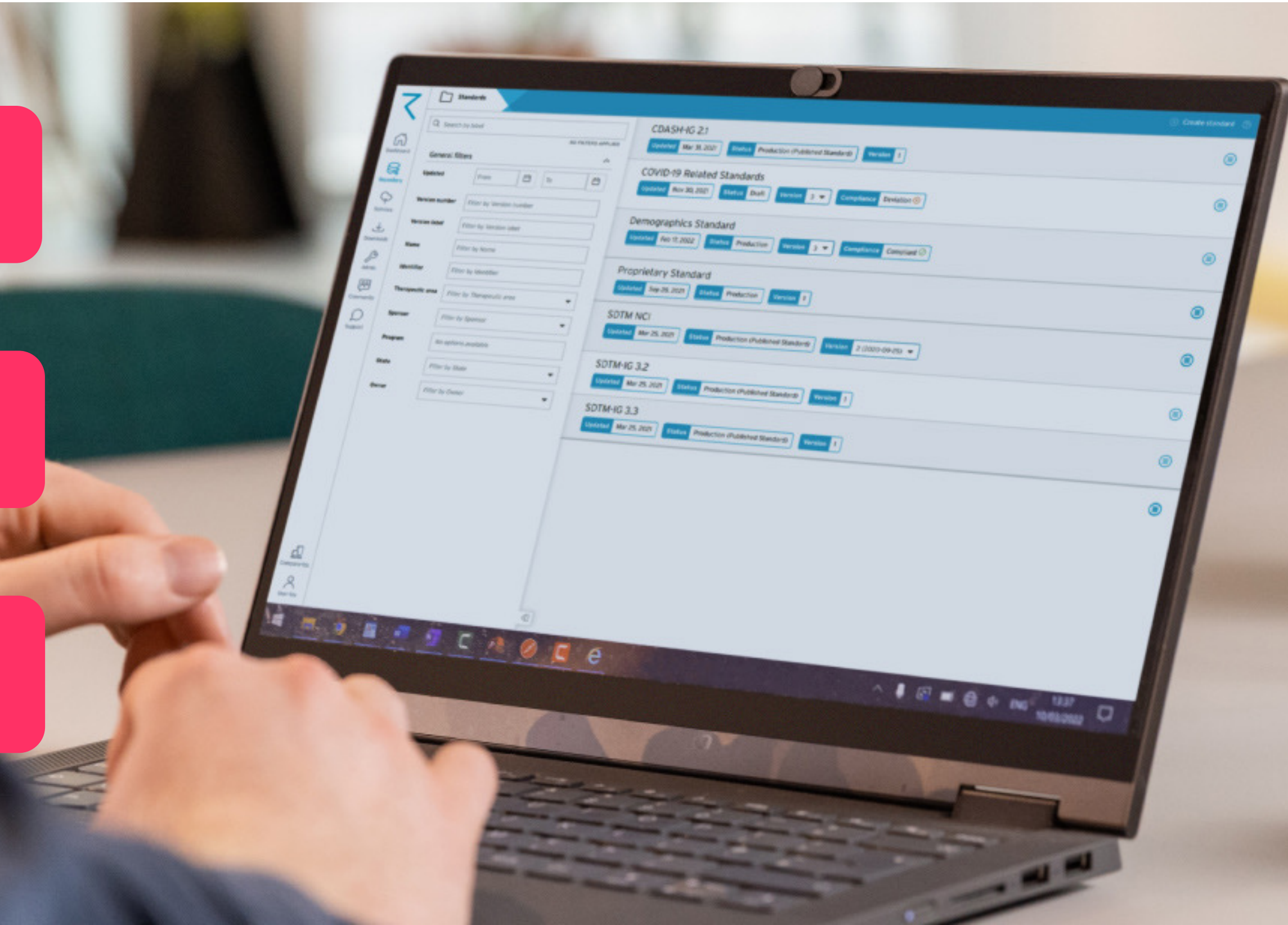
Gilbert Hunter | Customer Success Manager

The need for a Clinical Metadata Repository (CMDR)

Visibility and
control

Compliance

Reuse

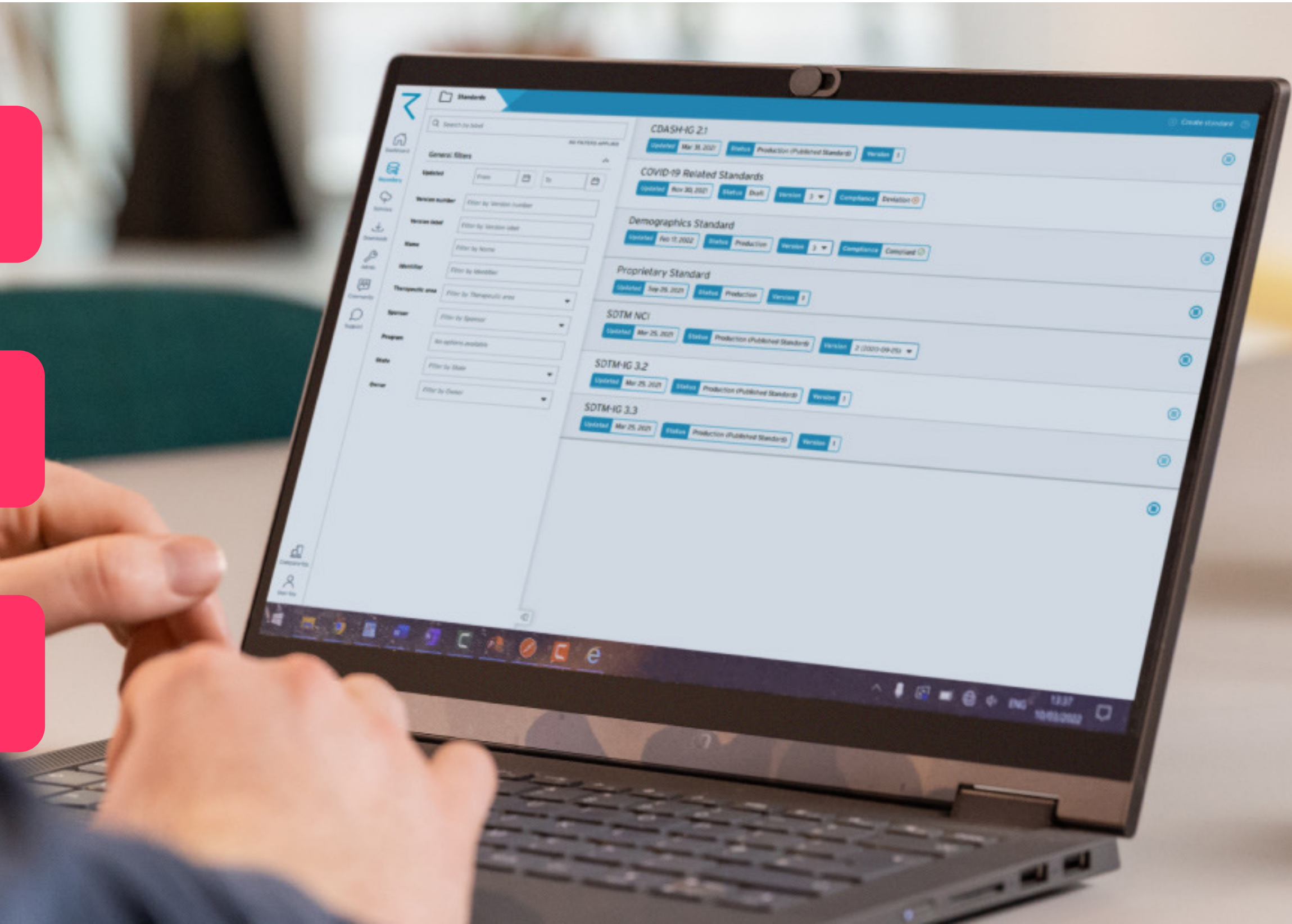


The need for a Clinical Metadata Repository (CMDR)

EDC Automation

Submission
Deliverables

SDTM Automation

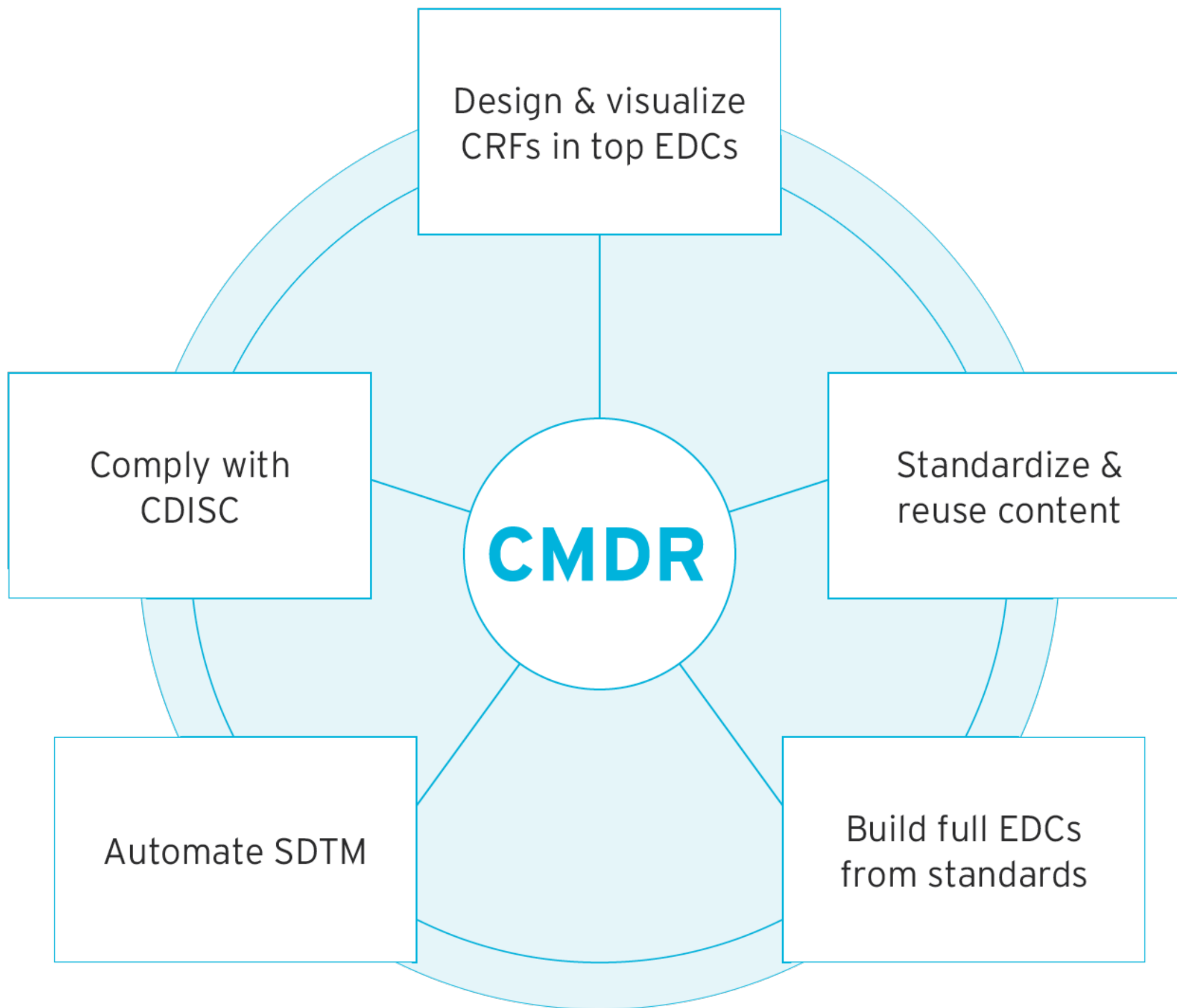


- Long study setup & build time.
- Lack of quality & consistency.
- Long wait for SDTM.
- Delays in submission deliverables.
- Delays in trial submission.
- A lot of time, costs and resources needed!



What's the answer?



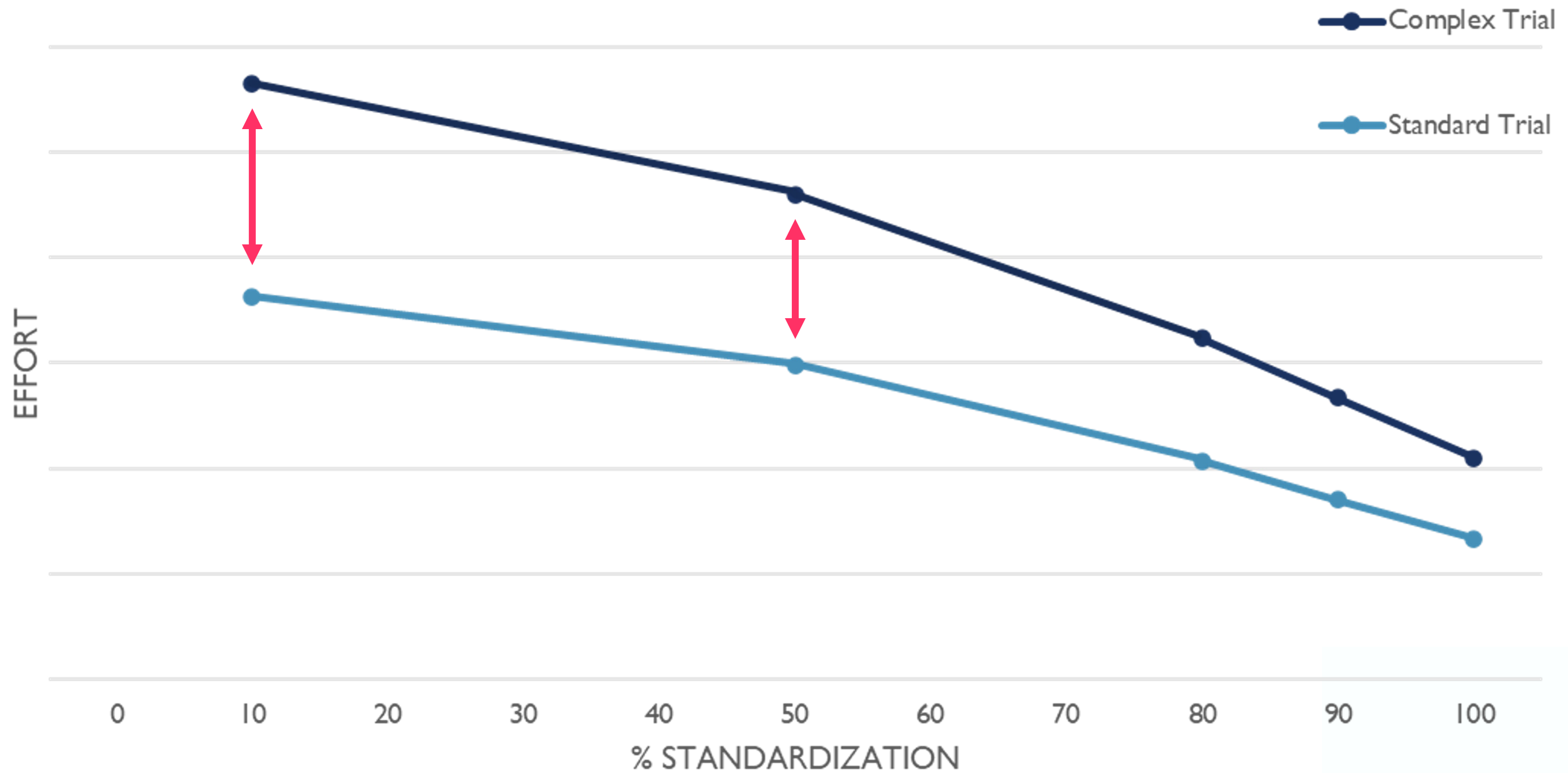


Standardization in trials

Standardizing metadata provides pre-approved content for reuse across future studies. This equates to time savings, and better data quality and consistency. Plus, it's easier for stakeholders to find the latest approved content.

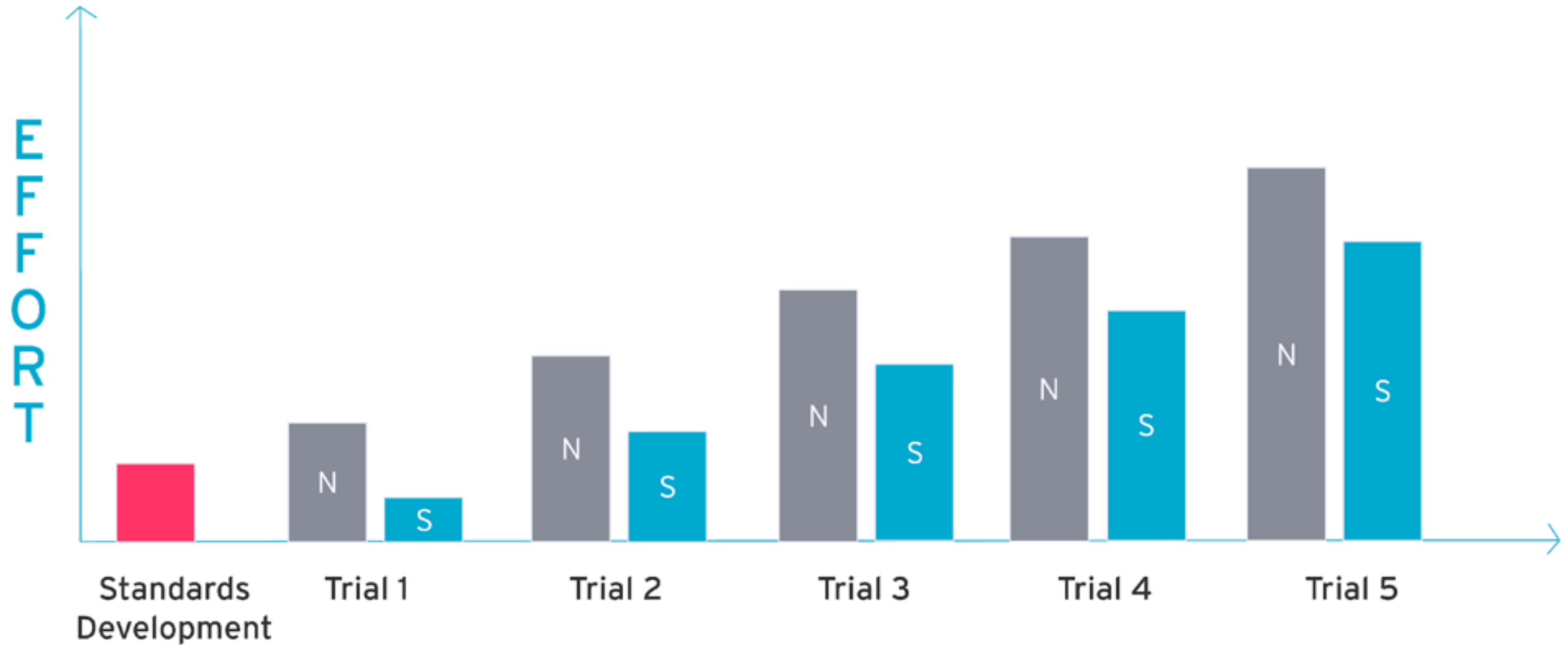


Impact of a Clinical MDR on trial set-up effort



Source: Innovion

Cost break-even point for complex trials



N = No Standardization
S = Standardization

Source: Innovion

SEND

NCI CT

ADaM

CDISC SDTM

ODM

Define-XML



Drive further benefits with automation

- Specifications.
- Design & build for leading EDCs.
- Automated CRF annotations.
- Built in quality & compliance.
- SDTM dataset conversions.

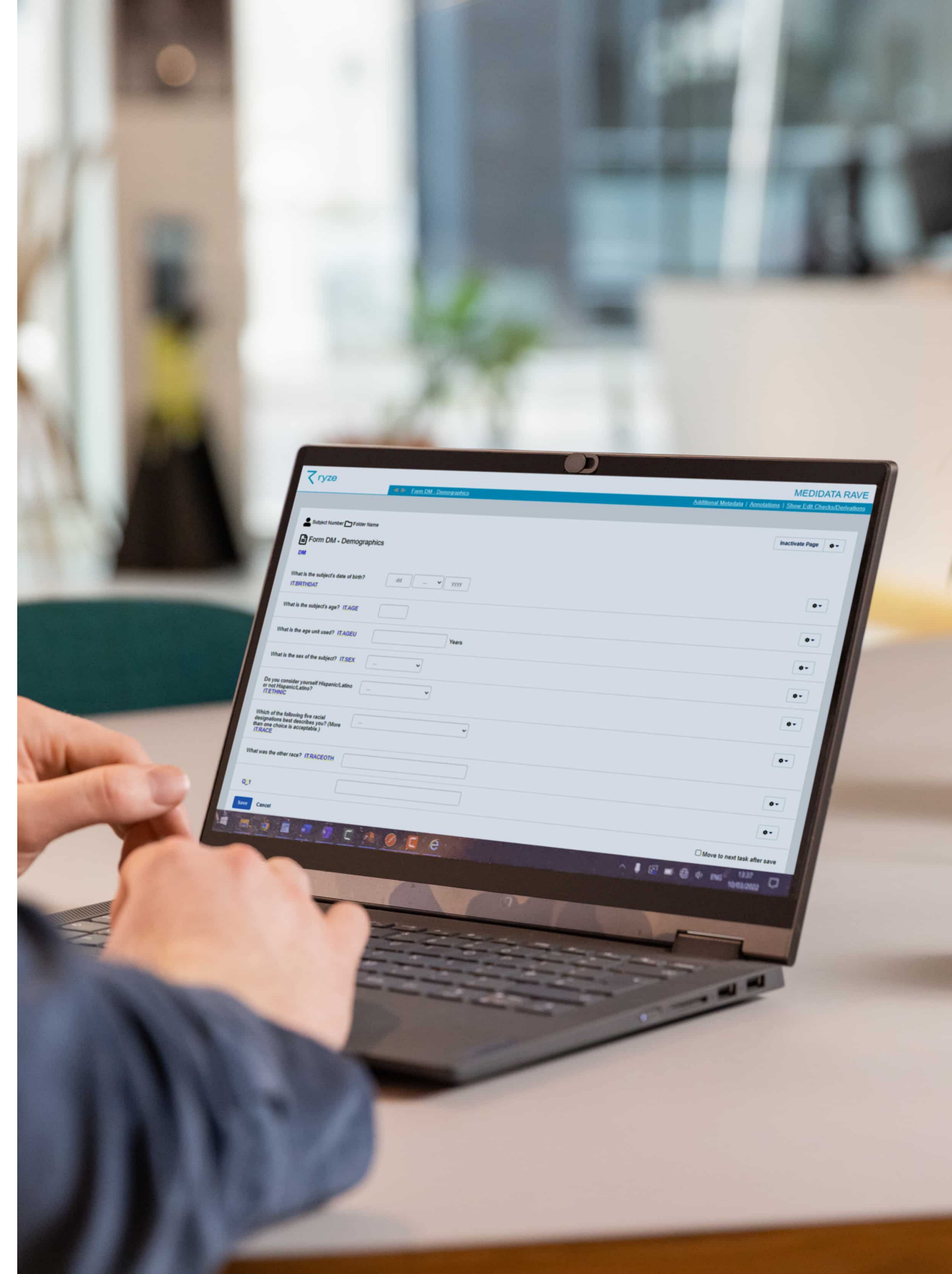


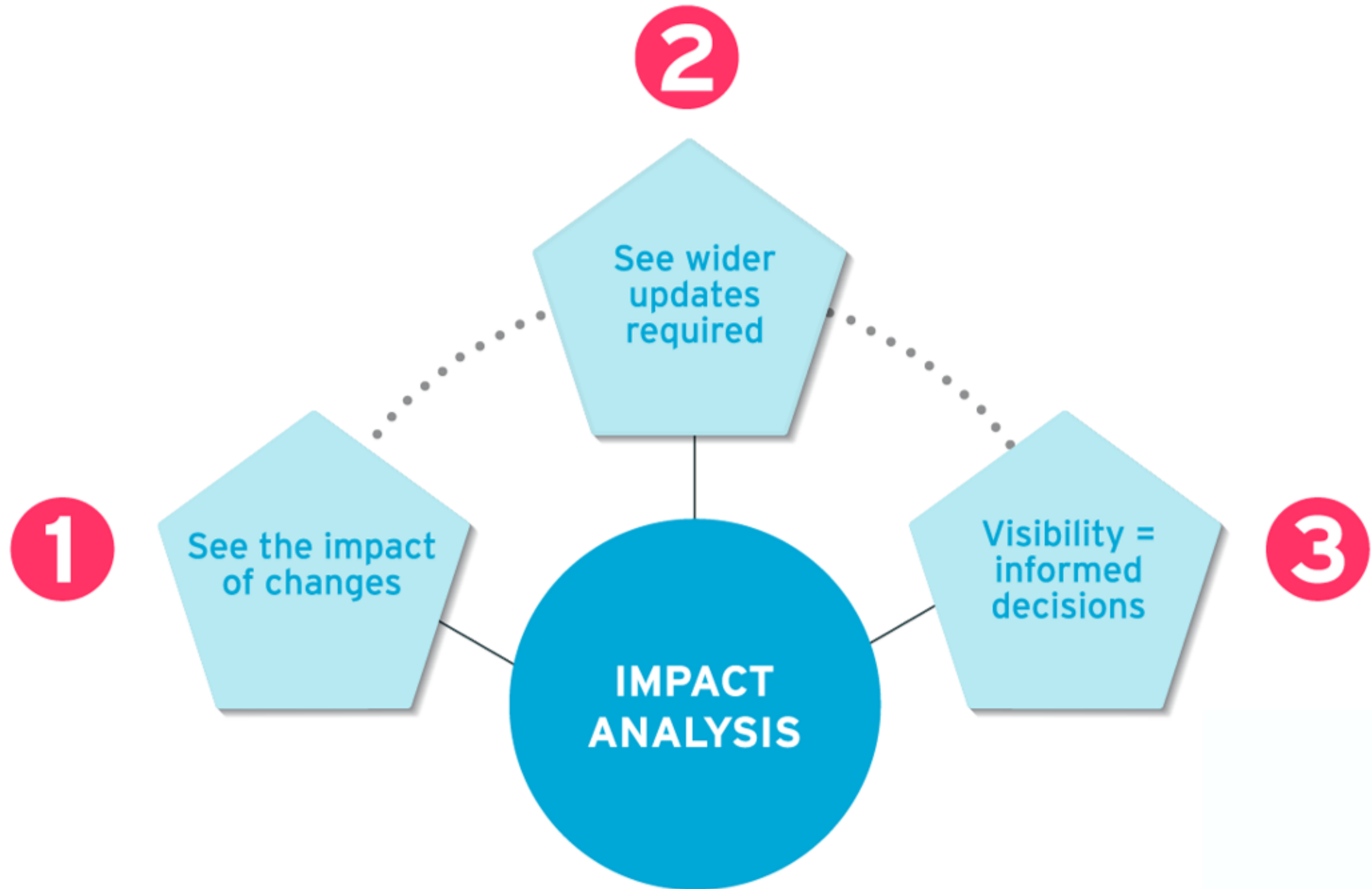
EDC integration



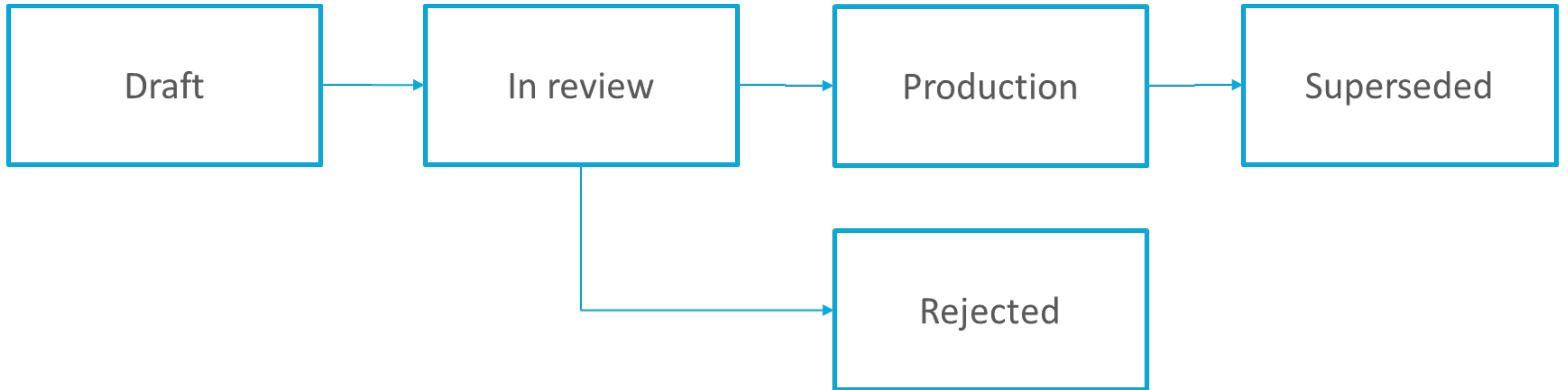
See how metadata looks *before* EDC build

- See how CRFs look for leading EDCs *as you design forms*.
- See metadata specifications.
- See visit structures.
- View edit check specs.
- See mapping specs.
- See submission ready annotated CRFs in PDF.
- Get SAS XPT and SAS v9 clinical views.



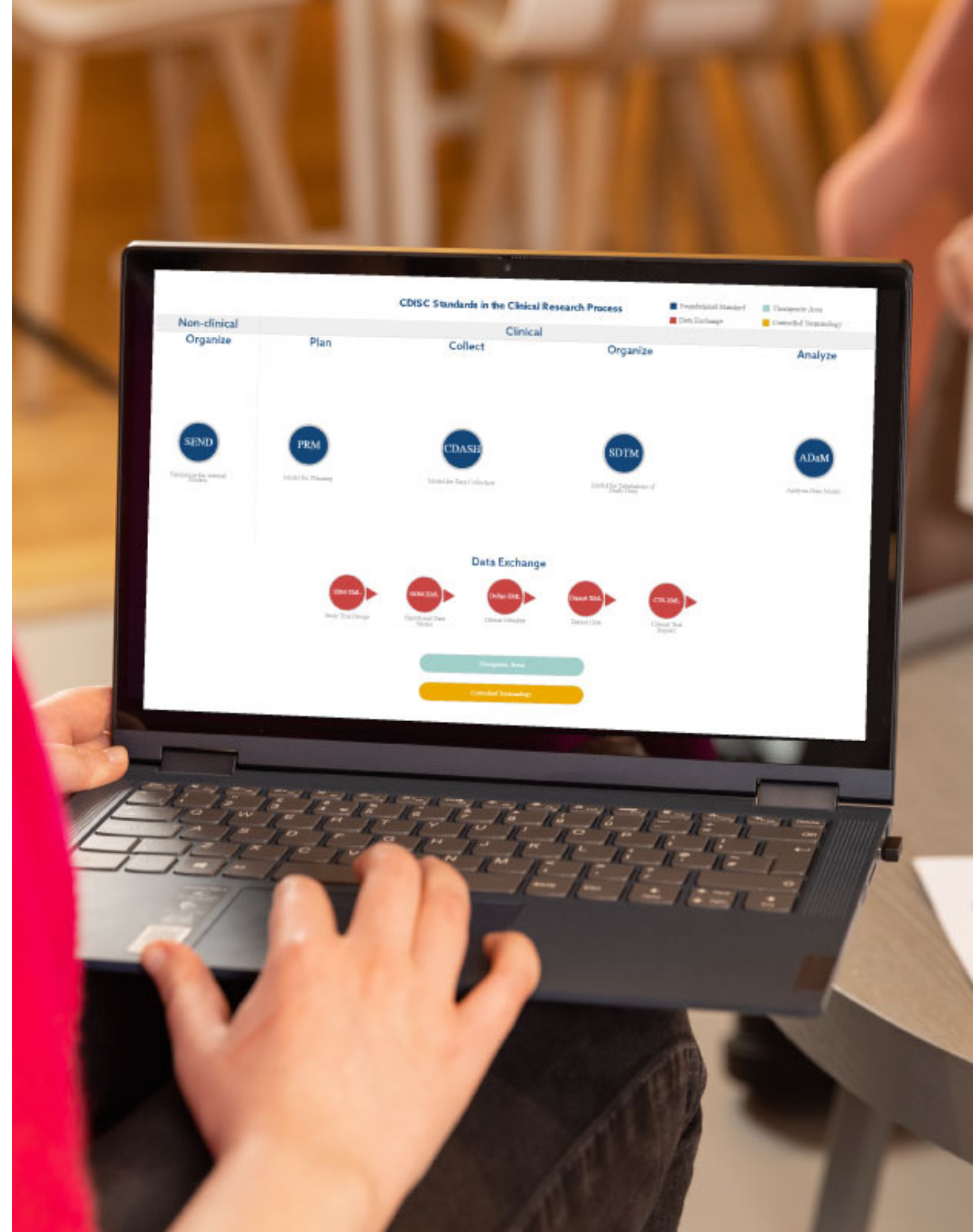


Control the approvals process



Design with compliance built-in

- Define rules for how your standards are used in studies.
- View the compliance of your studies to your standards.



Label: Demographics Name: DM Identifier: DM								
Variables								
	Name	Aliases	Label	Data type	Length	Origin	Comment	M
✓	STUDYID	None	Study Identifier	Text	200	Protocol - Sponsor	No comment	No
✓	DOMAIN	None	Domain Abbreviation	Text	2	Assigned - No source	No comment matching locale No documents	No
✓	USUBJID	None	Unique Subject Identifier	Text	200	Derived - No source	No comment matching locale No documents	No
✓	SUBJID	None	Subject Identifier for the Study	Text	200	No origins	No comment	No
✓	RFSTDTC	None	Subject Reference Start Date/Time	Datetime	None	No origins	No comment	No
✓	RFENDTC	None	Subject Reference End Date/Time	Datetime	None	No origins	No comment	No
✓	RFXSTDTC	None	Date/Time of First Study Treatment	Datetime	None	No origins	No comment	No
			Date/Time					

Label:

Demographics

12

Name:

DM

?

Identifier:

DM

2

Domain:

DM

Class:

SPECIAL PURPOSE

Repeating:

☐

Structure:

One record per subject

Purpose:

Tabulation

Is reference data:

☐

Location:

dm.xpt

Aliases:

+

 Add
 None

Description:

+

 Add
 None

Therapeutic area:

Select

» Vaccines

Clinical stage:

Select

» Study setup

Updated:

Sep 21, 2021 12:42:48 PM

◀ Expand

5 errors

Reset

Validate & Update

SDTM-IG 3.2

▼ Datasets

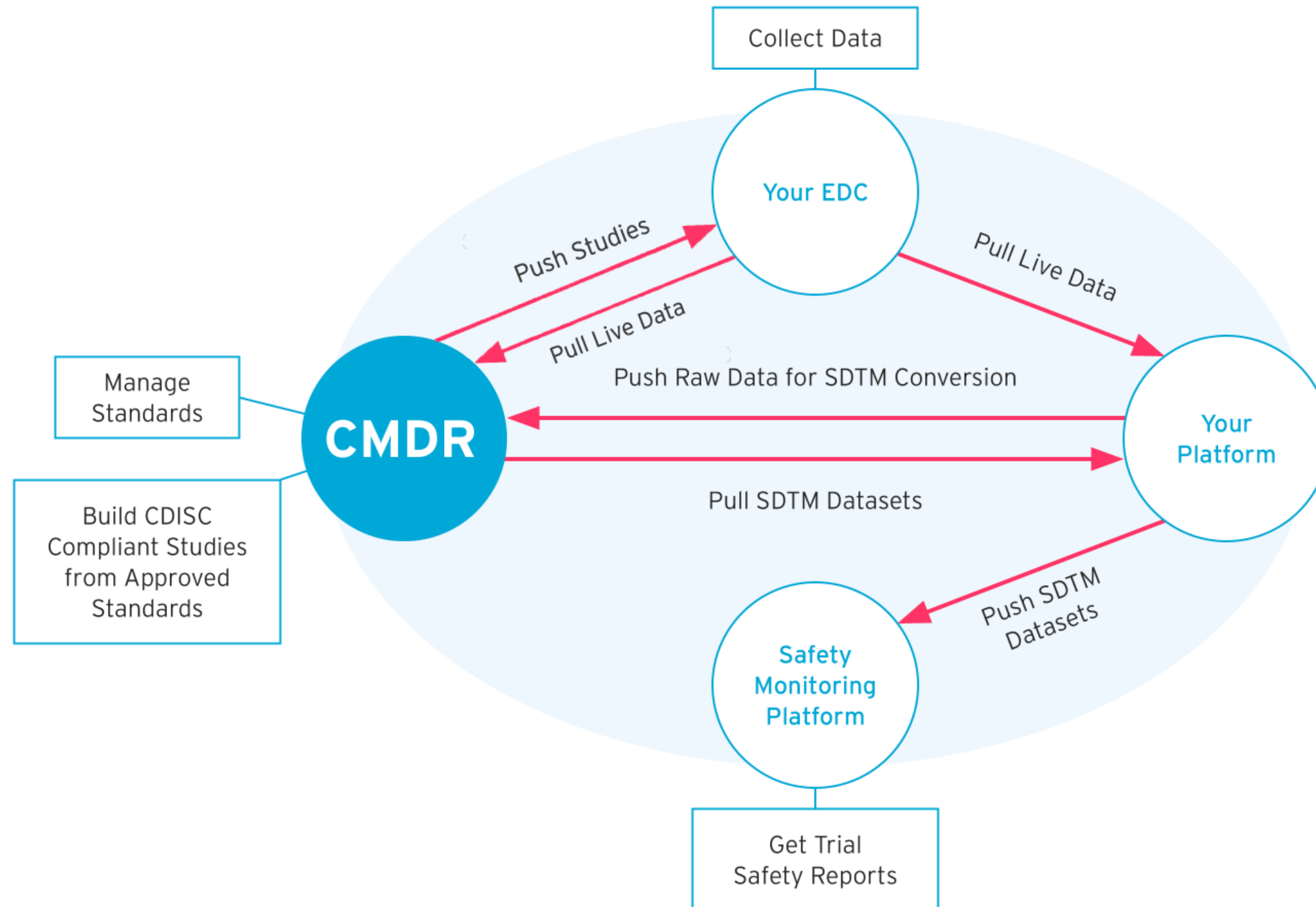
AE (Adverse Events)
 APRELSUB (Associated
 CE (Clinical Events)
 CO (Comments)
 CM (Concomitant Medications)
 DD (Death Details)
 DM (Demographics)
 RS (Disease Response)
 DS (Disposition)
 DA (Drug Accountability)
 EG (ECG)
 -- (Events class template)
 EX (Exposure)
 EC (Exposure as Collected)
 FA (Findings About Event)
 -- (Findings class template)
 HO (Healthcare Encounter)
 IS (Immunogenicity Study)
 IE (Inclusion/Exclusion)
 -- (Interventions class template)
 LB (Labs)
 MH (Medical History)
 MB (Microbiology Specimen)
 MS (Microbiology Susceptibility)

Datasets

Dataset	Description	Class	Structure	Purpose	Keys	Documentation	Location
AE	Adverse Events	EVENTS	One record per adverse event per subject	Tabulation			ae.xpt
APRELSUB	Associated Persons Related to Subjects	RELATIONSHIP	One record per relationship	Tabulation			aprelsub.xpt
CE	Clinical Events	EVENTS	One record per event per subject	Tabulation			ce.xpt
CO	Comments	SPECIAL PURPOSE	One record per comment per subject	Tabulation			co.xpt
CM	Concomitant Medications	INTERVENTIONS	One record per recorded intervention occurrence or constant-dosing interval per subject	Tabulation			cm.xpt
DD	Death Details	FINDINGS	One record per finding per subject	Tabulation			dd.xpt
DM	Demographics	SPECIAL PURPOSE	One record per subject	Tabulation			dm.xpt
RS	Disease Response	FINDINGS	One record per response assessment per visit per subject per assessor	Tabulation			rs.xpt
DS	Disposition	EVENTS	One record per disposition status or protocol milestone per subject	Tabulation			ds.xpt
DA	Drug Accountability	FINDINGS	One record per drug accountability finding per subject	Tabulation			da.xpt
EG	ECG	FINDINGS	One record per ECG observation per time point per visit per subject	Tabulation			eg.xpt
--	Events class template	EVENTS	One Record per Event	Tabulation			--.xpt

- Define mappings from source data to SDTM.
- Generate SDTM from EDC / source data.
- Link studies to the EDC.
- No double programming.
- See data faster – less lag time.
- Run conversions in real-time from go-live.

Go further by integrating with 3rd party technologies



How standardization was leveraged in COVID-19 trials



Improve compliance and accelerate clinical trials



Efficiencies

Quality

Consistency

Governance

To find out more visit our website
formedix.com

Stop by our booth for a demo.

