

SCDM **Live**



SCDM 2025 EMEA CONFERENCE

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Best practice for CDISC standards implementation and uses cases demonstrating successful adoption

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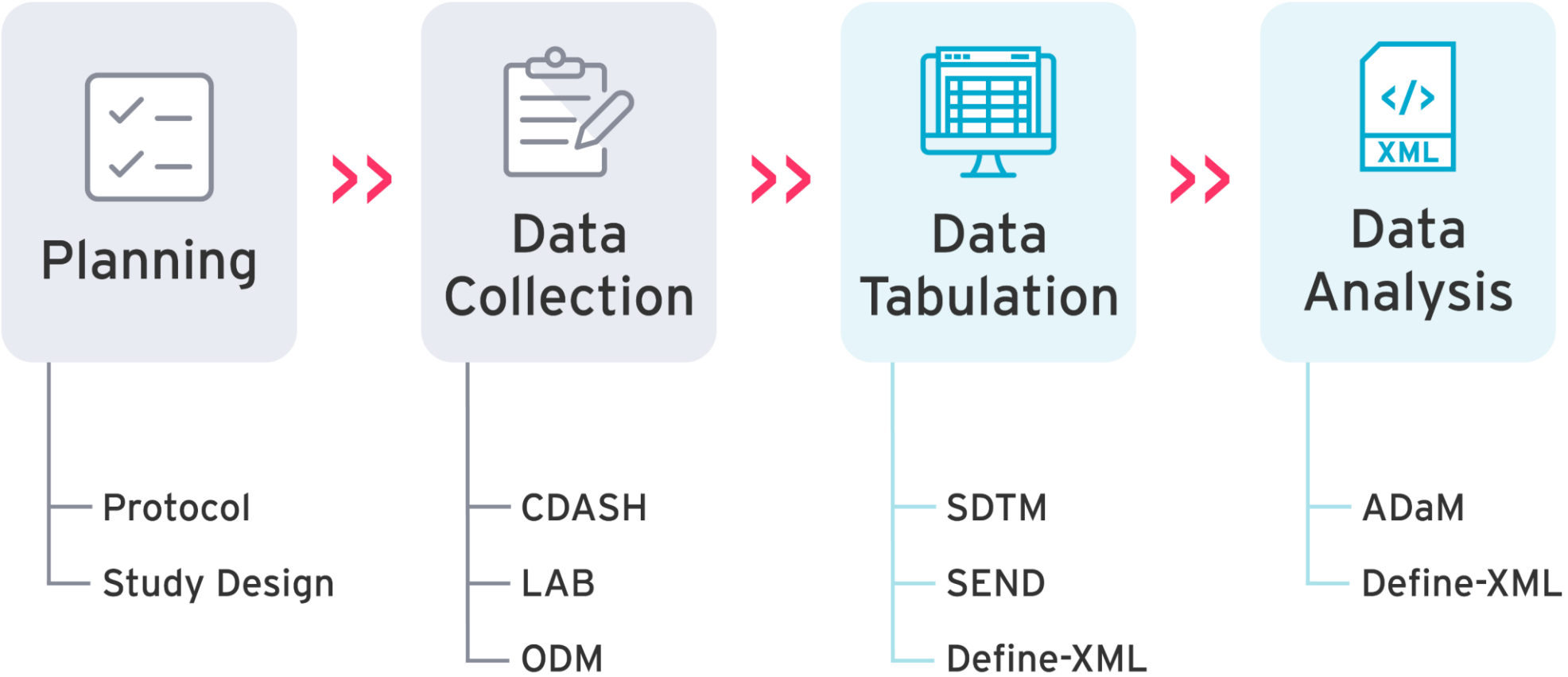
Senior Customer
Success Manager,
Cetera

Gilbert Hunter

Senior Customer Success Manager
Certara



CDISC standards

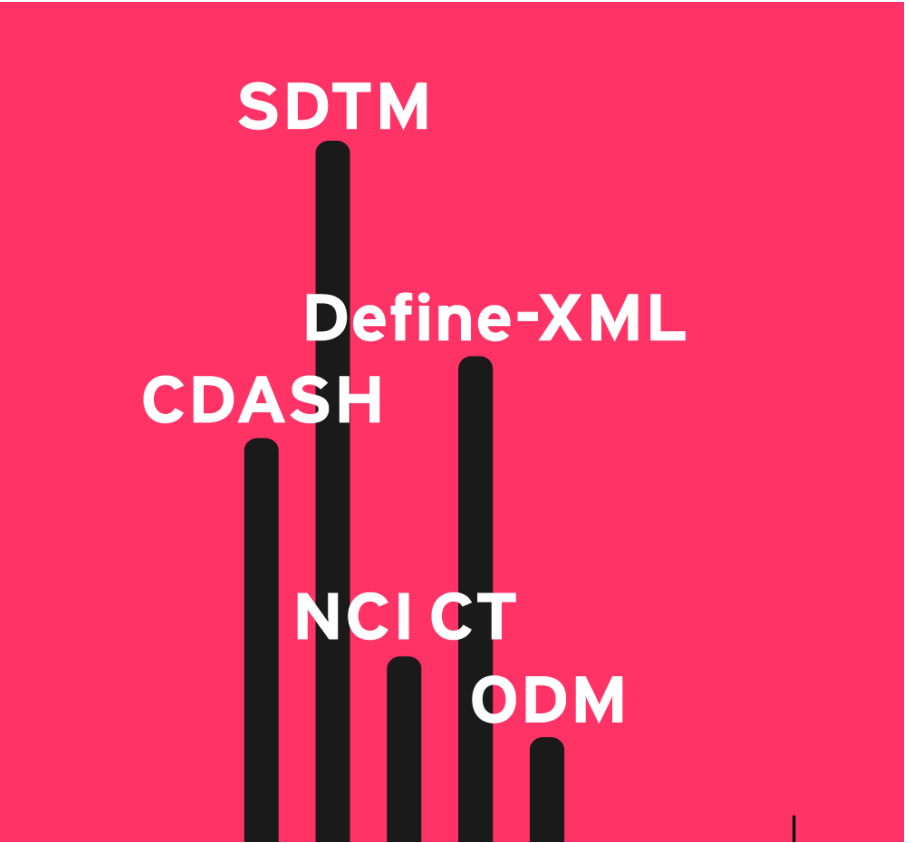


NCI Terminology

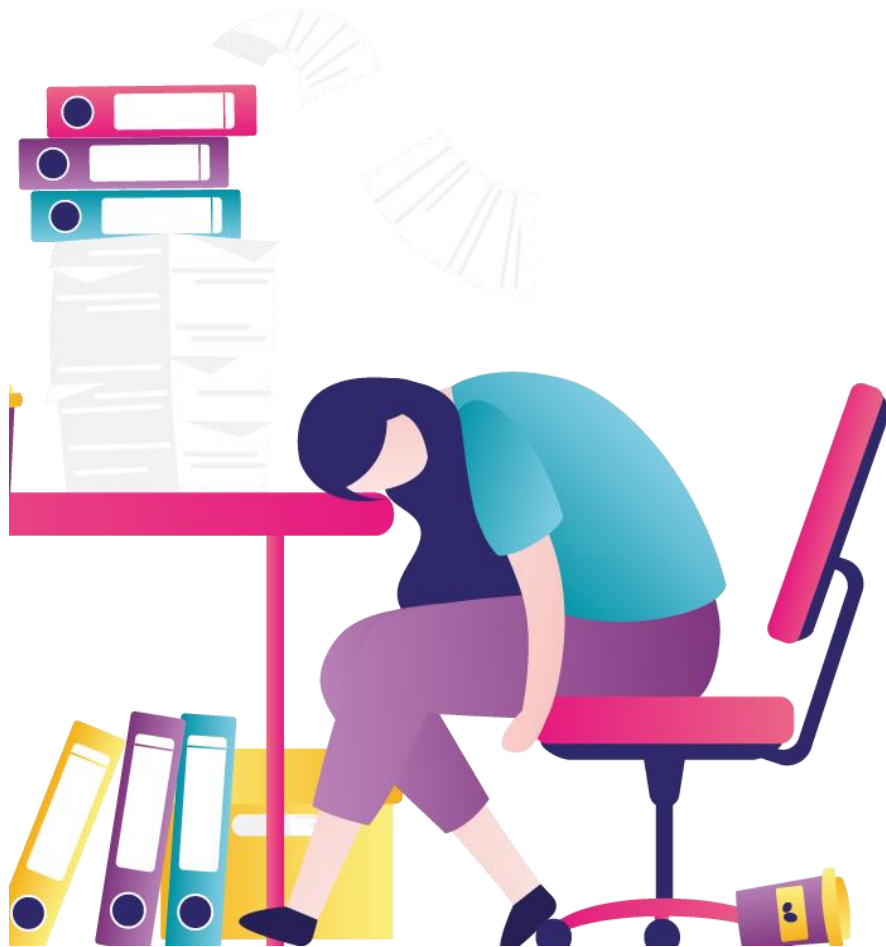
NCI Terminology



The need for data standards



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!



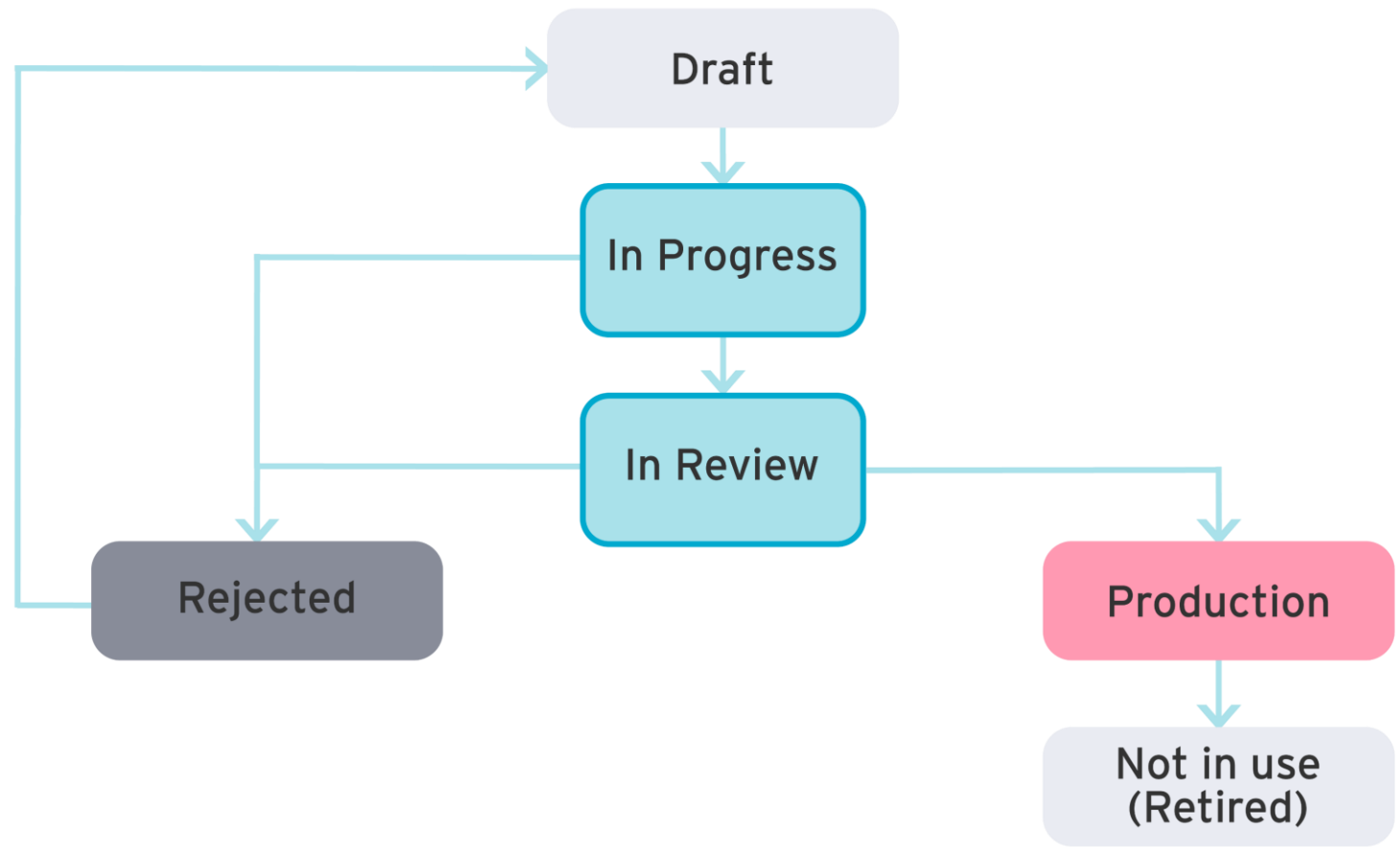
Design with SDTM in mind... not just a submission standard!

- 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

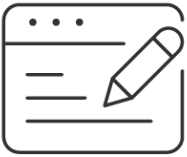




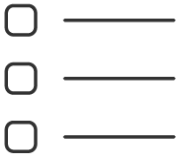
Establish an approved metadata content library



FORMS



ANNOTATIONS



TERMINOLOGIES



DATASETS



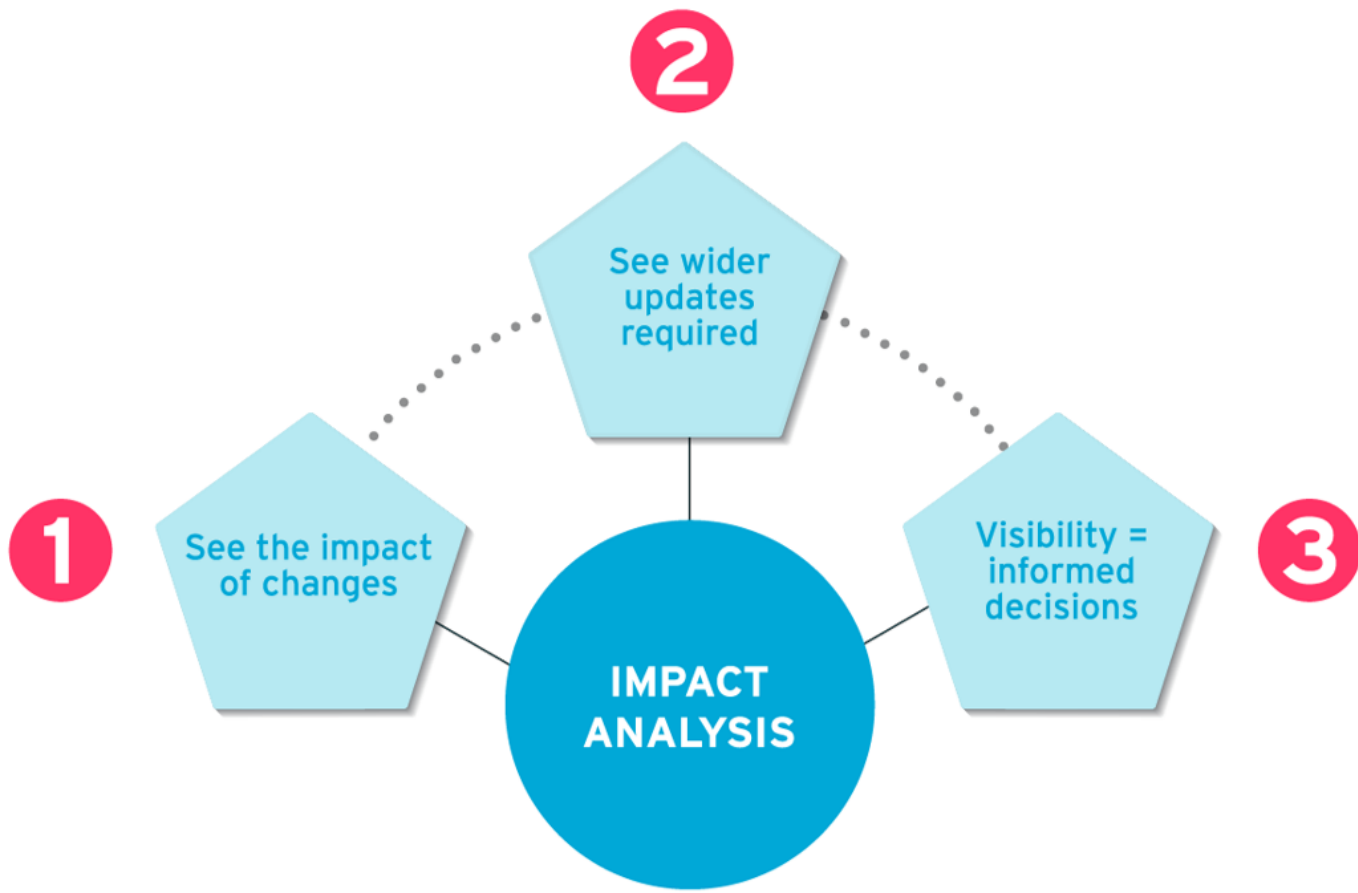
MAPPINGS



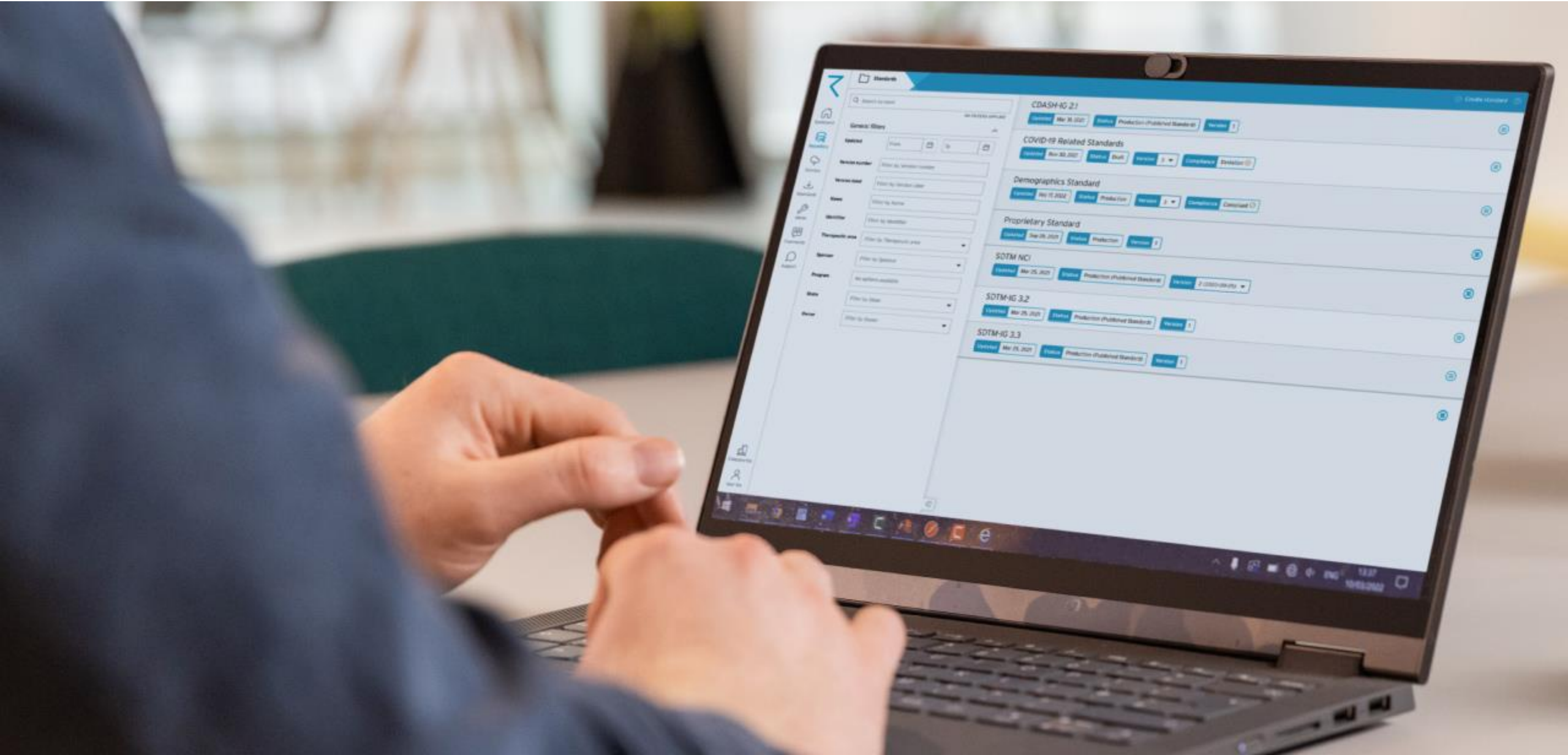
FILES



Understand the impact of change



Software tools can help!





How academia is adopting and leveraging CDISC standards



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

Daniil Teplitskii

Clinical Data Standards Manager, UCB



CDISC data standards adoption.

- The challenge is to organize the governance and compliance in an organization. Generally speaking, CDISC data standards are subject for **interpretation**/assumptions /understanding and, so, can vary widely among companies and users.
- Each organization must build their own **interpretation of CDISC standards**:
 - ❑ to ensure data structure and data consistency among their studies,
 - ❑ Implement workflows and processes to facilitate process of governance,
 - ❑ Define (for themselves) what it is – “to be compliant” with the CDISC data standards.

Best practice processes to achieve successful implementation of CDISC standards. DATA STANDARDS GOVERNANCE BOARD.

- If a company needs data standardization, a good solution is at least to have:
 - ❑ **data standards governance review board** (may go under different names in different organizations)
 - ❑ **dedicated team of data standards specialists** responsible for company's data standards.
- Members of the board might include:
 - ❑ subject matter experts in CDISC standards,
 - ❑ representatives from functional groups, responsible for implementing CDISC standards in their daily work (such as data managers, statistical programmers, statisticians).

Best practice processes to achieve successful implementation of CDISC standards. MAINTAINING DATA STANDARDS

- A company would need to have:
 - CMDR** - *Clinical Metadata Repository* – a key element for **Creating/updating/up-versioning/maintaining the standard** assets metadata
- Regarding Standards Governance, organization would need to define:
 - When and how to adopt new versions of data standards and metadata being released by CDISC, NCI, etc.
 - How to manage requests and suggestions

CMDR - Clinical Metadata Repository (example screenshot)

Standards > Demographics and...
Draft - ver. 23 > CRF SDTMIGv3.4
Data acquisition > Forms
View Favorite Visualize Asset

Back to asset list [Edit form](#) [Collapse all](#) [Refresh](#) [Filter](#) Locale: Default

Eligibility Criteria

Eligibility Criteria
IE_NOTMET_01

Description: For non-interventional studies, the following text replacements can be made, as appropriate: "eligibility criteria" can be replaced with "selection criteria" (or other appropriate verbiage), "informed consent" can be replaced with "data consent" (or other appropriate verbiage), "protocol" can be replaced with "observational plan" (or other appropriate verbiage), "study participant" can be replaced with "patient" (or other appropriate verbiage)

Repeating: No

Last updated:
Mar 26, 2025 5:26:32 PM

Aliases:
» IE (Inclusion/Exclusion ...
» Verification of in-/exclus...
» IE=Inclusion/Exclusion C...
» IECAT = INCLUSION for i...

Therapeutic area:
» All

Clinical stage:
None

IE_ELIG_CRIT_YN_NR (IE_ELIG_CRIT_YN_NR) ⊗ ∞ 📄 No condition

Questions

Label	Submission variable	Question	Data type	Length	Fraction digits	Mandatory	Terminology	Units
IEYN	None	Did study participant meet all eligibility criteri...	Text	1	None	Yes	✓ No Yes Response N/Y Only	Unavailable

IE_FAILED_CRIT_R (IE_FAILED_CRIT_R) ⊗ ∞ 📄 No condition

Questions

Label	Submission variable	Question	Data type	Length	Fraction digits	Mandatory	Terminology	Units
IETESTCD	None	If No, Failed Criteria	Text	5	None	No	✓ INC EXC Criteria	Unavailable

Properties | **Plugin properties** | **Relationships**

Label: Eligibility Criteria 20

Name: Eligibility Criteria 20

Identifier: IE_NOTMET_01 12

Repeating: No

Aliases:
» IE (Inclusion/Exclusion Criteria Not ...
» Verification of in-/exclusion criteria (...
» IE=Inclusion/Exclusion Criteria Not ...
» IECAT = INCLUSION for inclusion crit...

Description:
For non-interventional studies, the following text replacements can be made, as appropriate: "eligibility criteria" can be replaced with "selection criteria" (or other appropriate verbiage), "informed consent" can be replaced with "data consent" (or other appropriate verbiage), "protocol" can be replaced with "observational plan" (or other appropriate verbiage), "study participant" can be replaced with "patient" (or other appropriate verbiage)

See the Study Handoff Form in the CRF Metadata Repository for specific database setup instructions relating to screenina/eligibility/screen failures

[Expand](#)

Benefits

BEFORE Standards	AFTER Standards
15 days study build	3 days study build
8 days study draft review	4 days study draft review

- ✓ 85% reduction in study build time
- ✓ 50% reduction in review cycle time

The key point here – now CROs can pull the metadata **directly** from our Repository because we **use CMDR!**

Best practice processes to achieve successful implementation of CDISC standards. TOOLS TO FACILITATE GOVERNANCE ACTIVITIES

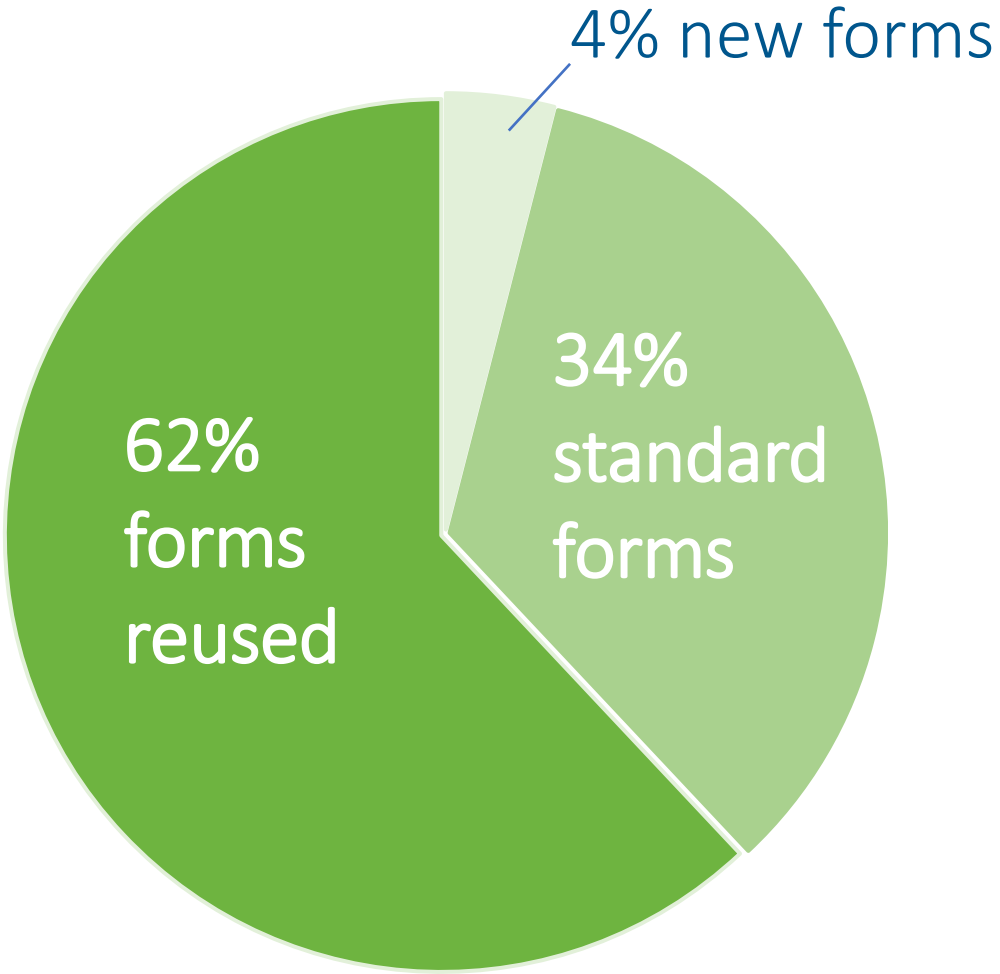
It would be useful to have:

- Systems for ticketing and tracking development of standards) for data standards governance workflow – to track **requests** for standards creation/update/up-versioning

It is useful for **CMDR** (*Clinical Metadata Repository*) to include the following functionality:

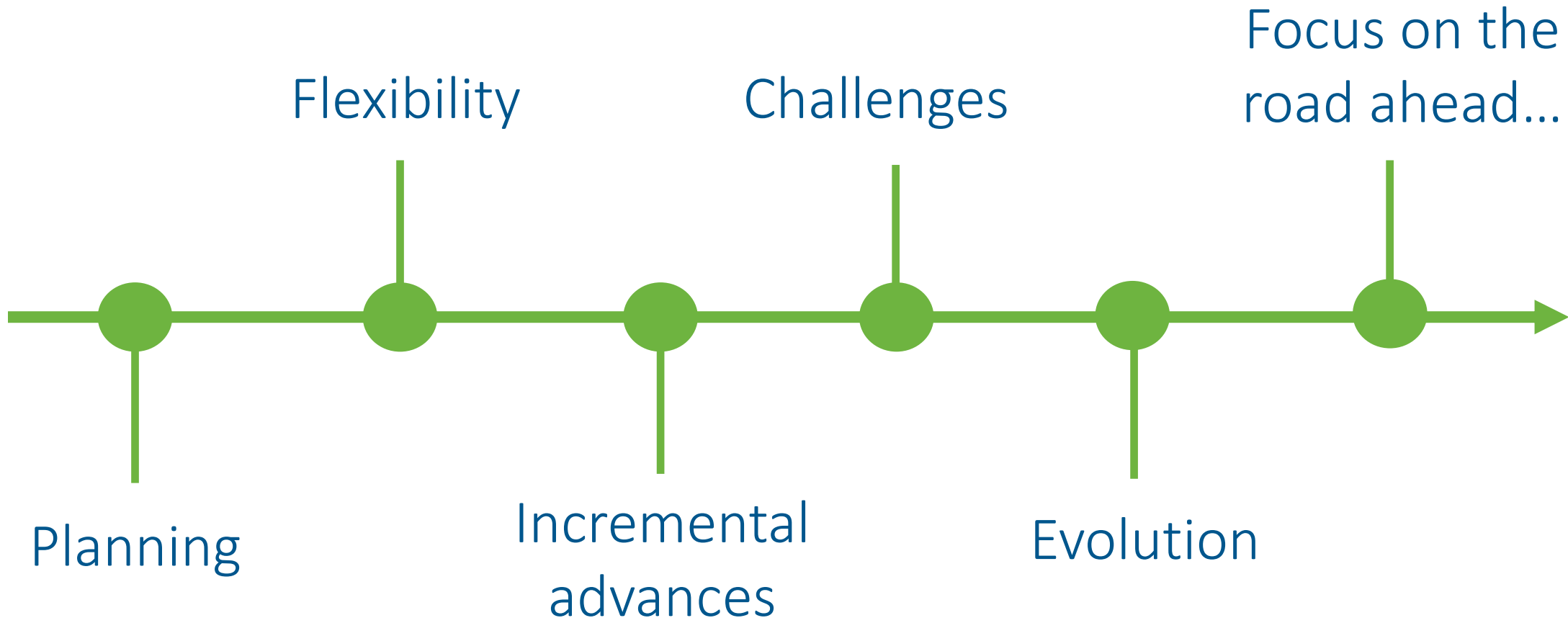
- versioning software - tracking & maintaining changes to data standards
- comparison tool - comparing versions of data standards or study metadata

CRF Reuse



Huge efficiencies in study set up from reuse!

Standards Adoption



Alan Cantrell

Director, Global Biometrics
Account Lead Parexel International

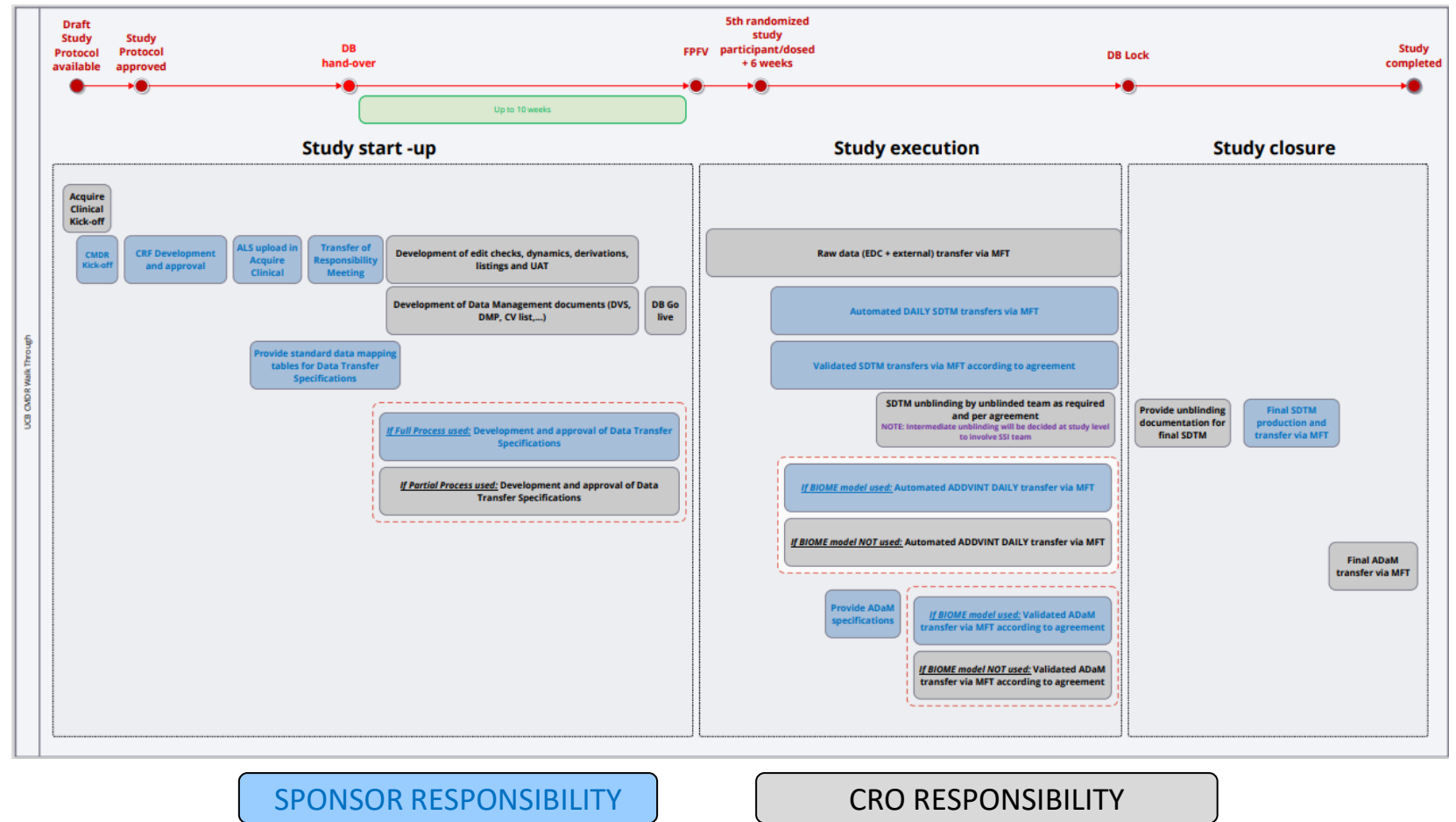


Why use a Clinical Metadata Repository (CMDR)?

- Sponsor strategic decision – business responsibility to enable E2E study automation
- CMDR implemented during 2022
- Roadmap created across study start-up; execution and closure defining the responsibilities between Sponsor and the CRO
- Around 10 studies utilized the CMDR
- New process for both Sponsor and CRO

Sponsor CMDR Roadmap

- Covered Sponsor and CRO responsibilities
- Sponsor develops and approves CRF
- CRO develop edit checks, dynamics, derivations and UAT
- Database go live



CMDR Kick-off – what is it?

- Objectives
- Process
- Review and set-up timelines
- Review process
- Example study feedback

Sponsor CMDR Timelines template

- Sponsor defines timelines for CRF development
- CRO define timelines taking from transfer of responsibilities to DB go live

Task Name	Duration	Start	Finish
Study Setup Phase	146 days	Tue 07/03/23	Thu 12/10/23
CRF Development and approval	44 days	Fri 14/04/23	Tue 20/06/23
Protocol review and Forms assessment	10 days	Fri 14/04/23	Thu 27/04/23
Review the Final Protocol (+Amendment if applicable)	1 day	Fri 14/04/23	Fri 14/04/23
Create the Forms assessment with the identification of Forms type (Standard/Standard to	3 days	Mon 17/04/23	Wed 19/04/23
If needed, create DST requests for Standard to adapt/New forms	1 day	Thu 20/04/23	Thu 20/04/23
Ongoing Update the Forms assessment based DST requests resolution	5 days	Fri 21/04/23	Thu 27/04/23
CRF V1.0	38 days	Fri 21/04/23	Mon 19/06/23
CRF V0.1	17 days	Fri 21/04/23	Tue 16/05/23
Create the study , and design the unique forms	10 days	Fri 21/04/23	Fri 05/05/23
Schedule/Lead the CMDR Kick Off meeting	2 days	Mon 08/05/23	Tue 09/05/23
Review of Unique + Casebook CRF v0.1 (eTMF) with the CRF Consolidated Comment Log	5 days	Wed 10/05/23	Tue 16/05/23
CRF V0.2	6 days	Wed 17/05/23	Fri 26/05/23
Update to CRF v0.2 based on CRF Consolidated Comment Log	3 days	Wed 17/05/23	Tue 23/05/23
If applicable create DST requests for Standard to adapt/New forms	3 days	Wed 17/05/23	Tue 23/05/23
If applicable meeting with the appropriate CRF team members	3 days	Wed 17/05/23	Tue 23/05/23
Update the Forms assessment and resolve the comments with CDS/DTS requests	3 days	Wed 17/05/23	Tue 23/05/23
Review of Casebook CRF v0.2 (eTMF) with the CRF Consolidated Comment Log	3 days	Wed 24/05/23	Fri 26/05/23
CRF V0.3	6 days	Tue 30/05/23	Tue 06/06/23
CRF V0.4	4 days	Wed 07/06/23	Mon 12/06/23
CRF V0.5	3 days	Tue 13/06/23	Thu 15/06/23
CRF V 1.0 approval	2 days	Fri 16/06/23	Mon 19/06/23
Team agreement on last vx.0 and no pending comments in CRF Consolidated Comment Log	1 day	Fri 16/06/23	Fri 16/06/23
Approval of Casebook v1.0 (eTMF)	1 day	Mon 19/06/23	Mon 19/06/23
Transfer of Responsibility Meeting (TRM)	1 day	Tue 20/06/23	Tue 20/06/23
ALS upload in Acquire Clinical/DM partner notification	1 day	Tue 20/06/23	Tue 20/06/23
Schedule/lead the Transfer of Responsibility Meeting (TRM)	1 day	Tue 20/06/23	Tue 20/06/23
EDC Database	50 days	Wed 21/06/23	Fri 01/09/23
GO LIVE	1 day	Fri 01/09/23	Fri 01/09/23
MFT process (iGrafix)	4 days	Wed 21/06/23	Mon 26/06/23
Non-EDC Programming activities	75 days	Wed 31/05/23	Tue 19/09/23
External data	66 days	Wed 31/05/23	Tue 05/09/23
aCRF and DTMS	19 days	Tue 20/06/23	Mon 17/07/23
SDTM mapping	44 days	Fri 14/07/23	Tue 19/09/23

2 review cycles expected

additional review cycles if needed

SDTM timelines details will be adjusted

Development of CRF

- Unique and casebook CRF shared with log
- List of unique forms as reference shared (and which are **Standard / Standard adapted** or **New**)
- Approval of CRF
- Upload of Architect Load Specification (ALS)

Development of database (programming and testing)

- Continuation of basic edit check programming using ALS
- Performing complex database programming (e.g. cross-form checks; custom functions and derivations)
- Performing user acceptance testing
- Achieve database go-live in less than 10 weeks and prior to FPFV
- Creation of CRF completion instructions

Change Management

- Following DB go live
 - Changes **not** impacting CRF content / SDTM
 - CRO makes updates to the database
 - CRO performs testing and validation activities
 - Changes impacting CRF content / SDTM
 - CRO aligns with Sponsor on required changes
 - Sponsor makes updates to the database
 - CRO performs testing and validation activities

External data

- Utilize CMDR for provision of standard data mapping table (each data type) to CRO
- CRO create first external data transfer specification
- Test data transfer from vendor (before FPFV)
- Review and approval
- Production data transfers (within 6 weeks after FPFV)



SDTM and ADaM

- Daily raw transfers provided from EDC
- Annotated SDTM CRF generated from CMDR
- SDTM adjustments from standards
- Daily automated SDTM (6 weeks after 5th study participant rand / dosed)
- Daily automated ADaM ADDVINT

Lessons Learned

- New process for both the sponsor and CRO
- Weekly study meetings at the CMDR study level to structure work at the execution level
 - **CMDR kick off meeting – focus on getting to know your team as engaged communication is key**
 - **Advertise regular CMDR calls and encourage teams to raise questions and share feedback**
- Lessons Learned meeting held in March 2023
- Process walk-through refresh in May 2023

Benefits of implementing CDISC data standards



Efficiencies

Quality

Consistency

Governance