WITH STANDARDS – UNLOCK THE POWER OF DATA

cdisc

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Clinical Data Standards, Governance Process: How Far We've Come and Where We're Going

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Sharon Hartpence, Associate Director, Clinical Data Standards, Bristol-Myers Squibb

Meet the Speakers

Donna Sattler

Title: Associate Director, Clinical Data Standards

Organization: Bristol-Myers Squibb

I've worked in various Data Management and Programming roles for over 25 years. I made a career change 20 years ago which brought me into the world of clinical research and data standards. I am deeply motivated by helping to influence, educate, and communicate Data Standards, through process improvements and best practices across the enterprise.

Sharon Hartpence

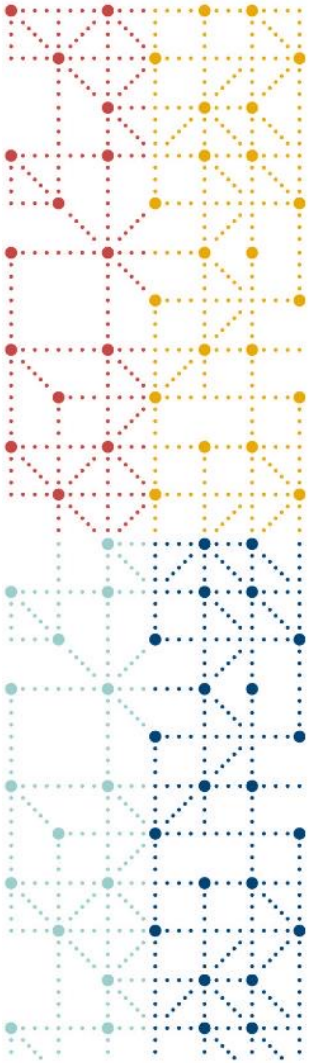
Title: Associate Director, Clinical Data Standards

Organization: Bristol-Myers Squibb

As an RN, BSN, MBA who has worked in Pharmaceutical Research and Development for over 25 .As an eDC data collection specialist; I've developed clinical trial processes to streamline efficiencies for end-users. I continue to increase my knowledge of CDISC implementation best practices by engaging in opportunities with CDISC collaboration initiatives

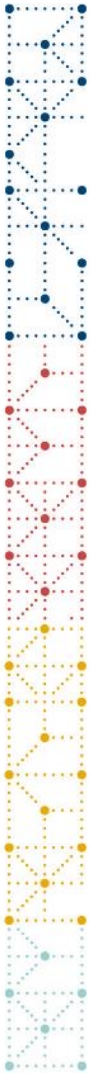
Disclaimer and Disclosures

- *The views and opinions expressed in this presentation are those of the author(s) and do not necessarily reflect the official policy or position of CDISC.*
- *Additionally, the presenters are expressing their opinions on how the industry has utilized data standards over the years and not representing the processes of BMS but rather best practices for all end users of data standards.*



Agenda

1. Data Standards, History…
2. Standards Governance and Guardrails
3. What's next…
4. Best Practices & Key Takeaways



"How are you going to analyze this new data?"

Which Domain?

"What does your Protocol Say"

SDTM

CDASH

"..my team has a Change Request"

"Did you review the TAUG"

"...my request is for a high priority study"

"Is your Study Team in agreement"

Subject Matter Experts

"Didn't we already discuss this?"

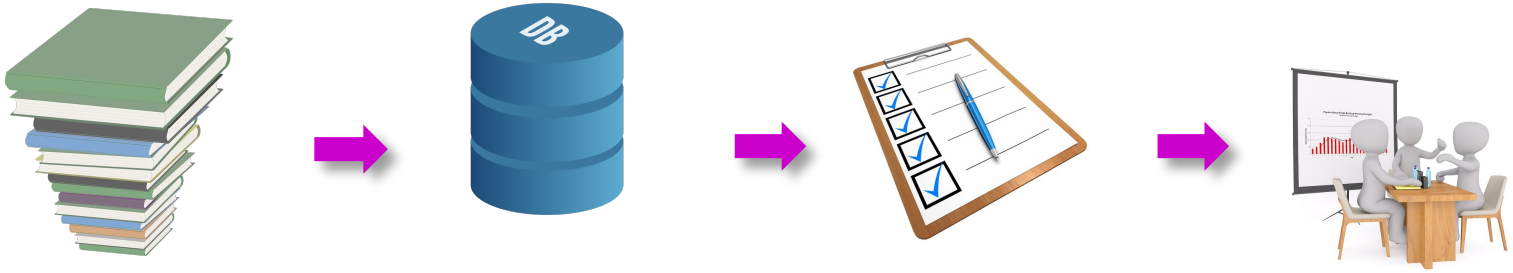
"Did they include the Specifications?"

"What does the SAP say?"

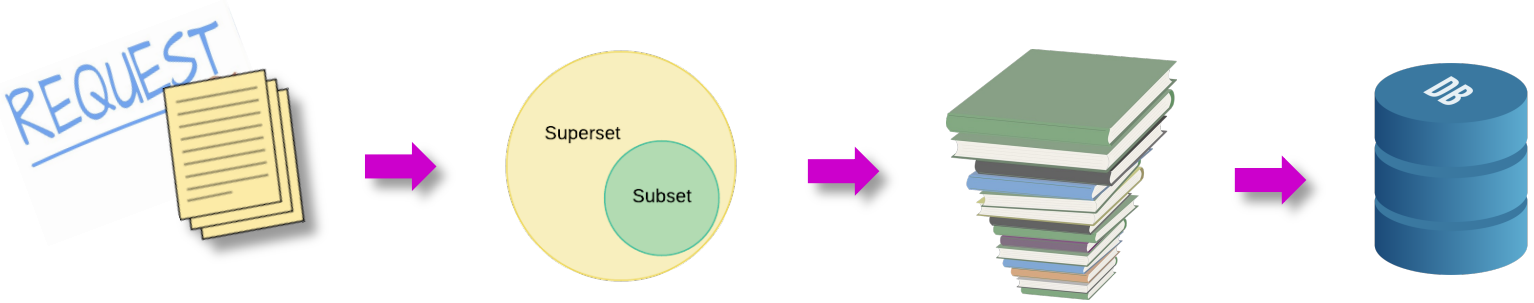
Impact analysis

Decisions, Decisions, Decisions

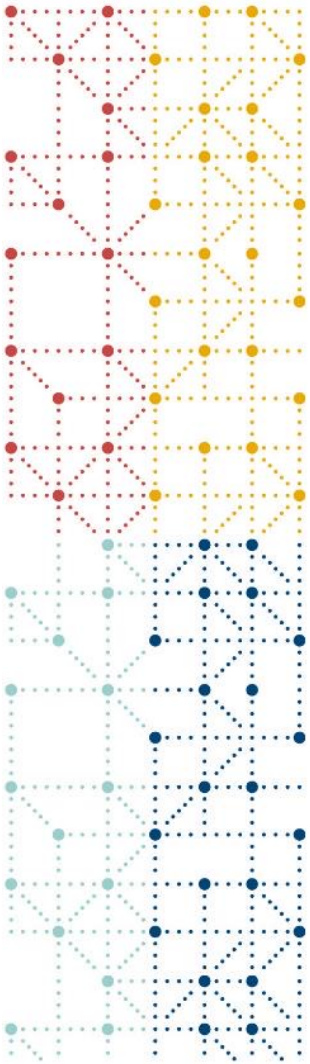
How will this impact ADaM?



Initiate DB Build with established standard libraries.



If collection is not appropriate for your study, you can request a change through a change request governance process



Remember When….

… Data Standards consisted of whatever study you last worked on …in any disease area and use that as your starting point…

- ✓ You were given a table mock-up with raw data annotations
- ✓ When there was a mismatch from QC you relied on quick fixes in the SAS code like: if then do; logic for updating any value in the final dataset to pass compliance. Each study had its own unique mapping spec which was always updated to match the code to the final output. But that was it…
- ✓ Standards SDTM Mapping specs were not the norm; we borrowed mapping templates from previous studies….by running a comparison between study metadata to then obtain a % close match.

Make this table…..

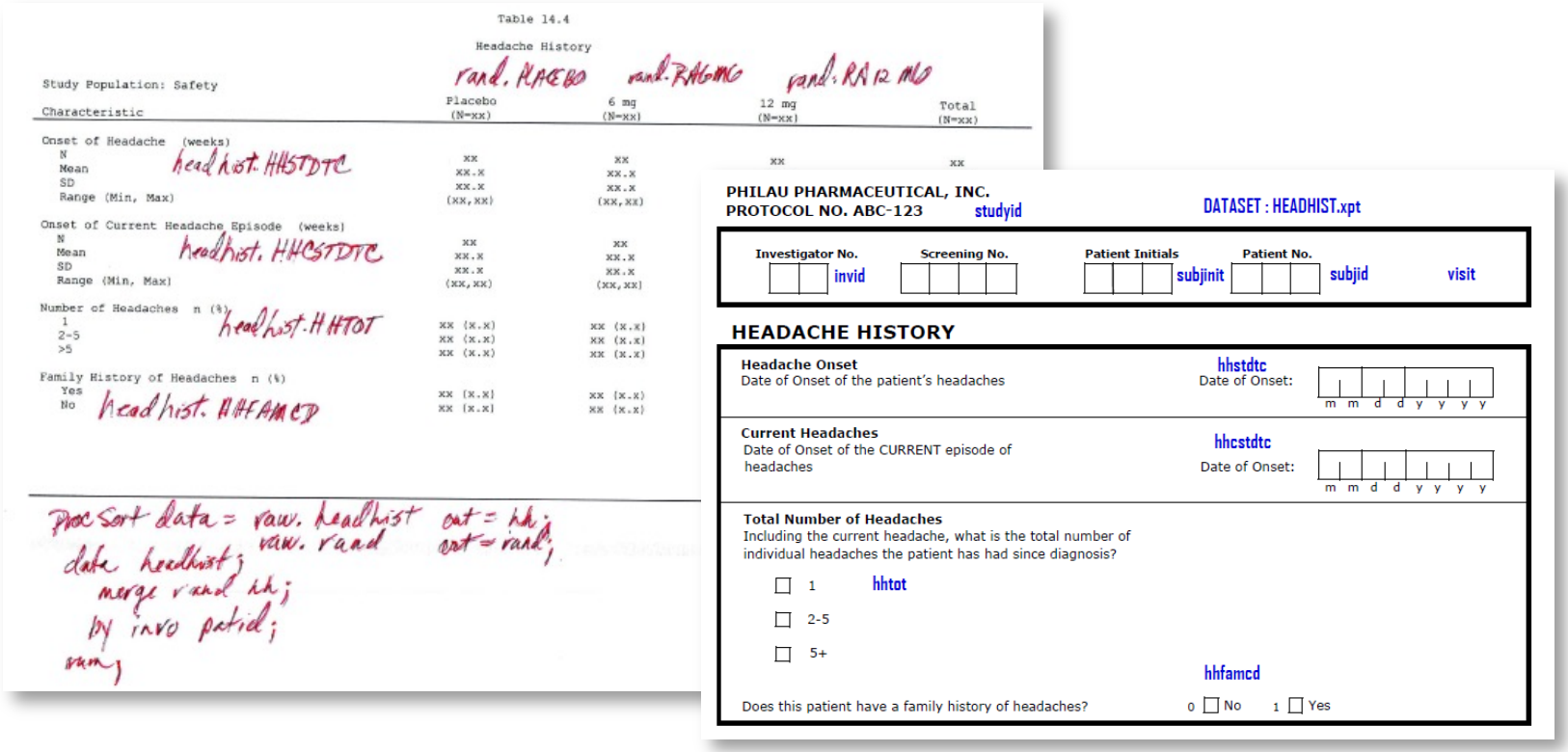


Table 14.4

Headache History

rand. PLACEBO rand. RA6MG rand. RA 12 MG

Study Population: Safety

Characteristic	Placebo (N=xx)	6 mg (N=xx)	12 mg (N=xx)	Total (N=xx)
Onset of Headache (weeks)				
N	xx	xx	xx	xx
Mean	xx.x	xx.x		
SD	xx.x	xx.x		
Range (Min, Max)	(xx,xx)	(xx,xx)		
Onset of Current Headache Episode (weeks)				
N	xx	xx		
Mean	xx.x	xx.x		
SD	xx.x	xx.x		
Range (Min, Max)	(xx,xx)	(xx,xx)		
Number of Headaches n (%)				
1	xx (x.x)	xx (x.x)		
2-5	xx (x.x)	xx (x.x)		
>5	xx (x.x)	xx (x.x)		
Family History of Headaches n (%)				
Yes	xx (x.x)	xx (x.x)		
No	xx (x.x)	xx (x.x)		

headhist.HHSTDTC

headhist.HHCSTDTC

headhist.HHTOT

headhist.HHFAMCD

proc sort data = raw.headhist out = hh;
raw.rand out = rand;
data headhist;
merge rand hh;
by invo patid;
run;

PHILAU PHARMACEUTICAL, INC.
PROTOCOL NO. ABC-123 studyid

DATASET : HEADHIST.xpt

Investigator No. invid | Screening No. | Patient Initials subjinit | Patient No. subjid | visit

HEADACHE HISTORY

Headache Onset
Date of Onset of the patient's headaches

hhstdtc
Date of Onset: m m d d y y y y

Current Headaches
Date of Onset of the CURRENT episode of headaches

hhcstdtc
Date of Onset: m m d d y y y y

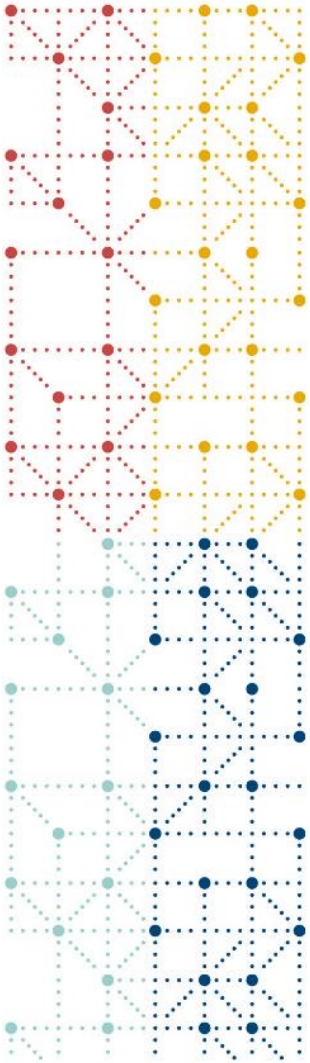
Total Number of Headaches
Including the current headache, what is the total number of individual headaches the patient has had since diagnosis?

☐ 1 hhtot
☐ 2-5
☐ 5+

hhfamcd
Does this patient have a family history of headaches? 0 ☐ No 1 ☐ Yes

…You first heard of CDISC?

- ✓ 20 years ago there was no understanding of the sustainability of CDISC standards, there was still a lot of hesitancy to put the long-term investment into standardizing
- ✓ Tables and listings were **company standards** based on raw data metadata. SDTM was still a concept.
- ✓ USUBJID was the first standards variable I ever created.
- ✓ No SDTM mapping specs, no SDTM Annotated CRFs



Governance Guardrails…

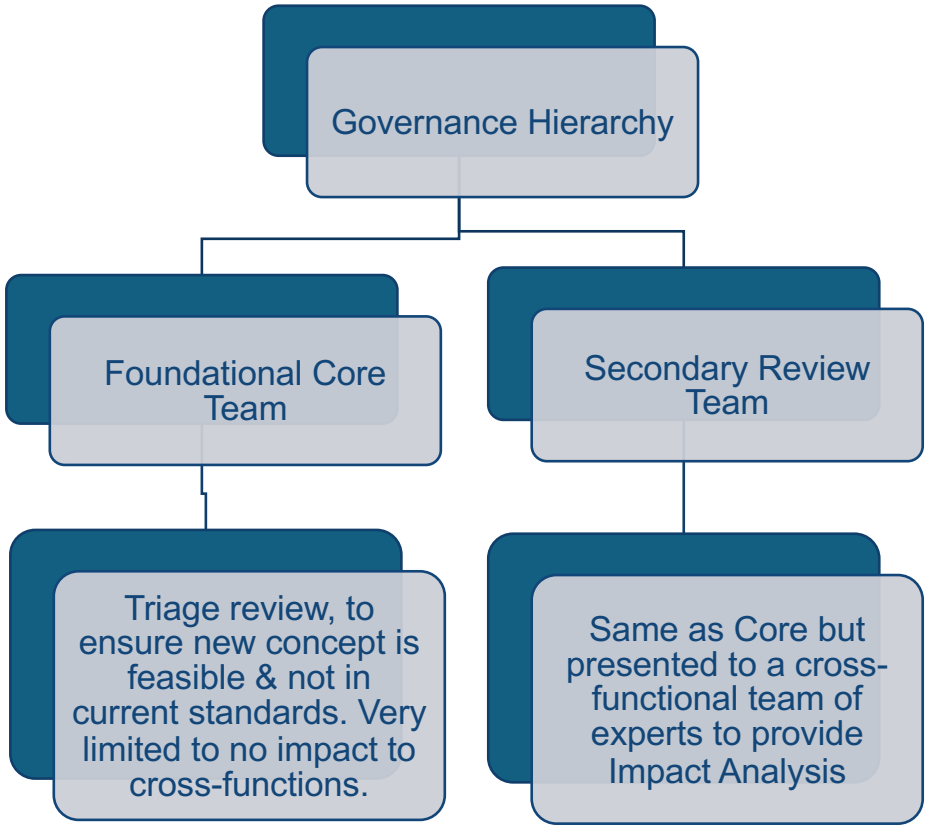
Governance Guardrails…

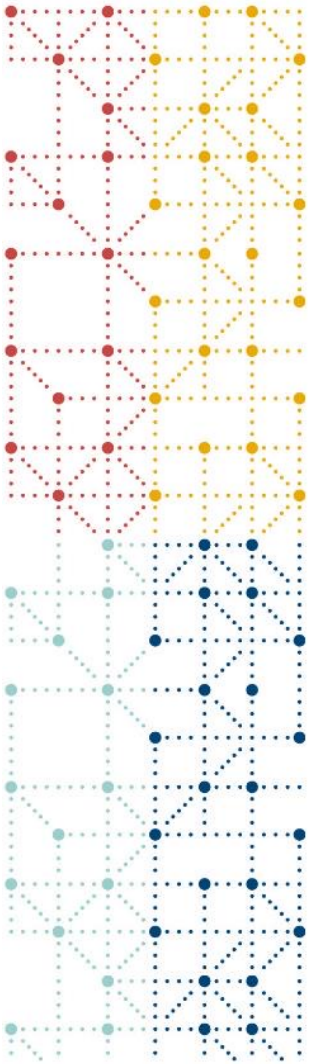
- Many different functions are a part of the content creation in addition to when changes can and should be made. No one function “owns” the standards. The same holds true for Governance. It is a collaborative effort to maintain standards and limit the changes to existing forms once they are considered universal or global.
- Many groups have a stake in the reusability of the standards; therefore, they too get to impart their function’s needs for what should not change or what must change to align to business needs.

Governance Team Charter Example

The primary responsibility of the Clinical Data Standards Governance Organization is to implement effective governance in the development and maintenance of clinical data standards.

This governance organization will enable standards implementation, ensure the necessary resources to implement clinical data standards, and create processes that support and facilitate the use of consistent evolving global clinical data standards.





Change Request Example

STANDARDS CHANGE REQUEST SCENARIO

The Clinical Team identified a need for **modification of an existing eCRF** (indication-specific change)

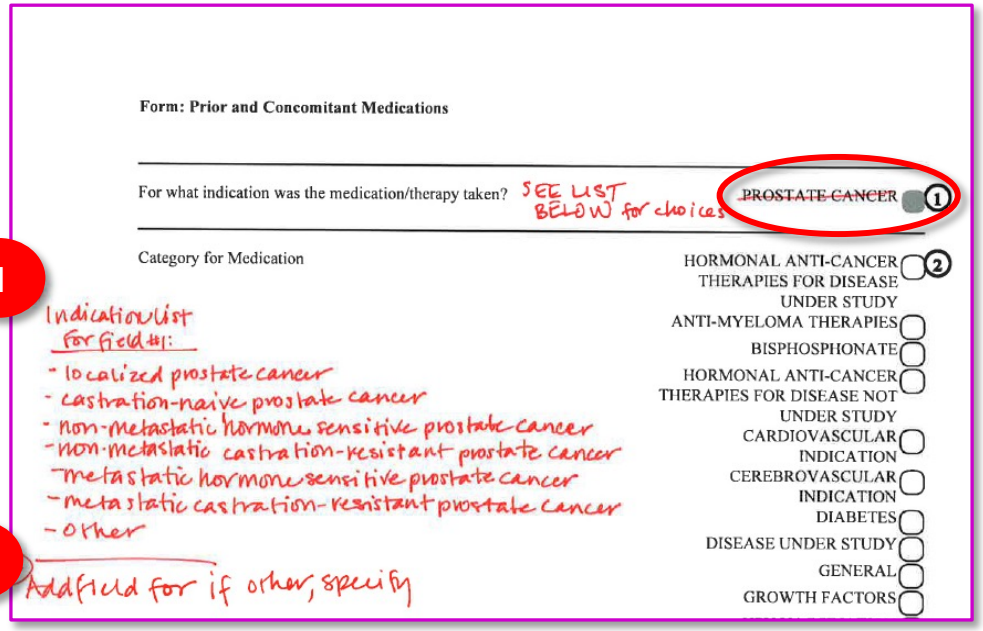
Request:

Add new options to the CMINDC code list (#1) plus Other, Specify field. (#2)

APPROVED

Rationale:

The team would like to know the specific type of Prostate Cancer each systemic therapy was used for. Currently the CMINDC dictionary only includes **Prostate Cancer**. The team would like to add additional types of prostate cancer as well as an **Other** option and a question to specify the other type of prostate cancer.



STANDARDS CHANGE REQUEST SCENARIO

The Clinical Team identified a need for **modification of an existing eCRF** (indication-specific change)

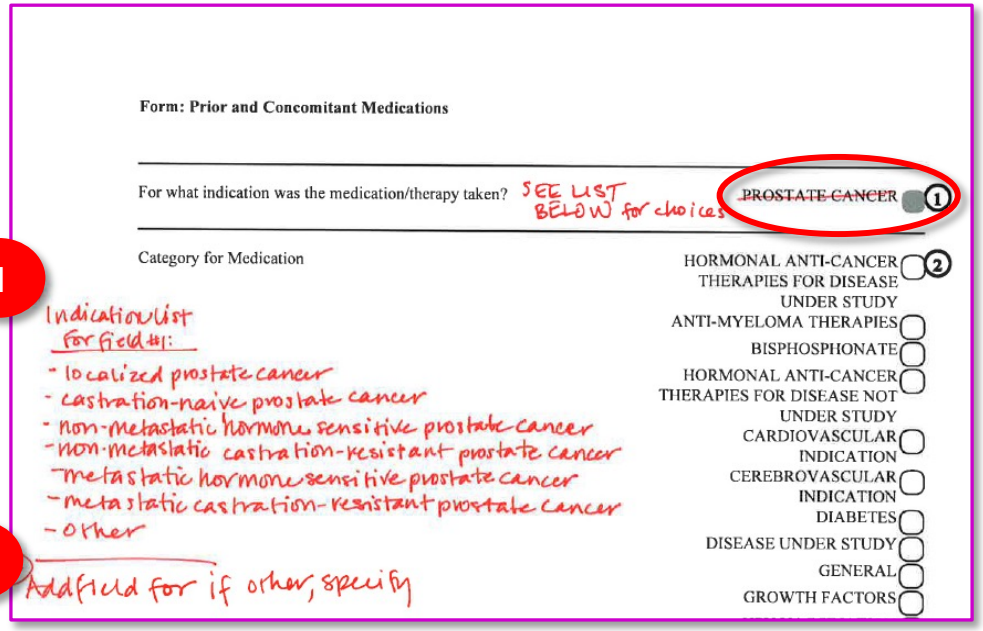
Request:

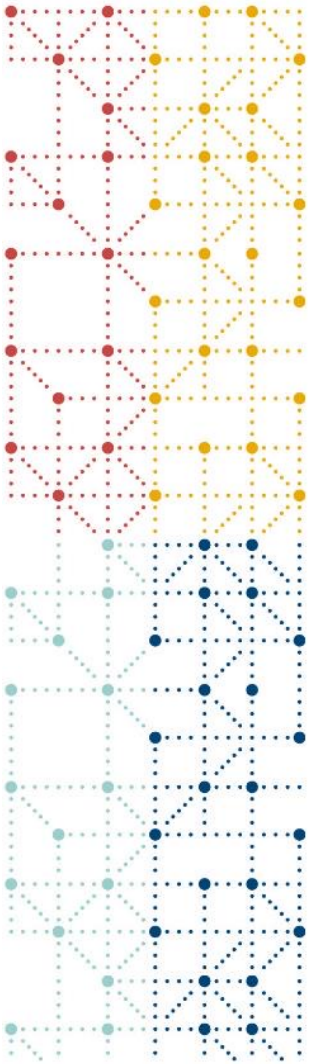
Add new options to the CMINDC code list (#1) plus Other, Specify field. (#2)

Rationale:

REJECTED

The team would like to know the specific type of Prostate Cancer each systemic therapy was used for. Currently the CMINDC dictionary only includes **Prostate Cancer**. The team would like to add additional types of prostate cancer as well as an **Other** option and a question to specify the other type of prostate cancer.

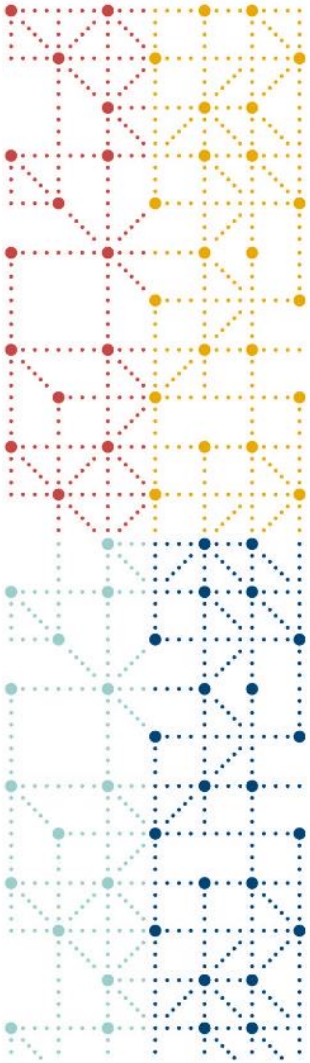




What's Next…

New ways of managing collection and reporting Standards….

New Ways	Pros	Cons
MDRs	Traceability, the promise of being one source of truth for all company Standardization, ie: when one concept/object changes, it's relationships are also updated.	Unexpected glitches Requires a lot of training and process workarounds for accommodating tool
External Data Collection Processes	Standardization SMEs are necessary to manage vendor expectations while keeping true to internal BMS standards. (i.e tablet, CGM, watch, etc)	Requires additional resources to manage external data requirements
eCOA/ePRO Processes	One data specification for all eCOA/ePRO data collection	Requires additional resources to manage external data requirements
Decentralized Study Data Considerations	Faster start-up, cleaner data, fewer resources	Requires systems to talk with one another

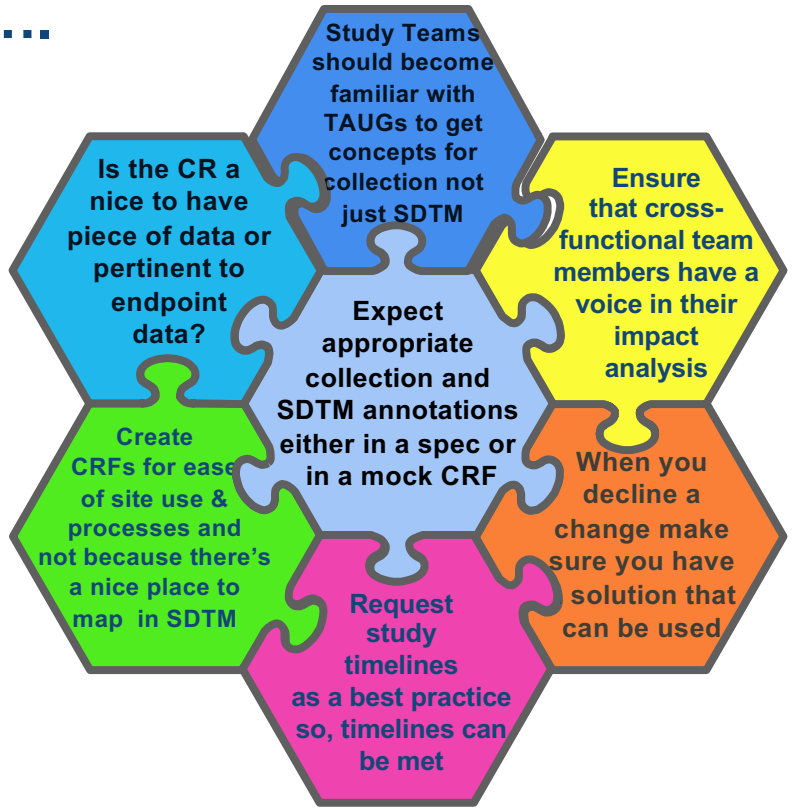


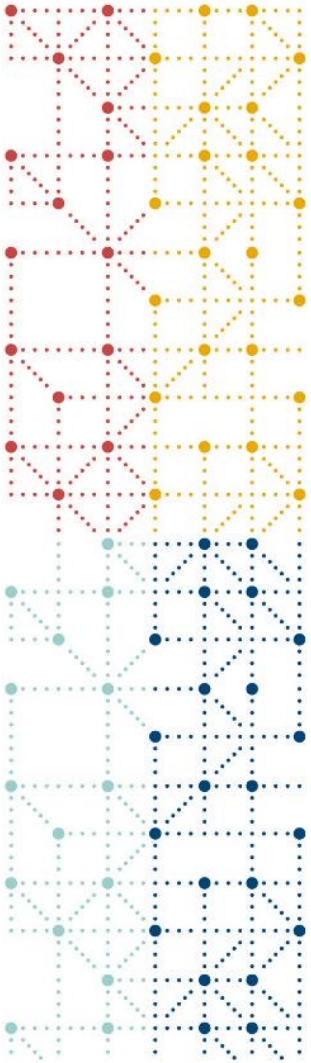
Consider these Best Practices & Key Takeaways….

Best Practices….

- Ensure Alignment for E2E Impact Assessment by training all users on the standards metadata
- Create Change Request Checklists and use a Change Request Template when changes need to be requested
- Do not assume what is being asked for is already in the protocol or that the requester is fully aware of all the possibilities in existing standards
- Front-load discussions and impact analysis prior to implementing a new change request.

Takeaways….


Study Teams should become familiar with TAUGs to get concepts for collection not just SDTM
Is the CR a nice to have piece of data or pertinent to endpoint data?
Ensure that cross-functional team members have a voice in their impact analysis
Expect appropriate collection and SDTM annotations either in a spec or in a mock CRF
Create CRFs for ease of site use & processes and not because there's a nice place to map in SDTM
When you decline a change make sure you have solution that can be used
Request study timelines as a best practice so, timelines can be met



Thank You!

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