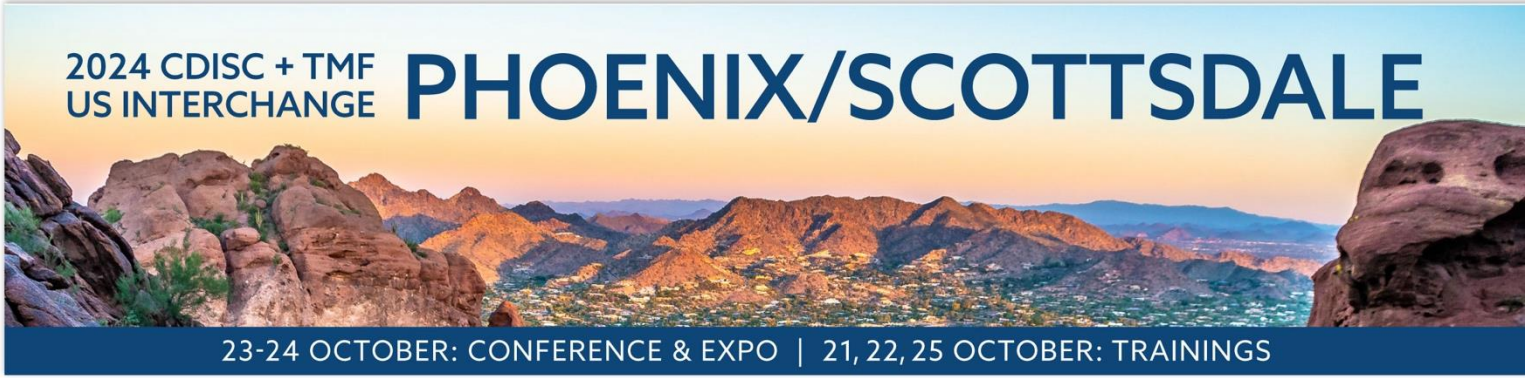


Conventional wisdom for conventional units

Presented by Lauren Shinaberry, Clinical Data & Reporting Standards, AbbVie

Meet the Speaker

Lauren Shinaberry

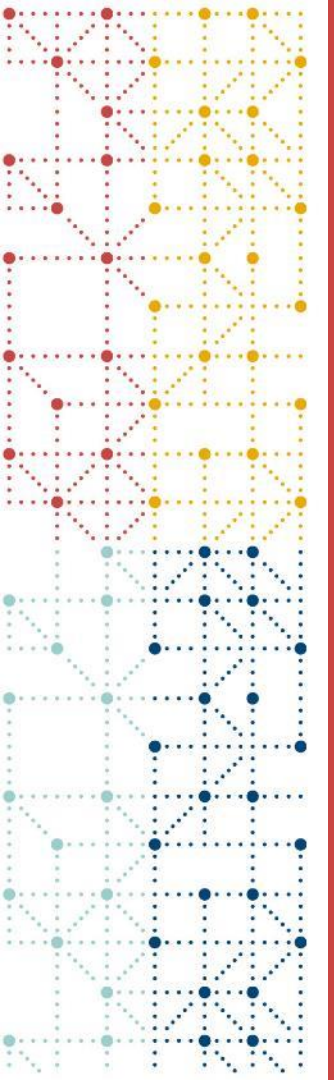
Title: Director, Clinical Data & Reporting Standards

Organization: AbbVie

Lauren's clinical research career spans nearly 3 decades and, in addition to standards, has included data management, database programming and statistical programming. She has worked at CROs as well as pharma, in both the US and Europe. She has been a volunteer for CDISC since 2004, led the CDASH team and has been a CDASH and SDTM trainer for CDISC during that time. Her current career focus is continuing to build a world class standards organization within AbbVie and driving innovation through metadata-based automation of the clinical research data flow.

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.*
- *The author(s) have no real or apparent conflicts of interest to report.*
- *The support of this presentation was provided by AbbVie. AbbVie participated in the review and approval of the content.*
- *Lauren Shinaberry is an employee of AbbVie.*



Agenda

1. Why this topic?
2. A little history
3. No perfect answer, but we chose the least bad for us
4. What have we learned?

Why this topic?

- Until last year…
  - FDA had not included specific way that they wanted to receive lab results in US conventional units when this was not what was used in the LB domain for analysis.
  - Sponsors could primarily weigh the pros and cons within their own data ecosystems.

- June 2023…
  - FDA sdTCG v5.4 introduces the specific way FDA would like to receive laboratory results in US conventional units as a custom findings domain named LC

June 2023	5.4	Section 4.1.1.3 (SDTM Domain Specification) – Updated language under LB Domain (Laboratory)

  - Sponsors now have an additional consideration outside their own data ecosystems

A little history

FDA has beer
communicating v
to receive lab res
in US conventio
units

AbbVie considered the options for how to meet these varying regulatory needs

Our starting point

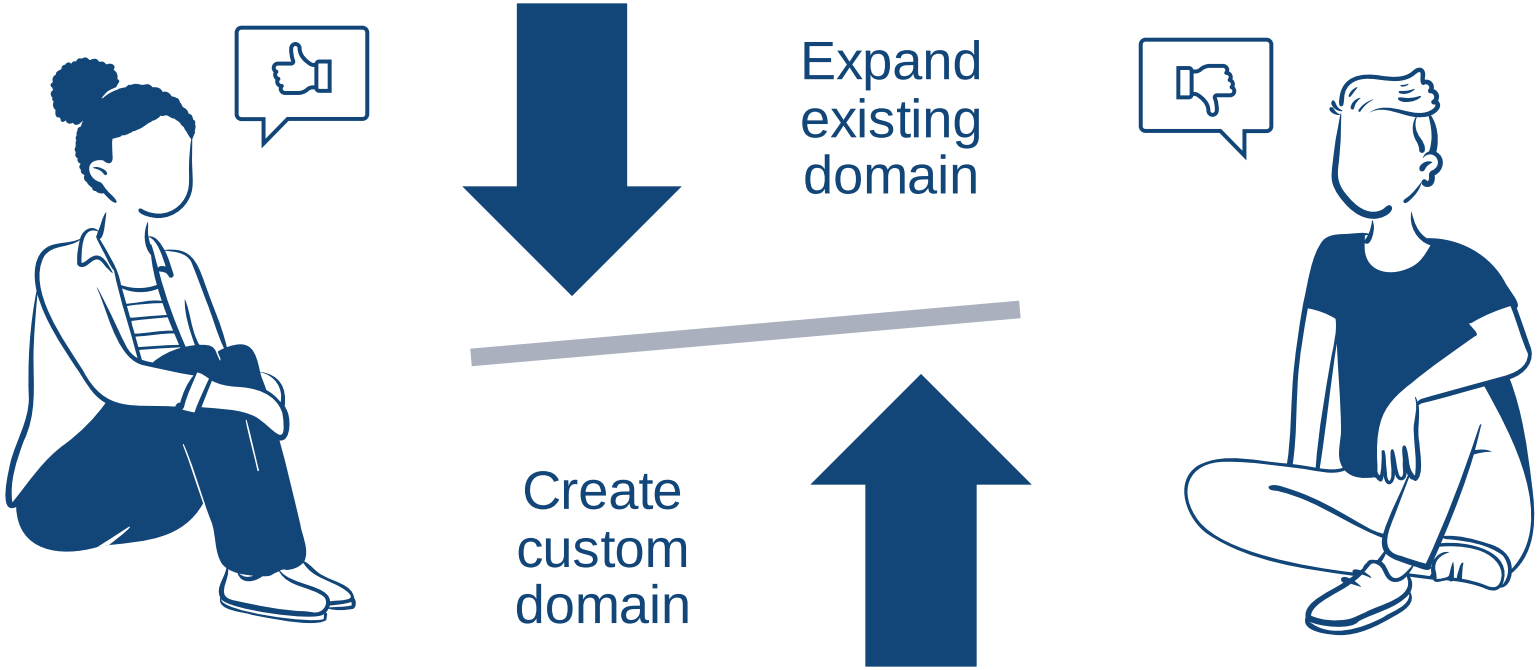
AbbVie uses SI units for summaries and analyses

We had a historic set of conversion factors for both SI and US conventional units

AbbVie creates SDTM mappings at the time of study start-up and automates the generation of both SDTM and ADaM throughout the conduct of the trial

Global submissions are common

No perfect answer



Keep it all in LB domain

Option 1: LBORRES/U for US results and continue SI results into LBSTRESN/C/U

Loses traceability with the results reported by the site

What to do if a result wasn't available in US conventional units? Can't leave LBORRES missing but have LBSTRESC populated

How to extend this if other agencies require different units?

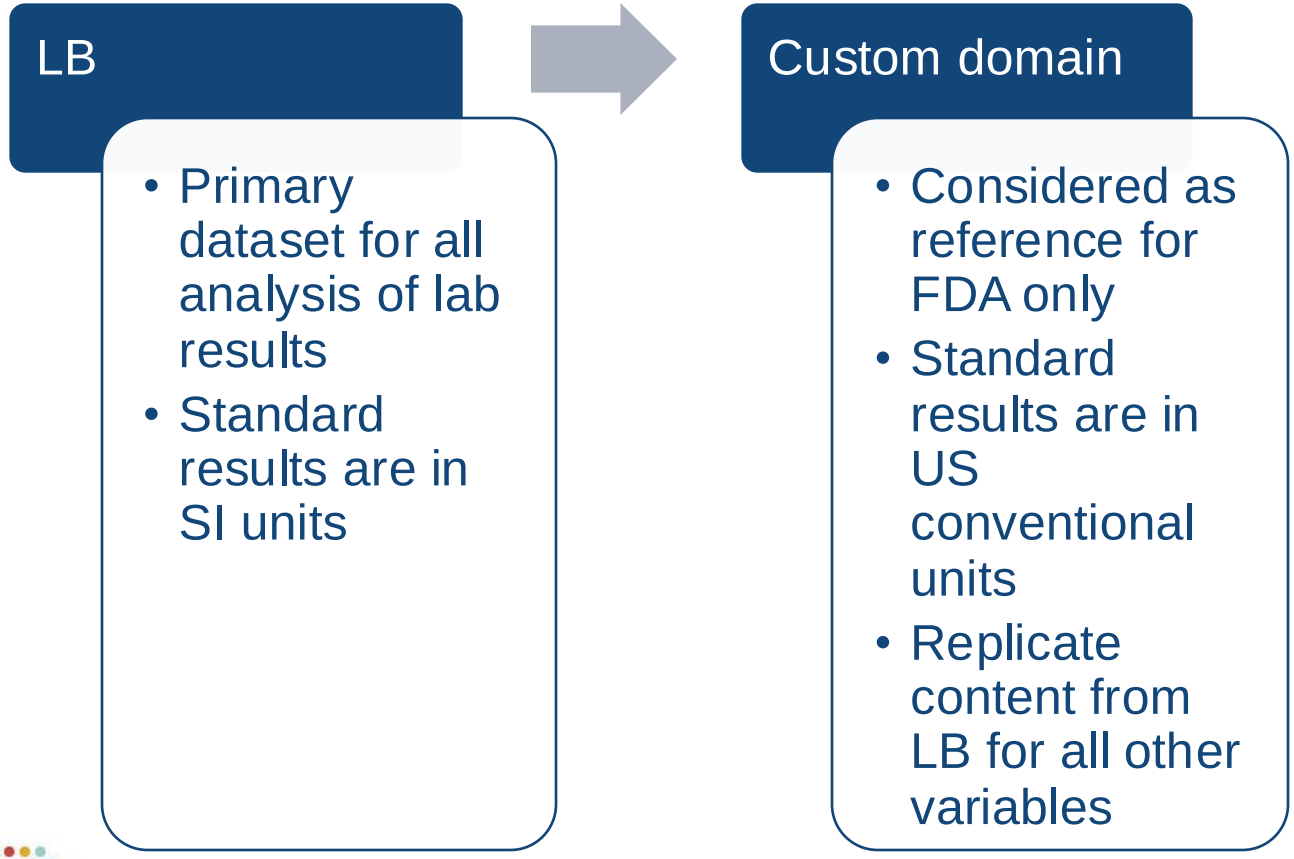
Option 2: Add US conventional results and units to SUPPLB

Concern that data in SUPP will not be easily accessible to regulatory reviewers who may rely on their default viewing tools

Violated the SDTM conformance of having qualifiers with their own qualifiers like units in SUPP

Raised the question of how many other qualifiers would need to be added in US conventional units, seemed to have the potential to quickly grow unmanageable in SUPP

Option 3: Create custom domain



The least bad option – custom domain(s)

- Scalable via different custom domains for any agency-specific request for units other than what we used for our analysis
- Any agency-specific results in alternative units would be provided in a custom domain for their reference.
- Metadata burden was assessed to be comparable to other options

Domain	US Conv	PMDA units
LB	**XL**	**XB**
VS	XV	**XS**
EG	XE	XG
Etc.	…	…

- *Replicating supplemental qualifiers is not mandatory*
- *Replicating RELREC for the custom domains is not mandatory*

Theoretical global submission example

Theoretical because PMDA has not required LB or VS in different units

Global Study	FDA submission	PMDA submission
• DM	• DM	• DM
• DS	• DS	• DS
• EX	• EX	• EX
• AE	• AE	• AE
• VS – Vital Signs in AbbVie standard units	• VS – Vital Signs in AbbVie standard units	• VS – Vital Signs in AbbVie standard units
• LB, SUPPLB – Labs in AbbVie standard units	• LB, SUPPLB – Labs in AbbVie standard units	• LB, SUPPLB – Labs in AbbVie standard units
• XL – Labs in US units	• XL – Labs in US units	
• XS – Vital Signs in PMDA units		• XS – Vital Signs in PMDA units

What have we learned over the past 8 years?

- Most studies are replicating SUPPLB as SUPPXL but not replicating relationships in RELREC
- We have not yet needed to create a PMDA-specific vital signs domain or lab domain
- We have not had any questions from submissions following this approach
- The switch to conform to the FDA's sdTCG update is a simple rename of a domain, which we already have a macro to do
- Change can be hard, no single way is perfect, custom domain approach has been working for us so far

Thank You!