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CDISC BASIC Implementation Guide

Diane Wold, CDISC
Gary Walker, CDISC

Meet the Speakers

Diane Wold

Title: Sr Director, Standards Development

Organization: CDISC

Diane Wold received her Ph.D. in Statistics from the University of North Carolina at Chapel Hill. She worked for Burroughs Wellcome/Glaxo Wellcome/Glaxo Smith Kline in a variety of roles for over 30 years. In 2002 she joined the CDISC SDS team. She was involved in other CDISC teams, including the CFAST initiative to develop therapeutic area standards. In 2015 she joined CDISC as an employee. She is currently upcoming versions of the SDTM and SDTMIG, and the CDISC Knowledge Base.

Insert Name

Title: CDISC Consultant and Trainer

Organization: Gary G Walker, LLC

Gary Walker has worked in the pharmaceutical industry since 1992, for Marion Merrell Dow, Hoechst Marion Roussel, Aventis, and Quintiles/IQVIA. He has worked in IT, Regulatory Publishing, Data Standards (Data Management, Global Standards, Innovations, and Biostatistics), before his own company. He began participating on the CDISC SDS team in 2001 and the CDASH team in 2006. He has participated in the development of a number of CDISC TAUGs and is a CDISC trainer of the SDTM and CDASH standards.
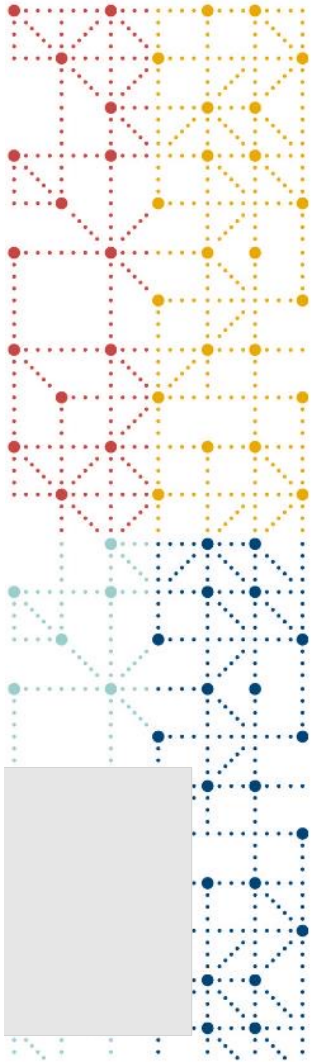
Agenda

1. How Does CDISC BASIC Relate to Real World Data?
2. Initial Scope
3. Approach
4. What Might CDISC BASIC Look Like?
5. Next Steps
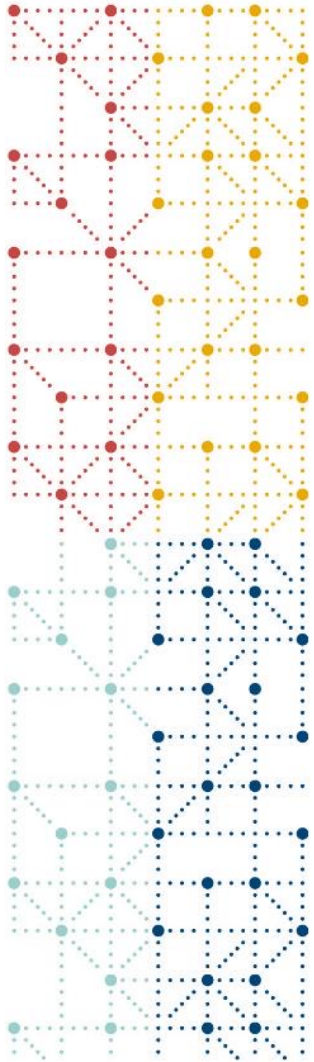
How Does CDISC BASIC Relate to RWD?

Lowering the Barrier to Using CDISC Standards

Increased Interest in Sharing Study Data

Results published in Clinicaltrials.gov

Multiple data sharing platforms, e.g.,

- Project Data Sphere https://www.projectdatasphere.org/
- Vivli https://vivli.org/

US Federal initiatives

- NIH Data Sharing policy https://sharing.nih.gov/data-management-and-sharing-policy/about-data-management-and-sharing-policy/data-management-and-sharing-policy-overview
- NIH Data Sharing Plan https://vivli.org/wp-content/uploads/2020/08/NIH-Data-Sharing-Plan.pdf
- White House Office of Science and Technology Policy https://www.whitehouse.gov/ostp/news-updates/2022/08/25/ostp-issues-guidance-to-make-federally-funded-research-freely-available-without-delay/

Journal requirements for making data available

- BMJ, JAMA, PLOS, WILEY, SCIENCE, SPRINGERNATURE

CDISC Standards for Shared Data

Shared data is hard to use if it is not in standard format

CDISC Standards were developed specifically for clinical research

Barriers to adopting CDISC standards:

- Overwhelming (sheer volume)
- Siloed (separate standards for collection, tabulation, analysis, metadata)
- Original written for those who worked with data in the pharmaceutical industry full time

Aim of CDISC BASIC: Lower Barriers to Using CDISC

Reduce volume by concentrating on most common data

Present collection and tabulation in an integrated manner

Write for an audience new to CDISC and less immersed in data handling
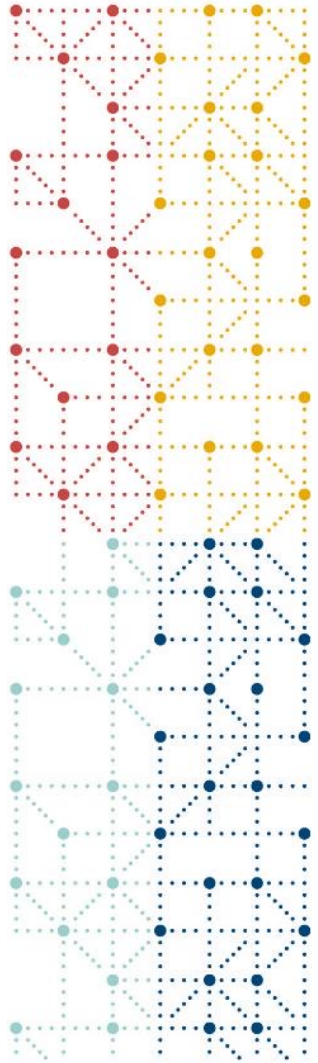
Link to other resources

REDCap and OpenClinica CRFs

CDISC resources such as

• eCRF Portal
• Knowledge Base
• Free educational courses and webinars

Specific CDISC Standards for more detail, when needed

Initial Scope

# Why We're Starting with Human Interventional Trials

- Want to produce a first version relatively quickly, so limited scope.
  - Figuring out how to make new kind of deliverable already a big job.
- Covers the many interventional trials not undertaken for regulatory approval of a product
- Close to use cases for which the standards were originally developed
- Expect to add other use cases in future versions
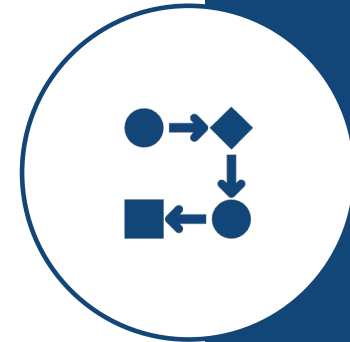
How Data Covered Was Chosen

- CDISC standards for collection (CDASH) and tabulation (SDTM) organize data into "domains."

- The current SDTM Implementation Guide for Human Clinical Trials (SDTMIG v3.4) has 48 domains

- The earliest SDTMIG version covered just 13, but covered most common data

- 16 Domains chosen for CDISC BASIC:
    - Demographics and Subject Characteristics
    - Medical History, Adverse Events, and Clinical Events
    - Exposure (study treatment) and Concomitant Medications
    - Vital Signs, Laboratory Test Results, Questionnaires, and Reproductive System Findings
    - Procedures and Healthcare Encounters
    - Inclusion/Exclusion, Product Accountability, and Disposition

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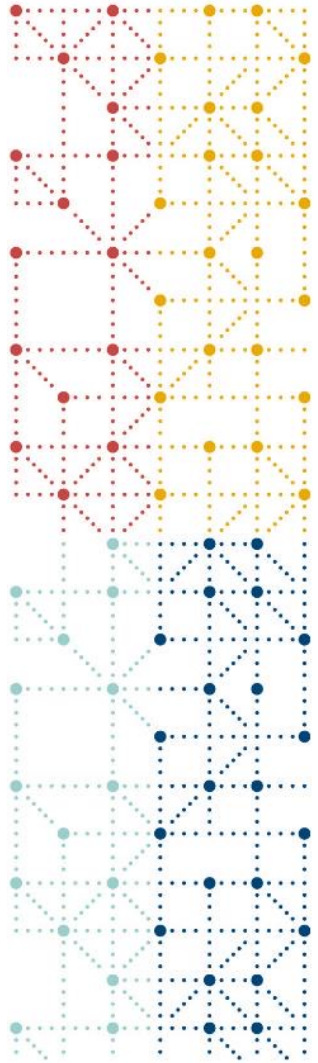
Approach

Approach

Web-based to allow navigation to what the user needs for a study

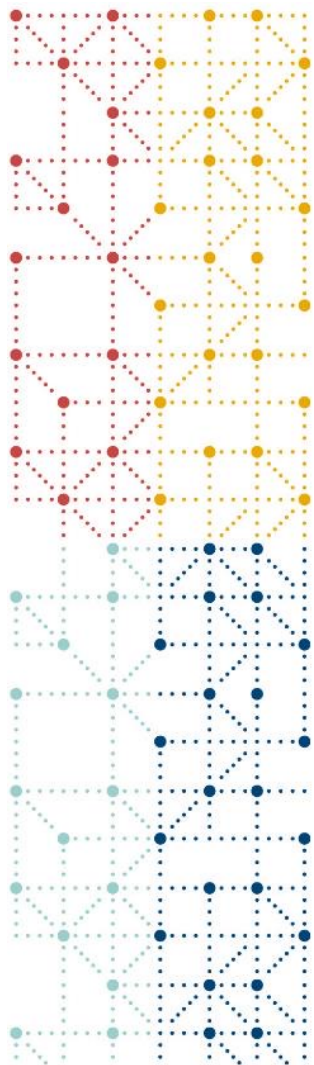Provide advice on which parts of the standards are more or less likely to be needed

Describe commonalities between data domains, to allow users to transfer what they learn about he CDISC BASIC domains to other domains
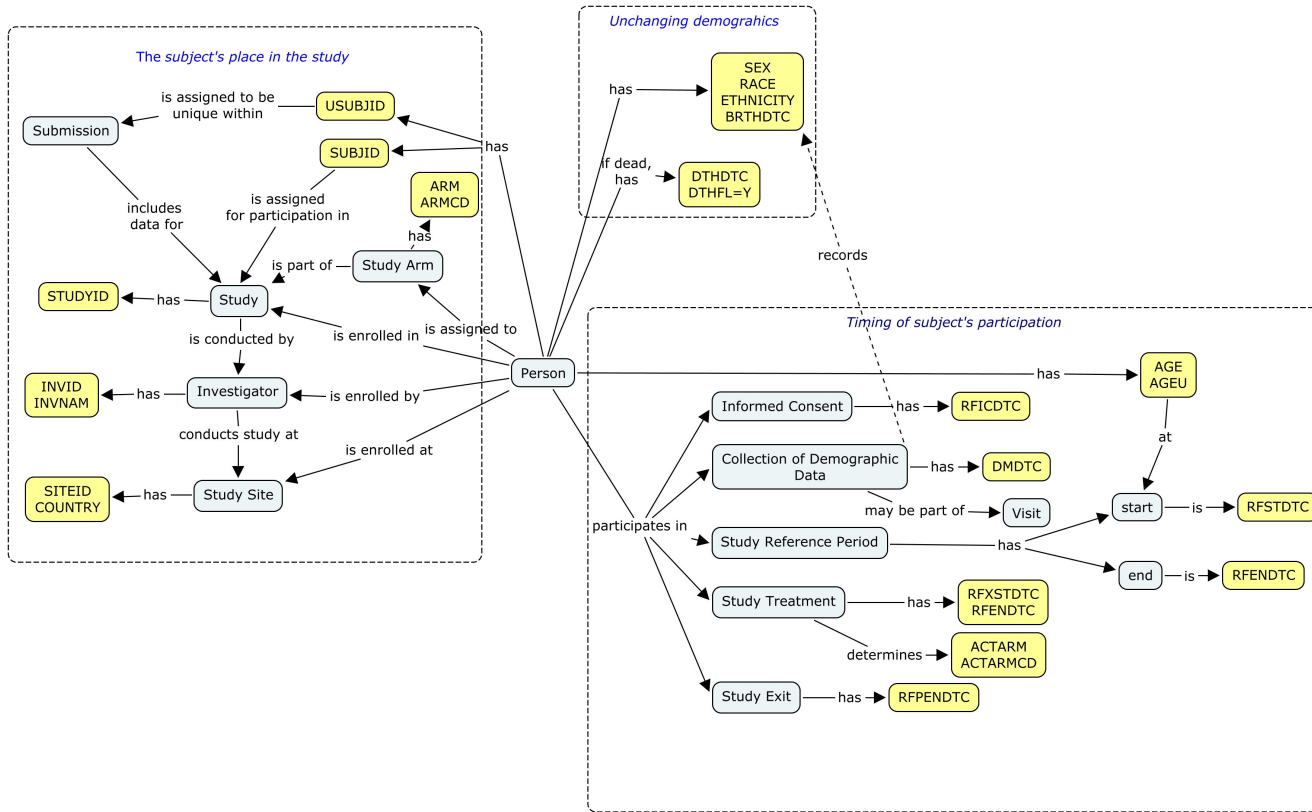
Include explanatory graphics

Leverage existing content (links to other resources and standards)

What Might CDISC BASIC Look Like?

Graphics, such as concept maps
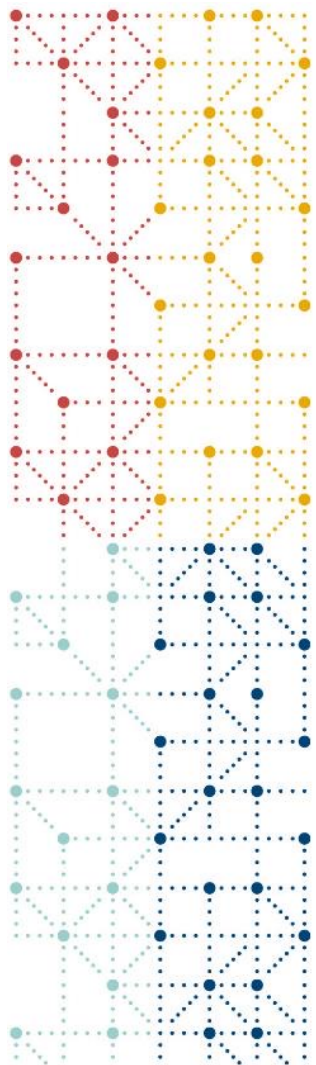
Integrated tables of CDASH and SDTM variables

CDASH Variable Name	SDTM Variable Name	Variable Label	Does a "Basic" study need this variable?
STUDYID	STUDYID	Study Identifier	Yes – a value that will be the same for all observations in the study
	DOMAIN	Domain Abbreviation	Yes – marks this dataset as demographics
SUBJID	SUBJID	Subject Identifier for the Study	Yes – provides traceability to subject identifier used for the study.
	USUBJID	Unique Subject Identifier	Yes – links subjects in the demographics data to subject data in other domains
BRTHDAT		Birth Date	Yes, if possible. Privacy rules may limit the precision of date of birth collection. Collection of age may be an alternative if there is a clear understanding of the time at which AGE is collected.
BIRTHTIM		Birth Time	Unlikely, except perhaps in neonate studies.
	BRTHDTC	Date/Time of Birth	Yes, if possible. Privacy rules may limit the precision of date of birth collection. Collection of age may be an alternative if there is a clear understanding of the time at which AGE is collected.

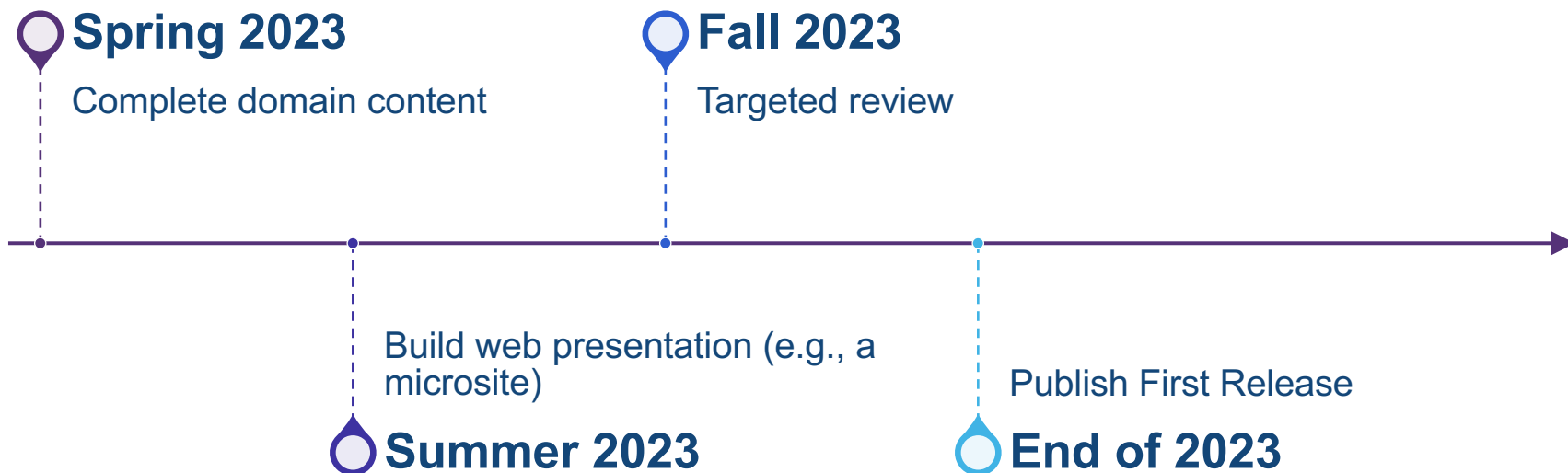# Links to Existing CDISC Standards and Other Resources

- Controlled Terminology

- Questionnaires, Ratings, and Scales (QRS) Supplements

- Free CDISC Education Courses

- Public Webinars

- Knowledge Base Articles
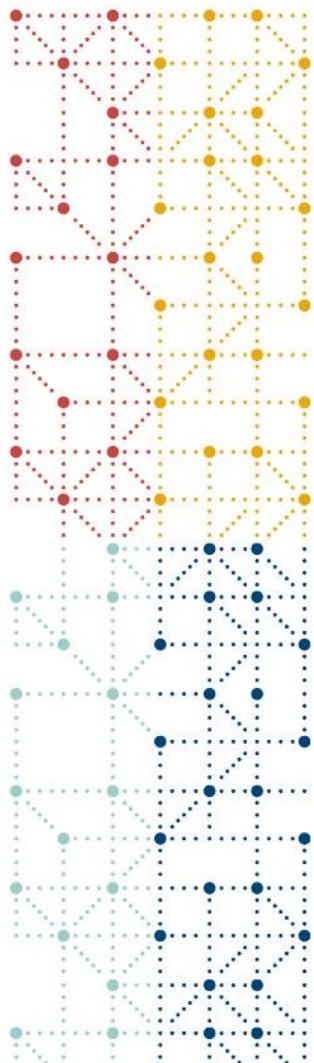
- Examples Library

- eCRF Portal

- CDISC Library

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Next Steps for CDISC Basic

Next Steps for CDISC Basic

Spring 2023

Complete domain content

Fall 2023

Targeted review

Build web presentation (e.g., a microsite)

Summer 2023

Publish First Release

End of 2023

Thank You!

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