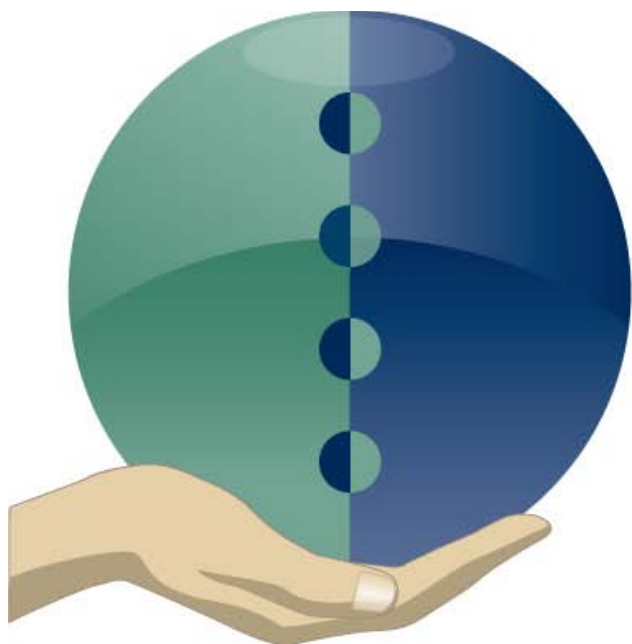




# CDISC SHARE

SHARED HEALTH AND CLINICAL RESEARCH ELECTRONIC LIBRARY

*PhUSE Conference  
31 August 2011  
San Francisco, CA*

*Rhonda Facile (NCI-EVS & CDISC)*

# CDISC SHARE

- Vision
- Background & Metadata Approach
- Project Plan
  - Current Status
  - Next Steps
- Acknowledgements

# CDISC SHARE Vision

A global, accessible electronic library, which through advanced technology, enables precise and standardized data element definitions and richer metadata that can be used in applications and studies to improve biomedical research and its link with healthcare.

*TRANSLATION: SHARE METADATA IS ENVISIONED TO HELP FIND,  
UNDERSTAND AND USE CLINICAL DATA EFFICIENTLY.*



# Today

- CDISC Standards now encompass the entire drug development process.
  - Work remains to be done
    - some elements don't fit in existing standards
    - standards are not aligned/linked
    - standards development too time consuming
    - paper/pdf orientated



# One Example

Slide By: Ellen Pinnow, MS Health Programs Coordinator FDA,  
Office of Women's Health, Slide from 2006 CDISC US Interchange



## Results

### Format of the variables evaluated

#### 5.1.1 Demographics Domain Model — DM

DM.xpt, Demographics — Version 3.1, June 25, 2004. One record

| Variable Name | Variable Label                     | Type | Controlled Terms or Format |
|---------------|------------------------------------|------|----------------------------|
| AGE           | Age in AGEU at Reference Date/Time | Num  |                            |
| AGEU          | Age Units                          | Char | ** YEARS, MONTHS, or DAYS  |
| SEX           | Sex                                | Char | **M, F, U                  |
| RACE          | Race                               | Char | *                          |

- SEX was reported using the SDTM controlled term or format of “M”, “F”, or “U” in 3/6 of the NDA submissions
- 1 used “male” or “female”
- 1 used “1” or “2”
- 1 reported both “male” or “female” AND “1” or “2”

# The Need for Richer Metadata

- enhance data quality and compliance
- decrease the time taken to aggregate and review results
- improve conformance via machine readability
- speed up standards development
- illustrate inherent relationships between metadata



# Current 2D World

| USUBJID     | VSSEQ | VSTESTCD | VSTEST                   | VSPOS   | VSLOC    | VSORRES | VSORRESU |
|-------------|-------|----------|--------------------------|---------|----------|---------|----------|
| ABC-001-001 | 12    | SYSBP    | Systolic Blood Pressure  | SITTING | LEFT ARM | 95      | mmHg     |
| ABC-001-001 | 13    | DIABP    | Diastolic Blood Pressure | SITTING | LEFT ARM | 44      | mmHg     |

Relationship

Relationship

| USUBJID     | VSSEQ | VSTESTCD | VSTEST                   | VSPOS   | VSLOC    | VSORRES | VSORRESU |
|-------------|-------|----------|--------------------------|---------|----------|---------|----------|
| ABC-001-001 | 12    | SYSBP    | Systolic Blood Pressure  | SITTING | LEFT ARM | 95      | mmHg     |
| ABC-001-001 | 13    | DIABP    | Diastolic Blood Pressure | SITTING | LEFT ARM | 44      | mmHg     |

Relationship



# CDISC SHARE Goals

- Provide an environment where:
  - existing content is easily maintained
  - accelerate new clinical research content development
  - encourage and facilitate the widest possible participation in the development of new clinical research content (asynchronous contribution, 24/7)
  - deliver CDISC's content in both human & machine-readable forms
  - enable better automated handling of clinical research data through the use of machine-readable content
  - assist in enabling the use of healthcare data in clinical research

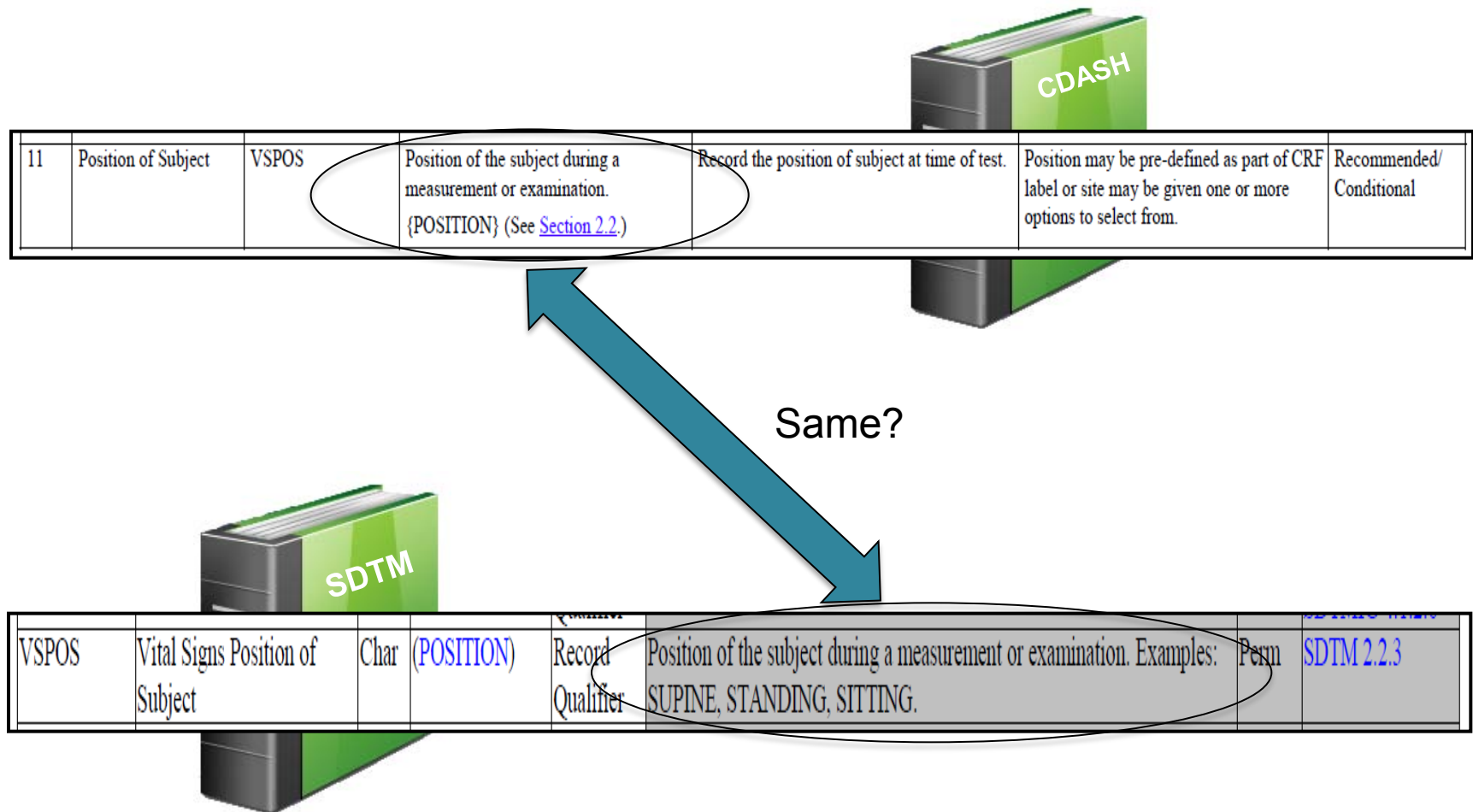


# How do we achieve this?

- Build concepts model based on BRIDG
- Link all CDISC Standards:
  - Controlled terminology
  - SDTM variables
  - CDASH variables
  - 21090 DTs
  - ADaM and SEND
  - TA content
  - Develop rigorous & unambiguous **definitions**  
(semantic interoperability)

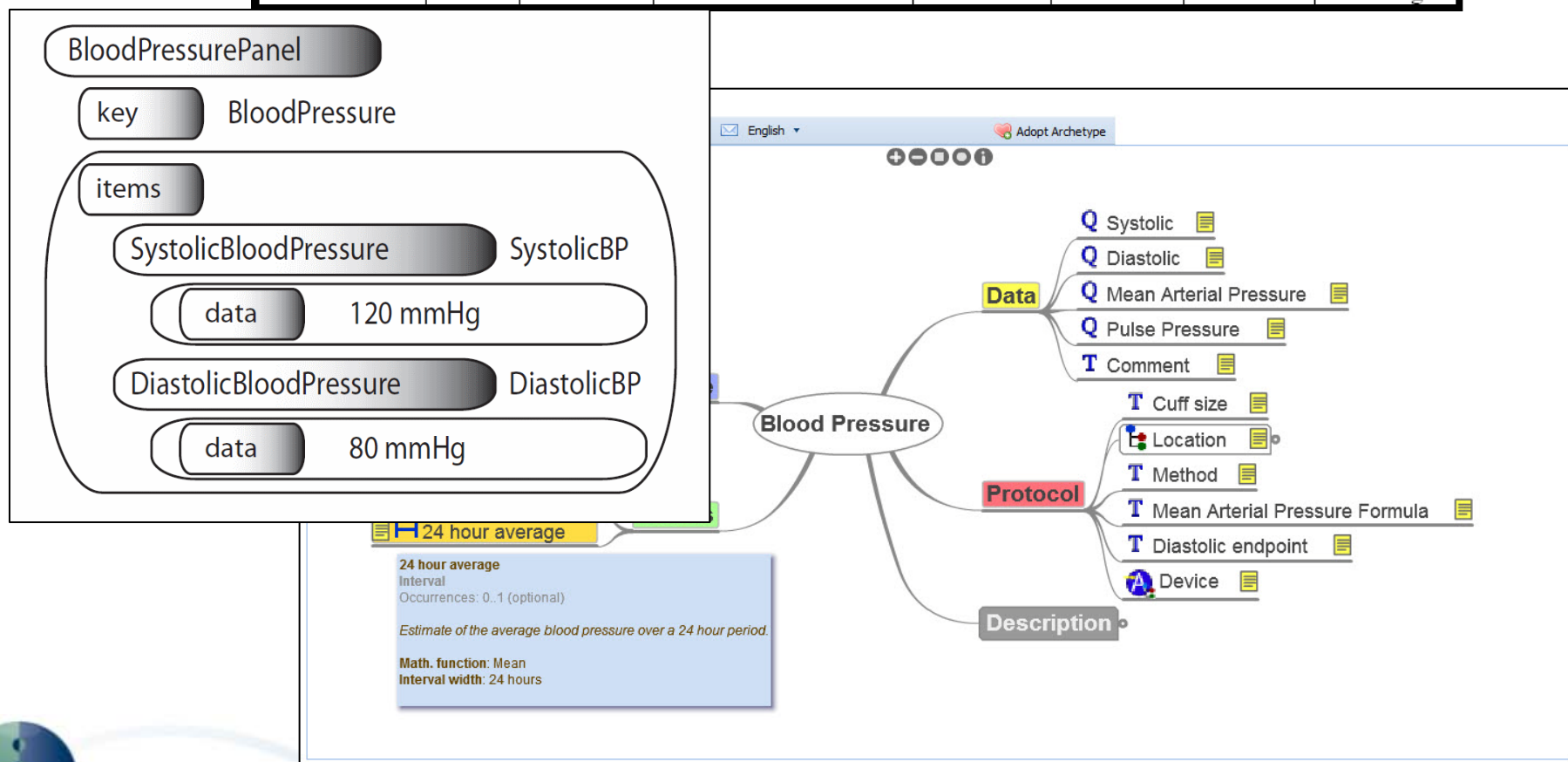


# Semantic Interoperability



# Which Metadata Model?

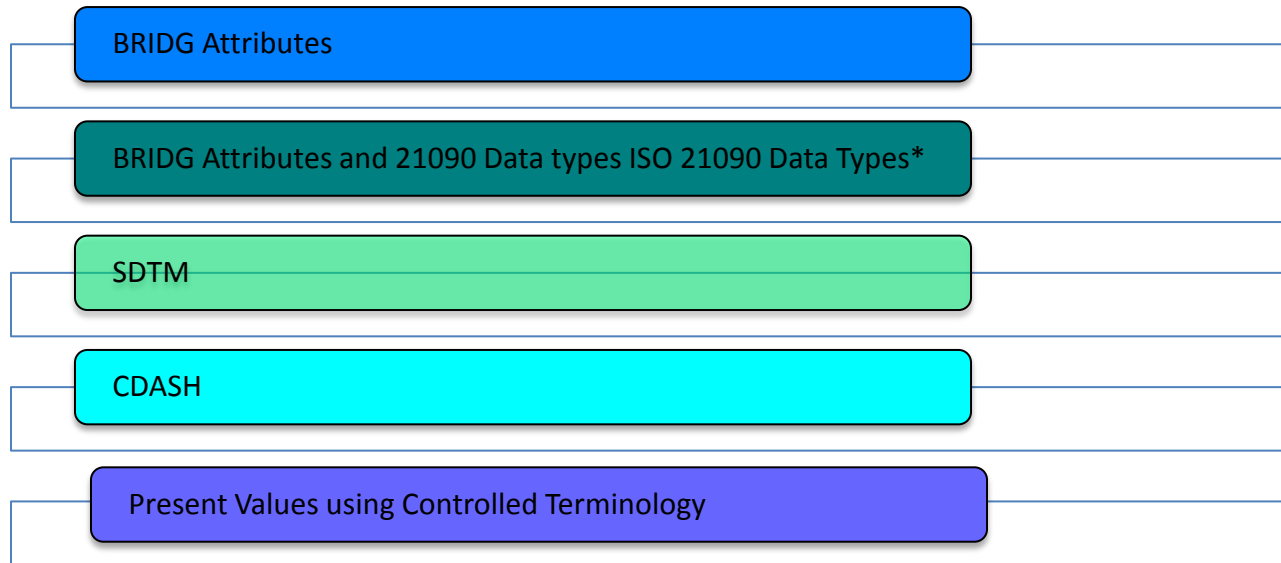
| USUBJID     | VSSEQ | VSTESTCD | VSTEST                   | VSPOS   | VSLOC    | VSORRES | VSORRESU |
|-------------|-------|----------|--------------------------|---------|----------|---------|----------|
| ABC-001-001 | 12    | SYSBP    | Systolic Blood Pressure  | SITTING | LEFT ARM | 95      | mmHg     |
| ABC-001-001 | 13    | DIABP    | Diastolic Blood Pressure | SITTING | LEFT ARM | 44      | mmHg     |



- A domain analysis information model representing protocol-driven biomedical/clinical research
- Provides a **basis for harmonization** among standards within the clinical research domain and between biomedical/clinical research and healthcare.
  - ISO 21090 compliant, HL7 alignment, RIM alignment

<http://www.cdisc.org/bridg>

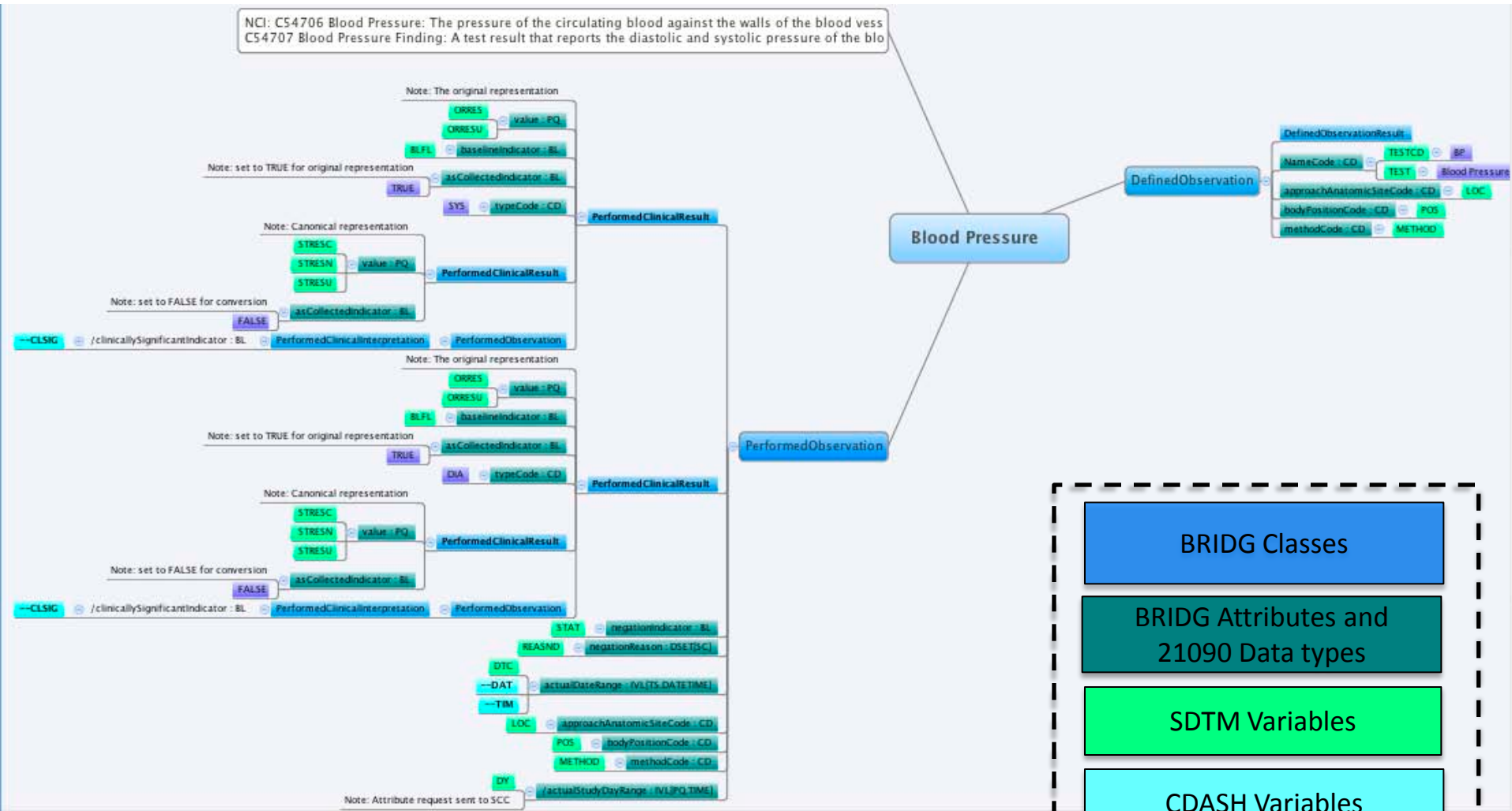
# The CDISC Share Metadata Model



\*ISO 11179 is also included

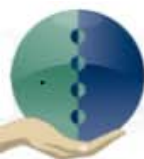


# Concept - Mind Map

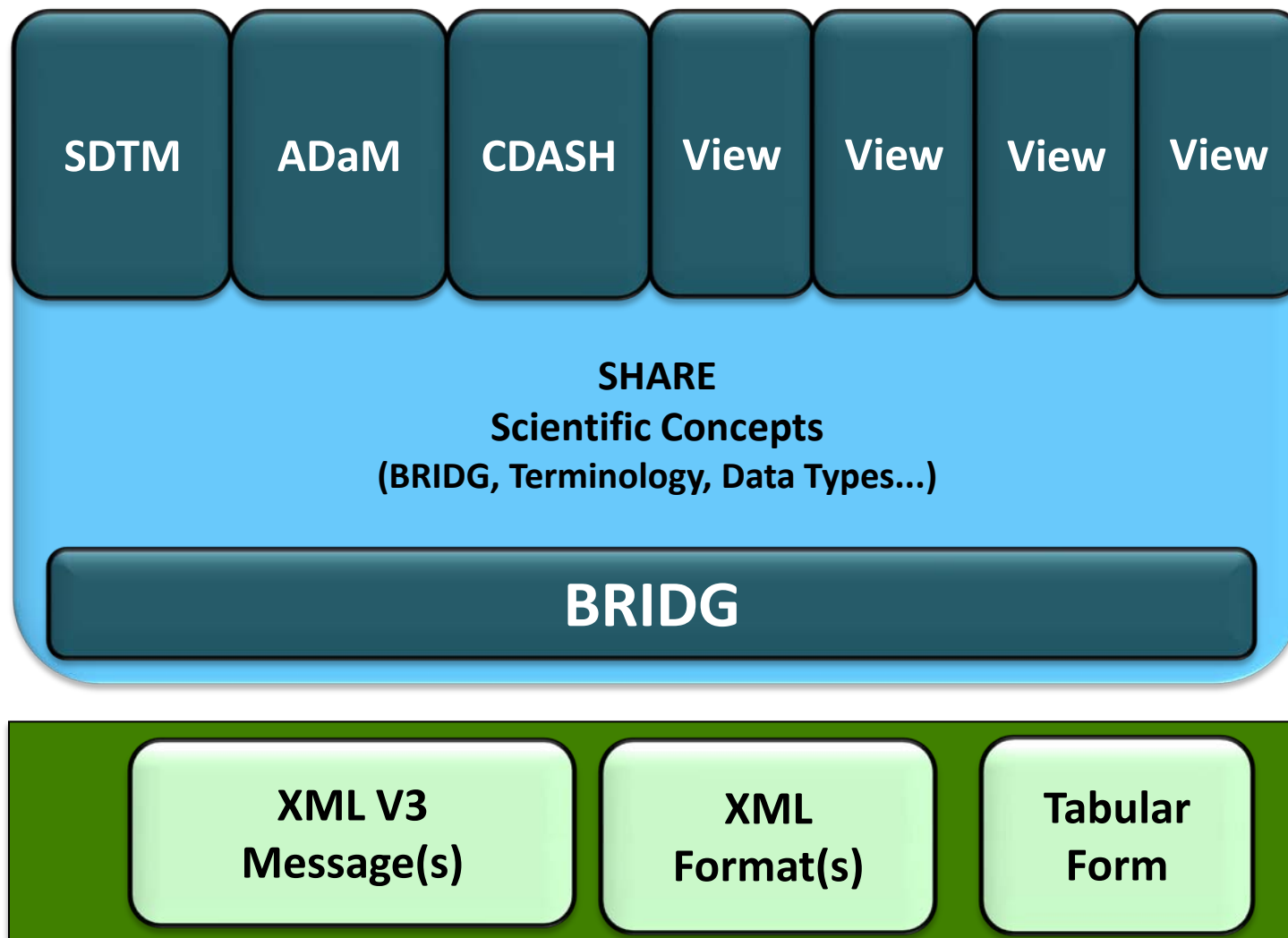


# Concept Spreadsheet (CM)

|    | A             | B                    | C                                                                                                                                                                                                                                                                       | D                                                                                                                                                | E          | F          | G                        | H              | I              | M                              | N                                        | O                                | P                                          | Q                                            | R                                                      | S                          | T                              | U            |
|----|---------------|----------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------|------------|------------|--------------------------|----------------|----------------|--------------------------------|------------------------------------------|----------------------------------|--------------------------------------------|----------------------------------------------|--------------------------------------------------------|----------------------------|--------------------------------|--------------|
| 1  | BRIDG version |                      | 3.0.3                                                                                                                                                                                                                                                                   |                                                                                                                                                  |            |            |                          |                |                |                                |                                          |                                  |                                            |                                              |                                                        |                            |                                |              |
| 2  | Minidmap Name |                      | Concomitant and Prior Substance Administration                                                                                                                                                                                                                          |                                                                                                                                                  |            |            |                          |                |                |                                |                                          |                                  |                                            |                                              |                                                        |                            |                                |              |
| 3  |               |                      |                                                                                                                                                                                                                                                                         |                                                                                                                                                  |            |            |                          |                |                |                                |                                          |                                  |                                            |                                              |                                                        |                            |                                |              |
| 4  | Domain        |                      | CM                                                                                                                                                                                                                                                                      |                                                                                                                                                  |            |            |                          |                |                |                                |                                          |                                  |                                            |                                              |                                                        |                            |                                |              |
| 5  | Definition    |                      | NCI Case report form (CRF) data that captures the Concomitant and Prior Medications/Therapies used by the subject. Examples are the Concomitant Medications/Therapies given on an as needed basis and the usual Background Medications/Therapies given for a condition. |                                                                                                                                                  |            |            |                          |                |                |                                |                                          |                                  |                                            |                                              |                                                        |                            |                                |              |
| 6  | Glossary      |                      | No term in CDISC glossary.                                                                                                                                                                                                                                              |                                                                                                                                                  |            |            |                          |                |                |                                |                                          |                                  |                                            |                                              |                                                        |                            |                                |              |
| 7  |               |                      |                                                                                                                                                                                                                                                                         |                                                                                                                                                  |            |            |                          |                |                |                                |                                          |                                  |                                            |                                              |                                                        |                            |                                |              |
|    | Variable Name | Variable Name C-code | Variable Label                                                                                                                                                                                                                                                          | SHARE Generic Definition                                                                                                                         | SDTM 3.1.2 | CDASH V1.1 | CDASH V1.1 Conceptual DT | SDTM Data Type | Used in Domain | Mapping to BRIDG Defined Class | Mapping to BRIDG Defined Class Attribute | Mapping to BRIDG Performed Class | Mapping to BRIDG Performed Class Attribute | Mapping to BRIDG Non-defined/Non-performed C | Mapping to BRIDG Non-defined/Non-performed C Attribute | BRIDG Class Mapping C-code | BRIDG Attribute Mapping C-code | ISO 21090 DT |
| 8  |               |                      |                                                                                                                                                                                                                                                                         |                                                                                                                                                  |            |            |                          |                |                |                                |                                          |                                  |                                            |                                              |                                                        |                            |                                |              |
| 9  | DOMAIN        | C49556               | Domain                                                                                                                                                                                                                                                                  | A domain is a grouping of related information.                                                                                                   | Y          | Y          | Enumerated               | Char           | Y              | na                             | na                                       | PerformedSubstanceAdministration |                                            |                                              |                                                        | C93439                     |                                |              |
| 10 | --ADJ         | C82555               | Reason for Dose Adjustment                                                                                                                                                                                                                                              | Reason why the treatment dose was adjusted. (Exposure)                                                                                           | Y          | Y          | Enumerated               | Char           | Y              | na                             | na                                       | PerformedSubstanceAdministration | changeReason                               | na                                           | na                                                     | C93439                     | C93529                         | ST           |
| 11 | --AENO        | C82543               | Substance Administration Adverse Event Number                                                                                                                                                                                                                           | Identifier for the adverse event that is the indication for this medication.                                                                     | N          | Y          | Identifier               | Num            | Y              | na                             | na                                       | PerformedObservationResult       | identifier                                 | na                                           | na                                                     | C93421                     | C25364                         | II           |
| 12 | --CAT         | C25372               | Category                                                                                                                                                                                                                                                                | A grouping of observations.                                                                                                                      | Y          | Y          | Enumerated               | Char           | Y              | DefinedActivity                | categoryCode                             | na                               | na                                         | na                                           | na                                                     | C93354                     | C93524                         | CD           |
| 13 | --CDUR        | C83168               | Collected Duration                                                                                                                                                                                                                                                      | The period of time from start to end of an observation. (event, intervention or finding).                                                        | N          | Y          | Amount of Time           |                | Y              | na                             | na                                       | PerformedSubstanceAdministration | duration                                   | na                                           | na                                                     | C93439                     | C25330                         | PQ.TIME      |
| 14 | --CDURU       | C82584               | Collected Duration Units                                                                                                                                                                                                                                                | Unit for the duration.                                                                                                                           | N          | Y          | Unit                     |                | Y              | na                             | na                                       | PerformedSubstanceAdministration | duration                                   | na                                           | na                                                     | C93439                     | C25330                         | PQ.TIME      |
| 15 | --CLAS        | C25346               | Class                                                                                                                                                                                                                                                                   | Drug classification description obtained from a coding dictionary. An example would be the ATC text from the WHO Drug Dictionary. (Intervention) | Y          | N          |                          | Char           | Y              | na                             | na                                       | na                               | na                                         | Product                                      | classCode                                              | C51980                     | C82501                         | DSET <CD>    |
| 16 | --CLASCD      | C82501               | Class Code                                                                                                                                                                                                                                                              | Drug classification code obtained from a coding dictionary. An example would be the ATC code from the WHO Drug Dictionary. (Intervention)        | Y          | N          |                          | Char           | Y              | na                             | na                                       | na                               | na                                         | Product                                      | classCode                                              | C51980                     | C82501                         | DSET <CD>    |
| 17 | --DECOD       | C82977               | Standardized Treatment Name                                                                                                                                                                                                                                             | Standardized or dictionary-derived description of (--TRT   --TERM) or --MODIFY. (Events or interventions)                                        | Y          | N          |                          | Char           | Y              | na                             | na                                       | na                               | na                                         | Drug                                         | code (RENAMED from nameCode)                           | C1909                      | C25162                         | CD           |
| 18 | --DOSE        | C25488               | Dose                                                                                                                                                                                                                                                                    | The amount of treatment administered, in numeric format. (Intervention)                                                                          | Y          | Y          | Physical Quantity        | Num            | Y              | na                             | na                                       | PerformedSubstanceAdministration | activeIngredientDose (NEW)                 | na                                           | na                                                     | C93439                     |                                | PQ           |
| 19 | --DOSFRM      | C42636               | Dose Form                                                                                                                                                                                                                                                               | The dosage form for the treatment administered. (Intervention)                                                                                   | Y          | Y          | Enumerated               | Char           | Y              | na                             | na                                       | na                               | na                                         | Drug                                         | formCode                                               | C1909                      | C93569                         | CD           |



# Ensure Protection of Content



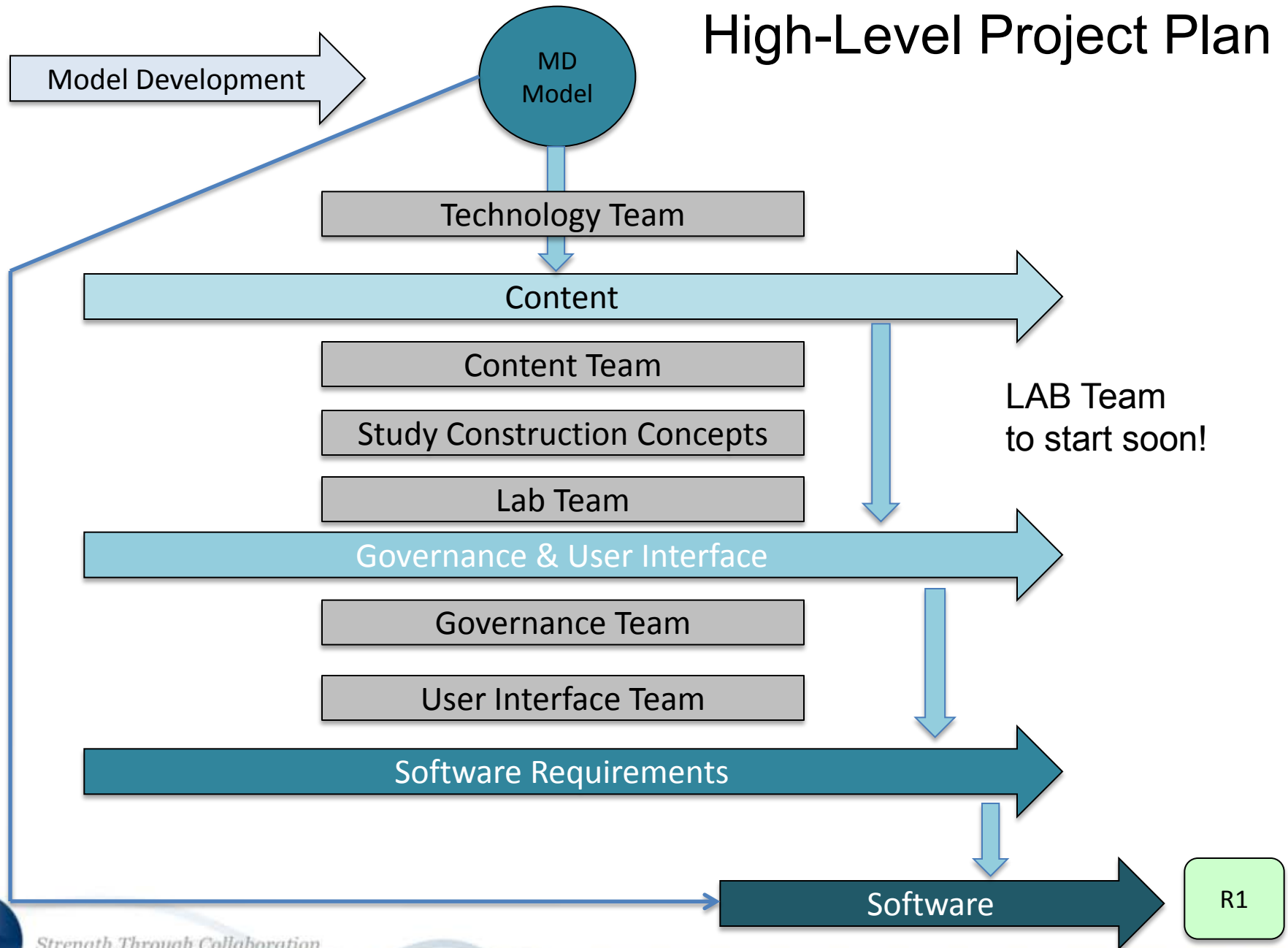
# Benefits

- Richer content
- Machine readable
- Layered / structured
- One definition used many times
- Structured using BRIDG constructs to reflect the nature of the data
- Protection of Content
- Evolution of where we are today



# Project Plan

# High-Level Project Plan



# Accomplishments 2010-2011

CDASH & SDTM definitions aligned



Implementation rules extracted



Draft Metadata model agreed



Model tested on all SDTM classes (Events, Findings, Interventions, etc.)

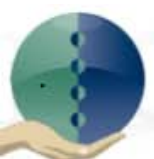


Scientific concepts & attributes mind mapping - ongoing





|   | A           |
|---|-------------|
| 1 | BRIG vers   |
| 2 | Mindmap Na  |
| 3 |             |
| 4 | Domain      |
| 5 | Refusio     |
| 6 | Glossary    |
| 7 |             |
|   | Variable Na |
| 8 |             |
| 9 | DOMAIN      |

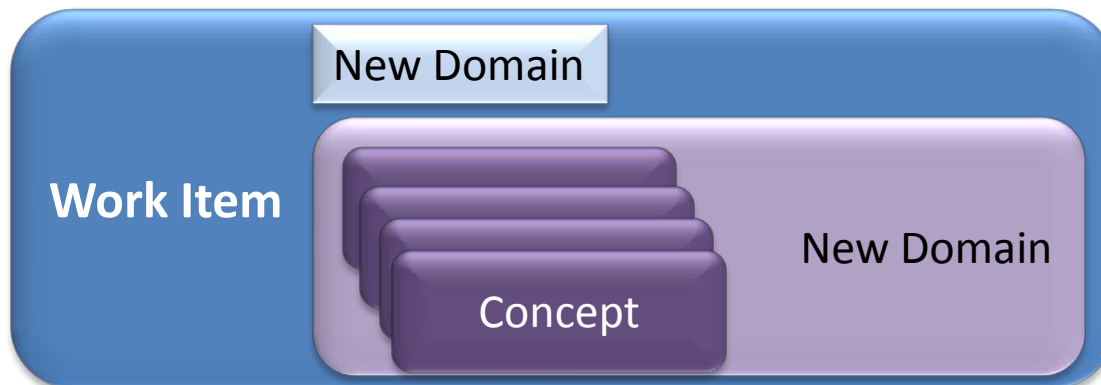
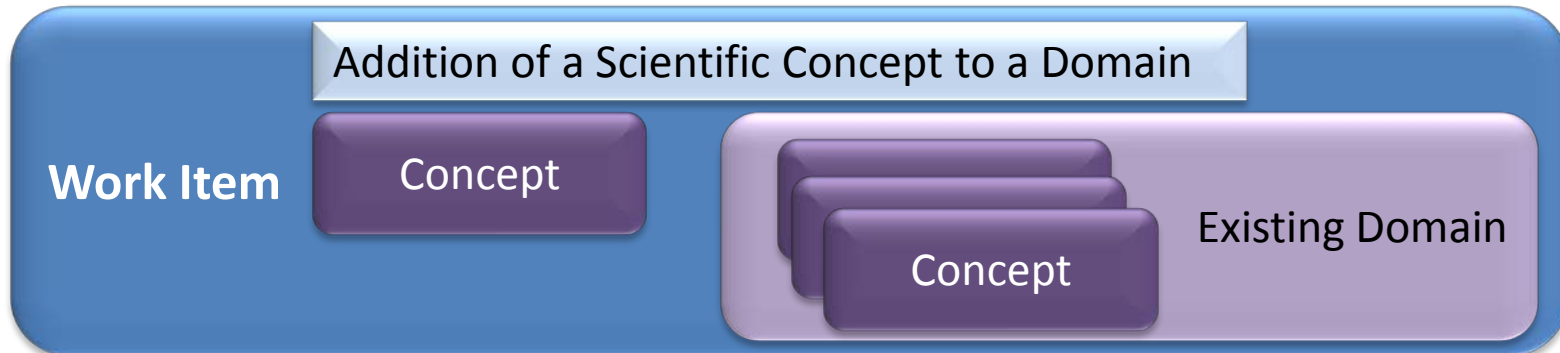
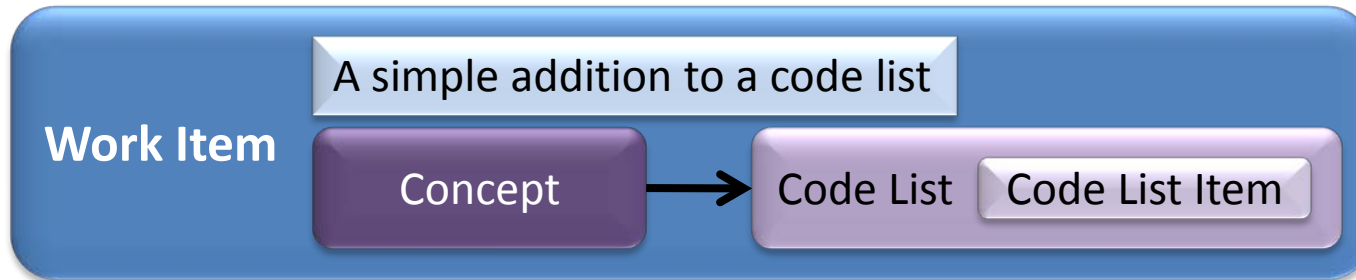


*Strength Through Collaboration*

# Governance Release 1 Goals

- Basic governance in place through mapping of simple scenarios
- Basic administrative and participant roles defined

# Governance Use Cases Under Development



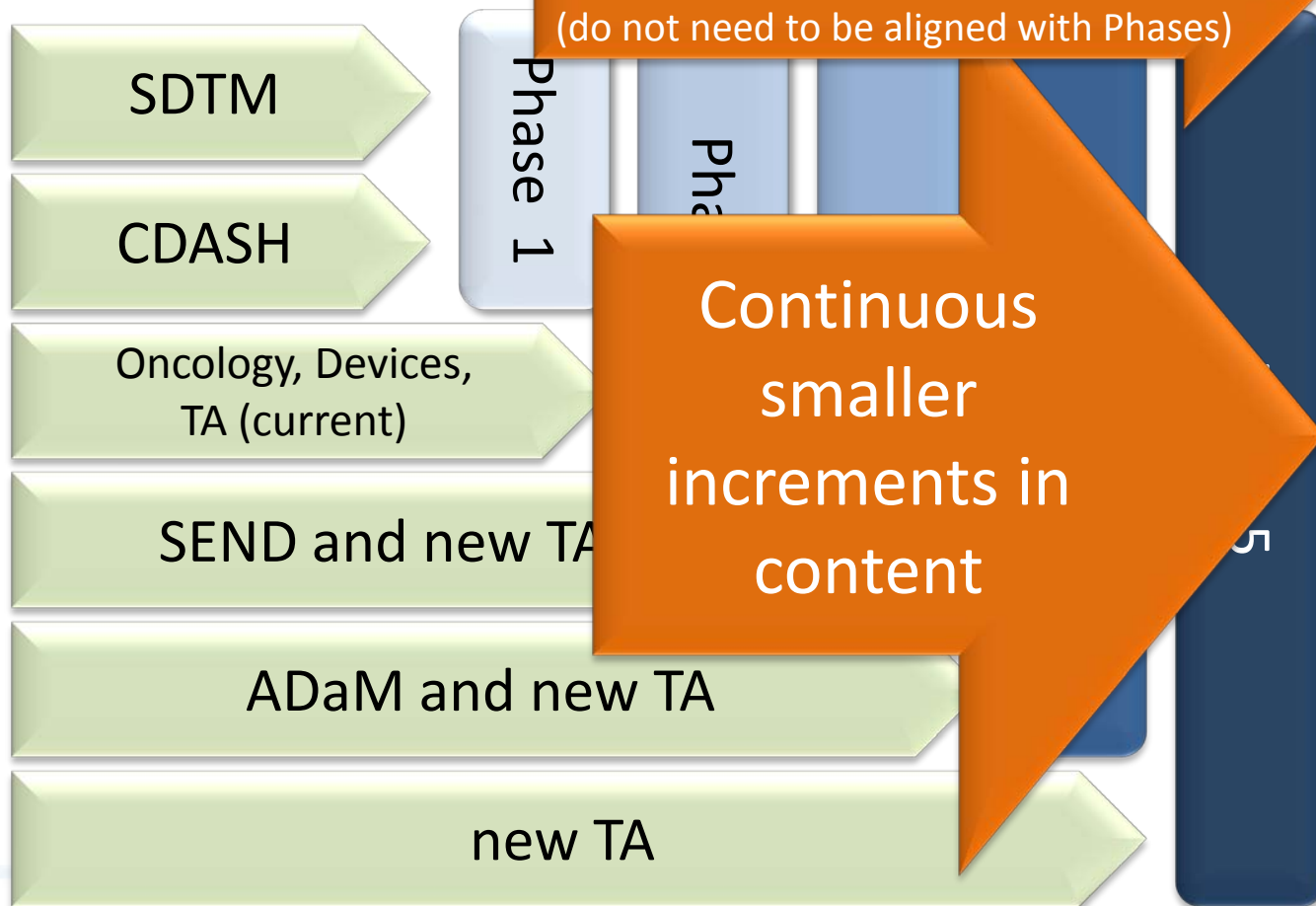
# Requirements Release 1 Goals

- Users should be able to import & export content.
- Users should be able manipulate data.
- Users should be able access an electronic equivalent of a subset in PDF of SDTMIG v3.1.2, CDASH v. 1.1 and Controlled Terminology.



# Longer Term CDISC Share Development Plan

Major Development Phases



# CDISC Share - Conclusion

- Precise definitions
- Rich metadata
- 24/7 access
- Linked to NCIt
- Links Clinical Research to Healthcare.



# Active Participants

- Clyde Ulmer - FDA
- Erin Muhlbradt NCI-EVS
- Fred Wood - Octagon
- Gary Walker - Quintiles
- Hanming Tu - Octagon
- Madhavi Vemuri – J & J
- Mary Lenzen - Octagon
- Melissa Cook - Octagon
- Mike Riben – MD Anderson
- Diane Wold - GSK
- Simon Bishop - GSK
- Terry Hardin - Parexel
- Tsai Yiyang - FDA
- Michael Morozewicz
- Shannen McGinnis - Amgen
- Barry Cohen - Octagon
- Dave Iberson-Hurst - Assero
- Rhonda Facile – NCI-EVS
- Chris Tolk - CDISC
- Dianne Reeves – NCI-CBIIT
- Barrie Nelson - Amgen
- Julie Evans - CDISC
- Jian Chen - Edetek

***CDISC acknowledges all volunteers, their affiliated companies and the NCI-EVS for their support of the CDISC Share project.***



Questions about CDISC Share?  
Interested in joining a team?

Contact

[rfacile@cdisc.org](mailto:rfacile@cdisc.org)

[Rhonda.Y.Facile@mail.nih.gov](mailto:Rhonda.Y.Facile@mail.nih.gov)

Or visit: [cdisc.org](http://cdisc.org)





*Strength through collaboration.*

*...and sharing*



CDISC  
SHARE  
CHANGE HEALTHCARE THROUGH PRODUCT RESEARCH ELECTRONIC SHARING

*As a catalyst for productive collaboration, CDISC brings together individuals spanning the healthcare continuum to develop global, open, consensus-based medical research data standards.*