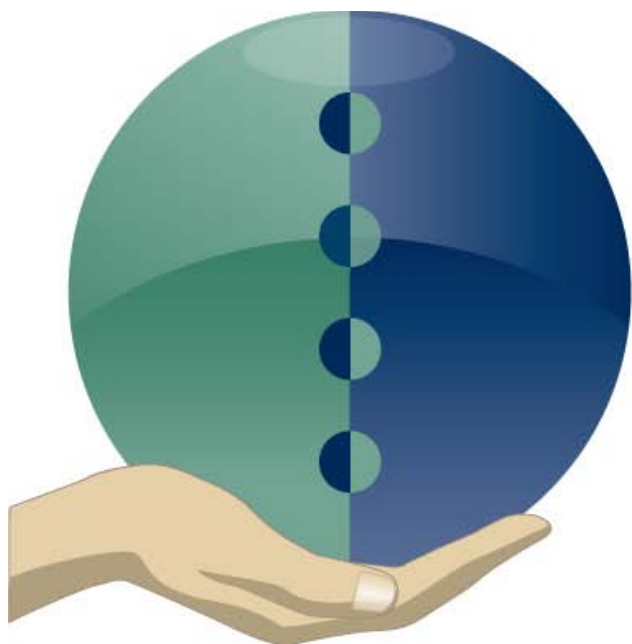




CDISC SHARE

SHARED HEALTH AND CLINICAL RESEARCH ELECTRONIC LIBRARY

*PhUSE Conference
11 August 2011
Philadelphia, PA*

Rhonda Facile (NCI-EVS & CDISC)

CDISC SHARE

- Vision
- Background
- Project Plan
 - Where we are today
 - 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.*



Background: The World Today

CDISC Standards now encompass the entire drug development process

(protocol, collection, analysis, submission, controlled terminology)

– but there is more to be done

- some elements don't fit in existing standards
- standards are not completely aligned or linked
- standards development too time consuming
- Paper/pdf orientated



Better Metadata Needed

- To enhance Data Quality and Compliance
- To decrease the time taken to aggregate and review results
- Machine readable standards can lead to better “enforcement”
- Illustrate inherent relationships between metadata
- Speed up standards development



Compliance Issues

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

5.1.1.1 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”

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

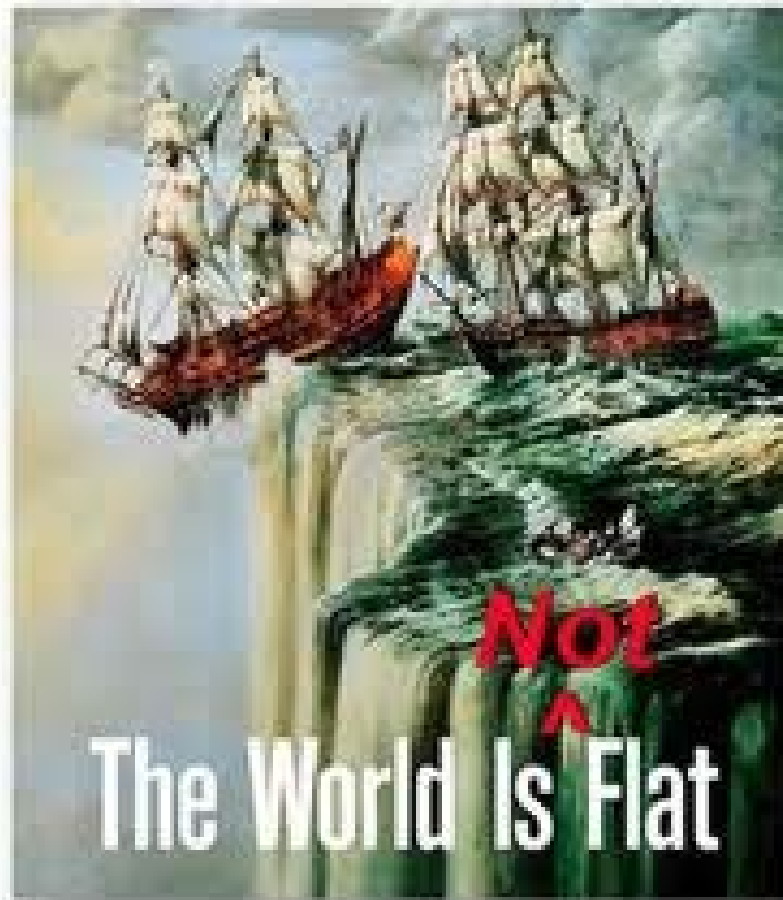
Relationship

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 Aims To:

- Provide an environment within which existing content is easily maintained
- Accelerate new clinical research content development
- Encourage the widest possible participation in the development of new clinical research content (asynchronous contribution 24/7)
- Deliver all of CDISC's existing and all new content in both human and 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?

- Focus on developing rigorous & unambiguous definitions (semantic interoperability)
- Build scientific concepts on BRIDG
- Link all CDISC Standards:
 - Controlled terminology
 - SDTM variables
 - CDASH variables



Semantic Interoperability



11	Position of Subject	VSPOS	Position of the subject during a measurement or examination. {POSITION} (See Section 2.2.)	Record the position of subject at time of test.	Position may be pre-defined as part of CRF label or site may be given one or more options to select from.	Recommended/ Conditional
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Same?

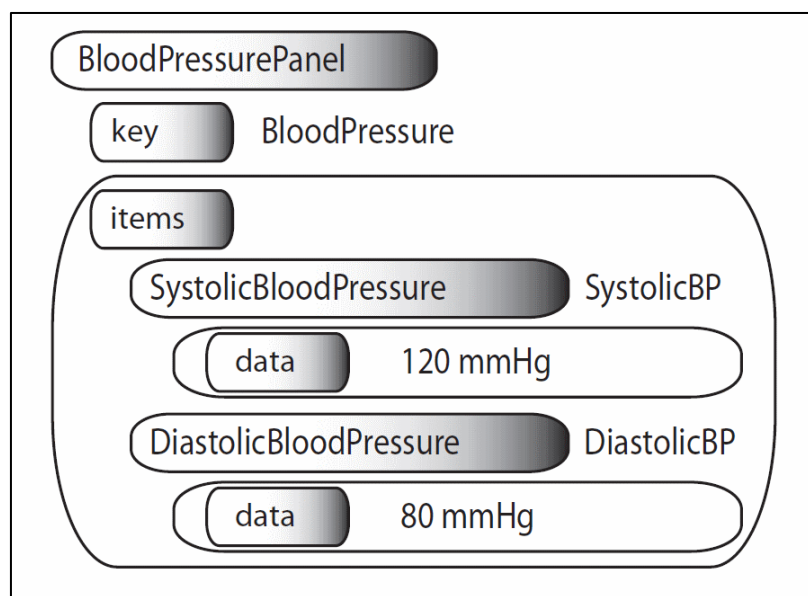


VSPOS	Vital Signs Position of Subject	Char	(POSITION)	Record Qualifier	Position of the subject during a measurement or examination. Examples: SUPINE, STANDING, SITTING.	Perm	SDTM 2.2.3
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Scientific Concepts – which model?

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

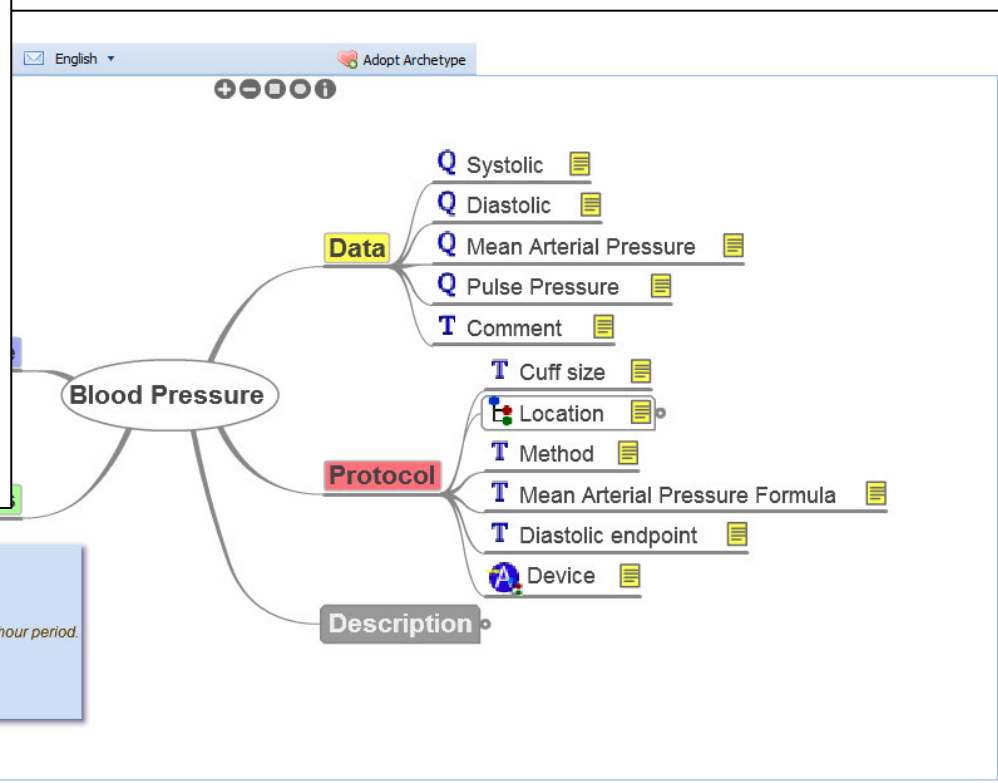


24 hour average

24 hour average
Interval
Occurrences: 0..1 (optional)

Estimate of the average blood pressure over a 24 hour period.

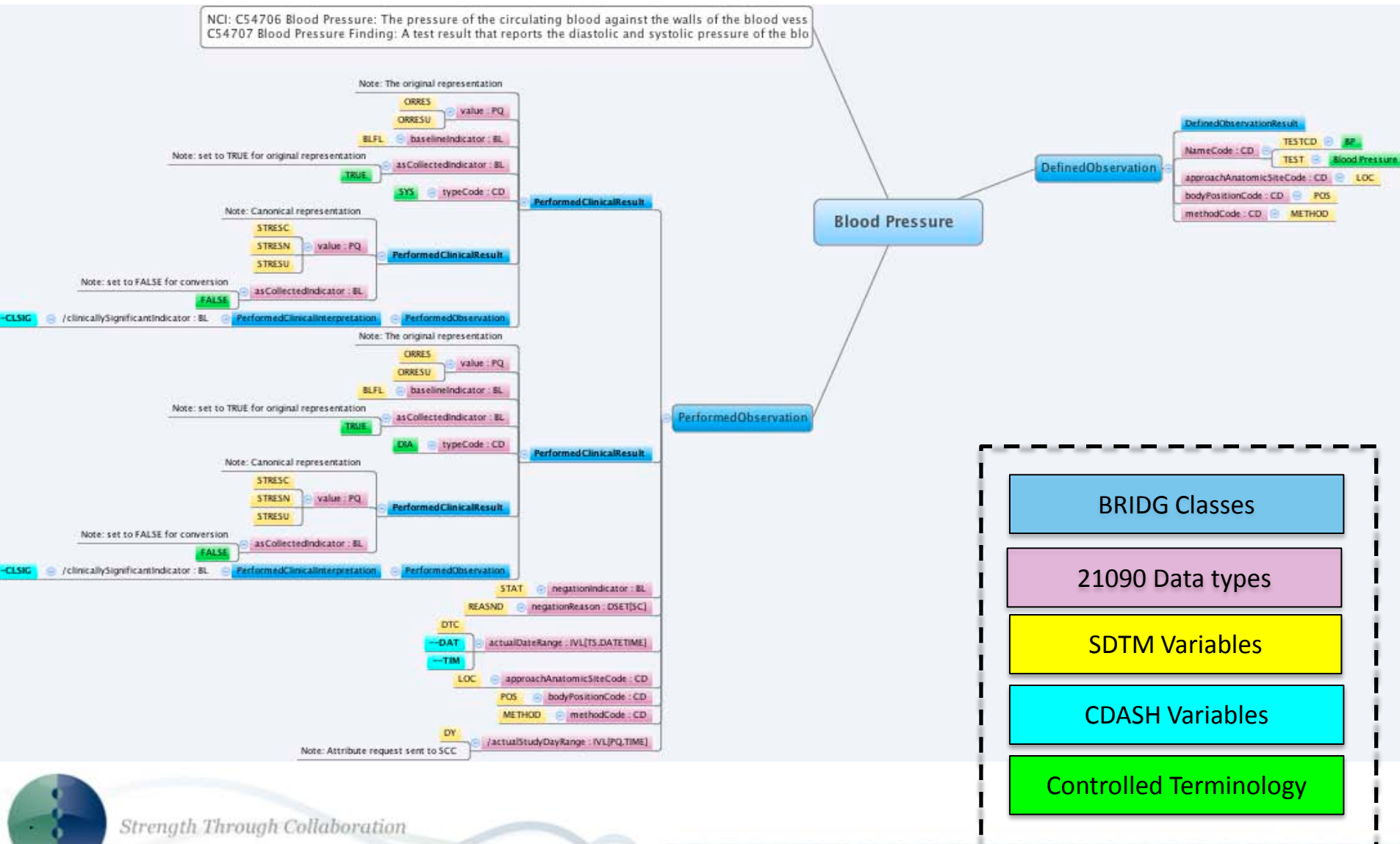
Math. function: Mean
Interval width: 24 hours



- 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>

Scientific Concept - Mind Map

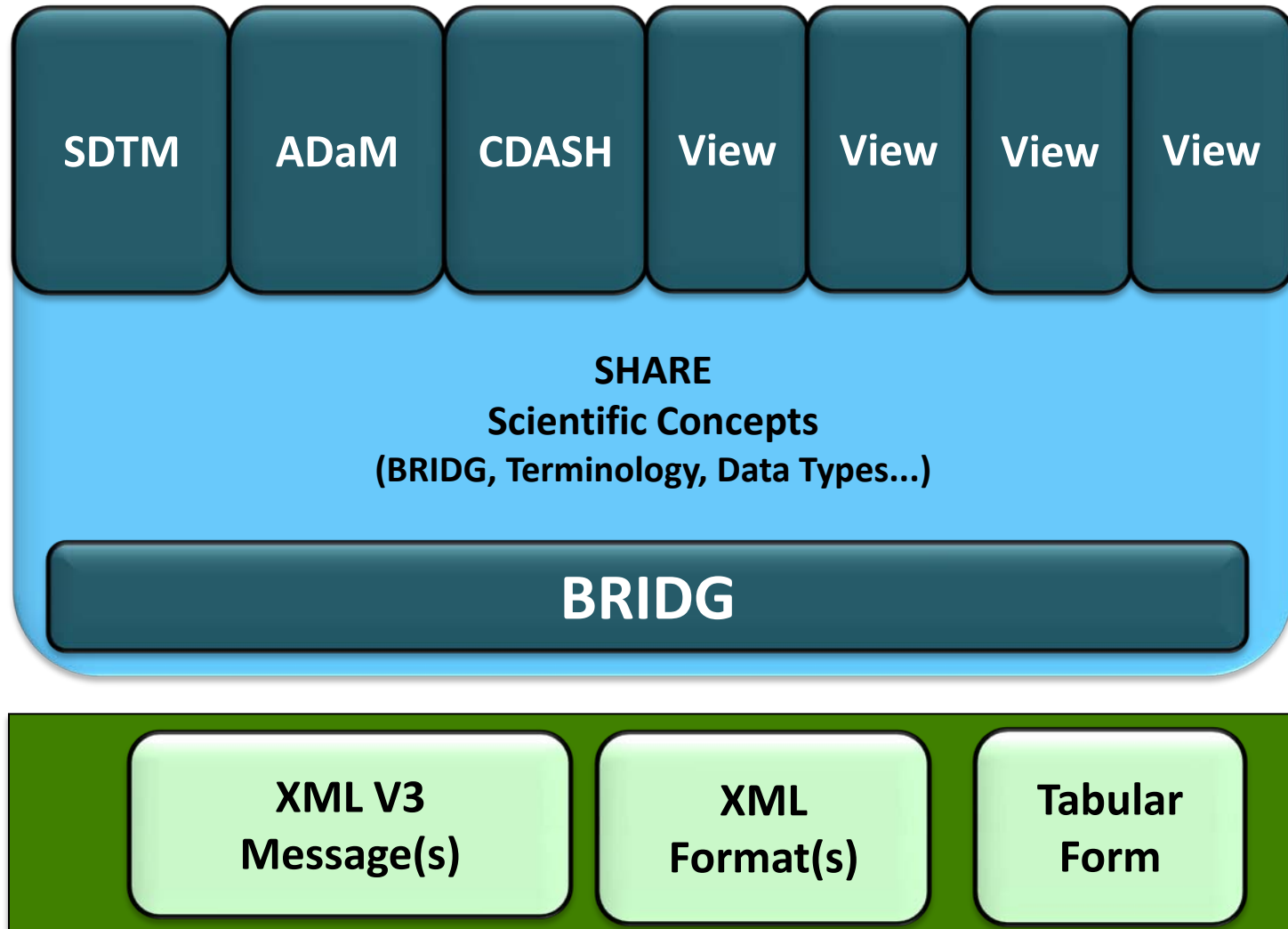


Scientific Concept in template Spreadsheet

	A	B	C	D	E	F	G	H	I	J	K	L	M	N
1	March 11, 2011													
2														
3	Domain	VS												
4														
5	Definition	NCI: Measurements including but not limited to blood pressure, temperature, respiration, body surface area, BMI, height and weight.												
6	Glossary	No term in CDISC glossary.												
7	Mindmap Name	Vital Signs												
8	Formula	Not Applicable												
9	BRIDG version	3.0.3												
10														
11	Decision		Source											
12	VSCAT, VSSCAT, VSDRVFL are valid VS variable per SDTMIGv3.1.2 pages 153 to 155 and can be added but is not included in the first release of SHARE. Decision: VSCAT and VSSCAT need terminology.			2010-11-17 to 19 Share F2F										
13														
14	Variable Name	Variable Label	Used	SHARE Generic Definition	DataType	Codelist Master	Set of Valid Values	Assigned Value	Defined BRIDG Mapping Class	Defined Attribute	Performed BRIDG Mapping Class	Performed Attribute	ISO 21090 Datatype Constraint	ISO 21090 Datatype Constraint Attribute
15	Domain	Domain	Y			C66734	C49622	C49622						
16	--TESTCD	Test Short Name	Y	The short name of the test described in --TEST.	Char				DefinedObservation	nameCode	na	na	CD	code
17	--TEST	Test Name	Y	Name of the test.	Char				DefinedObservation	nameCode	na	na	CD	displayName
18	--LOINC	LOINC Code	Y	The LOINC code of a test.	Char				DefinedObservation	nameCode	na	na	CD	translation_code
19	--METHOD	Method	Y						DefinedObservation	methodCode	PerformedObservation	methodCode	CD	displayName
20	--POS	Position	Y						DefinedObservation	bodyPositionCode	PerformedObservation	bodyPositionCode	CD	displayName
21	--LOC	Location	Y						DefinedObservation	approachAnatomicSiteCode	PerformedObservation	approachAnatomicSiteCode	CD	displayName
22	--LAT	Laterality	Y						DefinedObservation	approachAnatomicSiteLateralityCode	PerformedObservation	approachAnatomicSiteLateralityCode	CD	displayName
23	--DTC	Date/Time of Assessment	Y	The date and time of the result. General prompt question regarding whether or not any assessments were collected during the study.	Char (ISO 8601)				na	na	PerformedObservation	actualDateRange	IVL LOW<TS.DATETIME>	low_value
24	--PERF	Assessments Collected	Y	Indicator that a test (or a group of tests or all tests) has no available result(s).	Char				na	na	PerformedObservation	negationIndicator	BL	value
25	--STAT	Completion Status	Y	The rationale why an assessment was not obtained.	Char				na	na	PerformedObservation	negationIndicator	BL	value
26	--REASND	Reason Not Performed	Y	Study Day of collection of the assessment with respect to the date and	Char				na	na	PerformedObservation	negationReason	DSET(CD)	item_displayName



Protection of the Content



Summary

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

Project Plan

Done

CDASH & SDTM definitions aligned



Implementation rules extracted



Metadata model agreed



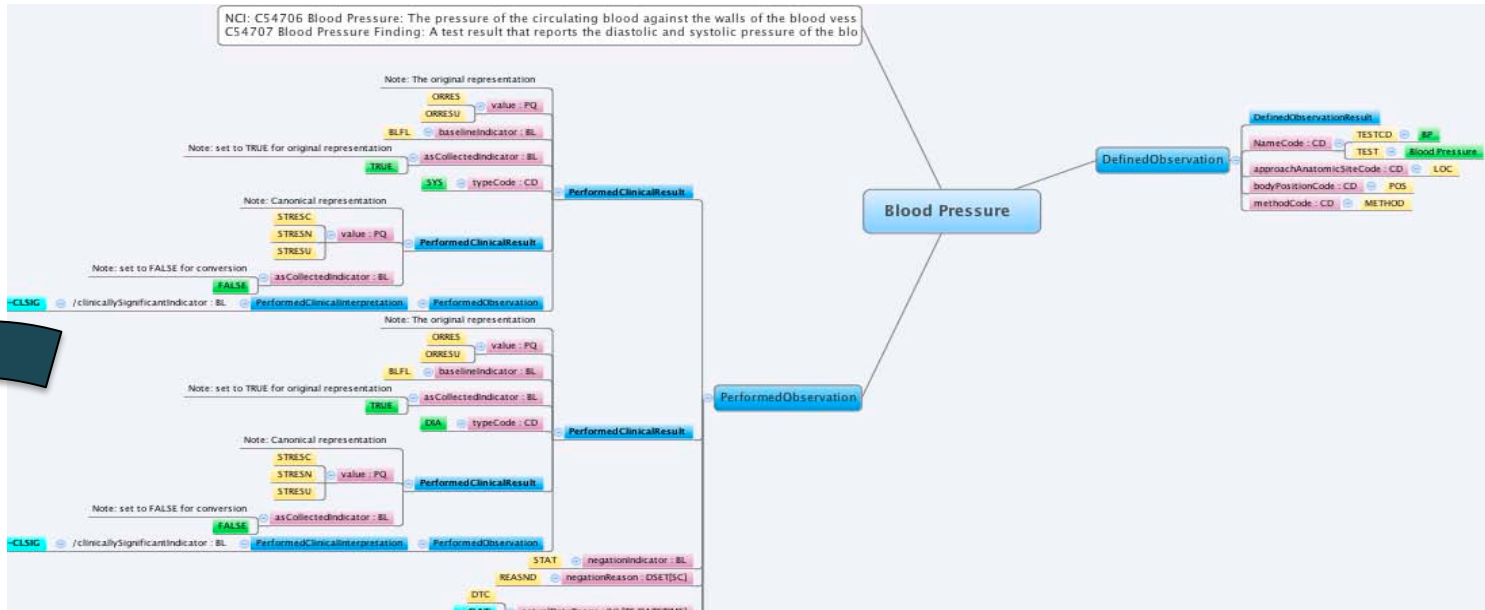
Model tested



Scientific concepts & attributes mind mapped (ongoing)



Content Mapping

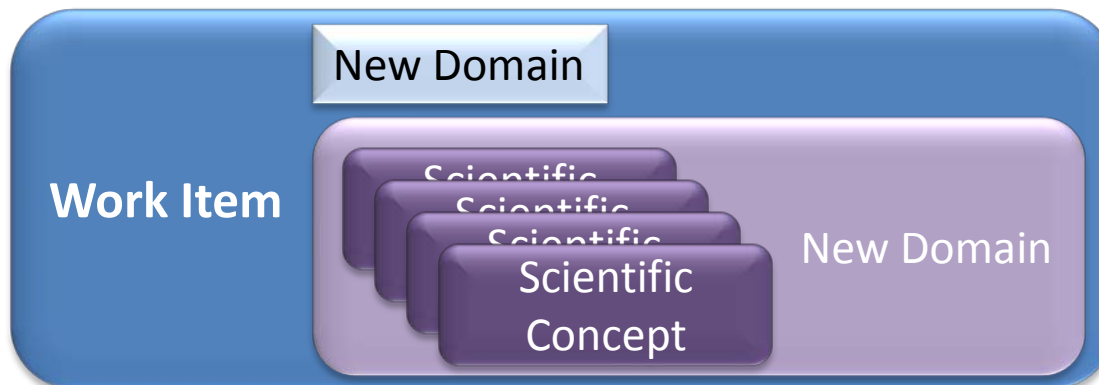
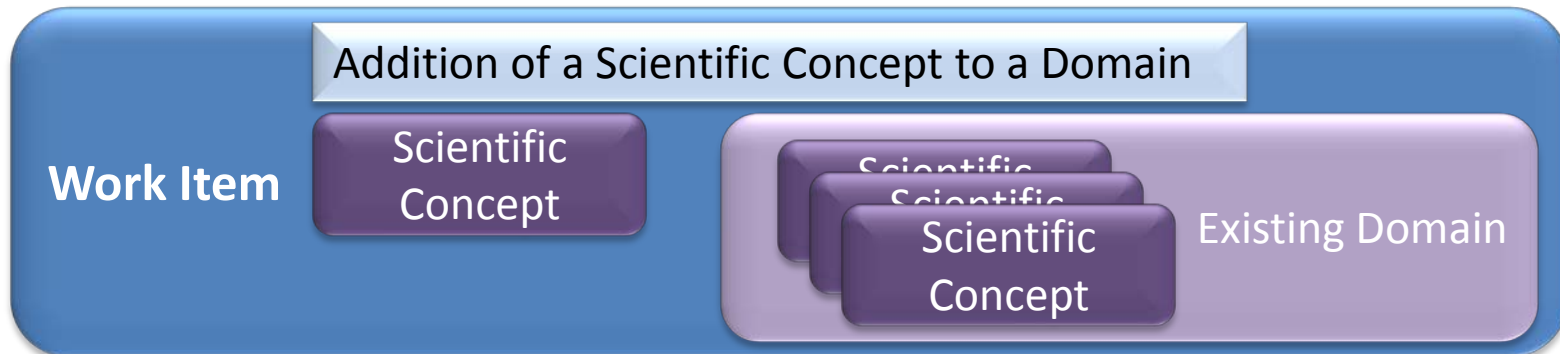
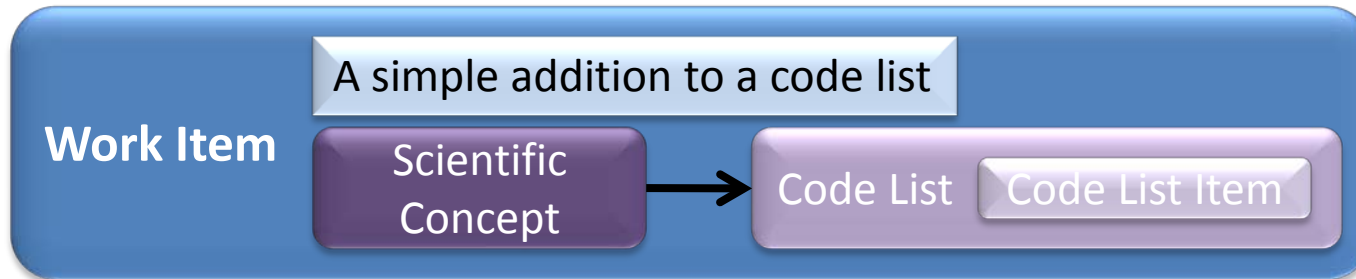


Variable Name	Variable Label	SHARE Generic Definition	SDTM Data Type	Used Domain	Codelist Master	Set of Valid Values	Assigned Value	Mapping to BRIDGE Defined Class	Mapping to BRIDGE Defined Class Attribute	Mapping to BRIDGE Performed Class	Mapping to BRIDGE Performed Class Attribute	Mapping to BRIDGE Non-defined/Non-performed Class
Domain	Domain	A domain is a grouping of related information.	Char	Y	C66734	C49622	C49622	DefinedObservation	nameCode	na	na	na
--TESTCD	Test Short Name	The short name of the test described in --TEST.	Char	Y				DefinedObservation	nameCode	na	na	na
--TEST	Test Name	Name of the test.	Char	Y				DefinedObservation	nameCode	na	na	na
--LOINC	LOINC Code	The LOINC code of a test.	Char	Y				DefinedObservation	nameCode	na	na	na
--EVLINT	Evaluation Interval	Evaluation interval associated with an observation.	Char (ISO 8601)	N				DefinedObservation	focalDuration	PerformedObservation	focalDuration	na
--METHOD	Method	Technique used to perform the test.	Char	Y				DefinedObservation	methodCode	PerformedObservation	methodCode	na
--POS	Position	Body position of the subject during a measurement or examination.	Char	Y				DefinedObservation	bodyPositionCode	PerformedObservation	bodyPositionCode	na
--LOC	Location	The location on the body where the treatment was administered, or the observation was made.	Char	Y				DefinedObservation	approachAnatomicSiteCode	PerformedObservation	approachAnatomicSiteCode	na
--LAT	Laterality		Char	Y				DefinedObservation	approachAnatomicSiteLateralityCode	PerformedObservation	approachAnatomicSiteLateralityCode	na
		General prompt question regarding whether or not any										

CDISC Share Phase 1 - Governance

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

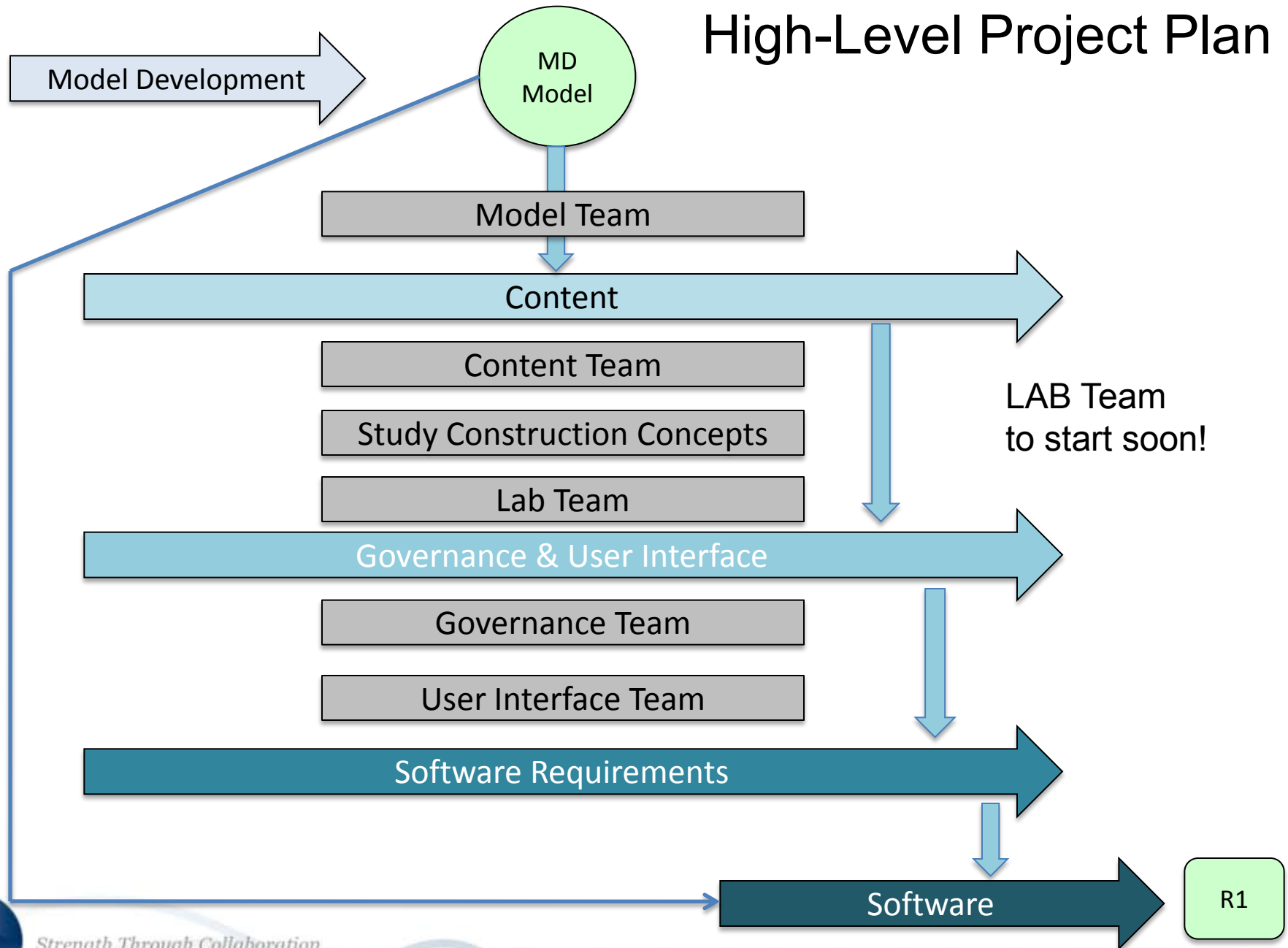
Governance Use Cases Under Development



CDISC Share Phase 1 – Key Functionality Requirements

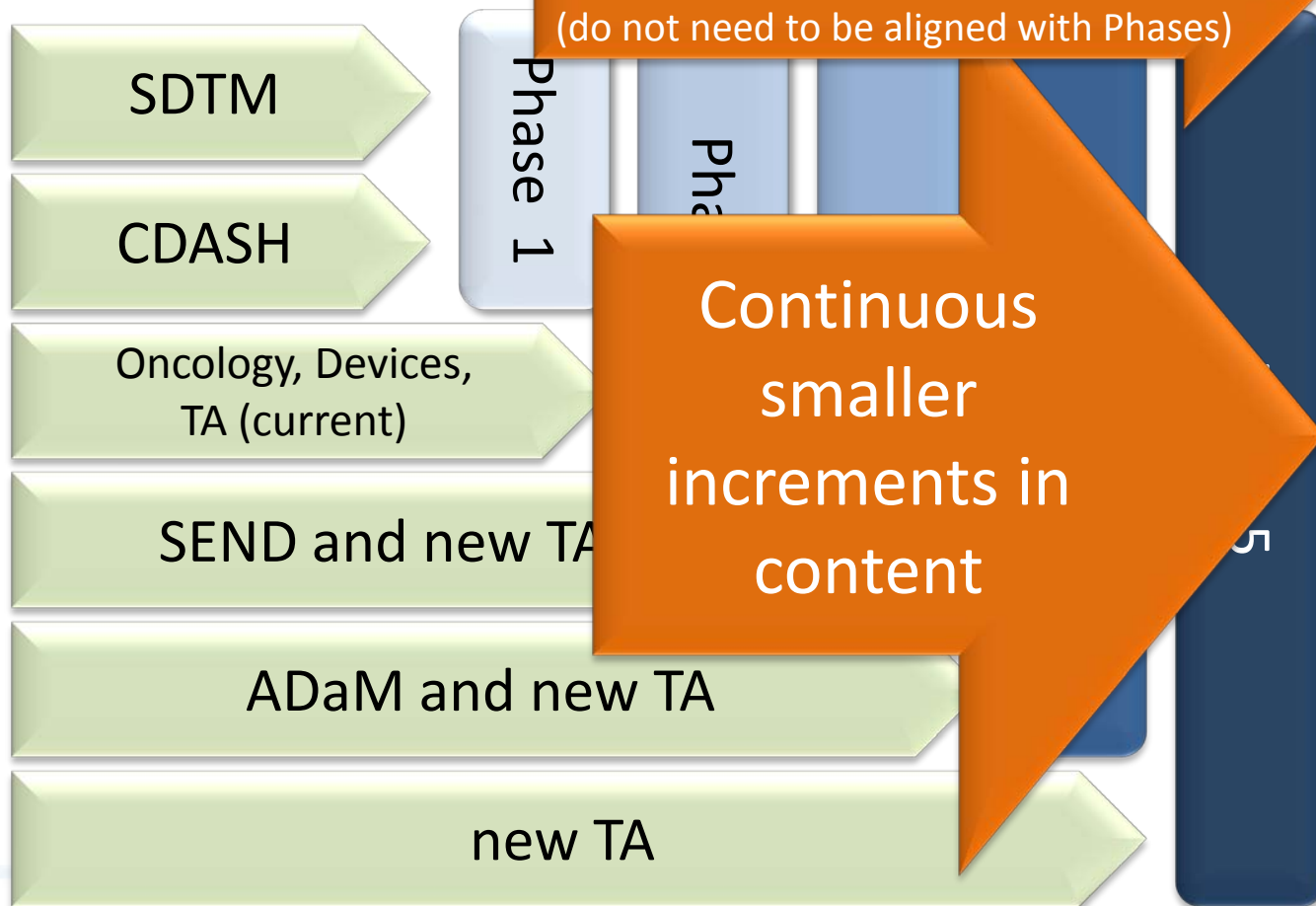
- Users should be able to import & export content.
- Users should be able to manipulate data.
- Users should be able to access an electronic equivalent of a subset in PDF of SDTMIG v3.1.2, CDASH v 1.1, Controlled Terminology.

High-Level Project Plan



Longer Term CDISC Share Development Plan

Major Development Phases



Strength Through Collaboration

CDISC Share - Conclusion

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

All-new design

Less in your hands.
More at your fingertips.



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 support of the CDISC Share project.



Questions about CDISC Share?
Interested in joining a team?

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Or visit: cdisc.org





Strength through collaboration.

...and sharing



CDISC
SHARE
CHANGE QUALITY OF PATIENT RESEARCH ELECTRONIC DATA

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