Improving Research with Data Standards: Now and to Come

Wayne Kubick

Strength *through Collaboration*

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Agenda:
Things Old, Things New and Things to Come

- CDISC, Standards and Me
- Foundational Standards
- Therapeutic Area Standards
- SHARE and Metadata
- Things to Come
- CDISC Standards and You

"It does not matter how slowly you go as long as you do not stop."
-- Confucius

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The Clinical Data Interchange Standards Consortium

- Global, open, multi-disciplinary, vendor-neutral, non-profit standards developing organization (SDO)
- 501(c)(3) charitable non-profit Founded 1997, incorporated 2000
- Member-supported (>300 academia, biopharma, service providers)
- Associations with ISO TC 215 (Liaison A), HL7 Joint Initiative Council, IHE, NCI-EVS, CFAST, IMI, PhUSE, others
- Coordinating Committees in Europe, China, Japan, others
  - Participants from > 90 countries
- Standards freely available.

The CDISC Vision: Informing patient care and safety through higher quality medical research

The CDISC Mission

The CDISC mission is to develop and support global, platform-independent data standards that enable information system interoperability to improve medical research and related areas of healthcare.

Wayne's Mission

Data Standards to Improve Clinical Research

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2015 CDISC Strategic Goals

- Promote and support the continued global **adoption** of **harmonized** data standards throughout the clinical research **lifecycle** by engaging regulatory agencies, research sponsors, academia and other stakeholders through education, advocacy and collaboration.

- Implement clinical research standards that are **compatible** with standards in the broader **healthcare ecosystem** and thus **add value** for clinical researchers, healthcare providers and patients.

- **Leverage** the Shared Health And Research Electronic Library (SHARE) and other **tools** to further **expedite** the development and facilitate the **implementation** of **harmonized** standards for clinical research.

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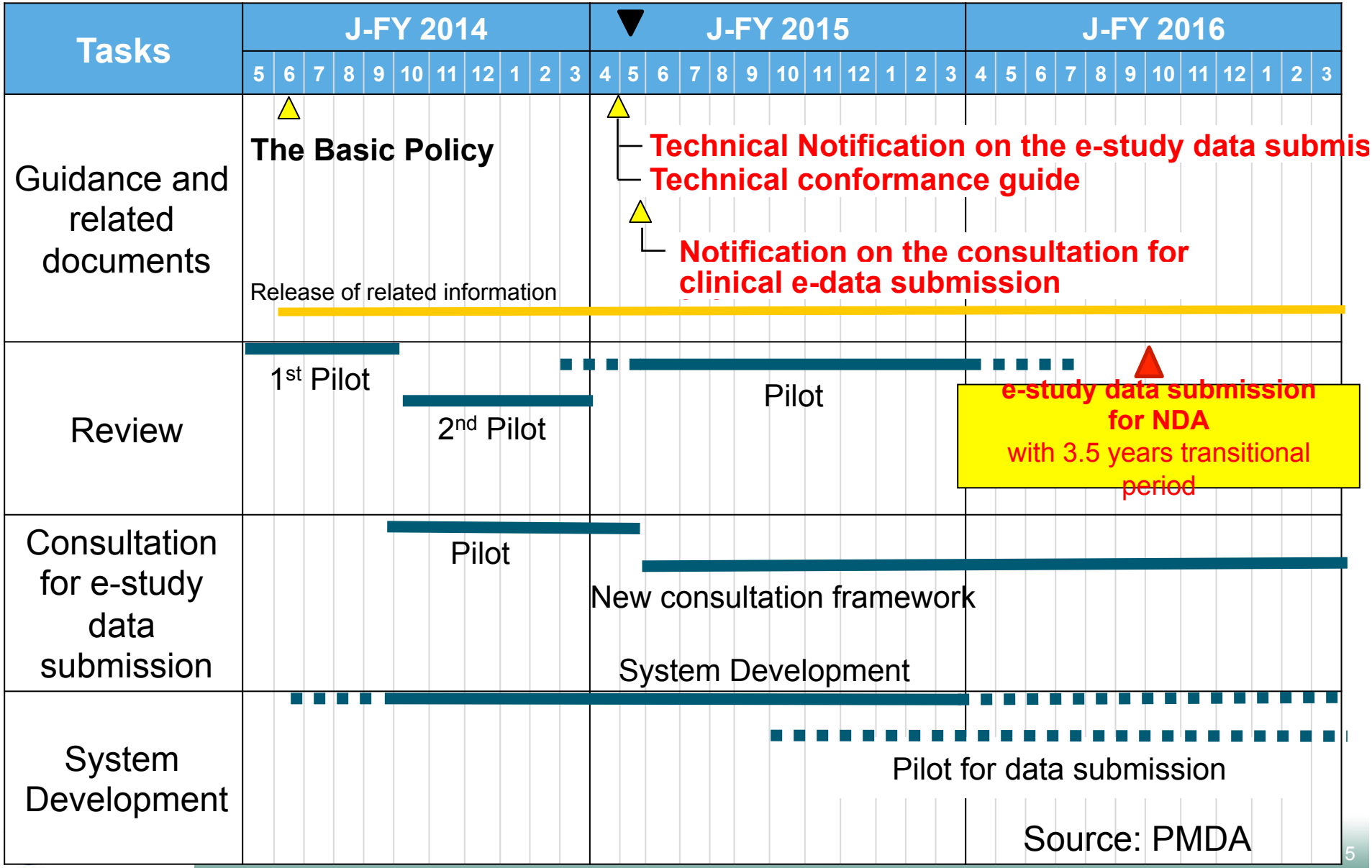
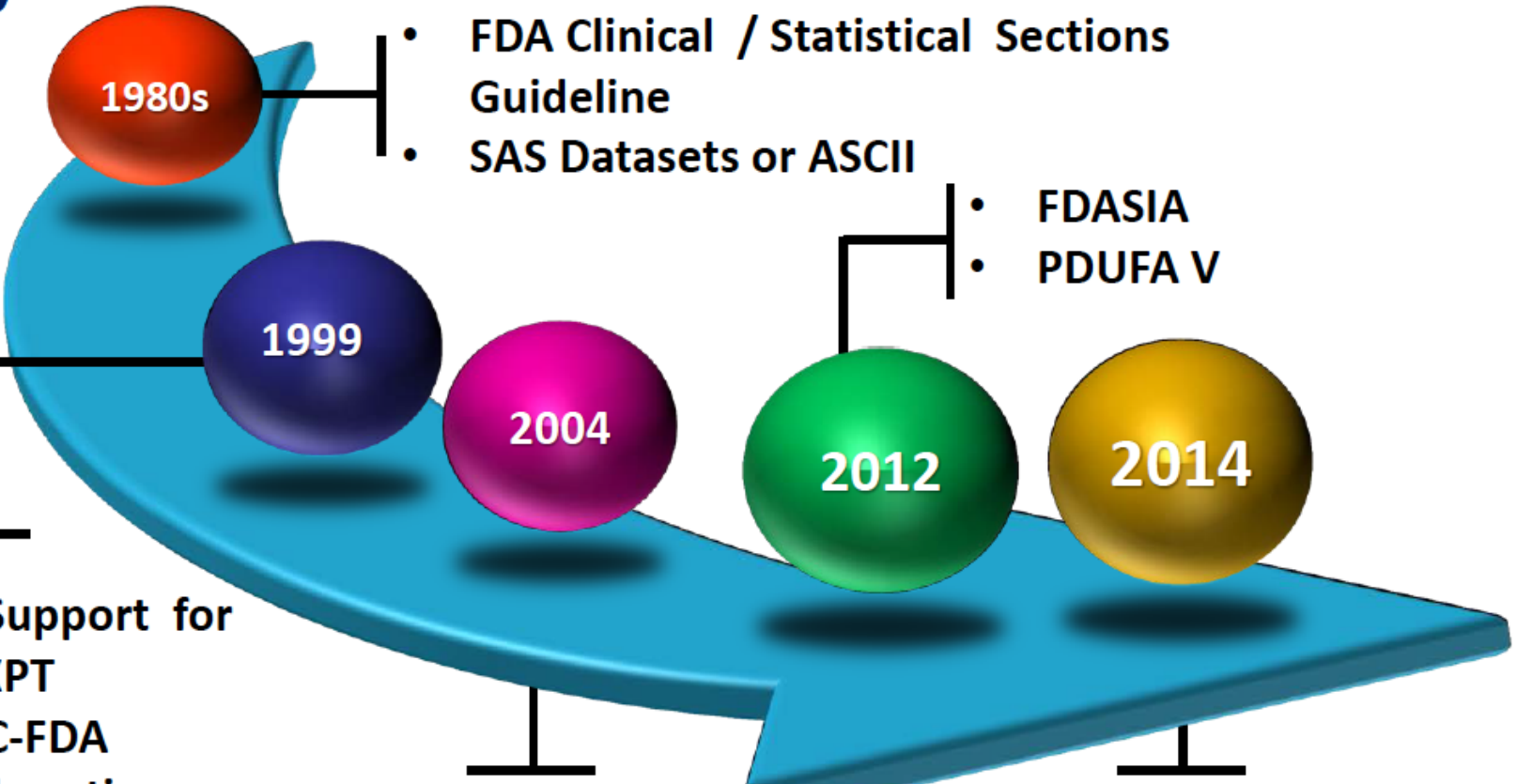
Timeline for Establishment of the Framework for Electronic Study Data Utilization in PMDA



U.S. Food and Drug Administration
Protecting and Promoting Public Health
www.fda.gov

Path to Electronic Standardized Study Data



- FDA Clinical / Statistical Sections Guideline
- SAS Datasets or ASCII

- FDASIA
- PDUFA V

- FDA Support for SAS XPT
- CDISC-FDA Collaboration

- FDA Support for CDISC Submissions

- Final 745A(a) Guidance
- Final eStudy Data Guidance
- Tech Conformance Guide

Source: FDA

2015 Guiding Themes for Standards Development

- Transparency
  - Share all, requirements and plans in advance; invite feedback
  - Make it easier for global participants to get more involved
- Agility - Scrum for standards development
  - Expand use of collaboration tools to improve team interactions
  - Smaller teams, scrum sprints, through JIRA
  - Get content into SHARE early – as soon as its stable
  - Rollout SHARE Collaborative Curation Initiative – to rapidly fill gaps in content
  - Engage a second class of Fellows
- Focus and Execution
  - Do what's necessary so industry and regulatory authorities get what they need when they need it to better realize the benefits of CDISC standards

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What is a CDISC Data Standard?

A CDISC data standard is any product (including specifications, implementation guides, models or schemas) provided by CDISC that describes representation of clinical* research data and has been properly developed, vetted and approved through the CDISC process.

** And non-clinical*

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Progress Update – Foundational Standards

Foundational Products Released in 2014-2015:

- Dataset-XML v1 Final
- ADaM v1.3 Validation Checks
- *ADaM Data Structure for Integration (ADSL)*
- **CDISC in RDF** (PhUSE)
- ***BRIDG R4***
- Periodic Terminology and QRS Packages
- Updated COP and Process Docs

Upcoming Major New Drafts for Comment:

- *CTReg XML Schema*
- *SDTMIG Batch 3 and Conformance Rules*
- *Define-XML v2.1 and IG*

QS=Questionnaires

VISIT Baseline

9 TCM Differentiation Syndrome/Pattern (Zheng) ***QSCAT***

QSTEST

Ⅰ **Primary Syndrome:** □Blood Heat □Blood Dryness □Blood Stasis □Others_____

QSORRES when QSTESTCD = TCM01 ***TCM01OTH IN SUPPQS***

Ⅱ **Secondary Syndrome:** □Blood Stasis □Heat □Dryness □Dampness □Others_____

QSORRES when QSTESTCD = TCM02 ***TCM02OTH IN SUPPQS***

10 Treatment Evaluation

Keeping up with CDISC Standards

New Projects: 2015 Technical Plan

Teams / Teams Home

2015 Technical Plan

Edit Watch Share ...

Created by Wayne Kubick, last modified on Aug 10, 2015

This page will be a brief list of all major team projects that may result in new product deliverables in 2015.

CFAST, SHARE and Healthcare Link projects are listed separately.

2015 Q1 Technical Plan for Distribution

FDA CDISC Technical Plan Meeting Notes.pdf

Team	Project	Description	Reqs Date	State	Target Date
PRG	Protocol Concepts	Protocol Concepts V1.0 release for review and collaboration with TransCelerate Common Protocol Template (concept mapping to Template)		Draft	Q4
CDASH	CDASHIG v2	CDISC Model, new domains (PR, HO, SR, DD, MI, MO, RP, PC, PP, FA,QS) to correspond to newer SDTMIG v3.2 domains.		Draft	Q4
SDTM	SDTM v1.5	New variables, domain-specific variable class, new special purpose domains to support SEND, PGx, Human Clinical Trials.		Draft Final	Q3 Q4
SDS	SDTMIG v3.3	New Intervention domains: Procedure Agents (AG) and Meal (ML) Decision on Physiology/Morphology domain(s), with changes to existing and draft domains and new domain(s). Broadening TU and TR domains to handle non-tumor lesions and RS to handle more kinds of disease responses, including clinical classifications. Proposal for "Non-Standard Variables" in parent domains rather than as supplemental qualifiers Proposal for Disease Milestones Proposal for MHEVTYP, a new domain-specific variable to deal with medical history events with multiple kinds of start dates Proposal to transition from BLFL to a new variable LOBXFL which will not conflict with ADaM baselines Proposal for handling subjects with multiple participations (and SUBJIDs) in the same study and the impacts on DM and observation class domains		Batch3 Final	Q3 Q116
SDS	SDTMIG v3.2 Conformance	Rules to validate conformance with SDTMIG v3.2		Draft	Q4

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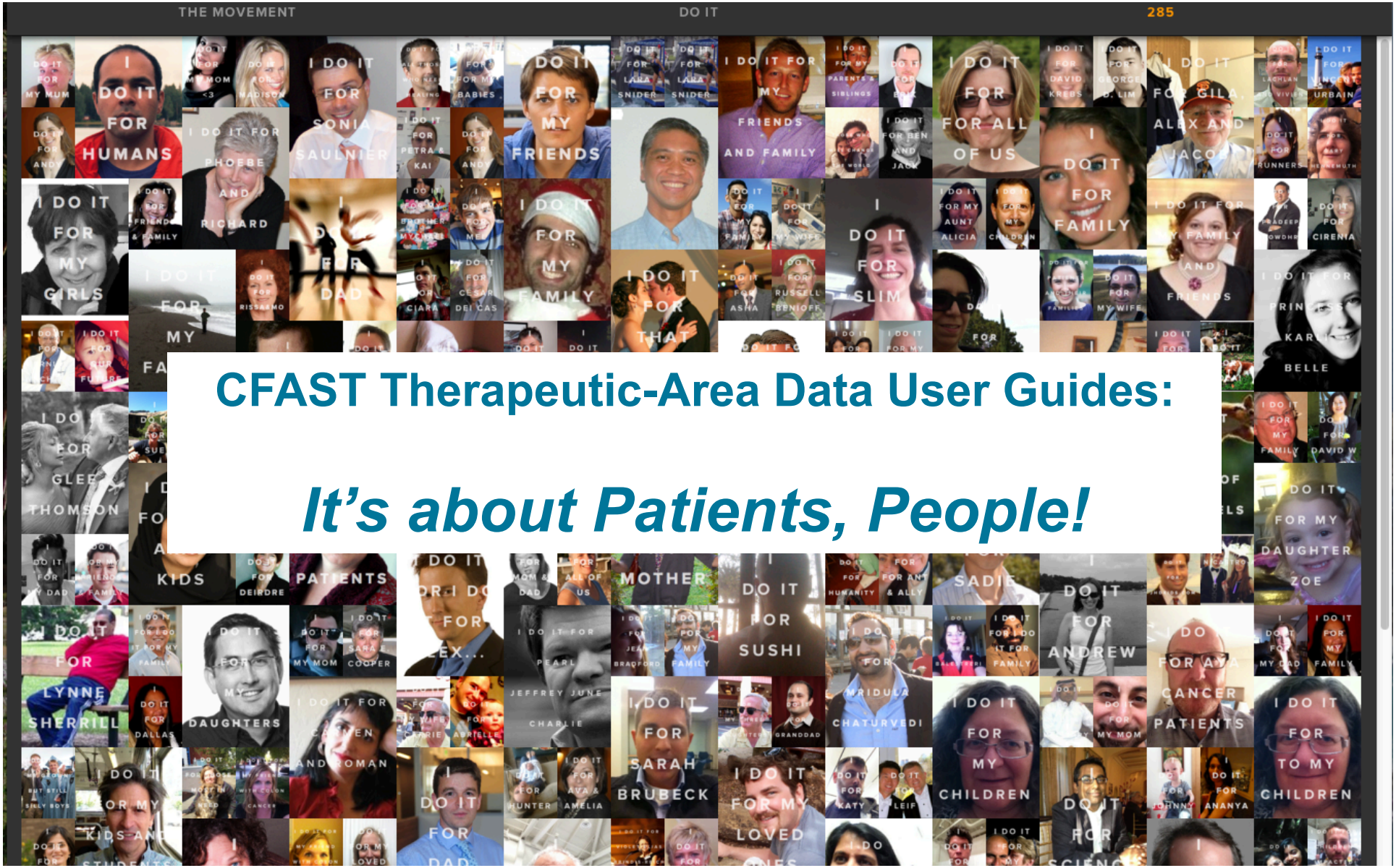

CFAST Therapeutic-Area Data User Guides:

It's about Patients, People!

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July 2015 Program Overview
Approved Therapeutic Area Standards Projects

Therapeutic Area	Coordinating Organization/PM	Notes
Traumatic Brain Injury v1	CDISC Amy Palmer	PR: July 21-Sep 21 (60 days)
Breast Cancer v1	CDISC John Owen	SRC review for PR Aug 10
COPD v1	CDISC Sherwood Barbee	R: July 10-July 31
ADaM Supp to Diabetes v1	TCB Rachael Zirkle	PR: July 20-Aug 21
Virology v2	C-Path Laura Butte	PR: July 21-Aug 24
Diabetic Kidney Disease v1	TCB Rachael Zirkle	R start goal: mid-Sept
Tuberculosis v2	C-Path Laura Butte	R start goal: early-Sept
Rheumatoid Arthritis v1	TCB Trisha Simpson	Charter approved 7/9
CV Imaging v1	CDISC Amy Palmer	
Prostate Cancer v1	CDISC John Owen	
Major Depressive Disorder	CDISC Amy Palmer	
General Anxiety Disorder	CDISC Amy Palmer	
Bi-Polar Disease	CDISC Amy Palmer	

TAUGs released in 2014-2015:

- Multiple Sclerosis
- Diabetes
- Cardiovascular
- Influenza
- QT Studies
- **Chronic Hep-C**
- **Schizophrenia**
- **Dyslipidemia**

Upcoming Provisionals:

- *Virology v2*
- *Diabetes ADaM Supplement*
- *Traumatic Brain Injury*

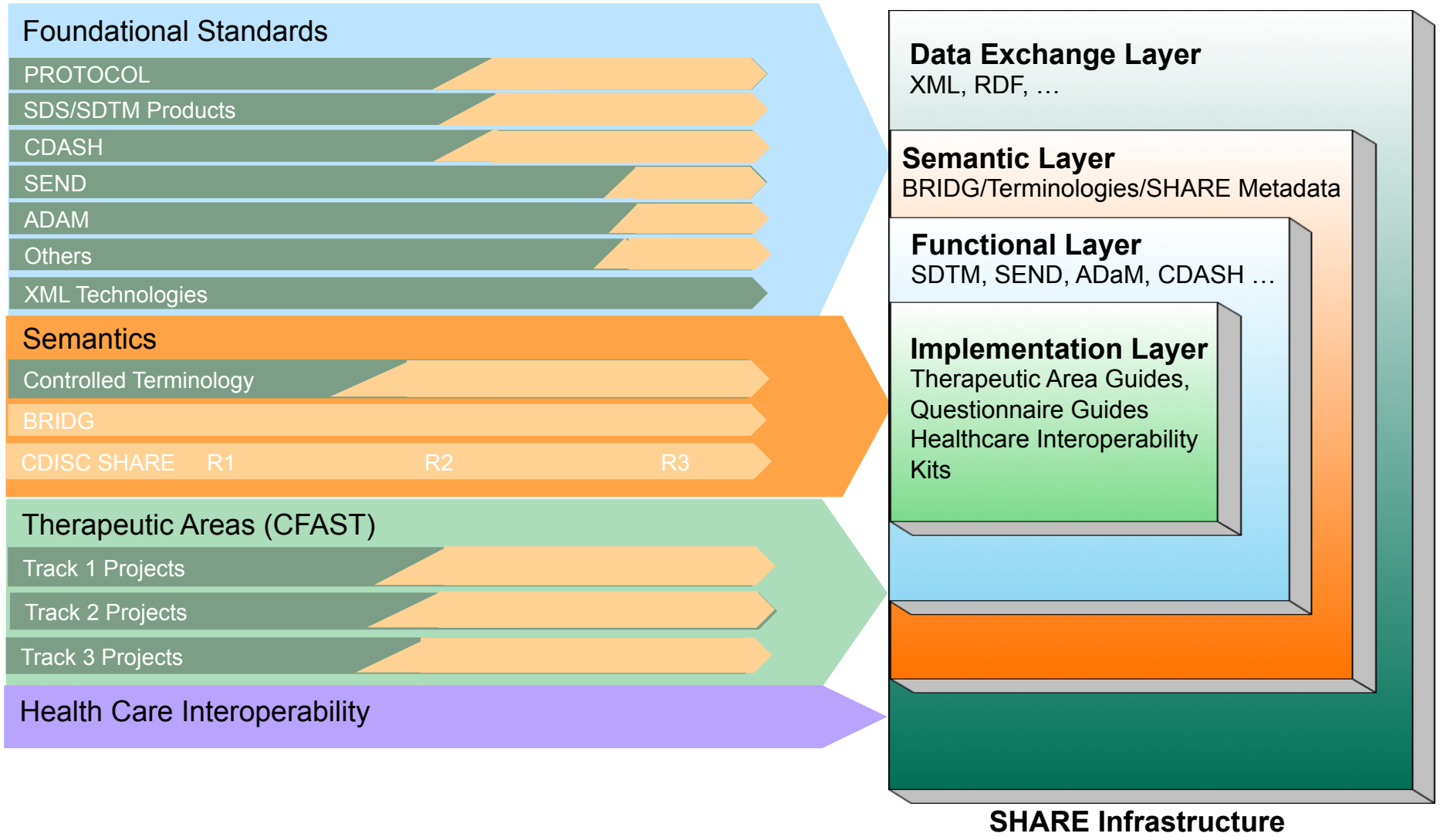
Upcoming Drafts:

- *Breast Cancer*
- *COPD*

Key | Stage completed | Stage ongoing | All months reflect when stage is, or is projected to be, completed.

*The Stage 3b concludes at the end of the 30-day review period and Stage 3c concludes when all tasks have been completed and the standard is publicly available.
** Specific projected publication dates to be added to the notes section at the conclusion of Stage 3b.

CDISC Technical Roadmap - 2015



The Roadmap depicts evolution from siloed standards to an integrated stack based on BRIDG and SHARE

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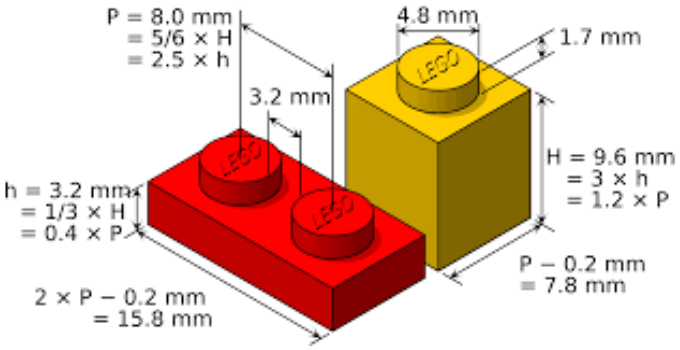
SHARE Through the Eyes of a Child

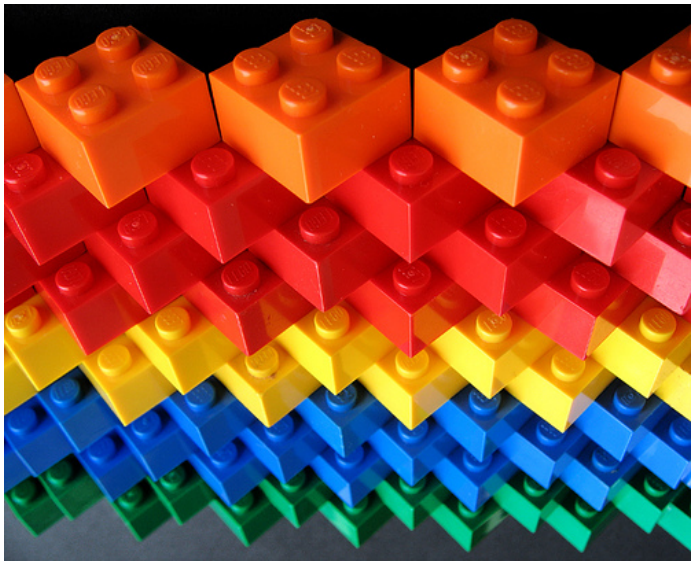
© CDISC 2015

A World Without Data Standards

© CDISC 2015

Elements, Metadata, Terminology





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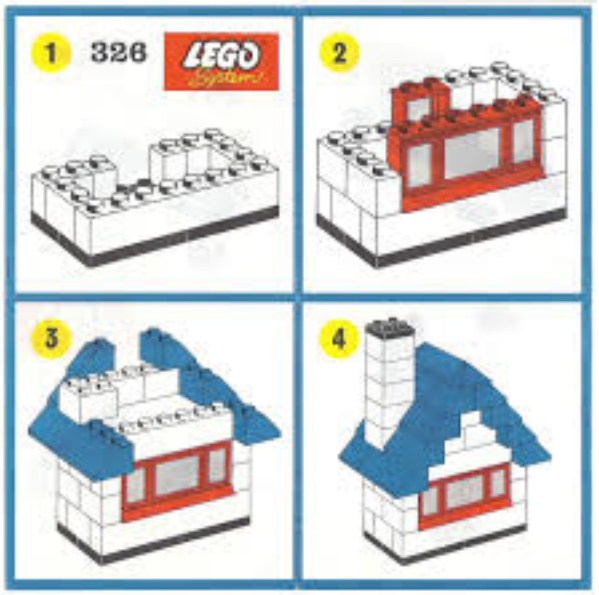
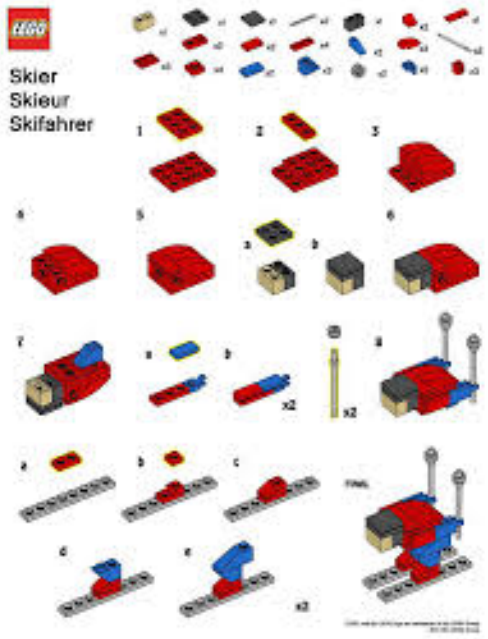
User Guides / Solution Kits





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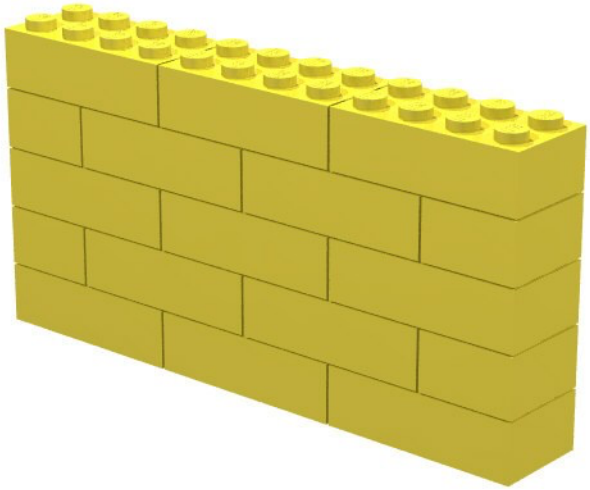
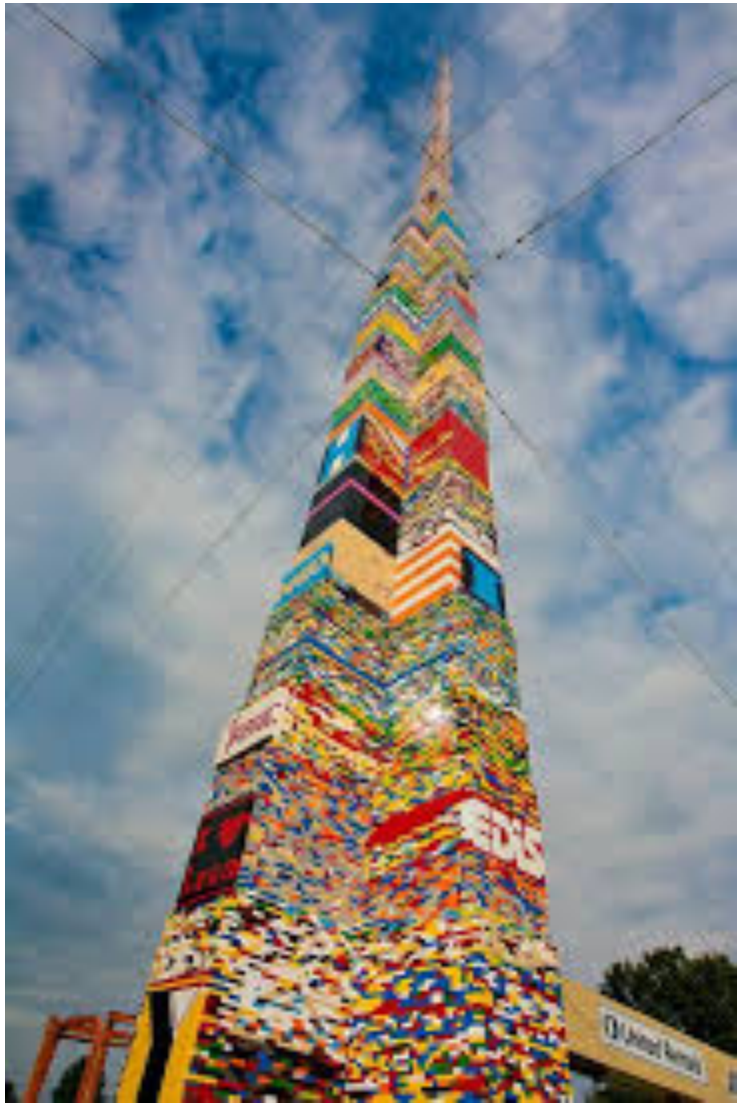
Research Concepts





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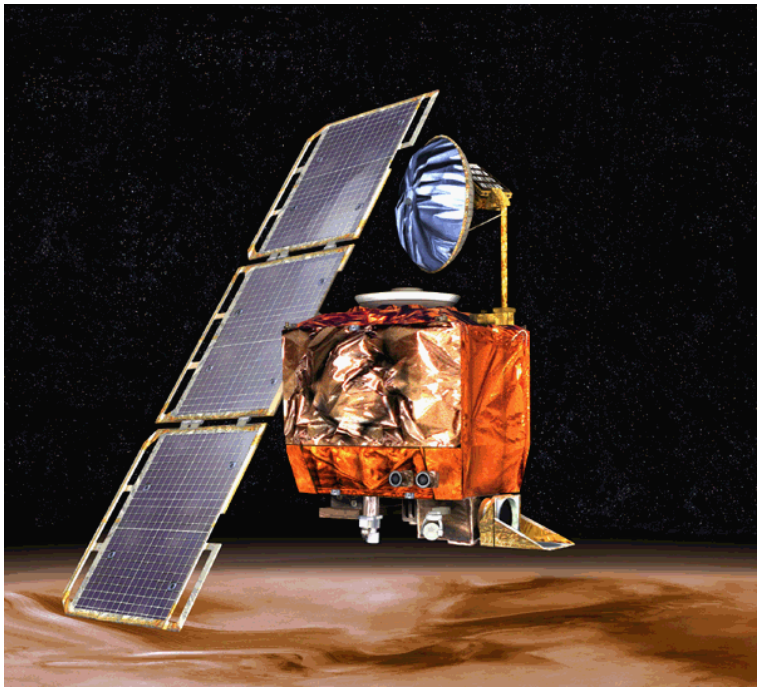
Begin with the End in Mind: How Important is Concept or Value-Level Metadata?

Event	Time	D	S	F
Begin	9/23/99 02:01:00	121,900,000	12,300	143.878
End	9/23/99 02:17:23		9,840	

Event	Time	D	S	F
Start	19990923 05:01:00	196,200,000	5.5	640
Finish	19990923 05:17:23		4.4	

Source: Dave Christiansen

In this case $125,000,000: Mars Climate Orbiter



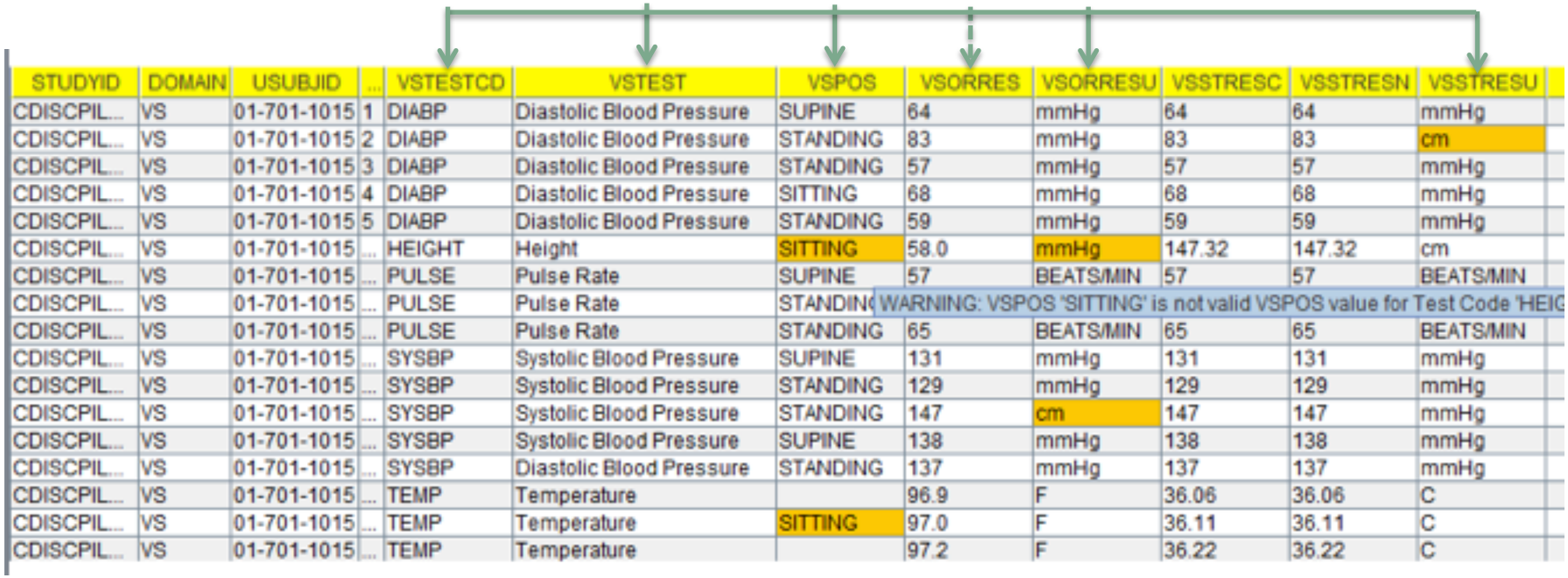
Mars Orbit Insertion Burn	M/D/Y HH:MM:SS PDT (Earth Receive Time, 10 min. 49 sec. Delay)	Distance (miles)	Speed (miles/hr)	Force (Pounds)
Begin	9/23/99 02:01:00	121,900,000	12,300	143.878
End	9/23/99 02:17:23		9,840	
Mars Orbit Insertion Burn	**YYYYMMDD EDT (Earth Receive Time, 10 min. 49 sec. Delay)**	**Distance (km)**	**Speed (km/sec)**	**Force (Newtons)**
Start	19990923 05:01:00	196,200,000	5.5	640
Finish	19990923 05:17:23		4.4	

Source: Dave Christiansen

© CDISC 2015

Research Concepts

Metadata set Components



STUDYID	DOMAIN	USUBJID	...	VSTESTCD	VSTEST	VSPOS	VSORRES	VSORRESU	VSSTRESC	VSSTRESN	VSSTRESU
CDISCPIL...	VS	01-701-1015	1	DIABP	Diastolic Blood Pressure	SUPINE	64	mmHg	64	64	mmHg
CDISCPIL...	VS	01-701-1015	2	DIABP	Diastolic Blood Pressure	STANDING	83	mmHg	83	83	cm
CDISCPIL...	VS	01-701-1015	3	DIABP	Diastolic Blood Pressure	STANDING	57	mmHg	57	57	mmHg
CDISCPIL...	VS	01-701-1015	4	DIABP	Diastolic Blood Pressure	SITTING	68	mmHg	68	68	mmHg
CDISCPIL...	VS	01-701-1015	5	DIABP	Diastolic Blood Pressure	STANDING	59	mmHg	59	59	mmHg
CDISCPIL...	VS	01-701-1015	...	HEIGHT	Height	SITTING	58.0	mmHg	147.32	147.32	cm
CDISCPIL...	VS	01-701-1015	...	PULSE	Pulse Rate	SUPINE	57	BEATS/MIN	57	57	BEATS/MIN
CDISCPIL...	VS	01-701-1015	...	PULSE	Pulse Rate	STANDIN	WARNING: VSPOS 'SITTING' is not valid VSPOS value for Test Code 'HEIG				
CDISCPIL...	VS	01-701-1015	...	PULSE	Pulse Rate	STANDING	65	BEATS/MIN	65	65	BEATS/MIN
CDISCPIL...	VS	01-701-1015	...	SYSBP	Systolic Blood Pressure	SUPINE	131	mmHg	131	131	mmHg
CDISCPIL...	VS	01-701-1015	...	SYSBP	Systolic Blood Pressure	STANDING	129	mmHg	129	129	mmHg
CDISCPIL...	VS	01-701-1015	...	SYSBP	Systolic Blood Pressure	STANDING	147	cm	147	147	mmHg
CDISCPIL...	VS	01-701-1015	...	SYSBP	Systolic Blood Pressure	SUPINE	138	mmHg	138	138	mmHg
CDISCPIL...	VS	01-701-1015	...	SYSBP	Diastolic Blood Pressure	STANDING	137	mmHg	137	137	mmHg
CDISCPIL...	VS	01-701-1015	...	TEMP	Temperature		96.9	F	36.06	36.06	C
CDISCPIL...	VS	01-701-1015	...	TEMP	Temperature	SITTING	97.0	F	36.11	36.11	C
CDISCPIL...	VS	01-701-1015	...	TEMP	Temperature		97.2	F	36.22	36.22	C

Source: Jozef Aerts (Adapted)

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A Voyage Through Visit Dates

What is the visit name?	Visit	VISIT	PlannedActivity.name*	A clinical encounter that encompasses planned and unplanned trial inventions, procedures, and assessments that may be performed on a subject.	When applicable (e.g., on paper CRFs), record the visit name.	This is typically pre-printed/pre-populated. *See the BRIDG model for complete path.
What is the visit number?	Visit Number	VISITNUM	PlannedSubjectActivityGroup.sequenceNumber	A number assigned to a clinical encounter.	When applicable (e.g., on paper CRFs), record the	ay be used to onological order counters.
What is the visit date?	Visit Date				format (DD-MON-YYYY).	collected are e should be collected some way. This may be done once for the visit using VISDAT or may be done at the CRF level using the domain-specific DAT field.

CDASH: 15-APR-2015

VISITNUM	Visit Numb					Exp
VISIT	Visit Name				r. ISITDY.	Perm
VISITDY	Planned Stu				C in Demographics.	Perm
QSDTC	Date/Time of Finding	Char	ISO 8601	Timing	Date of questionnaire.	Exp

SDTM: 2015-04-15

ADT	Analysis Date	Num		Perm	The date associated with AVAL and/or AVALC in numeric format.
AVISIT					ISIT), derived visit , Endpoint, etc.), or have to map to cord, but it does not mean that the record was analyzed. There are often multiple records for the same subject

ADaM: Integer with Format

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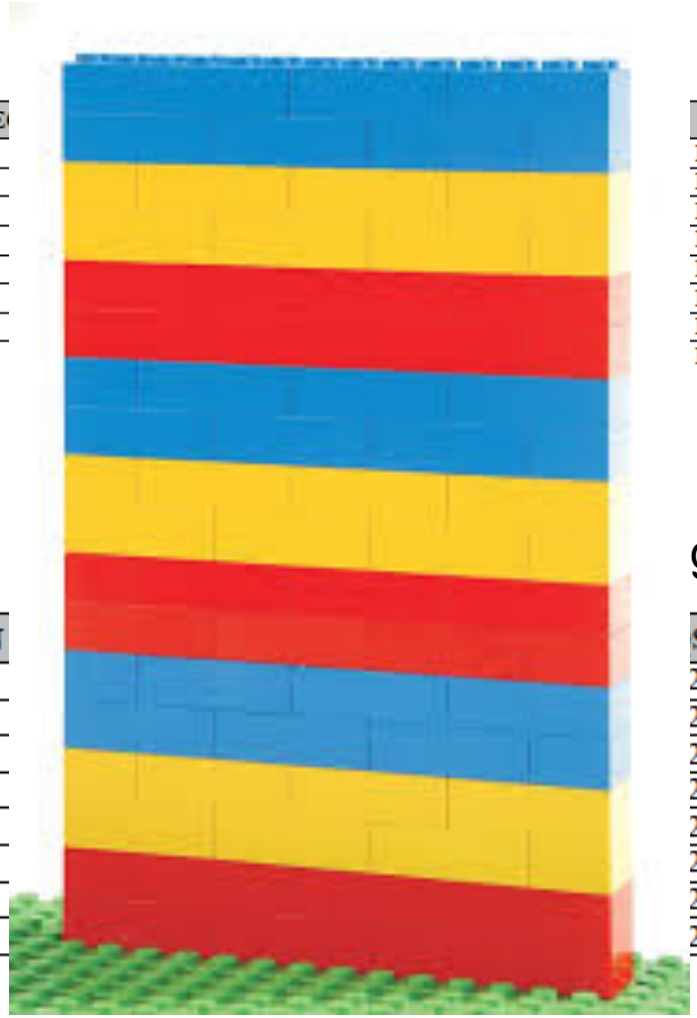
A Tour of a Finding: Record Structures

Identifiers

Row	STUDYID	DOMAIN	USUBJID	QSSE
1	STUDYX	QS	P0001	1
2	STUDYX	QS	P0001	2
3	STUDYX	QS	P0001	3
4	STUDYX	QS	P0001	4
5	STUDYX	QS	P0001	5
6	STUDYX	QS	P0001	6
7	STUDYX	QS	P0001	7
8	STUDYX	QS	P0001	8



Original Results

QSCAT	QSORRES
HAMD 17	Absent
HAMD 17	Self reproach, feels he/she has let people down
HAMD 17	Ideas or gestures suicide
HAMD 17	No difficulty falling asleep
HAMD 17	No difficulty
HAMD 17	No difficulty
HAMD 17	No difficulty
HAMD 17	Complete stupor

Standard Results

Row	QSSTRESC	QSSTRESN
1 (cont)	0	0
2 (cont)	1	1
3 (cont)	3	3
4 (cont)	0	0
5 (cont)	0	0
6 (cont)	0	0
7 (cont)	0	0
8 (cont)	4	4

g

SDTC	QSEVAL	QSEVLINT
2-08-11	INVESTIGATOR	-P1W
2-08-11	INVESTIGATOR	-P1W
2-08-11	INVESTIGATOR	-P1W
2-08-11	INVESTIGATOR	-P1W
2-08-11	INVESTIGATOR	-P1W
2-08-11	INVESTIGATOR	-P1W
2-08-11	INVESTIGATOR	-P1W
2-08-11	INVESTIGATOR	-P1W

Topics or elements may sometimes overlap with healthcare concepts or CDEs, but often at different levels of granularity. CDEs are not typically structured in this way.

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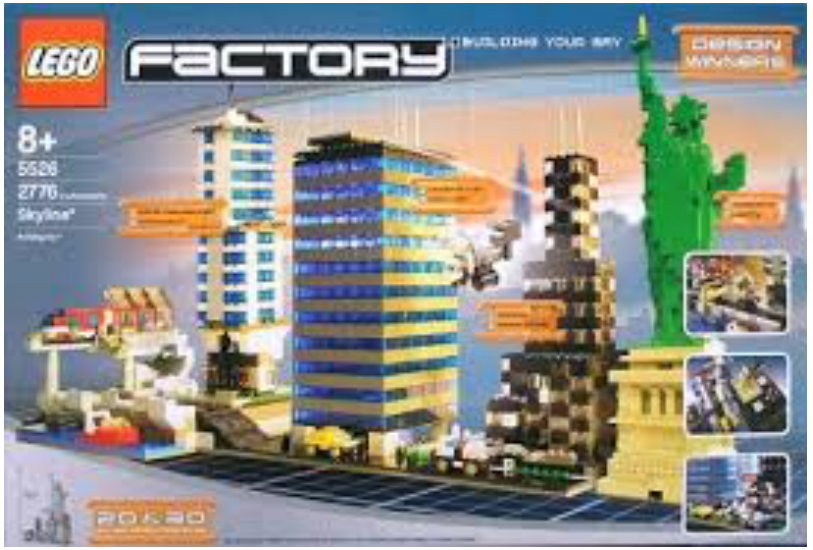
SHARE and End-to-End Standards

What? Protocol	When? SDM	How? CDASH	Where? SDTM	Why? ADaM
PEF	Each Visit	VS CRF Questions	**RS Domain Records**	△ ADEFF BDS From Baseline



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CDISC SHARE

What is SHARE?

CDISC SHARE, a cornerstone of the CDISC technical roadmap, is a global electronic repository for developing, integrating and accessing CDISC metadata standards in electronic format. SHARE is envisioned to help users find, understand and use rich metadata and controlled terminologies relevant to clinical studies more efficiently and consistently, and to improve integration and traceability of clinical data from protocol through analysis.

SHARE Team Still Accepting Volunteers

The SHARE Team is accepting new volunteers to our growing list of participants. There are a number of sub-teams that are either underway or planning to start in the near future. A current **list of sub-**

--Public Review--

ADaM Integration-IADSL v1 Draft
Comments due 10 July 2015

CDISC eSHARE Downloads Now Available for Platinum Members!

If your organization is a Platinum member, please sign in with your organization's email address.

Volunteer for CDISC

SHARE Related Downloads / Links

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SHARE on CDISC Wiki
CDISC SHARE Video
SHARE Requirements (pdf)
2013 International Interchange SHARE Presentation (pdf)

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SHARE

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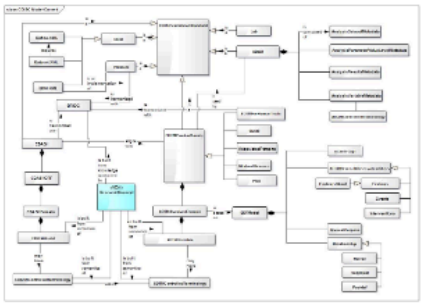
Added by Max Kanevsky, last edited by Julie Chason on May 05, 2015 (view change)



Quick Links

SHARE R3 Progress Report for Q2

SHARE page at CDISC website

eSHARE Downloads (CDISC Platinum Members)

FAQ

Blog

Volunteer for CDISC

Sub-Team Roster

How To: Log SHARE Review Comments in CDISC JIRA

Metadata Listing (Domain Catalog, SUPPQUAL Listing)

SHARE Wiki

Planning

R2 Milestones

SHARE Release 3

Wish List

CDISC Standards: Content and Meeting Notes

SDTM

SEND

ADaM

Therapeutic Area User Guides

Research Concepts

- RC Pilots
- RC Glossary

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Agenda:
Things Old, Things New and Things to Come

- CDISC, Standards and Me
- Foundational Standards
- Therapeutic Area Standards
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- CDISC Standards and You

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Semantic Modeling

2. Conte

CDISC Standards in RDF Reference Guide

Content

Schema

CDISC Standards in RDF Reference Guide

Version 1.0 Final

Prepared by

The PhUSE CS Semantic Technology Working Group

[redacted]

Everything is a Triple

Source: Frederik Malfait

ASTER (Adverse Event Reporting from EHRs)

30 Ambulatory care physicians at Brigham and Women's Hospital with Pfizer, CDISC, CRIX

Nov '08– Jun '09, > 200 Reports Sent to FDA

Physician Reporting:

*91% of participating physicians had submitted no adverse drug event reports in the prior year

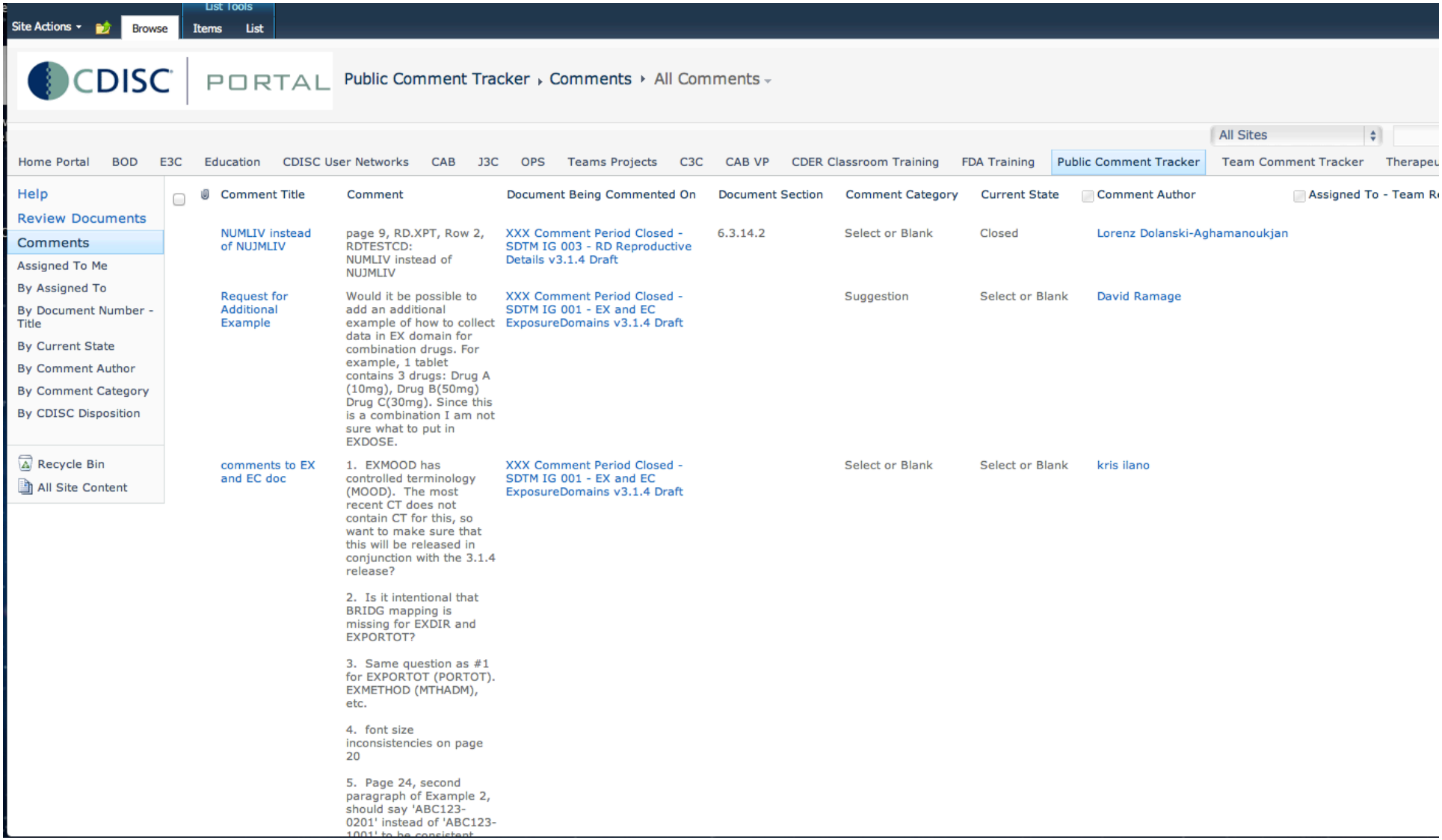
**During the study, participants reported an average of 5 reports in a 3 month time period*

*All participants reported at least 1 adverse event

* Process: *Time to report decreased from ~35 minutes to* ***< 1 min***

* Source: Michael Ibara, Pfizer

Public Comment Tracker – CDISC Needs You!



CDISC Wiki Spaces People Calendars Create

Dashboard

Welcome to CDISC Wiki

CDISC Wiki contains information relevant to CDISC standards and the activities of CDISC standards development teams. Please get involved and add your voice to the CDISC Community toward the advancement and increased use of CDISC standards worldwide. Volunteer Today!

2014 CDISC INTRAChange 25-27 February

2014 CDISC INTRAChange 25-27 February Home

2 Added by Amy Palmer, last edited by Wayne Kubick on Apr 02, 2014 (view change)

2014 CDISC Winter IntraChange: *Learn, Meet, Interact*

Final IntraChange Agenda and Rooms

Spaces Pages Network

Site Spaces

- 2014 CDISC INTRAChange 25-27 February
- Asthma
- CDASH
- CFAST
- CFAST TAPSC
- Define.xml

Popular | All Updates | Favourite Spaces | Network

Gary Walker
SDTM Rule Discussion Items
Updated 17 minutes ago (view change)

Alana St. Clair
2014-03-24 Terminology - CFAST PM Meeting Notes
Updated about an hour ago (view change)

John Glover
Re: CFAST TA Program Status Table
John updated notes section for LLD. 4 clinical experts to 3 and DB search date from 17Mar14 to week of 31Mar14.
Commented about 4 hours ago
CFAST TA Program Status Table
Updated about 4 hours ago (view change)

Anthony Chow
Installing SOA Rich Clients
Updated Mar 29, 2014 (view change)

Alana St. Clair
2014-03-25 Meeting Notes
Task marked complete
Updated Mar 29, 2014 (view change)
Volunteer Coordination Home

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Upcoming CDISC Education events in China

- Public Training in Guangzhou, China (8-10 Sep)
  - SDTM* & CDASH*
- Public Training in Beijing, China (20-23 Oct)
  - SDTM*, CDASH*, Define-XML, ODM
- Public Training in Shanghai, China (26-29 Oct)
  - SDTM*, CDASH*, Define-XML, ODM

**Course to be taught in Chinese*

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Strength *through collaboration.*

"The true meaning of life is to plant trees under whose shade you do not expect to sit."

-- Nelson Handerson

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