CDISC Standards: Now and to Come

Wayne Kubick
Chief Technology Officer, CDISC

Strength *through Collaboration*

Keynote From Wikipedia, the free encyclopedia

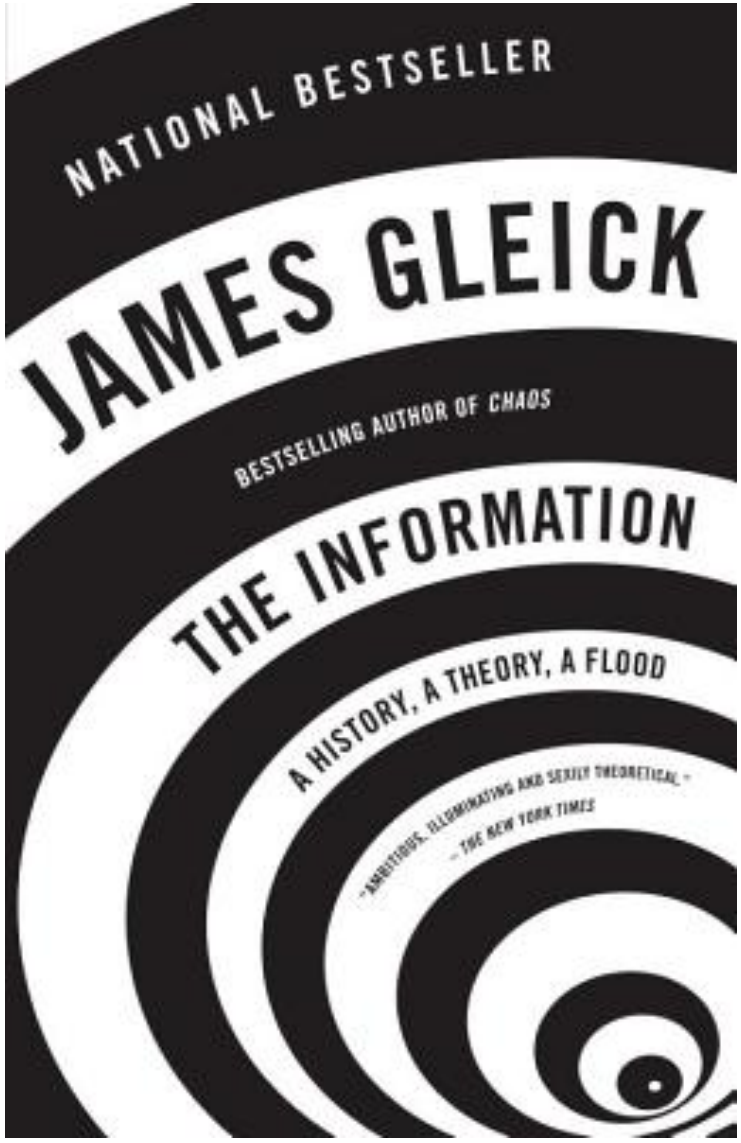
"A keynote is a talk that **establishes the main underlying theme**. The keynote lays the framework for the following programme of events or convention agenda.

Keynote speakers are often selected to raise interest in a particular event, and draw attendees to attend that program. Selecting a keynote speaker who is well known for his or her expertise in a particular field, or who has wide name recognition due to other accomplishments, **will probably raise enthusiasm** among prospective attendees for a meeting or conference.

The term *key note* comes from the practice of *a cappella*, often barbershop singers playing a note before singing. The note played determines the key in which the song will be performed."

"See how to apply SAS specifically to the challenges of the pharmaceutical and healthcare industry, understand issues related to FDA regulatory compliance, and explore emerging industry standards like CDISC, SDTM, and ADaM."

CDISC Standards Now



"First things first, but not necessarily in that order."

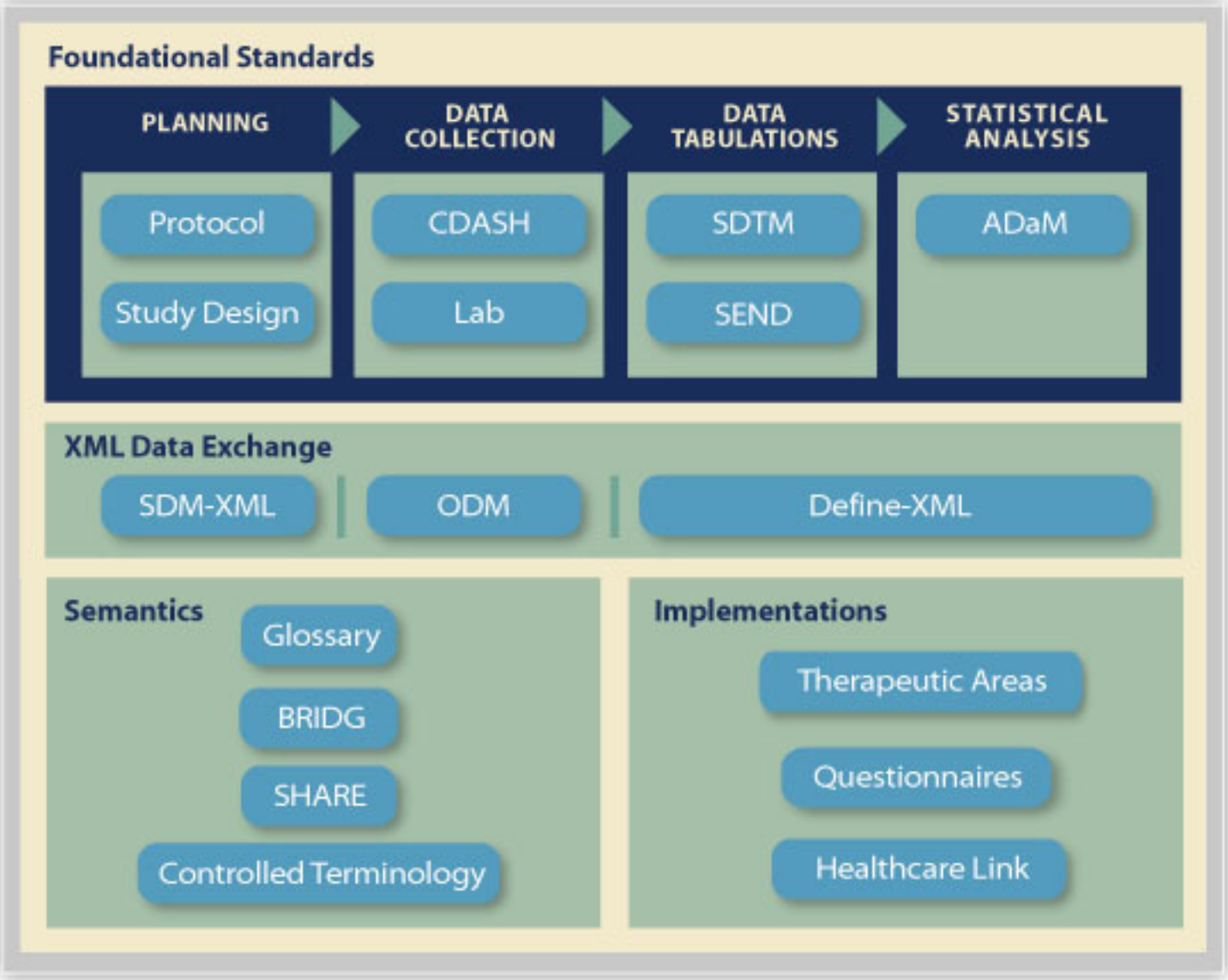
-- Dr. Who

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
- Coordinating Committees in Europe, Asia
  - Participants from > 90
- Standards freely available.

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

The CDISC Standards Guide



1-Click Standards

Pain v1	Provisional	August 7, 2012
Parkinson's Disease	Provisional	December 18, 2012
Polycystic Kidney Disease	Review Closed	November 30, 2012
Tuberculosis v1	Provisional	June 29, 2012
Virology	Provisional	December 6, 2012

Questionnaire	Version	Short Name (QSCAT)	Permission	Release Date
Alzheimer's Disease Assessment Scale - Cognitive (ADAS-Cog)	V1.0	ADAS-COG	Granted	January 26, 2012
Brief Pain Inventory-Interference Scale - Short Form (BPI-I)	V1.0	BPI SHORT FORM	Granted	
Brief Pain Inventory-Interference Scale (BPI-I)	V1.0	BPI	Granted	August 7, 2012
Brief Psychiatric Rating Scale-Anchored (BPRS-A)	V1.0	BPRS-A	Public Domain	January 29, 2013
Clinical Global Impression (CGI)	V1.0	CGI	Public Domain	August 7, 2012
Columbia Suicide Severity Rating Scale - Baseline	V1.0	C-SSRS BASELINE	Granted	August 7, 2012

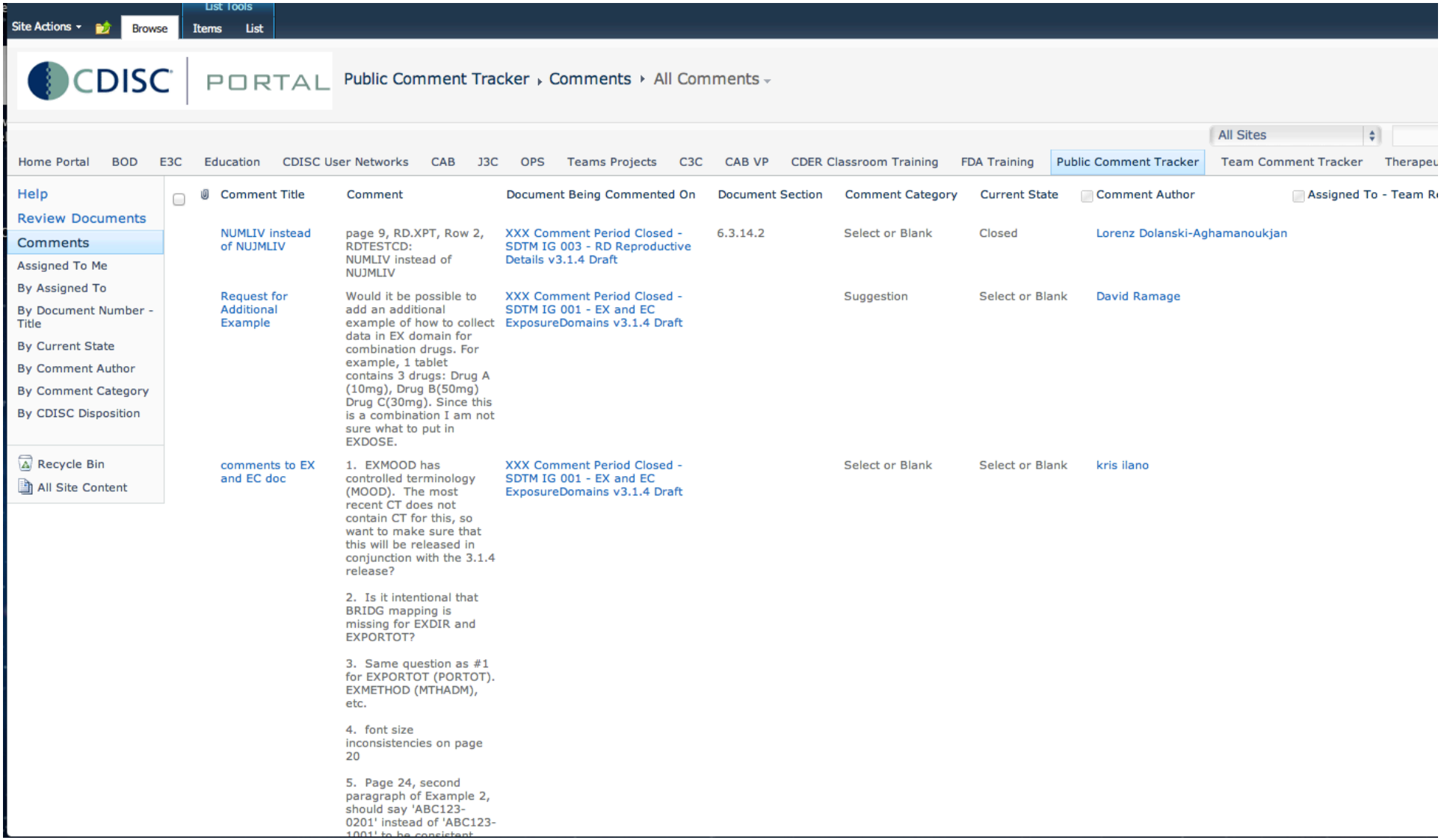
Key Technical Initiatives for 2013

- Communicate updated tech plan, roadmap, status
- Improve integration and cooperation across teams – host Intra-Changes
- Make SHARE real and sustainable
- Improve online collaboration tools for standards teams
- Improve involvement of global volunteers
- Still more transparency:
  - Publish new charters
  - Maintain schedule of milestones
  - Improve project tracking info
- Improve processes
  - Rollout new standards process, tools, training
  - Expand Stds Review Council
  - Appreciate volunteers
- Coordinated new versions of foundational standards (SDTM)
- Make CFAST succeed

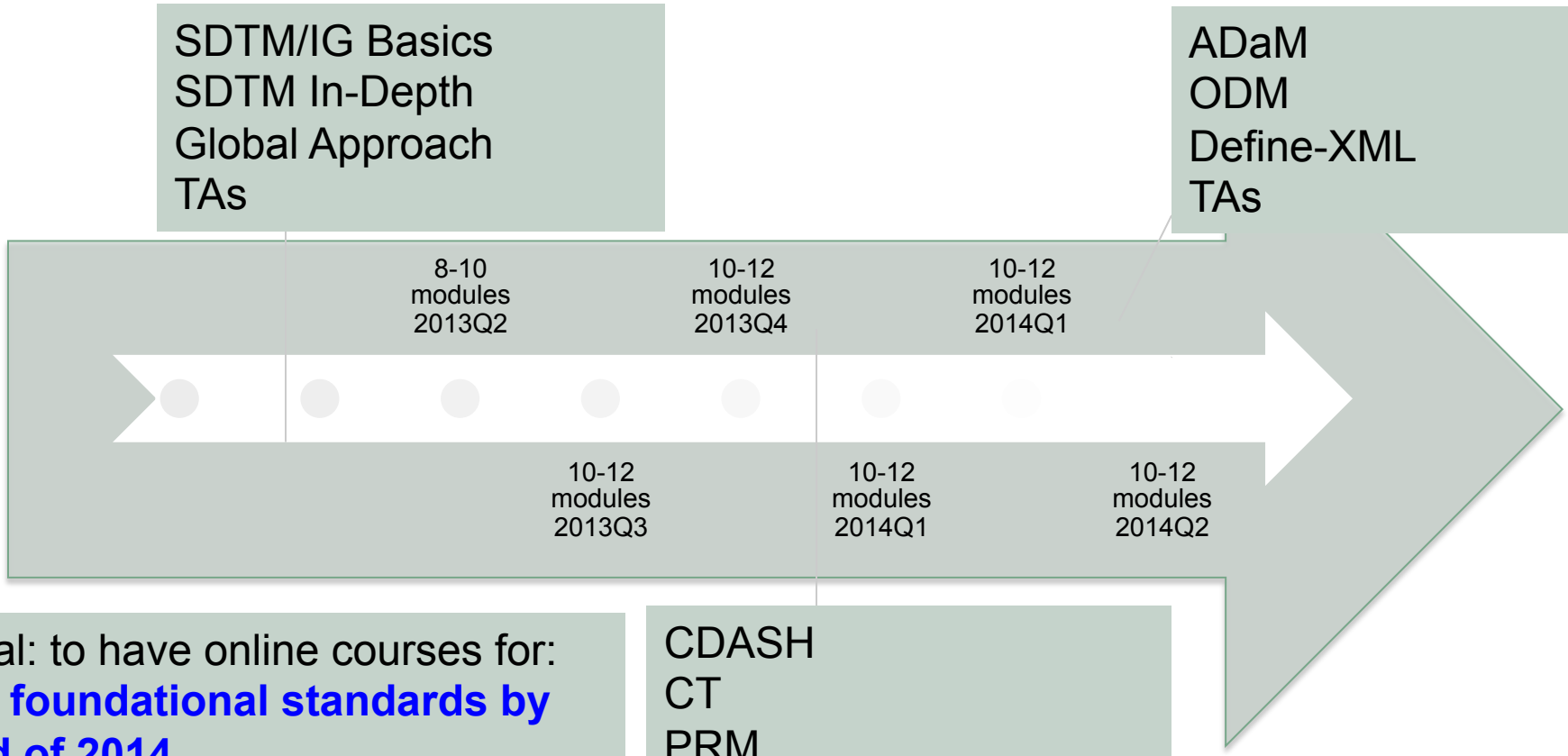
The CDISC Standards Review Council

- Reviews all standards prior to posting for comment or provisional or final use
- Verifies quality, completeness, and harmonious consistency with existing standards
- Provide input and advice on new initiatives or on issues escalated from teams as requested
- Meets biweekly; Chaired by CTO

Public Comment Tracker – CDISC Needs You!

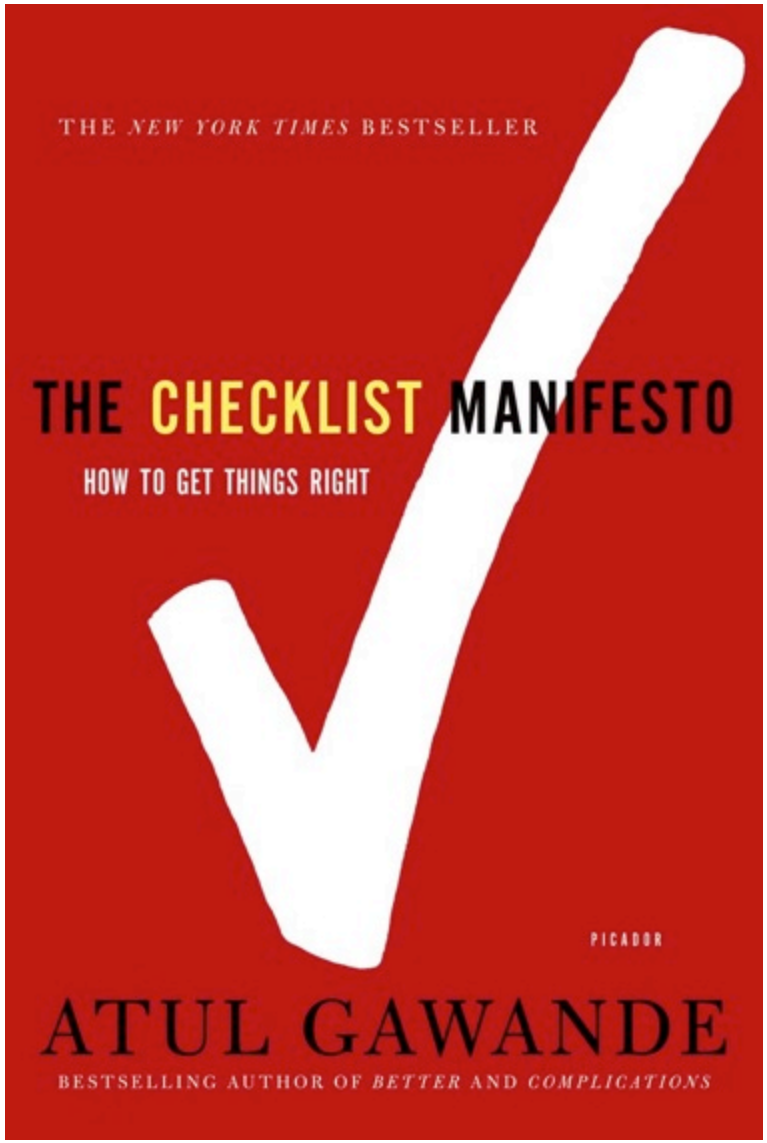


Proposed Online Course Release Schedule



Goal: to have online courses for:
- **all foundational standards by end of 2014**
- **all TAs** (ongoing as they go into production)

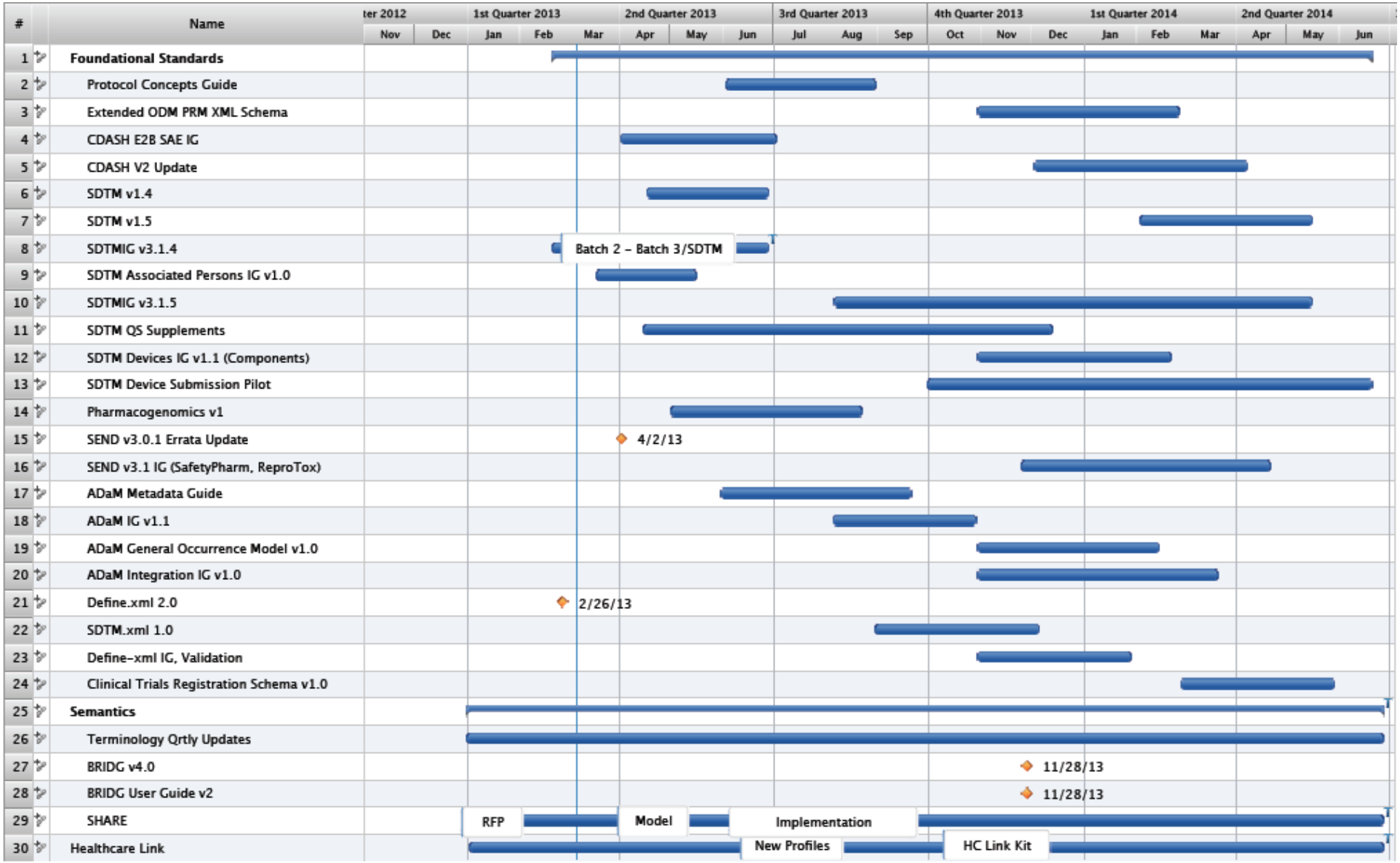
CDISC Standards to Come



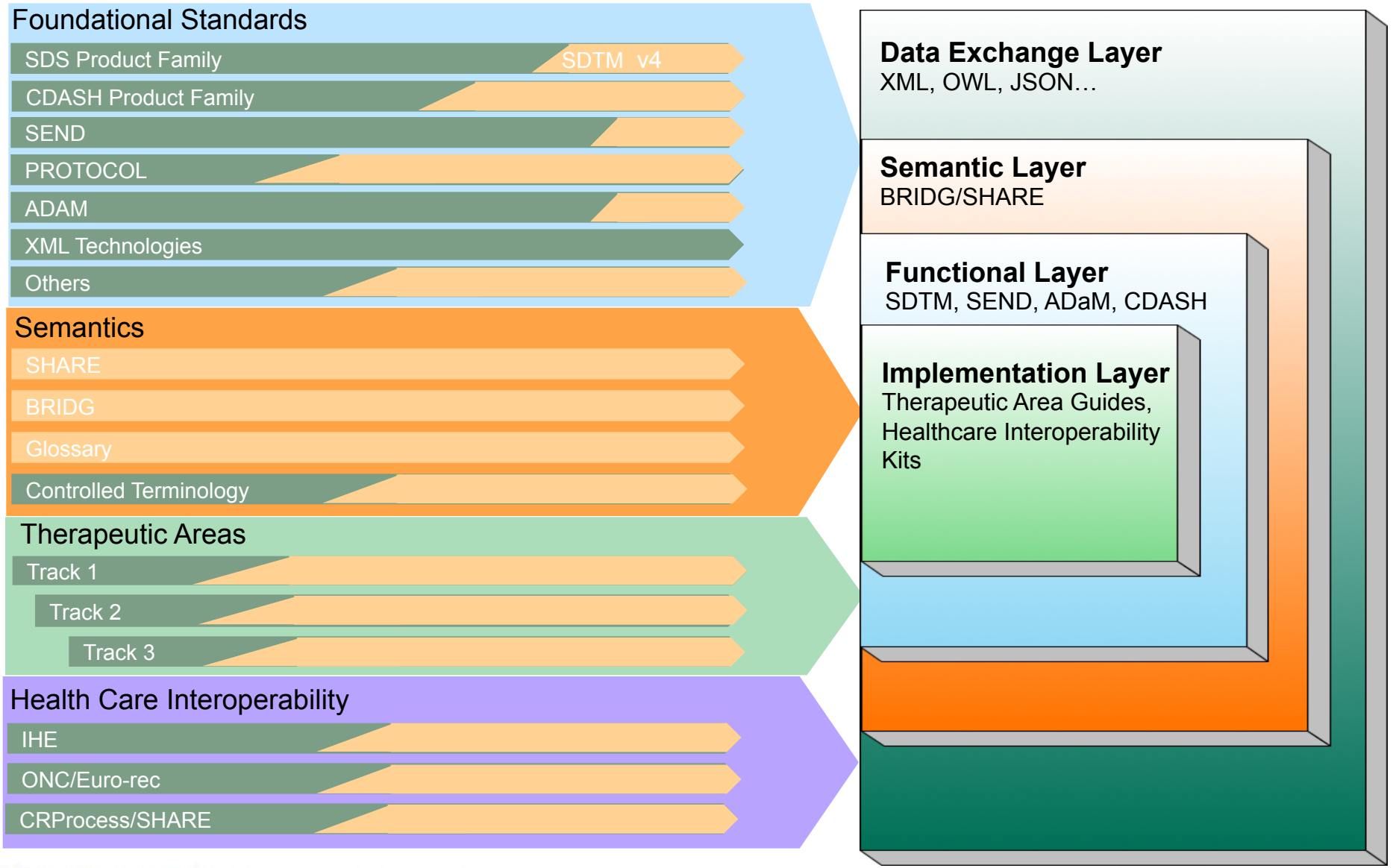
"If we don't change direction soon, we'll end up where we're going."

-- Professor Irwin Corey

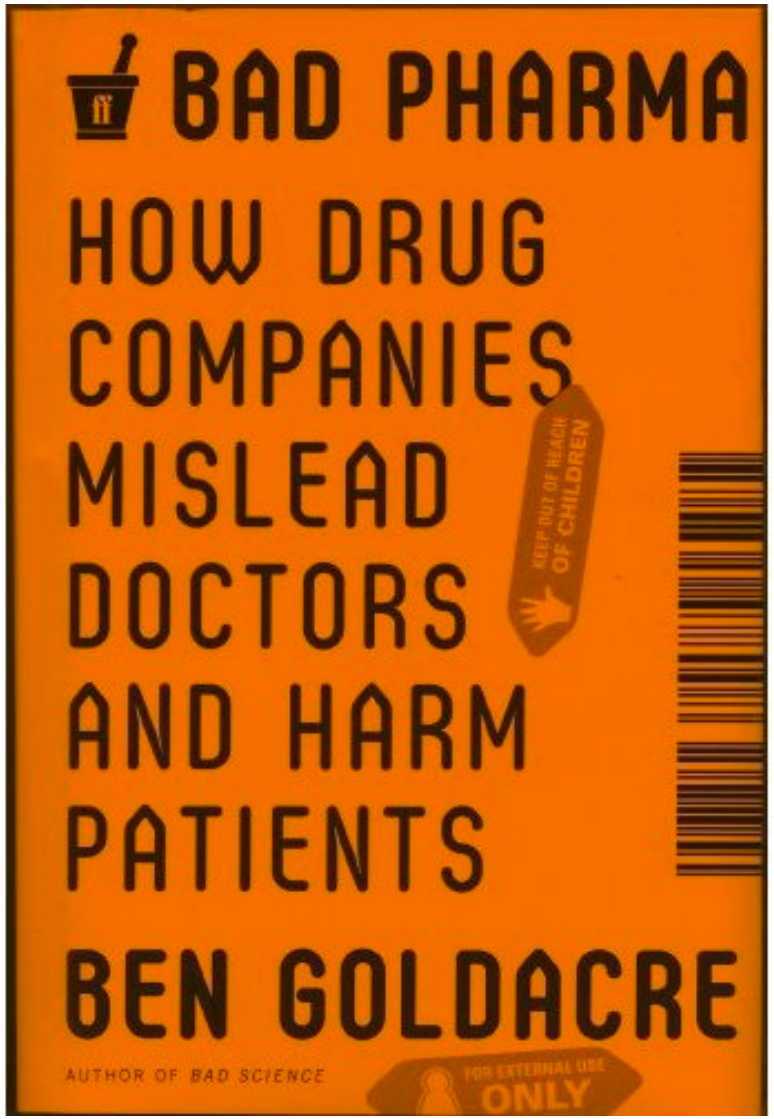
2013 CDISC Technical Plan – Foundational Standards



CDISC Technical Roadmap



Data Transparency & Accessibility



”Somebody has to do something, and it’s just incredibly pathetic that it has to be us."

-- Jerry Garcia


John Wilbanks: Let's pool our medical data | Video on TED.com
www.ted.com/talks/john_wilbanks_let_s_pool_our_medical_data.html
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When you're getting medical tr
medical testing, privacy is impo
what researchers can see and
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-- by anyone seeking to test a h
Wilbanks wonders if the desire
slowing research, and if openir
lead to a wave of health care ir
Imagine the discoveries that cc
pool of freely available health a
Wilbanks is working to build it.
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EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Access to clinical-trial data and transparency

Workshop report

An agency of the European Union

Agency moves towards proactive publication of clinical-trial data

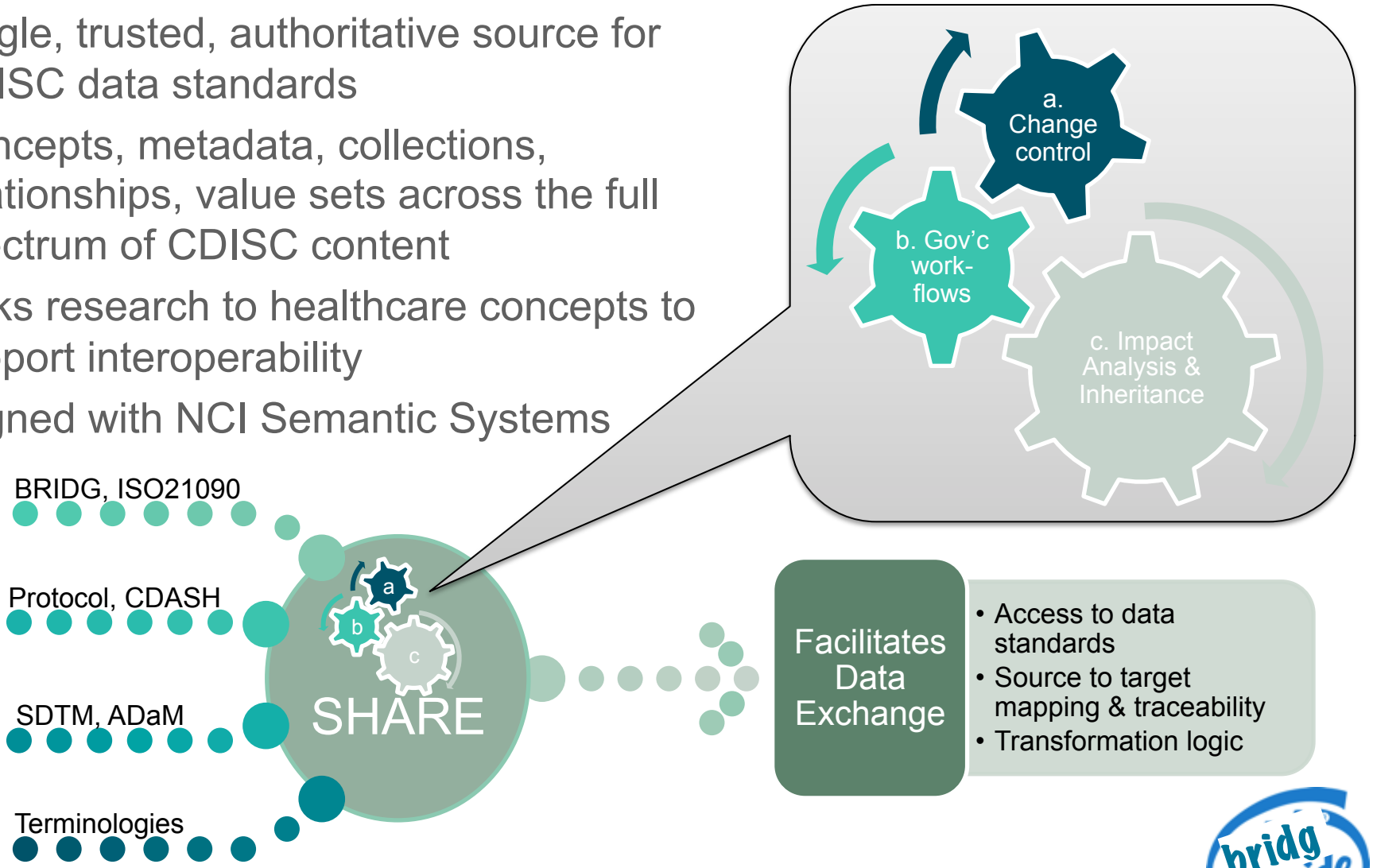
Across Europe, regulators and governments are turning their attention towards a key healthcare issue – the transparency of clinical trials, in particular the release and withholding of data.

CDISC

CDISC SHARE

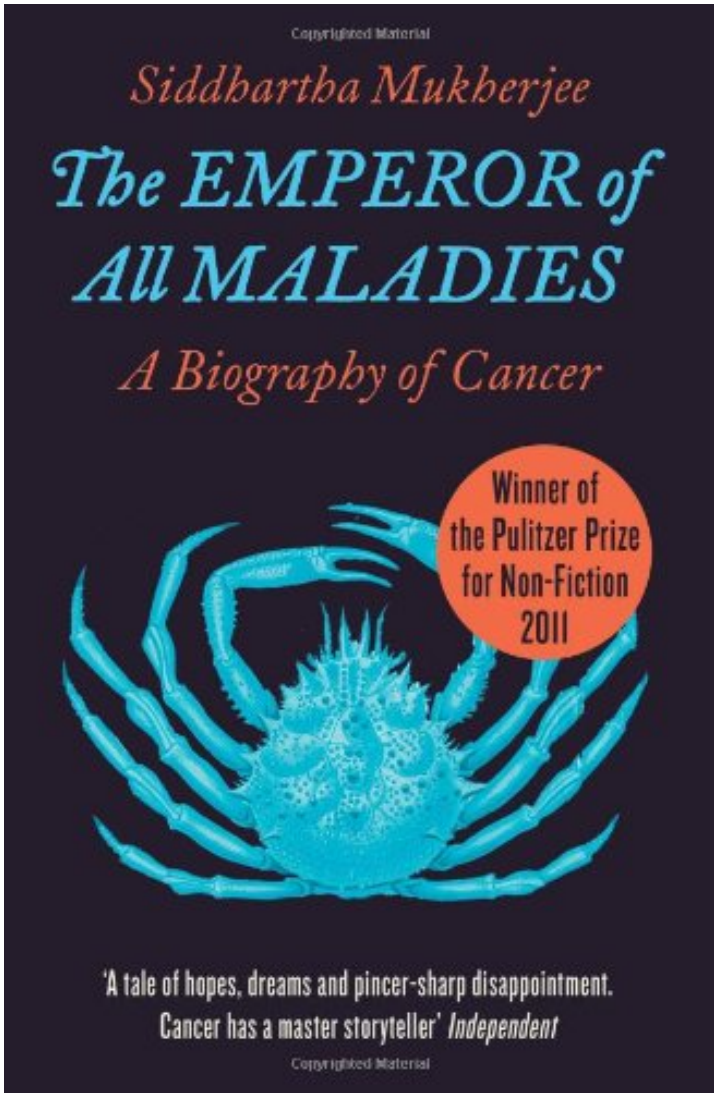
SHARED HEALTH AND CLINICAL RESEARCH ELECTRONIC LIBRARY

- Single, trusted, authoritative source for CDISC data standards
- Concepts, metadata, collections, relationships, value sets across the full spectrum of CDISC content
- Links research to healthcare concepts to support interoperability
- Aligned with NCI Semantic Systems



Adapted from Source by Sue Dubman, Sanofi-Aventis

CDISC, CFAST & Therapeutic Area Standards



"The art of medicine consists in amusing the patient while nature cures the disease."

--Voltaire

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DEADLIEST DISEASES

COULD BE PREVENTED

OR CURED BY

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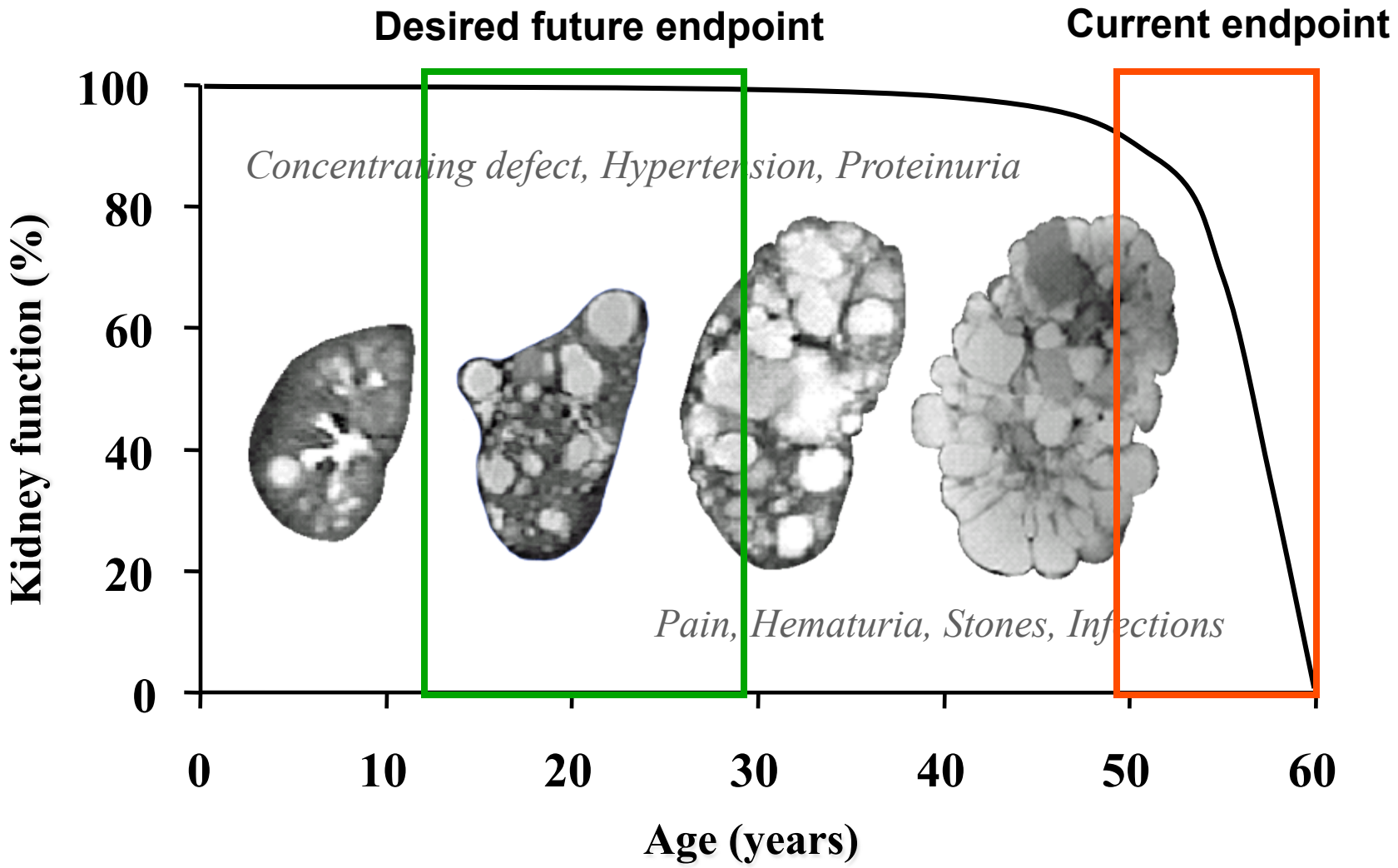
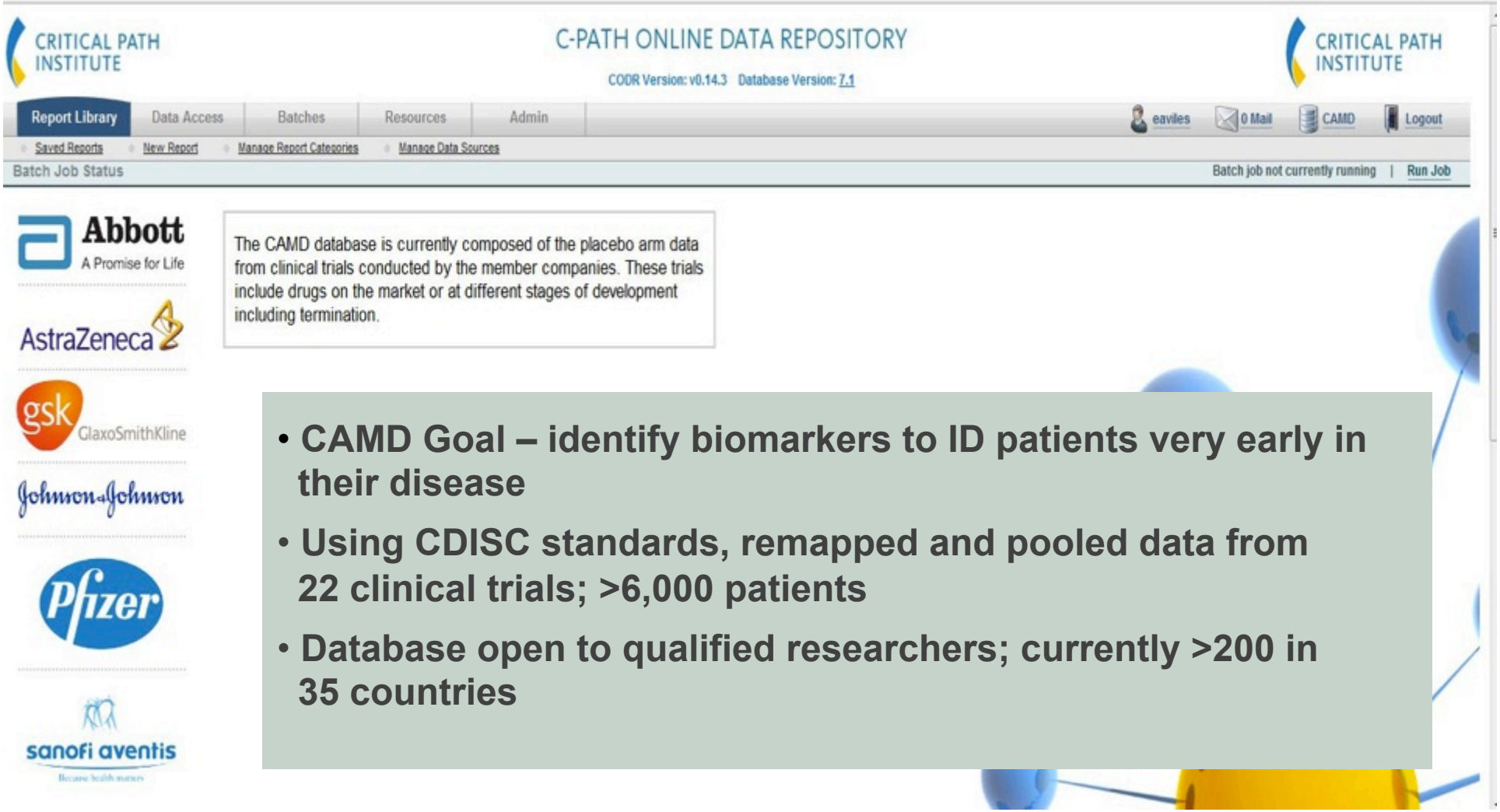
THE MOVEMENT
DO IT
285
I DO IT FOR HUMANS
I DO IT FOR SONIA SAULNIER
I DO IT FOR PHOEBE AND RICHARD
DO IT FOR MY FRIENDS
I DO IT FOR MY FRIENDS AND FAMILY
I DO IT FOR ALL OF US
I DO IT FOR FAMILY
I DO IT FOR ALEX AND JACOB
I DO IT FOR MY GIRLS
I DO IT FOR DAD
I DO IT FOR MY FAMILY
I DO IT FOR THAT GUY
I DO IT FOR SLIM
I DO IT FOR MY FAMILY
I DO IT FOR KARA BELLE
I DO IT FOR HUMANKIND
DO IT FOR LOVE
I DO IT FOR AYAN
I DO IT FOR NOAH
I DO IT FOR BOXES OF SQUIRRELS
I DO IT FOR ALL ARAB KIDS
I DO IT FOR PATIENTS
I DO IT FOR MY MOTHER
I DO IT FOR SADIE
I DO IT FOR MY DAUGHTER ZOE
I DO IT FOR SUSHI
I DO IT FOR LYNNE SHERRILL
I DO IT FOR MY DAUGHTERS
I DO IT FOR ANDREW
I DO IT FOR CANCER PATIENTS
I DO IT FOR SARAH BRUBECK
I DO IT FOR MY CHILDREN
I DO IT FOR TO MY CHILDREN
I DO IT FOR MY LOVED

PKD Clinical Use Case



Source: Dr. Ron Perrone PKD Foundation & Tufts Univ.

CAMD Data Repository for Alzheimer's Disease



- CAMD Goal – identify biomarkers to ID patients very early in their disease
- Using CDISC standards, remapped and pooled data from 22 clinical trials; >6,000 patients
- Database open to qualified researchers; currently >200 in 35 countries

FDA PDUFA V goals 2013-2017

Clinical Terminology Standards (Section XII E pg 28):

Using a public process that allows for stakeholder input, FDA shall develop standardized clinical data terminology through o al D goal of completing clinical data terminology and detailed implementation guides by FY 2017.

FDA has defined specific goals for development and use of data standards

http://www.fda.gov/downloads/forindustry/userfees/prescriptiondruguserfee/ucm270412.pdf

Coalition For Accelerating Standards & Therapies

- CFAST is an initiative to accelerate clinical research and medical product development by creating and maintaining data standards, tools and methods for conducting research in therapeutic areas that are important to public health
- With the enactment of FDASIA/PDUFA V, FDA recognized the opportunity to work with CFAST, along with TransCelerate Biopharma and the pharmaceutical industry, to develop therapeutic area data standards.

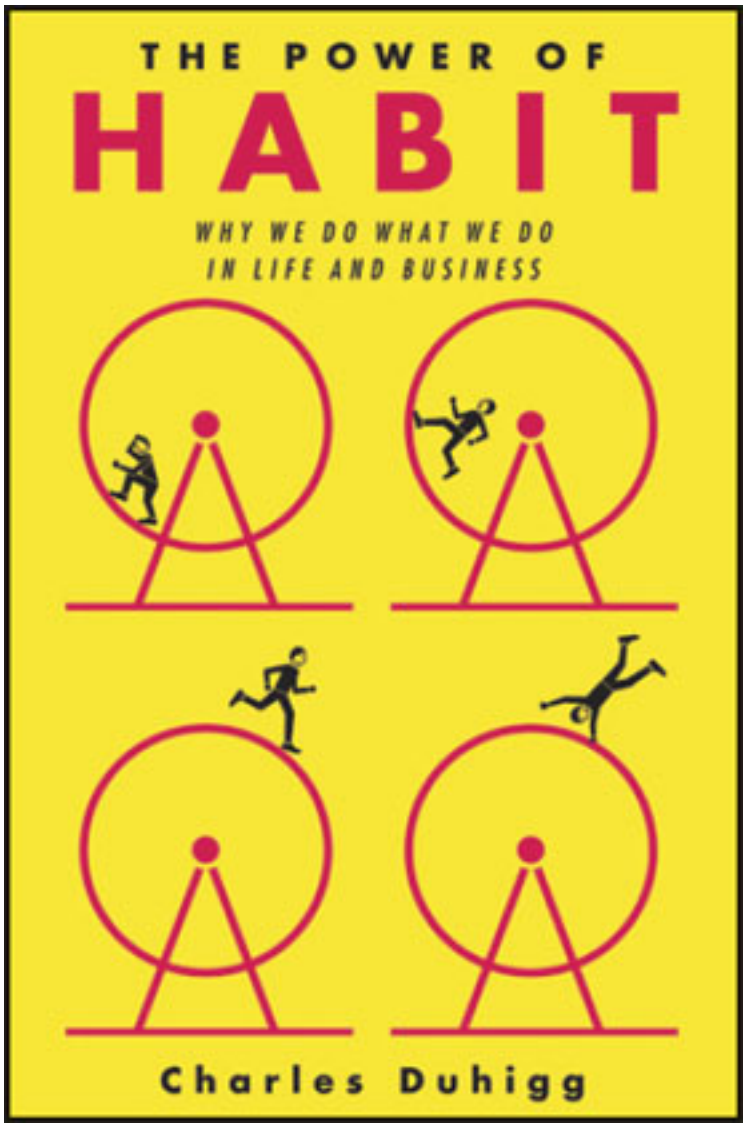
Current Status: Therapeutic data standards

Released Standards 2011-2012	Work in Progress	Planned for 2013
Alzheimer's Disease	Asthma	Traumatic Brain Injury
Pain	Alzheimer's v 1.1	Oncology
Tuberculosis	Multiple Sclerosis	Schizophrenia
Virology	Cardiovascular	Virology v2 – Hepatitis C
Parkinson's Disease	Diabetes	
Polycystic Kidney Disease		

Therapeutic Area Standards: Baseline Content

- Mindmap/model of disease area clinical concepts
- Essential core data elements with definitions, data types (simple & ISO 21090), BRIDG and SDTM mappings
- SDTM domains and examples
- Minimum value sets (code lists) with definitions and c-codes
- User/Implementation Guide with permissions statement
- Standard CDASH CRFs with SDTM annotations, as appropriate
- Ideally, ADaM Analysis model examples (e.g., ADSL)
- Possibly study design models, SEND examples, etc.

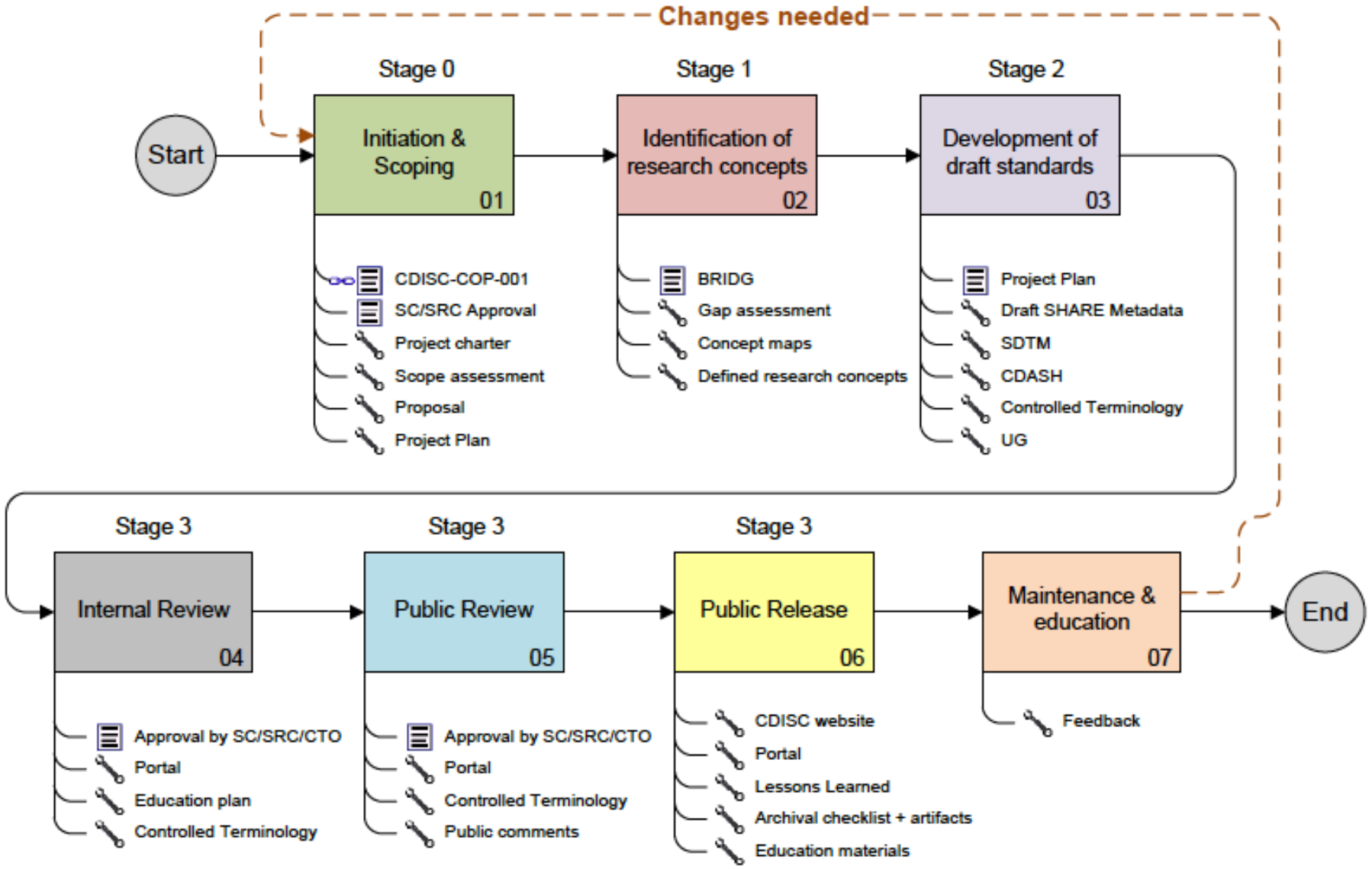
Developing CDISC Standards



”Mustard’s no good without roast beef.”

-- Chico Marx

A New Process



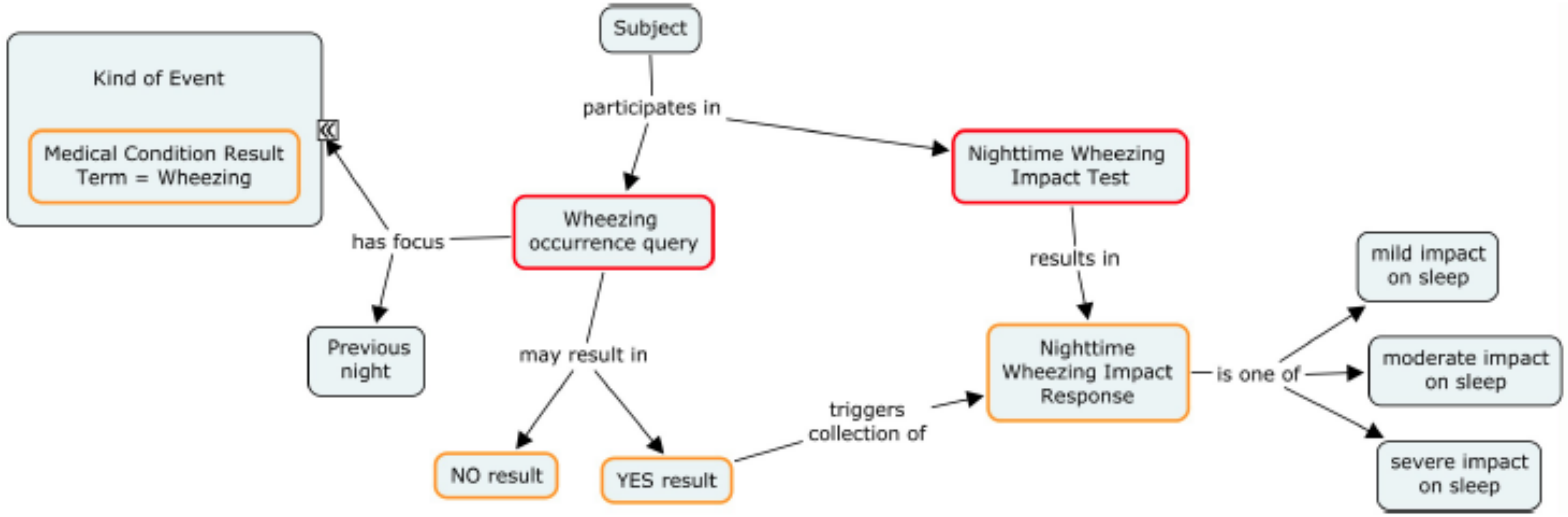
Asthma User Guide Example

5 Symptom Assessment

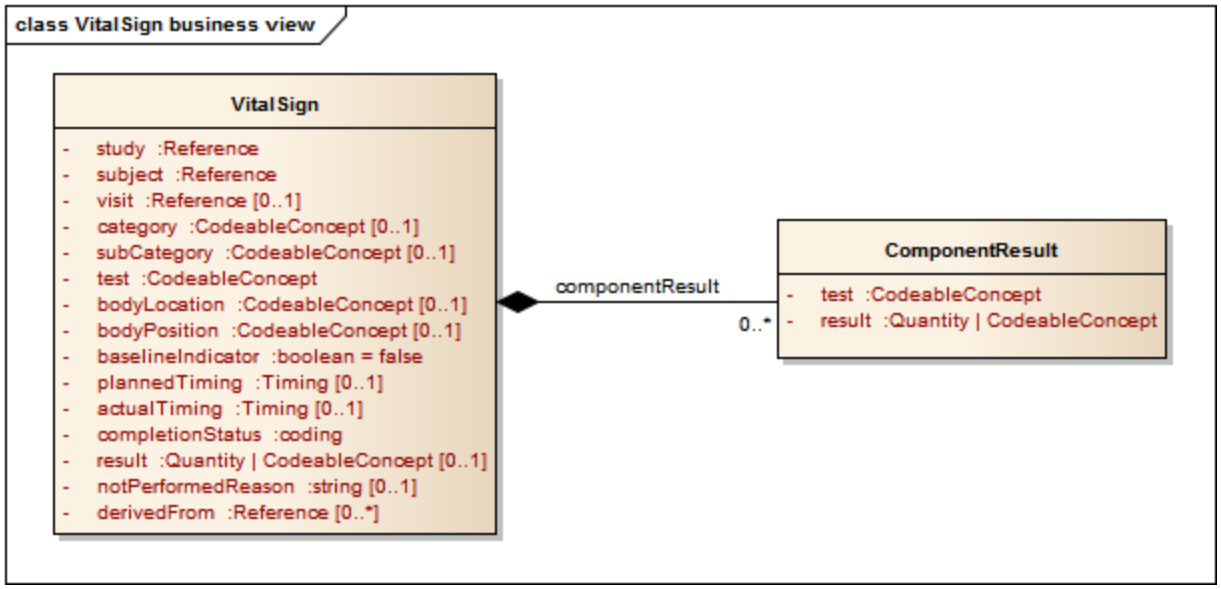
Asthma symptoms can present in various forms. The most common symptoms of asthma are wheezing, cough, breathlessness, chest tightness and night time awakenings. These symptoms are often assessed using validated instruments as described in the section on Patient Reported Outcomes. They may also be described using sponsor-defined Likert scales or visual analog scales.

Symptom	Closest MedDRA LLT	MedDRA Preferred Term
Wheezing	Wheezing	Wheezing
Cough	Cough	Cough
Breathlessness	Breathlessness	Dyspnoea
Chest tightness	Chest tightness	Chest discomfort
Nighttime awakening	Nocturnal awakening	Middle Insomnia

Data typically collected for asthma symptoms include the focal time period and the subject's rating of symptom severity or symptom impact. Occurrence is sometimes combined with severity or impact by including a value of "None" or "Absent" in the set of severity or impact responses.



SHARE Business Template Example for Vital Signs

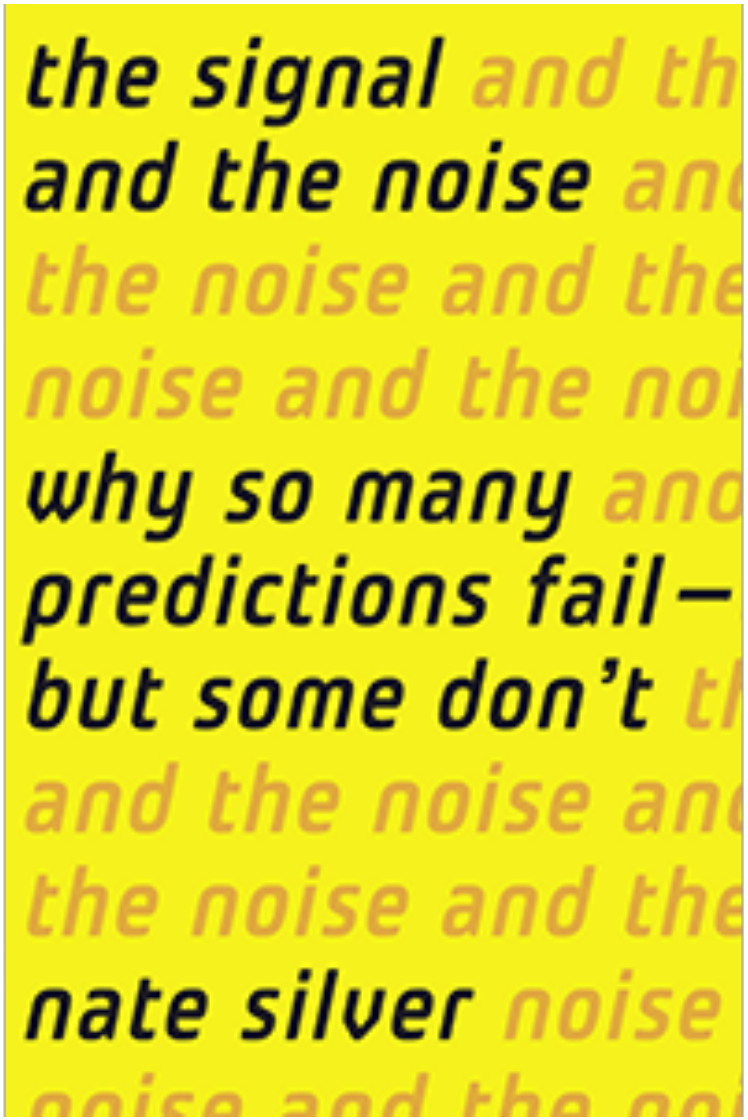


- Helps focus user attention on content rather than model details
- Domain friendly – Do not have to know the BRIDG model
- Do not have to understand the ISO 21090 data types

Target Timelines Under New Process

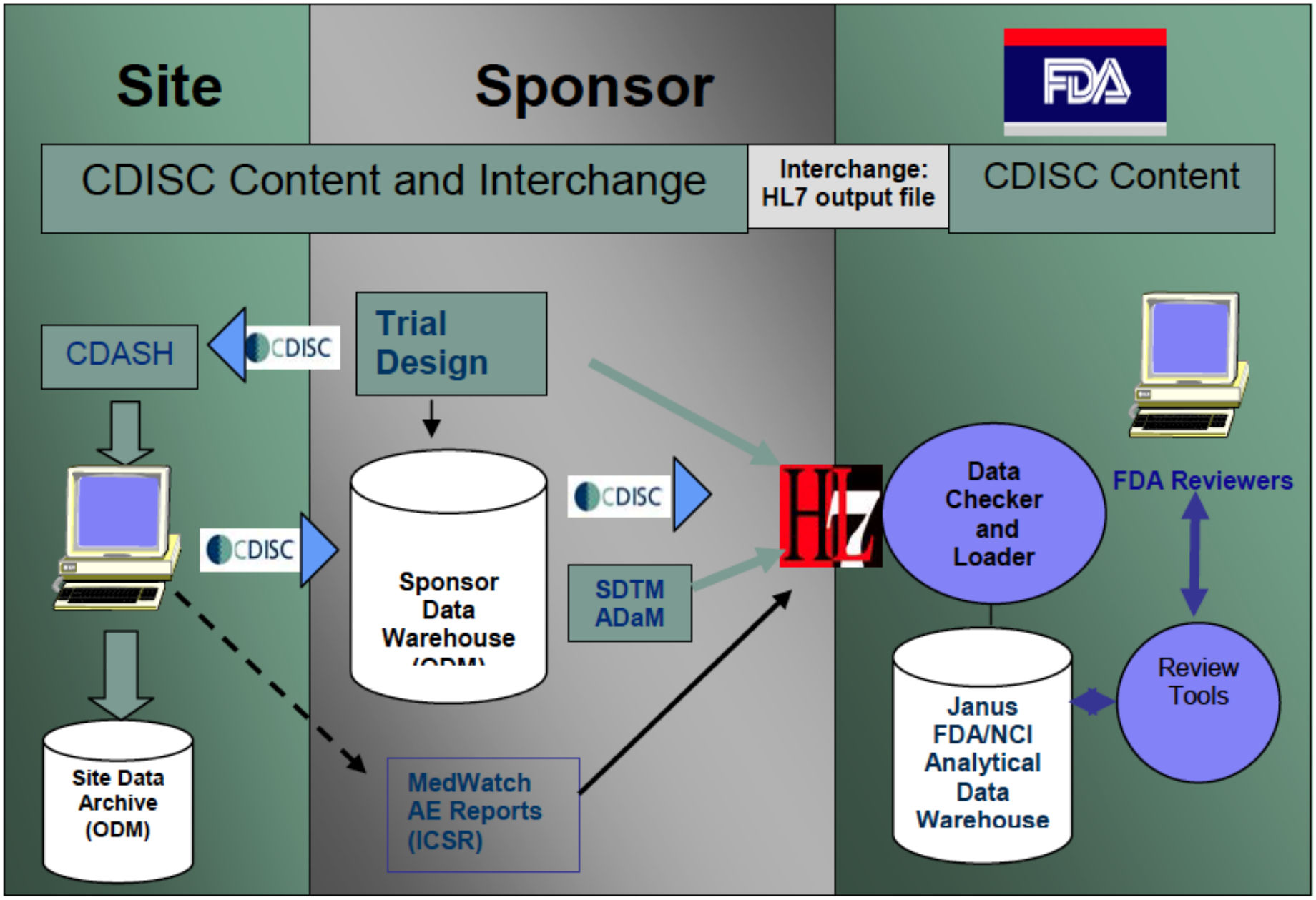
Stage 0	Stage 1	Stage 2	Stage 3		
Scoping, Inputs, Planning	Concept Definition and Modeling	Standards Development (Metadata, Terminology, User Guide, Examples)	Internal Review	Public Review	Publication
Months <1-2	Months 2-4	Months 3-6	Months 6-10+		

CDISC Standards and FDA



"It's not what you *don't* know that gets you in trouble. It's what you *think* you know that just ain't so."

--Mark Twain



Source: FDA PDUFA IV IT Plan

FDA Messages on Standards

- **"The World is Round"**
  - Clinical data are not flat and cannot be exchanged using flat two-dimensional files without significant loss of meaning
- **FDA is transitioning to a "round view of the world" of clinical research**
  - CDISC-HL7 standard will get us there
- **SDTM is here to stay**
  - Will transition from a standard submission format to a standard view of data in support of simple analyses (e.g. distribution, means, etc.)
- But Flat Files Don't Inherently Capture the Tree Structure, which is itself important to understand the data
  - **Better approach: data model that inherently captures relationships at the point of collection and can transmit them.**

Source: Armando Oliva, FDA


U.S. Department of Health & Human Services
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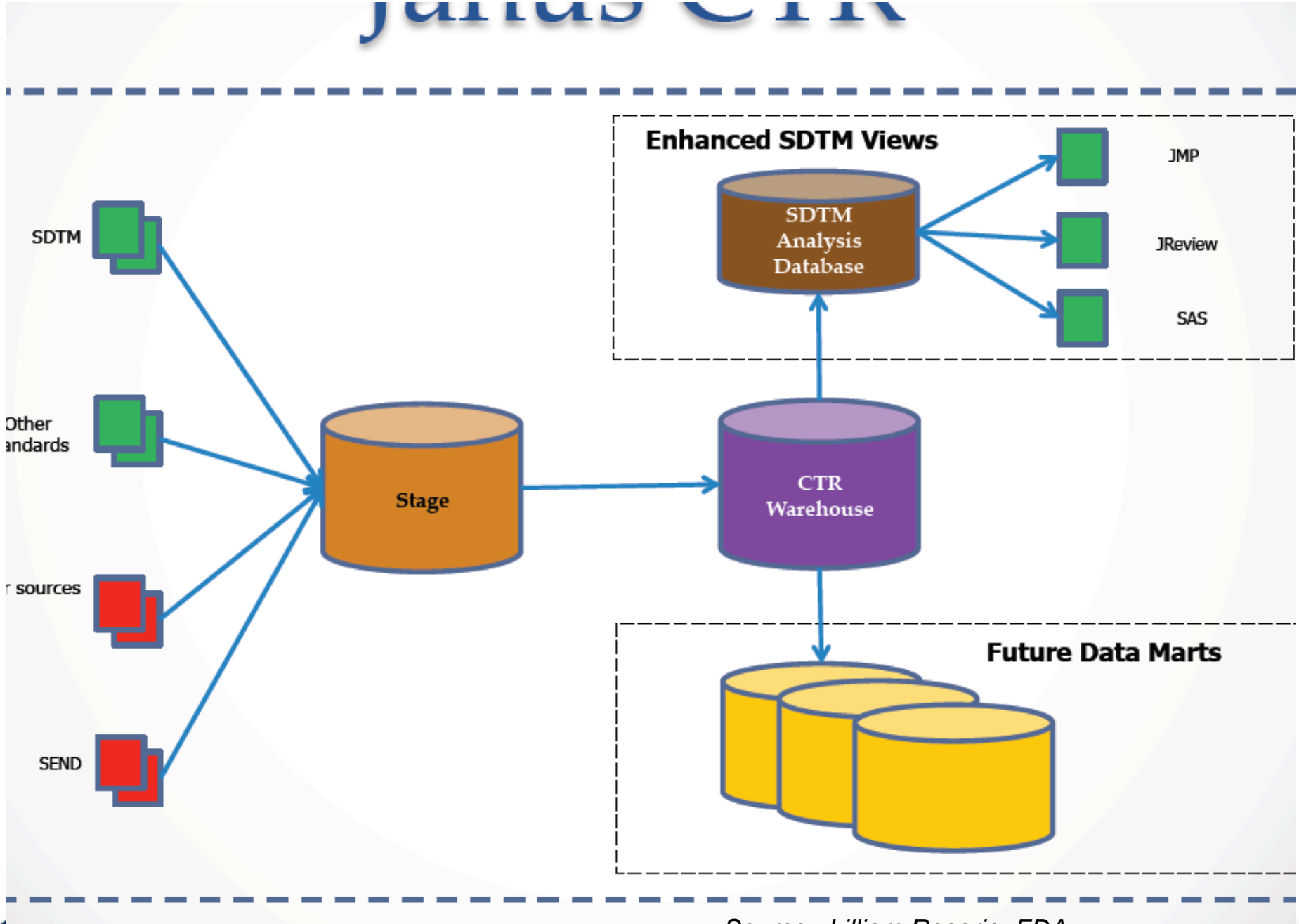
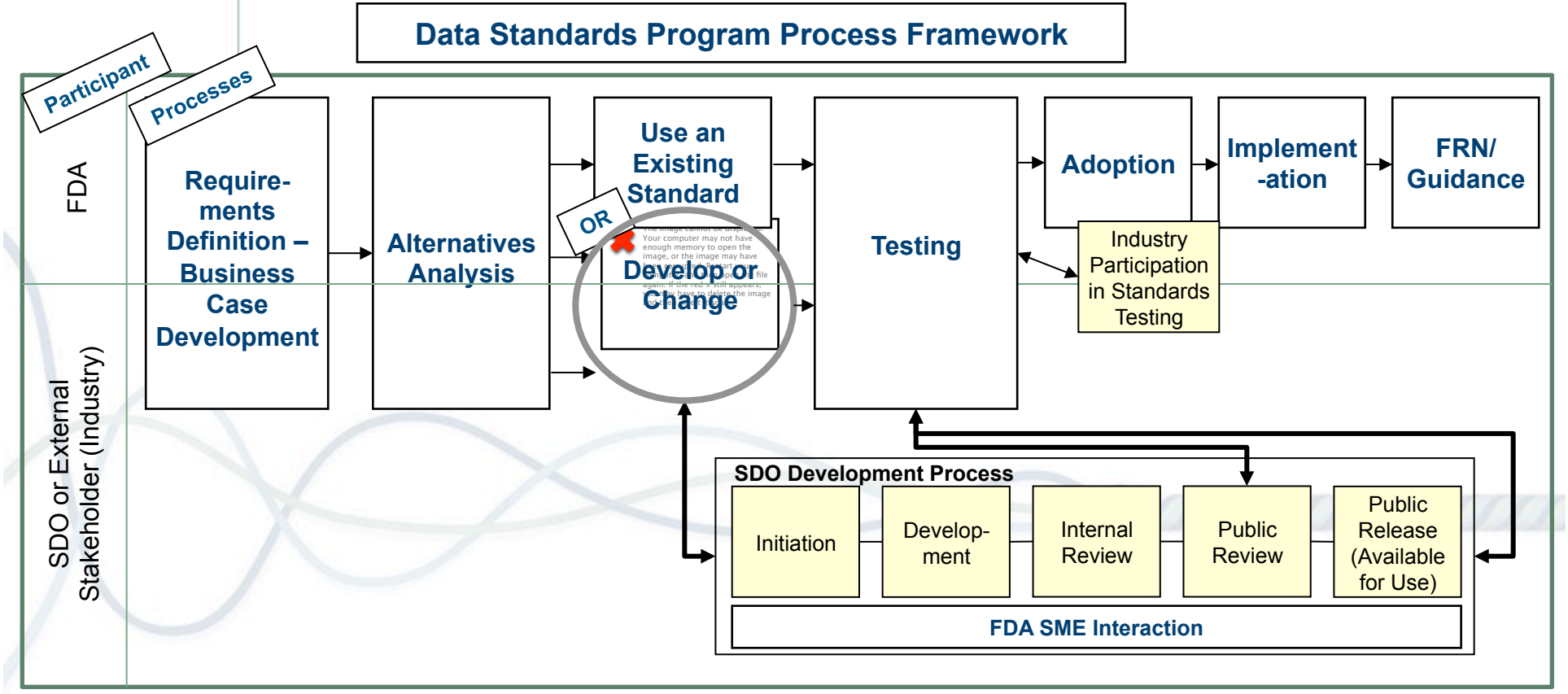
Forms & Submission Requirements
Electronic Submissions to CDER
CDER Data Standards Program
Electronic Common Technical Document (eCTD)
Electronic Regulatory Review
Electronic Regulatory Submissions and Review Helpful Links
Electronic Submissions Presentations
Study Data Standards for Submission to CDER
Data Standards Manual (monographs)
CDER Study Data Standards Research and Development
Study Data Exchange Standards R&D
Over the past few years, CDER has increased its support for standardized study data submissions using CDISC standards, and will continue to do so in the future.
Currently, CDER supports the submission of CDISC content using SAS Transport File version 5.
As adoption of CDISC standards increases in CDER and throughout the regulated industry, we recognize the inherent limitations of using SAS transport files for data exchange. These include:
8-character limitation for variable names
40-character limitation for labels for variables
200-character limitation for character fields
Flat, two-dimensional file structure for what we now recognize is multi-relational, multi-dimensional data
Within our overall drug review modernization efforts, CDER recognizes the need to identify a pathway for moving away from SAS Transport to a more modern, robust, and flexible transport mechanism for CDISC content and certain other study data currently submitted in PDF format.
Ongoing work on the CDISC-HL7 Study Data Standards project indicates that HL7 version 3 xml may be a promising solution for the exchange of study data. The potential benefits include:
No variable or data field size limitations
More multi-relational representation of the data
Ability to transport more content (e.g. unstructured text such as patient narrative information)
Improved harmonization with other HL7 v.3 data standards for healthcare and regulatory information (e.g. Individual Case Safety Report, Regulated Product Submission, Clinical Trials Registry and Results, Clinical Document Architecture)
Improved interoperability with healthcare and other regulatory information systems
In parallel with our ongoing robust CDISC implementation efforts, CDER intends to conduct a Proof of Concept (PoC) and test in a measured, iterative, and incremental fashion the use of HL7 v.3 xml as a possible exchange method for certain use cases. Testing will proceed incrementally for the following use cases:
Submission of Patient Narrative and Clinical Investigator Qualification Information (e.g. FDA Form 1572)
Submission of Structured Protocol Information
Submission of Subject Data
Testing will include an opportunity for interested stakeholders to participate in an open and transparent manner.
Careful evaluation of the test and an assessment of the costs, benefits and impacts of potential migration to a new exchange method—on both FDA and regulated industry-- will be conducted to inform possible next steps. A determination of whether and how to proceed will be based on that thorough evaluation of the pilots and proposals for further development or adoption.
CDER is committed to working throughout the standards development and implementation processes with

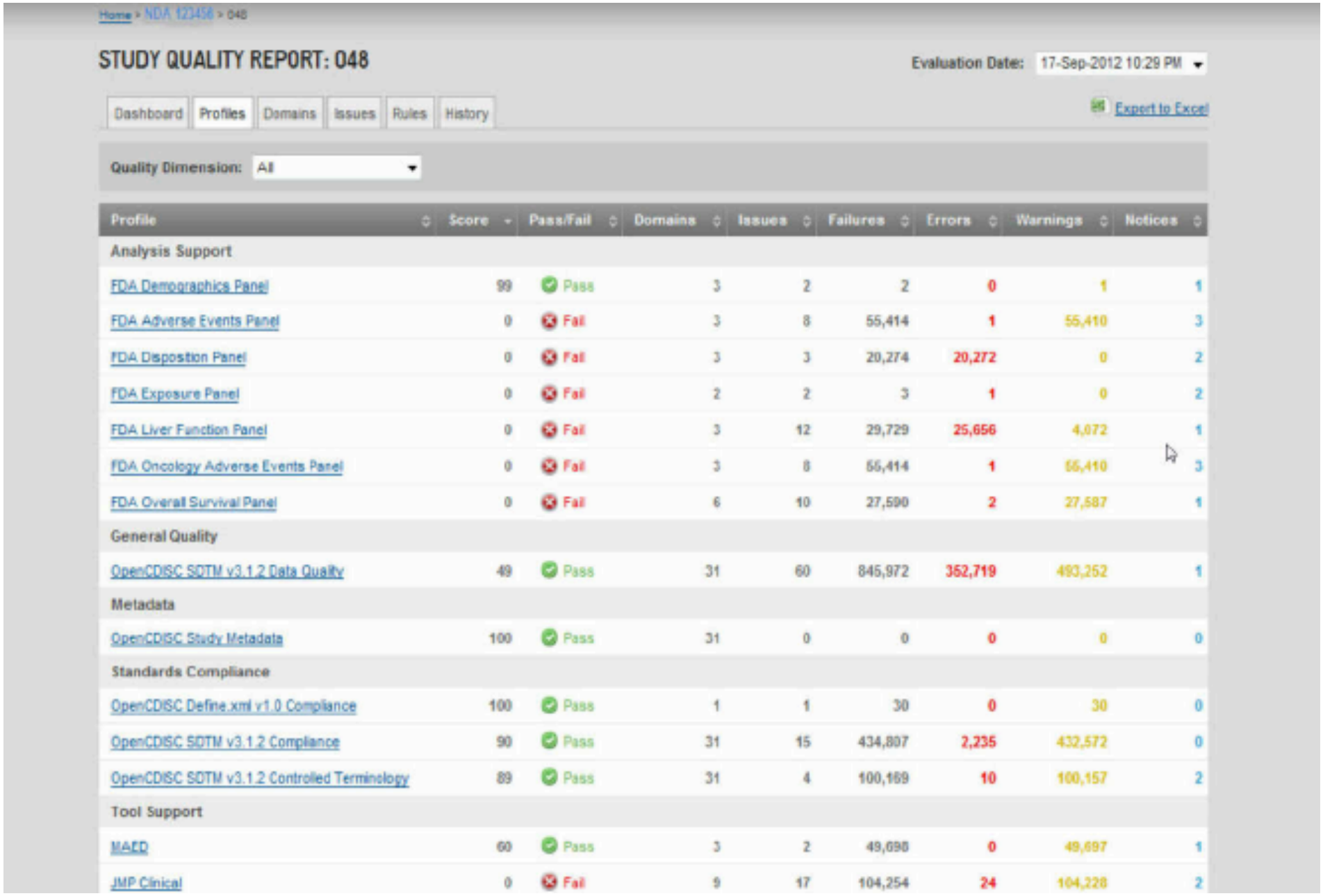


Source: Lilliam Rosario, FDA

CFAST TA SC Meeting – 21 March 2013
Draft FDA Standards Development Process



Source: Mary Ann Slack, FDA



Home > NDA 123456 > 048

STUDY QUALITY REPORT: 048

Evaluation Date: 17-Sep-2012 10:29 PM

Dashboard | Profiles | Domains | Issues | Rules | History

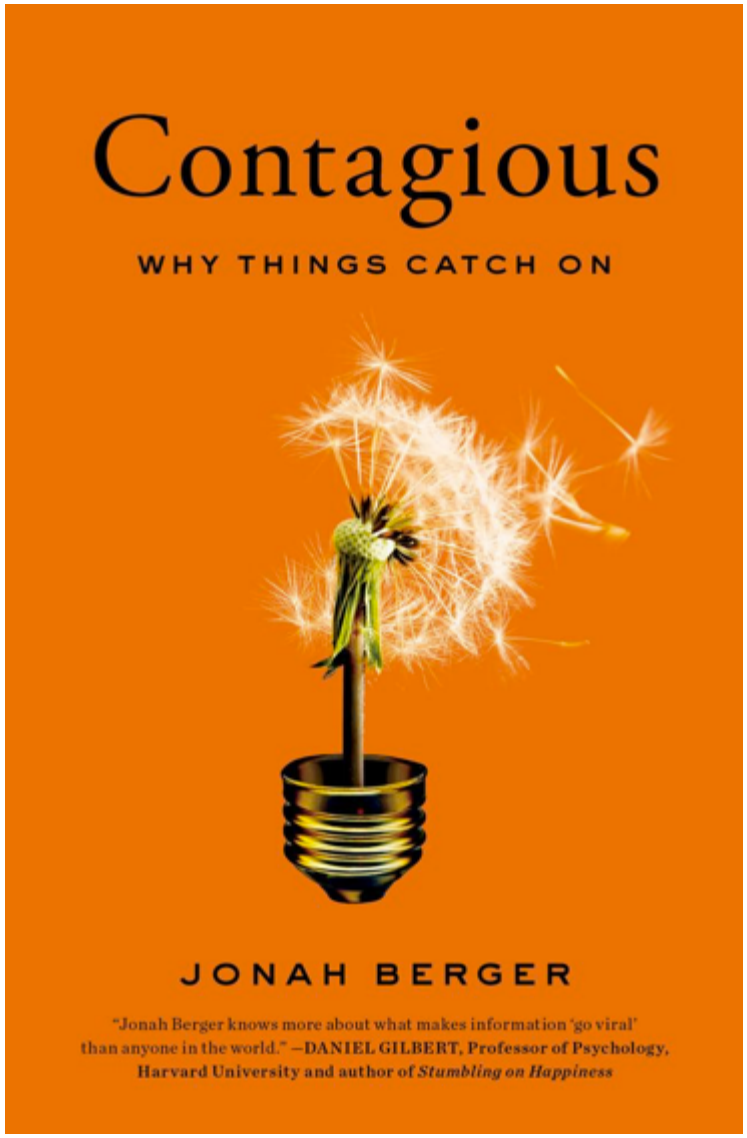
Export to Excel

Quality Dimension: All

Profile	Score	Pass/Fail	Domains	Issues	Failures	Errors	Warnings	Notices
Analysis Support								
FDA Demographics Panel	99	Pass	3	2	2	0	1	1
FDA Adverse Events Panel	0	Fail	3	8	55,414	1	55,410	3
FDA Disposition Panel	0	Fail	3	3	20,274	20,272	0	2
FDA Exposure Panel	0	Fail	2	2	3	1	0	2
FDA Liver Function Panel	0	Fail	3	12	29,729	25,656	4,072	1
FDA Oncology Adverse Events Panel	0	Fail	3	8	55,414	1	55,410	3
FDA Overall Survival Panel	0	Fail	6	10	27,590	2	27,587	1
General Quality								
OpenCDISC SDTM v3.1.2 Data Quality	49	Pass	31	60	845,972	352,719	493,252	1
Metadata								
OpenCDISC Study Metadata	100	Pass	31	0	0	0	0	0
Standards Compliance								
OpenCDISC Define.xml v1.0 Compliance	100	Pass	1	1	30	0	30	0
OpenCDISC SDTM v3.1.2 Compliance	90	Pass	31	15	434,807	2,235	432,572	0
OpenCDISC SDTM v3.1.2 Controlled Terminology	89	Pass	31	4	100,169	10	100,157	2
Tool Support								
MAED	60	Pass	3	2	49,698	0	49,697	1
JMP Clinical	0	Fail	9	17	104,254	24	104,228	2

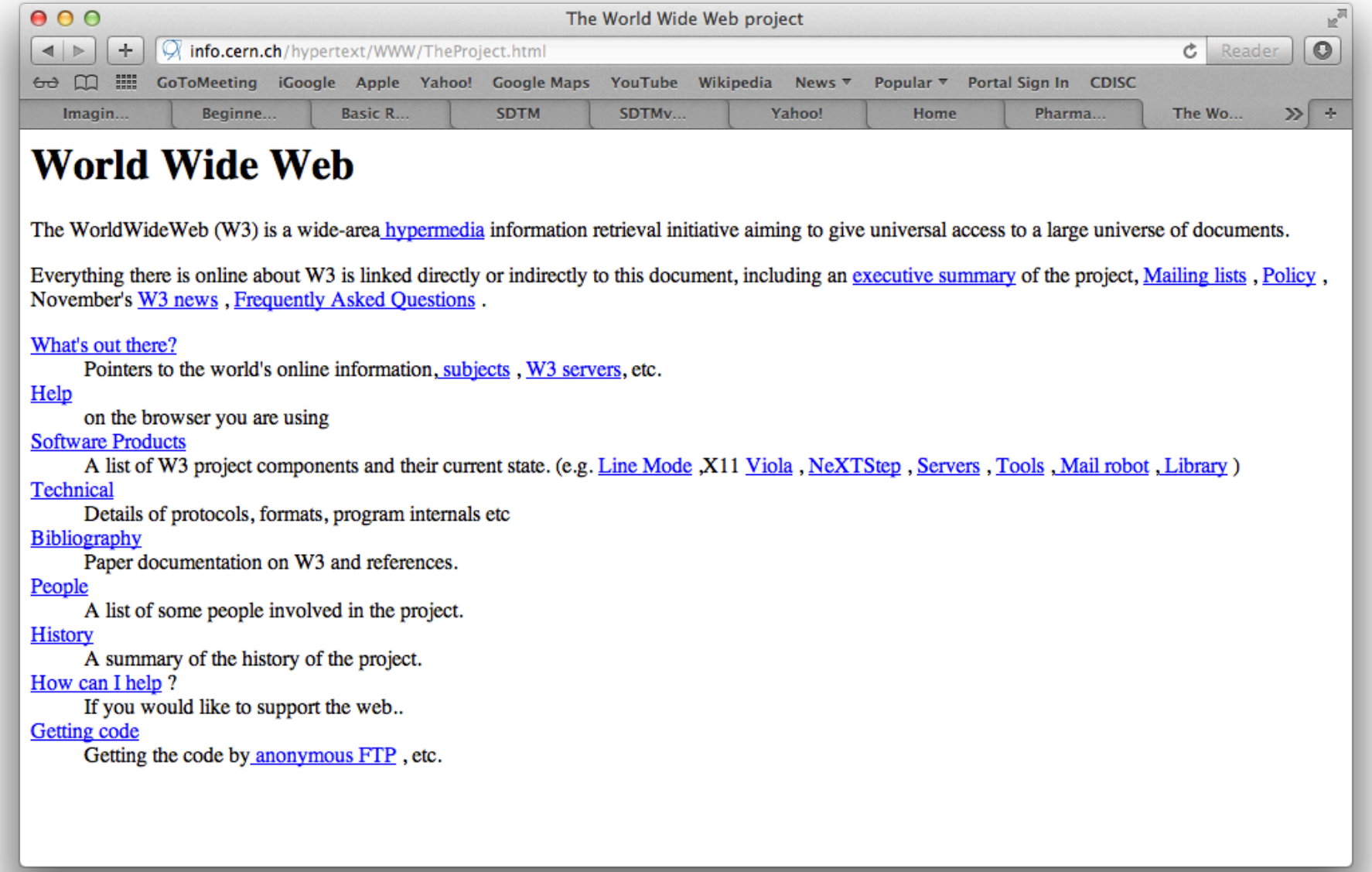
Source: Chuck Cooper, FDA

A Few Final Keynote Ideas for the Road



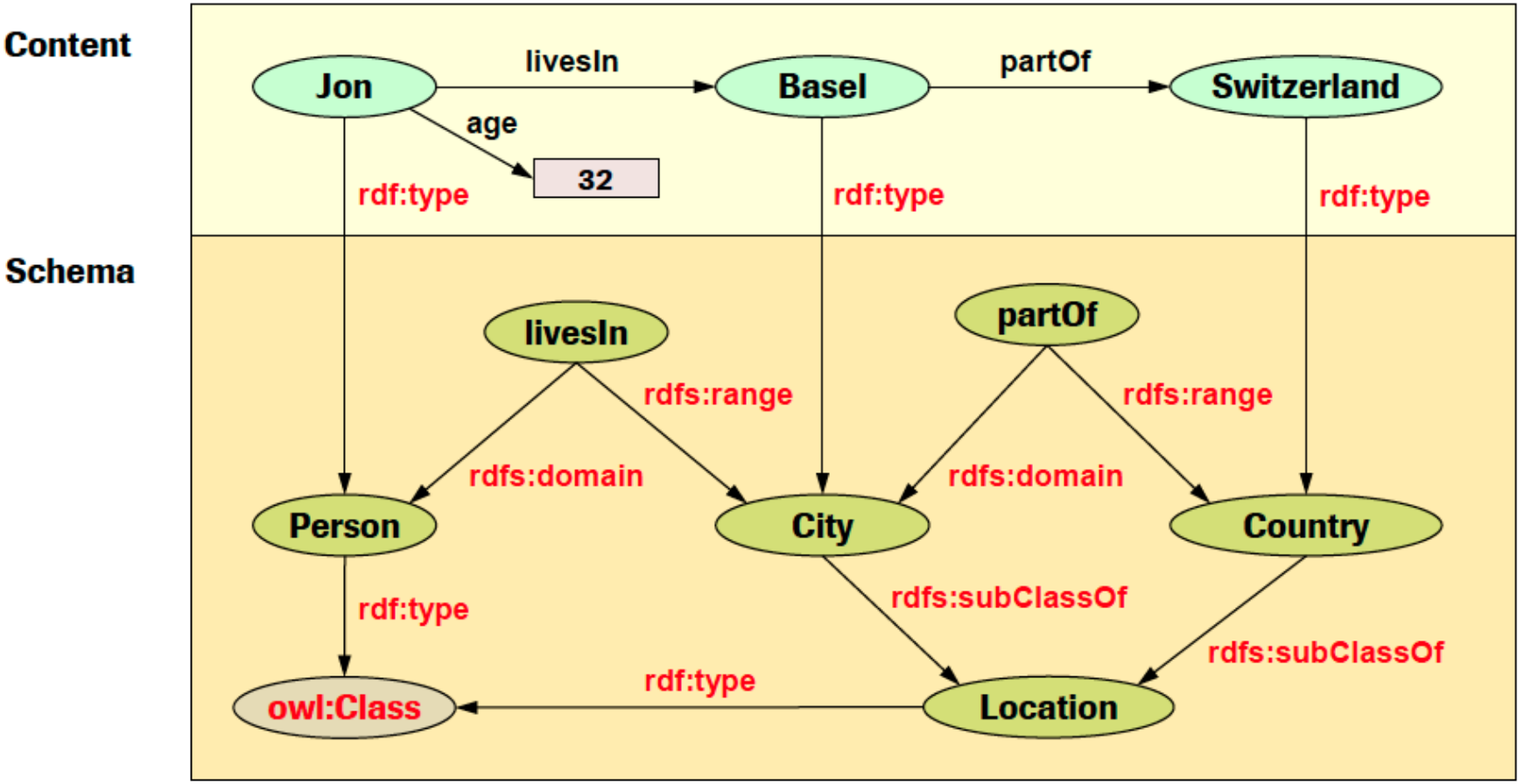
”I look to the future because that’s where I‘m going to spend the rest of my life.

George Burns


The World Wide Web project
info.cern.ch/hypertext/WWW/TheProject.html
Reader
GoToMeeting iGoogle Apple Yahoo! Google Maps YouTube Wikipedia News Popular Portal Sign In CDISC
Imagin... Beginne... Basic R... SDTM SDTMv... Yahoo! Home Pharma... The Wo...
World Wide Web
The WorldWideWeb (W3) is a wide-area hypermedia information retrieval initiative aiming to give universal access to a large universe of documents.
Everything there is online about W3 is linked directly or indirectly to this document, including an executive summary of the project, Mailing lists , Policy , November's W3 news , Frequently Asked Questions .
What's out there?
Pointers to the world's online information, subjects , W3 servers, etc.
Help
on the browser you are using
Software Products
A list of W3 project components and their current state. (e.g. Line Mode ,X11 Viola , NeXTStep , Servers , Tools , Mail robot , Library)
Technical
Details of protocols, formats, program internals etc
Bibliography
Paper documentation on W3 and references.
People
A list of some people involved in the project.
History
A summary of the history of the project.
How can I help ?
If you would like to support the web..
Getting code
Getting the code by anonymous FTP , etc.

Semantic Modeling

2. Content and Schema



Everything is a Triple

Source: Frederik Malfait

MAKE CDISC STANDARDS LINKABLE, COMPUTABLE AND QUERYABLE

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CDISC2RDF

About

A blog to present upcoming results from our explorative work making CDISC standards available in semantic web standards (RDF triple based) as proposed by early adopters in AstraZeneca and Roche, see Semantic models for CDISC based standard and metadata management.

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Towards practical, high-capacity, low-maintenance information storage in synthesized DNA
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Digital production, transmission and storage have revolutionized how we access and use information but have also made archiving an increasingly complex task that requires active, continuing maintenance of digital media. This challenge has focused some interest on DNA as an attractive target for information storage[1] because of its capacity for high-density information encoding, longevity under easily achieved conditions[2, 3, 4] and proven track record as an information bearer. Previous DNA-based information storage approaches have encoded only trivial amounts of information[5, 6, 7] or were not amenable to scaling-up[8], and used no robust error-correction and lacked examination of their cost-efficiency for large-scale information archival[9]. Here we describe a scalable method that can reliably store more information than has been handled before. We encoded computer files totalling 739 kilobytes of hard-disk storage and with an estimated Shannon information[10] of 5.2×10^6 bits into a DNA code, synthesized this DNA, sequenced it and reconstructed the original files with 100% accuracy. Theoretical analysis indicates that our DNA-based storage scheme could be scaled far beyond current global information volumes and offers a realistic technology for large-scale, long-term and infrequently accessed
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-- Samuel Goldwyn

“Ask not what you can do for your country, ask what’s for lunch.”

-- Orson Welles