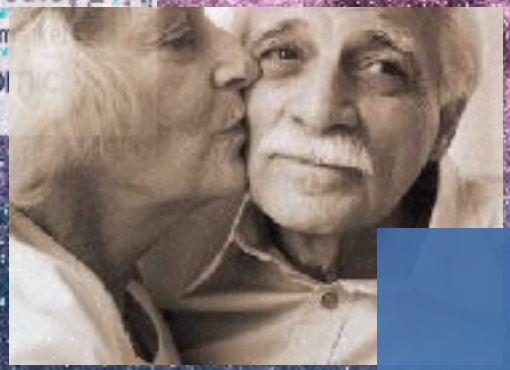

value
societal
thinking
opportunities
often
productivity
needs
benefits
business
companies
company
shared
create
products
new
social
costs
local
Shared
society

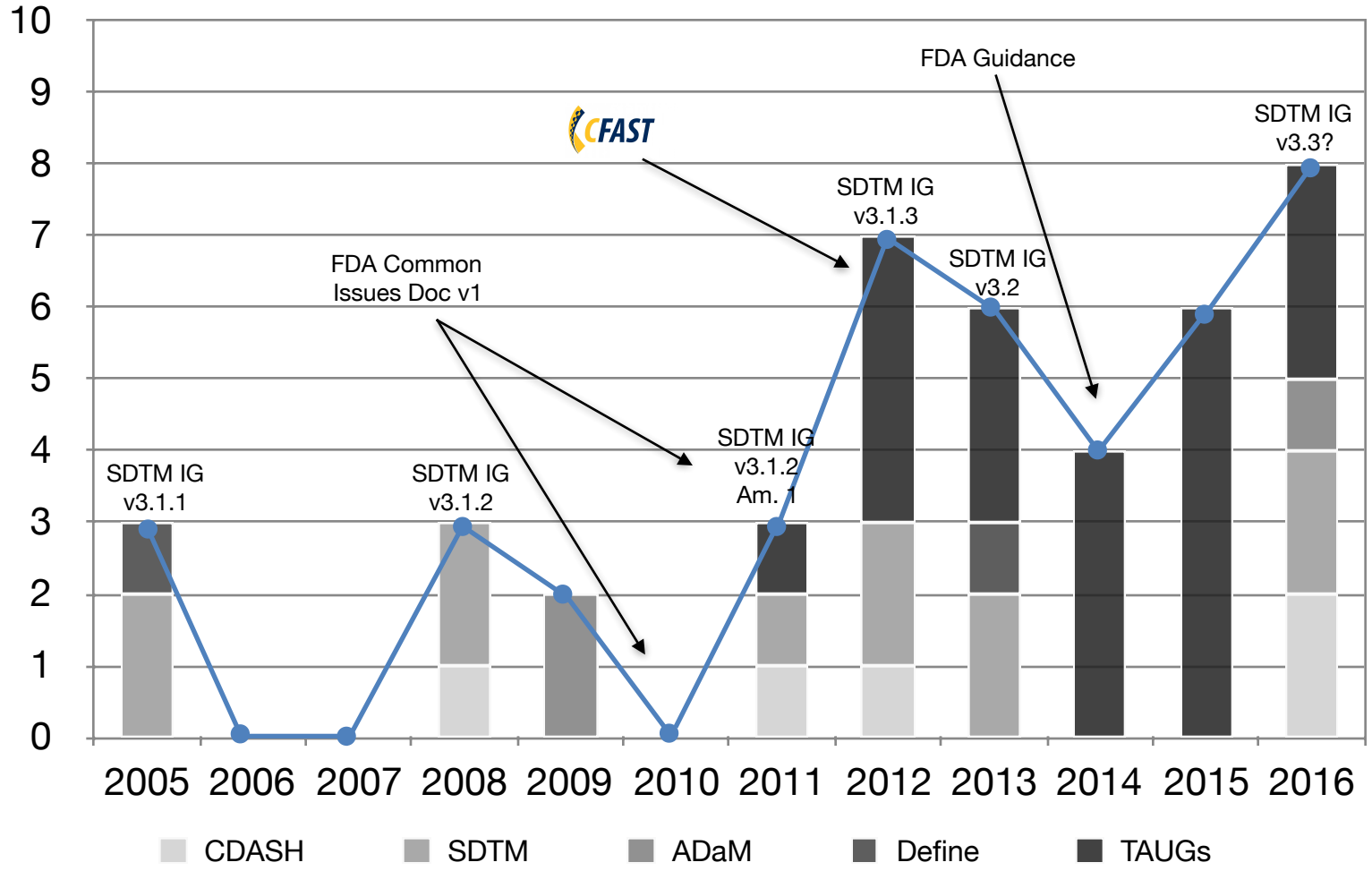



STOP

A Moratorium on the Standards Madness

Scott Bahlavooni, Senior Consultant

How did we get here?



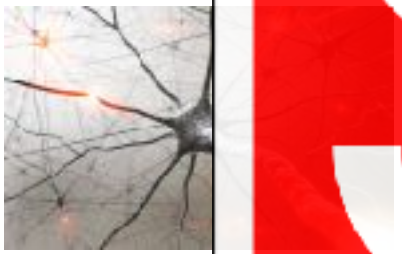
The problem in a heart beat

The morphology of the problem

- Morphology
  - *…study of words…and their relationships to other words in the same language - (linguistics) Wikipedia*
  - *…study of form and structure of organisms - (biology) Wikipedia*

The morphology of the problem

Volumetric endpoints from an MRI



RFNL thickness from an OCT

Vessel measurements from an angiography

SDTM IG v3.1.2 - v3.1.3 (2008 - 2011)

Dataset	Description	Class
ZD	Procedure Results	Findings

SDTM IG v3.2 (2012 - Present)

Dataset	Description	Class
MO	Morphology	Findings

- Do I adopt to SDTM v3.2?
- Do I update my controlled terminology?
- What is the impact to standard analyses and displays?
- How do I manage this change? Buy or build an MDR?
- Do I re-map ongoing studies? Older studies?

SDTMIG and SDTM IG Version 3.2 / SDTMIG v3.3 Batch 3

MO Decommissioning Statement

What do we do?

Recommendation:

*Industry and Regulatory Agencies place a **12 to 24 month moratorium** on the adoption of new or updated CDISC standards unless those standards add **significant value** to patient care*

What does a moratorium look like?

Preparation:

- Recognize and evangelize the business case
- Confirm, refine, and finalize adopted standards

Moratorium:

- Limit adoption of new and/or updated CDISC or sponsor-defined standards to those that provide **significant value**
- Assess and enhance existing standards adoption and implementation infrastructure
- Openly discuss the future state of standards that support clinical research and development

Would a moratorium work?

Why?

- Unofficial moratoriums exist **now**
- Regulators are methodical adopting standards
- Benefits **significantly** outweigh the risks

The Moratorium for Industry

Benefits:

- More effective operationalization of standards
- Greater realization of the benefits of standards adoption
- Opportunity to assess standards adoption and implementation landscape

Risks:

- Perceived by senior management as a lack of commitment to standards
- Moratorium not adopted by regulatory agencies

The Moratorium for Regulators

Benefits:

- Higher quality submissions
- Greater realization of the benefits of the guidances
- Opportunity for harmonizing requirements

Risks:

- Perceived lack of commitment to CDISC
- Moratorium not adopted by all regulatory agencies

The Moratorium for CDISC

Benefits:

- Celebrate the **EXCELLENT** work done by CDISC standards development teams
- Opportunity to refactor CDISC Foundational Standards for a scalable future state
- Influence and lead future state discussions

Risks:

- CDISC standards, in their current iteration, are not part of the future state of clinical research and development standards

As you CDISC Intrachange…

Decision	Status	Stakeholders	Outcome
LB and MB - to merge or not to merge	DECIDED	Microbiology and Lab Teams	
Representation of assistive devices and rehab therapy	DECIDED	DMD TA Team	

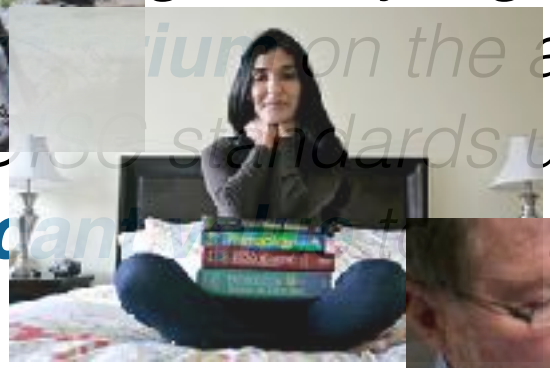
There is no change at present.

…using an existing domain was preferable…

The Moratorium in Summary

Recommendation:

*Industry and Regulatory Agencies place a **12 to 24 month moratorium** on the adoption of new or updated CDISC standards unless those standards add **significant** value to patient care*



A Moratorium on the Standards Madness

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