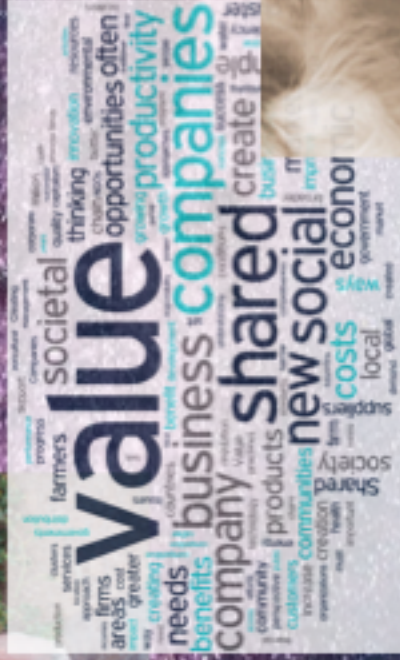




d-wise

Empowering innovation for a healthier world



STRATEGY



DATA



CLOUD



PRIVACY

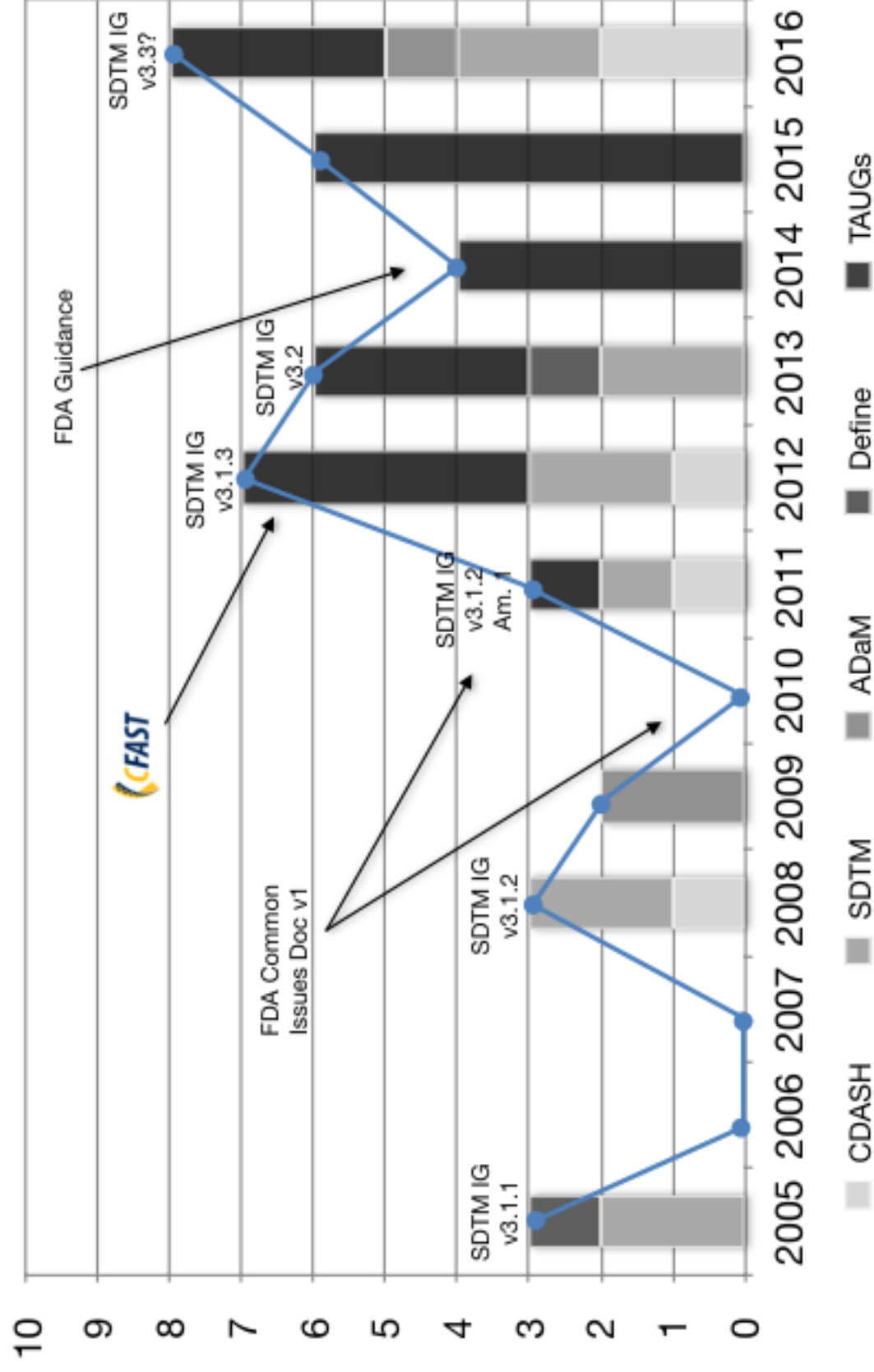


ANALYTICS

A Moratorium on the Standards Madness

Scott Bahlavooni, Senior Consultant

How did we get here?



The problem in a heart beat

CosmeticUpdate
SubmissionValueCDISC
CDASHFDA Vital Signs
MDR beats/min
Excel
BEATS/MINCTHeartRate
VSORRESUC
HelpSDTM

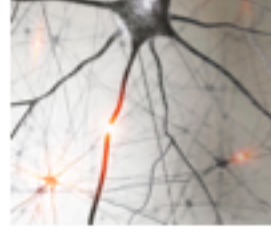
The morphology of the problem

- 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*

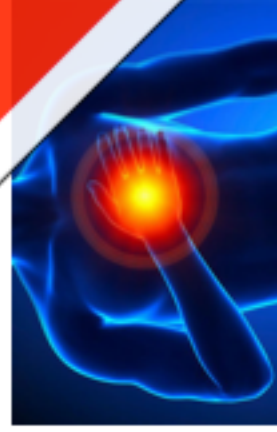
The morphology of the problem



Volumetric endpoints from an MRI



RFNL thickness from an OCT



Vessel measurements from intravascular 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? Order studies?

SDTMIG v3.2 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?



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

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

The Moratorium in Summary



on:

regulatory Agencies place a **12 to 24**
month moratorium on the adoption of new or
updated CE unless those standards
add **significant**



Empowering innovation for a healthier world



STRATEGY



DATA



CLOUD



PRIVACY



ANALYTICS

A Moratorium on the Standards Madness

Scott Bahlavooni, Senior Consultant

scott.bahlavooni@d-wise.com