A Moratorium on the Standards Madness

Scott Bahlavooni, Senior Consultant
How did we get here?

- FDA Guidance
- SDTM IG v3.3?
- FDA Common Issues Doc v1
- SDTM IG v3.1.3
- SDTM IG v3.1.2 Am. 1
- SDTM IG v3.1.1

- CDASH
- SDTM
- ADaM
- Define
- TAUGs
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

<table>
<thead>
<tr>
<th>SDTM IG v3.1.2 - v3.1.3 (2008 - 2011)</th>
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<tr>
<td>Class</td>
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- 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?

**MO Decommissioning Statement**

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- Volumetric endpoints from an MRI
- RFNL thickness from an OCT
- Vessel measurements from an angiography
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?

U unequivocally, YES!!!

Oct, 2016    Mar, 2017    Mar, 2019

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

Recommendation: Regulatory Agencies place a **12 to 24 month moratorium** on the adoption of new or updated OLED standards unless those standards add **significant**...
A Moratorium on the Standards Madness

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