MERCK

# Working Together: The Evolving Relationship of Biostatistics & Regulatory for Support of Study Data Standardization Plans and BIMO Reviewer's Guides

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# Presentation Overview

# Study Data Standardization Plan

**a brief history…**

A document that describes a Sponsor's **intended** use of FDA endorsed data standards

Purpose: Influence a Sponsor to meet FDA expectations for standards deployment or make a compelling argument for why they feel they can't

Origin

- FDA implemented a CRADA ~2011 that involved them working with an organization to lead them through an opportunity to create and utilize data based on CDISC standards to support specific meta-analyses
- The pain of this experience influenced the specification of the SDSP as well as the Reviewer's Guides that accompany SDTM & ADaM submission data packages
- The efforts of the PHUSE/CSS Working Group, Optimizing the Use of Data Standards, led to formally published templates and guidelines for the SDSP & Reviewer's Guides

# BIMO Reviewer's Guide

## a brief history…

BIMO Package – Goal to develop a more consistent, science-based approach to selection of clinical sites for inspection

- Tabular list of site information
- Line listings by site
- Site level data

Origin

- 1st requested in 2010 via Type C meetings
- 1st draft guidance issued in 2012; replacement draft guidance issued in 2018
- 1st BIMO TCG issued in 2017, revised in 2020 & 2022 (note: not a draft guidance)

BIMO Reviewer's Guide – Template/guideline/examples released by PHUSE in 2022

# Why are we having this conversation?

FDA impetus for these documents came from outside the eCTD guidance

Template and process for creating the SDSP & BIMO assets was designed and implemented by Clinical Data Scientists

- Outcome from workstreams from PHUSE/CSS meetings managed by Optimizing the Use of Data Standards working group

Statisticians / Programmers / Data Managers were telling Sponsor Regulatory Affairs/Regulatory Operations that these items needed to be included in a submission

Initially Sponsor Regulatory Affairs/Regulatory Operations viewed these documents as the domain of Statisticians / Programmers / Data Managers, much like Submission Data Packages

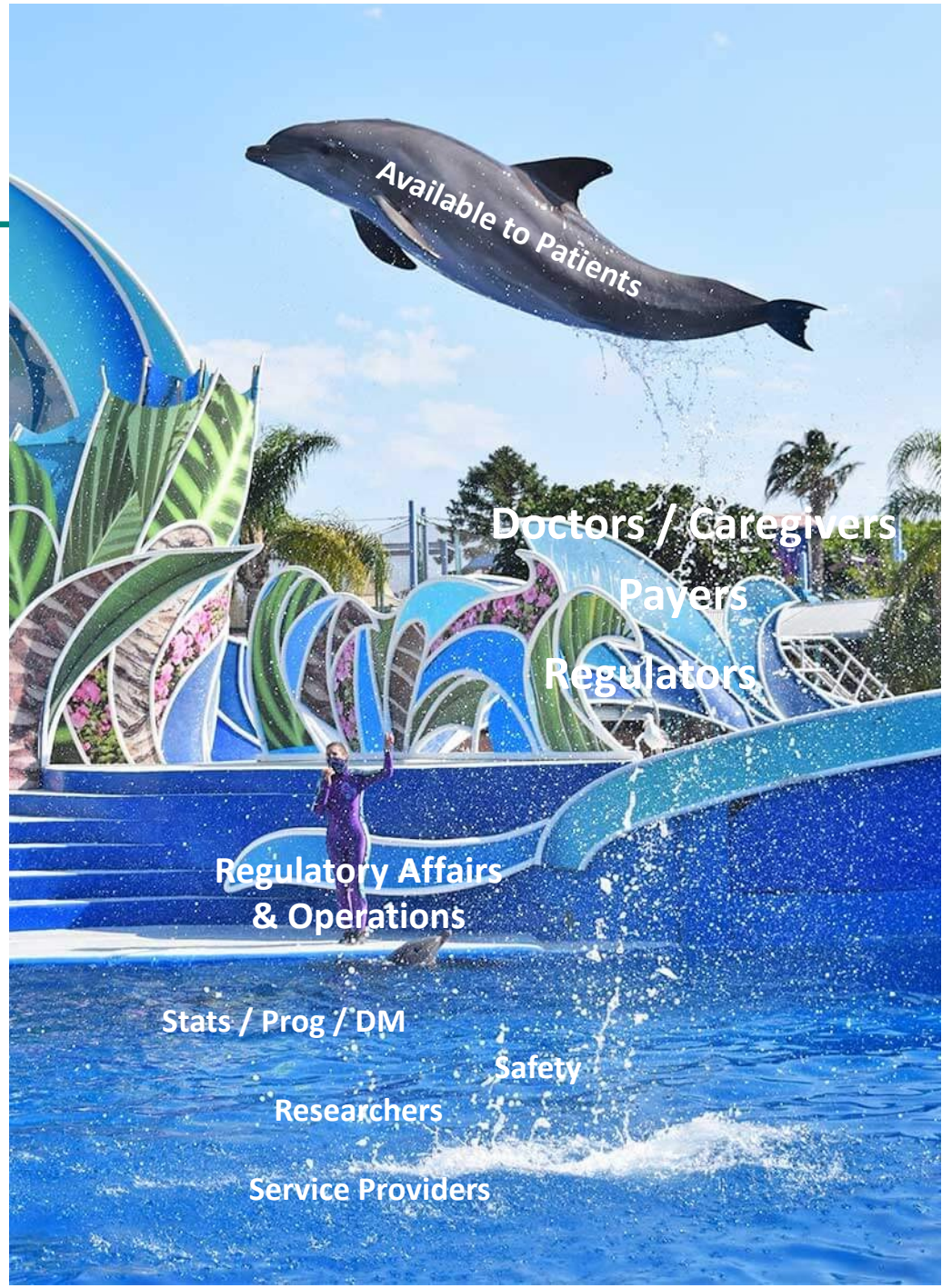
# What changed?

US FDA started **asking** for SDSP & BIMO

- SDSP @ time of PreIND meeting, no later than EOP2 meeting
- BIMO strategy typically @ PreNDA/BLA meeting, sometimes as early as the EOP2 meeting

Sponsor Regulatory Affairs / Operations now on notice to provide these assets

Led to a desire for **ownership** of these documents by Sponsor Regulatory Affairs / Operations



# Now what?

As Sponsor Regulatory Affairs/Regulatory Operations peeled back the onion layers on the documents, they realized they had a vested interest in **content**, not just existence

## SDSP

- Overview
- Interaction documentation

## BIMO

- Messaging
- Service Providers
- Financials

# Now what?

Coordination of document creation – not just a Stats / Programming / DM activity

## SDSP

- Non-clinical
- Clinical

## BIMO

- Trial Management (delegation of study responsibilities)
- Trial Master File (site information, financials)

# Evolution of the Process

Coordinating author assigned

- Someone who **specializes** in regulatory document authoring

Content providers defined; content developed

- Stats / programming / data management can **focus** on their content

Cross checks defined and executed

- List of sites from CTMS compared to clinical db
- Studies in SDSP compared to submission content plan

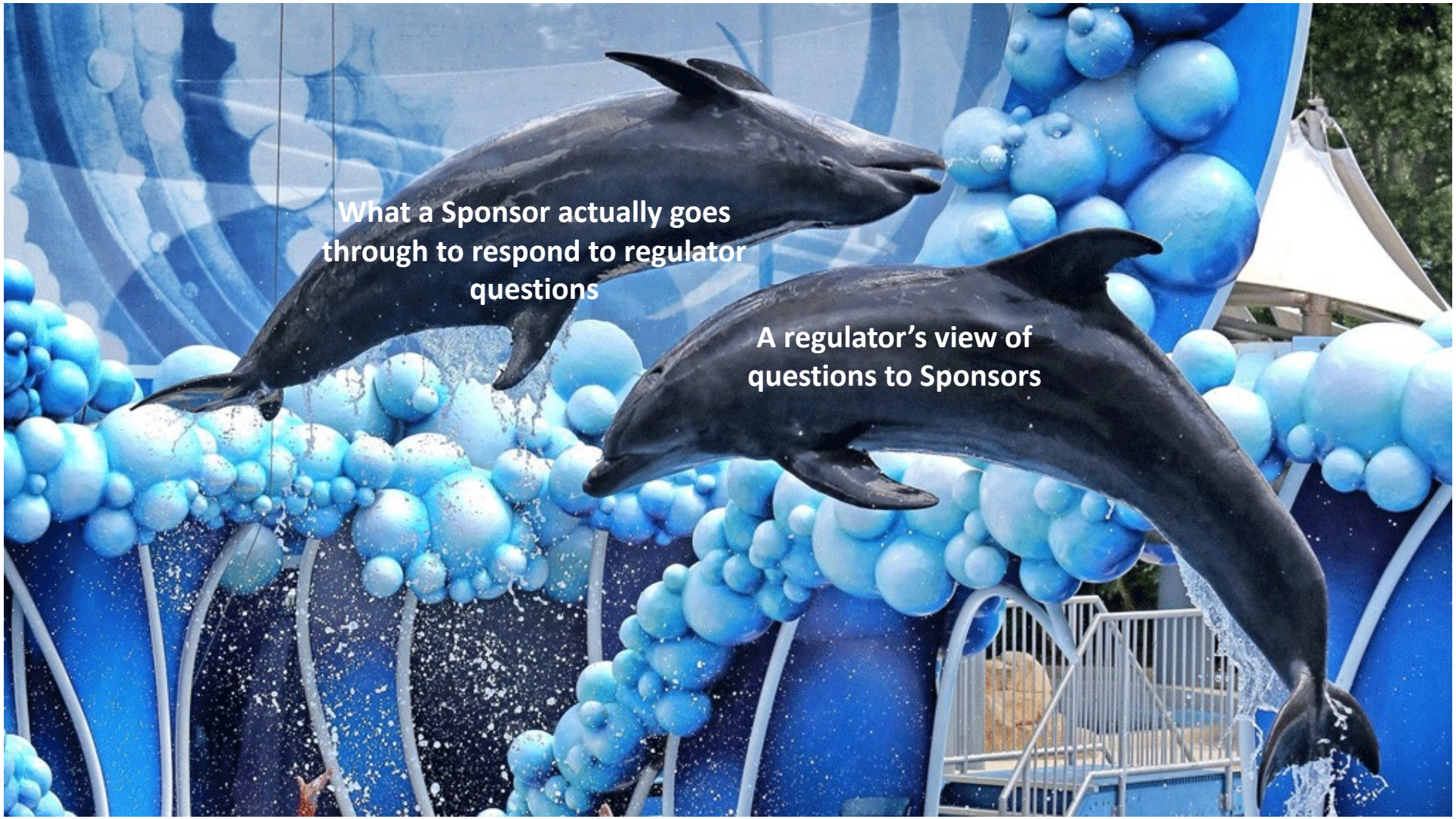
Seamless publishing into eCTD

# The Future

## PHUSE templates for SDSP & BIMO Reviewer's Guide universally available

- Made available as templates in Regulatory application
- Joint authoring - single document universally available to all authors

# Thank you!

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