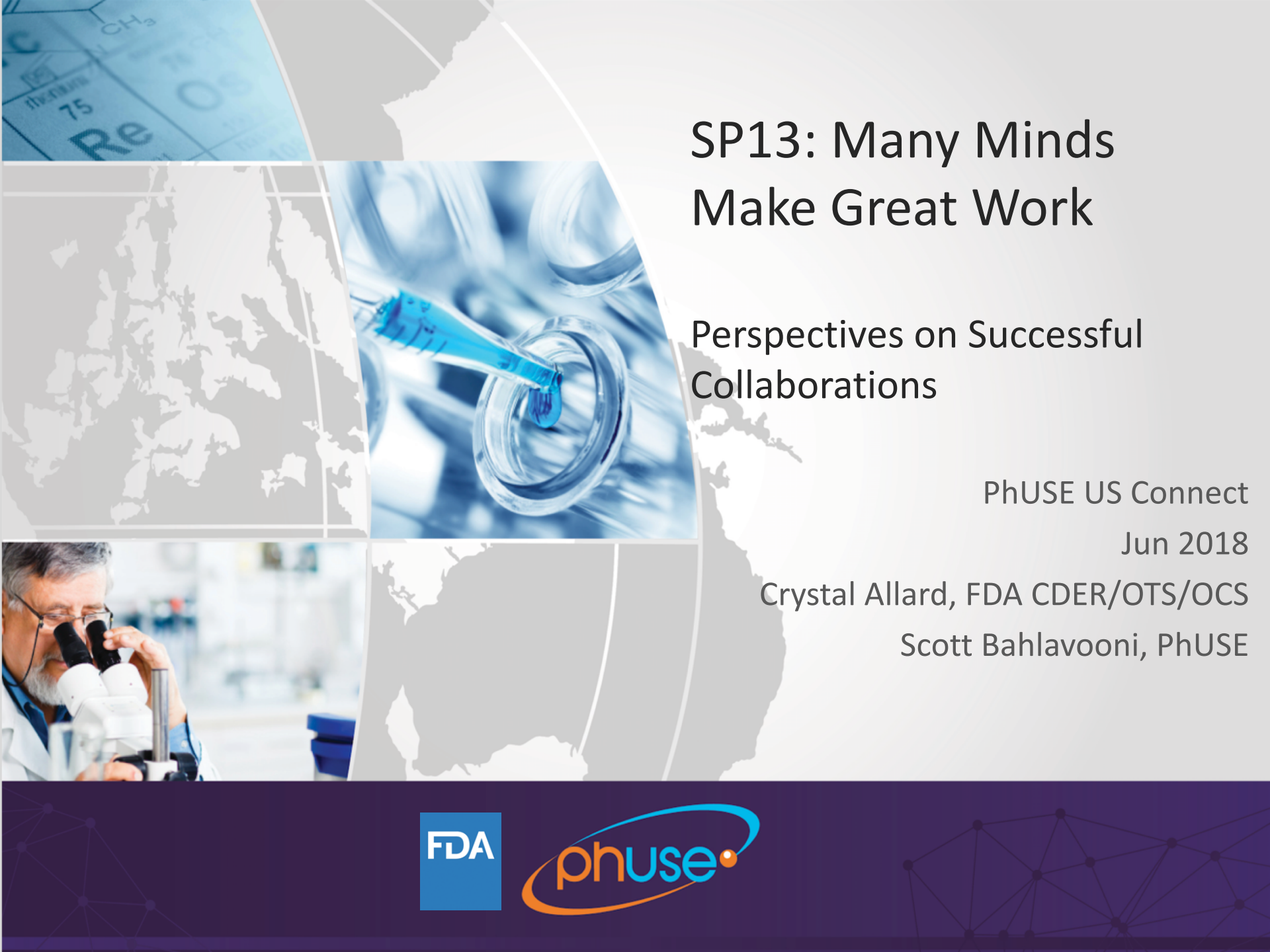




SP13: Many Minds Make Great Work

Perspectives on Successful
Collaborations

PhUSE US Connect

Jun 2018

Crystal Allard, FDA CDER/OTS/OCS

Scott Bahlavooni, PhUSE

FDA



Disclaimer:

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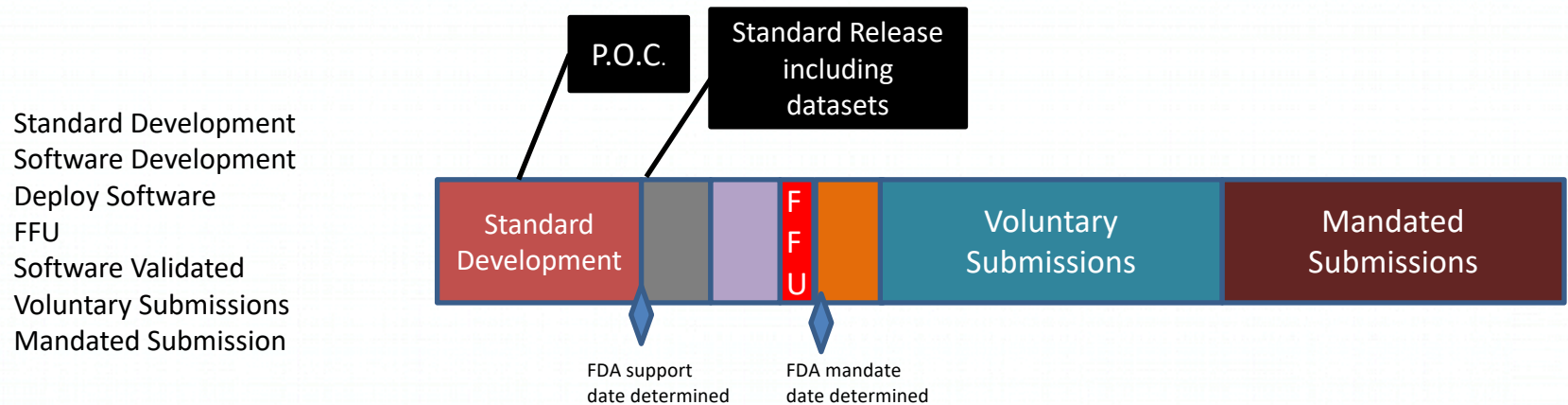




"...change is almost impossible
without industry-wide collaboration,
cooperation, and consensus."

SIMON MAINWARING

SEND Standards Development Lifecycle



- POC incl. extensive examples datasets in the during standards development
- POC datasets published along with new version of SEND IG
- FDA can more **confidently** state intentions to support a standard
- FFU depends on vendor tools
- After FFU, FDA can more **confidently** choose dates for mandating this standard

Study Data Reviewer's Guide

Study Data Reviewer's Guide

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STUDY DATA TECHNICAL CONFORMANCE GUIDE

March 2018

Provisional Translation (as of July 2015) *

Notification No. 0427001
April 27, 2015

To: Prefectural Health Department (Bureau)

Director of the Advanced Review with Electronic Data Promotion Group,
Pharmaceuticals and Medical Devices Agency

Technical Conformance Guide on Electronic Study Data Submissions



"Certain things catch your eye, but pursue
only those that capture your heart."

NATIVE AMERICAN PROVERB

Are PhUSE Collaborations Shiny?

Shiny?

Not Shiny?

Too Shiny?



PollEV.com/crystalallard597

What Do You See As a Shiny Object?



[PolleEV.com/crystalallard597](https://www.polleEV.com/crystalallard597)

What do you see as barriers to producing shiny objects as part of the PhUSE Collaboration?



A word cloud on a dark blue background. The words are in various shades of blue and green. The most prominent words are 'expertise of', 'object', 'and development', 'projects', 'the initiatives', 'Identifying', 'Differing', 'velocities for', 'Awareness', 'or', 'neutrality', 'similar', 'Resourcing', 'Vendor', 'and', 'right'.

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"Fear kills more dreams than failure ever will."

SUZY KASSEM





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