

FDA State of the Union

Preparedness, Perspectives, and
Updates

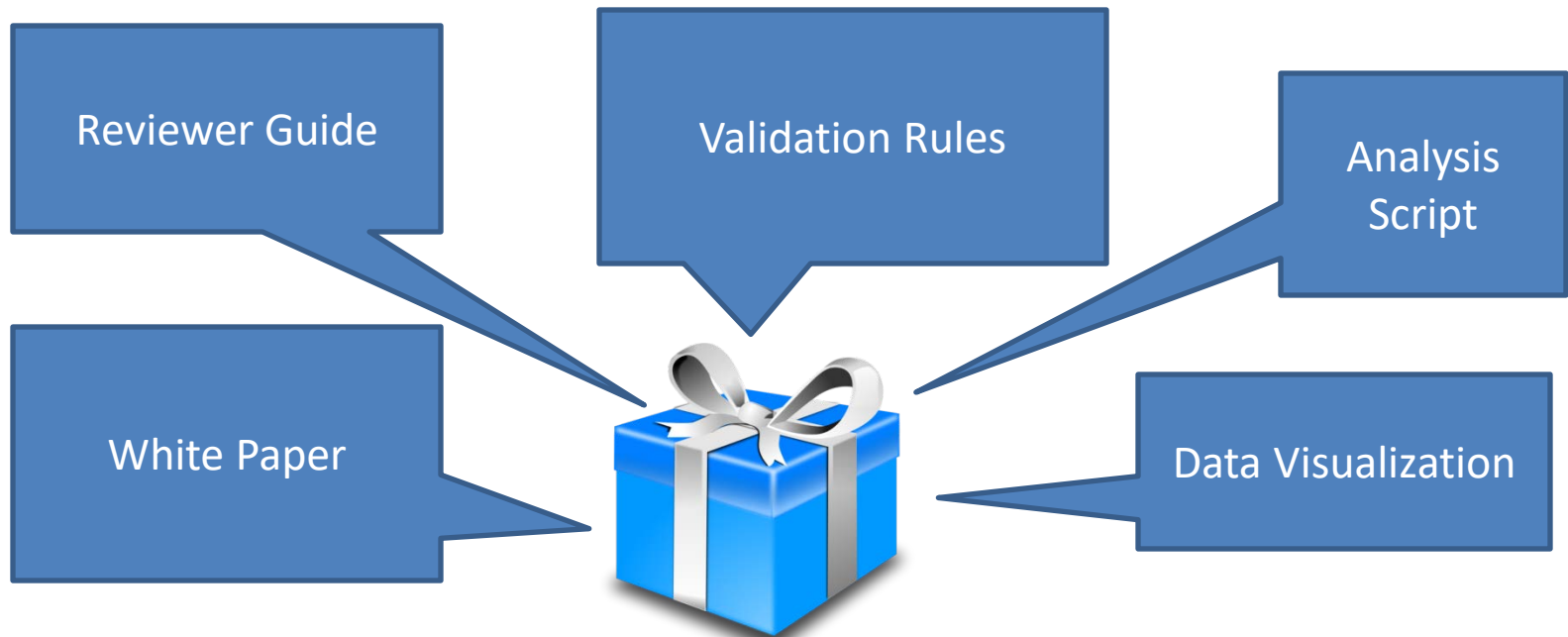


PhUSE Collaborations



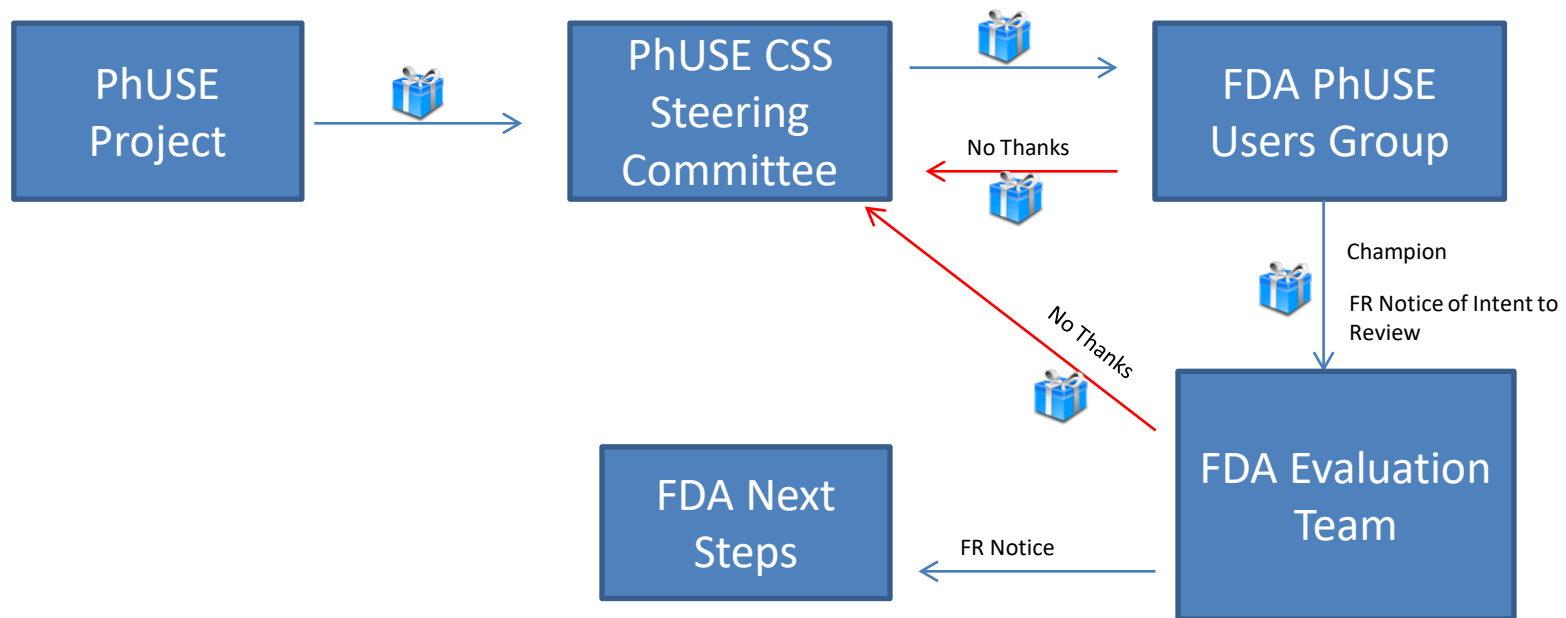
PhUSE Deliverable Review at FDA

- A PhUSE Project Team provides a deliverable to the PhUSE Steering Committee
- The Steering Committee reviews and forwards the deliverable to FDA



PhUSE Deliverables Review at FDA – The Process

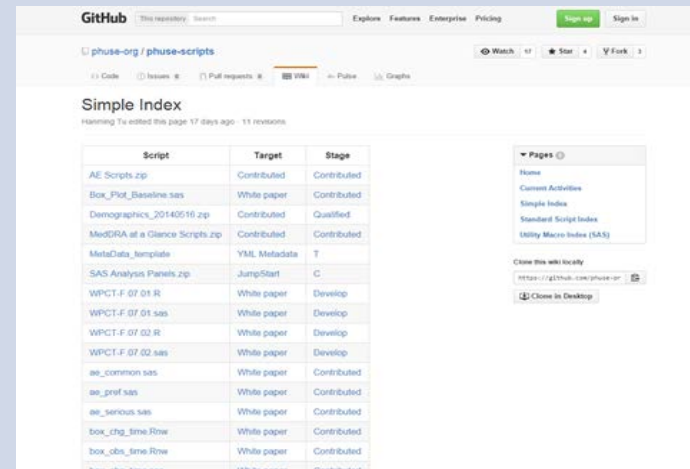
FDA Evaluation Process – The Graphical Representation



The Process – New Developments

PhUSE Steering Committee to develop a site for housing PhUSE Deliverables

PhUSE to develop process for Versioning of PhUSE Deliverables



Updates From CDER - SDRG



FEDERAL REGISTER

The Daily Journal of the United States Government

- SDRG = Study Data Reviewer's Guide
 - [FR Notice](#) published
 - FDA Review Ongoing
 - FDA Report expected Spring 2016

Intent To Review a Study Data Reviewer's Guide Template

A Notice by the Food and Drug Administration on 07/23/2015

ACTION Notice Of Availability; Request For Comments.

SUMMARY ☐ The Food and Drug Administration (FDA), Center for Drug Evaluation and Research (CDER), is establishing a public docket to collect comments related to a proposed Study Data Reviewer's Guide (SDRG) template. As part of FDA's ongoing collaboration with the Pharmaceutical Users Software Exchange (PhUSE), an independent, non-profit consortium addressing computational science issues, a PhUSE working group developed the PhUSE SDRG template. The purpose of this review is to evaluate the template and determine whether FDA will recommend its use either as is, or in a modified form, for regulatory submissions of study data. FDA is seeking public comment on the use of the PhUSE SDRG template for regulatory submissions.



Updates From CDER - NSDRG



FEDERAL REGISTER

The Daily Journal of the United States Government

- NSDRG = Nonclinical Study Data Reviewer's Guide
 - [FR Notice](#)
 - FDA Review Ongoing
 - FDA Report expected Spring 2016

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Updates From CDER – ADRG, SDSP, LDCP

- ADRG = Analysis Data Reviewer's Guide
 - Seeking FDA Champion
- SDSP = Study Data Standardization Plan
 - FDA Champion Identified
 - FDA expected to pick up in Summer 2016
- LDCP = Legacy Data Conversion Plan
 - Final plan coming to FDA Summer/Fall 2016

Updates From CDER - Standard Script Sharing

Name of Script	Current Status in JumpStart	Version sent to PhUSE in 2014/2015	Version sent to PhUSE in 2016
AE Severity	Active - updates implemented	ae_v1.sas	ae_v1.sas
AE Toxicity	Active - updates implemented	ae_oncology_v1.sas	ae_oncology_v1.sas
Demographics	Active	demographics_v1.sas	demographics_v1.sas
Disposition	Active - updates implemented	disposition_v1.sas	disposition_v2.sas
Exposure	Unused in JumpStart service	N/A	exposure_v1.sas
Liver Labs	Active - updates implemented	N/A	liver_v2.sas
MedDRA at a Glance	Active - updates implemented	ae_meddra_w_flag_generation_v1.sas	ae_meddra_w_flag_generation_v1.sas

Agenda

- 1. eStudy Guidance and Technical Conformance Guide:
Are you Ready?**
- 2. How Good is Your Data? Perspectives from the
Trenches:**
 - 1. SDTM**
 - 2. SEND**
 - 3. ADaM**
- 3. The State of the Data Reviewer's Guides**
- 4. Summary of Working Group Success and Projects
Moving Forward**

PhUSE Collaborations

