



FDA/PhUSE 
Computational Science Symposium

March 18th – 19th 2013

Silver Spring Civic Center | Silver Spring, Maryland, USA



Optimizing the Use of Data Standards

Working Group Overview and Projects Summary



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Working Group Overview



Optimizing the Use of Data Standards

Purpose:

Identify issues, challenges, and gaps in the interpretation and use of standards that prevent FDA and industry from optimizing the use of the standards then collaborate to address the issues and close the gaps

Working Group Leadership Team:

- Jingyee Kou, FDA
- Steve Wilson, FDA
- Scott Bahlavooni, Genentech
- Michael Brennan, Janssen R&D
- Jeff Conant, Vertex Pharmaceuticals



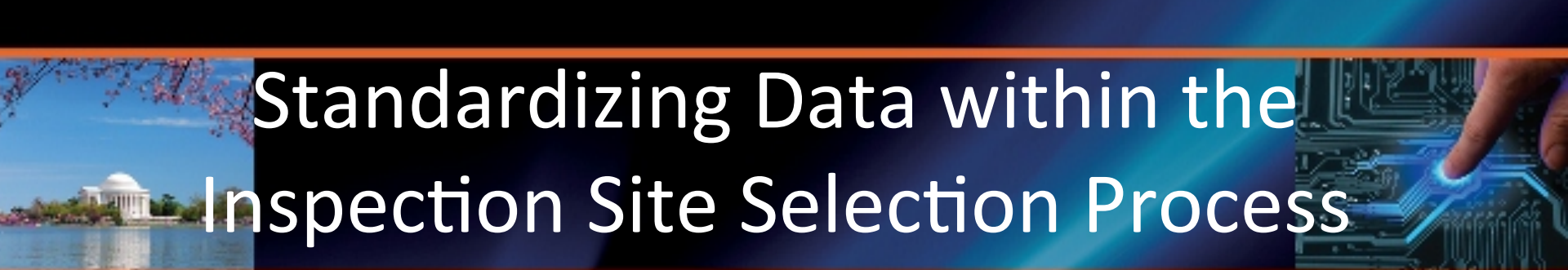
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2012 Project Summary



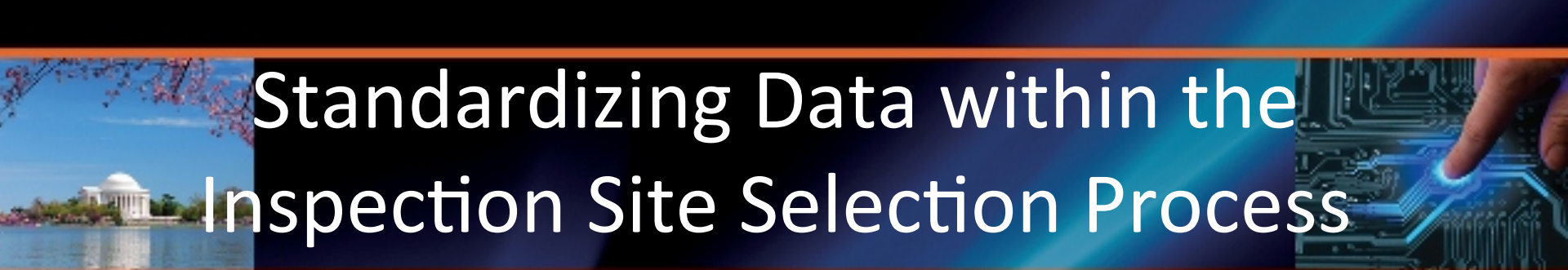
Standardizing Data within the Inspection Site Selection Process

Project Overview:

- Complete a gap analysis of the data elements that are identified by FDA/CDER Office of Scientific Investigation (OSI) to enable the site selection analysis

Activities:

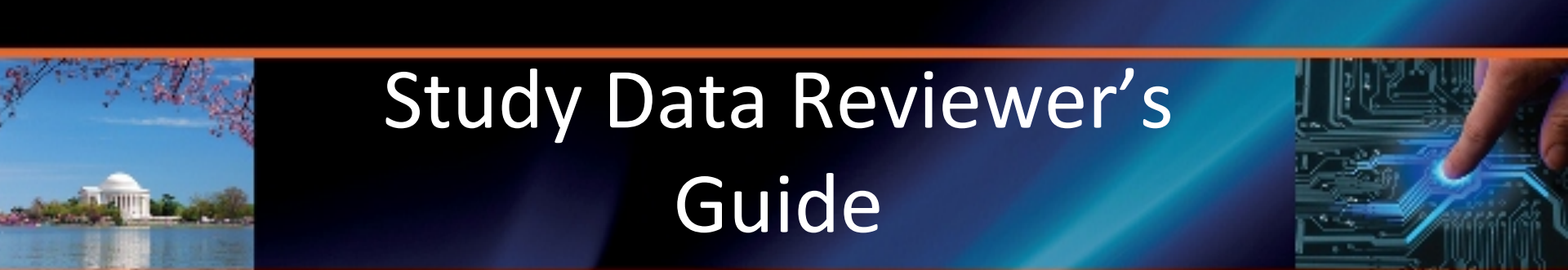
- Evaluated the alignment of each data element with existing CDISC (SDTM/ADaM) standards
- Identified cases where specific data elements needed further clarification or were not addressed by current CDISC standards
 - 26% (10/39) of the data elements required clarification
 - 62% (24/39) of the data elements not addressed by existing CDISC standards
- Analysis to be completed by the end of April 2013
- Analysis to be sent to CDISC for further action



Standardizing Data within the Inspection Site Selection Process

Project Leadership Team:

- Jonathan Helfgott, FDA
- Bhanu Kannan, FDA
- Paul Okwesili, FDA
- Michael Brennan, Janssen R&D
- Nate Freimark, Theorem Clinical
- Patty Gerend, Genentech



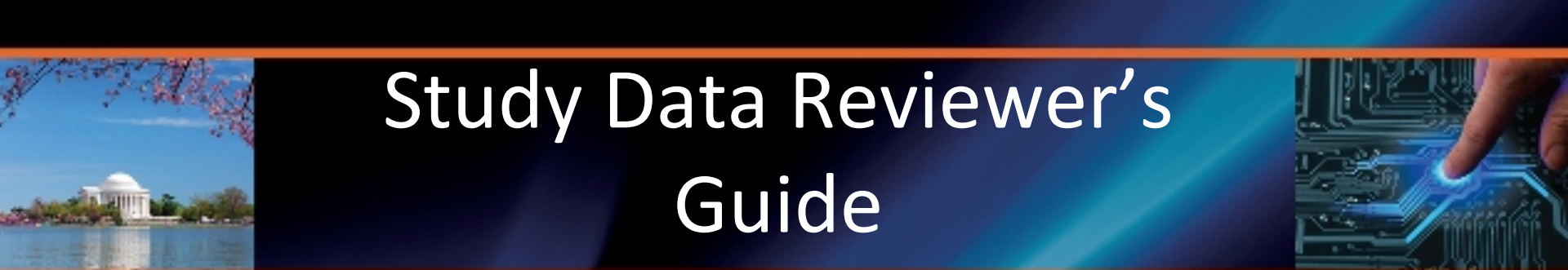
Study Data Reviewer's Guide

Study Data Reviewer's Guide (SDRG) Work Package:

- SDRG Template, SDRG Completion Guidelines, and SDRG Examples

Activities:

- Jul-2012/Aug-2012: SDRG sub-team content discussions
- 21-Oct-2012: SDRG co-lead F2F
- 15-Nov-2012: First draft of template and completion guidelines posted to PhUSE Wiki
- 18-Dec-2012: Prequalification completed
- 25-Feb-2013: Final work package released for WG4 review
- Mar-2013: v1 provided to FDA CSC



Study Data Reviewer's Guide

Project Leadership Team:

- Helena Sviglin, FDA
- Douglas Warfield, FDA
- Steve Wilson, FDA
- Scott Bahlavooni, Genentech
- John Brega, PharmaStat
- Joanna Koft, Biogen-Idec
- Gail Stoner, Johnson & Johnson

Acknowledgements:

- WG4 participants on SDRG sub-teams
- Biogen-Idec, J&J, and Genentech staff that took time from their day jobs to review the SDRG work package and develop the SDRG examples
- Special thank you to David Brega, PharmaStat, for his Microsoft Office wizardry and editorial genius



Traceability and Data Flow

Project Overview:

- Discuss and define traceability considerations and best practices for study level dataset and integrated datasets conversion for a variety of different data flow scenarios.

Activities (2012):

- Proposed best practice that target integrated datasets should be in ADaM format
- Proposed to draft white paper for 2 scenarios
 - Map from study level SDTM data
 - Map from study level ADaM data
- Traceability considerations agreed on
 - Build as much traceability as possible into the target dataset (retain source data variables)
 - Capture additional data transformations in define.xml
 - Any items not captured in the above can be documented in SAS code (requires submission of SAS code)



Traceability and Data Flow

Activities (New):

- Define traceability considerations and best practices for study level data conversion for following scenarios:
 - Complete study level utilization of CDISC standards
 - Partial utilization of CDISC standards, e.g. SDTM, but not ADaM
 - No utilization of CDISC standards
- Develop white papers outlining traceability considerations and best practices for creation of integrated datasets from study level source data for each of the aforementioned scenarios

Project Leadership Team:

- Jingyee Kou, FDA
- Paul Bukowiec, Millennium
- Sandra Minjoe, Octagon
- Tanja Petrowitsch, Bayer



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New Projects Overview



Analysis Data Reviewer's Guide

Project Overview:

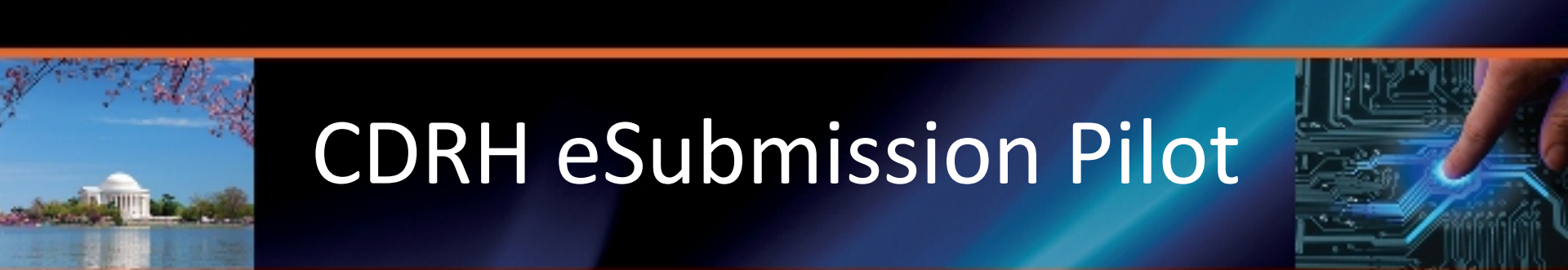
- Analysis Data Reviewer's Guide (ADRG) is an additional, human-readable, documentation of analysis methods, datasets, and programs that cannot be fully explained within the ADaM/analysis metadata
- Development of an ADRG template will ensure this documentation is provided to the FDA in consistent and usable format

Activities:

- During SDRG development, analysis data-related issues surfaced and will be considered for ADRG
- SDRG sub-team volunteered to work on ADRG project
- FDA representatives providing their viewpoint on content and format
- ADRG draft expected by mid-2013

Project Leadership Team:

- Susan Kenny, Amgen
- Gail Stoner, J&J



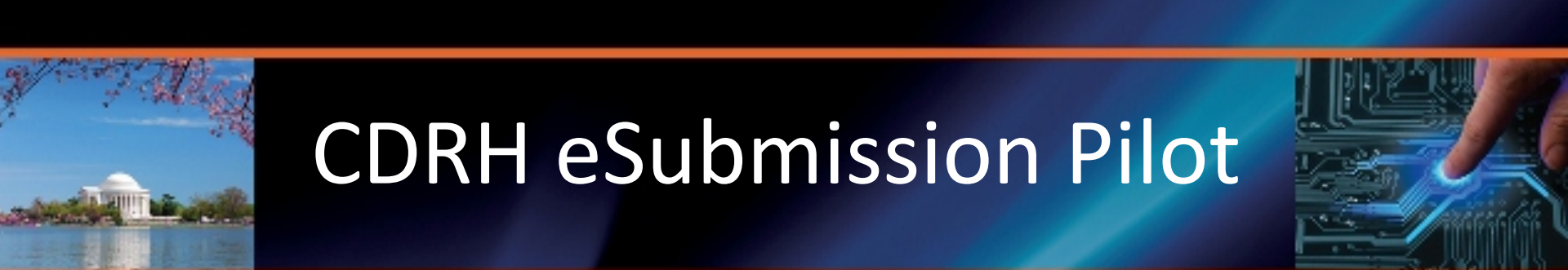
CDRH eSubmission Pilot

Project Overview:

- CDRH would like to conduct an electronic submission pilot with industry to evaluate the use of SDTM device domains for submission

Project Outcomes:

- Foster collaboration and communication between CDRH and industry
- Increase use of device standards
- Change CDRH internal thinking and resistance to standards
- Improve CDRH internal processes



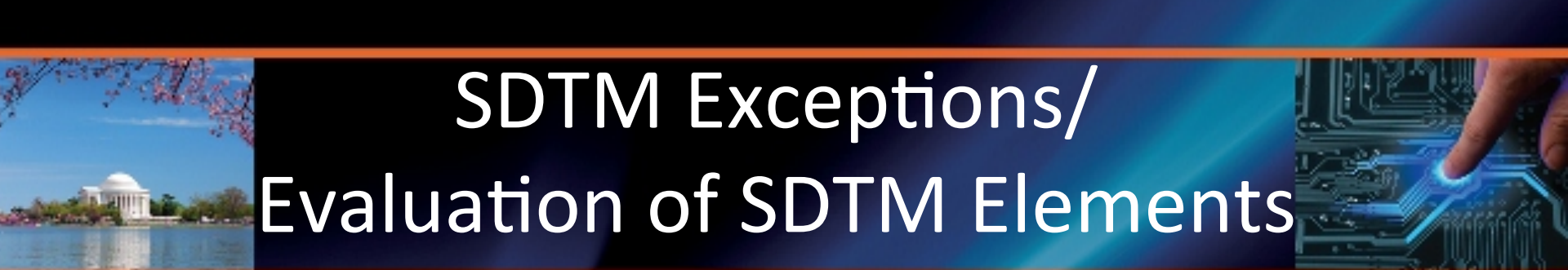
CDRH eSubmission Pilot

Project Timelines:

- 2013-Mar: Identify PhUSE process for FDA/industry communication
- 2013-Jun: Develop a CDISC submission roadmap as a “how to” for submitting medical device data
- 2013-Jul: Add members of the CDISC Device Domain Team as req.
- 2013-Sep (or sooner): Identify a sponsor to participate in pilot

Project Leadership Team:

- Ted Peterson, FDA
- Carey Smoak, Roche



SDTM Exceptions/ Evaluation of SDTM Elements

Project Overview:

- High priority issue from 2012 FDA/PhUSE CSS meeting
- Sponsors submit unnecessary operational and collected data in SDTM (e.g. subject initials)
- Project will identify data elements of limited utility including examples and rationale

Project Deliverables:

- Document/checklist of data elements, examples, and rationale
- Propose next steps for document/checklist use

Project Leadership Team:

- Jingyee Kou, FDA
- Joanna Koft, Biogen-Idec