



FDA/PhUSE 
Computational Science Symposium

March 18th – 19th 2013

Silver Spring Civic Center | Silver Spring, Maryland, USA



Improving Data Quality

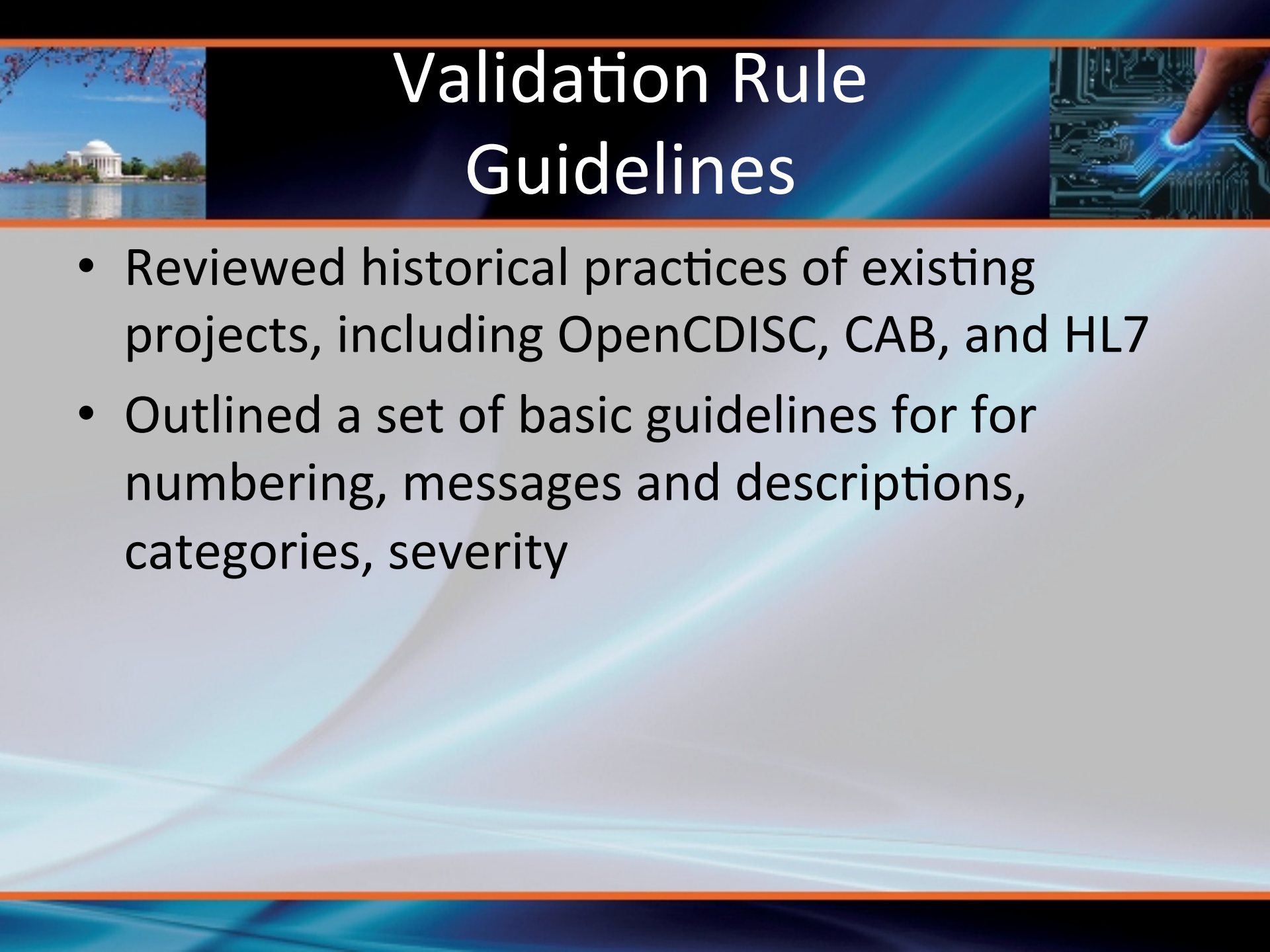
Working Group Update

March 18-19, 2013



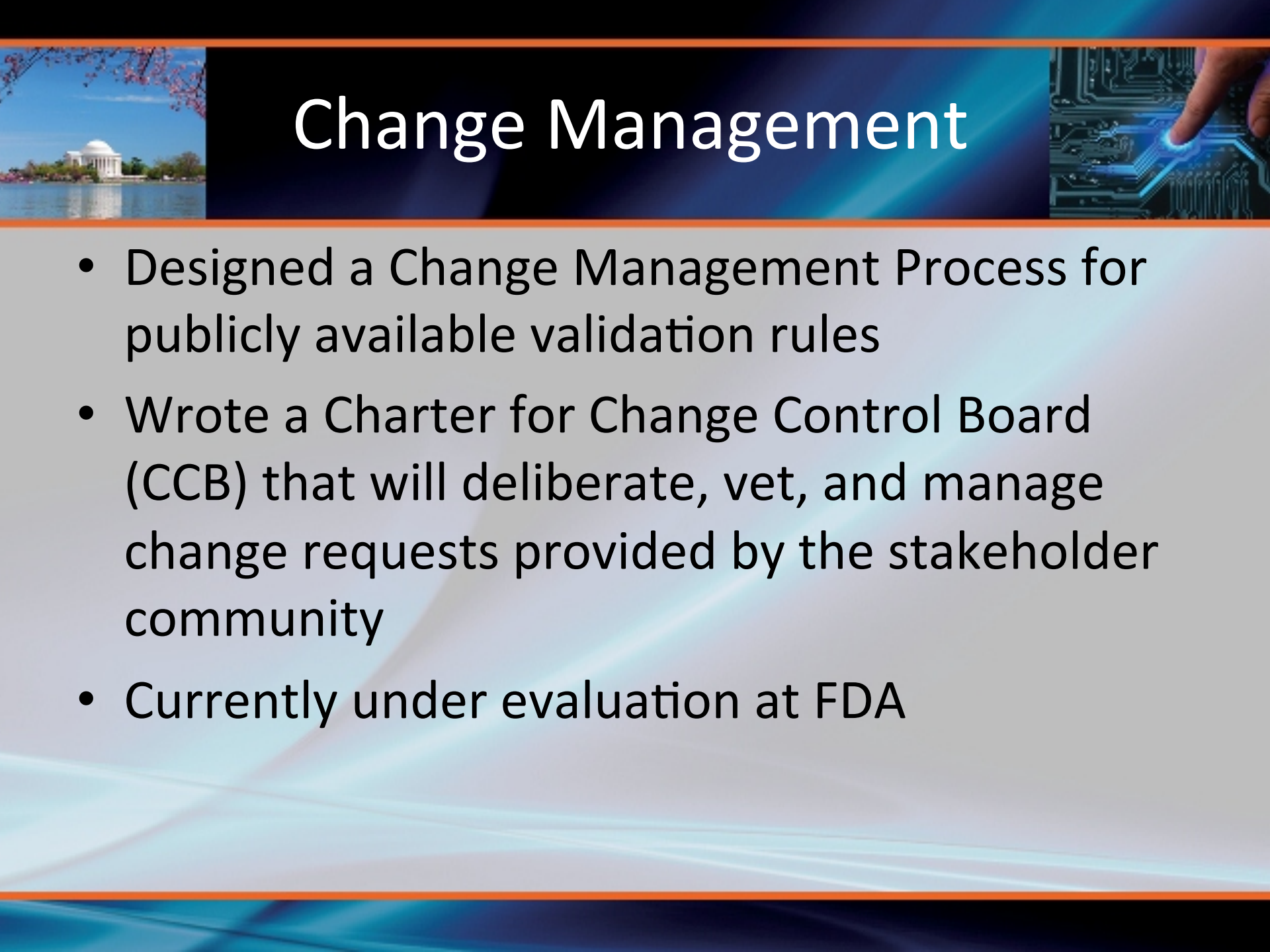
2012 Projects

- Develop Guidelines for Validation Rule Developers
- Design a Change Management Process
- Reconcile CAB/VP and OpenCDISC Rules
- Assess and Improve Existing Validation Rules



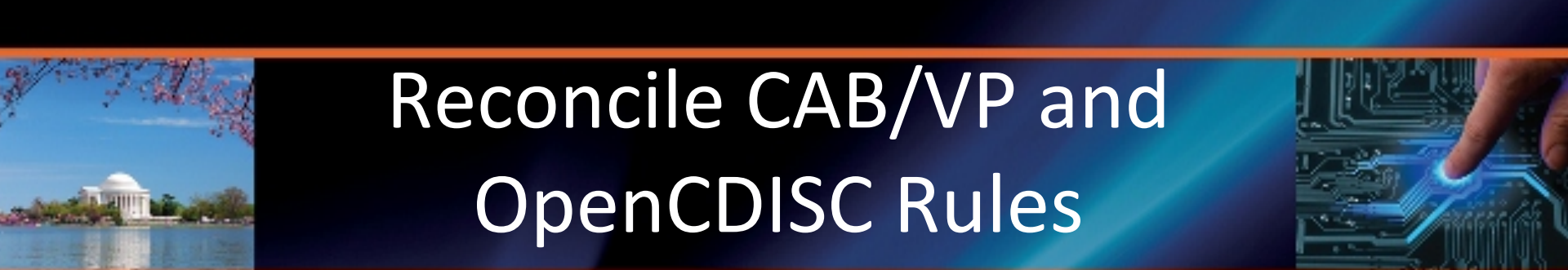
Validation Rule Guidelines

- Reviewed historical practices of existing projects, including OpenCDISC, CAB, and HL7
- Outlined a set of basic guidelines for for numbering, messages and descriptions, categories, severity



Change Management

- Designed a Change Management Process for publicly available validation rules
- Wrote a Charter for Change Control Board (CCB) that will deliberate, vet, and manage change requests provided by the stakeholder community
- Currently under evaluation at FDA



Reconcile CAB/VP and OpenCDISC Rules

- Compared CAB/VP results with v1.3 SDTM rules from OpenCDISC
- Identified 45 rules to be reconciled
- Resulted in 9 change requests to update existing rules and 14 requests for new rules



Assess and Improve Existing Validation Rules

- Evaluated top 20 validation rule failures at CBER, based on data from 30 submissions
- Determined the cause and coordinated with CDISC, OpenCDISC and FDA on a proposed solution
- Identified primary cause for rule failure as:
 - Unclear or conflicting underlying standards
 - Incorrectly implemented rule
 - Lack of understanding



Leadership

Name	Role	Organization	Email
Max Kanevsky	Industry Co-lead	OpenCDISC	max@opencdisc.org
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Anne Russotto	Steering Committee Liaison	Celgene	arusotto@celgene.com



2013 Projects

- Continue the effort of improving SDTM validation rules
- Ensuring that all rules are both clear and effective for use by industry and by FDA
- Determine new rules that will add value and manage rules that need clarification
- Coordinating with CDISC, OpenCDISC and FDA