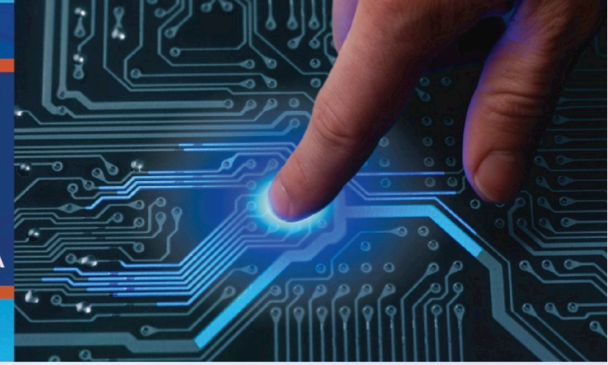




**FDA/PhUSE Annual
Computational Science Symposium**

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Standard Interactions: CDISC Standards and the CSS Workgroups

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Key Technical Initiatives for 2012

Technical Strategy

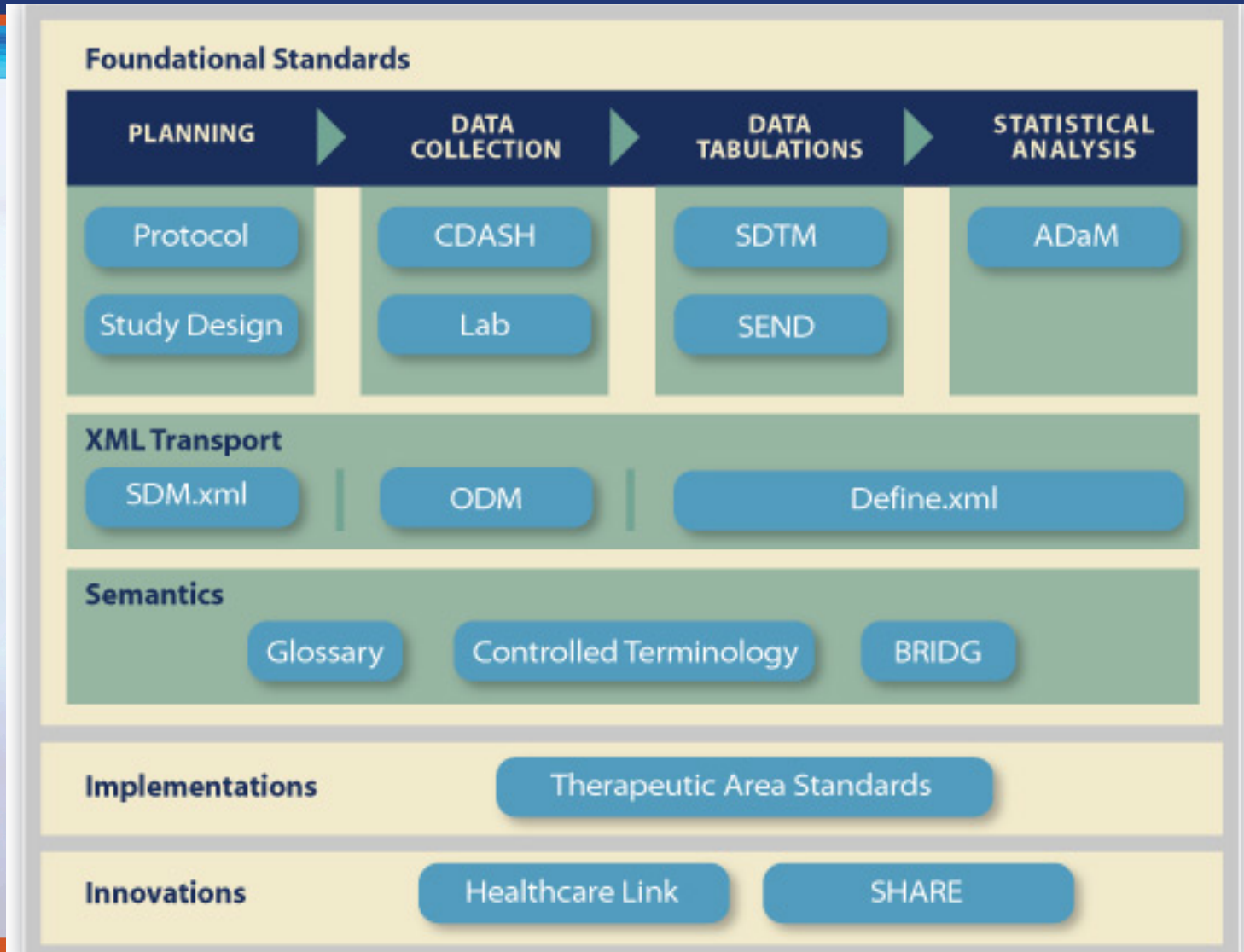
- Communicate updated CDISC vision and roadmap
- Incorporate BRIDG in standards development
- Begin transition to SHARE
- Improve use of online collaboration tools for standards development
- Increase involvement by global volunteers

Technical Projects

- Increase transparency:
 - Publish charters
 - Publish schedule of milestones
 - Improve project tracking
- Improve processes
 - Standards development process
 - New Stds Review Council
 - Appreciate volunteers
- Coordinated new versions of foundational standards
- Kickoff CFAST



Overview of CDISC Standards





WG 1: Data Validation and Quality Assessment

- Relevant CDISC Products:
 - CDASH, SDTM, SEND, ADaM
 - *SDM.xml, ODM, Define.xml*
- Work in Progress:
 - CDISC Validation Project, SHARE, Define.xml v2, SDTM.xml, Healthcare Link
- Relevant topics:
 - Data provenance, chain of custody, traceability, metadata



WG 2: Standardizing data within Inspection Site Selection

- Current CDISC Products:
 - SDTM, ADaM, Study Design, SDM.xml
- Work in Progress:
 - Healthcare Link, HL7 Study Participation Message, HL7 CTR&R
- Relevant topics:
 - When is this data available to FDA inspectors?



WG 3: Challenges of Integrating and Converting Data across Studies

- Current CDISC Products:
 - Study Design, CDASH, SDTM, ADaM, Controlled Terminology
 - SDM.xml, ODM, Define.xml
- Work in Progress:
 - ADaM ISS/ISE data integration project, C-Path CAMD and Therapeutic Area Standards projects, SDTM.xml
- Relevant topics:
 - How can sample research data be made available?
 - What can we learn from past meta-analysis projects?



WG 4: Standards Implementation Issues with the CDISC Data Models

- Current CDISC Products:
 - CDASH, SDTM, ADaM, Study Design, Controlled Terminology
 - ODM, SDM.xml, Define.xml, CDISC Validation Project
- Work in Progress:
 - FDA Legacy Data Conversion Project; FDA analysis of standard submissions
- Relevant topics:
 - Where do the challenges of potential transition to HL7 standards fit in?
 - How can we better incorporate feedback from all of industry in the standards development process?



WG 5: Developing Standard Scripts for Analysis and Programming

- Current CDISC Products:
 - SDTM, ADaM, Define.xml
- Work in Progress:
 - PhUSE, CAMD and CDISC Therapeutic Areas, BRIDG Statistics DAM, ADaM
- Relevant topics:
 - Where does HL7 fit with analysis data and programs?
 - How do we improve integrated use of SDTM and ADaM?



WG 6: Non-Clinical Road-map and Impacts on Implementation

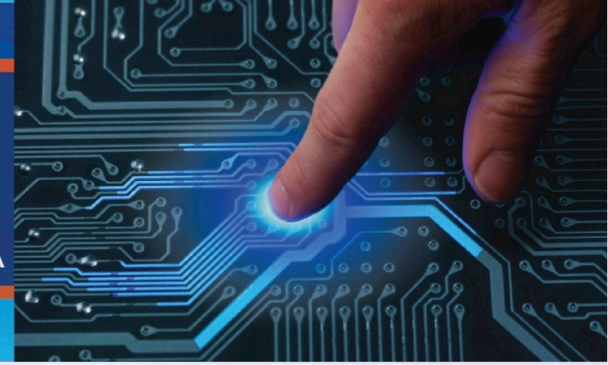
- Current CDISC Products:
 - SEND, Define.xml
 - *Protocol, SDM, ODM, ADaM*
- Work in Progress:
 - SEND v3.1 (Repro Tox and Safety Pharm), SDTM.xml
- Relevant topics:
 - How can we compare Non-Clinical to Clinical data?
 - How can we increase rate of SEND adoption?
 - How do we handle domains relevant to both humans and animals (e.g., PGx)?



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“If at first you don’t succeed, try, try again. Then quit. There’s no point being a damn fool about it.”

-- W. C. Fields

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