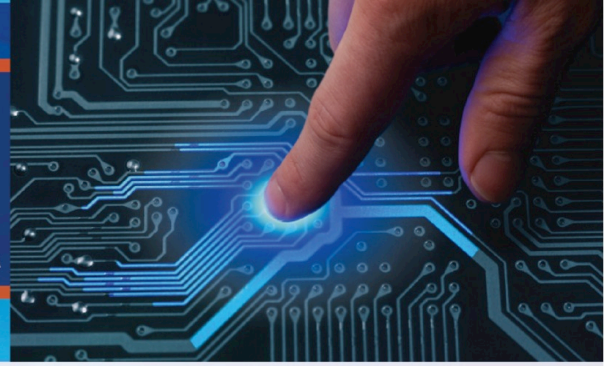
FDA/PhUSE Annual
Computational Science Symposium
March 19 - 20th 2012
Silver Spring Civic Center | Silver Spring Maryland, USA



FDA CSS Working Group Initiative

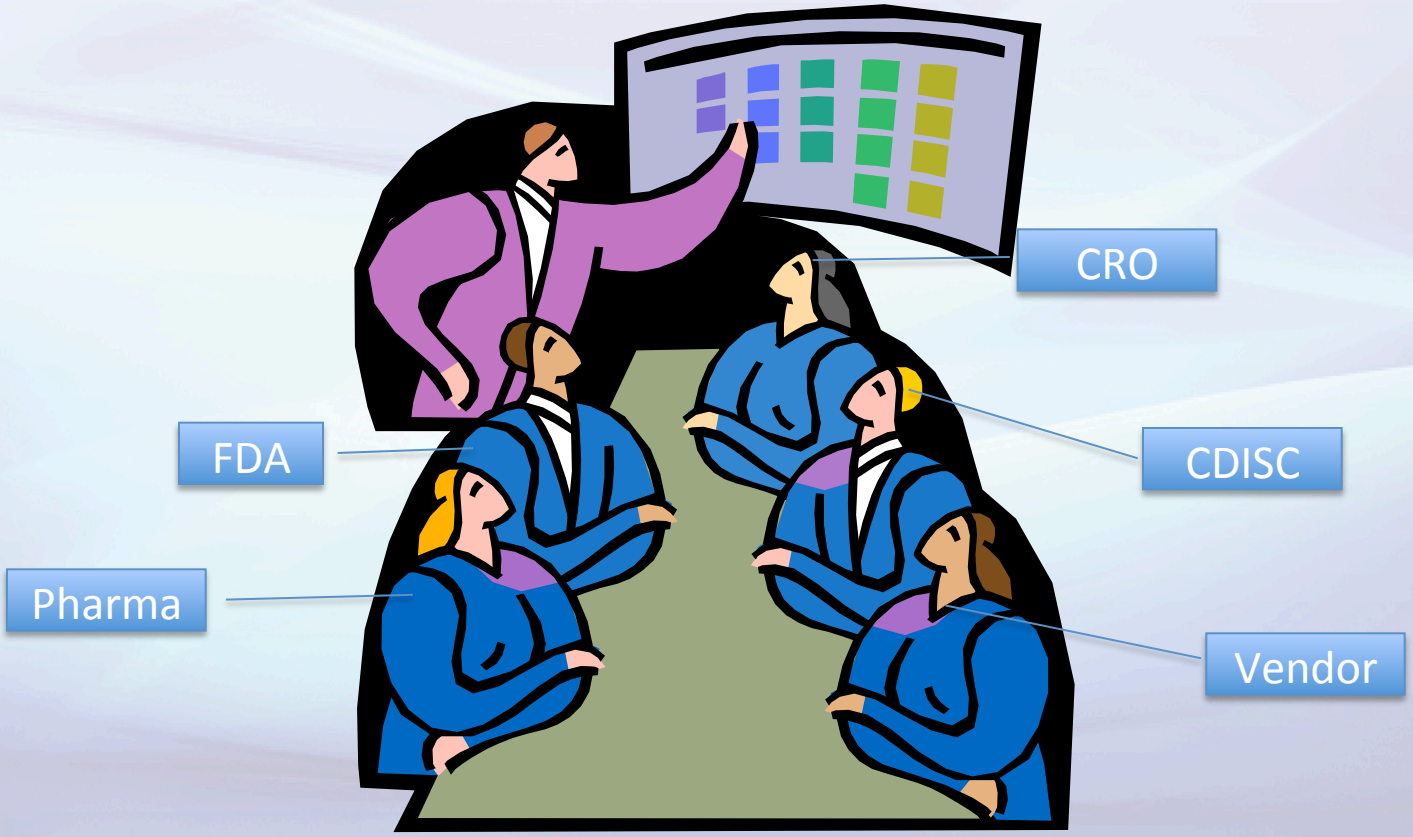
Steering Committee
Chris Decker
d-Wise Technologies

Past History

FDA Proclamation

We the Masses Yearning for Answers

Paradigm Shift



FDA/PhUSE Computational Science Symposium (CSS)

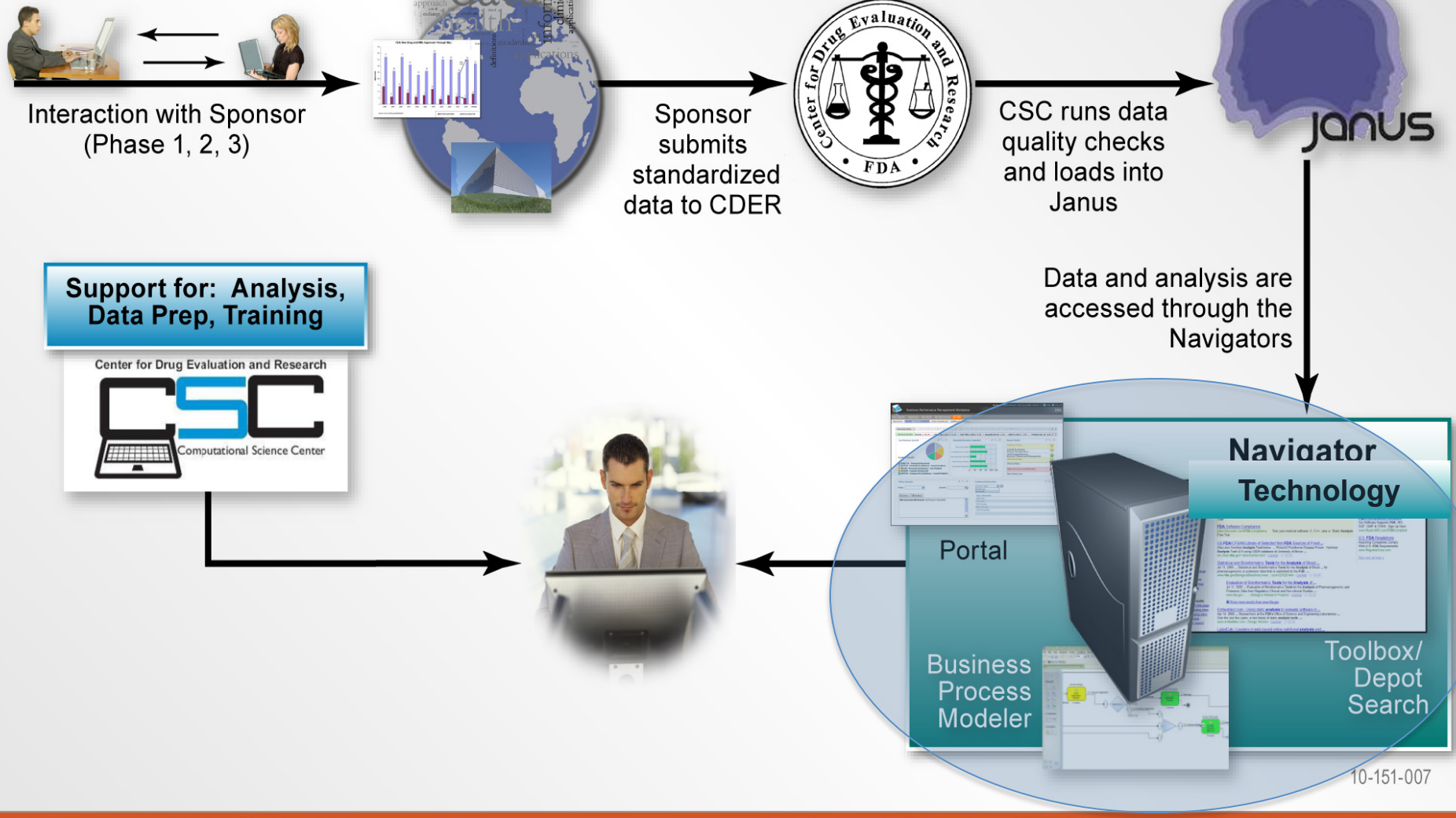
- 3rd in a Series of Annual Computational Science Meetings established to support the work of the CSC
- Intention: To work collaboratively with industry, vendors and regulators in a non-competitive space to find solutions and advance the computational sciences associated with the development and regulation of new medical products (drugs, biologics, etc.)
- Originally modeled on CaBIG meetings

Source: Chuck Cooper, FDA

Meetings 2.0 – FDA/PhUSE Computational Sciences Symposium

- A different kind of event
- Collaborative working meeting
- Initially defined 6 working groups focused on specific topics
- Work does not stop when people go home – Continue the collaboration
- Work Products, timelines, next steps

Future State



Focus of Work Groups

- The focus of the Work Groups (WGs) represents critical pieces of the puzzle for FDA to build its modern review environment
  - Groups have identified critical FDA needs
  - Overlap with industry needs
  - Together, we have the opportunity to identify possible solutions that help us both
- Without Working groups, FDA would have proceeded with development of solutions alone
  - Less than ideal
  - Solutions could significantly impact industry
  - Would not leverage broader stakeholder expertise
  - Unique opportunity for collaborative problem solving

Source: Chuck Cooper, FDA

Working Group Structure

Working Group Steering Committee
Consists of 8-10 members including one liaison to each working group

Working Group 1 FDA Co-Leads Industry Co-Leads Steering Committee Liaison	Volunteers FDA Industry SDOs Academia
Working Group 2 FDA Co-Leads Industry Co-Leads Steering Committee Liaison	Volunteers FDA Industry SDOs Academia
Working Group 3 FDA Co-Leads Industry Co-Leads Steering Committee Liaison	Volunteers FDA Industry SDOs Academia
Working Group 4 FDA Co-Leads Industry Co-Leads Steering Committee Liaison	Volunteers FDA Industry SDOs Academia
Working Group 5 FDA Co-Leads Industry Co-Leads Steering Committee Liaison	Volunteers FDA Industry SDOs Academia
Working Group 6 FDA Co-Leads Industry Co-Leads Steering Committee Liaison	Volunteers FDA Industry SDOs Academia

WG1: Data Validation and Quality Assessment

Objective: develop a robust process to rapidly validate and assess data quality as data moves through the product life cycle across both industry and regulatory review

- Guidelines for validation rule developers
- Change Control Board for public rules
- Evaluate the top 20 Rules

WG2: Standardized Data for Site Selection Process

Objective: Developing standards for the data set used in risk based modeling to improve the quality of site selection

- Define requirements for data needed and relationship to current standards
- How will data drive site selection process
- What is the impact for sponsors developing a risk based monitoring plan

WG3: Challenges of Integrating Data and converting Data across studies

Objective: Address the challenges of analyzing and integrating data from retrospective studies from both an industry and regulatory perspective and provide best practices

- Definition of Integration
- Appropriateness of integration
- Traceability
- Mechanics of Integration

WG4: CDISC Standards Implementation Challenges

Objective: identify specific challenges with implementing the CDISC data standards and make change recommendations or best practices

- Development of Data Guide
- Proposed SDTM Exceptions
- Identify 'top 10' submission issues and best practices around those issues

WG5: Standard Scripts for Analysis and Reporting

Objective: Identify potential standard scripts that can be developed and shared across industry

- Define an shared technical environment for code development
- Identifying what scripts/analyses can be standardized
- Determining the process and validation of the scripts

WG6: Non-Clinical Roadmap and Implementation

Objective: improve nonclinical assessments and regulatory science by identifying key needs and challenges in the field and then establishing an innovative framework for addressing them

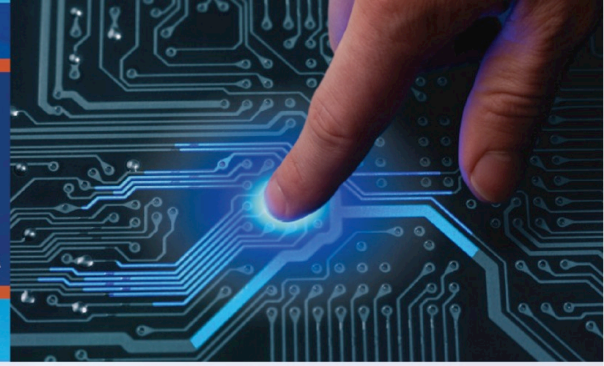
- Data Integration
- Endpoint predictivity
- Interorganizational SEND
- SEND implementation needs/challenges
- Roadmap

Working Group Challenges

- Pesky thing called a day job
- Volunteers stretched across activities
- Communication, communication, communication
- Keeping on top of activities
- Aligning industry and FDA

Ways to Contribute

- PhUSE Wiki is available for all
  - www.phusewiki.org
  - Set up a user name and start poking around
  - Add comments to discussion tabs
- Volunteer for a working group
  - Sign up for a mailing list
  - Send an e-mail to the co-leads
  - Be patient
- Attend the next event – March 18-19, 2013



Questions?