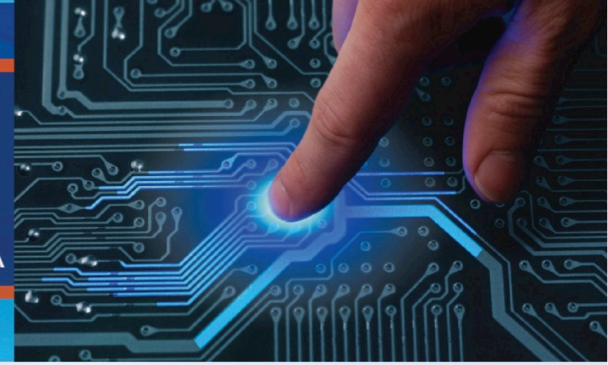




**FDA/PhUSE Annual
Computational Science Symposium**

March 19 - 20th 2012

Silver Spring Civic Center | Silver Spring Maryland, USA



Welcome to Silver Spring, Maryland!

[Flying the Plane](#)



FDA/PhUSE Computational Science Symposium (CSS)

- 3rd in a Series of Annual Computational Science Meetings established to support the work of the CSC
- Welcome and Thank You to our new partners – PhUSE
- 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



Meetings 1.0: The First Two Computational Science Meetings

- Clinical Data Submission Standards and Tools
- Terminology Standards
- Data Quality Assurance
- Chemistry and Manufacturing
- Post-Market Safety
- Community Repository of Program Code
- NCI CaBIG
- eCRFs
- Non-Clinical Data Submission Standards and Tools
- Janus
- Comparative Effectiveness Research
- HL7



Meetings 2.0 – FDA/PhUSE Computational Sciences Symposium

- A different kind of conference: A Collaborative Workgroup Symposium
- Organizing Committee: Broadly defined 6 working groups to continue the work
- Much bigger than these workgroups
- Looking to start and support collaborative workgroups that will continue until all of the work is done.
- Technical “Stakeholder Workgroups” – but we are asking you to move beyond “your stake” ... act as knowledgeable professionals seeking solutions
- Work Products, timelines, next steps



Phase	Task Functions	Personal Relations Functions
1	Orientation	Testing and Dependence
2	Organizing to Get Work Done	Intragroup Conflict
3	Information-flow	Group Cohesion
4	Problem-solving	Interdependence



Workgroup Stages

Phase Task Functions

Personal Relations Functions

1	Orientation	Testing and Dependence
2	Organizing to Get Work Done	Intragroup Conflict
3	Information-flow	Group Cohesion
4	Problem-solving	Interdependence



Tom Sawyer & The Fence





Start Your Engines....



Agenda - Day 1

Monday March 19th		
Session	Timing	Content (Speakers)
Introduction & Updates	8:30-10:00 Great Hall	Welcome to the 3rd Annual Computational Science Symposium (CSS) (Chuck Cooper & Steve Wilson, FDA) What's Coming in PDUFA V (Theresa Mullin, FDA) Computational Science Center Progress and Next Steps (ShaAvhrée Buckman, FDA) CBER Progress and Next Steps (Mark Walderhaug, FDA) Standard Interactions: CDISC Standards and the CSS Workgroups (Wayne Kubick, CDISC)
Break	10:00-10:30 Exhibit Hall	Exhibits & Networking
Challenges, Gaps & Opportunities	10:30-11:30 Great Hall	Challenges and Gaps Identified from FDA Initiatives CDER Perspective (Chuck Cooper, FDA) CBER Perspective (Amy Malla, FDA)
Working Group Introduction	11:30-12:00 Great Hall	Working Group Overview, Goals and Logistics
Lunch	12:00-1:00 Exhibit Hall	Exhibits & Networking
Working Group Breakout Session	1:00-2:30	Initiate Working Group discussions
Break	2:30-3:00 Exhibit Hall	Exhibits & Networking
Working Group Breakout Session	3:00-4:30	Continue Working Group discussions
Networking & Poster Session	4:30-6:00 Great Hall	An interactive and open networking session. Attendees are encouraged to visit exhibits, poster presentations and live demonstrations.
Close		



Agenda - Day 2

Tuesday March 20th		
Session	Timing	Content (Speakers)
Working Group Breakout Session	8:30-10:30	Continue from Day 1
Break	10:30-11:00 Exhibit Hall	Exhibits & Networking
Working Group Breakout Session	11:00-12:00	Working Group summarize their work and next steps
Lunch	12:00-1:00 Exhibit Hall	Exhibits and Networking
Working Group Summaries	1:00-2:30 Great Hall	Each Working Group presents findings (15 minutes each)
Break	2:30-3:00 Exhibit Hall	Exhibits and Networking
Best Poster Presentation Wrap Up & Next Steps	3:00-4:00 Great Hall	Working Group Plan moving forward Closing Remarks – (Chuck Cooper & Steve Wilson, FDA)
Close		



PhUSE Wiki

- www.phusewiki.org
- Lynchpin for post-conference collaborations
- Training available (slides with instructions)
- Also, helpful resource for new work group members
- Progress made will be represented



Considerations

- Tremendous collection of experts and skill sets
- Rare opportunity to accomplish something unique
- Set example for others to refer to
- Special Thanks to Chris Decker



Working Group Award

- At opening of 2013 FDA/PhUSE Computational Science Symposium
- One Work Group will be awarded
 - **2013 FDA/PhUSE Computational Science Gold Medal Award**
- Determined by Steering Committee