



FDA/PhUSE 
Computational Science Symposium

March 18th – 19th 2013

Silver Spring Civic Center | Silver Spring, Maryland, USA



Making Progress: The FDA/PhUSE Collaboration and Computational Science Symposium Part I

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Silver Spring, MD

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Disclaimer



This presentation reflects the views of the author and should not be construed to represent FDA's views or policies



Tom Sawyer & Painting the Fence



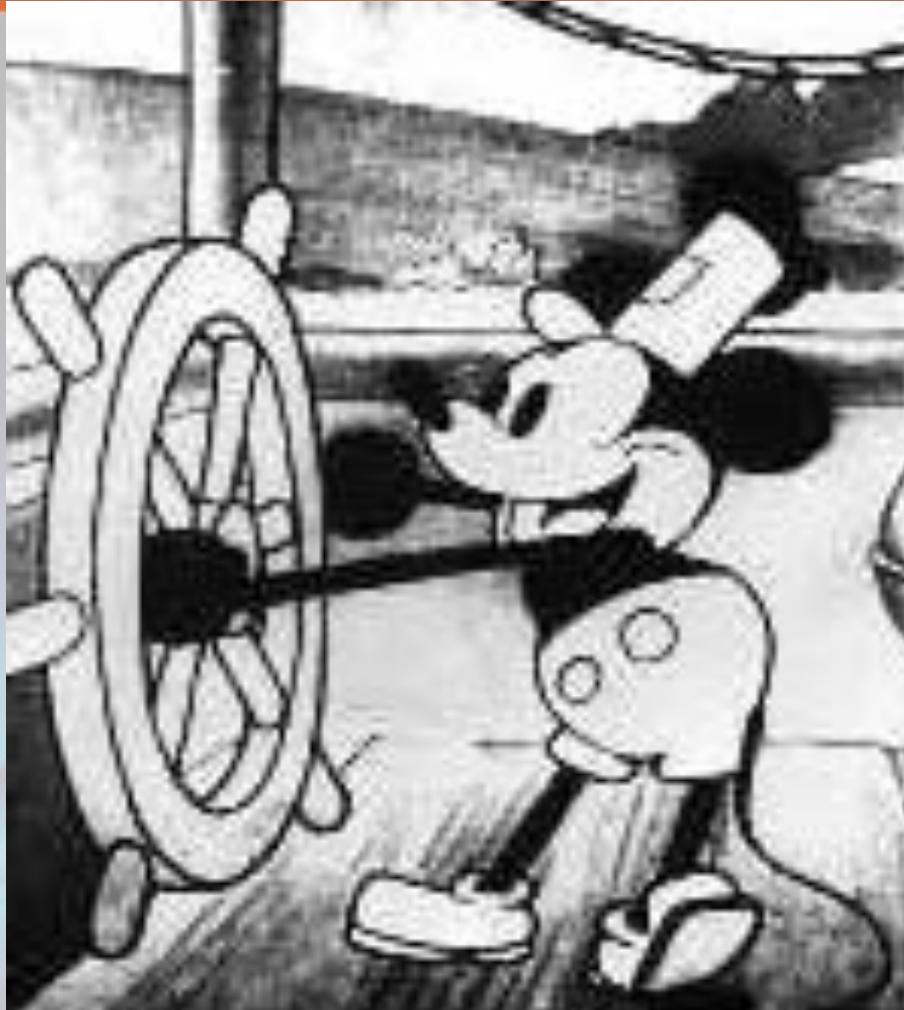


Some of My Lessons Learned



- Steering Committee
- Working Groups
- Communication Technology
- Annual Meeting
- Collaboration
- We Are Not Alone
- Moving Forward
- A Bigger Tent

Steering Committee





Steering Committee

- **Industry**

- Scott Bahlavooni
- Michael Brennan
- Chris Decker
- Anne Russotto
- Gale Heavner
- Scott A Getzin

- **SDO /CDISC**

- Frank Newby

- **FDA**

- Crystal Allard
- Chuck Cooper
- Tim Kropp
- Suzie McCune
- Liliam Rosario
- Steve Wilson



Working Groups



- 6 to 4 to 5
- Leadership (You Know Who You Are)
- Year around activity/commitment
- Patience – volunteer
- Not everybody can be here
- Project endpoint focus
- Recognition and Management support
- People are paying attention
- Adjust: Not everything will work
- Amazing “stuff” does get done



Communication Technology



- Wiki
- Mail List Serves
- Conference Calls
- Webinars



Annual Meeting



- Important
- “Business Model” and Risks
- Agenda
 - Welcoming
 - Update
 - Strategic
 - Working Group Focused
- Meeting Support & Venue



Collaboration

- “Future Search” (Marvin Weisbord) <http://www.futuresearch.net/>
 - Complex problems require diverse input
 - Use methods that get all your players' input
 - Focus on a future, desired state - this would be the "common ground" that unites the players
 - Acknowledge conflicts (don't bury or avoid them)
- It's not easy
- For regulators to be involved it needs to be open and transparent
- Really hard to find the time



Moving Forward

- Finishing Projects
- New Projects
 - CDRH Pilot for the Electronic Submission of Medical Device Data in an SDTM-Based Format
 - Analysis Data Reviewer's Guide (ADRG)
 - SDTM Exceptions
- New Working Group: Emerging Technologies
- An Even Bigger Tent / PhUSE support of scientific working groups



In Closing – A Welcome

- To collaborate – we need continue to be open/transparent
- Self-interest will not work
- We need to be patient with one another
- Partnerships, Understanding Relationships, Thinking About Past/Present/Future and Coordinating Activities: important elements of what we do – e.g., CDISC
- Lots of visions out there -- we need to “stay real”
- Welcome to Silver Spring, I’ m happy that you survived St. Patrick’ s Day and have joined us for this Grand Experiment – the FDA/PhUSE Computational Science Symposium