FDA/PhUSE
Computational Science Symposium
March 18th – 19th 2013
Silver Spring Civic Center | Silver Spring, Maryland, USA

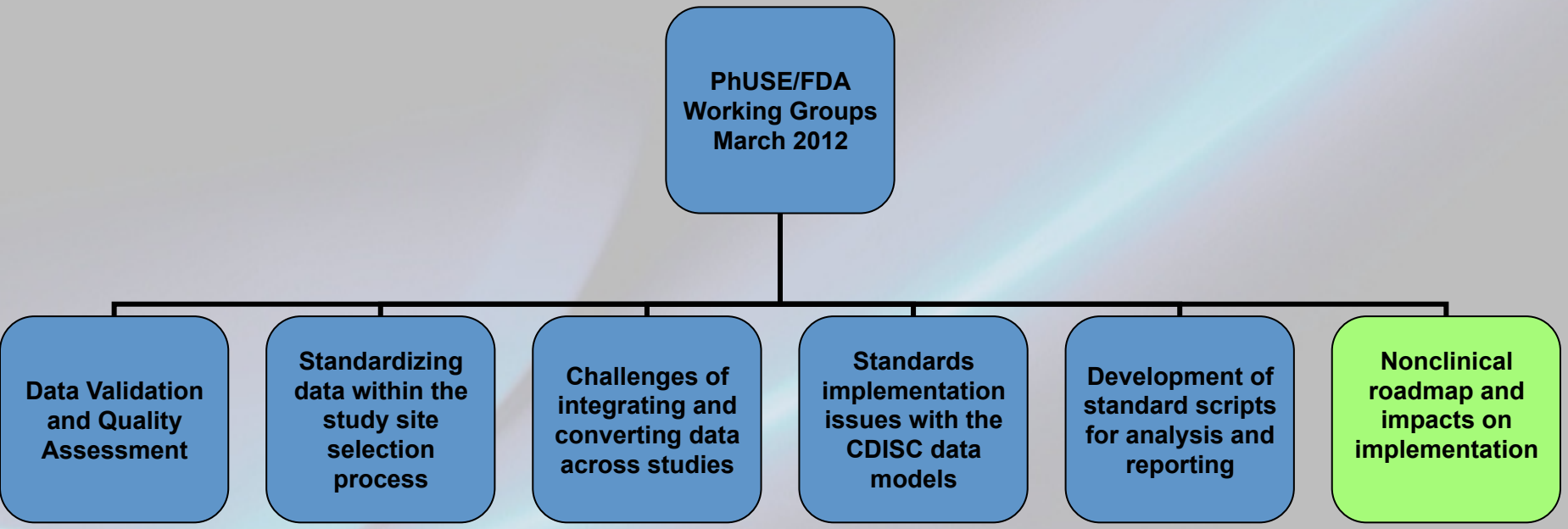
Nonclinical Roadmap and Impacts on Implementation

Orientation on
FDA/PhUSE Working Groups:
Projects Summary &
Project Membership

FDA/PhUSE Computational Sciences Symposium

March 2013

Orientation: PhUSE/FDA Working Groups Context of " Nonclinical"



Nonclinical Projects

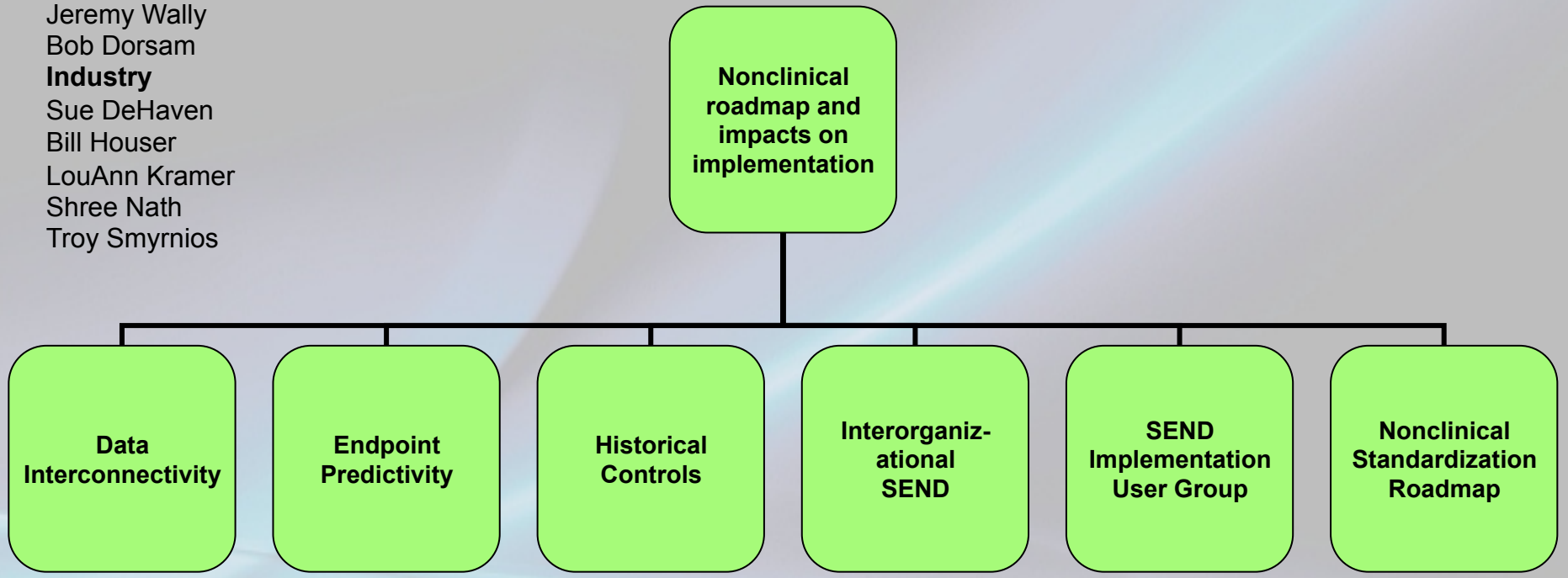
Core Team:

FDA

Tim Kropp
Lilliam Rosario
Jeremy Wally
Bob Dorsam

Industry

Sue DeHaven
Bill Houser
LouAnn Kramer
Shree Nath
Troy Smyrnios



Data Interconnectivity Project

Vision

1. Identify new ways of integrating, analyzing and interpreting trends across traditional data silos, disciplines and organizations.
2. Standardize a means to associate pharmacological classes with experimental compounds to enable connecting and relating data across pharmacological class.
3. Relating nonclinical data across the continuum of drug discovery and development with a view of clinical relevance and eventual correlation with clinical data.

- Membership
  - Jyotsna Kasturi, co-lead
  - Paul Brown, co-lead
  - Jeremy Wally
  - Latha Prabhakar
  - Donna Danduone (Former participant [April’12 – March’13]
  - Alan Brown
  - Suresh Madhavan
  - Henrik Drews (Former participant [March’12 – August’12])

Endpoint Predictivity Project

Vision

With the requirements for submission of nonclinical data in a standard electronic format (SEND) contained in PDUFA V, we expect that the problem of compilation and exploration of large sets of nonclinical data will become tractable in the near future. We hope to utilize this data in a number of ways, including (but not limited to):

- Enable better prediction (informing both drug development studies and the clinical protocols and monitoring)
- Build analysis panels for certain types of concerns
- Enable better study design (endpoints, timing of collection, etc)
- Reduce or streamline study endpoints or types based upon evidence

- Membership
  - Paul Cornwell, co-lead
  - Jeremy Wally, co-lead
  - Tim Gartner
  - Tim Kropp
  - Rich Khan-Malek
  - Jane Reed
  - Shree Nath
  - Sue DeHaven
  - Troy Smyrnios
  - Martha Lee
  - Dave Seyler
  - Joelle Ibanes
  - Manfred Kansy
  - Paul Bradley
  - Ron Filler
  - Jessica Behrle
  - Jon Kimball
  - Martha Lee

Interorganizational SEND

I-SEND

Need/Challenge

The responsibilities for creating the SEND files for a study is often shared across organizations. Clarity is needed on how these responsiblities can be effectively managed.

- Membership
  - Bill Houser, co-lead
  - Sue DeHaven, co-lead
  - Kathryn Brown
  - Pranav Agnihotri
  - Jennifer Feldmann
  - Jeff Foy
  - Jyotsna Kasturi
  - Lou Ann Kramer
  - Shree Nath
  - Louis Norton
  - Debra Oetzman
  - Lynda Sands
  - Troy Smyrnios
  - Peggy Zorn
  - Jackson Zalki (former participant)

Historical Data

Goal

Develop recommendations for high priority projects regarding the use of historical control data. These recommendations could include identification of areas where additional aggregation or analaysis of historical control data may be useful or identification of data standards to develop and pilot for exchange of historical data.

- Membership
  - Jennifer Feldmann, co-lead
  - Lauren Mihalcik, co-lead
  - Paul Brown
  - Serge Rochon
  - Joyce Zandee
  - Judy Henck
  - Nancy Everds

SEND Implementation User Group

Vision

Users will have clear places to go for assistance with SEND implementation, with the ability to ask questions, receive answers, discuss issues, and learn more about common implementation issues.

- Membership
  - Lynda Sands, co-lead
  - Troy Smyrnios, co-lead
  - Louis Norton
  - Jennifer Feldmann
  - Lou Ann Kramer
  - Audrey Walker
  - Bill Houser
  - Peggy Zorn
  - Wenxian Wang
  - Sarah Obbers
  - Debra Oetzman
  - Frederic Mura
  - Jeff Foy

Nonclinical Standardization Roadmap

Vision

Availability of useful electronic meta- and study data to enable more effective and efficient review of nonclinical data by both industry and regulatory reviewers. Data should be accessible to further investigate class effects and address regulatory science questions.

- Membership
  - Gitte Frausing, co-lead
  - Bob Dorsam, co-lead
  - Alain Nanzer
  - Lynda Sands
  - Debra Oetzman
  - Lou Ann Kramer
  - Anisa Scott
  - Sarah Obbers
  - Rick Thompson
  - Former participants
    - Jerker Ringstrom
    - Geoff Mann
    - John Anderson
    - Deborah Sholtes
    - Natalia Smeljanski

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PhUSE 2013
BREAKOUT Logistics

Nonclinical Working Group

March 2013

Breakout 1
Project Status

- Introduction
  - Core Team and Project team list
  - Overview of Breakout plan
- Project updates
  - Delivered and viewed via an "Appreciative Inquiry" perspective
  - 60 minutes (10 min/group)
  - Key elements for audience to focus
    - List of questions to think about; these will be discussed and answered in Breakout 2
- Discussion
  - Some minutes for discussion (time for clarifications, requests for further info or details.)
- Goal for this session: Understand projects' goals, accomplishments and challenges, enough to assess and provide recommendations.

Breakout 2
Project Synthesis and Reformation

- 1st half:
  - Develop an analysis of the projects
    - Break up into small groups to answer focus questions (15 min)
    - Come together and present observations
      - Determine what worked? what didn't? where there common themes?
      - Provide recommendations
    - Synthesize assessment & recommend project progression
- 2nd half:
  - Determine if new projects should be added to our PhUSE project portfolio
    - List and describe at high level, available project proposals
      - Sources: Project list from last year; New projects gathered from project updates
      - List provided
    - Group vote on adding projects
- Goal for this session: Recommend "Nonclinical…." Working Group activities going forward .

Breakout 3
GLP eData Forum

- Introduction
  - Frame the issue "Why are we having this session?"
  - Identify rules of engagement, including the concept of a parking lot for some issues.
- Present Questions via Powerpoint.
- Excel spreadsheet will be managed during session to capture elements of discussion.
  - Captured elements include: recommendations, ownership, risk vs. reward, and perhaps "if a question is, or is not, related to a GLP topic"
- Responses will be posted on SEND Implementation FAQ's (Wiki)
- The goal of the session: to develop responses to the questions that will be recommendations rather than policy
  - The end of this session may have a list of questions from a "parking lot" that need to be further investigated.

Breakout #4
Project Work

- With our topics confirmed, groups must now form and plan their work.
  - Membership situation assessed
  - Operating Plan
  - Identify deliverables and milestones for 2013-2014.
    - Same format as last year's form
- Project Team working time
  - complete Workstream Framework form
- Develop Summary for CSS