Closing Plenary Panel – Opening Remarks

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FDA/CDER/OTS/OB/DBIII

2013 CDISC Interchange
“Data are More Meaningful when SHARE-d”
Bethesda North Marriott Hotel and Conference Center
Rockville, MD
November 7, 2013
FDA Disclaimer

This presentation reflects the views of the author and should not be construed to represent FDA’s views or policies.
“The ‘New’ Now ... What a Difference a Couple of Years Makes!

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Getting to the FUN Parts”
Words and Acronyms

- Patients
- Privacy
- Transparency
- Standards
- Research
- Health Information Systems
- CDASH
- Site Support
- Protocol Templates
- Henry Ford
- SHARE
- EVS
- BRIDG
- Semantic Web
- Quality Data/Evidence
- SDS.xml
- Review
- SDTM, ADaM and ODM
- FDASIA/PDUFA V
- Pre-Competitive
- CFAST

- CFAST
- CDER OTS OB and OCS
- Meta-analysis
- Memorandum of Understanding
- PMDA/IMI/MFDA/EBI
- Traceability
- Therapeutic Area
- Downstream Users
- Adoption
- Clintrials.gov
- Diabetes
- Model T
- Black Swan
- Protocol Design
- Collaborative Design
- Standards Governance
- Metadata Repository
- Validation
- End-to-End
- SDRG/ADRG
- PhUSE
Words and Acronyms

Standards
SDRG/ADRG
Privacy
End-to-End
HENRY
Data/Evidence
Support
Pre-Competitive
SDS.xml
Memorandum
Templates
Design
SHARE OTS
Validation
Review
Protocol
SHARE OTS
CDM
Research
Meta-analysis
Model
CDER
Black
Web
FDASIA/PDUFA
Governance
Support
Pre-Competitive
CDASH
Area
FDA
Collaborative
Quality
Information
Site PhUSE
Adoption
Ford
Swan
CFAST
Patients
Metadata
Ob
Focus on Roles, Needs, Progress and Possibilities

- Sites and CDASH
- Health Information Systems and Research
- International Recognition/Momentum: Review and Transparency
- Using Standards: Regulatory Research and the Model T
- SHARE and Sustainability: Process, layers and experience
- FDA Commitment: FDASIA/PDUFA V – “Binding Guidance”
- Things Change. Waking Up – Office of Biostatistics & Statisticians
- Volunteers and Collaboration
- PhUSE Computational Science Symposium
- Learning Together
FDASIA/PDUFA V

Laws & Regulation

Guidance & Initiatives

Adapted from S. Woollen
“Binding” Guidance

Laws & Regulation

PDUFA V Guidance

Adapted from S. Woollen
Future Initiatives

- Analysis Data Working Group (*in the Office of Biostatistics*)
- Good review practice/efficiency
- Therapeutic area standards -- CFAST
- MOUs with academic institutions
  - Collaboration to advance data standards/quality/sharing as integral parts of statistical and medical research

Lavange, 2013
Volunteers & Collaboration

- C-DISC
- C-Path
- TransCelerate
- CFAST
- CSS Working Groups
Tom Sawyer & The Fence

FDA
FDA/PhUSE Computational Sciences Symposium (CSS)

Working Groups

• Improving Data Quality
• Optimizing the Use of Data Standards
  – Study Data Reviewer’s Guide (SDRG)
  – Analysis Data Reviewer’s Guide (ADRG)
• Development of Standard Scripts for Analysis and Programming
  – Platform
  – White Paper
• Non-Clinical Road-map and Impacts on Implementation
• Emerging Technologies
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Development of Standard Scripts for Analysis and Programming Working Group

2014 CSS Script-Athon

• The first ever "Script-athon" - a hands-on opportunity to jump-start the Standard Scripts Working Group code repository!
• Participants will collaborate to create standard scripts for predefined targeted analyses using various code languages.
• Bang through some code!
• Jump-start our code repository!
Twilight Zone Pioneer Episode: Data Standards, Applicants and Reviewers
Let’s Keep Meeting & Working Like This!

Thanks for All of Your Efforts!
& Thank You for Your Attention!