

Data Visualization Working Group

*Advancing clinical review through emerging technologies
and trends in data graphics*

SDE

June 8th, 2017

Agenda

- Data Visualization Working Group Background
 - Introductions
 - History
- 2017 Areas of Focus
 - Interactive Analysis Collaboration Project
 - Subject Level Review with Interactive Visualization
 - Data Anomaly Detection
- Collaboration Opportunities



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Background

- PhUSE Emerging Trends and Technologies
 - 2015: Started by Crystal Allard, FDA
 - 2016: Series of topics and presentations – i.e. Risk Based Monitoring, CTSpedia, etc.
 - 2017: Focus on Interactive Analysis topic areas
- Co-Leads:
 - Michael Rubison, Capish
 - Melissa Wissner, Medidata



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2017 Areas of Focus:

Use Cases for Data Visualization

- Group 1: Best Practices for Interactive Analyses for Decision-making & Submissions
- Group 2: Use of Data Visualization for Subject Level Data Review
- Group 3: Use of Data Visualization for Data Anomaly Detection



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Group 1: Leveraging Data Visualization Approach for Clinical Data Analysis and Submission

- Goal: Collaborate and evaluate the feasibility and benefits of an interactive analysis approach from a regulatory perspective and explore solutions to the challenges facing Interactive Analyses
- Status
 - Initiated March 2017
 - Project Request developed and submitted



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Group 1: Leveraging Data Visualization Approach for Clinical Data Analysis and Submission

- Key Questions:
 - What are the requirements of traceability and reproducibility for interactive analyses in the regulatory environment?
 - What is a feasible framework to share data and results, in an interactive fashion, between Sponsor and the FDA?
 - Have there been any cases where a sponsor has attempted to include an interactive analyses as part of a submission package, and if so, could we draw lessons learned on the case, or cases?
 - What constitutes a discrepancy of concern between data and results contained in a submission package and exploration by Regulatory Authorities? What types of discrepancies are of most concern to the Agency? In case of discrepancies between submitted results and exploration, what approaches and resolutions could be taken that impact the interactive suite?
 - What functions, features, and components would be expected in an acceptable interactive analysis package that supports a regulatory submission?



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Group 2: Use of Data Visualization for Subject Level Data Review

- Topic Areas of Interest
 - Patient Narratives
 - Patient Progress
 - Patient Profiles
 - Efficacy Visualizations for Analyses
 - Visualizations for QC & Analysis & Reporting
- Status
 - Initiated May 2017
 - Project Request in development



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Group 2: Use of Data Visualization for Subject Level Data Review

- Key Questions:
 - What are the traditional approaches to creating profiles and narratives versus more innovative approaches?
 - How are visualizations used to enhance profiles and narratives?
 - Are the current processes in creating patient profiles and narratives efficient? Are there opportunities? Automation?
 - Are there standardization or configurable options when creating profiles and narratives?
 - How does standardization of data (SDTM/AdaM) assist with standard data review tools?
 - Are dynamic/interactive profiles/narrative being used? Is this where the industry is going? Use of dynamic/interactive profiles in regulatory submissions?



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Group 3: Use of Data Visualization for Data Anomaly Detection

- Topic Areas of Interest:
 - Data Quality
 - Anomaly Detection
 - Data Cleaning
 - Metrics & Operational Performance
 - Central Monitoring
 - Signal Detection
 - Registries & Rare Diseases
 - RWD/RWE
- Status
 - Discussion groups forming June 2017



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Data Visualization Working Group Collaborations

- PhUSE Working Groups
 - Code Sharing and Standards
- Industry Groups
 - ASA Safety Monitoring WG
 - Biopharm WG
 - CTTI
 - Transcelerate
 - CTSpedia
- FDA



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Data Visualization Working Group Meetings:

2nd and 4th Tuesdays @ 10am Eastern

Come join us!

**The premier community for people
working in the biometric area**



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