Delivery of Data Visualizations within GlaxoSmithKline Clinical Development and Partners
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Agenda

- Integration of Data Visualization & Scalable Enterprise Level Delivery (ELD) Model
- Keys & Lessons Learned from Successful ELD Implementation

The graphs rendered herein are not referenced to any specific GSK study or asset, contain no personally identifiable information, and are shown for demonstrative purposes only.
Integration of Data Visualization & Scalable Enterprise Level Delivery (ELD) Model
Organizational Embedding of Data Visualization
Requires successful marriage of tool availability and user engagement

1. Limited Access/Limited Engagement
2. Wide Access/Limited Engagement
3. Limited Access/High Engagement
4. Wide Access/Strong Engagement
Clinical teams decide individually to use Spotfire

Teams were assisted with setup
GSK Legacy Approach: Team based

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Data Visualization is delivered via a centralized team

All teams are continuously supported
GSK Scalable Enterprise Level Delivery (ELD) Model

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GSK: Scalable Enterprise Level Delivery (ELD) Model

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- Dramatic and consistent increase in Spotfire adoption & requests for Data Visualization
  - 275% increase in deployed Spotfire Workflows in 2016 vs. 2015
  - 250% increase in Workflow Setups in Q1 2017 vs. Q1 2016
Key Stakeholders & Collaborators:
- Clinical Development Study Teams (i.e. OSLs, CILs, Medical Monitors, DQLs, Statistician)
- Clinical Programming
- GCSP: SERM
- R&D IT: Integrated Systems Support (ISS) and IT Support (near/off-shore vendors)
Keys & Lessons Learned from Successful Enterprise Level Delivery (ELD) Implementation
A. Define Programs Supported by Data Visualization

B. Standardize Collection of Data Visualizations (or Workflows)

C. Standardize Data Type Supported

D. Standardized, Scalable Process
Key Principles for Successful ELD Implementation

A. Define Programs Supported by Data Visualization

– Enterprise Level Delivery (ELD)
– GSK R&D Clinical Development; 3 major Programs:
  – In Stream Clinical Monitoring: CSTV Workflow
  – Safety Review Teams: SRT Workflow
  – Risk Based Monitoring: RBM Tool

– Each Program has different Stakeholders; same data represented differently and/or different questions

CSTV: TRT Duration

SRT: Hy’s Law

RBM: Visits Entered Late

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Keys for successful ELD implementation at GSK

B. Standardize Collection of Data Visualizations (or Workflows)

– Small number of Standard Templates
  – Templates designed to transcend therapeutic area & clinical phase
  – Collaboration: Statistics & Programming (S&P), Centralized Data Visualization, Data Management, Safety, & Clinical

– Standardize Workflow content & visualization outputs

Menu Page

<table>
<thead>
<tr>
<th>All Visualizations:</th>
<th>Key Visualizations by Role:</th>
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</thead>
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<tr>
<td><strong>Standard Visuals:</strong></td>
<td><strong>Medical Monitor:</strong></td>
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<td>S01 - Early Withdrawl</td>
<td>• S01 - Early Withdrawal</td>
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<tr>
<td>S02 - Vital Signs Distribution</td>
<td>• S12 - Safety Overview</td>
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<td>S07 - Connecs</td>
<td>• S01 - Early Withdrawal</td>
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<td>S10 - Study Visits</td>
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<tr>
<td>S11 - Study Population Overview</td>
<td>• S06 - Protocol Deviations</td>
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<td>S13 - Missed Doses</td>
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<td><strong>Labs/Liver:</strong></td>
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<td>S17 - Labs By Subjects</td>
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<td><strong>Patient Details:</strong></td>
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<td>S18 - Patient Profile - Detail Labs, AEs, Comments</td>
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<td>S19 - LFT Profile</td>
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<td><strong>Patient Selection:</strong></td>
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<td>S20 - Patient Selection - AE</td>
<td></td>
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<tr>
<td><strong>Other:</strong></td>
<td></td>
</tr>
<tr>
<td>S21 - Query Counts Glossary</td>
<td></td>
</tr>
</tbody>
</table>

Patient Profile

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Standardizing data inputs allows a large number of studies to be supported with a small number of standard templates.

- 2 Types Supported: System Independent (SI, GSK Proprietary) & SDTM (CDISC Standard)
- Standard process for data updates

Advantages:
- Investment upfront programming and coding
- Rapid Setup
- Reproducible and Outputs Validated

Only 6 Templates to support all Programs across clinical dev.
- CSTV: In-Stream Clinical Monitoring (2 Templates; SI/SDTM)
- SRT: Safety Review (3 Templates; Blinded/Unblinded)
- RBM: Risk Based Monitoring (1 Template)
Scalable ELD Process Model for Data Visualization

D. Standardized, Scalable Process

- Model Supports >80 Clinical Studies; >110 Production Workflows
- Single scalable process governs entire DV Support Portfolio
  - Define Programs in Support Portfolio
  - Define content of Standard Templates and visualization outputs
  - Defined data types
- ELD Supported Matrixed On/Off Shore Team (ON/S, OFF/S)
  - Flexible Resourcing Model
    - Best use of resources
    - GSK Oversight
  - Cross-Trained OFF/S staff allows demand-based expansion/contraction
    - GSK Staff Independent of Pipeline Changes
Scalable ELD Process Model for Data Visualization

D. Standardized, Scalable Process

– Standardized templates follow the 80:20 rule
– Single Delivery Process 2 Parts:
  a. Setup Standard Template
  b. Study Specific Customization

a. Standard Template Setup Process:

b. Study Specific Customization Process:

ELD = Enterprise Level Delivery
DVA = Data Visualization Analyst
DVP = Data Visualization Programmer
ELD Process Governance

a. Standard Template Setup Process

- **Quality Plan**
  - **Inputs:** Standard Workflow Specifications
  - **Outputs:** Study Specific Workbook (SSW); _Key Organizational Process Asset_

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**Diagram:**

- **Template Std Specifications**
- **QC Checklist**
- **SSW Issue Log**
- **User Request**
- **GSK DVA STD RQMTS**
- **Programming**: OFF/S DVP 1 Delivers STD TEMP
- **Quality Assurance**: OFF/S DVP 2 Performs QC
- **GSK DVA Fit for Purpose User Review**
- **Production Workflow**

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**Abbreviations:**
- ELD = Enterprise Level Delivery
- DVA = Data Visualization Analyst
- DVP = Data Visualization Programmer

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b. Study Specific Customization Process

- Quality Plan
  - Inputs: Study Team SSV Requirements in SSW
  - Outputs: Study Specific Workbook (SSW); Key Organizational Process Asset

ELD Process Governance

Study Team Requirements SSW

QC SSV Checklist & RQMTS SSW

Programming
- OFF/S DVP 1
  - Create Dataset
  - Build Visual

Quality Assurance
- OFF/S DVP 2
  - Performs QC

User Request
GSK DVA SSV RQMTS

Production Visuals

GSK DVA
SSV RQMTS

DVA = Data Visualization Analyst
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Centralization: Organizational Improvement Process

- Key benefit- Quality plan outputs track:
  - Template Issues (*Issue Log*)
  - Study Specific Visuals (*Study Specific Customization Process*)
    - Quality plan outputs are the inputs to drive the Improvement Process

- Improvement Process: Centralization captures key innovations & learnings. Redistribution across Portfolio drives greater efficiency;
  - Issue Logs form requirements for Up-versioning Standard Templates
  - Study Specific Visuals: Improve & innovate standard visuals

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Improvement Process: Innovation Cases
Pareto Driven Lab Analysis

Connected Charting Relates Study & Detail Level Information Seamlessly

- Pareto histogram drives successive, connected charts for lab analysis
- Allows analysis with rapid progression from study-level information, through outlier identification, to lab results of interest
Pareto Driven AE Analysis

Rapid assessment of study AEs relating to treatment, onset, and duration

Iron Python coding creates control panels to improve efficiency/utility
Swimlane Charts Clearly Relate Events Over Time

Patient Profile Connect Exposure, Labs, Conmeds & AEs Temporally

- Swimlane charts allowing onset and duration of events to be compared
- Potential correlations between exposure, conmeds, and AEs can be rapidly identified
  - Simple charts allow rapid monitoring as the study progresses
Swimlanes Aggregate Large Amounts of Information

*Duration on Treatment by Treatment Status*

Swimlanes of treatment duration by status provide excellent overviews of individual patient milestones and events:

- Utility is compromised when multiple filters need setting to access desired view
- Multiple pages provide functionality but add considerable overhead
- Creation of Filter/View Presets (e.g. Filters for Presentation, *above*) with Python provides new controls for rapid navigation and view customization
- Controls allow multiple types of views to be readily available on 1 page

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Conclusion
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– Interactive data visualization tools have enabled more robust and timely decision making for Safety Review, In-Stream Clinical Review, & Risk Based Monitoring

– Centralized DV Operations provides GSK rapid access and efficient management of Workflow Setup, Customization and Creation

– Successful organizational embedding of Data Visualization requires scalable plans for adoption & responsible Governance/Quality Plans ensuring risk/benefit balance maintained

– Centralized Data Analytics has delivered key benefits:
  – Unified knowledge capture; elegant study-level Tools are integrated centrally, into Standard Templates to drive innovation and capability
  – Central development and maintenance of sophisticated workflows augments in-stream analysis and enhances formal reporting
Questions?
Backups
Swimlane
Swimlane with Controls

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