

**Delivery of Data
Visualizations within
GlaxoSmithKline
Clinical Development
and Partners**

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- **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.

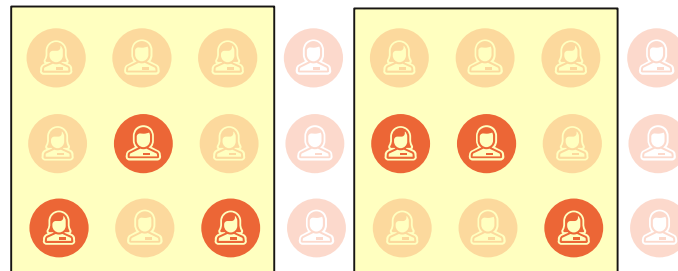
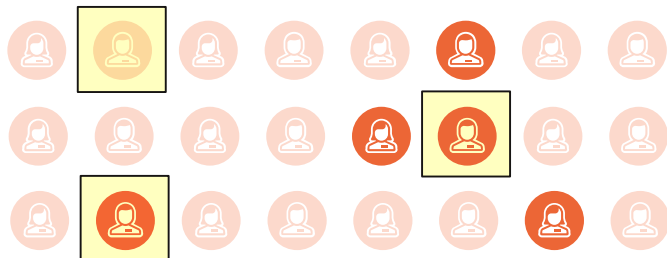
Integration of Data Visualization & Scalable Enterprise Level Delivery (ELD) Model

Organizational Embedding of Data Visualization

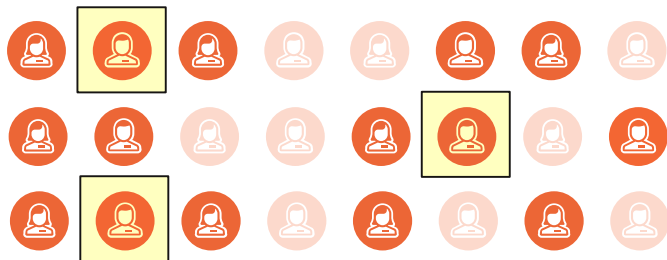
Requires successful marriage of tool availability and user engagement



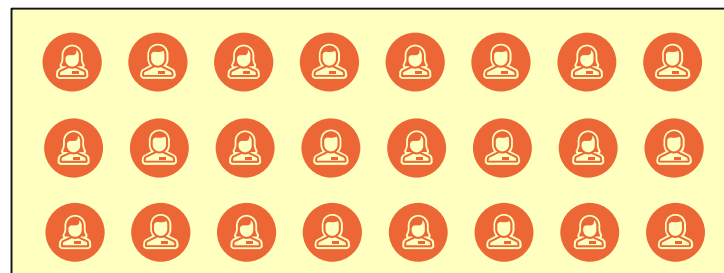
1. Limited Access/Limited Engagement 2. Wide Access/Limited Engagement



3. Limited Access/High Engagement



4. Wide Access/Strong Engagement



GSK Legacy Approach: Team based



- Clinical teams decide individually to use Spotfire



- Teams were assisted with setup



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- Teams were assisted with setup
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GSK Scalable Enterprise Level Delivery (ELD) Model



- Data Visualization is delivered via a centralized team



- All teams are continuously supported



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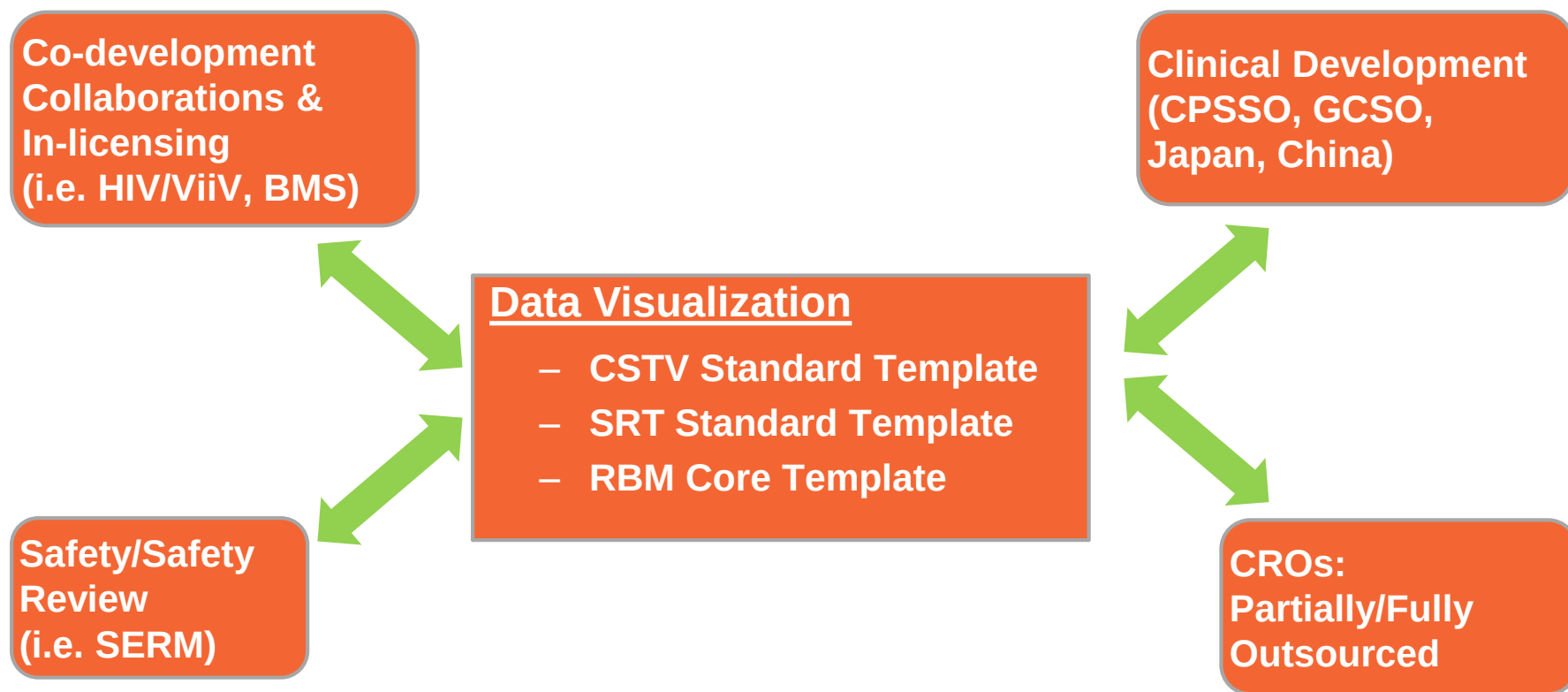


- All teams are continuously supported



- 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

GSK: Functional Areas Supported by DVO



– 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

Enterprise Level Delivery Model for Data Visualization

Key Principles Enabling 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**

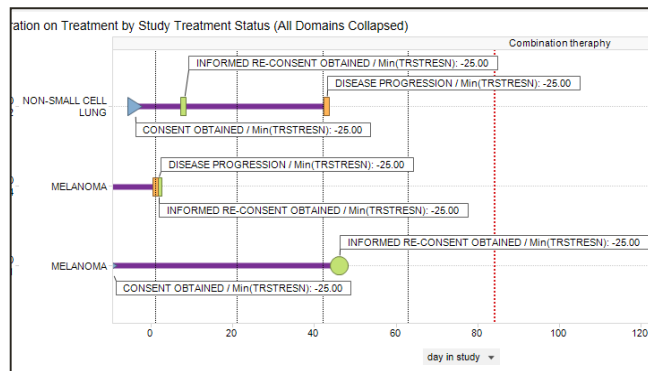
Key Principles for Successful ELD Implementation



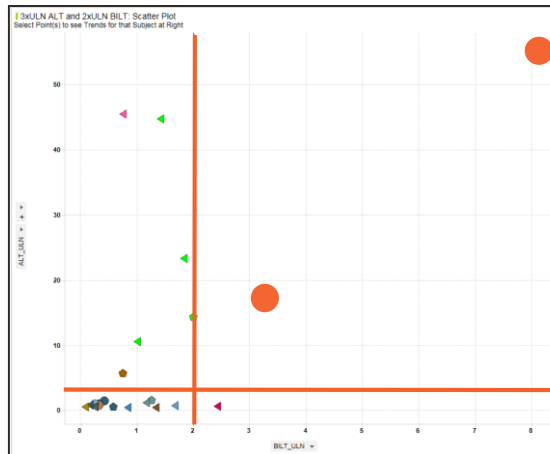
A. Define Programs Supported by Data Visualization

- 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

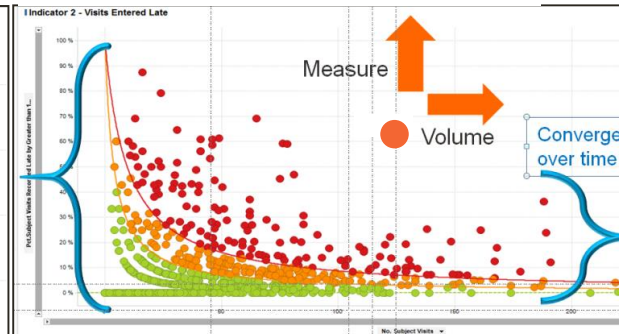
CSTV: TRT Duration



SRT: Hy's Law



RBM: Visits Entered Late



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

All Visualizations:

Standard Visuals:

[S01 - Early Withdrawal](#)
[S02 - Vital Signs Distribution](#)
[S03 - Vitals Analysis](#)
[S05 - Protocol Deviations](#)
[S06 - InForm Query Analysis](#)
[S07 - Entry Lag](#)
[S08 - Conmeds](#)
[S10 - Study Visits](#)
[S11 - Study Population Overview](#)
[S12 - Safety Overview](#)
[S13 - Missed Doses](#)
[S14 - Interval between doses](#)
[S15 - QTCB by Visit](#)

Labs/Liver:

[S16 - Lab Data](#)
[S17 - Labs By Subjects](#)

Patient Details:

[S18 - Patient Profile - Detail Labs, AEs, Conmeds](#)
[S19 - LFT Profile](#)

Patient Selection:

[S20 - Patient Selection - AE](#)

Other:

[S21 - Query Counts](#)
[Glossary](#)

Key Visualizations by Role:

Medical Monitor :

- S01 - Early Withdrawal
- S12 - Safety Overview

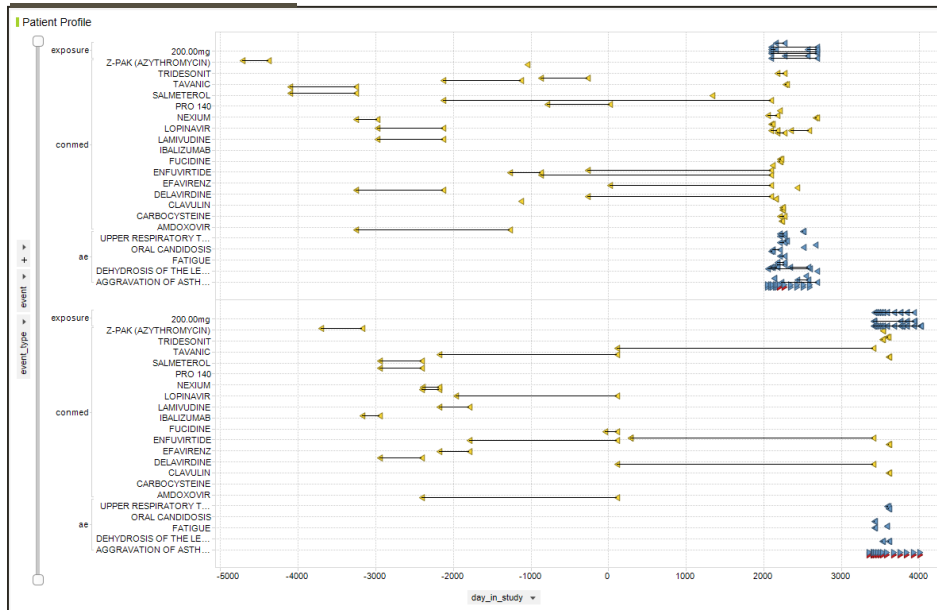
CIL/OSL:

- S10 - Study Visits
- S12 - Safety Overview
- S01 - Early Withdrawal

DQL:

- S05 - Protocol Deviations
- S07 - Entry Lag

Patient Profile



Keys for Successful ELD Implementation at GSK



C. Standardize Data Type Supported

- **Standardizing data inputs allows a large number of studies to be supported with a small number 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**

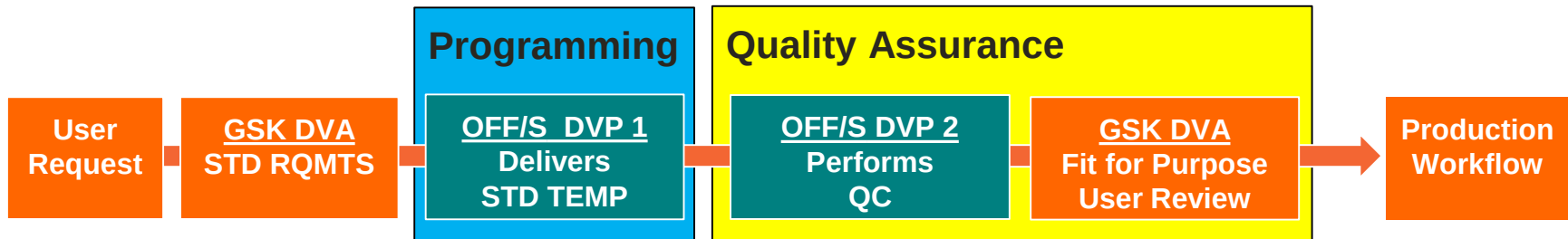
Scalable ELD Process Model for Data Visualization



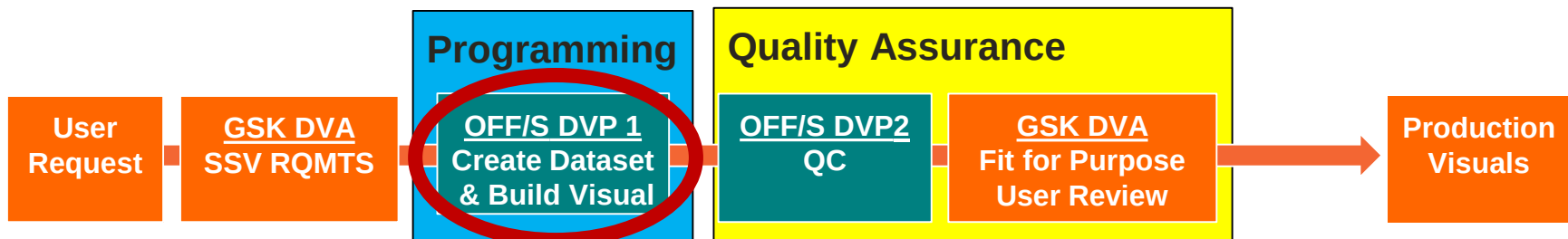
D. Standardized, Scalable Process

- 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:



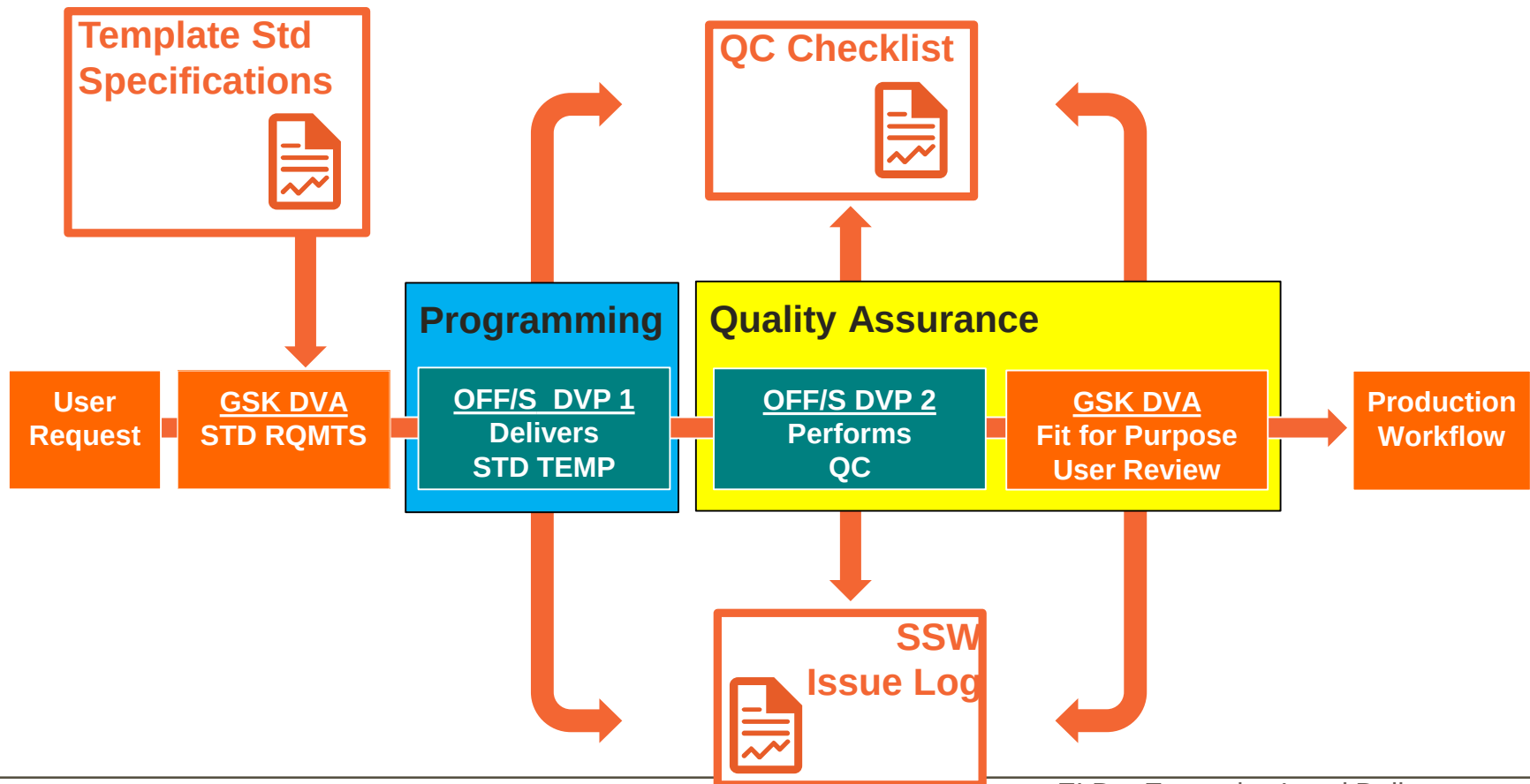
ELD Process Governance



a. Standard Template Setup Process

– Quality Plan

- Inputs: Standard Workflow Specifications
- Outputs: Study Specific Workbook (SSW); Key Organizational Process Asset



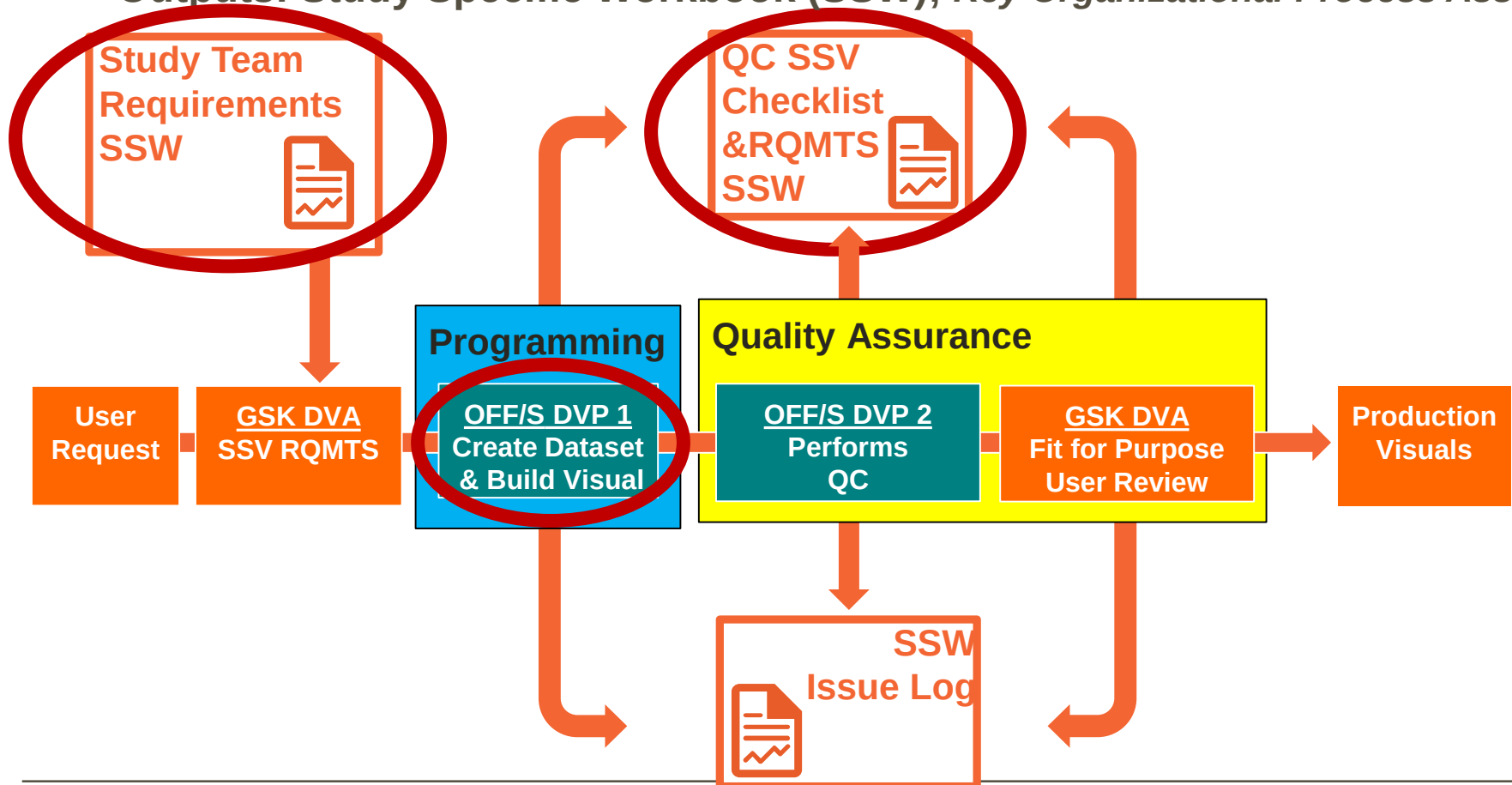
ELD Process Governance



b. Study Specific Customization Process

– Quality Plan

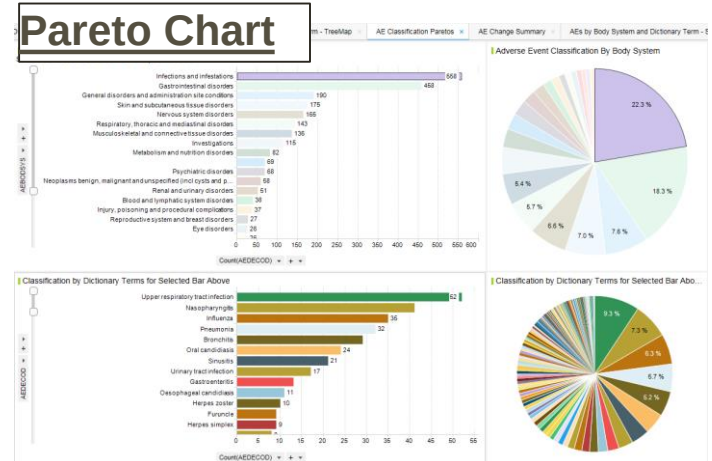
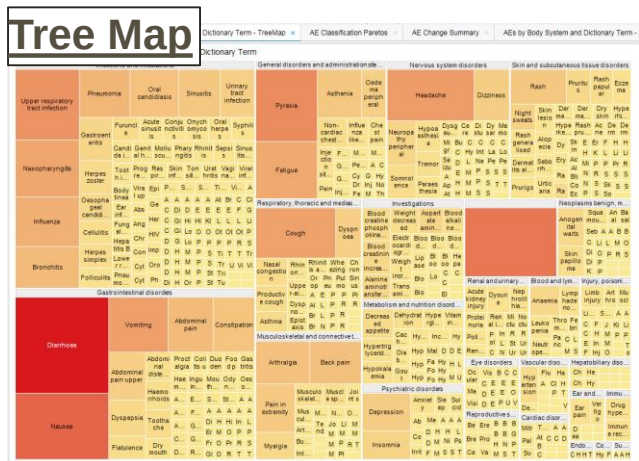
- Inputs: Study Team SSV Requirements in SSW
- Outputs: Study Specific Workbook (SSW); Key Organizational Process Asset



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

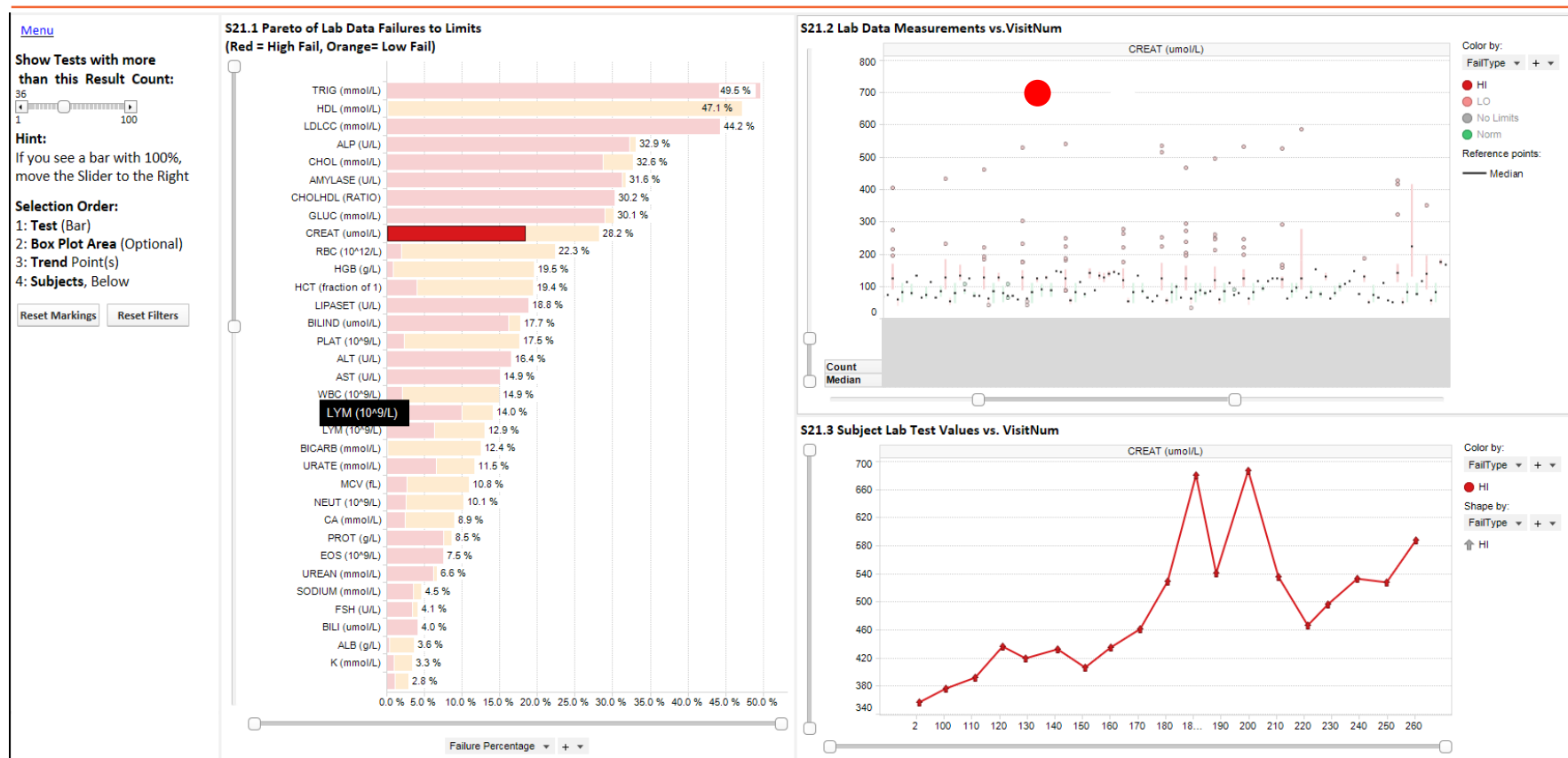


Improvement Process: Innovation Cases

Pareto Driven Lab Analysis



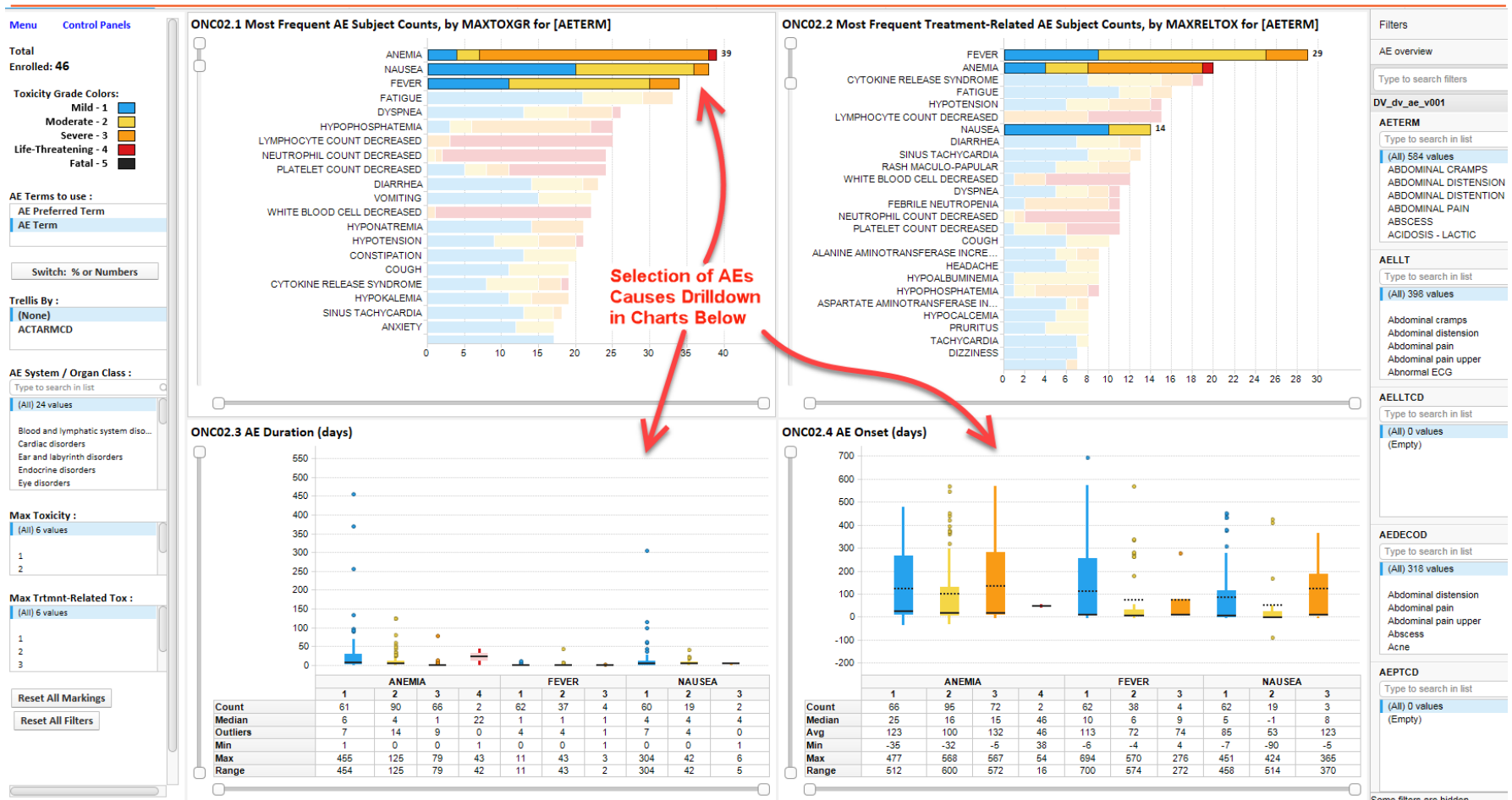
Connected Charting Relates Study & Detail Level Information Seamlessly



- 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

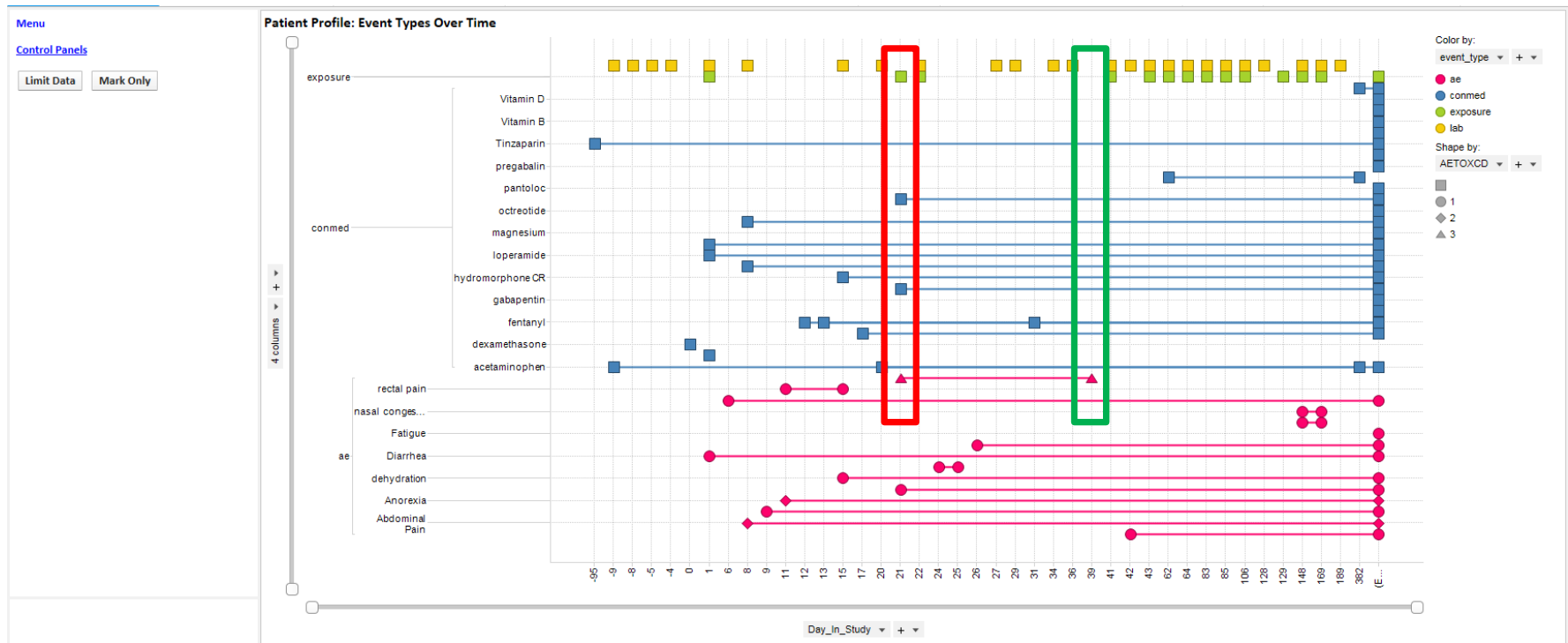


– Iron Python coding creates control panels to improve efficiency/utility

Swimlane Charts Clearly Relate Events Over Time



Patient Profile Connect Exposure, Labs, Conmeds & AEs Temporally

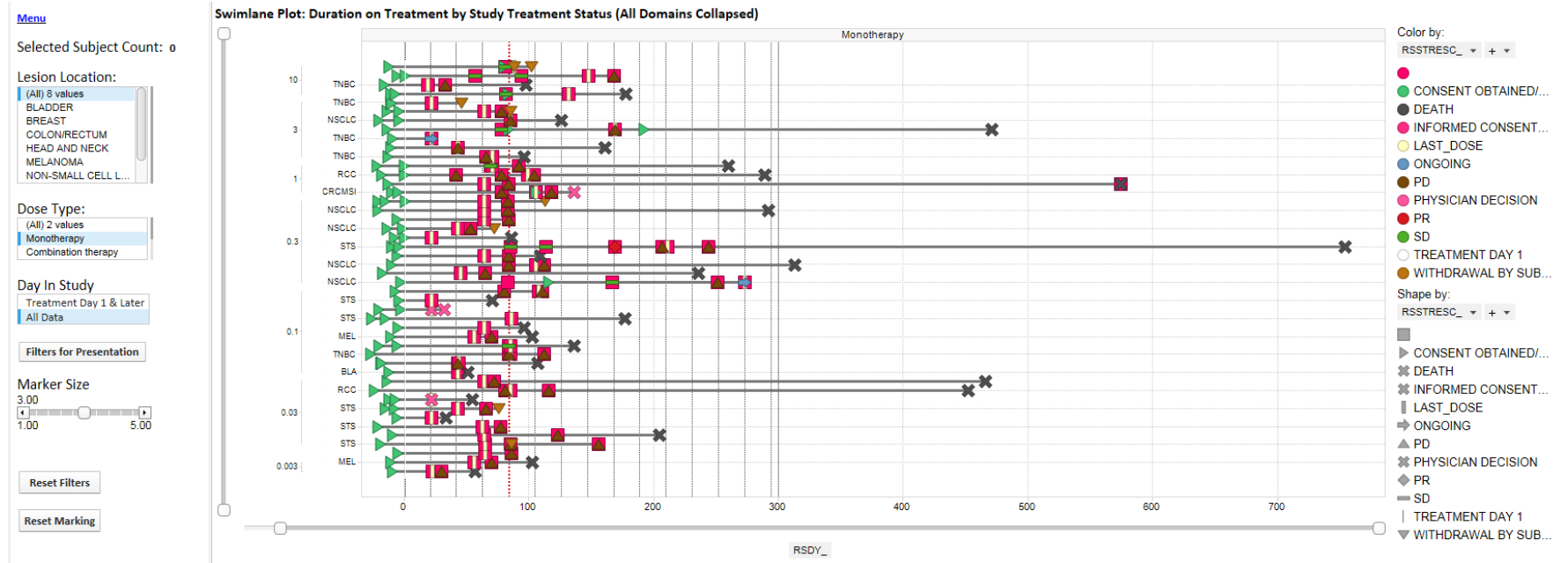


- Swimlane charts allowing onset and duration of events to be compared
- Potential correlations between exposure, conmeds, and AEs can be rapidly identified
 - Simple charts allow rapid monitoring as the study progresses

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

Conclusion

- **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

