

GSK Data Visualization:

*Successful Integration
of Enterprise Level Delivery
of Spotfire® Tools combined
with Technical Expertise from
Clinical Programming is
Transforming Data Analytics
at GlaxoSmithKline.*

Successful Integration of Enterprise Level Delivery of Spotfire® Tools Combined with Technical Expertise from Clinical Programming is Transforming Data Analytics at GlaxoSmithKline

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- Data Visualization Principles – Text/Tables/Figures
 - Benefits/Features of Spotfire®
 - Integration of Data Visualization & Scalable Enterprise Level Delivery (ELD) Model
 - Keys & Lessons Learned from Successful ELD Implementation
 - Examples of Clinical Programming collaboration and integrated data analysis using Spotfire®

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.

Data Visualization Principles – Text/Tables/Figures

Why data presentation is important



Visual displays enhances cognition and help express the significance of data

- Data displays can organize information by indexing it spatially – items ‘closer’ together are similar or related to each other
- Offloading of cognition
 - Data displays are stored externally on some visualization media, freeing up brain power to focus on interpretation instead of manipulation
 - Data displays can enable complex computations to be replaced by simple pattern recognition processes
 - The ability to interact, filter or rotate displays frees us from having to do it mentally



Why data visualization is important

Communication of information to key stakeholders



- Upper Management, Regulators, Healthcare Providers, Patients
- The key stakeholders:
 - May be naïve to the details of the study design, objectives or history of the disease
 - May be less quantitatively and analytically skilled than the data analyst
- The design of the data display will directly affect the ease or difficulty of interpretation of the intended message

- Use text for simple or headline results which can be stated in a single sentence
- Use text when a statement or written description can clearly and succinctly convey information and results without the need for tables or graphs
- When you want to leave no room for misinterpretation by the audience
- Use text when communication is limited to text

- Use text for simple or headline results which can be stated in a single sentence
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“44% response rate observed in patients receiving 25 mg Active Investigational Product; of these responders all experienced at least 60% tumor shrinkage within 16 weeks”

Data Visualizations



Types of data displays – Tables/Listings

- Tables present data in rows and columns organized in some fashion
- Tables can show raw (collected) data or summarized values
- Compared to figures:
 - The numerical values are more easily located, read and extracted
 - Allow for immediate and accurate computation (e.g., differences and ratios)
 - Less room for misinterpretation

A collage of several overlapping tables with numerical data. The tables are arranged in a way that they appear to be floating or layered on top of each other. The data is presented in rows and columns, with some cells highlighted in blue. The numbers are of varying sizes and are arranged in a way that suggests a complex dataset or a series of related calculations. The overall effect is one of a dense, organized collection of information.

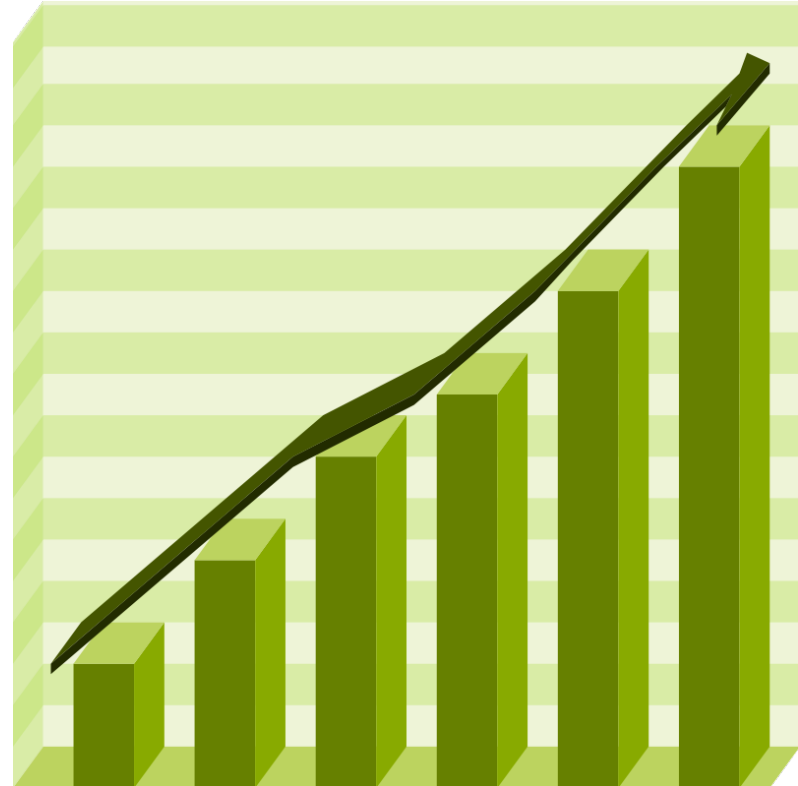
Data Visualizations

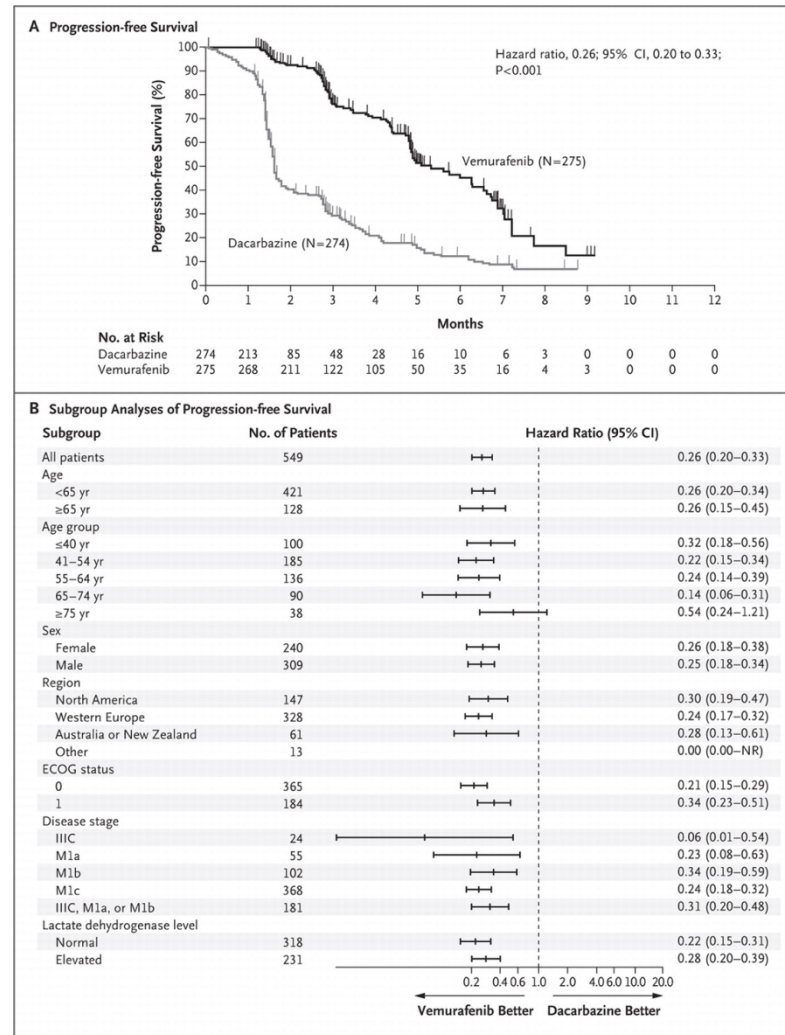


Types of data displays – Figures/Graphs

Show patterns, similarities and differences in the data that are not easily picked up by viewing text or tables

- Present spatially related information (e.g., map)
- Identify associations, trends, relationships, deviations, minima, maxima and orders of magnitude
- Hard to identify magnitude of differences from numbers alone
- Take advantage of symbols, lines, colors, sizes, etc to convey related information
- Visualize the by-subject detail to appreciate the granularity and complexity inherent in the data





Data Visualizations



Types of data displays – Interactive Visualization

- Advanced technology making it possible to interact with the data
- Ability for one to examine high level results and drill down into supporting details
- Manipulate and examine the data according to the user's cognitive strengths and time constraints
- Identify and discern meaningful trends, patterns, relationships and expectations

Every time I try to zoom in
this happens...



freshspectrum.com

Like I said before
the paper is not interactive



Data Visualizations



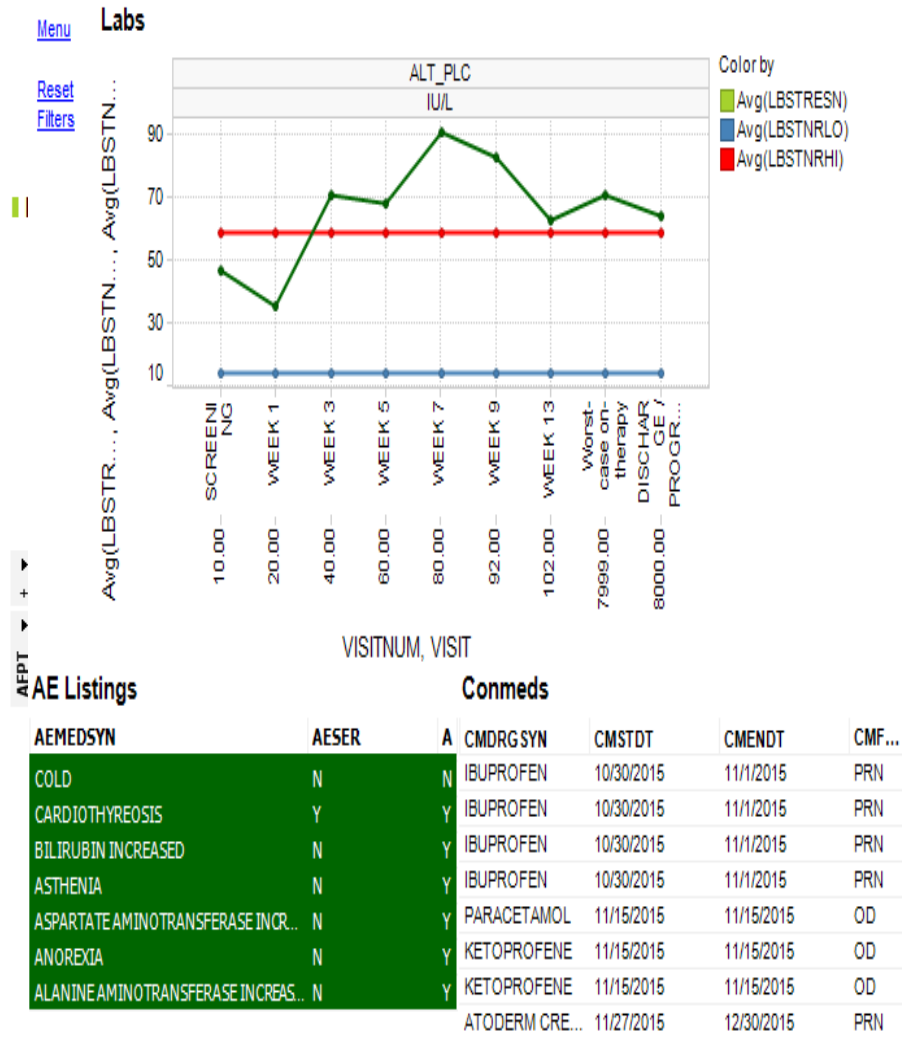
Types of data displays – Interactive Visualization

- Interactivity can have costs
 - Interactive displays put the burden of display choice and design on the user
 - Time and attention needed to decide to subtract irrelevant information
 - Users may not discover or know all the interactive functions available
 - Ensure controls are in place to prevent unblinding/unintended bias
 - Users may forget to reset filters or markings



Benefits/Features of Spotfire®

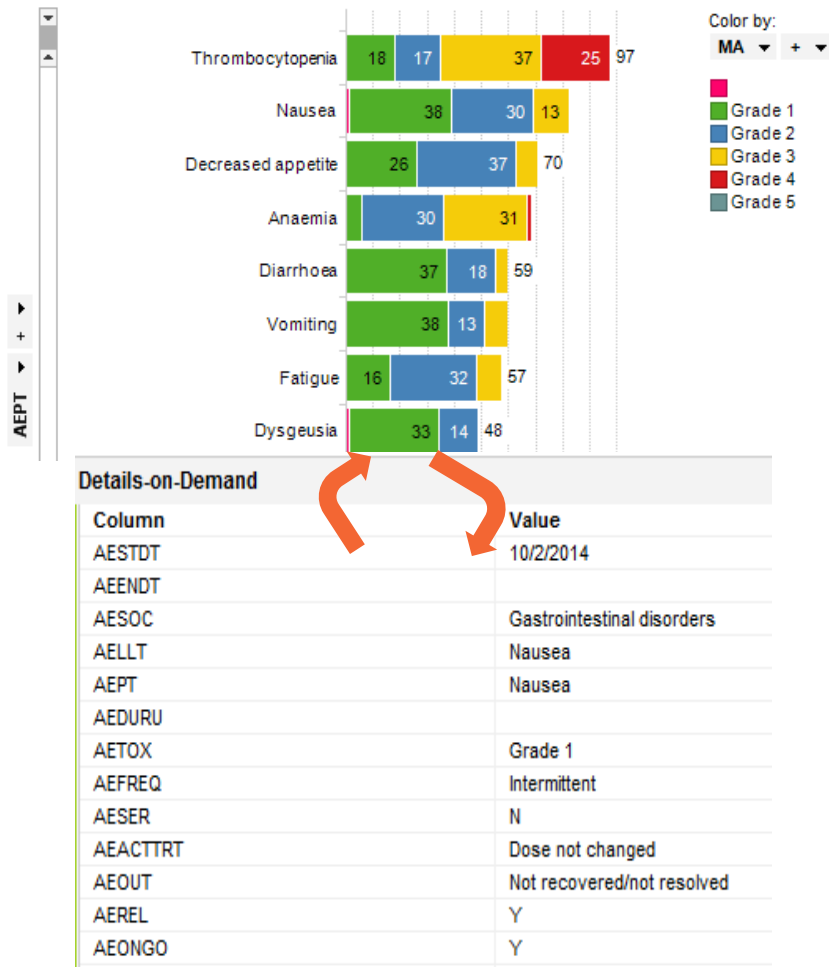
Why Spotfire® is a good collaborative tool



- Advanced visualization features
- Easy to use, intuitive, technical knowledge not required
- Ability to integrate cross functional data together into one tool
 - Study population, safety, efficacy, PK, PD, biomarker, PRO, HO
- Team members can analyze the data individually or collaboratively
- Exporting of visuals/datasets is effortless

Why Spotfire® is a good collaborative tool

Most Common AEs



- Seamlessly navigate between summary level and subject level details
- Flexible – user can change analysis elements (filters) instantly
- Can select or ‘mark’ subject(s) of interest
- Settings applied to one visual are ‘remembered’ in the other visuals

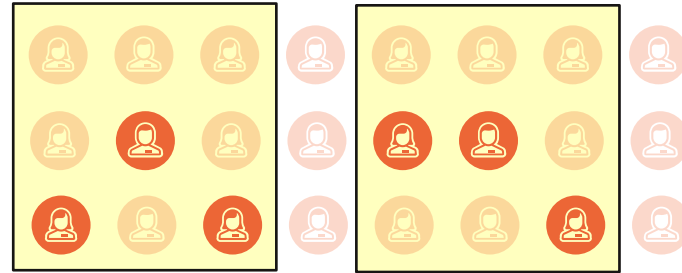
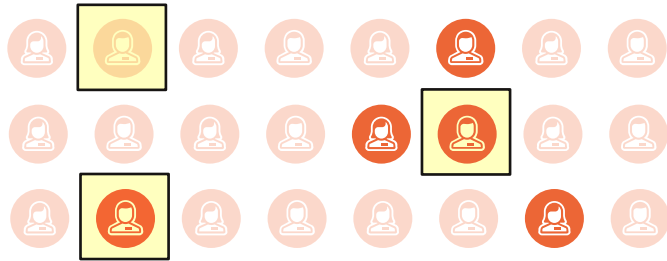
Integration of Data Visualization & Scalable Enterprise Level Delivery (ELD) Model

Organizational Embedding of Data Visualization

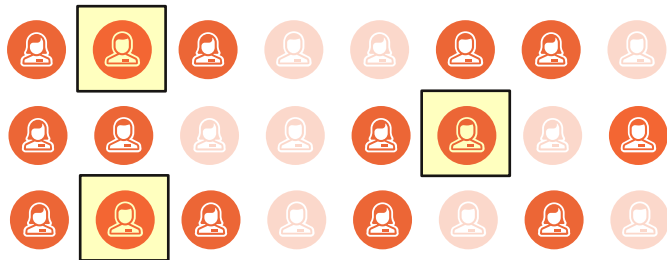
Requires successful marriage of tool availability and user engagement



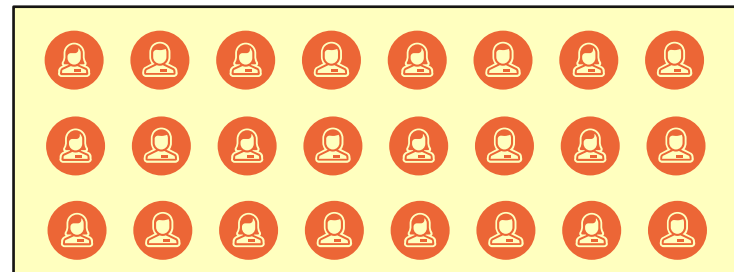
1. Limited Access/Limited Engagement 2. Wide Access/Limited Engagement



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



GSK Legacy Approach: Team based



- Clinical teams decide individually to use Spotfire



- Teams were assisted with setup
 - Initial adoption was high



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- Responsibility for data updates & maintenance was a team responsibility

GSK Legacy Approach: Team based



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- Responsibility for data updates & maintenance was a team responsibility



GSK Scalable Enterprise Level Delivery (ELD) Model



- Data Visualization is delivered via a centralized team



- All teams are continuously supported



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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

Keys & Lessons Learned from Successful Enterprise Level Delivery (ELD) Implementation

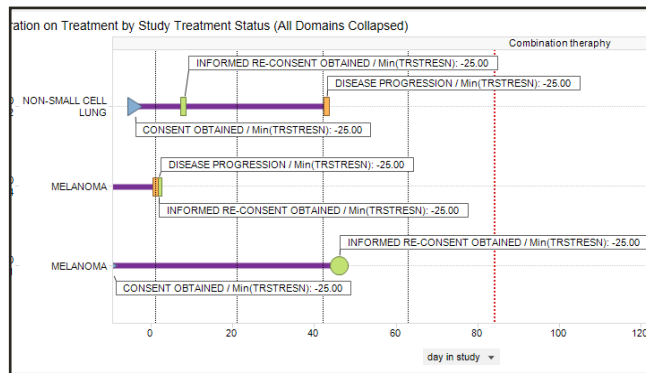
Key Principles for Successful ELD Implementation



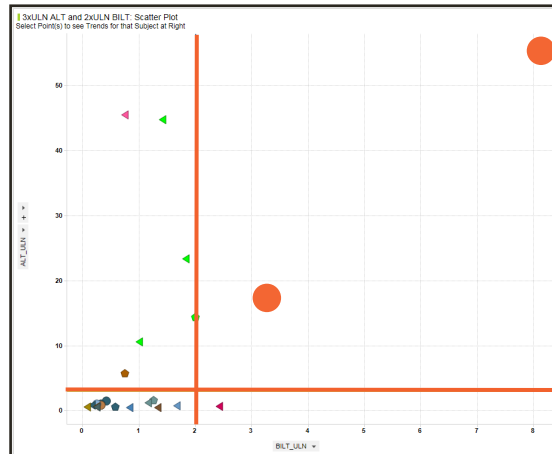
A. Define Programs Supported by Data Visualization

- 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

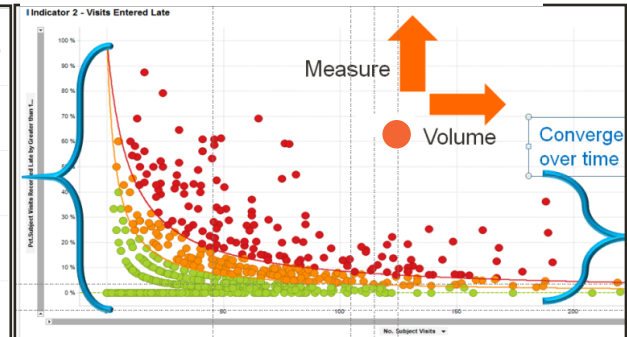
CSTV: TRT Duration



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

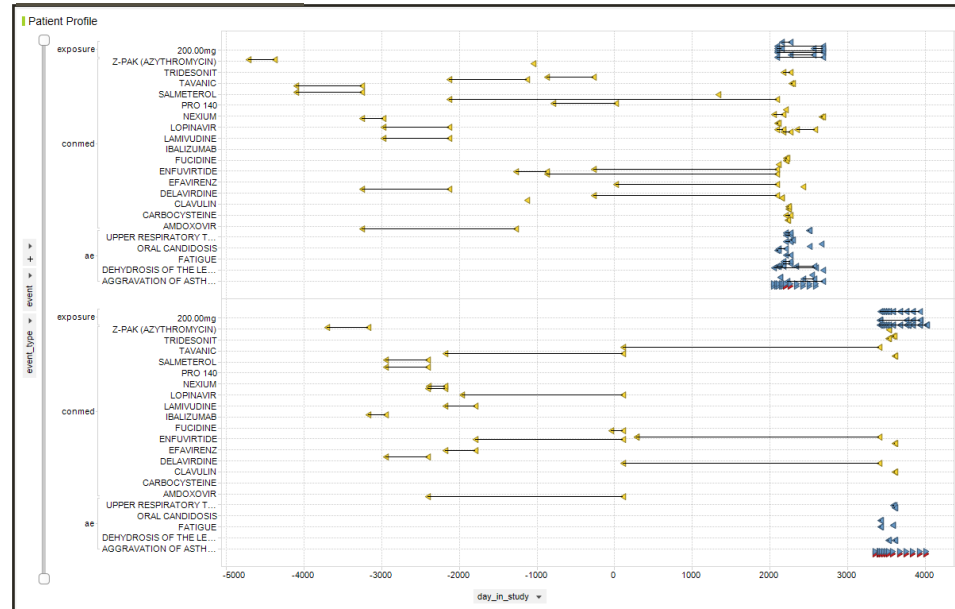
CIL/OSL:

- 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**

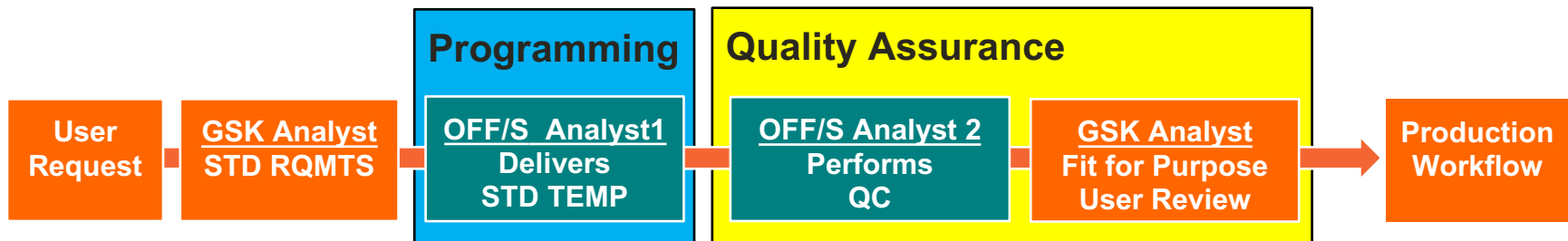
Scalable ELD Process Model for Data Visualization



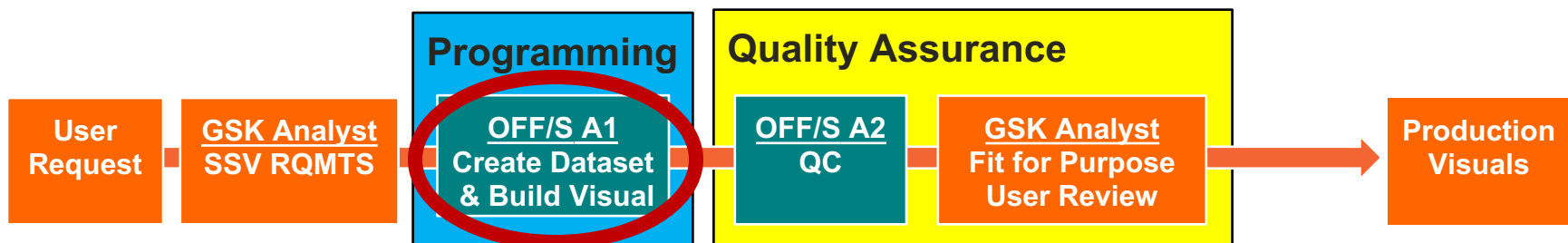
D. Standardized, Scalable Process

- 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:



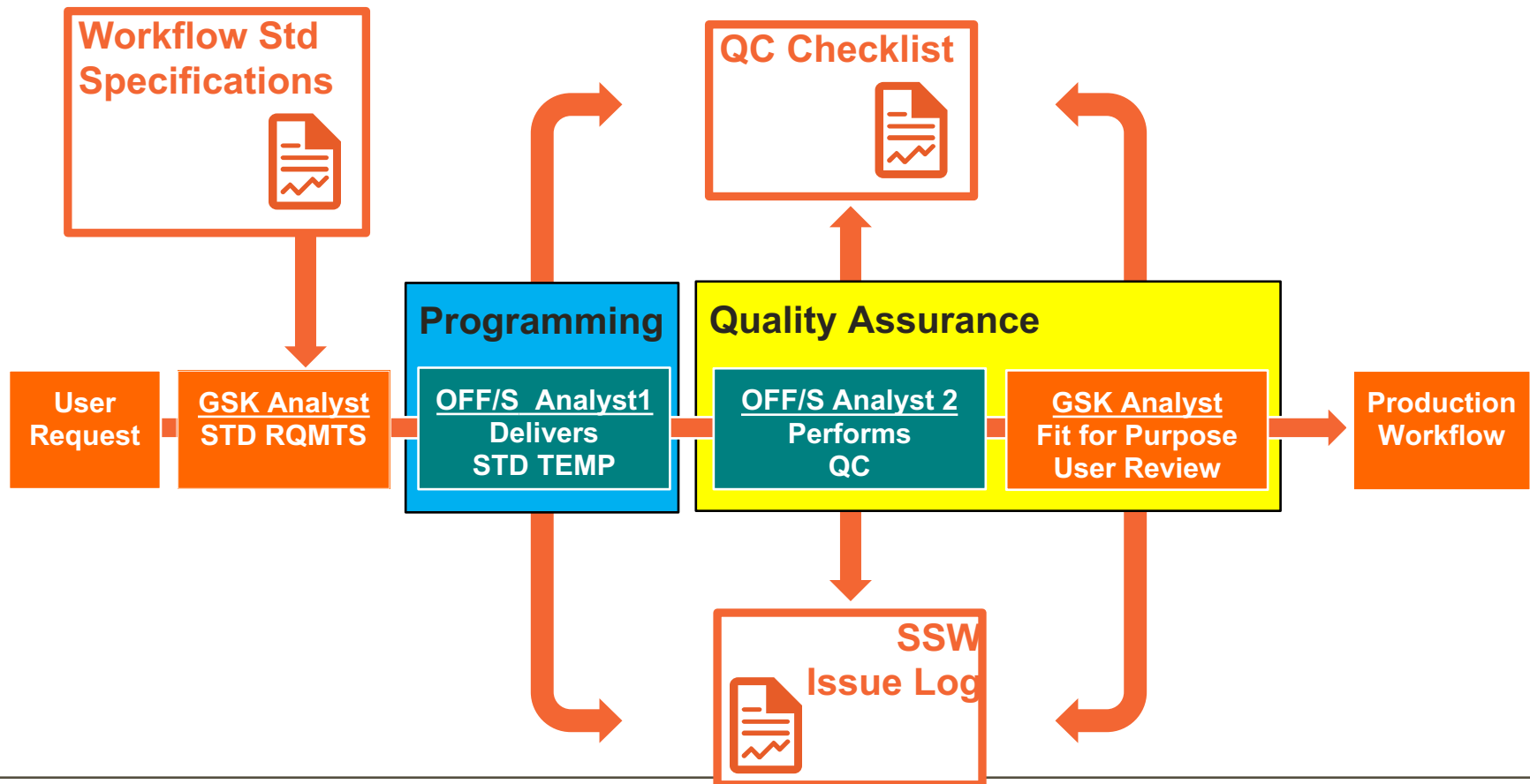
ELD Process Governance



Standard Template Setup Process:

– Quality Plan

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



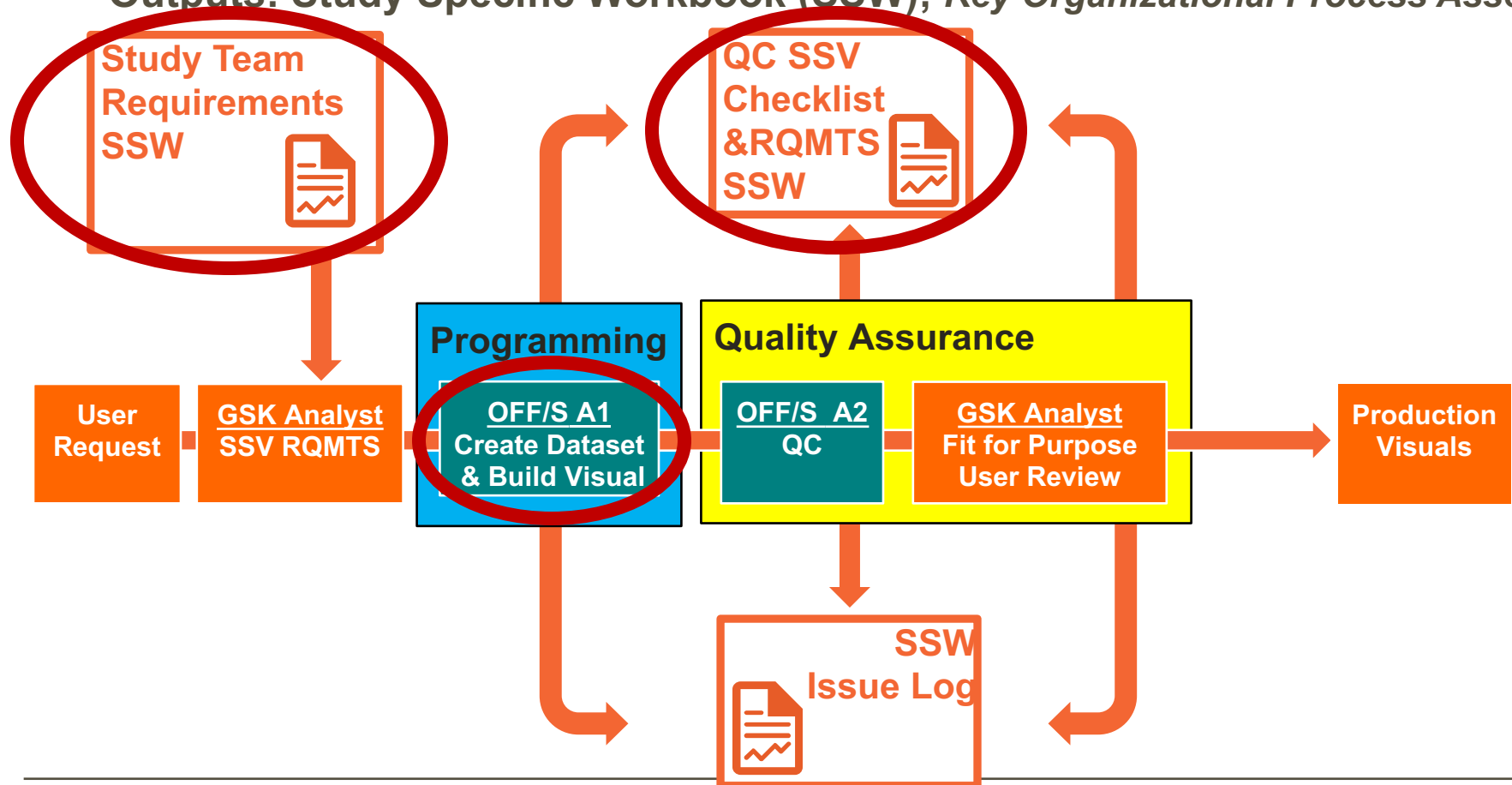
ELD Process Governance



Study Specific Customization Process:

– Quality Plan

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

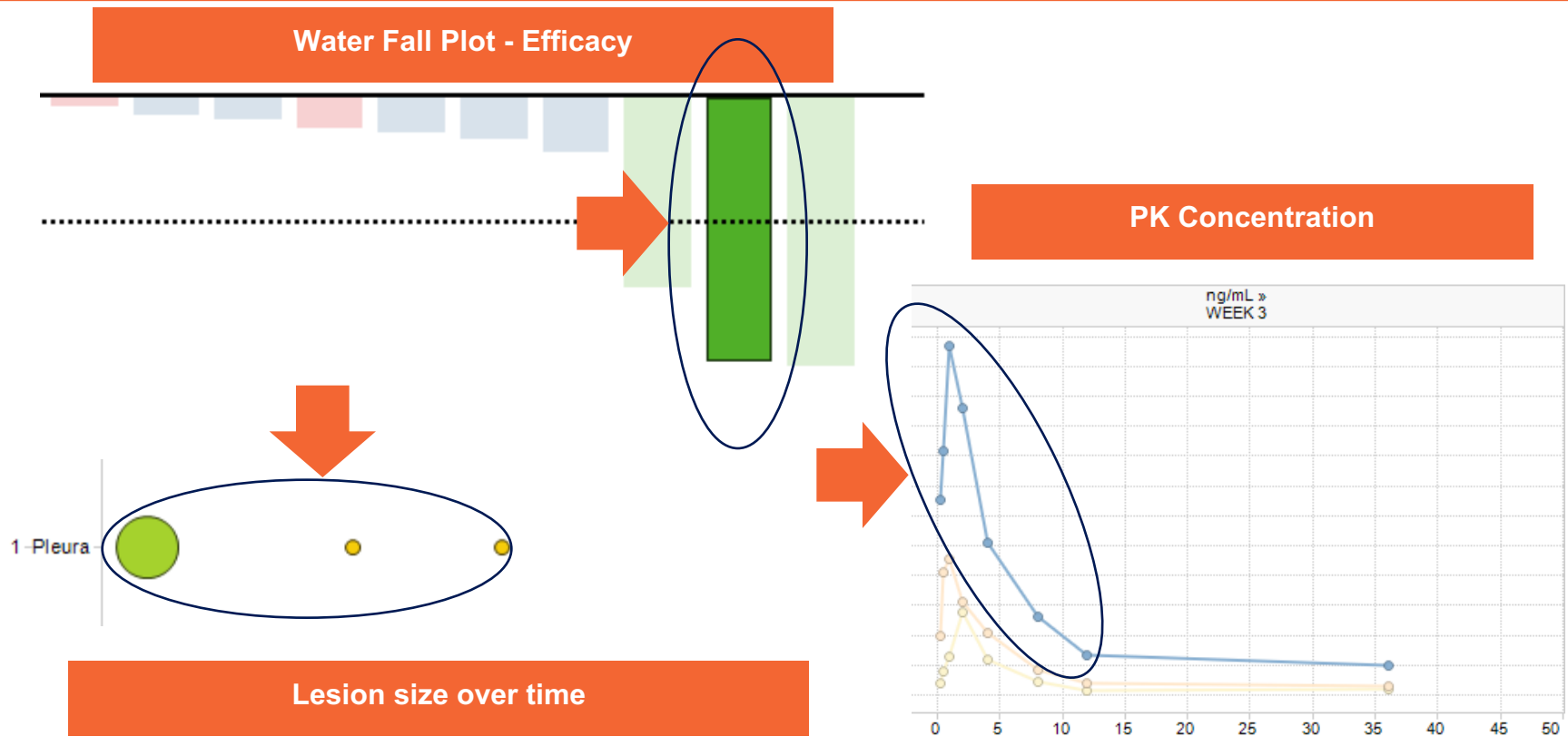


- [illegible]



Examples of Clinical Programming collaboration and integrated data analysis using Spotfire®

- Each trial has unique questions that need answered
- Traditional S&P TLFs are not well suited for exploratory analysis – lack of integration and ‘longer’ timelines
- The unique attributes of Spotfire® can be leveraged to answer those questions
- Combine the programming expertise of clinical SAS programmers and the powerful features of an interactive data visualization tool for the most efficient and robust collaboration with the study team

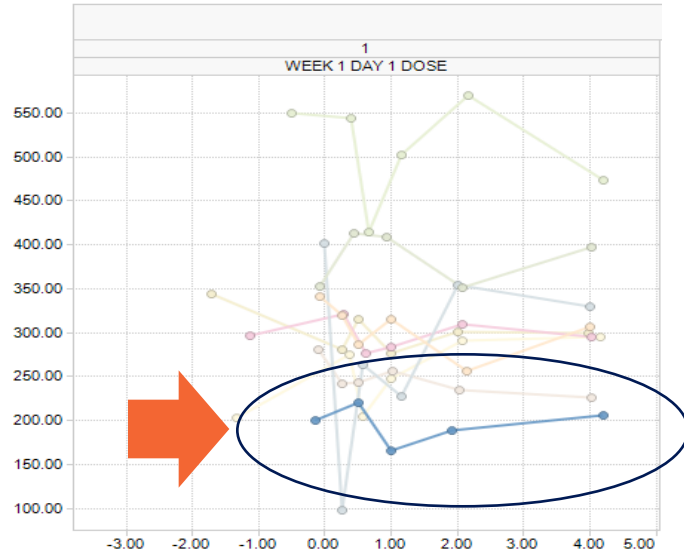


GSK Clinical Programming and Tibco Spotfire®

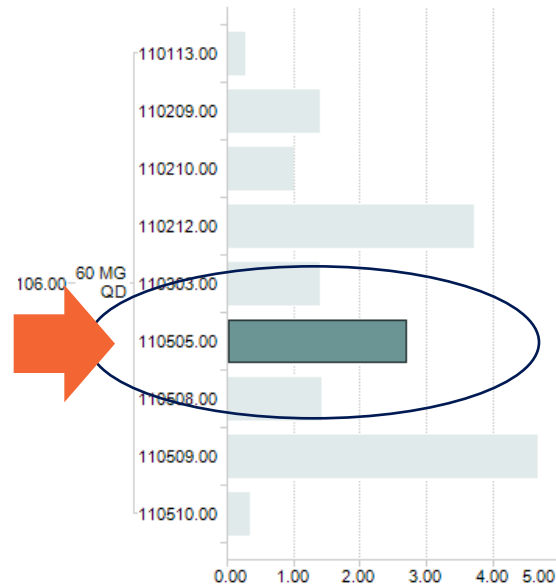


Clinical Programming Analysis Datasets and Spotfire®

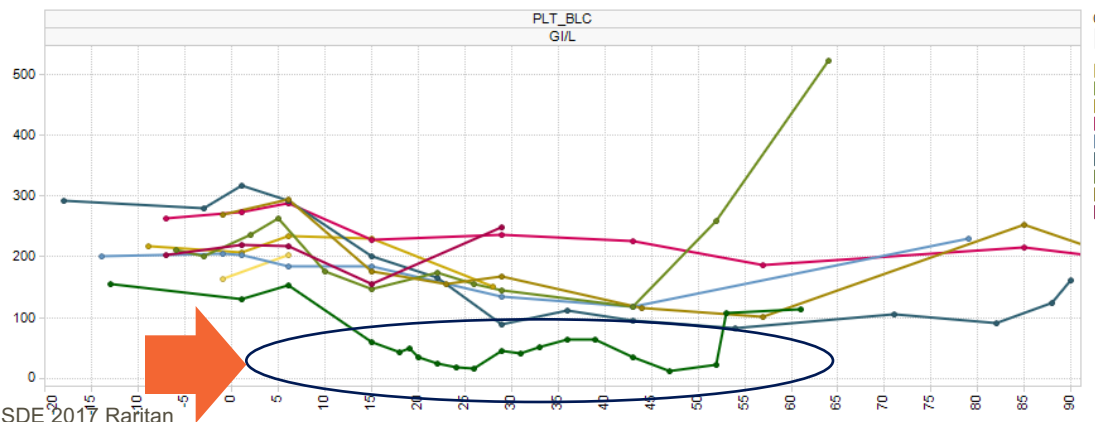
Biomarker/PD



Exposure/Dosing



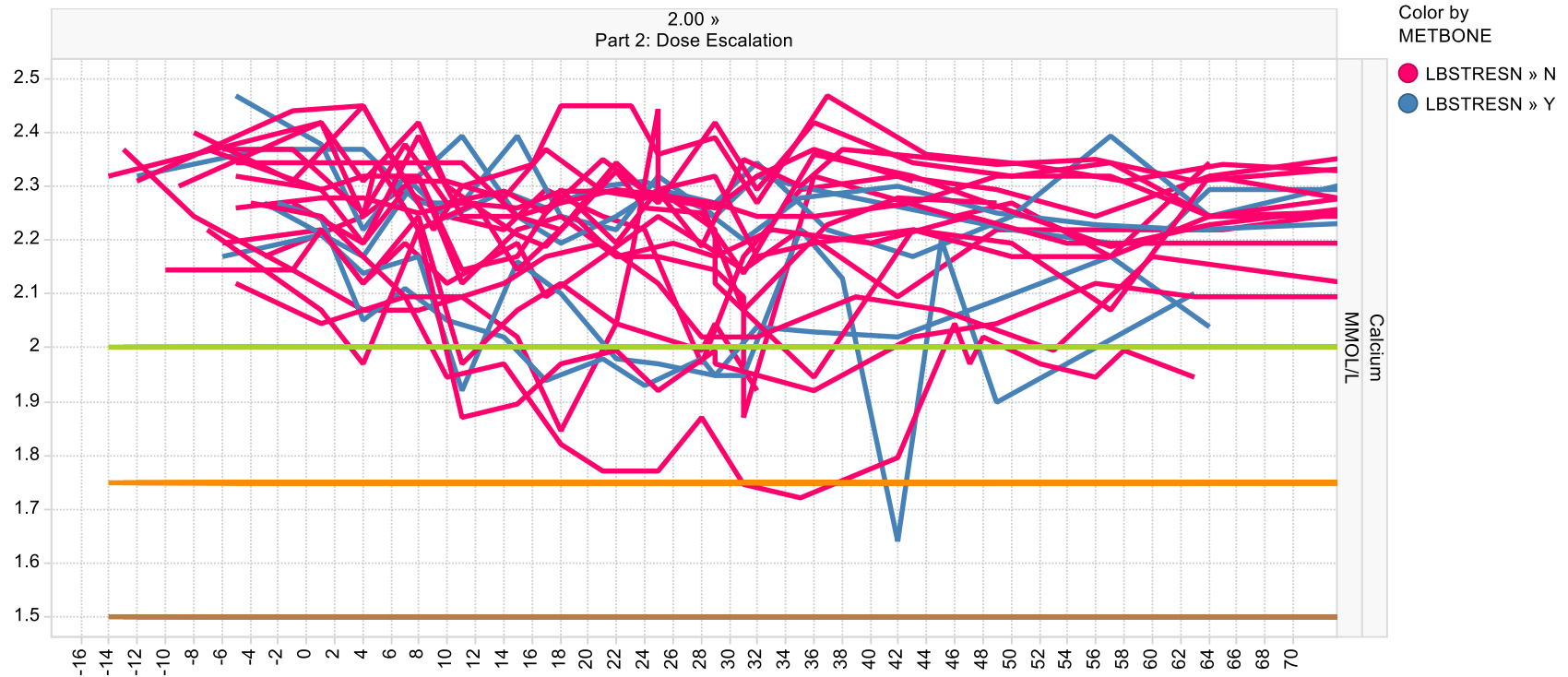
Safety



- Unexpected elevated lab toxicity for calcium
- Bone disease at baseline
- Spotfire® quickly setup to compare the calcium data between the two different groups
- Clinical programming derived bone disease at baseline flag (Y or N)
- Utilized existing visual template to speed up timelines

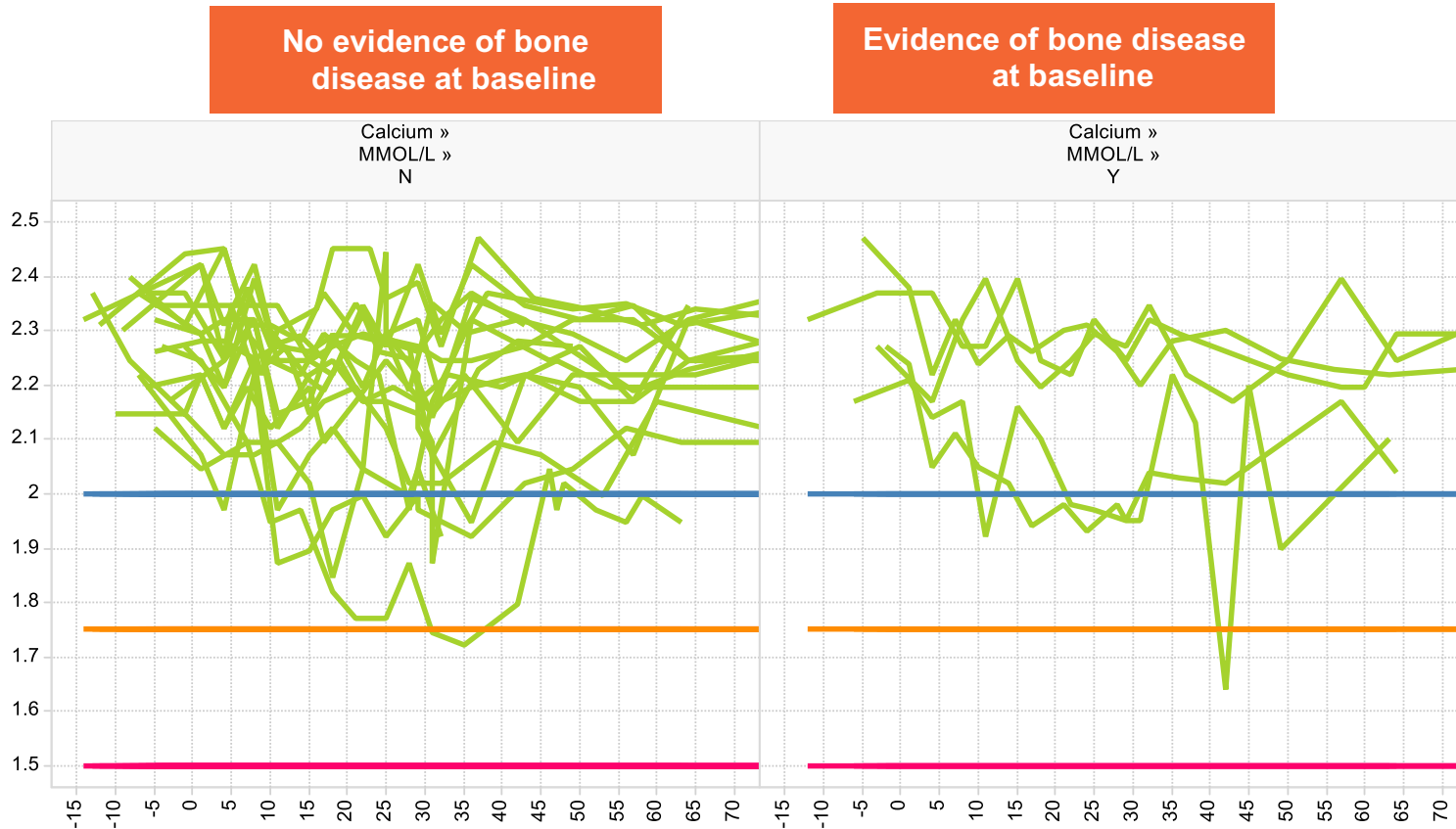
GSK Clinical Programming and Tibco Spotfire®

Collaboration and Integration – Safety Lab of Interest Exploration

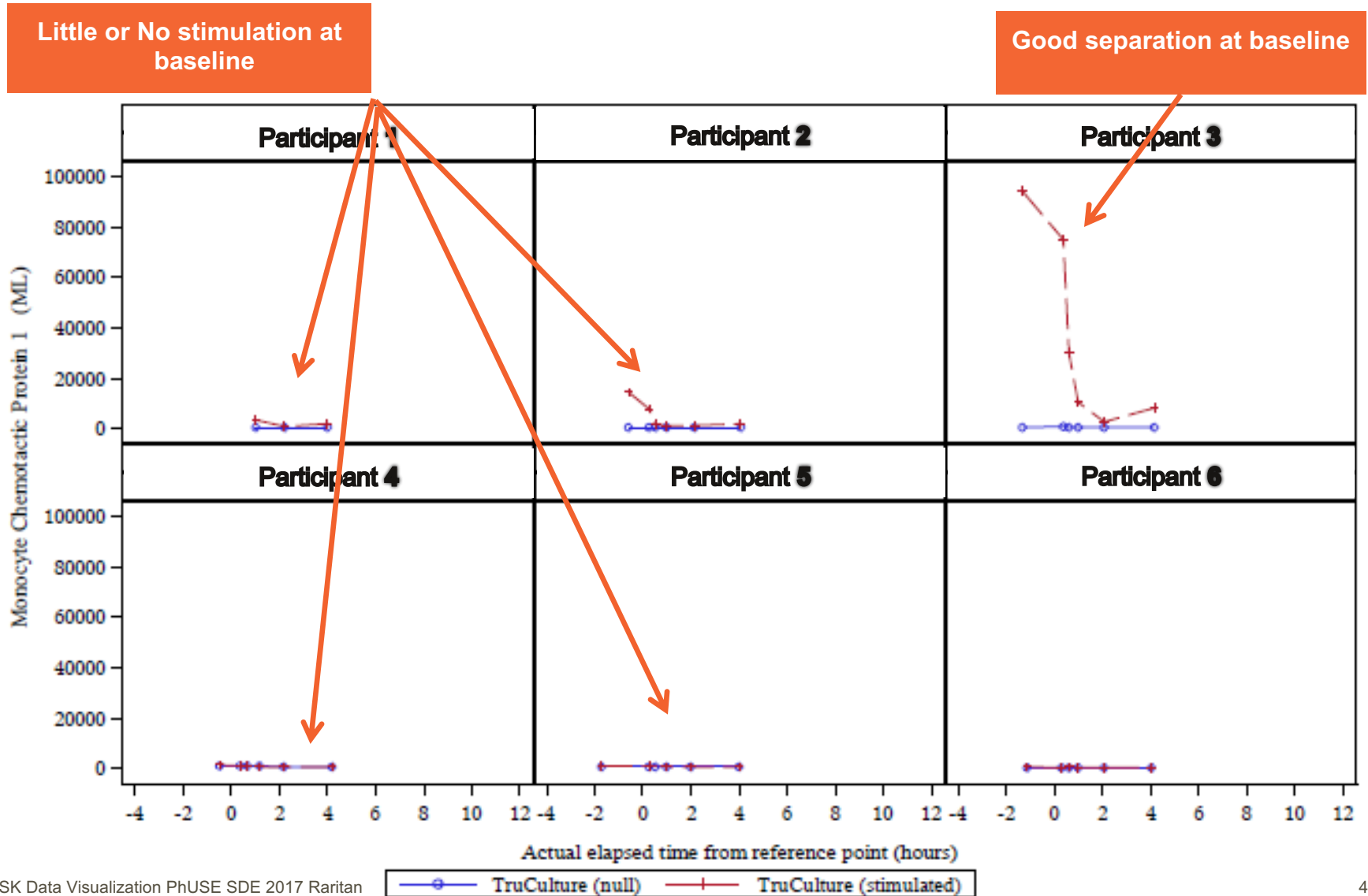


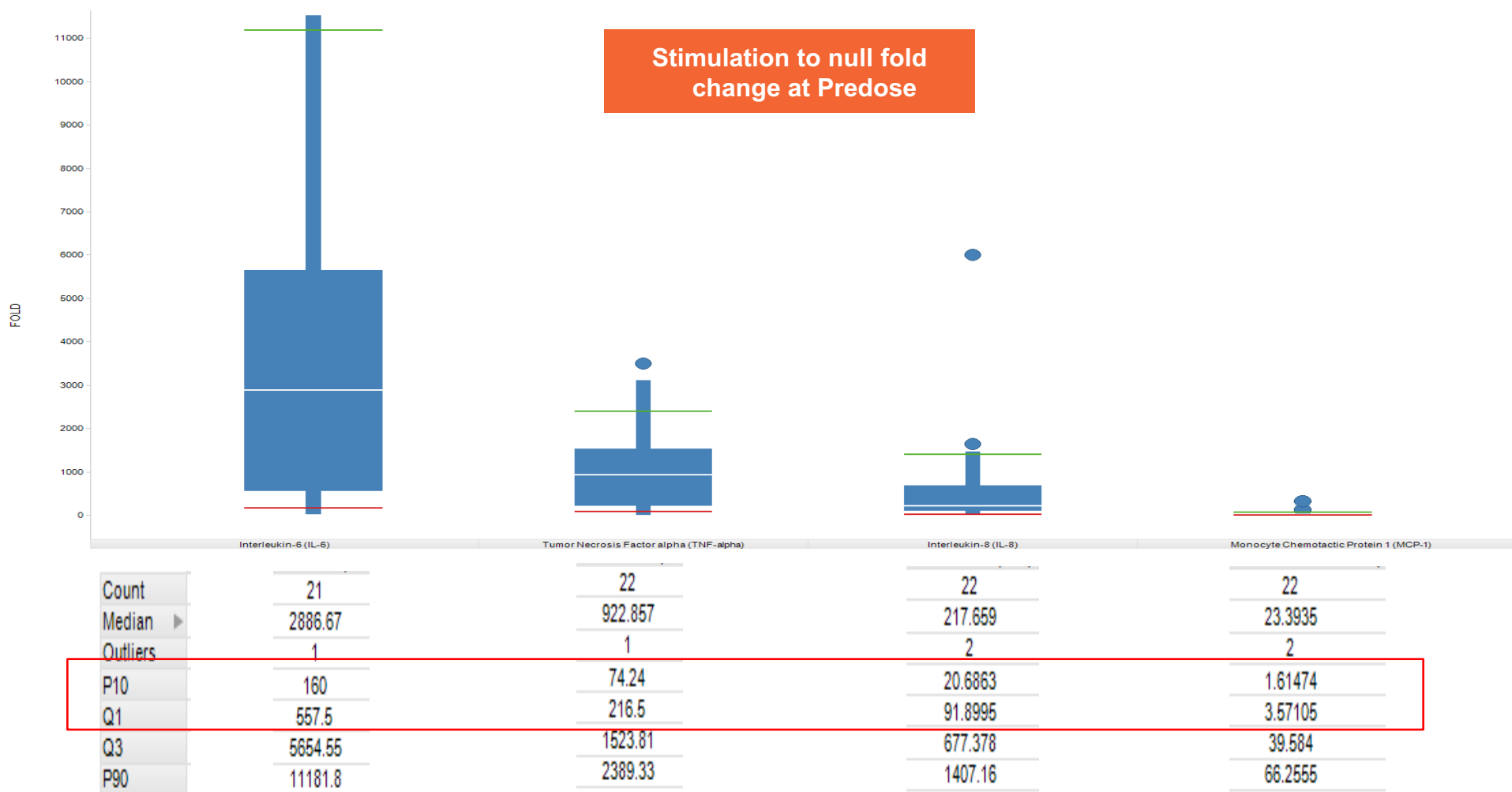
GSK Clinical Programming and Tibco Spotfire®

Collaboration and Integration – Safety Lab of Interest Exploration



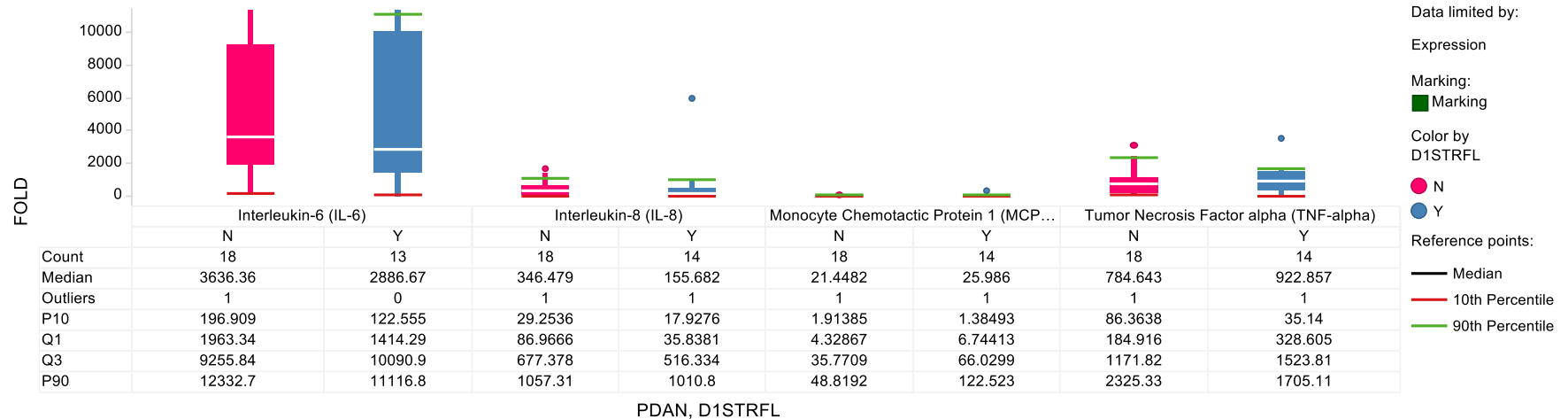
- Preclinical research showed dose dependent inhibition of LPS induced stimulation
- Expected same results in human data
- Some predose samples (no drug present) showed no inhibition
- Spotfire® was used to explore and interrogate the data to understand if there was some threshold that could be used for exclusion of samples that were not stimulated
- Collaboration with clinical programming to understand if baseline factors contributed to the issue





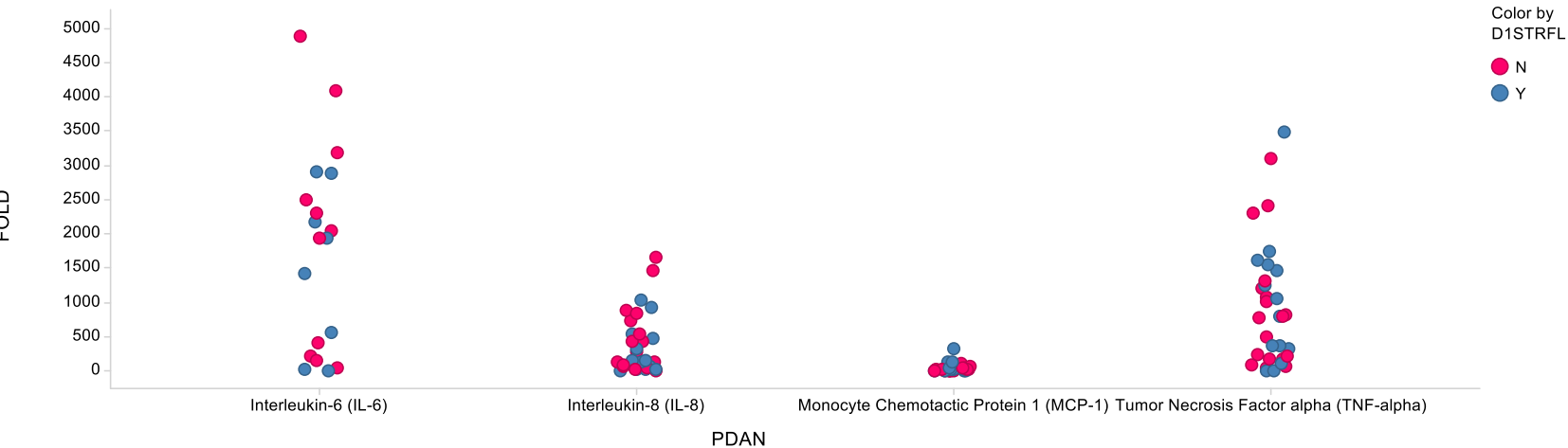
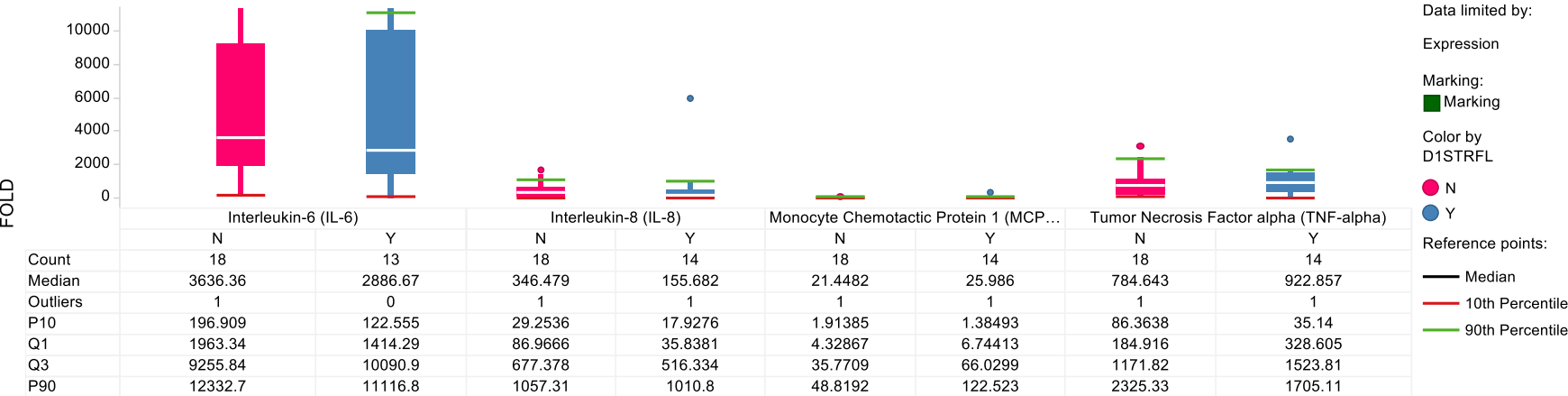
- Baseline factors
 - Anti-inflammatory medications
 - All AI meds
 - Steroids
 - Tumor Type at diagnosis
 - White blood cell baseline values

LPS Cytokine Analysis – Anti-inflammatory Medications – All Meds

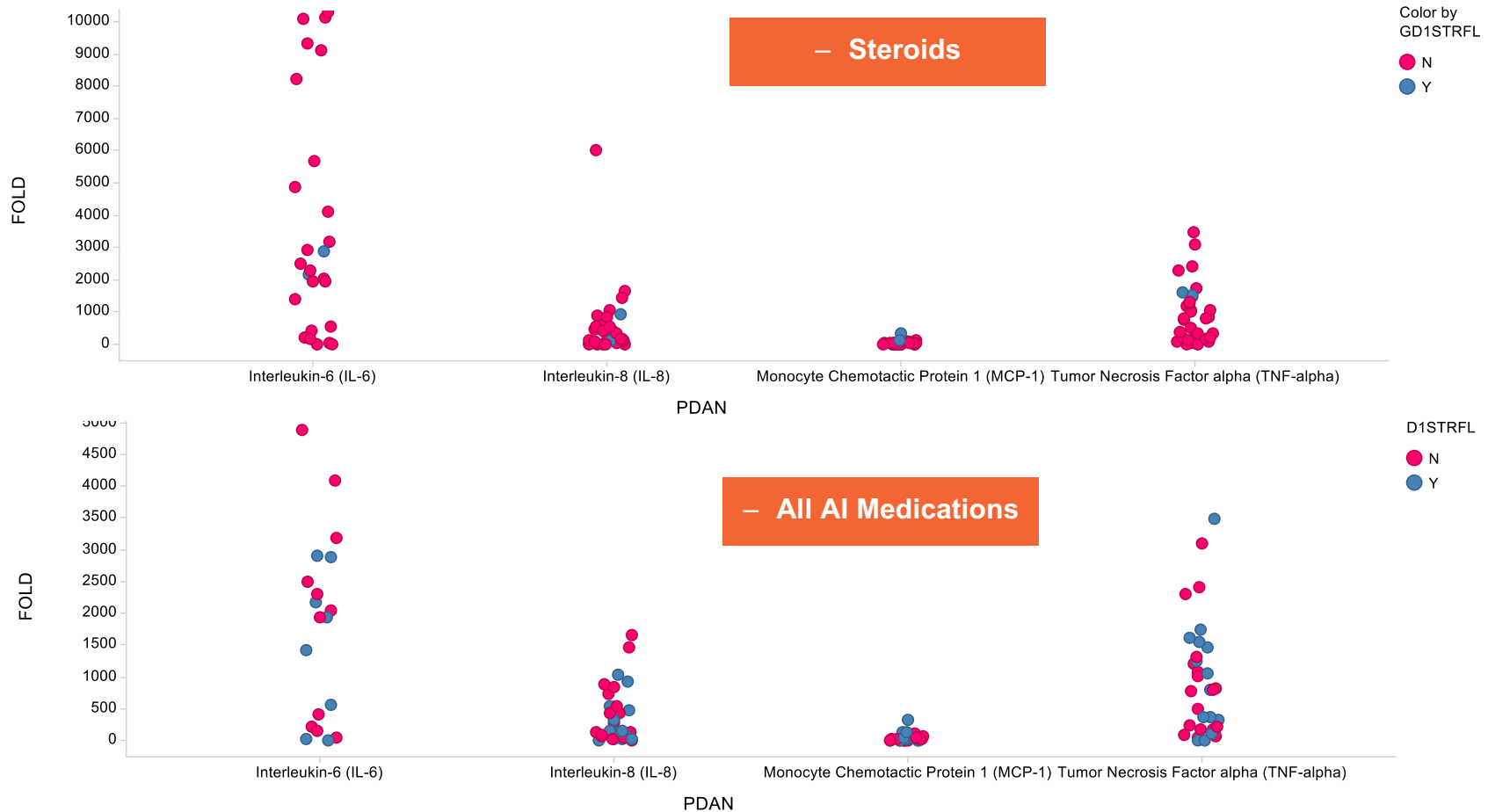




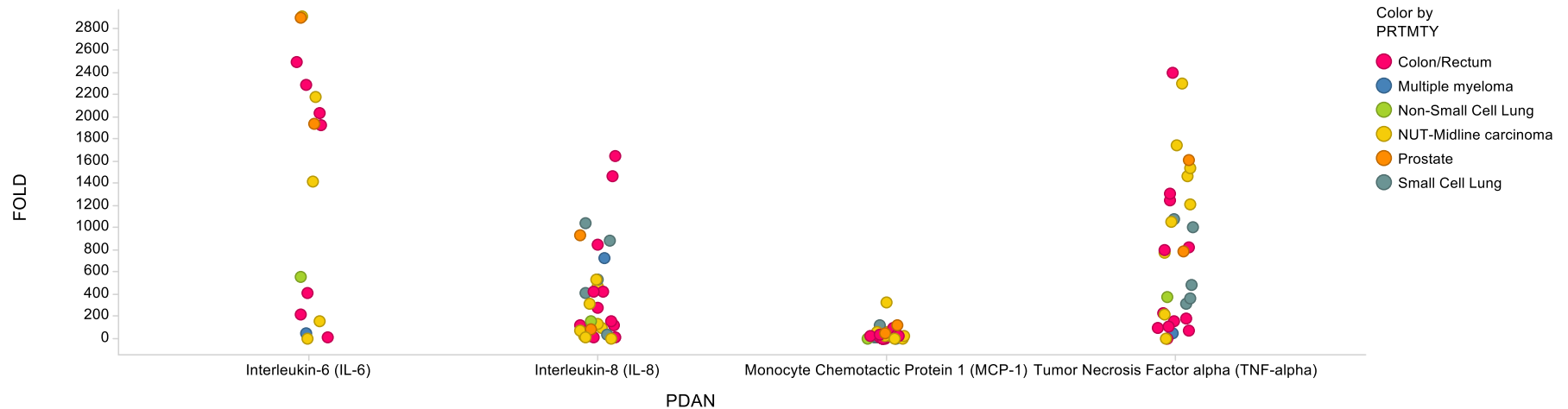
LPS Cytokine Analysis – Anti-inflammatory Medications – All Meds



LPS Cytokine Analysis – AI Medications – All Meds vs. Steroids

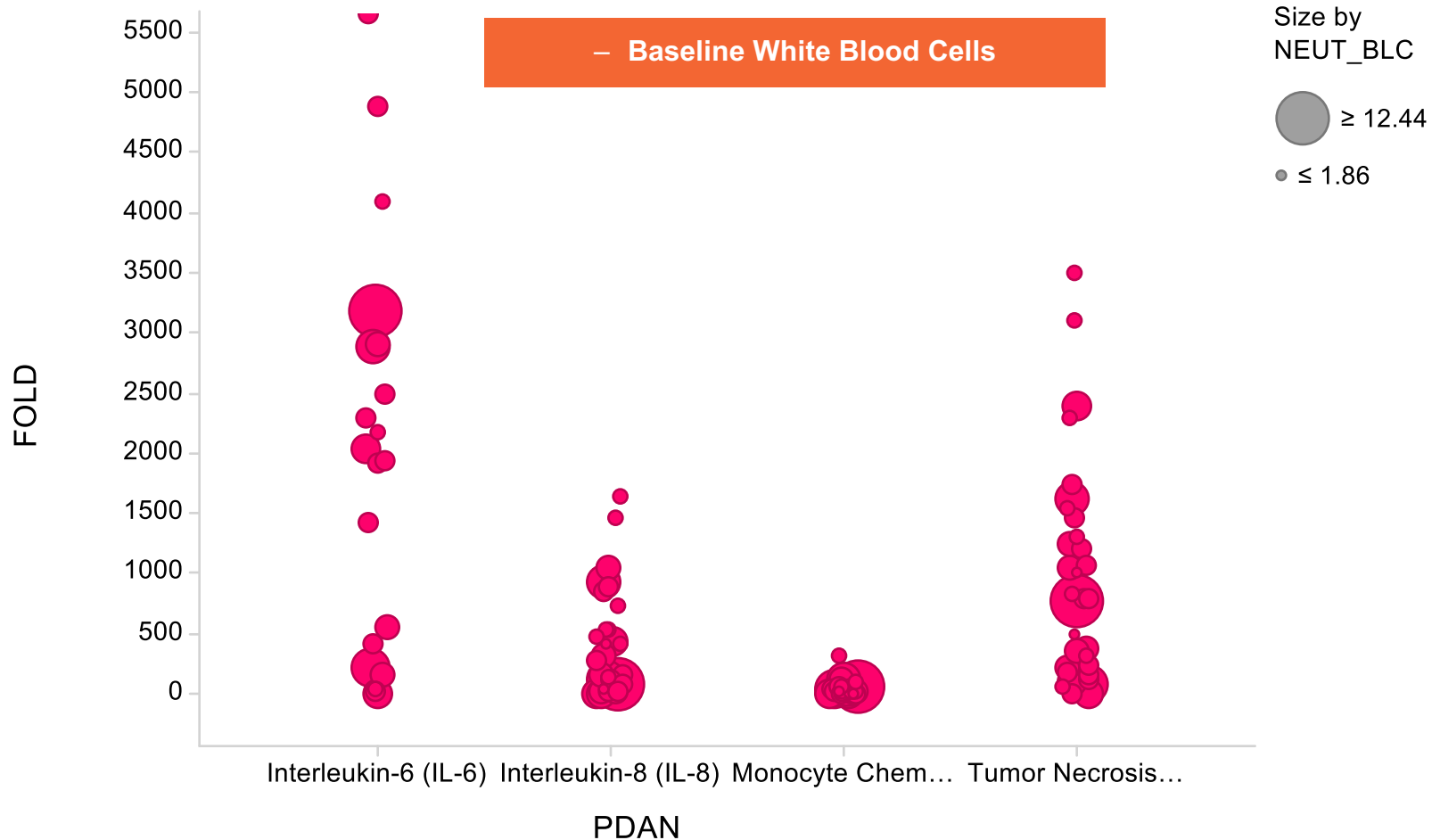


– Primary Tumor Type at Initial Diagnosis

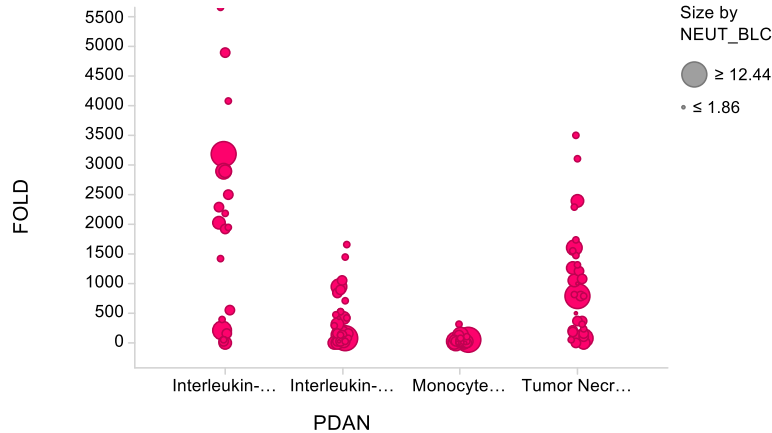


GSK Clinical Programming and Tibco Spotfire®

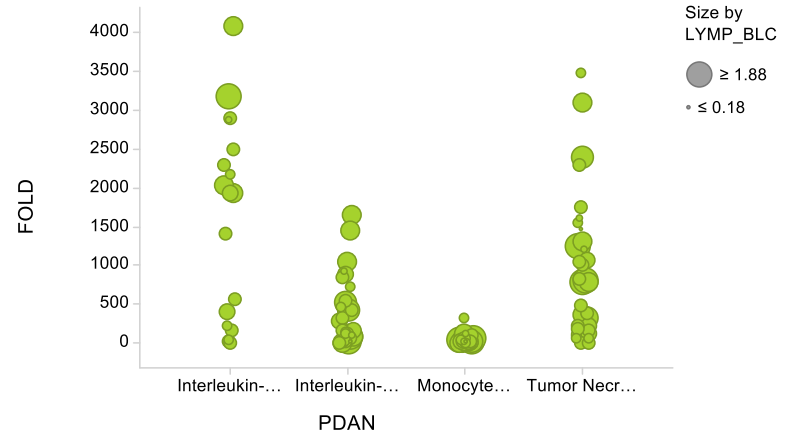
Collaboration and Integration – LPS Cytokine Analysis



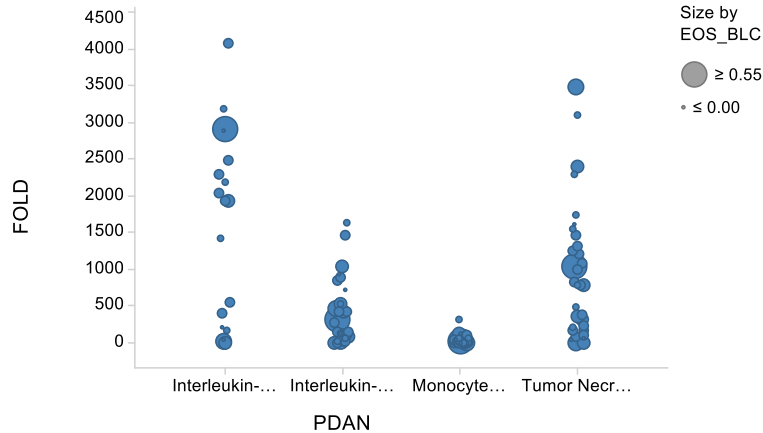
Neutrophils (thousands/Liter)



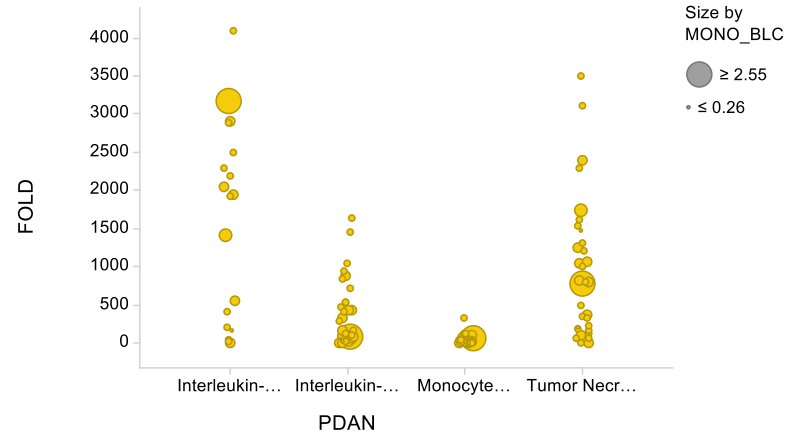
Lymphocytes (thousands/Liter)



Eosinophils (thousands/Liter)



Monocytes (thousands/Liter)



– Baseline White Blood Cells

- Traditional Oncology therapies –
 - Increase dose until MTD is found
 - Combine safety, study population, PK and clinical activity (if any) into one tool
 - Demonstrated reduction in timelines to dose escalation decisions
- Immuno-Oncology therapies –
 - treatments may not show the same toxicity as chemotherapy or targeted therapy
 - Focus on PD/biomarker data and target engagement
 - Combine safety, PK, efficacy, and biomarker data to show PD effects and optimal target engagement.

Conclusion

-
- **Data visualization enhances cognition and expresses the significance of data to key stakeholders**
 - **Interactive tools like Spotfire® have helped GSK stakeholders; enabling more robust and timely decision making**
 - **Centralized Data Visualization provides GSK rapid access to Data Visualization Tools with efficient management of Workflow Setup & custom Visualization creation**
 - **Interactive Data Visualizations are powerful engines for data interrogation**
 - **Successful organizational embedding of Data Visualization requires scalable plans for adoption & responsible Governance/Quality Plans ensuring risk/benefit balance maintained**
 - **Collaboration between Centralized Data Analytics & Clinical Programming has delivered key benefits:**
 - **Knowledge capture, elegant program visualizations integrated centrally driving innovation, and greater capability and sophisticated workflows augments in-stream analysis and enhances formal reporting**
-

Questions?