



Appropriate Use of Graphics in Advanced Visual Analytics Tools

PhUSE Single Day Event – Frenchtown

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Disclaimer

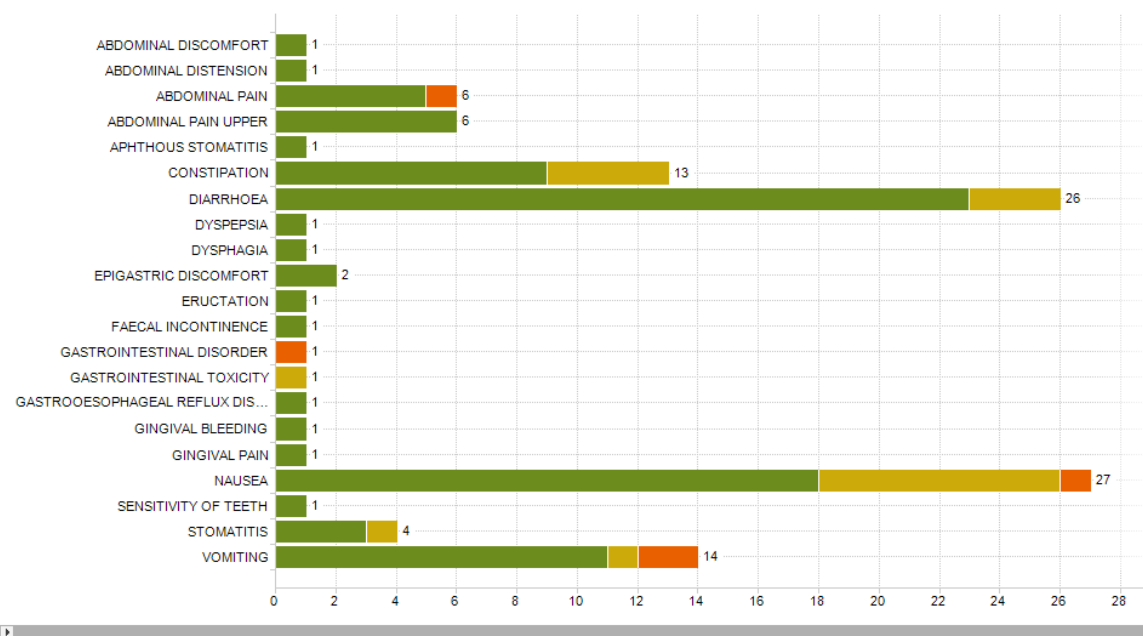
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A Picture is Worth a Thousand Words

Introduction

Adverse event	Grade ^a				Total
	1	2	3	4	
Transaminitis	3 (25)	0	0	0	3 (25)
Flu-like symptoms ^b	4 (33)	0	0	0	4 (33)
Anemia	3 (25)	0	0	0	3 (25)
Leukopenia	5 (42)	3 (25)	0	0	8 (67)
Lymphopenia	2 (17)	8 (67)	2 (17)	0	12 (100)
Neutropenia	2 (17)	1 (8)	0	0	3 (25)
Thrombocytopenia	2 (17)	0	0	0	2 (17)
Gastrointestinal ^c	8 (67)	1 (8)	0	0	9 (75)
Genitourinary ^d	5 (42)	4 (33)	1 (8)	0	10 (83)
Fatigue	3 (25)	0	0	0	3 (25)



Industry Trends

- Analytics tools offer advanced visualization capabilities
- Data visualization provides quick, summary views with detailed drill down, driving safety review, exploratory analysis & hypothesis generation
- Key players in the industry:
 - Spotfire
 - JReview
 - Tableau
 - SAS Visual Analytics
 - + more

Advantages of Analytics Tools

- Simple, intuitive user interface
- Interactive – drop downs, filters, highlighting
- Quick snapshot using summary views with drill-down capabilities
- Automated data flow, near real-time
- Easily deployed to large user base

Challenges with New Platforms & Technology

- Open and flexible
 - Users can easily change analysis parameters in seconds
- Limited audit trail
 - Tracks access, but not how the outputs was reviewed
- Controlling usage
 - Users can easily share complex outputs that may not be formally validated

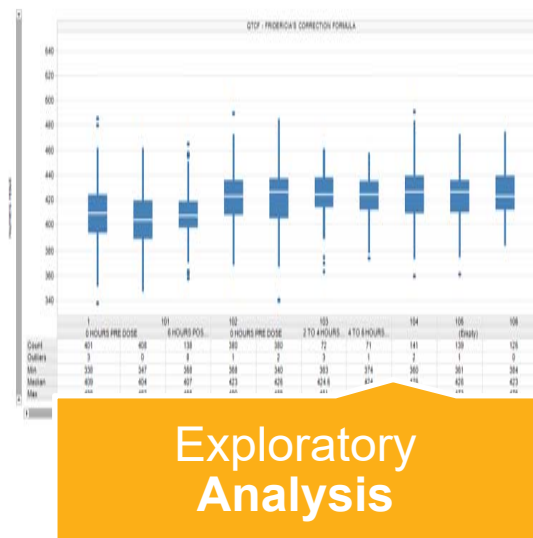


Keys to Successful Implementation

Establish a set of guiding principles for how these tools will be used within your organization

- Define use cases - who are the users and what are their needs?
- How and where will the insights and knowledge gained from these tools be used and/or applied?
- Can your system architecture support these use cases?

Our Use Cases



Scroll down to view the full list of terms.

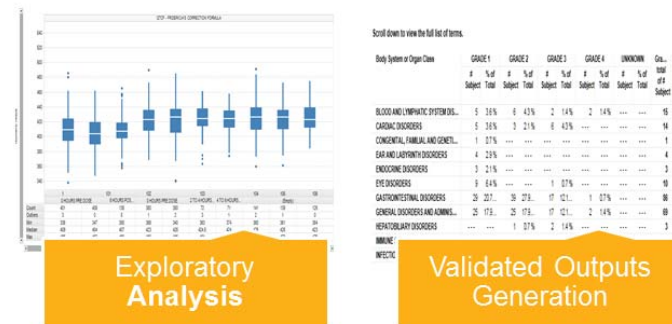
Body System or Organ Class	GRADE 1		GRADE 2		GRADE 3		GRADE 4		UNKNOWN		Gra...	Gra...
	#	% of Subject	#	% of Subject	#	% of Subject	#	% of Subject	#	% of Subject	total of #	total of %
BLOOD AND LYMPHATIC SYSTEM DIS...	5	3.6 %	6	4.3 %	2	1.4 %	2	1.4 %	...	...	15	10.7...
CARDIAC DISORDERS	5	3.6 %	3	2.1 %	6	4.3 %	...	...	...	...	14	10.0...
CONGENITAL, FAMILIAL AND GENETI...	1	0.7 %	...	...	...	...	...	...	...	...	1	0.7 %
EAR AND LABYRINTH DISORDERS	4	2.9 %	...	...	...	...	...	...	...	...	4	2.9 %
ENDOCRINE DISORDERS	3	2.1 %	...	...	...	...	...	...	...	...	3	2.1 %
EYE DISORDERS	9	6.4 %	...	...	1	0.7 %	...	...	...	...	10	7.1 %
GASTROINTESTINAL DISORDERS	29	20.7...	39	27.9...	17	12.1...	1	0.7 %	...	...	86	61.4...
GENERAL DISORDERS AND ADMINIS...	25	17.9...	25	17.9...	17	12.1...	2	1.4 %	...	...	69	49.3...
HEPATOBIILIARY DISORDERS	...	...	1	0.7 %	2	1.4 %	...	...	...	...	3	2.1 %
IMMUNE:	...	...	...	...	...	...	...	...	...	...	...	...
INFECTIO	...	...	...	...	...	...	...	...	...	...	...	...

Validated Outputs Generation

The remainder of this presentation will describe the three distinct approaches taken by our organization to support these three use cases

- The positioning of each tool is established by assessing our use cases against the tool's capabilities and system architecture
- JReview and Spotfire are currently used to meet the needs of our end users

Spotfire



Safety & Exploratory Data Review

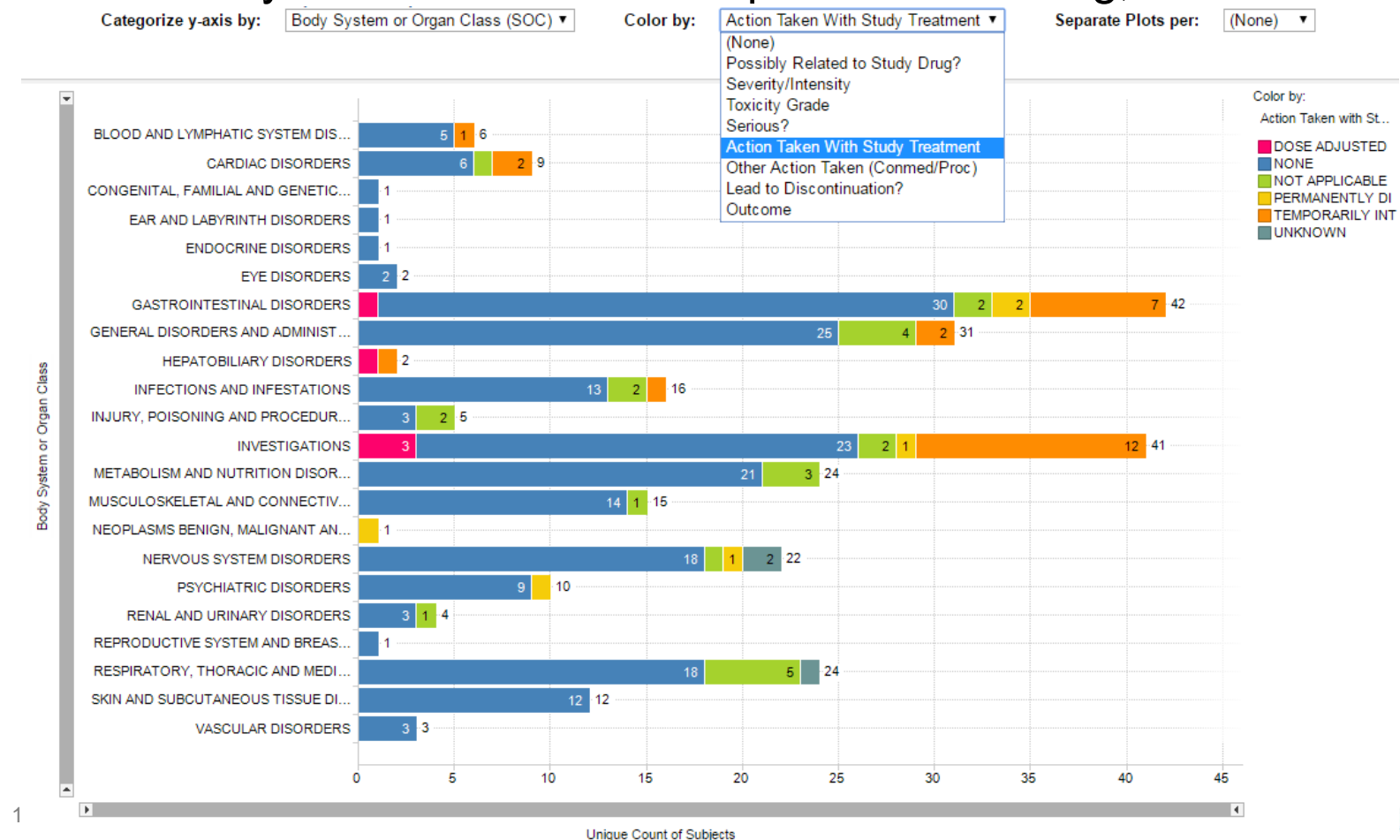
Use Case #1

Primary Users:	Medical and Study Leads
Types of Outputs:	High-level summary views with drill-down to discrete data points
Used for:	Identifying trends, outliers, correlation, status & metrics Hypothesis generation with confirmation supported by statistical outputs / TFLs
Data Requirements:	Raw / collected data, latest & greatest
Development/ Deployment Strategy:	Users are provided a global template with interactive options, but cannot create their own visualizations
Additional Considerations:	Findings will often result in a data query to site, follow-up with site staff, or follow-up with field monitors

Safety & Exploratory Data Review

Sample visualizations

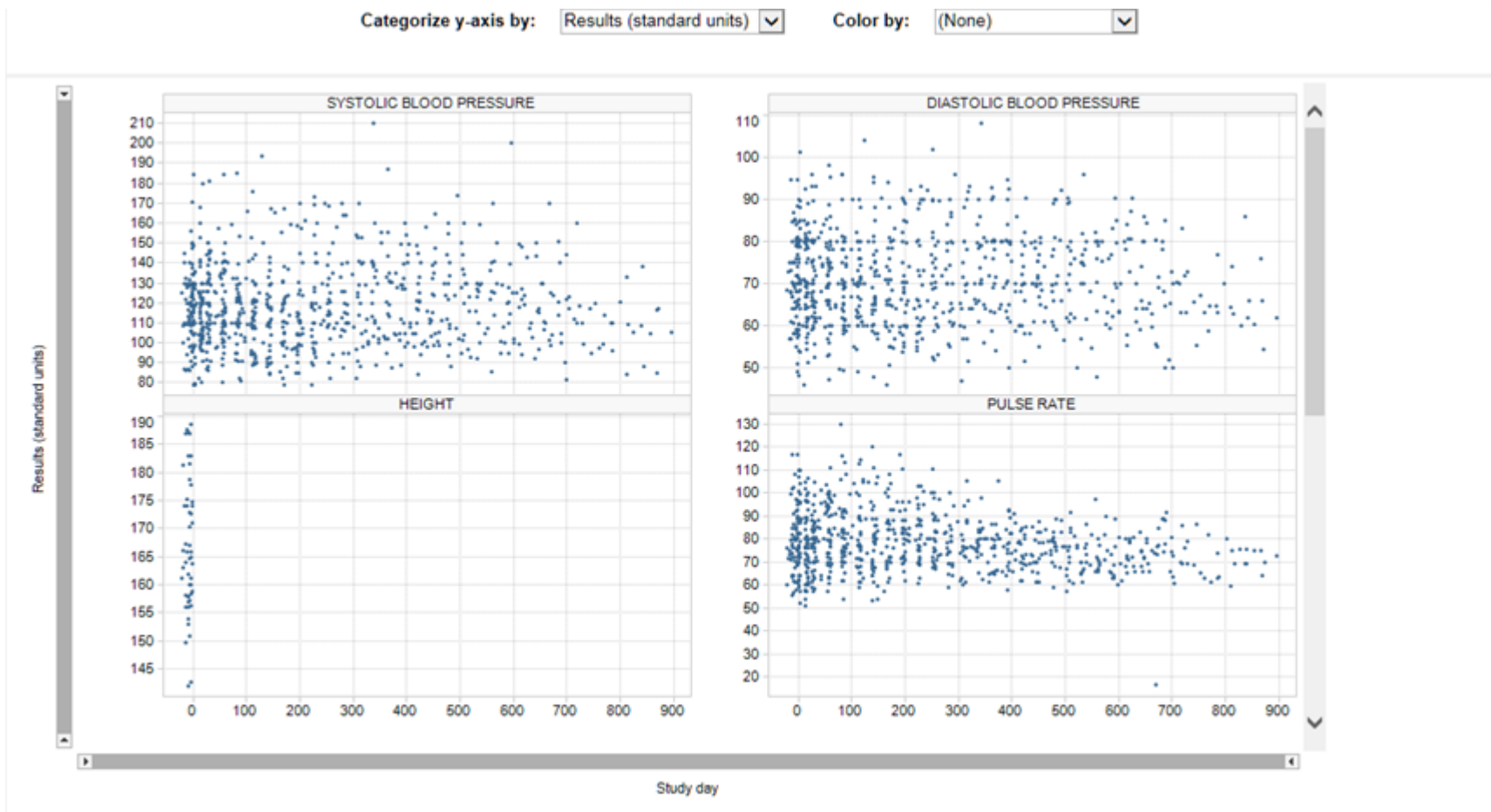
- Visualizations are intended to facilitate pattern recognition
 - Summary bar charts with user options for coloring, axis selection



Safety & Exploratory Data Review

Sample visualizations

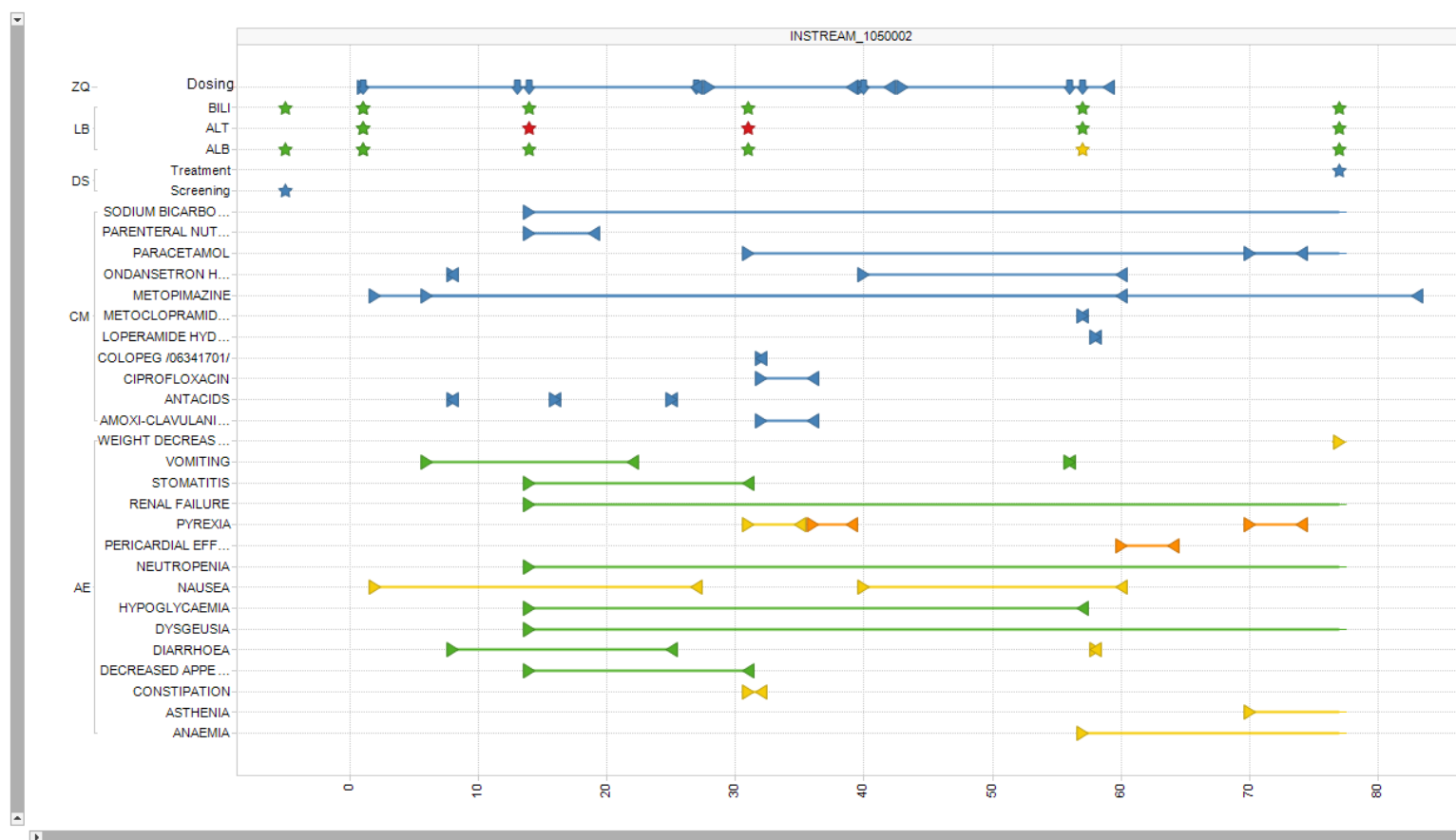
- Visualizations are intended to facilitate pattern recognition
 - Scatter plots – quick outlier identification



Safety & Exploratory Data Review

Sample visualizations

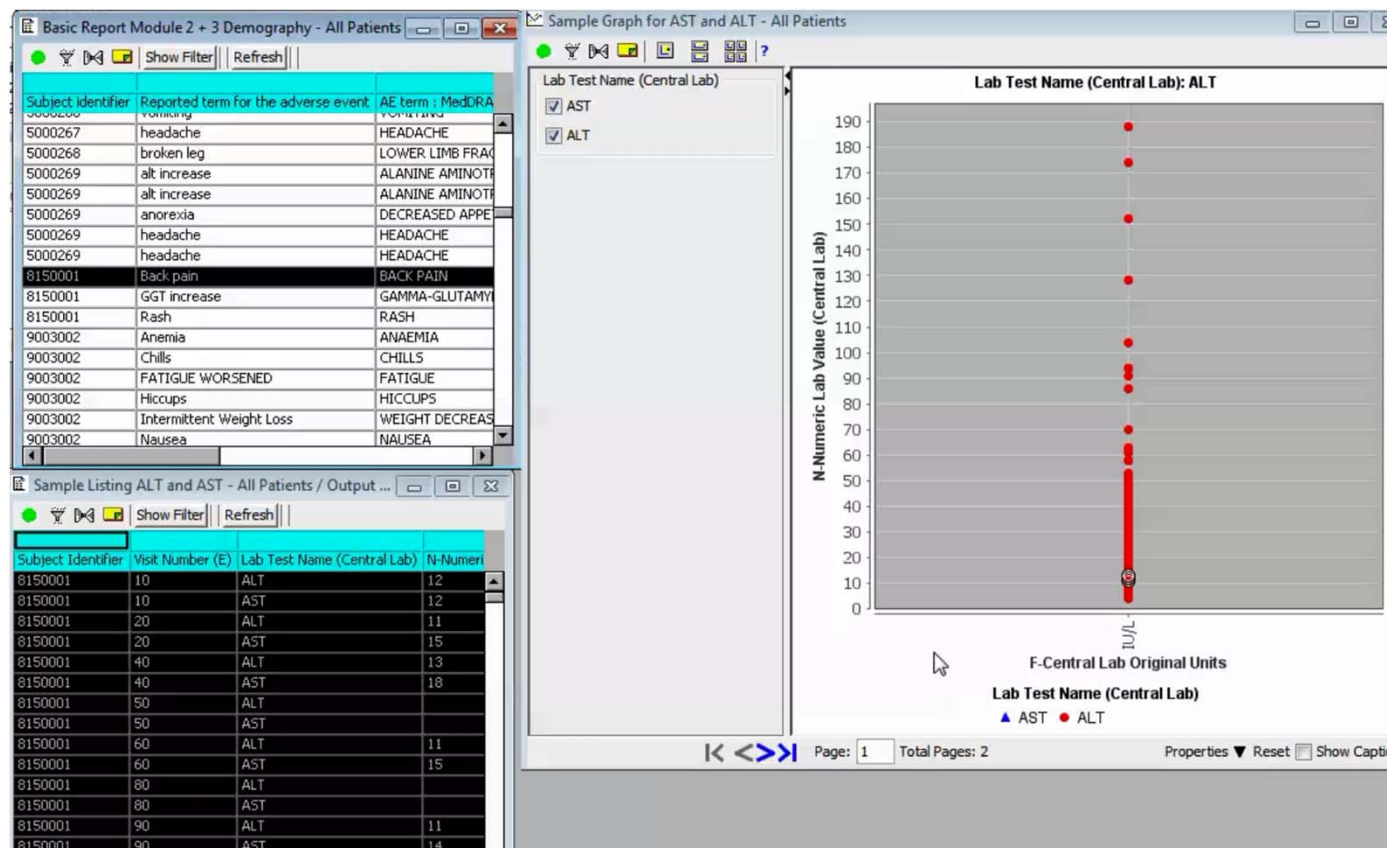
- Patient Profiles, to help correlate data from multiple domains



Safety & Exploratory Data Review

Sample Visualizations

- Details on demand – provides user the raw / discrete data points to facilitate follow-up



Safety & Exploratory Data Review

Sample Visualizations

- Provide users both graphics and data listings
 - Graphics provide big picture overview, listing provides a quick list of actionable data points that user can export & distribute for follow-up



Exploratory Analysis

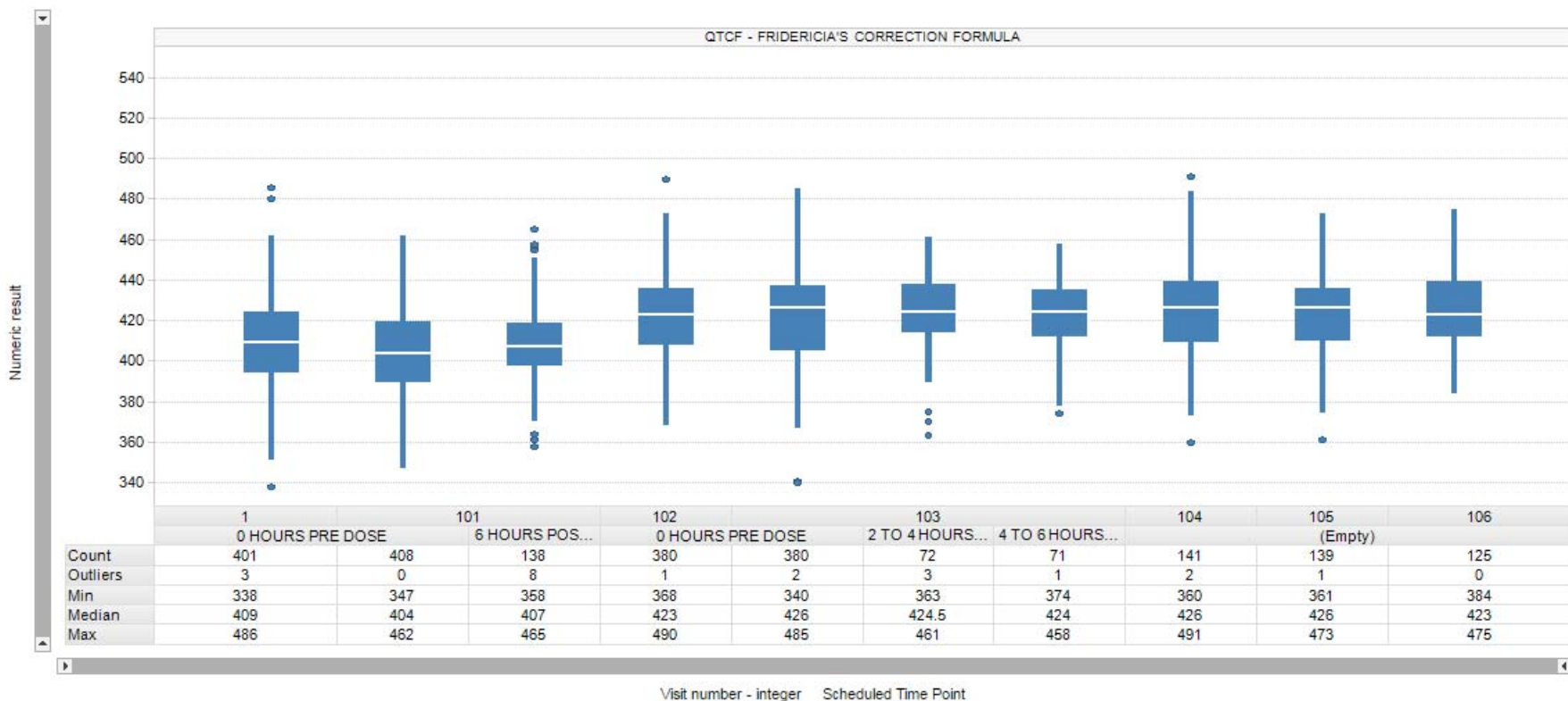
Use Case #2

Primary Users:	Statistical Programmers, Statisticians
Types of Outputs:	Advanced visuals including forest plots, summary tables, etc.
Used for:	Exploratory analysis traditionally outside of the scope of the statistical analysis plan, pooled analysis
Data Requirements:	Analysis Data (clean data) May require SAS/R integration within the tool enabling advanced data manipulation to generate graph ready datasets
Development/ Deployment Strategy:	Users are given full control of the source data and creation of visualizations to support their needs
Additional Considerations:	Primary users are self-sufficient and will quickly become power users of the tool/technology

Exploratory Analysis

Sample Visualizations

- Visualizations/outputs are aligned with traditional TFLs
 - Box plots of ECGs



Exploratory Analysis

Sample Visualizations

- Visualizations/outputs are aligned with traditional TFLs
 - Summary tables – Adverse Events by Worst Toxicity

Scroll down to view the full list of terms.

Body System or Organ Class	GRADE 1		GRADE 2		GRADE 3		GRADE 4		UNKNOWN		Gra... total of # Subject	Gra... total of % of Total
	# Subject	% of Total	# Subject	% of Total	# Subject	% of Total	# Subject	% of Total	# Subject	% of Total		
BLOOD AND LYMPHATIC SYSTEM DIS...	5	3.6 %	6	4.3 %	2	1.4 %	2	1.4 %	---	---	15	10.7...
CARDIAC DISORDERS	5	3.6 %	3	2.1 %	6	4.3 %	---	---	---	---	14	10.0...
CONGENITAL, FAMILIAL AND GENETI...	1	0.7 %	---	---	---	---	---	---	---	---	1	0.7 %
EAR AND LABYRINTH DISORDERS	4	2.9 %	---	---	---	---	---	---	---	---	4	2.9 %
ENDOCRINE DISORDERS	3	2.1 %	---	---	---	---	---	---	---	---	3	2.1 %
EYE DISORDERS	9	6.4 %	---	---	1	0.7 %	---	---	---	---	10	7.1 %
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HEPATOBIILIARY DISORDERS	---	---	1	0.7 %	2	1.4 %	---	---	---	---	3	2.1 %
IMMUNE SYSTEM DISORDERS	1	0.7 %	---	---	---	---	---	---	---	---	1	0.7 %
INFECTIONS AND INFESTATIONS	15	10.7...	21	15.0...	9	6.4 %	---	---	---	---	45	32.1...

Validated Outputs Generation

Use Case #3

Primary Users:	Medical Leads, Statisticians
Types of Outputs:	Varies; dependent on the purpose & audience but generally limited to very few outputs
Used for:	Planned internal presentations, potential for external use (publications, Data Monitoring Committees, health authorities)
Data Requirements:	Raw/collected or analysis data (clean data) May require SAS/R integration within the tool enabling advanced data manipulation to generate graph ready datasets
Development/ Deployment Strategy:	Users request a predefined set of outputs with disabled or limited interactivity
Additional Considerations:	Requires extensive controls to ensure data integrity & traceability

Validated Outputs for Presentation

- Controls may include:

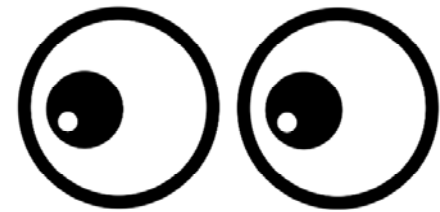
- Visual indicators of user selections. A filter indicator that changes color providing a clear visual cue whenever the user filters the dataset.



- Disabling filter options – to prevent users from unintentionally jeopardizing the analysis
 - Watermarks in the background, titles/footnotes within the output view
- It is also critical to establish a formal process for requesting and generating the outputs, including permanent storage

Benefits of Visualizations

- There are many advantages to using advanced analytics tools for data visualization:
 - User friendly & intuitive, with guided analysis
 - Stimulates creativity & self-discovery
 - Enables quicker insights & interpretation
 - Facilitates trend and pattern detection
 - Automates output generation and delivery
- However, a measured approach should be taken to ensure that the tools & technology are appropriately configured to support each use case



In Closing...

- While a picture is worth a thousand words, we need to make sure it's the original



Questions?

