

Redefining "Interactive" Dashboards to Enhance Safety Data Review

Andrew McGowan

Rho

andrew_mcgowan@rhoworld.com



Introduction

Increasing trial costs and data volume in trials has led to the need to re-evaluate trial conduct.



Requirements for Interactive Dashboards

Interactive dashboards use data visualizations which allow end users to explore any analyze data efficiently.

- Filtering
- Dynamic displays
- Drill-down functionality
- Collaboration



Dashboard Layout



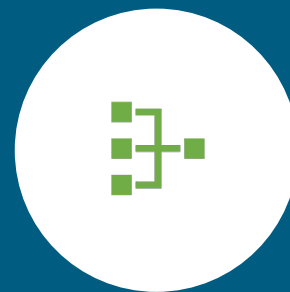
AE Summary

AE profile for study
by both subject
count and event
count



Individual Safety

Trends in safety
data for individual
participants



Grouped Safety

Trends in aggregate
safety data for study
across all
participants

AE Summary



Step 1: Select if all AEs should be displayed or only Treatment Emergent AEs (TEAEs) should be displayed. Note this affects the summary numbers displayed below, the bar chart, and the percentage table.

All

Count of dosed subjects: 151

Count of early terminated subjects: 6

Count of AEs/TEAEs (as selected above): 117

Count of dosed subjects with at least one AE/TEAE: 52

Percent of dosed subjects with at least one AE/TEAE: 34.44%

Count of SAEs/TEAEs: 1

Count of dosed subjects with at least one SAE/TEAE: 1

Percent of dosed subjects with at least one SAE/TEAE: 0.66%

Adverse Event Summary

*Total Subject counts represent all dosed subjects of a specific category. Subject counts will only be available for subject level variables (ex. Treatment Group, Sex, Age Group, Race)

*Total AE counts represent the count of reported events.



Subject Percentage is the percentage of total dosed subjects in the study who reported this value as an AE/TEAE.

AE Percentage is the SOC/PT/Reported Term percentage out of the count of SOC/PT/Reported events.

Preferred Term	Overall Subject Percentage	AE Percentage
Abdominal distension	1.32%	1.71%
Abdominal Pain	0.66%	0.85%
Abdominal pain upper	0.66%	0.85%
Allergy to arthropod sting	0.66%	0.85%
Amenorrhoea	0.66%	0.85%
Ankle fracture	0.66%	0.85%
Application site pain	0.66%	0.85%

Details on Demand

Subject ID	Site	Treatment Group	Sex	Age	Age Group	Race	Start Day	Start Date	End Day	End Date	Duration	Reported Term	Preferred Term
05-401	05 - Nashville Study Center (Pogba)	Placebo	Male	52	>= Median Age (49)	Black or African American	1	06-Dec-2020	6	11-Dec-2020	5	FATIGUE	Fatigue
07-401	07 - Franklin and Marshall Research...	Placebo	Female	33	< Median Age (49)	Black or African American	13	12-Mar-2021				FATIGUE	Fatigue

Individual Safety

Step 2: Apply any additional configuration

X Axis Selector

Visit

Show Unscheduled/Early Term Visits

Hide In-Range Subjects

Select Standard Deviation for the Visual



Select the Measurements that will be displayed on the details on demand

(Hold control or shift key to select multiple)

- (None)
- Alanine Aminotransferase
- Albumin
- Alkaline Phosphatase
- Aspartate Aminotransferase

Reset All Filters Reset Zoom Sliders

Step 1: Select the category and then the measurement that should be displayed on the main visual to the right

Lab Category

- ECG
- Labs
- Vital Signs

Specific Measurement

- Alanine Aminotransferase
- Albumin
- Alkaline Phosphatase
- Aspartate Aminotransferase
- Basophils

Note: you are able to select a single outstanding line from the main visual and get all other values for that category (e.g. Labs) for that subject. If you wish to also see other categories you can toggle the Lab Category Selector without disturbing the main visual

Step 2: Apply any additional configuration

X Axis Selector

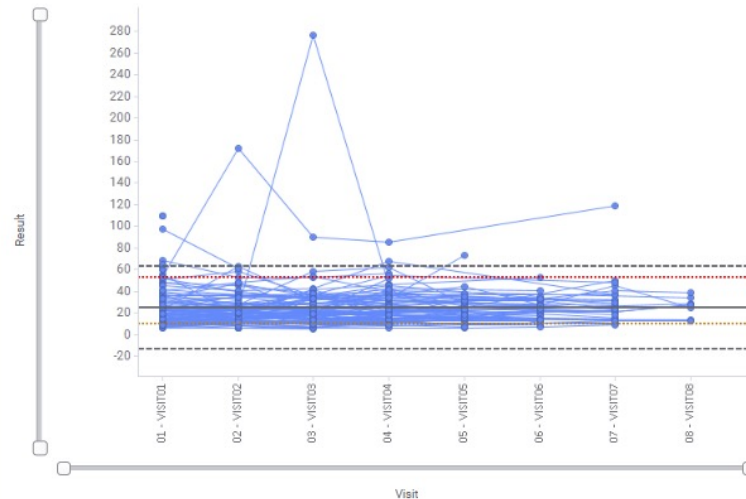
Visit

Show Unscheduled/Early Term Visits

Hide In-Range Subjects

Select Standard Deviation for the Visual

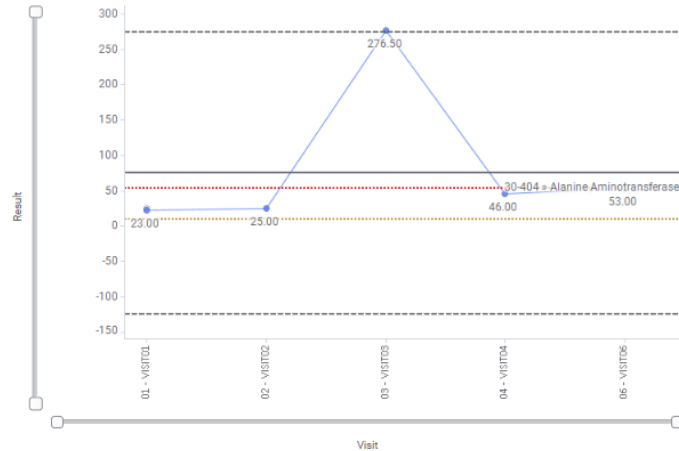
Alanine Aminotransferase (U/L)



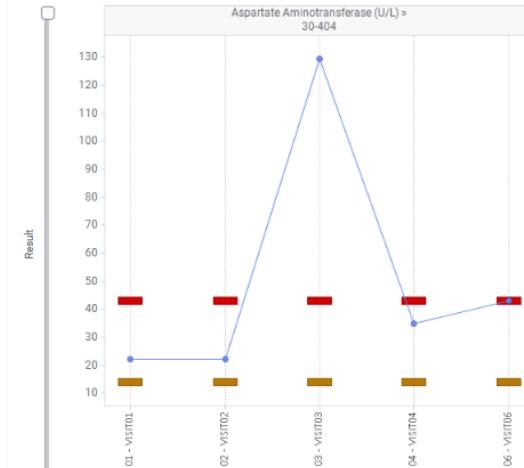
Standard Deviation Result Average Upper Limit Lower Limit

*The Upper and Lower Limits are the median values of the upper and lower limits per subject per measurement and do NOT vary based on filter selection (eg. Sex, Age)

Alanine Aminotransferase (U/L)



Details on Demand



Grouped Safety



Step 1: Select the category and then the measurement that should be displayed on the main visual to the right

Lab Category

ECG
Labs
Vital Signs

Specific Measurement

Step 2: Apply any additional configuration

X Axis by

Visits

Y Axis Scale

Linear Scale

[Hide Unscheduled Visits](#)

Step 3: If desired, you can further filter down with the filters below

Site

Type to search in list

(All) 24 values

05 - Nashville Study Center (Pogb...

06 - Lancaster Research Inc (Vara...

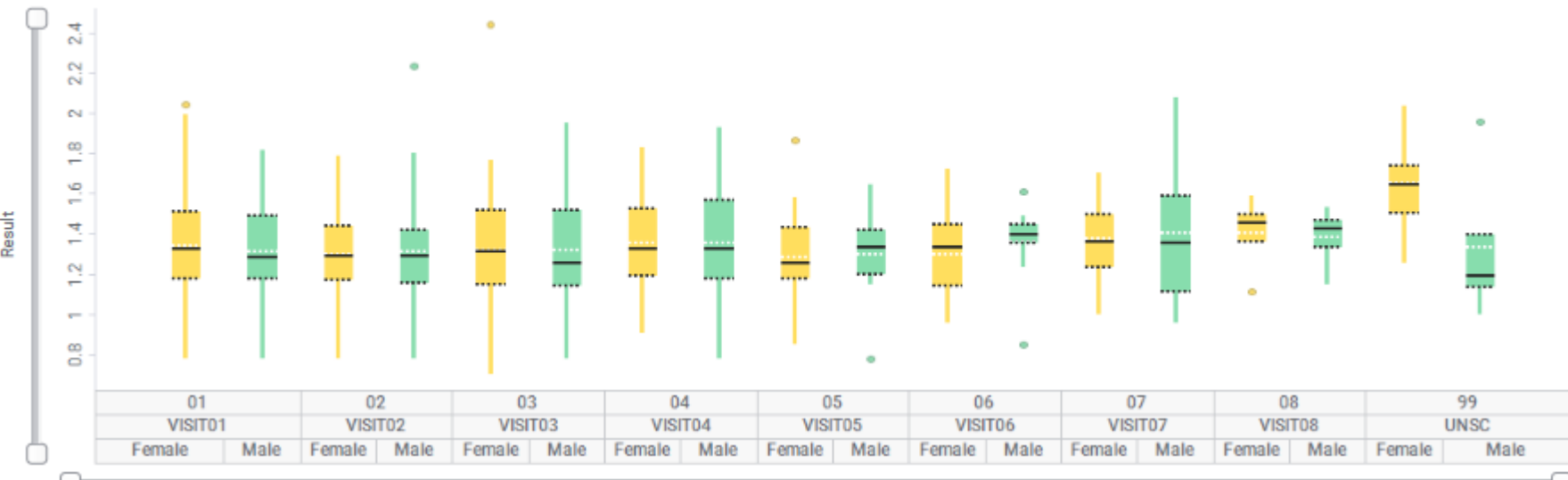
07 - Franklin and Marshall Resear...

12 - Embreeville Research (Wan-B...

13 - Durham Research Inc (Dalot)

22 - Cary Research Center (Willia...

Alanine Aminotransferase (U/L)



	01	02	03	04	05	06	07	08	99
	VISIT01	VISIT02	VISIT03	VISIT04	VISIT05	VISIT06	VISIT07	VISIT08	UNSC
	All	All	All	All	All	All	All	All	All
Count	137	106	94	84	46	34	29	8	13
StdErr	1.41	1.84	3.03	1.63	1.70	1.69	3.86	3.17	8.52
Max	110.00	172.50	276.50	85.00	73.00	53.00	119.00	39.00	108.00
Avg	25.18	23.73	26.04	26.24	21.70	22.79	28.34	26.25	45.08
Median	20.00	19.50	20.00	21.00	18.50	23.00	23.00	28.00	42.00
Min	6.00	6.00	5.00	6.00	6.00	7.00	9.00	13.00	10.00

Conclusion

Interactive dashboards maximize the limited resources available to the monitoring of clinical trial safety data.

- Aggregate all relevant data into single location
- Give study team members flexibility to manipulate displays
- Allow study team members to further investigate relevant findings
- Undergo continuous improvement based on interactions between programmers and other study team members

