
Standard Safety Visualization Set-up using Spotfire

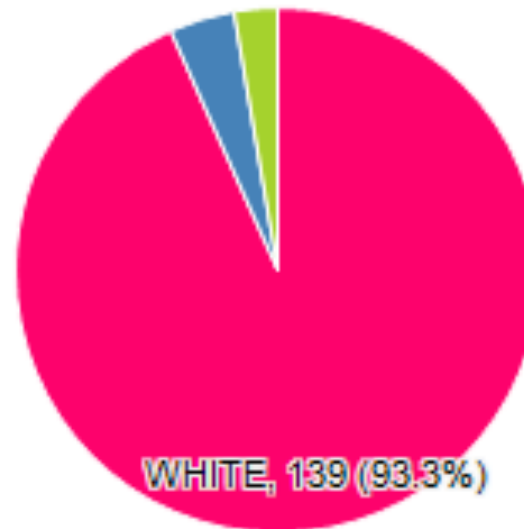
PhUSE 2016

Michaela Mertes

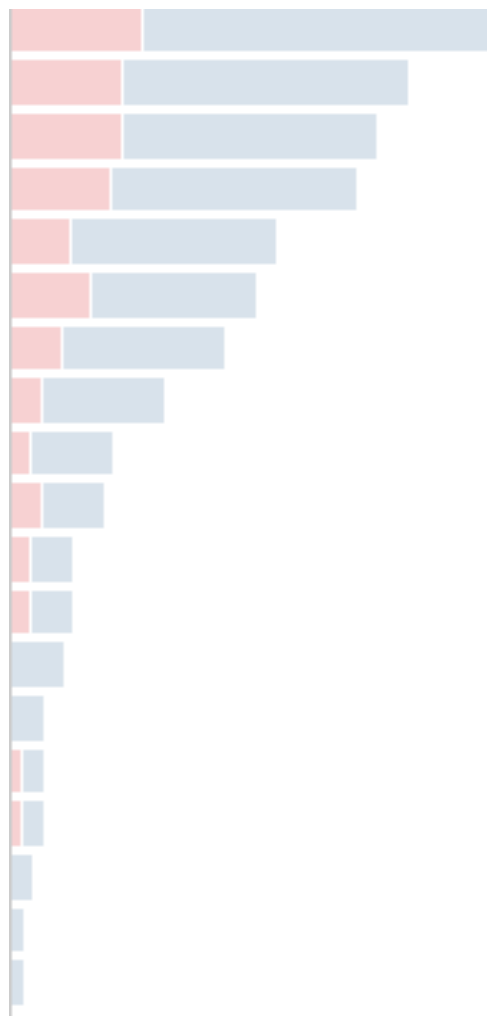


Agenda

- General Information
- Table of Contents
- Functionality
- Examples
- Feedback



General Information for Standard Safety Visualizations



Initiative with Statistical Programmers and Safety Scientists started 2014

Tibco Spotfire® version 6.5

- Existing infrastructure
- Safety Scientists are familiar with the tool

Source data: Analysis datasets

Open CoreSV – Table of Contents

Cover	Table of Contents																							
Pr																								
Rep																								
Extra																								
Clini																								
Data																								
Stud																								
Crea																								
Spot																								

DIS																								
This																								
revis																								
if re																								
	Safety Data Domain	Summary Tables/Plots	Listings / By-Patient Plots																					
	Demographics	Demographics 1 (Discrete) Demographics 2 (Continuous)	Listing: Demog																					
	AE	AE Graph Time to AE Onset AE Table by PT AE Table by SOC and PT AE Table by Highest Grade	Listing: AE																					
	Patient Profile	Patient Profile																						
	Lab	Lab Summary Lab Summary (Chg Fr BL)	Lab By-Patient Plot Listing: Lab Tests																					
	Vital Sign	VS Summary VS Summary (Chg Fr BL)	VS By-patient Plot Listing: VS																					
	Study Drug		Study Drug by-Patient Plot Listing: Dose Exposure																					
	Concomitant Medication	Conmed Summary	Listing: Conmed																					
	Medical History		Listing: Medical History																					
	<table border="1"> <tr> <td>Population_Category</td> <td>Population</td> <td>TRT 1</td> <td>TRT 2</td> <td>Grand total</td> </tr> <tr> <td>Intent-To-Treat Population Flag</td> <td>Y</td> <td>69</td> <td>81</td> <td>150</td> </tr> <tr> <td>Safety Population Flag</td> <td>N</td> <td>---</td> <td>1</td> <td>1</td> </tr> <tr> <td></td> <td>Y</td> <td>69</td> <td>80</td> <td>149</td> </tr> </table>				Population_Category	Population	TRT 1	TRT 2	Grand total	Intent-To-Treat Population Flag	Y	69	81	150	Safety Population Flag	N	---	1	1		Y	69	80	149
Population_Category	Population	TRT 1	TRT 2	Grand total																				
Intent-To-Treat Population Flag	Y	69	81	150																				
Safety Population Flag	N	---	1	1																				
	Y	69	80	149																				

Demographics 1 – How to Navigate

Cover Page

Instructions

Demographics 1

Demographics 2

ShowModifiedFilters

ShowModifiedFilters button displays filters used in the visualization

Input age category:

18,75

Select denominator for % calculation:

All Safety Evaluable Patients

Safety Evaluable Patients

(Column Names)	TRT 1	TRT 2	Grand total
Population N	69	80	149
Patients in subgroup	69	80	149
Percent	100,0%	100,0%	100,0%

Type to search filters

asl

aae

acm

alb

amh

Sex Distribution

Safety Evaluable

Color by: Actual Tr...

● TRT 1
● TRT 2

Age Distribution

Safety Evaluable

Race Distribut...

Safety Evaluable

Region Distribu...

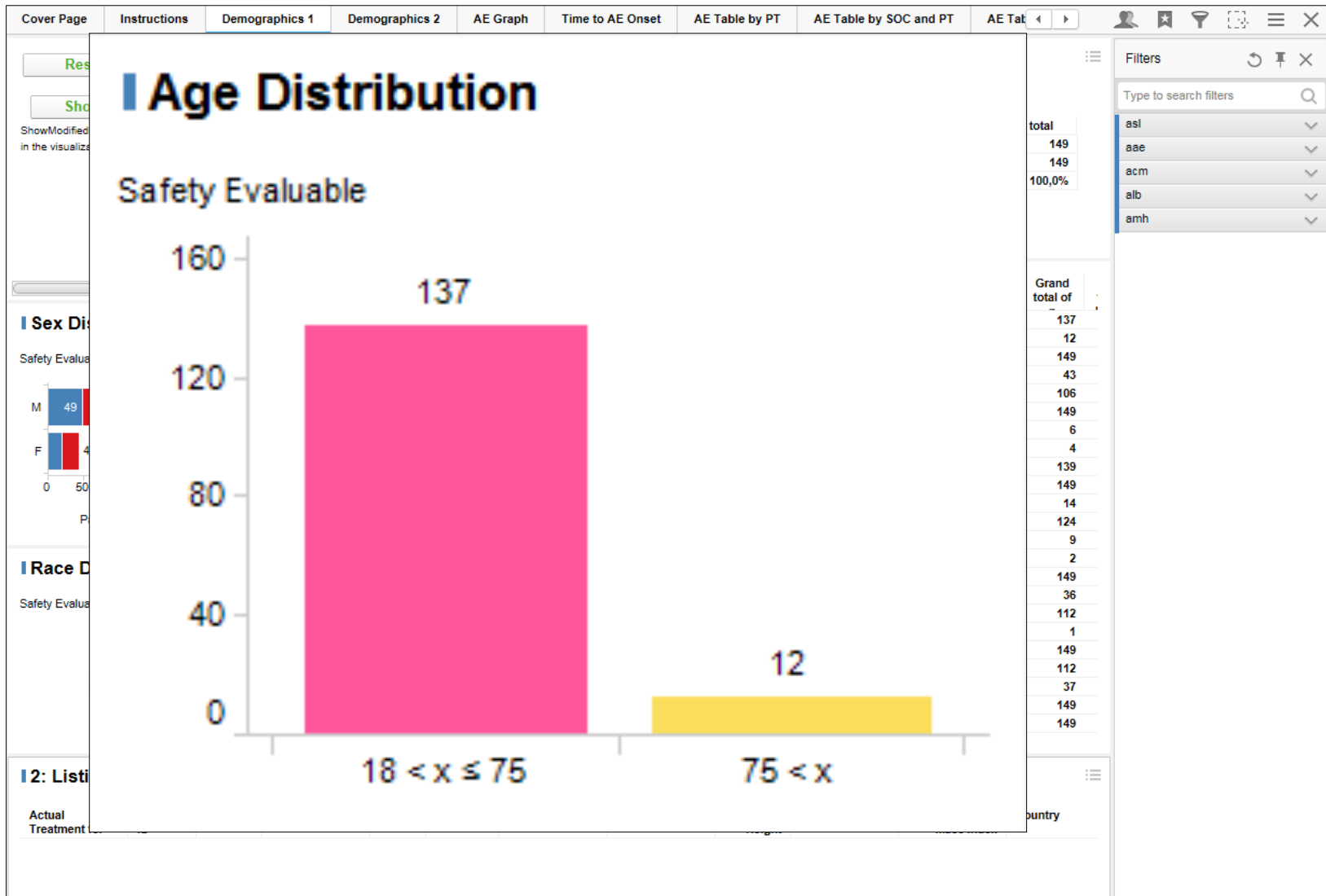
Safety Evaluable

Demo_Cate...	Value	TRT 1		TRT 2		Grand total of
		n	Percent	n	Percent	
	18 < x ≤ 75	64	92,8%	73	91,3%	137
	75 < x	5	7,2%	7	8,8%	12
Sex	Subtotal	69	100,0%	80	100,0%	149
	F	20	29,0%	23	28,8%	43
	M	49	71,0%	57	71,3%	106
Race	Subtotal	69	100,0%	80	100,0%	149
	ASIAN	5	7,2%	1	1,3%	6
	OTHER	1	1,4%	3	3,8%	4
	WHITE	63	91,3%	76	95,0%	139
Ethnicity	Subtotal	69	100,0%	80	100,0%	149
	HISPANIC OR...	8	11,6%	6	7,5%	14
	NOT HISPANI...	56	81,2%	68	85,0%	124
	NOT REPORT...	3	4,3%	6	7,5%	9
	UNKNOWN	2	2,9%	---	---	2
Region	Subtotal	69	100,0%	80	100,0%	149
	ASIA	16	23,2%	20	25,0%	36
	EUROPE	52	75,4%	60	75,0%	112
	ROW	1	1,4%	---	---	1
Patient Discontinued Study	Subtotal	69	100,0%	80	100,0%	149
	N	52	75,4%	60	75,0%	112
	Y	17	24,6%	20	25,0%	37
Patient Discontinued Treatment	Subtotal	69	100,0%	80	100,0%	149
		69	100,0%	80	100,0%	149

I 2: Listing of Demographics (Marked)

Actual Treatment for	Subject ID	Age	Binned Age	Sex	Race	Ethnicity	Baseline Weight	Baseline Height	Baseline Temp	Baseline Body Mass Index	Country
----------------------	------------	-----	------------	-----	------	-----------	-----------------	-----------------	---------------	--------------------------	---------

Demographics 1 – Age Distribution



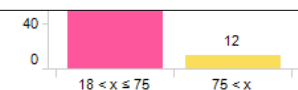
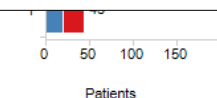
Demographics – Summary of Patients

Cover Page Instructions **Demographics 1** Demographics 2 AE Graph Time to AE Onset AE Table by PT AE Table by SOC and PT AE Table

1: Summary of Demographics - Categorical

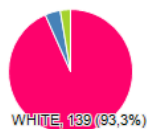
Safety Evaluable Patients

(Column Names)	TRT 1	TRT 2	Grand total
Population N	69	80	149
Patients in subgroup	69	80	149
Percent	100.0%	100.0%	100.0%



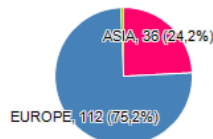
Race Distribut...

Safety Evaluable



Region Distribu...

Safety Evaluable

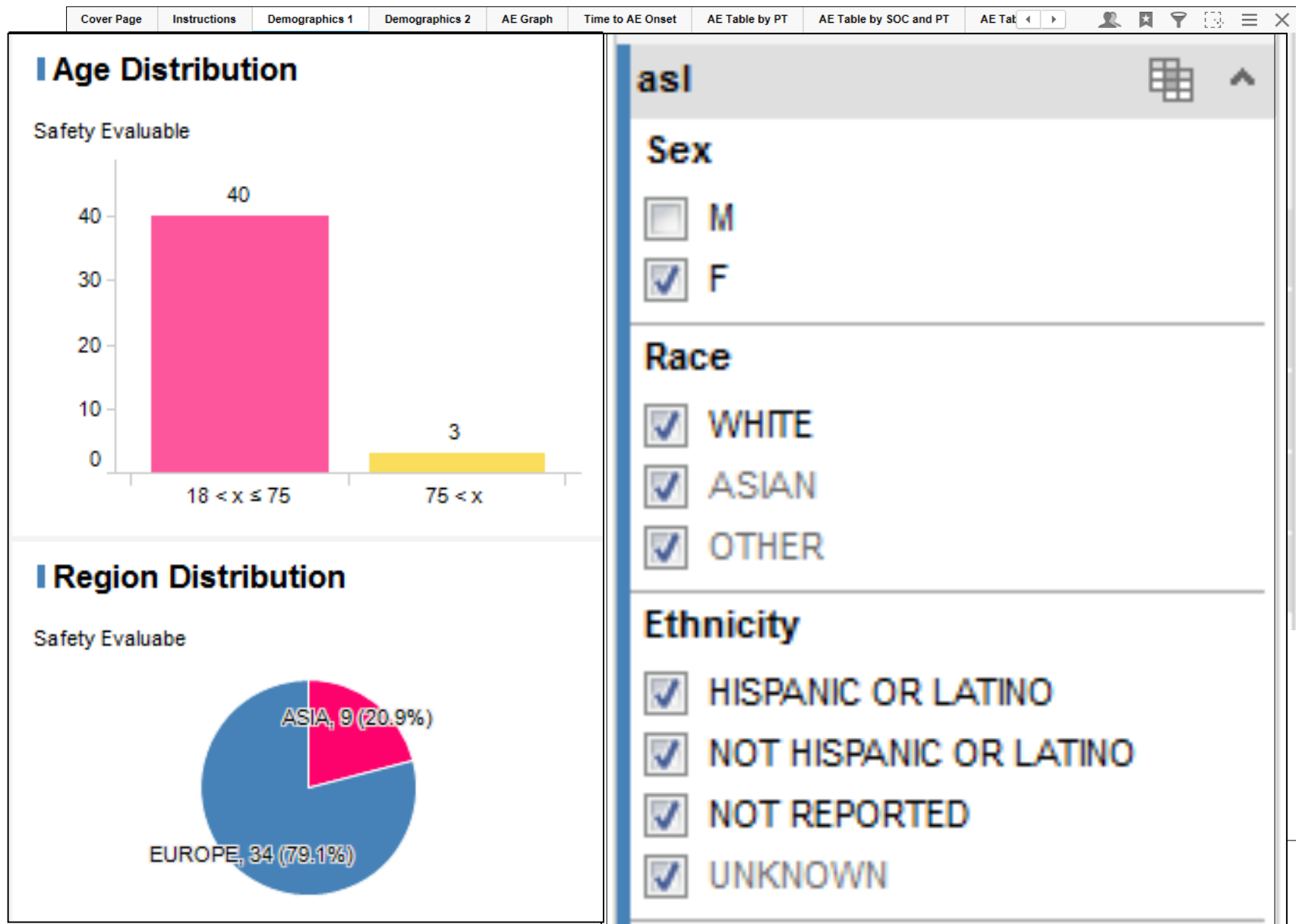


Ethnicity	WHITE	63	91.3%	76	95.0%	139
	Subtotal	69	100.0%	80	100.0%	149
	HISPANIC OR...	8	11.6%	6	7.5%	14
	NOT HISPANI...	56	81.2%	68	85.0%	124
	NOT REPORT...	3	4.3%	6	7.5%	9
Region	UNKNOWN	2	2.9%	---	---	2
	Subtotal	69	100.0%	80	100.0%	149
	ASIA	16	23.2%	20	25.0%	36
	EUROPE	52	75.4%	60	75.0%	112
	ROW	1	1.4%	---	---	1
Patient Discontinued Study	Subtotal	69	100.0%	80	100.0%	149
	N	52	75.4%	60	75.0%	112
	Y	17	24.6%	20	25.0%	37
Patient Discontinued Treatment	Subtotal	69	100.0%	80	100.0%	149
		69	100.0%	80	100.0%	149

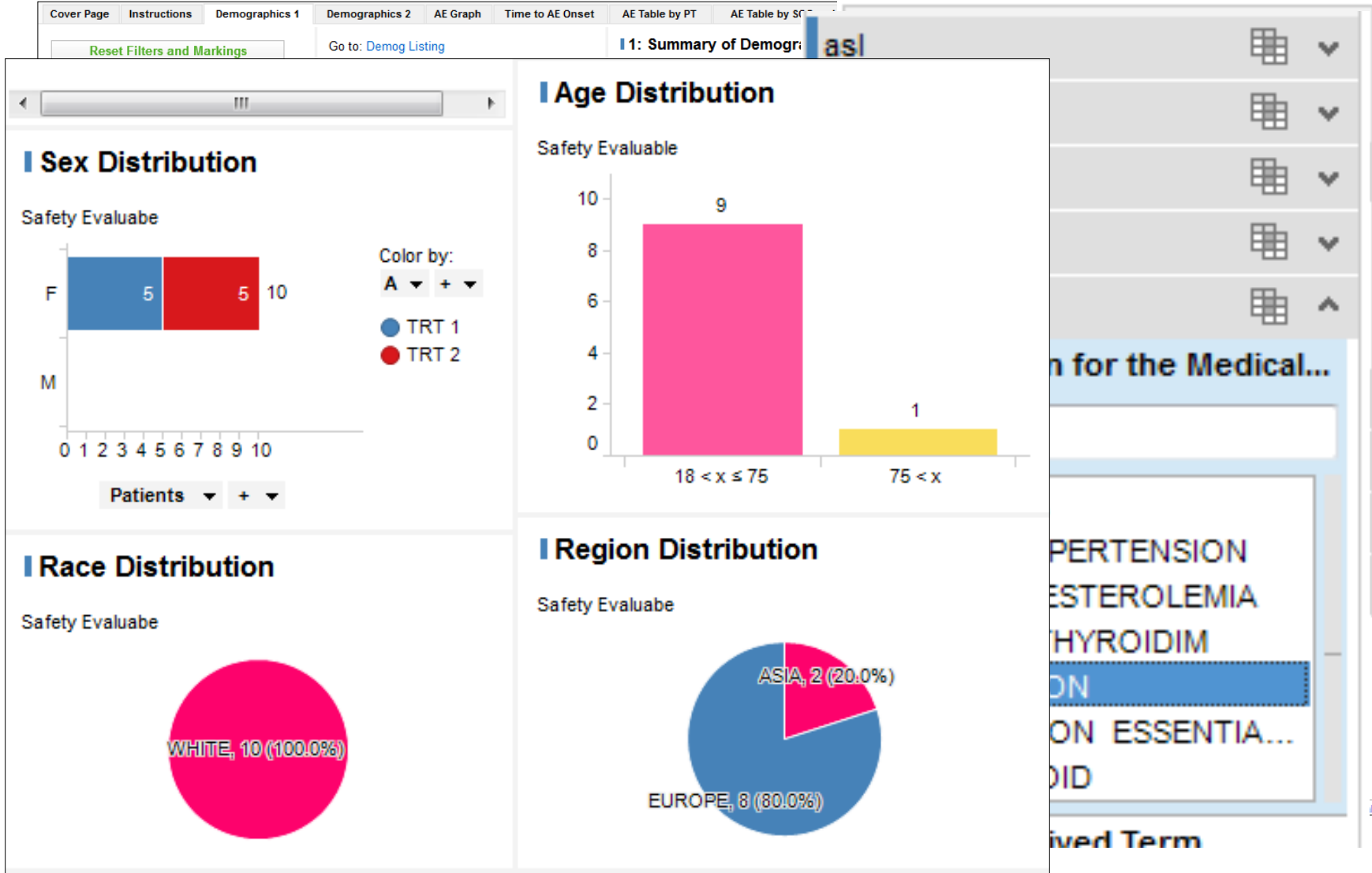
2: Listing of Demographics (Marked)

Actual Treatment for Subject ID Age Binned Age Sex Race Ethnicity Baseline Weight Baseline Height Baseline Temp Baseline Body Mass Index Country

Demographics 1 – Filter Panel



Demographics 1 – Female Pts with Hypertension



Demographics 1 – Summary Tables

Demo_Categ...	Value	TRT 1		TRT 2		Grand total of n	Grand total of Percent
		n	Percent	n	Percent		
Age Group	Subtotal	5	7.2%	5	6.3%	10	6.7%
	18 < x ≤ 75	4	5.8%	5	6.3%	9	6.0%
	75 < x	1	1.4%	---	---	1	0.7%
Sex	Subtotal	5	7.2%	5	6.3%	10	6.7%
	F	5	7.2%	5	6.3%	10	6.7%
Race	Subtotal	5	7.2%	5	6.3%	10	6.7%
	WHITE	5	7.2%	5	6.3%	10	6.7%
Ethnicity	Subtotal	5	7.2%	5	6.3%	10	6.7%
	NOT HISPANIC ...	5	7.2%	5	6.3%	10	6.7%
Region	Subtotal	5	7.2%	5	6.3%	10	6.7%
	ASIA	---	---	2	2.5%	2	1.3%
	EUROPE	5	7.2%	3	3.8%	8	5.4%
Patient Discontinued Study	Subtotal	5	7.2%	5	6.3%	10	6.7%
	N	5	7.2%	3	3.8%	8	5.4%
	Y	---	---	2	2.5%	2	1.3%
Patient Discontinued Treatment	Subtotal	5	7.2%	5	6.3%	10	6.7%
		5	7.2%	5	6.3%	10	6.7%

Lab Summary (Chg I)

Filters

Type to search filters

asl

aee

acm

alb

amh

Reported Term for the Medical...

Hyper

(All) 91 values

ARTERIAL HYPERTENSION

HYPERCHOLESTEROLEMIA

HYPERPARATHYROIDISM

HYPERTENSION

HYPERTENSION ESSENTIA...

HYPERTHYROID

Dictionary-Derived Term

Type to search in list

(All) 1 values

HYPERTENSION

Body System or Organ Class

Type to search in list

(All) 1 values

VASCULAR DISORDERS

Demographics 1 – Percentage Calculation

Demographics 1								
Demographics 2								
AE Graph								
Time to AE Onset								
AE Table by PT								
AE Table by SOC and PT								
AE Table by Highest Grade								
Patient Profile								
Lab By-Patient Plot								
Lab Summary								
Lab Summary (Chg)								
Demo_Categ...	Value	TRT 1		TRT 2		Grand total of n	Grand total of Percent	
		n	Percent	n	Percent			
Age Group	Subtotal	5	100.0%	5	100.0%	10	100.0%	
	18 < x ≤ 75	4	80.0%	5	100.0%	9	90.0%	
	75 < x	1	20.0%	---	---	1	10.0%	
Sex	Subtotal	5	100.0%	5	100.0%	10	100.0%	
	F	5	100.0%	5	100.0%	10	100.0%	
Race	Subtotal	5	100.0%	5	100.0%	10	100.0%	

Filters
Type to search filters
asl
aee
acm
alb
amh
Reported Term for the Medical...
Hyper
(All) 91 values
ARTERIAL HYPERTENSION
HYPERCHOLESTEROLEMIA
HYPERPARATHYROIDISM
HYPERTENSION
HYPERTENSION ESSENTIA...
HYPERTHYROID
Dictionary-Derived Term
Type to search in list

Region	Subtotal	5	100.0%	5	100.0%	10	100.0%
	ASIA	---	---	2	40.0%	2	20.0%
	EUROPE	5	100.0%	3	60.0%	8	80.0%

12: Listing

Actual Treatment

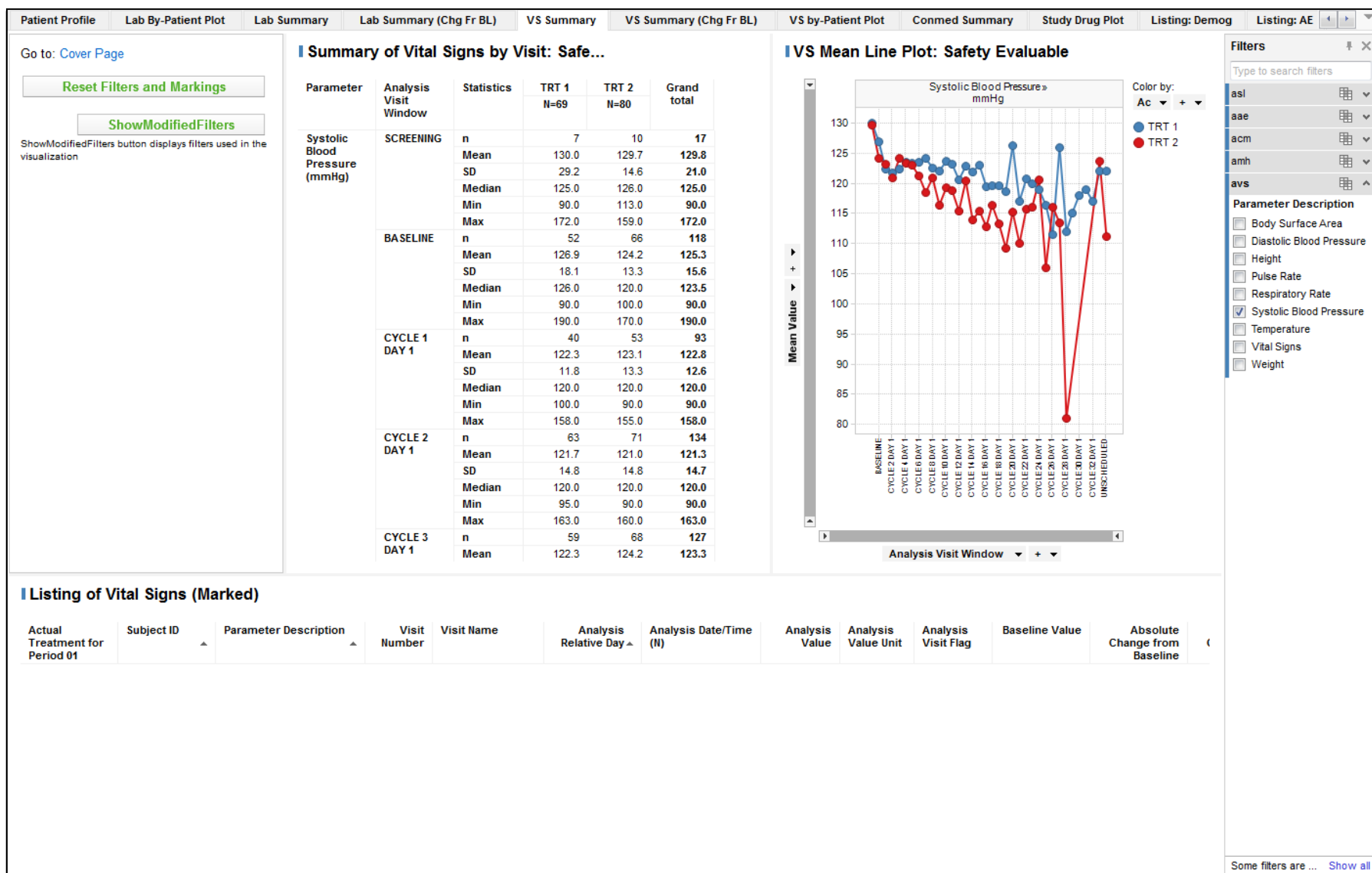
Patient Discontinued Study	Subtotal	5	100.0%	5	100.0%	10	100.0%
	N	5	100.0%	3	60.0%	8	80.0%
	Y	---	---	2	40.0%	2	20.0%
	Subtotal	5	100.0%	5	100.0%	10	100.0%
Patient Discontinued Treatment		5	100.0%	5	100.0%	10	100.0%

Vital Signs – ShowModifiedFilters

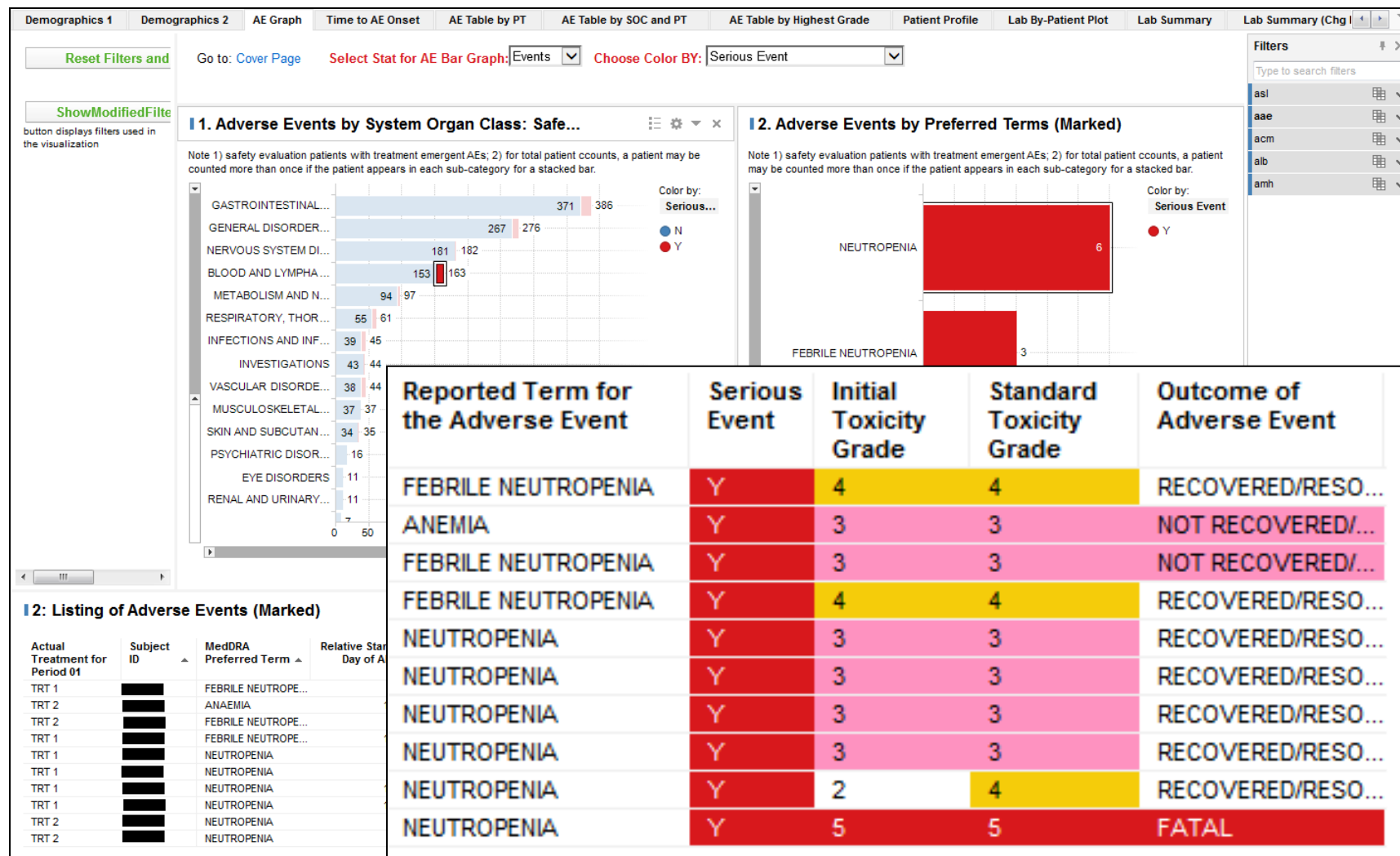
IVS Mean Line Plot: Safety Evaluable

Patient Profile Lab By-Patient Plot Lab Sur					
Summary of Vital Signs by Visit: Safe...					
Parameter	Analysis Visit Window	Statistics	TRT 1	TRT 2	Grand total
			N=69	N=80	
Systolic Blood Pressure (mmHg)	SCREENING	n	7	10	17
		Mean	130.0	129.7	129.8
		SD	29.2	14.6	21.0
		Median	125.0	126.0	125.0
		Min	90.0	113.0	90.0
		Max	172.0	159.0	172.0
	BASELINE	n	52	66	118
		Mean	126.9	124.2	125.3
		SD	18.1	13.3	15.6
		Median	126.0	120.0	123.5
		Min	90.0	100.0	90.0
		Max	190.0	170.0	190.0
	CYCLE 1 DAY 1	n	40	53	93
		Mean	122.3	123.1	122.8
		SD	11.8	13.3	12.6
		Median	120.0	120.0	120.0
		Min	100.0	90.0	90.0
		Max	158.0	155.0	158.0

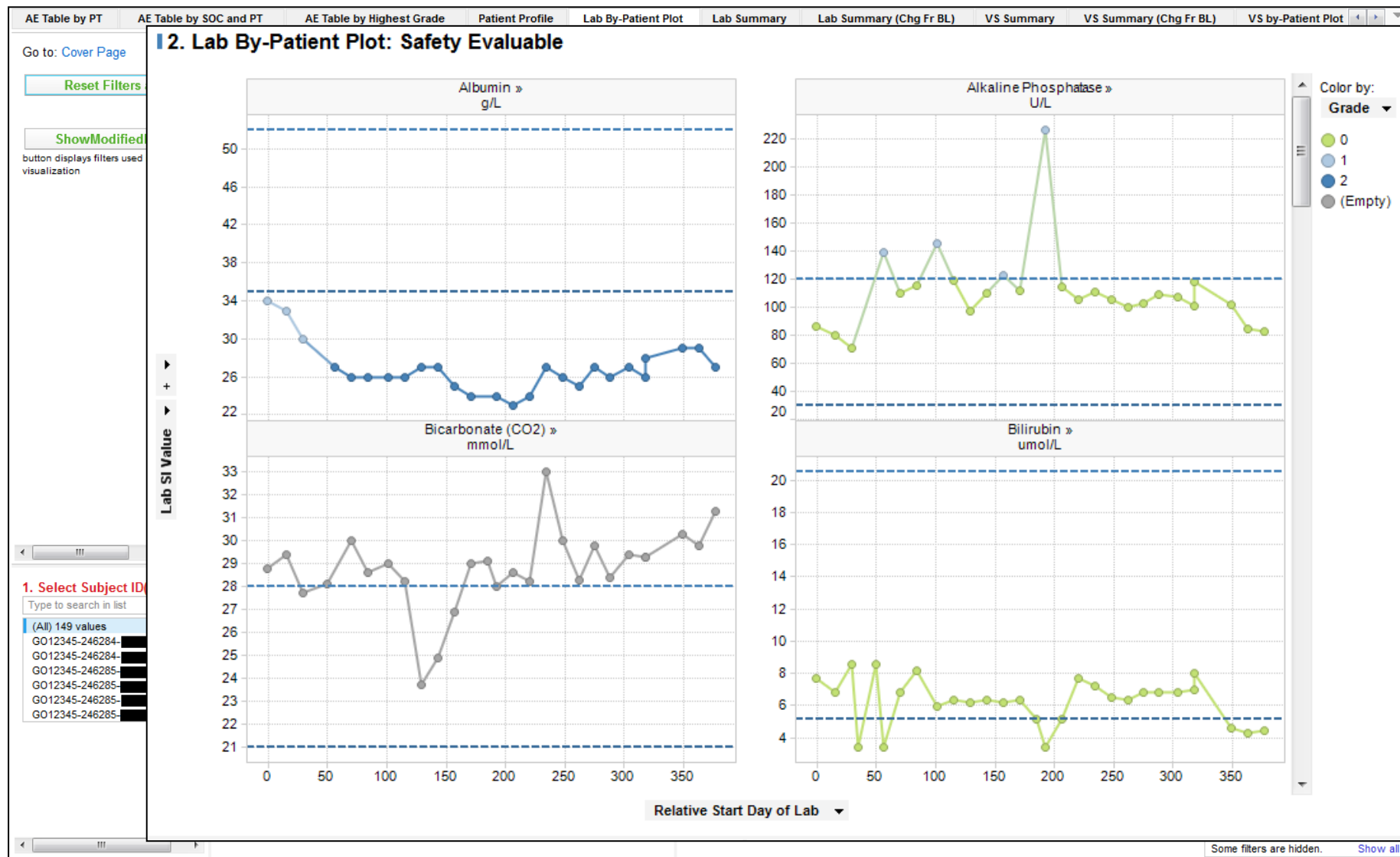
Vital Signs – Reset Filters and Markings



Adverse Events – Bar Charts

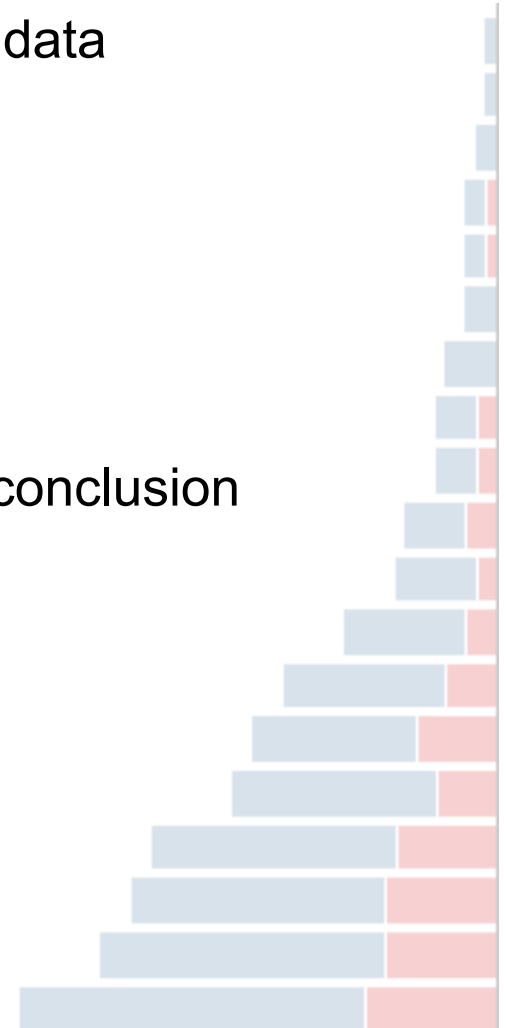


Laboratory – Spaghetti Plots / Patient Plot



Feedback from Stakeholders

- Easy for Statistical Programmers to upload study data
- Consistent with Clinical Study Report Outputs
- Better insight to data
- Request for official outputs can be more specific
- Concern of Safety Scientists to come to a wrong conclusion
- More time needed for Safety Scientists





**Any
Question
s ???**

***Doing now what patients need
next***

Open CoreSV – Table of Contents

Cover

Pr

Rep

Extra

Clini

Data

Stud

Crea

Spot

DIS

This

revis

if re

Table of Contents

Safety Data Domain	Summary Tables/Plots	Listings / By-Patient Plots
Demographics	Demographics 1 (Discrete) Demographics 2 (Continuous)	Listing: Demog
AE	AE Graph Time to AE Onset AE Table by PT AE Table by SOC and PT AE Table by Highest Grade	Listing: AE
Patient Profile	Patient Profile	
Lab	Lab Summary Lab Summary (Chg Fr BL)	Lab By-Patient Plot Listing: Lab Tests
Vital Sign	VS Summary VS Summary (Chg Fr BL)	VS By-patient Plot Listing: VS
Study Drug		Study Drug by-Patient Plot Listing: Dose Exposure
Concomitant Medication	Conmed Summary	Listing: Conmed
Medical History		Listing: Medical History

Population_Category	Population	TRT 1	TRT 2	Grand total
Intent-To-Treat Population Flag	Y	69	81	150
Safety Population Flag	N	---	1	1
	Y	69	80	149