



Standardization and Visualization of TFL in Safety Review

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Outline

- Safety Review
- Spotfire Intro
- Standardization
- Summary
- Q&A

Safety Review

- We always
 - Generate TFL by SAS
 - Production in txt/rtf/doc/xls format
- We may try
 - New tool - Spotfire

Spotfire Intro

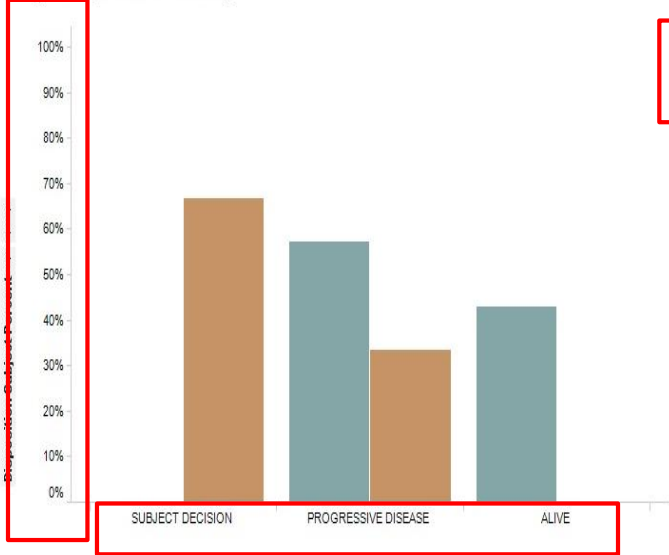
- Feature
 - Visualization
 - Interactivity
- Application in Pharma
 - safety review, clinical operations, market analysis, etc.

Spotfire Intro - Application

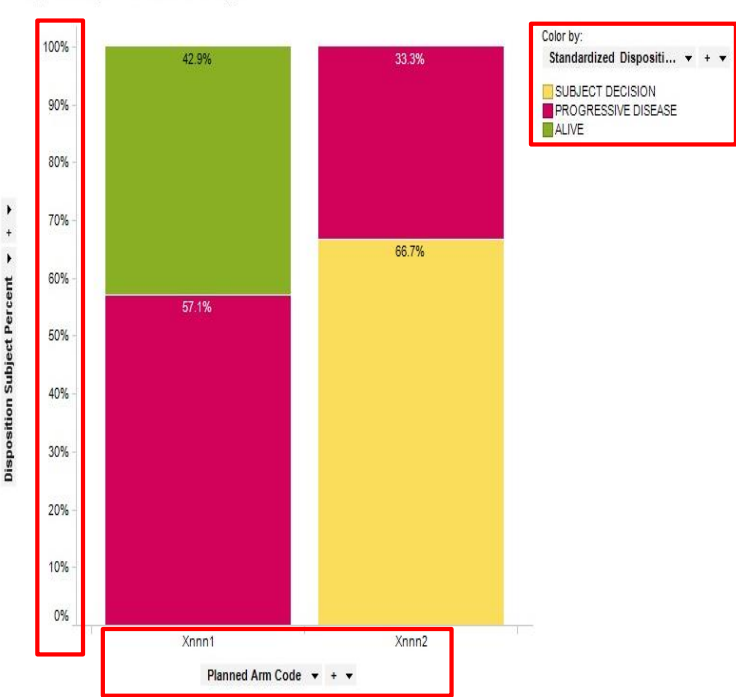
- TLSR - Trial Level Safety Review
- The goal of the Trial Level Safety Review (TLSR) process is to monitor and assess safety data collected during the conduct of a specific study.
- For example
 - Subject Disposition
 - AE Summary

Spotfire Intro - Demo

Subject Disposition Percentage



Subject Disposition Percentage

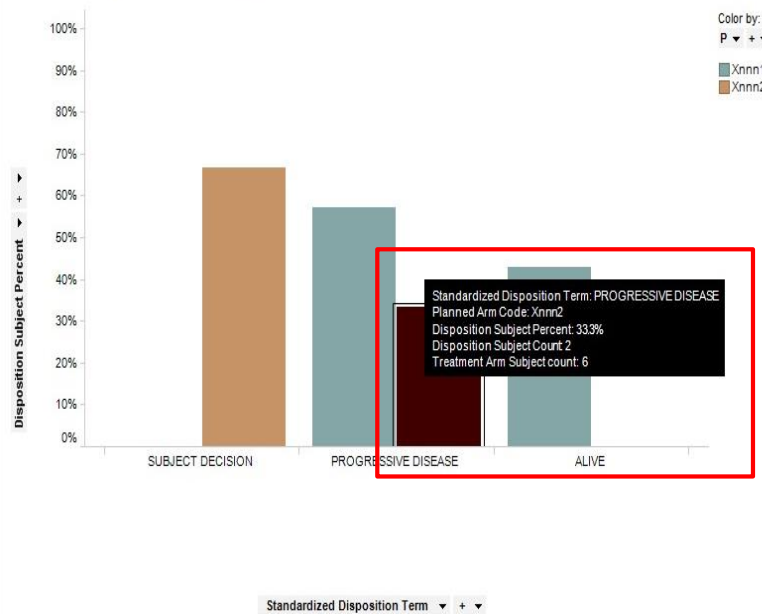


Link to Patient Profile (Highlight Patient Record)

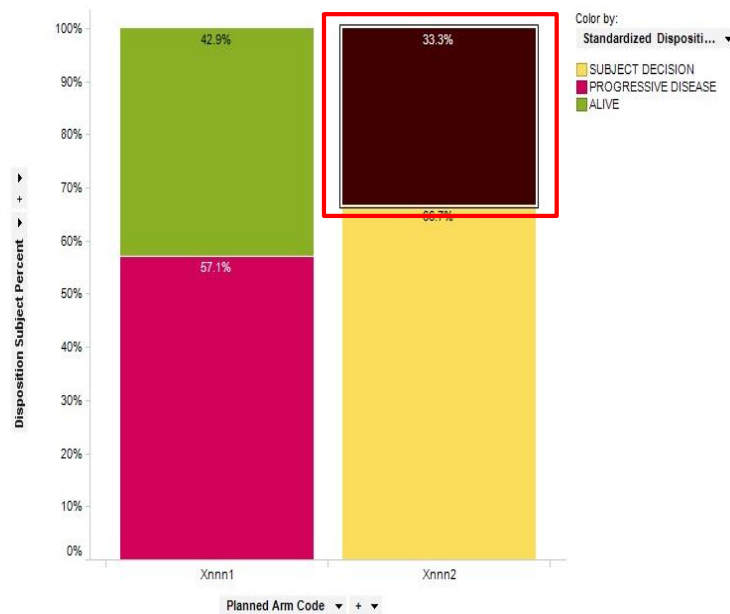
Study Identifier	Unique Subject Identifier	Description of Planned Arm	Sex	Race	Age	Standardized Disposition Term	Study Day of Start of Disposition Event	Start Date/Time of Disposition Event
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Spotfire Intro - Demo

Subject Disposition Percentage



Subject Disposition Percentage



[Link to Patient Profile \(Highlight Patient Record\)](#)

Study Identifier	Unique Subject Identifier	Description of Planned Arm	Sex	Race	Age	Standardized Disposition Term	Study Day of Start of Disposition Event	Start Date/Time of Disposition Event
XnnXnnXnnXXX1	XnnXnnXnnXXXXnnnnnnnn12	XXXXXnnXnnXnnnnxxnnX2	F	XXXX1	63	PROGRESSIVE DISEASE	37	2274-08-23
XnnXnnXnnXXX1	XnnXnnXnnXXXXnnnnnnnn14	XXXXXnnXnnXnnnnxxnnX2	F	XXXX2	83	PROGRESSIVE DISEASE	43	2274-12-07

Spotfire Intro - Demo

PTs within SOC



Link to Patient Profile (Highlight Patient Record)

Subject Identifier for the Study	Unique Subject Identifier	Age	Sex	Race	Planned Arm Code	Description of Planned Arm	Sequence Number	Group ID	Sponsor-Defined	Reported Term for the	Lowest Level Term	Dictionary-Derived Term
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12/5/2014

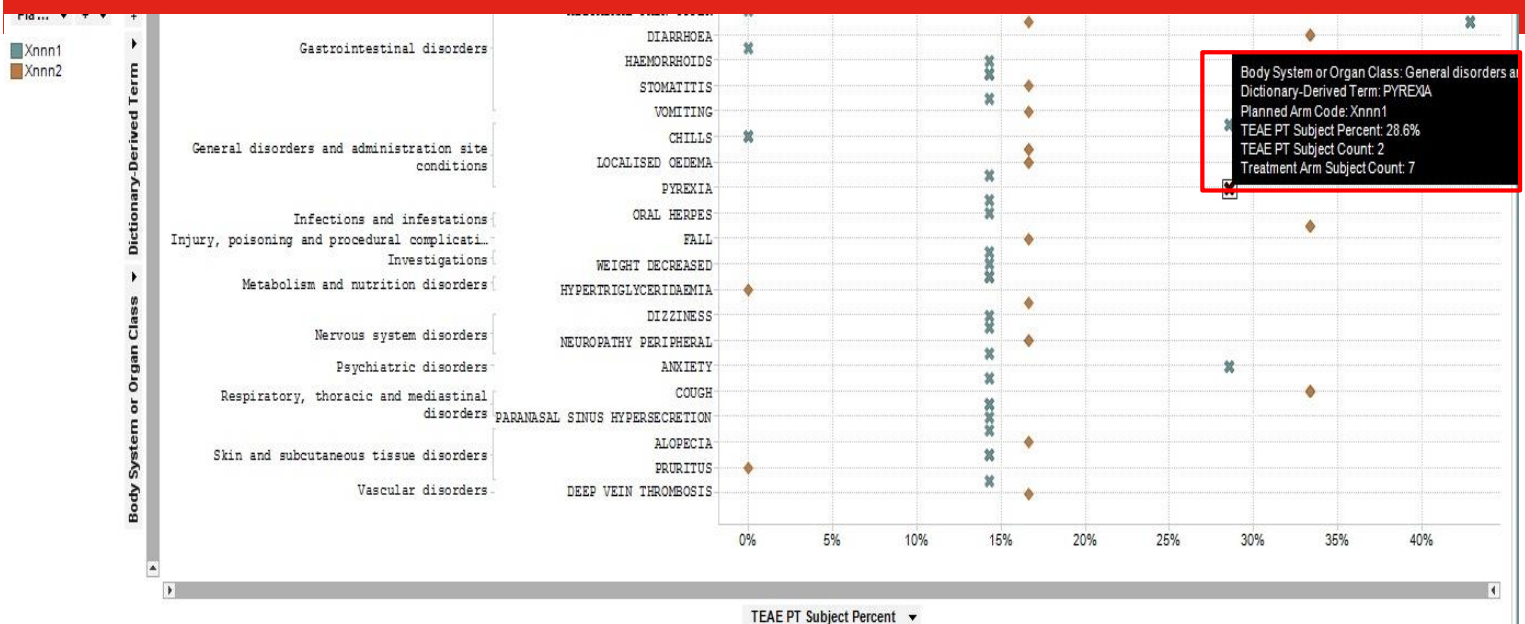
Company Confidential ©2014 Eli Lilly and Company

8

Spotfire Intro - Demo



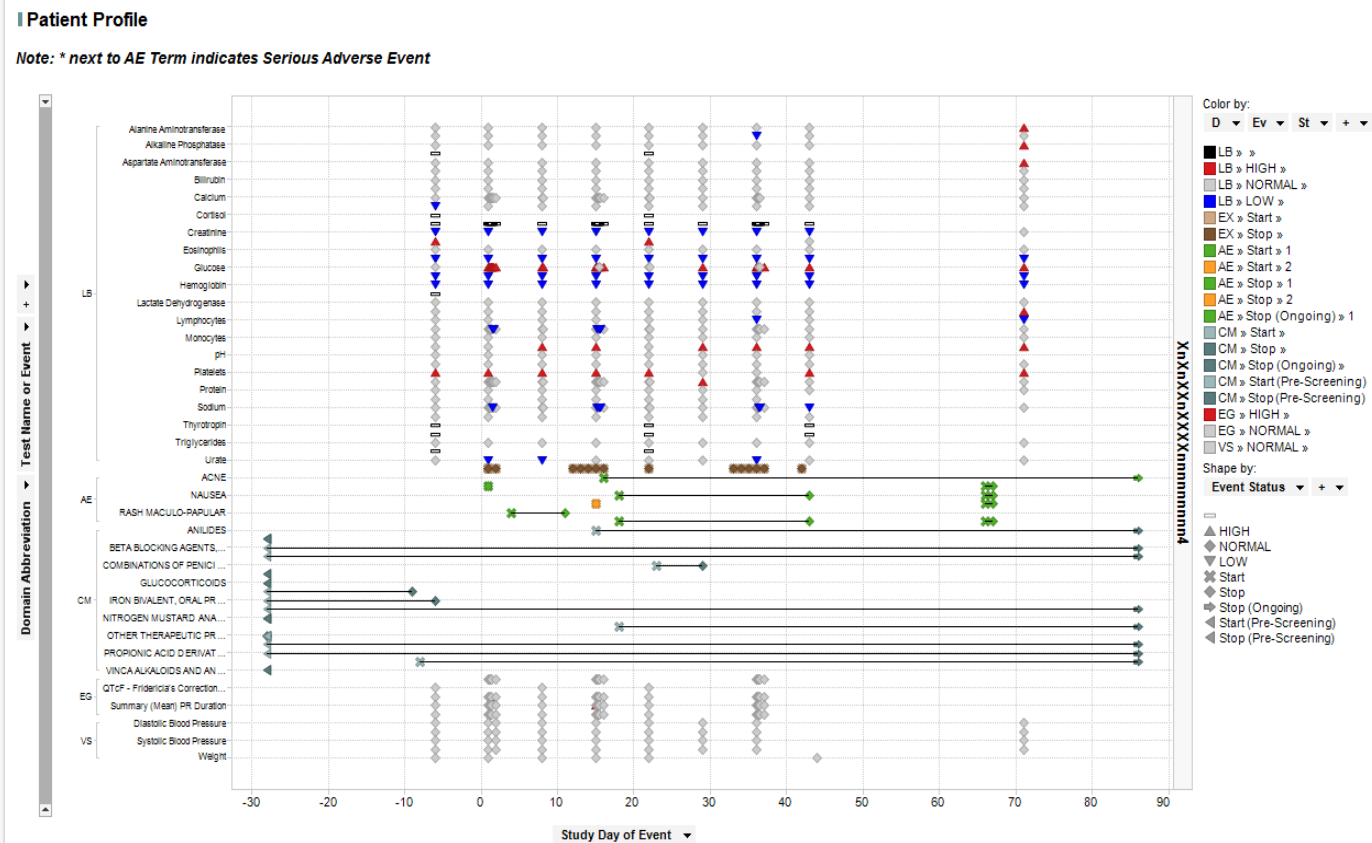
Spotfire Intro - Demo



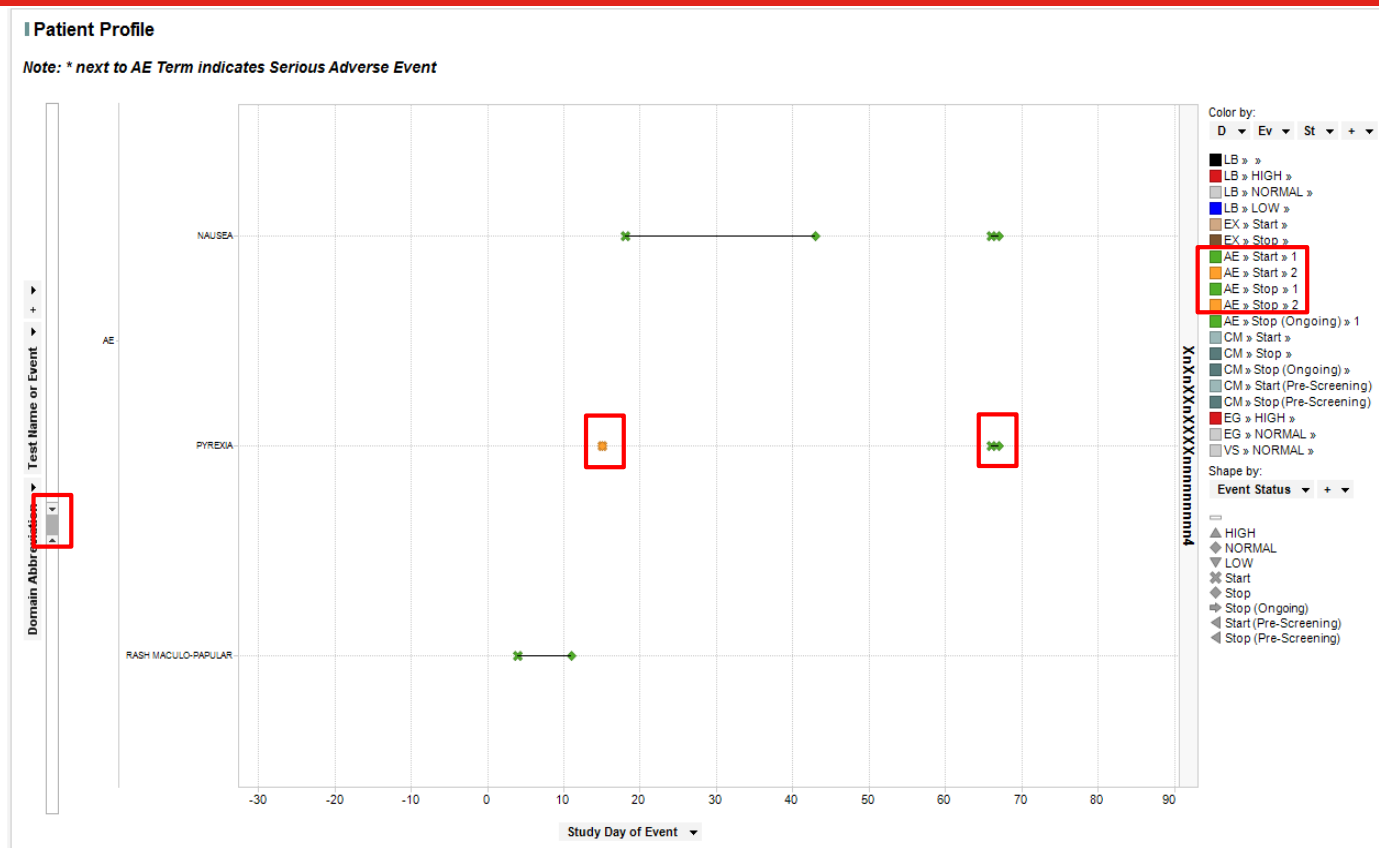
Link to Patient Profile (Highlight Patient Record)

Subject Identifier for the Study	Unique Subject Identifier	Age	Sex	Race	Planned Arm Code	Description of Planned Arm	Sequence Number	Group ID	Sponsor-Defined	Reported Term for the	Lowest Level Term	Dictionary-Derived Term	Preferred Term Code
nnnn4	XnXnXXnXXXXnnnnnnnn4	46	M	XXXX2	Xnnn1	XXXXXXnXnnXX...	3	11	1	FEVER	Fever	PYREXIA	100376
nnnn4	XnXnXXnXXXXnnnnnnnn4	46	M	XXXX2	Xnnn1	XXXXXXnXnnXX...	8	17	1	FEVER	Fever	PYREXIA	100376
nnnn5	XnXnXXnXXXXnnnnnnnn5	60	F	XXXXXX XXXXXXX	Xnnn1	XXXXXXnXnnXX...	6	15	1	FEVER	Fever	PYREXIA	100376

Spotfire Intro - Demo



Spotfire Intro - Demo



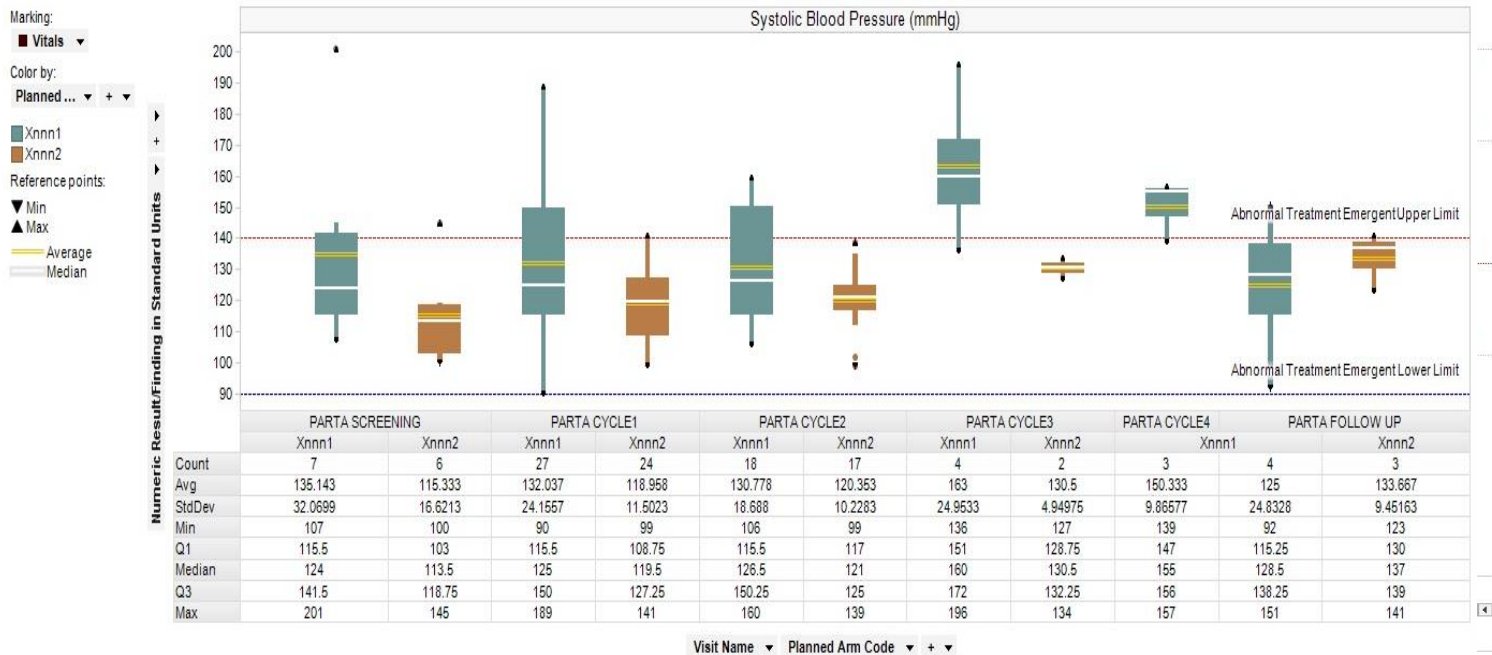
Spotfire Intro - Demo

Box Plot by Vital Sign Test Over Time

Patient ECG Results over Time

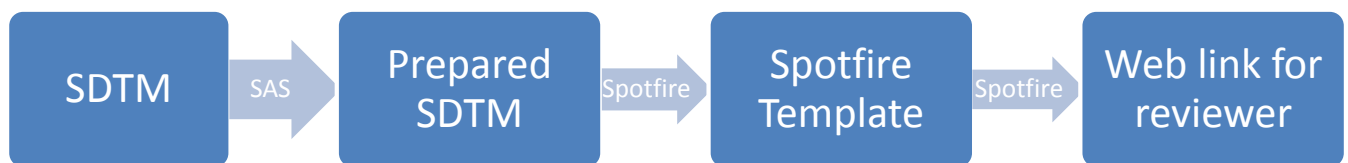
Magnify Visual. Zoom

Box Plot by Vital Sign Test Over Visit



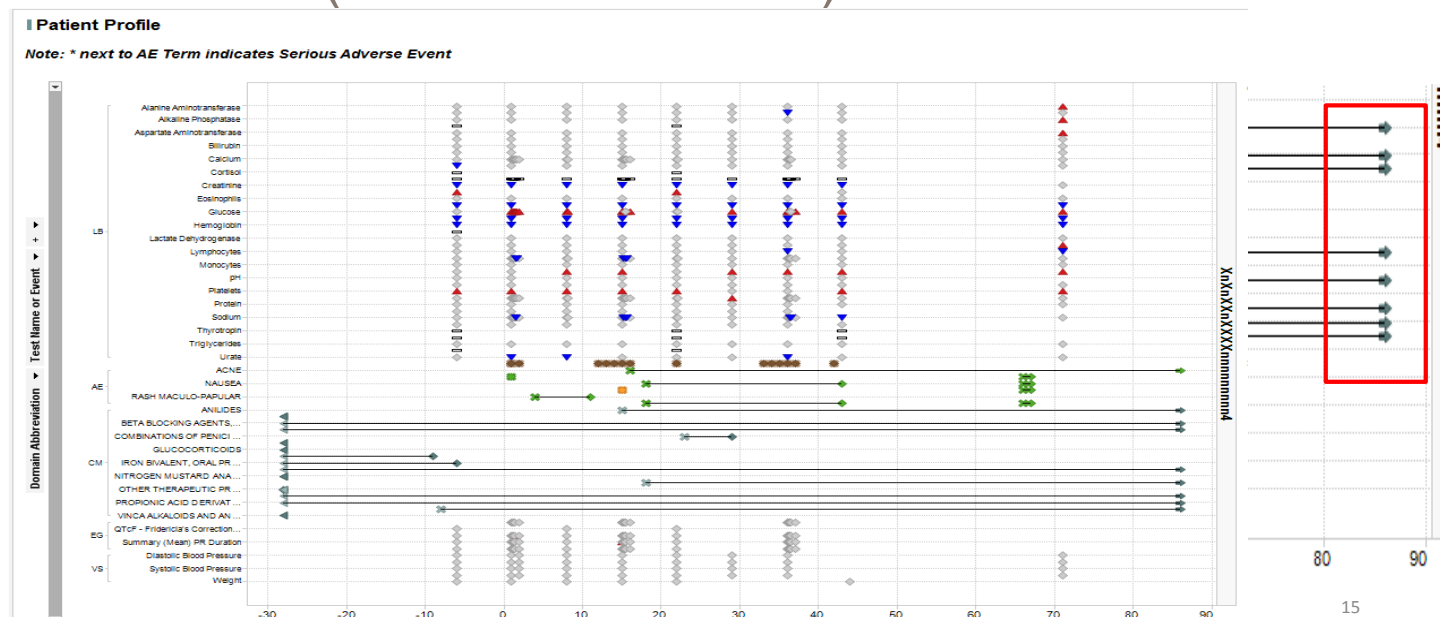
Standardization

- Standard Data(e.g. SDTM) + SAS codes + Spotfire Template
- SD/AE/CM/ECG/VS/LB/EX/PP



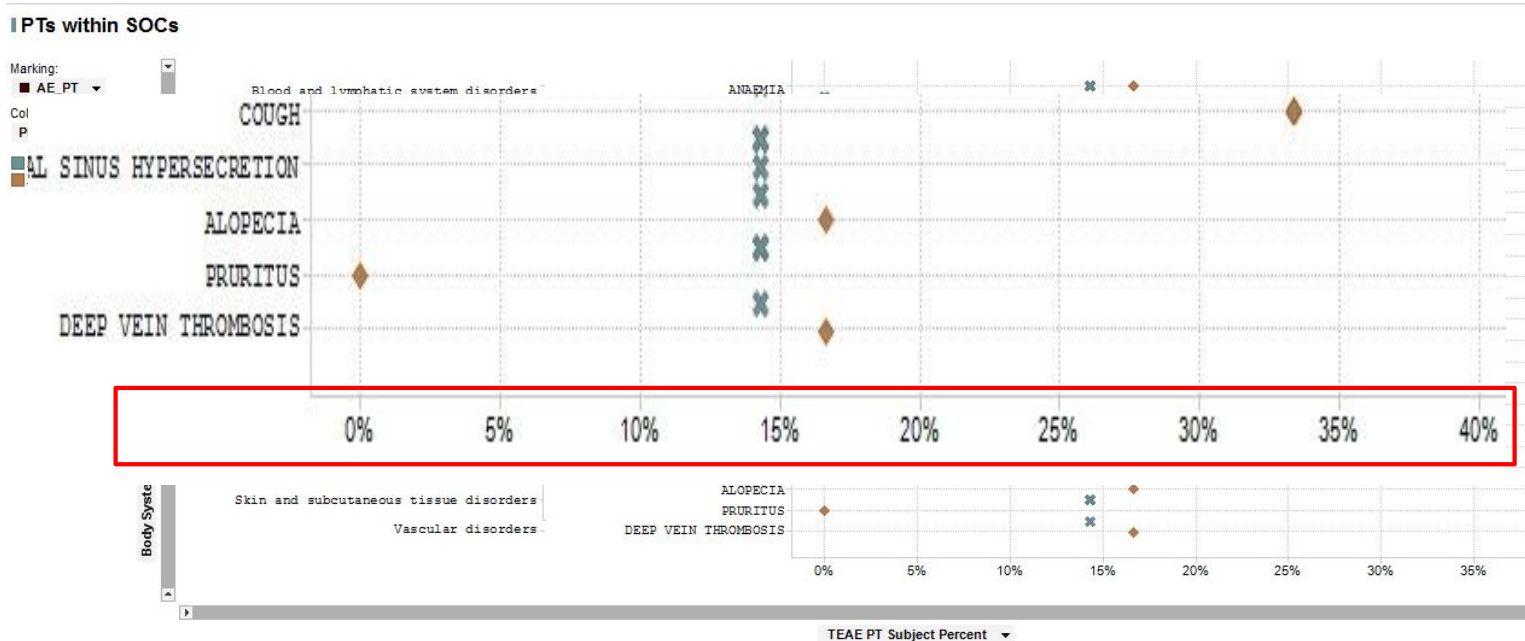
Standardization

- From SDTM to Prepared SDTM
 - specify a cut-off Study End Day for Ongoing Events (i.e. Last Visit Date)



Standardization

- From SDTM to Prepared SDTM
 - Calculate the percentage



Summary

- Visualization
 - Spotfire
 - JMP
 - Excel with VBA
- Standardization
 - Follow CDISC standards

EFFICIENCY

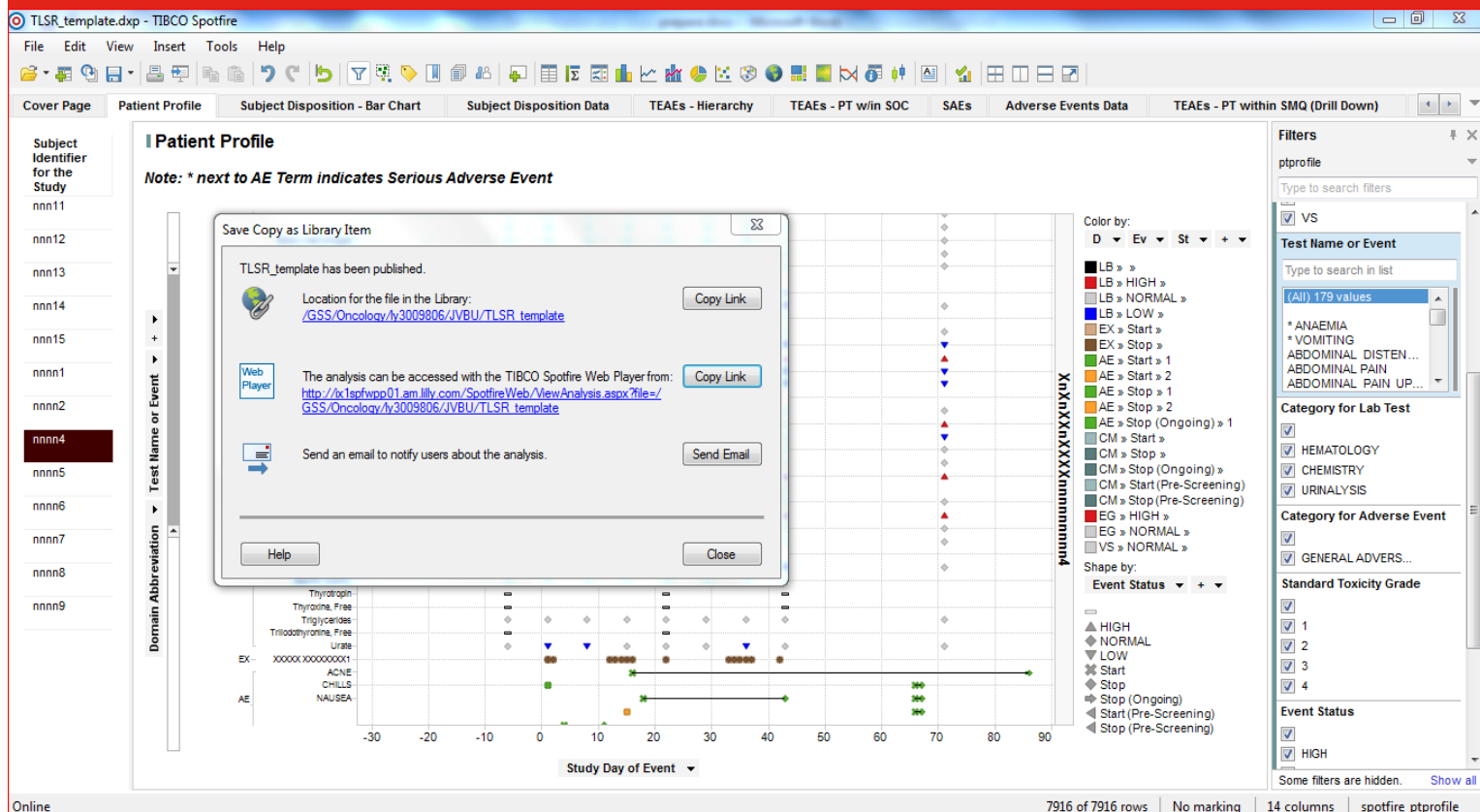
Acknowledge

- Yanping Wang
- Lucia Han
- Ying Lou

Q&A

- Thanks for listening!

Backup Slides



Backup Slides

TLSR_template_test.dxp - TIBCO Spotfire

File Edit View Insert Tools Help

Header Cover Page Patient Profile Subject Disposition - Bar Chart Subject Disposition Data TEAEs - Hierarchy TEAEs - PT w/in SOC SAEs Adverse Events Data TEAEs - PT within SMQ (Drill Down) Adverse Events (SMQ) Data

LYnnnnnnn XXX-YY-ABCD

TLSR Visualizations - Dose Design X - Data Transfer Date: DD-MMM-YYYY

Patient Profile	Patient Profile
Subject Disposition	Bar Chart of Subject Disposition
Subject Disposition Data	Data Table of Subject Disposition
TEAEs Hierarchy	Bar Chart of Treatment Emergent AEs at Different MedDRA Hierarchy Levels (Filtering)
TEAEs - PT w/in SOC	Scatter Plot of Treatment Emergent Preferred Terms Nested within SOC (Filtering)
SAEs	Scatter Plot of Serious Adverse Events in Preferred Terms (Filtering)
Adverse Events Data	Data Table of Adverse Events
SMQ / PT (Drill Down)	Scatter Plot of Treatment Emergent Preferred Terms Nested within SMQ (Drill Down)
AE_SMQ Data	Data Table of Adverse Events with SMQ (One Record Per SMQ)
ConMeds	Scatterplot of Concurrent Medications
ConMed Data	Data Table of Concurrent Medications
Labs Boxplot - CN	Box Plot of each Lab Test (CN Units) over Visit, by Treatment Arm
Labs Boxplot (Conservative Ref) - CN	Box Plot of each Lab Test (CN Units) over Visit (Conservative Reference Ranges)
Labs Boxplot - SI	Box Plot of each Lab Test (SI Units) over Visit, by Treatment Arm
Labs Boxplot (Conservative Ref) - SI	Box Plot of each Lab Test (SI Units) over Visit (Conservative Reference Ranges)

Online No active visualization

Backup Slides

standard_visuals_template.dxp - TIBCO Spotfire									
File Edit View Insert Tools Help									
Header Cover Page Patient Summary AEs over Time Summary of AEs Adverse Events Data ConMeds over Time Summary of ConMe									
Summary of AEs (Number of Patients with at least one occurrence), by CTC Grade									
Dictionary-Derived Term	Standard Toxicity Grade						Grand total		
	1	2	3	4	5				
	HYPERTENSION	13	5	---	---	---			17
	FATIGUE	13	5	---	---	---			16
	NAUSEA	9	7	---	---	---			14
	DIARRHOEA	8	7	---	---	---			13
	ANAEMIA	6	8	1	---	---			12
	MUCOSAL INFLAMMATION	4	6	5	1	1			12
	CONSTIPATION	7	3	---	---	---			10
	GASTROESOPHAGEAL REFLUX DISEASE	7	3	---	---	---			10
	INSOMNIA	8	2	---	---	---			10
	ANXIETY	9	---	---	---	---			9
	NEUROPATHY PERIPHERAL	6	1	---	---	---			7
	NEUTROPENIA	---	3	3	1	---			7
	ALOPECIA	4	2	---	---	---			6
	ARTHRALGIA	3	3	---	---	---			6
	DEPRESSION	5	1	---	---	---			6
	DYSPNOEA	5	2	1	---	---			6
	HEADACHE	5	1	---	---	---			6
	STOMATITIS	3	2	2	---	---			6
		3	3	---	---	---			5
	BONE PAIN	4	2	---	---	---			5
	PAIN	3	1	1	---	---			5
	BACK PAIN	2	2	---	---	---			4
	COUGH	3	1	---	---	---			4
	DECREASED APPETITE	4	1	---	---	---			4
	DEHYDRATION	---	3	1	---	---			4
	DERMATITIS ACNEIFORM	2	2	---	---	---			4
	DIABETES MELLITUS	1	3	---	---	---			4
UniqueCount(Subject Identifier for the Study)									
Details-on-Demand									
Unique Subject Identifier	Subject Identifier for	Description of Planned Arm	Sex	Race	Age in AGEU at RFSTDC	Visit Name	Visit Number	Planned Study Day of Visit	
XnXnXXnXXXXn...	nn12	XXnnXXnnnnnnnn... XXXXXXXXX1	M	XXXX2	67	CYCLE1	101.00	1.00	
XnXnXXnXXXXn...	nn15	XXnnXXnnnnnnnn... XXXXXXXXX1	M	XXXX2	66	CYCLE2	102.00	22.00	
XnXnXXnXXXXn...	nn18	XXnnXXnnnnnnnn... XXXXXXXX1	M	XXXX2	61	CYCLE1	101.00	1.00	

Backup Slides

- Professor Hans Rosling's [YouTube](#) video.

