

The Implementation of Spotfire in Clinical Trials to Review Safety and Patient Reported Outcome Data

Jingyuan Chen & Wenyi Liu

Hoffmann-La Roche

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Disclaimer

- This talk represents personal experience in our daily work.
- We have no financial relationships to the software company.

Overview

- Why interactive analysis and data visualization?
- Introduction to Spotfire
- Roche's implementation of Spotfire
 - Data review/cleaning
 - Patient Report Outcomes
 - Safety Data Review
- Understanding Pros and Cons of Spotfire

- ### (Row Count) per Race

Data table: m_astl

Color by: Race

 - ASIAN
 - OTHER
 - WHITE

Sector size by: (Row Count)

Histogram – Baseline Age

Color by: All values

Analysis Value – Visit Name

Data linking: Expression

Data table: Lab

Line by: (None)

Color by: (None)

All values

Row Count per MedDRA Preferred Term

NAUSEA	DIARRHOEA	MUCOSAL INFLAMMATORY	CONSTRICTION	THROMBOCYTOPENIA	FATIGUE	ANAEMIA	DYSGEUSIA
		STOMATITIS	OEDEMA	ABDOMINAL DISTENSION	HYPONATREMIA	DRY MOUTH	EPISTAXIS
		ABDOMINAL PAIN	HYPERDIPHTHERIA	OCULONASAL DISCHARGE	HYPERINFLATION	PERIPHERAL ALBURNIA	ALANINAMINOTRANSFERASE
		NOCTURNAL URINATION	COUGH	HYPOCALCAEMIA	ARTHRALGIA	ASCITIS	
		DECREASED APPETITE					
		VOMITING					

Data table: Adverse Event

Color by: (Row Count)

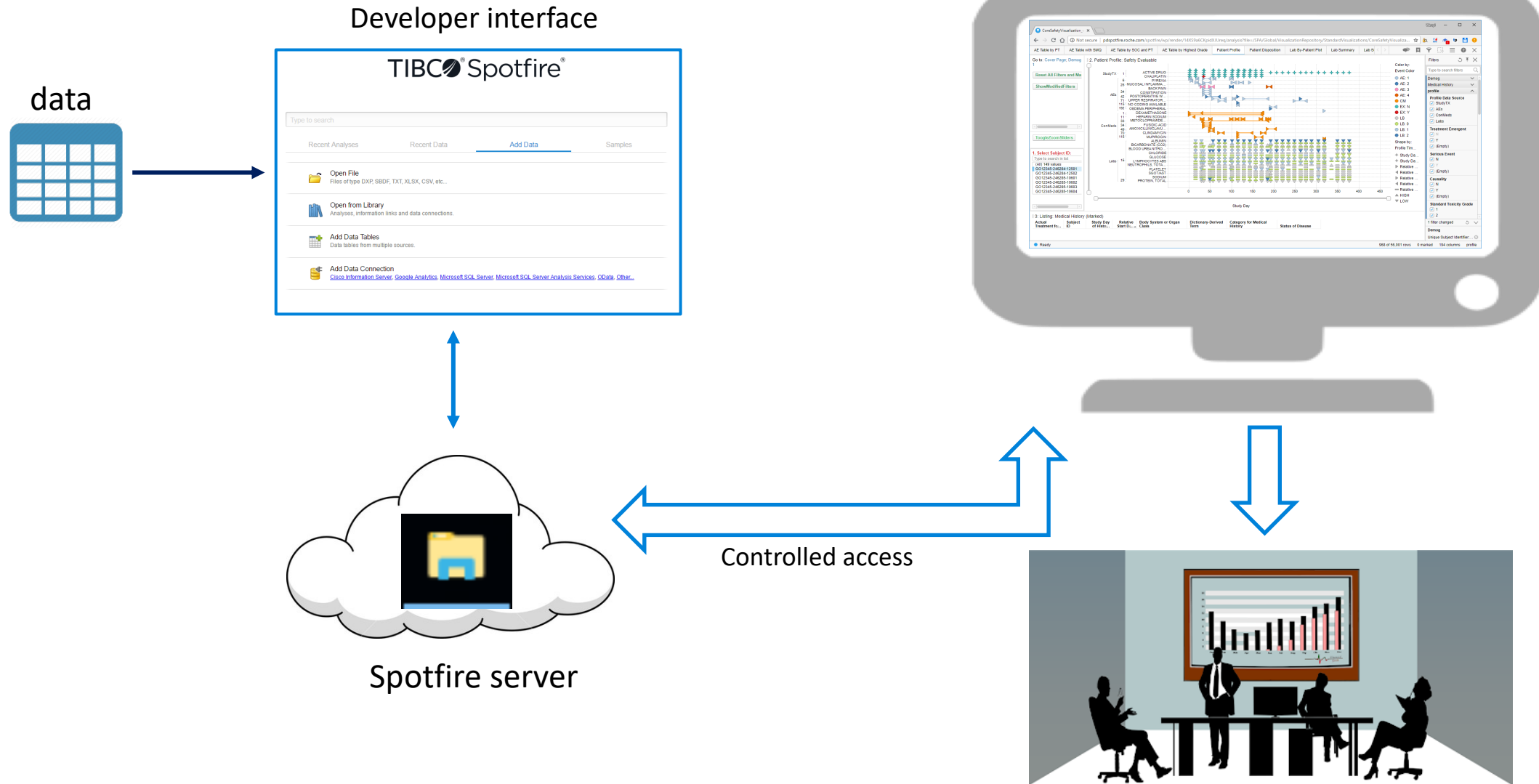
Size by: (Row Count)

Hierarchy: MedDRA P...

Introduction to Spotfire

- What is Spotfire?
 - A TIBCO product (<https://spotfire.tibco.com/>)
 - A platform to create data visualization
- Spotfire features
 - Compatible to various databases
 - Interactive and dynamic
 - Can do data manipulation and aggregate summary
 - Controlled access
 - Advanced use with IronPython and R

Introduction to Spotfire

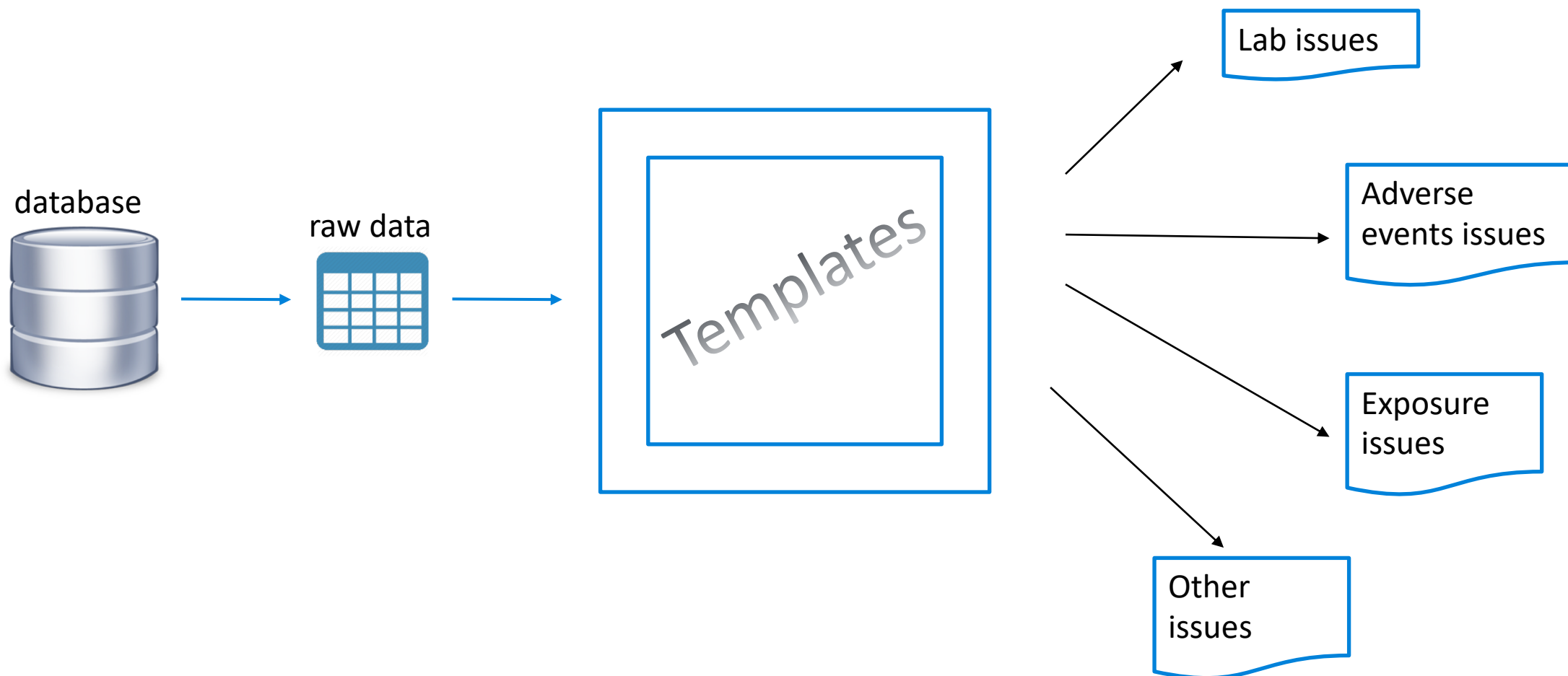


Roche's Implementation of Spotfire

- Data review and cleaning
- Patient Report Outcomes data review
- Safety Data Review
- Exploratory Analysis
- Administrative tools

Roche's Implementation of Spotfire ----

Data review and cleaning



Roche's Implementation of Spotfire ----

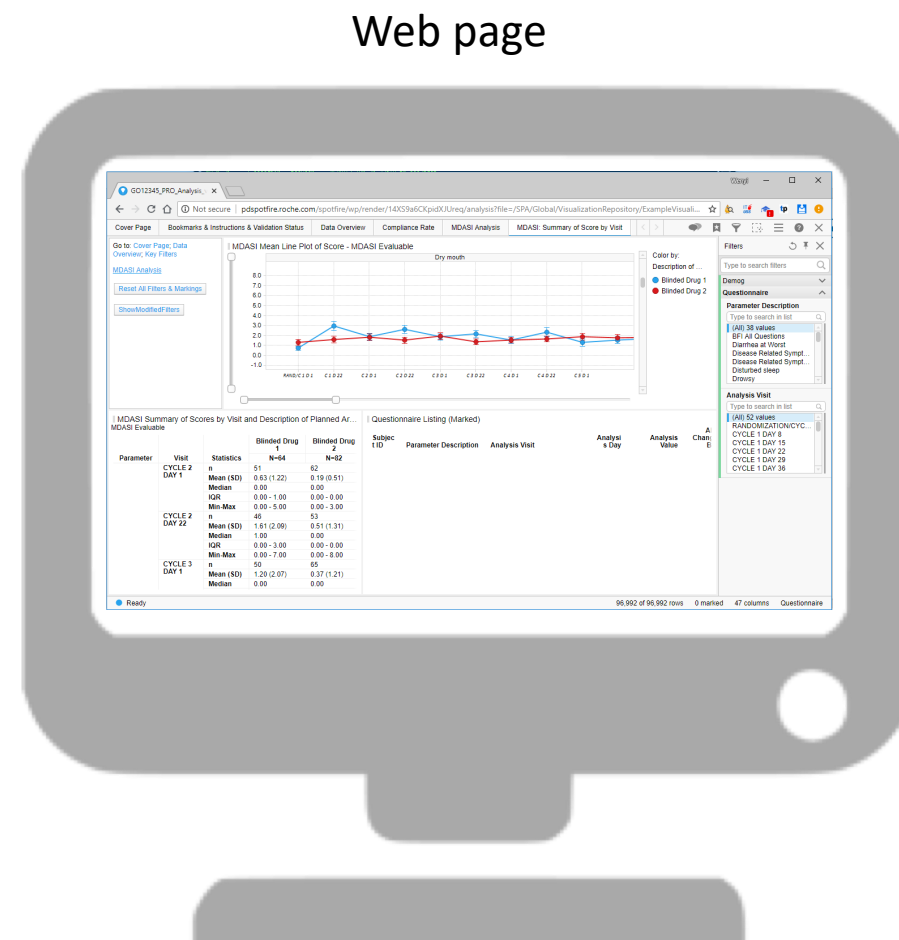
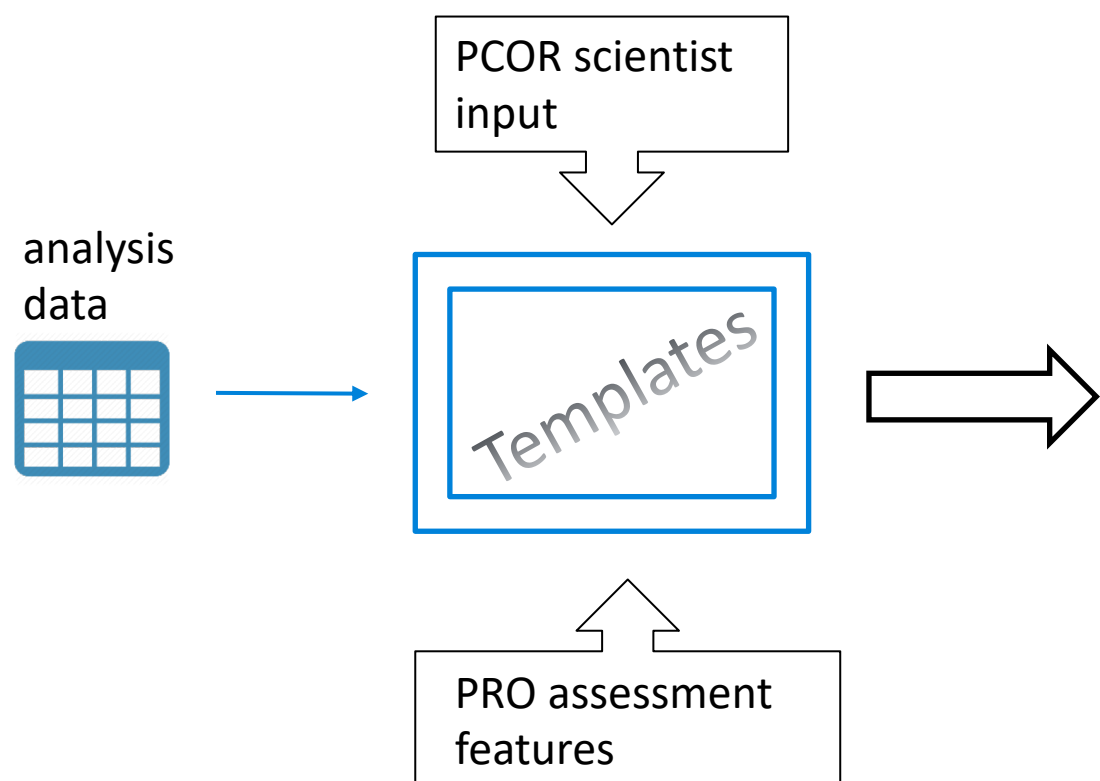
Patient Report Outcomes data review

- What is Patient Report Outcome (PRO) data?
 - Report directly from patients
 - To describe patient's experience on treatment
- Examples of PRO assessment
 - EORTC QLQ-C30
 - The Alzheimer's Questionnaire

Do you have any trouble taking a long walk?

**Does the patient repeat questions OR statements
OR stories in the same day?**

Roche's Implementation of Spotfire ---- Patient Report Outcomes data review

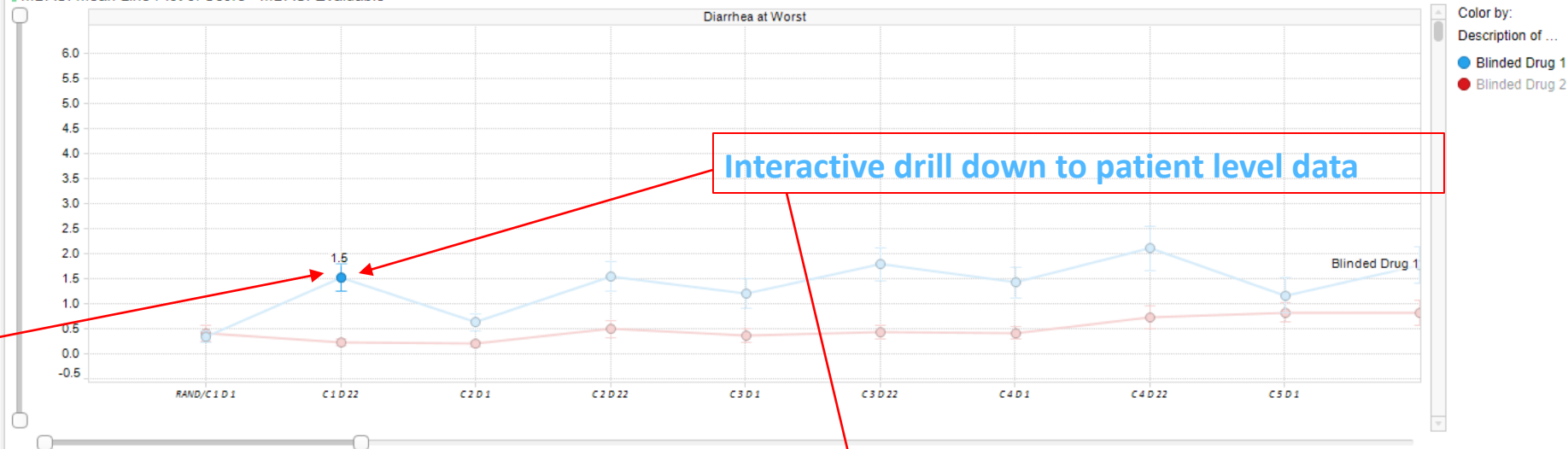


Go to: [Cover Page](#); [Data Overview](#); [Key Filters](#)

MDASI Analysis

[Reset All Filters & Markings](#)[Show Modified Filters](#)

MDASI Mean Line Plot of Score - MDASI Evaluator

MDASI Summary of Scores by Visit and Description of Planned Arm
MDASI Evaluator

Parameter	Visit	Statistics	Blinded Drug 1	Blinded Drug 2
			N=64	N=82
Diarrhea at Worst	RANDOMIZATION/CYCLE 1 DAY 1	n	62	78
		Mean (SD)	0.34 (0.92)	0.41 (1.38)
		Median	0.00	0.00
		IQR	0.00 - 0.00	0.00 - 0.00
		Min-Max	0.00 - 5.00	0.00 - 10.00
	CYCLE 1 DAY 22	n	44	55
		Mean (SD)	1.57 (1.84)	0.24 (0.51)
		Median	1.00	0.00
		IQR	0.00 - 3.00	0.00 - 0.00
		Min-Max	0.00 - 6.00	0.00 - 2.00
	CYCLE 2 DAY 1	n	51	62
		Mean (SD)	0.63 (1.22)	0.19 (0.51)
		Median	0.00	0.00
		IQR	0.00 - 1.00	0.00 - 0.00
		Min-Max	0.00 - 5.00	0.00 - 3.00
	CYCLE 2 DAY 22	n	46	53
		Mean (SD)	1.61 (2.09)	0.51 (1.31)
		Median	1.00	0.00
		IQR	0.00 - 3.00	0.00 - 0.00
		Min-Max	0.00 - 7.00	0.00 - 8.00
	CYCLE 3	n	50	65

Questionnaire Listing (Marked)

Subject ID	Parameter Description	Analysis Visit	Analysis Day	Analysis Value	Absolute Change from Baseline	Analysis Post-Baseline Flag	Analysis Baseline Flag	Baseline Value
1305	Diarrhea at Worst	CYCLE 1 DAY 22	25	0.00	0	Y		0.00
1317	Diarrhea at Worst	CYCLE 1 DAY 22	21	4.00	3	Y		1.00
1303	Diarrhea at Worst	CYCLE 1 DAY 22	27	1.00	1	Y		0.00
1323	Diarrhea at Worst	CYCLE 1 DAY 22	22	5.00	5	Y		0.00
1326	Diarrhea at Worst	CYCLE 1 DAY 22	23	0.00	0	Y		0.00
1328	Diarrhea at Worst	CYCLE 1 DAY 22	24	1.00	1	Y		0.00
1339	Diarrhea at Worst	CYCLE 1 DAY 22	25	0.00	0	Y		0.00
1348	Diarrhea at Worst	CYCLE 1 DAY 22	22	1.00	1	Y		0.00
1356	Diarrhea at Worst	CYCLE 1 DAY 22	23	1.00	1	Y		0.00
1335	Diarrhea at Worst	CYCLE 1 DAY 22	21	4.00	4	Y		0.00
1349	Diarrhea at Worst	CYCLE 1 DAY 22	22	0.00	0	Y		0.00
1306	Diarrhea at Worst	CYCLE 1 DAY 22	23	0.00	0	Y		0.00
1358	Diarrhea at Worst	CYCLE 1 DAY 22	26	4.00	4	Y		0.00
5225	Diarrhea at Worst	CYCLE 1 DAY 22	23	0.00	0	Y		0.00
5230	Diarrhea at Worst	CYCLE 1 DAY 22	24	0.00	0	Y		0.00
5226	Diarrhea at Worst	CYCLE 1 DAY 22	23	0.00	0	Y		0.00
5241	Diarrhea at Worst	CYCLE 1 DAY 22	24	1.00	1	Y		0.00
5224	Diarrhea at Worst	CYCLE 1 DAY 22	22	4.00	4	Y		0.00
5260	Diarrhea at Worst	CYCLE 1 DAY 22	22	1.00	1	Y		0.00
5208	Diarrhea at Worst	CYCLE 1 DAY 22	23	0.00	0	Y		0.00
1012	Diarrhea at Worst	CYCLE 1 DAY 22	27	0.00	0	Y		0.00
1012	Diarrhea at Worst	CYCLE 1 DAY 22	27	0.00	0	Y		0.00

Filters

Type to search filters

Demog

Questionnaire

Parameter Description

Type to search in list

(All) 38 values

BFI All Questions

Diarrhea at Worst

Disease Related Sympt...

Disease Related Sympt...

Disturbed sleep

Drowsy

Analysis Visit

Type to search in list

(All) 52 values

RANDOMIZATION/CYC...

CYCLE 1 DAY 8

CYCLE 1 DAY 15

CYCLE 1 DAY 22

CYCLE 1 DAY 29

CYCLE 1 DAY 36

Roche's Implementation of Spotfire ----

Safety Data Review

- User: Clinical Scientist and other study team members
- Purposes:
 - Enable exploratory analysis with integrated visualizations
 - Provide controlled access to reports via web browser, no additional software is needed
 - Quality and consistency

Roche's Implementation of Spotfire ----

Safety Data Review

Business Use

- Internal Regular Reporting, eg, IMC
- Topline Release
 - Quick data understanding
 - Accuracy, traceability and reproducibility
 - Prompt answer during meeting
- End user self-exploration.
 - Self service
 - Ability to interact with data with ease
 - Speed up for decision making
 - Visualization is easily interpretable and helps communication

--Demo

Demo_CoreSV_v1.dxp - TIBCO Spotfire

File Edit View Insert Tools Help



Cover Page x Data Overview x Key Filters & Bookmarks x Instructions x CSR: Demo Table x CSR: Study Disc x AE Graph x Time to AE Onset x AE Table by SOC and PT x AE Table by Highest Grade x Patient Profile x Lab By-Patient Plot x + x

Protocol: Study for Demo

Reporting Event: [Core Safety Visualization for Safety Data Review](#)

RAVE Extraction Date: [July 2018](#)

Clinical Data Cutoff Date: [30 May 2018](#)

Data location: xxxxxx

Study Status: [Phase III Study](#)

Created by: [Jingyuan Chen](#)

Spotfire Version: [7.7](#)

DISCLAIMER

This visualization package is developed to support internal safety data review and exploratory safety data analysis. **Please work with SPA/Biostat if results will be used for any decision-making.**

Table of Contents

Safety Data Domain	Summary Tables/Plots	Listings / By-Patient Plots
Demographics	Data Overview CSR: Demog Table	
AE	AE Graph Time to AE Onset AE Table by SOC and PT AE Table by Highest Grade	
Patient Profile	Patient Profile	
Study Discontinuation	CSR: Study Disc	
Lab		Lab By-Patient Plot

Understanding Pros and Cons of Spotfire

- Spotfire is
 - ✓ User friendly - no programming experience needed
 - ✓ Easy to play around and connect with Patient level information
 - ✓ Embed R or Python script
- And,
- You need to know:
 - database design and content
 - product and its risks
 - how to partner with your cross functional team
 - questions that are likely to come up
- So,
- you need to start early and prepare for the obvious questions.

Understanding Pros and Cons of Spotfire

Comparison between Spotfire and Shiny



Functionality	Spotfire	Shiny
Subgroup analysis	Easy to set up with built-in filter framework ✓	Typically require development from scratch.
Interactivity	Powerful for its built-in to drill-down into patient level data ✓ · Marking links at patient / data level across domains and visualization pages ✓ · Default tooltips for further customization ✓	Need to program for another layer
Graphics	Quick, easy, good quality and interactivity ✓ Need to leverage R or Java script for complex graphics	Complex graphics such as forest plot ✓
Statistical Analysis	Quick and easy with built-in drill-down capability ✓ Doubt with modeling and complex analysis	Good at stat modeling and analysis using ✓
Data manipulation	OK for simple transformation and manipulation	Powerful, and could be integrated in the workflow ✓
Reproducibility	Yes, may not seem intuitive for users.	GOOD! Can allow quick and easy code generation. ✓

Acknowledgement

Xiangyun Wang

Roche Spotfire Development Team





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