
Safety Signal Detection Visualization using Spotfire including R

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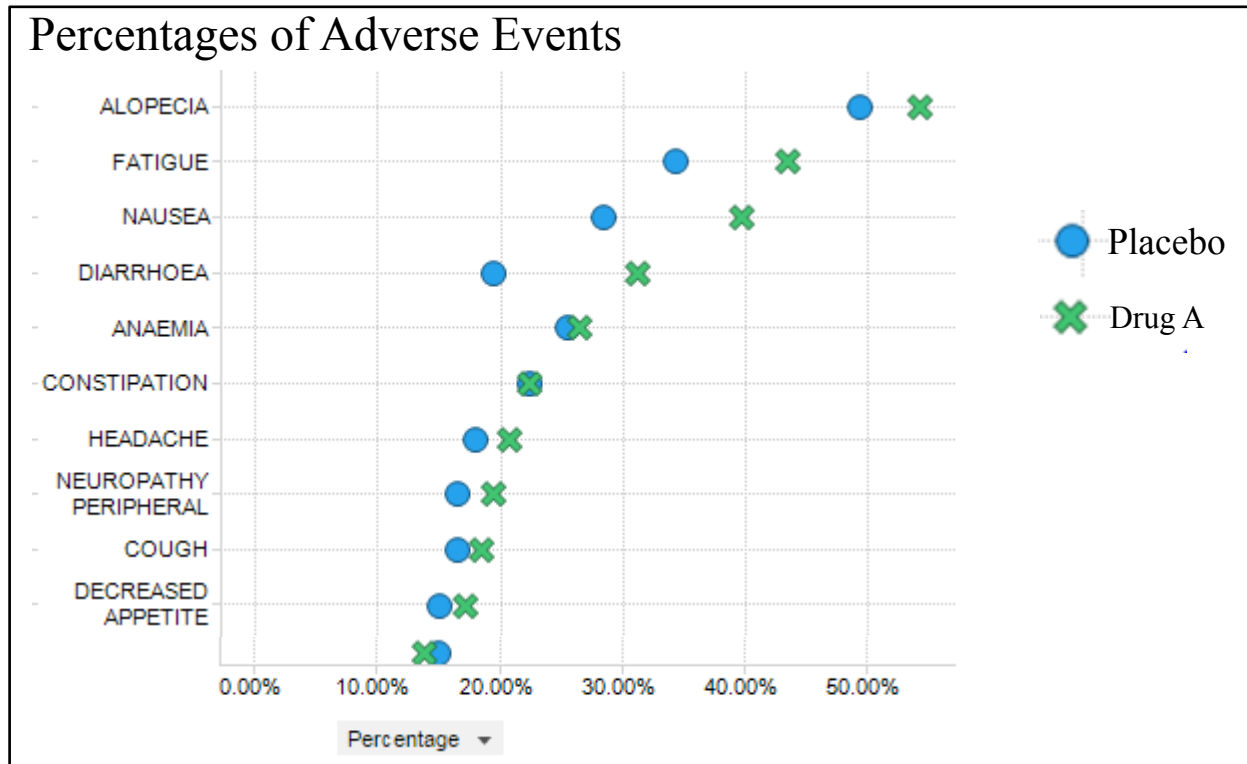
Agenda

- Sources
- Live Demo of Safety Signal Detection Visualizations in Spotfire
- Example to include simple R code into Spotfire

Presentation on visualization in signal detection

(e.g. The Forest for the Trees Visualizing Adverse Events (DIA 2011))

(Andreas Brueckner, Bayer Healthcare)

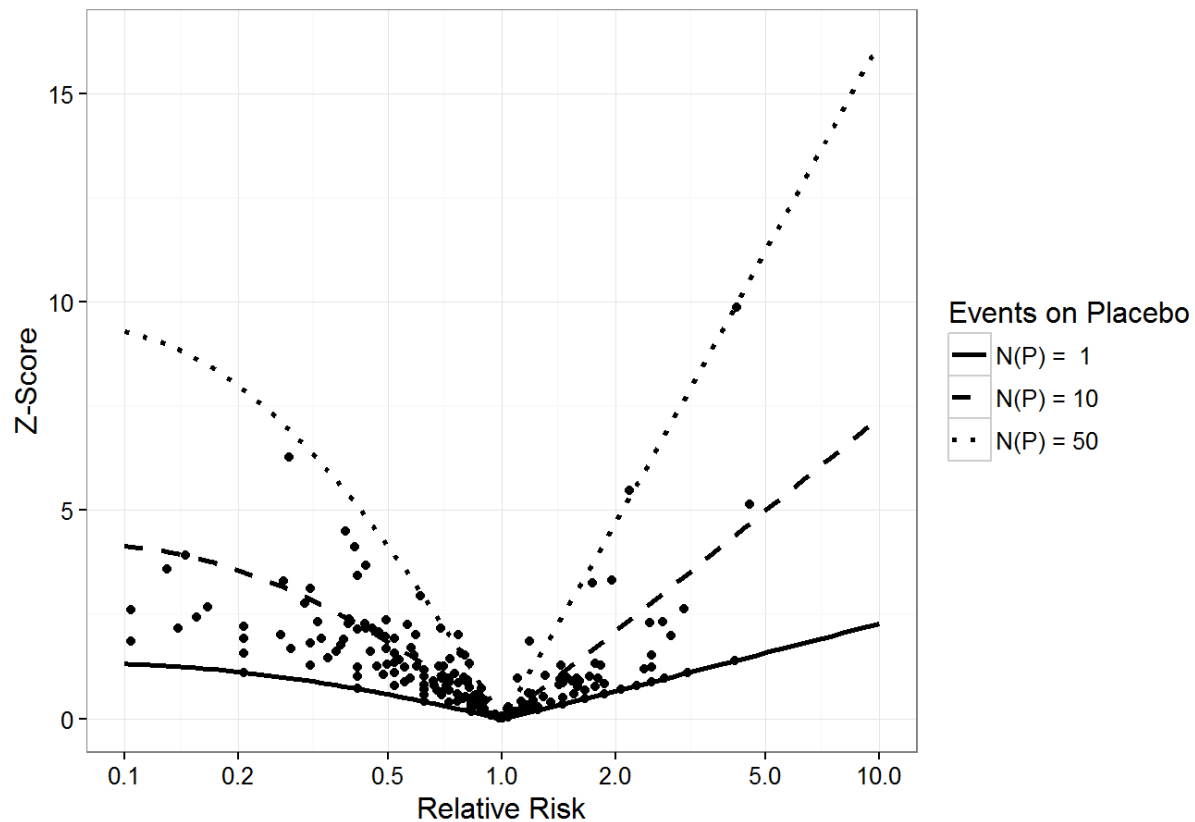


Summary of adverse events by Body System and Preferred Term

SKIN AND SUBCUTANEOUS TISSUE DISORDERS	Subtotal	43	81	64.18	588	1189	71.45
	ACNE	-	-	-	10	10	1.22
	ALOPECIA	33	35	49.25	446	451	54.19
	BLISTER	1	1	1.49	4	4	0.49
	CHLOASMA	-	-	-	1	1	0.12
	DERMAL CYST	-	-	-	2	2	0.24

P-Risk Plots / Volcano Plots

Relative risk (RR) versus z-score





Analysis and Displays Associated with Adverse Events

Project: Analysis and Display White Papers Project Team

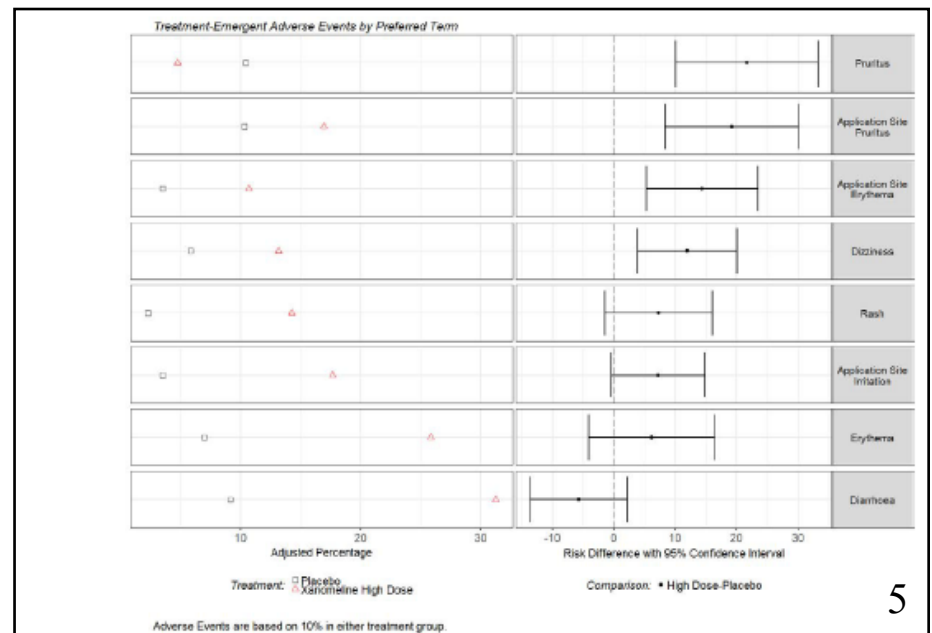
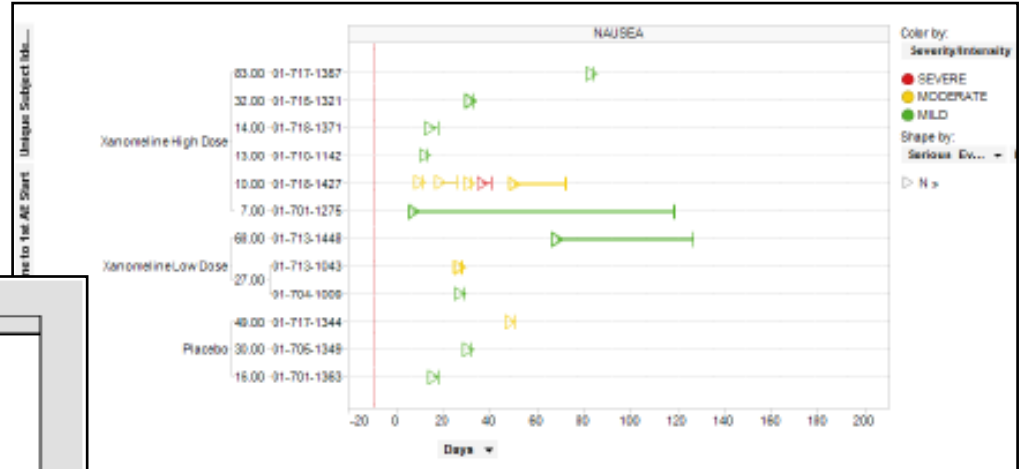
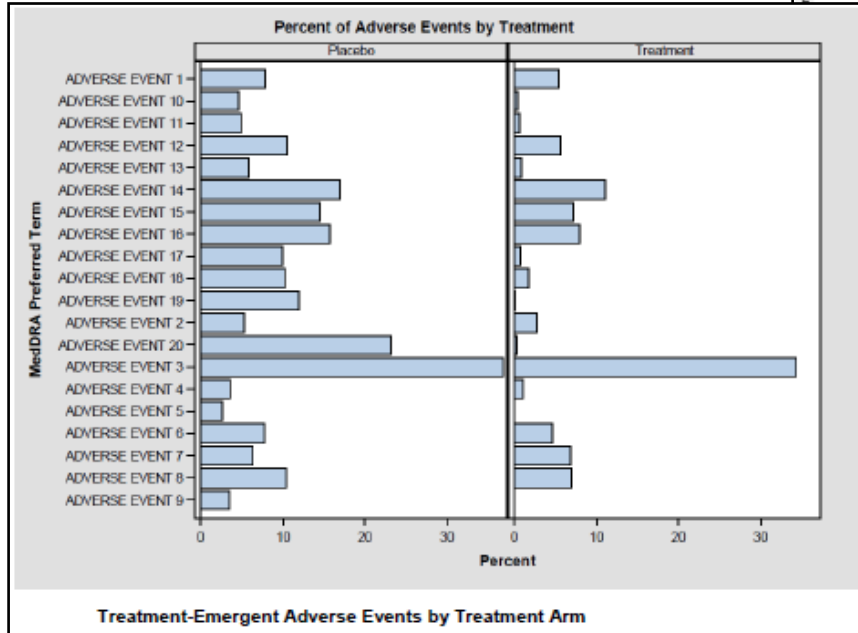
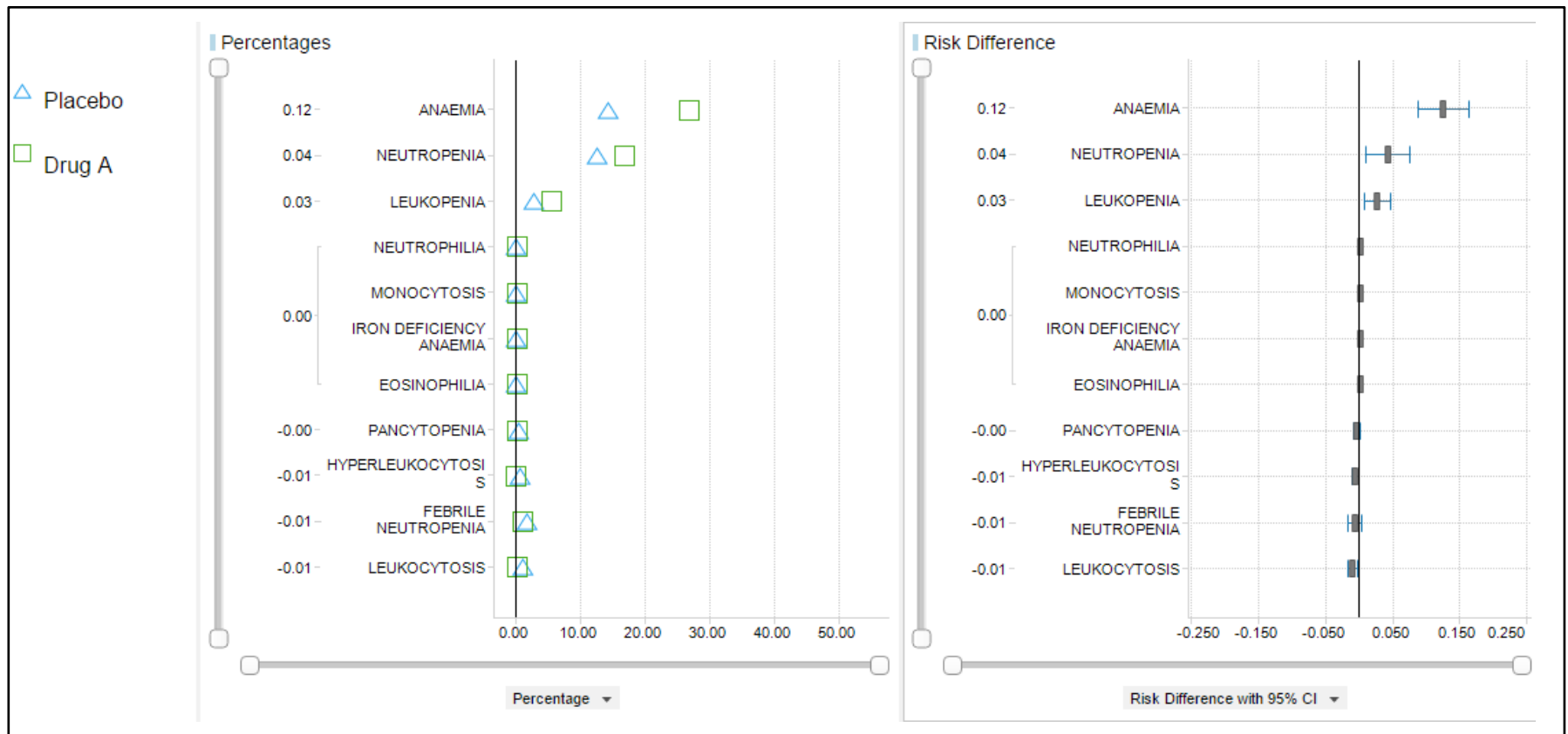


Figure 12.1.

Common Treatment-Emergent Adverse Events

Analysis and Displays Associated with Adverse Events I

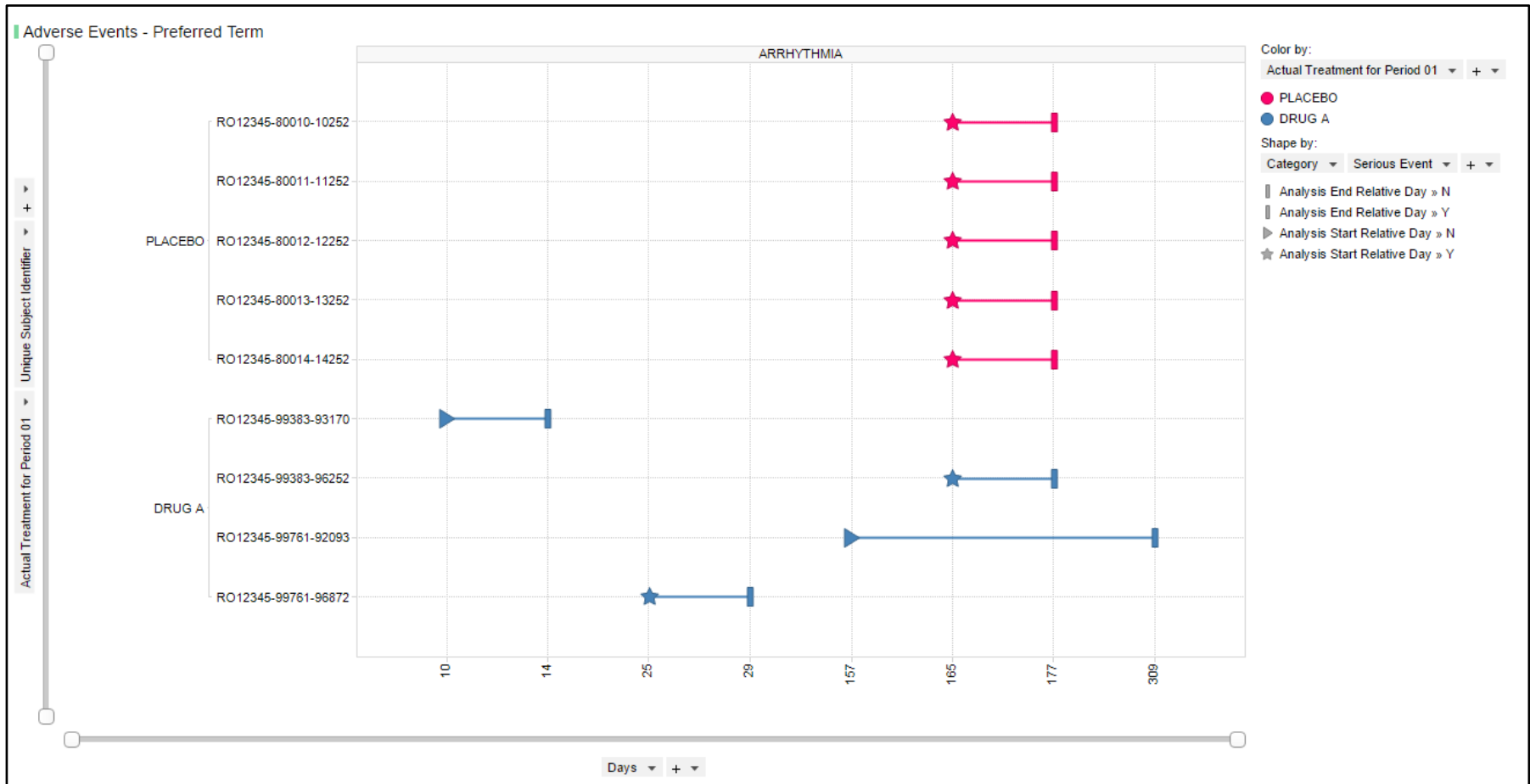
Percentages / Risk Difference with 95% Confidence Interval





Analysis and Displays Associated with Adverse Events II

Plot of Adverse Event Start and End Days per Patient



Analysis and Displays Associated with Adverse Events III

Percentages of Adverse Events

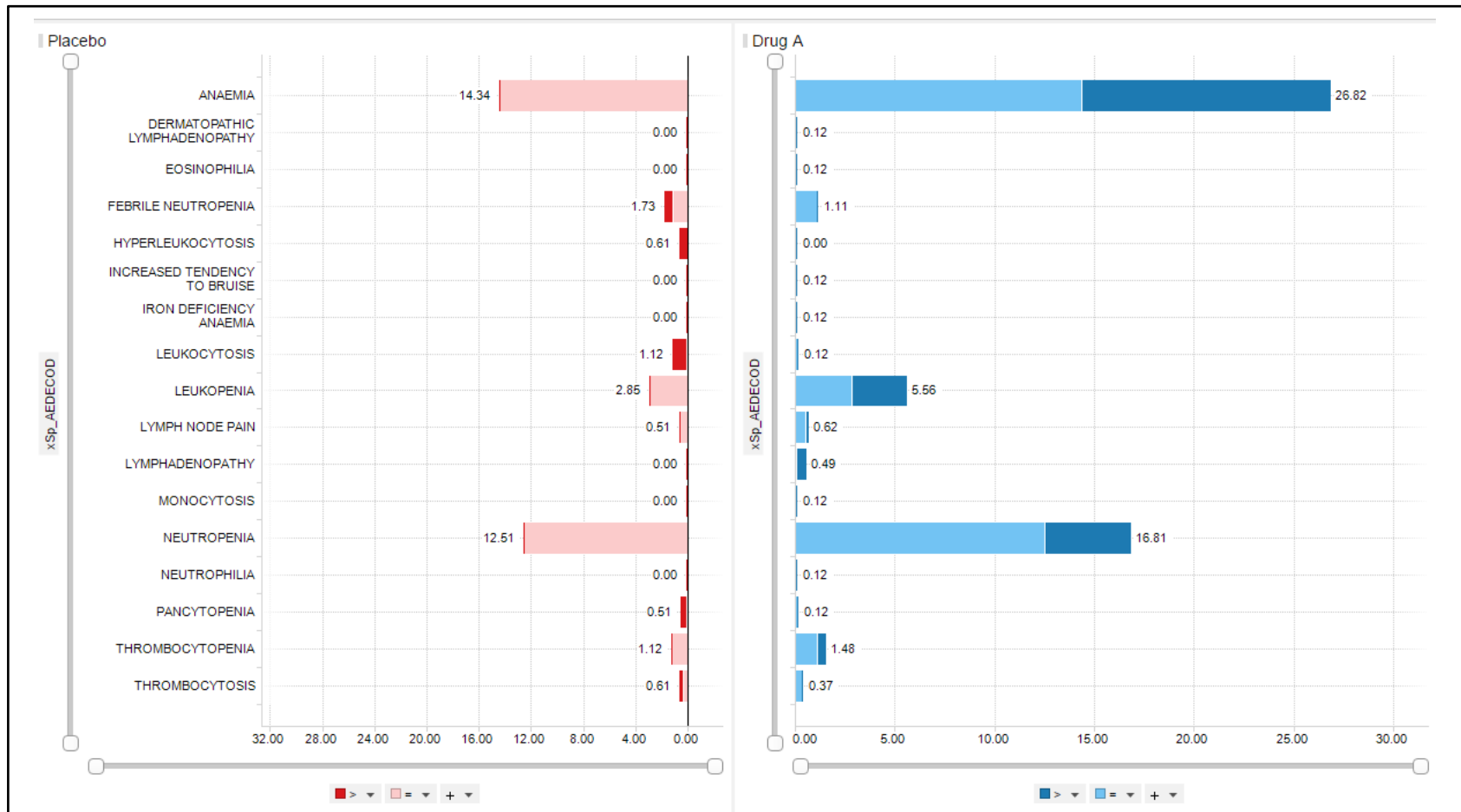


Table of Contents

Safety Data Domain	Summary Tables/Plots	Listings / By-Patient Plots
Demographics	Summary: Demographics *	Listing: Demographics
AE	Summary: Adverse Events	Listing: Adverse Events Plot: Adverse Event Start and End
	Scatter Plot (%) Scatter Plot (%) Severe AEs * Bar Chart (%) Related AEs (R) *	
	Tornado Plot Tornado Plot (Diff) *	
	Volcano Plot *	
	Risk Difference Percentage / Risk Difference Percentage / Risk by Subgroup *	Listing: Relative Risk$\geq$3 or p-value$<$0.1 Listing: Percentage and Risk Statistics
	Line Graph: Time To Event *	Listing: Time To Event
	Summary: Patient Years at Risk *	

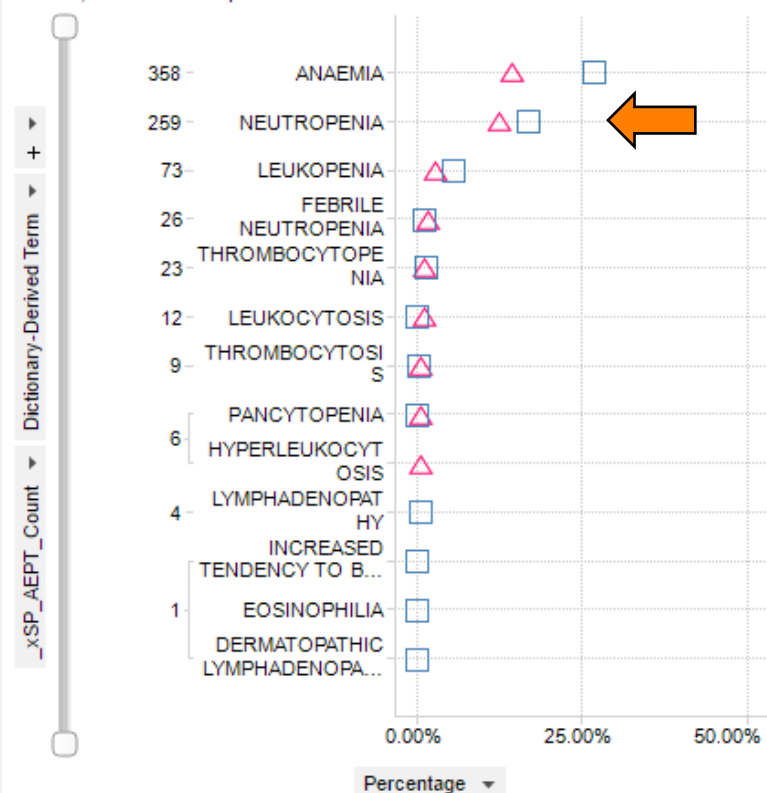


Summary: Demographics

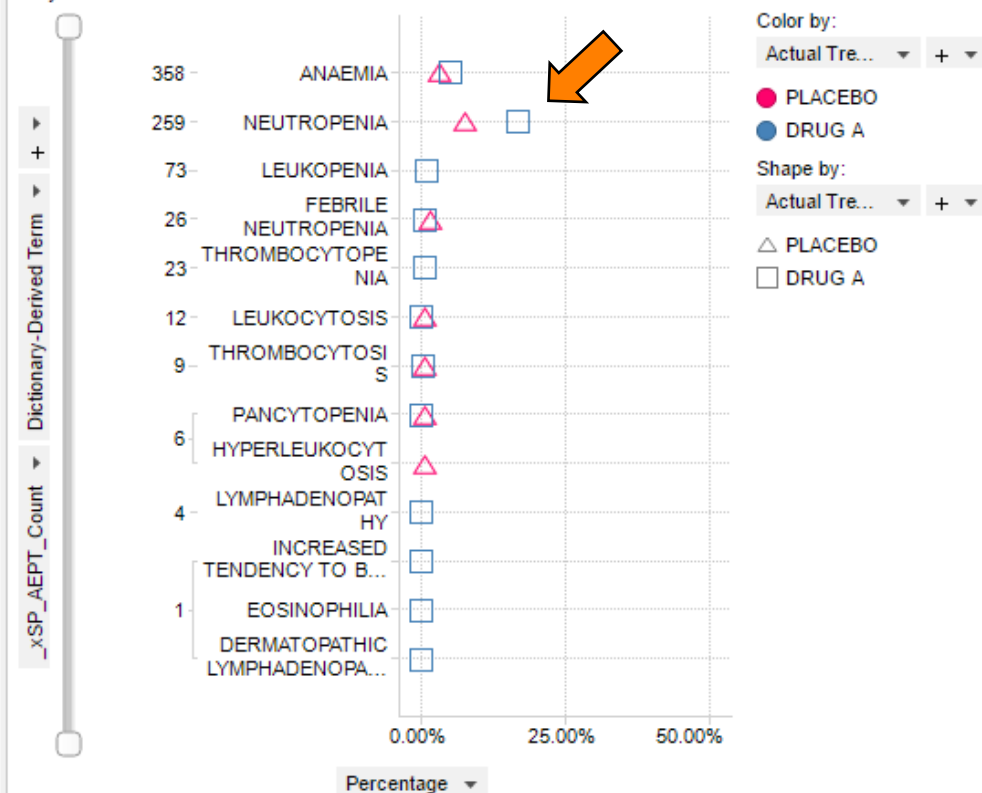


Scatter Plot: Severe AEs

Adverse Events - Preferred Term
All AEs, if at least one preferred term is severe



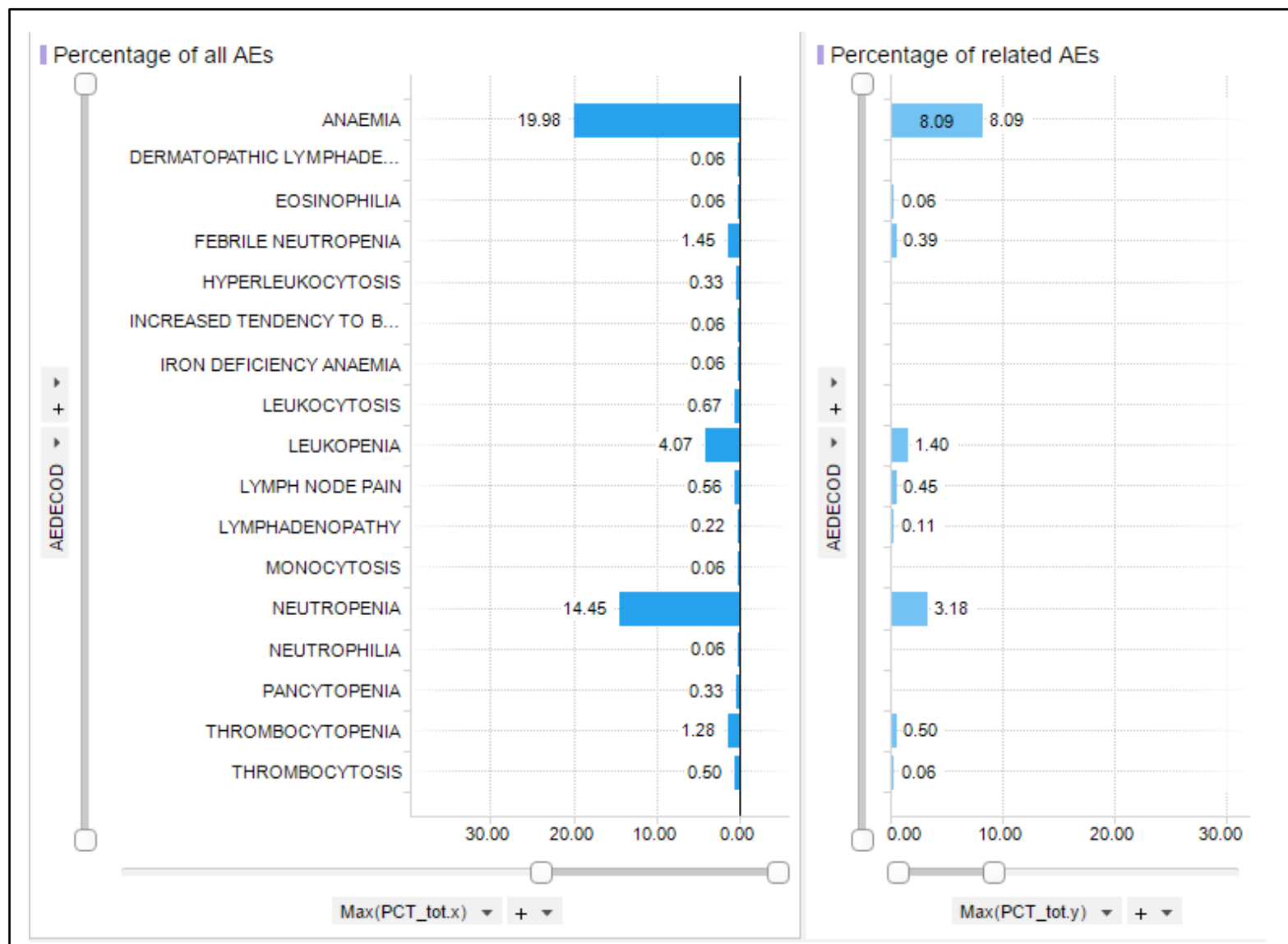
Adverse Events - Preferred Term
Only severe AEs



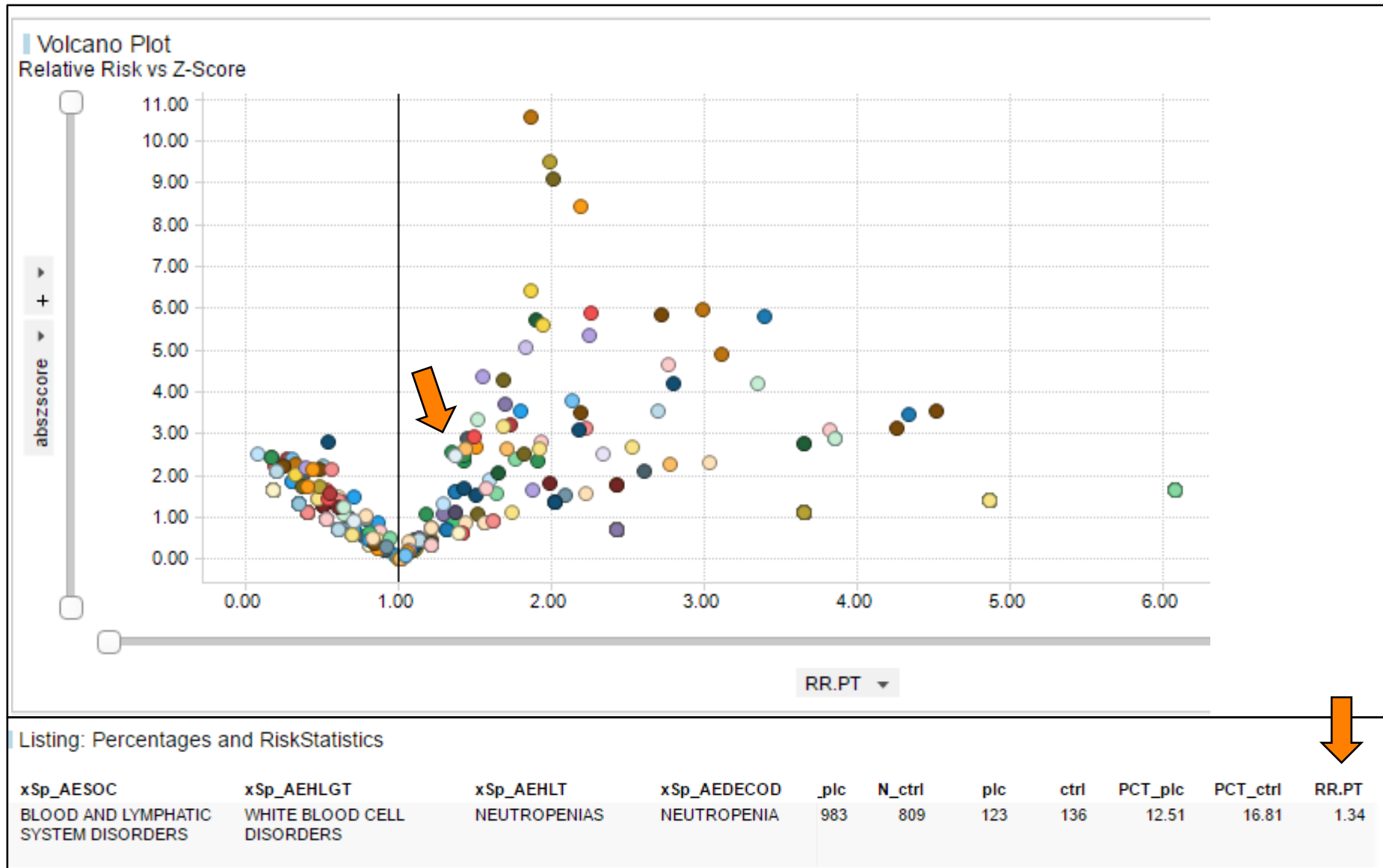
Listing: Adverse Events

Study Identifier	Unique Subject Identifier	Actual Treatment for Period 01	Dictionary-Derived Term	Analysis Start Time	Period Description	Subperiod within Period - Description	Analysis Duration (days)	End Date-Time of Last Dose	Last Dose Relative Time (min)
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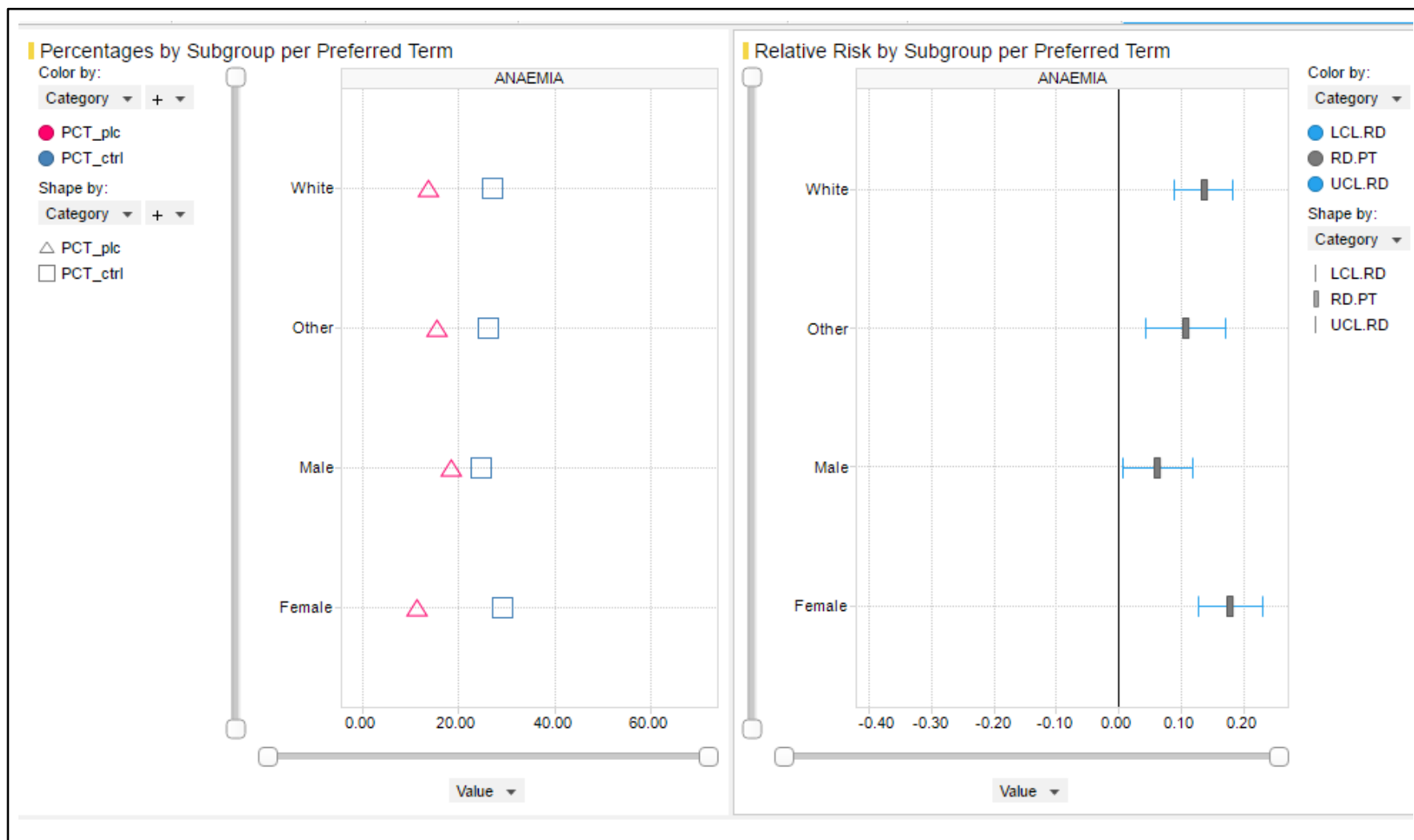
Bar Chart (%) Related AEs



Volcano Plot



Percent/Risk Diff. by subgroup



Include R program to Spotfire

USUBJID	BHT	BWT
1	178	95
2	165	55
3	174	62
4	160	49
5	170	59

- 1) Insert example data into Spotfire
- 2) Tools -> Register Data Function (Edit R Script)

Register Data Functions

New Function Open Import Save Save As Export Run

Name: example

Type: R script - Open Source R

Packages (separated by semicolons): dplyr

Description:

☒ Allow caching

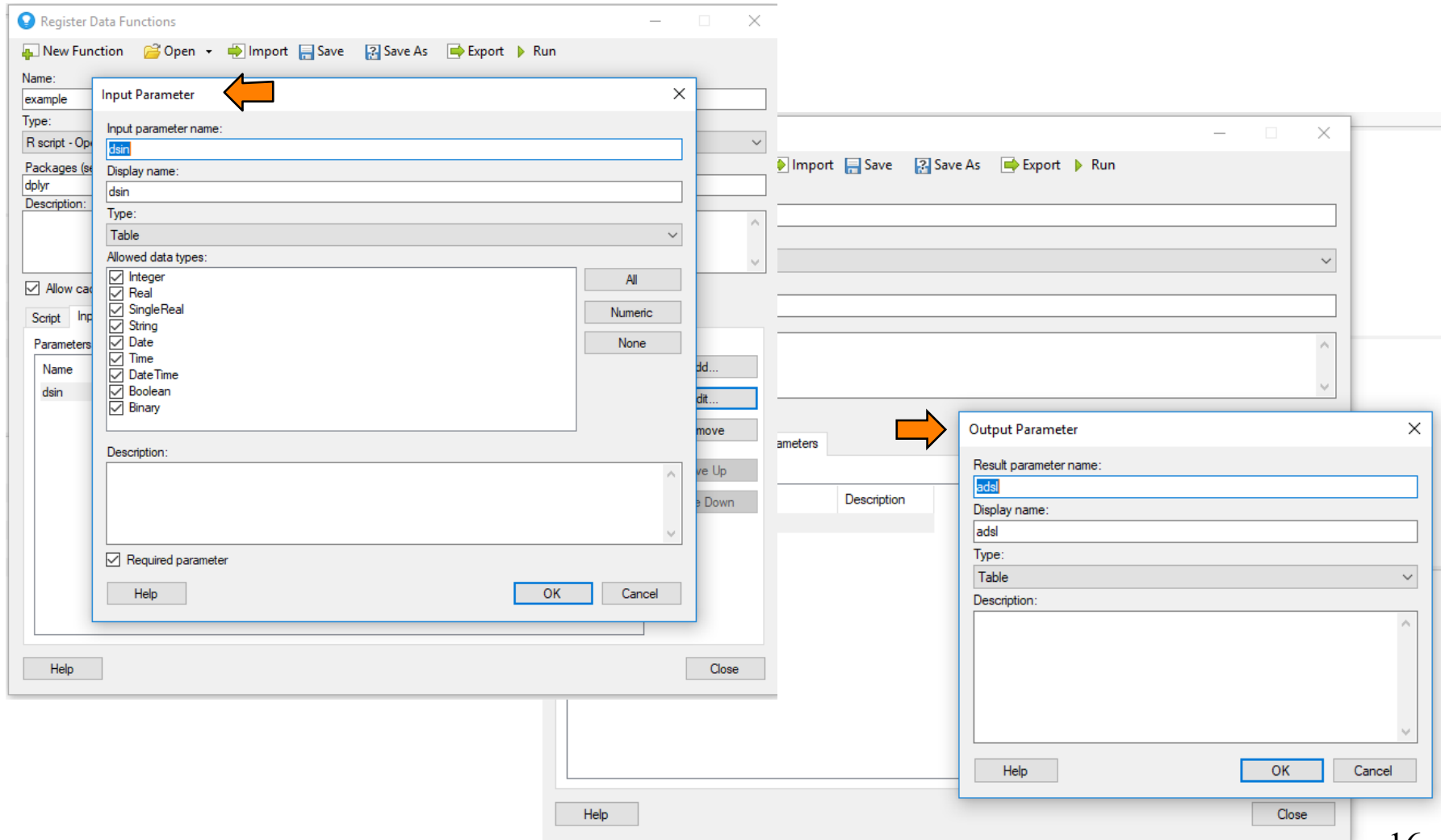
Script Input Parameters Output Parameters

```
1 adsl <- dsin
2
3 adsl$bhtn <- as.numeric(adsl$BHT)
4 adsl$bwtn <- as.numeric(adsl$BWT)
5
6
7 adsl$bbmi <- (adsl$bwtn*10000) / (adsl$bhtn*adsl$bhtn)
```

4) adsl needs to be specified as Output Parameter

3) dsin needs to be specified as Input Parameter

Specify Input and Output parameters needed in R function: dsin and adsl



Run the Function

Specify Input and Output for Spotfire

The screenshot shows the 'Register Data Functions' dialog box in Spotfire. The 'Edit Parameters' sub-dialog is open, showing the configuration for a function named 'example'.

Register Data Functions Dialog:

- Name: example
- Type: R script - Open Source R
- Packages (separated by semicolon): dplyr
- Description: (empty)
- ☒ Allow caching
- Script tab selected. Input Parameters tab also visible.
- Parameters table:

Name	Display
adsl	adsl
- Buttons: New Function, Open, Import, Save, Save As, Export, Run.

Edit Parameters Dialog:

- Name: example
- ☒ Refresh function automatically
- Input tab selected.
- Input parameters table:

Name	Description	Type	Required	Input	Data Types
dsin		Table	Yes		Integer, Real, SingleReal, String, Date, Time, ...
- Input handler: Columns (selected), Expression, None.
- Data table: Data Table (selected in dropdown).
- ☒ Columns: (empty list box)
- ☐ Search expression: (empty text box)
- Example input: (empty text box)
- Buttons: Select Columns..., OK, Cancel.

Doing now what patients need next