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

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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
Why interactive analysis and data visualization?

- Efficiency
- Agility
- Exploratory analysis
- More reasonable resource allocation
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

- Developer interface
- Web page
- Controlled access
- Spotfire server

Data flow:
- Data from cloud to Spotfire server
- Spotfire server sends data to Web page
- Web page displays data through the Developer interface.
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

- Lab issues
- Adverse events issues
- Exposure issues
- Other issues

database → raw data → Templates
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

- PCOR scientist input
- analysis data
- Templates
- PRO assessment features
- Web page
Interactive drill down to patient level data

Connected visualization section
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
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.
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

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

Xiangyun Wang

Roche Spotfire Development Team
Doing now what patients need next