

Holistic Review of Active Clinical Trial Data Using Spotfire

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October 4, 2016

Outline

- Background about development of data visualization tools supporting active clinical trial data review at Gilead
- Standardized approach to develop the visualizations using Spotfire
 - ✓ Data Flow
 - ✓ Framework
 - ✓ Standard templates for data visualizations
- Demonstration of study case using Spotfire

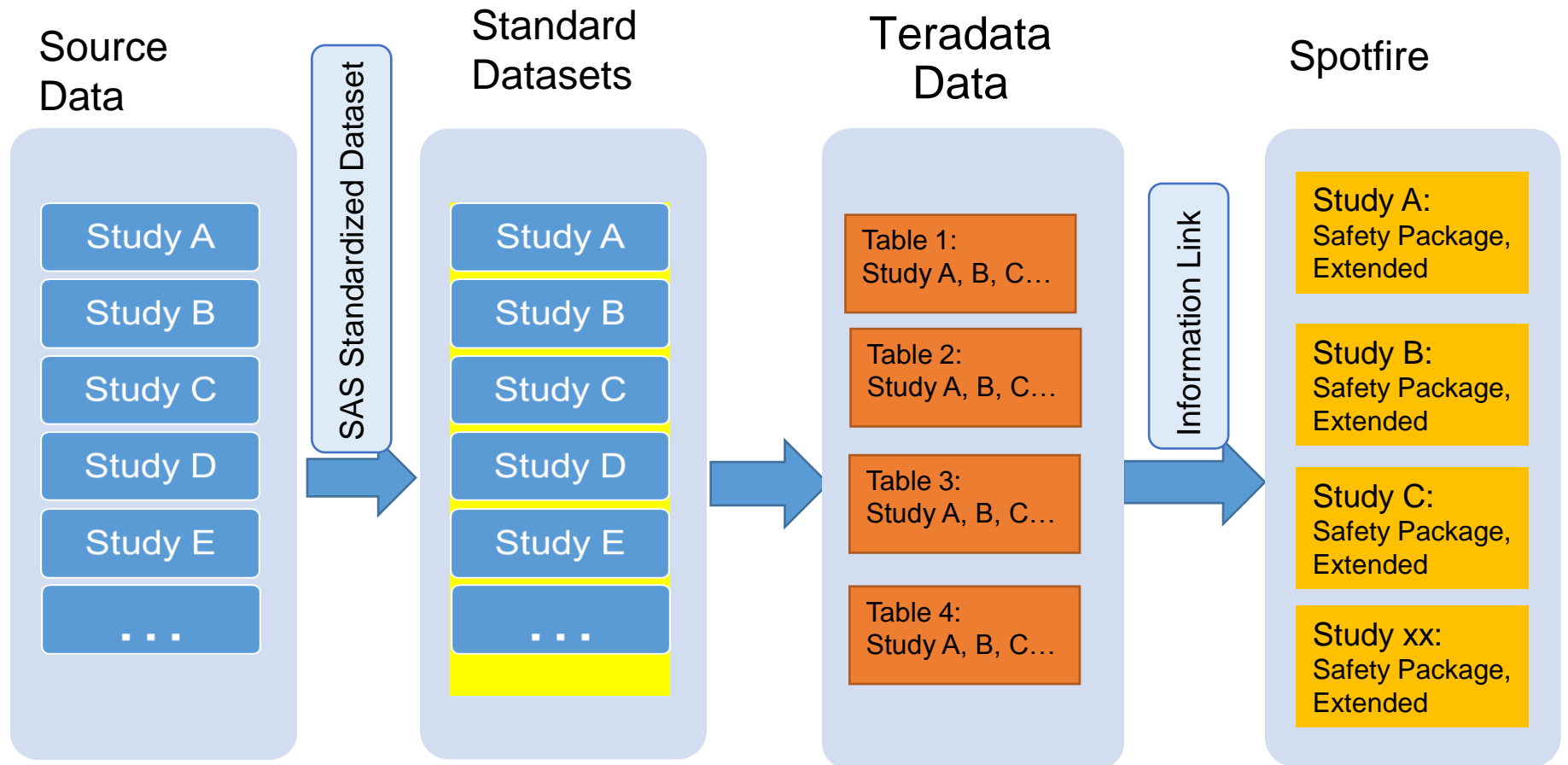
Background

- 1st Generation of data visualization tool – Biometric Data Review Portal (BDRP):
 - Home grown application
 - SAS based, Java script, Applet and Web Development technology
 - Link to EDC system, near real-time data review
 - Used by all TAs
 - Fast set up process:
 - ❖ Standard safety package
 - ❖ Extended efficacy package by indication
 - More limited than Spotfire

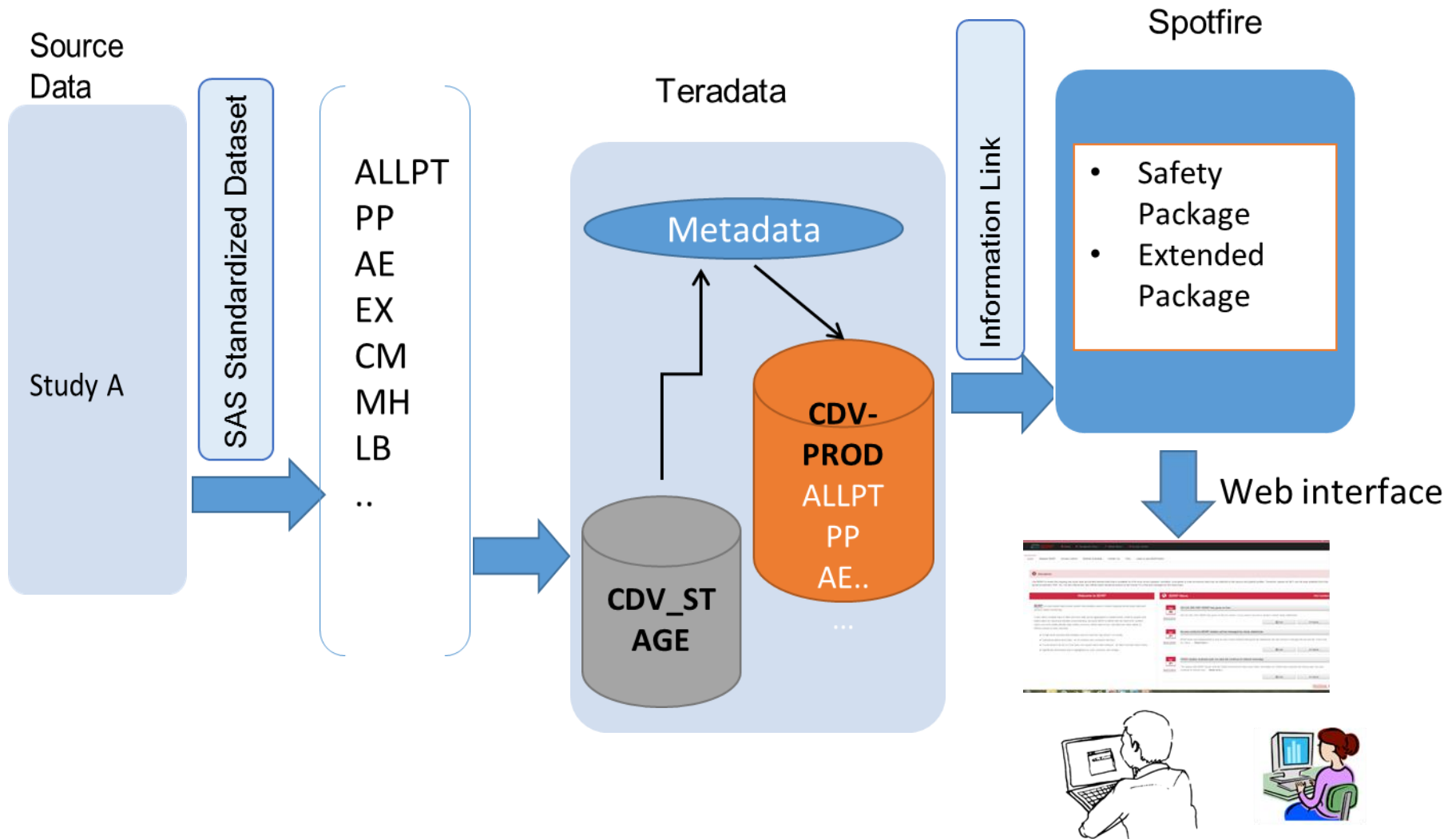
Background (Cont.)

- 2nd Generation of data visualization tool -
Spotfire
 - Leverage what we have done in BDRP
 - More visualizations are created to meet different functional needs
 - Still have Safety package and Extended efficacy validation package by indication
 - More comprehensive visualizations and easier drill down from the summary level to detailed patient level

Data Flow



Framework



Standard Visualizations in Spotfire

- Standard Safety Package:
 - Patient Profile
 - General Study information: study status, demographic information, disposition, off-treatment/off-study information, summary of death, etc.
 - Adverse Events and Concomitant Medication
 - Lab results plots, including the drug-induced liver injury plots
- Extended efficacy package:
 - Standardized by indication: solid tumor(RECIST), CLL (Hallek) or NHL (Cheson) in Oncology
 - Customized for individual study needs

Potential Users

- ❖ Clinical Researchers
- ❖ Medical Monitors
- ❖ Safety Scientists
- ❖ Clinical Data Manager
- ❖ Statisticians

Acknowledgments

- ***Data Visualization Team in Safety Statistical Programming:***
 - Chuck Ni, Jacky Xue, John Palukuri, Sean Huang, Shumin Zhang, Sukanya Dutta
- ***Biometric System Support Team***
 - Niall McSharry, Ziad Ahmed
- ***Gilead IT GVDI Team:***
 - Kishore Nandyala, Haibo Jiang et al
- ***Support from Gilead Biometrics Management Team***

Demo

Disclaimer:

The data used for this demonstration is dummy data. It is not reflective of any real study at Gilead Science Inc.

