

Standard Approach to Create Visualization for Clinical Trial Study Data Review

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Demo

Disclaimer:

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

Outline

- Introduction of clinical data review tool in Gilead
- Standardized approach to develop the visualizations using Spotfire
 - ✓ Data Flow
 - ✓ Framework
 - ✓ Standard templates for data visualizations
- Demonstration of study case using Spotfire

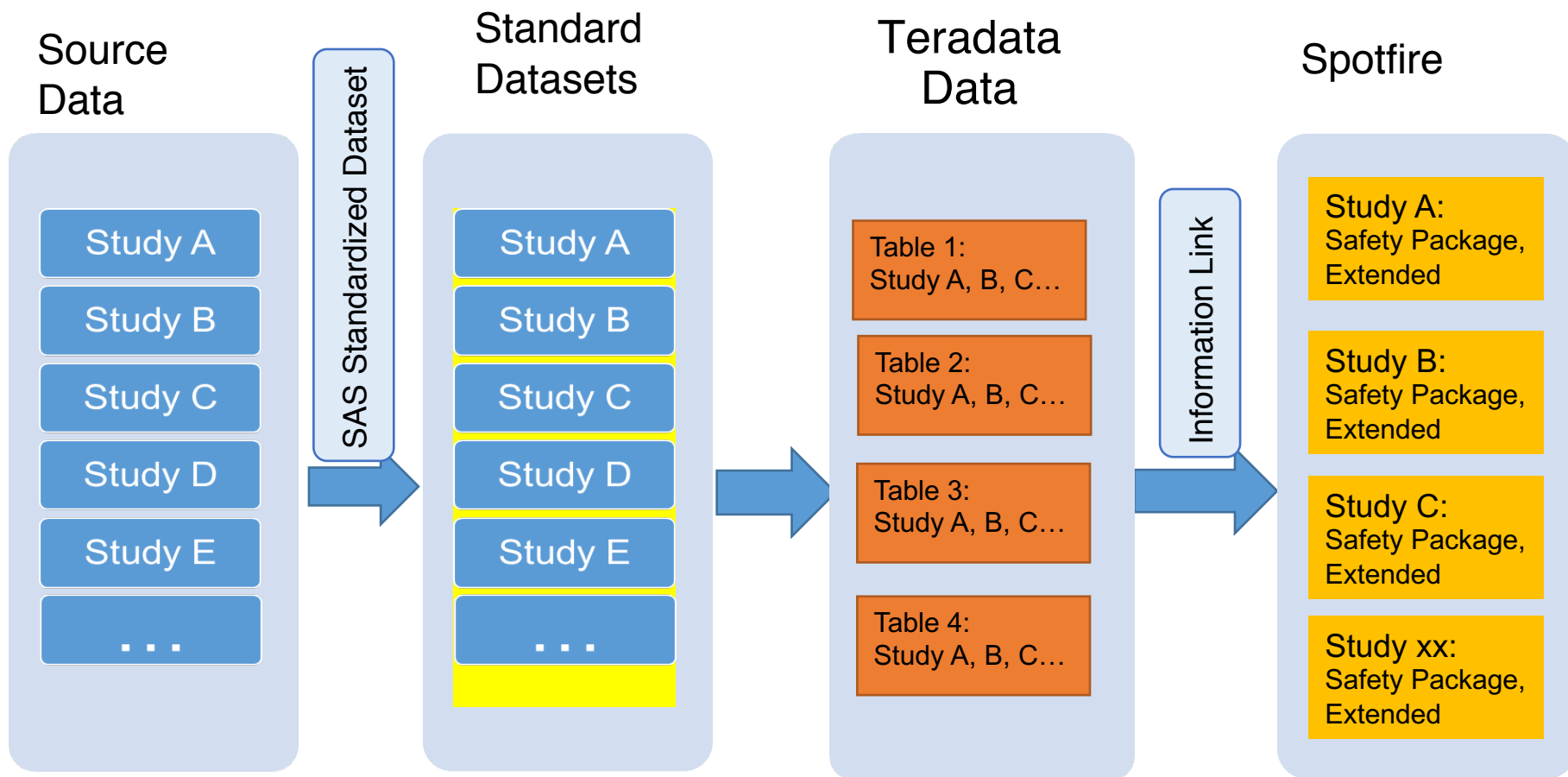
Introduction

- 1st Generation of data visualization tool – Biometric Data Review Portal (BDRP):
 - Home grown application
 - SAS based, Java script, Applet and Web Development technology
 - Web-based data review system for ongoing clinical study review
 - Provide 2 levels data review: summary and patient
 - 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

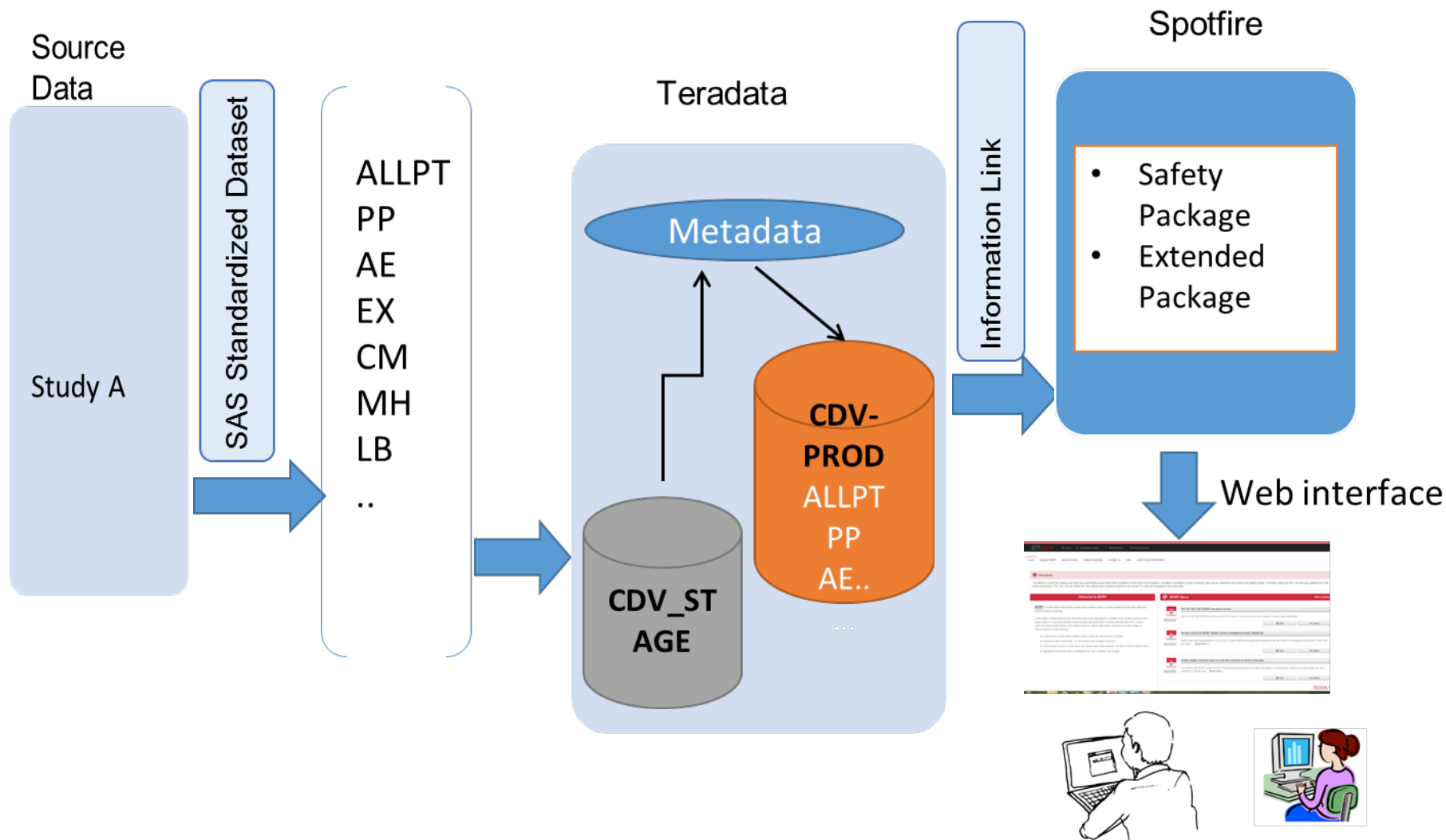
Introduction (Cont.)

- 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

Standardized Approach to Create Visuals: Data Flow



Standardized Approach to Create Visuals: Framework



Standardized Approach to Create Visuals: Standard Visualizations



- 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

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