

22. Data Visualization Working Group, Subject Level Data Review & Visualization

Ingeborg Holt¹, Jasmine Sen², Eric S. Herbel³, Rebeka M Revis⁴

¹Commonwealth Informatics, Waltham, MA; ²Bayer, Whippany, NJ; ³Integrated Clinical Systems, Inc.; ⁴Eli Lilly, Indianapolis IN

Background: Over time, approaches to subject level data review have evolved along with the needs of reviewers to link various data sources in a single longitudinal patient record. The patient profile and patient narrative accomplish such a comprehensive data review. However the approaches to generate these vary widely across the clinical industry. This poster evaluates ways in which visualizations are used to review data at the patient level.

The Data Visualization working sub-group conducted an updated analysis of the current tools used to review subject level data, including the use of interactive visualizations for generating patient profiles and patient narratives. This type of review has not been done in over 5 years. During this time, technology, regulations, and processes have evolved.

This poster focuses on 3 types of subject level data representations :

1. Tabular Patient Profiles or case summaries display information for a single patient in tabular format, allowing the user to view summarized data about a single patient’s clinical experience. For example, counts and SOC’s of adverse events during exposure and/or other information relevant to the trial can be displayed.

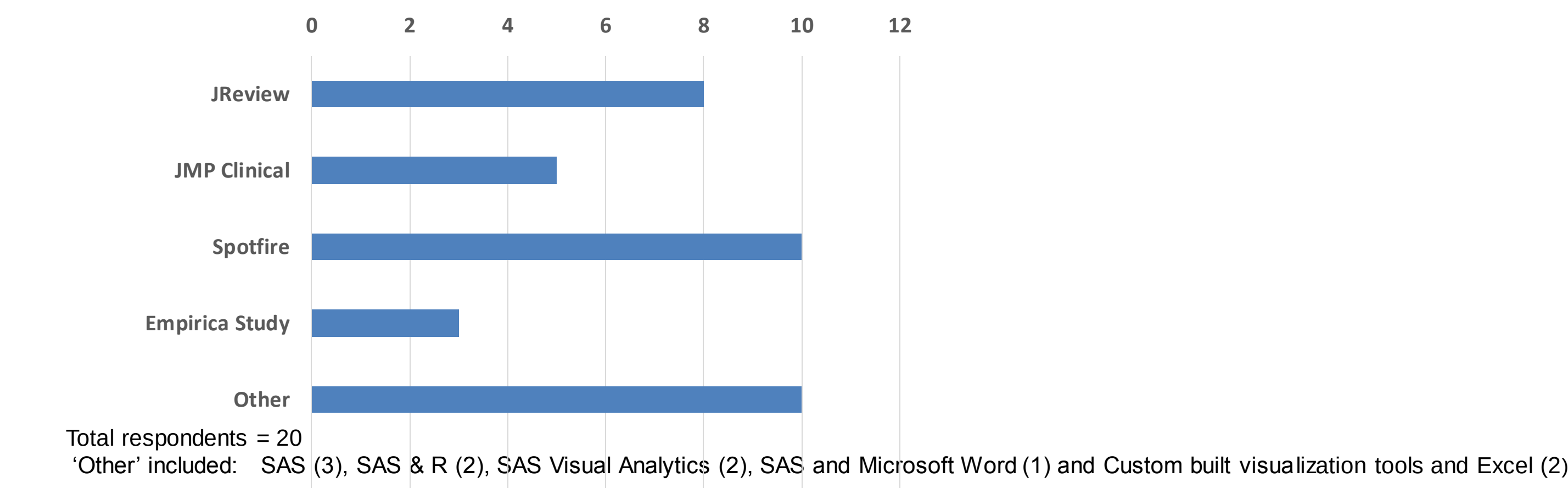
2. Graphical Patient Profiles are time oriented, visual presentations of subject level study data requiring little or no external data preparation or programming. These profiles may focus on a specific area such as liver function or depict a comprehensive view of the subject’s time in the trial and include exposure, adverse event, lab, disposition or other data.

3. Patient Narratives are summaries that describe a subject’s clinical experience resulting from participation in a clinical trial. Narratives contain elements of a patient profile but are primarily generated to communicate reasons for the event(s) the patient experienced during their participation in the trial.

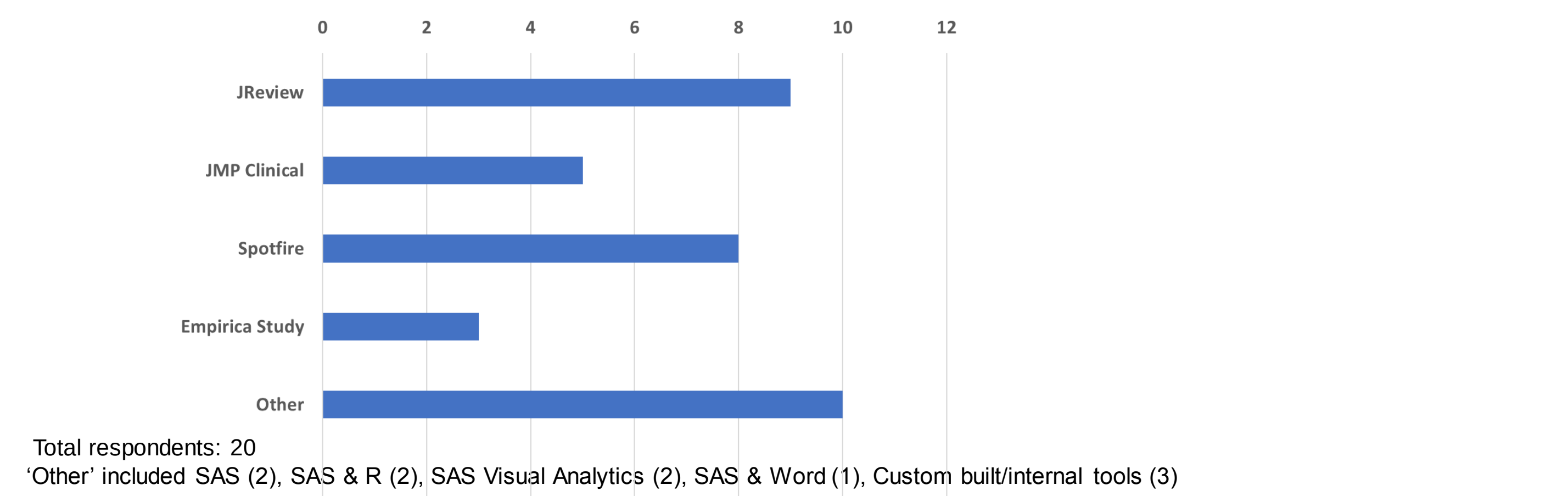
Methods: We designed a survey to gather information about the tools currently used to generate the 3 types of patient data displays described above. This survey was sent to the entire Emerging Trends Working Group of PhUSE and was conducted over the course of 4 weeks from December 20, 2018 to January 19, 2018. Both industry and FDA participated in the survey.

Results:

Survey question 1 What tools are currently being used within your company/organization to review summary information for patients? Given the broad definition (as opposed to using “tabular patient profiles”), many tools were included in the ‘Other’ response.



Survey question 2 What tools are currently being used within your company/organization to review patient profiles graphically over time?



Survey Question 3: What tools are currently being used within your company/organization to generate patient narratives?

Total respondents=16; JReview (1), JMP Clinical (2), Spotfire (1), Other (14). 'Other' included SAS (7), SAS & R (1), internal tools (1). Patient narratives are typically written in Microsoft Word based on input from SAS tables & listings, with some companies generating narrative text from SAS programs or using JReview or JMP Clinical (SAS) to directly generate the patient narrative text. Spotfire was included in the responses, presumably used as input to writing a patient narrative in Word.

Next, we assessed the commonly used tools for reviewing subject level data as found in our survey. **Only COTS tools were included.**

JReview®

Data Requirements and Setup: Works directly against SAS datasets (with SAS Share) or directly against a variety of clinical data sources/databases. Works with CDISC SDTM/ADaM or Legacy data structures. Uses study meta data available in the environment – no additional study setup required.

Relevant Features / Highlights of Functional Characteristics

Tabular Summary: Tabular Patient Profiles/Case Summaries, as well as a variety of tabular reports, as well as clinical relevant study graphic visualizations. No external programming needed.

Graphical Profile: Built-in graph patient profiles – no external data setup or programming required. Days on drug calculated on the fly.

Narratives: Patient narrative template defined in JReview with data substitution, conditional processing for inclusion of text blocks based on patient data, and embedded tables and figures.

JMP® Clinical from SAS®

Data Requirements and Setup: Requires CDISC SDTM data structures plus ADSL dataset.

Relevant Features / Highlights of Functional Characteristics

Tabular Summary: A wide variety of tabular reports and clinically relevant graphic visualizations are available.

Graphical Profile: Built-in graphical patient profiles – days since reference date.

Narratives: Configurable patient narrative for automatic generation of patient narrative.

TIBCO® Spotfire®

Data Requirements and Setup: works with data in a variety of formats including SAS datasets, CDISC complaint datasets and Excel or CSV files.

Relevant Features / Highlights of Functional Characteristics

Tabular Summary: generates tabular summaries for groups of patients or individual patients selected through a drill down menu. Summaries can be linked across domains of interest. E.g. the AE and LB domains can be linked such that the labs of a patient experiencing an adverse event can be further reviewed.

Graphical Profile: provides for a variety of visualizations that allow for detection and systematic assessment of safety signals. In case of CDISC datasets, the visuals and data can be linked across domains.

Narratives: No support for narratives is available using the standard configuration.

Oracle® Health Sciences Empirica Study

Data Requirements and Setup: Data must be in CDISC SDTM format. A Define.xml can be provided or generated from the data. Once the data is loaded, no other setup is needed. Configuration options allow the setup of customized dosing groups, time frames and other analysis variables.

Relevant Features / Highlights of Functional Characteristics

Tabular Patient Profiles: Case Summaries are presented as raw SDTM data for the individual and navigation assistance is provided.

Graphical Profiles: Individual Lab and Vital Signs Profiles can be displayed graphically. A second graphical patient profile displays a subject's entire experience in the study, showing safety information including exposure, adverse event, concomitant medication, lab, ECG and disposition data. No external programming is needed for these displays.

Narratives: No support for narratives available using the standard configuration.

Conclusion:

The tools reviewed vary with respect to setup, ease of customization of use and level of interactivity. Only 2 tools include support for narratives. Machine-readable patient narratives will enable more efficient use of narrative data. As a more patient centric approaches to subject level data review evolve, the tools will need to evolve with them. Next steps for this group will be to determine the functional characteristics that are most useful for the visualization of subject level data review.

Thank You to reviewers Karnika Dalal and Mike Robinson and to the Data Visualization Subject Level Data Review Team!

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