35. Data Visualization Working Group, Subject Level Data Review & Visualization – Final Results

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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 <white paper> evaluates ways in which visualizations are used to review data at the patient level. Last year the Data Visualization working sub-group conducted an analysis of the current tools used to review subject level data, including the use of interactive visualizations for generating patient profiles and patient narratives which had not been done in over 5 years. Based on the results of the initial survey, we did a follow on survey to explore in more detail topics presented on the first survey. The second survey covered Tabular Patient Profiles, Graphical Patient Profiles and Patient Narrative and explored feature areas including Data, Display/Use, Exporting/Printing, Licensing.

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 SOCs of adverse events during exposure and/or other information relevant to the trial can be displayed.

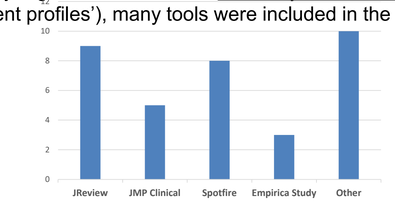
2. Graphical Patient Profiles are time oriented, visual presentations of subject level study data requiring little or no external data preparation or programming. These profiles may focus on a specific area such as liver function or depict a comprehensive view of the subject's time in the trial and include 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. A follow-up presentation and discussion with survey questions posed to the participants was conducted October 16, 2018.

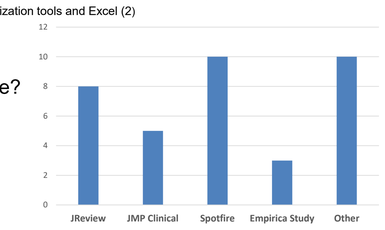
Results of Survey 1:

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.



Total respondents = 20
'Other' included: SAS (3), SAS & R (2), SAS Visual Analytics (2), SAS and Microsoft Word (1) and Custom built visualization tools and Excel (2)

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



Total respondents: 20
'Other' included SAS (2), SAS & R (2), SAS Visual Analytics (2), SAS & Word (1), Custom built/internal tools (3)

Survey Question 3: What tools are currently being used within your company/organization 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.**

Results of Survey 2 – desired functionality

1=Critical;2=Very Useful;3=Useful;4=Nice to have;5=Not needed – listed as (response-counts; response-counts)

Graphical Patient Profiles, Display/Use

1. Scrollable display – horizontally – through available days axis; vertically – through different types of data (1-1;2-1;4-2)
2. Ability to click a point or duration bar to drill into details (1-1;2-1;3-2;5-2)
3. Ability to include any data item from study – from standard SDTM (3-2;4-3); from custom domains (3-3;4-2)
4. Ability to display reference ranges for Vitals, Labs, ECG, other (1-2;4-2)
5. Ability to display duration bars for Aes, Conmeds, Dosing, etc. (1-1;2-3;3-1;4-1)
6. Ability to calculate days (based on dates in data) without external programming (2-4;4-1;5-1)
7. Ability to drill down from aggregated view of data (scatter plot, etc.) to a patient profile (1-4;2-1)
8. Settings to allow bookmarking or commenting on interesting findings when reviewing profile (1-2;3-1;4-2)
9. Ability to call other software (R or SAS) to run on underlying data and display results in current tool (3-1;2-3;5-1)
10. Ability to define/save multiple graph patient profiles – with different content-for targeted use (2-1;3-3;4-1)

Graphical Patient Profiles, Data

1. Ability to work with CDISC SDTM (1-1;2-1;3-2;4-1) with CDISC AdAM (2-2;4-4;5-1)
2. Ability to work with both CDISC SDTM and ADaM and merge datasets (2-2;3-1;4-1;5-1)
3. Ability to work with any clinical data source (e.g. legacy format) (1-1;2-3;3-2;4-4)

Tabular Patient Profiles, Display/Use

1. Display of nicely formatted tabular patient profile for selected patient (1-3;2-2)
2. Sufficient content, display, formatted for use both internally as well as submit to regulatory agencies (1-1;2-4)
3. Scrollable display – vertically and horizontally (1-1;2-3;3-1)
4. Export tabular profile as a PDF or print (1-2;2-2;3-4)
5. Batch processing of a set of profiles – to reduce time of generation (1-1;2-3;3-1)
6. Ability to easily drill down from an aggregated view (scatter plot, etc) to patient profile (1-1;2-2;4-1)
7. Settings to allow bookmarking or commenting on interesting findings when reviewing profile (2-1;3-1;4-2)
8. Highlight new or updated data since last patient review (1-1;2-1;3-2)

Tabular Patient Profiles, Data

Basically same responses to questions listed under Graphical Patient Profiles, Data section

Patient Narratives, Display/Use

1. Interactive display of generated 'automated text' with ability to insert 'free text' additional content where desired after review of 'automated text' for any of the patients (2-2)
2. Generate the completed narrative including any embedded reports or graphs (for current patient) (2-2;3-1)
3. Save the generated patient narrative as a PDF or RTF (1-3)
4. Batch schedule/batch processing of patient narratives – generating separate RTF per patient (3-2;4-1)

Patient Narratives, Definition within product/environment

1. Ability to define a patient narrative template – defining where/when to insert data items from the study (similar to MailMerge in Word). (1-1;2-1)
2. Ability to define 'conditional' inclusion of template text based on a condition definition, i.e., if patient reported a serious AE, then include a paragraph describing the serious AE. (1-1;2-2)
3. Ability to include 'aggregate function versions (min, max, mean, etc.) of data item – with definition of filtering of which rows should be included, for example, max systolic BP post baseline. (3-2)
4. Ability to insert reports or graphs to further illustrate information within the narrative (3-2)
5. Ability to define/save multiple patient narrative definitions – with different content – for different targeted use (2-2;3-1;4-2)
6. Ability to define the criteria for selection of patients who need to have narratives generated (1-3;2-3)
7. Works with any clinical data source (CDISC or legacy format) (1-3;2-1;3-1)
8. No need for external data transformation or data programming/preparation – all handled by the application(3-4)

Overview of products mentioned:

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. The second survey investigated detailed functional characteristics that are considered useful for the visualization of subject level data review.

Thank You to the Data Visualization Subject Level Data Review Team!

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