SCALABLE AND EFFICIENT BIOMARKER VISUALISATION TECHNIQUES FOR EARLY-PHASE CLINICAL TRIALS

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BACKGROUND

- Early-phase clinical trials analyses can address a wide array of biomarkers for:
  - Safety
  - Pharmacodynamics
  - Primary evaluations
  - Exploratory evaluations
- Objective: Develop an efficient, scaleable, and generic process to address biomarker visualization requirements for an early-phase study

METHODS

Step 1: SAS macro RMGSPOTTXT converts SDTM data (i.e. domain lb) to .txt files for input into TIBCO Spotfire®:

```
%rmgspottxt (indsn      = lb,
             adsl       = adsl,
             trt        = trt,
             outtxt     = biomarkers.txt,
             domain     = lb,
             testcd     = CEA|CA199||HER2|EGFR,
             testcdx    = ,
            %nrstr(Carcinoembryonic Antigen|CA 19-9 Radioimmunoassay|
                   Human Epidermal Growth Gactor Receptor 2|
                   Epidermal Growth Factor Receptor),
             suppname   = ,
             visits     = SCREENING|VISIT 1|VISIT 2|VISIT 3|VISIT 4|VISIT 5|
                          VISIT 6|VISIT 7|VISIT 8|VISIT 9|VISIT 10|END OF TRT,
             visitsx    = SCR|V1|V2|V3|V4|V5|V6|V7|V8|V9|V10|EOT);
```

Macro specifics:

- Allows SDTM domain (i.e. lb, vs) choice
- Can identify multiple tests for graphing
- Can specify additional test identifiers (i.e. lbspec, lbmethod)
- Data-driven visit padding by trt and test
- Generates mean result values for repeat tests
- Creates x-axis timepoint labels, graph test headers; output .txt

Step 2: : Input .txt file into TIBCO Spotfire® pre-defined template (.dxp file) for subject line graphs:

- Timepoints on x-axis; numeric test results on y-axis
- Trellised by trt, test, units
- Legend: subject by color
- Break line for missing timepoints

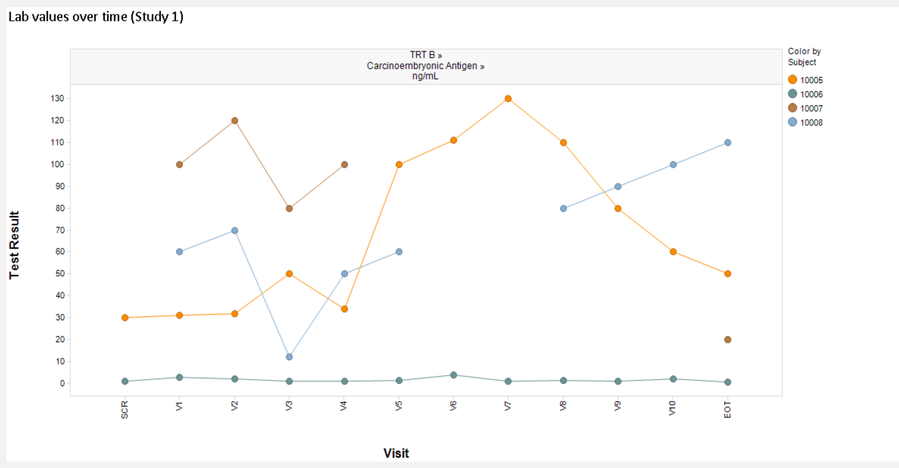
Step 3: Publish to internal server for clinical staff viewing via TIBCO Spotfire® Web Player, access with hyperlink

RESULTS

TIBCO Spotfire® Web Player:

- Allows interactive filtering (all fields available for filtering on right, can scroll down)
- Panels appear/disappear depending on field filter choices
- Hover over timepoint to see field values in record
- Sliders available for axis zoom

Export subject line graph for Carcinoembryonic Antigen test, treatment group B to .ppt slide:



- Possible process enhancement: Add to TIBCO Spotfire® pre-defined template library (i.e. subject mean bar charts per timepoint)

CONCLUSION

- Interactive graphing capability of TIBCO Spotfire® enables rapid, real-time changes to graph characteristics via .dxp template
- Clinical clients can independently customize developed graphs in TIBCO Spotfire® Web Player via hyperlink and export to .ppt slides
- TIBCO Spotfire® can be used to generate efficient and scalable biomarker visualizations for early-phase studies