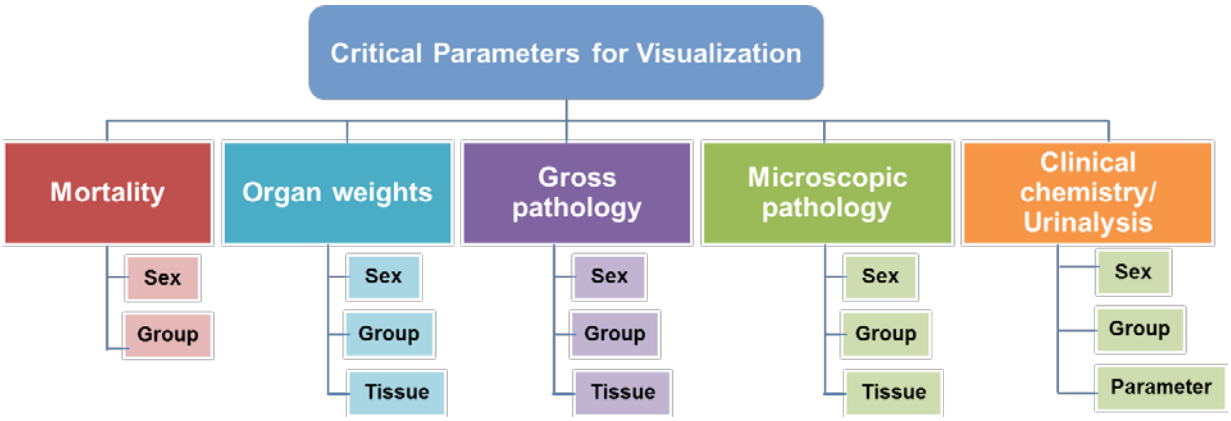
Collation of Survey Results (Questions A1 to B1)

A1. What scientific questions or specific analyses appear most appropriate for graphical displays of pathology data (gross observations, histopathology findings, pathology scoring systems)?

Based on survey results the following analyses are considered appropriate for graphical displays of pathology data:

- Mortality data (presented sex and also groups)
- Organ weights (presented for each organ separated based on sex and groups)
- Gross pathology (presented for each tissue separated based on sex and groups)
- Microscopic pathology (presented for each tissue separated based on sex and groups)
- Clinical laboratory data (presented for each parameter separated based on sex and groups)

Analyses considered appropriate for graphical displays are shown in the flow chart below:



Critical objective is to determine the purpose of graphical displays:

- For data analysis/interpretation
- For data presentation

Graphical displays should be helpful to compare/aggregate data across multiple studies and or multiple compounds. Historical control/background lesion data could be collected and displayed from multiple studies

Graphical displays will be more helpful if gross and histopathology data can be correlated to clinical laboratory/organ weight data.

A2: In what instances (use cases) would graphical/visual display of pathology data provide significant value?

Graphical displays would provide significant value in:

- To understand treatment or dose related effects
- To correlate between different findings in other domains
- To recognize patterns across studies
- For biomarker qualification studies
- To aggregate data from multiple studies
- To understand the trends based on historical control groups
- To communicate the pathology findings to project teams
- To understand the overall effects of a drug/compound at multiple systems level

B1: What software tools are individuals currently using for graphically displaying/ analyzing histopathology data? Are these tools commercially available or in-house custom designs?

Software tools currently being used for graphical display of pathology data:

- Pristima reporting tool (in-house custom design tool)
- TSP (in-house custom design tool)
- Spotfire (commercial tool)
- Sigma-Plot (display only) (commercial tool)
- Tableau/R (commercial tool)
- SAS (commercial tool)
- Matlab (commercial tool)
- MiniTab (commercial tool)
- Image Minor (commercial tool)
- Excel (commercial tool)
- PathData transferred to Excel (commercial tools)

Two in-house and several commercial tools were mentioned in the responses; however, Spotfire tool is mentioned several times as being currently used for the display of pathology data

It is also noted that some of the aforementioned tools are for statistical purposes rather for visual display.

B2: Are these tools being used for analyses within a single study or across multiple studies?

Both single (primarily) and multiple studies

B3: What are the strengths and weaknesses of the current tools? What functionalities are currently missing or unaddressed which would be beneficial ?

Strengths

- Graphical displays allow incorporation of datasets from other domains
- Standard data tables provide incidence, severity and lesion description

Weaknesses

- Software is not user friendly
- User interface and functionality challenges
- Lack of familiarity with software tools

C1: What visual displays, cues or guides would provide the greatest benefit for analysis and communication of treatment-related changes?

- Color coding/grey scale for severity scores
- Heat maps
- Histograms
- Boxes with variable size based on incidence of lesions
- Linking data from various domains
- New ways to display incidence and severity data

C2: What limitations or caveats exist for displaying and analyzing histopathology data using visual/graphical displays versus standard data tables and written statements? (Examples include variance in lesion terminology and the qualitative nature in assigning severity scores, differences across labs and studies, etc.)

- Impact of background lesions and/or changes in control group on interpretation of changes seen in drug-treated groups
- Statistical analysis of histopath data is problematic
- Variances in terminology for lesions across studies
- Differences in ranges and definitions for severity scores across studies
- Qualitative and subjective nature for describing/evaluating/scoring pathology data
- Ability to present detailed descriptive data in visual display

C3: What cross-domain analyses (e.g. histopathology, clinical lab data, organ weights, TK/exposure data) lend themselves to graphical display?

- Numerical data are important
- Macroscopic to microscopic correlations
- Important to use tools in focused fashion, versus general searches/"fishing expeditions"
- Cross-domain analysis on case-by-case basis to investigate specific questions
- Cross-domain analysis listed above plus linking to –omics data, cardiovascular assessments, clinical signs, imaging data