# CSS White Papers: Central Tendency Standard Analyses

#### General Requirements for Central Tendency Analyses

For output and formatting requirements that apply in broadly to CSS white paper analyses, see the co-located document ["CSS\_GeneralOutputandFormattingRequirements.docx"](https://github.com/phuse-org/phuse-scripts/tree/master/whitepapers/specification)

The following excerpts from the Central Tendency white paper apply generally to CT displays.

* Types of studies, focus of these analyses:
  + Phase 2 to 4 studies are in scope (p. 5)
  + trials that include a comparison arm (p. 9)
  + single and multiple active treatment arms are in scope (p. 11)
* Types of data, focus of this white paper pertains to specific safety measurements (p. 5):
  + vital signs,
  + ECG quantitative findings, and
  + laboratory analyte measurements
  + Active treatment intervals are primary interest (p. 9)
    - generally exclude data collected during a "follow-up" phase
    - recommend to exclude data collected after "study medication discontinuation"
  + Recommend attributing unscheduled "discontinuation" data to the next scheduled time point (p. 10)
* Types of Methodologies, purpose of these analyses:
  + to identify meaningful safety signals relative to a comparator group (p. 9)
  + descriptive statistics measurements include:
    - mean,
    - standard deviation,
    - minimum,
    - q1,
    - median,
    - q3 and
    - maximum
  + P-values presented are not for hypothesis testing, only for reviewing the data.
  + P-values can therefore be excluded from the display (p. 8)
  + Change from baseline vs. Min/Max change (p. 11)
    - For change from baseline to endpoint analyses, include only planned measurements
    - For Min/Max changes, include unplanned measurements