

# Statistical Analysis Template

<b>Statistical Analysis Overview</b>	* Comparison Group Selection ①	<input type="checkbox"/> Arm/Group 1	<input type="checkbox"/> Arm/Group 2	<input type="checkbox"/> Arm/Group 3	
	Comments ②				
	* Type of Statistical Test	(Select One) Superiority Non-inferiority	Equivalence Other (for example, single group or other descriptive analysis)		
	[*] Comments ③				
<b>Statistical Test of Hypothesis</b>	[*] P-Value (if applicable)	_____ (calculated value, not the a priori threshold for statistical significance)			
	Comments ②				
	[*] Method (required if p-value entered)	(Select One) ANCOVA ANOVA Chi-Squared Chi-Squared, Corrected Cochran-Mantel-Haenszel	Fisher Exact Kruskal-Wallis Log Rank Mantel Haenszel McNemar	Mixed Models Analysis Regression, Cox Regression, Linear Regression, Logistic Sign Test	t-Test, 1-Sided t-Test, 2-Sided Wilcoxon (Mann-Whitney) Other (_____)
	Comments ②				
<b>Method of Estimation</b>	[*] Estimation Parameter (if applicable)	(Select One) Cox Proportional Hazard Hazard Ratio (HR) Hazard Ratio, Log Mean Difference (Final Values)	Mean Difference (Net) Median Difference (Final Values) Median Difference (Net) Odds Ratio (OR)	Odds Ratio, Log Slope Risk Difference (RD) Risk Ratio (RR) Risk Ratio, Log	
	Estimated Value	_____ (calculated value)			
	Confidence Interval (if applicable)	Level: _____ % Confidence Interval Number of Sides: (Select One) 2-sided 1-sided Lower Limit: _____ Upper Limit: _____			
	Parameter Dispersion	Type: (Select One) Standard Deviation Standard Error of the Mean Value: _____			
	Estimation Comments ②				
<b>Other Statistical Analysis ④</b>					

\* Required      [\*] Conditionally required

- ① Use the checkboxes to select the Arms/Groups (pre-populated from the Outcome Measure) involved in the statistical analysis.
- ② (Optional) Include any relevant information about the row above (e.g., the null hypothesis, details of the power calculation, adjustment for multiple comparisons, the a priori threshold for statistical significance, the direction of the comparison). Do not include written results or conclusions.
- ③ If a non-inferiority or equivalence analysis, information on the definition of the non-inferiority or equivalence margin is required.
- ④ If the statistical analysis cannot be submitted using the Statistical Test of Hypothesis or Method of Estimation options, provide a description and the results of the scientifically appropriate test of statistical significance.