

# STATISTICS



**Outlined below are the key responsibilities of  
Statistics team:**

Phase	Activities Phase Performed
<b>Start up</b>	<p>Sample Size Calculation: Decide how many participants are needed</p> <p>Statistical Section in Protocol: Write the statistical part and randomization section of the trial protocol</p> <p><b>Statistical Analysis Plan (SAP):</b> Prepare SAP outlining exactly how the data will be analyzed</p> <p><b>Randomization Plan:</b> Create a method to assign participants to treatment groups fairly</p> <p><b>Review of Study Documents:</b> Check protocol, Case Report Form, Data Validation Plan, Data Specifications for statistical accuracy</p>
<b>During Study</b>	<p><b>Data Monitoring:</b> Review incoming data for trends, errors or missing values</p> <p><b>Interim Analysis:</b> Analyse early data to check safety or efficacy, if planned</p> <p><b>Protocol Deviations Review:</b> Assess impact of deviations on data quality</p> <p><b>Support DSMB/DMC:</b> Provide statistical reports for Data Safety Monitoring Board or Committee reviews</p>

<b>Study Closure</b>	<p><b>Final Data Analysis:</b> Conduct final statistical analysis on clean and complete data to give accurate and quality analysis</p> <p><b>Statistical Input to CSR:</b> Provide results and interpretation for the Clinical Study Report (CSR)</p> <p><b>Support Publications:</b> Help prepare tables, graphs and analysis for papers or presentations</p> <p><b>Archival of Analysis Outputs:</b> Store all final statistical files securely</p>
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Thus, the Statistics Department ensures scientific rigor by planning analyses, monitoring data quality and delivering reliable results that support clinical trial decisions and regulatory submissions

## Primary Technology / Tools used by Statistics

### Department:

- **Statistical Analysis System (SAS):** Software suite used for managing, analyzing and reporting clinical trial data to ensure regulatory compliance and facilitate evidence-based decision-making
- **PASSv2:** It is a specialized statistical software used for calculating sample sizes and power analysis to ensure the study is designed with adequate precision to detect treatment effects reliably
- **nQuery:** It is a specialized statistical software used to calculate sample size and power, helping design studies that are scientifically valid and regulatory compliant