# Biostatistician Key Responsibilities in Phase III Clinical Trials

## 1) Protocol Development

- Contribute to clinical protocol writing and statistical strategy
- Define study design, endpoints, estimands
- Develop randomization strategy and stratification
- Conduct sample size and power calculations

## 2) SAP Development

- Lead Statistical Analysis Plan (SAP) development
- Define analysis populations: ITT/mITT/PP/Safety
- Specify statistical methods for primary & secondary endpoints
- Define multiplicity control and interim analysis
- Plan sensitivity & subgroup analysis

## 3) Randomization Implementation

- Set up allocation and stratification
- Collaborate with IRT/IXRS vendors
- Validate randomization lists

## 4) Data Quality & Data Review

- Work with DM & clinical teams on data cleaning
- Review derivations for endpoints
- Ensure AE/SAE coding consistency

## 5) Interim Analysis & DMC Support

- Define IA boundaries (futility/efficacy)
- Ensure alpha control
- Support DMC safety reviews

## 6) Programming & TLF Review

- Define TLF shells

- Review SDTM/ADaM datasets
- Review analysis output (TLFs)

## 7) Final Analysis

- Perform primary & secondary analyses
- Conduct sensitivity & subgroup analyses
- Interpret results with clinical team

## 8) CSR Support

- Draft statistical sections in CSR
- Review and validate results tables/figures

## 9) Regulatory Submission

- Support NDA/BLA submission
- Prepare ISS/ISE
- Generate TLFs & datasets
- Respond to FDA inquiries

## 10) Publication & Post■hoc Analysis

- Support manuscript and conference work
- Conduct exploratory analyses