BIOSTATISTICS AND STATISTICAL PROGRAMMING

HCL's Team of Biostatisticians and SAS Programmers have a broad knowledge base in all aspects of the clinical trial process from the initial set-up to the final analysis.

The team has both Master's and PhD degree holders with experience of working on a broad range of therapeutic areas. As per client requirements, data is often formatted to CDISC standards for consistent reporting to regulatory authorities. We follow the global standard operating procedures and have detailed and extensive knowledge of worldwide regulatory requirements.

HCL's experts map the analyses you will need before the study begins, then create Statistical Analysis Plans (SAP), generate Tables, Listings and Figures, provide reports, statistical summaries, efficacy and safety analyses promptly and accurately as the study progresses. Our Biostatisticians follow SOPs to ensure the consistency and integrity of study results. We have a multi-stage procedural and scientific QC process. Our procedural QC process involves periodic review of programming standards (program structure, notation, unit testing and electronic filing of programs).

Our flexibility in accommodating changes to project specifications is paralleled with a complete audit trail; while maintaining quality of study data and adhering to expected study timelines. We can leverage our vast statistical experience to design studies in a way that speeds up submissions.

Biostatistics and statistical programming services include:

- Protocol development, including sample size and power calculations
- Randomization schedules
- Statistical Analysis Plans (SAP)
- Clinical and Statistical SAS® programming(Generation of Tables, Listings and Figures Programming)
- CDISC® Study Data Tabulation Model (SDTM) Mapping & Conversion, Generation of ADaM (Analysis of Data Models)
- Analysis Dataset Programming and Documentation
- Interim analysis for early decision making
- Tables, Listings and Figures Validation and Quality Control
- Integrated Summary of Safety (ISS) and Efficacy (ISE) summaries
- Ad hoc Statistical Support
- Meta Analysis – our expert Statisticians can advise on potentials for bias during a Meta Analysis as well as on statistical methods to use.
- Statistical Representative at FDA Pre and Post-Submission Meetings
- Interpretation and reporting of data for clinical trial reports and publications

HCL has done good number of high order crossover trial designs, for which a highly experienced team will be involved. As these are the very complex trials, each design depends on the number of periods and the number of treatments to be compared with. Our resources have extensive experience across several design types. HCL has developed a workflow management tool- CORP (Clinical Operations Reference Platform) specifically designed for supporting statistical services to provide Sponsors with real time visibility on the status of each work request and deliverables in alignment with the defined schedule.