CRO BIOSTATISTICAL SERVICES

Clinical Biostatistics & Statistical Programming

Pepgra's biostatisticians direct sponsors in trial design; conduct analysis and evaluation of clinical trials—on par with CDISC (SDTM and ADaM) standards.

"Comprehensive clinical and regulatory biostatistics and statistical programming services in all phases of drug and device development".

Pepgra offers regulatory biostatistics and statistical programming services as per International Conference on Harmonization (ICH) E9 guidelines. We have a thorough understanding of the science of diseases and compounds; this know-how equips us to provide comprehensive planning and assistance.

We offer advanced CRO biostatistical capabilities with solid experience in a wide range of therapeutics and complex study designs (e.g., adaptive, Bayesian BLRM statistics, especially for medical devices, outcome, depending on switching/crossover biomarker) and the implementation of complex methods in macros (RPFST, IPE, IPCW). Our regulatory biostatisticians have a firm grasp of time-tested and latest statistical methods to give you an accurate evaluation of scientific data with experience in handling all phases of drug development and medical device clinical studies in every therapeutic area.

Our regulatory biostatisticians and programmers are an integral part of the assessment process as we perform regular training sessions on relevant topics such as **CDISC** (SDTM, ADaM), **ICH** and agency guidelines (e.g. FDA, **Section 513(a)** of the Federal Food, Drug and Cosmetic Act (FFDCA) mandates the Bayesian approach as the least burdensome appropriate means of evaluating effectiveness of a device). Therefore, we guarantee that the statistical principles outlined in the ICH E9 are in conformation when we analyze and generate datasets, tables, listings, and graphs clinical trial data for submission to regulatory authorities. We adhere to QC phases: 1) validation of programming specifications, 2) code review and validation, 3) data quality checks, and 4) standard QC checklists.

Researchers develop innovative methodologies and analytical techniques using SAS and R Programming. We join hands with the best in the field of health and medicine to provide efficient and cost-effective analysis related to neuroimaging, cardiac and pulmonary diseases, and many other clinical disciplines. We customize services to meet your requirements and thus add value to the time and money you invest in us.

Comprehensive Biostatistics and Statistical Programming Solutions

Design and data collection

- Comment and describe the objectives, design, method--ology, statistical considerations, and organization of a trial from initial dose titration through post-marketing services.

- Analyze in real-time and present findings through scientifically sound interpretation and report those findings.
- Create randomization schedule.
- Craft techniques to circumvent bias in clinical trials – blinding, randomization.
- Consider various trial designs: parallel group design, cross-over design, and factorial.
- Estimate sample size based on the study objective (safety and efficacy) and clearly highlight null hypothesis and its alternative.
- Proffer support to collect primary and secondary documents from a wide range of source documents that includes hospital records, clinical and office charts, laboratory notes, memoranda, pharmacy dispensing records, subject diaries or evaluation checklists, copies or transcriptions certified, microfilm, x-day, and from any other documents.
- Streamline process for targeted on-site monitoring and selected sites.

CRO biostatistics offerings

- Identify missing data, inconsistent data, outliers, and unexpected lack of variability and deviation in the protocol.
- Perform data transformation, estimation, confidence intervals, hypothesis testing, adjustment of significance and confidence interval.
- Examine data trends in terms of consistency, range and data variability within and across sites.
- Statistical Analysis Plan (SAP) development, mock tables and LoT.
- Guide programmers and review (validate) TLGs (tables, listings, graphs)
- Compare multiple treatments: Intent-to-treat (ITT) analysis, multiple primary variables (e.g., Dunnett's, Bonferroni Correction, closed test procedures, and single primary treatment comparison), treatment through center interaction, dose response analysis, and magnitude effect.
- Evaluate significant or systematic errors in data collection and report on-site or across site. Report data integrity problems or potential data manipulation.
- Analyze characteristics of the sites and performance metrics.
- Interim analysis to compare treatment arms with respect to efficacy or safety.
- Develop statistical analysis plan: technical and detailed elaboration of the principle features stated in the protocol. Respond to request and queries from regulators.

Statistical programming services

- Develop patient profiles and in-text tables, figures, graphs and patient data listings.
- Customize offerings for process standardization and build standard macros.
- Develop datasets for Study Data Tabulation Model (SDTM).
- Define dataset and metadata support via Analysis Data Model (ADaM) datasets (required by FDA, US; PMDA, Japan) and create ".XML" file formats.
- Strategize program specs, analyze datasets and Tables, listings and Graphs (TLGs) for safety, efficacy, pharmacokinetic (PK), and Pharmaco Dynamic (PD) endpoints.
- Seamless support for interim analysis, data monitoring committee meetings, database lock related activities and regulatory submissions activities.
- SDTM Data mapping—conversion and migration—on par with industry standards; includes legacy applications. End-to-end submission in all facets of clinical trial development.
- Full-fledged programming support for regulatory functions, clinical operations, data management and statistics.
- Comprehensive programming support services: Clinical Study Report (CSR), Integrated Summaries of Safety (ISS), and Integrated Summaries of Efficacy (ISE) submissions.

Our Expertise and Experience

Here are the advantages of roping in Pepgra experts:

- Well-versed in working with various stakeholders like clinical operations, data management, biostatistics, medical and safety teams to deliver documents.
- Experience in writing documents for various phases of clinical development including Phase I to Phase IV, PMS and Post-Authorization Safety Studies (PASS).
- Includes medical devices, prescription drugs (with extensive knowledge of pharmacokinetics, pharmacodynamics, and pharmacogenomics), over-the-counter medicines, veterinary medicines, cosmetics, biologics and nutraceuticals.
- Complete understanding of drug development process, including New Chemical Entities (NCEs), generic, biologics and biosimilars.
- Adherence to country-specific guidelines and norms.
- Knowledge of guidelines pertaining to the following: GPP3, International Committee of Medical Journal Editors (ICMJE), Consolidated Standards of Reporting Trials (CONSORT), Strengthening the Reporting of Observational studies in Epidemiology (STROBE), Preferred Reporting Items for Systematic Reviews and Meta-analysis (PRISMA) and other applicable regulatory guidelines

Therapeutic Areas that we work

Vast experience in working across multiple therapeutic areas like Biochemistry, Diabetes, Gastrointestinal, Renal/Nephrology, Respiratory, Psychiatry, Rheumatology, Cardiovascular, Toxicology and Oncology

Editing & Formatting:

Submission-ready documents in terms of technical information, language, format, and template used to prepare the document

Our Quality Control & Assurance:

All our clinical development services are done in accordance with our SOPs compliant standards. All our regulatory documents undergo thorough scientific, medical, editorial, quality check and assurance to ensure that the clinical documents we produce are scientifically accurate.

The documents are prepared using sponsored-provided materials SOPs or Pepgra suite of International Conference on Harmonization ICH-compliant templates and style guides. In either case, Pepgra medical writing team ensures that the document we produce is of the highest quality in terms of scientific content, style and formatting.

ABOUT US

At Pepgra we are open to new ideas, different people and various cultures. We'd love to hear as to what you can offer us and we'd like to reciprocate as well. People with ideas, skills and qualifications in the medical and pharmaceutical industry are welcome to contact us for any kind of CRO engagements.

Pepgra has plenty of skills to offer you in various phases of clinical research trials. Be it regulatory writing, biostatistics, regulatory approvals, trial monitoring, drug/device development, and clinical reports.

Our native experts know your market, ethics, protocols and culture. Pepgra is your reliable CRO ally who can pitch in when it is critical. Become our partner today.

LEARN MORE

We have a team of more than 200 professionals, experienced editors in scientific, technical, and medical publications. For more information or to request a demonstration, visit us at **www.pepgra.com** or email us at **pepgrahealthcare@gmail.com**

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