Hill Research

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BIOSTATISTICS & BIOSTATISTICAL PROGRAMMING

DRUG DEVELOPMENT PROGRAM DESIGN FOR CLINICAL TRIALS OF ALL PHASES

- Development of clinical trial protocols, including study design, power and sample size determination, and creation of randomization schedules
- Preparation of the Statistical Analysis Plan (SAP) and development of TFL shells in accordance with the clinical study protocol

CDISC

- aCRF annotation
- SDTM and ADaM dataset specifications, SDTM, ADaM data set generation, independent validation of SDTM and ADaM datasets, including Pinnacle 21 validation and report
- Creation of Define.xml, SDTM and ADaM Reviewers Guides

FDA SUBMISSION

- New Drug Applications (NDA), Biologics License Applications (BLA), and Integrated Summaries of Safety and Efficacy (ISS/ISE)
- Clinical Data Interchange Standards Consortium (CDISC) deliverables, including Study Data Tabulation Model (SDTM) and Analysis Data Model (ADaM)
- Electronic Case Report Tabulation (eCRT) submission packages
- Define.xml / Data Definition Tables (DDT)
- Investigator's Brochures (IB)
- Investigational New Drug (IND) applications
- Statistical defense of data and analysis results
- Statistical evaluation of data and analysis results of drug candidates

Comprehensive Trial Support

Full-service expertise from study design, SAP, randomization, and dataset creation to final CSR and regulatory submission.

Regulatory Submission Excellence

Proven experience with NDA, BLA, IND, ISS/ISE, and FDA-compliant deliverables including SDTM, ADaM, Define.xml, and eCRT packages.

Unmatched Data Quality & Validation

Rigorous QC, independent validation, Pinnacle 21 checks, and BIMO readiness to ensure accuracy, integrity, and compliance.

Integrated Analysis & Communication

Advanced statistical analyses, interim monitoring, data integration, and collaborative medical writing to deliver impactful reports and publications.

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STATISTICAL PROGRAMMING AND REGULATORY SUBMISSION DELIVERABLES

- Development of analysis datasets and TFLs to support Clinical Study Reports (CSRs), ad-hoc analyses, publication, signal detection, planning and designing of new studies. These include analyses of data from combined studies and individual studies, post-hoc analyses
- Independent validation of datasets and TFLs to ensure accuracy and compliance with statistical standards
- Conduct database quality reviews, perform data reconciliation, and consistency checks across sources
- Execute dry runs and prepare final deliverables of datasets and TFLs in FDA-compliant formats for New Drug Application (NDA) submissions

DATA INTEGRATION

- Data integration activities, including preparation of Integrated Summary of Safety (ISS) and Integrated Summary of Efficacy (ISE)
- Conversion of legacy datasets into CDISC-compliant formats (SDTM and ADaM)
- Assembly and quality control of analysis datasets, statistical tables, listings, and figures (TLFs)
- Preparation and QC of study reports and submission-ready deliverables to support regulatory filings
- BIMO (Bioresearch Monitoring Program) readiness support, ensuring traceability, data integrity, and compliance of submitted datasets and documentation for FDA inspections

INTERIM ANALYSIS AND DMC

- Statistical analysis and programming support for Data Monitoring Committee (DMC) and Data and Safety Monitoring Board (DSMB) activities
- Preparation of the Statistical Analysis Plan (SAP) and development of TFL shells in accordance with the clinical study protocol

MEDICAL WRITING AND PUBLICATIONS

- Cross-functional teams of Medical Writers, Biostatisticians, and Medical/Regulatory Reviewers work together to produce abstracts, manuscripts, peer-reviewed publications, conference presentations, and posters
- Development of abstracts, manuscripts, publications, presentations, and posters through collaboration between Medical Writers, Biostatisticians, and Medical/Regulatory Reviewers

Hill Research specializes in delivering comprehensive Biostatistics and Statistical Programming services to support clinical development from trial design to global regulatory submission. Our expertise spans protocol development, statistical analysis plans, dataset generation, and submission-ready deliverables for NDA, BLA, and IND filings. With deep knowledge of CDISC standards and FDA/EMA requirements, we ensure accuracy, compliance, and inspection-ready quality across all projects. Through rigorous validation, independent quality checks, and seamless collaboration between biostatisticians, programmers, and medical writers, we transform complex clinical data into reliable evidence and impactful publications. Trusted by leading pharmaceutical and biotech companies, Hill Research provides the end-to-end statistical and regulatory support needed to accelerate timelines and maximize the success of clinical trials.

TRUSTED BY GLOBAL LEADERS

Hill Research has already partnered with more than ten of the world's leading pharmaceutical companies. Notably, our clients include 2 of the top 3 and 5 of the top 10 global pharma leaders. Through these collaborations, we help accelerate clinical trials, ensure compliance, and achieve regulatory success.

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