

# FSP

## FUNCTIONAL SERVICE PROVIDER



Hill Research FSP model offers biotech and pharmaceutical companies flexible, scalable access to specialized expertise across biostatistics, statistical programming, and advanced technology enablement. By combining highly skilled professionals with AI-driven innovation and modern infrastructure, we deliver measurable efficiency, quality, and compliance for clinical development programs.

### KEY ADVANTAGES OF OUR FSP MODEL

Scalability	Flexibility	Innovation	Compliance	Cost Efficiency
Rapid deployment of FSP resources to meet fluctuating workload demands.	Dedicated or shared resources, fully aligned with sponsor governance models.	Unique integration of AI engineers into the FSP team to improve speed and quality.	End-to-end adherence to regulatory and CDISC standards, with inspection-ready deliverables.	Optimized resourcing through global talent pools and technology automation.

### ENGAGEMENT MODELS

<b>DEDICATED FSP TEAMS</b>	Embedded resources fully integrated into sponsor processes (systems, SOP/WI, operation model).
<b>HYBRID FSP + PROJECT MODEL</b>	Combination of long-term dedicated staff with project-based delivery.
<b>AI-ENHANCED FSP</b>	Traditional FSP services enhanced with AI tools to maximize efficiency and reduce cycle times.



## STUDY BIOSTATISTICIANS

- Study design, sample size estimation, and statistical methodology support.
- Development of Statistical Analysis Plans (SAP), Mock Shell and randomization schedules.
- Statistical oversight of Data Monitoring Committee (DMC/DSMB) activities, interim analyses, and integrated summaries (ISS/ISE).



## EXPERT BIOSTATISTICIANS

- Adaptive trial designs applied to oncology studies to enable flexible modifications during conduct
- Innovative designs for rare disease studies, including crossover and randomized delayed-start approaches
- Simulation of operating characteristics to evaluate and optimize study design strategies
- Trial event projection to support accurate study planning and execution timelines
- Power and decision boundary analyses conducted using R to guide interim and final decision-making
- Comparisons with virtually matched historical data to strengthen study outcomes and interpretability
- Expectation-maximization (EM) algorithms and Bayesian classification methods applied to blinded data for early insights into treatment effect
- Data mining, predictive modeling, and meta-analyses performed to inform trial outcomes and strategies
- Signal detection and monitoring implemented for continuous safety and efficacy assessment
- Exploratory analyses conducted to guide planning and design of future clinical studies
- Expert statistical programming support provided to deliver robust implementation of advanced methodologies for FDA interactions



## BIOSTATISTICAL PROGRAMMERS

- Development and validation of SDTM/ADaM datasets, tables, listings, and figures (TLFs)
- Support for clinical study reports (CSR), interim analyses, ad-hoc requests, and regulatory submissions
- CDISC-compliant deliverables and FDA/EMA submission readiness



## AI ENGINEERS

- Implementation of AI-powered automation for dataset conversion, TLF generation, and QC processes
- Predictive modeling and machine learning integration to optimize trial design, recruitment, and analysis efficiency
- Development of custom tools to reduce manual workload and accelerate timelines



## SAS/R INFRASTRUCTURE ENGINEERS

- Design, deployment, and maintenance of secure, compliant, cloud-enabled SAS environments
- Support for hybrid infrastructures integrating on-premise and cloud solutions
- Ensuring 21 CFR Part 11, GxP, and GDPR compliance for validated systems



## MORE CUSTOMIZED SERVICES

Hill Research delivers a flexible Functional Service Provider (FSP) model that scales with your clinical development needs.

We provide experienced biostatisticians and programmers who seamlessly integrate into sponsor teams, ensuring inspection-ready deliverables, regulatory compliance, and faster timelines.

With tailored engagement models and proven expertise, Hill Research helps you reduce risk, optimize resources, and maximize the success of your 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.