VERISTAT

Accelerate Trial Success with Biostatistics and Programming Excellence

Maximize Clarity, Confidence, and Success with Veristat

Veristat's Biostatistics and Statistical Programming (BSP) team plays a critical role in the design, analysis, and interpretation of clinical trials from first-in-human studies through regulatory approval and beyond.

Our global team of expert statisticians and programmers provides strategic insights, rigorous data analysis, and high-quality outputs to support sound decision-making and regulatory success. Whether designing a novel trial, conducting complex analyses, or preparing submission-ready outputs, we offer flexible support tailored to each client's needs.

Our Impact in Numbers

In the past 5 years, our Biostatisticians and Programmers have:

Supported **440+ clinical studies** across all phases

Contributed to **25+ marketing applications** (NDA, BLA, MAA)

Grown **a global team** across North America, Europe, and Asia

Delivered **therapeutic expertise** in oncology, rare disease, CNS, infectious disease & more

Global BSP Support Throughout the Development Lifecycle

Strategic Biostatistics

- Program & study-level statistical consulting
- Study design & sample size determination
- Adaptive and complex designs
- Endpoint selection & estimand framework
- Statistical sections for protocols, SAPs, and IBs
- Regulatory meeting preparation & responses

Clinical Trial Analysis

- Randomization & blinding schemes
- Interim & final analyses
- DMC support & unblinded analysis
- PK/PD & biomarker analyses
- Support for efficacy, safety, & exploratory endpoints

Submission-Ready Programming

- SDTM/ADaM dataset creation and validation
- TLFs for CSR, DSUR, IB, and submissions
- ISS/ISE support
- Regulatory-compliant programming
- Traceability and audit-readiness

Biostatistics Success Stories: Trusted Results with Veristat

1 Navigating Clinical Trials with Precision: Enhancing DMC Services Through Veristat's Expert Biostatistics

A global biopharmaceutical company conducting a Phase 3 trial for relapsed refractory multiple myeloma turned to Veristat for biostatistical and program management support for their Data Monitoring Committee (DMC). Facing challenges with interim analyses, complex methodologies, and regulatory compliance, the sponsor needed a structured approach to ensure timely decision-making and trial integrity. Veristat assigned a skilled project manager and senior biostatistician with 30 years of experience to oversee DMC statistical reporting, interpret interim data, and maintain trial integrity while adhering to guidelines. The trial stayed on schedule, achieving key milestones without delays.

2 Supporting a Sponsor from SPA Rejection to BLA Submission

Veristat guided a biopharmaceutical company from FDA rejection of their Special Protocol Assessment (SPA) to regulatory approval and clinical advancement. By refining the trial design and statistical analysis, we helped them secure SPA approval, enabling the Phase III pivotal trial. A 'missing data problem' was skewing study results Our powerful fix? A trimmed means approach adjusts for bias and strengthens statistical accuracy. Our collaboration soon expanded, leading to the preparation of an Integrated Summary of Safety (ISS) for the sponsor's Biologics License Application (BLA).

3 Understanding and Operationalizing a Complex Adaptive Design

Veristat helped our biopharmaceutical sponsor navigate an adaptive Phase II trial for a promising cancer vaccine. Due to our biostatistics team's efforts and ability to explain the study to the FDA, EMA, and Japan PMDA, it received approval across 65 sites in 14 countries, enrolling 300+ patients. Our project teams implemented the design, and the study ran smoothly until the first interim analysis. The adaptive design led to a go/no-go decision, allowing the sponsor to reallocate resources toward developing the vaccine for other cancers.

Meet Veristat

The CRO and Consultancy That Delivers Results

Engage Veristat for the planning and biostatistical analysis of your clinical trials and regulatory submission projects. We offer strategic guidance from early development through approval, with flexible and scalable delivery models, a collaborative partnership across functions, and a proven record of regulatory success.

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