



BioStat Solutions, Inc. (BSSI) is a professional service corporation providing strategic consulting and statistical expertise to pharmaceutical and biotech companies as well as to the government and its contractors since 2001. We offer our clients access to a diverse in-house team of statisticians, biostatisticians, epidemiologists along with clinical pharmacology, biomarker, and clinical trial experts.

Clinical Study Support

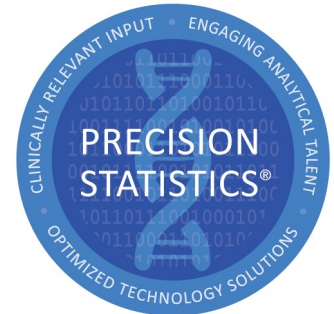
BSSI is not a Clinical Research Organization (CRO) though we assist many clients with their more complex clinical studies. Whether it is a small preclinical or Phase I study with complex safety, pharmacokinetic or pharmacodynamic data or a larger Phase II or Phase III study with complex or adaptive study designs and/or multifaceted biomarker data, BSSI provides not only tables, figures and listings (TFLs) but helps with the conceptualization, design, and interpretation of the results. BSSI has a strong and experienced team that welcomes challenges and surpasses expectations.

- Protocol conceptualization and design
- Statistical design, power and sample size
- Analysis of complex studies (crossover trials, basket trials, umbrella designs, adaptive designs)
- Statistical Analysis Plans (SAP), TFL generation, Statistical Analysis Reports (SAR)
- Development of Clinical Data Interchange Standards Consortium (CDISC) compliant data sets, Study Data Tabulation Model (SDTM) and Analysis Data Model (ADaM) for regulatory submissions
- Interim safety reports/analyses and interpretation for Safety Monitoring Committee (SMC) and Data Safety Monitoring Board (DSMB)
- Analysis and interpretation of Pharmacokinetics (PK), Pharmacodynamics (PD), Toxicokinetics (TK), and Toxicodynamics (TD) data
- Extensive experience in the design, analyses and interpretation of biomarker studies, including early phase biomarker discovery
- Supporting development of drugs, biologics, and medical devices
- Experienced in various therapeutic areas

Data Safety and Compliance

BSSI stores and analyzes substantial volumes of confidential information from clients worldwide. BSSI's core principles, policies, procedures, and training are designed to support compliance with patient privacy laws worldwide. Paramount are the data security measures BSSI takes to protect clinical trial data and personal information against unauthorized access or loss. BSSI's enterprise level data security policies, in conjunction with protocols for de-identification and records management ensure your clients' data meets international laws regarding data privacy and confidentiality.

With BSSI's Precision Statistics® approach our team provides tailored statistical strategies and analyses to address complex questions. Just as the "one-size-fits-all" approach does not work in health care, it also doesn't work when it comes to the analytical side of a study or development project. Our Precision Statistics® methodology is a personalized solution to complex and multifaceted problems our clients face every day.



Powered by Precision Statistics®

Contact us:

Call **301.829.4001** and ask to speak to Dr. Martina Fortin (extension 243) or email her at **mfo@biostatsolutions.com**.