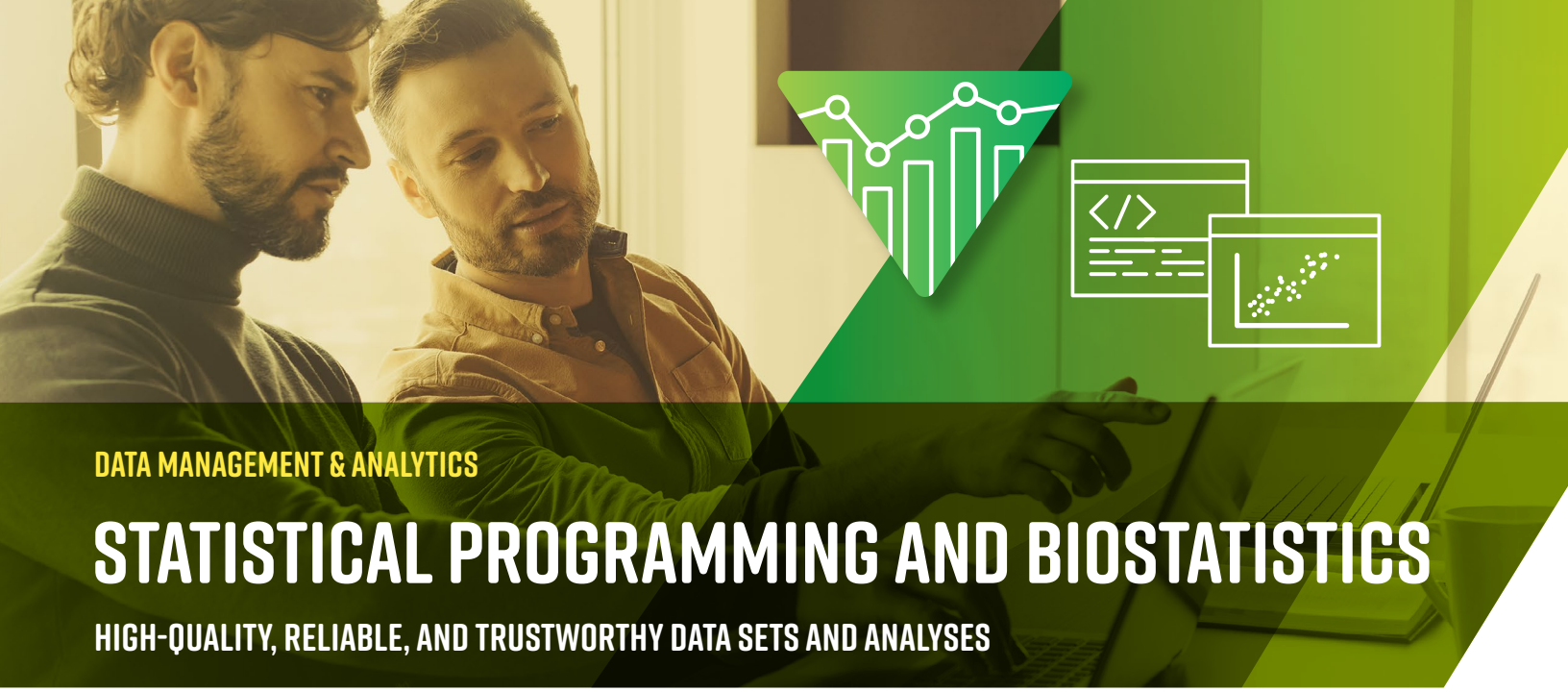

DATA MANAGEMENT & ANALYTICS

STATISTICAL PROGRAMMING AND BIOSTATISTICS

HIGH-QUALITY, RELIABLE, AND TRUSTWORTHY DATA SETS AND ANALYSES

OUR EXPERIENCE PROVIDING STATISTICAL PROGRAMMING AND BIOSTATISTICS

675+
studies for top-tier pharmaceutical, biotech, and medtech companies and CROs

15+
years

~20
therapeutic areas

FROM PRECLINICAL AND EARLY PHASE STUDIES TO REGULATORY SUBMISSIONS AND POSTMARKETING ACTIVITIES

DRUGS, VACCINE, AND DEVICE STUDIES

MULTIPLE STUDY DESIGNS INCLUDING ADAPTIVE METHODS, BAYESIAN TECHNIQUES, BASKET TRIALS, SIMULATIONS, SEAMLESS TRIALS, UMBRELLA TRIALS, AND REAL-WORLD STUDIES

OUR SCALABLE, COST-EFFECTIVE, GLOBAL TEAM IS SKILLED AT IDENTIFYING THE RIGHT DATA FOR ANALYSIS AND MEETING REGULATORY COMPLIANCE WORLDWIDE.

With Veranex Statistical Programming and Biostatistics services, your studies benefit from:

- A 250-person team continuously trained on new technology and solutions
- Right-sized team to meet study needs and timelines
- Consistent, dedicated resources who are integrated within your teams
- Flexible, around-the-clock coverage from team members worldwide
- Quality deliverables from a team that considers all aspects of the study and understands how their work affects other study components
- Close collaboration between our statistical programmers and statisticians for accurate analysis and reporting that adhere to the study specifications and plans
- Knowledge of multiple regulations, including 21CFR, ICH GCP, US FDA, UK/NICE SI, and EU CTR
- When needed, full study support from planning through completion or rescue studies

Veranex
Transforming Your MedTech Innovation

We provide a comprehensive set of Statistical Programming and Biostatistics services.

Our Statistical Programming services include the following:

- Blinded/unblinded data review and analysis support
- Creation, SAS programming, review, validation, and/or interpretation of TLFs based on the statistical analysis plan (SAP)
- Support for PK/PD parameter calculations
- Analysis supporting all therapeutic areas, including cardiac safety data (pilot and thorough QTc studies)
- Analysis of all study types, including observational studies
- ISS(SCS)/ISE(SCE) analysis
- Mapping and conversion of legacy study data to current standards
- CDISC services: SDTM, ADaM, Define.XML, Reviewer's Guide
- Patient profile reports, PD listings, BIMO listings, and Narratives
- Statistical and programming support for data monitoring committees (DMC, DSMB)
- Support with regulatory submissions, queries, and reporting for DSUR, PSUR, and 120-day safety updates
- Postmarketing data analyses and reporting

WE'VE PROVIDED SAS PROGRAMMING FOR 4 OF THE TOP 7 CROs ALONG WITH 3 OF THE TOP 5 GLOBAL LIFE SCIENCE COMPANIES.

Our Biostatistics services and consulting include the following:

- Protocol development and review, including statistical sections, sample size, power calculations, and randomization methodology
- SAP development and mock shell creation with adaptable approaches
- Development of the randomization plan development, schedule generation, review and implementation, and RTSM support
- Blinded/unblinded data review and analysis
- PK and PK/PD analyses and modeling
- Analysis supporting all therapeutic areas, including cardiac safety data (pilot and thorough QTc studies)
- Support and consulting for DSMB, DMC, and interim analysis
- Review and interpretation of TLFs
- Exploratory analyses for publications, abstracts, and marketing, including meta-analysis
- Representation at regulatory agency meetings

VERANEX HAS EARNED ISO 9001:2015 CERTIFICATION FOR ITS QUALITY MANAGEMENT SYSTEM AND ISO/IEC 27001:2013 CERTIFICATION FOR ITS SYSTEMS AND PROCESSES FOR MANAGING SENSITIVE COMPANY INFORMATION.

STATISTICAL PROGRAMMING, BIOSTATISTICS, OR BOTH – VERANEX HAS YOU COVERED.

Both our Statistical Programming services and Biostatistics services and/or consulting are available project-by-project or in combination to provide full-service support under our functional service provider (FSP) model. Our FSP model offers flexible services tailored to the unique needs of your clinical research, backed by our:

- Skilled resources trained on your processes
- Therapeutic area-based teams (based on therapeutic areas expertise) connected by a centralized governance structure for consistency across your portfolio
- Robust capacity management models for quick ramp-up and down
- Proven FSP process, starting with the selection of an appropriate data capture system through database lock of submission-ready data