



A SPECIALTY CRO SERVING PHARMACEUTICAL, BIOPHARMACEUTICAL AND MEDICAL DEVICE COMPANIES



STATISTICAL CONSULTING | REPORT PRODUCTION | DATA MANAGEMENT | PROGRAMMING SOLUTIONS

# STAT-TECH

SERVICES, LLC

## WHO WE ARE...



George E. DeMuth  
President

Since 1996, Stat-Tech Services has been serving companies in the pharmaceutical, biopharmaceutical and medical device industries. We understand that getting a drug or medical device to market is a high stakes proposition for sponsor companies and consumers. *Therefore, we approach every project with the same commitment – combining your goals with our experience and expertise to ensure the best possible result.*

Whether we're serving as your virtual biostatistics and/or data management group or supporting an in-house team, we consistently deliver exceptional quality service.

Explore the advantages that Stat-Tech Services can offer your organization:

- Over a decade of experience bringing drugs and medical devices to market
- The knowledge and experience to smooth the path to approval
- The efficiency and flexibility to decrease development time and expedite market entry
- Sensitivity to your budgets and development costs
- A dedicated team assigned to your project from start to finish



## HOW WE'RE DIFFERENT...

At Stat-Tech Services, our practices reduce the time and overhead required to achieve the results you seek. Our priority is building long-term relationships with clients rather than maximizing short-term returns on projects.

We are particularly adept at streamlining the cost of projects. We accomplish this by:

- Actively seeking optimal ways of communicating the information within the data
- Scheduling projects so that unanticipated issues can be easily addressed and unexpected deadlines met



*“Two weeks before we were scheduled to file an electronic NDA, the FDA requested specially formatted patient profiles be added. We were concerned that our NDA would be delayed. However, our Stat-Tech Services team told us they would finish the job on time. Not only did they finalize the patient profiles on time, but also provided a super package containing all bookmarks and hyperlinks. This was extremely convenient because it allowed us to ‘drop’ the profiles right into our NDA. We greatly appreciate their hard work and optimistic attitude.”*

Senior Director  
Biostatistics  
Pharmaceutical Company

Stat-Tech Services understands the development demands facing pharmaceutical, biopharmaceutical and medical device companies. From trial planning and design through FDA panel presentations to post-approval studies, we can assist in any phase of development. We'll help speed and smooth the path to approval by working on your project from inception to completion, or serving as your rescue team by helping get projects back on track.

## OUR SERVICES



### Biostatistics Services

We offer a complete range of biostatistics consulting and analysis services. Our statisticians have a broad range of knowledge across multiple therapeutic areas.

- Study Design
- Power/Sample Size Calculations
- Generation of Randomization Schemes
- Protocol Review
- CRF Design/Review
- Development of Statistical Analysis Plan
- Production and Validation of Interim Analyses and Reports
- Final Statistical Reports
- Ad hoc Analyses
- Independent Review of Statistical Analyses
- ISS/ISE (Integrated Safety Summary/Efficacy) Packages
- DSMB (Data Safety Monitoring Board) Packages

*“We needed to execute and document SAS programming validation for statistical analyses we conducted for multiple Phase I studies. Due to frequent and effective communication with our Stat-Tech Services team, we were able to successfully complete the project within our desired timeframe.”*

Director of Biostatistics  
Pharmaceutical Company



### Regulatory Consulting

Stat-Tech Services can provide valuable insight into managing your relationships with regulatory agencies. This knowledge can help speed and smooth your journey along the path to approval.

- Consultation and Planning
- FDA and EMEA Representation
- IND, NDA Submissions
- IDE, PMA, 510K Submissions





## Clinical Data Management

Stat-Tech Services provides Part 11 & CDISC compliant data management services. Our databases are designed to meet the needs of clients and are amenable to efficient and expedient statistical analysis.

- CRF Design/Review
- Database Design & Development
- Double Data Entry
- Quality Control and Data Cleaning
- Database Query, Tracking and Review
- MeDRA and WHODRUG Coding
- Status Reporting



*"I've worked with Stat-Tech Services on three PMAs for first-of-a-kind medical devices. Each PMA was reviewed by an FDA Advisory Panel for which Stat-Tech Services gave the statistical presentation and addressed the Panel's questions. Each PMA was approved within a little over a year. Our company has also worked with Stat-Tech Services on multiple IDEs and major PMA Supplements. Their statisticians know the statistical methods that will be acceptable to the FDA. Their communication and negotiation skills have been a real asset to our projects. Our continued partnership on many of our major projects is the highest form of praise I can give Stat-Tech Services."*

President & CEO  
Regulatory and Clinical Services Consulting Company

## Statistical Programming

Our staff of trained, experienced SAS programmers are able to customize our services to meet the specific needs of our clients. We utilize the most current SAS coding tools, as well as proprietary programming tools for maximum effectiveness and efficiency. We customize our programming to meet the unique needs of our clients.

- Analysis Data Set Creation and Validation
- Production and QC of Table, Listings and Graphs
- Creation of ISS/ISE Analysis
- Patient Profiles
- Customized Solutions Per Client Specifications

## OUR EXPERIENCE



Stat-Tech Services has provided support on many different types of projects including medical device studies, pharmaceutical studies, medical imaging and animal studies. This range of experience allows us to move rapidly into new projects. Our experience includes:

- FDA Panel Presentations
- DSMB Consulting
- IND, NDA Submissions
- Drug Development Phase I-IV
- IDE, PMA and 510K Submissions
- ISS/ISE Analysis

## THERAPEUTIC AREAS

Stat-Tech Services has experience working across a broad range of therapeutic areas. Our experience includes, but is not limited to the therapeutic areas listed below.

### Pharmaceuticals

- Cardiovascular (Imaging Agents & Therapies)
- Anti-viral Agents (HIV)
- Central Nervous System (Anticonvulsants, Neuromuscular Blockers, Pain)
- Oncology
- Anti-Infective
- Gastrointestinal
- Dermatology

### Medical Devices

- Urinary Incontinence
- Stimulators
- Pain Studies
- ESW Therapy
- Spinal Implants
- Stents
- Imaging Agents and Devices
- Diagnostics
- Orthopedics





## OUR PHILOSOPHY

At Stat-Tech Services, the best interest of our clients is always the top priority. We are committed to helping you realize your vision. We have established loyal and long-term relationships with our clients by adhering to the following principles:

- *Every project is unique*
- *Each client is important to our business*
- *Our role is to help save clients' time and resources*
- *We customize our service to meet the client's needs*
- *Communication is the key to successful relationships*
- *Responsiveness and flexibility are requirements when working with clients*
- *Meeting our internal expectations means exceeding yours*
- *The work we do together improves and saves lives*

***Consider Stat-Tech Services, LLC. Your success is our reward.***



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