

CARDIOVASCULAR



Stat One is a highly experienced partner in cardiovascular and peripheral vascular product submissions. The company's experience includes many products, such as interventional devices (stents, balloons, drug-coated products), stroke and embolism-related indications (clot removal devices, drug therapies), and diagnostic devices (contrast agents, adenosine products, AI algorithms, and imaging studies).

The Stat One Team strives to maintain an up-to-date understanding of the market and is adept at taking clients through the necessary steps for gaining approval for these types of submissions. Related statistical experience includes assisting in study design, FDA interaction, SAP generation, and analyses. Hence, we offer start-to-finish statistical support for cardiovascular and vascular products.

MEDICAL DEVICES

- ✓ Ablation Treatments
- ✓ Atrial Fibrillation
- ✓ Blood Pressure Monitoring Devices
- ✓ Catheter Devices
- ✓ Imaging for Heart Function
- ✓ Structural Heart
- ✓ Angiography
- ✓ Echocardiography
- ✓ MRI
- ✓ Valve Disease

PHARMACEUTICALS

- ✓ Heart Failure Therapies
- ✓ Clot Preventing Therapies
- ✓ Contrast Agents
- ✓ Stress Agents



LET YOUR DATA GROW®



ABOUT STAT ONE

Stat One is a speciality CRO providing expert statistical consulting, production programming, and data management services in support of clinical trials in the pharmaceutical, medical device, and biotechnology spaces. Our industry knowledge and experience of over three decades combined with our focus on quality makes us an excellent choice for your partner in growing a better future.

PROVEN TRACK RECORD

Our team has worked with and represented hundreds of clients on **FDA** submissions.

100+
FDA APPROVALS

25+
THERAPEUTIC AREAS

30+
YEARS OF INDUSTRY
SUCCESS

STATISTICAL CONSULTING

- ✓ Expert Statistics
- ✓ Study Design
- ✓ Sample Size
- ✓ FDA Representation
- ✓ Regulatory Strategy

PRODUCTION PROGRAMMING

- ✓ SAS Programming
- ✓ Patient Profiles
- ✓ Data Analysis
- ✓ Integrated Summaries
- ✓ Quality Control

DATA MANAGEMENT

- ✓ Stat One EDC®
- ✓ CRF Design
- ✓ Database Development
- ✓ Validation
- ✓ Customizable

YOUR PARTNER IN GROWING A BETTER FUTURE