

# MEDICAL DEVICE



Partnering with a medical device development expert is a crucial decision in the product development process. Stat One is one of few partners with in-depth and relevant medical device knowledge and experience covering a broad range of therapeutic areas. The Stat One team has been involved in the regulatory process starting with numerous Q-sub meetings through multiple approvals (de novo, 510 (k), and PMA).

## THERAPEUTIC AREAS

- ✓ Cardiovascular
- ✓ Imaging
- ✓ Spine & Joint
- ✓ Cosmetic Therapies
- ✓ Orthopedic
- ✓ Stents
- ✓ Diagnostic Devices (IVDs)
- ✓ Pain Relief
- ✓ Surgical
- ✓ Gastroenterology
- ✓ Peripheral Vascular
- ✓ Wound Healing

## STATISTICAL METHODOLOGY EXPERIENCE

- ✓ Sample Size Re-Estimation and Group Sequential Designs
- ✓ Multiple Imputation/Bayesian Analysis Approaches
- ✓ Propensity Scoring/Inverse-Probability Weighting

## REGULATORY PATHWAY SETTINGS

- ✓ 510k
- ✓ De Novo Devices
- ✓ First-of-type approvals
- ✓ International Experience
  - EU (CE Mark)/PMDAs & studies outside of the US
- ✓ PAS Studies
- ✓ PMA

LET YOUR DATA GROW<sup>®</sup>

# 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 that obtained **FDA** approval.

**100+**  
FDA APPROVALS

**25+**

THERAPEUTIC AREAS

**30+**

YEARS OF INDUSTRY  
SUCCESS

## STATISTICAL CONSULTING

- ✓ Expert Statistics
- ✓ Study Design
- ✓ FDA Representation
- ✓ Regulatory Strategy
- ✓ DMC/DSMB

## 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

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## Monthly Subscription Plan for Businesses & Enterprises

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### Get in Touch with Us



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📍 123 Anywhere St., Any City

🌐 reallygreatsite.com



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## Statistical Consulting

- Expert Biostatistics
- Regulatory Strategy
- Study Design
- FDA Representation
- DMC/DSMB



## Programming Services

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



## Data Management

- Stat One EDC<sup>®</sup>
- CRF Development
- Database Development
- Validation
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Statistical Consulting. eClinical Solutions. Efficient.

STAT ONE

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A BETTER FUTURE





# CARDIOVASCULAR

Stat One has extensive experience with cardiovascular and vascular devices and supports a variety of these types of projects annually. The technical specialists and scientists of our cardiovascular Stat One's team is well-informed on industry trends and navigating the overall approval process for a number of cardiac indications.

## Medical Devices

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

## Pharmaceuticals

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

THERAPEUTIC EXPERTISE

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## STAT ONE SERVICES



### Statistical Consulting

Our 30 plus years of experience include, protocol development and sample size calculation; statistical analysis planning, data analysis, study design, regulatory strategy, FDA representation, and DMC/DSMB activities.



### Production Programming

Stat One offers programming services in support of FDA submissions. Stat One statisticians and programmers work closely with clients to make sure all statistical packages meets regulatory requirements.



### Data Management

Our team has extensive experience in dealing with data from multiple sources, identifying proper data structures, and designing efficient databases. Stat One EDC® system and is the starting point for our data management services.

AGILE | DEPENDABLE | EFFICIENT