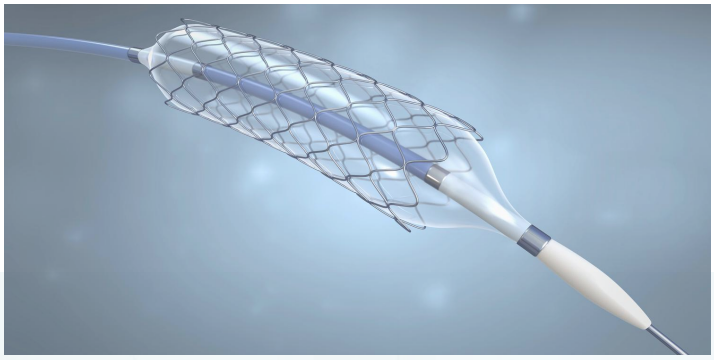
MEDICAL DEVICE

Let Your Data Grow®

Stat One has extensive experience supporting medical device submissions for small start-ups to some of the largest companies world-wide. Our knowledge and experience in this area allows us to address specific needs of our medical device clients and help them successfully interact with the FDA and EU authorities.

Stat One can also assist companies in locating regulatory and clinical resources working in the medical device area.



Medical Device Experience

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

Statistical Methodology Expertise

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

Regulatory Pathway Settings

- 510k & PMA Product Approvals including de Novo devices
- First-of-type approvals and PAS studies
- International Experience EU (CE Mark)/PMDAs & studies outside of the US

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ABOUT STAT ONE

Let Your Data Grow®

Stat One is a speciality CRO supporting clinical trials for pharmaceutical, biotech, and medical device companies. Our industry knowledge of over two decades combined with our focus on quality make us an excellent choice for your partner in growing a better future.

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®
CRF Development
Database Development
Validation
Customizable

Statistical Consulting. eClinical Solutions. Efficient.

STAT ONE

Your partner in growing a better future...

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