FDA REPRESENTATION

Let Your Data Grow®

Stat One has experience representing clients with the FDA in a broad range of therapeutic areas. We have been involved in numerous studies that were cleared or approved in all areas including PMAs, 510(k)s, NDAs, and BLAs.

Stat One has

- Presented at panel meetings
- Addressed study design & sample size
- Responded to deficiency letters
- Provided statistical analysis & programming

Stat One has been involved in the following types of products:

- PMA and 510(k) clinical studies
- Biologics
- Pharmaceutical agents

Stat One has contributed to studies that included:

- Sample size re-estimation and group sequential analyses
- de Novo medical devices
- First of type products

Stat One has supported numerous post marketing and registry studies.

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...