FDA

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.

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. Related statistical experience includes assisting in study design, FDA interaction, SAP generation, and analyses. Hence, we offer start-to-finish statistical support when navigating the FDA.

STUDY EXPERIENCE

- ✓ 510(k)
- ✓ Biologics
- ✓ De Novo Devices
- ✓ First of type products
- ✓ PMA
- ✓ Pharmaceutical gents

FDA STATISTICAL GUIDANCE INCLUDES BUT IS NOT LIMITED TO:

- ✓ Sample size re-estimation
- ✓ Group sequential analyses
- ✓ FDA meetings

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