

ORTHOPEDIC & SPINE



Stat One is well-versed in clinical trials for orthopedic and spine products. The company staff has supported trials for fusion, artificial discs, hip/joint implants, and pain treatments. With our industry knowledge of over 30 decades, Stat One can assist from start-to-finish with the product development process.

The Stat One Team has deep experience in study design and statistical analysis of orthopedic and spine devices. Our team has provided the entire statistical support process within the orthopedic space starting from sample size and protocol development to PMA submissions and FDA Panel meetings.

ORTHOPEDIC

- ✓ Cartilage Growth
- ✓ Bone Growth Stimulators
- ✓ 510 (k) Devices
- ✓ Heel Pain
- ✓ Hip Resurfacing
- ✓ Knee Pain

SPINE

- ✓ Artificial Discs
- ✓ Fusion Products
- ✓ Non-Invasive Procedures

THERAPEUTIC AREA ANALYSIS EXPERTISE

- ✓ Device Safety Data
- ✓ OUS & Observational Data
- ✓ Pain Measures
- ✓ Quality of Life Scales (ODI, NDI, SF36, EQ5D)
- ✓ Radiographic Endpoints
- ✓ Use of Composite Endpoints

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