

Let Your Data Grow<sup>®</sup>

Stat One has deep experience in study design and statistical analysis of orthopedic 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

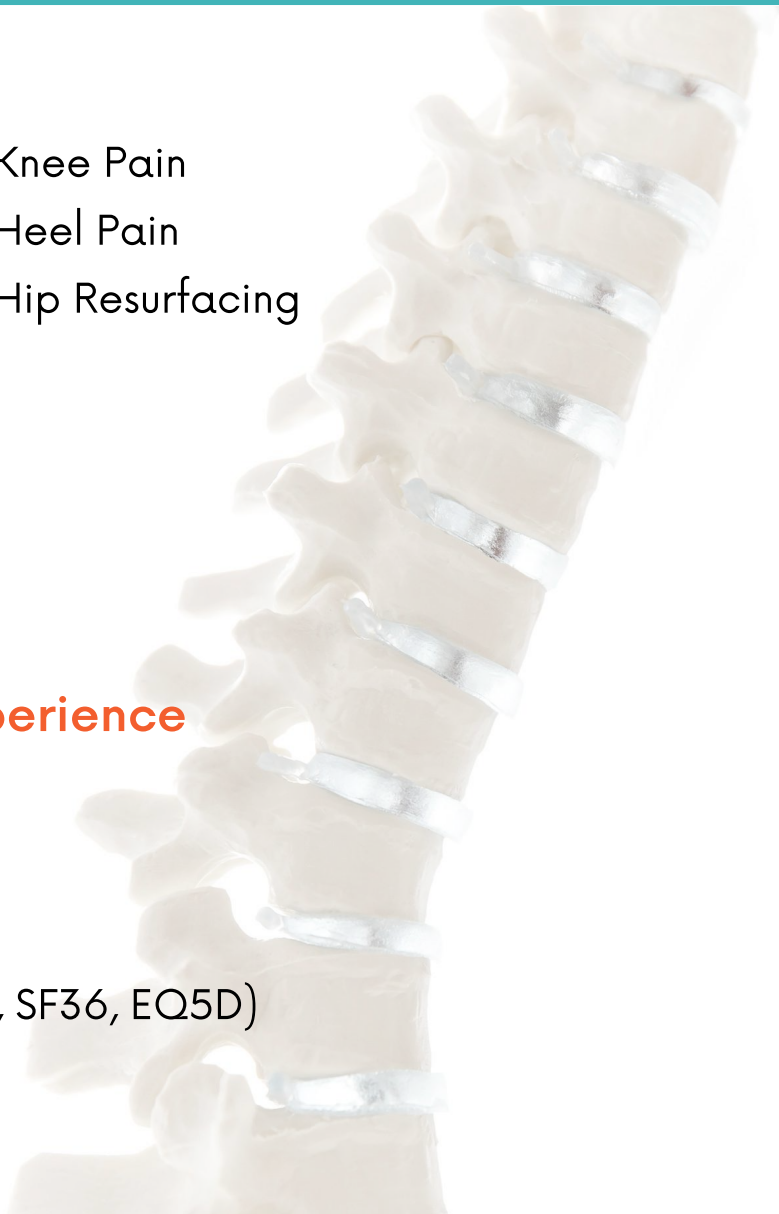
- Cartilage Growth
- Bone Growth Stimulators
- 510 (k) Device Product
- Knee Pain
- Heel Pain
- Hip Resurfacing

## Spine

- Fusion Products
- Artificial Discs
- Non-Invasive Procedures

## Therapeutic Area Analysis Experience

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



# ABOUT STAT ONE



Let Your Data Grow<sup>®</sup>

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<sup>®</sup>
- CRF Development
- Database Development
- Validation
- Customizable

Statistical Consulting. eClinical Solutions. Efficient.

STAT ONE

*Your partner in growing a better future...*

