MEDICAL DEVICE EXPERIENCE

Let Your Data Grow®

Stat One has extensive experience supporting medical device submissions. We have worked with small start-ups to some of the largest device 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.

SUBMISSION EXPERIENCE

Let Your Data Grow®

- **Statistical Methodology Expertise**
    - Sample Size Re-Estimation and Group Sequential Designs
    - Multiple Imputation/Bayesian Analysis Approaches
    - Propensity Scoring/Inverse-Probability Weighting
- **Regulatory Settings**
    - 510k submissions include de novo devices
    - PMA submission including first-of-type approvals and PASS studies
    - EU (CE Mark) and PMDA experience
    - Outside the United States Studies
- **Therapeutic Areas**
    - Ortho and Spine – have worked with top 100 spine companies
    - Cardiovascular and Peripheral Vascular
    - Oncology
    - Cosmetic Therapies
    - Diagnostic Devices (IVDs) and Medical Imaging
    - Pain Relief
    - Wound Healing