

# Your Medical Device Biometrics Partner



Medical device trials demand a different level of agility and operational precision. Efficacy brings decades of hands-on experience to rise to the challenge. We combine deep regulatory and device-specific expertise with flexible, cost-conscious delivery models that adapt as programs evolve. Acting as a true extension of your team, Efficacy helps you navigate complex trial designs and regulatory scrutiny without unnecessary delays or cost overruns.

## Built for the Realities of Medical Device Trials

Medical device, diagnostic, and combination-product studies introduce complexities that demand specialized experience.

**Efficacy delivers unparalleled efficiency, backed by:**

- **Extensive device experience:** 300+ programs supported
- **End-to-end regulatory partnership:** Collaboration from early study design through pivotal trials, with regulatory experience across PMA, De Novo, and 510(k) pathways and 100+ successful submissions
- **Superior flexibility:** Built to adapt to mid-study design changes, bridging strategies, or protocol adjustments
- **Operational readiness:** Prepared for dense data collection, complex randomization, and on-call statistical and data management support during critical study moments
- **Cost-conscious execution:** Balancing regulatory rigor with pragmatic solutions that help sponsors control costs while maintaining data integrity and inspection readiness



## Medical Device Biometrics Services

Efficacy tailors our comprehensive biometrics support to the demands of your medical device trial.

**Our services include:**

- Study design support, including endpoint and objective selection
- Regulatory strategy support for IDE, PMA, De Novo, and 510(k) submissions
- Clinical data management for complex, procedure-driven studies
- Database design optimized for dense, device-specific data collection
- Biostatistics support, including sample size estimation and interim analyses
- Statistical programming for regulatory-compliant outputs and submissions
- Randomization design and support for procedural and intraoperative use
- Ongoing FDA interaction support and response to regulatory queries
- Flexible delivery models: FSP, project-based, consulting, and hybrid



## Specific Medical Device & Diagnostic Expertise

Otolaryngology • Cardiology/Vascular Diseases • Obstetrics/Gynecology • Pulmonary/Respiratory Diseases  
Denta • Sleep • CNS • Oncology • Urology • Gastroenterology • Ophthalmology • Orthopedics • Musculoskeletal  
Dermatology • Plastic Surgery/Cosmetic • Nephrology • Smoking Cessation • Diagnostics • Resuscitation

Epicacy brings deep operational and regulatory experience across a broad range of medical device and diagnostic programs. Our teams understand the nuances that make device trials different and are built to support them.

### Our experience includes:

- Procedural and implantable devices, including trials involving surgical workflows and anesthesia
- Complex randomization scenarios, including intraoperative and real-time allocation
- Dense, one-shot data collection, where comprehensive evidence must be captured efficiently
- Imaging and diagnostic devices, including AI- and machine learning-enabled technologies regulated under CDRH
- Combination products requiring coordinated regulatory and statistical strategies
- First-in-human, bridging, and pivotal studies, with continuity from early development through approval



## Case Study: Supporting a Complex PMA Device Program

A medical device sponsor pursuing PMA approval faced evolving regulatory requirements and a mid-study design change that threatened to delay approval and significantly increase costs.

### Epicacy's Approach

- Played an active role in study design, including endpoint and objective selection aligned with FDA expectations
- Partnered closely with the sponsor to respond to FDA questions during both design and study conduct
- Supported a bridging study strategy to demonstrate that a device design change did not impact safety or effectiveness
- Enabled cost savings by integrating bridging study subjects into the existing PMA database

### Impact

- Maintained regulatory momentum without restarting the program
- Contained costs through pragmatic database and design decisions
- Supported a successful PMA approval while adapting to evolving study needs

## Trusted Medical Device Data Support

Whether you're designing an early feasibility study or preparing for pivotal trials and FDA review, Epicacy is ready to support your medical device biometrics needs. **Connect with us to explore how we can support your program.**

[Discover Our Biometrics Expertise](#)

Epicacy is a rapidly growing biometrics CRO headquartered in Iselin, NJ, with employees and operations across North America, India, and Europe. Epicacy's tenured experts provide outsourced statistical programming, biostatistics, data management, and real-world evidence analytics services to pharmaceutical and biotechnology companies. Since its founding in 2005, Epicacy has established itself as a leading player in the clinical analytics space, leveraging a global talent pool to help pharmaceutical and biotechnology companies reduce their time to market in a cost-effective manner. Explore the organization in more detail at [www.epicacy.com](http://www.epicacy.com)