EPHICACY

Your Medical Device Biometrics Partner

Medical device trials demand a different level of agility and operational precision. Ephicacy 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, Ephicacy 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.

Ephicacy delivers unparalleled efficiency, backed by:

- **Decades of device experience:** 300+ trials across 35+ years
- **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 40+ 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

Ephicacy 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

Oncology • Respiratory • Pulmonary • Cardiovascular • Ophthalmology • Orthopedics
Reproductive Health • Endocrinology • Urology • Sleep Apnea

Ephicacy 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.

Ephicacy'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, Ephicacy is ready to support your medical device biometrics needs. **Connect with us to explore how we can support your program.**

Discover Our Biometrics Expertise

Ephicacy is a rapidly growing biometrics CRO headquartered in Iselin, NJ, with employees and operations across North America and India. Ephicacy'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, Ephicacy 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.ephicacy.com