

# MEDPACE MEDICAL DEVICE

Medpace is a global, full-service CRO with a scientifically driven approach to clinical research. Our dedicated medical device and diagnostics team brings deep operational expertise to every stage of development—from first-in-human and feasibility studies to pivotal trials and large-scale post-market evaluations. With experience across a broad range of therapeutic areas and technologies, we partner with Sponsors to efficiently design and execute clinical investigations and performance studies that meet global regulatory requirements.

## THERAPEUTIC FOCUS

Medpace takes a therapeutically focused approach to clinical research, drawing on deep experience across a broad range of indications. Our teams specialize in your specific therapeutic area—bringing proven strategies, scientific insight, and firsthand knowledge of common challenges to help you navigate every phase of development, from pre- to post-marketing studies.

## CLINICAL AND REGULATORY SERVICES

Medpace offers regulatory, clinical and representation services to help bring products to market safely, effectively and efficiently. We have extensive experience all over the world, covering pre-market and post-market for a wide range of medical devices across all classes, including medical devices, active implantables, in-vitro diagnostics and device/drug combination products. Medpace works collaboratively with medical device companies and can support formulating and implementing strategies for pathways to market to comply with both existing and new regulations and standards.



## EXPERTS

- Cross-functional teams of medical, operational, and regulatory experts that are actively involved throughout the lifecycle of the project
- Our scientific reputation and relationships allow access to the right KOLs and sites
- Specialized in-house medical and device experts ensure efficient and high-quality results

## EXPERIENCE

- Our vast medical, regulatory, and clinical operations experience help navigate hurdles
- Long history of stability in leadership and deep institutional experience
- Integrated imaging, ECG management, and central lab to provide seamless logistics, review and testing

## EXECUTION

- Unique study management model expedites site activation and patient recruitment
- Rigorous training program and SOPs ensures consistent quality around the world
- Full-service approach provides cross-collaboration and insights from various medical perspectives
- Our purpose-built CTMS, ClinTrak®, delivers on-demand access to all your clinical study data in an intuitive interface – unlocking deeper insights and empowering objective, data-driven decision making



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## FULL-SERVICE

Medpace offers regulatory, clinical operations, and representation services to help bring your products to market safely, effectively, and efficiently. We partner with Sponsors through the complete product lifecycle.

### Services include:

- Regulatory and clinical strategy development
- Design, conduct, recording and reporting of clinical investigations and clinical performance studies
- Clinical protocol and investigator's brochure development
- Preparation and compilation of regulatory submissions and follow-up
- Market clearance/approval
- Post-market activities, including post-market clinical follow-up studies

Medpace is expertly positioned to help Sponsors through the clinical development pathway. Our experts can help determine the correct way to design and develop your clinical study. Medpace specialized teams execute your clinical study to a high level of quality to aid clinical and commercial success.

## GLOBAL ENGAGEMENT

Leverage our country-specific experience and breadth of in-house expertise to navigate languages, cultures, and clinical and regulatory environments around the globe. Our specialist knowledge of global medical device regulations, as well as our significant experience of interacting with regulatory authorities, ensures our Sponsors avoid significant delays and costly consequences. With dedicated device teams, Medpace Medical Device has the global scope to provide a comprehensive array of services to support the needs of your trial.

## INTEGRATED SERVICES

Medpace offers in-house imaging, ECG management, and central lab services. Our integrated core labs provide an end-to-end suite of global imaging services to enhance and expedite medical device development. This complements the state-of-the-art, standardized electrocardiogram (ECG) equipment to support clinical trials around the world. Our wholly-owned global laboratory facilities, standardized testing platforms, comprehensive test menu, and stellar project management teams allow Medpace to set up fully customized projects for our Sponsors. Combined with Medpace clinical research organization (CRO) expertise, we provide a fully integrated solution for your clinical development needs.

## FULL-SERVICE CLINICAL DEVELOPMENT

Medpace is a scientifically-driven, global, full-service clinical research organization (CRO) providing Phase I-IV for pharma studies and FIH-Post market for device studies. Medpace's mission is to accelerate the global development of safe and effective medical therapeutics through its high-science and disciplined operating approach that leverages local regulatory and deep therapeutic expertise across all major areas including oncology, cardiology, metabolic disease, endocrinology, central nervous system and anti-viral and anti-infective.

**WE CAN'T SIMPLIFY  
CLINICAL DEVELOPMENT –  
BUT WE CAN EXECUTE  
IT SEAMLESSLY.**

