MEDPACE

MEDPACE MEDICAL DEVICE

Medpace is a scientifically-driven, global, full-service clinical research organization (CRO). Within Medpace, a team of operations professionals is specifically dedicated to the design and conduct of clinical investigations for medical devices and performance studies for in-vitro diagnostic products. Our team has experience in all stages of clinical development – from single-center, first-in-human and feasibility trials to multi-center, full-service pivotal trials and large-scale, post-market studies.

THERAPEUTIC FOCUS

Medpace offers a therapeutically-specialized approach to clinical research. We apply everything we've learned throughout our extensive experience conducting pre- and post-marketing studies across many therapeutic areas to your study. You'll work with teams who specialize in your specific therapeutic area and who understand and have overcome the challenges you face.

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.

MAKING THE COMPLEX

SEAMLESS™

EXPERTS

- Embedded physician leadership provides therapeutic expertise from planning through the lifecycle of the study
- Our scientific reputation and relationships allow access to the right KOLs and sites
- Specialized in-house medical experts ensure efficiency 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
- Office-based research campus facilitates teamwork, communication, and execution
- Proactive Clinical Trial Management System (CTMS) at your fingertips: ClinTrak®

Exclusively dedicated to helping our medical device clients bring products to market safely, effectively and efficiently.

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. Regulatory professionals from the Scientific and Strategic Development (SSD) group provide guidance and support with regulatory strategies and pathways to market.

GLOBAL ADVANTAGE

Partnering with a global medical device CRO that fully understands how to navigate and accelerate clinical research and approvals around the world means your timelines and budgets will be managed as efficiently as possible. 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 CORE LABS

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.

MAKING THE COMPLEX SEAMLESS™