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

Discover the POWER OF X™

Experts.
Experience.
Execution.

Bring your medical device to market safely, effectively and efficiently with Medpace Medical Device

Broad experience, global resources and local knowledge

Medpace Medical Device designs and conducts device trials in all stages—from single-center, first-in-human and feasibility trials to multi-center, full-service pivotal trials and large-scale, post-market outcomes studies. We take clients' goals, operational preferences and communication needs into consideration to customize study designs and execution strategy.

The Medpace Difference for Medical Device Studies

- Medpace physicians are fully engaged throughout the study to ensure your trials start and stay on the right path
- Global regulatory experts ensure that your studies are carried out in a fully-compliant manner to meet your objectives as efficiently as possible
- Focused geography and site selection
- Our proven unique study management model ensures each milestone is met as efficiently, rapidly and effectively as possible
- Real-time data review model provides accurate metrics and data efficiency
- Integrated imaging, centralized ECG management, and central laboratory services deliver seamless logistics, review and testing

Experts.

Strategic Medical, Clinical and Regulatory Expertise

Our therapeutic, regulatory and operational leaders work closely with clients to ensure the most efficient and streamlined path to approvals nationally, regionally or globally.

Medpace Medical Device is managed by a team with extensive device industry experience, from large companies to small start-ups, giving us unique insight into a client's company culture and the ability to be responsive to your needs.

Physician-driven Approach

Our full-time staff physicians are fully engaged throughout the entire study. They provide strategic direction for study design and planning, train operational staff, work with primary investigators, provide medical monitoring, and meet with regulatory agencies.

Streamlined Operations

Our operational experts oversee pre-market, post-approval and post-market device trial management. We streamline the entire study process and ensure our personnel have the tools and processes in place to minimize delays, proactively identify risk areas, and implement strategies for success.

Regulatory development, planning and submission support

Our regulatory affairs team understands the challenges you face when embarking on the development of a new technology. We can provide guidance on the likely regulatory pathway through focused discussions and, if required, can coordinate and lead meetings with appropriate regulatory bodies. And if you intend to obtain approval in more than one country, our clinical and regulatory experts are experienced in developing strategies that ensure data can be used for multiple-country submissions, creating significant efficiencies. Our device headquarters in Europe can serve as your European authorized representative.

Clinical Services

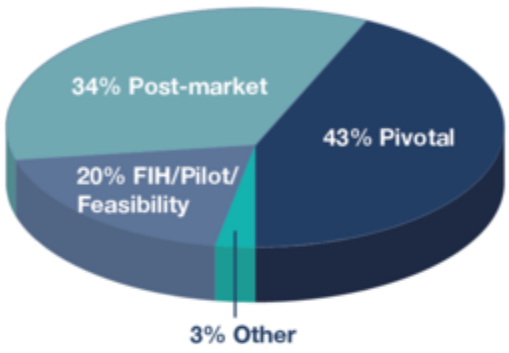
Early Device Development	Clinical Studies	Regulatory Approval	Post-market Studies
Assess clinical data needs	Full-service trial management	• Clinical study report preparation • Clinical literature reviews (EU)	Full-service trial management
Regulatory strategy including: • Device classification • Notified body discussions • Pre-submission FDA Meetings	• Regulatory approval documents • Interim and final reports	• Prepare technical files & design dossiers • Develop quality system including gap analysis & internal audit • EU authorized representative services	• Prepare regulatory approval applications • EU registrations & notifications

Quality/Regulatory Services

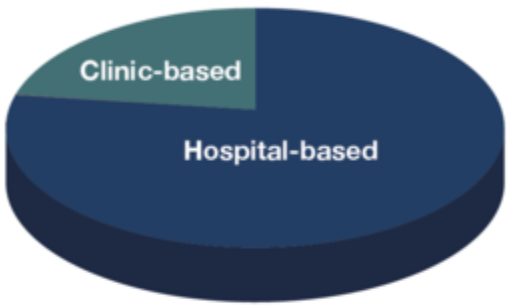
Experience.

Medpace Medical Device Experience

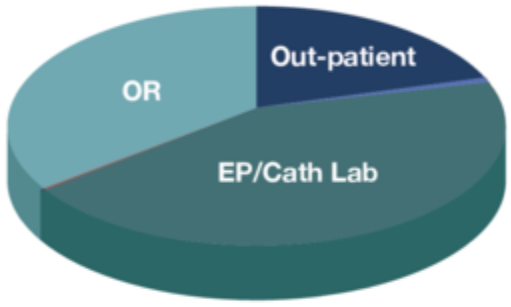
Experience by Stage



Experience by Type



Hospital-based Experience



Medpace Medical Device has conducted more than 300 pre-market, post-approval and post-market device studies, involving 3,500 sites and 65,000 patients in more than 45 countries.

We apply everything we've learned throughout our extensive experience conducting pre- and post-market 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.

Device Therapeutic Experience

We have significant experience in many therapeutic areas and particularly excel in:

Cardiovascular

- Valvular Disease
  - Aortic valve replacement (transcutaneous and surgical)
  - Mitral valve repair (transcutaneous and surgical)
- Coronary Artery Disease (interventional)
- Heart Failure
  - Left ventricular assist devices
  - Chronic resynchronization therapy
  - Autonomic stimulation
- Electrophysiology
  - Pacemakers/Implantable cardioverter defibrillators
  - Ablation catheters
  - Mapping systems
- Cardiac Surgery
  - Coronary bypass grafts
  - Vessel occluders
- Congenital Heart Disease
- Endovascular/Interventional
  - Peripheral vascular disease
  - Carotid artery disease
  - Thrombectomy/Embolic protection
  - Aortic aneurysm

Endocrine/Metabolic

- Glucose monitoring
- Insulin delivery
- Bariatric surgery
- Gastric stimulation
- Implantable pumps

Ophthalmology

- Micro stents
- IOLs
- Corneal inlays
- Scleral implants
- Contact lenses
- Ultrasound guided cryogenic therapy

Orthopedics/musculoskeletal

- Artificial discs
- Fracture fixation
- Spinal fusion
- Surgical mesh
- Bone grafts
- Pedicle screws

Urology/urogynecology

- Foley catheter
- Ostomy products
- Endometrial ablation
- Pelvic floor mesh
- Prolapse repair
- BPH therapies

We are also experienced in these therapeutic areas.

- Gastroenterology
- Hematology
- Intensive care
- Nephrology
- Neurology
- Pulmonology
- Wound Healing
- Aesthetics

Execution.

One CRO to provide consistent execution across national, regional and global studies.

With dedicated device teams in the U.S. and Europe, Medpace Medical Device has the global scope to provide a comprehensive array of services to support the needs of your trial and to manage your trial timelines as efficiently as possible. Our global presence and experience means more than just having feet on the ground. Our geographically diverse and multilingual employees understand the local cultural environment and the regulatory pathway.

Medpace Global Advantage

We select the ideal geographies and sites to ensure your study is completed in a timely way.

- Broad, global experience with country-specific submissions and enrollment rates
- Established relationships with clinical research sites, key opinion leaders and therapeutic networks experienced in medical device trials
- Staff who are multilingual, ensuring your program is interpreted and implemented efficiently and appropriately

Full Service Support

We support human trials in all phases, from single-center feasibility trials to large multi-center, randomized controlled trials, with a full range of clinical services, including:

Clinical strategy development

Trial design including:

- Protocol
- Patient Consent
- Patient Information
- Investigator Brochure
- CRF
- Statistical design including health economics

Trial management

- Clinical team management
- IRB/Ethics Committee submission
- Competent authority submission/notification
- Metrics and reporting
- CEC/DSMB management
- Episode adjudication

Site selection and qualification

Monitoring

- Site initiation
- Close out services

Data management

- Database development
- Data review and query management

Safety and risk management

- Safety and vigilance reporting
- Event management

Study report preparation

- Medical writing
- Data analysis

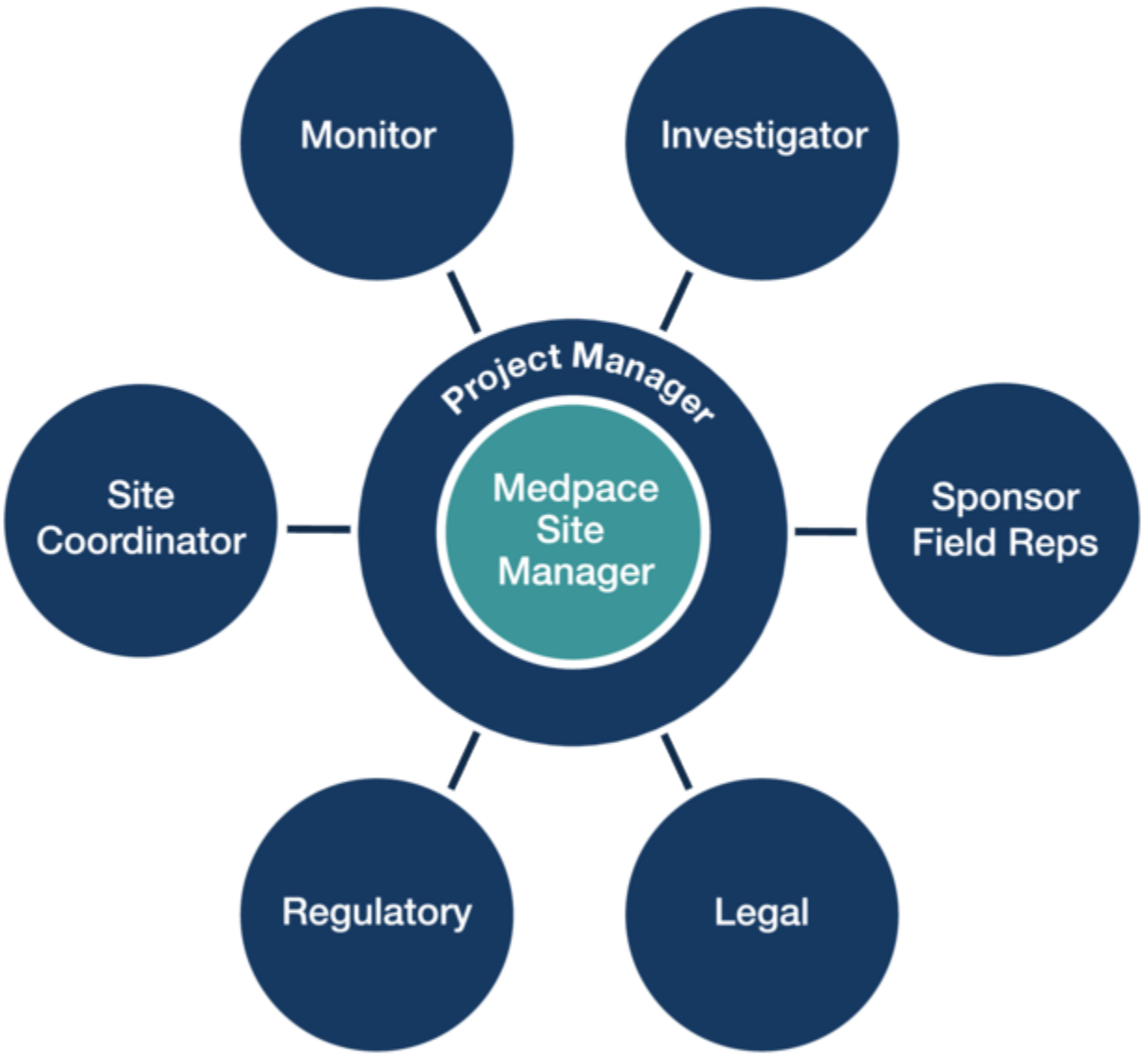
Device distribution services

In addition to clinical trial management, Medpace Medical Device provides global, integrated imaging, centralized ECG management and central laboratory services to ensure seamless logistics, review and testing.

Unique Study Management Model

We created a unique study management model to help streamline the study process and provide an advantage for our device clients. At the heart of the study management team is a specialized team member who is dedicated to site management—the in-house site manager. While the CRA remains focused on the tasks that have to be completed onsite, this specialized team member:

- Supports each site through study start up, site activation, enrollment and data review
- Maintains routine contact with the sites throughout the study
- Ensures each milestone is met as efficiently, rapidly and effectively as possible



Real-time Data Review

Studies stay on track and there are no surprises later

The in-house site manager, who maintains routine contact with the site staff throughout the study, reviews data in real-time to provide timely feedback to the site and to proactively address any questions the sites may have. This real-time data review ensures you receive the most up-to-date metrics without any significant delay in reporting. We can work collaboratively to address any data-related issues that are revealed by these metrics.

Event Management

To meet increasingly complex and diverse global regulatory requirements, Medpace has developed a comprehensive suite of services designed to ensure that events reported during your clinical trial are thoroughly understood, documented and reported within the mandated regulatory timelines.

Events/Vigilance Reporting

- SAEs, AEs, UADE expertise
- Safety monitoring plans, project team training, timeline management
- Daily event processing, site communication, report closures, follow up
- Medical/safety monitors review all reports, provide therapeutic expertise
- Prepare interim and final trial safety reports

Clinical Endpoints/ Adjudication

- Managed with ClinTrak® , web-based software
- Set up: select/contract members, develop character, endpoint management plan, adjudication algorithms, CRFs, training
- Case adjudication: compile and distribute event package, track determinations

Device Malfunction Reporting

- Includes MDR reporting
- Process events or malfunctions to determine root cause
- Work with sponsor manufacturing or complaint systems

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Medpace Medical Device

Medpace is a global full-service clinical research organization providing Phase I-IV core development services for drug, biologic, and medical device programs. Medpace Medical Device is a division of Medpace exclusively dedicated to the design and conduct of medical device trials. Medpace Medical Device is headquartered in Minneapolis, Minnesota, and is supported by a European office in Vaals, Netherlands and other locations strategically placed throughout the world. Medpace Medical Device is managed by a team with extensive device industry experience.

Medpace Medical Device (Global HQ)
3787 95th Avenue NE, Suite 100
Minneapolis, Minnesota 55014 USA
Tel: +1 612 234 8500
Fax: +1 612 234 8501

Medpace Medical Device B.V.
Maastrichterlaan 127-129
The Netherlands - 6291 EN Vaals
Tel: +31 43 306 3320
Fax: +31 43 306 3338

For more information, visit our website at
www.medpace.com/device or email us at **info.mmd@medpace.com.**