MEDPACE

MEDICAL DEVICE AND DIAGNOSTIC STUDIES

Medpace helps Sponsors accelerate the advancement of in-vitro diagnostics (IVD), laboratory developed tests and other diagnostic tools. We can help your diagnostics product reach its full potential with a comprehensive offering of services and expertise including:

- Strategic regulatory affairs leadership provides early guidance and execution for developing diagnostics
- Specialized medical expertise in key areas of diagnostic development including hematology and oncology, infectious diseases, and cell and gene therapies
- Protocol development, and high-volume site and investigator selection sets the stage for enrolling large patient populations
- Experience with varied medical settings including bed-side, laboratory or other healthcare professional settings
- Wholly-owned Central Laboratories and Bioanalytical Laboratories provide integrated biomarker research support
  - Development and validation of diagnostic assays for use in clinical trials
  - Sample management
- Relationships with specialized genomics labs

COMPANION DIAGNOSTICS

Matching the right drug to the patient based on each person's biological makeup is the foundation of precision, or personalized medicine. A companion diagnostic — defined as "an in vitro device that is essential for the safe and effective use of a drug" - is the backbone of identifying those matches. Typically classified as Class III devices, companion diagnostics require more rigorous regulatory controls that can increase complexity, extent timelines, and add costs.

Our dedicated medical device specialists are embedded within the global Medpace clinical research organization providing greater knowledge, better coordination, and a holistic approach to your clinical development for companion diagnostics.

MAKING THE COMPLEX

SEAMLESS™

THE MEDPACE DIFFERENCE FOR DIAGNOSTIC STUDIES

- **Benefit from the combined expertise and efficiency of our dedicated medical device specialists that are embedded within the global Medpace clinical research organization**
- **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**
- **Robust global feasibility and site selection process**
- **Expedited site activation and patient recruitment throguh a unique study managememnt model**
- **Real-time data review model provides accurate metrics and data efficiency**
- **Integrated Imaging, centralized ECG management, and central laboratory services deliver seamless logisitcs, review and testing**

FULL-SERVICE CLINICAL DEVELOPMENT

Medpace is a scientifically-driven, global, full-service clinical contract research organization (CRO) providing Phase I-IV clinical development services to the biotechnology, pharmaceutical and medical device industries. 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.

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