

M E D P A C E

DIAGNOSTIC STUDIES

Experts. Experience. Execution.

Discover the POWER OF X



Bring your diagnostic to market safely and efficiently with Medpace

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

- Strategic regulatory affairs leadership that provides early guidance and execution for developing diagnostics
- Specialized medical expertise in key areas of diagnostic development including hematology and oncology, infectious diseases, and gene and cell 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

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 through a unique study management model
- 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

Precision Medicine – 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, extend timelines, and add costs.

Given these added complexities, Medpace—with expert medical and regulatory leadership—can help navigate to success. 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.



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