

A DEEPER DIVE INTO CENTRAL LABORATORIES

A GLOBAL, SCIENTIFIC PARTNER

Medpace provides customized, quality central laboratory services to pharmaceutical and biotech clinical development industries. Our four wholly-owned laboratories offer full-service support to six continents for phase I-IV studies. We have extensive experience from small and simple clinical trials to those that are large, global, and complex.

Our scientific and technical leaders provide guidance from the onset, reviewing protocols, advising on the best testing options, proposing optimum courier and shipping routes, and delivering customized data solutions. Key capabilities and highlights include:

- Extensive capacity and global scalability in state-of-the-art facilities
- Biomarker development, validation and PD analysis
- Industry-leading quick validation timelines
- Fully-harmonized, high-throughput instrumentation delivering high quality data
- On-time data transfers
- Web-based data portal provides seamless data management delivered in a single integrated global database



From projects managers, medical technologists and laboratory scientists to logistics teams and data managers, Medpace is recognized for providing the highest level of service and quality.



GLOBAL LABORATORY SERVICES



ACCESSIBLE, SCIENTIFIC CONSULTING

Medpace provides early and ongoing access to scientists who provide expert advice and input regarding study design, test selection, and method validation protocols. This global team of hands-on laboratory PhDs are actively engaged with your study team throughout the entire clinical development process, while also collaborating with laboratory technologists and the project management team to seamlessly execute your trial. In addition, access to Medpace's medical department and to our specialty lab partners provides even greater depth of therapeutic and scientific insights.

SAFETY TESTING

As a full-service central laboratory, Medpace conducts global Phase I-IV trials for multiple therapeutic areas. We utilize global standard operating procedures, and identical assay platforms, calibrators, and quality control material. Data from Medpace's central laboratories has been key for assessing safety, tolerability, and efficacy of many new drugs.

With the increasing complexity and global scale of clinical trials, it is important to maintain testing harmonization among each Medpace laboratory. In order to ensure that all results generated globally are harmonized, Medpace has an extensive inter-laboratory comparison program. This ensures lab data reflects the impact of a compound and not differences in testing practices.

BIOMARKERS

Medpace offers an extensive menu of biomarkers that use state-of-the-art techniques and provide results that enable patient stratification and improve prediction of drug efficacy and safety. Biomarkers are validated in GLP / GCP / CLIA environments depending on use of biomarkers and requirements of the clinical trial.

Our biomarker team is led by PhD level scientists who oversee the robust pipeline of new biomarker validations. The central lab validates all assays based on guidelines from the Clinical and Laboratory Standards Institute (CLSI) and in accordance with CAP and CLIA regulations.

Medpace central laboratories validate new biomarkers quickly in an industry-leading 10 - 12 weeks.

Medpace's central lab and bioanalytical lab expertise in biomarker development and validation is enhanced by the experience and capabilities of our network of reference and strategic laboratory partners as a seamless service to our clients.

FLOW CYTOMETRY

Medpace has an experienced flow cytometry team overseen by PhD-level scientists with extensive experience designing, analyzing, and interpreting multicolor flow cytometry assays. Whether a custom panel needs to be developed or a method needs to be transferred to our laboratory to support a global clinical trial, we have the experience to quickly validate and implement the flow cytometry testing. Medpace has global flow cytometry capabilities at the US, Belgium, and Singapore laboratories. Examples of services offered:

- Immune cell phenotyping and Immune cell function assays
- Immune cell enumeration
- Intracellular cytokine assays
- Receptor occupancy assays
- CAR T-cell assays
- TBNK assay
- Epigenetic profiling assays
- Stem cell enumeration

MOLECULAR & GENOMICS

Medpace supports Sponsors with advanced testing to detect pathogenic events at the genome level. We offer an array of genetic testing services including:

- DNA, cfDNA and RNA purification (Blood, BM, etc.)
- PCR and RT-PCR (e.g. HBV, HCV, CMV, EBV, BKV, CAR-T cell etc.) CDx, Gene therapy, Organ transplant studies
- Sanger sequencing and fragment analysis
- Next Gen Sequencing



GLOBAL BIOREPOSITORY — SAMPLE MANAGEMENT

Medpace offers comprehensive specimen life cycle management from providing sample collection kits to sites through receipt, processing, storage, retrieval, and destruction. With over 19,000 square feet of sample management space (US, Belgium, Singapore and China) the Medpace Biorepositories are regulated facilities that follows guidance from CAP, WHO GCLP, ISBER and NCI best practices and functions with the level of compliance for services spanning the clinical trial continuum (e.g., proof of concept/early phase through later clinical phase).

GLOBAL LOGISTICS — SUPPLY CHAIN

Working directly with clinical sites and specialty labs, we are committed to managing the logistics life cycle from the delivery of our kits to the sites, and the shipment of the samples to their destination — and we do this across all clinical trial phases. We use an extensive, global, courier network to track samples from sites back to our labs where they're registered upon receipt into ClinTrak® — giving you transparency and confirmation that all samples have reached their destination, whether that is:

- Testing in one of our four global central labs
- Being forwarded to a third-party specialty lab
- Long term storage in one of Medpace's biorepositories

PROJECT MANAGEMENT — ACCESSIBLE AND ACCOUNTABLE

A stable and experienced team facilitates high quality and efficiency. We are committed to minimizing potential risks, reducing study costs, and ensuring study timelines are met. Our project management team is structured to increase quality, shorten timelines, and maintain an active and consistent dialogue with your operational teams. Our unique approach to project management keeps the same dedicated team throughout the life cycle of the entire study and clinical development program, including study start-up, maintenance, and database lock/closeout.

When it comes to speed, Medpace is known for its industry-leading study setup timelines and kit resupply. We also understand and navigate the complex import/export regulations around the globe.

DYNAMIC WEB PORTAL

ClinTrak Lab is a full-scale Laboratory Information Management System (LIMS) that provides seamless web-based access to global clinical trial management information and a smooth transfer of data between key personnel — including Medpace, Sponsors, and investigative sites. ClinTrak Lab provides customizable, study-specific, user-defined flagging and reporting options in addition to study monitoring tools, including graphing capabilities. Secure, web-based reporting provides near real-time access to study progress monitoring as well as cumulative and trending reports. ClinTrak Lab helps sites and key clinical teams by quickly providing them relevant information that they need for decisive actions.

At Medpace, the project manager will be your main point of contact and will manage the study from beginning to end.

FULL-SERVICE CLINICAL DEVELOPMENT

Medpace is a scientifically-driven, global, full-service clinical contract research organization 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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MAKING THE COMPLEX
SEAMLESS™

