

MEDPACE

Partner with a Specialty Team in Gastroenterology Clinical Research

Medpace has global experience conducting Phase I-IV trials for a variety of gastrointestinal indications. An international network of sites and strong relationships with gastroenterology (GI) Key Opinion Leader (KOLs) accelerates patient recruitment and study startup. Our fully integrated medical leadership, in-house imaging core labs, global central laboratories, and operational teams combine to maximize efficiency to provide strategic direction and seamless execution of clinical trials.

Gastrointestinal Indications

- Autoimmune Digestive Disorders/Inflammatory Bowel Diseases:
 - Ulcerative Colitis
 - Crohn's Disease
 - Celiac Disease
- Functional Gastrointestinal Disorders
 - Chronic Idiopathic Constipation
 - Irritable Bowel Syndrome
 - Postprandial Distress and Gastroparesis
- Liver Disease
 - Viral Hepatitis
 - Nonalcoholic steatohepatitis (NASH)

Therapeutic Leadership Across Multiple Indications

As a therapeutically focused, scientifically-driven global CRO, Medpace offers medical leadership in GI, as well as other cross-functional areas including autoimmune diseases, infectious disease, metabolic/diabetes, and hematology and oncology. Medpace employs a seasoned team of clinical trial managers, contract research assistants, data managers, statisticians, safety medical writers, and regulatory with experience across multiple indications.



GASTROENTEROLOGY

Accelerate GASTROENTEROLOGY Clinical Development



EXPERTS:

- In-house internist with nearly 20 years of experience in clinical drug development and pharmaceutical research
- A cross-functional team of experts in related indications such as autoimmune, endocrine and metabolic, hematology and oncology, and nephrology brings scientific, operational and regulatory experience and know-how to orchestrate complex studies



EXPERIENCE:

- Global experience conducting Phase I-IV GI clinical trials spanning adult and pediatric populations
- Deep understanding of the complex conditions that cause gastrointestinal disorders, inflammatory bowel diseases, functional gastrointestinal disorders, and liver diseases as well as the medical complications experienced by patients with these conditions
- Thorough understanding of the key aspects of GI trial design and patient eligibility criteria, as well as the ability to manage potential challenges and logistical requirements associated with screening and enrolling this patient population
- In-house experts helped pioneer work on standardization of central imaging in inflammatory bowel disease drug development



EXECUTION:

- Accelerated recruitment and study startup through established relationships with KOLs and Investigators
- Our physicians are embedded within the project team consulting with the Sponsor, project team, and investigative sites, ensuring our operational strategy is firmly aligned with objectives
- Integrated imaging and central laboratory services, ensuring seamless logistics, review, and testing
- ClinTrak® - Medpace's proprietary clinical trial management technology - facilitates team coordination, decision support, and greater efficiencies for sponsors, sites, and the study project teams

Key Differentiators for Gastroenterology Clinical Research

- Global experience conducting Phase I-IV GI clinical trials spanning adult and pediatric populations
- Deep understanding of the complex conditions that cause gastrointestinal disorders, inflammatory bowel diseases, functional gastrointestinal disorders, and liver disease
- In-house internist with nearly 20 years of experience in clinical drug development
- A cross-functional team of experts in related indications such as gastrointestinal disorders, autoimmune, endocrine and metabolic, hematology and oncology, and nephrology brings scientific, operational and regulatory experience and know-how to orchestrate complex studies
- Thorough understanding of the key aspects of GI trial design and patient eligibility criteria, as well as the ability to manage potential challenges and logistical requirements associated with screening and enrolling this patient population
- Strong global relationships with KOLs and experienced and successful Investigators to drive efficient enrollment
- Integrated imaging and central laboratory services ensuring seamless logistics, review, and testing

Add Efficiency with Integrated Core Imaging and Central Labs

We provide a fully integrated solution with our CRO, in-house imaging core lab and our global central labs to maximize efficiency for clinical development.

Endoscopy has become a standard outcome measure in many gastrointestinal indications including Inflammatory Bowel Disease. The concept of mucosal healing and deep remission in Crohn's Disease and Ulcerative Colitis has gained momentum with regulators and prescribers. Centralized imaging allows for standardization of patient inclusion and outcome assessment. Medpace Core Imaging Labs provides holistic central imaging service including site assessment, qualification and training, recording equipment, provisioning, image processing (blinding and quality control) and expert evaluation.

Medpace's central laboratories can help design and execute your protocol testing needs with a strong selection of inflammatory biomarkers and cytokines. Our four wholly-owned central laboratories (located in the US, Belgium, Singapore, and China) are experienced with a comprehensive test menu to deliver quality results.

Scientifically-Driven Clinical Development

Our scientifically-driven approach to clinical development provides you the advantage of early and ongoing insight and guidance from therapeutic experts throughout trial design and execution. Our highly experienced medical doctors work closely with our regulatory and operations experts to provide strategic direction for study design and planning, train operational staff, work with Investigators, provide medical monitoring, and meet with regulatory agencies. They are embedded throughout your studies, providing greater depth and the ability to tackle complex and challenging diseases.

Move Faster with a Global, Full-Service CRO

For more than 25 years, Medpace has steadfastly held to a model of providing full-service clinical development services to accelerate the development of safe and effective medical therapeutics. We partner to guide you through the fastest path to commercial success with hands-on and highly-qualified medical, regulatory and operational experts.

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. We leverage local regulatory and deep therapeutic expertise across all major areas including hematology, oncology, cardiology, metabolic diseases, endocrinology, nephrology and renal diseases, autoimmune diseases, central nervous system and anti-viral and anti-infective.