MEDPACE

GASTROENTEROLOGY CLINICAL RESEARCH

Medpace has global experience in Phase I-IV gastroenterology (GI) studies for a variety of gastrointestinal indications. Our expertise in GI clinical research and consistent track record of success as a full-service CRO ensures the flexibility to adapt to the unique needs of each trial.

Indication experience:

- Autoimmune Digestive Disorders and Inflammatory Bowel Diseases (IBD):
  - 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)

As a therapeutically-focused CRO, Medpace's experts and multi-disciplinary teams have experience in many different areas. Our experience with global regulatory authorities, coupled with early planning and collaboration with Sponsors, accelerates the path to approval. Our therapeutically trained teams, including clinical trial managers and program coordinators, provide knowledgeable training to sites and help mitigate challenges.

Our in-house medical expertise was involved in pivotal IBD and functional GI disorder studies that resulted in successful submissions and approvals.

MAKING THE COMPLEX

SEAMLESS™

EXPERTS

- Led by an in-house internist with 20 years' experience in pharmaceutical research
- Highly-trained medical, regulatory, and operations project teams
- In-house experts that helped pioneer the standardization of central imaging in inflammatory bowel disease research

EXPERIENCE

- Global Phase I-IV GI trial experience
- Spans adult and pediatric populations in GI
- Deep understanding of the complex conditions that cause GI disorders
- Knowledgeable in GI trial design and patient eligibility criteria
- Able to manage potential challenges and logistical requirements associated with screening and enrolling GI patients

EXECUTION

- Strong global relationships with key opinion leaders and Investigators
- Access to high-performing investigative sites
- Fully integrated imaging and central laboratory services, ensuring seamless logistics, review, and testing
- ClinTrak® technology for practice study management

CROSS-FUNCTIONAL TEAM

Our cross-functional team of medical experts experienced in many therapeutic areas, including GI, autoimmune, infectious disease, metabolic/ diabetes, and hematology and oncology, bring scientific experience to each trial. Further, Medpace employs a seasoned team of clinical trial managers, clinical research assistants, data managers, statisticians, safety, medical writers, and regulatory with experience across multiple indications. When our teams work together, we can perform at the highest levels to deliver quality results in a timely and efficient manner.

CORE IMAGING LAB

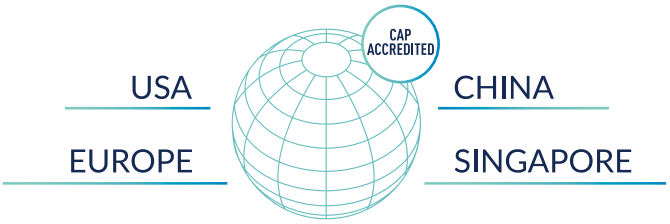
Medpace's imaging core lab provides comprehensive imaging expertise to integrate imaging components into each clinical trial seamlessly. Supported by a team of scientists, clinicians, technologists, project managers, and coordinators, our imaging core lab can successfully integrate standard and novel GI biomarkers into studies from concept through design and execution.

Centralized imaging allows for the standardization of patient inclusion and outcome assessments, including endoscopy for mucosal healing, and deep remission has become a standard outcome measure in IBD indications such as Crohn's Disease and Ulcerative Colitis.

Medpace's imaging core lab provides holistic central imaging services, including site assessment, qualification and training, recording equipment, provisioning, image processing (blinding and quality control), and expert evaluation.

CENTRAL LABS

Medpace central laboratories offer global lab services, including an extensive menu of inflammatory biomarkers and cytokines that use state-of-the-art techniques for all stages of the development process.



Focused on both the scientific and service aspects with four wholly-owned laboratories in the US, Europe, China, and Singapore, our central lab has the global reach to support studies, assist with regulatory requirements and deliver custom solutions for any need.

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.

WE CAN'T SIMPLIFY CLINICAL DEVELOPMENT – BUT WE CAN EXECUTE IT SEAMLESSLY.

MAKING THE COMPLEX SEAMLESS™