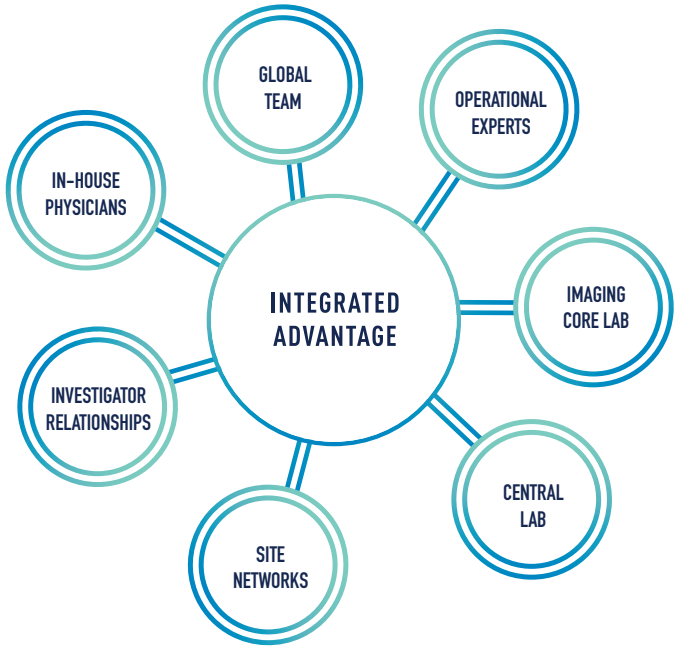
A DEEPER DIVE INTO GASTROENTEROLOGY, HEPATOLOGY AND NUTRITION CLINICAL DEVELOPMENT

AN INTEGRATED ADVANTAGE

As a therapeutically-focused Clinical Research Organization (CRO), Medpace specializes in the design and conduct of global trials in gastrointestinal disorders. With our proven full-service outsourcing model, Medpace delivers high-quality results. Our experience, coupled with our strong relationships with KOLs and investigative sites as well as our integrated in-house central lab and imaging core lab services, delivers efficiencies that will accelerate the clinical development of your compound.

Key differentiators include:

- In-house gastroenterology-team with bench-to-bedside experience that were pioneers in IBD diagnostics, biomarkers (big data and -omics technologies) and novel therapeutics. This includes:
  - The standardization of centrally reviewed endoscopy in inflammatory bowel disease research
  - First in-human use of anti- adhesion molecules (Integrins such as alpha4 beta7)
  - First in-human use of systemic antisense RNA therapeutics (alicaforsen)
  - First description of ACT-1 in human-derived IBD and normal intestinal lymphocytes, later to become vedolizumab
  - First to recognize and guide clinical development of a HIF agonist for IBD therapeutics
  - Cell transport pathways (Pgp-170, HIF, VEGF etc.)
  - Models of inflammation including transgenics and organoids
- Global experience conducting Phase I-IV GI, liver and nutrition disease clinical trials spanning adult and pediatric populations
- Strong relationships with successful, experienced investigative sites which regularly participate and successfully enroll gastroenterology studies
- A seasoned clinical operations staff with specific experience in conducting gastroenterology trials
- Fully integrated imaging and central laboratory services, ensuring seamless logistics, review, and testing



COLLABORATIVE & CROSS FUNCTIONAL TEAMS

Medpace is unique in its scientifically-driven approach to clinical research. Our model gives Sponsors the advantage of early and ongoing insight and guidance from a team of therapeutic experts throughout trial design and execution. Our highly-experienced team of medical, regulatory, and operational experts work collaboratively to conduct clinical trials. We understand issues from the perspective of Sponsors, clinical investigators, scientific leaders, and reviewers at regulatory agencies. With this insight, we successfully define and execute clear development plans from beginning to end.

EXPERTS

Serving as therapeutic team leaders, our in-house medical doctors provide strategic direction for study design and planning, train operational staff, work with Investigators, provide medical monitoring, and meet with regulatory agencies as well as our global regulatory affairs experts to provide strategic guidance into the best pathways to accelerate approvals. Our MDs are embedded throughout every study, providing greater depth of expertise and the ability to tackle complex and challenging diseases.

In-House Physicians:

Piotr Krzeski, MD, PhD, FFPM
Vice President, Medical Department

Bruce Yacyshyn, MD, FRCPC, FACG, AGAF
Vice President, Medical Department

Piotr Krzeski, MD, PhD, FFPM

Vice President, Medical Department

Dr. Piotr Krzeski is an experienced internist with 20 years of experience in gastroenterology and hepatology, including Inflammatory Bowel Diseases, Functional GI Disorders, cholestatic liver diseases, NAFLD and NASH.

Experience Summary

- An internist with a broad background in pharmaceutical research
- 20 years' experience in GI clinical drug development
- Global expertise in the design and medical oversight of clinical trials in the area of gastroenterology and non-infectious hepatology
- Recognized in the field for his contribution to the pioneering work on standardization of central imaging in drug development

Education Summary

- Diploma in Pharmaceutical Medicine, Royal Colleges of Physicians
- Doctor of Philosophy in Medical Sciences in Hepatology, Medical Centre for Postgraduate Education
- Medical Degree, Warsaw Medical Academy

Bruce Yacyshyn, MD, FRCPC, FACG, AGAF

Vice President, Medical Department

Dr. Yacyshyn is a Gastroenterologist/Internist with over 35 years of experience focusing on translational/clinical research of gastroenterology and hepatology, and nutrition.

Experience Summary

- A gastroenterologist and translational clinical researcher with a special interest in patients with inflammatory bowel disease (ulcerative colitis and Crohn's disease), gut inflammation, functional bowel disorders, enteric infections, big-data analysis, -OMICS applications to clinical medicine, models of disease and pre-clinical and early stage drug development
- Clinical research expertise in managing studies in therapeutic areas, including gastroenterology, hepatology, and nutrition
- Leadership in IBD research/patient care, first in-human use of anti-adhesion molecule targeted therapeutics (ISIS 2302), first in-human use of systemic antisense therapeutics (ISIS 2302), preclinical HIF agonist therapeutics
- An experienced clinical director for inpatient and outpatient care including: liver, including pre- and post-liver transplant recipients, and nutrition patients
- Well-published and cited in peer-reviewed medical and scientific literature

Education Summary

- Doctor of Medicine, University of Alberta – Edmonton, Canada
- Resident in Medicine, University of Toronto, Toronto General Hospital
- Clinical and Research Fellow, Gastroenterology, Washington University in St. Louis, School of Medicine
- Adjunct Professor, Department of Pharmacology and Systems physiology University of Cincinnati School of Medicine

EXPERIENCE

Our team of experts have conducted global studies across a wide variety of gastrointestinal indications. We understand the complexities and unique challenges involved in gastroenterology trials. Our experience with global regulatory authorities, coupled with early planning and collaboration with Sponsors, accelerates the path to approval. Our knowledge of effective GI trial design and patient eligibility criteria allow us to manage potential challenges and logistical requirements associated with screening and enrolling GI patients, accelerating recruitment timelines.

Medpace has conducted Phase I-IV trials around the world. Our physicians and staff are experienced in the following areas:

- Digestive Disorders including Inflammatory Bowel Diseases (IBD)
  - Ulcerative Colitis
  - Crohn's Disease
  - Celiac Disease
  - Eosinophilic Esophagitis
  - Infectious Enteritis
- Functional/Motility Disorders
  - Constipation (including opioid induced
  - Irritable Bowel Syndrome
  - Postprandial Distress Syndrome
  - Gastroparesis
- Peptic Ulcer Disease (including GERD)
- Precision GI Medicine (Diagnostics), -OMICS and Big Data analysis
- Short Bowel Syndrome
- Liver Disease, including Viral Hepatitis and Nonalcoholic steatohepatitis (NASH), cholestatic liver disease (primary biliary cholangitis, primary biliary sclerosis), cirrhosis of diverse origin
- Rare disease within GI/Hepatology (eg. Wilson's Disease, Alfa-1 Antitrypsin Deficiency)

EXECUTION

Medpace offers a distinct advantage to Sponsors developing therapeutics for gastroenterology and liver diseases. We have the in-house experts, extensive experience, as well as a unique model for execution that includes the integration of critical services such as labs, imaging, and safety.

KEYS TO SUCCESSFUL EXECUTION

Committed Teams: Your studies are assigned the best team from the onset and, with turnover rates that are lower than the industry standard, that team is with you from project initiation to completion. As a result, we typically develop better team dynamics that are based on trust and respect.

Resourcefulness: Medpace promotes a culture of problem-solving. Our global operational staff proactively identify potential issues and communicate solutions, ensuring your sites and studies are managed effectively and efficiently.

Site and KOL relationships: Through our experience and relationships with Investigators and key opinion leaders (KOLs) worldwide, we can select the best sites for your specific study or program. This provides an advantage in meeting your recruitment timelines with high quality data. Medpace has received multiple awards from sites recognizing Medpace as a leading global CRO, particularly noting the excellence and training of our CRAs and site staff.

Regulatory Support: Medpace offers a dedicated global regulatory submissions team as well as global regulatory affairs for comprehensive support.

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.

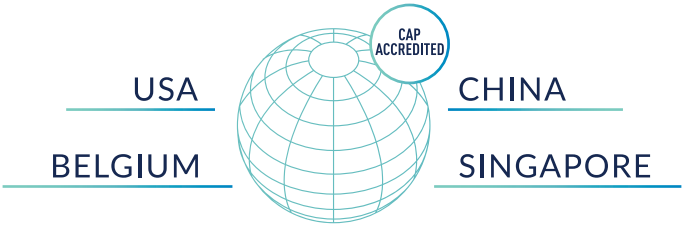
Centralized imaging allows for the standardization of patient inclusion and outcome assessments, including endoscopy for mucosal healing, and deep remission has become a standard outcome measure in IBD indications such as Crohn's Disease and Ulcerative Colitis.

Over the last decade Medpace's imaging core lab has developed thorough expertise of MR imaging in various gastroenterology/hepatology indications such as MRI PDFF or MRE, with proprietary processes, internal and external central reviewers.

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.

CLINTRAK® STUDY MANAGEMENT TECHNOLOGY

ClinTrak® (centralized CTMS) provides access to comprehensive study details in a single sign-on, facilitating team coordination and decision support for sponsors and sites.

Lab: The ClinTrak® Lab component is a full-scale Laboratory Information Management System (LIMS) that provides access to daily lab reports, management information, cumulative results and trend graphing, secure role-based access, and study specific project management pages.

Imaging: The ClinTrak® Imaging component integrates image tracking, quantitative and qualitative analysis, and data management to store and manage data from all imaging and reading centers.

Patient Reported Outcomes (ePRO/eDiary): Patients are more likely to be engaged in clinical trials when the process is transparent and they can understand their role in the research that may lead to advancements in the treatment or diagnosis of their conditions. Our TrialPACE™ app allows for the safe and secure collection of PRO data directly from patients through multiple platforms.

Sites: Our OnPace™ site app was developed to assist sites in preparing for each study visit by providing a clear overview of all assessments, access to study documentation such as the protocol and IB and links to all study websites.

PATIENT RECRUITMENT AND RETENTION PLATFORM

IntelliPACE® is Medpace's in-house program for successful and expedited patient recruitment. Driven by external and internal data sources (including our proprietary study management system, ClinTrak®), we leverage our well-profiled network of sites and relationships with PIs and KOLs to determine feasibility and to develop a well-vetted recruitment strategy. Once identified, our specialized recruitment teams ensure well-coordinated and efficient execution.

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™