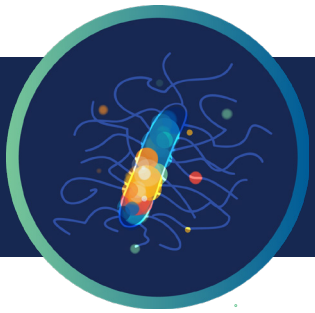
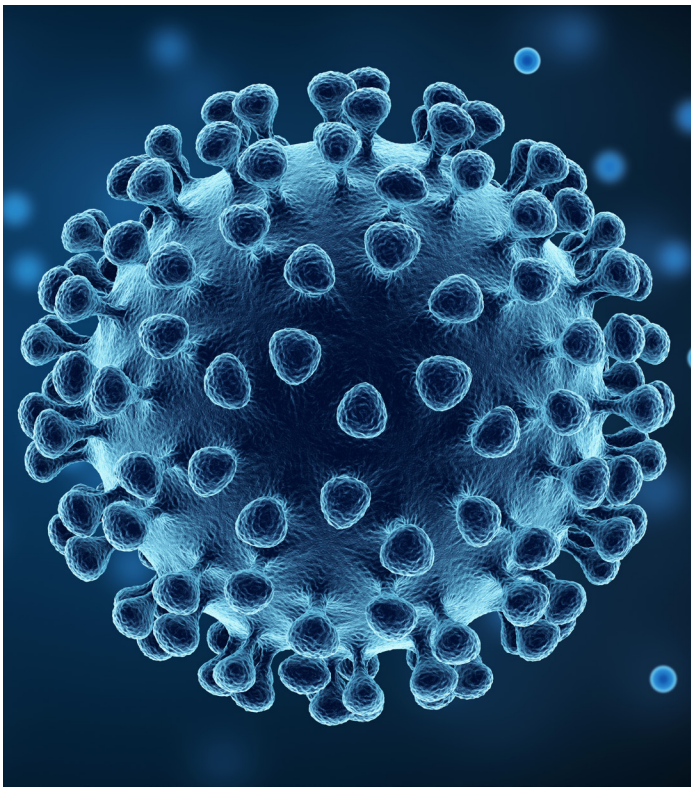
MEDPACE

INFECTIOUS DISEASES AND VACCINES CLINICAL DEVELOPMENT



Medpace supports our Sponsors who are advancing new anti-infectives and vaccines by providing specialized expertise in the design and management of their programs to maximize the compound's probability of success.

We have assembled a team of therapeutically focused physicians and professional staff who have extensive experience designing and conducting infectious diseases clinical trials and understand the issues from the perspective of the sponsor, the clinical investigator, the scientific leader, and the reviewer at the regulatory agencies.



Achieve quality results, meet deadlines, and maximize efficiencies by partnering with a CRO that excels in designing and executing ID research.

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 key opinion leaders, and regulatory agencies. With this insight, we successfully define and execute clear development plans from first time in human (FTIH) studies, Phase I-IV, through to project registration (NDA, MAA).

EXPERTS

THERAPEUTICALLY-FOCUSED, SCIENTIFICALLY-DRIVEN

Unique in its approach to clinical research, our model gives Sponsors the advantage of early and ongoing insight and guidance from therapeutic experts throughout trial design and execution. Our highly experienced medical doctors provide strategic direction for study design and planning, train operational staff, work with Investigators, provide medical monitoring, and meet with regulatory agencies. In addition, our medical monitors work collaboratively with our global regulatory affairs experts to provide strategic guidance into the best pathways to accelerate approvals.

Brian Murphy, MD, MPH, FIDSA
Sr. Vice President, Medical Department

Anibal Calmaggi, MD
Sr. Medical Director

Phillip Cole, MD
Sr. Medical Director

Slobodan Ilic, MD
Sr. Medical Director

Arlene Dent, MD, PhD
Medical Director

ADVANCED CLINICAL PRACTITIONERS ADD A PATIENT'S PERSPECTIVE

Our medical directors are supported by experienced ACPs whose unique perspective brings added value to the clinical development team. These highly-trained experts with advanced degrees and hands-on clinical experience provide an additional layer of knowledge and insights that can streamline your studies and address potential challenges early in the study planning. ACPs are embedded in the teams to ensure your study is feasible and operationalized for efficient execution by looking at the protocol through the lens of the patient and site staff. ACPs also help with the review of safety events, ongoing team education, recruitment strategies, and study document review. Their understanding of what works in a clinical setting makes them a valuable part of our embedded medical expertise model.

Jennifer Herminger, APRN
Advanced Clinical Practitioner

IN-HOUSE PHYSICIAN BIOGRAPHIES

Brian Murphy, MD, MPH

Sr. Vice President, Infectious Diseases & Vaccines

Dr. Brian Murphy is board certified in infectious diseases, internal medicine, and pediatrics and has over 22 years of experience in clinical research for anti-infectives and vaccines.

Experience Summary

- Extensive industry experience in Phase I-IV global infectious diseases studies, including antibacterials, antifungals, antivirals, vaccines, and device
- Eight years' experience as an academic PI and consultant on multiple infectious disease programs investigating the pathogenesis and management of serious infections in hospitalized patients, HIV, pulmonary respiratory pathogens, fungal diseases, vaccine development, bioterrorism, and immunotherapeutics
- Leadership roles in multiple translational and clinical research projects sponsored by the NIH (NIAID and NHLBI), CDC, Department of Defense, US Department of Health and Human Services, and other non-dilutive funded-projects in a broad range of patient populations
- Upholds an academic appointment and clinical practice and maintains close ties with his clinical and research colleagues who participate in clinical and translational research

Education Summary

- Doctor of Medicine, University of Louisville, School of Medicine
- Residency, University of Kentucky, School of Medicine
- Fellowship, Infectious Disease, University of Kentucky, School of Medicine
- Master of Public Health, University of Kentucky, College of Public Health
- Fellowship, Vaccine Research, NIH Center of Excellence for Bioterrorism

Anibal Calmaggi, MD

Sr. Medical Director, Infectious Diseases & Vaccines

Dr. Anibal Calmaggi is board certified in infectious diseases and has more than 21 years of experience in pharmaceutical and clinical research, including director-level clinical operations and medical affairs experience.

Experience Summary

- Extensively participated in the elaboration and review of several clinical guidelines in practice including upper respiratory infections, hospital-acquired pneumonia, and infection in recipients of hematopoietic stem cell transplants
- Held a variety of medical roles including senior director level positions while providing valuable insights into global infectious disease drug development programs
- Esteemed author of several chapters in infectious disease books as well as publishing articles in peer-reviewed journals

Education Summary

- Doctor of Medicine, University of La Plata, School of Medicine
- Internal Medicine Residency, Hospital San Martin, La Plata, Argentina
- Fellowship, Infectious Disease, Sanatorio Guemes, Buenos Aires

Phillip Cole, MD

Sr. Medical Director, Infectious Diseases & Vaccines

Dr. Phillip Cole is board certified in infectious diseases and internal medicine. He brings over 10 years of clinical and research experience with positions in academia and industry.

Experience Summary

- Extensive industry experience in Phase I-IV global studies, including antibacterials, antifungals, rare diseases, and solid organ oncology
- Primary author or key contributor for several IND amendments, sNDAs, briefing books, and regulatory requests for information for the FDA, EMA, MHRA, BfArM, and ANVISA
- Clinical practice experience as Infectious Diseases Consultant for Pulmonary Medicine Associates, Sacramento, California, and as a Hospitalist for the Permanente Medical Group, Oakland, California inclusive of management of critically ill patients and teaching roles for internal medicine residents
- Former volunteer clinical faculty at University of California, Davis, School of Medicine attending for Infectious Diseases Fellows at the Center for AIDS, Research and Services (CARES)

Education Summary

- Doctor of Medicine, University of California, San Francisco, School of Medicine
- Bachelor of Science, Biochemistry & Cell Biology and Bachelor of Arts, History, University of California, San Diego
- Internship, University of California, San Francisco Medical Education Program, Fresno
- Residency, Internal Medicine, Kaiser Foundation Hospital, Oakland
- Fellowship, Infectious Diseases, University of California, Davis, School of Medicine

Slobodan Ilic, MD

Sr. Medical Director, Infectious Diseases & Vaccines

Dr. Slobodan Ilic is a doctor of medicine bringing over 20 years of experience in infectious diseases clinical research.

Experience Summary

- Held multiple director roles in a global CRO, including Executive Medical Director, Head of Infectious Diseases and Vaccines Center of Excellence and Director of Medical Affairs
- Experience working with an international team of Medical Monitors and Drug Safety Physicians to ensure medical/clinical integrity and quality of studies
- Served as Medical Monitor and Pharmacovigilance Officer on international clinical trials, including drugs, biologics, and medical devices
- Extensive experience in clinical trials with previous experience as a clinical research associate

Education Summary

- Doctor of Medicine, University of Belgrade – Belgrade, Serbia
- Cardiac Surgery Resident, Clinical Centre of Serbia, Institute for Cardiovascular Diseases – Belgrade, Serbia
- Certified Clinical Research Associate

Arlene Dent, MD, PhD

Medical Director, Infectious Diseases & Vaccines

Dr. Arlene Dent is board-certified in Pediatrics and Pediatric Infectious Diseases with over 20 years of clinical experience in inpatient and outpatient pediatric Infectious Diseases practice.

Experience Summary

- Prior NIH funded research focused on human immunologic responses to infectious diseases using state-of-the-art technology
- Experience includes working with premature severely ill babies in the Neonatal Intensive Care Unit, patients in the Pediatric Intensive Care Unit, Transplant and Hematologic/ Oncologic patients who may be severely immunosuppressed, and general pediatric patients admitted with severe infections
- Experience developing research plans, including grant applications, grant project implementation, participant safety monitoring, research study procedures, and data analysis
- Well-published in peer-reviewed articles and publications on pediatric infectious diseases

Education Summary

- Doctor of Philosophy in Anatomy, Indiana University - Bloomington, IN
- Doctor of Medicine, Indiana University - Bloomington, IN
- Bachelor of Science in Biology, Indiana University - Bloomington, IN

Jennifer Heminger, MSN, APRN, FNP-BC

Advanced Clinical Practitioner

Ms. Heminger is a Board-Certified Family Nurse Practitioner bringing experience in the hospital and health care industry to the Medpace team.

Experience Summary

- Experienced in developing and coordinating comprehensive plans of care for patients
- Previous experience as an Infectious Disease Nurse Practitioner diagnosing complicated viral, bacterial, and fungal infections and developing targeted health education and treatment adherence strategies for patients
- Performed complete physical assessments in the inpatient, outpatient, and long-term care settings
- Provided evidence-based care in the adult medical/surgical intensive care setting
- Active member of the American Academy of Nurse Practitioners
- Associate Member of the Infectious Disease Society of America

Education Summary

- Master of Science in Nursing, Family Nurse
- Practitioner, University of Cincinnati – Cincinnati, OH
- Master of Science in Nursing, Mount St. Joseph University – Cincinnati, OH
- Bachelor of Science in Pre-Medical Studies, University of Dayton – Dayton, OH

Drive efficiencies and quality results with an Infectious Diseases team of medical, operational, and regulatory experts with global experience and strong site relationships

EXPERIENCE

The complex nature of conducting infectious diseases and vaccine studies, especially those in medically challenging patient populations, demands a thorough medical understanding of the disease, as well as the issues surrounding the geography, epidemiology, and prevalence of the disease. It is also critical that as strategic operational and regulatory decisions for the development of the study are made, the CRO has the ability to provide ongoing, real-time feedback to the Sponsor and to the Investigators. Medpace's therapeutic leaders and its clinical operations team have earned a strong reputation for addressing these challenges and for being responsive, reliable, and consistently delivering high-quality data.

Medpace has experience in conducting clinical trials in anti-bacterial, anti-fungal, anti-viral, vaccine, and diagnostics across all phases of development.

- Antivirals
  - Nucleos(t)ide analogs
  - RTIs
  - Entry inhibitors
  - Protease inhibitors and boosters
  - Allogeneic and stem cell therapies
  - RNAi
  - Monoclonal antibodies
- Anti-bacterial
  - Aminoglycosides
  - Oxazolidinones
  - Macrolides/ketolides
  - Fluoroquinolones
  - Fab-Inhibitors
  - Carbapenems
  - Beta-lactams
  - Beta-lactamase inhibitors
  - Pleuromutilins
  - Phage therapy
  - Microbiome
  - Monoclonal antibodies
- Antifungals
  - Polyenes
  - Echinocandins
  - Triazoles
- Vaccines/Biologics
  - Protein/polysaccharide
  - DNA

KEY PATHOGEN EXAMPLES

- SARS-CoV-2
- Hepatitis B and C
- Herpes viruses (including HSV, VZV, CMV)
- HIV
- Influenza virus
- West Nile virus
- Streptococcus pneumoniae
- Staphylococcus aureus including MRSA
- MDR Gram-negatives
- Aspergillus species and rare molds
- Candida species
- Tuberculosis
- Bordetella pertussis
- Clostridium difficile
- Bioterrorism agents
- Helicobacter pylori

EXECUTION

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.

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

Driving Efficiencies and Consistency of Data for Global Studies: Exceed your expectations by partnering with a CRO that delivers high-quality results, meets deadlines, and maximizes efficiencies. Operating under a full-service model, Medpace provides a therapeutically focused, integrated, global approach for seamless execution and quality results.

STRATEGIC SPECIALTY LABS

Lab requirements for infectious diseases drug development can be challenging. For example, in antibiotic drug development, it is necessary to understand the relationship among a range of potential pathogens with multiple resistance mechanisms and baseline susceptibility patterns, pharmacokinetic gradients in the urine, and patient variables. The Medpace team works collaboratively with some of the top leaders in microbiology, virology, immunology, and PK-PD modeling. Medpace's Central Labs provide support in virology testing, and when working with partnered specialty labs, coordinates the often complex logistics of global specialty testing. This approach streamlines timelines, simplifies requirements for sites, and provides a centralized model for communication.

MEDPACE CENTRAL LAB GIVES SPONSORS A COMPETITIVE ADVANTAGE

- Access to top research scientists who are therapeutically focused on infectious diseases, deliver regulatory quality reports and meet the tight timelines demanded in ID trials
- With Medpace Central Labs coordinating the shipping between sites and labs around the world, logistics are greatly simplified, resulting in higher efficiency
- Seamless integration with Medpace's full-service approach to clinical trial management

DATA INTEGRITY UNIT

A specialized Data Integrity Unit is dedicated to collaborating with the clinical team and ensuring the protocol is maximally operationalized to collect appropriate microbiological, diagnostic, and biomarker data to evaluate study outcomes. The team will also liaise with local and central labs as well as provide real-time review of study diagnostic and laboratory data to monitor protocol testing and identify trends or issues. The Data Integrity Unit works closely in collaboration with the Medpace Data Management team, on case report form design and data cleaning to ensure the quality and scientific integrity of the data are satisfactory.

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