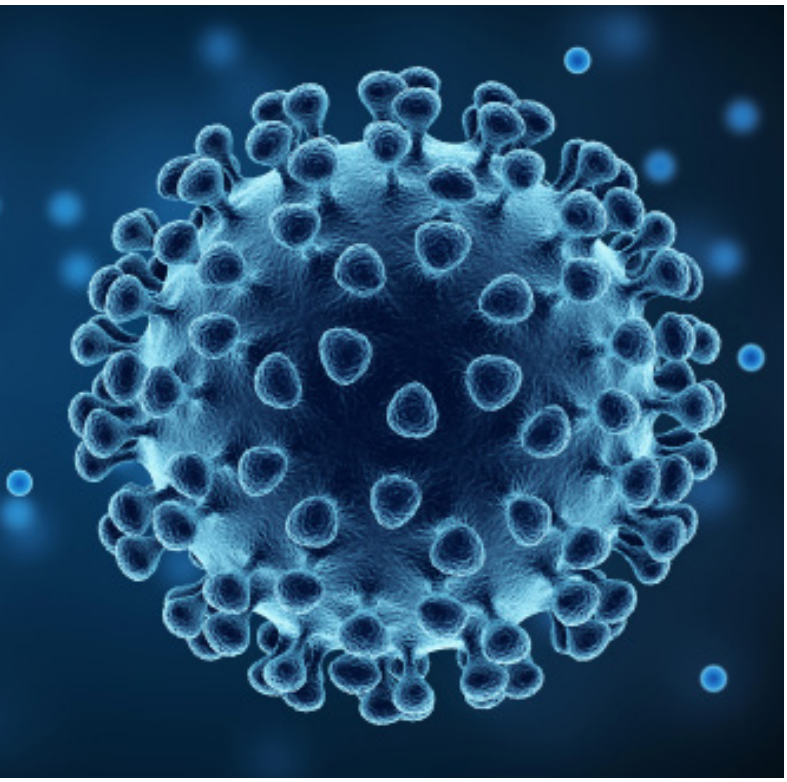
INFECTIOUS DISEASES AND VACCINES CLINICAL DEVELOPMENT

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 disease 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.

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.

Anibal Calmaggi, MD
Senior Medical Director

Phillip Cole, MD
Medical Director

Hervé Momméja-Marin, MD
Vice President, Medical Affairs

Brian Murphy, MD, MPH
Vice President, Medical Affairs

EXPERTS

Anibal Calmaggi, MD

Senior Medical Director, Infectious Diseases and Vaccines

Dr. Anibal Calmaggi is board certified in infectious diseases and has more than a decade of 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

Medical Director, Infectious Diseases and 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

Hervé Momméja-Marin, MD

Vice President, Medical Affairs, Infectious Diseases and Vaccines

Dr. Mommeja-Marin is board certified in internal medicine and has 15 years of director-level experience in clinical research.

Experience Summary

- Previously Vice President of Clinical Research at a major biopharmaceutical company that is dedicated to developing and commercializing oral antivirals
- Led a cross-functional team supporting the development of brincidofovir for the prevention of CMV post-hematopoietic cell transplantation and treatment of adenovirus in immunocompromised patients
- Key contributor to 6 NDA/MAA
- Extensive experience in coordinating medical affairs, regulatory functions, statistical analysis, data management, medical monitoring, marketing, and vendor management

Education Summary

- Doctor of Medicine, University Pierre et Marie Curie, Paris VII
- Baccalaureate in Mathematics, Tours France
- Certificate: Endocrinology Pharmacology, Epidemiology, Biostatistics

Brian Murphy, MD, MPH

Vice President, Medical Affairs, Infectious Diseases and Vaccines

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

Experience Summary

- Extensive industry experience in Phase I-IV global infectious disease 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

EXPERIENCE

The complex nature of conducting infectious disease 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 disease 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.

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.