A Deeper Dive into Infectious Diseases and Vaccines

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.

Physician-Driven Clinical Development

Meet our team of ID medical monitors

Medpace, a global drug and medical device Clinical Research Organization (CRO), is unique in its physician-driven approach to clinical research. The Medpace 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.
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

Hervé Mommeja-Marin, MD
Senior Medical Director, 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 for the 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-bacterials, anti-fungals, anti-virals, vaccines, and diagnostics across all phases of development.

Experience highlights of Medpace and its ID team members

- **Antivirals**
  - Nucleos(t)ide analogs
  - RTIs
  - Entry inhibitors
  - Protease inhibitors & boosters
- **Anti-bacterial**
  - Aminoglycosides
  - Oxazolidinones
  - Macrolides/ketolides
  - Fluoroquinolones
  - Fab-Inhibitors
  - Carbapenems
  - Beta-lactams
  - Beta-lactamase inhibitors
  - Pleuromutilins
- **Antifungals**
  - Polyenes
  - Echinocandins
  - Triazoles
- **Vaccines/Biologics**
  - Protein/polysaccharide
  - DNA

Examples of Key Pathogens

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

Driving Efficiencies and Consistency of Data for Global Studies

Achieve quality results, meet deadlines, and maximize efficiencies by partnering with a CRO that excels in execution. Medpace demonstrates a commitment to quality and a united dedication to conducting full-service studies in an exacting manner to produce the highest quality results.

Keys to successful execution include:

- **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.

**Strategic Specialty Labs:**

Lab requirements for infectious disease drug development can often be more challenging than any other therapeutic area. For example, in antibiotic drug development, it is necessary to understand the relationship among a broad range of potential pathogens with multiple resistance mechanisms and baseline susceptibility patterns, pharmacokinetic gradients in the urine, and patient variables. Because of the highly specialized requirements for lab services, the Medpace team works collaboratively with some of the top leaders in microbiology, virology, immunology, and PK-PD modeling. In addition, 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’s lab relationships plus central lab model gives sponsors a competitive advantage:

- Access to top research scientists who are therapeutically focused in 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.