MEDPACE

COVID-19 CLINICAL DEVELOPMENT

Medpace is committed to assist in the fight against COVID-19, which aligns with our mission of accelerating the global development of safe and effective medical therapeutics. We have a highly-experienced infectious disease team, including medical, regulatory, operational, and laboratory experts who have extensive experience designing and conducting infectious disease clinical trials. Our team is actively working with the global regulatory authorities and Sponsors responding to COVID-19.

WELL-EQUIPPED TO ASSIST WITH COVID-19

Speed: Our proven flat operating model and our multi-disciplined approach are designed for efficiency. We are well-equipped to move quickly and have taken steps to accelerate contracting and site-startup.

Site and investigator relationships: We can leverage strong relationships to quickly assess feasibility, accelerate enrollment, and move trials forward.

Regulatory engagement: Knowledgeable in the changing regulatory landscape at local, regional, and global levels, our team can support your regulatory strategy and execution.

Remote monitoring tools and technology: Our processes and technology platforms enable remote monitoring and fast data acquisition. We support both sites and patients with portals for accessing and recording data that is easily accessible. We can support alternative methods for safety assessment, including phone contacts and virtual visits.

Government and research agencies: Our experience and relationships allow us to collaborate with government agencies and other research institutions, such as BARDA, NIH, and Wellcome-Trust.

MAKING THE COMPLEX
SEAMLESS™

COVID-19 TESTING CAPABILITIES

To serve our clients in their COVID-19 programs Medpace has expedited COVID-19 assay validations to quickly meet clinical trial testing standards.

SARS-CoV-2 RT-PCR Testing

- **SARS-CoV-2 QUANTITATIVE RT-PCR**
  - Fully validated Lab Developed Test (LDT)
  - Absolute quantification of the virus copy number (viral load)
  - Validated sample types: NP/OP swabs
- **SARS-CoV-2 QUALITATIVE RT-PCR**
  - The Abbott RealTime SARS-CoV-2 assay is a dual target assay for the RdRp and N genes
  - The test is FDA-approved under an Emergency Use Authorization (EUA)
  - Specificity of 100% and a sensitivity of ≥95%
  - Validated sample types: NP/OP swabs, plasma (blood)
  - Validation in Progress: Saliva, sputum, BAL, urine, and stool
  - Reported result turnaround time: 24-48 hours after sample receipt

SARS-CoV2 Antibody Testing

- **Roche**
  - Test Name: Anti-SARS-CoV-2
  - Method: ECLIA on the Cobas e801
  - Antigen: nucleocapsid (N)
  - Detects: Pan-Ig
  - Specificity of 99.8% and a sensitivity of 100%
- **DiaSorin**
  - Test Name: SARS-CoV-2 S1/S2 IgG
  - Method: CLIA on the Liaison XL
  - Antigen: S1/S2 spike
  - Detects: IgG
  - Specificity of 99.3% and a sensitivity of 97.6%
- **Siemens**
  - Test Name: SARS-CoV-2 Total
  - Method: CLIA on the ADVIA Centaur
  - Antigen: S1 spike
  - Detects: IgG and IgM
  - Specificity of 99.8% and a sensitivity of 100%

Cytokine and Inflammatory Markers

- **Medpace supports COVID studies with an extensive test menu of cytokine and inflammatory marker biomarkers**

Critically ill patients: We have extensive experience in acute care settings with critically ill patients, spanning pediatric to geriatric patients.

Advanced therapies: Extensive experience working with Sponsors to overcome development challenges and accelerate cutting-edge technologies, including cell and gene therapies.

Integrated advantage: As a full-service CRO, Medpace specializes in the design and conduct of global clinical trials. Our combined expertise, including strategic medical, regulatory, and operational leadership as well as fully-integrated central labs, bioanalytical lab and core imaging services and phase I unit, provides a fully integrated solution.

Global reach: With coverage across six continents, Medpace has the global expertise and experience to plan and execute trials of all sizes.

Infectious disease experience: Extensive experience gives our staff a thorough understanding of the complexities of infectious disease trials from the perspectives of all the stakeholders involved in developing treatments for new and re-emerging infectious diseases.

- Led by noted experts in Infectious Diseases and vaccines, Medpace medical experts are deeply embedded in your trials from protocol design through submission
- Broad experience in anti-infective drug development, including antivirals, antibiotics, antifungals, biologics, and vaccines
- Phase I - IV clinical development experience including designing and executing first in man PK SAD/MAD studies, Phase II studies with complex PK/PD analyses, and large Phase III global trials

CENTRAL LAB SERVICES FOR INFECTIOUS DISEASE

- Bacterial identifications
- Microbial cultures
- Fungal identifications
- Molecular characterization
- Genotyping
- Phage testing
- In vitro drug susceptibility testing
- TB testing (Quantiferon Gold)
- Infectious disease serology
- Viral loads
- Viral infectivity
- Virus titer using $TCID_{50}$
- Respiratory virus PCR assays
- Assay development including viral functional assays and flow cytometry to support viral infection studies

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™