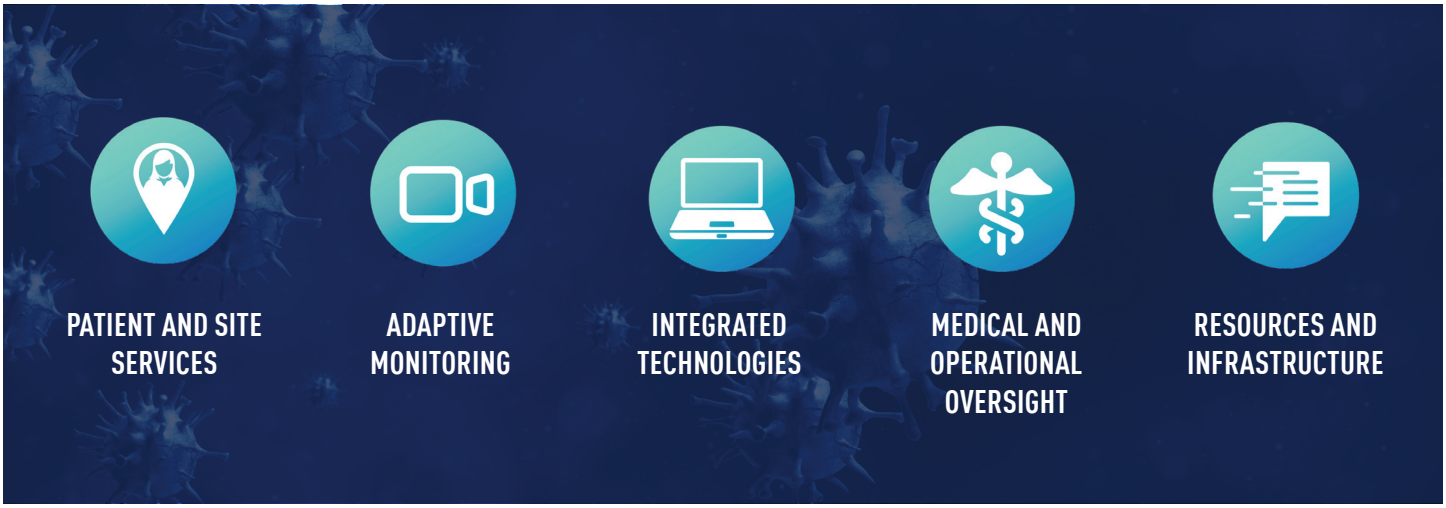
COVID-19 RESPONSE

KEEPING TRIALS ON PACE

Keeping clinical development on PACE *during* and *after* COVID-19

FLEXIBILITY DRIVES ADAPTATION

Conducting clinical research has always required resourcefulness and the ability to pivot quickly. With the COVID-19 pandemic, a new set of challenges have tested our industry's ability to adapt and maneuver in this demanding and fluid environment. With a long-standing culture of collaborative problem-solving, Medpace responded rapidly to ensure patient safety, maintain GCP and data protection rules, as well as minimize risk to data integrity.



Medpace has adopted strategies and technologies to overcome barriers, minimize disruption, and keep clinical development on PACE while ensuring patient, caregiver and site safety throughout the lifecycle of the study.

PATIENT AND SITE SERVICES

One of the biggest challenges during the COVID-19 pandemic has been patient and site engagement. It has required a retooling of strategies and enabling technologies to keep clinical development moving forward. A distinct advantage for Medpace is our ability to leverage our extensive experience in conducting research for rare diseases and orphan indications. These studies require specialized patient and site services and accommodations such as home health, patient travel, and direct-to-patient services. With established internal capabilities and study teams experienced in the delivery of these services, as well as Master Service Agreements (MSAs) in place with strategic vendors, we are able to extend these offerings with ease and speed.

Additional adaptations that have moved trials forward safely and with minimal disruption include:

Heightened Site Support

With trial sites under increased pressure during the COVID-19 pandemic, Medpace deploys highly qualified resources to provide additional site support. These value-add resources operate independent of the site's Clinical Research Associate (CRA) and become a working site coordinator under Principal Investigator (PI)/Clinical Research Coordinator (CRC) supervision to help maintain continuity and move trials forward. **Examples of services provided by this role include:**

- Supporting virtual or home visits with patients including:
  - Facilitating direct-to-patient shipments of necessary study supplies, including investigational product
  - Procurement of additional supplies to conduct home visits
- Review of patient records for patient identification if the study/site is continuing to recruit patients
- Creation of teaching videos for patients
- IP delivery, IP administration, diary inputs, etc.

Site-specific Start-up Strategies

Our regulatory submissions teams work with central and local IRBs to ensure fast and smooth study start-up. To minimize the administrative burden of sites with limited on-site access, Medpace 're-purposes' documents with agreed upon contract language from previous collaborations, where possible (e.g., CVs, medical licenses, contract legal language, certain site fees, and site required informed consent language). High-quality sites that can quickly start-up and recruit patients are prioritized. Those that have enrollment restrictions due to the pandemic are contacted often to confirm when restrictions are lifted.

Patient Concierge Services

Medpace has an in-house program focused on supporting the travel needs of individual patients and their caregivers. The program not only removes the burden of travel management from sites and Sponsors, it includes patient reimbursement services to eliminate out-of-pocket patient travel costs while reducing site administrative time and efforts. Our site and patient portal provides easy access to the travel details, in accordance with privacy requirements. Medpace travel vendors adhere to strict COVID risk reduction protocol so patients and sites can be confident all safety precautions are in place.

Supporting Out-of-Office Patient Visits

Prior to the pandemic, telemedicine and home health care were gaining acceptance; COVID-19 catapulted them into the mainstream. With our extensive experience using these tools (including e-consent) for managing clinical trials in rare disease and orphan indications, we have MSAs in place facilitating a quick start to service implementation. In addition, all patient and site service vendors have undergone quality assessments.

Patient Recruitment & Education Services

The needs of the patient are always our main priority and the center of our operational model. **Our patient engagement programs include:**

- Bringing treatments directly to patients through home health and telehealth
- Providing door-to-door travel assistance to complete study visits
- Educational tools that answer questions about clinical trial participation and how the patient's health is being protected
- Accelerated use of technology to enable engagement and retention

ADAPTIVE MONITORING

With minimal disruption or slowdown, Medpace continues to fulfill our regulatory monitoring obligation of ensuring patient safety and data integrity at our clinical trial sites. **Tools and approaches that are available include:**

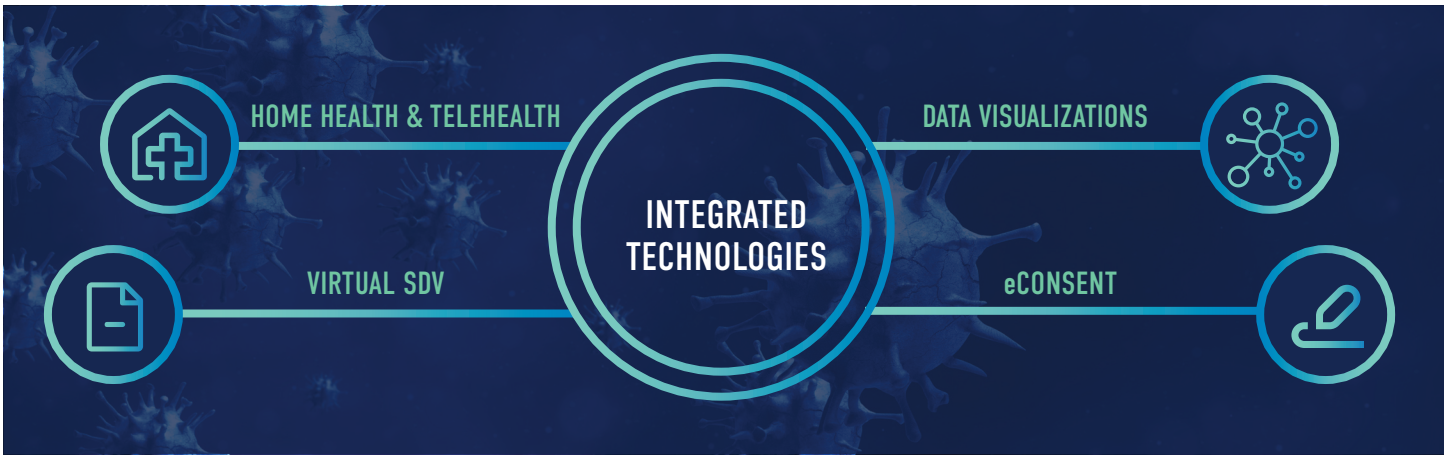
- Risk-based monitoring
- Hybrid approach including onsite and virtual visits
- Remote access to medical records
- Centralized data review
- Site Quality Indicators

One size does not fit all; we partner with sites to develop custom strategies that best align with their capabilities.

INTEGRATED TECHNOLOGIES

Technology has been instrumental in keeping clinical trials on PACE. Integrating technology to support home health and telehealth, e-consent, and virtual source document has expedited trials and enabled patients and sites to safely continue participation in clinical trials. To accommodate virtual monitoring visits and ease the burden on sites where remote access to electronic medical records (EMR) is not permitted, Medpace has released a source module within our ClinTrak® EDC Platform. The EDC Site Source Study Portal allows sites to upload source documents to a secure portal. All data is encrypted, and only authorized users can upload, view, or verify source documents, thereby enhancing remote source data verification capabilities. **Additional system updates include:**

- EDC capture of COVID-19-related protocol deviations in patient visits and procedures
- ClinTrak CTMS enhancement to alert teams to site-adjusted policies as well as specific country guidance
- Updated Protocol and Clinical Study Report templates for COVID-19 adaptations



MEDICAL AND OPERATIONAL OVERSIGHT

Our medical and operational teams undertake detailed risk assessment of study protocols for COVID-19 to ensure the safety of patients, caregivers, and site personnel including:

- Safety and efficacy variables/impact on data analysis/per patient population
- Protocol deviation handling and oversight
- Management of protocol-driven procedures and visits
- IP/Supply management strategies including direct-to-patient delivery and remote accountability
- Consenting options
- Statistical impact assessment
- Comprehensive Clinical Study Report
- Oversight of Site Quality Indicators
- Centralized data review

RESOURCES AND INFRASTRUCTURE

Internal tools, support and training enable our employees to respond and adapt in a flexible and efficient manner. **Some of the resources include:**

- An internal COVID-19 response team supports our project leaders with guidance and appropriate documentation across all functions. This hands-on leadership from executive management mitigates risk for our Sponsors and provides the training, guidance and tools to ensure internal teams are well prepared.
- With a cross-functional, centralized office, and flat organizational model already in place, our experts from medical, operations, regulatory and laboratories continue to work closely and collaboratively to address issues and rapidly adapt. While adopting remote work environments and staggered in-office schedules to protect the safety of our employees, this foundation enabled a quick, comprehensive response to the COVID pandemic.
- Electronic resource libraries are easily accessible and available to all employees.
- On-demand regulatory intelligence allows us to monitor regional, country and local regulations to ensure global compliance with all applicable regulations.

OUR COMMITMENT TO MAKING THE COMPLEX SEAMLESS

Our industry is being challenged as the COVID-19 pandemic adds a new layer of complexity. We are putting forth every resource to ensure your clinical trials continue to advance, that our efforts protect clinical site staff and patients from undue risk and our studies remain in compliance with governmental policies. As a full-service CRO with nearly 30 years of experience supporting Sponsors and advancing life-changing therapies, we remain more committed than ever to work by your side and to execute your studies as seamlessly as possible.

Medpace's response and capabilities related to COVID-19

LEARN MORE

MAKING THE COMPLEX SEAMLESS™