



The COVID-19 pandemic has been rapidly evolving and has had broad impacts on clinical research activities. As COVID-19 continues to spread, many clinical trials are being placed on enrollment hold, resources are being re-directed to support the pandemic, and institutional policies change daily and are becoming more restrictive. Here at CPC Clinical Research, we are focusing our efforts to support sponsors, our sites, our staff, and our participants during this unprecedented pandemic. Our shared goals are to protect patient safety as well as maintain the scientific integrity of our research programs.

Safety First

Our priority is the safety of patients, staff, healthcare workers, and study partners. To limit exposure and support community shelter-in-place orders, CPC implemented a travel ban for both international and domestic travel. As of 3/16/20, CPC physical office closed, and staff successfully transitioned to a fully remote work environment. To date, this transition has gone smoothly, and we remain fully operational. Our intention is to maintain remote working as long as mandated by local regulations and we do not anticipate any disruption in doing so for the foreseeable future.

Navigating COVID-19

Because of the COVID-19 pandemic, there are several challenges in conducting clinical trials. These include travel limitations, quarantines, site closures, study drug distribution and concerns of site personnel or trial participants becoming exposed or infected by COVID-19. As the situation is rapidly evolving, we have been monitoring daily, and sometimes hourly, each trial, each site, each enrolled patient to maintain the integrity of our ongoing clinical trials. We will continue to communicate with our sponsors, sites, and staff the details of our response and mitigation strategies as they apply to each project.

Accelerated Innovation

CPC has been working with our partners to minimize the impact on our ongoing trials and translating the lessons learned in to innovations that will allow us to deliver more efficient and innovative studies in the future. We are using this challenge as an opportunity to re-evaluate how we operate and have accelerated our innovation initiatives that leverage technology more effectively to maintain quality while decreasing costs. Several examples include:

CPC's Endpoint Quality Intervention Program (EQuIP®), a suite of services that decrease variability in functional endpoint testing, implemented its first virtual Site Endpoint Evaluation Visit (SEEV) on 3/20/20 to provide site staff a detailed review of the data collection methods, procedures, and equipment. To further innovate, EQuIP® is working on implementing a 6-minute walk "at home" test protocol that intends to allow for participants to complete the 6-minute walk test within their home while still optimizing quality and minimizing variability. This innovation will allow us to collect data even during the shelter-in-place orders that are pervasive. We are also examining how technology such as wearables may assist in collecting functional data in the home.

CPC's clinical operations program is implementing a more robust centralized and risk-based quality management system to allow for increased flexible remote monitoring, centralized monitoring and risk-



based monitoring. Remote monitoring coupled with enhanced data management and data analytics holds promise to maintain data quality with greater efficiency.

CPC's specialty services have implemented a virtual platform enabling scheduled Independent Data Monitoring Committees' to perform virtual critical reviews and oversight. Secure data distribution and tracking, remote meetings, and information dissemination are key components of this strategy. CPC's key opinion leaders and faculty are presenting virtually at conferences that have been postponed or canceled in response to the COVID-19 pandemic. This is enabling the "virtual" dissemination of new information traditionally tied to in person congresses which are expensive and have a limited audience.

CPC's Quality Assurance department is implementing remote auditing capabilities to ensure adherence to our audit schedules and vendor oversight programs. In addition, in collaboration with our IT and TMF teams, we are transitioning to a paperless office that enables efficient storage and easier data retrieval.

We continue to be inspired to develop new tools, processes, and programs that improve efficiency and reduce the burden of clinical trial execution that we expect to have benefits that outlast this COVID-19 crisis. We are committed to supporting our partners and our community during this challenging time.

Our Mission and Our Promise

We are a dedicated group of professionals who are united in our mission to improve health through innovative science and community engagement. We are not passive in this fight. Our faculty are on the front lines of this crisis and are working in close collaboration with our operational teams to conduct innovative science that will help us stem the tide of this pandemic. We are dedicated to the success of our shared projects and we are committed to our partnerships. Our promise to you is that CPC will be your dedicated partner in clinical research and we help you to achieve success.