# Save the Data.
# Protect the Patients.
# Prepare for What Comes Next.

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**The clinical trial environment faced a massive disruption in the wake of COVID-19, the scope of which was both unprecedented and incalculable. Clinical trial operators were in triage mode. There was no tested playbook for a pandemic, no standard operating procedure. And almost everything depended on sites. So how will clinical trial stakeholders continue to adapt for what's to come?**

In the Spring of 2020, everyone was  trying to figure out what to do. Federal guidance evolved constantly. States and cities put new measures in place nearly every day. Each hospital system was deciding what was essential and what wasn't. Changes and updates to changes occurred almost hourly.

Outside of oncology and Phase III trials, most clinical research had been deemed nonessential. Research sites, especially those affiliated with hospital systems and academic medical centers, ceased nonessential encounters. They put recruitment on hold. They paused studies. The message from many sites was, "Until this pandemic passes, nothing's going to happen."

It was almost unimaginable—except that, almost a year later, we're still living it . Some sponsors are writing off entire studies. The issue used to be the inability of patients to come to the clinic site. Now, many follow-up visits for ongoing clinical trials can be done remotely, but if a site's resources are being deployed elsewhere, who will manage it? So many sites are still putting studies on hold for no other reason than a lack of bandwidth: They don't have the research staff to spare. It doesn't need to be that way: Sponsors, CROs, and sites can rise to the challenge and adapt—with the right support.

## HELPING SPONSORS HELP SITES

WCG's Remote Clinical Research Coordinators (CRCs) are highly trained research professionals who have provided site support to site teams for years. Now, they're being deployed to help trials that have been paused (or are on a hard hold) and to support the ongoing trials that are being conducted remotely. As site staff are still dedicated to COVID-19- related activities, sponsors can leverage a remote study coordinator to assist sites in moving research forward—or at least ensure everything is ready for the next phase of the pandemic.  In a different scenario, some

trials are still in the recruitment/enrollment stage. In these situations, WCG Remote CRCs can conduct accelerated chart review and identify referral networks of physicians that research sites can tap into.

Each site presents a unique set of needs. Right now, sponsors and CROs are typically collecting study- or program-level information from sites. They don't know the specific needs of each site during this "new normal", but they want to know and they want to provide support quickly, efficiently, and strategically.

WCG ThreeWire recently met with a Top 10 pharmaceutical company to discuss remote support. A few years ago, WCG Remote CRCs helped this same client with a hurricane response in two or three states. Now, years later and faced with the next evolution of the COVID-19 pandemic, the request is, "Can you reach out to every one of our sites across the globe and offer on-site and remote support?" And while the scope of the situation at hand has changed, the service has not. Remote CRCs succeeded then, and they will now.

## COLLECTING SAFETY DATA THE RIGHT WAY

Remote CRCs can step in and provide virtual safety visits to check on any potential adverse events. A certified individual trusted by the research team needs to follow up on patients receiving investigational medications and collect the data. A simple telephone check-in can accomplish both data and safety

collections simply by asking questions such as, “Are you experiencing any physical, emotional or mental changes?” The ability to collect that safety data makes it easier to resume the trial when the time comes. Without that ability, sponsors may be forced to restart the trial from scratch, which loses both critical time and money.

That said, the job of a Remote CRC is not to merely collect data. Many are, for example, doing remote data entry during this time of COVID-19. WCG ThreeWire has access to certain institutions through EHRs and virtual data centers, and the CRCs are working from home collecting and entering that data.

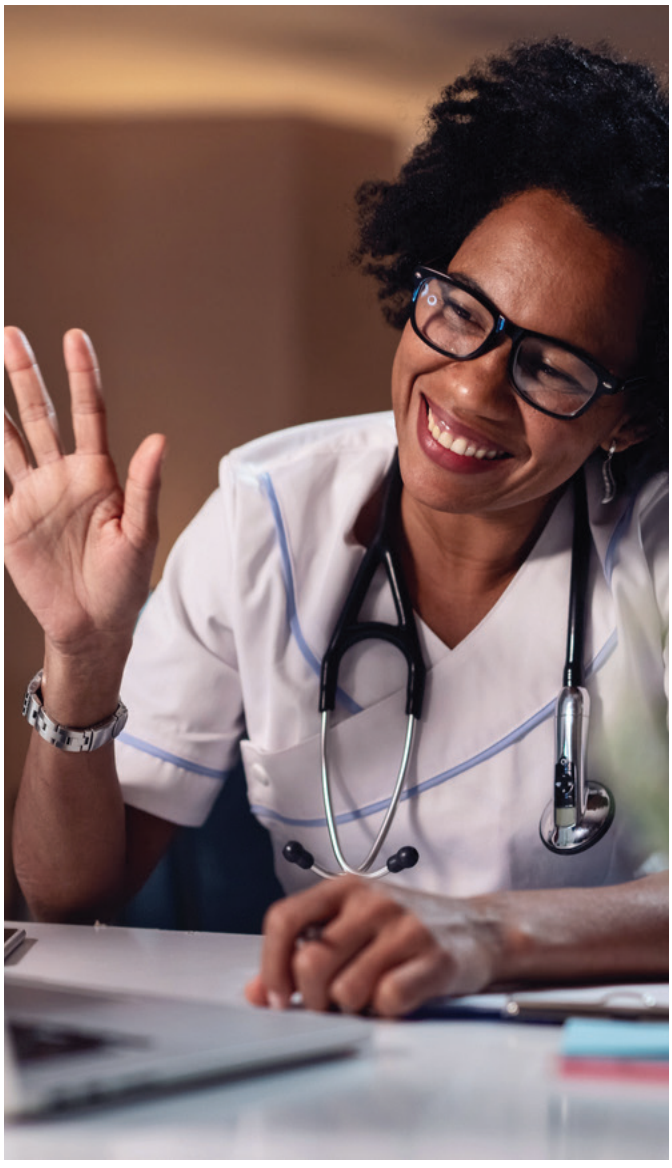
This set of particular responsibilities gives sponsors and CROs a more robust understanding of where the trial is and what needs to be done today to ensure it can go forward tomorrow.

## PATIENT CENTRICITY AND WARM CONNECTIONS

At many sites, WCG’s Remote CRCs have already become trusted resources for patients who are anxious about the future of their trial.

Because Remote CRCs are part of the site team, when they call a patient they’re not saying, “Hey, I’m from WCG ThreeWire.” They’re saying, “I’m a CRC with Dr. Smith. I’m calling to let you know the current status of your study.” The difference in these two exchanges enhances the relationship with the patient and the site, and in turn, supports retention.

These are warm connections, not a call center delivering a scripted, “This study is no longer available. You will be contacted at a future date.” These are research professionals. They will have conversations with patients about the status of the trial, their options for next steps, etc. At the same time, they are collecting valuable data and providing that data in a feedback loop to the site and sponsor.



## AGILE AND NIMBLE

Remote CRCs perform all manner of tasks (see the sidebar for a partial list). But make no mistake. Remote CRCs don't merely perform tasks: They solve problems and adapt as the situation changes and that agility is essential in this time of perpetual change. Sites can't anticipate every challenge, but they need to pivot quickly when a new one arises. Remote CRCs have the skills and tools to help them do this.

For example, WCG ThreeWire was supporting a multi-site clinical trial in Texas when Hurricane Harvey struck in 2017. In the aftermath, transportation to the research sites became difficult; many patients canceled appointments, and those who didn't often struggled to make the trip. Immediately, WCG Remote CRCs worked with ride-sharing companies to arrange transportation for the patients. This quick response allowed the sponsor to provide personalized services to volunteers and keep the study on schedule.

The outset of the COVID-19 pandemic was Hurricane Harvey times 1,000. But WCG helped sites, sponsors, and patients adapt. How? Because we all *remained* connected. Providing tailored site support protects your clinical trial data, your patients, and how you keep moving forward. Email info@wcgclinical.com to speak to our remote site support experts about how WCG can support your sites.

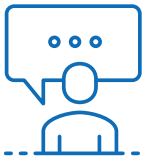
## EASING THE BURDEN

Here are just *some* of the tasks a WCG Remote CRC can manage:

Assist in completing feasibility and start up documentation

Remote chart review to build a backlog of potential patients

Remote screening and education of potential patients



Keeping current study participants engaged

Support for source document creation for the site

Perform remote data entry for the site

Handling query resolution in a timely manner

Ensure timely handling of safety documents and alerts to maintain compliance

**WANT TO HELP YOUR SITES MEET THEIR FULL POTENTIAL?**

Speak to an expert

## ABOUT THE AUTHOR

**Molly Hair, Director, Clinical Strategic Solutions and New Product Development, WCG ThreeWire**

Molly is currently the Director of Clinical Strategic Solutions and New Product Development at WCG ThreeWire. With more than 14 years of experience in clinical trial patient recruitment, Molly works with clinical research sites to develop and deploy unique support strategies based on their individual needs. Prior to her time at WCG ThreeWire, Molly worked as a lead recruitment coordinator at an independent research unit, where she led recruitment efforts on more than 150 clinical trials in a wide range of therapeutic areas.