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

Remote Clinical Research Coordinators give sites the resources they need now

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The clinical trial environment faces a massive disruption in the wake of COVID-19, the scope of which is both unprecedented and—so far—incalculable.

Clinical trial operators are in triage mode. There is no tested playbook for a pandemic, no standard operating procedure. And almost everything depends on the sites: Will they pause trials? Continue them? Close them entirely?

Everyone is trying to figure out what to do. Federal guidance continues to evolve. States and cities are putting new measures in place nearly every day. Each hospital system is deciding what's essential and what isn't. Changes and updates to changes have been occurring almost hourly.

Outside of oncology and phase III trials, most clinical research has been deemed nonessential. Research sites, especially those affiliated with hospital systems and academic medical centers, are ceasing nonessential encounters. They are putting recruitment on hold. They are pausing studies. The message from many sites is, "Until this pandemic passes, nothing's going to happen."

It's almost unimaginable—except that it's happening right now. Some sponsors are writing off entire studies. The issue isn't merely the inability of patients to come to the clinic site. 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 putting studies on hold for no other reason than 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—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 on a hard hold and to support the ongoing trials that are being conducted remotely.

As site staff are being reassigned 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 when the research restarts.

In a different scenario, some trials are still in the recruitment/enrollment stage. In these situations, 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 unprecedented time--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, remote CRCs helped this same client with a hurricane response in two or three states. Now, years later and faced with another crisis, the request is, "Can you reach out to every one of our sites across the globe and offer 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. That agility is essential in this time of extraordinary uncertainty and 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 cancelled appointments, and those who didn't often struggled to make the trip. Immediately, on-site 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 pandemic we find ourselves in now is Hurricane Harvey times 1,000. Providing site support protects your clinical trial data, your patients, and how you stand to recover once we begin 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 startup 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

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