On Site: Patients Can Be Partners in Continuing Clinical Trials During the Pandemic

Patient centricity is truly coming to the forefront as sponsors and investigators search for ways to battle the effects of COVID-19 and keep their trials afloat while protecting their participants’ health and safety.

The clinical trials industry is experiencing a shift toward more patient support, particularly for patients whose trials have been postponed or have moved to a strictly remote setting, according to patient advocacy experts. “Given that many trial participants have risk factors that can make exposure to COVID-19 more frightening,” says Lori Abrams, senior director of patient advocacy at WCG Clinical, “those of us in the clinical trials industry need to rethink what care looks like.”

Abrams says patient advocacy groups are increasingly being approached by pharmaceutical companies and CROs to provide timely clinical trial messaging to trial participants, including information on things like trial pauses, on-time and delayed study visits, when and where a study drug will come from as well as temporary study modifications.

“Advocacy groups have their ‘finger on the pulse’ of the patient population and have a clear understanding of the concerns often raised by patients participating in trials,” Abrams told participants in a WCG webinar on best practices for weathering the crisis. These advocacy groups can help research institutions, sites, sponsors and CROs develop COVID-19-specific communications about trials that are patient-friendly and meaningful to patients’ families.

She suggested developing study-related guidance or frequently-asked-questions documents that can be handed directly to advocacy groups to support patient communications. “Instead of waiting to be asked [by an] advocacy group for help,” Abrams said. “Ask them for help upfront. Some patient advocacy groups are partnering with sites to have daily morning Skype calls that allow for face-to-face interaction to share information and develop guidelines for trials.”

Some patients are not receiving any communication or assurances about the status of their trials, said Mary Elizabeth Williams, a journalist, patient advocate and clinical trial veteran. This lack of communication makes patient advocacy communities an important aspect of clinical trials during the COVID-19 pandemic and beyond. Williams said, “When we think about pausing a study, this is not abstract to people who have a rare debilitating disease or for people who are in a late-stage trial for their lung cancer.”

Williams hopes that this global experience will help improve the empathy of investigators for patients who are entering a clinical trial. “This is an unprecedented moment,” she said, “as every single person on the planet knows what it’s like to have your world completely turned upside down in a very short amount of time, which is what patients deal with when they get a diagnosis and enter a trial.”

“I hope this experience will change the treatment of participants as not just data points,” she said, “but as real human beings who are scared and vulnerable.”

According to Jonathan Zung, executive vice president of WCG, sponsors and sites are developing internal guidelines to separate the essential trials from the nonessential ones, with the treatment of patients with COVID-19 being the primary focus. “Research staff are beginning to shift from research studies to supporting patient needs,” Zung said.
In terms of best practices for trials during COVID-19, he said it is important to maintain regular communication among sponsors and CROs to ensure effective bi-directional communication. “It’s important to share what changes have been made at the site level, what changes have been made to study protocol, the availability of the study drug, and feedback from study participations,” Zung said. Internal guidelines and documentation can help facilitate these communications across study teams.

The industry is taking the long view, according to Zung. While there appears to be no definitive end date for this pandemic, many institutions, from small independent sites to large academic research centers, are continuing to plan for trials that will commence after the COVID-19 crisis has passed. “It’s important to develop plans for the resumption of clinical studies after COVID-19,” he stressed. Sites need to clearly understand their resource needs for these trials once they ramp back up, and many organizations may need to discuss which tasks need to be handled externally vs. internally for these post-COVID-19 studies.

Webinar speakers fielded hundreds of questions from attendees. Below is an edited excerpt of the question-and-answer session.

Q: Can you define “essential” studies? Also, some sites are saying that sponsors may delay payments. How can sites protect themselves from delayed payments from sponsors?

A: Studies that provide high potential direct benefit, such as a cancer study or rare disease study where there is no available treatment, are deemed “essential” studies. In terms of delayed payments, we have not heard the speculation or rumors that sponsors may delay payments to the sites. There doesn’t appear to be any evidence of this. – Jonathan Zung, executive vice president of WCG

Q: How can sponsors or sites find appropriate patient advocacy groups?

A: If you’re a site within a community, the national groups often have local advocacy groups/chapters. For sponsors/CRO affiliates, check in with your sites first to see if they have any relationships with advocacy groups. If not, reach out directly to advocacy organizations that are supporting your disease state. You will be able to offer guidelines and need-to-know information for their patient constituents. – Lori Abrams, WCG senior director of patient advocacy.

Q: What advice would you have for researchers/coordinators/site staff who have to tell participants that the nonessential study will be paused?

A: For the love of God, don’t use the word “nonessential.” That’s first and foremost. Very often, the language that is used in the clinical world feels devastating to the patient population. To be referred to as "participants" vs. “human subjects,” for example, means a lot. The words you use matter. When you’re saying “nonessential” and you’re pausing the study, it’s like you’re saying to the patient that they’re at the end of the line. It’s important to prioritize language now, while understanding that hard choices still need to be made. Put first and foremost the dignity and humanity of every single patient. Think about ways to have conversations that will support the patient and give them options. – Mary Elizabeth Williams, journalist and patient advocate

Q: If there’s a study that involves infusion or injection, and home healthcare services are put in place to keep people out of the hospital site, who typically sets that up?

A: I don’t know if there’s anything typical right now with COVID-19; but I would say that, at this stage, the sites are working with sponsors or CROs to get home healthcare services coordinated and out in the community. It’s being done differently depending on the research site. Some are using satellite clinics for that purpose. It’s really been done on an ad hoc approach from site to site. – Jonathan Zung, executive vice president of WCG
A: Sites should have close communication with the sponsor to determine the best approach. – Lindsay McNair, WCG chief medical officer

Q: Shouldn’t we assume that sites are going to shut down and won’t be able to perform research?

A: There are a number of sites and academic research centers that are focused on treating COVID-19 patients and related illnesses, but they’re also still planning on performing new studies once this pandemic ends. Sites are certainly planning studies in a post-COVID-19 world. Many are working on budgets and aspects of study start-up. – Jonathan Zung, executive vice president of WCG

Q: Will local IRB clinicians who are being pulled into treating COVID-19 patients affect IRBs?

A: Yes, that can happen. That’s why we’re actively seeing research institutions reaching out to us to get active support from one of the WCG IRBs. We’ve been working very closely with these institutions to review protocols so needed therapies can get to patients. – Jonathan Zung, executive vice president of WCG

-By Brandon May

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