

Lessons Learned from COVID-19

► Why CROs Must Continue Modeling Support and Compassion to Clinical Sites

When the COVID-19 pandemic hit in March 2020, a range of emotions followed, including shock and uncertainty. However, what we began to see was an increase in kindness and compassion both at home and at work.

Faced with the challenges of adjusting to life and work during COVID-19, sponsors and CROs pivoted with rapid flexibility to keep clinical trials moving forward. Sites closed, Ethics Committees stopped or slowed down their reviews, and much of routine healthcare moved to telemedicine. CROs, sponsors, and sites used every ounce of creativity to keep trials running. Research staff were sent home and could not access needed records or systems to do their work. As a CRO, Advanced Clinical witnessed many site personnel struggling to do their jobs. Site staff did their best to work from home, often while caring for children. The integrity of every trial had to be protected, while taking full account of the limitations and personal needs of the site staff.

Lessons Learned from the Global Pandemic

At Advanced Clinical, we learned four major lessons from the pandemic – and plan to keep these top of mind as we move into the post-pandemic world.

1. Be kind to site staff. Even in the absence of a pandemic, life is tough. People want to do a good job, but may be faced with anxiety, stress, and depression. This is likely to continue post-pandemic. People's lives have been

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disrupted in a significant way and kindness will continue to be needed. In fact, kindness is proving to be a business necessity. Organizations that demonstrate kindness are seeing increased customer and employee loyalty, according to a Forbes article from July 20, 2020.

2. Be generous. Remember during the early days of the pandemic when you couldn't find Clorox wipes? Caring friends offered to share their own supplies on social media. In the work environment, we also need to be generous. It might not be Clorox wipes, but we can be generous with our time and our knowledge. On one of our studies, when sites began to shut down but critical subject visits still needed to occur, project managers, clinical trial leads, and CRAs identified options with other study sites so subject visits could still be completed. Knowledge was shared and most of those critical subject visits occurred despite the shutdown.

3. Be flexible. During the pandemic, we adapted to extreme site limitations and restrictions. For example, most sites either could not see study subjects or had to immediately convert to telemedicine. Some insurers are now trying to implement telemedicine "to make it easier for patients to connect with regular help by using remote care that grew explosively during the COVID-19 pandemic," according to a May 2, 2021, Associated Press article.² We used whatever tools were available to sites, such as FaceTime or Zoom, for subject visits during the pandemic. This required rapid changes to protocols and databases, in addition to site training. In the future, protocols should be written with telemedicine visits as an option. Knowing that some sites may still not have access to long-term telemedicine solutions, we can offer this to sites.



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4. Be a partner to site staff. Challenging situations often require unique solutions. We should all listen with the intent to understand and then collaborate to find a way forward. In one example from our team, a study site was significantly restricted due to site and staff limitations. The CRA was not able to conduct an onsite/in-person visit due to COVID-19, and site staff could not meet remotely during the day within the timeframe needed. To accommodate the sites' limitations, our CRA conducted the monitoring visit remotely with the site in the evening.

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Our goal is for the kindness, generosity, flexibility, and partnering with site staff modeled by Advanced Clinical to continue into the post-pandemic world — and even to inspire others in the clinical research industry. ^{PV}

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