SPOTLIGHT

From Zero to Sixty: Why Yesterday's eClinical Trial Horizon Is Today's Reality

Signant Health discusses the possibilities for trials post-pandemic. After a digital revolution in the way we conduct research, why would we want to go back?

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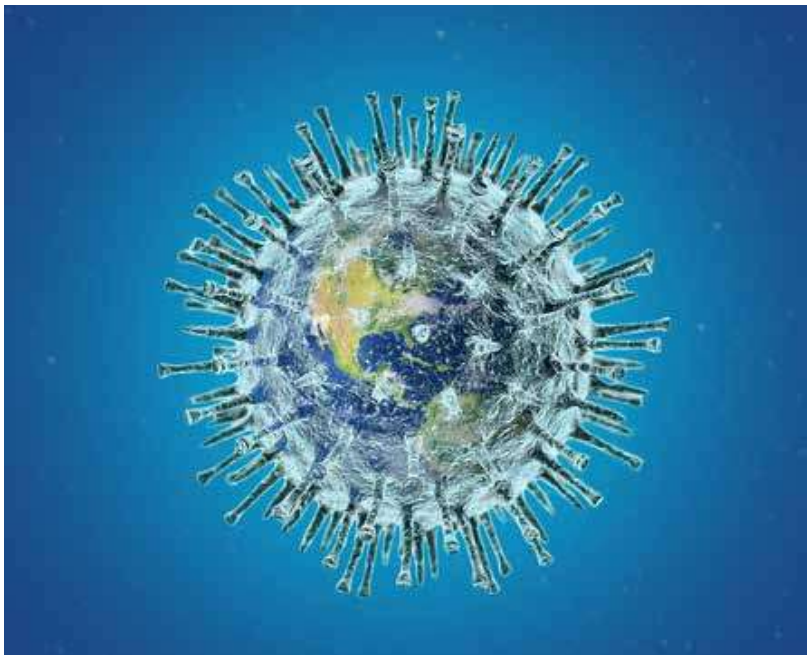

On 11 March 2020, WHO officially declared the rapidly spreading COVID-19 outbreak as a pandemic. The first in years, this pandemic caused the world to change its social behaviours in just a few weeks. Now, living in a post-COVID-19 society, several industries have been forced to stress test the capabilities of their remote work environment.

The clinical trials industry is no exception. As a result, ideas that were once touted as 'next generation' during keynotes just a few years ago are now being put to the test in live trial environments. However, it's not just the 'shiny and new' technologies on the front lines of post-COVID-19 trials. Instead, it's a unique blend of eClinical technologies, new and old. This mix, combined with strong processes and quick thinking, has helped lay the foundation for our industry's rapid pivot towards remote work.

Those curious about which technologies are at the forefront of the fight should first ask themselves: what clinical trial problems does physical distance create? As a starting point, consider any site and patient consultations that would have taken place. The inability to physically attend sites may include the patient only. It may also include the investigator, or multiple site staff at different locations even for the same visit. Now, add the fact that regions will differ in their physical distancing guidelines and even in one location those guidelines may change back and forth over time.

As you can see, there are several variables to consider.

The ability to continue some or all site visits in a remote setting has been long discussed within the industry in the context of hybrid trials. Hybrid trials leverage different paradigms to enable essential trial operations across a range of different settings and tools. This may encompass a blend of new and old approaches such as:

- Mobile devices/bring your own device (BYOD) for patient-reported outcomes data
- Sensors and wearables for new digital endpoints
- Home delivery of medication to simplify the process for patients around repeat dispensing
- Remote consenting capabilities using eConsent solutions, and video meetings to enhance interactions when replacing in-person consultations
- Formal clinician-reported outcomes (ClinRo) and other clinical assessments, and visits with distanced approaches

In fact, some organisations are rolling out video meetings as part of their patient engagement technologies in order to provide patients with a more stimulating experience to learn about the trial, communicate, and video meet with investigators and site staff. Patient engagement technologies also offer organisations with a prime opportunity to familiarise potential participants on how to receive, analyse, and communicate information to and from their site in a post-COVID-19 landscape. Additionally, they're a natural fit for easy use alongside electronic clinical outcomes assessment (eCOA) tools, such as patient diaries and sensors and wearables data.

Since the mid-2010s, eConsent has been touted as the next big step for the trials industry. Today, the industry leans on its remote features post-COVID-19 to help educate and consent their patients from afar. Video narrations and direct dialect translations help populations feel comfortable with study concepts, while patients flag parts of the consent materials for video or telephone review with the investigator. eConsent also helps organisations that find themselves needing to re-consent patients.

Often, trials may need to change protocol mid-study as new information is learned or priorities change. eConsent enables studies to quickly and easily summarise these changes while automatically tracking and storing consent and re-consent data instantaneously.

eCOA is another well-established eClinical technology that's being heavily utilised in the post-COVID era. Organisations that are faced with strict trial requirements have utilised the added flexibility offered by BYOD eCOA strategies, which rely less on global logistics. They've also turned to sensors and wearables as a natural extension of eCOA that can be paired with their BYOD trials to increase the types of outcomes measures that can be collected.

However, it's the organisations making clever pairings of old and new technologies and forward-thinking processes that will best adapt to the post-COVID-19 landscape. For example, knowing that patients and site personnel are consulting using video meetings, several organisations have begun to place their eClinRO instruments within the investigator's visit tools, streamlining the process for investigators. Others have set the sights of their blinded data analytics tools to understand the potential effects on data when moving assessments from 'face to face' to remote collection.

Nevertheless, the best adapting organisations are those that are open and willing to change. A post-COVID-19 landscape requires organisations to quickly think on and execute new ways to continue trials. Many organisations have started trials without video messaging or patient engagement apps, only to implement them later, realising the value they bring.

What remains to be seen in the post-COVID-19 landscape is how the value that eClinical technology brings will influence the remainder of the decade. While no one doubts the continued growth of new trial tools and trusted technologies, COVID-19 has forced some age-old processes to digitise, or distance themselves overnight. Thus, the question that many organisations will soon find themselves asking is: now that we're here, is there any reason to go back?

SIGNANT HEALTH

The best technology succeeds in the background. **Signant Health** provides solutions that simplify every step of the patient journey to make it easier for people to participate in, and for sites and study teams to run, clinical trials. Signant unites eCOA, eConsent, patient engagement, interactive response technology, clinical supplies, and endpoint quality into the industry's most comprehensive patient-centric suite – an evolution built on more than 20 years of proven clinical research technology. Our intense focus on the patient experience, deep therapeutic area expertise, and global operational scale enable hundreds of sponsors and CROs (including all top 20 pharmaceutical companies) to extend the reach of drug development, expand patient opportunities, and improve data quality – helping them bring life-changing therapies to our families and communities around the world.

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