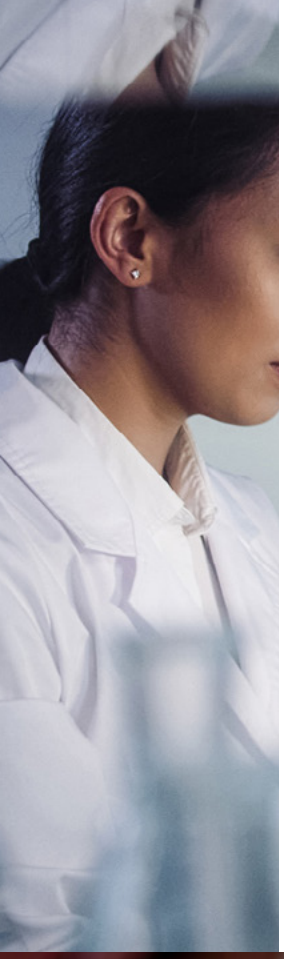

From telemedicine to remote site visits: the post-COVID face of pharma research and development

The acute phase of the COVID-19 pandemic not only brought delays, restrictions, and reconfigurations to pharmaceutical research & development in 2020, but also a more flexible response to some long-standing issues with the clinical trials process.

Lockdown rules and safety protocols certainly made it harder for patients to travel to trial sites, while a refocusing of clinical personnel to COVID projects slowed work that wasn't dedicated to the novel coronavirus.

At the same time, pharmaceutical research has very robust structures in place to guide and protect patient safety and those were adhered to, so the impact of the pandemic – at least in R&D – was more at the level of individual circumstances requiring a response.

For Dr Anna Christina Hoerster, director of clinical operations (Europe) at Advanced Clinical, the changes could best be characterised as a series of "very small things, which really did matter" in terms of the bigger picture of a project.

> "The challenge posed by COVID was a trigger for pharmaceutical companies to think outside of the box. We have these very strict rules and models for conducting clinical research, and now the industry was challenged to adapt faster. I believe all these adaptions would have come in the future, but they would have taken longer," she says.

MANAGING COVID'S IMPACT ON R&D

Initially, the pandemic caught much of the sector off-guard. A once-in-a-generation event, few could have anticipated the levels of disruptive change COVID-19 brought and that was certainly true for pharma and healthcare.

Companies scrambled to implement home-working arrangements in place for large numbers of their staff, maintain vital production and supply chains, and support a workforce concerned about their own health and that of their loved ones.

The slow, domino-like format shift of major medical conferences to virtual formats is indicative of just how difficult it was, even for the medical profession, to truly comprehend the implications of COVID.

> "The majority of the pharmaceutical industry were caught off guard by this pandemic," says Dr Ravi Nookala, senior medical writer at Advanced Clinical. "Although they were unprepared for such a global scale of disturbance, they reacted immediately."

The most important consideration within companies' ongoing clinical trials was how to ensure patient safety and then how quickly companies could adapt to ensure that studies continued as planned. "This meant that, while continuing to assess patient safely, companies also had to keep in mind that endpoints were met during a trial and that procedures were adapted on an ongoing basis as guidance shifted and new advice emerged."

"The pharmaceutical industry reacted very well in addressing these things, especially patient safety, by implementing measures where the on-site clinical visit is not necessary," says Nookala, who is PhD-trained and has a strong scientific background.

"They performed remote visits where possible and employed more healthcare providers to ensure patient safety was maintained. That shifted the paradigm a little bit. They also adapted to the demands of COVID-19 protocols, especially the regulatory and safety sides of that as those emerged from the FDA and EMA."

Nevertheless, particularly in the period from April to June 2020, many trials faced disruption, delayed initiation and slower or suspended enrolment. Those trials that went ahead forced pharmaceutical companies to negotiate the impact of local conditions.

> "We had to face the lockdowns and the restrictions on a very project-specific level," says Hoerster. "Looking at this, the implications of the restrictions were very different in different locations. In the US, for example, there were more options for new processes for remote data verification. In the EU, it was more complicated because of the GDPR law, and in addition some site-specific, hospital-specific regulations."

Meeting these challenges required "very unique, very individual solutions and workarounds to see how we can get data and how we can ensure patient safety", Hoerster says.

"Moving forward, I believe there will be a very strong evolution of clinical trials and what can be done remotely."

She's clear that, although not everything can be done remotely, there will be options for clinical trials that will be implemented to be prepared for any such similar situations in the future.

TRIAL SITE VISITS DURING, AND AFTER, THE PANDEMIC

COVID has provided plenty of lessons for pharmaceutical companies as the pandemic stress-tested almost every aspect of their operations.

Within clinical trials one of these lessons is that remote monitoring, though often beneficial, might not reduce the amount of work for site coordinators or other personnel. As Hoerster explains: "We experienced increased time and resource needs for remote monitoring in comparison to face-to-face visits. We thought when these CRAs do not need to travel to the site, we will save time and money, but actually, it was not the case."

Remote monitoring requires a great deal of site time and hours, while for site personnel, for example, if there's a need for in-person sharing of screens during a remote visit then someone must be at the site for the complete duration of the remote visit.

The benefits of overcoming these difficulties and increasing the use of remote site visits – where appropriate – are clear.

> "First of all, the patient burden will be reduced, there will be fewer site visits and it will be less time consuming," says Hoerster. "It will also be easier for the patient to participate and to stay in the study."

She also expects the current resource requirements of remote monitoring to ease off in the future, as new tools and techniques are adapted and developed.

One area of possibility, Nookala suggests, is through the use of online approaches to monitor for adverse events.

"One of the ways that the pharmaceutical industry should think ahead is to have an encrypted application or online portal where a patient can signal an adverse event. If the sponsor is willing to invest in that kind of technology, it could avoid some of these in-person visits."

This would be a way to allow someone from a pharma company's medical function to assess the severity of a potential adverse event and then determine the suitability of a remote visit. This sort of dual approach is likely to be increasingly seen in future projects, and it's likely site qualification visits will focus more on these capabilities in the future.

"The basic takeaway message," Hoerster says, "is that flexibility will increase and this will reduce the patient burden, even if documentation and effort levels stay the same."

Nookala adds: "We have to be innovative. We're in the 21st century and we can find ways to use remote visits and remote monitoring without compromising safety or data security. There are technologies available today, but it's up to the pharmaceutical industry to capitalise on what we experienced last year."

DIGITAL CHANGES TO STUDIES

One of the major changes that impacted healthcare during 2020 was a coming of age for telemedicine as participants did everything they could to avoid in-person visits as awareness increased of digital options for healthcare.

"This should have happened a long time ago," says Nookala, "this move toward digital platforms like telemedicine and utilising the available resources to minimise patients' need to travel, while safeguarding their safety. It should have happened a long time ago, but hindsight is always 20/20."

Nookala, who's passionate about the possibilities of telemedicine, says that if technology can be used in the form of an Apple Watch to take ECG measurements then there will be ways telemedicine can adapt and fit around patients.

"Every single trial is different," he notes, "but wherever possible, if we can do any assessments remotely, using an app or through a healthcare provider, let's go for it. Otherwise, bring them in to the clinic where it's not possible."

The early momentum towards telemedicine appears to be building. In the US, a recommendation by the Centres for Medicare & Medicaid Services (CMS) that was announced at the end of 2020 will see telemedicine offered to patients with more than 60 different acute conditions. Those needing treatment for the likes of asthma, heart failure, pneumonia and chronic obstructive pulmonary disease (COPD) could receive at-home care and monitoring.

Meanwhile, in the UK, the government has said the adoption of telemedicine across the NHS is a vital part of the response to COVID-19. Health secretary Matt Hancock spoke over the summer of the "moment of exposure, of stark clarity" provided by COVID-19. "Coronavirus has tested every single part of our infrastructure, giving us a new appreciation for what works and what doesn't," he said signalling that consultations should, wherever possible, be remote by default.

The same mindset should be applied to the way the pharma sector works in the future, Nookala says. "More and more during the pandemic, the pharmaceutical industry adapted quickly and used telemedicine much more than it normally would have. That would be one of the good things to be retained going forwards, because it worked. Perhaps it was not seamless, but it was tested, and it withstood the test. Going forward, we can make fine tweaks and make it much more seamless and streamlined."

THE FUTURE OF R&D

Divining the future of R&D from its recent past, it's clear that there's always room for further improvements in clinical trials and how they're conducted – and that pharma companies can be far more responsive than they might believe possible.

"Because of the pandemic, innovation is coming to the forefront, and companies are doing this as a matter of urgency," says Nookala, adding that now pharma's mindset needs to be one of "we can adapt, and we will adapt".

Looking to the future shape of pharma R&D, he says companies should look to continue to allow more people to work remotely, make trial endpoints more patient-centric, and be more responsive.

Clearly, flexibility will continue to be required – both on the part of pharma companies and the suppliers they work with. As Hoerster notes: "One of the things that I learned during 2020 was that it was really easy, for us as a mid-sized CRO, to support pharma companies with the changes they had to make because we were able to adapt very quickly to provide more customised or tailored solutions."

She concludes: "The new normal will have to include a massive element of flexibility and risk assessment upfront to be prepared for those kinds of situations. With this flexibility, we might develop new models, which will certainly include more remote monitoring visits and a greater use of telemedicine."

About the interviewees

Dr Anna Christina Hoerster, director, clinical operations (Europe)

Anna is a clinical development professional with more than thirty years of healthcare experience. As a health economist she graduated in theoretical medicine and is a proficient expert in clinical trials of phase I-III including IIT and medical devices with more than 16 years of industry experience in various roles of clinical operations.

Dr Ravi Nookala, senior medical writer, Europe

Ravi is a senior medical writer with over six years of medical writing experience in oncology. He writes clinical study reports, study protocols and various other GCP-compliant documents. Prior to taking up medical writing, he worked as a cancer biologist for 13 years in world-class laboratories at the University of Cambridge, UK.

About Advanced Clinical

Advanced Clinical is a global clinical development organisation that provides CRO, FSP and strategic resourcing solutions for biopharmaceutical and medical device organisations. Our mission is to deliver a better clinical experience. To learn more, visit www.advancedclinical.com.

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Dominic Tyer is a journalist and editor specialising in the pharmaceutical and healthcare industries. He is currently pharmaphorum's interim managing editor and is also creative and editorial director at the company's specialist healthcare content consultancy pharmaphorum connect.

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