Covid's silver lining: clinical trials will be faster, better and cheaper

Virtual appointments and real-time data collection are set to transform an industry that is traditionally slow to adapt

By Julia Bradshaw
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Some of the top science brains in the world predicted 12 months ago it would take two to three years to bring a vaccine against coronavirus to market. That was the best-case scenario. A year later, we've got three — nearly four — that have been approved in Britain.

The unprecedented speed at which the vaccines were discovered and launched was thanks, in part, to a big change in how clinical trials are run. In fact, the pandemic has fundamentally challenged the status quo of trial structure. From now on, they're likely to be faster, better and cheaper and this is good news for an industry in which time costs money — and lives.

The pandemic did two things that forced a rethink of clinical trial structure: it jeopardised the classical way of running trials for non-Covid patients as they were no longer able to go into hospital; meanwhile Covid trials had to speed up urgently. These factors jolted the industry and regulators, bodies known for being conservative and slow to adopt new practices, into action, resulting in a number of transformations, says Miro Reljanovic, executive chairman of clinical trial services company Ergomed.

"Regulators have accepted the changes in the way trials are run and there is no reason to go back. It is better for everyone, for patients, and for the pharmaceutical companies," he says.

One of the most significant ways trial designs are changing is the use of technology to allow patients to be monitored at home rather than in the clinic.

“The US and British regulators were the first to recognise the option of technology, and while it has been around for some time, the pandemic meant it became acceptable and put into use during the crisis successfully,” Reljanovic explains.

Patients were monitored at home, their vitals logged using wearable technology. They kept digital diaries of their symptoms, had Zoom meetings with nurses and in some cases medication was even couriered to their doors.

“Most of us believe this will stay as a new way of planning trials,” he adds.

Feeling at home

Covid prompted conservative regulators to shake up clinical trials, using Zoom as a way to monitor patients at home | CREDIT: Zoom/PA

Home-monitoring, it also turns out, helps keep patient attrition rates down, which is a major contributor to why trials get delayed. It means they don’t have to travel miles to take part. It also provides valuable real-world data both during and after the trial, showing how a treatment works in reality, rather than in a controlled setting.

Richard Marsden is chief executive of Synairgen, a company with an inhaled antiviral drug that was quickly put into trials to see if it could help Covid patients. The inhaler was delivered to patient homes, with nurses teaching them how to administer it via Zoom.

“We monitored their stats, assessed their symptoms daily. The patients loved it. And if you can do this without compromising on safety or data, it is scalable and will change the way trials are conducted in future,” he says.

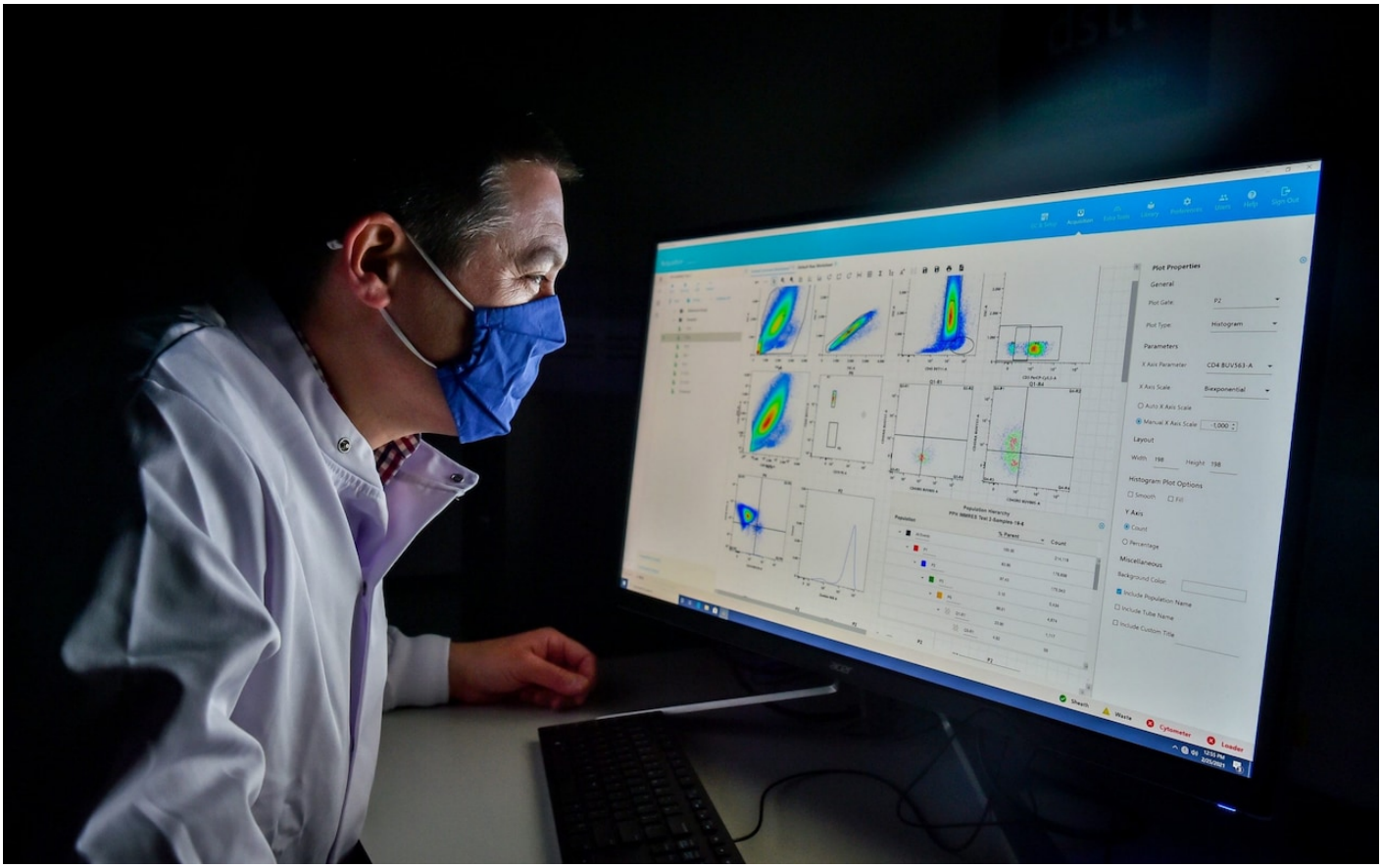
Tarek Sherif, chief executive of Medidata, a company that makes software for clinical trials, agrees.

“Historically all treatments and measurements have happened on site, but Covid has shown us that that is not always necessary. You can run a trial with minimal site visits, gathering all kinds of data remotely.

“So companies have built in that flexibility to help with data gathering in patients’ homes. That's a huge, philosophical change for the industry and opens up all sorts of new possibilities for patients, and I think in the next decade you are going to see hybrid trials a lot more.”

In fact, remote patient monitoring, he says, will be Medidata’s second largest business this year.

A dose of data



Scientists can monitor patients' immune responses to try and predict who is at risk of serious illness from Covid | CREDIT: Ben Birchall /PA

Martin Murphy, chief executive of FTSE 250 life sciences company Syncona, points to the Government's Recovery Trial — a national clinical trial set up to find treatments for people ill with coronavirus — as another example of how the industry could change post-Covid.

He says the speed at which the trials were established and the way they collected data from electronic medical records in real-time as they were logged by doctors in hospitals, rather than by clinical researchers, was unprecedented. In future the industry could use large, aggregated patient data banks to recruit candidates and design better trials.

"Is there potential? Yes. It could be a very significant innovation in the clinical trial process," he says.

Rolling regulatory reviews adopted during the pandemic could also carry on, provided there are enough resources. Here, regulators accept data piecemeal as they come through rather than in bulk at the end. This can slash months from the review process, say both Reljanovic and Murphy.

"Covid has just pushed everyone to be open-minded about what they can do," Reljanovic adds.

Pandemic's 'silver lining'

Murphy says: “Many of these trends were happening anyway, it’s just Covid has now demonstrated, like a proof of concept, that rolling reviews can work, that real-time data capture can work, that access to large data banks for trial designs can work, now we need to accelerate this as it’s a valuable chance to improve clinical development by reducing timelines and cost. It would be a silver lining to the pandemic.”

Martin Murphy, chief executive of Syncona, believes real-time data access will be one of a number of permanent improvements to clinical trials as a result of the pandemic | CREDIT: Syncona

Medidata has already shown how adjusting trial structure can cut time and costs. Start-up times — the time it takes to get a trial up and running — dropped by 70pc for Covid-

related treatments among Medidata's clients, and Sherif says it's reasonable to expect that in future 20pc to 30pc can be knocked off the start-up times of all sorts of clinical trials.

"With the right processes, there is no going back, clinical trials will be faster and more efficient," he says.

And as the industry and regulators become more open to changing trial design, Sherif expects other types of tech, like using synthetic control arms, also known as virtual patients, will become more common in trials.

"Synthetic arms are a wonderful tool, especially in rare disease or oncology where it is especially unethical if you give a patient a placebo, and it reduces the number of patients you need to enroll by 30pc to 40pc," he says.

Medidata has two studies using synthetic control arms that have been submitted to the FDA.

"It is a big area of interest for the regulators and our customers as it changes a lot of the logistical challenges around clinical trials. There has certainly been a turning point in the last year, a willingness to push the boundaries."

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