Trial by ordeal of unprecedented global pandemic

Innovations in precision medicine have the potential to transform healthcare and create tailor-made medical solutions for patients. *Clinical Trials Insight* talks to Mario Papillon, CEO of **Cerba Research**, about how his organisation is helping patients receive novel treatments faster by making clinical trials more efficient. This agility, combined with global access to industry-leading laboratories, has been key in the fight against Covid-19, and will continue to be an imperative in the new reality in which future clinical trials will have to exist.

The clinical research environment is becoming increasingly complex. Over the past decade, there has been a trend in drug development towards expensive personalised medicine. Biomarkers have become an important part of the drug discovery process, helping to significantly improve the success rates of trials. As a result, pharmaceutical and biotech companies are under pressure to accelerate drug discovery while, at the same time, continuing to slash the costs.

"Financially it just doesn't make sense," says Mario Papillon, CEO of Cerba Research. "You can spend over €2bn developing a medication and only have a 30% chance of success. That's where biomarkers make a lot of sense as they can double, sometimes even triple, your chance of finding the right medication."

Improving the efficiency of clinical trials is at the heart of what Cerba Research does. The company, a product of a recent merger of three leading providers – of central laboratory services, in vitro diagnostics (IVD) and biomarker research respectively – is part of Cerba Healthcare, an international network of medical biology laboratories with a long history of innovation. "In 2007 we acquired Barc, our central lab," says Papillon. "Parallel to this, we created a branch called Cerba Xpert to help IVD companies by supplying them with samples, and carrying out testing and validation for them."

In 2018, a third company was acquired, in line with the industry trend towards personalised medicine. "HISTALIM specialises in immunohistochemistry [IHC], identifying biomarkers at the tissue level," explains Papillon. "Developing biomarkers helps to identify the right patient, to give the right treatment at the right dose and for the right duration."

Tri-headed

At this point, it became clear that merging the three entities would provide key benefits for all their clients. "We realised that if we put all these services together, we could use companion diagnostics and, therefore, increase our efficiency," explains Papillon. "Bringing them [the three previously independent companies] under one umbrella meant we could help our clients from the pre-clinical to the post-approval stage of their medications."

By identifying the right biomarkers and developing specialised assays for their clients, the company is able to speed up research and accelerate programmes to market. "It's a real advantage of the merger," says Papillon. "Our capability has definitely increased. We're now able to offer our clients a better, more continuous service."

Data mining can also play an important role in optimising clinical trials. "The industry is using data to help make decisions and recruit patients," explains Papillon. "We have been investing in data mining at the central lab, which has helped us to pinpoint which hospitals have been enrolling in the past. And also in examining medical lab data like regular medical tests, where patients are not necessarily participating in trials. We have access to 25 million patients a year. There's very few laboratories that can claim that."

The outbreak of the Covid-19 pandemic has had a significant impact on clinical

Mario Papillon, CEO, Cerba Research

trials around the world, regardless of national virus-reaction performance. "It completely threw everything sideways," says Papillon. "Everything that was not judged to be essential has been delayed. Trials have been put on hold. Now it's restarting, the key question is: how do we restart in a different environment?"

The industry has faced an unprecedented series of challenges over the past few months, and a number of solutions have to be met before progress in the sector can be made. "First of all, our clients need to make sure their workforce is healthy," explains Papillon. "We have a corporate service to test staff [for Covid-19] – in both virology and serology. After this, patients that have active Covid-19 must be identified and excluded from trials. You need to know that the patient is not infected."

Cerba Research has been carrying out critical work, making full use of its network of industry-leading laboratories. "Right at the beginning of the pandemic, we were receiving samples in our speciality labs to be tested," says Papillon. "We carried out over 10,000 tests a day and were able to deliver this volume very quickly."

As well as developing and carrying out tests, Cerba has been assessing existing tests to differentiate between high and low-quality assays. "Because we do a lot

of IVD work, we were able to test the tests," explains Papillon. "It was surprising to see how many of them have very poor sensitivity and selectivity. You would test someone thinking they were positive, but they would turn out not to be, because of the poor quality of the original test."

The show must go on

In March, the worldwide average of new patient enrolment in clinical trials dropped 65% year-on-year. Researchers are having to work out how to structure trials and recruit participants in the evolving Covid-19 environment. Virtual trials and visits to patients in their homes may become increasingly common.

"Our clients need to think about how to recruit and follow up with patients in a way that protects both the patients and medical staff," says Papillon. "This is where we can definitely help by sending staff to patient homes to take blood samples, as well as offering our collection point. This is so that instead of going to a hospital, they are less exposed and are not stretching the healthcare system."

It is imperative to ensure that the right infrastructure is in place to allow clinical trials to continue, even during pandemics. "We had two teams in some countries – three in others – that would alternate and ensure business continuity," explains Papillon. "This meant that our clients were protected, and their samples were received and analysed on time."

The company has been able to help its clients to develop protocols during the pandemic. "We are able to tell companies which end points they should use, and how they should be interpreted when developing vaccines and treatments for coronavirus," he explains.

As the virus has spread around the world, the company's global footprint has been beneficial. "We have epidemiology data because we are testing affected regions day in-day out," says Papillon. "We know how many new patients there are, and can recommend which hospitals to use."

Working together is key, he insists. "We've been approached by governments in France, Belgium, South Africa and the US, to share data and help build kits, collect samples and develop software to track the samples in terms of when they were received, dispatched and analysed."

"Covid-19 has taught us that science is important, but when you have a pandemic, collaboration is critical. We have been able to work with governments, private companies, hospitals and universities to combine our forces and respond quickly in an efficient way."

Cerba Research is one-third of the international, multidisciplinary Cerba Healthcare network.

Although Covid-19 has been a top priority, Papillon is keenly aware of the need to continue existing trials. "Surprisingly, trials for serious diseases – such as malaria, tuberculosis and even oncology trials – have slowed down," he says. "These diseases are not waiting for Covid-19 to resolve. We need to keep treating these patients. To do this you have to have the right infrastructure, and I think our global footprint and scientific approach allows us to do this as we're able to move operations from one country to another."

Looking forward, Papillon and his colleagues plan to increase research on immuno-oncology biomarkers and anti-infectives. "For us, the expansion of platforms like NGS [next-generation sequencing], IHC and flow cytometry are really important," he says. "We're also looking towards winter, when there will be different viral infections coming up and we will need to differentiate between flu infections and Covid infections. Virology work will be essential."

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Despite already having a presence in Europe, Australia, Asia and the Americas, Cerba Research plans to expand its work to where it is needed most. "Africa has 20% of the global population and only 5% of clinical trials," says Papillon. "It's a really huge imbalance. We have the advantage of being part of Cerba Healthcare, so we're present in 13 countries in Africa, and we have access to these patients.

"They're craving pharmaceutical investment to have access to these new treatments. It's definitely something we would like to put on the agenda."

This ability to leverage a global patient base while embracing the latest innovations in precision medicine has enabled Cerba Research to help pharmaceutical and biotech companies around the world optimise their clinical trials and accelerate product development. Crises demonstrate just how essential this work is. ●

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