

Matching patients to trials: Cerba Research's digital tool for improved patient recruitment

Cerba Research is leveraging the biological and clinical data from patients visiting its parent company's network of clinics to help researchers find the right patient for the right study, as soon as they walk through the door.

Patient recruitment has always been a challenge for clinical research, with most clinical trials failing to enrol enough participants in time, let alone the right patients. When trying to get a study initiated, enrolment challenges are more than just inconvenient; they can also be incredibly costly.

With close to 100% of studies requiring timeline extensions for recruitment, it's no surprise the global clinical trials industry spends more than \$2bn on enrolment efforts and delays each year, according to research by Frost and Sullivan.

As pharma and biotech companies are facing these challenges, the industry has invested significantly to find solutions for these inefficiencies through digital platforms.

It's no wonder there's a booming market for digital patient recruitment tools – a market valued at around \$1.2bn. Most of these companies are offering medical networking through CRO data, with the goal of improving and accelerating patient recruitment.

But one company has taken a bold, yet simple, approach and is achieving the same or even better outcomes.

Cerba Research, a leading healthcare company and wholly owned subsidiary of Cerba HealthCare, has found a way to advance patient enrolment in clinical research by leveraging what it already has: a vast global network of medical laboratories that welcomes more than 35 million patients each year.

Recognising the recruitment pressures the clinical trials industry is under, Adrien Ko, medical advisor at Cerba Research and CEO of IT company Biokortex, realised there was an opportunity here.

"Imagine that we are able to structure all the data of each patient

Biography Adrien Ko Digital Strategy Advisor Cerba Research

or

Dr. KO Adrien MD – PhD (Male) Clinical Pathologist specialized for Lung Cancer, Digital strategy Advisor for Cerba Healthcare and CEO at Biokortex Company. Dr. Ko is a clinical pathologist and he spent 5 years in medical research at Gustave Roussy Institute after his medicine internship. He is a specialist in lung cancer and cell death phenomena. He's now working as a medical doctor for Cerba healthcare and advises the group's digital strategy. He is the founder and CEO of Biokortex.

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coming in every day to a Cerba HealthCare medical lab, across our global network," says Ko. "It means we have a very powerful database of complete patient files that we are now using to power a mobile application we have developed, called Clinical by Biokortex."

Streamlined pre-screening and patient identification

On one level, Clinical by Biokortex is a digital tool that helps Cerba's nurses and phlebotomists manage each patient's visit, guiding them to get the right information every time. "It allows them to validate all quality processes and to audit each step of the pre-analytical phase," explains Ko.

"But it's also an application that centralises and structures the biological and clinical data of patients, such as age, gender, treatments, disease, symptoms and tests."

"By taking a prospective approach, the idea was to see if it's possible to connect all the patients that visit our medical labs every day to a clinical trial. We included a matching system that can find the right patient for the right trial.

"There's a notification system in the application. If a patient fits the inclusion and exclusion criteria, the nurse or phlebotomist receives an information note and an e-consent form that can be signed directly on the tablet. Then they can ask the patient for more tubes, additional tests, or eCRF, depending on the trial."

For the trial sponsor or CRO, it's as simple as entering in the key details of the study, such as the name, contact information, location, regulatory documents, and the allimportant patient inclusion and exclusion criteria.

"All kinds of trials can identify, pre-screen and/or enrol participants via this service, including phase one to four clinical trials, IVD studies, real world evidence assessments and/or epidemiological surveys," adds Guillaume Franc, global sales director at Cerba Research, diagnostics, medical device and data unit.

Franc proceeds to list a few of the advantages this service has for sponsors: "We have today over 750 laboratories in France and overseas, including patients in city clinics and hospitals. It's a global solution that offers cross-biological and clinical data, and the patients are very diversified. We improve the inclusion rate for clinical trials. There is also a very quick implementation; even if there's a protocol modification, you can change the pre-recruitment process remotely in the application that same day."

Reimagining the medical laboratory

The patient also benefits from this unique approach, where the clinical trial is brought to them. "It's almost like you decentralise the patient recruitment," explains Ko. "Some people in clinical research think we should be carrying out trials remotely at the patients' home. I think when the patient is alone at home, it's not the same as a medical place dedicated to their care.

"At the same time, if the trial site is three hours away, it's not easy either. If, however, you can do the pre-screening in a medical site very close to the patient's home, it's a good choice for them. And if you do good for patients, I think you cannot lose."

Doing good for the patient also involves following the relevant ethical protocols. Whether or not patients have to consent to each trial their information is submitted into, depends entirely on the type of study and the approach taken by a country's ethics committee.

As Franc explains, "Non-interventional studies have low involvement and lower risk, so non-opposition is enough. For interventional studies, which are higher risk, the patient must give informed consent."

"In all cases, the patients are informed of the final use of the data that we collect, if it's clinical or biological data," he notes. "And any time after signing the consent, they can step back, and we would delete the information that we have collected."

As Cerba Research's new service is rolled out around the world, Ko believes the role of the medical laboratory is changing. "Medical labs are not just there to make analyses. Because of Covid, we better understand the changing role of the medical lab. When it comes to patient recruitment for studies, we can do it faster and easier through digital management.

"At Cerba Research, we already have the network, the patients, and the great team. By equipping them with the right digital tool, the set up can be very powerful and very positive for improving how clinical trials are organised and run."

A new paradigm for patient recruitment

Technology has transformed almost every aspect of our lives and can potentially offer the solutions needed to transform clinical trials if backed by sufficient investment and regulatory support.

We could, as a starting point, improve efficiency by moving from paper to digital recruitment. But this requires a complete rethinking and re-engineering of the clinical trial experience, focusing around the participant rather than the research site. While some trials could be entirely digital in a virtual environment, many will need a hybrid of virtual and clinical site-based activities.

This paper explores how Cerba Research is working to improve the clinical trial experience for patients, research sponsors and everyone else involved in the process. At the heart of this new approach is the more efficient and more effective use of patient data. Cerba is working with startup BioKortex to transform how patient data is collected and used to speed up and improve patient recruitment.

Clinical trials have the ability to transform health outcomes, but better use of data has the ability to transform how those trials are run, with the speeding up and improvement of recruitment a massive step forward.