Cerba Research

How Saint-Antoine Hospital is boosting patient recruitment with medical laboratory data

A staggering number of clinical trials fail to enroll enough patients. Most of the time, it's not because the patients don't exist; it's finding them that can be difficult.

This is a struggle that Professor Karine Lacombe's team at the infectious and tropical diseases department of Saint-Antoine Hospital in Paris know all too well. In addition to overseeing the department's clinical research activities, she is also an investigator and co-investigator of several national and international cohort studies and multi-center trials in the field of HIV-viral hepatitis co-infection and Covid-19, and is a scientific manager of interventional studies in public health.

Professor Lacombe spoke to Clinical Trials Arena about the difficulties of patient recruitment and a new application the department is using to boost patient numbers. She starts by outlining her team's previous approach to recruitment, which involved total reliance on the department's own digital database of inpatient records.

"To find patients for a trial, we go into the database and use the inclusion criteria to ask if we have patients that respond to the eligibility criteria," Professor Lacombe explains. "The problem with this approach is that we can only act on patients who are followed for chronic infection, whereas some of the trials we have recently started require patients who are in an ambulatory setting."

For help finding outpatients, the hospital started contacting colleagues in the wider community who could search databases of their own. Often, however, these individuals didn't have time to assist.

"It has been very difficult to identify the required patients," says Professor Lacombe. "This approach has not only delayed inclusions; in some trials we have not even been able to include patients, especially for Covid-19 trials that addressed ambulatory care or prevention. That's why we had to change."

And change came in the form of a revolutionary new patient recruitment application made possible through a collaboration

Biography

Karine Lacombe

Professor of Infectious Diseases

Karine Lacombe is a Professor of Infectious Diseases at Sorbonne University Faculty of Medicine and a Hospital Practitioner in Infectious Diseases, Head of Infectious and Tropical Diseases Department at Saint-Antoine Hospital. Regarding her research activities, she is part of Inserm unit UMR-S1136 - Institut Pierre Louis de Santé Publique (Epidemiology, Information Systems, Modeling) in CLEPIVIR team (Clinical Epidemiology of Chronic Viral Diseases).

Since 2002, Karine has been or is the supervisor of a clinical research team part of the Infectious Diseases Department at St. Antoine Hospital. She is also investigator or co-investigator of several national and international cohort studies and multicenter trials in the field of HIV-viral hepatitis co-infection and more recently Covid19 and is a scientific manager of interventional studies in public health. Karine is co-president of AFRAVIH, a French-speaking association of HIV, hepatitis and sexual health stakeholders and a plenary speaker at international "Post Graduate" conferences. She is also a member of prestigious societies such as European Society for Clinical Microbiology and Infectious Diseases (ESCMID), Société de Pathologie Infectieuse de Langue Française (SPILF), Collège des Médecines Infectieuses et Tropicales (CMIT), European Aids Clinical Society (EACS) and European Association for the Study of the Liver (EASL).

between healthcare diagnostic firm Cerba Research and digital solutions start-up BioKortex. The solution involves a digital tool, but at its center is a huge network of people – specifically, the 8,000 patients a day visiting Cerba HealthCare's medical laboratory sites in France.

"The clinical labs in town have a very high number of individuals coming in for blood tests for conditions like hypertension. With the patient's authorisation, the biological lab can screen for other diseases. If the characteristics match what we're looking for, the lab can suggest the individuals contact us or, depending on the ethical background, they put us in direct contact," the professor explains. "We can then offer the patient inclusion in our trial."

Saint-Antoine Hospital is one of the first sites to test the service out, and Professor Lacombe is very excited about its ability to increase their potential for recruitment. She plans to continue using the application on all future clinical trials.

The service, named Patient Connect from Cerba Research, has a positive impact for patients, too. Especially those with specialised diseases like Hepatitis B, typically followed in town by a general practitioner.

"When there is no indication for the treatment, the general practitioner will not think about clinical trials. This is a way for us to raise the public's awareness of trials and offer innovative treatments to patients with an innovative strategy. For the patient, it's a unique opportunity to participate in a trial. Some patients are very keen to help with the acquisition of scientific knowledge; it's a win-win exchange," says Professor Lacombe.

The right way to decentralise clinical trials

Patient Connect from Cerba Research is not only reimagining the patient's journey into a clinical trial. It's also changing how that patient is managed throughout the trial. The Saint-Antoine case study shows one of the two ways the system can work, where the medical laboratory pre-screens patients. The alternative approach involves patients being recruited first by the hospital and then followed up by a medical laboratory nearer to their home.

Long distances between the patient and the trial site has traditionally been another barrier to participation. With this approach, patients enjoy all the convenience of a decentralised trial while still receiving the experienced care of a medical professional in a medical setting. It's a hybrid care approach that Adrien Ko, CEO of BioKortex and medical advisor at Cerba Research, believes is the right way to decentralise clinical trials.

"My job as medical advisor is to create the medical link between a hospital like Saint-Antoine and Cerba," explains Ko. "We want to connect patients everywhere – in the hospital, the medical lab, everywhere. If you connect the private networks to the public hospitals everywhere in the world, you can achieve decentralisation."

And Ko is certain that a digital solution is the vital bridge between the two. As public and private health networks in France ease into a new era of collaboration, with a growing number of hospitals expressing their interest thanks to the power of word of mouth, Ko asserts "it can be the same everywhere".

Cerba Research is working hard to make this so, with projects underway in Belgium and Italy. In the future, a key opportunity will be Africa thanks to the company's joint venture with Lancet Laboratories. Cerba Lancet Africa currently operates in 12 countries in sub-Saharan Africa.

As more and more trial sites embrace the new application, study teams are discovering an easier, more patient-centric way of recruiting and conducting clinical trials. As a result, sponsors are directly benefiting from stronger clinical research. As these benefits continue to be felt throughout the community, the medical laboratory is showing the important role it has to play in the decentralisation of clinical trials.

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.