BarÄ±Å? ErdoÄ?an â?? CEO, Clinerion

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Clinerion, a leader in real-world data solutions, is helping bring medical data informatics to the life sciences industry. CEO BarÄ±Å? ErdoÄ?an explains how the company is creating and applying technology to significantly reduce the drug development timeline. Clinerion uses Big Data analytics technologies to help hospitals, pharmaceutical companies and research organizations identify high-risk patients for different diseases, improve the market access process, respecting privacy laws and regulations along the way.

Having recently taken over as CEO, what has your career progression up to this point been?

I took over the CEO role at the beginning of the year, yes, but I have been working at Clinerion for almost eight year in different roles. I was in charge of Clinerionâ??s first commercial project in Turkey in 2013 and founded the Turkey subsidiary in 2014. Two years later, I became the regional head for Eastern Europe, Middle East and Africa. And in 2019, I became the global VP responsible for Clinerionâ??s site and patient network.

You have taken on this challenge at quite an unusual time. How has the COVID-19 pandemic affected the company and what is at the top of your priority sheet at the moment?

Being a technology company, working remotely is not as big a challenge as it is for other companies in the industry. What we have seen as a positive challenge is the surge in industry and researcher demand for analysing real-world data since they are seeking to understand the spread and ramifications of COVID-19. They also want to be prepared for the next waves of different viruses in the future.

Therefore, there is a huge interest now for healthcare data analysis to better protect people from the effects of the virus. This is really opening new doors, allowing us to increase our client base, as well as increase our use cases.

Initially, back in 2012, the company started building its hospital network focusing on the clinical trials environment. The focus was more on clinical trial feasibility, site selection and patient recruitment. However, over the last two years, and especially after the COVID-19 outbreak, the focus is switching to data analytics for different commercial and research purposes. Real-world data can be used to identify high-risk patients for different diseases or to help pharma companies in market access or market research.

New tools on our platform are capable of doing this in real time with anonymized, aggregated data sets, and we are developing the accompanying infrastructure. Our model strictly adheres with data and privacy laws, the EUâ??s GDPR, and other regulations, meaning we do not access any identifiable personal data on our systems.

So, it is all anonymized and you are not dealing with individual patient data that can be traced back to individual patients.

Exactly. We have a patented technology that runs within the hospital under firewall protection that has the capability to allow the hospital itself to re-identify a patient from the original hospital records. That is one piece of the software that runs only within the hospital system, under the control of the hospital employees. The other piece, which is fully anonymized, is used for research, to identify disease patterns, treatment patterns, etc.

In addition, we have begun working on a project which was recently approved by Innosuisse (the Swiss Innovation Agency) to create an infrastructure for artificial intelligence (AI) and machine learning (ML) algorithms on the federated distributed system level. This machine learning infrastructure will be in alignment with our hospitals to keep the patient records on site and do any kind of calculations there.

Since patient data is delicate, there is a need to have the infrastructure running in a federated, distributed manner inside the hospitals without the need to extract the data from local systems. It is an 18-month project for us. We are working with two university hospitals in Switzerland; it is very exciting for our team, intellectually, we are very much interested in discovering the final product at the end of the project. I have a computer engineering background, so I am very much open to create new and innovative solutions.

We believe the future is in AI and ML since it will allow us to build models that track disease patterns, that identify high-risk patients earlier, that make predictions. This is what our hospitals are expecting from us and they are eager to be part of these developments. This is going to be one of our focus areas under my leadership.

Understanding that Switzerland is a global life sciences hub and one of the most open places to innovation, along with the US, is this project something that you are looking to roll out globally or do you plan to adapt to each market?

Our aim is to make it the default platform for real-world data, everywhere. It has the potential to offer solutions to many people. The idea is to enable better research while maintaining data privacy and security principles. We share everyoneâ??s concern about data breaches and cloud servicesâ?? vulnerabilities. Security-wise, it is better for data to stay within hospital systems.

We are currently active in 27 countries, working with many different systems and data structures. Data quality is equally or even more important than the data structure it uses. Interoperability between different data structures is something we, as experts, can manage, but data quality is different because it has multiple stakeholders. Hospitals understand the value of it and are creating data quality teams. Governments also issue data quality guidelines and ask hospitals to have data quality reviews, asking them to appoint data quality officers.

But of course, the efforts are uneven around the world. We are working with the Swiss Personalized Healthcare Network (SPHN), which brings together leading university hospitals across Switzerland, and uses Clinerionâ??s platform as the official technology infrastructure; it is a model we would like to export to the rest of the world.

Hospitals want to have access to each otherâ??s databases through our platform, with only counts/aggregate numbers from anonymized data leaving local databases. They want to have research collaborations to leverage their know-how expertise. That has increased our value to researchers.

We have also become a certified technology partner of a European health data and evidence network which is an IMI-funded five-year project. They have the ambition of creating a research ecosystem with a standardized data model. We are also encouraging our hospitals to be part of that network, because it will facilitate the use of healthcare data for secondary purposes, for healthcare outcomes, for research for publications, etc., a use case which is becoming more and more important for healthcare development.

Taking that standardized model, in which networks work across hospitals, regions and countries, as the ideal, how far away are we from something universal and less siloed? What role does Clinerion have in helping create this sort of dream world?

It mostly depends on the research appetite of regions, healthcare organizations and researchers. We have the power and expertise to integrate any hospital into this network in any part of the world, as long as they have the vision of participating in global, collaborative research, and as long as they have the high-quality data it requires. This year, we want to do more research, more publications, more academic activities, apart from all the commercial services our partners provide to the pharma industry. We want to help them reduce the time it takes to develop therapies. But you first have to educate people in the benefits of cooperating and in sharing their data somehow, at least partially, making it available for research and collaborations. We have the technological expertise to make it happen, but education is the higher hurdle. It is encouraging to see more and more hospitals using electronic health records, even though there is room to improve in many countries.

There are also countries with great electronic health records, like the Nordics, that are having a difficult time getting hold of the data to use it in their research efforts.

Indeed, that is the case in some countries, but we are seeing encouraging steps, especially coming from the FDA. If we look at their guidelines from 2017, they had clear rules for the use of real-world data in medical device development, and in 2018 they added guidelines for the use of electronic health records in clinical investigations. I believe that the smart use of data for research is being aided by regulators. The truth is that real-world data reduces the number of patients required for a study. Of course, then comes the question of quality of data. And again, we see in some countries that there are steps being taken on the governmental level. I think it is all coming together.

What is the value proposition for Clinerion and what is your relationship with hospitals to improve industry research?

Our coverage has increased exponentially over the years. We have captured data from 75 million patients in our federated network. Moreover, with external partners, we have patient data for over 200 million that can be used for real-world data purposes.

Our process is first signing contracts with hospitals and then spending on average two months to have the data extraction routine with high quality up and running online on our platform. We work with around 300 healthcare organizations worldwide in 27 countries at the moment.

When it comes to real-world data, different countries have different definitions. Some say registries are real-world data, others say electronic clinical trial data can be used as a real-world data source, and others are looking at mobile applications. The important thing is having an intelligent approach to data. For example, if a patient has chronic disease, can you analyse its evolution over years, even decades? That is one business, digging out quality data to be analysed. We also use it for site feasibility; since it is in real time, we can do an immediate site selection by typing in the criteria and advise pharma companies on the best location to conduct their trials. It increases the number of trials being conducted per year and makes the hospitals and sites more efficient.

Within our global hospital network, our hospital partners also have the chance to refer patients from one site to the other. This also increases the benefits for patients, as they have the possibility to be referred to other centres for experimental treatments.

Another priority for us is our work on rare diseases, helping countries across different regions better diagnose patients, which helps physicians as well. When it comes to rare diseases, hospitals are open to collaborating with peers across the world. It is part of our social responsibility.

What are your hopes for 2021 and beyond in terms of how stakeholders, your clients within hospitals and the pharma industry approach digital tools?

There is plenty of interest in digital solutions across the board. We want to increase our use cases. For example, in oncology, which is one of the biggest fields for clinical trials, we have clients interested in developing therapies by analysing images, MRIs, running AI algorithms on those images. We want to enable the merger of electronic health records with images, with genomic data, so that it becomes a full set of data that can help patients and researchers as well as the industry.

Also, in the clinical trials field, there is a movement for electronic data to flow automatically, electronically, to clinical trial case report forms (eCRFs) to reduce double entries. Data is also used by CROs during the monitoring for source data verification. We will be piloting that this year, the automatic flow of electronic records to eCRFs.

How important has been Switzerland in the journey of the company?

Switzerland has always been at the core of the company. It is a hub for innovation. Our product was developed in the country, it is Swiss-made software with its intellectual property helped by Swiss grants and protection. Our new AI and ML innovation project is supported by the countryâ??s ecosystem, mentality and training. We of course have great partners in the academic sector and the local industry that help us develop our use cases.

The benefits of our services go from Switzerland to all over the world. For example, we are working with a big pharma company at a university hospital in Turkey to run machine learning models to predict chronic kidney disease patients, to predict them before the risky period, so that they start the treatments and do not lose their lives or organs. I care about these kinds of things; I am trying to facilitate different partners to come together and provide value.

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