Mohamed Mostafa â?? CEO, PDC CRO

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20.07.2023

Tags:

UAE, PDC-CRO, CRO, Clinical Trials, Research

Only a small percentage of global clinical research takes place in the Middle East and Africa region today. This means that full-service MEA-focused clinical research organisation PDC CRO has a wealth of untapped opportunities to develop, according to the companyâ??s CEO Mohamed Mostafa. He outlines PDCâ??s important work on COVID-19 vaccine and therapeutics trials, how it is integrating new technologies like AI into its operations, and why MEA could come to host more clinical research in the coming years.

Could you begin by introducing PDC CRO to our international audience?

PDC is a full-service clinical research organisation covering the Middle East and Africa (MEA) region. Our role is to facilitate patientsâ?? access to innovative therapies and provide healthcare options through clinical research. Our top priority is promoting the region and facilitating biotechnology companies, Big Pharma, and venture capital funds to invest in clinical studies in MEA. We have the capabilities in terms of infrastructure in the region with some excellent hospitals and experienced physicians and are looking toward conducting R&D that meets the unmet needs of the region. This includes untapped areas with a high prevalence of indications such as rare conditions and infectious diseases.

Which areas do you manage and what services do you provide to your partners?

The company was founded in 2011 in Saudi Arabia, and we currently cover 31 countries across MEA with headquarters in Dubai. Our largest operations are in the UAE, Saudi Arabia and Egypt, and we also are strong in Lebanon, Jordan and Northern Africa. We have an established footprint in Sub-Saharan Africa in nations such as Ghana, Mali, Sierra Leone, Tanzania, Kenya, and South Africa.

PDC-CRO provides full services in areas such as clinical operations, project management, regulatory services, pharmacovigilance, site management, data management, medical writing, and biostatistics. We are also a functional service provider for our partners.

The company has established partnership agreements and set up clinical research units while providing quality management systems in terms of standard operating procedures and policies. Our unique quality is that we provide a site management team in the hospital to conduct the clinical trials. These clinical site managers and coordinators are hands-on, following up with investigators and patients and organising the logistics of the trial. This site service was actually part of a spin-off business set up last year, but we are very proud of this bespoke approach to our operations.

A testimony to the success of this model is our ability to recruit more than 120 thousand subjects over 3 years for more than 20 companies during the COVID-19 pandemic. Through this research, we put seven vaccines and two treatments on the market through Emergency Use Authorization or full registration. A range of regulatory authorities accepted the data, including the WHO for a vaccine, which is a huge success.

Furthermore, it showed companies that clinical trials can be conducted in MEA and that accreditation and registration of therapies can be done based on local data.

How have your experiences prepared you to run a company with such varied operations spread across such a diverse region?

I have been happy with my career progress over the years and have been able to gain experience from the ground up. Starting at the associate level in research activities I got to understand their KPIs and matrices as they are the people that validate if the data is correct. I then moved through the management ranks and supported business development activities while obtaining a good understanding of medical writing and data management.

Then, three years ago, I had the opportunity to invest in this business and become CEO. I love the clinical research industry and there is so much work to be done in the region. We only represent one percent of global clinical trials and this does not reflect our population size or consumption of medicines. Clinical trials should be part of routine medical care and always be an option, but here we do not have this privilege yet. In some areas like rare diseases and oncology we are moving forward well, but in other chronic areas, we are still lacking.

What strategy did you put in place when taking over as CEO three years ago?

We shifted the whole strategy of the company. In the past, we were mainly focused on GCC nations and on the core services mainly clinical operations and project management. We chose to expand to a larger range of countries that were untapped, such as those in Africa. Furthermore, we understood we had to get closer to hospitals, physicians, and investigators to enhance our collaborations and support capacity building. We put in place a solid quality management system and hired experienced

resources in the countries where we operate.

During this time the UAE government, particularly the Abu Dhabi Department of Health, accelerated the development of clinical studies. They have overseen what we are doing and appreciate the importance of building a legitimate ecosystem that meets international regulations.

Another catalyst for growth has been the COVID-19 pandemic, which has made people understand the importance of research. Our clinical studies within this area have given confidence to pharmaceutical and biotechnology companies to conduct more research and partner with us in the region. We partner now with many top 20 pharmaceutical global players through master services agreements or partnerships. Also, we have direct access to biotechnology companies and support them in their programs of clinical development through Phases I, II and III, with clients from the US, Europe and Asia Pacific.

Most of the pharmaceutical companies we have spoken with are not currently conducting clinical trials in the region. What do you see as the positives of conducting clinical research here?

We are very active in promoting the MEA region at global events and conferences. While other CROs from around the world are talking about their services, our main message is related to the advantages of the MEA region and the value added to conducting trials in these countries. We do not have the luxury of talking about ourselves as the leading regional CRO, but we talk about the territory and the advantages of doing business here.

MEA has varying levels of GDP and languages, so we subdivide it in many cases. But what is common is that it is very much untapped and not a lot of clinical research is being done, which means patients are not participating in competing trials, a huge plus. The UAE and Saudi Arabia have incredible infrastructure, medical resources, and leading experts and are nations that are driving forward innovative therapies. As a population group, we are very diverse with a good range of age groups

From an operational point of view, the processes are streamlined and we have quick site activation turnaround, backed by strong ethics committees and regulatory bodies. Furthermore, being an untapped region, we have many unmet medical needs that are unique to the region such as specific rare diseases. Also, high obesity rates are fuelling a surge in diabetes, with 5 out of the top 10 most prevalent nations being in the territory we control.

What about the negatives?

For the UAE it is the smaller patient population. Most of the people here are ex-pats, and because they are travelling here for work, they are generally in good health. Also, the population is 70 percent male, so women-specific studies or gender-diverse research becomes more challenging.

I was on the other side in the past, working for Big Pharma companies. Site allocation from HQ is based on two areas, operational and strategic. Now operationally we are fine, as mentioned before with a diverse population, rapid site activation, good infrastructure, and strong regulatory bodies.

Where we fail, except in Saudi Arabia, is strategic. All the other countries lack the population and commercial market size. Nevertheless, if we do have a pool of patients, like in rare diseases, it is a

lot easier to convince pharmaceutical companies to partner with us here.

Based on the parameters of the region, which disease areas are you focused on?

Mainly on infectious diseases, metabolic disorders, and rare conditions. We have a lot of expertise in genetic, haematological, and neurological disorders, with the majority being paediatric-related. It is especially important that these younger patients are diagnosed early as quick access to therapies gives them a big advantage later on in their lives. This is all being fuelled by the government and the Al Jalila Hospital, the leading paediatric hospital in the UAE. We have even been able to conduct trials that involve patients from outside the UAE by having them referred for treatment here.

What I will also say is many of the trials we do here are extremely complex. The region is typically considered to be a rescue region, as when companies cannot find patients across the world they come here as a last resort. This means we are well prepared and are ready for simpler clinical trials in the future.

There is a big push in pharmaceuticals today towards new technologies such as AI. How are you approaching this in your operations?

New technologies are definitely our future and we have been adapting to this for years. We started collecting paper records and have shifted to electronic data. We are integrating our systems with those of hospitals, and this is very important in many aspects.

Firstly, it gives us quality and credibility in clinical trial conduction as we have complete data entry throughout. Secondly, AI and data mining solutions give an opportunity to understand how many patients are available to be treated for a disease within each hospital. Therefore, we partner with these technology providers in the region, and this was accelerated even further during the COVID-19 pandemic.

Overall, we have begun relying more on Real World Data (RWD) as it could support us in many aspects such as in interventional clinical trials in terms of eligibility, outcomes and primary endpoints. Furthermore, it would help physicians have a better understanding of the population pool and characteristics of the disease. RWD will assist regulators and pharmaceutical companies to generate health economic outcomes and HTA assessments to show how to better understand and administer the correct medication to the right group of patients. Also, it will help health insurers better understand claims and set up reimbursement programs for a particular indication and condition.

The direct impact on us using new technologies has been significant. We are now looking at concepts such as home visits and remote monitoring and we envision a completely computerised clinical trial in the near future. Decentralised clinical trials will be a trend in the future, and we are preparing ourselves to be major players for this in the region and will use RWD and AI along this journey.

Where will we see PDC CRO in the upcoming years?

We will continue to be the leading CRO in the region and we need to be proactive in bringing clinical trials here. We will work with hospitals to strengthen their capabilities as well as always look to grow ours. This will fuel the goal to make clinical trials not just an occasional option for patients in the

region, but the standard in their treatment journey.

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