Mohamed Mostafa â?? CEO, PDC-CRO

> Our commitment to finding effective treatments for patients across the region remains unwavering

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Mohamed Mostafa explains how PDC-CROâ??s successful 2023 was driven by a direct-to-biotech strategy, with the company now well-established as a comprehensive partner for biotech firms across the Gulf and Levant regions. Mostafa also outlines why Saudi Arabia is a key market for PDC-CRO, especially with recent healthcare sector developments and the establishment of regulatory frameworks that support clinical trials. The countryâ??s growing importance is highlighted by its regulatory environment, commercial influence, and substantial patient population, making it a prime location for conducting clinical trials.

Can you give us an overview of how the year 2023 concluded for PDC-CRO, and what your expectations for 2024 are?

The year 2023 ended on a positive note for us. We have met our set goals and targets and managed to grow our portfolio and build a rich pipeline across various therapeutic areas. As we enter 2024, weâ??re optimistic and excited about the opportunities ahead, as it promises to be a busy and promising year for us.

What were the key factors driving the success of your company, especially considering the challenges posed by COVID-19?

The success of 2023 can be attributed to our strategic focus on a direct-to-biotech strategy. Unlike traditional approaches that heavily rely on subcontracting with major CROs, we adopted a model where 50 percent of our revenue comes from partnerships with global CROs, while the other 50 percent is derived from direct engagement with biotechs.

This approach involves providing comprehensive support to biotech firms, including full clinical development services in the Gulf and Levant regions, covering countries like Saudi Arabia, UAE, Jordan, and Lebanon. By guiding them through the entire development process, from clinical trials to market registration, we were able to achieve a balanced revenue stream and significant success. To support this strategy, we invested in building a robust setup, including quality management systems and IT infrastructure, aligning with the standards set by major players like Pfizer or Novartis. This investment has positioned us well to compete in the market and effectively serve our biotech partners. Another factor is our ability to manage patient recruitment and retention especially for complex trials and rare

Regarding clinical trials in the region, are the quality standards and requirements comparable to those in the US or Europe, or are there adjustments considering the regionâ??s capabilities and regulations?

The quality standards and requirements for clinical trials in the region align closely with those observed in the US or Europe, reflecting the global harmonization efforts initiated with ICH-GCP in 1996. These standards ensure consistency and reliability across trials conducted worldwide, with additional considerations for local regulations and cultural norms.

As PDC expands its regional role how will this growth be funded and what investments are necessary to achieve this objective?

Our focus is on enhancing our regional presence in the Middle East, Africa, and Eastern regions, rather than aspiring to become a global entity. To fuel this growth, we prioritize building capacity in hospitals and fostering partnerships with pharmaceutical and biotech companies. This involves enhancing hospital capabilities through training, quality assurance, development, and patient identification.

Our objective is to provide early access to innovative treatments, bypassing the typical delay of six to nine years caused by clinical development, market access, and insurance coverage processes. Currently, our services include operations support, site activation, medical writing, statistics, and capacity building through training. We also assist hospitals and regulators in aligning with guidelines *for patient benefit*. Despite the existing infrastructure, particularly in Saudi Arabia, there is a need for better organization and alignment between hospitals, pharma, and biotech companies to facilitate more clinical trials and effectively harness the regionâ??s potential.

Given your companyâ??s roots in Saudi Arabia and your extensive experience in the market, how do you view Saudi Arabia as a key market within the region, especially considering the recent changes and developments in the healthcare sector?

Saudi Arabia holds significant importance for us, being the birthplace of our company. Over the past decade, we have witnessed substantial transformations in the Saudi healthcare landscape. The

regulatory framework, led by bodies such as the Saudi FDA and NCE (NCE *oversees the entire framework of research ethics, including the approval and management of IRBs, as well as the evaluation of the performance of independent ethics committees*), has evolved remarkably, ensuring a robust system for clinical trials and research ethics.

Furthermore, the establishment of the Saudi NIH three years ago, under the directives of HRH Crown Prince Mohammed bin Salman, has further solidified the countryâ??s commitment to advancing clinical trials and the biotech Incubator plan. Unlike the NIH in the US, the Saudi NIH not only provides funding but also facilitates communication among stakeholders, including sponsors, CROs, hospitals, and regulators. This comprehensive approach has streamlined processes such as site activation and documentation, reducing hurdles for conducting clinical trials in the country. Additionally, the mandate for Big Pharma to establish regional offices in Saudi Arabia reflects the growing commercial significance of the market, which now rivals some of the largest countries in Europe in terms of size and potential.

Considering the significant population size and healthcare infrastructure advancements in Saudi Arabia, how do you assess its potential as a key market for clinical trials, especially in comparison to other countries in the region?

Saudi Arabia stands out as a significant player in the region, especially in terms of clinical trials. The countryâ??s prominence has grown substantially over the past decade, surpassing other nations like Egypt and Algeria. Saudi Arabiaâ??s size and commercial power make it a prime location for conducting clinical trials. Pharmaceutical companies, including giants like Novartis, MSD, and Pfizer, have recognized this and shifted their focus accordingly.

Strategically, Saudi Arabia has become increasingly attractive for clinical trials due to its regulatory environment and commercial influence. Initially seen as primarily a strategic location, Saudi Arabia is now emerging as a key operational hub as well. This shift is evident in the increased interest from pharmaceutical companies in conducting trials within the country.

Moreover, Saudi Arabia offers significant potential for a wide range of clinical trials, spanning various therapeutic areas such as oncology, genetic disorders, and metabolic diseases like obesity and diabetes. The countryâ??s large and relatively untapped patient population, combined with the establishment of Centers of Excellence and patient associations, further enhances its appeal as a clinical trial destination.

In addition to traditional clinical trial models involving small molecules and biologics, Saudi Arabia is well-positioned to support innovative drug development, including precision medicine, gene therapy, and stem cell research. The country boasts robust infrastructure, including specialized hospitals and phase one units accredited by the Saudi FDA, facilitating the conduct of cutting-edge clinical research.

https://alpha.pharma.kalyna.dev/wp-content/uploads/2024/04/Homepage_video_PDC-1.mp4

When considering the operational aspects of conducting clinical trials in Saudi Arabia, what improvements have you observed in recent years, and what challenges still need to be

addressed to ensure efficient trial management, particularly concerning investigator motivation and logistical coordination?

In Saudi Arabia, the motivation for investigators to participate in clinical trials is influenced by a combination of factors, with financial incentives playing a relatively minor role compared to logistical support and operational efficiencies. Historically, monetary compensation for conducting clinical trials has been limited, as the financial remuneration offered is often considered minimal compared to standard pay rates in the country. Instead, investigators are primarily motivated by other factors, such as professional development, access to cutting-edge research, and contributing to medical advancements.

However, over the past few years, there has been a notable shift in the clinical trial landscape in Saudi Arabia, with the establishment of dedicated clinical trial units within hospitals and the introduction of site management organizations (SMOs) to streamline trial operations. These developments have alleviated many of the administrative burdens traditionally associated with conducting clinical trials, making participation more attractive to investigators.

The emergence of SMOs has been particularly instrumental in enhancing logistical support for clinical trials. These organizations handle various aspects of trial management, including patient recruitment, logistics coordination, and budget management, allowing investigators to focus solely on medical aspects of patient care. This delegation of logistical responsibilities has significantly reduced the time and effort required from investigators, making clinical trial participation more feasible and appealing.

Furthermore, the establishment of a network of clinical trial units and SMOs has bridged the communication gap between pharmaceutical companies and investigators. With many biotech firms lacking a physical presence in Saudi Arabia, SMOs serve as intermediaries, facilitating collaboration and trial implementation between sponsors and investigators. This enhanced connectivity has increased the accessibility of clinical trials to investigators, further incentivizing participation.

Moreover, the professional recognition and visibility gained through clinical trial participation have become increasingly valued by investigators. By contributing to innovative research and presenting trial outcomes at international conferences, investigators enhance their professional reputation and academic standing. This recognition serves as an additional motivational factor for investigators to actively participate in clinical trials.

From both an industry and community perspective, how has the process of patient recruitment for clinical trials evolved in Saudi Arabia, particularly considering cultural factors and potential stigma?

Patient recruitment for clinical trials in Saudi Arabia has seen significant improvements driven by advancements in technology and the integration of electronic health records (EHRs) across healthcare institutions. From an industry standpoint, the consolidation of clinical trials in key hospitals has facilitated patient access to trials, although this has limited the spread of trials across the country. However, the integration of EHRs allows for more efficient patient identification based on eligibility criteria, enabling a larger pool of potential participants. Despite these advancements, there remains a stigma associated with clinical trials in the community, which requires ongoing efforts to raise awareness and destigmatize participation. However, in the rare disease community, where patients often have limited treatment options, there is a strong trust between patients and physicians, leading to a higher willingness to participate in trials and a reduced sense of stigma. Overall, while challenges persist, the use of advanced technology and the commitment of healthcare professionals

are key drivers in overcoming barriers to patient recruitment in clinical trials.

Given the national focus on rare diseases in Saudi Arabia, is PDC considering implementing managed access programs to bring products from global biotechs to the market, particularly those unlikely to enter the country under traditional commercialization strategies?

PDC has an active plan to introduce managed access programs in Saudi Arabia through our sister company specializing in the commercial industry. These programs aim to bring products developed by global biotechs, especially those with no immediate interest in the Saudi market, to patients in need. With support from Saudi authorities, such initiatives can facilitate access to treatments for rare diseases and ensure patient supply and treatment data are efficiently managed.

With the recent release of the biotech strategy in Saudi Arabia, how do clinical trials factor into this plan, and what was your initial reaction upon reviewing the document?

When examining the biotech strategy, itâ??s crucial to start with clinical trials as the foundational element. Typically, this involves progressing from clinical trials to registration and market strategy, utilizing local data generation to support registration requirements. The strategy should also encompass post-authorization studies for safety and efficacy, followed by the establishment of a biotech accelerator and incubator. Ideally, the incubator should be integrated with university hospitals to leverage basic research and translational medicine capabilities. While the current strategy appears focused on attracting external biotechs for co-development partnerships, it may benefit from a more comprehensive approach that includes building local biotech capacity.

How do you foresee the impact of increased clinical trials in Saudi Arabia as outlined in the Saudi FDA plan?

The Saudi FDAâ??s plan for 2023-2027 includes a provision for self-evaluation of new technology and biotech products, aiming for full implementation by 2027. This indicates a desire to move towards a more independent evaluation process rather than solely relying on external assessments.

While this goal sounds promising, itâ??s essential to consider historical precedents and current practices in the region. Many companies, including major players like Elanco, have significant ownership ties to entities in the Middle East. However, despite this financial investment, there is often a lack of strategic alignment and operational presence in the region. For instance, these companies may not have offices or conduct clinical trials locally, despite having substantial ownership stakes.

This disconnect between financial investment and operational strategy highlights a crucial gap that needs to be addressed. While there may be monetary resources available, there is often a disconnect in translating this investment into tangible strategic initiatives that benefit the region. For example, while companies may focus their clinical development efforts in markets like the US, China, and Europe, there is a missed opportunity to leverage Saudi Arabiaâ??s growing prominence as a clinical trial destination.

To fully capitalize on Saudi Arabiaâ??s potential as a hub for clinical trials, there needs to be alignment between scientific, strategic, and investment objectives. Companies must develop

comprehensive strategies that consider the unique opportunities and challenges present in the region. By aligning these elements and fostering collaboration between stakeholders, the vision of Saudi Arabia as a leading destination for clinical research can be realized.

In reality, this move is likely to increase the number of clinical trials conducted in the country. However, there are two critical considerations to address. Firstly, thereâ??s the need to accurately assess the potential opportunities available. Secondly, thereâ??s the readiness of the country to transition from conducting a limited number of trials to a significantly higher volume. Itâ??s crucial to acknowledge that such a transformation carries inherent risks, particularly in maintaining quality standards. Therefore, any expansion efforts should be accompanied by investments in infrastructure and capacity-building initiatives. Just as with vaccine production, having the vaccines is one thing, but having the necessary manufacturing facilities is equally vital. Similarly, understanding the need to scale up clinical trials must be met with the development of hospital networks and specialized centers of excellence for various diseases.

What projects are you excited about for 2024, particularly in the region and specifically in Saudi Arabia?

Our focus now is to engage in phase one clinical trials in Saudi Arabia, bringing full clinical development from the outset. Our hope is to receive support from regulatory authorities in Saudi Arabia by issuing guidance on adapting regulatory processes based on local data generation. This would streamline the process for biotechs to conduct trials in Saudi Arabia, providing clear incentives for them to do so. Weâ??re looking for answers from regulators on why biotechs should conduct trials in Saudi Arabia, similar to the incentives offered in countries like Australia and Ireland, such as tax advantages. Additionally, weâ??re seeking a direct-to-market strategy, allowing products to be evaluated and registered based on local data, independent of US FDA approvals.

Saudi Arabia stands out in the region as having all the necessary components for clinical trials, but whatâ??s needed is a well-structured framework to attract stakeholders. We aim to piece together these elements in an attractive manner to encourage participation.

Do you have any final message or closing thoughts youâ??d like to share with regard to clinical trials and patient care in the region?

At PDC, our commitment t0 finding effective treatments for patients across the region remains unwavering. We believe clinical trials should always be considered as a viable option to enhance treatment options. Itâ??s crucial to make this option more visible globally and to advance the clinical trial landscape to showcase the potential of the country.

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