Walid Abbas Zaher – CEO & Co-Founder, Carexso FZ LLC

Our goal is to catalyse the growth of local R&D, nurturing talent and supporting the entire clinical research landscape's development

26.06.2024

Tags: Saudi Arabia, MEA, Carexso, Clinical Trials, SMO, CRO

Dr Walid Abbas Zaher highlights Saudi clinical trial Site Management Organisation (SMO) Carexso's focus on addressing unmet needs in health economics, drug reinvestment modelling, and developing local talent. He emphasizes the importance of regional expertise and collaborations to advance R&D and envisions a robust local R&D ecosystem driven by competition and innovation.

How does Carexso address unmet needs in healthcare, and what specific services do you offer?

Carexso was founded to address significant unmet needs, particularly in health economics and drug reinvestment modeling. While many Clinical Research Organisations (CROs) and companies offer Research & Development (R&D) support services, few specialise in these critical areas, with most being international firms. We identified the complexities involved in getting drugs approved in countries like Saudi Arabia and the UAE, where navigating unique regulations and mandates for introducing biosimilars and other drugs is essential.

Carexso acts as a crucial bridge between pharmaceutical companies and regulators, facilitating the registration of new drugs and ensuring patient access. We serve the interests of drug companies by assisting in regional pricing adjustments and collaborate closely with regulators to evaluate and approve drugs according to local standards and needs. Our comprehensive services encompass health economics and drug reinvestment modelling, involving detailed market analyses, advocacy

for specific drugs to regulatory bodies, and negotiation of optimal introduction mechanisms.

In addition, we have a dedicated focus on rare diseases, partnering with regulators to develop disease registry models and establish databases for prevalent rare diseases in the region. This initiative enhances companies' understanding of these diseases, leading to the development of more effective treatments.

Carexso's mission is to foster collaboration and innovation in healthcare by bridging regulatory gaps and ensuring that patients benefit from timely access to innovative therapies.

Moreover, we provide comprehensive Site Management Organisation (SMO) services, boasting exclusive and non-exclusive partnerships with esteemed hospitals in the UAE and Saudi Arabia, such as Burjeel Holding and Abu Dhabi Health Services Company PJSC (SEHA). Our scope encompasses overseeing research initiatives within these institutions, encompassing real-world evidence generation, meticulous data management, and proficient clinical trial oversight.

Additionally, our consultancy services cater to health-related initiatives, including pivotal involvements for Saudi's Two Biggest National Program, although official announcements are pending. Our adept team of specialists also formulates strategic frameworks for significant national health endeavours spanning across the UAE, Saudi Arabia, and Bahrain.

How does Carexso manage clinical trials, and at what stages are these trials conducted?

As a Site Management Organisation (SMO), we don't initiate clinical trials ourselves. The negotiation and setup of clinical trials are typically managed by the Clinical Research Organisation (CRO) and the sponsor in collaboration with hospitals, a process in which we are not directly involved. Our role begins once hospitals are identified and fall under our exclusive or non-exclusive agreements. For example, if a CRO wishes to conduct trials in collaboration with hospitals, we serve as their research partner, facilitating their activities through our SMO platform. Essentially, we complement the CRO's efforts, stepping in after contract negotiations and initial setup are completed.

Regarding the stages of clinical trials, the landscape varies by location. In the UAE, there is a notable concentration of phase 1 and phase 2 trials. In contrast, Saudi Arabia predominantly engages in more advanced trials, typically phase 2B and phase 3 studies.

What are the regulatory challenges in the region for clinical trials, and what are your hopes for the future?

The regulatory landscape in Saudi Arabia, UAE and Bahrain has evolved significantly in recent years. Historically, one of the foremost challenges in clinical trials was the lengthy approval process. However, there has been a remarkable improvement in turnaround times, with these countries issuing decisions much more swiftly. A decade ago, the necessity for dedicated regulatory bodies similar to The European Commission, the European Medicines Agency (EMA) and the United States of America (USA) Food and Drug Administration (FDA) was not yet apparent in this region. Today, Saudi Arabia boasts its own Food and Drug Authority (SFDA), Bahrain operates under the National Health Regulatory Authority (NHRA), and the UAE has established the Emirates Drug Corporation (EDC).

These advancements have greatly enhanced the clinical trial environment. Previously, phase 1 clinical trials faced reluctance across the region. Since approximately 2015, there has been a positive shift, with both the Saudi Arabia and UAE increasingly accepting phase 1 and phase 2 trials. The entire ecosystem continues to progress, and we anticipate it will mature further in the coming years.

Our overarching aim is to see a unified regulatory framework across all GCC countries, similar to the EMA or FDA. Such a framework would simplify the clinical trial process by providing a single entity for approvals throughout the region. While this goal may still be on the horizon, the substantial progress witnessed thus far inspires confidence in a future marked by greater efficiency and coherence.

What is CAREXSO’s approach to partnerships, and what are the objectives behind these collaborations?

Carexso transcends its role as a Site Management Organisation (SMO) or consultancy by aiming to comprehensively support every facet of pharmaceutical Research and Development (R&D). Our strategy involves forging Memorandums of Understanding (MOUs) and strategic collaborations with partners dedicated to advancing the R&D landscape in the region.

For instance, Carexso have established a strategic partnership with Saudi Vax, a prominent entity in Saudi Arabia specialising in localising vaccine R&D efforts. In this collaboration, we provide targeted support in various R&D domains, leveraging our specialised knowledge and capabilities.

Additionally, Carexso collaborate closely with clinicians to develop disease registries tailored to local needs, aligning these efforts with regulatory requirements for enhanced data localiaation.

Recently, we formalised an agreement with a rare disease-focused Research and Pharmaceutical company based in the United States. This partnership aims to localise R&D initiatives within the region, specifically targeting treatments for rare diseases prevalent in the Middle East. This collaborative approach seeks to engage with organisations committed to advancing R&D within the GCC and broader Middle East, fostering a robust development ecosystem.

Our overarching goal is to shift from a model-centered on external drug development and importation towards integrating significant parts of the R&D cycle. By focusing on localisation and collaboration, Carexso strives to enhance the sustainability and innovation of pharmaceutical R&D in the region.

Are local and regional conditions conducive to investment in the R&D ecosystem, and is the system rewarding for participants in clinical trials?

Absolutely, local and regional conditions are becoming increasingly favorable for investment in the R&D ecosystem. The most mature aspect of our ecosystem is the quality of our Principal Investigators (PIs). Many of them are highly trained and certified, often having received their education on prestigious Medical University, where R&D is a fundamental part of medical training. These PIs return to the region with strong research expertise and continue to engage in research alongside their medical practice, making them valuable asset.

Moreover, the current system adheres to global Good Clinical Practice (GCP) guidelines. By following GCP guidelines, we ensure that PIs are properly rewarded for their participation in clinical trials. This compliance not only supports the PIs but also fosters a robust and reliable R&D environment, making the region increasingly attractive for investment.

What are the positives and challenges of clinical research in Saudi Arabia?

Saudi Arabia boasts one of the best healthcare systems in the region, with highly trained physicians, excellent mental health services, and well-equipped hospitals and infrastructure. These factors position Saudi Arabia to lead the region in clinical trials. However, there are historical challenges. Traditionally, the region has not been heavily involved in R&D, primarily focusing on

importing drugs rather than developing them. With initiatives like Saudi Vision 2030, there is a significant push to incentivise companies, regulators, and business owners to invest in R&D. The goal is to shift from merely producing oil to also producing drugs, which leads to drug security, and generating data, which is crucial for future advancements in medicine.

The main challenge is building an R&D ecosystem from the ground up. This involves establishing effective communication and collaboration between regulators, operators, private businesses, pharmaceutical companies, sponsors, and biotech firms. While some elements are still being developed, the strong initiatives and substantial budgets from countries like Saudi Arabia, UAE, and Qatar are driving progress. Despite these challenges, the region is well-positioned to become a global pioneer in the field of clinical research.

What distinguishes Carexso from its international competitors, and why should potential partners choose Carexso?

International companies bring a wealth of experience, proven track records, and extensive expertise that enable them to execute projects at a high standard. However, in some cases the approach can sometimes lack deep regional knowledge, even with a local presence. Often, their problem-solving strategies are based on global experiences, applying standardised approaches or one-size-fits-all strategy that may not always be suitable for our specific region. For instance, in genomics consultation projects, these companies typically offer global insights and historical data, but few possess the specialised regional expertise and connections to local key opinion leaders.

While international firms have access to regional data, they may not always optimise its full potential. Their tendency to benchmark international projects to this region may not yield the most effective outcomes. The optimal approach involves tailoring projects specifically to this region’s unique needs, leveraging insights from local experts. In my experience, international companies often bring in experts from the U.S., France, or the U.K., who are undoubtedly skilled but may not grasp the intricate nuances of this region.

This is where Carexso distinguishes itself. We specialise in providing a critical edge of regional knowledge, delivering solutions meticulously tailored to the distinctive requirements and dynamics of the region.

What is your assessment of the current availability of local skills in the clinical research field in Saudi Arabia?

Most of our employees in Saudi Arabia, as well as in other countries where we operate, are locals. We are committed to training these individuals, helping them advance in their careers, and eventually becoming leaders who can mentor others. This “train the trainer” approach is central to our mission. As a Saudi myself, I can confidently say there is no lack of talent here. Many fresh graduates are now eager to enter the R&D field, which is a relatively new trend. Historically, graduates with pharmacy backgrounds would work in pharmacies, and medical graduates would work in hospitals. Now, more are choosing to pursue R&D, which is a significant positive shift.

Local companies play a crucial role in this transformation. Ten years ago, there were very few local companies involved in R&D, but now, thanks to government initiatives, they are flourishing. These companies hire and train local talent, contributing to the growth of the R&D ecosystem. While there is still a gap in local skills, it has significantly decreased over the past few decades. When I transitioned from clinical practice to R&D in the 1990s, I was one of the few in the entire country doing so. Today, many are choosing R&D as a full-time career or alongside their clinical practice. The availability of programs and opportunities has grown tremendously, and I am pleased to see the substantial progress made in the past 25 to 30 years. We now have a much more robust and developed ecosystem for clinical research in Saudi Arabia.

What are your ambitions for Carexso in the next few years, both for the company and as a catalyst for the entire clinical research landscape?

In the coming years, I envision Carexso as a pivotal force in establishing a robust R&D ecosystem in the region. Our mission is to lead local R&D initiatives and integrate them deeply into our operations. While our approach may be familiar internationally, it represents groundbreaking progress for this region. I anticipate the emergence of more companies like Carexso, fostering healthy competition that drives local R&D forward. This competitive environment will stimulate innovation and ensure that R&D activities grow organically within the region, establishing a sustainable ecosystem.

Our goal is to catalyse the expansion of local R&D, nurturing talent and supporting the comprehensive development of the clinical research landscape.

See more interviews