

**Opinion**

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Accelerating Clinical Trial Trajectory in Saudi Arabia: A Strategic Perspective

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The global clinical trials market, valued at approximately USD 88 billion, is projected to reach USD 115 billion by 2030, with a steady CAGR of 6.10% [1]. Amidst this dynamic landscape, the Kingdom of Saudi Arabia (KSA) currently holds a modest 0.035% market share but is ambitiously aiming to capture 1% of the global market. This strategic pursuit promises significant economic and healthcare advancements. Achieving a 1% market share is more than just a numerical target; it signifies a transformative leap for the Kingdom's healthcare sector and its broader economy. By 2030, this growth is expected to generate over 400 high-skilled jobs and 5,000 indirect jobs, benefiting more than 10,000 patients through cutting-edge clinical trials. These developments highlight Saudi Arabia's commitment to fostering innovation and excellence in healthcare. Guided by the visionary leadership of HRH Prince Mohammed bin Salman, Chairman of the Supreme Committee for Research and Innovation, Saudi Arabia is diligently building a robust clinical trials ecosystem. The Saudi National Institute of Health (SNIH) and the Saudi Food and Drug Authority (SFDA) are playing pivotal roles in providing the essential support and regulatory framework to drive sectoral growth.

To achieve this ambitious goal, Saudi Arabia must establish dozens, if not hundreds, of clinical trial sites within governmental and private health networks across the Kingdom. The most effective and expeditious way to accomplish this is by adopting the site management organization (SMO) model. This model necessitates a shift from mere aspirations to engaging seasoned professionals equipped with the expertise to manage and operate

these sites efficiently. An ultra-operational model that emphasizes outsourcing, characterized by specialized expertise and impactful capabilities, is essential for success. By implementing an outsourcing framework specifically tailored to the Kingdom's unique requirements—such as the globally recognized SMO model—efficiency can be significantly enhanced, and operational burdens on local institutions can be alleviated. The SMO model provides flexibility, offering both comprehensive and targeted approaches to clinical trial management. This adaptability aligns with proven international practices, facilitating the overcoming of existing barriers and accelerating overall progress [2].

The SMO model offers significant advantages in enhancing the efficiency and effectiveness of clinical trials. One of the primary benefits is the specialization and focus that SMOs bring to trial management. By employing experienced clinical research professionals, SMOs can streamline operations, leading to faster patient recruitment and adherence to regulatory compliance. This expertise ensures the trials are conducted in accordance with local and international requirements, minimizing the risk of regulatory issues. Additionally, SMOs provide cost-effective solutions by reducing overhead expenses related to staffing, training, and maintaining research facilities, making it a financially attractive option for sponsors [2].

Moreover, the SMO model is highly scalable, allowing for rapid expansion of operations to meet the demands of sponsors, whether it's increasing the number of sites or boosting patient recruitment. SMOs' established networks and relationships with healthcare

providers enhance patient recruitment and retention strategies, ensuring a steady flow of participants. Quality assurance is another key advantage, as SMOs implement standardized procedures and quality control measures that ensure the consistency and reliability of trial data across multiple sites. The flexibility offered by SMOs allows sponsors to select specific services tailored to their needs, whether they require comprehensive management or focus on specific tasks like data management. These attributes make SMOs an essential partner for pharmaceutical companies and Contract Research Organizations (CROs) aiming to optimize their clinical trial efforts. In conclusion, achieving a 1% market share in the global clinical trials market is not just ambitious but nearly unattainable without incorporating the SMO model. The SMO model is a critical component in streamlining operations, ensuring regulatory compliance, and enhancing patient recruitment and retention,

especially with newly established, inexperienced sites. The current capabilities and lack of expertise in the region necessitate the utilization of the SMO model to overcome inefficiencies and regulatory hurdles that could hinder progress.

This raises an important question: Do we have adequate local or regional SMOs to support this endeavor, or must we rely on international organizations to fill the gap? The answer will shape the Kingdom's strategy and capacity to transform its clinical trial landscape effectively.

References

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