

30
YEARS OF
EXCELLENCE

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GROUP



Kingdom of Saudi Arabia
Saudi Food & Drug Authority

Advancing Health Care Innovation

Clinical Trials, Drug
Evaluation and Medical
Device Success Stories in
Saudi Arabia



Clinical Trials, Drug Evaluation and Medical Device Success Stories in Saudi Arabia

Saudi Arabia is rapidly emerging as a regional leader in health care innovation, with significant advancements in clinical trials, alongside drug and medical device development and evaluation.

The Saudi Food and Drug Authority (SFDA) has been instrumental in driving this

progress through strategic regulatory reforms, digital transformation, and international collaborations. These efforts are enhancing patient access to cutting-edge therapies while also positioning the Kingdom as a hub for medical research and technological innovation in line with Vision 2030.



Digital Transformation in Clinical Trials

A cornerstone of Saudi Arabia's clinical research advancement is the upgrading of an electronic clinical studies submission system. This innovative platform, set for launch this year, will automate the entire clinical trial lifecycle – from registration and evaluation to monitoring and inspection. Also, it would have the ability to be integrated with key government systems such as the Saudi National Institute of Health and the National Bioethics Committee, the system promises to streamline operations, reduce administrative burdens and improve the overall client experience. Its comprehensive coverage of all study phases, coupled with electronic archiving capabilities, ensures that Saudi Arabia remains at the forefront of digital regulatory innovation.

The SFDA has also prioritised the localisation of clinical studies through strategic memoranda of understanding with hospitals and research centres across the Kingdom. Announced in October 2024, this initiative aims to increase local participation in clinical research, bolster investment in infrastructure and enhance the quality of life by facilitating access to advanced medical treatments. The results are already evident, with a %40 increase in clinical studies in 2024 alone, including the evaluation of 51 early-phase trials and 1,497 study-related transactions.



Strengthening Regulatory Excellence

Quality assurance remains a key focus, as demonstrated by the SFDA's rigorous Good Clinical Practice (GCP) inspections. In 2024, 26 inspections were conducted across clinical study sites, bioequivalence centres and monitoring facilities. A recent study published in Therapeutic Innovation & Regulatory Science analysed these inspections, identifying common deficiencies and recommending tailored action plans for different organisational types. This research underscores the SFDA's commitment to continuous improvement and adherence to international standards.

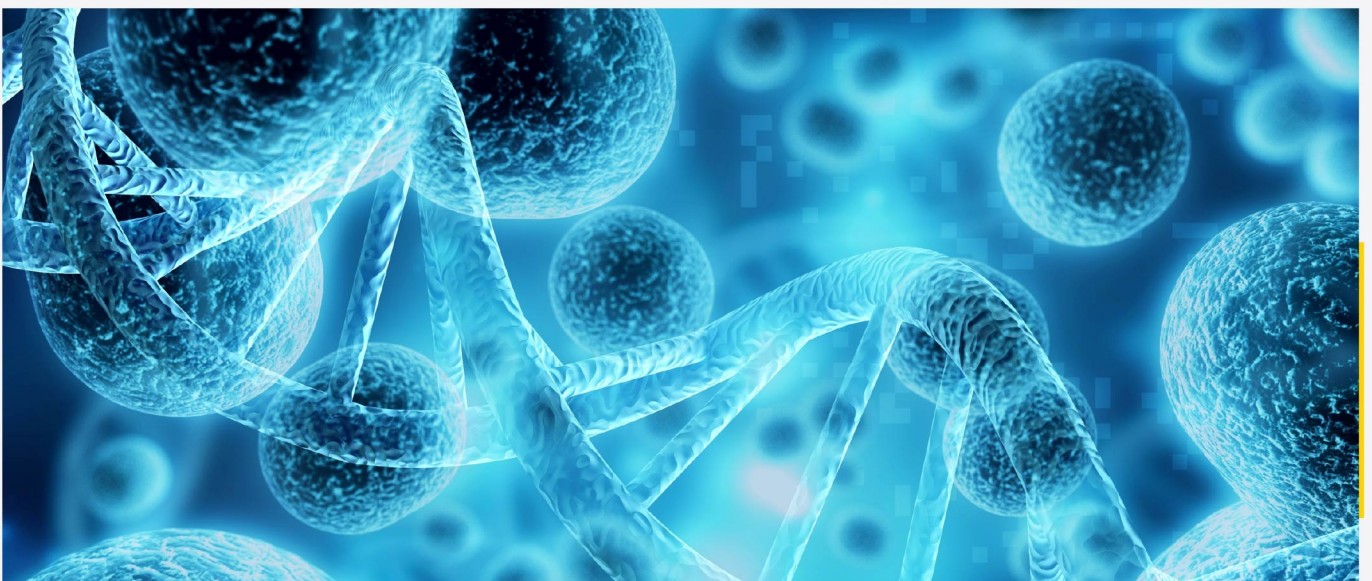
Training and capacity building have been equally prioritised. The SFDA has rolled out extensive GCP training programmes for researchers and health care professionals, alongside a nationwide awareness campaign to promote clinical research participation. Collaborative workshops with the International Council for Harmonisation (ICH) have further strengthened regulatory expertise, ensuring that Saudi Arabia remains aligned with global best practices.

Pioneering Gene and Cell Therapy Trials

Saudi Arabia's clinical trial landscape has seen remarkable breakthroughs in advanced therapies, particularly in gene and cell therapy. The approval of 10 genetic and cellular therapy studies since 2020 highlights the Kingdom's growing expertise in this transformative field. Among the most notable trials is the 2022 Zolgensma® study for spinal muscular atrophy, a groundbreaking gene therapy administered as a one-time infusion. Similarly, the 2024 Casgevy® trial – utilising

CRISPR-Cas9 gene editing for sickle cell disease and beta-thalassemia – represents a major leap forward in treating genetic disorders prevalent in the region.

Another significant development is the Hemgenix® study, evaluating a gene therapy for haemophilia B. With Saudi Arabia participating alongside global sites, this trial exemplifies the Kingdom's integration into international research networks while addressing local health care needs.




Medical Devices: A Surge in Innovation



The medical device sector has witnessed equally impressive growth, with the SFDA approving 149 clinical trials till the end of 2024. These span a diverse range of technologies, from implantable devices to artificial intelligence (AI)-driven diagnostics. Digital health has emerged as a particularly dynamic area, with trials such as the Dose Check app for diabetes management showcasing the potential of digital therapeutics in

chronic disease care.

AI is playing an increasingly pivotal role, as seen in the approval of AI-powered diagnostic tools like INOVA for diabetic retinopathy and Cardio-iSelfie for remote vital sign monitoring. Meanwhile, neurorehabilitation trials, including virtual reality mirror therapy and transcranial stimulation, are positioning Saudi Arabia as a leader in neurotechnology innovation.



Collaborative Leadership and Future Outlook

Saudi Arabia's progress is underpinned by robust collaborations, both domestically and internationally. The SFDA's active participation in ICH working groups, alongside engagements with the European Medicines Agency and the GCC Health Council, reflects its commitment to global regulatory harmonisation. Locally, partnerships with academic institutions such as King Saud University and King Faisal Specialist Hospital are driving research excellence.

Looking ahead, the SFDA plans to launch a national electronic registry for clinical trials and further streamline regulatory pathways to accelerate innovation. These initiatives, combined with Saudi Arabia's strategic investments in research infrastructure, signal a transformative era in health care—one in which the Kingdom transitions from a consumer of global medical technologies to a leading innovator.

Conclusion

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