

# Saudi FDA Advances Healthcare Innovation Through Clinical Trials and Gene Therapy

*Saudi FDA continues to drive healthcare innovation across Saudi Arabia through advancing clinical trials, and evaluating gene and cell therapies.*

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/EINPresswire.com/ -- The Saudi Food and Drug Authority (SFDA) continues to drive healthcare innovation across the Kingdom of Saudi Arabia. It's doing this through a series of regulatory and technological initiatives, including advancing clinical trials, evaluating gene and cell therapies, and approving innovative medical devices. These efforts aim to enhance patient access to advanced medical technologies and position the Kingdom as a regional hub for research and innovation, aligning with Saudi Vision 2030.

The SFDA is developing an integrated electronic system to automate clinical trial submissions, enhancing efficiency and user experience by interoperating with national entities like the Saudi National Institute of Health (Saudi NIH) and the National Bioethics Committee. To localize research, SFDA signed MoUs with hospitals and research centers, leading to a 40% increase in clinical trials in 2024.

The SFDA also conducts inspection visits to clinical trial sites, bioequivalence centers, and monitoring facilities to ensure adherence to Good Clinical Practice (GCP) standards. To further foster a research-oriented culture, the SFDA launched specialized training programs for researchers and healthcare professionals.

Since 2020, Saudi Arabia has seen significant growth in gene and cell therapy research. The SFDA has approved 10 clinical trials, including groundbreaking therapies like Zolgensma® for spinal muscular atrophy, Casgevy® for sickle cell disease, and participation in the Hemgenix® trial for Hemophilia B.

By late 2024, the SFDA approved about 149 clinical trials for medical devices, covering diverse



technologies including implantable devices and AI-powered digital tools. Notable innovations include the Dose Check app (diabetes), INOVA (diabetic retinopathy), and Cardio-iSelfie (remote vital signs monitoring).

The SFDA strengthens regulatory integration through partnerships with the Gulf Health Council, ICH, and European Medicines Agency, alongside agreements with leading Saudi institutions. Looking ahead, SFDA plans to launch a national electronic registry for clinical trials, further enhancing research infrastructure and supporting the Kingdom's healthcare ambitions.

Read More: [<https://www.sfda.gov.sa/en/node/3936881>]

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