

High Standard Clinical trials to pave the way to localisation of Biotech/Pharma : Strategic Industrial pillar for KSA

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10th Annual Forum for Medical research
Improving Healthcare through High Standard Clinical Trials



THE IMPORTANCE OF CLINICAL TRIALS FOR SAUDI HEALTHCARE

Experts at the forum stressed the importance of clinical trials for better healthcare and for localizing the biopharmaceutical industries

KAIMRC has been spearheading an initiative to develop clinical trials for the past three years, an effort that culminated in the official launch of the National Command Center for Clinical Trials (NCCCT) last April. The center's mission is to advance the clinical trial ecosystem in the kingdom, develop clinical research talents, and attract international experts.

With that strategic priority in mind, and in line with the Saudi Vision 2030, which focuses on diversifying the Saudi economy through a special focus on research and development, this year's forum shed light on how clinical trials are the pathway for better healthcare, developing

treatment that is specific to the needs of the Saudi population's genetics and needs. "This year's forum will focus on clinical trials," said Ahmed Alaskar, executive director of KAIMRC. "We have exerted a lot of effort to develop clinical trials and execute Vision 2030. We have collaborated with various institutions that led to several memoranda of understanding locally and internationally."

Clinical trials can address needs endemic to the population. A streamlined clinical trials framework and infrastructure could also attract biotechnological and biopharmaceutical companies to the kingdom, localizing drug manufacturing, and advancing the economy.

"The importance of clinical trials is that it is key to transfer research findings to benefit humans, and the development of the NCCCT is the crown on the kingdom's efforts to develop its pharmaceutical industry," Alaskar said. "We're aiming to reach 10,000 patients within the next 10 years to provide them with free, new treatments that wouldn't reach the market for another 10 years. We're looking to generate 5,000 new jobs, and increase clinical trials from six trials per 1,000 doctors, to 100 trials."

Currently, Saudi Arabia holds 15 trials per million people, compared with 341 in the US. Alaskar explained that his centre is spearheading the initiative to increase that figure and capture more than the current 1% of the \$1.5 billion annual pharmaceutical investments in clinical trials.

The kingdom has already seen an upward curve in the number of trials held over the past few years, but they are mostly academically driven trials. There is still a lack of trials held in areas of relevance to the Saudi context and the regional disease ecosystems, said Ali Alessandro Ayach, senior director of GE Healthcare.

The need to up the clinical trial game

"Clinical trials are essential to translate research findings to treatments that benefit people," said Bandar Al Knawy, CEO of the Ministry of National Guard Health Affairs and president of the KSAU-HS, during his opening remarks. "Through the clinical trials initiative [spearheaded



by KAIMRC through the National Command Center for Clinical Trials] we aim to reach 10,000 patients during the next five to seven years, and create more than 4,000 new jobs, as well as generate revenues worth 4 billion Saudi riyals annually.”

Alaskar added that while Saudi Arabia has a significant population size, a high physician-to-patient ratio, and excellent healthcare infrastructure, clinical research still lags other countries with similar economies.

The Saudi population, as any other population, has its own genetic characteristics and common diseases, such as diabetes and cardiovascular diseases. To offer the latest, most relevant and effective treatments, the kingdom needs to move into an era of translational research, taking lab research to in-human clinical trials.

Speakers discussed the importance of a tailor-made approach to clinical practice, and the key role clinical trials play in implementing this approach. “One size does not fit all,” said Adeel Chaudhary, professor of human molecular biology at King Abdulaziz University (KAU). “We need to increase clinical trials to increase the safety and efficacy of drugs.”


Localizing pharma


Investing in research and development (R&D) is essential to the kingdom’s short-term plan. “There are more than 178 strategic objectives in the Saudi Vision


2030,” said Ayach. “More than 10% of these objectives are related to R&D.” An essential component of this is developing the biopharma and biotech industries in the kingdom, supporting local companies


 Saudi Arabia consumes **0.5%** of the global pharmaceuticals market, but contributes only **0.02%**

 KSA holds **15** trials per million of the population, compared to **341** in the US

 Multi-site clinical trials form only **8%** of the trials held in KSA, while single sites form **46%** and multi-site and international trials form **46%**

 KSA aims to increase the number of clinical trials from the current six per **1,000** doctors to **100**

 KSA has **825** patients for each trial, the number is **28** in the US, which makes recruitment easier

 Current time needed to execute clinical trial is now between **270-365** days, the accepted time frame for execution is **151** days

and attracting international ones.

Saudi Arabia is attractive to pharmaceutical companies due to its population, as well as the potential it holds. Christian Fassotte, global chief medical officer of AB-Science, explains that Saudi Arabia scores well on various aspects considered by pharma countries, including demographic trends, the nature of the healthcare infrastructure, economic cycles, patient and disease characteristics and socioeconomic factors. “The ground is set, and you have lots of areas you can fertilize,” he said.

Fassotte added that the key to attracting biotech and pharmaceutical companies is to focus on specific research areas that are significant to Saudi Arabia. There are, for instance, specificities in diabetes and other diseases that are specific to each country, and epidemiological trials, for example, to observe and document needs are very important. “Selectivity is the keyword in terms of focus, disease characteristics, patients, and you can’t do everything. Match clinical trial ambitions with specific situation,” he said.

Streamlining the clinical trials regulatory framework and processes can attract the big players of the industry. Saudi Arabia has a strong network of hospitals, and the Ministry of National Guard-Health Affairs has some of the strongest hospitals and research centres in the kingdom, which means that it has access to a network of patient databases and a goldmine of potential trial participants. It has already led a nation-wide initiative to consolidate patients’ databases, and has launched several other initiatives to facilitate clinical research, including KAIMRC’s stem cell registry and biobank, which is attractive to pharmaceutical companies, if the framework is properly set up.

While most of the progress in trials has been on the academic side, patents and commercialization still lags. “At the core of the model is commercialization, marketing and operational excellence to strengthen clinical trials system in the kingdom,” said Ayach. “We need to bring the entrepreneurial concept at the beginning of each clinical trial to make sure the project can be commercialized to a certain extent and the funding process would go in parallel.” ■