



Putting Saudi Arabia on the clinical trial map

KAIMRC's new initiative stands to kickstart Saudi Arabia's clinical trials economy, and find treatments for its people.

Clinical trials are a cornerstone of medical R&D, a wellspring of jobs, revenues and a way to provide more cutting-edge treatments to patients in desperate need. Yet, despite a population of nearly 33 million and an array of excellent research centres that attract academics from across the globe, Saudi Arabia doesn't conduct nearly enough clinical trials. This represents a huge gap in the country's burgeoning research portfolio, and a challenge that KAIMRC is rising to meet with its initiative: the Saudi Network for Clinical Trials

(SNCT). Through increasing clinical trials around the country, researchers can also develop medicine for the specific genome of the Saudi population.

The SNCT aims to increase the quality and quantity of clinical trials conducted within Saudi Arabia through two main projects; one aimed to develop the kingdom's legal and regulatory framework to lessen the bureaucracy, and the other to train and retain the necessary talents.

The SNCT prioritizes attracting and maintaining clinical trials expertise within the country through a training

programme and by bringing international experts to educate current and future Saudi clinical research personnel, says the project's lead, Shuruq Al Yousef.

The centre also wishes to transform the regulatory environment within Saudi Arabia to make the country an attractive destination for national and international partners. In trying to achieve this, the initiative also finds its greatest challenge: Clinical trials are very time-sensitive, and the biopharma industry will use locations which are best suited to the fast pace of trials. "It's not open-ended," says Abdelali Haoudi, KAIMRC's head of strategy and business development. "We can't just wait six, 12 or 18 months for a decision to be made — we won't succeed unless our national framework adapts." On this issue, KAIMRC is working collaboratively with the Saudi Food and Drug Authority, in efforts to foster understanding and raise interest in clinical trials.

It's envisaged that by laying the two foundations of skill development and regulatory amenability, Saudi Arabia can start to transform its clinical trials ecosystem. The team behind the initiative also hopes the SNCT can become a regional hub for drugs and therapies, and a coordinating centre for clinical trials.

Laying the foundations

KAIMRC is working to further clinical research by giving scientists more time. "Clinicians are known to be extremely busy, and allocating time for their patients is their number one priority," says Haoudi, before explaining that some countries in Europe and North America designate protected time for clinicians so that they can afford to focus on research. "Unless we can provide that same opportunity here, they'll never find the time to lead clinical trials," he says.

To try to mitigate, KAIMRC is pushing more funding towards clinicians, to reduce the time sink of applying for grants. This effort is already underway and making an impact: in September 2018, researchers funded by KAIMRC unveiled a wealth of new data on the prevalence of cancer-affiliated BRCA1/2 mutations in high-risk Saudi patients

with breast cancer.

Haoudi wanted to make better use of KAIMRC's experience, and help develop clinical trials across the kingdom. "I started thinking about taking a clinical trials initiative to a national level about two years ago," recalls Haoudi. Noting the progress his own institution had taken in maintaining its own clinical trials, and their benefit to health-care and the economy, Haoudi realized "that the resources of only one institution aren't going to be enough."

Over about 15 months where Haoudi, Al Yousef and their team formulated a plan to take to the government. Their efforts paid off when the initiative was funded with SAR 55 million (more than \$14.6 million) and was earmarked as one of the country's top initiatives by Khalid al-Falih, the minister of Energy, Industry and Mineral Resources. Then in January 2019, the Crown Prince of Saudi Arabia, Mohammed bin Salman bin Abdulaziz Al Saud, announced the formation of the SNCT and signed a memorandum of understanding in support of the project.

Cross-border collaboration

The KAIMRC team is drawing inspiration and guidance from the clinical research success story of South Korea. In less than 10 years South Korea has transformed its unexceptional clinical trials profile into that of a world leader, explains Haoudi. KoNECT (the Korea National Enterprise for Clinical Trials) is now a close partner to the KAIMRC initiative, with the SNCT's creators hoping that they can replicate South Korea's exceptional growth in their own country. The architects of the Saudi-South Korea partnership hope their work will also deepen ties between the two countries.

Following meetings in both South Korea and Saudi Arabia, representatives from both organizations signed an agreement in 2017 to jointly explore avenues of innovation in medical R&D. Now, they're on the cusp of finalizing a new agreement to implement training courses for Saudi researchers. "I imagine there will be many more such agreements in the future," says Al Yousef. Haoudi adds that "they'll be our partner throughout

this whole initiative...We can learn from their success and hopefully improve our own practices here." Following the signing of the agreement in June 2019, the SNCT hopes to formally start its activities in September.

Houdi believes that a few main factors make KAIMRC the right institution to spearhead the country's new clinical trials programme. "We conduct the largest

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number of clinical trials in the country as an institution, averaging 70 per year," he says, adding that KAIMRC's sites spread around the country extends the institution's reach to "the entire Saudi population." In addition, KAIMRC already has its own clinical research organization (CRO), which brings with it key insights and experience to the business side of clinical research operations. The research centre's deep ties with government and academia offer the support for many leading

institutions across the country, including the Saudi Health Council, King Faisal Specialist Hospital and Research Center, King Abdulaziz University, and Princess Nourah bint Abdulrahman University. KAIMRC is also the only institution in Saudi Arabia constructing a Phase I clinical trials centre. "Phase I is the fundamental stage in clinical trials, and a good indicator of an institution's capacity for innovation in medical R&D," says Haoudi.

As well the huge revenue potential of the SNCT and the boost to Saudi clinical trials it stands to offer, the initiative also provides direct support to the goal of Saudi Vision 2030

Perhaps the biggest benefactors of the SNCT, however, will be Saudi patients. With the current lack of high-quality clinical trials in the country, there remains a largely-underexploited opportunity to tailor treatments to conditions arising from Saudi-specific genetics. An investment in Saudi clinical trials will inevitably lead to new treatments and interventions able to transform the lives of Saudi citizens. There's a long road ahead before this goal is realized, but KAIMRC is making daily progress. "Hopefully, this will set up the ecosystem that leads to facilitating local industrial drug development, manufacturing, and commercialization," says Haoudi. "One step at a time."

