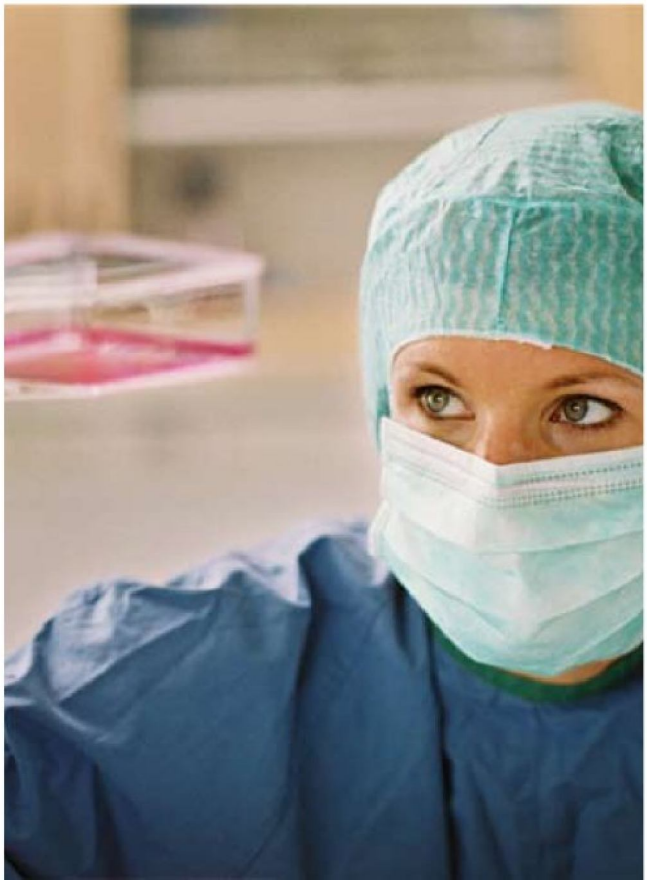
Clinical Research in Saudi Arabia: Central, Comprehensive and Well-Managed

Clinical research settings in the Kingdom of Saudi Arabia were controlled mainly by the National Bioethics Committee acting as a cornerstone in Saudi research; it is a central approving committee for other local committees. Major bioethics debates are taking place through the National Bioethics Committee, such as stem cell research, genetic research and the Islamic opinion of different types of research.

Although the National Bioethics Committee has invested massive efforts in organising the clinical research process in the Kingdom, there are still corners where clinical research is not fully managed; a good example of this is when you ask a major Saudi healthcare official; to which authority serious adverse events should be reported in Saudi Arabia. His answer will be not to a definite authority or committee. This forms a big ethical issue in clinical research, where any serious adverse event can occur without alarming other countries or research centres of that event, leaving a high probability that this adverse event will occur again elsewhere. Serious adverse events might not be the Saudi investigators' fault, however not reporting it is a major violation of bioethics and of all international clinical research standards.



One more area that needs to be managed in clinical research in Saudi Arabia is the import and export of investigational products and biological samples. Researchers used to import and export these products through major hospitals in the Kingdom where they can issue orders to Customs to allow specific samples or products in or out. This case is not applicable any more, thanks to the Saudi Food and Drug Administration who are managing almost all aspects of clinical research.

The Saudi FDA is now in charge of reviewing all clinical trials to be conducted in the Kingdom, which will create harmony among clinical research parties by having a guideline for all investigators to follow when they plan to perform a clinical research. Moreover, not only clinical trials will be handled, but also food and drug matters as well. After setting regulatory guidelines, the Saudi FDA role is expected to expand using different mechanisms of implementation, to control all aspects of drug and food safety in the Kingdom. According to the Saudi FDA, their role will be in two phases: "The Authority will commence its assigned tasks in two phases: the first one will last for a period of five years with effect from the date of the resolution of its establishment and considered preparative and inceptive for phase two" whereas the second phase will be composed of monitoring, testing and supervising drug and food matters. Their vision is to "be the leading regional regulatory authority for food, drugs and medical devices with professional and excellent services that contributes to the protection and advancement of the health in Saudi Arabia." (From www.sfda.gov.sa)

The Kingdom has been always in the heart of the Arab world, being a central contributor to the nations' civilisation and scientific progression. Now with the Saudi FDA as a regulating body in Saudi Arabia, we will witness more international pharmaceutical companies' determination to enter the Gulf market for clinical research. And as the Kingdom of Saudi Arabia has been in the past, it will continue to be the centre for clinical research, the largest among all surrounding countries in terms of the number of researches, but now with well-managed food and drug administration.

Dr. Ranya Shahrouri, MBA/HCM, HDVP, DVM
Regulatory Affairs Manager, ClinArt Fz LLC
Email: Ranya.Shahrouri@ClinArt.net