SFDA's New Contract Research Organization Draft Guideline

Saudi Arabia has positioned itself as a hub for healthcare and pharmaceutical companies in the GCC region and in recent years, has been providing further regulatory coverage for companies seeking to conduct clinical trials in Saudi Arabia. The Saudi Food and Drug General Authority ("**SFDA**") has published guidelines on conducting clinical trials in Saudi Arabia – these include the Guideline for Good Clinical Practice, Regulations and Requirements for Conducting Clinical Trials on Drugs, and Guidance for Investors on Licensing Contract Research Organizations ("**CROs**"). The SFDA has recently proposed a new draft guideline, which aims to regulate, support, improve and extend the collaboration between licensed CROs, clinical trials sponsors, and regulators (collectively referred to as "**Parties**"). The guideline aims to minimize gaps between licensed CROs clinical trial sponsors and regulators.

The draft guideline is intended to be read in conjunction with guidelines previously published by the SFDA on clinical trials and has been published by the SFDA on the Saudi Public Consultation Platform (Contract Research Organization Guideline). The draft guideline was subject to a period of public consultation, which ended on 14 March 2022. These guidelines may be subject to amendments and accordingly, we will issue another client alert once the guidelines are formally accepted and published in the Official Gazette.

The guideline outlines the process to submit a Clinical Trials Application. The process differs if such an application is made by a sponsor with a legal entity in Saudi Arabia, or by a sponsor without a legal entity in Saudi Arabia. The guideline also includes recommendations on organizational structure and service requirements for licensed CROs conducting clinical trials in Saudi Arabia. The SFDA encourages and recommends that licensed CROs include departments or individuals that ensure clinical trials are conducted in accordance with relevant regulations.

The guideline provides recommendations for the monitoring of clinical trials, which must be adhered to by licensed CROs and sponsors. These include, but are not limited to, recommendations for monitoring methods, monitoring plans, and the delegation of monitoring responsibilities to a licensed CRO. The SFDA also recommends that Clinical Research Associate ("**CRA**") employees working on clinical trials in Saudi Arabia should be citizens or permanent legal residents of Saudi Arabia, and should be authorized to work in Saudi Arabia, in accordance to local regulations.

The guideline highlights contractual obligations to be observed by Parties engaged in clinical trial activities in Saudi Arabia. All clinical trial and associated agreements must be submitted to the SFDA, in both Arabic and English. The terms and conditions governing these agreements must be in compliance with the Saudi Arabian laws and regulations.

All clinical trial documents and data must be retained by the Parties for at least 15 years after completion or discontinuation of the clinical trial or at least two years after registering the medicinal product at SFDA.

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