China Releases Vaccine Good Clinical Practices

On October 31, 2013, The China Food and Drug Administration ("CFDA") promulgated a regulation titled *Guiding Principles for the Quality Management of Clinical Studies on Vaccines* ("Vaccine GCP"), with immediate effect. The Vaccine GCP applies to registration studies and stipulates the requirements for study initiation, implementation, and quality management in detail. It also sets forth the responsibilities of sponsors, clinical research organizations, site/investigators, and ethics committees.

While vaccine studies normally involve healthy subjects and are conducted at vaccination stations rather than hospitals, the Vaccine GCP introduces a more stringent risk control mechanism compared to the existing Drug GCP.

- Site qualification: In addition to accreditation by the CFDA, prior to formal engagement, the study sponsor shall conduct an on-site assessment of potential study sites on their study administration and quality management systems including, personnel, capabilities of handling adverse events, storage and transportation facilities for study vaccines, and implementation of various policies and SOPs governing clinical studies.
- Safety reporting: The sponsor shall define an SOP for safety reporting jointly with the investigator(s), train all study personnel on the SOP, and assign dedicated persons to manage the reporting process. The sponsor shall also form a data and safety monitoring board as well as an end-point evaluation board to monitor and evaluate any risk signal in a timely manner. The sponsor shall report suspected and unexpected serious adverse events to the Center for Drug Evaluation within seven calendar days upon its first awareness and report any follow-up information within the subsequent eight calendar days. Sites/investigators shall promptly inform ethics committees of the latest safety information provided by the sponsor.
- Ethics review: The ethics committee shall consist of representatives from the medical fields, non-medical fields, legal profession and independent third parties. The ethics committee members shall include representatives not affiliated with the site and these outside representatives shall account for at least 40% of the ethics committee members. The composition of the ethics committee and contact information of each ethics committee member shall be publically disclosed and registered with the CFDA.
- Storage and transportation of vaccines: The sponsor shall clearly define requirements for cold-chain management throughout the course of the study and disposal process for study vaccines in the event of cold-chain disruption. The lead site shall assist study sites in developing systems for vaccine administration and ensure that the receipt, retention, dispensing, recycling, and return/disposal of study vaccines comply with applicable laws.

Vaccines manufacturers shall incorporate the requirements under the Vaccine GCP in its study agreements and study-related SOPs in a timely manner to avoid the CFDA's order for study suspension or termination.

If you would like to discuss the foregoing or any other related matter, please contact Katherine Wang or your usual Ropes & Gray advisor.