China Announces Revised Good Clinical Practices for Public Comments

The China Food and Drug Administration ("CFDA") recently released its proposed revisions to Good Clinical Practices ("GCP") for pharmaceutical clinical studies for public comments. The proposed revisions, if eventually promulgated, will be the first revision since the enactment of the current GCP in September 2003.

Without changing the structure of the current GCP, the revisions add specific responsibilities of sponsors, Ethics Committees ("ECs") and sites, aiming to enhance protection of study subjects. The revised GCP also require local FDAs to be more involved in day-to-day supervision of clinical studies. Highlights of the revisions include the following:

- To Strengthen the Responsibilities of Sponsors

  Under the revised GCP, sponsors continue to be permitted to outsource certain tasks in clinical studies to third parties, such as Contract Research Organizations ("CROs"), provided that such third parties' responsibilities are clearly documented in relevant contracts. Sponsors must evaluate and inspect such third parties and be ultimately responsible for the quality of their work performed. Concerning the administration of study drugs, the revised GCP requires sponsors of BA/BE studies to retain sufficient samples from the same batch of study drugs for at least two years after receiving marketing authorizations. The proposed revisions also clarify that sponsors are responsible for continuously evaluating the risks/benefits of study drugs, including analyzing any safety-related information they receive, and promptly reporting any Suspected Unexpected Serious Adverse Reaction to governmental authorities.

- To Enhance the Independence of ECs and Regulate the Procedures of Ethics Reviews

  The proposed revisions require ECs to be independent and disclose their charters and procedures to the public. Each member of an EC must disclose any potential conflict of interest. Ethics reviews can be initiated prior to the CFDA's issuance of clinical trial authorizations. ECs must review and approve all written documents to be provided to subjects (such as consent forms and recruiting materials), in addition to the clinical study protocols. ECs must also review any serious adverse event, or any other event or new information that may change the risk/benefit analysis, the reasons for any early termination of clinical studies and the follow-up studies on subjects, and the completion of clinical studies. ECs must conduct periodic evaluation of the subjects' risks and benefits at least once a year.

- To Require Sites to Properly Manage Clinical Studies

  Sites conducting clinical studies must have appropriate management systems and qualified personnel to properly manage clinical studies. They must closely collaborate with sponsors and investigators. All three parties must communicate among themselves and with governmental authorities regarding any suspension, termination, or any potential issues of the clinical studies.

- To Increase Daily Supervision by Provincial FDA

  Provincial FDAs will undertake a more important role in daily supervision of clinical studies under the proposed revisions. Each EC and each site must report annually to the provincial FDAs in their resident provinces regarding the clinical studies that they review or manage. In addition, sponsors and investigators are required to promptly report any serious adverse event to provincial FDAs.

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

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