China Aims to Tighten Supervision Over Clinical Studies

China's health authority, the National Health and Family Planning Commission ("NHFPC"), recently released the *Administrative Measures for the Clinical Study Projects of Medical Institutions* ("the Measures") jointly with China Food and Drug Administration ("CFDA") and the Administration of Traditional Chinese Medicine, effective as of October 16, 2014. According to the NHFPC, the Measures, as a specific code of conduct for research behaviors of hospitals and physicians, should be read in conjunction with the general anti-corruption disciplinary rules in the "Nine Prohibitions" issued in late 2013.

In the Measures, the authorities mandated several requirements for hospitals conducting studies as clinical sites. By way of background, China regulates clinical studies primarily by a compulsory ethics committee ("EC") review regime, a clinical trial authorization system for all drugs and certain high risk devices, the Good Clinical Practices ("GCP") governing drugs and devices respectively, and, last but not least, a certification system to permit eligible hospitals to undertake studies. The new Measures supplement the current regulatory regime with the following key requirements for hospitals:

- To establish internal rules and organizations administering clinical studies

  Hospitals must establish internal rules and SOPs for administering clinical studies. In addition to an EC, hospitals must also form a Clinical Study Administration Committee ("CSAC"). The CSAC, composed of the hospital's relevant leaders, division chiefs and clinical study experts, will make supervisory decisions over study-related matters of the hospital. A subordinate implementing body, Clinical Study Administration Division ("CSAD"), needs to be created to handle daily administration of study projects.

- To centralize financial management of clinical study projects at the hospital level

  Funding of clinical studies must be channeled to a dedicated hospital account and not to a particular clinical department or an individual physician involved in the project. The use and distribution of the clinical study funds must follow the hospital's financial rules and the budget plan for the specific study project. If a sponsor has already covered any of the participating subject's expenses, such as the cost of study drugs or a physical exam, the hospital cannot charge the patient subject for such fees.

- To maintain a project-based approval system and supervision throughout the study process

  The hospital must approve all clinical study projects before implementation. The applying physician must submit relevant information to the hospital for approval, such as the CV and qualifications of the investigators, summary of the scientific basis of the research (e.g., pre-clinical laboratory data and animal trial data), study protocol, quality management protocol, risk evaluation and risk management proposal, form of informed consent letter for patients, any covenant on intellectual rights, and the financial sources sponsoring the study. The hospital EC will carry out the first round review of the project. If the application passes the first round, the CSAD will submit the application for approval by the CSAC.

  After the hospital approves the project, it must within 30 days file the clinical study project for record with the local counterpart of NHFPC that has granted its medical practice license, in addition to a filing with the local FDA as per current rules.

> The CSAC and CSAD must continuously oversee the study throughout its entire course. They must periodically evaluate the project with regard to the research ethics, safety, effectiveness, and financial compliance and commercial bribery risks. The hospital must report any irregularities found during such evaluation to the local health authority and should adjust, suspend or terminate the study where necessary, subject to CSAC approval.

Life science companies are recommended to review their internal policies governing clinical studies to reflect the latest regulatory requirements. They also need to be mindful for potential delay in the conduct of clinical studies due to the additional layers of approvals within hospitals.

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