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CFDA Proposes New Regulations on the Accreditation of Medical Device Trial Sites: China Food and Drug Administration

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On December 15, 2014, the ***China Food and Drug Administratio (CFDA)*** released proposed ***Measures for the Accreditation of Medical Device Clinical Trial Institutions (Measures)*** for public comment. The comments are due on February 28, 2015. The Measures articulate the process by which medical institutions in China can apply to the government to *become accredited to conduct medical device clinical trials* used by sponsors to support medical device registration applications for marketing in China. Medical institution is a term in Chinese regulation that is typically used to refer to hospitals and clinics, both public and private. However, nearly half of these institutions are state-owned, and most patient visits occur at state hospitals and clinics.

The Measures are one of a number of steps that CFDA is taking to fulfill its mandate under the newly revised *Medical Device Supervision and Administration Regulation (MDSAR)* to create a more regulated system for device trials in China. Class III and some Class II medical devices require clinical trials for registration, unless they meet an exemption set forth in MDSAR or its implementing regulations. Under the MDSAR, applicants must conduct required device trials at government-accredited medical institutions.

Previously, there was not a separate system of medical institutions accredited for medical device trials. Rather, device trials could be conducted at a medical institution that was accredited by CFDA to conduct a drug trial. MDSAR calls for CFDA to create a system of device-specific institutions, as well as ensure that sponsors run those trials according to Medical Device Good Clinical Practices, which CFDA is drafting.

The Measures state that CFDA, “in consultation” with that *National Health and Family Planning Commission (NHFPC)*, which is China’s primary government agency for oversight of hospitals and the practice of medicine, will issue the ultimate approval for device trial institutions. The provincial-level food and drug and health authorities will assist in this process by conducting initial reviews of the applications and site inspections.

The applicant must provide documentation proving that it has the necessary facilities, equipment, and personnel to support device trials. The Measures themselves lack detail on what specifics are needed, but application forms and other materials are appended to the Measures. As part of the

application, the applicant must also demonstrate that it has an ethics committee and complies with ethical principles under the *Declaration of Helsinki* (the Measures do not cite a version) and applicable good clinical practices. The applicant must have procedures for reporting and resolving adverse events that may occur during the trial and must submit a record of any device trials that it has conducted over the last five years.

The materials are submitted to the provincial food and drug authority, which conducts an initial review and issues a review opinion. Provided that the materials are complete, the provincial authorities will then organize a site-inspection, consisting of 3-5 provincial inspectors plus one inspector from the applicant's local municipal government. At the close of the inspection, the province will issue an inspection opinion. The provincial authority then passes both the review opinion and the inspection opinion to CFDA for a decision on the application. If approved, the CFDA issues a medical device clinical trial institution certificate. The certificate will indicate the "scope of specialization," or what types of devices may be tested at that institution. The Measures do not make it clear whether this information will be made available to sponsors in a CFDA database as it is for the medical institutions authorized to conduct drug trials.

The certificate is valid for five years and may be renewed by submitting an application six months prior to the expiration of the certificate. Institutions with "no record of problems" may not need to be re-inspected for a renewal application.

In addition to these basic parameters for application and renewal, the Measures contain some brief provisions on reporting, monitoring, and enforcement. For example, all device trial institutions must submit an annual report each February, to the provincial-level food and drug regulatory authority, on the "circumstances" of the trials they are undertaking. That provincial authority will then report to CFDA in March on the "circumstances" in their jurisdiction and their efforts to supervise the trials. It is not clear what specifically will be reported.

The Measures also contain ethics and anti-corruption safeguards. Investigators are not permitted to handle trials for similar products of different sponsors at the same time, nor are they permitted to handle more than three trials at the same time. Any institution found to have acquired its certificate through fraud, bribery, or other similar inappropriate behavior will have the certificate revoked and be prohibited from re-applying for three years.

Medical device companies should continue to monitor the development of this system and consider submitting comments. This will help to facilitate the clinical development phase of the registration process and avoid delays.

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