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CNDA Releases New Rules on the Inspection of Medical Device Clinical Trials for Comment

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Last month, the China Nation Drug Administration (CNDA, formerly known as China Food and Drug Administration or CFDA), released a draft rule on Inspection Key Points and Guiding Principles of Medical Device Clinical Trials ("New Draft"). This is the third draft rule related to medical device clinical trial inspections that CNDA has issued in the last two years. The draft rules cover site inspections by CNDA, which began in 2016, of clinical trials for devices that are in the process of product registration. The purpose of the inspections is to evaluate the compliance of these trials with good clinical practices (GCP) and ensure data integrity, which has been a significant concern for CNDA in the drug and device spaces. The drafts refer to the inspections as assessing "authenticity" and "compliance."

The first draft rule was published by CNDA on April 12, 2016, and set forth some high level procedures and key points for device trial inspections. However, the first draft rule failed to provide detailed guiding principles on how to analyze inspection results to assess GCP compliance. CNDA then published a second draft rule about one month later, in May 2016, providing three guiding principles to evaluate compliance:

(1) Inconsistent records, untraceable data and counterfeit investigational products/samples would be deemed to have "authenticity" issues;

(2) Clinical trials that have not been strictly following device-related rules but have no authenticity issues would be deemed to have "compliance" issues; and

(3) Trials with no authenticity or compliance issued found would be determined "qualified."

Although the second draft rule was never finalized, CNDA has relied on its principles for determining the "authenticity" and "compliance" of clinical data when conducting inspections in 2016 and 2017.

The New Draft has provided eight principles for clinical trial inspections, making substantive additions to the content of the second draft rule. These eight principles that would be used to determine the authenticity of a medical device clinical trial are as follows:

(1) Falsified trial subject records, records of trial procedure, research data and testing data;

(2) Untraceable data;

(3) Counterfeit investigational device used for inspection;

(4) Failure to report serious adverse events or defects;

(5) Inconsistencies between safety and effectiveness data in the registration application and records at the sites;

(6) Inconsistencies between statistical analysis reports in the registration application and data base summary in relation to safety and effectiveness;

(7) Reusing clinical trial samples against the protocol; and

(8) Other situations under which intentional authenticity issues arise.

Any authenticity issues with a trial could materially affect the progress of the product registration. Domestic and foreign medical device companies conducting clinical trials in China should consider submitting comments on the New Draft and should monitor updates for the final version. Comments are due June 30, 2018.

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