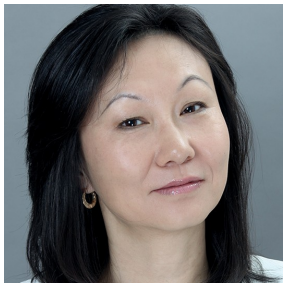
*CFDA to Ease Rules For Clinical Trial Certification, Overseas Data*

Grace fu Palma
MBA | Founder & CEO

gpalma@chinameddevice.com (U.S.)+1 978-390-4453



Grace fu Palma
MBA | Founder & CEO

**CFDA to Ease Rules For Clinical Trial Certification, Overseas Data**

*Grace Fu Palma, founder and CEO of Boston-based China Med Device, a firm specializing in commercialization and funding for U.S. medtech companies entering China, offers an update on CFDA's clinical trial reform.*

The China Food and Drug Administration issued a new draft policy on May 11 explaining how it plans to encourage the reform of clinical trials, promote technological innovation in medical devices, improve industrial competitiveness, and meet public needs.

Here are some highlights from the draft policy:

1. **Accreditation approval process replaced with simple filing:** The clinical trial institution qualification approval would change from the existing CFDA accreditation process and require a simple letter to be filed at the registration website. Clinical trial applicants may employ a third party to evaluate the accreditation of the clinical trial institution. The supervision and validation will be through on-site inspection by CFDA officials, and the inspection results will be made public
2. **Support researchers and clinical trial institutions to carry out clinical trials:** The CFDA would encourage healthcare institutions, teaching hospitals and research organizations to undertake clinical trials. The agency wants to encourage medical institutions to set up full-time clinical trial departments and also encourage clinicians to participate in technological innovation activities in pharmaceutical and medical equipment. It also wants to allow foreign enterprises and scientific research institutions in China to carry out clinical trials.
3. **Improving Ethnic Conformity Mechanisms:** CFDA's Ethnic Committee is responsible for clinical trial plan approval, modification or rejection. The Ethnic Committee needs to periodically monitor trials in real time.
4. **Improve the efficiency of Ethnic Committee professionals**: The clinical trial application organization should submit its trial plan for approval. If there are multiple trial sites, once the master trial site plan has been approved, the other sites do not need to go through the approval process. This is especially true when the trial is related to what China considers to be important science or research projects. Encourages recognition of clinical trial plan by different ethnic committees.
5. **Optimizing Clinical Trial Evaluation and Approval:** Need to improve communication between the approver and applicant. For phase I and III trials, 60 days after the trial approval body acceptance of the trial, if there are no rejects or questions, it shall be interpreted that the trial has been approved.
6. **Acceptance of Overseas Clinical Trial Data:** Overseas multi-site clinical trial data can be accepted if they meet CFDA regulatory requirements. If it is a first-time application in China, ethnic conformity needs to be proven. For medical devices, unless it is class III on the clinical trial requirement list, the data can be accepted.
7. **Expanded Clinical Trials:** Trials relating to treatments of fatal and no-cure diseases, after showing initial benefit, meeting ethnic conformity requirements, and patient consent, the trial can be used on other patients and their data can be used for approval. These are limited to phase II and III trials.