

January 19, 2018

China FDA Releases Guidance on Acceptance of Foreign Medical Device Study Data

On January 10, 2018, the China Food and Drug Administration (“CFDA”) announced the implementation of the *Technical Guidelines Governing Acceptance of Medical Device Clinical Data from Foreign Studies* (the “2017 Guidelines”). The long-awaited 2017 Guidelines explain the principles, acceptance criteria, technical requirements and considerations for accepting foreign study data in support of marketing submissions for medical devices. More importantly, the 2017 Guidelines provide a promising prospect for device manufacturers to avoid or reduce duplicating clinical studies in China and to accelerate their device approval timelines in China. Device manufacturers are advised to carefully review the 2017 Guidelines and analyze the implications on their device registrations in China.

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The CFDA has acknowledged the concept of referencing foreign study data in device approvals since 2015, i.e., the *Technical Guidelines Governing Medical Device Clinical Evaluation* (the “2015 Clinical Guidelines”).¹ Compared with the 2015 Clinical Guidelines, the 2017 Guidelines (i) provide acceptance criteria and considerations for the acceptance of foreign study data, and (ii) expand the eligible products to cover in-vitro diagnostic reagents and high-risk devices listed in the *List of Class III Devices Subject to Clinical Trial Approval*.²

According to the 2017 Guidelines, any foreign study data submitted to the CFDA must meet with three basic principles: (i) the foreign study must follow the ethic rules stipulated by the Declaration of Helsinki; (ii) the foreign study must be conducted in accordance with good clinical practices, and the device applicant and clinical site must accept CFDA’s inspections; and (iii) the foreign study data must be authentic, scientific, reliable and traceable, and the device applicant has to provide complete study data, not selected data.

Typical foreign study data materials generally include the ethics committee opinions, the clinical study protocol, and the clinical study report. Pursuant to the 2017 Guidelines, the CFDA will accept foreign study data, provided that (i) such data can meet the regulatory requirements in China, and (ii) such data is scientific, complete and sufficient. If the CFDA finds any foreign study data inadequate under applicable technical requirements, the device applicant may need to conduct a supplementary study in or outside China.

In addition, the 2017 Guidelines specify three special considerations that the CFDA may consider in its technical review process concerning whether, and to what extent, foreign study data can support the marketing approval of a device application, including (i) differences in regulatory requirements; (ii) differences in study populations; and (iii) differences in clinical conditions. Where such differences may have clinical significance, the device applicant will likely need to conduct a supplementary in-country study.

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

¹ See our [previous analysis](#) for the 2015 Clinical Guideline.

² On August 25, 2014, the CFDA promulgated the *List of Class III Devices Subject to Clinical Trial Approvals* (No.14 [2014] CFDA Notice), effective as of October 1, 2014.