appendix

Technical Guidelines for Accepting Data from Overseas Clinical Trials of Drugs

1. Scope This

guiding principle applies to guiding the work of accepting applicants to use overseas clinical trial data as clinical evaluation materials when applying for registration in the territory of the People's Republic of China.

The overseas clinical trial data involved in these guidelines includes but is not limited to the clinical trial data obtained overseas by the applicant through the simultaneous domestic and overseas research and development of innovative drugs. Generic drug R&D conducted overseas and complete and evaluable bioequivalence data can also be used for registration applications. 2. Basic principles for accepting overseas clinical trial data Applicants should ensure the authenticity, integrity, accuracy and traceability of overseas clinical trial data. The production process of overseas clinical trial data shall comply with the relevant requirements of the International Conference on Harmonization of Human Drug Registration Technology (ICH) Good Clinical Practice (GCP). The applicant should ensure that the overseas clinical trial design is scientific, the clinical trial quality management system meets the requirements, and the data statistical analysis is accurate and complete. In order to ensure scientific and reasonable clinical trial design and data statistical analysis, for drugs that are simultaneously developed at home and abroad and will be clinically tested in China, the applicant may contact the Center for Drug Evaluation of the State Food and Drug Administration (CFDA) before conducting key clinical trials. hereinafter referred to as the Center for Drug Evaluation) to communicate with each other to ensure that the design of key clinical trials meets the basic technical requirements for drug registration in China. 3. Accept the completeness of overseas clinical trial data. If overseas clinical trials are used for Chinese drug registration applications, all overseas clinical trial data shall be provided, and clinical trial data shall not be selectively provided. Ensuring the integrity of clinical trial data is a basic requirement for accepting registration applications.

For overseas early clinical trials and subsequent clinical research and development in China, the drug registration applicant should evaluate the early clinical trial data. Those with complete clinical trial data can be used to support subsequent clinical trials after communicating with the Center for Drug Evaluation. .

For all clinical trials that have been completed overseas but not yet on the market, a complete overseas clinical trial data package should be provided; those that have been listed should also provide updated safety and efficacy data before they can be used for registration applications in China. 4. Submission of overseas clinical trial data and basic technical requirements For simultaneous clinical research and development at home and abroad, when submitting a drug registration application, various domestic and foreign clinical trials should be sorted and summarized in accordance with the requirements of application materials in the "Administrative Measures for Drug Registration" to form a complete The clinical trial data package can only be used for drug registration applications in China. The data submitted for overseas clinical trial data for Chinese drug registration application should include biopharmaceuticals, clinical pharmacology, efficacy and safety data. Drug registration applicants are encouraged to submit in the Common Technical File Format (CTD).

Biopharmaceutical data should provide important in vitro or in vivo data and results related to bioavailability and bioequivalence, and provide support and data connection for formulation determination and formulation process optimization during clinical development. Clinical pharmacology data, mainly including pharmacokinetic and pharmacodynamic research data. Applicants for drug registration should conduct racial sensitivity analysis from multiple perspectives such as region and race, to provide support for the applicability of overseas clinical trial data to the Chinese population, and the evaluation of its efficacy and safety. Effectiveness data, mainly including overseas key clinical trial data and clinical trial data carried out in China, not only confirm the effectiveness of the research drug as a whole, but also analyze the consistency between the Chinese subgroup and the general population. Safety data, including all data used for safety evaluation at home and abroad, both

To analyze the overall safety, the consistency of the Chinese subgroup with the overall population was also analyzed.

Overseas clinical trial data should support efficacy and safety evaluation, and drug registration applicants should consider compliance with China's drug registration management requirements.

On the basis of package analysis, the key clinical trial data were evaluated to confirm the effectiveness of the study drug; following the ICH requirements on the racial influence factor (E5) of accepting foreign clinical data, the consistency between the Chinese subgroup and the general population was analyzed to determine the Support the extrapolation of overseas clinical trial results to the Chinese population. V. Acceptability of overseas clinical trial data According to the quality of clinical trial data, the acceptance of clinical trial data is divided into complete acceptance, partial acceptance and non-acceptance. Totally accepted. The overseas clinical trial data is authentic and reliable, and meets the requirements of ICH GCP and drug registration inspection; overseas clinical research data supports the efficacy and safety evaluation of the target indications; there is no ethnic sensitivity factor affecting efficacy and safety. Partially accepted. The data of overseas clinical trials are authentic and reliable, and meet the requirements of ICH GCP and drug registration inspection; the data of overseas clinical trials support the evaluation of efficacy and safety of the target indications, but there are ethnic sensitivity factors that affect efficacy and/or safety. There is great uncertainty in the evaluation of efficacy and safety when extrapolating data from overseas clinical trials to the Chinese population. The applicant for drug registration shall conduct relevant clinical trials according to the analysis of the influencing factors and after communicating with the Center for Drug Evaluation.

Not accepted. There are major problems in the authenticity, integrity, accuracy and traceability of overseas clinical trial data. Overseas clinical trial data cannot fully support the effectiveness and safety evaluation of target indications. Drug registration applicants should follow the innovative drug research and development ideas. , to conduct systematic clinical trials in China to support drug registration applications in China. For drug registration applications for critical diseases, rare diseases, paediatrics, and lack of effective treatment methods, if the overseas clinical trial data is assessed to be "partially accepted", the conditional acceptance of clinical trial data may be adopted and collected after the drug is marketed. Further efficacy and safety data were used for evaluation.