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PHARMACEUTICAL INDUSTRY STANDARD OF THE PEOPLE'S REPUBLIC OF CHINA

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Requirements for the management of biological samples in clinical trials of in vitro diagnostic reagents

体外诊断试剂临床试验生物样本管理要求

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Foreword

This document conforms to GB/T 1.1-2020 "Standardization Work Guidelines Part

1.Structure and Drafting Rules of Standardization Documents". Drafting is scheduled. Please note that some content in this document may involve patents. The issuing organization of this document assumes no responsibility for identifying patents. This document was proposed by the National Medical Products Administration. This document is under the jurisdiction of the national technical standardization authority for clinical evaluation of medical devices. This document was drafted by the Center for Medical Device Evaluation, National Medical Products Administration. The main drafters of this document are. He Jingyun, Zheng Shengwei, and Li Xiaoli. In vitro diagnostic reagents clinical trial biosamples Management Requirements

1.Scope of Application This document specifies the general requirements and confidentiality requirements for the management of human biological samples during clinical trials of in vitro diagnostic (IVD) reagents. Ethical requirements and requirements for sample collection, transportation and reception, preservation, pretreatment, testing, disposal, biosafety documentation and records. This document applies to clinical trials of in vitro diagnostic reagents for registration purposes.

2 Normative references

The contents of the following documents, through normative references within the text, constitute essential provisions of this document. Dated citations are listed below. For references to documents, only the version corresponding to that date applies to this document; for undated references, the latest version (including all amendments) applies. This document.

YY/T 1956-2025 Terminology and Definitions for Clinical Trials of In Vitro Diagnostic Reagents

3 Terms and Definitions

The terms and definitions defined in YY/T 1956-2025 apply to this document.

4.General Requirements During clinical trials, procedures should be established to guide the management of human biological samples and related sample information and data, including specific samples. The processes of collection, transportation, reception, preservation, pretreatment, detection, disposal, biosafety, and recording should include critical operations in each process. Clearly define and document it. The collection, preservation, use, and disposal of biological samples should ensure compliance with biosafety requirements, and relevant procedures should also assess risks and establish preventative measures. measure. The purpose of biological sample collection, preservation, and use in clinical trials should be clearly defined and feasible. The collection, preservation, and use of biological samples in clinical trials should comply with relevant ethical guidelines. The storage conditions and duration for biological samples after testing should be determined, as well as the recording of relevant information about biological samples after the completion of clinical trials. And the data retention time.

5.Confidentiality requirements The privacy and rights of clinical trial participants must be fully protected at all stages of the clinical trial. All individuals with access to clinical trial information must ensure this. All personnel handling clinical trial documents and databases must keep relevant information and data confidential. There should be relevant documents that clearly define the requirements for the release of information and data related to biological samples, such as agreements, protocols, authorization documents, and ethical approvals.

6.Ethical Requirements The collection, preservation, and use of human biological samples should be carried out in accordance with relevant ethical requirements.