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PHARMACEUTICAL INDUSTRY STANDARD OF THE PEOPLE'S REPUBLIC OF CHINA

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Clinical investigation of in vitro diagnostic reagents - Terms and definitions

体外诊断试剂临床试验 术语和定义

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Foreword

This document is in accordance with the provisions of GB/T 1.1-2020 "Guidelines for standardization work Part

1.Structure and drafting rules for standardization documents" Drafting. Please note that some of the contents of this document may involve patents. The institution does not bear responsibility for identifying patents. This document is proposed by the State Food and Drug Administration. This document is under the jurisdiction of the National Medical Device Clinical Evaluation Standardization Technical Authority. This document was drafted by: Medical Device Technical Review Center of the State Food and Drug Administration. The main drafters of this document. Lv Yunfeng, He Jingyun and Li Ran. Terms and definitions for clinical trials of in vitro diagnostic reagents

1 Scope

YY/T 1956 fixes the vocabulary for IVD clinical trials in China. It specifies the terms and definitions involved in clinical trials of in vitro diagnostic reagents, including those used in the design, conduct, recording and reporting of a trial. It is the terminology base under the operational standards that followed it: YY/T 1998 on the general quality requirements for IVD trials and YY/T 1997 on the management of biological samples both rest on the definitions fixed here. Diagnostic trials use words such as reference standard, comparator and clinical performance in ways that differ from therapeutic trials, and a protocol that uses them loosely will be read differently by its author and its reviewer. For anyone writing or assessing an IVD trial protocol for China, this is the document that settles the language.

This document defines the terms and definitions involved in clinical trials of in vitro diagnostic reagents, including the design, implementation, Terms and definitions used in the process of recording and reporting. In vitro diagnostic reagents referred to in this document are in vitro diagnostic reagents managed in accordance with medical devices. Reagents. This document applies to clinical trials of in vitro diagnostic reagents.

2 Normative references

This document has no normative references.

3 Terms and definitions

3.1 Safety When the product is used within its intended scope, the risks are acceptable compared with the benefits.

3.2 Case report form casereportform; CRF A document designed in accordance with the clinical trial protocol for in vitro diagnostic reagents to record the complete data of each subject obtained during the trial. Department information and data.

3.3 Adverse event; AE Adverse medical events occurring during clinical trials of in vitro diagnostic reagents, regardless of whether they are related to the in vitro diagnostic reagents. NOTE

1 Adverse events may result from, for example, inadequate instructions for use, deployment, installation, operation or any malfunction of the in vitro diagnostic reagent. Sufficient or inappropriate. NOTE

2 This definition includes equipment failure or reagent failure that has not resulted in death or serious injury but could result in death or serious injury. Note

3.This definition is not used to determine whether an event should be reported to a regulatory authority. Note

4.False-negative or false-positive results are not considered adverse events, but in interventional studies, inappropriate patient decisions based on these false-negative or false-positive results may be Except as decided by the management.

3.4 Recognized measurement procedures that provide measurement results suitable for evaluating the validity of measurement values obtained by other measurement methods of similar quantities Assignment of values to measurements, calibration or reference materials.

3.5 Comparator In vitro diagnostic reagents are in vitro diagnostic reagents that have been marketed in the People's Republic of China and used as controls in clinical trials.

3.6 protocol deviation Intentional or unintentional failure to comply with the requirements of the in vitro diagnostic reagent clinical trial protocol.