ICS 11.040
CCS C30

YY

PHARMACEUTICAL INDUSTRY STANDARD OF THE PEOPLE'S REPUBLIC OF CHINA

YY/T 2000-2026

Medical device real world data - Terms and definitions

医疗器械真实世界数据 术语和定义

Issued on: March 9, 2026 **Implemented on: March 1, 2027**

Issued by: National Medical Products Administration

Table of Contents

Foreword

This document complies with the provisions of GB/T 1.1-2020 "Standardization Work Guidelines Part

1.Structure and Drafting Rules of Standardization Documents". Drafting. Please note that some content in this document may involve patents. This document is published. The organization is not responsible 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: Center for Medical Device Evaluation, National Medical Products Administration; Hainan Lecheng Real World Research Institute; and New Biotechnology... Materials and High-End Medical Devices Guangdong Research Institute, and the Greater Bay Area Branch Center for Medical Device Technical Review and Inspection of the National Medical Products Administration. The main drafters of this document are. Cui Xinyue, Lu Hong, Teng Yingying, Cheng Weilu, Liu Lu, Liu Yinghui, Jia Jianxiong, Yuan Weihong, Zhuang Xiaojie, and Zhang Yidan. Cai Shuangshuang. Medical Device Real-World Data Terminology and Definitions

1 Scope

YY/T 2000 fixes the vocabulary for real world evidence in Chinese device regulation. It defines the terms and definitions relating to medical device real world data, including the terms used in the conduct of real world studies. China has been building a route by which real world data, from hospital records, registries and post-market follow-up, can support a device registration rather than only a post-market obligation, and a shared vocabulary is the precondition for that: a study protocol and a reviewer have to mean the same thing by each term. For a manufacturer planning a real world study to support a Chinese submission, or reusing evidence gathered abroad, this is the document that fixes the language the submission has to be written in.

This document defines the terms and definitions used in real-world data for medical devices, including those used in real-world medical device research. Terms and definitions. This document applies to the clinical evaluation of medical devices.

2 Normative references

This document has no normative references.

3 Terms and Definitions

3.1 identifier One or more attributes in microdata can enable the unique identification of the individual's personal information subject. [Source: GB/T 37964-2019, 3.6]

3.2 case-control study Patients who experienced the outcome event were assigned to the case group, and patients who did not experience the outcome event were assigned to the control group. The cases and control groups were compared. The proportion of the instrument under study is used to investigate the relationship between the instrument under study and the outcome event. [Source: Guiding Principles for Registration Review of Real-World Research Design and Statistical Analysis for Medical Devices, II (II) 3]

3.3 Case crossover study This is an observational study design commonly used to investigate the relationship between short-term exposure and acute outcome events. In the evaluation of device safety and effectiveness, Each case served as its own control at different time points before and after the event, and the use of the studied device was compared between the cases before and after the event. The relationship between the use of the device and the event is assessed based on the device's condition. [Source: Guiding Principles for Registration Review of Real-World Research Design and Statistical Analysis for Medical Devices, II (II) 4]

3.4 Traditional clinical investigation Trials conducted in specialized research institutions and on specific populations.

Note. Various measures are often employed to control variability and ensure data quality, such as detailed inclusion and exclusion criteria, and detailed case report forms (unlike ordinary ones). Medical records), enhanced monitoring and auditing (to ensure strict adherence to research protocols), and rigorous, accurate data collection are all typically involved. A significant amount of effort is also usually dedicated to this. To ensure treatment adherence and avoid the use of concomitant treatments that could affect the effectiveness of randomized therapy. [Source: FDA "Use of Real-World Evidence to Support Regulatory Decision-Making for Medical de- [vice] (modified)

3.5 representativeness Does the population included in the data cover the target population of the study?