**Notice on *The Technical Guidelines for the Application of Real-world Data in Clinical Evaluation of Medical Devices (Draft for Comments)* for Public Comments**

To whom it may concern,

　　Real-world data is a potential data resource of clinical evaluation of medical devices. It brings many benefits like huge data volume, easy to use in speculation, and we can get clinical conclusion data on a long-term basis through real-world data. So, supervision organizations and all the parties in the field attached greater importance on real-world data. In April 2019, NMPA launched a project called “Scientific Method of Medicine Supervision of China”. In this project, “Research on How to Apply Real-world Data in Clinical Evaluation of Medical Device Scientifically” is at the top of their project list. NMPA is exploring the feasibility and methodology of applying real-world data in supervision and decision-making. It will be a booster for pushing the reform of approval system of medical devices and it also helps in accelerating speed of innovation products to market.

This project is launched by Department of Medical Device Registration and Department of Medical Device Regulation. Center for Medical Device Evaluation is responsible for the implement of this project. Sichuan University, Zhejiang University, Peking University, Food and Drug Administration of Hainan, etc. are in the cooperating organization list. Based on the research, Center for Medical Device Evaluation drafted *The Technical Guidelines for the Application of Real-world Data in Clinical Evaluation of Medical Devices (Draft for Comments)* (attachment 1) to seek for public opinion. NMPA hopes that specialists, researchers, manufacturers and related personnel in this field can make comments on it.

If any comments, please download the attachment 2, and email NMPA before January 13, 2020.

<https://www.cmde.org.cn/CL0004/20139.html>