

Real-world data for medical devices

Guiding Principles of Clinical Evaluation Technology (Consultation Draft)

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- (1) Provide clinical evidence in the same variety clinical evaluation path
- (2) Used to support product registration as a supplement to existing evidence
- (3) The real-world data generated during the clinical use of imported devices that are urgently needed for clinical use can be used to support product registration as a supplement to existing evidence
- (4) As an external control for a single group of trials
- (5) Provide clinical data for the construction of a single set of target values
- (6) Support the modification of the scope of application and indications
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Appendix 1: Common statistical analysis methods

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