IMDRF International Medical Device Regulators Forum

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Uses of real-world evidence in a regulatory context

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OVERVIEW

1. The basic requirements of RWD;

Sources of RWD；

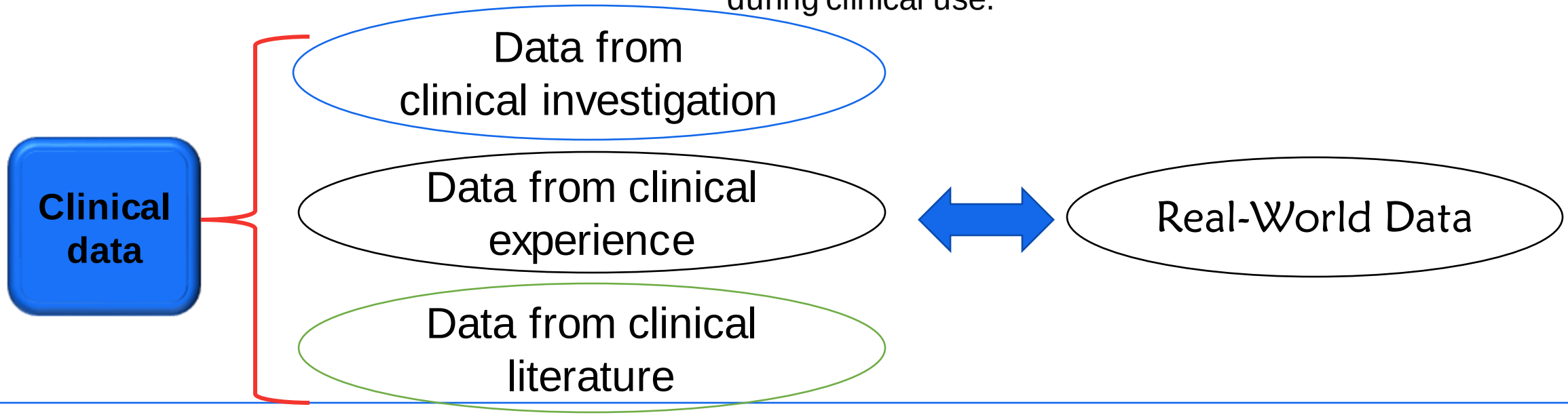
The differences between RWE and clinical investigation data;

Quality Control of RWD;

2.The application of real-world data in clinical evaluation of medical devices

Real-World Data (RWD)

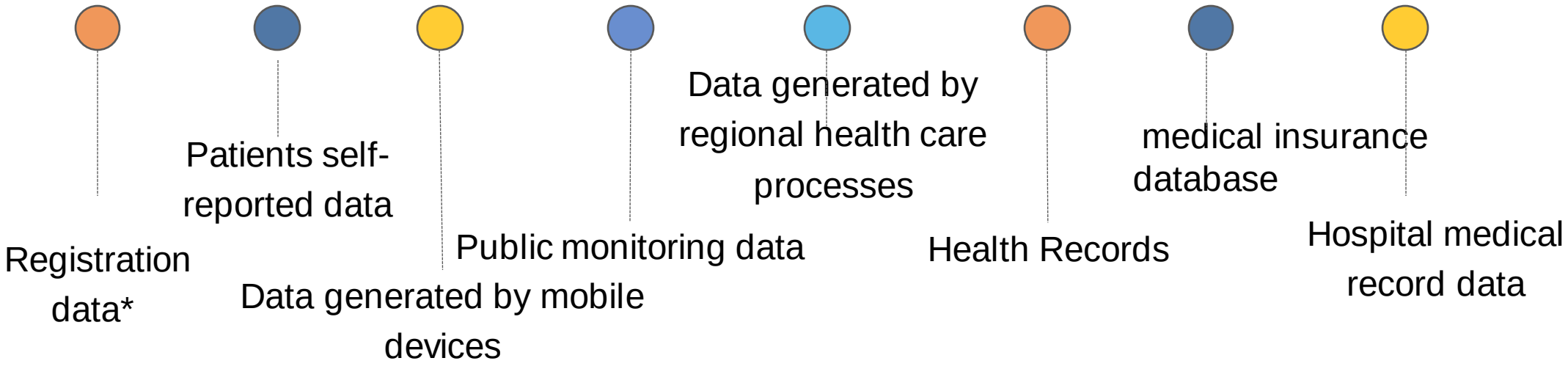
Clinical data: information on the safety, clinical performance, and/or effectiveness of a product generated during clinical use.



Real-World Data (RWD)： are data relating to patient health status and/or the delivery of health care routinely collected from a variety of sources（besides clinical investigation）.

Real-World Evidence (RWE) is the clinical evidence regarding the usage, and potential benefits or risks, of a medical product derived from analysis of RWD.

Sources of RWD



* Data Resources established in routine clinical practice, such as device registry data, etc.

- It comes from the process of providing and paying for health care services, such as hospital electronic medical record data, medical insurance data, health records, etc. .

The differences between RWE and clinical investigation data

	RWE	CLINICAL INVESTIGATION
Research populations	based on larger, more diverse, and more complex research populations	designed to control variability through detailed eligibility criteria and carefully designed clinical protocols, performed in specialized research populations
user	May be more inexperienced users	Investigators are selected based on their expertise and competence, often with more training than other users.
Advantage	These data help to identify device-related rare SAEs and provide long-term information on safety, clinical performance, and/or effectiveness, clarify the user “Learning curve”.	Increased confidence in the relationship between the test MD and the outcome

Quality Control of RWD

Representativeness: the extent to which the population in the data source represents the target population;

completeness: the level to which key variables for analysis are collected on a continuous basis.

Accuracy: extent to which collected data accurately record health-care events (eg, right patient age, right device, and right type of surgery)

consistency: data sources follow the same data-collection processes and procedures (including uniform data definitions and stable case report forms or other version-controlled data-collection forms)

authenticity: extent to which medical devices can be uniquely identified in the data source (UDI has been consistently recorded) , so that all operations using the MD can be identified and analyzed.

Reliability: the degree to which key variables are repeatable

Quality Control of RWD

A prospective or retrospective study by systematically collecting real-world data and using rational design and analysis methods.

1.The purpose of the research should be clear.

Based on available real-world data and scientific and reliable research methods

2. Regulatory and ethical considerations

Data Protection, personal information protection, ethical review and informed consent processes, data verification

Quality Control of RWD

3. Protocol design

type of study; study population; Study variables; follow-up time; sample size and test efficacy; device identification and use information; statistical analysis.

4. Bias and confounding

Selection of appropriate study populations;

identification of clear inclusion and exclusion criteria; randomization;

use of uniform survey tools and measurement methods; training of researchers;

appropriate statistical methods.

2.The application of RWD in clinical evaluation of medical devices

- To support pre-market clinical evaluation of products, as a supplement to the existing evidence
- To use RWD as external control of clinical investigation;
- Consider using RWD to construct target values for single-group investigation
- Expanded Indications for Use or Contraindications;
- To modify product IFU based on RWD ;
- Long-term safety and/or effectiveness evaluation of medical devices such as high-risk implants
- whole-life-cycle clinical evaluation of medical devices used to treat rare diseases
- Post market Surveillance Studies ;
- Post-Approval Device Surveillance as Condition of Approval

2.The application of RWD in clinical evaluation of medical devices

□To support pre-market clinical evaluation of products, as a supplement to the existing evidence

◆At present, the real-world evidence in the clinical evaluation of medical devices is more as a supplement to the existing clinical evidence, can-not replace the existing clinical investigation or clinical evaluation by comparison with comparable devices.

--- 《Technical guidelines for the use of real-world data for clinical evaluation of medical devices》

NMPA China

2.The application of RWD in clinical evaluation of medical devices

- To use RWD as external control of clinical investigation;
- Consider using RWD to construct target values for single-group investigations

--Applicability;
--limitations ;
--quality requirements on real-world data;
--research design and statistical methods.

2.The application of RWD in clinical evaluation of medical devices

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Postmarket Surveillance Studies

Post-Approval Device Surveillance as Condition of Approval

- MD for rare diseases
- MD used to treat a serious life-threatening disease for which no effective treatment is available
- MD urgently needed to respond to public health emergency

- New Technology/new application
- High risk products
- Expand the research population ……

- To evaluate long-term safety and effectiveness;
- To evaluate safety and effectiveness based on a larger population;
- To identify rare adverse events

It is suitable for different situations, to solve different problems and to meet different clinical evidence needs

RWD

Postmarket Surveillance Studies

Clinical evidence

Risk benefit analysis

Clinical evaluation of the whole life cycle

THANK YOU / QUESTIONS

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