Let's talk Re@l: What Are Real World Data?!

The Real World Data SIG talk, of course, about Real World Data – but what actually is that thing we talk about? Rima Izem reflects on what RWD is or isn't and according to who

How well do you know the term "real-world data" (RWD) that was popularized a few years ago? In your opinion, are these data only generated from non-interventional, non-randomized, and/or retrospective studies? Well…most regulators have a somewhat broader definition of what could generate RWD but there are still some grey areas on what the data are and how they are used in decision-making and we would love to hear where you fall in that grey area spectrum.

We think of the term "real-world data" as an umbrella term for recorded information on the patient in her/his/their daily life, especially health-related information. Most regulators, including FDA, EMA, MHRA, PMDA, and NMPA agree that any medical record resulting from routine clinical practice, such as electronic health records, pharmacy records, or insurance claims records, is real-world data (see table 1). However, the definition can be broader for some regulators on what routine care does or does not include. For example, the FDA considers randomized pragmatic clinical trials as a design generating RWD, if the schedule of follow-up visits and the patient recruited in the study are more aligned with routine care, despite the study being interventional, randomized, and prospectively designed. Conversely, the EMA excludes all clinical trials and randomized studies from potential sources generating RWD. Most regulators consider epidemiological studies or natural history studies collected in a registry as sources of RWD despite the prospective planning, prospective data collection, and a visit schedule or a set of measured outcomes exceeding what would happen in routine care. Beyond regulators, we can find more varying definitions from Health Technology Assessment bodies, professional societies and more. Furthermore, whether to draw a distinction between RWD on one hand and historical data from completed clinical trials on the other hand is a source of debate, because the use of either, as an external source of information to ongoing clinical trials, has a similar set of scientific considerations as any (secondary) use of data.

There are efforts underway to harmonize terminology of RWD leveraging the ICH network (press release). We invite you to join the conversation, share your experience with us (via rima.izem@novartis.com) or within your organization to ensure consistency or clarity of expectations and comment on what these sources of data are and where to draw the line on actionable evidence.

Table 1: Regulatory Definitions of RWD

FDA (US)	EMA (Europe)	MHRA (UK)	PMDA (Japan)	NMPA (China)
Real-world data are data relating to patient health status and/or the delivery of health care routinely collected from a variety of sources.	**RWD**: Healthcare related data that is collected outside of randomized clinical trials	**RWD** are defined as data relating to patient health status or delivery of health care collected outside of a clinical study.	**RWD**: Data that is electronically generated and stored by medical institutions	RWD: data, collected through regular practice, that are related to an individual patient's health status and/or diagnosis, treatment and healthcare

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References

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- US-Food and Drug Administration: https://www.fda.gov/science-research/science-and-research-special-topics/real-world-evidence
- EU- European Medical Agency: (recent piece about experience with RWD) https://www.ema.europa.eu/en/news/use-real-world-evidence-regulatory-decision-making-ema-publishes-review-its-studies
- UK- Medicines and Healthcare Products Regulatory Agency: https://www.gov.uk/government/publications/mhra-guidance-on-the-use-of-real-world-data-in-clinical-studies-to-support-regulatory-decisions
- PMDA: RWD WG | Pharmaceuticals and Medical Devices Agency (pmda.go.jp);
- NMPA: https://mp.weixin.qq.com/s/Rus8h-Cudpkk3thhX3IVug
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