Real World Data – ANVISA Status

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Real World Data Studies - Situation in Brazil

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**Regulatory Status**

- Anvisa published last September – Guide nº 64/23 (best practices for real-world data studies).

- Open for consultation and contributions until March/2024.

- Manufacturers are evaluating the document.
Highlights so far

- Real World Data (RWD) x Real World Evidence (RWE)
- RWD: data routinely generated during all processes related to the patient's state of health or the provision of healthcare collected from various sources.
- RWE: evidence about the use and potential benefits or risks of a medical product derived from the analysis of real-world data.
- Guidance on the structure of research protocols to evaluate the safety and efficacy of a drug using real-world data.
Highlights so far

- The guide does not make clear the use for biological products, but the understanding is that it is possible.
- Gold standard are still clinical trials.
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Thank You!
Obrigado!

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