

Real World Data – ANVISA Status



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DCVMN
INTERNATIONAL
Developing Countries Vaccine
Manufacturers Network International



Real World Data Studies - Situation in Brazil

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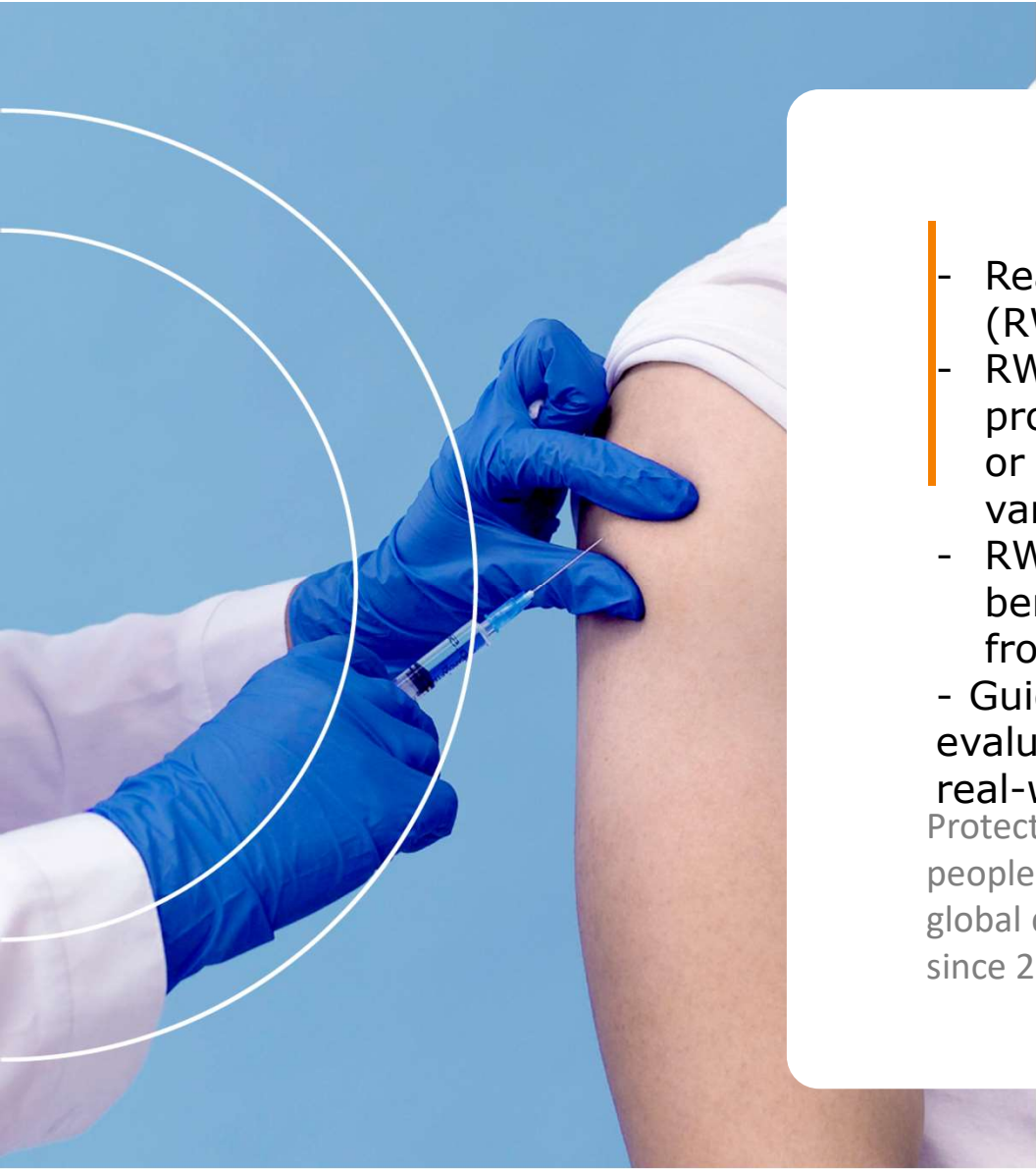


Regulatory Status

- 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.

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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 source
- 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

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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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