

The next three years: roadmap for RWE guidance

What is needed to promote fit-for-purpose data, study design, and methods to inform regulatory decision-making, and encourage global harmonisation?

| Data | Methods | Study execution | Global harmonisation |
|---|---|---|--|
| Framework for feasibility and fit-for-purpose Totality of evidence | Integration of quantitative bias analysis Approaches for integrating use of AI into RWE generation | Staged approach when conducting comparative analyses ^{1,2} | ICH M14 (safety) ICH reflection paper (effectiveness) |

¹ Muntner et al, 2024 PDS

² Desai et al, 2024, BMJ