Use of RWE in drug labelling

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EMA Scientific Advice

- Detailed feedback on the pre-specified analysis plan for RWE to contextualize the results of a single-arm trial

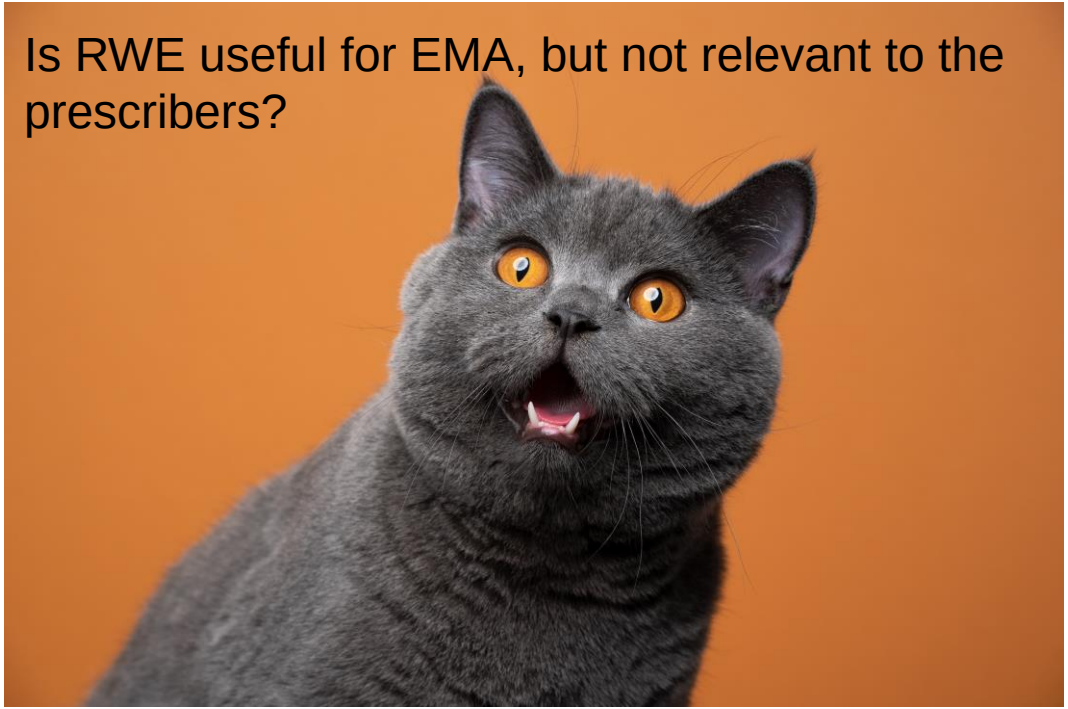
“Contextualization of the uncontrolled pivotal study results by indirect comparisons to patient-level external controls is considered useful to understand the efficacy of [...] in the current therapeutic landscape.“

18 months later, after a positive read-out and submission

Sponsor: Proposal to include indirect comparisons in SmPC

"These comparative data will be of particular value for clinicians in the decision-making process for the treatment in [...] At present there is no clearly established treatment [...] therapeutic options are very heterogeneous"

CAT Rapporteur: "Remove the data from SmPC"



What is the regulatory advice to sponsors for inclusion of RWE into the label (especially when it was pre-discussed) to help physicians to contextualize the clinical trial results?