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EVIDENCE MATTERS

Challenges to implementing real-world evidence (RWE)

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Objectives:

- Progress in science is outrunning the ability of using traditional clinical trials to generate the knowledge required to efficiently translate science into next-generation treatments, regulate drugs or make informed reimbursement and treatment decisions. Identifying ways to encourage patients to be tracked and included in patient registries after the RCTs is key to collecting the data needed to meet regulatory requirements. Manufacturers need to provide an evidence-based assessment of the benefits of a given therapy and plan follow-up studies and strategies for RWE. The aim of this study is to identify the main challenges to implementing RWE.

Methods:

- A literature search in the PubMed and Cochrane databases undertaken in May 2022 resulted in the identification of relevant publications. The findings on the pharma's biggest barriers to implementing are included in the subsequent analysis.

Results:

- The main barriers were identified as: operative challenges such as using multiple national data sources with different legal and ethical requirements and lack of patient's consent and anonymity protection techniques; technological challenges such as inconsistency of terminologies, data formats, quality, and content; methodological challenges such as apprehensions associated with the reliability and the validity of evidence as well as lack of integration of observational data with the data from trials.

Conclusion:

- The challenges of implementing RWE can be divided in three groups: technical, operational and methodological. The potential solutions to get ready and face such challenges put focus on the need of harmonization and transparency.

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