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RWE: The EMA's View

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The European Medicines Agency outlines the difficulties that impact regulators' ability to access and analyze real-world data.

The European Medicines Agency believes that real-world evidence is important for making many decisions about a medicine. It helps support pharmacovigilance activities and the assessment of safety signals, and it can also help measure the impact of any regulatory measures undertaken, says the agency. Such evidence also enables a better understanding of a medicine's risk-benefit balance and its effectiveness as well as informs HTA and health care utilization decisions. These activities apply to a wide range of medicines, including authorized medicines, innovative medicines, orphan medicines and medicines included in Adaptive Pathways. The agency says it sees a wide range of RWE collected from numerous sources, including e-health records, registries, hospital records and insurance data. Meanwhile, data from biobank, genomic and digital phenotyping information are increasingly being integrated into real-world evidence data sets.

Nevertheless, regulators face a number of difficulties that impact their ability to access and analyze real-world data. According to the EMA, these include:

- fragmentation and lack of interoperability of resources

- governance issues

- privacy concerns

- inadequate use of methods for integrating and analyzing heterogeneous data

- underuse of technological advances

- a lack of cross-border collaborations and sustained funding mechanisms for securing access to real-world data and then for analyzing it

It is therefore not surprising that the agency is calling for a "framework that provides the EU

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regulatory network with access to and analysis of an extensive range of multinational real-world data." This framework, says the EMA, should involve the development of "sustainable multi-stakeholder governance and funding mechanisms; a comprehensive characterization of EU-wide sources of real-world evidence; and identification or development of methods to integrate and analyze data and collaboration across stakeholders and borders."