European Federation of Pharmaceutical Industries and Associations

EMA Reflection paper on use of Real-World Data in Non-interventional Studies to Generate Real-World Evidence






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On behalf of EFPIA

Key Observations (1/2)

- **EFPIA welcomes the paper and recognizes the importance of establishing clear scientific principles for confidence in RWE.**

- **Reflection Paper should provide a balanced assessment of clinical trials and non-interventional studies, recognising that both have a role, depending on the research question.**

- **Scope, definitions and terminology – scope is not always clear (e.g. are disease epidemiology studies in scope?), NIS are defined by what they are not rather than what they are, does the definition cover a subset rather than the totality of NIS? Consultation on the RP provides an opportunity to enhance mutual understanding of terminology across stakeholder groups.**

Key Observations (2/2)

- **Predictability and consistency of interpretation will be important – how can this be supported in implementation plans? Fitness for purpose framework with criteria identifying where RWE may be suitable? Shared learnings?**
- **Transparency - EFPIA agrees that study /results registration is one component of building trust and confidence in research and has made proposals (Acha V et al; Principles for Good Practice in the Conduct of Non-interventional Studies: The View of Industry Researchers. Ther Innov Regul Sci. 2023 Nov;57(6):1199-1208.)**
- **Structure of the reflection paper could clarify applicability of relevant text to primary and secondary research, respectively.**