Increasing Recognition Towards Inclusion of Patient Preferences in Healthcare Intervention Development and Access – Current Landscape and Way Forward

HPR125

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Context: Incorporating patient preferences into the development and accessibility of healthcare interventions is increasingly acknowledged as essential for ensuring that interventions are better aligned with patient needs, improve satisfaction, support adherence, and enhance access. This growing awareness has led regulatory agencies like the Food and Drug Administration (FDA) and European Medicines Agency (EMA) to develop guidelines and actively engage in collecting patient preference information. Given the emergence of new guidelines, and their implications, the study aimed to analyze key regulatory guidelines on the inclusion of patient preferences in intervention development, assess the current landscape, and identify the path forward.

Methods: A comprehensive desk search was conducted using the databases of the FDA and EMA, supplemented by a grey literature search in March 2025.

Results: The following key guidance documents from the FDA[3,4] (2016 and 2024) and the Patient Preferences in Benefit-Risk Assessments during the Drug Life Cycle[5] (PREFER) consortium (2022) were identified and analyzed.

FDA (2016)

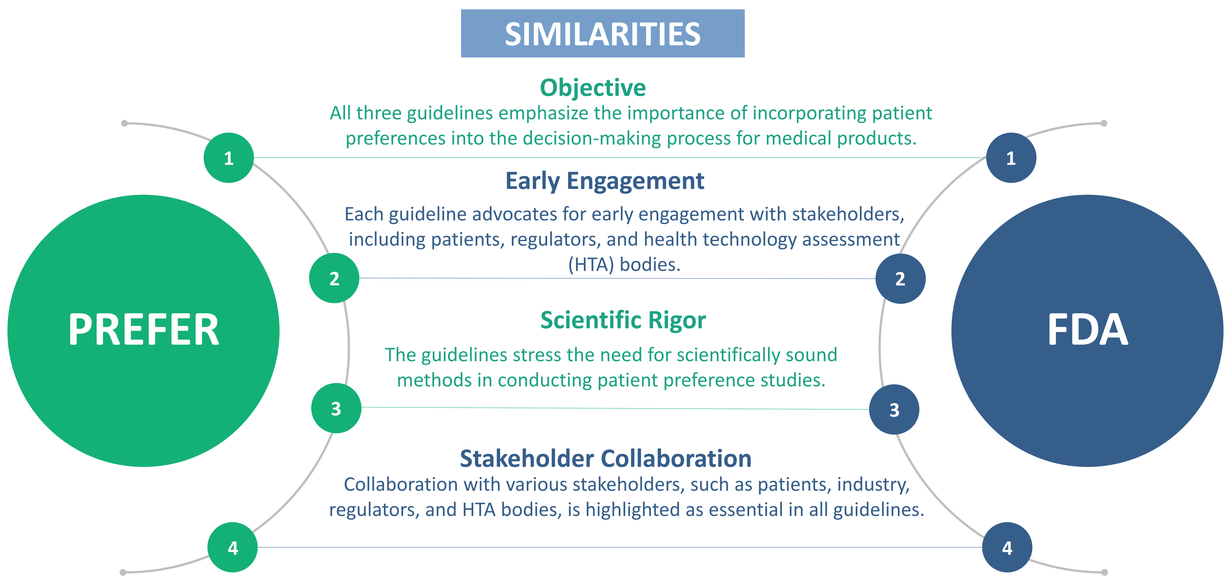
- Focuses on the inclusion of patient preferences in medical device decision-making.
- Encourages voluntary submission of patient preference information (PPI) to aid in benefit-risk assessments.
- Emphasizes the importance of including PPI in decision summaries and device labeling.
- Provides guidance on how to collect and use PPI, with an emphasis on medical device decision-making.

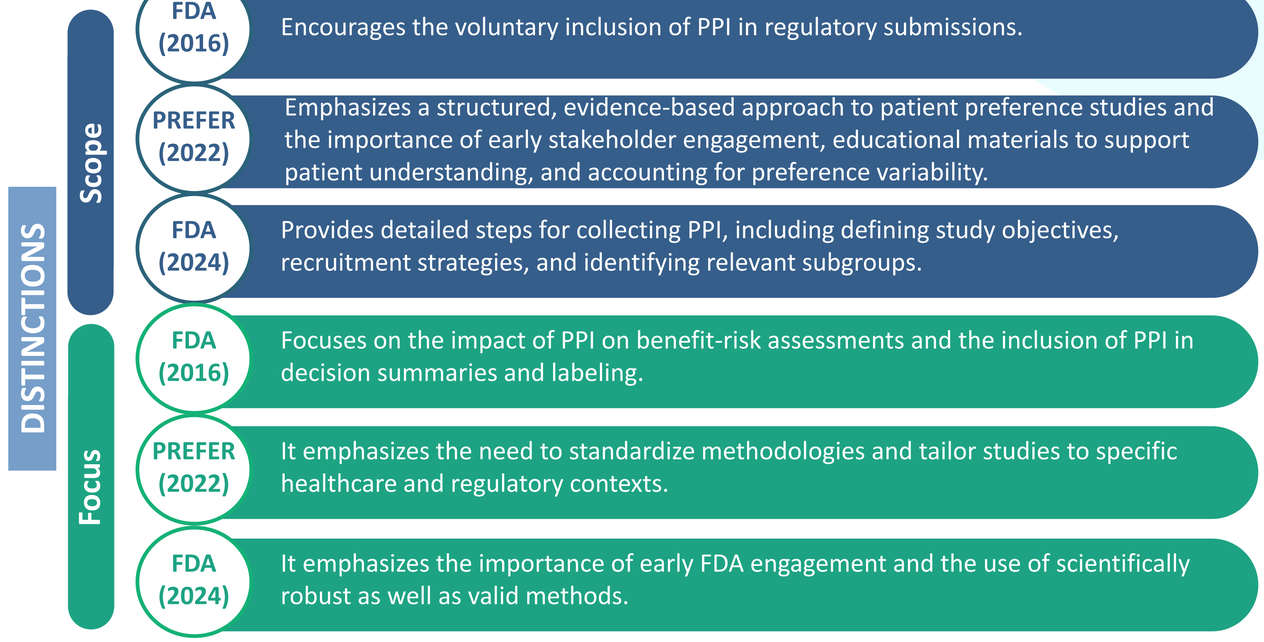
PREFER Consortium (2022)

- Provides a globally adaptable framework for incorporating patient preferences across the entire medical product lifecycle.
- Emphasizes the need for a structured, evidence-based approach to designing and applying patient preference studies.
- Highlights the importance of early stakeholder engagement, educational materials, and accounting for preference variability.

FDA (2024)

- Expands on the 2016 guidance with detailed recommendations for collecting and using PPI throughout the product lifecycle.
- Outlines specific steps for integrating PPI, including defining study objectives, recruitment strategies, and identifying relevant subgroups.
- Emphasizes early engagement of stake holders with the FDA and the use of scientifically robust and valid methods for better alignment, incorporating patient needs at every stage of the product cycle.





Implications and the way forward

The study highlights that integrating patient preferences into healthcare decision-making enhances patient-centered care and regulatory processes. Moving forward, standardizing methodologies, providing educational support, engaging stakeholders early, and addressing preference variability are crucial steps for effective implementation and broader adoption of patient preference studies. Several studies advocate for innovative strategies such as modifying existing measures, creating novel assessments, and incorporating alternative scoring methods to better reflect the diverse abilities and needs of patients.[4] Despite challenges like preference sensitivity and instability, the literature supports a shared decision-making paradigm that combines clinician expertise with patient values, offering a practical and holistic solution.[5]

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Abbreviations:
EMA: European Medicines Agency : FDA : Food and Drug Administration
PREFR: Patient Preferences in Benefit-Risk Assessments during the Drug Life Cycle; PPI; Patient preference Information

Financial Disclosure: Authors are employees of ConnectHEOR Limited. No external funding received to conduct this research and no conflict of interest to declare.

Poster presented at ISPOR in Montreal, Canada, May 13–16, 2025