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PATIENT PREFERENCES

EMA/EUnetHTA Qualification of the the IMI PREFER Patient Preference Framework and Points to Consider for Method Selection: Key Experiences, Outcomes, Values and Implications

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OBJECTIVE

To report

(i) **key experiences** and **(ii)** **outcomes** of the EMA/EUnetHTA qualification process, and

(iii) the **value and implications** of the qualification opinion itself on the IMI PREFER patient preference framework and points to consider for method selection

METHODOLOGY

The **IMI PREFER framework**, which provides considerations on the design, conduct and use of **patient preference studies** (PPS), and points to consider for method selection, were **assessed by EMA and EUnetHTA** via a joint qualification procedure. EMA qualification is a voluntary scientific pathway to establish the regulatory acceptability of a specific use of a methodology for the development of medicinal products.

RESULTS

PROCESS AND KEY EXPERIENCES

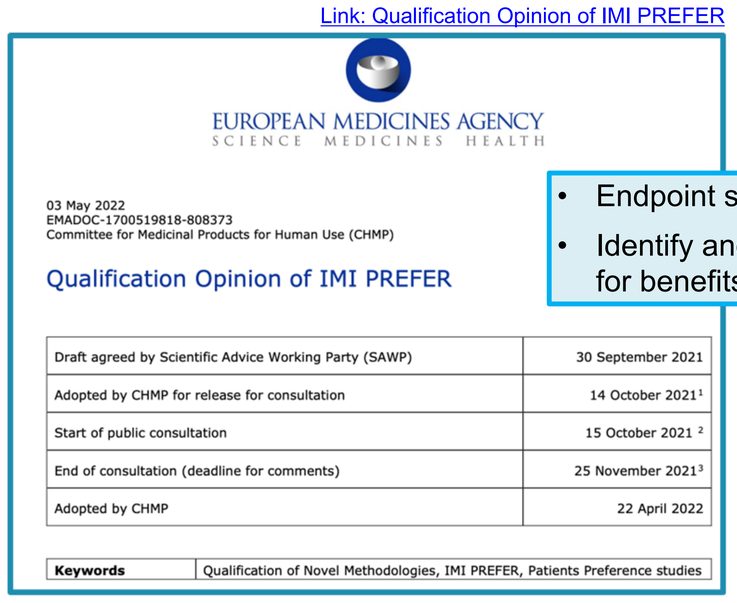
Refined objective → Qualification of method → Qualification of Framework; Points to consider for method selection

CHMP & EUnetHTA parallel		CHMP	
Pre-consultation		**Qualification advice**		**Qualification opinion (QO)**	
Preparatory call EMA	**10/18**	Start	11/19	Preparatory call EMA	02/21
EMA Premeeting	03/19	List of issues	02/20	Briefing book	03/21
Draft briefing book	10/19	Written response	03/20	Written response	04/21
		Discussion meeting	03/20	Discussion meeting	05/21
		CHMP advice	04/20	Draft opinion	09/21
				Public consultation	10-11/21
				Published final opinion	**05/22**

EUnetHTA input focused on the first step of the qualificaton

OUTCOME

Link: Qualification Opinion of IMI PREFER


EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

03 May 2022
EMADOC-1700519818-808373
Committee for Medicinal Products for Human Use (CHMP)

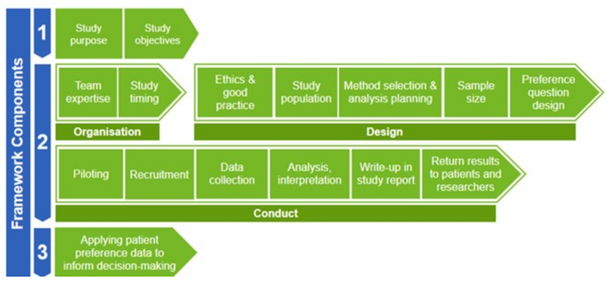
Qualification Opinion of IMI PREFER

Draft agreed by Scientific Advice Working Party (SAWP)	30 September 2021
Adopted by CHMP for release for consultation	14 October 2021[1]
Start of public consultation	15 October 2021 [2]
End of consultation (deadline for comments)	25 November 2021[3]
Adopted by CHMP	22 April 2022

Keywords	Qualification of Novel Methodologies, IMI PREFER, Patients Preference studies

- Endpoint selection
- Identify and value trade-offs for benefits and risks

PREFER Framework for PPS



Points to consider for method selection

VALUE AND IMPLICATIONS

Direct – value of the outcome

- **Regulatory assessment and opinion** of application of novel method in medicine development: "endpoint selection" & "identify and value trade-offs for benefits & risks
- **Value for patients, regulators, researchers and developers**

Move from *ad hoc,* direct to structured patient input in regulatory/HTA evaluation

Considerations on how to evaluate PPS and use it to support decision-making; foundation for further guideline development (ICH)

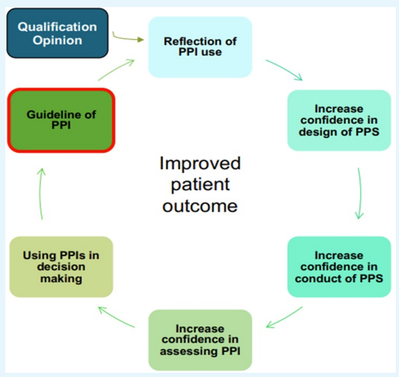
Set of tools to design, conduct and analyse PPS

Advice on why, when, and how to use PPS in medical product development; increased certainty to the development and presentation of PPI in submissions

Indirect – value of the process

- **Structured exchange** builds **familiarity & understanding**
- Informs scientific approach and methodological considerations; helps **redirect research**
- Helps refine thinking & **crystalize understanding** of value and regulatory applicability (context of use)
- Insight into different regulatory views & **consensus building**
- Public consultation & final opinion; **raises awareness and interest among wider audience**

Possible future benefits



ABBREVIATIONS

CHMP: Committee of Human Medicinal Products, EMA: European Medicines Agency, EUnetHTA: European Network for Health Technology Assessment, IMI: Innovative Medicines Initiative, PPI: patient preference information, PPS: patient preference studies, PREFER: Patient Preferences in Benefit-Risk Assessments during the Drug Life Cycle

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CONCLUSION

The EMA qualification opinion on IMI PREFER is a major step towards **more structured conduct and evaluation of PPS in decision-making**. Learnings from this qualification provide insight into the **value and appropriate use** of PPS in medical product development.