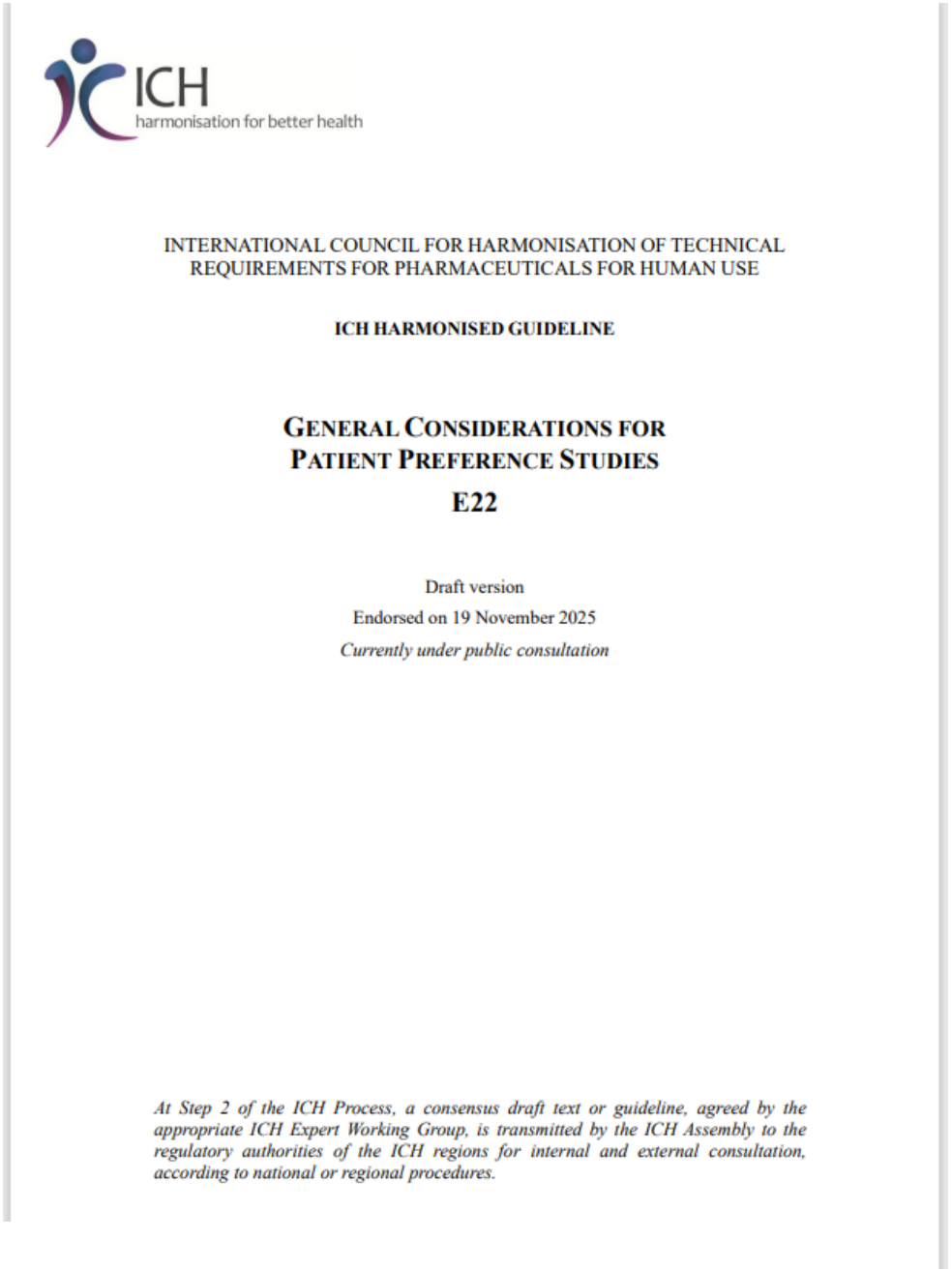
EMA
EUROPEAN MEDICINES AGENCY

ICH E22

Update on draft Technical Document; from public consultation to finalisation

Francesco Pignatti, 4 February 2026



ICH
harmonisation for better health

INTERNATIONAL COUNCIL FOR HARMONISATION OF TECHNICAL REQUIREMENTS FOR PHARMACEUTICALS FOR HUMAN USE

ICH HARMONISED GUIDELINE

GENERAL CONSIDERATIONS FOR PATIENT PREFERENCE STUDIES

E22

Draft version

Endorsed on 19 November 2025

Currently under public consultation

At Step 2 of the ICH Process, a consensus draft text or guideline, agreed by the appropriate ICH Expert Working Group, is transmitted by the ICH Assembly to the regulatory authorities of the ICH regions for internal and external consultation, according to national or regional procedures.

Contents

- Patient preference studies in drug development and regulation
  - An EMA study of patient preferences in benefit-risk assessment
- The ICH E22 draft guideline on “General considerations about patient preference studies”
  - Key messages
  - Current status, resources
  - How to contribute

How Might Patient Preference Studies (PPS) Inform Drug Development and Evaluation?

- Understand **unmet needs** and disease management priorities; identifying meaningful **endpoints**
- Informing **trial design**, **endpoint weighting**
- Guiding recruitment, retention, and **risk management strategies**
- Help **interpret outcomes** and **inform benefit-risk decisions**,
- Describe **distribution of preferences** across population (incl. subgroups)

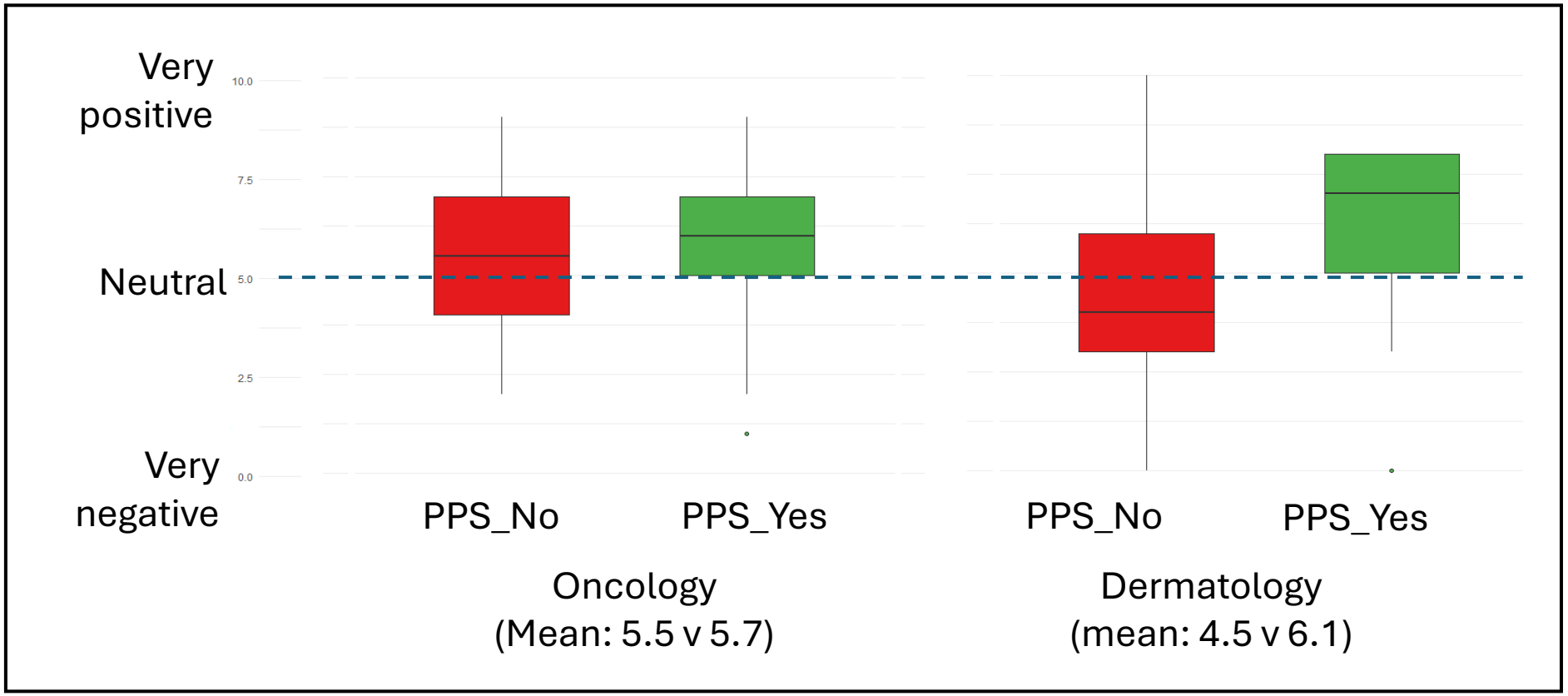
In practice, can patient preference studies have an impact on the benefit-risk assessment?

Do PPS Matter in Regulatory Evaluation?

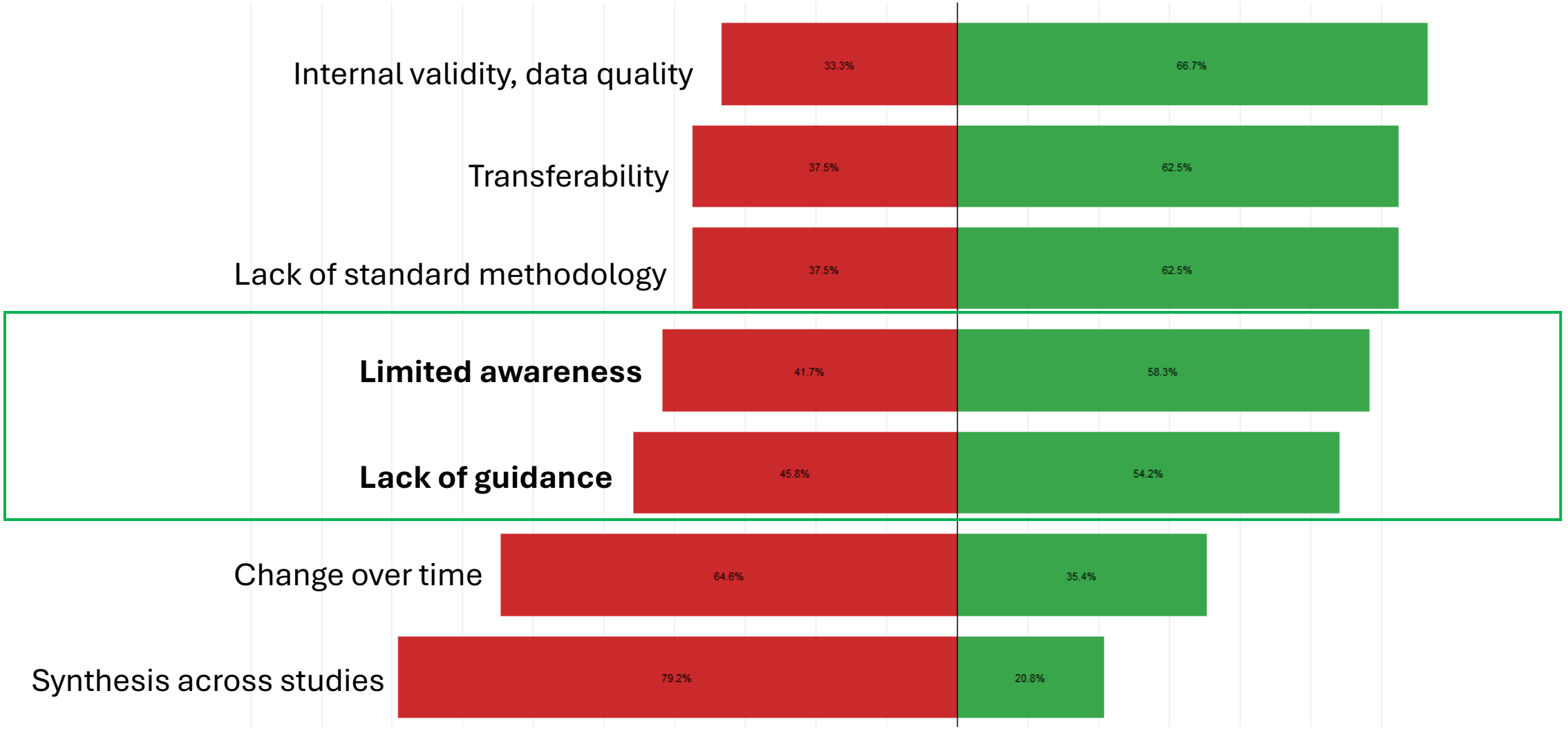
- Clinical Outcome Assessments (COA) generally accepted
  - Measures treatment outcomes
  - Although impact sometimes perceived as theoretical (Lancet Oncol. 2025 Jun;26(6):664-666)
- PPS have been more controversial
  - Measure relative utility (“preference”) of treatments or effects
  - Benefit-risk assessment being considered an objective scientific assessment; difference with COA not always understood
  - Preferences perceived as biased and unnecessary
  - Lots of recent activity (PREFER; ICH guidance; regulatory submissions)
- **What is the current status?**

Does PPI Matter in Regulatory Evaluation?

Participants from regulatory agencies were asked to rate from 0 to 10 the benefit-risk of hypothetical “neutral” treatments (small benefits; rare but significant side-effects) with or without “positive” PPS



Barriers to using PPS in regulatory decisions



EMA survey (2025; ackn. D. Mannini)

ICH E22 – status and timeline

- Step 2 endorsement in November followed by
  - Public consultation
  - Public stakeholder meeting on 6 February 2026
- Step 3 sign-off/Step 4 adoption (expected: December 2026)
- Explanatory video
  - https://database.ich.org/sites/default/files/E22%20Public%20Consultation%20Video.mp4
- Training material
  - https://database.ich.org/sites/default/files/ICH_E22%20Presentation_Step%202_Training%20material.pdf
  - https://database.ich.org/sites/default/files/ICH_E22%20Presentation_Step%202_Guideline_2025_1211.pdf

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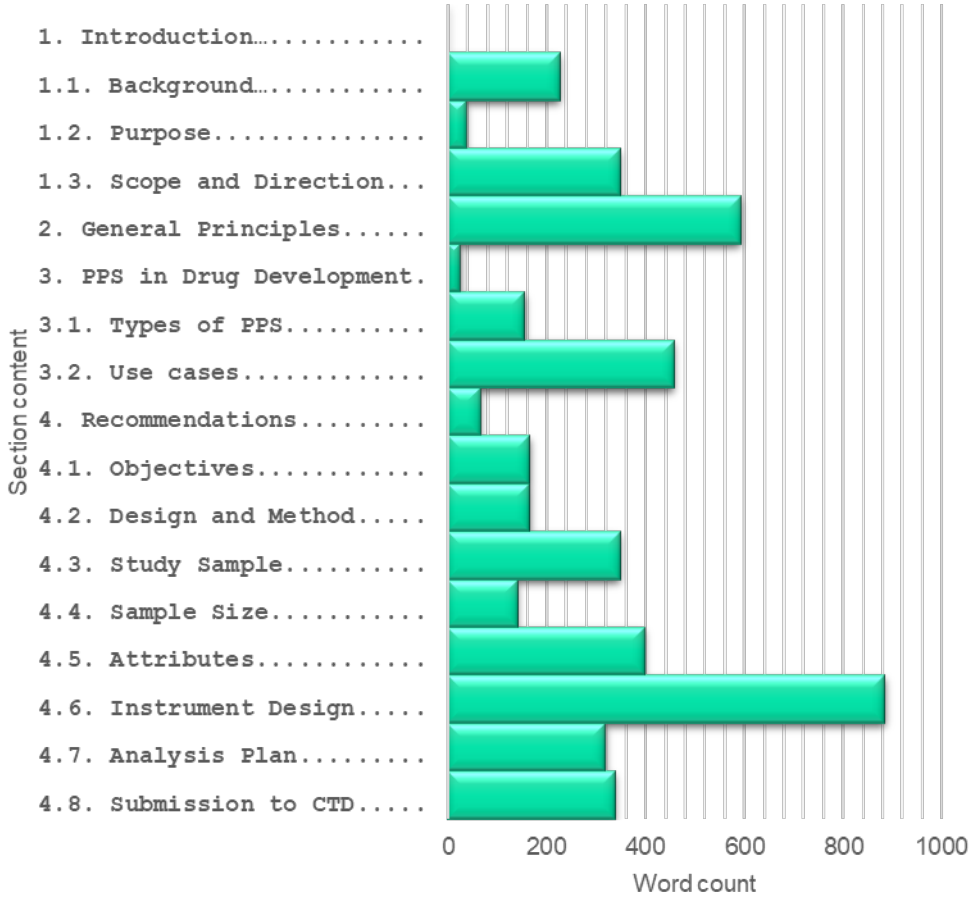

Length (English version): 16 pages

Scope and Direction of the Guideline

- Focus: **PPS to inform drug development, regulatory submissions, and evaluation** processes (approval; maintenance activities)
    - PPS not mandatory; PPS do not replace efficacy/safety data
    - Consider PPS systematically to inform evelopment
- **Patient Input:** Critical throughout drug development—helping with PPS purpose, design, attribute selection, feasibility, and interpretation
- ICH E22 does not address **patient-reported outcomes** or **labelling** considerations
- General methodological recommendations and challenges
    - Global applicability

Summary and Conclusions

- ICH E22 puts patient preference studies on the CTD/ICH map
- Opportunities
  - Interest in patient preference studies not merely theoretical
  - E22: Public consultation / contribute comments; webinar on 6 February
- Challenges for regulatory agencies/healthcare professionals
  - Familiarity with methods
  - Confidence in methodology

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Thank you

Francesco.pignatti@ema.europa.eu

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