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How to overcome the remaining challenges for successful implementation of the EU HTA Regulation: key insights from the 2023 European Access Academy Spring Convention and survey

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OBJECTIVES

- The European Regulation on Health Technology Assessment (**EU HTAR**) will be effective from January 2025 onwards.
- The EU HTAR seeks to create a harmonized system for Joint Clinical Assessments (JCAs) of new health technologies across Member States of the EU.
- As the preparation phase nears completion, we identified and prioritized remaining challenges and action points for implementation through a **multi-stakeholder survey** and **convention** organized by the European Access Academy (EAA).

METHODS

Pre-convention survey
- Mix of quantitative & qualitative questions
- Targeted at stakeholders in the field of HTA from different countries and backgrounds*

Goal: assess progress & remaining challenges of EU HTAR

Survey distribution (Jan-April '23)

Analysis of survey findings

EAA convention (April '23, Utrecht, NL)
- Break-out sessions in 4 themes†, diverse stakeholders*
- In-depth discussions (plenary & in break-out sessions) building upon survey findings

Goal: identify & prioritize action points for EU HTAR

Analysis of polls and notes

**health policy, patient associations, clinical societies, health technology developers (HTDs), HTA bodies, payers, regulators, and academia*

RESULTS

Survey findings

- The survey yielded N=61 responses from N=15 countries and N=8 stakeholder groups*.
- The perceived success of preparatory activities is shown in ***Fig. 1***.
- Key challenges that were identified included:
  - ✓ national readiness for JCAs;
  - ✓ HTA capacity limitations of Member States;
  - ✓ feasibility of the proposed methodological framework.

Convention takeaways

- The perceived readiness for the EU HTAR is shown in ***Fig. 2***.
- The break-out sessions† prioritized the following action points:
  1. Health policy (N=12): assess the need to adjust Member State laws and health policy processes;
  2. Stakeholders (N=14): build HTA capacity;
  3. Uncertainty (N=18): implement guidelines as living documents;
  4. Methodology (N=12): clarify the PICO identification process.

Fig. 1: *"Success" of preparatory activities as perceived by survey respondents (N=61).*

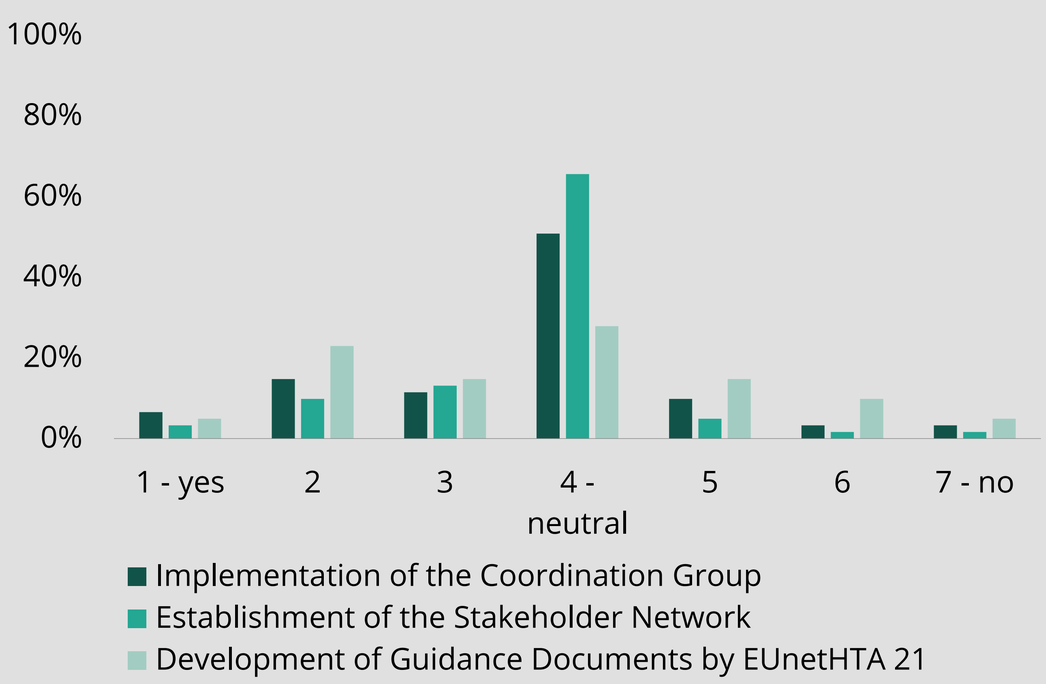
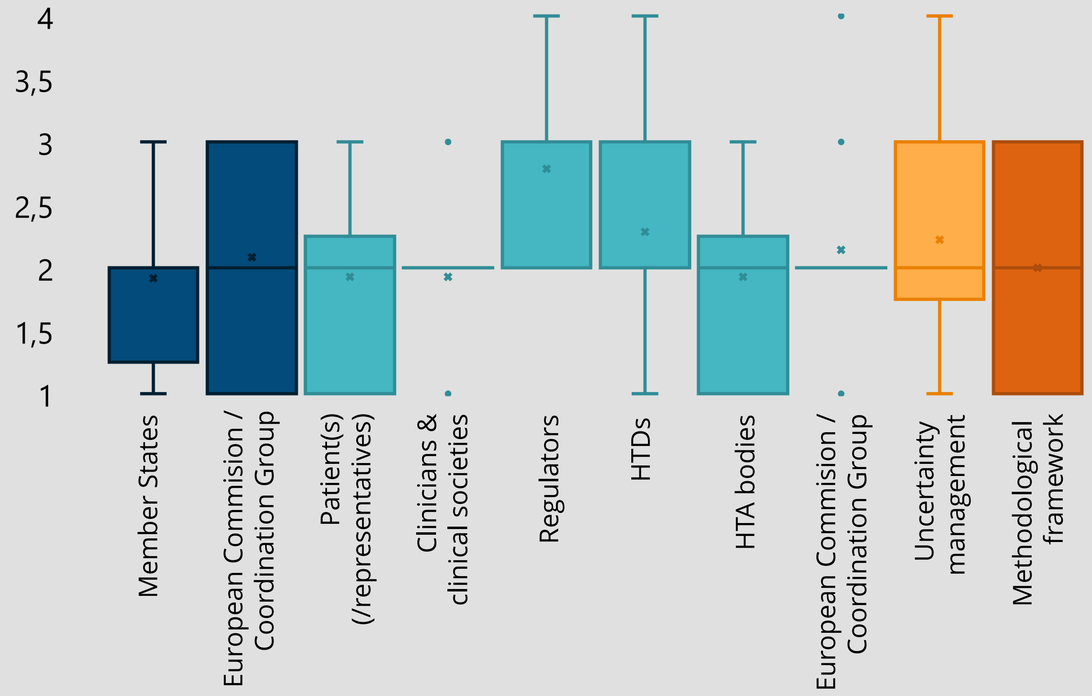


Fig. 2: *"Readiness" of stakeholders and methodology for EU HTAR as perceived in break-out sessions. 1= no; 4=yes.*



CONCLUSION

- Stakeholders emphasize continued efforts in national readiness, HTA capacity building, and addressing methodological concerns.
- Action points prioritize **harmonization & standardization**, **capacity building & collaboration**, and **uncertainty management based on robust data**.

REFERENCES

1. Brinkhuis F, *et al.* Evaluating progress towards EU HTA: Insights generated from the European Access Academy's multi-stakeholder questionnaire. *Health Policy Technol* (2024).
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