EUnetHTA's HTA Core Model®: A critical assessment and future outlook

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Background

EUnetHTA was established as an independent, science-based platform in 2006 to facilitate high-quality, sustainable HTA collaboration across Europe, as shown in Figure 1 (1,2). Coordinated by a network of 80+ organisations, EUnetHTA united on principal values resonating in universal access to quality care, equity, and the need for sustainability of health systems (1-3).

As part of the EUnetHTA activities, the Core Model® (herein referred to as "the Model") was developed. The Model, a common methodological framework, facilitates different HTA bodies and organisations in the EU to structure assessments consistently (1,2). This, in turn, supports the exchange of information and findings across EU member states, promotes collaboration, and reduces duplication of effort for the evaluation of healthcare technologies (4).

Objectives

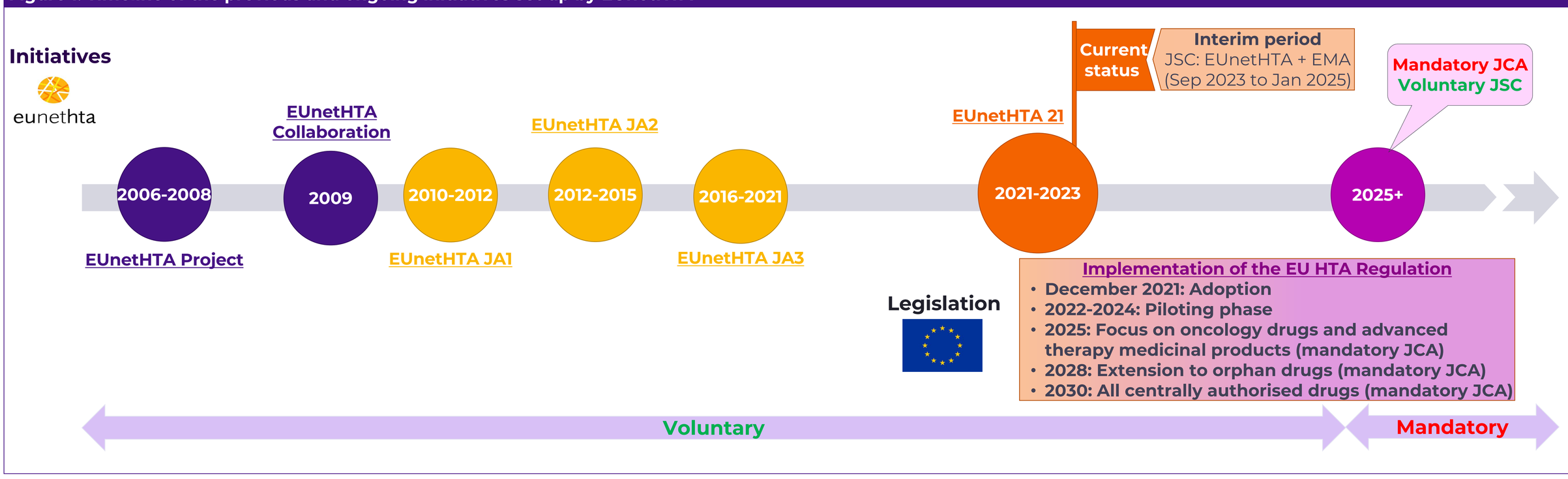
Given the prominence of the Model in supporting collaborative HTA policies in Europe, the following objectives were addressed:

1. To provide a brief overview and review of the key components of the Model developed
2. To explore the Model's current status, benefits, and limitations
3. To determine the likely impact of EU HTA Regulation in 2025 and provide recommendations regarding future development

Methods

We assessed the current and archived guidelines of the Model and conducted a targeted review of relevant publications evaluating the usage of the Model. Subsequently, a critical review of the Model's current status, key components, benefits, and limitations was performed, which allowed to generate recommendations for the Model to promote continual growth of the HTA bodies and collaboration between them.

Figure 1. Timeline of the previous and ongoing initiatives set up by EUnetHTA



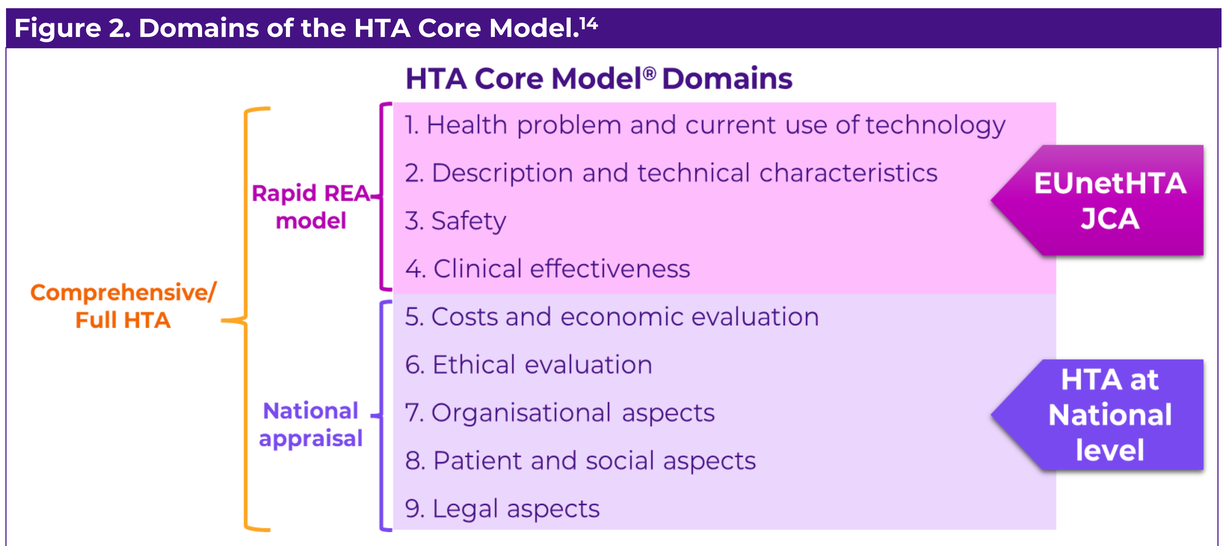
Results

Model overview

The introduction of EUnetHTA initiatives since 2006 has been facilitated by numerous methodological processes and frameworks, which in turn, has supported the development of the Model, as well as the current proposed EU HTA working structure. The Model consists of a standardised set of HTA questions (oncology) that define the specific research questions, methodological guidance, and a common reporting structure (4,5).

As shown in Figure 2, the Model comprises 9 domains. The first 4 domains are considered under JCA and are, therefore, more transferable across countries; however, at a national level, the remaining 5 non-clinical domains can be considered by local HTA bodies to provide context for decision-making (4,5).

Figure 2. Domains of the HTA Core Model.[14]



Current status, benefits, and limitations of the Model

The innovation and piloting of the Model during JA1 and JA2 led to a series of assessments and further refinements of the Model by EUnetHTA 21 for national uptake and implementation (4).

The strengths and challenges of the Model from multistakeholder perspectives are highlighted in Table 1.

- Regulatory agencies have praised the high flexibility and coverage of the Model, as it permits country-specific adaptation and alignment to the health technology under assessment (6-8). Furthermore, pilot application of the Model in Slovakia, a country with relatively less HTA infrastructure, although challenging, showed that the Model can be implemented without major legislative changes (9)
- From an industry perspective, the Model has been proposed to improve the ability to plan and predict assessment and reimbursement of technologies as well as improve communication across country affiliates and payers (10)
- During JA2/3, a critical review of the factors that limit or prevent local HTA bodies using EUnetHTA assessments was performed, and subsequently, corresponding recommendations have been put forth in EUnetHTA 21 (11)
- Notably, although patient contribution is vital to shaping assessment reports, improved support for systematic patient involvement is still warranted (12,13)

Table 1. Implications of the Model for different stakeholders.

Stakeholder	Strengths	Challenges
Regulatory agencies (6,8,18)	• Helpful for both the distribution of workloads and the comparison of results • Scientific rigour, methodology, usability, transparency, and independence raised confidence in utilisation of the assessment	• Limited resources • Acceptance by decision-makers • Tailoring EMA documents (e.g., EPARs) for use in JCAs
HTA bodies (15-17)	• Provides a standardised framework to produce HTA reports • REAs reduce duplication of work across European member states • Improves the quality of the submitted HTA evidence • Promotes collaboration between HTA bodies • Beneficial to establish a national process for countries lacking a robust HTA framework	• Changing and adapting national legislations and frameworks to fit the forthcoming JCAs • Non-binding JCAs: in case of major differences between EU REAs and national requirements (e.g., endpoints, comparators, comparison methods), national HTA bodies might still duplicate the assessment
Pharmaceutical industry (7,10,17)	• Improves the comparability and quality of HTA processes through a shared HTA terminology for communication • Saves time and resources, and reduces the administrative burden, by streamlining workflows with one JCA dossier (based on REA domains)	• Time-consuming for researchers, with ≤50% of all assessment elements deemed relevant • Satisfying the clinical evidence requirements of different member states and adequately representing different healthcare systems (i.e., unclear PICO process) for JCAs
Patients (9,19)	• The *patients and social aspects* domain captures patients' motivation to use a product, helps identify unmet needs from their perspective, and promotes counselling and information sharing • Emphasises the need for an organised and integrated methodology of stakeholder involvement, including patients • Ensures faster and equitable patient access to innovation through the JCA	• Identifying appropriate and relevant questions for patients to adequately address their perspective and obtain credible information • Providing training for patients to promote their involvement and impact in decision-making and HTA

Abbreviations: EMA, European Medicines Agency; EPAR, European public assessment report; EUnetHTA, European Network for Health Technology Assessment; HTA, health technology assessment; JA, joint action; JCA, joint clinical assessment; JSC , joint scientific consultation; PICO, population, intervention, comparison, and outcome; REA, relative-effectiveness assessment

Conclusions

In 2025, the mandatory implementation of joint HTA across Europe is set to commence with oncology products (13). The HTA bodies expect some initial obstacles in the implementation of the Model including additional time requirements and the adoption of a new terminology, which will ultimately lead to a methodological, standardised framework integral to a more collaborative HTA landscape. To further improve and adapt the Model's robustness and usability, we advise recurrent analysis and evaluation of the Model's national uptake, as well as continued opportunities for stakeholder input with emphasis on patient organisations as the collaborative HTA landscape evolves. We also encourage HTA bodies that wish to diverge from the Core Model to provide justification, and to highlight areas where improvement may be required that can benefit all markets.

References

1. About EUnetHTA Mission, vision and values. EUnetHTA; 2021. Available from: https://www.eunethta.eu/about-eunethta/mission-vision-and-values/
2. History of EUnetHTA. EUnetHTA; 2021. Available from https://www.eunethta.eu/about-eunethta/history-of-eunethta/
3. EUnetHTA and the HTA Network. EUnetHTA; 2021. Available from: www.eunethta.eu/about-eunethta/our-network/
4. EUnetHTA Joint Action 2, Work Package 8. HTA Core Model® version 3.0; 2016. Available from: www.htacoremodel.info/BrowseModel.aspx.
5. EUnetHTA Assessment FAQ [cited 21 September 2023]. Available from: https://www.eunethta.eu/ja3services/submission-guidelines/submissions-faq/
6. Pasternack et al. Comparing the HTA core model with a national health technology assessment report. Int J Technol Assess Health Care. 2014;30(5):530-5.
7. Kõrge et al. Evaluation of the HTA core model for national health technology assessment reports: comparative study and experiences from European countries. Int J Technol Assess Health Care. 2017;33(6):644-53.
8. Radaelli et al. Implementation of EUnetHTA core model® in Lombardia: the VTS framework. Int J Technol Assess Health Care. 2014;30(1):105-12.
9. Bilekova et al. Application of the HTA Core Model for complex evaluation of the effectiveness and quality of Radium-223 treatment in patients with metastatic castration resistant prostate cancer. Health Econ Rev. 2018;8(1):27.
10. Gyldmark et al. Is the EUnetHTA HTA core model® fit for purpose? Evaluation from an industry perspective. Int J Technol Assess Health Care. 2018;34(5):458-63.
11. EUnetHTA. EUnetHTA WP7: Implementation report; May 2018.
12. Engaging stakeholder in Joint Action 3 – now available for access. EUnetHTA; 2021. Available from: https://www.eunethta.eu/engaging-stakeholder-in-joint-action-3-now-available-for-access/
13. Garrett et al. Building a model of health technology assessment cooperation: lessons learned from EUnetHTA joint action 3. Int J Technol Assess Health Care. 2022;38(1):e14.
14. Barbuto V. Update on the implementation of Regulation (EU) 2021/2282 on Health Technology Assessment; 18 November 2022.
15. Kristensen et al. The HTA Core Model® —10 years of developing an international framework to share multidimensional value assessment. Value Health. 2017;20(2):244-50.
16. Wilsdon T, Pistollato M, Li L. EU REA – A discussion of barriers for adoption and possible actions to overcome them; 2017. Available from: https://www.crai.com/insights-events/publications/eu-rea-discussion-barriers-adoption-and-possible-actions-overcome-them/
17. Julian et al. How can a joint European health technology assessment provide an 'additional benefit' over the current standard of national assessments? Health Econ Rev. 2022;12(1):30.
18. Van Haesendonck et al. The role of stakeholder involvement in the evolving EU HTA process: Insights generated through the European Access Academy's multi-stakeholder pre-convention questionnaire. J Mark Access Health Policy. 2023;11(1):2217543.
19. Steigenberger C, Schnell-Inderst P, Siebert U. Integrating patients and social aspects into health technology assessment. In: Kohlhammer VW, author; Schildmann J, Buch C, Zerth J, editors. Defining the Value of Medical Interventions: Normative and Empirical Challenges [Internet]. Stuttgart (DE): W. Kohlhammer GmbH; 2021. Available from: https://www.ncbi.nlm.nih.gov/books/NBK585096/

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