

Digi HTA

Digital therapy assessment and reimbursement
models in the EU

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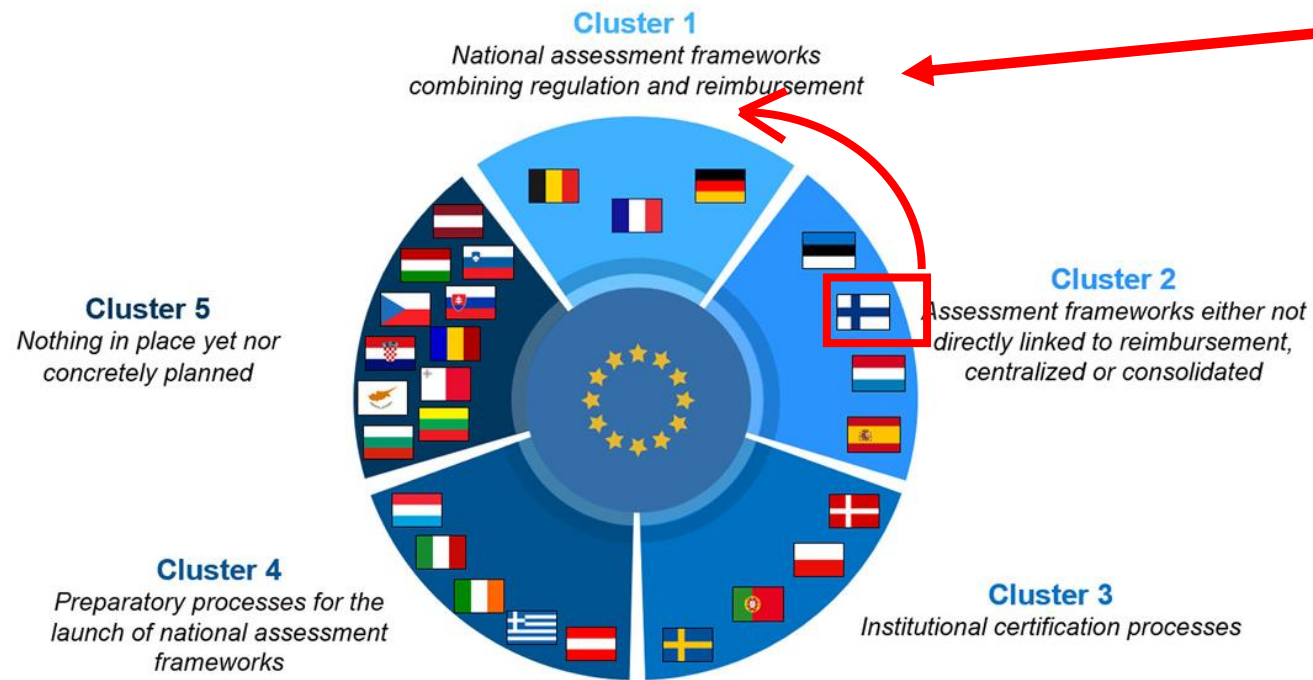
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The status of assessment and reimbursement models for digital health technologies (DHTs) in Finland

- In Finland, there are already practical examples of the use of different digital care modalities in healthcare, including digital therapeutics (DTx), remote patient monitoring (RPM) solutions, digital lifestyle interventions and digital care pathways
- Since 2019, Finland has applied an HTA methodology called Digi-HTA for digital health technologies (DHTs)
 - Digi-HTA covers a broad range of DHTs, including digital therapeutics (DTx) and remote patient monitoring (RPM) solutions, technologies supporting independent living at home, as well as AI- and robotics-based solutions
 - Some of the wellbeing services counties have used Digi-HTA assessments as part of their **regional decision-making**
- However, what has been lacking in Finland is a **national-level reimbursement model for digital therapies** that would enable their adoption based on evidence and through a systematic national-level process
 - For this reason, the Ministry of Social Affairs and Health has launched the **Digital Therapy Trial** to establish a foundation for a national operating model enabling the **effective** and **equitable** implementation of digital therapy solutions within public healthcare

Assessment and reimbursement models for digital health technologies in the EU



EU frontrunner countries with national HTA frameworks for digital health technologies (DHTs) that integrate both regulatory and reimbursement pathways

Fast-follower countries have implemented robust assessment frameworks at an early stage; however, these frameworks currently remain weakly linked to reimbursement decisions, fragmented across institutions, or under consolidation.

Fig. 1 | Mapping of assessment approaches for DMDs by EU Member States. Classification of EU Member States' approaches to DMD assessment into five clusters based on the status of the frameworks (active, under development, or

missing) and their primary purposes, including coverage and reimbursement, value assessment, orientation of individual choices and behaviors and taxonomy definition.

Source: Tarricone, R., Petracca, F. & Weller, HM. Towards harmonizing assessment and reimbursement of digital medical devices in the EU through mutual learning. *npj Digit. Med.* 7, 268 (2024). <https://doi.org/10.1038/s41746-024-01263-w> CC BY-NC-ND 4.0.

Presentations and practical arrangements

- The German assessment and reimbursement model (20 min):
Kristina Engler, BfArM
 - 5 minutes for questions: ***Kristina Engler and Florian Strauch***, BfArM
- The Belgian assessment and reimbursement model (20 min):
Wim Dunford, RIZIV-INAMI
 - 5 minutes for questions: Wim Dunford, RIZIV-INAMI
- The French assessment and reimbursement model (10 min):
Jari Haverinen, FinCCHTA
- **Practical arrangements**
 - You may submit your questions via the chat either during or after the presentation. You may also raise your hand and request to speak after the presentation

Thank You!

Digi  HTA

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