

Digi HTA

Health Technology Assessment Activities for Digital Health in Finland

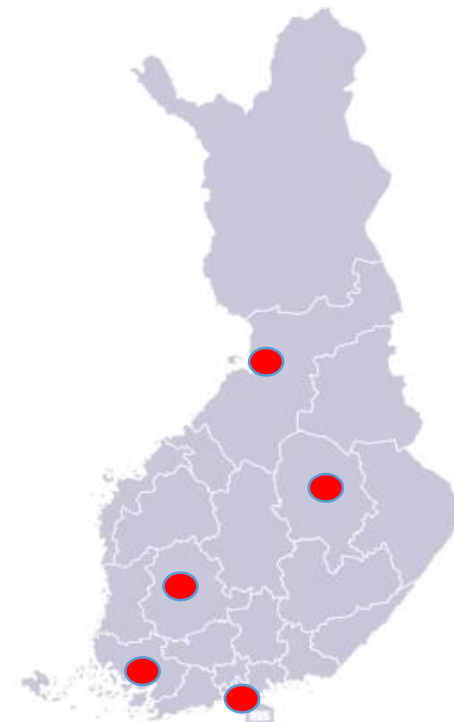
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The New Finnish Health Care system, Since 2023

1. The largest **reform** in health care and social welfare services since 50 years!
2. **Since 1st of Jan, 2023, 22 Wellbeing Service Counties + City of Helsinki** are in charge of **Public health care and social welfare services = total 23 actors.** (Instead of $21+137=158$ in 2022)
3. **All funding is coming from the state taxes**, the municipalities have not a role anymore.
4. Those Service Counties will join **Primary care, Secondary care and Social welfare services under one administration.**
5. **The information systems will be joined together in each of the counties**, many megaprojects that will take years.
6. 9/23 had a joint information systems for primary care and secondary care already in 2022, the rest 14 have work in progress
7. 7/23 had at least partly social care systems combined in 2022, the 16 have work in progress.
8. Physicians, nurses etc. work as salaried employees.



After 1st Jan 2023:
23 new actors in
charge of public
health care



Origin of the presentation slide: the lectures of Professor Jarmo Reponen

Many new and innovative DHTs will be offered to healthcare, social welfare and citizens in Finland – How to assess all of them?



Source: Department of Rehabilitation Medicine, NIH Clinical Center

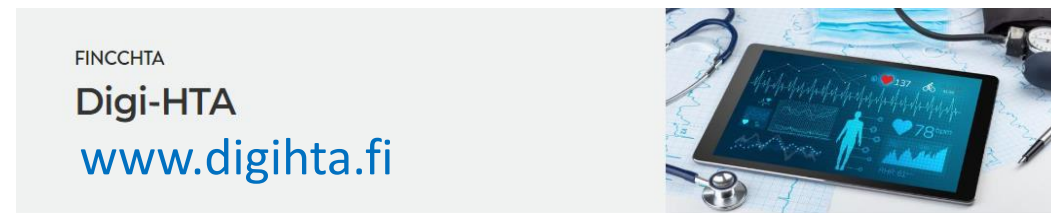


Digi-HTA

The Digi-HTA assessment method was developed to enable HTA activities for wide range of DHTs including e.g. health apps, AgeTech, AI and robotics solutions

- The process is applicable for non-medical devices and medical devices

Since beginning of 2020 Digi-HTA process has been part of daily HTA activities of the FinCCHTA for DHT products



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- About FinCCHTA
- Digi-HTA
 - Instructions for companies
 - [About Digi-HTA](#)
 - Digi-HTA Assessment Library

Digi-HTA is a method developed for digital products and services for social and health care and well-being. It is used to assess the suitability of a product or service for the use of customers and employees in the sector.

The aspects of the assessment are effectiveness, costs, safety, data protection and security, as well as usability and accessibility. In addition, issues affecting the commissioning of a digital product, such as the care process and changes in IT, are examined in particular.

The representatives of the wellbeing services counties can make use of Digi-HTA assessments, for example, before procurement, in connection with the procurement, when starting the piloting of products or in carrying out a market survey.

The Digi-HTA assessment enables a technology company to demonstrate the suitability of its digital product or service for the use in social and health care or in promoting well-being. The assessment allows the company to obtain an evaluation of its product by independent experts, so the company can also use the assessment in product development.

The Digi-HTA method

Health Technology Assessment (HTA) is an evidence-based review of the suitability of methods for use in healthcare. The assessment is used to support decision-making when considering the introduction of new equipment and methods or the removal of old ones.



Source: Haverinen, J., Turpeinen, M., Falkenbach, P., & Reponen, J. (2022). Implementation of a new Digi-HTA process for digital health technologies in Finland. *International Journal of Technology Assessment in Health Care*, 38(1), E68. doi:10.1017/S0266462322000502



Digi-HTA Domains






- Company information
- Product information
- Cost
- Effectiveness
- Safety
- Data security and protection
- Usability and accessibility
- Interoperability
- Technical stability
- Artificial intelligence
- Robotics

Key Assessment Domains

Points	Effectiveness	Safety	Cost	Data security and protection	Usability and accessibility
2	Sufficient	Sufficient	Reasonable	Sufficient	Sufficient
1	Promising but more evidence is needed	Probably at a sufficient level but not known well enough	High	Minor shortcomings	Minor shortcomings
-4	Weak or unknown	Weak or unknown	Unreasonably high	Shortcomings	Shortcomings

Note! The assessment scale has been modified from the Managed Uptake of Medical Methods (MUMM/HALO) model previously used in Finland in years 2005–2016.

Digi-HTA Domains

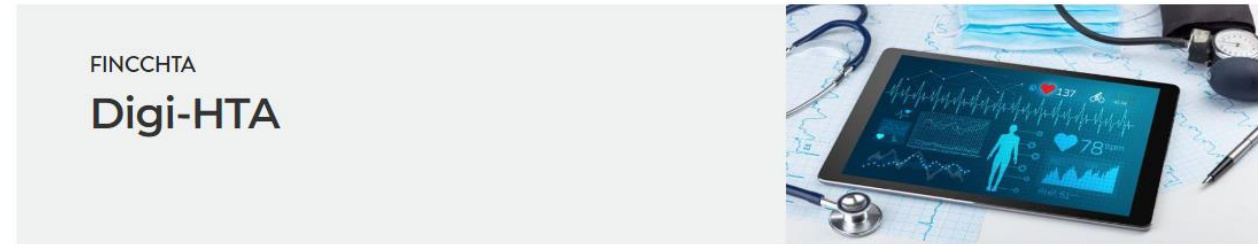
Total score	Digi-HTA assessment	Definition
10		THE PRODUCT FILLS THE ASSESMENT CRITERIA
9		THE PRODUCT MEETS THE ASSESMENT CRITERIA MAINLY
7-8		THE PRODUCT PARTIALLY MEETS THE ASSESMENT CRITERIA
5-6		THE PRODUCT ADEQUATELY MEETS THE ASSESMENT CRITERIA
≤4		THERE ARE CRITICAL THINGS TO CONSIDER WHEN USING THE PRODUCT

Digi  HTA



Digi-HTA publishing portal

- Published assessment can be found on FinCCHTA webpage: www.digihta.fi
- Assessments are available e.g. the following product categories:
 - Rehabilitation exoskeleton robot
 - Medicine dispensing robots
 - Digital therapeutics (DTx)
 - Digital medicine
 - Digital platform solutions
 - Remote monitoring solutions



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The Digi-HTA method

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The Digi-HTA assessment method is licensed under the [Creative Commons Attribution-Non Commercial-No Derivatives 4.0 International license \(CC BY-NC-ND 4.0\)](#).

How is the assessment done?

Experts from FinCCHTA and the University of Oulu assess the product from different perspectives. The assessment of key areas uses a "traffic light model" where the different areas are scored. FinCCHTA makes the conclusion based on the total score and agrees with the

Examples of Health Apps in the Digi-HTA process

Kaiku® Health Service for symptom management of cancer patients

Valid to: 09.2023

Information about the product

The Kaiku® Health service is a digital system that can be used to monitor the well-being of a patient with cancer. This service can be accessed via either a web browser or a mobile application. Through the service, the patient fills in symptom monitoring and a quality of life meter, and if necessary, the system sends information about the deterioration of well-being to the treating organization. The end user and the hosting organization can send non urgent messages through the system.

The device has a CE-mark. The device is a Class IIa medical device (Medical Device Directive (MDD) 93/42/EEC).¹

The manufacturer of the product is Kaiku Health Oy.¹

The company has an ISO 13485 quality management system in use.¹

Additional information

Language
 ✓ English ✓ Finnish ✓ Swedish ✓ Other: German, French

Certificates
 ✓ CE-marked ✓ Medical Device, level II a MDD

Quality control
 ✓ ISO 13485

Manufacturing/Distribution in Finland
[Kaiku Health Oy](http://KaikuHealthOy)
<https://www.kaikuhealth.com/>

Conclusion 23.6.2020



There is on thing to consider when using the product

The Kaiku Health service is suitable for monitoring the well-being of a patient with cancer during and after active cancer treatments. The service can help the patient manage their symptoms and get treatment when severe symptoms occur.

Conclusion is based on manufacturer data.

The Orla INR Remote Monitoring

Valid to: 01.2025

Information about the product

The Orla INR Remote Monitoring supports warfarin treatment with the help of self-measurement or self-care. The product consists of a mobile application intended for patients and a web-based service intended for professionals. The patient measures the INR value by using the Roche Diagnostics CoaguChek® INRange measurement device, which is connected to the Orla INR Remote Monitoring mobile application with a Bluetooth connection. The patient mobile application includes an electronic warfarin card and it seeks to remind the patient of the measurements to be made as well as to notify of any adjustments in the warfarin dosage made by the health care professionals. The patient's measurement data are available for the health care professionals with an access through the cloud service.

According to the company's declaration, this product is not a medical device, so it should not be used in any intended uses of the medical devices.

Additional information

Language
 ✓ Finnish ✓ Swedish ✓ English

Certificates
 ✓ CE-marked (NR-mittalaite)

Manufacturing/Distribution in Finland
[Orla INR Oy](http://OrlaINROy)
<https://orla.fi/web/Orla/terapian-ohjeet/orla-in-ohjeistot/>

Conclusion 19.1.2022



Use of product is recommended

The Orla INR Remote Monitoring is suitable for self-measurement or self-care of patients provided with warfarin treatment. Special attention must be paid to patient selection and patient counselling.

Conclusion is based on manufacturer data.

The first social welfare app is currently in Digi-HTA assessment process



Key findings during Digi-HTA assessments (1/2)

- Stronger research evidence about effectiveness would still be needed for several products
- The main identified shortcomings
 - Many cases there is evidence available in the perspective of healthcare organizations point of view but not for citizens or patients
 - The comparator group is missing
 - Valid indicators are not used
 - Measurements are subjective
 - The sample size in the studies has been small
 - Many peoples have discontinued their participation in the studies.



Key findings during Digi-HTA assessments (2/2)

- Although many products are classified as medical devices (MDD/MDR), the following problems or shortcomings were still observed
- Data security problems have also been typically identified in relation to the following
 - Passwords management
 - Unprotected or unverified software updates
 - One serious data security vulnerability found
- In terms of accessibility, the biggest challenge for many products has been to meet all the requirements set by the act on the provision of digital services.
 - Specially to fulfill WCAG 2.1 level AA requirements (not MDD/MDR requirement)



The current status

- Digi-HTA process provide informative recommendations for healthcare and social welfare decision-makers and public audience.
- There is no national level procurement or reimbursement decisions related digital health products and services at the moment in Finland
 - Well-being services counties make independent decisions related digital health
- Actions are ongoing EU-funded the Recovery and Resilience Plan (RRP) program with new wellbeing service counties how to better link Digi-HTA assessments to procurement and reimbursement decisions
 - The first procurement announcements, where Digi-HTA is included in the requirements, have been published.

Thank You!

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