A GUIDE ON EVIDENCE GENERATION FOR DIGITAL HEALTH TECHNOLOGIES IN THE CONTEXT OF SWEDISH HEALTH TECHNOLOGY ASSESSMENT

Evidence4Med.Tech

ABOUT THIS GUIDE

This work was developed by Adam S. Darwich and Bertil Guve at KTH Royal Institute of Technology with financial support from Medtech4Health VINNOVA as part of the VINN project grant number 2020-01905. We would like to acknowledge the support of Jari Haverinen (FinCCHTA), Björn-Erik Erlandsson (KTH), and eHälsomyndigheten.

The aim was to investigate what unique aspects are considered when assessing digital health technology products in context of the Swedish HTA (health technology assessment) system. For a broader perspective Swedish HTA, we refer the user to the following sources (Darwich *et al*. 2025; Evidence4Med.Tech 2025).

A mixed method was applied, combining a literature review with expert discussions, and an analysis of published regional HTA reports.

DIGITAL HEALTH TECHNOLOGIES

Here we define digital health technologies according to the European Commission, namely as tools and services that use information and communication technologies to improve prevention, diagnosis, treatment, monitoring and management of health-related issues or to monitor and manage lifestyle-habits that impact health (European Commission 2018).

WHAT THE GUIDE COVERS

This is a supplementary guide on evidence generation for digital health technologies in the context of the Swedish HTA system (also referred to as digital HTA here). The guide should be used together with the evidence generation tool, available at Evidence4Med.Tech.

FOR WHOM? AND HOW TO USE?

The material is aimed at innovators of digital health technology in start-ups, academia and healthcare. This document is meant to be an introduction to evidence generation for digital health technology and the current status of digital HTA in Sweden. Due to the changing landscape, it is not a comprehensive or exhaustive guide.

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TABLE OF CONTENT

DIGITAL HTA IN SWEDEN

Currently there is no national framework for health technology assessment (HTA) of digital health technologies or health apps in Sweden. (DigitalWell Arena 2024). As a result, many products lack evidence to support claims of benefit and safety in accordance with their intended use (eHälsomyndigheten 2022). Actors have raised the need for a national assessment and certification process based on relevant standards, technical specifications and frameworks (Swedish Medtech 2022).

Government organisations, agencies and key stakeholders have raised the need for national requirements for quality assurance of health apps and the appointment of an authority to be given the responsibility. This should be accompanied by a process for reimbursement (DigitalWell Arena 2024; eHälsomyndigheten 2022).

Ongoing initiatives exist with regards to digital HTA in Sweden, such as DigitalWell Arena, DigitalWell Ventures, Label2enable and NordDEC (DigitalWell Arena 2025; DigitalWell Ventures 2025; Label2Enable 2025; NordDEC 2025). The textbox below provides links to useful resources (underlined text). It is likely that a national assessment framework for health apps will be developed in the coming years.

Given the background we cannot formulate any definitive guidance on evidence generation for digital health technologies and health apps. However, it is reasonable to assume that any future national framework will be based on current initiatives as well as recent EU regulations and the ongoing discourse on health software assurance (such as, the health software technical specification, CEN-ISO/TS 82304-2:2021) (ISO 2025).

As it currently stands, we note a high methodological variability in regional HTA reports. These learnings are reported in the coming section.

CURRENT STATE OF DIGITAL HTA IN SWEDEN

The Swedish eHealth Agency's report on health apps

DigitalWell Arena's pre-study on quality assurance of health apps

INITIATIVES OF INTEREST TO INNOVATORS

Label2enable EU project on the develop-ment and testing of a label certification scheme based on CEN ISO/TS 82304-2.

DigitalWell Arena 10-year initiave on digital health innovation, with focus on enabling data use and digital technologies in health.

DigitalWell Ventures accelerator and incubator focusing on health tech and cyber security.

NordDEC assessment framework to meet digital health evaluation in the Nordics.

REGIONAL HTA REPORTS

- In total, 13 regional HTA reports assessed digital health products (between 2016 and 2024).
- The overall HTA process did not differ substantially for digital health products compared to other medical devices.
- Digital health technology-specific considerations included assessment with regards to patient data integrity, cyber security and data protection, integration with information technological systems, medical device software standards, among others.
- Similar to our previous findings, an overwhelming majority of reports found insufficient evidence to support product use.
- Study design issues and grading of evidence were common reasons for data exclusion.

Here is presented a summary analysis of regional HTA reports on digital health technologies. Results are contrasted with the broader analysis presented in the evidence generation tool and its accompanying publication (Darwich *et al*. 2025; Evidence4MedTech 2025).

Assessed Products A total of 13 regional HTA reports on digital health products were identified (published from 2017 to 2023, based on 92 HTA reports published from 2016 to 2024). These covered a broad range of products in the areas of remote and self-monitoring, digital interventions to prevent injury, promote health, treat conditions and disease. Table I gives an overview of the reports.

PICO: Patient Intervention Comparator Outcome

The table below provides a summary of PICO for the 13 regional HTA reports on digital health technologies. The colour coding corresponds to the following conclusions, *red: insufficient evidence*, *yellow: requires follow-up in case of implementation*, *green: evidence supports a positive effect of the technology*.

Regional Health Technology Asssessment Reports of Digital Health Products.

Patient/population	Intervention	Control	Outcome	Reference
In total, 26 defined patient groups	Remote self-monitoring as addition or replacement of existing care	Standard care without self-monitoring	Patient benefit, Risks, Costs	Region VG 2023
Pregnant women in maternity care	Use of the HealthyMoms app	Conventional care without the use of HealthyMoms app	Weight gain from enrollment at maternity care to end of pregnancy	Värmland 2023
Patients, aged 12 years and older, with heart failure or specialist care	Health data (physiological and patient reported variables) reported by patient to healthcare for assessment and feedback, using an app.	Standard care (physical visits)	Clinical effect: mortality, hospitalisation, length of treatment, health-related quality of life Negative effects: increased stress and concern for health due to technological issues Organisation: Patient flow, restructuring of healthcare organisaton Health economics: Costs, resource utilisation	CAMTÖ 2022
Patients, aged 12 years and older, with asthma or COPD	Mobile applications that transfer health data associated with asthma/COPD to healthcare for assessment and feedback.	Standard care (physical visits)	Clinical effect: Mortality, forced expiratory volume during one and six seconds, forced vital capacity, vital capacity, peak expiratory flow (L/min), patient adherence Negative effects: Adverse effects Organisation: resource utilisation Health economics: costs Ethics: health-related quality of life	CAMTÖ 2022
Patients, aged 18 years and older, with diagnosed arhrosis of the knee or hip	Digitally based physiotherapy education and training (through an app, online or telephone)	Clinic-based physiotherapy education and training in a group or individually	Function, pain, quality of life	CAMTÖ 2022
Patients with a need for self-registration of ECG	Self-registration of ECG	n/a	Diagnostic value compared to conventional ECG, or automatic assessment of ECG compared assessment by an experienced clinician	Sydöstra 2021
Individuals seeking contact with primary care due to symptoms	Digital triaging with AI-based interactive decision-making software where individuals seeking care register information and symtoms.	Conventional care, telephone contact with nurse for assessment, prioritisation and referral.	Agreement in prioritisation referral, accessibility, adherence to decision, patient safety (cyber security)	CAMTÖ 2021
Individuals with cardiac arrest outside of the hospital setting	SMS alarms to laypersons with self-assessed heart cardiopulmonary resuscitation that have registered in the app	Conventional care, CPR from rescue services and laypersons on the scene of the incident	Survival, time to start of CPR	CAMTÖ 2019
Patients in primary care with alcohol dependency in need of support and help to reduce alcohol consumption and prevention	Digital app Previct Alkohol alongside conventional treatment	Conventional care	Reduction in alcohol consumption and reduced number of relapses	Dalarna 2018
Persons seeking primary care for new symptoms	Digital care contact with sound and image at first contact with clinician	Conventional care	Number of conventional care visits at primary care	CAMTÖ 2018
Adults in hospital care	Fall preventive measures in the form of alarms	n/a	Number of falls, fall frequency, number of fall injuries	CAMTÖ 2018
Patients with chronic disease and regular care contact in the context of the Western World	Telemedicine	Conventional care	Outcome of chronic disease, care interventions / patient-managed care, cost effectiveness, patient reported experience	CAMTÖ 2018
Patients with heart failure, aged 18 years and older, receiving care in their home	Patient registration of body weight changes using electronic aids without a connection to healthcare systems	Manual registration of body weight, or no registration	Impact on patient-managed care, quality of life, effect on frequency of admissions to hospital	CAMTÖ 2017

Additional aspects considered during HTA The figure below presents health economic, organisational and patient ethical aspects considered during health technology assessment in the regions. Orange pentagons indicate aspects considered in regional HTA reports assessing digital health technologies.

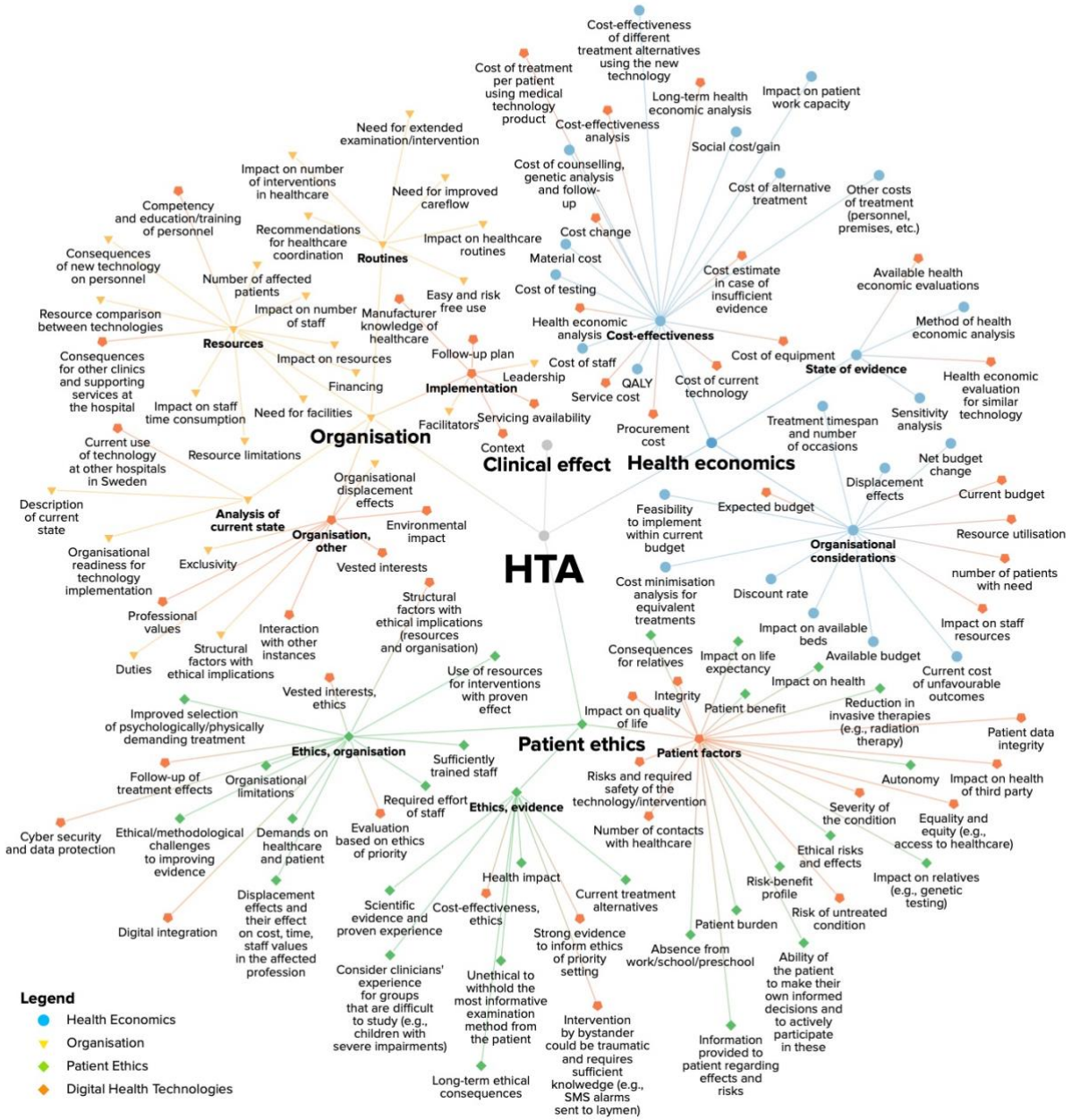

Figure. Map over aspects related to health economics, organisation and patient ethics considered during health technology assessment. Aspects identified in HTA reports related to digital health
Link to interactive map: https://embed.kumu.io/29c6cf290f24b45a1749d82ddc998b7f

EVIDENCE

Out of the 13 identified HTA reports, 12 concluded insufficient evidence, one report indicated a positive effect of the assessed product, and one report recommended follow-up following implementation.

Inclusion criteria In general, published randomised controlled trials and systematic reviews were the preferred sources of evidence. This is in line with previously analysed HTA reports, we therefore direct the user to general evidence generation tool (Evidence4Med.Tech 2025).

The break-down of included evidence across the reports were as follows: randomised controlled studies (n reports: 5), systematic reviews based on randomised controlled trials (n: 1), primary cohort studies with comparator (n: 3), systematic reviews (n: 3), PICO (n: 2), not stated (n: 3).

Reported reasons for excluding study data included wrong focus according to the defined PICO (n reports: 5 out of 13), wrong patient group (n: 2), wrong intervention (n: 2), lacking control group (n: 1), wrong study design (n: 2), wrong publication type (n: 3), high risk of bias (n: 1), wrong language of publication (n: 1), same dataset across published studies (n: 1), withdrawn publication (n: 1), other (n: 2).

Digital health technology specific considerations In general, HTA for digital health technologies were comparable to overall processes given in the regional reports. However, this varied widely.

Digital health technology-specific considerations included assessment with regards to patient data integrity, cyber security and data protection, integration with information technological systems, and the potential risk of remote monitoring due to fewer physical contacts between patients and healthcare.

The assessment of Coala Heart Monitor, published by Metodrådet i Sydöstra Sjukvårdsregionen (Sydöstra 2021), included an exceptionally comprehensive evaluation of conformity to relevant standards on hardware and software. A summary of considered standards are given in the textbox below.

ASSESSMENT OF PRODUCT FOR PATIENT REGISTRATION OF ECG

Assessment of relevant standards

IEC 60601-1 medical electrical equipment – general requirements for basic safety and essential performance.

IEC 60601-1-11:2015 medical electrical equipment – general requirements for basic safety and essential performance – collateral standard: requirements for medical equipment and medical electronic systems used in the home healthcare environment.

ETSI EN 300 328 Wideband transmission systems, data transmission equipment operating in the 2.4 GHz band

IEC 62133-2:2017 Secondary cells and batteries, lithium systems.

And relevant parts of:

IEC 60601-2-47 medical electrical equipment – particular requirements for the basic safety and essential performance of amulatory electrocardiographic systems.

IEC 60601-2-27 medical electrical equipment – particular requirements for the basic safety and essential performance of electrocardiographic monitoring equipment.

IEC 60601-2-25 medical electrical equipment – particual requirements for the basic safety and essential performance of electrocardiographs.

ANSI/AAMI EC57 testing and reporting performance of cardiac rhythm and ST segement measurement alrgorithms.

IEC 62304 medical device software – software life cycle processes

IEC 62366 medical devices - part 1: application of usability engineering to medical devices.

Source: Metodrådet i Sydöstra Sjukvårdsregionen. Egenmonitorering av hjärtrytm med Coala Heart Monitor. 2021-05-06

SUGGESTED CONSIDERATIONS

In the absence of a Swedish national framework, the diagram below provides a broad overview of initial considerations for evidence generation related to digital health technologies. Click the links (underlined text) to access additional information.

In addition, alternative digital HTA frameworks across Europe may be informative for setting the requirements during the evidence generation process (see the following section).

For international comparisons of digital HTA frameworks, we refer the user to the References section, Comparative studies and reports.

medical device

Is the software or product a medical device? The requirements of the Medical Device Regulations apply. Also, see Medical Device Software.

data protection and integrity

Does the product handle personal data and/or health data? The General Data Protection Regulation (GDPR) applies and recognises health data as a special category (Also, see health apps and the European Health Data Space). In Sweden, Patientdatalagen applies as a compliment to GDPR.

artificial intelligence

Is the product an Artificial Intelligence (AI) system? Check compliance with the EU AI Act.

usability and accessibility

Ensure accessibility of digital health products through the use of Web Content Accessibility Guidelines (WCAG) 2, conforming to AA level. See CEN ISO/TS 82304-2: 2021 on usability.

cyber security and integration

The NIS 2 Directive (EU 2022/2555) is a legal framework for cyber security of network and information systems, and includes the health sector. See, *e.g.*, CEN ISO/TS 82304-2: 2021 on interoperability.

frameworks

On evidence grading, see for example GRADE and the NICE process.
Internationally, and on an EU level, several digital health technology HTA frameworks exist. Sweden is yet to develop a process for digital HTA. Broadly speaking, the above suggestions are given. It is also likely that future models will be based on the CEN ISO/TS 82304-2:2021 (also, see Label2enable).

A BRIEF EUROPEAN PERSPECTIVE

The following table provides an overview of key aspects considered in several of the national frameworks developed for HTA of digital health products and health apps across Europe. Links are provided to additional resources.

Summary of select frameworks for assessment of digital health technologies

Frameworks	**Digi-HTA** Finland	**DiGAV** The Fast-Track Process for Digital Health Applications Germany	**DTAC** The Digital Technology Assessment Criteria for Health and Social Care United Kingdom	**mHealth Validation Pyramid** Belgium	**PECAN** France	**NordDEC** Denmark, Finland, Iceland Norway and Sweden	**Nævnet for Sundhedsapps** Denmark	**CEN-ISO/TS 82304-2:2021** **Health Software** **Part 2: health and wellness apps – quality and reliability**
Product(s)	Digital products and services for social care, healthcare and well-being (including robotics).	Medical devices, MDR class I or IIa based on digital technology. Medical purpose achieved through the main digital functions. Does not serve primary prevention. Used only by the patient or by the patient and the healthcare provider.	Digital health technologies.	A software application with a medical purpose that has a CE-marking and allows patients to share from their environment health-related information with a healthcare professional.	CE-marked digital medical device, including digital therapeutics and telemedical patient monitoring.	Medical devices, MDR class I or IIa based on digital technology. Medical purpose achieved through the main digital functions. Does not serve primary prevention. Used only by the patient or by the patient and the healthcare provider.	CE-marked medical device health apps and non-medical device health apps.	Health apps.
Select key aspects	**Effectiveness** Evidence is graded similarly to GRADE where randomised controlled trials preferred. Other assessments and recommendations taken into account. Considers evidence for clinical benefits, changes in client or patient behaviour, organisational benefits, promotion of social inclusion, functionality or well-being. **Safety** Risk analysis of any risks, side effects, or other undesirable effects. **Cost**. Implementation costs, training, integration with other systems, maintenance, other costs, uncertainties. **Data protection and information security** Life cycle, organisation and decommissioning. GDPR requirements (for additional information, See Jääskelä et al. 2022). **Usability and accessibility** Testing with user groups that match intended use. Following relevant standards, e.g., IEC 62366-1:2015, ISO 9241-210:2019, ISO/TR 16982:2002;. Technical accessibility according to EN 301 549; WCAG 2.1 and AA guidelines; iOS or Android accessibility features. **Interoperability** Interface with other systems and compliance with ISO/IEEE 11073 PHD. Interoperability with Kanta. **Technical stability** e.g., IEC 62304 on life cycle for medical devices. **AI** data sources, data collection, performance and continuity, decision-making. **Robotics** safety risks and mitigation, implementation. **Training and product support** **Distribution of the product**.	**Safety and suitability for use** valid certificate of conformity/declaration of conformity of the manufacturer. **Data protection** complying with GDPR and other data protection regulations. **Information security** based on relevant publications and recommendations of the Federal Office for Information Security (BSI), standards 200-1, 200-2, 200-3 and 200-4. And, supplemented by parts of the IT-Grundschutz catalogues, focusing on digital applications in healthcare. ISO 27001 implementation. **Interoperability** requirements according to Section 139e, paragraph 2 SGB V (e.g., ISO/IEEE 11073). **Further quality requirements** Robustness, Consumer protection, Ease of use, Support from healthcare providers, Quality of medical content, Patient safety. **Evidence of positive healthcare effects** Permissible evidence include observational descriptive/analytical studies, experimental intervention studies, meta-analyses.	**Clinical Safety** clinically safe to use. Development and maintenance of health IT systems according to the standard DCB0129. The standard DCB0160 applies to organisations where the health IT system is deployed. UK Medical Device Regulations 2002 Declaration of Conformity/Certificate of Conformity. **Data protection** compliance with regards to collection, storage and use of data, including personally identifiable data (e.g., UK GDPR). **Technical assurance** the product meets security standards. e.g., ISO/IEEE 11073 for wearables. **Interoperability criteria** should reflect standards within the NHS and social care. **Usability and accessibility** e.g., according to NHS Service Standard.	**MDR** CE certified medical device according to MDR. And, voluntary notification of app to the Federal Agency for Medicines and Health Products. **GDPR** Parent company and app comply with EU GDPR (General Data Protection Regulation) and the Belgian Chapter VII of the Act of December 13, 2006, on eHealth. **Secure connection and integration** Complying with ICT criteria Classification. For full ICT requirements, See the links below. **Interoperability** based on standards set by the Belgian eHealth platform. **Costs and financing.** **Socio-economic value** evidence and importance for care pathway.	**Meeting general safety and performance requirements** CE-marking. Technical specifications. **Innovation** in terms of clinical benefits or benefit with regards to organisational progress, based on first available data and any relevant comparators. **Clinical and/or organisational benefits** based on clinical studies. Preferably evidence from prospective, comparative, randomised, multicenter studies. Relevant endpoints and sufficient sample size. **Costs** Not mandatory. Evidence should be in real-world conditions. **Export of processed data** should be appropriate, interoperable, guarantee direct access to data. Or, include interfaces for data exchange. AI purpose, data, inputs relevant to decision-making, training, validation and testing. Functional characteristics, system robustness, resilience, explainability and interpretability.	**Effectiveness and Safety** Effectiveness assessed based on study design according to the tiers of NICE's Evidence Standards Framework (ESF) for Digital Health Technologies. **Data and privacy** including GDPR, regulations and Data Protection Impact Assessment (DPIA), privacy policy. **Professional assurance and clinical safety** If a medical device, the correct regulatory approval. Relevance of clinical safety assessment, competence of the responsible person, risk management process. **Usability and accessibility** e.g., WC3, WCAG 2.0 AA, WCAG 2.1 AA, ISO 9241, Apple HIG, Android App Quality Guidelines. **Security and technical stability** security across lifecycle, compliance with regulatory and data privacy obligations. Tests carried out, used testing standards, tools. Future product development. Data protection impact assessment (DPIA). **Interoperability** appropriate and secure data exchange, if applicable. NHS interoperabilities.	**Evidence for effect** For example, for CE-marked products this evidence should be in parity with risk classification. Graded according to study design, e.g., Level A - RCTs and systematic reviews. Level B - Cohort studies, etc. **User-friendliness** For example, usability testing, design and accessibility standards. **Pricing** Proportional to expected effects. **Societal value** Direct effects, such as cost reduction, and indirect effects, such as reduction of indirect costs. **Other evaluations** *e.g.*, DiGA, ORCHA, etc. **Interoperability** MedCom national system.	**Quality requirements for health and wellness apps. Including the following aspects:** **Quality Assessment.** **Product information** to customers and users. **Health and safety** health requirements, risks, ethics, health benefits, societal benefits. All sources of information disclosed. Maintenance process for health information. Evidence assessed according to NICE's Evidence Standards Framework (ESF) for Digital Health Technologies. **Costs** to achieve health benefit. Funding sources, advertising. **Technical robustness** Validation and verification plan. IEC 62304-1:2016. Measures to avoid user errors and misuse. Secure coding standard. **Interoperability** access to specifications and implementation guides. User access to personally identifiable information. Data validation. **Accessibility and usability** user-centred assessment. usability assessment plan, age-appropriate. Avoid misuse. **Secure data** Privacy and Security. Secure-by-design process. Secure programming standard. Warnings and notices. Validate received data. Authentication. Data retention policy. **Product safety and lifecycle process** ISO/IEC 27001. **Ethical considerations** **Medical devices.** The medical device regulations apply.
Resources	About Digi-HTA FINCCHTA The Digi-HTA model. Haverinen 2024 The Digi-HTA process. Haverinen et al. 2022 The Digi-HTA Assessment model and Inernational Comparison. Haverinen et al. 2024 Digi-HTA Information Security and Data Protection. Jääskelä et al. 2022	DiGAV Guide Comparison of DiGAV and Digi-HTA. Merja et al. 2023 DiGAV for Class IIB and Remote Monitoring Apps DiPA – Digital Care Apps Guide	DTAC – Digital Technology Assessment Criteria, NHS, England ORCHA – The Organisation for the Review of Care and Health Apps ESF – Evidence standards framework for digital health technologies, NICE, UK	mHealth Belgium Guide to Approval for Digital Health Apps – Quickbird Medical	PECAN Digital advance care G.NIUS, France Comparison of PECAN and Digi-HTA. Teemu et al. 2024	NordDEC – Nordic Digital Health Evaluation Criteria Comparison of NordDEC and Digi-HTA. Suominen et al. 2023 ESF – Evidence standards framework for digital health technologies, NICE, UK	Nævnet for Sundhedsapps, Lægemiddelstyrelsen, Denmark	ISO/TS 82304-2:2021 Quality label for health Apps, Label2enable Quality label of health apps. Biliunaite et al, 2024 Comparison of CEN/ISO TS 82304-2:2021 and Digi-HTA. Souminen et al. 2023 ESF – Evidence standards framework for digital health technologies, NICE, UK

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