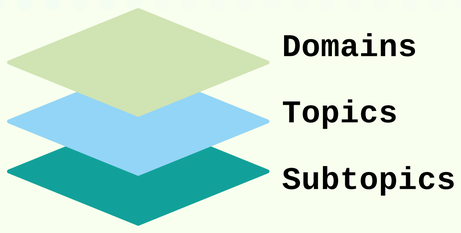
EDiHTA FRAMEWORK

The first European Digital Health Technology Assessment framework co-created by all stakeholders in the European Health Ecosystem

EDiHTA

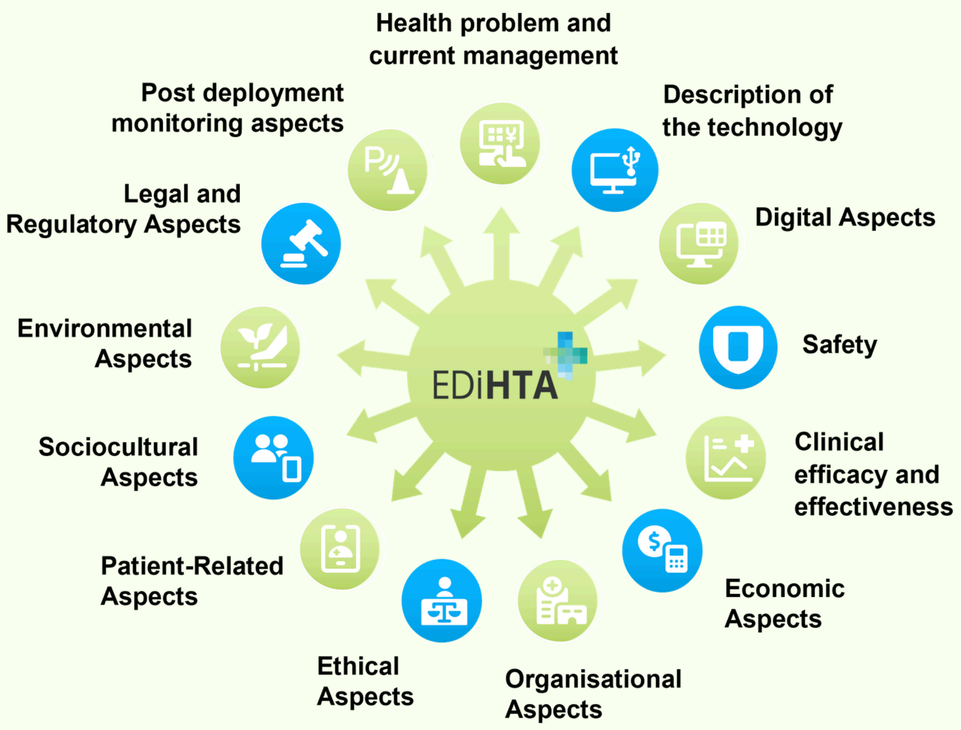
A harmonised EU framework for the evaluation of digital health technologies

The EDiHTA framework introduces a comprehensive and methodologically robust approach to assessing digital health technologies (DHTs) across Europe. This comprehensive framework will be harmonised across the EU to better capture the value of DHTs. Building on the architecture and standardised terminology of the EUnetHTA Core Model, the framework is organised into three structural layers.



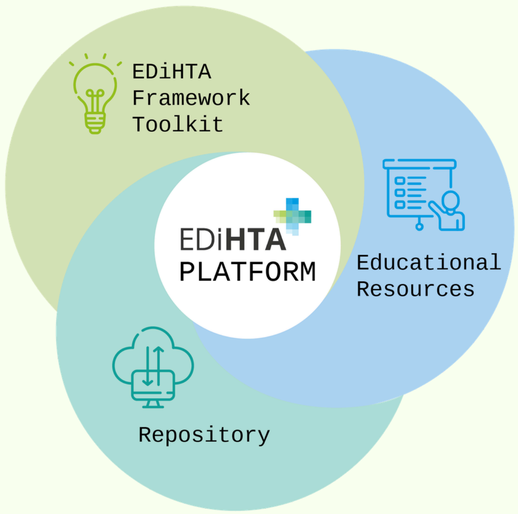
This structure enables a consistent and transparent evaluation process, supporting HTA agencies, decision-makers, researchers, patients, healthcare providers and developers/manufacturers in generating and using meaningful and comparable evidence for decision-making.
Each domain will provide information relevant to the lifecycle evaluation of the technology, supported by evidence requirements, measures and methods needed for the assessment.
By embracing a common methodology, EDiHTA aims to streamline evaluation pathways, enhance cross-border collaboration, and build readiness for the evolving European HTA landscape.

13 EDiHTA domains



Excellence and harmonisation in HTA of DHTs

The EDiHTA framework represents a strategic investment in Europe's capability to evaluate DHTs consistently, efficiently, and in a future-oriented manner. By providing a harmonised structure, clear methodology and practical digital tools, EDiHTA empowers stakeholders to navigate the evolving digital health landscape with confidence and clarity.



3 pillars of the EDiHTA platform that will be hosted in a digital environment and will be accessible for all stakeholders

A framework supported by purpose-built tools, repository and educational material

To ensure practical usability, the EDiHTA framework is complemented by tools to guide stakeholders (HTA practitioners/doers and beneficiaries/users) through the evaluation process, educational materials for using the framework, as well as an open-access repository of studies on the assessment of DHTs. More specifically, these pillars will address:

1 Pillar I: EDiHTA Framework Toolkit

Descriptive tool and stakeholder guidance

An informative, easy-to-navigate toolkit designed to introduce the EDiHTA framework to all healthcare stakeholders. It offers:

- Definitions of domains, topics, subtopics, with their related outcomes, methods and evidence requirements,
- Practical guidance to support consistent interpretation,

This toolkit strengthens a shared understanding and fosters alignment across diverse user groups and contexts.

Interactive tool for HTA doers

A dedicated tool that supports HTA doers in preparing and conducting assessments. This tool enhances operational efficiency and ensures uniform application of the EDiHTA methodology across HTA agencies, healthcare providers (clinicians, managers) and research teams. It helps users to:

- Identify the criteria relevant to the specific DHT,
- Tailor assessments based on lifecycle stage and context,
- Streamline the scoping and planning process.

Interactive tool for developers/manufacturers

A tool designed for developers/manufacturers. It enables lifecycle self-assessment by providing:

- Context-specific guidance on evidence requirements,
- Insights on lifecycle considerations and regulatory expectations,
- A structured approach to aligning product development with future evaluations.

This capability supports better-informed innovation and prepares developers for formal assessment pathways with an HTA-readiness assessment.

2 Pillar II: Open-Access Repository

A publicly accessible document library that will become a European reference point for evidence, methodologies and outcomes related to DHT evaluation. It will contain:

- Existing reports, methodologies and outcomes for the evaluation of DHTs,
- Future reports and methods where the EDiHTA framework will be applied.

3 Pillar III: Educational Resources

A comprehensive platform that will offer educational resources for all stakeholder groups and promote capacity building around the evaluation of DHTs across Europe, providing:

- Introductory modules on the use and application of the EDiHTA framework,
- Capacity-building resources for participation in HTA processes,
- Guidance for evaluators, developers/manufacturers, decision-makers and end-users.

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EDiHTA

EDiHTA Domains

Health problem and current management	Description of the health problem including epidemiology (prevalence, incidence), disease burden on individuals and society, physiopathology, natural history and the target population among which the digital health technology is applied or expected to be applied. It reports also the information regarding the current management of the condition and the specific context to which it is applied.
Description of the technology	Description of the digital health technology characteristics (e.g., design, operational features, evidence-based content, material requirements, needed training), including the context and conditions in which it is introduced, the purposes for which it is intended, the level of care at which it is applied and the regulatory status (certifications or licenses, compliance with recognised standards).
Digital aspects	Evaluation of the technological elements and functions that shape and characterise the digital health technology, including usability, interoperability, adaptability, reliability, technical stability, algorithmic performance metrics, generic reproducibility, interpretability and transparency to ensure that algorithmic processes are explainable and free from bias, and manageability and compatibility, including evaluations of system monitoring processes and error handling.
Safety	Evaluation of risks and unwanted, undesired or harmful effects arising by using digital health technology. This includes physical and psychological risks (clinical safety) as well as risks in terms of privacy or quality of information (technical safety).
Clinical efficacy and effectiveness	Evaluation of the clinical benefits and the impact on health status and quality of life of the digital health technology, compared to standard or alternative interventions, under controlled conditions (i.e., ideal circumstances for assessing efficacy), or uncontrolled conditions (i.e., under usual health care practice for assessing effectiveness).
Economic aspects	Evaluation of the costs (costs of acquisition, maintenance and use both at the patient/user and health system level) of the digital health technology and economic evaluation of it compared to existing alternatives.
Environmental aspects	Evaluation of the direct and indirect environmental impact associated with the development and implementation, use and disposal of digital health technology.
Organisational aspects	Evaluation of the organisational impact of the digital health technology and of the infrastructure and resources needed to be mobilized and organized to implement the technology (e.g. human resources and workload, skills and knowledge, training, work culture, attitudes and material artefacts).
Ethical aspects	Evaluation of the ethical concerns of the digital health technology, i.e., prevalent social and moral norms and values that the digital health technology itself constructs and influences in the (socio-political, cultural, legal, religious and economic) context in which it is implemented or intended to be used.
Patients-related aspects	Evaluation of patients', healthy individuals' and caregivers' perspectives that may have an impact on the use of the digital health technology (i.e., experiences, attitudes, preferences, values and expectations, such as acceptability to use the digital health technology, ease of using the digital health technology, digital health literacy, commitment/adherence to the digital health technology, perceived benefit of the digital health technology).
Sociocultural aspects	Evaluation of sociocultural impact that the digital health technology may have (e.g., accessibility to the service or health care, changes in workflows and roles, modification in the doctor-patient relationship, etc.) with respect to specific groupings of patients or individuals, such as older people, people living in remote communities, people with learning disabilities, ethnic minorities, immigrants etc.
Legal and regulatory aspects	Evaluation of the degree to which digital health technology complies with the regulations, rules and standards of the country/region in which it is planned to be implemented.
Post-deployment monitoring aspects	Description of the mechanisms established for post-deployment assessment of the digital health technology by its developers and/or those responsible for its management.

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