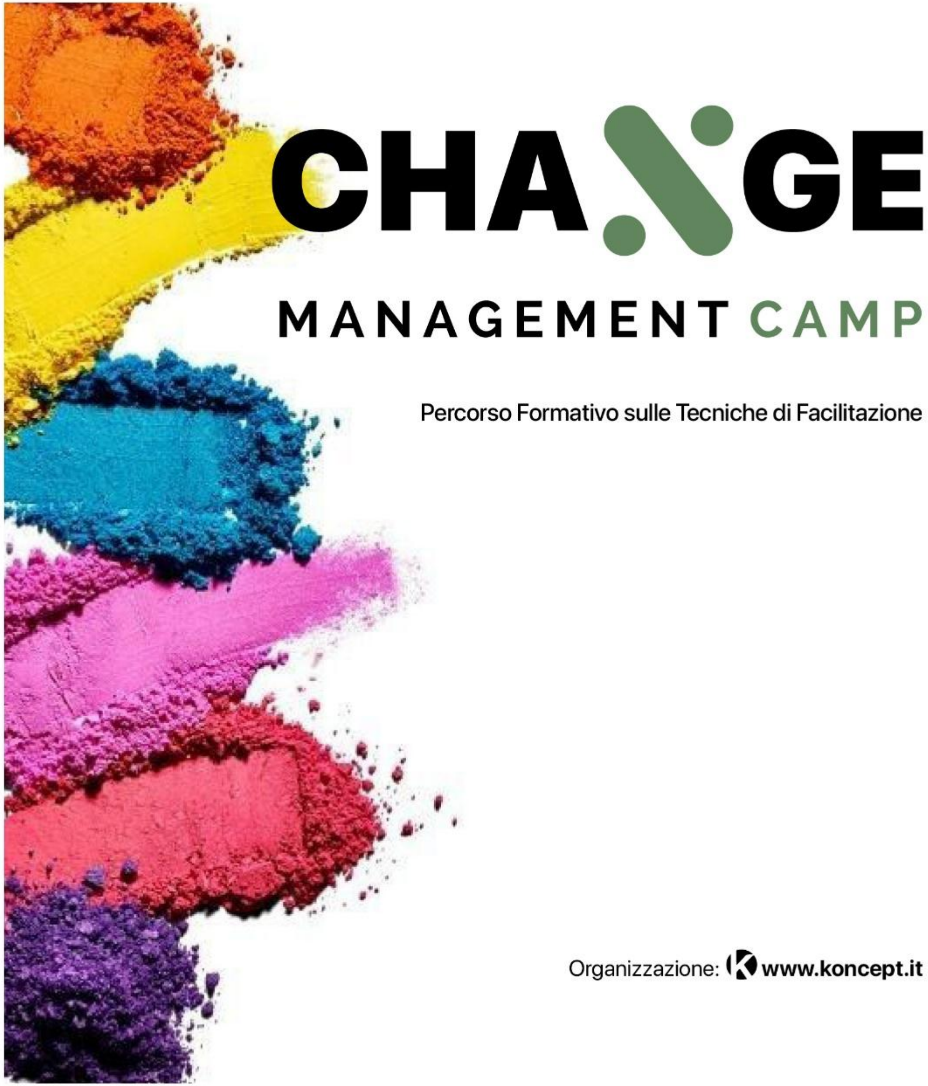


# L’IA in Italia: analisi e percorsi per un’adozione sostenibile

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# Health Technology Assessment

A **multidisciplinary process** that uses explicit methods to determine the **value of a health technology** at different points in its lifecycle. The purpose is to inform decision-making in order to promote an equitable, efficient, and high-quality health system.

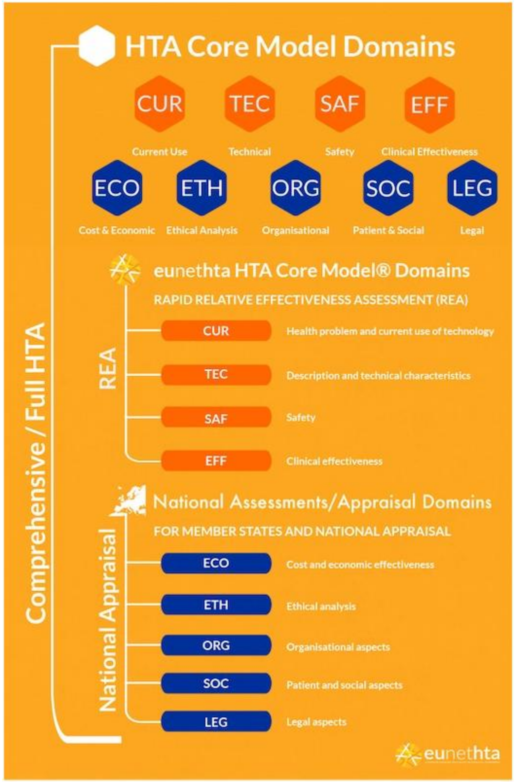
**Note 1**: Definition of **health technology.**
**Note 2:** The process is **formal, systematic and transparent**, and uses state-of-the-art methods to consider the best available evidence.
**Note 3:** The dimensions of value for a health technology may be assessed by examining the intended and unintended consequences of using a health technology **compared to existing alternatives**.
These dimensions often include clinical effectiveness, safety, costs and economic implications, ethical, social, cultural and legal issues, organisational and environmental aspects, as well as wider implications for the patient, relatives, caregivers, and the population. The overall value may vary depending on the **perspective** taken, the stakeholders involved, and the decision context.
**Note 4:** HTA can be applied at different points in the **lifecycle** of a health technology, i.e., **pre-market, during market approval, post-market, through to the disinvestment** of a health technology.

# Livelli del HTA

- Regolamento Europeo di HTA
- Agenzie nazionali di HTA
- Regioni
- ASL, Ospedali, IRCCS

- Finalità
- Responsabilità
- Processi decisionali
- Tempistiche
- Stadio di sviluppo della tecnologia

# EUnetHTA model




- European Network for Health Technology Assessment (EUnetHTA) is a network, established to create an effective and sustainable structure for health technology assessment (HTA) across Europe that could develop and implement practical tools to provide reliable, timely, transparent and transferable information to contribute to HTAs in Member States.

- The overall strategic objective of the network is to connect public national/regional HTA agencies, research institutions and health ministries, enabling an effective exchange of information and support to policy decisions by the Member States.

- EUnetHTA consists of a total of 83 organisations from 27 EU member states plus Norway, Switzerland, Ukraine, and the UK.

- A path of three different joint actions from 2020 to 2021 to develop the core model.

# Si valuta l’IA?

HEALTH INFORMATION TECHNOLOGY

DOI: 10.1377/hlthaff.2024.00842
HEALTH AFFAIRS 44, NO. 1 (2025): 90–98


By Paige Nong, Julia Adler-Milstein, Nate C. Apathy, A. Jay Holmgren, and Jordan Everson

## Current Use And Evaluation Of Artificial Intelligence And Predictive Models In US Hospitals

Data from the 2023 American Hospital Association Annual Survey Information Technology Supplement to identify **how AI and predictive models are used and evaluated for accuracy and bias in hospitals**.

- **61%** of hospitals that used models evaluated them for **accuracy** using data from their health system (local evaluation).
- Only **44%** reported **local evaluation for bias.**

**Descriptive statistics of artificial intelligence (AI) and predictive model use in US hospitals, 2023**

| | Number | Weighted percent |
|---|---|---|
| Use of any machine learning or other predictive models that display in the EHR | 2,425 | 100 |
| Machine learning | 887 | 33 |
| Other non–machine learning predictive models | 809 | 32 |
| Neither | 482 | 23 |
| Do not know | 247 | 11 |
| Specific uses of machine learning or other predictive models, among hospitals that integrated models into the EHR | 1,688 | 100 |
| Predict health trajectories or risks for inpatients | 1,569 | 92 |
| Identify high-risk outpatients for follow-up care | 1,380 | 79 |
| Facilitate scheduling | 849 | 51 |
| Recommend treatments | 772 | 44 |
| Simplify or automate billing procedures | 633 | 36 |
| Monitor health | 600 | 34 |
| Other (clinical use cases) | 548 | 34 |
| Other (operational process optimization) | 442 | 25 |
| Developer of predictive models used by the hospital, among hospitals that integrated models into the EHR | 1,689 | 100 |
| EHR developer | 1,381 | 79 |
| Third-party developer | 995 | 59 |
| Self-developed | 909 | 54 |
| Public domain | 77 | 4.4 |
| Local evaluation of most or all models for accuracy or bias[a] | 1,660 | 100 |
| Model accuracy | 1,009 | 61 |
| Model bias | 711 | 44 |
| Model accuracy and bias | 709 | 44 |

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# A cosa date la priorità?

OPEN TALKS

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# Le peculiarità dell'IA

**Human and cognitive (clinicians)**

- Disruption of interpersonal **communication styles** (eg, clinician-clinician and clinician-patient)
- AI as clinical mind: challenge of clinician's decision-making autonomy
- Absolute confidence in AI: **technical dependence**

**Clinical**

- Actual clinical added value in a real-world context of care and services: **difficult to distinguish the effect of the AI's decision from the rest of the preventive and/or therapeutic strategy**

**Professional and organizational**

- How will it fit into the patient care and **services trajectory**?
- What changes will result in terms of **service organization** (eg, waiting time)?
- How will it impact on professional jurisdictions (eg, reserved activities, **responsibility**, training, new skills,

**Technological aspects**

- Laboratory performance versus a **real-world** context of care and services
- **Data quality and representativeness** of the general population or other contexts

**Economic**

- **Investments** required: continuous performance tests, software and data quality tests, infrastructure and equipment upgrades, human expertise, and training
- Need of new financing mechanisms, appropriate **remuneration** and/or reimbursement models, and insurance models

**Legal and ethical**

- **If the AI makes a mistake (eg, black box), who will be held responsible? If the patient is harmed?**
- What would be the consequence if the **clinician does not comply with the recommendations of an AI and this leads to an error**?
- **Who owns the data? Who is responsible for it?**

# EU project

https://edihta-project.eu/

EDiHTA

## The first European Digital Health Technology Assessment framework co-created by all stakeholders along the value chain (EDiHTA)

HTA methods, hospital based HTA, health economics, AI, coordination, pilot site

Ministero della Salute

Italian Ministry of Health
Policy maker

agenas

Regulatory aspects, health care management, quality assurance

**EDiHTA solution**

- ✓ We are set to deliver the first innovative and first of its kind **digital HTA framework** that will be developed to assess digital health technologies
- ✓ **Flexible and customized** to the lifecycle level of the technology
- ✓ Integrates existing methodologies into a newly **co-created framework** where all relevant stakeholders are involved

# Formazione AI e HTA

Il Laboratorio di Health Technology Assessment (HTA) e Intelligenza Artificiale si pone i seguenti obiettivi:

1. Contribuire alla definizione dei metodi di HTA e degli standard di evidenze per le tecnologie sanitarie basate sull'IA;
2. Condurre valutazioni di HTA delle tecnologie sanitarie basate sull'IA;
3. Supportare nella valutazione e nell'implementazione delle soluzioni dell'intelligenza artificiale a supporto del management ospedaliero;
4. Condurre attività di ricerca mirata sulla valutazione secondo i principi e le logiche del HTA delle tecnologie basate sull'IA;
5. Sviluppare nuovi progetti e collaborazioni, a livello nazionale ed internazionale, sul Health Technology Assessment (HTA) e l'Artificial Intelligence.

Il Laboratorio quindi svolge attività di ricerca, consulenza e formazione.

https://altems.unicatt.it/altems-laboratori-e-osservatori-health-technology-assessment-hta-ed-intelligenza-artificiale

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# How to HTA?

**Che serve per gli ospedali per governare veramente la transizione che promette l’IA?**

**Competenze nuove, Unità nuove?**