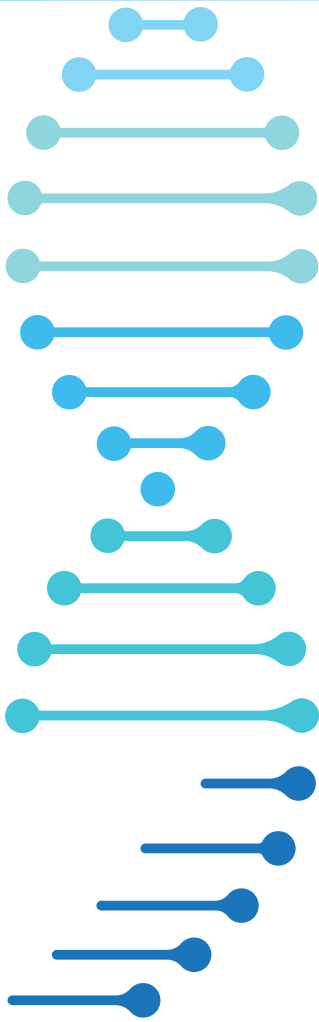


# PROPHET TOOLBOX FACTSHEET#4

JUNE 2025



## PROPHET FRAMEWORK

 **ROPHET**

a PeRsOnalized Prevention roadmap  
for the future HEalThcare

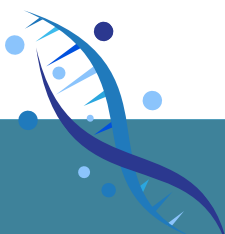
# Why a dedicated Framework was developed?



In the context of the PROPHET Project, a multidimensional framework was developed to appraise and support the implementation of personalized prevention (PP) approaches that include genomic applications within healthcare systems.

Despite growing interest in personalized prevention, existing frameworks do not adequately address the impact of policies implementing personalized prevention approaches (PPA). Most available models are primarily based on the ACCE framework—which takes its name from its evaluation components: Analytic validity, Clinical validity, Clinical utility, Ethical, legal and social implications—and on Health Technology Assessment (HTA). Pitini et al. listed 30 different frameworks used in genetic and genomic evaluation, recommending the European Network for Health Technology Assessment (EUnetHTA) HTA core model as the standard for assessing genomic technologies.

However, these models lack the scope to evaluate the health impact of implementing a policy, and do not put at the center of the evaluation the stakeholders' involvement and the equity aspects in formulating the recommendations.



# Methodology

The PROPHET Framework integrates three complementary components—HTA, Health Impact Assessment (HIA), and Monitoring—in a participatory evaluation approach in order to guide the appraisal and implementation of PP policies. This integrated methodology ensures that interventions are not only clinically and technically effective, but also equitable and sustainable when implemented in healthcare systems.

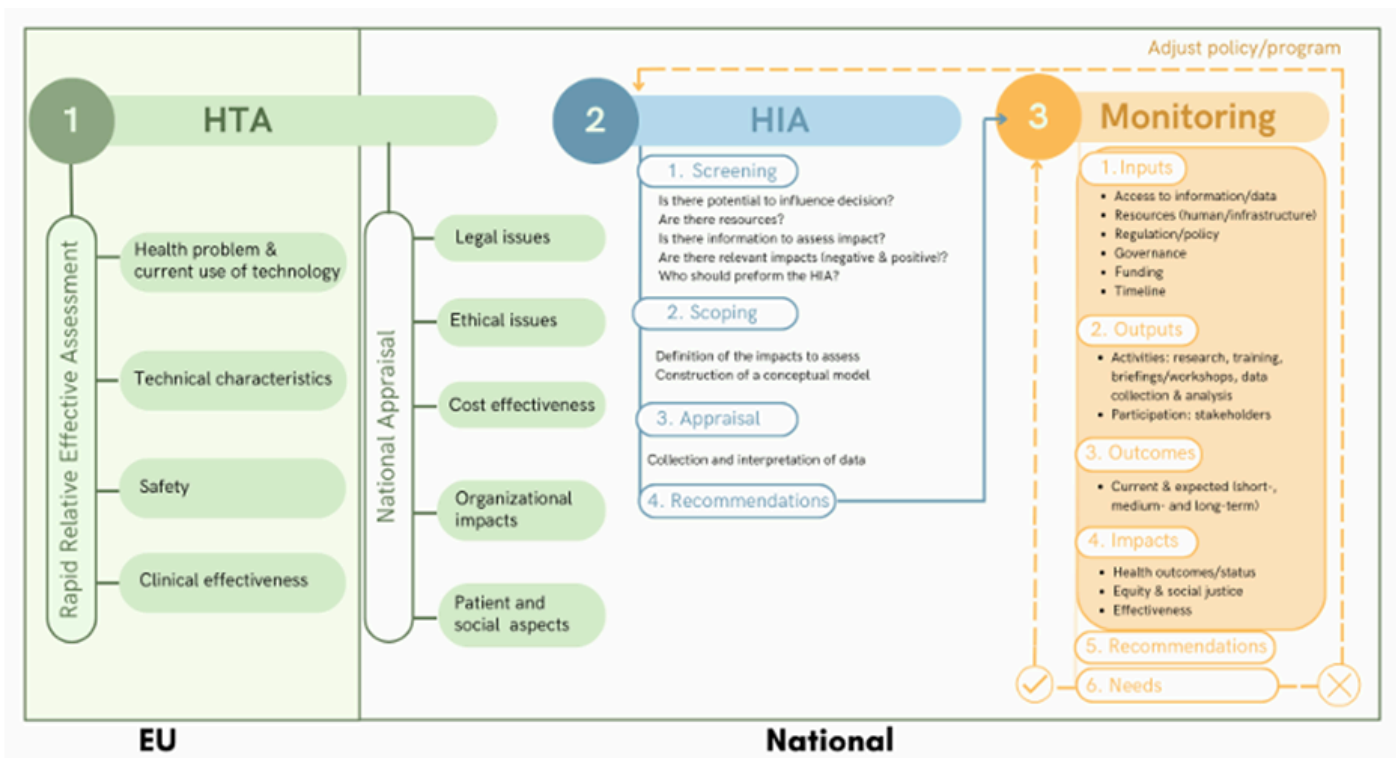
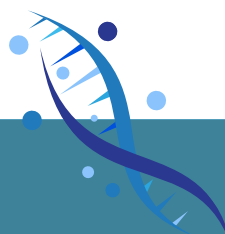


Fig.1 The PROPHET Framework



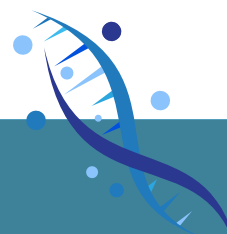
## 1 **Health Technology Assessment (HTA)**

HTA is a widely recognized method for evaluating health technologies, particularly medical devices and drugs. It considers multiple dimensions, including clinical effectiveness, safety, cost-effectiveness, organizational impact, organizational and patient aspects, and ethical, legal and social implications.

There is growing support for applying HTA to genetic tests, especially as a first step in evaluating personalized preventive interventions. A scoping review by Pezzulo et al. confirmed that HTA is the most frequently used framework for assessing genetic and genomic tests in PP. The study also outlined key indicators for evaluating clinical utility, such as analytical validity, clinical validity, and clinical efficacy—dimensions that are particularly relevant for the HTA component of the PROPHET Framework. The approach recommended by the framework aligns with the new European HTA regulation for other types of technologies, suggesting that key dimensions such as clinical effectiveness and safety be assessed at the European level, while context-specific dimensions should be evaluated at the national level.

## 2 **Health Impact Assessment (HIA)**

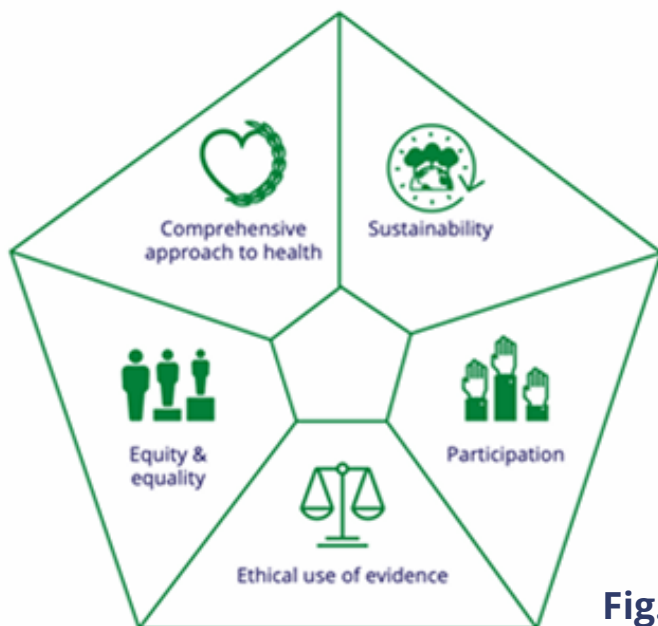
While HTA focuses on evaluating technologies, it often overlooks broader policy implications such as equity and acceptability. To address this gap, the PROPHET Framework incorporates HIA as a complementary tool of HTA.



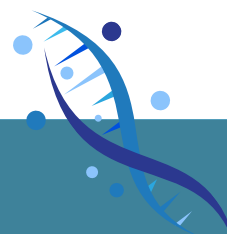
HIA is specifically designed to assess how PP policies affect health determinants, populations, societal well-being, and equity. This approach allows for a more comprehensive appraisal of PP strategies, gathering stakeholders' perspectives and supporting better-informed and more inclusive policymaking. As highlighted by Costa et al., engaging stakeholders and elevating visibility is essential to scale up and embed PP strategies within health systems.

According to WHO, HIA can be defined as *"a combination of procedures, methods and tools by which a policy, program or project may be judged as to its potential effects on the health of a population, and the distribution of those effects within the population"*.

Five core principles enhance the focus on social determinants of health: a comprehensive approach to health, equity & equality, stakeholder participation, ethical use of evidence, and sustainability.



**Fig.2 Core principles of HIA**



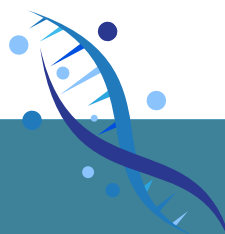
HIA is inherently prospective, aiming to inform decisions before policy implementation. It can also be done retrospectively, in which cases the HIA becomes closer to an outcome evaluation.

**The PROPHET Framework structures HIA into five sequential phases:**

- **Screening:** the first phase aims to determine the need and relevance of an HIA and a technical team is assembled to lead the process.
- **Scoping:** the focus shifts to identifying key issues, setting assessment priorities, and developing a conceptual framework. A stakeholder steering committee is also created to ensure inclusivity and diverse perspectives.
- **Assessment:** this is the core phase, combining qualitative and quantitative data to evaluate health impacts.
- **Reporting:** findings, challenges, and recommendations are documented in a transparent, decision-oriented report.
- **Monitoring and evaluation:** the objective is to define what aspects need to be monitored, including key indicators to track impact over time.

This approach is highly adaptable to the policy evaluation and design procedures of each country. The assessment can be conducted by extending the HTA evaluation, carried out at the national level on context-specific dimensions, and integrating the core principles and methods of HIA. It can also be carried out during the design phase of the policy or retroactively, to assess the need for modifications and adjustments, which may emerge during the monitoring phase.

The application of HIA in the context of PP represents an innovative extension of HIA, traditionally not used in this context.



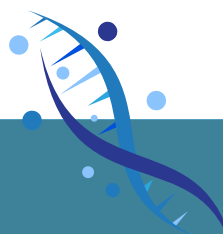
### 3 **Monitoring**

The PROPHET Framework includes a structured monitoring component to ensure the long-term effectiveness and adaptability of personalized prevention policies.

#### **Monitoring based on the logic model framework, which organizes the evaluation of implementation through four key elements:**

- **Identify Inputs:** gathering all the essential resources and data needed for monitoring.
- **Define Outputs:** immediate results of the policy being implemented—e.g., the number of individuals who did a personalized risk assessment or the training of healthcare professionals in specific PP areas.
- **Categorize Outcomes:** the expected short-, medium-, and long-term changes or benefits expected, such as increased awareness.
- **Assess Impacts:** broader effects on society, including improvements in quality of life and health system performance.

Indicators should be defined before policy implementation and developed in collaboration with stakeholders to reflect shared priorities and goals. This proactive approach enables timely tracking of progress and early detection of challenges. If monitoring reveals adverse trends or unmet objectives, the policy can be adjusted to optimise effectiveness and resource use.



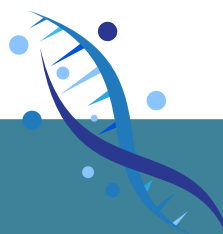
# Key Strengths

- **Multidimensional:** Combines clinical evidence with social, organizational, and ethical insights.
- **Stakeholder-Centered:** Involves policymakers, clinicians, and patients.
- **Practical:** Supports prospective (and retrospective) policy appraisal.
- **Scalable:** Adaptable to national and regional healthcare contexts.

The development of the PROPHET framework was supported through the analysis of a case study on *DPYD* genotyping in colorectal cancer patients treated with fluoropyrimidines, carried out across Portugal, Italy, and Finland. It was further validated through two case studies conducted in Italy: a national approach to implementing *BRCA 1/2* testing for the personalized prevention of hereditary breast and ovarian cancer, and the implementation of a population-based approach for therapy personalization through the use of a **Pharmacogenetic Passport**.

## Policy Relevance

The PROPHET Framework offers a robust, ready-to-use model for policymakers and healthcare leaders to assess personalized prevention initiatives across Europe. It ensures that new PP interventions are not only scientifically valid but also ethically sound, economically viable, and system-ready for sustainable scaling.



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More about the project on our website: <https://prophetproject.eu/>  
And follow us on LinkedIn:

