



Affordability and Sustainability  
improvements through new pricing, Cost-  
Effectiveness and Reimbursement models  
to Appraise iNnovative health  
technologies

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Webinar „Ongoing research on medical devices“

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# Key facts

- **Funding Programme:** Horizon Europe
- **Project Lead:** Erasmus University Rotterdam (Contact: Carin Uyl-de-Groot, project manager: Marcel Langone Marques)
- **Project partners:** Comenius University Bratislava, **Gesundheit Österreich GmbH**, University of Oslo, Association Internationale de la Mutualité (AIM), Nuromedia GmbH, European Hematology Association (EHA), Myeloma Patients Europe (MPE), Chino SRL and OptiMedis.
- **Duration:** 1 Dec. 2022 – 30 Nov. 2026 (4 years)
- **Budget:** EUR ~ 5 Mio. Euro
- **Project website:** <http://www.access2meds.eu/>



## Enhance current methods of (value-based) pricing, cost-effectiveness modeling, threshold-setting, reimbursement, and payment

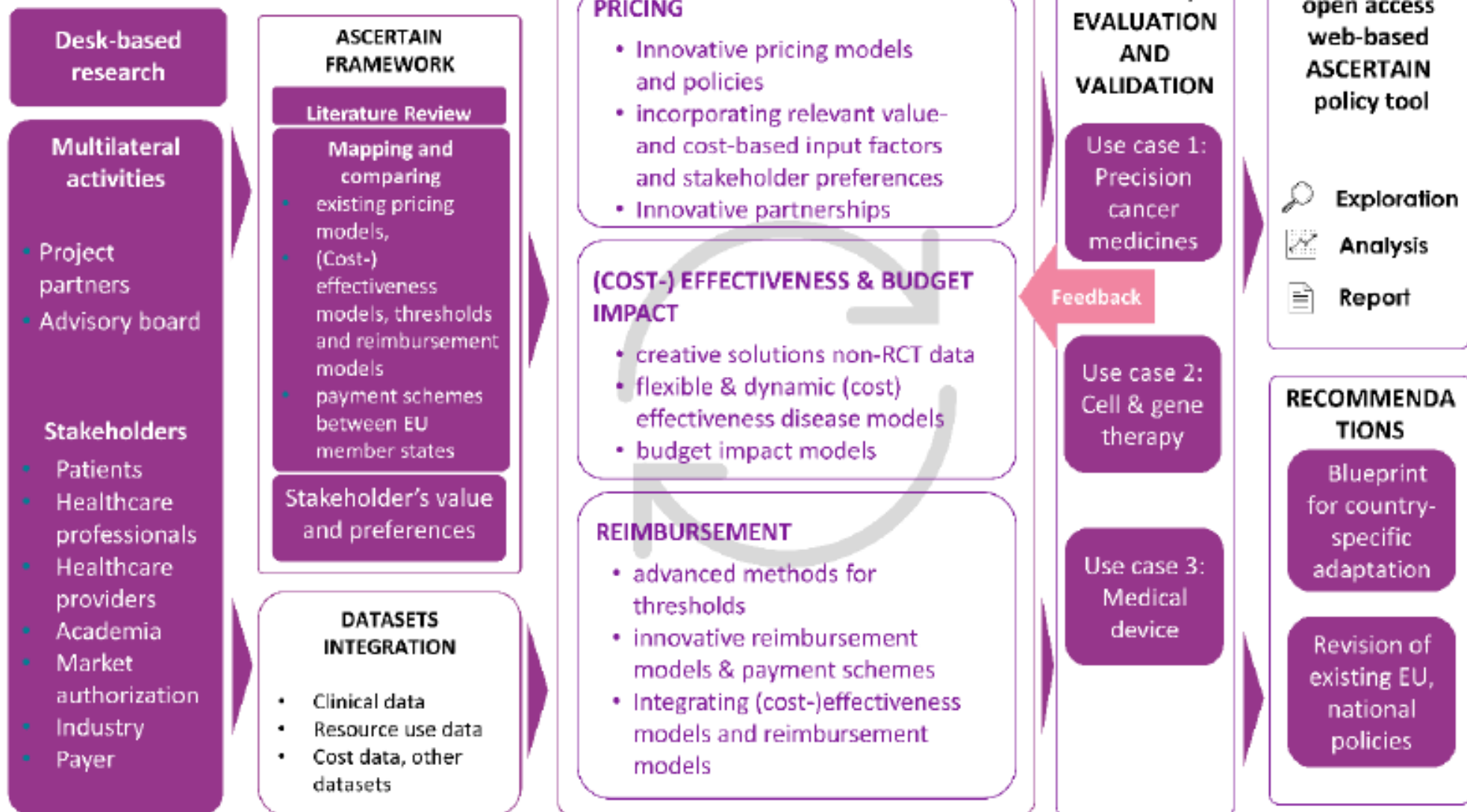
- ASCERTAIN addresses the need of patients, physicians, payers, regulators, and manufacturers to improve the affordability and accessibility to innovative health technologies (including pharmaceuticals) in Europe.
- Set affordable prices, and to facilitate a cyclic assessment of broader societal benefits including costs and risks.
- Seek to find a sustainable balance between access to affordable technologies, the need to stimulate innovation and entrepreneurship, and the need to consider the environmental impact of innovations.

Stakeholder involvement

Open-access, easy to use, policy-supporting tools including (i) pricing models, (ii) value assessment models, and (iii) reimbursement models, which will be adaptable to country-specific conditions

## Project summary

- Based on a **conceptual framework** integrating pricing, health technology assessment and reimbursement/ payment
- **Improve transparency and accountability** of decision-making, **reduce uncertainty** for all stakeholders, **reward innovation** in areas of high unmet need, accelerate access for patients, and support long-term planning in a sustainable way.
- These tools will be developed, tested, and validated for **three use cases**, including precision cancer medicine, cell- and gene therapy, and medical devices (class IIb and III) or in vitro diagnostic (IVD) class D.
- Complemented by an **international advisory board** consisting of key stakeholders, with whom the policy-supporting tools will be co-created
- All tools will be hosted on a **cloud-based, publicly accessible, user-friendly platform** following open science principles.





# Work Packages

1. Project management and coordination
2. Data management, privacy and ethics
3. Developing the ASCERTAIN framework (Task Lead)
4. Pricing methods for IHTs (WP Lead)
5. (Cost-)effectiveness and budget impact models for IHTs
6. Reimbursement for IHTs
7. Web-based platform to access ASCERTAIN models as a policy support tool
8. Dissemination and exploitation

Task 3.5 Selection  
case study medical  
devices

# Task 3.5 Selection case study medical devices

- to identify and select approved (in EU and US) medical devices (MDs, class II and III) or invitro diagnostics (IVD, class C or D) which are focused on cancer (applied in oncology and/or haematology) → **We need your support!**
- From the **perspective of your organisation**, what are the **most important approved medical devices (MDs) or in vitro diagnostics (IVDs)** which are focused on **cancer (applied in oncology and/or haematology)**? Please provide the **most important examples** and **explanation of importance**.

Importance might include: a potential significant impact on patients, public health or healthcare systems; covers an unmet medical need; provides essential modality in the patient pathway; has a significant cross-border dimension; has a major Union-wide added value; are first-in-class; or, incorporates software using artificial intelligence, machine learning technologies or algorithms.

MD or IVD Product name	Manufacturer	Explanation of importance

Feedback till  
15th June



# Additional slides



# WP 3 – Developing the ASCERTAIN framework

- Task 3.1 – Vertical stakeholder engagement and consultation
- Task 3.2 – Monitoring the evolving environment in the pharmaceutical and medical device sector and possible impact of changes to the ASCERTAIN framework
- Task 3.3 – Mapping the current state of the art
- Task 3.4 - Compilation and development of a global ASCERTAIN framework
- Task 3.5 – Selection case study medical devices

Developing new approaches for pricing innovative technologies (elements, principles and algorithms of novel pricing policies that take the value and cost perspective into account)

## WP4 - Pricing methods for IHTs

**Lead: GOEG**

**Involved partners:** AIM, EUR, MPE, EHA, UNIBA, UIO,

**Timeline:** M6-M36 (May'23-Nov'25)

### Task 4.1

Development of algorithms fitting each use case to estimate prices for IHTs

### Task 4.2

Testing verification and validation of the models

### Task 4.3

Final pricing policy proposal refinement