

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.

Stakeholder involvement

- 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.



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 countryspecific 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.





Desk-based research

Multilateral activities

- Project partners
- Advisory board

Stakeholders

- Patients
- Healthcare professionals
- Healthcare providers
- Academia
- Market authorization
- Industry
- Payer

ASCERTAIN FRAMEWORK

Literature Review

Mapping and comparing

- existing pricing models,
- (Cost-)
 effectiveness
 models, thresholds
 and reimbursement
 models
- payment schemes between EU member states

Stakeholder's value and preferences

DATASETS INTEGRATION

- Clinical data
- Resource use data
- Cost data, other datasets

MODELS

and policies

PRICING

IMPACT



· Innovative pricing models

· incorporating relevant value-

and cost-based input factors

and stakeholder preferences

(COST-) EFFECTIVENESS & BUDGET

creative solutions non-RCT data

effectiveness disease models

Innovative partnerships

flexible & dynamic (cost)

budget impact models

Associated with doon Ref. Ares(2022)8121591 -:

TESTING, EVALUATION AND VALIDATION

Use case 1: Precision cancer medicines

Feedback

Use case 2: Cell & gene therapy

Use case 3: Medical device Integrated open access web-based ASCERTAIN policy tool



Exploration



Analysis



Report

RECOMMENDA TIONS

Blueprint for countryspecific adaptation

Revision of existing EU, national policies

REIMBURSEMENT

- advanced methods for thresholds
- innovative reimbursement models & payment schemes
- Integrating (cost-)effectiveness models and reimbursement models



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

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- 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

Gesundheit Österreich

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

