Patient-centered, societally oriented, real-time decision-making on access to and reimbursement for health technologies throughout Europe
HTx: Vision for a new generation of HTA

- Imagine an individual patient who visits the doctor for a medical problem. The **doctor knows this patient’s clinical history** (including her use of different health technologies, such as medical devices, e-health technologies and drugs), **her preferences and health outcomes**.

- Adequate clinical studies and real-world data analysis have resulted in a **real-time decision support system that the doctor and the patient can use to obtain person-centered information** (in a user-friendly format) about risks, benefits, outcomes and costs associated with a range of possible strategies to manage the patient’s ailment.

- The **same information is made available to HTA agencies whose decisions are informed by means of this information**, analysed at the level of individuals and summarised at the subgroup and population level for the benefit of payers’ decision-making. **This framework is what we envision as HTx.**
What is Health Technology Assessment?

EUnetHTA definition:
Health technology assessment (HTA) is a multidisciplinary process that summarises information about the medical, social, economic and ethical issues related to the use of a health technology in a systematic, transparent, unbiased, robust manner.

Its aim is to inform the formulation of safe, effective, health policies that are patient focused and seek to achieve best value.

Source: https://www.who.int/health-technology-assessment/about/Defining/en/
About the HTx project

• HTx is a Horizon 2020 project supported by the European Union, kicking-off in January 2019 and lasting for 5 years.

• The main aim of HTx is to create a framework for the Next Generation Health Technology Assessment (HTA) to support patient-centered, societally oriented, real-time decision-making on access to and reimbursement for health technologies throughout Europe.
Objectives

• HTx will facilitate the development of methodologies to deliver more customized information on the effectiveness and cost-effectiveness of complex and personalised combinations of health technologies.

• HTx will also provide methods to support personalised treatment advice that will be shared with patients and their physicians.

• Finally, HTx will in close collaboration with the European Network for HTA (EUnetHTA) and its stakeholders pilot the implementation of these methods in Europe.
The concept of HTx

Stakeholders

HTA
Payers
Healthcare Providers, clinicians
Regulators
Patients/consumers
Pharma/medtech Technology industry/SMEs

Systems

Advanced analytics
RWE methods development
Rapid updates systems
Technology Appraisal and Clinical guidelines synergies

Learning healthcare systems + Data + Infrastructure

Combinations
Personalised Medicine (incl. diagnostics)
Treatment pathways
Outcomes in priority disease areas
Chronic diseases, multimorbidity
Orphan diseases

Projects and Products/Knowledge

Projects and Products/Knowledge

Interventions

Therapeutic areas

Projects and Products/Knowledge

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Consortium partners

- Utrecht University (project coordinator) (UU) Netherlands
- University of Copenhagen (UoC), Denmark
- University of Oulu (UoO) Finland
- University of York (UoY) UK
- Medical University of Sofia (MUS) Bulgaria
- University of Bern (UBERN) Switzerland
- Universidad Politecnia de Madrid (UPM) Spain
- European Organisation for Research and Treatment of Cancer (EORTC) Belgium
- Dental and Pharmaceutical Benefits Agency (TLV) Sweden
- National Health Care Institute (ZIN) Netherlands
- National Institute of Health and Care Excellence (NICE) UK
- Syreon Research Institute (SRI) Hungary
- Synapse research management (SYNAPSE) Spain
- EURORDIS Rare Diseases Europe (EURORDIS) France
- University of Maastricht (UM) Netherlands
Consortium partners

University of Utrecht
Project Coordinator
Advisory boards – HTx Forum

Role:
• to discuss the broader implications of methods and tools developed in project for society and healthcare systems.

Participants:
• senior representatives of the most important stakeholder groups, which are patients and consumers, payers, healthcare providers, technology producers and also regulators and HTA bodies.
Advisory boards – Expert Forum

Role:
• more of a scientific advisory board

Participants:
• representatives of relevant H2020 and IMI projects
• representatives from other organisations that play an important role in setting tools and methods for guideline development (e.g. ISPOR, Cochrane/GRADE, HTAi, ISPE)
HTx Project structure
Work Packages

• **WP1** Treatment pathways in specific therapeutic areas
• **WP2** Using real world data for evidence synthesis
• **WP3** Using artificial intelligence to forecast individualised treatments
• **WP4** Implementation into systems and processes
• **WP5** Transferability and dissemination
• **WP6** Scientific coordination and project management
WP1 Treatment pathways in specific therapeutic areas

- The specific objectives of this work package are:
  - To assess and determine average and individualised **real-world effectiveness and cost-effectiveness of health technologies and combinations** in the case studies.
  - To predict **real-world impact of treatment decisions** in the case studies.
  - To **explore generalisability of the results** of the case studies to other settings and jurisdictions.
WP2 Using real world data (RWD) for evidence synthesis

- The objectives of this work package are to enrich the methodological arsenal related to the use of RWD in order
- To facilitate the HTA of different treatment modalities including health technology combinations and treatment pathways
- To take into account personalised treatment choices
- To make real-world predictions of health outcomes at the population and individual level.
WP3 Using artificial intelligence (AI) to forecast individualised treatments

• The overall objective of WP3 is
• to support the further development of artificial intelligence (AI)/machine learning (ML) systems that can analyse data from different sources in order to predict individual patient treatment outcomes.
WP4 Implementation into systems and processes

- The specific objectives of this work package are:
- **International consensus building on the HTx methods.** That will include building consent between HTA organisations in Europe and between HTA organisations, regulators and guideline developing organisations.
- To increase patient-centricity in decision-making.
- To support the development of flexible funding and reimbursement models for complex health technologies. This also includes the assessment of the transferability of these models throughout Europe.
WP5 Transferability and dissemination

- The specific objectives of this work package are:
- To evaluate and support the transferability of knowledge and methods gained from case studies and analyses to Central and Eastern European countries;
- To develop and implement an extensive and targeted dissemination plan;
- To empower and engage patient representatives in HTX implementation.
WP6 Scientific coordination and project management

• The specific objectives of this work package are:

• To ensure the **project management and scientific coordination** of the overall project.

• To act as the **primary contact to the commission** with respect to legal, financial and administrative tasks