Future-proof HTA

The need for innovative HTA methods for more complex and personalized medicine

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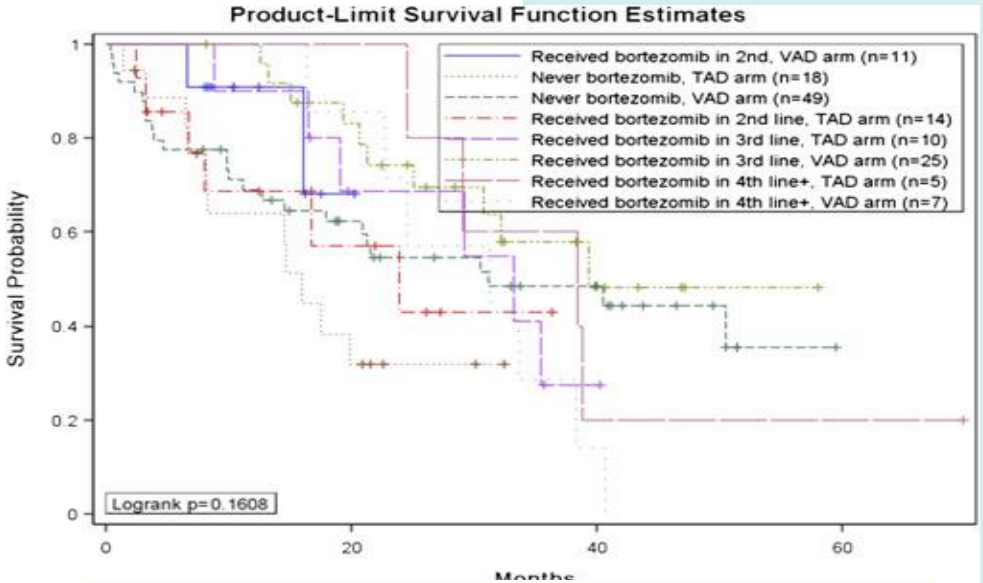
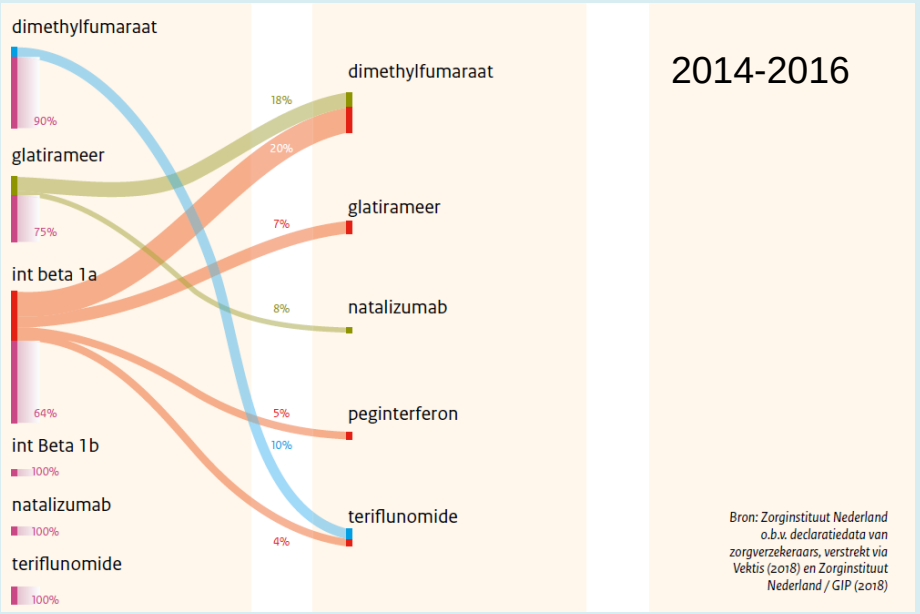
New realities?

MM treatment in NL daily practice



Franken, MG. et al. Policymaker, Please Consider Your Needs Carefully: Does Outcomes Research in Relapsed or Refractory Multiple Myeloma Reduce Policymaker Uncertainty Regarding Value for Money of Bortezomib? Value in Health 2014, Volume 17 , Issue 2 , 245 - 253

MS treatment in NL daily practice



Changing HTA paradigms (future-proof HTA?)

- **Personalized treatments**
  - Smaller populations
  - Combinations of treatments, different sequences
  - Companion diagnostics (genetic testing)

Next Generation Health Technology Assessment

- **Real world evidence (RWE)**

eunethta
EUROPEAN NETWORK FOR HEALTH TECHNOLOGY ASSESSMENT

- **Internationalization**
  - Clinical assessments on an European level for single technologies (pharma and medtech)


EUROPEAN COMMISSION

Brussels, 31.1.2018
COM(2018) 51 final

2018/0018 (COD)

Proposal for a

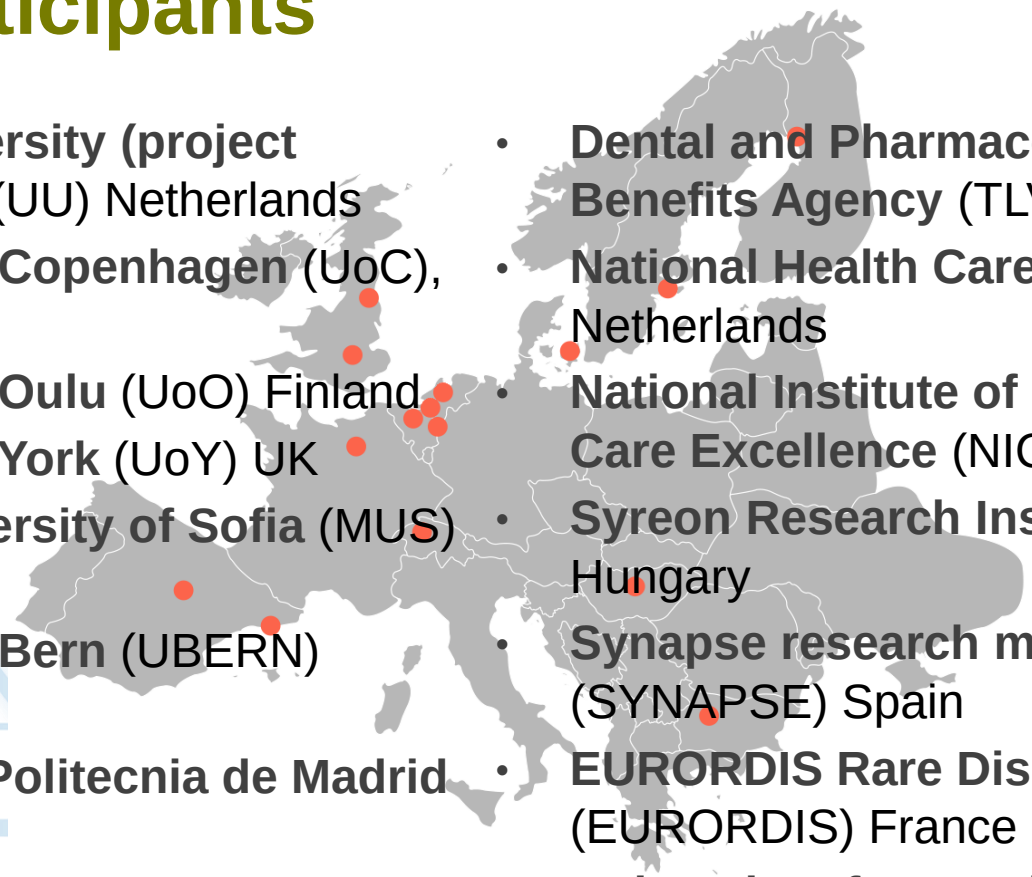
REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

on health technology assessment and amending Directive 2011/24/EU

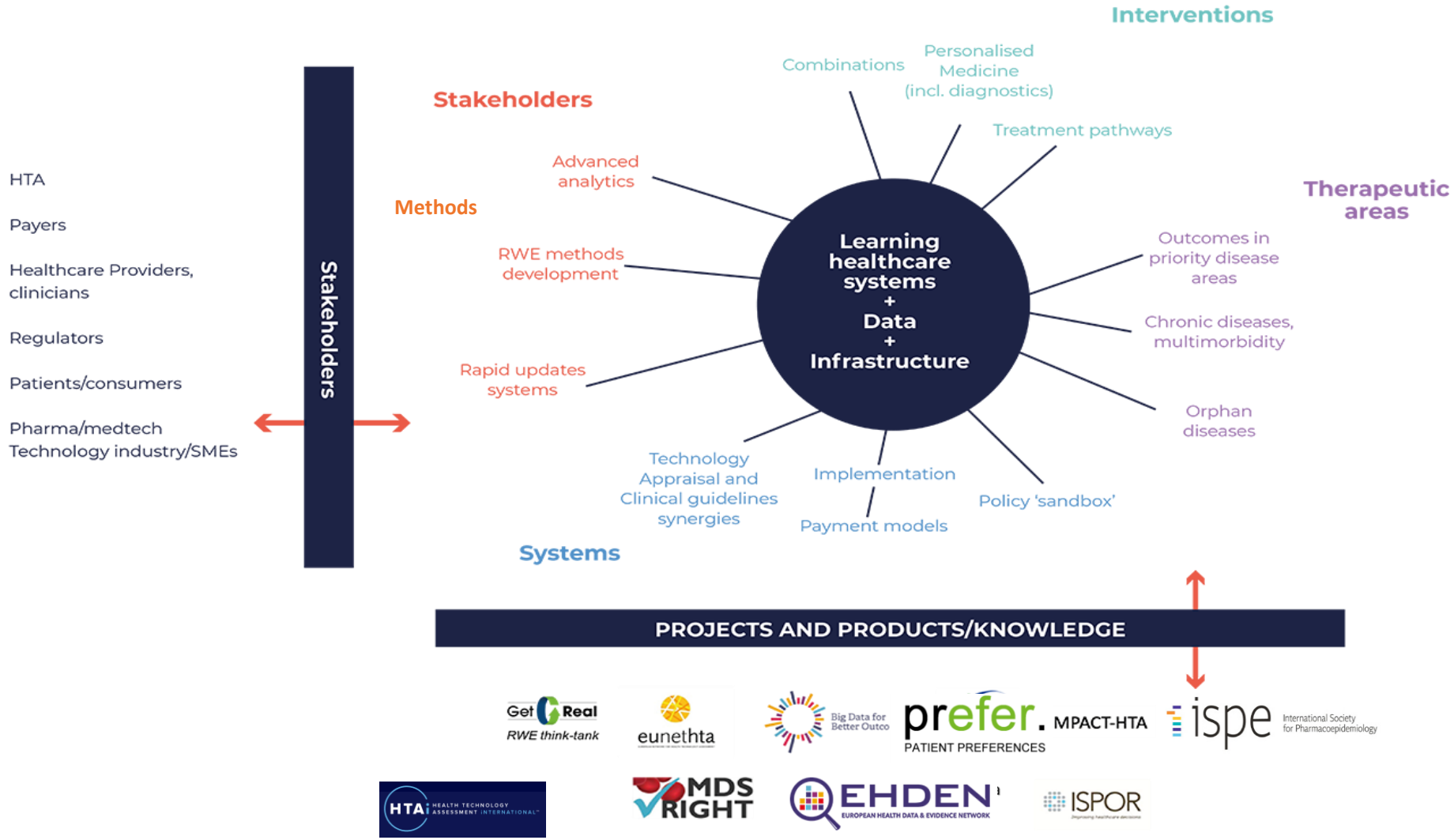
About the HTx project

- **Horizon 2020 project** supported by the **European Union**, kicking-off in **January 2019** and lasting for **5 years**.
- Facilitate the development of methodologies **to deliver more customized information on the effectiveness and cost-effectiveness of complex and personalised combinations of health technologies.**
- Provide methods **to support personalised treatment advice** that will be shared with patients and their physicians.
- In close collaboration with the European Network for HTA (EUnetHTA) and its stakeholders **pilot the implementation of these methods in Europe.**

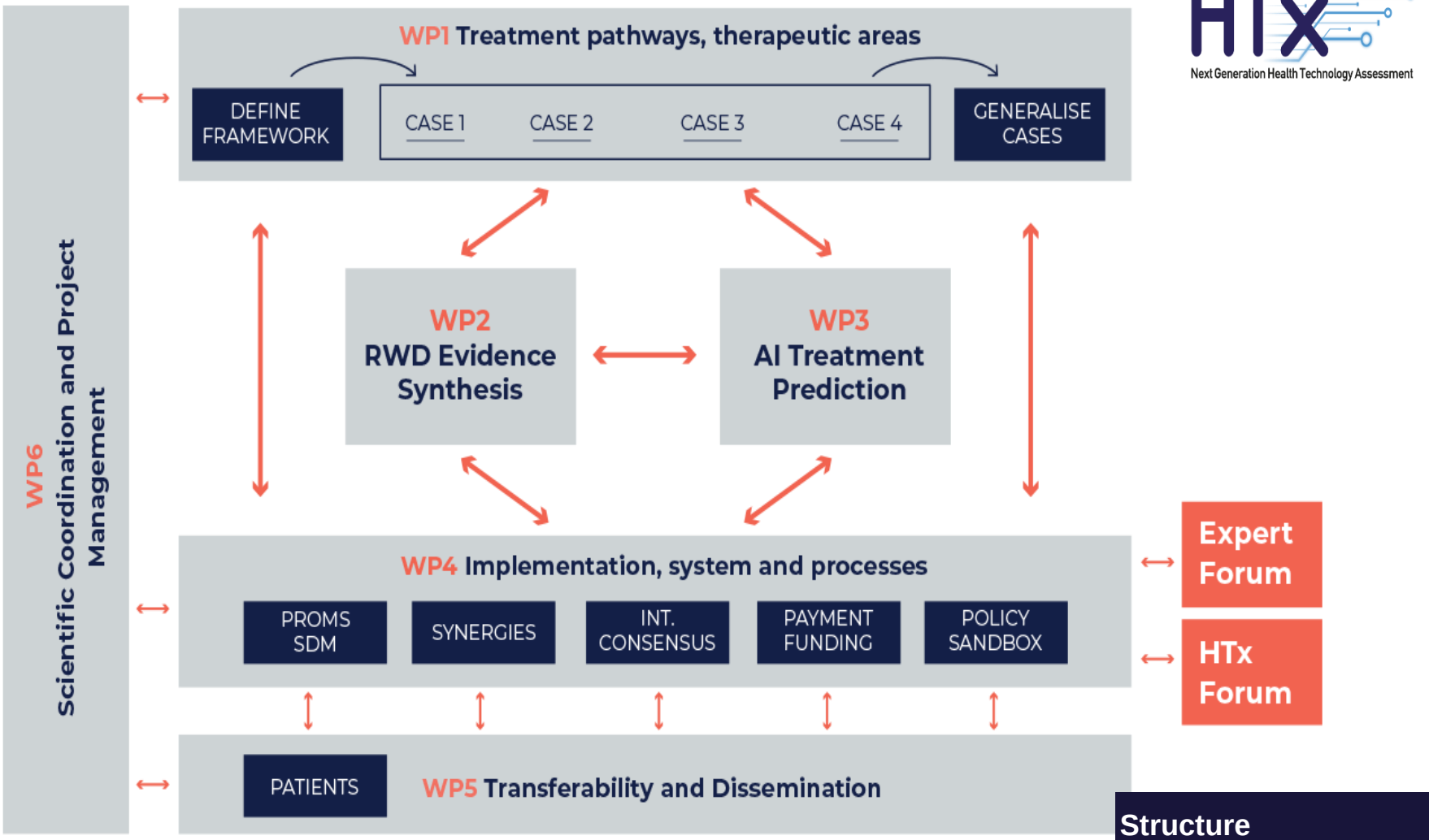
HTx – Participants



- **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



Concepts



Next Generation Health Technology Assessment

Structure

Methods

- Prediction modelling on the basis of data using different study designs (RCT, RWD etc) (WP2)
- Health-econometric tools to take into account effects and costs (WP2)
- Develop AI/ML methods to forecast individual patient treatment outcomes (WP3)

Focus on combinations (and/or sequences) of health technologies not evaluated in RCT as such

WP1

Case studies

- Proton therapy for head and neck cancer
- Monitoring and treatment pathways in diabetes (T1DM and T2DM)
- Pharmacological treatments for relapsing multiple sclerosis (MS)
- Different treatment modalities in patients with myelodysplastic syndrome (MDS)

Including framework to generalize results to other indications and settings

WP1

Implementation and transferability

- Developing PROMS that are fit for purpose
- Link to flexible funding and reimbursement models
- International consensus on RWD and resulting HTx models between HTA, regulators and guideline developers
- Transferability of case study findings and methods across participating countries
- Develop and disseminate training materials to patients

WP1

How can success of HTx be measured?

- Clear methods developed for certain disease area's;

- Are practically used in healthcare practice
  - By HTA organisations to facilitate HTA for personalised treatments (including support appropriate use);
  - By healthcare providers as part of new guidelines
  - For individual patients and their clinicians

- Provides a general framework that can help other groups to develop methods for specific disease areas

- Has a clear link to national reimbursement and pricing processes.