The CORE-RWE Methods Research Project

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As precision medicine and real-world evidence (RWE) reach a critical juncture, we at Vlerick HMC, in collaboration with KU Leuven, are launching the CORE-RWE (Causal Observational Research for Effectiveness using Real World Evidence) Methods Research project.

CORE-RWE will build the methodological foundation for using real-world evidence in health technology assessment and outcome-based payment decisions. By integrating Causal Machine Learning with Target Trial Emulation, it aims to deliver credible, comparable, and policy-relevant effectiveness estimation methods for high-impact medical innovations.

CORE-RWE's goal is to leverage current sentiment across Europe to develop a unified approach to assessing, evaluating, and implementing outcome-based payments for medical therapy technologies based on Real-World Evidence (RWE). From a geoeconomic perspective, this initiative will serve as a consortium for methodological research partnerships among biopharmaceutical and MedTech companies, in collaboration with European Health Technology Assessment (HTA) bodies. Our broader aim is to enhance Europe's competitiveness in accessing biopharmaceuticals and medical technologies by reliably and sustainably validating health innovations through RWE.

CORE-RWE aims to uncover the real-world effectiveness of drug or device-based therapies while designing innovative payment models based on their claimed performance through risk-sharing agreements. It addresses important policy questions, such as how much real-world evidence is sufficient for treatment access and whether and how causal machine learning can enhance the credibility of comparative estimates for cell and gene therapies, managed chronic precision therapies, and medical device interventions that involve structural and information-gathering components, especially when direct randomised controlled trials (RCTs) are impractical or provide unreliable initial pre-market therapy outcome data.

CORE-RWE will conduct research to validate the use of Causal Machine Learning (CML) within a Target Trial Emulation (TTE) framework. This study will apply the Bayesian Comparative Effectiveness method and utilise synthetic population-based disease models to evaluate two types of therapies: a single-administration curative therapy and a complex adaptive longitudinal therapy in both the biopharmaceutical and MedTech fields.

The EAA Spring Convention's adjunct session "How to leverage RWD for HTA – conceptual overview & case studies" will focus on the challenges and opportunities that RWE presents for conducting outcome assessments. We will emphasise the importance of designing a robust evaluation methodology that fosters trust among all parties involved. To illustrate these points, we will provide examples from both the biopharma and MedTech sectors.