HORIZON-HLTH-2026-01-DISEASE-11

Understanding of sex and/or gender-specific mechanisms of cardiovascular diseases

Background: Cardiovascular diseases (CVDs) are the leading cause of premature death in the European Union and represent a major burden for health systems and societies. While sex-based biological differences are increasingly recognised, they do not sufficiently explain the persistent gender-related disparities observed between women and men. Social roles, working conditions, income, education, caregiving responsibilities, cultural norms, health literacy, nutrition, physical activity, and structural biases in healthcare systems and treatment regimens fundamentally shape CVD risk and therapeutic pathways and outcomes. However, existing risk prediction models, clinical guidelines, and pharmacovigilance systems insufficiently capture the interaction between sex-based and gender-related determinants.

Project outline: This project addresses sex- and gender-related disparities in CVDs through an interdisciplinary framework that integrates biomedical research with social and behavioural science as well as gender studies. Its central innovation lies in strengthening and transforming pharmacovigilance by embedding sex- and gender-sensitive analyses into real-world data infrastructures based on valuable contextualisation of sociocultural and behavioural structures. By applying a broad-filtering approach to a portfolio of large-scale population-based cohort studies, registries, claims data, and clinical data, the project will generate comprehensive real-world evidence on how biological, behavioural, and sociocultural determinants interact across the life course to shape CVD risk, diagnostic trajectories, treatment allocation, safety and effectiveness. Particular emphasis will be placed on identifying sex- and gender-specific CVD diagnostic schemes, differential treatment safety and effectiveness, and prescribing patterns in routine care across European countries. To complement secondary data analyses, targeted primary data collection will close gaps in gender-related variables. The project will critically examine gender bias in health care settings, regulatory processes, and guideline development. We will derive evidence-based concepts for more inclusive and equitable guideline adaptation. Building on these insights, a complex sex- and gender-sensitive risk model will be developed and demonstrated through a public health–relevant case study focusing on a pre-defined diagnostic and therapeutic use case. This model will integrate biological, clinical, behavioural, and sociocultural determinants and explicitly support improved pharmacovigilance, diagnostic and treatment decisions, and equitable care pathways.

Project impact: This project will enhance our understanding of sex- and gender-specific risks and treatment strategies in CVDs. By generating gender-sensitive real-world evidence, it will contribute to guidelines and clinical practise and strengthen pharmacovigilance frameworks. It will increase the integration of social and behavioural perspectives into medical research and support the development of gender-responsive health policies. Ultimately, the project aims to reduce inequalities in CVD outcomes by ensuring that diversity is systematically integrated into drug safety monitoring, clinical decision-making, and personalised medicine strategies.