

## DISARM: A Cancer Mission project to upscale genetic testing and improve risk assessment and early detection of ovarian cancer.

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### Background

Ovarian cancer (OC) is the most lethal of female cancers, without effective methods for early detection. This unmet public health need represents a burden both for women diagnosed with the disease, and for those at OC risk. Indeed, the lack of early detection puts women at risk of facing infertility and pre-menopausal symptoms because bilateral salpingo-oophorectomy (BSO) is the only method to reduce OC risk. Polygenic Risk Scores (PRS) and early biomarker detection are an opportunity for personalized risk assessment and management. DISARM, with 28 partners from 12 countries, belongs to the Horizon Europe, Cancer Mission cluster of projects on "Prevention and Early Detection (early detection heritable cancers)".

### Objectives

1-to upscale and personalise OC risk assessment; 2-to test affordable and minimally-invasive methodologies for early detection of OC.

### Methods

Primary objective 1 will be addressed in the DISARM Clinical Study A (CSA) and primary objective 2 in Clinical Study B (CSB). CSA: this randomised controlled study will recruit 2,130 healthy women based on OC family history criteria in Portugal, Lithuania, Czech Republic and Greece. It will assess the feasibility, acceptability, and cost-effectiveness of the CanRisk-based OC risk assessment tool compared with standard of care. The CE-marked, freely accessible CanRisk tool operationalizes the validated BOADICEA risk prediction model. CSA also includes collection of healthcare providers and patient-reported outcomes (e.g., cancer worry, quality of life and decision regret). CSB is a case-control diagnostic performance study to validate liquid biopsy biomarker assays for the early detection of OC. It will recruit approximately 2,000 epithelial OC patients (prior to any treatment) and healthy controls in Greece, Portugal, Lithuania, Czech Republic and the UK. The proposed liquid biopsy assays include a glycoprotein/glycan structure recognition assay, a volatile organic compound assay, and a circulating miRNA assay. Both CSA and CSB feed social and cost-effectiveness studies embedded in the DISARM ecosystem, and are supported by a range of

digital assets and co-creation processes with stakeholders, including patients, high-risk individuals, healthcare providers and policy makers.

#### Implications/Conclusions

DISARM builds on previous data and research to inform on a sustainable change in the early identification and management of women at risk of OC. This project aligns with other European collaborations, which may inform future personalized EU cancer screening programs.

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