

DISARM: A Cancer Mission project to upscale genetic testing and improve early detection in ovarian cancer



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BACKGROUND



Ovarian cancer (OC) is **the most lethal of female cancers**, without effective methods for early detection. This public health **unmet need** represents a burden for women diagnosed with this deadly disease, and for those at OC risk. Indeed, the lack of early detection makes women at risk to face 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 more personalized risk assessment and management**.

28
PARTNERS

12
COUNTRIES



DISARM belongs to the Horizon Europe Cancer Mission cluster of projects on “Prevention & Early Detection – Early Detection of Heritable Cancers” (EARLYSCAN).

Pillar A Ovarian Cancer Risk Assessment

Clinical Study A aspires to upscale and personalize OC risk assessment in the routine healthcare of 4 EU member states. A multifactorial OC risk analysis with the CE-marked CanRisk tool will be compared to standard OC risk assessment

Pillar B Ovarian Cancer Early Detection: easy to use, specific and sensitive, affordable and accessible tests

Clinical Study B: will explore a set of minimally invasive, highly sensitive, blood-based technologies:

OVA-GLY, OVA-VOC and OVA-miRNA

METHODS

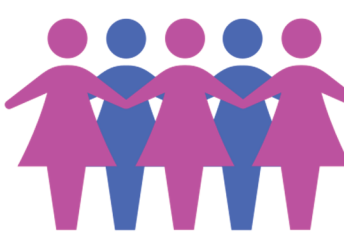
CLINICAL STUDY A

Low Interventional Randomised Controlled Study



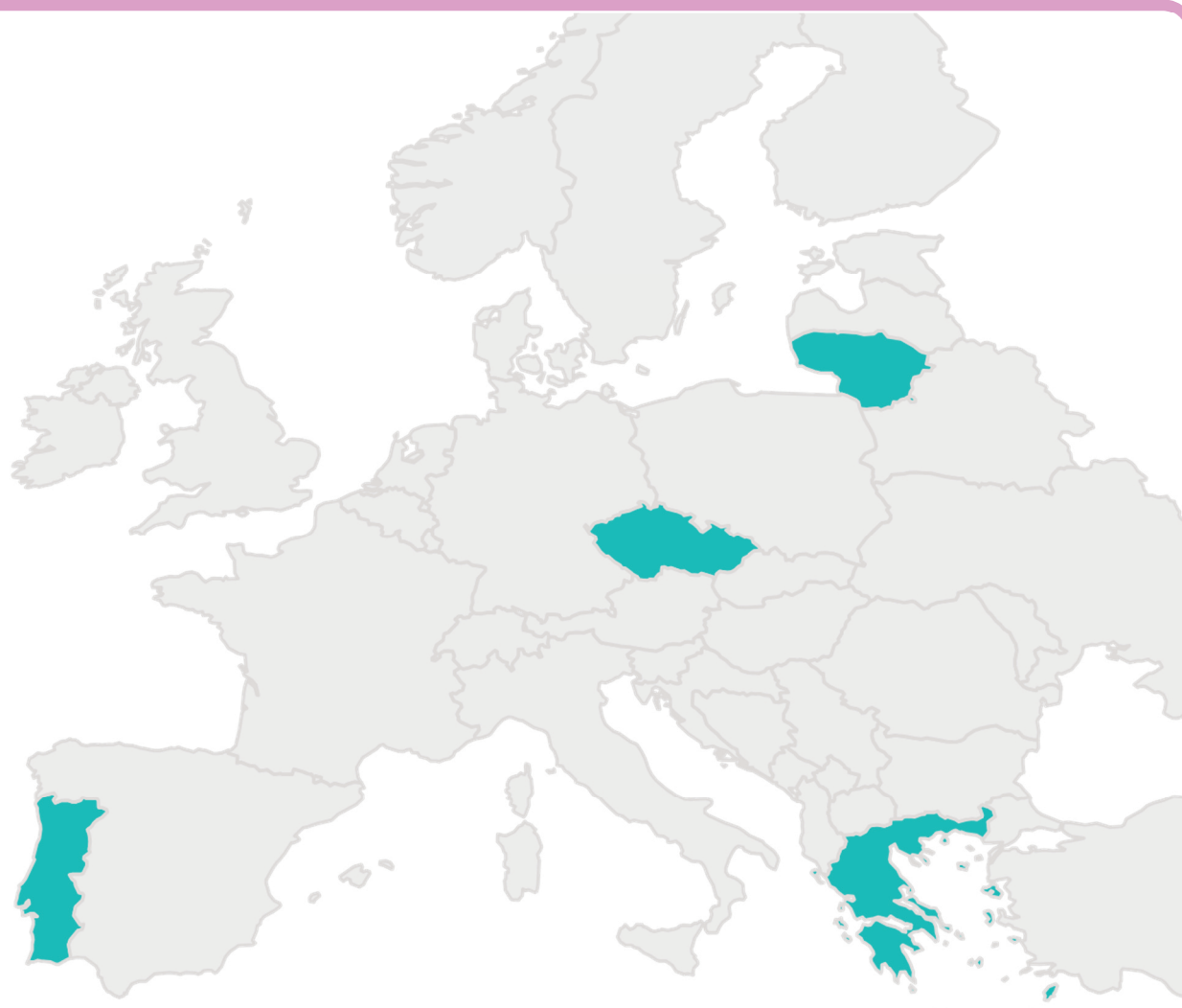
To assess the feasibility, acceptability, and cost-effectiveness of CanRisk-based OC risk assessment compared with standard practice

RECRUITMENT



2,130 healthy participants
based on OC family history criteria

Greece – NSCR ‘DEMOKRITOS and UOA
Portugal – IPOL
Lithuania – LMSU
Czech Republic – BUH and GUHP



INTERVENTION: CanRisk-based OC Risk Assessment

- CE-Marking
- Freely Accessible
- Operationalizes the Validated BOADICEA Risk Prediction Model

COMPARATOR: Standard Practice Assessment

Inclusion Criteria:

- Women, trans men, non-binary people with female reproductive organs
- Aged 18 to 75 years
- Family history of ovarian cancer or a pathogenic variant associated with OC risk in a relative
- Able to give informed consent
- Expected to remain in the study catchment area for the duration of follow-up
- Able to provide informed consent

OUTCOMES COLLECTION



Healthcare Provider-Reported Outcomes



Participant Reported-Outcomes
e.g. cancer worry, quality of life, acceptability



Socioeconomic Outcomes



To evaluate the discriminatory abilities of innovative liquid biopsy biomarker assays

RECRUITMENT



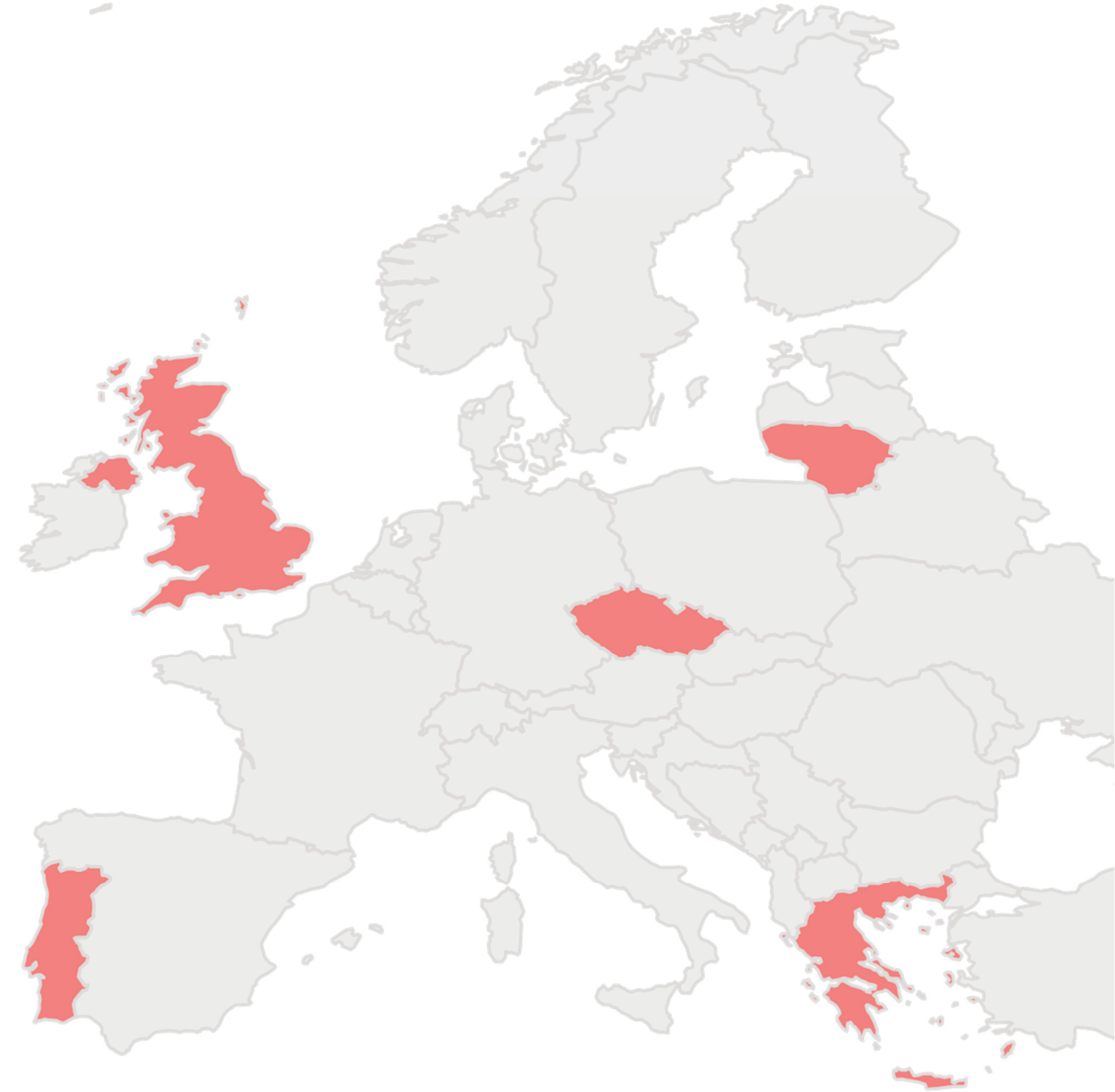
~2,000 participants

Epithelial Ovarian Cancer (EOC) Patients
+
Healthy Controls

Inclusion Criteria:

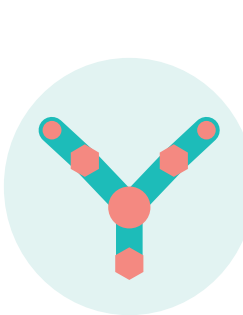
- Women, trans men and non-binary people with female reproductive organs,
- Aged ≥35 years
- Pathologically diagnosed, by biopsy, with EOC prior to surgical intervention or treatment,
- Presenting with adnexal mass suspicious of OC on imaging and scheduled for surgical resection or biopsy (and subsequent confirmation of OC)
- Able to provide informed consent

CLINICAL SITES

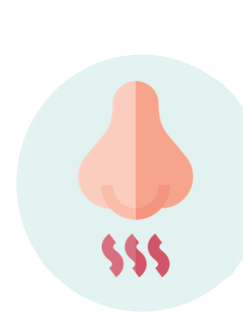


Greece – NSCR ‘DEMOKRITOS and UOA
Portugal – IPOL
Lithuania – LMSU
Czech Republic – BUH and GUHP
United Kingdom – ICL

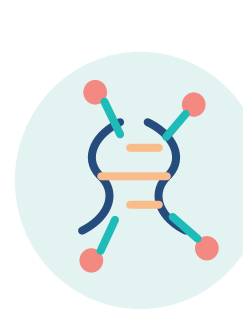
LIQUID BIOPSY ASSAYS



OVA-GLY
Blood Serum-based
Glycoprotein/Glycan
Structure Recognition
Assay



OVA-VOC
Blood Plasma-based
Volatile Organic
Compound Assay



OVA-miRNA
Blood Plasma-based
Circulating
miRNA Assay

IMPLICATIONS: DISARM builds on previous data and research to inform on a sustainable change in the 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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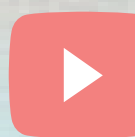
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