Press Release: PREDI-LYNCH - Validated non-invasive liquid biopsy tests for cancer PREDIction in LYNCH Syndrome

PREDI-LYNCH: A European initiative to develop validated, non-invasive biopsy tests for cancer prediction in people with Lynch syndrome funded by EU Cancer Mission - coordinated by Mev Dominguez Valentin,

On May 15th, 2025, the European Commission approved the project "*Validated non-invasive liquid biopsy tests for cancer PREDIction in LYNCH Syndrome, PREDI-LYNCH*". The project officially starts on May 1st and is funded by the European Commission Horizon Europe Mission on Cancer with 13.6 million Euro (project number 101213916). PREDI-LYNCH will run for six years (2025-2031), and the consortium consists of 28 partners from 16 European countries. The initiative is led by researcher Mev Dominguez Valentin at the Institute for Cancer Research, Oslo University Hospital (OUH). In addition, the University of Oslo (UiO) and Oslo Cancer Cluster (OCC) are partners in this ambitious research and innovation project.

Innovative project focusing on early detection of hereditary cancer

PREDI-LYNCH sets out to make a difference for people with Lynch syndrome (LS) by developing and implementing novel, non-invasive early detection methods for colorectal, endometrial and urothelial cancers in patients with LS. The research team addresses an unmet medical need in providing an innovative approach to biomarker discovery for early-stage cancers in LS patients. The consortium gathers leading European researchers, clinicians, biotech companies and patient advocates. Together they aim for setting new standards in early cancer detection for rapid upscaling, for clinical adoption across EU and globally. The project has potential to change clinical practice.

The project will use an innovative clinical trial design for evaluating several promising non-invasive liquid biopsy-based technologies in the three most common LS cancer types to detect cancer at an early stage. Artificial intelligence (AI) will also be utilized to identify traces of cancer and to ensure that the methods are applicable in different healthcare systems. In addition, socio-economic and ethical consequences will be assessed to ensure that the solutions are in line with patients and societal needs and in being implementable in different healthcare systems. The long-term ambition is to offer a multi-omics solution for affordable, accessible and effective testing to ensure early detection in LS patients.

Lynch syndrome and hereditary cancer

LS is an autosomal dominant cancer syndrome caused by pathogenic germline variants in one of the DNA mismatch repair (MMR) genes. It is the most common monogenic hereditary cancer predisposition syndrome worldwide. Carriers of pathogenic MMR variants have a high lifetime risk of developing colorectal (CRC), gynaecological, and urothelial tract cancers as well as, and less frequently other cancers at other sites, including gastric, duodenal, small bowel, pancreatic, biliary tract, prostate, kidney, brain, and skin cancers.

LS affects 1 in 440 people of European ancestry. However, many are unaware of their risk, and only 5% of the 2 million estimated LS carriers in Europe are under cancer surveillance. Tumor-based MMR screening is now routine, which has greatly increased the number of people diagnosed with LS, but this is meaningless without effective means to reduce their cancer risk. CRC, endometrial, and urothelial cancers are most common in LS. Despite CRC surveillance and aspirin use, up to 60% of LS carriers still develop CRC, and 80% get some form of cancer. Gynaecological surveillance in LS, i.e. transvaginal ultrasound and endometrial biopsy, is invasive and painful, while evidence of benefits is lacking. The studies are of low quality and have contradictory outcomes. Therefore, women are recommended to undergo a hysterectomy in their early forties. For urothelial cancers, there is no established means of surveillance, meaning that these cancers are often detected at an advanced stage. Uretero-cystoscopy, commonly used for urothelial cancer diagnosis, is invasive and expensive,

whereas urinalysis or urine cytology is ineffective. We therefore urgently need to improve cancer surveillance in LS to detect cancers at an early stage, utilising effective and minimally invasive strategies, so as to improve patient outcomes and compliance. This is what PREDI-LYNCH will focus on.

Pan-European commitment to an interdisciplinary and multiomic approach

The pan-European PREDI-LYNCH project is led by Mev Dominguez Valentin, project team leader at the Section of Tumor Biology at the Institute of Cancer Research, OUH. She is excited about the possibilities this project opens up and says *"I see this as a great opportunity for the benefit of the Lynch syndrome patients. The project will develop a unique biobank for Lynch syndrome patients that will serve as a unique resource for research and understanding on Lynch syndrome for many years to come. We will also, building on our long-standing research, develop effective and scalable early screening tests, based on our contributions to the existing European clinical guidelines towards the goal of precision medicine tailored to each patient."*

Quotes from our main partners

Jutta Heix, Head of International Affairs at Oslo Cancer Cluster said: "It has been a great experience working with all the partners and complementing the consortium. This was possible due to our EU Advisor role supported by Innovation Norway, and we are now looking forward to jointly work towards non-invasive early diagnostics solutions for people with Lynch Syndrome".

Volker Liebenberg, Chief Medical Officer at Elypta said "We are excited to collaborate and contribute our expertise in metabolism-based biomarkers to aid in the early detection of cancers associated with LYNCH Syndrome. Strong partnerships between academia and industry are essential for driving innovation and implementing diagnostic solutions, particularly in the field of rare diseases. By working together, we can overcome key challenges and accelerate the development of cutting-edge technologies that improve patient outcomes".

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