EUROPEAN UNION

Earlier cancer detection in Lynch syndrome — without the scope



PREDI-LYNCH

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5 years Cancer Mission:
Stronger Through Connection

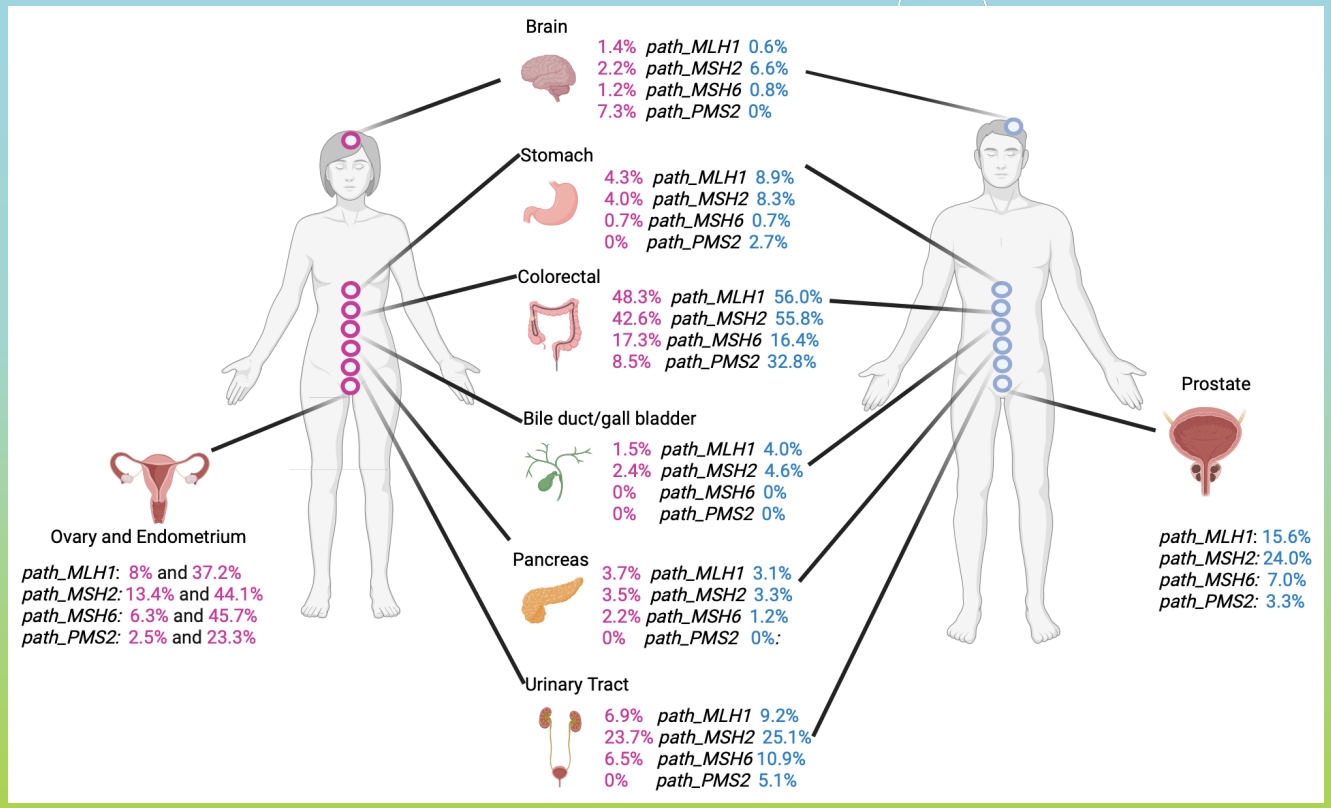
BRUSSELS
29 SEPTEMBER – 01 OCTOBER

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One in 440 people and cancer in eleven organs

- **Lynch syndrome is the commonest inherited cancer predisposition** — a pathogenic variant in *MLH1, MSH2, MSH6, PMS2* or *EPCAM*.
- **5–7% of carriers develop a cancer every year.**
- Risk spans colorectal, endometrial and urinary-tract cancer, and reaches the stomach, ovary, pancreas, brain, prostate, bile duct and small bowel.
- **Roughly 2 million Europeans carry it.**
- **About 5% are under any surveillance at all.**



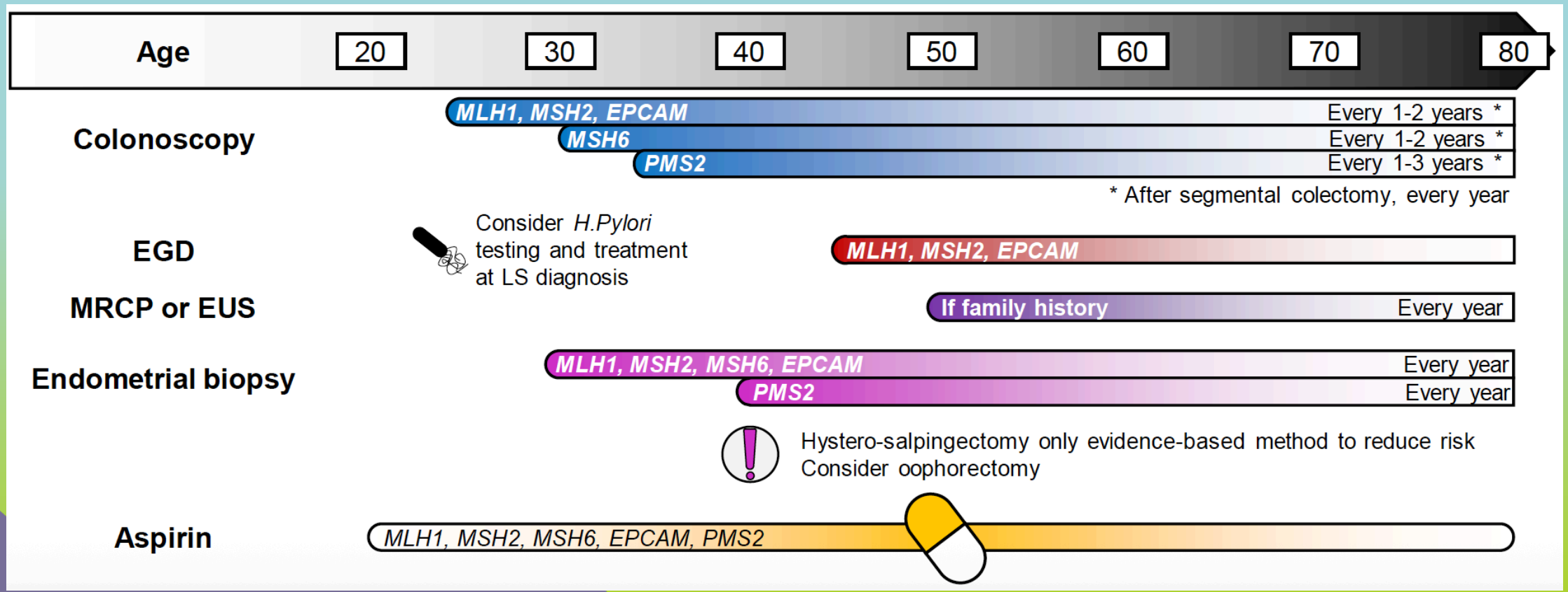
Cumulative risk to age 70 by gene, organ and sex. Domínguez-Valentín et al., 2023

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What a carrier lives through

Colonoscopy every one to two years, for life — and only about 5% of Europe's carriers get even that



EGD: esophagogastroduodenoscopy · MRCP: magnetic resonance cholangiopancreatography · EUS: endoscopic ultrasound.
Cavestro et al., in press, Nature Cancer

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One kit in the post. Four samples. No procedure.

Plasma, urine, a self-collected vaginal swab and stool — read together, and interpreted by AI risk models



PLASMA / BLOOD:
cfDNA / ultra low-coverage WGS data (~0.5x)



URINE:
utDNA — UroScout + MSI Plus



VAGINAL SWAB:
MSI Plus on self-collected vaginal swab



STOOL:
qFIT

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What each test actually measures

Four samples, four assays, one participant

Sample	Test	Laboratory	What it measures	How it is collected
Plasma	**GenoScan LB**	Geneton, Bratislava	Genome-wide cfDNA features at ~0.5× whole-genome coverage, classified by a machine-learning model	Blood draw at the site, Streck tube
Urine	**UroScout**	Tampere University	1,131-probe capture panel — 25 mutated genes, 8 copy-number loci, VHL and the MMR coding regions	Home kit, up to 100 mL, cell pellet
Urine and vaginal swab	**MSI Plus**	Newcastle University	Microsatellite instability at ~30 loci from under 1 ng of cell-free DNA, in a single multiplex PCR	Home: 6 mL urine supernatant; self-collected swab (Ellele device)
Stool	**qFIT**	Oslo University Hospital	Faecal haemoglobin — the established test, run in the same participant as the comparator	Home kit, OC-Auto bottle

Every participant gives all four samples at every round. Three of the four are collected at home and posted; residual material is biobanked in Oslo.

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If this works, here is what changes

- ✓ Detect earlier
- ✓ Cut procedures
- ✓ Make it affordable everywhere

For patients

Cancer found earlier — and beyond the colon, in the organs nothing currently watches well.

Fewer invasive procedures, and fewer of the ones people skip.

Surveillance tailored to gene, sex and age rather than one schedule for everyone.

For health systems

Surveillance costs a health service can sustain, evidenced by health technology assessment published alongside performance.

Equal access for people far from a specialist centre — a kit reaches them, a scope does not.

Adoption models built with regulators and payers from day one.

For science

Validated multi-omic biomarkers in a defined hereditary cancer population — the cleanest test bed there is.

Standardised AI pipelines and model cards others can reuse.

A permanent Lynch syndrome biobank in Oslo for the research that comes after us.

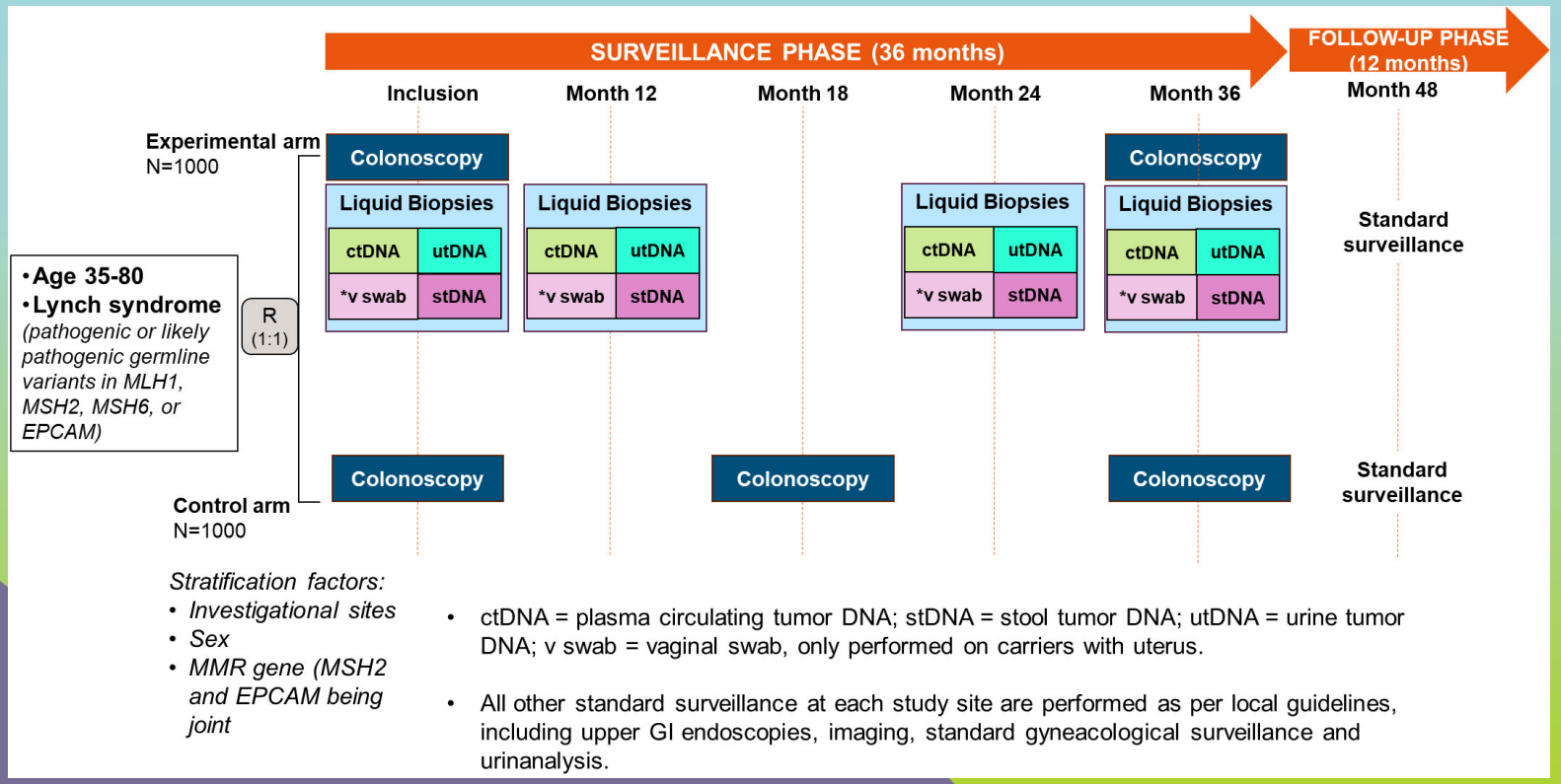
And beyond Lynch syndrome: the template for precision surveillance in every hereditary cancer syndrome

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The trial that will prove it

Randomised, two arms, against colonoscopy itself · NCT07360834



Stratification factors:
- *Investigational sites*
- *Sex*
- *MMR gene (MSH2 and EPCAM being joint*

- ctDNA = plasma circulating tumor DNA; stDNA = stool tumor DNA; utDNA = urine tumor DNA; v swab = vaginal swab, only performed on carriers with uterus.
- All other standard surveillance at each study site are performed as per local guidelines, including upper GI endoscopies, imaging, standard gyneacological surveillance and urinanalysis.

2,000
carriers, randomised 1:1

47
planned sites

9
countries recruiting

29
partner organisations

Ages 35–80 · 18 months of recruitment · 36 + 12 months of follow-up · stratified by site, sex and MSH2/EPCAM status·
sponsor UNICANCER · clinical coordination WP3, Tampere University

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PREDI-LYNCH



Accurate. Non-invasive. Accessible.

Surveillance in Lynch syndrome stops being a scope every other year and becomes a kit in the post — earlier detection beyond the colon, fewer procedures, and a pathway health systems can actually afford.

29 partners in 16 countries · 47 planned sites · patient organisations EVITA, SemiColon and EuropaColon Portugal

predi-lynch.eu

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Scan for the project

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PREDI-LYNCH General Assembly, Bratislava, 2026

29 partners, 16 countries — in one room



Host: Geneton team — Tomáš Szemes, Ondrej Pös, Dagmar Moravčíková et al.