EU4HEALTH PROGRAMME

EU4Health Project Grant

Equitable AI-Assisted Colorectal Cancer Screening Across Regions

CANCERSCREEN-EU

Field	Value
Call Identifier	EU4H-2026-SANTE-PJ
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EU Contribution	EUR 3,000,000

Abstract

CANCERSCREEN-EU pilots and evaluates an equitable, AI-assisted colorectal cancer (CRC) screening pathway in underserved regions across Italy, Romania, Portugal, and Lithuania over 42 months. CRC is the second leading cause of cancer death in the EU, yet screening participation in disadvantaged and geographically remote regions regularly falls below 25% - far beneath the targets set by the 2022 Council Recommendation on cancer screening and Europe's Beating Cancer Plan. Aligned with these strategic frameworks and the EU Cancer Screening Scheme target of reaching 90% of eligible EU citizens by 2025–2030, CANCERSCREEN-EU co-designs an integrated FIT-based pathway incorporating a clinically validated AI decision-support module for triage and colonoscopy prioritisation, deploys it across eight pilot regions enrolling a minimum of 40,000 eligible individuals aged 50–74, and conducts a rigorous mixed-methods evaluation of screening uptake, adenoma detection rates, and equity outcomes disaggregated by gender, socio-economic status, and geographic remoteness. The consortium - led by the National Cancer Institute of Italy and including national health authorities and oncology institutes in Romania, Portugal, and Lithuania - goes beyond the current state of the art by prospectively validating and deploying AI-assisted FIT triage within lower-capacity health systems, generating cross-national real-world evidence currently absent from the literature. The project produces a transferable scale-up playbook formally submitted to Joint Action EUCanScreen, secures replication commitments from at least six regional and national health authorities, and ensures full interoperability with the European Health Data Space and the Cancer Image Europe platform. All tools and training materials are released open-source and deposited in the EU Health Knowledge Gateway. CANCERSCREEN-EU advances the European Cancer Screening Scheme, reduces CRC outcome inequalities across Member States, and generates the real-world evidence required to support equitable, digitally enabled screening programmes at EU scale.
Keywords: colorectal cancer screening, AI decision support, health equity, Europe's Beating Cancer Plan, cancer prevention, FIT-based screening, underserved regions, implementation science, EU4Health, European Health Data Space

SECTION 1 - RELEVANCE

1.1 Objectives and Ambition

Colorectal cancer (CRC) is the second leading cause of cancer death in the European Union, with five-year survival rates varying by more than twofold across Member States. Organised CRC screening participation in underserved rural and socio-economically deprived regions of Romania, Lithuania, and Portugal routinely falls below 25%, far beneath the targets set by the 2022 Council Recommendation on strengthening prevention through early detection (OJ C 473, 13.12.2022). CANCERSCREEN-EU directly addresses this critical gap by piloting, evaluating, and generating scale-up guidance for an equitable, AI-assisted CRC screening pathway adapted to the structural realities of underserved regions across four EU Member States over 42 months.

The primary objective is to increase CRC screening participation rates by at least 15 percentage points relative to regional baselines in all eight pilot regions by month 42. Secondary objectives are: (i) to deploy and validate a CE-marked AI decision-support module for FIT result triage and colonoscopy prioritisation; (ii) to design and test culturally adapted community outreach strategies that measurably reduce equity gaps in screening uptake; (iii) to produce a transferable, evidence-based scale-up playbook suitable for wider EU adoption; and (iv) to strengthen national cancer registry linkage and real-world evidence capacity in all participating countries. These objectives are Specific, Measurable, Achievable, Relevant, and Time-bound (SMART), and are directly aligned with Europe's Beating Cancer Plan and the EU Cancer Screening Scheme target of offering CRC screening to 90% of eligible EU citizens by 2025–2030.

The project goes beyond the current state of the art in two critical respects. First, whereas existing AI-assisted colonoscopy tools have been validated primarily in high-resource academic settings, CANCERSCREEN-EU conducts prospective clinical validation and real-world deployment of an AI FIT-triage module explicitly within lower-capacity health systems, generating the cross-national performance evidence that is currently absent from the literature. Second, the project operationalises an equity-by-design implementation framework - disaggregating all outcomes by gender, socio-economic status, and geographic remoteness - that moves beyond generic uptake targets to produce actionable, population-specific guidance for reducing structural disparities in CRC outcomes across the EU.

1.2 Relation to the Work Programme

CANCERSCREEN-EU is directly responsive to the EU4H-2026-SANTE-PJ call, which invites actions piloting and implementing cancer screening programmes aligned with the 2022 Council Recommendation on cancer screening and Europe's Beating Cancer Plan. The action advances EU4Health Programme general objective Article 3(a) of Regulation (EU) 2021/522 - improving and fostering health in the Union - through the specific objectives set out in Article 4, points (a), (g), and (i): promoting health and preventing disease; addressing inequalities in health; and fostering digital transformation in health and care.

The project ensures mandatory synergies with Joint Action EUCanScreen (CR-g-23-38), the Cancer Image Europe platform under Digital Europe, and the upcoming third EU Cancer Screening Monitoring Report, to which it contributes harmonised, equity-disaggregated data from four Member States. The inclusion of Romania and Lithuania - countries with GNI per capita below 90% of the EU average - ensures that over 30% of the total budget is directed at lower-income Member States, directly reflecting the call's emphasis on reducing inter-country disparities. CANCERSCREEN-EU aligns with the European Health Data Space (EHDS) Regulation by adopting HL7 FHIR interoperability standards and FAIR data principles throughout, and with the EU AI Act's transparency and human-oversight requirements for high-risk medical AI systems, ensuring that the AI decision-

support tool is regulatorily compliant and nationally deployable from the outset.

1.3 Concept and Methodology

The CANCERSCREEN-EU methodology follows an implementation science framework structured in three interconnected phases, designed to move seamlessly from evidence synthesis and tool contextualisation through real-world deployment to transferable evaluation and scale-up.

Phase 1 (months 1–12): Pathway co-design and AI tool contextualisation. The consortium maps existing CRC screening infrastructure, equity gaps, and AI regulatory readiness across all four countries, producing national landscape assessments that inform the co-design of an integrated FIT-based pathway with AI-assisted triage. The AI module - based on validated algorithms trained on European colonoscopy and FIT datasets - undergoes prospective clinical validation at independent sites in Italy and Portugal before any pilot deployment, in full compliance with the EU Medical Devices Regulation (MDR) and the EU AI Act requirements for high-risk medical AI. Pre-specified statistical performance thresholds are defined a priori to ensure objective go/no-go decision-making prior to Phase 2.

Phase 2 (months 10–36): Regional pilot implementation. Eight pilot regions across Italy, Romania, Portugal, and Lithuania each enrol a minimum of 5,000 eligible individuals aged 50–74, for a combined target of at least 40,000 participants. Community health mediators, multilingual and culturally adapted invitation materials, and mobile screening units are deployed to systematically address structural access barriers. The overlapping start of Phase 2 at month 10 allows early pilot sites to benefit from landscape insights while AI validation is completed, optimising the overall timeline.

Phase 3 (months 30–42): Mixed-methods evaluation and scale-up guidance. A quantitative assessment of screening uptake, adenoma detection, and AI triage performance is combined with qualitative analysis of equity outcomes and community engagement processes. All outcome data are disaggregated by gender, age, socio-economic status, and geographic remoteness, consistent with EIGE gender mainstreaming methodology. This phase culminates in a validated, evidence-grounded scale-up playbook submitted to Joint Action EUCanScreen.

All activities comply with GDPR, the EU AI Act, and applicable clinical ethics standards. Where cross-border transfer of pseudonymised data is legally restricted, federated analysis approaches are employed, ensuring that the project's multi-country evidence base is not compromised by divergent national data governance frameworks.

1.4 Interdisciplinary Considerations

CANCERSCREEN-EU integrates equity, digital transformation, and ethical governance as structural - rather than supplementary - dimensions of the project, reflecting the fundamentally interdisciplinary nature of equitable cancer screening implementation.

On equity, a health-equity-in-all-policies lens is applied from inception: all pilot analyses are disaggregated by gender, age, socio-economic status, and geographic remoteness, and outreach strategies are co-designed with patient advocacy groups and civil society organisations to ensure cultural and linguistic acceptability across diverse community contexts. The EIGE gender mainstreaming methodology is applied to all communication materials and analytical frameworks, explicitly addressing documented gender differentials in CRC screening uptake and thereby ensuring that results are meaningful and actionable for both women and men.

On digital governance, the AI decision-support tool is developed with full auditability, explainability, and human oversight provisions as required by the EU AI Act for high-risk medical AI systems.

Clinician override is preserved at every decision point, and algorithm performance is continuously monitored for distributional shift across national deployment contexts. A consortium-level Data Protection Officer is appointed from month 1, and the project Data Management Plan is aligned with GDPR and EHDS interoperability standards from the outset.

Ethical oversight is provided by an independent ethics board at the coordinating institute, with ethics review completed before any participant recruitment commences. The board includes representation from bioethics, patient advocacy, and health equity research, ensuring that ethical scrutiny extends beyond regulatory compliance to encompass social justice considerations.

Open science principles apply to all project outputs: AI source code is released under an open licence, all peer-reviewed publications are submitted to open-access journals, and all training and pathway materials are deposited in the EU Health Knowledge Gateway, maximising accessibility for health systems across the EU regardless of resource level.

SECTION 2 - IMPACT

2.1 Pathways Towards Impact

Direct beneficiaries of CANCERSCREEN-EU are approximately 40,000 eligible individuals aged 50–74 residing in eight underserved pilot regions across Italy, Romania, Portugal, and Lithuania, who will be actively invited to participate in the AI-assisted CRC screening pathway during the pilot phase. Of these, individuals in the lowest socio-economic quartile and in geographically remote areas are explicitly targeted through tailored outreach, ensuring that the hardest-to-reach populations generate the largest proportional gains in access. Indirect beneficiaries include national and regional health authorities, which gain access to validated tools, workforce capacity, and a replication playbook, and the broader EU population, through the long-term contribution to reduced CRC-related morbidity and mortality.

The pathway to impact operates across three time horizons. In the short term (project lifetime, months 1–42), the action generates measurable increases in screening participation rates (target: ≥15 percentage points above regional baseline), improved adenoma detection through AI-assisted triage (target: ≥10% relative improvement in adenoma detection rate), and strengthened regional workforce capacity through trained community health mediators and clinical staff. In the medium term (2–5 years post-project), the scale-up playbook and replication toolkit - validated with health authorities and formally submitted to Joint Action EUCanScreen - enable national authorities to extend the pathway to additional regions without further EU grant support, with replication commitments secured from at least six health authorities before project end. In the long term (5–10 years), widespread adoption of the validated pathway is projected to contribute to a measurable reduction in late-stage CRC diagnoses across participating Member States, directly supporting the Europe's Beating Cancer Plan commitment to saving 3 million lives by 2030.

Sustainability beyond the grant period is assured through four concrete mechanisms: formal submission of the scale-up playbook to Joint Action EUCanScreen for integration into EU-level guidance; deposit of all training materials in the EU Health Knowledge Gateway; open-source release of the AI decision-support module; and written replication commitments from at least six regional or national health authorities secured at the final Brussels conference.

2.2 Dissemination, Exploitation and Communication

WP5 leads a structured, audience-differentiated communication, dissemination, and exploitation strategy targeting five defined audiences: national health authorities and screening programme managers; clinicians (gastroenterologists, general practitioners, and nurses); patient organisations; EU-level policymakers and DG SANTE; and the broader scientific community. Each audience is addressed through tailored channels, formats, and messages developed in collaboration with patient advocacy partners from month 6.

A public project website is launched by month 3 and maintained throughout the project lifetime, providing a central hub for public-facing content, open-access publications, and downloadable tools. A minimum of eight peer-reviewed open-access publications are targeted, covering AI validation results, equity analysis findings, implementation lessons, and scale-up evidence. Presentations are delivered at the European Cancer Congress and the ESGE Annual Meeting, ensuring visibility within the clinical communities most relevant to CRC screening practice. Targeted policy briefs are addressed to national ministries of health and DG SANTE at months 20 and 38, timed to coincide with key EU cancer policy milestones and national budget planning cycles.

Exploitation activities are designed to ensure durable post-project impact: the AI decision-support module is released as open-source under a clearly specified open licence; the scale-up playbook is

formally submitted to Joint Action EUCanScreen and the EU Health Knowledge Gateway; and all workforce training materials are made freely accessible in multiple EU languages. A final public conference in Brussels at month 40 brings together representatives of all four national health authorities, European Commission officials, and civil society, providing the formal venue for securing replication commitments and for presenting the project's evidence base to the EU policy community. Patient advocacy organisations are engaged from month 6 as co-designers of communication materials and community ambassadors throughout the pilot phase, maximising the reach, cultural appropriateness, and equity of the screening invitation campaign.

2.3 Summary of Impact Indicators

Indicator	Target	Measurement
CRC screening participation rate in pilot regions	Increase of ≥15 percentage points from regional baseline by month 42	Administrative screening registry data; monthly monitoring reports per pilot site
Adenoma detection rate (ADR) in AI-assisted vs. standard pathway	≥10% relative improvement in ADR in AI-assisted arm	Endoscopy unit records; blinded assessment by clinical evaluation committee at month 37
Equity gap in screening uptake (lowest vs. highest socio-economic quartile)	Reduction of equity gap by ≥20% relative to baseline across pilot regions	Screening uptake data disaggregated by socio-economic indicators; annual equity analysis report
Community outreach actions implemented	Minimum 48 events across 8 pilot regions by month 36	Activity logs and attendance records compiled by regional coordinators; WP3 monitoring report
Formal replication commitments from regional/national health authorities	≥6 signed letters of intent by month 42	Signed letters of intent recorded in final evaluation report and final conference proceedings
Open-access peer-reviewed publications	≥8 publications by month 42	Publication database maintained by WP5 lead; DOIs submitted to HaDEA with final report

SECTION 3 - QUALITY OF IMPLEMENTATION

3.1 Work Plan and Work Packages

WP	Title	Lead	PM	Duration
WP1	Project Management and Coordination	National Cancer Institute Italy (INCa-IT)	18	M1-M42
WP2	Pathway Co-Design and AI Tool Contextualisation	National Cancer Institute Italy (INCa-IT)	52	M1-M18
WP3	Regional Pilot Implementation	Romanian National Health Authority (RNHA-RO)	88	M10-M36
WP4	Monitoring, Evaluation, and Scale-Up Guidance	Lithuanian University of Health Sciences (LUHS-LT)	44	M10-M42
WP5	Dissemination, Communication, and Stakeholder Engagement	Portuguese Oncology Institute (IPO-PT)	30	M1-M42

WP1: Project Management and Coordination

Lead: National Cancer Institute Italy (INCa-IT) | Person-months: 18 | Duration: M1 - M42

WP1 ensures overall scientific, administrative, and financial coordination of the CANCERSCREEN-EU consortium throughout the full 42-month project lifetime. It establishes and maintains all governance structures from the outset, manages reporting obligations to HaDEA in accordance with the grant agreement, oversees ethics compliance across all national contexts, and maintains a living risk register and quality management framework. The coordinator holds full responsibility for inter-partner coordination, timely deliverable submission, and prompt escalation of any issues identified through quarterly management board reviews. WP1 also serves as the primary interface between the consortium and HaDEA, and coordinates input to the three mandatory progress reports at months 14, 28, and 42.

T1.1: Governance and legal setup - Establish the consortium agreement, project management board, scientific advisory board, and independent ethics oversight committee by month 2, ensuring clear lines of decision-making authority, conflict-resolution procedures, and ethics governance are in place before any research activities commence.

T1.2: Financial and administrative management - Coordinate financial management across all partners, including budget monitoring, audit preparation, and the timely submission of progress and final reports to HaDEA in full compliance with grant agreement obligations and EU4Health financial regulations.

T1.3: Quality assurance and risk monitoring - Implement and update the project risk register on a quarterly basis; conduct formal internal quality reviews at months 14, 28, and 40 to assess progress against KPIs, identify emerging risks, and initiate corrective actions where required.

WP2: Pathway Co-Design and AI Tool Contextualisation

Lead: National Cancer Institute Italy (INCa-IT) | Person-months: 52 | Duration: M1 - M18

WP2 establishes the evidence and regulatory foundation on which the entire pilot implementation rests. It maps CRC screening infrastructure, equity gaps, and AI regulatory readiness across all four partner countries; co-designs the integrated FIT-based AI-assisted screening pathway with clinical partners and national health authorities; and conducts prospective clinical validation of the AI triage module at independent sites in Italy and Portugal prior to any pilot deployment. All validation activities comply with EU MDR and EU AI Act requirements for high-risk medical AI systems, with pre-specified performance thresholds reviewed by an external clinical evaluator. Completion of WP2 validation milestones gates entry into WP3 pilot implementation, ensuring that no participant is exposed to an unvalidated AI tool.

T2.1: National screening landscape mapping - Conduct structured assessments of CRC screening programme status, AI regulatory readiness, and equity barriers in all four partner countries, producing four harmonised national

landscape reports that directly inform the pathway co-design process in T2.3.
T2.2: AI decision-support module contextualisation and clinical validation - Contextualise the FIT triage AI module to national regulatory and clinical environments and conduct prospective clinical validation at independent sites in Italy and Portugal, generating a statistical performance report reviewed against pre-specified thresholds by an external clinical evaluator before any pilot deployment is authorised.
T2.3: Integrated pathway protocol and workforce training - Co-design the integrated AI-assisted screening pathway protocol with clinical partners, national health authorities, and patient advocacy representatives, and deliver comprehensive workforce training to regional healthcare teams across all eight pilot sites by month 18, ensuring operational readiness before WP3 pilot launch.

WP3: Regional Pilot Implementation

Lead: Romanian National Health Authority (RNHA-RO) | Person-months: 88 | Duration: M10 - M36

WP3 constitutes the core implementation phase of CANCERSCREEN-EU, deploying the co-designed and validated AI-assisted CRC screening pathway across eight underserved pilot regions in Italy, Romania, Portugal, and Lithuania. A minimum of 40,000 eligible individuals aged 50–74 are invited to participate across the eight sites, with each site targeting at least 5,000 enrolments. Equity is operationalised through the deployment of community health mediators, mobile screening units, and multilingual, culturally adapted invitation materials, all developed in WP2 and co-designed with patient advocacy organisations. AI triage performance is continuously monitored throughout the pilot period, with anomalies flagged in real time to the WP2 and WP4 leads. WP3 generates the primary real-world evidence base - screening uptake, FIT positivity, AI triage outcomes, and colonoscopy referral rates - on which the WP4 evaluation and scale-up playbook are built.
T3.1: Pilot site preparation and recruitment infrastructure - Establish participant invitation systems, mobile screening unit deployment plans, and community health mediator networks at all eight pilot sites, ensuring full operational readiness before the first participant is enrolled at each site.
T3.2: Screening invitation campaigns and community outreach - Implement multilingual, culturally adapted screening invitation campaigns and deliver a minimum of 48 community outreach events - six per pilot region - across all eight pilot regions by month 36, with patient advocacy organisations serving as community ambassadors throughout.
T3.3: AI-assisted FIT triage and colonoscopy referral workflow - Deploy the validated AI triage module within routine screening workflows at all eight sites, continuously monitor AI performance metrics against pre-specified thresholds, and flag any anomalies or distributional shifts to the WP2 AI validation lead and WP4 monitoring lead for immediate review and action.

WP4: Monitoring, Evaluation, and Scale-Up Guidance

Lead: Lithuanian University of Health Sciences (LUHS-LT) | Person-months: 44 | Duration: M10 - M42

WP4 provides the monitoring, evaluation, and knowledge-synthesis infrastructure that transforms pilot implementation experience into transferable EU-level guidance. A harmonised monitoring framework, implemented across all eight pilot sites from month 10, ensures that comparable quantitative and qualitative data are collected throughout WP3. The mixed-methods impact evaluation - combining quantitative analysis of screening KPIs with qualitative equity and community engagement assessment - produces the definitive evidence base on project outcomes. All analyses are disaggregated by gender, age, socio-economic status, and geographic remoteness. The WP culminates in the production, validation, and formal submission of a transferable scale-up playbook and replication toolkit to Joint Action EUCanScreen, ensuring that CANCERSCREEN-EU findings are systematically incorporated into EU-level cancer screening guidance.
T4.1: Monitoring framework and harmonised data collection - Implement the project monitoring framework across all eight pilot sites from month 10, collect harmonised outcome data using standardised indicators, and produce six-monthly monitoring reports for the management board and HaDEA, flagging any deviations from enrolment targets or KPI trajectories.
T4.2: Mixed-methods impact and equity evaluation - Conduct a rigorous quantitative analysis of all primary and secondary screening KPIs and a qualitative assessment of equity outcomes, community engagement effectiveness, and AI implementation experience across all pilot regions, culminating in a comprehensive final evaluation report submitted to HaDEA.
T4.3: Scale-up playbook and replication toolkit - Synthesise evaluation evidence, implementation lessons, and health-authority feedback into a practical, transferable scale-up playbook and replication toolkit, validated through structured consultation with regional and national health authorities before formal submission to the Joint Action EUCanScreen secretariat.

WP5: Dissemination, Communication, and Stakeholder Engagement

Lead: Portuguese Oncology Institute (IPO-PT) | Person-months: 30 | Duration: M1 - M42

WP5 manages all external communication, scientific dissemination, open-access publication, and stakeholder engagement activities across the full project lifetime, ensuring consistent and high-quality visibility with EU policymakers, national health authorities, clinical communities, patient organisations, and the general public. The WP maintains a proactive policy engagement function, ensuring that project findings reach DG SANTE and national ministries at strategically relevant moments. It also leads the exploitation strategy, securing post-project sustainability through open-source tool release, playbook submission to EUCanScreen, deposit of training materials in the EU Health Knowledge Gateway, and formal replication commitments secured from at least six health authorities at the final Brussels conference.

T5.1: Communication strategy and project website - Develop and launch the project communication strategy and public-facing website by month 3; maintain and update both throughout the project lifetime, ensuring accessible, multilingual content for diverse target audiences including the general public in pilot regions.

T5.2: Scientific dissemination and policy engagement - Coordinate the submission of a minimum of eight peer-reviewed open-access publications, deliver presentations at the European Cancer Congress and the ESGE Annual Meeting, and produce targeted policy briefs addressed to DG SANTE and national ministries of health at months 20 and 38, aligned with EU cancer policy milestones.

T5.3: Final conference and replication commitment engagement - Organise the final public conference in Brussels at month 40, bringing together representatives of all four national health authorities, European Commission officials, and civil society, and secure a minimum of six formal replication commitments - in the form of signed letters of intent - from regional and national health authorities before project end.

3.2 Consortium Composition

Organisation	Country	Type	Role	Description
National Cancer Institute Italy (INCa-IT)	Italy	National public research and clinical institute	Coordinator	Overall coordinator; leads WP1 (management) and WP2 (pathway design and AI validation); provides scientific direction and ethics oversight for the full consortium
Romanian National Health Authority (RNHA-RO)	Romania	National public health authority	Partner	WP3 lead; coordinates pilot implementation in Romanian underserved regions; manages national cancer registry linkage and participant data flows
Portuguese Oncology Institute (IPO-PT)	Portugal	National oncology institute	Partner	WP5 lead; co-leads AI clinical validation (T2.2); coordinates Portuguese pilot sites; leads dissemination and stakeholder engagement
Lithuanian University of Health Sciences (LUHS-LT)	Lithuania	Public academic health institution	Partner	WP4 lead; evaluation methodology design; data governance and federated analysis; coordination of Lithuanian pilot sites

CANCERSCREEN-EU assembles a geographically and institutionally complementary consortium that is

uniquely equipped to address the multidimensional barriers driving CRC screening inequity across the EU. The scientific leadership of a major national cancer institute (INCa-IT) is combined with the implementation authority, data infrastructure, and community networks of national health bodies and oncology institutes spanning Southern, Eastern, and Northern Europe. This geographic spread is not incidental: it is a deliberate design choice that ensures the project is operationally grounded in contrasting health system realities and produces findings of genuine cross-EU transferability.

The inclusion of Romania and Lithuania - both with GNI per capita below 90% of the EU average - is central to the project's European added value. These partners bring direct access to the health system contexts where CRC screening inequity is most acute and where validated, low-cost implementation models are most urgently needed. At the same time, they provide established cancer registry infrastructure and existing community health mediator networks that are essential to the pilot's operational credibility and equity focus.

All four partners hold prior experience in EU-funded health projects and bring complementary expertise across scientific, clinical, regulatory, community engagement, and evaluation domains. No single partner could deliver the combined scientific rigour, health system access, regulatory navigation, and community reach that the consortium collectively provides. This complementarity, grounded in shared commitment to equitable cancer outcomes, constitutes the essential added value that justifies a four-country, multi-institutional approach over a single-country pilot.

3.3 Milestones

ID	Title	WP	Due	Verification
MS1	Consortium agreement signed and ethics approval confirmed	WP1	M3	Signed consortium agreement submitted to HaDEA; ethics committee approval letter from INCa-IT independent board
MS2	Four national landscape assessment reports approved	WP2	M9	Reports approved by scientific advisory board and submitted to HaDEA as deliverable D2.1
MS3	AI triage module clinically validated at two sites	WP2	M15	Validation report with pre-specified statistical performance thresholds met; reviewed by external clinical evaluator
MS4	All eight pilot sites operational and actively recruiting	WP3	M18	Site initiation reports and first-month recruitment data confirmed by WP3 lead; reported to management board
MS5	Interim evaluation report with equity analysis submitted	WP4	M30	Interim evaluation report submitted to HaDEA and reviewed by external evaluator; equity gap metrics reported
MS6	Scale-up playbook finalised and submitted to EUCanScreen	WP4	M40	Published playbook (D4.3) with acknowledgement of receipt from Joint

				Action EUCanScreen secretariat
MS7	Final conference held and replication commitments secured	WP5	M41	Conference proceedings published; minimum 6 signed letters of intent from health authorities appended to D5.3

3.4 Deliverables

ID	Title	WP	Due	Type	Dissemination
D1.1	Project Management and Quality Plan	WP1	M3	R	SEN
D1.2	Final Project Report	WP1	M42	R	PU
D2.1	National Landscape Assessment Reports (x4)	WP2	M9	R	PU
D2.2	AI Decision-Support Module Validation Report	WP2	M15	R	PU
D2.3	Integrated Screening Pathway Protocol and Training Materials	WP2	M17	OTHER	PU
D3.1	Pilot Implementation and Enrolment Report (all 8 sites)	WP3	M37	R	PU
D4.1	Interim Evaluation and Equity Analysis Report	WP4	M30	R	PU
D4.2	Final Mixed-Methods Impact Evaluation Report	WP4	M41	R	PU
D4.3	Scale-Up Playbook and Replication Toolkit	WP4	M40	OTHER	PU
D5.1	Communication and Dissemination Strategy and Project Website	WP5	M3	DEC	PU
D5.2	Policy Briefs for DG SANTE and National Ministries (x4)	WP5	M38	R	PU
D5.3	Final Conference Proceedings and Replication Commitment	WP5	M42	R	PU

	Report				

3.5 Resources and Budget Summary

Cost Category	Amount (EUR)
Personnel Costs	2850000
Subcontracting	350000
Travel & Subsistence	180000
Equipment	120000
Other Direct Costs	200000
Indirect Costs (25%)	300000
TOTAL	4000000

3.6 Risk Management

ID	Risk	Likelihood	Impact	Mitigation
R1	Low community participation in pilot regions due to screening hesitancy or low health literacy, resulting in insufficient enrolment to meet primary KPIs.	Medium	High	Early co-design of multilingual and culturally adapted invitation materials with community health mediators and patient organisations; deployment of mobile screening units; contingency protocol to extend recruitment window by up to 4 months within project timeline.
R2	Data governance and GDPR compliance challenges arising from cross-border sharing of pseudonymised screening and AI performance data between four national health systems with differing legal frameworks.	Medium	High	Consortium Data Protection Officer appointed from month 1; Data Management Plan aligned with GDPR and EHDS standards; federated analysis approaches used where cross-border data transfer is not legally permissible.
R3	AI triage module fails to meet pre-specified clinical validation thresholds in one or more national contexts, preventing deployment in the pilot phase on schedule.	Low	High	Validation conducted at two independent sites before pilot launch; modular pathway design allows FIT-based screening to proceed without AI triage component if required, preserving primary screening uptake objectives.
R4	Partner capacity constraints or staff turnover in lower-resource settings (Romania, Lithuania) causing delays in	Medium	Medium	Detailed staffing plans with named deputies for all key roles; subcontracting provision for temporary clinical

	pilot site preparation and recruitment.			support staff; quarterly management board reviews to identify and address capacity gaps early.
R5	Divergent national regulatory timelines for AI medical device certification under the EU AI Act and MDR delaying AI tool deployment in specific country contexts.	Low	Medium	Regulatory landscape assessed in WP2 national mapping (months 1–9); proactive engagement with national competent authorities from month 1; pathway operable without AI component in any single country if regulatory clearance is delayed.