THE JA PCM KICK-OFF MEETING

14-15 January 2026

JA PCM
Joint Action Personalised Cancer Medicine

10:00 - 11:00 **Welcome Session**

Welcome by the Coordination
Marc Van den Bulcke, Head of the Belgian Cancer Centre, Sciensano (BE)

Video message from the Minister
Frank Vandenbroucke, Deputy Prime Minister and Minister of Social Affairs and Public Health of Belgium

Introduction by HaDEA representative
Nadia Elhaggagi, Acting Head of Unit, EU4Health HaDEA.A.1, HaDEA

Introduction by DG RTD representative
Carmen Laplaza, Head of Unit, RTD.D.2, DG RTD

WP1: Project Vision & Objectives & Introduction Round
Els Van Valckenborgh, Cancer Centre, Sciensano (BE)
Nancy Frédérickx, Cancer Centre, Sciensano (BE)

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Kick-off Joint Action Personalised Cancer Medicine

January 14th, 2025, Brussels

EU Research & Innovation

on

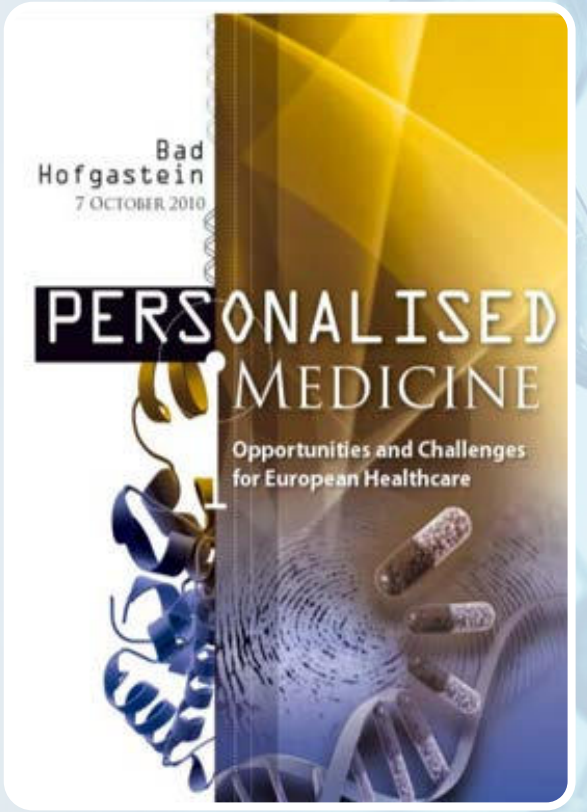
Personalised Medicine

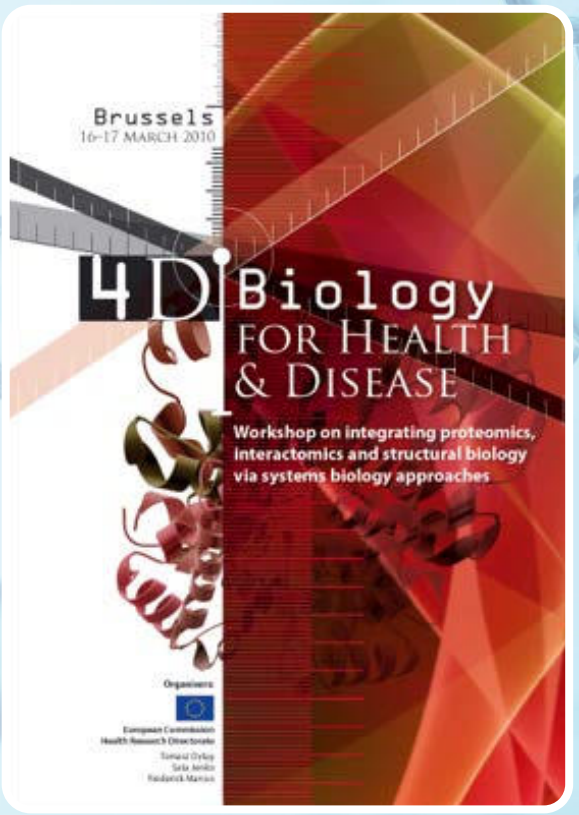
Carmen LAPLAZA SANTOS

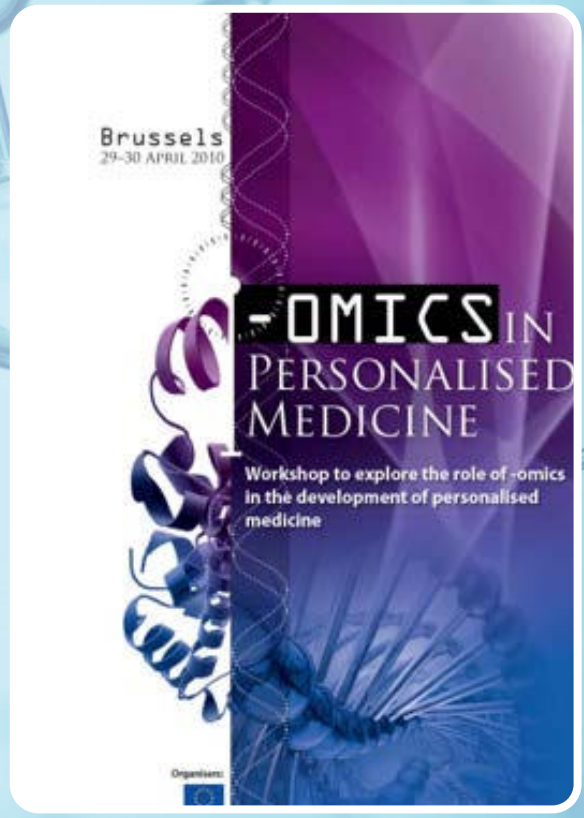
Head of Unit Health Innovation Ecosystems

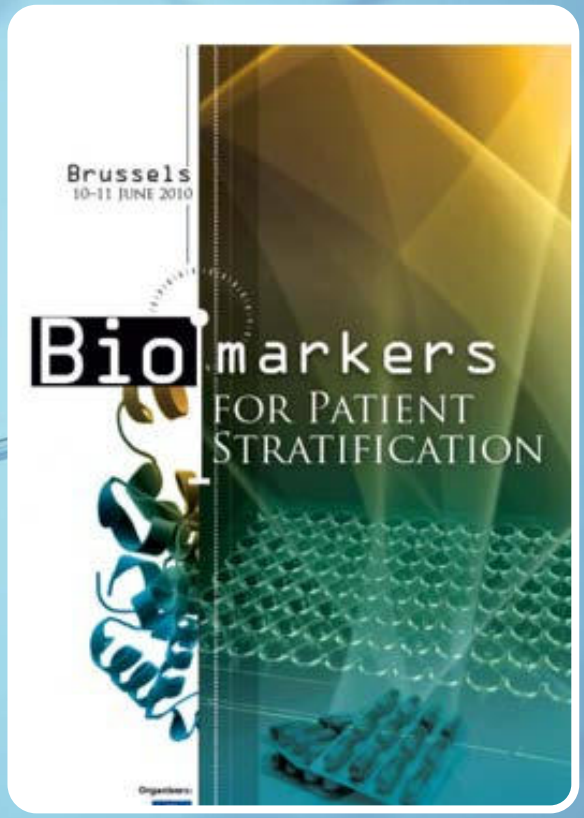
DG Research and Innovation, European Commission

How it all started… in 2010









EU support for personalised medicine

POLITICAL PUSH

EU Council conclusions of 7 December 2015 (15054/15)

FUNDING

R&I Framework Programmes FP7, Horizon 2020, Horizon Europe, IMI/IMI2/IHI, EU4Health, Digital Europe, …

COOPERATION

Facilitation of several new initiatives and knowledge transfer (e.g. 1+ Million Genomes, International Consortium on Personalised Medicine - ICPerMed), International Rare Diseases Research Consortium (IRDiRC))

LEGISLATION

Proposals for new legal acts on data (EuropeanHealthDataSpace, AI Act, Data Governance Act, Data Act) and review of existing legal acts (e.g. pharma package, orphan medicines, HTA, biotech act, medical devices,…)

EU-wide funding schemes and research initiatives supporting personalised medicine

SEVENTH FRAMEWORK PROGRAMME

HORIZON 2020

HORIZON EUROPE

ERA PerMed

innovative medicines initiative

EUROPEAN JOINT PROGRAMME RARE DISEASES

EP PerMed
European Partnership for Personalised Medicine
eppermed.eu

innovative health initiative

ERDERA
European Rare Diseases Research Alliance

EU-AMRI

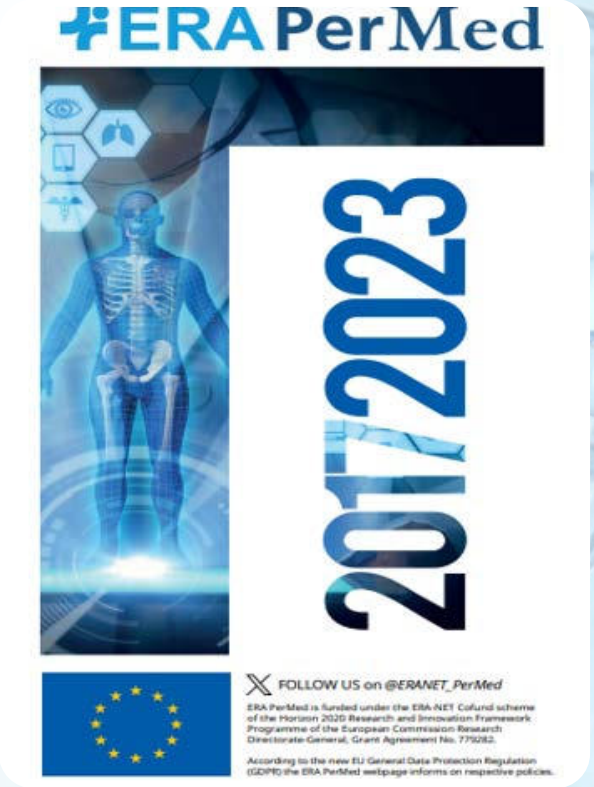
1+MillionGenomes

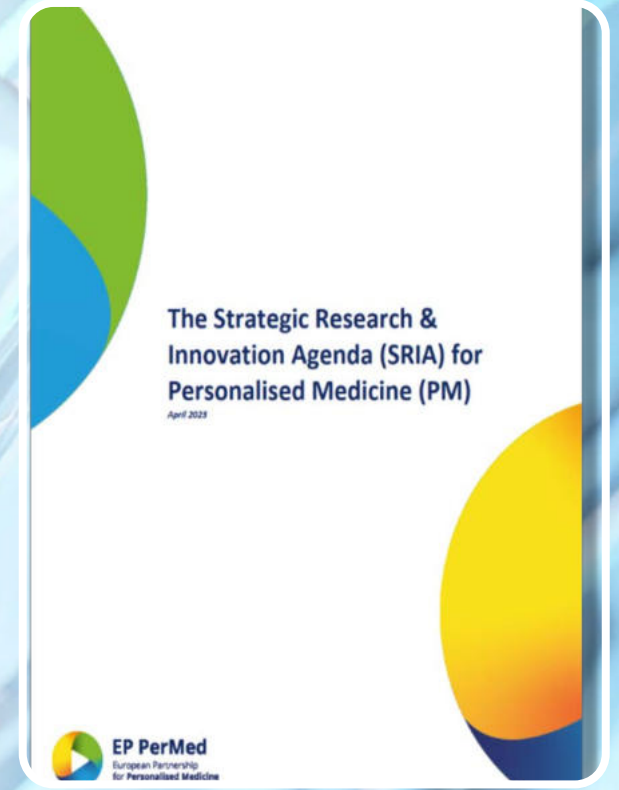
EU MISSIONS
CANCER

Partnerships for co-funding personalised medicine research

ERA PerMed 2017-2023
23 partners from 23 countries
>EUR 140 million

EP PerMed 2023 –
>50 partners
>EUR 300 million





Horizon 2020 complementary actions supporting IC PerMed

HEcoPerMed

Healthcare- and pharma-economic models in support of the International Consortium for Personalised Medicine

SAPHIRE

Securing Adoption of Personalised Health in REgions

REGIONS4PERMED

Interregional coordination for a fast and deep uptake of Personalised Health

EULAC-PerMed

Widening EU-CELAC policy and research cooperation in Personalised Medicine

SINO-EU-PerMed

Widening Sino-EU policy and research cooperation in Personalised Medicine

PERMIT

PERsonalised MedicIne Trials

IC2PerMed

Integrating China in the International Consortium for Personalised Medicine

ICPerMed Secretariat

Secretariat for the International Consortium for Personalised Medicine

EU-Africa PerMed

Building links between Europe and Africa in Personalised Medicine

Increased political attention – Council presidencies

SWEDISH PRESIDENCY

“Life sciences - The era of personalised medicine”

Stockholm, 26-27 June 2023

SPANISH PRESIDENCY

“Genomics-based health strategies: towards personalised and precision medicine”

Valencia, 5-6 October 2023

BELGIAN PRESIDENCY

“The convergence of technologies enabling R&I for the healthcare of the future”

Brussels, 28-29 May 2024

National law on personalised medicine

- On May 24, 2023, the Romanian President has promulgated a law **supplementing the earlier Law for patients' rights** no 46/2003
- The bill introduces two new articles, **defining personalised medicine and introducing personalised medicine as the right of every patient**
- Ensuring **fair access of patients to personalised medicin**e (to personalised treatments and to personalised prevention services)
- Creating the framework for the **implementation of new technologies** including new drugs

From research project to implementation?

How can we move from interesting research results to practical implementation for better health outcomes?

From research project to implementation?

EU-funded project demonstrates the clinical utility of pre-emptive pharmacogenetic testing

Setup

- Clinical study to test personalised drug prescribing and dosing, based on DNA sequencing data
- Analysis of 39 drugs, against the panel of 12 genes and 50 types of genetic variants
- Almost 7000 patients sequenced and tested in real-life healthcare
- Piloted in seven countries: Austria, Greece, Italy, the Netherlands, Slovenia, Spain, UK
- Several therapeutic areas: general medicine, oncology, cardiology, psychiatry…
- Project coordination: Leiden University Medical Center (prof. Henk-Jan Guchelaar)

Findings

- Patients experience 30% fewer side effects when drug dosing is tailored to patient's DNA sequence
- Drug prescription based on DNA sequencing is feasible across European healthcare systems
- Need for wide-scale implementation in healthcare

15 million EUR budget *2016-2021* *22 partners*

Pharmacogenomics - multistakeholder workshop

Recommendations and next steps:

- additional regulatory action
- facilitating uptake in health care
- leverage genomic and real world data
- increase impact of project results

Summary and presentations at EMA homepage and **Article in Nature Reviews Drug Discovery 21 Nov 2025**:

Joint EC/HMA/EMA multi-stakeholder workshop on pharmacogenomics | European Medicines Agency (EMA)

Advancing pharmacogenomics in medicines regulation and clinical practice: a call for collaborative action

A driver for personalised medicine development - cancer

EU Cancer mission's unique approach: connect R&I and care, engage with citizens in projects and other activities, create project clusters, focus on end-users, work across sectors

PANCAID

Develop a composite blood multi-marker panel that is sensitive and specific enough to detect **Pancreatic Ductal Adenocarcinoma via a blood draw** at earlier stages than current diagnostic measures – patients benefit from more personalized screening

ONCOSCREEN

Personalised **Risk Stratification methodology for colorectal cancer**

SANGUINE

A minimally-invasive, fast, cost-effective, patient centric, highly sensitive screening and monitoring tool for blood cancers using detection technology that combines several types of epigenetic biomarkers

17 Pragmatic Clinical Trial Projects Testing Better Diagnostic and Treatment Interventions (and more to come)

SAGITTARIUS

Liquid biopsy (LB), a new innovative assay for detecting the circulating tumor DNA (ctDNA) in the blood, to **personalize the post-surgical care** of patients with loco-regional **stage III and high-risk stage II colon cancer (LRCC)**

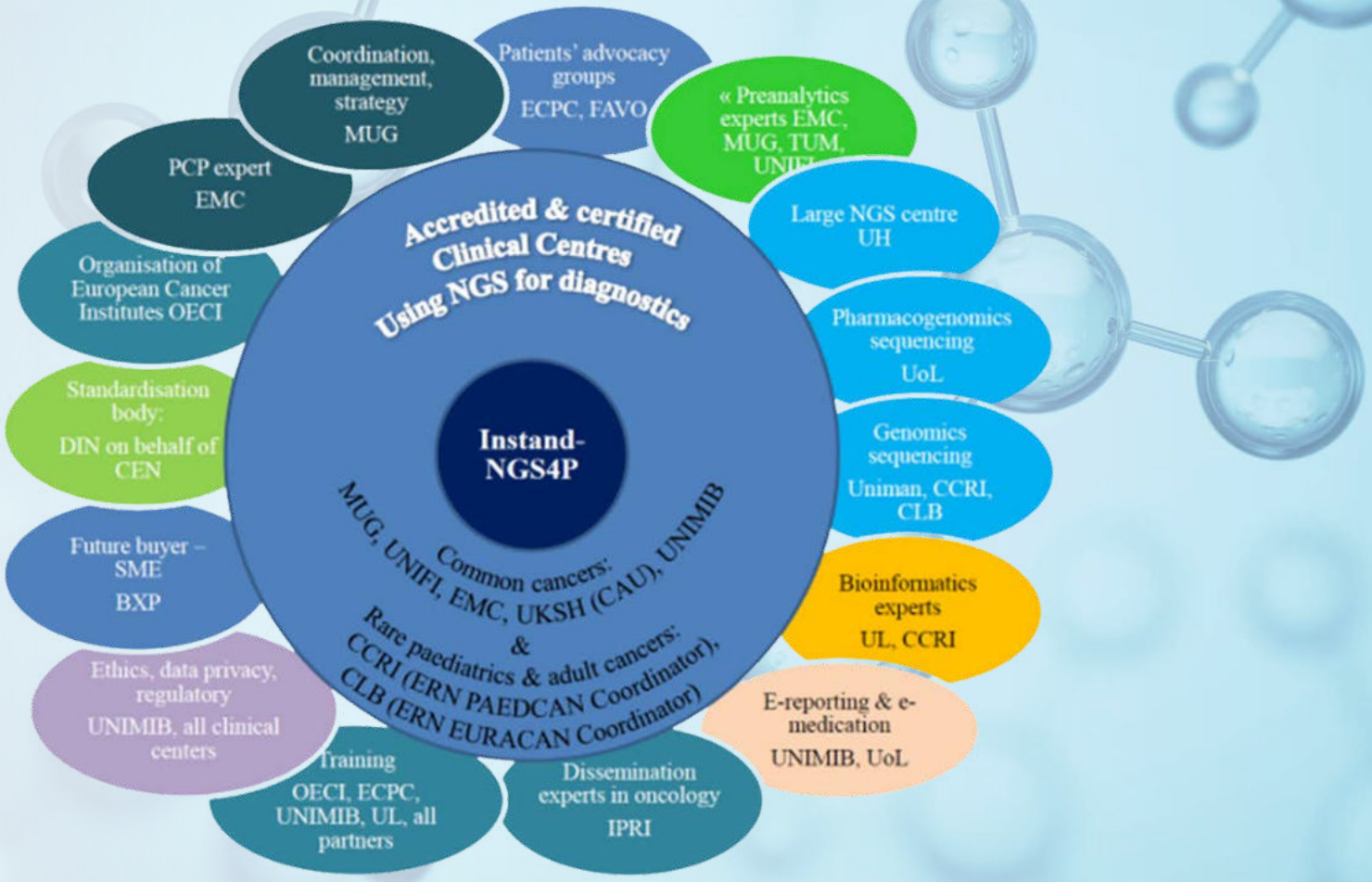
PRIME-ROSE

Access to affordable Precision Cancer Medicine (PCM) that prolongs life at the best quality possible for all cancer patients

MONALISA

A SIOPEN pragmatic **clinical trial to MOnitor NeuroblastomA relapse with LIquid biopsy Sensitive Analysis**

Pre-commercial procurement: Instand-NGS4P



https://www.instandngs4p.eu/

Integrated and Standardized NGS Workflows for Personalised Therapy
Bringing together the demand and supply in healthcare

A developing area: personalised prevention

- **A Personalised Prevention Roadmap for healthcare**, to support the definition and implementation of innovative, sustainable personalised strategies to prevent chronic diseases

- A **mapping** of the **existing predictive biomarkers** for chronicdiseaseswith major burden in the EU:
  - in terms of analytical and clinicalvalidity
  - but also in terms of clinical utility

- SRIA available on the projectwebsite

PROPHET
a PeRsOnalized Prevention roadmap for the future HEalThcare

https://www.prophetproject.eu/

Thank you!

#HorizonEU

https://ec.europa.eu/horizon-europe

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JA PCM
Joint Action Personalised Cancer Medicine

Any question?

→ Slido.com #JAPCM

Or scan the code below:

JA PCM
Joint Action Personalised Cancer Medicine

JA PCM KICK-OFF

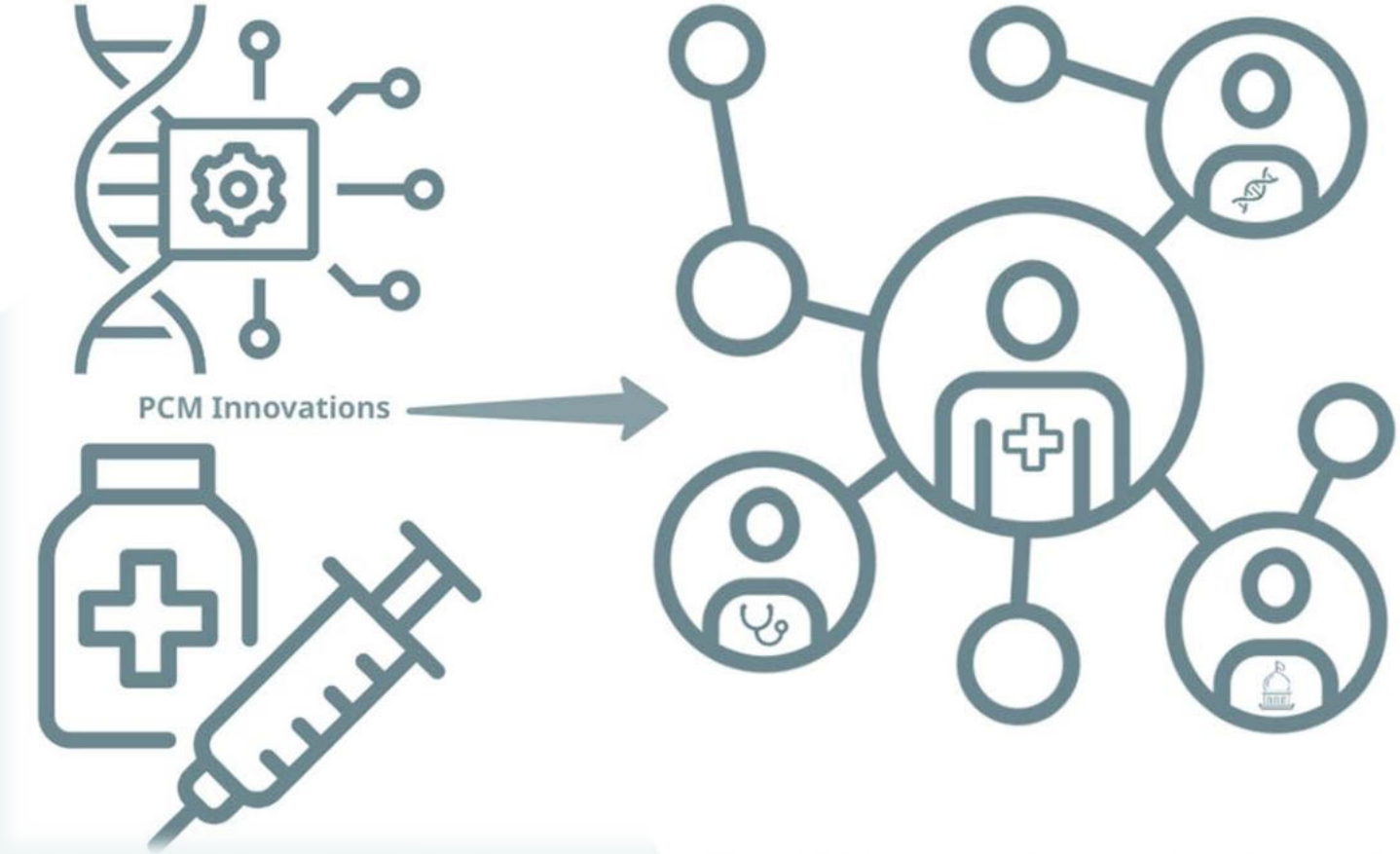
14/15 JANUARY 2026

Project Vision & Objectives Introduction

Els Van Valckenborgh & Nancy Frédérickx

Co-funded by the European Union

JA PCM
Joint Action Personalised Cancer Medicine



JA Personalised cancer Medicine (JA PCM)

Timeline: Nov 2025 – Nov 2029

Funding: 31.6 Million € (80% EU contribution / 20% in kind)

Consortium:

- 29 Countries
- 145 Partners (45 Competent authorities (CA) & 100 Affiliated entities (AE))
- 6 Associated Partners (AP)

Medical Care Organisation	71
Research Organisation	41
Public & Governmental Organisation	32
Professional Network	5
Patient Organisation	2

Building on:

MISSION & VISION

The JA PCM aims to strengthen the personalised cancer medicine network across Europe

- **Mission:** To leverage the potential of PCM within the EU by **increasing access to and knowledge of PCM in Europe**
- **Vision:** A comprehensive, **person-centred approach**, addressing multiple perspectives: from the healthy individual, to the cancer patient, to the survivors
- **Objectives:**

1	Ensure equitable access to PCM across the entire cancer pathway
2	Share data and best practices (e.g., digital tools, molecular diagnostics, liquid biopsy, molecular tumor board)
3	Build knowledge and capacity among healthcare professionals, patients, and the public

EXPECTED IMPACT

Key Impacts on Stakeholders

- Healthcare professionals & researchers gain competence in PCM, improve diagnostic and treatment capabilities, and contribute to evidence generation and collaborative data sharing

- Healthcare policymakers can align national policies with EU PCM goals, use pilot evidence, and support more efficient, equitable healthcare systems, ultimately reducing the cancer burden across populations.

- Cancer patients – Citizens benefit from more personalised care, active involvement in decision-making, and improved outcomes, gain awareness of cancer prevention, and earlier access to risk assessment

WORKPLAN

JA PCM
Joint Action Personalised Cancer Medicine

ARM 1
PERSONALISED PREVENTION

Map and assess frameworks for rapid development and implementation of **risk- and biology-based personalised prevention** in Europe, including **multicancer early detection**

WP5 Personalised Prevention
WP6 Early Detection

PILOT Risk-Informed Prevention (PARI)
PILOT Polygenic Risk Score (PRS)

ARM 2
PERSONALISED MEDICINE

Promote personalised cancer **diagnostics** by scaling up **ctDNA/liquid biopsy**, preparing for advanced diagnostics, and **expanding treatment options** through systematic evidence generation.

WP7 Diagnosis
WP8 Treatment

PILOT Molecular Tumor Board (MTB)
PILOT/USES CASES Data Collection & Sharing and Early Treatment Access

ARM 3
PERSONALISED FOLLOW-UP &TERTIARY PREVENTION

Enable optimal and equitable **digital tools** for remote monitoring, self-management, and supportive care, while advancing **tertiary prevention with liquid-biopsy-guided recurrence surveillance** to empower survivors

WP9 Digital Innovation
WP10 Tertiary Prevention

PILOT Digital Survivorship Tool

PILOT Cancer PredispositionCPS Compass
PILOT Liquid Biopsy ctDNA

TRANSVERSAL

Coordination (WP1)
Communication (WP2)
Evaluation (WP3)
Sustainability (WP4)

WP1 Lead

Sciensano, Belgium

Marc **Van Den Bulcke**

Els **Van Valckenborgh**

Nancy **Frédérickx**

Anouk **Waeytens**

An Catherine **Hoang**

WP2 Lead

Barthélémy **Moreau de Lizoreux**

Lieve **Dessing**

Pauline **de Wurstemberger**

WP3 Lead

Healthcare Quality and Evaluation Agency of Catalonia (AQuAS), Spain

Rossana **Alessandrello**

Claudia **Prats**

Ramon **Maspons**

WP4 Lead

National Board of Health and Welfare, Sweden

Malin **Eklund**

Malin **Berggrund**

WP4 colead

National Cancer Institute Luxembourg

Nikolai **Goncarenko**

Amélie **Gaignaux**

WP2 colead

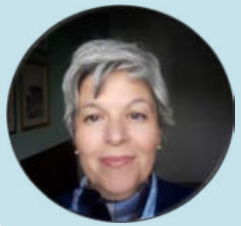
National Hellenic Research Foundation, Greece

TRANSVERSAL

Education and training and External Quality Assesment (WP11)
Legal, Ethics & Equity (WP12)
Data, Health Technology Assesment and Access (WP13)

WP11 Lead

Italian National Institute of Health, Italy



Roberta **De Angelis**

WP12 Lead

Karolinska University Hospital, Sweden

Frantzeska **Papadopoulou**

Eva **Jolly**

Katarina **Risbecker**

WP13 Lead

Leiden University Medical Center, The Nederlands

Sahar **Barjesteh van Waalwijk van Doorn-Khosrovani**

Floor **de Jong**

WP11 colead

University Medical Center Hamburg-Eppendorf, Germany

Klaus **Pantel**

Simon **Joosse**

WP12 colead

Sciensano, Belgium

Chloé **Mayeur**

Wannes **Van hoof**

Marlies **Saelaert**

WP13 colead

The Netherlands Cancer Institute, The Nederlands

Valesca **Retel**

Lifang **Liu**

Wim **Van Harten**

Gerrit **Meijer**

ARM1 PERSONALISED PREVENTION

Personalised Prevention (WP5)
Early Detection (WP6) & Related Pilots

ARM1 Lead

WP5 Lead

Pilot 5 Lead

Gustave Roussy, France

Suzette **Delaloge**

Maud **Kamal**

Lucie **Veron**

ARM1 Co-Lead

WP6 Lead

Pilot 5 Colead

Pilot 6 Colead

Netherlands Cancer Institute, The Nederlands

Gerrit **Meijer**

Beatriz **Carvalho**

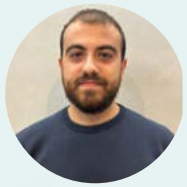
Marjanka **Schmidt**

WP5 Colead

A. Gemelli University Policlinic Foundation – IRCCS , Italy

Stefania **Boccia**

Erika **Giacobini**



Davide **Perrone**

Alessandra **Sabatelli**

Alessandra **Verduchi**

WP6 Colead

Institute for Health Sciences of Aragon, Spain

Juan **Gonzalez Garcia**

Pilot 6 Lead

Erasmus Medical Center, The Nederlands

Jeroen **Van Rooij**

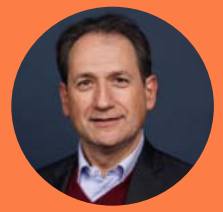
ARM2 PERSONALISED MEDICINE

Diagnosis (WP7)
Treatment (WP8) & Related Use Cases and Pilots

ARM2 Lead

Pilot 8 Lead

Alliance Against Cancer, Italy



Ruggero
De Maria

Valentina
Trapani

Lorenza
Meronetti

Patrizio
Giacomini

ARM 2 Colead

UC8,2 Lead

Unicancer, France

Christophe
Le Tourneau

Maud
Kamal

Venice
Hancock

Romain
Mignerat

ARM2 PERSONALISED MEDICINE

Diagnosis
Treatment & Related Use Cases and Pilots

WP7 Lead

The Netherlands Cancer Institute, The Nederlands

Gerrit
Meijer

WP8 Lead

Pilot 8 Colead

Oslo University Hospital, Norway

Kjetil
Taskén

Live
Fagereng

WP7 Colead

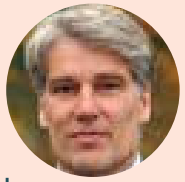
Karolinska University Hospital, Sweden

Päivi Östling

WP8 colead

UC 8.2 colead

Leiden University Medical Center, The Nederlands



Hans
Gelderblom

UC 8.1 Lead

University Medical Center Schleswig-Holstein, Germany

Nikolas
von Bubnoff

UC 8.1 colead

Vejle Hospital, Denmark

Torben
Frøstrup Hansen

Pilot 7&8 Lead

Vall d'Hebron Instute of Oncology, Spain

Alejandro
Piris

Christina
Stangl

Alberto
Hernando

Alba
López

Pilot 7&8 Colead

Catalan Institute of Oncology, Spain

Ernest
Nadal

Pilot 7&8 Colead

National Cancer Institute, Luxembourg

Nikolai
Goncharenko

Pilot 7&8 Colead

UC 8.1 colead

National Institute of Oncology Maria Skłodowska-Curie, Poland

Iwona
Ługowska

ARM3 FOLLOW UP & TERTIARY PREVENTION

Follow-up
Tertiary Prevention & Related Pilots

ARM3 Lead

Pilot T2 Lead

Aarhus University Hospital, Denmark

Claus
Lindbjerg Andersen

ARM3 Colead

WP9 colead

Pilot T1 colead

Sciensano, Belgium

Régine
Kiasuwa Mbengi

Marie
Lamberigts

WP9 Lead

Pilot 9 Lead

Gustave Roussy, France

Maria Alice
Franzoi

Sarah
Ball

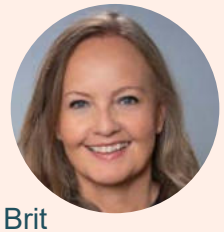
Petya
Zyumbileva

Ines
Vaz Luis

WP10 Lead

Vejle Hospital, Denmark

Torben
Frøstrup Hansen



Brit
Sandgren

Kamilla
Arp

Anette
Schulz

WP10 Colead

Regina Elena National Cancer Institute , Italy

Giovanni
Blandino

Matteo
Allegretti

Eriseld
Krasniqi

Roberta
Melchionna

Fabrizio
Fierro

ARM 1 – ARM 2 – ARM3

Transversal Pilots: T1 cancer predisposition and T2 Liquid biposy

Pilot T1 Lead

University Hospital and University Würzburg , Germany


Anke **Bergmann**


Nele **Loecher**


Annalisa **Musola**


Matt **McCrary**


Marie **Schnürer**

Pilot T1 Colead

Sciensano, Belgium


Hélène **Antoine-Poirel**


Maria Valeria **Freire Chadrina**

Pilot T2 Lead

The Netherlands Cancer Institute, The Nederlands


Remond **Fijneman**

Pilot T2 Colead

Alliance Against Cancer, Italy


Patrizio **Giacomini**

Pilot T2 Lead

Aarhus University Hospital, Denmark


Claus **Lindbjerg Andersen**

Pilot T2 colead

University Medical Center Hamburg-Eppendorf, Germany


Klaus **Pantel**


Simon **Joosse**

Stickers

JA PCM
Joint Action Personalised Cancer Medicine

ARM1

ARM2

ARM3

Transversal

Leaflet

- Agenda
- Executive Board’s Ambitions and Wishes for 2026
- Tools & Resources (Sharepoint, Zenodo, social media,…)

JA PCM
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JA PCM KICK-OFF

14/15 JANUARY 2026

WP1

Project Management & Coordination

Els Van Valckenborgh & Nancy Frédérickx

Co-funded by the European Union

sciensano

Project Management & Coordination Team

JA PCM
Joint Action Personalised Cancer Medicine

Cancer Centre , Sciensano Belgium

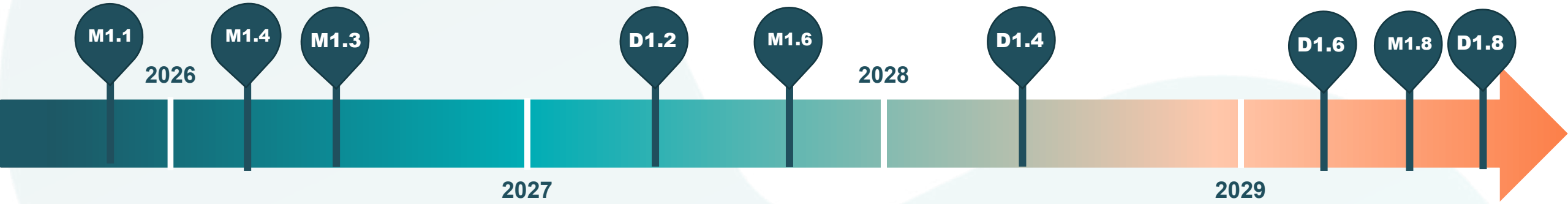
- Marc Van Den Bulcke
  Head of The Cancer Centre
- Els Van Valckenborgh
  Scientific & Lead Coordination Manager
- Nancy Frédérickx
  Scientific & Coordination Manager
- Anouk Waeytens
  Scientific & Coordination Manager
- An Catherine Hoang
  Administrative Manager

WORKPLAN

Consortium management:

- T1.1 Consortium management
- T1.2 Knowledge management
- T1.3 Technical and Financial Reporting
- T1.5 Ensure funding and operationalisation of the interventions

MILESTONE 1.1, 1.6, 1.8	Consortium meeting (Kick-off, GA, Final event)	M2, M24, M47
MILESTONE 1.3	Consortium agreement	M6
MILESTONE 1.4	Coordination Fund	M4
DELIVERABLE 1.2, 1.4, 1.6	Cumulative expenditure report I, II, III	M17, M29, M41
DELIVERABLE 1.8	Report on specific action-level indicator	M48

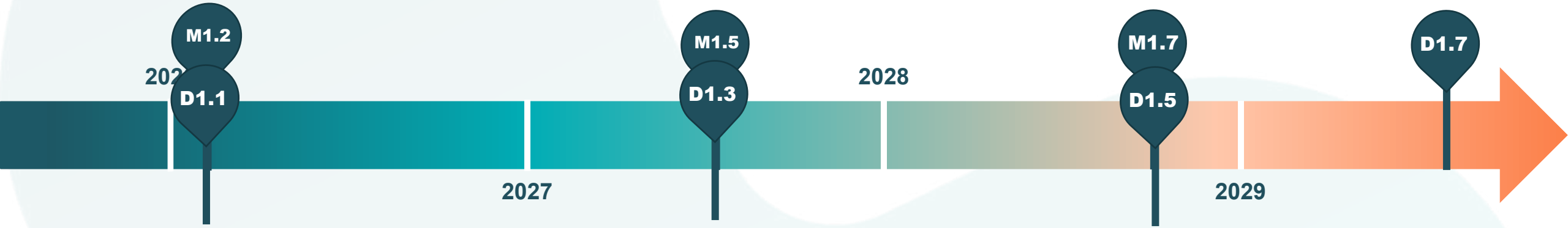


WORKPLAN

PCM network implementation:

- T1.4 PCM Roadmap in Europe, aligning with parallel initiatives

MILESTONE 1.2, 1.5, 1.7	JA PCM – SPARC Synergy I, II, III	M3, M18, M36
DELIVERABLE 1.1, 1.3, 1.5	JA PCM – SPARC Synergy I, II, III	M3, M18, M36
DELIVERABLE 1.7	PCM Roadmap in Europe	M47



WORKPLAN & OUTCOMES

JA PCM
Joint Action Personalised Cancer Medicine

Evolving process

Synergy & Alignment with parallel initiatives

Involvement of the public and private stakeholders

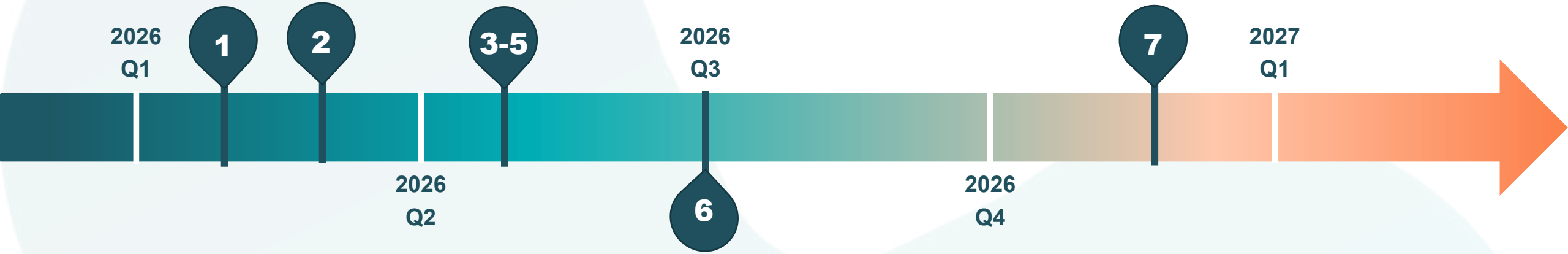
Informed by the action-level indicator

EU – PCM :
- Network
- Roadmap
- Platform

NEXT STEPS

Short-term steps and timeline

STEP 1	D1.1 JA PCM-SPARC Synergy I	M3
STEP 2	Planning meetings year 1+ Project management plan	M4
STEP 3	Consortium Agreement	M6
STEP 4	Action-level indicator strategy	M6
STEP 5	Establish Coordination fund for pilots	M6
STEP 6	Roadmap: PCM Mapping	M8
STEP 7	Cooperation mechanism with parallel initiatives	M13



Transversal

WP1 Project management and coordination

Our ambition

- Extend access to and knowledge of PCM across Europe
- Unite all relevant stakeholders
- Establish a European PCM network

Our wishes for 2026

- To connect more, share more, and learn from each other through trust and mutual respect
- That every partner feels heard, valued, and engaged
- Lots of inspiration and mutual growth

THE TEAM

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Marc Van den Bulcke
Sciensano, Belgium

Nancy Frédérickx
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Anouk Waeytens
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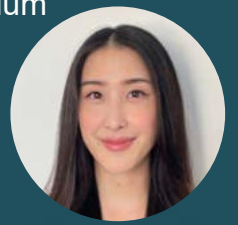

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JA PCM
Joint Action Personalised Cancer Medicine

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ENJOY A LITTLE COFFEE BREAK

Please be back on time for the next session

AGENDA

PICK UP YOUR STICKER(S)

ARM1

ARM3

ARM2

Transversal

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WP2

Communication

Barthélémy Moreau de Lizoreux

Lieve Dessing

Co-funded by the European Union

sciensano

WP2 Communication

JA PCM
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Lead

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Υπουργείο Υγείας
1η Υγειονομική Περιφέρεια Αττικής

ΕΘΝΙΚΟ ΙΔΡΥΜΑ ΕΡΕΥΝΩΝ
National Hellenic Research Foundation

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How would you explain the Joint Action to your mom, a policy maker, colleague, or a patient diagnosed with cancer?

MISSION & VISION

WP 2 will:

1. make JA PCM understandable, coherent, and visible inside and outside the consortium
2. build a strong EU-wide stakeholder network encouraging sharing of best practices, cross-border collaboration, and knowledge sharing

- **OBJECTIVES**
  - Maximise the impact of JA PCM
  - Establish and develop communication and dissemination strategies and tools
  - Foster stakeholders engagement
  - Ensure the adoption of project outputs
  - Ensure the visibility of EU funding

WORKPLAN

- Task 1 Create the JA’s visual and brand identity and set up the website and internal communication platform.
- Task 2 Develop the JA’s communication and dissemination plan
- Task 3 Implementation of the dissemination strategy to broadly spread the JA's objectives, development and results
- Task 4 Develop and manage internal communication within the JA
- Task 5 Stakeholders’ engagement

NEXT STEPS 2026

1	Synergies with SPARC (D1.1)	January 2026
2	Website (D2.1)	April 2026
3	Communication plan (D2.2)	April 2026
4	Communication handbook (MS 9)	April 2026
5	KPI report (MS11)	November 2026

JA PCM Expert Platform - SharePoint

JA PCM
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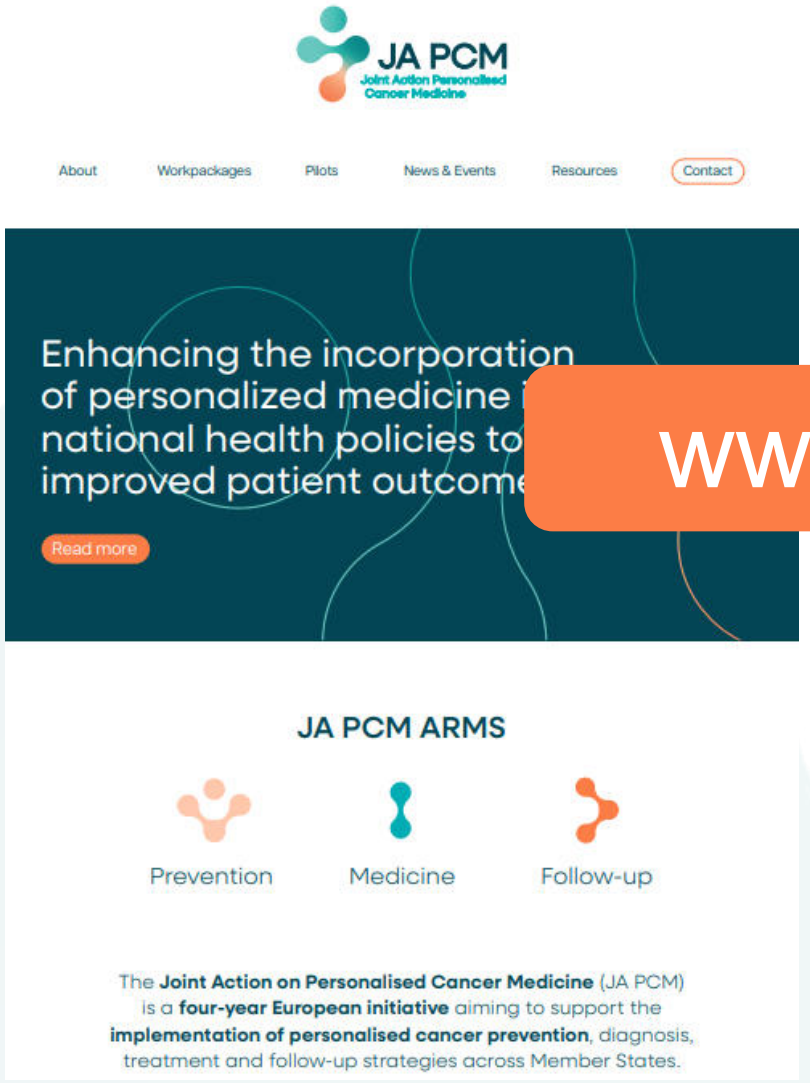
- The JA PCM Expert Platform will be our central collaboration hub for document sharing
- **Request an access** by scanning the QR code or using this link
- Manuals and login credentials will be sent to your email in the coming weeks

Website



www.japcm.eu

JA PCM
Joint Action Personalised Cancer Medicine

Connect, Share, Stay informed
Follow our channels!

LinkedIn

JA PCM

Bluesky

@japcm.bsky.social

Zenodo Repository

JA PCM

Conclusion

- Share and spread the word
- Keep us informed of any upcoming output or external activity (event, publication…)
- We are here to help!
- Guidance documents will be shared with you after the kick-off meeting
- Open for questions or suggestions
- Follow our channels!

JA PCM
Joint Action Personalised Cancer Medicine

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WP 11

Education and EQA

Roberta De Angelis, ISS, Italy

Co-funded by the European Union

ISTITVTO SVPERIORE DI SANITÀ

Education and EQA of Liquid Biopsy

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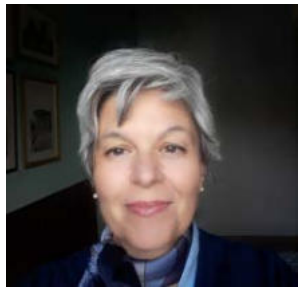
LEAD



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Italian National Institute of Health, ISS, IT

COLEAD

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University Medical Center Hamburg-Eppendorf, UKE, DE

Founder & chairman of the European Liquid Biopsy Society (ELBS)

Simon Joosse

University Medical Center Hamburg-Eppendorf, UKE, DE

Training and information needs in PCM

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Joint Action Personalised Cancer Medicine

Genomic data integrated into treatment planning

ct-DNA *Genomic testing* *Consensus guidelines for MTBs*

Tools for interpretation of genomic information

Standardised core curricula *Trustable information sources*

Hereditary cancers *Effective communication to patients*

Pharmacogenomics *Return of incidental findings*

Ethical guidelines for oncogenomic testing

Genetic counselling Citizens engagement

Germline or somatic variants

Gap analyses, health professionals, patients, citizens, CanHeal project, 2025

MISSION & VISION

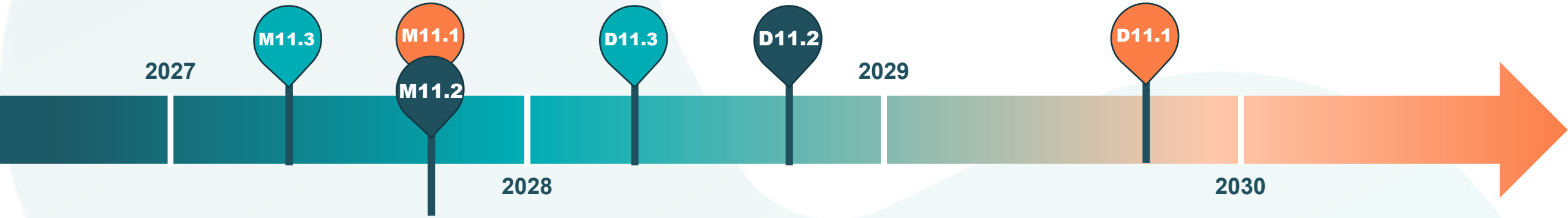
- In alignment with the overall mission & vision of the JA PCM, **WP 11 aims to build knowledge and capacity among healthcare professionals, patients, and the public**

- **OBJECTIVES**
  - **Objective 1 –** Support the implementation of MTBs, LB and other PCM innovations in Europe, by providing tailored training pathways addressing the needs of multiple professionals involved
  - **Objective 2 –** Foster knowledge and attitudes about PCM among the wider health workforce through educational interventions in the context of Continuing Medical Education (CME)
  - **Objective 3 –** Improving access to PCM innovations by improving patient literacy and public awareness of basic concepts of genetics and oncogenomics

WORKPLAN

- Task1 **Advanced training pathways for CCCs**, Lead VHIO (ES) + UKE (DE), IDIVAL (ES), RSU (LV)
- Task2 **Basic trainings for HPs**, Lead ISS (IT)
- Task3 **Communication to patients and citizens**, Lead INSA (PT) + IISLAFE (ES)

MILESTONE 11.1	Technical framework and strategy set up	Oct 2027
DELIVERABLE 11.1	Delivery of trainings on ESO platform	Oct 2029
MILESTONE 11.2	Updated educational materials finalised	Oct 2027
DELIVERABLE 11.2	Delivery on multiple national e-learning platforms	Oct 2028
MILESTONE 11.3	Production workflow finalised	Apr 2027
DELIVERABLE 11.3	Delivery of communication campaign strategy	Apr 2028



PARTICIPANTS
19 countries, 37 organizations

JA PCM
Joint Action Personalised Cancer Medicine

Belgium: Sciensano, KU
Croatia: KBC SM, RBI
Cyprus: BOCOC
Denmark: AUH
Estonia: UTARTU, TUH
France: Inserm, IC
Germany: UKE, Charité
Greece: NHRF
Italy: ISS, IFO, FPG, Promis, REGLOM
Latvia: LBMC, RSU, UL
Lithuania: LSMU, NVI
Luxembourg: INC
Moldova: IO
Poland: MSCI, MUB, MUW
Portugal: INSA
Romania: UMFIH
Slovenia: OIL
Spain: ICO, IISLAFE, VHIO, IDIVAL, SCS
Sweden: RS

WORKPLAN, approaches and methods

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1. Advanced trainings to CCCs

- **Topics:** molecular oncology, LBs, genetic susceptibility, PRS, risk stratified screening
- **Target:** health and non-health professionals involved in PCM
- **Links:** EUnetCCC, CCI4EU, Genturis, NoE Omics
- **Platform**: ESO e-learning platform

2. Basic Trainings to HPs

- **Topics:** PCM innovations
- **Target:** physicians, biologists, pharmacists
- **Model:** Can.Heal e-learnings, accreditation, natural language
- **Platforms:** national platforms for Continuing Medical Education (CME)

3. Communication to patients and citizens

- **Topics:** Personalised cancer prevention and care
- **Target:** patients, caregivers, general public
- **Model**: Can.Heal videos, communication campaign strategy, natural language, inclusivity/equality
- **Dissemination**: JA PCM consortium

EXPECTED OUTCOMES & IMPACT

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Expected Outcomes:

- Develop and provide training for professionals involved in PCM
- Strengthen the impact of initiatives to build capacity of CCCs in Europe
- Develop materials and scalable strategy to inform patients and citizens about PCM

Key Impacts on Stakeholders

- Healthcare professionals & researchers: gain competence in PCM
- Healthcare policymakers: adopt recommendations and education programs
- Cancer patients – Citizens: gain awareness, and earlier access to personalised prevention and care

NEXT STEPS

STEP 1	Synergy strategy with SPARC	Dec 2025
STEP 2	WP governance: meetings schedule & partnership	Feb 2026
STEP 3	Horizon scanning and alignment with parallel initiatives	Apr 2026
STEP 4	Design of production workflow for communication	Jun 2026
STEP 5	Needs analysis, co-design of planned training interventions finalised	Oct 2026

Conclusion

- Improving training of health professionals is crucial to foster PCM implementation in the clinical practice
- Comprehensive educational programs are needed: both foundational knowledge and advanced topics
- Patients and citizens need reliable sources of information and improved competences to fully benefit of the new opportunities offered by PCM

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WP 11

Education and EQA

Simon Joosse, UKE, Germany
Klaus Pantel, UKE, Germany

UKE HAMBURG

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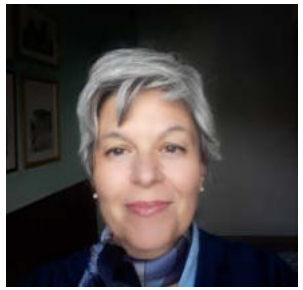

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University Medical Center Hamburg-Eppendorf, UKE, DE

Founder & chairman of the European Liquid Biopsy Society (ELBS)

Simon Joosse

University Medical Center Hamburg-Eppendorf, UKE, DE

Liquid biopsy lacks harmonization in the EU

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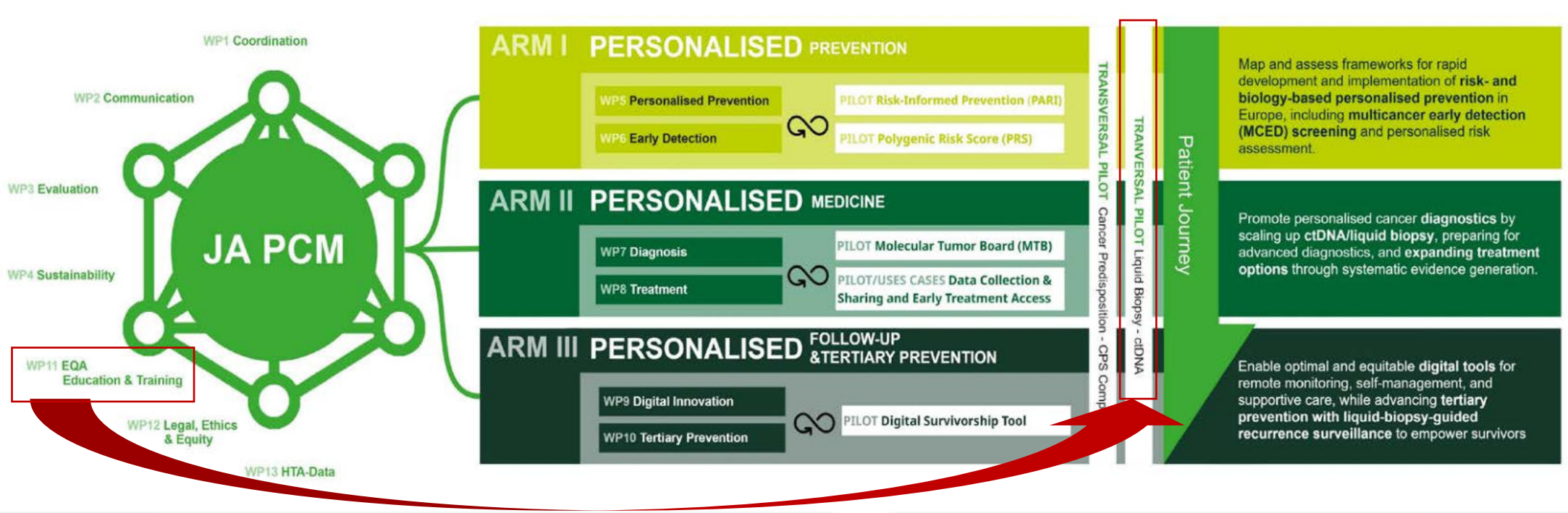
Work package 11 – External quality assessment

MISSION & VISION

To build a sustainable, EU-wide External Quality Assessment (EQA) framework that ensures liquid biopsy assays are accurate, comparable, and trusted everywhere.

Vision:

A Europe where ctDNA-based decisions are made with confidence, supported by harmonized standards, robust guidelines, and a long-term ecosystem that even outlives JA PCM.



WORKPLAN: Building the Journey

- Task 11.4 – Support partners in the LB pilot with EQA (AUH)
- Task 11.5 – Ensuring sustainability of EQA in EU (UKE/ELBS)

MILESTONE 11.4	Guidelines on EQA and sustainability roadmap	Oct 2029
DELIVERABLE 11.4	A platform for exchanging the outcomes of the LB EQA program with the JA affiliated partners	April 2029
DELIVERABLE 11.5	A publication with optimized guidelines on the use of LB in the EU based on the experience of the JA.	Oct 2029

WORKPLAN:
The Network Behind the Mission

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Countries & Institutions Involved

- AUH (T11.4) — Leading the EQA pilot, distributing RefMat, coordinating annual cycles.
- UKE / ELBS (T11.5) — Driving sustainability, harmonization, and long-term EQA strategy.
- Liquid biopsy pilot participants
- WP4 — Ensuring alignment with sustainability.
- WP13 — Integrating health-economic insights for sustainability.
- Patient advocacy groups — Ensuring patient-centred design and communication.

EXPECTED OUTCOMES & IMPACT

Contribution to the JA PCM Goal

WP11 ensures that precision medicine decisions based on liquid biopsy (LB pilot) are accurate across Europe.

Impact by Stakeholder

Patients
- More reliable diagnoses and treatment decisions
- Increased trust in liquid biopsy technologies
- Reduced disparities between countries

Clinicians & Molecular Tumor Boards (MTBs)
- Clear, optimized guidelines for LB use
- Confidence in assay performance
- Faster, more consistent decision-making

Laboratories & Hospitals
- Benchmarking against EU standards
- Support for continuous improvement
- Access to high-quality reference materials

Policy Makers & Health Systems
- A sustainable, EU-wide EQA model
- Evidence-based roadmap for long-term adoption
- Foundation for ISO17043-aligned quality assurance

NEXT STEPS

STEP 1	Finalize supply chain for RefMat and online database for collecting EQA results	Q1
STEP 2	Recruit and onboard pilot laboratories (LB pilot) Update the preliminary guidelines	Q2
STEP 3	EQA participant preparation workshop Distribute RefMat samples Initiate the first blinded external performance assessment	Q3
STEP 4	Begin centralized performance analysis Initiate sustainability roadmap workshops with ELBS and WP13	Q4
STEP 5	Prepare EQA results workshop Start reviewing first round EQA results with partners	End of year 1

Conclusion

“Three Messages to Remember”

1. Quality is the gateway to trust.
   - Without harmonized EQA, liquid biopsy cannot reach its full clinical potential.
2. Europe can lead the world in LB standardization.
   - WP11 unites expertise, institutions, and innovation into one coordinated framework.
3. Sustainability is our legacy.
   - We are not building a project, we are building a long-term European system that will serve patients for decades.

EU/IHI Consortia on Liquid Biopsy

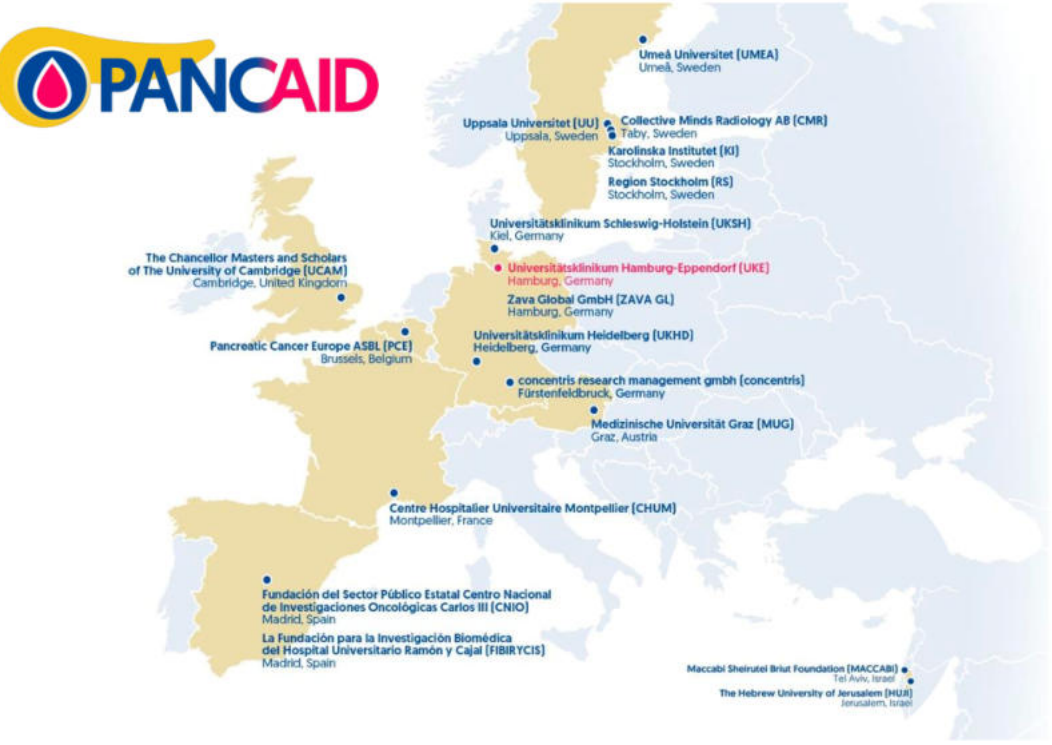
HORIZON-MISS-2021-CANCER-02-01 - Develop new methods and technologies for cancer screening and early detection

PANcreatic CAncer Initial Detection via liquid biopsy

Coordinator: Prof. Dr. Klaus Pantel Universitätsklinikum Hamburg-Eppendorf (UKE)

Co-Coordinator: Prof. Dr. Matthias Löhr Karolinska Institutet (KI)

Project duration: 01 January 2023-31 December 2027



HORIZON-JU-IHI-2022-01-03 - Personalised oncology: innovative people centred, multi-modal therapies against cancer

GUIding multi-moDal thErapies against MRD by liquid biopsies

Coordinator: Prof. Dr. Klaus Pantel Universitätsklinikum Hamburg-Eppendorf (UKE)

EFPIA project lead: Luigi Ravagnan Bristol-Myers Squibb (BMS)

Co-Coordinator: Prof. Dr. Claus L. Andersen Aarhus University

Project duration: 01 May 2023-30 April 2028

GUIDE.MRD

Coordinator: University Medical Center Hamburg-Eppendorf

innovative health initiative

Co-funded by the European Union

This project is supported by the IHI Joint Undertaking (JU) under grant agreement No. 101112066. The JU receives support from the European Union's Horizon Europe research and innovation programme and EFPIA (including Vaccines Europe), MedTech Europe and LGC Clinical Diagnostics Inc. Funded by the European Union, the private members, and those contributing partners of the IHI JU. Views and opinions expressed are however those of the author(s) only and do not necessarily reflect those of the aforementioned parties. Neither of the aforementioned parties can be held responsible for them.

Academic partners

UKE Hamburg · Aarhus University · umcg · chu de Nice · Aarhus University Hospital · Med Uni Graz · cnio stop cancer · CHU · LungenClinic Grosshansdorf · Karolinska Institutet · Karolinska Universitetssjukhuset

EFPIA partners

Bristol Myers Squibb · Roche · abbvie · AMGEN · labcorp · AstraZeneca

Patient partners

The Synergist · Lung Cancer Europe · Digestive Cancers Europe

MedTech partners

illumina · revvity

Operations partners

InoMed · Inn·Acta

Contributing partners

LGC Clinical Diagnostics

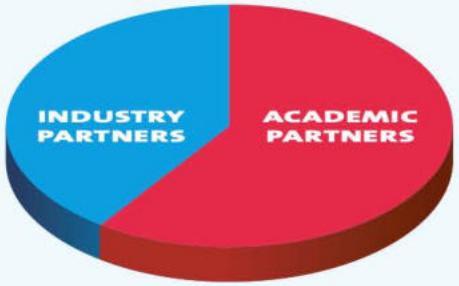
Consortium of 101 Institutions from academia and industry: Clinical implementation of Liquid biopsy

ELBS – “Legacy” (EU/IMI Factsheet 05/2022)

ELBS

EUROPEAN LIQUID BIOPSY SOCIETY

CURRENT MEMBERS



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WP12

Addressing Ethical, Legal and Societal Issues (ELSI) in JA PCM

Presenting: Katarina Risbecker

Co-funded by
the European Union

WP12 – ELSI in JA PCM

JA PCM
Joint Action Personalised Cancer Medicine

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ELSI expert
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ELSI unit lead
Sciensano

WP12 – ELSI in JA PCM

JA PCM
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TASK LEAD

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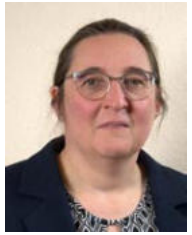
Sciensano
12.1 Task lead
Integrating ELSI into JA PCM

Jörg Haier
Rostock Medical University – CCC
12.2 Task lead
Inequalities and societal implications of PCM



Catharina Scholl
Bfarm
12.3 Task lead
Sharing data and scaling genomic platforms and remote services

Emmanuel Rial
INSERM
12.1 Task Co-lead

Giulia Puliani
IFO
12.2 Task co-lead

Arto Mannermaa
University of Eastern Finland
12.3 Task co-lead

OPINION | STEVEN PINKER

The moral imperative for bioethics

By **Steven Pinker** . August 1, 2015, 12:00 a.m.

> *...the primary moral goal for today's bioethics can be summarized in a single sentence. Get out of the way.*

JA PCM
Joint Action Personalised Cancer Medicine

A personal take on science and society

World view

Confusion over data-privacy law stalls scientific progress

By Robert Eiss

Our goal:

Leverage our EU regulatory and ethical frameworks to support a trusted and equitable implementation of precision cancer medicine

MISSION & VISION

- WP12 envisions a future where PCM is implemented across Europe in a trusted, ethical and equitable way, centred on patients and supported by harmonized standards. By aligning regulations, best practices and patient perspectives, WP12 seeks to lay the foundation for seamless cross-border collaboration, shared decision-making and equal access to innovation.

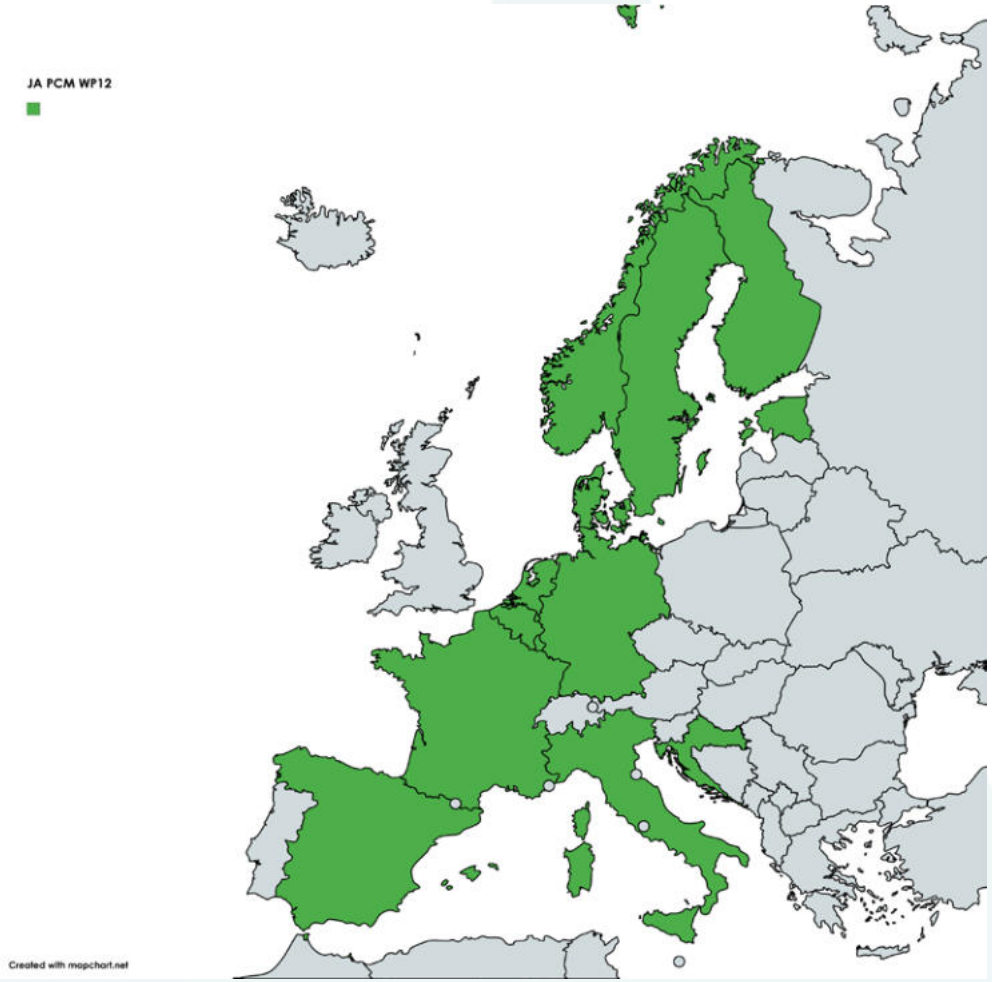
- **OBJECTIVES**
  - Enable legal, ethical and equitable implementation of PCM
    - Identify ethical, legal, regulatory and equity challenges and develop practical strategies and tools to support JA PCM use cases
  - Support cross-border collaboration
    - Align guidelines, frameworks and best practices across member states to enable data sharing, regulatory coherence and shared decision-making
  - Ensure patient integrated approaches
    - Actively involve patients and build on existing European initiatives to integrate best practices and maximise impact

MILESTONES & DELIVERABLE

- Task 12.1: Integrating ELSI into JA PCM
  Lead: Sciensano (Belgium), Co-lead: Inserm (France)
- Task 12.2: Inequalities and societal implications of PCM
  Lead: Rostock CCC (Germany), Co-lead: IFO (Italy)
- Task 12.3: Sharing data and scaling genomic platforms and remote services
  Lead: Bfarm, (Germany), co-lead: University of Eastern Finland, (Finland)

MILESTONE 12.1	Annual ELSI themed consensus workshops	Date M12,24,36,48
MILESTONE 12.1	Stakeholder engagement (workshops, interviews, focus groups) regarding new vulnerabilities in PCM	Date M36
DELIVERABLE 12.1	Toolkit for ELSI considerations in PCM	Date M48

PARTICIPANTS



WP12 Ethical, Legal & Equity considerations

Country	Organisation short name	Organisation name	Participation according to Grant Agreement
Belgium	SC	Sciensano	WP 12 co-lead & Task lead 12.1
Croatia	KBC SM	Klinicki Bolnicki Centar Sestre Milosrdnice Ustanova	1
Denmark	AUH	Aarhus University Hospital	1
Estonia	UTARTU	Tartu Ulikool	1
Finland	UEF	University of Eastern Finland	Task co-lead 12.3
France	CLB	Centre de Lutte Contre le Cancer Leon Berard	1
France	INSERM	Institute national de la santé et del a recherche medical	Task co-lead 12.1
Germany	BFARM	Federal Institute for Drugs and Medical Devices	Task lead 12.3
Germany	UMR	Rostock Medical University - CCC	Task lead 12.2
Germany	UKSH	University Hospital Schleswig Holstein	1
Italy	IFO	Istituti Fisioterapici Ospitalieri	Task co-lead 12.2
Luxembourg	LNDS	PNED GIE	1
The Nehterlands	EMC	Erasmus University Medical Centre Rotterdam	1
Norway	OUH	Oslo University Hospital	1
Norway	HDIR	Norweigan Directorate of Health	1
Spain	IISLAFE	Research Institute University Hospital Valencia	1
Spain	IRB	Barcelona Research Institute	1
Sweden	KI	Karolinska Institute	1
Sweden	KUS/RS	Karolinska University Hospital / Region Stockholm	WP 12 lead
Sweden	SIR	Stockholm School of Economics Institute for Research	1
	13 countires	**20 institutions**	

WORKPLAN

WP12 methodology – how we work

Monitor *activities and identify ethical, legal and societal needs through continuous dialogue*

Align *with EU-strategies, ELSI working groups and JA PCM WPs*

Joint development *of solutions with patients, experts and other stakeholders*

Apply *best practices to practical, scalable tools*

EXPECTED OUTCOMES & IMPACT

Expected outcomes

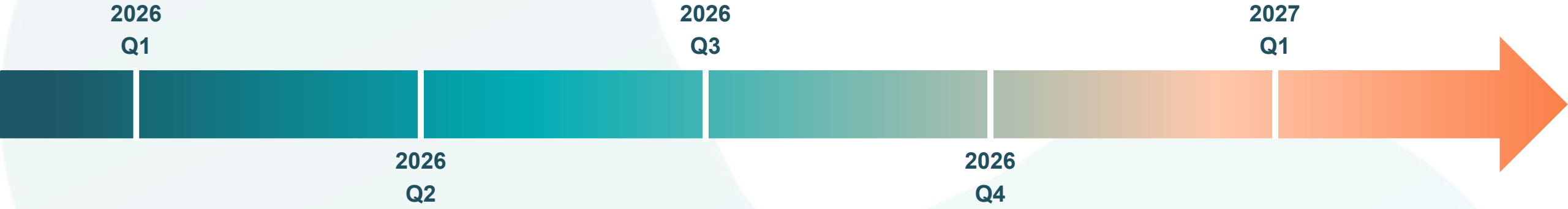
- Active patient involvement in ELSI
- Best practices and guidelines to support decision-making
- Cross-border knowledge exchange to leverage existing frameworks

Key impacts on stakeholders

- Cancer patients and relatives: early engagement to ensure patient-centred approaches
- Healthcare professionals & researchers: toolkit and guidance to facilitate implementation
- Healthcare policymakers: consolidated best practices to guide compliance and policy alignment

NEXT STEPS

STEP 1	Map existing ELSI frameworks
STEP 2	Engage patients
STEP 3	Monitor WP and pilot activities
STEP 4	Develop practical tools
STEP 5	Organise workshops



Conclusion WP12

- WP12 is available to support ELSI challenges identified in JA PCM, developing practical tools for safe, compliant and patient-centred cross-border PCM.
- Patients first – From equity to access, WP12 ensures that PCM respects patients' values, needs and vulnerabilities – leaving no one behind.
- Impact driven by collaboration – By identifying and proposing shared procedures, clarifying legal and ethical requirements for compliant and secure data sharing and aligne with other EU projects and ongoing initiatives WP12 contributes to make real-world PCM adoption possible across member states.

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Contact

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WP13

Data, HTA and Access

Valesca Retèl, Lifang Liu & Floor de Jong

Co-funded by the European Union

LUMC

NETHERLANDS CANCER INSTITUTE
ANTONI VAN LEEUWENHOEK

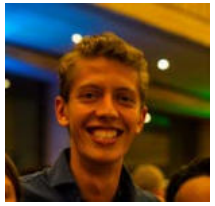
Data, HTA and Access

JA PCM
Joint Action Personalised Cancer Medicine

Lead

Sahar Barjesteh van Waalwijk van Doorn-Khosrovani, PhD, PharmD

13.3 Access



Floor de Jong, PharmD

13.3 Access

Co-lead

Valesca Retèl, PhD

13.2 HTA Framework

Wim van Harten, PhD

13.2 HTA Framework

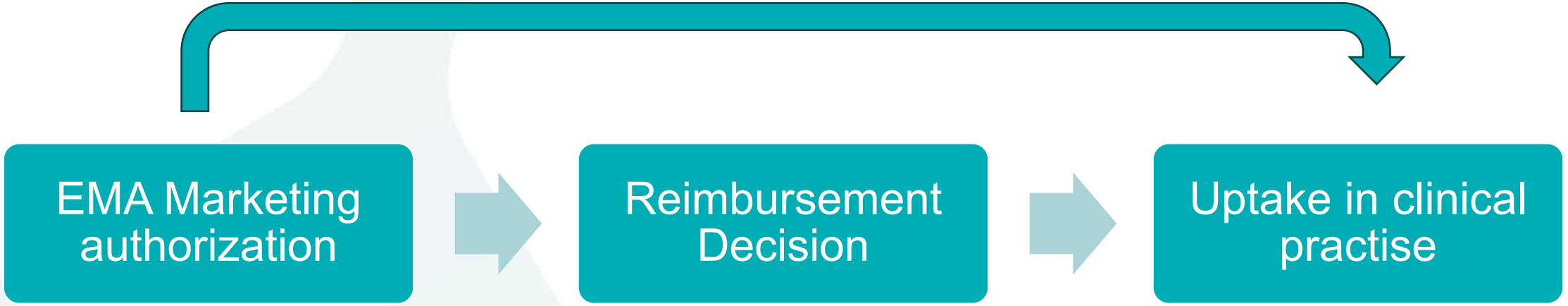
Gerrit Meijer, MD, PhD

13.1 Data infrastructure

Lifang Liu, MD, PhD

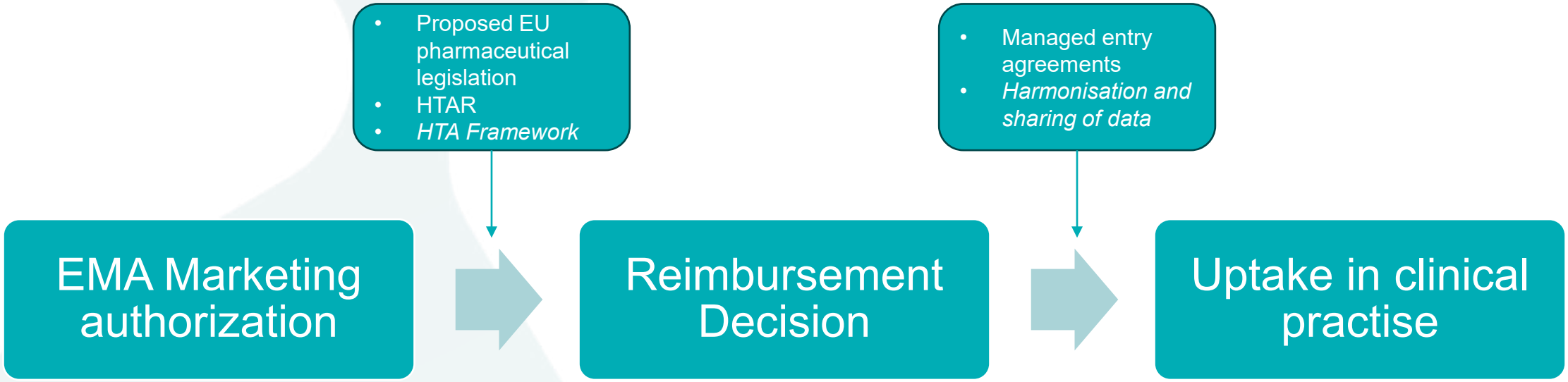
13.1 Data Infrastructure

Avg 766 days (*range: -328 – 2591 days)*



➢ ***Faster access to medicine saves lives***

Vancoppenolle et al, 2024



➢ ***Faster access to medicine saves lives***

Comparator Report on Cancer in Europe 2025

MISSION & VISION

- *Improve and fasten access to personalised cancer medicine by removing barriers and streamlining data collection and HTA*

- **OBJECTIVES**

Harmonise data collecting and sharing for PCM data

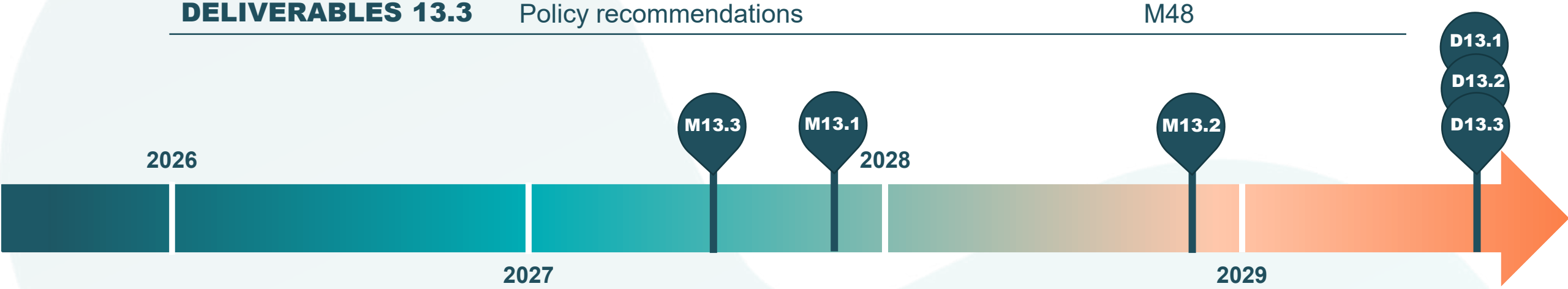
Build an HTA framework for PCM evaluation

Formulate policy recommendations to remove barriers and improve access to PCM

WORKPLAN

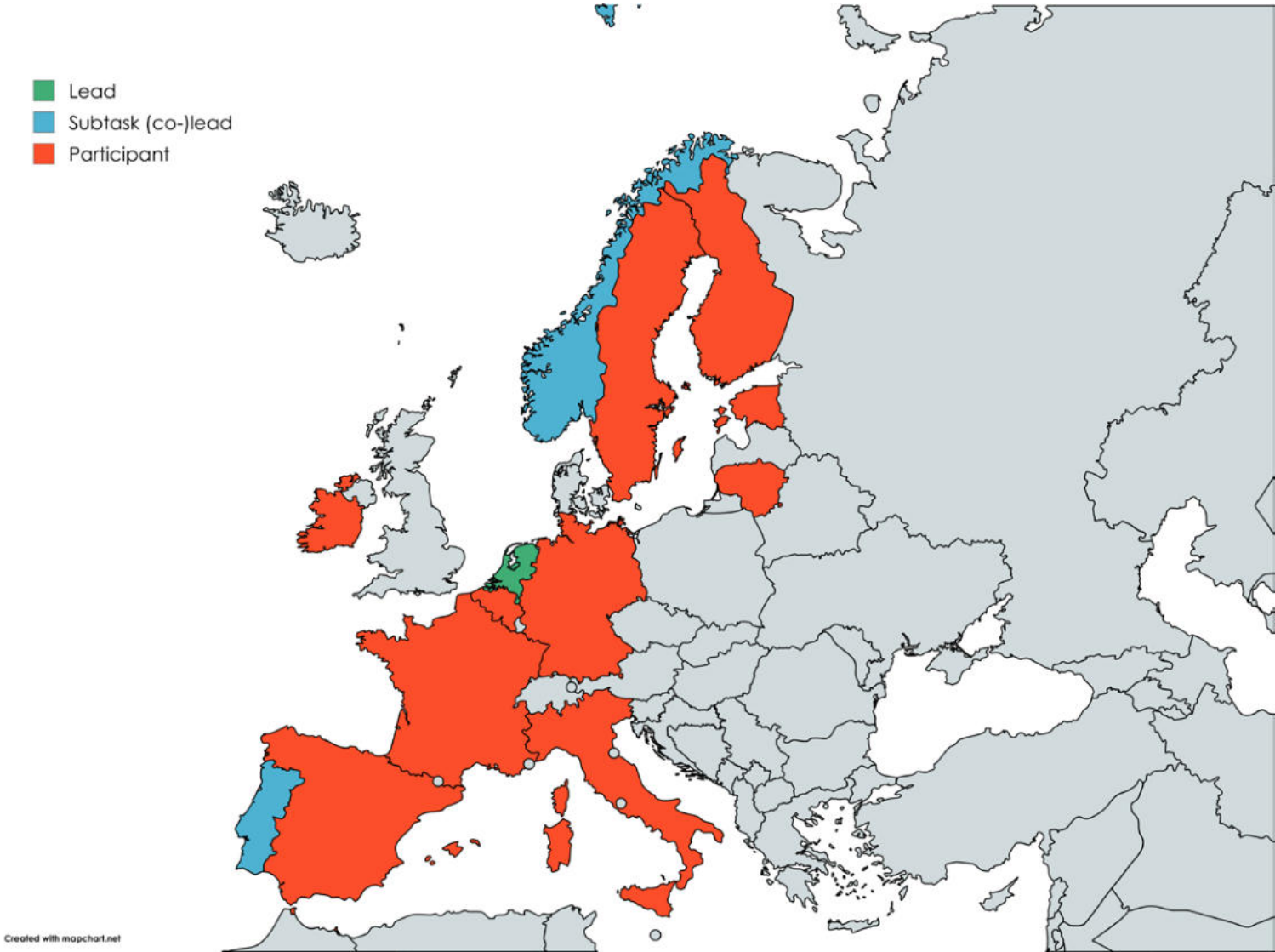
- Create a data infrastructure for PCM data (NKI-data)
- Build an HTA framework for PCM evaluation and perform on pilots/use cases within JA PCM (NKI-HTA)
- Explore uncertainties of stakeholders and make policy recommendations (LUMC)

MILESTONE 13.1	Data model recommendations	M24
DELIVERABLE 13.1	EHDS implementation templates	M48
MILESTONE 13.2	HTA framework on PCM per arm	M36
DELIVERABLE 13.2	HTA report on 1 pilot of each arm	M48
MILESTONE 13.3	Explore perspectives of stakeholders	M18
DELIVERABLES 13.3	Policy recommendations	M48

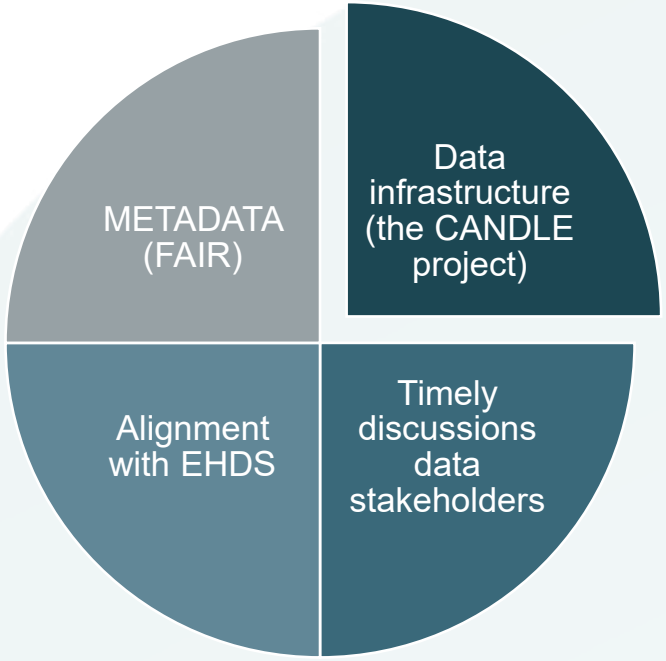


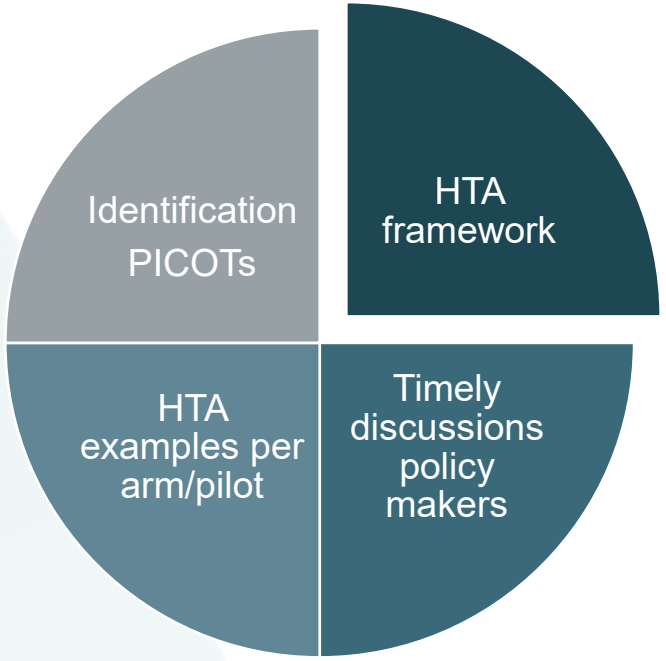
PARTICIPANTS

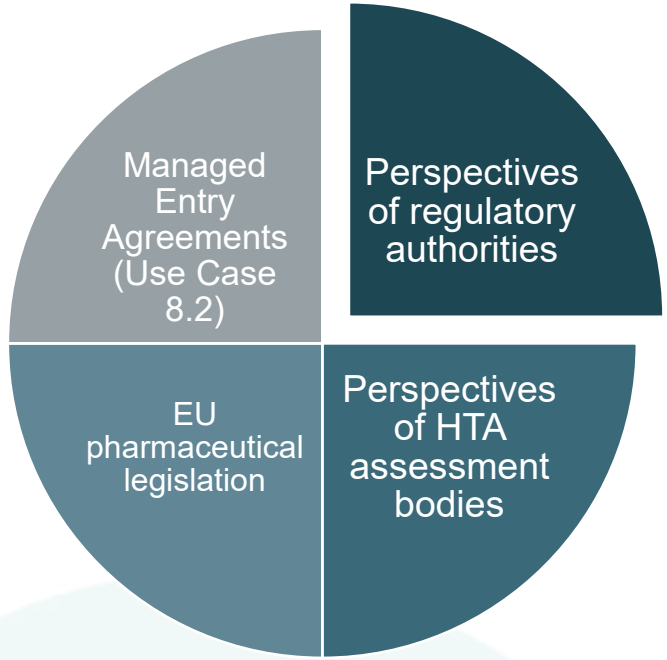
- Countries: 13
- Participants: 17



WORKPLAN


METADATA (FAIR)
Data infrastructure (the CANDLE project)
Alignment with EHDS
Timely discussions data stakeholders


Identification PICOTs
HTA framework
HTA examples per arm/pilot
Timely discussions policy makers

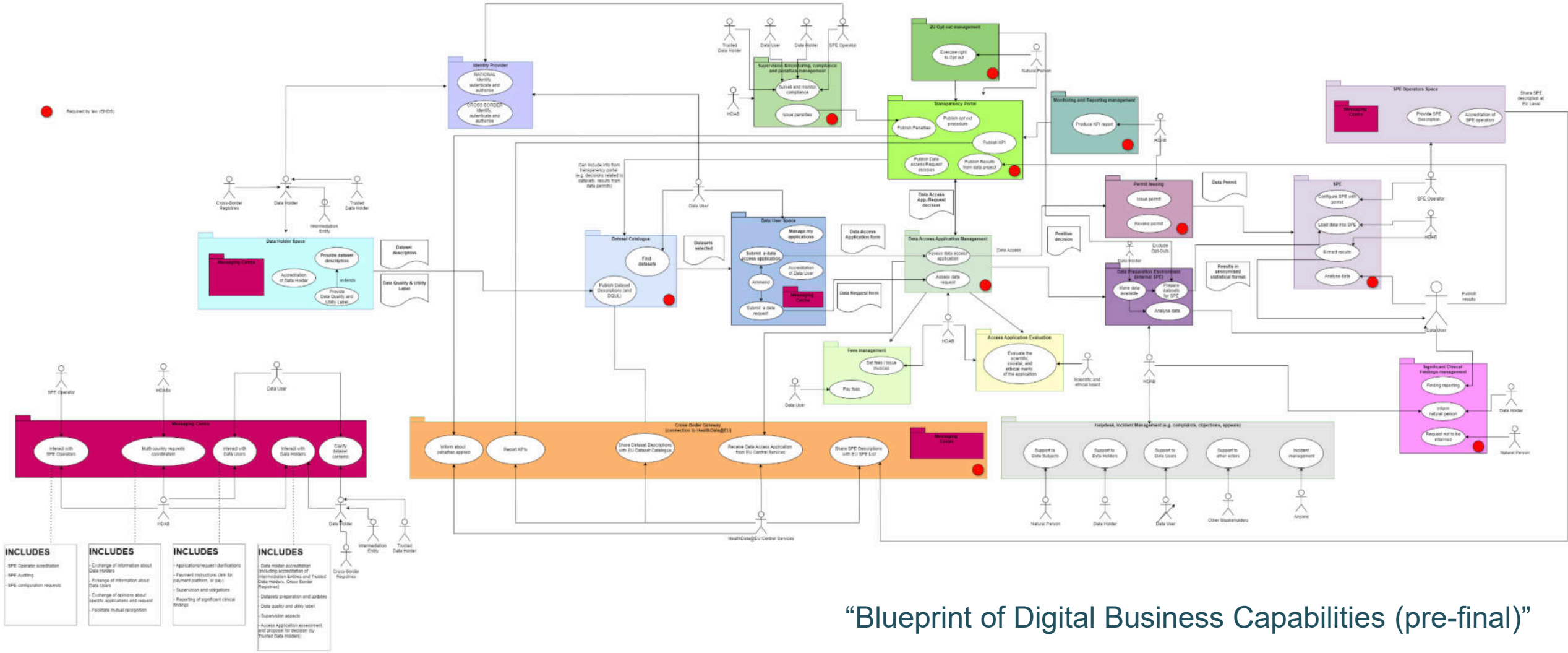

Managed Entry Agreements (Use Case 8.2)
Perspectives of regulatory authorities
EU pharmaceutical legislation
Perspectives of HTA assessment bodies

Align with the concept of national cancer data nodes

1. National networks of cancer data activities in every EU member state
2. Provide tools to improve data quality of cancer data at source
3. Provide tools for cancer data analysis to be used in secure processing environments (SPEs)
4. Ensure all cancer datasets have a metadata record in the EU dataset catalogue
5. Provide advice on common variables for cancer datasets
6. Capacity building at national level

defined by member state representatives of eCANCER thematic working group

EHDS- workflow template for secondary use of health data



"Blueprint of Digital Business Capabilities (pre-final)"

EXPECTED OUTCOMES & IMPACT

Expected outcomes:

- Data infrastructure and HTA framework will lead to higher rate of success for PCM applications
- Faster decision making and improved access to medicine for patients

Key Impact on Stakeholders:

Data harmonisation and sharing

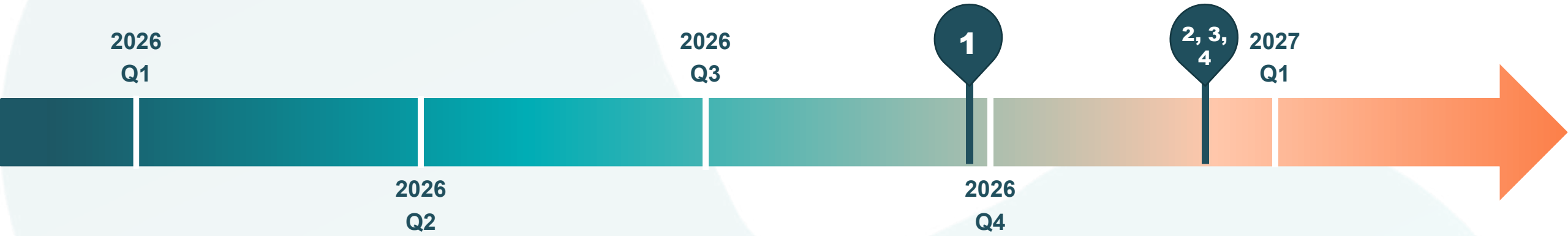
Faster decision-making

Faster access to medicine

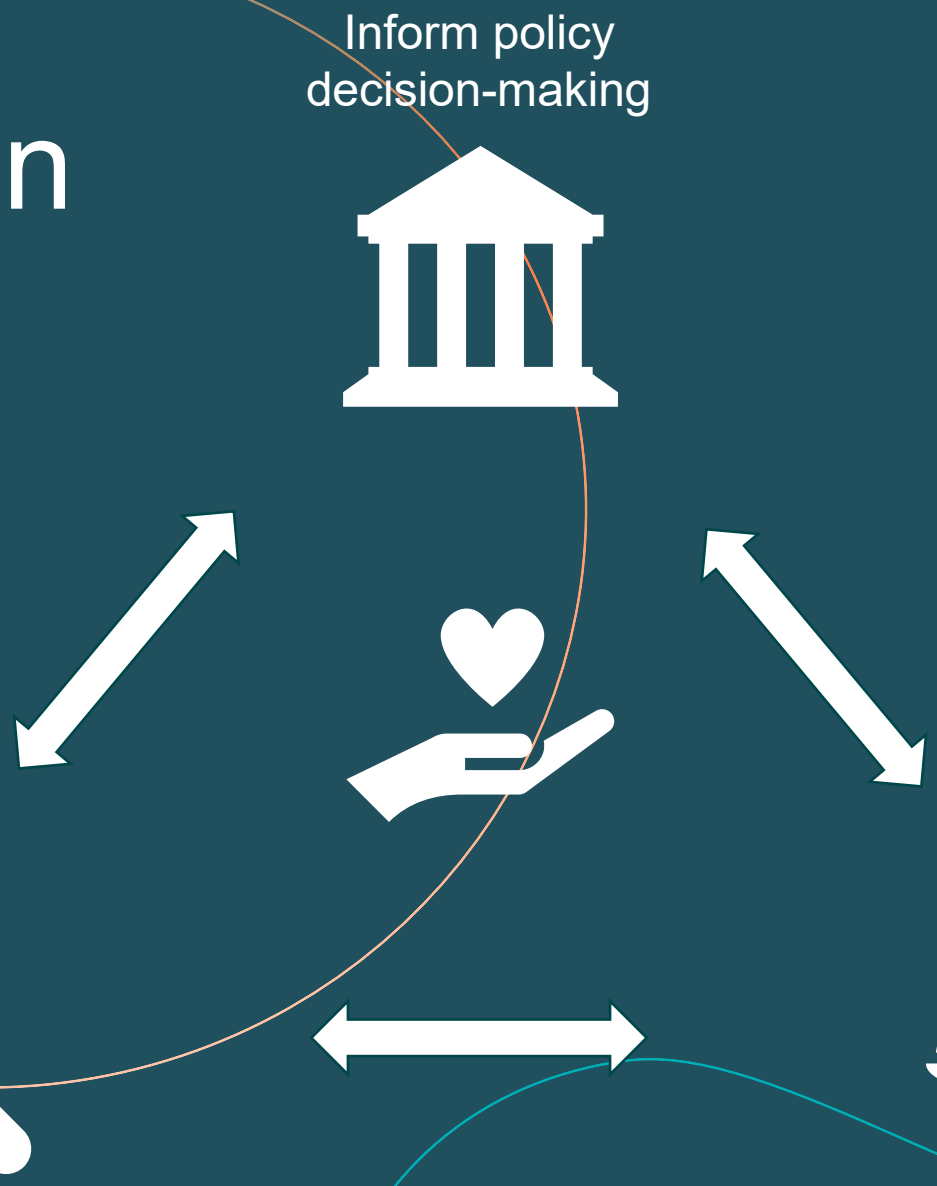
NEXT STEPS

Next immediate steps and timelines for at least year 1

STEP 1	Lessons learned of Well-Established Use pathway	M9
STEP 2	Retrospective analysis of Scientific Advice on single-arm oncology trials	M12
STEP 3	Identify PICO's of pilots/use cases	M12
STEP 4	EHDS-compliant data infrastructure solutions	M12



Conclusion



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FIRST PICTURE

THEN LUNCH - ENJOY

Please be back on time for the next session

AGENDA

PICK UP YOUR STICKER(S)

- ARM1
- ARM3
- ARM2
- Transversal

THE JA PCM KICK-OFF MEETING

14-15 January 2026

JA PCM
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14:50 – 15:30 Session II - Transversal WPs

WP4: Sustainability
Nikolai Goncharenko, Institut National du Cancer (LU)

WP3: Evaluation
Rossana Alessandrello, Agencia de qualitat i avaluacio sanitaries de catalunya (ES)

15:30 – 16:15 Session ARM1: Personalised Prevention

Introduction ARM1 lead
Maud Kamal, Institut Gustave Roussy (FR)

WP5: Roads to developing and implementing personalised prevention of cancers
Stefania Boccia, Fondazione Policlinico Gemelli (IT)

WP6: Early detection
Gerrit Meijer, Stichting Het Nederlands Kanker Instituut - Antoni van Leeuwenhoek Ziekenhuis (NL)

JA PCM KICK-OFF

14/15 JANUARY 2026

WP4

Sustainability

Nikolai Goncharenko and Malin Eklund

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NBWH: CA in most JA's, coordinates EBCP implementation at national level, experience in statistics, regulations, recommendations and knowledge (e.g. in oncology, patient safety, eHealth), provides statistics on medicine, causes of death and financial support, directs several advisory and decision-making bodies.

INC: national coordinating entity for cancer in LU, expertise in tackling challenges faced by small MS, in cross-border healthcare collaborations, in navigating a multilingual and multicultural environment. Will provide valuable insights into sustainable policy frameworks and healthcare integration and support the development of a long-term vision for PCM across EU.

Socialstyrelsen
THE NATIONAL BOARD OF HEALTH AND WELFARE

Institut National du Cancer

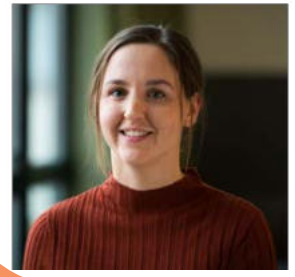
WP4 Sustainability: Team

JA PCM
Joint Action Personalised Cancer Medicine

National Board of Health and Welfare, Sweden

Malin Eklund, PhD

Background: PhD Biotechnology KTH,
Development and Process dev. of biologics AZ,
Sweden´s Innovation Agency, SWERI office
Brussels: EP PerMed, 1 Million Genomes, EHDS,
Precision Health, DIGITAL, Expert cluster 1 Health



Malin Berggrund, PhD

Programme officer (screening, cancer)
Background: medical genetics, Uppsala University

Institut National du Cancer (INC), Luxembourg

Nikolai Goncharenko, PhD

Director, INC Luxembourg
Background: PhD Molecular Biology - Immunology, M.Sc. Entrepreneurship and Innovation Management

Amélie Gaignaux, PhD

European Collaborations Manager,
INC Luxembourg
Background: PharmD, PhD
Biobanking, project management, quality assurance

What we bring

- **Policy + implementation perspective:** translating JA outputs into “how to embed this in real health systems” to achieve real impact for patients (governance, accountability, financing, standards)
- **Small MS and cross-border reality check:** sustainable solutions must work for Small MS/Associated Countries and cross-border pathways, not only for large systems
- **EU ecosystem approach:** systematic and structured ways of working to create synergies with parallel initiatives. A systemic and mission-driven approach to build on strengths and avoid duplication, build a “lean, fluid, cost-effective” pathway for access to PCM.

How do we make the outputs and activities of the JA Personalised Cancer Medicine endure after the Joint Action ends?

*Across the three arms (personalised prevention, personalised medicine, personalised follow-up/tertiary prevention), JA PCM requires a **system approach** to succeed. Sustainability is a challenge: **efficient structures for coordination, collaboration, knowledge exchange and communication are essential** in this endeavour.*

*WP4 will contribute to establishing **ways of working** built on a **mission-driven approach**: clear measurable goals, cross-sector collaboration, multi-level governance, and portfolios of interconnected actions.*

*In practice, sustainability depends on **efficient collaboration** within JA PCM, with other **European projects/initiatives**, and with **national and regional actors**. We will start by building a WP4 workplan together with WP4 participants and the Executive Board, using the governance meetings to keep alignment tight with the other WPs.*

WP4 Sustainability: Context

Principle of subsidiarity: healthcare delivery and organisation remain the responsibility of Member States.

EU role = coordination, support, and added value (not direct provision):

- Setting common objectives/standards (quality, safety, equity)
- Funding collaborative work (EU4Health, Horizon Europe, Digital Europe)
- Promoting cross-border cooperation (e.g., ERNs, EUnetCCC, National Cancer Mission Hubs)
- Building shared infrastructures (e.g., EHDS for secure data exchange)

Joint Actions are implementation-focused collaborations between MS/AC:

- They support coordination, capacity building, exchange of best practices and joint delivery of tools/guidance for uptake in national and regional health systems.
- They are not research projects (i.e., not primarily hypothesis-driven R&I), but policy- and system-oriented action to enable real-world implementation.

So what does sustainability mean for WP4?
We need outputs that are usable by MS/AC, adaptable to different system maturities, and capable of being embedded into routine practice, esp. where cross-border collaboration is required.

MISSION & VISION

WP4 mission (Sustainability):
Ensure the JA PCM results and outputs can contribute with long term value and be **embedded into healthcare systems** in a way that it supports **equity, resilience, and is future-proof**, by:

- understanding the PCM landscape and contribute to knowledge building,
- structures for efficient knowledge exchange
- proposing policy direction and mechanisms that can be sustained beyond the project.

WP4 vision (where we want to arrive):

- a shared understanding of “what exists and what’s missing” across MS/AC (country profiles + small/associated country needs).
- a **policy direction** that translates JA outputs (pilots, tools, guidelines) into **actionable strategies** for adoption, scale-up, and long-term maintenance.
- a sustainability pathway aligned with the wider EU ecosystem and the PCM Cluster/ Roadbook approach (synergies, no duplication, faster uptake).

WORKPLAN

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Two tasks:

- Task 4.1 (INC (LU)) PCM landscape: Country profiles (IFO (IT)), Small MS / Associated Countries and cross-border access (UTARTU (EE))
- Task 4.2 (NBHW (SE)) Policy direction: Policy dialogues with stakeholders, Readiness assessment (SIR (SE)), Sustainability Report

Key milestones:

MILESTONE 17, 18	Country profiles: Establishing framework; status report	M12, M24
MILESTONE 19, 20	Understanding and analysis challenges for implementation of PCM in small and associated countries.	M12, M24
MILESTONE 21	Develop a framework for health system readiness assessment	M42
DELIVERABLE 4.1	Policy Paper on Sustainable implementation of PCM in the EU	M48

WORKPLAN: Approach and methodology

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Build on previous work and collaborate with other initiatives

Build on planned work in JA PCM such as surveys and mapping activities

Our approach: knowledge base → policy direction → sustainability

1) Build the knowledge base (WP4 Task 4.1)
We will consolidate information from WP mappings/surveys and results from other European initiatives to create country profiles and a focused analysis for Small MS /Associated Countries and cross-border access, so that sustainability recommendations are grounded in real system contexts.

2) Convert knowledge into policy direction (WP4 Task 4.2)
We will run policy dialogues (e.g. GB, NCMH, 1+MG group), apply a readiness assessment, and then translate results into a Sustainability Report with “what to do next” recommendations that MS/AC can adopt.

3) Use sustainability theory to keep recommendations practical and durable
We will apply principles such as, balancing effort vs long-term impact, essential components (access to health data), feedback loops, holistic/long-term thinking, resilience and adaptive governance, diversity/redundancy, and an equity focus across remote regions, small MS and different healthcare environments.

4) Maintain alignment with evaluation and adoption mechanisms
WP3 evaluation framework integrates readiness, equity, and impact and explicitly links with WP4 (plus WP12 and WP13), ensuring sustainability is measurable and iteratively improved, as may be necessary.

GB: Governmental Bodies. NCMH: National Cancer Mission Hubs

PARTICIPANTS

24 partners from 12 MS/AC: Denmark, Estonia, Finland, France, Germany, Greece, Italy, Luxembourg, Netherlands, Norway, Spain, Sweden.

Budget allocation: €600,000.

How we will work with JA governance (to make sustainability real):

- Align with WP1 on the “PCM in Europe” roadmap (D1.7, M47) and Governmental Board engagement mechanisms.
- Use Executive Board / Governmental Board cycles to stress-test feasibility, ensure MS needs are reflected, and strengthen cross-border cooperation.

SYNERGIES are essential

Internal synergies (within JA PCM):

- **WP1:** “PCM in Europe” roadmap (D1.7, M47) + structured Governmental Board engagement to keep outputs policy-relevant.
- **WP2:** ensure WP4 outputs are adoption-ready via templates, website, internal platform, and stakeholder engagement channels (website + comms plan deadline M6).
- **WP3:** use the readiness/equity/impact lens and the self-assessment tool governance to track progress and sustainability risks over time.
- **WP12/WP13:** align on cross-border standards, ethics/ELSI, and data/HTA infrastructures so sustainability advice is implementable.

External synergies (to build a real sustainability pathway):

Align with relevant initiatives (e.g., EUnetCCC, JANE-2, TEHDAS-2, ERNs, EUCAIM, ECHoS, CCI4EU, 1+ Million Genomes) and contribute to a PCM Cluster and Roadbook approach aimed at bundling outputs into a coherent access pathway.

EXPECTED OUTCOMES & IMPACT

Expected outcomes:

- A shared, comparable PCM “baseline” across MS/AC (country profiles + status reporting) to guide targeted implementation support.
- Clear articulation of implementation barriers, opportunities and cross-border constraints for small MS/ Associated Countries, ideally with policy-relevant options.
- A readiness assessment framework to guide decision-makers toward continuous, sustainable, equitable integration of PCM into routine cancer care.
- A final sustainability package / policy paper (D4.1, M48) that harmonises JA outputs into actionable strategies for embedding PCM in MS/AC systems.

Impact on key stakeholders:

- **Healthcare professionals, researchers and innovators:** clearer pathways for knowledge building and exchange supporting adoption of PCM tools and practices, better cross-border collaboration routes, shared learning on “what works where.”
- **Healthcare policymakers:** structured evidence on system readiness, governance and accountability options, and cross-border enablers such as health data, supporting realistic adoption decisions.
- **Cancer patients / citizens:** improved equity in access (including for small MS/remote regions), clearer communication materials and engagement routes, and more consistent PCM availability across the continuum.
- **Life Science enterprises:** improves competitiveness trough more efficient collaboration structures and supporting regulatory framework, incentives and reimbursement models.

NEXT STEPS: YEAR 1

STEP 1	Confirm WP4 WG structure & roles (task/sub-task leads); Ensure Arm/WP leads are connected	Q1 2026
STEP 2	Align with WP1/WP2/WP3 on governance touchpoints + Roadmap, dissemination, and evaluation/self-assessment integration	Q1 2026
STEP 3	Kick off meeting – Workplan v0.1	Q1 2026
STEP 4	Deliver M12 milestones: MS17 country profile framework memo (structure + methods) MS19 methodology/tool to capture small MS /AC challenges	Q4 2026
STEP 5	Prepare the first round of policy dialogue topics	Q4 2026

Conclusion

1. Sustainability is not just a final report. It is a *continuous development process* that depends on coordinated action across multiple governance levels and actors.
2. WP4 aims to support the JA to turn outputs into support and structures on “how MS/AC can implement”: country profiles + cross-border/small MS reality checks + readiness + policy direction, ending in a sustainability package/policy paper.
3. We will aim to build sustainability by design, through contributing to efficient coordination structures and work processes that create tight synergies with WP1-WP3 and alignment with the wider EU ecosystem (incl. PCM Cluster/Roadbook), so that the JA PCM outputs can make a difference and be truly adopted.

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Joint Action Personalised Cancer Medicine

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14/15 JANUARY 2026

WP3

Evaluation

Rossana Alessandrello

Claudia Prats

Ramon Maspons

Co-funded by the European Union

Salut/ Agència de Qualitat i Avaluació Sanitàries de Catalunya

Generalitat de Catalunya

Fisabio Foundation

Stockholm School of Economics

WP3 Evaluation

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WP3 LEAD

Salut/ Agència de Qualitat i Avaluació Sanitàries de Catalunya
Generalitat de Catalunya

Rossana Alessandrello

Claudia Prats

Ramon Maspons

TASKS LEADS and CO-LEADS

T3.1 and T3.4 Co-lead

Ana Molina

Fisabio Foundation

T3.3 Leader

Ebba Hallersjö Hult

Bettina Ryll

Stockholm School of Economics

JA PCM
Joint Action Personalised Cancer Medicine

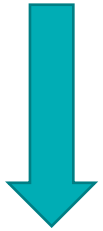
The challenge is not whether innovative PCM interventions work,

but whether they can be adopted equitably and achieve large-scale impact across Europe.

Promising PCM pilots often succeed in well-resourced settings,
yet "struggle to translate" into real adoption across diverse Member States(MS)
due to differences in readiness, capacity, and maturity of the adopters and the innovators.

=

Evaluating individual solutions readiness alone is insufficient to foster feasible, viable and equitable scale-up.



WP3 addresses this challenge by focusing on how pilots are defined, planned, executed, and deliver results,
ensuring that readiness, equity, and impact are systematically assessed to support PCM
implementation (Level 1 from design to proof of concept to implementation),
adoption (Level 2 from early adoption to multi health provider or health system adoption)
and scalability (Level 3 from one health system adoption to multi health systems scale up)
across the diverse Europe

MISSION & VISION

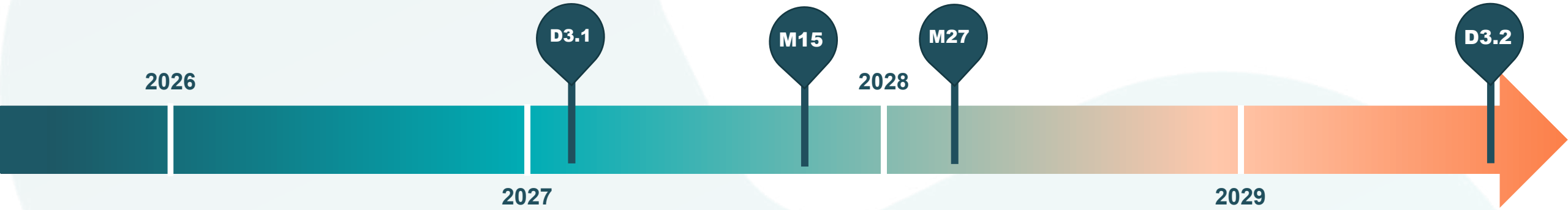
- **To provide guidelines and tools to innovative interventions in precision preventive health, medicine preventive, follow-up and tertiary prevention, education and training and quality assurance standards to improve their access to individuals and cancer patients, by planning key actions to address the equity, maximize their impact, and their eventual adoption and scalability.**

- **OBJECTIVES**
  - Develop PCM Evaluation framework applicable to any PCM pilot/healthcare intervention.
  - Taking into account the characteristics of the different pilots/healthcare interventions implemented during the projects and the transversal WPs, apply the PCM Evaluation framework to all (ARM I-III, WP11 EDU-EQA).
  - Plan the actions necessary for implementation, adoption and scale up and closely monitor the progress of selected pilots in agreement with the PCM JA priorities.

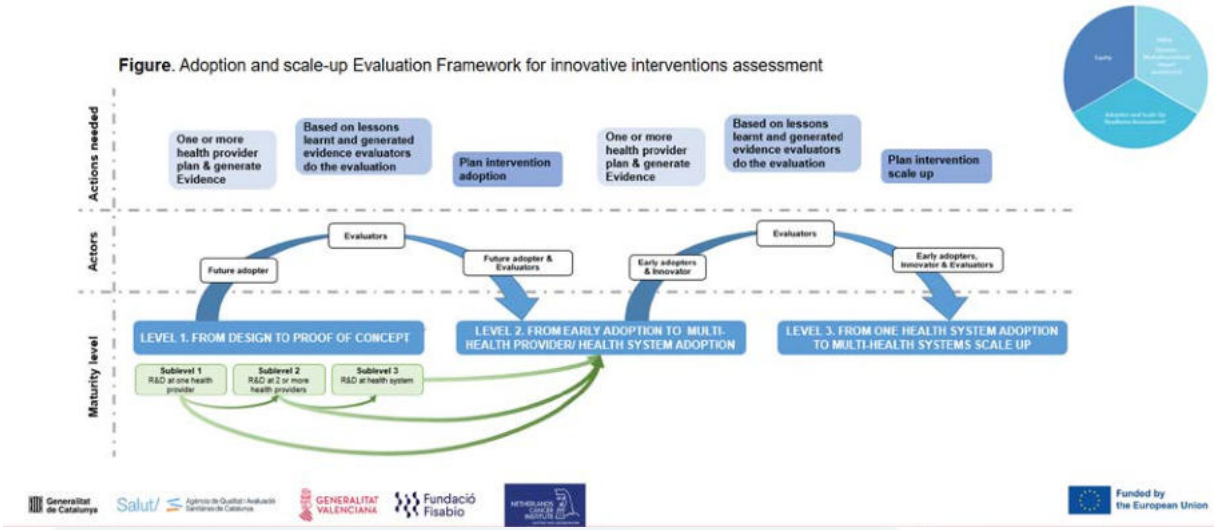
WORKPLAN

- T3.1 Development of PCM Evaluation Framework (AQuAS/FISABIO)
- T3.2 Automatisation of the self-assessment Tool (AQuAS)
- T3.3 Upskilling activities (SIR/AQuAS)
- T3.4 Monitoring & Analysis (AQuAS/FISABIO)

MILESTONE 15	PCM Evaluation Framework & self-assessment tool release	M24
MILESTONE 16	PCM Evaluation Upskilling activities	M27
D3.1	PCM Evaluation Framework	M15
D3.2	Evaluation report: PCM pilots and interventions evaluation report & PCM self-assessment tool governance	M48



WORKPLAN - TASKS



Equity	DMIA	Adoption & Scale Up Readiness
Capacity building	PICO/Effectiveness	Future and early adopters' needs desirability assessment
Genomic Research Actions	Costs	Innovators' maturity and feasibility assessment
Genomic Services and Personalised Medicine	Multidimensional aspects: • Feasibility, • Test journey, • Wider implications of diagnostics results, • Scientific spill-over, • Organization of laboratories	Future and early adopters' viability and feasibility
		Health systems' viability, feasibility and sustainability

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T3.1 Development of PCM Evaluation Framework

Salut/ Agència de Qualitat i Avaluació Sanitàries de Catalunya · Generalitat de Catalunya · Fisabio Foundation

By leveraging on the CAN.HEAL Evaluation framework:

- ***Fully integrating the three dimensions and their subdimensions*** (equity (FISABIO) (e.g. capacity building, networking, research equations, samples, protocols and methods, evidence assessment, literacy, informed decision making, ELSI, returning the results, patients experience, guidelines), impact (NKI) (e.g. study design, costs and multi-dimensional aspects) and readiness (AQuAS) (future and early adopters needs assessment, innovators/researchers maturity and feasibility assessment, future and early adopters feasibility and viability assessment, intervention assessment and appraisal).

Lead: AQuAS (ES)

Co-lead: FISABIO (ES)

Participants All pilot leads n=7, NKI, LUMC (NL), OUS, HDIR (NO), CLB, GR, INSERM, INCa, Unicancer (FR), ISS, PROMIS (IT), INC, LNDS (LU), MSCI (PL), UKW, DKG (DE), NBWH, KUH RS, SIR (SE), ICO, VHIO, IRB Barcelona, Sanidad Aragon (ES), SC (BE), UH-FICAN, UEF (FI), UMFCD (RO), RSD (DK), SAM LT (LT), UTARTU (EE)

WORKPLAN - TASKS

The patient journey is addressed through three "arms", each consisting of two technical work packages (WP) and supported by one or more dedicated pilot applications. In addition, two transversal pilots cover all arms and seven transversal WPs provide overarching support for the technical WPs and pilots.

T3.1 Development of PCM Evaluation Framework

By leveraging on the CAN.HEAL Evaluation framework:

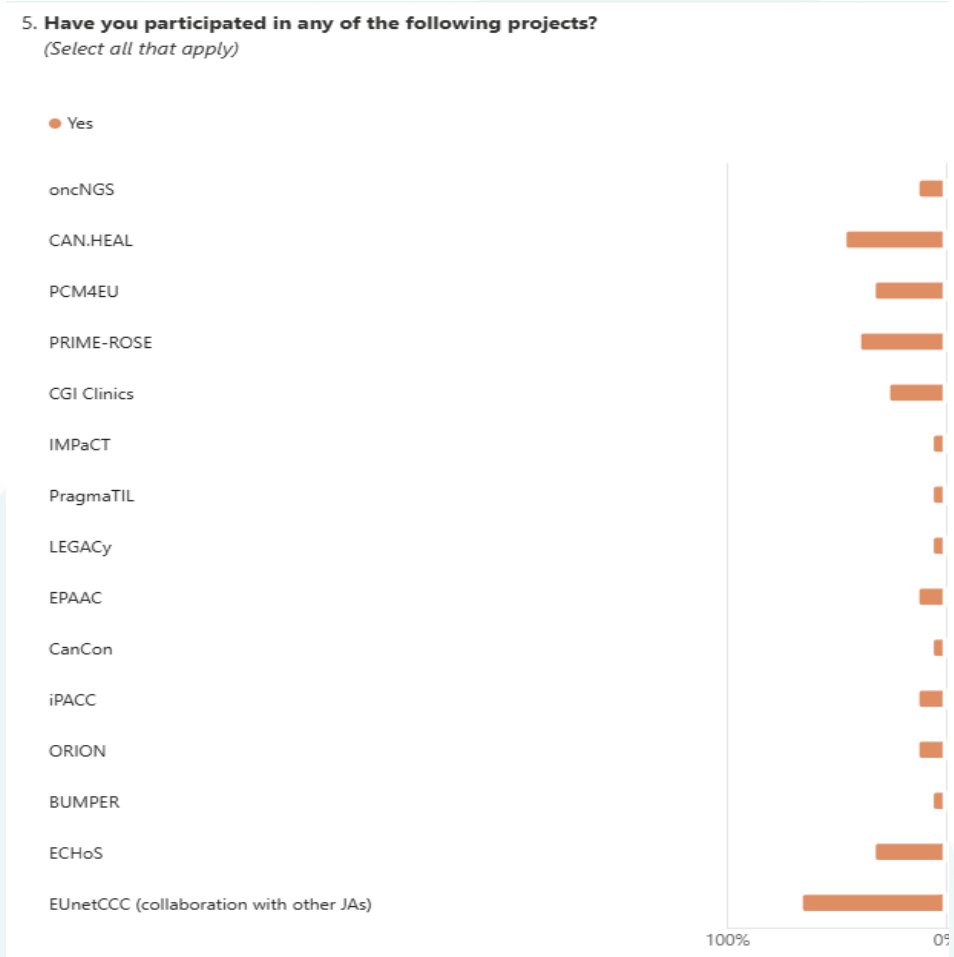
- Reinforcing framework levels, dimensions, subdimensions and key actions in terms of ***patients/citizens/researchers voice, readiness of the adopters (healthcare providers and health systems) (no clinical domain (little countries – remote regions)), integration with WP4, WP12, and WP13.***

- Addressing specifically aspects as clinical pathways, clinical trials, early clinical drug development, environmental sustainability, relevant existing and legacy data infrastructures and databases. ***Leverage on the knowledge generated in oncNGS, CAN.HEAL, PCM4EU, PRIME-ROSE, CGI Clinics, IMPaCT, PragmaTIL, LEGACy, EPAAC, CanCon, iPACC, ORION, BUMPER, ECHoS, PRIME-ROSE and collaborate with other JAs (EUnetCCC).***

-Expanding self-assessment tool ***applicability to diverse pilots/healthcare interventions in PCM (ARM I - III)***

Lead: AQuAS (ES)
Co-lead: FISABIO (ES)
Participants All pilot leads n=7, NKI, LUMC (NL), OUS, HDIR (NO), CLB, GR, INSERM, INCa, Unicancer (FR), ISS, PROMIS (IT), INC, LNDS (LU), MSCI (PL), UKW, DKG (DE), NBWH, KUH RS, SIR (SE), ICO, VHIO, IRB Barcelona, Sanidad Aragon (ES), SC (BE), UH-FICAN, UEF (FI), UMFCD (RO), RSD (DK), SAM LT (LT), UTARTU (EE)

WORKPLAN - TASKS



✓ ***15 responses***
(14 entities 8 countries)

T3.1 Development of PCM Evaluation Framework

By leveraging on the CAN.HEAL Evaluation framework:

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-Expanding self-assessment tool applicability to diverse pilots/healthcare interventions in PCM (ARM I - III)

Lead: AQuAS (ES)
Co-lead: FISABIO (ES)
Participants All pilot leads n=7, NKI, LUMC (NL), OUS, HDIR (NO), CLB, GR, INSERM, INCa, Unicancer (FR), ISS, PROMIS (IT), INC, LNDS (LU), MSCI (PL), UKW, DKG (DE), NBWH, KUH RS, SIR (SE), ICO, VHIO, IRB Barcelona, Sanidad Aragon (ES), SC (BE), UH-FICAN, UEF (FI), UMFCD (RO), RSD (DK), SAM LT (LT), UTARTU (EE)

WORKPLAN - TASKS

T3.2 Automatisation of the self-assessment Tool

- Increase the simplicity, self-explainability and accessibility of the evaluation self-assessment tool
- Automatise self-assessment tool to collect replies, return automatic key actions and plot the results (bar graphs, spider graphs, arrows graphs.
- Automatic translations in different EU languages and track history of pilots/healthcare interventions progresses.

Lead: AQuAS (ES)
Participants FISABIO (ES), NKI (NL), SIR (SE), UTARTU (EE), ICO (ES), LNDS (LU)

WORKPLAN - TASKS

T3.3 Upskilling activities

Prepare communication plan, create and launch upskilling activities (guides, glossary, templates, videos, collaborative workshops, upskilling material and quizzes, etc).

Lead: SIR (SE)
Co-lead: AQuAS (ES)
Participants All pilot leads n=7 NKI, LUMC (NL), FISABIO, ICO, VHIO (ES), CLB, GR, INSERM, INCa, Unicancer (FR), ISS (IT), INC, LNDS (LU), MSCI (PL), UKW, DKG (DE), NBWH (SE), SC (BE), UH-FICAN, EUEF (FI), OUS (NO), UMFCD (RO), RSD (DK), NVI (LT)

WORKPLAN - TASKS

T3.4 Monitoring & Analysis

- Launch and make the self-assessment tool available to all pilots/healthcare interventions.
- Monitor all pilots/healthcare interventions use the tool and track their progress. Perform Pilots Risk Assessment at M12, M24 and M36.
- Analyze and monitor progress of selected pilots/healthcare interventions based on JA PCM priorities.
- Evaluate the use of self-assessment tool and PCM Evaluation Framework.
- Establish governance to keep the self-assessment tool available and updated after the JA.

All pilot leads n=7, NKI,
Lead: AQuAS (ES)
Co-lead: FISABIO (ES)
Participants All pilot leads n=7, NKI, LUMC (NL), ICO, VHIO (ES), CLB, GR, INCa, INSERM, Unicancer (FR), ISS (IT), INC, LNDS (LU), MSCI (PL), UKW, DKG (DE), NBWH, SIR (SE), SC (BE), UH-FICAN, EUF (FI), OUS (NO), UMFCD (RO), RSD (DK))

EXPECTED OUTCOMES & IMPACT

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Expected outcomes:

Indicators in the mid term	Baseline Value	Target value
Project milestone achievement rate: Percentage of milestones completed within the established deadline	None before project starts	85%
Quality of deliverables: Percentage of mandatory deliverables meeting quality criteria specified in Evaluation Plan	None before project starts	100%
Participation rate of authorities and cancer centres in mapping and stakeholder surveys with respect to number invited	Country experts of 73% of countries reviewed JA PCM platform	85%
Participation rate in the evaluation of pilots and use cases with respect to expected number	In JA 100% for site level activities, with variable participation rate of individuals	90%
Risk management effectiveness: mitigation of risks within the JA	None before project starts	Qualitative description of identified risks and mitigation strategies
Evaluation framework, upskilling material and Self assessment tool: Pilot leads adherence	None before project starts	100%
Evaluation framework, upskilling material and Self assessment tool: Pilot leads satisfaction	None before project starts	60%

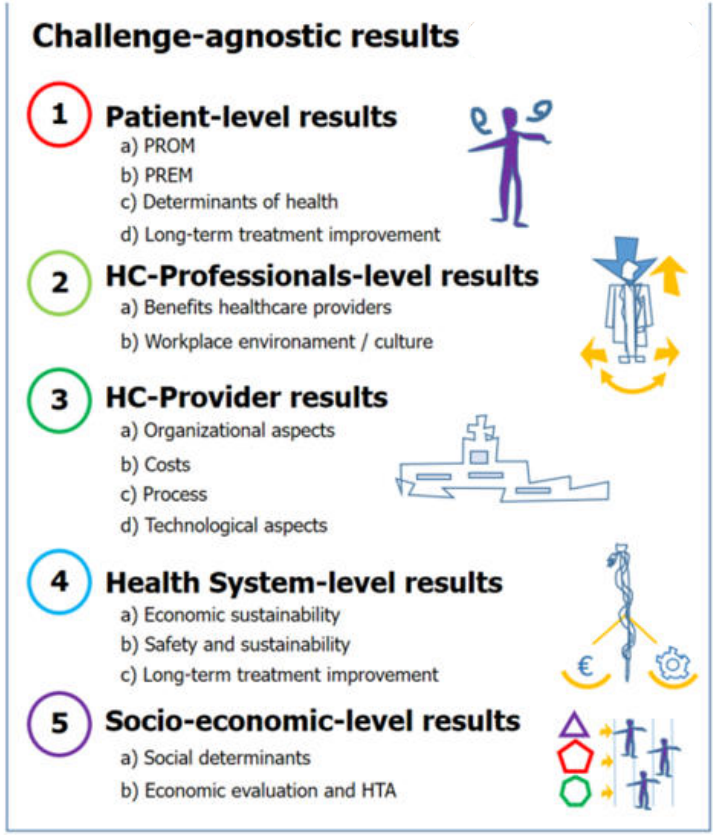
EXPECTED OUTCOMES & IMPACT

Methodological approach:
Challenge-agnostic results set

Theory of Change presented in a results chain per stakeholder

Inputs → Activities → Outputs → Outcomes → Impact

Arrizabalaga, I., Alessandrello, R., Meis, U., Maspons, R., & PiPPi consortium, P. (2020). PIPPI: D5.4 A core set of outcomes indicators. Zenodo. https://doi.org/10.5281/zenodo.15527571



EXPECTED OUTCOMES & IMPACT

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Iterative process

4 Input	5 Activities	3 Outputs	2 Outcomes	1 Impact
WP3 Team JA PCM Consortium	T3.1 Development of PCM Evaluation Framework T3.2 Automatisation of the self-assessment Tool T3.3 Upskilling activities T3.4 Monitoring & Analysis	MS15 PCM Evaluation Framework & self-assessment tool release MS16 PCM Evaluation Upskilling activities D3.1 PCM Evaluation Framework D3.2 Evaluation report: PCM pilots and interventions evaluation report & PCM self-assessment tool governance	Project milestone achievement rate: Percentage of milestones completed within the established deadline Quality of deliverables: Percentage of mandatory deliverables meeting quality criteria specified in Evaluation Plan Participation rate of authorities and cancer centres in mapping and stakeholder surveys with respect to number invited Participation rate in the evaluation of pilots and use cases with respect to expected number Risk management effectiveness: mitigation of risks within the JA Evaluation framework, upskilling material and Self assessment tool: Pilot leads adherence Evaluation framework, upskilling material and Self assessment tool: Pilot leads satisfaction	**Patients/Citizens**: maximize impact, address equity gaps, improving access and outcomes for individuals and cancer patients. **Healthcare professional/Researcher**: Provides a structured and harmonized framework to systematically evaluate innovative interventions in PCM. Supports continuous improvement through clear indicators, monitoring tools, and quality assurance Facilitates adoption, learning, and knowledge transfer across settings and countries **Healthcare organization:** differences in readiness, capacity, and maturity of the adopters and the innovators addressed focusing on how innovative interventions are defined, planned, executed, and deliver results when implementing (Level 1 from design to proof of concept to implementation), adopting (Level 2 from early adoption to multi health provider or health system adoption) and scaled up (Level 3 from one health system adoption to multi health systems scale up) **Healthcare System/Policy Maker:** accelerate the equitable adoption and large-scale impact of innovative precision cancer medicine and preventive health interventions across healthcare systems. Support strategic planning for equitable adoption and long-term sustainability

WP3 PARTICIPANTS and WORK IN PROGRESS

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52 beneficiaries

20 countries involved

Spain, Sweden, the Netherlands, Finland, Italy, France, Denmark, Luxembourg, Germany, Portugal, Lithuania, Poland, Slovenia, Estonia, Latvia, Belgium, Norway, Romania, Bosnia and Herzegovina, and Hungary

Work Done:

- *WP3 Roles and Experience Form set up and distributed*
- *WP3 pre-kick off meeting held with Romania, France, Sweden, Netherland and Spain held on October 7th, 2026*
- *WP3 kick off meeting held on January 8th, 2026*

Work In Progress:

- *Analysis of 15 responses to WP3 Roles and Experience Form*
- *Setting up periodic WP3 Tasks Leads and co-leads meeting*
- *Review surveys MTB (from VHIO) and LB (from Aarhus)*
- *Review of Adoption & Scale Up Readiness key action prior to integration with Equity and DMIA*

15 responses
(14 entities 8 countries)

Arms/WPs/Pilots		
Arm 1	Personalised prevention	Gustave Roussy
WP5	Personalised prevention	Gustave Roussy, Instituto Superiore di Sanità, ITALY, Lillebaelt Hospital, VHIO, University Hospital of Würzburg
WP6	Early detection	VHIO
Pilot	Risk-Informed Prevention - PARI	Gustave Roussy, VHIO
Pilot	PRS	
Arm 2	Personalised medicine	Gustave Roussy, Centre Léon Bérard
WP7	Diagnosis	Maria Sklodowska Curie National Research Institute of Oncology, VHIO, SciLifeLab, Karolinska Institute, Sweden
WP8	Treatment	SIR, Centre Léon Bérard, Lillebaelt Hospital, VHIO, Gustave Roussy
Pilot	MTB	VHIO, Maria Sklodowska Curie National Research Institute of Oncology, Catalan Institute of Oncology (ICO), Lillebaelt Hospital
Pilot/Uses Cases	Data Collection & Sharing and Early Treatment Access: Managed Entry Agreement	
Pilot/Uses Cases	Data Collection & Sharing and Early Treatment Access: Joint Cohorts	
Arm 3	Personalised follow-up & tertiary prevention	
WP9	Digital innovation	Gustave Roussy
WP 10	Tertiary Prevention	Lillebaelt Hospital
Pilot	Digital Survivorship Tool	Gustave Roussy
Transversal pilots		
Pilot	LB	Lillebaelt Hospital, VHIO
Pilot	Transversal CPS Compass	University Hospital of Würzburg
Transversal WPs		
WP1	Coordination	SCIENSANO, Haute Autorité de Santé (HAS)
WP2	Communication	Haute Autorité de Santé (HAS)
WP3	**Evaluation**	
WP4	Sustainability	
WP11	EQA - Education & Training	VHIO
WP12	Legal, Ethics & Equity	Luxembourg National Data Service (LNDS),
WP13	HTA - Data	Gustave Roussy, NKI

NEXT STEPS

Next immediate steps and timelines for at least year 1

STEP 1	Establish a collaborative working environment to support progress within the JAPCM gathering answers to WP3 Form and analysing responses	Date *Deadline January 31st*
STEP 2	Setting up periodic meetings with the co-leads	Date *January 2026*
	T3.1 Initiate expanding applicability to diverse pilots/healthcare interventions in PCM (ARM I - III) **by:**	
STEP 3	**- Reviewing the LB and MTB surveys provided**	Date *January 2026*
STEP 4	**- supporting pilots in defining their long-, mid- and short-term results/KPIs**	Date *February - March 2026*
STEP 5	T3.1 Initiate integration of the 3 domains (Equity, DMIA and Adoption & Scale Up Readiness)	Date *February - March 2026*
STEP 6	T3.1 Initiate reinforcing framework levels, dimensions, subdimensions and key actions in terms of patients/citizens/researchers voice, readiness of the adopters (healthcare providers and health systems) (no clinical domain (little countries – remote regions)), integration with **WP4, WP12, and WP13**.	Date *April 2026*
STEP 7	T3.1 Initiate leveraging on the knowledge generated in oncNGS, CAN.HEAL, PCM4EU, PRIME-ROSE, CGI Clinics, IMPaCT, PragmaTIL, LEGACy, EPAAC, CanCon, iPACC, ORION, BUMPER, ECHoS, PRIME-ROSE and collaborate with other JAs (EUnetCCC).	Date *April 2026*

WP3 PARTICIPANT ROLES & EXPERIENCE

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Please scan the QR code or use the link to join:

https://forms.cloud.microsoft/e/Q4T1T0Ywn4?origin=lprLink

Conclusion

Provide 3 key messages that the audience should remember about the WP

- **WP3 ambition is to accelerate the equitable adoption and large-scale impact of innovative precision cancer medicine and preventive health interventions across healthcare systems.**
- **By developing and applying a robust, adaptable PCM Evaluation Framework, we aim to systematically assess, guide, and strengthen preventive, follow-up, and tertiary prevention interventions, as well as education, training, and quality assurance initiatives.**
- **Through evidence-based planning, continuous monitoring, and close alignment with PCM Joint Action priorities, we seek to maximize impact, address equity gaps, and enable sustainable implementation, adoption, and scalability, ultimately improving access and outcomes for individuals and cancer patients.**

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Contact

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AQuAS

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Co-funded by the European Union

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Any question?

→ Slido.com #JAPCM

Or scan the code below:

THE JA PCM KICK-OFF MEETING

14-15 January 2026

JA PCM
Joint Action Personalised Cancer Medicine

Any question?

➔Slido.com #JAPCM

Or scan the code below:

14:50 – 15:30 Session II - Transversal WPs

WP4: Sustainability
Nikolai Goncharenko, Institut National du Cancer (LU)

WP3: Evaluation
Rossana Alessandrello, Agencia de qualitat i avaluacio sanitaries de catalunya (ES)

15:30 – 16:15 Session ARM1: Personalised Prevention

Introduction ARM1 lead
Maud Kamal, Institut Gustave Roussy (FR)

WP5: Roads to developing and implementing personalised prevention of cancers
Stefania Boccia, Fondazione Policlinico Gemelli (IT)

WP6: Early detection
Gerrit Meijer, Stichting Het Nederlands Kanker Instituut - Antoni van Leeuwenhoek Ziekenhuis (NL)

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JA PCM KICK-OFF

14/15 JANUARY 2026

ARM I

PERSONALISED PREVENTION

Maud Kamal

Gustave Roussy, France

GUSTAVE ROUSSY
CANCER CAMPUS GRAND PARIS

Co-funded by the European Union

ARM I

JA PCM
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Gustave Roussy, FRANCE

Suzette Delaloge

Maud Kamal

GUSTAVE ROUSSY
CANCER CAMPUS GRAND PARIS

NKI, The NETHERLANDS

Gerrit Meijer

Beatriz Carvalho

Marjanka Schmidt

NETHERLANDS CANCER INSTITUTE
ANTONI VAN LEEUWENHOEK

Personalised Prevention is timely

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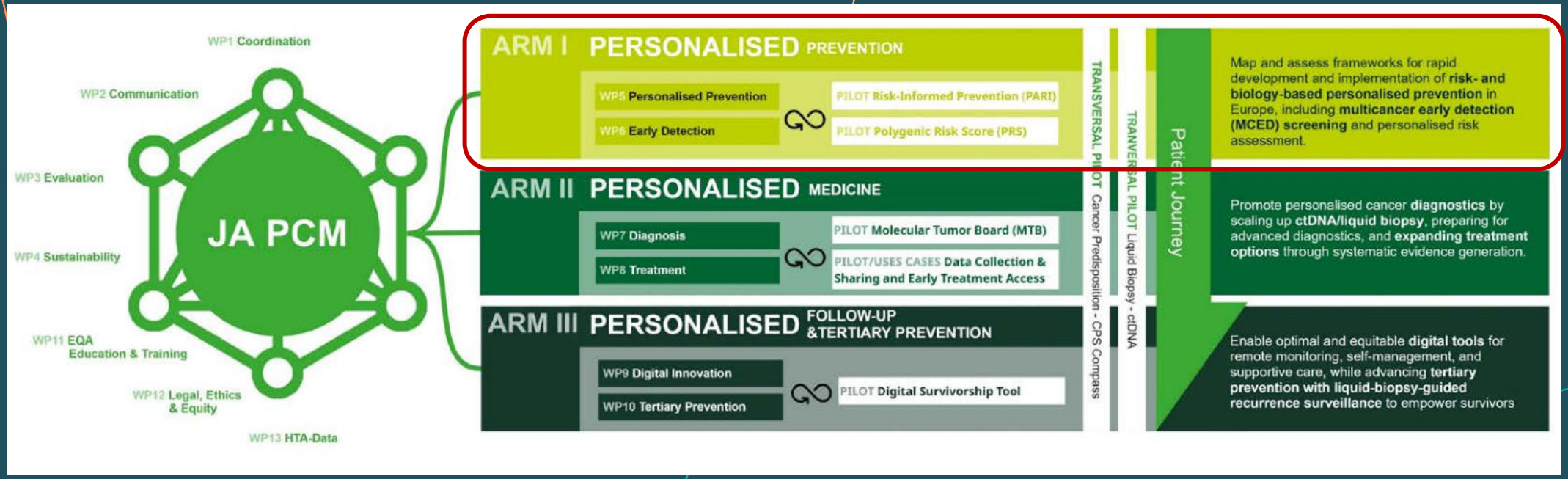
- Personalised prevention, fed by our knowledge on biology, genetics and exposures, is a major, new, timely strategy to complement primordial prevention and cancer treatments
- New avenues need to be implemented for risk identification, early detection and prevention



Contact

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JA PCM KICK-OFF

14/15 JANUARY 2026

WP5

Roads to developing and implementing personalised prevention of cancers

Stefania Boccia, Fondazione Policlinico Universitario Agostino Gemelli IRCCS

Italy

Gemelli

Fondazione Policlinico Universitario Agostino Gemelli IRCCS
Università Cattolica del Sacro Cuore

Co-funded by the European Union

Leadership Team

JA PCM
Joint Action Personalised Cancer Medicine

Suzette Delaloge

WP Leader

Department of Cancer Medicine, **Institut Gustave Roussy (GR)**

France

Stefania Boccia

WP Co-Leader

Section of Hygiene, Department of Life Sciences and Public Health, Università Cattolica del Sacro Cuore

Department of Woman and Child Health and Public Health, **Fondazione Policlinico 'A. Gemelli' IRCCS (FPG),**

Italy

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Work Package 5: Roads to developing and implementing personalised prevention of cancers

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MISSION & VISION

*To **accelerate** the implementation of **risk- and biology-based personalized cancer prevention** across Europe, fostering **proactive**, **integrated**, and **equitable** approaches within **healthcare** and **public health systems.***

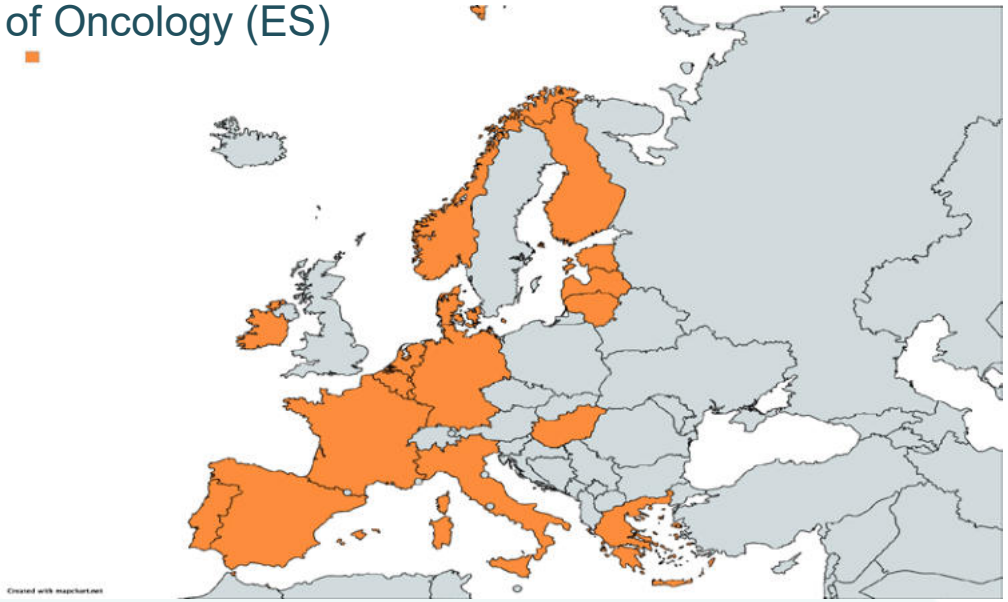
- **OBJECTIVES**
  - Map, assess, and translate ongoing and planned initiatives to inform future personalized prevention strategies.
  - Implement risk-informed cancer prevention pathways across Europe, including genetic susceptibility and lifestyle interventions.
  - Enhance early detection strategies and integrate emerging tools such as polygenic risk scores, biomarkers, and digital solutions.
  - Promote equitable access to personalized prevention interventions and support healthcare system readiness for scaling up.

Work Package 5: Roads to developing and implementing personalised prevention of cancers

JA PCM
Joint Action Personalised Cancer Medicine

PARTICIPANTS

- Sciensano (BE)
- Liège University Hospital (BE)
- University of Gent (BE)
- Antwerp University Hospital (BE)
- Region Southern Denmark (DK)
- University of Tartu (EE)
- University of Helsinki (FI)
- Centre Leon Berard (FR)
- Institut Gustave Roussy (FR)
- University Hospital Würzburg (DE)
- University Hospital of Rostock (DE)
- National Hellenic Research Foundation (EL)
- National and Kapodistrian University of Athens (EL)
- National Institute of Oncology (HU)
- Health Service Executive (IE)
- Fondazione Policlinico Gemelli (IT)
- Istituto Europeo Oncologia (IT)
- Istituti Fisioterapici Ospedalieri (IT)
- Riga Stradiņš University (LV)
- Pauls Stradiņš Clinical University Hospital (LV)
- National Cancer Center (LT)
- Netherlands Cancer Institute (NT)
- University of Oslo (NO)
- Portuguese Oncology Institute of Lisbon (PT)
- Portuguese Oncology Institute of Porto (PT)
- Institute for Research and Innovation in Health (PT)
- Institute for Health Sciences of Aragon (ES)
- Vall d'Hebron Institute of Oncology (ES)



TASK 5.1 GR/FPG M0-M36

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Mapping of past/ongoing/planned initiatives and their expected outputs, evidence TRL and healthcare organisations requirements

Subtask number	Description	Leader
5.1.1	To map and analyse **past, ongoing** and **planned personalised cancer risk reduction interventions** (high penetrance carriers, exposures …).	GR (FR)
5.1.2	To map and analyse **evidence and TRL of major developments for PP in the next decade.**	RSD (DK)
5.1.3	To map and analyse **healthcare organisations needs** for efficient PP (healthcare system, HCPs, costs, digital tools, infrastructure).	NKI (NL)
5.1.4	To map and analyse **pilot initiatives of PP in funded projects.**	FPG (IT)

MS22 (FPG)	List of initiatives and pilots related to personalised prevention	M30
D5.1 (GR)	Report on the mapping activities of the WP	M36

TASK 5.2 FPG/GR M7-M48

Assessment of the EU Member States' preparedness for personalized prevention delivery

Subtask number	Description	Leader
5.2.1	**Ensure EU Members States' preparedness for risk-based PP**, addressing EU heterogeneity based on visions from citizens, healthcare providers and system organisations, industry, EMA, and other EU and MS stakeholder.	SC (BE)
5.2.2	**Perform a global analysis and consensus vision on the preparedness**.	RSD (DK)
5.2.3	**Scale up EU-wide implementation** (sound + flexible) and **prepare PP** for adoption and upcoming advanced tools via capacity building activities.	KUL (BE)

TASK 5.3 SC/UKV M19-M48

Minimal requirements of personalised cancer prevention in the EU

Subtask number	Description	Leader
5.3.1	Define **minimal requirements of PP** in the EU via the **assessment** and **consensus** statement on the required levels of evidence, MCBS, impact, cost effectiveness and on the required ethics and access issues.	GR (FR)
5.3.2	**Assess the added value** of multidisciplinary advisory board to **support** the decision and the **genetic counselling** regarding monitoring (early detection) and **prevention** based on the risk assessment (high penetrant and PRS).	SC (BE)
5.3.3	Identify **appropriate models** according to country/regional specificities with consideration of a supra-national organisation with a **pool of experts.**	IACS-DSA(ES)

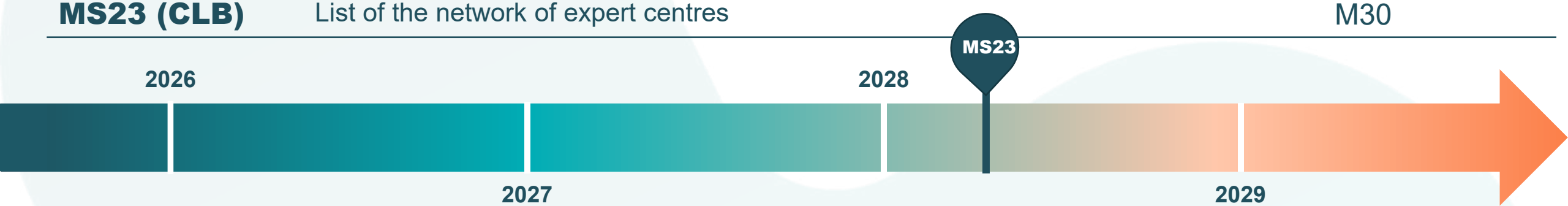
D5.2 (SC) Report on the minimal requirements of personalised cancer prevention in the EU M48

TASK 5.4 CLB/IPO Porto M7-M36

Identification and functioning requirement of the network of expert centres for interception clinical trials, exploring potential synergies with other ongoing EU initiatives

Subtask number	Description	Leader
5.4.1	To **capitalize** on a **network of expert centres** for interception clinical trials, exploring **potential synergies** with the network of CCC in development via the JA EUnetCCC, JANE2, JA PreventNCD with several aims. In collaboration with WP9 for digital tools, WP12 for ELSI and WP13 for data and HTA.	SC (BE)
5.4.2	To **define requirements regarding the setup of collaborative platforms** (precancer board) to centralize best practice in the diagnosis and management of precancer across EU.	CLB (FR)
5.4.3	To map existing databases and evaluate the need to create new depositories including real-world studies, prospective cohorts as well as clinical trials.	GR (FR)
5.4.4	To define the minimal requirements to develop and evaluate digital tools facilitating communication between patients and community-based care givers and disease experts in collaboration with WP9.	IPO Porto (PT)

MS23 (CLB) List of the network of expert centres M30



Personalized Prevention Synergies

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4PCAN

PROPHET
a PeRsOnalized Prevention roadmap for the future HEalThcare

MyPeBS

EU CanScreen
European Joint Action on Cancer Screening

JA PreventNCD
Joint Action Prevent Non-Communicable Diseases

EUnetCCC
ONEFORALL
Co-funded by the European Union

JA PCM
Joint Action Personalised Cancer Medicine

EP PerMed
European Partnership for Personalised Medicine

EU JOINT ACTION
JANE2
NETWORKS OF EXPERTISE ON CANCER

European Genomic Data Infrastructure

1+MG

Personalized Prevention Synergies

PROPHET

a PeRsOnalized Prevention roadmap for the future HEalThcare

JA PCM
Joint Action Personalised Cancer Medicine

COORDINATOR	Stefania Boccia
ORGANIZATION	Università Cattolica del Sacro Cuore
DURATION	September 2022 – August 2026
PARTNER	18 partners
BUDGET	3,000,000€

Since September 2022, PROPHET has been developed through three sequential and interconnected phases, **Mapping**, **Assessment** and **Building** (currently ongoing).
This work has enabled the co-creation of a **Strategic Research and Innovation Agenda (SRIA)** and a **Personalized Prevention Roadmap**, defining **priorities**, **actions** and **stakeholders**, and providing **practical guidance** on **how personalized prevention can be implemented within European healthcare systems**, taking into account governance, data infrastructure, workforce training and adaptation to local contexts.

SCAN THE QR CODE TO READ THE ROADMAP FACTSHEET

SCAN THE QR CODE TO READ THE SRIA FACTSHEET

Personalized Prevention Synergies

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SAVE THE DATE

Rome, 26-27 March 2026
Location TBD

Draft Agenda

Day 1 | 26 March 2026

13:30 – 14:00	*Registration*

14:00 – 14:15 | Opening

Walter Ricciardi, President of Mission on Cancer

14:15 – 14:45 | Welcome and Introduction

Framing Prevention in the European Context
Stefania Boccia, Università Cattolica del Sacro Cuore
Marius Gaenta, Romanian Center for Innovation in Medicine

14:45 – 15:15 | Enabling systems for scaling Personalized Prevention in Europe

European Partnership for Personalised Medicine
Monika Frenzel, EPPerMed representative

Transforming Health and Care Systems Partnership
Speaker TBD

15:15 – 15:45 | PROPHET in the EU Landscape

PROPHET in the EU Health Policy landscape: expectations and relevance
Cornel Riscanu, HaDEA, PROPHET Project Officer

Vision, objective and governance of PROPHET
Stefania Boccia, Università Cattolica del Sacro Cuore, PROPHET Coordinator

15:45 – 16:00	*Coffee Break & Networking*

16:00 – 17:30 | The European Prevention Ecosystem: Joint Actions and Flagship initiatives

JANE-2: building a European network for personalized prevention
Delia Nicoara, Institutul Oncologic „Prof. Dr. Ion Chiricuță" Cluj-Napoca

EUnetCCC and Prevention Hubs: integrating prevention within Comprehensive Cance Centres
TBD

Advancing risk-based and organized cancer screening in Europe: EUCanScreen
Marcis Leja, University of Latvia

The Joint Action on Personalized Cancer Medicine
Marc Van Den Bulcke, Sciensano

JA PreventNCD: strengthening prevention of non-communicable diseases across Europe
TBC

JACARDI: Strengthening European Action on Cardiovascular Diseases and Diabetes
Benedetta Armocida, Istituto Superiore di Sanità

Establishing of Cancer Mission Hubs: Networks and Synergies (ECHoS)
Hugo Soares, Portuguese Agency for Clinical Research and Biomedical Innovation

Day 2 | 27 March 2026

09:00 – 09:15 | Welcome & Recap of Day 1

Stefania Boccia, Università Cattolica del Sacro Cuore
TBC, European Commission, DG Research and Innovation

09:15 – 09:45 | The Strategic Research and Innovation Agenda (SRIA): Broad scope of promotion and prevention, and overview of Challenges

Roundtable with Challenge Leaders
Discussion moderated by **Roberta Pastorino, Fondazione Policlinico Universitario Agostino Gemelli IRCCS**

09:45 – 11:00 Parallel Breakout Sessions

B1) Evidence and Frameworks	B2) Data and Infrastructure	B3) People, Trust and Behavior	B4) Systems, Policy and Equity
Presentation of Challenges 2. ***Continuous evidence synthesis system*** 3. ***PROPHET Framework implementation***	Presentation of Challenges 4. ***Data collection and integration*** 7. ***Regulatory aspects and private sector synergy***	Presentation of Challenges 5. ***Community Engagement and trust*** 6. ***Health Professionals and Policy Makers involvement*** 10. ***Changing behavior***	Presentation of Challenges 8. ***Access, Equity and Coverage*** 9. ***Ethical, Legal, Social Issues (ELSI)***

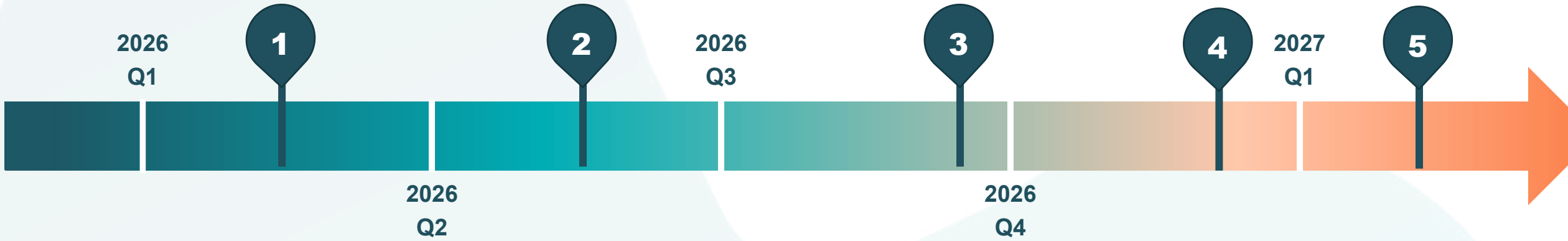
11:00 – 11:20 Coffee Break

11:20 – 11:50 Parallel Breakout Sessions

B1) Evidence and Frameworks	B2) Data and Infrastructure	B3) People, Trust and Behavior	B4) Systems, Policy and Equity

NEXT STEPS

STEP 1	Kick off meeting of the WP	February 2nd
STEP 2	Organization of monthly meetings	February
STEP 3	Templates of the details of the tasks to be shared with leadership	March
STEP 4	Monitoring of the progress of each task	Year 1
STEP 5	Reporting of Milestone and Deliverables and cross talks with other WPs	M30-M48



EXPECTED OUTCOMES & IMPACT

Expected outcomes:

- Mapping, identification, analysis of past ongoing and future PPC efforts and initiatives in the EU (and major players)
- Identification of a network of expert centers dedicated to PPC
- Assessment of preparedness at granular levels in the EU related to minimal requirements for PPC, together with gaps of preparedness and proposed solutions

Key Impacts on Stakeholders

- Healthcare professionals & researchers : WP5 will provide HCP and researchers with materials facilitating their understanding of the situation across the EU regarding PPC, current and future efforts, needs and gaps, as well as development frameworks and training materials
- Healthcare policymakers: WP5 will critically prepare the broad implementation of PPC in member states and provide policy makers with materials and frameworks allowing informed political and policy decisions in the field
- Citizens: JA PCM will advance the field of PPC in the EU, allowing broad and equitable access throughout the member states

Conclusion WP5

- PPC, a critical new avenue in oncology, is on its way but requires proper implementation to allow access, equity, feasibility and high impact
- WP5 of JA PCM will contribute to build the key foundations for the proper implementation and development of PCM in the EU
- Synergies with the other WPs of JA PCM, as well as ongoing EU initiatives and Joint actions are critical and will facilitate and accelerate these goals

Contact

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Gustave Roussy

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Stefania Boccia

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Co-funded by the European Union

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Any question?

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JA PCM KICK-OFF

14/15 JANUARY 2026

WP6

Early detection

Gerrit A. Meijer

NETHERLANDS CANCER INSTITUTE
ANTONI VAN LEEUWENHOI

Co-funded by the European Union

Early detection

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Gerrit A. Meijer, MD, PhD
NKI, the Netherlands

Juan Gonzalez Garcia, PhD
IACS, Spain

Overarching goal of WP6

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To improve ongoing cancer screening programs
by increasing cancer screening innovation preparedness

Multi-cancer early detection (MCED) & personalized risk factors as a timely and tangible "use case"

Why focus on MCED & polygenic / exposome risk factors (PRS/ERS)?

- Cancer incidences are rising
- Current screening strategies are in place only for a limited number of cancer types (e.g. cervical, breast, colorectal cancer, prostate, lung)
- Promising data from multi-cancer early detection studies
- Personalized risk profiling (PRS, ERS) opportunities are emerging
- Existing data are fragmented / hard to interpret:
  - Test parameters (sens/spec, etc)
  - Performance compared to current screening tests
  - ELSI / Wilson & Jungner screening criteria / participant attitudes

MISSION & VISION

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- **Importance:**
  - With the worldwide increasing attention for ctDNA based MCED & PRS/ERS screening, it is important that :
    - The merits of MCED ctDNA-based strategy are properly being evaluated
    - The added value of PRS/ERS are properly being evaluated
    - Memberstates prepare for future MCED implementations by harmonizing/standardizing logistics and (data)infrastructure to facilitate efficient performance evaluations based on RWD
- **Objectives:**
  - Prepare European cancer screening programs for implementation of MCED-based screening
  - Prepare European cancer sceening programs for implementation of personalised risk assessment

PARTICIPANTS

JA PCM
Joint Action Personalised Cancer Medicine

WORKPLAN

- Task 6.1 (**NL, FI**, BE, DE, DK, FR, GR, IE, IT, LU, LV, NO, PL, PT)
  - *Towards ctDNA-based MCED; document the path to implementation of ctDNA in MCED in the European setting by:*
    - Evaluating pros and cons of different ctDNA technologies
    - Evaluating ctDNA-based MCED compared to single cancer screening

Beatriz Carvalho
Lead

Sanna Livanainen
Co-lead

- Task 6.2 (**LV, BE**, DE, EE, FI, GR, NO, PO, PT)
  - *ELSI & MCED-based screening in Europe:*
    - Evaluating ethical, legal and social issues
    - Evaluating compliance with Wilson and Jungner/WHO
    - screening criteria

Vita Rovite
Lead

Wannes van Hoof
Co-lead

WORKPLAN

- Task 6.3 (**NL, NL**, BE, DE, EE, ES, FR, GR, HU, IT, LU, LV, NO, PL, PT)
  - *Polygenic risk scores (PRS) combined with clinical and lifestyle factors in multiple cancers (breast and prostate):*
    - Developing a harmonised protocol for the introduction of PRS together with clinical and lifestyle factors

Jeroen van Rooij
Lead

Marjanka Schmidt
Co-lead

- Task 6.4 (**NL, DE**, BE, EE, ES, FI, FR, GR, IE, IT, LU, LV, NO, PL, PT)
  - *Combining ctDNA testing with risk factors:*
    - Evaluating whether Polygenic risk scores (PRS) and Exposome risk scores (ERS) have added value in ctDNA-based MCED screening

Marjanka Schmidt
Lead

Anke Bergmann
Co-lead

WORKPLAN

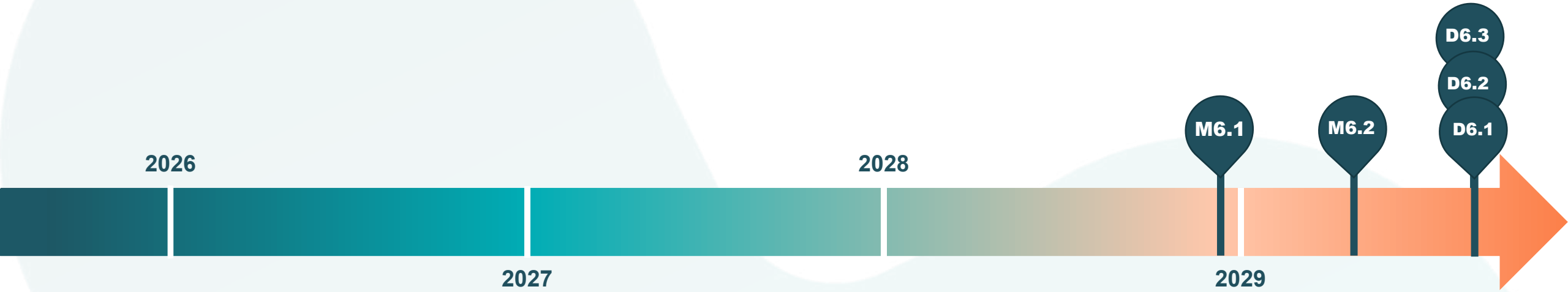
- Task 6.5 (**NL, ES**, DE, IT, LU, GR)
  - *Health Technology Assessment (HTA) analysis on MCED-based screening with or without risk factors, in Europe:*
    - Evaluating the long-term impact of MCED-based screening
    - Evaluating cost-effectiveness of MCED-based screening

Valesca Retèl
Lead

Juan Gonzalez Garcia
Co-lead

WORKPLAN

MILESTONE M6.1	MCED readiness	M36
DELIVERABLE D6.1	MCED for screening	M48
MILESTONE M6.2	PRS readiness	M42
DELIVERABLE D6.2	PRS for screening	M48
DELIVERABLE D6.3	MCED and risk assessment for screening	M48



EXPECTED OUTCOMES & IMPACT

- Multi-cancer early detection, with incorporation of personal risk assessment (PRS & ERS), fits the ambition of this Joint Action to improve on PCM.

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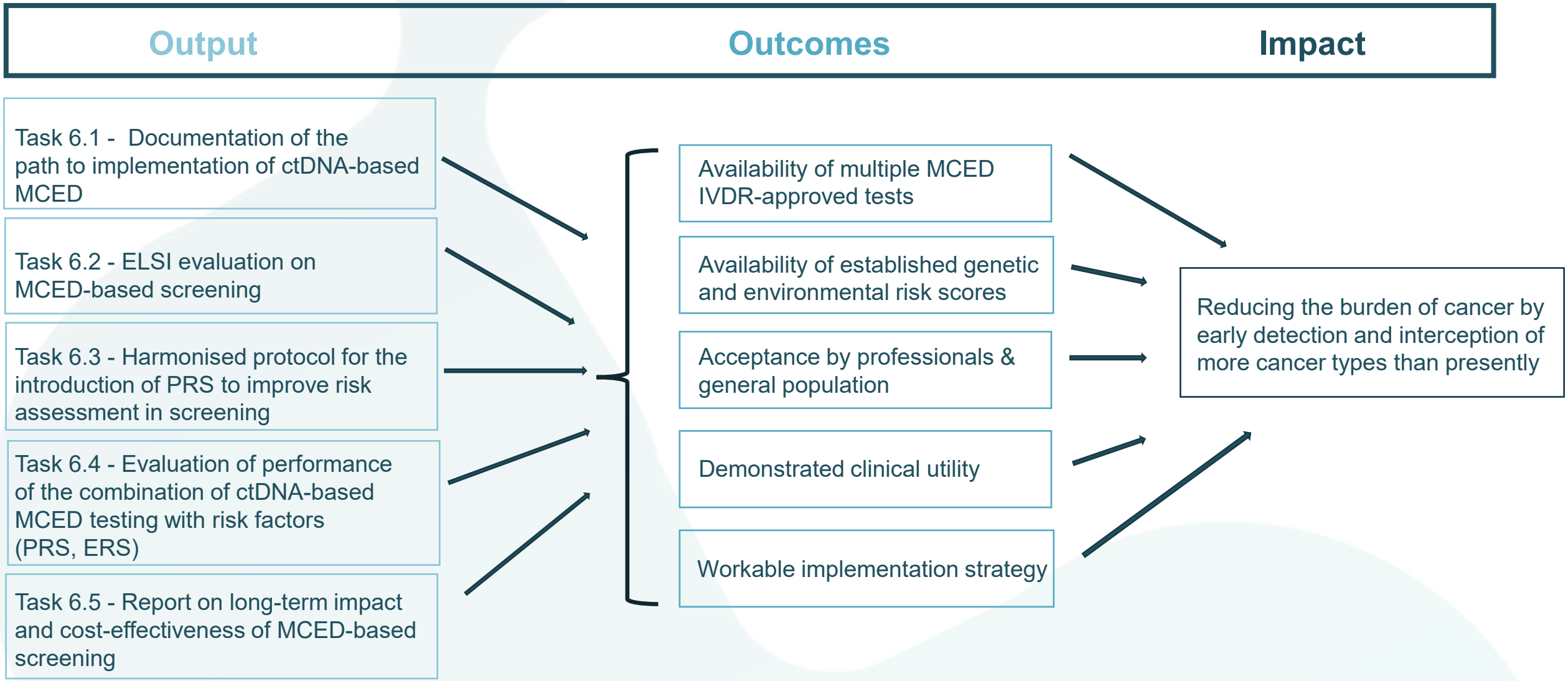

Pilot Polygenic Scores (PRS)

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Polygenic scores can help personalize screening of common cancers.

The technology and knowledge to do so largely exists, but implementation is slow-going and fragmented.

- **OBJECTIVES**
  - Write a joint protocol to integrate the breast cancer PRS into CanRisk
  - Validate this protocol in 100 at-risk healthy relatives of breast cancer patients in pilot studies (3-4 sites)
  - Enhance readiness of PRS use and provide implementation strategies in breast cancer and beyond

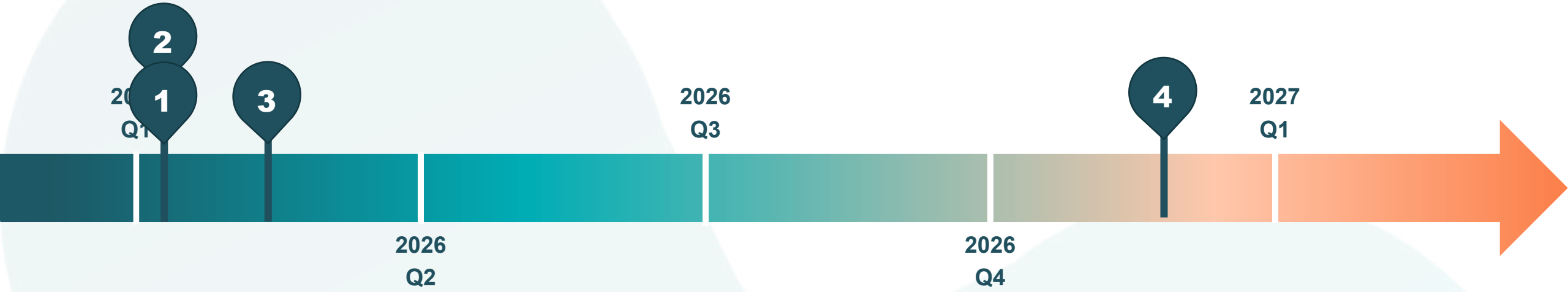
Workplan and further details outlined tomorrow. Survey ongoing to select Pilot sites.

Jeroen van Rooij
Erasmus MC, NL

Marjanka Schmidt
Netherlands Cancer Institute, NL

NEXT STEPS

STEP 1	Draft detailed working plan per task	M2
STEP 2	Plan monthly meetings	M2
STEP 3	Appoint staff per task (308 PM- whole WP6)	M6
STEP 4		Date
STEP 5		Date



Conclusion

- Personalized early detection and interception in principle is the most effective approach to prevent morbidity and mortality by cancer
- MCED and personalized risk profiling appear to be promising new approaches for cancer screening
- Yet, there are many open questions and WP6 aims to find answers

Contact: JAPCM_WP6@nki.nl

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ENJOY A LITTLE COFFEE BREAK

Please be back on time for the next session

AGENDA

PICK UP YOUR STICKER(S)

ARM1

ARM3

ARM2

Transversal

THE JA PCM KICK-OFF MEETING

14-15 January 2026

JA PCM
Joint Action Personalised Cancer Medicine

Any question?

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Or scan the code below:

16:50 – 17:35 **Session ARM2: Personalised medicine**

Introduction ARM2 lead
Ruggero De Maria, Alleanza Contro il Cancro (IT)

WP7: Diagnosis
Gerrit Meijer (TBC), Stichting Het Nederlands Kanker Instituut - Antoni van Leeuwenhoek Ziekenhuis (NL)
Païvi Östling, Karolinska Institutet (SE)

WP8: Expanding the treatment space by access under systematic evidence-generation
Kjetil Tasken, Oslo University Hospital (NO)

17:35 – 17:45 **Conclusion** of the day

Marc Van den Bulcke, Cancer Centre, Sciensano (BE)

17:45 – 19:00 **Networking event**

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JA PCM KICK-OFF

14/15 JANUARY 2026

Arm II WP7 - **Diagnosis**

Gerrit Meijer
NKI, Netherlands
Lead

Päivi Östling
KI, Sweden
Co-Lead

WP7

Co-funded by the European Union

WP7 Diagnosis

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Every cancer patient deserves the best possible treatment and that begins with the best possible diagnosis.

Yet across Europe, access to advanced diagnostic tools is unequal and implementation of new tools is slow.

WP7 asks a simple but urgent question:

"How do we make cutting-edge diagnostics the norm, not the exception?"

WP7 MISSION & VISION

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- *The best treatment of every cancer patient always starts with the best diagnosis*
- *In oncology, our increasing knowledge of disease mechanisms boosts the development of new treatments and diagnostics*
- *Implementation of molecular and other advanced diagnostics in routine cancer care is lagging behind*

OBJECTIVES

- Scale up ctDNA/liquid biopsies towards EU-wide implementation
- Prepare EU cancer care for upcoming advanced diagnostics
- Increase availability of diagnostics data for primary and secondary use
- Observational data platform to increase implementation of novel diagnostics

WP7 BUSINESS & WORKPLAN

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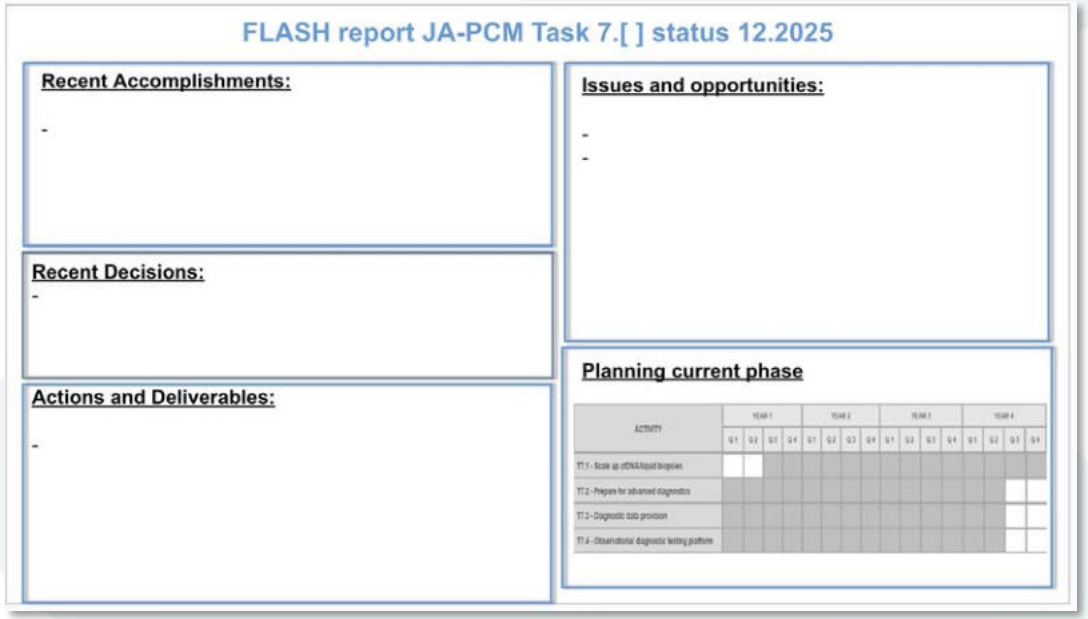
WP meetings

- Task lead/co-lead: monthly, started
- All participants: frequency tbd, will start after kick off meeting


FLASH report JA-PCM Task 7.[ ] status 12.2025

Recent Accomplishments:
-

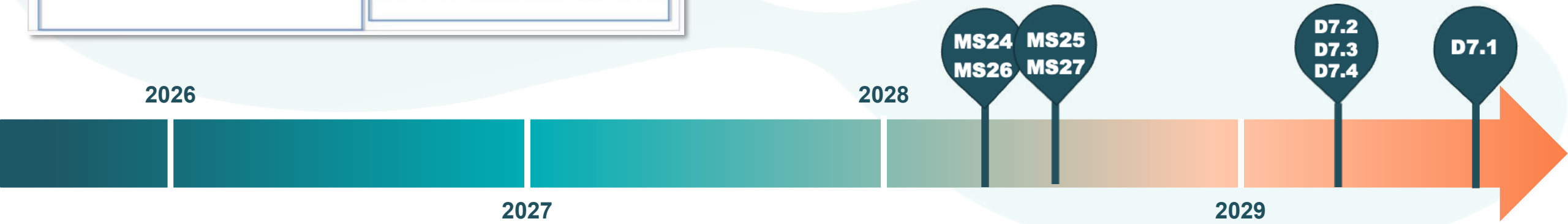
Issues and opportunities:
-
-

Recent Decisions:
-

Actions and Deliverables:
-

Planning current phase

MILESTONE 24	ctDNA readiness by self-assesment of partners	M28 (March 2028)
MILESTONE 25	Draft report from community of experts	M30 (May 2028)
MILESTONE 26	Draft version of data managment plan	M28 (March 2028)
MILESTONE 27	Draft version of a diagnostic testing platform	M30 (May 2028)
DELIVERABLE 7.1	Scale up of ctDNA/LB to EU wide implementation	M48 (Nov 2029)
DELIVERABLE 7.2	Prepare cancer care for upcoming diagnostics	M42 (May 2029)
DELIVERABLE 7.3	Diagnostic data provision (data managment plan)	M42 (May 2029)
DELIVERABLE 7.4	Observational diagnostic testing platform	M42 (May 2029)



PARTICIPANTS *WP7*

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	WP7 Countries
1	Belgium
2	Croatia
3	Cyprus
4	Czechia
5	Denmark
6	Estonia
7	Finland
8	France
9	Germany
10	Greece
11	Hungary
12	Iceland
13	Ireland
14	Italy
15	Latvia
16	Lithuania
17	Luxemburg
18	Malta
19	Netherlands
20	Norway
21	Poland
22	Portugal
23	Romania
24	Spain
25	Sweden

	Task 7.1 Countries
1	Belgium
2	Croatia
3	Cyprus
4	Denmark
5	Estonia
6	Finland
7	France
8	Germany
9	Greece
10	Hungary
11	Iceland
12	Ireland
13	Italy
14	Lithuania
15	Luxemburg
16	Malta
17	Netherlands
18	Norway
19	Poland
20	Portugal
21	Romania
22	Spain
23	Sweden

	Task 7.2 Countries
1	Belgium
2	Croatia
3	Cyprus
4	Czechia
5	Denmark
6	Estonia
7	Finland
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17	Luxemburg
18	Malta
19	Netherlands
20	Norway
21	Poland
22	Portugal
23	Romania
24	Spain
25	Sweden

	Task 7.3 Countries
1	Belgium
2	Estonia
3	Finland
4	Germany
5	Ireland
6	Italy
7	Latvia
8	Luxemburg
9	Norway
10	Spain
11	Sweden

	Task 7.4 Countries
1	Belgium
2	Cyprus
3	Estonia
4	Finland
5	Germany
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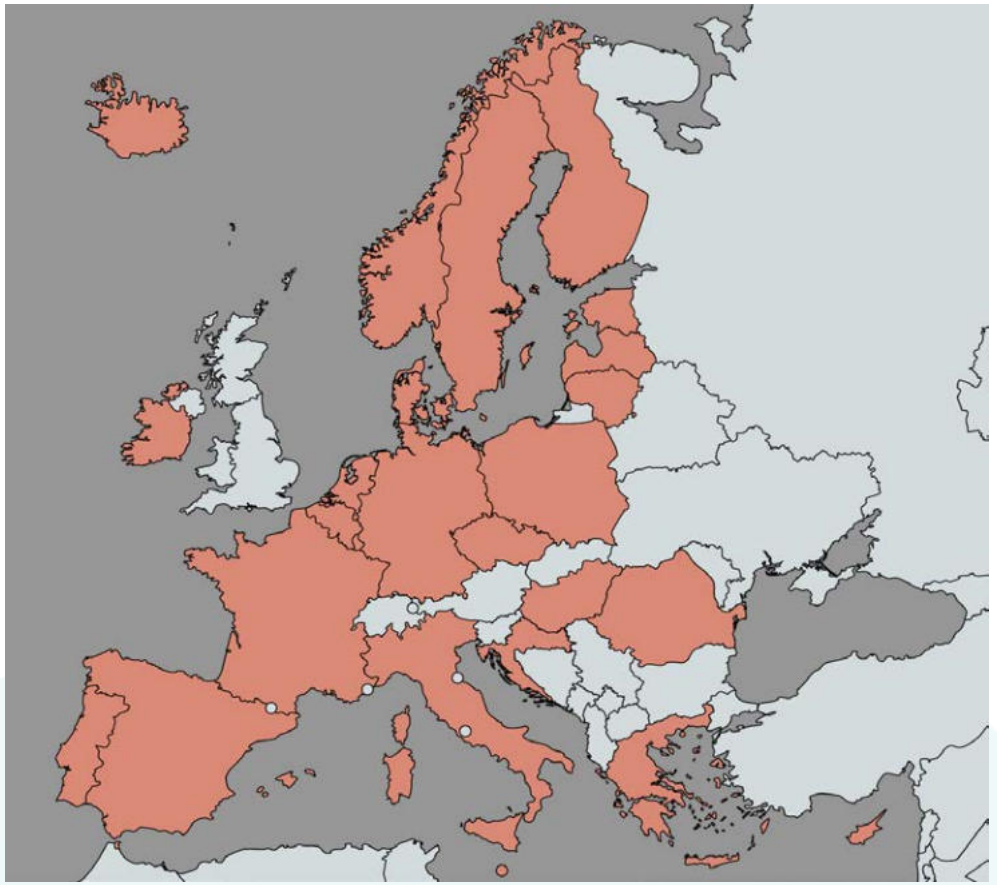
11	Poland
12	Portugal
13	Romania
14	**Spain**
15	Sweden



Task 7.1 Scale up high ctDNA/liquid biopsies to EU wide implementation

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Joint Action Personalised Cancer Medicine

Task lead

Remond Fijneman
NKI, The Netherlands

Sub-tasks

7.1.1 Implement ctDNA testing for tumor profiling
7.1.2 Implement ctDNA testing for treatment response monitoring
7.1.3 Pave the regulatory path to implementation

Pilot Liquid Biopsy

Task co-leads

Klaus Pantel & Simon Joosse,
UKE, Germany

Elena Giordiani (7.1.1)
Istituti Fisioterapici Ospitalieri - Istituto Nazionale Tumori Regina Elena, Italy

Karen-Lise Garm Spindler (7.1.2)
Aarhus University Hospital, Denmark

Daan van den Broek (7.1.3)
NKI, The Netherlands

Task 7.1 Scale up high ctDNA/liquid biopsies to EU wide implementation

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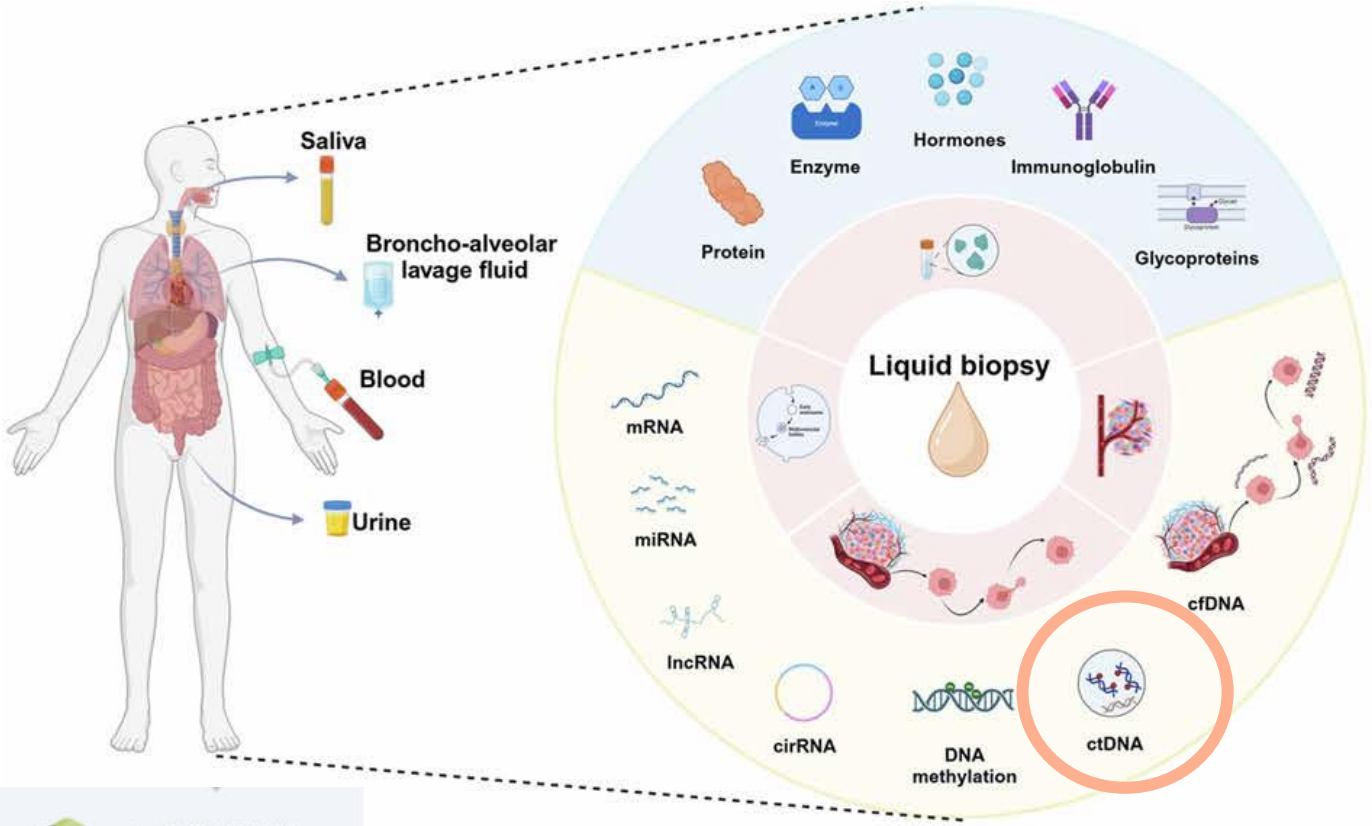

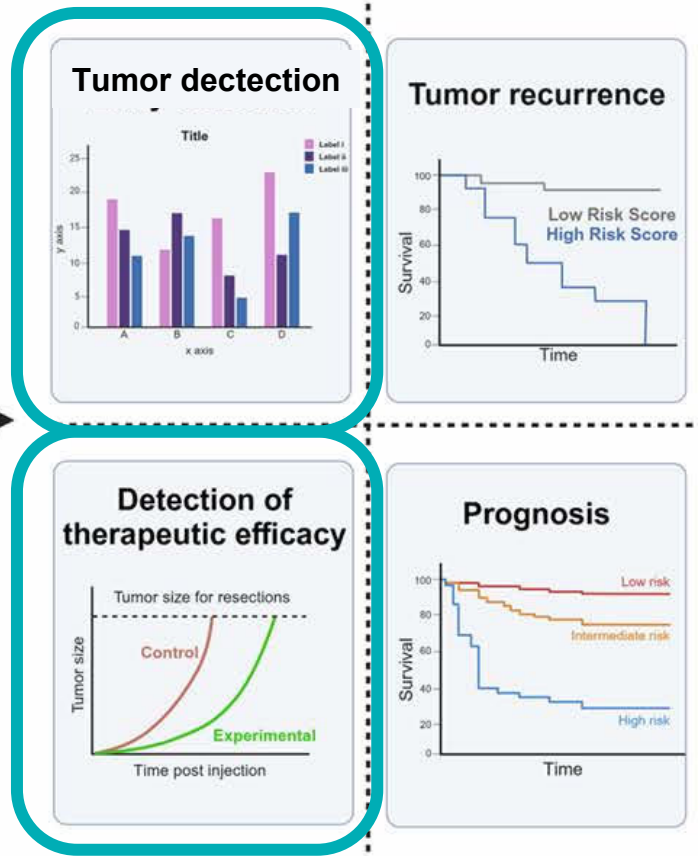

EUROPEAN LIQUID BIOPSY SOCIETY

Pilot Liquid Biopsy

Modified from
DOI: 10.1038/s41392-024-02021-w

Task 7.2 Prepare cancer care for adoption of upcoming advanced diagnostics

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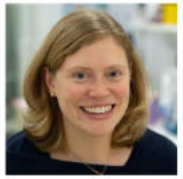

Task lead

Brinton Seashore-Ludlow
SciLifeLab, Karolinska Institutet, Sweden

Sub-tasks

7.2.1 Implementation hurdles for advanced genomics
7.2.2 Method alignment in Digital pathology
7.2.3 Standardized procedures for *f*PM
7.2.4 Identify bottlenecks in sample acquisition and preparation needed for advanced diagnostics
7.2.5 Horizon scanning

Task co-lead

Pierre Saintigny
Centre Léon Bérard, France

Tiina Kahre, (7.2.1)
Tartu University Hospital, Estonia

Carla Bartosch, (7.2.2)
Portuguese Oncology Institute of Porto (IPO Porto), Portugal

Inese Cakstina-Dzerve,
RSU, Latvia
(7.2.3)
Iwona Ługowska,
Maria Skłodowska-Curie National Research Institute of Oncology, Poland

Dovile Juozapaite (7.2.4.)
Vilnius University Hospital Santaros Klinikos, Lithuania

Theodora Katsila (7.2.5)
National Hellenic Research Foundation (NHRF), Greece

Task 7.2 Prepare cancer care for adoption of upcoming advanced diagnostics

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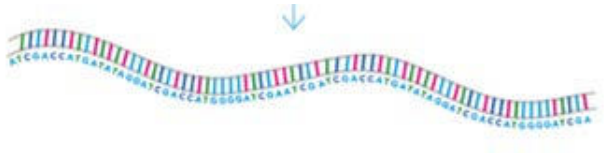
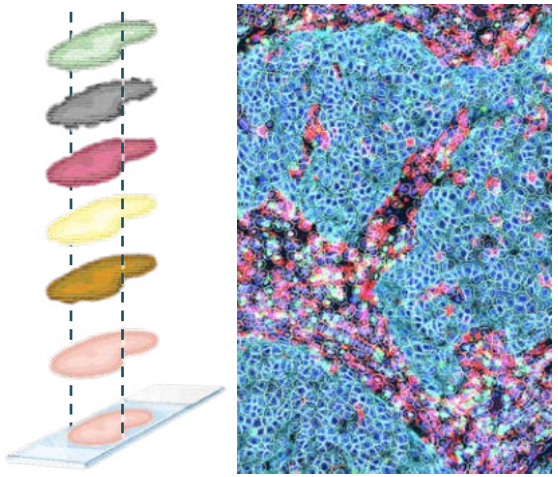
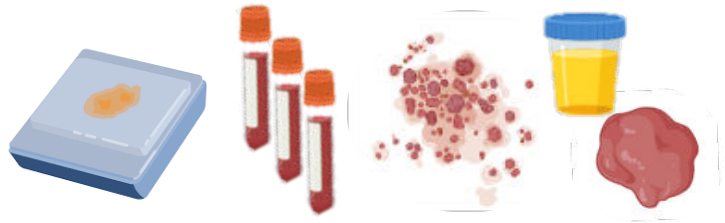


7.2.1 advanced genomics

7.2.2 digital pathology

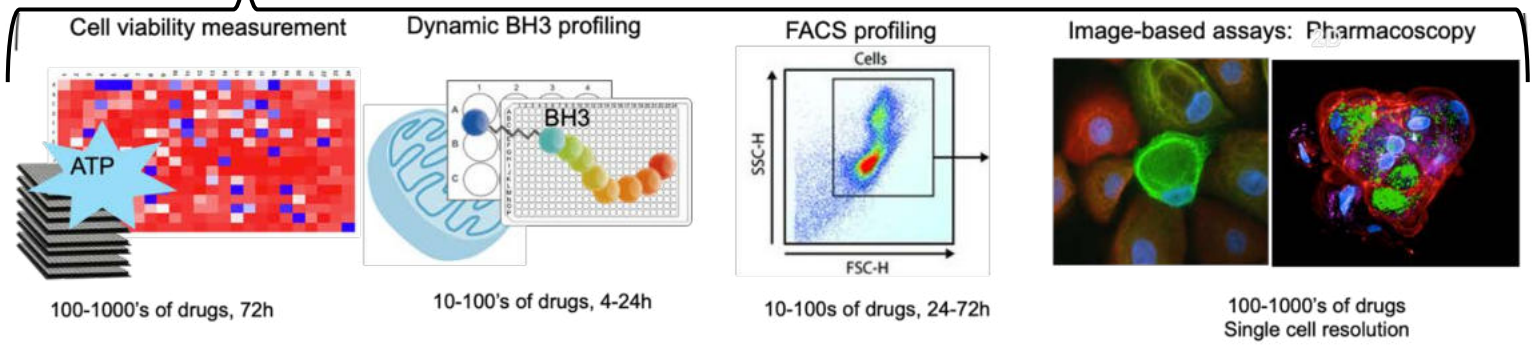


7.2.4 Sample acquisition & preparation



7.2.3 functional precision medicine

Sf(PM)



7.2.5

Horizon scanning

Task 7.3 Diagnostic data provision

Task lead

Aedin Culhane
UL and UHL, Ireland

Sub-tasks

7.3.1 Genomics – create a GENIE4-EU version, data standardization and interoperability

7.3.2 Imaging – enable data repositories, data standardization and interoperability

Molecular Tumor Board

Task co-lead

Arto Mannermaa
University of Eastern Finland, Finland

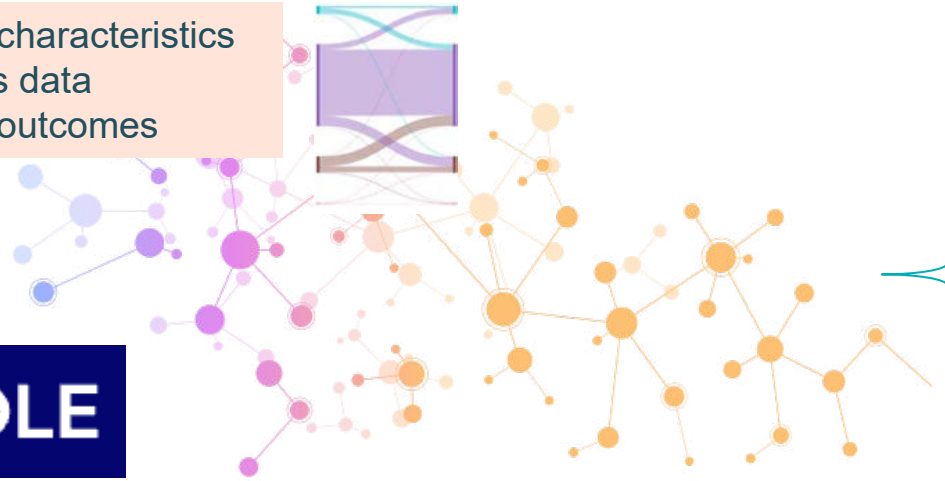
Stephan Ossowski (7.3.1)
University of Tübingen, Germany

Eivind Hovig (7.3.2)
Oslo University Hospital, Norway

Task 7.3 Diagnostic data provision

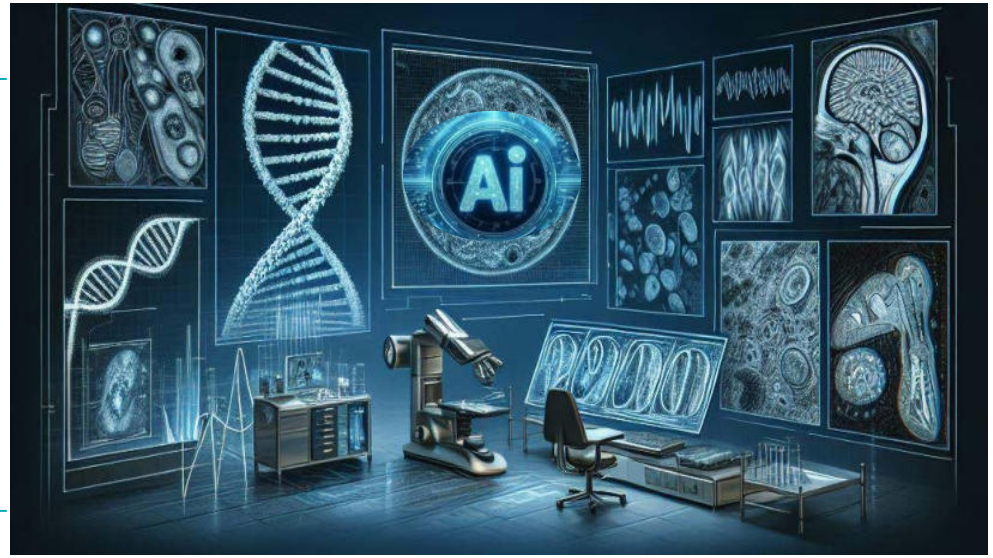
JA PCM
Joint Action Personalised Cancer Medicine

1. Patient characteristics
2. Analysis data
3. Patient outcomes



CANDLE

National Cancer Data Nodes



Co-pilot version of a modern diagnostics on molecular and imaging methods

Observational Medical Outcomes Partnership (OMOP) Common Data Model (CDM)

OHDSI

eosc | cancer

Data access

National Cancer Data Nodes

HDRUK
Health Data Research UK

Images

EUCAIM
CANCER IMAGE EUROPE

ECHoS
Cancer Mission Hubs

Genomics

FAIR

Global Alliance for Genomics & Health

AACR
American Association for Cancer Research
FINDING CURES TOGETHER

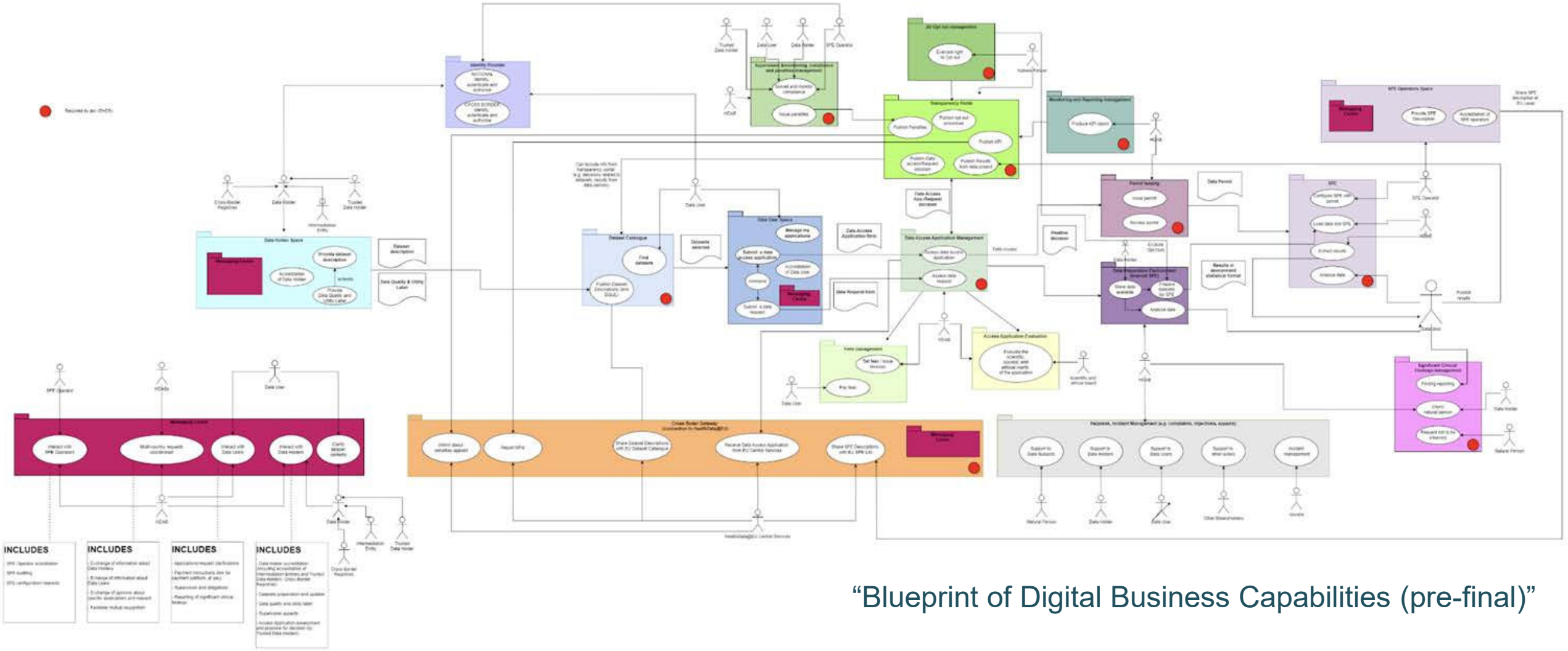
PROJECT GENIE
Genomics Evidence Neoplasia Information Exchange

cBioPortal
FOR CANCER GENOMICS

European Genomic Data Infrastructure

European Health Data Space

EHDS- workflow template for secondary use of health data



"Blueprint of Digital Business Capabilities (pre-final)"

defined by member state representatives of eCANCER thematic working group

Funded by the European Union

Task 7.4 Observational diagnostic testing platform

JA PCM
Joint Action Personalised Cancer Medicine

Task lead

Hege Russnes
Oslo University Hospital, Norway

Sub-tasks

7.4.1. RWD based clinical platform for evaluation of diagnostics for reimbursement and implementation

7.4.2. Protocol scoping - testing and validation of upcoming advanced diagnostics

Molecular Tumor Board

Task co-lead

Timon Vandamme
Antwerp University Hospital, Belgium

Juan González-García, (7.4.1)
IACS, Spain

Elisavet Papageorgiou (7.4.2)
BOCOC, Cyprus

Task 7.4 Observational diagnostic testing platform

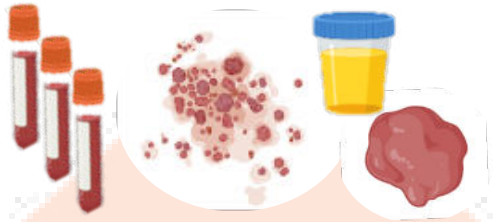
JA PCM
Joint Action Personalised Cancer Medicine

7.1. ctDNA/ liquid biopsies

7.3 Diagnostic data

7.2.1-3/5 Exploratory diagnostic analyses

7.2.4 Sample acquisition



Observational testing platform for evaluation of diagnostics for reimbursement and implementation

Pilot Molecular Tumor Board

WP8
WP13

EXPECTED OUTCOMES & IMPACT

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1. Increased availability for ctDNA for profiling and response monitoring across Europe
2. Improved preparedness for novel exploratory diagnostics on high quality samples
3. Closer to real time high quality interoperable evidence from real world multimodal
4. Plan towards a European-wide observational testing platform

The possibility of the best personalised diagnosis to match treatment for European cancer patients

Conclusion

- Availability of molecular and other advanced diagnostics is conditional for personalized cancer medicine
- Momentum around ctDNA/liquid biopsies provides a unique use case to develop a roadmap towards EU wide adoption, implementation and reimbursement of personalized cancer diagnostics
- Real time evidence from combined real-world diagnostic, treatment & outcome data is a critical success factor for personalized cancer medicine

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JA PCM KICK-OFF

14/15 JANUARY 2026

WP8

Treatment

Kjetil Taskén

Co-funded by the European Union

OSLO UNIVERSITY HOSPITAL

Leids Universitair Medisch Centrum

WP8 Treatment

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Context

Implementation *of Precision Cancer Medicine (PCM), is* ***hampered by lack of data and uncertainty*** *that inhibits inclusion of all potential effective indications on the label and of normal price negotiations leading to reimbursed treatments because "everything" becomes rare in PCM (combination organ specific cancer diagnosis, biomarker and treatment).*

WP8 will aim to ***address this bottleneck*** *by creating a framework allowing* ***more extensive data collection to build more evidence*** *to support decision makers (investigators, industry partners, HTA assessors, regulators and payers) in advancing more PCM treatments into standard of care.*

MISSION & VISION

- The vision of WP8 is to create a European evidence-generation system that provides more efficacy data and enables decision-makers to approve and make available more innovative new drugs to cancer patients throughout Europe.

- **OBJECTIVES**
  - Obj. 8.1: Establish a system for systematic evidence generation through a standardised collection of diagnostic and clinical variables
  - Obj. 8.2: Expand access to treatment alternatives for cancer patients
  - Obj. 8.3: Facilitate increased industry investments in Europe

WORKPLAN

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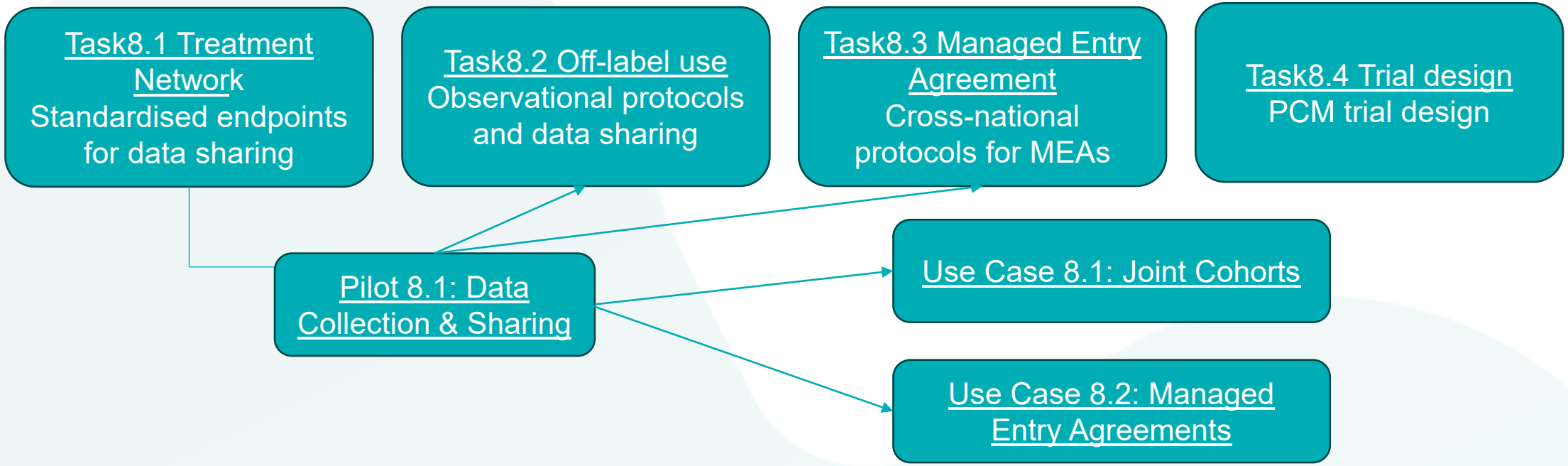
Build on existing successes to facilitate a continuous learning health care system in Europe to address uncertainties faced by different decision makers.

Aim to expand the treatment space for cancer patients in Europe. How?

- Can we facilitate joint cohorts, both industry-led and off-label cohorts?
- Can we increase patient recruitment to clinical trials?
- Can we facilitate joint outcome-based Managed Entry Agreements?



WORKPLAN

Task 8.1: This task aims to establish a European system for collecting and merging clinical outcome data from all patients discussed in Molecular Tumour Boards (MTB).

Method: This task will work across projects and with stakeholders to define a data-sharing framework (endpoints, variables, SAP)

Task 8.2: Increasing access to targeted treatment requires identification of (all) eligible patients for treatment, both for standard-of-care treatment and experimental treatment (e.g., recruitment to clinical trials) and through pragmatic data collection facilitating implementation.

Method: Incorporate comprehensive clinical genomic profiling, new diagnostic modalities and MTBs into standard of care coupled to systems for evidence collection from off-label use. Increase industry investment in clinical trials and marketing authorisations in EU to provide treatment alternatives. Involve industry through workshops, 1:1 meetings (e.g., at ASCO and ESMO). Establish proof-of-concept together with Pilot 8.1 and Use Case 8.2.

Task 8.3: Implement strategies to expand access of approved or soon-to-be-approved drugs via Managed Entry Agreements (MEA), with a focus on structured, outcome-based agreements.

Method: Expand the treatment space by providing a system for structured, outcome-based Managed Entry Agreements (MEA). Involve payers through EMA scientific advice, workshops, and 1:1 meetings in collaboration with WP13. Develop proof-of-concept with Use Case 8.3.

Task 8.4: Regulatory development to match clinical trial development and ensure the necessary flexibility in Europe to address clinical questions relevant for precision cancer medicine (PCM).

Method: Leverage and clarify existing flexibilities within CTR. Develop EU wide regulatory guidance specific for PCTs. Foster early multistakeholder dialoque and harmonize ethics review.

WORKPLAN

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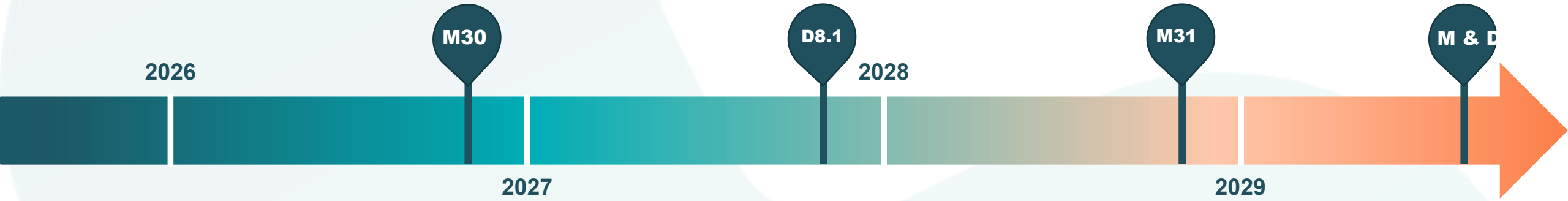
MILESTONE 30	Core-set of endpoints	M12
DELIVERABLE 8.1	Data Sharing Platform	M24
MILESTONE 31	Data sharing platform (data shared)	M36
DELIVERABLE 8.2	Key industry indicators	M48
MILESTONE 32	First industry sponsored treatment cohort	M48
DELIVERABLE 8.3	Managed Entry Agreement	M48
DELIVERABLE 8.4	Increased treatment acces	M48
MILESTONE 33	Format for managed entry agreement	M48



PARTICIPANTS

144 participants

66 institutions

22 countries

EXPECTED OUTCOMES & IMPACT

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Expected outcomes:

- A standardised and harmonised protocol for data collection from Molecular Tumour Boards (MTB), including shared inclusion numbers to enable enrolment of patients into clinical trials and cohorts for implementation decisions.
- Similar collection of data from patients that come through MTBs and get off-label treatment outside protocol
- Structured Managed Entry Agreements (MEA) that enable decision-makers to rely on cross-border data collection and analysis as part of the implementation of new treatments.
- Increased industry investment in clinical trials across Europe.

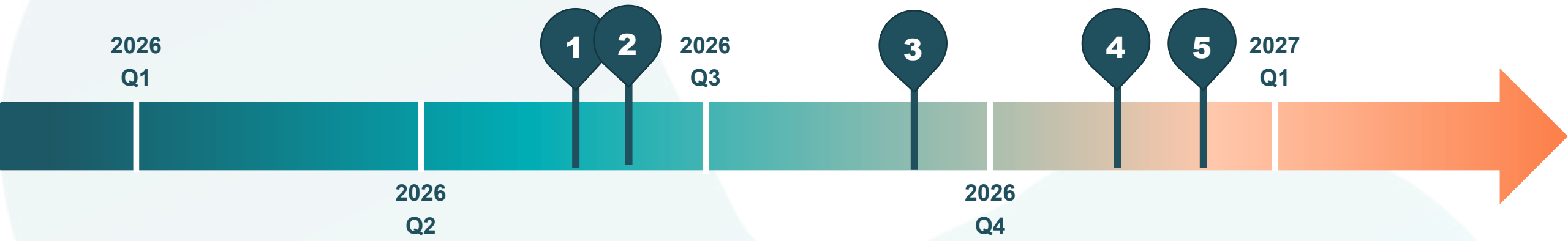
Key Impacts on Stakeholders

- Cancer patients/citizens: Increased access to treatment.
- Industry: Predictable market access strategies.
- Payers: Predictable access to data and analysis.
- Healthcare professionals & researchers: A learning healthcare system that provides more information on effectiveness and toxicity after implementation.
- Healthcare policymakers: Piloting the use of health data within the European Health Data Space.

NEXT STEPS

Next immediate steps and timelines for year 1

STEP 1	Define endpoints	Date: Q2 2026
STEP 2	Industry involvement at ASCO	Date: June 2026
STEP 3	Industry involvement at ESMO	Date: October 2026
STEP 4	Payer involvement	Date: .. 2026/7
STEP 5	Proof-of-concept	Date: .. 2026/7



Conclusion

Provide 3 key messages that the audience should remember about the WP

1. Message 1 — Clinical trial network across Europe connecting every hospital that operates MTBs exploiting the scale of the European population (>450 million citizens)

2. Message 2 — Increased European competitiveness in attracting trials and with MEAs working across Europe.

3. Message 3 — More data collected and evidence generated to support PCM implementation into Standard of Care (connected to EHDS, robust innovation ecosystem, clear pathway for to implementation).

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Co-funded by the European Union

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THE JA PCM KICK-OFF MEETING

14-15 January 2026

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Any question?

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16:50 – 17:35 **Session ARM2: Personalised medicine**

Introduction ARM2 lead
Ruggero De Maria, Alleanza Contro il Cancro (IT)

WP7: Diagnosis
Gerrit Meijer (TBC), Stichting Het Nederlands Kanker Instituut - Antoni van Leeuwenhoek Ziekenhuis (NL)
Païvi Östling, Karolinska Institutet (SE)

WP8: Expanding the treatment space by access under systematic evidence-generation
Kjetil Tasken, Oslo University Hospital (NO)

17:35 – 17:45 **Conclusion** of the day

Marc Van den Bulcke, Cancer Centre, Sciensano (BE)

17:45 – 19:00 **Networking event**

NETWORKING EVENT

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ARM3

ARM1

Transversal

ARM2