THE JA PCM KICK-OFF MEETING

14-15 January 2026

JA PCM
Joint Action Personalised Cancer Medicine

9:00 – 9:30 **Introduction** session

Innovative Health Initiative (IHI)
Niklas Blomberg, Executive Director, Innovative Health Initiative

SPARC Introduction and Synergy update
Manuel Ottaviano, Universidad Politecnica de Madrid (ES)
Denis Horgan, European Alliance of Personalised Medicine

The Innovative Health Initiative

Bold collaborations, transforming health

Niklas Blomberg, IHI Executive Director

2026 • Trials@Home• Brussels, BE

innovative health initiative

Bold collaborations, transforming health

Who?

IHI is a cross-sector EU public-private partnership

What?

We create bold collaborations – excellent health research and innovation projects that bring together the best minds

Why?

Our ultimate goal is to transform health across the entire spectrum of care, especially in areas of unmet need

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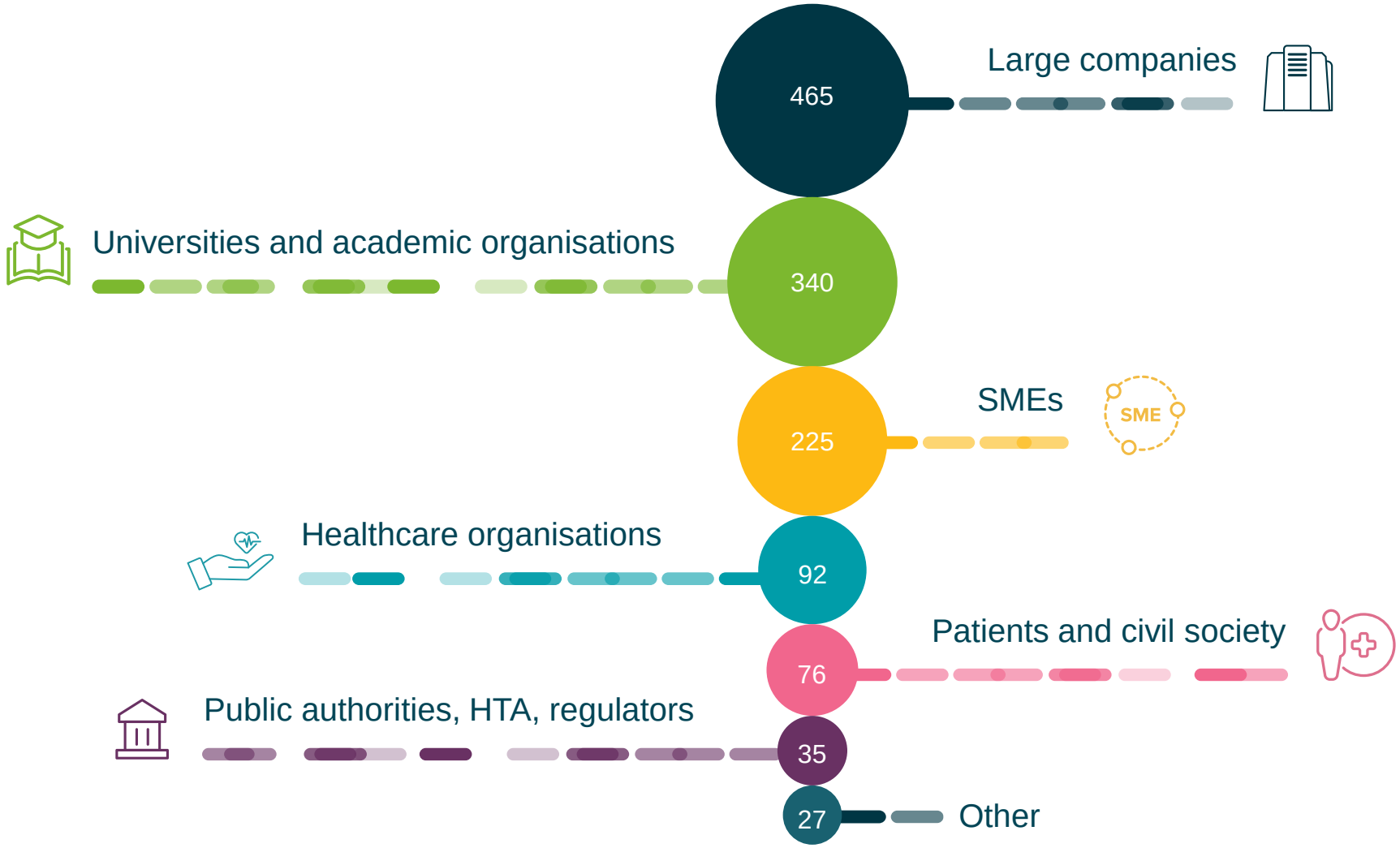
Bold collaborations – the IHI community



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We are a public-private partnership…

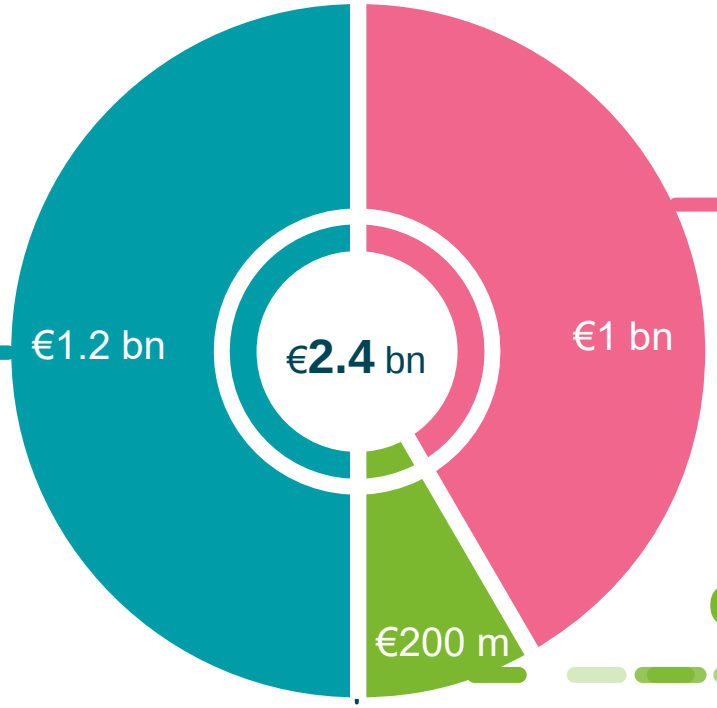
The partners contribute equally to our €2.4 billion budget

Public

EU
(Horizon Europe)

Funds go to: research orgs, SMEs, patients, healthcare, regulators…

Co-funded by the European Union



Industry members

In-kind or financial contribution

COCIR · efpia · EuropaBio · MedTech Europe from diagnosis to cure · Vaccines Europe

Contributing partners

In-kind or financial contribution

Private

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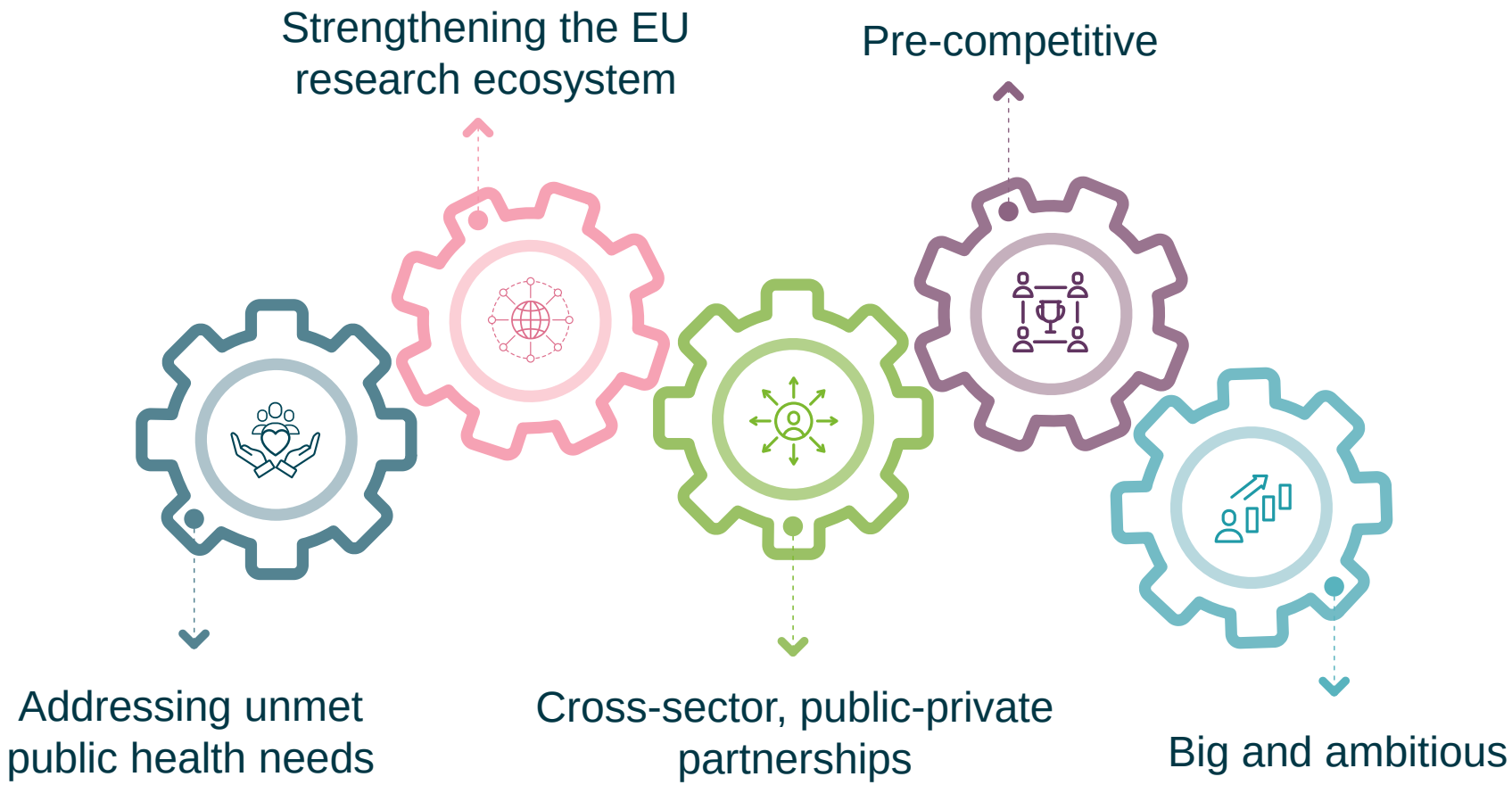
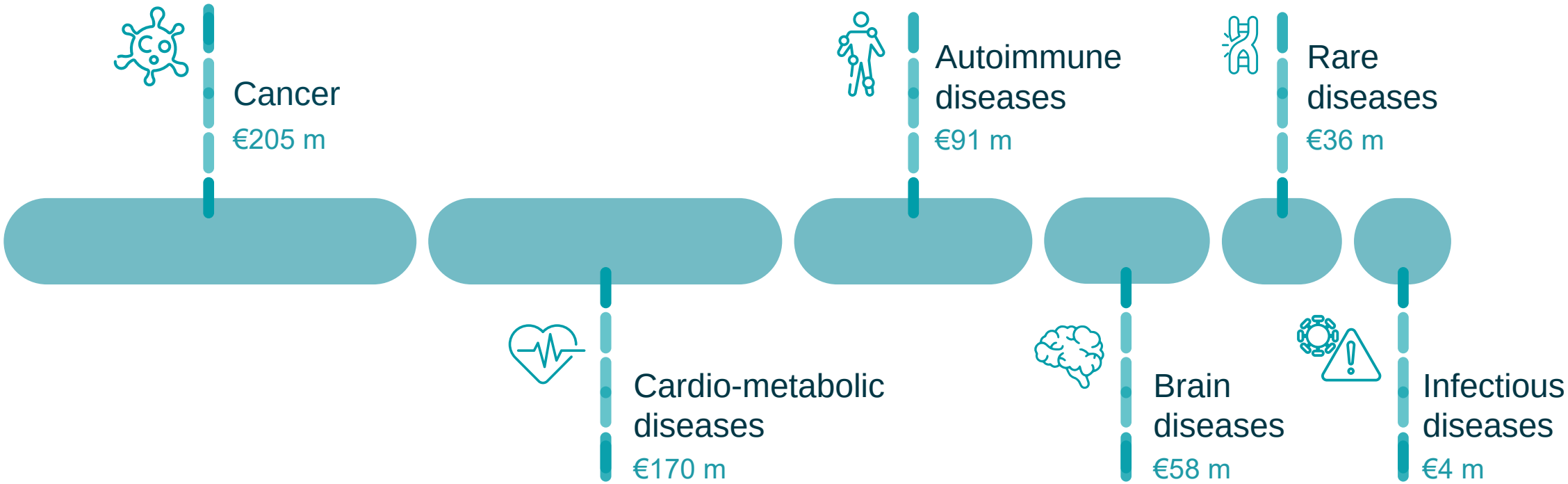
What does an IHI project look like?

IHI projects are…



Bold Collaborations. Transforming health



Not included in these figures: projects addressing more than one disease area (€75 m), and projects tackling cross-cutting issues in health research (€229 m).

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IHI Theranostics Budget

IHI financial contribution:
34 million €

Industry / CP contribution:
29 million €

63 Million €

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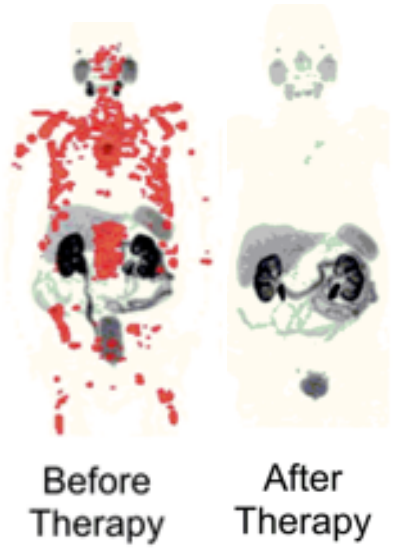
What is Theranostics

Pairing of Diagnostic biomarkers with Therapeutic agents that share a specific Target

This approach allows to
"**see what we treat**"
and "**treat what we see**"
at the **molecular level**.



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IHI Theranostics Projects in a Nutshell

Accelerate.EU

- ✓ **Works on agressive cancers**
  - Triple negative Breast cancer
  - Pancreatic cancer
  - Brain cancer
- ✓ **Use Alpha emitter Astatine 211**
  - Very promising radioisotope
  - High probability DNA damage
- ✓ **Aim at increasing the supply**
- ✓ **Phase 1 clinical trials for severe unmet clinical need**

THERA4CARE

- ✓ **Works on agressive cancers**
  - Ovarian cancer
  - Brain cancer
  - Sarcoma
- ✓ **Enhance treatment precision**
  Create Multi-Site Data-Sharing to integrate AI
- ✓ **Aim at increasing the supply**
- ✓ **Phase 1 clinical trial for severe unmet clinical need**

ILLUMINATE

- ✓ **Works on advanced cancer**
  Metastatic prostate cancer resistant to castration therapy
- ✓ **Deveolp early biomarker of response (MetMRI)**
  To avoid unnecessary treatment (30% non-responders)
- ✓ **Aim at increasing the supply**
- ✓ **Phase 1 clinical trial for severe unmet clinical need**

Aligned with the **SAMIRA** action plan

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IHI aligned with EU Beating Cancer Plan & Cancer Mission

IHI Projects	Early Detection	Diagnosis Treatment	Quality of Life
IMAGIO		✓	✓
GUIDE MRD	✓	✓	
IDERHA	✓		✓
BRECISE		✓	
ILLUMINATE		✓	
Thera4Care		✓	
Accelerate.eu		✓	
EASYGEN		✓	✓

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Stay in touch

Visit us

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Write to us

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Innovative Health Initiative (IHI)

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@ihieurope.bsky.social

Mastodon
@IHIEurope@mastodon.social

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the European Union

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Support of Personalized medicine AppRoaches in Cancer

Bruxelles, 15th January 2026

This project has received funding from the European Union's
EU4Health Programme under Grant Agreement No. 101232874

Project overall information

Budget: 3,749,951.96 €

EC contribution (80%): €2,999,961.57 €

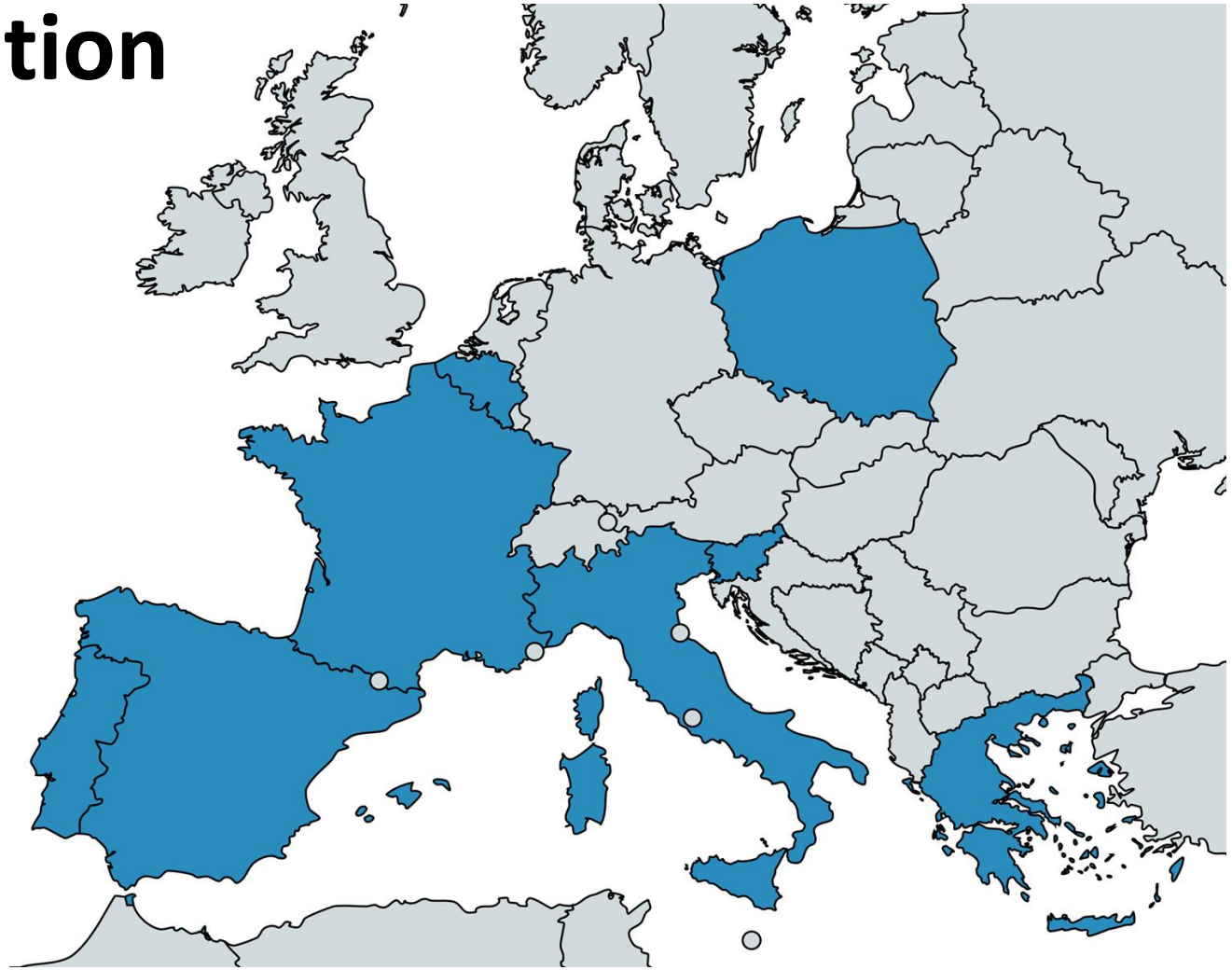
Duration: 1st November 2025, 31st October 2028

Coordinator: Universidad Politécnica de Madrid

Number of beneficiaries: 17

Beneficiaries:

- Hospitals (5)
- Universities (4)
- Patient associations (4)
- Medical associations (2)
- Research center (1)
- Stakeholder group (1)



The problem

☺ Personalized medicine (PM) in cancer treatment has emerged as a disruptive approach for managing cancer.

☹ Despite its transformative potential, personalized medicine in oncology encounters problems that hinder its widespread adoption and impact.

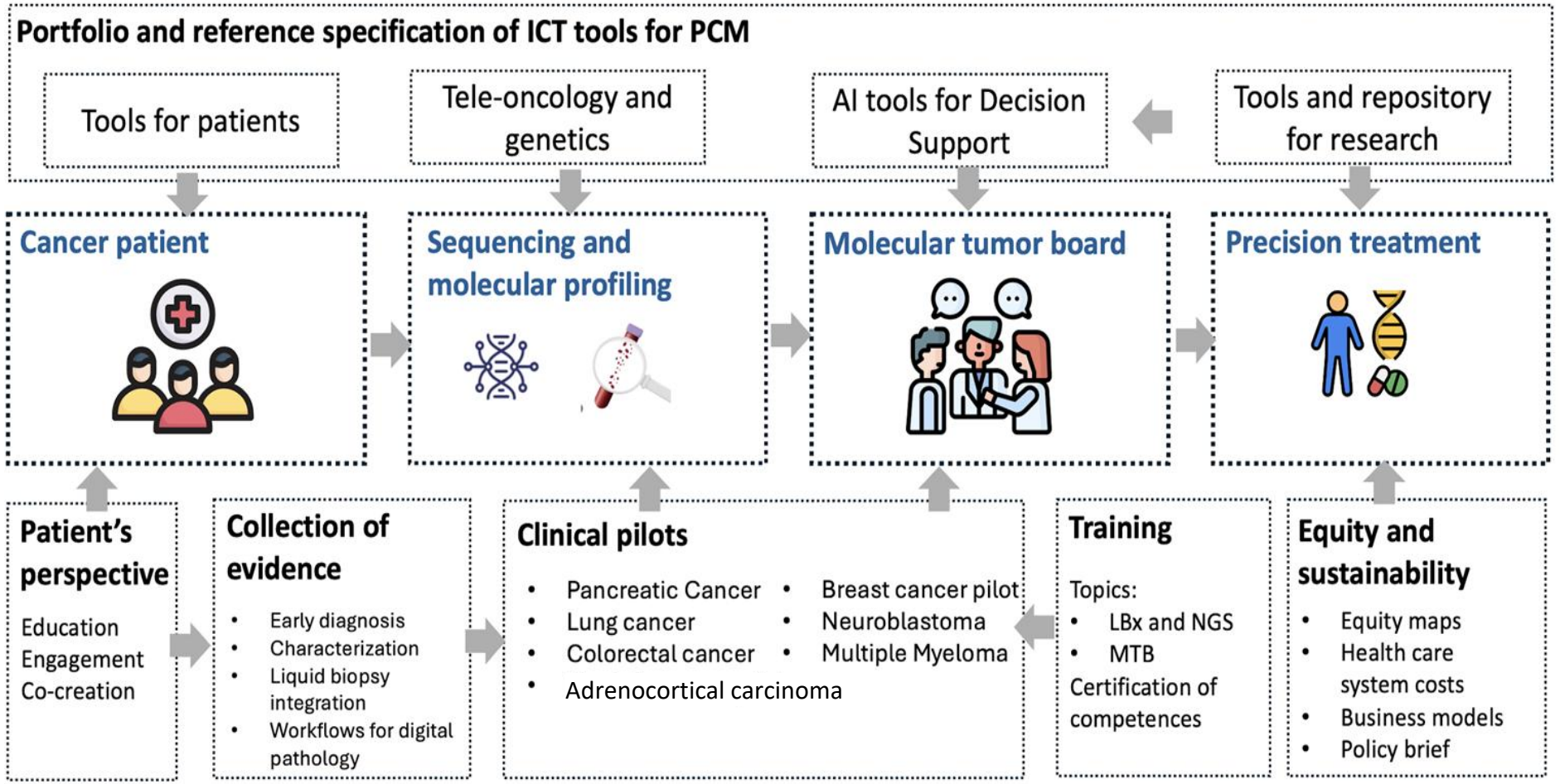
Problems:

- Lack of universally validated biomarkers
- The high costs of genomic testing
- The human capacity (culture of change, empowerment , training)
- Data are in silos and research needs to speed up

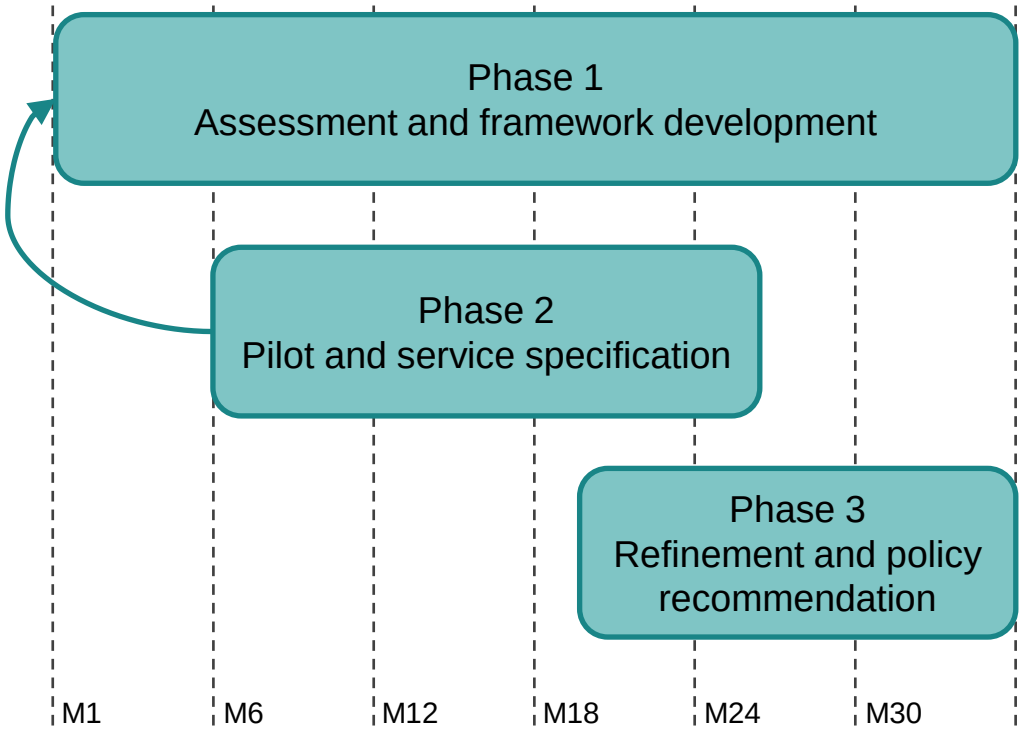
SPARC Objectives

- Support the **implementation of best practices** for the uptake of PM in cancer, contributing to the efforts in establishing knowledge networks.
- To complement ongoing and past robust initiatives via liaison, twinning and support to roll out of **new policy approaches**.
- Design and implement and validate of **innovative practices** (via pilot tests) to foster the uptake of PM in clinical practice
- Offer **targeted education** and specialized training multidimensional programs to all stakeholders with especial emphasis on Health Care Professionals
- Fostering the development of **human-centric PM solutions** involving all users' perspectives (patient organisations, civil societies, non-government associations and research institutions)
- Promote the **culture and the adoption** of the PM approach and disseminate the project results.

SPARC core activities



Timeline



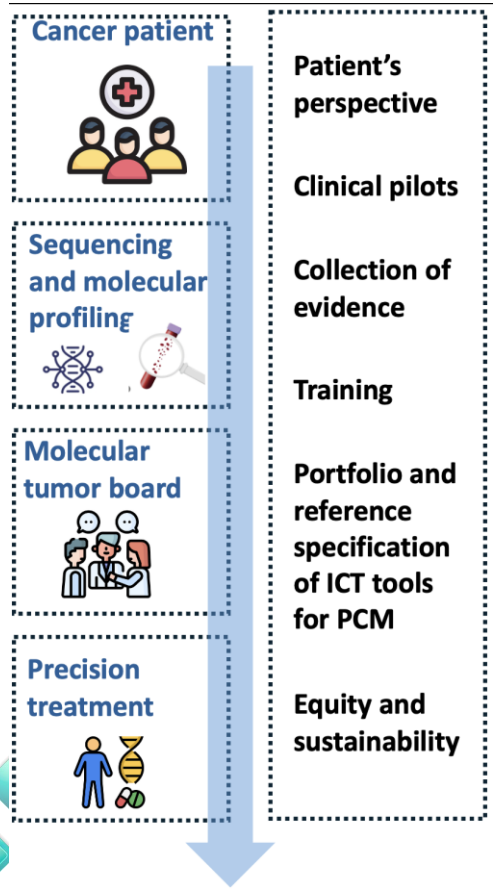
- Review: clinical workflows and technology
- Define: evidence-base protocols, gaps, research agenda

- Building capacities, pilots on liquid biopsy and Molecular Tumor Board,
- Specification and portfolio of technology

- Harmonized protocols
- Training materials
- Specification of advanced tools
- Policy brief

Patient centred approach, Stakeholder engagement, workshops, synergy with PCM JA and other initiatives

Expected Results and Benefits to the Patients and Society

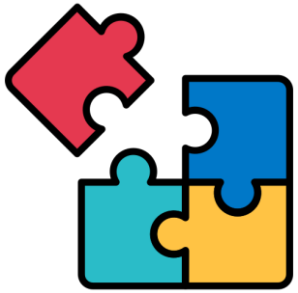


Seven cancer pilots:

- Multiple Myeloma (n=100)
- Breast (n=30)
- Pancreatic (n=40)
- Adreno Cortical Carcinoma (n=23)
- Lung (n= 50)
- Neuroblastoma (n=30)
- Melanoma (n=30)

Results

- Manual of protocols for NGS and liquid biopsy,
- Workflow Design for MTB and Digital Oncology
- Portfolio and reference specification of existing ICT services
- Certified training in Liquid biopsy and MTB
- Package of education materials for patients and the general public
- Policy recommendations for equitable and sustainable PCM adoption



The IMPACT will be maximized building synergies with PCM JA and other initiatives

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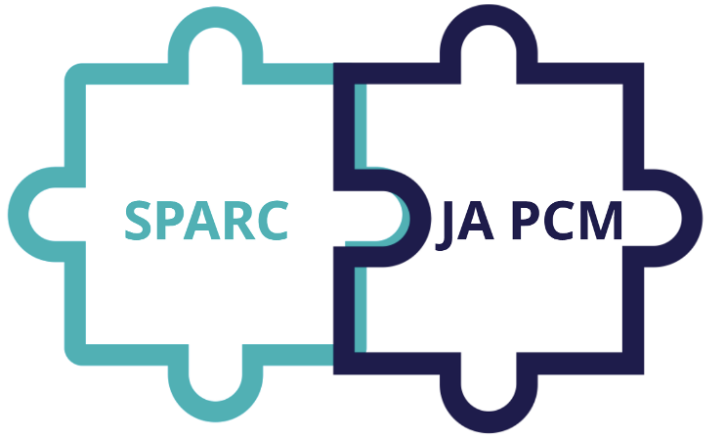
Project approach

- Collaborative framework
  - Sharing knowledge
  - Learn from others
  - Solve together
- Embedded synergy with JA PCM and others are ongoing
- User centric approach
- Multidisciplinary approach on two key aspects:
  - LB & NGS
  - MTB
- Stakeholder Engagement strategy

Synergy with JA PCM



Mission

- Build on and Bridge JA PCM & SPARC activities
- Deliver unified guidelines and policy recommendations for PCM

Strategy

- Coordinators of both projects proposed an initial proposal of synergies
- 3 common deliverables will be prepared :
  - Report 1: Synergy strategy (M3)
  - Report 2: Progress report and upcoming activities (M18)
  - Report 3: Final report on activities and outcomes (M36)
- Involvement of both consortia

SPARC supports JA PCM

- **Key contributions from SPARC:**

Integrate Patient Perspectives

Activities within the Personalised Medicine Arm

- **Areas of synergy:**

WG1: LB - NGS
Promote liquid biopsy and NGS for diagnostics and recurrence

- Map state of play
- Best practices for the implementation

WG2: MTB
Consolidate MTBs and federated approaches

- Data sharing protocols
- State of play of clinical centers
- Patient perspective
- Alignment on technology

WG3: T & EDU
Share work on training and education

- Training activities (for patients and professionals)
- Educational materials

WG4: COM & DIS
common communication and dissemination strategy

- Joint communication strategy
- Stakeholder engagement activities

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“Connecting the Dots” – JA-PCM & SPARC

THE CHALLENGE:

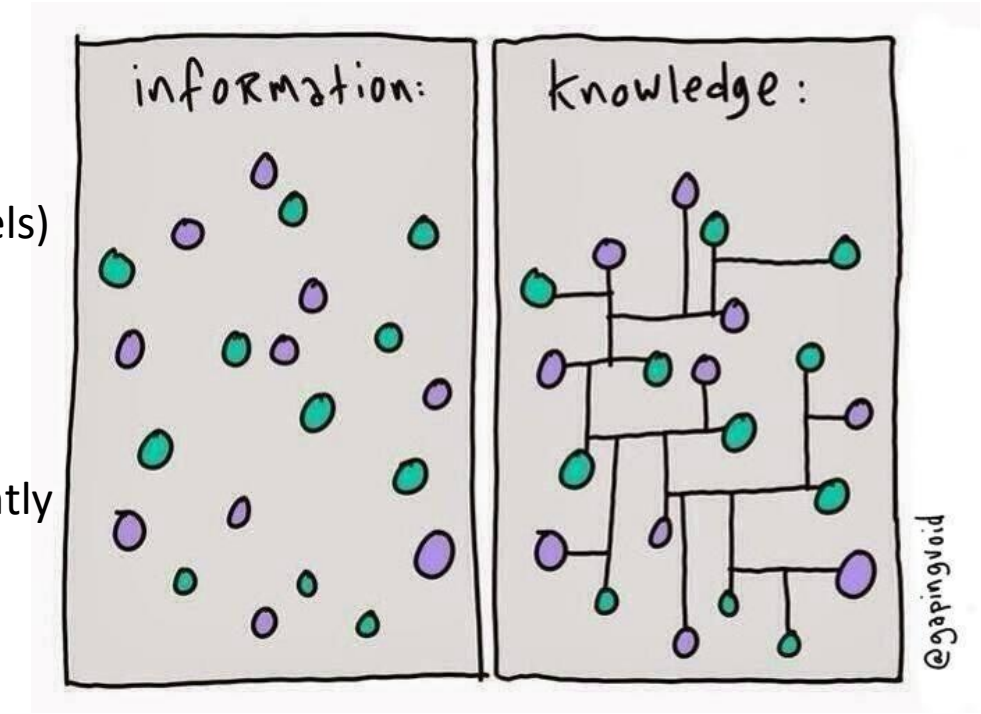
Ensure ***coherent*** policy ***alignment*** & ***inclusive*** **engagement** across:

- institutions and organizations
- all geographical levels (European, national, regional, and citizen levels)

SCIENSANO & EAPM -

dissemination, communication, policy outreach

as dialogue facilitator and impact amplifier, to support SPARC in efficiently translate science into policy



(too much...)

OUR GOAL: BE ON THE SAME PAGE WITHOUT ADDING WORK

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JA-PCM & SPARC

By combining Next Generation Technologies and Liquid Biopsy we are able to improve our resolution power.

This is leading to cancer dynamic de-codification allowing us to better select, treat and cure our patients

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A 3-level model for stakeholder engagement in SPARC - JA-PCM

Level	Name	Purpose	Main Stakeholders	How
1	**Alignment Group**	**EU-level** coordination board to ensure feedback integration at policy level	EC, HADEA, JA PCM coordinators, SPARC, EMA	• 1-2x year / online
	Embedded within level 1	**PCM cluster**	Involved in coordinating with parallel key initiatives and key PCM and SPARC experts (build on the HPP form JANE2)	TBD
2	**Stakeholder Coordination Group (SCG)**	Strategic and **expert-level** dialogue for coordination in translating feedbacks in structured recommendation (annual report)	Policymakers, clinicians, regulators, HTA bodies, payers, patient orgs, industry (connected to GB of JA PCM)	• 1 h workshop | 3-4x year • Annual summary report • Policy recommendations for Alignment Group • Contribute to policy papers
3	**Stakeholder Forum (SForum)**	**Broad engagement** to exchange best practices, educate, disseminate and gather feedback	Civil society, patient orgs, NGOs, national mirror groups, healthcare professionals	• EU Health Policy Platform • 1 event (online) / year

Co-funded by the European Union

This project has received funding from the European Union's EU4Health Programme under Grant Agreement No. 101232874

JA-PCM & **SPARC Stakeholder Coordination Group (SCG)**

IDEA: **6 nominated representatives X 6 thematic cluster** to ensure diversity and expertise balance:

Public Health Policymakers – national and regional representatives.

Industry Representatives – diagnostics, biotech, pharmaceutical, ICT sectors.

Clinicians & Medical Specialists – representing MTBs, oncology, rare cancers.

HTA Bodies & Payers – providing insights into cost-effectiveness and reimbursement.

Patient Organisations & Citizen Groups – ensuring patient-centred approaches.

Regulators & Competent Authorities – national/EU-level health agencies (e.g. EMA).

Engagement Formats for SPARC & JA-PCM, consortium (level 2)

OPEN OFFICE

on engagement & communication

1 h / month - LIVE ONLINE - hosted by EAPM

- open Q&A (event promotion, comm support...)
- quick problem solving
- parking slot for ideas and feedback

INSIGHT EXTRACTION

by joining existing meetings (one per month)

+15min - moderated by EAPM

- live micro-survey on the topic discussed
- invite 1 representative of a relevant different category

FLASH CONSULTATION

topic specific - max 10 participants

30min - LIVE ONLINE - facilitated by EAPM

- 3min pitch from 1 presenter introducing the topic
- quick round of introduction of participants
- 10min Q&A <=> live poll
- 5min summary of 3 takeaways

WORKSHOP

validation of input from the other engagement activities & other EU initiatives

max 1 h / quarter - LIVE - in person when possible*

- SCoordination Group (e.g. SPARC meeting in Pompei)
- SAlignment Group (e.g. 1x ESMO + 1 JA-PCM meeting

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Share your perspective on personalised cancer medicine - this survey takes only 2 min!

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This project has received funding from the European Union's EU4Health Programme under Grant Agreement No. 101232874

Thank you!

Manuel Ottaviano (UPM)

Denis Horgan (EAPM)

https://sparc-project.eu/

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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:

9:30 - 10:10 Session ARM3: Personalised follow-up and tertiary prevention

Introduction ARM3 lead
Claus Lindbjerg Andersen, Aarhus University (DK)

WP9: Digital innovation for improving survivorship care delivery
Maria Alice Borinelli-Franzoi, Institut Gustave Roussy (FR)

WP10: Tertiary Prevention
Torben Hansen, The Region of Southern Denmark (DK)

10:10 - 11:10 Session Pilots ARM1 & ARM3

WP9: Digital tools for remote monitoring need assessment, self-management and supportive care
Maria Alice Borinelli-Franzoi, Institut Gustave Roussy (FR)

WP5: Risk-Informed Prevention (PARI)
Stefania Boccia, Fondazione Policlinico Gemelli (IT)

WP6: Polygenic Risk Score (PRS)
Jeroen van Rooij (TBC), Erasmus Medical Centre (NL)

JA PCM
Joint Action Personalised Cancer Medicine

JA PCM KICK-OFF

14/15 JANUARY 2026

WP9

Digital innovation for survivorship care delivery

Maria Alice Franzoi, MD, PhD

Medical Oncologist

Med. Oncology Department & Cancer Survivorship Group

Gustave Roussy, Villejuif, France

Co-funded by the European Union

GUSTAVE ROUSSY
CANCER CAMPUS GRAND PARIS

sciensano

WP9: Digital innovation for survivorship care delivery

JA PCM
Joint Action Personalised Cancer Medicine

Gustave Roussy

Maria Alice Franzoi
Medical Oncologist
Cancer Survivorship Group
Gustave Roussy

Petya Zyumbileva
Postdoctoral Researcher
Cancer Survivorship Group
Gustave Roussy

Sarah Ball
Research Assistant
Cancer Survivorship Group
Gustave Roussy

Ines Vaz Luis
Medical Oncologist, Group Lead
Cancer Survivorship Group
Gustave Roussy

Siensano

Régine Kiasuwa Mbengi
Head of Supportive Care
Siensano

Marie Lamberigts
Postdoctoral Researcher
Siensano

The current survivorship care model is unsustainable

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Joint Action Personalised Cancer Medicine

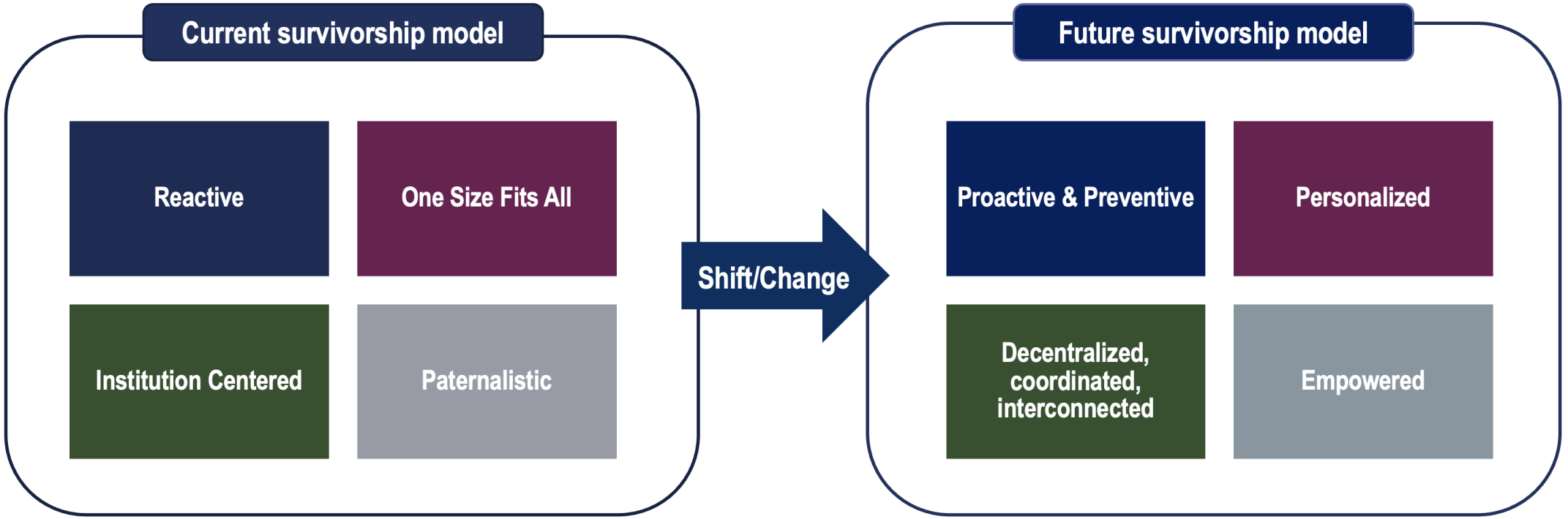
Large proportion of patients reporting deteriorated QoL after diagnosis:
• 50% severe physical symptoms[1]
• 30% emotional distress[1]
• 20% difficulties returning to work[2]
• 30-50% struggle to adhere to adjuvant ET[3]

Sub-optimal delivery of comprehensive survivorship care:
• 5 key survivorship care domains not systematically addressed[4]
• ↓ use of supportive care services: Severe Sexual concerns: <50% sexologist/psychologist[5] Fatigue: 40% don't adhere to PA guidelines, 15% psychosocial support[6]

Increased demand vs. limited healthcare resources:
• ↑ number of cancer survivors. (15.5 million currently, rising to 26 million by 2040)[7];
• Cancer survivors ≥65y (62% currently, but growing to 73% by 2040)[8]
• 56% growth in demand for oncology services, coupled with only a 14% growth in healthcare supply[9]; Shortage 4.1 million HCPs for 2021

1- Ferreira AR 2019; 2- Dumas A 2021; 3- Pistilli B 2021; 4- Brauer 2021 5- Franzoi MA 2023 (in press) 6- Di Meglio A 2021; 7-ASCO Survivorship Facts & Figures 2016 8- Bluethmann SM 2018, 9- ASCO 2014.

Rethinking current survivorship care



Digital Health: Proven benefit for Care coordination & Role Delegation; Patient Empowerement & Self-Management; Needs Assessment & Descentralized Supportive Care[1]

→ **Gaps: Implementation Lag; Literacy & Readiness; Skills & Infrastructure = Disparities**

1- Franzoi MA, ASCO Educational Book 2025.

MISSION & VISION

JA PCM
Joint Action Personalised Cancer Medicine

To prepare the **optimal and equitable implementation of digital tools** for remote patient monitoring, self-management and supportive care delivery during survivorship phase at EU MSs **to improve comprehensive survivorship care delivery, patient empowerment and quality of life.**

- **OBJECTIVES**
  - To **map existing digital solutions** for survivorship care; define minimum requirements and understand reimbursement policies across EU MSs.
  - To **build the components of an implementation package** (implementation best practices, resources needed, capacity building and equity and inclusion aspects) for integrating digital solutions for survivorship care in personalized medicine centres. *A pilot study will illustrate the feasibility and perceived benefit of this package during survivorship care delivery in different countries*.
  - To **prepare for the integration** of novel components into digital solutions to provide comprehensive follow-up and survivorship care.

WORKPLAN

JA PCM
Joint Action Personalised Cancer Medicine

Digital Ecosystem Mapping, Requirements & Reimbursement

Implementation, Capacity Building & Equity

Creating the future for digital survivorship care

Task 9.1

Map & evaluate digital tools available for survivorship care in Europe

Define key requirements for high-quality, effective digital solutions (what they should tackle? Priority domains)

Identify reimbursement pathways for digital survivorship care delivery

Task 9.2

Understand implementation barriers & facilitators

Prepare content of capacity actions (education and training) for HCPs and patients (short visits; webinars)

Identify/collect experience on digital health equity initiatives

Task 9.3

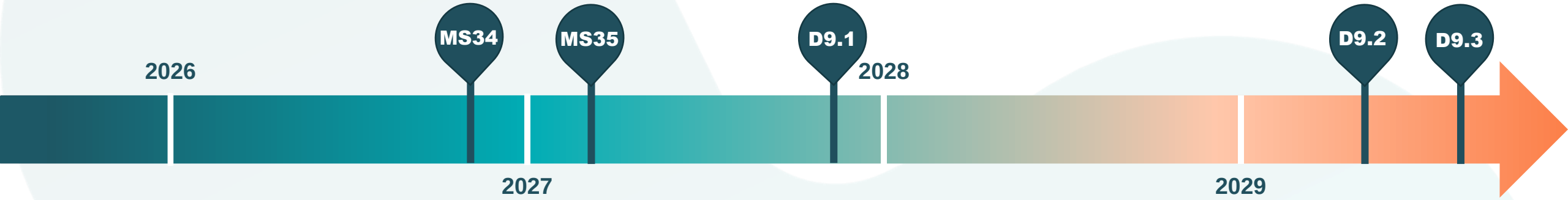
Prepare the implementation of innovative elements into digital survivorship care

(Wearables, ctDNA, Sharing data personal clouds European health data hub)

Pilot study evaluating a personalized implementation package to advance digital survivorship care delivery

WORKPLAN

MILESTONE S34	**Mapping of available digital solutions in the EU** Launch of survey on available digital tools for survivorship care	M12
MILESTONE S35	**Capacity building actions for digital survivorship care** Nb of attendees to Webinars for capacity building (for patients and providers) and short hospital exchange visits (for providers) on digital survivorship care.	M15
DELIVERABLE 9.1 **LEAD: SC (BE), CO-LEAD: AUH (DK)**	**Mapping of existing tools, minimum requirements and reimbursement** Digital repository for public search of the mapping of existing tools, minimum requirements and reimbursement policies for digital solutions for survivorship care delivery	M24
DELIVERABLE 9.2 **LEAD: GR (FR), CO-LEAD: OUS (NO)**	**Implementation package for digital survivorship care** Scientific paper highlighting all components of the implementation package for digital survivorship care including learnings from the pilot	M42
DELIVERABLE 9.3 **LEAD: KUL (BE), CO-LEAD: AUH (DK)**	**Integration of novel datasets and technology infrastructures into digital survivorship care tools** Report on suggested frameworks for integrating novel datasets (wearables and ctDNA) into digital solutions for patient monitoring, self-management and survivorship care delivery as well as interoperability with patient records in the EHDS	M48



PARTICIPANTS

Task 9.1

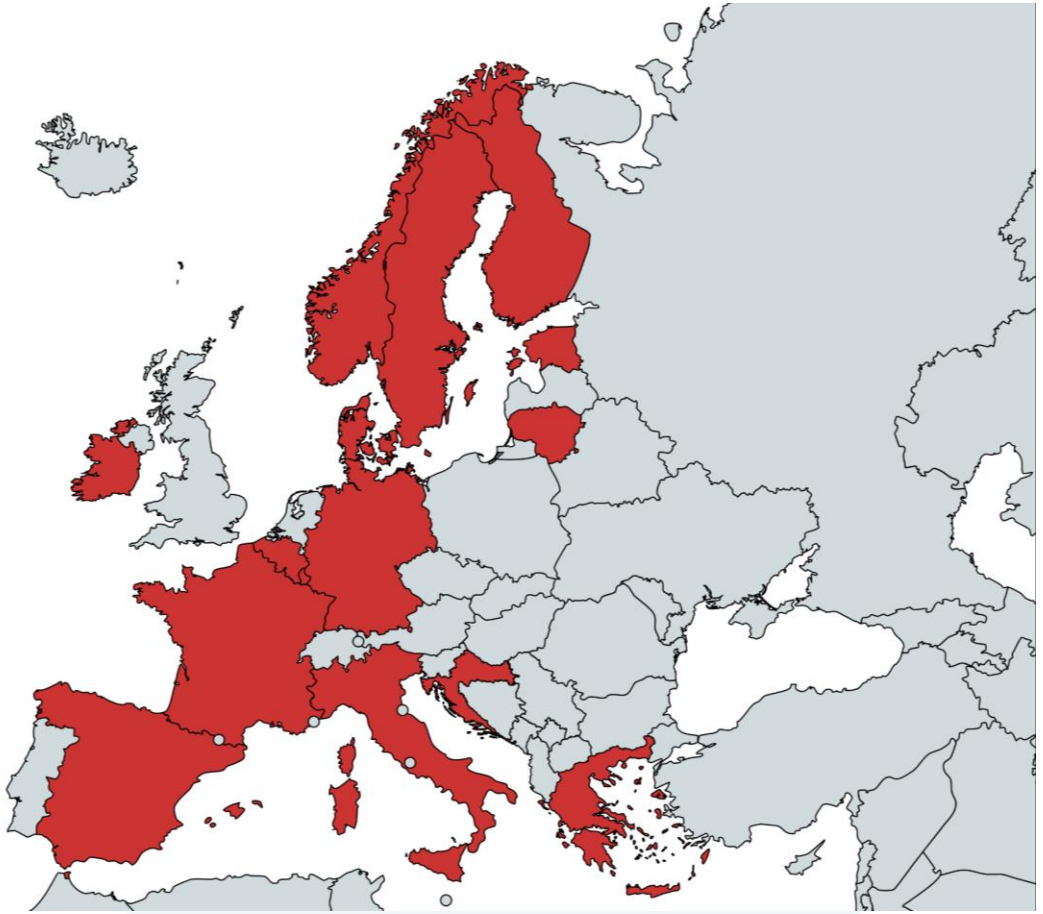
- Lead: SC (BE), Co-lead: AUH (DK)
  - Lead 9.1.1: SC (BE)
  - Lead 9.1.2: OUS (NO)
  - Lead 9.1.3: GR (FR)
  - Participants: KBC SM (HR), KUL (BE), DKG, UKW (DE), KUH RS (SE), UH-FICAN, HUS, PSHVA, OY (FI), SERGAS (ES), NKUA (GR), HSE (IE), SAM LT (LT), RSD (DK), HDIR (NO), INCa (FR), IFO (IT), NEMC (EE), CFB, ChDN, CHEM (LU)

Task 9.2

- Lead: GR (FR), Co-lead: OUS (NO)
  - Lead 9.2.1: CLB (FR)
  - Lead 9.2.2: AUH (DK)
  - Lead 9.2.3: IFO (IT)
  - Participants: SC, KUL (BE), KBC SM (HR), DKG, UKW (DE), RSD (DK), SERGAS (ES), NKUA (GR), HSE (IE), PSHVA, OY (FI), KUH RS (SE), INCa (FR), UTARTU (EE), INC, CHdN, CHEM (LU)

Task 9.3

- Lead: KUL (BE), Co-lead: AUH (DK)
  - Lead 9.3.1: KUL (BE)
  - Lead 9.3.2: RSD (DK)
  - Lead 9.3.3: SERGAS (ES)
  - Participants: SC, SCK CEN (BE), GR (FR), INSERM, INCa (FR) Unicancer (FR), DKG (DE), OUS, NKUA (GR), KUH RS (SE), KBC SM (HR), FSP CNIO (ES), HDIR (NO), UTARTU (EE), CFB, CHdN, CHEM (LU)



EXPECTED OUTCOMES & IMPACT

Expected outcomes:

- The results of Task 9.1 (Digital Ecosystem Mapping, Requirements & Reimbursement) and 9.2 (Implementation, Capacity Building & Equity) will be integrated in **real-time** into **a Pilot Implementation Package to advance digital survivorship care delivery**

Key Impacts on Stakeholders

- **Healthcare professionals & researchers:**
  - Increase knowledge/skills, confidence, and network needed to implement and evaluate digital tools for survivorship care delivery
- **Healthcare institutions:**
  - Increase readiness to implement digital tools for survivorship care in routine care
- **Cancer patients – Citizens:**
  - Increased access to evidence-based digital health tools to improve the quality of survivorship care delivered

NEXT STEPS

STEP 1	Task 9.1 Mapping of Digital tools, key requirements and reimbursements	Kick off: Dec/2025 - 50% ready by Oct/2026 - Monthly FU meetings
STEP 2	Task 9.2: Building Implementation Package: Mapping of implementation barriers and facilitators; definition of core CV for capacity building webinaires; identification of digital health equity principles and how to integrate it	Kick off: Feb/2026 FU with task leads every 5 weeks - Preliminary ident of barriers: Oct/2026 - List of Topics for webinaires Sept/2026 - First set of reccomendations for digital health equity : Oct/2026
STEP 3	Concomitant survey for pilot selection and readiness evaluation via survey (to feed the implementation package back)	Feb/2026

Conclusion

- As part of Arm III of the JA, WP9 advances personalized follow-up and tertiary prevention through **digital innovation**, aiming to strengthen the delivery of **comprehensive survivorship care**.

WP9 Tasks:

- Task 9.1: Maps existing resources, including digital tools, care pathways, and reimbursement mechanisms
- Task 9.2: Develops an implementation package to enhance readiness, equity, and adoption
- Task 9.3: Prepares future-oriented strategies for sustainable scale-up

- A pilot study will assess, in real time, the outcomes of Tasks 9.1 and 9.2, evaluating their impact across multiple countries and pilot sites with varying levels of readiness

Contact

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KICK-OFF 14/15 JANUARY 2026

Workpackage 10

Tertiary prevention

Professor, PhD, DMSc Torben Frøstrup Hansen

Co-funded by the European Union

Region of Southern Denmark
Lillebaelt Hospital

WP 10 – Tertiary prevention

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LEAD

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Senior Researcher, PhD
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Treatment completed
Scans normal
Blood tests normal
....but is the cancer really gone?

MISSION & VISION

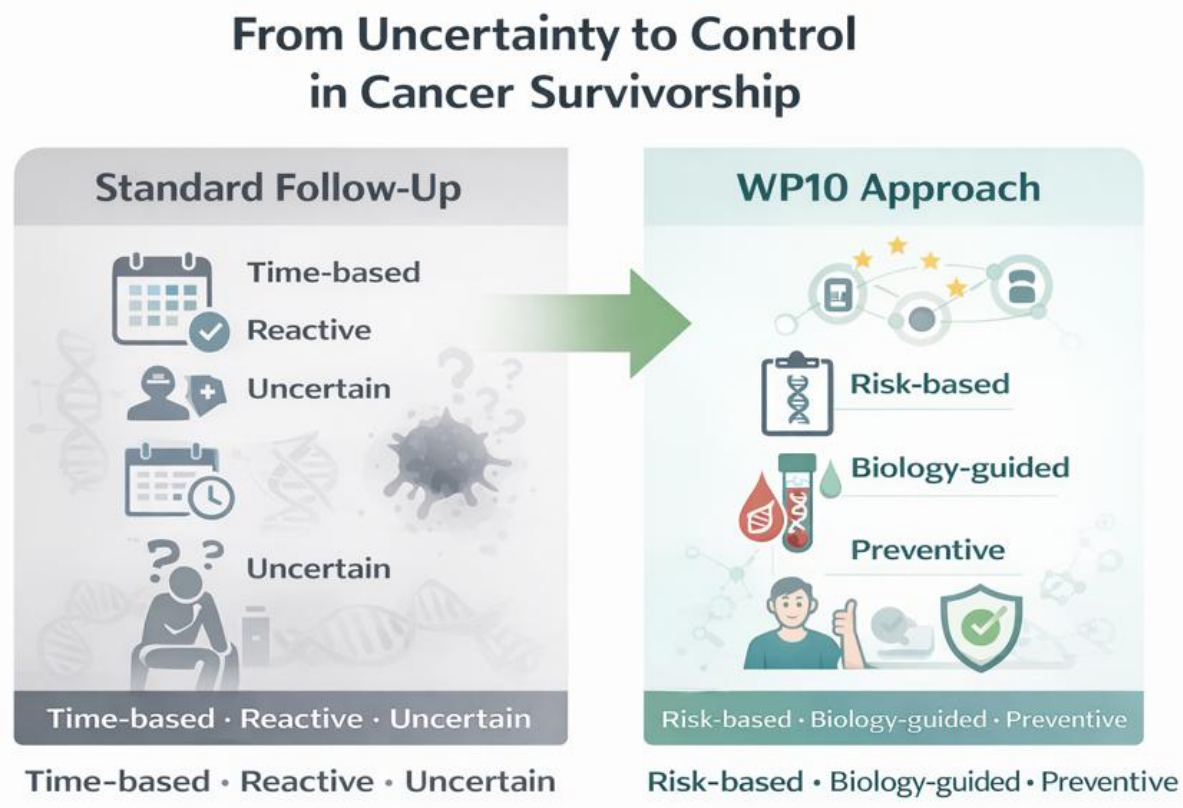
Vision of WP10

Better life. Longer survival. For every cancer survivor in Europe

Patient-centered, equitable, sustainable

Mission of WP 10

- **Personalize follow-up**
- **Detect earlier**
- **Support survivorship**
- **Enable systems**



OBJECTIVES – from care to control

WORKPLAN

Task 10.2 – pilot
Implementation of LB guided recurrence surveillance

A transnational pilot focousing on implemen-tation of personalised LB based risk stratified recurrence surveillance

Task 10.1
State of play for tertiary prevention in PCM

- Task 10.1.1
  Mapping the implementation of LB and MRD in tertiary prevention
- Task 10.1.2
  Analysing barriers to the integration of LB and MRD info clinical routines
- Task 10.1.3
  Patient-centered health care pathways for LB, MRD and tertiary disease
- Task 10.1.4
  Framework development for evidence synthesis and policy recommendations

Task 10.3
Empowering Survivors: integrating Long-term Care and Holistic Stategies

- Task 10.3.1
  Patient-focused interventions
- Task 10.3.2
  Enhancing equity and access
- Task 10.3.3
  Collaborative Care modelsd
- Task 10.3.4
  Practical guidelines and capacity building

PARTICIPANTS

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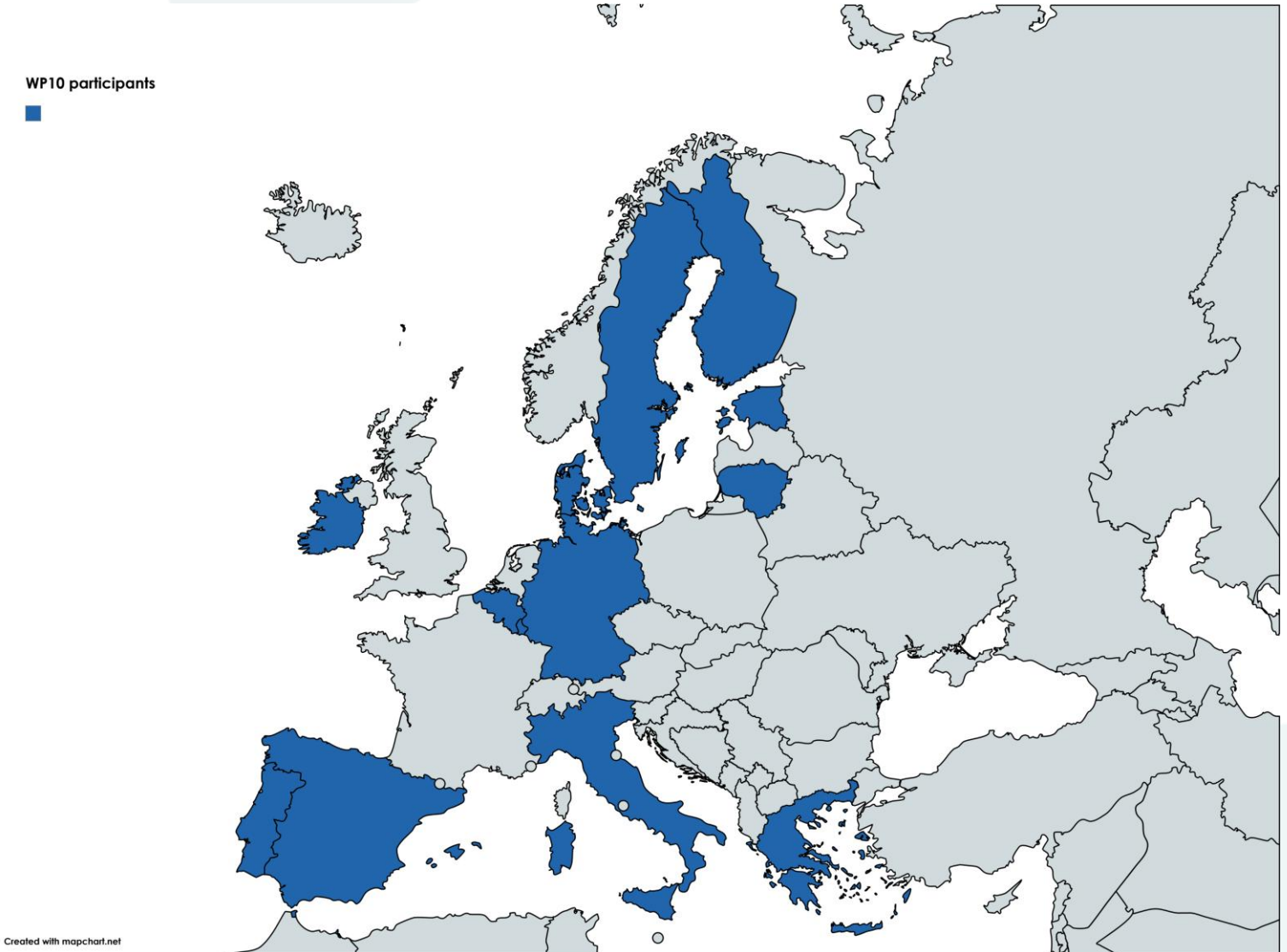

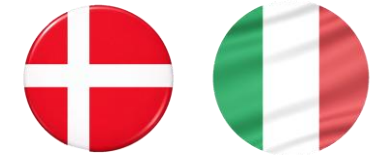

WORKPLAN

MILESTONE 36	Assessment report and gap analysis completed	M6
MILESTONE 37	Initial results of clinical testing and draft collaborative care model framework	M24
MILESTONE 38	Prototypes of Patient Decision Aids (PtDAs)	M24
MILESTONE 39	Care Model and Policy Deliverables	M36
DELIVERABLE 10.1	Policy recommendations and training toolkit developed	M48

WORKPLAN - methods

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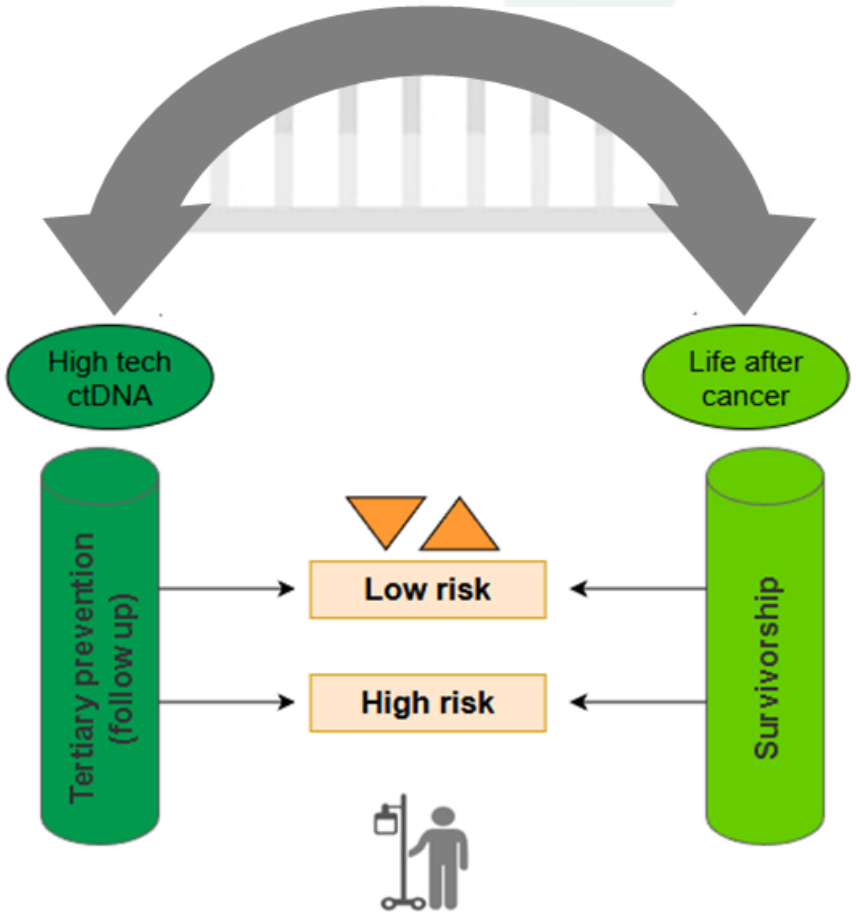
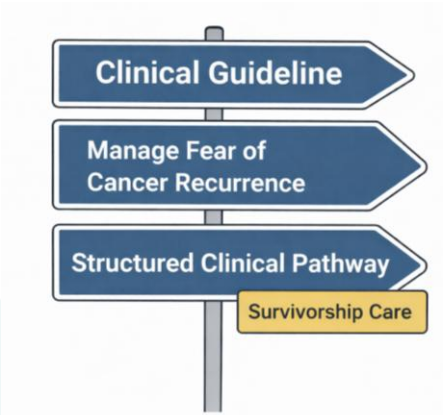


REDCap
Research Electronic Data Capture

iConquer Fear

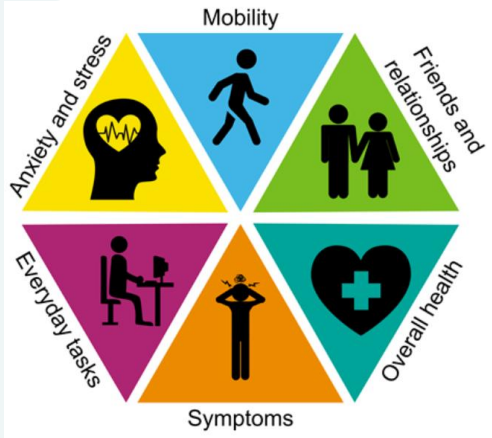


EXPECTED OUTCOMES

1. **Ready-to-use guidance**
   Practical EU-level guidelines for personalized survivorship care

2. **Implementation framework**
   Scalable framework for tertiary prevention, including liquid biopsies

3. **Measurable impact**
   Earlier recurrence detection • Smarter follow-up • Improved survivorship



KEY IMPACTS ON STAKEHOLDERS

Clinicians & researchers
Tools to deliver personalised, biology-guided follow-up

Policymakers
Evidence for equitable, cost-effective implementation

Patients & citizens
Better quality of life through personalised survivorship care

Across Europe • Across healthcare systems

NEXT STEPS

STEP 1	Include outcome after kick-off	Q1
STEP 2	Set up task specific calls	Q1
STEP 3	Ensure governance structure	Q1
STEP 4	Internal report I completed Assessment report and gap analysis	Q2
STEP 5	Detailed description	Q2-3

Conclusion

- **Survivorship is not “safe” by default**
- **Tertiary prevention must become personalized**
- **WP10 will provide an EU-scalable framework**

WP10 turns survivorship from passive follow-up into active prevention across Europe

Contact

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THE JA PCM KICK-OFF MEETING

14-15 January 2026

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9:30 - 10:10 Session ARM3: Personalised follow-up and tertiary prevention

Introduction ARM3 lead
Claus Lindbjerg Andersen, Aarhus University (DK)

WP9: Digital innovation for improving survivorship care delivery
Maria Alice Borinelli-Franzoi, Institut Gustave Roussy (FR)

WP10: Tertiary Prevention
Torben Hansen, The Region of Southern Denmark (DK)

10:10 - 11:10 Session Pilots ARM1 & ARM3

WP9: Digital tools for remote monitoring need assessment, self-management and supportive care
Maria Alice Borinelli-Franzoi, Institut Gustave Roussy (FR)

WP5: Risk-Informed Prevention (PARI)
Stefania Boccia, Fondazione Policlinico Gemelli (IT)

WP6: Polygenic Risk Score (PRS)
Jeroen van Rooij (TBC), Erasmus Medical Centre (NL)

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WP9 Pilot Study

Advancing Digital Survivorship Care Delivery

Maria Alice Franzoi, MD, PhD

Medical Oncologist

Medical Oncology Department / Cancer Survivorship Group

Gustave Roussy, Villejuif, France

Co-funded by the European Union

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sciensano

WP9 Pilot: Advancing Digital Survivorship Care Delivery

JA PCM
Joint Action Personalised Cancer Medicine

Gustave Roussy

Maria Alice Franzoi
Medical Oncologist
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Sarah Ball
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Ines Vaz Luis
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Siensano

Régine Kiasuwa Mbengi
Head of Supportive Care
Siensano

Marie Lamberigts
Postdoctoral Researcher
Siensano

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The Rising Tide of Innovation:

- Increased nb. of tools for remote monitoring; supportive care delivery; patient empowerment and self-management
- Evidence being built in RCTs (high income countries and high resource centers)

The Implementation Lag:

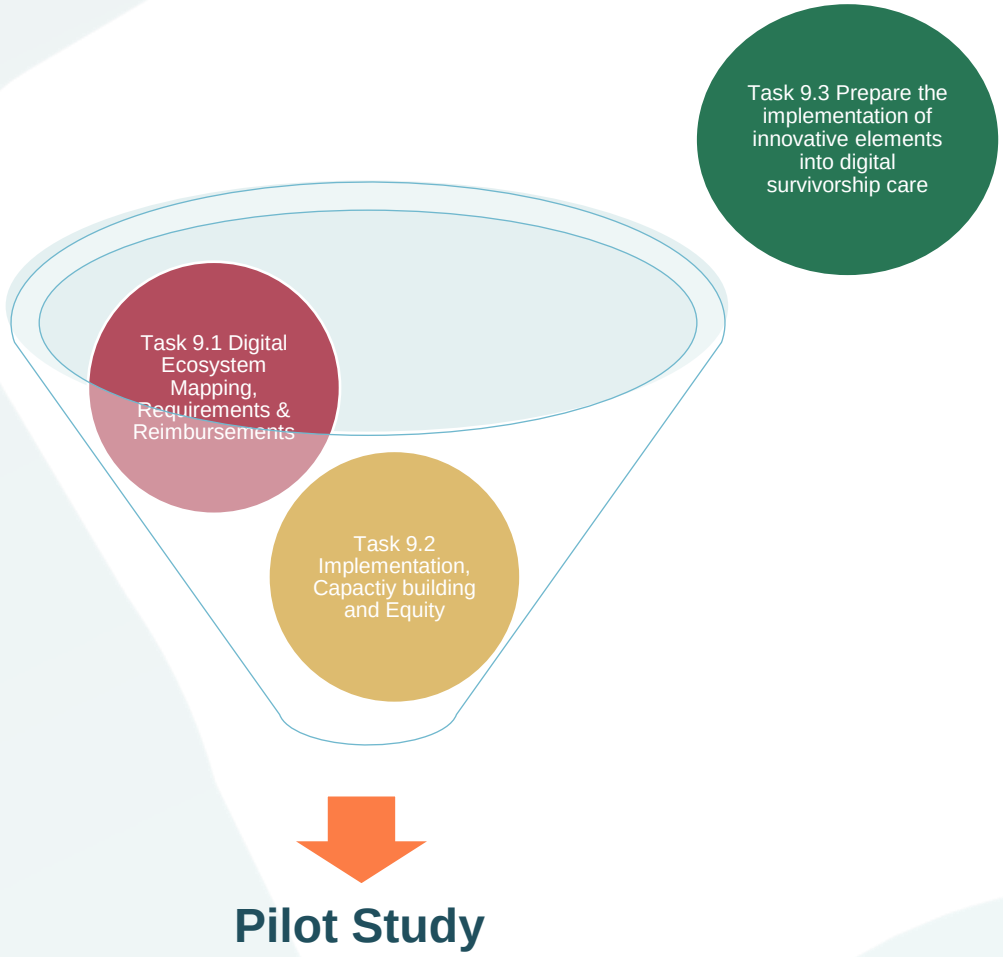
- Practical implementation and rigorous evaluation of these technologies are lagging behind; specially among diverse centers
- Organisational Readiness varies (Skills Gap, Resistance to Change; Infrastructure)

MISSION & VISION

- The study aims to **pilot a personalized, multilevel and multidimentional implementation package to accelerate digital survivorship care** in diverse clinical centres across the EU MSs

- **OBJECTIVES**
  - Stratify participating centres by their existing survivorship infrastructure and digital health readiness and tailor the implementation package based on their needs.
  - Evaluate the impact of the personalized implementation package on:
    - improving center readiness (level I); successfully deploying digital tools (level II); improving equitable and sustainable digital tools (level III)
  - Illustrate the feasibility of integrating digital tools for survivorship care and its potential benefit in the quality of care provided.

WORKPLAN



Pilot Study

Pilot Intervention:

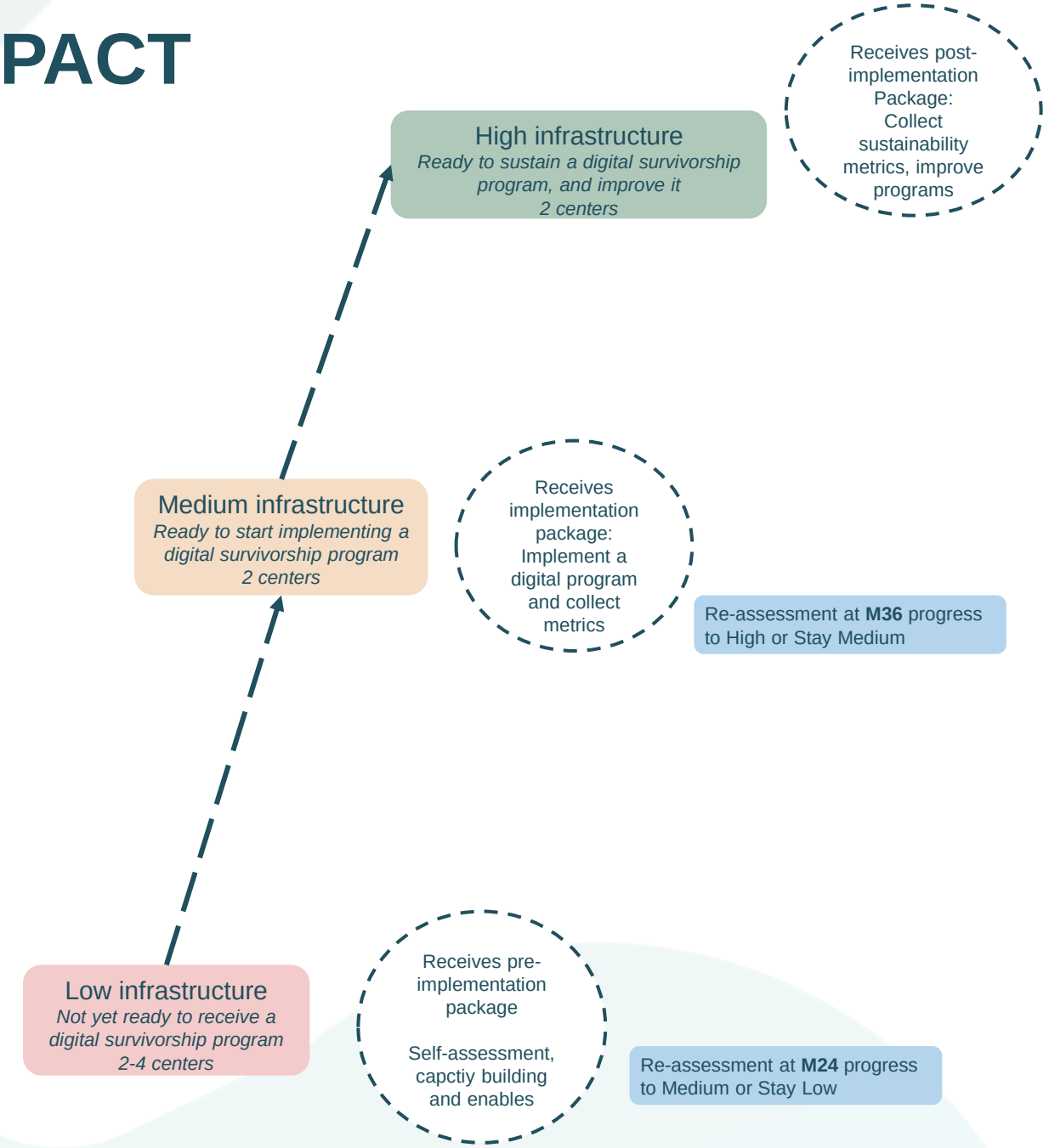
Three-phase personalized multilevel and multidimensional implementation package to advance digital survivorship care delivery in real-world clinical centers across Europe			
Phase	**Pre-Implementation phase**	**Implementation phase**	**Post-Implementation**
EPIS Dimension	Exploration/Preparation, *Objective: prepare organisations to adopt or develop a digital survivorship program*	Implementation *Objective: introduce and integrate new digital survivorship tools and workflows with at least 100 patients (pilot experience)*	Sustainability *Objective: sustain, refine, and enhance existing digital survivorship programs*
Timeline	M0-M24	M24-48	M36-M48
Participating Sites	Low/Middle resources sites (recipients) High resources sites (provide support)	Middle resources sites	High resources sites
Intervention Components	**Site self-assessment and Workflow analysis:** - Mapping current survivorship care delivery (gaps, resources, workflow) - Digital health readiness assessemnt - Survivorship workflow re-design by identified needs **Capacity building:** - Webinaires and exchange visits to centers experienced with digital survivorship care - Sharing documentation of established processes and best practices **Technology and regulatory Enablement** - Connecting sites with technology providers (based on mapping and requirements exercise) - Connecting sites with reimbursement/regulatory bodies - Identifying and supporting funding opportunities for cultural adaptation, tool customisation, and dedicated implementation staff	**Integration of digital tools into redesigned survivorship workflow** - Rollout of selected digital interventions (SCPs; PRO monitoring, referrals, digital supportive/ self-management tools) - Local adaptation and iterative problem solving with implementation leads - Research protocol approval and structured data collection	**Program Refinement and Monitoring** - Refining digital programs to enhance equity, diversity, engagement, and quality of care (by feeding sites with the results of task 9.1 and 9.2) - Ongoing collection of implementation and clinical metrics from established digital survivorship programs
Core Metrics	- Digital Health Readiness at M0 vs. M24 - Increased knowledge on digital survivorship opportunities and expected impact (M0 vs. M24) - Completion of redesigned survivorship workflow by M24 (including envisioned digital tools and resource requirements) - Establishment of partnerships with academic and industry collaborators (M0 vs. M24)	Reach: proportion and representativeness of survivors using the tool Effectiveness in quality of care indicators: - Symptom burden (based on selected domain) - Quality of Life (QLQC30, 5D5L) - Guideline concordant care & supportive care referrals (symptom triggered referrals captured in clinical records) - HCP workload (NASA Task load Index) Adoption: - By patients - By providers Implementation experience at patient, provider and organisation level (FG, key informative interviews) Maintenance: sustained use of the digital tool in routine practice, motivators and enablers to ongoing use after, progress toward reimbursement/financial pathways	RE-AIM metrics with explicit focus on equity and engagement Documentation of program adaptations and refinements proposed by each site

EXPECTED OUTCOMES & IMPACT

Improve quality, equity, and sustainability of digital cancer survivorship care across all centres

1. Empower lower-infrastructure centres through targeted capacity building and standardized support
2. Enable medium-infrastructure centres to effectively implement and evaluate digital survivorship programs
3. Support high-infrastructure centres to sustain, refine, and scale advanced digital solutions while sharing best practices for system-wide improvement

Improve patient's access to evidence-based digital health tools to advance comprehensive survivorship care delivery



PILOT SITE SELECTION: EXPRESSION OF INTEREST (EOI)

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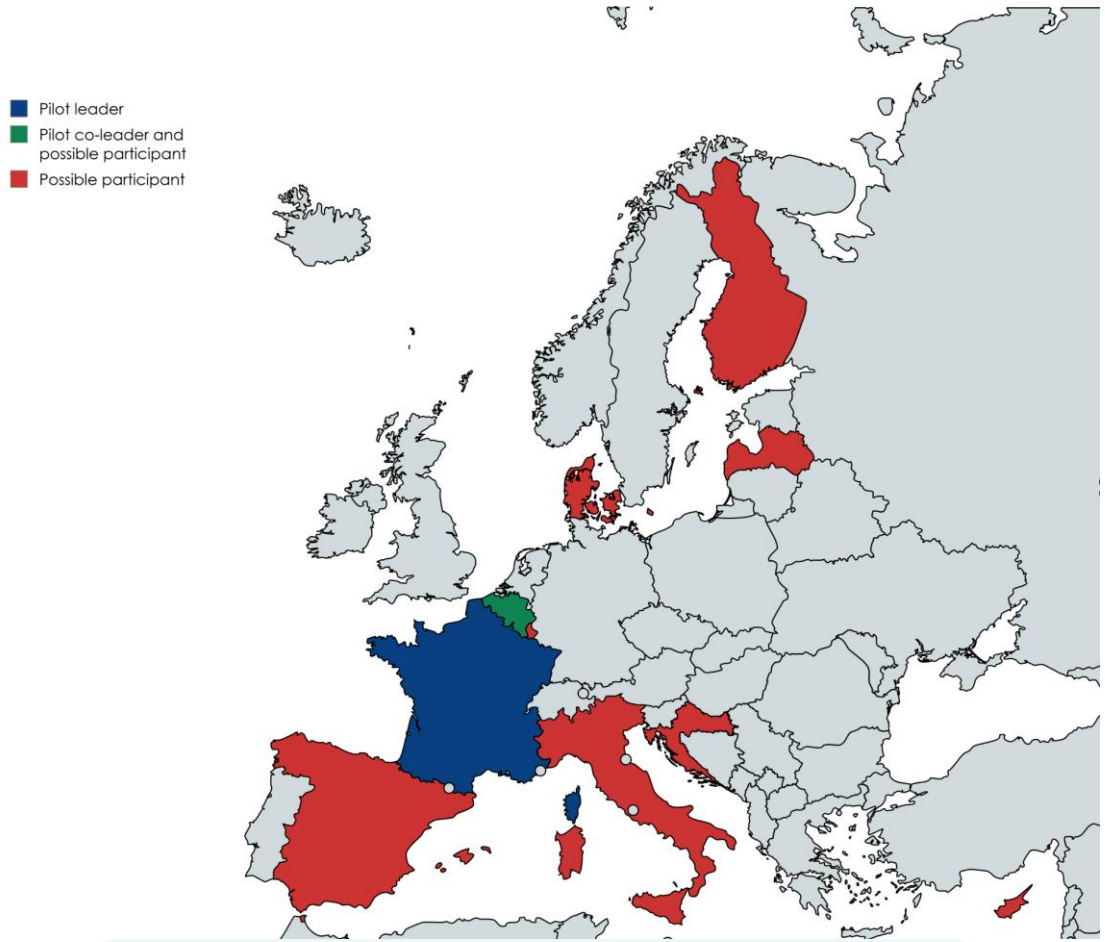
Pilot lead:
Gustave Roussy (Villejuif, France)

Pilot Co-lead:
Sciensano (Brussels, Belgium)

Possible centres as participants:

- Total Institut of Research in Biomedicine (Barcelona, Spain)
- Bank of Cyprus Oncology Centre (Cyprus)
- Aarhus University Hospital (Aarhus, Denmark)
- University of Southern Denmark (Vejle, Denmark)
- Faculty of Movement and Rehabilitation Sciences (Leuven, Belgium)
- Pauls Stradiņš Clinical University Hospital. Riga Stradins (Riga, Latvia)
- Centro Nacional de Investigaciones Oncológicas (CNIO), (Madrid, Spai
- IRCCS Regina Elena National Cancer Institute (Rome, Italy)
- Sestre Milosrdnice University Hospital Center (Zagreb, Croatia)
- Galician health service (Santiago de Compostela, Spain)
- FICAN, Finnish National Coordinating Cancer Center (Helsinki, Finland)
- Centre Hospitalier Emile Mayrisch (Esch an der Alzette, Luxembourg)



PILOT SITE SELECTION: RATIONALE FOR SITE STRATIFICATION

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A survey (RedCap) is being produced and will be sent to all centers who expressed interest:

Selected centers will be invited to repeat the assessment at M24

1) Baseline eREADY[1] assessment for digital health readiness

- Conditions for change at the workplace
- Individual conditions for change
- Perceived support and engagement among management
- Readiness among colleagues
- Perceived consequences on status quo
- Workplace attitudes

2) Status of Current Survivorship Care Delivery Practice (Components of the Quality of Care Framework[2] + Distress Termometer NCCN[3])

- Follow-up Care and Prevention of Recurrence (Y vs. No / Digital delivery)
- Management of physical side effects of treatment (Y vs. No / Digital delivery)
- Management of emotional and social side effects of treatment (Y vs. No / Digital delivery)
- Health behaviours and Health Promotion (Y vs. No / Digital delivery)
- Management of comorbidities (Y vs. No / Digital delivery)

Low infrastructure: 0-1 components; Medium infrastructure: 2-3 components; High infrastructure: 4-5 components

All centers that express interest participate in the publication

1- Danapffel. P; JMIR 2022;; 2- Nekhlyudov L JNCI 2019;
3- https://www.nccn.org/docs/default-source/patient-resources/nccn_distress_thermometer

NEXT STEPS

STEP 1	Regulatory approval for survey	Jan/2025
STEP 2	Finalize and distribute survey	Feb/2025
STEP 3	Stratify centres and final selection	Feb/2025
STEP 4	Validate budget for site participation (according to category)	Feb/2025
STEP 5	Start delivering first capacity building actions coordinated with advances on task 9.1 and 9.2	Oct/2026

Conclusion

- The pilot study will test in real-time the results produced in WP9 Tasks 9.1 (Digital Ecosystem Mapping, Requirements & Reimbursement) and 9.2 (Implementation, Capacity Building & Equity)

- The three-phase, personalized, implementation package is tailored to different levels of cente readiness

- Pilot outcomes:

  Advance readiness for low-infrastructure centers (eReady and Survivorship care delivery survey at M24)

  Perform an implementing study for a digital health pathway for survivorship care in at least 100 patients for medium infrastructure centers (Reach, Effectiveness, Adoption, Implementation, Maintenance)

  Enhance existing digital health pathways to advance equity and sustaibanility among high infrastructure centers

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Pilot WP5

PARI - Pathway, Access and Implementation of Risk-Informed cancer prevention across Europe

Suzette Delaloge / Maud Kamal

PARI

GUSTAVE ROUSSY
CANCER CAMPUS
GRAND PARIS

INTERCEPTION
GUSTAVE ROUSSY
Le programme de prévention personnalisée des cancers

Co-funded by the European Union

PARI - Pathway, Access and Implementation of Risk-Informed cancer prevention across Europe

JA PCM
Joint Action Personalised Cancer Medicine

Suzette Delaloge

Gustave Roussy, Fr

Marjanka Schmidt

NKI, Amsterdam, NL

Maud Kamal

Lucie Veron

Precision prevention has demonstrated benefits in various situations, including genetically-defined, exposome-related or mixed high risk contexts.

However, 2 key issues are:

1. how to allow the large-scale, equitable delivery of the **identification of individuals at relevant high risk** of cancer
2. How to guarantee the subsequent **access** of high risk individuals to **relevant clinical pathways and delivery of prevention intervention**

MISSION & VISION

This pilot will assess the preliminary feasibility of large-scale risk-informed cancer prevention in the general population through an international prospective cohort study.

The teams involved in this pilot have high, moderate or limited experience in such population-based risk identification.

This pilot study will test 3 different settings for high risk identification, across several countries, aiming at identifying the most efficient strategies at regional or national levels and allowing future broader implementation.

OBJECTIVES

1. Assess **the feasibility, acceptalitity, success, equity, preparedness, PROs and costs** of the implementation of a **population-based identification of individuals at high risk** of several cancers as per current guidelines, in different settings
2. Assess the feasibility, acceptalitity, success, equity and costs of **delivering a personalised prevention information and counselling to the individuals** identified at high risk of several cancers

WORKPLAN

Primary care practice

Systematic proposal of a personalised cancer risk assessment to persons aged 40-75

Screening coordination centers or national insurance system

Systematic invitation to a personalised cancer risk assessment to persons aged 40-75

Tertiary care structures

Systematic invitation to a personalised cancer risk assessment to first degree relatives of cancer patients (aged 40-75)

Pillar 1 → **Personalized risk assessment for frequent cancers** including breast, lung, colorectal, prostate, pancreas, endometrium, ovary and others using a unique online tool

No high-risk of cancer

Pursue standard screening and risk reduction measures

High risk of cancer

Pillar 2 → Specialised cancer prevention counselling delivery (primarily virtual)

Implementation of a personalised cancer early detection and risk reduction programme

WORKPLAN

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Pillar I: **This part will test the ability to deliver a large-scale population-based identification of individuals as high risk of various relevant cancers** in different settings. Its aim is to assess if, and how best (across various settings and contexts), can a systematic identification of individuals at high risk of **breast, colorectal, lung**, **prostate, pancreatic, endometrial, ovarian and other cancers** be conducted within the general population.
The population-based identification will be done using shared validated algorithms and digital tools and **3 strategic settings: i. primary care ii. Cancer screening coordinating centers or national insurance system iii. Tertiary care targeting first degree relatives of patients attending**

Pillar 2: **Assesses the ability to deliver personalized risk-based (and evidence-based) management care**. Common evidence-based cancer prevention protocols will be agreed within the consortium. Their implementation will at best use a common digital pathway and remote webinars + telemedicine built by the participating experts and teams.

EXPECTED OUTCOMES & IMPACT

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Expected outcomes:

- Demonstrate the feasibility of large scale, population-based cancer risk assessment in general populations in countries with different readiness regarding precision prevention
- Provide the EC with robust data regarding the feasibility, implementability, equity, costs, of the proposed digital prevention intervention
- Provide data on the most appropriate setting to deliver this care, by country and context

Key Impacts on Stakeholders

- Healthcare professionals & researchers : Capacity building, training, and knowledge transfer on risk-based personalised prevention of major cancers
- Healthcare policymakers: strong data enabling decision making regarding the implementation of personalised prevention of major cancers
- Cancer patients – Citizens: access to and implementation of personalised prevention of several cancers

EXPRESSION OF INTEREST (EOI)

Country	Region	Institutions	Role (Partern/ site)
Denmark	Southern DK	Lillebaelt hospital	clinical investigation
Finland	Helsinki	HUS Helsinki University Hospital	clinical investigation
Latvia	Riga	RSU (Riga Stradins University)	clinical investigation
Latvia	Riga	Paul Stradin clinical University	clinical investigation
Ireland	Dublin	RCSI	General practice. Delivery and evaluation of population-based risk assessment in general practice settings; Capacity-building and training activities for healthcare professionals;
Italy	Bologna	IRCSS	clinical investigation and conceptualisation
Bosnia Herzegovina		University Clinical Hospital Mostar	addressing cancer prevention challenges
France	Lyon	CLB	investigation
Sweden	Stockholm	Karolinska Instiutet	investigation
Sweden	Stockholm	Karolinska University Hospital	investigation
Portugal	Porto		observer

Strategy to select participating partners for the investigation: study feasibility (M2)

NEXT STEPS

Next immediate steps and timelines for year 1

STEP 1	Final selection of participating countries	M1-2
STEP 2	Set up of trial's steering committee	M3
STEP 3	Protocol writing and submissions	M0-M8
STEP 4	Preparation of trial materials	M0-M12
STEP 5	Aproval and launch of trial	M12

NEXT STEPS

Longer term

STEP 1	Writin, submissions and aproval of the clinical trial	M0-M12
STEP 2	Trial inclusions	M12-M18
STEP 3	Trial interventions	M12-M30
STEP 4	Full analysis of outcomes	M40
STEP 5	Publication and report	M42

Conclusion

- PARI is important and timely
- It will complement the knowledge of, and feed WP5
- The study will be co-constructed with the full set of partners constituting its steering committee, and invstigation will take place in 3-5 of these countries
- PARI should allow us to assess the feasibility of large-scale risk-informed cancer prevention in the general population across relevant countries from the EU

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PILOT/USE CASE 6

Polygenic Risk Scores

Jeroen van Rooij / Marjanka Schmidt

Co-funded by the European Union

Erasmus MC

NETHERLANDS CANCER INSTITUTE
ANTONI VAN LEEUWENHOEK

Polygenic Risk Scores

JA PCM
Joint Action Personalised Cancer Medicine

Jeroen van Rooij

Erasmus MC, NL

Assistant Professor

Genetic Epidemiology

Marjanka Schmidt

Netherlands Cancer Institute, NL

Professor

Cancer Epidemiology

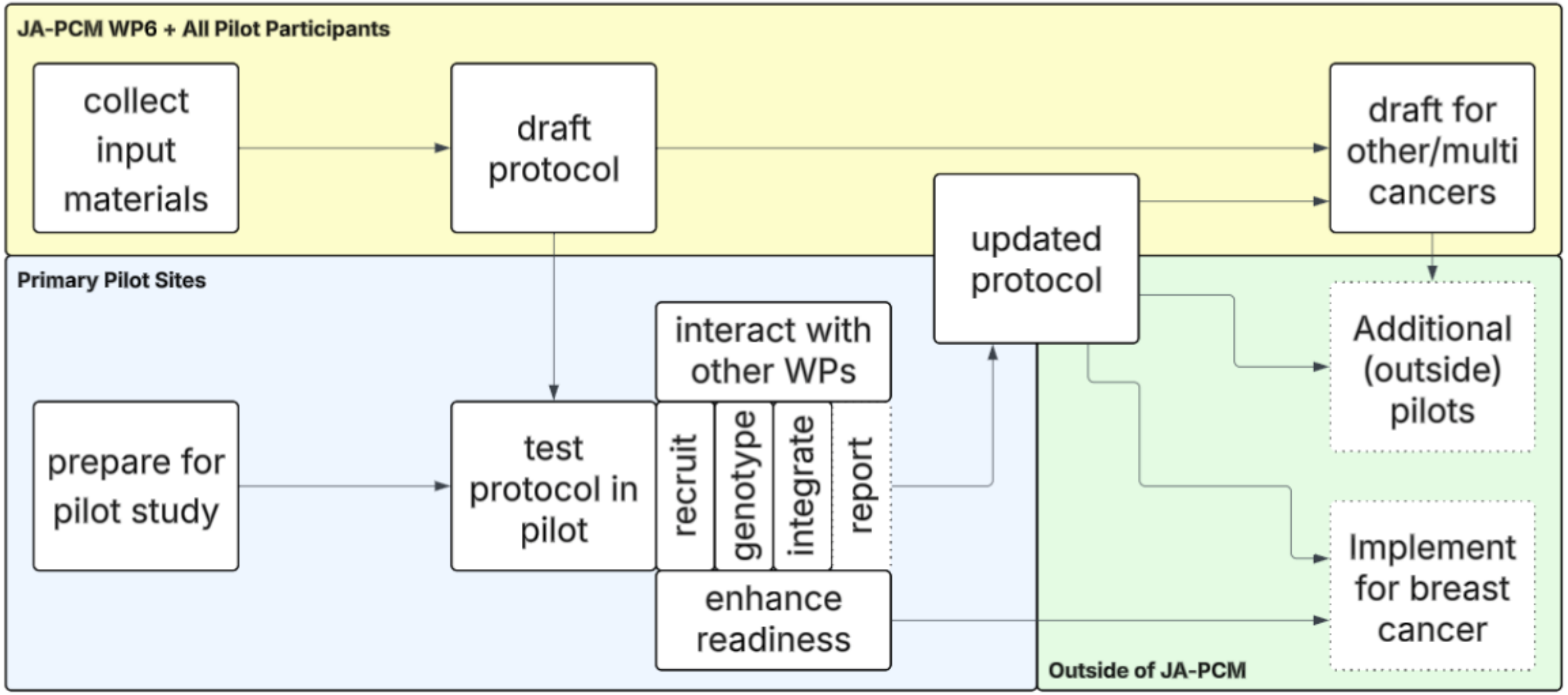
Polygenic scores can help personalize screening of common cancers.

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

MISSION & VISION

- **OBJECTIVES**
  - Write a joint protocol of breast cancer PRS implementation (using CanRisk)
  - Pilot this joint protocol in real-life setting (focused on breast cancer)
  - Provide guidance on implementation of this CanRisk + PRS protocol
  - Provide guidance on how to develop such a protocol for other cancers, other implementation settings or populations, or other models (such as multi-cancer early detection)

WORKPLAN (overall)



WORKPLAN (pilot studies)

- **Planned intervention:** calculate and integrate the PRS (most likely PRS-313) in breast cancer risk assessment and subsequent breast cancer screening advice

- **Target population:** at least 100 healthy adult female relatives of breast cancer patients, undergoing CanRisk assessment to guide population screening advice

- **Relevant inclusion/exclusion criteria:** intermediate risk families, such as those carrying a CHEK2 pathogenic variant or with strong family history, but no known pathogenic variant identified. Excluding BRCA1/2.

- **Duration of the pilot:** time needed to include 100 women between 1-1-2027 and 31-12-2028

Details of the pilot are pending further discussion.

EXPECTED OUTCOMES & IMPACT

Expected outcomes:

- Tested protocol that could be adopted for breast cancer in piloting institutes
- Tested protocol that could be adapted for breast cancer into other institutes
- Draft protocol that could be adapted to other cancer types
- Draft protocol that could be adapted to other implementation settings (e.g., directly into screening, multicancer early detection, integrated tests)
- Broad input onto implementation requirements to other WPs (ethics, HTA, communication, education, etc.)

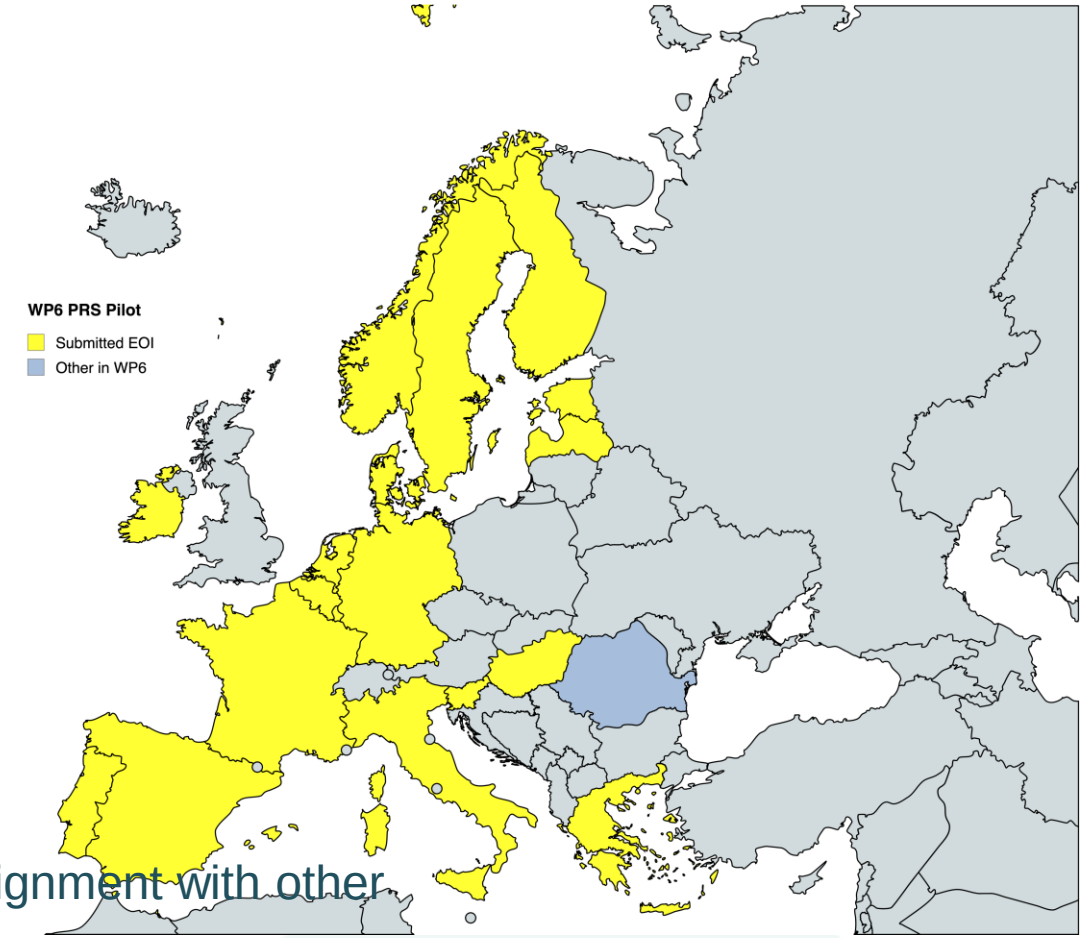
Key Impacts on Stakeholders

- Healthcare professionals & researchers : Shared and tested approach for PRS implementation
- Healthcare policymakers: Collected evidence and resources to populate decion-making models
- Women from cancer families, Cancer patients, Citizens: outlook on improved screening

EXPRESSION OF INTEREST (EOI)

Overview of the EOI exercise :

- Total number of EOI received : 50
- Number of countries : 18
- Number of institutions : 50



Pilot roles

	Role definition
Partner	Provide input on the pilot protocol and other relevant materials. All institutes can be partners, but the aim is to collect institutes that could put the PRS protocol into practice when it is completed.
Site	3 or 4 countries will be asked to test the PRS protocol in their implementation site(s). These should be countries close to implementing PRS, with (most of) the required infrastructure available. Returning the PRS results to participants is not mandatory. We ask for at least 100 participants tested per country, and feedback on the implementation protocol.

Strategy for primary site selection

- Setting up a survey to ask for readiness, costs, and alignment with other national/regional activities.
- Select countries with high readiness to implement CanRisk with the PRS, able to test out the protocol, preferable at not too high costs.

NEXT STEPS (YEAR 1)

STEP 1	Complete Survey & Pick sites	January/February
STEP 2	Work out detailed budget of pilot	February/March
STEP 3	Set draft protocol & collect input	March/June
STEP 4	Complete draft protocol	July/August
STEP 5	Initiate pilot preparations per site	May/Nov
STEP 6	Begin with pilots	Year 2

Conclusion

- Want to work towards harmonized PRS implementation protocol
- Start with breast cancer in CanRisk, expand to other cancers later
- Subset of partners will validate pilot protocol

Contact

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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

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11:50 – 12:30 Session Transversal Pilots

T1 CPS Compass: Personalised management of cancer predisposition across the patient journey
Anke Bergmann & Matt McCrary, University Hospital Würzburg / University Würzburg (DE)

T2 LB-ctDNA: Implementation of of ctDNA guided decision-making across the patient journey
Remond Fijneman, Stichting Het Nederlands Kanker Instituut - Antoni van Leeuwenhoek Ziekenhuis (NL)
Claus Lindbjerg Andersen, Aarhus University Hospital (DK)

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JA PCM KICK-OFF

14/15 JANUARY 2026

Pilot T1

CPS Compass:
Personalised management of cancer predisposition across the patient journey

J. Matt McCrary, PhD

Prof. Dr. med. Anke Bergmann

Uniklinikum Würzburg

Co-funded by the European Union

CPS Compass Pilot

JA PCM
Joint Action Personalised Cancer Medicine

Lead – University Hospital Würzburg

R to L: *Prof. Anke Bergmann; Dr. J. Matt McCrary; Marie Schnürer; Dr. Nele Loecher; Annalisa Musola*

Co-lead – Sciensano

Prof. Hélène Antoine-Poirel

Dr. Maria Valeria Freire Chadrina

Context

Realizing the promise of personalised cancer prevention and care requires:

1) Efficient identification of germline cancer predisposition syndromes (CPS)
2) Broad access to timely genetic counselling

Context

Realizing the promise of personalized cancer prevention and care requires:

1) Efficient identification of germline cancer predisposition syndromes (CPS)

Paediatric ALL use case – likely missing many cases of CPS using phenotype / screening first approach

2) Broad access to timely genetic counselling

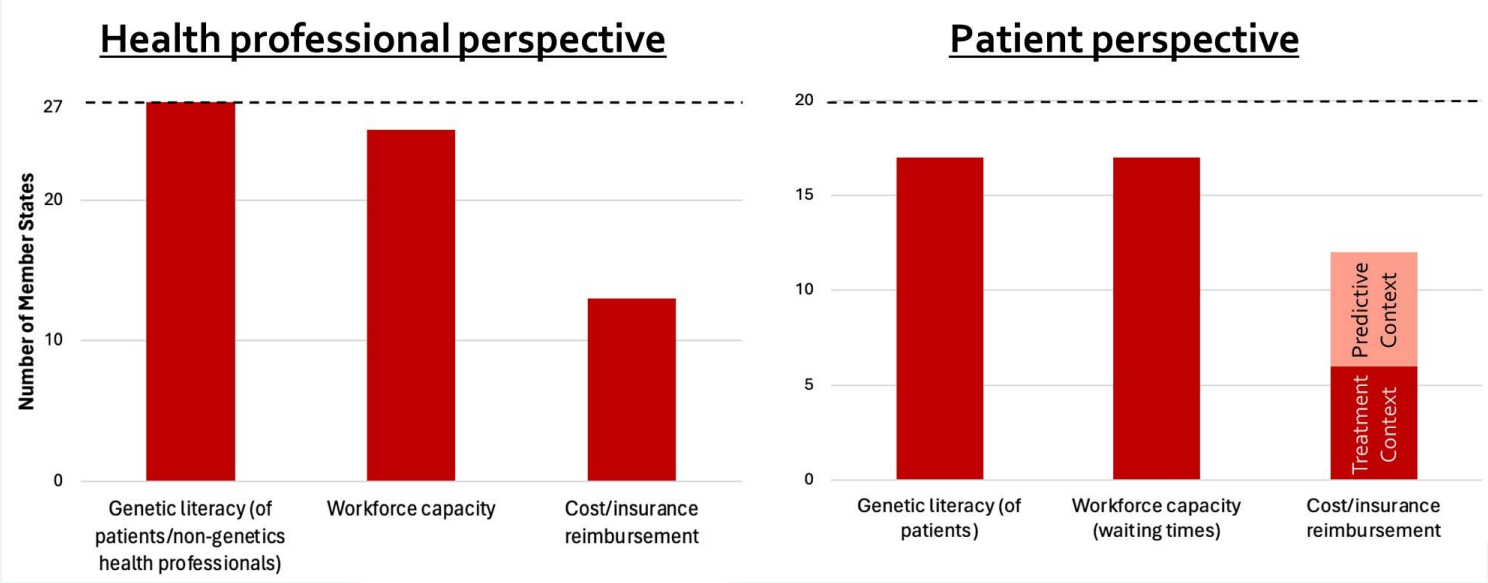
Context

Realizing the promise of personalized cancer prevention and care requires:

1) Efficient identification of germline cancer predisposition syndromes (CPS)

2) Broad access to timely genetic counselling

Common European barriers to genetic counselling access



Context

Realizing the promise of personalized cancer prevention and care requires:

1) Efficient identification of germline cancer predisposition syndromes (CPS)
2) Broad access to timely genetic counselling

Five Priority European Actions for addressing common European barriers to timely genetic counselling access

MISSION & VISION

MISSION

- Build capacity for efficient cancer predisposition syndrome (CPS) diagnostics & access to timely genetic counselling to expand possibilities for personalized prevention / treatment / survivorship management

OBJECTIVES

1. Evaluate the feasibility and cost-effectiveness of a genotype-first approach to CPS diagnostics performed at diagnosis

2. Address barriers to timely genetic counselling access by piloting implementation of CAN.HEAL recommended ‘Priority Actions’

WORKPLAN

Objective 1 – **CPS Diagnostics**

- ***Planned intervention***: Implementation of genotype-first CPS diagnostics performed at diagnosis in N=50 patients per Primary Site
  - *Evaluation of**:** Diagnostic timeframes; Usability; Patient psychological impact, Costs per patient; Barriers*

- ***Target population***: Paediatric and AYA cancer patients (age 39 or below)
- ***Relevant inclusion/exclusion criteria***: To be defined based on expected patient load at Primary sites
- ***Duration of the pilot***: 2 years

WORKPLAN

Objective 2 – Genetic counselling

- ***Planned activities***:
  1) Develop and pilot new strategies for ensuring inclusion of genetics expertise in oncology guideline development/updates --> **literacy barriers**
  2) Develop and pilot new strategies for increased genetic counsellor recognition / integration within EU genetics workforce --> **capacity barriers**
  3) Quantify the long-term cost-effectiveness of remote & in-person expert counselling --> **reimbursement barriers**

- ***Target population***: TBD
- ***Relevant inclusion/exclusion criteria***: TBD
- ***Duration of the pilot***: 3 years

EXPECTED OUTCOMES & IMPACT

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Expected outcomes

- Detailed insights into implementation barriers/facilitators & reimbursement potential of genotype-first approach to CPS diagnostics (*at diagnosis*)
- Enhanced capacity (*literacy, workforce, reimbursement possibilities*) to deliver timely genetic counselling across all phases

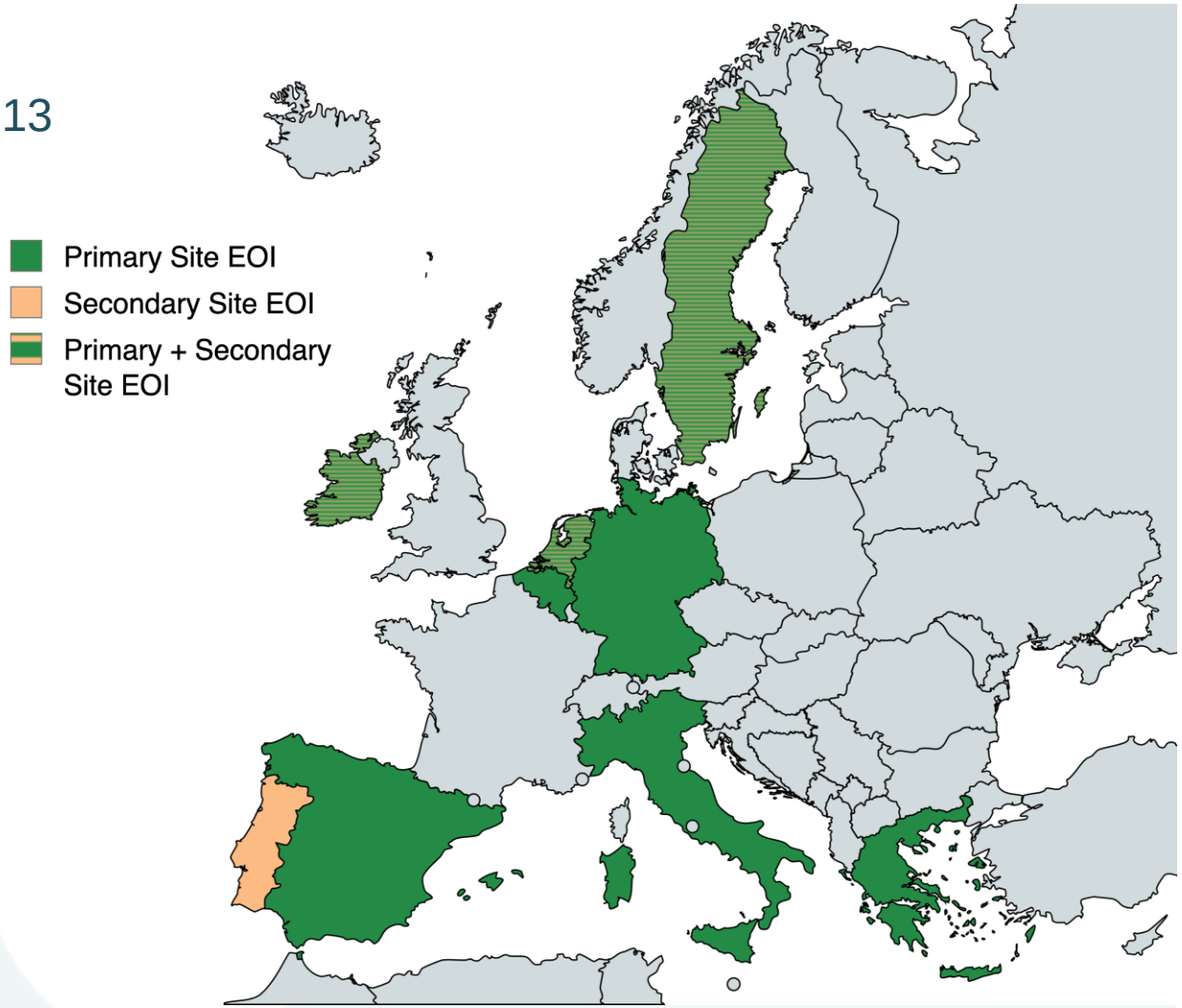
Key Impacts on Stakeholders

- ***Healthcare professionals & researchers***: Improved possibilities for reimbursement of WGS at diagnosis and (remote) genetic counselling across all phases
- ***Healthcare policymakers***: New, tested strategies for increased integration of genetics experts into oncology guidelines + genetic counsellors into health workforces
- ***Cancer patients – Citizens***: Improved access to timely genetic counselling across all phases; CPS diagnostic strategy sensitive to psychological impact

EXPRESSION OF INTEREST (EOI)

Overview of the EOI exercise:

- Total number of EOI received: 13
- Number of countries: 9
- Number of institutions: 13



EXPRESSION OF INTEREST (EOI)

Overview of the EOI exercise:

- Total number of EOI received: 13
- Number of countries: 9
- Number of institutions: 13

Pilot roles

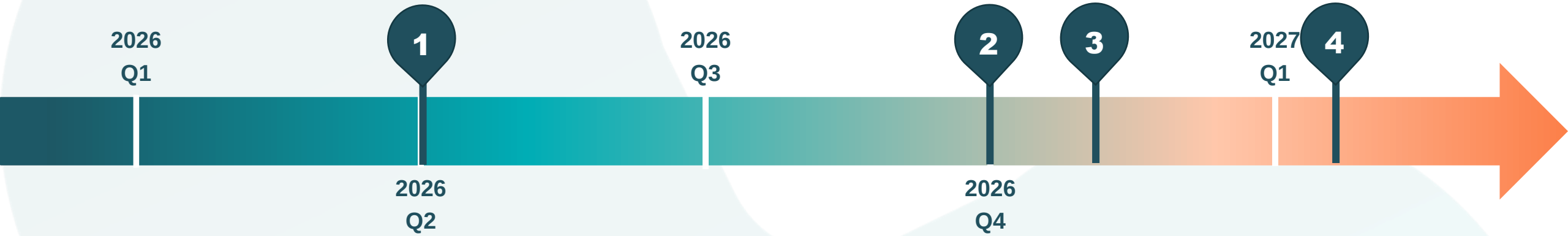
- *Primary site*: Pilot implementation of genotype-first diagnostic approach + feasibility/cost effectiveness data collection; Health economics analyses
- *Partner/Observer*: Contribute to development and pilot implementation of genetic counselling strategies (*guidelines* + *workforce*)

Strategy for primary site selection

- One per country
- *If needed*, survey regarding implementation readiness → mix of advanced / less advanced countries

NEXT STEPS

STEP 1	Ethics application(s) submission	**Date** April 2026
STEP 2	Secure industry funding	**Date** October 2026
STEP 3	Complete mapping exercises/health economic analysis planning	**Date** November 2026
STEP 4	Start implementation phase + primary data collection	**Date** January 2027



Conclusion

- Realizing the promise of personalized cancer prevention and care requires efficient identification of cancer predisposition syndromes (CPS) + broad access to timely genetic counselling across all phases.

- CAN.HEAL identified prospective advantages of a genotype-first CPS diagnostic approach + key actions for addressing barriers to genetic counselling access.

- CPS Compass (JA PCM) pilots the feasibility & cost-effectiveness of implementing a genotype-first approach at diagnosis + three key actions for increasing genetic counselling access across all phases.

Contact

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14/15 JANUARY 2026

PILOT T2: LB-ctDNA

Implementation of ctDNA guided decision-making across the patient journey

Remond Fijneman & Claus Andersen

Co-funded by the European Union

NETHERLANDS CANCER INSTITUTE
ANTONI VAN LEEUWENHOEK

AARHUS UNIVERSITY HOSPITAL

Implementation of ctDNA-guided decision-making across the patient journey

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LEADS

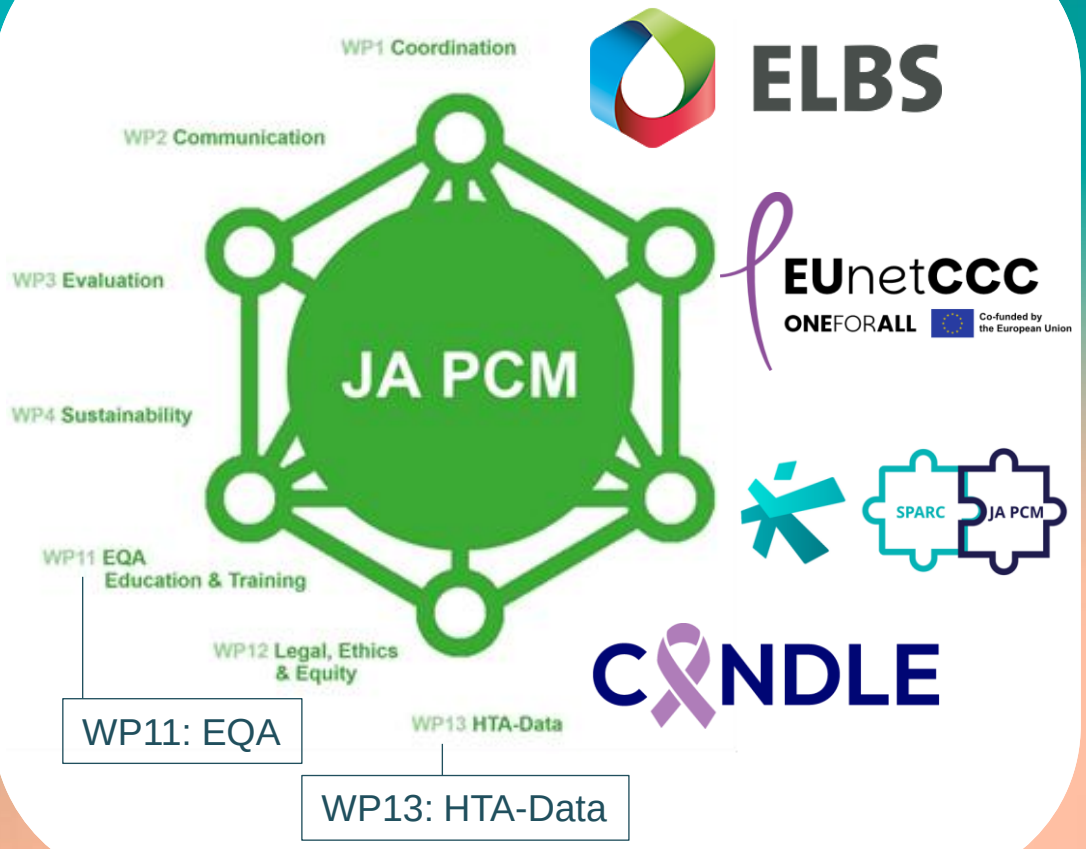
Remond Fijneman (NKI, NL)

Connected to Arm 2 (WP7)

Claus Andersen (AUH, DK)

Connected to Arm 3 (WP10)

PARTNERS



ctDNA molecular diagnostics =>

better diagnostics =>

better surveillance, better treatment =>

More cure and better care for patients with cancer

=> implement ctDNA-guided decision-making

MISSION & VISION

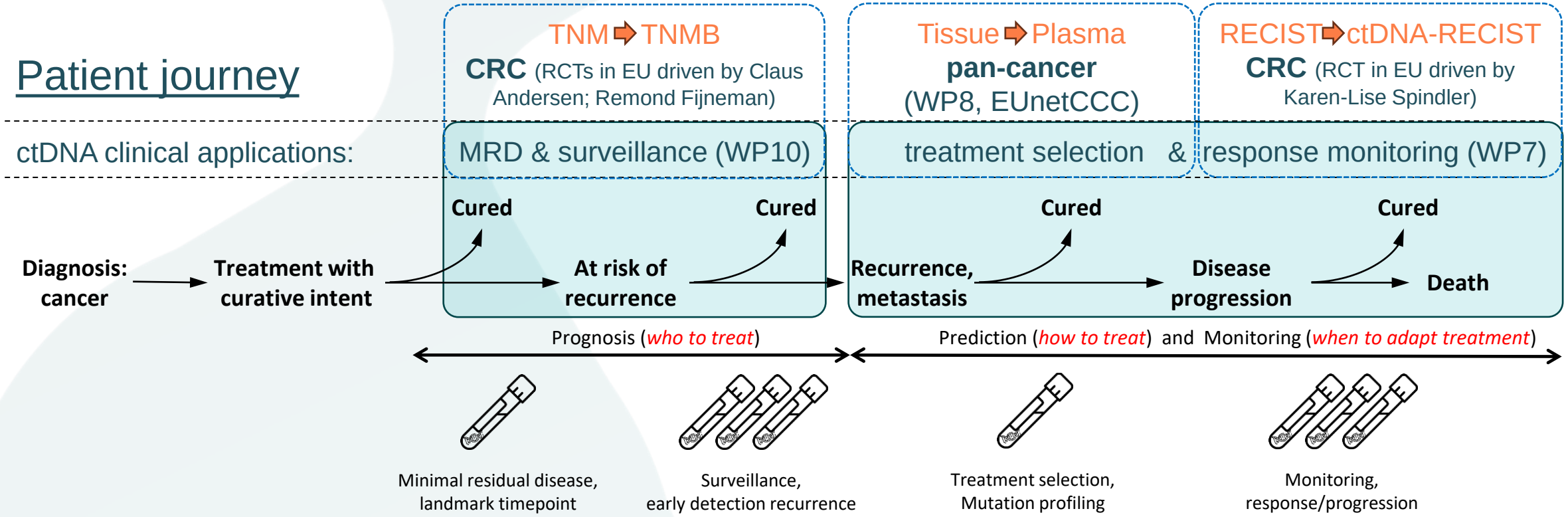
- **Extend access to and knowledge of liquid biopsy ctDNA molecular diagnostics in Europe**

- **OBJECTIVES**

  Implement ctDNA testing to guide:

  - Treatment selection (ctDNA mutation profiling – pan-cancer)
  - Treatment (de)escalation and recurrence surveillance (ctDNA minimal residual disease testing – CRC)
  - Treatment response monitoring (ctDNA dynamic changes over time – CRC)

WORKPLAN – transversal LB pilot



WORKPLAN – transversal LB pilot

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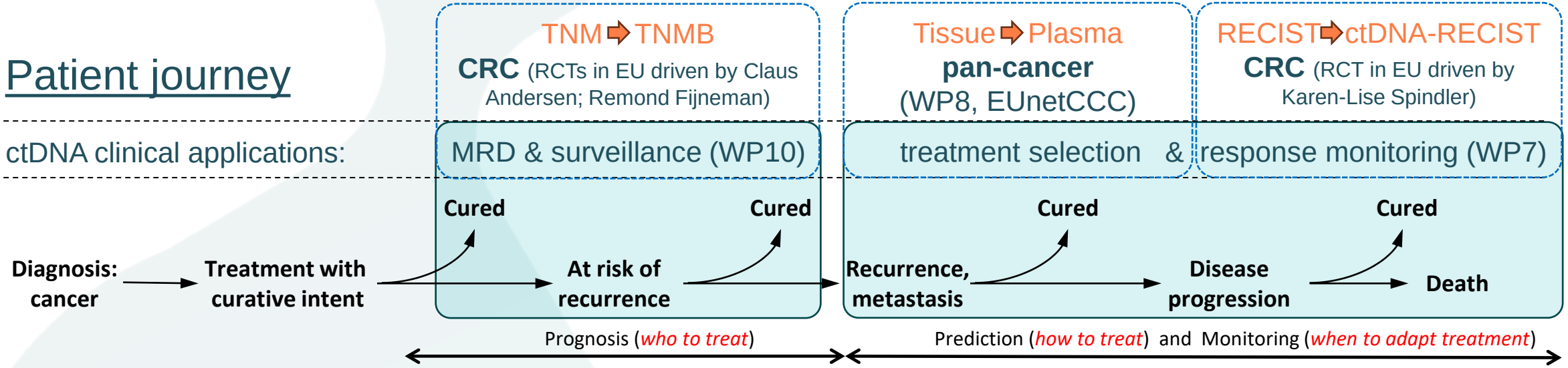
Patient journey



Implementation

Technical: * Use **scalable** and **sustainable** ctDNA assays that **meet IVDR** and **suit the clinical purpose** (ELBS, Guide.MRD)
* Laboraties **must participate in EQA (WP11)**

Clinical: * ctDNA results are discussed, e.g. in MTB (EUnetCCC) and **used to guide decisions**
* Demonstrate utility across the patient journey (HTA - WP13). Type of cancer selected: **colorectal cancer**

Organisational: Make ctDNA testing **available, accessible, affordable** for patients with cancer,
* Transpose international RCT results to national setting by performing **member state specific Real World Data studies** and **member state-specific HTA evaluation** (WP13, CANDLE). Data integration tool selected: **cBioportal**
* Interact with **regulatory authorities** on national level (JA PCM) and EU level (JA PCM, ELBS) for **reimbursement**

EXPRESSION OF INTEREST (EOI)

June 2025 - LB pilot presented, **EOI invited**

December 2025 - **EOI overview:**

- Number of countries: **19**
- Number of institutions: **44**

Jan-March 2026 – **Define pilot roles per institute:**

- Jan 7, 2026: LB pilot EOI meeting (>90 participants)
- Jan/Feb 2026: **circulate survey** to explore site readiness
- Feb 2026: **define 'low/medium/high' readiness** of centers
- March 2026: inform centers about proposed role and budget
  - Proposed by RF, CLA, Klaus Pantel, Simon Joosse, Patrizio Giacomini

Budget and work:

- **All centers participate in EQA**
- **JA PCM budget will be insufficient** to cover expenses
  - Embed activities in ongoing efforts = *in kind* per site
  - **Acquire private funding** to expand participating sites

WORKPLAN – survey LB readiness

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LB readiness

LB sample collection (primary processing)
- Knowledgeable of the needed blood volume, timing and frequency of sampling needed for the target clinical setting
- Infrastructure for blood collection and processing to plasma and PBMCs, sample traceability, sufficient short "Time from blood draw To Plasma"
- Infrastructure for plasma shipment and temporary storage

cfDNA extraction (secondary processing)
- Infrastructure for cfDNA extraction
- QC infrastructure (monitoring and actions)
  - cfDNA quantification
  - blood cell DNA contamination
  - purification efficiency
  - ratio of double to single stranded cfDNA
  - protein contamination

Key parameters
- ctDNA sensitivity and specificity
- Robustness and reproducibility
- Turn Around Time

Documented execution READINESS
e.g. from prospective interventional trial

ctDNA testing (tertiary processing)
- Analytical linearity
- Analytical LOD and LOB appropriate for the given clinical setting
- Sufficient robustness and reproducibility
- Statistics based ctDNA calling (Clinically actionable output)
- ctDNA test has necessary clinical sensitivity and specificity
- "Turn Around Time" sufficient for clinical use
- QC parameters determined (incl sample identity monitoring)
- Infrastructure for monitoring QC
- Participation in ctDNA testing EQA

ctDNA results storage and reporting
- Infrastructure for safe and secure storage of cfDNA results
- Infrastructure for reporting ctDNA results to clinicians

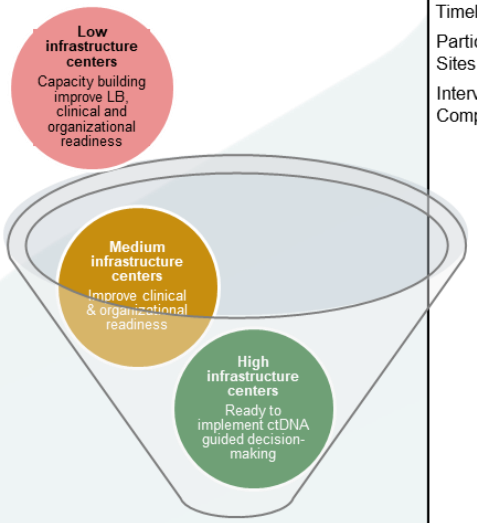
Tissue infrastructure (needed for tumor informed ctDNA assays)
- Tumor tissue collection - high Tumor fraction, histopathological assessed
- Tissue and PBMC to DNA (QC, quantity, concentration, fragmentation)
- Tumor mutational profiling (large panel, WES, WGS)

Clinical readiness
- **Documented clinical utility for the target clinical setting**
- **Impact on patient quality of life**
- Clinicians willing to use ctDNA to guide clinical decision making
  - To guide treatment selection
  - To guide adjuvant therapy
  - To guide surveillance
  - To guide therapy monitoring
- Professional consensus regarding implementation
- Implementation into clinical guidelines
- Clinicians (Surgeons, oncologists) trained in ctDNA guided decision making

Organizational readiness:
- Health economic assessment – consequences of implementation
- Health care system prepared and ready to implement ctDNA guided decision making
  Paradigm changes
  - Major organizational changes e.g. ctDNA vs radiology, ctDNA vs pathology
  - Major impact on cost
  - Who shall perform the ctDNA testing?
- Approval from decisionmakers (hospital owners, health authority, insurance companies etc)
  - Path for reimbursement
- Plan for local, regional, national implementation
- Infrastructure for monitoring impact of implementation – framework for real life data collection

Work in progress

WORKPLAN – LB pilot roles, activities



Pilot Study

Three-phase personalized multilevel and multidimensional implementation package to advance ctDNA guided decision making in real-world clinical centers across Europe			
Centers	**Low LB Infrastructure centers**	**Medium LB Infrastructure centers**	**High LB Infrastructure centers**
EPIS Dimension	Exploration/Preparation, *Objective: prepare organizations to develop or adopt a liquid biopsy decision-making program*	Preparation/Implementation *Objective: prepare to implement Liquid Biopsy guided decision-making* *(Pilot experience)*	Implementation/Sustainability *Objective: Implement, sustain, refine, and enhance Liquid Biopsy guided decision-making programs* *Pilot experience*
Timeline	M0-M24 and M25-48	M0-24 and M25-M48	M0-M48
Participating Sites	Low/Middle resources sites (recipients) High resources sites (provide support)	Middle resources sites	High resources sites
Intervention Components	**Site self-assessment and Workflow analysis:** - Mapping current infrastructures for liquid biopsy (gaps, resources, workflow) - Liquid biopsy guided decision-making readiness assessment - Design (re-design) liquid biopsy workflow by identified needs **Capacity building:** - Webinaires and exchange visits to centers experienced with liquid biopsy guided decision-making - Sharing documentation of established processes and best practices **Technology and regulatory enablement** - Connecting sites with technology providers (based on mapping and requirements exercise) - Identifying funding opportunities to acquire, implement, an sustain the needed technologies - Sites to identify and interact with national authorities and reimbursement/regulatory bodies	**Improve LB, Clinical and Organizational readiness** **1) Self-assessment to identify** gaps, lacking resources and missing workflows, at LB, Clinical, Organizational level **2) Receive implementation package, matching the <u>target clinical setting</u> of the center, either** • *To guide treatment selection* • *To guide adjuvant therapy* • *Guide surveillance* • *To guide therapy monitoring* **3) LB workflows** - Rollout of selected LB workflow - Integration with Clinic (Surgery, Oncology, Pathology and Radiology) - Local adaptation and iterative problem solving with implementation leads - *Participation in ctDNA EQA (LB pilot and WP11)*	**Implement and refine LB guided decision-making in ONE of FOUR clinical settings per center** Tasks include: • Obtain professional consensus to implement • Include ctDNA in the clinical guideline(s) • Build implementation plan: local, regional, and national • Determine medical specialty responsible for ctDNA testing • Reporting ctDNA result to Electronic Patient Record system • Implement ctDNA guided decision-making • Participation in ctDNA EQA (LB pilot and WP11) **Prepare stakeholder information packages**: • Clinicians (receivers of ctDNA info) • Patients • Related specialties impacted e.g. biochem, pathology, radiology **Prepare training packages:** • Stakeholders • JA PCM low resource sites **Approach National Authority and Payers for approval** • Implementation plan for ctDNA guided decision-making
Core Metrics	- LB Readiness at M0 vs. M24 - Increased knowledge of LB opportunities and expected impact (M0 vs. M24) - Completion of LB workflow designs, and implementation plan by M24 (including envisioned technology and resource requirements) - Establishment of partnerships with academic and industry collaborators (M0 vs. M24)	- LB, Clinical, Organizational Readiness at M0 vs. M24 - Addressed and solved self-identified gaps blocking implementation, at three levels - LB - Clinical - Organizational - Completion of implementation plan (M24) - Completion of transition from Medium to High Infrastructure center (M24)	**Implementation of structured data collection** RWD for - Assessment of adherence: Patients and clinicians - Assessment of Clinical outcome (validity) - HTA evaluation Implementation experience at patient, provider and organization level (Informative interviews with key persons) Maintenance: sustained use of the LB in routine practice, motivators and enablers to ongoing use after, progress toward reimbursement/financial pathways

Work in progress

EXPECTED OUTCOMES & IMPACT

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Expected outcomes:

- ctDNA guided clinical decision making implemented across Europe.
- Infrastructure for transnational RCTs and MS-specific RWDs established

Key Impacts on Stakeholders

- Healthcare professionals & researchers:
  - Training, increase awareness clinical utility
  - Adopt ctDNA for treatment decision-making
- Healthcare policymakers and decisionmakers:
  - Education, increase awareness regulatory obligations
  - Make ctDNA testing accessible to patients
- Cancer patients – Citizens:
  - **More cure and better care at affordable cost**

NEXT STEPS

Next immediate steps and timelines for year 1

STEP 1	1st LB pilot EOI meeting	7-Jan-2026
STEP 2	Circulate survey readiness levels	30-Jan-2026
STEP 3	Role and budget distribution	March-2026
STEP 4	Establish maze of meeting cycles, **initiate activities** [EQA (WP11); clin. appl (WP7, WP10); data (CANDLE); HTA (WP13), training (EUnetCCC); regulatory (ELBS); ..]	April 2026
STEP 5	Acquire private funding	October 2026

Conclusion

- ctDNA-guided treatment decision-making will change clinical practice.
- We must ‘play simultaneous chess’ (on technical, clinical and organisational level) to implement ctDNA-guided treatment decision-making across the patient journey.
- The JA PCM offers the seeds to initiate a coordinated ctDNA Joint Action across Europe, we must cultivate and leverage this opportunity to succeed.

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Contact

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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
Joint Action Personalised Cancer Medicine

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14:00 – 15:20 Session Pilots & use cases ARM2

WP7-8: Supranational MTB for complex cases/countries with no MTB
Alejandro Piris & Alberto Hernando, Vall d'Hebron Institute of Oncology (ES)

WP8: Continuous data collection in a federated data sharing platform
Live Fagereng, Oslo University Hospital (NO)

Use case 8.1: Expanding treatment space
Nikolas von Bubnoff, Medical Centre, University of Schleswig-Holstein (DE)

Use case 8.2: Managed Entry Agreements
Christophe Le Tourneau, Unicancer (FR)

15:20 – 15:30 Closing remarks

Philippe Roux, Head of Unit, SANTE.B.1, DG SANTE

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JA PCM KICK-OFF

14/15 JANUARY 2026

PILOT WP7-8

Supranational MTB for complex cases/ countries with no MTB

Alejandro Piris, Alberto Hernando-Calvo

VHIO
Vall d'Hebron Instituto de Oncología

Co-funded by the European Union

Supranational MTB for complex cases/countries with no MTB

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Alejandro Piris
VHIO, Spain

Alberto Hernando-Calvo
VHIO, Spain

Christina Stangl
VHIO, Spain

Alba López
VHIO, Spain

Nikolai Goncharenko
INC, Luxemburg

Ernest Nadal
ICO, Spain

Iwona Ługowska
MSCI, Poland

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To date, patient access to Precision Oncology and Molecular Tumor Boards is heterogeneous across EU member states

MISSION & VISION

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- **Overarching goal:** Expand Precision Oncology and Molecular Tumor Boards to EU member states lacking expertise
- **Vision:** a sustainable and scalable European framework where all patients with advanced solid tumors regardless of country of origin can benefit from access to biomarker testing, molecular interpretation and treatment recommendations through MTB

- **OBJECTIVES**
  - Create an **operational framework** including SOPs to set-up a transnational MTB and expanding biomarker access
  - Establish a **network of pilot cancer centres** that will allow to implement these transnational MTB pilots as well as a roadmap for onboarding of other institutions
  - Define **impact metrics** including sustainability measures to quantify the impact of the transnational MTB, with a particular focus on countries and regions with limited or no access to MTBs, to demonstrate tangible improvements

WORKPLAN

- **Planned intervention:** Implementation of a supranational, virtual Molecular Tumor Board providing biomarker access, molecular interpretation with expert case discussion and treatment recommendations
- **Target population:**
  - Adult Complex and Rare tumor cases
  - Paediatric cancers
- **Relevant inclusion/ exclusion criteria:**
  - Inclusion: Patients with advanced, rare or molecularly complex cancers lacking access to local MTB
  - Exclusion: Cases with established standard-of-care management not requiring molecular prioritisation
- **Duration of the pilot:** 4 years

WORKPLAN

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1. Framework & Workflows

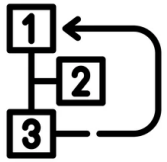
Establish a legal and operational framework based on successful models (e.g. CCE BoB), enabling standardized molecular profiling workflows, data sharing policies including countries with limited access to NGS.

2. Pilot Design & Expansion

Launch a pilot transnational MTB with a diverse mix of low-, middle-, and high-income European countries. Identify barriers and refine the framework, defining a roadmap for a stepwise and scalable expansion across Europe.

3. Case Prioritization

Prioritize rare and ultra-rare advanced cancer cases, patients without standard-of-care or trial options, and cases with complex molecular profiles or unusual treatment responses.



4. Outcome Evaluation

Assess the clinical impact of MTB recommendations using predefined outcome and impact metrics to continuously optimize the model.

WORKPLAN

WORKING GROUPS:

- Legal/ DPO (build on CCE, CAN.HEAL experiences) (VHIO & INC)
- Business Group (exploring funding opportunities, collaborations with companies, etc) (VHIO)
- Definition of rare & complex, case-prioritization guidelines, and follow-up criteria (MSCI)
- Operational Framework (VHIO & ICO -> with extensive input from all)
- Platform testing (MSCI)
- Sustainability & Impact (ICO & INC)

EXPECTED OUTCOMES & IMPACT

Expected outcomes:

- A validated operational and legal framework for supranational MTBs
- Harmonised SOPs for biomarker testing, case submission, prioritisation, discussion, and follow-up
- Improved access to molecular expertise and biomarker-driven treatment options
- A roadmap for scale-up and replication across EU Member States

Key Impacts on Stakeholders

- **Healthcare professionals & researchers :**
  - Access to multidisciplinary molecular expertise
  - Capacity building and shared learning across countries
  - Improved clinical decision-making in complex cases
- **Healthcare policymakers:**
  - Evidence to support cross-border collaboration models
  - Data on feasibility (*e.g.* access to precision oncology drugs and clinical trials), sustainability, and health-system impact
  - Support for policy decisions addressing inequities in cancer care
- **Cancer patients – Citizens:**
  - Improved access to precision oncology expertise
  - Reduced geographic inequalities in cancer care
  - Improved understanding of biomarker-matched therapies and treatment access

EXPRESSION OF INTEREST (EOI)

Overview of the EOI exercise

- Total number of EOI received: 44
- Number of countries: 23
- Number of institutions: 44

Pilot roles

- Primary site: Submitting cases/samples
- Partner/ Observer: Expert and Learning Contributors (clinicians, pathologists, genetic counsellors…)

Strategy for primary site selection: Survey will be sent out to standardise responses among all interested centres

- Selection of pilot sites and partners that meet the selection criteria

ADULT MTB

PAEDIATRIC MTB

NEXT STEPS

Next immediate steps and timelines for year 1

STEP 1	Selecting pilot sites and partners	March 2026
STEP 2	Defining vendors for biomarker testing	Q2-Q3 2026
STEP 3	Exploring funding opportunities in coordination with other partners	Q2-Q3 2026
STEP 4	Platform testing and secure data sharing policies and setup	Q3-Q4 2026
STEP 5	Definition of performance indicators and impact metrics	Q3-Q4 2026

Conclusion

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

- A pan-European Molecular Tumor Board is a necessary solution to reduce inequities in patients access to Precision Oncology across Europe
- This pilot aims to establish an operational, legal and clinical framework to be scaled across all EU Member States
- Targeting genomically complex, rare and pediatric cancers, this pilot will deliver immediate clinical value while aiming to generate evidence for long-term sustainability

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PILOT/USE CASE 8.1

Data Sharing Platform

Live Fagereng

ALLEANZA CONTRO IL CANCRO

OSLO UNIVERSITETSSYKEHUS

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Data Sharing Platform

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Project Lead, WP8.2.4 EUnetCCC, Project Manager PRIME-ROSE. OUS, Norway

Opening hook - Context

Imagine you're diagnosed with cutaneous angiosarcoma—a rare and aggressive cancer that places you among the approximately one in four cancer patients in Europe facing a rare cancer. Unfortunately, being diagnosed with a rare cancer means fewer treatment options because industry, regulators and payers have problems gathering enough data to sustain a label application and reimbursement decision. Fortunately, genomic profiling reveals your tumour has a High Tumor Mutational Burden (TMB-H). In the US, targeted immunotherapy (checkpoint inhibitors) has received tumour-agnostic approval for any solid tumor with TMB-H, offering a lifeline. Yet in Europe, the data for TMB as a broad biomarker is often considered insufficient for reimbursement in rare cancers without specific trials - leaving this potentially life-extending treatment inaccessible to many patients..

A joint European data sharing platform could solve this by aggregating data from molecular tumour board across borders, building robust cohorts to generate the real-world evidence needed to inform industry, regulators, payers and clinicians—ultimately expanding access to precision therapies all cancer patients.

MISSION & VISION

- The primary mission of the data sharing platform is to demonstrate how aggregating and merging real-world data from molecular tumour boards across regions and countries in Europe can generate analysis to support decision-makers in industry and government to expand therapeutic options and improve outcomes for cancer patients in Europe.

- **OBJECTIVES**

  Objective 1: Develop a Data Sharing Framework: Create a Data Sharing Agreement, including a detailed Data Management Plan and Data Sharing Protocol, that enables data exchange and joint analysis among participating European countries and regions.

  Objective 2: Demonstrate Proof-of-Concept for Cross-border Recuitment to Joint Cohorts: Establish a proof-of-concept by aggregating patient inclusion numbers from multiple countries into predefined cohorts, as outlined in Use Cases 8.1 and 8.2, to illustrate the feasibility of building sufficiently powered datasets for rare cancer research

  Objective 3: Validate Proof-of-Concept Through Data Analysis: Deliver a proof-of-concept by merging and analysing data from filled cohorts that includes patients from several countries, in accordance with a predefined Statistical Analysis Plan, to produce supporting documentation for decision makers as defined in Use Case 8.1 and 8.2.

WORKPLAN

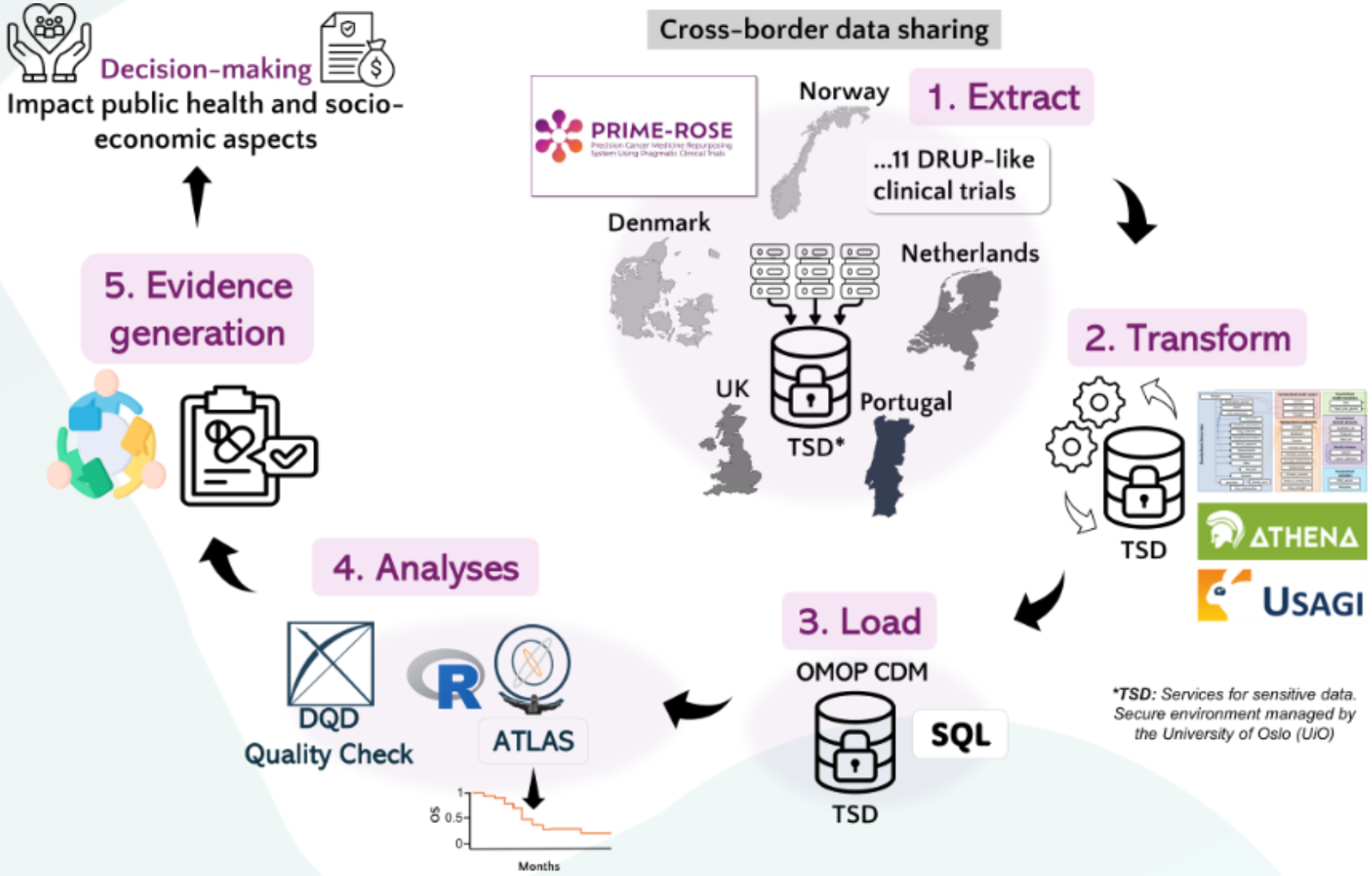
- Planned intervention: Aggegrate and merge data from exisiting data collection inititatives as Part of MTB operations.
- Target population: Existing data collection for MTB operations in target countries
- Relevant inclusion/exclusion criteria:
  - Established data collection that covers key variables
  - Sign data sharing framework,
- Duration of the pilot: 4 years

WORKPLAN

Establish a platform for merging data from different established systems

Federated combined with Centralised.

Minimum Data Set for Proof of Concept.



EXPECTED OUTCOMES & IMPACT

Expected outcomes:

- Data Sharing Framework including data sharing protocol, data management plan
- Inclusion numbers to relevant cohorts identified in Use Cases
- Analysis of key cohorts

Key Impacts on Stakeholders

- Pharmacutical Industry: Proof-of-concept of the power of data sharing platform and EHDS for providng relevant data on rare and ultra cancers.
- Payers/HTA: Examples of how data sharing platform can provide supportive data for structured Managed Entry Agreements and HTA.
- Regulators: Proof-of-Concept for how data sharing platform can provide supportive evidence for MA.

EXPRESSION OF INTEREST (EOI)

Overview of the EOI exercise :

- Total number of EOI received: 95
- Number of countries : 20
- Number of institutions : 47

Pilot roles

- Primary site: ACC, OUS, LUMC, MCI, Unicancer,
- Partner/Observer:
- Secondary site (optional):…

Strategy for primary site selection

- Wave Implementation based on:
  - Participation in Pilot & WP8
  - Existing Data Collection
  - Ability to Share Data in Harmonised and Standardised manner
- ….

NEXT STEPS

Next immediate steps and timelines for year 1

STEP 1	Description: Work Flow for Sharing	Date: January 2026
STEP 2	Description: Data Management Plan	Date: May 2026
STEP 3	Description: Data Sharing Protocol	Date: June 2026
STEP 4	Description: Work Flow for Federated	Date: September 2026
STEP 5	Description: First inclusion number	Date: December 2026

Conclusion

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

- Message 1: Bridging national and regional data collection initiatives from MTB to unleash the true potential of European health data.
- Message 2: True data sharing is not just about exchanging datasets; it is about good governance framework and a sharing culture of trust and use of data.
- Message 3: Systematic, real-world evidence generation enables multiple informed decision points throughout the treatment lifecycle — from approval and market access to post-implementation adaptation and optimisation.

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USE CASE 8.1

Expansion of Treatment Space and Cohort Design

Nikolas von Bubnoff
Torben Hansen

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Co-funded by the European Union

Expansion of Treatment Space and Cohort Design

JA PCM
Joint Action Personalised Cancer Medicine

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Institut for Regional Sundhedsforskningen

Iwona Ługowska

National Institute of Oncology - Maria Skłodowska-Curie (MSCI- Poland)

CONTEXT

- Molecular Tumor Boards (MTBs) link individual cancer genetic & molecular profiles to treatment recommendations, often beyond approved indications
- Long tail of druggable cancer targets are shared across cancer entities
- Genetic/molecular profiles associated with response or non response are not systematically investigated

MISSION & VISION

- ***Mission:*** *To design specific targeted-driven treatment cohorts to systematically generate evidence for drug repurposing*
- ***Vision:*** *To expand treatment space by providing an evidence-generating environment in PCM in collaboration with patent holders*

- **OBJECTIVES**
  - Showcase the potential for shared recruitment & data analyses to generate evidence for PCM
  - Proof-of-Concept: Aggregated retrospective analyses of pre-defined cohorts
  - Setup of prospective cohorts with specified treatment protocols

WORKPLAN

- Planned intervention:
  - Setting up MTB network with data sharing platform, statistical analysis plan and safety profiling strategy
  - Retrospective analysis of at least two molecular defined cohorts
  - Setup of at least one genetically defined prospective cohort
- Target population: tumour-agnostic, stratified by molecular basket and/or type of treatment
- Relevant inclusion/exclusion criteria: tbd, proposed retrospective cohorts include:
  - Atyp BRAF mts (class II/III)
  - KRAS G12C
  - ADC (HER2/TDxD, TROP2/SG)
  - ICI (+/- TKI)
  - Clonal hematopoiesis and cancer progression
  - Exceptional responder cohort: all pts with implemented Tx recomm and PFS > 6 mts
- Prospective cohort: In dialogue with MAH: e.g. pan KRAS, retrospective “winner” cohort
- Duration of the pilot : 48 months

WORKPLAN

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Prerequisite

⇔ P8 Data Sharing Platform

Task 8.1: PCM Treatment Network

- Data sharing platform
- Harmonized inclusion/exclusion criteria for cohorts
- Harmonized data items
- Defined endpoints

Set up retro cohorts

1. Poll to capture readiness (MTB, data collection)
2. Consent two retrospective cohorts
3. Develop statistical analysis plan with harmonised endpoints
4. Collection of data
5. Analysis of data

Setup prosp cohort

1. In dialogue with MAH (cohort design, access to drug)
2. Initiate prospective cohort to confirm retrospective analysis *or* independent cohort
3. Develop statistical analysis plan with harmonised endpoints
4. Collection of data
5. Analysis of data

⇔ U8.2 Managed Entry Agreements

Setup of network of participating MTBs and institutions

Identify key industry partners

- Specify key industry indicators (strategic demands, cohort design, endpoints, data integrity, safety, recruitment)
- Discus cohort design

Strongly suggested: Interconnection to Transversal Liquid Biopsy Pilot (Claus Lindbjerg Andersen, Remond Fijnemann)

EXPECTED OUTCOMES & IMPACT

Expected outcomes:

- Showcase feasibility of aggregated data analysis within European PCM network (Task 8.1)
- Demonstrate the impact of shared cohorts to generate evidence for PCM (Task 8.2)
- Identify the performance of key industry indicators (Deliverable 8.2)
- Explore potential to attract MAH for prospective trials

Key Impacts on Stakeholders

- Healthcare professionals & researchers: larger cohorts for hypothesis testing & confirmation; identification of predictive markers for response/non-response
- Healthcare policymakers: accelerated evidence generation
- Cancer patients – Citizens: expanded access to innovative medicine

EXPRESSION OF INTEREST (EOI)

Overview of the EOI exercise :

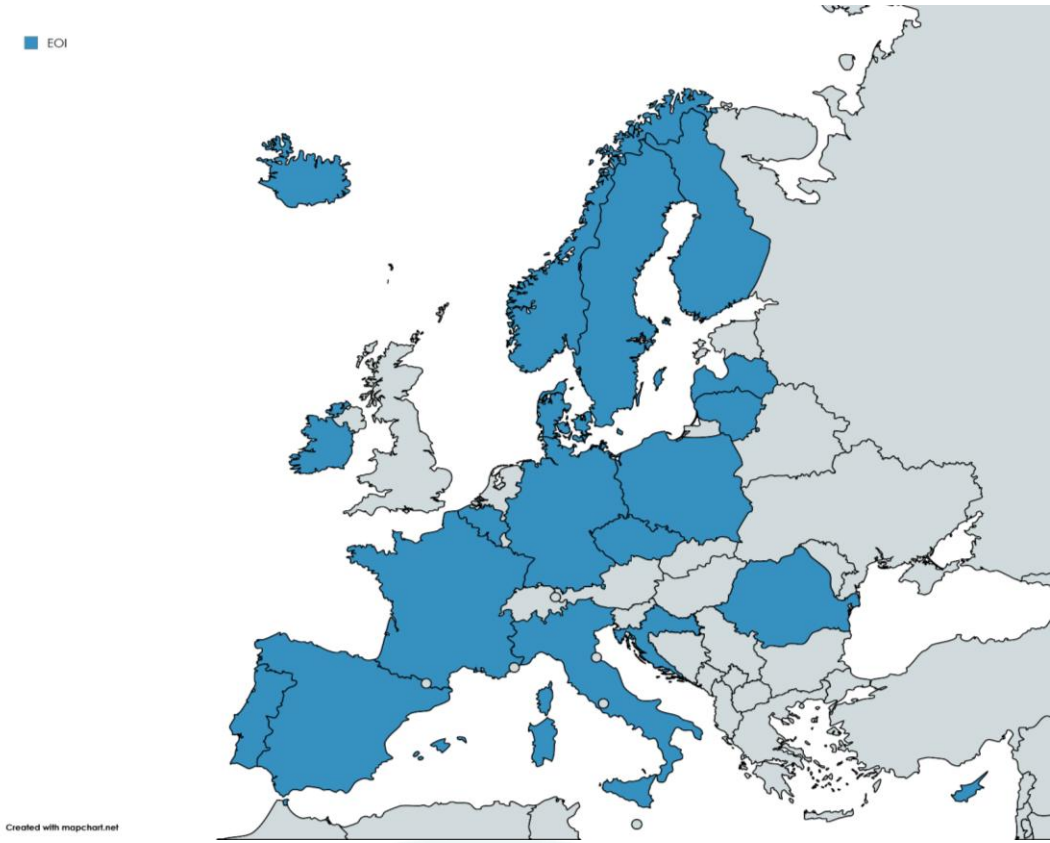
- Total number of EOI received : 32
- Number of countries : 19
- Number of institutions : 34 (including UKSH, RYSD)

Pilot roles

- Primary site: Contributing data (expected ~21)
- Partner/Observer: Contributing Systemic Support, Knowledge & Experience
- Secondary site (optional): Expecting Support for Development & Implementation; may contribute data

Strategy for primary site selection

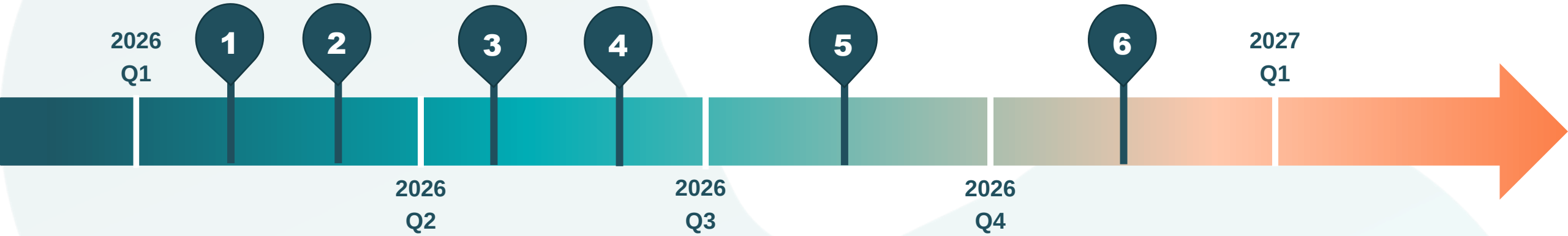
- EOI & poll exercise
- Collection of information on readiness (MTB performance; access to data)



NEXT STEPS

Next immediate steps and timelines for year 1

STEP 1	Poll exercise with all sites	February
STEP 2	Consent retrospective cohorts	March
STEP 3	Align with Task 8.1 (PCM network) and 8.3 (Managed entry agreements)	April - *continously*
STEP 4	Initiate MAH dialogue	June
STEP 5	Statistical analysis plan	August
STEP 6	Start Collection of Data	TBD



Conclusion

- The European PCM network provides a unique setting for an evidence-generating environment
- Shared data analysis of pre-specified cohorts will unveil predictive markers and improve treatment stratification
- Partnering with MAH for harmonized cohorts might accelerate setup of clinical trials, drug approval and will expand the treatment space for patients to PCM

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USE CASE 8.2

Managed Entry Agreements

Prof. Christophe Le Tourneau

unicancer

LUMC Leids Universitair Medisch Centrum

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8.2 Managed Entry Agreements

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Unicancer

Prof. Christophe Le Tourneau

Head of Personalised Medicine Group, Unicancer

Senior Medical Oncologist; Deputy Director General of the National Precision Medicine Center in Oncology (PRISM), Deputy Director of Clinical Research, Gustave Roussy

Dr. Maud Kamal

Contributor to Personalised Medicine Group, Unicancer

Executive Director of the National Precision Medicine Center in Oncology (PRISM); Head of Europe Unit, Gustave Roussy

LUMC

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Associate Professor of Medical Oncology, with a special focus on Accessibility of Medicines, LUMC

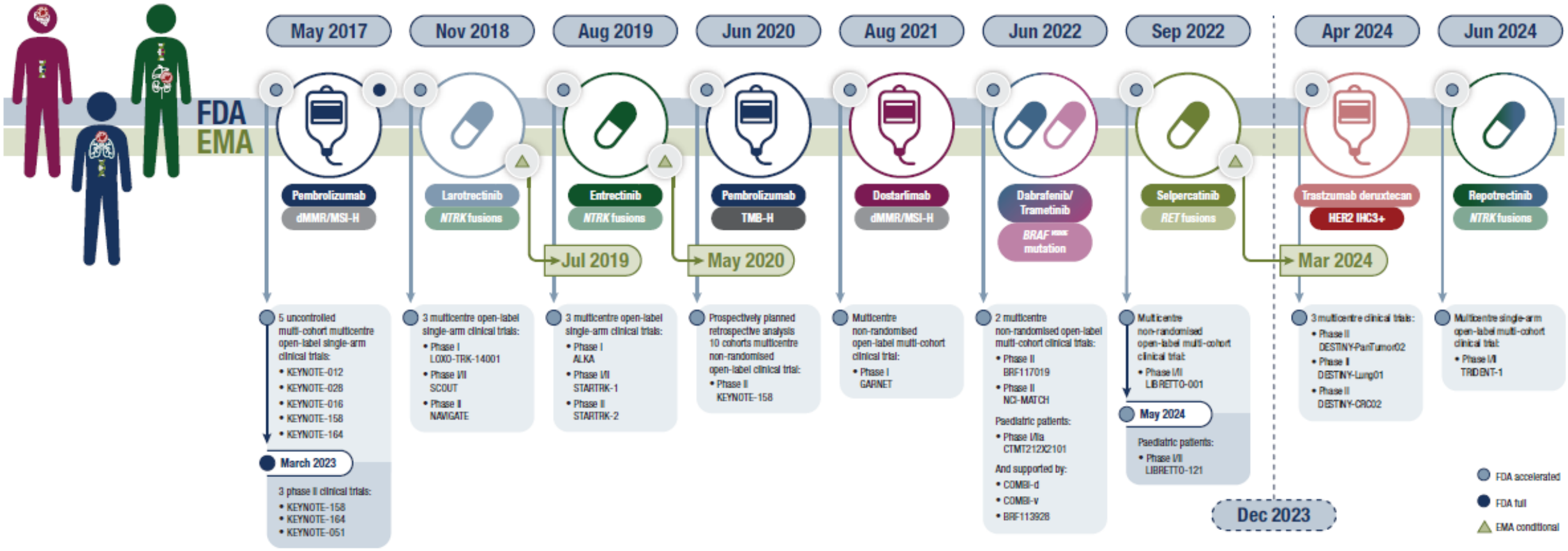
Floor de Jong

PhD Candidate Medical Oncology, LUMC

Prof. Hans Gelderblom

Medical oncologist and chair of the department of Medical Oncology, LUMC

PROBLEM TO SOLVE



Westphalen *et al*. *Ann Oncol* 2024;35:936-53

MISSION & VISION

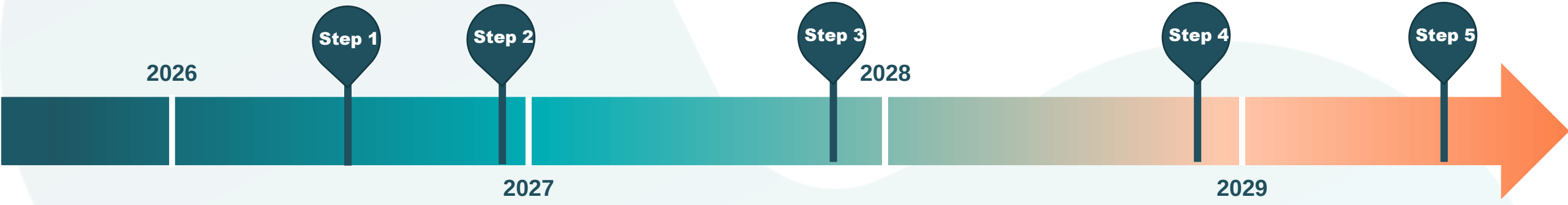
- The UC's mission is to support **equitable** and **timely access to therapies** within the JA PCM by developing a practical **framework** for the use of **Managed Entry Agreements** (MEAs)
- It aims to reduce uncertainty in **reimbursement** decision-making through cross-country collaboration, horizon scanning, and evidence-based analysis
- By identifying and addressing key system **bottlenecks** in close coordination with **WP13**, the pilot contributes to more sustainable, transparent, and patient-centred access pathways across **Europe**

- **OBJECTIVES**
  - Exploring the **role of managed entry agreements**, real-world evidence or external control arms in tailoring access pathways for MEA for both on-label and off-label use
  - Identifying **barriers** for tumour-agnostic reimbursement in pilot countries
  - Developing **guidelines** to support MEA for reimbursement

WORKPLAN

- **Planned intervention:** Develop the framework and the mapping
- **Target population:** patients eligible for tissue-agnostic drugs approved by FDA and EMA
- **Duration of the pilot:** 4 years

STEP 1	Mapping exercise	M9
STEP 2	Interpretation of the mapping	M12
STEP 3	Engage with national regulatory bodies and payers	M24
STEP 4	Meet with EMA	M36
STEP 5	Deliver the framework (report)	M48



EXPECTED OUTCOMES

- **Structured access framework:** The pilot will deliver a practical MEA-based framework, supported by reimbursement dossiers, to guide on-label and off-label access decisions across different stages of the patent life cycle

- **Reduced uncertainty through better evidence:** The pilot will strengthen evidence generation and use by combining horizon scanning, cross-country data, and tailored analyses to address key uncertainties in reimbursement decisions

- **Cross-country alignment and bottleneck identification:** The pilot will identify system barriers such as lack of comparators and budget impact constraints, supporting more aligned and informed decision-making across countries in collaboration with WP13 and EU initiatives

IMPACT

- **Healthcare professionals & researchers** : provide clearer evidence requirements and access pathways, strengthening research design, data use, and informed clinical decision-making for tumour-agnostic and off-label therapies

- **Healthcare policymakers**: support more transparent, evidence-based, and aligned reimbursement decisions by reducing uncertainty and strengthening the practical use of MEAs

- **Cancer patients – Citizens**: contribute to more timely, equitable, and predictable access to innovative cancer therapies across countries, including tumour-agnostic and off-label uses

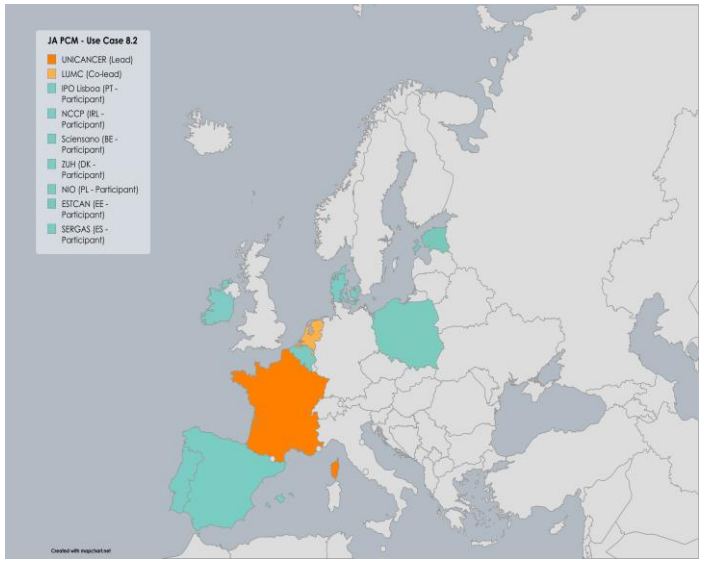
EXPRESSION OF INTEREST

Overview of the EOI exercise

- Total number of EOI received : 7
- Number of countries : 7
- Number of institutions : 7

Pilot roles

- Partner: The partner provides a structured interface with the relevant reimbursement, HTA and procurement systems in its country/region, ensures that appropriate contacts with payers are in place, and secures their agreement to explore and test MEA approaches using the outputs of JA PCM



NEXT STEPS

Next immediate steps and timelines for year 1

STEP 1	Mapping exercise to examine how the nine FDA approved tumour-agnostic drugs are accessed and reimbursed across Europe	M9
STEP 2	Explain key differences between FDA and EMA (interpretation of mapping exercise)	M12

Conclusions

- Only a third of tissue-agnostic drugs approved by the FDA are approved by EMA
- FDA approval leads to possible prescription, whereas national approvals are needed in Europe beside EMA approval
- The overall goal of the UC is to ensure equitable access to drugs all over Europe

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THE JA PCM KICK-OFF MEETING

14-15 January 2026

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14:00 – 15:20 Session Pilots & use cases ARM2

WP7-8: Supranational MTB for complex cases/countries with no MTB
Alejandro Piris & Alberto Hernando, Vall d'Hebron Institute of Oncology (ES)

WP8: Continuous data collection in a federated data sharing platform
Live Fagereng, Oslo University Hospital (NO)

Use case 8.1: Expanding treatment space
Nikolas von Bubnoff, Medical Centre, University of Schleswig-Holstein (DE)

Use case 8.2: Managed Entry Agreements
Christophe Le Tourneau, Unicancer (FR)

15:20 – 15:30 Closing remarks

Philippe Roux, Head of Unit, SANTE.B.1, DG SANTE

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GOODBYE COFFEE

Please be back next meeting

THANK YOU FOR YOUR PARTICIPATION

Let’s move forward together!