JA PCM
Joint Action Personalised Cancer Medicine

Private sector engagement: opportunities & next steps

JA PCM WEBINAR

26 May – 13:00-15:00

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Housekeeping rules

1. You are automatically muted
2. Ask your questions in the chat. Your questions will be addressed in the Q&A.
3. Please do not turn on your camera
4. This webinar is recorded and will be published on the JA PCM website
5. Please complete the Expression of Interest Survey
6. Reminder to speakers: stick to time

Agenda

1	Welcome
2	Introduction JA PCM project
3	Private sector engagement
4	JA PCM Pilots
5	Q&A

Welcome

Marc Van den Bulcke – Head of the Cancer Center

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Joint Action Personalised Cancer Medicine

Introduction
JA PCM Project

Els Van Valckenborgh - Scientific & Lead Project Coordinator

sciensano

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Joint Action (JA): a European instrument

Definition	Joint Actions are co-funded projects under the EU4Health Programme, involving Member States, public-level bodies, and the European Commission to tackle priority health challenges at European level
Aim	Promote cross-border collaboration to share knowledge, tools, and best practices, achieving greater impact than national efforts alone (e.g., policy development, capacity building, and innovation in areas like rare diseases, health equity, and digital health)
Funding	Co-financed by EU grants and national contributions

Read more on

- https://hadea.ec.europa.eu/programmes/eu4health_en
- https://hadea.ec.europa.eu/programmes/eu4health/how-apply_en
- JA PCM - Public Health - European Commission

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JA Personalised Cancer Medicine

Overview

Funding	EU4Health: €±25 million Total: €31.6 million
Duration	Nov 2025 – Oct 2029
Project Lead	Sciensano, Belgium
Consortium	151 Partners and 29 countries

71	Medical Care Organisation
41	Research Organisation
33	Public & Governmental Organisation
6	Professional Network
3	Patient Organisation

Builds on

can.heal

PCM4EU
Personalised Cancer Medicine
for all EU Citizens

JA PCM Coordination

JA PCM
Joint Action Personalised Cancer Medicine

Cancer Centre, Sciensano Belgium

Marc Van den Bulcke - Head of The Cancer Centre & Lead

Els Van Valckenborgh - Scientific & Lead Coordination Manager

Nancy Frédérickx - Scientific & Coordination Manager

An Catherine Hoang - Scientific & Administrative Manager

Anouk Waeytens - Scientific & Coordination Manager

Mission and Vision

Mission	To leverage the potential of PCM within the EU by increasing access to and knowledge of PCM in Europe
Vision	A comprehensive, person-centred approach, addressing multiple perspectives: from the healthy individual, to the cancer patient, to the survivors
Key actions	To create an EU-wide network for cross-border PCM collaboration, and to develop methodologies and tools that can help member states to give access to personalised prevention, diagnosis, treatment and follow-up.

Objectives

1 Ensure equitable access to PCM across the cancer pathway

2 Share data and best practices (e.g., digital tools, molecular diagnostics, liquid biopsy, molecular tumor board)

3 Build knowledge and capacity among healthcare professionals, patients, and the public

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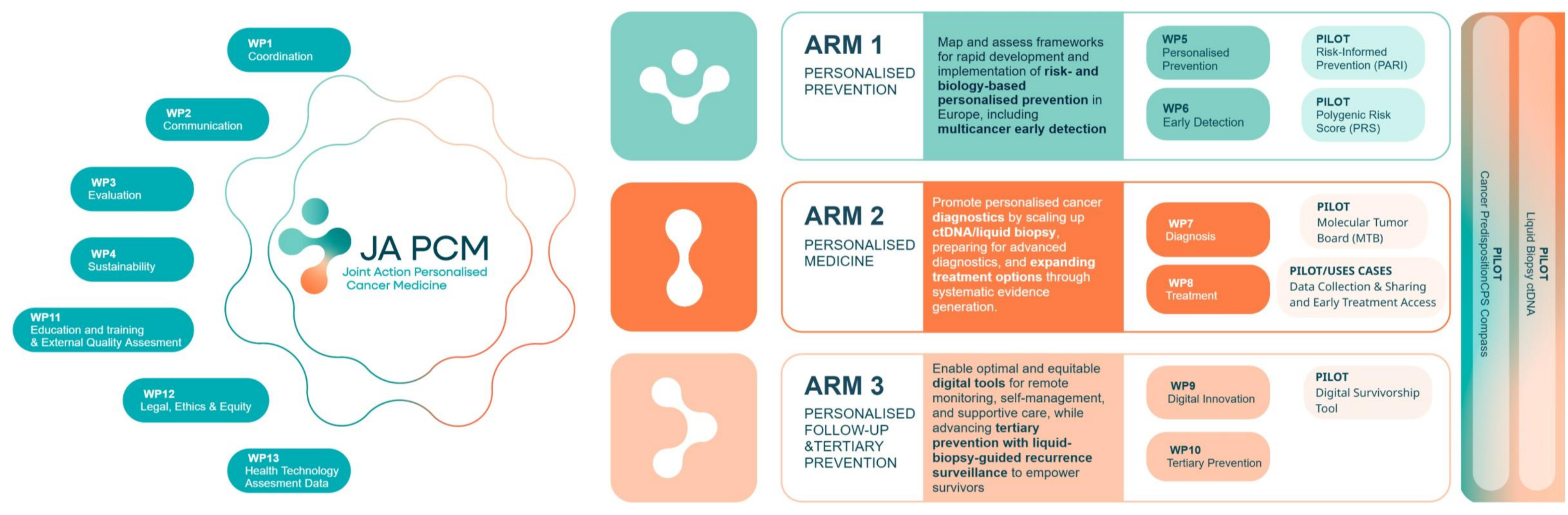
Action Plan



WP1 Coordination

WP2 Communication

WP3 Evaluation

WP4 Sustainability

WP11 Education and training & External Quality Assesment

WP12 Legal, Ethics & Equity

WP13 Health Technology Assesment Data

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ARM 1 PERSONALISED PREVENTION	Map and assess frameworks for rapid development and implementation of **risk- and biology-based personalised prevention** in Europe, including **multicancer early detection**	**WP5** Personalised Prevention **WP6** Early Detection	**PILOT** Risk-Informed Prevention (PARI) **PILOT** Polygenic Risk Score (PRS)
ARM 2 PERSONALISED MEDICINE	Promote personalised cancer **diagnostics** by scaling up **ctDNA/liquid biopsy**, preparing for advanced diagnostics, and **expanding treatment options** through systematic evidence generation.	**WP7** Diagnosis **WP8** Treatment	**PILOT** Molecular Tumor Board (MTB) **PILOT/USES CASES** Data Collection & Sharing and Early Treatment Access
ARM 3 PERSONALISED FOLLOW-UP &TERTIARY PREVENTION	Enable optimal and equitable **digital tools** for remote monitoring, self-management, and supportive care, while advancing **tertiary prevention with liquid-biopsy-guided recurrence surveillance** to empower survivors	**WP9** Digital Innovation **WP10** Tertiary Prevention	**PILOT** Digital Survivorship Tool

PILOT Cancer PredispositionCPS Compass

PILOT Liquid Biopsy ctDNA

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

Seven pilots

Pathway, access, and implementation of **risk-informed cancer prevention** across Europe

Developing and testing care pathways that adapt cancer prevention strategies to individual risk profiles

Implementation readiness for **polygenic risk scores** in screening (breast & prostate cancer)

Exploring how genetic information can help better estimate cancer risk and inform prevention.

Supranational **molecular tumor board** for complex cases/countries without MTB

Strengthening the use of molecular data to support clinical decision-making in multidisciplinary tumour board meetings

Continuous **data collection** via a federated sharing platform

Developing ways to securely collect and analyse real-world cancer data from multiple countries, in order to build larger patient cohorts and generate evidence that can inform decisions on cancer treatments and improve patient outcomes.

- The pilot contains two use cases: 1) Expanding Treatment Space; and 2) Managed Entry Agreements

Digital tools for remote monitoring, needs assessment, self-management, and supportive care

Developing and testing digital tools to support the remote monitoring of patients’ health status.

Personalised management of cancer predisposition across the patient journey (CPS Compass)

Integrating information on genetic predisposition into different stages of the patient journey, from screening to follow-up.

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

Assessing the use of blood-based tests to detect, monitor, or follow cancer in a less invasive way.

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Main activities

Technical activities

- Readiness and implementation of **risk-informed personalised prevention** across Europe, including multi-cancer early detection (screening) and personalised risk assessment
- **Liquid biopsy implementation** for early detection, tumour profiling, resistance monitoring, minimal residual disease, and recurrence surveillance (including EQA program)
- Set-up a **supranational molecular tumor board** for complex cases and countries without MTB
- **Expanding treatment options** through systematic evidence generation
- Enable optimal and equitable **digital tools for remote monitoring, self-management and supportive care**
- Personalised management of **cancer predisposition** across the patient journey

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Main activities

Transversal activities

- Develop and provide **training for professionals** and develop **material to inform patients and citizens**
- Generate **ELSI tools** prioritizing **patient-centered approaches**
- Creating a **data infrastructure** to offer an **HTA framework** for PCM
- Develop a **PCM Evaluation framework** addressing equity, impact, adoption and scalability
- Formulate **policy recommendations on sustainable implementation** of PCM in the EU
- Develop a **Roadmap 'PCM in Europe'** aligning with parallel activities

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Private Sector Engagement

Nancy Frédérickx – Scientific & Project Coordinator

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Pilot Development

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Phase 1: Expression of Interest (EOI)

- Consortium members express interest in participating in one or several pilots

Phase 2: Pilot Definition & Planning (in progress)

- Understand participants' expectations and technology readiness (surveys)
- Identify active contributing sites and observer roles

Phase 3: Execution & Implementation

- Expected in early 2027

PILOT
Risk-Informed Prevention (PARI)

PILOT
Polygenic Risk Score (PRS)

PILOT/USES CASES
Data Collection & Sharing and Early Treatment Access

PILOT
Molecular Tumor Board (MTB)

PILOT
Digital Survivorship Tool

PILOT
Liquid Biopsy ctDNA

PILOT
Cancer Predisposition CPS Compass

Pilot Opportunities: Why a Public-Private Approach?

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Advancing PCM requires the combined strengths of the public and private sectors.

PCM momentum is rapidly expanding: Phase 1 (EOI) saw up to 50 institutions expressing interest per pilot, exceeding what EU4Health funding can support alone.

JA PCM is inviting the private sector to collaborate on

- Fulfilling JA PCM ambitions
- Scaling up pilot participation
- Building capacity across participating institutions

Scope of collaboration:

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Two Main Objectives

1. **Immediate: Support JA PCM Pilots Through Targeted Contributions**
   - Delivered within project timeline and absorption capacity

2. **Long-term: Break the Silos between public and private PCM stakeholders to**
   - Expand uptake,
   - Reduce deployment disparities across the EU,
   - Leverage new collaborations

Today’s Webinar Focus

- Memorandum: Private Sector Engagement in the JA PCM
- Timeline and Next Steps
- Immediate Collaboration Opportunities Across the JA PCM Pilots

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Memorandum:
Private sector engagement in the JA PCM

Opportunities, Scope and Engagement Process for Private Sector Partners

Memorandum: Private sector engagement in the JA PCM

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- **Collaboration framework:**
    - Advantages
    - Scope
    - The modalities & timeline (JA PCM Private Sector Platform)

- **Immediate collaboration opportunities across JA PCM pilots**

What JA PCM offers

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- **Access to the PCM European Network**
  - 151 Partners and 29 countries
    - 71 medical care organisations, 41 research organisations, 33 public and governmental bodies, 6 professional networks, and 3 patient organisations
  - Connections to parallel EU initiatives: EUnetCCC, JANE2, eCan+ …
- **Early and meaningful input into evidence generation**
- **A growing and strategically relevant market**
- **Visibility and market exposure across Europe**
- **Flexible engagement designed for all**
  - From a global pharmaceutical company, a biotech, a small charity, or a consulting firm
- **Lasting recognition**
- **First access to landmark findings**
- **A direct and measurable contribution to patients**

What Your Contribution Will Deliver

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- **Advancing the evidence base for HTA and reimbursement**
  - Generating harmonised, multi-country real-world evidence to accelerate reimbursement decisions across Europe
- **Shaping EU-wide policy and clinical guidelines**
  - Informing regulatory alignment, clinical standards, and cross-country reimbursement frameworks for PCM
- **Reducing disparities and building capacity across Europe**
  - Extending access to molecular profiling, facilitates knowledge and technology transfer, create replicate models for supranational MTBs, ctDNA implementation, and digital survivorship tools
- **Delivering direct patient benefit across the full cancer care continuum**
  - Support shift from reactive to preventive cancer care, better therapy selection, and improved survivorship care

Scope of collaboration

- **The collaboration is framed within:**
    - Pre-competitive environment
    - In alignment with the Grant Agreement under EU4Health Programme and applicable regulatory requirements
- **Expectation in terms of collaboration**
    - JA PCM consortium members and the private sector
    - Respect the independence and public interest mandate of the consortium and its member institutions
    - Comply with all applicable legal, ethical and regulatory frameworks
- **Data, Intellectual Property & Secondary Use Governance**
- **Building Long-term public-private partnership**
    - Initial vision proposed in the memorandum
    - Invite private sector partners to co-shape PCM's future in Europe by contributing to this memorandum and extending the partnership beyond JA PCM

Webiste: JA PCM Private Sector Platform

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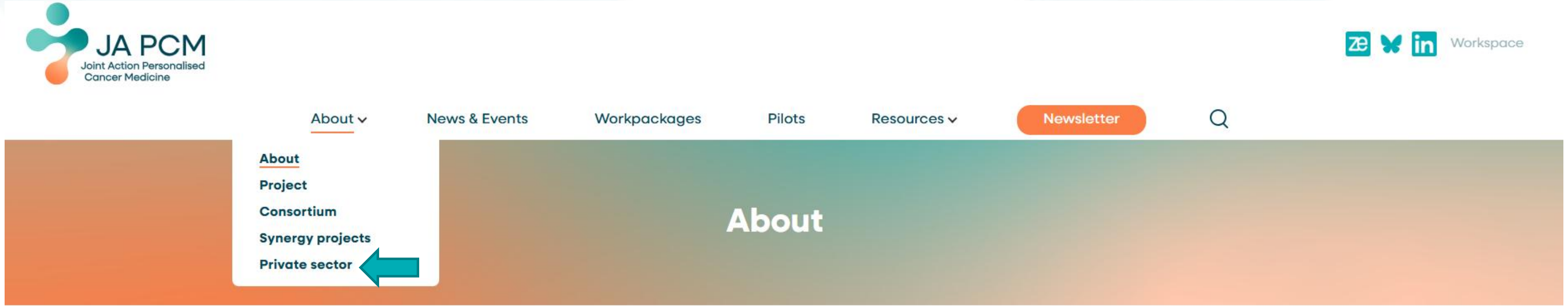
- Memorandum: Private sector engagement in the JA PCM
- Recording of this webinar and slide deck
- Private Sector EOI form
- Collaboration opportunities and link for contribution proposal submission (From Sept)

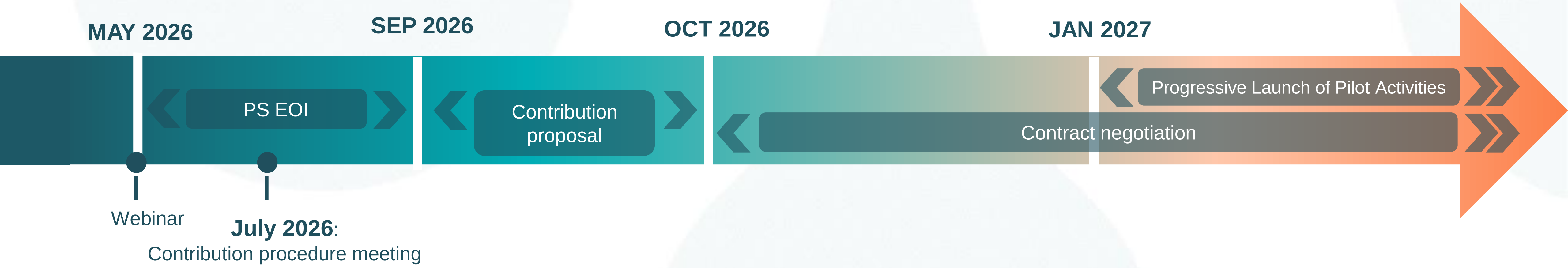
Private Sector EOI



TIMELINE

Next immediate steps

1	Webinar: Private sector engagement : opportunities and next steps	26 May 2026
2	Private Sector Expression of Interest (EOI)	May - Sep 2026
3	Contribution Procedure Meeting	Early July 2026
4	Submission of Contribution Proposals on the Platform	Sep - Oct 2026
5	Progressive Launch of Pilot Activities	From Jan 2027



MAY 2026

SEP 2026

OCT 2026

JAN 2027

PS EOI

Contribution proposal

Progressive Launch of Pilot Activities

Contract negotiation

Webinar

July 2026:
Contribution procedure meeting

Stay connected

Japcm.coordination@sciensano.be

www.japcm.eu

www.linkedin.com/company/ja-pcm

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Immediate: Collaboration Opportunities Across the JA PCM Pilots

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Immediate: Collaboration Opportunities Across the JA PCM Pilots

- **Medicinal Products & Cancer Treatment**
  - Pilot on Continuous Data Collection in a Federated Data Sharing Platform
- **Next Generation Sequencing: Germline, Liquid Biopsy and Tissue Biopsy Testing**
  - Pilot Implementing ctDNA-guided decision-making across the patient journey
  - Pilot: Polygenic Risk Score Implementation
  - Pilot on personalised management of cancer predisposition across the patient journey
  - Pilot Supranational Molecular Tumour Board
- **Digital Tools & Solutions**
  - Pilot on Digital tools for remote monitoring, needs assessment, self-management, and supportive care
- **Consultations: Surveys, workshops**
  - All activities

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WP8 Pilot/Use Cases: Evidence generation plan for PCM implementation in Europe

Live Fagereng

OSLO UNIVERSITY HOSPITAL

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Implementation of precision cancer medicine in Europe has made remarkable progress. Access to advanced diagnostics is expanding, and molecular tumour boards are becoming standard practice across countries.

But we have now reached the next **major barrier: access to treatment**.

In Joint Action PCM, we are tackling one of the biggest challenges facing decision-makers today: the lack of robust, **real-world data to support treatment access.**

Europe has a unique advantage. With a population of 450 million people, high-quality health registries, and a long tradition of following patients throughout their entire care journey, we well positioned to led the next step.

By leveraging these strengths, we aim to build a **continuous evidence-generation system—one that supports a true learning healthcare system**, where data drives decisions and access, and treatment is continuously improved.

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Molecular tumor boards across Europe are already prescribing your compounds (also beyond approved indiation)

The data exists.

The patients exist.

What's missing?

The infrastructure to turn that into evidence — until now.

Pilot 8 Data Sharing Platform

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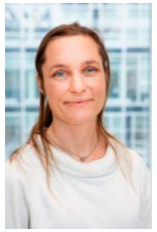
	Logo	Full name	Team Head	Team
ACC	ALLEANZA CONTRO IL CANCRO	Alleanza Contro il Cancro (Italy)	 Ruggero de Maria	Patrizio Giacomin, Ludovica Sierchio, Valentina Trapani, Pelicci Pier Giuseppe, Giovanni Tonon.
OSU	OSLO UNIVERSITY HOSPITAL	Oslo University Hospital (Norway)	 Live Fagereng	Jowita Sleboda Maria Agudo Gabriel Stav

USE CASE 8.1 Expansion of Treatment Space and Cohort Design

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	Logo	**Full name**	**Team Head**	**Team**
UKSH (DE)	UK SH UNIVERSITÄTSKLINIKUM Schleswig-Holstein UCCSH Universitäres Cancer Center Schleswig-Holstein	University Medical Center Schleswig-Holstein, Campus Lübeck	 Nikolas von Bubnoff	Christina Schwitlick Larissa Almeida
RSD (DK)	Region of Southern Denmark	Region of Southern Denmark	 Torben Hansen	Kamilla Arp Brit Sandgren Marianne Holt Hanne Grauslund
MSCI (PL)	Maria Sklodowska-Curie National Research Institute of Oncology	Maria Skłodowska-Curie National Research Institute of Oncology, Warsaw, Poland	 Iwona Ługowska	Izabela Agnieszczak

Use Case 8.2 Managed Entry Agreements

	Logo	Full name	Team Head		Team
Unicaner	unicancer	Unicancer, France		**Christophe Le Tourneau & Maud Kamal**	Venice Hancock Gilles Vassal
LUMC	LUMC Leids Universitair Medisch Centrum	LUMC, Netherlands		Sahar van Waalwijk	Floor de Jong

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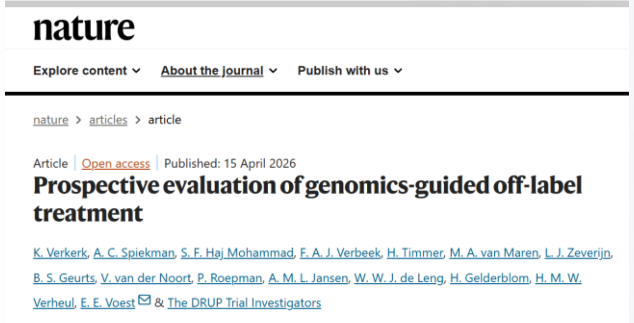
MISSION & VISION

- The evidence generation plan builds on the experience from several successful European PCM pilots to move forward with implementing use of real-world data from patients discussed in molecular tumour boards to support identification of all eligible patients (broader signal seeking also for rare cancers), and deliver actionable insights (analysis of safety and effect) for expanding treatment options and improving patient outcomes by supporting decision-makers (both public and private)

nature medicine

Article https://doi.org/10.1038/s41591-025-03918-x

Genomically matched therapy in advanced solid tumors: the randomized phase 2 ROME trial



nature

Article | Open access | Published: 15 April 2026

Prospective evaluation of genomics-guided off-label treatment

K. Verkerk, A. C. Spiekman, S. F. Haj Mohammad, F. A. J. Verbeek, H. Timmer, M. A. van Maren, L. J. Zeverijn, B. S. Geurts, V. van der Noort, P. Roepman, A. M. L. Jansen, W. W. J. de Leng, H. Gelderblom, H. M. W. Verheul, E. E. Voest ✉ & The DRUP Trial Investigators

PRIME-ROSE
Precision Cancer Medicine Repurposing
System Using Pragmatic Clinical Trials

BoB
Cancer Core Europe

MISSION & VISION

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- **OBJECTIVES**

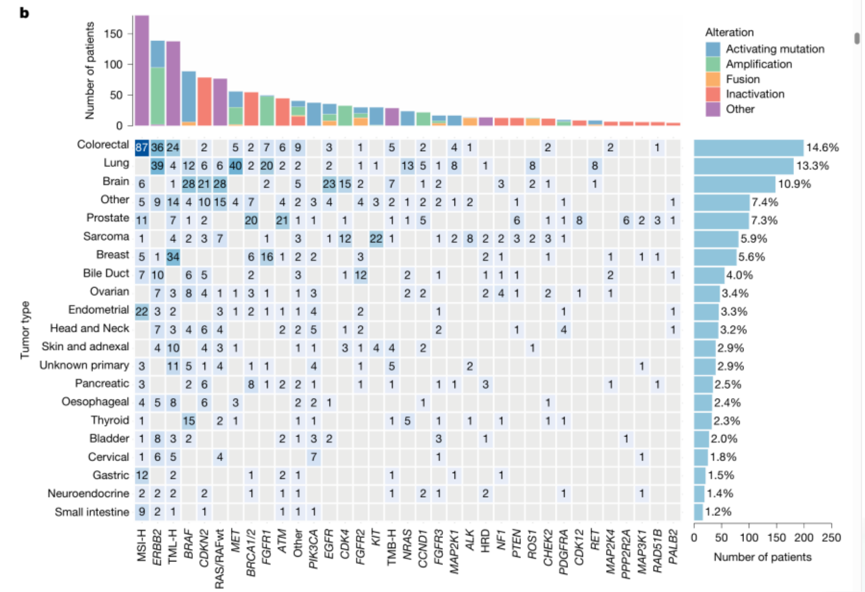
  Objective 1: Develop an evidence generation plan, including a data-sharing platform.

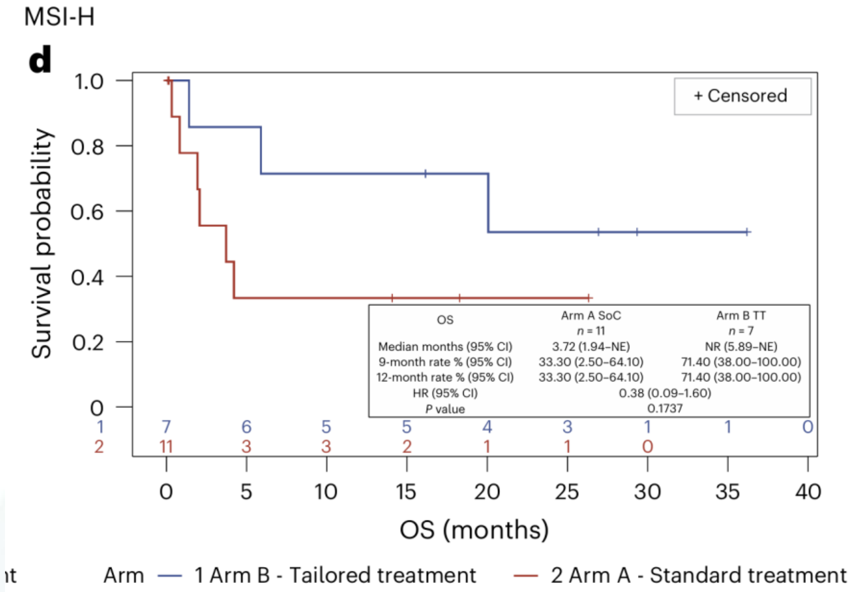
  Objective 2: Demonstrate proof of concept for cross-border recruitment and joint retrospective cohort analysis

  Objective 3: Validate the proof of concept through prospective data collection and subsequent analysis.

WORKPLAN

- **Planned intervention**:
  - Setting up MTB network leveraging the federated data-sharing infrastructure built by Pilot8, including statistical analysis plan and safety profiling strategy
  - **Proof of concept through retrospective analysis** of at least two molecularly defined cohorts
  - Setup of at least one **molecularly defined prospective cohort**
- **Target population**: tumour-agnostic, stratified by molecular basket, indication <u>and/or</u> type of treatment





OS	Arm A SoC n = 11	Arm B TT n = 7
Median months (95% CI)	3.72 (1.94–NE)	NR (5.89–NE)
9-month rate % (95% CI)	33.30 (2.50–64.10)	71.40 (38.00–100.00)
12-month rate % (95% CI)	33.30 (2.50–64.10)	71.40 (38.00–100.00)
HR (95% CI)	0.38 (0.09–1.60)	
P value	0.1737	

Verkerk K, et al 2026

WORKPLAN

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- **Planned intervention**:
  - Setting up MTB network leveraging the federated data-sharing infrastructure built by Pilot8, including statistical analysis plan and safety profiling strategy
  - **Proof of concept through retrospective analysis** of at least two molecularly defined cohorts
  - Setup of at least one **molecularly defined prospective cohort**
- **Target population**: tumour-agnostic, stratified by molecular basket, indication and/or type of treatment
- **Relevant inclusion/exclusion criteria for the first retrospective cohorts may include** *(final Q2 2026)*:
  - Molecular variants: e.g. BRAFamplif., FGFR amplif., HER2, LAG3, MTAPdel
  - Somatic variants: e.g. BRAF mutations (typical and atypical), HER2 mut, KRAS G12C
  - Fusions: e.g. NTRK, RET
  - Off label treatments: e.g. ADC (TDxD, SG), ICI (Nivo/Ipi, Pembro)
  - Exceptional responder cohort: all patients with implemented treatment recommendation and PFS > 6 months
- **Prospective cohort**: In dialogue with MAH: e.g. pan KRAS, retrospective high performing cohort
- **Duration of the pilot**: 48 months — retrospective analyses from M12, prospective cohort from M24

WORKPLAN

M1 M12 M24 M36 M48

Phase 1 · M1–M12

Foundation

Evidence Generation Plan
- Endpoints (abstract ESMO)
- First draft submitted to EMA
- Feedback from stakeholders

Data Sharing Platform
- ✓ Initial sites selected
- Describe the technical infrastructure
- Data-sharing governance
- Onboard first wave

Retrospective cohorts
- ✓ Feasibility survey
- Consent retrospective cohorts

Prospective cohorts cohorts
- Initiate discussion with MAE
- Initiate discussion with payers

Phase 2 · M12–M24

Proof-of-Concept

Evidence Generation Plan
- Patient advocate involvement
- Revised based on first analysis

Data Sharing Platform
- First data transfer
- Onboard second wave

Retrospective cohorts
- SAP
- Federated retrospective analysis

Prospective cohort cohorts
Initiate first prospective cohorts (probably platform trial)

Initiate MAH dialogue

Phase 3 · M24–M36

Industry Collaboration

Evidence Generation Plan
- Federated data analysis
- Meta data published regularly

Data Sharing Platform
- Onboard third wave

Retrospective cohorts

Prospective cohort cohorts
- Initiate more prospective cohorts
- Safety and efficacy reporting

MAH co-design

Phase 4 · M36–M48

Evidence Generation

Evidence Generation Plan
- Meta data published regularly

Data Sharing Platform
- Onboard third wave

Retrospective cohorts

Prospective cohort cohorts
Initiate more prospective cohorts

MS32: contract signed for first industry sponsored treatment cohort (T8.1)

Upstream dependency Pilot 8 federated data sharing platform — required forprospective analysis (M24)

Downstream Use case 8.2 Managed Entry Agreements - Create framework for evidence generation and earlier introduction to healthcare (M48)

PILOT GEOGRAPHIC COVERAGE

Overview of the EOI:

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

Pilot roles

- Primary site: Italy (ACC), Norway (OUS), France (Unicancer), the Netherlands (LUMC)
- Partner/Observer: 27 countries, 47 institutions
- Secondary site (optional):

Strategy for primary site selection

- Wave Implementation based on:
  - Readiness to share data from existing data collection initiatives

PRIVATE SECTOR ENGAGEMENT

We would like to collaborate on		Industry role
Input on the evidence generation plan, including endpoints, statistical analysis plan etc.	→	Review endpoints, output, data governance etc.
Relevant molecular targets for retrospective and prospective evidence-generating cohorts	→	Review candidate cohort shortlist and associated research questions
Cohort design and relevant endpoints for retrospective cohorts	→	Perspective on data aggregation, relevant objectives and endpoints
Cohort design and relevant endpoints for prospective cohorts	→	Perspective on relevant endpoints and schedule of assessments, SAP and safety monitoring

We invite industry partners to 1:1 meetings (online or face-to-face e.g. at ESMO):
Jowita Sleboda: jowita@ous-hf.no
Live Fagereng. gfageren@ous-hf.no
Kjetil Taskén: kjetil.tasken@medisin.uio.no

EXPECTED OUTCOMES & IMPACT

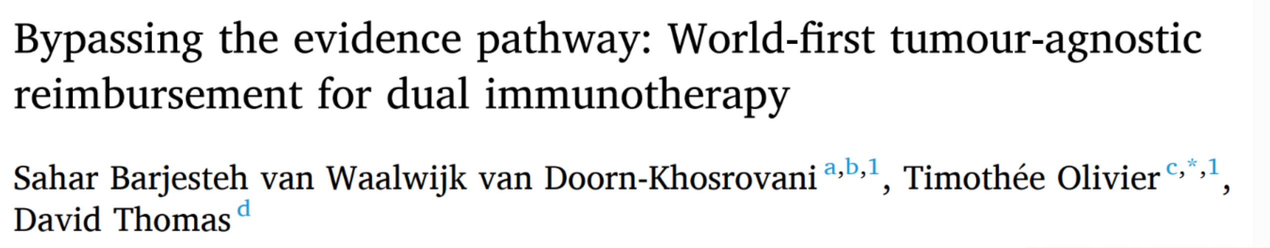
Expected outcomes:

- Evidence generation plan of interest to industry
- Relevant proof-of-concept cohorts
- Increase uptake of new innovative drugs
- Support tumour agnostic approvals

Key Impacts on Stakeholders

- Patients: Access to more treatment options
- HTA, payers and clinicians: learning healthcare system providing structured, iterative data analysis.

EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH



Bypassing the evidence pathway: World-first tumour-agnostic reimbursement for dual immunotherapy

Sahar Barjesteh van Waalwijk van Doorn-Khosrovani [a,b,1], Timothée Olivier [c,*,1], David Thomas [d]

HAS
HAUTE AUTORITÉ DE SANTÉ

Conclusion

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- Message 1: Merging data from ongoing data collection intative
- Message 2: Platform protocol implemented in all MS
- Message 3: Prospective data collection and analysis to support industry decision makers.

We invite industry partners to 1:1 meetings (online or face-to-face e.g. at ESMO):
Jowita Sleboda: jowita@ous-hf.no
Live Fagereng. gfageren@ous-hf.no
Kjetil Taskén: kjetil.tasken@medisin.uio.no


Joint Action Precision Cancer Medicine (JA-PCM) Work Package Treatment Mailing List

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Transversal Pilot: LB-ctDNA

Implementation of ctDNA guided decsion-making across the patient journey

Remond Fijneman & Claus Andersen

AARHUS
UNIVERSITY
HOSPITAL

NETHERLANDS
CANCER
INSTITUTE
ANTONI VAN LEEUWENHO

Co-funded by
the European Union

ctDNA molecular diagnostics =>

better diagnostics =>

better surveillance, better treatment =>

More cure and better care for patients with cancer

=> *implement ctDNA-guided decision-making*

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

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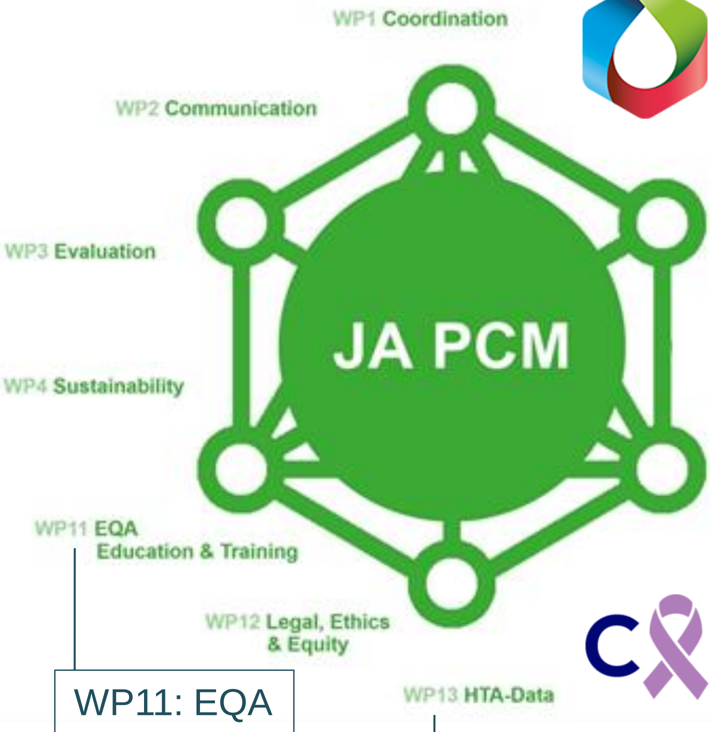
LEADS

Remond Fijneman (NKI, NL)
Connected to Arm 2 (WP7)

Claus Andersen (AUH, DK)
Connected to Arm 3 (WP10)

PARTNERS



WP11: EQA

WP13: HTA-Data

ELBS

EUnetCCC
ONEFORALL
Co-funded by the European Union

SPARC
JA PCM

CANDLE

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

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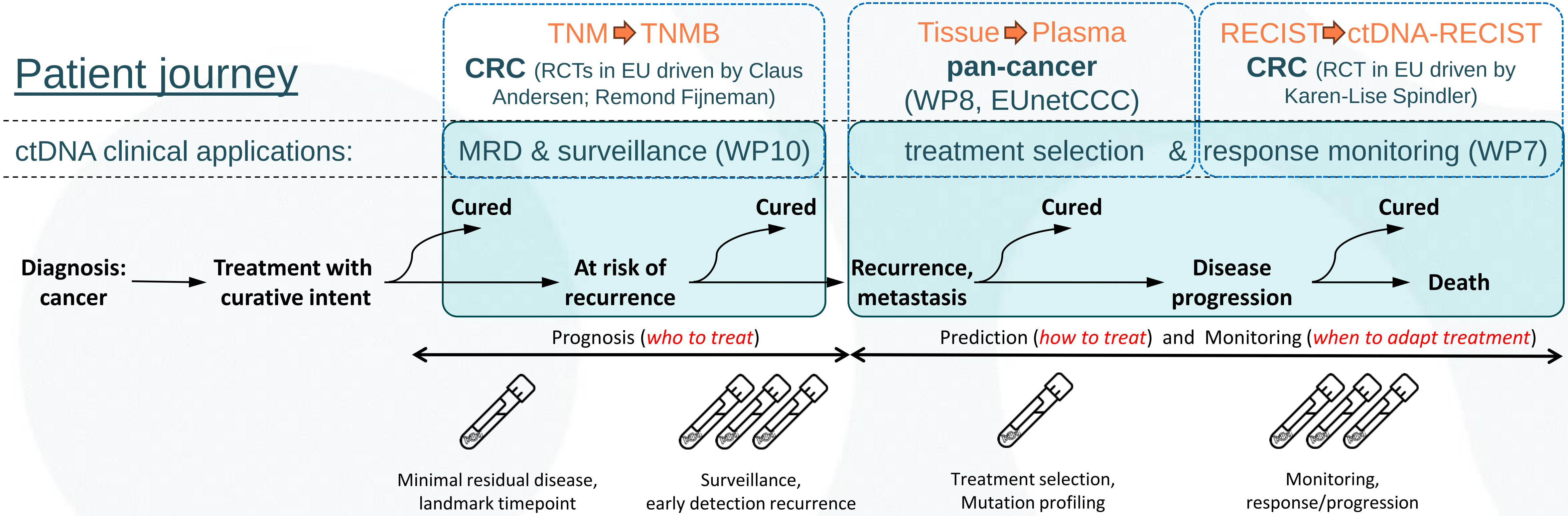

Patient journey

ctDNA clinical applications:

TNM ➔ TNMB
CRC (RCTs in EU driven by Claus Andersen; Remond Fijneman)
MRD & surveillance (WP10)

Tissue ➔ Plasma
pan-cancer (WP8, EUnetCCC)
treatment selection &

RECIST ➔ ctDNA-RECIST
CRC (RCT in EU driven by Karen-Lise Spindler)
response monitoring (WP7)

Diagnosis: cancer → **Treatment with curative intent** → **Cured** / **At risk of recurrence** → **Cured** / **Recurrence, metastasis** → **Cured** / **Disease progression** → **Cured** / **Death**

Prognosis (*who to treat*)

Prediction (*how to treat*) and Monitoring (*when to adapt treatment*)

Minimal residual disease, landmark timepoint

Surveillance, early detection recurrence

Treatment selection, Mutation profiling

Monitoring, response/progression

WORKPLAN – transversal LB pilot

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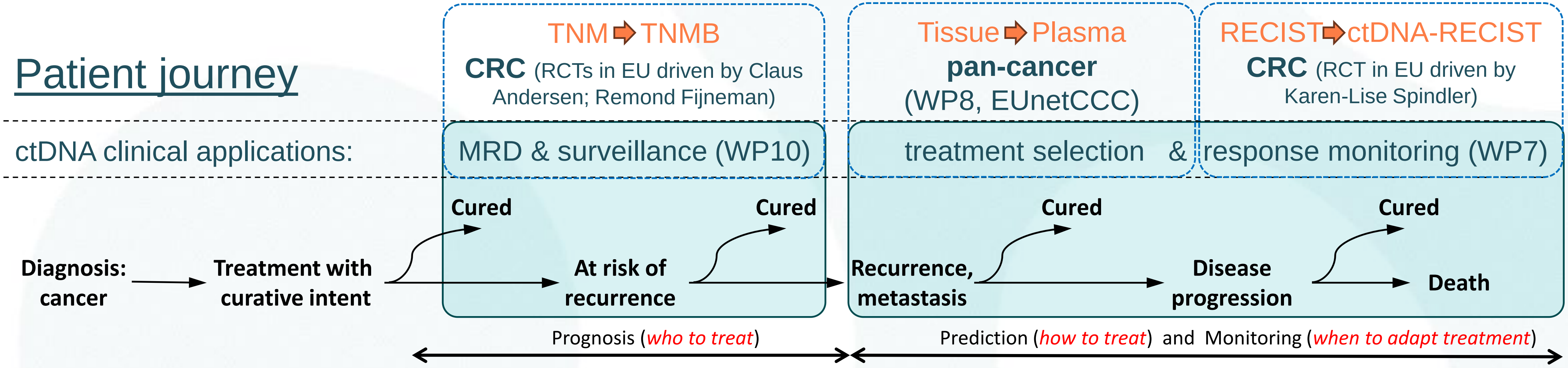

Patient journey

TNM → TNMB
CRC (RCTs in EU driven by Claus Andersen; Remond Fijneman)

Tissue → Plasma
pan-cancer
(WP8, EUnetCCC)

RECIST → ctDNA-RECIST
CRC (RCT in EU driven by Karen-Lise Spindler)

ctDNA clinical applications: MRD & surveillance (WP10) | treatment selection & response monitoring (WP7)

Prognosis (*who to treat*)

Prediction (*how to treat*) and Monitoring (*when to adapt treatment*)

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**

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LB CTDNA PILOT GEOGRAPHIC COVERAGE

Overview of the Expression of Interest:

- 51 organisations
- 41 ‘participating units’
- 21 countries

Country (n=21)	Organizations (n=51)
Belgium	Jessa Hospital, KU Leuven, University Hospital of Antwerp, Institut Jules Bordet
Croatia	Institut Ruđer Bošković, Sestre Milosrdnice University Hospital Center
Cyprus	Bank of Cyprus Oncology Center
Denmark	Copenhagen University Hospital, Lillebaelt, Hospital, Zealand University Hospital, Aalborg University Hospital, Aarhus University Hospital
Estonia	Tartu University Hospital, North-Estonian Medical Centre
Finland	University of Eastern Finland, TAYS Cancer Centre
France	NOVA consortium
Germany	University Medical Center Hamburg Eppendorf, University Medical Center Schleswig-Holstein, University of Tübingen, University Medical Center Rostock
Greece	National Hellenic Research Foundation (NHRF) and the Medical School of National and Kapodistrian University of Athens
Ireland	Beaumont RCSI Cancer Centre, Cork University Hospital, Trinity St James Cancer Centre, St. Vincent's University Hospital
Italy	Policlinico Universitario Agostino Gemelli, Regina Elena Institute
Lithuania	National Cancer Institute, Kauno Klinikos University Hospital
Luxembourg	Centre Hospitalier de Luxembour, Institut National du Cancer, Laboratoire National de Santé, Luxembourg Institute of Health
Malta	Mater Dei Hospital
Netherlands	Netherlands Cancer Institute
Norway	Haukeland University Hospital, Oslo University Hospital
Portugal	Ipatimup, Portuguese Institute of Oncology
Romania	Medfuture, Genomics Research and Development Institute
Serbia	IORS Belgrade
Spain	Hospital Clínico Universitario Lozano Blesa, MBU, Hospital la Fe, Consorcio Centro de Investigacion Biomedica en Red, Vall d'Hebron Institute of Oncology
Sweden	Karolinska Institutete, Karolinska University Hospital

LB CTDNA PILOT GEOGRAPHIC COVERAGE

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EOI Profiling:
- 46 organisations
- 19 countries

Pan-cancer

EOI MRD:
- 34 organisations
- 18 countries

Colorectal cancer

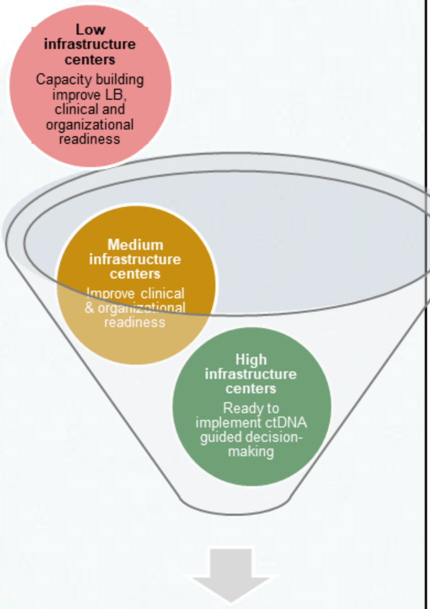
EOI Surveillance:
- 32 organisations
- 18 countries

Colorectal cancer

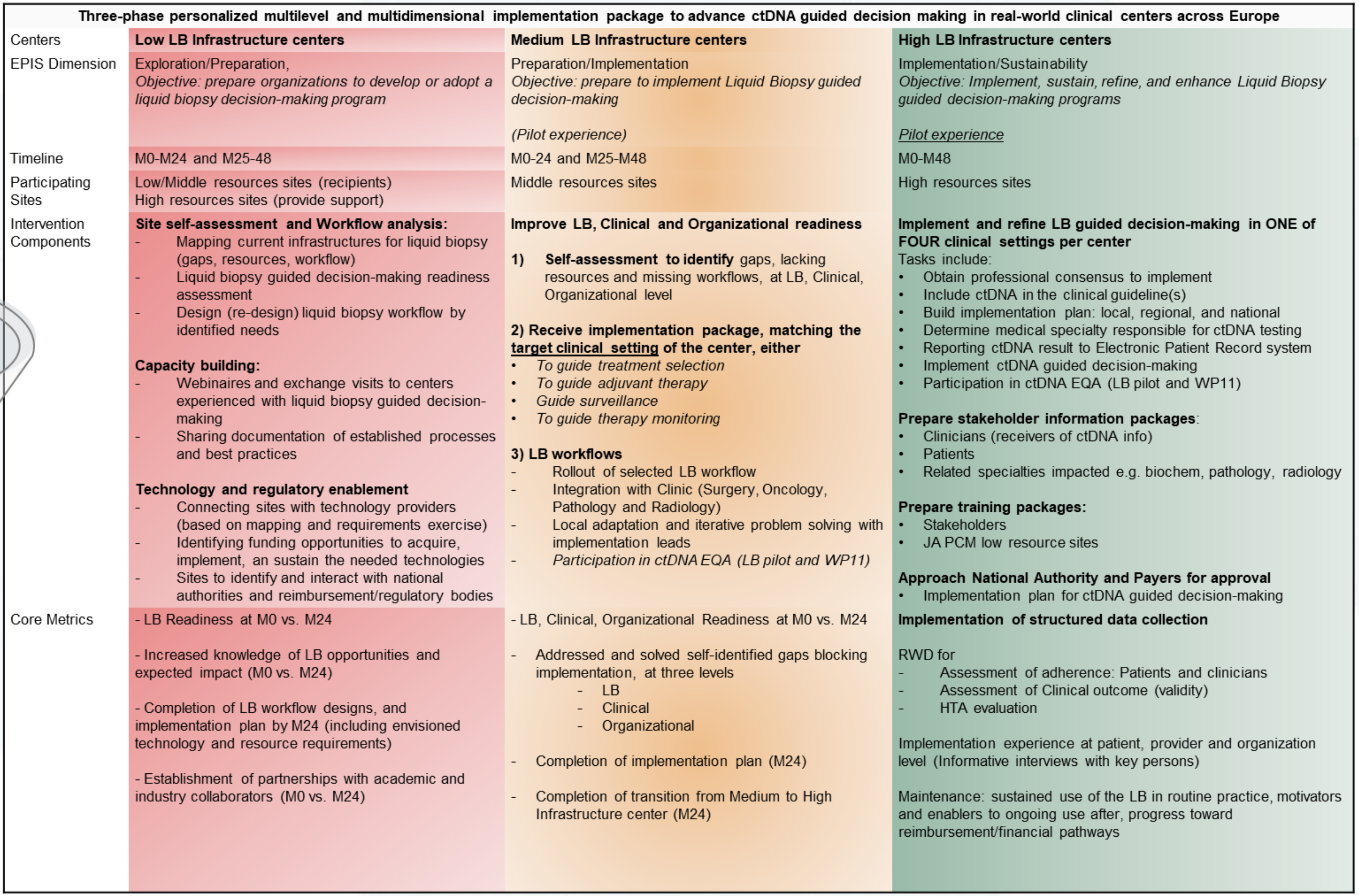
EOI Monitoring:
- 29 organisations
- 16 countries

Colorectal cancer

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 target clinical setting 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

Capacity building

Description	Need	Status without contributions	Added value of the contributions	Absorption capacity
Circulating tumour DNA (ctDNA) refers to small fragments of tumour DNA that circulate in the blood. Through liquid biopsy analysis of ctDNA, clinicians can monitor treatment response, detect minimal residual disease, and identify relapse earlier, often before it becomes visible on imaging. This enables more timely, personalised, and adaptive treatment decisions across the entire cancer care pathway. Led by the Netherlands Cancer Institute and Aarhus University Hospital (Denmark), the pilot has attracted strong pan-European interest from >50 institutions across 21 countries. The LB-ctDNA pilot addresses 4 different clinical settings where ctDNA is highly likely soon to become "standard" clinical practice: 1) in the metastatic setting use ctDNA mutational profiling to guide choice of therapy (pan-cancer), 2) after operation for colorectal cancer (CRC) use ctDNA analysis to guide the adjuvant therapy decision, 3) after end-of-primary CRC treatment use serial ctDNA analysis for recurrence surveillance, and 4) in metastatic CRC use ctDNA to monitor therapy response (ctDNA-RECIST).	From Industry we need ctDNA assays for a) detecting targetable genomic features (for guiding therapy decisions) b) ultra sensitive and specific ctDNA detection (for guiding adjuvant and surveillance) c) precise quantification of the ctDNA level (for therapy monitoring). For b) and c) both tumor-informed and tumor-agnostic assays are welcomed. Moreover, we welcome any industry contributions that enable and facilitate sustainable and scalable solutions for implementation of liquid biopsy ctDNA testing, including blood collection tubes and providers of cfDNA extraction kits. For the private sector it is important to demonstrate clinical validity and clinical utility, to pave the path to implementation of ctDNA-guided decision-making, including paving the path to reimbursement of ctDNA testing.	Without contribution, 21 cancer centers with high-readiness level can perform small Real World Data studies in one of 4 clinical settings. Other centers are getting prepared but will not perform ctDNA testing in clinical practice. This will limit the progress that can be made towards ctDNA implementation across many centers in Europe. In particular, this will be a missed opportunity to initiate and further develop ctDNA testing and implementation at centers that currently invest time and efforts to explore (with the help of the LB ctDNA pilot) what solutions fit best with their local/regional/national setting.	Contribution, will enable centers (n>20) with medium-readiness level to initiate ctDNA testing in clinical practice. This will enable them to build up capacity and progress towards ctDNA implementation in compliance with their regional/ national setting. Participation from the additional sites/countries will expand the real-world evidence on ctDNA-guided decision-making generated in the pilot, directly relevant to HTA processes and reimbursement frameworks across consortium members. Furthermore, more centers/countries will strengthen our ability to build an EU-wide policy for integration of ctDNA guided-decision making into standard oncology care.	Involving industry will not increase the number of centers in the LB-ctDNA pilot. However, the availability of industry contributions, like the requested ctDNA assays, will increase the number of centers getting real-life experience with harmonized implementation of ctDNA guided decision making. Accordingly, industry participation will accelarate rather than delay EU-wide ctDNA implementation. However, the coordination task will undoubtly increase, and there is some risk that industry funded centers will start later, than the JAPCM funded centers, due to the time it will take to establish the necessary agreements with the industry partners.

PRIVATE SECTOR ENGAGEMENT

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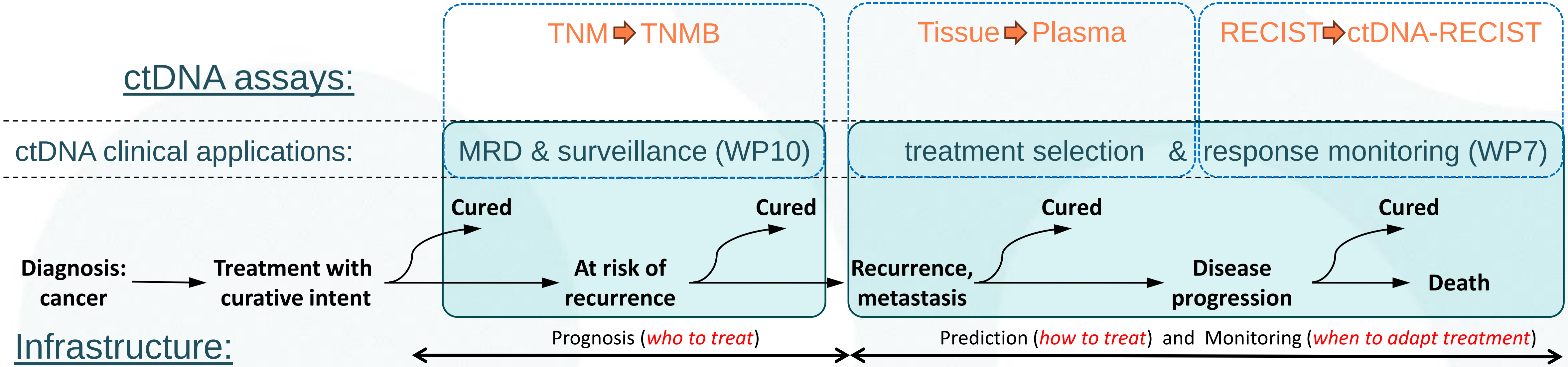


ctDNA assays:

TNM → TNMB

Tissue → Plasma

RECIST → ctDNA-RECIST

ctDNA clinical applications:

MRD & surveillance (WP10)

treatment selection & response monitoring (WP7)

Prognosis (*who to treat*)

Prediction (*how to treat*) and Monitoring (*when to adapt treatment*)

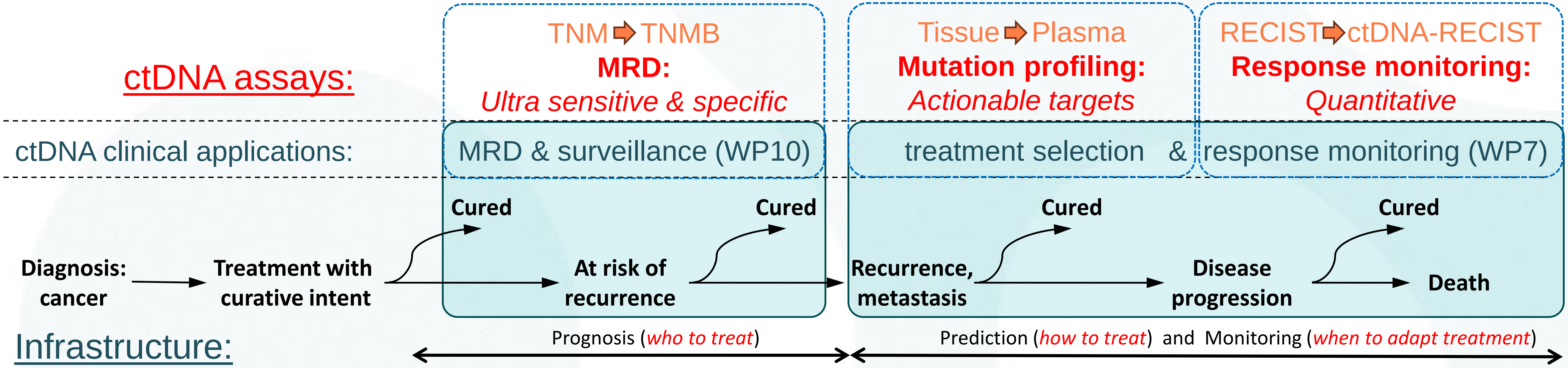
Infrastructure:

Technical:

Clinical:

Organisational:

PRIVATE SECTOR ENGAGEMENT



ctDNA assays:

TNM ➡ TNMB
MRD:
Ultra sensitive & specific

Tissue ➡ Plasma
Mutation profiling:
Actionable targets

RECIST ➡ ctDNA-RECIST
Response monitoring:
Quantitative

ctDNA clinical applications: MRD & surveillance (WP10) | treatment selection & response monitoring (WP7)

Prognosis (*who to treat*)

Prediction (*how to treat*) and Monitoring (*when to adapt treatment*)

Infrastructure:

Technical:

Clinical: * ctDNA assays (*suited for intended use*)

Organisational:

PRIVATE SECTOR ENGAGEMENT

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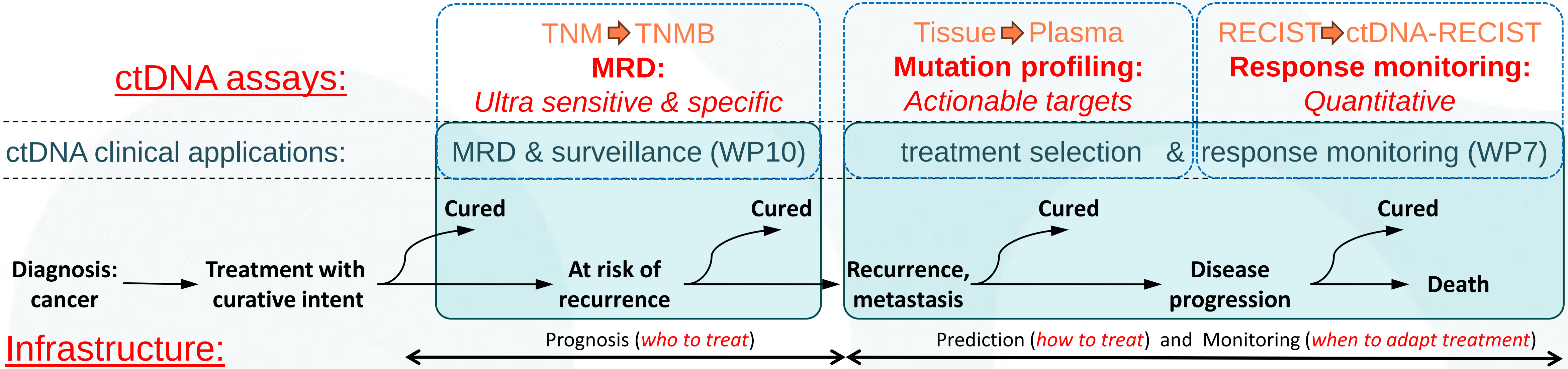
ctDNA assays:



TNM ⇨ TNMB
MRD:
Ultra sensitive & specific

Tissue ⇨ Plasma
Mutation profiling:
Actionable targets

RECIST ⇨ ctDNA-RECIST
Response monitoring:
Quantitative

ctDNA clinical applications: MRD & surveillance (WP10) | treatment selection & response monitoring (WP7)

Prognosis (*who to treat*)

Prediction (*how to treat*) and Monitoring (*when to adapt treatment*)

Infrastructure:

Technical:
- Cell stabilizing blood collection tubes
- cfDNA extraction kits and equipment
- Sequencing technologies

Clinical:
- ctDNA assays (*suited for intended use*)

Organisational:

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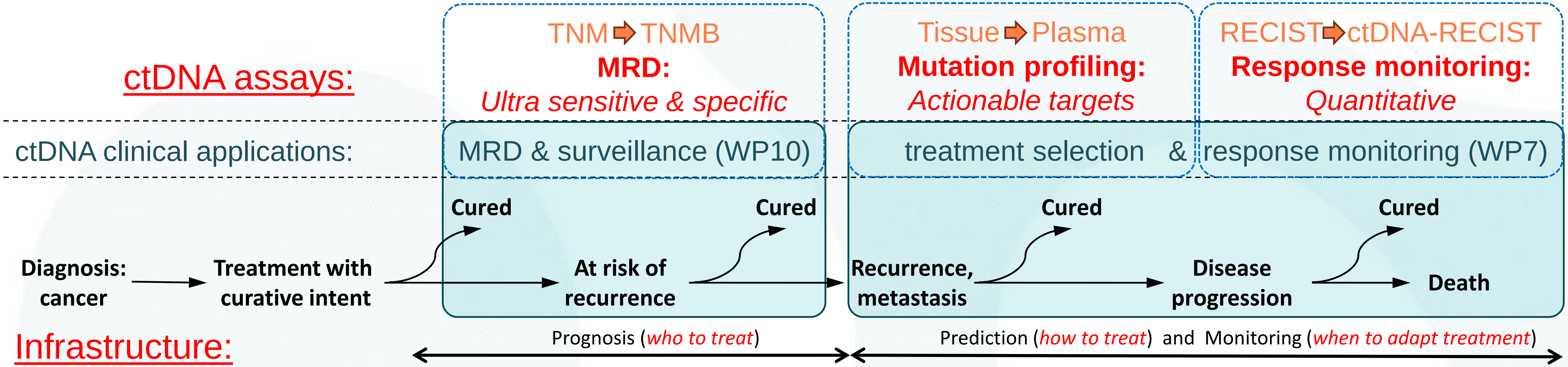
PRIVATE SECTOR ENGAGEMENT



ctDNA assays:

	TNM ➡ TNMB **MRD:** *Ultra sensitive & specific*	Tissue ➡ Plasma **Mutation profiling:** *Actionable targets*	RECIST ➡ ctDNA-RECIST **Response monitoring:** *Quantitative*
ctDNA clinical applications:	MRD & surveillance (WP10)	treatment selection &	response monitoring (WP7)

Infrastructure:

Technical: * Cell stabilizing blood collection tubes
* cfDNA extraction kits and equipment
* Sequencing technologies

Clinical: * ctDNA assays (*suited for intended use*)
* Support for initiation and execution of clinical studies (*infrastructure patient accrual*)
* Support for data collection and integration (*MTB, HTA*)

Organisational:

PRIVATE SECTOR ENGAGEMENT

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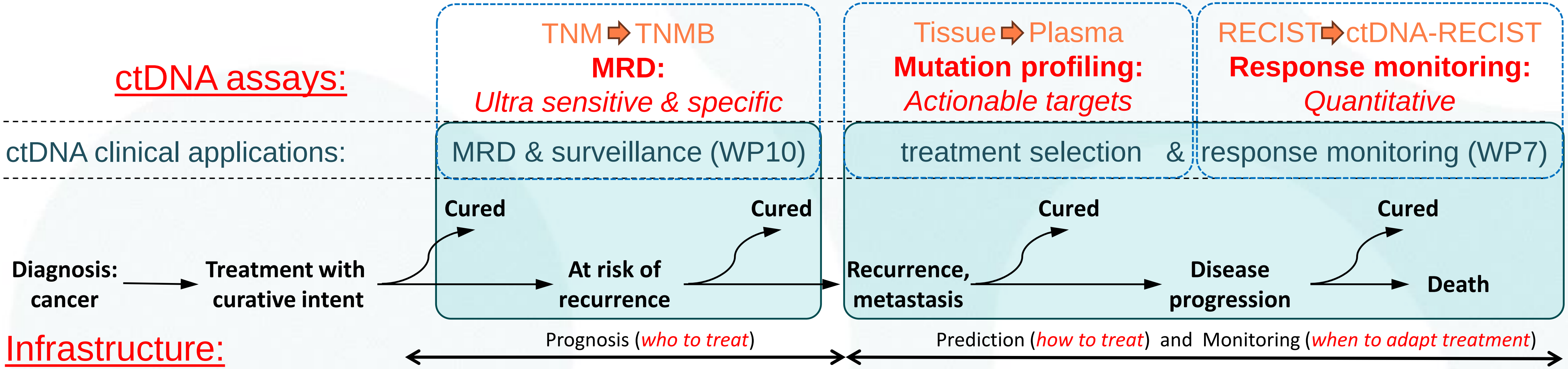

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Mutation profiling:
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Prognosis (*who to treat*)

Prediction (*how to treat*) and Monitoring (*when to adapt treatment*)

Infrastructure:

Technical: * Cell stabilizing blood collection tubes
* cfDNA extraction kits and equipment
* Sequencing technologies

Clinical: * ctDNA assays (*suited for intended use*)
* Support for initiation and execution of clinical studies (*infrastructure patient accrual*)
* Support for data collection and integration (*MTB, HTA*)

Organisational: Make ctDNA testing **available, accessible, affordable** for patients with cancer,
* Participation stakeholder community (*through ELBS, BLOODPAC, JAPCM, ..*)
* Support for health technology assessment (*demonstrate clinical utility*)
* Reimbursement enablers (*e.g. health insurance companies*)

Organisational needs pending readiness level per clinical application

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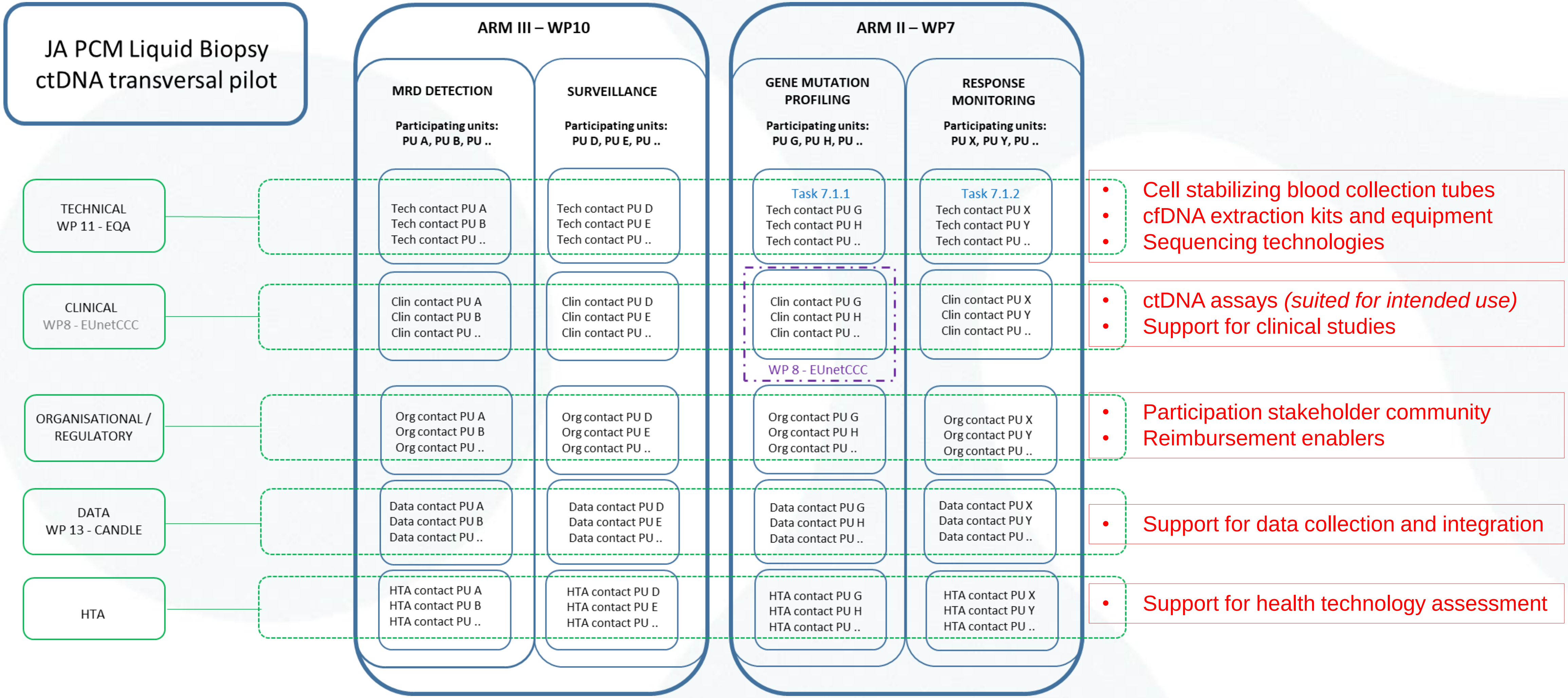
MRD
34 organisations
18 countries

Surveillance
32 organisations
18 countries

Mutation Profiling
46 organisations
19 countries

Monitoring
29 organisations
16 countries



JA PCM Liquid Biopsy ctDNA transversal pilot

	ARM III – WP10		**ARM II – WP7**	
	MRD DETECTION **Participating units:** **PU A, PU B, PU ..**	**SURVEILLANCE** **Participating units:** **PU D, PU E, PU ..**	**GENE MUTATION PROFILING** **Participating units:** **PU G, PU H, PU ..**	**RESPONSE MONITORING** **Participating units:** **PU X, PU Y, PU ..**
TECHNICAL WP 11 - EQA	Tech contact PU A Tech contact PU B Tech contact PU ..	Tech contact PU D Tech contact PU E Tech contact PU ..	Task 7.1.1 Tech contact PU G Tech contact PU H Tech contact PU ..	Task 7.1.2 Tech contact PU X Tech contact PU Y Tech contact PU ..
CLINICAL WP8 - EUnetCCC	Clin contact PU A Clin contact PU B Clin contact PU ..	Clin contact PU D Clin contact PU E Clin contact PU ..	Clin contact PU G Clin contact PU H Clin contact PU .. WP 8 - EUnetCCC	Clin contact PU X Clin contact PU Y Clin contact PU ..
ORGANISATIONAL / REGULATORY	Org contact PU A Org contact PU B Org contact PU ..	Org contact PU D Org contact PU E Org contact PU ..	Org contact PU G Org contact PU H Org contact PU ..	Org contact PU X Org contact PU Y Org contact PU ..
DATA WP 13 - CANDLE	Data contact PU A Data contact PU B Data contact PU ..	Data contact PU D Data contact PU E Data contact PU ..	Data contact PU G Data contact PU H Data contact PU ..	Data contact PU X Data contact PU Y Data contact PU ..
HTA	HTA contact PU A HTA contact PU B HTA contact PU ..	HTA contact PU D HTA contact PU E HTA contact PU ..	HTA contact PU G HTA contact PU H HTA contact PU ..	HTA contact PU X HTA contact PU Y HTA contact PU ..

- Cell stabilizing blood collection tubes
- cfDNA extraction kits and equipment
- Sequencing technologies

- ctDNA assays *(suited for intended use)*
- Support for clinical studies

- Participation stakeholder community
- Reimbursement enablers

- Support for data collection and integration

- Support for health technology assessment

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**

Conclusion

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- 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 *– in collaboration with the private sector.*

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WP6 Pilot: Polygenic Risk Scores

Jeroen van Rooij / Marjanka Schmidt

Erasmus MC

NETHERLANDS
CANCER
INSTITUTE
ANTONI VAN LEEUWENHO

Co-funded by
the European Union

Polygenic scores can help personalize screening of common cancers.

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

Pilot WP6: Polygenic Risk Scores

	Logo	Full name	Team Head		Team
EMC	Erasmus MC	Erasmus MC, Rotterdam, NL		Jeroen van Rooij Assistant Professor	Danielle Bosch, Maartje Hooning, Margriet Collee, Rick van Minkelen, Andre Uitterlinden
NKI	NETHERLANDS CANCER INSTITUTE ANTONI VAN LEEUWENHO	Netherlands Cancer Institute, Amsterdam,NL)		Marjanka Schmidt Professor	Beatriz Carvalho Irma van de Beek Caroline Drukker Roelof Koster Margreet Ausems

MISSION & VISION

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Improve early cancer detection by implementing polygenic risk scores

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 - Study Design

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

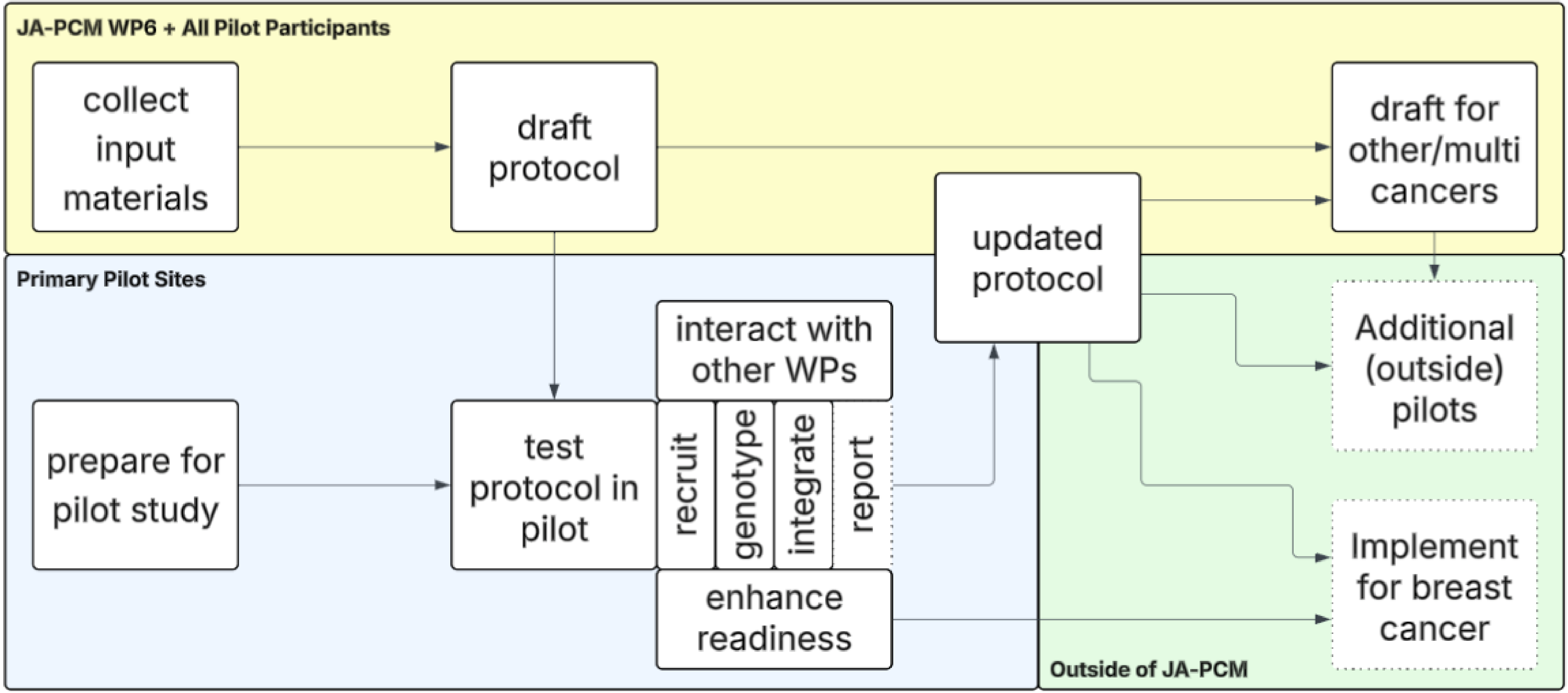
- **Target population:** at least 100 healthy adult female relatives of breast cancer patients, undergoing CanRisk assessment to guide population screening advice, at each pilot site

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

- **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.

WORKPLAN - Structure

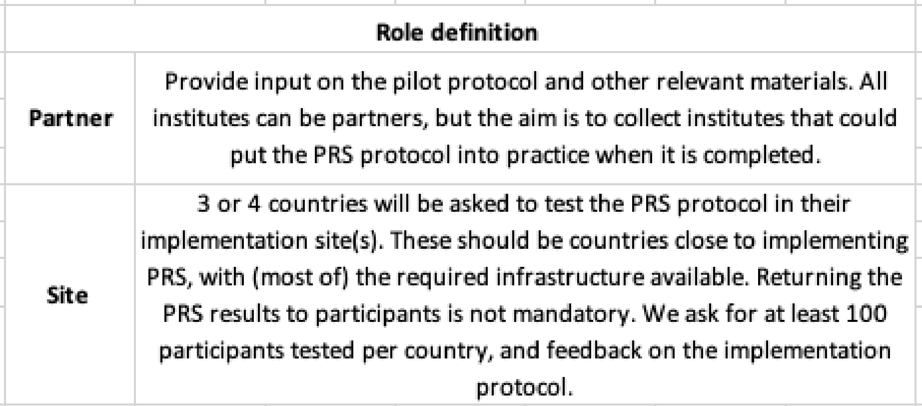


PILOT GEOGRAPHIC COVERAGE

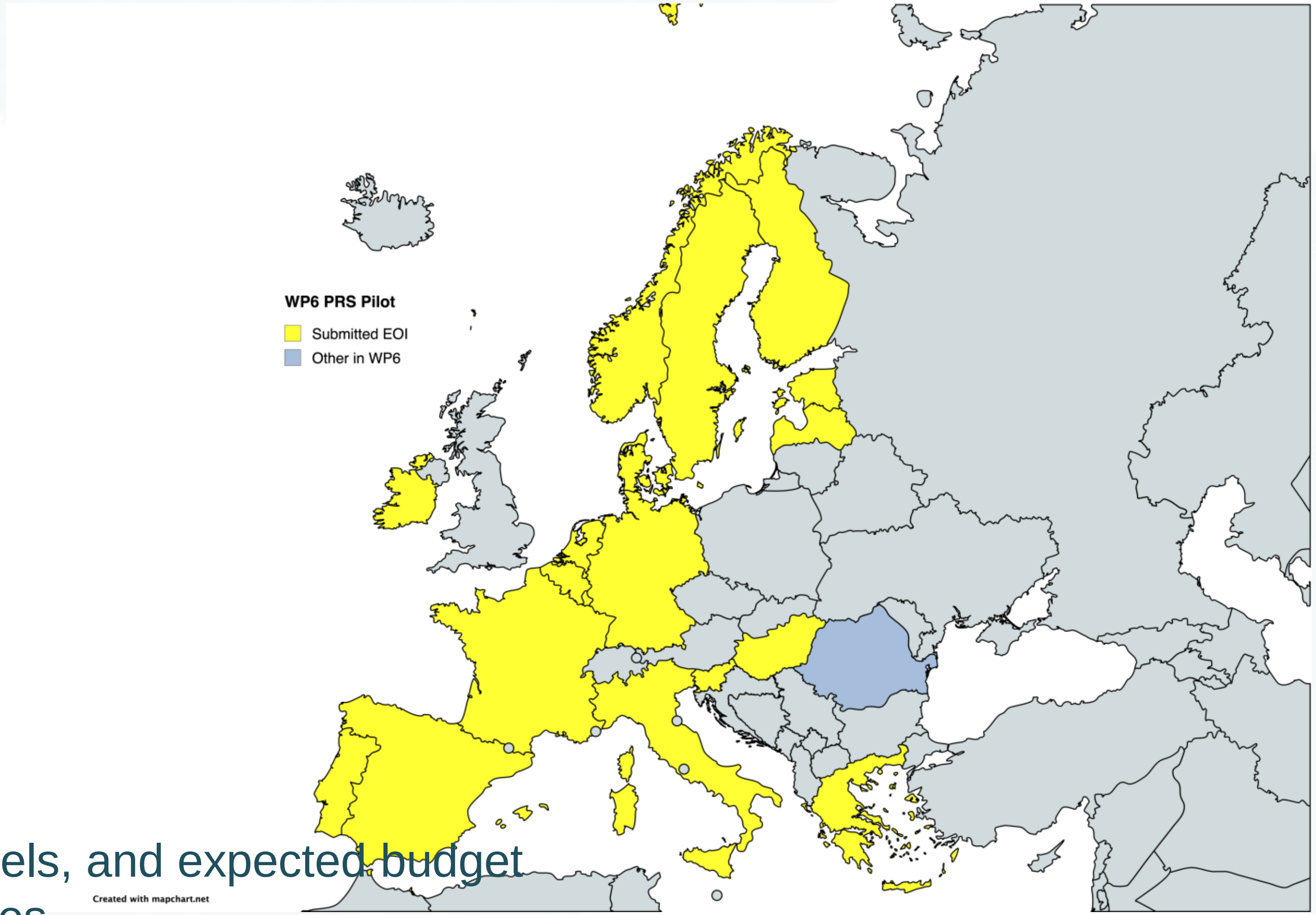
Overview of the EOI exercise :

- 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

- Used a survey to determine readiness levels, and expected budget
- 20 potential primary sites, from 13 countries
- Due to budget constrains, currently limiting to 7-9 sites from 5 countries
- Final budget & design drafting ongoing

PRIVATE SECTOR ENGAGEMENT

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We received more interest than this pilot (budget) can sustain. Large part of the costs are the germline genetic measurements. A smaller set of costs is on the IT side, processing the data and calculating the PRS.

Some sites integrate PRS into their clinical genetic testing (mostly sequencing, panels extended with PRS variants, or WGS), others use arrays. Especially Sequencing is expensive and not always reimbursed.

The pilot focuses on implementation with a modest number of samples. Upscaling this approach to more samples, outcomes, or institutes, will largely depend on the costs of the genetic measurements.

We need:

- **Side by side comparisons of the technology options, in terms of performance, and costs**
- **Clinically certified genetic measurements, PRS calculation, CanRisk integration in clinical workflow**
- **Reimbursement strategies, including guidance on which technology to use in which setting**

Industry can provide input on these items and contribute by *1) running pilot samples with additional technologies*, *2) provide input on current and optimized performance and cost estimates*, *3) assist in acquiring clinical accreditation for PRS tests*, *4) data processing, integration and interpretation pipelines*, *5) other*.

EXPECTED OUTCOMES & IMPACT

Expected outcomes:

- **Side-by-side comparison of technologies, versus only one technology run**
- **Estimates on project efficacy gains and cost projections of technologies**
- **Pathway towards clinically accredited and reimbursed PRS313+CanRisk testing**

Key Impacts on Stakeholders

- Healthcare professionals & researchers: **access to tools & technology for PRS testing**
- Healthcare policymakers: **detailed information needed for HTA & implementation strategies**
- Cancer patients – Citizens: **more accurate early detection for common cancers**
- Private Sector: **market for germline genetic testing in cancer hugely increased (potentially)**

Conclusion

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Working towards harmonized PRS implementation protocol

Start with breast cancer in CanRisk, expand to other cancers after

Subset of partners will validate pilot protocol

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Transversal Pilot: CPS Compass

Personalized management of cancer predisposition syndromes across the patient journey

J. Matt McCrary, PhD

Uniklinikum Würzburg

Co-funded by
the European Union

Context

Up to 18% of cancers in pediatric, adolescent, and young adult (CAYA) patients are estimated to be derived from a germline cancer predisposition syndrome (CPS)

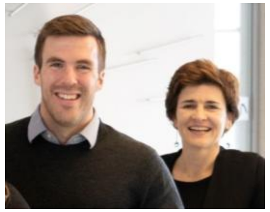
Presents opportunities for targeted management, but only with accurate and efficient diagnostics

can.heal

Pediatric ALL Use Case – *~50% of germline CPS not identified using current screening approaches*

Diagnostic advantages to genotype-first approach

Transversal Pilot – CPS Compass

	Logo	Full name	Team Head		Team
UKW	Uniklinikum Würzburg	University Hospital Würzburg		Dr. J. Matt McCrary Prof. Anke K. Bergmann	Dr. Nele Loecher Marie Schnürer
SC	sciensano	Sciensano		Prof. Hélène A. Poirel	Dr. Valeria Friere

MISSION & VISION

JA PCM
Joint Action Personalised Cancer Medicine

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’

MISSION & VISION

JA PCM
Joint Action Personalised Cancer Medicine

MISSION

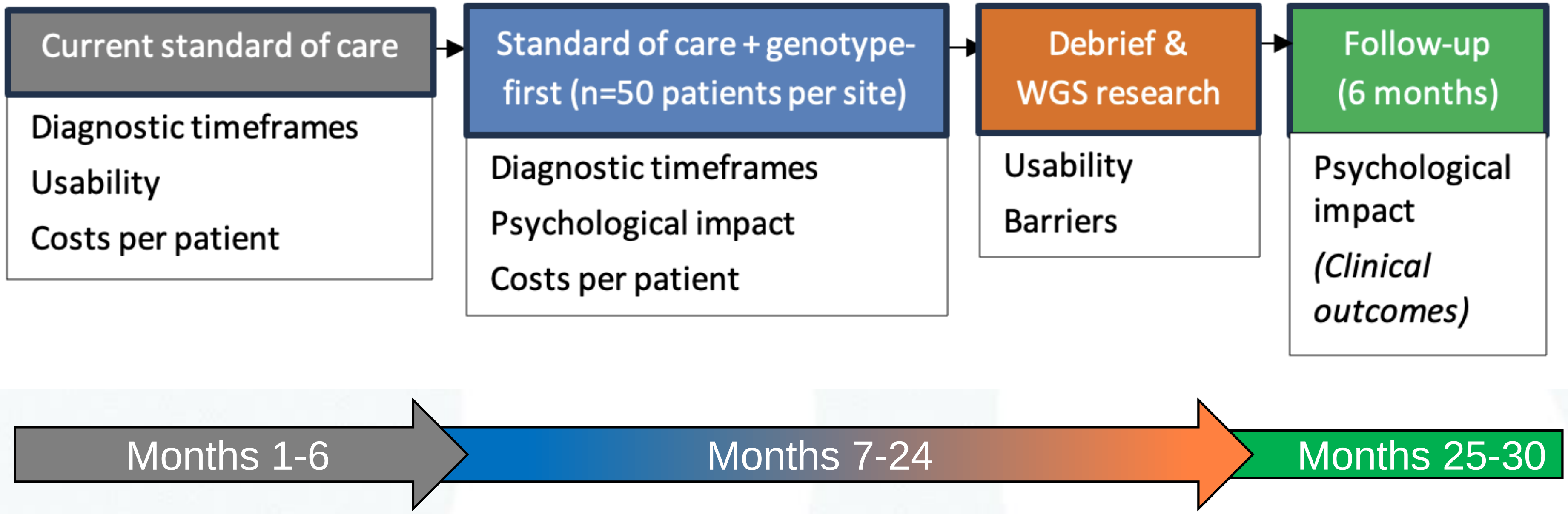
- Build capacity for efficient cancer predisposition syndrome (CPS) diagnostics & access to timely genetic counselling to expand possibilities for personalized prevention / treatment / survivorship management

OBJECTIVES

1. Evaluate the feasibility and cost-effectiveness of a genotype-first approach to CPS diagnostics performed at diagnosis ← ***OPPORTUNITY/NEED FOR INDUSTRY SUPPORT***

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

WORKPLAN



Current standard of care
- Diagnostic timeframes
- Usability
- Costs per patient

Standard of care + genotype-first (n=50 patients per site)
- Diagnostic timeframes
- Psychological impact
- Costs per patient

Debrief & WGS research
- Usability
- Barriers

Follow-up (6 months)
- Psychological impact
- *(Clinical outcomes)*

Months 1-6 → Months 7-24 → Months 25-30

Target population: Paediatric and AYA cancer patients (age 39 or below)

Relevant inclusion/exclusion criteria: Cancer diagnosis in target population

Duration of the pilot: 2 years (*2.5 years incl. follow-up data*)

PILOT GEOGRAPHIC COVERAGE

Overview of the Expression of Interest:

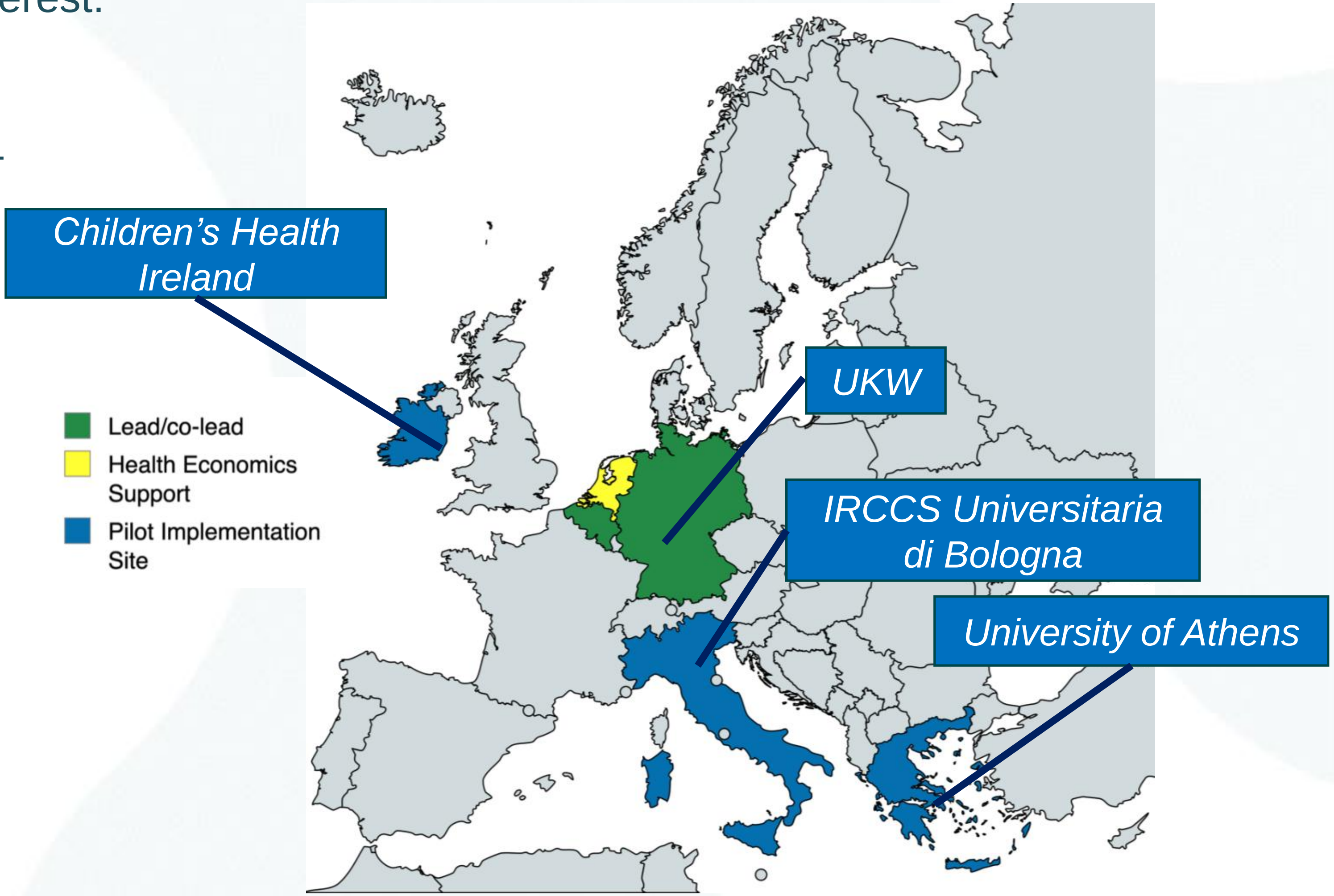
- Total number of sites: 20
- Number of countries: 10
- Number of institutions: 14

PILOT GEOGRAPHIC COVERAGE

Overview of the Expression of Interest:

- Total number of sites: 20
- Number of countries: 10
- Number of institutions: 14

Costs for germline WGS at diagnosis from EU grant

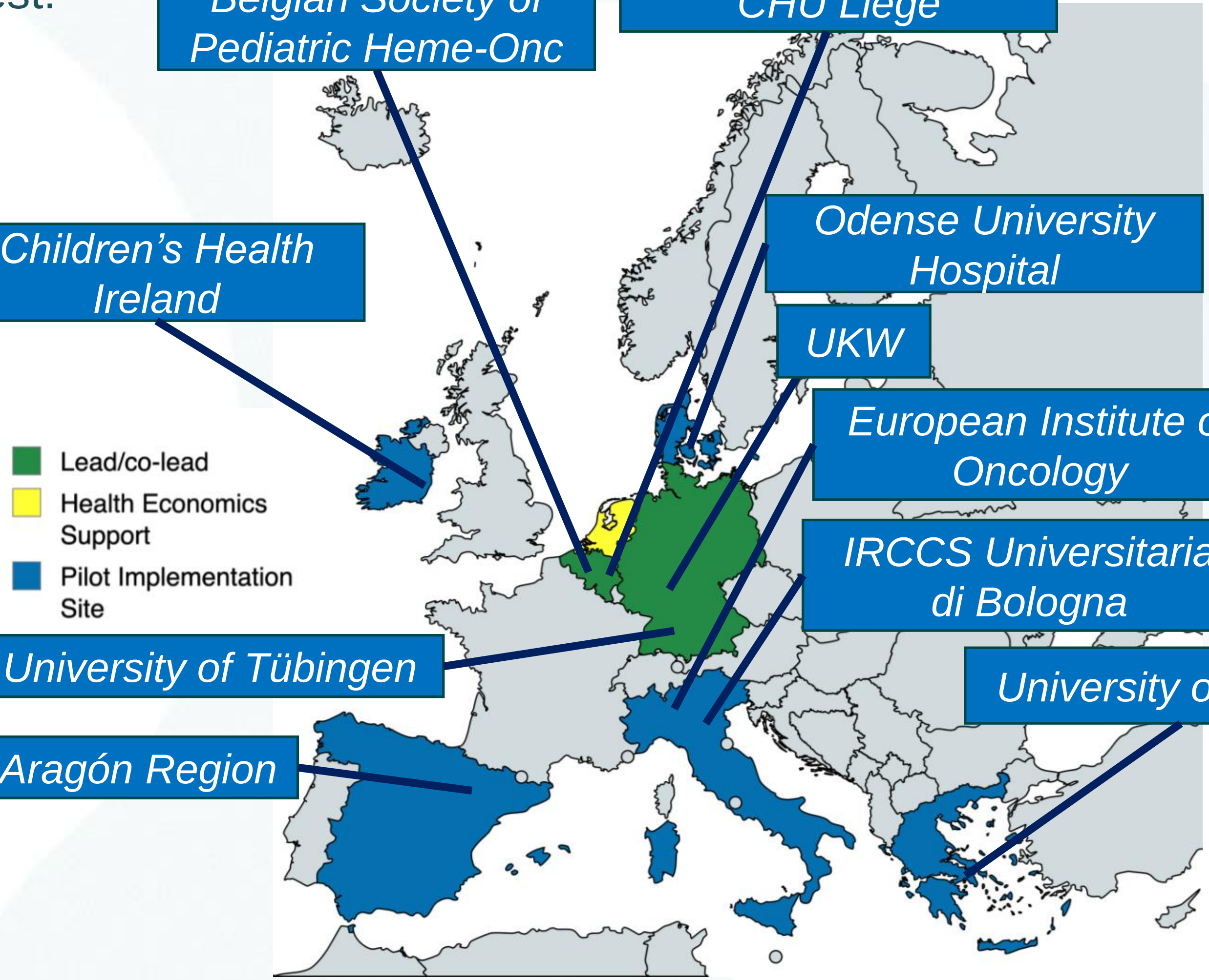


PILOT GEOGRAPHIC COVERAGE

Overview of the Expression of Interest:

- Total number of sites: 20
- Number of countries: 10
- Number of institutions: 14

Prospective – contributions for germline WGS at diagnosis from private sector partners



Belgian Society of Pediatric Heme-Onc

CHU Liége

Odense University Hospital

Children's Health Ireland

UKW

European Institute of Oncology

IRCCS Universitaria di Bologna

University of Tübingen

University of Athens

Aragón Region

PILOT DEMOGRAPHIC COVERAGE

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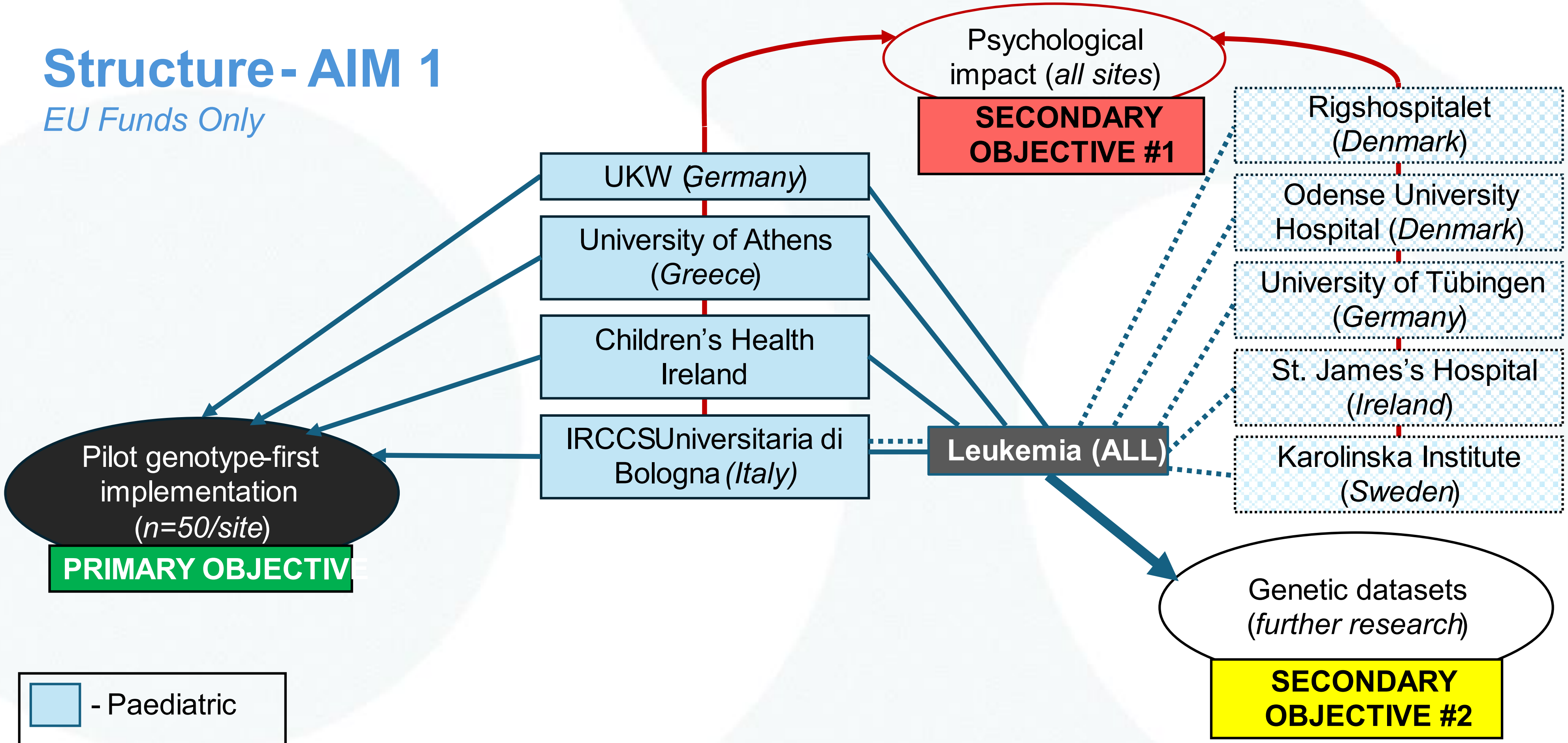
Structure - AIM 1

EU Funds Only



Psychological impact (*all sites*)

SECONDARY OBJECTIVE #1

UKW (*Germany*)

University of Athens (*Greece*)

Children's Health Ireland

IRCCS Universitaria di Bologna (*Italy*)

Leukemia (ALL)

Rigshospitalet (*Denmark*)

Odense University Hospital (*Denmark*)

University of Tübingen (*Germany*)

St. James's Hospital (*Ireland*)

Karolinska Institute (*Sweden*)

Pilot genotype-first implementation (*n=50/site*)

PRIMARY OBJECTIV

Genetic datasets (*further research*)

SECONDARY OBJECTIVE #2

🟦 - Paediatric
🟪 - Adolescent
🟧 - Young Adult

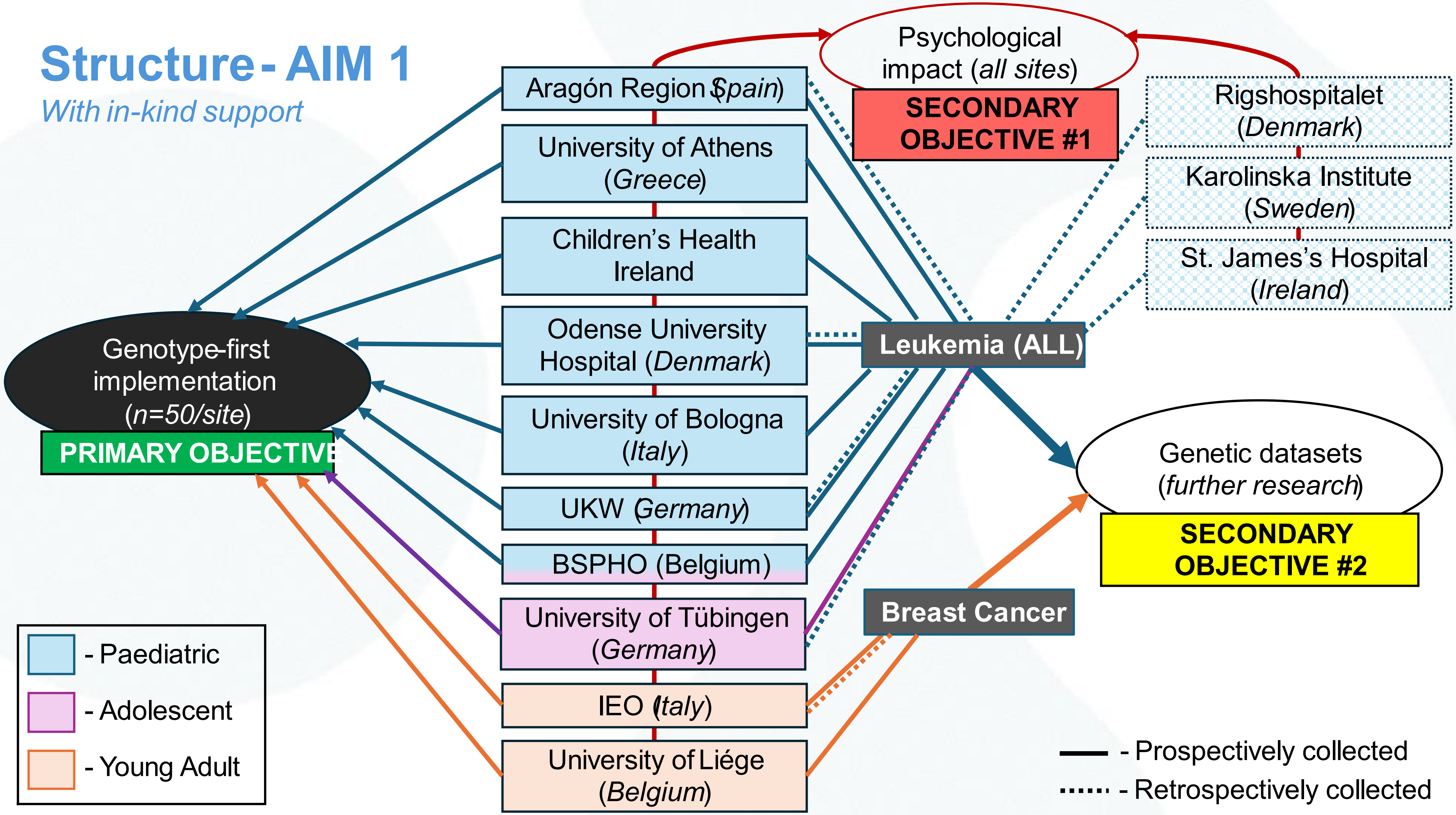
—— - Prospectively collected
······ - Retrospectively collected

PILOT DEMOGRAPHIC COVERAGE

JA PCM
Joint Action Personalised Cancer Medicine

Structure - AIM 1

With in-kind support



Aragón Region (*Spain*)

University of Athens (*Greece*)

Children's Health Ireland

Odense University Hospital (*Denmark*)

University of Bologna (*Italy*)

UKW (*Germany*)

BSPHO (Belgium)

University of Tübingen (*Germany*)

IEO (*Italy*)

University of Liége (*Belgium*)

Genotype-first implementation (*n=50/site*)

PRIMARY OBJECTIVE

Psychological impact (*all sites*)

SECONDARY OBJECTIVE #1

Rigshospitalet (*Denmark*)

Karolinska Institute (*Sweden*)

St. James's Hospital (*Ireland*)

Leukemia (ALL)

Breast Cancer

Genetic datasets (*further research*)

SECONDARY OBJECTIVE #2

- 🟦 - Paediatric
- 🟪 - Adolescent
- 🟧 - Young Adult

- ▬ - Prospectively collected
- ┅ - Retrospectively collected

PRIVATE SECTOR ENGAGEMENT

Needs:

- Contributions of consumables to facilitate up to 500 germline whole genome sequencing tests in 10 sites across 7 countries

- Existing equipment from Illumina and Oxford Nanopore Technologies across majority of sites

EXPECTED OUTCOMES & IMPACT

Expected outcomes (*with additional industry support*):

- Ability to pilot the implementation of a genotype-first approach to cancer predisposition syndrome diagnostics with a broader geographic and demographic scope
- More robust and generalizable insights regarding feasibility and cost-effectiveness
- Increased capacity to deliver germline WGS as part of routine diagnostics for CAYA patients

Key Impacts on Stakeholders

- *Healthcare professionals & researchers*: Improved possibilities for integration/reimbursement of germline WGS at diagnosis in CAYA
- *Healthcare policymakers*: Broad feasibility/economic data to inform decisions regarding genotype-first approach integration
- *Cancer patients – Citizens*: Enhanced possibilities for cancer predisposition syndrome diagnosis, management, and targeted treatments
- *Private Sector*: Data to inform increased integration of germline WGS in routine cancer diagnostics

Conclusion

- A genotype-first approach to cancer predisposition syndrome (CPS) diagnostics performed at first cancer diagnosis promises to significantly increase CPS diagnostic efficiency (*particularly critical in CAYA populations with higher CPS incidence*)
- CPS Compass will provide insights into the feasibility & cost-effectiveness of implementing a genotype-first approach in a CAYA population, to inform future integration into routine diagnostic workflows
- Industry support for WGS consumables would enable greater pilot geographic and demographic breadth, supporting more robust and generalizable results

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WP7 Pilot: Supranational MTB for rare and complex cases

Alejandro Piris

VHIO
Vall d'Hebron
Institute of Oncology

Co-funded by
the European Union

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Joint Action Personalised Cancer Medicine

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

Supranational MTB for rare and complex cases

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	Logo	Full name	Team Head		Team
VHIO	VHIO Vall d'Hebron Institute of Oncology	Vall d´Hebron Institute of Oncology Spain		Alejandro Piris Alberto Hernando	Christina Stangl Guillem Torcal
INC	Institut National du Cancer	Institut National du Cancer Luxemburg		Nikolai Goncharenko	Mukaddes Izci
MSCI	Maria Skłodowska-Curie National Research Institute of Oncology	Maria Skłodowska-Curie National Research Institute of Oncology Poland		Iwona Ługowska	Izabela Agnieszczak
ICO	ICO Institut Català d'Oncologia	Institut Català d´Oncologia Spain		Ernest Nadal	

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MISSION & VISION

Vision: a sustainable and scalable European framework where all patients with rare and complex advanced solid tumors regardless of country of origin can benefit from access to biomarker testing, molecular interpretation and treatment recommendations through a 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

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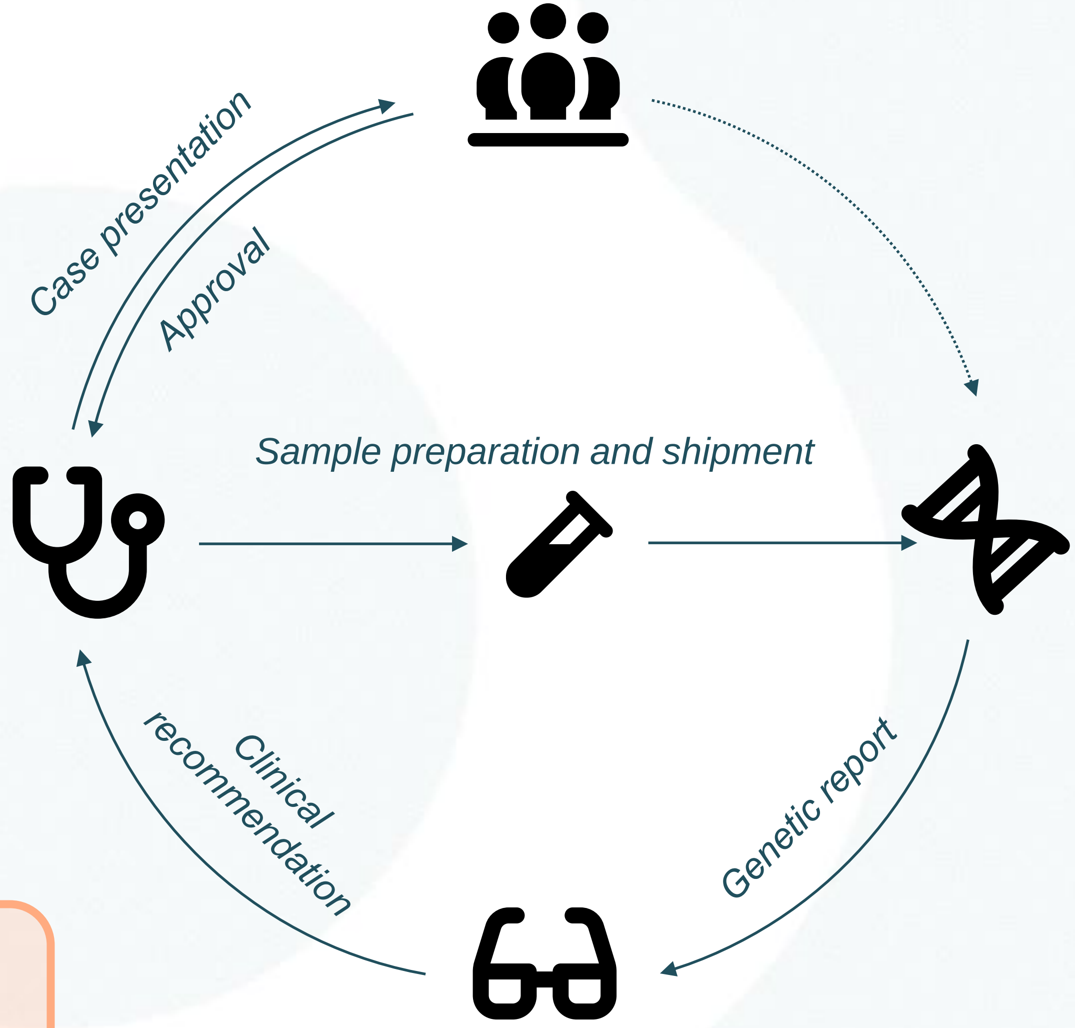


Case Selection Committee

Case presentation

Approval

Sample preparation and shipment

Clinical Pilot Site

- Sample + data

OR

- Only data

Molecular Diagnostics Lab

Clinical recommendation

Genetic report

Virtual MTB

Experts

Pilot Observer

Modalities:

Adult rare and complex cases

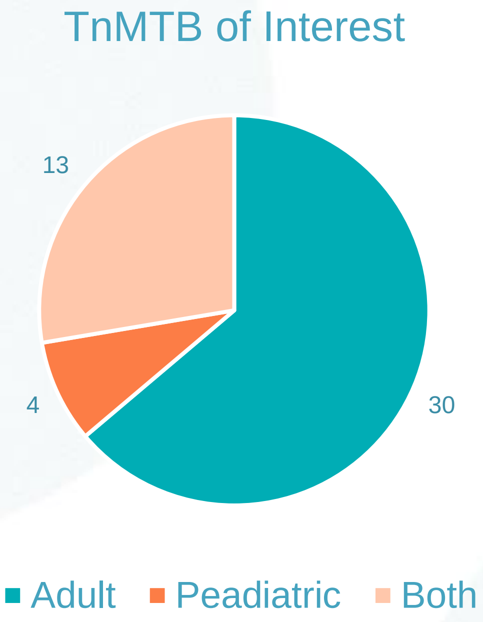
Pediatric Cancers

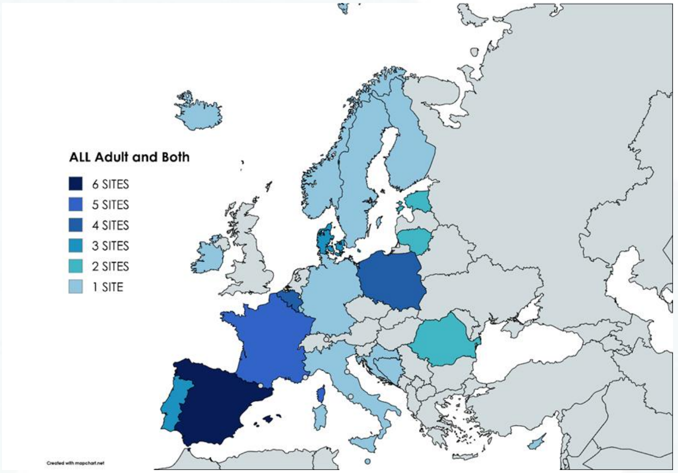
Infrastructure:

- **Project Management**
- **Data-sharing platform**
- **Legal framework**

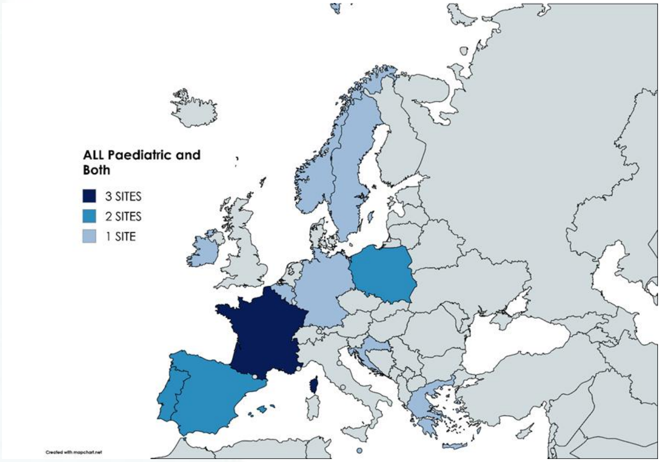
PILOT GEOGRAPHIC COVERAGE

Overview of the Expression of Interest:
- Total number of sites: 47
- Number of countries : 22
- Number of institutions : 47





Adult (n = 43)



Pediatric (n = 17)

PRIVATE SECTOR ENGAGEMENT

Sustainable Implementation relies on critical support—across both adult and paediatric settings

- Access to a broad range of molecular analyses, including
  - Whole Genome Sequencing (WGS),
  - Whole Transcriptome Sequencing (WTS)
  - Companion diagnostics
  - Liquid biopsies

- Pathways enabling access to therapies (e.g. off-label, compassionate use, clinical trials)

- Clinical trial enrolment based on MTB recommendations

EXPECTED OUTCOMES & IMPACT

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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 across Europe
- 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
- **Cancer patients – Citizens:**
  - Improved access to precision oncology expertise
  - Reduced geographic inequalities in cancer care
- **Private Sector:**
  - Common strategies for implementation in health systems
  - Visibility & Market Exposure

Conclusion

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- 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 generating evidence for long-term sustainability

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WP9 Pilot:
Digital Survivorship Care Delivery

Sarah Ball

GUSTAVE ROUSSY
CANCER CAMPUS GRAND PARIS

sciensano

Co-funded by the European Union

WP9 Pilot Study: Rationale

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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)

WP9 Pilot: Digital Survivorship Care Delivery

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Joint Action Personalised Cancer Medicine

	Logo	Full name	Team Head	Team
GR	GUSTAVE ROUSSY CANCER CAMPUS GRAND PARIS	**Gustave Roussy**	 Maria Alice Franzoi Medical Oncologist Cancer Survivorship Group Gustave Roussy	 Petya Zyumbileva Postdoctoral Researcher  Sarah Ball Research Assistant
SC	sciensano	**Sciensano**	 Regine Kiasuwa Mbengi Head of Supportive Care Siensano	 Marie Lamberigts Postdoctoral Researcher

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 sites 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 (low readiness centers); successfully deploying digital tools in routine care (middle readiness centers); improving equitable and sustainable digital health pathways (high readiness centers)
  - Illustrate the feasibility of integrating digital tools for survivorship care and its potential benefit in the quality of care provided.

WORKPLAN

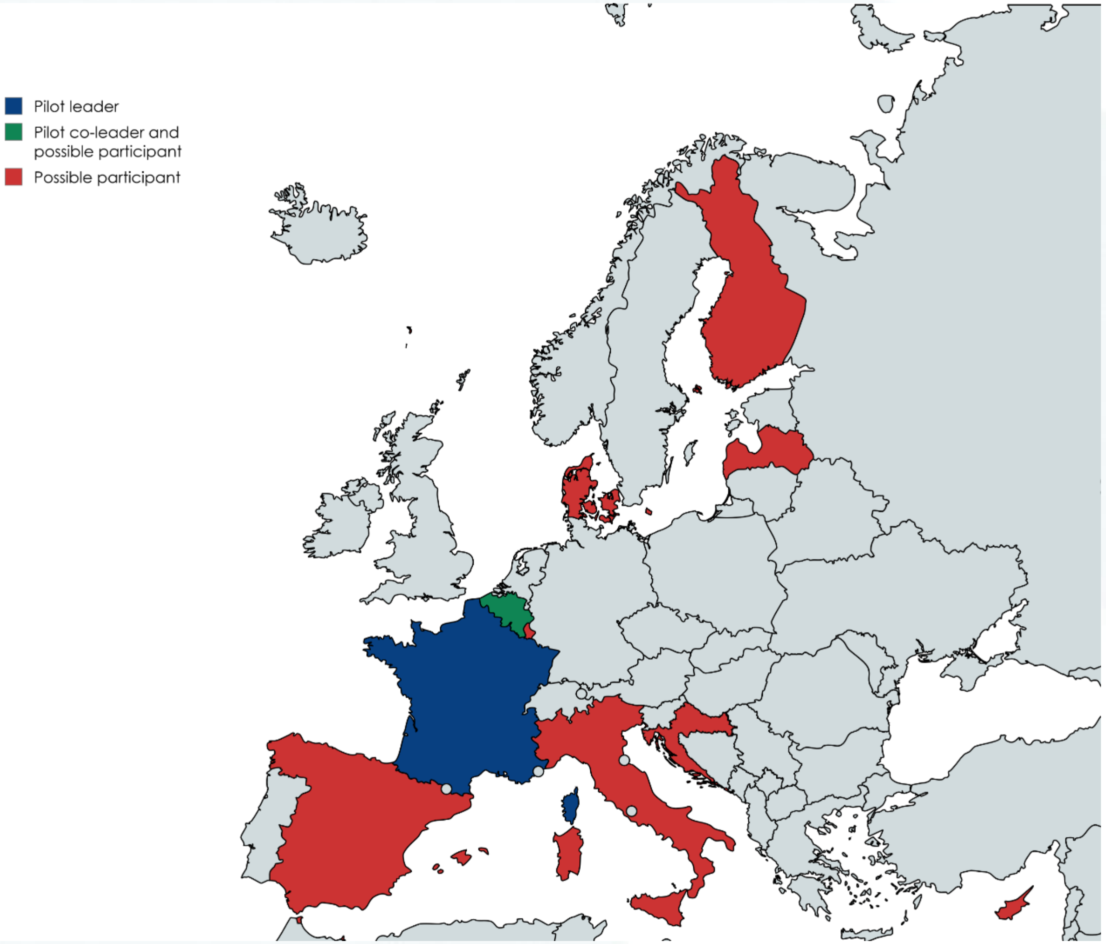
Three-phase personalized multilevel and multidimensional implementation package to advance digital survivorship care delivery in real-world clinical centers across Europe

Phase	**Pre-Implementation phase**	**Implementation phase**	**Post-Implementation**
EPIS Dimension	Exploration/Preparation, *Objective: prepare organizations 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 readiness sites (recipients) High readiness sites (provide support)	Middle readiness sites	High readiness sites
Intervention Components	**Site self-assessment and Workflow Redesign:** - Mapping current survivorship care delivery (gaps, resources, workflow) - Digital health readiness assessment - Survivorship workflow re-design exercise (by identitifed needs) - Local workshops (patients; HCPs; IT; managers) **Capacity building:** - Webinars (open classroom); exchange visits to centers experienced with digital survivorship care - Sharing documentation of established processes and best practices **Technology, Regulatory, Financial Enablement** - Connecting sites with technology providers (based on mapping and requirements exercise) - Providing sites examples of reimbursement/sustainability pathways (reimbursement models; institutional cost-effectiveness trade-offs) - Identifying and supporting funding opportunities for cultural adaptation, digital too customization, 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 - Local Research protocol approval with structured patient-level data collection (cohort study, n=100 patients)	**Program Refinement and Monitoring** - Collect/Reflect on existing metrics od diversity and engagement of digital health pathways in place - Refining digital health pathways to enhance equity, diversity, engagement, and quality of care (by feeding sites with the results of task 9.1 and 9.2) - Sharing knowledge of existing/implemented 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 organization 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	Documentation of program adaptations and refinements proposed by each site Documentation of knowledge transfer to low readiness sites

PILOT GEOGRAPHIC COVERAGE

Overview of the **Expression of Interest**:

- Total number of sites: 19
- Number of countries : 12



SITE SELECTION PROCESS

Results: 15 complete survey responses to analyze

Elements evaluated for stratification/selection:

1. Current practice status for 5 key domains of **survivorship care delivery** (0 = Not part of routine practice; 1 = Partially integrated; 2 = Fully integrated into routine care)
    a) Surveillance and follow-up planning
    b) Management of physical late and long-term effects
    c) Management of psychological and psychosocial effects
    d) Management of chronic comorbidities
    e) Prevention and health promotion
2. **Level of digital support** for same 5 domains (0 = None; 1 = Limited or pilot use; 2 = Routine care use)
3. **eREADY** validated digital readiness questionnaire

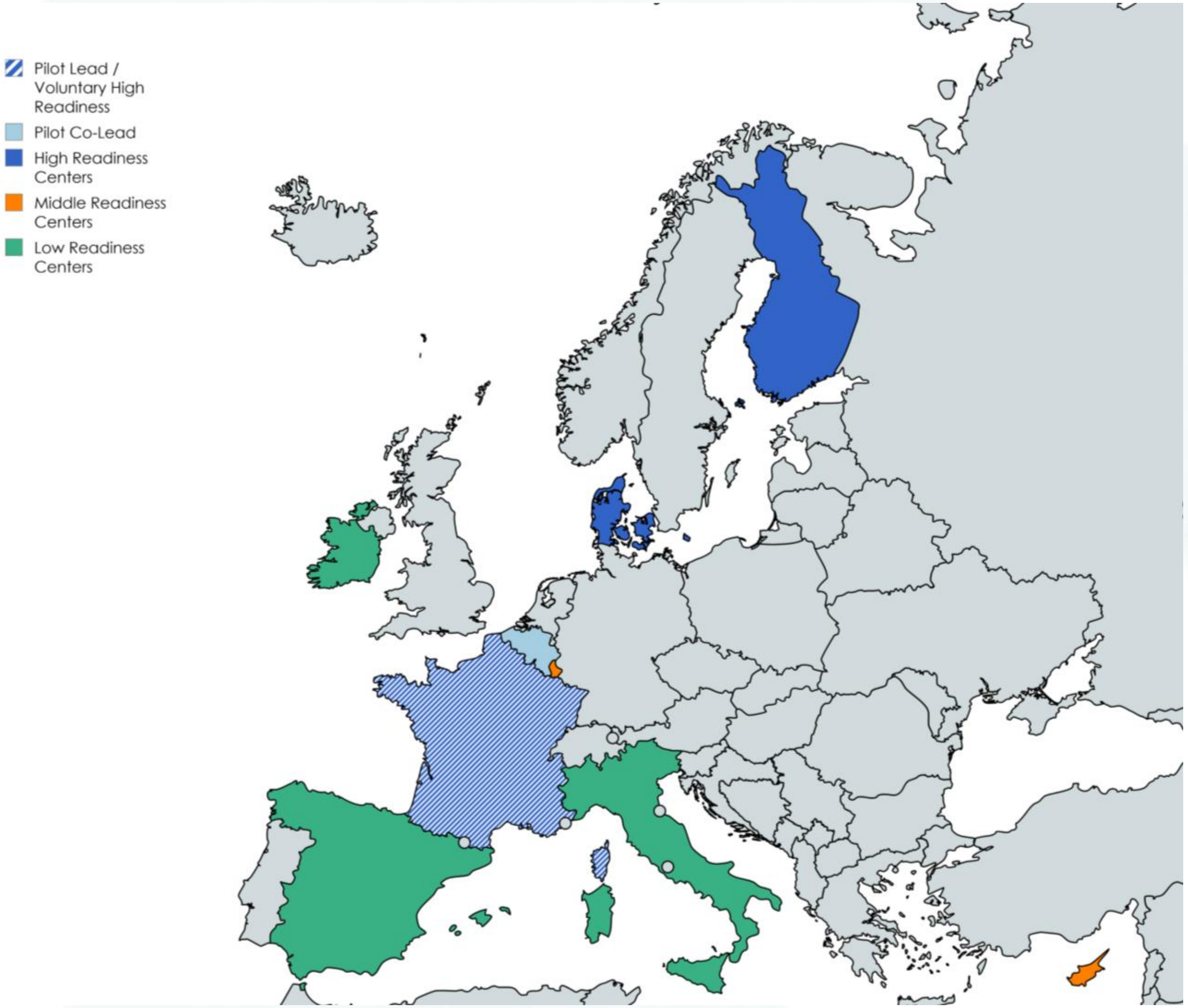
- High and Low readiness centers were selected based on **current practice status + level of digital support** for domains of survivorship care delivery
- eREADY used secondarily to differentiate between potential Middle readiness centers

PILOT GEOGRAPHIC COVERAGE

Overview of **Selected Sites**:

- Total number of sites: 9
- Number of countries : 8

- **High readiness**
  - Gustave Roussy (FR)
  - FICAN (FI)
  - Aarhus University Hospital (DK)
- **Middle readiness**
  - Bank of Cyprus Oncology Center (CY)
  - CHEM (LU)
- **Low readiness**
  - IRCCS (IT)
  - VHIO (ES)
  - DoH Aragon (ES)
  - St. Vincent’s UCD (IE)



PRIVATE SECTOR ENGAGEMENT

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Contributions are sought to provide participating sites with access to established digital tools for survivorship care delivery, including needs assessment, monitoring, education, and self management.

Welcomed support includes:

- **Contribution access to the digital tool itself** in the native language of the implementation site to be used in a prospective cohort study of at least 100 patients in 2 centers, but with the overall goal of building a mechanism to sustain the tool into routine care.
- **Implementation support** for integrating the tool into routine care (including access to ops teams, user engagement, interoperability and equity teams)

TYPES OF RELEVANT DIGITAL TOOLS

Category	Proposed definition	In-scope examples	Typical interaction model
Remote monitoring tools (ePRO ± wearables)	Digital tools that collect patient-reported outcomes (ePROs) and/or sensor data outside the clinic to support survivorship self-management and/or clinical decision-making.	ePRO symptom tracking; wearable activity/sleep capture; dashboards; alerts/thresholds	Autonomous; HCP-in-the-loop
Digital supportive care programs	Structured interventions delivered via digital platforms to prevent or manage survivorship symptoms and support quality of life.	Physical activity/rehab; psychosocial support; sexual health; return to work; nutrition; fatigue/sleep	Autonomous self-management; Guided/coached (virtual individual or group)
Education & information tools	Digital resources that provide survivorship information, education, and decision support to patients and/or caregivers.	AI-enabled chatbots (governed); educational portals; videos/podcasts; interactive learning	AI-developed (draft) + HCP validation; HCP-curated
Care coordination & digital follow-up	Digital functions that organise, document, or deliver survivorship care across providers and time (including follow-up visits).	Digital survivorship care plan documents; navigation/reminders; messaging; virtual follow-up appointments	AI-developed (draft) + HCP validation; HCP-authored/approved

BENEFITS OF CONTRIBUTION

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Benefits to the pilot:

- Enables additional sites to join the pilot study and access high quality digital survivorship tools
- Supports the accelerated integration of digital health into routine survivorship care across a diverse European ecosystem
- Aims to ultimately improve survivorship care delivery and patient quality of life

Benefits to industry partners:

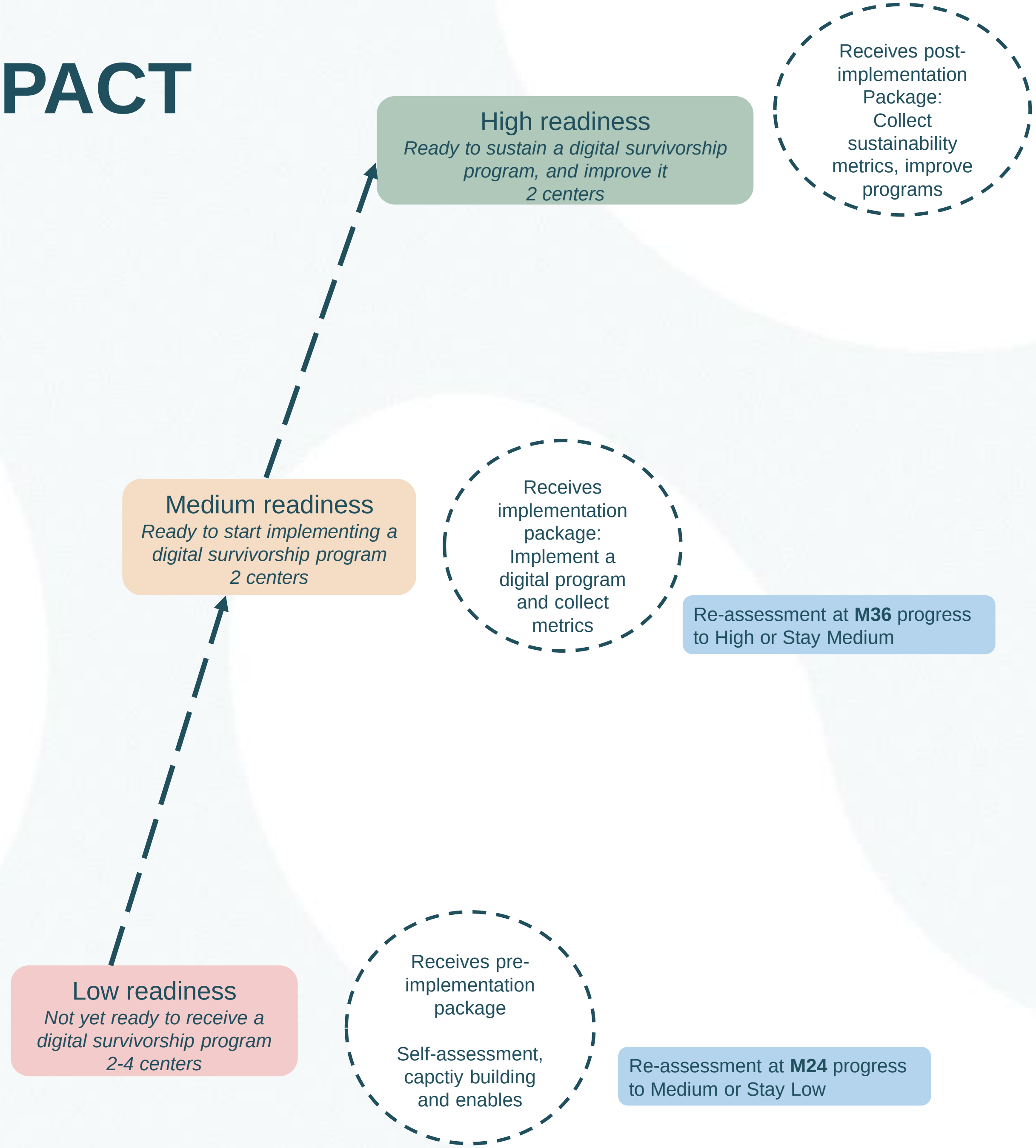
- Demonstrating implementation outcomes across diverse real world contexts
- Generating insights on reach, efficacy, adoption, implementation, and maintenance
- Increasing visibility, value, and market reach in Europe
- Enhancing evidence for scalability and real world effectiveness

EXPECTED OUTCOMES & IMPACT

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

1. Empower low-readiness centres through standardized pre-implementation practices (capacity building and workflow redesign)
2. Enable medium-readiness centres to effectively implement and evaluate digital survivorship programs
3. Support high-readiness centres to sustain, refine, and scale advanced digital solutions while sharing best practices for system-wide improvement

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



High readiness
Ready to sustain a digital survivorship program, and improve it
2 centers

Receives post-implementation Package: Collect sustainability metrics, improve programs

Medium readiness
Ready to start implementing a digital survivorship program
2 centers

Receives implementation package: Implement a digital program and collect metrics

Re-assessment at **M36** progress to High or Stay Medium

Low readiness
Not yet ready to receive a digital survivorship program
2-4 centers

Receives pre-implementation package

Self-assessment, capctiy building and enables

Re-assessment at **M24** progress to Medium or Stay Low

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-readiness 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 readiness centers (Reach, Effectiveness, Adoption, Implementation, Maintenance)
  - Enhance existing digital health pathways to advance equity and sustaibanility among high readiness centers

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Q&A

Post your questions in the chat!

Moderated by Marc Van den Bulcke

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Private Sector Expression of Interest

Private Sector EOI

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Japcm.coordination@sciensano.be

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