#prime-rose #horizoneu #missioncancer

Funded by the European Union
Grant no. 101104269

PRIME-ROSE

PCM4EU
Personalised Cancer Medicine for all EU Citizens

@PRIME-ROSE_EU
@PRIME-ROSE
www.prime-rose.eu

Prime-Rose

Combining Expertise Across Borders to Promote Precision Cancer Medicine in Europe

PRIME-ROSE

(Precision Cancer Medicine Repurposing System Using Pragmatic Clinical Trials) is a Horizon Europe Mission on Cancer project with 28 partners from altogether 19 European countries. Moreover, PRIME-ROSE is part of the Cancer Mission cluster of projects on Diagnosis and Treatment.

5 year project

– 28 partners, 19 European countries, €6.0M budget

Project Coordinator:

Prof. Kjetil Taskén, Oslo University Hospital

Project Manager:

Dr. Live Fagereng, Oslo University Hospital

DLCTs - DRUP-Like Clinical Trials

Network of independent, investigator-initiated, pragmatic clinical trials in precision medicine inspired by the design of the original DRUP protocol.

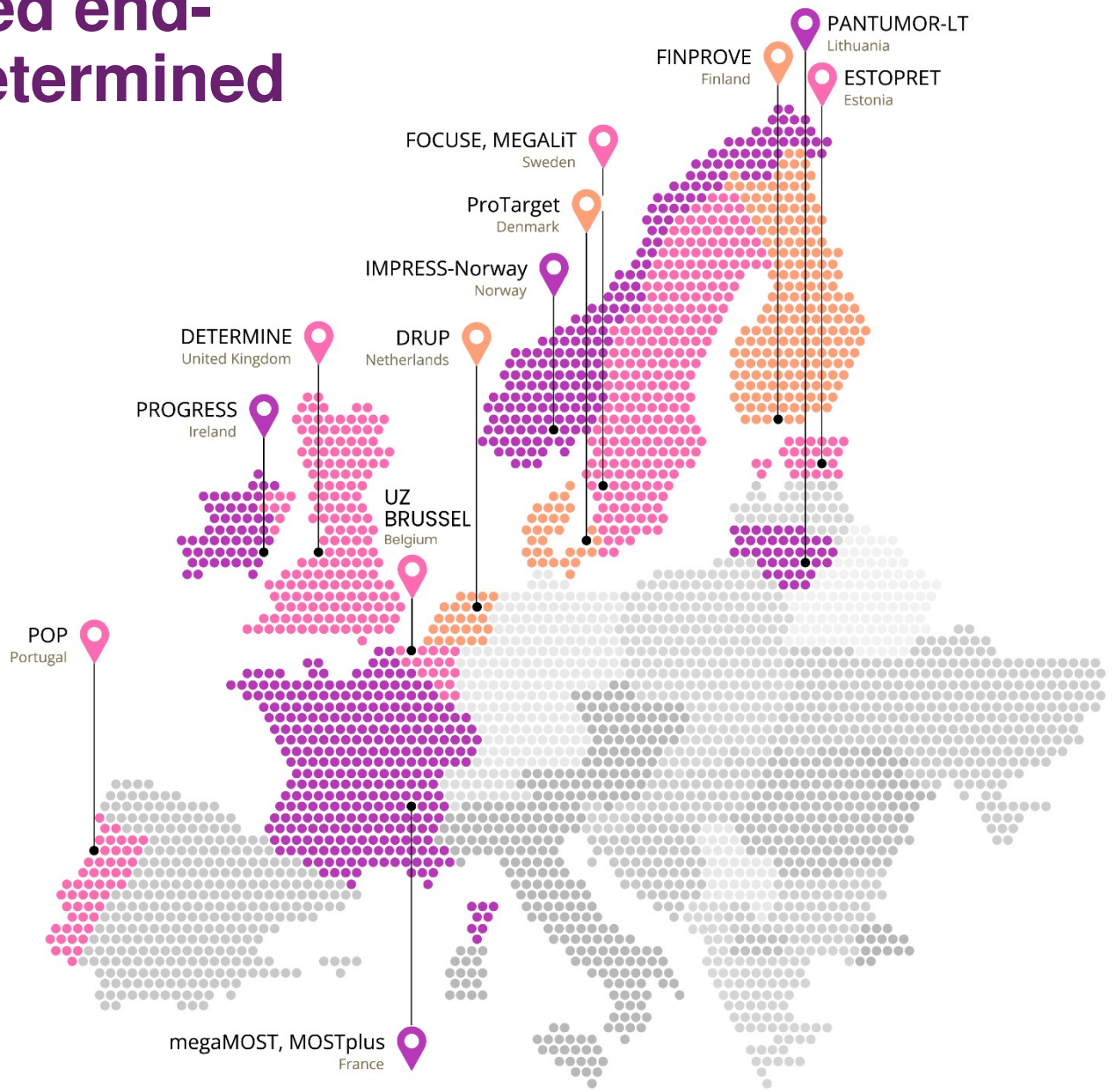
Read more:

van der Velden DL, et al. The Drug Rediscovery protocol facilitates the expanded use of existing anticancer drugs. Nature. 2019 Oct;574(7776):127-131.

Verkerk K, et al. DRUP Trial Investigators. Prospective evaluation of genomics-guided off-label treatment. Nature. 2026 May;653(8114):558-566.

DLCTs have a core set of shared end-points, in addition to locally determined end-points of interest

Trial	Country	STATUS	Read more
DRUP (D3.2)	Netherlands	Recruiting	PMID: 31570881
ProTarget (D3.8)	Denmark	Recruiting	PMID: 36814246
IMPRESS (D3.5)	Norway	Recruiting	PMID: 35568909
FINPROVE	Finland	Recruiting	PMID: 38779937
DETERMINE	UK	Recruiting	
MEGAMOST (D3.17)	France	Recruiting	PMID: 38807312
MOSTplus (D3.17)	France	Recruiting	PMID: 37444551
MegaLIT (D3.14)	Sweden	Ended	PMID: 40468525
FOCUSE	Sweden	Open	PMID: 41972845
POP	Portugal	Open	PMID: 38910310
ESTOPRET	Estonia	Open	
UZ Brussel	Belgium	Open	PMID: 41962308



- Dialogue with the US based TAPUR study for data-sharing.

Merging of clinical data between trials

- Core set of **common endpoints**
- **Aligned** inclusion & exclusion criteria
- **Aligned** schedule of activites

An overview of overlapping main endpoints in the ongoing DRUP-like trials. *Durable Clinical Benefit, defined as the absence from disease progression for at least 24 weeks from the start of trial treatment.

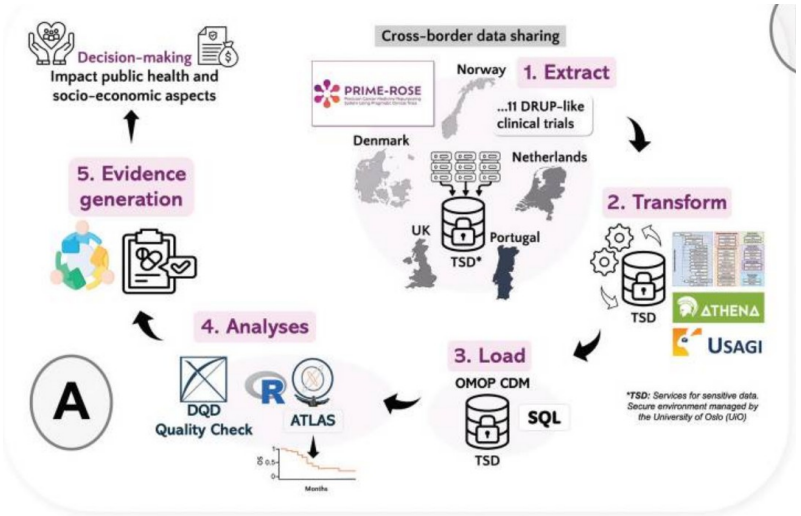
- 100% similarity across trials
- 90% similarity across trials
- 80% similarity across trials

Endpoint in DRUP-like clinical trials	DRUP	ProTarget	IMPRESS	FINPROVE	MOSTplus	DETERMINE	POP	FOCUSE	ESTOPRET
Disease control after 16 weeks after treatment initiation	X	X	X	X	X	X	X	X	X
Progression-free and overall survival	X	X	X	X	X	X	X	X	X
Duration of treatment on study (time on drug)	X	X	X	X	X	X	X	X	X
Treatment related grade ≥3 and SAE	X	X	X	X		X	X	X	X
Objective tumour response	X	X	X		X		X	X	
Percent of patients treated based on their molecular profile	X	X	X		X		X	X	X

Read more: **Van der Pol H** et al. Procedures of data merging in precision cancer medicine: the PRIME-ROSE project. **Acta Oncol.** 2026; **65**:1-8

Merging of data

- We have developed and tested an operational data-sharing framework, with defined
- Patient-level data from multiple national cohorts (1100 patients in 400 cohorts) have been aggregated, and analyses
- Joint analysis on merged cohorts ongoing



VARIABLE	DESCRIPTION	
COHORT NAME	Name of the cohort	DEMOGRAPHIC ++
TUMOR TYPE	IDC10 code	
BIOMARKER/TARGET	Description of the biomarker.	
ESCAT-SCALE	If available	
AGE	Age at treatment start	
SEX		
ECOG	At baseline, if available	
TREATMENT START	First dose in first cycle (YYYY-MM-DD)	TREATMENT INFORMATION
STUDY DRUG	INN	
NUMBER OF CYCLES	Total number of cycles given	
TREATMENT START LAST CYCLE	First day in last treatment cycle (YYYY-MM-DD)	
TREATMENT END	Date for End of Treatment if available (YYYY-MM-DD)	
DOSE DELIVERED	Dose deliver in each cycle	
AE GRADE	Worst CTCAE severity grade of the Adverse Event	
AE DESCRIPTION	The Adverse Event term	SAFETY
AE START DATE	AE start date (YYYY-MM-DD)	
AE END DATE	AE end date (YYYY-MM-DD)	
AE OUTCOME	What was the outcome of this AE? (pull down menu should be added to the annex	
AE MANAGEMENT	AE treatment/management (discontinuation/dose reductions)	
SAE	Was the Adverse Event serious (SAE)	
RELATED	Is the AE related to the study treatment	
EXPECTEDNESS	SUSAR (specify which drug)	EFFECT
TUMOR ASSESSMENT	Type of tumor assessment (RECIST, iRECIST, LUAGNO, RANO..	
EVENT DATE	Date for tumor assessment (YYYY-MM-DD)	
BASELINE EVALUATION	Sum Size of target lesion at baseline, non-target-lesions	
ASSESSMENT	Sum size of target lesion at visit, % change from baseline	
END OF TREATMENT	Patient ended treatment (YYYY-MM-DD)	
REASON EOT	The reason for EOT: PD, not evaluated, Death etc.	
BEST OVERALL RESPONSE	Confirmed best overall response (CR, PR, SD, PD)	
RESPONSE W16	Confirmed response W16 (CR, PR, SD, PD)	
HRQOL	HrQoL collected in the trial (will vary between trials)	

Read more: **Martin Agudo M** et al. 'Crossing borders' in data standardisation: application of OMOP CDM in an international clinical trial network in precision cancer medicine. **Acta Oncol. 65:**159-163**.**

Current status and results

PRIME-ROSE Updates on Cohort Merging and Biomarker Alignment

PRIME-ROSE has established a dedicated data-sharing team that have regular, monthly meetings. In the most recent meeting that took place om May 27, representatives from all the ongoing DRUP-like clinical trials merged another Stage I cohort. Altogether, 1051 patients have now been included in 355 shared cohorts, and of these cohorts, 27 have so far been filled across the trials. Data analysis of the filled cohorts will now be initiated, and the results will be published.

In the meeting, biomarker alignment across trials was also addressed. In particular, the current practice of using FGFR2 receptor alternations as a biomarker for FGFR inhibitors, was discussed. Harmonisation of interpretation is key for robust data sharing.

Cohort monitoring in Prime-Rose:

Patients	Cohorts	Biomarkers	Tumor types	Treatments	Companies
1191	489	71	104	26	11

23 Cohorts expanded to stage II through sharing of data from all the open trials.
4 Cohorts filled stage II.
Several specific cohorts now undergoing analysis based on data from all the trials

First cohorts being analysed jointly cross country

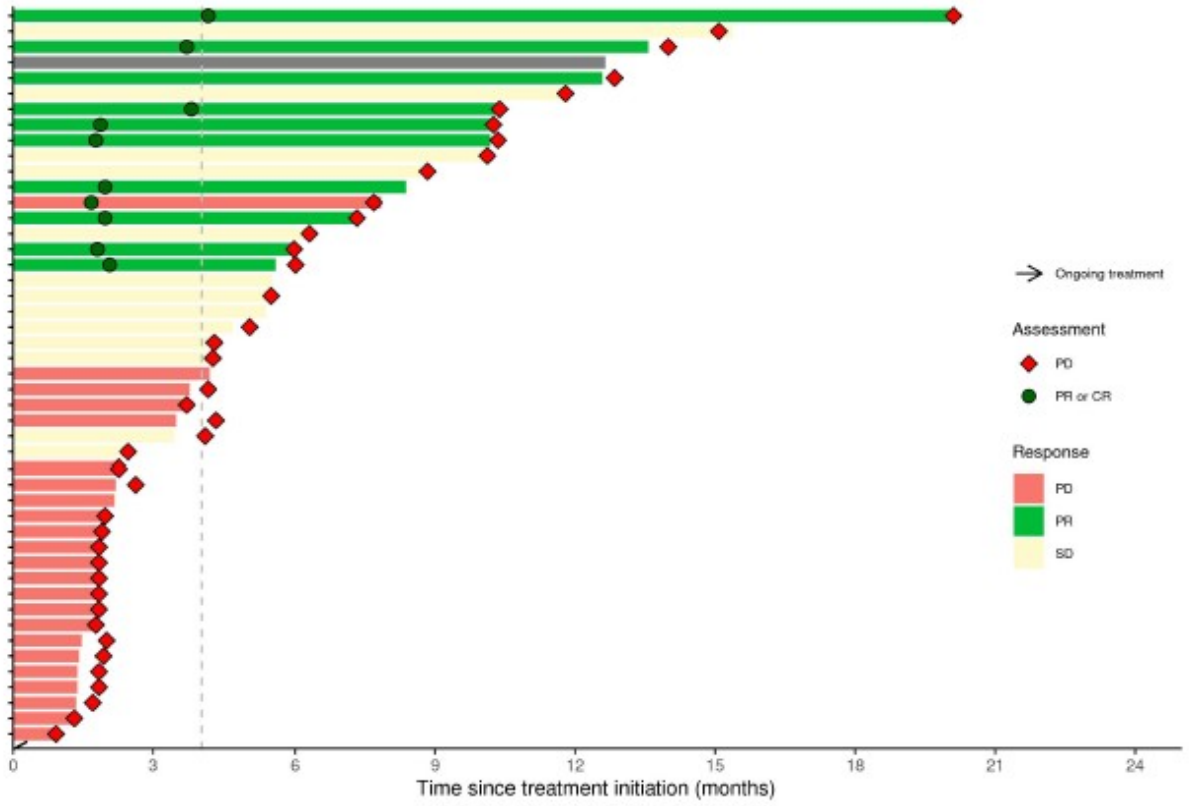


Figure 2: Swimmers plot for the time on treatment, separated by response.

Table 2: Number of inclusions per trial and total.

Trial	Number of inclusions
DRUP	29
FINPROVE	4
IMPRESS-Norway	11
ProTarget	6
Total	50

Table 9: Frequency table of treatment-related grade 3 and higher, separated by grade.

CTCAE Term	Grade 3
hypertension	2
Left ventricular systolic dysfunction	1
Skin infection	2

Table 10: Table of treatment-related grade 3 and higher, separated by patient.

ID	AE Term	AE Grade
DRUP-01-01-0007	hypertension	3
DRUP-01-01-0007	hypertension	3
DRUP-01-06-0052	Left ventricular systolic dysfunction	3
IMPRESS-0128	Skin infection	3
IMPRESS-0245	Skin infection	3

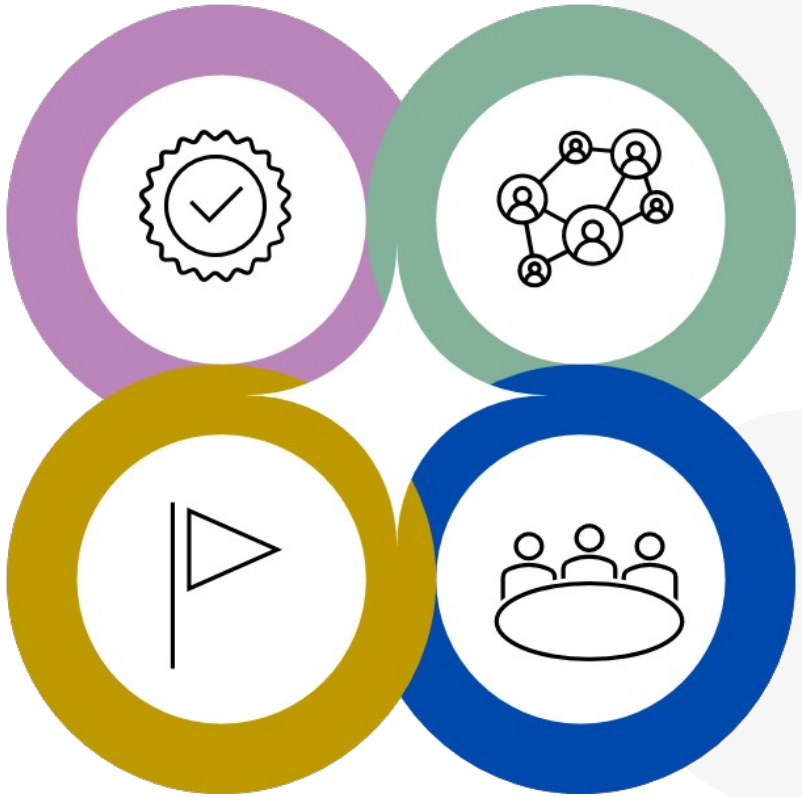
Unpublished data

European Health Data Space (EHDS)

Harmonisation

Collaboration on patient data and analyses

International collaboration



What clinical needs do we have?

Define needs and solutions

Develop protocol (define endpoints)

Discuss with the various stakeholders

Streamlining trial initiation and recruitment

PRIME-ROSE connects DLCTs across Europe via a joint Data Sharing Agreement and a data aggregation. Close collaboration with HTA and regulators to ensure data meets respective requirements.

Distributed organisation with mixed financing models integrated into local healthcare systems for rapid uptake

Various initiatives to build diagnostic capacity (PCM4EU, WIDERA, WHO, EP PerMed calls, JA on PCM Implementation)

Catchment area larger than

70 M population

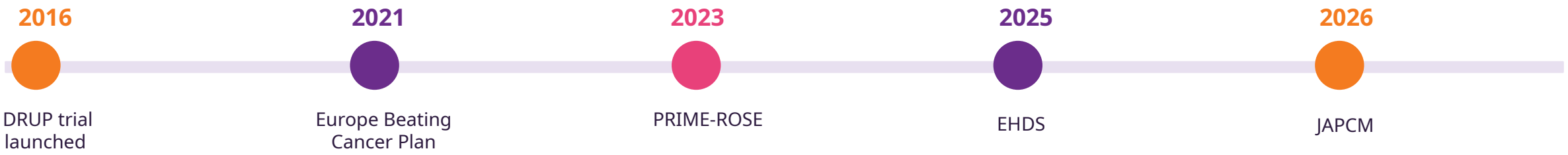
at present, increasing

Competitive advantages:

- Single point of entry and joint negotiations:
  One contract – whole consortium.
- Drug supply can be distributed within the network
- Floating treatment slots between trials – competitive recruitment

Effective tool for the industry partners and investigators to initiate novel, molecularly defined DLCT cohorts with reach across Europe- potential backbone for other trials.

Precision Cancer Medicine: A Decade of European Progress



Growing Diagnostic Infrastructure

- Several countries has set up access to advanced molecular testing e.g.
  - France: Plan France Médecine Génomique — nationwide genomic sequencing
  - Sweden: Genomic Medicine Sweden
  - Denmark: National Genome Center
  - Germany – NCT Master program
- Increased access to national and regional molecular tumour board

Top-down & bottom-up development

- Important EC regulations:
  - European Health Data Space for primary and secondary use of data
  - IVDR & MRD
  - Biotech Act
  - Pharmaceutical legislation
- Bottom-up
  - Many large scale PCM trials and projects
  - Demonstrated data sharing between PCM trials

Why This Matters Now

- Patients with advanced cancer increasingly profiled which needs to be matched with access to treatment
- European collaboration for signal seeking and data collection on protocol
- Knowledge output to serve decision makers in private and public sector (regulators, HTA, clinicians, payers)
- European network provides scale that no single country can achieve alone

JA PCM
Joint Action Personalised Cancer Medicine

Joint Action on Personalised Cancer Medicine

Co-funded by
the European Union

JA Personalised Cancer Medicine (JA PCM)

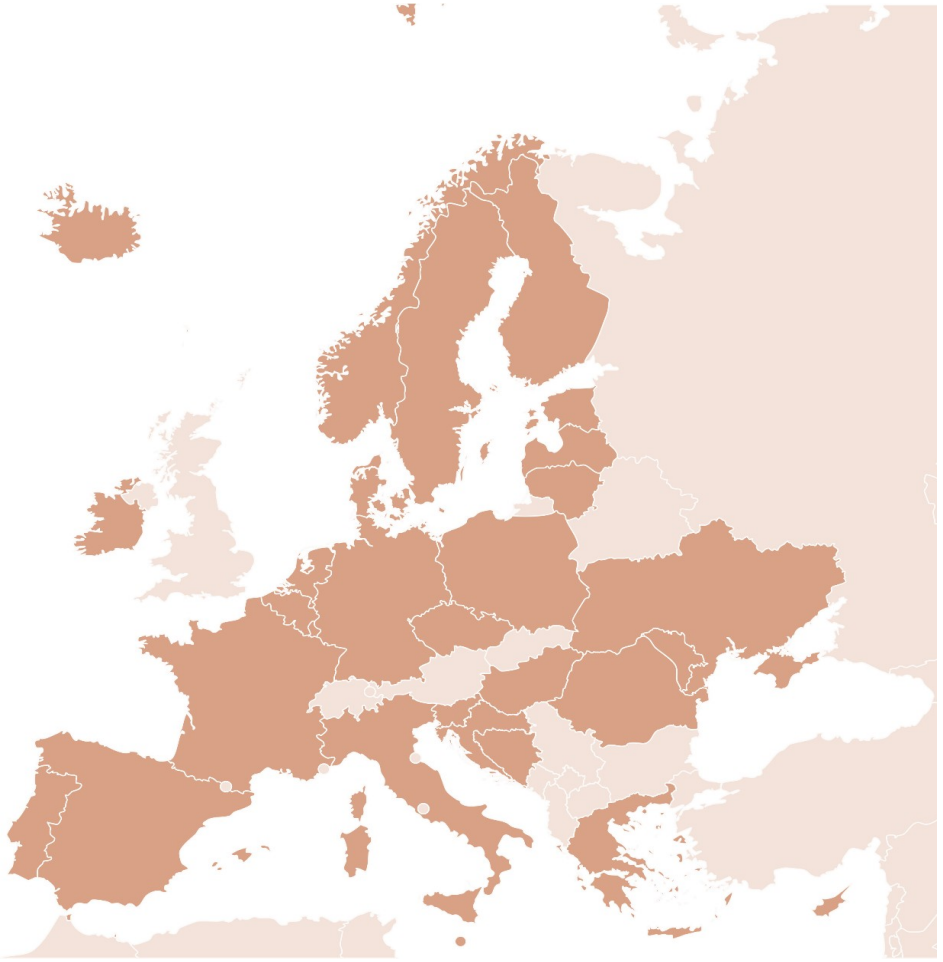
- Timeline: Nov 2025 – Nov 2029
- Funding: 31.6 Million € (80% EU contribution / 20% in kind)
- Consortium:
  - 29 Countries
  - 145 Partners (45 Competent authorities (CA) & 100 Affiliated entities (AE))
  - 6 Associated Partners (AP)
  - Coordinator Marc van den Bulcke and team @Sciensano, BE

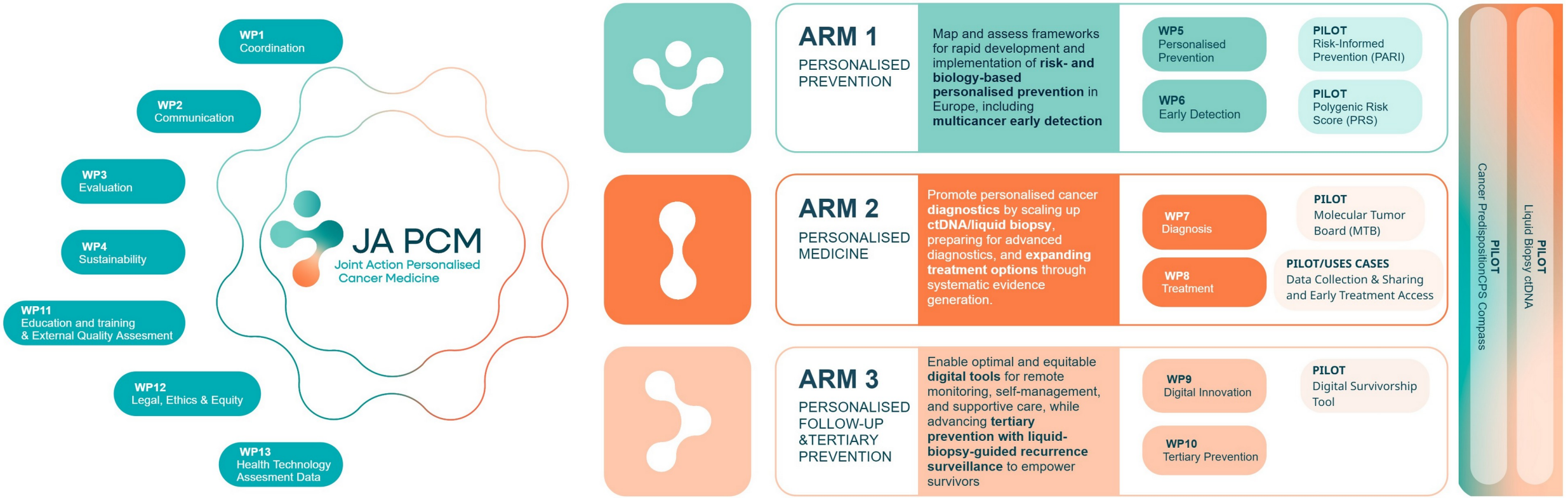
Medical Care Organisation	71
Research Organisation	41
Public & Governmental Organisation	32
Professional Network	5
Patient Organisation	2

- Building on:

can.heal

PCM4EU
Personalised Cancer Medicine for all EU Citizens




WP1
Coordination
WP2
Communication
WP3
Evaluation
WP4
Sustainability
WP11
Education and training
& External Quality Assesment
WP12
Legal, Ethics & Equity
WP13
Health Technology
Assesment Data
JA PCM
Joint Action Personalised
Cancer Medicine
ARM 1
PERSONALISED
PREVENTION
Map and assess frameworks for rapid development and implementation of risk- and biology-based personalised prevention in Europe, including multicancer early detection
WP5
Personalised
Prevention
WP6
Early Detection
PILOT
Risk-Informed
Prevention (PARI)
PILOT
Polygenic Risk
Score (PRS)
ARM 2
PERSONALISED
MEDICINE
Promote personalised cancer diagnostics by scaling up ctDNA/liquid biopsy, preparing for advanced diagnostics, and expanding treatment options through systematic evidence generation.
WP7
Diagnosis
WP8
Treatment
PILOT
Molecular Tumor
Board (MTB)
PILOT/USES CASES
Data Collection & Sharing
and Early Treatment Access
ARM 3
PERSONALISED
FOLLOW-UP
&TERTIARY
PREVENTION
Enable optimal and equitable digital tools for remote monitoring, self-management, and supportive care, while advancing tertiary prevention with liquid-biopsy-guided recurrence surveillance to empower survivors
WP9
Digital Innovation
WP10
Tertiary Prevention
PILOT
Digital Survivorship
Tool
PILOT
Cancer PredispositionCPS Compass
PILOT
Liquid Biopsy ctDNA

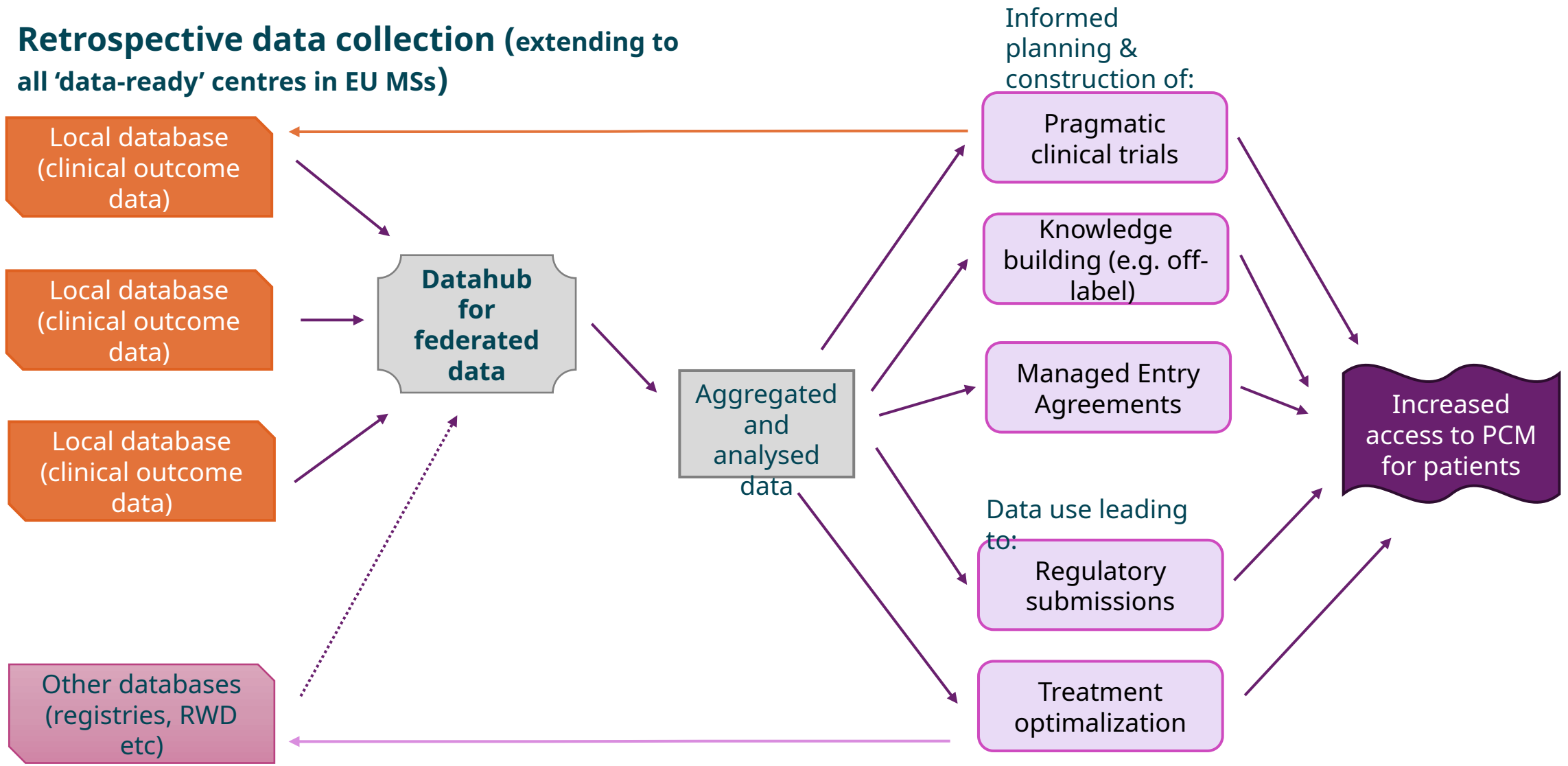
Context – Treatment

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

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

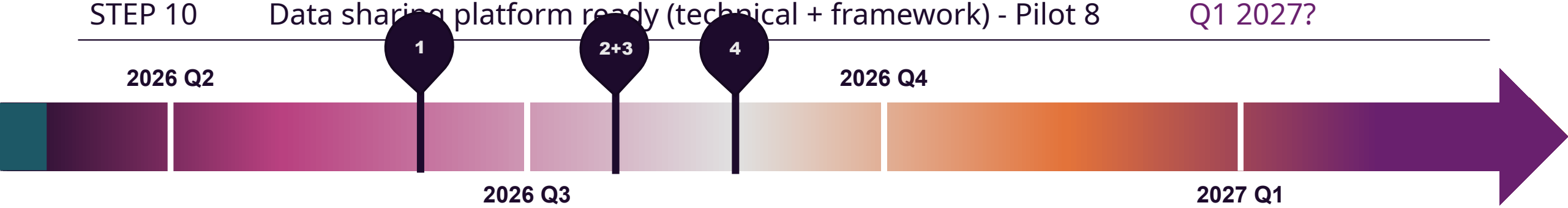
Learning healthcare system requires identification of knowledge gaps both pre- and post-market authorisation.

Flow of activities (I)



Evidence Generation Plan

STEP 1	Introductory meeting w/EMA (discuss regulatory strategy)	27MAY2026
STEP 2	Core set of endpoints (draft) - Task 8.1	JUL2026
STEP 3	Data sharing platform framework (draft) - Pilot 8	JUL2026
STEP 4	Platform PCT protocol (synopsis) – Task 8.1, Pilot 8 and UseCase 8.1	AUG2026
STEP 5	Method of data collection (Task 8.1/Pilot 8) extended to Tasks 8.2 & 8.3, UseCase 8.2	Q3 2026?
STEP 6	Submission of briefing package to EMA (+HTA?)	Q3 2026?
STEP 7	Feedback from EMA (+HTA?)	Q4 2026?
STEP 8	Final set of endpoints and platform protocol	Q4 2026 / Q1 2027?
STEP 9	Pilot first sharing of data - UseCase 8.1	Q3 2026?
STEP 10	Data sharing platform ready (technical + framework) - Pilot 8	Q1 2027?



Conclusion

Key messages to young oncologist

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

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

3. Message 3 — Evidence generated to support PCM implementation into Standard of Care

Identify and close knowledge gaps

JA PCM
Joint Action Personalised Cancer Medicine