PCM4EU
Personalised Cancer Medicine for all EU Citizens

State of the Union
precision medicine implementation in cancer

1st edition

Co-funded by the European Union

2025

Impressum PCM4EU

PCM4EU is a project co-funded by the European Union and Europe’s Beating Cancer Plan under grant agreement 101079984.

PCM4EU

foreword

Precision cancer medicine (PCM) is about treating patients individually based on the tumour's molecular profile and all other information available, and after considering treatment options in a molecular tumour board (MTB).

The **PCM4EU** project (PCM for EU citizens) funded under the EU4Health programme (GA101079984), runs from January 2023 till June 2025 and includes 17 partners in 15 European countries.

The project supports the equitable implementation of advanced molecular cancer diagnostics across the European Union. It assists the operation of MTBs, links MTBs between countries, establishes and shares best practices and provides cost analyses.

PCM4EU supports additional countries in the implementation of PCM through decentralised, federated pragmatic clinical trials, like the DRUP-Like Clinical Trials trials, cross-border access to PCM and training of the next generation of pcm practitioners.

This 'State of the Union' intends to provide a snapshot of the status of PCM implementation in different European countries as of April 2025, going beyond the number of countries originally represented in the PCM4EU consortium.

As the network expands, now with 28 partners in 19 countries in the PRIME-ROSE project, and important new initiatives such as the upcoming Joint Action for PCM starting November 2025 with 146 or more partners in 31 European countries and the WHO Europe Novel Medicines Platform, we hope that this State of the Union on pcm implementation report becomes a helpful tool to provide pcm practitioners and decision-makers, including policy makers, with a timely overview of the rapidly evolving pcm landscape of in Europe.

Hans Gelderblom

Leiden University Medical Centre

Coordinator PCM4U

PCM4EU

precision cancer medicine implementation in

Belgium
Croatia
Denmark
Estonia
Finland
France
Germany
Hungary
Ireland
Italy
Lithuania
Netherlands
Norway
Poland
Portugal
Romania
Spain
Sweden
United Kingdom

PCM4EU

introduction

The **State of the Union of precision medicine implementation in cancer 2025 report** provides a snapshot of the implementation efforts in personalised cancer medicine in different EU member states **as of April 2025**.

In its first edition, this crowd-sourced resource exists thanks to the efforts of many. Created by the cancer community for the cancer community, it captures information deemed relevant by community members at the time of the design. Countries are listed in alphabetical order and predominantly cover the countries represented in the PCM4EU consortium. However, we would be delighted to add additional country profiles, so if you are interested to be included, please reach out to bettina.ryll@hhs.se.

By necessity, a snapshot captures a moment in time and can neither be extensive nor provide in-depth information. It rather signposts relevant information on precision medicine implementation that at times might be in the planning stage or only be available in national language. We therefore invite you to reach out to the respective **section authors** for more information.

The country profiles are part of the PCM4EU Work package 5 Deliverable 5.2 'Recommendations for the successful implementation of equitable access to personalised cancer medicine, including cross-border access' that have been met with great interest. PCM4EU is a project co-funded by the European Union and Europe's Beating Cancer Plan under grant agreement 101079984.

Bettina Ryll
PCM4EU WP5 co-lead
April 2025

impressum PCM4EU 2025

PCM4EU

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Date 11 April 2025

Co-funded by the European Union

PCM4EU

Belgium

Country by figures

Population

~ 11 M

Comprehensive Cancer Centres

2 (OECI certified)

New cancer cases per year

~ 70 000

Precision Cancer Medicine

Does the country have a national PCM initiative? ComPerMed commission and **Precision Initiative** launched by BSMO

Feasibility studies / multi-stakeholder/ extra funding? GENEO and **BALLET** studies for CGP testing

National guidelines on PCM?
ComPerMed: tumor-specific clinical practice guidelines as workflows, updated twice a year.

Does the country have regional PCM initiatives? NO

PCM diagnostics

How is genomic testing organised in your country? Through national framework. Indications outlined in NGS convention. Funded by national health system.

Reimbursement

NGS is reimbursed for certain clinical indications via NGS convention

Molecular Tumour Boards

Multidisciplinary Oncology Consultation (**MOC**) is formal, regulated, and government-funded. National Molecular Tumor Boards (**nMTBs**) for various precision medicine clinical studies involving comprehensive genomic profiling (CGP) testing (not reimbursed)

Access to PCM treatments

Specific reimbursement regulations within **INAMI/RIZIV.** Molecular tests reimbursed according to reimbursement framework

DRUP-Like Clinical Trial

BeDRUP (in preparation)

Challenges

Implementation of CGP in clinical routine, Implement Liquid biopsy, access to innovative drugs

Opportunities

Different EU projects (PRIME-ROSE, JA PCM) and national projects (GENEO 2.0)

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Date April 2025

Co-funded by the European Union

PCM4EU

Croatia

Country by figures

Population

3.9 M

Comprehensive Cancer Centres

7

New cancer cases per year

28 809

Precision Cancer Medicine

Does the country have a national PCM initiative? Croatian Health Insurance

Feasibility studies / multi-stakeholder/ extra funding? Since July 2019, memorandum of collaboration with Roche on precision medicine implementation

National guidelines on PCM?
Croatian oncological society published guidelines; since 2023, all patients diagnosed with locally advanced or metastatic disease have right to be tested (comprehensive genomic profiling)

PCM diagnostics

How is genomic testing organised in your country? PCM (CGP) is covered by Croatian Health Insurance, new Institute performs CGP, Roche is the vendor who performs the test- currently only for liquid biopsy testing and a limited number of tissue testings

Reimbursement

PCM (CGP) is covered by Croatian Health Insurance, new Institute performs CGP, Roche is the vendor who performs the test currently for only liquid testing and limited number of tissue testings

Molecular Tumour Boards

weekly MTBs, comprised of different disciplines, including clinical oncologists, medical oncologists, pathologists, molecular biologists, biostaticians

Access to PCM treatments

based on MTB recommendation, possible coverage via Croatian Health Insurance or from donations

DRUP-Like Clinical Trial

no but registries for molecular alterations.

Challenges

administrative burden, shortage of personnel, turnaround times, technical and organisational issues

Opportunities

additional treatment options for patients

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Date 10 April 2025

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PCM4EU

Denmark

Country by figures

Population

6 M

Comprehensive Cancer Centres

0 (3 in accreditation)

New cancer cases per year

46 000

Precision Cancer Medicine

Does the country have a national PCM initiative? Yes, including a national PCM strategy.

Feasibility studies / multi-stakeholder/ extra funding? public and private funding; diverse feasibility studies

National guidelines on PCM?
in progress

Does the country have regional PCM initiatives? Yes

PCM diagnostics

How is genomic testing organised in your country? Public/ private vendors/ private initiatives- centralised vs distributed : Public and centralised

Reimbursement
Everything is reimbursed

Molecular Tumour Boards

A weekly, national, virtual MTB

Access to PCM treatments

- Pts with advanced cancer are offered NGS test
- Results are discussed at weekly MTB
- Treatment proposal based on findings: DLCT, pharma-sponsored trials or in rare cases, off-label treatment
- Fully reimbursed

DRUP-Like Clinical Trial

ProTarget: https://protarget.dk/

https://pubmed.ncbi.nlm.nih.gov/36814246/

Challenges

Running out off drugs for the trial

Opportunities

Collaboration within PRIME-ROSE

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PCM4EU

Estonia

Country by figures

Population

1.4 M

Comprehensive Cancer Centres

0 comprehensive, 1 OECI accredited, 2 associated OECI

New cancer cases per year

9191 (2022)

Precision Cancer Medicine

Does the country have a national PCM initiative? add text

Feasibility studies / multi-stakeholder/ extra funding? add text

National guidelines on PCM?
add text

Does the country have regional PCM initiatives? add text

PCM diagnostics

How is genomic testing organised in your country?

- Comprehensive molecular testing centralised: TUH
- TSO500 + HRD + PanCancer fusion panel
- Reimbursed for all endometrial and ovarian cancers + all other cancers based on treating physicians/MDT choice
- Single gene testing (EGFR, KRAS, NRAS, BRAF, MSI etc): decentralised (TUH, NEMC, ETCH)
- Although rare, patients can order testing themselves from private companies/from hospitals and pay out-of-pocket
- ctDNA testing in implementation phase: 2025

Molecular Tumour Boards

n/a

Access to PCM treatments

Specialists organisations or pharmaceutical companies fill in the drug reimbursement application: drug and indication

The Estonian Health Insurance Fund will evaluate: often not positive decision

Challenges

Lack/ uncertainties in funding, no innovation fund; lack of attractiveness to pharmaceutical companies; Lack of workforce

DRUP-Like Clinical Trial

ESTOPRET

planned to be active in Q3 2025

Opportunities

- Creation of the Estonian Cancer Network (ESTCAN): coordination body bringing together people working on cancer in Estonia.
- Momentum: people want change
- National and international collaboration
- ESTOPRET active = better treatment options

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Date April 2025

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PCM4EU

Finland

Country by figures

Population

5.5 M

Comprehensive Cancer Centres

3 + 2 (5 university hospitals)

New cancer cases per year

All cancers: 37 712 (2022)

Precision Cancer Medicine

Does the country have a national PCM: Yes, FINPROVE study runs in all 5 University hospital.

Feasibility study/ multi-stakeholder/ extra funding: No.

National guidelines on PCM: In progress.

Does the country have regional PCM initiatives: Not outside of FINPROVE.

PCM diagnostics

How is genomic testing organised in your country? Each region has their own – lack of national guidance and reimbursement.

Reimbursement

Only standard of care is reimbursed – fully dependent on tumour type.

Molecular Tumour Boards

Regional MTBs run in 3 sites, National through Helsinki.

Access to PCM treatments

Off-label use is not possible. Patient specific applications can be used but are not accepted unless strong rationale (at least phase 2 data). Funding through hospital budget. National mechanisms do not exist.

DRUP-Like Clinical Trial

FINPROVE, **www.hus.fi/finprove**

Challenges

Lack of sustainable funding, national guidance and national network for comprehensive genomic profiling.

Opportunities

Structured network for collaboration within all hospital districts – applies to both university and regional hospitals. The importance of PCM is well- understood!

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Date April 2025

Co-funded by the European Union

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France

Country by figures

Population

68 M

Comprehensive Cancer Centres

18

New cancer cases per year

433 136

Precision Cancer Medicine

Does the country have a national PCM initiative? Yes (PFMG2025)

Feasibility studies / multi-stakeholder/ extra funding? add text

National guidelines on PCM?
Diagnostic PFMG2025, treatments HAS

Does the country have regional PCM initiatives? Yes (eg PROFILER feasibility study)

PCM diagnostics

How is genomic testing organised in your country? mostly public, some private, distributed. Only centralized are PFMG2025 and PRISM (foundation medicine)

Reimbursement

not consistent; hospitals can partially get reimbursement for the test through the RIHN but under considerable administrative burden

Molecular Tumour Boards

MTBs in several hospitals centralizing cases

Access to PCM treatments

n/a

DRUP-Like Clinical Trial

MOST, MOST plus, MEGAMOST

https://pubmed.ncbi.nlm.nih.gov/38807312/

Challenges

number and variety of trials options

Opportunities

Cross border access, visibility for pharmas, networking, trial matching tools, funding, vision

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PCM4EU

Germany

Country by figures

Population

84 M

Comprehensive Cancer Centres

15 excellence centres (7 involving several univ. hospital/city); 27 major centres

New cancer cases per year

493 000

Precision Cancer Medicine

Does the country have a national PCM initiative? YES- German Network for Personalized Medicine (DNPM)-Model Project

Feasibility studies / multi-stakeholder/ extra funding? YES- within the DNPM network

National guidelines on PCM? YES – on a national level, usually cancer-type specific; and within DNPM

Does the country have regional PCM initiatives? YES-Based on local Centers for Personalized Medicine (ZPM) within the DNPM network

PCM diagnostics

How is genomic testing organised in your country? Testing is reimbursed through public and private health insurance

Carried out by both non-for-profit and for-profit institutions

(WES and WGS only through non-for-profit institutions)

Reimbursement

Single gene testing and panel sequencing; WES and WGS in a 5-year evaluation period within the model project

Molecular Tumour Boards

Clinically: Mainly local MTB

Research Programs: Partly within national networks (e.g. DKTK MASTER)

Access to PCM treatments

On Label: Treatment is granted according to EMA and HTA-body decisions

Last line: Decision in MTB => i) off-label treatment or ii) inclusion in clinical trial

DRUP-Like Clinical Trial

DNPM nationwide trial structure (in progress)

DKTK-MASTER (young onset/rare cancers)

Challenges

Access to reimbursement for testing is still supoptimal
Access to testing has regional differences
National regulations regarding clinical trials

Opportunities

- Improvement of clinical trial infrastructure in Germany
- Awareness for patients

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Date 9 April 2025

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Hungary

Country by figures

Population

9.5 M

Comprehensive Cancer Centres

1

New cancer cases per year

70 000

Precision Cancer Medicine

Does the country have a national PCM initiative? Yes. **Feasibility studies / multi-stakeholder/ extra funding?** No.

National guidelines on PCM?
In 2021 the National Molecular Oncoteam was established by NEAK, the National Institute of Health Insurance Fund Management. All comprehensive genetic profiling and treatments are covered by this fund.

Does the country have regional PCM initiatives? All regional precision cancer medicine applications are evaluated by NEAK, all regional patient–centered application are evaluated by National MTB.

PCM diagnostics

How is genomic testing organised in your country? In oncology, the majority of tests are performed within the public health system, and it is centralised. The main centre is the Molecular Pathology Department at NIO (performing approx. 60% of all tests), followed by 3 University centers.

Reimbursement

Yes, under NEAK.

Molecular Tumour Boards

All oncology care providers have MTBs. In addition, a national molecular tumor board was initiated in 2019. Its main role is to evaluate all applications for comprehensive genetic profiling and to issue therapeutic recommendations. In addition, organ-specific MTBs are regularly working at NIO and University Centers.

Access to PCM treatments

All treatments are covered by The National Institute of Health Insurance Fund Management (NEAK)

DRUP-Like Clinical Trial

n/a

Challenges

The best diagnostic procedures are not uniformly accessible within Hungary; therefore, best practice guideline and quality assurance in pathology diagnostics have been initiated

Opportunities

Mandatory, centralised, digital medical informatic system (eHEalth) for all health care providers. All diagnostic and medical reports are available in this system, facilitating and accelerating the introduction of new technologies.

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Date 6 April 2025

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PCM4EU

Italy

Country by figures

Population

59 M

Comprehensive Cancer Centres

10- 15

New cancer cases per year

395 000

Precision Cancer Medicine

Does the country have a national PCM initiative? Law 190/2023: establishment of MTBs and definition of the centers that can perform comprehensive genomic profiling.**Feasibility studies / multi-stakeholder/ extra funding?** n/a

National guidelines on PCM?
AIOM guidelines define the biomarkers and the treatment of choice for solid tumors.

Does the country have regional PCM initiatives? The national law is binding for regions; these however have different models for implementing PCM.

PCM diagnostics

How is genomic testing organised in your country? The Italian NHS provides universal healthcare coverage and reimburses testing for biomarkers that have approved TT.

Reimbursement

Comprehensive genomic testing reimbursement is defined at a regional level. In Lombardy, it is reimbursed for certain cancer types (NSCLC, biliary, rare tumors) and for patients without standard options, after MTB discussion

Molecular Tumour Boards

Different models in different regions:

Some regions implemented hub-and-spoke models, others opted for a unique centralized MTB.

Access to PCM treatments

Standard TT available: Oncologist -> genomic testing -> TT reimbursed by NHS

Standard TT not available in the setting of the patient: Oncologist -> MTB -> genomic testing -> MTB discussion -> expanded access/clinical trial/off label (off label possible only for ESCAT I-II alterations).

DRUP-Like Clinical Trial

ROME trial

Challenges

Genomic testing reimbursement for all the patients in early lines of treatment

Simplified access to off-label treatments

Opportunities

Creation of DRUP-like protocols; Nationwide initiatives for PCM data sharing are ongoing; Large, randomized, multicentric studies to grant access to TTs generating high-level evidence (e.g. ROME trial).

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PCM4EU

Lithuania

Country by figures

Population

2.9 M

Comprehensive Cancer Centres

0 CCC, 1 OECI- accredited

New cancer cases per year

16 413 (2022)

Precision Cancer Medicine

Does the country have a national PCM initiative? No

Feasibility studies / multi-stakeholder/ extra funding? Feasibility study 2024, PCM dedicated research funding programme prepared 2025

National guidelines on PCM?
No

Does the country have regional PCM initiatives? PCM academy, PANTUMOR-LT

PCM diagnostics

How is genomic testing organised in your country? Single gene tests or small panels performed in 4 genetic labs in university hospitals, comprehensive gene testing only in 2 labs

Reimbursement

Genetic panel (Prosigna) covered by HIF since 2022
- 16 gene panel for solid tumors covered by HIF since 2025
- Large panel testing only in research projects

Molecular Tumour Boards

At NCI since 2024, no National MTB

Access to PCM treatments

- On label use reimbursed from HIF (does not cover all EU-registered indication, reimbursement process is slow
- Ultra rare disease and conditions board at the State Health Fund considers individual applications for ultra rare diseases (1/200 000)
- Off-label treatments usually not reimbursed

DRUP-Like Clinical Trial

PANTUMOR-LT (2025)

Challenges

- No national PM strategy and coordinated action plan sustained through changing government
- Lack of consolidated PM ecosystem
- Low expenditure for healthcare
- Low availability of innovative drug, long waiting times
- Drug and genetic testing reimbursement model does not fit PM needs

Opportunities

a national plan, EU projects, collaboration

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Date 23 April 2025

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PCM4EU

Netherlands

Country by figures

Population

18 M (Feb 2024)

Comprehensive Cancer Centres

7, 3 OECI- accredited

New cancer cases per year

128 927 (2023)

Precision Cancer Medicine

Does the country have a national PCM initiative? Feasibility studies / multi-stakeholder/ extra funding? National guidelines on PCM? Does the country have regional PCM initiatives? PCM: no general national guidelines but there are national agreements and clinical guidelines for use + reimbursement of molecular diagnostics / targeted therapies with close collaboration between medical oncologists, pathologists, payers/HTA-bodies etc.

National research initiatives for PCM e.g. Drug Rediscovery Protocol (DRUP) and Drug Access Protocol (DAP)

PCM diagnostics

How is genomic testing organised in your country? Extensive molecular diagnostics are mainly performed in the regional academic medical centers. Most of the smaller panel genomic testing is also performed in smaller hospitals. Reimbursed by public healthcare insurers.

Molecular Tumour Boards

Regional MTBs in every academic medical center and the Netherlands Cancer Institute (Comprehensive Cancer Center) Medical oncologists, clinical molecular biologists, pathologists, clinical geneticist, researchers; separate reimbursement for MTBs as service.

Reimbursement

- Small and large NGS panels for DNA analysis are reimbursed for specific indications (i.e. tumour type, disease stage).
- Several targeted NGS panels for RNA analysis are reimbursed for specific indications, but no full RNA sequencing.
- WGS or WES not reimbursed, except WGS for diagnosis of cancer of unknown primary.

DRUP-Like Clinical Trial

Drug Rediscovery Protocol (**DRUP trial**):

A Dutch National Study on behalf of the Center for Personalized Cancer Treatment (CPCT) to Facilitate Patient Access to Commercially Available, Targeted Anti-cancer Drugs to determine the Potential Efficacy in Treatment of Advanced Cancers with a Known Molecular Profile.

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

Website: www.drupstudy.nl

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Co-funded by the European Union

PCM4EU

Norway

Country by figures

Population

5.5 M

Comprehensive Cancer Centres

1

New cancer cases per year

38 000

Precision Cancer Medicine

Does the country have a national PCM initiative? Yes

Feasibility studies / multi-stakeholder/ extra funding? Yes

National guidelines on PCM?
Yes (at high level)

Does the country have regional PCM initiatives? Yes

PCM diagnostics

How is genomic testing organised in your country? Genomic testing is conducted through the public healthcare system. Comprehensive genomic testing is accessible as part of a national initiative, InPreD.

Reimbursement

i)TSO500 for all metastatic cancer patients with need

ii) Whole genome sequencing for refractory pediatric patients iii) Methylation analysis for brain tumours

Molecular Tumour Boards

The National MTB is organised by Oslo University Hospital as part of the national infrastructure of precision diagnostics, InPreD. The diagnostic work-up is done by the six university hospitals.

Access to PCM treatments

On-Label Treatment: i) The company submits documentation to the HTA body. ii)The HTA body provides the HTA report iii) The Procurement Trust negotiates prices iv) The Heads of the four Regional Health Authorities (budget holders) determine if the drug should be reimbursed.

Off-Label Treatment: Reimbursement is approved by the local hospital or department (local budget holder).

DRUP-Like Clinical Trial

IMPRESS-Norway

impress-norway.no

Challenges

Long delays in reimbursement decisions (2–3 years); Lack of a structured framework for Managed Entry Agreements (MEA) to facilitate access to PCM treatments.

Opportunities

Strong collaboration between Nordic countries (joint HTA processes and procurement). This collaboration might provide a foundation for broader European cooperation.

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Date January 2025

Co-funded by the European Union

PCM4EU

Poland

Country Information

Country by figures

Population

37.6 M (2023)

Comprehensive Cancer Centres

2 OECI members + several regional centres

New cancer cases per year

170 000

Precision Cancer Medicine

Does the country have a national PCM initiative? National Cancer Strategy 2020-2030 sets a direction for integrating precision oncology into the national healthcare framework (investment in science and innovation as one of its five priority areas); **Center of Excellence for Precision Oncology at MSCI, Warsaw**

Feasibility studies / multi-stakeholder/ extra funding? Non-governmental organisations supporting PCM developement: **Polish Personalized Medicine Coalition**, **Polish Society of Oncology**

PCM diagnostics

How is genomic testing organised in your country? Decentralized, available in major cancer centers and academic institutions.

Reimbursement

Reimbursed: single-gene tests or small multi-gene panels

Not reimbursed: Comprehensive multi-gene NGS sequencing - only through commercial options (e.g., Foundation Medicine), and commercial clinical trials.

Molecular Tumour Boards

area of development

DRUP-Like Clinical Trial

POLARIS: A Phase 2 Open-Label Precision Oncology Tumoroid-Enhanced Multi-Drug Repurposing Study in non-operable/metastatic cancers - *proposal submitted to Medical Research Agency for funding*

Opportunities

- **Poland's participation in European PCM consortia** provides access to best practices and expertise in the PCM field, while aligning national policies and strategies with EU priorities.
- **Medical Research Agency (MRA) resources and activities** - a proposal to establish the DLCT initiative (POLARIS study) in Poland has been prepared and submitted (results in May 2025)
- **Government funding priorities: The National Cancer Strategy 2020-2030, as well as National Oncology Network**
- **A robust landscape of cancer patient organizations** provides an opportunity to educate the general public, as well as offers unique insights into patient needs, which can inform the development of more patient-centered PCM strategies and policies.
- **Increased media interest in oncology** provides a platform to disseminate PCM knowledge and advocate for systemic improvements

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Date 25 April 2025

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Portugal

Country by figures

Population

10 M

Comprehensive Cancer Centres

1

New cancer cases per year

69 567

Precision Cancer Medicine

Does the country have a national PCM initiative? No comprehensive pcm strategy but several initatives (Estratégia Nacional para a Medicina Genómica - Portuguese Strategy for Genomic Medicine; PT_ MedGen)

Does the country have regional PCM initiatives? IPO Porto has developed a local molecular screening program (Precision Oncology Program of IPO Porto: POP-IPOP) that is now expanding at regional level, with agreements with already 3 other hospitals in the region currently regularly participating in multidisciplinary MTB discussions.

PCM diagnostics

How is genomic testing organised in your country? Genomic testing is heterogeneous and reimbursement decisions are not made at national level.

In the public sector, the costs of genomic testing are covered by hospitals, and the decision on which panels and kit to use is made locally at hospital level. Frequently, comprehensive genome sequencing is done externally (assigned to third parties or to private vendors), few public hospitals perform comprehensive genome sequencing in-house.

Additionally, private vendors are available to provide NGS testing (in the private sector).

Molecular Tumour Boards

IPO Porto implemented the first formal Molecular Tumor Board in Portugal, to support its molecular screening program (POP-IPOP), with in-house NGS testing and the multidisciplinary cases discussion has been made available to other centers for second opinion consultation at regional and national level. Other initiatives of MTB are being established in other institutions. IPO-Porto MTB is evolving fast to build a national MTB through agreements that are being set with other hospitals and research institutions.

Access to PCM treatments

Currently, there is no HTA formal evaluation for other than market authorization indications. Off-label treatment is not assessed for reimbursement decision at national level: decision is made locally at hospital level.

DRUP-Like Clinical Trial

POP trial – Precision Oncology Platform *in implementation, expected application JUN2025, pending decisions from pharma companies*

Challenges

Lack of harmonization and standardization in the access to diagnostic and treatment, whit heterogeneity across the country

Opportunities

Possible ease of implementation of structured national strategy in small/medium size country through a network of well-organized cancer centres.

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Date 25 April 2025

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Romania

Country by figures

Population

18.9 M

Comprehensive Cancer Centres

Oncology Institutes (3), private Cancer Centers with reimbursed services (2)

New cancer cases per year

100 471

Precision Cancer Medicine

Does the country have a national PCM initiative? The law on personalized medicine

Feasibility studies / multi-stakeholder/ extra funding? None available

National guidelines on PCM?
Not available

Does the country have regional PCM initiatives? Romania does not currently have regional PCM initiatives but is participating in EU programs such as EPPerMed.

PCM diagnostics

How is genomic testing organised in your country? Genetic tests to guide the use of reimbursed therapies are available through private laboratories, but reimbursement is not ensured for all cancer types.

Reimbursement

Since 2023, tumour genetic testing for breast, ovarian, lung and colorectal cancer is reimbursed through the National Oncology Programme.

Molecular Tumour Boards

Molecular tumor boards are not available. The number of geneticists is very limited, partly due to the lack of specialized training programs for medical professionals.

Access to PCM treatments

Liimited to reimbursed therapies; outside of four cancer types, patients lack access to both molecular diagnostics and matched therapies.

DRUP-Like Clinical Trial

Not available

Challenges

Romania lacks data infrastructure, including a national cancer registry, with limited coordination between centers and fragmented oncology care.

Opportunities

Legal framework in place; strong private sector enhancing competition and diagnostic quality.

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PCM4EU

Spain

Country Information

Country by figures

Population

48.7 M

Comprehensive Cancer Centres

1

New cancer cases per year

286 664

Precision Cancer Medicine

Does the country have a national PCM initiative? No. Some regions have regional PCM initiatives.

National guidelines on PCM?
There are some joint guidelines from the Spanish Society of Pathology (SEOM) and the Spanish Society of Medical Oncology (SEAP) with a minimum number of biomarkers to be cover by tumor type.

PCM diagnostics

How is genomic testing organised in your country?

Reimbursement

Regional strategies are covered by the funds for the regional health system. Some centers, such as VHIO, have larger and ISO certified panels thanks to the support of charities ISO certified panels thanks to the support of charities.

Molecular Tumour Boards

n/a

Access to PCM treatments

n/a

Challenges

Regional health system reluctant to reimburse an off -abel medication (even with a shared-risk strategy)

Disparities in the coverage of the NGS (technical challenge), in the certification and in the access of the population

DRUP-Like Clinical Trial

open a DLCT with a stage 3 of Olaparib cohort

Opportunities

Some key stakeholders involved in reimbursement identified in Catalonia.

Support from PCM4EU has been essential in our interactions with AZ

Stage 3 – Olaparib arm is envision as great opportunity to overcome some of the challenges.

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PCM4EU

Sweden

Country by figures

Population

10.6 M

Comprehensive Cancer Centres

5 CCC, 1 preparing for accreditation

New cancer cases per year

69 000 (2021, incidence rising)

Precision Cancer Medicine

Does the country have a national PCM initiative?

No state-level strategy for personalised cancer medicine. State-funded infrastructures for life science research (SciLifeLab), clinical implementation of precision medicine (Genomic Medicine Sweden) and clinical trials for precision cancer medicine (Testbed Sweden Precision Health Cancer). Newly formed Proteome Medicine Sweden.
No specific PCM recommendations, National Cancer Care Program Groups within the Confederation of Regional Cancer Centers issue recommendations on diagnostics and treatment (including PCM).

Regional Genomic Medicine Centers are in place and closely related Precision Medicine Centers just starting. No substantial specific funding for feasibility studies in any of these (programs at KI an exception).

PCM diagnostics

How is genomic testing organised in your country? Biomarker testing in 30 pathology departments in 21 regions. Genomic testing for cancer performed mainly at the 7 university hospital laboratories (gene panel testing in 2 regional centers as well). Very limited role for private labs.

Reimbursement

WGS/WTS for pediatric malignancies in clinical routine, pilot on WGS/WTS for acute leukemias, gene panels for comprehensive genomic profiling under implementation.

Molecular Tumour Boards

Local, regional and national MTBs but only for specific malignancies. The pan-cancer, late-stage MTB planned for the FOCU.SE trial under formation.

Access to PCM treatments

Swedish patients pay a limited part of the actual treatment costs directly, the rest tax funded. The Board of Pharmaceutical Benefits decide on pricing and reimbursement of new pharmaceuticals for out-patients, county councils procure medicines for hospital use and the cost for PCM treatment is generally covered by the budget of the individual clinical department.

DRUP-Like Clinical Trial

BoB trial running at Karolinska Institutet as part of the CCE collaboration. MEGALiT, a trial at two sites, recently closed. Intense work with starting up and funding of the national **FOCU.SE** trial.

Challenges

Lack of a national strategy for personalised cancer medicine on a state level and thus lack of clear mandates. Legal framework for data sharing not in place. Upscaling of testing and targeted treatments lagging. Fragmented PCM efforts, lacking coordination.

Opportunities

National infrastructures for cutting- edge PCM research and a high quality clinical implementation in place. Intense activity in several PCM intiatives. Newly awakened, high interest from the regions.

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PCM4EU

UK

Country by figures

Population

67 M (Jan 2024)

Comprehensive Cancer Centres

15- 20 major cancer centres

New cancer cases per year

392 000 (Mcmillian 2024)

Precision Cancer Medicine

Does the country have a national PCM initiative? NHS Genomic Medicine Service, Genomics England, NHS Long Term Plan. DETERMINE team are linked closely with NHS-England. **Feasibility studies / multi-stakeholder/ extra funding?** 100,000 Genomes project (sequence 100,000 genomes to explore feasibility of genomic medicine in routine clinical practice – completed 2015) **National guidelines on PCM?** NHS England, National Institute for Health and Care Excellence (NICE), Health Technology Assessment (HTA). **Does the country** Genomic Medicine Centres – focus integrating genomic testing into clinical practice, Cancer Alliances – embed and mainstream genomic/genetic testing across oncology pathways, NIHR BioResource – collecting diverse biological and health data from patients, Precision Medicine Catapult – translating scientific discoveries into real-world applications through partnership ecosystem across the UK.

PCM diagnostics

How is genomic testing organised in your country? National Genomics Medicine Service is delivered through seven Genomic Laboratory Hubs within NHS – testing according to National test directory (WGS/gene panels etc.)

Reimbursement

Genomic profiling funded by NHS-England as per National Test Directory (NTD), WGS for specific indications, tests for rare diseases. All reimbursed PM therapies have linked genomic testing available (as per NTD)

Molecular Tumour Boards

Genomic Tumour Advisory Boards (GTAB) run by Genomic Laboratory Hubs in framework of the NHS Genomic Medicine service - (assistance to interpret NHS and WGS – multidisciplinary group in NHS interprets complex/challenging genomic cases emerging from the National Test Directory)

Several initiatives and networks have been developed – i.e. TARGET National MTB to assist the decision-making process in a regional setting.

DRUP-Like Clinical Trial

DETERMINE (cruk.org/determine)

Presented at ESMO (DOI: 10.1016/j.annonc.2023.09.1902)

Challenges

Complexity of testing pathways – gap between research and clinical practice.

Opportunities

Potential for novel route to reimbursement for re-purposed Precision Medicine Therapies.

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