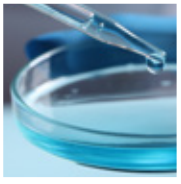
Advancing precision oncology treatment and testing across Europe

An evidence-based roadmap for healthcare system stakeholders to improve cancer care









Contents

Glossary

AAC
Accelerated Access Collaborative (United Kingdom)

ALK
Anaplastic Lymphoma Kinase

API
Application Programming Interface

BMBF
Federal Ministry of Education and Research (Germany)

CAR
Chimeric Antigen Receptor

CaSP
Cancer Screening Program

CatSalut
Catalan Health Service (Spain)

CCP
Clinical Communication Platform

CDx
Companion Diagnostic

CGP
Comprehensive Genomic Profiling

CoC
Chain of Custody

ComPerMed
Commission of Personalised Medicine (Netherlands)

CPCT
Cente r for Personalized Cancer Treatment (Netherlands)

ctDNA
Circulating Tumour DNA

DBO
Data Backbone for Oncology

DKFZ
German Cancer Research Centre (Deutsches Krebsforschungszentrum) (Germany)

DKTK
German Cancer Consortium (Deutsches Konsortium für Translationale Krebsforschung) (Germany)

DRG
Diagnosis-Related Group

DRUP
Drug Rediscovery Protocol (Netherlands)

EBCP
Europe's Beating Cancer Plan

EBM
Uniform Value Scale (Einheitlicher Bewertungsmaßstab) (Germany)

EGFR
Epidermal Growth Factor Receptor

EHDS
European Health Data Space

EMA
European Medicines Agency

EQA
External Quality Assessment

ER
Estrogen Receptor

ESR1
Estrogen Receptor 1

EU
European Union

FAIR
Findable, Accessible, Interoperable and Reusable

G-BA
Federal Joint Committee (Gemeinsamer Bundesausschuss) (Germany)

GDP
Gross Domestic Product

GDPR
General Data Protection Regulation

GDI
Genomic Data Infrastructure

GTD
Genomic Test Directory (United Kingdom)

HCP
Healthcare Professional

HSE
Health Service Executive (Ireland)

HTA
Health Technology Assessment

ICS
Catalan Health Institute (Institut Català de la Salut) (Spain)

INCa
Institut National du Cancer (France)

IQWiG
Institute for Quality and Efficiency in Health Care (Institut für Qualität und Wirtschaftlichkeit im Gesundheitswesen) (Germany)

IVDR
In Vitro Diagnostic Medical Devices Regulation

JCAs
Joint Clinical Assessments

LDT
Laboratory-Developed Test

LEA
Essential Levels of Assistance (Livelli Essenziali di Assistenza) unsw(Italy)

MDT
Multidisciplinary Team

MEA
Managed Entry Agreement

MS
Member State(s)

MTB
Molecular Tumour Board

NCCP
National Cancer Control Programme

NCIS
National Cancer Information System

NGS
Next-Generation Sequencing

NHS
National Health Service (United Kingdom)

NICE
National Institute for Health and Care Excellence (United Kingdom)

NKI
Netherlands Cancer Institute (Netherlands)

OECD
Organisation for Economic Co-operation and Development

OMIQ-HES
Oncology Molecular Information and Quality – Health Ecosystem of Catalonia (Spain)

PACO
Patients' Advisory Committee

PALGA
Dutch Pathology Registry (Netherlands)

PCM4EU
Personalised Cancer Medicine for all EU Citizens

PrOSPeCT
Precision Oncology Screening Platform Enabling Clinical Trials

PRO
Patient-Reported Outcome

QA
Quality Assurance

R&D
Research and Development

RNA
Ribonucleic Acid

RWD
Real-World Data

RWE
Real-World Evidence

SACT
Systemic Anti-Cancer Therapy

SES
Socioeconomic Status

SHI
Statutory Health Insurance

SISCAT
Integrated Public Health System of Catalonia (Spain)

SLA
ervice-Level Agreement

SOP
Standard Operating Procedure

TAT
Turnaround Time

UMC
University Medical Centre

UNSW CMO
University of New South Wales Centre for Molecular Oncology (Australia)

WGS
Whole-Genome Sequencing

WIDE
Whole Genome Sequencing Implementation in Standard Diagnostics for Every Cancer Patient

1. Executive Summary

Cancer is the second leading cause of death in Europe and is projected to become the first by 2035. Conventional, "one-size-fits-all" healthcare system pathways cannot keep pace with cancer's biological complexity, leaving too many patients without timely, effective care. **Precision oncology, rooted in genomics, molecular diagnostics, and data science, offers a proven path to better outcomes, fewer adverse effects, and smarter use of resources**. Europe already has the scientific excellence and policy momentum to deliver precision medicine at scale, yet access remains highly unequal, both within and across Member States.

This white paper translates that challenge into an agenda and implementation manual for national and regional decision-makers. The paper assembles a practical evidence base of fifteen case studies and promising practices from EU countries and beyond, a diagnostic lens of recurring "archetypes" that impede progress, and a sequenced toolkit of policy actions (Figure 1). It will enable Ministries of Health, payers/Health Technology Assessment (HTA) bodies, regional authorities, cancer institutes, and clinical networks to progress from case studies and good practices towards predictable, equitable precision oncology. Success depends on a whole-ecosystem effort in which every actor does their part, together.

Precision oncology reform is both urgent and feasible. This white paper shows that successful reform relies on three priority areas: (i) raising awareness among patients, professionals, and payers; (ii) building the infrastructure and workforce to deliver high-quality, timely testing, and expert deliberation; and (iii) aligning funding and reimbursement so testing and therapy access advance together. **The longer reforms are delayed, the higher the risk of late diagnosis and rising system costs; the wider the access gap, the harder and more expensive it is to close**.

Europe has the tools, knowledge, and shared frameworks to make precision oncology a pillar of cancer care in every Member State. Decision-makers should diagnose system archetypes, (taking each system's level of maturity into consideration), select the right reforms, and mobilise EU levers, tracking outcomes with transparency. **If EU institutions sustain coherent frameworks and targeted investment, if cancer communities are enabled, and if every Member State implements this toolkit with urgency, then Europe can ensure the promise of precision oncology becomes a lived reality for every patient**. The benefit of action will be a healthier, more resilient, and more competitive Europe. Now is the moment to turn alignment into access, and access into outcomes.

2. Introduction

As of 2025, cancer remains one of Europe's most pressing health challenges. Precision oncology is one of the most promising innovations in modern medicine. By using molecular and genomic data to tailor therapies to each individual tumour, it enables more effective treatment, fewer side effects and smarter use of healthcare resources. Approved precision oncology treatments and diagnostics already exist in Europe and have demonstrated clear clinical and system-level benefits. Yet these advances are not reaching all patients equally. **Fragmented implementation, regional disparities, and persistent structural barriers are preventing the full potential of precision oncology from being realised**.

This white paper goes beyond describing those challenges. It is designed to mobilise Member States by offering concrete, actionable solutions grounded in real-world evidence. Building on these insights and on previous work by the EFPIA and partners (1,2), and confirmed through continued engagement with policy and clinical stakeholders, **this work focuses on three critical areas: (i) awareness about precision oncology; (ii) infrastructure and workforce; and (iii) funding and reimbursement**. These areas have been consistently identified as the most urgent and actionable levers where national-level reform can unlock meaningful progress in the short-to-medium term.

This work has been shaped through an extensive process of expert engagement, over the course of more than one year, in the form of interviews, bilateral meetings, joint drafting sessions, and a multi-stakeholder workshop. Participants included clinicians, regional health authorities, patient representatives, health economists, academics, and industry leaders. Through their input, we gathered and assessed a wide range of **case studies**, evaluated their transferability, identified **system problems** (clustered by area), and co-developed a set of **policy recommendations**. Taken together, the result is a **toolkit for policy actions** that outlines how Member States can raise awareness of precision oncology among patients and professionals, strengthen the infrastructure and skills needed to deliver it, and adapt funding and reimbursement systems to reflect the realities of personalised medicine. Finally, **EU Policy levers and additional instruments** were identified to support Member States in improving precision oncology in their respective systems. In doing so, this paper aims to serve as a practical tool to inform national planning, support reform agendas, and guide future investment decisions.

By advancing precision oncology, these actions also lay the groundwork for more equitable, innovation-ready health systems that can benefit other therapeutic areas beyond oncology. Seen in this context, precision oncology is not only a scientific promise but also a strategic opportunity. Member States now have the chance to act collectively and make precision oncology a central pillar of their national cancer plans and Europe's broader health agenda.

3. The Case for Action

Why Political Leadership is Critical to Realising the Promise of Precision Oncology

3.1 The Promise of Precision Oncology

Cancer imposes a profound and growing impact on Europe's health, wellbeing, and prosperity. **EU cancer cases and deaths are expected to reach 3.2 million new diagnoses and 1.6 million annual deaths by 2040 (3,4)**. According to the latest comprehensive pan-European comparison, cancer has become the second leading cause of death in Europe, accounting for 23% of all deaths and poised to become the leading cause by 2035 (5). Considering this steady rise, the necessity for building on and strengthening current policy efforts has never been clearer. In addition to its toll on patients and families, cancer also exacts a massive, rising, economic cost. Based on modelling for the period 2018–2040, cancer-related premature mortality among people of working age (15–64 years) across Europe is estimated at approximately 8 million deaths (6) causing cumulative productivity losses of €1.3 trillion, or an annual average of €58.7 billion. **This substantial loss is further compounded by the direct costs of treatment and care, which continue to climb alongside cancer incidence and Europe's population ages**.

Generalised therapeutic approaches have struggled to address cancer's complexity and heterogeneity. Cancer spans hundreds of genetically and clinically distinct diseases, leaving many patients with limited or suboptimal options (3,4). Furthermore, the economic weight of cancer is deeply felt in both lost workforce productivity and in the strain on health and social systems, making **strategic investment in equitable, effective cancer control essential for Europe's future prosperity and resilience**.

Important as it may be, investing in cancer prevention and early diagnosis through screening is not enough. We must also make optimal use of the possibilities to improve the effects of cancer treatment. **Precision oncology offers a fundamentally new solution (8,9), delivering higher response rates, fewer unnecessary side effects, and new hope for patients with rare or previously untreatable cancers** (3,5). These technical advances have the potential to transform patient experience, system efficiency, and societal outcomes, making Europe a leader in cancer science, care, and innovation (8,9). Continued EU-level commitment is indispensable for realising the full promise of precision oncology and securing Europe's strategic position in the global genomics and health innovation ecosystem (3,10–12).

3.2 Critical Barriers to Expanding Access to Precision Oncology in the EU

Despite ongoing improvements, access to precision oncology remains far from being equitably available within and between EU countries (13–16). Access disparity has resulted in a two-tier system where patients in wealthier regions often benefit from advanced care, while others face significant barriers for access to even basic cancer care, posing a critical challenge to health equity and European solidarity. The urgency of addressing these barriers aligns with the strong policy momentum at the EU level. Initiatives such as Europe's Beating Cancer Plan, the Cancer Mission and the European Health Data Space underscore the commitment to integrate genomics, data sharing, and innovation into national health systems, setting ambitious targets aimed at reducing disparities, fostering innovation, and improving patient outcomes (10,12). **This policy landscape offers a foundation for coordinated action but also highlights the considerable work still needed to translate strategy into widespread, equitable implementation of precision oncology** (13–18).

There are persistent critical gaps in **awareness** of precision oncology. Many patients lack accessible, plain-language information to make informed choices (19) and their perspective and preferences are not consistently incorporated into treatment decision-making. Precision oncology should therefore be presented with clear, decision-relevant information that transparently conveys potential benefits, harms and uncertainties. Healthcare professionals, especially in certain regions, often face barriers to up-to-date training and multidisciplinary support, limiting the effective adoption of the latest advancement in precision medicine in clinical care (20).

Similarly, **policymakers and payers often have insufficient opportunities for ongoing knowledge exchange**, hindering their ability to support the integration of precision oncology within healthcare systems (1).

Investment in the **infrastructure and workforce** for precision oncology is lagging. Development of educational programmes, upskilling initiatives, and expanded testing centres is still needed to ensure all patients have access to the necessary expertise and resources (13–16). **Enhancing working conditions and fostering multidisciplinary collaboration are essential to keeping healthcare professionals up-to-date and systematically guiding patient care**. Persistent inconsistencies in laboratory standards and quality assurance reinforce inequities and limitations in data sharing and interoperable digital platforms further hamper both routine care and research, highlighting the need for robust frameworks that balance privacy protection with the seamless exchange of data across borders (1,11,12,16).

Current **funding and reimbursement** models for precision oncology are often outdated. Separate or inconsistent approaches to covering diagnostics and targeted therapies in EU healthcare systems create fragmentation, unequal access to care and high out of pocket expenses for patients (13,17,21,22). Traditional value assessments often fail to capture the full benefits and long-term impact of precision medicine. Furthermore, budget planning rarely reflects precision oncology's real-world efficiency and potential system-wide savings may not always fall into the hands of the sector making the investments (17,21,23,24). Guidelines for comprehensive value assessments of test–treatment combinations exist but are often not adhered to (25). It is also important to recognise that **strategic investment in precision oncology could position Europe as a global leader in health innovation, enhancing competitiveness in a rapidly evolving landscape**, particularly in comparison to advancements in the US and Asia, where genomic infrastructure and reimbursement processes are advancing faster. More adaptive, inclusive, and forward-looking approaches, that incorporate broader health and economic benefits, research-driven value models, and the perspectives of clinicians and patients, are needed (1).

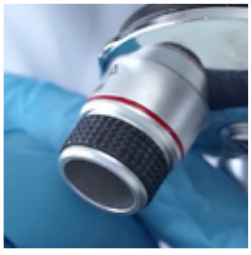
These barriers are the product of risk-aversion, inaction, siloed policymaking, and uneven investment. Overcoming them is a practical policy task: clarify responsibilities, provide stable funding for core capabilities, and coordinate programmes across levels (10,18). Doing so will **accelerate the arrival of new standards in cancer care, replace fragmented pilot projects with scalable international systems, and unlock the full potential of Europe's scientific and healthcare communities (10,18)**.

3.3 Ensuring Sustainable Leadership in Precision Oncology Across Europe

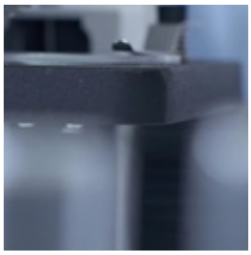
The imperative to act arises from several converging priorities reflecting the EU's collective agenda and healthcare systems, as well as stakeholders across the cancer research and care ecosystems. First, it is essential to **ensure that advances in precision oncology benefit all patients across Europe**, not only those near centres of excellence or in well-resourced regions, but all who could gain from personalised cancer care (13–16). Second, **maintaining and strengthening Europe's leadership in cancer research and care** requires the development of resilient, future-ready healthcare ecosystems that foster scientific excellence, retain skilled professionals, and encourage cross-border collaboration and knowledge sharing (10–12). Third, **achieving equity and sustainability depends on the design and implementation of policies** that guarantee universal access to high-quality, tailored cancer treatment, so no patient is left behind due to geographic or socioeconomic disparities (17,18). This includes understanding the significant economic benefits of enabling patients to live longer, contribute productively to society, and provide care to others, which are all critical for sustainable health systems and societies as a whole. As other global regions ramp up investment in genomic infrastructure and precision diagnostics, Europe must act decisively to maintain its leadership and retain strategic autonomy in healthcare innovation.

The following section highlights selected case studies from a range of EU Member States and other countries. It showcases tangible, context-specific approaches that have successfully surmounted key obstacles to precision oncology implementation. These examples offer valuable lessons on overcoming challenges related to awareness, infrastructure, workforce, reimbursement, and funding, illustrating how aligned efforts can translate scientific advances into substantial patient benefits and reinforce national health system resilience.

Case Studies







4. Case Studies

The following case studies and promising practices were chosen to reflect a geographically diverse mix of contexts and healthcare systems in Europe and beyond. These examples were derived from different regions and from both national programs and regional initiatives. This ensured coverage of small and large countries, centralised and decentralised health systems, and varying levels of precision oncology maturity. The selection process was informed by literature review and expert inputs via a co-design workshop convening stakeholders across sectors, including academia, clinical practice, patient and civil society groups, and industry partners. Expert engagement focused on settings where precision approaches showed strong potential or momentum.

The case studies were clustered by theme, using the three priority areas, described above in this report, and derived from EFPIA's roadmap on advancing precision oncology in the EU (1), which synthesises insights on where health systems most consistently encounter barriers to precision oncology adoption and where policy action is most likely to yield measurable gains in access and outcomes.

Each case study was analysed via collected quantitative metrics and qualitative insights on implementation. Evidence sources and metrics considered in each case included measurable outcomes, as well as qualitative assessments of implementation challenges, future development needs, and strengths. To answer the question "can the initiative expand or be replicated?", factors such as scalability (within the country) and transferability (across countries) are addressed.

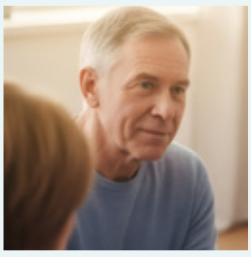
This analysis is intended to feed directly into an implementation toolkit for Member States, presented in the following section. **Table 1** summarises the case studies and promising practices, clustered by area, and provides the numeric IDs used throughout the paper.

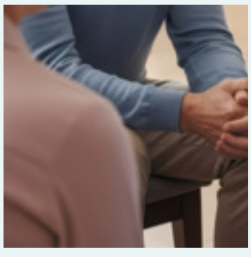
Table 1: Case studies and promising practices included in the evidence base

Case studies are grouped and color-coded by corresponding Area. Each entry shows the Case study Number, Type (case study or promising practice), Country, and Title.

Area	Number	Type	Country	Case study
Awareness about precision oncology	1	Case study	France	Promoting oncogenetics and testing networks with INCa
	2	Case study	Netherlands	Raising awareness and supporting implementation of precision oncology
	3	Promising practices	France Germany Italy Spain United Kingdom	Assessing awareness levels of genomic testing for metastatic breast cancer patients in Europe
Infrastructure and Workforce	4	Case study	Australia	Promoting Genomic Cancer Medicine with Omico in Australia
	5	Case study	Germany	DKTK's precision-oncology infrastructure and the EXLIQUID liquid-biopsy roll-out
	6	Case study	Ireland	Implementing a national cancer information system
	7	Promising practices	Italy	Emilia-Romagna: Integrated NGS platforms, a single regional MTB, and a shared oncology data backbone (DBO)
	8	Promising practices	Spain	Catalonia: OMIQ-HES - a centralized clinico-genomic data and a networked bioinformatics workforce
Funding and reimbursement	9	Case study	Spain	Ensuring patient representation in Catalonia
	10	Case study	Sweden	National infrastructure for precision oncology
	11	Case study	Germany	Reimbursement of companion diagnostics
	12	Case study	Belgium	Fast-track reimbursement pathway for biomarker
	13	Promising practices	Finland	Coordinated public funding and pathway embedding.
	14	Promising practices	Italy	Targeted national funds as a bridge to permanent reimbursement.
	15	Promising practices	England	HTA-anchored funding mandate and a continuously updated National Genomic Test Directory

Area 1
Awareness about precision oncology




1 Promoting oncogenetics and testing networks with INCa in France

The French National Cancer Institute (INCa) is a public health and scientific agency under the Ministries of Health and Research **created by the French Public Health Act of 9 August 2004**. It coordinates the national response to cancer across prevention, screening, care, and innovation, working with healthcare professionals, researchers, patient groups, public health agencies, and policymakers. In February 2021, France launched a ten-year national cancer strategy (2021–2030) co-constructed with diverse stakeholders. A core pillar of this strategy is **raising awareness** about cancer prevention and precision oncology among professionals, patients, and the public, with a focus on reducing inequalities in access to innovation, expanding screening participation, and addressing hard-to-treat cancers through research and new therapies.

INCa drives numerous initiatives to engage society in precision oncology. For the public and patients, **multimedia outreach campaigns** and user-friendly information platforms are central. For example, INCa's official portal (cancer.fr) offers accessible resources on cancer genomics, personalised screening and treatment, and helping individuals and families better understand advances in care. INCa also promotes inclusive public dialogue, developing educational materials for schools, hosting forums with patient groups, and using digital campaigns to demystify topics like genetic testing and targeted therapies across all ages and communities.

At the same time, **professional awareness and capacity-building** are a priority. INCa funds a nationwide network of 28 regional molecular genetics centres, established in 2007, that provide oncogenetic and molecular tests for patients across all regions. These centres serve both as diagnostic providers and knowledge hubs, ensuring clinicians remain up to date on biomarkers and testing protocols. INCa supports this through clinical guidelines, precision oncology toolkits, and regular seminars and symposia involving experts, clinicians, and patient advocate. National conferences have, for example, showcased patient diagnostic journeys to inform medical education and strengthen multidisciplinary collaboration.

Measurable Outcomes

- **Expansion of hereditary-risk awareness and services:** In 2022, INCa reported 94,855 oncogenetic consultations across the national network, compared with just 12,696 in 2003. This represents a more than sixfold increase over two decades, reflecting the success of sustained public information, physician referral pathways, and outreach to families with suspected hereditary cancer syndromes.

- **Nationwide network delivering precision testing at scale:** Since their establishment in 2006, the 28 INCa-backed molecular genetics platforms have become a mature ecosystem for tumour profiling. National activity reports indicate approximately 117,000 mutation analyses carried out in around 70,000 patients in 2011, and the dedicated non-small cell lung cancer program tested 17,664 patients in 2012–2013 with a median turnaround of just 11 days from analysis to written report. These figures illustrate how robust infrastructure, combined with professional training and communication, drives broad clinical uptake and timely decision-making.

- **Rising participation in population screening programs:** Awareness initiatives supported by INCa and the national strategy are beginning to reverse declines in screening. Standardised participation in breast cancer screening rose from 44.8 percent in 2022 to 48.2 percent in 2023, equivalent to more than five million women screened out of a target population of 10.8 million.

- **Clear public commitment to expand early detection further:** The ten-year cancer strategy sets a measurable objective of increasing annual screening tests from nine million to ten million by 2025. This explicit, time-bound target aligns with INCa's public communication mandate and provides a benchmark for evaluating the impact of awareness initiatives on preventive behaviours. It underscores the political and institutional drive to connect awareness with concrete prevention outcomes at the population level.

Strengths

- **Strong national leadership and resourcing:** INCa provides a single institutional anchor for France's cancer and precision oncology agenda, ensuring that awareness initiatives are integrated into the national strategy and sustained over time. The ten-year plan was launched with €1.7 billion for its first five years, demonstrating high-level political and financial commitment. This investment underpins prevention campaigns, educational resources, and professional training, while the broad stakeholder consultation behind the strategy strengthens legitimacy and continuity.

- **Broad public communication and education:** INCa employs a multi-channel approach to raise awareness about prevention and precision oncology. National campaigns are delivered through television, radio, digital platforms, and local events, while the official portal (cancer.fr) provides reliable, plain-language information. Educational materials, including booklets and school-level resources, are designed to reach younger audiences. This proactive outreach supports public understanding of genomics, genetic risk, and new therapies, and normalises concepts such as tumour profiling and trial participation, building trust in personalised cancer care.

- **Professional networks and clinical capacity:** Awareness efforts are directly connected to nationwide service provision through 28 molecular genetics platforms and more than 140 oncogenetics consultation sites, which provide equitable access to tumour and hereditary-risk testing. INCa supports capacity by issuing national guidelines, organising external quality assessments, and supporting continuing medical education through conferences, online courses, and updated toolkits. This ensures that healthcare professionals remain aware of new biomarkers and diagnostics and are equipped to integrate them into routine practice.

  Inclusive multi-stakeholder engagement: The French approach emphasises participation from patient associations, primary care providers, researchers, policymakers, and regional authorities. Patients and survivors co-create educational content and share experiences in public forums, while schools and local authorities help adapt messages for different audiences. This model amplifies reach through trusted community voices and helps address cultural and literacy barriers, ensuring communication about prevention and precision oncology resonates with diverse groups.

Challenges

- **Low screening uptake and inequities:** Despite national campaigns, screening participation in France remains below European benchmarks. Breast cancer screening participation was 43 percent in 2022, compared to the EU average of roughly 60 percent and a European target of 70 percent. Colorectal screening reached only 29 percent, well short of the target 45 percent. Social and territorial disparities persist, driven by health literacy gaps, cultural factors, and access barriers.

- **Linking awareness to research participation:** Progress in precision oncology relies on clinical research and patient enrolment, yet awareness of research opportunities is limited. The ten-year strategy stresses the need for more trials, particularly for cancers with poor prognosis, making public engagement crucial.

- **Building public trust in novel therapies:** Breakthrough treatments in precision oncology, such as CAR T-cell therapies and other gene-based interventions, are complex and relatively new. Communicating their benefits and risks in clear, accessible terms is essential to strengthen public understanding and avoid hesitation.

- **Sustaining workforce and infrastructure for awareness:** Awareness initiatives depend on trained professionals who can counsel patients, interpret genomic results, and support participation in research. France faces uneven capacity in oncogenetics and molecular pathology across regions, and heavy workloads risk slowing consultations. Without parallel investment in human resources and infrastructure, awareness campaigns may increase demand faster than services can respond, potentially eroding public confidence if access delays occur.

Future Development Needs

- **Targeted outreach to underserved populations**: To reduce inequities in screening and oncogenetics uptake, campaigns should be tailored for groups with persistently low participation. Using community health workers, local influencers, and multilingual, culturally adapted materials can help reach rural and socioeconomically disadvantaged populations. Partnering with primary care physicians, as trusted points of contact, would ensure messages about prevention and genomic testing resonate more effectively at local level and bring participation closer to EU benchmarks.

- **Continuous education on emerging innovations:** Precision oncology advances quickly, with new biomarkers, sequencing panels, immunotherapies, and cell therapies. INCa should keep informing the public and professionals through updates on the cancer.fr portal concise patient guides and expanded medical education. General practitioners and specialists need clear referral pathways and explanatory resources to apply innovations in practice and support patient understanding of new technologies.

- **Strengthened public engagement in research and data use:** France's research infrastructure, including the France Médecine Génomique 2025 program and national trial networks, requires continued efforts to strengthen public engagement. Campaigns should demystify participation by sharing patient stories, clarifying data privacy, and explaining how enrolment accelerates therapies. Collaborating with patient associations will help normalise research as part of cancer care, improve participation in studies, and generate real-world evidence that benefits both science and patients.

- **Sustained workforce and infrastructure capacity:** Awareness must be matched by service readiness. Expanding oncogenetic consultations and molecular testing requires trained professionals, sufficient laboratory capacity, and timely access to tumour boards. Investment in workforce development, especially genetic counsellors and bioinformaticians, along with financing for post-analytical services and coordination services, is needed to prevent bottlenecks. Without this, growing awareness risks creating demand the system cannot meet, which can undermine public trust and delay care.

Scalability (within the member state)

INCa's nationally coordinated awareness model is already deployed across France (testing platforms, oncogenetics network, standardised guidance, national campaigns). Further scaling should concentrate on equity, more targeted outreach, and territories where uptake remains low.

- **What:** INCa governance and stakeholder coordination; 28 tumour-molecular genetics platforms and the nationwide oncogenetics network; standardised guidelines, pathways, and communication toolkits; and a central public portal with monitoring and annual reporting.

- **How:** Shift from broad campaigns to more targeted outreach in low-uptake areas; equip providers with referral prompts and plain-language explainers; partner with patient and community groups for culturally adapted messages; link campaigns to convenient access points (mobile units, one-stop clinics); track impact using routine indicators (screening participation, oncogenetic consultations, turnaround times).

- **Where:** Regions with persistent gaps in screening and familial-risk referrals; primary-care networks, hospitals, and community-based settings (schools, workplaces, local authorities); national digital channels complemented by local media.

- **Considerations:** Uniform national offers do not guarantee equitable outcomes. Awareness and access must be adapted to people's literacy, language, and cultural context; scaling up requires sufficient trained staff (e.g. genetic counsellors, laboratory experts, bioinformaticians, and tumour board coordinators) to manage growing demand; high standards for data quality and privacy must be maintained, with systems that feed results back into practice; stable financing is needed not only for laboratory testing but also for outreach, patient counselling, and the interpretation and storage of complex genomic data.

Transferability (across member states)

France's approach can be transferred to other countries as a set of practical building blocks. These are strong national leadership, clear patient pathways, consistent quality standards, and coordinated communication with both professionals and the public. Success depends on adapting these elements to each country's health technology assessment (HTA) processes, financing models, and data-governance frameworks.

- **What:** A national cancer authority or equivalent that coordinates awareness and access; a trusted public information portal in plain language; a structured oncogenetics consultation network and designated molecular-testing hubs; and national guidance supported by quality assessments and regular, transparent reporting.
- **How:** Create a steering mechanism that brings together payers, providers, and patients; link awareness campaigns directly with service access such as referral pathways, booking systems, and reimbursement processes; align awareness with reimbursement rules so that tests are available when therapies are approved; start with high-value pilots while publishing annual progress indicators.
- **Where:** Transfer is most straightforward in systems with national tariff-setting or coordinated social insurance. In more decentralised systems, a national network of regional hubs can provide consistency. There is also scope for cross-border collaboration on standards, training, and quality assurance.
- **Considerations:** Each country's payer and HTA rules will require tailored adoption timelines. Awareness efforts must be matched by workforce, IT, and post-analytical capacity to avoid generating demand the system cannot meet. Investment in health literacy and culturally adapted communication is needed to ensure equity, while robust data protection, transparency, and consent processes are essential to maintain public trust.

Relevant Sources

- Institut national du cancer [Internet]. [cited 2025 Oct 17]. Cancer.fr . Available from: https://www.cancer.fr/
- Institut national du cancer [Internet]. [cited 2025 Oct 17]. Institut National du Cancer (INCA) French National Cancer Institute. Available from: https://rencontresinca.fr/en/exposants/french-national-cancer-institute/
- Unicancer [Internet]. [cited 2025 Oct 17]. Fight against cancer: French strategy 2021-2031. Available from: https://www.unicancer.fr/en/unicancer-group/strategy-commitment/fight against-cancer-french-strategy-2021-2031/
- EU Country Cancer Profile: France 2023. OECD; 2023.
- Nowak F. International Association for the Study of Lung Cancer. 2016 [cited 2025 Oct 17]. NGS Lung Cancer Genotyping Program in France. Available from: https://www.ilcn.org/next-generation-sequencing-across-the-world-reports-from-france-germany-and-china/
- Akbraian E. Partners4Access. 2021 [cited 2025 Oct 17]. France's new 10-year cancer strategy and its implications on the rare disease space. Available from: https://partners4access.com/frances-new-10-year-cancer-strategy-and-its-implications-on-the-rare-disease-space/
- Dupays S, Leost H, Le Guen Y. Inspection générale des affaires sociales. 2022 [cited 2025 Oct 17]. Organized cancer screening in France. Available from: https://igas.gouv.fr/Organized-cancer-screening-in-France
- Ministère de la Santé [Internet]. [cited 2025 Oct 17]. INCa (Institut national du cancer). Available from: https://sante.gouv.fr/ministere/acteurs/agences-et-operateurs/article/inca-institut-national-du-cancer
- Panorama des cancers en France 2025 [Internet]. 2025 Jun [cited 2025 Oct 17]. Available from: https://www.cancer-environnement.fr/app/uploads/2025/09/INCa_2025_Panorama-des-cancers.pdf
- Taux de participation au programme de dépistage organisé du cancer du sein en 2022-2023 et évolution depuis 2005 [Internet]. 2024 [cited 2025 Oct 17]. Available from: https://www.santepubliquefrance.fr/maladies-et-traumatismes/cancers/cancer-du-sein/articles/taux-de-participation-au-programme-de-depistage-organise-du-cancer-du-sein-en-2022-2023-et-evolution-depuis-2005

2. Raising awareness and supporting implementation of precision oncology in the Netherlands

The Netherlands has built a visible, patient-facing, and clinician-ready ecosystem for precision oncology. At its core, **Hartwig Medical Foundation** runs a national whole-genome sequencing (WGS) service (OncoAct) and a large open research database, publishing clear patient- and clinician-facing explainers that demystify the pathway from biopsy to report and support shared decision-making. OncoAct is delivered in an **ISO-accredited laboratory** with standardised reporting, which reinforces public trust that comprehensive DNA testing is quality-assured and usable in routine care.

Implementation science has helped normalise genomics in day-to-day practice. In 2020, **The Netherlands Cancer Institute (NKI)** in collaboration with the **Hartwig Medical Foundation** and **UMC Utrecht** launched the Whole genome sequencing Implementation in standard Diagnostics for Every cancer patient (**WIDE) study**. The WIDE study showed that WGS can be embedded in routine pathology for metastatic cancer without prolonging turnaround time. It matched the accuracy of existing methods and expanded treatment options, with results discussed in regular **Molecular Tumour Boards (MTBs)**. MTBs operate across all eight Dutch tertiary cancer centres with a nationally aligned workflow, giving clinicians and patients consistent access to expert interpretation of genomic results.

Public- and policy-facing outreach runs in parallel. National dialogues such as the **DNA Dialogues** brought citizens, patients, and professionals together to discuss genomics and data use, improving literacy and surfacing concerns that can be addressed in communications. The **Netherlands Cancer Agenda** explicitly prioritises access to comprehensive molecular diagnostics and awareness for rarer cancers, aligning stakeholders around common goals. Funding and patient voice reinforce legitimacy: **KWF's** Patients' Advisory Committee (**PACO**) formally weighs patient perspectives at **30%** of grant scores, and Dutch institutions regularly publish accessible summaries of evidence to keep the public informed.

The Dutch **data backbone** makes awareness credible with numbers. **Hartwig's database** contains WGS data from more than **5,000** patients (the world's largest metastatic-tumour WGS resource), and national registries (**IKNL/NCR** and **PALGA**) enable linkage of diagnosis, treatment, and pathology data for real-world follow-up. Strategic work on **federated, privacy-by-design data access** (the Personal Health Train within Health-RI) underpins a public message that data can be used responsibly while protecting privacy.

Policy has moved in step with communication and evidence. After staged HTA discussions, the **Dutch Health Care Institute (ZiNL)** approved **reimbursement of WGS** in 2025 for defined targeted-therapy contexts (e.g. detecting **NTRK** fusions), signalling to clinicians and the public that comprehensive testing is clinically valid, quality-assured, and increasingly covered by healthcare reimbursement.

Measurable Outcomes

- **Clinical impact and no delay in care**: The WIDE study (1,200 patients) showed that WGS can be embedded in routine diagnostics with turnaround times comparable to existing tests—99.2% concordance was achieved, 71% of evaluable patients gained new treatment options, and 24% were treated on WGS findings: This is evidence of clear patient-relevant benefits that sustain professional and public confidence.
- **Genomic data at national scale**: The Hartwig Medical Database now holds WGS data from more than 5,000 patients, combined with treatment and outcome data. New analyses continue to emerge (e.g. viral landscapes across ~5,000 metastatic tumours), providing tangible stories and visuals (accessible evidence) that feed back into awareness materials.

- **From awareness to access via trials**: The Drug Rediscovery Protocol (DRUP) has evaluated >2,500 patients and treated >1,500, with an overall 33% clinical benefit rate, demonstrating that genomic profiling can unlock real treatment options. This is a clear and accessible message for patients and payers and a strong awareness anchor.
- **Coverage decisions aligned with communication**: In 2025, ZiNL extended coverage to WGS (as an alternative to panel NGS) for specific targeted-therapy indications (e.g. NTRK), representing a concrete policy outcome that turns public messaging about "comprehensive DNA testing" into funded access.
- **Equity footprint beyond academic centres**: Participation extends outside university hospitals. The CPCT consortium encompasses >45 hospitals nationwide, and 35 hospitals participate in DRUP. OncoAct requires hospital service agreements, offering a countable proxy for non-academic reach. Together, these indicators show that awareness-to-access pathways are spreading beyond tertiary hubs.

Strengths

- **Connected national ecosystem**: A coordinated web of NGOs, academia, and registries (Hartwig, NKI, IKNL/NCR, PALGA, professional societies) keeps messages consistent and evidence-based, while PACO gives patients a formal seat in funding decisions, reinforcing public legitimacy.
- **Clinician-ready delivery with national MTB coverage**: WGS is delivered through an ISO-accredited workflow (OncoAct), MTBs operate in all eight tertiary centres, and feasibility has been demonstrated for routine pathology practice, making awareness actionable in real clinical pathways across the country.
- **Clear public information and engagement**: OncoAct provides plain-language resources for patients and physicians. National dialogues on DNA/genomics (DNA Dialogues)build literacy and trust, in turn providing useful foundations for explaining results, data use, and participation in research.
- **Data transparency and privacy-by-design infrastructure**: The Hartwig database, NCR/IKNL, and PALGA enable national-scale insights, while Health-RI's Personal Health Train advances federated, FAIR data access. This combination supports honest, data-driven outreach without compromising privacy.

Challenges

- **Uneven implementation outside academic centres**: Access to comprehensive genomics and MTB expertise remains more robust in university centres than in some regional hospitals, risking geographic disparities in awareness-to-access conversion.
- **Communication and literacy barriers**: Genomic reports are complex. Patients with lower health literacy, and some clinicians, may need clearer materials and decision aids to understand benefits, limits, and data use. DNA Dialogues have shown the value, but continued effort is required.
- **HTA/reimbursement timelines and scope**: Despite the 2025 WGS decision, coverage still evolves indication by indication (e.g. NTRK). Broader, earlier-stage use will require sustained evidence generation and payer engagement to avoid mixed messages about availability.
- **Linking genomics to real-world outcomes**: Data remain fragmented across registries and providers. Stakeholders note that without structured real-world data, it can remain "guesswork about who truly benefits", which weakens persuasive communication to the public and payers.

Future Development Needs

- **Expand capacity and equity beyond academic hubs**: Extend WGS logistics, MTB access, and trained roles (genetic counsellors and bioinformaticians) into regional hospitals; use shared protocols and virtual MTBs so awareness campaigns reliably translate into timely, local access.

- **Strengthen education and decision support**: Scale accredited clinician e-learning on molecular diagnostics and provide patient-ready decision aids that explain testing, results, and data use in plain language, building on existing NVMO modules and OncoAct explainers.

- **Coverage with evidence development**: Use the 2025 WGS decision as a template for broader "reimburse while learning" models that condition payment on outcomes/data capture, aligning awareness messages with guaranteed access and learning loops.

- **Integrate real-world data flows**: Link Hartwig genomics with NCR and PALGA routinely and scale Personal Health Train-style federated analytics so results-to-outcomes analyses can be reported publicly and updated regularly, reinforcing trust.

- **Track public and patient perception over time**: Move from one-off dialogues to a yearly "Genomics Awareness Barometer" that repeats DNA Dialogue items (i.e. acceptability, trust, data-use comfort) with appropriate sample size and demographics; complement with digital engagement analytics from OncoAct's patient pages and helpline/email volumes about genomic testing; publish an annual summary so shifts in attitudes and literacy are visible.

Scalability (within the member state)

The Dutch model is designed for national reach with ISO-accredited WGS, MTBs across tertiary centres, a large national WGS database, and public-facing portals. The next phase is scaling **beyond academic hubs** so that awareness consistently translates into access everywhere.

- **What:** A coherent bundle, including, for example, OncoAct, with standardised reporting, MTBs as interpretation hubs, national registries for outcomes linkage, and clear patient/clinician communications, which can provide the building blocks for system-wide delivery.

- **How:** Expand logistics and staffing to regional sites, use virtual or shared MTBs, and embed referral/booking pathways so that campaigns point to concrete, nearby services. Align scale-up with payer pathways (coverage with evidence development) and report progress annually to sustain public confidence.

- **Where:** Priority areas include regional hospitals without on-site sequencing or MTBs and networks serving populations with lower health literacy. National portals and professional platforms can amplify consistent messages while local providers anchor access.

- **Considerations:** Scaling awareness without parallel investments in workforce, bioinformatics, and post-analytical services risks bottlenecks. Maintain data quality, privacy, and feedback loops (NCR/PALGA linkages; federated analytics) and ensure stable financing for outreach, interpretation and counselling services, not just the laboratory test.

Transferability (across member states)

The Dutch approach is transferable as a **set of building blocks** – national leadership around a trusted portal and WGS service, MTBs for interpretation, strong patient involvement, and learning-health-system data practices – provided that countries adapt these to their HTA, financing and data-governance contexts.

- **What:** A nationally recognised genomic test with quality accreditation, structured MTB access, patient-facing communications, and links to cancer registries create a credible pathway from awareness to access and outcomes.

- **How:** Start with high-value pilots (e.g. metastatic cohorts), co-design communications with patient groups, align early with payers on coverage-with-evidence models, and publish annual indicators (testing volumes, MTB referrals, time-to-report, treatment changes) to build trust.

- **Where:** This is most straightforward in systems with coordinated payers or national tariff-setting. In decentralised settings a national network of regional hubs and virtual MTBs can deliver consistency while respecting local structures.
- **Considerations:** Different HTA and payer rules will shape timelines and scope; avoid awareness outpacing capacity by planning workforce and IT requirements upfront; invest in health-literacy and culturally adapted materials;embed robust privacy-by-design data access so communications about data use are demonstrably true.

Relevant Sources

- Mendelaar PAJ, Smid M, van Riet J, Angus L, Labots M, Steeghs N, et al. Whole genome sequencing of metastatic colorectal cancer reveals prior treatment effects and specific metastasis features. Nat Commun. 2021 Jan 25;12(1):574.
- Haj Mohammad SF, Timmer HJL, Zeverijn LJ, Geurts BS, Spiekman IAC, Verkerk K, et al. The evolution of precision oncology: The ongoing impact of the Drug Rediscovery Protocol (DRUP). Acta Oncol (Madr). 2024 May 23;63:368–72.
- Groenland SL, van Eerden RAG, Westerdijk K, Meertens M, Koolen SLW, Moes DJAR, et al. Therapeutic drug monitoring-based precision dosing of oral targeted therapies in oncology: a prospective multicenter study. Annals of Oncology. 2022 Oct;33(10):1071–82.
- Samsom KG, Bosch LJW, Schipper LJ, Roepman P, de Bruijn E, Hoes LR, et al. Study protocol: Whole genome sequencing Implementation in standard Diagnostics for Every cancer patient (WIDE). BMC Med Genomics. 2020 Dec 10;13(1):169.
- Hartwig Medical Foundation [Internet]. [cited 2025 Oct 16]. Hartwig Medical Foundation. Available from: https://www.hartwigmedicalfoundation.nl/en/
- Hartwig Medical Foundation [Internet]. 2022 [cited 2025 Oct 16]. Whole genome sequencing is reliable, has added value, and can be embedded perfectly into everyday pathology diagnostics. Available from: https://www.hartwigmedicalfoundation.nl/en/whole-genome-sequencing-is-reliable-has-added-value-and-can-be-embedded-perfectly-into-everyday-pathology-diagnostics/
- Netherlands Cancer Institute [Internet]. 2022 [cited 2025 Oct 16]. Whole genome sequencing is reliable, has added value, and can be embedded perfectly into everyday pathology diagnostics. Available from: https://www.nki.nl/news-events/news/whole-genome-sequencing-is-reliable-has-added-value-and-can-be-embedded-perfectly-into-everyday-pathology-diagnostics/
- Hartwig Medical Foundation [Internet]. 2025 [cited 2025 Oct 16]. Dutch Healthcare Institute approves reimbursement of whole genome sequencing (WGS) for targeted cancer treatment . Available from: https://www.hartwigmedicalfoundation.nl/en/dutch-healthcare-institute-approves-reimbursement-of-whole-genome-sequencing-wgs-for-targeted-cancer-treatment/
- Integraal Kankercentrum Nederland [Internet]. [cited 2025 Oct 16]. Cancer in The Netherlands - Facts & Figues. Available from: https://iknl.nl/international/cancer-in-the-netherlands
- Rathenau Instituut [Internet]. 2021 [cited 2025 Oct 16]. The DNA-dialogue: analysis and outcomes. Available from: https://www.rathenau.nl/en/health/dna-dialogue-analysis-and-outcomes
- Health-RI [Internet]. [cited 2025 Oct 16]. Genomic Data Infrastructure (GDI). Available from: https://www.health-ri.nl/en/node/906
- KWF Kankerbestrijding [Internet]. [cited 2025 Oct 16]. Beoordeel wetenschappelijk onderzoek naar kanker. Available from: https://www.kwf.nl/help-mee/vrijwilliger/beoordeel-wetenschappelijk-onderzoek-naar-kanker
- DNA-dialoog [Internet]. [cited 2025 Oct 16]. DNA-dialoog. Available from: https://www.dnadialoog.nl/
- Willemsen AECAB, Krausz S, Ligtenberg MJL, Grünberg K, Groen HJM, Voest EE, et al. Molecular tumour boards and molecular diagnostics for patients with cancer in the Netherlands: experiences, challenges, and aspirations. Br J Cancer. 2019 Jul 27;121(1):34–6.
- Nederlandse Vereniging voor Medische Oncologie [Internet]. [cited 2025 Oct 16]. E-learning. Available from: https://www.nvmo.org/e-learning/
- MTRC [Internet]. 2025 [cited 2025 Oct 16]. Coverage positions published by the Dutch Healthcare Institute in Q1-Q2 2025. Available from: https://mtrconsult.com/news/coverage-positions-published-dutch-healthcare-institute-q1-q2-2025

3. Assessing awareness levels of genomic testing for metastatic breast cancer (mBC) patients in Europe

Across Europe, patient-led evidence is now driving how we talk about precision oncology. Cancer Patients Europe's (CPE) white paper on **ESR1 and liquid biopsy surveyed 1,268 breast-cancer respondents in five countries** – France, Germany, Italy, Spain, and the United Kingdom—and mapped specific knowledge gaps that awareness campaigns can target. **70% did not know which biomarkers they had been tested for, 75% had not discussed biomarker testing with their oncologist, 70% of ER$^+$/HER2-mBC respondents were unaware that ESR1 mutations drive endocrine resistance, and only 16% knew of therapies targeting ESR1. ctDNA testing** itself was poorly understood and trusted, despite expert guidance to test ESR1 at each progression and to prefer blood-based testing for detection and monitoring. A key insight from this case study is the importance of structured collaboration with patient organisations to identify unmet educational needs about genomic testing and to co-develop targeted materials. This collaboration should include patients, oncologists, pathologists, and policymakers, creating a shared agenda to address knowledge gaps systematically.

The survey is light, modular, and immediately reusable across tumour types and countries; questions map cleanly onto clinical steps (testing offered, biomarkers covered, MTB discussion, therapy linkage), which lets health systems benchmark awareness against service data and close gaps with targeted materials. Because outputs translate into concrete assets. Member States and EU networks can scale the approach without new infrastructure, while maintaining a common evidence base that supports equitable access to precision oncology. The data further support the development of EU-wide awareness campaigns targeting both patients and healthcare professionals, including centralised, multilingual information platforms providing accessible, reliable resources on genomic testing and precision medicine. The findings also indicate a need for training programs for oncologists and other healthcare providers to improve their communication with patients about testing options and personalised treatment strategies. Engagement and support of cancer patient associations could be instrumental in reducing informational gaps and enhancing trust.

In addition to targeted awareness messaging, the survey results highlight the potential value of harmonised clinical guidelines across Member States for biomarker and genomic testing in metastatic breast cancer care, including routine ESR1 mutation screening and standardised protocols for when and how tests are performed.

Crucially, these findings can be used to strengthen several current European actions. Programs such as the Personalized Cancer Medicine for all EU citizens (PCM4EU) can use the gap map to tailor clinician education and MTB materials to ESR1/liquid-biopsy myths seen in the data. The Drug Rediscovery Protocol (DRUP)–style clinical networks—pan-cancer, pragmatic trials that match already approved targeted or immunotherapies to tumour genomics—can strengthen consent and pre/post-test counselling where comprehension is weakest. The One Million Genomes Initiative (1+MG)/Genomic Data Infrastructure (GDI)—the EU's political initiative and its implementation project that build federated, privacy-by-design genomic data services, common standards and ready-to-use outreach toolkits for citizens and health professionals—can align country communications on why genomic data are used, how privacy is protected, and what benefits patients can expect. The Cancer Mission Hubs can target public events to countries or subgroups with the largest deficits, and pan-EU patient groups can carry the same, harmonised messages in campaigns on genomic tumour testing and personalised medicine.

The survey could also form the foundation of a **replicable EU template**, with the steps of **measuring the gaps, targeting the messages, linking to services, and tracking movement over time**. A continuous improvement loop can be created by pairing the survey with an annual "Genomics Awareness Barometer" and

then reporting equity metrics by hospital type or region (testing uptake, MTB referrals, time-to-result). This would enable awareness efforts to be tuned year-by-year and beyond tertiary centres.

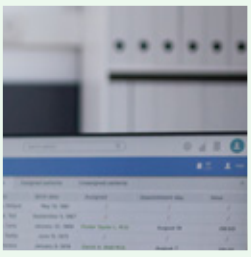
Taken together, these elements align with Recommendations 1-4 (Section 5.3) of the White Paper: establishing **shared clinical standards, coordinated EU-level awareness materials, structured professional training and support for patient organisations, and embedding patient voice and literacy into policy goals**.

Relevant Sources

- Verlingue L, Antouly M, Witczak M, Blay JY, Lugowska I. 157P PCM4EU academy: An educational program for precision oncology. ESMO Open. 2023 Oct;8(1):102006.
- Cardone A, Bell D, Biurrun C, Cognetti F, Cardoso F, Piris AR, et al. Awareness of genomic testing among patients with breast cancer in Europe. The Breast. 2025 Jun;81:104436.
- Cancer Patients Europe. New Biomarkers in Metastatic Breast Cancer & Awareness on ESR1 and Liquid Biopsy: Analysis of an European Patient Survey [Internet]. 2025 [cited 2025 Oct 16]. Available from: https://cancerpatientseurope.org/new-biomarkers-in-metastatic-breast-cancer-awareness-on-esr1-and-liquid-biopsy-analysis-of-a-european-patient-survey/
- Cancer Patients Europe. myC – my Cancer my Concern Infographics [Internet]. [cited 2025 Oct 16]. Available from: https://cancerpatientseurope.org/myc-my-cancer-my-concern-infographics/
- Personalised Cancer Medicine for all EU Citizens [Internet]. [cited 2025 Oct 16]. Personalised Cancer Medicine for all EU Citizens. Available from: https://www.matrix-fkb.no/en/pcm4eu/home
- GDI Newsletter. European Genomic Data Infrastructure; 2024.
- Cancer Mission Hubs. ECHoS Project. [cited 2025 Oct 16]; Available from: https://cancermissionhubs.eu/the-project
- AstraZeneca [Internet]. 2025 [cited 2025 Oct 16]. #laMquefalta en el CHUAC: paciente y equipo médico comparten sus necesidades frente al cáncer de mama metastásico. Available from: https://www.astrazeneca.es/medios/notas-prensa/2025/LaMquefaltaen_el_CHUAC_paciente_y_equipo_medico_comparten_sus_necesidades_frente_al_cancer_de_mama_metastasico.html

Area 2
Infrastructure and workforce





4.Promoting Genomic Cancer Medicine with Omico in Australia

Australia's precision oncology effort is organised as a national, public–private consortium anchored by the Australian Genomic Cancer Medicine Centre (Omico) and powered by the **Precision Oncology Screening Platform Enabling Clinical Trials (PrOSPeCT)**. Announced in July 2023 by the Australian Government and launched at the University of New South Wales' Centre for Molecular Oncology (UNSW CMO), PrOSPeCT is a ~A$185 million program (including A$61.2 million in Commonwealth funding) providing free comprehensive genomic profiling (CGP) to tens of thousands of people with advanced or poor-prognosis cancers and routing them to evidence-generating treatment pathways. The program links hospitals and research centres across all states and territories into a single screening, interpretation, and trial-matching pipeline integrated with Australia's clinical-trials ecosystem. **This architecture gives clinicians uniform access to CGP, decision support, and trial options, while creating a large, continuously refreshed cohort for precision-medicine studies**. Building on this, Omico's network also supports both companion studies with academic partners and industry-sponsored trials that leverage the same national screening and clinical-trial infrastructure.

Operationally, PrOSPeCT's **Cancer Screening Program (CaSP)** standardises the end-to-end workflow: referral and consent, CGP performed at accredited partner laboratories, centralised bioinformatics and quality control, and case review by a national Molecular Oncology Board that issues a harmonised report with therapy and clinical-trial recommendations. Sequencing and data processing leverage national research infrastructure ensuring scalable compute, storage, and pipelines as volumes rise. **Embedding the program within the UNSW CMO, the Garvan Institute of Medical Research, and other leading centres concentrates scarce expertise** (such as molecular pathology, medical oncology, clinical genetics, and bioinformatics) and supports structured training pathways for the genomics workforce.

The platform aligns with national policy and investment signals. The **Genomics Health Futures Mission** (under the Medical Research Future Fund) and a growing state/industry co-investment base underwrite core infrastructure, while **Cancer Australia's National Framework for Genomics in Cancer Control (2025) sets out the system changes needed to mainstream genomics**: equitable access, culturally safe care, sustainable funding for tests and multidisciplinary services, robust data systems, and systematic workforce development across oncology, pathology, and primary care.

Since 2016, Omico's programs have enabled over 23,906 Australians, referred by more than 1,388 clinicians, to access precision oncology innovations. Moreover, the network has facilitated 98 oncology clinical trials, strengthening Australia's research capacity, attracting global investment, and offering patients and families access to treatment options.

Critically for infrastructure and workforce, Australia's model couples federated delivery with national coordination: a single program spec, shared pipelines and governance standards, and central boards that de-risk interpretation for frontline teams, while state-based partners host laboratories, recruit patients, and staff clinics. This "national backbone + local hubs" design accelerates capability building, supports continuing professional development, and creates a dependable service environment that can transition from time-limited grants to routine funding. The result is a platform that can absorb rising demand, improve equity of access, and shorten the path from discovery to standard care.

Measurable Outcomes

- **Nationwide screening coverage and equitable access**: PrOSPeCT/CaSP has provided CGP to over 22,000 Australians with advanced cancer (targeting ~23,000 by end 2025). Early data show that ~57% of screened patients receive a targeted treatment recommendation, and around 17% proceed to receive matched therapy. Patients enrolled in CaSP typically receive their personalised Molecular Oncology Board report within 8–10 weeks, with urgent cases prioritised within 5–6 weeks, enabling timely access to matched therapies or clinical trials.
- **Expanded trial access and integrated decision-making**: Omico's platform has enabled >90 new oncology trials nationwide by systematically identifying patients with actionable mutations and increasing enrolment in both investigator-led and industry-sponsored studies. A unified genomic workflow supports centralised sequencing and bioinformatics, while Omico's national Molecular Oncology Board reviews every CGP result and issues standardised reports, ensuring consistent interpretation of complex genomic data and streamlined clinical decision-making.
- **Equitable reach and access across Australia**: Patients are recruited from all states and territories, including urban, rural, and remote areas. The program explicitly prioritises underserved groups, with paediatric and Indigenous outreach components. As a result, 36% of participants come from rural or regional communities, despite these areas representing only 25% of Australia's population. This highlights progress in addressing geographic disparities in access to genomic testing and clinical trials.
- **Workforce capacity growth and economic impact:** The initiative has built substantial new human capital. For example, the UNSW CMO supports >50 dedicated researchers in genomic cancer care and houses Omico staff on-site. In total, PrOSPeCT has generated 212 direct highly skilled jobs and an estimated 1,063 indirect jobs. The initiative has generated $41M in economic activity, including $19.3M in R&D and $13.5M in capital equipment, plus contributions to technology, licenses and IP.
- **Major funding investments**: Over A$185M in combined public/private funding has been mobilised to establish this infrastructure. This covers sequencing platforms, IT systems, and trial coordination. Such a multi-source funding model has enabled a scale of genomic testing not previously possible in Australia.

Strengths

- **Unified national coalition**: Omico's public–private structure aligns federal and state stakeholders in a single consortium. Its membership covers every state and territory, ensuring coordinated planning and minimising duplication in Australia's decentralised health system.
- **Robust multi-source funding**: Australia has backed precision oncology with strong investments. Federal programs (e.g. the Genomics Health Futures Mission) and state partners (e.g. NSW Health) have committed dedicated funds for PrOSPeCT. Industry and research institutions also co-invest, creating a sustainable funding ecosystem for infrastructure build-out.
- **Integration with top research centers**: The platform leverages Australia's leading cancer institutes. Partnerships with UNSW's new CMO, the Garvan Institute, the Australian National University, and others ensure access to high-end sequencing and analysis expertise. Embedding the program in academic centres accelerates innovation and quality assurance.
- **Equity focus and reach**: PrOSPeCT was designed for inclusivity and explicitly enrols rural/regional patients and links statewide clinical sites. The parallel Zero Childhood Cancer program provides WGS for children with rare cancers, showing the model's adaptability. Together, these reduce geographic and demographic disparities in genomic care.
- **Rapid scale-up and national impact**: In a short time, Australia has built one of the most comprehensive precision oncology networks. The launch of PrOSPeCT unified previously fragmented efforts, bringing genomics to tens of thousands of patients. This momentum positions Australia as a leader with infrastructure

Challenges

- **Sustainable funding gaps**: Much of the current service relies on time-limited grants. There is no permanent reimbursement mechanism for broad CGP panels or WGS. Without Medicare (Australia's publicly funded universal healthcare system) item numbers or state tariffs for these tests, hospitals must absorb costs or restrict usage. This threatens long-term service continuity once pilot funding ends.
- **Complex governance**: Coordinating a national program across separate state health systems and numerous stakeholders is difficult. Aligning policies, budgets, and data-sharing rules across jurisdictions requires extensive negotiation. A lack of a single national genomics agency (unlike Sweden's GMS) means continued effort is needed to maintain coherence.
- **Workforce shortages**: Australia faces a shortage of genomics-trained professionals. There are too few molecular pathologists, genetic counsellors, and bioinformaticians to keep up with rising test volumes. Existing education is largely ad hoc; a systemic training framework is only now being developed. This skills gap could delay processing and interpretation as services expand.
- **Data infrastructure limitations**: Although ProSPeCT has achieved strong national coordination, Australia's genomic data environment remains fragmented, with clinical and genomic data held in siloed systems and no unified national cancer genomics registry. This fragmentation limits system-wide learning and the scalability of precision oncology. Stakeholders have therefore emphasised the need for interoperable infrastructure, consistent national standards, and integrated digital ecosystems.
- **Data and IT integration**: Currently there is no unified national cancer genomics registry or shared IT platform. Genomic data are often stored in siloed hospital or research systems with limited interoperability. This fragmentation constrains data aggregation, cross-centre linkage, and system-wide learning in precision oncology.
- **Equity of access**: Despite efforts, reaching remote and Indigenous communities remains challenging. The Cancer Australia framework highlights the need for on-Country services. Additional investments (e.g. mobile units, tele-genomics, culturally safe care models) are needed to ensure no patient is left behind due to location or background.

Future Development Needs

- **Formal reimbursement for genomic tests**: Establish permanent funding codes or Medicare items for CGP panels and whole-genome sequencing, as Cancer Australia recommends. This will allow laboratories to bill these tests like any other diagnostic procedure.
- **Embed infrastructure funding**: Transition core sequencing facilities and bioinformatics resources from grant funding into ongoing healthcare budgets. Ensuring continuous funding for sequencing instruments, data storage, and analysis pipelines will prevent service interruptions as demand grows.
- **National data systems**: Create a standardised national registry for cancer genomic data and outcomes. Consistent processes for collecting, storing, and sharing genomic and clinical data across states will enable continuous learning and policy evaluation. This should include Indigenous Data Sovereignty measures.
- **Workforce development programs**: Invest in genomics education and training for all cancer care professionals including integrating genomics into medical/nursing curricula, offering dedicated fellowships (genomic pathologists, bioinformaticians, genetic counsellors), and providing continuing professional development. Alongside workforce expansion, greater use of automation and artificial intelligence can streamline analysis, reduce turnaround times and help mitigate current workforce shortages as demand for precision oncology grows.
- **Fund multidisciplinary services**: Recognise and fund molecular tumour boards, genetic counselling, and bioinformatics reporting as essential clinical services. For example, creating reimbursement bundles or grants to cover the time spent by multidisciplinary teams on interpreting CGP and guiding patient management. Stable funding for these downstream processes is critical to realise the value of genomic testing.

- **Governance and partnerships**: Strengthen federal–state coordination (e.g. via a national steering body) and seek co-funding with international partners. For instance, pursue multinational research projects or shared data initiatives to complement domestic investments. Also plan from the start to transition from pilot grants to routine care funding, avoiding reliance on short-term projects. Long-term capacity will depend on continuous evaluation of outcomes to justify funding (e.g. via coverage-with-evidence models).

Scalability (within the member state)

Australia's precision oncology program is already designed for nationwide reach. PrOSPeCT will unify an extensive national cancer network while building our capabilities, infrastructure, and skills. Since Omico's network covers every state, scalability now means expanding capacity and embedding genomics into routine pathways.

- **What**: A fully national genomics framework (PrOSPeCT/CaSP) linking major cancer centres, standardised testing panels, and a central reporting board. This includes all essential elements: sequencing labs, bioinformatics pipelines, tumour boards, and trial-matching services.
- **How**: Scale up laboratory throughput and workforce training to handle higher volume. Secure permanent funding (Medicare or state budgets) to replace grant funding. Gradually broaden use of CGP (e.g. to high-risk earlier-stage cancers or cancer predisposition cases) and integrate results into electronic health records. Require participants to follow national guidelines and contribute data to the shared registry.
- **Where**: Leverage existing hubs as genomic referral centres and link them with regional hospitals via sample transport and telemedicine. Expansion can also extend to other specialties (e.g. inherited disorders using the same sequencers). Locally, new samples flow from hospitals into the established Omico network rather than duplicating labs.
- **Considerations**: Sustained government support and strong federal-state coordination are essential to maintain national services. Workforce growth, consistent operating standards, and interoperable information systems must keep pace as demand increases. Monitoring a small set of core performance indicators (service readiness, turnaround times, and workforce capacity) will be critical to identifying bottlenecks and supporting scalable, high-quality delivery nationwide.

Transferability (across member states)

Australia's experience can inform other countries building precision oncology systems. The key lessons are central coordination, multi-sector collaboration, and stable financing.

- **What**: A national consortium-led model (like Omico) that brings together government, academia, and industry to run a shared genomic screening and trial-matching platform. This would use common testing protocols or panels and a unified data/reporting infrastructure.
- **How**: Other nations could pilot similar programs via research grants or innovation funds, then transition to mainstream funding. Essential steps include establishing a national steering group, defining reimbursable genomic tests linked to available therapies, and building laboratory and IT capacity. Lessons from PrOSPeCT (e.g. public–private funding, integrated tumour boards) can guide implementation.
- **Where:** This approach suits federated or large countries (e.g. Canada's provinces, Germany's federal states, or U.S. health systems) as well as regional collaborations across smaller nations, such as the Nordic countries, where genomic and digital health cooperation is already well established. These contexts align with the European landscape and offer opportunities for applying lessons from PrOSPeCT's nationally coordinated but locally embedded model.
- **Considerations**: Significant upfront investment is required to build laboratories and data systems. Legal frameworks for data sharing (privacy, consent, Indigenous sovereignty) must be established. Reimbursement policies should explicitly cover not only assays but also post-test services such as reporting and counselling. Crucially, countries should plan funding transitions from initial grants to permanent healthcare budgets, to avoid gaps when pilot projects end.

Relevant Sources

- Dall G, Harris K, Chan N, Luen SJ, Frentzas S, Day D, et al. Equitable Access to Genomic Molecular Testing for Australian Cancer Patients: Insights from the Victorian Precision Oncology Summit. Current Oncology. 2024 Aug 6;31(8):4519–30.
- Rare cancers Australia [Internet]. 2025 [cited 2025 Oct 16]. Advancing genomic-led cancer care in Australia. Available from: https://www.rarecancers.org.au/wp-content/uploads/2025/02/RCA5251-Advancing-Ge00c99enomic-led-Cancer-Care-in-Australia_FA2.pdf
- Omico [Internet]. [cited 2025 Oct 16].
- Omico - Together, cancer meets its match. Available from: https://www.omico.com.au/
- Emma McBride MP. Australian Government. 2023 [cited 2025 Oct 16]. Genomic profiling offers hope for 23,000 cancer patients. Available from: https://www.health.gov.au/ministers/the-hon-emma-mcbride-mp/media/genomic-profiling-offers-hope-for-23000-cancer-patients
- UNSW [Internet]. 2023 [cited 2025 Oct 16].
- Pioneering national genomics initiative to fight cancer launched at UNSW. Available from: https://www.unsw.edu.au/newsroom/news/2023/07/pioneering-national-genomics-initiative-to-fight-cancer-launched
- Bioplatforms Australia [Internet]. 2022 [cited 2025 Oct 16]. Bioplatforms proud to support precision medicine cancer PrOSPeCT Trial. Available from: https://bioplatforms.com/bioplatforms-proud-to-support-precision-medicine-cancer-prospect-trial/
- Omico [Internet]. [cited 2025 Oct 16]. Cancer Screening Program - CaSP. Available from: https://www.omico.com.au/our-programs/cancer-screening-program-casp/
- NCI Australia [Internet]. [cited 2025 Oct 16]. $185 million investment to fast-track treatments for rare and 'untreatable' cancers. Available from: https://nci.org.au/news-events/news/185-million-investment-fast-track-treatments-rare-and-untreatable-cancers
- Omico [Internet]. [cited 2025 Oct 16]. The Precision Oncology Screening Platform Enabling Clinical Trials (PrOSPeCT). Available from: https://www.omico.com.au/prospect/
- Cancer Australia [Internet]. 2025 [cited 2025 Oct 16]. National Framework for Genomics in Cancer Control. Available from: https://www.canceraustralia.gov.au/sites/default/files/2025-02/national-framework-for-genomics-in-cancer-control-cancer-australia-january-2025.pdf

5. DKTK's precision-oncology infrastructure and the EXLIQUID liquid-biopsy roll-out in Germany

Germany's national cancer research network is anchored by the German Cancer Consortium (DKTK, Deutsches Konsortium für Translationale Krebsforschung), a federally funded initiative launched in 2012 to link the German Cancer Research Centre (DKFZ) with leading university clinics. **DKTK integrates the core German Cancer Research Centre** (DKFZ, Deutsches Krebsforschungszentrum) **with eight regional "translation centres" and over 20 oncology institutes nationwide**. This networked model was set up by the Federal Ministry of Education and Research (BMBF, Bundesministerium für Bildung und Forschung) together with participating states to overcome regional infrastructure gaps and accelerate research translation into patient care. To date, over 1,000 cancer researchers and clinicians (with roughly 20% PhD students) are engaged across the consortium, supported by dedicated professorships and junior research groups at each site. **DKTK's joint funding program and governance structures encourage multicentre projects and clinical trials**, ensuring resources (labs, equipment, protocols, and personnel) are shared across sites.

DKTK's infrastructure includes both physical and digital components. Clinically, **each partner hospital hosts a "translational centre" that combines routine cancer care with research laboratories** (for example, molecular pathology and genomics units). On the digital side, DKTK developed the Clinical Communication Platform (CCP), a federated data network linking hospital records, biobanks and registries across all sites. Technical "bridgeheads" were deployed at every partner site (completed by 2017) to enable secure, interoperable data exchange under local data sovereignty. Through the CCP's tools, researchers can query clinical case numbers and request biospecimens consortium-wide, while still complying with GDPR standards. In practice, this means a physician in Berlin can search for suitable patient cases or tissue samples in Dresden or Munich and coordinate multi-centre projects. By harmonising IT systems, DKTK has created a national backbone for oncology data that did not previously exist. Within this network, t**he EXLIQUID liquid-biopsy consortium brings expertise from all DKTK partner sites together to establish blood-based (ctDNA) liquid biopsy as a minimally invasive tool in routine precision oncology, build shared Standard Operating Procedures** (SOPs) and training, biobank blood from molecular tumour board patients, and create a platform to compare mutation- and methylation-based assays across centres.

Building the skilled workforce has been an explicit priority. **DKTK has established an interdisciplinary School of Oncology to train clinician-scientists in translational cancer research**. Medical and PhD trainees from all partner sites participate in summer schools, symposia, and joint courses, learning both laboratory and clinical skills. For example, the school's cross-disciplinary training helps oncologists, pathologists, and bioinformaticians to speak the same technical language and follow common workflows. In parallel, dozens of new faculty positions (W2/W3 professorships) have been funded by DKTK at partner universities, growing local expertise in areas like immuno-oncology, molecular diagnostics, and bioinformatics. DKTK also supports clinician-led programs like the DKFZ/NCT/DKTK MASTER, a nationwide molecular profiling platform that brings together oncology departments at Heidelberg, Dresden, and other sites. Through these initiatives, hospitals share not only machines and biobanks but also skilled personnel. Regular inter-site tumour boards and shared protocols mean that nurses, pharmacists, and data managers use standardised processes, and that workforce training materials (e-learning modules, user manuals) are centrally developed and used at all centres.

Measurable Outcomes

- **Multi-source funding leveraged:** Sustained federal and state investment has invested in DKTK funding at ~€28M annually, complemented by matching state and research grants. This has enabled deployment of specialised equipment and clinical laboratory infrastructure at each site that would not have been affordable locally.

- **Shared liquid biopsy and biospecimen platforms:** EXLIQUID established a DKTK-wide, SOP-driven workflow for ctDNA sampling/processing, alongside integrated biobank catalogues and query tools. Together, these platforms enable cross-site access to high-quality tumour samples and support routine

- **Shared biospecimen access:** An integrated biobank catalogue and query tools allow scientists at any DKTK centre to locate and request high-quality tumour samples from across the consortium. This builds one of Europe's largest multicentre oncology sample repositories.

- **Workforce growth and training:** DKTK now involves >1,000 professionals (scientists, clinicians, technical staff), up from about 160 at launch. Common curricula and dedicated training programs have strengthened genomics, bioinformatics, and oncogenetics expertise, with around 20% of personnel being graduate students, reflecting sustained investment in capacity building.

- **Increased clinical trial capacity:** Unified infrastructure has accelerated patient referral and enrolment into clinical trials, allowing eligible patients to be enrolled through any partner site's tumour board and increasing overall trial participation across the network.

- **Federated data platform:** By 2017 the DKTK CCP "bridgeheads" were deployed at every partner site, creating a secure data-sharing infrastructure across the network. This enables centralised searches of patient and sample data, effectively giving researchers multi-hospital visibility while each site retains control over its data.

Strengths

- **Coordinated national model:** DKTK's structure aligns federal, state, and institutional efforts through a central steering council that sets common standards, avoids duplication, and builds trust across sites. This coordination is underpinned by a stable joint federal–state funding model, with a predictable annual budget of around €28M, enabling long-term maintenance of shared infrastructure, trained personnel, and translational research capacity.

- **Federated IT and data:** The CCP and related IT solutions knit together disparate hospital systems. This "plug-and-play" architecture means DKTK did not need to replace local systems, only to install data interfaces. It delivers a scalable foundation—new sites or registries can join by adding a bridgehead node.

- **National liquid biopsy implementation engine:** EXLIQUID gives centres a common playbook (SOPs, training, shared repository) to adopt ctDNA testing consistently, accelerating workforce upskilling in molecular pathology and bioinformatics.

- **Unified protocols and training:** Nationwide libraries of diagnostic and treatment protocols (e.g. radiotherapy plans, pathology reporting formats) ensure consistency. Shared e-learning and on-site training crews have meant that even smaller centres benefit from the same expertise as the large hubs. Staff mobility across sites (for rotations or secondments) fosters a common culture.

- **Dedicated translational workforce:** By funding professorships and programs such as the School of Oncology, DKTK has grown an interdisciplinary cadre fluent in both bench and bedside. This has shortened communication gaps and enabled smoother implementation of new techniques (for example, bioinformatics pipelines are now a standard part of tumour boards at every site).

- **Enhanced patient access:** The consortium design empowers patients. Through DKTK's network, individuals in Munich have access to diagnostic tests or trials developed in Dresden or Heidelberg. The CCP's trial-matching function means eligible patients can be offered studies regardless of where they present.

Challenges

- **Complex integration work:** Linking eight different hospital IT systems, each with its own legacy software and hardware, required significant effort. Interfaces for lab, pharmacy, and record systems had to be customised for each site. In practice, roll-outs often needed extra technical support at local hospitals.

- **Liquid biopsy adoption in routine care remains limited**; scaling requires cross-site SOPs and quality control (QC) for sampling, processing, and storage, and the coordination of a real-world multicentre biobank. Significant workflow change, training, and operational alignment slowed integration into diagnostic and treatment pathways.

- **Standardising practices:** Clinical and laboratory procedures varied between centres before DKTK. Harmonising these (for example, chemotherapy labelling or consent forms) took repeated meetings and sometimes regulatory tweaks. Achieving consensus on national clinical guidelines has been time-consuming.

- **Training and adoption:** Deploying new workflows meant clinicians and staff had to learn new skills. Busy oncologists, nurses, and data managers needed protected time for training and "go-live" support. Initial resistance occurred when digital processes temporarily slowed routines—some centres required extended floor support to reach full proficiency.

- **Funding sustainability:** DKTK's core network is secured by long-term federal/national funding (~€28M/yr), but key expansion projects (e.g. EXLIQUID and CCP upgrades) are grant-based and need transition plans into steady budgets. In parallel, routine reimbursement remains incomplete (limited panel NGS coverage, pilot WGS, and selective liquid-biopsy codes), so scaling advanced diagnostics still depends on mixed funding streams.

- **Workforce continuity:** Attracting and retaining skilled staff (bioinformaticians, data analysts, research nurses) is a perpetual need. Some partner sites (especially in less-populated regions) may face shortages of specialised clinicians. Succession planning for the many core staff trained by DKTK must be addressed, to avoid loss of expertise if leaders move on.

Future Development Needs

- **Expand digital capabilities:** DKTK should build on its data platforms by adding advanced analytics and AI tools. For example, developing national dashboards for monitoring throughput and safety could help optimise resources (e.g. predicting workforce shortages or equipment needs). Integrating the CCP with emerging national health data initiatives would further enhance longitudinal patient tracking.

- **Complete integration of all service lines:** Next steps include linking additional data sources (e.g. radiology archives, remote pathology) and onboarding affiliated hospitals. Enhancing interoperability will reduce manual workflows. New modules, e.g. standardised e-consultation tools for remote tumour boards, could further unify practice.

- **Sustain training and support:** Ongoing investment in the School of Oncology and similar programs is needed as technology evolves. This means refreshing curricula (for instance, adding training in machine learning or telemedicine) and expanding offerings to more specialties (e.g. precision radiotherapy). Establishing career pathways for clinician-informaticians or oncology genetic counsellors would solidify the workforce gains.

- **Governance and funding models:** DKTK must secure long-term budgets for its shared infrastructure. This may involve transitioning to stable institutional funding lines at DKFZ and the states. Formal evaluation frameworks should be set up so that operational data (case volumes, safety metrics) inform continuous improvement and justify ongoing support.

- **Broaden network reach:** There is room to extend the consortium's scope. For example, incorporating paediatric oncology clinics or partnering with the German Network of Centres of Integrated Oncology (National Cancer Centres) could broaden patient access. However, any expansion should preserve DKTK's unified architecture to avoid fragmentation.

- **Align with European-wide data initiatives:** To maximise interoperability, sustainability, and transnational research potential, DKTK/EXLIQUID should link its infrastructure with the European Health Data Space (EHDS) and related EU cancer-data efforts (e.g. national cancer-data nodes, EU Cancer Mission). Shared registries, harmonised data models, secure cross-border data exchange, and reuse of genomic and clinical data for research, policy, and care should be enabled, while maintaining compliance with privacy and data-governance standards.

Scalability (within the member state)

Germany's federated health system poses scaling challenges, but DKTK's design is inherently expandable. The core model (eight coordinated centres plus DKFZ) is fixed, so scalability now means boosting capacity and extending reach without losing coherence.

- **What:** The infrastructure to scale includes DKTK's eight-site network, the CCP and biobanking platforms, a DKTK-wide liquid biopsy infrastructure, joint funding calls and training programs, and standardised clinical protocols. In essence, it is a national oncology ecosystem of shared tools and content, governed by DKFZ and partner site leadership.

- **How:** Scaling involves broadening or deepening existing components. For example, increasing data storage and compute power as genomics volumes grow, rolling out updated software (e.g. AI-assisted diagnostics) across all bridgeheads, and running additional waves of staff training using the established "train-the-trainer" model. DKTK could also pilot new services (e.g. digital pathology review) at one centre and then deploy them network-wide using its playbook of interfaces, super-user training, and floor support.

- **Where:** To scale within Germany, focus should be on (a) filling remaining gaps at partner regions (e.g. integrating all affiliated community clinics and day-ward sites under each centre); (b) extending to state or regional cancer programs not yet linked (for example, linking to cancer registries in currently non-covered federal states); and (c) possibly opening selective collaborations with well-equipped private hospitals under DKTK umbrella. Any new site would connect through the existing CCP architecture and adopt the same national protocols.

- **Considerations:** Key enablers are sustained financing for expanded compute and storage, and dedicated staff time for each new roll-out. Strict change-control is needed to keep one configuration baseline (avoiding local customisation drift). Clinician engagement remains critical: continued co-design with end-users will ease adoption as features (e.g. mobile access, new data fields) are added. Finally, privacy and data protection must be vigilantly managed, especially if new cross-linkages (e.g. national death registry, cross-border cases) are introduced.

Transferability (across member states)

DKTK's experience offers lessons for other countries building national oncology networks. Its model – a government-backed consortium of academic centres with shared IT, biobanks, and training – can be adapted where health systems have multiple cancer institutes. Key is combining centralised coordination with local hubs: national policy and funding bodies set common standards, while regional hospitals host the clinical activities.

- **What:** The transferable elements are a nationally sponsored consortium that links top cancer centres (and core research institutes) into a unified infrastructure. This includes a federated data-sharing platform (like the CCP), shared biobanks and laboratory services, standardised clinical content libraries, and joint training programs. A dedicated governance structure (steering committees, user groups) underpins it.
- **How:** To replicate DKTK's approach, a country should start by identifying its major cancer hospitals and rallying them under one umbrella with government backing. A pilot network (for example, a project like EXLIQUID) can build trust in the collaboration. Then it can procure or develop interoperable IT systems centrally and deploy interfaces at each site. Simultaneously, clinical protocols are harmonised through multidisciplinary working groups. Phased rollouts with local "super-user" training, regular cross-institution workshops, and a central helpdesk will help embed the platform across sites.
- **Where:** This model suits any member state with multiple oncology centres and research universities, whether it is a large country (linking regions) or a smaller one (scaling to all hospitals). It can also be applied in federated systems by creating regional consortia that eventually interlink. As DKTK shows, even nations with mixed public–private healthcare can adopt a public-led backbone, then allow private centres to plug into it.
- **Considerations:** Reimbursement pathways for ctDNA (coding/coverage) are often the rate-limiter. EXLIQUID's consortium model plus a national application process can serve as a blueprint for other systems given Germany's currently limited routine coverage and MTB-driven use. Also important is early planning for data/semantic standards and privacy frameworks, funding change-management and ongoing workforce training (not just software/hardware), maintaining a single national configuration with tight change control to avoid local drift, and building formal evaluation loops so operational metrics (throughput, safety, access) justify sustained funding and guide continuous improvement.

Relevant Sources

- Mack M, Broche J, George S, Hajjari Z, Janke F, Ranganathan L, et al. The DKTK EXLIQUID consortium – exploiting liquid biopsies to advance cancer precision medicine for molecular tumor board patients. Journal of Laboratory Medicine. 2022 Aug 26;46(4):321–30.
- Deutsche Konsortium für Translationale Krebsforschung [Internet]. [cited 2025 Oct 16]. Platforms and Technical Expertise Networks - Data bases. Available from: https://dktk.dkfz.de/en/research/core-facilities/datenbanken
- Deutsche Konsortium für Translationale Krebsforschung [Internet]. [cited 2025 Oct 16]. Platforms and Technical Expertise Networks - Technology & IT Solutions. Available from: https://dktk.dkfz.de/en/clinical-platform/working-groups-partners/ccp-it
- Deutsche Konsortium für Translationale Krebsforschung [Internet]. [cited 2025 Oct 16]. School of Oncology – Training in Translational Oncology for Scientists and Clinicians. Available from: https://dktk.dkfz.de/en/training/school-oncology/about-program
- Deutschen Krebsforschungszentrum [Internet]. [cited 2025 Oct 16]. German Cancer Consortium (DKTK). Available from: https://www.dkfz.de/en/research/translational-centers/dktk
- Deutsche Konsortium für Translationale Krebsforschung [Internet]. [cited 2025 Oct 16]. DKTK Facts and Figures. Available from: https://dktk.dkfz.de/en/about-us/facts-and-figures
- National Center for Tumor Diseases Heidelberg [Internet]. [cited 2025 Oct 16]. DKFZ/NCT/DKTK MASTER Program. Available from: https://www.nct-heidelberg.de/en/research/molecular-stratification/master.html
- The German Consortium for Translational Cancer Research (DKTK). Health Care in Europe [Internet]. 2013 Jan [cited 2025 Oct 16]; Available from: https://healthcare-in-europe.com/en/news/the-german-consortium-for-translational-cancer-research-dktk.html

6. Implementing a national cancer information system in Ireland

Ireland's National Cancer Information System (NCIS) is a nationwide oncology electronic record led by the national health authority, the **Health Service Executive** (HSE)'s National Cancer Control Program (NCCP) with eHealth (Technology & Transformation) as delivery partner. **Conceived to tackle long-standing fragmentation regarding paper files, disconnected local systems, and inconsistent standards, the program provides a single, secure platform for sharing and harmonising cancer data across institutions**. Initiated in 2013 and procured via EU tender, NCIS was piloted in late 2019 (St Luke's, Rathgar; Galway University Hospital) and has since moved through a phased national roll-out. Its purpose is to standardise systemic anti-cancer therapy (SACT) prescribing and administration, record multidisciplinary decision-making in real time, and consolidate patient demographics, diagnoses, and treatment plans into a longitudinal record that follows the patient, securely storing comprehensive clinical information to support precision oncology.

Scope and governance are national by design and aligned with Ireland's National Cancer Strategy. The NCIS is being implemented across all public hospitals delivering cancer services: eight designated adult cancer centres plus the national paediatric centre at Children's Health Ireland (Crumlin), alongside affiliated hospitals running multidisciplinary teams (MDT) and SACT. The program is sponsored by senior health executives (NCCP Director, HSE CIO, Director of Acute Hospitals) and overseen by a multidisciplinary Steering Group and Implementation Board. A national user group convened by NCCP and eHealth Ireland shares implementation insights and promotes consistent practice. **As of May 2025, NCIS is live in 22 of a planned 26 hospitals (including nine designated cancer centres)**, with go-live milestones publicly tracked on the HSE's NCIS page. Built-in hospital-level operational reporting supports service management, covering prescribing, preparation, administration, and MDT documentation, giving managers and clinical leads new visibility on activity, safety, and workflow. To date, however, these lessons remain internal and are not yet published as formal quantitative evaluations.

Technically, NCIS combines the BD Cato chemotherapy management system (closed-loop e-prescribing/administration) with a tumour board module for **multidisciplinary team** meeting scheduling and documentation, integrated via an interoperability engine to each hospital's systems of patient administration and laboratory information (PAS/LIS). **National libraries of NCCP-approved regimens, structured assessment forms and tumour-specific datasets mean clinicians work to the same content everywhere, improving the consistency and quality of clinical information while reducing duplication**. For the workforce, this translates into shared training pathways, common templates, and safer, barcode-enabled workflows for pharmacists and nursing teams. For infrastructure, it delivers a scalable, interoperable backbone that links sites and standardises care processes as additional hospitals come online.

Measurable Outcomes

- **National roll-out**: NCIS implementation has progressed steadily: after the first go-live in November 2019 (St Luke's, Galway), it expanded to all regional centres through 2022–2025. By end-2023 NCIS was live in 16 of the 26 targeted hospitals, and by mid-2025 about 22 sites were operational. Deployment typically occurred in waves (4–6 hospitals per year), allowing lessons from earlier sites to improve later rollouts.
- **System usage**: Although a formal outcome evaluation is pending, early reports indicate high uptake of NCIS functions in live sites. For example, one case study noted that thousands of SACT doses had already been prescribed through NCIS within the first years. The system now supports hundreds of weekly chemotherapy sessions at each implementation site (Ireland delivered ~130,000 chemo infusions nationally in 2023). Common system tasks include generation of e-prescriptions for SACT, scheduling of therapy sessions, bar-coded compounding in pharmacy, and full documentation of weekly MDT meetings.

- **Clinical and safety metrics**: User feedback suggests measurable benefits, in terms of reduced errors in medication dispensing, improved efficiency in care provision, and increased patient satisfaction. The closed-loop prescribing (with dose-checking and barcode labelling) has significantly improved chemotherapy safety at go-live sites. Standardised NCIS reporting provides each hospital with operational dashboards (e.g. number of SACT cases, regimen usage), allowing managers to track service volume and turnaround times. In addition, NCIS automatically captures structured cancer case data during tumour boards, contributing ongoing case information to national audits and the cancer registry.

- **Training and adoption**: A dedicated NCIS project office coordinated multi-professional training at each hospital. Comprehensive e-learning resources (user guides, quick-reference manuals) have been published by NCCP and made available on the HSE's HSeLanD platform. To date, hundreds of clinical staff (oncologists, haematologists, pharmacists, nurses) have completed NCIS training modules. Adoption has been aided by the NCCP's National User Group (clinicians/IT from all sites), which meets regularly to share lessons and best practices. As a result, adoption rates have generally been high in sites post-go-live, with physicians and pharmacists increasingly relying on the NCIS for daily workflows.

Strengths

- **Patient-centered unified record**: The NCIS delivers a single national oncology record for each patient. All relevant data (demographics, diagnoses, treatment history) travel with the patient in the system, eliminating paper charts and fragmented files. Clinicians nationwide have real-time, secure access to each patient's cancer care record, which ensures continuity of care when patients move between hospitals. This "longitudinal" record is a major milestone in Irish oncology and aligns with EU goals for shared patient summaries.

- **Enhanced patient safety and equity through standardisation**: NCIS automates complex chemotherapy prescribing using nationally standardised regimens and structured order sets. Built-in dose calculations, laboratory checks, and alerts significantly reduce prescribing and dispensing errors, while national standardisation ensures consistent, guideline-aligned care regardless of treatment location, reducing unwarranted variation.

- **Multi-disciplinary meeting (MDT) support**: The NCIS includes a dedicated tumour board scheduling and documentation module. It standardises MDT planning (adding patients to conferences, recording attendees and specialty) and requires structured therapy recommendations by tumour type. Upon conclusion, the NCIS automatically generates a detailed consultation report and letters to share with the patient and primary care. This replaces paper tumour board notes with consistent electronic documentation, making audit and care coordination much more efficient.

- **Coordinated national roll-out**: A key strength has been the project's national governance and stakeholder engagement. Clinicians from all sites were involved early: the NCCP chaired a Steering Committee and an Implementation Board to oversee standards, and the NCCP even commissioned a National User Group that meets every 6–8 weeks to share implementation stories. This co-design approach, involving IT specialists, doctors, nurses, and pharmacists, has been credited as crucial to success. For example, feedback from early pilot sites has been rapidly incorporated into configuration adjustments for later rollouts.

- **Shared training, resources, and system integration:** National pooling of training materials, super-user networks, and digital skills initiatives has supported workforce readiness across all hospitals. The NCIS integrates with existing hospital IT systems rather than replacing them, reducing data entry errors and enabling scalable roll-out using existing infrastructure.

Challenges

- **Complex integration work**: Connecting the NCIS to each hospital's IT proved labour-intensive. Even though a centralised messaging system, this still required coordination with each site's IT team and vendors. Delays or variations in local IT (old hardware, differing PAS versions) could slow rollout. In practice, many hospitals needed extra support from eHealth Ireland's infrastructure team to complete integrations before go-live.

- **Standardising local practices**: Before NCIS, hospitals had slightly different regimens and paper forms. Aligning them was challenging. The NCCP led working groups to standardise chemotherapy protocols, patient assessment forms, and tumour board data fields ahead of go-live. In some cases, local teams had to change long-standing practices (e.g. labelling conventions) to fit the national template. Achieving consensus across all sites on clinical content and workflows took repeated rounds of consultation.
- **Workforce training and adoption**: Rolling out a new system for cancer care demanded extensive staff training. Oncologists, pharmacists, and nurses had to learn new digital skills. For example, physicians now enter chemotherapy orders on-screen instead of paper, and pharmacists use the NCIS to manage compounding schedules. Allocating clinical time for this was hard in busy hospitals. Despite the online guides, some users required hands-on support during go-live to feel confident. Initial resistance was seen where workflow efficiency temporarily dipped during learning. Pharmacy staff had to adopt a "transcription" step when dealing with non-cancer meds: the NCIS allows pharmacists to enter an external prescription so it can be compounded under NCIS barcoding, but this new process required training and policy rules.
- **Data privacy and access rules**: Ensuring patient privacy has been critical. A data protection impact assessment noted that NCIS records are only accessible to users at the patient's registered hospital. In effect, if a patient has a tumour case open at Hospital A, clinicians at Hospital B can only see that NCIS record if the patient has also been registered on Hospital B's PAS. This protects data but also means that until all hospitals are on NCIS, some cross-site views remain restricted. Planning secure access (and single sign-on via HealthIdent) has been non-trivial.
- **Phased roll-out limitations**: Because the NCIS went live site-by-site, Ireland still has a period where some patients' care is split between "digitised" and "non-digitised" units. During 2020–2023 especially, a patient might move from an NCIS-equipped hospital back to one on paper. In these gaps, staff had to maintain dual records or send printouts. Closing this gap requires fully completing the roll-out, which is still in progress. This transitional state has been a persistent challenge. This dual-track situation not only added administrative burden, but also risked prolonging inequities in access to streamlined, safe cancer care particularly for patients receiving treatment in hospitals still operating on paper systems.

Future Development Needs

- **Complete rollout and new care models**: Implementation teams will continue until all 26 targeted hospitals (and any future cancer service sites) are live on the NCIS. Achieving full coverage is essential to eliminate remaining data silos. Beyond rollout, the NCIS could be expanded to cover additional oncology-related services. For example, incorporating a module for radiotherapy planning, or linking to cancer genetics clinics, would broaden the NCIS's scope.
- **Usability improvements**: Ongoing user feedback will drive software refinements. Implementation feedback has already led to configuration tweaks between go-live waves. Planned developments include better mobile/tablet views for clinicians, more efficient user interfaces, and expanded decision-support (e.g. automatic alerts when patients miss laboratory tests). The NCCP also plans to review and update training materials regularly, as well as add e-learning modules for new system features.
- **Advanced analytics and reporting**: To leverage the rich data, future needs include building advanced dashboards and reports at both hospital and national levels. Aggregated NCIS metrics could inform workforce planning (e.g. number of oncology nurses needed) and policy (e.g. national SACT uptake trends). Some hospitals are already using NCIS reports for local management; this should be harmonised across all sites for consistent national key performance indicators (KPI).
- **Ongoing workforce development**: The digital transformation extends beyond the NCIS. Ireland continues to invest in staff digital literacy. The HSE's "Digital Health Learning Passport" initiative, for example, will help ensure cancer care staff have the foundational IT skills needed. As the NCIS evolves (e.g. adding new modules), the training strategy must evolve too, with refresher courses and clinical simulation exercises. Building IT-support capacity within hospitals (super-users, local informatics teams) will be crucial for long-term success.

- **Governance, collaboration, and interoperability**: Maintaining the NCIS governance structures including the Implementation Board and national user group should be sustained to oversee system updates and future digital health initiatives. Closer collaboration between the NCCP, eHealth Ireland, and hospital management will be needed, alongside stronger interoperability with national cancer registries and alignment with EU-level initiatives such as the European Health Data Space and EU Cancer Mission.

Scalability (within the member state)

Ireland designed the NCIS as a single national platform with shared governance, standard clinical content, and centrally supported training, so scaling is chiefly about finishing deployment, increasing throughput, and extending functionality without fragmenting care.

- **What**: A national oncology record, an MDT/tumour board module for multidisciplinary documentation, and an interoperability layer under NCCP/eHealth governance, accompanied by national regimen libraries, structured templates, a user group, and hospital-level operational reporting.
- **How**: Complete roll-out in remaining sites using the established onboarding playbook (site readiness, interfaces, data validation, super-user training, go-live floor support), scale hosting, storage, and interfaces, standardise KPIs and dashboards, expand content (e.g. additional tumour datasets, survivorship), and deepen integrations (laboratory, pharmacy, day-unit scheduling), while keeping a single national configuration to avoid local drift.
- **Where**: Final four hospitals and affiliated day units, Children's Health Ireland network, and satellite chemotherapy services linked to designated centres. There is a potential extension to private providers or cross-border referral pathways where policy allows, but always ensuring it is anchored to the national instance and governance.
- **Considerations**: Sustained funding for infrastructure and backfill for staff training, protected time for clinicians, pharmacists, and nurses during adoption, tight change-control to preserve a single national build, privacy/access controls when patients move across sites, vendor and interoperability roadmaps to future-proof,; and a formal evaluation framework so operational data (safety, timeliness, throughput) inform continuous improvement and workforce planning.

Transferability (across member states)

NCIS shows how a centrally governed oncology IT platform can replace paper and disparate local tools with one national service that standardises SACT and MDT workflows and strengthens the workforce with common training and templates.

- **What:** A cancer-programmed-led model (national sponsor + steering/implementation boards) that procures a mature oncology e-prescribing system, adds an MDT module, integrates via a national interoperability engine, and ships a single content library (regimens, forms, datasets) plus a national user group and shared training resources.
- **How:** Start with pilot centres to co-design clinical content and workflows, standardise chemotherapy protocols nationally, procure the platform through competitive tender, build PAS/LIS interfaces with a reusable integration pattern, phase deployment in waves with super-users and floor-walking, and publish go-live milestones and operate a central helpdesk, training catalogue, and release management.
- **Where:** Most applicable to countries with a national cancer program and public hospital network. Equally adaptable to federated systems via regional hubs that share one configuration. Can be implemented within hospital groups first, then scaled nationally once content and interfaces stabilise.
- **Considerations:** Harmonising legacy practices and data standards, budgeting not just for software and hosting but for change-management and ongoing training, clinician buy-in (early co-design reduces resistance), clear data-governance and privacy rules, interoperability standards to link labs/pharmacy/registries, and a plan to avoid partial roll-outs (or to mitigate them) so workforce and service benefits materialise uniformly.

Relevant Sources

- All.Can [Internet]. [cited 2025 Oct 16]. Implementing a National Cancer Information System in Ireland. Available from: https://www.all-can.org/efficiency-hub/implementing-a-national-cancer-information-system-in-ireland/
- eHealth Ireland [Internet]. 2024 [cited 2025 Oct 16]. The HSE Digital Health Learning Passport. Available from: https://www.ehealthireland.ie/news-media/news/2024/the-hse-digital-health-learning-passport
- Government of Ireland [Internet]. 2024 [cited 2025 Oct 16]. Minister for Health publishes the National Cancer Strategy 2017-2026 Implementation Report 2023. Available from: https://www.gov.ie/en/department-of-health/press-releases/minister-for-health-publishes-the-national-cancer-strategy-2017-2026-implementation-report-2023/
- Policy mapping on ehealth policies and initiatives (including on cancer care) in Ireland [Internet]. eCAN; 2024 [cited 2025 Oct 16]. Available from: https://ecanja.eu/downloads/eCAN_WP4_Policy_Mapping_Country_Factsheet_IE_not_reviewed_final.pdf
- eHealth Ireland [Internet]. [cited 2025 Oct 16]. National Cancer Information System. Available from: https://www.ehealthireland.ie/technology-and-transformation-functions/acute-delivery/national-cancer-information-system
- Health Service Executive [Internet]. [cited 2025 Oct 16]. NCIS - About the National Cancer Information System. Available from: https://www.hse.ie/eng/services/list/5/cancer/profinfo/medonc/projects/mocisproject.html
- Health Service Executive [Internet]. [cited 2025 Oct 16]. FAQs - National Cancer Information System. Available from: https://www.hse.ie/eng/services/list/5/cancer/profinfo/medonc/projects/frequently%20asked%20questions%20-%20ncis.html

Promising practices

Regional blueprints that align high-volume genomic infrastructure with multidisciplinary workforce models

In Europe, the most promising infrastructure programs make advanced sequencing and data analytics a system function, while empowering clinicians, pathologists, geneticists, bioinformaticians, and MTB coordinators to act as one network. Emilia-Romagna (Italy) pairs a regional molecular tumour board (MTB) and integrated NGS hubs with a data backbone, the oncology data backbone (DBO, Database Oncologico) that tracks real-world oncology care, including genomic tests. Catalonia (Spain) deploys the Omics Integrated Quantification-High-throughput Execution Service (OMIQ-HES), a cloud-scale platform that unifies clinical and genomic data and backs clinicians with a region-wide bioinformatics workforce. Both show how to couple technology consolidation with multidisciplinary capacity so every patient can benefit from precision oncology.

7. Emilia-Romagna (Italy): Integrated NGS platforms, a single regional MTB, and a shared oncology data backbone (DBO)

Emilia-Romagna has translated national MTB requirements and extended genomic profiling into a concrete regional setup: **one multidisciplinary MTB embedded in the oncology network, plus a small number of integrated NGS platforms that serve defined catchment areas**: This pools molecular pathology, genetics, and bioinformatics across university hospitals/IRCCS **to standardise quality and access**. The 2024 regional resolution (DGR 1571/2024) explicitly links these governance moves to the National Cancer Plan 2023–2027 and the Comprehensive Cancer Care Network, with annual, indicator-based objectives to consolidate prevention, diagnosis, care, and research, to reduce inequities across the territory.

The DBO is the region's shared data infrastructure for oncology governance. It was designed to: (a) integrate with all health archives, (b) monitor real-world effectiveness and adherence to evidence-based recommendations from the Emilia-Romagna Region Oncology Medicines Group (GREFO), and (c) support planning and equity in access to oncology services. **The data flow has been active since 1 January 2017 and, crucially, from 2021 it also captures genomic tests for early hormone-responsive breast cancer, even when testing leads to no chemotherapy** (tests guiding de-escalation). This feature supports one of the National Cancer Plan's core aims: reducing overtreatment. The structured tracking of genomic tests and treatment decisions enables regional audits on whether biomarker-driven decisions are being used to de-escalate unnecessary chemotherapy, especially in early-stage hormone-sensitive cancers.

Regarding operation and workforce, the local MDTs escalate eligible cases to the regional MTB for coordinated interpretation and therapy matching. Accredited NGS hubs concentrate test production with shared QA, bioinformatics pipelines, and turnaround targets. **The DBO's standardised data model, deadlines, and feedback loops reinforce consistent practice and enable outcome/equity audits across hospitals and provinces**. Median turnaround times for genomic test results are defined regionally and monitored through the DBO. According to implementation SOPs, all complex or actionable cases are to be escalated to the regional MTB. This structure enables tracking of geographic equity: the DBO collects data disaggregated by province and facility, allowing the region to monitor delays, access gaps, and alignment with evidence-based recommendations. Sustaining this model requires stable investment. By aligning the NGS hubs and MTB operations with the National Cancer Plan indicators, Emilia-Romagna ensures access to recurring public funding. However, regional planners also face challenges in recruiting and retaining skilled personnel, particularly in university hospitals where demand for molecular pathologists, geneticists, and bioinformaticians outpaces supply.

Consolidating testing in a few high-volume platforms reduces duplication and variation. A single MTB ensures uniform interpretation and the DBO makes the whole pathway measurable (from test to treatment), aligning clinical work with planning and budget governance under the regional oncology network and the National Cancer Plan objectives.

This model's **transferability** rests on its modular governance and funding logic rather than on any single laboratory configuration. Other publicly funded systems can replicate the combination of a light central mandate (to set objectives, quality guardrails, and common processes) and regional university hospital hubs (to deliver testing, tumour board deliberation, and trials), embedding genomic testing and MTB discussion as funded and structured elements of the national cancer pathway, rather than as discretionary tests. The integration of a single regional MTB directly into patient pathways, with systematic referral of eligible cases, provides a replicable governance model that can be scaled in other decentralised systems. The scalability comes from the ability to add tumour indications and participating centres incrementally within an existing network, and from the tight coupling of care and research: as regional and national precision-oncology programs mature, results can be recycled into pathway and reimbursement updates without reinventing governance or payment each time.

8. Catalonia (Spain): OMIQ-HES - a centralised clinico-genomic data and a networked bioinformatics workforce

The OMIQ-HES is a public, high-performance platform that integrates clinical, genomic, and healthcare data to support precision oncology decision-making across the Catalan Health Service (CatSalut). Health authorities presented OMIQ-HES with Bioinformatics Barcelona (BIB) and TIC Salut Social, developed in collaboration with Fujitsu, Genomcore, and Microsoft. **OMIQ-HES centralises ingestion from hospital EHRs and sequencing labs, provides standardised variant analysis/reporting, and enables privacy-preserving reuse for research and system learning**, as a single service for all clinicians and centres.

A distinctive feature is the workforce model: Catalonia couples the platform with a region-wide network of bioinformaticians made available to professionals throughout the system, so **oncologists and pathologists anywhere can access expert interpretation without duplicating teams in every hospital**. The launch emphasised equity, confidentiality, and security, framing OMIQ-HES as a scalable, sustainable way to embed personalised medicine in routine care while improving medical decision-making and research capacity. On the tech side, Genomcore's Biomedical Information Management System underpins OMIQ-HES with secure data storage, advanced bioinformatic processing, a shared genomic-variant knowledge base, automated clinical reports, and interoperability with existing systems, explicitly designed to interact with distributed datasets and on-premises datacentres. One cloud-scale platform instead of siloed hospital tools, allows **OMIQ-HES to reduce fragmentation and standardise variant interpretation and reporting, sharing expertise via the bioinformatics network**, so a clinician in any district can order testing and receive the same high-quality analysis. This model explicitly avoids duplication of local bioinformatics infrastructure by centralising variant analysis and sharing a region-wide network of experts. This ensures that all hospitals—regardless of their internal capacity—receive the same quality of interpretation which maximises efficiency and supports equity of access. Catalan health authorities have framed OMIQ-HES as a scalable, integrative model for embedding personalised medicine into routine care across the entire regional system. The result is a system-wide uplift in capability that is secure, with clear governance and partner support.

As the platform was launched recently with support from technology partners, ensuring **long-term funding sustainability and institutional governance** will be essential. Transitioning from a pilot phase to a fully embedded system requires public investment in maintenance, workforce retention, and platform updates. The model's **transferability** rests on its modular governance and funding logic rather than on any single laboratory configuration. Other publicly funded systems can replicate the combination of a light central mandate (to set objectives, quality guardrails, and common processes) and regional university hospital hubs (to deliver testing, tumour board deliberation, and trials), embedding genomic testing and MTB discussion as funded elements of the national cancer pathway rather than as discretionary tests. The model's **scalability** comes from the ability to add tumour indications and participating centres incrementally within an existing network, and from the tight coupling of care and research: as national initiatives (e.g. Spain's clinico-genomic data networks) and platform-enabled studies mature, results can be recycled into pathway and reimbursement updates without reinventing governance or payment each time.

Further development could include aligning OMIQ-HES with Spain's national clinico-genomic initiatives to strengthen system-wide integration and support data sharing across autonomous communities.

Relevant Sources

Emilia-Romagna (Italy)

- Regione Emilia-Romagna. Deliberazione della giunta regionale 12 dicembre 2023, N. 2140 [Internet]. Bolletino Ufficiale della Regione Emilia-Romagna. 2023 [cited 2025 Oct 16]. Available from: https://bur.regione.emilia-romagna.it/dettaglio-inserzione?i=f24c39a0814f401792626d3d90887d15

- Regione Emilia-Romagna, Servizio Sanitario Regionale Emilia-Romagna, Rete Oncologica ed Emato-oncologica Regione Emilia-Romagna. Molecular Tumor Board nell'ambito della Rete Oncologica ed Emato-Oncologica della Regione Emilia-Romagna [Internet]. 2024 [cited 2025 Oct 16]. Available from: https://bur.regione.emilia-romagna.it/area-bollettini/gennaio-periodico-parte-seconda-2a-quindicina-secondo-fascicolo/istituzione-del-gruppo-multidisciplinare-molecular-tumor-board-nellambito-della-rete-oncologica-ed-emato-oncologica-della-regione-emilia-romagna-individuazione-delle-piattaforme-integrate-per-la-profilazione-genomica-estesa-next-generation-sequencing-ngs/allegato_documento-istituzione-2024-01-12-1705053070

- Regione Emilia-Romagna. Sistema Informativo Politiche per la Salute e Politiche Sociali. 2016 [cited 2025 Oct 16]. Database Oncologico. Available from: https://salute.regione.emilia-romagna.it/siseps/sanita/dbo

- Regione Emilia-Romagna. Deliberazione della giunta regionale 8 luglio 2024, N. 1571 [Internet]. Bolletino Ufficiale della Regione Emilia-Romagna. 2024 [cited 2025 Oct 16]. Available from: https://www.farmindustria.it/app/uploads/2024/09/DGR-1571_2024-obiettivi-Piano-Oncologico.pdf

- Regione Emilia-Romagna. Specifiche funzionali: Flusso DBO Data Base Oncologico [Internet]. 2022 [cited 2025 Oct 16]. Available from: https://salute.regione.emilia-romagna.it/siseps/sanita/dbo/files/dbo_specifiche_funzionali_v1-6.pdf

Catalonia (Spain)

- Catalonia consolidates itself as a benchmark in personalised and precision medicine with the new genomic data platform OMIQ-HES. Bioinformatics Barcelona (BIB) [Internet]. 2025 Feb [cited 2025 Oct 16]; Available from: https://bioinformaticsbarcelona.eu/catalunya-es-consolida-com-a-referent-en-medicina-personalitzada-i-de-precisio-amb-la-nova-plataforma-de-dades-genomiques-omiq-hes/

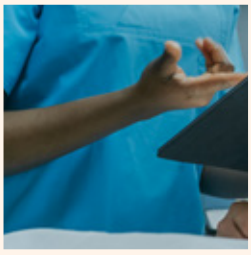
- Genomecore [Internet]. [cited 2025 Oct 16]. OMIQ-HES, a high-performance genomic analysis platform. Available from: https://genomcore.com/use-cases/omiq-hes/

- Govern de Catalunya [Internet]. 2015 [cited 2025 Oct 16]. Catalunya es consolida com a referent en medicina personalitzada i de precisió amb la nova plataforma de dades genòmiques OMIQ-HES. Available from: https://govern.cat/gov/notes-premsa/678902/catalunya-es-consolida-com-a-referent-en-medicina-personalitzada-i-de-precisio-amb-la-nova-plataforma-de-dades-genomiques-omiq-hes

- Generalitat de Catalunya [Internet]. 2024 [cited 2025 Oct 16]. OMIQ-HES. Available from: https://salutweb.gencat.cat/ca/ambits-actuacio/linies/tic/solucions-siscat/desenvolupament/omiq-hes

Area 3
Funding and reimbursement




9. Ensuring patient representation in Catalonia (Spain)

Catalonia's health system Servei Català de la Salut (**CatSalut**) covers ~8.1 million people under Spain's devolved National Health Service. CatSalut contracts 68 public hospitals under the integrated SISCAT system. **Cancer care is organised via the Catalan Network of Oncology, a strategic alliance of the Catalan Health Institute (ICS, Institut Catala De La Salut), and the Catalan Institute of Oncology (ICO, Institut Catala d'Oncologia)**. This network treats about 60% of Catalan cancer patients, linking major hospitals with ICO centres in the region. Successive Catalan Cancer Plans (e.g. 2016–2020, 2022–2026) and the national personalised medicine strategy (IMPaCT project) provide a policy framework, but implementation is largely regional. In fact, Spain's public health is highly decentralised, so precision oncology rollout has been fragmented across regions.

Over the past few years, Catalonia has built dedicated infrastructure to embed genomics in routine care. **In 2021 CatSalut issued Instruction 03/2021, launching a Precision Oncology Program (POP) to standardise access to NGS**. Twelve reference laboratories now provide NGS panels for solid tumours, hematologic cancers, paediatric cases and germline testing. As of Dec 2023, these centres had performed ***23,135 molecular tests*** on 22,501 patients, achieving a 98.5% sample compliance rate. The average turnaround is ~4 weeks, and importantly ~24.7% of patients saw their treatment plan modified based on NGS findings. **Catalonia also has a robust hereditary cancer program**: the ICO molecular diagnostics laboratory processes panels for ***>3,000 patients per year***, driving early detection and tailored surveillance. These efforts rest on a centralised governance model, such as CatSalut oversight, multidisciplinary committees, and common data platforms, that allocates funding per panel type and continuously updates testing criteria.

Public and professional awareness is tightly linked to these services. Catalonia operates population screening with high coverage: for example, ~430,000 women aged 50–69 are invited to mammography biannually, **under the Breast Cancer Early Detection Programme**, and about 65% participate. **Other early detection programs focus on colorectal cancer and cervical cancer**. Annual reports (e.g. on World Cancer Day) and campaigns by the Department of Health emphasise early detection: breast cancer five-year survival is ~89% thanks to such programs. **Patient engagement is institutionalised**: CatSalut's **Patients' Advisory Council (PAC)** (24 members from patient organisations) nominates representatives with voting rights to health technology appraisal panels. From 2017–21, the PHF appraisal program included patient representatives in every decision, resulting in 96 appraisals of 168 medicines, building trust and optimism about future treatment possibilities. **Professional outreach is also prioritised**: Catalan oncology societies, such as the Agency for Health Quality and Assessment of Catalonia (AQuA)—which leads HTA, data analysis, and knowledge transfer—and ICO convene seminars and publish plain-language resources, and tumour boards across the network keep clinicians updated on emerging biomarkers. Digital tools (the SISCAT EHRS, My Health (La Meva Salut) patient portal, and integrated tumour registries) further enable information sharing. **Catalonia explicitly aims to eliminate access inequities:** the POP's core values include universal testing access and it has aligned its plan targets (e.g. rising screening counts) with this goal.

Measurable Outcomes

- **Scale and integration of genomic testing**: The Precision Oncology Program now operates across twelve reference centres, delivering 23,135 next generation sequencing reports for 22,501 patients by 2023 and embedding genomic testing as a routine step in the care pathway.

- **Actionable change in clinical management**: Clinicians used the results to adjust treatment plans for about 25% of tested patients, most often by introducing targeted options in solid tumours, showing that awareness of testing is converting into personalised therapy choices.
- **Operational quality and timeliness**: Sample handling meets high standards with 98.5% compliance, and average turnaround from receipt to report is close to four weeks, supporting timely discussions with patients and rapid decision making in multidisciplinary teams.
- **Hereditary risk identification and prevention**: The ICO molecular diagnostics laboratory now delivers more than 3,000 germline diagnoses each year, enabling cascade testing for relatives and risk-adapted surveillance that strengthens prevention alongside treatment.
- **Population awareness translating to earlier detection and trust**: Around 430,000 women are invited to breast screening each year and uptake is near 65%, with breast cancer survival at about 89% at five years. In parallel, CatSalut's pharmacotherapeutic harmonisation program held 96 appraisal sessions from 2017 to 2021 with patient representatives participating throughout and covering 168 medicines, reinforcing transparency and confidence in access to precision treatments.

Strengths

- **Integrated Networks:** Catalonia's cancer network tightly links top hospitals and ICO's regional centres covering 60% of patients. Shared tumour boards and interoperable registries ensure that genomic findings travel with the patient across sites.
- **Professional and Patient Outreach:** Patient representatives have formal roles in appraisal and policy (PAC with voting rights), creating a culture of inclusion. Physician networks receive continuous education via, for example, seminars, e-learning, ICO toolkits, while public campaigns, such as the breast cancer ribbons and Department of Health materials, demystify genomics.
- **Institutional Leadership:** CatSalut provides centralised leadership and funding for precision oncology, ensuring sustainability. The POP's governance (executive board + 12-center network) embeds precision testing into planning. Long-term cancer plans and ICO guidelines give clear direction on when and how to test.
- **Data and Digital Tools:** Catalonia's unified health records (SISCAT), laboratory information systems, and tumour registries underpin quality control and tracking. The centralised POP data platform and SFTP reporting mean patient data from any hospital are accessible for care and research. These robust IT foundations support professional confidence in precision testing.
- **Robust Outcomes:** The infrastructure and network have already delivered impact: thousands of NGS results, thousands more genetic screenings, and rising screening volumes. High compliance (98.5%) and rapid turnarounds (~4 weeks) in the POP attest to operational efficiency. Breast screening covers ~65% of eligibles, and Catalonia exceeds EU averages in some diagnostics.

Challenges

- **Equity Gaps:** Despite high averages, disparities persist. Immigrant and underserved groups have lower follow-up rates (e.g. second-round cervical smears lag in some immigrant communities). Rural areas may have less access to MTBs or specialised counselling. Ensuring all demographics benefit equally remains a work in progress.
- **Genetic Counselling Capacity:** Demand for genomic counselling (germline and somatic) is growing fast, but Spain lacks a formal genetic counsellor profession. Clinicians and laboratories may face bottlenecks advising patients on complex results. Building a trained workforce (via new roles or expanded specialist training) is needed to match testing capacity.

- **Trust and Literacy:** Understanding of genomics is uneven among both the public and providers. Complex test results can challenge informed consent, especially for patients with limited health literacy. Catalonia should continue investment in plain-language resources and dialogue (in Catalan, Spanish, and other languages) to build trust.

- **Resource Constraints:** Precision oncology requires sustained funding. While CatSalut budgets for NGS panels, new innovations (e.g. whole-genome sequencing, liquid biopsies) could strain budgets. Maintaining fast turnaround as volume grows will depend on sufficient investment in laboratories and data infrastructure.

- **Fragmentation in Wider System:** Spain's decentralised health model means Catalonia leads within its region, but patients moving elsewhere may face different standards. A lack of national coordination can limit economies of scale (e.g. sharing best practices or bulk procurement). Aligning with other regions or national bodies remains a challenge.

Future Development Needs

- **Evidence-based expansion and standardisation of testing**: Broaden indications beyond late-stage disease where clinical utility is proven, and pilot whole-genome sequencing in clearly defined high-need cohorts. Set uniform service levels across the twelve reference centres for panel choice, reporting format, multidisciplinary review and turnaround time, underpinned by external quality assessment.

- **Counselling and MTB communication as defined service standards**: Embed pre- and post-test counselling, plain-language report summaries, and timely MDT feedback as routine elements of the pathway, with clear targets for delivery and documentation. Use templated summaries and digital scheduling so every genomic result is explained consistently and promptly.

- **Navigation and communication architecture built into routine care**: Publish a reusable toolkit of multilingual materials, primary-care prompts and patient decision aids, and surface these within My Health (La Meva Salut) alongside referrals, follow-up reminders, and trial-matching signposts. Track engagement through page use, initiated bookings and kept follow-ups.

- **Learning health-system data flow and public reporting**: Link POP outputs with cancer registry, pharmacy, and outcomes datasets using privacy-by-design analytics. Maintain a shared indicator set via testing volumes, actionability, time-to-result, MDT referral, and treatment change. Publish regular dashboards to drive iterative improvement.

- **Sustainable financing and aligned incentives**: Establish multi-year budget lines that include post-analytical work (interpretation, counselling, data curation) and tie payment to quality benchmarks such as external quality assurance (EQA) participation and reporting timeliness. Use coverage-with-evidence or outcomes-linked contracts where appropriate to accelerate adoption while generating decision-grade evidence.

Scalability (within the member state)

Catalonia's model can scale nationally if regional delivery is paired with national coordination. Spain's Ministry of Health and the Inter-territorial Council of the National Health System (CISNS) can set common specifications and indicators, the Carlos III Health Institute (ISCIII, Instituto de Salud Carlos III) can provide the technical backbone (data standards, research linkage, training), and national HTA/payment channels (e.g. the Therapeutic Positioning Reports Network (REvalMed, Red de Evaluación de Medicamentos del Sistema Nacional de Salud), coordinated by the Spanish Agency of Medicines and Medical Devices (AEMPS, Agencia Española de Medicamentos y Productos Sanitarios), and the Common Services Portfolio of the National Health System (SNS, Cartera Común de Servicios del Sistema Nacional de Salud) can align coverage so awareness reliably converts to funded access across autonomous communities.

- **What:** A replicable bundle combining a payer-led precision oncology program specification, a hub-and-spoke laboratory network in each region with shared molecular tumour boards, a national communication toolkit for patients and clinicians (plain-language, co-official languages), a common indicator set for testing volumes, actionability, time-to-report, and MTB referrals, and a learning data layer linking regional outputs to national registries via ISCIII.

- **How:** Use CISNS to agree a national playbook, including testing indications, reporting format, counselling standards, EQA participation, and turnaround targets. Stand up an ISCIII technical office to support regions on data and training, pilot in three early-adopter communities and scale in phases, align tariffs and reimbursement between, for example, REvalMed/AEMPS and SNS portfolio, and where helpful, use coverage-with-evidence pilots. Publish an annual national dashboard to maintain public confidence and guide improvement.

- **Where:** Begin in regions with mature oncology ecosystems and extend to provinces without on-site sequencing or MTBs, prioritise hospitals serving populations with lower health literacy, deploy national and regional portals for consistent messages while local providers anchor access and counselling close to home, ensure materials are in Spanish, co-official languages, and English.

- **Considerations:** Interoperability across regional EHRs and registries is essential. To avoid bottlenecks, scale awareness with parallel investments in workforce, bioinformatics, and post-analytical services. Secure multi-year financing that covers outreach, interpretation and counselling, maintain robust data-privacy safeguards and EQA, formalise patient representation nationally so legitimacy and trust travel with the model.

Transferability (across member states)

Catalonia's approach is transferable as a practical bundle that links awareness directly to access: payer-led governance, a designated laboratory network with shared molecular tumour boards, patient-facing communication embedded in routine pathways, and a data platform that reports what care teams and the public need to know. It is especially suited to decentralised health systems but can also be implemented nationally in smaller countries.

- **What:** A payer-backed precision oncology program with clear testing indications, a hub-and-spoke laboratory network, shared MTBs for interpretation, standardised reporting, and counselling assets, patient and clinician communication through existing portals, and a common data layer with routine dashboards for volumes, actionability, time-to-report, and MTB referrals.

- **How:** Start with high-value tumour–biomarker pairs and expand in phases. Route samples to reference hubs while providing virtual or shared MTBs. Set uniform service standards for referral, report format, counselling, and turnaround. Adopt coverage-with-evidence pilots where needed. Publish regular performance reports to maintain public trust and guide improvement.

- **Where:** Strong fit for regions with integrated hospital networks or purchaser–provider models, such as Spanish autonomous communities or regional systems. Equally applicable as a national model in smaller Member States with centralised cancer services.

- **Considerations:** Align with local financing and legal frameworks and ensure EHR and registry interoperability. Invest in workforce and post-analytical capacity so awareness does not outpace service readiness, adapt materials to language and culture and formalise patient representation to preserve legitimacy, maintain external quality assessment and data-privacy safeguards to support confidence and comparability.

Relevant Sources

- Mur P, Pozuelo A, Tabernero J, Albanell J, Bellosillo B, Bosch F, et al. Implementation of the precision oncology program in catalonia's public health system: results, lessons learned, and future prospects. Clinical and Translational Oncology. 2025 Sep 3;
- Generalitat de Catalunya [Internet]. [cited 2025 Oct 16]. CatSalut. Servei Català de la Salut. Available from: https://catsalut.gencat.cat/ca/inici/
- Vall d'Hebron Barcelona Hospital Campus [Internet]. [cited 2025 Oct 16]. Catalan Network of Oncology. Available from: https://www.vallhebron.com/en/about-us/strategic-projects/catalan-network-oncology
- Over 5,000 cases of breast cancer diagnosed in Catalonia in 2022. Catalan News [Internet]. 2023 Oct [cited 2025 Oct 16]; Available from: https://www.catalannews.com/society-science/item/over-5000-cases-of-breast-cancer-diagnosed-in-catalonia-in-2022
- Rodríguez-Salés V, Roura E, Ibañez R, Peris M, Bosch FX, de Sanjosé S. Coverage of Cervical Cancer Screening in Catalonia for the Period 2008–2011 among Immigrants and Spanish-Born Women. Front Oncol. 2013;3.
- Gasol M, Fontanet M, Guarga L, de Maria A, Castillo C, Ramirez S, et al. HTA8 The Catalan Health Service, An Example Where Patients Have Full Medicine Appraisal and Decision-Making Representation. Value in Health. 2022 Dec;25(12):S297.
- Servei Català de la Salut [Internet]. 2025 [cited 2025 Oct 16]. Població de referència del Servei Català de la Salut. Any 2025. Dades d'ABS-UP assignada (2024) [PDF]. Generalitat de Catalunya. Available from: https://scientiasalut.gencat.cat/bitstream/handle/11351/11946.2/poblacio-referencia-servei-catala-salut-any-2025dades-ABS-UP-assignada-2024.pdf?sequence=4&isAllowed=y

10. National infrastructure for precision oncology in Sweden

Sweden's precision oncology framework is built on strong national and regional collaboration. In 2018, stakeholders launched **Genomic Medicine Sweden (GMS)** as a national initiative to integrate genomics into clinical care across the country. The Swedish healthcare system is tax-funded and highly decentralised, with 21 county councils (regions) organising care locally. **To ensure nationwide coverage in this decentralised model, GMS established seven regional Genomic Medicine Centres (GMCs) at university hospitals, covering all major health regions**. Each GMC is a partnership between a university hospital and a medical university, linked through the national SciLifeLab Clinical Genomics platform, which provides the technological backbone for sequencing and bioinformatics. Together, the seven GMCs provide nationwide coverage. This reduces the postcode disparities of access to genomic testing that occur despite regional autonomy.

This governance structure is overseen by a national GMS Steering Board with broad representation: all seven university hospital regions, additional regional delegates, academia, industry, patient organisations, SciLifeLab, and Biobank Sweden are included. Such inclusive governance has been key to aligning regional efforts. **GMS's mission is supported by multi-source funding**. Initial implementation was supported through a combination of innovation grants, regional co-financing, and state allocations which together enabled the infrastructure and pilot programs needed to embed precision oncology in routine care. These funders include Vinnova (the Swedish Innovation Agency), the Swelife programme, the Ministry of Health and Social Affairs, SciLifeLab, the Swedish Childhood Cancer Fund, as well as co-financing from participating regions and universities.

Reimbursement for cancer therapies in Sweden is coordinated centrally even within the regional system. The Dental and Pharmaceutical Benefits Agency (TLV, Tandvårds- och läkemedelsförmånsverket) conducts health technology assessments and decides if new cancer drugs will be state-subsidised. The New Therapies (NT) Council—an expert group with regional representation—then issues nationwide recommendations on the introduction of novel treatments. While regions ultimately decide on implementation, this mechanism promotes uniform access to new oncology drugs. In short, therapies follow a centralised HTA and recommendation pathway, whereas diagnostics, especially broad NGS and WGS, remain largely funded via hospital budgets or temporary grants, creating a policy gap.

Genomic testing reimbursement is less formalised. Advanced diagnostics are generally funded through hospital budgets or special projects rather than a national benefits catalogue. For example, broad next-generation sequencing (NGS) panels are not explicitly listed for nationwide reimbursement in standard care.

The TLV has begun evaluating high-cost companion diagnostics: it assessed the FoundationOne CDx 324-gene panel in 2019, but found its cost-effectiveness varied by scenario. The NT Council advised against routine use of such comprehensive tests except in specific cases or research contexts. **In practice, standard single-gene or small-panel tests (e.g. for EGFR, ALK) are covered as part of regional healthcare services, whereas broader genomic profiling has relied on GMS-funded programs or regional initiatives**. Recently, the national government acknowledged the need to support diagnostics infrastructure more directly: in 2025 it committed a special allocation of **SEK 80 million** to GMS to **sustainably implement precision medicine** (including genomic testing for cancer, rare diseases, and other areas) in routine healthcare. **This allocation bridges current funding gaps and accelerates the transition from grant-funded pilots to permanent, reimbursed services.**

Measurable Outcomes

- **Nationwide access and scale-up of genomic testing and drugs:** Comprehensive genomic profiling is available in all 21 regions, coordinated through seven regional genomic centres. At the same time, Sweden funds 86% of new oncology drug-indication pairs (one of the highest rates in Europe) and has a median time of ~203 days from EMA approval to reimbursement, faster than the EU average of 586 days). In parallel, NGS testing volumes have increased rapidly, with annual sequencing more than doubling since 2017 and routine practice now delivering around 10,000 solid tumour and 7,000 haematological tests per year.

- **Standardisation through a national panel:** The GMS560 panel (covering over 500 genes) was introduced in 2022 and is being rolled out nationwide with uniform protocols, ensuring that patients receive the same comprehensive tumour profiling regardless of geography. This panel was developed and validated through a national collaboration involving all seven regional GMCs, with validation involving more than 200 clinical samples and reference standards prior to implementation. In parallel, a national myeloid panel now underpins over 60% of tests for myeloid malignancies, showing rapid clinical adoption.

- **Whole-genome sequencing as standard in paediatrics:** Sweden became one of the first countries to introduce WGS for 100% of children with all paediatric cancer as part of routine diagnostics. This shortens the diagnostic process and improves matching to targeted therapies. For rare diseases, WGS now yields a diagnosis in around 40% of previously undiagnosed patients, demonstrating clear clinical utility.

- **Integrated IT and registry infrastructure:** A National Genomics Platform links all centres for data processing, variant interpretation, and reporting, while new registries (e.g. for paediatric cancer) connect genomic results with therapies and survival outcomes. This enables continuous quality monitoring and provides real-world evidence to inform future reimbursement and guide decision-making.

- **Public investment secured:** The government committed SEK 80 million in 2025 to sustain the national precision medicine infrastructure. This bridges the gap between grant-funded pilots and routine reimbursement.

Strengths

- **Unified governance in a decentralised system:** Sweden has successfully coordinated its 21 regions under a single national initiative, Genomic Medicine Sweden, aligning health authorities, academia, and patient organisations around common goals despite local autonomy.

- **Balanced funding model:** Early reliance on innovation grants and charitable funds has been complemented by regional co-financing and, more recently, direct state allocations. Sustained cross-party political support across multiple budget cycles has reinforced resilience, demonstrated long-term commitment, and enabled the transition from pilots to integrate national infrastructure.

- **Efficient decision-making for therapies:** The combination of TLV's central HTA process and the NT Council's national recommendations provides a clear route from drug approval to patient access, minimising delays and regional disparities in treatment availability.

- **Integration research infrastructure and learning health system orientation:** By leveraging SciLifeLab and Biobank Sweden, GMS has embedded clinical testing within existing research ecosystems. This enables continuous generation of real-world evidence, supports adaptive reimbursement decisions, and allows clinical practice to evolve in response to emerging data.

- **Multi-stakeholder collaboration and international alignment:** Patients, clinicians, payers, and industry are formally included in GMS governance structures, building legitimacy and aligning incentives across the health system. Active participation in EU and Nordic initiatives further accelerates harmonisation of standards, strengthens collaboration, and supports evidence pooling to inform national implementation.

Challenges

- **Fragmented reimbursement and regional funding disparities:** While cancer medicines are centrally reimbursed, large NGS panels and WGS still rely on regional budgets or project funds. Without national tariffs, access remains uneven across regions, with smaller or less resourced countries facing delays or constrained availability.
- **Financial fragility of national infrastructures and services:** Core assets such as the National Genomics Platform and shared bioinformatics pipelines remain partly grant-funded, creating uncertainty around long-term continuity. Current funding mechanisms often cover laboratory work but exclude post-analytical activities such as data storage, bioinformatics, and interpretation, placing additional strain on hospital budgets and limiting scalability.
- **Underfunded multidisciplinary functions and workforce constraints**: MTBs and clinical interpretation are central to effective precision oncology but are not systematically reimbursed, leaving hospitals to absorb these costs. At the same time, recruiting and retaining genomic pathologists, clinical scientists, and bioinformaticians is increasingly challenging, which raises the risk of capacity bottlenecks as testing volumes grow.
- **Data governance and interoperability:** Evolving interpretations of GDPR and fragmented budgeting for data storage and security create uncertainties in long-term planning. Ensuring interoperable systems and clear legal frameworks is essential for seamless cross-regional sharing.

Future Development Needs

- **National reimbursement for testing:** Establish permanent payment codes and tariffs for NGS panels and WGS so laboratories can bill these tests as part of standard care, rather than relying on project or hospital budgets.
- **Long-term financing of infrastructure:** Move the National Genomics Platform and related IT systems from time-limited grants into core healthcare budgets, ensuring continuous funding for data storage, analysis, and security.
- **Predictable funding for multidisciplinary services:** Create reimbursement mechanisms for MTBs and clinical interpretation, recognising them as essential services that require stable financing.
- **Outcome-linked funding models:** Expand use of managed entry agreements and coverage with evidence development so reimbursement of costly diagnostics and therapies is tied to real-world data on patient benefit.
- **Capacity-building investments:** Secure earmarked funds for training and retaining genomic medicine specialists, ensuring that workforce growth keeps pace with increasing test volumes.
- **International funding partnerships:** Explore EU and Nordic collaborations for co-financing registries, joint evaluations, and shared data platforms, which could reduce duplication of national spending while expanding evidence bases.

Scalability (within the member state)

Sweden's precision oncology framework was deliberately designed to be scalable across its decentralised healthcare system. Genomic Medicine Sweden coordinates seven regional genomic centres that already cover the entire population, making scaling a matter of expanding capacity, harmonising financing, and embedding comprehensive genomics into routine reimbursement. With strong governance and IT infrastructure in place, the main challenge is to ensure that sustainable funding mechanisms replace temporary grants as volumes increase.

- **What:** national governance framework through GMS, seven genomic centres covering all regions, standardised testing panels such as GMS560, the National Genomics Platform for bioinformatics and reporting, and project-based financing that needs conversion into permanent reimbursement.

- **How:** expand use of the national panel to all solid tumours, gradually introduce WGS into adult oncology, secure permanent tariffs in the national benefits catalogue, and formalise reimbursement for interpretation and MTBs. Oversight should include mandatory registry uploads and quality assurance participation to guarantee consistent national standards.

- **Where:** scalability is most straightforward within the existing GMC network, which already serves as referral hubs for surrounding hospitals. Expansion can reach beyond oncology into other disease areas (rare diseases, infectious diseases) using the same infrastructure. National funding pools or earmarked regional budgets could provide the financial scale needed for 60,000–65,000 tests per year.

- **Considerations:** scaling will require stable government financing, mechanisms to redistribute resources across regions to avoid postcode disparities, and sustained investment in workforce and IT. Infrastructure and governance are well suited to scale, but reimbursement must evolve from project-based funding to a permanent model if precision oncology is to become routine care nationwide.

Transferability (across member states)

Sweden's model offers a transferable blueprint for other countries with decentralised systems, showing how national coordination and targeted funding can create equitable access. Its success stems from blending innovation grants, regional co-financing, and direct government allocations into a unified national program, combined with strong governance and shared infrastructure.

- **What:** a national genomics network with regional centres, a common national panel and protocols, a unified data platform, and a funding model that combines central government allocations with regional co-financing.

- **How:** establish a national steering body like GMS, define a set of reimbursed biomarkers or panels tied to drug coverage, and create national tariffs or bundled payments for NGS and WGS. Early implementation can be supported by innovation funds or EU programs, with the long-term goal of shifting costs into permanent reimbursement structures.

- **Where:** particularly relevant for countries with regional healthcare organisation (e.g. Spain, Italy, Germany) or smaller member states that could pool resources across borders. Sweden's approach can also inform EU-level initiatives that seek to harmonise reimbursement and data collection across systems.

- **Considerations:** substantial upfront investment is required to build laboratories and data infrastructure. Reimbursement must explicitly include post-analytical costs and multidisciplinary services and legal frameworks for data use must be in place. Transferability depends less on technical capacity and more on sustained political and financial commitment. Countries adopting this model should ensure that funding transitions from grants to benefits catalogues are planned from the outset, to avoid reliance on temporary pilots.

Relevant Sources

- Edsjö A, Lindstrand A, Gisselsson D, Mölling P, Friedman M, Cavelier L, et al. Building a precision medicine infrastructure at a national level: The Swedish experience. Cambridge Prisms: Precision Medicine. 2023 Feb 27;1:e15.
- Jennifer Gill, Anna-Maria Fontrier, Aurelio Miracolo, Panos Kanavos. Access to personalised oncology in Europe [Internet]. 2020 Nov [cited 2025 Oct 16]. Available from: https://eprints.lse.ac.uk/107505/
- Genomic Medicine Sweden [Internet]. [cited 2025 Oct 16]. GMS - About us. Available from: https://genomicmedicine.se/en/about-us
- SciLifeLab [Internet]. 2022 [cited 2025 Oct 16]. New report highlights national capacity for Next Generation Sequencing. Available from: https://www.scilifelab.se/news/new-report-highlights-national-capacity-for-next-generation-sequencing/
- MTRC [Internet]. 2019 [cited 2025 Oct 16]. Swedish recommendations for FoundationOne CDx genomic test by the New Therapies Council. Available from: https://mtrconsult.com/news/swedish-recommendations-foundationone-cdx-genomic-test-new-therapies-council
- Genomic Medicine Sweden receives SEK 80 million to strengthen precision medicine. Nordic Life Science [Internet]. 2025 Apr [cited 2025 Oct 16]; Available from: https://nordiclifescience.org/genomic-medicine-sweden-receives-sek-80-million-to-strengthen-precision-medicine/
- Regeringskansliet [Internet]. 2025. Fortsatt stöd till projekt om bättre diagnostik och mer individanpassad behandling.
- Newton M, Stoddart K, Travaglio M, Troein P. European Federation of Pharmaceutical Industries and Associations (EFPIA) Patients W.A.I.T. Indicator 2024 Survey [Internet]. 2025 May [[cited 2025 Oct 16]. Available from: https://efpia.eu/media/oeganukm/efpia-patients-wait-indicator-2024-final-110425.pdf

11. Reimbursement of companion diagnostics in Germany

Germany's healthcare system links the reimbursement of companion diagnostics directly to the approval of targeted therapies. Once a new cancer drug is approved by the European Medicines Agency (EMA) and covered by the statutory health insurance (SHI), **any required biomarker test is automatically incorporated** into the outpatient reimbursement schedule. This policy ensures that diagnostic and treatment pathways are integrated from the outset, preventing delays in patient access or out-of-pocket expenses for testing. **The objective is to safeguard equitable, timely access to precision oncology**: patients can receive the right test and the right targeted therapy without separate approval processes for the test. As a result, Germany has positioned itself as a European frontrunner in implementing sustainable, patient-centered precision medicine pathways. This integrated approach aims to streamline molecular testing into routine care so that the moment a therapy is available, the companion test is also available. In the outpatient setting, SHI pays laboratories via the Uniform Value Scale (EBM, Einheitlicher Bewertungsmaßstab) schedule, and patients face no co-payment for indicated companion diagnostics. Inpatient testing is paid through diagnosis-related groups (DRGs), which currently lack stable test coverage.

Since 2024, Germany has also run the genomDE. This is a national genomic medicine model program, which funds whole genome and whole exome sequencing for selected oncology and rare disease patients at designated centres, builds shared data and IT capacity, and generates evidence to inform permanent inclusion of comprehensive genomics in statutory health insurance. GenomDE complements the companion diagnostics framework by piloting pathways, data governance, and reimbursement models for comprehensive genomics beyond small panels. GenomDE is financed under §64e SGB V as a time-limited model with dedicated federal funding, designed to inform future SHI benefits.

Companion diagnostics in Germany are reimbursed through an established coding and tariff system in the outpatient sector. The EBM, a fee-for-service catalogue for SHI, contains specific codes (subchapter 19.4) for molecular pathology procedures and biomarker tests. Laboratories can bill these codes once a test is indicated for an eligible patient, provided the test is conducted according to national guidelines and quality standards. Importantly, **the reimbursement codes are technology- and biomarker-specific but not tied to any particular brand of test kit**, providing flexibility and encourages competition, while ensuring that reimbursement is available as soon as a biomarker's clinical utility is established. EBM reimburses the testing service result, while capital equipment, kits, and post-analytical bioinformatics are typically not separately paid, which can pressure laboratory finances.

The German Clinicians Evaluation Committee (Bewertungsausschuss Ärzte) responsible for updating the EBM adapts the reimbursement schedule to include new testing services required by an approved medicine. In practice, this means that, **when a targeted oncology drug is approved and reimbursed, any companion diagnostic mandated by its label will immediately have an applicable reimbursement code and fee in the outpatient list**. No separate HTA or funding decision is needed solely for the test if it falls under this rule, which greatly accelerates implementation in clinical practice. Physicians can order the test, and laboratories can perform it with the confidence that the service is billable under SHI, typically within 100 days of EMA drug approval.

In cases of novel diagnostics that are not automatically covered (for example, multi-gene prognostic assays or tests used beyond a specific drug indication), the Federal Joint Committee (G-BA, Gemeinsamer Bundesausschuss) and its HTA arm the Institute for Healthcare Quality and Efficiency (IQWiG, Institut für Qualität und Wirtschaftlichkeit im Gesundheitswesen) come into play. The G-BA can conduct a methods evaluation to decide if a new diagnostic procedure should be included as a benefit in SHI. Following the G-BA's approval, the Clinicians Evaluation Committee then assigns a specific EBM code and payment rate for the test. **This two-step process provides a pathway to integrate innovative diagnostics that are not directly linked to a single new drug**. It enables evidence-based adoption of companion diagnostics and other molecular tests beyond the automatic EMA-linked inclusion.

It should be noted that while the outpatient sector in Germany has a clear mechanism for funding companion diagnostics, the hospital (inpatient) sector historically lags. **Hospital treatments are reimbursed viaDRGs, which until 2020 did not include any companion diagnostic testing costs**. If a patient needed molecular testing during a hospital stay, there was no dedicated payment, causing institutions to either absorb the cost or delay testing until the patient was seen in outpatient care. Hospitals could apply for special one-year funding of new procedures under the New Examination and Treatment Methods scheme (Neue Untersuchungs- und Behandlungsmethoden, NUB), but until 2020 every request for including a companion test in DRGs was declined.

Measurable Outcomes

- **Speed to funded access:** New oncology medicines and their required companion diagnostics are funded at launch in the SHI outpatient sector. Mean time from EMA authorisation to reimbursement decision is typically under 100 days.
- **Breadth of NGS coverage:** In 2020, Germany publicly reimbursed 90% or more of existing NGS tests. This places German in the top category in the 2024 OECD's *Access to oncology medicines in EU and OECD countries.*
- **Automatic drug–test linkage:** Germany is among the minority of countries with a legal requirement to automatically cover the companion diagnostic when the matched medicine is covered.
- **Complete coverage of high-benefit indications:** For the OECD sample of 13 high-benefit breast and lung cancer indications, Germany reported all indications covered as of 1 April 2023.

Strengths

- **Linked reimbursement by design**: When a new targeted medicine is reimbursed, its required companion test is simultaneously included in the outpatient statutory scheme, which aligns testing and treatment from day one.
- **National codes that laboratories can bill**: The EBM catalogue includes specific items for oncology biomarkers and next generation sequencing, giving laboratories a clear route to reimbursement across the country.
- **Service-based and brand-neutral payment**: Reimbursement pays for the validated biomarker servicerather than a specific kit, enabling any qualified laboratory method to be used, thus supporting competition and access.
- **Guidelines and quality guardrails**: Use of reimbursed tests is embedded in national practice guidance and quality standards, which supports appropriate ordering and consistent results nationwide.
- **Capacity to evaluate and adopt new diagnostics**: Formal evaluation mechanisms exist for high impact assays within the German system, allowing evidence-based expansion of reimbursed testing over time.
- **Broad population coverage**: Statutory insurance covers most residents and private insurance covers the remainder, meaning that positive decisions translate into wide access without regional variation.

Challenges

- **Fragmentation between inpatient and outpatient care:** While companion diagnostics are automatically covered in the outpatient SHI pathway once a matched therapy is reimbursed, hospital testing remains constrained under DRG-based payment. This can still incentivise hospitals to defer or shift molecular testing to outpatient settings, creating avoidable delays and administrative friction along the patient pathway.
- **Administrative limits on panel size and coding granularity:** Outpatient reimbursement via the EBM provides a clear route for many biomarker services, but routine statutory payment caps sequencing volume (around ~25 kb), with larger panels often requiring additional review or alternative arrangements. This creates a threshold effect where comprehensive profiling is harder to fund consistently outside dedicated initiatives (e.g., model programmes).

- **Tariff adequacy for advanced testing:** Current tariffs primarily reimburse the validated testing service and reported result, while key cost drivers—capital equipment, consumables, post-analytical bioinformatics, data processing/storage, and specialist interpretation time—sit with laboratories. Over time, this can strain provider sustainability and slow adoption of more complex assays despite clinical demand.

- **Process and evidence hurdles for new tests:** When a diagnostic does not fall under automatic drug–test linkage, integration depends on formal evaluation and code updates (e.g., via G-BA / IQWiG and subsequent EBM revisions). These steps can be resource-intensive and time-consuming, delaying uptake of emerging biomarkers or multi-gene assays even when the clinical need is well recognised.

Future Development Needs

- **Close the inpatient gap**: Build a permanent way to pay for genomic tests during hospital stays through DRG inclusion or stable add-on payments so testing happens when clinically indicated.

- **Expand EBM for comprehensive genomics**: Move routine coverage beyond small panels and recognise the full workflow, including bioinformatics and clinical interpretation, in reimbursed items.

- **Fund multidisciplinary decision support**: Create dedicated reimbursement for MTBs and for complex result interpretation to scale equitable precision care.

- **Publish and use national metrics**: Track turnaround times, testing volumes, and equity by tumour type and region, and use these data to steer tariff updates and guideline revisions.

- **Execute and scale the genomDE model**: Use the five-year genome sequencing project to generate evidence, standardise data flows, and transition whole-exome and whole-genome sequencing into routine benefit.

- **Align timelines for drug and diagnostic reimbursement**: Reduce the delay between EMA approval of new oncology therapies and the inclusion of corresponding diagnostic tests in the EBM system. The current 6–12-month gap creates administrative burden through individual reimbursement requests, leads to repeated rejections, and can delay initiation of targeted therapies as clinicians defer testing until reimbursement is in place.

- **End-to-end test-to-therapy alignment**: Define clear, rules-based routes from test result to funded treatment, including when therapies are outside label but supported by board recommendations.

Scalability (within the member state)

Germany's framework is anchored in a legal link between medicines and tests and a national fee schedule that laboratories already use. This makes it practical to scale within statutory insurance by broadening indications, updating codes, and **moving comprehensive genomics from model program into routine care**, while aligning inpatient and outpatient funding.

- **What:** a rules-based coupling of drug and test coverage, a national code set in the outpatient fee schedule, quality guidance from professional societies, and a model program that generates evidence for whole exome and whole genome sequencing.

- **How:** expand the code set to larger gene panels beyond twenty-five kilobases and new biomarkers, recognise analysis and interpretation work in reimbursed items, translate evidence from the model program into permanent national coverage decisions with corresponding codes and tariffs, and establish a national reporting cycle with published metrics on volumes, turnaround, and equity to drive iterative updates.

- **Where:** scale through the existing statutory insurance infrastructure, with the Clinicians Evaluation Committee updating codes and prices, sickness funds contracting uniformly, and designated centres acting as hubs for complex testing.

- **Considerations:** close the hospital funding gap so that tests performed during admission are paid, introduce reimbursement for MTBs and expert case reviews, and plan and finance workforce and data capacity so that growth in testing does not outpace bioinformatics and clinical interpretation.

Transferability (across member states)

Key elements of the German approach can be adapted by systems that wish to synchronise access to targeted medicines and the tests that enable them. The combination of a legal or policy rule that ties test payment to therapy coverage, a national code set for biomarker services, and an evaluation route for novel diagnostics creates a coherent adoption pathway that other countries can tailor to their context.

- **What:** a formal rule that when a targeted therapy is covered the required companion test is covered, brand neutral service codes for biomarker testing, national guidance and quality assurance, and a pilot to routine pathway for comprehensive genomics.

- **How:** mandate coverage linkage in payer policy or law, create or update a national schedule for molecular pathology and sequencing, require proficiency testing and standard reporting, and use a time-limited model programme to build evidence and infrastructure before enshrining comprehensive genomics in routine benefit.

- **Where:** most feasible in social insurance or centrally funded systems with authority to set national tariffs and quality standards, and in countries that can designate reference laboratories or hubs to concentrate complex testing.

- **Considerations:** ensure post-analytical costs are explicitly financed, align inpatient and outpatient payment so care setting does not determine access, build data stewardship and registry functions with clear custodianship, and establish rules that translate validated results and board recommendations into timely funded treatment.

Relevant Sources

- MTRC [Internet]. 2019 [cited 2025 Oct 16]. Oncotype DX to be covered by state insurance for the breast cancer early stages treatment decisions in Germany. Available from: https://mtrconsult.com/news/oncotype-dx-be-covered-state-insurance-breast-cancer-early-stages-treatment-decisions-germany

- Hedblom AH, Pruneri G, Quagliata L, Costa JL, Dumanois R, Rolando C, et al. Cancer patient management: Current use of next-generation sequencing in the EU TOP4. J Cancer Policy. 2023 Mar;35:100376.

- Access to oncology medicines in EU and OECD countries. 2024 Sep.

- Pixberg C, Schulze M, Buschhorn L, Suppelna JP, Mock A, Hlevnjak M, et al. Reimbursement in the Context of Precision Oncology Approaches in Metastatic Breast Cancer: Challenges and Experiences. Breast Care. 2024;19(1):10–7.

- CDx Reimbursement and Funding Challenges and Potential Solutions from the European Perspective. Inside Precision Medicine [Internet]. 2022 Jun [cited 2025 Oct 16]; Available from: https://www.insideprecisionmedicine.com/news-and-features/cdx-reimbursement-and-funding-challenges-and-potential-solutions-from-the-european-perspective/

12. Fast-track reimbursement pathway for biomarkers in Belgium

Belgium's National Cancer Plan emphasises the integration of biomarker testing into reimbursement policies, specifically supporting the use of Next-Generation Sequencing (NGS) in routine clinical care. The approach was guided by a **national Roadbook** approved in 2016 which outlined the **governance, technical steps, budget, data/IT, quality assurance, and awareness-raising needed** to implement NGS in routine oncology/haemato-oncology care. The Roadbook also **created the multidisciplinary expert Commission of Personalized Medicine (ComPerMed)** and linked it to **Platform CDx,** which brings together the expertise of two advisory bodies within the National Institute for Health and Disability Insurance (RIZIV/INAMI): the Commission for Reimbursement of Medicines (CRM/CTG), which advises on pharmaceutical reimbursement, and the Technical Medical Council (TMC/TGR), which oversees the nomenclature and reimbursement of diagnostic tests. This joint platform ensures coordinated, evidence-based recommendations for diagnostic reimbursement.

In 2019, a pilot project was launched through an agreement between RIZIV/INAMI and ten expert NGS networks, comprising laboratories and hospitals that met predefined criteria. **With a budget of €6 million, the pilot covered up to 20,000 reimbursed tests**. The pilot's success, evidenced by a threefold increase in reimbursed tests, led to a **permanent reimbursement agreement in 2024** for specific solid tumours and haematological malignancies. Beyond conventional NGS tests, reimbursement now includes RNA sequencing for genetic rearrangement detection and HRD testing when combined with NGS tests for certain indications.

However, the implementation and interpretation of NGS has been complex. First, **reimbursement was structured through agreement-based reimbursement** rather than inclusion in the official nomenclature, using **pseudo-nomenclature codes** and detailed conditions for each indication. This approach, covering 28 codes for solid tumours and 23 for malignant haematological diseases, **provided flexibility while ensuring that only institutions with proven expertise could perform NGS testing** (with less experienced centres placed under the supervision of an annual Steering Committee). Second, the pilot confirmed the need for adaptability, as indications and reimbursement conditions had to be updated almost yearly—changes that could be made more efficiently through agreements than through formal nomenclature updates. Finally, the model of institutional collaboration evolved: due to uneven performance across networks, participation in NGS networks is no longer mandatory, and **INAMI now works directly with individual institutions** to simplify and clarify collaboration.

Measurable Outcomes

- **Permanent, indication-based reimbursement with explicit tariffs:** Belgium moved from the pilot to permanent convention funding on 1 July 2024. The number of reimbursed indications has tripled, and annexes now list indication-specific pseudocodes and tariffs, including examples at €600 per test, with RNA sequencing for fusion detection and HRD testing reimbursed for defined indications, as specified in the reimbursement annexes.
- **Funded volumes and delivery concentration:** Reimbursed NGS tests rose from 12,000 in 2019—the first year of the convention pilot—to 23,000 in 2023; 96% of funded activity was delivered by 12 high-volume institutions, confirming capacity where tariffs are in place.

Measurable Outcomes

- **Permanent, indication-based reimbursement with explicit tariffs:** Belgium moved from the pilot to permanent convention funding on 1 July 2024. The number of reimbursed indications has tripled, and annexes now list indication-specific pseudocodes and tariffs, including examples at €600 per test, with RNA sequencing for fusion detection and HRD testing reimbursed for defined indications, as specified in the reimbursement annexes.
- **Funded volumes and delivery concentration:** Reimbursed NGS tests rose from 12,000 in 2019—the first year of the convention pilot—to 23,000 in 2023; 96% of funded activity was delivered by 12 high-volume institutions, confirming capacity where tariffs are in place.
- **Pilot scale and budget that enabled permanence:** The 2019–2024 convention provided €6 million to fund up to 20,000 tests and supported ten NGS networks covering about 115 hospitals and about 30 laboratories. This created the national footprint used to transition to permanent reimbursement.
- **Quality and standardisation tied to payment:** National guidance and benchmarks were issued. Seven national external quality assessment rounds were run between 2017 and 2021 with sixteen to twenty laboratories. Reimbursement is linked to reporting and quality participation.

Strengths

- **Coordinated governance mechanism**: creation of the multidisciplinary advisory body ComPerMed and its structured collaboration with the Platform CDx to advise on test and medicine reimbursement, reducing fragmentation between diagnostic and therapeutic pathways.
- **Flexible reimbursement**: agreement-based model with pseudo-nomenclature codes enabled rapid adaptation of indications and conditions, ensuring alignment with fast-moving scientific developments.
- **Data infrastructure:** Healthdata.be platform centralises and securely stores NGS data from multiple accredited health registries, supporting research, quality monitoring, and public health, while reimbursement is tied to PITTER uploads and Sciensano EQA participation, creating a feedback loop between finance and quality.
- **Clear national annexes:** The annexes list eligible indications, minimum biomarker content, and tariff amounts, giving laboratories and payers an operational playbook.
- **Ethics and consent:** clear guidance developed on informed consent and ethical data use, informed by mapping patient attitudes and information needs through focus groups and citizen laboratories.
- **Quality assurance**: benchmarking trial launched to evaluate laboratories' baseline performance in routine NGS diagnostics.

Challenges

- **Governance scope**: while ComPerMed provides a coordinated advisory mechanism, it falls short of a full cross-governance model, as its scope remains confined to technical advisory bodies rather than integrating broader policy, payer, and patient perspectives.
- **Heterogeneity across labs**: EQA baselines revealed variation in performance, highlighting the need for stronger standardisation in analytical procedures, platforms, and interpretation.
- **Institutional collaboration**: uneven performance within NGS networks led to the removal of mandatory network participation, with INAMI now contracting directly with individual institutions.

- **Rapid technology evolution**: frequent changes in indications and bioinformatics pipelines demand annual adjustments, challenging stability of reimbursement and guidelines.
- **Data volume & interoperability**: Payment conditionality on PITTER and EQA, and the massive NGS datasets require robust, secure, and scalable storage, plus stronger IT coordination between labs, registries, and public health authorities.
- **Limited coordination**: lack of fully harmonised procedures across stakeholders in data quality, interpretation, and reporting.

Future Development Needs

- **Sustainable funding**: post-analytical costs (analysis, interpretation, storage) require durable financing models beyond benchwork reimbursement.
- **System-wide monitoring**: national oversight remains incomplete, as reporting of invoiced tests is not yet routine across all providers.
- **Long-term data stewardship**: registry operations (helpdesks, IT investments, retention policies) require stable resources and clear custodianship.
- **Visibility of outcomes**: utilisation and impact metrics are improving, but comprehensive national-level data coverage is still lacking.
- **Governance evolution:** ComPerMed needs to evolve beyond a technical advisory role into a broader governance model that balances adaptability with stability and integrates policy, payer, and patient perspectives.
- **Expanding scope**: ComPerMed's mandate should gradually extend to assessing conditions for implementing other 'omics' technologies (e.g. WGS), supported by ongoing monitoring and regular updates to NGS usage guidelines with greater detail and specificity as the field evolves.

Scalability (within the member state)

Belgium's NGS framework was designed stepwise and modularly, making it inherently scalable within the national system. While close oversight is still needed and networks proved difficult to scale, core components such as the governance model, registry, and reimbursement bundle can be expanded nationally and to other disease areas.

- **What**: ComPerMed and Platform CDx governance, mandatory EQA and registry reporting, indication-based pseudocodes with listed tariffs, and a standing convention mechanism.
- **How**: Begin with high-utility indications. Adopt pseudocode lists tied to reimbursed therapies, mandate EQA participation, and require registry uploads.
- **Where**: Expansion across oncology and into haematology is already tariffed: further cancer indications can be added through annex updates, with clear amounts per pseudocode. Belgium's €6m pilot budget (~20,000 tests) illustrates the required scale.
- **Considerations**: Close oversight remains necessary to ensure funded access remains equitable across regions. Networks as a scaling mechanism have proved less effective, while data management components are highly transferable.

Transferability (across member states)

Belgium's model is highly transferable, but adaptation to each national context is essential. Certain elements (e.g. indication lists based on clinical utility) can be transferred almost directly, while governance and ethics require local tailoring.

- **What**: Indication lists based on clinical utility, guideline templates (technical and clinical), and EQA playbooks.
- **How**: Establish a ComPerMed-style advisory body linked to the payer, embed Platform-CDx-like coordination between drug and test committees, integrate ethics and consent via citizen laboratories and focus groups.
- **Where**: EU countries developing national genomics strategies or cancer plans. Also transferable to systems with HTA or social insurance structures after contextual adaptation.
- **Considerations**: Successful transfer depends on baseline HTA capacity, stable post-analytical funding, interoperable data systems, and locally adapted consent and governance. When these are in place, countries can harmonise guidelines, reduce heterogeneity, and build shared laboratory standards.

Relevant Sources

- Schittecatte G, Delnord M. The Belgian Inventory of Cancer Care & Control Policies - A State-of Play for 2023 [Internet]. Sciensano. 2023 [cited 2025 Oct 16]. Available from: https://www.sciensano.be/sites/default/files/inventory_april23_final.pdf
- Van Valckenborgh E, Hébrant A, Antoniou A, Van Hoof W, Van Bussel J, Pauwels P, et al. Roadbook for the implementation of next-generation sequencing in clinical practice in oncology and hemato-oncology in Belgium. Archives of Public Health. 2018 Dec 6;76(1):49.
- Roadbook for the implementation of Next-GenerationSequencing (NGS) in Routine diagnostics in (hemato) oncology in Belgium [Internet]. Innovative Partnership for Action Against Cancer. [cited 2025 Oct 16]. Available from: https://www.ipaac.eu/res/file/roadmap/id001.pdf
- Bourgeois J, Costa E, Devos C, Hulstaert F, Luyten J, Ombelet S, et al. Pharmacogenetic tests in Belgium [Internet]. Federaal Kenniscentrum voor de Gezondheidszorg. 2024 [cited 2025 Oct 16]. Available from: https://kce.fgov.be/sites/default/files/2024-05/KCE382_Pharmacogenetic_tests_in_Belgium.pdf#page=125.16
- Projet de budget général des dépenses [Internet]. Chambre de représentant de belgique. 2018 [cited 2025 Oct 16]. Available from: https://www.lachambre.be/doc/FLWB/pdf/54/3294/54K3294038.pdf
- Institut national d'assurance maladie-invalidité [Internet]. [cited 2025 Oct 16]. (Hémato-)oncologie : Remboursement des tests de biologie moléculaire avec « Next Generation Sequencing ». Available from: https://www.inami.fgov.be/fr/professionnels/etablissements-et-services-de-soins/laboratoires/hemato-oncologie-remboursement-des-tests-de-biologie-moleculaire-avec-next-generation-sequencing
- Institut national d'assurance maladie-invalidité [Internet]. [cited 2025 Oct 16]. La nomenclature des prestations de santé. Available from: https://www.inami.fgov.be/fr/nomenclature
- Convention Next Generation Sequencing Annex 1.
- NGS implementation in routine diagnostic in oncology in Belgium symposium [Internet]. Sciensano. 2021 [cited 2025 Oct 16]. Available from: https://www.sciensano.be/sites/default/files/20211123_symposium_ngs_koen_de_smet_implementation_in_routine_diagnostic_in_oncology_in_belgium_en.pdf

Promising practices

National examples to financing precision oncology as part of routine care

Across Europe, several countries have implemented funding reforms to incorporate molecular diagnostics into standard oncology care pathways. These approaches combined governance frameworks, defined payment rules, and developed operational structures to ensure that diagnostic testing is linked to treatment delivery.

In Finland, publicly funded genomic profiling has been embedded into standard care through a coordinated national cancer network, supported by regional university hospital hubs. Italy has used ministerial decrees to establish temporary national funds with regional implementation and clinical guideline alignment, providing a transitional model toward permanent tariffs. In the United Kingdom, central HTA by the National Institute for Health and Care Excellence (NICE) is linked to a legal funding mandate, and implementation is supported through a regularly updated Genomic Test Directory that defines test availability across the National Health Service (NHS).

Although the institutional models differ, each approach addresses the integration of precision diagnostics into routine care by establishing structured links between clinical use, evaluation, and reimbursement.

13. Finland: Coordinated public funding and pathway embedding.

Over the past decade, Finland has pursued a system-level route to finance precision oncology by building a coordinated cancer network and writing genomic testing into publicly funded care. **The Finnish Cancer Centre (FICAN) was established under a Centralisation Decree with a legal mandate to plan and coordinate cancer prevention, diagnostics, treatment, and rehabilitation nationally** through a hub-and-network model linking 5 - regional centres anchored at university hospitals and 18 regional healthcare providers (wellbeing service counties) with the Helsinki University Hospital (HUS) as the coordinating unit. By design, FICAN couples service delivery with research capacity and supports the health sector growth strategy, creating a governance spine that can host advanced diagnostics as standard of care rather than as project-based add-ons. Additionally, these centres are also embedded in academic teaching and research, enabling seamless knowledge transfer from bench to bedside.

On this governance base, **HUS and FICAN launched a national precision cancer medicine implementation initiative in 2021 to make genomic profiling routine and secure equitable access to molecular testing and clinical trials**. The initiative's architecture uses university hospital centres to concentrate molecular pathology, medical genetics, and bioinformatics capability inside publicly financed care pathways.

Clinical access and evidence generation are tied together through **FINPROVE (NCT05159245)**, an investigator-initiated, non-randomised multi-centre phase II program coordinated by the HUS Comprehensive Cancer Centre and open across all Finnish university hospitals. FINPROVE enrols patients with advanced cancers lacking standard options and matches them to molecularly targeted agents, thereby expanding access while producing nationally coherent outcome and safety data that can inform commissioning for hard-to-treat tumours. One of the key strengths of the Finnish model lies in how **companion diagnostics and targeted therapies are offered free-of-charge at the point of care, including access to genetic counselling**.

This model's **transferability** rests on its modular governance and funding logic rather than on any single laboratory configuration. Other publicly funded systems can replicate the combination of a light central mandate (to set objectives, quality guardrails, and common processes) and regional university hospital hubs (to deliver testing, tumour board deliberation, and trials), embedding **genomic testing and MTB discussion as funded elements of the national cancer pathway** rather than as discretionary tests. Its **scalability** comes from the ability to add tumour indications and participating centres incrementally within an existing network, and from the tight coupling of care and research. As national trials such as FINPROVE mature, results can be recycled into pathway and reimbursement updates without reinventing governance or payment each time.

14. Italy: Targeted national funds as a bridge to permanent reimbursement.

Italy has piloted a pragmatic path to finance precision oncology within a decentralised system by coupling decree-based national funds with cost-realistic tariff proposals, while the national Essential Levels of Care tariff catalogue (LEA, Livelli Essenziali di Assistenza) tariff catalogue is updated. A 30 September 2022 Ministerial Decree created a ring-fenced fund of €5 million per year (2022–2023) for NGS profiling in non-small cell lung cancer (NSCLC) and published in the Gazzetta Ufficiale with regional allocations. The decree operationalised testing as part of oncology pathways rather than an optional add-on. By June 2023, 18 regions and autonomous provinces had implemented the national NSCLC fund of €200,000 per year, enabling NGS testing to be aligned with clinical guidelines. A subsequent 6 March 2023 decree expanded the national fund to cholangiocarcinoma for 2023–2025, setting out organisational and financing arrangements consistent with evidence-based biomarker panels. Regional implementation documents, including the 2023 Agreement of the State–Regions Conference (CDR, Conferenza Stato-Regioni) between the Ministry of Health and Regions, translate decree-based funding into routine service delivery by specifying eligible patients, MTB-led clinical decision-making, accredited centres, evidence-based biomarker panels, and mandatory reporting. This ensures NGS is delivered as an integral component of oncology pathways rather than as an ad-hoc diagnostic add-on, with clinical use and monitoring requirements defined at provider and network level.

The financing levels in these decrees were anchored in Italian real-world cost analyses by the Gruppo Multidisciplinare Innovatività (GMI), which estimated €1,150 as the average clinical-practice cost per NGS test (with a separate €1,850 estimate for comprehensive genomic profiling), and showed that, at scale, NGS replaces multiple single-gene assays and can reduce overall diagnostic outlays—arguments that informed the decrees and subsequent proposals to align LEA tariffs with production costs. National media and policy analyses have reinforced the budget impact logic: **aligning oncology NGS tariffs to real costs could generate savings and transparency relative to heterogeneous regional prices, while enabling planning and equity of access across the national health system (SSN, Sistema Sanitario Nazionale)**. Patient and civil-society sources, as well as regional oncology governance documents, converge on the same operational requirement: precision testing must be embedded in the formal care pathway, supported by MTB structures, tracked with timeliness and outcome metrics, and paired with genetic counselling pathways where germline findings are relevant.

As a financing instrument, Italy's approach is **transferable** because it does not require an immediate, system-wide overhaul: decree-based, time-limited national funds can rapidly equalise access for priority indications in any decentralised setting, provided that central guidance specifies eligibility, routing, and reporting. It is **scalable** because the template, which includes central decree, explicit indications and biomarkers, cost-realistic reference tariffs, and regional implementation through networked centres, can be extended stepwise to further tumour types as costings and clinical pathways are defined. The pending structural task is to complete LEA integration with oncology-specific NGS codes and to recognise MTB-related work. Recent national discussions on the new LEA and tariff catalogue highlight both the opportunity and the budget governance required to achieve this alignment sustainably. Methodologically, Italy's economic case for NGS is bolstered by peer-reviewed evidence that multi-gene panel strategies can be cost-saving versus sequential single-gene testing in relevant indications, providing a generic underpinning for tariff reform beyond the two decree-funded cancers. In short, Italy demonstrates a credible bridge-to-coverage pathway: use ring-fenced national funds to currently stabilise access, codify costs transparently, and migrate to permanent LEA tariffs that make precision testing a normal, budgeted component of oncology care.

15. England: HTA-anchored funding mandate and a continuously updated National Genomic Test Directory

In England, reimbursement for precision oncology diagnostics is tied to central, methods-driven appraisal and an operational commissioning framework that translates guidance into funded services. The **National Institute for Health and Care Excellence (NICE)'s 2025 HealthTech program manual consolidates diagnostics, devices, and interventional technologies into a single evaluation pathway that can issue recommendations for early, routine, or existing use**.

It also enables multi-technology assessments when several tests address the same use case, reducing duplication and shortening time to guidance while keeping explicit clinical- and cost-effectiveness tests at the core. The **technology appraisal** regime also underpins a legal funding direction: **when NICE recommends a technology, the NHS is obliged to fund and resource it, which turns appraisal into entitlement and supports equity of access across regions**.

Commissioning then flows through the NHS National Genomic Test Directory (GTD), which specifies the genomic tests commissioned for the NHS and the patient eligibility criteria. Updates are published by NHS England and implemented through the Genomic Laboratory Hubs (GLHs), providing a national "single source of information" that links evaluation to reimbursement and service delivery. In 2025 the GTD was updated to add, among other items, **multi-target ctDNA testing for non-small cell lung cancer (NSCLC)**; national communications from NHS England and GLH networks emphasised that this liquid-biopsy route broadens access where tissue is inadequate and can accelerate turnaround times for therapy selection, with commissioning routed via GLHs once listed in the directory. This is reinforced by adoption levers such as the **Accelerated Access Collaborative**, which provides spread and implementation support for NICE-recommended technologies across the NHS. Methodologically, NICE's approach to **companion diagnostics** – via publishing explicit criteria and experience for evaluating tests alongside or separate from therapies – has long formalised how **evidence on analytical validity, clinical validity, and clinical utility is weighed within cost-effectiveness frames, a practice that underlies today's HealthTech processes**.

The England model's **transferability** lies in its modular design: jurisdictions can adopt the core elements—transparent, technology-agnostic HTA, a policy or legal **funding mandate** following positive guidance, and a **regularly updated national test directory** that operationalises commissioning—without reproducing UK institutions wholescale. The **scalability** stems from the GTD's update cadence and multi-tech assessments in the HealthTech program: as evidence matures, new biomarkers and test modalities can be added via directory revisions rather than ad-hoc tariffs, and where several platforms address the same clinical question, a single evaluation can cover them collectively, supporting volume growth without re-engineering the pathway. Recent policy coverage of NICE's program reform underscores this shift from "cost-saving only" to broader **cost-effectiveness and system benefit**, which better reflects the realities of precision oncology diagnostics.

Relevant Sources

Finland

- HUS Helsingin yliopistollinen sairaala [Internet]. [cited 2025 Oct 16]. FINPROVE - targeted anticancer therapy study. Available from: https://www.hus.fi/en/research-and-education/scientific-research/cancer-research/finprove-targeted-anticancer-therapy
- Jalkanen KJ, Alanne E, Iivanainen S, Kääriäinen OS, Tanner M, Auranen A, et al. A national precision cancer medicine implementation initiative for Finland. Acta Oncol (Madr). 2024 May 23;63:395–7.
- Finnish Cancer Center [Internet]. [cited 2025 Oct 16]. Finnish Cancer Center FICAN. Available from: https://fican.fi/en/about-us/finnish-cancer-center-fican/
- HUS Helsingin yliopistollinen sairaala [Internet]. [cited 2025 Oct 16]. HUS Diagnostic Center. Available from: https://www.hus.fi/en/about-us/departments/hus-diagnostic-center

Italy

- Ministero della salute - Decreto 30 settembre 2022 [Internet]. Gazzetta Ufficiale della Repubblica Italiana. 2022 [cited 2025 Oct 16]. Available from: https://www.gazzettaufficiale.it/eli/id/2022/10/28/22A06125/sg
- Testa S. Fondazione Mutagens. 2024 [cited 2025 Oct 16]. Test NGS somatici e genetici: senza i LEA la medicina di precisione non può decollare. Available from: https://www.mutagens.it/test-ngs-somatici-e-genetici-senza-i-lea-la-medicina-di-precisione-non-puo-decollare/
- Pruneri G, De Braud F, Sapino A, Aglietta M, Vecchione A, Giusti R, et al. Next-Generation Sequencing in Clinical Practice: Is It a Cost-Saving Alternative to a Single-Gene Testing Approach? Pharmacoecon Open. 2021 Jun 4;5(2):285–98.
- Nomenclatore Lea: risparmio di 27 milioni con l'inserimento di tariffe per test Ngs oncologici coerenti con i costi di produzione. Il Sole 24 Ore [Internet]. 2023 Jul [cited 2025 Oct 16]; Available from: https://www.ilsole24ore.com/art/nomenclatore-lea-risparmio-27-milioni-l-inserimento-tariffe-test-ngs-oncologici-coerenti-i-costi-produzione-AFqApHN
- Pinto C, Normanno N, Martini N, Jommi C, Pruneri G, Ravasio G. Oltre 31.000 pazienti oncologici in attesa di TEST NGS: necessari Fondi 2024 aspettando Tariffe LEA, per rendere effettivi i risparmi per SSN e garantire diagnosi e terapie appropriate [Internet]. Economia
- Politica del Farmaco e delle Tecnologie sanitarie. 2023 [cited 2025 Oct 16]. Available from: https://i2.res.24o.it/pdf2010/Editrice/ILSOLE24ORE/QUOTIDIANO_SANITA/Online/_Oggetti_Correlati/Documenti/2023/10/26/Oncologia_test_NGS.pdf
- Deliberazione della giunta regionale n. 1120/DGR del 19/09/2023 [Internet]. Regione del Veneto. 2023 [cited 2025 Oct 17]. Available from: https://salute.regione.veneto.it/contents/2024-12/Dgr_NGS%20Colangio.pdf?VersionId=kWefwC5kcY8HAVAGlJM3cGHgK9Euw3yg
- Ministero della salute - Decreto 6 marzo 2023 [Internet]. Gazzetta Ufficiale della Repubblica Italiana. 2023 [cited 2025 Oct 16]. Available from: https://www.gazzettaufficiale.it/eli/id/2023/04/04/23A02089/SG
- Atto Rep. n. 195 del 6 novembre 2025 [Internet]. Presidenza del Consiglio dei Ministri. 2025 [cited 2025 Dec 17]. Available from: https://www.statoregioni.it/media/35bpnola/p-3-csr-atto-rep-n-195-6nov2025.pdf
- Conferenza Stato-Regioni. Ok a fabbisogno formativo professioni non mediche e Registro nazionale strutture Pma. Rinvio per la sperimentazione su cefalea cronica. quotidianosanita.it [Internet]. 2025 Nov 6 [cited 2025 Dec 17]; Available from: https://www.quotidianosanita.it/regioni-e-asl/conferenza-stato-regioni-ok-a-fabbisogno-formativo-professioni-non-mediche-e-registro-nazionale-strutture-pma-rinvio-per-la-sperimentazione-su-cefalea-cronica/

United Kingdom

- Odelle Technology [Internet]. [cited 2025 Oct 16]. Liquid Biopsy Gains Ground: NHS England's 2025/26 Genomic Test Directory Expands Access to ctDNA for NSCLC. Available from: https://odelletechnology.com/liquid-biopsy-gains-ground-nhs-englands-2025-26-genomic-test-directory-expands-access-to-ctdna-for-nsclc/
- Government of Finland, Ministry of Social Affairs and Health [Internet]. [cited 2025 Oct 16]. The National Cancer Centre promotes equal care, research and development. Available from: https://stm.fi/en/personalized-medicine/national-cancer-center
- National Institute for Health and Care Excellence [Internet]. [cited 2025 Oct 16]. NICE HealthTech programme manual. Available from: https://www.nice.org.uk/process/pmg48/chapter/introduction
- National Institute for Health and Care Excellence [Internet]. [cited 2025 Oct 16]. About technology appraisal guidance. Available from: https://www.nice.org.uk/what-nice-does/our-guidance/about-technology-appraisal-guidance
- NHS England [Internet]. [cited 2025 Oct 16]. The National Genomic Test Directory. Available from: https://www.england.nhs.uk/genomics/the-national-genomic-test-directory/
- MTRC [Internet]. 2025 [cited 2025 Oct 16]. 2025/26 National Genomic Test Directory released in England. Available from: https://mtrconsult.com/news/202526-national-genomic-test-directory-released-england
- NHS North Thames Genomic Medicine Service [Internet]. 2025 [cited 2025 Oct 16]. New genomic test for lung cancer available for patients across England. Available from: https://norththamesgenomics.nhs.uk/new-genomic-test-for-lung-cancer-available-for-patients-across-england/
- NHS Accelerated Access Collaborative [Internet]. [cited 2025 Oct 16]. How can the AAC help me? Available from: https://www.england.nhs.uk/aac/what-we-do/how-can-the-aac-help-me/
- Byron SK, Crabb N, George E, Marlow M, Newland A. The Health Technology Assessment of Companion Diagnostics: Experience of NICE. Clinical Cancer Research. 2014 Mar 15;20(6):1469–76.
- National Institute for Health and Care Excellence [Internet]. [cited 2025 Oct 16]. NICE. Available from: https://www.nice.org.uk/
- Major health technology reforms proposed. National Health Executive [Internet]. 2025 Feb [cited 2025 Oct 16]; Available from: https://www.nationalhealthexecutive.com/articles/major-health-technology-reforms-proposed

5. Implementation Toolkit for Member states

The real-world examples from the following section and their lessons can guide national policymakers in Europe in selecting and adapting strategies, by mapping what works and what obstacles exist. Member States can use the resulting toolkit to benchmark their respective system's maturity level and adopt proven solutions.

This toolkit is intended for a broad range of stakeholders, including health ministries, HTA/payer bodies, regional health authorities, cancer institutes, healthcare professionals, civil society and patient organisations, industry, and clinical networks.

How to use this toolkit

Diagnose your starting point
Undertake a brief system assessment against the archetypes described below. These recurrent problem patterns observed across European settings and beyond, help stakeholders recognise the current configuration of the system of reference and the obstacles most likely to impede progress.

Select recommendations by pillar
For each of the three pillars identified in this report—Awareness, Infrastructure and Workforce, Funding and Reimbursement—the toolkit provides evidence- and literature-informed recommendations as well as an overarching recommendation in 5.3.4 to support Member States for alignment with EU frameworks and programmes.

5.1 Diagnose your starting point: problem patterns ("archetypes") observed across European systems

This section presents a structured set of problem patterns ("archetypes") that recur in the implementation of precision oncology across Europe. They were derived by integrating prior analyses produced by the EFPIA and partners (1,2) with the full set of case studies assembled for this report. By naming and defining these archetypes, the toolkit enables a straightforward progression. Stakeholders may diagnose the configuration that most closely matches their national or regional context, examine the linked real-world examples that have overcome the same obstacles, and then adapt and/or adopt the tested instruments and governance models that those examples provide. In this way, **the archetypes function as a bridge between evidence and action**, ensuring that reforms are both locally relevant and consistent with the wider European effort aiming to achieve equitable access to precision oncology.

Archetypes are grouped by their primary theme, while several naturally cut across more than one area of delivery. In **Table 2**, each archetype is linked with their relevant case study, to help readers assess which real-world examples address – directly or indirectly– a specific problem in their results or with the approach deployed. These examples are not intended as "off-the-shelf" solutions: their transferability depends on factors such as patient population characteristics, healthcare system design (including pricing and reimbursement), and cultural context, which will require local adaptation.

5.2 Archetypes

5.2.1 Awareness

A. Operational strain from rapid innovation
The rapid evolution of biomarkers, panels, and companion diagnostics places a continuous burden on laboratories, expert boards, and payers. Without clear change-management and communication plans that focus on the most cost-effective innovations, stakeholders face uncertainty.

B. Gap in consent and public trust for data reuse
Patients and clinicians lack clear and accessible explanations of how data will be stored, managed, and reused for learning, quality improvement, and other secondary purposes. Opt-outs and slow approval processes for the reutilisation of data limit the potential of a learning health system; targeted communication tools and consent pathways are needed to build confidence.

5.2.2 Infrastructures and workforce

C. Pilot heavy and fragmented system

Multiple local initiatives proceed with uneven methods and messages. There is no single national strategy to implement a clinical guideline into a patient pathway from diagnostic testing to MTB deliberation to the therapy decision. Data are captured inconsistently, which prevents reliable comparison of outcomes and limits scale up: A national, end-to-end pathway and common operating standards are required.

D. Strong laboratories with weak pathways from test to therapy

Laboratories meet high technical standards, yet ordering of tests, documentation of expert deliberation, and access to funded therapy are not aligned in time or in process. Clinicians face uncertainty about the next steps after a test result, which leads to underuse or delay. Standardised referral procedures, MTB documentation, and treatment authorisation workflows are needed.

E. Regional champions with national gaps

One or several regions operate mature laboratory capacity, multidisciplinary expert boards, and integrated data platforms, while other regions in the same country lag behind. Mechanisms to replicate and scale these models, share expertise remotely, and align datasets nationally are limited, resulting in uneven access and variable quality of precision oncology.

F. Over-centralised bottleneck

A single expert board or a small number of reference laboratories handle most activity, which creates constraints on throughput. Peripheral hospitals disengage and turnaround times increase. The overall system becomes less resilient. Distributed capacity and virtual MTB participation can relieve bottlenecks.

G. Strong data constrained by privacy and governance

Information technology and datasets are robust, but secondary use is slowed by consent procedures, legal interpretation, and governance arrangements. Cross-site analysis approaches are limited, and public communication about the value and safeguards of data reuse is insufficient. Pragmatic governance templates and approval timelines are needed to unlock routine learning.

H. Implementation without outcome measurement

Testing expands but common indicators, registries, and audit cycles are not in place. Value, equity, and quality cannot be demonstrated or improved at system level. A minimal national indicator set and regular audit cycles are required.

I. Digital fragmentation in clinical records

Molecular results and expert board decisions are stored as static documents rather than as structured fields. Interoperability is poor, routine indicators cannot be produced, and feedback to policy and practice is limited. Structured reporting and interface standards should be mandated.

J. Workforce limited with significant skills gaps

There are shortages in molecular pathology, clinical genetics, bioinformatics, and counselling. Protected time and formal recognition for work in MTBs are insufficient. Genomic literacy across disciplines varies widely. Role recognition, training pathways, and funded MTB time are needed.

K. Reliance on rare cancer models

Access depends on expertise concentrated across centres and evidence from small cohorts. Logistics and funding are fragile. Collaboration across borders and shared evidence generation are necessary to reach scale; hub-and-spoke logistics and shared protocols can generalise access beyond rare settings.

L. Logistical constraints for peripheral sites

Hospitals in rural areas and low volume sites face difficulties with specimen transport, chain of custody. and turnaround time. Expert boards are underused because of distance and scheduling barriers. Standard courier service-level agreement (SLAs) and virtual MTB slots can reduce delays.

M. Procurement lock-in limits laboratory flexibility

Procurement choices constrain laboratories to narrow testing menus and increase switching costs. Validation effort is duplicated and adaptability to new biomarkers is reduced. Outcome-based modular procurement and shared validation reduce lock-in.

5.2.3 Funding and reimbursement

N. Lag between value assessment, guideline updates, and funding decisions

Assessments of the added value of new diagnostic strategies are often conducted on timelines that are poorly aligned with updates to clinical guidelines and downstream funding instruments such as reimbursement schedules, directories, or billing codes. Even when evidence supports added value, delays in guideline updates and the adaptation of funding mechanisms slow down implementation in routine care. This lack of a predictable cadence for change creates uncertainty for laboratories and clinicians.

O. Policy-ready and reimbursement-led system

There is political commitment and payer readiness, but diagnostic and therapeutic pathways remain misaligned. The cycle for updating payment codes, directories, and annexes is not embedded in routine operations, which creates delays and confusion; embedding reimbursement mechanics into operational pathways is essential.

P. Friction between budget silos

Budgets for medicines, diagnostics, and hospital activity are not aligned. Work such as bioinformatics, counselling, and MTB board deliberation is not explicitly funded, which stalls uptake even when laboratory capacity exists. Bundled payments or cross-silo budget rules can align incentives.

Q. Advanced system with uneven equity

Overall testing and innovation are high, but access varies by geography, hospital type, or socioeconomic status. Equity is not routinely measured with transparent indicators and is therefore not systematically addressed. Targeted financing and equity metrics should be tied to reimbursement.

R. Private network-led landscape with parallel systems

A large private sector presence results in pathways that run in parallel to the public system. Data are siloed, quality standards differ, and reporting into national indicators is weak, which risks the emergence of two tiers of access. Contracting and reporting rules should ensure interoperability and common standards.

Table 2: Matching problem patterns to real-world solutions

The table lists system Archetypes (recurring problem patterns), clustered and colour-coded by delivery Area. For each archetype, the Related case studies column provides the numeric IDs of the case studies that directly or indirectly address the problem. A key to the case study IDs is provided in Table 1 (Chapter 4).

Area	Archetypes	Related case studies
Awareness about precision oncology	A – Operational strain from rapid innovation	5, 7, 15
	B – Gap in consent and public trust for data reuse	1, 2, 3, 9
Infrastructure and workforce	C – Pilot heavy and fragmented system	3, 6, 7, 10
	D – Strong laboratories with weak pathways from test to therapy	11, 12, 15
	E – Regional champions with national gaps	1, 7, 8
	F – Over-centralised bottleneck	1, 4, 10
	G – Strong data constrained by privacy and governance	6, 7, 10
	H – Implementation without outcome measurement	6, 10, 15
	I – Digital fragmentation in clinical records	6, 7, 8
	J – Workforce limited with significant skills gaps	4, 5, 8
	K – Reliance on rare cancer models	4, 10, 15
	L – Logistical constraints for peripheral sites	2, 4, 7
	M – Procurement lock-in limits laboratory flexibility	5, 7, 15
Funding and reimbursement	N – Lag between value assessment, guideline updates, and funding decisions	11, 12, 14, 15
	O – Policy-ready and reimbursement-led system	11, 12, 13, 14, 15
	P – Friction between budget silos	12, 13, 14
	Q – Advanced system with uneven equity	1, 2, 10
	R – Private network-led landscape with parallel systems	1, 4

5.3 Select recommendations by area

For each of the three pillars identified in this report, the toolkit provides evidence-informed recommendations and concrete actions tailored to address the most common problem archetypes and to match the maturity of the health system in scope. The objective is twofold: (i) to help national and regional leaders translate precision oncology from pilots into routine standard of care, and (ii) to ensure that the sequencing of reforms is realistic and coherent across governance levels, so that communication, clinical pathways, data use, and reimbursement evolve together.

Recommendations are clustered by focus area: Awareness, Workforce and infrastructures, Funding and Reimbursement, and Overarching. Each recommendation can be adopted as a standalone "building block" or combined into a staged program. Effectiveness depends on clear ownership and cross-sectoral collaboration between health and finance ministries (with regional authorities), cancer and laboratory agencies, HTA bodies and payers, hospital leadership and core clinical services, laboratory networks and MTBs, data/IT partners, procurement/logistics and biobanks, clinical-trial networks, industry, and patient organisations. In Table 3, each archetype is associated to the relevant recommendation that address it, either directly or indirectly. Table 4 provides the rationale for these linkages by explaining how each recommendation addresses the underlying system problem for each relevant archetype.

5.3.1 Awareness

- **Recommendation I — Establish a national or regional, co-designed communication program**
  Fragmented messaging fuels confusion about eligibility, consent, turnaround times, and the clinical consequences of test results. A single, trusted national source—co-created with patients and healthcare professionals—prevents conflicting guidance and accelerates adoption beyond academic hubs. To increase effectiveness, this should target specific misconceptions by different stakeholders. A short, reusable survey instrument provides a repeatable way to identify who lacks what information.

- **Recommendation II: — Standardise pre-/post-test counselling**
  Many patients and non-specialist clinicians are unclear on what testing entails and how results should influence decisions. Treating counselling and MTB feedback as mandatory steps with clear artefacts and timeframes raises comprehension and adherence to guidance. The development of decision-support tools can support this counselling.

- **Recommendation III — Enforce active clinician-focused guideline/protocol dissemination**
  Outside major centres, clinicians are often unsure how to translate clinical guidelines on precision oncology into day-to-day practice; for example, which guideline-recommended panels to order, how to route samples, and under what conditions testing is reimbursed. Passive publication of guidelines is insufficient. Proactive outreach, implementation-focused education, and point-of-care aids are needed to support guideline-concordant behaviour change.

- **Recommendation IV — Institutionalise patient voice and literacy in testing policy**
  Sustainable awareness depends on (i) informed decision-makers, (ii) structured patient/citizen participation where coverage, coding, pathway, and communication rules are set, and (iii) transparent, accessible public reporting on where and how patients can access guideline-recommended precision testing and treatment, how services perform and whether access is equitable. Unifying these strands prevents policy/communication drift and accelerates adoption.

5.3.2 Infrastructures and workforce

- **Recommendation V — Deliver a workforce plan to close the capacity gap**
  Precision oncology requires pathology, genetics, bioinformatics and care coordination/patient navigation teams, just to name a few, to be up-to-date with the latest developments. Upskilling is fundamental but systems need new role design, protected time, and better working conditions. Investment in education, human resources, and testing-centre capability will mean all patients can access the required expertise, while maintaining robust, ongoing training to keep staff current with advances in precision medicine.

- **Recommendation VI — Interdisciplinary collaboration**
  Multidisciplinary MTBs should be established and empowered to interpret molecular data and guide optimal strategies. This will evolve them into a scaled service with predictable access and reproducible recommendations (especially for hospitals without on-site genomics expertise) while incentivising interdisciplinary partnerships and advanced training to build cross-functional skills.

- **Recommendation VII — Address infrastructure inequity**
  Without a common standard for quality and a shared way of writing reports, clinicians and MTBs struggle to interpret test results consistently and payers doubt reliability, driving regional variation. Implementing a hub-and-spoke model that centralises complex assays while enabling local single-biomarker testing where appropriate would reduce rework, delays, and denials, and make test quality and access uniform across regions, including smaller or remote hospitals.

- **Recommendation VIII — Foster data sharing and interoperability**
  Decisions improve when labs, MTBs, and clinicians share structured information. A minimal, interoperable dataset enables learning health systems, supports reimbursement decisions, and accelerates research, while maintaining public trust. Collaborative data-sharing under privacy-focused governance and common interoperability standards should be promoted. This will ensure compatibility with GDPR and related laws for secure primary and secondary use.

5.3.3 Funding & reimbursement

- **Recommendation IX — Parallel assessment and appraisal of testing and treatment**
  Patients face avoidable delays when the added value of a biomarker test and its linked therapy are assessed and reimbursed on different timelines. Within existing national HTA and pricing structures—whether integrated or sequential—regulatory and reimbursement pathways should be planned so that the test and its dependent therapy are evaluated using linked evidence plans, aligned milestones, and coordinated funding decisions. The goal is not to redesign HTA architectures, but to minimise misalignment so that access to testing and treatment becomes as simultaneous and predictable as possible, and laboratories and clinics can plan capacity accordingly.

- **Recommendation X — Fit-for-purpose value assessment**
  Conventional appraisal can struggle when evidence in precision oncology arrives unevenly. Reimbursement frameworks that recognise Phase III patient-centred endpoints should be adopted when available and, where uncertainty remains, conditional access under lifecycle evidence plans with staged updates and real-world data should be granted. Pre-specifying how new evidence will adjust price, coverage or appropriate use (i.e. managed-entry/risk-sharing agreements/de-implementation of test strategies that are not cost-effective) and ensure system-level benefits are captured, including fewer adverse events, reduced hospitalisations, and better resource use. Clinical, patient, and economic expertise should inform these rules, so decisions remain fair and transparent.

- **Recommendation XI — Sustainable and timely test funding**
  Unfunded or late-funded testing undermines therapy access and entrenches inequity. Guaranteeing dedicated public budgets and clear payment routes for biomarker testing that has proven to be cost-effective, keeping timing aligned with therapy access, covering the full testing episode (pre-analytics to reporting), ensuring on-time reimbursement, and targeting under-funded regions will help laboratories remain stable, turnaround times improve, and equitable uptake.

- **Recommendation XII — Public–private cooperation for scale-up**
  Siloed efforts duplicate work and slow translation from research to routine care. Creating well-governed collaboration platforms across government, academia, industry, and non-profits to pool expertise and resources, accelerating the uptake of evidence into clinical pathways and laboratories, and avoiding duplication, will result in faster responsible adoption scales and benefit patients across Member States.

5.3.4 Overarching: advancing precision oncology as a whole

- **Recommendation XIII — Harmonise EU-level methods, data and quality**
  Precision oncology should be treated as a single, pan-European pathway by aligning national methods, core datasets, coding, and quality assurance with EU standards, while reimbursement decisions should remain a national responsibility reflecting local context and affordability. This convergence enables "adopt once, adapt fast": it reduces duplication, speeds equitable access, and lets smaller or earlier-maturity systems borrow scale through comparable evidence, interoperable data flows, and mutually trusted quality signals. Member States and stakeholders should commit to interoperable registries, compatible outcome and PRO measures, and transparent, plain-language reporting co-governed with patients to target inequities and sustain public trust. The specific EU levers—without replacing national HTA and reimbursement competences—that can operationalise this alignment are detailed in the following section.

Table 3: Recommendations crosswalk
Each row presents the Archetypes (full list of archetypes in Table 2) addressing each Recommendation, clustered and color-coded by Area.

Archetypes	Recommendation	Area
A, B, C, E, Q, R	I — Establish a national or regional, co-designed communication program	Awareness about precision oncology
B, D, H, J	II — Standardise pre-/post-test counselling	
A, D, E, L, O	III — Enforce active clinician-focused guideline/protocol dissemination	
B, C, G, Q, R	IV — Institutionalise patient voice and literacy in testing policy	
A, F, J, K, L	V — Deliver a workforce plan to close the capacity gap	Infrastructures and workforce
D, F, I, J, L	VI — Interdisciplinary collaboration	
E, F, L, M, Q	VII — Address infrastructure inequity	
G, H, I, R	VIII — Foster data sharing and interoperability	
N, O, P	IX — Parallel assessment and appraisal of testing and treatment	Funding and reimbursement
A, K, N, P	X — Fit-for-purpose value assessment	
D, L, N, O, P	XI — Sustainable and timely test funding	
C, E, J, M, R	XII — Public–private cooperation for scale-up	
A, C, E, G, H, I, K, M, N, P, Q, R	XIII — Harmonise EU-level methods, data, and quality	Overarching

Table 4: Mapping recommendations to problem archetypes

The table links each Area to its Recommendation and describes, for each relevant archetype, how that recommendation addresses the underlying system problem. Letters A-R correspond to the archetype list provided in the report in Table 2.

Area	Recommendation	How this recommendation addressed the related archetypes
Awareness	I — Establish a national or regional, co-designed communication program	**A:** Sets a predictable update cadence so communications keep pace with fast biomarker change. **B:** Co-design clarifies consent/data-reuse/opt-outs to build public trust. **C:** Replaces fragmented pilot messaging with one national source across test–MTB–therapy. **E:** Lets lagging regions mirror leaders with consistent materials and FAQs. **Q:** Targets gaps by geography/GDP to narrow inequities in information and access. **R:** Brings private networks into the same language and reporting rules as the public system.
	II — Standardise pre-/post-test counselling	**B:** Shared consent materials make data reuse transparent and consistent. **D:** Defines next clinical steps after results, reducing clinician uncertainty. **H:** Embeds structured **decision-support tools** so counselling/MTB artefacts are auditable, linking implementation to outcomes. **J:** Lifts baseline literacy and reduces burden on stretched teams via scripts/tools.
	III — Enforce active clinician-focused guideline/protocol dissemination	**A:** Converts rapid science into timely, pushed practice updates. **D:** Pushes concrete "order/send/funded" guidance to close test–therapy handoffs. **E:** Extends standard practice beyond hubs via outreach and point-of-care aids. **L:** Gives peripheral sites practical job aids for specimen/referral logistics. **O:** Aligns practice with payer instruments/timelines so reimbursement matches use.
	IV — Institutionalise patient voice and literacy in testing policy	**B:** Co-governed consent/communication builds durable trust. **C:** Public input reduces centre-to-centre variation in rules. **G:** Patient-facing governance speeds lawful secondary use decisions. **Q:** Equity-focused reporting exposes geographic/SES access gaps. **R:** Requires private providers to report into national indicators/QA.
Infrastructures and workforce	V — Deliver a workforce plan to close the capacity gap	**A:** Builds change-management capacity for rapid updates. **F:** Distributed/virtual MTBs relieve over-centralised bottlenecks. **J:** Funds roles, protected time, and upskilling across disciplines. **K:** Pools scarce expertise for rare/paediatric-first settings. **L:** Adds logistics coordination tailored to peripheral hospitals.
	VI — Interdisciplinary collaboration	**D:** Standardises decision paths after results via MTB outputs. **F:** Virtual/pooled MTBs cut single-centre bottlenecks. **I:** Encodes MTB outputs as structured data for interoperability and reporting **J:** Recognises MTB time; grows cross-disciplinary literacy. **L:** Guarantees remote hospitals scheduled virtual access to experts.
	VII — Address infrastructure inequity	**E:** Lets lagging regions plug into hubs while keeping local basics. **F:** Centralises complex assays, localises essentials to avoid bottlenecks. **L:** National logistics/CoC/TATs support remote sites. **M:** Shared validation/menus and modular procurement curb vendor lock-in. **Q**: Sets a national "floor" to narrow geographic/SES gaps
	VIII — Foster data sharing and interoperability	**G:** Clear governance templates/approvals enable lawful reuse. **H:** Links implementation to indicators/audit so outcomes drive change. **I:** Moves to structured fields/APIs to produce routine indicators. **R:** Integrates private-sector data into registries and QA.

Area	Recommendation	How this recommendation addressed the related archetypes
Funding and reimbursement	IX — Parallel assessment and appraisal of testing and treatment	**N:** Aligns guideline/value assessment and reimbursement to one cadence. **O:** Embeds codes/directories/annexes in the same timeline. **P:** Coordinates budgets so test, interpretation, and therapy are funded together.
	X — Fit-for-purpose value assessment	**A:** Update triggers keep appraisal in step with rapid innovation. **K:** Proportionate methods for small/rare/paediatric subgroups. **N:** Staged updates reduce guideline–assessment–funding lag. **P:** Captures cross-silo spillovers (fewer admissions) for budget alignment.
	XI — Sustainable and timely test funding	**D:** Funds the full diagnostic episode (including MTB documentation). **L:** Stabilises reimbursement for non-urban sites, improving TAT/uptake. **N:** Matches funding-update cadence to guideline/value changes. **O:** Activates clear payment routes at therapy launch. **P:** Creates dedicated budgets across silos to avoid stop-start access.
	XII — Public–private cooperation for scale-up	**C:** Standardises beyond pilots via pooled platforms/resources. **E:** Scales champion-region methods nationally. **J:** Joint programmes expand training, role design, and protected time. **M:** Collaborative procurement/validation reduces lock-in/switch costs. **R:** Governs private/public pathways with common QA/data/reporting.
Overarching	XIII — Harmonise EU-level methods, data, and quality	**A:** Predictable EU update cycles enable planned adoption. **C:** A single reference pathway collapses pilot fragmentation. **E:** Regions converge using common methods/datasets/QA. **G:** GDPR-compatible governance speeds cross-border lawful reuse. **H:** Common indicators/registries make outcomes drive improvement. **I:** Structured data/coding make MTB outputs computable across borders. **K:** Pooled evidence/protocols scale rare/paediatric care. **M:** Reference panels/modular validation reduce lock-in. **N:** EU cadences shrink guideline–assessment–funding misalignment. **P:** Comparable value frameworks support cross-silo budgeting. **Q:** Comparable equity metrics expose/fix access gaps. **R:** Private networks report into interoperable registries/QA.

Abbreviations:

API, application programming interface; CoC, chain of custody; EQA, external quality assessment; EU, European Union; GDP, gross domestic product; GDPR, general data protection regulation; HTA, health technology assessment; LDT, laboratory-developed test; MEA, managed-entry agreement; MTB, Molecular Tumour Board; PRO, patient-reported outcome; QA, quality assurance; RWD, real-world data; RWE, real-world evidence; SES, socioeconomic status; SLA, service-level agreement; SOP, standard operating procedure; TAT, turnaround time.

6. European Union Policy Levers and Supporting Instruments

The European Union (EU) already has many tools to advance precision oncology in Europe: a political mandate, the rules to align decisions, the money to scale capacity, and the safeguards to sustain trust. What is missing is using these levers together, with urgency and discipline.

6.1 Main Levers

Europe's Beating Cancer Plan (EBCP) and the EU Mission on Cancer provide the political mandate to act. Together, they give Member States a shared vision and the tools to deliver it. The EBCP sets an EU-wide strategy and funding commitment to reduce the burden of disease, tackle inequality, and accelerate advances in personalised medicine (26), with ten flagship initiatives that directly support precision oncology – notably the Cancer Diagnostic and Treatment for All Initiative, which seeks to expand access to biomarker-driven care. The Cancer Mission, as part of Horizon Europe, is the Union's innovation engine to turn that ambition into reality. Its goal to improve the lives of 3 million people by 2030 (1). It is backed by major research investment from projects like UNCAN.eu to new diagnostics, treatments, and living labs for translational research. These frameworks do more than set direction: they create accountability, shared milestones, and political visibility for cancer. By aligning national cancer plans, budgets, and accountability with these EU-wide priorities, countries will benefit from shared knowledge, avoid duplication, and accelerate the adoption of personalised oncology solutions born from European collaboration (18).

Aligning methods and data is the bridge between innovation and access. The **Health Technology Assessment (HTA) Regulation (27)** and the **European Health Data Space (EHDS) (28)** together redefine how Europe evaluates, shares, and acts on evidence. Under the HTA Regulation, joint clinical assessments (JCAs) compile in a single EU report the available evidence on relative effectiveness and relative safety versus agreed comparators. These reports do not draw an EU-level conclusion on clinical value and do not replace national appraisal or reimbursement decisions; rather, they provide a common clinical evidence base that Member States can interpret in their own context, reducing duplication of assessment and supporting more consistent timelines. The EHDS complements this by creating a secure European framework for data sharing, built on strong privacy, interoperability, and governance standards. But legislation alone is not enough: Member States must ensure that joint clinical assessments translate swiftly into national reimbursement of test and treatments that have proven to be effective and cost-effective. Equally, embedding EHDS standards into oncology pathways will allow clinical-genomic data to move seamlessly across hospitals and borders—turning information into insight, and insight into access.

Quality is non-negotiable. The ***In Vitro* Diagnostic Medical Devices Regulation (IVDR)** raises the evidence and certification bar for diagnostics that underpin precision oncology, strengthening patient safety and reliability of results (29). Member States can use the transition period to help laboratories and manufacturers adapt. At the same time, implementation has created bottlenecks for clinical trials that rely on IVDs. EFPIA's recommendations to alleviate these include: (i) delaying application of IVDR requirements for IVDs used in clinical trials, (ii) organising voluntary coordinated assessments at Member-State level, (iii) publishing clarifying guidance on assessment pathways, (iv) applying a risk-based approach to avoid assessing very low-risk IVDs, (v) allowing case-by-case derogations with agreement of the Member States involved, and (vi) clarifying the scope of in-house testing (30,31). Applying these targeted flexibilities during the transition can protect trial set-up and patient access without compromising safety, while consistent, proportionate IVDR implementation across Member States will improve the reliability of genomic and pathology results and facilitate cross-border recognition of test outputs, building confidence in precision oncology tools.

6.2 Supporting Instruments

Main levers only deliver if backed by the right operating system. These are: networks that spread excellence, data fabrics that generate real-world answers, bridges that move research into clinics, and purchasing power that turns specifications into affordable reality.

Networks to raise quality of care

The Joint Action on Networks of Expertise (JANE) 1 (2022 - 2024) and 2 (2024 - 2027), have "developed an ambitious vision for the creation of seven transversal Networks of Expertise (NoEs) in the area of oncology". These Networks of Expertise focus on critical cross-cutting areas, including personalised cancer prevention. By linking national cancer institutes, comprehensive cancer centres, and specialist clinics across Europe, these networks enable smaller or less-resourced health systems to benefit from the capabilities of larger ones. Similarly, the European Reference Networks (ERNs) for rare diseases connect specialised centres, including several dedicated to uncommon and complex cancers.

Additionally, there are several pan-European initiatives aimed at enhancing clinical and professional capacity in precision oncology that are not directly funded by the EU. For example, Cancer Core Europe (CCE) connects leading comprehensive cancer centres to co-develop precision-oncology protocols and implementation playbooks that smaller centres can adopt, accelerating diffusion of best practice beyond early adopters. Through virtual multidisciplinary boards and harmonised guidelines, clinicians in any Member State can seek expert advice and ensure patients receive care consistent with European best practice. Member States should map national centres to these EU structures, formalise cross-border and virtual referrals, and adopt network-endorsed pathways and audit tools.

Data to turn experience into evidence

The EU is building a dedicated Genomic Data Infrastructure (GDI) to interconnect national genome databases and biobanks, enabling authorised researchers and clinicians to access linked genomic and clinical data. A flagship of this effort is the 1+ Million Genomes (1+MG) Framework, through which 26 countries have committed to make at least one million sequenced genomes securely accessible for health research and clinical care, improving the statistical power to discover biomarkers and informing treatment choices beyond what any single nation's data could achieve. The Data Analysis and Real-World Interrogation Network (DARWIN EU) strengthens this ecosystem by enabling high-quality, real-world evidence generation across European data partners in support of the EHDS (32). Member States can align Coverage-with-Evidence-Development (CED) with HTA by plugging national registries and clinico-genomic datasets into DARWIN EU studies using common protocols and outcomes, and by feeding results into national reassessments and updates to Joint Clinical Assessments (JCAs).

The Joint Research Centre (JRC) knowledge assets play a cross-cutting role in supporting precision oncology implementation through data-driven policy tools and evidence-based guidelines. The JRC-hosted Knowledge Centre on Cancer acts as the EU's scientific backbone for cancer control, it manages the European Cancer Information System (ECIS) database, develops a European quality assurance schemes and clinical guidelines, and brokers common standards across initiatives like the EHDS. In practice, JRC's cancer datasets and indicator platforms equip Member States with actionable insights on gaps and outcomes. The European Cancer Inequalities Registry (ECIR) can also be used to monitor disparities in precision oncology implementation (33). With this evidence infrastructure in place, reassessment becomes routine rather than exceptional, giving payers confidence to fund what works.

To connect clinical evidence with value and affordability decisions, several EU projects are already in place. The Horizon Europe-funded ASCERTAIN develops practical methods for value-based pricing and reimbursement of advanced diagnostics and targeted therapies, including approaches to address cost-effectiveness, uncertainty, budget impact, and threshold values for the maximum costs per quality-adjusted life year gained. The Horizon Europe-Funded ONCOVALUE builds tools to use routine EHR and registry data for effectiveness assessment and reassessment, supporting CED schemes that loop back into JCAs and national updates. PCM4EU and PRIME-ROSE connect MTBs, laboratories, and payers to streamline pathways from genomic testing to treatment and reimbursement, with practical outputs on governance, data standards, and outcomes that Member States can adopt in national cancer plans (34). Together, these initiatives ensure that the same data fabric that discovers biomarkers also generates the economic and outcomes evidence payers need to fund what works making reassessment routine rather than exceptional and giving payers confidence to sustain access.

Bridge research to practice

Connecting innovation to delivery requires coordinated research and implementation frameworks. The Personalised Medicine Partnership (EP PerMed) is a key Horizon Europe initiative now augmenting the Cancer Mission. Its core aim is to accelerate the translation of personalised medicine research into clinical practice and to foster alignment of national R&I efforts. Complementing this, the PRECISEU project aims to accelerate the adoption of personalised therapies across Europe and reduce fragmentation between regions

Implemented in two phases, PRECISEU will (i) strengthen coordination and knowledge exchange among partners, and (ii) provide financial support for innovation through open calls focused on health data and patient-centred solutions. By addressing barriers such as data sharing under the EHDS framework, workforce training, and ethical and legal issues, PRECISEU will help Member States operationalise European strategies for personalised medicine and connect regional ecosystems into a coherent European network.

Taken together these instruments show how European coordination amplifies national efforts in precision oncology. Designing reforms in awareness, infrastructure, workforce, and funding within the EU policy frame helps reduce fragmentation, speed shared learning, and broaden access to integrated, data-driven, equitable care.

6.3 Securing continuity for the next EU cycle

Many of the instruments that have powered today's momentum, most notably the EU4Health Programme (2021-2027), are approaching the end of their cycle. Unless Europe now moves from time-limited projects to predictable, multi-year investment, we risk a familiar pattern: pilots that impress on paper but fade at scale. Precision oncology and personalised medicine cannot be run on short grants. They require stable financing, workforce plans, quality systems, and data infrastructures that endure beyond any single call for proposals.

The immediate pipeline proves that the model works. The European Network of Comprehensive Cancer Centres (EUnetCCC), under the EBCP, with its implementation to be completed by 2028, is developing common standards and certification pathways that can level up care across the Union. The forthcoming outputs of the Joint Action on Personalised Cancer Medicine (JA PCM) will give Member States a shared playbook for integrating genomics and tailored pathways into routine cancer care, building on groundwork from CAN.HEAL, which is developing recommendations to improve access to personalised approaches across cancer prevention, diagnosis, and treatment. These are exactly the kind of EU investments that help countries to advance quality of care. There is a pressing need for continuity, which will give countries funding and policy certainty to move from demonstration to deployment.

Continuity must be deliberate. At EU level, the next **multiannual financial framework** should lock in a dedicated, ring-fenced stream for quality cancer care and personalised medicine, aligning EU4Health's legacy with the Cancer Plan, the Mission on Cancer, HTA implementation, and the EHDS. This is a choice about permanence. Europe can let the programme cycle dictate the pace of patient benefit, or it can encourage Member States to make precision oncology and personalised medicine core public services: planned, budgeted, and auditable. The EU should continue the EU4Health's momentum into the next cycle, tie funding to implementation and equity outcomes, and require Member States to mainstream successful projects into routine care. In this way Europe will secure a decade of durable progress: turning today's projects into tomorrow's guaranteed access for every patient.

7. Conclusions

Cancer is the second leading cause of death in Europe and is projected to become the first by 2035. As Europe's cancer burden continues to rise, the need for equitable access to precision oncology has become ever more urgent. In the EU as well as globally, late detection is the main factor holding back the fight against cancer. This is driven by insufficient and unequal screening and early-diagnosis capacities. At the same time, breakthroughs in genomics, molecular diagnostics, and data science are opening unprecedented opportunities to combat the disease. Precision oncology, which adapts treatment to the genetic profile of each tumour, has demonstrated higher response rates, fewer side effects, and new hope for patients with even the most challenging cancers. The increasing cancer burden can be taken together with this revolutionary scientific innovation to create a clear imperative: **we must ensure all patients, in every EU Member State, can benefit from these advances without delay**.

The foundations for bold action are already in place: pioneering initiatives such as Europe's Beating Cancer Plan, the EU Cancer Mission, and the European Health Data Space have established a strong policy framework and momentum to reduce disparities, scale innovation, and embed data-driven practice.

The task now is implementation. This white paper (i) sets out key figures illustrating the opportunity and the risks of inaction, with a focus on equity for citizens and competitiveness for Europe; (ii) curates Member-State case studies that demonstrate measurable improvements and offer transferable blueprints that other regions and countries can adapt and scale to their local context; (iii) distils recurring system problems into actionable archetypes so teams can diagnose their starting point and choose effective solutions; (iv) provides a sequenced toolkit linking each recommendation to archetypes; and (v) maps EU policy levers and supporting instruments so national and regional leaders can "adopt once, adapt fast," reusing EU-agreed methods, data models, and quality conditions to speed rollout and improve comparability of results. There are already available EU levers to accelerate domestic reform, avoid duplication, and make outcomes comparable across borders. By combining this leverage with recommendations from this White Paper, leaders are equipped to implement bold action.

Moreover, **delivery is a shared responsibility; advancing precision oncology requires coordinated effort from all stakeholders**. Above all, its advancement requires leadership by Member States, but also active support from EU institutions, healthcare professionals, industry, citizens, and patients themselves. Multi-stakeholder commitment is necessary, but not sufficient alone: progress will ultimately be shaped by structural differences in resources and affordability across Member States. National governments must prioritise precision oncology in cancer plans and budgets, hospitals and clinicians must adopt and champion new diagnostics and therapies, payers must update reimbursement models to encourage innovation, industry should continue to drive R&D to deliver new and better precision oncology treatments alongside robust evidence generation and responsible access strategies, and patients and the public should be empowered to advocate for and participate in this transformation. Unless efforts to align methods and pathways are matched by attention to differing fiscal capacities, there is a real risk that gaps in access will persist or widen. **Each stakeholder has a crucial role to play, but closing inequities will require both coordinated action and realistic recognition of these affordability constraints**.

The cost of inaction will be measured in lives and widened inequalities. **Without decisive, coordinated efforts, existing disparities in cancer care, both between countries and within regions, are likely to deepen**. Precision oncology could risk entrenching a two-tier dynamic, where patients with greater resources or proximity to specialised centres benefit first, while others face delays or gaps in access. Recognising that wealth and health system capacity vary across the EU, our aim should be to minimise inequalities and steadily narrow access gaps. Every delay in expanding access translates into preventable suffering and loss. Rather than allowing postcode or socioeconomic status to shape outcomes, **our mission should be to lift all regions over time, so progress in precision oncology advances equity as well as excellence**.

Europe now stands at a crossroads: **the rising tide of cancer can be met either with a rising tide of innovation and commitment, or with a complacency that would cost countless lives**. This White Paper has shown that Europe possesses both the tools and the collective knowledge to change the trajectory of cancer care. Thanks to our scientists, clinicians, innovative industry partners, patient advocates, and forward-looking policymakers, we know what needs to be done and how to do it—the path forward is clear. What remains is the courage and resolve to walk it: European leaders have not only an opportunity but a responsibility to act. **By making precision oncology a pillar of our health systems, we can fundamentally improve patient outcomes, reduce inequalities, and secure Europe's place at the forefront of medical innovation**. If we unite in this effort, we can ensure that precision oncology becomes a cornerstone of a healthier, more equitable future for all Europeans. Together, we have the power and the responsibility to transform the promise of precision oncology into reality.

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9 Bibliography

1. Ivana Cattaneo. European Federation of Pharmaceutical Industries and Associations. 2024 [cited 2025 Oct 16]. Advancing the precision oncology agenda in the EU: developing a roadmap at country level to address the growing burden of cancer in Europe. Available from: https://efpia.eu/news-events/the-efpia-view/blog-articles/advancing-the-precision-oncology-agenda-in-the-eu-developing-a-roadmap-at-country-level-to-address-the-growing-burden-of-cancer-in-europe/

2. European Federation of Pharmaceutical Industries and Associations, International Quality Network for Pathology, European Cancer Patient Coalition. Improving cancer care through broader access to quality biomarker testing [Internet]. [cited 2025 Oct 16]. Available from: https://www.efpia.eu/media/589727/unlocking-the-potential-of-precision-medicine-in-europe.pdf

3. Joint Research Centre - European Commission [Internet]. 2023 [cited 2025 Oct 16]. 2022 new cancer cases and cancer deaths on the rise in the EU. Available from: https://ecis.jrc.ec.europa.eu/sites/default/files/2024-01/jrc_CancerEstimates2022_factsheet.pdf

4. Joint Research Centre - European Commission [Internet]. 2024 [cited 2025 Oct 16]. Impact of population ageing on the burden of cancer by 2040 in EU/EFTA countries. Available from: https://ecis.jrc.ec.europa.eu/sites/default/files/2024-11/2024-11_A4_Factsheet_Cancer-2040Estimates.pdf

5. European Federation of Pharmaceutical Industries and Associations. European Federation of Pharmaceutical Industries and Associations. 2025 [cited 2025 Oct 16]. Cancer care 2025: an overview of cancer outcomes data across Europe. Available from: https://www.efpia.eu/news-events/the-efpia-view/statements-press-releases/ihe-cancer-comparator-report-2025/

6. Ortega-Ortega M, Hanly P, Pearce A, Soerjomataram I, Sharp L. Projected Impact on Labour Productivity Costs of Cancer-Related Premature Mortality in Europe 2018–2040. Appl Health Econ Health Policy. 2023 Nov 8;21(6):877–89.

7. Mass General Brigham [Internet]. 2024 [cited 2025 Dec 15]. 100+ Mass General Brigham Leading Experts Identify Top Unmet Needs in Healthcare. Available from: https://www.massgeneralbrigham.org/en/about/newsroom/press-releases/leading-experts-identify-top-unmet-needs-in-healthcare

8. Subbiah V, Curigliano G, Sicklick JK, Kato S, Tasken K, Medford A, et al. Cancer treatment paradigms in the precision medicine era. Nat Med. 2025 May 20;

9. Jamalinia M, Weiskirchen R. Advances in personalized medicine: translating genomic insights into targeted therapies for cancer treatment. Ann Transl Med. 2025 Apr;13(2):18–18.

10. World Economic Forum [Internet]. 2022 [cited 2025 Oct 16]. Four agile ways policy-makers can advance precision medicine. Available from: https://www.weforum.org/stories/2022/03/four-ways-policy-makers-advance-precision-medicine/

11. Horgan D, Plebani M, Orth M, Macintyre E, Jackson S, Lal JA, et al. The gaps between the new EU legislation on in vitro diagnostics and the on-the-ground reality. Clinical Chemistry and Laboratory Medicine (CCLM). 2023 Jan 27;61(2):224–33.

12. Várhelyi O. Commissioner-designate for Health and Animal Welfare mission letter [Internet]. European Commission Sep, 2024. Available from: https://commission.europa.eu/document/download/b1817a1b-e62e-4949-bbb8-ebf29b54c8bd_en?filename=Mission%20letter%20-%20VARHELYI.pdf

13. Normanno N, Apostolidis K, Wolf A, Al Dieri R, Deans Z, Fairley J, et al. Access and quality of biomarker testing for precision oncology in Europe. Eur J Cancer. 2022 Nov;176:70–7.

14. Bayle A, Bonastre J, Chaltiel D, Latino N, Rouleau E, Peters S, et al. ESMO study on the availability and accessibility of biomolecular technologies in oncology in Europe. Annals of Oncology. 2023 Oct;34(10):934–45.

15. Horgan D, Curigliano G, Rieß O, Hofman P, Büttner R, Conte P, et al. Identifying the Steps Required to Effectively Implement Next-Generation Sequencing in Oncology at a National Level in Europe. J Pers Med. 2022 Jan 8;12(1):72.

16. Jennifer Gill, Anna-Maria Fontrier, Aurelio Miracolo, Panos Kanavos. Access to personalised oncology in Europe [Internet]. 2020 Nov [cited 2025 Oct 16]. Available from: https://eprints.lse.ac.uk/107505/

17. Phillips KA, Douglas MP, Wordsworth S, Buchanan J, Marshall DA. Availability and funding of clinical genomic sequencing globally. BMJ Glob Health. 2021 Feb 11;6(2):e004415.

18. Tim Wilsdon, Antun Sablek, Tosin Adeyemo, Tunahan Kirabali. Adoption of precision health and precision medicine approaches in addressing population health needs in Europe [Internet]. 2023 Jun [cited 2025 Oct 16]. Available from: https://www.efpia.eu/media/zv5ppxry/adoption-of-precision-health-and-precision-medicine-approaches-in-addressing-population-health-needs-in-europe.pdf

19. Pichler T, Mumm F, Dehar N, Dickman E, Díez de Los Ríos de la Serna C, Dinkel A, et al. Understanding communication between patients and healthcare professionals regarding comprehensive biomarker testing in precision oncology: A scoping review. Cancer Med. 2024 Feb 31;13(3).

20. Vetsch J, Wakefield CE, Techakesari P, Warby M, Ziegler DS, O'Brien TA, et al. Healthcare professionals' attitudes toward cancer precision medicine: A systematic review. Semin Oncol. 2019 Jun;46(3):291–303.

21. Ehman M, Punian J, Weymann D, Regier DA. Next-generation sequencing in oncology: challenges in economic evaluations. Expert Rev Pharmacoecon Outcomes Res. 2024 Nov 25;24(10):1115–32.

22. Koleva-Kolarova R, Buchanan J, Vellekoop H, Huygens S, Versteegh M, Mölken MR van, et al. Financing and Reimbursement Models for Personalised Medicine: A Systematic Review to Identify Current Models and Future Options. Appl Health Econ Health Policy. 2022 Jul 4;20(4):501–24.

23. Henderson RH, French D, Stewart E, Smart D, Idica A, Redmond S, et al. Delivering the precision oncology paradigm: reduced R&D costs and greater return on investment through a companion diagnostic informed precision oncology medicines approach. J Pharm Policy Pract. 2023 Dec 31;16(1).

24. Chakravarty D, Johnson A, Sklar J, Lindeman NI, Moore K, Ganesan S, et al. Somatic Genomic Testing in Patients With Metastatic or Advanced Cancer: ASCO Provisional Clinical Opinion. Journal of Clinical Oncology. 2022 Apr 10;40(11):1231–58.

25. Vellekoop H, Huygens S, Versteegh M, Szilberhorn L, Zelei T, Nagy B, et al. Guidance for the Harmonisation and Improvement of Economic Evaluations of Personalised Medicine. Pharmacoeconomics. 2021 Jul 16;39(7):771–88.

26. European Federation of Pharmaceutical Industries [Internet]. [cited 2025 Oct 17]. Working together to beat cancer. Available from: https://www.efpia.eu/about-medicines/use-of-medicines/disease-specific-groups/fighting-cancer/working-together-to-beat-cancer

27. Regulation (EU) 2021/2282 of the European Parliament and of the Council of 15 December 2021 on health technology assessment and amending Directive 2011/24/EU [Internet]. Official Journal of the European Union EUR-Lex; Dec, 2021. Available from: https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32021R2282

28. European Federation of Pharmaceutical Industries [Internet]. 2024 [cited 2025 Oct 17]. EFPIA position on EHDS. Available from: https://www.efpia.eu/news-events/the-efpia-view/statements-press-releases/efpia-position-on-ehds

29. Sideri E, Bates C, Abreo EF. Arnold & Porter. 2025 [cited 2025 Oct 17]. EU Medical Devices Legislation: What You Need To Know Given Latest Developments and Ongoing Challenges. Available from: https://www.arnoldporter.com/en/perspectives/advisories/2025/03/eu-medical-devices-legislation-what-you-need-to-know

30. Critical impacts of IVDR implementation on patient access to clinical trials [Internet]. European Federation of Pharmaceutical Industries. 2023 [cited 2025 Nov 6]. Available from: https://efpia.eu/media/677143/efpia_ivdr-survey-slides.pdf

31. European Federation of Pharmaceutical Industries [Internet]. 2023 [cited 2025 Nov 6]. New European legislation designed to protect patients is delaying clinical trials for thousands of people with cancer and rare diseases. Available from: https://www.efpia.eu/news-events/the-efpia-view/statements-press-releases/new-european-legislation-designed-to-protect-patients-is-delaying-clinical-trials-for-thousands-of-people-with-cancer-and-rare-diseases/

32. The networking approach: Europe embraces real-world data [Internet]. European Federation of Pharmaceutical Industries. 2022 [cited 2025 Oct 17]. Available from: https://efpia.eu/media/636976/darwin-eu-interview-april-2022-1.pdf

33. European Network of Cancer Registries [Internet]. [cited 2025 Oct 17]. Europe launches CancerWatch: improving cancer data quality and timeliness to strengthen cancer control. Available from: https://www.encr.eu/CancerWatch

34. Taskén K, F. Haj Mohammad S, Fagereng GL, Sørum Falk R, Helland Å, Barjesteh van Waalwijk van Doorn-Khosrovani S, et al. PCM4EU and PRIME-ROSE: Collaboration for implementation of precision cancer medicine in Europe. Acta Oncol (Madr). 2024 May 23;63:385–91.


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