Unlocking the potential of precision medicine in Europe – improving cancer care through broader access to quality biomarker testing

Introduction

The burden of cancer continues to grow globally, putting significant pressure on patients, their families and communities, and on healthcare systems.

However, knowledge of cancer has improved vastly in the last two decades. Precision medicine is a transformative healthcare approach that uses patient data and preferences to inform personalised treatment decisions. Biomarker testing is a crucial pillar of precision medicine, promising superior treatment outcomes for all cancer patients.

High quality oncology biomarker testing will lead to better outcomes for patients with cancer. However, current access to biomarker testing is inconsistent and contributes to health inequities across Europe. The International Quality Network for Pathology (IQN Path), the European Cancer Patient Coalition (ECPC), and the European Federation of Pharmaceutical Industries and Associations (EFPIA) have partnered on a study to analyse the current state of biomarker testing in the EU and the UK, and to lay out recommendations to achieve a vision of universal access to precision medicine in cancer care for all European cancer patients.

What are biomarkers?

A biomarker is a biological characteristic of the body that can be objectively measured and quantified; essentially, any gene, molecule, or characteristic derived from tissues or bodily fluids, including blood. In oncology, biomarkers are abnormalities or mutations found in cancer cells.

What is biomarker testing?

A biomarker test is a biochemical measurement developed to measure one, or several, biomarkers for the screening, diagnosis and/ or prognosis of cancer patients. Testing patients for biomarkers is an essential pillar of precision medicine. In oncology, precision medicine is a treatment approach tailored specifically to certain biological features of different cancer tumours.

How can biomarkers affect the treatment of cancer?

Biomarker tests are essential tools in the diagnosis and treatment of cancer for several reasons: they can be used to provide precise diagnoses and identify patients most likely to respond to treatment, therefore informing treatment selection. They can also help predict and monitor disease progression and identify patients at increased risk of developing a given condition. Identifying biomarkers and developing biomarker tests have become increasingly important in drug development.

Precision Medicine

EFPIA Definition Precision medicine is a healthcare approach that utilises molecular information, phenotypic and health data from patients to generate care insights to prevent or treat human disease resulting in improved health outcomes.

Benefits

1. **Improved patient outcomes**
   Optimal treatment for each person
2. **Socioeconomic benefits**
   Shorter hospital stays, better quality of life, longer working years
3. **Cost efficiencies**
   More targeted therapies reduce ineffective treatments which lead to long-term savings on healthcare budgets

Single biomarker testing	Comprehensive multi-biomarker testing
Test evaluating the presence of a single gene mutation, gene, or protein expression within a biopsy associated with a particular form of cancer.	Use of genomic/ complex biomarker testing (e.g. next generation sequencing (NGS)) of tumour or blood samples to detect multiple alterations in genes that are known to drive cancer growth.

Challenges to biomarker testing in Europe

Biomarker testing plays a fundamental role in fulfilling the potential of precision medicine to transform patient outcomes. Yet current access to high quality oncology biomarker testing is inconsistent across the EU27 and the UK. While there has been considerable progress in biomarker testing (for example, in genomic and molecular profiling of tumours and liquid biopsies, or in the development of tools to help physicians to match test results to existing medicines), **key barriers stand in the way of more widespread biomarker testing adoption.**

Regulatory & Reimbursement Approval

Precision medicines and biomarker testing work in tandem. Physicians will not order tests unless the results can be used to inform treatment decisions. But in many countries, there are significant delays between the approval of precision medicines and corresponding biomarker tests, and their inclusion on reimbursement lists. Parallel approval of the medicine and the test will improve timely availability.

Testing & Laboratory Infrastructure

Some countries in Europe lack sufficient laboratory infrastructure to support access to new biomarker testing technologies. In some countries there are also shortages of trained laboratory personnel to perform biomarker tests, and many laboratories do not participate in quality assurance schemes.

Value Assessment & Public Budgets

The value assessment for new diagnostic tests is unclear and inefficient, often leading to delays in the integration of testing into clinical practice. A lack of dedicated funding is a key contributor to limited access to biomarker testing.

Stakeholder Awareness & Education

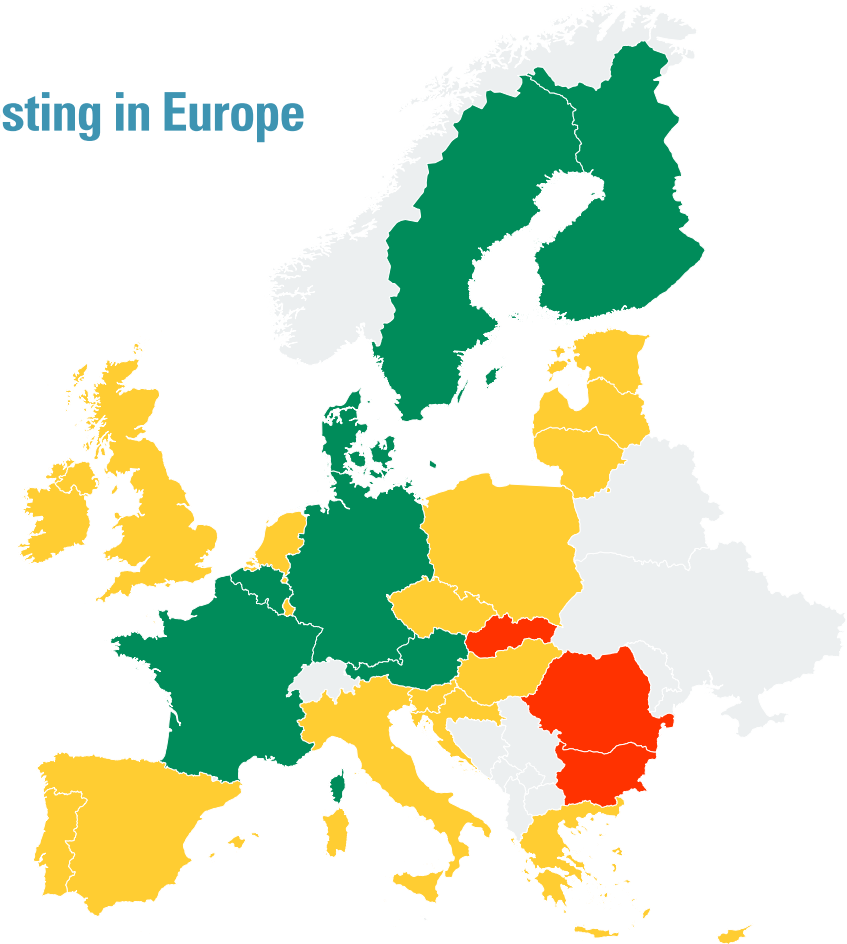
Many physicians, payers, patients, and policymakers are not sufficiently aware of the benefits of biomarker testing.

Data Collection & Sharing

Currently, there is little to no co-ordinated data collection across Europe, and in countries where data is collected, the quality and consistency varies. This makes it difficult to compare data and to identify actionable trends in patients' response to therapies.

The State of Biomarker Testing in Europe Quality and Access

This map illustrates the ease of access and the quality of biomarker testing across all EU countries and the UK. There are still big divides in Europe. Northern and Western European countries generally perform better in biomarker testing, reflecting their higher investment in healthcare. Southern and Central European countries, as well as the Baltic states, tend to have more variability in access to test infrastructure and funding. Countries in Eastern Europe require more significant structural changes to achieve equity in access to quality biomarker testing. Test quality also varies, with laboratories in several countries lacking the funds or the capacity to participate in quality assurance schemes.

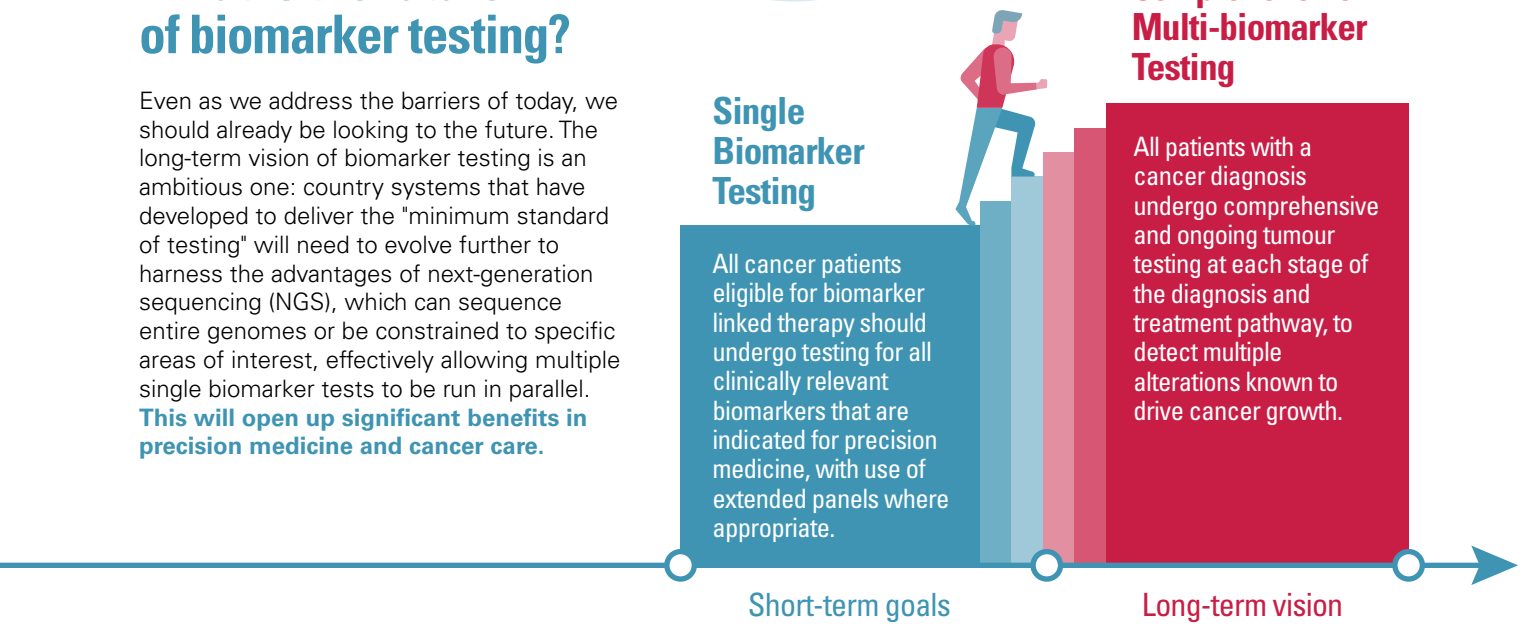


How does biomarker testing work?

Ever increasing knowledge of biomarkers is driving the use of broader tests of hundreds of genetic variants, allowing for precise treatment decisions and monitoring. Biomarker testing exists in a complex health ecosystem – with physicians, patients, hospitals, laboratories, pharmaceutical companies, universities, cancer patient organisations, public-private partnerships, governments, regulators, health technology assessment bodies, among others – all playing a crucial role in enabling access to biomarker testing and unlocking the potential of precision medicine.

What is the future of biomarker testing?

Even as we address the barriers of today, we should already be looking to the future. The long-term vision of biomarker testing is an ambitious one: country systems that have developed to deliver the "minimum standard of testing" will need to evolve further to harness the advantages of next-generation sequencing (NGS), which can sequence entire genomes or be constrained to specific areas of interest, effectively allowing multiple single biomarker tests to be run in parallel. **This will open up significant benefits in precision medicine and cancer care.**



Policy Recommendations

To provide a pathway for the improvement of access and quality of biomarker testing in the EU27 and the UK, the study proposes recommendations relating to both the short term (i.e., realise within the next 2-3 years) and the longer term (i.e., 5-10 years).

	Short-Term Recommendations (2-3 years)	Long-Term Recommendations (5-10 years)
Regulatory & Reimbursement Approval	**Develop a process for the parallel regulatory and reimbursement approval of the precision medicine and the associated biomarker test**	
Value Assessment & Public Budgets	• **Adopt a national system for biomarker test value assessment,** harmonised across countries, which considers overall health system benefits while incorporating new data as it is generated • **Introduce dedicated biomarker test budgets:** increased funding to support reimbursement for biomarker tests	**Create harmonised approaches in Europe across the test development continuum, including guidance on biomarker use during clinical trials and test value assessment**
Testing & Laboratory Infrastructure	• **Set up mandatory accreditation and quality assurance schemes for laboratories** • **Create regional testing centres** to drive cost efficiencies, develop technical expertise and invest in test technologies	**Promote centralised testing infrastructure** and networks of specialised labs at the national level that carry out complex biomarker testing to ensure consistent test access and develop a shared knowledge base of patient outcomes
Stakeholder Awareness, Education, & Guidelines	**Educate stakeholders on the value of biomarker testing,** including physicians, pathologists, payers, patient advocacy groups and policy makers	**Develop EU and UK-wide guidelines in cooperation with stakeholders** to promote the use of comprehensive testing at various stages of the disease journey and the implementation of best practice methods
Data Collection & Sharing	• **Set up centralised national data collection** to identify actionable trends in patients' response to therapies • **Establish horizon scanning** to better anticipate future requirements for infrastructure and funding for biomarker testing and precision medicine	**Encourage data sharing** and harness data on comprehensive testing to optimise presonalised treatment decisions

How can we make this happen?

> **"The vision for precision medicine in oncology is transformative: to deliver superior outcomes for all cancer patients and ultimately reduce the suffering caused by cancer"**

Immediate action is needed to ensure the provision of adequate biomarker testing across countries. Individual countries will be responsible for overseeing the implementation of national initiatives for the short term recommendations highlighted above. In addition, we propose creating a European-level task force to monitor and guide national initiatives and co-ordinate pan-European initiatives in line with the long-term recommendations.

The vision for precision medicine in oncology is transformative: to deliver superior outcomes for all cancer patients and ultimately reduce the suffering caused by cancer. But with cancer rates continuing to rise across Europe and around the globe, we must move quickly if we are to deliver on the benefits of biomarker testing and ensure that the pace of innovation can be sustained. This requires a coordinated effort from policy makers, payers, pathologists, physicians, industry participants and patient advocacy groups.