

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

Advances in biomarker testing are having a transformative impact on cancer care, but Europe will have to overcome significant barriers in equitable access and quality of these tests to realise their full potential, concludes an important new study released by the International Quality Network for Pathology (IQN Path), the European Cancer Patient Coalition (ECPC) and the European Federation of Pharmaceutical Industries and Associations (EFPIA).

The study presents the results of research conducted in 2020 to assess the availability, quality and reimbursement of biomarker tests in the EU27 and the United Kingdom, identify country-specific shortcomings, and develop policy recommendations to improve equitable access to and quality of biomarker testing across Europe.

Biomarker tests are essential tools in the diagnosis and treatment of cancer. 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. In this way, identifying biomarkers and developing corresponding biomarker tests have become increasingly important in the development of new therapies. Biomarkers and biomarker testing are a significant pillar of precision medicine, which uses patient data to inform personalised treatment decisions.

By assessing a selection of key biomarkers according to four access metrics (laboratory access, test availability, test reimbursement, test order rate) and three quality metrics (quality scheme participation, laboratory accreditation, and test turnaround time), the study has found that access to high quality oncology biomarker testing is inconsistent across Europe and contributes to health inequalities both within and between countries.¹ Northern and Western European countries generally perform well in biomarker testing, reflecting their higher investment in healthcare. Southern and Central European countries as well as the Baltic countries 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.

Nicola Normanno, President of IQN Path and Principal Investigator of the study, noted: *“The advances in our understanding of cancer over the last two decades in mapping out the genome have fuelled powerful discoveries and have been fundamental to getting us to this point where we can tailor cancer treatment to individual patients. While there has been significant progress, many barriers remain. Limited availability of precision medicine linked to biomarkers, unclear value assessment, a lack of laboratory infrastructure and awareness – all these hurdles are holding us back from reaping the enormous benefits of biomarker testing.”*

To provide a pathway for the improvement of access to and quality of biomarker testing in the EU27 and the UK, the study makes recommendations relating to both the short term (i.e., the next 2-3 years) and the longer term (i.e., 5-10 years), which should help achieve the vision of transitioning to

¹ The study has drawn on a wide range of secondary sources, surveys of 141 laboratory managers and of 1,665 patients, and 58 in-depth interviews with laboratory managers, physicians, and payers.

comprehensive and ongoing tumour testing throughout the episodes of care for all patients with a cancer diagnosis.

Parallel approval of the medicine and associated testing, adopting a national system for biomarker test value assessment, dedicated biomarker test budgets, stakeholder education, centralised data collection and horizon scanning are among the short-term recommendations outlined in the study. As regards the achievement of the longer-term vision, the study calls for centralised testing infrastructure, harmonised approaches along the test development continuum, data sharing and guidelines on comprehensive testing.

“The EU’s Beating Cancer Plan sets out an ambitious vision – to leverage new technologies, research and innovation and set out a new approach to cancer prevention, treatment and care. We consider this study an important contribution to these efforts,” said Kathi Apostolidis, Board Member of ECPC. *“One of the key recommendations of the study is to educate physicians, payers, regulators, policymakers, and, above all, patients about the benefits of biomarker testing. Patients need this knowledge to better understand their condition and to have more say in their treatment,”* Ken Mastris, ECPC President, added.

Nathalie Moll, Director General of EFPIA added that *“there is plenty of reason to be optimistic about the future of cancer treatment. Medicine development in oncology is rapidly evolving, facilitated by a greatly improved understanding of cancer as a genetic disease. However, we cannot afford to be complacent. Cancer is on the rise throughout Europe. It is therefore a matter of urgency to provide physicians and health systems with the biomarker testing infrastructures and processes required in order to deliver the benefits of these therapeutic advances to patients, and to ensure that the pace of innovation can be sustained. This study is a strong first step in that direction and we look forward to working with all stakeholders in the health and policy space to make this a reality”*.

ABOUT IQN PATH

IQN Path is an international multi-stakeholder expert group focused on improving quality of clinical biomarker testing, bringing together organisations and key stakeholders involved in quality implementation of biomarker testing in pathology globally.

www.iqnpath.org

Contact: executive@iqnpath.org

ABOUT ECPC

European Cancer Patient Coalition is the voice of cancer patients in Europe. With over 450 members, ECPC is Europe’s largest umbrella cancer patients’ association, covering all 27 EU member states and many other European and non-European countries. ECPC represents patients affected by all types of cancers, from the most common to the rarest.

<https://ecpc.org/>

Contact: paulina.gono@ecpc.org



ABOUT EFPIA

The European Federation of Pharmaceutical Industries and Associations (EFPIA) represents the biopharmaceutical industry operating in Europe. Through its direct membership of 36 national associations, 39 leading pharmaceutical companies and a growing number of small and medium-sized enterprises (SMEs), EFPIA's mission is to create a collaborative environment that enables our members to innovate, discover, develop and deliver new therapies and vaccines for people across Europe, as well as contribute to the European economy.

<https://www.efpia.eu/>

Contact: info@efpia.eu