



# Breast cancer in Europe: **from policy to progress**

Policy report by **Transforming Breast Cancer Together**



# Transforming Breast Cancer Together

**Transforming Breast Cancer Together** is a unique multistakeholder group representing patient and healthcare professional organisations, experts and industry whose mission is to place the needs of those living with breast cancer at the heart of European policymaking, with the ultimate objective of improving outcomes for breast cancer patients, survivors, and their families.

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*Breast cancer remains one of Europe’s most urgent health challenges, and progress must reach every patient in every Member State equally. This report shows how Europe can build on the foundations of Europe’s Beating Cancer Plan with policies that help further improve breast cancer prevention, screening, and treatment—leveraging science and innovation.*

*As Chair of Transforming Breast Cancer Together, I urge EU and national policymakers to turn ambition into measurable progress, ensuring breast cancer care is equitable, patient-centred and fit for the future.”*



**Romana Jerković, MEP (S&D, HR)**  
Chair of TBCT

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## 01

### Introduction

**The EU must step up its action against breast cancer, building on its achievements to drive sustainable and equitable progress across the region**

Breast cancer is the leading cause of cancer and cancer death in women, and one of the most costly cancers for economies. Europe's Beating Cancer Plan (EBCP) has set the foundations to reduce its impact, but policymakers must build on these at EU level and promote national implementation. Further EU level actions must target continuing variations in breast cancer incidence, care access, and outcomes to enable all patients to benefit from advances in care.

**Transforming Breast Cancer Together**, a unique multistakeholder platform, presents policy recommendations to drive equitable and sustainable progress in prevention, screening, diagnosis, and treatment—leveraging science and innovation. Underpinning these actions, we urge EU policymakers to continue EBCP funding within a dedicated EU health programme in the next multiannual financial framework.

## 02

### Prevention

Up to 25% of all breast cancer cases could be prevented by addressing risk factors. EU policies and initiatives should ensure that all EU citizens benefit from awareness campaigns (including an annual European Breast Health Day on 15 October) and projects to further explore the potential role of targeted breast cancer prevention based on patients' risk levels.

## 03

### Screening

Early detection of breast cancer improves patient outcomes and lowers healthcare costs. EU health policies and initiatives should further support Member States to increase participation in population-based breast screening programmes and to assess and leverage new technologies. Specific recommendations relate to dedicated funding and awareness-building, incentivising participation and certification within the ECIBC quality assurance scheme for breast cancer services, and evaluating AI and targeted screening.

## 04 Diagnosis & treatment

Breast cancer care has been transformed in recent years by precision oncology via biomarkers and targeted therapies. Together with novel AI technologies, these approaches offer promise to personalise outcomes, improving patient survival and quality of life (QoL). However, equity gaps and disparities limit the benefit of these advances.

EU policies and initiatives should ensure all patients with breast cancer can access specialist multidisciplinary care, building on the ECIBC Quality Assurance Scheme and networks of comprehensive cancer centres, and driving workforce education and retention, integrated, patient-centered breast cancer pathways, digital health capacities, and specialist breast cancer surgical care.

Specific policies and initiatives should promote precision breast cancer oncology via: alignment of decision-making processes for biomarkers and targeted therapies; funding and reimbursement of biomarker testing and laboratory investment; improved value assessment for precision oncology treatments; harmonised data collection and sharing across breast cancer registries; and further evaluating and supporting evidence-based AI implementation.



## 05 Metastatic breast cancer

Metastatic breast cancer (MBC) warrants specific policy action owing to its poor prognosis, limited treatment options, and profound impact on QoL among patients and families. EU policies and initiatives should address the needs of patients with MBC via an EU-level action plan for metastatic cancers and greater inclusion of patients in policymaking. Key priorities include the need to promote harmonised collection of high-quality data, enabling equitable access to specialist MBC care, and to assessing and valuing innovation in ways that reflect the particular challenges of MBC, including patient-centric trial methods.

## 06 Patient empowerment & QoL

All patients with breast cancer should be empowered to participate in shared decision-making regarding their care and relevant policies. Beyond clinical outcomes, holistically improving the wellbeing of cancer patients is central to reducing the impact of breast cancer. EU actions should include educational tools and resources, mechanisms to integrate patient perspectives both in EU and national policymaking, and assessment of patients' QoL and experience throughout breast cancer care pathways and the development, regulatory approval, and health technology assessment of new breast cancer medicines.

## 07 Conclusion & call to action

We call on EU policymakers to place breast cancer at the heart of a renewed and sustained EU commitment to tackle cancer.

Full details of all recommendations in the report and collated on [page 22](#).

# The European Union (EU) must step up its action against breast cancer, building on its achievements to drive sustainable and equitable progress across the region.

## ***Breast cancer must remain an EU priority***

Addressing the vast impact of cancer on citizens, health systems and economies is a public health priority across Europe.<sup>1,2</sup> Breast cancer should remain a key focus given its particular impact and the major disparities that exist in care and outcomes across EU Member States.

Breast cancer accounts for almost one third of all new cancer cases in women — twice as many as the next most common cancer.<sup>3</sup> Responsible for almost 93,000 deaths across the EU in 2024, it is the leading cause of cancer death in women and the third most common overall.<sup>3</sup> While early-stage disease is often associated with high cure rates, around 20–30% of cases recur as advanced or metastatic disease (i.e. disease that has spread to other parts of the body).<sup>4,5</sup> Metastatic breast cancer remains an incurable disease with median survival between 2 and 5 years, depending on the breast cancer subtype.<sup>6,7</sup> Breast cancer also significantly worsens patients' quality of life (QoL), especially when the disease is advanced.<sup>7</sup>

By 2040, the annual number of new cases of breast cancer is projected to increase by 10%, and deaths by 20%.<sup>3</sup> While this increase is primarily due to demographic aging, early-onset breast cancer is also rising in younger women and driving an overall greater rise in cancer cases among women versus men.<sup>8</sup> Around 1% of breast cancer cases occur in men.



### **Did you know?**

**Per capita mortality rates from breast cancer vary approximately two-fold across EU Member States, from 21/100,000 in Croatia to 40/100,000.<sup>3</sup>**

Breast cancer also places a heavy toll on health systems and economies. Globally it is estimated to confer the third highest macroeconomic costs of any cancer<sup>9</sup> and the second highest socioeconomic costs of premature death.<sup>10</sup> In Europe, the total economic impact of breast cancer has been estimated at €344 million/year in Poland<sup>11</sup> and >€1 billion/year in Italy.<sup>12</sup> "Indirect" societal costs tend to exceed direct medical costs:<sup>13</sup> across 22 European countries the value of productivity loss alone from breast cancer was €4.1 billion in 2019.<sup>14</sup>

Advances in diagnosis and treatment, including precision medicine approaches, are helping to drive down cancer mortality rates and socioeconomic costs.<sup>8,15</sup> Across Europe, the total value of health gains driven by medical advancements in cancer between 2012 and 2022 was

recently estimated at €29.2 billion (range €7.5–63.3 billion).<sup>16</sup> Specifically, at a national level, every \$1 spent on breast cancer treatment is estimated to return \$4.9 in economic benefit.<sup>15</sup> Improving breast cancer prevention, detection, and care is therefore a smart investment for EU economies. Failing to act

leaves the prospect of rising breast cancer cases, with the commensurate impact on patients, families, healthcare systems, and economies.

## ***Why the EBCP must build on breast cancer actions***

Europe's Beating Cancer Plan (EBCP) and the European Cancer Mission are major EU investments in health. Their achievements include particularly important milestones in fighting breast cancer, including the EU-wide guidelines for screening and diagnosis, and the Quality Assurance Scheme for care services, delivered via the EC Initiative on Breast Cancer (ECIBC).

The EBCP has set the foundations to reduce the impact of breast cancer across Europe, but policymakers must now

build on these at EU level and promote consistent national implementation.<sup>1718</sup> Further EU-level actions must target the variations in breast cancer incidence, care, and outcomes that still exist between and within Member States—enabling all patients to benefit from advances in diagnosis and treatment.<sup>719–23</sup> These actions are key to the better EBCP alignment necessary among national cancer control plans<sup>24</sup> and to delivering benefit from broader EU initiatives, including EU4Health, the Gender Equality Strategy, the Biotech Act, the Multiannual Financial Framework (MFF), and the EU Competitiveness Fund.

## ***TBCT: putting breast cancer at heart of policies***

Transforming Breast Cancer Together is a multistakeholder platform comprising patient and healthcare professional organisations, and industry. Its mission is specifically to place the needs of those living with breast cancer at the heart of EU-level policymaking, with the ultimate objective of improving outcomes for breast cancer patients, survivors, and their families.

***We urge EU policymakers to devote renewed attention to breast cancer. Here we present our collective policy recommendations to drive equitable and sustainable progress in prevention, screening, diagnosis, and treatment—building on existing initiatives and leveraging science and innovation.***

Critically, to underpin these actions, we urge EU policymakers to continue EBCP funding within a dedicated EU health programme in the 2028–2034 MFF, as per the European Parliament resolution on World Cancer Day 2026.<sup>18</sup>





## Up to 25% of breast cancer cases could be prevented by effectively addressing modifiable risk factors, especially obesity, low physical inactivity, and alcohol use.<sup>21</sup>

The latest European Code Against Cancer (ECAC5) recommends policy changes to help address these risks, and increase rates of breastfeeding (a protective factor).<sup>25</sup>

The EBCP has included various cancer prevention initiatives, including some addressing address modifiable breast cancer risk factors, but progress on some aspects has been delayed.<sup>26</sup>

Key challenges in this respect include:

- ▶ Limited proportion of national health spending dedicated to public health and disease prevention: the EU average of ~6%<sup>19</sup> remains a low proportion relative to its benefit.
- ▶ Variable implementation of risk reduction measures across EU.
- ▶ Higher prevalence of risk factors in communities with low levels of income and education.



### Recommendations

EU policies and initiatives should ensure that all EU citizens benefit from EU-wide and national actions to reduce breast cancer risk factors by:

- ◆ Promoting higher spending on breast cancer risk awareness and prevention by Member States, including by supporting research to quantify the return on investment.
- ◆ Driving awareness of breast cancer prevention and screening via 1) an annual European Breast Health Day on 15 October<sup>23</sup> and 2) EU-wide guidance and best practices to help Member States reach communities at greatest risk, created in collaboration with patient organisations and civil society groups.
- ◆ Funding projects to further explore the role of targeted breast cancer prevention based on patients' risk levels, e.g. by proactive risk assessment (including genetic testing) and personalised prevention advice.<sup>21</sup> This could build upon work on personalised prevention in the ongoing [JANE-2](#) Joint Action.



## TBCT supports the European Cancer Organisation<sup>27</sup> and others in calling for sustained EU and national action and investment to ensure equitable access to early cancer detection as a priority to realize the EBCP's gains for public health.

Early detection of breast cancer improves patient outcomes and helps reduce long-term healthcare costs.<sup>28,29</sup> Between 2018 and 2023, 56% of breast cancers among women aged 50–69 were diagnosed at early stages (stages 0–I).<sup>8</sup> Increasing this proportion via screening remains a key priority.

EU countries are recommended to implement nationwide, organised, population-based mammography screening programmes according to the ECBIC guidelines and quality assurance standards.<sup>30</sup> All but three EU countries (Bulgaria, Lithuania and Romania) now have population-based breast screening programmes in place.<sup>8</sup>

The EU Cancer Screening Scheme goal is for 90% of qualifying EU citizens to be offered breast cancer screening. However:

- ▶ Across EU countries, only 55.7% of target (at-risk) populations participate in breast cancer screening. Screening rates vary almost 10-fold, from 9.2% in Romania to 83.0% in Denmark.<sup>19</sup> People with lower education and income levels, and migrant populations, show particularly low participation.<sup>8</sup> The [EUCanScreen](#) Joint Action includes work packages to identify evidence-based means to improve participation.

- ▶ Advanced imaging and artificial intelligence (AI) approaches that could improve detection rates and efficiency<sup>31</sup> are not widely or consistently used, and EU-wide data on their uptake are lacking. Ongoing EU initiatives to address this include the [EUCAIM](#), BreastScan, and [UNICA](#) projects.
- ▶ There is limited use of precision or personalised screening based on individuals' risk levels, as indicated by genetic testing for alterations associated with a higher risk.<sup>8</sup>



### Did you know?

Breast cancer screening rates vary 10-fold across the EU and are *falling* in half of countries.<sup>19</sup>



### Recommendations

EU health policies and initiatives should further support Member States to increase participation in population-based breast screening programmes and to assess and leverage new technologies via:

- ◆ A dedicated budget in the next MFF to support breast cancer screening programme implementation and uptake.
- ◆ Dedicated health and cohesion/structural funds to support implementation of evidence-based measures to improve participation, e.g. mobile outreach units, community navigators, digital tools and reminders) and technical assistance packages (guidelines, IT tools, training).
- ◆ An EU Breast Health Day to raise awareness of screening.
- ◆ EU institutional backing for an EU-wide breast cancer screening awareness campaign for use in all Member States, targeting communities with low participation.
- ◆ Measures to further promote and incentivise participation and certification within the ECIBC Quality Assurance Scheme for breast cancer services.
- ◆ Research funds to further evaluate the potential role of AI in supporting national breast cancer screening programs and informing EU guidelines.
- ◆ Extended EU-wide actions to evaluate the role and implementation of targeted screening based on genetic testing.



## Breast cancer care has been transformed in recent years by the introduction of precision oncology approaches that aim to ensure that each patient receives the treatment of their specific cancer, at the right time.

In particular, biomarker tests can help to predict the prognosis and to select a targeted treatment with better effectiveness and lower toxicity than conventional chemotherapy. Advances in AI offer additional promise to personalise treatment and improve survival and QoL among patients with breast cancer.

However, gaps and disparities between and within Member States limit the benefit of these advances. Generally the EBCP has so far lacked means to ensure that innovation reaches EU patients.<sup>17,26</sup> Key priorities are to ensure patients have access to specialist multidisciplinary care, to further implement precision oncology, and to leverage advances in AI and data science.

### *Ensuring access to specialist multidisciplinary care*

Breast care is complex and can include many different modalities. Care should be delivered in a patient-centred manner according to European-level guidelines<sup>6,32,33</sup> in a specialist breast cancer unit by a multidisciplinary team. The team normally includes medical, surgical, and radiological oncologists, pathologists, nurses and allied healthcare professionals—all with specific expertise in breast cancer.<sup>34,35</sup>

TBCT welcomes ongoing EU actions to build cancer care capacity and expertise to reduce variations and disparities, via the ECIBC quality assurance scheme and networks of comprehensive cancer centres (CCCs) ([EUnetCCC Joint Action](#)) and expertise ([JANE-2 Joint Action](#)).



## Did you know?

Surgery is a vital component of multidisciplinary breast cancer care across all disease states.<sup>36</sup> Breast cancer surgery is increasingly complex and innovative, with robotics being used in some cases. However, important gaps and variations exist in surgical oncology capacity and practices in Europe<sup>8</sup> limiting equitable access for patients. In particular there is no EU-wide recognition of the speciality of breast cancer surgeon, nor any European standards for training and accreditation.<sup>37</sup>

## Driving precision oncology in breast cancer

Precision oncology is already improving patient outcomes in breast cancer. In particular, biomarker tests can help predict the prognosis and guide treatment using targeted therapies. Patients' tumours are categorised according to the presence of three key proteins that accelerate breast cancer development, namely receptors for the hormones oestrogen and progesterone, and human epithelial growth factor 2 (HER2) (see panel).<sup>38</sup> Ongoing biomarker research is enabling even more precise targeting of treatment.

However, biomarker tests are unequally accessible among EU Member States, limiting patient access to targeted treatment.<sup>39-41</sup> Barriers include regulatory delays, variations in national health technology assessment (HTA) processes and evidence requirements, and fragmented reimbursement pathways that separate tests and the corresponding targeted therapies. Low levels of awareness among breast cancer patients also contribute to the limited use of biomarkers.<sup>40-42</sup>

**~80%  
of cases**

### Subtype

#### Hormone receptor-positive

- ◆ Oestrogen receptor-positive (ER+)
- ◆ Progesterone receptor-positive (PR+)



**Best prognosis and more likely to respond to hormone therapy**

~9% are also HER2+

**~10-15%  
of cases**

### Subtype

#### Human epidermal growth factor receptor-positive (HER2+)



**Worse prognosis than HER2-negative but much more likely to respond to HER2-targeted therapies**

**~10-15%  
of cases**

### Subtype

#### Triple-negative (i.e. ER, PR, and HER2 negative)



**Most aggressive subtype: worst prognosis and fewer treatment options**



## Did you know?

**In 2024–2025, only four of 14 surveyed EU Member States reported equitable access to molecular diagnostics, including for breast**

Patients' access to new breast cancer therapies, including precision medicines, also varies substantially across Europe. Generally, Western European countries tend to reimburse more cancer medicines and reimburse them faster than countries in Central and Eastern Europe and smaller countries.<sup>15,43,44</sup>

- ▶ In 2025, EU Member States on average reimbursed only 51% of the cancer medicines approved by the European Medicines Agency (EMA) in 2021–2024. This varied enormously, from >86% in Germany, Italy, and Austria to ≤20% in eight Member States.<sup>43</sup>
- ▶ More specifically, in 2023, Member States reimbursed on average 59% of indications for a sample of new breast and lung cancer medicines designated to have high clinical benefit. This varied markedly from 100% in Germany to 30% in Latvia and Cyprus, and 0% in Malta.<sup>19,44</sup> The time to reimbursement also varied more than 10-fold, between 100 and >1100 days.

Moreover, even when medicines are officially reimbursed, other restrictions can inhibit the widespread use of a reimbursed medicine in practice.<sup>44</sup>

The “Back Innovation, Boost Access” agenda of the European Federation of Pharmaceutical Industries and Associations (EFPIA) and its recent precision oncology roadmap<sup>41</sup> highlight the urgent need to improve access to targeted therapies and biomarker testing for cancers such as breast cancer. TBCT reinforces the report's central message that, while Europe now possesses the scientific and technological capabilities to deliver more personalised cancer care, implementation and access remain inconsistent across Member States. For breast cancer, this underscores the importance of embedding precision oncology into routine care pathways through coordinated European action, including equitable access to biomarker and genomic testing, as well as reimbursement systems that support both diagnostics and targeted therapies to ensure patients can fully benefit from innovation.

Various EU initiatives are promoting precision oncology, including the new [Joint Action on Personalised Cancer Medicine](#) (2025–29), the [JANE-2](#) Joint Action, the Personalised Cancer Medicine for all EU citizens (PCM4EU) project, the [ASCERTAIN](#) project, and the European Health Data Space (EHDS). National initiatives to promote precision oncology are also underway in some countries.<sup>41</sup>



## Data & AI

AI offers numerous opportunities to improve the quality and efficiency of breast cancer care, including triaging, imaging, precision oncology, and surgery. These gains are vital to realize, given the rising demands on health systems associated with demographic aging, workforce shortages, and fiscal constraints.<sup>45</sup> Although the EU has many foundations in place to harness AI, its deployment has been slow and variable, owing in part to limited, scattered datasets and regulatory barriers.<sup>17,45</sup>

The EHDS must be leveraged to unlock the power of data and AI to improve breast cancer care and drive research and innovation. TBCT welcomes other ongoing EU initiatives, including the European Initiative to UNDERstand CANcer ([UNCAN.eu](#)), the European Cancer Imaging Initiative, the Cancer Image Europe Platform (developed by the EUCAIM project), and the [BreastSCan](#), UNICA, and [COMPASS-AI](#) projects. TBCT also applauds national EHDS-aligned initiatives, such the Spanish [National Health Data Space](#).



## Recommendations

In order to ensure all patients have access to specialist multidisciplinary care, EU policies and initiatives should:

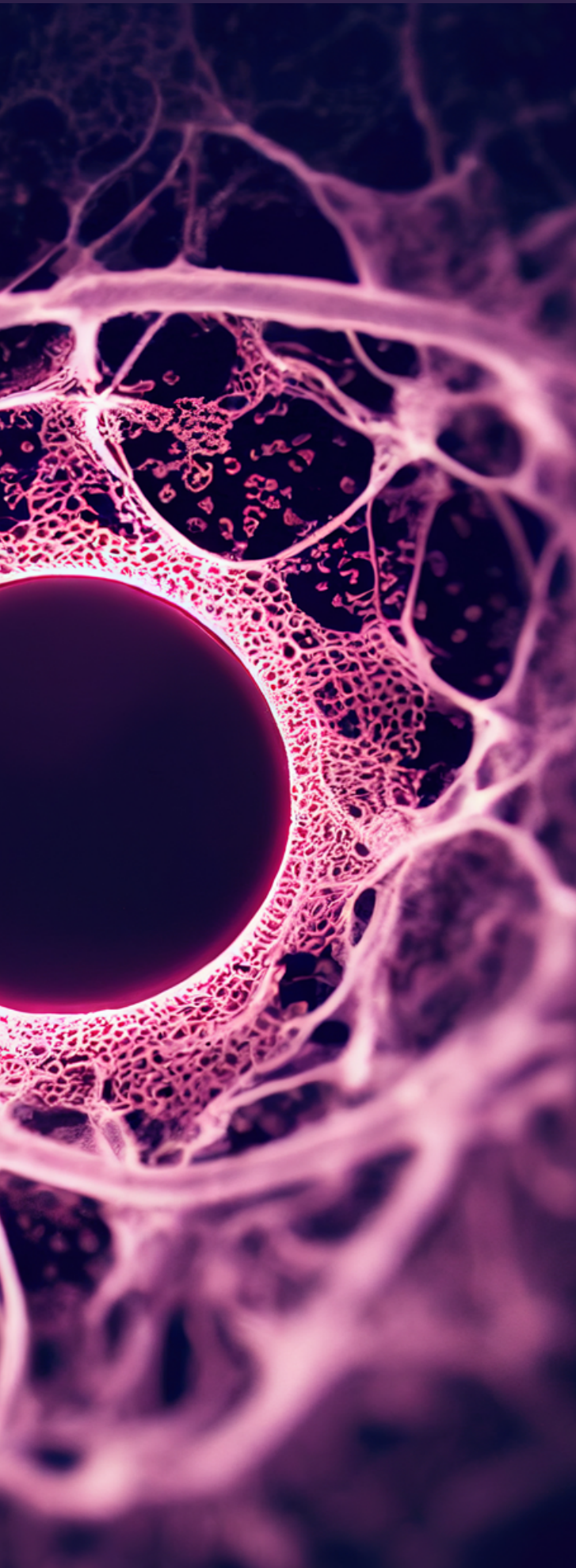
- ◆ Support the operationalisation of EUnetCCC with specific inclusion of breast cancer centres.
- ◆ Promote and incentivise uptake and certification within the ECIBC quality assurance scheme for breast care services, together with linked workforce initiatives (e.g. EU-level curricula and certification).
- ◆ Support Member States in breast cancer workforce education and retention, e.g. promoting access among specialist cancer nurses to evidence-based education according to an EU-wide framework developed by the European Oncology Nursing Society.<sup>46</sup>
- ◆ Promote integrated, patient-centred breast cancer pathways that link diagnosis, specialist multidisciplinary treatment, and survivorship, benefitting from digital information sharing, as recommended by the OECD.<sup>8</sup> This could be achieved via best practice sharing between countries and other cancer types, e.g. as in Denmark and Sweden.
- ◆ Extend measures to strengthen the digital health capacities of breast cancer centres (e.g. telemedicine and data sharing), leveraging the cCANPlus Joint Action with specific inclusion of breast cancer centres and initiatives.
- ◆ Promote patient access to high-quality surgical care via EU-wide recognition of the role of breast cancer specialist, positioning breast cancer surgery as a core expertise required within CCCs, supporting harmonised specialist training and accreditation, and using expert network mechanisms to foster surgical expertise and capacity building.



**EU policies and initiatives should ensure that all patients can benefit from advances in precision oncology, data science and AI via:**

- ◆ An EU initiative (e.g. a Communication) toward a comprehensive genetic and genomic testing strategy, including breast cancer, that aims to ensure awareness and access for all patients to appropriate, high-quality biomarker testing according to harmonised guidelines.
- ◆ Measures to better align the assessment, authorisation, and reimbursement of breast cancer biomarkers and corresponding targeted therapies, enabling parallel consideration of both the medicine and test.
- ◆ Measures to promote evidence-based public funding and reimbursement of breast cancer biomarker testing, and investment in biomarker laboratory facilities where necessary, among all Member States.
- ◆ Development of a value assessment process for precision oncology treatments for breast cancer, incorporating real-world evidence and broader societal cost-effectiveness aspects. This process should guide pricing and reimbursement decisions, ensure equitable access, and adapt to new data while considering long-term health and system-wide benefits.
- ◆ Promoting harmonised data collection and sharing across breast cancer registries in all Member States spanning early and advanced disease, including via comprehensive and uniform implementation of the EHDS Regulation in relation to both primary and secondary uses of data supporting advances in breast cancer care, research, and innovation.
- ◆ Further evaluating and supporting evidence-based AI implementation in breast cancer care across Member States.





## **Advanced or metastatic breast cancer (MBC) is stage IV breast cancer in which the cancer cells have spread beyond the original tumour to other organs or tissues, most commonly the bones, lungs, liver, or brain.**

Approximately 5-10% of breast cancers are metastatic at diagnosis and ~20-30% of women diagnosed with early breast cancer will eventually progress to MBC.<sup>4,5</sup>



### **Did you know?**

**Breast cancer commonly spreads to the brain—one study found that this occurred in almost half of patients with MBC.<sup>47</sup>**

EU and national cancer policies often focus on early-stage disease, leaving MBC underrepresented. However, MBC differs in important ways from early-stage disease, including:

- ▶ MBC has a far worse prognosis than early-stage disease. On average patients survive for between 2 and 5 years after diagnosis, depending on subtype.<sup>6,7</sup> Overall, only one third are alive after 5 years.<sup>7</sup>
- ▶ MBC cannot be cured and treatment options are limited across biomarker subtypes.<sup>6,7,29,48,49</sup>
- ▶ In light of these aspects, MBC has a profound impact on QoL among patients and families and its unique

and under-recognised challenges can leave patients feeling isolated and stigmatized.<sup>7</sup> Improving patients' QoL is therefore a priority alongside extending life.

MBC warrants urgent and specific policy attention and action.<sup>7,21,22</sup> Key priorities include the need to generate more data on MBC, to enable access to specialist MBC care, and to assess and value innovation in ways that reflect the particular challenges of MBC.



## Did you know?

**Patients with metastatic triple-negative breast cancer on average have a 15% chance of surviving past 5 years.<sup>50</sup>**

## Generating data

Comprehensive and accurate data are vital to inform cancer care services and policies. However, most national breast cancer registries do not capture on relapses. Rather, MBC cases are counted as cancers of the areas to which the breast cancer has spread. This hinders our understanding of how many patients progress to MBC, and the associated disease course, treatment patterns, clinical outcomes, QoL impacts, and costs. As a result, the scale and impact of MBC is poorly understood, contributing to its under-prioritisation in policies and resource allocation.

The importance of collecting high-quality MBC data has been recognised by key organisations.<sup>7</sup>

For example, the European Society of Breast Cancer Specialists' (EUSOMA) Requirements of a Specialist Breast Centre now mandate collection of data on all people with breast cancer, including those with MBC.<sup>34</sup>

**Comprehensive and accurate data are vital to inform cancer care services and policies. However, most national breast cancer registries do not capture on relapses(...) This hinders our understanding of how many patients progress to MBC**

## Promoting access to specialist MBC care

Patients with MBC have different clinical and psychosocial needs than those with early-stage disease and hence require access to patient-centred, guideline-led care by multidisciplinary teams with specific MBC expertise.<sup>7,32,35</sup> However, at present, this access is limited by a shortage of workforce expertise and other equity barriers.

## Assessing & valuing innovation

Although MBC is currently incurable, targeted treatments can extend survival and improve patient's QoL.<sup>7</sup> In the United States, the 5-year overall survival rate for MBC has increased from 23% in 1992–1999 to 33% in 2015–2021 in association with the introduction of new therapies,<sup>7</sup> with improvements also in QoL.

However, access to these therapies varies widely between countries, and there remains an urgent need to address these disparities and ensure access to guideline-recommended standards of care and innovative treatments for all patients with MBC. Challenges in evaluating new therapies for MBC require specific policy attention.

- ▶ Typically, new treatments are first tested on patients with advanced disease, ensuring that those with the greatest need can access potentially life-extending therapies. MBC presents unique challenges that demand a tailored, ethical approach to trial design. For example "crossover" trials,

which allow patients in control groups to switch to the investigational treatment after disease progression or once efficacy is demonstrated, can increase trial participation, maintain trust, and ensure that patients receive promising therapies when they need them most.

- ▶ However, crossover designs make it difficult to measure overall survival, which currently is widely considered the "gold standard" endpoint for testing and valuing new cancer medicines. When patients switch treatments mid-trial, it becomes difficult to determine whether survival benefits are due to

the investigational drug or the crossover itself. To address this, progression-free survival (PFS) is often used as a surrogate endpoint. PFS measures the time during which a patient lives without disease progression and is unaffected by treatment crossover. It provides a meaningful and quantifiable measure of clinical benefit and results are achieved faster. However, it does not always correlate with improved overall survival, which remains the most relevant endpoint for patients.

- ▶ Regulatory bodies such as the EMA and United States Food and Drug Administration (FDA), together with the European Society for Medical Oncology

(ESMO), recognise PFS as a valid endpoint for approval decisions. However, barriers remain since many HTA bodies and payers still rely heavily on overall survival data for treatment approval decisions, which can delay access to innovative treatments. A compromise could be to accept PFS as a valid endpoint for early decision-making, allowing earlier access to new therapies, while still requiring long-term data and impact on survival and QoL for later discussion and final decisions.

To improve access to novel therapies for MBC, policy and decision-making frameworks must evolve so that people living with MBC receive care that is not only scientifically sound but also ethically responsible and patient-centred.



## Recommendations

EU policies and initiatives should give specific attention to addressing the needs of patients with MBC by:

- ◆ Developing an EU-level action plan for metastatic cancers, including MBC. This should be directed to address current deficiencies, including in data collection, workforce expertise and capacity, HTA, patient support and patient representation in policymaking.
- ◆ Seeking the unique perspectives of patients with MBC (e.g. via dedicated hearings within Parliament Committees) and incorporating these within tailored policies that address their specific needs.
- ◆ Supporting national cancer registries to collect comprehensive, harmonised MBC data.
- ◆ For example, a specific project could be funded to provide EU-wide guidance, standards, and platforms for reporting data by stage for breast and other cancers, via the European Network of Cancer Registries, aligned with the EHDS. When available, comparable data should feed into the European Cancer Inequalities Registry (ECIR). Pilots underway in [England](#) and [Australia](#) should be studied to inform the implementation of data collection across Europe.
- ◆ Fostering equitable MBC specialist access within-countries via a project to identify barriers and share best-practices on addressing these.
- ◆ Enabling EU-wide MBC expertise and capacity building in cancer centres via a dedicated project, building on existing networks and initiatives, e.g. JANE and [JANE-2](#).
- ◆ Fostering enhanced access to innovative treatments for MBC by supporting Member States to better recognise their value. This could include: 1) Nuanced definitions of unmet need in EU legislation, 2) Aligning stakeholders (including patients, clinicians, regulators, HTA bodies, payers, and industry) on the value of patient-centric crossover trial designs and surrogate endpoints such as PFS, with these approaches better recognised in value assessment methodologies for early decision-making and earlier access while maintaining the need for long-term data on impact on survival and QoL, 3) Systematically incorporating patient and clinician perspectives into HTA and policy decisions, 4) Modernise national value assessment evidence standards to give sufficient weight to clinically meaningful surrogate endpoints and reflect the impact of MBC and prioritise timely access to effective treatments.
- ◆ Promoting continued R&D in MBC diagnosis, treatment, and support via EU investments and fostering national investment.

The needs of patients with MBC should also be met in the policies relating to patient empowerment and QoL (Section 6).

## All patients with breast cancer should be empowered to participate in shared decision-making regarding their care and relevant policies.

Beyond clinical outcomes, holistically improving the wellbeing of cancer patients is central to reducing the impact of breast cancer in Europe.<sup>2,8</sup> These dimensions have had less attention under EBCP actions to date<sup>17</sup> and now warrant increased attention.

### *Shared decision-making*

Patients need access to up-to-date information and opportunities for meaningful dialogue during decision-making points during their care pathway. Beyond their own care, breast cancer patients should be empowered to participate in decision-making processes relating to policies, including on services, access and research.

At present, education and communication approaches often fail to meet the needs of patients with breast cancer, especially those with MBC, and to adequately support shared decision-making.<sup>7</sup> Digital eHealth tools hold promise to improve patients' access to information and data, including their own medical records.

TBCT welcomes the flagship European Cancer Patient Digital Centre initiative, underway via the European Cancer Information Portal ([EU-CIP](#)) project. This EU-wide platform aims to provide high-quality information and for national and regional cancer information portals, which should include breast cancer. More specifically, TBCT welcomes the [CHOICE](#) project, which aims to facilitate shared decision-making by empowering patients with genetic profiles conferring increased breast cancer risk, equipping healthcare practitioners, and engaging policymakers and the public.



### *Patient-reported outcomes*

TBCT has previously called for actions to raise awareness on the unmet needs and realities of living and working with breast cancer. Moreover, TBCT urges all parties to work toward improving the QoL and emotional wellbeing of cancer patients and their families as a priority, as well as extending life. For example, the EU-supported European Oncology Quality of Life Toolkit (EUonQoL-kit) offers promise to promote standardised QoL assessment among patients and survivors across Europe.<sup>7</sup> TBCT also welcomes the EMA's encouragement for the use of patient experience data during medicines development.<sup>51</sup>



## Recommendations

EU policies and initiatives should give increased attention to improving QoL among patients with cancer, including breast cancer, including by:

- ◆ Initiatives to support Member States to: 1) provide patients with evidence-based educational tools and other eHealth resources that meet the needs of patients at all stages of their breast cancer and 2) support and incentivise health professionals to improve patient-centred communication and apply shared decision-making.
- ◆ Mechanisms to ensure that breast cancer patients are involved in all relevant EU policy and research decision-making.
- ◆ Implementing mechanisms to integrate patient perspectives in the ECIBC European Breast Cancer Guidelines and Quality Assurance Scheme.
- ◆ Supporting platforms that educate patients to allow them to participate as expert breast cancer patient advocates to help inform policy and research at EU and national level.
- ◆ Promoting patient inclusion in decision-making among Member States. The EU HTA process could offer an example.<sup>52</sup>
- ◆ Further projects to implement the assessment of patients' QoL and experience throughout 1) the breast cancer care pathway, including both early disease and MBC, and 2) the development, regulatory approval, and HTA of new breast cancer medicines.
- ◆ Supporting the adaptation of the EUonQOL-kit for breast cancer.





## **We call on EU policymakers to place breast cancer at the heart of a renewed and sustained EU commitment to tackle cancer.**

The EBCP and other initiatives have helped lay the foundations for true progress in reducing one of Europe's most impactful cancers for patients, families, health systems and economies. The region has many of the tools it needs to provide its citizens with world-leading prevention, detection, treatment, and support. But to ensure all Europeans benefit equally, the EU must foster consistent, equitable access to these tools in all Member States. Moreover, it should leverage EU-level resources, expertise, and data to drive further progress and ensure that the region's research and innovation ecosystem is fit for purpose to meet persisting unmet needs.

TBCT urges EU policymakers to act on these recommendations and its participants stand ready to collaborate on their implementation.



## Summary of recommendations

### Prevention

EU policies and initiatives should ensure that all EU citizens benefit from EU-wide and national actions to reduce breast cancer risk factors, including by:

- ▶ Promoting higher spending on breast cancer risk awareness and prevention by Member States.
- ▶ Driving awareness of breast cancer prevention and screening via 1) an annual European Breast Health Day on 15 October and 2) EU-wide guidance and best practices to help Member States reach communities at greatest risk.
- ▶ Funding projects to further explore the potential role of targeted breast cancer prevention based on patients' risk levels.

### Screening

EU health policies and initiatives should further support Member States to increase participation in population-based breast screening programmes and to assess and leverage new technologies via:

- ▶ A dedicated budget in the next MFF to support breast cancer screening programme implementation and uptake.
- ▶ Dedicated health and cohesion/structural funds to support implementation of evidence-based measures to improve participation and technical assistance packages.
- ▶ An EU Breast Health Day to raise awareness of screening.
- ▶ EU institutional backing for an EU-wide breast cancer screening awareness campaign for use in all Member States, targeting communities with low participation.
- ▶ Measures to further promote and incentivise participation and certification within the ECIBC Quality Assurance Scheme for breast cancer services.
- ▶ Research funds to further evaluate the potential role of AI in supporting national breast cancer screening programs and informing EU guidelines.
- ▶ Extended EU-wide actions to evaluate the role and implementation of targeted screening based on genetic testing.

### Diagnosis & treatment

In order to ensure all patients have access to specialist multidisciplinary care, EU policies and initiatives should:

- ▶ Support the operationalisation of EUnetCCC with specific inclusion of breast cancer centres.
- ▶ Promote and incentivise uptake and certification within the ECIBC Quality Assurance scheme for breast care services, together with linked workforce initiatives.
- ▶ Support Member States in breast cancer workforce education and retention, e.g. promoting access among specialist cancer nurses to evidence-based education.
- ▶ Promote integrated, patient-centred breast cancer pathways that link diagnosis, specialist multidisciplinary treatment, and survivorship, benefitting from digital information sharing.
- ▶ Extend measures to strengthen the digital health capacities of breast cancer centres (e.g. telemedicine and data sharing), leveraging the cCANPlus Joint Action with specific inclusion of breast cancer centres and initiatives.
- ▶ Promote patient access to high-quality surgical care via EU-wide recognition of the role of breast cancer specialist, positioning breast cancer surgery as a core expertise required within CCCs, supporting harmonised specialist training and accreditation, and using expert network mechanisms to foster surgical expertise and capacity building.

EU policies and initiatives should ensure that all patients can benefit from advances in precision oncology, data science and AI via:

- ▶ An EU initiative (e.g. a Communication) toward a comprehensive genetic and genomic testing strategy, including breast cancer, that aims to ensure awareness and access for all patients to appropriate, high-quality biomarker testing according to harmonised guidelines.
- ▶ Measures to align the assessment, authorisation, and reimbursement of breast cancer biomarkers and therapies, enabling parallel consideration of both the medicine and test.

# 07 Conclusion: call to action

- ▶ Measures to promote evidence-based public funding and reimbursement of breast cancer biomarker testing, and investment in biomarker laboratory facilities where necessary, among all Member States.
- ▶ Development of a value assessment process for precision oncology treatments for breast cancer, incorporating real-world evidence and broader societal cost-effectiveness.
- ▶ Promoting harmonised data collection and sharing across breast cancer registries in all Member States spanning early and advanced disease, including via comprehensive and uniform implementation of the EHDS Regulation in relation to both primary and secondary uses of data supporting advances in breast cancer care, research, and innovation.
- ▶ Further evaluating and supporting evidence-based AI implementation in breast cancer care across Member States.

## **Metastatic breast cancer**

EU policies and initiatives should give specific attention to addressing the needs of patients with MBC by:

- ▶ Developing an EU-level action plan for metastatic cancers, including MBC.
- ▶ Seeking the unique perspectives of patients with MBC (e.g. via dedicated hearings within Parliament Committees) and incorporating these within tailored policies that address their specific needs.
- ▶ Supporting national cancer registries to collect comprehensive, harmonised MBC data.
- ▶ Fostering equitable MBC specialist access within-countries via a project to identify barriers and share best-practices on addressing these.
- ▶ Enabling EU-wide MBC expertise and capacity building in cancer centres via a dedicated project, building on existing networks and initiatives
- ▶ Fostering enhanced access to innovative treatments for MBC by aligning stakeholders on the value of patient-centric crossover trial designs and surrogate endpoints such as PFS, with these approaches better recognised in value assessment methodologies for early decision making and earlier access while maintaining the need for long-term data on impact on survival and QoL.
- ▶ Promoting continued R&D in MBC diagnosis, treatment, and support via EU investments and fostering national investment.



## **Patient empowerment & QoL**

EU policies and initiatives should give increased attention to improving QoL among patients with cancer, including breast cancer, including by:

- ▶ Initiatives to 1) support Member States to provide patients with evidence-based educational tools and other eHealth resources that meet the needs of patients at all stages of their breast cancer and 2) support and incentivise health professionals to improve patient-centred communication and apply shared decision-making.
- ▶ Mechanisms to ensure that breast cancer patients are involved in all relevant EU policy and research decision-making.
- ▶ Implementing mechanisms to integrate patient perspectives in the ECIBC European Breast Cancer Guidelines and Quality Assurance scheme.
- ▶ Supporting platforms that educate patients to allow them to participate as expert breast cancer patient advocates to help inform policy and research at EU and national level.
- ▶ Promoting patient inclusion in decision-making among Member States.
- ▶ Further projects to implement the assessment of patients' QoL and experience throughout 1) the breast cancer care pathway and 2) the development, regulatory approval, and HTA of new breast cancer medicines.
- ▶ Supporting the adaptation of the EUonQOL-kit for breast cancer.

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