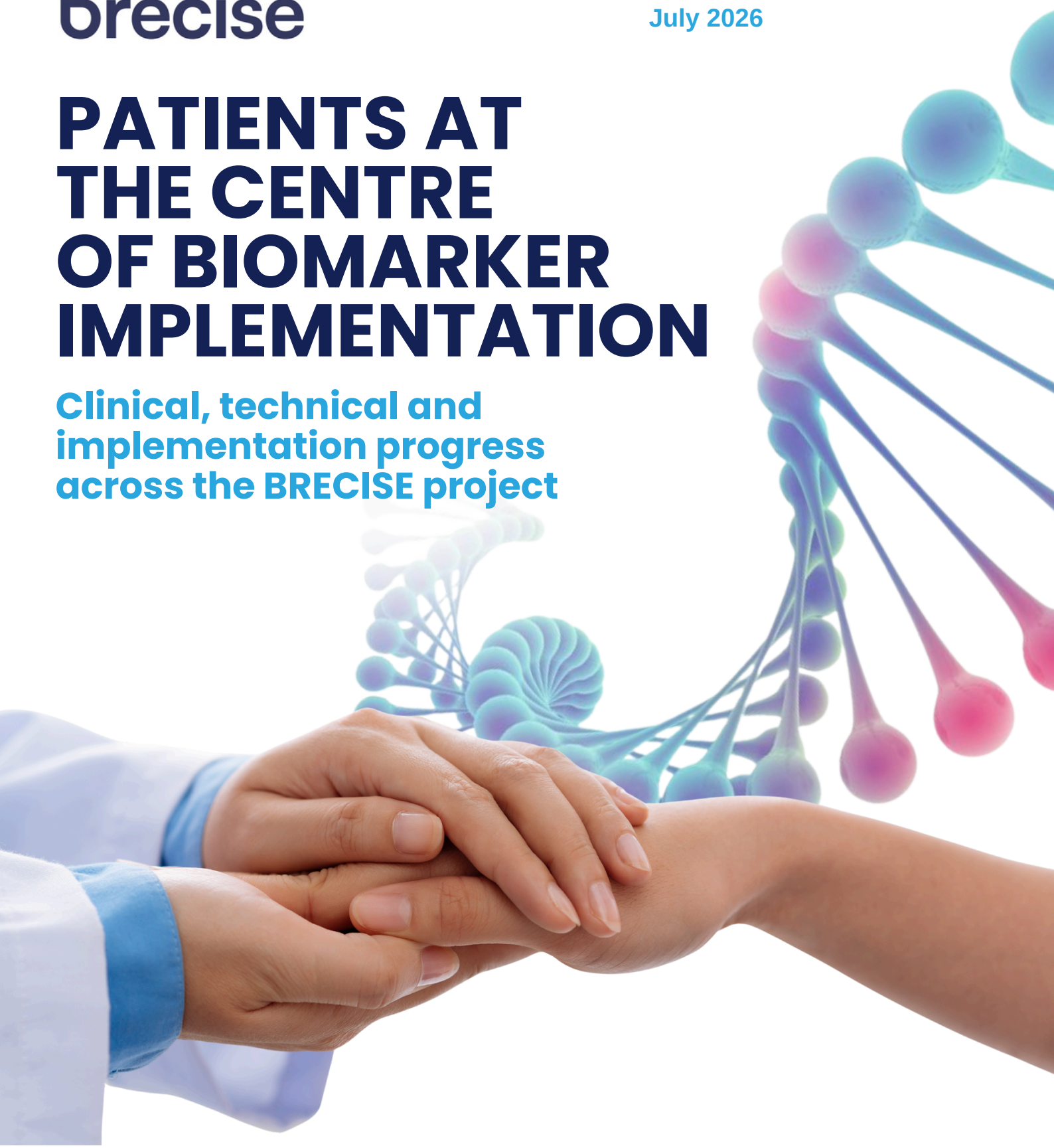
brecise

Newsletter – Issue No. 2
July 2026

PATIENTS AT THE CENTRE OF BIOMARKER IMPLEMENTATION

Clinical, technical and implementation progress across the BRECISE project



innovative health initiative

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Funded by the State Secretariat for Education, Research and Innovation (SERI), Switzerland.

This project has received funding from the Innovative Health Initiative Joint Undertaking (IHI JU) under Grant Agreement No. 101194784. The JU receives support from the European Union's Horizon Europe research and innovation programme, COCIR, EFPIA, EuropaBio, MedTech Europe, and Vaccines Europe

COCIR efpia EuropaBio MedTech Europe from diagnosis to cure Vaccines Europe

Co-funded by the European Union

From Shared Plans to Coordinated Delivery

The BRECISE consortium met in **London** on **12-13 March 2026** for its second face-to-face **plenary meeting.** Partners reviewed progress across the five clinical use cases, biomarker testing, data infrastructure, regulatory planning, health technology assessment and patient engagement.

The meeting marked a transition from project design towards coordinated clinical and analytical work in prostate and bladder cancer. It also confirmed the shared approach that will connect biomarker evidence with clinical workflows, regulatory requirements and health-system decision-making. This issue places particular emphasis on patient partnership. For BRECISE, innovation is relevant only when it supports better decisions, reduces unnecessary interventions and treatment burden, and can be implemented equitably in real healthcare settings.

- **London Plenary** 12-13 March 2026
- **Coordinated Clinical & Analytical work**
- **Implementation in real settings**
- **Patient Partnerships at the Centre**

AT A GLANCE:

All five use cases have been defined, with harmonised clinical, technical and implementation requirements.

Clinical protocols and ethics activities are progressing, while the PRECISE2 study is approved and open for enrolment.

The BRECISE Clinical Data Lake is operational and supports secure, structured data exchange.

AIMAC and ELLOK have mapped 79 patient and citizen education resources to guide future co-created materials.

Molecular profiling, computational drug assignment, organoid development and ex vivo testing are moving forward.

Patient perspective from AIMAC and ELLOK

This section presents the patient perspective contributed by Associazione Italiana Malati di Cancro, parenti ed amici (AIMAC) and the Hellenic Cancer Federation (ELLOK), the two patient organisations participating in BRECISE.

Rapid advances in precision oncology are transforming cancer diagnosis and treatment, creating important opportunities to tailor care to each patient. However, **scientific progress alone does not guarantee better outcomes.** Its value depends on translating innovation into clinical practice and ensuring that new technologies are accessible, clinically meaningful, and responsive to patients' needs.

From a patient perspective, innovation matters when it leads to earlier and more accurate diagnoses, more effective and less burdensome treatments, fewer unnecessary interventions, and better quality of life and survival. It should also help reduce inequalities in access to high-quality cancer care, so that the benefits of precision medicine reach all patients, regardless of where they live.

In this context, **BRECISE aims to accelerate the clinical implementation of next-generation sequencing (NGS)-based, multimodal artificial intelligence (AI) biomarkers.** By generating robust evidence for their validation and supporting their integration into healthcare systems, the project addresses the limited availability of clinically validated biomarkers for routine use.

Through improved disease risk stratification, prediction of disease progression, and treatment selection, BRECISE aims to support personalised care pathways, reduce ineffective treatments and unnecessary toxicity, and contribute to more efficient, equitable, and patient-centred cancer care across Europe.

Why patient involvement matters:
For decades, research followed a traditional model: researchers designed studies, clinicians conducted trials, and patients participated. As precision oncology increasingly relies on technologies such as NGS and AI, this model must evolve. Progress requires patient organisations to be involved not as a final compliance step, but as active co-designers of research.

Within initiatives such as BRECISE, which aims to validate AI-driven biomarkers and improve treatment pathways for prostate and bladder cancer, patient experience should help guide the project. **Involving patients from the earliest design stages can ensure that complex, multimodal data remains aligned with the real-world needs of the people it is intended to support.**

Co-design helps ensure that every phase, from defining research questions to selecting clinical endpoints, reflects the realities of living with cancer. By working alongside scientists, clinicians and technology developers, patient organisations can keep research focused on outcomes that matter to people, rather than only on technical data markers.

Early collaboration can also improve trial design by making studies more accessible, reducing the burden of participation, and supporting recruitment and retention.

HELLENIC CANCER FEDERATION ELLOK aimac associazione italiana malati di cancro, parenti e amici

FIVE REAL-WORLD CASES

ASPRO-BIO Use Case 1

ASPRO-BIO is validating the PDE4D7 biomarker to improve risk stratification for men with prostate cancer under active surveillance. Study protocols have been completed, approvals for tissue and urine components are progressing, and transcriptomic workflows are being tested on archived tissue. The aim is to support safer surveillance, reduce unnecessary biopsies and identify higher-risk disease earlier.

PARIS-BIO Use Case 2

PARIS-BIO is evaluating the PCAI ImmunoScore to predict which patients with high-risk prostate cancer may benefit from neoadjuvant androgen receptor signalling inhibition before surgery. The protocol and ethics approvals are in place, while sequencing procedures and the biomarker panel are being refined. The intended benefit is more targeted treatment selection and less exposure to ineffective therapy.

IMPASSE-BIO Use Case 3

IMPASSE-BIO is validating the BCAI ImmunoScore in high-risk non-muscle invasive bladder cancer to predict response to BCG treatment. The study is supported by an established clinical cohort and existing ethics arrangements, with molecular profiling, follow-up analysis, organoid work and ex vivo testing advancing. Earlier identification of likely non-responders could support timely consideration of alternative treatment.

PRECISE2 Use Case 4

PRECISE2 is evaluating a multimodal liquid biopsy biomarker that combines circulating tumour DNA with an immune gene panel in metastatic bladder cancer. The protocol is approved and enrolment is open. The study aims to identify early non-response to immune checkpoint inhibitors, allowing treatment to be adapted sooner and unnecessary toxicity to be reduced.

ProACT Use Case 5

ProACT is the prototype-driven use case and focuses on clinical workflow integration, decision support and predictive models. It has been defined for connection with ASPRO-BIO and will examine how biomarker-guided care can be incorporated into routine clinical systems in a usable and sustainable way.

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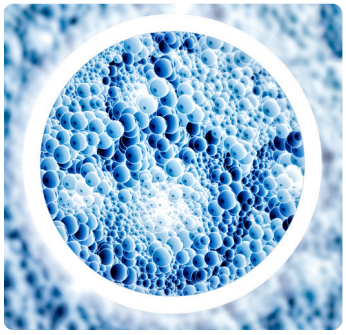
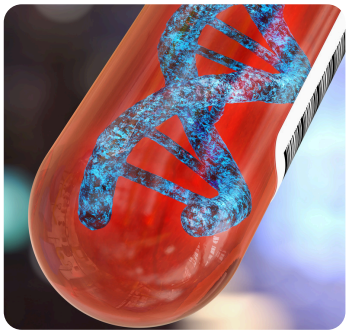
From Samples to Decision Support



Molecular profiling

Partners are evaluating RNA sequencing, DNA sequencing and targeted transcriptomic approaches for prostate and bladder cancer samples. This includes TempO-Seq testing directly from formalin-fixed tissue and the optimisation of sample preparation and analytical workflows. In parallel, genomic analyses of bladder cancer datasets are being used to identify potential drug sensitivities and resistance mechanisms for subsequent functional testing.



Patient-derived organoids and ex vivo testing

A bladder cancer patient-derived organoid biobank is being developed to support drug sensitivity studies. At the time of the London plenary, 47 models had been established, 33 additional models were in progress, and more than 40 had undergone DNA and RNA sequencing. The next steps include quality control, molecular characterisation, expansion of the biobank and pilot drug screens. Ex vivo prostate tumour testing is also progressing. Current work addresses tissue sourcing, assay miniaturisation, cryopreservation and adaptation to biopsy-sized samples, to make functional testing feasible when only limited tissue is available.

Digital infrastructure and implementation readiness

The BRECISE Clinical Data Lake
The shared BRECISE Clinical Data Lake became operational in February 2026. It provides a secure, role-based environment for storing and exchanging clinical, molecular and other project data, and can connect with partner analysis tools. Partners are now developing a common codebook to define data items, formats and metadata across the use cases, supporting consistent entry, interoperability and reliable cross-site analysis.

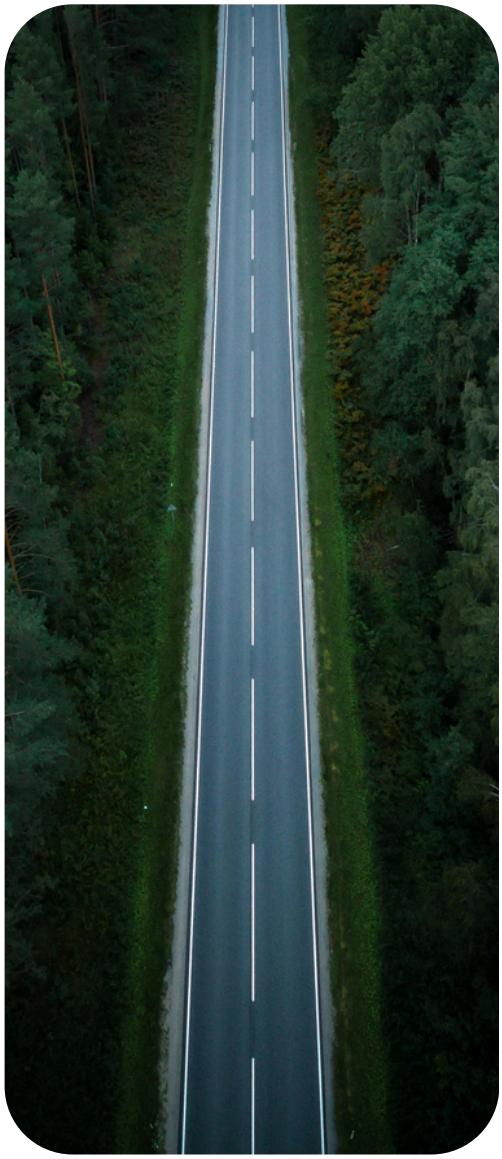
Biomarker readiness, regulation and health-system value
BRECISE is refining its Biomarker Readiness Level approach to connect scientific validity and analytical performance with clinical evidence, technical maturity and real-world implementation. The framework is supported by indicators covering clinical and patient value, regulation, reimbursement, health technology assessment and economic considerations.
Work is also progressing on intellectual property, market acceptance, regulatory planning and cost-effectiveness. The consortium is considering how clinical, safety, cost and quality-of-life evidence should be collected so that BRECISE solutions can be assessed by regulators, payers and healthcare systems.

Recent scientific dissemination and project visibility

New publication on patient-relevant immunotherapy models
BRECISE partner Crown Bioscience published research in Frontiers in Immunology on advanced 3D in vitro platforms for testing cancer immunotherapies. By combining organoid co-culture models with ex vivo patient tissue models, the work aims to better represent the tumour microenvironment and support more predictive, patient-relevant research.

BioClavis at AACR 2026
BioClavis presented research at the AACR Annual Meeting 2026 on TempO-Seq transcriptomic profiling and machine learning for breast cancer recurrence risk stratification. Although conducted outside the BRECISE disease areas, the work demonstrates expertise relevant to the project's transcriptomic and biomarker validation activities.

BRECISE at MedTech Forum 2026
Genomate Health represented BRECISE at MedTech Forum 2026 in Sweden through a dedicated project poster. The presentation introduced the five use cases and highlighted how collaboration between industry, academia, healthcare organisations, patient groups and regulatory experts can help move biomarkers from discovery into clinical decision-making.



Looking ahead

No single organisation or discipline can transform cancer care in isolation. As BRECISE moves forward, the impact of current efforts will depend on bridging the gap between patient advocacy and the technical, clinical and regulatory partners driving the project. The next step is to foster active and ongoing dialogue with AI developers, molecular biologists, oncologists and health economists, so that technology serves healthcare needs and patient priorities.

Moving forward, the collaboration will focus on turning innovative tools into real-world solutions. By working closely with scientific and technical partners, AIMAC and ELLOK will help ensure that AI-driven biomarkers are not only accurate, but also practical and understandable for both doctors and patients. The patient organisations will also engage with healthcare authorities and wider stakeholder communities to support the integration of these technologies into national health systems and advocate for fair and equal access. By leveraging the combined reach of AIMAC and ELLOK, BRECISE can share its framework across Europe and contribute to a patient-centred standard for precision oncology. By combining the lived experience of patients with the expertise of scientific and technological partners, BRECISE is not only developing tools for the future. It is contributing to an implementation ecosystem in which innovation, patient needs and equity are advanced together.

What comes next in 2026

Advance recruitment, approvals, sample processing and data generation across the clinical use cases.

Evaluate mapped patient education resources and begin co-creating accessible, multilingual materials.

Expand the bladder cancer organoid biobank and progress pilot drug sensitivity testing.

Further refine the data, regulatory, HTA, cost-effectiveness and sustainability pathways.

A patient-centred route to implementation

BRECISE aims to demonstrate that successful biomarker implementation requires more than technical accuracy. It also depends on meaningful patient involvement, understandable information, trustworthy data governance, evidence of clinical and economic value, and practical integration into healthcare workflows.

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