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FAST-TRACKING CANCER BIOMARKERS FROM PROMISE TO PRACTICE

innovative health initiative

Schweizerische Eidgenossenschaft
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COCIR Advancing Healthcare
efpia
EuropaBio The European Association for Bioindustries
MedTech Europe from diagnosis to cure
Vaccines Europe
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Just over nine months after its launch under IHI Call 7, BRECISE is moving from planning to delivery. As we approach the holiday season, this first newsletter sets out what BRECISE is about, why it matters for patients and health systems, and how it will contribute to Europe's wider cancer and data agenda in the years ahead.

Across Europe, clinicians and patients are being asked to embrace precision oncology, yet the tools to do so are not always available, validated or reimbursed. In prostate and bladder cancer in particular, decisions around active surveillance versus radical treatment, systemic intensification, BCG use or immunotherapy are still often based on imperfect risk stratification and limited predictive information. The result is familiar: some patients receive too much treatment, too late or of the wrong type; others do not receive the intensified or alternative care they would actually benefit from.

BRECISE – **Biomarker Research and Evaluation for Clinical Implementation and Supporting Sys-tems Enhancement** – was created to tackle this gap in a very practical way. Rather than adding an other layer of abstract methodology, it aims to show, in real time and in real clinical settings, how robustly evaluated biomarkers can be embedded into care pathways, supported by appropriate digital infrastructure, regulatory planning, health technology assessment (HTA) and policy dialogue. The ambition is not only to validate four concrete biomarker solutions in prostate and bladder cancer, but also to leave behind a reusable "playbook" that others can apply in different disease areas and health systems.

The project brings together a cross-sector partnership spanning biomarker discovery and diagnostics, clinical oncology, radiology and pathology, AI and data platforms, regulatory science, HTA, industry, training and patient engagement. This reflects a central lesson learned from previous initiatives: biomarkers do not fail because science is weak, but because the chain from laboratory to bedside is fragmented. BRECISE is designed to connect that chain – from analytical performance and clinical evidence to regulatory files, business models and policy relevance.

This newsletter provides an overview of the project's core elements – the four real-world use cases, the Biomarker Readiness Level (BRL) framework, the digital platform and the policy dimension – as well as a short update on what has been achieved in the first nine months and what to expect in 2026.

What is BRECISE?

BRECISE is an Innovative Health Initiative (IHI) project dedicated to one core challenge: how to move promising cancer biomarkers out of research silos and into everyday clinical practice.

Despite rapid advances in precision oncology, very few biomarkers are robustly validated and rou-tinely used to guide treatment decisions. Many hospitals still lack reliable tools to predict:

- Who can safely remain on active surveillance.
- Who needs intensified systemic therapy.
- Who is unlikely to respond to BCG instillations or immunotherapy.

The consequences are avoidable toxicity, missed opportunities for early intervention, and inefficient use of scarce health-system resources. BRECISE aims to change that, starting with prostate and bladder cancers, which together account for more than 1.7 million new cases globally each year.

Five real-world use cases

BRECISE is built around five concrete, real-world use cases, not theoretical models. While the first four use cases are already underway, a fifth is currently in the planning and development phase. Together, they address critical decision points in prostate and bladder cancer care, ensuring that BRECISE's scientific and technological innovations are directly linked to clinical needs and patient benefit.

- **Use Case 1: Improving Active Surveillance in Prostate Cancer:** For men with low-risk prostate cancer, active surveillance allows treatment to be safely delayed, but current monitoring methods can lead to uncertainty and unnecessary biopsies.

BRECISE is validating the PDE4D7 biomarker to better distinguish truly low-risk patients from those at higher risk of disease progression. This use case aims to improve risk stratification, reduce patient burden, and support safer, more confident surveillance strategies

- **Use Case 2: Predicting Response to Neoadjuvant Therapy in High-Risk Prostate Cancer:** In high-risk prostate cancer, some patients may benefit from hormone-based therapy before surgery, but responses vary widely. BRECISE is validating the PCAI ImmunoScore to predict which patients are most likely to respond to neoadjuvant androgen receptor signalling inhibitors. This approach supports personalised treatment selection, helping clinicians avoid ineffective therapies while improving outcomes for patients most likely to benefit.
- **Use Case 3: Identifying Response to BCG Treatment in Bladder Cancer:** For patients with high-risk non-muscle invasive bladder cancer, treatment with Bacillus Calmette–Guérin (BCG) can be effective, but not all patients respond. Through the BCAI ImmunoScore, BRECISE aims to identify patients who are likely to benefit from BCG therapy and those who may require alternative strategies. Earlier identification of non-responders could reduce toxicity, prevent disease progression, and improve quality of life.
- **Use Case 4: Predicting Immunotherapy Response in Metastatic Bladder Cancer:** Immunotherapy has transformed care for metastatic bladder cancer, yet only a subset of patients responds. BRECISE is evaluating the NOVI I/O BC biomarker to predict which patients are unlikely to benefit from immune checkpoint inhibitors. This use case aims to support earlier treatment adjustments, avoid unnecessary side effects, and enable more efficient use of healthcare resources.

The BRECISE framework and Biomarker Readiness Level

BRECISE is not only validating four tests – it is building a framework that others can use.

At the centre of this is the Biomarker Readiness Level (BRL) concept, which maps biomarkers along a transparent maturity scale:

- From early discovery and analytical validation,
- Through prototype development and clinical performance studies,
- To pre-industrial maturation and integration into real clinical workflows.

This framework will:

- Clarify what type of evidence, technology development and regulatory planning is expected at each stage.
- Align expectations between clinicians, regulators, payers, industry and patients.
- Provide a practical roadmap that can be reused beyond prostate and bladder cancer, and even beyond oncology.

Data, AI and the BRECISE platform

To make this possible, BRECISE is establishing a shared digital platform that will integrate clinical, imaging, molecular and biomarker data in a secure, FAIR-compliant environment.

Built around the Philips Clinical Data Lake and connected to AI and advanced analytics tools, the platform will:

- Allow harmonised data collection across sites and technologies.
- Support cohort building, predictive modelling and outcome analysis.
- Align with emerging European frameworks such as the European Health Data Space, the AI Act and the In Vitro Diagnostic Regulation.

In short, the platform is designed to turn fragmented datasets into a powerful, reusable resource for biomarker evaluation and clinical decision support.

Policy and health-system perspective

BRECISE has been conceived not only as a research project, but as a **policy-relevant demonstrator** for Europe's wider cancer and health-data agenda.

By translating biomarker development into a clear BRL scale and concrete clinical use cases, BRECISE can support:

- Implementation of **Europe's Beating Cancer Plan** and the Cancer Mission, by providing tools to improve early detection, treatment personalisation and survivorship in prostate and bladder cancer.
- Discussions around **reimbursement and HTA**, by linking biomarker maturity to evidence packages, cost-effectiveness analyses and real-world outcomes that payers and HTA bodies can actually use.
- Operationalisation of the **European Health Data Space**, by showing how securely shared, high-quality datasets can accelerate innovation while respecting governance, ethics and patient trust.
- The rollout of the **AI Act** and **IVDR**, by illustrating how AI-enabled diagnostic support and in vitro diagnostics can be developed and assessed within a coherent regulatory and meth-odological framework.

In practical terms, BRECISE will generate:

- Policy-relevant insights on how biomarker-guided pathways affect resource use, waiting times, overtreatment and under-treatment.
- Recommendations for integrating biomarker testing into national cancer control plans, clinical guidelines and procurement strategies.
- A reusable methodological and digital blueprint that other regions and disease areas can adapt when planning their own precision medicine programmes.

Through targeted dialogue with ministries of health, cancer plan leads, regulators, HTA agencies and patient organisations, BRECISE aims to ensure that its outputs do not remain in project reports, but inform real decisions on investment, service design and access.

Nine months in: what has been achieved?

During 2025, the consortium has focused on laying strong foundations:

- Co-designing the four clinical use cases, including inclusion criteria, endpoints and work-flows.
- Drafting study protocols, informed consent documents and ethics/regulatory submissions.
- Defining the core components of the BRECISE framework and the BRL guidance.
- Designing the architecture of the BRECISE platform and agreeing a common "codebook" for data collection across all sites.
- Launching communication, policy and engagement activities to ensure that the project is visible to clinicians, regulators, policymakers, patients and the wider public.

This early work prepares the project for a decisive shift into full clinical and analytical activity in 2026.

Looking ahead to 2026

In the coming year, BRECISE will:

- Begin recruitment at scale into the four clinical studies and start generating the first major datasets.
- Test and refine the BRL-based framework in a real regional healthcare setting.
- Deepen engagement with regulators, HTA bodies, payers and policymakers to define regulatory roadmaps, value propositions and market-access strategies for the biomarker solutions.
- Roll out training and public-facing materials to build literacy and confidence in biomarker-guided care among healthcare professionals and patients.
- Start translating technical and clinical findings into concrete policy messages, including options for guideline adaptation, procurement models and performance indicators.

The overarching goal remains clear: by the end of the project, the project's biomarkers solutions should be close to regulatory phase, supported by a robust framework and platform that can be applied to aditional biomarkers and disease areas.

A seasonal note

The first nine months of BRECISE have been about alignment, design and building trust across disciplines and sectors. The next phase will be about evidence and impact – demonstrating how smarter biomarker use can translate into earlier diagnosis, better-targeted treatment and improved outcomes for patients with prostate and bladder cancer.

On behalf of the BRECISE consortium, we thank all partners and stakeholders for their commit-ment to date and wish you a restful holiday season. We look forward to sharing further updates in early 2026 as BRECISE moves from promise to practice.

BRECISE Kick-Off Meeting – Madrid, March 2025

The BRECISE project officially launched with a successful kick-off meeting in Madrid on March 20–21, 2025. Over two days, consortium partners came together to align strategies, discuss work packages, and ensure that the project's research remains clinically relevant. This meeting marked an important milestone in our journey to advance biomarker-driven precision medicine and transform cancer care.

Capturing Insights from BRECISE's Kick-Off Meeting

During the BRECISE kick-off in Madrid (March 20–21, 2025), interviews were conducted with participants to capture their perspectives and document the start of the project. These interviews are now available on the project's YouTube channel and are being shared across BRECISE's social media platforms.

Upcoming BRECISE Plenary Meeting

BRECISE is looking forward to its next face-to-face plenary meeting, which will take place in London on 12–13 March 2026. The meeting will be held near the EAU Congress (EAU26) at ExCeL London, allowing participants the opportunity to attend both events.

The plenary will start at 12:00 on 12 March and conclude at 14:00 on 13 March, giving plenty of time for networking, discussions, and collaboration. Final details about the venue and the agenda will be shared in early 2026. Stay tuned for updates!

Fresh from LinkedIn

- BRECISE at Vision Europe 2030: Insights from Xenia Beltrán on Biomarkers & Precision Oncology
- We're on YouTube! The BRECISE project is expanding its communication channels.
- From Precision Promise to Practice: BRECISE at ESMO 2025

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