From Biomarker Discovery To Clinical Decision

Brecise consortium

FACTS & FIGURES

Start date: January 1, 2025
End date: December 31, 2029
IHI Grant Agreement No.: 101194784
IHI/EU contribution: €13,615,935.25
Industry contribution: €9,397,760
Total Cost: €23,013,695.25
Project website: www.brecise.eu

CHALLENGE:

- Many biomarkers lack sufficient large-scale clinical validation.
- Clinicians cannot reliably predict which patients will benefit from specific treatments.
- Patients may be overtreated or exposed to ineffective therapies.
- Regulatory and health technology assessment pathways are complex.
- Integrating NGS and multi-modal AI tools into hospital workflows remains challenging.

APPROACH & METHODOLOGY:

BRECISE translates biomarker research into clinical practice by standardising testing, bridging research and regulatory pathways, and developing frameworks for healthcare integration.
It leverages AI and digital health tools for biomarker interpretation and patient stratification while engaging healthcare professionals, patients and policymakers through training, guidelines and targeted outreach.

CLINICAL USE CASES:

BRECISE validates five clinical biomarker use cases across prostate and bladder cancer:

PDE4D7 for improved risk stratification in prostate cancer active surveillance;
PCAI ImmunoScore to predict response to neoadjuvant hormonal therapy/ARSI;
BCAI ImmunoScore to predict BCG response and progression risk in high-risk bladder cancer;
Liquid biopsy biomarkers to predict response to immune checkpoint inhibitors in metastatic bladder cancer; and
Prototype workflow demonstrating integration of validated biomarkers into clinical decision-support systems.

VALUE OF IHI COLLABORATION:

The IHI public-private partnership connects expertise in oncology, genomics, artificial intelligence, clinical research, regulatory science, health technology assessment, healthcare implementation and patient engagement.

This cross-sector collaboration creates the ecosystem needed to validate biomarkers across real clinical settings and support their progression from scientific development towards safe, scalable adoption in healthcare systems.

MISSION:

To make clinically meaningful biomarkers usable in everyday cancer care, helping translate biomarker research into better-informed, more personalized treatment decisions for patients with prostate and bladder cancer.

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