

BRECISE USE CASE #3: The BCAI ImmunoScore Biomarker – Enhancing Bladder Cancer Treatment

Introduction

Bladder cancer is a common and aggressive disease, often requiring intensive treatment strategies. Patients with high-risk non-muscle invasive bladder cancer (HR-NMIBC) are typically treated with Bacillus Calmette-Guérin (BCG) therapy, an immunotherapy designed to reduce recurrence and progression.

However, BCG therapy fails in up to 40% of patients, leading to tumor progression and worse outcomes. Currently, clinicians have no predictive tools to determine which patients are likely to fail BCG therapy before starting treatment.

As part of BRECISE, researchers aim to validate the BCAI ImmunoScore biomarker, a gene expression-based tool designed to stratify bladder cancer patients before treatment and identify those at high risk of failing BCG therapy.

How Will BCAI ImmunoScore Work?

The BCAI ImmunoScore measures immune-related gene expression levels in bladder tumors. By analyzing RNA sequencing data from tumor samples, researchers will classify patients as likely responders or non-responders to BCG therapy.

Key features of BCAI ImmunoScore include:

- Stratification of HR-NMIBC patients into low-risk vs. high-risk groups for disease progression.
- Prediction of BCG failure before treatment initiation, allowing for earlier alternative therapy selection.
- Identification of molecular pathways linked to treatment resistance, potentially guiding future immunotherapy strategies.

Why is This Important?

- Identifies Patients at High Risk of Treatment Failure – Enables clinicians to proactively adjust treatment plans.
- Allows for Early Intervention with Alternative Therapies – Reduces the likelihood of tumor progression and metastasis.
- Reduces Unnecessary Exposure to Ineffective Treatments – Lowers treatment burden and healthcare costs.

Next Steps in BRECISE

As part of BRECISE, the BCAI ImmunoScore biomarker will be validated in a multi-center prospective clinical study. Researchers will:

- Analyze tumor samples from HR-NMIBC patients before BCG treatment to determine predictive accuracy.
- Compare BCAI ImmunoScore risk classifications with real-world patient outcomes, assessing disease progression and survival rates.
- Explore molecular pathways enriched in high-risk patients, such as immune checkpoint signaling (PD-1, CTLA-4), to identify potential alternative treatment strategies.

By validating BCAI ImmunoScore, BRECISE aims to improve bladder cancer treatment selection, ensuring that high-risk patients receive timely and effective therapies, while low-risk patients can safely remain on standard BCG protocols.



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.

