brecise

BRECISE USE CASE #4:
The NOVI I/O BC Biomarker – Personalizing Immunotherapy for Metastatic Bladder Cancer

Introduction

Metastatic bladder cancer (also known as metastatic urothelial carcinoma, mUC) is a highly aggressive disease with limited treatment options and poor survival rates. Immune checkpoint inhibitors (ICIs) have transformed treatment strategies, particularly for patients who are ineligible for cisplatin-based chemotherapy. However, only about 30% of patients respond to ICIs, leaving many exposed to costly and potentially toxic treatments without benefit.

The BRECISE project aims to validate the NOVI I/O BC biomarker, a liquid biopsy-based test designed to predict early which patients are unlikely to respond to ICIs. By identifying non-responders sooner, clinicians can adjust treatment strategies earlier, potentially switching patients to more effective therapies before disease progression worsens.

How Will NOVI I/O BC Work?

The NOVI I/O BC biomarker integrates two key molecular components:

1. Circulating Tumor DNA (ctDNA) Dynamics – Detects early changes in tumor burden and biological activity, reflecting response or resistance to ICIs.
2. Whole-Blood RNA Sequencing (RNAseq) – Measures immune cell adaptation and proliferation, providing insight into the tumor microenvironment.

By monitoring longitudinal gene expression changes, NOVI I/O BC aims to:

- Predict early non-responders to ICI therapy, allowing for timely treatment modifications.
- Provide a non-invasive, blood-based alternative to imaging scans, reducing the need for frequent radiological evaluations.
- Enable more personalized immunotherapy decisions, improving patient outcomes.

Why is This Important?

- Saves patients from ineffective treatment – Prevents prolonged exposure to ICIs in patients unlikely to respond.
- Allows doctors to switch to better alternatives sooner – Facilitates earlier transitions to second-line treatments, preventing rapid disease progression.
- Reduces unnecessary toxicity and costs – Minimizes side effects from unnecessary immunotherapy cycles, optimizing healthcare resources.

Next Steps in BRECISE

The NOVI I/O BC biomarker will undergo validation in a prospective clinical study within BRECISE. The study will:

- Recruit patients with metastatic bladder cancer receiving ICIs and track their treatment response.
- Analyze serial blood samples before and after treatment initiation, assessing ctDNA and immune transcriptome changes.
- Compare biomarker predictions with real-world patient outcomes, validating its accuracy in identifying early non-responders.
- Refine the multi-modal predictive model, incorporating machine-learning algorithms to enhance clinical decision support.

By validating NOVI I/O BC, BRECISE aims to set a new standard for immunotherapy decision-making, ensuring that patients receive the most effective treatment as early as possible.

innovative health initiative

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