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A transatlantic perspective on the integration of Immuno-Oncology Prognostic and Predictive Biomarkers in innovative clinical trial design

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Abstract

Immuno-therapeutics aim to activate the body's own immune system against cancer and are one of the most promising cancer treatment strategies, but currently limited by a variable response rate. Biomarkers may help to distinguish those patients most likely to respond to therapy; they may also help guide clinical decision making for combination therapies, dosing schedules, and determining progression versus relapse. However, there is a need to confirm such biomarkers in preferably prospective clinical trials before they can be used in practice. Accordingly, it is essential that clinical trials for immuno-therapeutics incorporate biomarkers. Here, focusing on the specific setting of immune therapies, we discuss both the scientific and logistical hurdles to identifying potential biomarkers and testing them in clinical trials.

Abbreviations
EORTC : European Organization for Research and Treatment of Cancer
NCI-MATCH : National Cancer Institute- Molecular Analysis for Therapy Choice
RECIST : Response Evaluation Criteria In Solid Tumors
SITC: Society for Immunotherapy of Cancer
SPECTA : Screening Patients for Efficient Clinical Trial Access

Keywords
Immune therapies, PD-L1, biomarkers, clinical trial, tumor micro-environment

I. Introduction

Immuno-therapeutics represents a promising class of agents in oncology. Immuno-oncology (IO) approaches aim to activate the body's own immune system against cancer. Despite successes, response to immunotherapy occurs in a minority of patients. Attempts to improve the efficacy of immunotherapy include novel combination therapies and