Standardization and clinical implementation of liquid biopsy assays - IMI's CANCER-ID

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INTRODUCTION

CANCER-ID (www.cancer-id.eu) is a five-year (2015-2019) international public-private partnership project supported by Europe’s Innovative Medicines Initiative (IMI). The consortium of currently 40 partners from 14 countries (Fig. 1) aims at the establishment of harmonized liquid biopsy protocols for patient sample collection, pre-analytical sample handling, and sample and bioinformatic analyses, and actionable information guiding patient selection for personalized treatment.

CANCER-ID tests and supports the development of standards for liquid biopsy as well as the clinical implementation of liquid biopsy-based protocols in the clinical setting. This includes interaction with regulatory bodies, such as EMA (European Medicines Agency) Innovation Task Force (ITF) and CDSBEO/DMCA (U.S. Center for Drug Evaluation and Research/Food and Drug Administration) Clinical Pathway Innovation (CFPIM), to support future adoption of liquid Biopsies in multi-centred worldwide clinical studies.

At the core of CANCER-ID’s activities in the liquid biopsy field is the evaluation of technologies for circulating tumor cell (CTC) circulating tumor DNA (ctDNA), microRNA (miRNA) and exosome extraction, isolation and analysis.

Liquid biopsy protocols are being implemented in an observational study evaluating the utility of analyzing PD-1 (programmed death-ligand 1) expression on CTCs in non-small cell lung cancer (NSCLC) and metastatic breast cancer. To this end, the potential predictive value of monitoring treatment response towards immune checkpoint inhibition (IC) is assessed in advanced NSCLC patients at the University Medical Center Groningen (UMCG) as well as in two ICICI chemotherapy combination studies in triple-negative breast cancer and luminal B breast cancer, respectively. run by the University of Oslo (ALKS, ClinicalTrials.gov ID: NCT03176785) and University Clinical Trials.ano BV. ID: NCT01401989.

The aim is to assess whether the allelic frequency of a mutational hotspot as a potential marker for tumour mutational burden (TMB) or the number of PD-L1-positive/overall tumor cell count. Different time points is indicative of treatment success.

As a follow-up activity of the CANCER-ID program, the European Liquid Biopsy Society (ELBS) is currently being established. The ELBS will be open to all interested liquid biopsy stakeholders worldwide as a platform to exchange ideas and experiences.

The CANCER-ID consortium

The CANCER-ID consortium is funded by IMI (Fig. 1). This public-private partnership between the EU Commission and the European Federation of Pharmaceutical Industries and Associations (EFPIA) provides a legal framework for addressing unmet challenges in the healthcare sector. All partners are as equally engaged in the project, with the exception of Janssen (US) and ABBOTT (US), which support the project with specific competencies.

In 2015, academic and clinical research groups, public research organizations, small and medium-sized enterprises (SMEs), and pharmaceutical and diagnostic corporations joined forces to evaluate technologies and establish analytical and clinical evidence for the liquid biopsy field.

The academic leaders of CANCER-ID, Professor Klaus Pantel (UK, Germany), who has published >500 reports on liquid biopsy and marker-based diagnostic methods, and Professor Leon Terstappen (Universtiy Of Twente, The Netherlands), developer of the TAC-approved methodology for CTC detection system, are pioneers in the field of blood-based cancer biomarkers.

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