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 pre-analytical 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 clinical implementation of liquid biopsy-based protocols in the clinical setting. This includes interaction with regulatory bodies, such as the European Medicines Agency (EMA) Innovation Task Force (ITF) and CDSF/PTDA (U.S. Center for Drug Evaluation and Research/Food and Drug Administration) Clinical Pathway Innovation (CPIM) Initiative, to support future adoption of liquid biopsies in multi-centered worldwide clinical studies.

At the core of CANCER-ID’s activities in the liquid biopsy field is the evaluation of CANCER-ID tests and supports the development of standards for liquid biopsy as well as clinical implementation of liquid biopsy-based protocols in the clinical setting. This includes interaction with regulatory bodies, such as the European Medicines Agency (EMA) Innovation Task Force (ITF) and CDSF/PTDA (U.S. Center for Drug Evaluation and Research/Food and Drug Administration) Clinical Pathway Innovation (CPIM) Initiative, to support future adoption of liquid biopsies in multi-centered worldwide clinical studies.

The University Medical Center Hamburg-Eppendorf (UKE, Hamburg) is currently involved in the ‘European Liquid Biopsy Society’ (ELBS) (Fig. 7) with the following goals:

- Foster the introduction of liquid biopsy into clinical practice.
- Develop guidelines for liquid biopsy-compatible protocols.
- Foster the introduction of liquid biopsy into clinical practice.
- Establish interactions between academic and industry as well as other related initiatives (e.g. The US-based Blood Profiling Atlas in Cancer, BloodPAC; FNIH).
- Provide a platform for regulatory agencies, healthcare providers and patient advocacy groups.
- Foster the implementation of liquid biopsy tests into clinical trials.
- Develop guidelines and provide training in liquid biopsy for medical scientists, pathologists and military personnel.
- Address regulatory issues and support the implementation of liquid biopsy in clinical practice.

In this study, CANCER-ID partners following a well-defined protocol have involved 111 patients with advanced stage non-small cell lung cancer (NSCLC) and metastatic breast cancer. To this end, the CANCER-ID tests and supports the development of standards for liquid biopsy as well as clinical implementation of liquid biopsy-based protocols in the clinical setting. This includes interaction with regulatory bodies, such as the European Medicines Agency (EMA) Innovation Task Force (ITF) and CDSF/PTDA (U.S. Center for Drug Evaluation and Research/Food and Drug Administration) Clinical Pathway Innovation (CPIM) Initiative, to support future adoption of liquid biopsies in multi-centered worldwide clinical studies.

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