**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 best practice protocols for patient sample collection, pre-analytical sample handling, sample and bioinformatic analyses, and actionable information guiding patient selection for personalized treatment.

**CANCER-ID** 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 EMA (European Medicines Agency) Innovation Task Force (ITF) and CDSBIO/ITF (U.S. Center for Drug Evaluation and Research/Food and Drug Administration) Clinical Pathway Innovation (CPIM), to support future approval 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 technologies for circulating tumor cell (CTC), circulating tumor DNA (ctDNA), microRNA (miRNA) and immune cell enrichment, isolation and analysis.

- Liquid biopsy protocols are being implemented in an observational study evaluating the utility of for PTM (prospero-dead/alive) expression on CTCs in non-small cell lung cancer (NSCLC) and metastatic breast cancer. To this end, the patient potential predictive value of monitoring treatment response to immune checkpoint inhibition (ICI) is assessed in advanced NSCLC patients at the University Medical Center Göttingen (UMCG) as well as in two ICICI clinical combination studies in triple-negative breast cancer and luminal B breast cancer, respectively, run by the University of Oslo (Akre, ClinicalTrials.gov ID: NCT01921019).

The aim is to assess whether the allelic frequency of mutations as a potential measure for tumor mutational burden (TMB) or the number of PD-L1-positive/overall checkpoint inhibition (ICI) is assessed in advanced NSCLC patients at the University Medical Center Hamburg-Eppendorf (UKE, Hamburg) is currently running the ‘European Liquid Biopsy Society’ (EUBS) (Fig. 7) with the following goals:

- Foster the introduction of liquid biopsy into clinical practice.
- Create interactions between academia and industry as well as other related initiatives (e.g. the US-based Blood Profiling Atlas in Cancer, BloodPAC IMPRINT).
- Provide a partner for regulatory agencies, healthcare providers and patient advocacy groups.
- Standardization of implementation of liquid biopsies into clinical trials.
- Develop guidelines and provide training in liquid biopsy for medical scientists, patients, and regulatory agencies.

Hence, there is a need to standardize liquid biopsy technologies. The standardization and clinical implementation of liquid biopsy assays - IMI's CANCER-ID consortium have led to plans for sustained activity in the field by academic and industrial partners.

**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.

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

The academic leaders of CANCER-ID, Professor Klaus Pantel (UKE, Germany), who has published >300 reports and high-impact review articles on disseminating tumor cells, and Leon Terstappen (Universitätsklinikum Ulm, Germany) are thanked for editorial assistance in the preparation of this paper, funded by Bayer AG.

**ACKNOWLEDGMENTS**

CANCER-ID is supported by Innovation Medicines Initiative (IMI) Joint Undertaking under Grant Agreement n° 115749, resources of which are composed of financial contribution from the European Union’s Seventh Framework Programme (FP7/2007-2013) and EFPIA companies’ in-kind contributions. Founder's agreed contributions were collected under signed informed consent.

Aurexel Life Sciences Ltd (www.aurexel.com) is thanked for editorial assistance in the preparation of this paper, funded by Bayer AG.

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**The European Liquid Biopsy Society**

- IMI's CANCER-ID project ended in December 2019. The requirement for continued data and sample storage, further updating of best practice documents and standard operating procedures (SOP) and scientific support of liquid biopsy proficiency testing henceforth will be handled in the field of analytical proficiency testing.

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

- Foster the introduction of liquid biopsy into clinical practice.
- Create interactions between academia and industry as well as other related initiatives (e.g. the US-based Blood Profiling Atlas in Cancer, BloodPAC IMPRINT).
- Provide a partner for regulatory agencies, healthcare providers and patient advocacy groups.
- Standardization of implementation of liquid biopsies into clinical trials.
- Develop guidelines and provide training in liquid biopsy for medical scientists, patients, and regulatory agencies.

For more information please visit the EUBS website.

**IMPACT**

- Improved patient selection for immune checkpoint inhibition (ICI) treatments

**Steadman**

**EFFORTS TO IMPROVE THE CTC yield in NSCLC patients**

In this study, CTC presence at baseline and CTC change after therapy was used as a stratification tool, and the percentage of early responders (partial and complete response according to RECIST 1.1) was significantly higher in patients with CTCs (CTC: OR=0.28, p<0.002; CTC+DR: OR=4.04, p=0.011 (Fig. 5))

- First-line data show that a decline in ctDNA mutation variant allele frequency (VAF) predicts progression-free survival (PFS) and overall survival (OS) (Fig. 6).

**EVALUATION OF CT-CORE**

In this case study, patients treated with ICIs, stratified for CTC presence at baseline.

**Support the implementation of liquid biopsy tests into clinical trials.**

- Support the introduction of liquid biopsy into cancer research and therapy.

- Focused on being included in May 2019 in 16th ESMO in Hamburg, Germany. For additional information please contact Prof. Klaus Pantel (pantel@uke.de).