Cancer treatment and monitoring through identification of circulating tumor cells and tumor related nucleic acids in blood (CANCER-ID)

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<table>
<thead>
<tr>
<th>Research Areas</th>
<th>At a Glance</th>
</tr>
</thead>
<tbody>
<tr>
<td>Tool Development</td>
<td>• Status: Active Consortium</td>
</tr>
<tr>
<td>Biomarker Research</td>
<td>• Year Launched: 2015</td>
</tr>
<tr>
<td>Basic Research</td>
<td>• Initiating Organization: Innovative Medicines Initiation</td>
</tr>
<tr>
<td>Data-Sharing Enabler</td>
<td>• Initiator Type: Government</td>
</tr>
<tr>
<td>Product Development</td>
<td>• Location: International</td>
</tr>
</tbody>
</table>

Abstract

CANCER-ID is a public-private partnership within the Innovative Medicines Initiative (IMI) with the aim to evaluate technologies for enrichment, isolation and analysis of Circulating Tumor Cells (CTCs), circulating free tumor DNA (ctDNA) and microRNAs (miRNAs) as biomarkers for cancer liquid biopsy.

Mission

The consortium aims to:

- Establish criteria for evaluation of different CTC isolation technologies;
- Develop sample collection and developing storage protocols (SOPs) allowing shipment and bio banking for collection and analysis at different research sites;
• Compare methods for the molecular analysis of CTCs with respect to correlation with primary tumor material, clinical outcome, treatment response and ctDNA status of patients;
• Evaluate different ctDNA/miRNA analysis methodologies in terms of compatibility with sample collection and storage as well as reproducibility in clinical samples;
• Develop database and data analysis infrastructure for correlative studies of CTCs, ctDNAs and miRNAs in clinical samples;
• Develop technologies for blood-based companion diagnostics ideally up to proof of clinical utility supporting regulatory approval. In order to show clinical utility CANCER-ID is aligned with three clinical studies enrolling Non-Small Cell Lung Cancer (NSCLC) patients:
  ◦ TRACERx
  ◦ NVALT-17
  ◦ SPECTAlung

Consortium History

2015 – Start of the consortium with a 5-year duration; integration of diagnostics companies as new partners to the project; Critical Path Innovation Meeting with FDA/CDER (Oct 2015); 52 presentations and 16 publications triggered by the project in year one.

Structure & Governance

Currently 37 partners from 13 countries in Europe and the US collaborate in 5 Work Packages (WPs) subdivided into different tasks. The WPs address the following topics:
 WP0: Implementation and evaluation of liquid biopsy technologies at different partner sites, SOPs for preanalytical sample handling
 WP1: Establishment of technologies and according protocols for CTCs, ctDNA and miRNA in Non-Small Cell Lung Cancer (NSCLC) clinical samples
 WP2: Establishment of technologies and according protocols for CTCs, ctDNA and miRNA in anti-HER2-treatment refractory metastatic breast cancer clinical samples
 WP3: Bioinformatics and data infrastructure
 WP4: Project management and dissemination

Both WPs and tasks have leaders from academia and industry to ensure optimal representation of...
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Different stakeholder needs and expertise. The Project Executive is formed by the academic project leader and the EFPIA coordinator together with their deputies and decides in biweekly teleconferences about administrative topics, and scientific and strategic positioning of CANCER-ID. The Project Executive reports to the General Assembly in which all partners convene once a year and have one vote to decide about topics of general relevance to the whole consortium. A Steering Committee consisting of the WP, and task leaders meets every 6 months to discuss and decide about scientific topics.

The Scientific Advisory Board (SAB) of the project consists of internationally renowned experts in the field of liquid biopsy and a patient organization. The SAB members are invited to the General Assembly of CANCER-ID and regularly updated about the progress of the consortium and asked for their input.

**Financing**

CANCER-ID has a total funding of currently €18.3 million, including IMI funding (€6.6 million), in-kind funding contributions from the European Federation of Pharmaceutical Industries and Associations (EFPIA; €7.6 million), and €2.9 million from other non-EFPIA companies.

**Intellectual Property**

CANCER-ID operates under the IMI intellectual property (IP) umbrella. IP to all discoveries is owned by the partner(s) who made a discovery within the project (foreground IP). Other participants are granted access rights to the foreground IP for research use, while the partners in possession of the IP have the right to out-license to third parties. Third parties may request access rights, which do not involve the ability to sublicense without receiving authorization from the IP-owning partners.

**Patent Engagement**

CANCER-ID reaches out to patient organizations and advocacy groups requesting their feedback on
technologies under evaluation in order to ensure involvement of patients into developments in the liquid biopsy field. One patient organization is part of the Scientific Advisory Board of CANCER-ID and other groups active in the field of non-small cell lung cancer or breast cancer are invited to interact with the consortium.

Data Sharing

Data are shared within CANCER-ID using a consortium database (original data and documents) and a password-protected portal linked to the consortium’s website (protocols, SOPs, administrative documents). An infrastructure for sharing clinical data across national and organizational borders that complies with the different regulations applicable to the various stakeholders is currently being planned.

Impact/Accomplishment

Dissemination activities in 2015:

- AACR poster about the project increasing ex-EU visibility
- 52 presentations
- 16 publications
- 25 press releases
- More than 3,000 visits on the website

Links/Social Media Feed

Homepage  www.cancer-id.eu
LinkedIn  CANCER-ID Group planned for May 2016

Points of Contact
Sponsors & Partners

Participant / Sponsor
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Terumo BCT, United States of America (James Ladtkow)
Illumina, United States of America (Jennifer Stone)
ANGLE Plc, United Kingdom (Michael O’Brien)

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