P2.06-039
Searching for Standards: Multicenter Ring Trials to Evaluate Technologies for the Enrichment of Circulating Tumor Cells

Topic: LAB, Other

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Background: Circulating tumor cells (CTCs), which can be found in the peripheral blood of cancer patients, represent a simple and minimal-invasive source for monitoring neoplastic evolution or response to anti-cancer therapy. In recent years, numerous technology platforms for the enrichment and molecular characterization of CTCs have emerged, but comparative results and data demonstrating clinical utility are lacking for most of these platforms. To overcome this, the Innovative Medicines Initiative (IMI) consortium CANCER-ID (www.cancer-id.eu), which represents a joint undertaking of experts from academia and pharmaceutical industry, joined forces to define standards in blood-based biomarkers including the evaluation of different CTC enrichment technologies.

Methods: CTC enrichment technologies including the CellSearch system, Parsortix PR1 and the Siemens filtration device were evaluated in a multicenter ring trial by using standardized spike-in samples of non-small cell lung cancer (NSCLC) cell lines, which were selected based on their different molecular/genetic features. NSCLC cells were spiked into blood of healthy volunteers with informed consent. To increase the comparability of results, spike-in samples were generated following well-defined protocols for pre-analytic sample handling including sample fixation, storage and shipment. Spike-in samples were subsequently analyzed using different CTC enrichment technologies by at least three CANCER-ID partners in a blinded way according to standard operating procedures (SOPs).

Results: To reflect clinically relevant disease subtypes, NSCLC cell lines were extensively profiled for copy number aberrations, mutational status (e.g. KRAS, EGFR), expression of cell surface antigens (e.g. EPCAM) as well as cell size. Based on this, cells lines with different molecular/genetic profiles were used to generate complex spike-in samples modeling the heterogeneity of real-life patient material. Spike-in samples were subsequently analyzed by at least three different CANCER-ID partners to determine sensitivity and specificity of the different platforms. In addition, comparative data was generated using the FDA approved CellSearch system, which represents the gold-standard for CTC detection and enumeration.

Conclusion: IMI CANCER-ID is a public-private partnership in the field of liquid biopsies with 37 partners from 13 countries providing access to a variety of CTC enrichment technologies and patient samples. Making use of this major advantage, we describe the first efforts to establish standards in CTC enrichment and molecular characterization by generating comparative data in a multicenter ring experiment. The results will be used to improve SOPs for the analysis of patient blood samples, which represents a promising tool to monitor disease progression and/or therapeutic response. Support: IMI JU & EFPIA (grand no. 115749).

Keywords: Innovative Medicines Initiative, Circulating tumor cells, liquid biopsy

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WINNERS Study: Does a Formal Interactive Patient Education Program Positively Impact Patient Outcomes and Satisfaction after Thoracic Surgery

Topic: LAB, Other

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Background: Post-operative complications in the thoracic surgery patient population can be costly to healthcare systems and devastating to patients and their families. The most common complications are respiratory, cardiac and gastrointestinal in nature. It is estimated that these complications occur at a rate of 3-5%. In an effort to improve patient outcomes, a nurse led