ImmunoTools *FlowISiAM* Award 2025

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FlowISiAM-FDG PET/CT

A Non-Invasive Liquid Biopsy Approach for early detection of cancer in combination with FDG PET/CT

Recognizing the inherent challenges in early cancer detection, particularly in asymptomatic individuals, the medical community is continuously seeking innovative and less invasive diagnostic methodologies. One particularly attractive and potentially transformative approach involves the proactive identification of asymptomatic individuals who exhibit specific laboratory markers suggestive of an underlying, as yet undiagnosed, malignancy. This strategy holds immense promise for improving patient outcomes by enabling earlier intervention and more effective treatment strategies, ultimately reducing morbidity and mortality associated with advanced-stage cancers. Research consistently shows that **macrophages** in cancer patients exhibit **elevated expression of tumor epitopes DNaseX (Apo10) and transketolase-like protein (TKTL1)**. This suggests these markers could signal the presence of cancer.

Unlike traditional tissue biopsies, which are invasive and often carry risks, liquid biopsy offers a minimally invasive alternative by analyzing biological fluid samples, such as blood. In this context, the *FlowISiAM* **test** represents a specific application of liquid biopsy. By quantifying the expression of Apo10 and TKTL1 in specific immune cells-macrophages - isolated from peripheral blood, the *FlowISiAM* test aims to provide a sophisticated yet accessible snapshot of the body's response to potential malignancy. This non-invasive test could help pinpoint individuals who would benefit most from a **whole-body, highly sensitive,**

and non-invasive cancer localization using FDG PET/CT. While PET/CT is a powerful imaging tool, it's not practical for widespread screening due to cost and radiation exposure. Therefore, the *FlowISiAM* **test** proposes a strategic pre-selection mechanism: by identifying individuals with elevated Apo10 and TKTL1 in their macrophages, it could act as a crucial filter, directing the high sensitivity of FDG PET/CT to those with a higher pre-test probability of malignancy. This targeted approach promises to enhance the cost-effectiveness and efficiency of cancer screening programs while minimizing unnecessary radiation exposure for the general population.

Despite the compelling theoretical underpinnings and the intuitive appeal of this approach, it is critical to acknowledge that **sufficient robust clinical data to definitively support this hypothesis are not yet available**. This project aims to bridge that gap. The project's objective is to perform the *FlowISiAM* test on patients with no previously known or treated malignancy who are undergoing routine FDG PET/CT examination. The primary goal is to **verify the concordance** between the PET/CT findings and the *FlowISiAM* test results for malignancy.

The results from this study are critical. They could provide the foundational evidence needed to explore the *FlowISiAM* test's role as a **tool for selecting individuals for highly sensitive malignancy screening with PET/CT with FDG**. This would represent a paradigm shift in cancer diagnostics, potentially enabling earlier detection in asymptomatic populations, leading to more effective treatments, improved prognoses, and ultimately, a significant reduction in cancer-related morbidity and mortality. The project's findings could therefore lay the groundwork for a more targeted, efficient, and patient-friendly approach to early cancer identification.

For persons bearing confirmed or suspected malignancy, the access to patient cohorts and blood samples is achieved by active recruitment performed by investigators at the department of Nuclear medicine. The *FlowISiAM* analysis is proposed to patients referred to FDG PET/CT as a part of routine clinical practice. The blood sampling does not represent any additional discomfort to patients since the intravenous access is necessary for FDG PET/CT examination anyway. For healthy persons (volunteers), the access to subject cohorts and blood samples is achieved by active recruitment performed by investigators.

ImmunoTools *FlowISiAM* AWARD for
Luba Hunakova and **Soňa Balogová** includes
antibodies for *FlowISiAM*, know how transfer and protocol, support regarding selection of specific antibodies against specific biomarkers from INVIGATE, expert assistance in evaluating the results obtained, and integration into the ImmunoTools *FlowISiAM* network.

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