CLINICAL EVALUATION STUDY

Health Innovation Hub Ireland

Project Sirius

Dublin City University (DCU) Project Sirius is a follow-on project from a European Union funded project, which successfully demonstrated automated and low-cost separation of Extracellular Vesicles (EVs). The use of Surface Enhanced Raman Spectroscopy with Artificial Intelligence to identify and classify EVs based on their cell of origin with exceptional accuracy levels has been demonstrated by several groups.

Principal PI, Prof. Tia Keyes, Co-PIs Prof. Damien King and Prof. Mark Roantree are leveraging their diverse scientific and technological strengths to combine a range of proven technologies to diagnose cancers from a blood sample with a very high degree of accuracy. Project Sirius is now developing a simple to use, one step, low-cost and scalable diagnostic platform.

Project Sirius has secured significant follow-on commercialisation funding from Enterprise Ireland.

About Health Innovation Hub Ireland

Health Innovation Hub Ireland (HIHI) was established by the Department of Business, Enterprise and Innovation and the Department of Health and is supported by Enterprise Ireland (EI) and the Health Service Executive (HSE) to drive collaboration between the health service and enterprise. We offer companies the opportunity for pilot and clinical evaluation studies and we provide the health service access to innovative products, services and devices that they may not otherwise be exposed to.

HIHI is built on the recognition that collaboration with enterprise can benefit patient care, patient pathways and outcomes. We assess all concepts for healthcare innovation from those on the frontline – from clinician to porter. We encourage healthcare professionals to get in touch with HIHI if they have an idea or solution to how something in your job might work better.

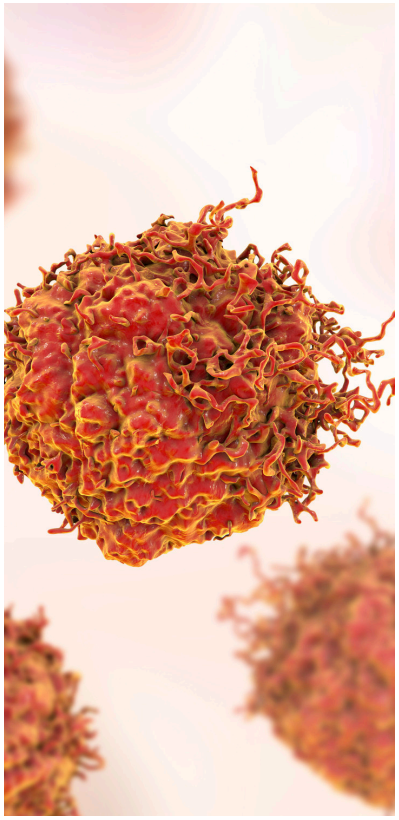
The Healthcare Challenge

Cancer occurs where cells in a specific part of the body grow and reproduce uncontrollably and lead to damage in surrounding healthy tissue. It's estimated that one in two people will develop some form of cancer in their lifetime. Early detection through screening improves treatment outcomes, as early-stage cancers are less likely to spread.

Screening programmes in Ireland exist for breast, bowel and cervical cancers offering routine checks for eligible individuals. However, cancers such as lung, pancreatic and ovarian currently lack national screening programmes. In these cases, patients are advised to see their GP if they experience symptoms. Ovarian cancer, in particular, often lacks clear early signs and diagnostic tests, leading to late diagnoses. Regardless of cancer type, a tissue biopsy is required for a definitive diagnosis and treatment planning.

Cancer screening programmes for specific cancers within specific patient demographics require a specific pathway of tests to identify cancers as early as possible. owever the current screening format is subject to false positives, which can lead to unnecessary tests and interventions in a health service under immense pressure. The ability for early identification of specific types of cancer from one blood test would be hugely beneficial to patients and the healthcare system.

The Healthcare Solution



Project Sirius aims to identify and classify specific extracellular vesicles called Exosomes. Exosomes are nanovesicles that are actively released from cells at each stage of tumour formation and are involved in promoting the growth, vascularisation, and even the dissemination and metastatic process of cancer. Exosomes range in size from 30–200 nm in diameter and are part of a broad class of Extracellular Vesicles.

Exosomes carry 'biological cargo', such as a variety of biomarkers from the tumour, including those involved in the tumorigenic process. Specifically, exosomes have been implicated in driving key attributes of malignant cell behaviour, including stimulation of tumour cell growth, suppression of the immune response, promotion of tumour cell migration and establishment of metastases, making them particularly useful as cancer biomarkers.

Project Sirius is a highly sensitive minimally invasive liquid biopsy (i.e blood sample) test. Project Sirius uses AI analysis of Surface Enhanced Raman Spectroscopy data to identify exosomes which are specific to each breast cancer subtype. Project Sirius is expected to detect cancers considerably earlier than current detection and in due course also could be used to detect other cancers where no gold standard diagnostic screening test exists or improve existing diagnostic screening pathways.

The project initially focussed on breast cancer but has applications across many different cancer types and may be particularly valuable for cancers that are not easily detected using current technology (e.g. dense breast tissue).

HIHI Role

Health Innovation Hub Ireland (HIHI) evaluates product need with key health opinion leaders or focus groups in HIHI clinical evaluations. A clinical evaluation is a key stage that allows feedback from end-users that can inform product application, market approach and offers the company an opportunity to build a cohort of clinical champions and supports. HIHI adds value by connecting clients with key opinion leaders.

HIHI facilitated five separate evaluation sessions with seven clinical experts including key personnel in the National Cancer Screening Programme and several consultant medical oncologists.

Outcome Report

It was recognised that Project Sirius has developed an innovative technology with the potential to significantly advance cancer screening and early detection. This technology may enable the identification of cancers much earlier than is currently possible using traditional diagnostic methods. In addition, it could potentially identify cancers that traditionally have no specific screening tests.

This lab-based test needs clinical trials with significant evidence prior to implementation in clinical practice. However, if real world results are similar to lab-based results, then it could be hugely impactful to cancer testing transforming patient outcomes and reducing the burden on healthcare systems.

Testimonials

"HIHI provided invaluable support during our clinical evaluation. Through their network, we were able to engage directly with expert clinicians who provided invaluable feedback on our innovation. Their insights not only validated key aspects of our solution but also highlighted practical considerations for further development. The access to clinical expertise through HIHI helped us refine our product in a real-world context. We're incredibly grateful for the opportunity and would highly recommend HIHI to any innovator looking to make a real impact in healthcare."

Peter Kidney, Commercial Lead, Project Sirius

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