# NHS Cancer Programme

Innovation in the early detection and diagnosis of cancer

Networking event

26 September 2023 Royal College of Physicians







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## **NHS Cancer Programme**

The NHS Cancer Programme leads the delivery of the NHS Long Term Plan ambitions for cancer:

- By 2028, the proportion of patients diagnosed at stage one and two will rise from just over half to three quarters.
- By 2028, 55,000 more people each year will survive their cancer at least five years after diagnosis.

The NHS Cancer Programme also supports the recovery of cancer services, helping systems to rise to the challenge of record high levels of suspected cancer referrals by increasing capacity and optimising existing pathways to diagnose more people faster.

# NHS Cancer Programme Innovation Open Calls

The Innovation Open Calls were developed by the NHS Cancer Programme, supported by SBRI Healthcare and the Accelerated Access Collaborative to facilitate the practical translation of leading research and innovation, and fast-track high quality, developed innovations into front-line settings. There have been two rounds of the Open Call competition, Round 1 was launched in March 2021 and Round 2 in April 2022. The competitions aim to identify market ready innovations that can support the NHS Long Term Plan ambition for the early detection and diagnosis of cancer.



# **SBRI Healthcare programme**

The Small Business Research Initiative (SBRI) Healthcare programme is funded by the Accelerated Access Collaborative and delivered in partnership with the Academic Health Science Networks (AHSNs). The programme accelerates technologies in the NHS, tackling unmet needs. It provides funding and support to early-stage innovations to enable feasibility testing and development, as well as to more mature products by supporting real world NHS implementation studies.

# Agenda of the day



#### 9.30 Registration

<u>Welcome and introductions</u> Chair: Professor Richard Gilbertson Programme Advocate for the NHS Cancer Programme Innovation Open Calls

#### 10.00 Welcome

10.05 Introduction - The NHS Cancer Programme Professor Peter Johnson, National Clinical Director for Cancer

#### Artificial Intelligence Chair: Mr Dominic Cushnan, Director AI, Imaging & Deployment, NHS England

10.15 Case study and Q&A

PinPoint Data Science Ltd

10.35 **Pitch session and Q&A** Skin Analytics Qure.ai

#### 10.55 Networking coffee break

#### <u>Genomics</u> Chair: Dr Louise Jopling, Commercial Director, Eastern Academic Health Science Network

#### 11.30 Pitch session and Q&A

The Royal Marsden NHS Foundation Trust (Guardant Liquid Biopsy) Newcastle upon Tyne Hospitals NHS Foundation Trust (MSI-PLUS assay) Institute of Cancer Research (BRCA-DIRECT)

Screening and proactive case finding Chair: Dr Jodie Moffat, Deputy Director, Policy and Strategy, NHS Cancer Programme

#### 12.00 Pitch session and Q&A

Cyted The Royal Marsden NHS Foundation Trust (Whole-body MRI) iPLATO

#### 12.30 Networking lunch

Improving pathways Chair: Victoria Doyle, Head of Transformation Programmes, East of England Cancer Alliance North

#### 13.30 Case study and Q&A Open Medical

13.50 Pitch session and Q&A Orion MedTech Ltd Modality Partnership endoscope-i Ltd University of Manchester (Elecsys® GAAD test, Roche)

> <u>Meeting close</u> Chair: Professor Richard Gilbertson

#### 14.20 Final remarks

#### 14.30 Meeting ends and networking coffee







"The companies and hospitals pioneering these innovative ideas are leading the way, and will help us to diagnose cancer earlier when it is easier to treat – potentially saving thousands of lives.

Our Open Call initiative is just one of many opportunities to attract and fast-track high quality innovations into the NHS, supporting the ambitions of the NHS Long Term Plan and vitally, improving care for our patients."

# Professor Peter Johnson, National Clinical Director for Cancer



"The projects supported by these awards are the first of many new devices and diagnostics that we hope will bring us closer to the day when no patient dies of cancer."

Professor Richard Gilbertson, Programme Advocate for the NHS Cancer Programme Innovation Open Calls



NHS Cancer Programme Innovation Open Calls -Impact

# 14 £21m+ 82 Innovations Invested **Applications** assessed supported **Participants** potentially 160K+ involved in implementations 10 270+ رسّ مرب 17 Cancer **AHSNs** Alliances supporting **Sites** involved in the projects participating implementation

# **Supported by the Cancer Alliances**

"The Lancashire and South Cumbria Cancer Alliance have been instrumental to the success of our previous SBRI Healthcare project. In the project funded through the Innovation Open Call they have been joined by the East of England and the Wessex Cancer Alliances, which have been exemplary. The rest of the Cancer Alliances have been critical to national adoption via the NHS Cancer Programme."

### Cyted

"The Cancer Alliances have supported us by inviting us to an innovation day and giving us a platform to share information about what we do. Some have also supported Trusts with funding to pilot our technology."

**Skin Analytics** 

"The support of the Surrey and Sussex Cancer Alliance has been extensive and ongoing, providing assistance throughout the entire project life cycle and facilitating connections with multiple providers in the region. With their assistance we have identified our lead provider sites. Thanks to the leadership of Greater Manchester Cancer Alliance we have established partnerships with Royal Salford and Bury, and are now working primarily at the provider level within this locality."

### **Open Medical**





Innovation Open Calls: Project Pitches from Innovators

# pinpoint

# Optimising urgent cancer referrals through an Al-driven blood test



Funding received by: NHS Cancer Programme Innovation Open Call 1

#### **Contact**

Name and role of Project Lead: Giles Tully, CEO Organisation: PinPoint Data Science Limited Email: giles.tully@pinpointdatascience.com Website: www.pinpointdatascience.com Twitter: @PinPointDataSci



# **CLINICAL PROBLEM**

Between 2022-23, 3 million people in England received an urgent referral for suspected cancer. This number has risen at approximately 10% every year for the last decade. The pressure on the system is unsustainable and the situation has only been exacerbated by the impact of COVID-19.

However, despite soaring patient numbers, only 6% of urgent suspected cancer referrals are ultimately diagnosed with cancer. The remaining 94% of patients (2.8 million people in 2022-23) do not have cancer at all.

An affordable solution is needed to triage patients by risk as they enter the referral pathway, relieve systemic pressure, free up capacity and more effectively focus resources on the patients that need help most.

# **PROPOSED SOLUTION**

The PinPoint Test is an affordable Al-driven blood test for cancer that promises to deliver intelligent triage and stratification of suspected cancer patients based on individual risk.

The test aggregates signal across 33 biomarkers to generate a single number: the chance a patient has cancer. Those at high risk can be prioritised for rapid investigation in secondary care, whilst those at lowest risk can be safely ruled out of the urgent suspected cancer referral pathway for further consultation with their GP. PinPoint data suggests up to 20% of current urgent suspected cancer referrals could be ruled out, equating to 600,000 patients per year based on 2022-23 data.

PinPoint is a purely software solution which upgrades existing systems, rather than replacing them. No procurement of novel hardware is required; the test is processed in existing pathology labs and is seamlessly integrated into NHS infrastructure, meaning low cost and low barriers to clinical rollout across regions.

- The PinPoint Test is in the final stages of a service evaluation in West Yorkshire & Harrogate, and preparation for deployment into three further regions has been completed in collaboration with Cheshire & Merseyside, Lancashire & South Cumbria, and Surrey & Sussex Cancer Alliances.
- Ongoing commercial talks under NDA with key global providers of laboratory services and equipment.



#### Early detection and diagnosis of cancer

Multi-cancer early detection, contributing to UK government ambition of 75% of all cancers being identified early by 2028:

- Rule out up to 20% of symptomatic patients at the start of the urgent suspected cancer referral pathway, reclaiming capacity for those at higher risk to move more quickly through to investigation.
- Identifying patients at greatest risk of cancer for prioritisation into secondary care; improving early detection and compliance with national targets for diagnosis and start of cancer treatment.
- Over 1 in 6 cancers are missed in an initial urgent suspected cancer referral, with diagnosis delayed by up to 12 months. PinPoint will help the system catch these cancers earlier.

#### Patient outcomes and experience

- PPIE sessions already run in five participating Cancer Alliance regions, demonstrating patient acceptability and support.
- Early identification of high-risk patients and the freed up capacity in referral pathways will lead to faster diagnosis and start of treatment, in turn improving clinical outcomes.
- Improved patient experience: rapid delivery of results will mean peace of mind for those ruled out so they can investigate other possible causes of their symptoms with their GP; and reassurance for those prioritised that everything possible is being done to see them quickly.

#### **Service delivery**

- Improved diagnostic capacity (University of Leeds, 2022 publication on Breast pathway).
- Reduced numbers in pathway will release clinic resources in Acute Trusts (see previous).
- Improved compliance to targets.
- A more robust pathway, better focused on those at high-risk will be more resistant to system shocks like COVID-19.



DERM, UKCA Class IIa AlaMD, enabling early diagnostic skin cancer assessments in the community



Funding received by: NHS Cancer Programme Innovation Open call 2

#### Contact

Name and role of Project Lead: Neil Daly (pictured), CEO Organisation: Skin Analytics Email: neil@skinanalytics.co.uk Website: <u>skin-analytics.com</u> LinkedIn: <u>/skin-analytics</u>, <u>/ndaly</u>



## **CLINICAL PROBLEM**

GPs see over 13 million patients annually for dermatological concerns resulting in more than a million referrals to secondary care. About half of these are urgent suspected skin cancer referrals of which only ~8% will be diagnosed with melanoma and squamous cell carcinoma, the majority of patients having been referred for benign skin lesions. Nationally, urgent suspected skin cancer referrals are increasing by more than 11% each year and this growing demand for dermatology appointments is placing significant pressure on the workforce, already dealing with 250 unfilled consultant posts.

## **PROPOSED SOLUTION**

DERM is an AI device that can be utilised to triage and assess skin lesions for cancer. DERM is the only Class IIa certified AI Dermatology medical device in the UK. Since launch in April 2020, it has analysed >60,000 cases across 13 NHS pathways.

Patients will be screened in Community Diagnostic Hubs using DERM to obtain a highly accurate skin lesion assessment, without the need for a face-to-face appointment. Ease of access and the ability to obtain a highly accurate assessment closer to home will encourage patients to present earlier with a concerning skin lesion. The specific urgent suspected cancer referral pathways will be adapted to the needs of the local clinical service and patient population.

# MARKET TRACTION & IMPLEMENTATION

 Skin Analytics has conducted over 67,000 skin cancer assessments since launching. Our first service was a remote skin cancer assessment service for Vitality Health which has since been expanded to cover Bupa members.

Within the NHS, Skin Analytics:

- Launched the world's first AI skin cancer pathway with University Hospitals Birmingham in April 2020.
- Has enabled over 12,000 of potential urgent suspected cancer referrals to be discharged while finding more than 5,300 cancers. Skin Analytics has gratefully received both an AI in Health and Care Award and an NHS Cancer Programme SBRI Healthcare Award to deploy our technology across the NHS.
- DERM is now live or launching with 13 NHS organisations across both primary care (pre-referral) and secondary care (post referral), including the following Community Diagnostic Hubs:

- Lancashire & South Cumbria ICB CDH, Herefordshire & Worcestershire ICB CDH, and Suffolk and North East Essex ICB CDH - Supported by SBRI Healthcare.

- Other sites: University Hospitals of Birmingham CDH, Mid Cheshire Hospitals NHS Foundation Trust, Ashford & St Peter's NHS Foundation Trust, University Hospitals Bristol and Weston NHS Foundation Trust, Chelsea & Westminster NHS Foundation Trust, University Hospitals of Leicester NHS Trust, University Hospitals of Birmingham NHS Foundation Trust, West Suffolk NHS Foundation Trust, Royal Devon University Healthcare NHS Foundation Trust, University Hospitals of Morecambe Bay NHS Foundation Trust.



"I am impressed with my treatment. The suspicious growth was excised 48 hours ago only 7 days after seeing my GP. I now await the results of dermatological analysis."

### Patient

## **IMPACT**

#### Early detection and diagnosis of cancer

We expect our innovation will improve early diagnosis of skin cancer by:

- Encouraging patients to present early.
- Increasing melanoma sensitivity at the first review to the level of a skin cancer specialist.
- Supporting the mismatch between dermatologist capacity and demand.

#### Evidence:

- Demonstrated through prospective clinical studies and in real world clinical settings, DERM can recognise melanoma with a similar accuracy to skin cancer specialists. It can be used to support more patients to be reassured that they do not have skin cancer, saving unnecessary extension of anxiety, but also reduce the number of unnecessary referrals into dermatologists so that they can focus on the patients who need it most. Our most recent performance report demonstrated DERM was performing as expected with a malignancy sensitivity >97%.
- DERM helps to support better triage of cases that warrant specialist review and onward referral to biopsy or excision. DERM has identified over 40% of urgent suspected cancer referral cases assessed in secondary care as suitable for discharge, leaving a smaller case volume requiring specialist review. Our most recent performance report showed that DERM is 99% accurate in ruling out skin cancer.

"The service is helping us to safely triage patients to the next appropriate step in their care. Patients with benign lesions can be seen closer to home for their photographs and given the reassuring news that they do not have cancer more quickly."

### Dr Elizabeth Roberts, Dermatology Consultant, University Hospitals of Leicester NHS Trust

"If you could describe a perfect NHS appointment end to end, then it would have been this appointment. Seen in a day and reassured a few days later. Thank you."

### Patient

DERM will provide communities with specialist level assessment, increase the proportion of cancers found in the referral population, and reduce the number of skin cancers inappropriately referred on routine pathways, thus speeding up skin cancer detection.

#### Patient outcomes and experience

- Chelsea & Westminster saw their average wait time from urgent suspected cancer referral to appointment fall from 14 days to 3 days. West Suffolk Hospital saw their average wait time from urgent suspected cancer referral to appointment fall by 4.9 days. University Hospitals Birmingham have met the urgent suspected cancer referral target every month since April 2021.
- Chelsea & Westminster saw a 10% reduction in biopsies.
- 83% of patients at Chelsea & Westminster would recommend the service to friends and family.

#### **Service delivery**

- Our latest DERM performance evaluation showed that DERM found >97% of cancers while potentially removing up to 42% of cases assessed from the urgent suspected cancer referral pathway.
- Skin Analytics pathways using DERM in secondary care have identified 40% of cases assessed as being eligible for discharge which had previously been referred in by GPs. This has wider benefits for all NHS dermatology services since AI can support clinical assessment and truly release clinical capacity for both urgent skin cancer referrals and routine dermatology referrals.

# qure.ai

qXR, deep learning AI software swiftly analyses Chest X-rays to triage scans for patients with lung cancer suspicion, enhancing efficiency and shortening time to diagnosis



Funding received by: NHS Cancer Programme Innovation Open Call 1

#### **Contact**

Name and role of Project Lead: Dr Prashant Warier (pictured), CEO Organisation: Qure.ai Technology Limited Email: Prashantwarier@qure.ai Website: <u>gure.ai</u> Twitter: @pwarier LinkedIn: <u>/pwarier</u> Name and role of presenter: Anumeha Srivastava, Chief Customer Officer



# **CLINICAL PROBLEM**

Lung cancer is the biggest cause of cancer deaths in the UK. 5-year survival rate is poor at just 14.6% and 30% of patients die within 90 days of diagnosis, with around 48,600 new cases and 35,300 deaths annually. The National Optimal Lung cancer Pathway (NOLCP) recommends rapid progression from chest X-ray (CXR) to computerised tomography (CT) scan to reduce time to diagnosis for Lung cancer patients. However, radiology capacity and increasing workload hinders implementation of NOLCP, with the current average time at 63 days. Recently published work found that immediate radiographer CXR reporting and triage straight to CT significantly reduced time to diagnosis of Lung cancer by almost half from a median of 32 days compared to routine CXR reporting. Using qXR, an Artificial Intelligence (AI) solution for immediate CXR reporting should have a similar impact on time to diagnosis.

# **PROPOSED SOLUTION**

qXR is AI-powered X-ray software which will be utilised for triaging CXRs immediately after they have been captured. This triage should allow for quicker and more accurate reporting. The project investigates the impact of AI triage of CXRs against routine non-triaged reporting on time to CT and final diagnosis of a patient. The triage alert could lead to faster reporting of suspicious X-rays reducing the wait time for CT appointments.

qXR double-read also enhances accuracy of reporting, potentially improving lung cancer detection. The project tests AI CXR triage using qXR across NHS sites, assessing clinical effectiveness, economic viability, and integration. Data collection measures impact on Lung cancer diagnosis time, influencing NOLCP implementation.

- InHealth, the UK's largest specialist provider of diagnostic and healthcare solutions, has announced a partnership with Qure.ai. Through this partnership, InHealth will be deploying Qure.ai's AI solution to aid in the classification of CXRs into normal and abnormal exams. The solution will be deployed across InHealth's entire Tele-reporting service arm to help enhance the quality and accuracy of reporting using AI.
- India Medtronic Private Limited, a wholly owned subsidiary of Medtronic plc, announced a partnership with Qure.ai to integrate AI for advanced stroke management in India.
- qXR holds CE Class IIb certification and is clinically validated. It is successfully deployed across LMIC countries with AstraZeneca and has been tested in the UK for CXR Triage at NHS East Kent, showing high accuracy and sensitivity.
- Qure.ai announced a new partnership with Therapixel, a French firm that uses AI to improve early breast cancer detection. Qure.ai will be a global distributor for Therapixel's MammoScreen.
- Medica and Qure.ai have partnered to use Artificial Intelligence to improve the efficiency of workflow and clinical decision support.
- The software is deployed at 1,400 sites globally and is in use in various NHS Trusts, including NHS Frimley Health Foundation Trust, East Kent Hospitals University NHS Foundation Trust, and Greater Manchester Cancer Alliance. For the current SBRI Healthcare project qXR is deployed at University College London Hospitals NHS Foundation Trust and University Hospitals of Leicester NHS Trust.



Early detection and diagnosis of cancer

- In a recent study conducted with a high sensitivity operating point, qXR had a specificity of 83% on normal versus abnormal triage. The false positive rate would be around 17% (Diagnostics 2022, 12(11), 2724).
- In a study conducted by Qure.ai with Dubai Health Authority and the University of Sharjah to evaluate the effectiveness of qXR in detecting lung nodules on CXRs which can be a potential case of cancer, results showed that qXR had a higher sensitivity of 0.93 as compared to the radiologists' sensitivity of 0.758. The negative predictive value (NPV) was also high for qXR at 0.956 compared to radiologists (0.87) at 95% confidence interval.

#### Patient outcomes and experience

Patient feedback supports the need for timely reporting. Patients who undergo investigations are often anxious about the results, with research suggesting that the time between having a test and receiving the results is particularly worrying for the patient. This waiting period is typically characterised by the uncertainty of all possible scenarios. Indeed, reduced anxiety from immediate results was emphasised as a benefit of patients receiving the results at the time of their CXR by the patient panel that supported the initial review of the study design and grant application. "As a patient, the worst thing is the waiting. Once I knew, I felt relieved that there was a diagnosis and that I was doing something about it." [Patient Representative] "Speed of diagnosis is critical to achieve the best outcomes in Lung cancer and to reduce stress and worry for patients. Al solutions such as qXR should improve the pathway logistics by flagging abnormalities on chest X-rays as soon as they are undertaken helping patients to progress rapidly through to CT scanning. This will also assist our incredibly busy workforce."

### Professor David Baldwin, Chair, UK Clinical Expert Group for Lung Cancer, NHS England

"Chest X-rays are frequently performed and for many different reasons. Many chest Xrays are normal; using AI to identify those patients who would benefit most from a rapid report is likely to improve patient outcomes and experience."

Dr Nick Woznitza MBE, Consultant Radiographer & Clinical Academic at University College London Hospitals NHS Foundation Trust & Canterbury Christ Church University

#### **Service delivery**

Published prospective studies have demonstrated that using AI as an assistance tool can be beneficial in high-workload healthcare facilities. AI tools with high NPV like qXR can be utilised for screening purposes to screen out normal patients, allowing clinicians to focus more on patients with abnormalities and their treatment pathways, positively impacting the time spent for screening of abnormal patients.

### The ROYAL MARSDEN NHS Foundation Trust

# 💧 GUARDANT

Liquid biopsy for faster diagnosis in advanced pancreatic and biliary tract cancers in the NHS



Funding received by: NHS Cancer Programme Innovation Open Call 1

#### **Contact**

Name and role of Project Lead:Dr Naureen Starling,Consultant Medical Oncologist & Clinical LeadOrganisation: The Royal Marsden NHSFoundation TrustEmail: Naureen.Starling@rmh.nhs.ukWebsite: www.royalmarsden.nhs.ukTwitter: @royalmarsdenNHS



# **CLINICAL PROBLEM**

Cancers of the pancreas and bile duct have the worst outcomes of any cancer and yet the time taken to diagnose them is longer than for most cancers. Faster diagnosis is critical to improving outcomes in these patients.

Because of their location deep within the body, the NHS relies on invasive investigations such as endoscopy. One in four patients do not get a diagnosis from the first test and need repeated tests. Complications including bleeding, pain and infection occur. One in four patients also have health conditions or frailty that make these tests riskier. These factors significantly delay cancer diagnosis.

# **PROPOSED SOLUTION**

Guardant360® is an approved blood test or 'liquid biopsy' by Guardant Health that uses established technology to find tiny amounts of cancer in the blood and could revolutionise cancer diagnosis. It also provides genomic information that can identify patients for targeted drug treatments.

Incorporating this non-invasive 'liquid biopsy' into the diagnostic pathway could improve outcomes for patients through faster diagnosis and access to treatment. It can have the additional benefit of reducing the number of repeated invasive diagnostic procedures needed to establish a diagnosis, avoiding potential procedure-related complications, delays and saving valuable NHS resources.

- Brought the first FDA-approved liquid biopsy to market (2020).
- Successfully partnered with the Royal Marsden to bring the technology to the UK (live April 2023).
- Liquid biopsy (LB) test used in the study SAFIR ABC010, led by UCL PI (advanced biliary tract).
- Awarded a place on NHS England's ctDNA transformation pilot to help speed up and improve Lung cancer diagnosis in the image-suspected setting.
- Currently running the largest de-escalation study in colorectal cancer minimal residual disease to help spare patients in the UK unnecessary chemotherapy post-surgery.
- Published over 420 high-impact factor peer-reviewed publications across multiple tumour types.
- Over 250 publications and orals out of the UK in advanced Non-Small Cell Lung Cancer, Biliary Tract Cancer and Cancer of Unknown Primary.
- Our solution is currently implemented at RM Partners, West London Cancer Alliance, The Royal Marsden NHS Foundation Trust, Epsom and St Helier Hospitals, Croydon University Hospital, Kingston Hospital, Chelsea and Westminster Hospital, and West Middlesex Hospital.



Early detection and diagnosis of cancer

• Currently being evaluated.

Patient outcomes and experience

- 75% of patients in the ACCESS project reported as very satisfied or satisfied with the Guardant360® liquid biopsy blood test.
- Impact on patients' quality of life is currently being evaluated.

#### Service delivery

• Currently being evaluated.

"Cholangiocarcinoma (CCA; bile duct cancer) can be very difficult to accurately diagnose. One of the reasons for this is the problem of obtaining tissue samples. Liquid biopsy offers significant potential as an alternative to tissue biopsy, and the ACCESS study represents a promising initiative that could potentially streamline the diagnostic process and so enable CCA patients to access the treatments they need in a far more timely manner."

## Helen Moremont, CEO of AMMF, The Cholangiocarcinoma Charity

"[The ACCESS Programme] was very important to me. I could see my initial diagnosis and it was incorrect and the liquid biopsy gave me hope. Amazing experience."

### Patient from Patient Satisfaction Survey

"Early diagnosis is so important for us all to beat this devastating disease and this liquid biopsy is able to do this with the added benefits of being safe and offering personalised treatment."

### Jackie Edgeller, ACCESS Steering Group PPI member

The Newcastle upon Tyne Hospitals





# The Newcastle Microsatellite Instability-Plus assay for high throughput Lynch syndrome screening

Newcastle MSI-Plus Assay



Funding received by: NHS Cancer Programme Innovation Open Call 1

#### Contact

Name and role of Project Lead: Dr Ciaron McAnulty, Deputy Head of Laboratory (Rare Disease Lead, Newcastle Genetics Laboratory) Organisation: The Newcastle Upon Tyne Hospitals NHS Foundation Trust Email: Ciaron.McAnulty@nhs.net Twitter: @GeordieGenomes @CaPP3 Name and role of presenter: Pichard Gallon (pictured), Research Associate

Richard Gallon (pictured), Research Associate, Newcastle University

# **CLINICAL PROBLEM**

Lynch syndrome (LS) affects ~3/1,000 people. LS carriers often get bowel and other cancers from early adulthood; by age 65 years more than two thirds will have had at least one cancer. LS cancers can be prevented or detected early, but only ~5% of carriers are known to the NHS. In 2017, NICE required all colorectal cancers (CRCs) to be tested for Mismatch Repair (MMR) defects to help identify people with LS. Implementation remains a work in progress: A national audit of NHS data from 2019 found only 22% of CRCs completed testing, meaning an estimated ~700 LS diagnoses were missed.

# **PROPOSED SOLUTION**

One in six CRCs are MMR deficient. MMR deficiency can be detected by testing for microsatellite instability (MSI) mutations in repetitive DNA sequences called microsatellites. Approximately 20% of MMR deficient CRCs are caused by LS. LS CRCs lack the driver mutation BRAF V600E that is found in half of the sporadic cases. Currently, MSI and BRAF V600E are tested separately to screen for LS. The Newcastle MSI-Plus assay combines analysis of novel MSI markers and BRAF/RAS driver mutations in a single tumour test using next generation sequencing. The multiplex polymerase chain reaction approach allows rapid preparation of sequencing libraries from ~1 nanogram of DNA. Custom analysis software presents a clear YES/NO result on referral for germline testing, allowing reporting at scale without senior scientist/pathologist involvement. A single technologist can analyse and report on all CRCs across 3 million people for high volume and low-cost LS screening, making the service more efficient and effective.

People being treated for cancer will be approached for a blood sample for germline testing while still under hospital care rather than being approached long after discharge or lost to follow-up. Thousands of LS families at risk of recurrent cancers and early deaths will also be offered effective surveillance and simple proven prevention using regular aspirin.



- Cancer Research UK manage the Intellectual Property of the MSI-Plus assay for Newcastle University and has licensed the assay to Newcastle Hospitals. Income will derive from service provision via the Genomic Test Directory. The assay will be validated for IVDR and FDA 510K for sale in other health systems.
- The assay is being validated across all tumour types to facilitate use of Immune Checkpoint Inhibitors and has been shown to effectively identify urothelial cancers as a "urine liquid biopsy" - a research evaluation of the assay as a routine postal screening service for urinary tract and endometrial cancers for LS carriers is underway.
- The assay is currently implemented in: The Newcastle upon Tyne Hospitals NHS Foundation Trust, Northumbria Healthcare NHS Foundation Trust, Gateshead NHS Foundation Trust, South Tyneside and Sunderland NHS Foundation Trust, County Durham and Darlington NHS Foundation Trust, South Tees Hospitals NHS Foundation Trust, North Tees and Hartlepool NHS Foundation Trust, and North Cumbria Integrated care NHS Foundation Trust.



"As a GI pathologist, the availability of MSI-Plus technology has made testing for MSI easy and straightforward to use. Feedback from clinical users namely oncologists and surgeons has been complimentary, in particular, as a one-stop shop which includes Lynch screening function, triaging oncological management with the MSI/RAS status as well as the simplicity and clarity of reports. From a management perspective as the Lynch Champion for North East & North Cumbria region, MSI-Plus has made it possible to streamline and optimise the Lynch detection services in a relatively large scale which covers a population of over 2,000 new colorectal cancer patients annually in 8 separate NHS Foundation Trusts."

Dr Peh-Sun Loo Consultant Histopathologist, The Newcastle upon Tyne Hospitals NHS Foundation Trust

## IMPACT

#### Early detection and diagnosis of cancer

- We have now replaced expensive, time-consuming immunohistochemistry screening in all eight hospitals in the North East and Cumbria with MSI-Plus; a cheap simple "one stop" analysis of CRC biopsies with a seven day turnaround, enhancing the search for LS cases. Identified LS carriers will benefit from cancer prevention and surveillance.
- SBRI Healthcare have supported further roll out of the assay to the rest of our North East and Yorkshire Genomic Laboratory Hub (GLH) and to four of the other six GLHs in England.
- Around a third of CRCs have BRAF V600E or another Ras/MAPK driver mutation and 1 in 6 are MMR deficient. Timely testing by MSI-Plus will enhance therapy by targeting appropriate drugs such as the new highly effective Immune Checkpoint Inhibitors.

#### Patient outcomes and experience

• The LS community is fully engaged and supporting further research to effectively treat, detect and prevent cancer.

#### **Service delivery**

- The North East Region's pathology community has agreed to replace immunohistochemistry with the MSI-Plus assay as the first line tumour screening approach, cutting costs and reducing pressure on pathology services.
- More than 5,000 tests have been reported in the North East and Cumbria with an increase from well below 30% to close to 100% completion of the tumour screening pathway. There has been a reduction in the loss of patients between the tumour test and the offer of a blood test thanks to the 7 day turnaround. Other parts of England will soon begin to use the assay at scale once the current UKAS assessment is complete.
- An independent review by the Academic Health Science Network showed strong professional support. Multidisciplinary teams now routinely ask for the MSI-Plus result. A formal economic analysis by Newcastle University is underway.



Streamlined, patientdirected pathways for germline genetic testing of cancer susceptibility genes



Funding received by: NHS Cancer Programme Innovation Open Call 2

#### Contact

Name and role of Project Lead: Prof Clare Turnbull, Professor of Translational Cancer Genetics and Consultant in Clinical Genetics Organisation: Institute of Cancer Research Email: Clare.Turnbull@icr.ac.uk Website: www.brca-direct.org/ Twitter: @clare\_turnbull



# **CLINICAL PROBLEM**

The identification of patients with a germline genetic variant within cancer susceptibility genes supports the risk stratification of people at high genetic risk of developing cancer for targeted screening and prevention. Current pathways for the consenting of patients for testing are labour intensive, with 1-to-1 'genetic counselling' with a trained healthcare professional prior to consent, and blood sampling primarily used as a DNA source.

Eligibility for testing is therefore restricted to patients, based on personal and/or family history of cancer, adding an additional step of complex assessment prior to referral. This can lead to missed opportunities for identifying people at high genetic risk of developing cancer.

# **PROPOSED SOLUTION**

Much of the information patients need to receive ahead of consenting to germline genetic testing is largely generic in specific testing contexts, for example testing for breast and ovarian cancer susceptibility genes BRCA1 and BRCA2. There is well established knowledge relating to variant interpretation, the cancer risks associated with gene changes and lifestyle factors, and clinical actionability with regards to preventative options and screening for early diagnosis.

Our solution, BRCA-DIRECT offers an alternative pathway for germline genetic testing. It reduces the need for healthcare professional involvement in generic aspects of the pathway, allowing resources to be focused on managing individualised issues and/or patients with positive results and increasing testing capacity. This is done by providing patients with standardised written or digital information containing information about genetic testing, alongside a consent form and saliva sample kit for at-home patient-initiated testing. Support is freely accessible from a genetic counsellor via a centralised telephone helpline. The solution offers more opportunities to reduce a patient's risk of developing future cancers (e.g. during primary surgery), with better outcomes by utilising targeted treatments for germline variants. It also increases identification of unaffected, at-risk family members, via cascade testing, who may benefit from targeted screening and prevention.

- The pathway is being implemented within the North Thames Genomics Laboratory Hub (NTGLH). This involves delivery of testing via the Centre for Molecular Pathology, at the Royal Marsden NHS Foundation Trust, part of the NTGLH network.
- The first phase includes the Royal Marsden, Princess Alexandra, Imperial College, Royal Free and Northwick Park hospitals.



Early detection and diagnosis of cancer

- The BRCA-DIRECT pathway was established on the premise that all patients diagnosed with breast cancer could be offered testing because studies have demonstrated that expanded access to testing is (a) cost effective and (b) an opportunity to identify up to twice the number of people with a genetic variant compared with current family history-based eligibility criteria.
- Patients identified through the study can now access increased screening or preventative options to reduce their future cancer risks, and on average will have six family members who become eligible for testing, each with a 50% risk of also having the genetic variant.

#### Patient outcomes and experience

• Our study at two NHS Trusts identified high levels of patient satisfaction with the pathway. Additional patient interviews and clinician feedback also support evidence for the value of the pathway in terms of expanding access to testing and the benefit this can have for alleviating patient anxiety around family members being at-risk of developing cancer at the time of a personal diagnosis.

#### **Service delivery**

 The majority of surveyed clinicians and healthcare professionals considered all aspects of the pathway to be equivalent or superior as compared with standard-of-care pathway, with >95% believing that the pathway was acceptable for the majority (>70%) of patients, and supporting larger roll-out of the pathway within the NHS as standard-of-care. "It's been great. It's brought me a huge deal of relief to have this opportunity and also the method through which I was given to participate. I personally find reading information, especially information which can cause different responses, better to receive privately because it gives me more space to somehow process it than if I was in a conversation with a health professional."

# BRCA-DIRECT study participant

"BRCA-DIRECT enables me to offer all newly diagnosed patients access to testing in a straightforward, timely manner. It means results are available to use during their treatment pathway and for future cancer prevention. I am delighted to offer this."

### Royal Marsden Hospital Clinician

Uptake of the hotline requiring genetic counsellor input was shown to be modest, with the vast majority of calls for support being administrative in nature (i.e. support registering online or completing the saliva sampling).

# Cyted

The capsule sponge test transforms patient outcomes from oesophageal cancer by finding people at risk earlier and faster



Funding received by: NHS Cancer Programme Innovation Open Call 2

#### Contact

Name and role of Project Lead: Charlene Tang, Head of Growth Organisation: Cyted Ltd Email: charlene.tang@cyted.ai Website: cyted.ai LinkedIn: /charleneostang/



# **CLINICAL PROBLEM**

An estimated 9,300 patients are diagnosed with oesophageal cancer in the UK each year. Unfortunately, 7 in 10 patients are diagnosed at a late stage, when only ~20% of patients survive the year. By contrast, when detected at the pre-cancerous Barrett's oesophagus stage, patients can be monitored for signs of cancer and receive prompt treatment, increasing survival to 80%.

Over 90% of ~1.5 million individuals with Barrett's oesophagus have not yet been diagnosed so cannot be proactively monitored or treated. It is estimated that 4,000 patients with oesophageal cancer have been missed, as a likely consequence of 14,800 missed upper gastrointestinal (GI) referrals during the pandemic.

# **PROPOSED SOLUTION**

The capsule sponge test detects early oesophageal cancer and its precancerous condition, Barrett's oesophagus, with high sensitivity and specificity. Randomised clinical trials have demonstrated its clinical effectiveness, that it is cost effective as a case finding tool for Barrett's oesophagus, and that it is more tolerable for patients than endoscopy.

This minimally invasive test can be delivered by a single trained healthcare professional in an office setting in under 20 minutes, making it ideally suited to primary care. The sample is sent to the Cyted laboratory for processing and analysis by our team of consultant pathologists. Here, a positive result for intestinal metaplasia or atypia and dysplasia biomarkers indicates Barrett's oesophagus or early oesophageal cancer respectively, fast-tracking the right patients for endoscopy and treatment.

The capsule sponge test offers a way to proactively check individuals with persistent heartburn or chronic reflux symptoms and to risk stratify patients on endoscopy waiting lists with these symptoms or requiring Barrett's surveillance. Altogether, this minimally invasive test helps recover endoscopy backlogs, enrich endoscopy lists and transform the upper GI care pathway.

- Cyted has raised a total of \$30 million of venture capital and grant funding to date, including from London-based BGF and USbased Morningside, as well as SBRI Healthcare and Innovate UK.
- Cyted work closely with NHS organisations across the UK including AHSNs and Cancer Alliances, as well as patient advocacy group Heartburn Cancer UK.
- Pilots are scheduled to start in late 2023/ early 2024 outside of the UK in the Nordics and in the US.
- The capsule sponge test is available in over 60 hospitals and 10 GP practices across the UK.
- The ongoing SBRI Healthcare implementation in primary care is being led by three Cancer Alliances: East of England, Lancashire and South Cumbria, and Wessex.



#### Early detection and diagnosis of cancer

- The capsule sponge test has been shown to be safe and acceptable to patients in clinical trials involving over 4,000 individuals across three continents and real-world implementation involving over 15,000 individuals across the UK.
- The capsule sponge test detects Barrett's oesophagus and early oesophageal cancer with a specificity and sensitivity of over 90% (Ross-Innes 2015; Ross-Innes 2017; Pilonis et al 2022) and increases the number of Barrett's cases diagnosed by more than 10-times when offered to individuals with chronic reflux compared to usual care (Fitzgerald 2020).
- Health economic analyses of clinical trial data showed that offering the capsule sponge test in primary care for proactive case finding is a cost-effective solution falling below the NICE threshold (Swart 2021).

#### Patient outcomes and experience

- GP-based clinics for the capsule sponge test in the North West Coast region offer Barrett's patients a surveillance option in the community who are at high risk of oesophageal cancer and are often those waiting the longest for endoscopy.
- Appointment attendance rates were high and patients reported being pleased to have an alternative option to endoscopy that came with shorter waiting times, felt less invasive, and was more accessible in the community. Health inequity was found not to be a barrier to access with 56% of patients tested coming from the most deprived neighbourhoods compared to 49% of the population as a whole.
- Similar findings have been observed in capsule sponge clinics based in hospitals (pending publication) and community care (unpublished), including a case of an individual who was too worried to go into hospital for an endoscopy during the pandemic, but was able to access the capsule sponge test in a mobile unit, where signs of concerning pathology were found and they were able to be prioritised for care.

"Our first reaction was: Why hasn't anyone thought of this before? Our patients' reactions were overwhelmingly positive when we offered capsule sponge test as an alternative procedure."

Stephanie Driver Practice Manager, Oswald Medical Centre, Lancashire

#### **Service delivery**

Since its introduction to the NHS in 2020 in response to the pandemic, the capsule sponge test has helped recover endoscopy backlogs and improve operational efficiencies in endoscopy units.

- The capsule sponge test can be offered to eligible patients waiting for routine endoscopy for chronic reflux symptoms or surveillance of Barrett's oesophagus. Approximately 15% of these patients are found to have signs of suspected cancer or Barrett's, and can be fast-tracked for urgent or routine endoscopy respectively, helping clinical teams risk stratify and prioritise patients. At least 78% of patients are found to have no signs of cancer or Barrett's and so can be safely taken off waiting lists (unpublished, data from NHS England), releasing endoscopy resources and saving costs.
- In NHS Scotland, the introduction of the capsule sponge test for Barrett's surveillance has increased the proportion of patients having clinically significant pathology at endoscopy from only 10% to over 50% (unpublished), enriching endoscopy lists and improving operational efficiencies.
- In 2022, GP-based clinics for the capsule sponge test proved how practice nurses and paramedics can be up-skilled to offer Barrett's surveillance clinics in the community, further reducing pressures on hospital-based endoscopy units. In the North West Coast, GP-based clinics reduced the number of patients waiting over 6 weeks from referral to procedure by 31% and delivered a positive returnon-investment within 12 months, with a projected £3.9 million released and £1.20 returned for every £1 spent when implemented at an ICS level over 5 years (unpublished, data from Lancashire & South Cumbria Cancer Alliance).

The ROYAL MARSDEN NHS Foundation Trust



Whole-body Magnetic refonance imaging screening in U Fraument Syndrome for Early Cancer Diagnosis (SIGNIFIED)

Funding received by: NHS Cancer Programme Innovation Open call 2

#### <u>Contact</u>

Name and role of Project Lead: Dr Angela George (pictured), Principal investigator, Clinical Director of Genomics and Consultant Medical Oncologist in Gynaecology Organisation: The Royal Marsden Hospital Website: www.royalmarsden.nhs.uk/ Email: angela.george@rmh.nhs.uk Name and role of presenter:

Dr Angela George/ Dr Elena Cojocaru, Clinical Research Fellow

# **CLINICAL PROBLEM**

Li Fraumeni syndrome (LFS) is an inherited familial predisposition to a wide range of cancers. This is due to an alteration in the tumour suppressor gene TP53. LFS individuals have a 70-90% lifetime risk of developing cancer, often before the age of 50. The only screening for TP53 mutations in the NHS is annual MRI breast for females, therefore all the other cancers are not routinely screened for. A whole-body MRI (WB-MRI) scan looks at the body from head to toe to find cancers, aiming to detect tumours when these are very early and potentially curable.

# **PROPOSED SOLUTION**

We propose that patients with LFS undergo annual whole-body magnetic resonance imaging with diffusion weighting (WB-MRI with DWI) in addition to usual care (e.g. breast MRI and symptom awareness). WB-MRI with DWI is a recent but standard technology within the NHS used more commonly for imaging of multiple myeloma, melanoma and prostate cancer. It is not in routine clinical use in the NHS for inherited cancer syndromes. We have undertaken an implementation pilot as a service evaluation at the Royal Marsden Hospital and have invited 50 patients with LFS to participate. Our aim is to demonstrate that WB-MRI is a cost-effective tool in detecting early tumour and can be established as standard of care of screening in adults with LFS.

# MARKET TRACTION & IMPLEMENTATION

- This project is currently running at the Royal Marsden Hospital, a leading cancer hospital in the UK and Europe.
- If our pilot project is successful in demonstrating cost-efficacy of undertaking an annual whole-body MRI in patients with Li Fraumeni syndrome, this examination could be implemented in the NHS and the whole-body MRI could be offered annually to all Li Fraumeni individuals in the UK.



## Whole-body MRI screening for early cancer diagnosis in Li Fraumeni syndrome



"Whole-body MRI in Li Fraumeni patients has the potential of diagnosing cancers when they are very early, when treatment with a curative aim is still possible. By offering a WB-MRI to this population, which is at very high risk of developing cancers throughout their lifetime, we can improve early detection, offer effective treatments and ultimately a better outcome and quality of life."

### Dr E Cojocaru, Clinical Research Fellow, Study Physician

"Li Fraumeni, or more so, cancer, has dominated my family's lives for many years, from growing up not ever knowing my grandmother to losing my sister at the age of 34. I know for a fact that if we had had these MRIs our family history would be so different, and my hope is that with these on offer my family's future will be better. It has, in my opinion, already saved my life this year."

LG, Li Fraumeni patient

# IMPACT

#### Early detection and diagnosis of cancer

- The SIGNIFY study published in 2017 (PMID 28091804) has shown that the rate of detection of asymptomatic cancer in Li Fraumeni patients through a one-off whole-body MRI was approx. 10%.
- A large meta-analysis published in 2018 showed that whole-body MRI in Li Fraumeni patients has a detection rate for new, localised primary cancers of 7%.

#### Patient outcomes and experience

 Early tumours detected by a whole-body MRI have the potential of being treated curatively, meaning that patients' outcomes are excellent when the tumour is diagnosed very early. It has been shown that by diagnosing a cancer before metastasis, cancer-related deaths could be potentially reduced by 15% within 5 years (PMID 32229577). The main cause of death for Li Fraumeni patients is metastatic cancer and often they have more than one diagnosis of cancer throughout their lifetime.

#### **Service delivery**

- Whole-body MRI is a standard technology used in certain cancers (PMID 29334236) but is not routinely used in the NHS for inherited cancer syndromes to detect asymptomatic tumours.
- Many studies have underlined the high sensitivity of whole-body MRI for the detection of organ metastases, especially for prostate, breast and colorectal cancers.
- There have been reports that WB-MRI can modify a patient's treatment by correctly characterising the tumour stage (PMID 28390297), highlighting the increased sensitivity of the whole-body MRI for accurate detection of tumours.



A centralised patient engagement platform to minimise health inequalities and improve identification and engagement in bowel cancer screening



Funding received by: NHS Cancer Programme Innovation Open Call 2

#### **Contact**

Name and role of Project Lead: Jonathan Selby (pictured), Managing Director Organisation: iPLATO Healthcare Email: jonathan.selby@iplato.com Website: www.iplato.com LinkedIn: /iplato-Itd Name of presenter: Simon Chowdhury, Clinical Lead



# **CLINICAL PROBLEM**

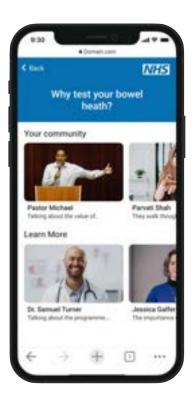
16,808 people in the UK die from bowel cancer each year. It is also the second most common cause of cancer death. The five year survival rate of bowel cancer is 97% at stage 1, 85% at stage 2, 63% at stage 3 and 7% at stage 4. iPLATO will increase uptake into bowel cancer screening services via tailored multi-channel screening communication at scale and home delivered Faecal Immunochemical Tests.

# **PROPOSED SOLUTION**

iPLATO's platform sends multi-channel, demographic specific screening invitations at scale, utilising tailored reminders and digital educational content to boost uptake. Our solution increases screening uptake whilst reducing health inequalities and increasing earlier diagnosis of bowel cancer. This solution builds on existing bowel cancer screening services, focusing on those at higher risk of health inequalities and lower screening uptake. This includes those with lower socio-economic status and ethnic minority groups, and people with serious mental health issues. Our key USPs and patient benefits are:

- Identification of target population for those most in need of bowel cancer screening.
- Communication to eligible people through GP-endorsed communications.
- Delivery of digital educational resources tailored to each demographic e.g. educational content will be designed for target patient cohorts to reduce misconceptions and overcome barriers, to improve confidence to uptake screening.
- Measuring results and comparing to historical uptake rates across population cohorts.

- iPLATO is a UK healthcare technology company, founded 20 years ago, and is a wholly owned subsidiary of Huma. Huma is a UK headquartered healthcare technology company with international operations in Europe, USA and China.
- iPLATO is currently providing patient engagement programmes for both Cervical & Bowel cancer screening for NHS London and for NHS East of England. The technology has also been adapted for use with National Diabetes Prevention Programmes and Diabetes Structured Education in London and Greater Manchester.
- This programme is being undertaken in partnership with the South East London Cancer Alliance (SELCA) who are providing support and guidance, including evaluation, metrics and feedback. SELCA are also leading the introduction of the programme to South East London GP Practice leads across SEL to ensure the successful onboarding of GP practices to the programme.
- iPLATO is also working with the NHS England screening Research, Innovation and Development Advisory Committee (RIDAC) to ensure that the data sharing and patient communication process is secure and beneficial.
- Guy's Cancer Academy (GCA), with support from NHS South East London ICB and SELCA are leading the Patient and Public Involvement and Engagement (PPIE) with leaders from the targeted communities, patients from these communities, and clinical experts. GCA are also creating the educational content for the programme.



"I believe this innovative collaboration with iPLATO will meaningfully benefit these four patient groups. We know that early identification of cancer has the greatest impact on cancer survival."

Professor Arnie Purushotham, Director, King's Health Partners Cancer Centre, King's College London, and Consultant Surgeon, Guy's and St Thomas' NHS Foundation Trust, representing SELCA

"I welcome this important programme which I strongly believe is the start of an important health initiative within our community."

### Pastor Modupe Afolabi, Executive Director, Redeemed Christian Church of God

"When we sent an SMS reminder, women were twice as likely to attend screening than those who were only sent a letter."

### Samar Pankanti, Public Health System Transformation Lead, NHS England

# **IMPACT**

#### Early detection and diagnosis of cancer

- Our clinical outcomes from similar projects (e.g. cervical cancer screening uptake) show increased uptake from health inequality groups and improved patient data.
- Cervical screening attendance increased by 100% in the NHS East of England region.
  Following six months of using iPLATO's Population Health Service results showed:

- 29,000 extra screenings. Those who received programme communications were twice as likely to attend a screening compared to those who only received a letter.

- Earlier attendance of 17 days. Those who received a reminder attended their screening sooner.

- Equal success within deprived communities. Engagement methods achieved equal increases in screening attendance.

#### Patient outcomes and experience

Our previous deployment to improve cervical cancer screening uptake in the NHS East of England showed:

- Increased uptake by 5-10%: Saving lives and achieving financial savings of £43m.
- Improved patient experience, with confidence scores increasing two-fold to engage in the East of England cervical cancer screening programme, when compared with traditional GP letter invitations.
- Indices of multiple deprivation (IMD) Decile 1 attendance scores increased by x1.89 to engage in East of England cervical cancer screening programmes, when compared with traditional GP letter invitations.

#### Service delivery

- For all cancers, the earlier detection of cancer reduces the cost of treatment. For example, the average cost to the NHS per person diagnosed with stage 2 or later cervical cancer is £19,261, compared to £1,379 for those diagnosed at stage 1a (Jo's Cervical Cancer Trust data, 2017).
- For this project, the objective is to increase bowel screening uptake by 5% to 10% (based on past evidence). At a national scale this would result in savings to the NHS of £13m to £26m.

# **OpenMedical**

# Pathpoint eDerma - Beyond Teledermatology



Funding received by: NHS Cancer Programme Innovation Open Call 1

#### Contact

Name and role of Project Lead: Dr Piyush Mahapatra & Dr Tim Hoogenboom, Chief Innovation Officer & Clinical Data Scientist Organisation: Open Medical Name and role of presenter: Dr Tim Hoogenboom (pictured), Clinical Data Scientist Email: tim@openmedical.co.uk Website: www.openmedical.co.uk LinkedIn: /openmedical Twitter: @OpenMedicalLtd



# **CLINICAL PROBLEM**

In the UK, there are around 156,000 non-melanoma and 16,700 malignant melanoma cases annually, projected to rise by 9%. Limited dermatologists and patient access create challenges in meeting faster diagnostic standards, causing delays in treatment. Early diagnosis is crucial for skin cancer.

## **PROPOSED SOLUTION**

eDerma is an award-winning, cloud-based digital solution designed for dermatology service coordination. Developed by NHS clinicians and in collaboration with dermatologists and patients, it represents true innovation. Its success stems from its remarkable flexibility, seamlessly integrating into existing workflows and catering to specific community needs. This adaptability efficiently addresses the resource constraints in UK dermatology, making the most of limited time and resources. Notably, eDerma includes a patient questionnaire co-designed with both dermatologists and patients, enhancing patient accessibility and understanding to improve referral quality and patient assessments. Moreover, by integrating with legacy and modern hospital systems, it ensures continuous care, minimising fragmentation. With its unique approach, eDerma delivers maximum benefits to patients and service users, proving to be a transformative solution in dermatology service coordination.

- Supported by the NHS Innovation Accelerator and SBRI Healthcare.
- eDerma currently serves 8.8 million individuals over 10 care organisations: East Kent Hospitals University NHS Foundation Trust, University Hospitals Sussex NHS Foundation Trust, Northern Care Alliance NHS Foundation Trust, Bedfordshire Hospitals NHS Foundation Trust, West Hertfordshire Teaching Hospitals NHS Trust, Mid and South Essex NHS Foundation Trust, Norfolk and Norwich University Hospitals NHS Foundation Trust, Guy's and St Thomas' NHS Foundation Trust, King's College Hospital NHS Foundation Trust, Lewisham and Greenwich NHS Trust.



"eDerma has removed the barriers to care that patients referred to dermatology used to experience. We now benefit from a joined up community model through this easy to use digital platform. High-quality images combined within an accessible workflow system have made huge efficiency savings."

Dr Veronique Bataille, Consultant Dermatologist, Co-Author of BAD Teledermatology Guidelines

# IMPACT

#### Early detection and diagnosis of cancer

- East Kent Hospitals University NHS Foundation Trust reduced face to face appointments by 85.8% and 93.6% of patients were diagnosed or given a decision to treat at telederm assessment.
- Ability to address health inequalities with the innovation being accessed by a more diverse population.
- 15% of patients were booked for a diagnostic biopsy directly following dermoscopy review, bypassing an initial clinic waiting list and likely shortening the time to diagnosis.

#### Patient outcomes and experience

- 85% of patients believe our innovation saves time, and 87% think that it is a good way of managing their skin lesion concerns.
- 87% of patients favoured our teledermatology service and patient reported experience measures demonstrate high acceptability particularly for patients from deprived areas. Initial data suggests that the eDerma teledermatology model is reaching communities that are otherwise not accessing skin cancer care.
- Reduced patient travel by decentralising the care model.

#### **Service delivery**

- Referral to assessment time is frequently under one week with 99% first seen within two weeks.
- Assessments took on average approximately 5.5 minutes, up to 4 times as fast as face to face appointments, saving dermatologist time and thus increasing capacity (79.7% if face to face saved, University Hospital Sussex).





RAPID: Implementing a digital infrastructure and pathway for improving time to treatment in brain cancer



Funding received by: NHS Cancer Programme Innovation Open Call 1

#### **Contact**

Name and role of Project Lead: Christine Rowland (pictured), Chief Operating Officer Organisation: Orion MedTech Ltd. CIC Email: christine.rowland@orion.net Website: www.orionmedtech.org Twitter: @orion medtech Name and role of presenter: Michael Martin, Director of Operations

## **CLINICAL PROBLEM**

Co-ordination of definitive cancer treatment from initial diagnosis can lead to delays until a final treatment plan can be established. This is particularly challenging with centralisation of tertiary cancer services requiring co-ordination across multiple sites with approximately 20,000 patients considered annually within a brain cancer multi-disciplinary team (MDT).

At present, patients diagnosed with a brain tumour face a median waiting time of 31 days before surgery. The consequences of such delays are significant: one-quarter of patients experience deterioration while waiting for surgery. Those who deteriorate before surgery experience hospital stays that are twice as long with worse treatment outcomes compared to patients who receive timely interventions. These findings highlight the need to reduce delays in brain tumour treatment, offering an opportunity for the RAPID project to improve patient outcomes and care quality.

# **PROPOSED SOLUTION**

The RAPID project has established regional digital infrastructure and an optimised clinical pathway for initial management of brain tumours. The platform enables initial brain tumour referrals to be screened and triaged prior to specialist consideration by an MDT. This enables clinical review, MDT discussions, and further diagnostic tests to be conducted in parallel across different sites, thus eliminating inefficiencies and delays. Treatment planning is also stratified through a dashboard to enable clinical prioritisation and flagging of any breaches in treatment targets.

Data acquired during this process creates a unique and global perspective of the patient pathway encompassing KPIs and clinical outcomes, as well as enabling continuous evaluation, evolution, and quality improvement. Ultimately, patients and service users benefit by receiving faster, personalised, and effective neuro-oncology care. The RAPID care model and digital platform are scalable and can be readily adapted to different cancer types.

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- Our work builds on the Innovate UK-supported DAMSEL project which has been operational within the Eastern and North West regions for five years. DAMSEL's outputs were recognised through a Macmillan Service Excellence Award in 2018.
- An independent evaluation by health economic consultants will support market traction within the wider NHS.
- Our solution is currently implemented in the Eastern regional cancer network (Cambridge University Hospitals NHS Foundation Trust, East Suffolk and North Essex NHS Foundation Trust, Norfolk and Norwich University Hospital NHS Foundation Trust), and The Walton Centre NHS Foundation Trust.



#### Patient outcomes and experience

- More than half of patients who have been assessed through the RAPID triaging tool to date have benefited, reducing time from initial diagnosis to treatment, including proceeding to MDT discussion faster and not being lost to follow up.
- Through RAPID, 24% more patients were seen in clinic the same week as MDT discussion. This has significantly reduced the anxious wait time between referral and consultation which was the top reported issue in our patient workshop.
- Over 60% of brain tumour patients are diagnosed following emergency presentation. RAPID enables definite advice and treatment plans quickly, meaning that patients can be discharged home sooner following their initial diagnosis.

#### Service delivery

- RAPID's framework of a comprehensive screening process ensures that referrals are complete and include all necessary information upfront. This eliminates the need for clinicians to spend valuable time discussing incomplete referrals during MDT meetings. As a result, MDT discussions become more efficient, focused, and productive, allowing clinicians to concentrate on developing optimal treatment plans.
- Interoperability and electronic sharing of patient records across hospital sites alerts local teams to new cases, enabling them to start the specialist assessment process sooner and provides more accurate information to the MDT. Furthermore, it avoids duplication of investigations across hospital sites, such as MRIs, saving time and money.

"RAPID acts as an important safety net and highlights patients that need to be seen promptly, preventing delays in the brain cancer pathway."

Anna Mannina, Neuro-oncology Clinical Nurse Specialist



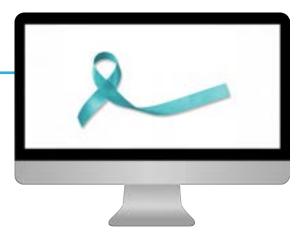


Funding received by: NHS Cancer Programme Innovation Open Call 2

#### Contact

Name and role of Project Lead: Aamena Salar, Primary Care Lead Organisation: Modality Partnership Email: aamena.salar@nhs.net LinkedIn: aamena-salar-720219aa/

# Introduction of a novel biomarker to improve the early detection of ovarian cancer in primary care



# **CLINICAL PROBLEM**

7,500 women are diagnosed with Ovarian cancer (OC) each year. Five-Year Survival drops from 93% in S1 to 13% in S4. More advanced stages mean more complex surgery, chemotherapy and targeted therapies. 50% of women diagnosed through the current rapid access pathway for symptoms have early-stage cancer.

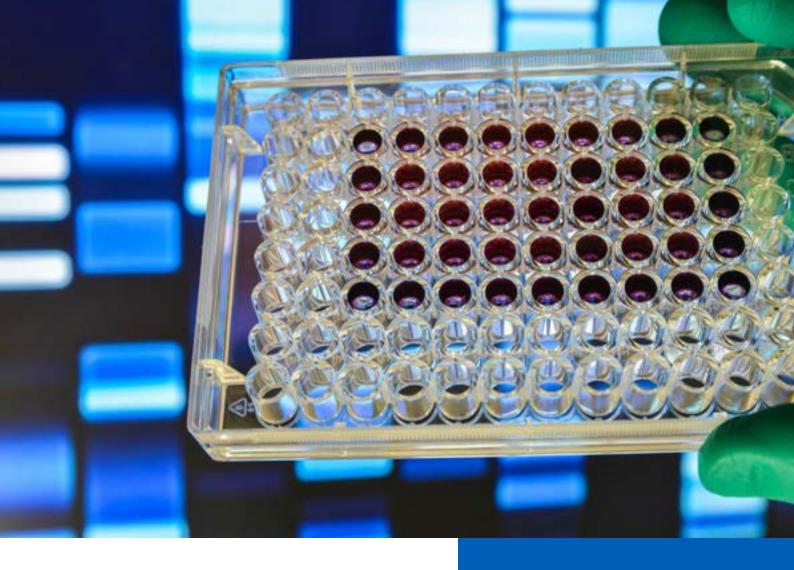
# **PROPOSED SOLUTION**

The novel biomarker ROMA test (that combines existing tumour marker CA125 with another serum biomarker He4 in an algorithm) has the potential to increase the earlier detection of Ovarian cancer. ROMA picks up about 20% more early-stage cancers than the current standard of care test CA125 but is not used in current UK primary care practice. Evidence has been supported by secondary care data in the ROCkeTS study.

The innovation does not require any additional tests to be done, the novel tumour marker will be added to the existing blood sample for CA125. The test is minimally invasive with blood tests a well accepted investigation in all populations.

Our solution proposes a patient and community engagement work package aimed at encouraging patients to present earlier with symptoms. The Primary care engagement work package is aimed at facilitating change in clinical practice to incorporate ROMA into the investigation of suspected Ovarian cancer.

- A pilot project in 14 Modality Birmingham and Walsall practices is due to start in August 2023. Partners include the Sandwell and West Birmingham Hospitals NHS Trust (SWBH), Walsall Healthcare NHS Trust, South Tyne and Wear Pathology Centre, Black Country Pathology Services, The University of Birmingham, Roche and Abbott.
- The project is supported by West Midlands AHSN, West Midlands Cancer Alliance, Target Ovarian Cancer and Patient Participation Groups (PPG): Modality / SWBH.
- The innovation is licensed to Roche and Abbott and owned by Fujirebio.



#### Early detection and diagnosis of cancer

- Cochrane analysis 2022 shows that ROMA is superior to a combination of CA125 and ultrasound for diagnosis of Ovarian cancer.
- A systematic review from Dayyani *et al.*, 2016 suggests ROMA is 20% more sensitive than CA125 in diagnosis of early-stage Ovarian cancer. ROMA is currently advocated by American College guidelines for the diagnosis of Ovarian cancer in secondary care.

#### Patient outcomes and experience

• The ROCkeTS study is investigating the downstream impacts of accuracy of ROMA on patient outcomes and is due to report later in 2023.

#### **Service delivery**

 The impact on cost effectiveness is one of the outcomes that will be measured as part of the ongoing SONATA project. "It's an exciting pilot which is a great example of integrated working between all the organisations involved. We are looking forward to finding out the results so that we can change the way Ovarian cancer is detected in the future and drastically improve survival rates."

Prof Sudha Sundar, Professor of Gynaecological Cancer, Institute of Cancer and Genomic Sciences, University of Birmingham



Secure mobile endoscopic imaging on iPhone to detect early cancer of the throat from any location



Funding received by: NHS Cancer Programme Innovation Open Call 1

#### **Contact**

Name and role of Project Lead: Mr Ajith George, Medical Director Organisation: endoscope-i Ltd Email: ajith@endoscope-i.com Website: www.endoscope-i.com Twitter: @ajithpgeorge



# **CLINICAL PROBLEM**

Head and neck cancer is rare and difficult to detect. From over a quarter of a million referrals in the UK last year only 5% of these patients are diagnosed with cancer and many at late presentation. Endoscopy is the key tool for diagnosis but is limited to the secondary care setting mainly due to its expense, complexity and need for an onthe-spot consultant diagnosis. Endoscope-i have packaged up endoscopy into a secure and mobile system for iPhone used by nurses. High quality examination videos are securely shared with head and neck surgeons to detect throat cancer earlier.

# **PROPOSED SOLUTION**

The Telescopic Referrals Service is a pathway redesign incorporating the endoscope-i mobile endoscopy solution. It is used to streamline efficiency of the Head and Neck urgent suspected cancer referral pathway. Patients are triaged into HIGH and LOW risk groups using a validated risk scoring system. Most referrals are LOW risk and can be managed via the Telescopic pathway leaving HIGH risk patients to be seen in the limited consultant slots, increasing hospital efficiency. In the LOW-risk telescopic clinic, a nurse performs the endoscopic examination which is recorded on a secure mobile device using endoscope-i's bespoke software. This examination is then shared over a secure cloud network with consultants who can rapidly exclude cancer and generate a patient report. Remote reporting for consultants is faster allowing for more patients to be reported on. In doing so more examinations can be performed of patients with mild symptoms to detect early cancer.

- Listed as an ideal urgent suspected cancer referral Head and Neck pathway in the 2023 Getting it Right First Time (GIRFT) report.
- Engagement with North East London Cancer Alliance and Wessex Cancer Alliance.
- Engagement with NHS Scotland.
- Implemented in University Hospitals of North Midlands, Dorchester County Hospital, and University Hospitals Birmingham.



Early detection and diagnosis of cancer

- 0% of head and neck cancers missed by Telescopic reporting.
- 1% cancer pickup in a LOW RISK group who would have otherwise been discharged or delayed.
- LOW Risk reporting within 28.6 days on average when using only one extra nurse practitioner clinic.

#### Patient outcomes and experience

- Fast results: Patient reporting within 23 hours of having the endoscopy.
- High satisfaction of outcome: Only 2.7% of patients were re-referred back into the system within a two year follow up period.
- Efficient service: 84% of patients reassured and discharged on first appointment.

#### **Service delivery**

- Telescopic service contract extended at University Hospitals of North Midlands due to the HIGH impact on urgent suspected cancer referral service results.
- Reduction of the number of consultants needed to manage the urgent suspected cancer referral service from 10 to 3.
- Increased use of remote working has improved staff wellbeing and time management.

"Thank you for reviewing my endoscopy so quickly, I am incredibly thankful and relieved the results have found nothing to worry about. I must say I'm thoroughly impressed with the way this has all been handled, the AP was very professional and reassuring - your department is an absolute credit to the NHS. Thanks again."

University Hospitals of North Midlands patient of the Telescopic Service



The University of Manchester

Real-world Elecsys® GAAD algorithm implementation and validation to improve surveillance and early detection of hepatocellular carcinoma (REVISE HCC)



Funding received by: NHS Cancer Programme Innovation Open Call 2

#### Contact

#### Name and role of Project Lead:

Varinder Athwal, Principle Investigator for the REVISE HCC project, Consultant Hepatologist, Manchester University NHS Foundation Trust and Honorary Senior Clinical Lecturer at The University of Manchester **Organisation:** Manchester University NHS Foundation Trust / University of Manchester **Email:** Varinder.athwal@manchester.ac.uk LinkedIn: /varinder-athwal-24a608102/ Twitter: @VSAthwal



# **CLINICAL PROBLEM**

Hepatocellular carcinoma (HCC) surveillance urgently needs innovation to improve early HCC detection, better equity for access to surveillance and for curative treatment to become the norm rather than the exception.

Approximately 3,000 people are found to have HCC in the UK per year. Unfortunately, with current tests less than 1,000 people are identified when they can have potentially curative treatment. This leaves over 2,000 people per year with HCC that cannot be cured. By using our innovation alongside additional improvements to the surveillance pathway, we believe that over 1,000 people per year could be additionally detected at an earlier stage when their cancer is potentially curable.

# **PROPOSED SOLUTION**

The current testing recommendation is that all eligible people with cirrhosis are offered an ultrasound scan and a blood test (alpha fetoprotein – AFP) every 6 months to screen for HCC.

Our project will implement a new test called Elecsys® GAAD at Manchester University NHS Foundation Trust. The test, manufactured by Roche Diagnostics, uses AFP alongside another blood test (Elecsys® PIVKA-II), age and gender to calculate a risk score.

In our study, people with cirrhosis will be offered Elecsys® GAAD on a 6-monthly basis, alongside standard of care. This will allow us to determine if the test reduces unnecessary further scans and improves early detection of HCC. Ultimately, we want to know if Elecsys® GAAD could be used on its own, as this would be a considerable cost saving to the NHS, benefit patients and improve on the current standard of care.

- Elecsys® GAAD has currently been sold, or is being evaluated in early evaluation programmes in different countries across the world. Roche currently has commercial contracts in place in Holland and Poland.
- In addition to the REVISE HCC project, early evaluation programmes are running with customers in Germany, New Zealand, Australia, and Thailand.



#### Early detection and diagnosis of cancer

- Clinical evidence shows that Elecsys® GAAD had high performance in detecting HCC (sensitivity 86.5%), particularly early stage (sensitivity 78.9%), with 91.4% specificity for both early and all stages, out-performing current standard of care.
- Elecsys® GAAD has superior specificity (91.4% vs 84%) for all stages of HCC leading to a lower false positive rate.

#### Patient outcomes and experience

- Elecsys® GAAD has a lower false positive rate than standard of care. This means fewer patients are referred for unnecessary confirmatory MRI or CT testing, reducing patient anxiety, inconvenience and enabling the NHS to optimise its utilisation of imaging resources.
- Elecsys® GAAD has a higher sensitivity for detecting early stage HCC than standard of care. Therefore, patients diagnosed with early-stage disease have significantly better 5-year survival rates than those diagnosed with late-stage disease.

#### Service delivery

An accurate and integrated solution such as the Elecsys® GAAD, which is based on patient demographics and measurement of blood based tumour markers from a small volume of blood (already incorporated into the patient pathway), can increase the efficiency of the surveillance programme. This is based on modelling, reducing unnecessary patient investigations such as in demand services including MRI/CT, a cost saving of ~£5,250,000 on a lifetime cohort of 10,000 patients undergoing twice yearly surveillance, and improving the rate of detection of early stage HCC (increasing the chance of curative therapies such as liver resection, percutaneous ablative therapies and liver transplant).

"We are thrilled this funding award from NHS England gives us the opportunity to build on the trusted partnership we already have with colleagues in Manchester and the important work we are doing together to identify liver disease more accurately and sooner. By bringing together the collective knowledge and expertise of academic, medical and industry partners, this new project has the potential to streamline the diagnosis and treatment pathway for patients with liver cancer across the UK. to improve their experience and outcomes, and help alleviate pressure on the NHS."

Chris Hudson, Director of Access and Innovation at Roche Diagnostics UK and Ireland

# **CONTACT US**

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## Funding alert: NIHR & OLS Cancer Mission - Early Cancer Diagnosis Clinical Validation and Evaluation Call

The NIHR i4i Programme, in collaboration with the Office for Life Sciences (OLS), invites applications to the Cancer Mission: Early Cancer Diagnosis Clinical Validation and Evaluation Call. The aim of the call is to support the clinical validation and evaluation of breakthrough technologies that can increase the proportion of cancers which are detected earlier in the disease course and/or target health inequalities in stage of cancer diagnosis. Funding will be deployed to facilitate the generation of evidence on safety, test performance characteristics, clinical efficacy and/or effectiveness that can support regulatory approvals requirements and subsequent clinical implementation or implementation research. Applications that address health inequalities in early cancer diagnosis are particularly welcomed.

The Cancer Mission: Early Cancer Diagnosis Clinical Validation and Evaluation Call is a one-stage call inviting applications for projects up to 36 months in duration, with no upper funding limit.

The call will be open to organisations which are UK legal entities, that have an innovative solution with the potential to increase the proportion of cancers diagnosed at stages 1 and 2. This call is open to small/medium commercial entities, NHS and Third Sector Service Providers, charitable organisations, local government bodies, as well as universities and research institutions.

More information can be found in the call specification here.

The application window will open on October 24th 2023, 13:00 and will close on December 12th 2023, 13:00. A launch event will be held on Friday October 6th at 13:00, please register to attend the event at this link.



### i4i Cancer Mission: Early Cancer Diagnosis Clinical Validation and Evaluation Call

The call is open to organisations which are UK legal entities, that have an innovative solution with the potential to increase the proportion of cancers diagnosed at stages 1 and 2.

Launch event: 6 October Call opens: 24 October