NHS Cancer Programme

Innovation in the early diagnosis of cancer

Networking event

12 February 2025

British Medical Association (BMA) House, London

SBRI HEALTHCARE

Accelerated Access Collaborative

NHS Cancer Programme Innovation Open Calls

The proportion of patients being diagnosed with cancer at an early stage in England has risen to its highest ever level.

Following a major drive by the NHS over the last two years to encourage millions of people to come forward for potentially life-saving checks, especially those who may be at higher risk as a result of hereditary or lifestyle factors, latest data on 13 of the most common cancers, such as breast, prostate and lung cancer, shows that nearly three in five patients are now being diagnosed at stages one or two, when the cancer is easier to treat.

The Innovation Open Calls were developed and funded by the NHS Cancer Programme and supported by SBRI Healthcare and the Accelerated Access Collaborative, to fast-track high-quality, proven, late-stage innovations into front-line settings and address implementation evidence gaps.

The calls support the NHS ambitions to diagnose cancer earlier thereby improving survival.

NHS Cancer Programme

The NHS Cancer Programme has three main priorities:

- **Early diagnosis** - improving survival by increasing the proportion of cancers we diagnose at stage 1 and 2;
- **Operational performance** - improving performance against the three cancer waiting times standards; and,
- **Treatment and care** - providing the best possible treatment and experience of care, both during and beyond treatment, and for those living with cancer.

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.

SBRI Healthcare programme

The Small Business Research Initiative (SBRI) Healthcare programme is funded by the Accelerated Access Collaborative and delivered in partnership with the Health Innovation Networks (HINs). 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

9.30 **Registration and breakfast**

10.00 **Welcome and housekeeping**

Professor Richard Gilbertson, Chair of the NHS England Innovation Expert Advisory Group

10.10 **Introduction - The NHS Cancer Programme**

Chair: Professor Richard Gilbertson, Chair of the NHS England Innovation Expert Advisory Group
- Overview of the role of the NHS Cancer Programme, its impact and current strategic initiatives with Professor Peter Johnson, National Clinical Director for Cancer and Chair of the Office for Life Sciences Cancer Goals

10.25 **Case studies: Screening and proactive case finding**

Chair: Dr Jodie Moffat, Deputy Director, Policy and Strategy, NHS Cancer Programme, NHS England
- Cyted Health (Mrs Basirat Afinowi, Head of Projects)
- The Royal Marsden NHS Foundation Trust - Whole-body MRI (Dr Angela George, Clinical Director of Genomics and Consultant Medical Oncologist in Gynaecology)

11.05 **Networking coffee break**

11.35 **Case studies: Improving pathways**

Chair: Mrs Sally Rickard, Director, Wessex Cancer Alliance
- Endoscope-i (Dr Ajith George, Consultant Head and Neck Surgeon and Medical Director)
- The Institute of Cancer Research - BRCA-DIRECT (Professor Clare Turnbull, Professor of Translational Cancer Genetics and Consultant in Clinical Genetics; Mrs Bethany Torr, Scientific Programme Manager)

12.15 **Panel discussion: Improving pathways**

Chair: Dr Neville Young, Director of Enterprise and Innovation, Health Innovation Yorkshire and Humber
Panellists:
- Mr Piyush Mahapatra, Chief Innovation Officer, Open Medical
- Dr Aamena Salar, Primary Care Lead, Modality
- Dr Dan Mullarkey, Medical Director, Skin Analytics
- Dr Varinder Athwal, Consultant Hepatologist and Hon. Senior Clinical Lecturer, University of Manchester/Elecsys®GAAD
- Mrs Emily Bryant, Transformation Lead for Earlier Diagnosis, NHS England
- Ms Smitha Nathan, Deputy Managing Director, South East London Cancer Alliance

13.00 **Networking lunch**

13.55 **The "up and coming": Projects funded as part of NIHR i4i/OLS Cancer Healthcare Goals Programme**

Chair: Dr Colin Wilson, Deputy Director for Research Infrastructure at the Office for Life Sciences
- Imperial College London - PANACEA: PAN Alimentary Cancer Exhaled breath Analysis
- Optellum Ltd - CLEAREST: Clinical evaluation of lung cancer detection and diagnosis software
- The Institute of Cancer Research, London, and The Royal Marsden NHS Foundation Trust: Integration of the PRODICT ™ test into the prostate cancer risk pathway
- XGENERA Ltd - miONCO-Dx: A novel multi cancer early diagnostic test
- University of Southampton, and Proteotype Diagnostics Ltd: Cost-effective multi-cancer early detection by measuring patient plasma amino acid cross sections with the Enlighten test
- Imperial College London: Artificial Intelligence to support cancer early diagnosis in general practice (AI-DIP)

14.25 **The future of cancer innovation**

Chair: Dr Gillian Rosenberg, Innovation Transformation Lead, NHS Cancer Programme, NHS England
- Setting the scene: Professor Peter Johnson, National Clinical Director for Cancer and Chair of the Office for Life Sciences Cancer Goals; Dr Colin Wilson, Deputy Director for Research Infrastructure at OLS
- Discussion - All to contribute

15.25 **Concluding remarks**

Professor Richard Gilbertson, Chair of the NHS England Innovation Expert Advisory Group

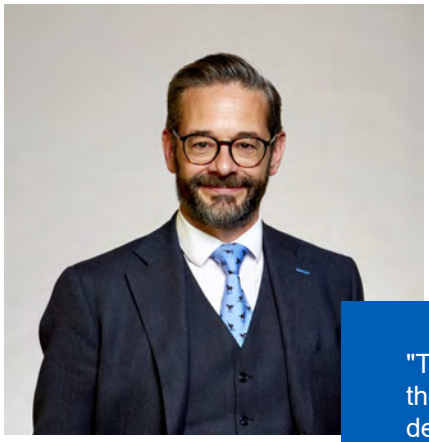
15.30 **Networking and departure**

SBRI HEALTHCARE

Accelerated Access Collaborative

"Cancer is more treatable at an early stage, so it is vital we continue to seek new methods of early detection and diagnosis. The NHS Cancer Programme and the Office for Life Sciences are working together on this, investing in high quality innovations and partnering with companies that have novel technologies to support NHS patients."

Professor Peter Johnson, National Clinical Director for Cancer at NHS England and Chair of the Office for Life Sciences Cancer Goals



"The innovations, technologies and collaborations supported by the NHS Cancer Programme Innovation Open Call are making detection and diagnosis of cancer faster, more efficient, and accessible to more people. They are pioneering opportunities for pathway improvement to ultimately save lives."

Professor Richard Gilbertson, Chair of the NHS England Innovation Expert Advisory Group

NHS Cancer Programme Innovation Open Calls - Impact

122
Applications Assessed

14
Innovations supported

£25m+
Invested

7

Companies with sales in the NHS

160K+

Patients involved in the pilots to date

£42.7m
Private investment leveraged

369

Sites participating

17

Cancer Alliances involved in implementation

10

Health Innovation Networks supporting the projects

Supported by Cancer Alliances

"The Northern Cancer Alliance has supported our work for several years and provided the first seed funding which underpinned the successful SBRI Healthcare bid."

Newcastle University

"West Midlands Cancer Alliance has been very supportive and helped us disseminate the findings to Trusts across the region."

Endoscope-i

"We have a long standing partnership with the West Yorkshire and Harrogate Cancer Alliance going back to 2018. Yorkshire is our home. Through our SBRI Healthcare work we have worked with other Alliances to prepare the innovation for scaling and joined up their labs to our systems."

PinPoint

"We would particularly like to thank Surrey and Sussex and Lancashire and South Cumbria Cancer Alliances for their support continuing to deploy and innovate eDerma through various initiatives including projects with community diagnostics and centralised virtual triage."

Open Medical

Innovation Open Calls: The innovations funded

The following pages contain case studies of the projects funded. The content has been provided by the project leads and is accurate as of January 2025.

To find out more about a project, please contact the project lead on the details they have provided.

Cancer Alliances can access published evaluation reports on FutureNHS.

General queries should be directed to england.cancerpolicy@nhs.net.

The capsule sponge test helps to identify and prioritise patients at risk of oesophageal cancer earlier and faster

Funding received by: NHS Cancer Programme Innovation Open Call 2

Featured at the event as a case study

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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 rates to 80%.

The current endoscopic pathways to identify and monitor Barrett's do not offer an efficient way to prioritise patients at risk. This leads to a large proportion of endoscopic investigations yielding no significant findings when aiming to identify Barrett's in those with chronic reflux, and invites backlogs and resource-strains when monitoring existing Barrett's patients. The challenge in both patient groups is how to minimise these unnecessary endoscopies and offer targeted interventions to the most at risk patients.

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 and community care. The sample is sent to the Cyted Health laboratory for processing and analysis by Cyted Health's 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, by improving patient selection throughout the upper GI pathway, the test helps clinicians ensure the right patients get the right treatment.

MARKET TRACTION & IMPLEMENTATION

- Cyted Health has raised a total of $30 million of venture capital and grant funding to date, including from London-based BGF and US- based Morningside, as well as SBRI Healthcare and Innovate UK.
- Cyted Health launched the EndoSign® capsule sponge test, improving safety and usability, along with a digital results portal to help clinicians manage their workflow. A US clinical trial is starting in early 2025, and EU testing has been carried out in Poland, Sweden and the Netherlands.
- Over 23,000 patients have now benefitted from capsule sponge testing in over 60 hospitals and 20 GP practices – including national adoption in Scotland.
- NHS England is supporting further adoption with increased funding in community diagnostic centres (CDCs) and reviews of existing funding in hospital settings.

"Thousands of people have now benefitted from this incredibly efficient test on the NHS – while the sponge on a string is small in size, it can make a big difference for patients."

Amanda Pritchard
Chief Executive, NHS England
(February 2024)

IMPACT

Early detection and diagnosis of cancer

- The capsule sponge test has been shown to have a high level of accuracy in detecting Barrett's oesophagus, with a specificity of 92% and sensitivity of 90%, as demonstrated in the BEST3 study.
- Introducing capsule sponge testing can support improved detection of concerning pathologies and early dysplasia. In Scotland, 1 in 2 endoscopies now find concerning pathologies, compared to 1 in 10 before, and the ratio of early to late dysplasia has increased from 28% to 53.9%.

Patient outcomes and experience

- The NHS England pilot in secondary care found that the majority of patients were satisfied with the procedure, citing reasons including:

  - It being a less invasive procedure compared to an endoscopy.
  - More confidence in the method of sampling cells rather than assessing visually.
  - Fewer staff and facilities being needed.
  - Timeliness and speed of getting an appointment.
  - In primary care, the majority of patients also had a positive experience with the testing pathway.

- Capsule sponge testing is now available in GPs, CDCs, community hospitals and acute sites – making it more convenient than ever for patients to access care. In some sites, being able to move testing to these more accessible locations has dramatically improved attendance rates and helped cut waiting times.

Service delivery

- The evaluation of capsule sponge testing in routine reflux referrals during the NHS England trial found the test can help triage endoscopy waiting lists to improve patient selection, diverting 78% of unnecessary endoscopies to boost clinical capacity and save over £420 per patient.
- The national adoption of capsule sponge testing for the surveillance of Barrett's oesophagus reduced the median delay to surveillance for NHS Scotland by 3 months. This helped promote the earlier detection of dysplasia and reduce the burden on endoscopy services.
- In the SBRI Healthcare-backed Cytoprime2 project, over 2,000 patients across the UK were tested with EndoSign® as part of the proactive case finding cohort. This involved testing at risk members of the public in GPs to help identify and treat oesophageal cancer earlier:

  - Results included 73 patients diagnosed with Barrett's oesophagus, and 3 incidences of cancer.

  - The capsule sponge test demonstrated a positive return on investment for the health and social care system across a 10-year time horizon, with a benefit-to-cost ratio of 1.2. This presents a valid economic case for using capsule sponge as a proactive case finding tool, alongside endoscopy triage for Barrett's surveillance.

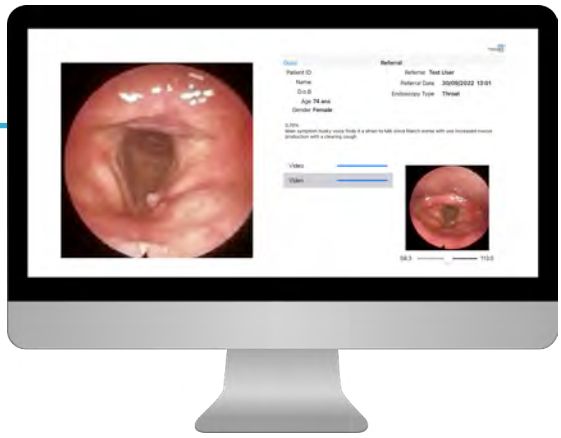
  - For patients, 89% reported having a positive experience throughout the pathway.

  - For healthcare staff, 87% believe the capsule sponge test was a reliable and acceptable method for the detection of Barrett's oesophagus and oesophageal cancer.

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

Featured at the event as a case study



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CLINICAL PROBLEM

Head and neck cancer is rare and difficult to detect. From over a quarter of a million referrals in the UK annually 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 on-the-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.

MARKET TRACTION & IMPLEMENTATION

- Featured on the BBC and Sky News as a groundbreaking innovation for the early detection of throat cancer.
- Re-contracted at University Hospitals North Midlands.
- Procured at University Hospitals Birmingham.
- Procured at Portsmouth University Hospitals.
- Planned roll out across West Midlands Cancer Alliance.

IMPACT

Early detection and diagnosis of cancer

- Maintains 0% of head and neck cancers missed by Telescopic reporting over 4 years of implementation.
- 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.

"With how fast my cancer developed after the first appointment to the stage where I needed a big laryngectomy surgery it makes me so grateful that it was picked up and in time and I believe that has saved my life."

Kyle Jones, 31
University Hospitals of North Midlands patient of the Telescopic Service

Streamlined, patient-directed pathways for germline genetic testing of cancer susceptibility genes

Funding received by: NHS Cancer Programme Innovation Open Call 2

Featured at the event as a case study

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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.

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.

MARKET TRACTION & IMPLEMENTATION

- 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.
- Roll out started in August 2023 at the Royal Marsden NHS Foundation Trust as part of this funded programme of work. There are now 15 breast oncology and surgical units from across North Thames actively referring patients for testing via BRCA-DIRECT.

IMPACT

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

- The 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).

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

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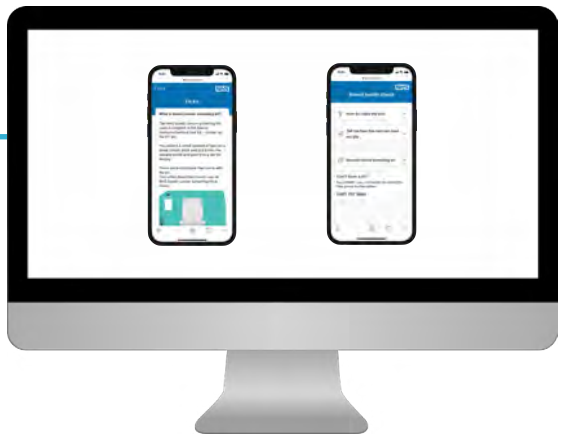


CLINICAL PROBLEM

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 (FIT).

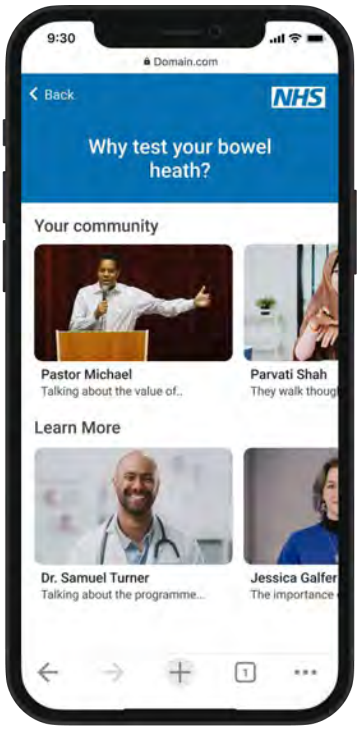
PROPOSED SOLUTION

iPLATO's platform sends multi-channel, demographic specific screening invitations at scale, utilising tailored reminders and digital educational content to boost uptake. The 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, those with learning disabilities, and people with severe mental health issues. The key unique selling points (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 designed for target patient cohorts to reduce misconceptions and overcome barriers, improving confidence to uptake screening.
- Measuring results and comparing to historical uptake rates across population cohorts.

MARKET TRACTION & IMPLEMENTATION

- 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 East of England and has previously done so for NHS London. The technology has also been adapted for use with Health Checks, National Diabetes Prevention Programmes and Diabetes Structured Education across the UK.
- This programme is being undertaken in partnership with NHS East of England, Cambridgeshire and Peterborough ICB, Bedfordshire, Luton and Milton Keynes ICB and the Bowel Cancer Screening Eastern Hub. King's College London and Queen Mary University London are providing the evaluation.
- iPLATO worked 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), lead the Patient and Public Involvement and Engagement (PPIE) with leaders from the targeted communities, patients from these communities, and clinical experts. GCA also created 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 South East London Cancer Alliance (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

- At the time of writing (December 2024), the project is at the midpoint of the delivery stage. As such, outcomes are preliminary and are expected to increase as the project progresses.
- 16,246 non-responders identified by the Bowel Cancer Screening Hub and 13,772 successfully contacted by iPLATO (85%).
- 3,438 FIT kits returned and 4,646 engagements with the educational content.
- Preliminary analysis showing non-responders are nearly 3 times more likely to return their bowel screening kit after receiving the intervention (29%), compared to those who don't (11%).
- 64 abnormal results and 1 confirmed cancer case diagnosed.
- 207 FIT kits reordered, 44 using the digital reordering function which was introduced on the 26 November 2024.

Patient outcomes and experience

iPLATO expects to see similar outcomes as seen in previous deployment to improve cervical cancer screening uptake in the NHS East of England, which 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 bowel cancer, the average cost to the NHS per person diagnosed at stage 2 is £3,559, compared to £13,206 for those diagnosed at stage 4 (Public Health England data, 2016).
- 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.

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

Funding received by: NHS Cancer Programme Innovation Open Call 2

Featured at the event in the panel discussion

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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

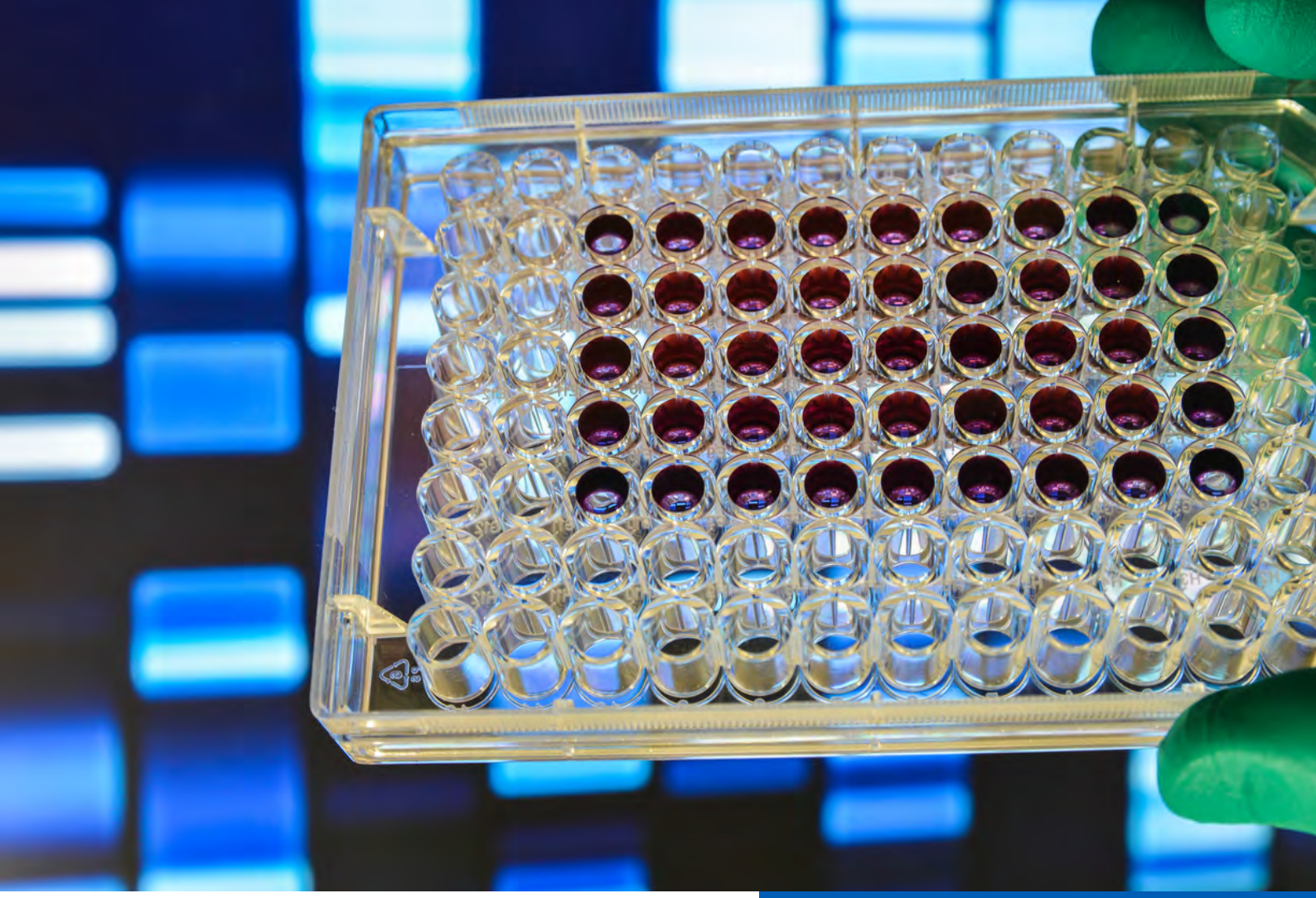
The novel biomarker ROMA test (that combines existing tumour marker CA125 with another serum biomarker He4 in an algorithm) has the potential to increase the earlier detection of ovarian cancer. ROMA picks up about 20% more early-stage cancers than the current standard of care test CA125 but is not used 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.

The 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.

MARKET TRACTION & IMPLEMENTATION

- A community awareness campaign has been designed, targeted to groups that face additional barriers to ovarian cancer diagnosis within geographic locations served by the Modality GP Practices.
- Working alongside the voluntary sector, partnering with Ovarian Cancer Charity, Ovacome.
- The SBRI Healthcare funded pilot (SONATA) has been presented to Cancer Research UK trustees and the Gynaecological Cancer Clinical Studies Group.
- A pilot project in 14 Modality Birmingham and Walsall Practices is currently ongoing, co-designed with primary and secondary care.
- Successful lab and IT integration.
- Primary care champions within the Modality Practices are taking part.
- 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 Health Innovation West Midlands, 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. Roche and Abbott have obtained CE Marking for ROMA testing.



IMPACT

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 was published in Lancet Oncology on October 1st 2024, investigating the downstream impacts of accuracy of ROMA on patient outcomes.
- SONATA is addressing health inequalities and issues with access.

Service delivery

- The team are working with stakeholders to scale.
- The impact on cost effectiveness is one of the outcomes that will be measured.

"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."

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

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

Funding received by: NHS Cancer Programme Innovation Open Call 1

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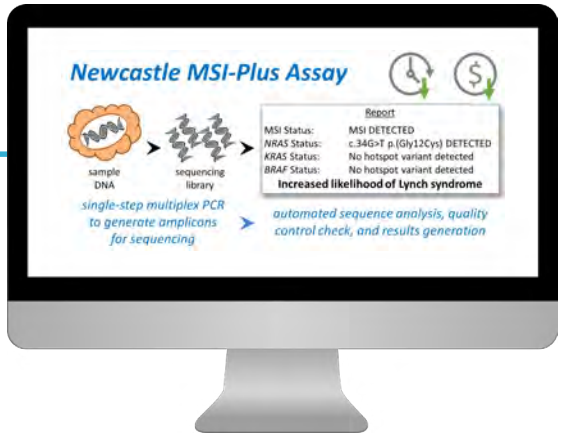


CLINICAL PROBLEM

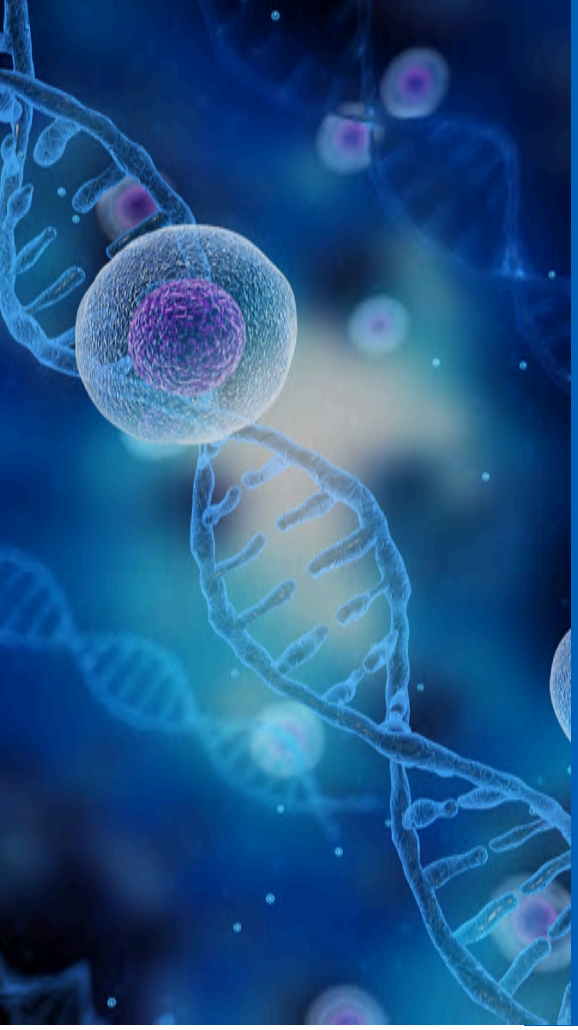
Lynch syndrome (LS) affects ~3/1,000 people. LS carriers often get bowel and other cancers from early adulthood; by age 65 years more than two thirds will have had at least one cancer. LS cancers can be prevented or detected early, but only ~5% of carriers are known to the NHS. In 2017, NICE required 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.

MARKET TRACTION & IMPLEMENTATION

- 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

- Expensive, time-consuming immunohistochemistry screening has been replaced 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 the 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 seven 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 Health Innovation Network showed strong professional support. Multidisciplinary teams now routinely ask for the MSI-Plus result. A formal economic analysis by Newcastle University is underway.

Gallon, R., Herrero-Belmonte, P., Phelps, R. *et al.* A novel colorectal cancer test combining microsatellite instability and *BRAF/RAS* analysis: Clinical validation and impact on Lynch syndrome screening. *BJC Rep* **2**, 48 (2024). https://doi.org/10.1038/s44276-024-00072-8

OpenMedical

Pathpoint eDerma®
Beyond Teledermatology

Funding received by: NHS Cancer Programme Innovation Open Call 1

Featured at the event in the panel discussion

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CLINICAL PROBLEM

In the UK, around 156,000 non-melanoma and 16,700 melanoma cases are diagnosed annually, with cases expected to rise by 9%. Dermatology services receive 500,000 referrals for suspected skin cancer each year, and with a shortage of dermatologists and limited patient access this makes it challenging to meet faster diagnostic standards, leading to treatment delays. Early diagnosis remains critical for effective skin cancer care.

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.

MARKET TRACTION & IMPLEMENTATION

- Supported by the NHS Innovation Accelerator and SBRI Healthcare.
- eDerma's reach continues to grow, with 13 regional deployments, representing multiple NHS Trusts, two full ICS-wide deployments, and a private healthcare provider:
  East Kent Hospitals University NHS Foundation Trust, Northern Care Alliance NHS Foundation Trust, Bedfordshire Hospitals NHS Foundation Trust, West Hertfordshire Teaching Hospitals NHS 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, DMC Healthcare, East Lancashire Hospitals NHS Trust, Lancashire and South Cumbria NHS Foundation Trust, University Hospitals of Morecambe Bay NHS Foundation Trust, Blackpool Teaching Hospitals NHS Foundation 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

- Most patients receive their diagnosis 14 days faster with eDerma compared with traditional pathways.
- More patients achieve diagnosis within the 28-day faster diagnostic standard with eDerma, even with 88% increase in referrals.
- Assessments take on average 5.5 minutes, up to 4 times faster than face-to-face appointments, saving dermatologist time and increasing capacity.
- 93.6% of patients diagnosed or given a decision to treat at time of telederm assessment.

Patient outcomes and experience

- 88.9% of patients found the teledermatology questionnaire easy to complete.
- 85% of patients believe eDerma saves time.
- 87% think it is a good way of managing their skin lesion concerns.
- Patients from all Index of Multiple Deprivation (IMD) groups provided positive feedback for eDerma, as shown by Patient Reported Experience Measure (PREM) results.
- There is no significant difference in patient experience with eDerma across various IMD groups.
- eDerma is well-received by patients from diverse ethnicities, sexual orientations, genders, and educational levels.
- Patients in various IMD groups experienced no significant difference in referral to diagnosis times.

Service delivery

- The average cost of diagnosing a skin lesion using eDerma was £45 lower per patient compared to traditional face-to-face appointments.
- With eDerma, patients are 18% less likely to be referred for a diagnostic biopsy and instead diagnosed directly by dermoscopy assessment or booked straight to treatment. For these patients, cost savings could reach up to £135.
- An ICS is projected to save over £1.2 million within its first year of using eDerma.
- Waiting list simulation of eDerma at an NHS Trust significantly accelerated all stages of the diagnostic pathway compared to traditional care models:
  - 54.18 days shorter for diagnosis communication, 9.90 days shorter for clinical diagnosis, and 62.80 days shorter for histopathological diagnosis.
  - Streamlined the triage process, reducing the need for in-person appointments without compromising care quality.

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

Funding received by: NHS Cancer Programme Innovation Open Call 1

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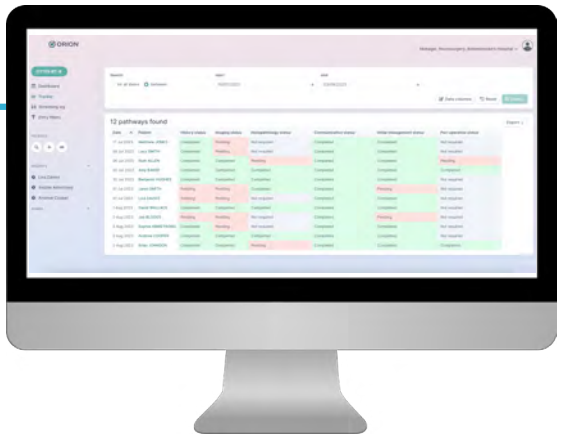


CLINICAL PROBLEM

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.

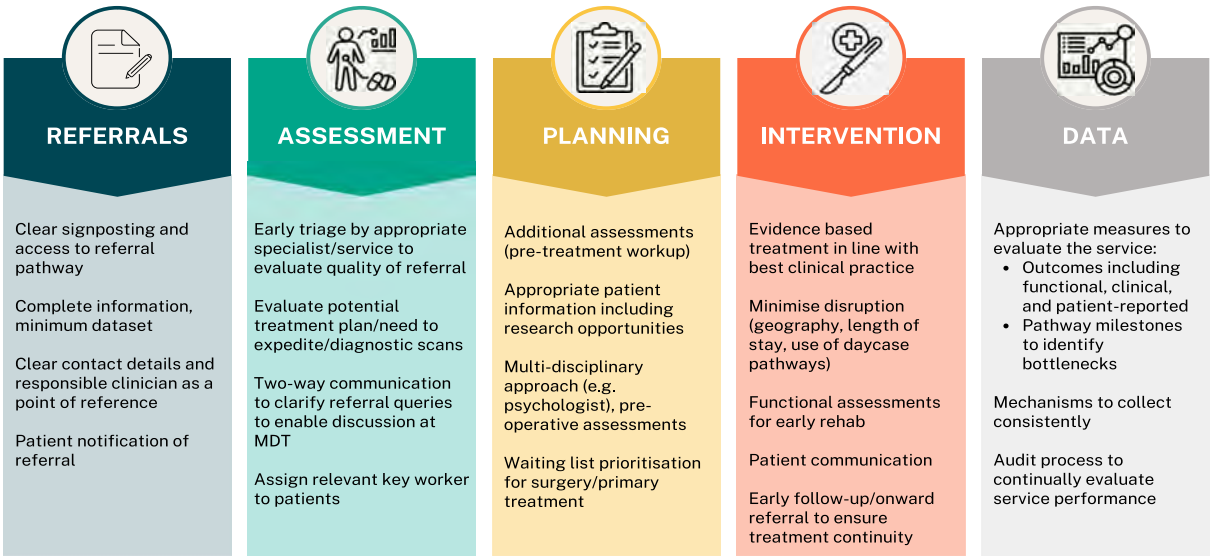
PROPOSED SOLUTION

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.

MARKET TRACTION & IMPLEMENTATION

- The project 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.
- The 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.



IMPACT

Patient outcomes and experience

- **Early Specialist Input:**
  The co-produced pathway introduced through RAPID ensures timely access to specialist care for patients with suspected brain cancer. This approach has significantly reduced waiting times for definitive treatment decisions, enabling faster, life-changing interventions.

- **Faster Neurosurgical Treatment Decisions:**
  RAPID has reduced the average waiting time for neurosurgical treatment decisions by 7 days across all tumour types (from 13 to 6 days). For suspected high-grade gliomas, the waiting time decreased by 5 days (from 7.3 to 2.5 days). The shortened waiting period is crucial for high-grade gliomas, which typically double in size every 50 days.

- **Reduced Hospital Stays:**
  Patients triaged through RAPID spent less time waiting for regional MDT decisions in their local hospital. Post-operative recovery times also improved significantly, with the average hospital stay reduced from 10.6 days to 5.6 days. These reductions enhance both patient outcomes and the overall care experience.

Service delivery

- **Optimised Referrals for Efficient MDT Discussions:**
  RAPID's comprehensive screening process ensures all referrals are complete and include the necessary information from the outset. This eliminates the need for clinicians to address incomplete referrals during MDT meetings, allowing discussions to be more efficient, focused, and productive. As a result, clinicians can dedicate their time to devising optimal treatment plans for patients.

- **Enhanced Collaboration Through Interoperable Systems:**
  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 has reduced duplication of data entry and investigations across hospital sites, such as MRIs, saving time and money.

- **Cost Savings:**
  The reduction in post-operative hospital stays (from 10.6 to 5.6 days) results in substantial savings in a neurosurgical unit. Additionally, an independent evaluation of the RAPID framework estimated monthly savings of £5,000 for patients managed through the neuro-oncology MDT pathway.

"RAPID led to a change in practice and there is an acknowledgement that the patient pathway is smoother and kinder with this input."

Judith Battersby, Neuro-oncology Clinical Nurse Specialist

Optimising urgent cancer referrals through an AI-driven blood test

Funding received by: NHS Cancer Programme Innovation Open Call 1

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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.

As a result, diagnosis and start of treatment can be delayed by the sheer volume of referrals, only 6% of whom are ultimately diagnosed with cancer. The remaining 94% of patients often go through anxious waits and potentially invasive tests to find they do not have cancer at all.

An affordable solution is needed to triage patients by individual risk as they enter the referral pathway, thereby reducing systemic pressures, freeing up capacity and focusing resources on the patients that need help most.

PROPOSED SOLUTION

The PinPoint Test is a solution to the twin challenges of early cancer detection and capacity management in the Faster Diagnosis Standard (FDS) pathway.

It is a software product which applies machine learning to the results of a single draw of blood processed in local pathology labs. It is hosted on NHS servers and integrated into local Laboratory Information Management (LIM) systems for ease of use and built-in data security.

Cancer signal from 31 standard analytes, plus age and sex, is aggregated into ONE strong signal: the chance that a patient has cancer. The result is a tool for intelligent triage and stratification of suspected cancers: prioritisation for those at highest risk and rule-out for those at lowest risk.

PinPoint data suggests that up to 20% of patients could be safely ruled out, improving pathway performance and the patient experience.

PinPoint upgrades existing systems rather than replacing them. No procurement of new diagnostic hardware is required; the test is seamlessly integrated into NHS infrastructure, meaning low cost and low barriers to clinical deployment. Evaluation results show the process of iterative AI improvements to diagnostic accuracy in action. Just like an app, future versions will be rolled out as they are validated and regulated at no extra cost, and with no interruption to service.

MARKET TRACTION & IMPLEMENTATION

- A service evaluation in West Yorkshire & Harrogate is nearing completion. ~16,000 tests complete to date.
- The test for the Lower GI pathway is the first to begin the process of implementation, starting with an Innovate UK-funded optimal use case pilot.
- Recent interim results for the Upper Gastrointestinal, Gynaecological, and Head & Neck pathways are extremely encouraging and will be made available in the coming months.
- SBRI Healthcare-funded groundwork for rollout of the test has been completed in 4 Cancer Alliance areas.
- The PinPoint Test is UKCA marked. Public sector buyers have a compliant route to procurement via both G-Cloud and HTE frameworks.
- Commercial talks with key global providers of laboratory services and equipment are ongoing.

IMPACT

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:

- In 2023-24, over 570,000 people received Lower GI FDS referrals in England alone. Implementation of the PinPoint prioritisation use case would quickly yield enough new data to increase statistical confidence in the rule-out tool.
- Total potential savings in PinPoint's priority pathways, based on a 20% reduction on 2023-24 referral numbers in England, are as follows:
  Lower GI: £41m
  Upper GI: £18m
  Gynaecological: £24m
  Head & Neck: £20m
  Breast: £46m
  TOTAL: £149m
- Multi-cancer sensitivity: Evaluation results show PinPoint is sensitive to the ~25-30% of non-Lower GI cancers initially referred to the Lower GI pathway, offering the potential for earlier diagnosis and treatment of those cancers.
- Data modelling shows that PinPoint used in combination with FIT increases diagnostic accuracy to a level that out-performs either test on its own – a software upgrade to the existing bowel cancer pathway.

Patient outcomes and experience

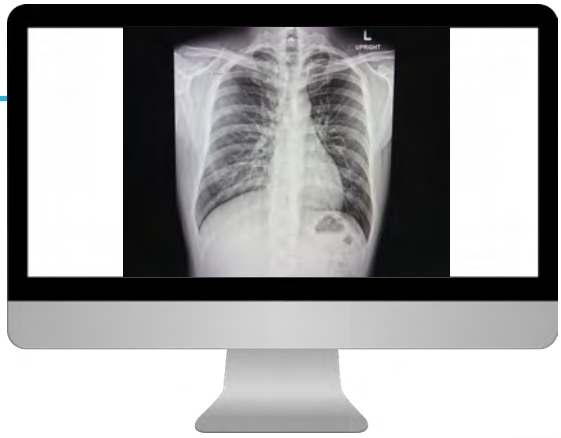
- Patient and Public Involvement and Engagement (PPIE) sessions run in five Cancer Alliance territories demonstrate high levels of patient support.
- Early identification of high-risk patients and the freed-up capacity in referral pathways that comes from rule-out can lead to faster diagnosis and start of treatment, in turn improving clinical outcomes.
- In line with the results of PPIE and useability conversations with GPs, test results will be returned using a numerical scale, accompanied by guidance such as a traffic light system to indicate next steps. This simpler way of communicating results will help clinicians manage patient expectations and anxiety.

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 with 62-day treatment targets.
- Pathways able to more efficiently allocate diagnostic resources based on risk will be more robust and resistant to system shocks like COVID-19.

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



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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.

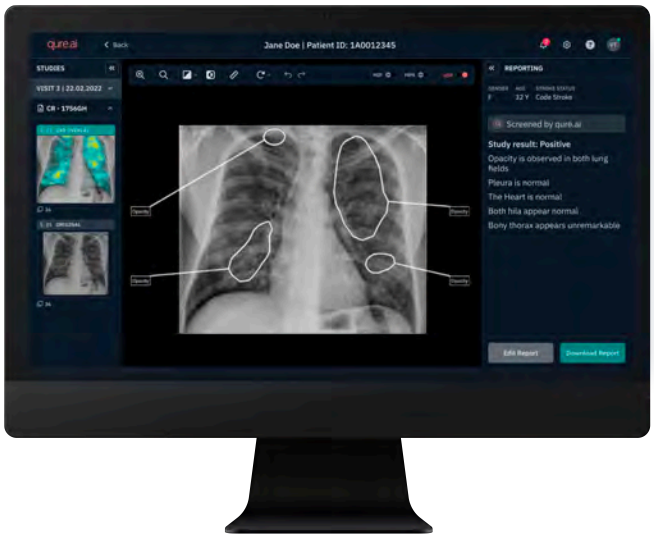
PROPOSED SOLUTION

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.

MARKET TRACTION & IMPLEMENTATION

- Globally, Qure products have impacted 25 million lives, across 90+ countries and 3,100 sites. This work has been validated and evidenced across 60 + publications (https://www.qure.ai/evidences).
- qXR holds CE Class IIb certification and is clinically validated. It is successfully deployed across Low and Middle Income Countries (LMIC), and with AstraZeneca where 4 million chest x-rays have been processed globally across 33 countries and 446 sites.
- In the UK, qXR has been deployed across 30 NHS Trusts and Health Boards, and processed over 700k chest X-rays. Some Trusts and Health Boards include: Barts; Homerton; Barking, Havering and Redbridge; East Kent; with more Trusts expected to go live in 2025 supported by the NHS England AI Deployment Fund.
- For the present SBRI Healthcare project – LungImpact trial, qXR is deployed at University College London Hospitals, University Hospitals of Leicester, East Sussex and North Essex, University Hospitals Birmingham and Nottingham University Hospitals NHS Trusts – highlighting the diversity of sites included in this trial.
- Over the duration of the LungImpact trial, over 100k GP referred patients with chest X-rays were randomized into two groups for triaging of reporting – AI triaged and non-triaged. This is the largest multisite randomized implementation of AI and was recognised by Nature Medicine as one of the “11 clinical trials to shape medicine in 2024”.



"Speed of diagnosis is critical to achieve the best outcomes in lung cancer and to reduce stress and worry for patients. AI 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 X-rays 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

IMPACT

Early detection and diagnosis of cancer

- In partnership with the Greater Manchester Cancer Alliance, qXR demonstrated a 43% improvement in reporting turnaround time for suspected lung cancer (SLC) patients, increased same day reporting of SLC patients by 26% (to 52%), picking up 97% of lung cancers, with a 99.9% negative predictive value (ability to identify individuals that don't have a condition).
- In partnership with NHS Greater Glasgow and Clyde, as part of the RADICAL study, qXR demonstrated an 80% improvement in reporting turnaround time across all sectors for urgent suspect cancer cases flagged by AI.

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]

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 negative predictive value (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.

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

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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.

MARKET TRACTION & IMPLEMENTATION

- 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.
- The 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, St George's University Hospitals NHS Foundation Trust, Chelsea and Westminster Hospital, and West Middlesex Hospital.

"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

IMPACT

Early detection and diagnosis of cancer

- Reduction of 7 days in the diagnostic pathway using liquid biopsy compared to invasive tissue based biopsy (10 vs 17 days).
- 84% ctDNA detection rate in patients with suspected stage 3 or 4 pancreatic or biliary tract cancers.

Patient outcomes and experience

- 46% reduction in repeat invasive tissue based biopsies, reducing procedure-related complications such as pancreatitis.
- 86% of patients in the ACCESS project reported as very satisfied or satisfied with the Guardant360® liquid biopsy blood test.

Service delivery

- Liquid biopsy testing established across 7 hospital sites in West London.
- Efficiency gains in the molecular testing pathway by providing genomic profiling information at point of diagnosis and treatment options for patient.
- 100% discussion rate at Molecular Tumour Board, increasing specificity of Guardant360® test to 83%.

The ROYAL MARSDEN NHS Foundation Trust

ICR The Institute of Cancer Research

Whole-body Magnetic reSonance Imaging screening in Li Fraumeni Syndrome for Early Cancer Diagnosis (SIGNIFIED)

Whole-body MRI (WB-MRI) screening for early cancer diagnosis in Li Fraumeni syndrome

Funding received by: NHS Cancer Programme Innovation Open call 2

Featured at the event as a case study

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CLINICAL PROBLEM

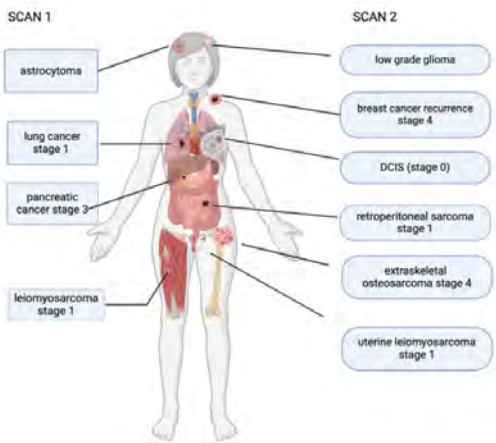
Li Fraumeni syndrome (LFS) is an inherited familial predisposition to a wide range of cancers. This is due to an alteration in the tumour suppressor gene TP53. LFS individuals have a 70-90% lifetime risk of developing cancer, often before the age of 50. The only screening for TP53 mutations in the NHS 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

The solution proposes 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. An implementation pilot as a service evaluation has been undertaken at the Royal Marsden Hospital and 50 patients with LFS have been enrolled in the study. The aim was 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 was completed at the Royal Marsden Hospital, a leading cancer hospital in the UK and Europe.
- The project has demonstrated that WB-MRI could detect early cancers in asymptomatic patients with Li Fraumeni syndrome.
- In the cohort, ten cancers were diagnosed with the help of WB-MRI. Seven cancers (70%) were early stages (TNM stage 0-2) and were treated with curative intent; three cancers (30%) were late stages (TNM stage 3-4).



"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 Finn, 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."

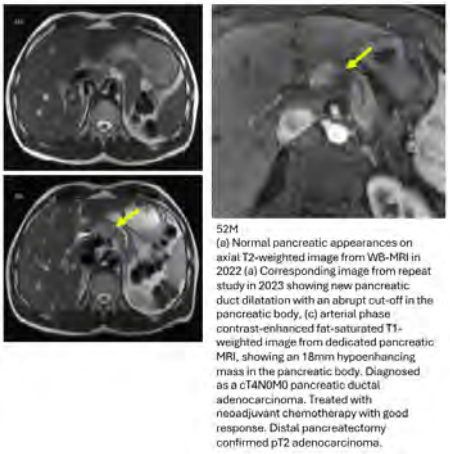
LG, Li Fraumeni patient

IMPACT

Early detection and diagnosis of cancer

The project has demonstrated that WB-MRI is a valuable and useful radiological tool for detecting early cancers in patients with LFS and should be implemented as a regular screening test for this population. A health economics analysis is ongoing to determine if screening with WB-MRI is cost-efficient.

69F
Subpleural paramediastinal consolidation in the superior segment of the right lower lobe shown on (a) T2-weighted imaging, (b) b900 diffusion-weighted imaging, and subsequently confined with CT chest (c). Diagnosis was a pT1b lung adenocarcinoma.



52M
(a) Normal pancreatic appearances on axial T2-weighted image from WB-MRI in 2022 (a) Corresponding image from repeat study in 2023 showing new pancreatic duct dilatation with an abrupt cut-off in the pancreatic body, (c) arterial phase contrast-enhanced fat-saturated T1-weighted image from dedicated pancreatic MRI, showing an 18mm hypoenhancing mass in the pancreatic body. Diagnosed as a cT4N0M0 pancreatic ductal adenocarcinoma. Treated with neoadjuvant chemotherapy with good response. Distal pancreatectomy confirmed pT2 adenocarcinoma.

DERM, UKCA Class IIa AI as a Medical Device (AIaMD), enabling early diagnostic skin cancer assessments in the community

Funding received by: NHS Cancer Programme Innovation Open call 2

Featured at the event in the panel discussion

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CLINICAL PROBLEM

Dermatology is the largest referring cancer speciality in the UK and referrals are growing by over 10% year on year. Concurrently, 1 in 4 consultant dermatologist posts remain unfilled. Despite sustained and considerable effort from dermatology departments, this has led to waitlists growing significantly. In 2023 >180,000 patients waited more than 28 days after urgent cancer referral for their diagnosis, while provisional NHS data suggests that, as of September 2024, around 450,000 patients are waiting on Referral to Treatment pathways, with 39% of dermatology patients waiting more than 18 weeks.

Despite the high volume of patients being referred, only 6-8% result in a diagnosis of melanoma or squamous cell carcinoma, with the majority of patients being referred for benign skin lesions.

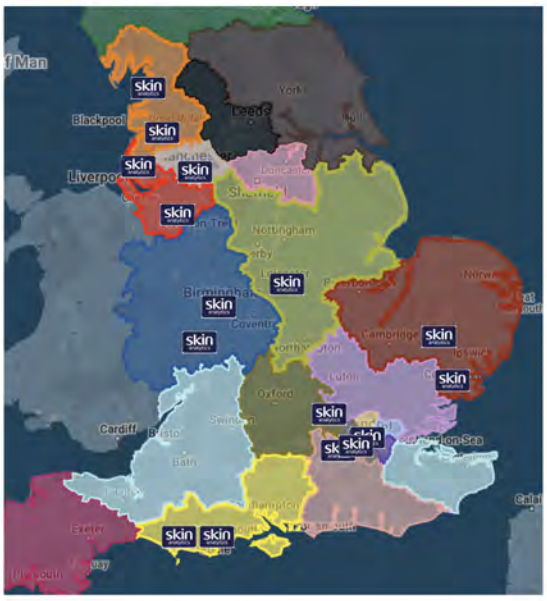
PROPOSED SOLUTION

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, NHS pathways using DERM have assessed more than 145,000 people and DERM has found more than 9,000 cancers.

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.

MARKET TRACTION & IMPLEMENTATION

Skin Analytics has conducted over 145,000 skin cancer assessments for NHS patients since launching. The first service was a remote skin cancer assessment service for Vitality Health which has since been expanded to cover Bupa members. Skin Analytics launched the world's first AI skin cancer pathway with University Hospitals Birmingham in April 2020 and is now live across 20 NHS sites, shown below:



"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

"The role of AI, as far as I'm concerned, is here to stay. We need to use it as part of a pathway that redefines the whole process, reduces the work pressures, but also increases efficiencies in terms of costs - underpinning it all is a [positive] patient journey."

Dr Nimal Muttu, GP & PCN Clinical Lead, Buckshaw Village Surgery

"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

IMPACT

Early detection and diagnosis of cancer

It is expected that the innovation will improve early diagnosis of skin cancer by:

- Encouraging patients to present early.
- Increasing cancer 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 utilised to provide quicker reassurance to patients with benign lesions thus reducing onward dermatology referrals. Capacity can therefore be directed to patients who need their expertise the most.
- The most recent post-market surveillance data demonstrated that DERM continues to perform at or above the level of specialists. Real-world malignancy sensitivity was >96% across all pre-referral sites.
- DERM helps to support better triage of cases that warrant specialist review and onward referral to biopsy or excision. Across pre-referral sites, DERM avoids Urgent Suspected Cancer referrals for 60-70% of patients including 35-50% of patients being routed towards discharge. Across all sites, the most recent performance report showed that DERM is 99.8% accurate at ruling out skin cancer.
- 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 and treatment.

Patient outcomes and experience

- 1,785 out of 1,892 patients who responded to surveys SBRI Healthcare supported, primary care sites rated the service as excellent and would recommend the pathway to their friends and family.
- 83% of patients at Chelsea & Westminster would recommend the service to friends and family.
- 95% of patients at West Suffolk Hospital Foundation Trust & East Suffolk and North East NHS Foundation Trust consent to DERM making autonomous discharge decisions on their care.
- 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.
- Independent Evaluations:
  - **2022 Edge Health**: Benefit cost ratio of 1.9, 98% of University Hospitals of Leicester patients surveyed would recommend the service to family & friends. 70% did not feel that something was missing not seeing a doctor face-to-face. 65% of patients reported that the service saves time compared to face to face [1].
  - **2023 Exeter Test Group**: The savings from using DERM are £51.89 per patient. Estimated savings of £34.5m across NHS England [2].
  - **2024 Edge Health**: Benefit: cost ratio 2.3 → up to £86 saved per patient. Reduction in downstream biopsies and streamlined operational workflows [3].

1. Edge Health. 2024. Available from: https://www.edgehealth.co.uk/news-insights/evaluation-nhs-ai-skin-cancer/ 2. 2023. Available from: https://skin-analytics.com/wp-content/uploads/2023/12/Skin-Analytics-Health-Economics-impact.pdf 3. 2024. Available from: https://www.edgehealth.co.uk/wp-content/uploads/2024/08/Evaluating-Pathways-for-AI-Dermatology-in-Skin-Cancer-Detection.pdf

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

Featured at the event in the panel discussion

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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 GAAD- a navify® Algorithm alongside additional improvements to the surveillance pathway, 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.

A new test called GAAD- a navify® Algorithm has been fully implemented and integrated 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 the study, people with cirrhosis are offered GAAD on a 6-monthly basis, alongside standard of care. Patients are currently being recruited for the study to get the real world dataset. This will help determine whether the test reduces unnecessary further scans and improves early detection of HCC. Ultimately, the aim is to know if 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.

MARKET TRACTION & IMPLEMENTATION

- GAAD- a navify® Algorithm has currently been sold, or is being evaluated in early evaluation programmes in many different countries across the world. Roche currently has 35 commercial contracts in place across Europe and Asia.
- In addition to the REVISE HCC project, early evaluation programmes are running with customers in Asia-Pacific (APAC) with more planned.

IMPACT

Early detection and diagnosis of cancer

- Clinical evidence from case control studies demonstrated that GAAD- a navify® Algorithm 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 (Chan et al., 2021).

Patient outcomes and experience

- GAAD- a navify Algorithm has demonstrated higher sensitivity for detecting early stage HCC than standard of care. Therefore, patients diagnosed with early-stage disease are likely to have significantly better 5-year survival rates than those diagnosed with late-stage disease.

- GAAD-a navify® Algorithm has also demonstrated a lower false positive rate than standard of care. This could mean fewer patients are referred for unnecessary confirmatory MRI or CT testing, reducing patient anxiety, inconvenience and enabling the NHS to optimize its utilization of imaging sources.

Service delivery

- GAAD- a navify® Algorithm leverages patient demographics and measures tumor markers from a small blood sample already collected as part of the current patient pathway. Its accuracy and seamless integration mean it has the potential to enhance the efficiency of the surveillance program. This has been highlighted by a published analysis evaluating the cost-effectiveness of HCC surveillance strategies from a UK NHS perspective (Garay, 2024). These findings suggest that GAAD- a navify® Algorithm, whether used alone or in combination with ultrasound, is a cost-effective approach when compared with ultrasound and ultrasound + AFP, with its use alone being the most cost-effective strategy.

"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

Building the Pipeline

The National Institute for Health and Care Research (NIHR), and the Office for Life Sciences (OLS), have funded six projects through NIHR's Invention for Innovation (i4i) and the OLS Cancer Healthcare Goals Programme. These six projects are receiving almost £11 million to support further testing of early-stage innovations to help increase the early detection and diagnosis of cancer. The funding is part of a wider package of new schemes that will bring the power of the UK's life sciences sector and the NHS to bear on tackling cancer and other life threatening diseases, with better treatments and faster diagnoses.

Office for Life Sciences

NIHR | National Institute for Health and Care Research

IMPERIAL

PANACEA: PAN Alimentary Cancer Exhaled breath Analysis. A new breath test for multiple gastrointestinal cancers (oesophageal, gastric, pancreatic, liver and colorectal)

Funding received by: NIHR & OLS

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Project: Researching the accuracy of a new breath test for multiple gastrointestinal cancers (oesophageal, gastric, pancreatic, liver and colorectal) as well as studying how to introduce it into primary care.

Optellum

CLEAREST: Clinical evaluation of lung cancer detection and diagnosis AI software

Funding received by: NIHR & OLS

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Project: Studying how artificial intelligence (AI) software could help medical imaging experts to find suspicious 'spots' in the lungs and assist them in deciding if they could be early lung cancer.

ICR The Institute of Cancer Research

The ROYAL MARSDEN NHS Foundation Trust

IMPERIAL

PRODICT ™: Integration of the PRODICT ™ saliva genetic test into the prostate cancer risk pathway

Funding received by: NIHR & OLS

Contact
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Project: Evaluating a 'saliva' genetic test to identify people at risk of developing prostate cancer, to find out how it can be integrated into the NHS.

XGENERA

miONCO-Dx : A novel multi cancer early diagnostic blood test

Funding received by: NIHR & OLS

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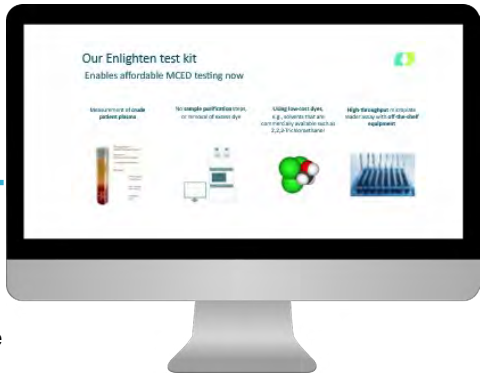
Project: Improving the efficiency and evaluating the performance of a new cancer blood test for use as a screening tool. The test aims to detect 12 of the most lethal and common cancers at an early stage.

University of Southampton

Proteotype DIAGNOSTICS

The Enlighten test: Multi-cancer early detection by measuring patient plasma amino acid cross sections



Funding received by: NIHR & OLS

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Project: Testing how a new type of multi cancer early detection test performs in an NHS context. Researchers will also plan for how the test could be used within deprived communities.

IMPERIAL

AI-DIP: An Artificial Intelligence (AI) Assistant to support early cancer diagnosis in general practice using pancreatic and lung cancer as case studies

Contact
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Project: Developing an Artificial Intelligence (AI) Assistant to improve the early diagnosis of cancer in general practice, using pancreatic and lung cancer as case studies.

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