

Memorandum of Understanding

between

NHS ENGLAND

and

Gateshead Health NHS Foundation Trust

in relation to

National NHS-Galleri Implementation Pilot Operations Service

Clause

1. Background
2. Key objectives for the project
3. Principles of collaboration.....
4. Project governance
5. Roles and responsibilities.....
6. Escalation.....
7. Intellectual property
8. Confidential Information
9. Publicity
10. Term and termination
11. Variation
12. Assignment.....
13. Costs and liabilities.....
14. Status
15. Governing law and jurisdiction.....

ANNEX

- Annex A. The Project
- Annex B. Collaborators' Board terms of reference **Error! Bookmark not defined.**
- Annex C. Information Governance

THIS AGREEMENT is dated **29/04/2024**

PARTIES

- (1) **NHS England** of [REDACTED]
[REDACTED].
- (2) **Gateshead Health NHS Foundation Trust** of [REDACTED]
[REDACTED]

1. BACKGROUND

- 1.1 NHS England and Gateshead Health NHS Foundation Trust have agreed to work together on the project detailed in page 11 (the "**Project**").
- 1.2 The parties wish to record the basis on which they will collaborate with each other on the Project. This Memorandum of Understanding (**MoU**) sets out:
 - (a) the objectives of the Project;
 - (b) the principles of collaboration;
 - (c) the governance structures the parties will put in place; and
 - (d) the respective roles and responsibilities the parties will have during the Project.

2. OBJECTIVES FOR THE PROJECT

- 2.1 The parties shall undertake the Project to achieve the objectives set out in this MoU (the "**Objectives**").
- 2.2 The parties acknowledge that the current position with regard to the Project and the contributions already made (financial and otherwise) are as detailed in page 11 to this MoU.

3. PRINCIPLES OF COLLABORATION

- 3.1 The parties agree to adopt the following principles when carrying out the Project (the "**Principles**"):
 - (a) collaborate and co-operate. Establish and adhere to the governance structure set out in this MoU to ensure that activities are delivered and actions taken as required;
 - (b) be accountable. Take on, manage and account to each other for performance of the respective roles and responsibilities set out in this MoU;
 - (c) be open. Communicate openly about major concerns, issues or opportunities relating to the Project;

- (d) learn, develop and seek to achieve full potential. Share information, experience, materials and skills to learn from each other and develop effective working practices, work collaboratively to identify solutions, eliminate duplication of effort, mitigate risk and reduce cost;
- (e) adopt a positive outlook. Behave in a positive, proactive manner;
- (f) adhere to statutory requirements and best practice. Comply with applicable laws and standards including procurement rules, data protection and freedom of information legislation.
- (g) act in a timely manner. Recognise the time-critical nature of the Project and respond accordingly to requests for support;
- (h) manage stakeholders effectively;
- (i) deploy appropriate resources. Ensure sufficient and appropriately qualified resources are available and authorised to fulfil the responsibilities set out in this MoU. And;
- (j) act in good faith to support achievement of the Objectives and compliance with these Principles.

4. PROJECT GOVERNANCE

- 4.1 The following guiding principles are agreed. The Project's governance will:
 - (a) provide strategic oversight and direction;
 - (b) be based on clearly defined roles and responsibilities at organisation, group and, where necessary, individual level;
 - (c) align decision-making authority with the criticality of the decisions required;
 - (d) be aligned with Project scope (and may therefore require changes over time);
 - (e) provide coherent, timely and efficient decision-making; and
 - (f) ensure any change is mutually agreed and approved prior to the changes being implemented
- 4.2 The parties will form a board to provide overall strategic oversight and direction to the Project (the "**NOS Collaborators' Board**").
- 4.3 The terms of reference of the NOS Collaborators' Board are set out in Annex B to this MoU.
- 4.4 The provider will join the appropriate MCBT Programme governance groups.
- 4.5 To enable the Provider to comply with clause 4.4 above, NHSE will inform the Provider of the meeting dates in advance and provide sufficient notice.

5. ESCALATION

- 5.1 If either party has any issues, concerns or complaints about the Project, or any matter in this MoU, that party shall notify the other party and the parties shall then seek to resolve the issue by a process of consultation. If the issue cannot be resolved within [14] days, either party may escalate the matter to the Collaborators' Board, which shall decide on the appropriate course of action to take.
- 5.2 If either party receives any formal inquiry, complaint, claim or threat of action from a third party (including, but not limited to, claims or requests for information made under the Freedom of Information Act 2000) in relation to the Project, the matter shall be promptly referred to the Collaborators' Board. Each party shall use reasonable endeavours to consult with the Collaborators' Board before any action is taken in response to any such inquiry, complaint, claim or action but for the avoidance of doubt, such action may be taken without consultation with the Collaborators' Board where the recipient of the inquiry, complaint, claim or action considers it reasonable to do so, for example where an urgent response is required. The parties shall each provide all reasonable assistance to the other, including but not limited to the provision of information in a timely manner, in order for the other party to deal with any inquiry, complaint, claim or action.

6. INTELLECTUAL PROPERTY

- 6.1 For the purposes of this MoU the term "Intellectual Property Right" shall have the following meaning:

patents, rights to inventions, copyright and related rights, moral rights, trademarks and service marks, business names and domain names, rights in get-up, goodwill and the right to sue for passing off, rights in designs, [rights in computer software,] database rights, rights to use, and protect the confidentiality of, confidential information (including know-how and trade secrets) and all other intellectual property rights, in each case whether registered or unregistered and including all applications and rights to apply for and be granted, renewals or extensions of, and rights to claim priority from, such rights and all similar or equivalent rights or forms of protection which subsist or will subsist now or in the future in any part of the world.
- 6.2 The parties intend that any Intellectual Property Rights created in the course of the Project shall vest in the party whose employee created them.
- 6.3 Where any Intellectual Property Right vests in either one of the parties in accordance with the intention set out in clause 6.2 above, that party shall grant an irrevocable, royalty-free, non-exclusive licence to the other party to use that intellectual property for the purposes of the Project.

7. CONFIDENTIAL INFORMATION

- 7.1 “Confidential Information” means any information which has been designated as confidential by either party in writing or that ought to be considered as confidential (however it is conveyed or on whatever media it is stored) including information the disclosure of which would, or would be likely to, prejudice the commercial interests of any person, trade secrets, Intellectual Property Rights and know-how of either party and all Personal Data and special categories of personal data within the meaning of the Data Protection Act 2018. Confidential Information shall not include information which:
- (a) was public knowledge at the time of disclosure (otherwise than by breach of clause 7);
 - (b) was in the possession of the receiving party, without restriction as to its disclosure, before receiving it from the disclosing party;
 - (c) is received from a third party (who lawfully acquired it) without restriction as to its disclosure; or
 - (d) is independently developed without access to the Confidential Information.
- 7.2 Except to the extent set out in this clause or where disclosure is expressly permitted elsewhere in this MoU, each party shall:
- (a) treat the other party's Confidential Information as confidential and safeguard it accordingly; and;
 - (b) not disclose the other party's Confidential Information to any other person without the owner's prior written consent.
- 7.3 Clause 7.2 shall not apply to the extent that:
- (a) the law requires such disclosure by the party making the disclosure, including any requirements for disclosure under the Freedom of Information Act 2000, or the Environmental Information Regulations 2004; and
 - (b) the information is contained in the MoU and is to be disclosed under the Government's Transparency policy.
- 7.4 A party may only disclose the other party's Confidential Information to its staff who are directly involved in the provision of the Project and who need to know the information, and shall ensure that its staff are aware of and shall comply with these obligations as to confidentiality.
- 7.5 Each party shall not, and shall procure that its staff do not, use any of the other party's Confidential Information received, otherwise than for the purposes of the Project.

- 7.6 Nothing in this MoU shall prevent a party from disclosing the other party's Confidential Information:
- (a) for the purpose of the examination and certification of its accounts; or
 - (b) for any examination pursuant to Section 6(1) of the National Audit Act 1983.
- 7.7 Nothing in this clause 7 shall prevent either party from using any techniques, ideas or know-how gained during the performance of the MoU in the course of its normal business to the extent that this use does not result in a disclosure of the other party's Confidential Information or an infringement of Intellectual Property Rights.

8. PUBLICITY

- 8.1 A party shall not make any public statement, announcement or communication relating to the existence or performance of the MoU [or the relationship between the parties] without the other party's prior approval in writing, which shall not be unreasonably withheld.
- 8.2 This clause does not override either party's duties for transparency with regard to notices legally required.
- 8.3 The provider is fully authorised to use all information and materials pertinent to this contract in respect to recruitment and internal governance including internal updates across the provider organisation.
- 8.4 The clause specifically applies to any external communication by either party used in the context of marketing or promotion.

9. TERM AND TERMINATION

- 9.1 This MoU shall commence on the date of signature by both parties and unless terminated earlier in accordance with the terms set out in this MOU, shall continue until the expiry date of 30/09/2026.
- 9.2 Either party may terminate this MoU by issuing a Termination Notice to the other Party providing at least [three] months' notice in writing to the other party [at any time].
- 9.3 In the event of early termination a result of a no-go decision, Gateshead Health NHS Foundation Trust will present NHS England with a full book of accounting occurred to date.
- 9.4 Early termination following the commencement of services NHSE agrees to pay Gateshead Health NHS Foundation Trust for the Services which have been delivered and completed.

- 9.5 In the event of termination or expiration of the contract, the provider will engage with any incoming provider in the transparent delivery of obligations under the TUPE legislation. Termination of this MoU shall not affect the continuing rights, remedies, or obligations of the parties.

10. VARIATION

This MoU, including the Annexes, may only be varied by written agreement of the Collaborators' Board.

11. ASSIGNMENT

Neither party shall assign, transfer, mortgage, charge, subcontract, delegate, declare a trust over or deal in any other manner with any or all of its rights and obligations under this MoU without the prior written consent of the other party (such consent not to be unreasonably withheld or delayed).

12. PRICE & PAYMENT

- 12.1 The Contract Price shall be calculated as set out in the Commercial Schedule and be paid the 15th month of each calendar month in equal instalments.

Unless otherwise stated in the Commercial Schedule the Contract Price:

- (a) shall be payable from the Actual Services Commencement Date;
- (b) shall remain fixed during the Term; and
- (c) is the entire price payable by NHSE to Gateshead Health NHS FT in respect of the Services, acknowledging changes in activity will require further discussion and agreement as detailed in annex A commercial schedule
- (d) Where the Authority raises a query with respect to a payment Parties shall liaise with each other and agree a resolution to such query within thirty (30) days of the query being raised.
- (e) The Supplier shall pay to the Authority any service credits and/or other sums and/or deductions (to include, without limitation, deductions relating to a reduction in the Contract Price) that may become due in accordance with the provisions of the Specification and Tender Response Document
- (f) VAT is not chargeable and CQUIN is not applicable

13. COSTS AND LIABILITIES

- 13.1 Except as otherwise provided, the parties shall each bear their own costs and expenses incurred in complying with their obligations under this MoU.

- 13.2 Both parties shall remain liable for any losses or liabilities incurred due to their own or their employees' actions and neither party intends that the other party shall be liable for any loss it suffers as a result of this MoU.
- 13.3 The cost of the bid is £10,882m. If a no-go decision is made costs will be scaled back to reflect actual costs incurred and include any associated overhead and profit. We expect this maximum exposure to be no more than [REDACTED].
- 13.4 If a go decision is made costs will be recharged in accordance with the tender award subject to annex A commercial schedule.
- 13.5 If a partial go decision is made, both parties shall renegotiate the costs based on the new activity assumptions and any changes made to the operational requirements of the NOS service

14. STATUS

- 14.1 A Financial Draw down schedule is included at table F1
- 14.2 Unless otherwise stated, this MoU is not intended to be legally binding, and no legal obligations or legal rights shall arise between the parties from this MoU. The parties enter into the MoU intending to honour all their obligations.
- 14.3 Nothing in this MoU is intended to, or shall be deemed to, establish any partnership or joint venture between the parties, constitute either party as the agent of the other party, nor authorise either of the parties to make or enter into any commitments for or on behalf of the other party.

15. GOVERNING LAW AND JURISDICTION

This MoU shall be governed by and construed in accordance with English law and, without affecting the escalation procedure set out in clause 5, each party agrees to submit to the exclusive jurisdiction of the courts of England and Wales.

Signed for and on behalf of NHS England

Signed.....

Name.....

Position.....

Date.....

Signed for and on behalf of Gateshead Health NHS Foundation Trust

Signed.....

Name.....

Position.....

Date.....

CONTACT POINTS

For NHS England

Name:

[REDACTED]

Office address:

[REDACTED]

[REDACTED]

Tel No:

E-mail Address:

[REDACTED]

For Gateshead Health NHS
Foundation Trust

Name:

[REDACTED]

Office address:

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

Tel No:

[REDACTED]

E-mail Address:

[REDACTED]

Annex A. The Project

SCHEDULE 2 – THE SERVICES

A. Service Specifications

Service name	NHS-Galleri Interim Implementation Pilot National Operations Service Specification v1.0
Service specification number	
Population and/or geography to be served	<p>Participants living in the following Cancer Alliances:</p> <ul style="list-style-type: none">• East of England (South)• Wessex• Peninsula• Thames Valley• Humber and North Yorkshire• North Central London• Northwest and Southwest London• Surrey and Sussex• Somerset, Wiltshire, Avon, and Gloucestershire (SWAG)• West Yorkshire and Harrogate• Northeast London• Lancashire and South Cumbria• South Yorkshire and Bassetlaw
Period	July 2024 to June 2026
Date of Review	TBC

• 1. Population Needs

1.1 National/local context and evidence base

1.1.1 The NHS Long-Term Plan has set out key ambitions for cancer diagnosis and care (NHS, 2019). By 2028, the aim is to ensure that an extra 55,000 people each year will survive their cancer for five years or more, and 75% of people with cancer will be diagnosed at an early stage. Increasing the rate of earlier-stage diagnosis raises the likelihood of curative treatment and improves long-term survival.

- 1.1.2 A Cancer Blood Test, the Galleri^(R) test, is being assessed as part of a large-scale clinical trial, the NHS-Galleri study (Neal, R. et al., 2022). This test has been shown in studies to be effective at finding cancers that are typically difficult to identify early - such as head and neck, bowel, lung, ovarian and pancreatic cancers. By assessing the Galleri test at a population scale, we have the opportunity to better understand the performance of this test and assess whether it is suitable for use as a screening test in a population without symptoms.
- 1.1.3 **Should the [NHS-Galleri Trial](#)¹ meet agreed interim goals, to be assessed in Spring 2024**, NHSE has agreed to purchase up to 1,000,000 Galleri® tests for a Pilot, which would run 2024-2026. The Galleri tests would be offered to asymptomatic people aged 50-77 in the [Cancer Alliance \(CA\)](#) areas not involved in the NHS-Galleri trial. The Pilot would be the next stage in assessing the effectiveness of the Galleri test as a screening tool and would give us an opportunity to learn more about how it could be used at scale.
- 1.1.4 The proposed delivery model for this Pilot uses a nationally commissioned service, the 'National Operations Service,' to deliver vital participant-facing functions such as telephone booking and results management and will enable local services to deliver testing effectively.
- 1.1.5 The National Operations Service will ensure participants can easily engage with the pilot, ensure safe and effective management of positive results, and support local systems with safe and effective pathways to manage the demand and capacity requirements. The programme would like to draw on the experience of organisations that already deliver other complex services, leveraging their experience, capability, and reach to ensure we provide an integrated, safe, and multi-faceted service across pilot areas in England (see Appendix 3).
- 1.1.6 This specification aims to ensure a consistent and equitable approach to providing and monitoring the IIP operations across pilot areas in England.
- 1.1.7 This document outlines the service and quality indicators expected by NHSE from the National Operations Service to ensure that a high standard of service is provided to NHSE's responsible population.
- 1.1.8 The service specification is not designed to replicate, duplicate, or supersede any relevant legislative provisions which may apply, e.g., the Health and Social Care Act 2008 or the work undertaken by the Care Quality Commission. The nature of the service, in pushing at the very cutting edge of innovation, means that new evidence may well emerge, which requires changes to the specification for the service. In the event of new evidence emerging, the specification will be reviewed

¹ The NHS Galleri clinical trial is a three-year study examining the effectiveness of GRAIL's Galleri test as a potential screening tool.

and amended as quickly as possible if changes are required. Where necessary, both NHSE and Service providers should work proactively and rapidly to agree on contract variations before producing a revised specification.

- 1.1.9 Population-based cancer detection programmes require a high degree of organisation to ensure that the invitation and results activities are performed reliably, effectively, equitably, and are adequately coordinated with the subsequent steps in the process (European Commission, 2017). At the same time, the pilot requires different services to deliver elements of the pathway (outlined in Figure 1 below); where possible, integrated service models that can provide person-centred and coordinated services are preferable.

• 2. Outcomes

2.1 NHS Outcomes Framework Domains & Indicators

Domain 1	Preventing people from dying prematurely	✓
Domain 2	Enhancing quality of life for people with long-term conditions	✓
Domain 3	Helping people to recover from episodes of ill health or following injury	
Domain 4	Ensuring people have a positive experience of care	
Domain 5	Treating and caring for people in a safe environment and protecting them from avoidable harm	✓

2.2 Nationally Defined Outcomes

- 2.2.1 The National Operations Service will support the delivery of the strategic priorities of the NHSE Cancer programme by:

- Providing effective telephone support for booking and queries (general or clinical).
- Offering prompt, effective and safe clinical management of results and onward referrals.
- Supporting local trusts by ensuring referrals are appropriately managed.
- Supporting selection of the invitation cohort and balancing national and local demand and capacity.

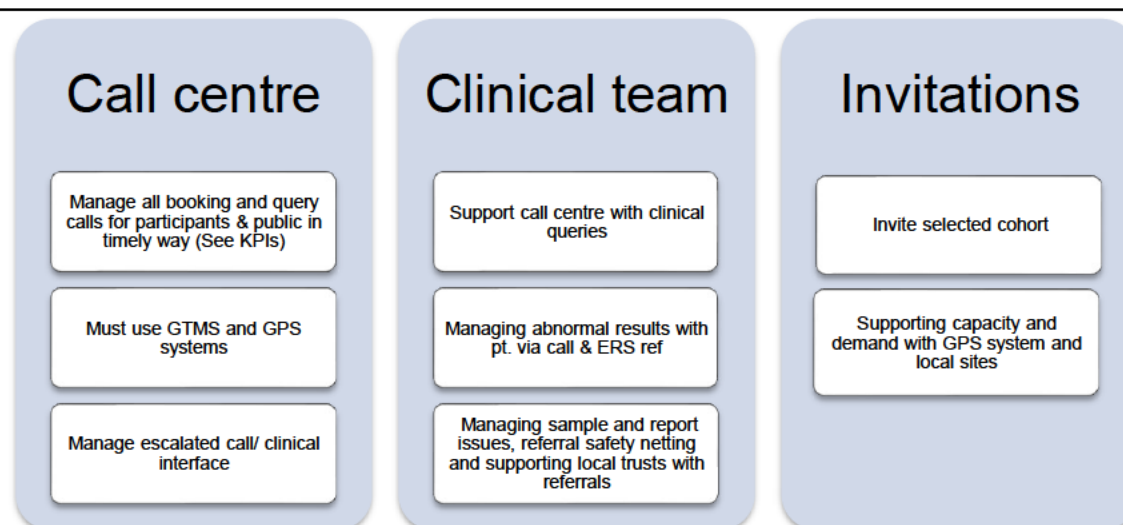


Figure 1 Service Function outline

The NOS will operate alongside other key providers and local NHS services; for example, bespoke digital systems and mail house solutions are being built to support the IIP and are not expected to be delivered by NOS.

3 Scope

3.1 Aims

- 3.1.1** The provision of a National Operations Service to provide critical enabling support to the IIP (see Appendix 2 for high-level context and supporting documents²) to detect earlier-stage cancer and reduce mortality from cancer. This will be achieved by delivering effective operations to the pilot population-based early cancer detection programme that:
- supports NHSE to invite³ the algorithmically stratified cohort, ensuring demand management of the eligible population and supporting efficient capacity use locally.
 - provide a high-quality and effective clinical and call centre team to meet the demands of the pilot population.
 - are safe, effective, of high quality, and meeting the key Quality Standards outlined in the specification (will form part of the IIP Quality Assurance Framework)
 - prevent missed cancer through rigorous results processes that support earlier detection and improved outcomes.
 - are delivered and supported by suitably trained, competent, and qualified clinical and non-clinical staff who, where relevant, participate in recognised ongoing continuous development schemes.

² Supporting documents include *NHS-Galleri IIP Clinical Guidance and SOP* and *NHS-Galleri IIP Implementation plan*.

³Cohort list will be managed by GPS, and the physical invitation process will be managed by GPS via a mail house.

3.2 Objectives

3.2.1 Activities before testing:

The provider must:

- ensure that the eligible and ranked individuals⁴ identified by the NHSE Transformation team/GPS (Galleri Pilot System) are invited at a rate (demand modelling) that manages the local biosampling capacity and Galleri test capacity effectively. This must be at an acceptable run rate to support sample management.

3.2.2 Booking and queries

The provider must:

- provide telephone booking with a high-quality, effective, and people-centred service.
- support optimal participation rates and support accessibility (e.g. translation) for all groups in the community.
- use the purpose-built GRAIL booking system Galleri Test Management System (GTMS), ensuring all staff are trained in its use.
- provide adequate numbers of appropriately trained, qualified, and competent staff to carry out high-quality booking and query support (clinical or general).
- have the ability to manage spikes in demand, particularly in response to managing queries following a media event.
- support urgent cancellations of appointments that can't be done via letter/text.

3.2.3 Results management

The provider must:

- support rebooking and possible resolution if there are issues around the sample, meaning a result cannot be given (e.g. gender anomalies)
- undertake clinical calls with individuals with a Cancer Signal Detected (CSD) in appropriately staffed and equipped settings⁵.
- refer the individual on the NHS e-Referral Service to a chosen NHS trust with an Urgent Suspected Cancer Referral Non-Specific Symptoms (NSS) with supporting test and consultation information.

⁴ The pilot's invitation strategy algorithm is applied by the GPS; this will be based on ranking individuals based on deprivation and ethnicity using Lower Layer Super Output Areas (LSOA) information to support equitable uptake.

⁵ In the unlikely circumstances that an individual gets an [s-flag](#) on their records after the time of booking, the clinical team will support in communicating with the individual to ensure careful and required communications are delivered.

- offer signposting advice to support individuals who may need psychosocial or accessibility support.
- track and monitor referrals, ensuring robust consolidation and rigorous follow-up of non-actioned or partially actioned referrals.
- ensure that test results are communicated clearly and promptly to participants with a CSD (a copy is also sent to the GP).
- ensure that the individual and GP receiving the CSD letter can seek advice from the clinical team at any stage prior to the diagnosis or discharge from cancer services.

3.2.4 Administration

The provider must:

- ensure effective and timely communication with the individuals who are using telephone booking or support and have received a CSD result (see KPIs).
- ensure effective and timely communication with local cancer teams, NHSE, GRAIL, Alliances/ICS, GPs and NHS Transformation.
- work within a seamless and integrated pathway.
- build robust failsafe measures into all stages of the pathway, such as reconciliation mechanisms.
- use the automatically generated reports on their own system or the Galleri Pilot System (GPS) to ensure all persons referred can be reconciled with trust Urgent Suspected Cancer Referral.
- ensure robust Quality Assurance (QA) standards for the service handling safety concerns, safety incidents and serious incidents are adhered to, in addition to local reporting procedures.

3.2.5 Audit and Quality Assurance (QA)

The provider and NHSE should work collaboratively to:

- audit and evaluate the programme to ensure that the service is delivered in a safe, effective, timely, equitable, and ethical way, in accordance with specifications, national guidelines, internal and external quality assurance arrangements, and risk assessments.
- monitor, collect, and report statistical data and other relevant performance information to relevant bodies and use this to promote continuous improvement in

service performance and outcomes; give formal feedback to NHSE and the population served by the programme; and provide key information and models of good practice/ innovation/ achievement to those working in the area of NHS – Galleri pilot.

- the National Operations Service manage the day-to-day operational issues in the system, supporting effective management of invitations, bookings and results management. Prompt action if there are any issues that require attention, escalating serious incidences and issues to NHSE.
- participate willingly in quality assurance visits organised by the NHSE Cancer Programme.
- demonstrate quality improvement processes that used lessons learnt and systematic analysis of data to monitor incidents, complaints and escalations.

3.2.6 Information Technology

The provider must:

- use the GTMS and GPS IT systems to manage people through the IIP process and to capture key IIP data/ outcomes promptly and accurately, supporting local and national quality assurance and cancer registration processes and programme evaluation. The use of local systems may be required to enable full pathway needs.
- comply fully with local and NHS information governance requirements relating to the confidentiality and disclosure of patient information and system/information security.
- ensure that technologies interfacing the GTMS and GPS IT systems have an up-to-date compatible internet browser as specified by NHS Transformation.
- use the [ERS platform](#) to make onward referrals to local trusts.

3.2.7 Workforce, accreditation, training and research

The provider must:

Ensure a minimum qualification for nurses:

- NHS Band 5 qualified for query support and NHS Band 7 or above to manage results pathways; and
- registered with the Nursing and Midwifery Council; and
- for those delivering results and supporting pathways: cancer-specific experience.

Minimum training course requirements for nurses:

- communicating with individuals about the NHS-Galleri test. trained on ERS referrals.
- locally designed training covering telephone assessment process, call quality expectations, risk management, information governance, psychological support, and control measures.

Minimum qualifications for call centre staff:

- NHS band 3 qualified or equivalent for call handlers with senior administrator and management leads

Minimum training course requirements for support staff:

- communicating with individuals about the NHS-Galleri test.
- use of the NHS-Galleri GTMS and GPS system
- locally designed training covering telephone assessment process, information governance, call quality expectations and control measures.

Ensure that staff are appropriately trained and have access to national continuing professional development and skills frameworks, enabling them to develop their skills, competencies, and potential.

3.2.8 Safety and Safeguarding

The provider must:

- refer to and comply with the safety and safeguarding requirements as set out in the NHS Standard Contract.

3.2.9 Equality

The objectives of the IIP programme must include:

- help reduce health inequalities through the delivery of the programme.

National Operations Service key deliverables:

- invitations, booking and results management should be delivered to address local health inequalities, including removing barriers and increasing access for people who face disadvantage, for example, high levels of deprivation.
- the service should be delivered in a culturally sensitive way to meet the needs of diverse populations.
- user involvement should include representation from service users with equality characteristics reflecting the local community, including those with protected characteristics.

- providers should exercise high levels of diligence when considering excluding people with protected characteristics in their population from the programme and follow both equality, health inequality and screening guidance (where possible) when making such decisions.

3.2.10 The provider will be able to demonstrate what systems are in place to address health inequalities and ensure equity of access to invitations, booking and CSD results management. This will include, for example, how the services are designed to ensure no obstacles to access on the grounds of the nine protected characteristics as defined in the Equality Act 2010.

3.2.11 The provider will have procedures in place to identify and support those considered vulnerable/hard to reach (in particular for results management).

3.2.12 Providers are expected to meet the public sector Equality Duty which means that public bodies have to consider all individuals when carrying out their day-to-day work – in shaping policy, in delivering services and in relation to their own employees

<https://www.gov.uk/equality-act-2010-guidance>

It also requires that public bodies:

- have due regard to the need to eliminate discrimination.
- advance equality of opportunity.
- foster good relations between different people when carrying out their activities.

3.3 Service Description/Care Pathway

3.3.1 The service will be accessible to participants invited to the programme and wishing to book a local appointment for a blood draw (See **Early Cancer Detection Using the Galleri Test – Interim Implementation Pilot Standard Protocol** for details).

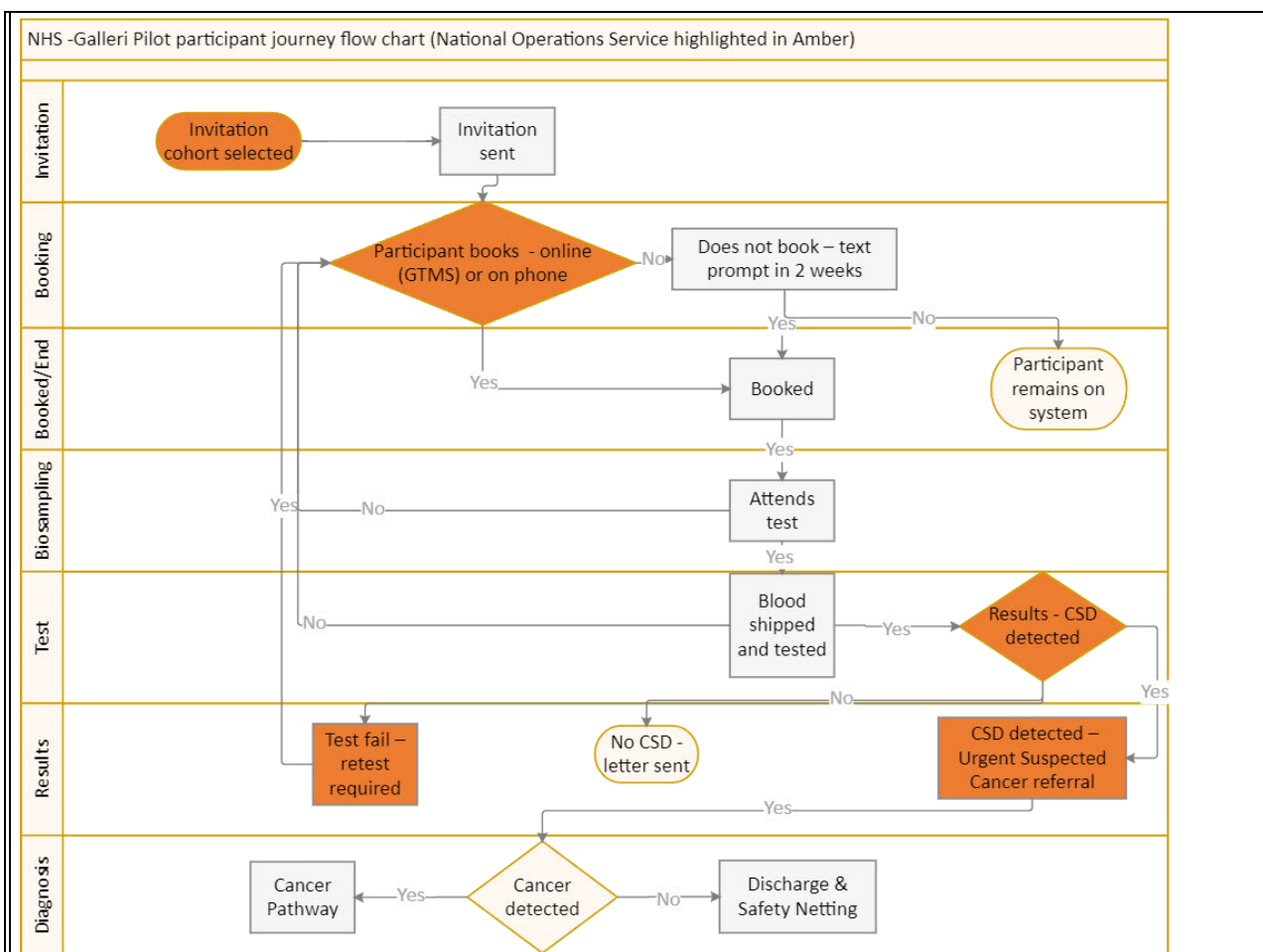


Figure 2 NHS-Galleri Pathway – National Team high-level responsibility highlighted in amber. (Abbreviations: CSD- Cancer Signal Detected)

3.3.2 NHSE is committed to delivering a rapid rollout of the IIP. This ground-breaking pilot has delivery implications on an international, national, and local basis and will require multiple organisations to provide a safe and effective Minimal Viable Product (MVP).

3.4 Service model summary

3.4.1 Programme Coordination

The provider will:

- be responsible for ensuring that the part of the programme they deliver is coordinated. Where collaboration is necessary, each part of the programme should interface seamlessly with others, particularly with timeliness and data sharing.

- ensure that the National Operations Service has a named programme manager responsible for coordinating, planning and delivery. This individual should be given appropriate administrative support to ensure timely reporting and responses to requests for information.
- ensure that adequate cover arrangements are in place to deliver the programme sustainably and consistently; this will include looking to second clinical staff from Cancer Alliance areas as appropriate to support the clinical team.
- meet with NHSE at regular intervals (weekly initially and then at least monthly). The meetings will include representatives from clinical services and service management.

3.4.2 Governance and Leadership

The provider will:

- cooperate with and have representation on national oversight bodies as agreed with NHSE commissioners.
- identify a clinical services director who is responsible for the National Operations Service.
- ensure internal clinical oversight and governance are overseen by an agreed-named clinical lead and a senior programme manager, who regularly meet with NHSE.
- provide documented evidence of clinical governance that includes:
 - compliance with the [NHSE information governance](#) /records management standards
 - procedures in managing system issues and escalations.
 - user involvement, experience, and complaints
 - failsafe procedures
 - referral safety netting procedures
 - risks and mitigation plans, including staff cover plans.

3.4.2.1 Compliance with the NHSE Cancer Programme quality assurance standards and metrics⁶.

- ensure that there is regular monitoring and audit of the IIP programme. As part of the organisation's clinical governance arrangements, the NHS-Galleri Joint Steering Committee and National Cancer Board is assured of the quality and integrity of the service.
- produce an annual report of services, to be submitted to the NHS-Galleri Joint Steering Committeeⁱ for scrutiny.

⁶ Please note that the IIP Quality Assurance Standards are still in draft form, however the key elements related to the NOS team are embedded in this specification.

- ensure the programme is delivered by a trained workforce that meets national requirements.

3.5 Programme delivery

Demand & capacity management team:

Assess and manage capacity in terms of the number of clinic slots per area, the GRAIL test lab and total logistics capacity:

- need to measure the demand for capacity and modulate the invite flow, e.g. looking at % of take-up per area, the types of services they require (accessibility), and rectifying underrepresentation⁷.
- match clinic slots and GRAIL laboratory and logistics capacity with the demand for tests (people invited and then booked on).
- must forecast future demand for tests, taking into account demographic trends in the initial rollout and support retrospective reviews of clinic suitability

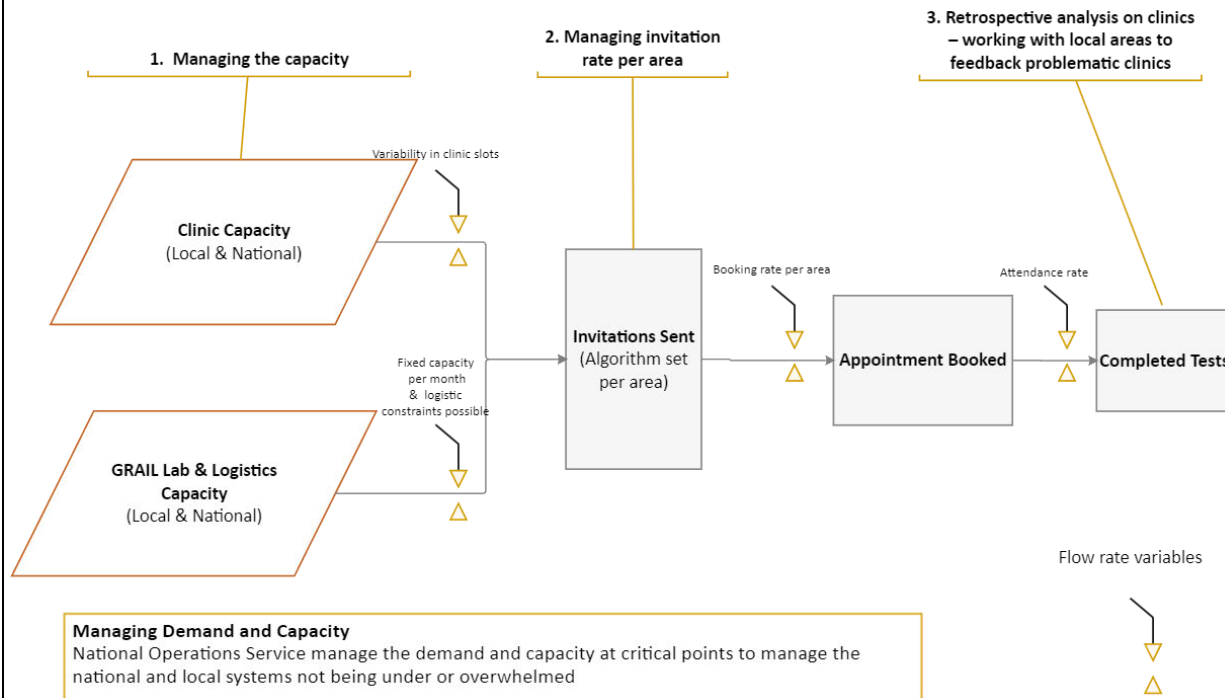


Figure 3 Demand and Capacity Function Overview

Call centre team:

⁷ GPS allows an uptake moderator to be set at LSOA. These will be initially set based on the relative uptake in the bowel screening programme. Over time, the Demand and Capacity team may want to reset these moderators. They can do so by supplying a file to the GPS support team which could upload the adjusted uptake moderators.

- provide a telephone booking helpline for people invited for the test; based on the NHS-Galleri trial, this is expected to be 30% of all bookings.

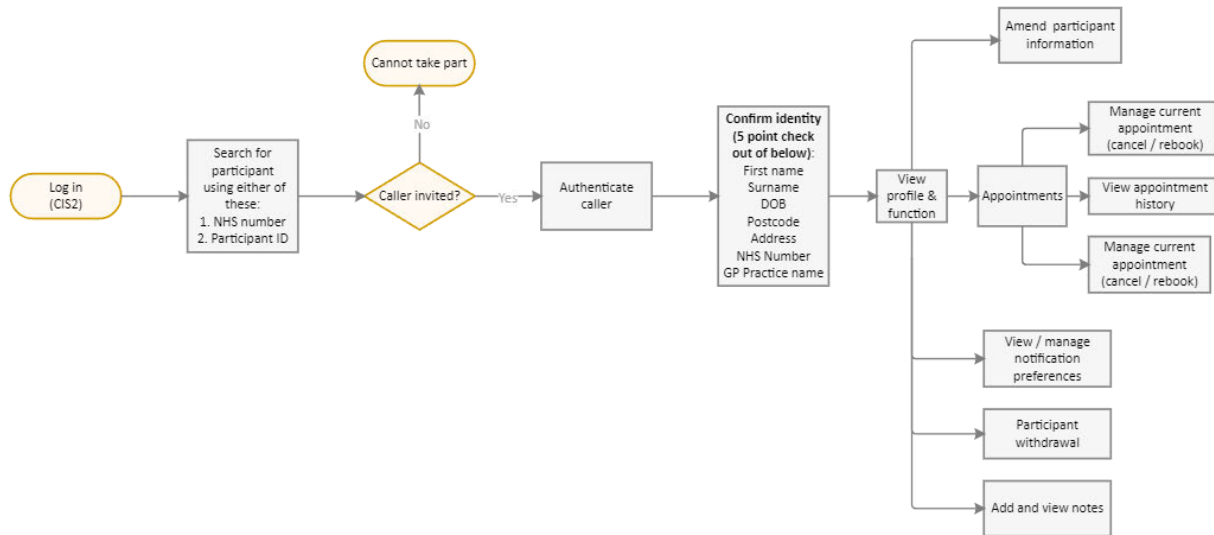


Figure 4 High-level Call Centre operations pathways (see Appendix 4 National Operations booking flow & Appendix 5 National Operations Service Rebook or Cancel flow for further details)

- manage recall for retesting based on the NHS-Galleri trial; this is expected to be less than 5% of the total invitations via the telephone booking service.
- manage public queries⁸ about the IIP or test.
- use the software developed by GRAIL (GTMS) for participant booking, cancellations, and rebooking.

Clinical Team:

- to provide telephone clinical consultations for individuals with a definitive CSD (minimum Band 7 or above; see 3.2.7).
- to refer to the local NSS Urgent Suspected Cancer Referral pathway via ERS (see Figure 5 below).
- to ensure appropriate follow-up and reconciliation for individuals after referral⁹.
- to provide information and support to the local trusts receiving referrals and promote adherence to the guidance.
- To provide a safety netting call 10 days after referral where referral challenges can be managed and escalated as appropriate.

⁸ Calls may come from outside the Pilot Alliances areas from people interested in taking part in the pilot.

⁹ Please note the NOS cannot take clinical responsibility for the referral once referred and acknowledged on ERS, any safety netting procedures are to support the process only.

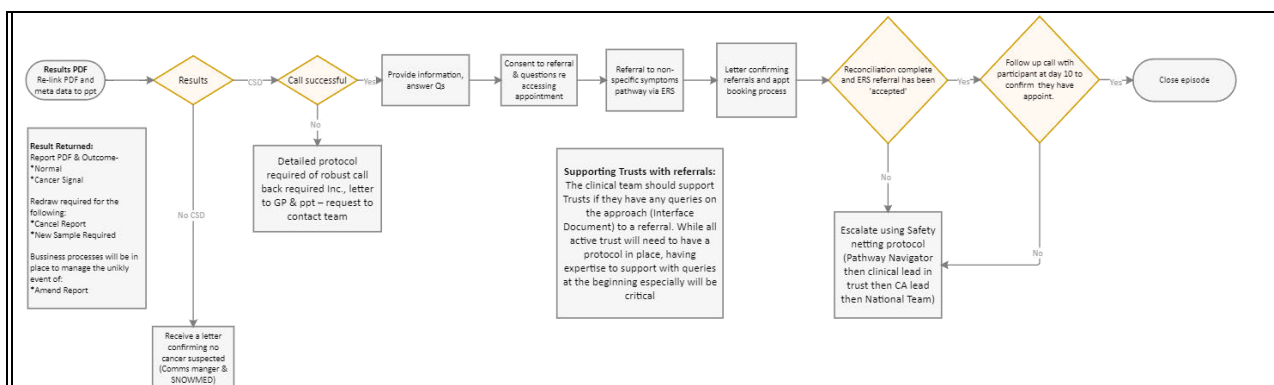


Figure 5 National Operations Results Management flow overview

- to provide information and support for people with clinical queries about the test (minimum level of clinical support is Band 5).
- to ensure that data are collected to enable performance management, audit, and evaluation of the IIP programme.
- To ensure that the participant's GP receives a copy of the CSD-detected result letter and a copy of the referral information.

3.5.1 Days/ hours of operation

The days and hours of operation should be at minimum, Monday to Friday 8am to 6pm, however its important the service looks at how to support working-age participant access this service. The timeliness of booking response and results management is essential, a key quality criterion along all parts of the pathway (see KPIs 3.7). The provider must therefore be able to:

- demonstrate efficient and effective use of resources.
- meet minimum level KPI's on response.

3.5.2 Working across interfaces

The National Operations Service is dependent on strong working relationships (both formal and informal) between the professionals and organisations involved in the NHS-Galleri pathway. Accurate and timely communication and handover across these interfaces are necessary to reduce potential errors and ensure a seamless care pathway. The provider will:

- ensure that there is clear, named lines of clinical responsibility at all times, particularly where there is a handover of care.
- state these lines of clinical responsibility in an operational policy within the programme.

- 3.5.2.1 The provider will ensure appropriate systems are in place to support an inter-agency approach to the interface between these services. This will include, but is not limited to:
- agreeing and documenting roles and responsibilities relating to all elements of the IIP pathway across organisations.
 - providing strong clinical leadership and clear lines of accountability.
 - developing joint audit and monitoring processes.
 - planning to, and meeting, agreed NHSE standards and policies.
 - agreeing jointly, between all agencies, on the failsafe mechanisms required to ensure safe and timely processes across the whole IIP pathway.

3.5.3 Transfer of, and discharge from care obligations

The service covers the period from the invitation of the eligible population (in part) to full Urgent Suspected Cancer Referral completion. The provider will ensure that:

- individuals are referred efficiently to Urgent Suspected Cancer Referral services on completion of results call with the participant. Any diagnostics will be the responsibility of the local cancer services.
- adequate safety netting to ensure the patient has a first USCR appointment.

3.5.4 Inclusion and Exclusion Criteria (Managed by GPS)

(Please see *NHS-Galleri IIP Clinical Guidance and SOP in supporting documentation* for full details)

- up to 1 million participants aged between 50 and 77 inclusive at the date of their first invitation for IIP, registered with a General Practitioner (GP) practice within a participating cancer alliance, will be invited for a Galleri test.
- records will be drawn from the Patient Demographic Dataset held by NHS Transformation.
- exclusions apply to the cohort to be invited for a Galleri test. This will be done before the appointment where possible and includes:
 - participant has a diagnosis of cancer¹⁰ recorded in the Cancer Registry within the previous 3 years.
 - participants undergoing current investigation for suspected cancer, defined as having been referred to a two-week wait clinic or undergoing investigations at a Rapid Diagnostic Centre (RDC) or other clinics with a stated suspicion of cancer.

¹⁰ This will not include non-melanoma resected skin cancers prostate cancer patients whose only treatment is active surveillance.

- participants who had taken part in the NHS-Galleri trial.
- patients who have opted out of the NHS-Galleri IIP programme.
- patients currently on a palliative care pathway.
- pregnant women.

3.5.5 Staffing

The provider will:

- ensure that there are adequate numbers of trained, qualified, and competent staff in place to deliver a high-quality service in line with Nursing and Midwifery Council best practice guidelines.
- ensure that all staff demonstrate competence in their area, linked to training (qualifications will be specific to the groups of staff delivering the service across the care pathway – see 3.2.7).
- implement a workforce plan designed to maintain a sustainable programme where there are difficulties in the recruitment of appropriately qualified healthcare staff with local connections (local area secondments of senior Cancer Nurse Specialists (CNS) is the recommended approach).
- ensure that professionals in service are required to keep up-to-date with nationally approved training programmes and CPD.

3.5.6 User involvement

In accordance with good practice, to gain feedback on services provided and to have public involvement on the provision of services, the provider will collect the views of service users via surveys or questionnaires. It is expected that such surveys will be hosted by the provider and the link will be sent out by text after every completed booking.

The provider will:

- demonstrate how those responses will influence service delivery for the purposes of raising quality or feedback to be given to over-delivery arms in invitation or booking.
- show that all participants are given information about how to provide feedback about services they receive, including the complaints procedure.

3.5.7 Premises and Equipment

The provider will ensure that:

- suitable premises and equipment are provided for the service.

- the IT system is able to support the programme and to supply data for the purpose of auditing performance against national standards and KPIs if outside the GTMS or GPS system.
- the IT system is able to perform failsafe checks.
- the IT equipment is able to support the programme and maintain a high quality service

3.5.8 Data collection and monitoring

The provider will:

- provide routine data to NHSE in a timely manner to monitor performance.
- contribute to national data collection exercises where required.
- provide data measuring performance against both standards and the Key Performance Indicators to monitor performance and measure trends.
- host and collate the experience questionnaire (TBD) response post-booking and present monthly.

3.5.9 National standards, risks and quality assurance

The provider will:

- meet the acceptable national programme standards and work towards attaining and maintaining the achievable standards.
- adhere to specific professional standards and Guidance.
- maintain a register of risks, working with NHSE and quality assurance teams within NHSE to identify key areas of risk in the IIP pathway and ensure that these points are reviewed in contracting.
- participate fully in national quality assurance (QA) processes, which may include:
 - submitting agreed minimum data sets and quality reports from external quality assurance schemes.
 - undertaking ad-hoc audits and reviews as requested
- completing self-assessment questionnaires/tools and submitting associated evidence.
- responding to recommendations within agreed timescales, providing specified evidence.
- producing, with agreement of commissioners of the service, an action plan to address areas for improvement that are identified in recommendations.

- operate and evidence checkpoints that track individuals through the IIP pathway via GPS system.
- identify, as early as possible, individuals who may have missed results or where results are incomplete or where referral has not happened.
- have a process in place to mitigate against weakness in the pathway.
- have arrangements in place to refer individuals to appropriate cancer services promptly, and these should meet programme standards (Go/No go checklist).
- demonstrate that there are audited procedures, policies, and protocols in place to ensure the IIP programme consistently meets programme requirements.
- comply with Guidance on managing safety incidents in national screening programmes and NHSE serious incident framework where appropriate <https://www.gov.uk/government/publications/managing-safety-incidents-in-nhs-screening-programmes>.
- ensure business continuity - business continuity plans must be in place where required.
- ensure sub-contracts and/or service level agreements with other providers meet national standards and Guidance.

3.5.10 Teaching and Research Activities

- research activities are encouraged but must be operationally based and have the appropriate approvals, including the NHSE GRAIL Evaluation Group, and not compromise delivery.

3.6 Activity and Reporting

3.6.1 The KPI's and quality assurance standards will be monitored by the NHSE Cancer team every month, and some agreed metrics will be formally reported quarterly. As part of the pilot, NHSE is committed to regularly reviewing activity and demand to inform future commissioning plans and address challenges in delivery.

3.6.2 The provider shall ensure an appropriate activity record is developed and maintained for audit, quality assurance, and payment purposes. The provider shall provide monthly activity and quarterly quality data to the National Cancer team with the return sheets provided.

Activity data shall include items outlined below:

Figure 6 Key Performance Indicators for National Operations Service

Key Performance Indicators for National Operations Service			
*Please note that some of this data must come from internal monitoring systems and some from GPS. Some of the measures are not directly linked to NOS-delivered services but monitoring and management of the pathway (with agreed escalation routes to NHSE) from invitation until booking and then from receipt of results until the patient is seen in acute with a CSD			
KPI	Measurement	Target	Reporting Timescales
Call Centre			
	Total number of people attempting to call the service		Monthly
Calls taken	% of total calls	95%	Monthly
Calls taken with 90 seconds	% of total calls	90%	
Call abandoned	% of total calls	5%	
Calls taken after 120 seconds	% of total calls	5%	
Calls received to book	% of calls taken	TBC	
Calls received for clinical queries	% of calls taken	TBC	
Calls received for other queries	% of calls taken	TBC	
Calls received to re book/change	% of calls taken	TBC	
Invitations & Booking			
Local systems slots at booked to maximises capacity use	% of available appointments booked	95%	
Local slots registered on the system does not exceed Grail lab/ logistics capacity	% of GRAIL test capacity	99%	
Number of people invited unable to book due to no capacity	% of total invited from an area but no clinic availability	3%	
Expected % invited per demographic parameters	TBC	TBC	
Number of first invitation sent	No. sent by Cancer Alliance and demographics	Monitoring only	
Time between invite and booking	Average time between invite date and booking appointment (first time)	Monitoring only	Weekly and then by agreement monthly

Time between invite and appointment	Average time between invite date (first) and appointment	Monitoring only	
Number of reminders send	Number of reminders sent split by cancer alliance and demographics	Monitoring only	
Method of booking	Number who booked by phone Number who booked online	Monitoring only	
Invitations Outcomes	Number of people who did not respond Number of people who withdraw Number of people who have booked and location (Clinic ID/ICB/ CA)	Monitoring only	
Results			
Number and percentage of people with a CSD	No. of people with results	No target set	Monthly
	No of people with CSD		
	No of people with failed test		
	% patients no CSD		
Number of people contacted with a result	No. referred to NHS trust	No target set	
	No. requesting to be managed privately		
	No. of people with results and declined referral		
	No. requiring onward signposting (e.g., psychosocial)		
Clinical call on results	% of booking post results within 3 calendar days	90%	
	% of booking post results within 5 calendar days	97%	
	% of booking post results after 7 calendar days	3%	
	% of people that are uncontactable following contact protocol	0.50%	
	Average wait time from result to call	2.5 days	
Time from result received to letter sent to participant	Days from result received to result letter sent split by CSD/CSO, NCSD,	Target to be set per outcome - NO	

	Redraw, sent to participant	CSD will not be a NOS target	
10-day follow-up call (must be booked down by CA, ICS, and Trust)	No. of referrals in progress and closed	Target TBD with other delivery arms	
	No. of referrals requiring navigator escalation		
	No. requiring local clinical director escalation		
	No requiring cancer alliance escalation		
	No. requiring national escalation		
No of clinical queries from the system on referral management	No of clinical queries from the system on referral management	Monitoring only	
Other KPI's			
Staff trained on IT systems	% of total service	95%	Quarterly
No. of system education sessions delivered	No. of education sessions requested, booked, and delivered (completed)	80% of requested visits completed within 3 months	Monthly
Feedback for people using accessing the program	Number of responses received	report breaking down the response metrics	
	Number of people happy with invitation and booking service	TBD	
	Number of people happy with telephone booking service	90%	
<p>The provider shall provide monthly quality data sets similar to Figure 7 below. This should include:</p> <ul style="list-style-type: none"> • <i>participant complaints & compliments</i> • <i>adverse incidents</i> 			

Figure 7 Quality Performance Measures for National Operations Service

Quality Performance Measures for National Operations Service					
Area	Date Recd	No.	Description	Action Taken	Lesson Learnt
Complements			Complements received about the service and actions taken		
Complaints			Complaints received about the service and actions taken		
Incidents			Quarterly report is required to be presented to the Steering group, with an annual report		
Serious Incidence			N.B Must be reported immediately, with an investigation report to be submitted within the national timeframe		

3.8 Population Covered

This service contract is available to all participants invited and booked into the Galleri pilot.

The table below is indicative only but outlines what is required and the likely translation of activity from the test.

Table 1 Population in IIP

Pilot Alliances	Total population eligible	Test available for 10% of the eligible population over 2 years	Conversion of tested pop. to Urgent Suspected Cancer Referral over 2yrs (1%)	Conversion to Urgent Suspected Cancer Referral per annum ¹¹	Conversion to Urgent Suspected Cancer Referral per month
East of England - South Cancer Alliance	1,127,699	112,770	1,128	564	47
Humber and North Yorkshire Cancer Alliance	612,559	61,256	613	306	26
Lancashire & South Cumbria Cancer Alliance	587,198	58,720	587	294	24

¹¹ This number is an average based on overall tests.

North Central London Cancer Alliance	372,367	37,237	372	186	16
Northeast London Cancer Alliance	441,566	44,157	442	221	18
Peninsula Cancer Alliance	670,893	67,089	671	335	28
Somerset, Wiltshire, Avon, and Gloucestershire Cancer Alliance	1,028,254	102,825	1,028	514	43
South Yorkshire Cancer Alliance	440,010	44,001	440	220	18
Surrey and Sussex Cancer Alliance	1,155,545	115,555	1,156	578	48
Thames Valley Cancer Alliance	538,057	53,806	538	269	22
Wessex Cancer Alliance	901,225	90,123	901	451	38
West London Cancer Alliance	947,548	94,755	948	474	39
West Yorkshire and Harrogate Cancer Alliance	712,852	71,285	713	356	30
Grand Total	9,535,773	953,577	9,536	4,768	397

• **4. Applicable Service Standards**

4.1 Applicable national standards (e.g., NICE (National Institute of Clinical Excellence))

The provider must:

- meet the acceptable national programme standards and work towards attaining and maintaining the achievable standards.
- adhere to specific professional standards and guidance.
- maintain a register of risks and work with the Commissioner to identify key areas of risk in the pathway and ensure that these areas are reviewed in contracting.

The provider must:

- operate and evidence checkpoints that track individuals through the screening pathway.
- identify, as early as possible, individuals where results are incomplete or where referral has not happened/ been processed.
- have processes in place to mitigate against weaknesses in the pathway.
- demonstrate that there are audited procedures, policies, and protocols in place to ensure the service consistently meets programme requirements.
- comply with guidance on managing safety incidents in national screening programmes and NHSE 's serious incident framework:
<https://www.gov.uk/government/publications/managing-safety-incidents-in-nhs-screening-programmes>
- ensure business continuity – business continuity plans will be in place and submitted to the Commissioner on request.
- ensure subcontracts and/or service level agreements with other providers are robust and approved by the Commissioners prior to their start and meet national standards and guidance.
- appropriate CQC registration.

4.2 Applicable standards set out in Guidance and/or issued by a competent body (e.g., Royal Colleges)

Where applicable, National Cancer Screening protocols can help in using precedence to manage NHS –Galleri IIP approaches ([Population screening programmes - GOV.UK \(www.gov.uk\)](https://www.gov.uk/population-screening-programmes)).

4.3 Applicable local standard

N/A

• **5. Applicable quality requirements (TBD)**

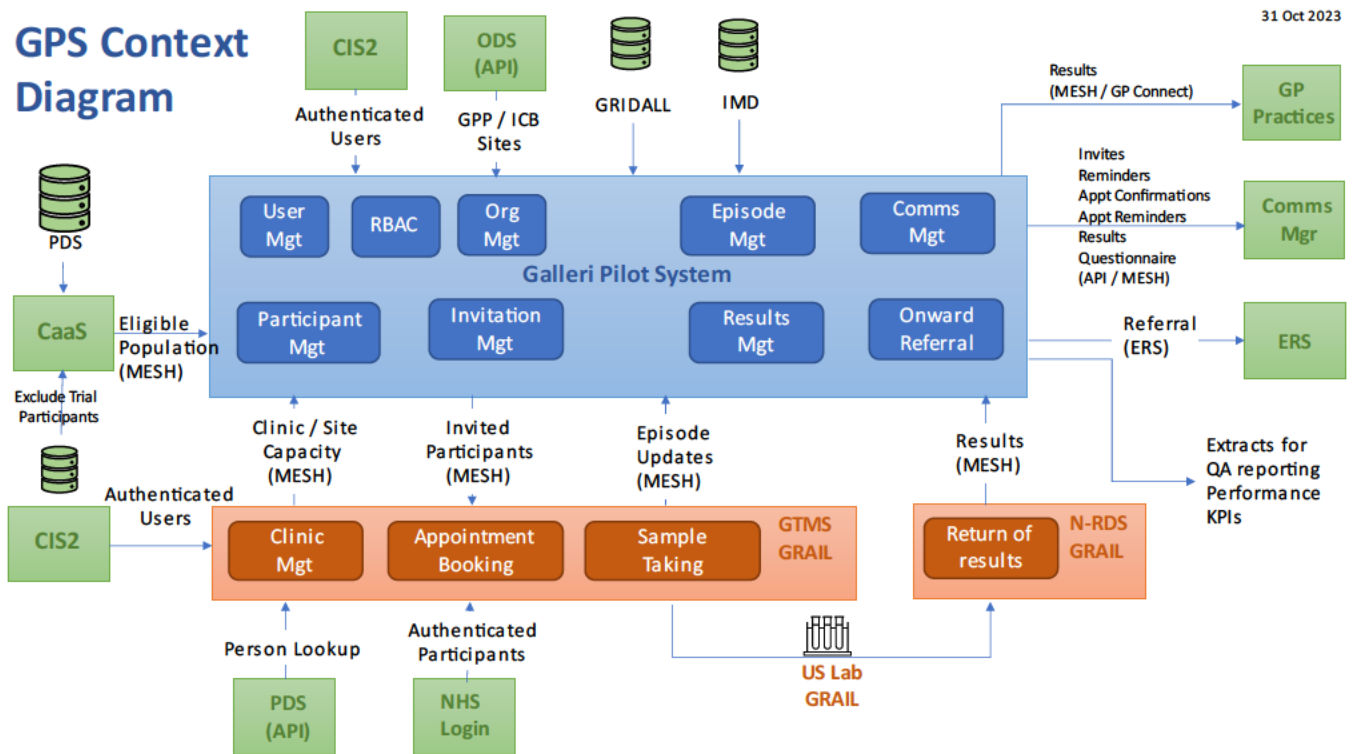
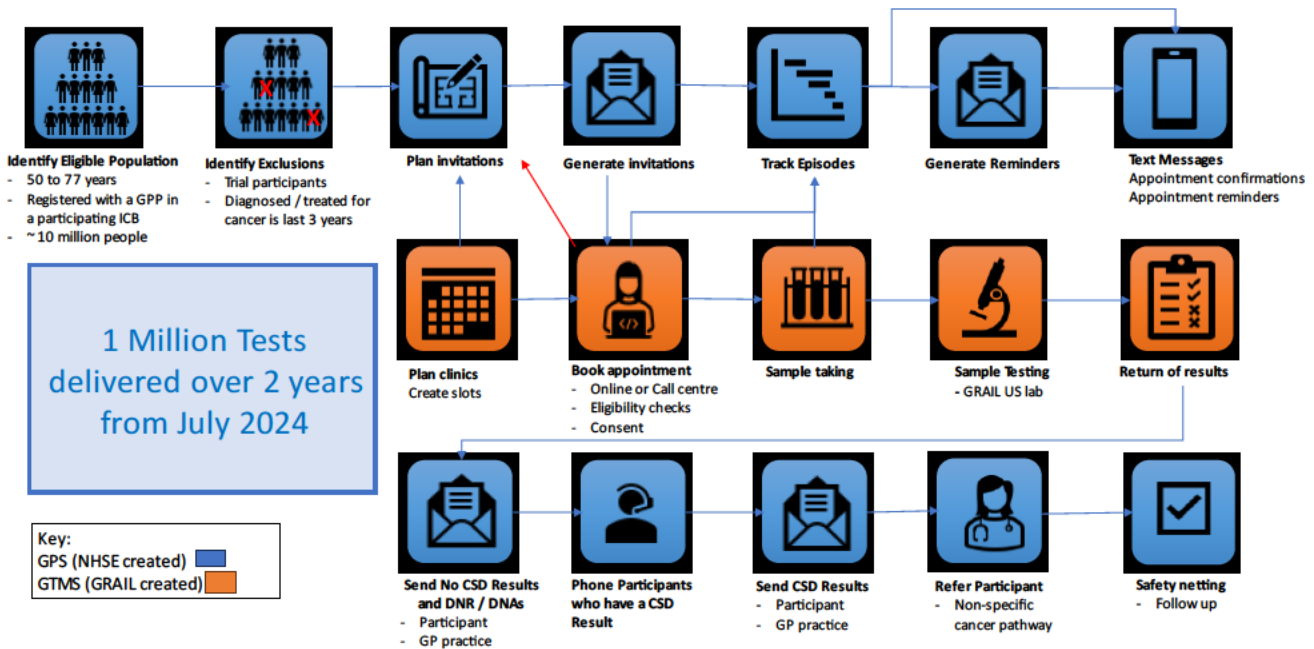
- **5.1 Applicable quality requirements**

Standards outlined in the Objectives part of this document will be used to form the overarching Quality Assurance Standards Framework for the IIP

6. <i>Location of Provider Premises</i>
The Provider's Premises are located at: N/A
7. Individual Service User Placement
THIS SECTION IS NOT MANDATED FOR THE SHORT-FORM CONTRACT N/A

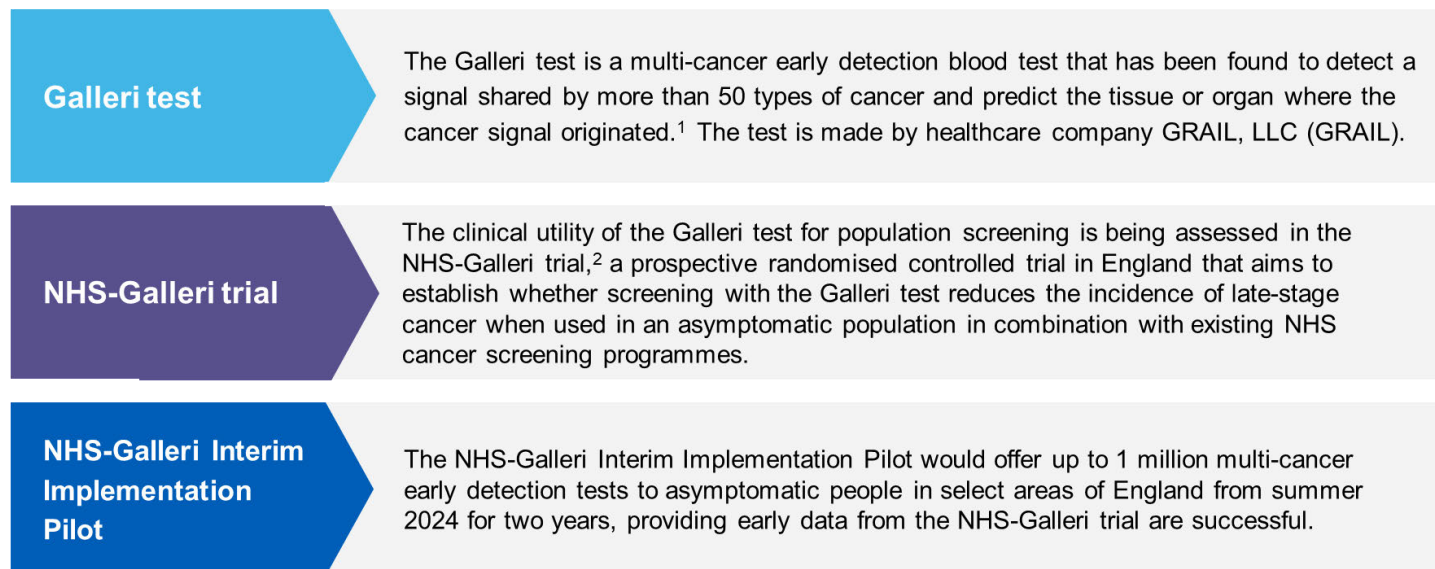
Appendix 1 – Overview of Digital systems being built to support IIP.

NHS- Galleri Blood Test – Pilot Implementation



Appendix 2 IPP summary, high-level timeline, high-level process, test timelines and indicative numbers

Summary of the NHS-Galleri Interim Implementation Pilot



Galleri is a screening test and does not diagnose cancer. Diagnostic testing is needed to confirm cancer.
¹Liu MC, et al. *Ann Oncol.* 2020;31(6):745-759. DOI:10.1016/j.annonc.2020.02.011. ²Neal R, et al. *Cancers.* 2022; 14(19):4818. DOI: 10.3390/cancers14194818.

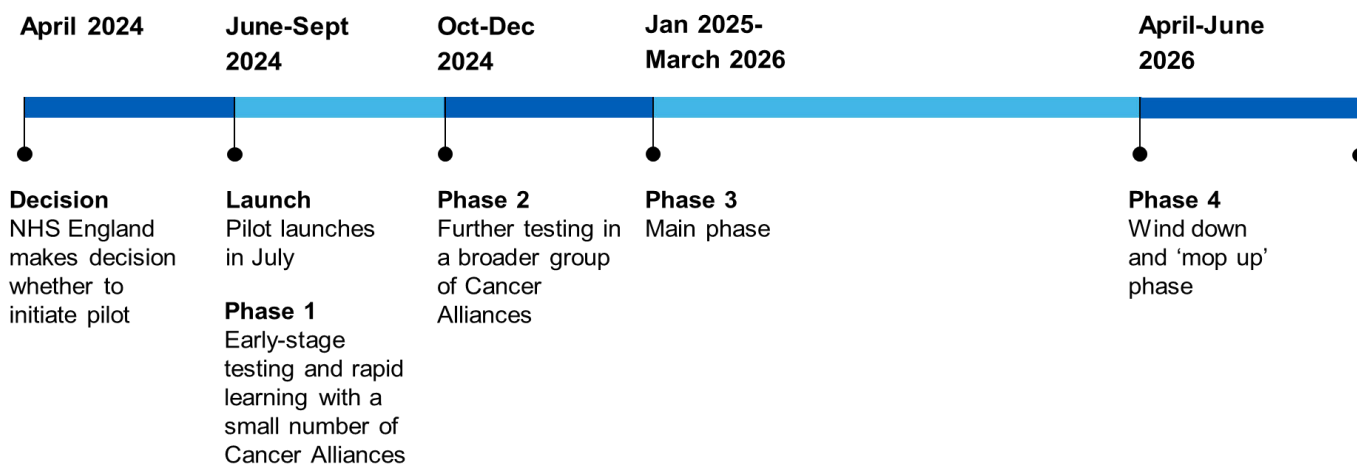


Figure 8 Pilot timeline: phased approach

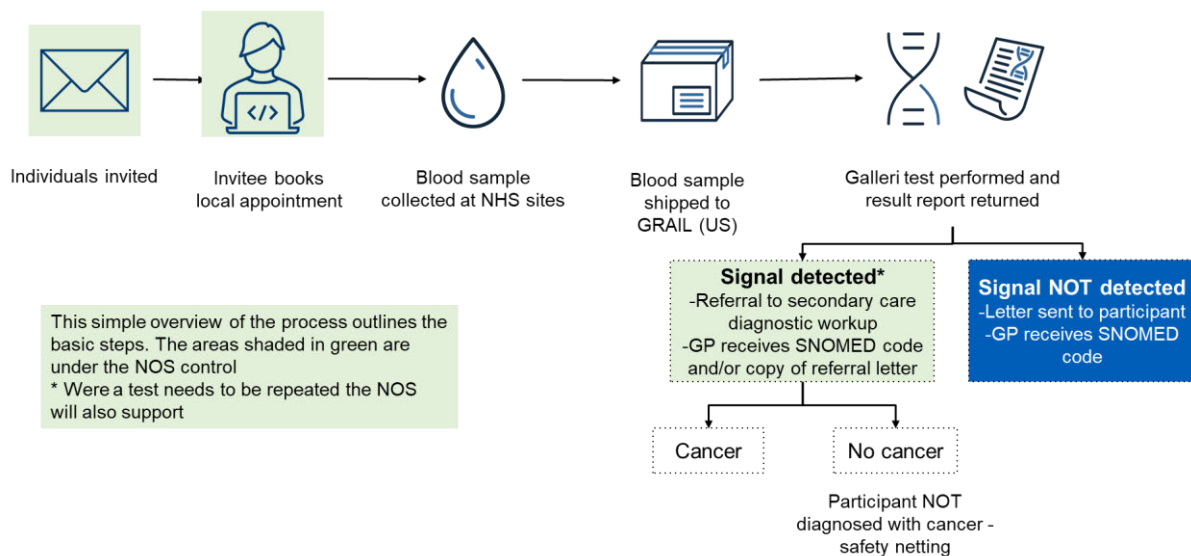


Figure 9 IIP Process (High level)

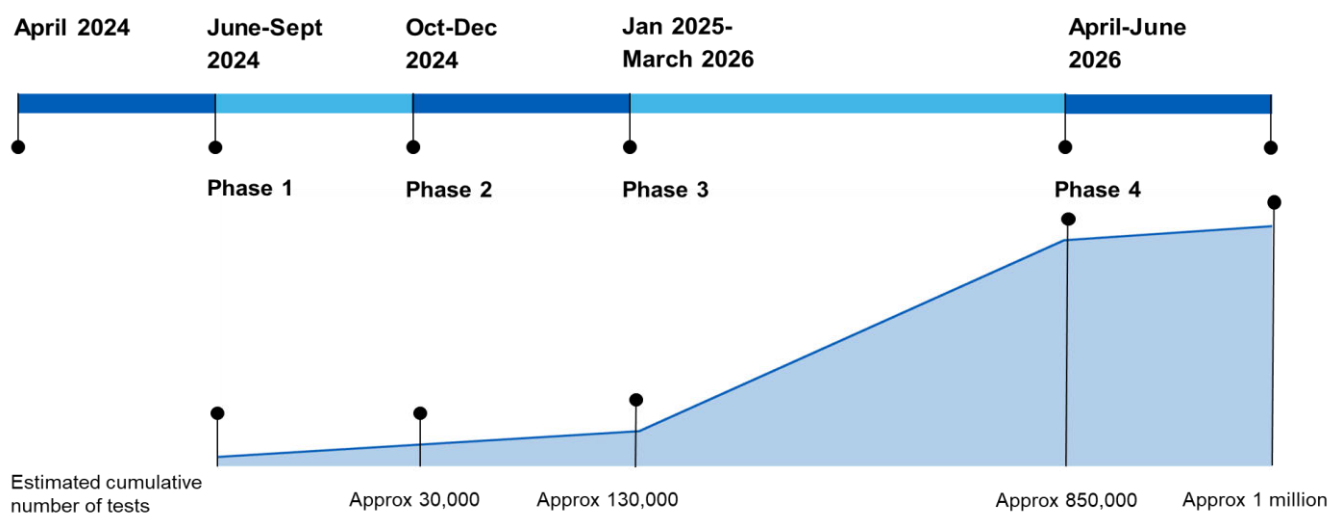
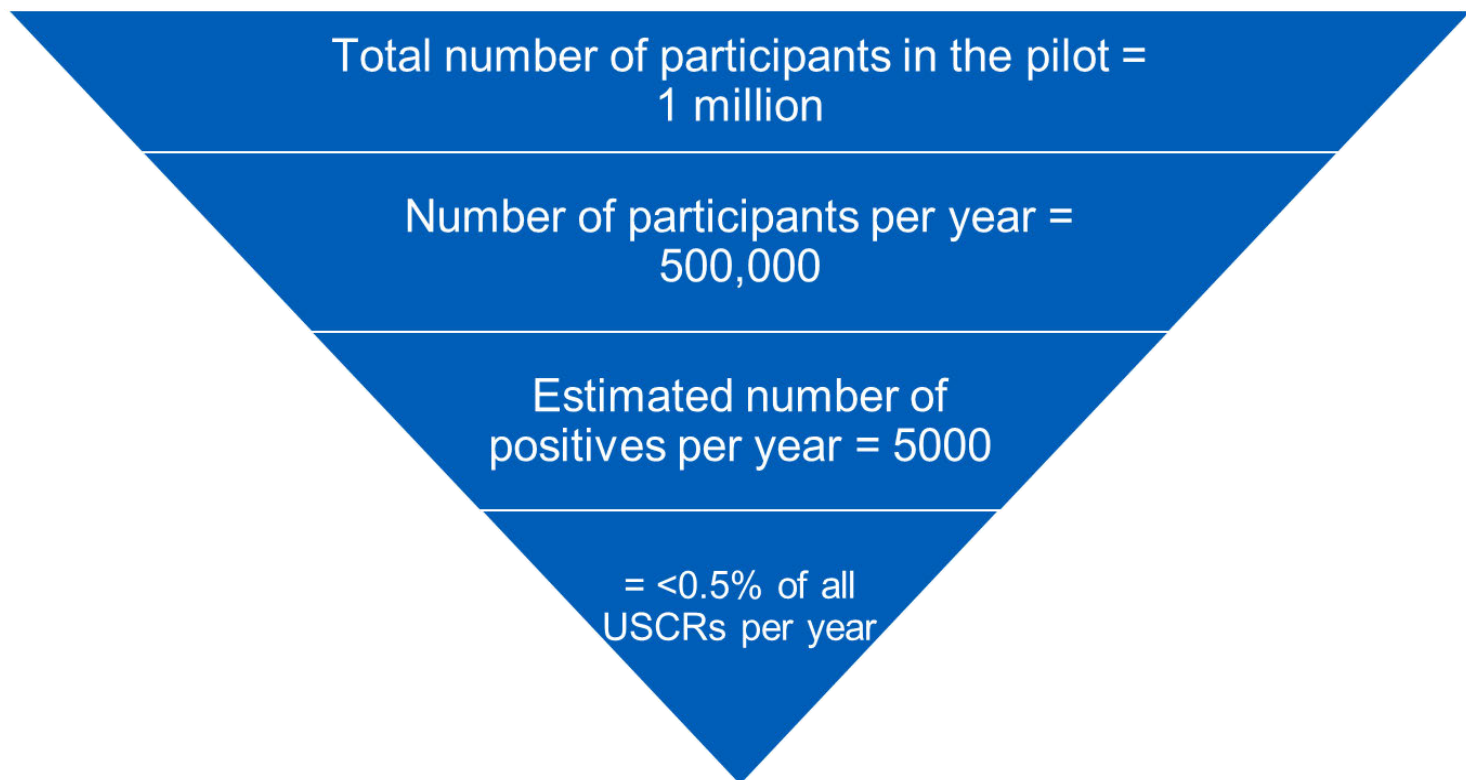


Figure 10 Pilot timeline: cumulative number of tests



*Figure 11 Indicative numbers - *Please note that many of the numbers used are an approximation. Many of these numbers are complex or are uncertain and should not be used as unequivocal data.*

Appendix 3 - Pilot Locations

13 Alliances

- East of England - South Cancer Alliance
- Humber and North Yorkshire Cancer Alliance
- Lancashire & South Cumbria Cancer Alliance
- North Central London Cancer Alliance
- North East London Cancer Alliance
- Peninsula Cancer Alliance
- Somerset, Wiltshire, Avon and Gloucestershire Cancer Alliance
- South Yorkshire Cancer Alliance
- Surrey and Sussex Cancer Alliance
- Thames Valley Cancer Alliance
- Wessex Cancer Alliance
- West London Cancer Alliance
- West Yorkshire and Harrogate Cancer Alliance



23 ICBs

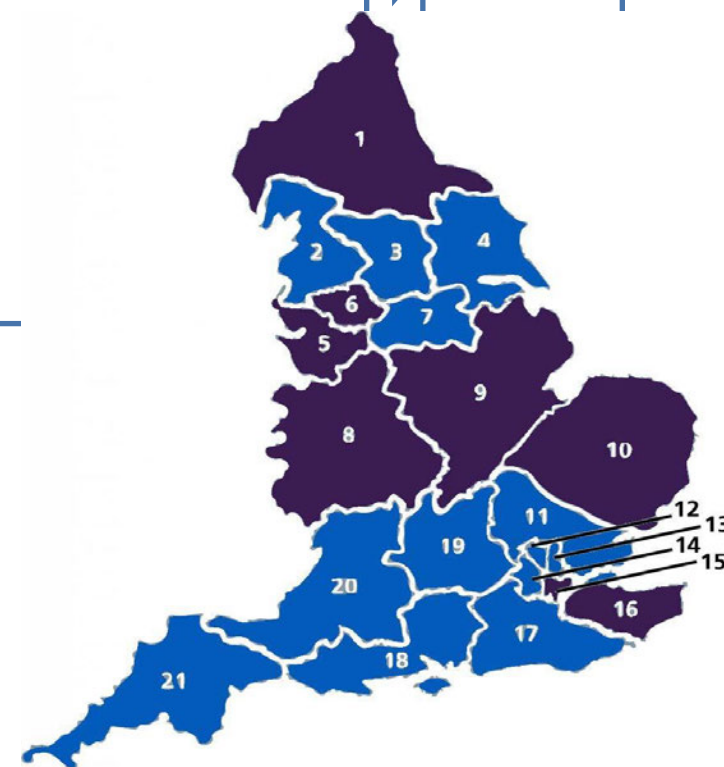
- NHS Bath and North East Somerset, Swindon and Wiltshire Integrated Care Board
- NHS Bedfordshire, Luton and Milton Keynes Integrated Care Board
- NHS Bristol, North Somerset and South Gloucestershire Integrated Care Board
- NHS Buckinghamshire, Oxfordshire and Berkshire West Integrated Care Board
- NHS Cornwall and the Isles of Scilly Integrated Care Board
- NHS Devon Integrated Care Board
- NHS Dorset Integrated Care Board
- NHS Frimley Integrated Care Board
- NHS Gloucestershire Integrated Care Board
- NHS Hampshire and Isle of Wight Integrated Care Board
- NHS Hertfordshire and West Essex Integrated Care Board
- NHS Humber and North Yorkshire Integrated Care Board
- NHS Lancashire and South Cumbria Integrated Care Board
- NHS Mid and South Essex Integrated Care Board
- NHS North Central London Integrated Care Board
- NHS North East London Integrated Care Board
- NHS North West London Integrated Care Board
- NHS Somerset Integrated Care Board
- NHS South West London Integrated Care Board
- NHS South Yorkshire Integrated Care Board
- NHS Surrey Heartlands Integrated Care Board
- NHS Sussex Integrated Care Board
- NHS West Yorkshire Integrated Care Board



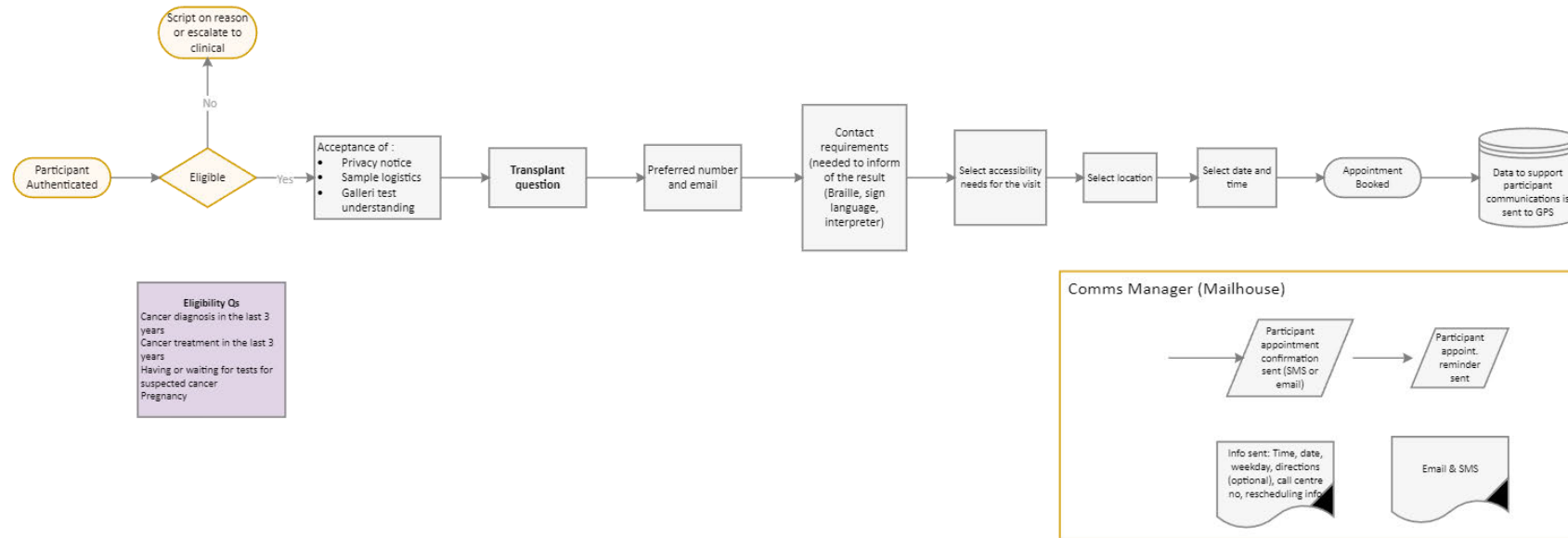
Local

53 Sub ICB regions (CCGs)
84 Acute Hospitals**

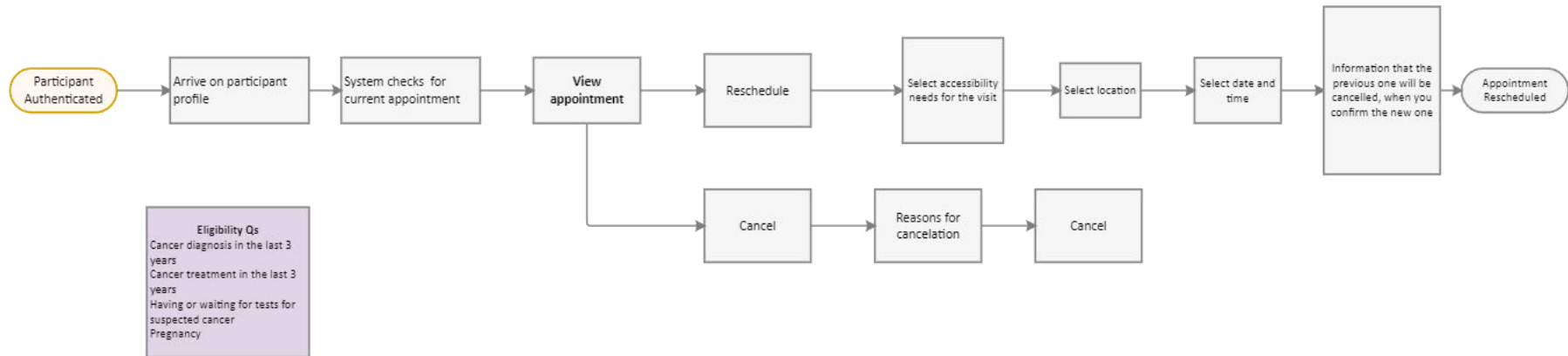
- | | |
|-----------------------------------|--|
| 2 - Lancashire and South Cumbria | 14 - RM Partners |
| 3 - West Yorkshire and Harrogate | 17 - Surrey and Sussex |
| 4 - Humber, Coast and Vale | 18 - Wessex |
| 7 - South Yorkshire and Bassetlaw | 19 - Thames Valley |
| 11 - East of England – South | 20 - Somerset, Wiltshire, Avon, and Gloucestershire (SWAG) |
| 12 - North Central London | 21 - Peninsula |
| 13 - Northeast London | |



Appendix 4 National Operations booking flow.

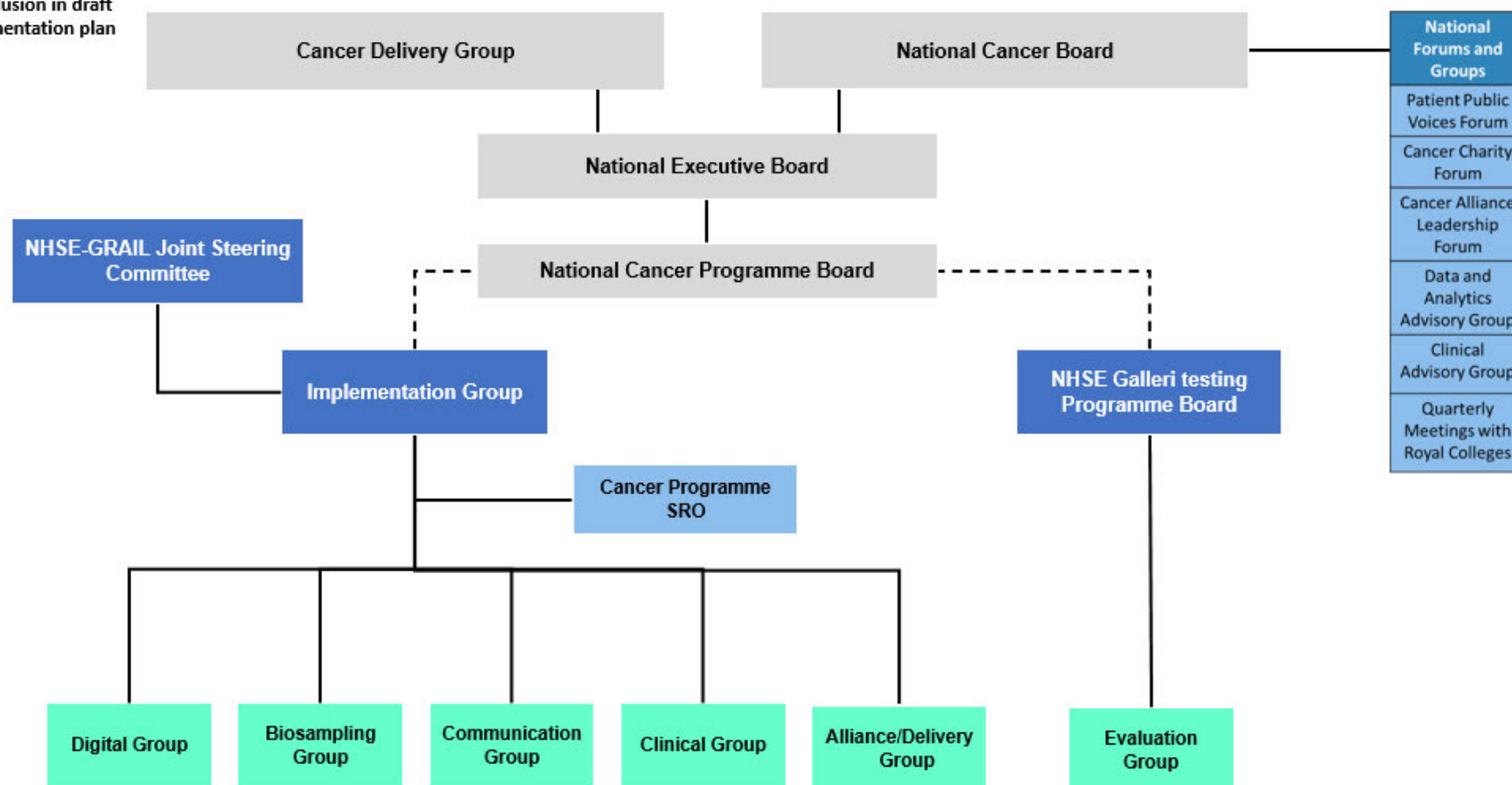


Appendix 5 National Operations Service Rebook or Cancel flow.



Appendix 6

For inclusion in draft
implementation plan



Changes to structure may occur when we move out of implementation stage (groups may dissolve or change function)

List of Acronyms

Acronym	Full Name
CA	<u>Cancer Alliances</u>
CNS	Cancer Nurse Specialist
CPD	Continuing professional development
CQC	Care Quality Commission
CSD	Cancer Signal Detected
CSO	Cancer Signal Origin
ERS	Electronic Referral System
GPS	Galleri Pilot System
GTMS	Galleri Test Management System
ICS	Integrated Care System.
IIP	Interim Implementation Pilot
KPI	Key Performance Indicators
NHSE	National Health Service England
NOS	National Operations Service
NSS	<u>Non-Specific Symptoms</u>
QA	Quality Assurance
RDC	Rapid Diagnostic Centre
SOP	Standard Operating Procedure
TBD	To be decided
USCR	Urgent Suspected Cancer Referral (formally 2 Week Wait referral)

Annex A. Commercial Schedule

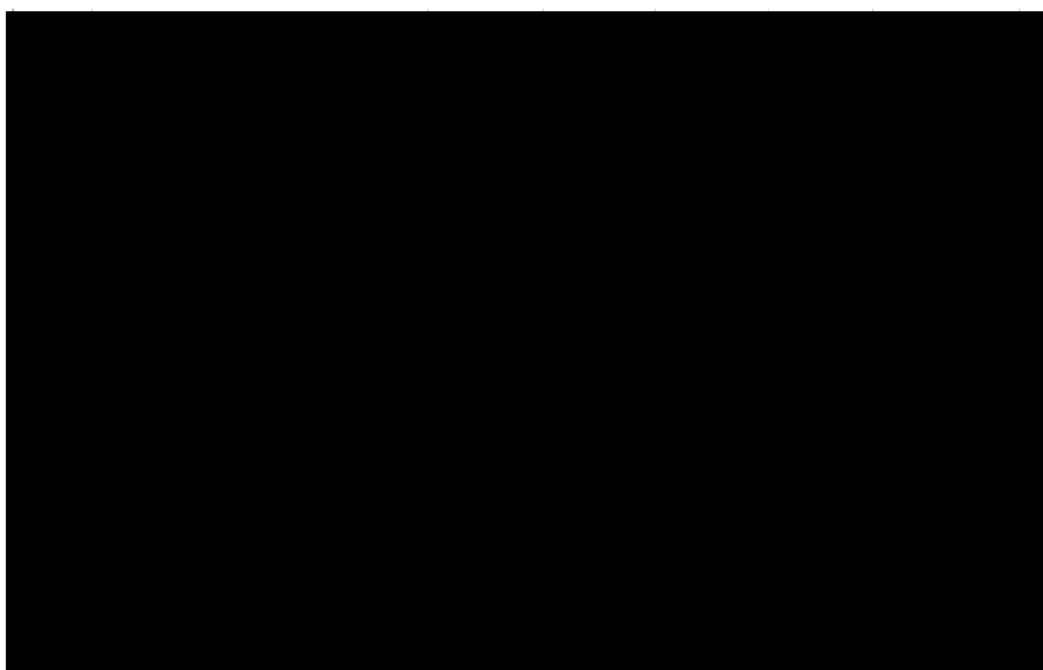


Table F1

	24/25	25/26	26/27	Total
Total staff				
Total staff Non Pay				
Total Non staff				
Total				
Contingency				
Profit				
Overhead				
Total				
Total				10,881,887

The awarded tender is for Call Centre, Clinical and Invitation infrastructure to support the delivery of up to 1,000,000 tests. Both parties understand that a reduction in tests (less than 1,000,000) may create a reduction in costs. NHS England and Gateshead

Health NHS Foundation Trust have established a cost reduction approach in the event that less than 100% of tests are required. Based upon the level of fixed costs within the model, this is estimated at a reduction of circa £500K on 80% of tests.

The above values reflect the awarded tender and are provided as a base for the discussion, with neither party to be bound by these without further agreement following a go/no go/partial go decision. If a partial go decision is made, both parties shall renegotiate the costs based on the new activity assumptions and any changes made to the operational requirements of the NOS service

The process for agreement will be enshrined within the terms of reference of the collaboration board and approved by both parties.

Annex B. National Operations Service Collaborators' Board terms of reference

1. PURPOSE

- 1.1 The NOS Collaborators' Board has been established to provide overall strategic oversight and direction to the Project. The TOR will be developed during the mobilisation period to reflect the emerging needs of the mobilisation. Therefore, this TOR is indicative only and will be version-controlled separately within the governance of the NOS Collaborators Board Group.
- 1.2 Each party shall delegate to its representative on the NOS Collaborators' Board such authority as is agreed to be necessary in order for the NOS Collaborators' Board to function effectively in discharging the duties within these Terms of Reference. Each party shall ensure that its representative has the relevant delegated authority.

2. RESPONSIBILITIES

- 2.1 The NOS Collaborators' Board will:
 - (a) provide strategic management of the Project;
 - (b) identify key personnel for the project and agree their roles and responsibilities;
 - (c) review progress against objectives and key milestones;
 - (d) hold the operational management team to account for progress against key deliverables;
 - (e) review and update the Project plan;
 - (f) be responsible for oversight of legal compliance;

3. ACCOUNTABILITY

- 3.1 The NOS Collaborators' Board is accountable to the parties.
- 3.2 The minutes of the NOS Collaborators' Board will be sent to the parties within 2 weeks following each meeting.

4. MEMBERSHIP AND QUORUM

- 4.1 The Collaborators' Board will comprise:

- [REDACTED]
- [REDACTED]
- [REDACTED]
- [REDACTED]

■ [REDACTED]
■ [REDACTED]

4.2 The Collaborators' Board will be quorate if at least two members of the NHSE Cancer Programme and two members from Gateshead FT are present. Where a key member cannot attend a meeting, the member can nominate a named deputy to attend. Deputies must be able to contribute and make decisions on behalf of the party that they are representing. Deputising arrangements must be agreed with the Chair prior to the relevant meeting. Both parties will develop this ToR further during the implementation phase.

4.3 The chair of the NOS Collaborators' Board will be agreed upon by both parties.

5. CONDUCT OF BUSINESS

5.1 Meetings will be held monthly.

5.2 The agenda will be developed in discussion with the Chair. Circulation of the meeting agenda and papers via email will take place one week before the meeting is scheduled to take place. In the event members wish to add an item to the agenda they need to notify [REDACTED] who will confirm this with the Chair accordingly.

5.3 At the discretion of the Chair business may be transacted through a teleconference or videoconference provided that all members present are able to hear all other parties and where an agenda has been issued in advance.

5.4 At the discretion of the Chair a decision may be made on any matter within these Terms of Reference through the written approval of every member, following circulation to every member of appropriate papers and a written resolution. Such a decision shall be as valid as any taken at a quorate meeting but shall be reported for information to, and shall be recorded in the minutes of, the next meeting.

6. DECISION MAKING AND VOTING

6.1 The Collaborators' Board will aim to achieve [majority] [unanimous] consensus for all decisions in respect of the Project.

7. CONFLICTS OF INTERESTS

7.1 The members of the Collaborators' Board must declare any actual or potential conflicts of interest in relation to the Project and all declarations should be recorded in a register of conflicts of interest. When a conflict of interest is declared, the remaining members of the Collaborators' Board may put in place such arrangements as they deem necessary to preclude the person declaring the conflict of interest from taking part in decision making in relation to relevant

issues, including restricting that person from attending or voting at meetings or parts of meetings and restricting that person's access to relevant papers, on a case by case basis.

8. CONFIDENTIALITY

- 8.1 Information obtained during the business of the Collaborators' Board must only be used for the purpose it is intended. Particular sensitivity should be applied when considering financial, activity and performance data associated with individual services and institutions.
- 8.2 Members of the Collaborators' Board are expected to protect and maintain as confidential any privileged or sensitive information divulged during the work of the Project. Where items are deemed to be privileged or particularly sensitive in nature, these should be identified and agreed by the Chair. Such items should not be disclosed until such time as it has been agreed that this information can be released.

9. REVIEW

9.1

These terms of reference are effective from 08/04/2024 and will remain in force until such time as they are amended by agreement of the Collaborator Board, or termination of the project.

Annex C. Information Governance

Please see NOS NHSE Data Processing Agreement (NHSE Controller)
