SCHEDULE 2 – THE SERVICES

A. Service Specifications

Service name	Galleri Pilot Biosampling Service Specification 1.7
Service specification number	
Population and/or geography to be served	Participants living in the following Cancer Alliances: ● East of England (South) ● Wessex ● Peninsula ● Thames Valley ● Humber Coast and Vale ● 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	2024/25 - 2026/27
Date of Review	

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. To achieve the milestone of greater early diagnosis, the NHS Long Term Plan sets out to improve the existing cancer screening programmes.

1.1.2 A Cancer Blood Test, the Galleri(R) test, is being assessed by the NHS as part of a large-scale clinical trial, the NHS-Galleri study. 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 that can detect a cancer signal across more than 50 types of cancer before symptoms appear.

1.1.3 The participant pathway will cover the alliances that were not part of the research trial.

1.1.4 The proposed delivery model for the Interim Implementation Pilot uses local NHS-commissioned phlebotomy services. To ensure comprehensive access to bio sampling (blood draw) for all eligible invited participants in the pilot areas. The programme wants to draw on the experience, capability and reach of local phlebotomy services. In addition, ensure end-to-end sample transportation to support safe and effective processes.

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 safe environment and protecting them from avoidable harm	

2.2 Local-Defined Outcomes

The Galleri Test – Interim Implementation Pilot bio sampling service will support the delivery of the strategic priorities of the NHSE Cancer programme by:

- Providing easy access to blood draws closer to home;
- Offering prompt, effective and appropriate care;
- Improving the quality of the user experience;
- Supporting vulnerable adult patient groups and that staff are appropriately trained;
- Effective management of Streck tubes (supply TBC and use);
- Recording, packing and transporting samples in a timely manner to a national or regional GRAIL hub (TBC).

2.3 Local Strategic Direction

Phlebotomy services within the ICB and Alliance are encouraged to collaborate to deliver at scale and ensure good opportunity and accessibility, particularly for underrepresented groups.

3 Scope

3.1 Aims and objectives of service.

The provision of local Galleri Test Pilot bio sampling service aims to provide a much more convenient service for participants that require the Galleri blood test to detect earlier-stage cancer.

3.2 Service description/care pathway

The service will be accessible to participants that have been invited to the programme and have booked a local appointment for a blood draw (See **Early Cancer Detection Using the Galleri Test – Interim Implementation Pilot Standard Protocol** for details). These blood draw appointments will be booked on the national booking website or on the phone following an invitation letter to participate.

The service will provide:

- Blood draw clinics at times to complement participation accessibility and blood transportation. These must be produced at least two months in advance for the national service to book into.[1]
- Ensure an adequate supply of Streck tubes (TBC)[2]
- Provide the transportation end to end of the sample to the local hub (TBC).

The Phlebotomist will complete the following tasks:

- Confirm the participant's identity and check test results form is correct[i]
- Complete blood draw for two 10ml samples per participant to be collected in Streck tubes, labelled with requisite information for participant identification and sample processing (exact details to be confirmed).
- Complete the usual post-blood draw procedure with the participant.
- Complete the bloods process linking to the GRAIL record and prepare ready for transportation to the national processing lab.
- All blood samples shall be accompanied by appropriate documentation and identifiers to enable each sample taken to be accurately and confidentially assigned to an individual participant and matched to the participant record (specimen labelling procedure TBC).
- Participants who are challenging to bleed may need a senior phlebotomist to perform the blood draw, or the participant will be advised to rebook for a retest with advice[3]
- If the participant has any queries about the blood test, they are encouraged to ring the call centre to support.

In addition, Phlebotomists require specific training:

- Streck tubes need different handling by phlebotomy than standard blood tubes. GRAIL will provide a sample handling manual, and the GRAIL team will provide specific training on Galleri kits /Streck tubes (TBC). Attendance will be the responsibility of the provider.

The designated local phlebotomy site will:

- Ensure all samples are recorded and packaged appropriately, ready for transportation.

[1] A National invitation, booking and results system will be built to support the pathway end to end – this is being developed by NHS Digital and GRAIL

[2] 504 Galleri kits per pallet

[3] If a blood sample is unable to be collected, ideally the provider will be able to have the draw completed at a clinically appropriate secondary care phlebotomy service.

- All samples will be transported daily from the sample location with the necessary packaging for transportation (TBC).
- Samples must reach the national processing centre[4] within 48hrs of the blood draw.
- Samples should be stored at room temperature (6°C - 20°C) for filled blood tubes until shipment and during transportation. Do not refrigerate or freeze.

Location for phlebotomy clinic must have:

- A dedicated space that can be used for phlebotomy.
- Provide chairs and stock of equipment required to deliver the service.
- Hand washing facilities for the use of phlebotomists and any other professionals
- Facilities allowing connection to the invitation and booking system portal that will be developed for this interim implementation pilot.
- Access to a barcode label printer to allow easy labelling of sample tubes.
- Access to a barcode scanner to allow easy scanning of Galleri kits (TBC).
- Access to a drinking water fountain.
- Blood samples must be stored in a safe clinical environment prior to transportation to the hub for analysis.
- Samples must be transported via an approved courier service to ensure a safe delivery and quality conditions of the samples (TBC).
- Have a procedure for dealing with any vasovagal fainting episodes.

Within the locations available to offer to participate, they should be some that offer the following:

- Readily accessible by public transport
- Easily accessible for those with restricted mobility
- Car parking
- Can facilitate language support
- Provide access and facilities for patients with disabilities, in accordance with the Equality Act 2010

The local Alliance /ICB may wish to support underserved communities by piloting different approaches to blood draws, e.g., housebound participants' support.

The provider shall ensure that:

- Staff are employed by the trust or through a subcontract/commissioned arrangement. with another provider for the provision of care within the area;
- Staff providing the service are suitably qualified and competent, and there are in place appropriate arrangements for maintaining and updating relevant skills and knowledge and for supervision;
- All premises and equipment used for the provision of the service are at all times suitable for the delivery of those services and sufficient to meet the reasonable needs of participants (see above);
- Information on how participants can access the service is available via the national booking website;
- Treatment and care provided are culturally appropriate and are available in a form that is accessible to people who have additional needs, such as people with physical,

[4] Samples will be processed by GRAIL or their designated sample processing partner in the United Kingdom

cognitive or sensory disabilities and people who do not speak or read English (nationally available literature);
- Appropriate plans are in place for cover of leave (both anticipated and unanticipated) and planning to meet the need of required clinics;

The Provider shall inform their local Cancer Alliance and the national booking team at the earliest opportunity if there is a significant disruption to the service so that continuity can be maintained through an alternative provider, or another date offered.

3.3 Activity and Reporting

The clinics and activity will be monitoring activity by the alliance on a monthly basis and 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 increasing attendance.

The Provider shall ensure an appropriate record of activity is developed and maintained for audit and payment purposes. The provider shall provide monthly activity and quarterly quality data to the local Alliance on a quarterly basis using the return sheets provided.

Activity data shall include:

- Number of clinics slots available and participants' contacts.
- Number of DNA's, failed blood draws, participants that attended and decided not to have bloods taken.

The provider shall provide quarterly quality data sets. This could include:

- *Participant complaints*
- *Adverse incidents*
- *Patient feedback on the provision of services*

3.4 Population Covered

This local service contract is available to all participants booked into the GRAIL clinic by the national GRAIL pilot team. Clinic availability is required for 15% minimum coverage of the eligible population in the area.

An indicative example of expected activity
Each ICS will have a different % of the eligible population (50-77 years old). In the pilot population, this is usually less than 1/3 of the total population on average. Based on the Galleri trial take-up rate in the eligible population, this has been modelled at approximately 10% (on average, 3.3% of the total population). For example, Hertfordshire and West Essex have an estimated population of 1.5 million, and we would expect 45,000 people to be tested over two years across this ICB. There is a small failure rate; however, we would expect a DNA rate of approx. 10% based on the trial experience, therefore we would expect the HWE ICB to provide 49,500 slots over the two years.

In simple terms, at max capacity of a one-person phlebotomy clinic[5], this would be 9500 appointments per year. Each area is likely to arrange this differently to maximise access, efficiency and transportation.

3.5 Any acceptance and exclusion criteria.

Acceptance Criteria

- *The Provider will ensure access to the service for participants booked to have bio-sampling.*

Exclusion Criteria

- *See Standard protocol for GRAIL pilot exclusion criteria.*

3.6 Monitoring

The table below needs to be confirmed but it indicates what is likely to be required.

Activity Monitoring			
Activity Performance Indicators	Threshold	Method of measurement	Consequences of breach
• Number of clinic slots provided. Each service provider to also report on/input on the system:- • Number of Participants attended • Number of participant DNA • Number of patients attended where no blood sample was extracted (unable to draw or declined)	Service providers must deliver a phlebotomy clinic available for x% of ICB eligible population.	• All activity is to be captured on a GRAIL Platform. Reports to be provided monthly (automatically generated TBC). • Quality metrics are to be provided monthly, and experience measures and frequency TBC	If the Clinic slots available far below the agreed ramp plan of x% in the second quarter of delivery, payment is to be withheld until agreed recovery target met
Additional data requirements are set out in the Quality and performance indicators will be agreed with the providers to inform the KPI dashboard.			

4. Applicable Service Standards

[5] 10 min slots over 250 days per year with 1 hr built into a 9-5 day of break time (38 per day)

4.1 Applicable national standards (e.g., NICE)

The provider will be required to ensure the community based phlebotomy service is compliant with the required NHS regulatory requirements, including Care Quality Commission regulations, etc.

The service provider must have in place appropriate health and safety and risk management systems that adhere to:

Department of Health Primary and Social Care Premises and Planning and Design Guidance (www.dh.gov.uk/en/Procurementandproposals/Publicprivatepartnership) and www.dh.gov.uk/en/Publichealth/Healthprotection/Healthcareacquiredinfection

World Health Organisation (2010) WHO guidelines on drawing blood – best practice in phlebotomy

http://www.who.int/injection_safety/phleb_final_screen_ready.pdf

NICE Clinical Guideline 2. Infection Control (2003) - Prevention of healthcare-associated infection in primary and community care

http://www.nice.org.uk/nicemedia/pdf/cg2fullguidelineinfectioncontrol.pdf

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

4.3 Applicable local standard

Completion of GRAIL Streck tube training module (TBC)

5. Applicable quality requirements

5.1 Applicable quality requirements
Schedule to TBC

6. Location of Provider Premises

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

Change Log			
Date	Version	Author	Section and notes
04.01.2023	1.4	Marie Ahern	• 3.1 Service description/care pathway Following a meeting with senior cancer Programme leads, it was agreed to remove much of the 'checking process' from the phlebotomy task process (recorded in the programme decisions log). This will now move into the booking process. – notes of removed in endnote 1 Removal of Figure 1 - now changed. • 3.1 Service description/care pathway Separation of transport, this may need to be commissioned separately. An indicative example of expected activity Additional of DNA approx. rate and expected available clinics example. Programme questions added as comments
03.02.2023	1.5	Marie Ahern	• 2.2 & 3.2 update hub/TBC • 3.2 Tubes collected updated, 'processed' removed, and a line added about the responsibility of attendance being with the provider. • 3.3 Additional standards and requirements • 3.6 Draft KPI's set out. • 4.1 additional NHS standards
27.02.2023	1.6	Marie Ahern, with CWG input	• 1.3 -Make explicit that NHS commissioned phlebotomy
14.03.2023	1.7	Marie Ahern, with David Fitzgerald's input	• 2.1 Focus on primary outcomes (1 and 2)