

NHS

East Genomics

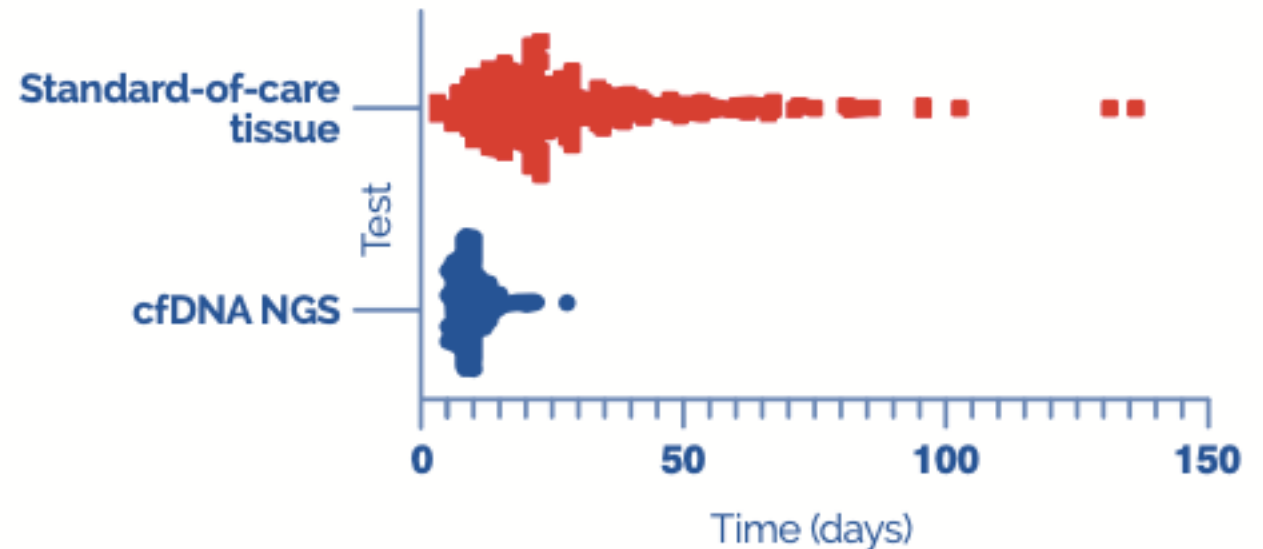
Circulating Tumour DNA (ctDNA) in lung cancer



Benefits to patients with a genomic profiling liquid biopsy assay

Compared to SOC tissue diagnostic pathway for lung cancer, ctDNA could offer:

- Less invasive and faster diagnosis
- Reduction in time to treatment
- More lives saved

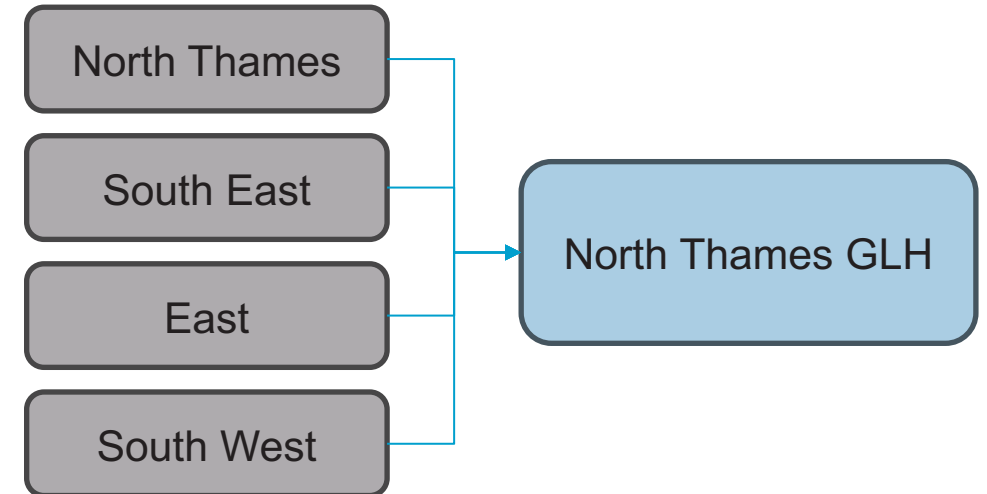


Turnaround Time – Liquid Biopsy vs Tissue Biopsy

Cui W, Milner Watts C, O'Sullivan H, et al. Up-front cell-free DNA next generation sequencing improves target identification in UK first line advanced non-small cell lung cancer

NHSE ctDNA pilot in suspected advanced lung cancer - Phase III

- Phase III is easier and streamlined:
 - No data collection
 - Samples posted *via* Royal Mail
- 1st April 2024 – 31st March 2025
- North Thames will continue to offer all testing from 01/04/2024 - 01/07/2024



- No test allocation number per region, goal is 10,000 tests nationally (East represents 15% of the population)
- Focus is patient outcomes and transitioning ctDNA testing to BAU (on the test directory)

Eligibility Criteria for Patients

- Radiologically suspected stage III/IV Lung cancer, likely unsuitable for curative treatment
- ECOG PS 0-3
- Histological diagnosis of NSCLC where molecular testing has failed and alternative option would be re-biopsy

Provide the patient with a patient information sheet- signed consent not required.

Requesting Blood Collection Kits (BCK)

Ordering a Marsden360

1 To order Blood Collection Kits (BCK), containing two Streck tubes, absorbent tube pouches, biohazard bag and rigid pre-paid postage mail box, please contact **Marsden360@rmh.nhs.uk**.

Please allow three working days for delivery to the designated site.



Complete the BCK form: Number of BCKs requested (1 BCK per patient. Minimum 10 and maximum 50 BCKs per order), address where to ship and contact name.

Royal Marsden will also share:

- Test request form (TRF), Instructions for use (IFU) leaflet, Tube labels, Patient information sheet.

Please contact **Marsden360@rmh.nhs.uk** should you have any queries about any of the documents

The ROYAL MARSDEN
NHS Foundation Trust

Marsden360
Developed in partnership with Guardant Health

Blood Collection Kit (BCK) Order Form
Please email completed form to **Marsden360@rmh.nhs.uk**
Save completed form for future BCK requests

Hospital name	
ODS code	
Address Line 1	
Address Line 2	
City	
County	
Postcode	
First Name Contact for the delivery at the site	
Last Name Contact for the delivery at the site	
Genomic Medicine Service Alliances (GMSA) region	<input type="radio"/>
Number of BCK required One BCK per patient (minimum order 10 BCK)	<input type="radio"/>
Date BCK required by Please allow 3 days for the BCK to arrive	
Completed by (PRINT)	Date
Office use	
Approved by (PRINT)	Date
Sent to portal by	Date

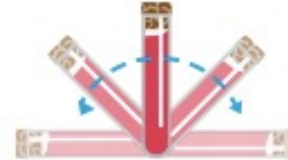
Blood Collection

Blood draw instructions

- 1 Collect specimen by venipuncture, filling the two Streck tubes completely



- 2 Mix by gentle inversion 8 to 10 times



- 3 Ensure tubes are labelled as instructed in step 2 on the following page



Do not refrigerate or freeze blood samples

Shipping instructions

- 1 Complete the Test Requisition Form (TRF)



- 2 Fill out labels on each tube including:
- Patient name
 - Hospital number
 - Date of birth (dd/mm/yyyy)
 - Collection date (dd/mm/yyyy)



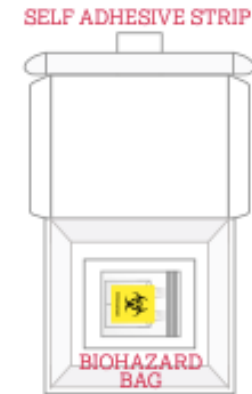
- 3 Open the pre-paid mail box. Place the tubes in the absorbent pouches provided, fold over and place into the biohazard sample bag and seal securely



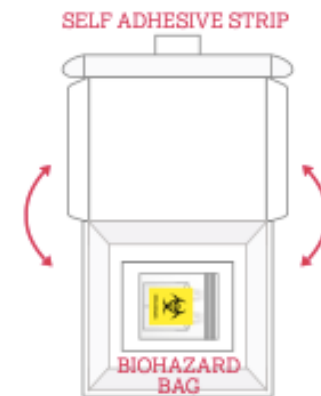
- 4 Place the sealed biohazard bag and completed Test Requisition Form (TRF) into the pre-paid rigid mail box. **Please note only one BCK per patient**



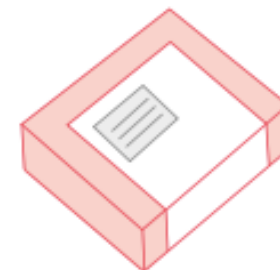
- 5 **CHECK** all contents are included as required before closing



- 6 Close the mail box, ensuring the self adhesive security strip is securely sealed



- 7 Please record the Royal Mail tracking number on the TRF from the pre-paid postage label, to enable the BCK to be tracked during transit

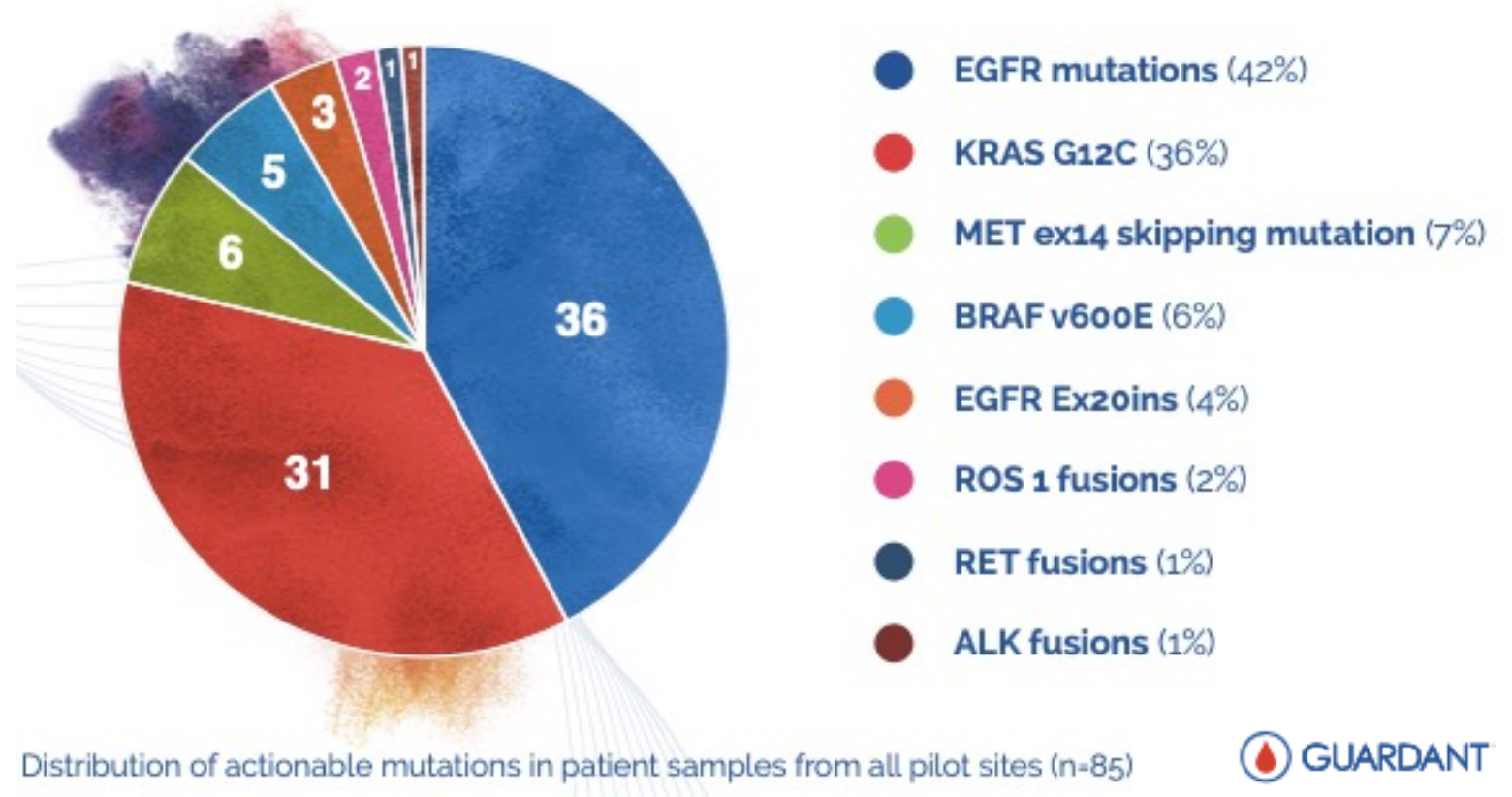


Results

Results will be sent securely to the emails provided on the test request form *via* NHS.net or hospital email (.nhs.uk).

Please allow upto 14 calendar days.

Summary of Guardant Health data collected across 19 pilot sites (4 GMSAs) - 1 in 5 (n=85) patients were identified to have alterations treatable with targeted therapies.

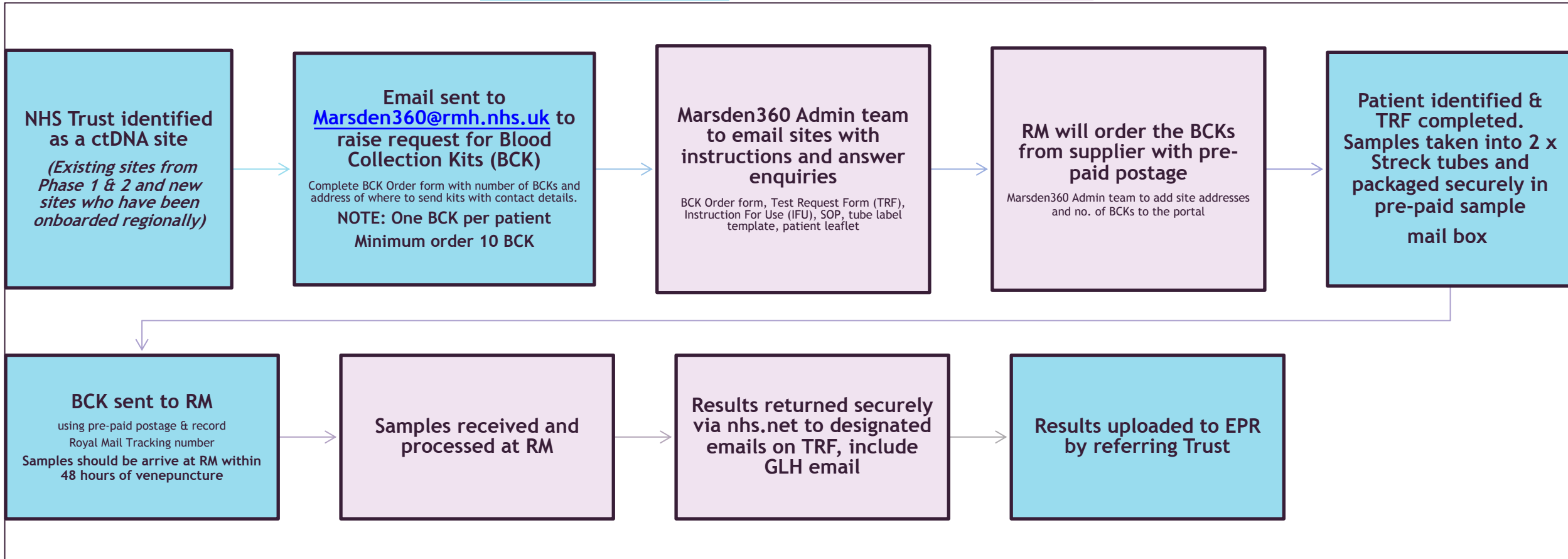


Sample pathway for Phase 3 Lung ctDNA Pilot

Site responsibility

Clinical unit

Royal Marsden (RM)



Supporting documents available from Marsden360@rmh.nhs.uk

- Blood Collection Kit (BCK) Order Form
- Test Requisition Form (TRF)
- Instructions for Use (IFU)
- Standard Operating Procedure (SOP)
- Patient leaflet
- Streck tube label template

Common Questions

Is it ok to not fill the blood volume upto the marked line on the tube?

The more blood volume you provide, the more likely RMH are going to obtain enough plasma for testing. Therefore, it is fine to not have the tubes filled completely, but they might request for more material if they cannot obtain enough plasma. They will let you know if that is the case.

If we post samples on a Friday, will they be received the next day before 1pm on Saturday, or will it be the Monday?

The 48 hours TAT is a preferred time. RMH can process blood samples up to 7 days after collection. If the sample is sent on Friday afternoon, they will book that in and start processing it on Monday.

What is the escalation process if results aren't received within 14 days?

First escalation contact if results aren't received on day 14

marsden360@rmh.nhs.uk

Second escalation contact if results aren't received on day 16

marsden360@rmh.nhs.uk

Third escalation contact if results aren't received on day 25

Mikel.ValganonPettrizan@rmh.nhs.uk

Will ctDNA testing be offered for other indications?

Expansion of CI's will be through the NoE – the NoE will be recommending to NHSE what CI's could benefit from ctDNA for NHSE to make a decision on commissioning.

Contacts / questions

Programme manager: Dr Sobia Hamid sobia.hamid1@nhs.net

Clinical lead: Dr Brent O’Carrigan b.ocarrigan@nhs.net

Strategy lead: Col Spencer colin.spencer@nuh.nhs.uk

Royal Marsden central testing team: marsden360@rmh.nhs.uk

More information (including patient information): Google “east genomics ctDNA”

https://www.eastgenomics.nhs.uk/about-us/genomic-medicine-service-alliance/Transformation_Projects/ctdna/