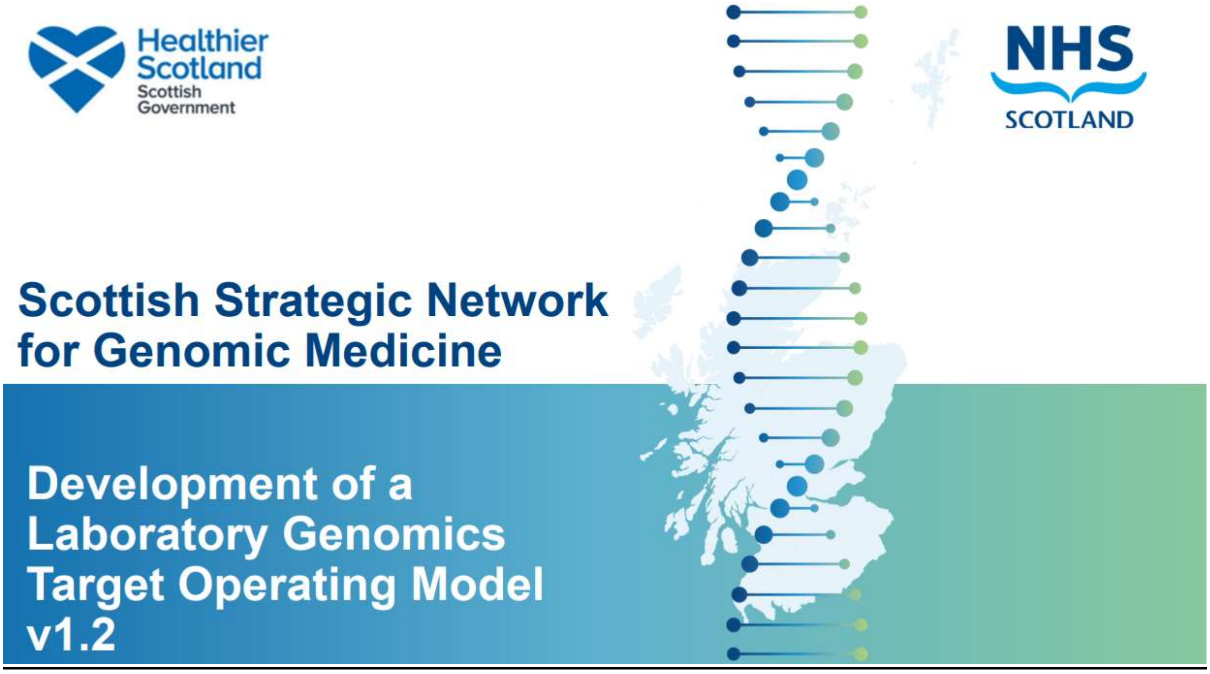
Appendix 1: Outline

1. Powerpoint slide, TOM Outline, 20 November 2024. Attached as separate file with no redactions.



What is included in the Target Operating Model (TOM)?

In scope

- Laboratory management structure
- Laboratory finance
- Laboratory estate
- Laboratory workforce
- Data and digital
  - ✓ Storage and sharing
  - ✓ Bioinformatics
- Rare and inherited disease genomics
- Cancer genomics (solid tumour and haematological malignancy)
- Innovation and development
- Whole Genome Sequencing

Out of scope

- Other NHS disciplines
  - ✓ Clinical Genetics
  - ✓ Pathology
  - ✓ Haematology
  - ✓ Oncology
- Other NHS laboratory services
  - ✓ Pathogen genomics
  - ✓ Tissue typing
  - ✓ Immunogenetics
  - ✓ Histopathology
- Pharmacogenomics developments
- National LIMS

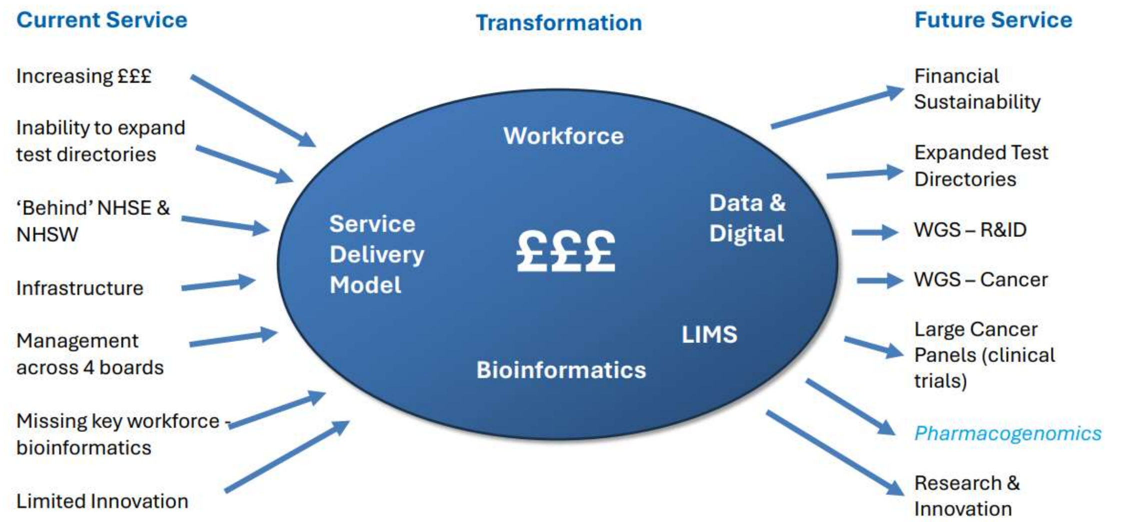
Progress to Date: Genomics Medicine Strategy 2024 - 2029

During the development of the Genomics Medicine Strategy, **7** Strategic Working Groups were established covering the following areas:

- ✓ Workforce & Education
- ✓ Data & Information
- ✓ Rare & Inherited Disease
- ✓ Solid Tumour
- ✓ Haematological Malignancy
- ✓ Research & Innovation
- ✓ Pharmacogenomics

These working groups contained **128** members as key stakeholders of genomics across Scotland. **13** high level strategic aims were agreed as priority for inclusion into the Genomic Medicine Strategy for the patients of Scotland.

Transformation of the Genomics Laboratories



Transformation of the Genomic Laboratories: Progress to Date

Transformation Working Groups

- Data standardisation
- Demand Optimisation
- Laboratory workforce planning
- Implementation of cancer priorities

Progress has been slow across all operational working groups with significant challenges around existing organisational boundaries and duplication of effort (every objective/ work area considered across four laboratories).

Transformation Delivery Plan

- Laboratory finance
- Laboratory delivery model
- Workforce
- Data & Digital/ bioinformatics
- Innovation

A two year genomics delivery plan has been developed which included detailed workplans to prioritise transformation of the laboratories.

Development of a TOM

- Transformation Delivery Plan
- High Level TOM- Transformation Team Recommendations

The TOM focuses on the Transformation Delivery Plan themes making key recommendation on what is required to transform laboratory services. A detailed TOM will follow with Stakeholder Engagement.

Management Structure and Laboratory Workforce

Current State

Four centre model, each managed differently.

- Top heavy management structure.
- Key management roles missing.
- Key staff roles missing.
- No regulation for technical staff.
- Lack of national planning and coordination of delivery.
- Local way of working inhibiting national standardisation.
- Local training plans.
- No local or national workforce plans.
- Not enough trainee scientists.

Desired Future State

New leadership model that looks beyond traditional delivery model.

- New single management structure.
- Well-staffed and supported management across Scotland.
- New roles implemented.
- Nationally agreed job descriptions and skills profiles.
- Better use of skills to support expansion of genomics.
- National training plans including for bioinformatics.
- National workforce plan.
- Succession planning.

Co-dependencies

Ensuring Scotland doesn't drift too far from structures elsewhere in the UK.

- Healthcare Science Strategy.
- NHS Education Scotland.
- Academy for Healthcare Science.

Laboratory Finance

Current State

Laboratory budgets managed by four different boards.

- Financially unsustainable.
- No standardisation of finance returns so not comparable.
- Not possible to accurately benchmark spend vs activity.
- No national costing model.
- Inability to expand testing.
- No national negotiation with suppliers.
- Difficult to manage change due to different budgets.
- Duplication of equipment means larger than needed running costs.

Desired Future State

One finance profile across entire laboratory genomics service.

- Financial sustainability.
- Finance managed by one board.
- Better understanding of spends.
- National negotiation with suppliers.
- Opportunity to consider reagent rental.
- Reduction in laboratory running costs e.g. capital charges, overheads.
- Better management of change.
- National working for income generation.

Co-dependencies

Ensuring Scotland doesn't drift too far from structures elsewhere in the UK.

- Board finance teams.
- NSD commissioning team.
- Additional funding for expansion of testing.

Laboratory Estate and Delivery Model

Current State

Four regional laboratories spread across Scotland.

- Good regional links to users and other laboratory disciplines.
- Inequity of service across Scotland.
- Only one of four laboratories has space to expand.
- Equipment not used to capacity.
- Inefficiencies in current operating model.
- Reporting turn-around time routinely not met.

Desired Future State

New delivery model with potential reduction in number of laboratories.

- Reduction in laboratory footprint whilst ensuring contingency.
- Redistribution of key equipment to ensure better capacity use.
- Centralisation of large volume/ high through put tests.
- Ability to deliver urgent results without detriment to outcomes.
- Ability to expand.
- Reports issued within turn-around times.

Co-dependencies

Samples for cancer testing where consultant medics are key to testing pathways.

- Pathology labs across Scotland.
- Haematology labs across Scotland.
- Oncology.
- MDT working.

Samples for rare and inherited disease testing where clinical expertise is local to one centre.

- Clinical genetics across Scotland.
- MDT working.

Data and Digital: Data storage, sharing & bioinformatics

Current State

Data and digital is delivered within each centre, so fragmented and no coordinated delivery across Scotland.

- No national electronic order comms.
- No national data store or ability to share data.
- No national approach to governance.
- Fragmented delivery of bioinformatics with limited trained staff.
- Limited data and digital staff.
- No standardisation of analysis pipelines.
- No standardised national data returns.

Desired Future State

New national approach to data and digital for genomics.

- National electronic order comms.
- National data store for genomic data.
- National governance for genomics.
- National centralised bioinformatic team.
- New data and digital staff.
- Standardisation of bioinformatic pipelines.
- Standardised national data returns.

Co-dependencies

There are multiple partners in the data and digital space for our genomic service which must be considered.

- eHealth teams across Scotland.
- Information Governance.
- National Digital Strategy.
- Academic and industry partners.
- Digital Pathology.

Rare and Inherited Disease Genomics

Current State

Expansion of genomic tests required but current delivery model not suitable.

- Inability to expand testing (funding).
- Limited standardisation of testing technologies.
- Limited access to WES.
- No access to WGS.
- Reporting turn-around time routinely not met.

Desired Future State

Flexible and scalable rare and inherited disease genomics service that implement new tests and technology at pace.

- Centralise germline testing to fewer laboratories.
- Delivery of urgent results without detriment to outcomes.
- Standardised testing, analysis and reporting pathways.
- Expansion to testing.
- Evaluation and implementation of new technology for rare and inherited disease.
- WGS for rare and inherited disease.

Co-dependencies

Samples for rare and inherited disease testing where clinical expertise is local to one centre.

- Clinical genetics across Scotland.
- Horizon Scanning Advisory Board.
- SSNGM horizon scanning.
- MDT working.

Cancer Genomics

Current State

Expansion of cancer genomic tests required but current delivery model not suitable.

- Inability to expand testing (funding).
- No routine access to large cancer NGS panels.
- No access to WES or WGS.
- No cancer genomics innovation (ctDNA).
- Poor access to clinical trial targets for cancer patients.
- Limited standardisation of testing technologies.
- Reporting turn-around time routinely not met.

Desired Future State

Flexible and scalable cancer genomics service that implement new tests and technology at pace.

- Centralise somatic testing to fewer laboratories.
- Delivery of urgent results without detriment to outcomes.
- Standardised testing, analysis and reporting pathways.
- Delivery of large cancer panels.
- Delivery of clinical trial targets.
- Expansion to testing.
- Evaluation and implementation of new technology for cancer.
- WGS for cancer.

Co-dependencies

Samples for cancer testing where consultant medics are key to testing pathways.

- Pathology labs across Scotland.
- Haematology labs across Scotland.
- Oncology.
- Scottish Medicines Consortium.
- Horizon Scanning Advisory Board.
- SSNGM horizon scanning.
- MDT working.

Innovation and Developments

Current State

Inability to develop and implement new tests in a timely manner.

- Limited innovation.
- Limited genomics research.
- Long delays to implement or evaluate new tests and technology.
- Duplication of effort across laboratories which increases costs.
- No standardisation.
- Poor working with academia and industry in some centres.
- No capacity to identify alternative funding sources.

Desired Future State

Rapid development and implementation of new tests and technologies.

- National centralised development team.
- Standardisation of processes and roll-out across laboratories.
- Bioinformatics linked to developments.
- New working partnerships with academia and industry.
- Leading innovation and genomics research.
- Securing alternative funding sources for innovation.

Co-dependencies

Partnership working across Scotland.

- National working with universities.
- Industry collaborations.

Proposed Timelines & Next Steps

Nov 2024	Dec 2024	Jan 2025	Feb 2025	Mar 2025
TOM high level proposal to OB for consideration	TOM to SG for agreement on next steps	Stakeholder engagement	Draft TOM to SG for approval	Draft TOM to OB for approval
1	2	3	4	5
Develop work, timeline & comms plans	Collect data from labs to inform TOM	Scoping of requirements, analyse data	Draft TOM for approval by SG	Amend TOM for approval by OB

2. SSNGM-NSD communication to Boards on TOM 15 January 2025. Personnel names and email addresses redacted on grounds of personal data of a third party (38(1)(b)).

Specialist Healthcare Commissioning

National Services Directorate (NSD)
Gyle Square,
1 South Gyle Crescent
EDINBURGH, EH12 9EB
www.nsd.scot.nhs.uk

NHS National Services Scotland

[Redacted]

Date 15/01/2025
Your Ref
Our Ref
Enquiries to [Redacted]
Direct Line [Redacted]
Email [Redacted]

Dear [redacted],

THE DEVELOPMENT OF A NEW TARGET OPERATING MODEL (TOM) FOR THE DELIVERY OF NHS SCOTLAND GENOMIC LABORATORY SERVICES.

NHS Scotland has a vision of delivering sustainable, resilient, accessible, and equitable services for the population of Scotland and recognises that this can only be achieved by a significant change in the way we plan, organise, deliver and fund services. Work is therefore underway to develop a single transformation plan for our diagnostic services across NHS Scotland.

In 2022, a major review of the genomic laboratories carried out by NSD identified 17 recommendations. The focus of the recommendations was in relation to increasing demand resulting in a £14million increase in costs over 4 years. This along with scientific workforce challenges, a wide variation in practice resulting in regional inequity, challenges with much of the estate and infrastructure, was evident across the 4 boards delivering genomic testing across Scotland. As a result, NSD received funding to establish a Genomics Transformation Team to support the need for transformation of the Genomic Laboratory Service in Scotland.

Over the past two years the Genomics Transformation Team have worked under the auspices of the Scottish Strategic Network for Genomic Medicine (SSNGM) Oversight Board to work with the genomic laboratories to collate key information to support reformation.

In 2024 the Genomics in Scotland: Building our Future strategy for genomics was published by Scottish Government (see reference below), and the SSNGM and Transformation Team were asked to develop a Target Operating Model for Genomic Laboratory Services in Scotland.

The TOM process is being used to drive transformational change and its purpose is to outline the current genomic laboratory service, the desired future state we want to achieve and what is required to deliver the vision. A high-level options appraisal was presented to the SSNGM

Specialist Healthcare Commissioning

Oversight board in August 2024, who endorsed the proposal that a reduction in the number of laboratories should be considered as part of the TOM on the basis of evidence submitted.

We will now need to work with teams and stakeholders to collate further information to ensure the TOM proposal can be delivered. Once this process is completed the TOM will be considered by the SSNGM Oversight Board before being presented to the NHS Scotland Strategic Planning Board and the National Planning and Delivery Board before final sign of by the NHS Executive Group. Over the coming months the team will visit the genomic laboratories to meet with managers and staff and will produce a stakeholder engagement plan for wider discussion with clinical users of our genomic laboratories in Scotland.

A detailed project plan is being developed and key milestones including a communication plan will be shared with the 4 genomic laboratories in due course. Updates on progress will be reported through the SSNGM governance groups, where your board has representation.

I would like to extend thanks on behalf of the NSD team to all stakeholders and staff who have worked hard to engage in this process, and we look forward to continuing in this collaborative venture and would be more than willing to have a more detailed conversation is needed.

Yours faithfully,

Susan Buchanan
Director of National Services Directorate
NHS National Services Scotland

cc
[Redacted]

3.Extract within scope of request: Scottish Strategic Network for Genomic Medicine – Oversight Board Minutes. 14th January 2025. Personnel names and email addresses redacted on grounds of personal data of a third party (38(1)(b)).

TOM Update

The high-level outline proposal for the TOM was presented at the last SSNGM Oversight Board meeting and has been approved by the SSNGM Steering Group. There has been collaboration with the Programme Management Support Team (PgMS) from NSD and [redacted] Programme Manager and [redacted] Business Analyst have joined the SSNGM team to develop this work. Discussions have been initiated with laboratories to collect additional data related to their activities. The transformation team has prepared a template that will be used for collecting the required information. The goal is to finalise the data collection process and receive the information promptly from the labs. The team is still waiting for workforce returns from one service, but it is anticipated this will be received soon. [redacted - Lead Clinical Scientist] highlighted that engagement with staff-side/ Unions in the TOM process has posed a challenge. To address this, [redacted – Lead Clinical Scientist] will send regular email updates on the progress of the TOM to staff-side representatives. It was emphasised that if staff-side have any concerns, they can flag them via email. There have been ongoing discussions with [redacted – Chair] regarding transitioning to a single finance profile for the TOM. It was noted that [redacted – Chair] will present the finance slide from the high-level TOM document to the Directors of Finance and will provide an update at the next Oversight Board meeting on Tuesday 22nd April.

4. Extract within scope of request: Scottish Strategic Network for Genomic Medicine – Oversight Board Minutes. 16th May 2025. Personnel names and email addresses redacted on grounds of personal data of a third party (38(1)(b)).

TOM Update

It was highlighted that original timescales shared at the SSNGM Oversight Board meeting on Tuesday 14th January were delayed due to complex stakeholder engagement significantly impacting progress from November to March. Work is now moving forward following a productive workshop on Thursday 15th May which has enabled progress in the co-design process. It was noted that revised timescales are under review following Workshop 1 and will be presented to the SSNGM Oversight Board at a future meeting. It was highlighted that the labs have agreed on a standardised method for data collection to inform the TOM based on annual report data.

Next Steps

- Second workshop will be scheduled for early summer.
- Confirm an independent Senior Responsible Officer for the work moving forward.
- Finalise data collection via lab staff/clinical surveys, PgMS site visits, and outstanding data gathering.
- Establish a short-life working group (SLWG) to support stakeholder engagement and input.

Future considerations include introducing a process for more frequent reporting between meetings to maintain momentum and defining a clear escalation pathway for support within the TOM process.

5. Extract within scope of request: Scottish Strategic Network for Genomic Medicine – Steering Group Minutes. 27th February 2025. Personnel names and email addresses redacted on grounds of personal data of a third party (38(1)(b)).

TOM Update

[redacted – PgMS team] provided an update on the TOM development for genomics labs in Scotland. Challenges with data collection, StaffSide engagement, and discrepancies in practices between labs to be considered.
Two workshops will be held: one to validate data and review the current model, and another to explore future changes. Next Steps: engage with StaffSide and labs to design the future service model.

6. Extract within scope of request only: Scottish Strategic Network for Genomic Medicine – Steering Group Minutes. 12th June 2025. Personnel names and email addresses redacted on grounds of personal data of a third party (38(1)(b)).

TOM Update

- Site visits completed in Dundee and Glasgow.
- Surveys issued to lab staff and clinical users:
  - 65 lab staff responses
  - 30 clinical user responses
- The first stakeholder workshop was held on the 14th May and a Short Life Working Group has been established to support co-design and data discussions.

Next steps

- Complete remaining site visits in Aberdeen and Edinburgh.
- Circulate outputs from workshop 1 for stakeholder review.
- Lab activity data collection to be finalised, with spreadsheets to be submitted to SSNGM by 20th June.
- Data analysis of surveys. Spreadsheets and benchmarking data to be completed.
- Workshop 2 is scheduled for 26th June in Edinburgh.

7. Extract within scope of request only: Scottish Strategic Network for Genomic Medicine meeting with Board Chief Executive core team. 3rd July 2025. Personnel names and email addresses redacted on grounds of personal data of a third party (38(1)(b)). Discussion redacted on grounds of free and frank discussion (30(b)(ii)).

TOM Update

[Director of NSD] sought support from the group to progress with a new TOM aimed at ensuring the financial sustainability of genomics services in Scotland. The model will be designed to optimise demand and create capacity for new and evolving genomic tests, which must be funded through efficiencies within the existing system. A key element of TOM will be the implementation of a single national data platform, particularly through the Laboratory Information Management System (LIMS), to support data storage and sharing. This will require investment. It was highlighted that recent workshops with stakeholders have shown growing consensus that a single management structure would help address inefficiencies. Consolidation of testing and reduction in estate assets are expected to also generate the savings required to support future service growth.

In 2024, the Transformation Team presented several options for the future configuration of Scotland's genomics laboratory estate to the SSNGM Oversight Board. Maintaining four independent laboratories was deemed financially unsustainable due to inconsistent processes, management structures, and laboratory information systems.

Three alternative models were proposed:

• Three-lab model: Estimated cost of £71 million over three years.
• Two-lab model: Estimated cost of £69 million.
• Single “super lab” model: Estimated cost of £60 million but ruled out due to significant operational risk (if the single lab experienced

8. Scottish Strategic Network for Genomic Medicine - Oversight Board 48 Hour Action Note. 15th July 2025. Personnel names and email addresses redacted on grounds of personal data of a third party (38(1)(b)).

SSNGM Oversight Board – 15th July 2025 Actions

Action Summary	Assigned	Due
Agenda Item 3- Cancer Research UK Update The update from Cancer Research UK was provided on the report that was published in 2024 regarding genomics and cancer. There was discussion on the disconnect between drug approval and test availability. It was highlighted that the companion tests are often not funded alongside new drugs which creates access delays. It was noted that moving to large cancer panels could help resolve this issue. The Horizon Scanning Advisory Board has been established to assess the full impact of new medicines, including testing requirements and service delivery needs. Suggestion to scope a national process for precision medicines to ensure companion tests and service implications are being considered.		
Action: Work with SMC to understand how costings for precision medicines companion test are factored into decision making and implications on service delivery.	TBC	
Agenda Item 4- UK Nation Strategic Update An update on UK National Strategic was presented. There was a question regarding access to the data and digital component of the tender specifications in NHS England. NW to follow up and clarify if this is available and can be shared. The suggestion for a strategic update on NHS Wales and Northern Ireland to be brought to the next Oversight Board meeting for broader comparison. The discussion whether the current level of genetic testing across the population is consistent enough to make comparisons and drive targets. Scope on population-level standards for genetic testing to allow for benchmarking and assessing compliance across regions was suggested.		
Action: NW to follow up the data and digital component of the tender specifications around the tendering process in NHS England.	NW	30/08/2025
Action: Strategic update on NHS Wales and Northern Ireland to be brought to a future Oversight Board meeting.	NW/HE	TBC

Agenda item 5- Scottish Government Update

Work is underway to adapt the NSD Prioritisation Framework for genomics, to help assess and prioritise genomic tests and associated funding needs. It was highlighted there is a requirement for a clear plan outlining the investment need based on the prioritisation of genomic services and includes alignment with NHS Board Chief Executives and NHS Directors of Finance.

Agenda item 6- Target Operating Model Update

The PgMS team will produce a report on the TOM work to-date by the end of July 2025. The report will make recommendations against the high-level TOM from November 2024.
The NHS England Demand Management paper will be circulated to members.
The importance of HR Director involvement in the development of the TOM was emphasised. NW/JJ to meet to discuss HR involvement further.
Benchmarking data between NHS Scotland, NHS England and NHS Wales was presented to the group. It was suggested the variance between the data to be explored further to inform how NHS Scotland can optimise capacity and manage the demand on the laboratories appropriately.

OB members were asked to approve the following recommendations:

- Move to a **National Population Level Planning** approach for the delivery of genomics laboratory services.

- From August 2025, propose to establish a **Task and Finish Group**.
- **Terms of reference** for this group will consider what are the genomics needs for the population of Scotland, and what can it afford.
- **Membership** – key stakeholders, executive management teams from the NHS boards, NSD National Planning Team.
- Remit is to review options and make clear recommendations for the future genomics laboratory delivery model by the end of **January 2026.**

Decision Made: The OB members agreed to move forward with the proposed recommendations for the delivery of genomic laboratory service.

Action: Share NHS England Demand Management paper to OB members.	SM	18/07/2025
Action: [redacted] to meet to discuss HR Director involvement with the development of the TOM.	SM	31/07/2025