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Innovation Value Proposition in Histopathology

Advancing diagnostic excellence through innovation

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Liverpool Clinical Laboratories

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One of the largest providers of pathology services within North-West of England
Serving a population of ~2.3m people

Cellular Pathology is the highest throughput single centre site

- Histopathology - 70,000 cases/year, 200,000 blocks, 330,000 slides
- Non-gynaecological cytology – 5,000 cases/year
- Immunohistochemistry – 150,000 slides/year
- Molecular Pathology – 4,000 cases/year
- Ophthalmic Pathology – 1,200 cases/year (1 of 4 in England)

- Mortuary – 400 autopsies
- Forensic Pathology (1 of 4 training schools in the UK)
- Bereavement service
- Regional Medical Examiners service

National Strategic Context

Histopathology is essential for supporting delivery of key UK ambitions, including the NHS Long Term Plan, Faster Diagnosis Standards, NHS Genomic Medicine Service, Genome UK, The Life Sciences Vision and the NHS Genomics Strategy. This includes delivery against these shared ambitions:

- 55,000 more people each year will survive their cancer for at least five years after diagnosis.
- 75% of cancer patients will be diagnosed at an early stage.
- Delivery of the 28- and 62-day pathway targets
- Offer genomic testing routinely to all people with cancer
- Provide patients an opportunity to participate in research
- To accelerate the development of cancer vaccines
- To create the most advanced and integrated genomic research healthcare ecosystem in the world
- To use data to drive the next generation of Life Sciences discoveries

Histopathology Services – Need for Innovation

- Pathology services are fundamental to the provision of healthcare with an estimated 95% of all decision making that affect diagnosis or treatment involving a pathology investigation.

- Annually c.23 million histopathology slides are produced and reviewed

- Histopathology is
  - A core diagnostic service, central to several patient pathways and critical to almost all cancer pathways
  - Essential for achieving the aspirations of the Faster Diagnosis Standard
  - Essential for achieving the Long Term Plan commitment to reduce unwarranted variation in access to high quality pathology services
  - Increasingly becoming more complex, requiring specialist multidisciplinary approaches
  - Experiencing increased demand above capacity across both laboratory processing and clinical reporting, resulting in backlogs and worsening turnaround time performance

In 2023/24, histopathology services received c.3.7 million cases, of which only **54% were reported within 10 days.**

This means that over **1.7 million cases waited** more than 10 days for a report, **of which 337 thousand cases were cancer or suspected cancer.**

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Histopathology Services – National Picture

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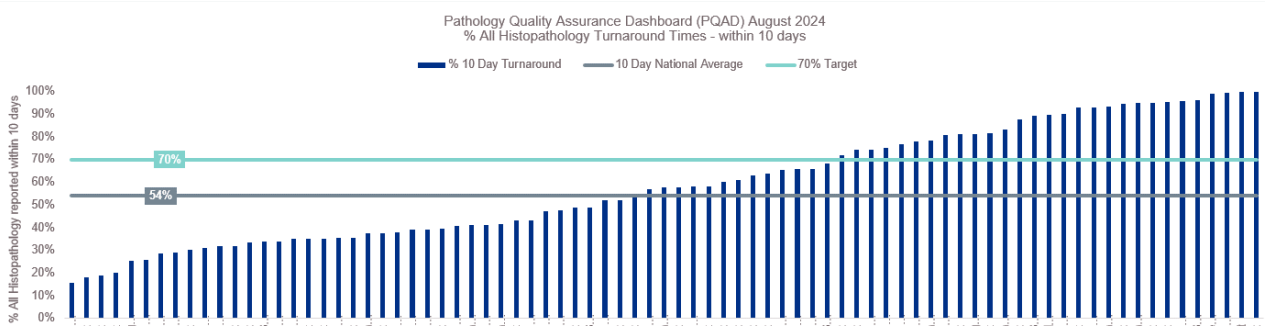
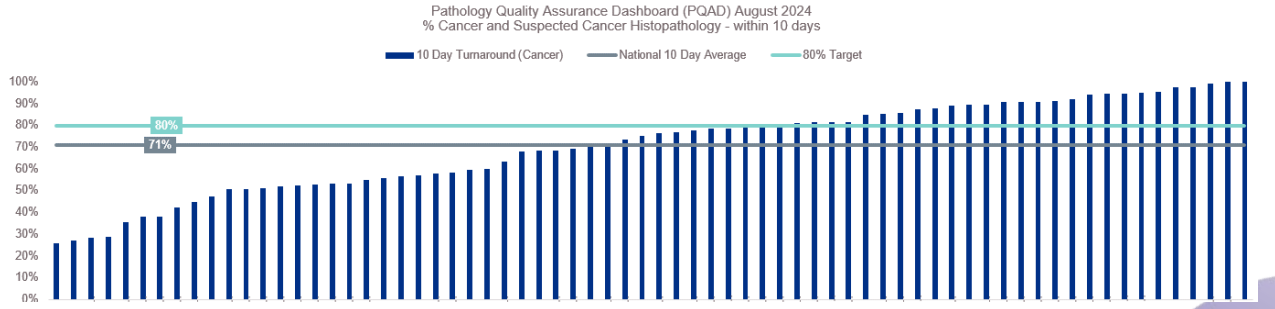
Summary of Histopathology Performance in **August 2024**, using laboratory and reporting turnaround times as a primary indicator:

Reporting Month >	Mar-24	Apr-24	May-24	Jun-24	Jul-24	Aug-24*
Percentage of histopathology cases reported within 10 days						
% of All histopathology reported within 10-days (Inc. Cancer)	55%	53%	56%	56%	55%	55%
➢ % of non-cancer Histopathology reported within 10 days	49%	47%	52%	50%	48%	48%
➢ % of Cancer or Suspected Cancer Histopathology reported within 10-days	68%	66%	66%	69%	71%	71%
Number of Histopathology Cases waiting more than 10 days for report (000s)						
Number of all histopathology cases waiting more than 10 days for report (000s)	124148	130118	129624	123998	129810	102062
➢ Of which, number of **non-cancer** cases waiting more than 10 days for report (000s)	97585	100154	98731	97620	103661	82645
➢ Of which, the number of **cancer cases** waiting more than 10 days for a report (000s)	26563	29964	30893	26378	26149	19417
*% Data Completeness**	76%	74%	79%	78%	74%	60%

To note: 'All histopathology' includes cancer and suspected cancer histopathology. It is vital that turnaround times across all histopathology cases improve, as cancer and other clinically urgent conditions can be diagnosed in cases received outside of cancer pathways. From Aug 24, 'Zero' returned will be included within missing submissions.





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What is Innovation in Histopathology?

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- Application of new technology, methods and workflows in order to enhance services

Six-Point Histopathology Improvement Plan

1 Workforce
Network histopathology workforce strategy (train, retain and reform)

Thinking differently about skill mix and working to the top of competency

Integration and expansion of Advance Practice

2 Process Optimisation
Data-driven optimisation of functional laboratory capacity through review of workflow processes

Identify and address unwarranted variation in performance and quality

3 Estate and equipment upgrades
Encourage local investment to locate histopathology laboratories in suitable estate.

Estate in many services is a physical barrier to embedding optimised workflows and automation.

Six Point Histopathology Improvement Plan

6 Automation
Integrated laboratory automation enhances the efficiency and throughput of pathology services, delivering faster test results and improved patient pathways.

The reduction of manual, repetitive, time-consuming processes in favour of progressing scientific and service innovation also helps to attract/retain workforce.

5 Digital Pathology
Enhance collaboration between pathologists allowing better use of capacity across a network.

Digital pathology also readies histopathology services for AI as the technology rapidly advances.

The benefits of extended and flexible working can be further realised through the implementation of home reporting.

4 Service Consolidation
One of the benefits of consolidating pathology services into 27 networks, there are opportunities to consolidate several of the smaller labs within each network either physically or functionally, to leverage economies of scale to best effect.

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Value proposition in Histopathology

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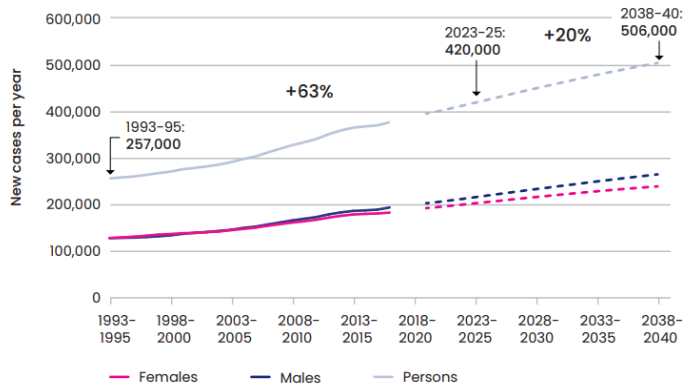
What is the problem or unmet need?

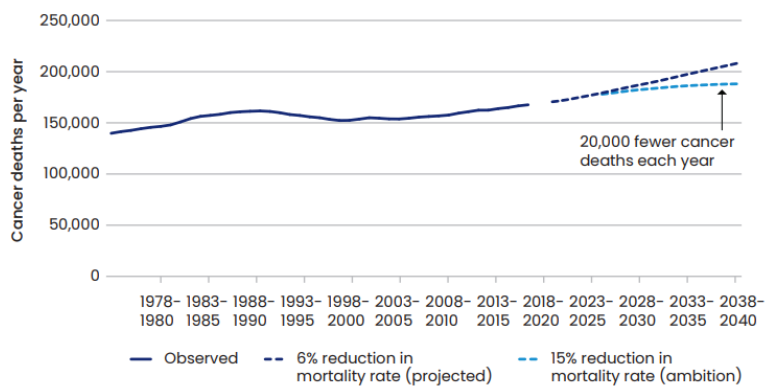
What are the consequences of the problem?

- 1 in 2 will be diagnosed with cancer
- Cancer is the UKs biggest killer
- Population growth and ageing mean absolute deaths could increase by 20%
- Rate of survival improvement has slowed
- Survival in the UK is lagging behind comparable countries

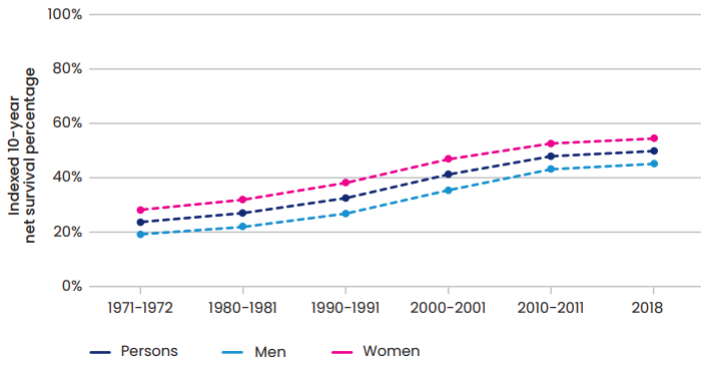
Cancer incidence in the UK projected to 2038–2040



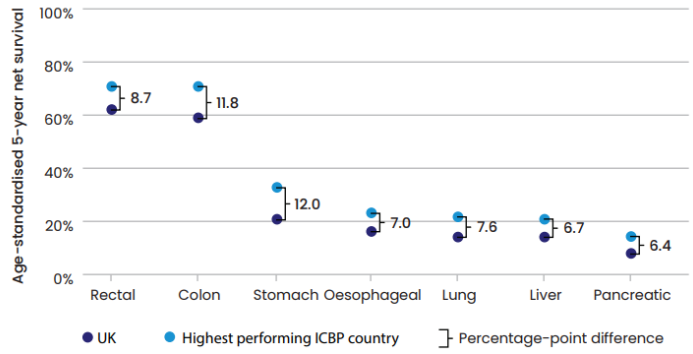
Cancer mortality in the UK projected to 2038–2040



Trends in the index of 10-year survival for all cancers combined, adults, England and Wales, 1971–2018



Differences in 5-year net survival between the UK and the highest performing International Cancer Benchmarking Partnership countries, 2010–2014



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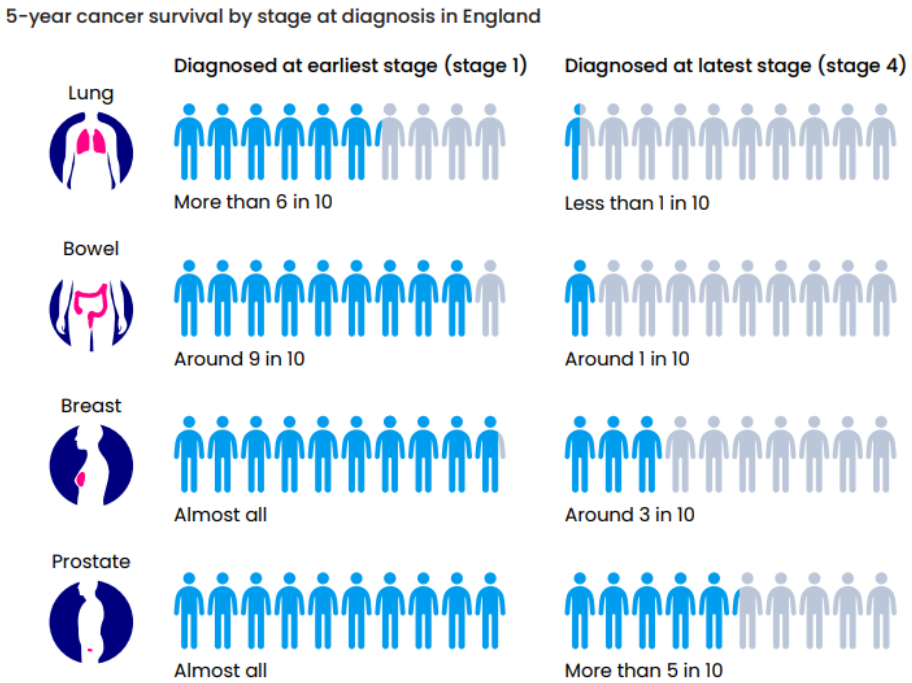
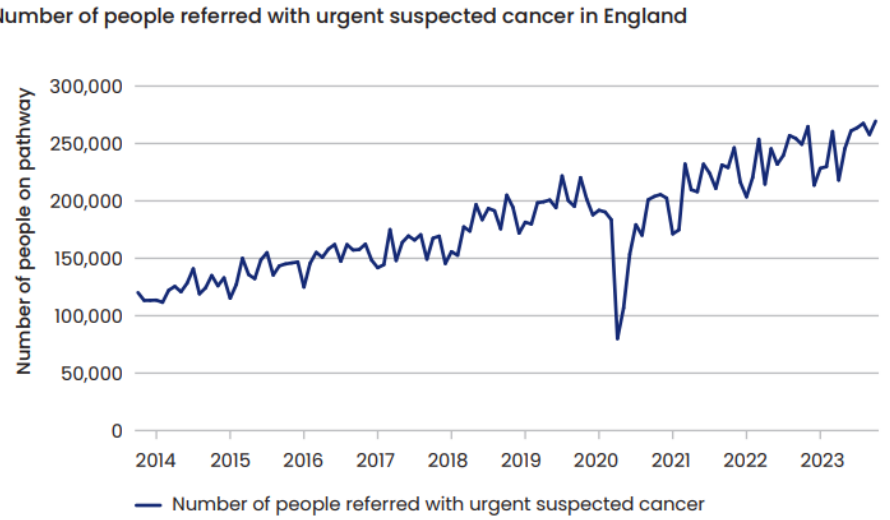
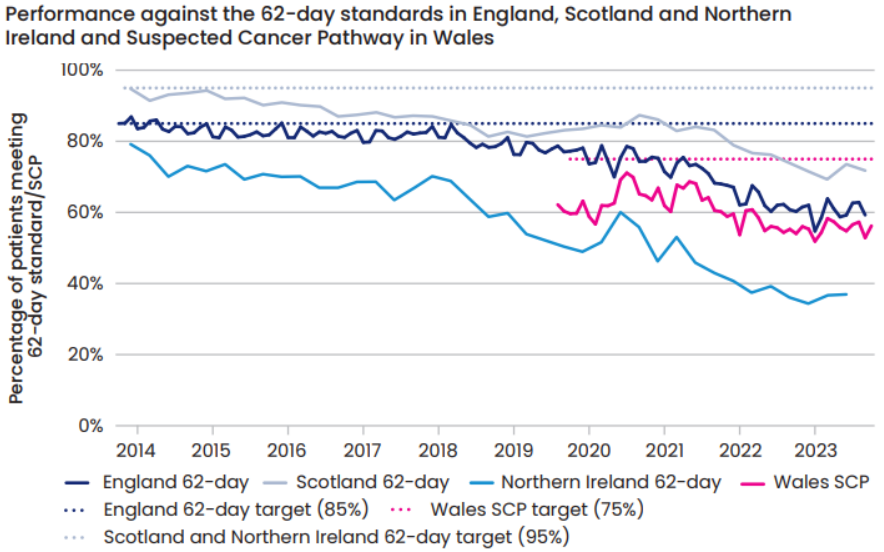
What is the problem or unmet need?

What are the consequences of the problem?







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Value proposition in Histopathology

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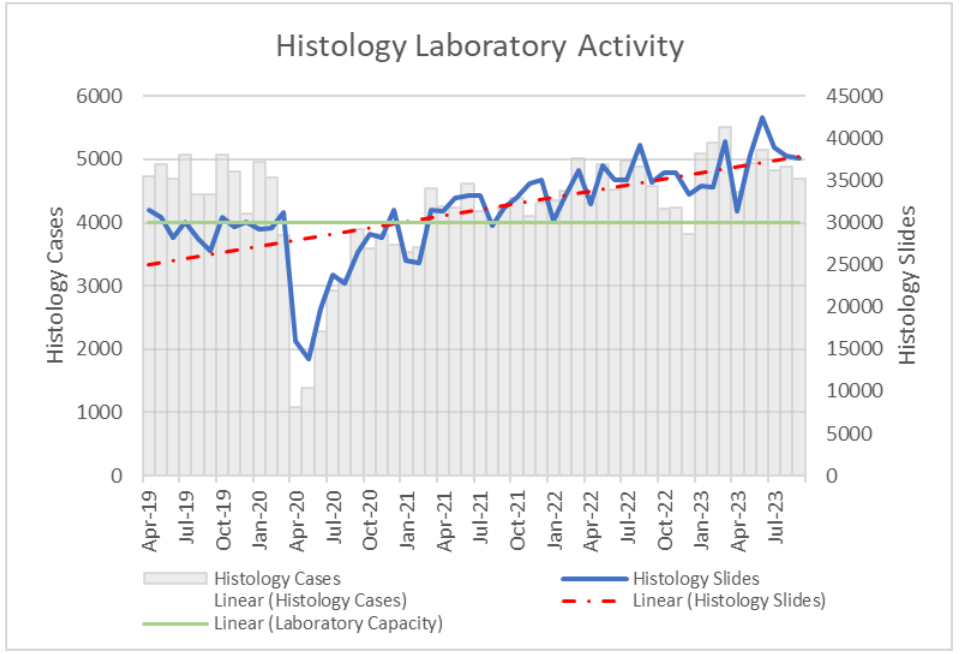
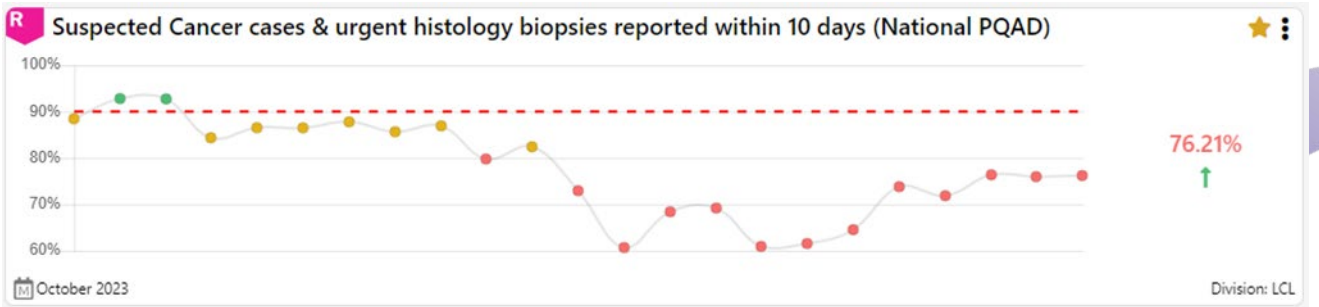
What is the problem or unmet need?

What are the consequences of the problem?

- Current demand outstripping capacity and workload patterns with year-on-year increases
- Difficulties in recruitment and retention and opportunities for workforce change
- Significant risk of staff burnout associated with overtime
- Succession planning (6 consultant pathologists anticipated to retire in next 5 years)
- Estate/ventilation issues since move to CSSB November 2022
- Poor morale as evidenced by staff survey and GMC survey results
- Aging equipment which requires replacing and access to automation opportunities



Risk ID	Description	Initial Score	Current Score
6351	Increased medical reporting workload will be unsustainable	10	10
7628	Failure to meet cytopathology turnaround time assurance	11	9
9578	Number of dissection benches is insufficient to deliver workload requirement	12	9
7562	Risk of failing to meet diagnostic pathology requirements of NHS Faster Diagnosis Standard	14	11
7501	Non-core cost pressure associated with locums and outsourcing to maintain clinically relevant turnaround times	11	10
7323	Risk to staff health and safety and mental wellbeing due to equipment failure and environmental conditions	12	10
7098	Delay of results and reduced turnaround time compliance for cancer patients	13	9
6969	Increased demand on histology laboratory service above operational capacity	11	10
6904	Failure to deliver regional gynaecological pathology service	11	8
7207	Failure to deliver regional musculoskeletal pathology service	11	7



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Technological Innovation Driving Value

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Alignment against NHSE six-point improvement plant

1. **Workforce** ✓ – Ensures investment in training and advanced practice within the scientific workforce. Enabling improvements in medical training to be made by increasing the capacity of the consultant workforce. Comprehensive workforce plan to address the capacity deficit.

2. **Optimisation** ✓ – Optimisation of processes through automation to enable timely diagnosis, maximising capacity, addressing unwarranted variation, and ensuring patients have equity of access to a high-quality histopathology in line with GIRFT principles. Reduces non-core expenditure.

3. **Estate and Equipment upgrades** ✓ – Invests in estate and equipment upgrades. Investment in novel, innovative automation to refresh ageing equipment.

4. **Laboratory consolidation** ✓ – Maximises the potential for Cheshire and Merseyside system working and laboratory consolidation through installation of high-throughput laboratory automation.

5. **Automation** ✓ – Only option that involves investment in world class high-throughput automation innovation.

6. **Faster Diagnosis Standard** ✓ – Enables delivery against 98% in 10-day ambition. Improves system 28-day and 62-day pathway compliance

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Histology performance improvement roadmap

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Q1 2024

Invest in:

- Laboratory staffing
- 3 Consultant Pathologist roles
- 3 Trainee Consultant Scientists (Annex 21)
- Undertake enabling capital works
- Procure laboratory automation

Q3 2024

- Investment will enable **delivery of 80% 10-day turnaround target**
- Associated impact to overall Trust and **system 28-day pathway compliance**
- Laboratory automation fully embedded within workflow

Q2 2025

- Automation and new clinical staff fully embedded
- 3 remaining Consultant Pathologist roles recruited to
- **Delivery against 98% 10-day turnaround time ambition**

Q4 2025

- Additional capacity starts to benefit C&M system histopathology delivery

2026/27

- **Continued delivery against 98% 10-day ambition across all clinical specialties**
- Progression of Scientific reporting (Annex 21)
- **Consistent 28-day compliance across C&M system associated with automated and fully staffed histopathology service**

2028

- Completion of Consultant Scientific reporting training
- Continue to implement novel innovations
- **Robust clinical service in place delivering world class histopathology service for C&M patients**

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LCL case study utilising Axlab AS410M automated microtomes

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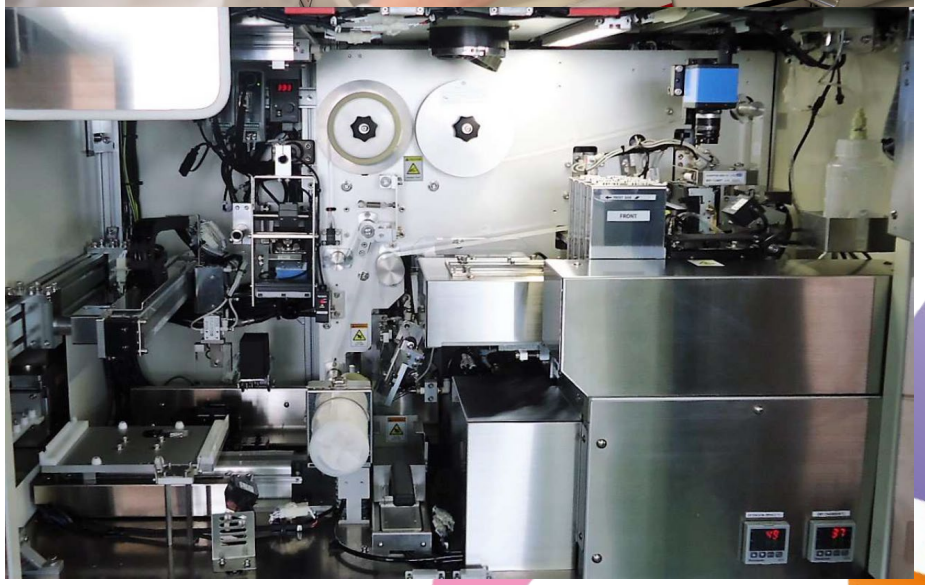
AS410M automated microtomy

- Standardized high section quality perfect for digital scanning
- Standardized placement of sections
- Sectioning performed all day & during night
- No patient mix ups
- Preventing bottlenecks in pathology laboratories
- 2D – barcode scanner(data matrix and QR-code)
- 4 surface detecting springe sensors
- Block surface temperature detected and controlled (c.17^{o}C)
- Humidifies block surface
- Section thickness: 3～10μm
- Vacuuming of remaining debris
- Print unit
- Blade mark check for visualizing section quality
- Auto trimming unit



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AS410M automated microtomy

- Might not be as fast as skilled AP/BMS
  - Can you find and retain skilled workforce at Band 4 level to keep up with demand? Difficult
  - Should Band 6+ being undertaking microtomy to backfill? No
  - Should we be paying Band 6 locum rates for microtomy? No
  - Will only do what you tell it to do.
  - Won't mix up blocks/slides.
  - Won't cut itself/get RSI/take 2-hour lunch breaks/complain
- Does churn away in the background, removing 'boring' manual work
- Does enable staff to work at the top of their grade, increasing morale and retention
- Does enable assessment of section quality prior to staining, reducing re-cuts
- Does work overnight – up to 188 blocks pre-loaded, or up to 800 control slides
- Could further increase throughput by extending working day to 16 hours (theoretical daily capacity over 2 instruments – 960 blocks)

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AS410M automated microtomy

Aim

- The 2x Axlab AS410M microtomes will be initially used for resection cases.
- Once fully operational can section up to **576 blocks per day**.
- Reduce the daily backlog of blocks and free staff time from manual microtomy in order to be redeployed to other areas of the laboratory, or focus on training, education and quality.
- Improve 7-day & 10-day TAT, seek to improve 28-day, and regional 62-day pathway performance (reduce histology associated breaches)

First stage of validation (April/May)

- 240 control blocks across 12 different tissue types (GB, appendix, liver, lung, uterus, LLETZ, kidney, prostate, skin, breast, GI resections & post mortem)
- Blocks were sectioned at varying thickness (3-5µm) and the stained slides scored by a pathologist.

Second stage of validation (May/June)

- Further 12 blocks being sectioned of each tissue type at the previously determined optimum section thickness.
- Scored by the pathologists and all sections were deemed an appropriate level of quality to pass.

Third stage of validation (June)

- Comparison of 10 patient cases cut both manually and on the AS410M
- Pathologist assessment with ‘pass’ determined as equivalent or better section quality to manual

Go live

- 17th June 2024

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Measuring success in Innovation

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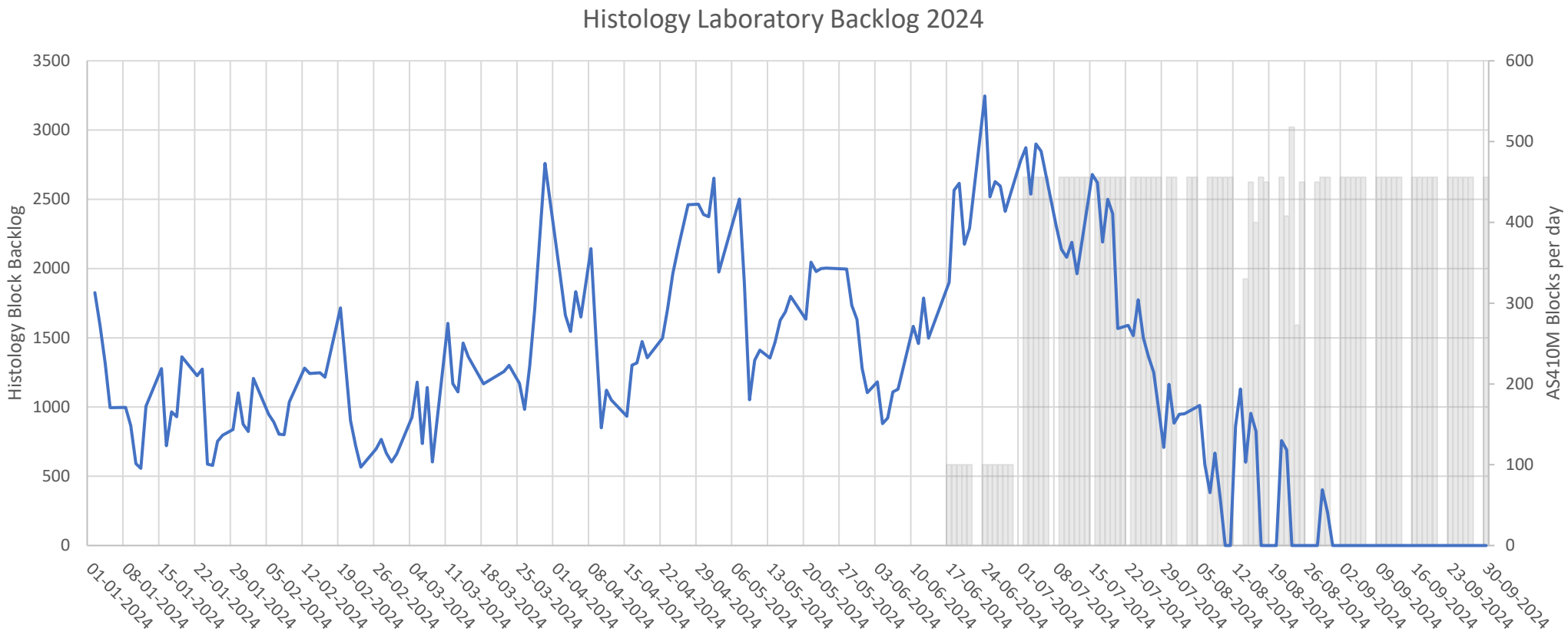

30,821 blocks cut since 17th June

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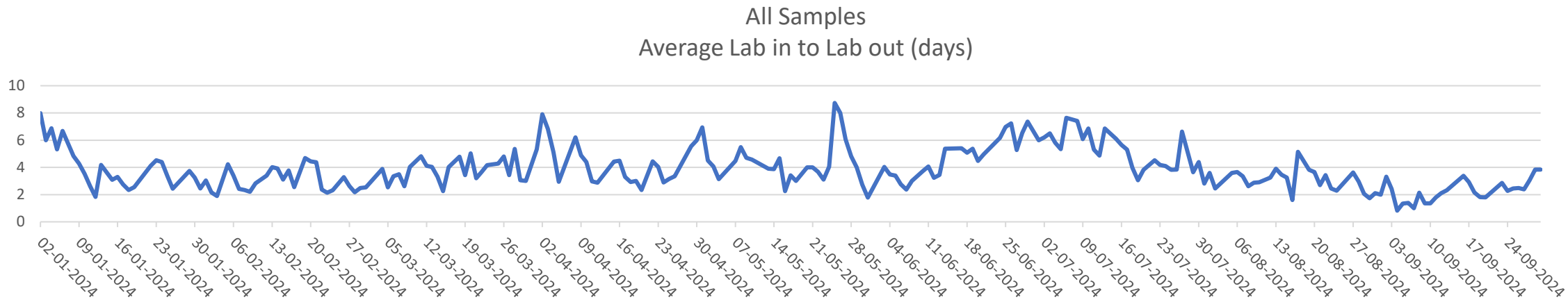

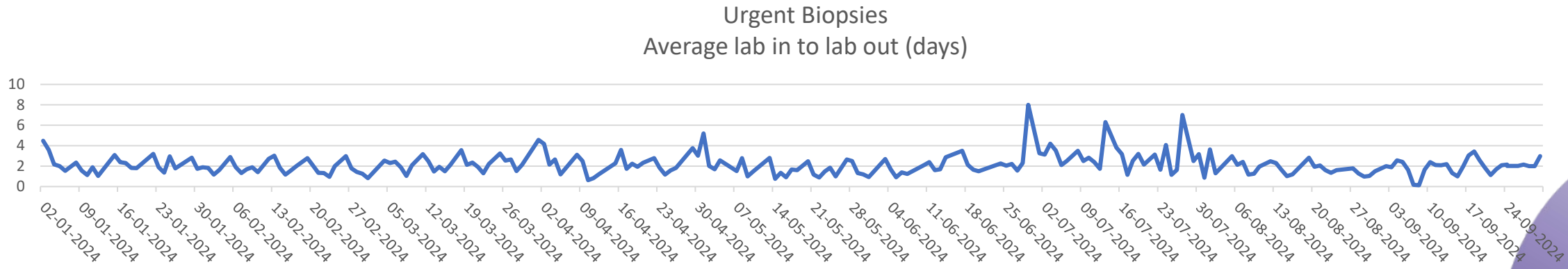

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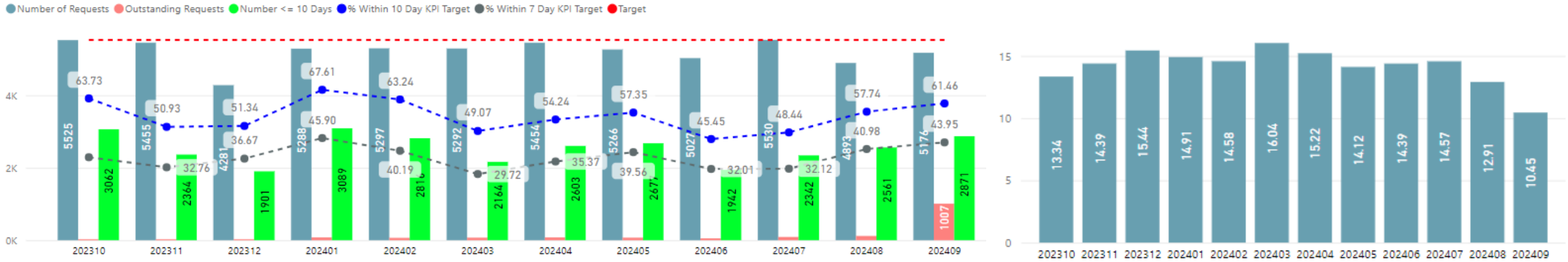
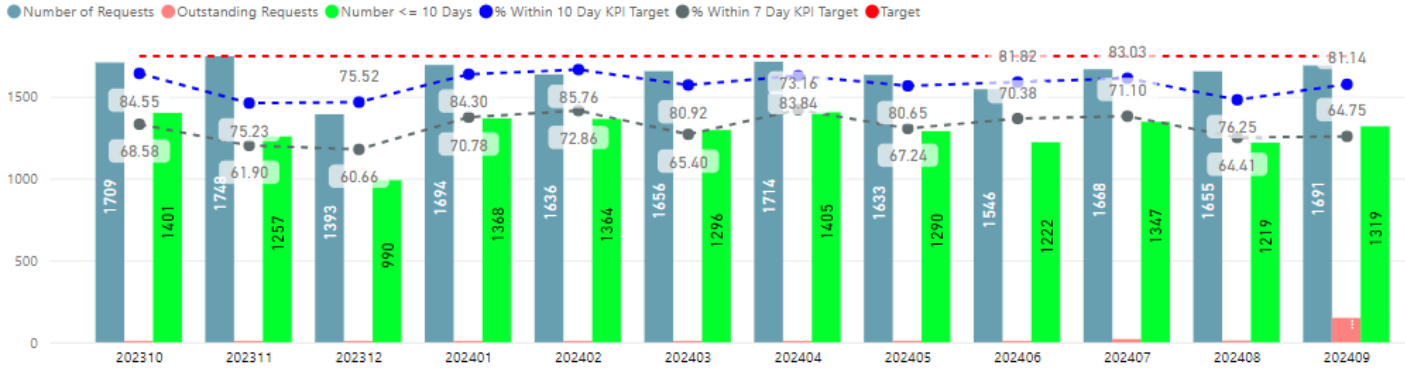
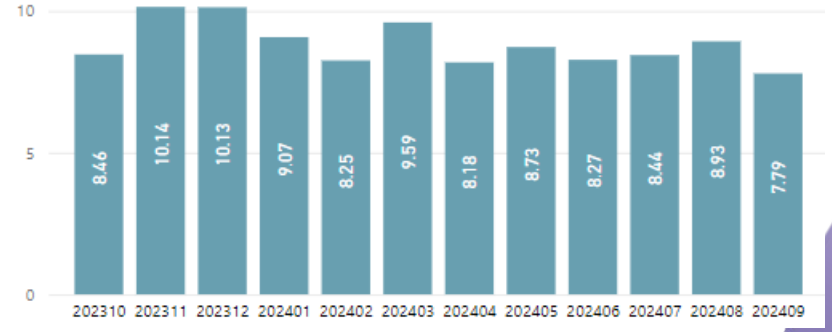
All samples 10-day turnaround time performance



Urgent biopsies10-day turnaround time performance





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Addressing barriers to Innovation

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Challenges

- Funding constraints
- Resistance to change
- Training requirements
- IT integration
- Estates and facilities

Solutions

- Revenue + Capital models, business cases ready to go, senior management/executive/ICB engagement
- Robust staff engagement and training programmes
- Strong integration strategy, understand limitations and how to overcome them
- Robust estates plan with appropriate engagement with senior estates colleagues

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Innovating for the Future of Histopathology

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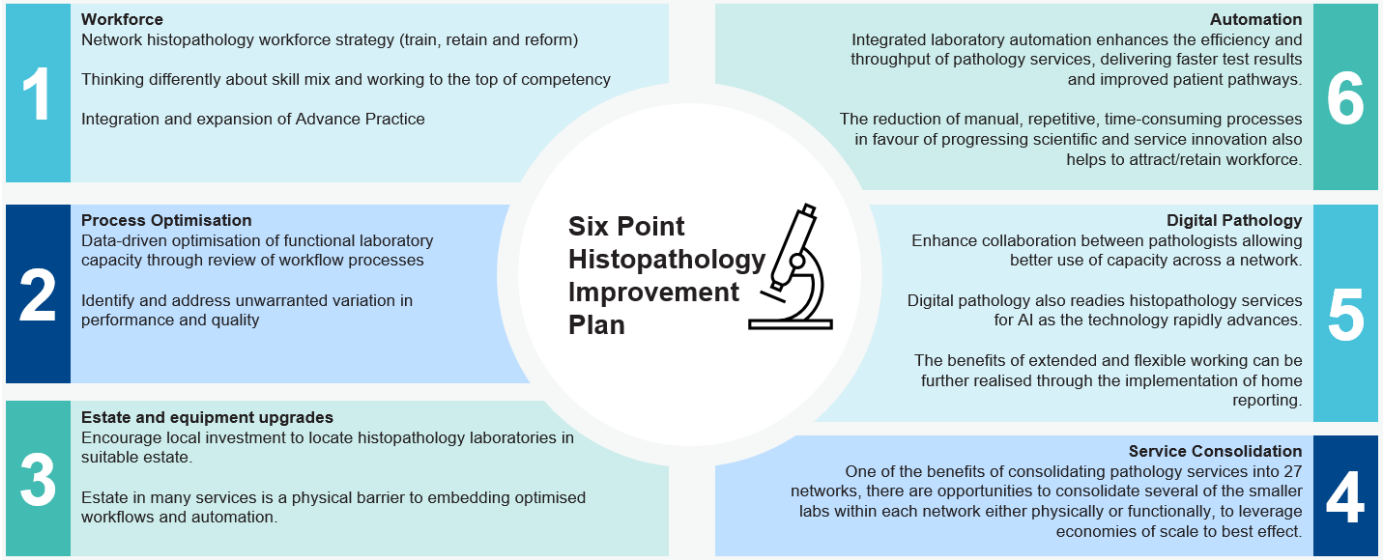
Adopting strategic innovation approaches in histopathology will enable

- Improvements to patient care
- Histopathology performance improvements (10-day, FDS best practice timed pathways)
- System performance improvements against 28-day, 62-day pathway targets & biopsy to genomic results pathways
- Deliver succession planning and address workforce challenges
- Delivery against national strategic ambitions

Six-Point Histopathology Improvement Plan



Strategic ambitions:

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- 75% of cancer patients will be diagnosed at an early stage.
- Delivery of the 28- and 62-day pathway targets
- Offer genomic testing routinely to all people with cancer
- Provide patients an opportunity to participate in research
- To accelerate the development of cancer vaccines
- To create the most advanced and integrated genomic research healthcare ecosystem in the world
- To use data to drive the next generation of Life Sciences discoveries

Acknowledgements

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