Business Justification Case for National Digital Cellular Pathology Project Phase 3 –

National Scale Up

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1 Executive Summary

Introduction

It is now clear that digitisation of cellular pathology services is realistically the only option to enable delivery of a robust and sustainable diagnostic cellular pathology service fit for the future. The national move towards scanning of histological material for primary diagnosis and more recently, the adoption of artificial intelligence (AI)/computational pathology to improve the accuracy, reliability and quality of reports, means that most Pathologists, especially new trainees who are already using digital technology, will, in the future, choose to work in departments where digital technology will enhance and underpin their diagnosis thus benefiting the quality of patient care.

The last four years have posed significant challenges to the NHS and the cellular pathology service generally. In particular, it is becoming increasingly difficult to attract and retain suitably skilled professionals and demand is growing, both in terms of volume and the complexity of cases. The impact of the pandemic has resulted in a growing backlog of activity. These factors combined have created a capacity gap and the service urgently needs mitigations to address this and to ensure it is fit for the future.

In addition, Wales are at real risk of falling behind the rest of the UK. Northern Ireland have a fully digitised cellular pathology service and Scotland are almost fully digital. In England, the practice is building up of digital networks. For example, Nottingham, Leeds and surrounding (NPIC), and PathLink (pathlake) Midlands, Norwich area are all fully digital and almost every network is at various stages of deployment.

As clinical and service leads for cellular pathology across Wales, we are therefore requesting your support to procure the most suitable equipment which will help us mitigate these challenges and ensure we provide a high quality and reliable cellular pathology service for Wales.

The purpose of this Business Justification Case (BJC) is to set out the proposals for Phase 3 of the National Digital Cellular Pathology (NDCP) Project. This will build upon the previous work, where investment in infrastructure and staffing has allowed us to evidence proof of concept, most recently identifying the opportunities and benefits of AI & computational pathology.

We can only progress this and fully understand and realise the related benefits by providing further digital enablement allowing cellular pathology services to digitise services as completely as possible. National Scale Up (to enable full digital reporting) will require investment in scanning and reporting hardware, a laboratory management software system, digital image storage and staff resource.

This document seeks approval to undertake full procurement of the new solution and commitment to provide the following funding:

- **Non-recurring revenue funding of £423,000 requested from Health Boards (£71,000 per HB)** for the implementation costs associated with the project team and DHCW support between 2025/26 – 2027/28.

- **Ongoing revenue funding which in total equates to £34.4m between 2025/26 – 2034/35 requested from Health Boards,** related to annual recurring revenue costs associated with the managed service contract for the solution and additional staff required to support Health Boards with the implementation and ongoing management of the solution.

Table 1 Indicative Revenue Costings

	Year 0	Year 1	Year 2	Year 3	Year 4	Year 5	Year 6	Year 7	Year 8	Year 9	
	2025/26 £'000	2026/27 £'000	2027/28 £'000	2028/29 £'000	2029/30 £'000	2030/31 £'000	2031/32 £'000	2032/33 £'000	2033/34 £'000	2034/35 £'000	Total £'000
Project Team (non-recurring)	101	101	50								251
DHCW Support (non recurring)	34	34	34								101
20% Contingency	27	27	17								71
Non-recurring revenue costs	**161**	**161**	**101**	-	-	-	-	-	-	-	**423**
Project Team (recurring - contract manager)	57	57	57	57	57	57	57	57	57	57	574
Solution Costs (recurring)	28	3,336	3,103	3,172	3,251	3,333	3,418	3,493	2,525	2,525	28,184
Health Board Additional Staff (recurring)	263	525	525	491	491	491	491	491	491	491	4,749
DHCW Support (recurring)	86	86	86	86	86	86	86	86	86	86	864
Recurring revenue costs	**434**	**4,005**	**3,772**	**3,807**	**3,886**	**3,967**	**4,053**	**4,127**	**3,160**	**3,160**	**34,371**
Total costs	**595**	**4,167**	**3,873**	**3,807**	**3,886**	**3,967**	**4,053**	**4,127**	**3,160**	**3,160**	**34,795**

		Year 0	Year 1	Year 2	Year 3	Year 4	Year 5	Year 6	Year 7	Year 8	Year 9	
	Apportionment	2025/26 £'000	2026/27 £'000	2027/28 £'000	2028/29 £'000	2029/30 £'000	2030/31 £'000	2031/32 £'000	2032/33 £'000	2033/34 £'000	2034/35 £'000	Total £'000
ABUHB	16.32%	72	656	618	623	636	650	664	676	518	518	5,631
BCUHB	17.18%	72	685	645	651	664	678	693	706	540	540	5,874
CTMUHB	11.42%	71	493	466	468	477	487	496	505	394	394	4,251
CVUHB	24.53%	75	930	873	884	903	923	944	963	725	725	7,945
HDUHB	12.96%	71	544	514	517	527	538	549	558	433	433	4,684
SBUHB	17.58%	73	698	657	663	677	692	707	720	550	550	5,986
Total Recurring Revenue Costs	**100.00%**	**434**	**4,005**	**3,772**	**3,807**	**3,886**	**3,967**	**4,053**	**4,127**	**3,160**	**3,160**	**34,371**

	Year 0	Year 1	Year 2	Year 3	Year 4	Year 5	Year 6	Year 7	Year 8	Year 9	
	2025/26 £'000	2026/27 £'000	2027/28 £'000	2028/29 £'000	2029/30 £'000	2030/31 £'000	2031/32 £'000	2032/33 £'000	2033/34 £'000	2034/35 £'000	Total £'000
ABUHB	27	27	17								71
BCUHB	27	27	17								71
CTMUHB	27	27	17								71
CVUHB	27	27	17								71
HDUHB	27	27	17								71
SBUHB	27	27	17								71
Total Non-Recurring Revenue Costs	**161**	**161**	**101**	-	-	-	-	-			**423**

This investment will deliver a wide range of benefits *(please see page 51),* most critically the ability of the service to keep pace with the rest of the UK and enable it to attract and retain the highly skilled staff required to address the growing capacity gaps within the service.

While many of the benefits related to this investment are not easily quantifiable in monetary terms, service leads at each of the Health Boards have identified a range of productivity gains as a result of a more streamlined workflow which will reduce the time currently spent on existing manual processes. A prudent assessment of the total number of hours saved across Wales equates to around £750k of staff time saved each year which can be re-directed to deal with growing demand.

As demand continues to grow in the future, the value of these productivity gains will be even greater and combined with greater ability to attract and retain workforce will increase internal capacity. It is estimated that almost £4million was spent on outsourcing for 23/24 (an increase from £1.2million that was reported in previous version of the BJC). While investment in digital cellular pathology will not necessarily reduce this, as there are multiple factors influencing this expenditure, it will help reduce the risk of increased activity needing to be outsourced to external providers, or covered by expensive temporary staffing, in the future, and the risk of this expenditure increasing in line with growing demand.

In addition to this, realisation of the substantial wider system benefits offered by AI/computational pathology, will only be possible following investment in the digital cellular pathology solution.

STRATEGIC CASE

Strategic Context

There is no single pathology service across Wales. Services are delivered through the six University Health Boards (UHBs) and Trusts (N.B. Powys Teaching Health Board has no district general hospitals or associated pathology services therefore pathology services are provided by neighbouring UHBs and Trusts). Pathology services in Wales are being developed in line with the vision set out in the Pathology Statement of Intent 2019 and, more recently, the Diagnostics Recovery and Transformation Strategy for Wales 2023-25.' The National Pathology Programme has been established to deliver these aims and is managed by the NHS Wales Executive (formerly NHS Wales Health Collaborative).

Working as part of the wider National Pathology Programme, the NDCP Project was set up to capitalise on a previous investment to modernise Cellular Pathology services at Betsi Cadwaladr University Health Board (BCUHB). The aim of the NDCP Project is to scale up and digitise cellular pathology services as completely as possible for the whole of Wales.

Digital pathology is critical to the ongoing development of an efficient, effective and optimal pathology service that contributes to the delivery of the current national strategy. Crucially, the NDCP Project will support delivery of the **NHS Planning Framework 2023-2026** which builds on learning from the pandemic and sets out Ministerial priorities for the recovery and sustainability of health services. It is similarly aligned with the **Diagnostics Recovery and Transformation Strategy for Wales 2023-25**, published in April 2023, which outlines plans to recover diagnostic services by 2025, addressing the impact of the pandemic, and sets the groundwork for longer term sustainability. This is because the NDCP Project will:

- Provide opportunities to create additional diagnostic capacity to support the National Recovery Programme, a key priority of all Health Boards, which will help reduce the numbers of people waiting for diagnostic tests.
- Provide opportunities to reduce reporting time which will contribute to the achievement of national cancer pathway targets and reduce the backlog of patients waiting too long on their cancer pathway.
- Enable the workforce to operate across boundaries, reducing inequality of access and reducing the pressure on the wider system.
- Utilise digital technology to enable the service to deploy existing and future workforce to best effect, including supporting multidisciplinary teamworking and advanced practice models, while enabling people to develop their careers and work at the top of their license. It will also provide greater opportunities to support hybrid working and 'reporting from home'.
- Ensure that digital, innovation, technology and transformation underpins plans to deliver optimum care and services for patients. The resulting digital solution will provide more opportunities to work with others in line with NHS Wales' approach to innovation. In particular, this will:
    - Enable investment and support for national diagnostic programmes in endoscopy, pathology, genomics, and imaging.
    - Provide opportunities to adopt innovative digital technology solutions including AI/computational pathology.

In supporting the key strategies, the NDCP Project aligns with a number of other national strategies, including *(for more details please refer to page 26)*:

- Review of Histopathology Services in Wales (2010)
- National Clinical Framework: A learning health and care system (2021)
- The Parliamentary Review of Health and Social Care in Wales. Final Report. (January 2018)
- A Healthier Wales: Our Plan for Health and Social Care (June 2018)
- The Wellbeing of Future Generations (Wales) Act (2015)
- Prudent Healthcare: Securing Health and Well-Being for Future Generations
- Welsh Government's Digital Strategy for Wales (2021)
- Welsh Government's Digital and Data Strategy for Health and Social Care in Wales (2023)

It should be noted that the NDCP Project is critical to Pathology's ability to support ongoing NHS Wales activities and current and future initiatives. In particular, this includes:

- Supporting the elective pathway and enabling NHS Wales to deliver on the associated Recovery Plan depends on the service's capacity to meet target turnaround times
- Supporting public health initiatives such as screening programmes and the cancer pathway, depends on the service's ability to meet target turnaround times
- Genomics pathway – histological identification and classification of a tumour by histopathologists is paramount in delivering a precise and accurate genomic profile
- R&D – pathology has steadily expanded its role in tumour diagnostics and beyond from disease entity identification via prognosis estimation to precision therapy prediction. Recent applications for the analysis of molecular profiling data from different sources and clinical data support the notion that AI/computational pathology will enhance both histopathology and molecular pathology in the future
- Developing the role of advanced practitioners requires input from pathologists, which a digital cellular pathology solution could support
- Supporting the development of regional diagnostic hubs depends on the service capacity to deliver on turnaround times and having the appropriate infrastructure in place to support regional working. It is essential that we have an integrated and standardised cellular pathology service for Wales to provide a robust and reliable service for the future
- Ongoing transformation initiatives such as regionalisation and a 'Centre of Excellence' as outlined below
- Recruitment will be very challenging if Wales is not utilising digital technology within the next few years. Many cellular pathology national quality assurance schemes are already using digital technology. Within the next few years, it is anticipated that the RCPath exam for Consultant Histopathologists will be based on digital technology rather than glass slides
- Allowing working from anywhere in the UK which allows greater potential for working when convenient (potential additional hours worked) and would allow for collaboration

There are two ongoing regionalisation pieces of work, both require digital cellular pathology as key enablers. The ARCH (A Regional Collaboration for Health) Project in South West Wales plans to merge the departments in Hywel Dda and Swansea Bay University Health Boards into a single managed network. The South East looks to do the same with a similar project bringing together the cellular pathology services from Cwm Taf Morgannwg, Cardiff and Vale and Aneurin Bevan University Health Boards. Both will require digital pathology to be able to report cases from any laboratory by the combined reporting capability in the network. Digital pathology has proved a key facilitator in the successful regionalisation of cellular pathology services in BCUHB.

Genomics Partnership Wales, All Wales Medical Genomics Service, Pathogen Genomics Unit (PenGU), Wales Gene Park and Public Health Genomics Programme, have moved to a bespoke modern facility at Cardiff Edge Science Park, Coryton. Co-localisation with cellular pathology will create a 'Centre of Excellence' that will be of benefit to patients by making progress in terms of precision medicine as well as creating a bioscience park that will be of huge benefit in terms of recruitment and retention as well as future collaborative work with university and third sector companies. This requires a digital pathology service to fully realise the benefits.

Spending Objectives

The following spending objectives and associated benefits have been identified based on the aims of the overall NDCP Project and specifically the goals of Phase 3 which are informed by the strategic context.

Table 2 Spending Objectives

SO1	Build a standardised, robust and sustainable cellular pathology service for the whole of Wales
SO2	Introduce national scanning equipment with the capability to fully digitise cellular pathology service for Wales with a footprint that allows for service increase over the next seven years
SO3	Fully integrate with both the current All Wales Laboratory Information Management System (LIMS) and its successor
SO4	Enable reporting and review of any case from any location, using any device.
SO5	Enable rapid, specialist, second opinion both internal and external to Wales
SO6	Enable the routine use of Artificial Intelligence, Machine Learning and Deep Learning to enhance diagnosis, teaching and research
SO7	Build stronger relationships between NHS, Academia and Commercial Partnerships

Existing Arrangements

Cellular pathology services in Wales processed more than 1 million slides in 2022/2023, with actual and forecast growth suggesting that by 2025/26 the service will be processing approximately 1.5 million slides.

The forecast growth in activity is compounded by the increasing complexity of the workload along with an increasing proportion of urgent specimens being processed and the number of tests per specimens generally increasing. As a result, turnaround times are slower and there are increasing backlogs of cases in all

Health Board areas. Services face increasing challenges in achieving target turnaround times of 7 days for Urgent Suspected Cancer (USC), 14 days for urgent and 28 days for routine specimens.

Increased turnaround times have a significant negative impact on patients and the wider system creating the following risks:

- Costly cancellations and stressful appointment delays when results are not ready.
- Additional anxiety for patients and their families awaiting results.
- Diseases, especially cancer, become more advanced while patients are waiting for results.
- Prioritising urgent specimens to meet cancer and screening targets has a significant impact on turnaround times for routine specimens. This increases the risk of a delayed diagnosis of cancer in samples clinically thought to be benign
- The General Medical Council (GMC) undertook a national training survey in 2023 and reported an increase in burnout for histopathology trainers (25% high risk, 62.5% moderate to high risk).

The increased turnaround times also mean that fewer specimens can be processed within existing capacity and this has contributed to a growing backlog of cases, placing the staff and service under additional pressure. Work is ongoing to accurately quantify the extent of the capacity gap. However, given the forecast growth in volumes, prioritisation and complexity of cases, it is clear that significant mitigation measures are urgently required at all Health Boards to address this.

Outsourcing adds to the pressure as well as dramatically increasing costs - it is estimated that almost £4million was spent on outsourcing for 23/24. Unless action is taken to facilitate an all-Wales digital service, this cost will inevitably increase rapidly.

This is particularly difficult given the ongoing challenges recruiting and retaining appropriately skilled workforce. There is a well-documented shortage of diagnostics professionals across the UK and various studies have identified specific issues related to the pathology service in Wales. This results in a high dependency on outsourcing of work to locums or external providers to mitigate workforce capacity gaps, which increases costs and impacts on service quality, and has a very negative effect on staff morale and reputation of the service.

A large proportion of the workforce are approaching retirement age or have already retired and returned to the service. There are 20 substantive pathologists are over the age of 55 and over 8 of these have already retired and returned. Pathology is a highly specialised field, and it takes around a decade to train a pathologist from scratch and the service competes with other disciplines for trainees from the reducing number of junior doctors who successfully complete foundation training and progress into specialty training. Many trainee pathologists are now using digital pathology and are likely to seek employment in departments where digital technology is available to support and enhance their diagnosis. Mitigations are therefore urgently required to address these ongoing workforce risks.

Currently the reporting for this service is largely based on the traditional method of glass slides and light microscopes. Gathering slides and reports for multi-disciplinary team (MDT) meetings and for sending out to specialists for second opinion is time-consuming and often causes delay. Irreplaceable diagnostic material can also be lost or damaged in transit – digital imaging removes this risk.

Technological advances in the digitisation (scanning) of glass microscope slide preparations have reached a level of quality, efficiency and effectiveness where immediate adoption in NHS diagnostic cellular pathology services is now not only possible, but is essential to keep pace with the rest of the UK. Digital pathology is fundamental to support the pathologists in decision making and while AI/computational pathology is not designed to replace the pathologists, the use of AI/computational pathology tools has already shown improvements in quality and capacity in the service as detailed below.

The NDCP Project was established to modernise cellular pathology services in Wales and to maximise the use of digital technologies nationally. To date, two phases have been achieved:

Phase 1: Rapid Evaluation and Verification – demonstrated proof of concept and confirmed accuracy.

Phase 2: Partial National Scale Up – partial procurement and installation of digital equipment for each of the Health Boards.

Each Health Board is currently connected to the digital hub in a spoke model and has some limited scanning capability. There is irrefutable evidence that the digital technology delivers many benefits as already experienced in BCUHB who are acting as a pilot site for digital pathology in Wales. Scanners are currently in everyday use in BCUHB and are being used to scan routine and cancerous slides enabling both on site and remote digital reporting. Images of scanned slides are shared at MDTs, and cross site working with Swansea Bay University Health Board (SBUHB) is enabling rapid reporting of digital images by the All Wales Lymphoma panel reducing from 2 weeks to just 24 hours. The All Wales Lymphoma panel is only partly supported by digital cellular pathology, for instance cases referred to the panel from BCUHB will be seen much quicker than those from ABUHB, which results in an inequitable service for patients until a digitisation is scaled up across all Health Boards.

BCUHB have successfully completed Phases 1 and 2 of a Small Business Research Initiative (SBRI) Project where AI has been successfully used to pre-analyse prostatic biopsies and triage malignant cases for early reporting. Phase 2 of the Project included rolling out to SBUHB and ABUHB and over 1900 prostatic cases were scanned between the 3 Health Boards. The project has recently also been rolled out to Cwm Taf Morgannwg UHB, Hywel Dda UHB and Cardiff & Vale UHB and by mid-May 2024, all Health Boards in Wales will be using the AI platform to assist pathologists in the reporting of prostatic biopsies. The benefits from Phase 2 have shown an improvement in accuracy of around 13% and a possible 50% reduction in the demand for immunohistochemistry (IHC) to support clinical suspicion of cancer, and other benefits are being considered. In BCUHB, the Moondance Breast AI Project has carried out the validation phase and is now processing breast biopsies and in CVUHB, a pilot project is due to commence shortly for gastric biopsies.

During a visit to BCUHB Cellular Pathology laboratory, the Minister for Health and Social Services, Eluned Morgan said "*we are seeing how AI presents incredible opportunities to transform the way we interact and deliver NHS services. The benefits of using AI to help diagnose cancer has exceeded all our expectations and it is fantastic that six Welsh Health Boards are undertaking further trials of this technology. The IBEX system has shown real promise and the possibilities of what this type of technology can do and how it could be used in the future across a number of suspected cancers is an exciting prospect.*"

BCUHB, SBUHB and ABUHB are using voice recognition and command software to improve dissection and report turnaround times by as much as 5 days. Despite the partial success, none of the Health Boards currently has sufficient scanning capability to fully maximise the use of digital technologies.

Business Needs

It is now the intention of the NDCP Project to build on the previous phases by increasing digital scanning, reporting and capacity for Wales in line with the global direction of travel. This includes *(please refer to page 36 for more detailed Business Needs)*:

- **Business Need 1:** Procurement of All Digital Pathology Capability
- **Business Need 2:** Determine and Agree a National Image Store
- **Business Need 3:** Management of the Future Digital Hub
- **Business Need 4:** Work with Health Boards to find a Solution for Cross-Boundary Working as part of a National Network of Cellular Pathologists
- **Business Need 5:** Work with Health Boards to Develop Workflows and Workforce to ensure maximum benefits are realised from the implementation of the new LIMS

Potential Scope and Services

The NDCP Project agreed that the following would be included within the scope of Phase 3 *(please refer to page 38 for more details on the scope)*:

- **Slide scanners**
- **Medical grade screens** (with the appropriate graphics cards).
- **Management systems** (additional software or as part of the scanning package – to include voice recognition)
- **Additional workstations/laptops**
- **Image storage** (investigation of cloud storage options)
- **AI/computational pathology**
- **Standardisation of services** (via Standardisation Group)
- **Adoption of standardised technical standards for image formats**

It should be noted that the procurement scope does not include tissue processors, stainers and other specialist laboratory equipment. These are out of scope since the standardisation of existing equipment is not currently considered achievable due mainly to cost.

ECONOMIC CASE

Options Framework

In accordance with the HM Treasury Green Book and Welsh Government Better Business Cases guidance, a long list of options was identified and evaluated against spending objectives and critical success factors using the options framework. The results of this are presented in the following table:

Table 3 Options Framework

Project	Do Nothing	Do Minimum	Intermediate	Do Maximum
1. Service Scope *As outlined in Strategic Case*	All cases are reported using microscopes and glass slides. Would leave Wales behind the rest of the UK and could lead to collapse of service	Most cases are reported using microscopes and glass slides plus some limited digital reporting.		Most cases are reported digitally. Would ensure Wales keeps pace with rest of cellular pathology global community
	Carried Forward	**Carried Forward**		**Preferred Way Forward**
2. Service Solution *In relation to the preferred scope*	Return to previous process (glass slides and microscope)	Partial procurement and installation of digital capability for each Health Board.		National scale up of digital capability including image storage and digital hub solution.
	Carried Forward	**Carried Forward**		**Preferred Way Forward**
3. Service Delivery *In relation to the preferred scope and service solution*		NHS Wales purchases equipment and support provided via a maintenance contract		Fully managed service contract where provider owns and manages the digital solution
		Carried Forward		**Preferred Way Forward**
4. Implementation *In relation to preferred scope, solution and method of service delivery*		Phased approach in which HBs transition one at a time		Big Bang approach in which all HBs transition together
		Preferred Way Forward		**Discounted**
5. Funding *In relation to preferred scope, solution, method of service delivery and implementation*		Fully capital funded	Combination of capital and revenue funded (NHS owned asset/revenue model)	Fully revenue funded
		Discounted	**Carried Forward**	**Preferred Way Forward**

Main Options

The resulting shortlist of options comprises:

- **Do Nothing:** Return to the pre-Project position with cellular pathology services reporting all cases using microscopes and glass slides. This would put the service at considerable risk and is no longer a viable option.
- **Do Minimum:** Continue with existing arrangements whereby cellular pathology services continue to report most cases using microscopes/glass slides and perform some digital reporting using current limited digital

capability. This would require two pathways to operative simultaneously and would be prone to error and considerable inefficiency.

- **Intermediate - Capital and Revenue Funding Model:** Cellular pathology services utilise as much digital reporting as possible through national scale up of digital enablement, digital storage and digital hub solution, along with AI/computational pathology functionality. Funded through a combination of capital and revenue funding.
- **Preferred Way Forward - Fully Revenue Funded Managed Service Model:** Cellular pathology services utilise as much digital reporting as possible through national scale up of digital enablement, digital storage and digital hub solution, along with AI/computational pathology functionality. Funded through a fully revenue funded managed service option.

Options Appraisal

An economic appraisal was prepared to determine the value for money of the shortlisted options. This was based on indicative costs, benefits and risks which were estimated in accordance with the level of information available at this stage in the process. An overview of the results is presented in the table on page 58.

Preferred Option

Based on the financial and non-financial analysis outline in the Economic Case, the Preferred Way Forward delivered via a fully revenue-funded model, which reflects a cellular pathology service that utilises as much digital reporting as possible through national scale up of digital enablement, digital storage and digital hub solution, along with AI/computational pathology functionality.

It will improve sustainability and equity of the service ensuring realisation of Project benefits including:

- Sustainable, equitable, and future proofed cellular pathology service across NHS Wales
- Ability to report nationally across Health Board boundaries to realise the Project ethos of any Consultant, reporting any case, from any location
- National image sharing
- Improvement in attractiveness of service for recruitment and retaining of staff
- AI/computational pathology can be utilised to support the pathologists and improve the quality and efficiency of clinical diagnosis
- Supports delivery of Single Cancer Pathway targets as detailed in 'A Cancer Improvement Plan for NHS Wales 2023-2026'
- Utilise digital equipment purchased during Phase 1 & 2
- Utilise integration developed between current and new LIMS
- Improved quality and drive innovation through AI/computational pathology
- The sharing of specialist clinical resource/expertise through improved digital networking of services in Wales progressing towards a proposed national network of cellular pathologists
- Greatly improved rapid access to different specialities as already demonstrated by referral of digitalised lymphoma cases between BCUHB and SBUHB and digitally supporting MDTs for national screening services such as cervical cytology from a remote site.
- Improve patient care through the use of a national digitalised network, facilitating quicker second opinions and facilitate cross boundary working

- Improved MDT preparation by eliminating time spent collating cases for MDT review also saving laboratory staff time retrieving slides from file storage and re-filing following review.
- Enable pathologists to interact easier with colleagues e.g. virtual multi-disciplinary team meetings and virtual review of cases online.
- Improvements in education, training (both in class and virtual) and for presenting at MDTs, tumour boards, audit etc
- Aligned to international direction of travel for the service
- Heat mapping and annotation of images will assist with identifying areas for molecular genetics improving precision medicine
- Reduce risks associated with HTA regulations on slide storage

COMMERCIAL CASE

Procurement Route

Three procurement models were considered as part of the options framework:

1) Traditional purchase and service support model
2) Managed service provider model
3) Hybrid model:

The managed service provider model has been selected as the preferred way forward. The extent of the managed service provider model may be limited, for example with NHS Wales taking ownership of some infrastructure either located in NHS organisations and/or an NHS Data Centre, but with the supplier taking responsibility for management and ongoing service support. As with the traditional purchase and service support model this would involve capital and revenue accounting treatment of costs and associated funding.

Two procurement routes were explored: full tender and a framework agreement. It has been agreed that a full tender process is the most suitable route.

Procurement Scope and Specification

The principal aim of the procurement is to procure additional software and equipment to create a cellular pathology service that will maximise the use of digital reporting, replacing as much of the existing traditional microscopy service as possible. The scope of the procurement includes *(please refer to page 38 for a more detailed description):*

- **Slide scanners**
- **Medical grade screens**
- **Management systems**
- **Additional workstations/laptops**
- **Image storage**
- **AI/computational pathology solution**

It should be noted that the procurement scope does not include tissue processors, stainers and other specialist laboratory equipment. These are out of scope since the standardisation of existing equipment is not currently considered achievable due mainly to cost. The final specification will be agreed following pre-tender engagement with suppliers.

Timeline for Procurement

The following table sets out the procurement milestones and complies with all applicable legal requirements.

Table 4 Procurement Timeline

Activity	Date
Update specification of requirements	Ongoing
Sign off final specification and agree award criteria	April 2025
Publish ITT	April 2025
ITT response deadline	June 2025
Evaluation of responses	June - October 2025
Contract award	November 2025
Contract start date	April 2026 (staggered across Health Boards)

Payment Mechanism

Payment mechanisms will be confirmed with the preferred bidder.

Contractual Arrangements

The final contractual arrangements will be confirmed with the preferred bidder.

Legal and Personnel Implications

A Programme Manager will be appointed to lead the Procurement Project working to the National Pathology Portfolio Programme Lead.

It is likely that specific individuals will be involved across multiple activities. The combined staff and consultancy team will cover the following roles for the procurement:

- **Digital Cellular Pathology Project Team:** Comprising the Senior Responsible Owner, National Pathology Programme – DCP Clinical Lead, National Pathology Portfolio Programme Lead, Programme Manager, Senior Project Manager, and Senior Project Support Officer
- **Procurement Project Team:** NWSSP Procurement Project Manager/Category Manager will be appointed to manage the Project and deliver the planned outputs as expected within quality, time and budget constraints. The Procurement Project Manager will report to the Programme Manager and be supported by the Project Team.
- **Health Board representatives** (Pathologist, Manager and IT)
- **DHCW Representatives**
  Other representatives will be co-opted as appropriate

Each Health Board has a laboratory manager and a clinical lead who act as digital pathology champions from within their laboratory. The work done so far with AI/computational pathology implementation has benefited from a "do once and share approach" which also supports national standardisation. The role in the local laboratories is not envisaged to be full time position but a duty required by all laboratory managers as part of the modernisation of pathology. Each laboratory

will already have a quality manager in place who should be able to help support the quality/regulatory and assurance work required. The NDCP Project will assist in developing documentation such as SOPS/risk assessments and governance documents. Also, included in the Health Board revenue costs is Band 3, Band 6 biomedical scientist (BMS) and a part time Band 7 IT (one day per week) which will also form part of the membership.

It is not expected that any Phase 3 activities will fall under TUPE – Transfer of Undertakings (Protection of Employment) Regulations 1981.

FINANCIAL CASE

Affordability Analysis

Indicative costs have been estimated at this stage based on current market knowledge and resourcing requirements. Costs are outlined in Appendix F1, and a detailed explanation of the costing methodology is included above. In summary:

- **Solution costs:** Procurement of a managed service contract to provide digital scanners, workstations, other hardware, integration with other systems, software, training and the ongoing storage and service to maintain the system. Costs at this stage are based on the results of recent market testing.
- **Project Team:** Including non-recurring costs of Programme Manager and Senior Project Support Officer and recurring costs of NWSSP Procurement Project Manager/Category Manager. It is assumed that the National Pathology Portfolio Programme Lead and Senior Project Manager will continue to be funded through the National Pathology Programme budget.
- **DHCW Support:** Non-recurring and recurring costs based on anticipated DHCW requirements for Lead Engineer Networking, Support Integration, Development Integration and Infrastructure Design roles.
- **Additional Health Board Staff**: Ongoing cost of a Band 6 BMS, Band 3 Healthcare Support Worker and 1 day per week of Band 7 IT support for each Health Board.

Based on these assumptions, it is anticipated that funding is below: *(please see a more detailed breakdown on page 5).*

- **Non-recurring revenue funding which in total equates to £423,000 requested from Health Boards**
- **Ongoing revenue funding which in total equates to £34.4m between 2025/26 – 2034/35 requested from Health Boards**

MANAGEMENT CASE

Project Management Arrangements

The Project is being managed in accordance with the standards set out in Managing Successful Programmes (MSP).

Structure

The suggested structure to enable the NDCP Project to effectively develop and deliver the "new capability" is outlined in the following diagram.

Figure 1 Structure

Timescales

The high-level timeline for the Project is set out in the following table:

Table 5 Project Timeline

Tranche 1	Tranche 2	Tranche 3
Pre-procurement	Procurement	Implementation
Apr 24 – Mar 25	Apr 25 – Mar 26	Apr 26 – Mar 27
Standardisation approach Development of the Business Justification Case Health Board Executive approval of the BJC (x 6) Update service specification	Tender process Supplier engagement Finalise service specification Contract Award Implementation Preparation Digital hub/storage preparation Recruit HB staff	Digital hub/storage implementation Implementation in Health Boards (phased approach) Training

Assurance

The NDCP Project has a Quality and Assurance Strategy developed in accordance with MSP to ensure that all management aspects of the Project are working appropriately and that the Project stays on target to achieve its objectives. Project reviews to be undertaken at the end of each tranche.

Change Management Arrangements

The NDCP Project is a transformational change Project underpinning the development of modern, safe, sustainable Pathology services the use of innovative systems resulting in sustainable futureproofed services. The Project is aligned to the principles of the Pathology Statement of Intent 2019 and ensures continued alignment through a robust governance structure and reporting mechanism into the National Pathology Programme. Transformational service change forms the basis of the NDCP Project which seeks to deliver the change in a way that is welcomed, supported and embraced by the Pathology service and the wider NHS. The NDCP Project will deliver this through leadership, vision, stakeholder engagement, strong governance, excellent communications and robust plans. Building on lessons learned from Phases 1 and 2, Phase 3 will:

- Appoint an executive level SRO

- Reinforce clinical leadership arrangements, for instance the National Pathology Programme now has a National Clinical Lead and a Clinical Lead for Digital Cellular Pathology
- Strengthen existing membership ensuring IT representation from each organisation
- Formalise DHCW membership
- Continue to update National Diagnostics Strategic & Operational Group at regular intervals
- Continue to work with the Cellular Pathology Standardisation Group to drive the Project forward and ensure Subject Matter Expert (SME)

This approach will ensure the continuation of a robust, governance structure ensuring enabling high quality delivery at pace.

Transformational Leadership

The NDCP Project is providing transformational leadership enabling the Pathology service to create their vision and own the Project at every stage of the process.

Health Board and Trust Leadership

Health Boards and Trusts will provide the leadership necessary for the successful implementation of the new NDCP Service by supporting the following:

- Approval of the BJC at National Strategic Planned Care Board;
- The level of business change required to support the standardisation of services as far as possible to deliver a modern, high quality, safe and sustainable Pathology service;
- Establish a Local Deployment Project team to oversee the implementation and deployment of the new digital enablement and ensure the pathology service has the support and resources it requires to contribute to the Project
- Include NDCP Project in their integrated medium-term plans (IMTPs)
- Enable their pathology services to contribute to the development, testing and validation of the new service;
- Release their staff for training for the new service

Management of Requests for Change

Requests for change can take several forms and will be managed accordingly. Throughout the life of the Project until the new digital service is fully deployed, all requests for change will be recorded in a dedicated Project change log and managed by the Project Team. The Project Team will decide the appropriate route for the change to be dealt with. A decision is needed regarding ongoing arrangements following handover of services to operations, and the ongoing the management of change requests during the managed service contract.

Benefits Realisation

The Benefits Management Strategy developed in Phases 1 and 2 of the Project will continue to be developed and refined to model benefits in more detail, determine methods for measuring them and ensure there is a process for tracking their realisation (see Section 3.8 for list of benefits). It is recognised that this will require buy-in and support from Health Boards.

Risk Management Arrangements

The Risk Management Strategy developed in Phases 1 & 2 of the Project will continue to be developed and will outline how risks and issues will be identified and managed during Phase 3 of the Project. It is recognised that this will require buy-in and support from Health Boards. The Programme Manager will work with key leads to detail potential risks and issues in the Project Plan. A detailed Risk & Issues Register has been developed by the Project Team to assist with risk & issue management throughout the development process. Risks will be assessed and values attributed to each area.

Contract Management Arrangements

The contract will be managed by maintaining relationships with the successful supplier(s) throughout the duration of the Project, including engaging through supplier performance management (SPM). Regular contract review meetings will be held by NWSSP Procurement Services with input from the working group, using the SPM standardised agenda.

Post Evaluation Arrangements

The Project has a Quality and Assurance Strategy developed in accordance with MSP to ensure that all management aspects of the Project are working appropriately and that the Project stays on target to achieve its objectives. To complement the Quality and Assurance Strategy, gateway reviews will be planned at the end of tranches 2 and 3, to assure the readiness for service prior to go live and once the project has finished and the new digital service is fully deployed to assess operations and review benefits realisation.

Contingency Plan

There is a contingency built into Tranche 3 should there be any delays in the implementation of the Project. In the event that the Project fails, the aim will to be to ensure business continuity by:

- Exploring the opportunities to contract with another supplier within the procurement, should the supplier fail to deliver;
- Undertaking a re-procurement.
- Ensuring traditional reporting via glass slides and microscope as contingency

2 Introduction

Purpose of Business Justification Case

As outlined in the Executive Summary on page 5, the purpose of this BJC is to set out the proposals for Phase 3 of the NDCP Project. This will build upon the previous work of the Project, where investment in infrastructure and staffing has allowed us to evidence proof of concept, most recently identifying the opportunities and benefits of AI/computational pathology. We can only progress this and fully understand and realise the benefits by providing further digital enablement allowing cellular pathology services to digitise services as completely as possible. National scale up (to enable full digital reporting) will require investment in scanning and reporting hardware, a laboratory management software system, digital image storage and staff resource.

This document seeks approval to undertake full procurement of the new solution and commitment to provide the following funding:

- **Non-recurring revenue funding of £423,000 requested from Health Boards (£71,000 per HB)** for the implementation costs associated with the project team and DHCW support between 2025/26 – 2027/28.
- **Ongoing revenue funding which in total equates to £34.4m between 2025/26 – 2034/35 requested from Health Boards,** related to annual recurring revenue costs associated with the managed service contract for the solution and additional staff required to support Health Boards with the implementation and ongoing management of the solution.

Structure and Content of the Document

The BJC has been prepared using the agreed standards and format for business cases, as set out in the Welsh Government Better Business Cases guidance. The approved format is the Five Case Model, which comprises the following key components:

- The **Strategic Case** outlines the strategic context and demonstrates that there is a compelling case for change.
- The **Economic Case** demonstrates that the preferred option best meets the existing and future needs of the service and optimises value for money (VFM).
- The **Commercial Case** outlines the procurement route and the content and structure of the negotiated deal.
- The **Financial Case** confirms funding arrangements and affordability and outlines the impact on balance sheet and income and expenditure.
- The **Management Case** demonstrates that the scheme is achievable and can be delivered successfully to cost, time and quality.

3 Strategic Case

Strategic Context

Pathology Overview

Pathology is involved in 70% of all diagnosis made in the NHS, however, this figure does not reflect the role that pathology has in screening and monitoring and in relation to chronic conditions. Pathology underpins all clinical services and 95% of clinical pathways including those referred from primary and community care rely on patients having access to efficient, timely and cost-effective pathology services, within secondary care. Cellular pathology is also integral to the delivery of precision medicine and genomic services.

During 2018, pathology processed more than 34 million tests at an estimated cost of 1.9% of the total healthcare budget. A key component in the delivery of prudent health services, pathology is an enabler to other Welsh Government health strategies including those in cancer and stroke services.

Organisation Overview

The NHS Wales Executive is a national support body which has been operational since 1st April 2023. Its key purpose is to drive improvements in the quality and safety of care - resulting in better and more equitable outcomes, access and patient experience, reduced variation, and improvements in population health. The NHS Wales Executive will also provide strong leadership and strategic direction through the National Strategic Planned Care Board which is attended by all Chief Executives of UHBs, Trusts, and enabling organisations, providing support and directing NHS Wales to transform clinical services in line with national priorities and standards.

The National Pathology Programme

The National Pathology Programme is managed by the NHS Wales Executive. The National Pathology Programme was established to:

- Develop and implement a Programme of strategic work which contributes to delivering the vision of the Pathology Statement of Intent 2019.
- Ensure the adoption of all Wales standards and protocols for pathology services in NHS Wales.

The National Pathology Programme Strategic Group, chaired by a CEO Lead, was formed to ensure oversight and ongoing development of the implementation plan and report to the National Diagnostics Strategic & Operational Group and the National Strategic Planned Care Board.

Delivery of the agreed actions of the Pathology Statement of Intent 2019 is the responsibility of the National Pathology Programme Strategic Group who have oversight of each of the dedicated all Wales delivery groups, which include Pathology Workforce and Education Group, Point of Care Strategy Group, National Pathology Operational Managers Group, Pathology Quality and Regulatory Compliance Group, and the NDCP Group. See section below for more details on the NDCP Project.

The development of pathology services across Wales includes:

- Some progress to consolidate pathology services into three regions, in line with the Carter Report (2008), completed in north Wales.
- A Regional Collaboration for Health (ARCH) is a partnership between SBUHB and Hywel Dda UHB to deliver service transformation across south west Wales.
- Regionalisation work ongoing with CVUHB, CTMUHB and ABUHB in south east Wales
- Maximise digitisation and IT connectivity for cellular pathology – in line with the long-term requirement documented in the Richards Report 'Diagnostics: Recovery & Renewal' October 2020 and more recently WG's Digital and data strategy for health and social care in Wales (2023).
- Expansion and retention of the workforce within cellular pathology – as identified in the Pathology Statement of Intent (2019).
- Impact of COVID-19 on pathology – as documented in the Richards Report and WG's Diagnostics Recovery and Transformation Strategy for Wales 2023 to 2025.
- Realignment to support the National Clinical Framework.
- A pilot in digital cellular pathology has created the capacity for reporting on digital images for a wider area.
- Boundary changes have taken place with CTMUHB now managing the Princess of Wales Hospital in Bridgend.
- The Public Health Wales (PHW) microbiology network has consolidated many investigations to a regional or national model of delivery and continues to transform services, such as the six additional hot labs for COVID-19 testing.

The National Digital Cellular Pathology Project

The NDCP Project is critical to the continued delivery of a modern and sustainable Pathology service as well as ongoing transformation initiatives.

Established in 2016, under the auspices of the National Pathology Programme (then National Pathology Programme Board), the NDCP Project was formed following a successful bid to the Efficiency through Technology Fund, on behalf of the National Pathology Operational Managers Group. The bid was submitted to capitalise on a previous investment made to modernise cellular pathology services at BCUHB, through rapid verification of the procured equipment and then national implementation if verification was successful. Benefits were expected to include but would not be limited to the pooling of clinical resource and standardised working across Wales to enable any consultant to report any case using any device from any location in Wales. This would reduce costs by reducing the necessity to outsource work.

Pathology Service Strategic Aims

Plans for the development of modern, sustainable pathology services are described in the Pathology Statement of Intent (2019). The NDCP Project supports many of the key priorities set out in the Statement, including:

- **Workforce Development**. A modern and innovative digital cellular pathology service will make it easier to recruit and retain staff. The Project will also improve operational efficiency and support changing roles, MDT working and cross-boundary collaboration.

- **Equipment.** The modernisation and standardisation of scanning equipment (as detailed within the scope) will increase service productivity and will fully integrate with the wider NDCP Project.
- **Quality and Safety**. The current digital system has been fully verified for accuracy and safety. It enables treatments to be more easily tailored to individuals, supporting evidenced-based care. Errors and loss of slides are minimised as all samples are held digitally.
- **Services** A fully digital system will improve service efficiency and support the aim to work beyond geographical barriers by exploiting new technologies.
- **Informatics & Information**. Informatics support and enhanced business intelligence will be a key feature of the new solution including a national image storage repository.
- **Research and Innovation**. The new infrastructure supports the sharing of information and will promote and accelerate innovative practice for cellular pathology. There will be enhanced opportunities for learning, development, and research.
- **National and Regional Working.** The new service will provide one seamless system for the whole of Wales, which is co-ordinated nationally and delivered regionally and locally.

Alignment to National Policies and Strategies

The national strategies informing the NDCP Project are summarised in the following table:

Table 6 Alignment to National Policies & Strategies

Strategy/ Policy	Summary	How the National Digital Cellular Pathology Project supports this
NHS Planning Framework 2023-2026	This NHS Planning Framework for 2023-26 builds on the learning from the pandemic and sets out the Ministerial priorities to support recovery and sustainability of health services, with the three-year context being a commitment to improving population health and reducing the burden of disease. Delivering efficiently, effectively, and optimising service delivery is how the improvements must be embedded in the DNA of NHS in Wales.	Provide opportunities to create additional capacity to support Planned Care and Recovery as led by the National Recovery Programme and prioritised by Health Boards. The Framework outlines that Diagnostics services improvements must result in a reduction in numbers of people waiting for diagnostic tests to pre-pandemic levels as a minimum. Provide opportunities to reduce reporting time which will contribute to the achievement of national cancer pathway targets and reduce the backlog of patients waiting too long on their cancer pathway. Ensure that digital, innovation, technology and transformation underpins plans to deliver optimum care and services for patients. The resulting digital solution will provide more opportunities to work with others as part of NHS Wales' approach to innovation. Focus on ways to deploy the existing and future workforce to best effect, including enhanced use of multidisciplinary teamworking, role redesign, developing new roles, and

Strategy/ Policy	Summary	How the National Digital Cellular Pathology Project supports this
		advanced practice models, enabling people to develop their careers and work at the top of their license.
Diagnostics Recovery and Transformation Strategy for Wales (2023-2025)	Outlines plans to recover diagnostic services by 2025, addressing the impact of pandemic, and set the groundwork for longer term sustainability including: • Catch up unmet diagnostics demand for important conditions • Transform services and move beyond traditional boundaries to put patients at the centre, reduce inequality, improve outcomes and reduce secondary care demand • Create and sustain safe services with prudent value-based pathways and workforce models • Be informed by evidence and be data driven • Create an environment where research and innovation improve outcomes and experience and success is scaled. • Connect seamlessly with the National Clinical Plan	Provides opportunities to create additional diagnostic capacity, addressing the current gap and contributing to the recovery of waiting list volumes. Enables the workforce to operate across boundaries, reducing inequality and reducing the pressure on the wider system. Provides a digital solution that can help mitigate capacity gaps, contribute to the attraction and retention of suitably skilled staff, support training of diagnostic specialists and advanced practice roles, and enable hybrid working and 'reporting from home'. Builds on the success of earlier stages, allowing the service to scale up the benefits across NHS Wales. Provides a digital solution that will enable investment and support for national diagnostic programmes in endoscopy, pathology, genomics, and imaging. Provides opportunities to adopt innovative digital technology solutions including AI/computational pathology
National Clinical Framework: A Learning Health and Care System (2021)	The Framework builds on the vision described in A Healthier Wales for a National Clinical Plan. Recognising that healthcare should be driven by planning rather than the market, the Framework sets out a health system that is coordinated nationally and delivered locally or through regional collaborations. It includes all clinical services and clinicians. The Framework will be underpinned by a suite of new commitments outlined in 'Quality Statements', which provide the next level of detail for specific clinical services.	A nationally planned pathology service that is delivered locally and regionally. Will act as an enabler to personalise medicine where therapies can be tailored to individuals, leading to more efficient and prudent provision of evidenced-based care. Will enable the extraction and analysis of data to understand the links between tests and treatment, improving clinical outcomes.
Quality & Safety Framework – Learning & Improving	Building on the aspirations set out in a Healthier Wales, the Framework provides guidance and direction for NHS Wales, focusing on requirements for multi-level, strong quality management systems – in turn reducing variation in quality.	Improving quality and equity through the implementation of a nationally planned service.

Strategy/ Policy	Summary	How the National Digital Cellular Pathology Project supports this
Healthcare Science in NHS Wales – Looking Forward	Referred to the role of healthcare professionals in realising the potential from new technologies and diagnostics to allow services to address challenges associated with increasing diagnostic demand and ageing population.	Utilising technological advances such as AI/computational pathology will help increase capacity and capability.
The Parliamentary Review of Health and Social Care in Wales. Final Report. (January 2018)	The Parliamentary Review set out a vision for the future, to include health and social care moving forward together and developing primary care services out of hospitals. The Review's recommendations focus on key themes around seamless care, a great place to work and maximising the benefits of technology and innovation.	Improving the efficiency of the patient care pathway. Improving facilities. Providing greater opportunities in order to attract a highly skilled workforce Maximising the benefits of technology and innovation.
A Healthier Wales: Our Plan for Health and Social Care (June 2018)	'A Healthier Wales' is the Welsh Government's response to the Parliamentary Review. It sets out the vision of a 'whole system approach to health and social care' which is focused on health and wellbeing, and on preventing physical and mental illness. It focuses on 'providing more joined-up services, in community settings', and shifts the emphasis from treating illness to prevention and supporting people to stay well and lead healthier lifestyles.	Addressing the recommendations set out in the Parliamentary Review as described above Focusing on improving services that will enable better targeted treatments.
The Wellbeing of Future Generations (Wales) Act 2015	The Wellbeing of Future Generations Act is about improving the social, economic, environmental, and cultural wellbeing of Wales. It makes the public bodies listed in the Act think more about the long-term, work better with people and communities and each other, look to prevent problems and take a more joined-up approach.	Deliver a sustainable service that focuses on: • Addressing health inequalities • Improving outcomes for patients • Attracting and developing a highly skilled workforce.
Prudent Healthcare: Securing Health and Well-being for Future Generations	Contributing to the four prudent healthcare principles: • Public and professionals are equal partners through co-production • Care for those with the greatest health need first • Do only what is needed and do no harm • Reduce inappropriate variation through evidence-based approaches	Better information sharing Patients are prioritised according to their need Treatments can be more easily personalised Improved business intelligence supports evidence-based care

Strategy/ Policy	Summary	How the National Digital Cellular Pathology Project supports this
Digital Strategy for Wales, March 2021	The purpose of the strategy is to develop a digital approach for people, public services and the business community across Wales. It has six main aims: 1. Digital services – deliver modern and user-friendly digital services 2. Digital inclusion – ensure people can engage with the digital world 3. Digital skills – ensure the workforce has the digital skills and confidence to excel 4. Digital economy – exploit digital innovation to drive economic prosperity 5. Digital connectivity – ensure services are supported by fast and reliable infrastructure 6. Data and collaboration – improve services by sharing data and working together	Creating a more efficient and cost-effective service by ensuring that: • reporting times are reduced; • productivity is increased; • digitised slides can be shared easily facilitating quicker second opinions and cross boundary working, leading to better clinical outcomes for patients.
Digital Service Standards for Wales	Sets out what's expected from new or redesigned digital services funded by Welsh public sector organisations, in three main areas: • Meet user needs • Create digital teams • Use the right technology	Supports several of the Future Generations Wellbeing goals including reducing health inequalities, improving outcomes for patients and developing a skilled workforce. Embeds digital ways of working in the service Ensures flexibility by using software that meets open standards, is cloud based and is widely supported Supports the use of data analytics to improve patient pathways and deliver better clinical outcomes

Supporting Other Initiatives

It should be noted that the NDCP Project is critical to Pathology's ability to support ongoing NHS Wales activities and current and future initiatives. In particular those outlined in the Executive Summary on page 8.

In addition, there are two ongoing regionalisation pieces of work, both require digital cellular pathology as key enablers. The ARCH (A Regional Collaboration for Health) project in south west Wales plans to merge the departments in Hywel Dda and Swansea Bay University Health Boards into a single managed network. The south east looks to do the same with a similar project bringing together the Cellular Pathology services from Cwm Taf Morgannwg, Cardiff and Vale and Aneurin Bevan University Health Boards. Both will require digital pathology to be able to report cases from any laboratory by the combined reporting capability in the network.

Genomics Partnership Wales, All Wales Medical Genomics Service, Pathogen Genomics Unit (PenGU), Wales Gene Park and Public Health Genomics Programme, have moved to a bespoke modern facility at Cardiff Edge Science Park, Coryton. Co-localisation with cellular pathology will create a 'Centre of Excellence' that will be of benefit to patients by making progress in terms of precision medicine as well as creating a bioscience park that will be of huge benefit in terms of recruitment and retention as well as future collaborative work with university and third sector companies. This requires a digital pathology service to fully realise the benefits.

Integration

The ability to use a single integrated all Wales LIMS system to provide a secure national reporting platform for cellular pathology is key to the NDCP Project. The ability to securely share images with pathology colleagues in any part of Wales for specialist reporting and consultation has already been shown to reduce reporting times for Lymphoma case by several days and has been recognised as a vital step in improving outcomes for some of our most severely ill patients. The reports generated using digital images can be linked to patients clinical data and health outcomes through the single patient record and the clinical portal. Quicker, more accurate and comprehensive reports are facilitated by digital images supported by AI/computational pathology platforms. Digital images will also support the All Wales Medical Genomics Service in identifying specific areas of tumour which will improve analytical outcomes and improve targeted therapies. It has recently been shown how data from the all Wales LIMS system can be interrogated to produce valuable information relating to workloads, backlogs, outsourced work as well as productivity and turnaround times for each laboratory in Wales. This can be used to enable future service planning and provide data to drive more efficient innovative and productive health care. Information form standardised reports generated by AI platforms could be fed automatically into the big data projects.

Foundational Economy

The foundational economy is focused on reversing the deterioration of employment conditions and encouraging local excellence to support the Welsh economy. This will be vital in retaining and attracting cellular pathology staff to NHS Wales. It will make it possible for specialist staff to work remotely and to benefit from work life balance policies. The use of digital pathology enhances flexibility and could help retain experts approaching retirement age by allowing more flexibility in working practices such as part time or flexible working. The IBEX AI prostate biopsy project has been supported by SBRI to work with commercial partners to pilot new ways of working. AI/computational pathology could provide opportunities for Welsh universities to work with Health Boards to support developmental and research projects that could support future diagnostic projects. Digital pathology can not only help remove Health Board boundaries but can also deliver shared learning and necessary documentation to quickly roll out a robust digital diagnostic service. The training of future pathologists and laboratory staff must be tailored to ensure the workforce can be recruited locally and the working environment meets the expectations of trainee staff who are now developing skills in digital services. There are opportunities to facilitate national imaging training centres with remote learning material that would attract trainees from across Wales and provide future generations with a robust cutting-edge pathology

service. Failure to deliver a fully digitised service within the next 3-5 years would adversely impact abilities of laboratories to meet the necessary quality standards.

Case for Change

Spending Objectives

Spending objectives describe what the NDCP Project is seeking to achieve and provide a basis for post-Project evaluation. The following spending objectives have been identified based on the aims of the overall Project and specifically the goals of Phase 3.

Table 7 Spending Objectives & Outcomes

Ref	Spending Objective	Outcomes
SO1	Build a sustainable robust and sustainable cellular pathology service for Wales	• Remote working • Flexible working • Improved ergonomics • Reduction in temporary staffing • Reduction in insourcing and outsourcing
SO2	Introduce national scanning equipment with the capability to fully digitise cellular pathology service for Wales with a footprint that allows for service increase over the next seven years	• Use of 2D bar codes to identify requests, specimens, blocks, slides and images • Reduced risk of tissue/slide loss or damage during transport or storage • Use of annotated scanned image to identify tumour areas required for genomic analysis • Electronic case assembly • Transfer of information on electronic request direct to report. Storage of post mortem images to improve management of cases to meet HTA standards
SO3	Fully integrate with both the current All Wales Laboratory Information Management System (LIMS) and its successor	• Reporting of H&E samples • Diagnostic efficiency (of digital tech) • Digital dictation direct into report in dissection room
SO4	Enable reporting and review any case from any location, using any device	• Case sharing and collaboration • Single identifier for a sample across Wales • Assessing disease progression • Digitally generated request information available to pathologist on screen
SO5	Enable rapid, specialist, second opinion both internal and external to Wales	• Link H&E and IHC /special stains on screen • Synchronous analysis of slides • Flip and rotate images to aid interpretation • Measurement and annotation • Easy access to archived images, slides & case tracking, archival and retrieval • Image storage and retrieval & slide storage and retrieval - where cases need to be referred for second opinion or second review, electronic images can be retrieved quickly and efficiently, improving turnaround time. • Speedier diagnosis of urgent cases • Improved access to external second opinion & improved case transfer times • Clearer diagnostic audit trails • Faster access to molecular testing
SO6	Enable the routine use of Artificial Intelligence, Machine Learning and Deep Learning to enhance diagnosis, teaching and research	• Improved quality in obtaining section • Improved turnaround times due to digital workflow • Case allocation to pathologist

Ref	Spending Objective	Outcomes
		• Electronic test request and workload management in laboratory enabling improved planning and workforce management • Reduced risk of patient/slide misidentification errors • Quantification of specific cells and markers • Highlighting and heat mapping of areas of abnormality • Quality control and audit • Prioritisation of cases to meet cancer targets • Automatic formatting of certain reports such as normal colonic biopsies based on AI pre-screened slides • Improved confidence in diagnosis if slide pre-screened by AI • Convenient and reproducible cancer staging • AI to identify micro-organisms • AI to identify special features not readily recognised by pathologist • AI/computational pathology for enhanced cancer research • Fewer microscopes to service in the future • Capture of digital image at macro dissection using macropath systems • Decrease in number of costly IHC tests • Reduction in number of repeat biopsies • Reduction in requirement of 2nd review pre-MDT
SO7	Build stronger relationships between NHS, Academia and Commercial Partnerships	• To increase teaching, training and mentoring • Improved recruitment and retention • Research resource

Existing Arrangements

Traditional Cellular Pathology

Cellular pathology services in Wales make a major contribution in many disease pathways, most significantly the early detection, diagnosis, staging and monitoring of cancer. Cellular pathology laboratories produce microscope slides from tissue samples sent for analysis from patients in surgical/outpatient settings. Consultant cellular pathologists subsequently make their diagnoses by evaluating microscope slide preparations using a light microscope.

Cellular pathology services are typically organised to be as regional to the clinical teams they support as possible, with regular engagement in MDT meetings the top priority for consultant cellular pathologists. Departments prioritise cases identified for MDT review so as not to delay the patient pathway.

Primary care cellular pathology services are organised in various ways across Wales to support their local health boards. There is a need for regular engagement with MDT meetings across sites, this is now often done via videoconferencing.

Due to increasing complexity in diagnosis, sub-specialisation has become the norm. Increasing sub-specialisation within cellular pathology often requires external opinion to be obtained – this currently requires microscope slides to be physically sent for external review within the UK NHS and sometimes further afield. The consequence of this is significant time delays (and costs) transporting slides by courier/post for expert review, and further time delays in receiving reviewed case reports.

In addition, severe difficulties in recruiting and retaining medical staff mean most departments have vacant posts at any moment in time. The Royal College of Pathologists' workforce census of 2018 showed that only 3% of NHS histopathology departments have enough staff to meet clinical demand.

This capacity gap results in backlogs of unreported cases, with either expensive medical agency locum or external outsourcing used to maintain minimum performance levels. These solutions also contribute to delays in reporting turnaround times.

Demand and Capacity

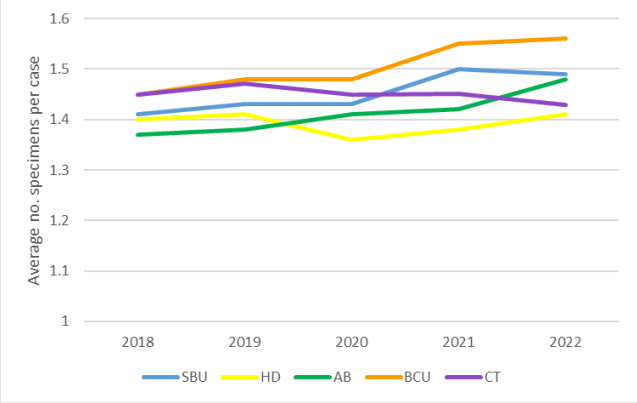
Pathology services in Wales processed more than 1 million slides in 2022/2023 Although activity reduced significantly during the early months of the pandemic, it has been increasing steadily since and by early 2022 had returned to pre-pandemic levels in most UHBs.

It is anticipated that factors such as the Recovery Plans outlined in the NHS Planning Framework 2023-2026 will mean that activity continues to increase during 2023/24. Forecast activity analysis suggests that by 2025/26 the service will be processing approximately 1.5 million slides.

The recent and forecast growth in demand is compounded by the increasing complexity of the workload including:

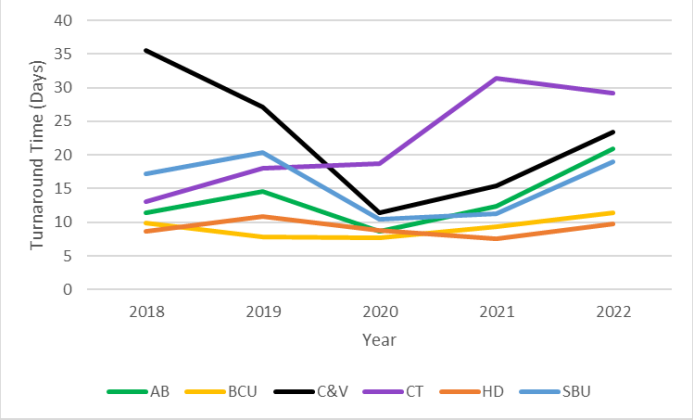
- The most urgent specimens making an increasing percentage of specimens in most Health Boards.
- The number of specimens per case is generally increasing and increasing number of tests are needed for many specimens.

Figure 2 Average no Specimens per case



As a result of this, turnaround times are now at, or are higher than, pre-Covid levels.

Figure 3 Turnaround times



This is impacting on the service's ability to achieve target turnaround times for specimens of 7 days for Urgent Suspected Cancer (USC), 14 days for urgent and 28 days for routine specimens. Target time breaches have increased across the board during 2022, with the percentage of USC and routine specimens processed within target time having decreased in recent years.

Prioritising urgent specimens to meet cancer and screening targets has a significant impact on routine specimens. This creates several risks including:

- Reduced opportunities for early intervention in the routine specimens that lead to a cancer diagnosis, particularly since audits have shown the cancer rate in routine specimens to be between 8% and 11%.
- Cancellations and appointment delays when results are not ready.
- Additional stress for patients and families awaiting results.

The backlog of activity has been gradually increasing following a previous reduction in 2020. This creates additional pressure to create more capacity to address this, which is challenging given the workforce pressures outlined below.

This has resulted in a gap between demand and capacity since mid-2022, particularly in south Wales where there are a number of pathologist vacancies. BCUHB following implementation of digital technology, have been able to attract pathologists to any vacant posts. Work is ongoing to accurately quantify the size of this gap but given the forecast growth in volumes, prioritisation and complexity of cases, then mitigation measures are required at all HBs to address this.

Workforce

It is widely recognised that there is a shortage of diagnostics professionals across the UK, and this is particularly evident in the Pathology service in NHS Wales. The Royal College of Pathologists published 'Briefing: The pathology workforce in Wales' in June 2019 and the 'Royal College of Pathologists' Priorities for Wales' in March 2021. Both papers outlined the workforce challenges and highlighted the need to invest in the workforce for patients and to achieve the Welsh Government's commitment to earlier cancer diagnosis.

NHS Wales Executive modelling in 2022 showed a capacity gap of 25% in west Wales for cellular pathology, with only 3 substantive cellular pathology consultants in HDUHB and a requirement for 9 to satisfy current levels of service. In addition, for south east Wales, the current gap is the equivalent of 8.5 cellular pathology consultants.

The associated studies referenced in these reports highlight a growing retirement crisis in the service. In 2019 it was estimated that 36% of the consultant workforce was over 55 years old and 10% of histopathologists 'retired and returned'. This largely remains the case based on the current pathologist workforce establishment outlined in the table below:

Table 8 Number of Pathologists (November 2023)

	BCUHB	ABUHB	CVUHB	SBUHB	HDUHB	CTMUHB
Number of substantive pathologists in post	12	14 (13 Medics, 1 reporting BMS)	20 "general" pathologists, 2 paediatric pathologists 2 neuropathol-ogists 1 consultant reporting scientist.	16 plus an external pathologist providing 2 digital sessions working from Birmingham 1 post out to advert	2	8
Number of above pathologists aged over 55	4	4	6	4	2	0
Number who have 'retired and returned'	3	0	2	2 (1 currently & 1 pending imminently)	1 retiring & returning Apr	0

The Royal College of Pathologists estimated in 2019 that 17% of consultant pathologists in Wales were locums. The service continues to rely on outsourcing to mitigate capacity gaps in the service, as outlined earlier, at an overall cost to NHS Wales of almost £4million at the time of writing.

Table 9 Outsourcing & Agencies (November 2023)

	BCUHB	ABUHB	CVUHB	SBUHB	HDUHB	CTMUHB
Cost of outsourced reporting in last 12 months	0	£660,100	£389,194	£900,000	Currently don't outsource to external companies however have significant In-lieu of locum costs for in house consultant reporting above their contracted sessions – Approx. £400,000	£2 million
Number of agency pathologists employed	nil but heavy insourcing in place	0	0	Nil, we are however issuing an average of 20 extra sessions to existing consultants per week	2 NHS locums on long term contracts 1 high cost agency locum	0
Average number of cases sent to agencies for reporting each work	No send any cases away for reporting, the extra work generated is reported as out of hours work by the Pathologists on site.	Wet to slide capped at 226 cases per week	Slides to outsourcing each week is around 150 but depends on admin support to get them out and back in, push to do in house WLI's as well	Currently sending 100 wet specimens per week	No send any cases away for reporting, the extra work generated is reported as out of hours work by the pathologists on site.	400-500 specimens wet tissue/ week. Plus 30-50 slides for reporting/ week

As well as increasing costs, reliance on outsourcing impacts on the quality of the service.

This is clearly not sustainable and is expected to worsen over time due to ongoing challenges recruiting and retaining staff. Short to medium term mitigations are limited. Pathology is a highly specialised field, and it takes around a decade to train a Pathologist from scratch. The Royal College of Pathologists highlighted that pathology competes with other disciplines for trainees from the reducing number of junior doctors who successfully complete foundation training and progress into specialty training.

Table 10 Current BMS vacancies and trainee Pathologists (November 2023)

	BCUHB	ABUHB	CVUHB	SBUHB	HDUHB	CTMUHB
Number of BMS vacancies	1 x B6 waiting to interview	2 x B6 whole time equivalents	2 x BMS B5 1 x BMS B6	5 x B3 support workers	3 x B4 1 x B5 1 x B6 currently vacant, adverts out or waiting for a start date	2 x B6, 6 x fixed term B3 MLA current vacancies do not enable the department to meet the demand placed on it
Number of trainee pathologists	3 +2 fellows	One	Trainee pathologists: 6 x Year 1 6 x Year 2 2 x Year 3 1 x Year 4 2 x Year 5 /Stage 4	2, but we have a request to increase from the deanery	No trainee Pathologists.	0
Number of BMS dissection roles currently filled / vacant	1 but a split role – part Senior BMS	2 (training started awaiting examination results)	2 BMS reporting / dissection for GI in post	4 advanced practitioners in dissection with one of these posts vacant 1 advanced practitioner reporting Gynae	We do not currently do BMS dissection.	1 advanced practitioner in Histological dissection

Mitigations are therefore urgently required to address these ongoing workforce risks.

Digitisation of Cellular Pathology Services

Technological advances in the digitisation (scanning) of glass microscope slide preparations have reached a level of quality, efficiency and effectiveness where immediate adoption in NHS diagnostic cellular pathology services is now not only possible but is essential to keep pace with the rest of the UK.

The system consists of a slide scanner, capable of creating high resolution images of microscopic preparations of human tissue, at comparable magnifications to that of a traditional light microscope. Other components of the system are a software interface, data storage servers, and computer workstations with high power graphics cards and high-resolution monitors to enable viewing and manipulation/sharing of slide images. Integration of the software interface with LIMS enables cases to be reported within an all-digital environment.

Consequently, moving to digitise cellular pathology services as completely as possible would eliminate many of the physical, time-consuming steps involved in

transporting microscope slides to consultant cellular pathologists, both locally and externally. Digital images can reduce the turnaround time from two days to a couple of hours. In addition, the preparation of slides for MDT review is much faster: the time taken to find and share physical slides is significant (there are currently up to 28 MDTs per week in BCUHB). When compared with radiology, which has been digitised for many years, it is estimated that the number of MDT administrative staff for pathology could be reduced from two to one.

An example of this occurred in SBUHB when, at a recent central urology MDT, the slides had not been received for review. During the MDT, SBUHB were able to email HDUHB and requested that the slides were scanned and the report sent electronically. The case was then immediately reviewed, discussed at MDT, saving another week on the pathway for MDT review.

Voice command is a major advantage, also supporting quicker turnaround times, improved reporting and a reduced need for secretarial support. And the risk of misplacing slides is also reduced, which reduces duplication and litigation risks.

Digitisation also offers benefits in terms of the time saved in retrieving and storing slides. Exact figures on this won't be available until Phase 3 is complete but, based on early studies from the digitisation of cellular pathology services in Leeds, it is estimated that a saving of between two and three WTE administrators will be possible with a fully digitised service. In addition, case review and external expert opinion can be undertaken electronically in real-time, with the likelihood that additional diagnostic expertise/precision will be more attainable than before.

Remote consultant MDT attendance through videoconferencing such as Microsoft Teams (including display of images), increasing the potential for greater sub-specialisation and shared working across NHS Wales.

Finally, without national scale up, the full benefits of AI/computational pathology cannot be realised across Wales. The benefits of AI/computational pathology are significant. For example, a pathologist cannot manually count one million cells, but this will now be possible through machine learning, leading to greater accuracy and faster reporting times.

The NDCP Project was established to modernise cellular pathology services in Wales and to introduce a fully digitised national service. To date, two phases have been achieved.

Phase 1: Rapid Evaluation and Verification
Phase 1 demonstrated proof of concept through the high correlation achieved when comparing the results obtained using both traditional glass slide methodology and digital image to report 3000 cases. This resulted in receipt of a mandate from All Wales CEOs to proceed with national implementation of digital enablement.

Phase 2: Partial National Scale Up
Phase 2 has realised, through investigation, procurement, and installation, the delivery of partial, standardised, digital enablement for each of the Health Boards including the delivery of local storage and an interim hub solution. Phase 2 has

also progressed the work of integrating the current digital scanning solution into the current LIMS with work expecting to be completed quarter 1 2024/25.

Current position

The current position is outlined previously in the executive summary on page 9.

Business Needs

It is now the intention of the NDCP Project to build on the previous phases by increasing digital scanning, reporting and capacity for Wales in line with the national direction of travel. This includes:

Business Need 1: Procurement of All Digital Pathology Capability
The budget for Phase 2 was not sufficient to digitise cellular pathology services as completely as possible. It was agreed at the time that an incremental approach to implementation would be taken ensuring that work progressed at pace giving some digital capability to each Health Board. The aim of the final Phase is to fund the procurement and installation of the remaining infrastructure, equipment and software to digitise services as completely as possible solution for the whole of Wales.

Business Need 2: Determine & Agree National Image Store
As an interim measure during Phase 2 images were stored on additional server space purchased at each of the Health Boards with local IT back up providing the required resilience. This current storage availability will greatly limit digital reporting in the future. Going forwards a national long-term storage solution (including plans for back up) is required which should meet the following:

- Images should be accessible easily and quickly by any reporting pathologist from any location
- Image storage needs to be compliant with retention schedules and GDPR.
- Images should be available for research purposes.
- The size of a 20x20 slide is approximately 1GB-1.5GB per slide and a megaslide would be around 3GB each, however megaslides are not currently being scanned.
- For governance reasons, a backup file of all clinically significant images including any AI heat maps, would be required.
- It is important to have instant access to current and the most recent cases (probably around 12 months). However, images more than 12 months old could be stored where access would be available within 24-48 hours which will hopefully help to reduce storage costs.

Business Need 3: Management of the Future Digital Hub
There are currently interim arrangements for managing the digital hub. The aim of Phase 3 is to investigate all options for managing a national central hub and to procure the agreed solution. The hub would act as a repository for meta data relating to the images for all Health Boards.

Business Need 4: Work with Health Boards to find a Solution for Cross-Boundary Working as part of a National Network of Cellular Pathologists
Cross-boundary working is needed to maximise access to specialisms available within different organisations to provide equity to patients across Wales. A 'virtual lab' will support cross-boundary working by enabling anyone from any location to

review any slide. This has been critical during the COVID-19 pandemic when 20-30% of staff have been off site. Cross-boundary working will need to be underpinned by the recruitment of more cellular pathologists to address current gaps in the workforce. The RCPath workforce census (2018) proposed a range of solutions to address the shortages, including:

- More funded training places for specialist cellular pathology trainees;
- Better IT for day-to-day work;
- Investment to implement digital pathology more widely so staff can work efficiently and flexibly;
- The development of advanced clinical practitioners to work alongside medically qualified cellular pathologists.

Business Need 5: Work with Health Boards to Develop Workflows and Workforce to Ensure Maximum Benefits are Realised from the Implementation of the New LIMS

Workflows are being developed as part of the wider Project of digital work to standardise pathology processes for integration in the LIMS system. LIMS is the national reporting system for all pathology and all reports from different disciplines need to be available for easy review by reporting pathology clinicians. Nationally sample numbering and identification depends on unique identifiers generated by the LIMS. The unique identifiers for episode, case and sample are printed in bar code which is used to identify and track the samples in LIMS. The barcode label on the glass slide is scanned to identify the image and link it to the request in LIMS. All reporting is done on LIMS and authorised digital results are stored and transmitted via LIMS to the Welsh Clinical Portal where results are nationally available to clinicians and GPs treating patients anywhere in Wales, LIMS is the agreed reporting system and will be integrated to any scanners procured either directly or through laboratory workflow management middle-ware.

Future cellular pathology workforce requirements will be determined by the Pathology Workforce and Education Group (PWEG) in collaboration with Health Education and Improvement Wales (HEIW) and academia.

Potential Scope and Services

During a NDCP Project Board meeting, held on 22nd February 2021, members agreed that the following would be including within the scope:

In Scope

- **Slide scanners**
- **Medical grade screens** (with the appropriate graphics cards).
- **Management systems** (additional software or as part of the scanning package – to include voice recognition)
- **Additional workstations/laptops** (appropriate graphics cards for the new screens would need to be compatible. Possibility of workstations in MDT and seminar rooms, and for trainees and hot-desking. High-specification laptops to support working from home, which could also be used with docking stations and medical grade screens in the MDT/seminar rooms as an alternative to a full workstation. Keyboards and mice should be washable. Joysticks to be included)
- **Image storage** considering the different file formats, storage over a defined length of time, the file sizes and the bandwidth needed etc. In line with the

DHCW principle of 'cloud first' (which will deliver benefits such as secure, fully managed, predictable performance, rapidly available, and resilient), cloud storage will be the storage method of choice. Most of the AI systems use cloud storage to analyse copy images- the analysed diagnostic images will need to be stored along with the original image as long as deemed necessary for the active case.

- **AI** is a rapidly developing computational tool designed to support pathologists in reaching a quick and reliable diagnosis. It is not designed to replace the pathologists. Described at a high level only, to remain as flexible as possible, as the technology is developing rapidly. AI provider would need to be system 'agnostic'. Several different providers can deliver targeted analytical platforms to suit different tissue types.
- **Standardisation of services** (via Standardisation Group)
- **Adoption of standardised technical standards for image formats** (e.g. DICOM) and Interoperability (e.g. HL7 FHIR)

Out of scope

- **Tissue processors**
- **Stainers**
- **Other specialist laboratory equipment**

These are out of scope since the standardisation of existing equipment is not currently considered achievable due mainly to cost.

By considering the range of business functions, areas and operations to be affected and the key services required to improve organisational capability, 'scope creep' can be avoided during the options appraisal stage of the Project.

Coverage and services are considered on the following continuum of need:

- **Core:** Essential elements that must be included in the Project to address immediate risks and ensure service continuity.
- **Desirable:** Additional elements that should be included in the Project to enhance the service and deliver greater value for money through additional benefits.
- **Optional:** Possible elements that could be included in the Project to maximise benefits providing they can be justified on a marginal low cost and affordability basis.

The potential scope of service coverage was reviewed at various points of the Project and categorised the main elements in line with this continuum of need. The results of this analysis is provided in the table below.

Table 11 Summary of items in scope

	Core	Desirable	Optional
Scanners			
• Cellular pathology scanners	✓		
• High resolution haematology scanners			✓
Workstations			
• Medical grade screens	✓		
• Keyboards and mice	✓		

• Joysticks		✓	
Management systems (including voice recognition)	✓		
Additional workstations/PCs			
• High resolution laptop, docking station and medical grade screen	✓		
Image storage	✓		
AI	✓		
Standardisation of services	✓		
Integration with current/future LIMS	✓		

Main Benefits

Investment in the NDCP Project is expected to deliver a wide range of benefits, many of which were proven during Phases 1 and 2. Benefits include:

- Enabling greater information sharing that will lead to better collaboration including facilitating cross boundary working and improving turnaround times for second opinions and peer review.
- Providing access to digital images enables remote and cross-site working, reducing travel time which will have a positive impact on staff welfare and enables more efficient ways of working. It will also help reduce the carbon footprint.
- Improved efficiency and cost savings associated with reduced transportation of physical slides and time spent retrieving and collating data. Further reduction of carbon footprint.
- Improving the quality of patient care by enabling the tailoring of therapies, risk-based case prioritisation, better control over samples managements and improved reporting that leads to more accurate diagnosis.
- Contributing to improvements in treatment by improving data analysis and business intelligence used in the day to day management as well as teaching and research.
- Creating a modern and efficient service by adopting up to date technologies will improve staff satisfaction and support recruitment and retention.
- Meet standards of prudent healthcare and improve the service's reputation.
- Opportunities to adopt AI/computational pathology technologies and maximise efficiencies.

The quantification of these benefits are explored in the Economic Case and plans to manage realisation of them in the Management Case. The full benefits register is provided in Appendix M1.

Main Risks & Issues

All outstanding risks and issues from Phases 1 and 2 have been carried forward into Phase 3. These are identified in Appendix M2 and include:

Table 12 Risk & Issues

Ref	Risk Type	Risk	Mitigation
PROGRAMME RISKS & ISSUES			
008 (Issue)	Financial	Funding for NDCP procurement and implementation not secured:	Funding avenues are currently being explored.

		• WG confirmed no funding available for the procurement phase of NDCP • HB revenue funding for 2025/2026 (and ongoing) has not yet been secured, which could impact progress of the work.	Revisions to the BJC are in progress.
039 (Risk)	Financial	If revenue funding is no longer available for NDCP, there is a risk of not being able to procure a managed service contract which may result in obsolete equipment being out of date and HB's not in financial position to replace	Capital funds are now looking an unlikely option therefore revenue managed service contract. Alternative funding streams being investigated
OPERATIONAL RISKS & ISSUES			
002 (Risk)	Operational	Delays in integrating Leica scanners with current WLIMS1 data infrastructure. Risk that integration is not implemented within Project timescales. Impact on the ability for National reporting and, there will not be an interface for new LIMS if the interface for current LIMS not implemented.	Interface is available to link LIMS and Leica. Work ongoing to operationalise
004 (Risk)	Operational	NDCP Image Storage: risk of individual Cellular Pathology departments being unable to store images and therefore being unable to use DCP as a reporting tool.	NPP progressing the Phase 3 BJC which includes a long term national storage solution. WG funding provided to HBs for interim storage solution
040 (Risk)	Operational	Risk of a delay to the integration of new LIMS2.0 with newly procured DCP solution	Mitigation around specification and DCP specification working group working with potential suppliers and Intersystems. Implementation of new solution due to commence after LIMS2.0 deployment has finished

Constraints

The Project is subject to the following constraints:

- **Funding**. Phase 2 funding was not sufficient to digitise cellular pathology services as completely as possible. A partial implementation only has been achieved. Without further funding Phase 3, national scale up, will not be possible.
- **Image storage**. The 49TB of server storage initially purchased at each of the Health Boards is now almost full and further scanning will not be possible without the development of a long-term solution for image storage. In 2023, £150,000 has been allocated to each Health Board as an interim solution prior to a move to cloud storage as part of the full BJC.
- **Resources** For Phase 2, BCUHB agreed as an interim measure, to host the data hub (hub to store the meta data for all images). A permanent national image storage solution will be identified and agreed in Phase 3

The Project is subject to the following dependencies:

- The requirement for digital pathology system to integrate with the new LIMS service.

- Revenue funding from each of the individual Health Boards
- Local staff resource to support implementation and ongoing scanning capability incorporated once into the routine service.

4 Economic Case

Critical Success Factors

Critical Success Factors (CSFs) are the essential attributes for successfully delivering the Project and are used along with spending objectives that are outlined in the Strategic Case to evaluate the options. The CSFs are provided in the table below.

Table 13 Critical Success Factors

Critical Success Factor	How well the option:
Strategic Fit and Business Needs	• Meets the agreed spending objectives, related business needs and service requirements, and • Provides holistic fit and synergy with other strategies, Programmes and Projects.
Potential Value for Money	• Optimises public value (social, economic and environmental), in terms of the potential costs, benefits and risks.
Supplier Capacity and Capability	• Matches the ability of potential suppliers to deliver the required services, and • Is likely to be attractive to the supply side.
Potential Affordability	• Can be funded from available sources of finance, and • Aligns with sourcing constraints.
Potential Achievability	• Is likely to be delivered given the organisation's ability to respond to the changes required, and • Matches the level of available skills required for successful delivery.

Options Framework

The options framework, outlined in HM Treasury Green Book and Welsh Government Better Business Cases guidance, provides a systematic approach to identifying and filtering a broad range of options. An overview of the key dimensions within the options framework is provided in the table below.

Table 14 Key elements of the options framework

Dimension	Description
Scope	What to include in the future service model
Service solution	How to deliver the future service model
Service delivery	Who will deliver the future service model
Implementation	Timescales and phasing for delivering the future service model
Funding	Financing the future service model

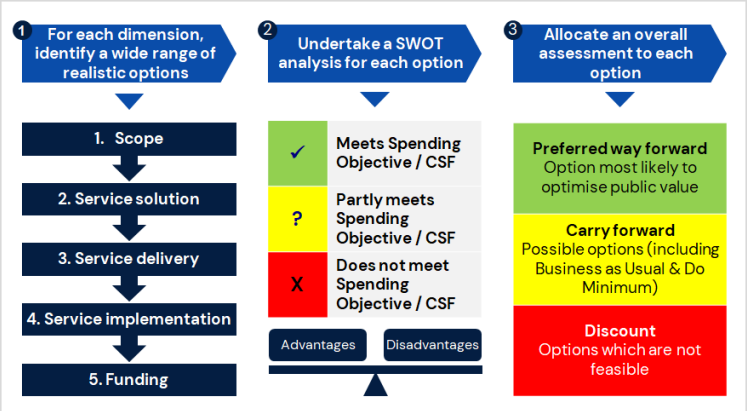
The process for identifying and assessing options takes each of the key dimensions in turn and undertakes the following steps:

- Identify a wide range of realistic potential options within that dimension
- Undertake an analysis for each option to:
  - Assess how well the option meets the Project's spending objectives and critical success factors; and

  - Identify the option's main strengths, weaknesses, opportunities and threats (SWOT analysis).
- Use the outputs of the analysis to determine whether the option will be carried forward as the preferred way forward, carried forward as a possible solution, or discounted at this stage.

A diagram illustrating this process is shown in the figure below.

Figure 4 Process to identify and assess the long list of options



A long list of options for each of the five dimensions was developed by the NDCP Project and evaluated to determine how well each meets the spending objectives and critical success factors at a series of workshops. The detailed analysis is provided in Appendix E1 and an overview in the table below.

Table 15 Summary of long list assessments

Project	Do Nothing	Do Minimum	Intermediate	Do Maximum
1. Service Scope *As outlined in Strategic Case*	All cases are reported using microscopes and glass slides. Would leave Wales behind the rest of the UK and could lead to collapse of service	Most cases are reported using microscopes and glass slides plus some limited digital reporting.		Most cases are reported digitally. Would ensure Wales keeps pace with rest of cellular pathology global community
	Carried Forward	**Carried Forward**		**Preferred Way Forward**
2. Service Solution *In relation to the preferred scope*	Return to previous process (glass slides and microscope)	Partial procurement and installation of digital capability for each Health Board.		National scale up of digital capability including image storage and digital hub solution.
	Carried Forward	**Carried Forward**		**Preferred Way Forward**
3. Service Delivery *In relation to the preferred scope and service solution*		NHS Wales purchases equipment and support provided via a maintenance contract		Fully managed service contract where provider owns and manages the digital solution
		Carried Forward		**Preferred Way Forward**

4. Implementation *In relation to preferred scope, solution and method of service delivery*		Phased approach in which HBs transition one at a time		Big Bang approach in which all HBs transition together
		Preferred Way Forward		**Discounted**
5. Funding *In relation to preferred scope, solution, method of service delivery and implementation*		Fully capital funded	Combination of capital and revenue funded (NHS owned asset/revenue model)	Fully revenue funded
		Discounted	**Carried Forward**	**Preferred Way Forward**

The possible options are carried forward to the shortlist as outlined in the table below.

Table 16 Developing the shortlist

Options	Do Nothing	Do Minimum	Intermediate Option	Preferred Way Forward (PWF)
Project Scope	All cases are reported using microscopes and glass slides.	Most cases are reported using microscopes and glass slides plus some limited digital reporting.	Most cases are reported digitally.	Most cases are reported digitally.
Project Solution	Return to previous process (glass slides and microscope).	Partial procurement and installation of digital capability for each Health Board.	National scale up of digital capability including image storage and digital hub solution.	National scale up of digital capability including image storage and digital hub solution.
Service Delivery	N/A	NHS Wales purchases equipment and support provided via a maintenance contract	NHS Wales purchases equipment and support provided via a maintenance contract	Fully managed service contract where provider owns and manages the digital solution
Project Implementation	N/A	Phased approach in which HBs transition one at a time	Phased approach in which HBs transition one at a time	Phased approach in which HBs transition one at a time
Project Funding	N/A	Combination of capital and revenue funded (NHS owned asset/revenue model)	Combination of capital and revenue funded (NHS owned asset/revenue model)	Fully revenue funded

Main Options

The resulting shortlist of options comprises:

- **Do Nothing:** Return to the pre-Project position with cellular pathology services reporting all cases using microscopes and glass slides. This would put the service at considerable risk and is no longer a viable option
- **Do Minimum:** Continue to with existing arrangements whereby cellular pathology services continue to report most cases using microscopes/glass slides and perform some digital reporting using current limited digital capability. This would require two pathways to operative simultaneously and would be prone to error and considerable inefficiency.

- **Intermediate Option:** Cellular pathology services utilise as much digital reporting as possible through national scale up of digital enablement, digital storage and digital hub solution, along with AI/computational pathology functionality. Funded through a combination of capital and revenue funding (NHS owned asset and ongoing support/maintenance contract).
- **Preferred Way Forward:** Cellular pathology services utilise as much digital reporting as possible through national scale up of digital enablement, digital storage and digital hub solution, along with AI/computational pathology functionality. Delivered through a fully revenue funded managed service contract (provider owns and manages the digital solution).

Options Appraisal

The key features of the shortlisted options included an analysis of advantages and disadvantages is provided below.

Table 17 Key features of Do Nothing

OPTION 1	**DO NOTHING**
Description	The 'do nothing' option reflects the position pre-Project where cellular pathology services reported all cases using microscopes and glass slides. If this option was to be used, all digital enablement and voice command procured pre-Project and in Phases 1 & 2 would not be utilised. The benefits demonstrated in the AI prostate project could not be realised.
Advantages	• No training on digital systems required • No digital image storage requirements • No requirement for digital hub
Disadvantages	• Wales not benefitting from digital technology whilst the rest of the UK takes advantage of the latest technology resulting in an adverse impact on patients as well as recruitment and retention. • Unsustainable in the long term likely to lead to backlogs • Decreased recruitment and retention of staff due to non-innovative practice • Unlikely to support Single Cancer Pathway TATs • Not utilising digital equipment purchased for Phases 1 & 2 • Not utilising the integration development between current supplier & LIMS • Unable to employ AI solutions • Inequity of service provision across Wales • Not aligned to international direction of travel for the service • Light microscopy will become a virtually obsolete diagnostic modality and it will be even harder to recruit pathologists particularity newly qualified pathologist and almost certainly impossible to support histopathology training in Wales again exacerbating the current recruitment issues
Conclusion	Cellular pathology services in NHS Wales are incredibly fragile and probably unsustainable in the long term. The increase in demand such as the current increase in volume of work during the Recovery Phase of COVID-19 has put additional strain on

	the service which has led to very lengthy backlogs in reporting and a significant increase in the volume and cost of outsourcing. As well as inability to deliver target turnaround times for many cancers.

Table 18 Key features of Do Minimum

OPTION 2	**DO MINIMUM**
Description	The 'do minimum' option reflects the current position whereby cellular pathology services continue to report most cases using microscopes /glass slides and perform some digital reporting using current limited digital capability.
Advantages	• Some digital enablement in each of the Health Board's • A small amount of cross boundary working e.g. BCUHB/SBUHB • Proved the proof of concept through interim hub and spoke formation and sharing of images • Ability to use a very limited amount of AI
Disadvantages	• Not aligned to international direction of travel for the service • Decreased recruitment and retention of staff • Unsustainable in the long term and already leading to significant backlogs • Unable to maximise the benefit from the use of AI • Unlikely to be able to support Single Cancer Pathway TATs • Inequity of service provision across Wales • Limited digital image storage
Conclusion	Cellular pathology services in NHS Wales are incredibly fragile and probably unsustainable in the long term. The increase in demand such as the current increase in volume of work during the Recovery Phase of COVID-19 has put additional strain on the service which has led to very lengthy backlogs in reporting and a significant increase in the volume and cost of outsourcing. As well as inability to deliver target turnaround times for many cancers.

Table 19 Key features of Preferred Way Forward Option - Capital

OPTION 3	**INTERMEDIATE**
Description	This option reflects a cellular pathology service that utilises as much digital reporting as possible through national scale up of digital enablement, digital storage and digital hub solution. Funded through a combination of capital and revenue funding.
Advantages	• Aligned to international direction of travel for the service • Digital storage solution • Sustainable equitable cellular pathology service across NHS Wales • The sharing of specialist clinical resource/expertise through improved digital networking of services in Wales progressing towards a proposed national network of cellular pathologists • Improvement in attractiveness of recruitment and retaining of staff

	• Ability to report nationally across Health Board boundaries to realise the Project ethos of any Consultant, reporting any case, from any location • National image sharing • AI/computational pathology can be better utilised to support and improve the quality of clinical diagnosis • Improve quality and drive innovation through the development of AI • Supports Single Cancer Pathway TATs • Access to different specialities e.g. lymphoma cases between BCUHB and SBUHB • Improve patient care through the use of a national digitalised network, facilitating quicker second opinions and facilitate cross boundary working • Improved MDT preparation by eliminating time spent collating cases for MDT review • Enable pathologists to interact easier with colleagues e.g. multi-disciplinary team meetings • Use in education, training (both in class and virtual) and for presenting at MDTs, tumour boards etc • Access to NHSE and UK wide expert networks for fragile services such as paediatric pathology and neuropathology which are difficult to sustain unilaterally in Wales. • Minimises revenue impact for Health Boards • Utilise digital equipment purchased during Phase 1 & 2 • Utilise integration developed between current supplier and new LIMS • Reduces risks associated with the transfer of tissues, tissue blocks and slides. • Digital images are not covered by the Human Tissue Act and therefore moving toward the use and storage of digital image for autopsy cases removes a significant existing HTA compliance risk with management and disposal of post mortem slides. • Reduces costs associated with secure storage and retrieval of PM slides across Wales. • Frees up existing internal space and reduce footprint refurbishment or new build costs. • Reduction in the carbon footprint
Disadvantages	• Training on digital systems required (much of this is already underway) • Digital image storage requirements • Requirement for digital Hub • Capital funding unlikely to be available over the longer term.
Conclusion	Option 3 would improve sustainability and equity of the service ensuring realisation of Project benefits but is unlikely to be affordable over the longer term because of ongoing capital

	investment requirements to replace and maintain the digital equipment in the future.

Table 20 Key features of Preferred Way Forward Option - Revenue

OPTION 4	**PREFERRED WAY FORWARD**
Description	The 'Preferred Way Forward' option reflects a cellular pathology service that utilises as much digital reporting as possible through national scale up of digital enablement, digital storage and digital hub solution. Delivered through a fully revenue funded managed service contract.
Advantages	• Aligned to international direction of travel for the service • Digital storage solution • Sustainable equitable future proofed cellular pathology service across NHS Wales • The sharing of specialist clinical resource/expertise through improved digital networking of services in Wales progressing towards a proposed national network of cellular pathologists • Improvement in attractiveness of recruitment and retaining of staff • Ability to report nationally across Health Board boundaries to realise the Project ethos of any Consultant, reporting any case, from any location • National image sharing • AI and computational pathology can be utilised to support and improve the quality of clinical diagnosis • Improved quality & drive innovation through the development of AI/computational pathology • Supports Single Cancer Pathway TATs • Greatly improved rapid access to different specialities as already demonstrated by referral of digitalised lymphoma cases between BCUHB and SBUHB and digitally supporting MDTs for national screening services such as cervical cytology from a specific site. • Improve patient care through the use of a national digitalised network, facilitating quicker second opinions and facilitate cross boundary working • Improved MDT preparation by eliminating time spent collating cases for MDT review • Enable pathologists to interact easier with colleagues e.g. multi-disciplinary team meetings • Use in education, training (both in class and virtual) and for presenting at MDTs, tumour boards etc • Ensures that all equipment and technology remains up to date over the life of the contract without the need for capital investment • Avoids the need for capital investment upfront and in the future. • Reduces risks associated with the transfer of tissues, tissue blocks and slides.

	• Reduces costs associated with secure storage and retrieval of PM slides across Wales. • Frees up existing internal space and reduce footprint refurbishment or new build costs. • Reduction in the carbon footprint • Utilise digital equipment purchased during Phase 1 & 2 • Utilise integration developed between current supplier and LIMS
Disadvantages	• Training on digital systems required (already ongoing) • Digital image storage requirements • Requirement for digital Hub • Increased revenue consequences for Health Board
Conclusion	Option 4 would improve sustainability and equity of the service ensuring realisation of Project benefits without the need for initial and future capital investment. A managed service contract will provide the flexibility to take advantage of innovations in the future however NHS Wales cloud could be considered too.

The options have been considered in further detail with a cost benefit analysis below.

Estimating Costs

For the purposes of the BJC, indicative costs have been estimated based on the information that is currently available. This includes:

- **Do Nothing:** It has not been possible to determine baseline costs at this stage as costs differ significantly across the service and are impacted by various factors. In any event, existing operating costs are expected to continue since there will be an ongoing need for the acquiring, using, and storing glass slides. Baseline costs are therefore excluded for comparison purposes as it is expected they would apply consistently to all options. Any opportunities for efficiency savings or cost reductions are dealt with in the benefits section.
- **Do Minimum:** Indicative costs have been estimated for the continuation of partial digital capability. This includes the cost of initial set up in each of the Health Boards (although this does not include costs for image storage, integration with LIMS or integration costs for speech) and ongoing annual costs for maintenance and warranty.
- **Intermediate Option:** Indicative costs have been estimated based on current knowledge of the market and anticipated resource requirements as outlined in the Financial Model (Appendix F1).
- **Preferred Way Forward:** Indicative costs have been estimated based on current knowledge of the market and anticipated resource requirements as outlined in the Financial Model (Appendix F1).

The table below outlines the resulting indicative costs for each of the options over a 20-year appraisal period:

Table 21 Indicative Costs

	Option 0 - BAU	Option 1 - Do Min	Option 2 - Cap/Rev	Option 3 - PWF (Rev)
	£'000	£'000	£'000	£'000
Project Team	0	0	826	0
DHCW Support	0	74	0	0
Solution Costs	0	672	8,184	0
Initial capital costs	**0**	**746**	**9,010**	**0**
Lifecycle costs (20-year appraisal period)	0	1,492	16,368	0
Whole life capital costs	**0**	**2,238**	**25,377**	**0**
Project Team inc. DHCW element (non-recurring)	0	0	0	423
DHCW Support (Recurring)	0	0	966	1,728
Additional Health Board staff (20-year appraisal period)	0	0	9,498	9,498
Solution Costs (20-year appraisal period)	0	0	53,980	56,368
Maintenance and Warranty (20-year appraisal period)	0	608	0	0
Whole life revenue costs	**0**	**608**	**64,443**	**68,017**
Total whole life costs (20-year appraisal period)	**0**	**2,846**	**89,821**	**68,017**
Equivalent Annual Costs	**0**	**142**	**4,491**	**3,401**

Estimating Benefits

The Project to date has identified specific benefits associated with these factors and work has been undertaken to quantify them, building on experience of the first two phases and establishing baseline positions and target improvements. Where possible, these metrics have been stated in monetary equivalent values to enable a thorough cost benefit analysis to be prepared.

For the purposes of the BJC, indicative values have been estimated to determine the potential opportunities available to NHS Wales organisations for the following categories of financial benefits:

- **Cash releasing benefits:** Direct cost saving as results of reduced resource requirements.
- **Non-cash releasing benefits:** Productivity savings that can be quantified in monetary equivalent values but are not expected to directly reduce costs although they will release staff time to focus on alternative activities.
- **Societal benefits:** Indirect benefit that will be realised by wider society and can be quantified in monetary equivalent values.

For the purposes of the BJC, efficiency benefits are assumed to be non-cash releasing to give an indication of the scale of opportunity available, but this will be reviewed in detail as the benefits are developed and opportunities sought to convert into cash releasing benefits.

Calculations are based on the early phases and findings at BCUHB and individual Laboratory Managers' assessments of how this is expected to apply at a Health Board level. The main assumptions are outlined in the following table with the total NHS Wales impact outlined. Specific Health Board assumptions and values are provided in Appendix M1.

Table 22 Benefits Overview

ID	Description	Measure	Target Improvement	Value £'000	Assumptions
Increased capacity to meet growing demand					
B01	Streamlined workflow and greater ability to recruit and retain suitably skilled staff will contribute to increasing capacity to enable the service to meet growing demand. This will reduce reliance on outsourcing in the future.	Outsourcing and temporary staffing costs	Potential cost avoidance in the future	**See risk R2 below**	It is not possible to reduce current outsourcing costs because there are multiple factors which drive the need for external capacity. However, full digitisation could potentially reduce the need for increased outsourcing / use of locums in the future to deal with growing demand, as the streamlined workflow and better recruitment/retention will increase future internal capacity.
Streamlined workflow leading to productivity gains					
B02	Greater ability to get the section quality right first time will reduce the need to re-work slides	Number of reworked slides	**823 fewer slides re-worked** each year across Wales	**£4k p.a.** Non-cash releasing	Based on Health Boards' assessments of the potential in reduced number of reworked slides for each lab, based on estimated average cost per re-cut.
B03	Use of voice recognition/command software reduces workforce time spent reporting on H&E samples	Number of hours spent reporting on H&E samples	**2,984 fewer hours spent reporting on H&E samples** each year across Wales	**£146k p.a.** Non-cash releasing	Based on Health Boards' assessments of the potential in time saving, based on average salaries of staff involved in the process.
B04	Ability to link H&E and IHC /special stains on screen will reduce the amount of time workforce spend linking individual cases	Number of hours spent linking cases	**2,866 fewer hours spent linking cases** each year across Wales	**£63k p.a.** Non-cash releasing	Based on Health Boards' assessments of the potential in time saving, based on average salaries of staff involved in the process.
B05	Ability to undertake online real time consultations and reviews will reduce the amount of time workforce spend searching for and sharing case information	Number of hours spent searching for and sharing case information	**4,491 fewer hours spent searching for and sharing case information** each year across Wales	**£80k p.a.** Non-cash releasing	Based on Health Boards' assessments of the potential in time saving, based on average salaries of staff involved in the process.

ID	Description	Measure	Target Improvement	Value £'000	Assumptions
B06	Easier access to archived slides and case tracking, archival and retrieval will reduce the amount of time workforce spent filing and retrieving slides	Number of hours spent slide filing and retrieval	**5,764 fewer hours spent on slide filing and retrieval** each year across Wales	**£78k p.a.** Non-cash releasing	Based on Health Boards' assessments of the potential in time saving, based on average salaries of staff involved in the process.
B07	Improved access to external second opinion and improved case transfer times will reduce the amount of workforce time spent sending slides	Number of hours spent sending slides	**5,357 fewer hours spent sending slides** each year across Wales	**£78k p.a.** Non-cash releasing	Based on Health Boards' assessments of the potential in time saving, based on average salaries of staff involved in the process.
B08	Easier access to archived slides and case tracking, archival and retrieval will reduce the amount of workforce time spent preparing for MDT meetings	Number of hours spent preparing for MDT meetings	**9,558 fewer hours spent preparing for MDT meetings** each year across Wales	**£139k p.a.** Non-cash releasing	Based on Health Boards' assessments of the potential in time saving, based on average salaries of staff involved in the process.
B09	Fully automated electronic case assembly will reduce the amount of workforce time spent assembling cases	Number of hours spent assembling cases	**7,643 fewer hours spent assembling cases** each year across Wales	**£155k p.a.** Non-cash releasing	Based on Health Boards' assessments of the potential in time saving, based on average salaries of staff involved in the process.
Non-pay costs					
B10	Use of 2D bar codes to identify requests, specimens, blocks, slides and images reduces the need for paper labels	Number of labels printed	Limited information available to measure improvement	Unmonetisable	Data is not currently available from Health Boards to quantify at this stage. However, when fully integrated, this is likely to be cash releasing.
B11	Single identifier for a sample across Wales will reduce the need to transport slides	Number of slides transported	Limited information available to measure improvement	Unmonetisable	Data is not currently available from Health Boards to quantify at this stage. However, BCU identified this as a cash releasing benefit during earlier phases
B12	Reduced risk of tissue/slide loss or damage will reduce the need to repeat tissue collection	Number of tissue samples/slid	Limited information available to measure improvement	Unmonetisable	Data is not currently available from Health Boards to quantify at this stage

ID	Description	Measure	Target Improvement	Value £'000	Assumptions
		es lost or damaged			
Improved workforce experience					
B13	More flexible of ways of working open to the workforce as the new system will enable remote working	Not easily measurable	Qualitative	Unmonetisable	Not easily measurable but enabling more flexible ways of working will contribute to the recruitment and retention of staff
B14	Teaching, training and mentoring	Not easily measurable	Qualitative	Unmonetisable	
B15	Improved recruitment and retention of highly skilled staff	Not easily measurable	Qualitative	Unmonetisable	Not easily measurable but investing in digitisation which keeps pace with the rest of the UK and wider global Pathology community will support the recruitment and retention of staff
Improved patient outcomes					
B16	Prioritisation of cases to meet cancer targets	Not easily measurable	Qualitative	Unmonetisable	
B17	Speedier diagnosis of urgent cases	Not easily measurable	Qualitative	Unmonetisable	
B18	Reduced risk of patient/slide misidentification errors	Not easily measurable	Qualitative	Unmonetisable	
Opportunities to deliver benefits of Computational Pathology and AI					
B19	AI/computational pathology for enhanced cancer research	Not easily measurable	Qualitative	Unmonetisable	
Other system improvements					
B20	Automated case allocation to pathologist	Not easily measurable	Qualitative	Unmonetisable	
B21	Electronic test request and workload management in lab	Not easily measurable	Qualitative	Unmonetisable	

ID	Description	Measure	Target Improvement	Value £'000	Assumptions
	enabling improved planning and work force management				
B22	Synchronous analysis of slides	Not easily measurable	Qualitative	Unmonetisable	
B23	Flip and rotate images to aid interpretation	Not easily measurable	Qualitative	Unmonetisable	
B24	Measurement and annotation	Not easily measurable	Qualitative	Unmonetisable	
B25	Improved ergonomics	Not easily measurable	Qualitative	Unmonetisable	
B26	Use of annotated scanned image to identify tumour areas required for genomic analysis	Not easily measurable	Qualitative	Unmonetisable	
B27	Transfer of information on electronic request direct to report	Not easily measurable	Qualitative	Unmonetisable	
B28	Clearer diagnostic audit trails	Not easily measurable	Qualitative	Unmonetisable	
B29	Quantification of specific cells and markers	Not easily measurable	Qualitative	Unmonetisable	
B30	Highlighting and heat mapping of areas of abnormality	Not easily measurable	Qualitative	Unmonetisable	
B31	Quality control and audit	Not easily measurable	Qualitative	Unmonetisable	
B32	Automatic formatting of certain reports such as normal colonic biopsies based on AI pre-screened slides	Not easily measurable	Qualitative	Unmonetisable	

ID	Description	Measure	Target Improvement	Value £'000	Assumptions
B33	Research resource	Not easily measurable	Qualitative	Unmonetisable	
B34	AI to identify micro-organisms	Not easily measurable	Qualitative	Unmonetisable	
B35	Assessing disease progression	Not easily measurable	Qualitative	Unmonetisable	
B36	Fewer microscopes to service in the future	Not easily measurable	Qualitative	Unmonetisable	
B37	Capture of digital image at macro dissection using macro path systems	Not easily measurable	Qualitative	Unmonetisable	
B38	Digital dictation direct into report in dissection room	Not easily measurable	Qualitative	Unmonetisable	

The resulting indicative benefits values have been applied to the options as follows:

- **Do Nothing:** will not deliver any benefits.
- **Do Minimum:** will only allow partial delivery of benefits since it will provide limited digital capability. For the purposes of the BJC it is assumed that 10%-20% of activity will use digital reporting. However, to reflect the inefficiencies that will be inherent in dual running of a system, this is reduced by half and so it is assumed that just 7.5% of potential benefits are deliverable.
- **Preferred Way Forward:** Provides the opportunity to deliver 100% of the benefits value.

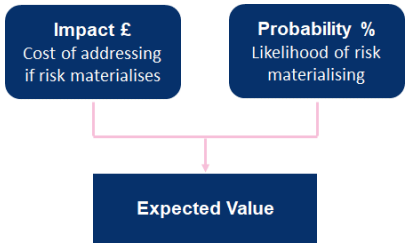
Estimating Risks

To present a comprehensive cost benefit analysis, an indicative assessment of risks has been undertaken and efforts made to quantify these in monetary equivalent values. The main risks that have been considered for this purpose are:

- Risk that digital cellular pathology information and images are not backed up as data storage is not resolved.
- Risk that inadequate systems impact on sustainability of services

These risks have been quantified by calculating an 'expected value'. This provides a single value for the expected impact of all risks. It is calculated by multiplying the likelihood of the risk occurring (probability) by the cost of addressing the risk (impact) and summing the results for all risks and outcomes.

Figure 5 Risk quantification approach using single-point probability analysis



The assumptions included to assess the impact and probability of these risks are outlined in the tables below:

Table 23 Risk Assumptions

	Do Nothing	Do Minimum	Preferred Way Forward
R1: Data storage			
Risk	**Digital cellular pathology information and images are not backed up as data storage is not resolved.**		
Consequence	**Data images could be lost impacting on diagnostic reporting**		
Impact	Benefits will not be realised - Do Minimum: £56k p.a.; Preferred Way Fwd.: £773k p.a.		
Probability	N/A	75%	1%
Timescales	N/A	Years 0-20	Years 0-20
Risk Value £'000 (Total 20-year)		**836**	

	Do Nothing	Do Minimum	Preferred Way Forward
R2: Sustainability			
Risk	**Risk that inadequate systems impact on service sustainability**		
Consequence	**In addition to patient impact (which is not quantifiable in monetary terms), staff morale and ability to recruit impacted.**		
Impact	Vacancies will increase - Assume that between 20% - 40% of current established Pathologists posts (equates to between 12 – 24 WTE) become vacant and cannot be recruited to and that this would result in additional temporary staff costs. Assuming 25% premium on average pay costs, equates to an impact of £288k - £576k p.a.		
Probability	80%	80%	1%
Timescales	Years 0-20	Years 0-20	Years 0-20
Risk Value £'000 (Total 20-year)	**6,912**	**6,912**	**86**

Economic Appraisal Results

The indicative assumptions above have been incorporated into a discounted cash flow for each of the options, using DHSC's Comprehensive Investment Appraisal (CIA) model, to support the appraisal of overall value for money and cost-benefit analysis of the shortlisted options. In line with HMT Green Book requirements:

- Costs, benefits and risks are calculated over a 20-year appraisal period.
- Year 0 is 2025/26.
- Costs and benefits use real base year prices – all costs are expressed at 2023 prices in line with the baseline costs.
- The following costs are excluded from the economic appraisal:
- Exchequer 'transfer' payments, such as VAT.
- General inflation.
- Sunk costs.
- Non-cash items such as depreciation and impairments.
- A discount rate of 3.5% is applied.

The results of the economic appraisal suggest that the Do Minimum provides a better net present cost than the two Preferred Way Forward options because of the minimal costs involved. However, there are several other factors that should be considered in comparing the options:

- The Do Nothing and Do Minimum options represent significant risks that it is not possible to express in monetary values and so are not accounted for in this analysis, such as sustainability impact on patients and the wider service and inequity of service across Wales.
- The Preferred Way Forward is necessary to deliver a service that is in line with international best practice and provides opportunities for maximising benefits through the adoption of AI/computational Pathology technologies.

A summary of the overall options appraisal is provided in the following table:

Table 24 Options appraisal summary

	Do Nothing	Do Minimum	PWF – Capital / Revenue	PWF - Revenue
Net Present Cost (£'000)	**Unable to be calculated, see pg.49**	**4,749**	**41,715**	**34,370**
Benefit Cost Ratio	**-**	**0.05**	**0.67**	**0.81**
Significant non-financial benefits	N/A	Some benefits for small proportion of activity.	Service in line with international direction of travel. Improved collaboration and flexibility of service. Opportunities to maximise benefits e.g. adoption of AI.	Service in line with international direction of travel. Improved collaboration and flexibility of service. Opportunities to maximise benefits e.g. adoption of AI. Managed service contracts provide opportunities to keep pace with technological advances
Residual risks	Significant risk to sustainability and inequitable service across Wales. Unable to provide modern Pathology service leading to challenges recruiting and retaining workforce.	Significant risk to sustainability and inequitable service across Wales. Unable to provide modern Pathology service leading to challenges recruiting and retaining workforce. Ongoing inefficiencies of running two systems.	Capital investment required initially and in the future Restricts opportunities to keep pace with technological advances	Additional revenue funding required from HBs

Preferred Option

Based on the financial and non-financial analysis above, the Preferred Way Forward has the highest cost benefit ratio, based on delivering cash benefits in the form of significantly reducing the requirement for outsourcing from year 3 when the digital cellular pathology solution is fully in place and based on Health Boards/Trust experience, organisations are more able to attract consultant staff. This option involves a national scale up digital reporting which is recommended as

the preferred option. This will be delivered via a combination of Health Board revenue funding - both non-recurring and recurring.

Although Option 2 Capital/Revenue model could deliver the same benefits, it is at a higher cost so the cost benefit ratio is lower. Option 1, Do minimum has the lowest cost benefit ratio due to only delivering 10% of the benefits that options 2 and 3 are able to deliver.

5 Commercial Case

The Commercial Case sets out the procurement route and seeks to demonstrate that the preferred option will result in a viable procurement and a well-structured deal between the public sector and the supplier.

Procurement Route

Three procurement models were considered as part of the options framework. These are:

1) **Traditional Purchase and Service Support Model**: In this model the equipment and software is purchased outright as a capital asset and is owned by NHS Wales. The supplier implements the system, but once implemented it would be managed by NHS Wales with the supplier providing technical and service support under a contract arrangement requiring recurrent revenue funding. The service support contract would still include all the same management responsibilities and KPIs etc as a managed service provider model.
2) **Managed Service Provider Model**: In this model, NHS Wales purchases a "service" from the supplier. The supplier then implements and manages the system with charges based on fee-per-service arrangements. NHS Wales does not own the hardware or software. This model moves most of the capital acquisition costs into recurrent revenue budget, spreading that expenditure across the life of the system.
3) **Hybrid Model**: The extent of the managed service provider model may be limited, for example with NHS Wales taking ownership of some infrastructure either located in NHS organisations and/or an NHS Data Centre, but with the supplier taking responsibility for management and ongoing service support. As with the traditional purchase and service support model this would involve capital and revenue accounting treatment of costs and associated funding.

The managed service provider model has been selected as the preferred way forward, following review by the NDCP Project Board and NHS Wales Executive. Two procurement routes were explored: full tender and a framework agreement. The strengths and weaknesses of each route are outlined in the table below.

Table 25 Procurement route options - strengths and weaknesses

Tender Process		**Framework Agreement**	
Strengths	Weaknesses	Strengths	Weaknesses
All suppliers can bid therefore not limiting market	Can increase timelines slightly	Doesn't require an advert out to Find a Tender Service (FTS)	Some suppliers on potential framework 1 and other suppliers on potential framework 2 limiting bidders.
Can shape specification exactly to requirements		Could reduce timelines slightly	Having engaged with the market, suppliers could potentially challenge why we have used a framework limiting competition. Justification would be required as to why framework used.
Other procedures can be used that may aid			QE Procurement Framework only

the process e.g. a competitive procedure with the negotiation, or a competitive dialogue if required			permits purchase of a full solution so scanners and PACS must be from same supplier (albeit this could be a primary bidder who is supplying products from another manufacturer)

It has been agreed by the NDCP Project Board that a full tender process is the most suitable route.

Procurement Scope and Specification

The principal aim of the procurement is to procure appropriate services to create a fully digitised cellular pathology service that will replace the existing traditional microscopy service. The scope of the procurement (as agreed by the NDCP Project Board) is explained in more detail on page 38:

- **Slide scanners**
- **Medical grade screens**
- **Management systems**
- **Additional workstations/laptops**
- **Image storage**
- **AI/computational pathology**
- **Standardisation of services**
- **Adoption of technical standards for image formats**

It should be noted that the Procurement scope does not include tissue processors, stainers and other specialist laboratory equipment. These are out of scope since the standardisation of existing equipment is not currently considered achievable due mainly to cost.

The final specification will be agreed following pre-tender engagement with suppliers. It will be made clear as part of any procurement exercise that all images remain the property of the Health Boards. The Health Boards will remain responsible for ensuring data protection and security. This provides extra resilience and security through independent review. It is anticipated that all data collected will form part of the single patient record.

Timeline for Procurement

The table below sets out the procurement milestones and complies with all applicable legal requirements.

Table 26 Key Procurement Milestones

Activity	Date
Update specification of requirements	Ongoing
Sign off final specification and agree award criteria	April 2025
Publish ITT	April 2025
ITT response deadline	June 2025

Activity	Date
Evaluation of responses	June - October 2025
Contract award	November 2025
Contract start date	April 2026 (staggered across Health Boards)

Payment Mechanism

Payment mechanisms will be confirmed when the preferred bidder is identified.

Contractual Arrangements

An FTS tender procedure has been established as the most suitable procurement route. This will require the development of a specification of requirements. This will be undertaken by the NDCP Project, taking account of lessons learned from other similar initiatives.

Key aspects of the contractual relationship that the NDCP Project is seeking to achieve will be reflected in the contract as follows:

- Value for Money (VfM) – the proposed procurement will have an underpinning financial model that provides transparency and certainty around costs for key system and service elements. These costs can be considered alongside how well the system design meets the clinical and technical requirements. The aim is to secure the optimum combination of whole-of-life costs and quality (or fitness for purpose) of the system and services to meet NHS Wales requirements. A value-based approach to procurement should be adopted to deliver long-term outcomes for patients, including improved patient experience and better clinical outcomes. A key contractual issue when considering the VfM is how risks are allocated between the supplier and NHS Wales.
- Intellectual Property Rights (IPR) – The IPR from the application and the interfaces is not envisaged to have significant value for the Contracting Authority and need not be pursued to any major extent. In instances where the Authority works with the successful Contractor to develop and refine clinical content, question sets and workflow, then IPR equivalent to the invested resource by the Authority shall be retained.
- Warranties and guarantees – this is notionally a high-cost deal and the perceivable risk of loss (of the service) is moderate, given its intended use by the NHS in Wales. These should be pursued within the contract.

Legal and Personnel Implications

It is anticipated that a Programme Manager will be appointed to lead the Procurement Project working to the National Pathology Portfolio Programme Lead. The Programme Manager will manage the procurement, working with the Procurement Lead allocated by NWSSP and specialist advice as required.

It is likely that specific individuals will be involved across multiple activities and/or may undertake more than one role in order to ensure consistency and assist in securing an appropriately robust outcome. The combined staff and consultancy

team will cover the following roles for the procurement (for more details see page 17):

a) **National Digital Cellular Pathology Project Team**
b) **NWSSP Procurement Project Team**
c) **Health Board Representatives**
d) **DHCW Representatives**

It is not expected that any Phase 3 activities will fall under TUPE – Transfer of Undertakings (Protection of Employment) Regulations 1981.

6 Financial Case

Introduction

At the time of writing the BJC, limited supporting information is available to determine accurate costs, therefore indicative figures have been estimated based on initial information received from suppliers and the assumptions outlined below.

Accounting Treatment

Given the lack of clarity around costs at this stage, assumptions have been made about the appropriate financial treatment. These will be validated during the procurement process as specifications are drafted and tenders received by potential suppliers outlining firm costs and potential contractual arrangements.

Capitalisation

Since the preferred option involves delivering the digital cellular pathology solution via a managed service contract, it is anticipated that no assets will be created, and therefore all costs associated with the scheme will be treated as revenue costs.

IFRS16

The baseline assumption of this business justification case is that this will be a revenue cost driven solution, however as part of the procurement exercise an assessment of the service offering, contractual requirement, terms & conditions and ownership will be required to ascertain whether there are any portions of the "managed service" (broken down within the supplier financial model) that constitute a "right of use asset".

This principle would mean that any embedded lease's C-DEL (Capital Delegated Expenditure Limit) impact will occur at the time of procuring the right of use asset & lease liability and will equal the value of the right of use asset necessitating a transfer from revenue to capital, the mechanism for completing this via the "revenue recovery" process will be made clear within the final case (if required).

VAT

Initial advice will be sought from one of the NHS Wales VAT advisors as to the possible VAT accounting treatment for the procurement in order to ascertain the likely VAT treatment of the contract. Initial review of VAT guidance would suggest:

- In relation to Software as a Service (SaaS) and Cloud Services, the current HMRC view is based on the question - is the solution as a whole something that can be demonstrated to be 'to the specification of' NHS Wales. If NHS Wales can demonstrate that the answer to this question is yes, as appears to be the case for this procurement, the costs should be VAT recoverable.
- All participating organisations, at the time of placing local deployment orders, should consult with their own VAT advisors and auditors to ensure VAT treatment is compliant with HMRC definitions. For the purposes of this iteration of the BJC, it is assumed that all capital costs (excluding capitalised staff) are not deemed VAT recoverable whilst ongoing service provision, support and maintenance will be recoverable as per COS Heading 14 - Computer services supplied to the specification of the recipient.

This assumption regarding VAT accounting will be confirmed with NHS Wales VAT Advisors as the procurement progresses and the design of the solution and contract terms become clearer.

Costing Methodology

Indicative costs for delivering the preferred option have been estimated for the following categories:

- Project team
- DHCW support
- Solution costs
- Additional Health Board staff

Further details are available in Appendix F1. The methodologies for estimating these cost categories are outlined below.

Implementation Plan

While a detailed project plan will need to be developed and agreed with the final preferred bidder for the solution, for the purposes of the BJC the following timescales are assumed:

- Procurement process: April 2025 – March 2026
- Implementation period: April 2026 – March 2027

Project Team

The cost of the Project team has been estimated based on the staff required to provide support in the initial 3 years of the programme including:

- 1 WTE Band 8a Programme Manager.
- 1 WTE Band 4 Senior Project Support Officer.

The cost of the following will be required for procurement and length of contract:

- 1 WTE Band 7 NWSSP Procurement Project Manager/Category Manager

It is assumed that the National Pathology Portfolio Programme Lead and Senior Project Manager will continue to be funded through the National Pathology Programme budget.

DHCW Support

The cost of DHCW support has been based on anticipated requirements for the development of the infrastructure and integration of the new solution plus the ongoing support including:

- 0.5 WTE Band 8b Lead Engineer Networking.
- 0.5 WTE Band 8a Infrastructure Design (non-recurring).
- 0.5 WTE Band 6 Support Integration.
- 0.5 WTE Band 6 Development Integration.

Solution Costs

Market testing was undertaken to obtain an indication of the likely cost of procuring a solution. Potential bidders provided anticipated costs for each of the

Health Boards based on current cellular pathology activity levels. This included annual charges associated with:

- Digital scanners, workstations and any other hardware required.
- Integration into LIMS
- Storage
- Software (including voice recognition)
- Artificial Intelligence.
- Service.
- Training.
- Managed service contract fee.

The annual running costs are therefore estimated at an average of £3.2m p.a. over a 9-year period based on the following:

- Contingency of 20% to reflect the high degree of uncertainty around these costs in advance of the procurement process.
- At this stage, it is assumed that these costs will be classified as revenue expenditure. It should be noted that this will be subject to further review and advice from specialist advisors.
- As outlined above, it is assumed for the purposes of the BJC that VAT will be recoverable.

Solution costs are expected to be incurred from April 2026 at the start of the implementation period (bandwidth/infrastructure due to be incurred during 2025/26 in readiness for implementation of new solution).

Additional Health Board Staff

It is anticipated that there will be ongoing revenue costs associated with Health Board staff requirements from 2025/26 including:

- Band 6 Biomedical Scientist – 1 WTE per Health Board.
- Band 3 Healthcare Support Worker – 1 WTE per Health Board.
- Band 7 IT – 1 day per week per Health Board, reducing to 0.5 day per week from 2028/29 onwards.

It is anticipated that these roles are recruited and in post 6 months prior to implementation.

Capital Requirements

As the solution is anticipated to be delivered via a managed service contract, no capital investment is expected.

Revenue Requirements

Based on the assumptions outlined above, it is anticipated that the revenue consequences of implementing the preferred option will include the following:

- **Non-recurring revenue funding of £423,000 requested from Health Boards (£71,000 per HB)** for the implementation costs associated with the project team and DHCW support between 2025/26 – 2027/28.
- **Ongoing revenue funding which in total equates to £34.4m between 2025/26 – 2034/35 requested from Health Boards,** related to annual recurring revenue costs associated with the managed service contract for the

solution and additional staff required to support Health Boards with the implementation and ongoing management of the solution.

An indicative apportionment of the recurring revenue costs by Health Board based on potential providers assessment of existing workload is provided below.

Table 27 Indicative Revenue Costings

	Year 0	Year 1	Year 2	Year 3	Year 4	Year 5	Year 6	Year 7	Year 8	Year 9	
	2025/26 £'000	2026/27 £'000	2027/28 £'000	2028/29 £'000	2029/30 £'000	2030/31 £'000	2031/32 £'000	2032/33 £'000	2033/34 £'000	2034/35 £'000	Total £'000
Project Team (non-recurring)	101	101	50								251
DHCW Support (non recurring)	34	34	34								101
20% Contingency	27	27	17								71
Non-recurring revenue costs	**161**	**161**	**101**	-	-	-	-	-	-	-	**423**
Project Team (recurring - contract manager)	57	57	57	57	57	57	57	57	57	57	574
Solution Costs (recurring)	28	3,336	3,103	3,172	3,251	3,333	3,418	3,493	2,525	2,525	28,184
Health Board Additional Staff (recurring)	263	525	525	491	491	491	491	491	491	491	4,749
DHCW Support (recurring)	86	86	86	86	86	86	86	86	86	86	864
Recurring revenue costs	**434**	**4,005**	**3,772**	**3,807**	**3,886**	**3,967**	**4,053**	**4,127**	**3,160**	**3,160**	**34,371**
Total costs	**595**	**4,167**	**3,873**	**3,807**	**3,886**	**3,967**	**4,053**	**4,127**	**3,160**	**3,160**	**34,795**

		Year 0	Year 1	Year 2	Year 3	Year 4	Year 5	Year 6	Year 7	Year 8	Year 9	
	Apportionment	2025/26 £'000	2026/27 £'000	2027/28 £'000	2028/29 £'000	2029/30 £'000	2030/31 £'000	2031/32 £'000	2032/33 £'000	2033/34 £'000	2034/35 £'000	Total £'000
ABUHB	16.32%	72	656	618	623	636	650	664	676	518	518	5,631
BCUHB	17.18%	72	685	645	651	664	678	693	706	540	540	5,874
CTMUHB	11.42%	71	493	466	468	477	487	496	505	394	394	4,251
CVUHB	24.53%	75	930	873	884	903	923	944	963	725	725	7,945
HDUHB	12.96%	71	544	514	517	527	538	549	558	433	433	4,684
SBUHB	17.58%	73	698	657	663	677	692	707	720	550	550	5,986
Total Recurring Revenue Costs	**100.00%**	**434**	**4,005**	**3,772**	**3,807**	**3,886**	**3,967**	**4,053**	**4,127**	**3,160**	**3,160**	**34,371**

	Year 0	Year 1	Year 2	Year 3	Year 4	Year 5	Year 6	Year 7	Year 8	Year 9	
	2025/26 £'000	2026/27 £'000	2027/28 £'000	2028/29 £'000	2029/30 £'000	2030/31 £'000	2031/32 £'000	2032/33 £'000	2033/34 £'000	2034/35 £'000	Total £'000
ABUHB	27	27	17								71
BCUHB	27	27	17								71
CTMUHB	27	27	17								71
CVUHB	27	27	17								71
HDUHB	27	27	17								71
SBUHB	27	27	17								71
Total Non-Recurring Revenue Costs	**161**	**161**	**101**	-	-	-	-	-			**423**

Affordability

Indicative costs have been estimated at this stage based on current market knowledge and resourcing requirements. Costs are outlined in Appendix F1, and a detailed explanation of the costing methodology is included above. In summary these include:

- **Solution costs:** Procurement of a managed service contract to provide digital scanners, workstations, other hardware, integration with other systems, software, training and the ongoing storage and service to maintain the system. Costs at this stage are based on the results of recent market testing.
- **Project Team:** Including non-recurring costs of Programme Manager and Senior Project Support Officer and recurring costs of NWSSP Procurement Project Manager/Category Manager. It is assumed that the National Pathology Portfolio Programme Lead and Senior Project Manager will continue to be funded through the National Pathology Programme budget.
- **DHCW Support:** Non-recurring and recurring costs based on anticipated DHCW requirements for Lead Engineer Networking, Support Integration, Development Integration and Infrastructure Design roles.
- **Additional Health Board Staff**: Ongoing cost of a Band 6 BMS, Band 3 Healthcare Support Worker and 1 day per week of Band 7 IT support for each Health Board.

Based on these assumptions, it is anticipated that funding is required as follows:

- **Non-recurring revenue funding of £423,000 requested from Health Boards (£71,000 per HB)** for the implementation costs associated with the project team and DHCW support between 2025/26 – 2027/28.
- **Ongoing revenue funding which in total equates to £34.4m between 2025/26 – 2034/35 requested from Health Boards,** related to annual recurring revenue costs associated with the managed service contract for the solution and additional staff required to support Health Boards with the implementation and ongoing management of the solution.

This investment will deliver a wide range of benefits, most critically the ability of the service to keep pace with the rest of the UK and enable it to attract and retain the highly skilled staff required to address the growing capacity gaps within the service.

While many of the benefits related to this investment are not easily quantifiable in monetary terms, service leads at each of the Health Boards have identified a range of productivity gains as a result of a more streamlined workflow which will reduce the time currently spent on existing manual processes. A prudent assessment of the total number of hours saved across Wales equates to around £750k of staff time saved each year which can be re-directed to deal with growing demand.

As demand continues to grow in the future, the value of these productivity gains will be even greater. This combined with greater ability to attract and retain workforce will reduce the risk that increased activity will need to be outsourced to external providers or covered by expensive temporary staffing in the future.

In addition to this, realisation of the substantial wider system benefits offered by AI/computational pathology, will only be possible following investment in the digital cellular pathology solution.

7 Management Case

Project Management Arrangements

The Project is being managed in accordance with the standards set out in Managing Successful Programmes (MSP).

Project Management Principles

The principles that will be observed by the work undertaken by the NDCP Project are:

- Remaining aligned with national strategy
- Leading change
- Envisioning and communicating a better future
- Focusing on benefits such as improving outcomes, patient benefit and service efficiencies
- Adding value
- Designing and delivering coherent capability
- Learning from experience

Governance

Governance Framework

The Governance Framework that will be developed will build on current arrangements, ensuring that:

- Governance, decision-making and escalation routes are transparent.
- Decisions, including investment decisions, are better informed.
- Lines of accountability are clear, as are limits of authority and delegations.
- Efforts are focused on delivering results rather than on processes.
- Standards and processes are simple and clear.
- Strategic oversight and governance of the Project is maintained.
- The whole contributes towards a clear and consistent vision.
- There is adequate design assurance (business and technical).
- Risks and interdependencies are identified and managed
- SROs, and Project teams, are clear about their roles and responsibilities for delivering outcomes and what they are being asked to achieve.
- There is clear ownership of and accountability for delivering benefits
- Programme and Project Management (PPM) knowledge and best practice can be readily shared.
- PPM capability is developed and relevant behaviours become embedded.
- The need for support or resources can be identified at an early stage.

Structure

The suggested structure to enable the NDCP Project to effectively develop and deliver the "new capability" is outlined in the following diagram:

Figure 6 Programme Structure

Sponsoring Group

The key role of the Sponsoring Group is to ensure the Project remains aligned with the strategic objectives for NHS Wales and resolve any conflicts arising from directional/policy changes or overlap with interfacing Programmes or initiatives. Its role is also to approve any investment decisions and sign off final delivery and closure of the Project. The National Strategic Planned Care Board will be performing this role.

Senior Responsible Owner

The SRO role is concerned with the leadership, direction and ultimate accountability for delivery of the Project and management of risk.

National Pathology Portfolio Programme Lead

The National Pathology Portfolio Programme Lead is responsible for ensuring the Project remains aligned to the deliverables within the Pathology Statement of Intent, reporting on progress to National Pathology Programme Strategic Group.

Programme Manager

The Programme Manager is responsible for establishing the Project arrangements, governance and the delivery of new capabilities or outcomes. This role is accountable to the SRO.

National Digital Cellular Pathology Project Board

The Board's role is to drive the Project forward, manage the risks and ensure the outcomes are delivered. It reports to the SRO, who chairs the Board and members are individually accountable to the SRO for their area of responsibility within the Project. Key responsibilities are:

- Define acceptable risk thresholds for the overall Project;
- Ensure the Project delivers its objectives on time, within budget and to the required quality standard;
- Resolve strategic issues between Projects;
- Ensure the integrity of benefits profiles and the benefits realisation plan;
- Provide assurance for operational stability through transition.

Established and chaired by the SRO, and coordinated and supported by the Programme Manager, the prime purpose of the Board is to:

- Drive the Project forward to deliver the outcomes and benefits;
- Provide assurance that the Project meets needs of stakeholders;
- Resolving dependencies with other Projects and areas of work;
- Ensure that members provide resource and specific commitment to support delivery;
- Have ownership for ensuring resolution of risks.

The Board reports to the SRO, and whilst the SRO may delegate responsibilities and action to members of the Board, its existence does not dilute the SRO's accountabilities and decision-making authority.

Members of the Board are individually accountable to the SRO for their areas of responsibility and delivery within the Project as follows:

- Defining the acceptable risk profile and risk thresholds for the Project;

- Ensuring the Project delivers within its agreed parameters (e.g. cost, organisational impact, rate/scales of adoption, expected/actual benefits realisation);
- Resolving strategic and directional issues between Projects, which need the input and agreement of senior stakeholders to ensure the progress of the Project;
- Ensuring the integrity of benefits profiles and benefits realisation plans and ensuring that there is no double-counting of benefits;
- Providing assurance for operational stability and effectiveness through the Project delivery cycle.

Each member of the Board will provide and commit to the SRO for some or all of the following as appropriate for the area they represent:

- Understanding and managing the impact of change;
- Benefits estimates and achievement;
- Owning the resolution of risks and issues that the Project faces;
- Resolving dependencies with other pieces of work, whether change or business operations;
- Representing local strategy as expressed in, for example, medium-term plans and operational blueprints;
- Supporting the application of and compliance with operating standards.
- Making resource available for planning and delivery purposes

The current NDCP Group will be enhanced to provide procurement and implementation oversight in order to deliver Project success. Members (*however subject to change)* include:

- Senior Responsible Owner (SRO)
- National Pathology Programme – DCP Clinical Lead
- National Pathology Portfolio Programme Lead
- Programme Manager
- Senior Project Manager
- Senior Project Support Officer
- Pathologists (one representative for each Health Board)
- Laboratory Managers (one representative for each Health Board)
- IT (one representative for each Health Board)
- DHCW/LIMS Representative
- DHCW Cyber Security Representative
- DHCW Information Governance Representative
- NWSSP Specialist Diagnostic and Therapies Equipment Representative
- NWSSP Procurement Project Manager/Category Manager

Other members will be co-opted as appropriate.

Timescales

The high-level timeline for NDCP Project is set out in the table below.

Table 29 Timescales

Tranche 1	Tranche 2	Tranche 3
Pre-procurement	Procurement	Implementation
Apr 24 – Mar 25	Apr 25 – Mar 26	Apr 26 – Mar 27
Standardisation approach Development of the Business Justification Case Health Board Executive approval of the BJC (x 6) Update service specification	Tender process Supplier engagement Finalise service specification Contract Award Implementation Preparation Digital hub/storage preparation Recruit HB staff	Digital hub/storage implementation Implementation in Health Boards (phased approach) Training

Assurance

The NDCP Project has a Quality and Assurance Strategy developed in accordance with MSP to ensure that all management aspects of the Project are working appropriately and that the Project stays on target to achieve its objectives. Project reviews to be undertaken at the end of each tranche.

Change Management Arrangements

The NDCP Project is a transformational change Project underpinning the development of modern, safe, sustainable pathology services and the use of innovative systems resulting in sustainable futureproofed services. The Project is aligned to the principles of the Pathology Statement of Intent 2019 and ensures continued alignment through a robust governance structure and reporting mechanism into the National Pathology Programme. Transformational service change forms the basis of the NDCP Project which seeks to deliver the change in a way that is welcomed, supported and embraced by the Pathology service and the wider NHS. The NDCP Project will deliver this through leadership, vision, stakeholder engagement, strong governance, excellent communications and robust plans.

Building on lessons learned from Phases 1 and 2, Phase 3 will:

- Request an executive level SRO
- Reinforce clinical leadership arrangements, for instance The National Pathology Programme now has a National Clinical Lead and a Clinical Lead for Digital Cellular Pathology
- Strengthen the existing Group ensuring IT representation from each organisation
- Formalise DHCW membership and responsibilities

- Continuing to update the National Diagnostics Strategic & Operational Group at regularly intervals, obtaining document sign off when required
- Continuing to work with the cellular pathology Standardisation Group to drive the Project forward and ensure SME

This approach will ensure that a robust governance structure is put in place ensuring high-quality delivery at pace.

Transformational Leadership

The NDCP Project is providing transformational leadership enabling the pathology service to create its own vision and own the Project at every stage of the process.

Health Board and Trust Leadership

Health Boards and Trusts are expected to provide the leadership necessary for the successful implementation of the new national digital cellular pathology service by supporting the following:

- Approval of the BJC
- The level of business change required to support the standardisation of services as far as possible to deliver a modern, high quality, safe and sustainable pathology service;
- Establish a local deployment project team to oversee the implementation and deployment of the new digital enablement and ensure the pathology service has the support and resources it requires to contribute to the Project;
- Include the NDCP Project in their integrated medium-term plans (IMTPs);
- Enable their Pathology services to contribute to the development, testing and validation of the new service whilst maintaining any ongoing services;
- Release their staff for training for the new service.

Management of Requests for Change

Requests for change can take several forms and will be managed accordingly. Throughout the life of the Project until the new digital service is fully deployed, all requests for change will be recorded in a dedicated Project change log and managed by the Project Team. The Project Team will decide the appropriate route for the change to be dealt with. A decision is needed regarding ongoing arrangements following handover of services to operations, and the ongoing management of change requests.

Benefits Realisation

The Benefits Management Strategy developed in Phases 1 and 2 will continue to be developed and refined to model benefits in more detail, determine methods for measuring them and ensure there is a process for tracking their realisation following implementation of the agreed service model. Work has been undertaken to identify key benefits of investing in this Project.

A Benefits Management Framework has been developed to ensure the Project benefits are realised from the initial investment. It helps the Project focus on achieving its strategic objectives and getting best values from its investment.

The approach being adopted is based on the Public Sector Programme Management approach with the 'Managing Successful Programmes' (MSP®) and APM's 'Managing Benefits' publications the main source of guidance on the benefit

realisation management process. Benefit Realisation Management is a core element of Programme/change management. It provides a systematic approach to identifying, defining, tracking, realising, optimising, reviewing and communicating benefits during and beyond a Programme/Project lifecycle.

The reason for having processes in place to manage and realise benefits include:

- Ensuring benefits are identified and clearly defined clearly
- Ensuring benefits are aligned to the vision, objectives and to the strategic direction of the organisation.
- Ensuring service areas take ownership of the benefits and are committed to their realisation.
- Ensuring that the Project outputs support the benefits and business changes that will be needed;
- Ensuring benefits are tracked and recorded and that achievements are properly recognised.
- Ensuring key benefit measures are mainstreamed into the performance framework.

The NDCP Project will manage, track, and control the realisation of benefits through the Benefits Realisation Plan. The Benefits Realisation Plan is to be maintained by the Project Team, in detail by a designated Benefits Lead working in conjunction with the benefits group.

The plan will contain and provide information on:

- A schedule that details when each benefit or groups of benefits (including any dis-benefits) will be realised
- Milestones for undertaking Benefits Review(s), to determine progress and inform questions about the likelihood of ongoing success in the future
- Dates when specific outcomes (i.e. business transition(s)) that will bring about benefits, are planned to be achieved
- Details of the handover and embedding activities necessary to realise any benefits after the Project has closed.

The key objectives of benefit realisation are to understand how the new system has made a difference to the service, to patients and patient care both in terms of outcomes and experience of services.

Work is ongoing with Health Technology Wales to fully evaluate the wider benefits of IBEX AI application.

Risk Management Arrangements

The Risk Management Strategy developed in Phases 1 and 2 will continue to be developed and will outline how risks and issues will be identified and managed during Phase 3. The Programme Manager will work with key leads to detail potential risks and issues in the Project Plan.

The management of risk is be embedded into the project management process as follows:

- The requirements of Corporate Governance will be adopted, including more focused and open ways of managing risk;

- The SRO will be the 'risk owner' at senior level – supporting, owning and leading on risk management;
- All members of the Project Team will own risk in commensurate quantum to their role;
- The Project reporting structure will encourage reporting and upward referral of significant issues. Risks will be actively monitored and regularly reviewed at each Project Team meeting;
- The risk management framework for the consistent treatment of risk will be established at an early stage and will be shared at all levels of the organisation and also with partners, particularly in the context of the complex types of risk arising from partnerships etc;
- The Project risk will be managed in the wider context of the whole business.

The Project Team is accountable for managing risk with regard the delivery of their respective workstreams. The Programme Manager is responsible for ensuring that all workstream leads have effective risk management strategies in place.

- Manage risks effectively each lead is required to:
- Understand at any point in time their major risks to delivery and ensure that they are taken into account within their workstream delivery plans;
- Ensure that those risks are allocated to a Risk Owner, who is actively managing a plan to mitigate the risks. The Risk Owner will be held accountable for action to mitigate the risks;
- Share and review risks at NDCP Project Team meetings and NDCP Project Board meetings to ensure that the Risk Register is fully representative of all risks, that these are up to date and being actively monitored;
- Where necessary escalate and bring to the attention of the Programme Manager and/or other key stakeholders, key risks they should be aware of.
- Be supported in this by the Project Manager whose role is to actively manage risk activities, ensuring that the risk register is compiled, maintained, regularly reviewed and refreshed to ensure that they represent the most up to date information and status;

A detailed Risk Register has been developed by the Project Team to assist with risk management throughout the development process. Risks will be assessed and values attributed to each area. The latest Risk Register can be found at Appendix M2.

The RAG Rating key for risks is as illustrated below:

Table 30 Risk Rating Matrix

			IMPACT				
			Very Low	Low	Medium	High	Very High
			1	2	3	4	5
PROBABILITY	Very Low	1	1	2	3	4	5
	Low	2	2	4	6	8	10
	Medium	3	3	6	9	12	15
	High	4	4	8	12	16	20
	Very High	5	5	10	15	20	25

Contract Management Arrangements

The contract will be managed by maintaining relationships with the successful supplier(s) throughout the duration of the Project, including engaging through supplier performance management (SPM).

Regular contract review meetings will be held by NWSSP Procurement Services with input from the working group, using the SPM standardised agenda:

- Supplier preparedness/resilience
- Price management/invoice discrepancies
- Product/service quality
- Delivery
- SMTL product defects
- Accreditation
- Benchmarking
- Information governance
- Innovation
- Regulatory changes
- Sustainability
- Supplier issues/concerns/update
- Supplier performance rating

Post Evaluation Arrangements

The Project has a Quality and Assurance Strategy developed in accordance with MSP to ensure that all management aspects of the Project are working appropriately and that the Project stays on target to achieve its objectives.

To complement the Quality and Assurance Strategy, gateway reviews will be planned at the end of Tranches 2 and 3, to assure the readiness for service prior to go live and once the Project has finished and the new digital service is fully deployed to assess operations and review benefits realisation.

Contingency Plan

There is a contingency built in should there be any delays in the implementation Phase of the Project. In the event that the Project fails, the aim will to be to ensure business continuity by:

- Exploring the opportunities to contract with another supplier within the procurement, should the supplier fail to deliver;
- Undertaking a re-procurement.
- Ensuring traditional reporting via glass slides and microscope as contingency

8 Document Control

Document Information

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Amended by	Version	Status	Date	Purpose of Change
Archus	1.0	Draft	08/07/21	First draft for initial review and address gaps
CT	1.1	Draft	09/07/21	Second edition of the draft report in response to queries
Archus	1.2	Draft	14/07/21	Updated based on further information received from the Collaborative
Archus	1.3	Draft	16/07/21	Further revisions
CT	1.4	Draft	21/07/21	Further responses
Archus	1.5	Draft	27/07/21	Further revisions
Archus	1.6	Draft	05/08/21	Economic and Financial Cases
Archus	1.7	Draft	09/08/21	Finalise Benefits and Risks, revise Do Minimum
CT	1.8	Draft	02/09/21	Included comments from DCP Board
Archus	1.9	Draft	09/09/21	Included comments from DCP Board
CT	1.10	Draft	29/09/21	Updated formatting & Tranche timeline
MB	1.11	Draft	05/10/21	Further revisions
Archus	2.0	Draft	08/10/21	Updated costs
Archus	3.0	Draft	08/11/21	Minor corrections
Archus	4.0	Draft	31/01/22	Further work to Benefits & Costs
CT	5.0	Draft	01/02/22	Updated timeline
CT	5.1	Draft	01/02/22	Minor corrections
Archus	5.2	Draft	03/02/22	Minor corrections
CT	5.3	Draft	09/02/22	Updated following DCP PB
CT	5.4	Draft	15/02/22	Minor corrections
Archus	6.0	Draft	15/02/22	Updated following comments
CT	7.0	FINAL	16/02/22	Minor corrections
CT	7.1	Draft	07/09/22	Updates following comments
CT	7.1	Draft	07/09/22	Updates following comments
CT	9.2	Draft	30/11/22	Updates
Archus	10.0	FINAL	05/12/22	Final amendments
Archus	11.0	FINAL	09/01/23	Further updates
Archus	12.0	FINAL	13/02/23	Amend to capital funded business case and address comments from HBs and reviewers
CT	12.1	Draft	14/02/23	
Archus	13.0	Draft	28/04/23	Updates – Digital Strategy Wales 2021

Archus	14.0	Draft	26/04/23	Updates to commercial case following comments from Procurement
Archus	15.0	Draft	31/05/23	Updated Economic and Financial Cases and benefits analysis
Archus	16.0	Draft	02/06/23	Final review and strengthen VFM and affordability conclusions
CT	17.0	Draft	07/06/23	Final amendments
CT	17.1	Draft	01/12/23	Update following comments and refreshed costings
CT	17.2	Draft	19/12/23	Minor amendments
CT	17.3	Draft	19/12/23	Minor amendments
CT	17.4	Draft	04/04/24	Revision of costings and updated content following feedback
CT	18.0	FINAL	02/05/24	

9 The Appendices

Appendix 1: Glossary of Terms

Acronym	Full Title
ABUHB	Aneurin Bevan University Health Board
AI	Artificial Intelligence
APM	Association of Project Management
ARCH	A Regional Collaboration for Health
BCUHB	Betsi Cadwaladr University Health Board
BJC	Business Justification Case
CCS	Crown Commercial Services
CSF	Critical Success Factor
CTMUHB	Cwm Taf Morgannwg University Health Board
CVUHB	Cardiff & Vale University Health Board
DHCW	Digital Health and Care Wales
H&E	Haematoxylin and Eosin
HDUHB	Hywel Dda University Health Board
IMTP	Integrated Medium Term Plan
IPR	Intellectual Property Rights
KPI	Key Performance Indicator
LIMS	Laboratory Information Management Service
MDT	Multi-Disciplinary Team
MSP	Managing Successful Programmes ™
NDCP	National Digital Cellular Pathology
NPP	National Pathology Programme
NWSSP	NHS Wales Shared Services Partnership
PHW	Public Health Wales
RCPath	Royal College of Pathologists
SBUHB	Swansea Bay University Health Board
SRO	Senior Responsible Owner
SWOT	Strengths, Weaknesses, Opportunities, Threats
TUPE	Transfer of Undertakings (Protection of Employment) Regulations 1981
VFM	Value For Money