Meeting Date	**28th March 2019**	**Agenda Item**	**4.2**
Report Title	Development of a Mid and South West Wales Regional Centre of Excellence Cellular Pathology Laboratory, Regional Diagnostic Immunology Laboratory & Regional Medical Microbiology Facility at Morriston Hospital, Swansea		
Report Author	Heather Edwards, Business Planning Manager Ian MacDonald, Head of Strategic Capital Finance		
Report Sponsor	Mrs Christine Morell, Deputy Director of Therapies and Health Science, Therapies And Health Sciences		
Presented by	Mrs Christine Morell, Deputy Director of Therapies and Health Science, Therapies And Health Sciences		
Freedom of Information	Open		
Purpose of the Report	To seek Health Board approval on the Strategic Outline Case (SOC) prior to submission to Welsh Government.		
Key Issues	Nationally NHS Pathology services face a number of challenges. Within the Mid and South West Wales' region, Abertawe Bro Morgannwg University Health Board (ABMUHB) Hywel Dda University Health Board (HDUHB), and Public Health Wales NHS Trust (PHW) are struggling to manage workforce and sustainability pressures, to maintain quality and safety issues and to meet clinically driven targets. Without investment in sustainable services we cannot deliver essential improvements and fit for purpose laboratories. Investment would allow us to co-locate and develop regionalised services and to support more innovative and sustainable service models which could be future-proofed, and be flexible enough, to respond to changing demand, new technologies and innovations. In 2017 a South West Wales Regional Pathology Reconfiguration Project Board was established to draft a Strategic Outline Business Case (SOC) to address these regional challenges in line with the national direction of travel for regional pathology services. The purpose of a SOC is to focus on; a) Confirm the strategic context of the proposal b) The presentation of a robust case for change c) Outline with indicative costs only at this stage, a short-list of options indicating a preferred way forward. At OBC stage these will be subject to a detailed economic analysis to include costs, benefits and risks.		

Specific Action Required ***(please ✓one only)***	**Information**	**Discussion**	**Assurance**	**Approval**
				✓

Recommendations	Members are asked to: • **NOTE** the development of business continuity plans. • **NOTE** the short-listed options with estimated capital and revenue costs and identification of the preferred way forward. • **APPROVE** this SOC and agree it can be submitted to Welsh Government to support this project progressing to Outline Business Case stage

Development of a Mid and South West Wales Regional Centre of Excellence Cellular Pathology Laboratory, Regional Diagnostic Immunology Laboratory & Regional Medical Microbiology Facility at Morriston Hospital, Swansea

1. INTRODUCTION

Nationally NHS Pathology services face a number of challenges as follows:

- Workforce and sustainability pressures - ensuring the service has 'the right staff with the right skills';
- Quality and safety issues (including estate and facility constraints;
- Technological innovations (including automation, digital technology and innovative technologies/equipment) - this is a significant driver for change and is the catalyst for policy and strategy responses;
- Major growth in demand, both demographically (aging population with more complex investigations; antibiotic resistance and control of infection issues) and in cancer services e.g. Single Cancer Pathway, and;
- Changing models of care – moving from traditional models of care towards personalised treatment.

Within the Mid and South West Wales' region, Abertawe Bro Morgannwg University Health Board (ABMUHB), Hywel Dda University Health Board (HDUHB), and Public Health Wales NHS Trust (PHW) are struggling to manage workforce and sustainability pressures, to maintain quality and safety issues and to meet clinically driven targets. Without investment in sustainable services we cannot deliver essential improvements and fit for purpose laboratories. Investment would allow us to co-locate and develop regionalised services and to support more innovative and sustainable service models which could be future-proofed, and be flexible enough, to respond to changing demand, new technologies and innovations.

2. BACKGROUND

In 2017 a South West Wales Regional Pathology Reconfiguration Project Board was established to draft a Strategic Outline Business Case (SOC) to address these regional challenges in line with the national direction of travel for regional pathology services. Project Board agreed the case for change could be supported by developing a Mid and South West Wales Regional Centre of Excellence Cellular Pathology Laboratory, a Regional Diagnostic Immunology Laboratory & a co-located Regional Medical Microbiology Facility at Morriston Hospital, Swansea.

The Project Board has identified the key investment objectives of this project as follows:

- To develop more sustainable South Wales Regional Cellular Pathology, Regional Diagnostic Immunology Laboratory and Regional Medical Microbiology services
- To improve the quality and safety of South Wales Regional Cellular Pathology, Regional Diagnostic Immunology Laboratory and Regional Medical Microbiology services

- To improve the efficiency and productivity of South Wales Regional Cellular Pathology, Regional Diagnostic Immunology Laboratory and Regional Medical Microbiology services
- To improve the effectiveness of South Wales Regional Cellular Pathology, Regional Diagnostic Immunology Laboratory and Regional Medical Microbiology services
- To improve economies within South Wales Regional Cellular Pathology, Regional Diagnostic Immunology Laboratory and Regional Medical Microbiology services

To meet these key challenges, satisfy the project's investment objectives and to support development of a 'one-site' Cellular Pathology solution a potential range of options were identified by Project Board (Option 1, the 'Business As Usual' option was rejected for further detailed analysis but will be included as a baseline comparator for detailed economic appraisal at OBC stage). These potential options were as follows, with option 3 identified as the Preferred Way Forward at this stage:

Functional Content by Health Board		**Option 2** **Do Minimum**	**Option 3** **PREFERRED WAY FORWARD** **Intermediate – more ambitious**	**Option 4** **Intermediate – far more ambitious**	**Option 5** **Do Max ambitious**
HDUHB ABMUHB	Develop Regional Cellular Pathology (Cytology and Histopathology)	✓	✓	✓	✓
HDUHB ABMUHB	Regional Diagnostic (Laboratory) Immunology service;	✓	✓	✓	✓
ABMUHB	Co-locate Singleton's Body Store at Morriston Hospital service (future proofed capacity)	✓	✓	✓	✓
	A 500 m² ATTC, i.e. Cell and Gene Therapy indicative shell and core area	✓	✓	✓	✓
ALL	Provide dedicated car parking to support regionalised services (300 spaces)	✓	✓	✓	✓
PHW	Relocate ABMUHB's PHW Medical Microbiology service to Morriston Hospital		✓	✓	✓

Functional Content by Health Board		Option 2 Do Minimum	Option 3 PREFERRED WAY FORWARD Intermediate – more ambitious	Option 4 Intermediate – far more ambitious	Option 5 Do Max ambitious
HDUHB	Reconfigure and refurbish local non-regionalised Blood Sciences services' accommodation to provide fit for purpose facilities - Refurbishment of Cell Pathology - Withybush Hospital, Prince Philip Hospital, Llanelli & West Wales General Glangwili (approx. 486 m2)		✓	✓	✓
ABMUHB	Develop a temporary modular Body Store solution at Singleton Hospital			✓	✓
ABMUHB	Re-provide ABMUHB's Essential Laboratory Service				✓

Depending on the scale of the investment, in the short term, this investment aims to improve recruitment and retention within the Mid and South West Wales Cellular Pathology and wider Pathology service, improve quality and safety, foster training opportunities therein, and support modernisation of the workforce and service innovations. In the longer term, this investment supports more sustainable Pathology services in the region, supports technological innovations, promotes benefits in terms of improved specialist healthcare services, facilitates access to modern techniques and innovations, and enhances the patient experience and improve quality outcomes. Overall, this investment delivers urgent improvements in quality, safety and sustainability within Mid and South West Wales' pathology services.

The assumption at SOC stage is that the work currently undertaken in the Swansea laboratories for Princess of Wales activity will continue following the boundary change. Further work on this will undertaken at OBC stage.

Work is progressing with the development of a business continuity plan, in relation to the immediate workforce challenges, including an action plan on how the three organisations could work together in the short, medium and long-term – with a focus on digital technology, joint posts, links to academia, joint training opportunities etc.

We anticipate this project will be delivered via the *Designed for Life – Building for Wales3* procurement route.

The indicative programme is as follows:

Activity	Due Date
Welsh Government endorse SOC	May 2019
Appoint Supply Chain Partner, Health Board Cost Advisor & Health Board Project Manager from Designed for Life Regional Framework	July 2019
Welsh Government approval of OBC	September 2020
Welsh Government approval of FBC	January 2022
Mobilise and commence new build/extension main works	February 2022
New build completed (subject to contractor's programme)	January 2024
New build commissioning (subject to accreditation arrangements & technical commissioning)	February 2024
New build operational	March 2024
Commence refurbishment	April 2024
Refurbishment completed (subject to contractor's programme)	October 2024
Refurbishment commissioning (subject to accreditation arrangements & technical commissioning)	November 2024
Refurbishment operational	December 2024

3. GOVERNANCE AND RISK ISSUES

The main risks are as follows:

Risk Description	Probability	Impact	Score	Mitigating Actions
Internal approvals delayed - There is a risk that board approvals are delayed.	3	4	12	(1) Continued liaison with key stakeholders' SROs
Planning approval & planning conditions - Failure to achieve planning permission conditions are excessive, that S106 demands building control approvals are more involved than anticipated	5	4	20	(1) Early engagement with Local Planners; (2) Appoint a Planning Advisor and further investigate future planning development risks at Morriston Hospital & Submit a pre-planning application; (3) Monitor progress on Project and its interrelationship(s) with ARCH & other Morriston Hospital projects currently at planning stage; (4) Coordinate

Risk Description	Probability	Impact	Score	Mitigating Actions
				with ARCH Master Planners.
Funding approval delayed or timing of funding does not match our current programme due to WGov cashflow constraints	4	4	16	(1) Maintain regular dialogue re the procurement arrangements with WG and other key stakeholders.
Revenue affordability - Affordability of revenue model is over/under estimated	5	4	20	(1) Develop and sign off revenue model with DoFs; (2) Project Board to review at each formal meeting.
Availability of capital - There is a risk that the scope of the project is reduced in order to fit within financial limit	5	3	15	Continued liaison with WGov.
Staffing levels - Additional staffing levels / activity cannot be supported at Morriston Hospital, e.g. car parking provision and essential infrastructure are insufficient to support planned operations	3	4	12	(1) Develop Staff Modelling to inform, e.g. future car parking requirements on site; (2) Liaise with Morriston Hospital/ARCH projects currently at planning stage.
Staffing model is over/under estimated	3	4	12	Establish a Project Management Team and secure project management support
Recruitment of key staff - Sufficient numbers of essential staff with key skills cannot be recruited	3	4	12	Project Board monitors recruitment progress/issues and report regularly to Project Board/Executive level

4. FINANCIAL IMPLICATIONS

The indicative capital implications of the proposed investment for each shortlisted option were identified as follows:

	(£000 incl non-recoverable VAT)			
	Option 2 Do Minimum	**Option 3 Intermediate1 *Preferred Way Forward***	**Option 4 Intermediate**	**Option 5 Do Maximum**
Departmental Costs	17,249	25,729	27,121	31,168
On Costs	13,041	20,332	20,475	25,499
Provisional location adjustment	-908	-1,382	-1,427	-1,700
Works Costs Total	**29,382**	**44,679**	**46,169**	**54,967**
Fees	4,701	7,149	7,387	8,795
Non Works Costs	1,741	2,694	2,641	2,745
Equipment Costs	3,611	5,059	5,231	5,718
Planning Contingency	3,943	5,958	6,142	7,222
VAT (adjusted for reclaim)	7,576	11,678	12,036	14,130
Base Project Cost	**50,954**	**77,217**	**79,606**	**93,577**

The revenue impact on each of the shortlisted options are as follows:

Costs	**Option 2 Do Minimum**	**Option 3 Intermediate 1 *Preferred Way Forward***	**Option 4 Intermediate 2**	**Option 5 Do Maximum**
Service Pay	0	0	0	0
Service Non-Pay	0	0	0	0
Support Services	197	236	263	503
Total	**197**	**236**	**263**	**503**

A number of costs pressures associated with the staffing models exist, whether the service moves to a new facility or remains in-situ. These relate to increasing demand for pathology services. For that reason it is reasonable to recognise the current service and projected future demand, but to exclude them from the revenue financial model at this stage in the development of the business case.

In moving to a single facility, Hywel Dda would need to manage the workload of their Consultant staff using the Royal College points based system. This would mean an increased revenue cost pressure. However, over the last few months, work undertaken between both organisations, suggest this cost increase will be less than previously anticipated. In addition it now seems likely that as a result of the closer working

relationship of the two organisations, Hywel Dda will be moving to the points based system in advance of any new building. This will allow them to reap the benefits of also moving to partly implement the Advanced Practitioner role that is being successfully adopted in ABM. The adoption of the Advanced Practitioner role will in effect lessen the cost base if it had not been adopted. At the SOC stage it has been assumed no additional cost pressure

Further work will be required at Outline Business Case stage (OBC) to assess the impact of travel. There are likely to be additional lab specimens travelling to Morriston. However it is too early to estimate the extent of any additional costs, as it is likely that existing transportation journeys can be utilised. Further work will also be required during the OBC to assess the impact on IT.

There are likely to be additional costs associated with running a modern facility built to conform with the latest building and engineering standards. This will be due to the new facility requiring increased space to meet these requirements, approx. a 30% increase of an additional 2,000 sq metres and the cost of servicing a modern building environment are normally greater than older non-complaint buildings. At this stage no detailed building design work has been undertaken but a high level estimate indicates that it would not be unreasonable to expect additional annual running costs of around £236k for the preferred way forward.

The share of the estimated additional revenue costs for each organisation on the preferred way forward is as follows:

Organisation	%
ABMU	31
Hywel Dda	16
PHW	39
Genomics	13
Total	**100**

5. RECOMMENDATION

Members are asked to:

- **NOTE** the development of business continuity plans.
- **NOTE** the short-listed options with estimated capital and revenue costs and identification of the preferred way forward.
- **APPROVE** this SOC and agree it can be submitted to Welsh Government to support this project progressing to Outline Business Case stagestage

Governance and Assurance

Link to corporate objectives *(please ✓)*	Promoting and enabling healthier communities	Delivering excellent patient outcomes, experience and access	Demonstrating value and sustainability	Securing a fully engaged skilled workforce	Embedding effective governance and partnerships
		✓	✓	✓	✓

Link to Health and Care Standards *(please ✓)*	Staying Healthy	Safe Care	Effective Care	Dignified Care	Timely Care	Individual Care	Staff and Resources
		✓	✓		✓	✓	✓

Quality, Safety and Patient Experience

This investment delivers advanced techniques and combines different modalities to give more accurate diagnostic information and provides more timely and improved diagnostic pathways for patients; improved standardisation, service delivery, patient safety and communications, including patients' access to information

Financial Implications

The indicative capital implications of the proposed investment for each shortlisted option were identified as follows:

	(£000 incl non-recoverable VAT)			
	Option 2 Do Minimum	**Option 3 Intermediate1**	**Option 4 Intermediate**	**Option 5 Do Maximum**
Base Project Cost	**50,954**	**77,217**	**79,606**	**93,577**

The revenue impact on each of the shortlisted options are as follows:

Costs	**Option 2 Do Minimum**	**Option 3 Intermediate 1**	**Option 4 Intermediate 2**	**Option 5 Do Maximum**
Total	**197**	**236**	**263**	**503**

A number of costs pressures associated with the staffing models exist, whether the service moves to a new facility or remains in-situ.

Further work will be required at Outline Business Case stage (OBC) to assess the impact of travel and the impact on IT.

There are likely to be additional costs associated with running a modern facility built to conform with the latest building and engineering standards. At this stage no detailed building design work has been undertaken but a high level estimate indicates that it would not be unreasonable to expect additional annual running costs of at least £236k.

Legal Implications (including equality and diversity assessment)

This investment supports improved turn-a-round time especially for urgent suspected cancers and for All Wales Lymphoma panel patients and improves the patient experience. Furthermore, this investment supports standardised protocols that reduce variability, reduce clinical risk, and strengthen clinical governance within the region.

Furthermore, this investment will provide new technology which will improve diagnostic services for, e.g. molecular testing, improve quality systems and reporting structures in pathology services, and provide all patients in the secondary care, and those attending acute and regional hospital based services, with more reliable/ timely and equitable cellular pathology, histopathology specialists and services. Facilities will include appropriate changing facilities that are congnisant of the needs of the privacy & dignity of staff and the needs of disabled staff and visitors.
Staffing Implications
A detailed Workforce Plan is being developed for OBC stage. A business continuity plan is in development.
Long Term Implications (including the impact of the Well-being of Future Generations (Wales) Act 2015)
Pathology is a key component in the delivery of prudent health services to the population of Wales and is a key enabler to Welsh Government health delivery plans including cancer and stroke. Investment in regionalised Pathology services will support the principles of Prudent Healthcare, enable the service to work more closely with clinical teams, to develop new techniques and innovate to realise benefits of more personalised health monitoring/ preventative medicine, e.g. providing more rapid treatment for patients / improved outcomes / timely responses, and providing more proactive management of patients. Development of regionalised Diagnostic Immunology services will more support effective treatment and deliver better results and improved outcomes patients following Prudent Healthcare principles; to meet the All Wales Diagnostic Specification and ensure the highest quality of evidence based care and improve accessibility for patients.

Report History	November 2018 - Draft Discussion SOC was supported by ABMU Execs; December 2018 - Draft Discussion SOC discussed by Local Executive Team and Welsh Government, and; 12th March 2019 - SOC approved by ABMUHB's Investment & Benefits Group (IBG). 13th March 2019 - SOC approved by ABMUHB's Executive Team.
Appendices	SOC attached for information (please note appendices are embedded)

Strategic Outline Case (SOC)

Development of a Mid and South West Wales Regional Centre of Excellence Cellular Pathology Laboratory, Regional Diagnostic Immunology Laboratory Facility and Regional Medical Microbiology facility at Morriston Hospital, Swansea

v. Final

Document control sheet

Client	Hywel Dda University Health Board (HDUHB), Abertawe Bro Morgannwg University Health Board (ABMUHB) and Public Health Wales NHS Trust (PHW)
Document Title	Development of a Mid and South West Wales Regional Centre of Excellence Cellular Pathology Laboratory, Regional Diagnostic Immunology Laboratory Facility and Regional Medical Microbiology facility at Morriston Hospital, Swansea
Version	Final (4)
Status	Final
Reference	
Author	Heather Edwards, ABMUHB
Date	14th March 2019
Further copies from	**email:** heather.edwards2@wales.nhs.uk **quoting reference and author**

Contact details			
Main point of contact	Telephone number	Email address	Postal address
Heather Edwards	01792 286119	heather.edwards2@wales.nhs.uk	

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Executive Summary

Introduction

1. This Strategic Outline Business Case (SOC) was prepared through a process of engagement with key stakeholders. Principally, it seeks support from Welsh Government in the form of investment in Mid and South West Wales' Pathology services in the range of £50.954 - £93.577m (including non-recoverable VAT) to support the development of a Mid and South West Wales Regional Centre of Excellence Cellular Pathology Laboratory, Regional Diagnostic Immunology Laboratory and Regional Medical Microbiology facility at Morriston Hospital, Swansea.

2. We envision a Mid and South West Wales' Pathology services Regional Centre of Excellence supporting the following:

- Wales being at the forefront of digital pathology – delivering fully digitised pathology across Wales which allow us to assess images from a range of disease areas and work with partners to develop and validate emerging Artificial Intelligence (AI) tools; Promoting opportunities for AI/Machine Learning (ML) to improve microscopic assessment of diseases.
- Using advanced techniques and combining different modalities to give more accurate diagnostic information & to provide more timely and improved diagnostic pathways for patients; Improving quality and reducing screening times in, e.g. Cervical screening; Building on partnerships with Universities and industry.
- Supporting Genomics and Genetics to enhance diagnosis and treatment; 'Tailoring' therapies to individual patients; Promoting gene and cell therapy research and development.
- Improving standardisation, service delivery, patient safety and communications, including patients' access to information.
- Developing new technologies that allow to embrace research opportunities and innovations, and allow the NHS to a deliver better service in a faster and more efficient way.

Background

3. The main challenges facing NHS Wales' Pathology services are:

- **Workforce and sustainability pressures** - recognising that a significant number of current vacancies, an ageing workforce, and loss of staff due to retirement creates pressures for the service we must ensure, that the service has 'the right staff with the right skills';
- **Quality and safety issues** (including estate and facility constraints**;**
- **Technological innovations** (including automation, digital technology and innovative technologies/equipment) - this is a significant driver for change and is the catalyst for policy and strategy responses;
- **Major growth in demand**, both demographically (aging population with more complex investigations; antibiotic resistance and control of infection issues) and in cancer services e.g. Single Cancer Pathway, and;
- **Changing models of care** – moving from traditional models of care towards personalised treatment.

4. Pathology services must address these challenges by providing a sustainable workforce, safer and higher quality services whilst improving outcomes but these will not be achieved simply by investing in new local facilities; we need to co-locate within the region and adopt new and more acceptable delivery models that can improve service resilience and business continuity , demonstrate quality

through independent accreditation assessments, reduce potential error-rates, better support diagnosis, be more acceptable and accessible to users, and reduce risk.

5. Furthermore, new service models must be future-proofed, and flexible enough, to respond to changing demand, new technologies and innovations, and complement the UK's playing a lead role in developing a network of emerging Advanced Therapy Treatment Centres (ATTCs) - the promotion of gene and cell therapy's Advanced Therapy Medicinal Products (ATMPs) research and development. ATMP's having the potential to benefit patients with challenging conditions that cannot be cured with current treatments by promoting access to breakthrough medicines.[1]
6. This investment aligns with the recently approved Swansea Bay City Region's 'Internet Coast' £1.3bn City Deal for South West Wales, which supports public and private investment in Carmarthenshire, Neath Port Talbot, Pembrokeshire and by developing sustainable and energy efficient laboratory facilities, by promoting regional state-of-the-art digital innovations and, by delivering a sustainable and resilient workforce with the required scientific and technological skills necessary for modern health services.
7. This investment supports *Informed Health and Care – A Digital and Social Care Strategy for Wales (*WGov 2015*)*[2] by improving Pathology in Wales' clinicians' access to information and by supporting opportunities for delivering care with new digital technologies in support of prudent and value based healthcare. Overall, benefits to the service could include improvements in standardisation, service delivery, patient safety and communications, including patients' access to information, as well as reduced potential error rates, lower costs, and better and more efficient use of data.

The Strategic Case

A. Strategic Context

8. The key national and regional strategic drivers for this investment are summarised as follows:

- ***Review of NHS Pathology services in England*** (DoH, 2006)
- ***Report of the Second Phase of the Review of NHS Pathology Services in England*** (DoH, 2008)
- ***The Future Delivery of Pathology Services in Wales*** (WG, 2008)
- ***The National Pathology Framework (NPF) for Wales*** (NHW Wales, 2008)
- ***Review of the Histopathology Services in NHS Wales*** (2010)
- ***Digital First: Clinical Transformation through Pathology Innovation*** *(*National Pathology Programme, NHS England, February 2014)
- **Prudent Healthcare** – *Securing Health and Well-Being for Future Generations (Wales) Act* 2015
- **The Carter Review** - *Review of Operational Productivity and Performance in English NHS Acute Hospitals: Unwarranted Variation* (UK Government, 2016)
- **Pathology Statement of Intent** (Draft: 19th April 2018 – *endorsed by All Wales Chief Executives, following endorsement by the Pathology Service, and currently is with Welsh Government awaiting publication*)

9. This investment supports partners organisation clinical strategies: HDUHB's A Healthier Mid and West Wales: Our Future Generations Living Well strategy; ABMUHB's Clinical Services Plan (2019 –

[1] Innovate UK Competition: Establishing UK Treatment Centres for Advanced Therapies - 01 Nov 2017
[2] Pathology Statement of Intent (Draft: 19th April 2018)

2024), and; and Public Health Wales' Long Term Strategy: Working to Achieve a Healthier Future for Wales (2018 – 2030)

10. This investment supports HDUHB's, ABMUHB's and Public Health Wales'[3] long term Service Strategies (please refer to Section 3) support these strategic drivers and we are working with the *A Regional Collaboration for Health* (ARCH) programme to develop a sustainable regional strategy for pathology services in Mid and South West Wales. It is consistent with the recommendations from the All Wales Pathology Collaborative Project and the *Pathology Statement of Intent* (Draft: 19th April 2018), which addresses the challenges facing Pathology services and identifies strategic approaches to facilitate the development of high quality, effective and resilient pathology services for NHS Wales consistent, with Welsh Government ambitions outlined in *Taking Wales Forward: Healthy and Active,* the key recommendations of *The Parliamentary review of Health and Social Care in Wales, and 'A Healthier Wales'* strategy released by WGov in 2018 in response to the Parliamentary Review. This SOC will be shared with the Pathology Network to ensure full alignment with the national approach.

B. The Case for Change

11. Pathology services within Mid and South West Wales must provide *the right level of services in the right place*, be sustainable, resilient and improve quality and safety.

Future Vision

12. Depending on the scale of the investment, in the short term, this investment aims to improve recruitment and retention within the Mid and South West Wales Cellular Pathology and wider Pathology service, improve quality and safety, foster training opportunities therein, and supports modernisation of the workforce and service innovations. In the longer term, this investment supports more sustainable Pathology services in the region, supports technological innovations, promotes benefits in terms of improved specialist healthcare services, facilitates access to modern techniques and innovations, and enhances the patient experience and improve quality outcomes. Overall, this investment delivers urgent improvements in quality, safety and sustainability within Mid and South West Wales' pathology services.

13. The 'status quo' cannot be maintained and this document proposes investment to support development of regional pathology services where they promote tangible regional benefits, support delivery of more sustainable regional services and satisfy international, national, regional and local strategic direction.

The Economic Case

Investment Objectives and Benefits

14. The main benefits to staff, patients and visitors are classified in terms of cash releasing benefits (CRBs), non-cash releasing benefits (NCRBs), quantifiable benefits (QBs), and non-quantifiable benefits (Non QBs) are outlined in **Appendix F – Investment Objectives and Benefits**.

Service Scope

15. The South West Wales Regional Pathology Re-configuration Project Board agreed the following range of service scope options:

[3] Public Health Wales Long term strategy 2018-2030.
http://www.wales.nhs.uk/sitesplus/documents/888/Long%20Term%20Strategy_English_single%20pages%20%28print%20version%20191118%29.pdf

Figure – Service Scope

Functional Content by Health Board		Option 2 Do Minimum	Option 3 PREFERRED WAY FORWARD Intermediate – more ambitious	Option 4 Intermediate – far more ambitious	Option 5 Do Max ambitious
HDUHB/ABMUHB	Develop Regional Cellular Pathology (Cytology and Histopathology)	✓	✓	✓	✓
HDUHB/ABMUHB	Regional Diagnostic (Laboratory) Immunology service;	✓	✓	✓	✓
ABMUHB	Co-locate Singleton's Body Store at Morriston Hospital service (future proofed capacity)	✓	✓	✓	✓
	A 500 m² ATTC, i.e. Cell and Gene Therapy indicative shell and core area	✓	✓	✓	✓
ALL	Provide dedicated car parking to support regionalised services (300 spaces)	✓	✓	✓	✓
PHW	Relocate ABMUHB's PHW Medical Microbiology service to Morriston Hospital		✓	✓	✓
HDUHB	Reconfigure and refurbish local non-regionalised Blood Sciences services' accommodation to provide fit for purpose facilities - Refurbishment of Cell Pathology - Withybush Hospital, Prince Philip Hospital, Llanelli & West Wales General Glangwili (approx. 486 m2)		✓	✓	✓
ABMUHB	Develop a temporary modular Body Store solution at Singleton Hospital			✓	✓
ABMUHB	Re-provide ABMUHB's Essential Laboratory Service				✓

The Shortlist

17. The Project Board recommends the following shortlisted options for more detailed evaluation at the OBC stage:

Figure – Short List of Options

Option 2 – Do Minimum	
Service Scope	SC02 - 'Core' services, i.e. Develop Regional Cellular Pathology (Cytology and Histopathology) & Regional Diagnostic (Laboratory) Immunology service; Co-locate Singleton's Body Store at Morriston Hospital service (future proofed capacity) & a 500 m² ATTC, i.e. Cell and Gene Therapy indicative shell and core area
Service Solution	SS01 – New Build/Reconfigure co-located regionalised services' accommodation on one site &; Provide dedicated car parking to support regionalised services

Service Delivery	DEL1 - NHS in-house solution
Implementation	IMP02 - Single Phase with staged occupancy of new build and concurrent local refurbishments
Funding	FUN02 - Public funding
Option 3 – Intermediate 1	
Service Scope	SC03 - 'Core' plus Relocate ABMUHB's PHW Medical Microbiology service to Morriston Hospital
Service Solution	SS02 – New Build all co-located regionalised services' accommodation on one site; Provide dedicated car parking to support regionalised services; plus Reconfigure and refurbish local non-regionalised services accommodation to provide fit for purpose facilities
Service Delivery	DEL1 - NHS in-house solution
Implementation	IMP01 - Phased (e.g. build some elements as a shell and occupy later and phase local refurbishments)
Funding	FUN02 - Public funding
Option 4 – Intermediate 2	
Service Scope	SC03 - 'Core' plus Relocate ABMUHB's PHW Medical Microbiology service to Morriston Hospital & Develop a temporary modular Body Store solution at Singleton Hospital
Service Solution	SS02 – New Build all co-located regionalised services' accommodation on one site; Provide dedicated car parking to support regionalised services; plus Reconfigure and refurbish local non-regionalised services accommodation to provide fit for purpose facilities
Service Delivery	DEL1 - NHS in-house solution
Implementation	IMP02 - Single Phase with staged occupancy of new build and concurrent local refurbishments
Funding	FUN02 - Public funding
Option 5 – Do Maximum	
Service Scope	SC04 - 'Core' plus Relocate ABMUHB's PHW Medical Microbiology service to Morriston Hospital & Develop a temporary modular Body Store solution at Singleton Hospital & Re-provide ABMUHB's Essential Laboratory Service
Service Solution	SS02 – New Build all co-located regionalised services' accommodation on one site; Provide dedicated car parking to support regionalised services; plus Reconfigure and refurbish local non-regionalised services accommodation to provide fit for purpose facilities
Service Delivery	DEL1 - NHS in-house solution
Implementation	IMP02 - Single Phase with staged occupancy of new build and concurrent local refurbishments
Funding	FUN02 - Public funding

18. **The preferred way forward is Option 3 – Intermediate 1** (Develop Regional Cellular Pathology (Cytology and Histopathology) & Regional Diagnostic (Laboratory) Immunology service; Co-locate Singleton's Body Store at Morriston Hospital service (future proofed capacity), a 500 m² ATTC, i.e. Cell and Gene Therapy indicative shell and core area, & relocate ABMUHB's PHW Medical Microbiology service to Morriston Hospital to new build/reconfigured and co-located regionalised services' accommodation, supported by dedicated car parking.

The Commercial Case

Procurement Strategy

19. It is anticipated this scheme's procurement strategy will follow the *Designed for Life – Building for Wales3* procurement route and be publicly funded.

The Financial Case

20. The indicative financial implications of the proposed investment for each shortlisted option are as follows:

Figure – Capital Requirements (£000 incl non-recoverable VAT)

	Option 2 Do Minimum	Option 3 Intermediate – more ambitious	Option 4 Intermediate – far more ambitious	Option 5 Do Max ambitious
Departmental Costs	17,249	25,729	27,121	31,168
On Costs	13,041	20,332	20,475	25,499
Provisional location adjustment	-908	-1,382	-1,427	-1,700
Works Costs Total	**29,382**	**44,679**	**46,169**	**54,967**
Fees	4,701	7,149	7,387	8,795
Non Works Costs	1,741	2,694	2,641	2,745
Equipment Costs	3,611	5,059	5,231	5,718
Planning Contingency	3,943	5,958	6,142	7,222
VAT (adjusted for reclaim)	7,576	11,678	12,036	14,130
Base Project Cost	**50,954**	**77,217**	**79,606**	**93,577**

Based on BCIS PUBSEC Firm Price Index 248 reporting level

Overall Affordability and Balance Sheet Treatment

21. The additional revenue impact on each of the shortlisted options are as follows:

Figure – Revenue Impact £000's

Costs	Option 2 Do Minimum	Option 3 Intermediate – more ambitious	Option 4 Intermediate – far more ambitious	Option 5 Do Max ambitious
Service Pay	0	0	0	0
Service Non-Pay	0	0	0	0
Support Services	197	236	263	503
Total	**197**	**236**	**263**	**503**

22. The revenue cost impact of the short-listed option includes the estimated costs of running a modern facility built to conform with the latest building and engineering standards. There will be other costs that will need to be reviewed during the OBC stage, including travel and IT support. There are two areas of cost additionality that have not been included in this case, as both exist whether the service moves to a new facility or remains in-situ; current staffing pressures due to increasing demand and the need for Hywel Dda to manage the workload of their Consultant staff using the Royal College points based system.

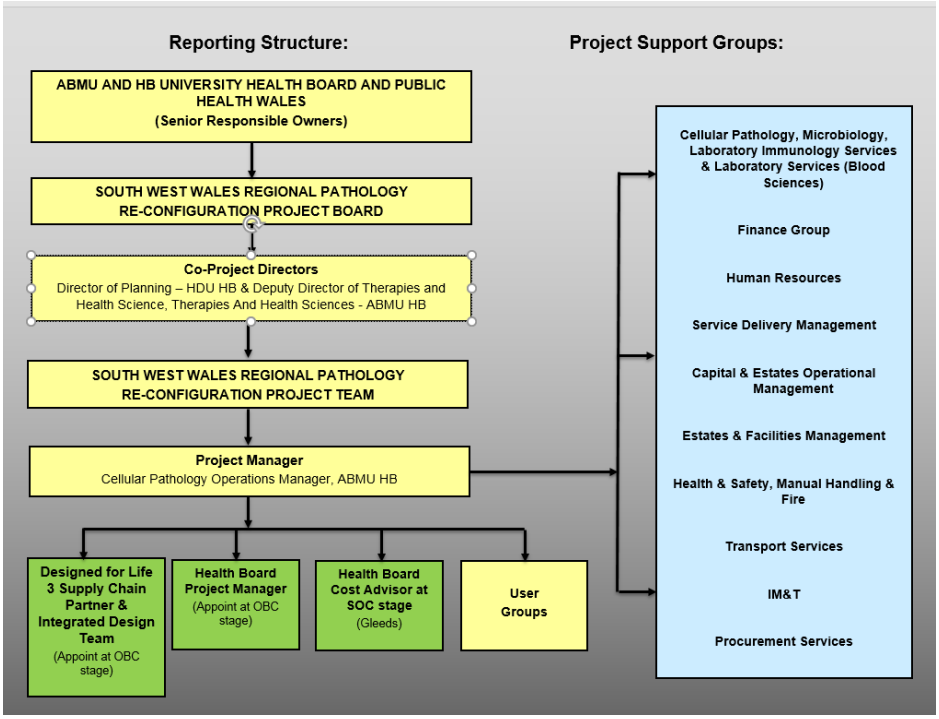
23. A full assessment of capital and revenue affordability will be made at OBC stage.

The Management Case

Project Management Arrangements

24. The project management arrangements are shown below:

Figure – Project Structure



Indicative Project Milestones

25. The indicative milestones are set out below:

Figure – Key indicative milestones

Activity	Due Date
HDUHB & ABMUHB Executive Teams endorse 'Discussion' SOC	November/December 2018
HDUHB Executive Team approves SOC	February 2019
ABMUHB's Investments and Benefits Group (IBG) endorses SOC	12th March 2019
ABMUHB Executive Team approves SOC	13th March 2019
ABMUHB Board approves SOC	28th March 2019
Submit SOC to Welsh Government for endorsement	April 2019
Welsh Government endorse SOC	May 2019
Appoint Supply Chain Partner, Health Board Cost Advisor & Health Board Project Manager from Designed for Life Regional Framework	July 2019
ABMUHB's IBG and HDUHB & ABMUHB Executive Teams approve OBC	June 2020
Submit OBC to Welsh Government for approval	June 2020
Welsh Government approval of OBC	September 2020
ABMUHB's IBG and HDUHB & ABMUHB Executive Teams approve FBC	October 2021
Submit FBC to Welsh Government for approval	October 2021
Welsh Government approval of FBC	January 2022
Mobilise and commence new build/extension main works	February 2022
New build completed (subject to contractor's programme)	January 2024
New build commissioning (subject to accreditation arrangements & technical commissioning)	February 2024
New build operational	March 2024

Activity	Due Date
Commence refurbishment	April 2024
Refurbishment completed (subject to contractor's programme)	October 2024
Refurbishment commissioning (subject to accreditation arrangements & technical commissioning)	November 2024
Refurbishment operational	December 2024
Technical PPE (approx. 3 months post new build handover)	March 2025

Recommendation

26. This SOC presents a compelling case for change and supports the development of a regional Mid and South West Wales Regional Centre of Excellence Cellular Pathology Laboratory, Regional Diagnostic Immunology Laboratory and Regional Medical Microbiology facility at Morriston Hospital, Swansea.

27. We recommend on this basis that Welsh Government endorse this SOC and that this project progress to Outline Business Case (OBC) stage.

Signed & dated:

Mrs Tracey Myhill, Chief Executive Senior Responsible Owner **Abertawe Bro Morgannwg University Health Board**	**Mr Steve Moore Chief Executive** **Senior Responsible Owner** **Hywel Dda University Health Board**	**Dr Tracey Cooper Chief Executive** **Senior Responsible Owner** **Public Health Wales**
……	……	……

1 Purpose

1.1 Introduction

1.1.1 This document outlines the strategic direction supporting investment in Mid and South West Wales Regional Centre of Excellence Cellular Pathology Laboratory, Regional Diagnostic Immunology Laboratory and Regional Medical Microbiology facility at Morriston Hospital, Swansea.

1.2 Structure and Content of this Document

1.2.1 The SOC is in two volumes:

- Volume 1 – The SOC comprises the following components:
  - The Strategic Case section.
  - The Economic Case section.
  - The Commercial Case section.
  - The Funding and Affordability Case section.
  - The Management Case section.
- Volume 2 - SOC Appendices

1.2.2 This document has been prepared using 5-case Model guidance:

- HM Treasury - The Green Book: Central Government Guidance on Appraisal and Evaluation (2018).
- Welsh Government – WHC 2018 043 NHS Wales Infrastructure Investment Guidance (2018).

2 Strategic Case Part A: The Strategic Context

2.1 Introduction

2.1.1 This Strategic Outline Business Case (SOC) was prepared through a process of engagement with key stakeholders. Principally, it seeks support from Welsh Government in the form of investment in Mid and South West Wales' Pathology services in the range of £50.954 - £93.577m (including non-recoverable VAT) to support the development of a Mid and South West Wales Regional Centre of Excellence Cellular Pathology Laboratory, Regional Diagnostic Immunology Laboratory and Regional Medical Microbiology facility at Morriston Hospital, Swansea.

2.2 Background

2.2.1 Pathology is the study of disease. It bridges science and medicine and underpins every aspect of patient care, from diagnostic testing and treatment advice to the use of cutting-edge technologies and the prevention of disease.[4] Pathologists work with other doctors, healthcare scientists, nurses and healthcare professionals in hospitals and GPs' surgeries to diagnose, treat and prevent illness[5].

2.2.2 Pathology services are integral to health care provision. Access to effective and efficient pathology services is essential to the delivery of a significant proportion of national priorities and targets for the NHS. Pathology is involved in 70% of all diagnosis made in the NHS[6]. Pathology also play a significant role in screening and monitoring and in relation to chronic conditions, and underpins all clinical services. Over 95% of clinical pathways rely on patients having access to efficient, timely and cost-effective pathology services[7].

2.2.3 There are 19 specialties within Pathology of these the four main specialties are Blood Sciences (this includes Haematology & Chemical Pathology services and is also called Laboratory Medicine, Blood Transfusion, Cellular Pathology (the study of disease in human tissue) and Medical Microbiology (the study of infection).

2.2.4 Pathology is a key component in the delivery of prudent health services to the population of Wales and is a key enabler to Welsh Government health delivery plans including cancer and stroke.

2.2.5 Current Pathology services are under increasing pressure with changing clinical models shifting the balance of care, which has resulted in a major growth in demand as a result of more effective clinical pathways; increasing numbers of older people; increasing cancer incidence, and; improved technology, new techniques and workforce pressures.

2.2.6 Pathology is a key enabler within healthcare in NHS Wales and undertakes around 50 million tests per annum. Analysis of the costing information available highlights we currently spend in excess of £117.6 million[8] per year (2015/16) on Pathology services in Wales, representing 1.9% of the total budget for health (£6.1bn 2015/16).

2.2.7 Diagnostic Immunology services are under pressure to deliver evidence based services which support effective treatment and deliver better results and improved outcomes patients following Prudent Healthcare principles; to meet the All Wales Immunology Specification and ensure the highest quality of evidence based care, to provide sustainable Diagnostic Immunology services, and; to improve accessibility for patients.[9]

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[4] The Future Delivery of Pathology Services in Wales 2017 onwards: Proposals for Change v0.7 Draft 060917
[5] Royal College of Pathologists, www.rcpath.org (2017)
[6] Report of the Second Phase of the Review of NHS Pathology Services in England, Lord Carter of Coles (2008)
[7] Service Improvement in Blood Sciences, NHS Improvement - Diagnostics (Jan 2013)
[8] Pathology Costs NHS Wales 2015/16, NHS Wales Health Boards (R.Tovey) May 2017
[9] Recommendations Paper to develop services throughout Wales which meet the All Wales Immunology Service Specification (NHS Wales Health Collaborative) May 2012 (v0.1)

2.2.8 Cellular Pathology, Molecular Pathology and Diagnostic Immunology services are vital for patients. Almost all cancer patients, plus many patients with non-malignant diseases, require a histological or cytological test for initial diagnosis. Increasing stratified treatment options and prolonged survival with disease, including cancer relapses, are creating new requirements for further cellular pathology input. There is a rapidly escalating need for innovative testing to assess prognosis and to support stratified medicine approaches.[10] These services are explained in more detail as follows:

Cellular Pathology Services

2.2.9 Cellular Pathology services provide essential diagnostic information to enable the care of patients in and out of hospital. Histopathology services play a crucial role in the diagnosis, prognosis and management of both benign and malignant diseases, and make a major contribution to treatment selection and monitoring. Implementation of the Single Cancer Pathway will place further demands on this service with a requirement for faster turnaround times and more specialist testing and reporting. Pathology research generally is critical for many diseases, especially cancer – almost every cancer patient requires a histological or cytological test from pathology for initial diagnosis. Furthermore, personalised medicine and the rapidly increasing need for innovative testing to assess prognosis and to support stratified medicine approaches will also impact on this service.

Laboratory Medicine/Blood Sciences & Laboratory/Diagnostic Immunology

2.2.10 Laboratory Medicine & Blood Sciences are terms to describe the integrated laboratory disciplines of clinical biochemistry, laboratory haematology, Diagnostic Immunology, genetics and blood transfusion. Analysis of clinical samples will establish information about the health of a patient as pertaining to the diagnosis, treatment, and prevention of disease.

Diagnostic Immunology / Laboratory Immunology Services

2.2.11 Diagnostic Immunology studies the immune system and is an important branch of the medical and biological sciences. The immune system protects us from infection through various lines of defense. If the immune system is not functioning as it should, it can result in disease, such as autoimmunity, allergy and cancer. It is also now becoming clear that immune responses contribute to the development of many common disorders not traditionally viewed as immunologic, including metabolic, cardiovascular, and neurodegenerative conditions such as Alzheimer's.

Workforce for Essential Laboratory Services

2.2.12 Essential Laboratory Services comprises Consultant Haematologists, Consultant Biochemists, Clinical Scientists, Biomedical scientists and supporting laboratory staff.

Medical Microbiology Services

2.2.13 Medical Microbiologists study the causes and management of infectious diseases and play a key role in the prevention, management and control of infection in both hospitals and the community. The service is clinically led and is supported both by local and specialist laboratories which deliver diagnostic support.

2.2.14 In Wales, this service is in a period of transition due to the planned introduction of molecular and genomic services which aims to provide a more detailed and responsive service. The re-design of the Medical Microbiology service is subject to a national programme and needs to take account of possible consolidation of some testing and/or expanding the number of locations for near/point of care testing. Rapid access to results is essential to influence acute management of infection in patients and the prevention of infection in others. The long-term plan for Medical Microbiology is for PHW to develop itself into an Infectious Disease Service for Wales as this recognises the need for more local clinical engagement within a national structure.

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[10] "A National Co-ordinating Cellular and Molecular Pathology Programme (CM-Path) to reinvigorate UK academic cellular pathology" by Dr Bridget & S. Wilkins CM-Path Summary April-May 2015.

2.2.15 In recognition that health security has become a greater public health priority, and following their having signed up to the UK Antimicrobial Resistance (AMR) Action Plan the Welsh Government is seeking to strengthen the National Health Protection Service so our health security can at all times provide an effective response. One of the challenges the Welsh Government faces is ensuring we have fit for purpose laboratory estates which are able to implement rapid testing technologies. PHW, in collaboration with policy colleagues in Welsh Government, has been working on a model to strengthen our National Health Protection Service by providing comprehensive diagnostic testing. Key to this is development of two centres for 'cold' tests in Wales, one in north Wales and one in mid & south Wales, and the development of more 'hot' tests' laboratories in other parts of Wales, including Carmarthen.

2.2.16 This will involve reconfiguration of microbiology laboratory establishment across Wales to provide fit for purpose, value for money and high quality diagnostic services that support local care. Delivery of this model will involve expansion of 'hot' diagnostics (in all 16 acute hospitals) to provide rapid (<4 hour) molecular facilities to provide testing for CSF, blood cultures, respiratory samples, norovirus, C. difficile, MRSA and CPO. Welsh Government are taking forward proposals to strengthening the National Health Protection Service and is holding a workshop with NHS Wales' Medical Directors & Nurse Directors, and Directors of Public Health to ensure we are resilient at both a local and national level so plans can be taken forward at pace during 2019-20.

Cell and Gene Innovations – Opportunities for Collaboration

2.2.17 This project complements the UK's, Wales and the regional ambitions under the Industrial strategy and also playing a lead role in developing a network of emerging Advanced Therapy Treatment Centres (ATTCs) and the promotion of gene or cell therapy's Advanced Therapy Medicinal Products (ATMPs) research and development. ATMP's having the potential to benefit patients with challenging conditions that cannot be cured with current treatments by promoting access to breakthrough medicines.[11]

2.2.18 Working together to develop complementary infrastructure and partnership arrangements, a co-located Regional Pathology Unit and ATTC development, will have the potential to deliver breakthrough therapies and treatments to patients throughout the region and across the UK. The benefits of both projects being at feasibility stage is that this project has been able to incorporate a 500 m2 indicative shell and core area into its schedule of accommodation to host a future ATTC development. A co-located and integrated Regional Pathology and ATTC will benefit the region and optimise opportunities for carrying out clinical trials to develop "novel medicines" and stimulate domestic and international investment.

Challenges facing Pathology Services in NHS Wales

2.2.19 Since *The Future Delivery of Pathology Services in Wales* was published in 2008 the pathology service or community within Wales has been promoting a modernisation agenda, that is in part, responsive to increasing sustainability, workforce and major growth demand pressures on the service or community, and; is responsive to rapidly changing technology, new techniques and demographic change. This document and the views expressed herein are reflective of these challenges.

2.2.20 The key challenges and the future vision for pathology services in Wales are summarised in the below:

- **Current strategic role is focused on "cost"** of Pathology services need to focus on 'quality', reduce duplication and variation and the number of errors, do less unnecessary testing, to standardised testing protocols, provide and have access to more robust management information and data, implement best practice, and add more 'value', e.g. through innovative service design projects
- **Major growth in demand** Pathology services need to develop more effective clinical

[11] Innovate UK Competition: Establishing UK Treatment Centres for Advanced Therapies - 01 Nov 2017

pathways, 'optimise' pathways, introduce new techniques to support cancer diagnosis (recognising the incidence of cancer is increasing) and demographic pressures (recognising there are increasing numbers of older people, many of whom have multiple health conditions as they age), and re-design the workforce skills to meet future needs.

- **Changing models of care** Pathology services need to support the principles of *Prudent Healthcare, Work more closely w*ith clinical teams, develop new techniques and innovate to realise benefits of more personalised health monitoring/ preventative medicine, provide more rapid treatment for patients / improved outcomes / timely responses, and provide more proactive management of patients.
- **Workforce pressures** Pathology services need to support more sustainable and resilient pathology services, improve recruitment, retention and make more effective use of scare resources, support more modern workforce models that are flexible and appropriately skilled and equipped to deliver future requirements, and support innovative & sustainable solutions. There are national crises related to shortage of healthcare professionals in these services, and most particularly Consultant Histopathologists.
- **Technology and Informatics** Pathology services need to promote digital technologies to improve patient safety and which support multidisciplinary team communications, develop IT platforms that support transformation of Pathology delivery model, improve Information Governance/Performance Indicators, support Genomics and Genetics enhance diagnosis and treatment, 'tailor' therapies to individual patients and 'empower' patients to manage their own health.

Service Change

2.2.21 NHS Pathology services throughout the UK have been undergoing a transformational process over the last ten years since publication of the Carter Review (2006). Traditionally, Pathology services are delivered from main District General Hospitals (DGHs) in Wales. Moves to rationalise appropriate elements of this service, based on our experience of the pressures expressed in Figure 2, support the development of a single site solution for regionally co-locating Cellular Pathology Laboratory Services at Morriston Hospital. This equally applies to other elements of the service, e.g. Diagnostic Immunology, and the final scope of this business case shall be determined following a review of further regional opportunities this development might present.

2.2.22 Co-location and integration of these services supports a number of **national and regional strategic drivers** allowing delivery of a modern, efficient, effective, responsive and more economical evidence-based healthcare, leading to better health outcomes and improved patient pathways, including screening for disease, diagnosis and treatment, as well as optimising treatment for patients and stakeholders.

2.2.23 It supports working with research partners and oncology to develop **personalised medicine**, benefitting patients' with access to more effective and targeted treatments and benefitting the NHS in terms of time and cost savings.

2.2.24 Development of this service also supports **Emergency Preparedness Resilience and Response** initiatives in accordance with the civil protection duties and under the auspices of the Civil Contingencies Act (CCA), 2004 by strengthening the resilience of Morriston Hospital's Delivery Unit response to a major incidents, by providing access to dedicated CT Scanner diagnostic services and by providing infrastructure to support access to temporary emergency mortuary facilities in our capacity as a Category 1 Responder.

The NHS Wales Health Collaborative, The National Pathology Board & The All Wales Pathology Collaborative

2.2.25 Ensuring the sustainability of future services by concentrating expertise and enhancing efficiency, the group, building on the significant work already undertaken by the **NHS Wales Health Collaborative**, which was established in February 2015 and brought together, into a single structure, three teams undertaking work on a regional or national basis on behalf of Health Boards and NHS Trusts. The NHS Wales' Collaborative's work programme, including Diagnostic services modernisation programme (pathology and imaging), is directed by Chief Executives. **The National Pathology Network** is also supported by the **All Wales Pathology Collaborative** which is leading work on individual pathology disciplines.

All Wales Pathology Collaborative's Cellular Pathology Project Group's Preferred Model

2.2.26 In January 2014, under the auspices of the All Wales Pathology Collaborative, the Cellular **Pathology Project Group** was formed. Chaired by an Executive Director of Therapies and Health Science, membership of the Cellular Pathology Group included Cellular Pathology representation from each of the health boards (both medical and biomedical scientists), academic representation from Cardiff University and Swansea University, workforce representation and members of the NHS Wales Health Collaborative. Recognising the existing Cellular Pathology Services in South Wales are fragile and unsustainable, with many of the services experiencing difficulties in recruiting consultant Cellular Pathologists and in gaining accreditation of the service, the Group was tasked with identifying options for the future provision of the Cellular Pathology service in South Wales (including the West) whilst aligning with advances made in North Wales.

2.2.27 The Cellular Pathology Project Group, building on the significant work already undertaken by both the South East and South West of Wales, developed proposals for the reconfiguration of Cellular Pathology services within South Wales. A clear steer was provided by All Wales Chief Executives and the proposed model options underwent a robust non-financial and financial option appraisal process between 2014 and 2015.

2.2.28 The Cellular Pathology Project Group's non-financial and financial appraisals outcomes (see **Figure 1**) support the creation a Two Site solution for the location of Cellular Pathology services' in South Wales (i.e. one in Cardiff and one in Swansea). Their findings were presented to the All Wales Chief Executives for approval before proceeding to the next stage, the development of a detailed Implementation Plan for the preferred option.

2.2.29 Please refer to **Appendix L - AWCP Group's non-financial and financial appraisals** for a detailed summary of the AWCP process and timeline. Please see Appendix P – Summary of the AWCP non-financial and financial appraisal timeline and process to date for information:

2.2.30 The solution proposed in this SOC (i.e. the development of a Mid and South West Wales Regional Centre of Excellence Cellular Pathology Laboratory and Regional Diagnostic Immunology Laboratory Facility at Morriston Hospital, Swansea) 'fits' strategically with the Cellular Pathology Project Group's preferred Two Site Cellular Pathology services model outcome; 'Fits strategically with Morriston Hospital's site Development Control Plan (SDCP) and with the City & County of Swansea's Local Development Plan for the north and east of Morriston (published in June 2016) as regards proposals for development of an ARCH/Morriston Health Campus and further development as a regional 'Hub' hospital site for specialist treatments for South West Wales, and; Supports excellent communication links due to this site's adjacency to the M4 corridor. As a centre of excellence, we aim for the new co-located service to be recognised as a centre of excellence in clinical diagnostics and investigations service.

2.2.31 Furthermore, the solution is consistent with the recommendations from the All Wales Pathology Collaborative Project and the Pathology Statement of Intent (Draft: 19th April 2018), which addresses the challenges facing Pathology services and identifies strategic approaches to facilitate the development of high quality, effective and resilient pathology services for NHS Wales consistent, with WGov ambitions outlined in Taking Wales Forward: Healthy and Active and the key recommendations of The Parliamentary Review of Health and Social Care in Wales.

All Wales Pathology Collaborative's National Immunology Project Group's Preferred Model

2.2.32 The **National Immunology Project** was formed under the auspices of the All Wales Pathology Collaborative (AWPC). Its objective was to develop, explore and appraise options for the establishment of safe, sustainable, affordable and high quality immunology services throughout Wales, which meet the **All Wales Immunology Service Specification** (as developed by the National Immunology Project Group and was adopted by the Combined Pathology Group).

2.2.33 On the 3rd November 2016 the National Immunology Project Group identified six options, including a Business As Usual option. This list was analysed and a short list presented to the then All Wales Pathology Collaborative.

2.2.34 A non-financial Sub Option Appraisal for Immunology Services was undertaken by representatives from Immunology, Biochemistry and Haematology Specialist Standing Advisory Committees (SSAGs). The outcome of the Immunology Project Groups non-financial and high-level financial option appraisal was to consolidate testing to four laboratory sites in South Wales and to one site in North Wales, along with the re-distribution of some assays, in particular specific IgE tests to rare allergens, in South East West (considered to be achievable without equipment, capital or infrastructure being required).

2.2.35 The NHS Wales Collaborative Executive Group National Immunology Project's Recommendation's Paper (January 2018) noted "it will be difficult to consolidate, reorganise or centralise anything in Immunology without considering the wider Blood Sciences, Biochemistry and Haematology laboratories within which Immunology sits" and that key benefits, e.g. improved efficiencies, improvements in quality and the ability to achieve accreditation, etc. will be achieved by consolidating testing to four laboratory sites in South Wales and one in North Wales.[12]

2.2.36 Concerns exist as to the sustainability of the current models, the lack of accreditation of services and as a result, the ability to deliver high quality, cost effective Immunology services in the future. Consideration should also be given to what is thought to be an aging workforce, the predicted loss of expertise over the coming years and the resulting skills gap. The implementation of shift work within laboratories has also had an impact on the Immunology service leaving the service short staffed due to the need to cover shifts on a 24/7 basis. Staff are required to cover other disciplines within Blood Sciences and form part of the core group required to cover 24/7 working.

2.2.37 The solution proposed in this SOC (i.e. the development of a Mid and South West Wales Regional Diagnostic Immunology service) 'fits' strategically with Morriston Hospital's site Development Control Plan (SDCP) and under the ARCH programme.

Medical Microbiology Services

2.2.38 We recognise that Medical Microbiology services within the region (currently provided by PHW and by Health Boards) need to be aligned. As set out in paragraphs 2.2.14-16, Medical Microbiology's strategic intentions are to review the clinical and service model across Wales to create a fit for purpose arrangement that allows for appropriate and clinically informed turn-a-round of diagnostics and the use of these to inform clinical decision-making. The way Microbiology services operate differs from other Pathology specialities, for example, in sample preparation and the requirement for incubation. Taken together with our proposed new service model this introduces some distinct differences in our modus operandi, for example, extended times between taking samples and definitive guidance given back to the requesting clinician. For these reasons regional centralisation for specific Microbiology services will form one element, albeit significant, in the future arrangements PHW establishes.

[12] NHS Wales Collaborative Executive Group National Immunology Project Recommendations Paper 30th January 2018 v.1.3

2.2.39 The transfer of ABMUHB's current Medical Microbiology services from Singleton Hospital to the new site in Morriston Hospital would bring the microbiology service closer to its main clinical customers and this adjacency would have a number of advantages. Space within Singleton Hospital is not optimal and restricts access to technologies. Furthermore, the Singleton site does not support good flow of samples from principal sources, Key to this investment is significantly decreased transport times leading to a more rapid service with shortened turnaround time and concatenation for real-time patient results and shorten patient pathway.

Dedicated Mid and South West Regional Cellular Pathology Laboratory

2.2.40 A dedicated Regional Cellular Pathology Laboratory development on the Morriston Hospital site provides a fit for purpose facility to support the healthcare needs of nearly 1 million people living in the Mid and South West Region of Wales. This new facility will:

- Support delivery of a new service delivery model, replacing the existing fragmented and inefficiently configured Cellular Pathology services in ABMUHB & HDUHB Health Boards and align with the Welsh Ministerial Directive for Pathology services in Wales by providing Mid and South West Wales Region with an integrated and more effective Cellular Pathology service;
- Support the strategic objectives and vision of the National Pathology Programme Board (now National Pathology Network), which was established in April 2009 to ensure that the integrated approach to service planning and delivery established through the Pathology Modernisation Project was maintained at both national and local levels;
- Support the CEO's of ABMUHB and HDUHB Health Boards as guided by the South West Wales Regional Pathology Re-configuration Board;
- Support the review recommendations of the South West Wales Regional Cellular Pathology & Histopathology Re-configuration Boards that Pathology services in Wales be provided from two sites within South Wales;
- Support the aims and objectives of the ARCH Prospectus - This project is part of the first tranche of projects under ARCH, and fits strategically within the emerging ARCH Portfolio Delivery Plan (PDP);
- Support technological innovations and increase potential for investment in the regional economy from national and international health care providers;
- Promote regional benefits in terms of improved specialist healthcare services;
- Promote stronger ties with training organisations, promote a more sustainable and resilient regional workforce, and facilitate access to modern technology and techniques, and;
- Enhance the patient experience and outcomes, and improve access to high quality Cellular Pathology services.

2.2.41 This project is sponsored by The Swansea City Region Board, a UK Government and HM Treasury (HMt) sponsored 'Health and Wellbeing' regional development, and aligns with ARCH vision by promoting development of medical technologies, economic development and regeneration, and evidence based health and wellbeing benefits within the Mid and South West Wales Region. The Internet of Health and Wellbeing Programme interconnects with its complementary Internet of Energy and Internet of Economic Acceleration Programmes in the City Deal to create a coherent City Region-led vision.

2.2.42 The submission of a high-level Strategic Outline Business Case (SOC) application for investment support from City Deal funds in October 2016 to support the development of a Regional Pathology Laboratory service for Cellular Pathology in Mid and South West Wales was well received and was formally approved by Mrs Theresa May (Prime Minister), on the 20th March 2017.

2.2.43 This project 'fits' strategically within HDUHB's Clinical Strategy (agreed November 2018) and ABMUHB's Clinical Services' Plan 2019 - 2024 (agreed January 2019).

2.3 Organisational Overview

Abertawe Bro Morgannwg University Health Board (ABMUHB)

2.3.1 As of the 1st April 2019 ABMUHB will cover a population of approx. 400,000 within West Glamorgan and its bordering counties. Currently it has a budget of over £1 billion and employs around 16,000 staff, 70% of whom are involved in direct patient care. In 2017/18 it treated in excess of 16,000 planned inpatients and 54,000 emergency inpatients per year as well as undertaking 53,000 day case procedures. Over 442,000 outpatient and 78,000 accident and emergency attendances are also seen per annum. The total number of beds in the Health Board was 2,288 as at 2016/17.

Hywel Dda Health Board (HDUHB)

2.3.2 HDUHB provides health services for 384,000 people in Mid and West Wales covering Carmarthenshire, Ceredigion, Pembrokeshire and bordering counties, and has a budget of over £947 million. Employing approx. 9,891 staff, 70% of whom are involved in direct patient care. The Health Board covers the second most sparsely populated health board area in Wales, 47.9% of the population in the region live in Carmarthenshire, 20.7% in Ceredigion and 31.4% in Pembrokeshire.

Public Health Wales (PHW)

2.3.3 PHW NHS Trust is *the* national public health agency in Wales. We have an annual budget of £108 million and employ around 1,500 employees 43% of whom are clinical, professional, scientific and technical staff. Our estate is located across Wales and currently comprises of 53 properties, including Screening Centres, Laboratories and Support Accommodation.

2.4 Regional Geography and Catchment Population

2.4.1 Pathology tests are provided for patients within the South and West Wales area including, Swansea, Bridgend, NeathPortTalbot, Pembrokeshire, Ceredigion, Carmarthenshire, and parts of Powys and South Gwynedd.

2.5 Stakeholder Engagement

2.5.1 Stakeholder engagement shall be managed in accordance with the Organisational Change Policy for the NHS in Wales (commonly known as OCP).

2.5.2 Key partners under the auspices of the South West Wales Regional Pathology Re-configuration Project Board and ARCH Project Board shall directly manage the formal staff consultation process.

2.5.3 A Consultation document shall be drafted and circulated to all staff directly affected by the changes together with their Trade Union representatives. This will be supported by a series of ongoing staff communications, including staff meetings (collective and\or individual, as requested) to ensure staff are supported during this period of change.

2.5.4 Based on the range of preferred options the staff directly affected includes the following (list is not exhaustive):

- Consultant Cellular Pathologists and Consultant Microbiologists
- Cellular Pathology Management staff
- Biomedical Scientists, Associate Practitioners/Health Care Scientists
- Biomedical Support Workers, Anatomical Pathology Technicians & Anatomical Pathology Support Workers
- Medical Secretaries & Clerical Staff

2.5.5 This project engages with the wide range of stakeholders and organisations including the following:

- Cellular Pathology, directly and indirectly affected by the project, including Scientific Technical staff and Support staff & Service Users, including Cervical and Bowel Screening Wales
- Professional Groups & The Royal College of Pathologists
- Cellular Pathology, Cytology/Gynae, staff groups, laboratory managers, staff managers, staff and HR/staff side representatives
- Diagnostic Immunology staff
- GPs in Mid & South West Wales area
- CEO's of ABMUHB & HD Health Boards
- Welsh Government
- Community Health Councils

2.5.6 The following partners and key stakeholders shall be consulted with via the following collaborative and consultative forums (list is not exhaustive):

- NHS Wales Health Collaborative Project
- The National Pathology Network
- The South Wales Regional Pathology Re-configuration Board

2.6 Regional Population

2.6.1 The following figure provides the latest population statistics for Wales, HDUHBs and ABMUs Health Board's population:

Figure 1 – Population Base (as at March 2019)

Key Statistics	Wales	HDUHB	ABMUHB
Total population	3,099,100	383,200	525,500
Population aged 75 and over	9.1%	10.4%	8.8%

Source: Public Health Wales Observatory (ONS)

2.6.2 Comparing the latest population estimates for mid-2015 with the mid-2014 estimates shows the population of Wales increased by 7,100 (up 0.23%) to 3,099,100 since mid-2014 and accounts for 5% of the UK's population. Population growth in the year to mid-2015 was greatest in southern and eastern England. In Wales, the population growth was only 0.23%, one of the lowest in the UK. This rate is reflective Wales having the lowest net international migration and birth rates, i.e. a similar number of births and deaths resulted in no natural change to the population of Wales.

2.7 Health Status

2.7.1 The following figure provides the latest morbidity statistics for Wales and details HDUHB's and ABMUHB's populations:

Figure 2 – Morbidity

Key Statistics	Wales	HDUHB	ABMUHB
Life expectancy at birth – males (years)	78.3 years	79.2 years	77.4 years
Life expectancy at birth – females (years)	82.3 years	82.9 years	81.7 years
Adults who are overweight or obese	58.6%	59.8%	58.0%
Adults who smoke	20.0%	18%	18.7%
Adults who drink above guidelines	40.1%	38.1%	41.3%
MMR take up	95.3%	93.6%	95.1%
Live births per 1,000 women aged 15-44 years	59.1	56.8	56.9
Emergency hospital admissions	112.4	105.3	112.8

Source: Public Health Wales Observatory (ONS)

2.7.2 The number of males aged 85 and over in the UK has increased by 54% since mid-2005, compared to a 21% increase for females, largely driven by changes in tobacco smoking and advances in health treatments for circulatory illnesses. However, the incidence of cancer is increasing. In particular, the rising incidence of cancer and an ageing population (many of whom experience multiple health conditions as they age) is a major issue for pathology services.

2.8 Health Board Boundary Changes

2.8.1 Following a period of public consultation Vaughan Gething AM, Cabinet Secretary for Health and Social Services, announced on the 14th June 2018 that from 1st April 2019, the responsibility for providing healthcare services for people in the Bridgend County Borough Council area will move from ABMUHB to Cwm Taf University Health Board (CTUHB). It is anticipated that transition changes discussions regarding Pathology services will take account of recent Carter principles' reviews, promoting cost efficiency, effectiveness, standardisation and consolidation, and efficiencies from maximising economies of scale. Executive support exists for continuation, with for example, Histology activity levels continuing as predicted, with delivery of the services to the population of Bridgend by ABMU Pathology via a Service Level Agreement (SLA) with CTUHB. Responsibility for PoWH's existing microbiology activity will remain with PHW.

2.9 Benchmarking

2.9.1 Benchmarking visits to similar Pathology facilities have been undertaken, including North Bristol NHS Trust, which has .similar current pathology workloads. Their Department of Cellular Pathology provides a wide-ranging and comprehensive diagnostic Histopathology, diagnostic Cytopathology and Cervical cytology screening service.

2.9.2 The Department of Cellular Pathology is well-equipped and provides routine histological and cytological techniques, together with a wide range of immunofluorescence and immunohistochemical techniques. There is shared provision of an electron microscopy service, particularly for the examination of renal biopsies, in their Neuropathology department. The department works closely with the Bristol Genetics Laboratory for the provision of a portfolio of molecular genetics testing. Clinical consolidation of services had brought together the work of some teams whilst in others Cellular Pathology has instigated this.

2.10 Business Strategies

2.10.1 Pathology services have been the subject of a wide series of reviews and the All Wales Pathology Collaborative Project was established to respond to the significant points raised in the following strategic documents and reviews:

- ***Review of NHS Pathology services in England*** (DoH, 2006)
- ***Report of the Second Phase of the Review of NHS Pathology Services in England*** (DoH, 2008)
- ***The Future Delivery of Pathology Services in Wales*** (WG, 2008)
- ***The National Pathology Framework (NPF) for Wales*** (NHW Wales, 2008)
- ***Review of the Histopathology Services in NHS Wales*** (2010)
- ***Digital First: Clinical Transformation through Pathology Innovation*** *(*National Pathology Programme, NHS England, February 2014)
- **Prudent Healthcare** – *Securing Health and Well-Being for Future Generations (Wales) Act* 2015
- **The Carter Review** - *Review of Operational Productivity and Performance in English NHS Acute Hospitals: Unwarranted Variation* (UK Government, 2016)
- **Emergency Preparedness Resilience and Response** initiatives in accordance with the civil protection duties and under the auspices of the **Civil Contingencies Act (CCA) 2004**

2.10.2 In particular, Lord Carter of Coles' **Report of the Second Phase of the Review of NHS Pathology Services in England (DoH, 2008)**, which advised significant savings could be made throughout the NHS by consolidating pathology services influenced this project's direction of travel by focusing on the key themes of modernisation, improving quality and patient safety and improving efficiency.

Background

2.10.3 Over the last ten years ABMUHB's and HDUHB's pathology services have introduced many modernisations and have contributed towards the development of regional and national best practice within the service. Savings and efficiencies realised from those modernisations have been re-invested in services in response to local pressures. For example, ABMUHB consolidated and re-designed its cytology, histology, laboratory medicine, immunology and post mortem pathology services by 2015, and; HDUHB Blood Sciences laboratories at Prince Philip, Withybush and Bronglais Hospitals were designed with LEAN strategies in terms of workflow. Cellular Pathology processing was centralised to Glangwili Hospital, but due to infrastructure constraints Non-gynae cytology is processed in Prince Philip Hospital. Post mortems were centralised to the new Mortuary facility at Glangwili Hospital (the benefits of this and other process engineering strategies include maximization of workforce efficiencies and empowerment, and improved quality particularly for processes, which remain largely manual[13]).

2.10.4 Both Health Boards actively participate in the ARCH programme to support Pathology service change within the region and are supportive of work of All Wales Pathology Collaborative Project in Diagnostic Immunology and Cellular Pathology, and previously the SWW Regional Cellular Pathology Project.

2.10.5 ABMUHB has supported national benchmarking using Keele University Benchmarking Services' (KUBSs') and is fully engaged in feedback processes. HDUHB's Cellular Pathology service is actively involved in the Cancer Pathway through weekly feedback via Patient Tracking List (PTL) to cancer services and HDUHB's Microbiology service provides tailored feedback on reports to educate and nudge good practice.

2.10.6 In HDUHB, additional pre-analytical automation is being implemented as part of the Roche managed service contract in Chemistry and Diagnostic Immunology services have been centralised to a single site based at Prince Philip Hospital. Whilst in ABMUHB, Six sigma was used as the methodology for re-design of four-sample receptions across the Health Board and to establish fully automated laboratory facilities for Biochemistry and Haematology as part of the procurement programme.

2.10.7 In ABMUHB, skill mix reviews have been conducted as part of pathology clinical strategy across Laboratory Medicine and Cellular Pathology, with a reduction in senior staff and increase in Support Workers. Associate Practitioner roles have been developed. Cross discipline training within Laboratory Medicine has commenced with staff to develop dual expertise in support of service sustainability. Enhanced Biomedical Scientist roles in specimen dissection and slide reporting have been developed in Histology in line with The Royal College Pathology framework in support of Consultant Histopathologists' workloads.

2.10.8 In HDUHB, continual skill mix assessments are evaluated as opportunities arise and investment in support worker grades have been undertaken wherever possible in Blood Sciences, Cellular Pathology and Microbiology and staff are encouraged to achieve the associated level of qualifications.

2.10.9 Both Health Boards have been working together under the ARCH programme to develop a regional strategy for pathology services, which is consistent with the preliminary recommendations from the All Wales Pathology Collaborative Project.

[13] The Future Delivery of Pathology Services in Wales, August 20018 (p38)

2.11 Accreditation Requirements

2.11.1 Welsh Health Circular *Diagnostic Services Strategy* WHC (2004)061 recommends that all Pathology service providors should enrol in accreditation schemes where they exist and meet licensing and accreditation requirements.

2.11.2 Laboratory compliance against the international standard ISO 15189 is a mark of quality and provides objective evidence that a laboratory is not only competent, but safe, patient-focused, efficient and reliable. Through an externally assessed accreditation process, medical laboratories can demonstrate that they comply with defined standards and best practice and provides authoritative assurance of their technical competence to undertake specific analysis or measurements according to validated methods. The accreditation of laboratories against the ISO 15189 standard in Wales is not statutory but has been mandated by Welsh Government

2.11.3 All laboratories in Wales are working towards quality accreditation. Pathology laboratories are accredited by the United Kingdom Accreditation Services (UKAS). PHW has UKAS ISO:15189 and been re inspected once and is scheduled for re-insertion in May 2019. The relevant standards are:

- **The Human Tissue Authority (HTA)** ensures that there is compliance regarding the obtaining of tissue for further investigation, storage of such tissue etc.;
- Compliance with Medical Laboratories accreditation **ISO15189:2012** (replacing current **Clinical Pathology Accreditation (CPA) requirements**, which ensures laboratories operate a quality management system to integrate the organisation, procedures, processes and resources. The standards which have to be complied with include those around the building infrastructure of the laboratories, continuing professional development of staff, quality assessment of performance and individual performance review);
- **ISO standard 22870:2006** Point-of-care testing (Near-patient testing), and;
- **National External Quality Assessment (EQA)** schemes, both medically and scientifically. Performance against EQA standards.

Summary

2.11.4 Without investment the following 'Status Quo' or 'Business as Usual' scenarios are real possibilities:

- Pathology services, which are already struggling to maintain quality, fail to deliver essential quality improvements and will fail to meet clinically driven targets.
- Workforce arrangements, which are already unsustainable due to staff shortages and problems recruiting & retaining consultant and scientific staff, further destabilise; services fail to meet minimum safety standards, and; services incur more errors and delays in diagnosis and treatment, which in turn, attracts more legal claims and loss of reputation.
- The resilience of Mid and South West Wales' NHS pathology services further weakens, placing more even more pressure on existing staff and local services.
- Service costs continue to increase as the service fails to eliminate duplication/adopt innovative digital technologies and techniques,
- Local pathology services remain fragmented and increasingly operate within non-fit for purpose facilities and with aging equipment.
- Production rates fall, staff morale suffers and we experience more skill mix issues, and restrictive and traditional working patterns persist.
- Local pathology services' increasingly fail to support their local populations, fail to meet rising demand, and will not deliver be capable of delivering personalised treatment.

- Pathology services, if left in their current form, become increasingly unsustainable, lack resilience, and risk becoming unsafe.
- Clinical services in Mid and South West Wales will no longer have access to a medical and technical expert Cellular Pathology service for the diagnosis, prognosis and treatment planning for their populations

2.11.5 The case for change is supportive of these strategies and processes and proposals, which, given the challenges currently facing pathology services, clearly need to adopt a new strategic approach to the development of safer, high quality, effective and resilient pathology services for NHS Wales that addresses the needs of the population, is responsive to current and future policy direction and ensures long term sustainability.

2.11.6 Central to this ambition, are alternatively configured service models for pathology, which support workforce development and increased modernisation of skill mix, embrace new innovative technologies and automation e.g. digital, requiring informatics and information support which can lead to optimisation of the opportunities from further research and innovation.

2.11.7 This SOC supports this ambition by promoting the development of a sustainable Regional Cellular Pathology Laboratory service at Morriston Hospital. This solution will provide the best outcomes for Welsh patients, and will be supportive of Ministerial direction and of the All Wales Pathology Collaborative Project's recommendations. It will provide a state-of-the-art modern facility and attract opportunities for R&D across the region, which in turn, will encourage local workforce stability and sustainability.

2.11.8 This investment builds on other planned regional infrastructure developments, e.g. internet expansion, websites, IM&T, and transport infrastructure, etc. and contributes towards improvement of regional GVAs.

3 Strategic Case Part B: The Case for Change

3.1 Investment Objectives

3.1.1 In accordance with HMT's *The Green Book: Central Government Guidance on Appraisal and Evaluation* (2018), the key investment objectives have been identified as follows:

Figure 3 – Investment Objectives

Investment Objective 1: To develop more sustainable South Wales Regional Cellular Pathology, Regional Diagnostic Immunology Laboratory and Regional Medical Microbiology services
Develop a more sustainable Regional and All Wales pathology service as evidenced by compliance with Royal College of Pathologist's guidance to improve our workforce and to recruit and retain staff, supporting All Wales Pathology Collaborative Project's strategic plans and the National Immunology Project, maintaining business continuity, supporting innovation and new investment in the Region, improving the relationship between pathology services and clinical research, working more closely with the University to widen academic access to the range of undergraduate and postgraduate courses, which include Pathology services, and repatriation of some tests currently commissioned out of region due to lack of capacity, as appropriate. The presence of the regional microbiology laboratory at the regional centre will improve the attractiveness of the service, providing adjacency between laboratory and clinical settings. This will help recruitment and retention, particularly of specialist and medical microbiology staff, without which the service will not be sustainable. *To be fully realised 24 months after full scheme delivery, i.e. by mid 2026/27.*
Investment Objective 2: To improve the quality and safety of South Wales Regional Cellular Pathology, Regional Diagnostic Immunology Laboratory and Regional Medical Microbiology services
Improve the quality of Pathology services in support of the Carter Report's recommendations as evidenced by supporting achievement of the new Cancer Strategy for South Wales including the Single Cancer Pathway, improved turn-a-round time for tests, including Urgent Suspected Cancers and All Wales Lymphoma panel patients against current levels as per Royal College guidance, implementing new technology and innovation, which improves diagnostic services, e.g. digital technology, support for standardised protocols and improving the patient experience. The appropriate consolidation of cold tests will improve the processing and standardisation of the tests which will facilitate our compliance with quality standards and reporting e.g. UKAS. This regionalised approach to sample flow will support the provision of hot labs at all acute hospitals in the region. These will provide rapid and timely diagnostics to guide treatment resulting in improved Turn Around Times in particular for situations such as sepsis, CNS infection urgent screening for Infection Control.*To be fully realised 12 months after full scheme delivery, i.e. by mid 2025/26 (metrics to be detailed at OBC stage).*
Investment Objective 3: To improve the efficiency and productivity of South Wales Regional Cellular Pathology, Regional Diagnostic Immunology Laboratory and Regional Medical Microbiology services
Improve efficiency in support of the Carter Reports recommendations as evidenced by providing access to state-of-the-art technology and equipment, one-site single management structure, improved quality systems; reduced duplication and variation and co-location on a main acute site. The current spatial layout of the main microbiology laboratory in Singleton is not conducive to optimal sample flow. A purpose built space will allow the optimisation of automated systems. This will allow workforce redesign with more practitioners delivering routine diagnostics freeing our biomedical workforce to provide greater clinical engagement and hands on infection management skills to the Health Board clinical services. *To be fully realised 12 months after full scheme delivery, i.e. by mid 2025/26.*
Investment Objective 4: To improve the effectiveness of South Wales Regional Cellular Pathology, Regional Diagnostic Immunology Laboratory and Regional Medical Microbiology services

Improve effectiveness as evidenced by providing all patients in secondary care, and those attending acute and regional hospital based services, with more sustainable and equitable cellular pathology services and improved access to new technology / more personalised diagnosis and more sensitive and specific tests for patients within the Region. For microbiology, the provision of a cold laboratory at Morriston which can process routine non-time urgent samples will enable the hot laboratories to concentrate on implementing new molecular technology equitably across the region. This will provide effective guidance to clinicians to improve the care to scheduled and unscheduled patients across secondary care. The cold laboratory will be able to provide a genomic diagnostic service due to more space and its attractiveness to staff with the required skills. *To be fully realised 24 months after full scheme delivery, i.e. by mid 2026/27.*
Investment Objective 5: To improve economies within South Wales Regional Cellular Pathology, Regional Diagnostic Immunology Laboratory and Regional Medical Microbiology services
Improve economy and optimise use of scare resources in support of the Carter Reports recommendations on improving cost effectiveness as evidenced by operational economies and economies of scale and improved regional GVAs. Being able to deliver the regional service from a fit for purpose facility will provide economies of scale through better use of automation and the resultant workforce redesign. The use of hot laboratories will also reduce the logistical demands on moving urgent samples around the region by applying the right technology locally when appropriate. *To be fully realised 24 months after full scheme delivery, i.e. by mid 2026/27.*

3.1.2 Delivery and operational dates are dependent on timely planning, funding approvals and agreed construction programmes.

3.2 Existing Arrangements

Cellular Pathology Services (including Histopathology and Cytology)

3.2.1 In ABMUHB, pathology services are delivered by laboratories based at Morriston and Singleton Hospitals, Swansea to the population of ABMUHB. ABMUHB's Cytology service is located at Singleton Hospital, Swansea; In HDUHB, cellular Pathology services are mainly delivered by the laboratories at Glangwili Hospital, Carmarthen; due to a lack of facilities and space at Glangwili, non-gynae cytology has to be processed at Prince Philip Hospital, Llanelli.

Medical Microbiology Services

3.2.2 Medical Microbiology services to the population of ABMUHB are provided by PHW via laboratories at Singleton Hospital, Swansea. HDUHB provides Medical Microbiology services to the population of Pembrokeshire via laboratories at Withybush Hospital, Haverfordwest. PHW provides Medical Microbiology services to the population of Ceredigion and Carmarthenshire via laboratories at Bronglais Hospital, Aberystwyth and at Glangwili Hospital, Carmarthen.

Mortuary and Body Store Services

3.2.3 In ABMUHB Post Mortem services to the population of ABMUHB are located at Morriston Hospital and at Princess of Wales Hospital, Bridgend. ABMUHB's Body Store services are provided at Morriston and Singleton Hospitals, Swansea, and at NeathPortTalbot Hospital and the Princess of Wales Hospital, Bridgend.

3.2.4 HDUHB's Post Mortem services are centralised at Glangwili Hospital, Carmarthen. HDUHB's Body Store services are provided at Bronglais Hospital, Aberystwyth, Prince Philip Hospital, Llanelli, Glangwili Hospital, Carmarthen, and Withybush Hospital, Haverfordwest. Contingency Post Mortem services are located at Withybush Hospital, Haverfordwest.

Blood Sciences' / Laboratory Medicine and Diagnostic Immunology Services

3.2.5 In ABMUHB Laboratory Medicine (Blood Sciences') services are located at Morriston, Singleton Hospitals, Swansea and the Princess of Wales Hospital, Bridgend. A small sample reception and blood issue facilities are located at NeathPortTalbot Hospital with transfer of samples as relevant to Morriston or Singleton Hospitals. In ABMUHB Laboratory Immunology services are located at Morriston and Singleton Hospitals, Swansea.

3.2.6 HDUHB provides Blood Sciences' services at Prince Philip Hospital, Llanelli, Glangwili Hospital, Carmarthen, Bronglais Hospital, Aberystwyth and Withybush Hospital, Haverfordwest. HDUHB provides centralised Diagnostic Immunology services at Prince Philip Hospital, Llanelli.

Location of Pathology Services within South & West Wales

3.2.7 The following figure illustrates the distribution of HDUHB's local pathology services by service provider (pre Health Board boundary changes end 2018/2019):

Figure 4 – Location of Current Pathology Services within HDUHB

3.2.8 The following figure illustrates the distribution of ABMUHB's local pathology services by service provider (post 1st April 2019, delivery of the services to the population of Bridgend by ABMU Pathology will be managed via a Service Level Agreement (SLA) with CTUHB):

Figure 5 – Location of Current Pathology Services within ABMUHB

Service Modernisations

3.2.9 Both Health Boards have made innovations and modernisations in their pathology services in recent years, for example: Between 2010 and 2015, HDUHB completed a series of modernisation projects including developing a new Mortuary at Glangwili Hospital, centralising post mortems in the Health Board; Centralising Cellular Pathology laboratory processing at Glangwili and centralising Diagnostic Immunology workload at Prince Philip Hospital;; Providing Blood Sciences' laboratories with integrated specimen reception areas at Bronglais Hospital Aberystwyth, Withybush Hospital, Haverfordwest and at Prince Philip Hospital, Llanelli as well as improved Phlebotomy facilities at Withybush Hospital, Haverfordwest and Prince Philip Hospital, Llanelli and new Microbiology laboratory and Containment level 3 facilities at Bronglais Hospital, Aberystwyth.

3.2.10 From 2011 ABMUHB has re-configured its laboratory medicine (blood science) services to create a main hub laboratory in Morriston for all ABMUHB OPD and Primary Care testing of bloods, and 2 smaller essential service labs in Singleton and POWH for acute urgent testing of bloods from ward and A&E services. NPT hospital testing is all undertaken in Morriston, and; As recently as 2015, Health Board-wide, ABMUHB rationalised its Cellular Pathology services by relocating activity in its entirety from the PoWH at Bridgend to Morriston and Singleton Hospitals in Swansea. This relocation supported service efficiencies with pathology services and the expansion of the existing PoWH radiology services to support local service demand.

3.3 Estates Profile

3.3.1 Welsh Government's and Health Boards' have been investing in their estate in recent years but currently both ABMUHB's and HDUHB's Cellular Pathology service's accommodation experiences significant issues with aging and inadequately configured accommodation, poor environmental systems, and general non-compliance with Health Building Note (HBN) requirements, for example, Glangwili's pathology floor space is functionally unsuitable for its personnel and equipment operating requirements (floor space therein is currently 1,028 m² - it should be 2,064 m²). Likewise, ABMUHB's Singleton and Morriston Hospital Cellular Pathology service's and Medical Microbiology accommodation are similarly constrained by accommodation and configurations that are no longer fit for purpose. Regional Cellular Pathology laboratory services should be fully compliant, fit for purpose, fully accredited and would preferably be co-located and equipped with appropriate support services and IM&T infrastructure.

3.4 Current Workforce

3.4.1 HDUHB/ABMUHB's laboratory based staff currently operate similar shift patterns over a 5-day working week, with the majority ABMUHB's laboratory staff working Monday to Friday on flexible shifts between the hours of 07:00 and 18.30; HDUHB's histology staff work between the hours of 08:00 to 17:00. ABMUHB's Mortuary staff work between the hours of 08:00 to 18:30 Monday to Sunday. HDUHB and ABMUHB currently employs the following cellular pathology/histology staff:

Figure 6 – Cellular Pathology/Histopathology/Diagnostic Immunology/ Medical Microbiology Workforce Profile (2018)

Staff Grades/Bands:	Cellular Pathology/Histology				Diagnostic Immunology				Medical Microbiology	
	HDUHB		ABMUHB		HDUHB		ABMUHB		ABMUHB	
	Staff No.	wte	Staff No.	wte	Staff No.	wte	Staff No.	wte	Staff No.	wte
Laboratory Technical Staff	21	20.02	40	38.67	3	2.8*	4*	4.0	96	87.08
Consultants	5	9.00[14]	11	14[15]			1	0.2	10	10.10
Management & Admin.	8	7.40	28	26.2					10	9.43
Total	**38**		**83**		**3**		**5**		**116**	

** Includes bands 2/3, 4, 5/6 & 7 day & night staff due to OOHs*

3.4.2 All of HDUHB/ABMUHB's cellular pathology/histology staff will re-locate from their current Glangwili and Singleton Hospital bases to a new facilities at Morriston Hospital together with ABMUHB's Singleton Hospital's mortuary staff. The regionalisation and co-location of these services supports the introduction of more flexible working patterns, with aspirations of expanding cellular pathology/histology services into 6-day and 7-day day working. We anticipate this and other workforce initiatives will alleviate traffic/car parking pressures on hospital sites and will support more flexible and attractive working arrangements for staff.

[14] HDUHB have budgeted for 9.00 consultants. In post there are 3 wte substantive consultants; 1 wte NHS Locum,on a one year fixed contract, and ; 1 wte Agency Locum (appointed 12th March for 6 months). HDUHB has 4 vacancies. HDUHB is unable to provide support to Cancer speciality MDT meetings.

[15] ABMUHB have budgeted for 14 wte consultants.

3.5 Pathology Activity

3.5.1 The following histology activity was recorded in HDUHB and ABMUHB during 2010 – 2018 inclusive:

Figure 7 – HDUHB: Histology Activity (2010 to 2018)[16]

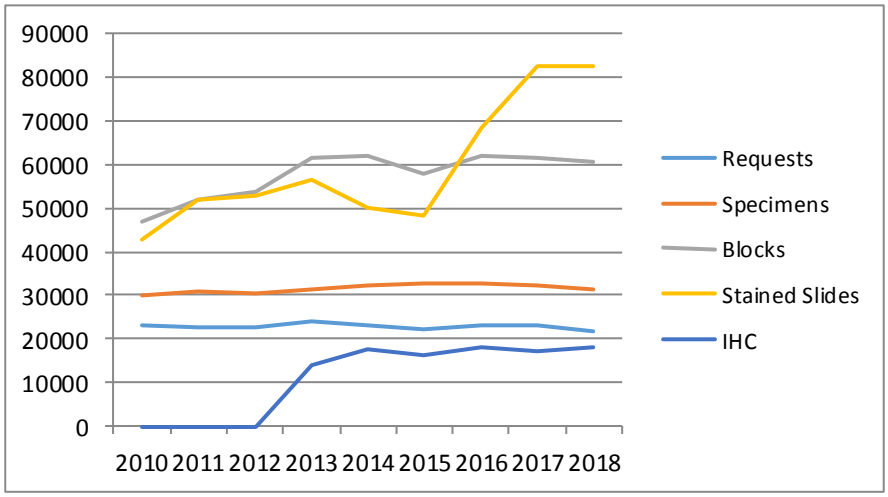
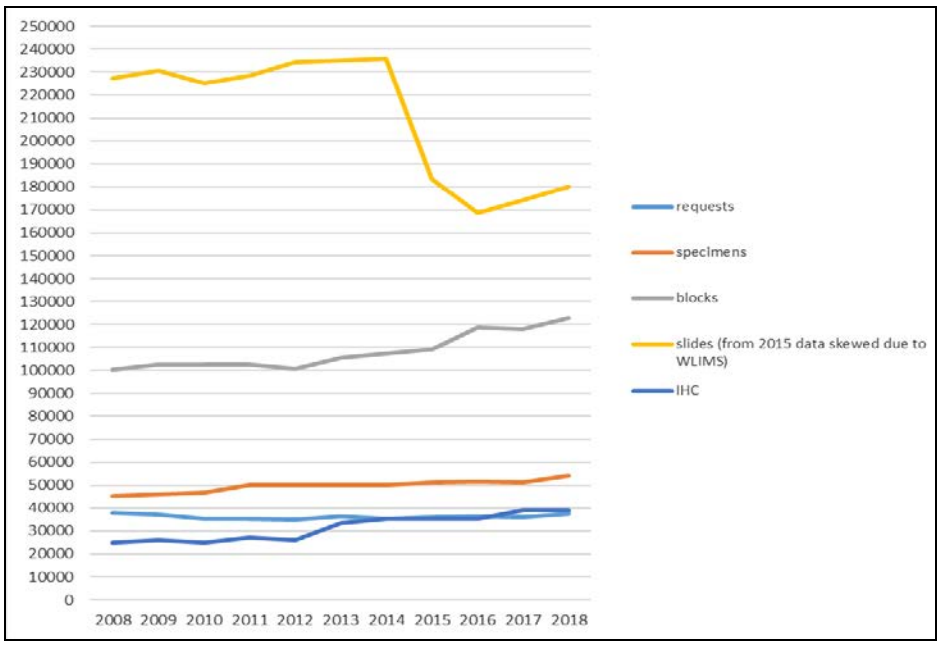


Figure 8 – ABMUHB: Histology Activity (2010 to 2018)[17]



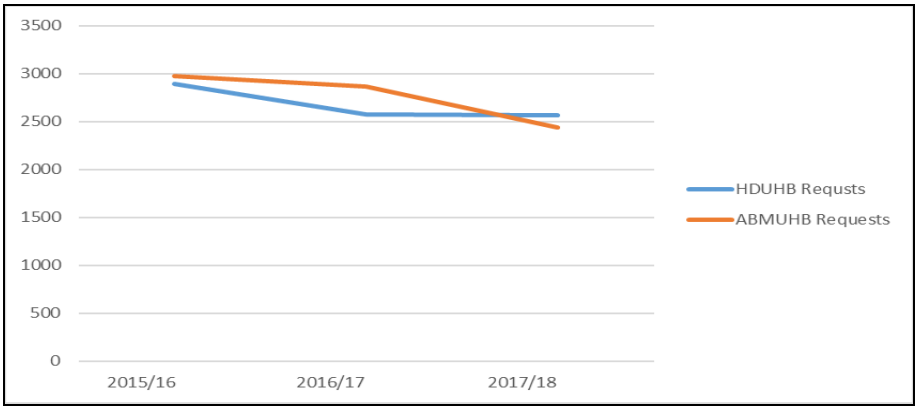
[16] Prior to implementation of the All wales LIMs in the summer 2015, HDU were utilising Telepath to record activity.

[17] Prior to implementation of the All Wales LIMs in the summer 2015, ABMU were utilising Master Lab to record activity.

3.5.2 Figures 7 & 8 (above) show Pathology Laboratory projected activity is increasing slightly each year but this does not reflect a true picture of the level of complexity, which has increased significantly due to reliance on immune-histochemistry and personalised medicine to deliver more specific diagnosis. For example, ABMU has expanded its Immunohistochemistry (IHC) repertoire in 2018 by 30% since 2015 (this includes expansion of the lymphoma panel and introduction of PDL-1, MMR and ALK-1 tumour markers. An increased repertoire of tests has impacted significantly on pathology services' staff time and resources and on consultant and technical grades' time. The benefits of this include the ability to provide cancer services' clinicians' in particular, with more targeted treatment options from the wider range of tests currently available compared to traditional delivery.

3.5.3 The following non-gynae cytology activity was recorded in HDUHB and ABMUHB during 2015/6-2017/18:

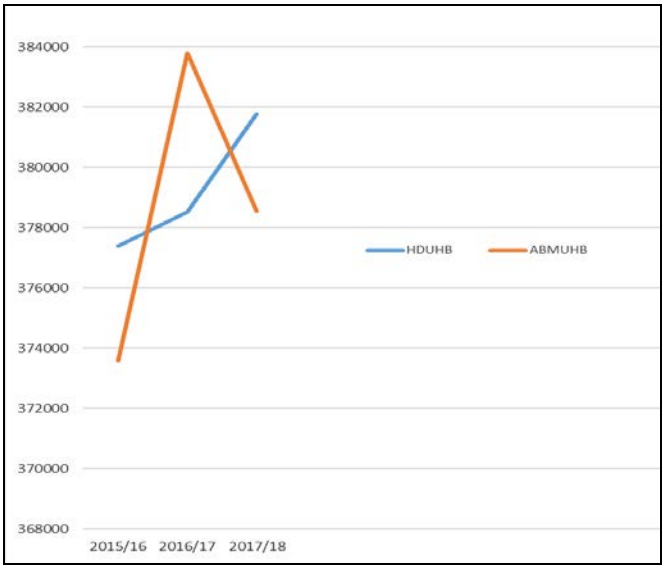
Figure 9 – HDUHB & ABMUHB: Non-Gynae Cytology Activity (2015/16 to 2017/18)



3.5.4 Figure 9 (above) shows non-gynae and histology tests, the sample activity appearing to remain static because specimens of non-clinical value have been removed. This level of activity in recent years does not demonstrate the increased complexity of laboratory analysis which is integral to the final reported result.

3.5.5 The following number of tests processed by Health Board was recorded by PHW 2015/6-2017/18:

Figure 10 – PHW Activity by Health Board (2015/16 to 2017/18)



Summary

3.5.6 Whilst activity for Cellular Pathology work only increases slightly over time workload increases year-on-year significantly in terms of complexity to support complex clinical service needs and developing more personalised treatment. Immunohistochemistry increased in the 2016-2017 period by 13%, illustrating the increased complexity on each request. Correspondingly, in situ hybridisation (this process is used in the diagnosis of breast cancer) has increased by 18.2% in the period, reflective of the more complex testing regime now required to support more definitive diagnoses.

3.5.7 Within PHW, technology has enabled high productivity with batching of high volume work whilst the complexity particularly associated with Antimicrobial resistance continues to grow e.g. dealing with joint fluids and sepsis.

3.5.8 Service changes will continue to re-shape pathology services over the next three years. These will have a significant impact on sustainability and workforce. These changes includes: The adoption of LEAN principles; standardisation of working practices and re-defining of roles; Adoption of 24/7 working and shared rotas - supporting regional processing and autopsy services (this investment could provide flexible and resilient contingency support for West Wales autopsy services) ; Improvements in quality standards and Standard Operating Procedures (SOPs); New imaging technologies - improving quality and reduce screening times in, e.g. Cervical screening; All Wales LIMS; Building on partnerships with Universities and industry, and; Modernisation of scientific careers within pathology services and empowering staff to rise to new challenges.

3.6 Business Needs

Problems with the 'Status Quo'

3.6.1 The problems, difficulties and service gaps associated with the existing arrangements are as follows:

Quality, Sustainability & Workforce Issues

3.6.2 Both health boards are struggling to manage workforce and sustainability pressures, to maintain quality and safety issues and to meet clinically driven targets. Workforce re-modelling based on meeting future demand and moving to a points based consultant staff and support system was jointly established in September 2017 and is ongoing. It is important to note that these workforce pressures will exist whether the service moves to a new facility or remains in-situ and that HDUHB will be moving to the points based system in advance of any new regionalised solution. This will allow HDUHB to supplement the benefits of regionalisation to partly implementing the Advanced Practitioner role that has already been successfully implemented in ABMHB.

3.6.3 Services' are fragmented and are struggling to appropriately support their local populations. The current workforce is over stretched trying to meet rising demand.

3.6.4 Reviews of regional and local staffing assumptions recognise the 'gap' between historical staffing models and future staffing models. For example, HDUHB currently has only three substantive consultant staff, relying on the ability to attract NHS locum and expensive agency locum staff, it actually needs nine consultants to satisfy current levels of service, and predicts the need for another two consultants to maintain quality of service and timely reporting through implementation of the points based system in the future.

3.6.5 Recruitment and retention, especially of Consultant grade staff are major issues within Mid and South West Wales' Pathology services. Staff morale is suffering and a retirement 'bulge' will further compromise service sustainability.

3.6.6 Maintaining the 'status quo' is unsustainable and not in the interests of patients in the region. Providing a sustainable, resilient workforce with the appropriate skills and education and ensuring we have the right staff in the right place to meet national guidelines is an essential requirement.

3.6.7 Pathology services are struggling to maintain quality and meet clinically driven targets. In their current configuration and with existing staffing levels they have limited success delivering essential quality improvements and meeting current demand. Pathology services need the right skill mix in place and access to innovative and state-of-the-art technology and equipment in order to meet demand, support best quality outcomes (specifically the new Cancer Strategy for South Wales) within the region.

Accommodation & Configuration Issues

3.6.8 Lack of space and insufficient storage within cellular Pathology services in ABMUHB and HDUHB contribute to increased risk of health and safety related incidents. The PHW Medical Microbiology service based in Singleton Hospital is spread across two floors and has limited adjacency between the different parts of the laboratory. This is not conducive to cross-cover nor does it facilitate collaboration. Significant space is 'wasted' as corridors and the diagnostic areas are sub-optimally configured, and the existing physical layout makes for inefficient workflows.

Infrastructure Issues

3.6.9 ABMUHB's Cellular Pathology services do not fully comply with ISO15189, HSE guidance, the Human Tissue Act (HTA) requirements or with WHBN 15 *Accommodation for Pathology Services* as regards existing environmental standards. This threatens staff welfare, compromises quality and safety, and places wider health services at threat by compromising Pathology services' ability to comply with mandatory requirements and licenses. In HDUHB, specifically Glangwili Hospital, inadequate pathology infrastructure and space across all disciplines, which is not fit for purpose or conducive to 21st century laboratory technology or work flow and is also non-compliant with WHBN 15, sits as a high level risk within the Health Board.

3.6.10 Morriston and Glangwili Hospitals' Histology facilities experiences issues with inadequate temperature controls. This leads to, e.g. intermittent analyser failures in Histology during times of extremes of hot and cold weather, which significantly delays tissue-processing tissue and compromises appropriate storage of reagents. Poor temperature controls generally make for unacceptable working conditions for Laboratory staff. Glangwili Hospital's Histology tissue processing and cut up room is not fit for purpose and additional co located space is required to segregate the tissue processing equipment and reduce the time staff are exposed to chemicals such as xylene and formalin through improved segregation and ventilation controls.

Future Requirements

3.6.11 The Mid and South West Wales Cellular Pathology service urgently needs a co-located facility which can support technological innovations, promote benefits in terms of improved specialist healthcare services, facilitate access to modern technology and techniques, enhance the patient experience, and increase potential for investment in the local economy.

Projected Activity

3.6.12 Pathology Laboratory projected patient activity is forecast to continue to increase over the next ten years to support a predicted 10% increase in cancer in that period.

3.6.13 Changes in clinical service delivery, including a move towards seven-day working in Endoscopy Services, implementation of the Single Cancer pathway, proposed changes to Bowel Screening age eligibility, and a predicted increase in the number of Cervical Screening Services' 'opportunistic' cervical biopsies, activity will impact on Cellular Pathology service activity within the region and potentially across Wales. The service has seen increasing workloads dependent on services that ensure appointments of clinicians, e.g. Dermatology Locums are generating more biopsies in 2017 compared with 2016 activity. In general requests for molecular testing are increasing, although this increasing Pathologists' block and slide work workloads.

3.6.14 Precision Medicine will continue to evolve over the next decade and it is anticipated blood based biomarkers will be used routinely to assess a person's risk for cancer and to aid personalizing cancer treatment. Genomic testing to personalize cancer screening will also become routine in clinical practices all over the world through rapid adoption of technology that allows for the assessment of cancer risk among the population. These advances will lead to a dramatic drop in deaths from preventable cancers. Further advances in genetic analysis and gene mutation will result in more patients being monitored for early detection of cancer. This, in time, could increase pathology activity from screening programmes.

3.6.15 The forecast increase in obesity levels in the UK – with 35% of the population projected to be obese in 2030, will impact on Pathology Laboratory services. Overweight and obesity is associated with increased risk of several cancers, including uterine, kidney, oesophageal, gallbladder, bowel, pancreas and breast cancers. Cancer incidence in the UK is expected to continue to rise further if current trends in overweight and obesity prevalence persist. Overall, overweight and obesity causes, a conservatively estimated, 5% of cancer cases in the UK each year[18].

Summary of Business Needs

3.6.16 The 'status quo' cannot be maintained and this document proposes investment in a realistic 'Do Minimum' solution plan for service re-design of 'Core' regional services. Specifically, it supports development of a Regional Cellular Pathology (Cytology and Histopathology) & Regional Diagnostic (Laboratory) Immunology service, and co-location of Singleton's Body Store at Morriston Hospital with future proofed capacity. This solution, which largely excludes local service scope solutions (as detailed in the 'Intermediate' and 'Do Maximum' solutions) except where they promote tangible regional benefits, support delivery of more sustainable regional services and satisfy national, regional and local strategic direction.

3.6.17 In terms of volume, the majority of the work undertaken by the new facility will be direct pathology activity as part of the primary, secondary care and acute hospital activity in Mid and South West Wales Region. Merged cellular pathology services and access to state-of-the-art technology should facilitate improvements in the patient experience. Management arrangements will be streamlined and skill mix will be modernised and should support more efficient and effective ways of working. The involvement of the private sector should boost technological innovation and assist a direction of travel for the service, focusing on delivering more personalised treatment to the population of Mid and South West Wales.

3.7 Potential Scope

3.7.1 This section describes the potential scope for the project in relation to the above business needs in terms of modalities and service drivers. The potential scope has been assessed against a continuum of need ranging from:

- **A *Business As Usual*** – essential for baseline comparison.
- A ***Do Minimum*** – essential or core requirements/ outputs.
- An ***Intermediate*** – with essential and desirable delivery requirements/ outputs to a greater and lesser extent.
- A ***Do Maximum*** – with essential, desirable and optional requirements/outputs.

3.7.2 ABMUHB's Cellular Haematology Laboratory services may form part of this project's final service scope solution. Currently these services are provided at Singleton Hospital and a short-term solution is being considered in that site's emerging Site Development Master Control Plan. In the longer-term (i.e. within 6-7 years) a more appropriate longer-term solution may be considered. All new build options included a 500 m² ATTC, i.e. Cell and Gene Therapy indicative shell and core area.

[18] *cf*

3.8 Main Outcomes and Benefits

3.8.1 The main outcomes and benefits to patients, the Health Board and the wider health community are classified in terms of cash releasing benefits (CRBs), non-cash releasing benefits (NCRBs), quantifiable benefits (QBs), and non-quantifiable benefits (Non QBs) as follows:

3.8.2 The main benefits of this project are outlined in **Appendix I – Benefits Realisation Plan.**

3.8.3 At OBC, stage benefits will be quantified in accordance with the principles of additionality. This is defined as "the extent to which something happens as a result of an intervention that will not have occurred in the absence of the intervention"[19]. An assessment of benefits on this basis will be applied at key stages of this project's lifecycle, success will be measured against clear and measurable criterion, which will in turn be assessed at key stages of the project under the OGC 'Gateway' process, and benefits realisation Welsh Government led assessment processes. Additionality benefits will be categorised as follows:

- **Economic multipliers analysis** will capture additional economic activity stimulated locally and throughout the region by this project.
- **Leakage effects analysis** will capture non-direct effects both in qualitative and quantitative cash and non-cash terms, demonstrating VfM, as per Welsh Government and Treasury guidance.
- **Displacement or Substitution analysis** will take into account the re-location of staff between different Health Boards and other organisations because of service change across health Board boundaries and between current locations and Morriston Hospital.
- **Deadweight analysis** - what will happen, or will not happen if this project did not proceed.

3.9 Main Risks

3.9.1 The main business and service risks and mitigations are as follows:

Figure 11 – Main Risks and Mitigations

Risk Description	Probability	Impact	Score	Mitigating Actions
Internal approvals delayed - There is a risk that board approvals are delayed.	3	4	12	(1) Continued liaison with key stakeholders' SROs
Planning approval & planning conditions - Failure to achieve planning permission conditions are excessive, that S106 demands building control approvals are more involved than anticipated	5	4	20	(1) Early engagement with Local Planners; (2) Appoint a Planning Advisor and further investigate future planning development risks at Morriston Hospital & Submit a pre-planning application; (3) Monitor progress on Project and its interrelationship(s) with ARCH & other Morriston Hospital projects currently at planning stage; (4) Coordinate with ARCH Master Planners.

[19] Additionality Guidance, 3rd Edition, English Partnerships, October 2008

Funding approval delayed or timing of funding does not match our current programme due to WGov cashflow constraints	4	4	16	(1) Maintain regular dialogue re the procurement arrangements with WG and other key stakeholders.
Revenue affordability - Affordability of revenue model is over/under estimated	5	4	20	(1) Develop and sign off revenue model with DoFs; (2) Project Board to review at each formal meeting.
Availability of capital - There is a risk that the scope of the project is reduced in order to fit within financial limit	5	3	15	Continued liaison with WGov.
Staffing levels - Additional staffing levels / activity cannot be supported at Morriston Hospital, e.g. car parking provision and essential infrastructure are insufficient to support planned operations	3	4	12	(1) Develop Staff Modelling to inform, e.g. future car parking requirements on site; (2) Liaise with Morriston Hospital/ARCH projects currently at planning stage.
Staffing model is over/under estimated	3	4	12	Establish a Project Management Team and secure project management support
Recruitment of key staff - Sufficient numbers of essential staff with key skills cannot be recruited	3	4	12	Project Board monitors recruitment progress/issues and report regularly to Project Board/Executive level

3.9.2 Please refer to **Appendix K – Risk Register.**

3.10 Constraints

3.10.1 The scheme is subject to the following constraints:

- The solution must provide a regional solution for Cellular Pathology Laboratories and Immunology Laboratories services' capacity and quality requirements.
- The solution must be fit for purpose (i.e. it must comply with ISO, WHBM/HBN & WHTM/HTM requirements and guidance) and make best use of the available development space.
- The delivery of Pathology Laboratory services to patients must be maintained seamlessly during the works, commissioning periods and re-location of services.
- Revenue resources are limited and the solution should offer value for money.
- The solution must be affordable in capital and revenue terms.
- The solution must be delivered within project budget/programme.
- The solution must 'fit' within the available developable footprint.
- The solution must provide adjacency and connectivity with the existing Pathology facility at Morriston Hospital.
- The solution must allow the service to meet national targets for turn-a-round of pathology

tests.

3.11 Dependencies

3.11.1 The success of this scheme is subject to the following dependencies:

- Obtaining planning permission approval. NB Planning permission approval is dependent upon Site Development Control Plans for Morriston Hospital; and on demonstrating a sustainable travel plan and improving road infrastructure at Morriston Hospital.
- Continued support for the agreed service care and workforce model locally and regionally.
- Availability of capital funding from the Welsh Government.
- Ability of ABMUHB & HDUHB to support any revenue consequences from this investment.
- The commitment of ABMUHB & HDUHB at the highest level, to drive the project.
- Continued effective and transparent engagement with key stakeholders at all stages of the project and support the transformational process.
- Senior pathology services' management commitment to an integrated transformational and modernisation project.
- Development of a single management structure to ensure smooth daily operation of the new Regional Pathology Unit.
- Continued commitment of the project owner(s), senior Health Board management and pathology services' senior staff to develop and own the new regional service model.
- Ensuring that appropriate governance structures and change management procedures are embedded throughout the development, delivery and benefits realisation stages of this project.
- Development of a Formal Staff Engagement Process, Change Management Process and Communications Plan.
- Co-ordination of recruitment and training processes to support future staffing arrangements.
- Access to appropriate / experienced construction resources.

4 The Economic Case

4.1 Introduction

4.1.1 In accordance with the Capital Investment Manual and requirements of HM Treasury's Green Book (*A Guide to Investment Appraisal in the Public Sector*), this section of the business case demonstrates the wide range of options that have been considered in response to the potential scope identified in this SOC.

4.2 Critical Success Factors

4.2.1 The Critical Success Factors (CSFs) have been identified to allow evaluation of the potential options. These are shown below:

Figure 12 – Critical Success Factors (CSFs)

- **CSF 1 Business needs** How well the option satisfies the existing and future needs of the service and NHS Wales, i.e. by providing more sustainable Pathology Laboratory services across the region.
- **CSF 2 Strategic fit** How well the option provides holistic 'fit' and synergy with other key elements of the national, regional and local strategies, i.e. supporting ABMUHB's & HDUHB's IMTPs and the All Wales Pathology Collaborative Project's strategic objectives.
- How well the option optimises the potential return on expenditure.
- **CSF 4 Potential achievability** The organisations' ability to innovate, adapt, introduce, support and manage the required level of change, including the management of associated risks, and; the need for supporting skills (capacity & capability) .
- **CSF 5 Supply side capacity and capability** The ability of the marketplace and the potential suppliers to deliver the required services and deliverables.
- **CSF 6 Potential affordability** The organisation's ability to fund the required level of expenditure, viz, the capital and revenue consequences associated with the proposed investment.

4.3 Methodology

4.3.1 The Appraisal Group (please see **Appendix E – Option & Risk Appraisal Group Membership**). identified a range of options in accordance with Treasury Green Book and Capital Investment Manual the five categories of framework options have been considered as follows:

- **Potential Service Scope Options** – what is the potential coverage of the service to be delivered (the 'what');
- **Potential Service / Technical Solution Options** – potential options for delivering the preferred service scope option (the 'how');
- **Potential Service Delivery Options** – who will deliver the preferred scope & preferred service / technical solution options (the 'who');
- **Potential Implementation Options** – potential timescales options for delivering the preferred scope, preferred service / technical solution and preferred delivery options (the 'when');
- **Potential Finance Options** – potential funding and affordability options for delivering the preferred scope, preferred service / technical solution, preferred delivery preferred implementation options.

4.3.2 The Mid & South West Wales Regional Pathology Re-configuration Board previously considered and rejected the following options:

- Business As Usual – retained as a baseline comparator.

- Develop one single site for the future configuration of Cellular Pathology services in Mid and South West Wales (in either Cardiff or Swansea) with 'hot' laboratories based on a number of other hospital sites – rejected following non-financial appraisal.
- Develop a 'hub and spoke' model (with variants on the same) on one or two spokes with the hub located in either Cardiff or Swansea – rejected following non-financial appraisal.

4.3.3 A one-site Cellular Pathology solution was supported by the South West Wales Regional Pathology Re-configuration Project.

4.3.4 The South West Wales Regional Pathology Re-configuration Project Board met in May 2018 and agreed the following:

- The preferred location of the one-site Cellular Pathology solution was Morriston Hospital;
- The 'Do Nothing' option should be discounted from further detailed evaluation;
- All new technical solutions should include a dedicated 300 space car park and a 500 m² ATTC shell and core.

4.3.5 The long list and shortlist of options are summarised in Section 4.5. Please refer **Appendix N – Framework Options Appraisal** for a detailed SWOT analysis.

4.3.6 An independent Health Care Planner (KD Health) assessed the draft Schedule of Accommodation (SoA) against WHBN/HBN requirements (please see **Appendix M – SoA**).

4.4 Benefit Measurement

4.4.1 The economic gross value added benefits shall be measured at OBC stage in terms of additionality guidance (Additionality Guide, 3rd Edition, English Partnerships - October 2008), measuring, and the extent to which something happens within regional Pathology services as a result of an intervention as against, the absence of the intervention. The principal focus of this economic appraisal will be the direct employment related benefits the project is expected to deliver in the short, medium and long-term. The quantification of these benefits will concentrate on the wider-NHS and Welsh economy rather than the UK generally.

4.5 Framework Options Summary

4.5.1 The framework options long list options findings are summarised below:

Figure 13 - Long List Options

Framework Options		
Potential Service Scope	SC01 - Business As Usual	Discount (retained as baseline comparator)
	SC02 - **'Core'** services, i.e. Develop Regional Cellular Pathology (Cytology and Histopathology) & Regional Diagnostic (Laboratory) Immunology service; Co-locate Singleton's Body Store at Morriston Hospital service (future proofed capacity) & a 500 m² ATTC, i.e. Cell and Gene Therapy indicative shell and core area	Take forward for further evaluation
	SC03 - 'Core' services **plus** Relocate ABMUHB's PHW Medical Microbiology service to Morriston Hospital &/or Develop a temporary modular Body Store solution at Singleton Hospital	Take forward for further evaluation
	SS04 - 'Core' services **plus** Relocate ABMUHB's PHW Medical Microbiology service to Morriston Hospital; Develop a temporary modular Body Store solution at Singleton Hospital **plus** Re-provide ABMUHB's Essential Laboratory Service.	Take forward for further evaluation
Potential Service Solution	SS01 - New Build/Reconfigure co-located regionalised services' accommodation on one site &; Provide dedicated car parking to support regionalised services	Preferred

	SS02 - New Build all co-located regionalised services' accommodation on one site; Provide dedicated car parking to support regionalised services; **plus** Reconfigure and refurbish local non-regionalised services accommodation to provide fit for purpose facilities	Carried forward - do more ambitious
Potential Service Delivery	DEL1 - NHS in-house solution	Preferred Way Forward
Potential Implementation	IMP01 - Phased (e.g. build some elements as a shell and occupy later and phase local refurbishments)	Carried forward - do less ambitious
	IMP02 - Single Phase with staged occupancy of new build and concurrent local refurbishments	Preferred Way Forward
Potential Funding	FUN01 - Private funding	Discount
	FUN02 - Public funding	Preferred Way Forward
	FUN03 - Mix of Public and Private funding	Discount

4.6 Summary of Shortlisted Options Framework Findings

4.6.1 The South West Wales Regional Pathology Re-configuration Project Board agreed the following range of service scope options:

Figure 14 – Service Scope

Functional Content by Health Board		Option 2 Do Minimum	Option 3 Intermediate – more ambitious	Option 4 Intermediate – far more ambitious	Option 5 Do Max ambitious
HDUHB/ABMUHB	Develop Regional Cellular Pathology (Cytology and Histopathology)	✓	✓	✓	✓
HDUHB/ABMUHB	Regional Diagnostic (Laboratory) Immunology service;	✓	✓	✓	✓
ABMUHB	Co-locate Singleton's Body Store at Morriston Hospital service (future proofed capacity)	✓	✓	✓	✓
	A 500 m² ATTC, i.e. Cell and Gene Therapy indicative shell and core area	✓	✓	✓	✓
ALL	Provide dedicated car parking to support regionalised services (300 spaces)	✓	✓	✓	✓
PHW	Relocate ABMUHB's PHW Medical Microbiology service to Morriston Hospital		✓	✓	✓
HDUHB	Reconfigure and refurbish local non-regionalised Blood Sciences services' accommodation to provide fit for purpose facilities - Refurbishment of Cell Pathology - Withybush Hospital, Prince Philip Hospital, Llanelli & West Wales General Glangwili (approx. 486 m2)		✓	✓	✓
ABMUHB	Develop a temporary modular Body Store solution at Singleton Hospital			✓	✓

ABMUHB	Re-provide ABMUHB's Essential Laboratory Service				✓

4.6.2 The range of potential service solutions identified in the table above were carried forward into the short list for further appraisal and evaluation. All the options that were 'discounted' as impracticable were excluded at this stage. The recommended short list for further appraisal was confirmed as follows

Figure 15 – Short List of Options

Option 2 – Do Minimum	
Service Scope	SC02 - 'Core' services, i.e. Develop Regional Cellular Pathology (Cytology and Histopathology) & Regional Diagnostic (Laboratory) Immunology service; Co-locate Singleton's Body Store at Morriston Hospital service (future proofed capacity) & a 500 m² ATTC, i.e. Cell and Gene Therapy indicative shell and core area
Service Solution	SS01 - New Build/Reconfigure co-located regionalised services' accommodation on one site & Provide dedicated car parking to support regionalised services
Service Delivery	DEL1 - NHS in-house solution
Implementation	IMP02 - Single Phase with staged occupancy of new build and concurrent local refurbishments
Funding	FUN02 - Public funding
Option 3 – Intermediate 1	
Service Scope	SC03 - 'Core' **plus** Relocate ABMUHB's PHW Medical Microbiology service to Morriston Hospital
Service Solution	SS02 - New Build all co-located regionalised services' accommodation on one site; Provide dedicated car parking to support regionalised services; plus Reconfigure and refurbish local non-regionalised services accommodation to provide fit for purpose facilities
Service Delivery	DEL1 - NHS in-house solution
Implementation	IMP01 - Phased (e.g. build some elements as a shell and occupy later and phase local refurbishments)
Funding	FUN02 - Public funding
Option 4 – Intermediate 2	
Service Scope	SC03 - 'Core' **plus** Relocate ABMUHB's PHW Medical Microbiology service to Morriston Hospital & Develop a temporary modular Body Store solution at Singleton Hospital
Service Solution	SS02 - New Build all co-located regionalised services' accommodation on one site; Provide dedicated car parking to support regionalised services; plus Reconfigure and refurbish local non-regionalised services accommodation to provide fit for purpose facilities
Service Delivery	DEL1 - NHS in-house solution
Implementation	IMP02 - Single Phase with staged occupancy of new build and concurrent local refurbishments
Funding	FUN02 - Public funding
Option 5 – Do Maximum	
Service Scope	SC04 - 'Core' **plus** Relocate ABMUHB's PHW Medical Microbiology service to Morriston Hospital & Develop a temporary modular Body Store solution at Singleton Hospital & Re-provide ABMUHB's Essential Laboratory Service
Service Solution	SS02 - New Build all co-located regionalised services' accommodation on one site; Provide dedicated car parking to support regionalised services; plus Reconfigure and refurbish local non-regionalised services accommodation to provide fit for purpose facilities
Service Delivery	DEL1 - NHS in-house solution
Implementation	IMP02 - Single Phase with staged occupancy of new build and concurrent local refurbishments
Funding	FUN02 - Public funding
Funding	FUN02 - Public funding

4.6.3 Confirmation of the Preferred Way Forward Option (Option 3)

4.6.4 **The preferred way forward is Option 3 – Intermediate 1,** i.e. Develop Regional Cellular Pathology (Cytology and Histopathology) & Regional Diagnostic (Laboratory) Immunology service; Co-locate Singleton's Body Store at Morriston Hospital service (future proofed capacity), a 500 m² ATTC, i.e. Cell and Gene Therapy indicative shell and core area, & relocate ABMUHB's PHW Medical Microbiology service to Morriston Hospital to new build/reconfigured and co-located regionalised services' accommodation, supported by dedicated car parking.

4.7 Transport Arrangements

4.7.1 The development of a co-located Regional Laboratory service must be supported by appropriate, safe and reliable transport arrangements. Transport arrangements going forward will support the NHS Wales' Health Collaborative's Diagnostic Services Modernisation Programme's **National Pathology Transport Project Group's** key recommendations, which recognising the variety of providors ion Wales advised, requested All Wales Chief Executives comply with the **National Pathology Transport Service Specification**. This specification promotes higher quality, safer, temperature controlled services, which encompass robust performance measurements through the contained key performance indicators.[20] Please see **Appendix O – Transport Arrangements** for further details.

4.8 Information Management & Telecoms (IM&T) Arrangements

4.8.1 Similarly, the development of a co-located Regional Laboratory must be supported by sustainable and reliable local and regional IM&T systems. The development of detailed IM&T requirements will be managed by an IM&T Sub-Group with representation from key stakeholders.

[20] NHS Wales' Health Collaborative's Diagnostic Services Modernisation Programme's National Pathology Transport Project Group's recommendations, February 2018 v. final 1.0

5 The Commercial Case

5.1 Introduction

5.1.1 This section of the SOC outlines the proposed 'deal' as outlined in the Economic Case and is seeking to secure public funding from the Welsh Government's 'All Wales Capital Programme'.

5.2 Required Services

5.2.1 The required services are as follows:

- Enabling works, including development of approx. 300 car parking spaces to support this development;
- 1st phase - Development of a fit for purpose, co-located, state-of-the-art facility for South West Wales' Cellular Pathology and ABMUHB's Medical Microbiology service. This new facility could be located at Morriston Hospital, Swansea (this includes a 500 m² ATTC, i.e. Cell and Gene Therapy indicative shell and core area), and;
- 2nd Phase - Refurbishment of existing Morriston Hospital accommodation to support a Regional Diagnostic Immunology service & Extension of the Mortuary facility at Morriston Hospital (future proofed capacity).

5.3 Potential for Risk Transfer and Management

5.3.1 Following agreement of the target cost the final allocation of risk between the Health Boards and the SCP/Main Contractor will be agreed.

5.3.2 A risk register has been compiled and costed relative to risks that apply over the whole of the project lifecycle at this stage (please see **Appendix K – Risk Register**). The risk register will be developed by the Health Board Project Liaison Manager in consultation with the Health Board's Cost Advisor during the development and construction phases of the project, through to hand over and operational commissioning. It is planned to review the risk register, which will be regularly reviewed and updated accordingly, to maintain tight financial cost control relative to the risks noted in the register.

5.3.3 The Project Director will report to the South West Wales Regional Pathology Re-configuration Project Board. It is planned to review the risk register regularly and update accordingly to maintain tight financial cost control relative to the risks noted in the register.

5.3.4 Cellular Pathology and Diagnostic Immunology services' management will manage service implications and will endeavour to mitigate any risk of disruption to hospital services and performance during the works and re-instatement phase.

5.4 Personnel Implications (Including TUPE)

5.4.1 TUPE (Transfer of Undertaking and Protection of Employee) will apply to this investment.

5.5 Indicative Timescales

5.5.1 The indicative milestones are set out below:

Figure 16 – Key indicative milestones

Activity	Due Date
HDUHB & ABMUHB Executive Teams endorse 'Discussion' SOC	November/December 2018
HDUHB Executive Team approves SOC	February 2019
ABMUHB's Investments and Benefits Group (IBG) endorses SOC	12th March 2019
ABMUHB Executive Team approves SOC	13th March 2019
ABMUHB Board approves SOC	28th March 2019

Activity	Due Date
Submit SOC to Welsh Government for endorsement	April 2019
Welsh Government endorse SOC	May 2019
Appoint Supply Chain Partner, Health Board Cost Advisor & Health Board Project Manager from Designed for Life Regional Framework	July 2019
ABMUHB's IBG and HDUHB & ABMUHB Executive Teams approve OBC	June 2020
Submit OBC to Welsh Government for approval	June 2020
Welsh Government approval of OBC	September 2020
ABMUHB's IBG and HDUHB & ABMUHB Executive Teams approve FBC	October 2021
Submit FBC to Welsh Government for approval	October 2021
Welsh Government approval of FBC	January 2022
Mobilise and commence new build/extension main works	February 2022
New build completed (subject to contractor's programme)	January 2024
New build commissioning (subject to accreditation arrangements & technical commissioning)	February 2024
New build operational	March 2024
Commence refurbishment	April 2024
Refurbishment completed (subject to contractor's programme)	October 2024
Refurbishment commissioning (subject to accreditation arrangements & technical commissioning)	November 2024
Refurbishment operational	December 2024
Technical PPE (approx. 3 months post new build handover)	March 2025

5.5.2 Please see **Appendix J – Management Control Plan**. Note, are subject to confirmation of planning and funding approvals and agreed construction programmes.

5.6 FRS5 – Accountancy Treatment

5.6.1 It is assumed public funding will be allocated for this project and therefore capital will be included on the balance sheet.

6 Funding and Affordability

6.1 Introduction

6.1.1 The purpose of this section is to set out the indicative financial implications as set out in the Economic Case.

6.2 Capital

6.2.1 A capital cost assessment of the shortlisted options has been undertaken by Gleeds, Cost Advisors based on NHS Departmental Cost Allowances (DCAGs) applied to the proposed schedules of accommodation. The costing was undertaken in accordance with guidance for the costing of capital schemes.

6.2.2 The hi-level capital costs of the shortlisted options (including revoverable VAT) are as follows:

Figure 17 – Capital Requirements (£000 incl non-recoverable VAT)

	Option 2 Do Minimum	Option 3 Intermediate – more ambitious	Option 4 Intermediate – far more ambitious	Option 5 Do Max ambitious
Departmental Costs	17,249	25,729	27,121	31,168
On Costs	13,041	20,332	20,475	25,499
Provisional location adjustment	-908	-1,382	-1,427	-1,700
Works Costs Total	**29,382**	**44,679**	**46,169**	**54,967**
Fees	4,701	7,149	7,387	8,795
Non Works Costs	1,741	2,694	2,641	2,745
Equipment Costs	3,611	5,059	5,231	5,718
Planning Contingency	3,943	5,958	6,142	7,222
VAT (adjusted for reclaim)	7,576	11,678	12,036	14,130
Base Project Cost	**50,954**	**77,217**	**79,606**	**93,577**

Capital Assumptions

6.2.3 The key planning assumptions are as follows:

- Capital Costs include a breakdown of works and non-works elements.
- Where in-house fees will usually have been outsourced these fees have not been charged against revenue. Their contribution towards delivery of this scheme has been based on an agreed resource allocation.
- Construction costs were calculated applying the BCIS PUBSEC Firm Price Index 248 reporting level. The Location Factor is 0.97.
- A VAT rate of 20% has been reflected in the capital costs. The level of revoverable VAT is 100% on professional fees. Other elements of VAT recovery will be limited to areas of refurbishment and an assessment of this oppourtunity will be assessed by specialist VAT advisors at OBC stage.
- Planning contingencies of 10% has been allowed to the shortlisted options, as appropriate, and in line with the generally accepted norm at this stage of the project.
- Optimism Bias has been excluded as per guidance.
- The Business As Usual option (Option 1) was rejected for further detailed analysis. It provides a baseline comparator.

6.3 Revenue

6.3.1 A number of costs pressures associated with the staffing models exist, whether the service moves to a new facility or remains in-situ. These relate to increasing demand for pathology services. For that reason it is reasonable to recognise the current service and projected future demand, but to exclude them from the revenue financial model at this stage in the development of the business case.

6.3.2 In moving to a single facility, Hywel Dda would need to manage the workload of their Consultant staff using the Royal College points based system. This would mean an increased revenue cost pressure. However, over the last few months, work undertaken between both organisations, suggest this cost increase will be less than previously anticipated. In addition it now seems likely that as a result of the closer working relationship of the two organisations, Hywel Dda will be moving to the points based system in advance of any new building. This will allow them to reap the benefits of also moving to partly implement the Advanced Practitioner role that is being successfully adopted in ABM. The adoption of the Advanced Practitioner role will in effect lessen the cost base if it had not been adopted. At the SOC stage it has been assumed no additional cost pressure

6.3.3 Further work will be required at OBC to assess the impact of travel. There are likely to be additional lab specimens travelling to Morriston. However it is too early to estimate the extent of any additional costs, as it is likely that existing transportation journeys can be utilised. Further work will also be required during the OBC to assess the impact on IT.

6.3.4 There are likely to be additional costs associated with running a modern facility built to conform with the latest building and engineering standards. This will be due to the new facility requiring increased space to meet these requirements and the cost of servicing a modern building environment are normally greater than older non-complaint buildings. At this stage no detailed building design work has been undertaken but a high level estimate indicates that it would not be unreasonable to expect additional annual running costs of at least £200k.

6.3.5 Further work on depreciation and impairment will be undertaken at OBC stage.

6.4 Income and Expenditure Analysis

6.4.1 The estimated additional recurring revenue costs for the shortlisted options are outlined in the figure below:

Figure 18 – Revenue cost impact of the Shortlisted Options (£000's)

	Option 2 Do Minimum	Option 3 Intermediate – more ambitious	Option 4 Intermediate – far more ambitious	Option 5 Do Max ambitious
Service Pay				
Service Non-Pay				
Support Services	197	236	263	503
Total	**197**	**236**	**263**	**503**

7 The Management Case

7.1 Introduction

7.1.1 The section of the SOC addresses the achievability of the scheme.

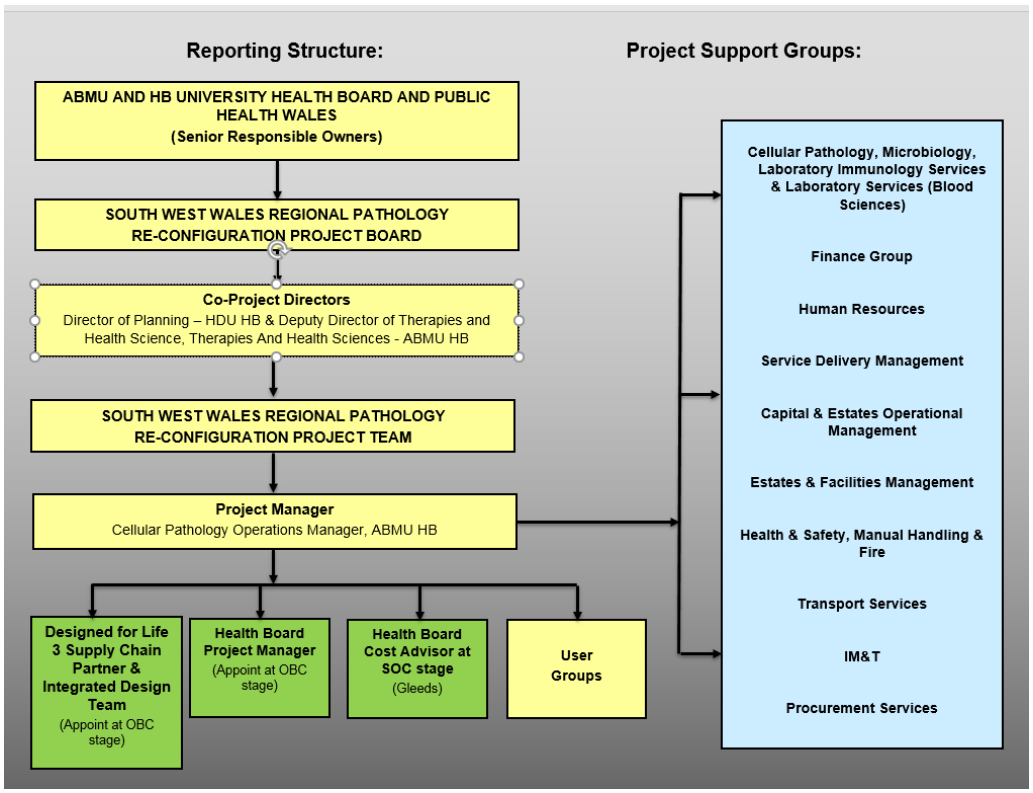
7.2 Project Management Arrangements

7.2.1 To ensure successful project delivery a robust project management reporting structure has been established. The structure is based on the Prince2 principles, with key members of the project team trained in Prince2 methodology. Our experience of developing and delivering complex projects in a Prince2 environment ensures diligent management and thorough clinical involvement throughout all parts of the development.

Reporting Structure

7.2.2 There are three Senior Responsible Owners (SROs). These are the Chief Executive Officers of ABMUHB and HDUHB Health Boards and Public Health Wales respectively. The co-Project Directors are, Mrs Karen Miles (Director of Planning HDUHB) and Mrs Christine Morrell (Deputy Director of Therapies and Health Science, ABMUHB). They have the authority and responsibility to manage delivery of the project on behalf of the key stakeholders. The Project Director reports via the South West Wales Regional Pathology Re-configuration Project Board to the SROs. A nominated Project Manager, Mr Chris Bowden (Cellular Pathology Operations Manager, ABMUHB), supports the Project Director. The reporting structure is below:

Figure 19 – Reporting Structure



7.3 Project Roles and Responsibilities

7.3.1 The Project Director takes lead responsibility for the overall success of the project, and the services which support the change; Agrees and directs the activity of the project; Takes the lead responsibility for risk relating to the project and for the realisation of associated benefits; Agrees and directs the activity of the project; Instructs and manages external consultants; Ensures the brief set by South West Wales Regional Pathology Re-configuration Project Board is adhered too, and; Provides the key contact in respect of high level decisions required in order to progress work.

7.3.2 The Project Manager, Mr Chris Bowden (Cellular Pathology Operations Manager, ABMUHB) provides effective liaison with the wider clinical team. The Project Manager provides highlight reports and exception reports to the Project Board on all aspects of project performance; Ensures the project team (which will include technical and capital planning, construction and service planning leads) is effectively directed and managed during SOC stage; Supports effective liaison with the wider team; Ensures effective monitoring of all project activities is undertaken regarding time, quality and cost, and; Develops the Post Project Evaluation plan.

7.3.3 A Health Board Project Manager and Health Board Cost Advisor will be appointed from the Designed for Life: Building for Wales Framework once this scheme is approved to enter OBC stage.

7.3.4 For the terms of reference and South West Wales Regional Pathology Re-configuration Project Board and Project Team's membership, please see **Appendix G – Terms of Reference**.

7.4 Use of Special Advisors

7.4.1 The following special advisors have been appointed:

Figure 20 – Special Advisors

Role	Appointment
VAT Advisor	Ernst & Young
Cost Advisor (SOC stage)	Gleeds
Health Care Planner	KD Health

7.5 Workforce Planning & Operational Arrangements

7.5.1 The Project Director is lead for service change and operational arrangements in collaboration with agreed service stakeholder representatives. These arrangements will be detailed at OBC stage.

7.6 Health Impact Assessment (HIA)

7.6.1 A HIA is attached in **Appendix A – HIA** for information.

7.7 Equality Impact Assessment (EIA)

7.7.1 An EIA is attached in **Appendix B – EIA** for information.

7.8 Building Research Establishment Environmental Assessment Method (BREEAM)

7.8.1 A pre-construction BREEAM assessment will be provided at OBC stage, following confirmation of detailed design and consultation with the BREEAM Advisor and planning authorities once outline planning permissions are agreed.

7.9 Achieving Excellence Design Evaluation Toolkit (AEDET)

7.9.1 An AEDET assessment will be progressed with NWSSP-SES representatives at OBC stage once design proposals has been detailed.

7.10 Arrangements for Benefits Realisation

7.10.1 A Benefits Register and Benefits Realisation Plan have been developed which will provide a working document throughout the life of this project. A draft register and benefits realisation plan are attached in **Appendices H & I – Benefit Realisation Register & Plan**. These arrangements will be detailed at OBC stage.

7.11 Arrangements for Risk Management

7.11.1 A risk framework has been established which outlines the process for managing risk associated with developing a Regional Pathology project, including a structure for identifying and mitigating operational and construction related risks.

7.11.2 The risk register will use qualitative and quantitative measures to calculate the overall level of risk according to likelihood of any risk occurrence multiplied by the potential impact and South West Wales Regional Pathology Re-configuration Project Board will formally review the risk register at key stages of the project.

7.12 Post Evaluation Arrangements

7.12.1 All projects are subject to post construction review evaluation in accordance with recognised best practice and NHS guidance. Post evaluation arrangements and timescales detailed at OBC stage will be agreed with the key stakeholders. A team constituting planning, construction and design will undertake PPE, and management leads at key stages, as appropriate. Please refer to **Appendix C – Post Evaluation Arrangements** for information.

7.13 NHS Wales Gateway Review (Stage 0 – Business Justification)

7.13.1 A Risk Potential Assessments 1 (RPA 1) has been carried out for this scheme. A copy is included in **Appendix D - Gateway Review - RPA1.** A Gateway '0' review will be arranged Welsh Government post submission of this SOC and prior to the submission of an OBC in accordance with Welsh Government Investment Guidance. Further Gateways will be completed according to Office of Government Commerce (OGC) guidelines following further evaluation.

7.14 Contingency Plans

7.14.1 The Health Board can identify two major category of project failure: failure to achieve business case approval to deliver the scheme; failure of the main contractor(s) to deliver the new build and complex series of refurbishments to time.

7.14.2 The contingency plan for the project in the event of failure to achieve business case approval is for the Health Board to continue to revise its plans, working with Welsh Government to develop an acceptable pathology solution for the region.

7.14.3 In the event of Supply Chain failure, ABMUHB will seek recompense in line with the agreed contractual arrangements and other contractor(s) to complete the project.

Appendix A – HIA

Appendix A - HIA v3.doc

Appendix B – EIA

Appendix B - EIA v3.doc

Appendix C – Post Evaluation Arrangements

Appendix C - PPE v2.doc

Appendix D – Gateway Review - (RPA1)

Appendix D - RPA1 (2).doc

Appendix E – Option & Risk Appraisal Group Membership

Appendix E - Membership.docx

Appendix F – Investment Objectives and Benefits

Appendix F - Investment Objectiv

Appendix G – Terms of Reference

Appendix G - Terms of Reference (2).doc

Appendix H – Benefits Realisation Register

Appendix H -
Benefits Realistion F

Appendix I – Benefits Realisation Plan

Appendix I -
Benefits Realisation

Appendix J – Management Control Plan

Appendix J -
Indicative Programm

Appendix K – Risk Register

Appendix K - Risk Register v8.xlsx

Appendix L – AWCP Group's non-financial and financial appraisals

Timeline diagram.doc

Appendix M – SoA

Appendix M - SoA.pdf

Appendix M2 - SOA.xlsx

Appendix N – Framework Options Appppraisal

Appendix N - Framework Options

Appendix O – Transport Arrangements

Appendix O - Transport Arrangem

Appendix P – Summary of South Wales Cellular Pathology Project's (SWCPP's) Key Milestones

Appendix P - South Wales Cellular Pathc

Abbreviations

ABMUHB	Abertawe Bro Morgannwg University Health Board
AEDET	Achieving Excellence Design Evaluation Toolkit
AME	Annually Managed Expenditure
ARCH	A Regional Collaboration for Health
ATMPs	Advanced Therapy Medicinal Products
ATTC	Advanced Therapy Treatment Centre (i.e. Cell and Gene Therapy)
BIS PUBSEC	Firm Price Index
BREEAM	Building Research Establishment Environmental Assessment
BRP	Benefits Realisation Plan
CPA	Clinical Pathology Accreditation
CSF	Critical Success Factor
CTUHB	Cwm Taf University Health Board
DECAG	Departmental Cost Allowance Guide
DGH	District General Hospital
DGM	Divisional General Manager
DoH	Department of Health
DOSA	Day of Surgery Admission
ECAG	Equipment Cost Allowance Guide
EIA	Equality Impact Assessment
EPRR	Emergency Preparedness Resilience and Response
EQA	External Quality Assessment
FBC	Full Business Case
GEM	Generic Economic Model
GIRFT	*Get it Right First Time*
GMP	Guaranteed Maximum Price
GVA	Gross Value Added
HAI	Hospital Acquired Infection
HBCA	Health Board Cost Adviser
HBPM	Health Board Project Manager
HDUHB	Hywel Dda University Health Board
HIA	Health Impact Assessment
HMt	Her Majesty's Treasury
HTA	Human Tissue Authority
IMTP	Integrated Medium Term Plan
LIMS	Laboratory Information Management System
MDT	Multi-Disciplinary Team
NEC	New Engineering Contract
NPF	National Pathology Framework
NWSSP – SES	NHS Wales Shared Services Partnership – Specialist Estates Services
OBC	Outline Business Case
OCP	Organisational Change Policy
OGC	Office of Government Commerce
PACU	Post Anaesthetic Care Unit
PDP	Portfolio Delivery Plan (ARCH)
PEP	Project Execution Plan
PHW	Public Health Wales NHS Trust
PIA	Privacy Impact Assessment
PLU	Pathology Laboratory Unit
POCT	Point of Care Testing
PPE	Post Project Evaluation
PTL	Patient Tracking List
RIBA	Royal Institute of British Architects
RPA	Risk Potential Assessment
RTT	*Right to Treatment*
SDCP	Site Development Control Plan
SLA	Service Level Agreement
SOC	Strategic Outline Business Case
SOP	Standard Operating Procedure
SSAGs	Specialist Standing Advisory Committees
TAT	Turn Around Time
TPN	Total Parenteral Nutrition
WG	Welsh Government
WHBN	Welsh Health Building Note
WHTM	Welsh Health Technical Memorandum

Glossary

Term	Definition
'Cold tests'	Generally, means non-inpatients e.g. outpatients and GP tests whose Turn Around Time (TAT) requirements can exceed 8 hours.
'Diagnostic Immunology'	Also known as 'Laboratory Immunology'.
Gross Value Added ('GVA')	The measure of the value of goods and services produced in an area, industry or sector of an economy.
'Hot Lab'	This is a shared laboratory facility, staffed by a BMS for pre-booked frozen sections. The facility must have appropriate digital communication with a "Site". This option only to be used when transport to the centralised site(s) will render an unacceptable clinical delay.
'Hot tests'	Generally, means inpatients prioritising unscheduled care e.g. A&E whose TAT requirements are 8 hours or less.
'LEAN' principles	LEAN is an improvement approach, developed by Toyota, to improve flow and eliminate waste. It is about getting the right things to the right place, at the right time, in the right quantities, while minimising waste and being flexible and open to change. Lean is increasingly being applied to healthcare in both the United Kingdom and overseas to: Improve the quality of patient care; Improve safety, and; Eliminate delays and reduce length of stay.
'Pathology'	An 'umbrella' term used within this document to describe the four main specialties, i.e. Blood Sciences (Haematology & Chemical Pathology services, also called Laboratory Medicine, Blood Transfusion, Cellular Pathology and Medical Microbiology.
Temporary Mortuary	A pre-designated location which can be used as a mortuary if the scale of the incident renders existing facilities inappropriate. Such locations require detailed pre-planning and will be used as a centre for the examination and identification of the deceased