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<b>Meeting Date</b>	<b>31 January 2019</b>		<b>Agenda Item</b>	<b>4.2</b>
<b>Report Title</b>	Laboratory Information Network Cymru (LINC) Outline Business Case			
<b>Report Author</b>	Judith Bates (National Programme Director, LINC Programme)			
<b>Report Sponsor</b>	Matt John, Associate Director of Informatics			
<b>Presented by</b>	Matt John, Associate Director of Informatics			
<b>Freedom of Information</b>	Open			
<b>Purpose of the Report</b>	This Outline Business Case makes the case for investment in an electronic solution and services for Pathology across Wales, at the heart of which is the procurement of a new laboratory information management system (LIMS) service. This investment is required as the contract with InterSystems for the current LIMS, TrakCare Lab (TCL), expires in June 2020.			
<b>Key Issues</b>	<p>The key risks and issues faced by the LINC Programme are:</p> <ul style="list-style-type: none"> <li>• Requirement to upgrade current LIMS</li> <li>• Programme timeframe</li> <li>• The apportionment of costs</li> <li>• Programme costs</li> <li>• Treatment of capital</li> <li>• National Informatics Management Board (NIMB) feedback</li> </ul>			
<b>Specific Action Required</b>	<b>Information</b>	<b>Discussion</b>	<b>Assurance</b>	<b>Approval</b>
				✓
<b>Recommendations</b>	<p>Members are asked to:</p> <ul style="list-style-type: none"> <li>• <b>APPROVE</b> the LINC OBC, in order to allow the procurement to proceed;</li> <li>• <b>APPROVE</b> the inclusion of the estimated costs of the OBC and the LINC Programme in IMTP plans.</li> </ul>			



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## **Laboratory Information Network Cymru (LINC) Programme LINC Outline Business Case (OBC)**

**Author:** Judith Bates, Programme Director, LINC Programme

**Date:** 8 January 2018

**Version:** 1.0

### **Purpose and Summary of Document:**

This OBC makes the case for investment in an electronic solution and services for Pathology across Wales, at the heart of which is the procurement of a new laboratory information management system (LIMS) service. This investment is required as the contract with InterSystems for the current LIMS, TrakCare Lab (TCL), expires in June 2020.

LINC is an enabling programme to support the delivery of a modern, high quality Pathology service as part of a wider transformation set out in the Pathology Statement of Intent. A key driver is the need to standardise as far as possible to deliver a sustainable service. Electronic test requesting (ETR) is critical to deliver key benefits including financial savings.

On a revenue only basis, the overall estimated cost is £42 million and £4.8 million per annum. Alternatively, with a minimum of £8 million capital, the revenue cost is £37 million and £4 million per annum. The combined cost of the three current LIMS (TrakCare Lab (TCL), Telepath and Masterlab) is £4.2 million so, excluding benefits, the new Pathology solution will be £0.6 million per annum more or £0.2 million per annum less depending on the funding model.

It is estimated that a potential £4 million per annum can be realised in benefits that, with capital monies, would cover the cost of the new LIMS.

# **1 Introduction**

This OBC seeks approval to invest in an end-to-end technical solution and services for Pathology across Wales at the heart of which is the procurement of a new laboratory information management system (LIMS) service.

This paper sets out the OBC background and scope, anticipated benefits, progress to date, strategic risks and issues, any local issues and financial implications. It asks each Health Board/Trust to support the LINC OBC.

# **2 Background**

The current TCL system (also known as WLIMS1) was procured in 2010 as a single, national system on a seven year contract, extendable for up to three years until June 2020. There is no available legal basis to further extend this contract. A TCL system licence was procured, with NWIS responsible for the system hardware and hosting arrangements in NHS data centres.

A LINC Programme Board has been in place since December 2017, managed on behalf of NHS Wales through the NHS Wales Health Collaborative, with representation from all health boards running Pathology services, Public Health Wales, the Welsh Blood Service, Point of Care Testing, All Wales Medical Genetics Service, Strategic Programmes, NWIS, National Pathology Network, Directors of Therapies and Health Sciences, Laboratory Services Sub-Committee and Associate Directors of Informatics. Adrian Thomas, Executive Director of Therapies and Health Sciences, Betsi Cadwaladr University Health Board is the Senior Responsible Owner and Judith Bates is the Programme Director.

# **3 OBC Scope**

The OBC scope is for an end-to-end electronic solution and services that seeks to modernise and transform Pathology as a high quality, sustainable service. Building on the lessons learned from WLIMS1, this scope is broader than the replacement of the current LIMS licence and includes:

- Procurement of a new LIMS service, where the supplier is responsible for the hosting arrangements, potentially using cloud services;
- Standardisation of Pathology services as far as possible;
- Electronic test requesting (ETR) from acute and primary care services;
- A national quality management system and team;
- Improved business intelligence;
- Enhanced NWIS management of the LIMS as a national application.

The OBC considers an extensive longlist and evaluates three shortlisted options: (1) business as usual, (2) implementing the latest InterSystems solution (TCL Enterprise) without a procurement, and (3) procuring a new LIMS service. Option 3, to procure a new LIMS offers the best value for money.

## 4 Anticipated Benefits

Workshops have been held to assess the benefits that can be delivered from the proposed investment. These include financial benefits (cash releasing), economic benefits (non-cash releasing) and quantitative benefits.

- *Financial savings* will arise from electronic test requesting (ETR) and the implementation of a simpler, more standardised LIMS that eliminates inefficient workarounds in place with the current LIMS;
- *Economic savings* will be made from improved demand management (e.g. reduced unnecessary repeated requests) and business intelligence, enhanced operational, service and document management, improved cross-site working, minimal system down-time, improved environment and interface management and easier sample tracking;
- *Qualitative benefits* will arise from improved patient care, pathways and outcomes with faster turnaround times, better audit facilities, reduced transcription errors and fewer clinical incidents.

Potential financial benefits are estimated as 3% of the total costs of Pathology Services, which equates to approximately £4 million per annum.

A Benefits Project will be established to put in place robust mechanisms to assess and realise benefits and these will be included in the full business case.

## 5 Progress to Date

During 2018, significant supplier and stakeholder engagement has taken place, including:

- Programme Director providing monthly updates to and attendance at the NHS Wales Collaborative Executive Group (CEG);
- Market soundings following a Prior Information Notice and supplier engagement day in February;
- Engagement with the service and NWIS including ~40 workshops
  - To develop the outline business case;
  - To develop the requirements for the new LIMS service;
  - To develop the Pathology requirements for ETR and complete a gap analysis with the Welsh Clinical Portal.
- Presentations to the Welsh Clinical Informatics Council, Associate Directors of Informatics, Directors of Planning and Deputy Directors of Finance;
- A monthly newsletter widely circulated to keep the service up-to-date with progress.

## 6 Risks and Issues

The key risks and issues faced by the LINC Programme are:

- Requirement to upgrade current LIMS
- Programme timeframe
- The apportionment of costs

- Programme costs
- Treatment of capital
- National Informatics Management Board (NIMB) feedback

## **Requirement to upgrade current LIMS**

There is a requirement to maintain the current LIMS for up to three years after the contract with InterSystems expires and until the new LIMS is fully deployed. The technical platform supporting the current LIMS (Microsoft Windows Server 2008) is end of life in 2020 and requires a system upgrade from TCL 2011 to TCL 2016 at an estimated cost of £2.5 million.

In addition, due to the delay in the implementation of blood transfusion, there may be a requirement for some health boards to upgrade their original Telepath LIMS for this service. This is because, at the end March 2019, Telepath is also end-of-life, with significant risk of failure without investment in hardware. Given the investment being made, health boards that need to make this investment may not wish to migrate to TCL and stay with Telepath until the new LIMS is available. Therefore costs may be incurred to maintain dual running of both LIMS until the new LIMS is fully deployed.

## **Programme timeframe**

The programme timeframe is estimated to be five years from March 2019 to March 2024. Extensive work has been undertaken and scrutinised in the development of the OBC. A delay in the sign off of this OBC will delay the procurement and the programme as a whole and add to the risks. In recognition of the importance of this programme, the NHS Wales Collaborative Leadership Forum has advised that it does not wish the timescale to be delayed and OBC approval is therefore essential to allow the programme to proceed.

## **The apportionment of costs**

The CEG approved, in principle, the costs presented in the OBC and approved the costs of the programme at their meeting on 23 October 2018. They requested that an approach to the apportionment of costs to be agreed with the Directors of Finance (DoFs). An options paper has been submitted to the Deputy DoFs in the first instance. For the purpose of costing in the OBC, a working assumption of organisations' financial allocations has been used for the apportionment of costs. Public Health Wales are not currently included in the apportionment of costs but have indicated they should make a contribution, which will reduce the costs to health boards.

## **Programme costs**

The cost of the programme over the five years is estimated at £6 million. This does not include the cost that will be incurred by the Pathology service to support the programme. The CEG agreed at their meeting on 18 December 2018 that these costs should be estimated and included in the programme costs. This cost is currently being evaluated.

## **Treatment of capital monies**

The OBC does not currently include the treatment of capital monies, which is awaiting specialist financial advice from NWIS finance team. The OBC includes both revenue only and capital / revenue cost options. However, International Financial Reporting Standard (IFRS) 16 regulation in relation to a managed service, would imply that a capital approach will be required. Financial advice is awaited as to the extent to which the costs can be capitalised and so a minimum of £8 million capital has been included, to be requested from Welsh Government.

## **NIMB feedback**

The LINC OBC was considered at the NIMB meeting held on 11 December 2018. NIMB did not approve the OBC but did not wish to delay its progress. It will be taken to the Welsh Government scrutiny panel and to all Health Boards / Trusts for consideration in January 2019. NIMB requested two main changes to the document:

(1) to remove the option to deliver electronic test requesting (ETR) either via the Welsh Clinical Portal or by procuring a separate tool and to decide on the way forward in the OBC rather than as proposed, in the full business case (FBC), and

(2) to provide a more robust benefits analysis despite the difficulty of obtaining accurate baseline information and the delay this could cause.

The CEG, at their meeting on 18 December 2018, disagreed with the recommendation to decide on the option for ETR in the OBC as this would impact the confidence of the Pathology service in the LINC Programme. They preferred to retain both options and for a decision to be made in the FBC. They further accepted that the benefits realisation is work in progress that can also be enhanced in the FBC.

## **7 ABMU Context / Issues**

***This section has been inserted by ABMU leads to provide local context***

Due to expiry of the contract, for WLIMS1 (called TrakCare Lab, or TCL), with InterSystems in June 2020, there is the need to procure a replacement for WLIMS1 or all Health boards would be under pressure to revert to having their own LIMS solutions. This is contrary to NHS Wales Strategy.

Note: WLIMS1 replaced 13 different health board solutions. A single system supports standardisation across Wales of testing and results reporting and facilitates improved patient care.

There have been many problems with WLIMS 1 (not yet fully implemented in any Health Board across Wales) and these problems have been identified to enable an improved replacement in WLIMS 2 (LINC)

- All Wales Pathology disciplines have agreed to promote standardisation to be delivered through LINC as far as reasonably possible
- Governance arrangements for the national LIMS are advised to be improved
- The Business intelligence tool is currently being improved (ahead of LINC)

- LINC product will be more resilient compared with the instability issues currently being worked on LIMS1 by NWIS

The financial tables within the OBC reflect the current ABMU Health Board configuration and would need to be revised to recognize Bridgend Boundary Change in due course.

It also refers to future Costs for LINC vs existing costs of existing Laboratory systems - in ABMU these are predominately WLIMS1 + MasterLab costs.

Once WLIMS is fully deployed ie Blood Transfusion module for ABMU, ABMU was planning to recognise the MasterLab cost savings as recurrent, however this needs to be reviewed as LINC costs are likely to be in excess of current costs WLIMS1 + MasterLab.

## 8 Financial Implications

The estimated whole life costs of the preferred option to procure a new LIMS is £42 million revenue only or £37 million revenue plus £8 million capital to be requested from the Welsh Government. In addition, the costs of the programme are £6 million.

The annual running costs of the new service is estimated at £4.8 million (revenue only option) or £4 million (revenue/capital option). This compares to the annual running costs of the current LIMS (TCL, Telepath and Masterlab) of £4.2 million. The new LIMS will therefore incur an additional cost per annum of £0.6 million or a saving of £0.2 million across Wales.

If realised, total potential savings of £4 million per annum have been estimated, which would release £3.4 million savings (revenue only model) or £4.2 million (capital and revenue model).

The whole life costs and costs per annum for each health board are summarised in Table 1. The per annum costs also show per health board:

- The costs of the current LIMS (TCL, Telepath and Masterlab)
- The potential savings as a consequence of the investment.

## 9 Summary and Recommendation

The LINC OBC makes the case for investment in an end-to-end technical solution and service for Pathology across Wales. It will contribute towards the development of a modern, high quality, sustainable Pathology service. At the heart of this, the option to procure a new LIMS service is a legal requirement that has demonstrated the best value for money. There are risks associated with any delay in the programme.

Members are asked to:

- **APPROVE** the LINC OBC, in order to allow the procurement to proceed;
- **APPROVE** the inclusion of the estimated costs of the OBC and the LINC Programme in IMTP plans.

**Table 1: Whole life and per annum costs of the Pathology solution and LINC Programme**

Health Board / Trust	Revenue Only £k						
	Whole Life Costs (2019/20 - 2026/7)			Per Annum Costs of Pathology Solution £k			
	Pathology Solution	LINC Programme	Total Cost	New Annual Cost	Costs of Current LIMS'	Potential Savings	Additional Costs / Savings
ABM UHB	7,249	1,037	8,286	830	859	716	-745
Aneurin Bevan UHB	7,916	1,133	9,049	906	688	784	-566
Betsi Cadwaladr UHB	9,374	1,341	10,716	1,073	765	928	-620
Cardiff and Vale UHB	5,833	835	6,667	668	803	579	-714
Cwm Taf UHB	4,333	620	4,953	496	386	429	-319
Hywel Dda UHB	5,125	733	5,858	587	483	506	-402
Velindre NHST	0	0	0	0	220	0	-220
Powys Teaching HB	1,833	262	2,095	210		59	151
<b>Grand Total (Revenue only)</b>	<b>41,663</b>	<b>5,961</b>	<b>47,624</b>	<b>4,768</b>	<b>4,205</b>	<b>4,000</b>	<b>-3,436</b>

Health Board / Trust	Capital and Revenue £k						
	Whole Life Costs (2019/20 - 2026/7)			Per Annum Costs of Pathology Solution			
	Pathology Solution	LINC Programme	Total Cost	New Annual Cost	Costs of Current LIMS'	Potential Savings	Additional Costs / Savings
ABM UHB	6,483	1,037	7,521	690	859	716	-884
Aneurin Bevan UHB	7,080	1,133	8,213	754	688	784	-718
Betsi Cadwaladr UHB	8,384	1,341	9,726	893	765	928	-800
Cardiff and Vale UHB	5,217	835	6,051	556	803	579	-826
Cwm Taf UHB	3,875	620	4,495	413	386	429	-403
Hywel Dda UHB	4,583	733	5,317	488	483	506	-501
Velindre NHST	0	0	0	0	220	0	-220
Powys Teaching HB	1,640	262	1,902	175		59	116
<b>Grand Total (Revenue)</b>	<b>37,263</b>	<b>5,961</b>	<b>43,224</b>	<b>3,968</b>	<b>4,205</b>	<b>4,000</b>	<b>-4,236</b>
<b>Welsh Government</b>							
<b>Grand Total (Capital)</b>	<b>8,000</b>		<b>8,000.00</b>				



### ABMU Yearly Revenue Breakdown of Whole Life Costs

	19/20 £k	20/21 £k	21/22 £k	22/23 £k	23/24 £k	24/25 £k	25/26 £k	26/27 £k	Total £k
	National Readiness, Procurement and Implementation					Business As Usual			
Revenue only model	401	1,086	1,714	1,555	1,038	830	831	832	8,286
Revenue/Capital	401	1,086	1,644	1,415	899	690	692	693	7,521

Until ABMU completes the local implementation of the LINC solution, the cost of the current LIMS (£859k) will also be incurred. The rollout will be on a Health Board by Health Board basis between 21/22 and 23/24. The rollout order is yet to be determined. The local staffing requirements for the readiness, procurement and implementation phases of the programme are yet to be determined. The LINC programme is focussing on building central expertise to reduce the burden on local teams.

Governance and Assurance										
<b>Link corporate objectives</b>  (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	
			✓		✓		✓		✓	
<b>Link to Health and Care Standards</b>  (please ✓)	Staying Healthy	Safe Care	Effective Care		Dignified Care		Timely Care	Individual Care	Staff and Resources	
		✓	✓				✓	✓	✓	
Quality, Safety and Patient Experience										
A functional LIMS system is critical to quality and safety										
Financial Implications										
For ABMU, the indicative annual revenue cost ranges from £690k (capital/revenue model) to £830k (revenue only model). We currently pay £859k. Once implemented, there are potential savings of £716k.										
The indicative costs for the whole life costs are:										
	19/20 £k	20/21 £k	21/22 £k	22/23 £k	23/24 £k	24/25 £k	25/26 £k	26/27 £k	Total £k	
	National Readiness, Procurement and Implementation					Business As Usual				
Revenue only model	401	1,086	1,714	1,555	1,038	830	831	832	8,286	
Revenue/ Capital	401	1,086	1,644	1,415	899	690	692	693	7,521	
Until ABMU completes the local implementation of the LINC solution, the cost of the current LIMS (£859k) will continue to be incurred. The rollout will be on a Health Board by Health Board basis between 21/22 and 23/24. The order is yet to be determined. Costs do not cover the local implementation resources which are yet to be determined. See Staffing implications.										

<b>Legal Implications (including equality and diversity assessment)</b>	
No contractual obligations at this point.	
<b>Staffing Implications</b>	
The local staffing requirements for the readiness, procurement and implementation phases of the programme are yet to be determined. The LINC programme is focussing on building central expertise to reduce the burden on local teams.	
<b>Long Term Implications (including the impact of the Well-being of Future Generations (Wales) Act 2015 - <a href="https://futuregenerations.wales/about-us/future-generations-act/">https://futuregenerations.wales/about-us/future-generations-act/</a>)</b>	
A functional LIMS system is critical to quality and safety	
<b>Report History</b>	Executive Board 16 November 2018
<b>Appendices</b>	Appendix 1: LINC OBC Executive Summary Appendix 2: LINC Outline Business Case



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## Outline Business Case Executive Summary



## Document Control

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## 1. Executive Summary

### 1.1. Introduction and Overview

This OBC seeks approval to invest in an end-to-end technical solution for Pathology services at the heart of which is the procurement of a new laboratory information management system (LIMS) service for Wales. This investment is required as the contract with InterSystems for the current LIMS, TrakCare Lab (TCL), expires in June 2020.

The Laboratory Information Network Cymru (LINC) Programme, part of the NHS Wales Health Collaborative (NHSWHC) is leading the procurement and implementation of the new LIMS, and the wider change programme associated with this OBC. LINC is an enabling programme to support the delivery of a modern, sustainable Pathology service as part of a wider transformation plan set out in the Pathology Statement of Intent.

The strategic case makes the case for change addressing current challenges, such as staffing, future service and technical developments and the scope in terms of the disciplines covered, functional and technical requirements. A key driver is the need to further standardise services as far as possible to deliver a sustainable service. Electronic test requesting is critical to deliver key benefits including financial savings.

A long list has been assessed, from which a short list of three options has been derived:

- Option 1: Business as usual - to upgrade to TCL 2016
- Option 2: Do Minimum - to take TCL Enterprise
- Option 3: Preferred - to procure a new LIMS service

In addition to the new LIMS service, the scope of the OBC includes a national quality team and quality management system and improved management of the LIMS by NWIS as a national application.

The OBC costs are evaluated over eight years from 2019/20 to 2026/27, the first year covering the procurement via competitive dialogue and design work. A master services agreement contract form is proposed for seven years, extendable on an annual basis for a further seven years.

On a revenue only basis, the overall cost is £42 million and £4.8 million per annum. With a minimum of £8 million capital, the revenue cost is £37 million and £4 million per annum. The combined cost of the three current LIMS (WLIMS1, Telepath and Masterlab) is £4.2 million so, excluding benefits, the new Pathology solution will be £0.6 million per annum more or £0.2 million per annum less depending on the funding model.

It is estimated that a potential £4 million per annum can be realised in benefits that would cover the cost of the new LIMS, with capital monies

## 1.2. Strategic Case

### *The strategic context*

Pathology is the study of disease and is involved in 70% of all diagnosis made in the NHS, underpins all clinical services, is a key component in the delivery of prudent health services to the population of Wales and an enabler to other Welsh Government health delivery plans including cancer and stroke services.

Pathology comprises a wide variety of disciplines and the main disciplines comprise *National Services* (PHW Microbiology and Screening Services, Welsh Blood Service, All Wales Medical Genetics Service and Welsh Point-of-care Testing) and *Local Laboratory Services*, comprising Andrology, Blood Sciences (including Blood transfusion), Cellular Pathology and Microbiology (not provided by PHW).

Pathology services undertook around 30 million authorised test sets during 2017/8. The service is under increasing pressure from growth in demand and the development of new technologies. Pathology services cost around £118 million, at least 1.9% of the total health care budget. In March 2017, it was estimated that there were 2,026 FTE staff in healthcare science and 200 FTE medical staff, of which 133 were consultants. One of the key issues faced by the service is recruitment and retention of skilled staff.

There is no single Pathology service across Wales and, although some services are provided nationally, most sit under the responsibility of the six University Health Boards (UHBs) and Public Health Wales (PHW).

The Pathology service is undergoing change in relation to boundary changes, implementation of the Carter recommendations to create hub and spoke services, reconfiguration of services in the West as part of the Arch initiative, the new Grange University Hospital due to open in Cwmbran in 2021 and piloting Digital Cellular Pathology in Glan Clwyd Hospital.

### *Business strategies*

The development of an end-to-end technology solution for pathology services will contribute to the delivery of [\*A healthier Wales; our plan for health and social care\*](#) and the new LIMS will be a national application as part of [\*Informed health and care: a digital health strategy for Wales\*](#). The solution will be a key deliverable towards the *Pathology Statement of Intent*, a national plan to modernise Pathology services across Wales, currently being finalised for sign off by Welsh Government.

### *The case for change*

The current LIMS (known as WLIMS1) is InterSystems TCL 2011, which was procured in 2010 as a single, national system intended to replace 13



standalone systems. Significant progress has been made but further work remains to complete implementation. The contract includes an upgrade TCL 2016 but in 2017, the NHS and InterSystems jointly decided against this upgrade. However, TCL 2011 is not supportable after January 2020 because the Microsoft operating system is end of life. Consequently, the upgrade will have to go ahead as the delay in the re-procurement means that it is not possible to deploy a new solution by June 2020. Many lessons have been learned from WLIMS and being taken into account within LINC.

Standardisation is critical to underpin the transformation of the Pathology service to be more sustainable in terms of delivering a high quality service, creating capacity to cope with increasing demand at the same time as reducing costs. The service has agreed the definition of standardisation and warranted variation (e.g. because of using different equipment) as a basis for taking forward standardisation as far as possible.

Electronic test requesting (ETR) is also critical to deliver benefits and underpin service transformation. The current ETR service is provided by the Welsh Clinical Portal (WCP), but does not currently meet the needs of the Pathology service as a whole. A Pathology ETR requirement has been defined and the current and planned WCP capability is being assessed to determine the gap. If the WCP cannot be developed to meet Pathology requirements, then the procurement of a separate system with the LIMS has been included as an option. Substantial financial savings can be realised if paper requests no longer have to be manually booked in and scanned.

LINC has multiple and complex stakeholders with different levels of interest in the LINC programme. Key stakeholders have been engaged in the development of this OBC through events, meetings and email. More than thirty workshops have been held or are planned during 2018 to contribute to this business case and / or develop the requirements for the new service.

The spending objectives for the LINC Programme have evolved throughout 2018. They provide the basis for this OBC:

- SO1** To improve patient care, patient safety and patient outcomes;
- SO2** To enable the transformation of healthcare services to be leaner, standardised, more sustainable and provide long-term stability;
- SO3** To deliver a seamless, end-to-end electronic solution for Pathology services;
- SO4** To contribute to the more prudent use of Pathology resources through demand management, predictive costing and minimised financial risk;
- SO5** To meet current and future service requirements.

### 1.3. Economic Case

In accordance with national guidance, this section of the OBC documents the wide range of options that have been considered to deliver the spending objectives and recommend a preferred option for investment. The OBC covers eight years from 2019/20 – 2026/7, the first year for procurement.

#### *The long list*

A wide range of options have been generated that identifies and analyses choices for scope (SCO), service solution (SSO), technical solution (TSO), configuration (CON), service delivery (SDO) and implementation (IMP). Discussions at the LINC Programme Board and various workshops has generated and reviewed the long list options.

#### *Scope Options*

The scope includes systems and services that collectively deliver an end-to-end technical solution to support the modernisation of Pathology services, including:

- A solution that support all Pathology disciplines and sub-disciplines
- Core and discipline specific functionality
- Business intelligence
- Pathology, quality, informatics and validation standards
- Business change including training and development
- Documentation
- Additional systems including vein-to-vein blood tracking with remote issue, scanning, dictation and voice recognition, business intelligence, a national quality management system, NPEx to manage referrals in and out of Wales and an optional ETR system
- Legacy data migration and repository
- Technical requirements, including integration services
- Capacity to support future service and technical developments

The scope excludes:

- New systems for Medical Genetics, Point-of-care-testing, Bowel screening, Downs screening and WTAIL;
- All local hardware including peripherals, networks, fridges, blood transfusion kiosks and other local equipment;
- Local costs of deployment such as backfill for training;
- Wide area networking as the service will use the All Wales Public Sector Broadband Aggregation (PSBA);

The scope is considered in relation to four options: Business as usual, Do minimum, Intermediate and Maximum.

Table 1 provides a summary of the long listing evaluation for all options.

Table 1: LINC Long List of Options: Summary of Inclusions and Exclusions

Category	Title	Conclusion
<b>Scoping Options</b>		
SCO1	Business as usual	Discounted
SCO2	Do Minimum	Discounted
SCO3	Intermediate	Preferred
SCO4	Maximum	Possible
<b>Service Solution Options</b>		
SSO1	Local LIMS for each health board	Discounted
SSO2	Best of breed LIMS per main discipline	Discounted
SSO3	Separate Cellular Pathology LIMS	Possible
SSO4	Single, national LIMS	Preferred
<b>Technical Solution Options</b>		
TSO1	Supplier cloud hosted solution	Preferred
TSO2	National data centre – supplier hosted	Possible
TSO3	National data centre – NWIS hosted	Discounted
TSO4	Local data centres – Health Boards	Discounted
<b>Configuration Options</b>		
CON1	In-house configuration (NWIS)	Possible
CON2	Supplier configuration	Preferred
<b>Service Delivery Options</b>		
SMO1	In-house system delivery	Discounted
SMO2	NHS service management	Discounted
SMO3	Supplier partial service management	Preferred
SMO4	Supplier total service management	Possible
<b>Implementation Options</b>		
IMP1	All disciplines phased by site	Discounted
IMP2	All disciplines phased by HB	Preferred
IMP3	Phased by discipline by HB	Possible
IMP4	Phased nationally by discipline	Discounted
IMP5	Big bang	Discounted

## The Shortlist

Following the longlisting exercise, three shortlisted options have been generated:

- **Option 1: Business as usual** option, for benchmarking purposes. This option is to upgrade to TCL 2016. It is rejected as TCL 2016 is end of life by 2025 and Wales will be in the same position as now;
- **Option 2: Do minimum option**, to put in place a new contract with InterSystems without going out to procurement to take their latest product, TCL Enterprise (TCLE). This option is likely to incur legal challenge if no procurement is undertaken;
- **Option 3: Preferred approach** to go out to procurement for a new LIMS service.

## Net Present Costs (NPC)

Overall costs over the life of the contract covered by the OBC (seven years from 2020/21 to 2026/7) has been combined with the financial value of the benefits and the costs of the risks to calculate the NPC for each option.

Only financial benefits have been considered with more work to be completed for the full business case, which will also add the value of economic benefits. Financial benefits are estimated at £4m per annum (3% of the costs of the Pathology service), which are considered in relation to:

- Electronic test requesting (1%);
- Improved business intelligence and demand management (1%);
- Improved patient pathways and outcomes (1%).

The NPC presented in Table 2 shows that, although Option 3 is marginally the most expensive, it has the least net present cost.

Table 2: Net Present Cost

Financial Details	Option 1: BAU	Option 2: Do Minimum	Option 3: Preferred Approach
	£k	£k	£k
Financial cost total	26,875	42,916	44,478
Optimism Bias @ 20%	0	8,583	8,896
<b>Total including optimism bias</b>	<b>26,875</b>	<b>51,499</b>	<b>53,374</b>
Quantification of benefits	-6,222	-12,444	-18,667
Risk Quantification	22,719	14,400	2,424
Total – Pre-Discounting	43,371	53,455	37,131
<b>Net Present Cost</b>	<b>40,105</b>	<b>51,447</b>	<b>35,713</b>

In conclusion, option 3, to procure a new LIMS service is recommended as the way forward. The rest of the OBC takes forward this recommendation.

#### **1.4. Commercial Case**

The contract will provide a managed service for a single, national LIMS service with one supplier responsible for the national application and associated tools in partnership with NWIS for integration services to national applications and local, clinical downstream systems.

As NHS Wales organisations are public sector bodies; all NHS Wales procurements must comply with Standing Orders and the Public Contracts Regulations 2015 (PCR2015).

Velindre NHS Trust is the host of the NHS Wales Informatics Service and will be the Contracting Authority for the purposes of this procurement.

#### ***Procurement strategy***

The principle aim of the procurement is to procure a LIMS service to replace the existing legacy solution/s. In line with the infrastructure strategy of NHS Wales, the solution will be hosted either in an NHS Wales data centre or an accredited data centre and delivered across NHS Wales' network infrastructure (currently provided by the Welsh Government's PSBA network).

The procurement approach envisages a single supplier provided solution with the chosen supplier taking prime contractor responsibility for the range of infrastructure, systems and services that comprise the LIMS service.

The length of contract will be tailored to give best value for money but the option will be explored during the procurement for a 14 years contract offering a minimum of seven years with the option to extend on an annual basis for another seven years.

The contract form of Agreement will be a Master Services Agreement, based on an amended form of the IT Services Contract having regard to the Crown Commercial Services and other best practice guidance of IM&T procurement. Each health board will "call off" their requirements from the Master Services Agreement and via this process will execute their own distinct local contracts "Deployment Orders" with the contractor.

The NWIS Head of Commercial Services will lead the procurement supported by a Procurement Team comprising suitably qualified and competent resources, including legal and commercial advisers.

Subject to the Welsh Government signing off this OBC, it is intended to publish the OJEU notice in March 2019. It is anticipated that the implementation under the proposed contract will start in 2020, taking into account the migration/exit off the legacy solutions and in accordance with the LINC programme plan.

## **1.5. Financial Case**

The primary purpose of the financial case is to set out the financial implications of the preferred option to ensure that the solution is affordable.

### ***Apportionment of Costs***

The NHSW Collaborative Executive Group has requested that a different approach to WLIMS1 apportionment of costs be agreed and a paper has been submitted to the Deputy DoFs for consideration. For the purposes of the OBC, a working assumption has been made that the apportionment will be based on the annual allocation to health boards and NHS trusts, in accordance with the WHC (2017) 053 Health Board 2018-9 Allocations.

### ***Financial expenditure***

Tables 3-5 present the costs per organisation based on the revenue apportionment by allocation for revenue only and for capital and revenue. Given the latest guidance in IFRS16, a capital/revenue model is most likely. The overall cost over the life of the OBC is £42 million revenue only or £37 million revenue + £8 million capital from the Welsh Government. In addition, there is the £6 million cost of the LINC Programme. The NHSW CEG has approved the revenue costs, which comprise:

- Current LIMS (dual running) - £11m
- New LIMS service - £22m (rev only) or 18m rev+ £8m capital
- National quality management system and quality team - £3m
- NWIS technical services and support costs - £5m

The annual cost of the new Pathology solution overall is estimated as £4.8m (revenue only) or £4m (with capital funding), compared to the costs of the three current LIMS (TCL, Masterlab and Telepath), which is £4.2m.

Potential savings of 3% of Pathology costs have been estimated, which equates to £4 million per annum, that could cover all or most of the cost of the new Pathology solution.

There is a potential impact on the balance sheet if a capital / revenue approach is taken and capital assets have been purchased.

### ***Overall affordability and balance sheet treatment***

The most expensive years are 2020/21 and 2022/23, where between £5m - £8m additional revenue funds are required per annum (unless some implementation costs can be converted to capital monies).

As part of the sign off for this OBC, each health board and trust will be required to provide a letter supporting the programme and costs signed by their Chief Executive and Director of Finance.

Table 3: LINC OBC whole life costs plus per annum costs per organisation

Health Board / Trust	Revenue Only £k						
	Whole Life Costs (2019/20 - 2026/7)			Per Annum Costs of Pathology Solution £k			
	Pathology Solution	LINC Programme	Total Cost	New Annual Cost	Costs of Current LIMS'	Potential Savings	Additional Costs / Savings
ABM UHB	7,249	1,037	8,286	830	859	716	-745
Aneurin Bevan UHB	7,916	1,133	9,049	906	688	784	-566
Betsi Cadwaladr UHB	9,374	1,341	10,716	1,073	765	928	-620
Cardiff and Vale UHB	5,833	835	6,667	668	803	579	-714
Cwm Taf UHB	4,333	620	4,953	496	386	429	-319
Hywel Dda UHB	5,125	733	5,858	587	483	506	-402
Velindre NHST	0	0	0	0	220	0	-220
Powys Teaching HB	1,833	262	2,095	210		59	151
<b>Grand Total (Revenue only)</b>	<b>41,663</b>	<b>5,961</b>	<b>47,624</b>	<b>4,768</b>	<b>4,205</b>	<b>4,000</b>	<b>-3,436</b>

Health Board / Trust	Capital and Revenue £k						
	Whole Life Costs (2019/20 - 2026/7)			Per Annum Costs of Pathology Solution			
	Pathology Solution	LINC Programme	Total Cost	New Annual Cost	Costs of Current LIMS'	Potential Savings	Additional Costs / Savings
ABM UHB	6,483	1,037	7,521	690	859	716	-884
Aneurin Bevan UHB	7,080	1,133	8,213	754	688	784	-718
Betsi Cadwaladr UHB	8,384	1,341	9,726	893	765	928	-800
Cardiff and Vale UHB	5,217	835	6,051	556	803	579	-826
Cwm Taf UHB	3,875	620	4,495	413	386	429	-403
Hywel Dda UHB	4,583	733	5,317	488	483	506	-501
Velindre NHST	0	0	0	0	220	0	-220
Powys Teaching HB	1,640	262	1,902	175		59	116
<b>Grand Total (Revenue)</b>	<b>37,263</b>	<b>5,961</b>	<b>43,224</b>	<b>3,968</b>	<b>4,205</b>	<b>4,000</b>	<b>-4,236</b>
<b>Welsh Government</b>							
<b>Grand Total (Capital)</b>	<b>8,000</b>		<b>8,000.00</b>				

Table 4: LINC OBC Costs per Annum by Organisation (Revenue only)

Health Board	% Cost per HB	Apr 19 - Mar 20 £k	Apr 20 - Mar 21 £k	Apr 21 - Mar 22 £k	Apr 22 - Mar 23 £k	Apr 23 - Mar 24 £k	Apr 24 - Mar 25 £k	Apr 25 - Mar 26 £k	Apr 26 - Mar 27 £k	Total Cost £k
<b>Total Costs of the Pathology solution including dual running costs - capital &amp; revenue (based on a working assumption of apportionment by allocation)</b>										
ABM UHB	17.4%	136	855	1,478	1,332	955	830	831	832	7,249
Aneurin Bevan UHB	19.0%	149	933	1,614	1,455	1,043	906	907	908	7,916
Betsi Cadwaladr UHB	22.5%	177	1,105	1,911	1,723	1,235	1,073	1,074	1,076	9,374
Cardiff and Vale UHB	14.0%	110	688	1,189	1,072	769	668	668	669	5,833
Cwm Taf UHB	10.4%	82	511	883	796	571	496	497	497	4,333
Hywel Dda UHB	12.3%	97	604	1,045	942	675	587	587	588	5,125
Velindre NHST	0.0%	0	0	0	0	0	0	0	0	0
Powys Teaching HB	4.4%	35	216	374	337	242	210	210	210	1,833
<b>Total Path Solution Costs</b>	<b>100.0%</b>	<b>786</b>	<b>4,912</b>	<b>8,495</b>	<b>7,658</b>	<b>5,491</b>	<b>4,768</b>	<b>4,774</b>	<b>4,780</b>	<b>41,664</b>
<b>LINC Programme Costs per HB / Trust</b>										
ABM UHB	17.4%	265	232	236	222	83	0	0	0	1,037
Aneurin Bevan UHB	19.0%	289	253	258	243	90	0	0	0	1,133
Betsi Cadwaladr UHB	22.5%	342	300	305	287	107	0	0	0	1,341
Cardiff and Vale UHB	14.0%	213	186	190	179	67	0	0	0	835
Cwm Taf UHB	10.4%	158	138	141	133	49	0	0	0	620
Hywel Dda UHB	12.3%	187	164	167	157	58	0	0	0	733
Velindre NHST	0.0%	0	0	0	0	0	0	0	0	0
Powys Teaching HB	4.4%	67	59	60	56	21	0	0	0	262
<b>Total Programme Costs</b>	<b>100.0%</b>	<b>1,522</b>	<b>1,332</b>	<b>1,356</b>	<b>1,277</b>	<b>475</b>	<b>0</b>	<b>0</b>	<b>0</b>	<b>5,961</b>
<b>Combined Cost Current LIMS, Pathology Solution and Programme</b>										
ABM UHB		401	1,086	1,714	1,555	1,038	830	831	832	8,286
Aneurin Bevan UHB		438	1,186	1,872	1,698	1,134	906	907	908	9,049
Betsi Cadwaladr UHB		519	1,405	2,216	2,010	1,342	1,073	1,074	1,076	10,716
Cardiff and Vale UHB		323	874	1,379	1,251	835	668	668	669	6,667
Cwm Taf UHB		240	649	1,024	929	620	496	497	497	4,953
Hywel Dda UHB		284	768	1,212	1,099	734	587	587	588	5,858
Velindre NHST		0	0	0	0	0	0	0	0	0
Powys Teaching HB		102	275	433	393	263	210	210	210	2,095
<b>Grand Total (Revenue only)</b>		<b>2,307</b>	<b>6,244</b>	<b>9,851</b>	<b>8,934</b>	<b>5,966</b>	<b>4,768</b>	<b>4,774</b>	<b>4,780</b>	<b>47,624</b>



Table 5: LINC OBC Costs per Annum by Organisation (Capital &amp; Revenue)

Health Board	% Cost per HB	Apr 19 - Mar 20 £k	Apr 20 - Mar 21 £k	Apr 21 - Mar 22 £k	Apr 22 - Mar 23 £k	Apr 23 - Mar 24 £k	Apr 24 - Mar 25 £k	Apr 25 - Mar 26 £k	Apr 26 - Mar 27 £k	Total Cost £k
<b>Total Costs of the Pathology solution including dual running costs - capital &amp; revenue (based on a working assumption of apportionment by allocation)</b>										
ABM UHB	17.4%	136	855	1,409	1,193	816	690	692	693	6,483
Aneurin Bevan UHB	19.0%	149	933	1,538	1,303	891	754	755	756	7,080
Betsi Cadwaladr UHB	22.5%	177	1,105	1,821	1,543	1,055	893	894	896	8,384
Cardiff and Vale UHB	14.0%	110	688	1,133	960	657	556	556	557	5,217
Cwm Taf UHB	10.4%	82	511	842	713	488	413	413	414	3,875
Hywel Dda UHB	12.3%	97	604	996	843	577	488	489	490	4,583
Velindre NHST	0.0%	0	0	0	0	0	0	0	0	0
Powys Teaching HB	4.4%	35	216	356	302	206	175	175	175	1,640
<b>Total Path Solution Costs</b>	<b>100.0%</b>	<b>786</b>	<b>4,912</b>	<b>8,095</b>	<b>6,858</b>	<b>4,691</b>	<b>3,968</b>	<b>3,974</b>	<b>3,980</b>	<b>37,264</b>
<b>LINC Programme Costs per HB / Trust</b>										
ABM UHB	17.4%	265	232	236	222	83	0	0	0	1,037
Aneurin Bevan UHB	19.0%	289	253	258	243	90	0	0	0	1,133
Betsi Cadwaladr UHB	22.5%	342	300	305	287	107	0	0	0	1,341
Cardiff and Vale UHB	14.0%	213	186	190	179	67	0	0	0	835
Cwm Taf UHB	10.4%	158	138	141	133	49	0	0	0	620
Hywel Dda UHB	12.3%	187	164	167	157	58	0	0	0	733
Velindre NHST	0.0%	0	0	0	0	0	0	0	0	0
Powys Teaching HB	4.4%	67	59	60	56	21	0	0	0	262
<b>Total Programme Costs</b>	<b>100.0%</b>	<b>1,522</b>	<b>1,332</b>	<b>1,356</b>	<b>1,277</b>	<b>475</b>	<b>0</b>	<b>0</b>	<b>0</b>	<b>5,961</b>
<b>Combined Cost Current LIMS, Pathology Solution and Programme</b>										
ABM UHB		401	1,086	1,644	1,415	899	690	692	693	7,521
Aneurin Bevan UHB		438	1,186	1,796	1,546	982	754	755	756	8,213
Betsi Cadwaladr UHB		519	1,405	2,126	1,830	1,162	893	894	896	9,726
Cardiff and Vale UHB		323	874	1,323	1,139	723	556	556	557	6,051
Cwm Taf UHB		240	649	983	846	537	413	413	414	4,495
Hywel Dda UHB		284	768	1,162	1,001	635	488	489	490	5,317
Velindre NHST		0	0	0	0	0	0	0	0	0
Powys Teaching HB		102	275	416	358	227	175	175	175	1,902
<b>Total (Revenue)</b>		<b>2,307</b>	<b>6,244</b>	<b>9,451</b>	<b>8,134</b>	<b>5,166</b>	<b>3,968</b>	<b>3,974</b>	<b>3,980</b>	<b>43,224</b>
Capital										
Capital from Welsh Government			8,000							8,000
<b>Total (Capital)</b>		<b>0</b>	<b>8,000</b>	<b>0</b>	<b>0</b>	<b>0</b>	<b>0</b>	<b>0</b>	<b>0</b>	<b>8,000</b>
<b>Grand Total (Capital &amp; Revenue)</b>		<b>2,307</b>	<b>14,244</b>	<b>9,451</b>	<b>8,134</b>	<b>5,166</b>	<b>3,968</b>	<b>3,974</b>	<b>3,980</b>	<b>51,224</b>

## 1.6. Management Case

### ***Programme governance***

The LINC Programme sits within the portfolio of the NHS Wales Health Collaborative. The LINC Programme Board was established in December 2017 with membership from each HB and professional bodies, and is chaired by Adrian Thomas, Executive Director of Therapies and Health Sciences for Betsi Cadwaladr UHB, the LINC Senior Responsible Owner.

The LINC Programme reports to the NHSW CEG and seeks professional advice from the National Pathology Network, Standing Specialist Advisory Groups (SSAGs), Standardisation Groups and the Pathology service directly. NWIS, Pathology IT Managers and the Associate Directors of Informatics provide technical advice and informatics assurance.

Risk and issue management is in place. Benefits realisation and stakeholder management strategies are being developed.

### ***National Programme Team***

Judith Bates is the LINC Programme Director leading a national programme team comprising the *LINC programme management office*, *National Pathology team* of subject matter experts, *NWIS programme resources* and *specialists advisers* (e.g. legal, commercial and NHS) for the procurement.

### ***Programme Timescale and Costs***

The timescale for the programme from April 2019 - March 2024 will cover four tranches of work:

- Procurement until March 2020
- Development, testing, validation until Sept 2021
- Deployment until Sept 2023
- Benefits realisation and handover to operations by March 2024

The cost of the programme including non-pay and 10% contingency is £6 million, which has been approved by the NHSW CEG.

### ***Operational Governance***

A service management board will be responsible for the day-to-day management of the new LIMS service and report to a national contract management board. Both Boards will be facilitated by NWIS and chaired by the NHS. Given the use of a Master Services Agreement, there will be a relationship between the national CMB and local HB/PHW contract and service management boards for the new LIMS to ensure good communications and contract management.

***Post project evaluation arrangements***

Gateway Reviews are being planned for the end of each tranche of the programme starting with tranche 2 to assure the delivery strategy.

A post implementation review (PIR) and post evaluation review (PER) will be conducted between March and September 2023.

***Recommendation***

It is recommended that this LINC Outline Business Case be reviewed by NHS Wales Health Boards and Trusts.

**Signed:**



**Date: 13 December 2018**

**Adrian Thomas**

**Senior Responsible Owner Project**

**LINC Programme**



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lechyd GIG Cymru  
NHS Wales Health  
Collaborative

## Laboratory Information Network Cymru (LINC) Programme

### Outline Business Case Version 0.17



## Document Control

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### Circulation of Previous OBC Versions

Version	Circulation List	Date Issued
V0.1	Mike Flanagan, Brent Varley, NWIS	10-Apr-2018
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V0.3	Mike Flanagan, NWIS	30-May-2018
V0.4	LINC Programme Board, Mike Flanagan Rob Tovey, NHSWHC Brent Varley, NWIS Dan Phillips, Velindre NHST Hugh Morgan, NWIS	11-Jun-2018 12-Jun-2018 13-Jun-2018 13-Jun-2018 11-Jul-2018
V0.5	Hugh Morgan, Mike Flanagan, Brent Varley, NWIS Michelle Sell, Julie Francis, Noel Bevan	31-Jul-2018 1-Aug-2018
V0.6	Mike Flanagan, Hugh Morgan, Brent Varley NWIS Kevin Williams BCU	20-Aug-2018
V0.7	Judith Bates (reviewed by Kevin Williams)	23-Aug-2018
V0.8	LINC Programme Board + Circulation list IPAD Hugh Morgan, NWID Rob Orford, Peter Jones, Ian Gunney WG	12-Sep-2018
V0.9	LINC Programme Board + Circulation list	12-Sep-2018
V0.10	LINC Programme Board + circulation list Dan Phillips, Director of Informatics Planning Development, Velindre NHST <b>Welsh Government</b> Rob Orford, Chief Scientific Adviser (Health)	30-Oct-2018 31-Oct- 2018 31-Oct- 2018

	Peter Jones, Deputy Director Digital Health and Care, Ian Gunney, Deputy Head NHS Capital, Estates & Facilities <b>NWIS</b> Mike Flanagan, Director of Finance and Business Assurance Hugh Morgan, Head of Business Assurance Mark Cox, Head of Management Accounting Brent Varley, National Diagnostic IT Prog. Lead	31-Oct-2018
V0.11	National Pathology Network Mike Flanagan, Director of Finance and Business Assurance Hugh Morgan, Head of Business Assurance Mark Cox, Head of Management Accounting Brent Varley, National Diagnostic IT Prog. Lead	12-Nov-2018
V0.12	LINC PB NHS Wales Collaborative Executive Group National Pathology Network IPAD Subgroup Mike Flanagan, Director of Finance and Business Assurance Hugh Morgan, Head of Business Assurance	5-Nov-2018
V0.13	IPAD Subgroup Directors of Therapies and Health Sciences Adrian Thomas, LINC SRO Mike Flanagan, Director of Finance and Business Assurance Hugh Morgan, Head of Business Assurance Brent Varley, National Diagnostics IT Prog. Lead Rob Tovey, Assistant Director of Finance, NHSWHC	5-Nov-2018
V0.14	Adrian Thomas, LINC SRO Mike Flanagan, Director of Finance and Business Assurance Hugh Morgan, Head of Business Assurance Brent Varley, National Diagnostics IT Prog. Lead Rob Tovey, Assistant Director of Finance, NHSWHC	25-Nov-2018
V0.15	National Informatics Programme Board LINC Programme Board NWIS Business Assurance	3-Dec-2018
V0.16	National Informatics Management Board	6-Dec-2018

**Document History:**

Amended by	Version	Status	Date	Purpose of Change
Judith Bates	0.1	Draft	4-04-18	Create draft of first two cases
Judith Bates	0.2	Draft	29-05-18	Create first full draft and update economic case after meeting with NWIS DoF
Judith Bates	0.3	Draft	30-05-18	Revise longlist after feedback from NWIS DoF
Judith Bates	0.4	Draft	09-06-18	Revise document after feedback from NWIS DoF
Judith Bates	0.5	Draft	29-07-18	Revise to take account of feedback and economic case to required format
Judith Bates	0.6	Draft	14-08-18	Revise economic case to take account of feedback and workshop held on 17 August. Revise commercial case based on feedback from NWIS Commercial services.
Kevin Williams	0.7	Draft	22-08-18	Review commercial case, complete tables, update investment outcomes and update shortlist criteria.
Judith Bates	0.8	Draft	12-09-18	Redraft as advised by NWIS
Judith Bates	0.9	Draft	30-10-18	Revised following feedback from Welsh Government and IPAD
Judith Bates	0.10	Draft	31-10-18	Add executive summary
Judith Bates	0.11	Draft	2-11-18	Add additional lessons learned, feedback from Mike Redman, costs of BAU & upgrade plus revised NPC
Judith Bates	0.12	Draft	9-11-18	Revise financial analysis in Economic Case, add Financial Case. Plus feedback from Julie Francis on the Commercial Case and Brent Varley on the OBC
Judith Bates	0.13	Draft	15-11-18	Amend cost savings and NPC, reference to downtime & Citrix and add a lesson learned.
Judith Bates	0.14	Draft	25-11-18	Amend following feedback from CEG, NHS Business Assurance, DOTHs & Dan Phillips
Judith Bates	0.15	Draft	3-12-18	Amend following feedback from NHS Business Assurance, PHW, WBS & Frances Duffy
Judith Bates	0.16	Draft	6-16-18	Amend for IPAD Subgroup feedback
Judith Bates	0.17	Draft	12-16-18	Amend executive summary to take account of NIMB feedback and minor changes



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## 1. Executive Summary

### 1.1. Introduction and Overview

This OBC seeks approval to invest in an end-to-end technical solution for Pathology services at the heart of which is the procurement of a new laboratory information management system (LIMS) service for Wales. This investment is required as the contract with InterSystems for the current LIMS, TrakCare Lab (TCL), expires in June 2020.

The Laboratory Information Network Cymru (LINC) Programme, part of the NHS Wales Health Collaborative (NHSWHC) is leading the procurement and implementation of the new LIMS, and the wider change programme associated with this OBC. LINC is an enabling programme to support the delivery of a modern, sustainable Pathology service as part of a wider transformation plan set out in the Pathology Statement of Intent.

The strategic case makes the case for change addressing current challenges, such as staffing, future service and technical developments and the scope in terms of the disciplines covered, functional and technical requirements. A key driver is the need to further standardise services as far as possible to deliver a sustainable service. Electronic test requesting is critical to deliver key benefits including financial savings.

A long list has been assessed, from which a short list of three options has been derived:

- Option 1: Business as usual - to upgrade to TCL 2016
- Option 2: Do Minimum - to take TCL Enterprise
- Option 3: Preferred - to procure a new LIMS service

In addition to the new LIMS service, the scope of the OBC includes a national quality team and quality management system and improved management of the LIMS by NWIS as a national application.

The OBC costs are evaluated over eight years from 2019/20 to 2026/27, the first year covering the procurement via competitive dialogue and design work. A master services agreement contract form is proposed for seven years, extendable on an annual basis for a further seven years.

On a revenue only basis, the overall cost is £42 million and £4.8 million per annum. With a minimum of £8 million capital, the revenue cost is £37 million and £4 million per annum. The combined cost of the three current LIMS (WLIMS1, Telepath and Masterlab) is £4.2 million so, excluding benefits, the new Pathology solution will be £0.6 million per annum more or £0.2 million per annum less depending on the funding model.

It is estimated that a potential £4 million per annum can be realised in benefits that would cover the cost of the new LIMS, with capital monies

## 1.2. Strategic Case

### *The strategic context*

Pathology is the study of disease and is involved in 70% of all diagnosis made in the NHS, underpins all clinical services, is a key component in the delivery of prudent health services to the population of Wales and an enabler to other Welsh Government health delivery plans including cancer and stroke services.

Pathology comprises a wide variety of disciplines and the main disciplines comprise *National Services* (PHW Microbiology and Screening Services, Welsh Blood Service, All Wales Medical Genetics Service and Welsh Point-of-care Testing) and *Local Laboratory Services*, comprising Andrology, Blood Sciences (including Blood transfusion), Cellular Pathology and Microbiology (not provided by PHW).

Pathology services undertook around 30 million authorised test sets during 2017/8. The service is under increasing pressure from growth in demand and the development of new technologies. Pathology services cost around £118 million, at least 1.9% of the total health care budget. In March 2017, it was estimated that there were 2,026 FTE staff in healthcare science and 200 FTE medical staff, of which 133 were consultants. One of the key issues faced by the service is recruitment and retention of skilled staff.

There is no single Pathology service across Wales and, although some services are provided nationally, most sit under the responsibility of the six University Health Boards (UHBs) and Public Health Wales (PHW).

The Pathology service is undergoing change in relation to boundary changes, implementation of the Carter recommendations to create hub and spoke services, reconfiguration of services in the West as part of the Arch initiative, the new Grange University Hospital due to open in Cwmbran in 2021 and piloting Digital Cellular Pathology in Glan Clwyd Hospital.

### *Business strategies*

The development of an end-to-end technology solution for pathology services will contribute to the delivery of [\*A healthier Wales; our plan for health and social care\*](#) and the new LIMS will be a national application as part of [\*Informed health and care: a digital health strategy for Wales\*](#). The solution will be a key deliverable towards the *Pathology Statement of Intent*, a national plan to modernise Pathology services across Wales, currently being finalised for sign off by Welsh Government.

### *The case for change*

The current LIMS (known as WLIMS1) is InterSystems TCL 2011, which was procured in 2010 as a single, national system intended to replace 13

standalone systems. Significant progress has been made but further work remains to complete implementation. The contract includes an upgrade TCL 2016 but in 2017, the NHS and InterSystems jointly decided against this upgrade. However, TCL 2011 is not supportable after January 2020 because the Microsoft operating system is end of life. Consequently, the upgrade will have to go ahead as the delay in the re-procurement means that it is not possible to deploy a new solution by June 2020. Many lessons have been learned from WLIMS and being taken into account within LINC.

Standardisation is critical to underpin the transformation of the Pathology service to be more sustainable in terms of delivering a high quality service, creating capacity to cope with increasing demand at the same time as reducing costs. The service has agreed the definition of standardisation and warranted variation (e.g. because of using different equipment) as a basis for taking forward standardisation as far as possible.

Electronic test requesting (ETR) is also critical to deliver benefits and underpin service transformation. The current ETR service is provided by the Welsh Clinical Portal (WCP), but does not currently meet the needs of the Pathology service as a whole. A Pathology ETR requirement has been defined and the current and planned WCP capability is being assessed to determine the gap. If the WCP cannot be developed to meet Pathology requirements, then the procurement of a separate system with the LIMS has been included as an option. Substantial financial savings can be realised if paper requests no longer have to be manually booked in and scanned.

LINC has multiple and complex stakeholders with different levels of interest in the LINC programme. Key stakeholders have been engaged in the development of this OBC through events, meetings and email. More than thirty workshops have been held or are planned during 2018 to contribute to this business case and / or develop the requirements for the new service.

The spending objectives for the LINC Programme have evolved throughout 2018. They provide the basis for this OBC:

- SO1** To improve patient care, patient safety and patient outcomes;
- SO2** To enable the transformation of healthcare services to be leaner, standardised, more sustainable and provide long-term stability;
- SO3** To deliver a seamless, end-to-end electronic solution for Pathology services;
- SO4** To contribute to the more prudent use of Pathology resources through demand management, predictive costing and minimised financial risk;
- SO5** To meet current and future service requirements.

### 1.3. Economic Case

In accordance with national guidance, this section of the OBC documents the wide range of options that have been considered to deliver the spending objectives and recommend a preferred option for investment. The OBC covers eight years from 2019/20 – 2026/7, the first year for procurement.

#### *The long list*

A wide range of options have been generated that identifies and analyses choices for scope (SCO), service solution (SSO), technical solution (TSO), configuration (CON), service delivery (SDO) and implementation (IMP). Discussions at the LINC Programme Board and various workshops has generated and reviewed the long list options.

#### *Scope Options*

The scope includes systems and services that collectively deliver an end-to-end technical solution to support the modernisation of Pathology services, including:

- A solution that support all Pathology disciplines and sub-disciplines
- Core and discipline specific functionality
- Business intelligence
- Pathology, quality, informatics and validation standards
- Business change including training and development
- Documentation
- Additional systems including vein-to-vein blood tracking with remote issue, scanning, dictation and voice recognition, business intelligence, a national quality management system, NPEx to manage referrals in and out of Wales and an optional ETR system
- Legacy data migration and repository
- Technical requirements, including integration services
- Capacity to support future service and technical developments

The scope excludes:

- New systems for Medical Genetics, Point-of-care-testing, Bowel screening, Downs screening and WTAIL;
- All local hardware including peripherals, networks, fridges, blood transfusion kiosks and other local equipment;
- Local costs of deployment such as backfill for training;
- Wide area networking as the service will use the All Wales Public Sector Broadband Aggregation (PSBA);

The scope is considered in relation to four options: Business as usual, Do minimum, Intermediate and Maximum.

Table 1 provides a summary of the long listing evaluation for all options.

Table 1: LINC Long List of Options: Summary of Inclusions and Exclusions

Category	Title	Conclusion
<b>Scoping Options</b>		
SCO1	Business as usual	Discounted
SCO2	Do Minimum	Discounted
SCO3	Intermediate	Preferred
SCO4	Maximum	Possible
<b>Service Solution Options</b>		
SSO1	Local LIMS for each health board	Discounted
SSO2	Best of breed LIMS per main discipline	Discounted
SSO3	Separate Cellular Pathology LIMS	Possible
SSO4	Single, national LIMS	Preferred
<b>Technical Solution Options</b>		
TSO1	Supplier cloud hosted solution	Preferred
TSO2	National data centre – supplier hosted	Possible
TSO3	National data centre – NWIS hosted	Discounted
TSO4	Local data centres – Health Boards	Discounted
<b>Configuration Options</b>		
CON1	In-house configuration (NWIS)	Possible
CON2	Supplier configuration	Preferred
<b>Service Delivery Options</b>		
SMO1	In-house system delivery	Discounted
SMO2	NHS service management	Discounted
SMO3	Supplier partial service management	Preferred
SMO4	Supplier total service management	Possible
<b>Implementation Options</b>		
IMP1	All disciplines phased by site	Discounted
IMP2	All disciplines phased by HB	Preferred
IMP3	Phased by discipline by HB	Possible
IMP4	Phased nationally by discipline	Discounted
IMP5	Big bang	Discounted

## The Shortlist

Following the longlisting exercise, three shortlisted options have been generated:

- **Option 1: Business as usual** option, for benchmarking purposes. This option is to upgrade to TCL 2016. It is rejected as TCL 2016 is end of life by 2025 and Wales will be in the same position as now;
- **Option 2: Do minimum option**, to put in place a new contract with InterSystems without going out to procurement to take their latest product, TCL Enterprise (TCLE). This option is likely to incur legal challenge if no procurement is undertaken;
- **Option 3: Preferred approach** to go out to procurement for a new LIMS service.

## Net Present Costs (NPC)

Overall costs over the life of the contract covered by the OBC (seven years from 2020/21 to 2026/7) has been combined with the financial value of the benefits and the costs of the risks to calculate the NPC for each option.

Only financial benefits have been considered with more work to be completed for the full business case, which will also add the value of economic benefits. Financial benefits are estimated at £4m per annum (3% of the costs of the Pathology service), which are considered in relation to:

- Electronic test requesting (1%);
- Improved business intelligence and demand management (1%);
- Improved patient pathways and outcomes (1%).

The NPC presented in Table 2 shows that, although Option 3 is marginally the most expensive, it has the least net present cost.

Table 2: Net Present Cost

Financial Details	Option 1: BAU	Option 2: Do Minimum	Option 3: Preferred Approach
	£k	£k	£k
Financial cost total	26,875	42,916	44,478
Optimism Bias @ 20%	0	8,583	8,896
<b>Total including optimism bias</b>	<b>26,875</b>	<b>51,499</b>	<b>53,374</b>
Quantification of benefits	-6,222	-12,444	-18,667
Risk Quantification	22,719	14,400	2,424
Total – Pre-Discounting	43,371	53,455	37,131
<b>Net Present Cost</b>	<b>40,105</b>	<b>51,447</b>	<b>35,713</b>

In conclusion, option 3, to procure a new LIMS service is recommended as the way forward. The rest of the OBC takes forward this recommendation.



#### **1.4. Commercial Case**

The contract will provide a managed service for a single, national LIMS service with one supplier responsible for the national application and associated tools in partnership with NWIS for integration services to national applications and local, clinical downstream systems.

As NHS Wales organisations are public sector bodies; all NHS Wales procurements must comply with Standing Orders and the Public Contracts Regulations 2015 (PCR2015).

Velindre NHS Trust is the host of the NHS Wales Informatics Service and will be the Contracting Authority for the purposes of this procurement.

#### ***Procurement strategy***

The principle aim of the procurement is to procure a LIMS service to replace the existing legacy solution/s. In line with the infrastructure strategy of NHS Wales, the solution will be hosted either in an NHS Wales data centre or an accredited data centre and delivered across NHS Wales' network infrastructure (currently provided by the Welsh Government's PSBA network).

The procurement approach envisages a single supplier provided solution with the chosen supplier taking prime contractor responsibility for the range of infrastructure, systems and services that comprise the LIMS service.

The length of contract will be tailored to give best value for money but the option will be explored during the procurement for a 14 years contract offering a minimum of seven years with the option to extend on an annual basis for another seven years.

The contract form of Agreement will be a Master Services Agreement, based on an amended form of the IT Services Contract having regard to the Crown Commercial Services and other best practice guidance of IM&T procurement. Each health board will "call off" their requirements from the Master Services Agreement and via this process will execute their own distinct local contracts "Deployment Orders" with the contractor.

The NWIS Head of Commercial Services will lead the procurement supported by a Procurement Team comprising suitably qualified and competent resources, including legal and commercial advisers.

Subject to the Welsh Government signing off this OBC, it is intended to publish the OJEU notice in March 2019. It is anticipated that the implementation under the proposed contract will start in 2020, taking into account the migration/exit off the legacy solutions and in accordance with the LINC programme plan.

## **1.5. Financial Case**

The primary purpose of the financial case is to set out the financial implications of the preferred option to ensure that the solution is affordable.

### ***Apportionment of Costs***

The NHSW Collaborative Executive Group has requested that a different approach to WLIMS1 apportionment of costs be agreed and a paper has been submitted to the Deputy DoFs for consideration. For the purposes of the OBC, a working assumption has been made that the apportionment will be based on the annual allocation to health boards and NHS trusts, in accordance with the WHC (2017) 053 Health Board 2018-9 Allocations.

### ***Financial expenditure***

Tables 3-5 present the costs per organisation based on the revenue apportionment by allocation for revenue only and for capital and revenue. Given the latest guidance in IFRS16, a capital/revenue model is most likely. The overall cost over the life of the OBC is £42 million revenue only or £37 million revenue + £8 million capital from the Welsh Government. In addition, there is the £6 million cost of the LINC Programme. The NHSW CEG has approved the revenue costs, which comprise:

- Current LIMS (dual running) - £11m
- New LIMS service - £22m (rev only) or 18m rev+ £8m capital
- National quality management system and quality team - £3m
- NWIS technical services and support costs - £5m

The annual cost of the new Pathology solution overall is estimated as £4.8m (revenue only) or £4m (with capital funding), compared to the costs of the three current LIMS (TCL, Masterlab and Telepath), which is £4.2m.

Potential savings of 3% of Pathology costs have been estimated, which equates to £4 million per annum, that could cover all or most of the cost of the new Pathology solution.

There is a potential impact on the balance sheet if a capital / revenue approach is taken and capital assets have been purchased.

### ***Overall affordability and balance sheet treatment***

The most expensive years are 2020/21 and 2022/23, where between £5m - £8m additional revenue funds are required per annum (unless some implementation costs can be converted to capital monies).

As part of the sign off for this OBC, each health board and trust will be required to provide a letter supporting the programme and costs signed by their Chief Executive and Director of Finance.

Table 3: LINC OBC whole life costs plus per annum costs per organisation

Health Board / Trust	Revenue Only £k						
	Whole Life Costs (2019/20 - 2026/7)			Per Annum Costs of Pathology Solution £k			
	Pathology Solution	LINC Programme	Total Cost	New Annual Cost	Costs of Current LIMS'	Potential Savings	Additional Costs / Savings
ABM UHB	7,249	1,037	8,286	830	859	716	-745
Aneurin Bevan UHB	7,916	1,133	9,049	906	688	784	-566
Betsi Cadwaladr UHB	9,374	1,341	10,716	1,073	765	928	-620
Cardiff and Vale UHB	5,833	835	6,667	668	803	579	-714
Cwm Taf UHB	4,333	620	4,953	496	386	429	-319
Hywel Dda UHB	5,125	733	5,858	587	483	506	-402
Velindre NHST	0	0	0	0	220	0	-220
Powys Teaching HB	1,833	262	2,095	210		59	151
<b>Grand Total (Revenue only)</b>	<b>41,663</b>	<b>5,961</b>	<b>47,624</b>	<b>4,768</b>	<b>4,205</b>	<b>4,000</b>	<b>-3,436</b>

Health Board / Trust	Capital and Revenue £k						
	Whole Life Costs (2019/20 - 2026/7)			Per Annum Costs of Pathology Solution			
	Pathology Solution	LINC Programme	Total Cost	New Annual Cost	Costs of Current LIMS'	Potential Savings	Additional Costs / Savings
ABM UHB	6,483	1,037	7,521	690	859	716	-884
Aneurin Bevan UHB	7,080	1,133	8,213	754	688	784	-718
Betsi Cadwaladr UHB	8,384	1,341	9,726	893	765	928	-800
Cardiff and Vale UHB	5,217	835	6,051	556	803	579	-826
Cwm Taf UHB	3,875	620	4,495	413	386	429	-403
Hywel Dda UHB	4,583	733	5,317	488	483	506	-501
Velindre NHST	0	0	0	0	220	0	-220
Powys Teaching HB	1,640	262	1,902	175		59	116
<b>Grand Total (Revenue)</b>	<b>37,263</b>	<b>5,961</b>	<b>43,224</b>	<b>3,968</b>	<b>4,205</b>	<b>4,000</b>	<b>-4,236</b>
<b>Welsh Government</b>							
<b>Grand Total (Capital)</b>	<b>8,000</b>		<b>8,000.00</b>				

Table 4: LINC OBC Costs per Annum by Organisation (Revenue only)

Health Board	% Cost per HB	Apr 19 - Mar 20 £k	Apr 20 - Mar 21 £k	Apr 21 - Mar 22 £k	Apr 22 - Mar 23 £k	Apr 23 - Mar 24 £k	Apr 24 - Mar 25 £k	Apr 25 - Mar 26 £k	Apr 26 - Mar 27 £k	Total Cost £k
<b>Total Costs of the Pathology solution including dual running costs - capital &amp; revenue (based on a working assumption of apportionment by allocation)</b>										
ABM UHB	17.4%	136	855	1,478	1,332	955	830	831	832	7,249
Aneurin Bevan UHB	19.0%	149	933	1,614	1,455	1,043	906	907	908	7,916
Betsi Cadwaladr UHB	22.5%	177	1,105	1,911	1,723	1,235	1,073	1,074	1,076	9,374
Cardiff and Vale UHB	14.0%	110	688	1,189	1,072	769	668	668	669	5,833
Cwm Taf UHB	10.4%	82	511	883	796	571	496	497	497	4,333
Hywel Dda UHB	12.3%	97	604	1,045	942	675	587	587	588	5,125
Velindre NHST	0.0%	0	0	0	0	0	0	0	0	0
Powys Teaching HB	4.4%	35	216	374	337	242	210	210	210	1,833
<b>Total Path Solution Costs</b>	<b>100.0%</b>	<b>786</b>	<b>4,912</b>	<b>8,495</b>	<b>7,658</b>	<b>5,491</b>	<b>4,768</b>	<b>4,774</b>	<b>4,780</b>	<b>41,664</b>
<b>LINC Programme Costs per HB / Trust</b>										
ABM UHB	17.4%	265	232	236	222	83	0	0	0	1,037
Aneurin Bevan UHB	19.0%	289	253	258	243	90	0	0	0	1,133
Betsi Cadwaladr UHB	22.5%	342	300	305	287	107	0	0	0	1,341
Cardiff and Vale UHB	14.0%	213	186	190	179	67	0	0	0	835
Cwm Taf UHB	10.4%	158	138	141	133	49	0	0	0	620
Hywel Dda UHB	12.3%	187	164	167	157	58	0	0	0	733
Velindre NHST	0.0%	0	0	0	0	0	0	0	0	0
Powys Teaching HB	4.4%	67	59	60	56	21	0	0	0	262
<b>Total Programme Costs</b>	<b>100.0%</b>	<b>1,522</b>	<b>1,332</b>	<b>1,356</b>	<b>1,277</b>	<b>475</b>	<b>0</b>	<b>0</b>	<b>0</b>	<b>5,961</b>
<b>Combined Cost Current LIMS, Pathology Solution and Programme</b>										
ABM UHB		401	1,086	1,714	1,555	1,038	830	831	832	8,286
Aneurin Bevan UHB		438	1,186	1,872	1,698	1,134	906	907	908	9,049
Betsi Cadwaladr UHB		519	1,405	2,216	2,010	1,342	1,073	1,074	1,076	10,716
Cardiff and Vale UHB		323	874	1,379	1,251	835	668	668	669	6,667
Cwm Taf UHB		240	649	1,024	929	620	496	497	497	4,953
Hywel Dda UHB		284	768	1,212	1,099	734	587	587	588	5,858
Velindre NHST		0	0	0	0	0	0	0	0	0
Powys Teaching HB		102	275	433	393	263	210	210	210	2,095
<b>Grand Total (Revenue only)</b>		<b>2,307</b>	<b>6,244</b>	<b>9,851</b>	<b>8,934</b>	<b>5,966</b>	<b>4,768</b>	<b>4,774</b>	<b>4,780</b>	<b>47,624</b>

Table 5: LINC OBC Costs per Annum by Organisation (Capital &amp; Revenue)

Health Board	% Cost per HB	Apr 19 - Mar 20 £k	Apr 20 - Mar 21 £k	Apr 21 - Mar 22 £k	Apr 22 - Mar 23 £k	Apr 23 - Mar 24 £k	Apr 24 - Mar 25 £k	Apr 25 - Mar 26 £k	Apr 26 - Mar 27 £k	Total Cost £k
<b>Total Costs of the Pathology solution including dual running costs - capital &amp; revenue (based on a working assumption of apportionment by allocation)</b>										
ABM UHB	17.4%	136	855	1,409	1,193	816	690	692	693	6,483
Aneurin Bevan UHB	19.0%	149	933	1,538	1,303	891	754	755	756	7,080
Betsi Cadwaladr UHB	22.5%	177	1,105	1,821	1,543	1,055	893	894	896	8,384
Cardiff and Vale UHB	14.0%	110	688	1,133	960	657	556	556	557	5,217
Cwm Taf UHB	10.4%	82	511	842	713	488	413	413	414	3,875
Hywel Dda UHB	12.3%	97	604	996	843	577	488	489	490	4,583
Velindre NHST	0.0%	0	0	0	0	0	0	0	0	0
Powys Teaching HB	4.4%	35	216	356	302	206	175	175	175	1,640
<b>Total Path Solution Costs</b>	<b>100.0%</b>	<b>786</b>	<b>4,912</b>	<b>8,095</b>	<b>6,858</b>	<b>4,691</b>	<b>3,968</b>	<b>3,974</b>	<b>3,980</b>	<b>37,264</b>
<b>LINC Programme Costs per HB / Trust</b>										
ABM UHB	17.4%	265	232	236	222	83	0	0	0	1,037
Aneurin Bevan UHB	19.0%	289	253	258	243	90	0	0	0	1,133
Betsi Cadwaladr UHB	22.5%	342	300	305	287	107	0	0	0	1,341
Cardiff and Vale UHB	14.0%	213	186	190	179	67	0	0	0	835
Cwm Taf UHB	10.4%	158	138	141	133	49	0	0	0	620
Hywel Dda UHB	12.3%	187	164	167	157	58	0	0	0	733
Velindre NHST	0.0%	0	0	0	0	0	0	0	0	0
Powys Teaching HB	4.4%	67	59	60	56	21	0	0	0	262
<b>Total Programme Costs</b>	<b>100.0%</b>	<b>1,522</b>	<b>1,332</b>	<b>1,356</b>	<b>1,277</b>	<b>475</b>	<b>0</b>	<b>0</b>	<b>0</b>	<b>5,961</b>
<b>Combined Cost Current LIMS, Pathology Solution and Programme</b>										
ABM UHB		401	1,086	1,644	1,415	899	690	692	693	7,521
Aneurin Bevan UHB		438	1,186	1,796	1,546	982	754	755	756	8,213
Betsi Cadwaladr UHB		519	1,405	2,126	1,830	1,162	893	894	896	9,726
Cardiff and Vale UHB		323	874	1,323	1,139	723	556	556	557	6,051
Cwm Taf UHB		240	649	983	846	537	413	413	414	4,495
Hywel Dda UHB		284	768	1,162	1,001	635	488	489	490	5,317
Velindre NHST		0	0	0	0	0	0	0	0	0
Powys Teaching HB		102	275	416	358	227	175	175	175	1,902
<b>Total (Revenue)</b>		<b>2,307</b>	<b>6,244</b>	<b>9,451</b>	<b>8,134</b>	<b>5,166</b>	<b>3,968</b>	<b>3,974</b>	<b>3,980</b>	<b>43,224</b>
Capital										
Capital from Welsh Government			8,000							8,000
<b>Total (Capital)</b>		<b>0</b>	<b>8,000</b>	<b>0</b>	<b>0</b>	<b>0</b>	<b>0</b>	<b>0</b>	<b>0</b>	<b>8,000</b>
<b>Grand Total (Capital &amp; Revenue)</b>		<b>2,307</b>	<b>14,244</b>	<b>9,451</b>	<b>8,134</b>	<b>5,166</b>	<b>3,968</b>	<b>3,974</b>	<b>3,980</b>	<b>51,224</b>

## 1.6. Management Case

### ***Programme governance***

The LINC Programme sits within the portfolio of the NHS Wales Health Collaborative. The LINC Programme Board was established in December 2017 with membership from each HB and professional bodies, and is chaired by Adrian Thomas, Executive Director of Therapies and Health Sciences for Betsi Cadwaladr UHB, the LINC Senior Responsible Owner.

The LINC Programme reports to the NHSW CEG and seeks professional advice from the National Pathology Network, Standing Specialist Advisory Groups (SSAGs), Standardisation Groups and the Pathology service directly. NWIS, Pathology IT Managers and the Associate Directors of Informatics provide technical advice and informatics assurance.

Risk and issue management is in place. Benefits realisation and stakeholder management strategies are being developed.

### ***National Programme Team***

Judith Bates is the LINC Programme Director leading a national programme team comprising the *LINC programme management office*, *National Pathology team* of subject matter experts, *NWIS programme resources* and *specialists advisers* (e.g. legal, commercial and NHS) for the procurement.

### ***Programme Timescale and Costs***

The timescale for the programme from April 2019 - March 2024 will cover four tranches of work:

- Procurement until March 2020
- Development, testing, validation until Sept 2021
- Deployment until Sept 2023
- Benefits realisation and handover to operations by March 2024

The cost of the programme including non-pay and 10% contingency is £6 million, which has been approved by the NHSW CEG.

### ***Operational Governance***

A service management board will be responsible for the day-to-day management of the new LIMS service and report to a national contract management board. Both Boards will be facilitated by NWIS and chaired by the NHS. Given the use of a Master Services Agreement, there will be a relationship between the national CMB and local HB/PHW contract and service management boards for the new LIMS to ensure good communications and contract management.

***Post project evaluation arrangements***

Gateway Reviews are being planned for the end of each tranche of the programme starting with tranche 2 to assure the delivery strategy.

A post implementation review (PIR) and post evaluation review (PER) will be conducted between March and September 2023.

***Recommendation***

It is recommended that this LINC Outline Business Case be reviewed by NHS Wales Health Boards and Trusts.

**Signed:**



**Date: 13 December 2018**

**Adrian Thomas**

**Senior Responsible Owner Project**

**LINC Programme**

## 2. Introduction

This OBC seeks approval to invest more in an end-to-end technical solution for Pathology services at the heart of which is the procurement of a new laboratory information management system (LIMS) service for Wales. This investment is required as the contract with InterSystems for the current LIMS system, TrakCare Lab (TCL), expires in June 2020. The investment will fund an enabling programme supporting a wider transformation plan to deliver a modern, sustainable Pathology service.

### 2.1. Structure and content of the document

This OBC has been prepared using the agreed standards and format for business cases, as set out in the Welsh Government [Better Business Cases](#) website. The approved format is the Five Case Model, which comprises the following key components:

- The **strategic case** section. This sets out the strategic context and provides a compelling case for change in terms of the existing and future business needs of the Pathology service;
- The **economic case** section. This demonstrates that the organisation has selected the choice for investment which best meets the existing and future needs of the service and optimises value for money (VFM);
- The **commercial case** section. This outlines the content and structure of the proposed deal;
- The **financial case** section. This confirms funding arrangements and affordability and explains any impact on the balance sheet of the organisation;
- The **management case** section. This demonstrates that the scheme is achievable and can be delivered successfully to cost, time and quality.

### 2.2. Point of Contact

For more information about this LINC OBC, please contact:

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### 3. The Strategic Case

#### 3.1. The Strategic Context

##### *Pathology Overview*

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. Pathologists and healthcare scientists work with a range of healthcare professionals in different settings to diagnose, treat and prevent illness.

Pathology is involved in 70% of diagnoses and underpins all clinical services and 95% of clinical pathways within secondary care. A key component in the delivery of prudent health services, Pathology is an enabler to other Welsh Government health strategies including cancer and stroke services.

Pathology comprises a wide variety of disciplines and those in scope are:

- **National Services**, comprising:
  - **Screening services**, including Antenatal Serum and Newborn Blood Spot provided by Blood Sciences at CAV UHB; and Cervical Cytology provided by Public Health Wales (PHW);
  - **Microbiology Services**, including Bacteriology, Food, Water & Environmental Microbiology, Infection Genomics, Mycology, Parasitology and Virology provided by PHW;
  - **Welsh Blood Service**, collects, processes and tests blood and provides blood products to hospitals in Wales;
  - **All Wales Medical Genetics Service**;
  - **Point of Care Testing (POCT)**.
- **Local Laboratory Services**, comprising:
  - **Andrology**;
  - **Blood Sciences**, including Blood Transfusion, Clinical Biochemistry, Haematology, Immunology and Toxicology;
  - **Cellular Pathology** including Diagnostic Cytology, Histopathology and Mortuary services;
  - **Microbiology Services** provided by local health boards.

Pathology services undertook around 30 million authorised test sets during 2017/8, as detailed in [Appendix 1](#). Pathology services cost around 1.9% of the total health care budget, a total of £118 million based on 2018/9 allocations. However, consensus suggests the total spend is higher.

In March 2017, there were an estimated 2,026 FTE staff in Healthcare Science and 200 FTE medical staff, of which 133 were consultants. One of

the key issues faced by the Pathology service is the recruitment and retention of skilled staff (around 26% of Consultant Histopathology posts are vacant) and the lack of accurate workforce information.

The service is under increasing pressure as more effective clinical pathways are changing the balance of care. Increasing numbers of older people with chronic health conditions, increasing cancer incidence, improved technology, new techniques and workforce pressures have all increased demand for Pathology services by around 5% per annum for Blood Sciences and 2% per annum for Microbiology where requests are becoming more complex linked to antibiotic resistant and an aging population. Complexity of Cellular Pathology tests has also dramatically increased and demand has grown arising from the development of other areas, such as genetic and genomic testing and take up of Point of Care Testing.

### **Organisational Overview**

There is no single Pathology service across Wales and, although much is delivered through the six University Health Boards (UHB), Microbiology is substantially delivered through a national network by Public Health Wales.

Pathology laboratories are located in 20 locations across Wales, as shown in Figure 1.

- **Abertawe Bro Morgannwg UHB:** Morriston Hospital, Neath Port Talbot Hospital, Princess of Wales Hospital and Singleton Hospital;
- **Aneurin Bevan UHB:** Royal Gwent Hospital, Nevill Hall Hospital and Ysbyty Ystrad Fawr;
- **Betsi Cadwaladr UHB:** Ysbyty Glan Clwyd, Wrexham Maelor Hospital and Ysbyty Gwynedd;
- **Cardiff and Vale UHB:** University Hospital of Wales and Llandough Hospital;
- **Cwm Taf UHB:** Prince Charles Hospital and Royal Glamorgan Hospital;
- **Hywel Dda UHB:** Bronglais General Hospital, Glangwili General Hospital, Withybush Hospital and Prince Philip Hospital;
- **Velindre NHS Trust, Public Health Wales Microbiology Services:** Bronglais Hospital, Glan Clwyd Hospital, Glangwili General Hospital, Llandough Hospital, Morriston Hospital, University Hospital of Wales and Ysbyty Gwynedd Hospital
- **Velindre NHS Trust, Public Health Wales Screening Services:** Cervical Screening Wales, Llantrisant
- **Velindre NHS Trust** Welsh Blood Service.

There has been some progress to consolidate Pathology services into three regions, in line with the Carter Report (2008), especially in the North. Progress is being made to develop Histopathology services into the three regions. A pilot in Digital Cellular Pathology in the North has created the

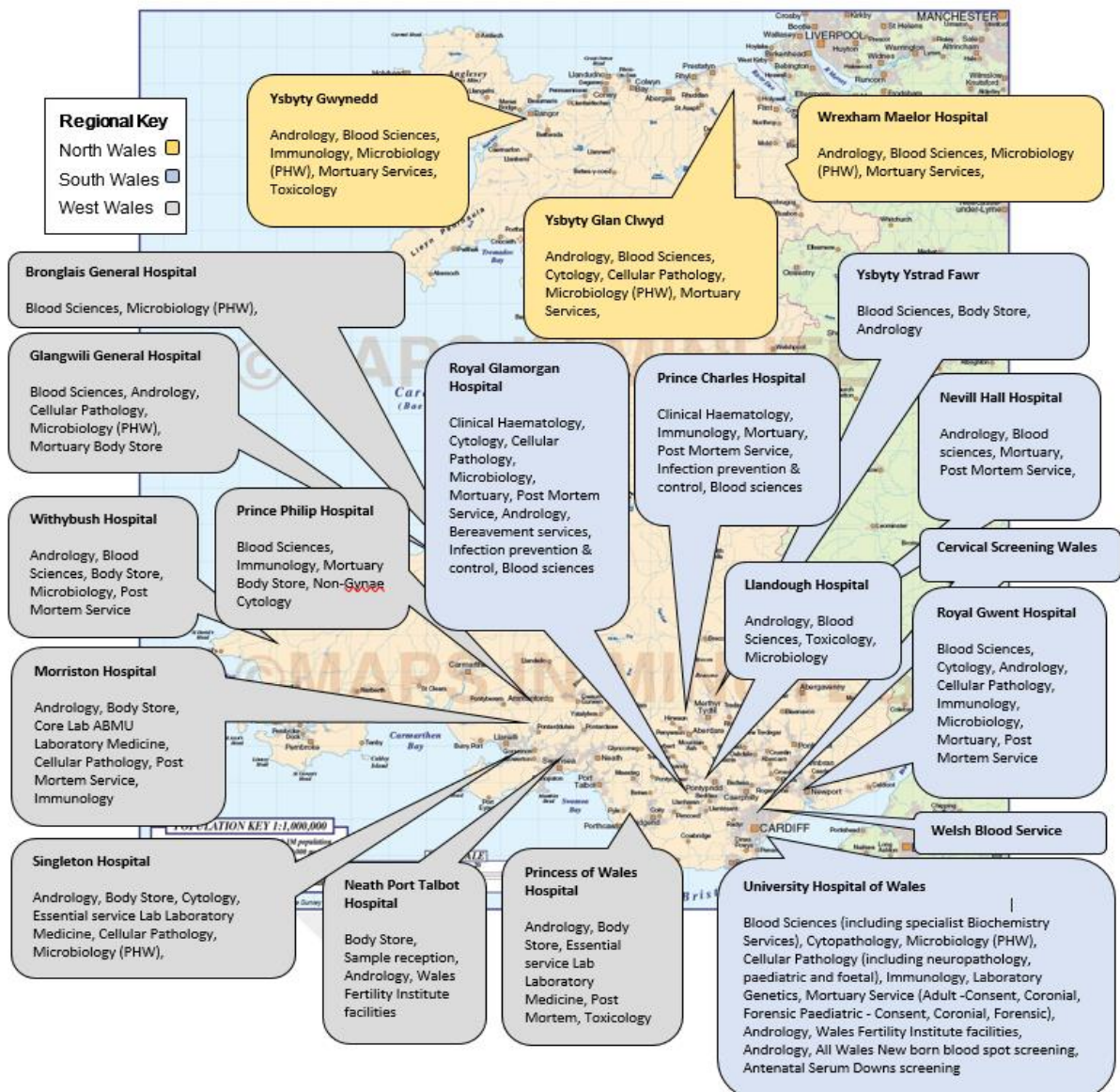


Figure 1: Map of Pathology Services across Wales

capacity for reporting on digital images for a wider area. Abertawe Bro Morgannwg (ABM) University Hospital Board (UHB) has created a Pathology hub at Morrison Hospital for the majority of blood sciences tests with satellite services for urgent tests at the other hospitals. Restructuring is taking place with the management of the Princess of Wales Hospital being transferred to CWM Taf UHB. Aneurin Bevan UHB is building a new hospital, the Grange University Hospital that will have Pathology services on site transferred from Nevill Hall Hospital and the Royal Gwent Hospital. A Regional Collaboration for Health (Arch) Project, is a partnership between ABM and Hywel Dda University Health Boards and Swansea University to deliver service transformation across South West Wales, including the centralisation of Pathology services at Morrison Hospital. The Public Health Wales Microbiology network has consolidated many investigations to a regional or national model of delivery, and is undergoing a further transformational change.

## **Business Strategies**

A number of national strategies inform this investment:

- *A healthier Wales: Our plan for health and social care* (2018)
- *Informed health and care: a digital health strategy for Wales* (2015)
- *The Pathology Statement of Intent* (2018)

### **A Healthier Wales: Our plan for health and social care**

The vision is that everyone in Wales should have longer healthier and happier lives, able to remain active and independent, in their own homes, for as long as possible. A transformation programme is being developed to maximise value for patients by achieving best outcome for lowest cost based on the principles of the *quadruple aim* and *prudent* health care.

Making better use of digital, data, and communication technologies will help us to raise the quality and value of health and social care services, so that they are cost-effective, sustainable and meet increasing expectations of technology in people's day-to-day lives.

The development of modern, sustainable Pathology services has a key role to play in delivering this plan. Key linkages are:

- to support the Quadruple Aims through improved processes and reporting services; seamless integration with other systems and services, and enabling initiatives like *Laboratory Anywhere*, *Choose Wisely* and *Design for Demand*;
- The new LIMS to be seamlessly integrated with systems to ensure the flow of the right information to the right place at the right time and for patients to see their results presented in a meaningful way;
- Staff will be trained in the new LIMS, which should support the smooth running of the service and improve staff morale;
- The new LIMS will incorporate new technologies like mobile working, smartphone apps, artificial intelligence and machine learning.

### **Informed health and care: a digital health strategy for Wales**

The development of digital services underpins the development of health and care, including Pathology services. The digital health and social care strategy for Wales<sup>1</sup> recognises that improving access to information and introducing new ways of delivering care with digital technologies must be at the heart of service plans and vision for prudent / value based healthcare. The new LIMS will be a national application integrated into the wider national technical platform as set out in [Appendix 2](#), and comprising:

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<sup>1</sup> *Informed health and care: A digital health and social care strategy for Wales* 2015, Welsh Government



- Public sector broadband aggregation (PSBA) service;
- Welsh Clinical Portal (WCP);
- GP Test Requesting (GPTR);
- Welsh Results and Reports Service (WRRS)
- Welsh Reference Data Service (WRDS);
- eMaster Patient Index (eMPI);
- My Health Online (MHOL);
- The Welsh Image Archiving Service storing digital images;
- Fiorano integration services.

The new LIMS will also integrate with other national Pathology systems, including:

- Tarian Health Protection system;
- The new Phlebotomy module of the WCP;
- The Point of Care Testing system – POCcelerator;
- The Medical Genetics system – Soft Genomics;
- The Welsh Transplantation and Immunogenetics Laboratory;
- In the future, digital microscopy and digital cellular pathology.

## **The Pathology Statement of Intent**

Plans for the development modern, sustainable Pathology services are set out in the *Pathology Statement of Intent*<sup>2</sup>, which has been circulated for consultation and is now being finalised for sign off by the Welsh Government. The statement sets out eight key areas, which are listed in [Appendix 3](#) along with their relationship to LINC.

### **3.2. The Case for Change**

#### ***Existing Arrangements***

The current LIMS, InterSystems TCL2011, was procured in 2010 as a single, national system intended to replace 13 standalone systems: 11 Telepath LIMS (now owned by DXC) and two Clinisys Masterlab LIMS. The contract with InterSystems expires in June 2020. Initially for seven years, the contract was extended for a further three years, after which there is no contractual basis for a further extension. NWIS (via Velindre NHST) are the contracting authority and take overall responsibility for managing the contract. InterSystems provide the licence for the use of TCL but NWIS are responsible for the hardware and software environment hosted in the NHS Wales data centres and for the service management of TCL.

TCL is now in use across most services although Cellular Pathology is not yet live in Cardiff and Vale UHB and Mortuary services are yet to be fully deployed. Blood Transfusion will be deployed by mid-2019. Some HBs are

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<sup>2</sup> *Pathology statement of intent* Draft February 2018, Director Strategic Programmes, NHS Wales Health Collaborative  
Outline Business Case  
Author: Judith Bates

exploring the costs of maintaining their current systems for Blood Transfusion in the event of any issues in transferring to TCL.

TCL is a national application that is integrated into the *Once for Wales* technical platform and national architecture. The infrastructure has not been stable during 2018 resulting in the loss of availability of the application for up to six hours on 14 occasions during 2018 (two planned). An upgrade of the servers has now improved performance including the time to login. The hardware refresh will be completed in early 2019.

A National Pathology IT Project Board (NPPB) governs the implementation of WLIMS1, supported by the NWIS ICT Programmes division. [Appendix 4](#) presents the overall governance framework, which includes the management of other pathology and diagnostic projects.

A LIMS Service Management Board (LIMS SMB) oversees the service management of the live service and a Change Advisory Board considers requests for change. There has been no budget for changes, which has made some change requests difficult to deliver and dependent on end of year monies being made available. NWIS provides first line support via ServicePoint and second line support via the LIMS application support team. PHW has its own Pathology IT Manager to support the LIMS for Microbiology and Screening services. Third line support is available from InterSystems.

A Clinical Strategy Group assures design decisions meet the requirements of the service and patient safety supported by the Standing Specialist Advisory Groups for each of the main disciplines.

The contract did include an upgrade to a later version (TCL2016) but not to the latest version. TCL Enterprise (TCLE), which is a completely different solution on a different technical platform. In 2017, the SMB along with the WLIMS1 Senior Responsible Owner and InterSystems decided against an upgrade based on the lack of perceived benefits, lack of take up by other clients, timescale for deployment and lack of NHS Wales' capacity. However, it appears that TCL 2011 is not supportable after January 2020 because the Microsoft operating system (Windows Server 20012 R2) is end of life and no longer supported by Microsoft.

It has been confirmed that an upgrade to TCL 2016 is required to maintain TCL until the new LIMS is fully deployed. NWIS has initiated discussions with InterSystems to explore the implications of continuing to support TCL 2011 after the end of their contract for up to five years. InterSystems has advised that TCL 2016 will be end of life in 2025 and, if the new LIMS is not deployed by then, Wales will have to implement TCLE.

A joint subgroup across the WLIMS1, LINC and the LIMS SMB has been set up at the request of the LINC Programme Board. The subgroup is considering the costs, risks and benefits of upgrading to TCL 2016 versus

staying with TCL 2011 or taking TCLE. At their meeting on 11 December, they recommended an upgrade to TCL 2016.

The total cost of the WLIMS1 as set out in the full business case<sup>3</sup> for the ten years 2010/11 – 2020/21 for hardware, software, maintenance and support was anticipated to be £31m, comprised:

- £12m capital;
- £19m revenue (£7m revenue and £12m capital charges)

The current annual costs of the existing service is £4.2m, which includes £3.7m for WLIMS1 (significantly more than estimated in the FBC) as set out in Table 6 plus £540k per annum for Telepath and Masterlab. These costs do not take account of the additional costs that NWIS and the service have had to contribute to develop, implement and continue to maintain the WLIMS1 service.

*Table 6: Current annual cost of WLIMS1 charged out to HBs.*

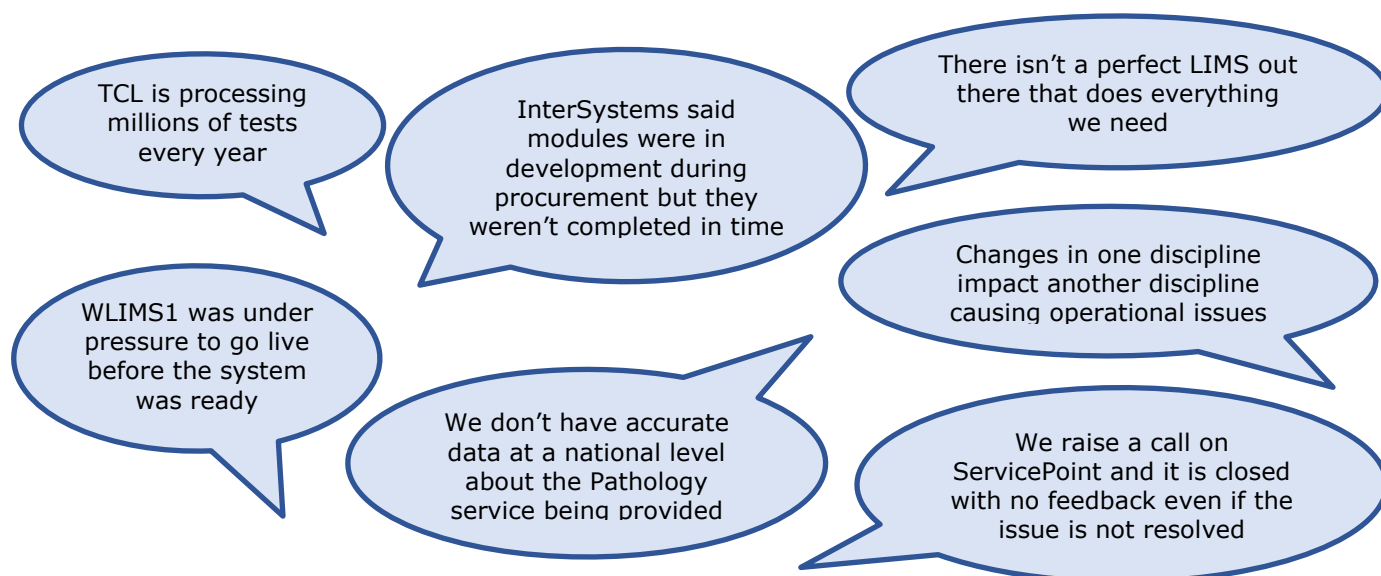
<b>Current LIMS Costs per annum</b>	<b>Annual Cost £k</b>
<b>WLIMS1 (InterSystems Trakcare)</b>	
InterSystems - Trak Care Technical Assistance & Software Updates	1,728.00
3rd Party Validation Services	40.00
Hosting - Environment & Support	315.30
Infrastructure - 3rd Party Maintenance	829.50
National Service Desk/Service Management	92.30
Technical Support - Analysts/Development/Integration & Test	659.80
<b>Total (WLIMS1)</b>	<b>3,664.90</b>

### ***Lessons Learned and Benefits Realised***

There are many lessons to be learned from WLIMS1 and a lessons learned log has been created and listed in [Appendix 5](#). This log lists the issues faced by WLIMS1, the lessons for LINC and the way in which each lesson is being applied to the LINC Programme. The lessons have been categorised so as to make it easier to identify within LINC where they need to be addressed and include strategic fit, governance, communications, procurement, development and testing, implementation, operational fit, business intelligence, technical issues, resources and application support.

Many staff have made comments that help to illustrate the lessons that need to be learned.

<sup>3</sup> Full Business Case: All Wales Laboratory Information Management System (LIMS), March 2010, Final Version (2.7)



Despite the challenges faced by WLIMS1, Table 7 shows some of the improvements that have been achieved. It also sets out the vision for how the investment proposed in this OBC could build on the progress to date and deliver further service improvements, in particular in relation to the standardisation of services.

*Table 7: Historical and Potential Future Improvements in Pathology*

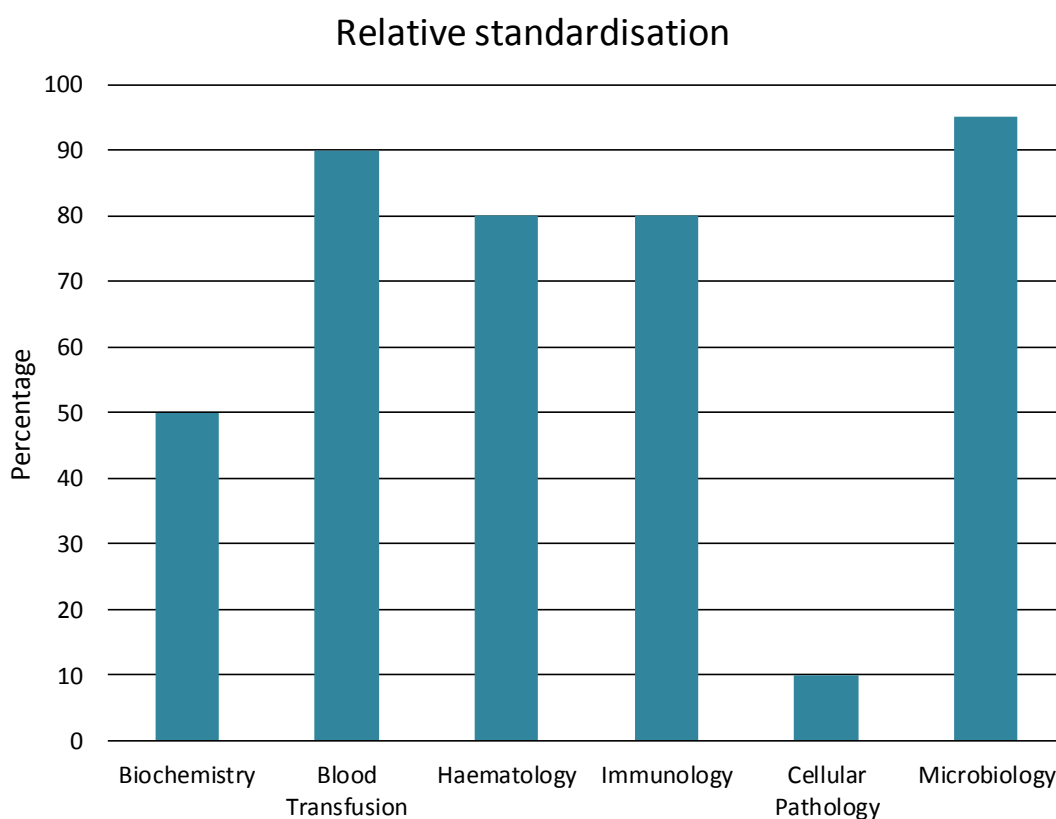
Pre 2010 Multiple Systems	2010 – 2022 TCL Vision	2022 – 2036 LINC Vision
Multiple laboratory systems independently run	Migrate to single laboratory platform centrally hosted and managed	Maintain benefits of single LIMS platform with improved service management
Limited standardisation	High level of test standardisation	Increase standardisation of workflows and outputs
Limited comparability of results across sites	High level of comparability across results across Wales	Improvements and further standardisation in clinical reporting outputs
Reduced functionality	Improved functionality	Improved functionality and performance
Limited electronic requesting	Improved use of electronic requesting	Full use of electronic requesting
Lack of comparability of business intelligence	Improvements in business intelligence	Fully integrated business intelligence and extended reporting outputs



## Standardisation of Services

Standardisation is critical to underpin the development of a sustainable Pathology service. Significant progress has been made to standardise the configuration of tests and workflows as part of the implementation of InterSystems TCL but further work remains to complete this. Figure 2 provides an indication of relative standardisation although the figures are not absolute. Microbiology has made most progress but initially underestimated the level of resources that were required to maintain standardisation, as new tests, methods, equipment and pathogens emerge as the service evolves. Cellular Pathology has made the least progress towards standardisation due to the extent to which the service is clinically led and the high number of vacancies for consultant Histopathologists.

A Standardisation and Design Project is being created to run alongside the Procurement Project, so that this work can be completed in readiness for when the new LIMS supplier has been chosen. Combined with the implementation of a more standard LIMS, this will deliver a standardised approach across Wales. Business change will prepare local services for the proposed changes and address any issues raised up front.



*Figure 2: Relative standardisation achieved per discipline*

### 3.3. Business Needs

#### *Stakeholder Engagement*

LINC has multiple and complex stakeholders with different levels of interest in the LINC programme. Some are *shareholders*, for whom Pathology is providing a clinical service that impact on the quality of care and risk to patients. A stakeholder analysis will be undertaken to differentiate the different stakeholders and their level of interest and develop a stakeholder engagement strategy to design appropriate communications, consultation and active engagement in LINC. Overall, the stakeholders, shown in [Appendix 7](#) include:

- The **Pathology service** including all the staff working in Pathology;
- **Service users**, including patients and carers;
- **Service customers**, who request Pathology tests (in Wales, the UK and internationally) and who receive test results. For Microbiology, this is wider including environmental services with samples for food and water as well veterinary services.
- The **wider community** including the general public, media, community health councils and government;
- **Suppliers** of goods and services both internal (NWIS, local ICT services and the PSBA service run by Welsh Government) and external (pathology systems, equipment and consumables):
- **All Wales Directors groups:**
- **Other national IT programmes;**
- **Governance bodies** including corporate, commercial, operational, clinical, professional and programme governance; informatics strategy and business case assurance and regulatory bodies:

Key stakeholders have been engaged in the development of this business case and consulted on the development of the LINC Programme through events, workshops, meetings and email correspondence, including:

- Representatives of the Pathology service are members of the LINC Programme Board and a vehicle for consultation;
- The LINC Programme Board meetings monthly and consulted at all stages and on all programme risks and issues and papers will that inform the OBC;
- A monthly update and requested papers are submitted to the NHSW CEG;
- Meetings have been held with Directors, the Pathology service and NWIS, which has informed the scope and requirements of the OBC. In particular the NWIS Director of Finance and Business Assurance and his team along with the NWIS National Pathology IT Diagnostic Lead is advising on the development of this OBC and will assist with the completion of the financial aspects of the OBC;

- A supplier engagement event was held in February as part of the market research following the publication of a Prior Information Notice in January 2018;
- Presentations have been held or planned to all of the All Wales Groups and the LSSC and feedback incorporated into the OBC;
- Thirty workshops have been held or planned, as listed in [Appendix 8](#), on the business case and development of requirements with a wide range of participants from the Pathology service, health boards and trusts and NWIS;
- The SSAGs are a vehicle for consultation on all documentation and feedback incorporated into revised versions. The Cellular Pathology SSAG is not currently active so an email group has been created to consult with this discipline incorporating the original SSAG members;
- LINC is represented on the Laboratory Services Sub Committee, National Pathology Network, WLIMS1 Programme Board, and the WLIMS1 Service Management Board

### ***End-to-end Pathology solution***

Potentially, the safest and most efficient technical solution for Pathology is one that supports the whole end-to-end process providing a truly paperless service. This is the best solution to support the delivery of the Pathology Statement of Intent and the development of a modern, sustainable Pathology service, which meets the requirements of its users.

To appreciate the complexity of such a solution requires an understanding of the nature and variety of the samples received and the end-to-end processes that they follow, laboratory quality management requirements and the way in which the data collected is used for secondary purposes (business intelligence).

### ***Electronic test requesting***

There are potentially thousands of Pathology tests that could be requested. Some are very common, such as a full blood count, whereas others are very rare and may be very expensive to analyse requiring specialist skills and equipment.

Most tests are currently ordered using paper request forms. This is not ideal because of potential mistakes in handwriting, which has to be interpreted by administrative staff in the laboratory reception, who have to manually enter the request into the LIMS. Nor can they control what tests are requested, which has to be checked by laboratory staff. Other mistakes include the wrong labels on test tubes. One A&E made three such errors in one hour, and the samples had to be rejected and the patients re-bled.

Electronic test requesting (ETR) is potentially much safer because the requester, patient and test(s) requested are all chosen electronically.

Benefits include demand management to restrict available tests and show if the patient has recently had the test to avoid unnecessary requests. In Wales, ETR is offered via the WCP for secondary care and the GPTR for primary care. Take up of the WCP is improving, as shown in Figure 3 but GPTR take up remains low overall. A new version of the GPTR has just been launched and being implemented by the GP clinical systems suppliers. It is hoped that this will improve take up. In Wrexham, where the GPs are using a separate product, Sunquest ICE, the take up is 98%.

ETR will not only improve demand management and clinical incidents but will also reduce the need for administrative reception staff. It is not just the time for booking in, but all paper requests and any other paper documentation related to a patient or a request has to be scanned in to attach an electronic version to the patient record. This is time consuming and the scanning solution in WLIMS1 has been problematic to get up and running.

Take up of the WCP is variable and depends on factors such as access to computers and printers on the wards to make requests. Even where take up seems high, the WCP does not provide ETR for all Pathology disciplines. The Pathology service feels that ETR was promised with WLIMS1 but has not been fully developed to meet the needs of the service. They are sceptical that this will be available via the WCP for the new LIMS. On 29 March 2018, the Microbiology SSAG wrote to the LINC Programme to say that they did not consider the test requesting via the WCP to be fit for purpose and requested the purchase of an alternative requesting solution as part of the LINC procurement of a new LIMS.

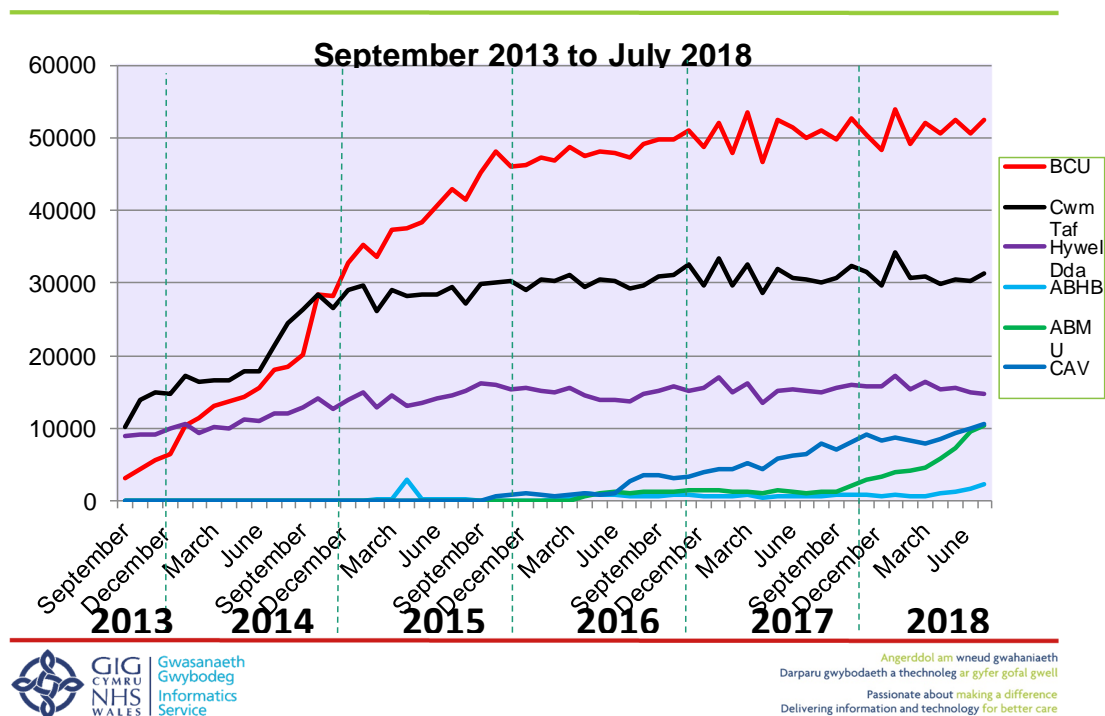


Figure 3: Take up of Pathology electronic test requesting via the WCP

In order to facilitate discussion between NWIS and the Pathology service, a conference was organised on 3 September for NWIS to share its plans for the WCP. LINC has drawn up an ETR requirement for Pathology and NWIS has reviewed this in relation to what the WCP can do or is planned in future releases and what is not yet planned; 'the gap'. An initial joint LINC-NWIS workshop was held on 24 October to go through the requirement and a further all day event planned on 14 December to complete this. NWIS has stated that from April next year they can devote the resources needed to develop the WCP for Pathology. The Pathology service remains to be convinced that NWIS has the capacity to develop the WCP to meet their requirements.

Consequently, the ETR requirement is included in the scope of the procurement as an optional extra and funding for a separate ETR solution or to meet the costs of developing the WCP has been included in the preferred option and approved, in principle, by the NHS Wales CEG at their meeting on 23 October 2018. It should be noted that NIMB has requested that a decision be made as part of this OBC as to which option will be taken and a further version of the OBC will be developed to reflect this once a decision has been made.

### ***Pathology samples***

Pathology can receive samples in many shapes and forms, including blood, urine, faeces, other body fluids, organs and tissues, as well as food and water as shown in Figure 4. Requesters may be doctors, nurses, pharmacists and a variety of other health care workers in the NHS, private hospitals and prisons, as well as environmental health and veterinary practices.

Blood may be collected by clinicians directly, but more likely by a phlebotomist, nurse or health care assistant. NWIS are currently developing a phlebotomy module of the WCP that will be integrated to the new LIMS and provide better information to the phlebotomists and to the Pathology service. This module will be tested in ABM UHB early in 2019.

### ***Point of Care Testing***

A growing service is Point of Care Testing (POCT), where the patient is bled and using a hand held device allowing them to have the result immediately. NHS Wales is in the process of implementing an All Wales POCT solution, POCcelerator. To provide Pathology clinicians and lab based POCT Co-ordinators with a full picture of pathology tests, there needs to be a feed into the new LIMS.



Figure 4: Range of sample types from different sources and requesters

### Pathology process

Once a sample is taken there is an end-to-end process that it follows to get to the lab, be tested and for the results to go back to the requester, as shown in Figure 5. In addition, for Blood Transfusion a further step allows blood products to be issued to patients after testing has been completed to ensure the patient has been matched to the correct type of blood.

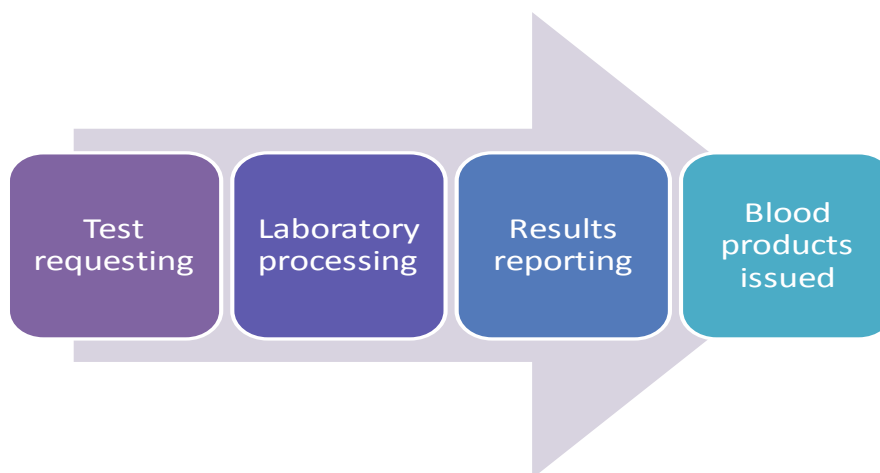


Figure 5: End-to-end Pathology process

### Laboratory Processing

Once the sample has been enrolled into the laboratory (i.e. the request has been entered into the LIMS and the sample received), the laboratory has a number of processes to follow to analyse the sample and report on the results as set out in Figure 6.



Testing may be carried out using automated equipment. Other testing may take time such as TB culture tests for Microbiology that take six weeks for a culture to grow to determine the result. Consequently when a set of tests are ordered at the same time, the results of some may be ready before others and interim results reported, which may have to be amended once all the results are available. Cellular Pathology tests take time to prepare cutting sections from an organ or tissue and preparing it into a slide that can be read via a Microscope to interpret the results.

Technical validation assures that the accuracy and precision of results. Clinical validation is undertaken by clinical staff, who consider the results in the light of the clinical information provided on the request form, such as medication, testing for a known disease or monitoring a chronic disease. Quality control is used to ensure that the analysers are consistently reporting accurate results. A full audit trail is required to ensure that any changes to a patient record at any point can be traced, which is essential to track errors not only in results reporting but also to ensure that results are reported against the correct patient or sample. WLIMS1 has a poor audit capability, which has been raised as a critical issue for the service.

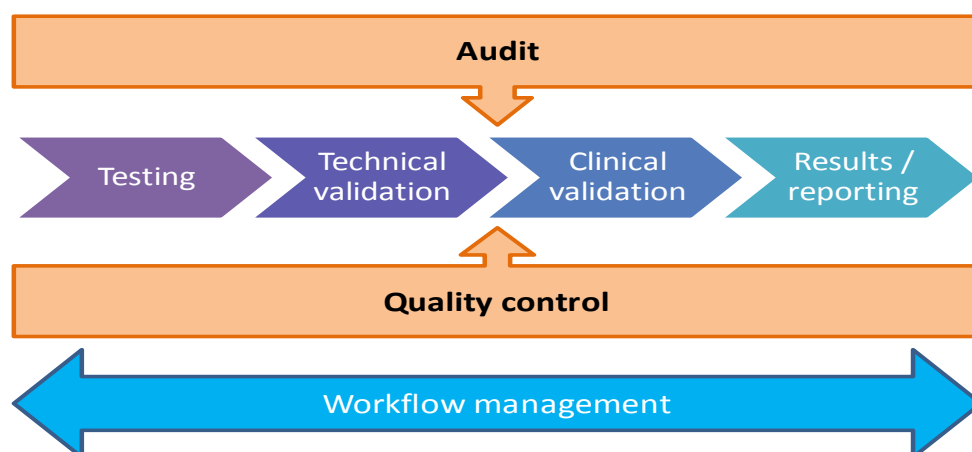


Figure 6: Pathology laboratory processes

Not all tests need to be clinically validated. For example, blood tests within a normal range can be published without further review. This is essential, as it would not be feasible to validate the millions of blood tests analysed every year. At the moment, where clinical validation is required, the results are sent to a validation queue ready for clinicians to review and report on the results. Considerable variation exists across Wales in terms of validation with the same tests being clinically validated in some places but not in others, especially larger sites with high volume.

Not all tests are analysed where they are received. Some locations may only have a reception to receive the samples and enrol them onto the LIMS. Some laboratories may only have the equipment to analyse certain tests or

be a 'hot' lab. So some tests received are sent to other laboratories for analysis. They may be sent to a laboratory in Wales, in which case they are managed via the LIMS as 'sendaways'. Other very specialist tests may be sent to laboratories outside of Wales and these are sent with paper requests, which can be generated from the LIMS as a packing slip. Specialist tests may also come into Wales especially to Cardiff and Vale UHB, such as for Medical Genetics. The management of these incoming and outgoing tests on paper causes significant issues, from delays and lost results to loss of potential income. The NHSW CEG has approved the inclusion of NPEx in the OBC at their meeting held on 21 August 2018. NPEx is a tool developed by the NHS in England to manage inter-laboratory referrals.

Workflow management is key to ensuring that all samples have been processed within the required time and outstanding work lists help the laboratory to keep track of the status of all the samples received. Within Blood Sciences, this could be hundreds, if not thousands, every day.

Sample tracking is also critical so that laboratory staff can know where a sample is at any point in time. WLIMS1 sample tracking does not meet the requirement and this will be a key improvement in the new LIMS.

For Blood Transfusion, sample tracking is taken further to include the tracking of the blood product issued to the patient. 'Vein-to-vein' reflects the need to track the sample taken from the patient to match their blood to the actual blood product sent to the local fridge for that patient and then transfused into the patient. WLIMS1 includes a separate blood tracking system, Haemonetics, but as Blood Transfusion has yet to go live, this tool has not been used, unless already in use locally. This version of Haemonetics tracks blood to the local fridge but not to the patient. For the new LIMS, the service has requested a full vein-to-vein solution with remote issue, which will require training and support of NHS staff beyond the Pathology service.

### **Results Reporting**

When the result has been clinically validated, the result may be reported directly, such as blood tests results; or may require the clinician to write a report documenting their findings and making recommendations to the requesting clinician. In this case, the clinician will dictate a report that will be typed up by their medical secretary. The new LIMS will require dictation and voice recognition to be an integral part of the service.

Once the result has been verified or reported, it is either then printed and posted, or more commonly, sent electronically. Within the NHS, results are sent to the Welsh Results Reporting Service (WRRS), which allows users of the WCP to view diagnostic reports and requests for their patients, regardless of where they are produced. NWIS are working hard to roll out



the WCP for results reporting so there should be significant coverage by the time the new LIMS is ready to deploy. Results to GPs are sent via the GP links to their clinical system, irrespective of where the test was ordered or processed.

In addition to sending results to the requesting clinician, WLIMS1 also have interfaces to more than 60 downstream, clinical systems across Wales to report results, as shown in [Appendix 2](#). Now that the WRRS is more widespread, it is planned to review the systems that require an interface to receive the result or whether the service could view the results via the WCP.

Whenever WLIMS1 falls over, it is the resetting of all these interfaces to the downstream clinical systems that takes the time for the system to come back online. It is therefore proposed that for the new LIMS, the supplier will produce a single extract that NWIS will integrate to required downstream systems reducing the cost of managing direct interfaces. Additional integration staff will be appointed to manage these interfaces but the overall costs will be less than the current arrangements.

### **Quality Management System**

Every process and procedure within the laboratory is documented in a standard operating procedure (SOP). Each laboratory may have hundreds or thousands of these SOPs, which have to be updated if analysers change or new guidance is issued. The laboratory has a responsibility to make sure that all their procedures meet legal, accreditation and validation requirements and have to be regularly reviewed. Evidence has to be provided to maintain accreditation, which is becoming increasingly more stringent. This includes the training records of staff to make sure they are competent to perform the analysis and validation undertaken. Many laboratories, but not all, have a quality management system (QMS), most commonly Q-Pulse, the de facto Pathology QMS. Some are using SharePoint to manage documentation but finding it increasingly difficult to manage their documentation to the standard required. There has never been a national QMS, which makes standardisation difficult to maintain, as there is no central management of standard SOPs, other than for Microbiology. The NSW CEG has approved the procurement of a national QMS supported by a national quality management team. This team will not only maintain standardised SOPs but also LIMS system and training documentation. It is planned to ensure a more standardised implementation with system documentation maintained so that testers sitting with the national quality management team can support local sites with their user acceptance testing. This team will also have a Validation Officer that can support accreditation and validation, significantly reducing the cost incurred in validating WLIMS1.

## Business intelligence

Business intelligence (BI) is critical to plan, manage and deliver a safe, efficient, sustainable Pathology service and for secondary uses such as epidemiology. One of the important business benefits identified in the business case for WLIMS1 was to have the ability to collect and compare data consistently, accurately and comparably across all health boards and hospital sites within Wales. Previously this was not possible due to the lack of standardisation of tests and test sets, differing definitions of “units of measure” and multiple methods of collecting, analysing and presenting the data. An all Wales LIMS would be significantly more standardised with common test sets containing the same test items, with data collected using a standard data collection tool provided by the supplier.

InterSystems BI solution is DeepSee Business Intelligence, did not meet expectations. The lack of good BI remains an issue to the extent that it has been difficult to plan services nationally and inform the Pathology Statement of Intent. A much more detailed specification has been developed for the requirement for the new LIMS. Figure 7 presents a potential model for the delivery of BI for the new LIMS.

NHS Wales has now identified the development of a National Data Resource (NDR) to harness the power of big data that can be used for strategic planning and research. This could meet some of the BI requirement for Pathology although timescales for development have yet to be confirmed.

No national resource was funded to support the development of the WLIMS1 BI capability, so two informatics analysts are proposed for the new LIMS, so that BI can be developed to meet the needs of the service from day one, and ensure a standardised approach to BI. In addition, as part of the Pathology Statement of Intent, NHS Wales will revisit the current Pathology informatics arrangements across Wales and develop a new configuration that best meets the needs of Pathology services.

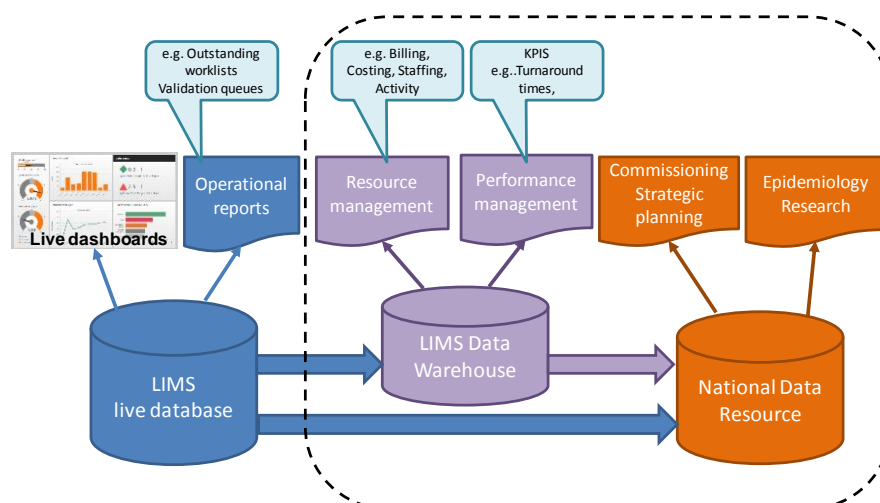


Figure 7: New LIMS business intelligence model

### ***Potential business scope and key service requirements***

This section describes the potential scope for the project in relation to the above business needs. The scope is about more than the LIMS, and includes systems and services that collectively delivery an end-to-end technical solution to support the modernisation of Pathology services. The potential scope is set out in [Appendix 6](#) and includes:

- Pathology disciplines and sub-disciplines
- Core functionality
- Discipline specific functionality
- Integration requirements
- Additional systems / tools
- Business intelligence
- Standards
- Business change
- Documentation

A key requirement is that the new LIMS system must be modular in design, so that changes in one discipline do not impact another discipline and that each discipline is in control of its own change programme, unless absolutely critical to the whole system. For example, adding a new test or changing comments in a test report should be straight forward and quick to achieve and not dependent upon having to retest the system for other disciplines.

Additional systems and tools to the LIMS include:

- Optional electronic test requesting system, if the WCP cannot be developed to meet the needs of the Pathology service;
- A blood tracking system supporting the delivery of a vein-to-vein solution with remote issue;
- Scanning system to support scanning any paper documentation to attach to the patient record;
- Dictation and voice recognition to support clinical reporting of results;
- Business intelligence tool to support the production of business intelligence for the Pathology service;
- All Wales quality management system (QMS) and quality team to maintain and assure the quality of an all Wales standardised service, including the quality of documentation, data and information required for accreditation and validation. The NHSW CEG approved the inclusion of a QMS in the LINC OBC at its meeting held on 26 June 2018;
- NPEx, a tool to manage test referrals into, and out of Wales, and for specialist services, such as medical genetics. The tool improves data quality and completeness, including image management and the turnaround of results reporting and potential for income generation.

The NSW CEG approved the inclusion of NPEX in the LINC OBC at its meeting held on 21 August 2018;

- Legacy data system that will be developed using the All Wales National Data Repository (NDR), which will store all historic data, provide a data viewer to look up and extract records and provide the ability to transfer historic data into the live LIMS as required.

The scope excludes:

- Systems for Medical Genetics and Point of Care Testing, where separate solutions have been purchased and are currently being implemented (SCC Soft Genetics and Siemens POCcelerator);
- A new solution for the Welsh Transplantation and Immunogenetics Laboratory (WTAI) has also been excluded. Steiner is currently developing the WTAI solution under the terms of the same InterSystems contract as TCL. It was planned to include WTAI in the scope of this OBC but with a separate procurement but costings are not available, so will have to be considered separately;
- All local hardware including PCs, printers, local network infrastructure, fridges and Blood Transfusion kiosks; Pathology analysers and other equipment;
- Wide area networking to each site, as it is assumed that the supplier will use the PSBA service. If the supplier chooses to use their own data centre, they will have to provide a connection to this service;
- Systems for Bowel Screening and Downs Screening, although these could be offered as optional extras in the Maximum option.

It is essential that with a potential 14 year contract, the supplier can demonstrate how they can develop their LIMS service within the terms of the agreed contract to support service transformation and new technical developments, such as digital microscopy, digital cellular pathology, artificial intelligence and machine learning. The aim is to avoid significant additional costs to the service to take advantage of new developments.

### ***Spending Objectives***

The spending objectives for the LINC Programme have evolved throughout 2018 during discussions in workshops, presentations and board meetings:

- SO1** To improve patient care, patient safety and patient outcomes;
- SO2** To enable the transformation of healthcare services to be leaner, standardised, more sustainable and provide long-term stability;
- SO3** To deliver a seamless, end-to-end technical solution for Pathology services;
- SO4** To contribute to the more prudent use of Pathology resources through demand management, predictive costing and minimised financial risk;
- SO5** To meet current and future service requirements.

## Main Benefits Criteria

This section describes the main outcomes and benefits associated with the implementation of the potential scope in relation to business needs.

Satisfying the potential scope for this investment will deliver high-level strategic and operational benefits. These are set out in relation to the spending objectives and programme outcomes. More detail is provided in the [Economic Case](#), where benefits are linked to strategic benefits.

Key benefits will be realised as a result of:

- Further standardisation that will avoid the need for manual workarounds delivering:
  - Reduced overheads and administrative costs
  - Easier training
  - Staff able to work anywhere
  - Common tests can be analysed anywhere
  - Reconfiguration of services easier to achieve
- Electronic requesting, which can deliver
  - Reduction in reception staffing levels
  - Automated booking in and sample sorting, speeding up the testing process reducing turnaround times
  - Reduced need for centrifuging samples as more analysis can be completed within the sample shelf-life
- Service management arrangements that allow agile support and maintenance of the system

[Appendix 9](#) sets out the benefits in relation to the spending objectives.

### 3.4. Risks

The main business and service risks associated with the potential scope for this project are shown in [Appendix 10](#) together with their mitigation.

A key risk that the service has identified is that no resources have been included in this OBC to cover the local costs of supporting the programme and deployment, such as for time to support the procurement and backfill to release staff for training. Even though a different approach is being taken with the system being configured by the supplier, a more standardised system being implemented and a central team of subject matter experts to provide support to local services, local staff will need to be involved and resources provided to cover this.

### 3.5. Constraints

***The project is subject to the following constraints:***

- Lack of resources to release staff from NWIS and the service to support the procurement, development, testing and training and to take forward the work on standardisation of workflows;
- Gaining the commitment of the whole service to the benefits of standardisation;
- The requirement for the new LIMS to work within the All Wales national architecture;
- The limited financial resources available to the NHS for a new system, to support the procurement and further standardisation.

### **3.6. Dependencies**

The project is subject to the following dependencies that will be carefully monitored and managed throughout the lifespan of the LINC Programme:

- An agreement with InterSystems to support TCL 2016 after their contract expires in June 2020;
- The development of the WCP to deliver electronic requesting to meet Pathology requirements in time for deployment if the new LIMS;
- The development of the NDR as a legacy solution for Pathology data;
- Re-procurement of the eMPI service for which the contract also expires in 2020;
- The approval of Welsh Government, NIMB, Health Boards/Trusts/PHW and professional bodies to this OBC.

## 4. The Economic Case

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 OBC documents the wide range of options that have been considered in response to the potential scope identified within the Strategic Case.

### 4.1. Critical Success Factors

The key Critical Success Factors (CSFs) for the programme are set out in Table 8, have been derived from the core CSFs contained within the OBC guidance. These CSFs are used alongside the investment objectives to evaluate the long-list of possible options.

Table 8: LINC Programme Critical Success Factors

ID	Critical Success Factors
CSF1	<b>Business Needs:</b> How well the option satisfies the existing and future business needs of NHS Wales
CSF2	<b>Strategic Fit:</b> How well the option provides fit and synergy with other key elements of the national and local strategies relevant to Pathology services
CSF3	<b>Benefits Optimisation:</b> How well the option optimises the business outcomes and potential benefits (both qualitative and quantitative, direct and indirect to NHS Wales), and assists to improve overall VFM (economy, efficiency and effectiveness)
CSF4	<b>Potential Achievability:</b> How likely is this option to be achievable having regard to the ability of stakeholders to innovate, adapt, introduce, support and manage the required level of change, including the management of associated risks; the need for supporting skills (capacity and capability) and engender acceptance by staff and patients.
CSF5	<b>Supply Side Capacity and Capability:</b> The ability of the marketplace and its potential suppliers to deliver the required services and deliverables.
CSF6	<b>Potential Affordability:</b> The ability of the relevant stakeholders – both national and local – to fund the required level of expenditure viz., the capital and revenue consequences associated with the proposed investment.

### 4.2. Longlist of Options

This section documents the wide range of options considered that have been generated using the options framework that identifies and analyses choices for scope, service solution, technical solution, configuration, service delivery and implementation.

Funding options are not assessed as the latest financial guidance IFRS16 makes it clear that expenditure on an asset delivered as a managed service,



where the client controls the use of the asset should be treated as capital. A capital / revenue only option is therefore presented.

Up to five options within each category are evaluated and one will be identified as the *preferred* option. Others may be a *possible* option or *discounted*.

The longlist has come about following consultation with the key stakeholders and the LINC Programme Board and specifically reviewed at an OBC workshop held on 17 August 2018 and a technical workshop (joint NWIS and Pathology IT Leads) on 7 September.

### 4.3. Evaluation of Longlist Options

#### Scope Options amend

The scoping options are set out in [Appendix 6](#) and comprise.

- **SCO1: Business as Usual Scope** – The level of functionality that will be provided by InterSystems TCL 2016;
- **SCO2: Minimum Scope** – The level of functionality anticipated to be provided by InterSystems TCLE;
- **SCO3: Intermediate Scope** – This scope involves procuring a new LIMS service that would deliver the requirements requested by the NHS Wales Pathology stakeholders, support the standardisation of services, statutory compliance, emerging, more stringent quality standards and provide a platform for future development;
- **SCO4: Maximum Scope** – This scope involves procuring a state of the art Pathology service that would meet all current and know future requirements as requested by the NHS Wales Pathology stakeholders.

#### Evaluation of Scope Options

Each scope option is described in more detail in Table 9, which also provides an evaluation of the advantages and disadvantages of each and a comparison against spending objectives and critical success factors to determine whether the option is preferred, possible or discounted.

#### Overall Conclusion: Scope Options

In summary, the preferred scope is Option 3: procure a new LIMS service that provides intermediate functionality, which will meet the current requirements of the Pathology stakeholders in NHS Wales. Option 1 is carried forward as the BAU benchmarking option, Option 2 is possible and Option 4 is discounted. However, it is essential that the supplier can demonstrate how they can develop their LIMS service within the terms of the agreed contract to support service transformation and new technical developments to allow the service to take advantage of new developments.



Table 9: Review of the Longlist Options for Scope (SCO)

Scope Options	SCO1: Business as usual	SCO2: Minimum	SCO3: Intermediate	SCO4: Maximum
Description	Scope determined by capability offered by InterSystems TCL Version L2016.	To improve the scope to capability offered by InterSystems TCL Enterprise	To procure a new solution that meets current requirements, supports standardisation of services, statutory compliance, emerging more stringent quality standards and provide a platform for future development.	To procure a state of the art solution that meets all current and known future requirements to support all Pathology services.
Advantages (Strengths and opportunities)	Very little change in operational capability to TCL 2011, most improvements relating to DeepSee business intelligence. Known, familiar service; Easy to continue with current arrangements; Minimal training requirements.	Modern web based system with much improved functionality.	Meets functionality requirements as requested by the service; Meets current and emerging quality standards; Provide potential to meet future requirements e.g. mobilisation; Full end-to-end solution including phlebotomy and electronic requesting; Enables transformation of Pathology services to be more sustainable from a service and financial perspective.	As per Intermediate, plus: Delivers capability to support future requirements such as AI and machine learning; On-site supplier provided training.
Disadvantages (Weaknesses and threats)	Not compatible with future objectives / services; Ignores known developments; Does not meet future requirements e.g. mobilisation;	Unclear to what extent InterSystems will meet all requirements given agreement reached without procurement. Formal procurement advice is risk of legal challenge as no procurement.	Requirements may not be fully available in current LIMS solutions; More complex to integrate with current systems e.g. WRRS; May be more expensive, increased cost.	Requirements may not be fully available in current LIMS solutions; Cost, may not provide value for money; Supplier ability to deliver;

Scope Options	SCO1: Business as usual	SCO2: Minimum	SCO3: Intermediate	SCO4: Maximum
	No development opportunities Technical platform not supported after 2025; Formal procurement advice is risk of legal challenge as no procurement.			Lack of clarity on delivery options for the future; Culture change may be too challenging to deliver
<b>Match to Spending Objectives (SOs) and Critical Success Factors (CSFs) (Yes, No, Partial)</b>				
SO1: Patient care, safety & outcomes	No	Partial	Yes	Yes
SO2: Enable service transformation	No	Yes	Yes	Yes
SO3: Deliver end-to-end solution	No	Partial	Yes	Yes
SO4: More prudent use of resources	No	Partial	Yes	Partial
SO5: Meet current & future reqts	No	Partial	Partial	Yes
CSF1: Business needs	No	Partial	Yes	Yes
CSF2: Strategic fit	No	Partial	Yes	Yes
CSF3: Benefits optimisation	No	Yes	Yes	Yes
CSF4: Potential achievability	Yes	Yes	Yes	Partial
CSF5: Supply side capacity&capability	Partial	Yes	Yes	Yes
CSF6: Potential affordability	Yes	Yes	Yes	Partial
Conclusion	<b>Carried forward (benchmark)</b>	<b>Discounted</b>	<b>Preferred</b>	<b>Possible</b>

## Service Solution Options

The service solution options are listed below and Table 10 provides a review of these options:

- **SSO1: Local LIMS** - each Health Board separately procures and manages its own LIMS;
- **SSO2: Best of breed LIMS** – Separate national systems are procured for each major discipline: Blood Sciences, Cellular Pathology and Microbiology;
- **SSO3: Separate Cellular Pathology LIMS** – a system is procured for Cellular Pathology including digital services separately to a combined, national system for Blood Science and Microbiology;
- **SSO4: Single, national LIMS** – a single, national LIMS is procured for all Pathology disciplines across Wales.

A consequence of the experience with TCL has been the request to consider *best of breed* options for services such as Cellular Pathology and Blood Transfusion. Consequently, a Prior Information Notice was published in OJEU in January 2018 to give suppliers the heads up that a procurement is planned and to test the market in particular to see what best of breed systems were available. Sixteen suppliers responded and invited to a Supplier Engagement day on 6 February; ten suppliers attended and six gave presentations on their system and described how they would work with Wales. Five suppliers were offering best of breed although, they were either too focused (Mortuary services or New Born Spot Screening), with two offering Cellular Pathology and one offering Blood Transfusion. Feedback from the supplier day indicated that there remained a split in views on whether to continue to explore *best of breed* solutions versus a single, full LIMS for Wales<sup>4</sup>. A paper<sup>5</sup> was prepared for the April meeting of the LINC Programme Board, which considered the issues relating to these options and the Board decided that the right approach was to continue to build on a single, national LIMS. The NHSW CEG ratified this decision at their meeting on 18 September 2018.

Subsequently, the option for Microbiology to buy its own system was raised at the National Pathology Network meeting in September and again at the LINC Programme Board in October. In various workshops held during the year and at the LINC Programme Board in August and September, it has been requested that the option for separate LIMS for each health board be considered as a shortlisted option. Both of these options had already been rejected and the NHSW CEG unanimously decided in favour of a single, national LIMS at their meeting held on 18 September 2018. In discussion with Ian Gunney and Peter Jones at Welsh Government on 17 September

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<sup>4</sup> WLIMS2 Supplier Engagement Day Report V0.4, 7Mar2018, LINC Programme, NHSWHC

<sup>5</sup> LINC Programme Challenges and Approach V0.2, 9Apr2018, LINC Programme, NHSWHC  
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Author: Judith Bates 13-December-2018

about the OBC, they requested that the rationale for a single, national LIMS be reinstated in the longlist.

### **Evaluation of Service Solution Options**

Each service solution option is described in more detail in Table 10, which also provides an evaluation of the advantages and disadvantages of each and a comparison against spending objectives and critical success factors to determine whether the option is preferred, possible or discounted.

### **Overall Conclusion: Service Solution Options**

In summary, the preferred service solution is Option 4: a single, national LIMS. Option 3 is shown as Possible and the others are rejected.

Table 10: Review of the Long List Options for Service Solutions

Service Solution Options	SSO1: Local LIMS for each Health Board	SSO2: Best of breed LIMS	SSO3: Separate Cellular Pathology LIMS	SSO4: Single, national LIMS
Description	Each Health Board separately procures, implements and manages its own LIMS.	Separate national systems are procured for each major discipline: Blood Sciences, Cellular Pathology and Microbiology.	A system is procured for Cellular Pathology including digital services separately to a combined, national system for Blood Science and Microbiology.	A single, national LIMS is procured for all Pathology disciplines across Wales.
Advantages (Strengths and opportunities)	Each health board is in control of its own LIMS as it used to be with the Telepath and Masterlab systems	Each discipline would have its own dedicated LIMS chosen as the best of breed for their service.	Cellular Pathology would have a combined LIMS and Digital Cellular Pathology solution. Blood Sciences and Microbiology would have their own national solution	A single national system would be implemented once with a single hosting arrangement, have one set of interfaces to national applications and have one service management arrangement in place.
Disadvantages (Weaknesses and threats)	There may be multiple suppliers providing these systems across Wales with six separate data centres. The interfaces would have to be developed, implemented, tested and maintained to the national applications for six separate LIMS systems. There would be six separate service management arrangements, which may vary for each health board. Legacy data would have to be delivered separately for each LIMS. It would be difficult to produce consistent, comparable,	The market soundings earlier this year did not provide evidence of any supplier offering a viable best of breed option. There is no evidence that a best of breed option would provide any additional benefit over and above a single, national LIMS and the costs of three	Digital Cellular Pathology tends to be an additional toolset separate to the LIMS and the market place did not offer a combined solution that was currently live in the UK as part of the market soundings earlier this year.	It has proven difficult to implement a national system, which is still not yet fully deployed in all disciplines. A different approach would need to be taken to business change and standardisation and approach to implementation to

Service Solution Options	SSO1: Local LIMS for each Health Board	SSO2: Best of breed LIMS	SSO3: Separate Cellular Pathology LIMS	SSO4: Single, national LIMS
	national data for Pathology services and to implement or maintain a standardised service across Wales. In addition, it would be much more difficult to move work around Wales or reconfigure services. Overall, this option would be costly to procure, implement and maintain; and not provide value for money.	separate LIMS would be more significant, as per option one.	This would also be more complex and costly to procure, implement and maintain as per options one and two.	develop, test and enable local services to take up the new service.
SO1: Patient care, safety & outcomes	No	Partial	Partial	Yes
SO2: Enable service transformation	No	Partial	Partial	Yes
SO3: Deliver end-to-end solution	No	Partial	Partial	Yes
SO4: More prudent use of resources	No	No	No	Yes
SO5: Meet current & future reqts	No	Partial	Partial	Yes
CSF1: Business needs	Partial	Partial	Partial	Yes
CSF2: Strategic fit	No	Partial	Partial	Yes
CSF3: Benefits optimisation	No	No	Partial	Yes
CSF4: Potential achievability	Partial	Partial	Partial	Partial
CSF5: Supply side capacity&capability	No	No	No	Yes
CSF6: Potential affordability	No	No	Partial	No
Conclusion	<b>Discounted</b>	<b>Discounted</b>	<b>Possible</b>	<b>Preferred</b>

## Technical Solution Options

The technical solution options are listed below and describe how the technical platform for the LIMS service will be delivered:

- ***TSO1: Supplier cloud hosted solution*** – the supplier hosts a technical solution using cloud services, subject to meeting NHS Wales information governance and security requirements, e.g. or Infrastructure as a Service (IaaS), Software as a Service (SaaS) or Platform as a Service (PaaS);
- ***TSO2: National data centre (supplier hosted)*** – the supplier hosts a dedicated technical solution in the NHS Wales data centres;
- ***TSO3: National data centre (NWIS hosted)*** – NWIS hosts a dedicated technical solution in the NHS Wales data centres
- ***TSO4: Local data centres (health boards)*** – a dedicated technical solution is hosted in local data centres managed by health boards or regional services.

## Evaluation of Technical Solution Options

Each technical solution option is described in more detail in Table 11, which also provides an evaluation of the advantages and disadvantages of each and a comparison against spending objectives and critical success factors to determine whether the option is preferred, possible or discounted.

## Overall Conclusion: Technical Solution Options

In summary, the preferred technical solution is Option 1: a supplier hosted solution. Option 3 is carried forward as the BAU option for benchmarking purposes. Option 2 is possible and Option 4 is discounted.

Table 11: Review of the Longlist Options for Technical Solutions (TSO)

Technical Solution Options	TSO1: Supplier cloud hosted	TSO2: National data centre – Supplier hosted	TSO3: National data centre - NWIS hosted	TSO4: Local data centres – Health Boards
Description	Solution technical platform implemented and managed by the supplier utilising cloud services from Infrastructure as a service (IaaS), Software as a Service (SaaS) or Platform as a Service (PaaS).	Solution technical platform implemented and managed by the supplier from an NHS Wales Data Centre – the successful supplier would manage the software and hardware environment, but the solution would be housed within the NHS Wales national data centres. NHS Wales role would be limited to providing access to premises, data centre services and charging arrangements for its use with no service delivery.	Solution technical platform implemented and managed by NWIS from an NHS Wales Data Centre. This is the current model for WLIMS1.	Solution technical platform implemented and managed by the supplier, utilizing one or more local health board data centres.
Advantages (Strengths and opportunities)	Fewer NHS staff resources and responsibilities Responsibility for contract performance lies with the supplier. Supplier responsible for the whole environment; Management of operational issues less complex; Technology refresh managed by provider as part of a service;	Potential cost, compared to TSO1; Reduce governance risk; Data is held by NHS Wales and service is provided from the NHS Wales network; Supplier responsible for end-to-end service with NHSW only providing the data centre(s)	NHS understanding of the system; The data is held by NHS Wales and service is provided from the NHS Wales network; National data centres are connected directly to the PSBA network;	Local data centres are connected directly to the PSBA network.



Technical Solution Options	TSO1: Supplier cloud hosted	TSO2: National data centre – Supplier hosted	TSO3: National data centre - NWIS hosted	TSO4: Local data centres – Health Boards
	Capital costs reduced as this option would be revenue funded.	infrastructure (racks, networking etc.); National data centres are connected directly to the PSBA network.	Supplier would manage the software environment.	
Disadvantages (Weaknesses and threats)	<p>Potential cost;</p> <p>Data would not be directly within NHS control although this would be controlled via the contract and service levels;</p> <p>Risks around service provision including potential loss of service and data from a technical perspective;</p> <p>Supplier would need to provide a connection to the PSBA<sup>6</sup> network from their data centre.</p> <p>Suppliers would have to comply with national standards for information governance and security such as the National Cyber and Security Centre Health and Social Care cloud Security - Good Practice Guide.</p>	<p>Supplier would need access to the national data centers;</p> <p>Access issues e.g. firewall, integration.</p> <p>Supplier may be constrained by the capacity available in the national data centers;</p> <p>Service may be impacted by NWIS work in the data centers.</p> <p>Potential supplier / NWIS conflict.</p>	<p>NHS resource heavy;</p> <p>Supplier would need access to the national data centers;</p> <p>Supplier may be constrained by the capacity available in the national data centers;</p> <p>NWIS required to manage the hardware environment with potential conflict with supplier over management of the software environment and where the boundaries between these responsibilities are divided, especially when incidents arise.</p>	<p>HBs unlikely to agree to their local data centres being used for a national system;</p> <p>LIMS is held in a single database, so it would not be technically feasible to host the software in disparate data centres.</p> <p>Separate HB instances to provide resilience within a national solution would still be managed via a single technical solution</p>

<sup>6</sup> Public sector broadband aggregation (PSBA) – the national network for the NHS, public sector and education services across Wales.  
Outline Business Case  
Author: Judith Bates

Technical Solution Options	TSO1: Supplier cloud hosted	TSO2: National data centre – Supplier hosted	TSO3: National data centre - NWIS hosted	TSO4: Local data centres – Health Boards
SO1: Patient care, safety & outcomes	Partial	Partial	Partial	No
SO2: Enable service transformation	Partial	Partial	Partial	No
SO3: Deliver end-to-end solution	Partial	Partial	Partial	No
SO4: More prudent use of resources	Partial	Partial	Partial	No
SO5: Meet current & future reqts	Partial	Partial	Partial	No
CSF1: Business needs	Yes	Yes	Yes	No
CSF2: Strategic fit	Yes	Yes	Yes	No
CSF3: Benefits optimisation	Partial	Partial	Partial	No
CSF4: Potential achievability	Yes	Partial	Partial	No
CSF5: Supply side capacity&capability	Yes	Partial	Partial	No
CSF6: Potential affordability	Partial	Partial	Partial	No
Conclusion	<b>Preferred</b>	<b>Possible</b>	<b>Carried Forward (benchmark)</b>	<b>Discounted</b>

## Configuration Options

There are two configuration options as listed below.

- **CON1: In-house Configuration (NWIS)** – NWIS to configure the application as part of the development of the solution;
- **CON2: Supplier Configuration** – The supplier to configure the application as part of the development of the solution.

## Evaluation of Configuration Options

Each configuration option is described in more detail in Table 12, which also provides an evaluation of the advantages and disadvantages of each and a comparison against spending objectives and critical success factors to determine whether the option is preferred, possible or discounted.

## Overall Conclusion: Configuration Options

In summary, the preferred option for configuration is Option 2: supplier configuration. Option 1 is carried forward as the BAU benchmarking option.

Table 12: Review of the Longlist Configuration Options

Configuration Options	CON1: In-house configuration (NWIS)	CON2: Supplier configuration
Description	NWIS application team to configure the application and other tailoring as part of the development of the solution to meet the Pathology service requirements.	The supplier to complete the entire configuration and other tailoring as part of the development of the solution to meet the Pathology service requirements.
Advantages (Strengths and opportunities)	Application team in place and have experience and knowledge of local requirements	Supplier has experience of the solution and how best to design and develop and efficient system to meet Pathology service requirements.
Disadvantages (Weaknesses and threats)	Limited resources and current team unable to complete all the changes required and in a constant cycle of development. Consequently current staff unable to take on any other development work due to configuration demands	Supplier does not have in depth knowledge of how the Pathology service works in Wales. May be more expensive.
<b>Match to Spending Objectives (SOs) and Critical Success Factors (CSFs) (Yes, No, Partial)</b>		
SO1: Patient care, safety and outcomes	Partial	Partial
SO2: Enable service transformation	Yes	Partial
SO3: Deliver end-to-end solution	Partial	Partial
SO4: More prudent use of resources	Partial	Yes
SO5: Meet current and future requirements	Partial	Yes
CSF1: Business needs	Yes	Partial
CSF2: Strategic fit	Partial	Yes
CSF3: Benefits optimisation	Partial	Yes
CSF4: Potential achievability	Yes	Yes
CSF5: Supply side capacity & capability	Partial	Yes
CSF6: Potential affordability	Yes	Partial
Conclusion	<b>Carried forward (benchmark)</b>	<b>Preferred</b>

## Service Delivery Options

The service delivery options are listed below and describe who will deliver the service solution, comprising a number of separate components as presented in Figure 11.

- **SDO1: In-house system delivery** – The NHS is responsible for the development of the LIMS system and its management in terms of updates, environment, integration & configuration and implementation;
- **SDO2: NHS service management** – the current service management model for WLIMS1, with most service management components provided by NWIS, only application development and third line support provided by InterSystems;
- **SDO3: Supplier partial service management** – some of the service management components, such as application management, being shared between the supplier and NHS Wales and second line support (in addition to ongoing development);
- **SDO4: Supplier total service management** – all of the service management components provided by the supplier with only NHS contract management governance processes in place to manage the supplier's performance against the contract.

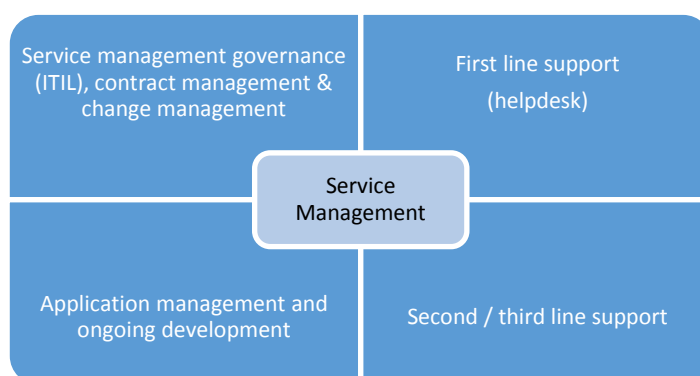


Figure 11: Service Management Components

## Evaluation of Service Delivery Options

Each service delivery option is described in more detail in Table 13, which also provides an evaluation of the advantages and disadvantages of each and a comparison against spending objectives and critical success factors to determine whether the option is preferred, possible or discounted.

## Overall Conclusion: Service Delivery Options

In summary, the preferred option for service delivery is Option 3: Supplier partial service management. Option 2 is carried forward as the BAU option for benchmarking purposes. Option 4 is possible and Option 1 is discounted.

Table 13: Review of the Longlist Options for Service Delivery (SDO)

Service Delivery Options	SDO1: In-house service delivery	SDO2: NHS service management	SDO3: Supplier partial service management	SDO4: Supplier total service management
Description	The NHS is responsible for the development of the LIMS system and all service management including updates, environment, integration, configuration and implementation.	The NHS procures a system licence but then takes responsibility for managing the system, its configuration, integration and environment and support. The supplier provides LIMS updates to the NHS to apply. This is the current model for WLIMS1	NHS procures a service, which the supplier initially develops and configures but ongoing service management is divided between the supplier and the NHS.	The NHS procures a service totally supported by the supplier with no in-house service management only contract management.
Advantages (Strengths and opportunities)	NHS has total control of the development and management of the solution.	NHS controls the management of the solution.	NHS can choose what services to manage and which the supplier will manage. This option is potentially more responsive to change.	NHS has no responsibilities and all services are provided by the supplier directly to the service; The quality of the service is managed by the service levels in the contract, with financial incentives to meet the required standards.
Disadvantages (Weaknesses and threats)	The NHS could not develop a Pathology solution, as it is far too complex and would take an inordinate amount of resources and time; This solution is not feasible.	Conflict between NWIS, the service and the supplier arise because of difficulties in managing the supplier relationship, especially when incidents arise.	The NHS will need to resource the skills required to manage the services being provided by the NHS. Local resources will be required in each HB.	This is likely to be more expensive and dependent on the quality of the supplier's service management. The NHS would have no direct control over the system.

Service Delivery Options	SDO1: In-house service delivery	SDO2: NHS service management	SDO3: Supplier partial service management	SDO4: Supplier total service management
<b>Match to Spending Objectives (SOs) and Critical Success Factors (CSFs) (Yes, No, Partial)</b>				
SO1: Patient care, safety and outcomes	No	Partial	Partial	Partial
SO2: Enable service transformation	No	Partial	Partial	Partial
SO3: Deliver end-to-end solution	No	No	Partial	Partial
SO4: More prudent use of resources	No	Partial	Partial	Partial
SO5: Meet current and future requirements	No	No	Yes	Partial
CSF1: Business needs	No	No	Yes	Yes
CSF2: Strategic fit	No	No	Partial	Partial
CSF3: Benefits optimisation	No	No	Partial	Partial
CSF4: Potential achievability	No	Partial	Yes	Yes
CSF5: Supply side capacity & capability	No	No	Yes	Partial
CSF6: Potential affordability	No	No	Yes	Partial
Conclusion	<b>Discounted</b>	<b>Carried forward (benchmark)</b>	<b>Preferred</b>	<b>Possible</b>

## Implementation Options

The implementation options examine the various approaches to implementation once the chosen system has been designed, developed and tested for Wales including integration with the national technical platform and signed off as ready to deploy in all disciplines as listed below:

- **IMP1: All disciplines phased by site** – all disciplines deployed one laboratory at a time;
- **IMP2: All disciplines phased by health board** – all disciplines deployed one health board but phasing designed to best meet the needs of the HB;
- **IMP3: Phased by discipline per health board** – service rolled out one discipline at a time phased by health board followed by the next discipline;
- **IMP4: Phased by discipline nationally** – one discipline rolled out across all health boards at the same time;
- **IMP5: Big bang approach** – all disciplines rolled out across all health boards at the same time.

## Evaluation of Implementation Options

Each implementation option is described in more detail in Table 14, which also provides an evaluation of the advantages and disadvantages of each and a comparison against spending objectives and critical success factors to determine whether the option is preferred, possible or discounted.

## Overall Conclusion: Implementation Options

In summary, the preferred option for implementation is Option 2: phased by health board, which is also the BAU option for benchmarking purposes. Option 3 is possible but will take a long time to deliver and require more resources as evidenced by the roll out of WLIMS1. Options 1, 4 and 5 have been discounted.



Table 14: Review of the Longlist Options for Implementation

Implementation Options	IMP1: All disciplines phased by site	IMP2: All disciplines phased by HB	IMP3: Phased by discipline by HB	IMP4: Phased nationally by discipline	IMP5: Big bang
Description	Implement all disciplines for all laboratories on a single site at a time.	Implement all disciplines for all laboratories a single HB at a time	Implement one major discipline in one HB at a time	Deploy one discipline at a time nationally, so sites at the same time.	Deploy all disciplines for all laboratories across Wales at the same time.
Advantages (Strengths and opportunities)	Resources could be concentrated on one site; Laboratories can go live at each site and issues addressed before moving onto the next site; If problems encountered rollback would be simpler.	Laboratories can go live within each health board and issues addressed before moving onto the next health board; Standardised reporting at one HB achievable on the same day; Processes same for all HB services; Implementation team can be concentrated at one HB; Path towards national implementation would be shorter.	This would enable concentration of resources on one discipline; If a problem with one discipline, it would not affect the others; This model was tested with WLIMS1 implementation. Health Boards do not have to provide such a high level of IT support at the same time.	A problem in one discipline would not affect another discipline. HBs would not have to provide IT support to all disciplines at the same time. Only 6 discipline implementations Workflow within disciplines across other Welsh laboratory sites would not be significantly disrupted.	Standardised system delivered on the same day; Can refer samples between HBs immediately and manual interim arrangements not required; Dual running is not required once the new LIMS goes live; All requesting and results are to and from the same system reducing interim management of interfaces.
Disadvantages (Weaknesses and threats)	HBs working as hub and spokes would not be able to transfer work or function; Patient safety issues; With ~ 30 sites, would take a very long implementation	Referred work affected between HBs but could use NPEX as an interim solution; Problems with implementation would affect the whole HB – A problem with one	~30 implementation phases, so it would take longer and cost more in terms of supplier and programme team resources; Unable to refer work between	The Model would have not been tested. The supplier may have resource implications to support all sites at one time. There would be patient safety implications if a	High risk strategy, could affect all Pathology services nationally; Resource implications to support all sites at the same time; Patient safety compromised if

Implementation Options	IMP1: All disciplines phased by site	IMP2: All disciplines phased by HB	IMP3: Phased by discipline by HB	IMP4: Phased nationally by discipline	IMP5: Big bang
	phase to achieve a national system; Most laboratories across a HB are interdependent and would have to go live at the same time.	discipline would affect all disciplines; Each HB needs resources to go live across all disciplines on all its sites including IT support.	HBs. Could use NPEX as an interim solution; May affect cross-discipline working and interdependencies	whole discipline across Wales failed, roll back to existing LIMS and back up of data would be compromised.	implementation fails- roll back and back up compromised.
<b>Match to Spending Objectives (SOs) and Critical Success Factors (CSFs) (Yes, No, Partial)</b>					
SO1: Patient care, safety & outcomes	No	Yes	Yes	No	No
SO2: Enable service transformation	No	Partial	No	No	No
SO3: Deliver end-to-end solution	No	Partial	Partial	Partial	Yes
SO4: More prudent use of resources	No	Partial	Partial	Partial	Partial
SO5: Meet current & future reqts	No	Yes	Partial	Partial	Yes
CSF1: Business needs	No	Partial	Partial	Partial	Partial
CSF2: Strategic fit	No	Partial	Partial	Partial	Partial
CSF3: Benefits optimisation	No	Partial	Partial	Partial	Partial
CSF4: Potential achievability	No	Yes	Partial	No	No
CSF5: Supply side capacity&capability	Yes	Yes	Partial	No	No
CSF6: Potential affordability	Yes	Yes	Partial	Partial	No
Conclusion	<b>Discounted</b>	<b>Preferred (benchmark)</b>	<b>Possible</b>	<b>Discounted</b>	<b>Discounted</b>

#### 4.4. The Long List of Options: Summary of Inclusions and Exclusions

The long list has appraised a wide range of possible options, summarised as summarised in Table 15.

Table 15: LINC Long List of Options: Summary of Inclusions and Exclusions

Category	Title	Conclusion
<b>Scoping Options</b>		
SCO1	Business as usual	Discounted
SCO2	Do Minimum	Discounted
SCO3	Intermediate	Preferred
SCO4	Maximum	Possible
<b>Service Solution Options</b>		
SSO1	Local LIMS for each health board	Discounted
SSO2	Best of breed LIMS per main discipline	Discounted
SSO3	Separate Cellular Pathology LIMS	Possible
SSO4	Single, national LIMS	Preferred
<b>Technical Solution Options</b>		
TSO1	Supplier cloud hosted solution	Preferred
TSO2	National data centre – supplier hosted	Possible
TSO3	National data centre – NWIS hosted	Discounted
TSO4	Local data centres – Health Boards	Discounted
<b>Configuration Options</b>		
CON1	In-house configuration (NWIS)	Possible
CON2	Supplier configuration	Preferred
<b>Service Delivery Options</b>		
SMO1	In-house system delivery	Discounted
SMO2	NHS service management	Discounted
SMO3	Supplier partial service management	Preferred
SMO4	Supplier total service management	Possible
<b>Implementation Options</b>		
IMP1	All disciplines phased by site	Discounted
IMP2	All disciplines phased by HB	Preferred
IMP3	Phased by discipline by HB	Possible
IMP4	Phased nationally by discipline	Discounted
IMP5	Big bang	Discounted

#### 4.5. Short-Listed Options

The summary of the long-list using the options framework has been used to map option choices into a summary of the shortlist as shown in Table 16.

Table 16: LINC Long List of Options mapped to the Shortlist

Longlist of Options		Shortlist of Options		
		1. BAU	2. Do minimum	3. Preferred approach
<b>Scope Options (SCO)</b>				
SCO1	Business as usual	BAU		
SCO2	Do minimum		Upgrade	
SCO3	Intermediate			Intermediate
<b>Service Solution Options (SSO)</b>				
SSO4	Single, national system	BAU	BAU	BAU
<b>Technical Solution Options (TSO)</b>				
TSO1	Supplier hosted solution			Supplier hosted
TSO2	National data centre – supplier hosted		NDC Supplier hosted	
TSO3	National data centre – NWIS hosted	NDC NWIS hosted		
<b>Configuration Options (CON)</b>				
CON1	In-house configuration (NWIS)	Not applicable		
CON2	Supplier configuration		Supplier config.	Supplier config.
<b>Service Delivery Options (SMO)</b>				
SMO1	NHS service management	NHS service management		
SMO3	Supplier partial management		Supplier partial SM	Supplier partial SM
<b>Implementation Options (IMP)</b>				
IMP2	Phased by health board	Not applicable		Phased by HB
IMP3	Phased by discipline per HB		Phased by discipline per HB	

The shortlisted options comprise:

- A **business as usual** option, to upgrade to InterSystems TCL 2016, for benchmarking purposes;
- A **do minimum** option, to agreement a new contract with InterSystems for TCL Enterprise without a procurement;
- A **preferred approach** using the preferred longlist options across all categories.

### Option 1 – Business as Usual

This option, to upgrade to TCL 2016, provides the benchmark for value for money and is predicated upon the following parameters:

- **Scope:** Option 1 of the scope options in terms of the capability of TCL 2016. The upgrade will be kept to a minimum to keep costs as low as possible and implement as quickly as possible;
- **Solution:** Upgrade to TCL 2016 and use this version until 2027;
- **Service delivery:** The same as at present with NWIS hosting the service and InterSystems providing software updates and third line support. There will be no changes to the method of integration to clinical, downstream systems;
- **Implementation:** The upgrade is anticipated to take 18 months from January 2019 to June 2020. Most of the work during 2019/20 will be behind the scenes with go live across the whole service at the same time between April and June 2020;
- **Funding:** The costs of the upgrade are unknown at this stage, but a notional capital cost of £2.5m has been assumed. This is deemed to be a sunk cost to the LINC Programme. NWIS will take the lead on securing funding and delivering the upgrade as part of the management of WLIMS1. WLIMS1 apportionment method will continue. However, the costs payable to InterSystems may increase after the current contract expires in June 2020.

It has been suggested that given the cost and effort required to undertake the upgrade, that the service should get some benefit by using the system for some time before replacing with a new LIMS and therefore delaying the procurement. However, delaying the procurement is not recommended because:

- It is already known that there will be minimal operational benefits from the upgrade. For example, there is no evidence to suggest that there will be an improvement in poor functionality such as document scanning and voice recognition;
- The current complex configuration will just be copied over with no opportunity to streamline the improve standardisation;
- Although there is an improvement in business intelligence capability with DeepSee 2, InterSystems proposal is to just copy across the current reporting, so there would be no immediate benefits;
- The upgraded solution will be required until the new LIMS is fully deployed anyway, which is anticipated to be for a minimum of three years until March 2023 if the deployment is completed to time;
- The health boards are under considerable financial pressure to deliver efficiency savings. The new LIMS is an enabler to deliver an efficient solution that will deliver financial benefits. A delay in the procurement will delay the realisation of these financial benefits;
- TCL 2016 is also an old system now and InterSystems has stated that it will not be supported after 2025, so if there is a delay in deployment of the new LIMS, NHS Wales could be in the same position as it is now with TCL 2011;

- Delay in the procurement will compromise the transformation of Pathology services as set out in the Pathology Statement of Intent.

In terms of providing a viable option for the business case, this option is risky because it does not involve going out to procurement and the service is at risk of challenge. Moreover, the solution does not provide a modern platform to support the delivery of the spending objectives and the development of a modern, sustainable Pathology service.

### ***Option 2 – Do Minimum Option***

This option is to negotiate a new contract with InterSystems to take TCLE without a procurement:

- **Scope:** Option 2 of the scope options subject to clarification with InterSystems about what can be delivered by TCLE. It is not currently live in the UK, so the scope has not been assessed;
- **Solution:** Implement TCLE after taking the TCL 2016 upgrade;
- **Service delivery:** InterSystems take over the hosting of the service in an NHS data centre but, otherwise the same application support arrangements remain;
- **Implementation:** Upgrade to TCL2016 by June 2020, then InterSystems has indicated that TCLE will go live by the end 2023;
- **Funding:** Indicative costs for the option have been assessed and will require capital and revenue funding.

In addition to proving a compliant, supported solution, the upgrade should improve performance and stability. However, like option 1, this option is risky because it does not involve going out to procurement and the service is at risk of challenge. NHS Wales is also a hostage to fortune as InterSystems offering will not have been tested against the market. Although the cost of the core LIMS may look cheaper, the incremental costs of the wider LIMS solution including other tools may easily result in the overall costs being greater than a procured solution.

### ***Option 3 – The preferred approach***

This option using the preferred longlist options across all categories considered:

- **Scope:** Option 3 of the scope options providing intermediate scope;
- **Solution:** The procurement of a new LIMS service;
- **Service delivery:** Hosting provided by the new LIMS supplier combined with partial service management but with more support from the LIMS supplier than presently provided;
- **Implementation:** The service would be developed, tested and validated for the whole of Wales and then deployed in across Wales one health board at a time;

- **Funding:** The costs are based on a capital / revenue model in accordance with IRFS16 definition of assets in a managed service. The costs of the preferred option were considered and approved in principle by the NHSW CEG at its meeting on 23 October 2018.

#### 4.6. Economic Appraisal

This section provides an explanation of the general approach taken with regard to the identification and calculation of the costs and benefits shown within the economic appraisals. They cover the seven-year contract period of 2020/21 to 2026/7.

#### 4.7. Estimating Benefits

Benefits, set out in Table 17 have been developed through a series of workshops during 2018:

- A business case workshop on 23 January reviewed the WLIMS1 benefits and proposed additional benefits for the new LIMS;
- Discipline specific workshops identified further potential benefits;
- A benefits workshop on 27 June refined the benefits and how they will be measured, baselined and whether they are Financial (cash releasing), Economic (financial non-cash releasing) or Qualitative;
- A workshop on 17 August evaluated the outcomes arising from the spending objectives in relation to following strategic benefits;
  - Patient safety increased
  - Positive patient outcome increased
  - Convenience of care increased
  - Patient confidence increased
  - Legal / policy compliance increased
  - Health system efficiency increased
  - Overall health system costs decreased
- A workshop on 8 October to financially quantify the benefits.

The financial quantification of benefits has proven difficult due to the lack of comparative data available. It was therefore decided to assess the potential financial benefits based on possible savings in the overall cost of the pathology service. This seemed like a realistic approach as, in England, the aim is to reduce the cost of pathology services from 1.9% to 1.6% of the overall NHS budget. As an enabling programme, LINC could not deliver all of these savings but could contribute to them.

Although, the total cost of the Pathology service is not readily available, 1.9% of the total allocation of £6,185 million revenue monies to Welsh Health Boards and Trusts in 2018/9 is equates to £118m. The NHS Wales Collaborative Executive Group at its meeting on 20 November 2018 asked that the financial benefits be considered in three levels:

- Benefits from electronic test requesting (reduced administrative costs);
- Benefits from improve demand management and business intelligence (reduced number of repeat requests);
- Benefits from the wider improvement in clinical pathways and patient outcomes (such as diagnosing cancer at an earlier stage reducing the cost of treatment and improving patient outcomes).

For the purpose of this OBC therefore, the financial benefits have been estimated as 3% of the cost of the Pathology Service, which equates to £4 million per annum, equally divided across each benefit level. This level of saving is considered achievable. For example, electronic test requesting will reduce the number of administrative staff required to book in tests manually and to scan paper requests into the patient record. Keele benchmarking data for each health board in Wales<sup>7</sup> during 2016/7 identifies that £4.7m is being spent on '*Other Staff*', the bulk of which are the administrative staff in Pathology. One Health Board alone has identified a potential saving of £436k per annum; the cost of halving the number of band 2 two administrative staff (from 40 to 20 staff).

A benefits realisation strategy will be developed to better define and deliver the benefits identified. The possibility of working with the academic sector develop robust mechanisms for defining and realizing benefits will be explored, especially in relation to wider clinical pathways. A LINC Benefits Project will be established to take this work forward and an improved assessment of benefits will be included in the LINC Full Business Case.

In terms of each of the shortlisted options, the extent to which they could deliver these benefits has been explored:

- **Option 1 Business as Usual:** This could deliver up to 1% of the savings identified due to electronic test requesting, given that the upgrade proposed by InterSystems includes no change in the solution per se.
- **Option 2 Do Minimum:** Based on the scope of the recent proposal from InterSystems in relation to the option to taking TCLE, this will not match the Intermediate scope proposed in the preferred option. It is therefore estimated that a possible 2% of the savings could be achieved by this option.
- **Option 3 Preferred Approach:** It was considered that the preferred approach had the potential to deliver all 3% of the potential savings.

It should be noted that NIMB has requested that the benefits work be evaluated more thoroughly for inclusion in the next version of the OBC.

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<sup>7</sup> HBs not submitting benchmarking data to Keele completed the Keele template to provide the data for the analysis of the apportionment of costs for the new LIMS service.



Table 17: LINC Benefits

Benefit ID	Benefit Description	How Measured	Comment	Benefit Type	Data Source (tbc)	Target (tbc)
<b>Patient safety increased</b>						
B1	Improved clinical safety	Clinical incidents reduced	Reduction in in the number of incidents where patient outcomes have been compromised that involve wholly or in part pathology investigations e.g. Delays in treatment. There is a potential financial risk if HB are sued for a clinical incident.	Qualitative	Datix incidents	Halve
B2	Improved service performance	Turnaround times measured according to national definition	Reduce breaches in targets e.g. ED waiting times.	Qualitative	Current TATs	95% within time
B3	Reduced transcription errors	Proportion of tests ordered electronically	Reduce errors due to manual booking in from handwritten forms. Dependent electronic requesting	Qualitative	Datix incidents	Zero
B4	Safer LIMS environment	Automated environment synchronisation	WLIMS1 environments no longer manually synchronised reducing errors.	Economic	Manual	Time saved
<b>Positive patient outcome increased</b>						
B5	Paperless reporting	Time saved in costs on administration, transport, paper & ink	Paperless reporting requires that assurance that all results are reviewed and appropriate action taken. Would be delivered by development in the WCP	Qualitative & Financial	Audit	All results have auditable actions logged on the system.
<b>Convenience of care increased</b>						
B6	Mobile access to results	Measure number of requesters that can access results from any location.	Dependent on WCP being available on tablets or phones.	Economic	Not available	Mobile access working for those that require it.
B7	Vein-to-vein blood tracking solution	Reduction in nursing time	Two nurses are currently needed to check blood before being transfused, but with a vein-to-vein solution, only one nurse is required,	Economic	Audit	Saved nursing time
B8	Improved clinical decision making	Enhanced patient notepad functionality		Qualitative	User survey	Improved user satisfaction

Benefit ID	Benefit Description	How Measured	Comment	Benefit Type	Data Source (tbc)	Target (tbc)
<b>Patient confidence increased</b>						
B9	Improved service quality	Reduced repeat requests	Currently there are 1200 repeat requests per week in C&V UHB alone. This will be delivered via improved demand management.	Economic	Audit needed	Halve
B10	Improved sample traceability	Fewer incidents from missing samples	Full end-to-end traceability of samples via phlebotomy module, electronic requesting and LIMS audit capability.	Qualitative	Datix QMS	Zero
<b>Legal / policy compliance increased</b>						
B11	Reduction in validation costs	Reduced number of test assessments to meet validation requirements	Validation required for MHRA	Financial	Audit of WLIMS1	Halve
B12	Improved document management	Duplicated controlled documents, documents past review date.	Requires enterprise QMS to be in place, but will allow central management of standardised documentation.	Qualitative	Qpulse documents	Halve
B13	Automated testing	Time taken to make configuration changes	No workarounds whilst change is being implemented.	Qualitative	Service Point records	Define standards
<b>Health system efficiency increased</b>						
B14	Mobile access to results	Reduced calls to the labs for results	Dependent on WCP being available on tablets	Economic	Needs audit	Halve
B15	Time saved in scanning forms	Number of forms scanned per agreed time period	A quicker process for scanning forms would release staff time from one to several hours per day per staff member per site. This could release sizeable savings across Wales.	Economic	Needs audit	Halve
B16	Improved cross site working	Ability to validate and report on samples analysed from any site	Currently unable to do this, without being given access to another user site by permission and changing the site logged into on the system.	Economic	Not available	Can do
B17	Improved efficiency	Reduced login time	Currently have to login in twice and can take 20 mins or more	Economic	Needs audit	<1 minute
B18	Increased availability of the system	Hours downtime per quarter	Down time to consider any issue with system that has implicate workflow e.g unable to book in samples.	Economic	WLIMS1 baseline data	100%

Benefit ID	Benefit Description	How Measured	Comment	Benefit Type	Data Source (tbc)	Target (tbc)
<b>Patient confidence increased</b>						
<b>Overall health system costs decreased</b>						
B19	Sustainable pathology service	Overall costs of pathology service	The target in England is 1.6%. This OBC can contribute to but not deliver the whole target.	Financial	1.90%	1.80%
B20	Improved income from referrals	Number and value of referrals outside Wales	Use of NPEx for referrals in and out of Wales and internally for specialist services, like Medical Genetics.	Financial	Needs audit	Generate income
B21	Minimal downtime	Less overtime paid per month	WLIMS1 significant downtime being experienced in a month	Financial	HBs estimate of overtime paid	No overtime paid
B22	Reduction in integration costs to downstream systems	Reduced number of direct connections to downstream systems	Need to put in place a different approach to integration and review business need for integration to individual downstream systems and, where possible, use WCP instead.	Financial	Cost per interface	2 interfaces per HB
B23	Automated sample tracking	% samples tracked online	Dependant on available data that can be sent from analyser middleware	Financial	Audit	0.25 WTE per lab
B24	Reduced manual booking in of samples	Reduction of reception staff.	Significant benefits in efficiency and data quality. Taken to the limit can include auto receipting of samples using analyser pre analytical equipment.	Financial	Current costs	Halve current costs (WTE) of staff used to book in samples using manual methods.

## 4.8. Estimating Costs

In accordance with the business case guidance, these figures exclude VAT, capital charges and inflation, other than staffing costs where increments have been included for costs based on mid-point of the banding scales and 1% annual pay rises. The costs are presented using a capital / revenue funding model and relevant notes are listed in [Appendix 11](#).

### *Option 1 Costs*

The costs of Option1: Business as usual is presented in Table 18 and acts as a benchmark for the other options. The costs cover the period June 2020 – March 27 from the end of the current contract with InterSystems. This totals £24.4 million revenue plus £2.5 million capital for the upgrade, a total of £26.9 million. This represents the cost of the maintaining TCL 2016 from the end of the current contract for the life of the OBC. It does not allow for any increase in InterSystems charges and assumes that all health boards are live with all TCL modules and not continuing to maintain Telepath or Masterlab.

### *Option 2 Costs*

The estimated costs of Option 2: Do minimum, to negotiate an agreement with InterSystems to take TCLE without a procurement is £32.7 million plus £11 million capital a total of £43.7 million. These costs are detailed in Table 19, which includes:

- The dual running costs of the current solution for three years from June 2020 until June 2023;
- The costs of TCLE including the costs of InterSystems taking over the management of the hosting arrangements from NWIS, based on indicative costs included in the recent proposal to NWIS;
- Integration services;
- Legacy data (considered to be lower in this option as InterSystems has already developed a legacy database);
- Scanning, dictation and voice recognition;
- Blood tracking with remote issue
- Using NPEx to manage referrals in and out of Wales
- Electronic test requesting as an optional extra;
- NWIS support costs;
- National quality management team and system.

### *Options 3 Costs*

The costs of Option 3, the preferred approach to procure a new LIMS is £37.3 million revenue and £8 million capital, a total of £45.3 million. These costs are presented in Table 20 and include the same as Option 2, other than the cost of the new LIMS service, which is based on market soundings carried out in January 2018.

Table 18: Costs of Option 1: Business as usual (TCL 2016)

Notes Ref	Resource	Grade	Apr 19 - Mar 20 £k	Apr 20 - Mar 21 £k	Apr 21 - Mar 22 £k	Apr 22 - Mar 23 £k	Apr 23 - Mar 24 £k	Apr 24 - Mar 25 £k	Apr 25 - Mar 26 £k	Apr 26 - Mar 27 £k	Total Cost £k
<b>1</b>	<b>TCL 2016 costs wef June 2020</b>										
2	TrakCare technical assistance & software updates			1,296	1,667	1,667	1,667	1,667	1,667	1,667	11,301
3	Third party validation services			30	40	40	40	40	40	40	270
3	NWIS Hosting environment and support			236	315	315	315	315	315	315	2,128
3	Infrastructure - third party maintenance			622	830	830	830	830	830	830	5,599
3	National service desk / service management			69	92	92	92	92	92	92	623
3	NWIS Technical Support (analysts/development/integration & test)			495	660	660	660	660	660	660	4,454
	<b>Total Option 1 (BAU) Revenue</b>			<b>2,749</b>	<b>3,604</b>	<b>3,604</b>	<b>3,604</b>	<b>3,604</b>	<b>3,604</b>	<b>3,604</b>	<b>24,375</b>
<b>4</b>	<b>Upgrade to TCL 2016</b>										
	Capital cost of upgrade			2,500							2,500
	<b>Grand Total (Option 1 BAU) Capital and Revenue</b>		<b>0</b>	<b>5,249</b>	<b>3,604</b>	<b>3,604</b>	<b>3,604</b>	<b>3,604</b>	<b>3,604</b>	<b>3,604</b>	<b>26,875</b>

Table 19: Costs of Option 2: Do Minimum (TCLE)

Notes Ref	Option 2: Do Minimum Resources	Grade	Apr 19 - Mar 20 £k	Apr 20 - Mar 21 £k	Apr 21 - Mar 22 £k	Apr 22 - Mar 23 £k	Apr 23 - Mar 24 £k	Apr 24 - Mar 25 £k	Apr 25 - Mar 26 £k	Apr 26 - Mar 27 £k	Total Cost £k
<b>1</b>	<b>Pathology Solution</b>										
<b>2</b>	<b>TCL 2016 dual running costs wef June 2020</b>										
3	TrakCare technical assistance & software updates			1,296	1,728	1,728	432				<b>5,184</b>
4	Third party validation services			30	40	40	10				<b>120</b>
4	NWIS Hosting environment and support			236	315	315	79				<b>946</b>
4	Infrastructure - third party maintenance			622	830	830	207				<b>2,489</b>
	National service desk / service management			69	92	92	23				<b>277</b>
	NWIS Technical Support (analysts/development/integration & test)			495	660	660	165				<b>1,979</b>
	<b>Total (TCL 2016 dual running costs)</b>		<b>0</b>	<b>2,749</b>	<b>3,665</b>	<b>3,665</b>	<b>916</b>	<b>0</b>	<b>0</b>	<b>0</b>	<b>10,995</b>
<b>5</b>	<b>TCLE - InterSystems hosted service in NHS data centre</b>										
6	InterSystems hosting costs				775	1,550	1,550	1,550	1,550	1,550	<b>8,525</b>
7	Integration costs			500	1,000						<b>1,500</b>
8	Legacy data			250	750						<b>1,000</b>
9	Scanning system				23	45	45	45	45	45	<b>248</b>
10	Voice recognition				10	20	20	20	20	20	<b>110</b>
11	Blood tracking				12	24	24	24	24	24	<b>132</b>
12	NPEX (for sendaways)			45	15	30	30	30	30	30	<b>210</b>
13	Electronic test requesting			500	88	175	175	175	175	175	<b>1,463</b>
	<b>Total (TCLE - InterSystems hosted service in NHS data centre)</b>		<b>0</b>	<b>1,295</b>	<b>2,672</b>	<b>1,844</b>	<b>1,844</b>	<b>1,844</b>	<b>1,844</b>	<b>1,844</b>	<b>13,187</b>
<b>14</b>	<b>NWIS Support Costs</b>										
15	Change management		50	50	100	100					<b>300</b>
16	Change budget for new LIMS						100	100	100	100	<b>400</b>
17	National service desk / service management						69	92	92	92	<b>346</b>
18	NWIS Technical Support (analysts/development/integration & test)						495	660	660	660	<b>2,474</b>
19	Senior Support and Business Analyst (NODi)	6 (M-P)	39	41	42	43	46	47	47	48	<b>353</b>
20	Principal Support & Business Analyst (Integration)	7 (M-P)	48	50	52	54	55	55	56	57	<b>427</b>
21	Senior Software Developer (Integration)	6 (M-P)	39	41	42	43	46	47	47	48	<b>353</b>
22	Technical Architect (Applications Design)	8b (M-P)	69	73	76	76	77	78	79	80	<b>607</b>
	<b>Total (NWIS Support Costs)</b>		<b>246</b>	<b>254</b>	<b>311</b>	<b>318</b>	<b>889</b>	<b>1,079</b>	<b>1,081</b>	<b>1,084</b>	<b>5,261</b>
<b>23</b>	<b>National Quality Management Team &amp; System</b>										
24	Quality management system		220	37	37	37	37	37	37	37	<b>479</b>
25	Quality Manager / Validation Lead	8a (Top)	63	64	64	65	66	66	67	68	<b>523</b>
25	Validation Officer	7 (M-P)	48	50	52	54	55	55	56	57	<b>427</b>
25	QMS Configuration Librarian	6 (M-P)	39	41	42	43	46	47	47	48	<b>353</b>
25	Administrative Support Officer	4 (M-P)	27	28	28	29	30	30	30	31	<b>234</b>
26	UAT Tester x 2	6 (M-P)	39	41	42	43	46	47	47	48	<b>353</b>
27	Informatics Manager	8a (Top)	63	64	64	65	66	66	67	68	<b>523</b>
27	Informatics Officer	6 (M-P)	39	41	42	43	46	47	47	48	<b>353</b>
	<b>Total (National Quality Management Team &amp; System)</b>		<b>540</b>	<b>364</b>	<b>372</b>	<b>381</b>	<b>392</b>	<b>395</b>	<b>399</b>	<b>403</b>	<b>3,245</b>
	<b>Total Option 2 (Do Minimum) Revenue</b>		<b>786</b>	<b>4,662</b>	<b>7,020</b>	<b>6,208</b>	<b>4,041</b>	<b>3,318</b>	<b>3,324</b>	<b>3,330</b>	<b>32,689</b>
	<b>Capital</b>										
28	InterSystems implementation costs as capital			4,200	6,813						<b>11,013</b>
	<b>Total Option 2 (Do Minimum) Capital</b>		<b>0</b>	<b>4,200</b>	<b>6,813</b>	<b>0</b>	<b>0</b>	<b>0</b>	<b>0</b>	<b>0</b>	<b>11,013</b>
	<b>Grand Total Option 2 (Do Minimum) Capital &amp; Revenue</b>		<b>786</b>	<b>8,862</b>	<b>13,833</b>	<b>6,208</b>	<b>4,041</b>	<b>3,318</b>	<b>3,324</b>	<b>3,330</b>	<b>43,702</b>

Table 20: Costs of Option 3 – Preferred Option

Notes Ref	Resource	Grade	Apr 19 - Mar 20 £k	Apr 20 - Mar 21 £k	Apr 21 - Mar 22 £k	Apr 22 - Mar 23 £k	Apr 23 - Mar 24 £k	Apr 24 - Mar 25 £k	Apr 25 - Mar 26 £k	Apr 26 - Mar 27 £k	Total Cost £k
<b>1</b>	<b>Pathology Solution</b>										
<b>2</b>	<b>TCL 2016 dual running wef June 2020</b>										
3	TrakCare technical assistance & software updates			1,296	1,728	1,728	432				<b>5,184</b>
4	Third party validation services			30	40	40	10				<b>120</b>
4	NWIS Hosting environment and support			236	315	315	79				<b>946</b>
4	Infrastructure - third party maintenance			622	830	830	207				<b>2,489</b>
4	National service desk / service management			69	92	92	23				<b>277</b>
4	NWIS Technical Support (analysts/development/integration & test)			495	660	660	165				<b>1,979</b>
	<b>Total (TCL 2016 dual running costs)</b>		<b>0</b>	<b>2,749</b>	<b>3,665</b>	<b>3,665</b>	<b>916</b>	<b>0</b>	<b>0</b>	<b>0</b>	<b>10,995</b>
<b>5</b>	<b>New LIMS Service supplier hosted in NHS data centre</b>										
6	New LIMS (VAT recoverable)				1,100	2,200	2,200	2,200	2,200	2,200	12,100
7	Integration costs			500	1,000						1,500
8	Legacy data			500	1,500						2,000
9	Scanning system				23	45	45	45	45	45	248
10	Voice recognition				10	20	20	20	20	20	110
11	Blood tracking				12	24	24	24	24	24	132
12	NPEX (for sendaways)			45	15	30	30	30	30	30	210
13	Electronic test requesting			500	88	175	175	175	175	175	1,463
	<b>Total (New LIMS Service supplier hosted in NHS data centre)</b>		<b>0</b>	<b>1,545</b>	<b>3,747</b>	<b>2,494</b>	<b>2,494</b>	<b>2,494</b>	<b>2,494</b>	<b>2,494</b>	<b>17,762</b>
<b>14</b>	<b>NWIS Support Costs</b>										
15	Change management		50	50	100	100					<b>300</b>
16	Change budget for new LIMS						100	100	100	100	<b>400</b>
17	National service desk / service management						69	92	92	92	<b>346</b>
18	NWIS Technical Support (analysts/development/integration & test)						495	660	660	660	<b>2,474</b>
19	Senior Support and Business Analyst (NODi)	6 (M-P)	39	41	42	43	46	47	47	48	<b>353</b>
20	Principal Support & Business Analyst (Integration)	7 (M-P)	48	50	52	54	55	55	56	57	<b>427</b>
21	Senior Software Developer (Integration)	6 (M-P)	39	41	42	43	46	47	47	48	<b>353</b>
22	Technical Architect (Applications Design)	8b (M-P)	69	73	76	76	77	78	79	80	<b>607</b>
	<b>Total (NWIS Support Costs)</b>		<b>246</b>	<b>254</b>	<b>311</b>	<b>318</b>	<b>889</b>	<b>1,079</b>	<b>1,081</b>	<b>1,084</b>	<b>5,261</b>
<b>23</b>	<b>National Quality Management Team &amp; System</b>										
24	Quality management system		220	37	37	37	37	37	37	37	<b>479</b>
25	Quality Manager / Validation Lead	8a (Top)	63	64	64	65	66	66	67	68	<b>523</b>
25	Validation Officer	7 (M-P)	48	50	52	54	55	55	56	57	<b>427</b>
25	QMS Configuration Librarian	6 (M-P)	39	41	42	43	46	47	47	48	<b>353</b>
25	Administrative Support Officer	4 (M-P)	27	28	28	29	30	30	30	31	<b>234</b>
26	UAT Tester x 2	6 (M-P)	39	41	42	43	46	47	47	48	<b>353</b>
27	Informatics Manager	8a (Top)	63	64	64	65	66	66	67	68	<b>523</b>
27	Informatics Officer	6 (M-P)	39	41	42	43	46	47	47	48	<b>353</b>
	<b>Total (National Quality Management Team &amp; System)</b>		<b>540</b>	<b>364</b>	<b>372</b>	<b>381</b>	<b>392</b>	<b>395</b>	<b>399</b>	<b>403</b>	<b>3,245</b>
	<b>Grand Total Option 3 (Preferred Approach) Revenue</b>		<b>786</b>	<b>4,912</b>	<b>8,095</b>	<b>6,858</b>	<b>4,691</b>	<b>3,968</b>	<b>3,974</b>	<b>3,980</b>	<b>37,264</b>
	<b>Capital</b>										
28	Hosting costs as capital			8,000							8,000
	<b>Total Option 2 (Do Minimum) Capital</b>		<b>0</b>	<b>8,000</b>	<b>0</b>	<b>0</b>	<b>0</b>	<b>0</b>	<b>0</b>	<b>0</b>	<b>8,000</b>
	<b>Grand Total Option 2 (Do Minimum) Capital &amp; Revenue</b>		<b>786</b>	<b>12,912</b>	<b>8,095</b>	<b>6,858</b>	<b>4,691</b>	<b>3,968</b>	<b>3,974</b>	<b>3,980</b>	<b>45,264</b>

#### 4.9. Quantifiable Risks

A workshop was held on 12 October to financially quantify the risks of each shortlisted option, based on:

- **Option 1: Business as usual**
  - Supplier sues for breach of contract as no procurement undertaken;
  - Supplier unable to deliver a fit for purpose solution within required timescales;
  - Each health board implementation takes longer than planned
  - System continues to have unplanned downtime;
  - Inadequate funding;
  - System no longer supported and have to take TCLE (as indicated will be the case by InterSystems after 2025).
- **Option 2: Do Minimum**
  - Supplier sues for breach of contract as no procurement undertaken;
  - Supplier unable to deliver a fit for purpose solution within required timescales;
  - Each health board implementation takes longer than planned
  - System continues to have unplanned downtime;
  - Inadequate funding;
  - Supplier costs are higher than indicated, because TCL is £1 million more per annum than anticipated in the WLIMS1 full business case and differential between recent indicative figures and original market soundings.
- **Option 3: Preferred Approach**
  - Supplier unable to deliver a fit for purpose solution within required timescales;
  - Each health board implementation takes longer than planned
  - System continues to have unplanned downtime;
  - Inadequate funding.
  - Supplier issues, potential re-procurement of system;
  - Supplier costs are higher than indicated but lower risk if a consequence of a procurement.

#### *Risk Summary and Analysis*

The risk evaluation is presented in Table 21 and the overall summary in Table 22. This demonstrates that the preferred approach is the least risk financially.





LINC Risk  
Evaluation 3Dec2018

Table 21: LINC risk evaluation

Table 22: Financial quantification of the risks

Quantifiable Risks			
	Option 1	Option 2	Option 3
	Business As Usual	Upgrade to 2016	Commercial Procurement
Estimated Financial Impact	£22,718,750	£14,400,000	£2,424,000
Rank			
(1 <sup>st</sup> = lowest risk)	3rd	2nd	1st

#### 4.10. Net Present Cost (NPC) Findings and Analysis

The NPC of each option has been calculated to establish the preferred option on an economic basis taking into account financial costs (excluding inter-governmental transfers such as VAT and depreciation), quantification of cash and non-cash releasing benefits, quantification of risks and discounting. The calculations are shown in [Appendix 12](#).

The overall position in terms of the NPC is set out in Table 23. This shows that although option 3 is the most expensive, taking account of benefits and risks, it has the least NPC.

Table 23: LINC OBC net present cost

Financial Details	Option 1: BAU	Option 2: Do Minimum	Option 3: Preferred Approach
	£k	£k	£k
Financial cost total	26,875	42,916	44,478
Optimism Bias @ 20%	0	8,583	8,896
<b>Total including optimism bias</b>	<b>26,875</b>	<b>51,499</b>	<b>53,374</b>
Quantification of benefits	-6,222	-12,444	-18,667
Risk Quantification	22,719	14,400	2,424
Total – Pre-Discounting	43,371	53,455	37,131
<b>Net Present Cost</b>	<b>40,105</b>	<b>51,447</b>	<b>35,713</b>

#### 4.11. The Preferred Option: Summary of Overall Findings

Because of this economic appraisal, Options 1 and 2 are rejected and option 3 is the preferred option.

The remainder of this OBC is based on option 3, the preferred approach to procure a new LIMS service.

## 5. The Commercial Case

The commercial case considers the commercial feasibility of the preferred option.

### 5.1. Procurement Scope

Based on an assessment of the current solutions available in this market, the procurement approach envisages a single supplier-provided solution with that supplier taking prime contract responsibility for in-scope aspects of the requirement. A service requirement is therefore under consideration whose key components would include:

- Provision, ongoing development, upgrade and maintenance of an All Wales Laboratory Information Management application;
- Development and testing of the solution by the Supplier, including system configuration;
- Deployment of the solution in NHS Wales clinical and laboratory environments and any other hosting locations;
- Seamless end-to-end solution covering electronic requesting and reporting;
- Supplier managed hardware and software environments:
  - In NHS data centres or accredited data centre;
  - Using Welsh PSBA;
- Business intelligence and reporting tools.

The successfully procured solution will include the following core disciplines, broken down into more detail in the Pathology Overview **Error! Reference source not found.:**

- Andrology
- Blood Sciences
- Cellular Pathology
- Microbiology
- Screening services (Ante-natal, Cervical and New born blood spot)

The new LIMS will be a national application integrated with the national technical architecture to provide a seamless solution from requesting to reporting results.

The contract will be a managed service with one supplier responsible for the national application in partnership with NWIS for integration services.

## **5.2. Procurement Regulations**

As NHS Wales organisations are public sector bodies; all NHS Wales procurements must comply with Standing Orders and the Public Contracts Regulations 2015 (PCR2015).

Velindre NHS Trust is the host of the NHS Wales Informatics Service and will be the Contracting Authority for the purposes of this procurement.

Approval to proceed with any contract will be governed by the authorisation of a Full Business Case by the Welsh Government.

## **5.3. Procurement Strategy**

### **Purpose of the Procurement Strategy**

The purpose of the LINC Procurement Strategy is to set down in a formalised manner the key aspects of the scope of the procurement of the LIMS solution, including the route to market in accordance with Procurement regulations, the contractual form and the governance required to be established to ensure that a robust contract is developed. The strategy will enable the procurement to be planned and run in advance of final approval via a Full Business Case (FBC) so that all key issues have been considered and, where appropriate, decisions made on such key aspects. FBC approval will be managed in parallel with the final stages of the procurement so that it is obtained prior to the award of contract.

The Procurement Strategy will form an important part of the audit trail for this procurement as it sets out the strategic objectives of the procuring body in advance of the commencement of the formal process. The strategy was signed off at the LINC Programme Board.

### **Objectives of the Procurement**

The principle aim of the procurement is to procure a LIMS to replace the existing Legacy solution/s.

The objectives of the procurement are that the new LIMS will:

- Meet the identified functional characteristics and requirements
- Meet the investment objectives as set out in the business case
- Provide additional functional capabilities over the contract term (future proof the solution)
- Be interoperable with other national infrastructure, systems and services
- Provide value for money
- Meet national information and business strategies in accordance with Welsh Government strategies for health.

- Be implemented in a fully supported manner within the required timescale for migration off the existing legacy solution

### **Single Supplier versus Multiple Supplier**

Based on an assessment of the current solutions available in this market, the procurement approach envisages a single supplier-provided solution with that supplier taking prime contract responsibility for in-scope aspects of the requirement.

In line with the infrastructure strategy of NHS Wales, the solution will be hosted in either an NHS Wales data centre and delivered across NHS Wales' network infrastructure (currently provided by the Welsh Government's PSBA network) or an accredited datacentre. Solution delivery therefore has a 'multi-supplier environment' characteristic and it is thought efficient to procure the solution from a single prime supplier in order to achieve:

- A full end-end solution i.e. a managed service;
- Flexibility in bringing about business change-driven requirements for the solution and its development;
- Clear responsibility for integration and end-to-end delivery of the solution. This approach removes the risk of "boundary disputes" with other contractors.

### **Contract Duration**

The length of contract for the Laboratory Information Solution Procurement will be tailored to give best value for money for the project. The appropriate length will need to:

- Allow for adequate flexibility for the Authority during the investment life;
- Attract a sufficient range of bidders for the project;
- Enable a viable return on any investment;
- Ensure continuity of support as a minimum to achieve the potential; short to medium term aims of the Programme.

The OJEU will indicate a maximum length of contract of 14 years a minimum of 7 years (initially with options to extend on a year-by-year basis up to a maximum contract term of 14 years). Value for money will be tested on various options, which will be explored during the procurement phase. The subsequent contract will include benchmarking provisions to ensure that the Authority is able to secure benchmarking services from an independent contractor to assess that value for money is being achieved under the LIMS contract.

## **Contracting Approach**

The contract form of Agreement will be a Master Services Agreement, based on an amended form of the IT Services Contract having regard to the Crown Commercial Services and other best practice guidance of IM&T procurement.

Advice will be sought on the construction of the draft contract using the NHS Wales Informatics Service commercial, legal and technical advisers. Each health board will “call off” their requirements from the Master Services Agreement and via this process will execute their own distinct local contracts “Deployment Orders” with the Contractor.

## **Procurement Route**

The value of the procurement will exceed current EU thresholds of approximately £118,000.00 ex VAT, and therefore the procurement must comply with the Public Contracts Regulations 2015, including the requirement to place an advertisement in the Official Journal of the European Union. There are a number of procurement routes and procedures open to NHS Wales for procuring its clinical IT solutions, each is dependent upon the complexity of what is being procured. They are as set out below:

- Procurement under an existing Framework Agreement
- Open Procedure (OJEU)
- Restricted (OJEU)
- Competitive Dialogue Procedure (OJEU)

Following an evaluation of these alternative routes, undertaken by the Commercial Lead for this procurement, the LINC Programme Board has agreed that this requirement is procured under the Public Procurement Directives 2015 Competitive Dialogue Procedure. This procedure, according to the Public Contracts Regulations 2015, should be used in the case of particularly complex contracts, where purchasers may be well aware of their needs but not know in advance, what the best technical, legal or financial solution for satisfying those needs is.

The LINC Programme is keen to explore a range of technical solutions, in conjunction with suppliers, including the introduction of new and potentially innovative solutions, as well as ensuring that the most appropriate commercial deal is secured, and therefore considers the Competitive Dialogue appropriate for this requirement.

## **Procurement Approach**

The following is an outline of the basic procurement approach, which will be developed further in a more detailed Procurement Plan:

- 1) **Supplier engagement/ Market assessment** has been undertaken to validate the proposed approach and ensure an adequate level of interest, capability and capacity to deliver the requirements. Whilst a preliminary engagement has been undertaken, further presentation days will be required closer to the commencement of the formal procurement process. This approach will be supported through advertisements on national platforms and via the use of Social Media. Such events will be managed formally in line with the spirit of procurement regulations.
- 2) **Procurement training and awareness sessions** for key staff on an ongoing basis throughout the Competitive Dialogue process is a requirement. Initial briefing sessions will set the scene for ongoing training allowing the procurement team to ascertain the level of experience of this type of procurement and the amount of additional training that will be required. The Procurement team will augment such training with ongoing advice and attendance at key supplier meetings during the competitive procurement process.
- 3) **Contract Notice** – Issue of a Contract Notice to be placed in the OJEU under the Competitive Dialogue Procedure.
- 4) **Prequalification** – screening of responses to the Pre-Qualification Questionnaire will be undertaken with pre-qualification information to be received from candidates within 35 days of the issue of the Notice (in accordance with the statutory timescale of 30 days for the Notice). Assessment of pre-qualification information (to include details of previous relevant experience as well as financial and technical capability and capacity questions).
- 5) **An Invitation to Participate in Dialogue (ITPD)** will be issued to long-listed suppliers. The ITPD will require supplier responses to the Specification, initial pricing, Contract Terms and Conditions and Draft Contract Schedules and adherence to the Commercial Principles governing the procurement.
- 6) **ITPD Evaluation.** ITPD responses will be evaluated to arrive at a shorter list of suppliers. Reference checks will be included during this period. From this exercise, a final list of providers (anticipated to be four suppliers) will be invited to participate in the detailed dialogue process to develop a common set of contract schedules.
- 7) **Detailed Dialogue.** A second stage of dialogue with providers passing the first stage of the ITPD stage will be conducted to finalise draft contracts to an appropriate level and identify the commercial terms on which the solution would be provided. The draft contracts will be based on an amended version of the CCS standard form IM&T contract. It is anticipated that three suppliers will be taken forward to the Invitation to Submit Final Tenders Stage to maintain competition in the process and ensure that the Authority's options are not restricted prematurely.
- 8) **Trial Invitation to Submit Final Tender** will be issued in order to assess the readiness of suppliers to proceed to the final ISFT stage.

Submissions will not be formally evaluated but will be reviewed to ensure completeness and appropriate understanding of the Authority's requirements.

- 9) **Invitation to Submit Final Tender** is the stage at which bidders will provide their final tender and solutions.
- 10) **Final Tenders** will be evaluated and a most favoured tender selected based on the most economically advantageous tender.

Subject to fine-tuning and minor refinements concerning the final tender submission, if required, and approval of the Final Business Case, a contract will be awarded to the supplier with the most economically advantageous tender, executed, and come into force following the ten-day standstill period. The Award Notice will be placed within 48 days of the award decision.

### **Selection and Evaluation**

Selection and evaluation criteria will guide the evaluation at the three stages of the procurement:

- 1) PQQ responses;
- 2) Invitation to Participate in Dialogue (IPD) responses (Dialogue Stage);
- 3) Final Tenders (at the end of the Detailed Dialogue Stage)

In accordance with PCR 2015, all key documents for the procurement will be issued at the start of the procurement i.e. when the OJEU Advert is issued to the market.

### **Contract Award**

On conclusion of the ISFT phase and final evaluation of the ISFT responses, a recommendation will be made on the most economically advantageous tender. This recommendation will be recorded in a final evaluation report, which will set out the basis for the award decision and will require to be signed via the agreed governance process

Any award will be subject to a mandatory 10-day standstill period. Final award will also be subject to approval by the LINC Programme Board, the NHSW CEG, the CIO (Health)/Director of NWIS and the Velindre Trust Board. Full Business Case Approval and Notification will be required from the Welsh Government Cabinet Secretary for Sport, Health and Wellbeing.

Suppliers will be allowed an opportunity for a full debrief following the formal decision being ratified and approved.

Following the completion of the formal award process a Contract Award Notice will be placed in OJEU (Official Journal of the European Union).

## Risk Transfer

Project risks have already been documented as part of the preparation stage of the project. (See Project Risk register). Risk transfer as part of the contract will need to be identified as part of the dialogue process.

## Resources

The Head of Commercial Services, NHS Wales Informatics Service supported by appropriately experienced members of the Commercial Services team, will manage the procurement and specialist advisers sourced through external consultancy organisations if required.

With a procurement of this complexity, a Procurement Team will be created comprising suitably qualified and competent resources. NWIS Commercial Services has provided an estimate of costs for the external specialist advisers, which has been included in the costs for the economic analysis. It is likely that specific individuals will be involved across multiple activities and/or may undertake more than one role in order to ensure consistency and assist in securing an appropriately robust outcome. The combined staff and consultancy team will cover the following roles for the procurement:

- a) **NWIS Procurement Team:** comprising four full time staff, including administrative support for the procurement;
- b) **LINC Programme National Team:** comprising the Programme Director, Programme Manager, Senior Project Support Officer and Discipline Specific Subject Matter Experts. A full time Project Manager will be appointed to manage the Procurement Project and deliver the planned outputs as expected within quality, time and budget constraints;
- c) **Legal Advisers:** NWIS will utilise its current legal services provider, Blake Morgan LLP to provide the required legal advice;
- d) **Commercial Advisor:** This resource will be secured under a new contract via a competitive procurement process;
- e) **Laboratory Information Solution Subject Matter Experts:** Laboratory Scientists, who understand the requirements for the new LIMS and are experienced with the procurement of WLIMS1 and the InterSystems TCL will provide SME expertise;
- f) **Financial Expert:** A financial expert will be needed to assist with the financial modelling required for this project.

Specialist teams will be created, as required at key stages during the procurement process, to provide the specific skills and expertise required to support the procurement, including:

- **Requirements definition teams:** to specify the service and technical requirements to be delivered by the new LIMS service



utilising Pathology subject matter experts, NWIS technical experts and IT experts from across NHS Wales;

- **Supplier evaluation team:** to screen the PQQ responses, score responses against the IPD and evaluate the final Tenders;
- **Dialogue team:** to negotiate the draft Contracts including representation from the Evaluation Team, commercial, legal and technical advisers.

## Timescale

Subject to the Welsh Government signing off this OBC, it is intended to publish the OJEU notice in March 2019. It is anticipated that the design and development of the new service under the proposed contract will start in 2020, taking into account the migration/exit off the legacy solutions and in accordance with the LINC programme plan. The aim will be to complete the implementation by the end of March 2023, subject to detailed negotiations with the chosen commercial supplier and the commitment of the local HBs. Further details are provided in the [Management Case](#).

## 6. Financial Case

### 6.1. Introduction

The primary purpose of the financial case is to set out the financial implications of the preferred option, as set out in the Economic Case, to ensure that the solution is affordable.

### 6.2. Apportionment of Costs

The NHSW Collaborative Executive Group has requested that a different approach to WLIMS1 apportionment of costs be agreed with the DoFs for the LINC Programme. A paper was prepared and submitted to the Deputy DoFs for their meeting on 19 September 2018. The Deputy DoFs did not make a recommendation on the basis that they wished to see the full costs of the preferred option and are discussing this again at their meeting on 20 December.

For the purposes of the OBC, a working assumption has been made that the apportionment will be based on the annual allocation to health boards and NHS trusts. Based on the information provided in the WHC (2017) 053 Health board 2018-9 Allocations, the apportionment is presented in Table 24.

Table 24: Percentage allocation by health board and NHS trust

	2018/9	
	Total Revenue Resource Limit £m	Percentage Total Revenue Resource Allocation
<b>Abertawe Bro Morgannwg UHB</b>	<b>1,073.228</b>	17.4%
<b>Aneurin Bevan UHB</b>	<b>1,175.837</b>	19.0%
<b>Betsi Cadwaladr UHB</b>	<b>1,391.509</b>	22.5%
<b>Cardiff and Vale UHB</b>	<b>868.527</b>	14.0%
<b>Cwm Taf UHB</b>	<b>643.137</b>	10.4%
<b>Hywel Dda UHB</b>	<b>758.962</b>	12.3%
<b>Powys Teaching HB</b>	<b>273.478</b>	4.4%
<b>Total</b>	<b>6,184.678</b>	100.0%

### 6.3. Scope of the OBC Costs

The scope of the LINC OBC is set out in the Strategic Case: Potential business scope and key service requirements. In summary, this includes:

- Dual running of the upgraded TCL 2016 from June 2020 – June 2023;
- The procurement of a new LIMS service, which also includes additional tools including document scanning, dictation and voice recognition, blood tracking with remote issue, NPEX for referrals in and out of wales and, optionally, electronic test requesting.

- A national quality management team and quality management system (QMS);
- NWIS costs including technical, service management, application support and business change services.

The scope excludes:

- LINC Programme costs for 2018/9, for which a budget has been agreed;
- The replacement of Welsh Blood Service WTAIL system;
- Local pathology and ICT service resources to support the LINC programme, such as backfill for staff training;
- Any local infrastructure, peripherals and laboratory equipment;

The costs of maintaining Telepath and Masterlab has been show in the current costs but excluded from the dual running costs on the basis that all HBs have agreed to fully migrate to TCL. However, some HBs may choose to continue to use their current LIMS for Blood Transfusion if issues arise in migrating to TCL.

In accordance with the guidance, no VAT or inflation has been included in the figures. Staff costs are based on the NHS agenda for change pay scales 2018/9 and have allowed for increments (as appropriate) and a 1% annual cost of living increase.

Revenue only costs have not been considered in the light of the recent financial guidance. IFRS16 has clarified the definition of a service contract where the client controls the use of the identified asset, in this case a supplier-hosted service. As NHS Wales intends to secure economic benefits in the form of savings and direct the use of the asset to support current and future Pathology services, expenditure should be classified as capital. It may be that more of the cost could be classified as capital than that currently shown.

#### **6.4. Impact on the Health Boards and Trusts Income and Expenditure Account**

In summary, the costs of the preferred option for the Pathology solution are and set out per health board in Table 25 and broken down per annum in Table 26:

- Total cost over the eight years of the life of the OBC from 2019/20 – 2026/27 = £41.6 million (revenue only) or £37.2 million revenue plus £8 million capital from Welsh Government
- Per annum cost around £4.8 million (revenue only) or £4 million (with a capital injection) following deployment.

The cost of the current systems is £4.2 million, comprising TCL (£3.7 million) and Telepath & Masterlab (£0.5 million).

Table 25: Whole Life Costs and Per Annum Costs of the Preferred Option

Health Board / Trust	Capital and Revenue £k						
	Whole Life Costs (2019/20 - 2026/7)			Per Annum Costs of Pathology Solution			
	Pathology Solution	LINC Programme	Total Cost	New Annual Cost	Costs of Current LIMS'	Potential Savings	Additional Costs / Savings
ABM UHB	6,483	1,037	7,521	690	859	716	-884
Aneurin Bevan UHB	7,080	1,133	8,213	754	688	784	-718
Betsi Cadwaladr UHB	8,384	1,341	9,726	893	765	928	-800
Cardiff and Vale UHB	5,217	835	6,051	556	803	579	-826
Cwm Taf UHB	3,875	620	4,495	413	386	429	-403
Hywel Dda UHB	4,583	733	5,317	488	483	506	-501
Velindre NHST	0	0	0	0	220	0	-220
Powys Teaching HB	1,640	262	1,902	175		59	116
<b>Grand Total</b>	<b>37,263</b>	<b>5,961</b>	<b>43,224</b>	<b>3,968</b>	<b>4,205</b>	<b>4,000</b>	<b>-4,236</b>

NHS Wales CEG approved an earlier version of the costs of the preferred option at its meeting held on 23 October 2018 based on a revenue only model.

### **6.5. Overall Affordability**

The annual running costs of the new solution for Pathology services is estimated at £4 million per annum, which is more than TCL but less than the current overall costs. However, the potential to realise savings of up to £4 million per annum could cover the cost of the new LIMS service, once the new service is deployed and benefits have been realised.

Ignoring potential savings, some organisations will see a saving just compared to the current costs of the solution, but this is dependent on the decision relating to apportionment. All organisations will see a reduction of costs once the potential savings are taken into account but this is dependent on the extent to which they have already transformed their services and, for example, reduced administrative overheads as far as possible. Velindre shows a potential saving but is essentially the cost of WTAIL for which ongoing costs will continue.

The treatment of capital and the impact on the balance sheet has yet to be assessed and will be included in the next version of this OBC

The most expensive years are 2020/21 and 2022/23, where between £6m - £10m (revenue only) or £5m - £8m (with capital injection) additional revenue funds are required per annum due to dual running costs and one off costs of development. This could be reduced if development costs can be converted to capital monies, plus the costs of the programme. For 2019/20, £790k is required and programme costs.

As part of the sign off for this OBC, each health board and trust will be required to provide a letter supporting the programme and costs signed by their Chief Executive and Director of Finance.

Table 26: Costs of preferred option per health board / trust (Revenue only)

Notes Ref	Resource	Grade	Apr 19 - Mar 20 £k	Apr 20 - Mar 21 £k	Apr 21 - Mar 22 £k	Apr 22 - Mar 23 £k	Apr 23 - Mar 24 £k	Apr 24 - Mar 25 £k	Apr 25 - Mar 26 £k	Apr 26 - Mar 27 £k	Total Cost £k
<b>1</b>	<b>Pathology Solution</b>										
<b>2</b>	<b>TCL 2016 dual running wef June 2020</b>										
3	TrakCare technical assistance & software updates			1,296	1,728	1,728	432				<b>5,184</b>
4	Third party validation services			30	40	40	10				<b>120</b>
4	NWIS Hosting environment and support			236	315	315	79				<b>946</b>
4	Infrastructure - third party maintenance			622	830	830	207				<b>2,489</b>
4	National service desk / service management			69	92	92	23				<b>277</b>
4	NWIS Technical Support (analysts/development/integration & test)			495	660	660	165				<b>1,979</b>
	<b>Total (TCL 2016 dual running costs)</b>		<b>0</b>	<b>2,749</b>	<b>3,665</b>	<b>3,665</b>	<b>916</b>	<b>0</b>	<b>0</b>	<b>0</b>	<b>10,995</b>
<b>5</b>	<b>New LIMS Service supplier hosted in NHS data centre</b>										
6	New LIMS (VAT recoverable)				1,500	3,000	3,000	3,000	3,000	3,000	16,500
7	Integration costs			500	1,000						1,500
8	Legacy data			500	1,500						2,000
9	Scanning system				23	45	45	45	45	45	248
10	Voice recognition				10	20	20	20	20	20	110
11	Blood tracking				12	24	24	24	24	24	132
12	NPEX (for sendaways)			45	15	30	30	30	30	30	210
13	Electronic test requesting			500	88	175	175	175	175	175	1,463
	<b>Total (New LIMS Service supplier hosted in NHS data centre)</b>		<b>0</b>	<b>1,545</b>	<b>4,147</b>	<b>3,294</b>	<b>3,294</b>	<b>3,294</b>	<b>3,294</b>	<b>3,294</b>	<b>22,162</b>
<b>14</b>	<b>NWIS Support Costs</b>										
15	Change management		50	50	100	100					<b>300</b>
16	Change budget for new LIMS						100	100	100	100	<b>400</b>
17	National service desk / service management						69	92	92	92	<b>346</b>
18	NWIS Technical Support (analysts/development/integration & test)						495	660	660	660	<b>2,474</b>
19	Senior Support and Business Analyst (NODi)	6 (M-P)	39	41	42	43	46	47	47	48	<b>353</b>
20	Principal Support & Business Analyst (Integration)	7 (M-P)	48	50	52	54	55	55	56	57	<b>427</b>
21	Senior Software Developer (Integration)	6 (M-P)	39	41	42	43	46	47	47	48	<b>353</b>
22	Technical Architect (Applications Design)	8b (M-P)	69	73	76	76	77	78	79	80	<b>607</b>
	<b>Total (NWIS Support Costs)</b>		<b>246</b>	<b>254</b>	<b>311</b>	<b>318</b>	<b>889</b>	<b>1,079</b>	<b>1,081</b>	<b>1,084</b>	<b>5,261</b>
<b>23</b>	<b>National Quality Management Team &amp; System</b>										
24	Quality management system		220	37	37	37	37	37	37	37	<b>479</b>
25	Quality Manager / Validation Lead	8a (Top)	63	64	64	65	66	66	67	68	<b>523</b>
25	Validation Officer	7 (M-P)	48	50	52	54	55	55	56	57	<b>427</b>
25	QMS Configuration Librarian	6 (M-P)	39	41	42	43	46	47	47	48	<b>353</b>
25	Administrative Support Officer	4 (M-P)	27	28	28	29	30	30	30	31	<b>234</b>
26	UAT Tester x 2	6 (M-P)	39	41	42	43	46	47	47	48	<b>353</b>
27	Informatics Manager	8a (Top)	63	64	64	65	66	66	67	68	<b>523</b>
27	Informatics Officer	6 (M-P)	39	41	42	43	46	47	47	48	<b>353</b>
	<b>Total (National Quality Management Team &amp; System)</b>		<b>540</b>	<b>364</b>	<b>372</b>	<b>381</b>	<b>392</b>	<b>395</b>	<b>399</b>	<b>403</b>	<b>3,245</b>
	<b>Grand Total Option 3 (Preferred Approach) Revenue</b>		<b>786</b>	<b>4,912</b>	<b>8,495</b>	<b>7,658</b>	<b>5,491</b>	<b>4,768</b>	<b>4,774</b>	<b>4,780</b>	<b>41,664</b>

Table 27: Costs of preferred option per health board / trust (Capital &amp; Revenue)

Notes Ref	Resource	Grade	Apr 19 - Mar 20 £k	Apr 20 - Mar 21 £k	Apr 21 - Mar 22 £k	Apr 22 - Mar 23 £k	Apr 23 - Mar 24 £k	Apr 24 - Mar 25 £k	Apr 25 - Mar 26 £k	Apr 26 - Mar 27 £k	Total Cost £k
<b>1</b>	<b>Pathology Solution</b>										
<b>2</b>	<b>TCL 2016 dual running wef June 2020</b>										
3	TrakCare technical assistance & software updates			1,296	1,728	1,728	432				<b>5,184</b>
4	Third party validation services			30	40	40	10				<b>120</b>
4	NWIS Hosting environment and support			236	315	315	79				<b>946</b>
4	Infrastructure - third party maintenance			622	830	830	207				<b>2,489</b>
4	National service desk / service management			69	92	92	23				<b>277</b>
4	NWIS Technical Support (analysts/development/integration & test)			495	660	660	165				<b>1,979</b>
	<b>Total (TCL 2016 dual running costs)</b>		<b>0</b>	<b>2,749</b>	<b>3,665</b>	<b>3,665</b>	<b>916</b>	<b>0</b>	<b>0</b>	<b>0</b>	<b>10,995</b>
<b>5</b>	<b>New LIMS Service supplier hosted in NHS data centre</b>										
6	New LIMS (VAT recoverable)				1,100	2,200	2,200	2,200	2,200	2,200	<b>12,100</b>
7	Integration costs			500	1,000						<b>1,500</b>
8	Legacy data			500	1,500						<b>2,000</b>
9	Scanning system				23	45	45	45	45	45	<b>248</b>
10	Voice recognition				10	20	20	20	20	20	<b>110</b>
11	Blood tracking				12	24	24	24	24	24	<b>132</b>
12	NPEx (for sendaways)			45	15	30	30	30	30	30	<b>210</b>
13	Electronic test requesting			500	88	175	175	175	175	175	<b>1,463</b>
	<b>Total (New LIMS Service supplier hosted in NHS data centre)</b>		<b>0</b>	<b>1,545</b>	<b>3,747</b>	<b>2,494</b>	<b>2,494</b>	<b>2,494</b>	<b>2,494</b>	<b>2,494</b>	<b>17,762</b>
<b>14</b>	<b>NWIS Support Costs</b>										
15	Change management		50	50	100	100					<b>300</b>
16	Change budget for new LIMS					100	100	100	100	100	<b>400</b>
17	National service desk / service management					69	92	92	92	92	<b>346</b>
18	NWIS Technical Support (analysts/development/integration & test)					495	660	660	660	660	<b>2,474</b>
19	Senior Support and Business Analyst (NODI)	6 (M-P)	39	41	42	43	46	47	47	48	<b>353</b>
20	Principal Support & Business Analyst (Integration)	7 (M-P)	48	50	52	54	55	55	56	57	<b>427</b>
21	Senior Software Developer (Integration)	6 (M-P)	39	41	42	43	46	47	47	48	<b>353</b>
22	Technical Architect (Applications Design)	8b (M-P)	69	73	76	76	77	78	79	80	<b>607</b>
	<b>Total (NWIS Support Costs)</b>		<b>246</b>	<b>254</b>	<b>311</b>	<b>318</b>	<b>889</b>	<b>1,079</b>	<b>1,081</b>	<b>1,084</b>	<b>5,261</b>
<b>23</b>	<b>National Quality Management Team &amp; System</b>										
24	Quality management system		220	37	37	37	37	37	37	37	<b>479</b>
25	Quality Manager / Validation Lead	8a (Top)	63	64	64	65	66	66	67	68	<b>523</b>
25	Validation Officer	7 (M-P)	48	50	52	54	55	55	56	57	<b>427</b>
25	QMS Configuration Librarian	6 (M-P)	39	41	42	43	46	47	47	48	<b>353</b>
25	Administrative Support Officer	4 (M-P)	27	28	28	29	30	30	30	31	<b>234</b>
26	UAT Tester x 2	6 (M-P)	39	41	42	43	46	47	47	48	<b>353</b>
27	Informatics Manager	8a (Top)	63	64	64	65	66	66	67	68	<b>523</b>
27	Informatics Officer	6 (M-P)	39	41	42	43	46	47	47	48	<b>353</b>
	<b>Total (National Quality Management Team &amp; System)</b>		<b>540</b>	<b>364</b>	<b>372</b>	<b>381</b>	<b>392</b>	<b>395</b>	<b>399</b>	<b>403</b>	<b>3,245</b>
	<b>Grand Total Option 3 (Preferred Approach) Revenue</b>		<b>786</b>	<b>4,912</b>	<b>8,095</b>	<b>6,858</b>	<b>4,691</b>	<b>3,968</b>	<b>3,974</b>	<b>3,980</b>	<b>37,264</b>
	<b>Capital</b>										
28	Hosting costs as capital			8,000							<b>8,000</b>
	<b>Total Option 2 (Do Minimum) Capital</b>		<b>0</b>	<b>8,000</b>	<b>0</b>	<b>0</b>	<b>0</b>	<b>0</b>	<b>0</b>	<b>0</b>	<b>8,000</b>
	<b>Grand Total Option 2 (Do Minimum) Capital &amp; Revenue</b>		<b>786</b>	<b>12,912</b>	<b>8,095</b>	<b>6,858</b>	<b>4,691</b>	<b>3,968</b>	<b>3,974</b>	<b>3,980</b>	<b>45,264</b>

## 7. The Management Case

### 7.1. Introduction

The management case addresses the *achievability* of the proposed investment and the actions required to ensure successful delivery in accordance with best practice.

### 7.2. Programme Management Arrangements

The LINC Programme sits within the portfolio of the NHS Wales Health Collaborative. The Programme is managed in accordance with the OGC Managing Successful Programmes and PRINCE2 standards.

The LINC Programme Board is well established and has been meeting monthly since December 2017. The membership is made up of representatives from each HB and key Pathology organisations and groups as presented in [Appendix 13](#). Adrian Thomas, Executive Director of Therapies and Health Sciences for Betsi Cadwaladr UHB is the LINC Senior Responsible Owner and chairs the Board. Judith Bates is The LINC Programme Director supported by a Programme Management Office (PMO).

NHSW CEG approved the proposed programme governance, presented in Figure 8, at their meeting on 23 October 2018. Roles and responsibilities of each organisation are listed in [Appendix 14](#) and their specific role in relation to LINC is detailed below:

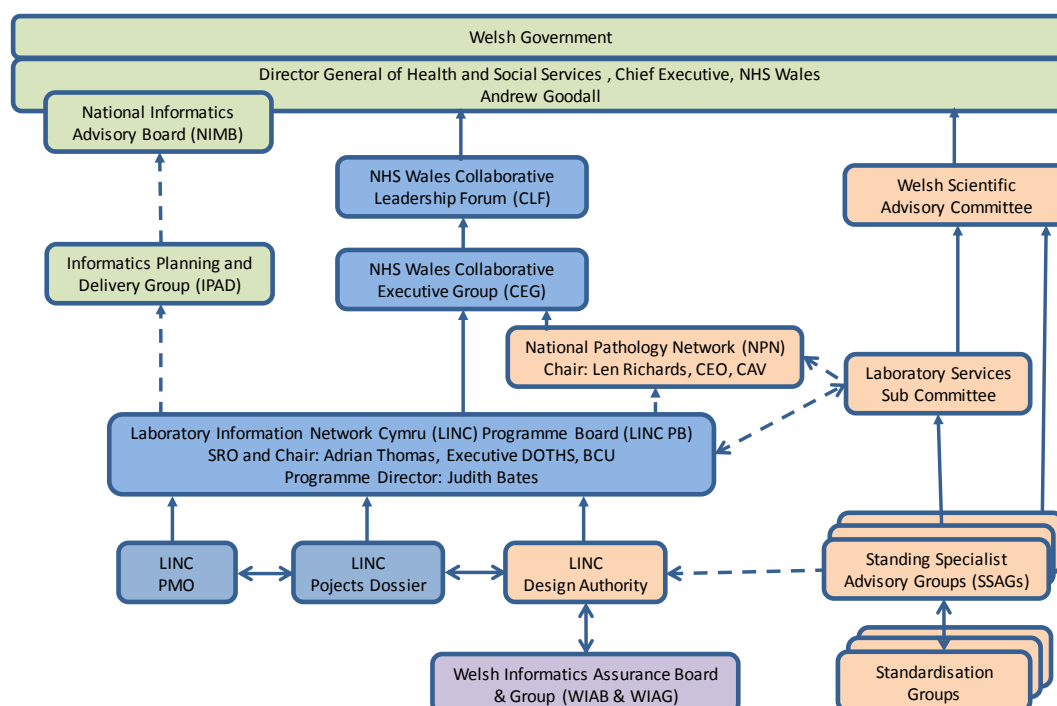


Figure 8: LINC programme governance

LINC programme governance comprises several strands:



- Corporate governance (shaded blue)
- Business case assurance process (shaded green)
- Pathology service and professional assurance (shaded orange)
- Informatics assurance (shaded purple)

### ***Corporate governance and funding***

The LINC Programme Board reports to the CEG to secure corporate approval of health boards / trusts / PHW to the programme approach and to requests for revenue funding and provides a monthly update to the CEG.

### ***Business case assurance process***

Welsh Government has agreed that a Strategic Outline Case (SOC) is not required for LINC, as it is driven by the need to re-procure a new LIMS. LINC has produced this Outline Business Case (OBC) and, following the procurement, will produce a Full Business Case (FBC). A robust business case assurance process is in place to assure that the OBC had made the case for investment in public monies. It has been reviewed or is planned to be considered by the following groups:

- Advice and assurance from NHS Wales Informatics Service Business Assurance (Mike Flanagan, Hugh Morgan, Gail Medcraft and Brent Varley) throughout the OBC development by email and in meetings;
- IPAD reviewed version 0.8 at its meeting on 19 October;
- Informal feedback on version 0.8 at meetings held with Peter Jones and Ian Gunney on 17 September and with Frances Duffy and Rob Orford on 22 November;
- IPAD Subgroup reviewed version 0.13 at its meeting on 27 November;
- NIMB considered version 0.16 at its meeting on 11 December and has asked that a decision be taken on the approach to delivering ETR and that benefits be better evaluated as part of the OBC;
- Welsh Government has offered support by taking the OBC to their scrutiny panel early in 2019. In the meantime work has already started on benefits evaluation and discussions planned with NWIS to assess their capacity to develop the WCP for ETR.;
- The aim is still to achieve Ministerial sign off by the end of February 2019.

In addition, the business case is going through a corporate assurance process, including:

- Review by the LINC Programme Board throughout OBC development;
- Funding model considered and approved by NHS Wales Collaborative Executive Group at its meeting on 18 September;
- Apportionment of costs considered by the Deputy DoFs at their meeting on 19 September, to be finalised on 20 December;

- Financial costs of the preferred option sent to the DoFs and deputy DoFs on 15 November to include in IMTP planning;
- Review via the Health Boards / Trusts / PHW internal business case assurance process during December
- Approval by each Health Board in January 2019;
- Signed letter of approval from each health board / trust / PHW CEO, Director of Finance and Director responsible for Pathology services to commit to the programme and funding by the end of February 2019.

The business case is also going through a professional assurance process including:

- Version 0.10 was sent to the SSAGs for review on 31 October;
- Version 0.11 was sent to the National Pathology Network and discussed at their meeting on 30 November;
- The Laboratory Services Subcommittee will receive the OBC at its quarterly meeting on 18 January 2019.

### ***Pathology service and professional assurance***

The National Pathology Network is responsible for the implementation of the Pathology Statement of Intent, of which LINC is a key element. The LINC SRO and the LINC Programme Director are members of the NPN.

The LINC Programme Director is also a member of and provide regular updates to the LSSC.

LINC documentation is sent out to SSAG leads to secure feedback from their SSAG. For the Cellular Pathology SSAG, which is does not currently have a lead, a circulation list has been created to share documentation and seek feedback. SSAGs are invited to and promote workshops and events.

In addition, presentations have been made to a range of All Wales groups and bodies, including ADIs, Deputy DOFs, Directors of Planning and the Welsh Clinical Informatics Council.

### ***Informatics assurance***

NHS Wales has an informatics assurance process in place via WIAB and WIAG. A well-documented assurance process is in place and will be applied at all stages of the LINC Programme and work closely alongside the LINC Design Authority to assure that the new services and systems are safe.

## **7.3. Proposed LINC Operational Governance**

One of the key questions asked of LINC is '*who owns the new LIMS system*'. This has been widely discussed and the proposed operational governance discussed by the NSW CEG at its meeting on 23 October. The interim arrangements are presented in Figure 9. This will be updated

following the national review of governance arrangements. Roles and responsibilities of each organisation are listed in [Appendix 14](#) and their specific role in relation to LINC is detailed below:

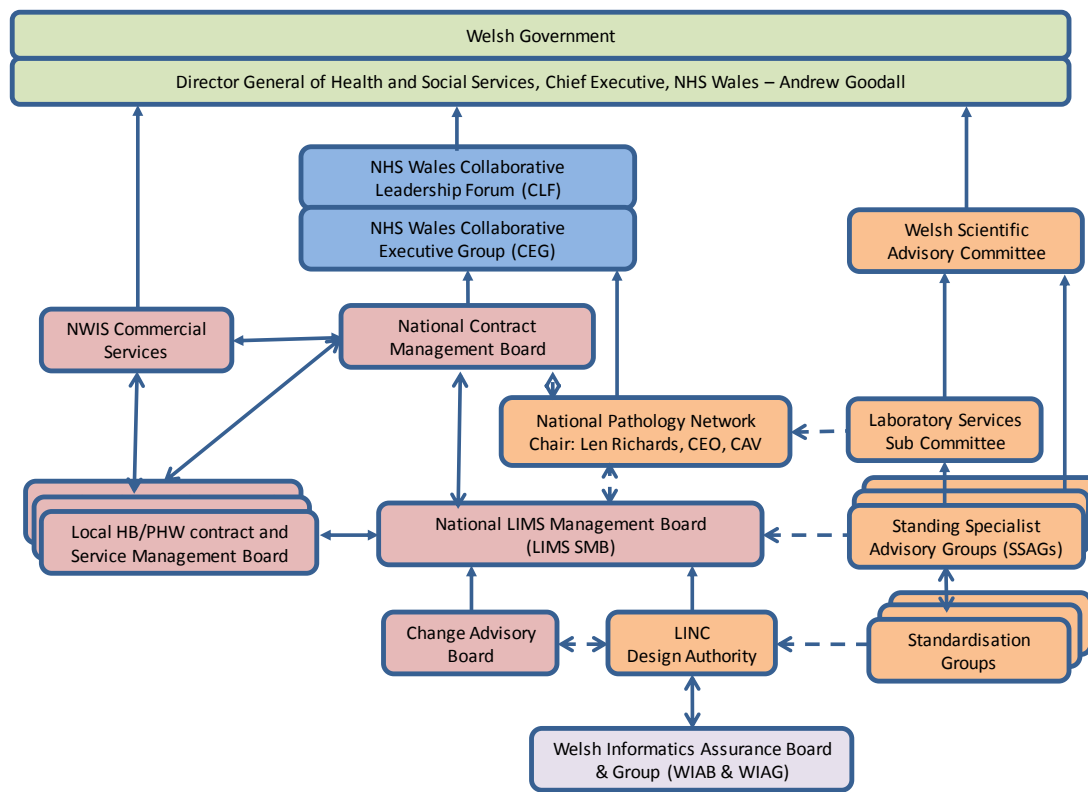


Figure 9: LINC operational governance

It has been agreed that the contract form will be a Master Services Agreement providing a national framework agreement with a single supplier. NWIS will be the contracting authority and will facilitate a national contract management board (CMB) and service management board (SMB) both chaired by the NHS. The SMB Chair will be a member of the NPN.

Each health board / PHW will have its own deployment order with the supplier and put in place a local Contract and Service Management Board to manage the relationship with the supplier and link to the national CMB.

The national LIMS SMB will monitor service levels provided by the LIMS supplier in accordance with Schedule 2.2 service levels and compliance against the wider national contract schedules for the live LIMS service. It will also monitor service levels for the internal service provided by NWIS and in accordance with an agreed service level agreement (SLA).

All health boards / PHW providing Pathology services and holding a deployment order as part of an MSA will have a place on the SMB. The NHSW CEG will approve the Chair of the SMB, which will report to the CMB and each HB Contract and Service Management Board on performance of the service. Local Contract and Service Management Boards can also escalate issues to the national LIMS SMB as required.

The national contract management board (CMB) will deal with issues escalated by the local C&SMB and the national LIMS SMB. The NHSW CEG will approve the Chair of the CMB, which will report by exception to the NHSW CEG. The mechanism for representation of the local C&SMB on the national CMB will need to be agreed but collectively they will resolve contractual issues supported by NWIS commercial services.

The Change Advisory Board (CAB) reviews and approves any changes to the LIMS. This has been a challenge for WLIMS1 as there has been no budget allocated to support this work. Consequently, it has depended on superfluous end of year monies. A change budget has therefore been included in the OBC to ensure funding is available for changes in future. Each main discipline should be able to request and manage changes specific to its own discipline to allow agile system maintenance and configuration without compromise to other disciplines.

#### 7.4. LINC Workstreams

The LINC Programme is being delivered through four workstreams as set out below:

- **Clinical workstream:** to engage the Pathology and wider NHS service in defining the requirements, take forward standardisation to eliminate all unwarranted variation in service and design the standard solution, and the deployment of the developed solution;
- **Commercial workstream:** to deliver the business case, manage the procurement of the new service and the chosen supplier;
- **Technical workstream:** to define and deliver the technical requirements to design and deliver a seamless end-to-end solution from electronic requesting to results reporting, develop the new standard solution at national level, migrate the data and the local ICT develops required to be in place to deploy the new solution;
- **Programme Governance workstream:** to ensure the LINC Programme is professionally managed and assured.

Some activities within each workstream are best delivered by a project. A Projects Dossier has been defined as presented in Figure 10. WTAIL will also need to come on board once their business case is completed.

#### 7.5. High Level Programme Plan

The programme will be delivered in tranches over four – five years from 2018/19 to 2023/24 as set out in Table 28, subject to OBC approval and sign off. This timescale is very tight with some contingency built in. The NHS needs to commit to delivering this plan or accepting a longer timescale, for which the costs of the programme and dual running of the systems will add to the overall costs of implementation.

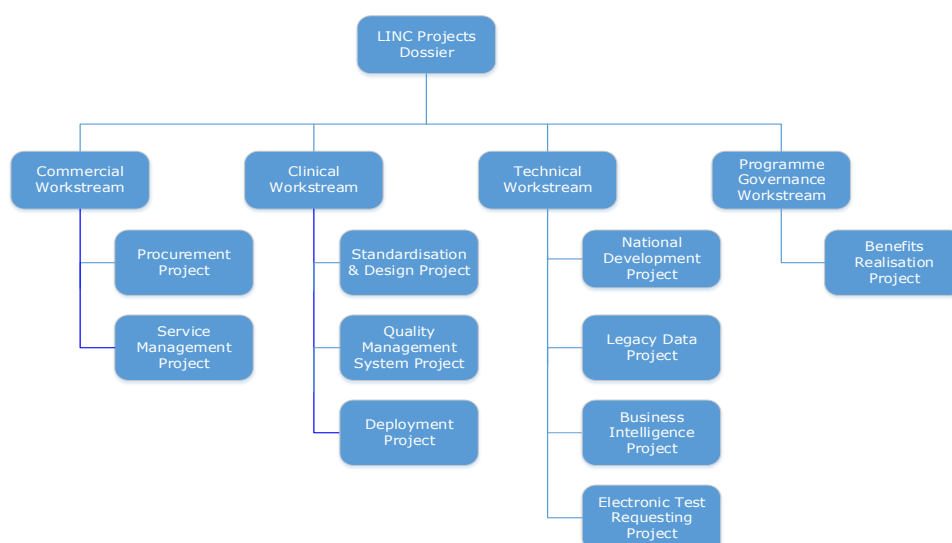


Figure 10: LINC Projects Dossier

Table 28: LINC Programme Tranches

Tranche	Scope	Key Milestones	Timeframe
0	Pre-Procurement	<ul style="list-style-type: none"> <li>OBC developed &amp; signed off</li> <li>Procurement planned and draft schedules completed</li> <li>Gateway review 2</li> </ul>	Jan 2018 – February 2019
1	Procurement Standardisation & Design work National QMS & team Integration work designed Benefits realisation planned	<ul style="list-style-type: none"> <li>OJEU notice published</li> <li>Contract in place</li> <li>Standardised design</li> <li>National QMS implemented</li> <li>Integration designed</li> <li>Benefits realisation</li> <li>FBC signed off</li> <li>Gateway review 3</li> </ul>	March 2019 – Mar 2020
2	Develop, test and validate the service for Wales	<ul style="list-style-type: none"> <li>End-to-end Pathology solution designed, developed and tested including electronic test requesting</li> <li>User acceptance testing</li> <li>Clinical assurance sign off</li> <li>Validation / accreditation</li> <li>Gateway review 4</li> </ul>	Apr 2020 – Sep 2021
3	Deployment	<ul style="list-style-type: none"> <li>Go live in CAV UHB</li> <li>Go live in remaining UHBs</li> </ul>	Oct 2021 – Mar 2022 Apr 2022 – Jun 2023
4	Benefits realisation	<ul style="list-style-type: none"> <li>Benefits realisation</li> <li>Gateway Review 5</li> <li>Programme Closure</li> </ul>	Jul 2023 – Mar 2024

## **7.6. Resource Requirements**

### ***Programme Team***

The LINC programme team comprises:

- The Programme Management Office (PMO)
- The Pathology Team
- NWIS Programme Resources
- Procurement Advice

### **The Programme Management Office (PMO)**

The Programme Director is supported by the PMO, comprising seven staff to plan, coordinate and manage the programme on a day-to-day basis. The Programme Manager will manage the PMO staff.

### **LINC Pathology Team**

The LINC Pathology Team will comprise subject matter experts (SME) and analysts in each of the main disciplines to collectively support the work on standardisation and business change, as well as procurement, development, testing, training and deployment of the new LIMS, including:

### **NWIS Programme Resources**

NWIS are dedicating some staff to the programme as follows:

- LIMS Service Manager to act as the subject matter expert for service management to coordinate NWIS resources for the programme;
- Head of Procurement to act be the procurement lead for the programme;
- A contractor (special adviser) who specialises in the new integration service product, Fiorano to support the development of the new interfaces and transfer skills to new staff.
- Testing services team to support the testing of the new solution
- Business change team to support the business change required to enable service integration.

### **Procurement Advice**

The Procurement Team will include 'special advisers' for commercial and legal adviser plus two advisers from the Pathology service.

Special advisers will be used in a timely and cost-effective manner in accordance with the Treasury Guidance: Use of Special Advisers. This has been limited to advice for legal and commercial services as set out in the Commercial Case.

Funding agreements for the NHS advisers will be put into place to cover their time or backfill their post.

### ***Programme Costs***

The costs of the programme is presented in Table 29, which includes the costs of the staff listed above plus non-pay and 10% contingency with effect from 2019/20. These costs exclude 2018/9, for which a budget has been agreed with the NHSW CEG to be apportioned on the same basis as WLIMS1 national costs.

Notes associated with the assumptions underpinning each of these costs are provided in [Appendix 15](#). In summary, the LINC Programme costs total £6 million over 5 years, comprising

- Programme management office £1.9 million
- Pathology team £2.4 million
- NWIS programme resources £687k
- Procurement costs £226k
- Non-pay & contingency £767k

## **7.7. Outline Arrangements for the Programme**

### ***Outline arrangements for change and contract management***

The strategy, framework and plan for dealing with change and associated contract management is as follows:

- A LINC Procurement Project will manage the procurement and completion of all contract documentation, including any changes requested;
- A Contract Management Board, chaired by the NHS and facilitated by NWIS will manage the contract and any contract changes will be managed in accordance with contract schedule 8.2 change control;
- A LIMS Service Management Board (SMB) will monitor the service, supported by a LIMS Change Advisory Board to control changes to the live service.
- All documentation will be configured and managed to provide an audit trail of any changes made.

### ***Outline arrangements for benefits***

The strategy, framework and plan for dealing with the management and delivery of benefits will be developed and include a benefits register that will identify how each benefit will be assessed and who will be responsible for delivering each benefit. A Benefits Project will be set up and run throughout the life of the programme. A draft benefit template for a benefit profile is listed in [Appendix 16](#).



Table 29: LINC Programme Costs

Notes Ref	Resource	Grade	Apr 19 - Mar 20 £k	Apr 20 - Mar 21 £k	Apr 21 - Mar 22 £k	Apr 22 - Mar 23 £k	Apr 23 - Mar 24 £k	Total Cost £k
<b>1</b>	<b>LINC Programme</b>							
<b>2</b>	<b>Programme Management Office (PMO)</b>							
3	Programme Director	8d (Actual)	97	102	108	109	110	<b>525</b>
4	Programme Manager	8a (Actual)	54	56	58	61	62	<b>290</b>
5	Senior Project Manager	7 (M-P)	48	50	52	54	55	<b>260</b>
5	Project Manager	6 (M-P)	39	41	42	43	46	<b>212</b>
6	Programme Officer / Planner	6 (M-P)	39	41	42	43	46	<b>212</b>
6	SPSO (Procurement & Technical Projects)	4 (M-P)	27	28	28	29	30	<b>143</b>
7	Senior Project Support Officer (PMO)	4 (Actual)	25	26	26	27	28	<b>133</b>
8	SPSO (Standardisation and Deployment Projects)	4 (Actual)	26	27	28	28	29	<b>140</b>
	<b>Total (PMO)</b>		<b>356</b>	<b>370</b>	<b>384</b>	<b>396</b>	<b>407</b>	<b>1,913</b>
<b>9</b>	<b>Pathology Team</b>							
9	Standardisation leads 2 sessions per week x 5	9 (Top)	129	131	132	133		525
9	Blood Sciences SME	8a (Top)	63	64	64	65		256
9	Biochemistry Analyst	7 (M-P)	48	50	52	54		205
9	Haematology Analyst	7 (M-P)	48	50	52	54		205
9	Immunology Analyst	7 (M-P)	48	50	52	54		205
9	Blood Transfusion Analyst	7 (M-P)	48	50	52	54		205
9	Cellular Pathology SME	8a (Top)	63	64	64	65		256
9	Cytology Screening SME	8a (Top)	63	64	64	65		256
9	Microbiology SME	8a (Top)	63	64	64	65		256
	<b>Total (Pathology Standardisation Team)</b>		<b>575</b>	<b>586</b>	<b>597</b>	<b>611</b>		<b>2,369</b>
<b>10</b>	<b>NWIS Programme Resources</b>							
11	LIMS Service Manager (backfill)	7 (M-P)	48	50	52	54		205
12	Procurement Lead (backfill)	8c (M-P)	77					77
13	Senior Software Developer (Integration)	Contractor		55				55
14	Testing services	SLA		50	50			100
15	Business change	SLA	50	50	100	50		250
	<b>Total (NWIS Short Term Resources)</b>		<b>176</b>	<b>205</b>	<b>202</b>	<b>104</b>		<b>687</b>
<b>16</b>	<b>Procurement Project (Additional resource requirements)</b>							
17	Legal Adviser	Contract	96					<b>96</b>
18	Commercial Adviser	Contract	96					<b>96</b>
19	Service Adviser (Kevin Williams)	Backfill	26					<b>26</b>
20	Service Adviser (Mike Redman)	Backfill	8					<b>8</b>
	<b>Total (Procurement Project Additional Resources)</b>		<b>226</b>					<b>226</b>
21	Non-Pay Costs		50	50	50	50	25	225
22	Contingency @ 10%		138	121	123	116	43	542
	<b>Grand Total (LINC Programme Costs)</b>		<b>1,522</b>	<b>1,332</b>	<b>1,356</b>	<b>1,277</b>	<b>475</b>	<b>5,961</b>



### ***Outline arrangements for risk management***

The strategy, framework and plan for dealing with the management of risk are as follows:

- Risks can be raised by anyone on the programme and added to the risk register;
- The risk register has been designed in accordance with good practice guidelines within PRINCE2 and NHS Wales Health Collaborative standards;
- The risks are reviewed at least once a month by the PMO and the LINC Programme Board;
- The LINC Programme Manager will escalate any risks that cannot be managed by the PMO and require urgent action to the LINC Programme Director. If required, she will in turn escalate to the LINC SRO and jointly decide on the appropriate action;
- The LINC Programme Director in liaison with the LINC SRO will escalate any risks that cannot be dealt with at the level of the LINC Programme Board to the National Pathology Network for professional advice and to the NSW CEG for corporate decision, having first consulted with the service via the LINC Programme Board and / or appropriate service networks.

A copy of the programme risk register is attached at [Appendix 17](#) and the guidance in [Appendix 18](#).

### ***Outline arrangements for post project evaluation***

The outline arrangements for post implementation review (PIR) and project evaluation review (PER) have been established in accordance with best practice and are as follows.

#### ***Post implementation review (PIR)***

These reviews ascertain whether the anticipated benefits have been delivered and are timed to take place between March and September 2023.

#### ***Project evaluation reviews (PERs)***

PERs appraise how well the project was managed and delivered compared with expectations and are timed to take place between March and September 2023.

### ***Gateway review arrangements***

Gateway reviews are planned for at the end of each tranche of the programme, starting with the gateway review 2 to assure the delivery strategy.

### ***Contingency plans***

In the event that this programme fails, the following arrangements are in place for continued delivery of the required services and outputs. The aim will be to ensure business continuity, managed by:

- Ensure the continuity of the current LIMS system until the new LIMS has been developed, tested and fully deployed;
- A regular 'health check' to ensure the new LIMS has the capacity to maintain a service past the anticipated replacement date;
- Review the contractual issues as an option as the programme progresses;
- Explore the opportunities to contract with another supplier within the procurement.



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NHS Wales Health  
Collaborative

## Laboratory Information Network Cymru (LINC) Programme

# Outline Business Case Appendices

## Version 0.17 Draft

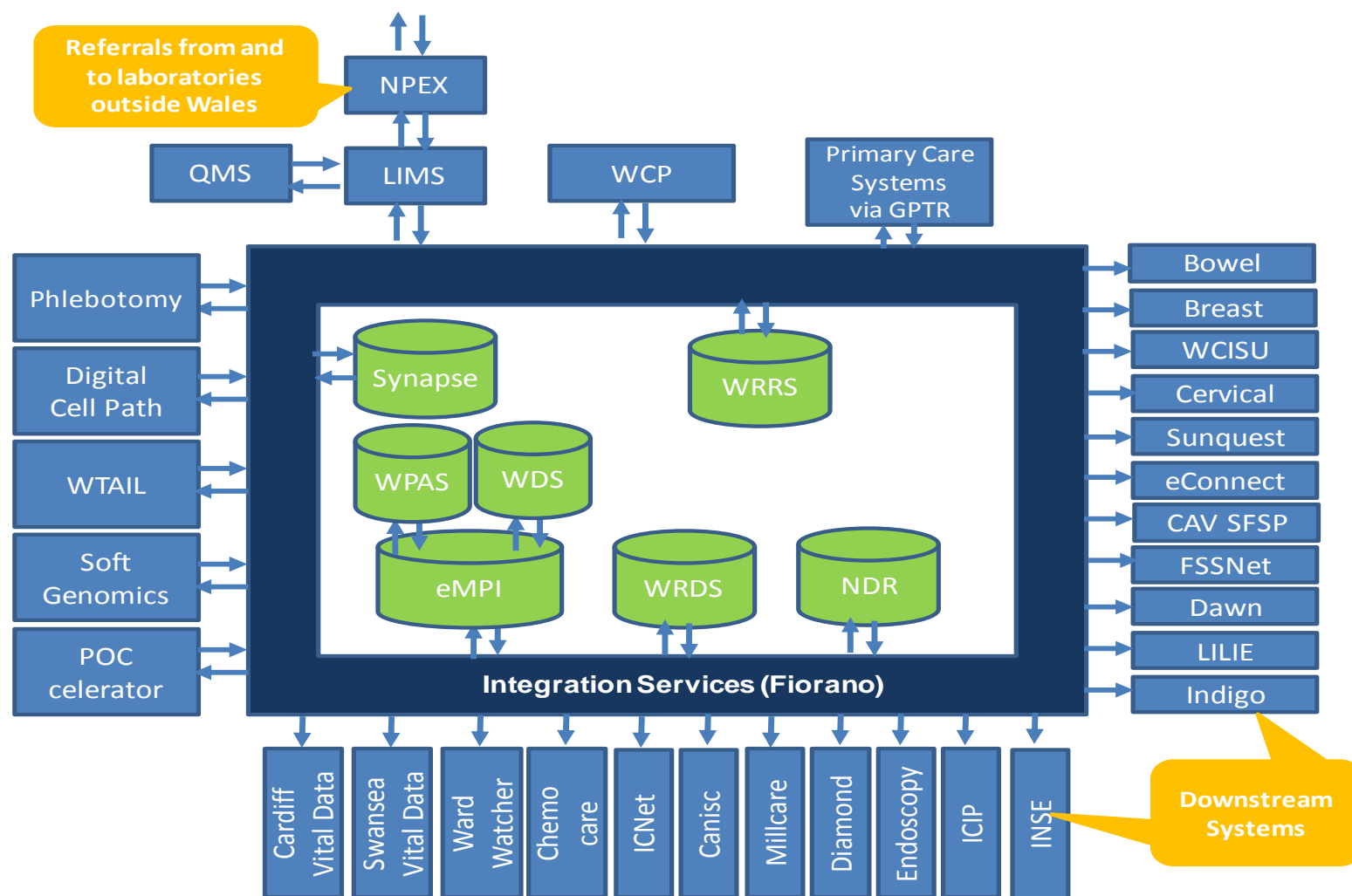


## Appendix 1: Pathology Tests

Discipline	Activity	Year	ABM UHB	AB UHB	BC UHB	CAV UHB	CT UHB	HD UHB	PHW	Total	Source
Andrology	Auth Test Sets	2017/8	1,142	1,719	1,474	1,101	419	704		6,559	TrakCare
Blood Sciences	Auth Test Sets	2017/8	5,388,203	5,692,385	6,063,215	4,840,657	2,491,488	3,775,297		28,251,245	TrakCare
Cellular Pathology	Auth Test Sets	2017/8	39,713	17,250	45,665	67	1,654	25,976		130,325	TrakCare
Cervical Cytology	Auth Test Sets	2017/8							96,137		TrakCare
Microbiology	Auth Test Sets	2017/8	442,884	392,176	419,029	549,935	285,036	216,412		2,305,472	TrakCare
<b>Sub-Total</b>			<b>5,871,942</b>	<b>6,103,530</b>	<b>6,529,383</b>	<b>5,391,760</b>	<b>2,778,597</b>	<b>4,018,389</b>	<b>96,137</b>	<b>30,693,601</b>	
Cellular Pathology	Episodes	2017/	38,832	30,567		40,999	22,095	227		132,720	Telepath
Blood Products & Components	Total Tests	2016/7	33,977	21,522	34,441					89,940	Keele data
Blood Bank	Total Tests	2016/7	110,043	118,685	153,200					381,928	Keele data
Histopathology	No. of slides	2017	215,584		132,017					347,601	
Mortuary	Post Mortems	2017	935		1,350					2,285	Keele data
Cervical Cytology	Specimens	2017			35,198					35,198	Keele data
Cervical Cytology	Samples	2017/8	42500	25500	29000				45000	142000	Trakcare
Diagnostic Cytology	Specimens	2017	2,983		3,164					6,147	Keele data

N.B. Data for all organisations not yet all-available.

## Appendix 2: The new LIMS as a component of the national technical platform



### Appendix 3: Pathology Statement of Intent: Key areas and relationship to LINC

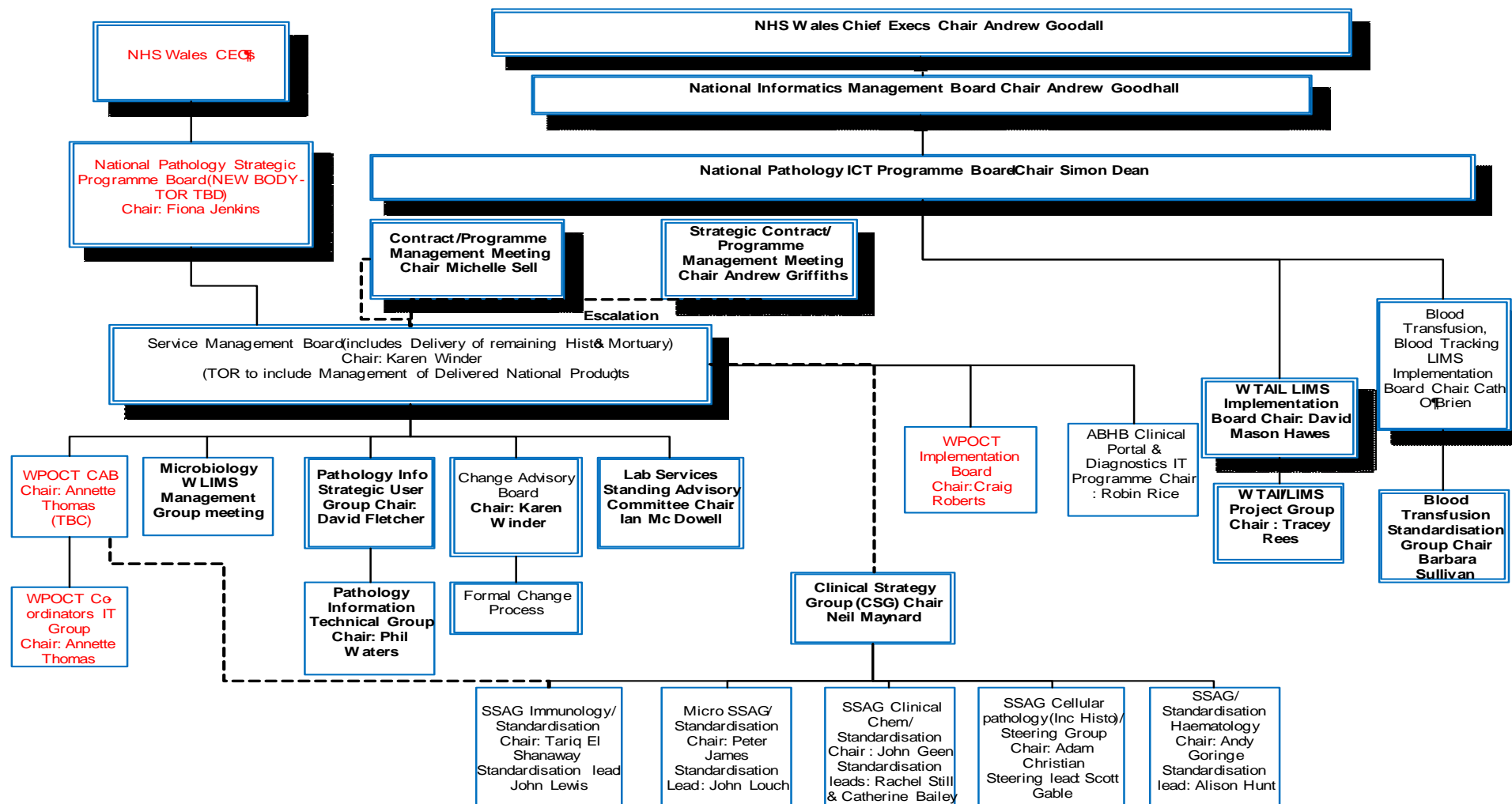
Ref	Priority	Key features	Relationship to LINC
1	Public involvement & engagement	NHSW to develop meaningful linkages with the public to facilitate co-production of Pathology services.	LINC aims to improve patient care, safety and outcomes, for which measurable benefits have been developed.
2	Workforce development	NHSW will support a prudent, cross discipline and flexible skill-mix approach to future workforce models HEIW <sup>8</sup> will support the development of targeted strategies for workforce development	The new end-to-end technical solution will automate processes and support changing roles and associated access controls
3	Equipment	WG will support the development of a prioritised and sustainable capital replacement programme NHSW will co-ordinate planning and adoption of new Pathology technologies taking account of regional working & workforce issues	To fully integrate to other technologies Standardisation of equipment as far as possible will reduce costs and simplify maintenance of the new LIMS
4	Quality and Safety	WG will support the introduction of a Regulated National Quality Framework to ensure: <ul style="list-style-type: none"> <li>• A fully accredited Pathology service for NHS Wales</li> <li>• Patient safety will remain a priority</li> <li>• Evidence based standardised practice</li> <li>• Unwarranted variation evidenced and acted upon</li> <li>• Patient feedback mechanisms are developed</li> <li>• Errors / sample losses and waste are minimised</li> </ul>	A single quality management system for Wales with single standard operating procedures (SOPs) will make the design, development and maintenance of the new LIMS easier and more cost effective; minimise variation of practice and facilitate validation of services
5	Services	WG & NHSW will direct regional Pathology planning to improve service efficiency and effectiveness, including	The new solution will enable the redesign of Pathology services and the delivery of

<sup>8</sup> Health Education and Improvement Wales  
Outline Business Case  
Author: Judith Bates

Ref	Priority	Key features	Relationship to LINC
		<ul style="list-style-type: none"> <li>Service reconfiguration based on regions</li> <li>A formal structured network for POCT services</li> <li>The adoption of the "Choose Wisely" campaign</li> <li>Ensure services are "designed for demand"</li> <li>WG and NHS Wales to include Pathology in service planning</li> </ul>	the 'Choose Wisely' and 'Designed for Demand' initiatives.
6	Informatics & information	<p>NHSW to review Pathology informatics arrangements to best meet service and clinical needs.</p> <p>NHSW will develop new performance indicators to improve the quality and consistency of services.</p>	Informatics support for the new LIMS and enhanced business intelligence will be a key feature of the end-to-end technical solution via the new LIMS and the National Data Resource (NDR).
7	Research & information	<p>NHSW will develop the relationship with academia to improve innovation and improvement outcomes.</p> <p>WG will develop collaborative working to exploit opportunities in innovation and technology.</p> <p>NHSW will develop a strategic plan to seize research and innovation opportunities.</p>	The new solution will support developments in innovation and technology such as artificial intelligence and machine learning and Digital Cellular Pathology.
8	Regional working & governance	<p>NPN accountable to NHSW Chief Executives</p> <p>Service specification developed to support development of Pathology services</p> <p>Laboratory Services Subcommittee and SSAGs to support service development</p>	<p>The new solution will support the development of Pathology services</p> <p>LINC to work with NPN to define ownership of new LIMS and relationship to NPN going forward.</p> <p>LSSC and SSAGs are key stakeholders in the LINC Programme</p>



## Appendix 4: WLIMS1 Governance Model





## Appendix 5: Lessons Learned from WLIMS1

Ref	Category	Title	WLIMS1 Issue	Lessons Learned	Applied to LINC Programme
1	Strategic fit	IO1: A fully supported networked LIMS available for implementation by January 2011	Implementation took far longer than planned	The new LIMS will be developed and tested once for Wales and be the same solution subject only to agreed warranted variation. It will then be deployed as is to local sites.	Programme approach and plan
2	Strategic fit	IO2: To support improved clinical data and management information flows to meet NHS Wales' needs	It has not been possible to share workload across sites	Information governance to be addressed so that the system can be configured to allow tests to be processed, validated and reported at different sites	Information governance
3	Strategic fit	IO3: To improve the functionality and flexibility of the Pathology IT system to meet current and future strategic service needs	The system has proven to be less efficient to use with more screens and workarounds and only one version has been implemented.	Increased standardisation resulting in a simpler design and build that's easier to use, maintain and keep up-to-date.	Standardisation and Design Project
4	Governance	Programme governance	WLIMS1 programme governance not sufficient to ensure service commitment to the programme.	Whole system responsibility to be clarified for LINC.	Programme governance clearly defined via the Collaborative Executive Group.
5	Governance	Programme governance	LINC SRO accountability	Clarify SRO accountability	LINC SRO to be a member of the National Pathology Network and individual accountability to be aligned to the revised Welsh Government governance arrangements that will impact NPN
6	Governance	LIMS ownership	Who owns the LIMS as no single pathology service	National Pathology Network (NPN) does not have the authority to take ownership. It is proposed that LIMS ownership sits with the Collaborative Executive Group with professional advice from the NPN.	Proposals shared with LINC Programme Board, National Pathology Network and Collaborative Executive Group.
7	Governance	Contract management	NWIS contracting authority with little service input. InterSystems see NWIS, and not the Pathology service, as the customer	Use a master services agreement and review membership of the contract management board.	Procurement strategy includes using a Master Services Agreement. Organisational governance arrangements to include the chair of the LIMS Service Management Board.
8	Governance	Contract management	No visibility of InterSystems performance against the contract and plans for delivering against the requirements matrix	Progress reported via LIMS Service Management Board	Terms of reference and design of contract management reporting to the SMB and the service.
9	Governance	Service management	Service feel ill-informed in relation to WLIMS1 live service	Review communications mechanisms to the service for the Contract Management board, WLIMS1 Service Management Board and Change Advisory Board.	Review terms of reference of the WLIMS1 Contract Management board, WLIMS1 Service Management Board and Change Advisory Board and consult with the service about communications.

Re	Category	Title	WLIMS1 Issue	Lessons Learned	Applied to LINC Programme
10	Governance	Change management	Small changes can take a long time to implement in the live service.	Put an SLA in place with supplier and the LINC SMB in relation to turnaround times for changes.	Agree the turnaround times for changes to be completed and have monitoring processes to report on progress.
11	Communications	Communications to primary care	Asking GPs to reduce workload during go live	Ensure GPs aware of change and can plan to reduce workload during go live	Include in stakeholder engagement strategy and communications plan
12	Communications	Communications to secondary care	This went well with Go LIVE comms - global emails and letters going out to consultants and GPs and contact made to nurses and specialist teams.	Plan go live comms with local comms team to maximise distribution of information.	Include in stakeholder engagement strategy and communications plan
13	Communications	Communications to all lab staff	Difficult to get the same message to all lab staff	Need to ensure method of cascading information within the lab	Include in stakeholder engagement strategy and communications plan
14	Communications	Communications of changes	Insufficient communications of changes during implementation	Ensure changes are notified so that staff know what to expect	Deployment communications plan
15	Procurement	Requirements specification	Requirements were well specified mostly but weak in some areas like business intelligence and audit	Ensure requirements well specified and widely reviewed and approved by the service with a separate section on business intelligence and audit	Ensure requirements well specified and widely reviewed and approved by the service with a separate section on business intelligence and audit
16	Procurement	Requirements specification	Requirements not sufficiently future proofed in terms of size and capacity and deal with business change and technological developments	Ensure requirements and the contract cover the need to support future requirements	Requirements and contract to explicitly cover future requirements
17	Procurement	Procurement process	Supplier demonstrated really good system but provided a vanilla product for Wales NHS to configure with a new, inexperienced supplier team	Ensure that supplier can deliver what has been demonstrated and the the solution will not need development to deliver what has been demonstrated	Ensure that supplier can deliver what has been demonstrated and the the solution will not need development to deliver what has been demonstrated
18	Procurement	Procurement process	Underestimation of the complexity and the effort required to develop WLIMS1 to meet the needs of the service.	To procure a solution that has a proven track record and met national accreditation and validation requirements	(1) to ensure the the requirements include the need to for a working solution; (2) to ensure that the procurement process requires suppliers to demonstrate current and not potential capability; (3) to ensure that payment milestones are related to delivery.
19	Procurement	Need to communicate with other systems	WLIMS1 cannot communicate with other systems. For example, inability to communicate with NHS England means that Welsh laboratories are at a significant disadvantage when competing for sendaway (income generating) work.	Include NPEx (or similar) in required specification.	NPEx has been included in the requirements specification for the new LIMS.
20	Procurement	Be wary of suppliers who state a requirement is under development	InterSystems stated that Blood Transfusion, full-featured BI and a working Mortuary module were all under development but WLIMS1 was delivered without these modules being completed.	Careful scoring of supplier responses that state 'under development'	Evaluation criteria to take note of supplier responses 'under development'.

Re	Category	Title	WLIMS1 Issue	Lessons Learned	Applied to LINC Programme
21	Development & testing	Testing	The service does not have the capacity to support testing causing delays in the development, roll out and maintenance of WLIMS1.	Ensure system documentation is maintained and employ testers to support user acceptance testing.	Two testers included in the OBC costs, approved by the CEG.
22	Development & testing	Data migration	Data migration did not progress as originally planned and has proven to be time consuming and problematic.	To have a clear plan for data migration taking account of the issues experienced with WLIMS1 and to explore the potential to use the national data resource, if this will be ready in time.	Draw up a plan for data migration and explore the potential to use the national data resource.
23	Development & testing	Validation	Validation has been time consuming and costly, using external consultancy.	Put in place national post as part of the quality management team to develop in-house expertise in validation.	Validation post part of the proposed national quality management team and approved by the CEG to include in the OBC
24	Development & testing	Development of new requirements	Missing requirements needed development in early stages.	Clearly map out all new requirements and ensure a plan in place to show by when they will be delivered against the requirements traceability matrix.	Contract to include plan for delivery of requirements.
25	Implementation	Business change	Staff say they didn't know what they were going to get until they got it and changes were not well communicated, combined with significant variation and workarounds at a local level.	To put in place a business change programme from the outset to promote standardisation, respond to local queries and keep all staff up-to-date with progress as well as manage expectations.	Funding has been requested to support business change in the LINC Programme
26	Implementation	Implementation planning	Implementation plan did not take account of the complexities of the roll out	To ensure the implementation plan sufficiently detailed and interdependencies well defined, taking account of lessons from WLIMS1.	Robust implementation planning
27	Implementation	Training	There was not enough training provided and no training has been offered for new staff or in relation to upgrades. There is no longer a training environment and training materials are not kept up-to-date. The responsibility for training sat with the supplier but has not been fully delivered or supported throughout the contract.	Training requirements need to be recognised, supported and resourced. A train the trainer approach to be adopted from the outset.	The contract with the supplier to include a train the train approach, ensuring the supplier provides and continues to support a training database and system documentation to support training maintenance of training materials. The national pathology team will support training for the programme and the responsibility will sit with the national application team going forward.
28	Implementation	Training	For Cellular Pathology, learning the new LIMS was only achieved by visiting the live sites and not from the trainer.	The standard of training needs to be improved but also the value of visiting live sites to be recognised and resourced.	Training strategy, plans and resources to ensure training is the required standard. The opportunity to learn from live sites included in the deployment planning.
29	Implementation	Health Board readiness for implementation	HBs not fully prepared for implementation causing delays.	Ensure HBs are ready for implementation.	(1) Communications and engagement in place with each HB to ensure good planning for implementation; (2) Readiness checklist and good communications during implementation to ensure HB is ready.

Re	Category	Title	WLIMS1 Issue	Lessons Learned	Applied to LINC Programme
30	Implementation	Roll out	Delays in deployment caused by delays in LIMS development and rectification of issues raised by the supplier, compounded by the lack of service availability for revised timelines to support deployment	Will not go deploy until solution developed, tested and validated across all disciplines for all Wales. Then deploy fully at one site across all disciplines before moving to the next site.	(1) Stronger procurement (2) Requirements better scoped (3) Use of a MSA contract form (4) Robust planning and communications
31	Implementation	Incident logging	Mechanism for incident logging not clear to staff	Make sure there is a clear and easy mechanism for incident logging and follow up shared with all staff	Deployment planning change management and
32	Operational fit	Electronic test requesting	No budget for changes to the LIMS once live	Include a budget for changes to the live services into the OBC	Annual budget available to support changes requested by the service.
33	Operational fit	Laboratory processes	WLIMS1 does not fully support efficient running of the lab or meet all the original requirements.	To ensure the requirements are specified to meet service requirements and the supplier is held to account for delivery against a requirements traceability matrix.	(1) Wide consultation and engagement to develop requirements. (2) Strong contract management to hold the supplier to account for requirements.
34	Operational fit	Laboratory equipment	It takes a long time and costs a lot to get each new analyser integrated to the LIMS	To include turnaround times and negotiate reduced costs to connect analysers as part of the contract.	(1) Service levels to include turnaround times for analyser interfaces (2) Costs to be included in the contract.
35	Operational fit	Quality management	The lack of a national quality management system makes standardisation hard to deliver and maintain.	To put in place a national quality management system (QMS) like Q-Pulse to support standardisation.	The procurement of a national QMS and a team to support this system has been approved by the CEG to include in this OBC.
36	Operational fit	Sendaways	Sendaways managed manually causing errors and delays and reducing potential income from offering a service outside Wales.	To use NPEx to manage sendaways and referrals into Wales	The use of NPEx has been approved by the CEG to include in this OBC.
37	Operational fit	Combined reporting across different disciplines	The need for combined reporting for Haematology, and for Cellular Pathology, was specified at the start of the WLIMS1 project but never delivered.	The company was never forced to provide this functionality. Four years past "go-live", there is still no functional combined reporting mechanism, beyond what can be configured locally.	The absolute need for Combined reporting across different disciplines MUST be identified upfront as a key specification requirement for LINC, and tendering companies MUST show how this will be delivered. Delivery of this functionality should be included in the KPI.
38	Business intelligence	TrackCare BI - DeepSee	Supplier demonstrated huge potential but service left to develop BI solution for themselves	Ensure clarity about what supplier will provide in terms of solution and experienced resources.	Stronger procurement and detailed BI requirements specified in advance.
39	Business intelligence	TrackCare BI - DeepSee	DeepSee not working before go live or post go live	Ensure BI solution developed, tested and signed off prior to go live	Contract with supplier clearly includes requirement for BI to be working before any milestone payments are made.
40	Business intelligence	TrackCare BI - DeepSee	A lack of resource and expertise within the service to help to develop the product;	Have staff dedicated to developing and supporting BI tool in conjunction with the supplier and not going live until BI working.	Two staff included in the OBC

Re	Category	Title	WLIMS1 Issue	Lessons Learned	Applied to LINC Programme
41	Business intelligence	TrackCare BI - DeepSee	Keele Benchmarking returns and feedback from the service reveals that different methods of collecting data has resulted in continued inconsistencies and lack of comparability of data, despite having a national LIMS.	Require a national solution to BI	(1) Stronger procurement (2) Requirements better scoped (3) Detailed, standardised design ready at the outset for solution development
42	Technical	National technical platform	NWIS hosting the technical platform has experienced difficulties in supplier relationship over where the boundaries lie in responsibility for hardware and software	Supplier to host and be responsible for the whole technical environment	Procure a managed service based on service levels where the supplier can host the solution in an NHS data centre, or a data centre of their choice, using cloud services if preferred.
43	Technical	Unplanned downtime	Significant unplanned downtime has been experienced during 2018 causing service issues and overtime costs.	Supplier to guarantee no unplanned downtime and to demonstrate reliability of their service before any milestone payment is made.	Contract with supplier clearly includes requirement for no unplanned downtime and for this to be proven during development and testing before any milestone payments are made.
44	Technical	Planned downtime	Planned downtime for updates and patches causing issues with business continuity.	No planned downtime required for routine patches and minimal downtime for annual upgrades.	Contract with supplier clearly includes requirement for minimal planned downtime and for this to be proven during development and testing before any milestone payments are made.
45	Technical	Integration to downstream systems	WLIMS1 is integrated to more than individual 60 downstream systems. This causes significant issues when the system goes down and takes a long time to restore and allow the system to go live.	(1) The new LIMS to generate a single data extract and NWIS to manage the integration to downstream systems (2) To reduce the number of interfaces to those systems with a workflow dependent on the result. Otherwise results provided via the WCP.	(1) Requirements to specify a single downstream system (2) Additional NWIS staff to support integration, potentially saving money on current costs of integration (3) To develop interfaces during the upgrade to TCL2016 so that the new integration service is up and running in time for the new LIMS potentially reducing time for development and testing.
46	Technical	Local HB technical environment	Local ICT environments not ready for deployment of WLIMS1, in part due to lack of communications with local ICT services and, in part, due to local HBs not procuring the required peripherals to support WLIMS1.	Local ICT infrastructure and peripherals are excluded from the LINC OBC, so clear communications and local plans required to ensure the local infrastructure is developed and tested ready for local deployment.	Ensuring the Collaborative Executive Group and the Associate Directors of Informatics are kept informed of progress with LINC, what is expected of local HBs and plans in place to deliver.
47	Technical	Technical architecture of the solution too interdependent across the disciplines.	Technical changes made to one discipline impact on other disciplines causing service issues.	The new solution must be able to separate the different disciplines so that changes made to the system for one discipline do not impact another discipline.	(1) Technical requirements to specify this (2) Supplier to demonstrate how this will be achieved (3) Requirement to be included in the contract

Re	Category	Title	WLIMS1 Issue	Lessons Learned	Applied to LINC Programme
48	Technical	Incorrect reference ranges	applied to Folate test results by the Laboratory at Royal Glamorgan Hospital since the go-live of the Wales Laboratory Information Management Systems (WLIMS) on 25th November 2013,	Any future go-live of modules must include a redundant check of the test items, analysers and reference ranges where applicable	(1) Technical requirements to specify this (2) Testing requirements to specify this
49	Resources	National resources	Key national resources were requested but not provided to support data quality, quality management, informatics, business change, testing and training causing delays, additional costs, lack of development of a national BI solution and system complexity.	To ensure the right level of national support is in place to support the development and deployment of the new solution	Required staffing has been included in the LINC OBC.
50	Resources	Local resources	No funding was provided for local resources to support the development and testing of WLIMS1 resulting in a lack of consistency of staff involved, delays in development and implementation and an inconsistent approach to the solution design.	Staffing is even more stretched now due to move to on call arrangements and resource constraints impacting staffine levels, so a different approach is proposed, based on a national team of subject matter experts and analysts to support the bulk of the work, whihc will be more standardised but in consultation with local services.	Funding for a national pathology team has been included in the LINC OBC and a paper on standardisation and warranted variation agreed as a basis for moving forward with standrdisation.
51	Application Support	Changes (even small changes) to the live service have taken too long to deliver	Microbiology was the first main service to go live but then found it took too long to get small changes made such as two years for a comment in a report to be changed impacting patient safety. Since other services have gone live this difficulty has been replicated across specialities across Wales. Changes which used to occur in less than an hour can now take months (sometimes years).	Adequately resourced application support has to be in place for the live service from day one. The culture from the support provider needs to change - "requests for change" should perhaps be renamed "required changes" and are important for service safety, efficiency and quality improvement.	(1) Service level agreement in place for application support for the NHS team as well as the supplier. (2) Need to agree where responsibilities lie for changes between the NHS and supplier.
52	Application support	ServicePoint is not fit for purpose	Putting a request for change on ServicePoint does not mean that it will be actioned, nor is there necessarily any feedback if the call is not actioned. Calls are closed even when they haven't been resolved.	There needs to be a cultural change to recognise that requests put through service point are important for the safe, effective delivery of pathology services. Users of Servicepoint (or equivalent) should receive feedback and calls should not be closed inappropriately.	Review the first line of support provided for the live LIMS service to meet the needs of pathology.
53	Application support	Lack of engagement from NWIS	NWIS application support team do not have the capacity to meet with all the standardisation groups. Improvements in service safety, efficiency and quality are hindered.	The application support team needs to have the capacity to attend the discipline specific standardisation meetings.	Additional SME support for standardisation work to be provided by the LINC Programme

## Appendix 6: New LIMS Scoping Options

Business as Usual	Minimum	Intermediate	Maximum
Disciplines:	Disciplines:	Disciplines:	Disciplines:
Andrology <b>Blood Sciences:</b> Haematology Biochemistry/Toxicology Immunology Laboratory Blood Transfusion <b>Cellular Pathology:</b> Diagnostic Cytology Histopathology Mortuary <b>Microbiology:</b> Bacteriology Food, Water & Environ Services Infection Genomics Mycology Parasitology Virology <b>Screening Services:</b> Antenatal Serum Cervical Screening New Born Blood Spot Screening	<b>Blood Sciences</b> Phlebotomy  <b>Cellular Pathology:</b>  <b>Microbiology:</b>  <b>Screening Services:</b>	<b>Blood Sciences</b> Full vein-to-vein blood tracking  <b>Cellular Pathology</b>  <b>Microbiology:</b>  <b>Screening Services:</b>	<b>Blood Sciences</b>  <b>Cellular Pathology:</b>  <b>Microbiology:</b>  <b>Screening Services:</b> Bowel Cancer Screening Downs Syndrome Screening

Business as Usual	Minimum	Intermediate	Maximum
Core Functionality:	Core Functionality:	Core Functionality:	Core Functionality:
Limited electronic requesting Patient demographics Request registration Testing Results entry Scientific validation Clinical validation Quality management Referrals inside Wales Referrals outside Wales Results enquiry Results reporting Access controls Coding & classification Configuration Data validation Results viewed capability Remote validation Rules based functionality Search facilities Legacy data Specimen tracking Stock control	Reagent module Enhanced specimen tracking Enhanced stock control Enhanced electronic requesting	Electronic requesting in full for all disciplines Image management Mobile working	Artificial intelligence Machine learning



Business as Usual	Minimum	Intermediate	Maximum
<b>Discipline Specific Functionality:</b>	<b>Discipline Specific Functionality:</b>	<b>Discipline Specific Functionality:</b>	<b>Discipline Specific Functionality:</b>
<b>Blood Sciences</b> Remote issue Batch products Blood fating <b>Cellular Pathology</b> Mortuary <b>Microbiology</b> <b>Screening</b>	<b>Blood Sciences</b> Enhanced blood tracking <b>Cellular Pathology</b> Post mortem Standard data sets <b>Microbiology</b> Non-human testing <b>Screening</b>	<b>Blood Sciences</b> Full vein-to-vein blood tracking with remote issue <b>Cellular Pathology</b> <b>Microbiology</b> System driven workflows <b>Screening</b>	<b>Blood Sciences</b> Digital Microscopy <b>Cellular Pathology</b> Digital Cellular Pathology <b>Microbiology</b> <b>Screening</b>
<b>Integration:</b>	<b>Integration:</b>	<b>Integration:</b>	<b>Integration:</b>
<b>National Applications:</b> Enterprise master patient index Electronic test requesting (ETR) GP links and test requesting Point of care testing Welsh clinical portal Welsh reference data service Welsh results & reporting service <b>Pathology Applications:</b> Blood tracking WTAAIL	<b>National Applications:</b> Enhanced ETR <b>Pathology Applications:</b> Medical genetics Phlebotomy NPEx QMS	<b>National Applications:</b> Clinical data repository Fully developed ETR Synapse (image repository) <b>Pathology Applications:</b> Digital Cellular Pathology	<b>National Applications:</b> National data resource (NDR) <b>Pathology Applications:</b>

Business as Usual	Minimum	Intermediate	Maximum
<b>Downstream Systems:</b> Direct interfaces to downstream systems	<b>Downstream Systems:</b> Single extract from LIMS to NWIS integration services to replace all direct interfaces to downstream systems	<b>Downstream Systems:</b>	<b>Downstream Systems:</b> Artificial intelligence systems
<b>Additional Systems</b>	<b>Additional Systems</b>	<b>Additional Systems</b>	<b>Additional Systems</b>
Blood tracking system (vein to vein with remote issue)	Dictation and voice recognition Scanning NPEX Quality management system Legacy data system		
<b>Business Intelligence:</b>	<b>Business Intelligence:</b>	<b>Business Intelligence:</b>	<b>Business Intelligence:</b>
Limited audit capability Benchmarking extracts National data extracts Limited billing	Some improvement in business intelligence functionality such as enhanced billing	Billing (full functionality) Costing Epidemiology data Full audit capability Outbreak data Real time reporting Real time dashboards Turnaround times Performance management Ad hoc research	Artificial intelligence
<b>Standards:</b>	<b>Standards:</b>	<b>Standards:</b>	<b>Standards:</b>
<b>Andrology:</b> PVSA for Andrology WHO guidelines <b>Blood Transfusion:</b>	GPDR Current GMP GAMP5 Human Tissue Act 2004	SNOMED CT fully standardised HL72.5 / FHIR integration standards W3C Web standards	

Business as Usual	Minimum	Intermediate	Maximum
BSQR BT requirements MHRA BT requirements <b>Generic:</b> ISO90001 QMS Read codes mapped to SNOMED Clinical Terms	ISO/IEC 20000 ITSM ISO27001: 2013 ISMS MHRA CE marking Improve SNOMED CT standardisation UKAS ISO15189:2012	ISO13485: Medical devices ISO9241-11:2018 Ergonomics of human-system interaction	
Business Change:	Business Change:	Business Change:	Business Change:
Standardisation continues at current rate No business change  No additional validation support  Initial deployment training Initial training materials  Training database for deployment	Standardisation work completed as part of the LINC Programme Minimal business change run by the LINC PMO Validation support in programme team Train the trainer (TTT) training Training materials maintained by NHS Training database maintained by Supplier	Standardisation work completed as part of a LINC Project Plus some external support for business change Validation support in programme team Train the trainer (TTT) training Training materials maintained by Supplier Training database maintained by Supplier	Standardisation work completed as part of a LINC Project Plus significant external support for business change Plus external validation support  Permanent on-site supplier provided training  Training database maintained by Supplier
Documentation:	Documentation:	Documentation:	Documentation:
Full system documentation Release notes	Electronic repository of the system documentation provided by the supplier, including e.g.: <ul style="list-style-type: none"> <li>• Hardware validation</li> <li>• Software validation</li> <li>• Change control</li> <li>• System documentation</li> <li>• Risk assessments</li> </ul>		

## Appendix 7: LINC Stakeholders



## Appendix 8: LINC Workshops and Events 2018

Date	Time	Workshop Name	Location
23 Jan	11.30-15.30	Business Case Workshop	Mawr Room, River House
30 Jan	11.00-15.00	Requirements Planning Workshop	Mawr Room, River House
6 Feb	9.00-17.00	Supplier Day	Holiday Inn, Cardiff Central
16 Feb	9.30-13.30	Technical Workshop	Hafren Room, NWIS
27 Feb	12.30-17.00	Core Requirements	Mawr Room, River House
7 Mar	14.00-17.00	Business Intelligence & Reporting	Mawr Room, River House
15 Mar	19.30-16.00	Antenatal, Cervical & Newborn Bloodspot Screening Requirements	3/6 , 3 <sup>rd</sup> floor No.2 CQ
23 Apr	10.00-13.00	Andrology Requirements	Mawr Room, River House
23 Apr	14.00-17.00	Blood Transfusion Requirements	Mawr Room, River House
24 Apr	10.00-13.00	Cellular Pathology Requirements	Mawr Room, River House
24 Apr	14.00-17.00	Clinical Biochemistry Requirements	Mawr Room, River House
25 Apr	14.00-17.00	Haematology Requirements	Mawr Room, River House
26 Apr	10.00-13.00	Microbiology Requirements	Mawr Room, River House
27 Apr	10.00-13.00	Immunology Requirements	Mawr Room, River House
3 May	12.30 - 15.30	Quality workshop	Mawr Room, River House
12 June	13.30 - 16.30	Andrology Requirements	Mawr Room, River House
13 June	12.30 - 15.30	Blood Transfusion Requirements	Mawr Room, River House
18 June	12.30 - 15.30	Cellular Pathology Requirements	Mawr Room, River House
20 June	10.30 - 13.30	Clinical Biochemistry Requirements	Mawr Room, River House
21 June	12.30 - 15.30	Haematology Requirements	Mawr Room, River House
26 June	12.30 - 15.30	Microbiology Requirements	Mawr Room, River House
27 June	12.30 - 15.30	Benefits Realisation Workshop	Mawr Room, River House
16 July	12.30 - 15.30	Security and Role Based Access Controls	Mawr Room, River House
23 July	12.30 - 15.30	Schedule 2.2 Service Management	Mawr Room, River House

Date	Time	Workshop Name	Location
17 Aug	10:30 – 13:30	OBC Economic Case	Canolig Room, River House
3 Sep	10:30 – 15:30	LINC-NWIS Joint Conference	Life Sciences Hub, Cardiff Bay
7 Sep	10:00 – 13:00	Technical Workshop	Yr Hen Llyfrgell, Cardiff Central
25 Sep	10:30 – 12:30	Feedback from Informal Site Visits	Mawr Room, River House
27 Sep	10:30 – 13:30	Schedule 2.2 Service Levels	Mawr Room, River House
8 Oct	11:30 – 14:30	Financially Quantify the Benefits	Bach Room, River House
12 Oct	12:30 – 14:30	Financially Quantify the Risks	Bach Room, River House
24 Oct	12:30 – 15:30	Electronic Requesting and the WCP Gap Analysis	Innovation Area, NWIS Cardiff offices
14 Nov	13:00 – 16:00	Technical Workshop	Taf Room, NWIS Cardiff offices
28 Nov	11:00 – 13:00	BI Reporting	Bach Room, River House
3 Dec	9:30 – 12:30	Mortuary & Histopathology Requirements	Bach Room, River House
10 Dec	10:30 – 16:30	Electronic Requesting and the WCP Gap Analysis	Life Sciences Hub, Cardiff Bay
14 Dec	10:30 – 16:30	Overall Requirements	Life Sciences Hub, Cardiff Bay

## Appendix 9: Benefits mapped to spending objectives

Spending objectives	Main benefits criteria by stakeholder group (source of data)
<b>S01:</b> To improve patient care, patient safety and patient outcomes	<b>Patients</b> <i>Economic (Non cash releasing (£s))</i> <ul style="list-style-type: none"> <li>Automated LIMS environment synchronisation (staff time saved)</li> <li>Repeated tests halved (WLIMS1 audit)</li> </ul> <i>Qualitative</i> <ul style="list-style-type: none"> <li>Clinical incidents halved (Datix)</li> <li>95% turnaround times within standard (BI systems)</li> <li>Zero transcription errors via electronic requests (Datix)</li> <li>Auditable action in WCP against viewed results (baseline survey required)</li> <li>Zero incidents of missing samples (Datix, QMS)</li> </ul>
<b>S02</b> To enable the transformation of healthcare services to be leaner, standardised, more sustainable and provide long-term stability	<b>Service Management</b> <i>Economic</i> <ul style="list-style-type: none"> <li>Ability to validate and report on samples analysed from any site (Currently unable to do this)</li> </ul> <i>Qualitative</i> <ul style="list-style-type: none"> <li>Halve the number of duplicated controlled documents &amp; documents past review (QMS systems)</li> </ul>
<b>S03</b> To deliver a seamless, end-to-end technical solution for Pathology services	<b>Service Management, Operations &amp; Laboratory Staff</b> <i>Financial</i> <ul style="list-style-type: none"> <li>Generate income from referrals (use of NPEx)</li> <li>Halve integration costs to downstream systems (cost analysis)</li> </ul> <i>Economic</i> <ul style="list-style-type: none"> <li>Reduced system downtime, availability to meet required standard (Hours per quarter)</li> </ul> <i>Qualitative</i> <ul style="list-style-type: none"> <li>Configuration changes delivered within defined turnaround times (Service Point records)</li> </ul>
<b>S04</b> To contribute to the more prudent use of Pathology resources through demand management, predictive costing and minimised financial risk	<b>Service Management, Operations &amp; Laboratory Staff</b> <i>Financial</i> <ul style="list-style-type: none"> <li>Reduce overall costs of Pathology service by 1%</li> <li>0.25WTE BMS per lab tracking samples (% tracked online)</li> <li>Halve WTE sample reception staff booking in samples (Staffing figures)</li> </ul> <i>Economic</i> <ul style="list-style-type: none"> <li>Halve the WLIMS1 costs of validation (WLIMS1 costs)</li> <li>Reduced calls for blood availability (WCP development)</li> <li>Reduced calls to the labs for test results (WCP on tablets)</li> <li>Halve number of forms scanned (Audit)</li> <li>Reduced overtime costs (Survey)</li> </ul>
<b>S05</b> To meet current and future service requirements	<b>Clinicians</b> <i>Economic</i> <i>Qualitative</i> <ul style="list-style-type: none"> <li>Mobile access to results (Take up of mobile working)</li> <li>Improved clinical decision making (notepad functionality)</li> </ul>

## Appendix 10: LINC Programme main risks and their mitigation

Main risk	Counter Measure
<b>Design Risks</b>	
Design	<p>To take forward standardisation, develop the design as far as possible during the procurement, and complete the design with the supplier for the chosen solution once the procurement is completed.</p> <p>To ensure that the design of the integration requirements have been completed, assured and approved.</p> <p>To design and run the LINC Programme in accordance with Managing Successful Programmes (MSP) and PRINCE2 and ensure appropriate governance, programme and projects controls are in place including risk, issue and change management.</p>
<b>Development Risks</b>	
Supplier	<p>To assure the supplier has the record of accomplishment and can evidence the required competencies, methods and approach as part of the procurement process and build incentives into the contract for delivery.</p> <p>NWIS does not have the technical capacity to support the development work so backfill costs have been included for technical, infrastructure and service management. The application support team are fully committed to TCL2011 but their expertise is required for the new LIMS design, so discussions will need to take place to enable their contribution.</p>
Specification	<p>To assure that the requirement is fully developed and approved by the Pathology stakeholders (including the service and NWIS) through workshops, consultation and formal approval mechanisms. In particular to build in standardisation to the design.</p> <p>Also to ensure that the integration is fully specified and approved by all technical parties including NWIS, ADIs, Pathology IT Managers and the supplier.</p> <p>To ensure full end-to-end, regression and volume testing are planned for and undertaken.</p>
Timescale	<p>To assure the timescale is robust but also include key milestones and contingency, allowing for design, development, testing and validation prior to implementation.</p>
Change management	<p>To build in change management into the LINC Programme to create the capacity for change, provide training and support and address resistance to change. In particular to build the support for standardisation.</p> <p>To ensure changes can be made within each discipline without dependency or conflict with other pathology services.</p>



Main risk	Counter Measure
Project management	To design and run the Development Project in accordance with PRINCE2, with clear product definitions, plans, roles and responsibilities, governance and project controls to manage risks, issues and change.
<b>Implementation Risks</b>	
Supplier	To assure that the supplier has the right capacity, method and approach to support implementation as part of the procurement process and build incentives into the contract for delivery.
Timescale	To ensure detailed planning of the implementation process with preparation milestones, training and cutover plans and ensure that local services are prepared and their organisation committed to delivering within the agreed timescale. To assure business continuity of the current LIMS until the new LIMS is ready to deploy.
Specification & data transfer	To ensure that all legacy data agreed to go into the live system has been successfully migrated, that all interfaces are live and that data flows are working as planned with tests for data integrity. To ensure that the technical specification for legacy data is fully defined, that the legacy data solution is fully populated and data accessible and transferable to the live LIMS as specified.
Cost risks	To develop and assure detailed plans that will identify all cost requirements and cost pressures. To include payment milestones into the supplier contract, which along with the use of a Master Services Agreement contract form will commit the supplier and health boards to deliver agreed outputs and meet agreed deadlines to minimise impact on costs.
Change management	To design a change management strategy to build into the LINC Programme to minimise resistance to change, have mechanisms to avoid prevarication, support decision making and provide the necessary leadership to ensure local and national resources are available when required. Combined with governance processes for managing change requests. To ensure changes can be made within each discipline without dependency or conflict with other pathology services.
Project management	To design and run the Deployment Project in accordance with PRINCE2, with clear product definitions, plans, roles and responsibilities, governance and project controls to manage risks, issues and change.
Training and user	To develop a training strategy, undertake a training needs analysis, develop training materials and then plan and deliver training in flexible ways to meet the needs of the service. The service does not have the capacity to support the LINC Programme especially if an interim upgrade to TCL2016 is required, which may affect programme timescales.

Main risk	Counter Measure
<b>Operational risks</b>	
Supplier	To assure that the supplier has the capacity and capability to support the development, testing and delivery of an All Wales Pathology LIMS service and to engage with end users during the procurement process with well-defined governance mechanisms and escalation procedures. InterSystems may not agree to support TCL2011 after their contract expires in June 2020. Informal discussions are underway to agree a way forward.
Availability	To assure the business continuity plans and technical architecture design, delivery and testing to ensure it can deliver the availability required to provide a stable service.
Performance	Put in place a contract and schedule 2.2 on service management to clearly define the supplier's responsibilities and have the governance mechanism in place to monitor supplier performance, combined with financial incentives to deliver and other good practice mechanisms to address an issue with supplier performance.
Operating cost	To ensure that all costs are known up front through thorough review of anticipated costs with a wide range of stakeholders and mechanisms in place to manage change and costs. InterSystems have indicated that they will wish to increase their costs to continue to support TCL after the end of the contract, so this risk has to be tolerated dependent on the outcome of the discussions. Early engagement with HBs and / or the Welsh Government is essential in case they do not agree to the resources required at a national or local level to deliver the programme causing delays and consequent additional costs.
Project management	To ensure well defined processes and procedures in place to close down the deployment project and handover to operations
<b>Termination risks</b>	
Termination risks	To ensure that termination risks are addressed as part of the procurement process and contract schedules.

## Appendix 11: Notes of the Pathology Solution Costs

Notes Ref	Notes
1	<b>Pathology Solution</b> includes dual running costs of the current LIMS until the new LIMS is fully deployed; the costs of the new LIMS plus other tools including the QMS and NPEx; and the proposed additional support services for the new LIMS
2	<b>Dual Running Costs:</b> This includes the cost of the InterSystems and NWIS support services for the current LIMS plus third party hardware support costs. No uplift has been applied so same costs for the contract period.
3	Dual running costs of InterSystems TrakCare: Assumes costs of current LIMS continued. No costs included for an upgrade. Also assumes required for 2.5 years although up to five years is being negotiated.
4	NWIS dual running costs: Cost of proving application, technical, integration and testing support services, the service desk and service management costs.
5	<b>New Pathology solution:</b> Costs of the new LIMS and associated tools. Some of these (Blood tracking, NPEx) may be included in the new contract with the supplier but initial market soundings did not include these tools.
6	Market soundings has indicated £30m over 10 years revenue only or £22m over 10 years revenue plus £8m capital. Excludes integration costs. Assumes initial payment once system developed, tested, validated and signed off ready for deployment during 2021/22.
7	Notional estimate of integration costs to national applications, create a single data extract for integration with downstream systems and laboratory equipment. Needs to cover InterSystems and NWIS costs.
8	Notional estimate of legacy data costs. InterSystems quoting £250k per extract. Assumed one plus delta per HB/PHW = 8 overall
9	Notional costs for a scanning system system, using annual maintenance costs for BCU rounded up for each HB. Assume this will be provided via the chosen supplier. Will be included in supplier service.
10	Notional costs for voice recognition. Will be included in supplier service.
11	Notional costs for a blood tracking system, using annual maintenance costs for Cwm Taf rounded up for each HB. Assume this will be provided via the chosen supplier and may be able to novate current licence to new supplier. Will be included in supplier service.
12	Crude estimated costs of an electronic requesting solution for primary and secondary care either to develop WCP to meet pathology ETR requirements or to procure a separate to ETR tool.
13	Costs of a quality management system being hosted via NWIS using an NHS data centre. This includes the costs based on a quotation from Ideagen of a Q-Pulse licence and implementation and estimated NWIS hosting costs.
14	Costs based on NPEx quote from December 2017 to Brent Varley. Will include this in the requirements for the LIMS supplier to provide as part of the whole solution. Will be included in supplier service.
15	Annual budget for changes to the new LIMS system, after go live.
16	<b>Proposed Additional LIMS Support Services Costs</b> These are posts over and above the current establishment to support the new LIMS based on lessons learned from WLIMS1.
17	Band 6 Senior Support and Business Analyst for integration services. The National Operational databased and Information (NODi) Team are fully stretched at the moment, supporting current and upcoming Test Result and document feeds, including the current LIMS system. There will be no resource available to support the new LIMS and in particular the complex number of message flows to be transitioned to the new environment. NODi look after the WRRS, WCRS and WRDS. This post would look after the LIMS components of these systems. Vacant so mid-point assumed wef April 2019.

Notes Ref	Notes
18	Principal Support & Business Analyst. The Integration Team requires a band 7 to assist with the coordination between the development of the new implementation and the User Acceptance Testing of the new LIMS, while providing continuity of service to the current environments. The significant number of message flows to be migrated will require a considerable amount of coordination, and I would expect this role to take the lead on this, under the guidance of the Senior Product Specialist. Vacant so mid-point assumed wef April 2019.
19	Senior Software Developer. A band 6 development is required as the Integration Team currently has only one active developer. We have 6 active flows for LIMS which are extremely complex and the expectation is that the additional flows will have the same impact to develop. We would require a dedicated developer for this work so that this does not leave the team with no capacity to develop other system flows or carry out essential system upgrades. Due to the complexity of FIORANO it requires a substantial amount of time to train an individual up to develop and support the service. We are unlikely to find contract resource with these skills, and hence the recommendation for a permanent resource. Vacant so mid-point assumed wef April 2019.
20	NWIS application architect required dedicated to LIMS. Vacant, so mid-point assumed wef April 2019
21	Quality Management Team to support the development and implementation of a national quality management system to facilitate and maintain a standardised approach across Wales and manage system documentation. All posts assumed wef April 2019 Quality Manager / Validation Lead vacant but have assumed top of the scale as experience essential. Validation Officer required to facilitate standardisation and prepare for validation (mid-point assumed) Configuration Librarian to manage QMS documentation (mid-point assumed) Administrative support office for the team (mid-point assumed)
22	Two UAT testers to be part of the Quality team to support the laboratories in testing new releases, patches and updates to support validation requirements
23	Informatics roles to maintain and develop operational reports, real time dashboards and business intelligence for the new LIMS Experienced 8a top of the scale supported by a band 6 (mid-point assumed) wef April 2019.
24	<b>Capital Monies</b> Typical value of capital monies identified as part of the market soundings exercise.

## Appendix 12: Net Present Cost Calculations

Table 30: Net Present Cost Option 1 Business as usual

Net present costs of Option 1 BAU: Upgrade to TCL 2016	Apr 20 - Mar 21 £k Year 1	Apr 21 - Mar 22 £k Year 2	Apr 22 - Mar 23 £k Year 3	Apr 23 - Mar 24 £k Year 4	Apr 24 - Mar 25 £k Year 5	Apr 25 - Mar 26 £k Year 6	Apr 26 - Mar 27 £k Year 7	Total Cost £k
Upgrade to TCL 2016	2,500	0	0	0	0	0	0	2,500
<b>Total Capital (excluding optimism bias)</b>	<b>2,500</b>	<b>0</b>	<b>0</b>	<b>0</b>	<b>0</b>	<b>0</b>	<b>0</b>	<b>2,500</b>
Optimism Bias @ 20%	0	0	0	0	0	0	0	500
<b>Total Capital (including optimism bias)</b>	<b>2,500</b>	<b>0</b>	<b>0</b>	<b>0</b>	<b>0</b>	<b>0</b>	<b>0</b>	<b>3,000</b>
TCL 2016	2,749	3,604	3,604	3,604	3,604	3,604	3,604	24,375
<b>Total Revenue (excluding optimism bias)</b>	<b>2,749</b>	<b>3,604</b>	<b>3,604</b>	<b>3,604</b>	<b>3,604</b>	<b>3,604</b>	<b>3,604</b>	<b>24,375</b>
Optimism Bias @ 20%	0	0	0	0	0	0	0	4,875
<b>Total Revenue (including optimism bias)</b>	<b>2,749</b>	<b>3,604</b>	<b>3,604</b>	<b>3,604</b>	<b>3,604</b>	<b>3,604</b>	<b>3,604</b>	<b>29,250</b>
<b>Total annual costs excluding optimism bias</b>	<b>5,249</b>	<b>3,604</b>	<b>3,604</b>	<b>3,604</b>	<b>3,604</b>	<b>3,604</b>	<b>3,604</b>	<b>26,875</b>
<b>Total annual costs including optimism bias</b>	<b>5,249</b>	<b>3,604</b>	<b>3,604</b>	<b>3,604</b>	<b>3,604</b>	<b>3,604</b>	<b>3,604</b>	<b>26,875</b>
Deduct: calculation of benefits	0	-222	-667	-1,333	-1,333	-1,333	-1,333	-6,222
Add: Risk quantification	13,130	50	50	50	50	866	1,273	15,469
<b>Total</b>	<b>18,379</b>	<b>3,432</b>	<b>2,988</b>	<b>2,321</b>	<b>2,321</b>	<b>3,137</b>	<b>3,544</b>	<b>36,121</b>
Discounting	1.00	0.97	0.93	0.90	0.87	0.84	0.81	
<b>Net Present Cost</b>	<b>18,379</b>	<b>3,316</b>	<b>2,789</b>	<b>2,093</b>	<b>2,023</b>	<b>2,641</b>	<b>2,883</b>	<b>34,124</b>

Table 31: Net Present Cost Option 2 Do minimum

Net present costs of Option 2 Do Minimum	Apr 20 - Mar 21 £k Year 1	Apr 21 - Mar 22 £k Year 2	Apr 22 - Mar 23 £k Year 3	Apr 23 - Mar 24 £k Year 4	Apr 24 - Mar 25 £k Year 5	Apr 25 - Mar 26 £k Year 6	Apr 26 - Mar 27 £k Year 7	Total Cost £k
No capital costs	4,200	6,813	0	0	0	0	0	11,013
<b>Total Capital (excluding optimism bias)</b>	<b>4,200</b>	<b>6,813</b>	<b>0</b>	<b>0</b>	<b>0</b>	<b>0</b>	<b>0</b>	<b>11,013</b>
Optimism Bias @ 20%	840	1,363	0	0	0	0	0	2,203
<b>Total Capital (including optimism bias)</b>	<b>5,040</b>	<b>8,176</b>	<b>0</b>	<b>0</b>	<b>0</b>	<b>0</b>	<b>0</b>	<b>13,216</b>
Current LIMS dual running wef June 2020	2,749	3,665	3,665	916	0	0	0	10,995
TCLE in NHS data centre	1,295	2,672	1,844	1,844	1,844	1,844	1,844	13,187
NWIS support costs	254	311	318	889	1,079	1,081	1,084	5,015
National quality management team and system	364	372	381	392	395	399	403	2,706
<b>Total Revenue (excluding optimism bias)</b>	<b>4,662</b>	<b>7,020</b>	<b>6,208</b>	<b>4,041</b>	<b>3,318</b>	<b>3,324</b>	<b>3,330</b>	<b>31,903</b>
Optimism Bias @ 20%	932	1,404	1,242	808	664	665	666	6,381
<b>Total Revenue (including optimism bias)</b>	<b>5,594</b>	<b>8,424</b>	<b>7,449</b>	<b>4,849</b>	<b>3,982</b>	<b>3,989</b>	<b>3,996</b>	<b>38,284</b>
<b>Total annual costs excluding optimism bias</b>	<b>8,862</b>	<b>13,833</b>	<b>6,208</b>	<b>4,041</b>	<b>3,318</b>	<b>3,324</b>	<b>3,330</b>	<b>42,916</b>
<b>Total annual costs including optimism bias</b>	<b>10,634</b>	<b>16,600</b>	<b>7,449</b>	<b>4,849</b>	<b>3,982</b>	<b>3,989</b>	<b>3,996</b>	<b>51,499</b>
Deduct: calculation of benefits	0	-444	-1,333	-2,667	-2,667	-2,667	-2,667	-12,444
Add: Risk quantification	11,950	950	360	360	260	260	260	14,400
<b>Total</b>	<b>22,584</b>	<b>17,105</b>	<b>6,476</b>	<b>2,542</b>	<b>1,575</b>	<b>1,582</b>	<b>1,589</b>	<b>53,455</b>
Discounting	1.00	0.97	0.93	0.90	0.87	0.84	0.81	
<b>Net Present Cost</b>	<b>22,584</b>	<b>16,527</b>	<b>6,045</b>	<b>2,293</b>	<b>1,373</b>	<b>1,332</b>	<b>1,293</b>	<b>51,447</b>

Table 32: Net Present Costs Option 3 Preferred option

Net present costs of Option 3 Preferred Option	Apr 20 - Mar 21 £k Year 1	Apr 21 - Mar 22 £k Year 2	Apr 22 - Mar 23 £k Year 3	Apr 23 - Mar 24 £k Year 4	Apr 24 - Mar 25 £k Year 5	Apr 25 - Mar 26 £k Year 6	Apr 26 - Mar 27 £k Year 7	Total Cost £k
	8,000	0	0	0	0	0	0	8,000
<b>Total Capital (excluding optimism bias)</b>	<b>8,000</b>	<b>0</b>	<b>0</b>	<b>0</b>	<b>0</b>	<b>0</b>	<b>0</b>	<b>8,000</b>
Optimism Bias @ 20%	1,600	0	0	0	0	0	0	1,600
<b>Total Capital (including optimism bias)</b>	<b>9,600</b>	<b>0</b>	<b>0</b>	<b>0</b>	<b>0</b>	<b>0</b>	<b>0</b>	<b>9,600</b>
Current LIMS dual running wef June 2020	2,749	3,665	3,665	916	0	0	0	10,995
New LIMS Service	1,545	3,747	2,494	2,494	2,494	2,494	2,494	17,762
NWIS support costs	254	311	318	889	1,079	1,081	1,084	5,015
National quality management team and system	364	372	381	392	395	399	403	2,706
<b>Total Revenue (excluding optimism bias)</b>	<b>4,912</b>	<b>8,095</b>	<b>6,858</b>	<b>4,691</b>	<b>3,968</b>	<b>3,974</b>	<b>3,980</b>	<b>36,478</b>
Optimism Bias @ 20%	982	1,619	1,372	938	794	795	796	7,296
<b>Total Revenue (including optimism bias)</b>	<b>5,894</b>	<b>9,714</b>	<b>8,229</b>	<b>5,629</b>	<b>4,762</b>	<b>4,769</b>	<b>4,776</b>	<b>43,774</b>
<b>Total annual costs excluding optimism bias</b>	<b>12,912</b>	<b>8,095</b>	<b>6,858</b>	<b>4,691</b>	<b>3,968</b>	<b>3,974</b>	<b>3,980</b>	<b>44,478</b>
<b>Total annual costs including optimism bias</b>	<b>15,494</b>	<b>9,714</b>	<b>8,229</b>	<b>5,629</b>	<b>4,762</b>	<b>4,769</b>	<b>4,776</b>	<b>53,374</b>
Deduct: calculation of benefits	0	-667	-2,000	-4,000	-4,000	-4,000	-4,000	-18,667
Add: Risk quantification	420	470	570	429	335	100	100	2,424
<b>Total</b>	<b>15,914</b>	<b>9,517</b>	<b>6,799</b>	<b>2,058</b>	<b>1,097</b>	<b>869</b>	<b>876</b>	<b>37,131</b>
Discounting	1.00	0.97	0.93	0.90	0.87	0.84	0.81	
<b>Net Present Cost</b>	<b>15,914</b>	<b>9,195</b>	<b>6,347</b>	<b>1,856</b>	<b>956</b>	<b>732</b>	<b>713</b>	<b>35,713</b>





## Appendix 13: LINC Programme Board Membership

Name	Representing
Adrian Thomas	Senior Responsible Owner
Judith Bates	Programme Director
Melanie Barker	Senior Programme Manager, Pathology PMO, NHWSHC
Jane Long	Senior Project Support Officer, Pathology PMO, NHSWHC
Jane Fitzpatrick	Director Strategic Programmes, NHSWHC
Andar Gunneberg	Abertawe Bro Morgannwg University Health Board Representative
Rachel Still	Abertawe Bro Morgannwg University Health Board Deputy
Craig Roberts	Aneurin Bevin University Health Board Representative
Michael Redman	Aneurin Bevin University Health Board Deputy
Rachael Surridge	Betsi Cadwaladr University Health Board Representative
Pearl Huey	Betsi Cadwaladr University Health Board Deputy
Matthew Temby	Cardiff & Vale University Health Board Representative
Carol Evans	Cardiff & Vale University Health Board Deputy
Esther Youd	Cwm Taf University Health Board Representative
Paul Seddon	Cwm Taf University Health Board Deputy
Andrea Stiens	Hywel Dda University Health Board Representative
Dylan Jones	Hywel Dda University Health Board Deputy
Ruth Young	All Wales Medical Genetics Service Representative
Rachel Butler	All Wales Medical Genetics Service Deputy
Robin Howe	Public Health Wales Representative - Microbiology
Annette Thomas	Point of Care Testing Representative
(various)	Point of Care Testing Deputy
David Heyburn	Public Health Wales Deputy - Microbiology
Helen Clayton	Public Health Wales Representative - Screening
Guy Stevens	Public Health Wales Deputy – Screening
David Mason Hawes	Welsh Blood Service Representative
Emyr Adlam	Welsh Blood Service Deputy
Declined	Nominated Powys Teaching Health Board Representative
Declined	Nominated Welsh Ambulance Trust Representative
Michelle Sell	NHS Wales Informatics Service Representative
Elizabeth Waites	NHS Wales Informatics Service Deputy
Carol Evans	Laboratory Services Sub Committee Representative
Tariq El-Shanawany	Laboratory Services Sub Committee Deputy
Rob Tovey	Deputy Directors of Finance Representative
Karen Winder	Directors of Informatics Representative
Anthony Tracey	Directors of Informatics Deputy
Clive Morgan	Directors of Therapies and Healthcare Sciences Representative
Michael Redman	Directors of Therapies and Healthcare Sciences Deputy
Fiona Jenkins	National Pathology Programme Board Chair

## **Appendix 14: Organisational Roles and Responsibilities**

### ***Welsh Government***

The Welsh Government is the devolved Government for Wales with responsibility for the economy, education, health and the Welsh NHS, business, public services and the environment of Wales. It provides capital and revenue funding subject to approved business cases.

### ***Director General of Health and Social Services, Chief Executive, NHS Wales – Andrew Goodall***

Dr Goodall will head the Welsh Government's Department for Health and Social Services, and will be responsible and accountable to the Minister for Health and Social Services and Deputy Minister for Social Services for all health, public health and social care policy in Wales. In addition, he will also serve as Chief Executive of NHS Wales.

### ***National Informatics Advisory Board (NIMB)***

NHS Informatics Management Board (NIMB) The Informatics Service's direction is overseen by the NIMB, which is chaired by Chief Executive of the NHS in Wales – Dr. Andrew Goodall. The board oversees the delivery and operation of national information and technology programmes and services.

### ***Informatics Planning and Delivery Group (IPAD)***

IPAD reports directly to NIMB, will advise NIMB on IM&T-related business cases.

### ***Welsh Scientific Advisory Committee (WSAC)***

Part of the Welsh Government Directorate of Public health, WSAC advises the Welsh Government on matters relating to health sciences and the health scientist profession

### ***Laboratory Services Sub Committee (LSSC)***

A subcommittee of WSAC, providing expert scientific and professional advice to Ministers of the Welsh Government through the Welsh Scientific Advisory Committee on laboratory and clinical Pathology services. In addition, advising on policy matters and the education and training of staff involved the provision of cost-effective, quality laboratory and clinical Pathology services in Wales.

### ***Standing Specialist Advisory Groups (SSAGs)***

SSAGs for Biochemistry, Cellular Pathology, Haematology Immunology and Microbiology report to the LSSC. SSAGs for Point of Care Testing (POCT) and Genetics will report directly to WSAC.

### ***Standardisation Groups***

Reporting to each SSAG, standardisation groups consider and agree on the standardisation and warranted variation for their discipline across Wales.

### ***NHS Wales Collaborative Leadership Forum (CLF)***

The CLF is a quarterly meeting of the Chairs and CEOs of the Health Boards, Trusts and national services, such as Public Health Wales (PHW) and Health Education and Improvement Wales (HEIW) to consider all Wales issues and initiatives.

### ***NHS Wales Collaborative Executive Group (CEG)***

Reporting to the CLF, the CEG is a monthly meeting of the CEOs of the Health Boards, Trusts and national services, such as Public Health Wales (PHW) and Health Education and Improvement Wales (HEIW) to agree and oversee all Wales programmes. The NHS Wales Health Collaborative (NHSWHC) is the body set up to run and deliver these programmes on behalf of the CEG. This includes collective corporate accountability for the LINC Programme.

### ***National Pathology Network (NPN)***

Reporting to the CEG, the NPN acts in lieu of a national Pathology service to develop a modern, sustainable Pathology service providing high quality, safe and prudent services to the NHS contributing to the national strategy of *A healthier Wales: Our plan for health and social care*. The NPN provides a voice for the Pathology service at a national level and will have overall responsibility for the Pathology Statement of Intent. This includes professional oversight of the LINC programme, which is a key component of the PSOI.

### ***LINC Programme Board (LPB)***

The LPB is responsible for managing a portfolio of programmes and projects to deliver an end-to-end technical solution to support Pathology services including the procurement and implementation of a new, national laboratory information management system (LIMS) for Wales. These programmes and projects are being designed and managed in accordance with the managing successful programmes (MSP) and PRINCE2 project management methodologies.

The membership of the LPB includes representatives of:

- Associate Directors of Informatics (ADIs)
- Deputy Directors of Finance (DDoFs)

- Directors of Therapies and Health Sciences (DOTHS)
- Each Health Board and PHW
- LSSC
- NHSWHC Strategic Programmes
- NWIS
- POCT, Welsh Blood Service (WBS) and Medical Genetics

### ***LINC Design Authority (LDA)***

The LDA, currently being set up, will maintain a consistent, coherent and complete perspective of the programme design, defining the programme critical interfaces, such that business operations can be changed and benefits secured in a coordinated manner across Wales. The LDA is accountable for ensuring the integrity of the programme; focusing inwardly on the internal consistency of the programme; and outwardly on its coherence with Health Board (HB) corporate and operational requirements and, other national programmes and external requirements such standards, validation and accreditation.

The proposed membership of the LDA includes the following with the aim to cover all health boards and services as part of the membership:

- Clinical leads for each main discipline
- SSAG chairs
- LINC Programme Director
- NWIS key personnel including: LIMS Service Manager, LIMS Technical Architect, National Diagnostic IT Programme Manager
- Plus representatives of: ADIs, Pathology Clinical Directors, Pathology IT Managers, Pathology Quality Managers and Pathology Service Managers.

### ***Welsh Informatics Assurance Board (WIAB)***

The WIAB provides independent advice and support to the Clinical Chief Information Officer for Wales, Rhidian Hurlle on all aspects of quality assurance related to the delivery of national informatics services. The board has the authority to exercise clinical, managerial and technical judgement to ensure that health informatics services are safe and ready to be used by NHS Wales and Welsh social care services. It has a scrutiny role to ensure that the national informatics services provided to NHS organisations, from whatever source, are safe and have been appropriately assured.

### ***Welsh Informatics Assurance Group (WIAG)***

The WIAG provides quality assurance to WIAB on all aspects of assurance related to the delivery of national informatics services. WIAG has the authority to exercise clinical, managerial and technical judgement to ensure

that national informatics services are safe and ready to be used by NHS and Social Care services in Wales once approved by the WIAB.

### ***National LIMS Service Management Board (SMB)***

The LIMS SMB is hosted by NWIS as part of the IT service management arrangements and will provide governance in accordance with ISO 20000.

### ***National Contract Management Board (CMB)***

The national CMB, chaired and led by the NHS, will directly manage the contract with the supplier, agree any contractual change notices (CCNs) and ensure compliance against the contract. The supplier will be held to account against a requirements traceability matrix to ensure delivery of The Authority's Requirements (Schedule 2.1) against an agreed delivery plan.

### ***LIMS Change Advisory Board (CAB)***

The purpose of the LIMS CAB is to review and approve changes to the LIMS and to consider the impact of any changes in relation to other national and local applications. Clinical changes will be managed via the SSAGs and standardisations groups in conjunction with the LDA.

## Appendix 15: Notes for the LINC Programme Costs

Notes Ref	Notes of Programme Costs
1	<b>Costs of the LINC Programme:</b> comprising the LINC PMO, Standardisation team, NWIS programme costs, Additional procurement costs, non-pay costs and contingency. Staffing costs based on NHS employers AfC 25% on-costs per increment for Mid-Point (M-P) or Top of the scale. Plus an annual 1% cost of living increase assumed.
2	<b>LINC PMO</b> assumes costs from staff take-on until September 2023. Initially three year appointments, it is assumed contracts will be extended until the end of the programme.
3	Programme Director actual salary costs. Currently on a three year contract due to end November 2020
4	Programme Manager actual salary costs. Currently on a three year contract due to end July 2021
5	Senior Project Manager and Project Manager posts, currently out to advert on three year contracts. Mid-point assumed wef December 2018.
6	Programme Officer / Planner for the programme and SPSO for the Procurement & Technical Projects Mid-point assumed wef April 2019.
7	SPSO (PMO) actual salary costs. Currently on a three year contract due to end August 2021
8	SPSO actual salary costs, currently based in ABM supporting Biochemistry standardisation and funded via LINC Programme
9	<b>Pathology Standardisation Team</b> Vacant but top of the scale estimated as it is assumed these will be secondments from the service wef April 2019 for four years. Assumed all posts will be full-time except for the standardisation leads which will be 2 sessions per week x 5 (2 for Biochemistry)
10	<b>NWIS Programme Costs</b> These are short term costs for NWIS to provide staff of services to the programme
11	Band 7 backfill for LIMS Service Manager to be relased to work full time on the LIMS Programme wef November 2018
12	Band 8c backfill for NWIS Procurement Lead to be relased to work full-time on the procurement wef November 2018
13	Band 6 Senior Software Developer contractor for NWIS integration services. Assumed top of the scale plus 20% agency fees. Depending on the precise detail of the requirement, it is anticipated that this could be a significant piece of work, which would see the NODi service used as a hub for test result and document dissemination. A dedicated resource will be required to ensure delivery of such a complex piece of work.
14	Potential to use the busines schange service being explored, notional costs included
16	<b>Procurement Project Additional Resource Requirements</b> Costs of providing legal and commercial advice and Service representation on the procurement project
17	Quote for legal adviser = £96k
18	Quote for commercial adviser assumed to be the same
19	On secondment 2 days a week @ £288.90 per day = £26,001 (45 weeks) Expenses to be covered by non-pay budget
20	On secondment 2 days a month. Top band 8d assumed @£330 per day = £7,920 Expenses to be covered by non-pay budget
21	Notional estimate of non-pay costs
22	10% contingency assumed of total LINC Programme costs incuding non-pay

## Appendix 16: Draft benefit profile template

Benefit Profile	
Item:	BP/18/001
Title:	Category
Description:	
Programme Objectives Supported	
Observable Outcomes	
KPIs in business operations that will be affected by this benefit:	
Immediately after realisation	
In the future	
Current/Baseline Performance levels	
Anticipated Trajectory	Improvement / Detrioriation ( <i>Delete as appropriate</i> )
Benefit realisation and business change costs	
Capabilities required for benefit realisation	
Related projects	
Outcomes required for benefit realisation	
Business change required for benefit realisation	
Risks	
Issues	
Dependencies	
Owner	
Attribution	
Measurement	

## Appendix 17: LINC Risk Register

Ref	Date Raised	Raised By	Risk Description (including Impact)	Current Overall Rating	Since last review	Owner	Risk Status	Date Reviewed	Reviewer	Mitigation	Proposed Mitigation	Closure/ Transfer Date	Related Risks & Issues	Update Sep-18	Update Oct-18	Update Nov-18
4	27/12/2017	Judith Bates	Failure to complete implementation of WLIMS1 impacting LINC implementation plan and WLIMS1 resources to support LINC	H	↔	Simon Dean	Open	22/11/2018	PMO	Tolerate	To monitor progress with WLIMS1 implementation			TCL2011 BT implementation has been delayed due to instability of the technical platform, so this remains an ongoing risk	BT implementation has been delayed and won't necessarily be completed by the end of March. This risk will be expanded to include upgrade to TCL2016. This risk is linked to risk 20	No change
7	27/12/2017	Judith Bates	Lack of capacity of Pathology, NWIS and HB ICT staff to work on the Programme due to lack of resources to backfill or lack of operational capacity	H	↔	Adrian Thomas	Open	22/11/2018	PMO	Treat - Contingent	To identify resource requirements in the Resource Management Strategy for the attention of the CEOs			NWIS has identified resource requirements and the LINC Programme Resource requirements have been drafted. CEG has approved funding for the rest of 2018/9, so probability has been reduced to medium	A mapping exercise is required to look at resource requirements. This is will be undertaken by the joint LINC-WLIMS1-SMB sub-group	There is a meeting planned between KT and Allison Roblin to discuss resource mapping.
16	17/04/2018	Judith Bates	The appetite may not be there to support the culture change required to deliver further standardisation	H	↔	Adrian Thomas	Open	22/11/2018	PMO	Treat - Contingent	Prepare a paper for NIMB addressing this risk			Biochemistry and Haematology SSAGs did not agree on the wording in the paper of standardisation & warranted variation, but revised wording has now been agreed and paper on the Oct LPB meeting for sign off.	The NHSW CEG has approved a National Pathology Team as part of the LINC Programme to take forward the work on standardisation. The LPB were given more time to comment on the paper but no comments received.	No change
21	18/09/2018	LPB	Delay in HBs sending letters of commitment to the LINC OBC may delay the programme	M/H	↔	Adrian Thomas	Open	22/11/2018	PMO	Treat - Contingent	Judith Bates to raise the risk with the CEG		Risk 22	Risk raised	LPB agreed to reduce this risk to medium/high as the procurement process has been delayed.	No change
23	06/11/2018	LPB	Health Boards/Trusts/PHW may not agree to fund LINC	H		Adrian Thomas	Open	22/11/2018	PMO	Treat - Contingent	Ensure potential savings cover any additional costs in the OBC					OBC updated to show savings



## Appendix 18: Risk Guidance

Item	Definition
<b>RISK</b>	A risk is one or more uncertain event(s) that, should it occur, will have an effect on the achievement of objectives. It consists of the probability of a perceived threat or opportunity occurring and the magnitude of its impact on objectives.
<b>ISSUE</b>	An issue is any relevant event that has happened, that was not planned, and requires management action. They can be anything to do with the project such as a concern, query, request for change or suggestion.

Mitigation	
Treat - Contingent	Lessen the likelihood before the risk materialises
Treat - Containment	Actions to be put in place after the risk has happened to reduce the impact
Transfer	Moved to third party
Tolerate	Accept but monitor
Terminate	Do things differently and remove the risk

Risk Matrix		Low	Low/Medium	Medium	Medium/High	High
<b>Impact</b>	Impact if the risk materialises	2	4	6	8	10
<b>Probability</b>	Probability that the risk materialises	2	4	6	8	10

The overall rating is (impact) x (probability). The overall rating is **High** if >60, **Medium** if between 35 and 60, and **Low** if <35

Overall Rating Matrix		Impact				
		Low	Low/Medium	Medium	Medium/High	High
Probability	<b>Low</b>	4	8	12	16	20
	<b>Low/Medium</b>	8	16	24	32	40
	<b>Medium</b>	12	24	36	48	60
	<b>Medium/High</b>	16	32	48	64	80
	<b>High</b>	20	40	60	80	100

Issue Scoring	
Scoring	Guidance
<b>Critical</b>	A show stopper that impacts the whole programme or the critical path and requires immediate remedial action
<b>High</b>	A serious issue that impacts one or more workstreams and / or the critical path
<b>Medium</b>	A moderate issue that impacts one or more projects within a workstream that may impact the critical path
<b>Low</b>	A minor issue within a project that does not impact other projects or workstreams

Movement		
Category	Movement	Input Value
Improvement	↑	#
No Change	↔	1
Worsened	↓	\$

## Appendix 19: Glossary of Terms

Acronym	Full Title
A&E	Accident & Emergency
ABA	<a href="#">Association of Biomedical Andrologists</a>
ABMULHB	<a href="#">Abertawe Bro Morgannwg University Health Board</a>
ABUHB	<a href="#">Aneurin Bevan University Health Board</a>
ACB	<a href="#">Association of Clinical Biochemistry</a>
ADIs	Associate Directors of Informatics
AI	Artificial intelligence
AWMGS	<a href="#">All Wales Medical Genetics Service</a>
BAU	Business As Usual
BCUHB	<a href="#">Betsi Cadwaladr University Health Board</a>
BI	Business Intelligence
BMA	<a href="#">British Medical Association</a>
BSQR	<a href="#">Blood Safety and Quality Regulations</a>
C&SMB	Contract & Service Management Board
CAB	Change Advisory Board
CANISC	<a href="#">Cancer Network Information System Cymru</a>
CAV SFSP	Cardiff and Vale Secure File Sharing Portal
CDR	<a href="#">Clinical Data Repository</a>
CEO	Chief Executive Officer
CMB	Contract Management Board
CSF	Critical Success Factor
CTUHB	<a href="#">Cwm Taf University Health Board</a>
CVUHB	<a href="#">Cardiff and Vale University Health Board</a>
DATIX	<a href="#">Patient Safety Software</a>
DAWN	<a href="#">Anti-coagulation downstream system</a>
DCP	Digital Cellular Pathology
DDoFs	Deputy Directors of Finance
DIAMOND	Downstream System
DoFs	Directors of Finance
DoTHS	Directors of Therapies and Health Sciences
Downstream system	A local clinical system electronically updated with Pathology results

Acronym	Full Title
DXC	<a href="#">Owner of TCL</a>
eMPI	<a href="#">Enterprise Master Patient Index</a>
ETR	Electronic Test Requesting
FBC	Full Business Case
FHIR	<a href="#">Fast Healthcare Interoperability Resources</a>
FSS NET	Food Surveillance System
FTE	Full Time Equivalent
GMC	<a href="#">General Medical Council</a>
GP	General Practitioner
GPTR	<a href="#">GP Test Requesting</a>
HB	Health Board
HDUHB	<a href="#">Hywel Dda University Health Board</a>
HL72.5	<a href="#">Protocol for Electronic Data Exchange in Healthcare</a>
HTA	<a href="#">Human Tissue Authority</a>
ICIP	Intensive Care System
ICnet	<a href="#">Infection control downstream system</a>
ICT	Information Communication Technology
IM&T	Information Management & Technology
INDIGO	<a href="#">Locum Provider</a>
INSF	National Service Framework
IPAD	Informatics Planning and Delivery group
ISFT	Invite to Submit Final Tender
ISMS	<a href="#">Information Security Management System</a>
ITIL	<a href="#">IT Management Service</a>
ITPD	Invitation to Participate in Dialogue
IUVO	<a href="#">Healthcare Messaging Service</a>
KPI	Key Performance Indicator
LDA	LINC Design Authority
LILIE	<a href="#">Sexual health downstream system</a>
LIMS	<a href="#">Laboratory Information Management Systems</a>
LINC	<a href="#">Laboratory Information Network Cymru</a>
LLP	Limited Liability Partnership
LPB	LINC Programme Board

Acronym	Full Title
LSSC	Laboratory Services Sub Committee
MHOL	<a href="#">My Health Online</a>
MHRA	<a href="#">Medicines and Healthcare Products Regulatory Agency</a>
Millcare	<a href="#">Sexual health downstream system</a>
MSA	Master Services Agreement
NDR	<a href="#">National Data Resource - planned big data capability for Wales</a>
NHS	<a href="#">National Health Service</a>
NHSW	<a href="#">NHS Wales</a>
NHSW	<a href="#">NHS Wales</a>
NHSW CEG	<a href="#">NHS Wales Collaborative Executive Group</a>
NHSW CLF	<a href="#">NHS Wales Collaborative Leadership Forum</a>
NHSWHC	<a href="#">NHS Wales Health Collaborative</a>
NIMB	<a href="#">National Informatics Management Board</a>
NPEx	<a href="#">National Pathology Exchange</a>
NPN	<a href="#">National Pathology Network</a>
NPPB	<a href="#">National Pathology Programme Board</a>
NWIS	<a href="#">NHS Wales Informatics Service</a>
NWSSP	<a href="#">NHS Wales Shared Service Partnership</a>
OBC	Outline Business Case
OGC	<a href="#">Project Management Service</a>
OJEU	<a href="#">Official Journal of the European Community</a>
PACS	<a href="#">Picture Archiving and Communications System</a>
PBM	Programme Board Meeting
PCR2015	<a href="#">Public Contracts Regulation 2015</a>
PER	Post Evaluation Review
PHW	<a href="#">Public Health Wales</a>
PIN	Prior Information Notice
PIR	Post Implementation Review
PMO	Programme Management Office
POCcelerator	<a href="#">Point of Care Testing system</a>
POCT	Point of Care Testing
PQQ	Pre-Qualification Questionnaire
PRINCE2	<a href="#">Project Management Service</a>

Acronym	Full Title
PSBA	<a href="#">Public Sector Broadband Aggregation</a>
PSOI	Pathology Statement of Intent
PTHB	<a href="#">Powys Teaching Health Board</a>
QMS	Quality Management Service
Q-PULSE	<a href="#">Quality Management Software</a>
RCN	<a href="#">Royal College of Nursing</a>
RCP	<a href="#">Royal College of Pathology</a>
SIR	<a href="#">Synapse image repository</a>
SLA	Service Level Agreement
SMART	Specific, Measurable, Achievable, Realistic, Time-based
SMB	Service Management Board
SME	Subject Matter Expert
SME	Subject Matter Expert
SNOMED	<a href="#">Healthcare Standards Service</a>
SOC	Strategic Outline Case
Soft genomics	<a href="#">Medical genetic system currently being implemented</a>
SOP	Standard Operating Procedures
SPSO	Senior Project Support Officer
SRO	Senior Responsible Owner
SSAG	Standing Specialist Advisory Group
Sunquest ICE	<a href="#">Order communications system used in Wrexham, North Wales</a>
Synapse	<a href="#">Database store for radiology images from Welsh PACs</a>
TB	Tuberculosis
TCL	<a href="#">InterSystems TCLab - TCL2011 is the current LIMS</a>
TCLE	<a href="#">InterSystems TCLab Enterprise</a>
TTT	Train The Trainer
UHB	University Health Board
UKAS	<a href="#">UK Accreditation Service</a>
VAT	Value Added Tax
VFM	Value for Money
WBS	<a href="#">Welsh Blood Service</a>
WCIC	<a href="#">Welsh Clinical Informatics Council</a>
WCISU	<a href="#">Welsh Cancer Intelligence and Surveillance Unit</a>

Acronym	Full Title
WCP	<a href="#">Welsh Clinical Portal</a>
WDS	<a href="#">Welsh Demographics Service</a>
WG	Welsh Government
WIAB	<a href="#">Welsh Informatics Assurance Board</a>
WIAG	<a href="#">Welsh Informatics Assurance Group</a>
WLIMS1	<a href="#">Welsh Laboratory Information Management System One</a>
WMIC	<a href="#">Welsh Medicines Information Centre</a>
WPH	<a href="#">Welsh Pathology Handbook</a>
WPOCT	Welsh Point of Care Testing
WPOCT	<a href="#">Welsh Point of Care Testing system, POCcelerator</a>
WRDS	<a href="#">Welsh Reference Data Service</a>
WRRS	<a href="#">Welsh Results and Reporting Service</a>
WSAC	<a href="#">Welsh Scientific Advisory Committee</a>
WTAI	<a href="#">Welsh Transplantation and Immunogenetics Laboratory</a>
WTE	Whole Time Equivalent