



Laboratory Information Management System and Order Communication System for NHS Lanarkshire

Full Business Case

Draft v0.8 05/01/2018



Commercial in Confidence

NSS Information Technology

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Document Author:

| Version | Name | Contact Details |
|---------|---------------|--|
| 0.1 | Val Borland | val.borland@nhs.net |
| 0.2 | Val Borland | val.borland@nhs.net |
| 0.3 | Val Borland | val.borland@nhs.net |
| 0.4 | Val Borland | val.borland@nhs.net |
| 0.5 | Val Borland | val.borland@nhs.net |
| 0.6 | Val Borland | val.borland@nhs.net |
| 0.7 | Val Borland | val.borland@nhs.net |
| 0.8 | Donald Wilson | donald.wilson@lanarkshire.scot.nhs.uk |

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1 Proposal

1.1 Recommendation

This Full Business Case (FBC) has been developed to identify the preferred way forward to deliver a Laboratory Information Management System (LIMS) and electronic Order Communications System (OCS) able to support all Laboratory Services provided by NHS Lanarkshire. This includes Clinical Biochemistry, Haematology, Blood Transfusion, Microbiology and Cellular Pathology but excludes Radiology.

1.2 Request

The NHS Lanarkshire Board is asked to approve:

- The Full Business Case and its proposed implementation.

This Full Business Case will then be submitted to the NHS Lanarkshire Capital Investment Group (CIG) for approval.

1.3 Executive Summary

The main LIMS contract with InterSystems came to an end in June 2017. Due to the nature of the contract, the Board was unable to extend the agreement and a re-procurement exercise was approved as the way forward within the Outline Business Case (OBC). A replacement LIMS must therefore be commissioned and fully implemented as a priority.

NHS Lanarkshire operates the InterSystems LIMS across all laboratory disciplines with the exception of Blood Transfusion where there are two systems supplied by Clinisys and Technidata. This has resulted in three LIMS systems across the three acute hospital sites.

It is recognised that this exercise also presents an opportunity to undertake a concurrent procurement of an Order Communication System able to support electronic laboratory test requesting and results reporting from both Primary Care and Acute Hospital services which, if integrated with this replacement LIMS, will optimise the realisation of both clinical and financial efficiencies and deliver significant benefits to the service. A single LIMS also offers opportunities to enhance the efficiency and effectiveness of current service delivery including multi-disciplinary working, standardisation of operational workflow and improvements in the service to clinicians and patients. The Order Communication System would provide end-to-end electronic data flow with a reduction in manual data entry and consumables as electronic requesting replaces paper forms. A major impact of this is a potential reduction in the number of duplicate or unnecessary tests and specimens due to improved management of test requesting at the GP practice and acute hospital.

Efficiencies and cost avoidance would be realised across GP practices as well as the acute hospital and laboratory service. A single procurement would also ensure the LIMS and OCS systems and contracts are co-ordinated with single supplier responsibility for both.

These cost avoidance measures potentially have a value of up to £239k (See Section 5.3).

The procurement of a replacement Laboratory Information Management System would provide the opportunity to realise the vision of a single pan-NHS Lanarkshire Laboratory Information Management System.

The key shortcomings identified with the current situation are summarised below;

- **Order Communications:** Unable to progress the implementation of Order Communications across Primary and Acute Hospital Care.
- **Poor Architecture:** Three electronic systems are currently used across laboratory services. The lack of integration results in limited data sharing leading to duplication of data entry and the potential for inconsistent data capture and/or transcription errors.
- **Unavailability of Data:** Limited data availability to support medical audit, research, clinical risk management, outcome evaluation FOI requests, service evaluation, planning and delivery.
- **Inefficiency:** Information available at the point of care needs to be gathered from multiple sources. These inefficient processes and data availability reduce time available for patient care and can lead to duplicate tests and investigations.
- **Poor Value for Money:** All of the above results in an increasing cost of ownership, through inefficiency and duplication of effort.

Key Investment Objectives for this FBC were identified as to:

- Support all business and clinical functions and processes currently delivered by NHS Lanarkshire Laboratory Services (excluding Radiology).
- Provide a flexible solution that can respond to future business requirements.
- Support the integration and interoperability of eHealth systems within NHS Lanarkshire.
- Support electronic ordering of laboratory requests and results reporting from both Primary Care and Acute Hospital services.

Steps were taken to prepare for the provision of a new LIMS supplier through the production of an Outline Business Case in February 2017. This considered the options for a replacement LIMS as well as the provision of an electronic Order Communications System and appraised four options:

- Option 1 – Do Nothing
- Option 2 – Buy an existing Commercial off the Shelf (COTS) LIMS and OCS via an OJEU procurement
- Option 3 – Buy and existing Commercial off the Shelf (COTS) LIMS and OCS as part of a new National Framework Contract
- Option 4 – InterSystems Settlement Offer

The recommendation of this Outline Business Case to deliver the investment objectives was:

- Option 2 - Buy an existing Commercial off the Shelf (COTS) LIMS and OCS via an OJEU procurement.

Following approval of Option 2 by the eHealth Strategy Group, the Capital Investment Group and the Corporate Management Team, recommendation to proceed to tender was approved by the Scottish Government. As a result a Contract Notice for a LIMS and OCS for NHS Lanarkshire was published on 22nd May 2017.

Seven suppliers responded to the Contract Notice to provide a Laboratory Information Management System and integrated Order Communication System able to support all laboratory disciplines within NHS Lanarkshire.

Each option was the subject of a structured, thorough and objective evaluation process the format of which was agreed and overseen by an NHS National Services Scotland Procurement Manager. The following activities were undertaken within this evaluation:

1. Financial Appraisal by the NHS Lanarkshire LIMS Project Board
2. Scoring of the supplier response against each of the requirements contained within the Specification for a Laboratory Information Management System (LIMS) for NHS Lanarkshire v1.5
3. Semi-structured teleconference with one or more reference sites provided by each supplier. The structured question designed to ensure comparability is contained in Appendix B
4. Supplier demos of their proposed solution to NHS Lanarkshire clinicians, managers and IT personnel where further clarification of functionality was required
5. One or more site visits to supplier identified reference site(s) within the UK
6. Review and re-scoring of the supplier response against taking account of references, demos and site visits

The process allowed for unclear responses and queries to be returned to the supplier for further clarification prior to final scoring. Three of the supplier bids required presentations and/or site visits to allow completion of scoring. The demonstration and site visits were used to address areas where clarification or additional information was required which resulted in a revision of the functionality scoring.

Every attempt was made to ensure consistency of evaluators throughout the evaluation process and the scores assigned were agreed by consensus.

A cost appraisal was also undertaken on each option. Costs are based on implementation and support over a seven year period and include:

- LIMS/OCS supplier costs as provided in response to the Contract Notice including software licences, support and maintenance (7 years) and implementation support.
- NHS Lanarkshire LIMS hardware and software costs
- NHS Lanarkshire staff costs to implement the replacement LIMS
- NHS Lanarkshire cost of additional devices to support OCS in Primary Care and Acute services

- NHS Lanarkshire staff costs to implement an OCS in Primary Care (GPs)
- Supplier costs (InterSystems) to integrate the InterSystems OCS with the LIMS
- NHS Lanarkshire staff costs to implement an OCS in Acute Hospital services

The NHS Lanarkshire costs of implementing the LIMS and OCS in primary care and acute hospital services will be the same for each supplier.

The FBC evaluation of options consisted of an Economic appraisal, Non-financial benefits appraisal and Non-financial risk appraisal. Each option was assigned a score and rank within each category. The overall score for each option provided an overall ranking for each supplier. .

The outcome of the evaluation process outlined above formed the basis of the Non-financial benefits appraisal.

The risks identified in the original OBC were reviewed and updated for the FBC evaluation. Each option was scored against these and assigned a ranking which is included under the Non-financial risk appraisal score.

The conclusion is that Technidata represents the best balance of cost, benefit and risk.

The anticipated high level timetable for the implementation of the preferred option is as follows:

| | |
|---------------|---|
| January 2018 | FBC Approved |
| February 2018 | Contract Awarded |
| March 2018 | LIMS implementation start |
| March 2018 | Software installation |
| March 2019 | New LIMS "GO LIVE" |
| April 2019 | Primary Care OCS Implementation Start |
| March 2020 | Primary Care OCS Complete |
| April 2020 | Acute Hospital OCS Implementation Start |
| March 2021 | Acute Hospital OCS Complete |

It is important to note that the implementation timetable above is ambitious and the minimum likely achievable.

While electronic laboratory Order Communications is included within this FBC, with the expiry of the current LIMS contract the following will be particularly critical to the success of the project.

- Locum cover in place to release clinical staff able to for the implementation stages
- Early recruitment of a full time project manager, ideally during the procurement phase
- Early discussions with key staff in relation to annual leave planning including continuity planning
- Early discussions with current ISC LIMS supplier to ensure robust data extraction process are in place and tested
- Supplier/NHSL roles and responsibilities clarified e.g. supplier versus local configuration requirements

The critical tasks and timeline supporting these mitigating actions are outlined below.

| Timescale | Critical Tasks |
|------------------|--|
| January 2018 | LIMS/OCS Full Business Case Approved Contract Awarded Discussion with relevant staff regarding planning/scheduling of annual leave throughout the implementation. Project Manager appointed Locums appointed |
| February 2018 | Big bang versus phased implementation agreed (pre-contract) Supplier/NHSL Lanarkshire roles and responsibilities agreed Project plan agreed Infrastructure implemented and configured |

| | |
|------------|--|
| March 2018 | LIMS software installed |
| June 2018 | Architecture and workflow Analysis complete NHS Lanarkshire staff training complete |
| April 2018 | Laboratory discipline (phased) Implementation start |
| March 2019 | LIMS "GO LIVE" |

The recommendation is the procurement and implementation of a Technidata TD-NexLabs Laboratory Information Management System and electronic Order Communications System via OJEU procurement which represents the best balance of cost, benefit and risk. The total capital cost of purchasing this solution is £1,386,000. Assuming a contract period of 7 years the revenue implications of implementing and running this system are £3,323,000.

1.4 Definitions and Acronyms

| | |
|------|--|
| BMS | Biomedical Scientist |
| CDS | Clinical Decision Support |
| CIG | Capital Investment Group |
| COTS | Commercial off the Shelf |
| FBC | Full Business Case |
| GP | General Practitioner |
| FOI | Freedom of Information (request) |
| GP | General Practitioner |
| HEAT | Four groups of targets (H - Health Improvement. E - Efficiency. A - Access to Treatment) |
| IRMA | Integrated Risk Management Approach |
| ISC | InterSystems Corporation |
| ISS | Integrated Software Solutions |
| KPI | Key Performance Indicator |
| LDP | Local Delivery Plan |
| LIMS | Laboratory Information Management System |
| MLSO | Medical Laboratory Scientific Officer |
| NHS | National Health Service |
| NHSL | NHS Lanarkshire |
| NSS | National Services Scotland |
| OBC | Outline Business Case |
| OCS | Order Communication System |
| OJEU | Official Journal of the European Union |
| RPI | Retail Price Index |
| SCC | SCC Soft Computer |
| T&C | Terms and Conditions |
| TCLE | TrakCare Laboratory Enterprise |
| UK | United Kingdom |
| WTE | Whole Time Equivalent |

1.5 References

- [1] Transforming Patient Safety and Quality Care in NHS Lanarkshire, Healthcare Quality Assurance and Improvement Strategy 2014-2017
<http://www2.nhslanarkshire.org.uk/publications/Documents/Transforming-Patient-Safety-and-Quality-of-Care-QAI-Framework.pdf>
- [2] A Healthier Future, NHS Lanarkshire, June 2012
<http://www.nhslanarkshire.org.uk/publications/Documents/Healthier-Future.pdf>
- [3] NHS Scotland 2020 Vision <http://www.gov.scot/Topics/Health/Policy/2020-Vision>
- [4] The Healthcare Quality Strategy for NHSScotland, the Scottish Government, May 2010
- [5] eHealth Strategy 2011-2017, The Scottish Government, 2011
<http://www.scotland.gov.uk/Publications/2011/09/09103110/0>
- [6] Specification for a Laboratory Information Management System (LIMS) for NHS Lanarkshire, v1.5, NHS Lanarkshire, October 2016
- [7] Outline Business Case: Procurement of a Replacement Laboratory Information Management System and Order Communication System, v 1.0, NHS National Services Scotland, April 2016

2 Case Development

The scope of this Full Business Case is for the procurement of a replacement Laboratory Information Management System (LIMS) for NHS Lanarkshire including an integrated electronic laboratory Order Communication System (OCS) from primary care (GP practices) and acute hospital services. The electronic ordering of radiology services is out of scope.

At a prior stage Outline Business Case development was led by NSS with input from senior laboratory, clinical, technical and managerial staff within NHS Lanarkshire. Quality Assurance for the business case was provided by the LIMS Project Board.

The project team also received technical, architecture and clinical expertise as required throughout the case development process.

The development of the OBC included the following areas of activity:

- Agreement of a long list of options and evaluation criteria.
- A market scanning exercise was undertaken to inform the long list
- Evaluation of long list options and approval of shortlisted options for economic appraisal
- Economic appraisal of shortlisted options and recommendation of a preferred way forward.

The outcome of the prior OBC was the approval of the recommendations to:

- Buy a Commercial Off The Shelf (COTS) Laboratory Information Management System and electronic Order Communication System via an OJEU procurement
- Develop a Full Business Case for the procurement of a LIMS and OCS from the preferred supplier

This document is structured in line with a standard five-case Full Business Case (FBC):

- **Strategic Case** – presents the case for change for NHS Lanarkshire, including the drivers to implement a new Laboratory Information Management System and electronic Order Communication System;
- **Economic Case** – includes a description of each option considered and a high level appraisal of each option against benefit, risk and financial criteria;
- **Financial Case** – presents the financial costs and the funding requirements of the preferred option, and therefore sets out the affordability of the preferred option;
- **Commercial Case** – presents the appetite in the marketplace to meet NHS Lanarkshire's LIMS requirements, including a high level procurement strategy and
- **Management Case** – provides an overview of how the project will be commissioned and delivered.

3 Strategic Case

3.1 Context

NHS Lanarkshire delivers laboratory services from three acute hospital sites; University Hospital Hairmyres, University Hospital Monklands and University Hospital Wishaw. The health board processes approximately 1.3m requests for laboratory services covering Clinical Biochemistry, Haematology, Cellular Pathology, Microbiology and Blood Transfusion resulting in around 3.5m reports per annum.

A number of disparate laboratory management systems had historically been in operation across the three hospital sites. Reconfiguration of these, along with the implementation of a single laboratory management system, offered significant opportunities to improve the efficiency and effectiveness of services including facilitation of multi-disciplinary working, standardisation of operational workflow and improvements in the quality of service to clinicians and patients.

As a result procurement for a new Laboratory Information Management System (LIMS) was carried out in 2009 with a contract awarded to InterSystems in 2010.

The Intersystem's LIMS has been successfully implemented across the Biochemistry, Haematology, Microbiology and Pathology disciplines, all of which went live between May and September 2012. However a number of outstanding issues remain unresolved within Blood Transfusion resulting in retention of the original two laboratory systems; CliniSys at University Hospital Hairmyres and University Hospital Monklands and Technidata at University Hospital Wishaw. As a result NHS Lanarkshire continues to support three separate laboratory management systems and has not been able to fully realise the planned efficiencies and benefits of a single LIMS.

With the expiry of the InterSystems in 2017 and recognising the additional clinical and financial benefits to be gained from the concurrent procurement of an OCS, NHS Lanarkshire is now looking to procure both a LIMS and integrated OCS from a single supplier.

The development of a Full Business Case for a single, pan NHS Lanarkshire Laboratory Information Management System and integrated electronic laboratory Order Communication System is required as part of this process.

3.2 Links to Strategy

NHS Lanarkshire's quality vision is to achieve transformational improvement in the provision of safe, person centred and effective care for patients. *Transforming Patient Safety and Quality Care in NHS Lanarkshire, Healthcare Quality Assurance and Improvement Strategy 2014-17* [1] supports the ongoing implementation of *Achieving Excellence* [2] (NHS Lanarkshire's strategic framework taking forward the NHS Scotland 2020 Vision [3]) with its four strategic aims:

- To reduce health inequalities and improve health and health expectancy
- To support people to live independently at home through health and social care working
- For hospital day case treatment to be the norm, avoiding admissions where possible
- To improve palliative care and supported end of life service.

This quality vision is to be achieved through a number of key quality goals. A high quality Laboratory Information Management System with integrated electronic laboratory OCS will play a key role in achieving these goals. In particular:

Aim 5: Development of a patient safety prioritised plan (2014-17) enabling development of whole system patient pathways and implementation in prioritised areas e.g. reduction in catheter associated urinary tract infections (reduce by 30%), zero pressure ulcers and 20% reduction in sepsis.

Aim 8: Service and specialities measuring the quality of care they provide and leading their own improvement strategy.

Aim 10: Further reduce healthcare associated infections

These aims also support the NHS Quality Strategy [4] which aims to deliver the highest quality healthcare to the people of Scotland to ensure that the NHS, Local Authorities and Third Sector work together, and with patients, carers and the public towards a shared goal of world leading healthcare. Healthcare policy and eHealth strategy [5] are being aligned to drive the delivery of three Quality Ambitions which are:

Safe - There will be no avoidable injury or harm to people from healthcare, and an appropriate, clean and safe environment will be provided for the delivery of healthcare services at all time.

Person-Centred - Mutually beneficial partnership between patients, their families and those delivering healthcare which respect individual needs and values and which demonstrate compassion, continuity, clear communication and shared decision making.

Effective - The most appropriate treatments, interventions, support and services will be provided at the right time to everyone who will benefit, and wasteful or harmful variation will be eradicated.

High quality, accessible data is essential to evaluate service provision against the Key Performance Indicators (KPIs) which support these aims as well as for planning future service design and delivery. The laboratory services within NHS Lanarkshire are required to contribute to a number of Scottish Government Local Delivery Plans (LDPs) through delivering results within an appropriate turnaround time. These LDPs have replaced the former HEAT targets and include:

- Detect Cancer Early
- Cancer Waiting Times
- 18 Weeks Referral to Treatment (RTT)
- Treatment Time Guarantee
- 12 Weeks First Outpatient Appointment
- IVF Waiting Times
- Clostridium Difficile Infections
- SAB (MRSA/MSSA)
- Accident and Emergency Waiting Times
- Financial Performance

The project to implement a replacement Laboratory Information Management System and integrated Order Communication System for NHS Lanarkshire directly supports the aims of each of these three national Quality Ambitions as well as the local strategic framework to provide safe, person centred and effective care for patients.

3.3 Current Situation – The Case for Change

Laboratory services are currently unable to effectively support the NHS Lanarkshire Vision for a single LIMS which is to provide:

Integration of reports – Common working practices on a single LIMS will enable both clinical and laboratory users to access the entire laboratory patient record for all three sites as a single entity, irrespective of the site carrying out the analysis. Results will be available in seamless, cumulative format.

User-Based Requesting – A single LIMS will provide the most cost effective model to support integration with an Electronic Order Communications system from both primary care (GPs) and acute hospital based clinicians. This will streamline the pre-analytical process, currently a labour intensive and rate limiting step, and will reduce risk. The system will facilitate the use of an end-to-end, electronic, user-based requesting and results reporting in accordance with the Carter report on laboratory services.

A number of key shortcomings have been identified with the current situation

- **Order Communications:** Unable to progress the implementation of Order Communications across Primary and Acute Hospital Care.
- **Poor Architecture:** Three electronic systems are currently used across laboratory services. The lack of integration results in limited data sharing leading to duplication of data entry and the potential for inconsistent data capture and/or transcription errors.
- **Unavailability of Data:** Limited data availability to support medical audit, research, clinical risk management, outcome evaluation FOI requests, service evaluation, planning and delivery.
- **Inefficiency:** Information available at the point of care needs to be gathered from multiple sources. These inefficient processes and data availability reduce time available for patient care and can lead to duplicate tests and investigations.
- **Poor Value for Money:** All of the above results in an increasing cost of ownership, through inefficiency and duplication of effort.

3.4 Investment Objectives

The new Laboratory Information Management System solution and electronic Order Communications System is proposed to address current needs but also support better integration with other eHealth systems and facilitate improved sharing of information, therefore delivering improvements in effectiveness, efficiency and quality of health care delivery. The following Investment Objectives have been set for the project:

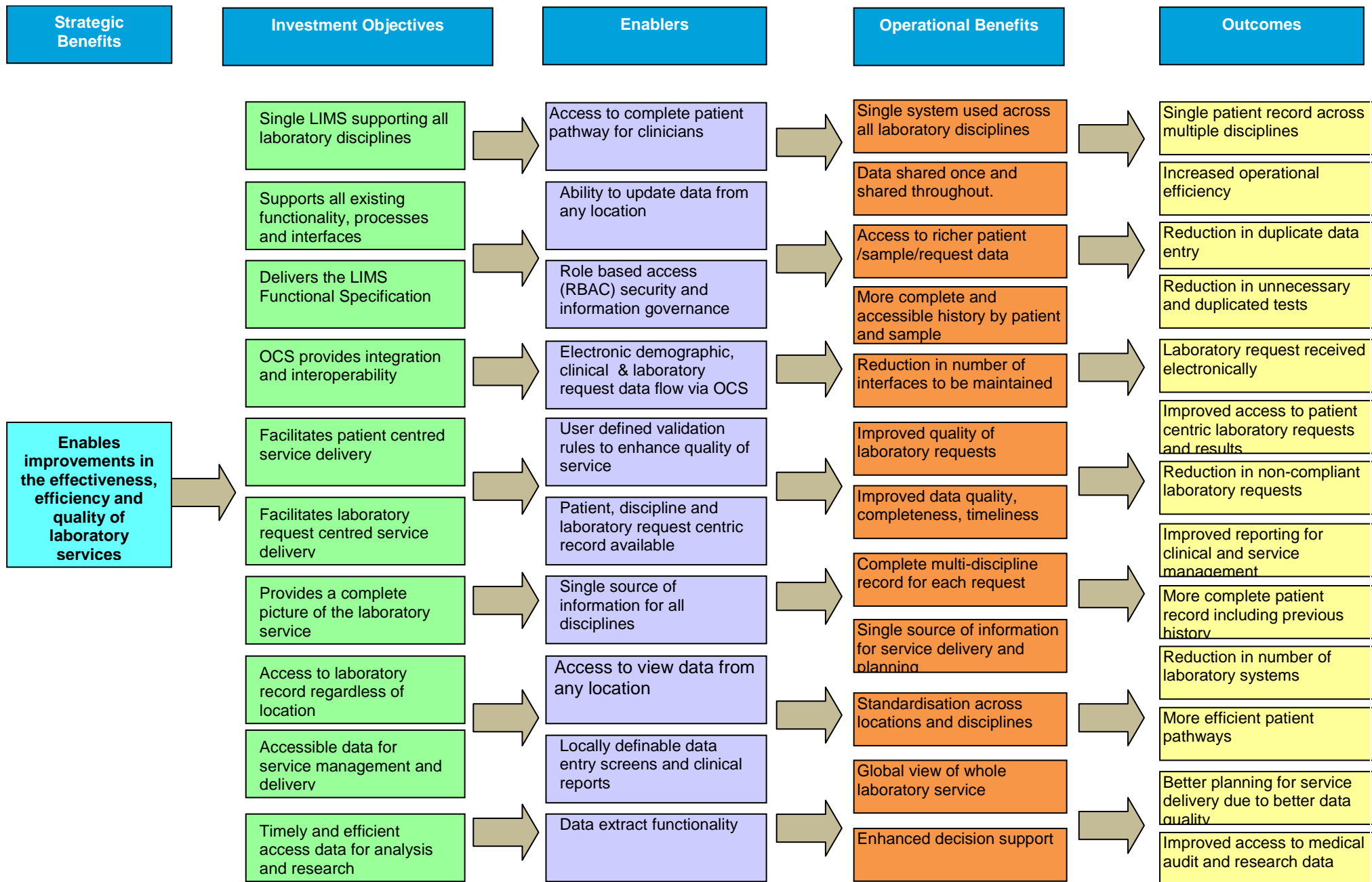
- Support all business and clinical functions and processes currently delivered by NHS Lanarkshire Laboratory Services
- Provide a flexible solution that can respond to future business requirements
- Support the integration and interoperability of eHealth systems within NHS Lanarkshire
- Support electronic ordering of laboratory requests from Primary and Acute Hospital Care

While service efficiencies are expected, it is likely quantifiable cost savings will be limited. Rather additional time will be released from administrative tasks, for example duplicate data entry and retrieval of full patient history from multiple systems to enable delivery of improved patient care.

3.5 Benefits Map

Stakeholders from the Laboratory service have identified a number of benefits which would be delivered from the implementation of a replacement Laboratory Information Management System with integrated Order Communication System and the realisation and tracking of these benefits is required to assess the success of the project.

The project team has developed a benefits map that outlines the anticipated benefits and outcomes from the implementation of a Laboratory Information Management System which supports all five laboratory disciplines. These are aligned to high level strategic benefits and investment objectives. The Benefits Map is outlined in Figure 1 below.



3.6 Case for Change – Summary

A viable, flexible, efficient, and effective Laboratory Information Management System to support and contribute to the Electronic Patient Record forms a critical and fundamental part of the national and local eHealth Strategies. Key issues with the current situation are:

- **End of Contract:** The current InterSystems LIMS contract expired in June 2017. This along with a decommissioning period requires that a replacement LIMS must be commissioned and fully implemented as a priority.
- **Current LIMS is not Fully Operational:** Unresolved issues with the Blood Transfusion module has prevented full implementation across all laboratory disciplines as planned. This has resulted in the requirement to support three LIMS within NHS Lanarkshire.
- **Inefficient:** Duplication of effort in maintaining multiple disparate electronic systems Impacts on data quality and availability. Inefficient processes reduce the time available for request and sample processing and management and increase costs.
- **Patient Safety:** Incomplete and/or unavailable information at the point of care has an adverse impact on Clinical Decision Support (CDS) and patient safety.
- **Electronic Patient Record (EPR):** There is no single, complete laboratory record accessible to all clinicians involved in the patient's care pathway.
- **Data Availability:** The lack of accessible, high quality data impacts on effective service evaluation, planning and delivery. Opportunities for research, medical audit, clinical risk management and outcome evaluation are restricted.
- **Order Communications:** Unable to progress the implementation of Order Communications across Primary and Acute Hospital Care.

4 Economic Case

4.1 Value for Money

The results of the economic appraisal are presented in the table below: The costs are based over a 7-year project period.

4.2 Option Comparison

Seven suppliers responded to the OJEU Contract Notice to provide a Laboratory Information Management System and integrated Order Communication System able to support all laboratory disciplines within NHS Lanarkshire.

Each option was the subject of a structured and objective evaluation process the format of which was agreed and overseen by an NHS National Services Scotland Procurement Manager. The evaluation team members are outlined in Appendix A. Each tender submission was evaluated in line with the detail provided in the tender documentation. This was apportioned as follows:

- 70% Functionality
- 30% Price

The following activities were undertaken within this evaluation:

1. Financial Appraisal by the NHS Lanarkshire LIMS Project Board
2. Scoring of the supplier response against each of the requirements contained within the Specification for a Laboratory Information Management System (LIMS) for NHS Lanarkshire v1.5
3. Semi-structured teleconference with one or more reference sites provided by each supplier. The structured questions designed to ensure comparability are contained in Appendix B
4. Demonstrations of shortlisted LIMS and OCS systems to NHS Lanarkshire clinicians, service managers and IT leads
5. One or more site visits to supplier identified reference site(s)
6. Review and re-scoring of supplier responses against each of short list taking account of references, demos and site visits

The process allowed for unclear responses and queries to be returned to the supplier for further clarification prior to final scoring.

Three of the supplier bids required presentations and/or site visits to allow completion of scoring. The demonstration and site visits were used to address areas where clarification or additional information was required which resulted in a revision of the functionality scoring.

Every attempt was made to ensure consistency of evaluators throughout the evaluation process and the scores assigned were that agreed by consensus.

The scoring methodology agreed with the NSS Procurement Manager is outline in Appendix C.

A zero score was recorded where the contractor did not meet a primary requirement in the scored section or had not provided a response. This was judged to be of very high risk and sufficient justification for that supplier bid to be rejected.

On-site demos provided an opportunity for the evaluation team to obtain additional information on areas identified for further clarification during the initial scoring exercise.

On-site visits provided an opportunity for more detailed investigation and feedback from a comparable peer group currently using the software application(s).

The final score assigned to each supplier is outlined in Table 2 below:

The Functionality evaluation criteria are outlined in Appendix D.

The scoring of price was undertaken by the Financial Advisor appointed by NSS. For the purpose of evaluation price was considered as the total cost for a seven year term. The scoring criteria are illustrated in Appendix E.

4.3 Economic Appraisal

Risk Assessment

The risks highlighted in the OBC were reviewed, updated and scored by key stakeholders. The agreed risks used to assess the options are listed below:

1. The proposed solution is not technically viable and does not meet the requirements
2. The solution does not achieve the investment objectives
3. Solution will require significant additional development to meet the agreed requirements resulting in delayed implementation
4. Solution is not capable of supporting the required performance, capacity and scalability
5. The solution is not capable of integrating successfully with existing systems and infrastructure
6. The system does not support true clinical use due to lack of resilience and disaster recovery
7. The system cannot support all five laboratory disciplines resulting in the retention of one or more legacy systems
8. The system cannot adapt to future technology trends and/or the supplier no longer has the capacity or capability to deliver the service required
9. The total cost to implement the solution is unknown or relies on a number of external dependencies or constraints
10. There is insufficient buy-in to adapt clinical processes to implement the solution
11. Contract terms cannot be agreed or the process of reaching agreement results in significant delays
12. The system does not have an established record of successful implementations within the UK resulting in a requirement for additional development and/or delayed implementation

Each risk was assigned an impact weighting and scored on a range of 1-5 as per the NSS IRMA standard. Table 3 summarises the scores for each option and a ranking, where 1 carries the least risk to the NHS.

Appendix F contains the detailed weighting and scores for each risk and option.

Non-financial benefit of shortlisted options

Non-financial benefits will be realised through the functionality provided by the LIMS and OCS solution. The non-financial benefit map for a replacement Laboratory Information Management System was reviewed and consideration given to the extent to which the shortlisted options could deliver the non-financial benefits. Each supplier was scored on each requirement and a total percentage score calculated. These scores were used to generate the Non-financial benefits ranking score.

Financial benefit of shortlisted options

The direct financial benefits of implementing a replacement LIMS and OCS are limited. Whilst there may be some tangible savings in terms of ongoing running costs e.g. replacement of the current three LIMS with a single system, these are likely to be negated by the cost of implementation and switchover. However, it is anticipated that the impact of the implementation of an OCS has the potential to realise future cost avoidance of approximately £239k through reductions in the number of tests requested, data entry and paper costs (see Table 7, Section 5.3). There are also likely to be significant non-cash releasing savings in changes to work flow, reduction in workarounds and the burden these create.

Indicative Cost of shortlisted options

The total cost of implementing each system is shown in Table 4 below. This cost includes:

- Supplier costs for a LIMS
- Supplier costs for an OCS
- NHS Lanarkshire LIMS hardware and software costs
- Additional NHS Lanarkshire devices for GP practices, acute hospital and laboratory services
- NHS Lanarkshire staff costs to implement the LIMS solution are included. These costs account for project management, local configuration, implementation support, local training, user acceptance testing and implementation support including locum resource to free up clinical time.
- NHS Lanarkshire staff costs to implement the OCS solution are included. These costs include business analysis in preparation for the implementation of OCS across GP practices.

All respondents to the OJEU Contract Notice have been included.

4.4 Economic and Financial Assumptions

The following economic and financial assumptions have been made:-

Costs include NHS Lanarkshire hardware and software costs, the provision of additional devices and the staff resource to implement and support the new LIMS and OCS system(s).

It is assumed departmental implementation costs will not be chargeable to the project e.g. staff time for training. This cost is expected to be the same regardless of the option and system implemented.

4.5 Economic Case – Summary

Table 5 below summarises the economic evaluation. For each of the evaluation criteria (i.e. cost and risk) it shows each option's score and ranking, plus an assessed overall ranking.

5 Financial Case

5.1 Introduction

This financial case is based on the preferred option - buy the Technidata TD-NexLabs LIMS and OCS via OJEU procurement.

It is assumed additional NHS Lanarkshire resource will be required during the implementation phase and that post live ongoing maintenance will be supported within the current service provision.

The cost of a technical refresh of hardware and/or software e.g. to upgrade laboratory PCs has not been included.

5.2 Cash Flow Statement

| | | Lims and OCS Implementation Cashflow | | | | | | | | | | |
|---|------|--------------------------------------|-------|-------|-------|-------|-------|-------|-------|-------|-------|---------------|
| | | Total | 17/18 | 18/19 | 19/20 | 20/21 | 21/22 | 22/23 | 23/24 | 24/25 | 25/26 | |
| Capital | | | | | | | | | | | | |
| Supplier Licences | 460 | 460 | | | | | | | | | | |
| Supplier Implementation | 740 | 148 | 592 | | | | | | | | | |
| NHSL Hardware | 186 | 160 | 26 | | | | | | | | | |
| | 1386 | 768 | 618 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | |
| Revenue | | | | | | | | | | | | |
| Technidata Maintenance and Support | 1098 | | | 145 | 149 | 153 | 157 | 161 | 164 | 169 | | Note 1 |
| NHSL Implementation Costs Lims | 1119 | 517 | 602 | | | | | | | | | |
| NHSL Implementation Costs OCS | 950 | | 33 | 603 | 314 | | | | | | | |
| Project Management | 156 | 12 | 48 | 48 | 48 | | | | | | | |
| Depreciation | 1386 | | | 198 | 198 | 198 | 198 | 198 | 198 | 198 | 198 | |
| | 4709 | 529 | 683 | 994 | 709 | 351 | 355 | 359 | 362 | 367 | | |
| Note 1 | | | | | | | | | | | | |
| Budget already exists to cover these costs. | | | | | | | | | | | | |

Table 6- Cash Flow Statement for Preferred Option Technidata

Note:

Annual RPI increase of 2.6% has been applied to on-going maintenance and support.

5.3 Funding Statement

Capital funding for this project has been included in the Capital Plan. The revenue consequences of implementation have been included in our on-going financial plan.

Budget for on-going maintenance and support is already available.

Future cost avoidance of up to £239k should be achieved on implementation OCS, particularly across primary care. This will be realised in Year 3 and achieved through the following:

| 1 Measure | Value |
|--|--------------|
| Additional staff for data entry | £119k |
| Reduction in consumables (paper) costs | £20k |
| Potential reduction in number of tests requested | £100k |
| Total | £239k |

Table 7 – Cost Avoidance

5.4 Payment Schedule

The payment schedule will be determined as part of the contract negotiations.

5.5 Financial Case - Summary

Source of funding as indicated in statement in 5.3

This Full Business Case will provide the information required to:

- Recommend a preferred supplier of a LIMS and OCS
- Assess the affordability of potential solutions
- Provide the information to allow the organisation to make a decision on whether to proceed

6 Commercial Case

6.1 Agreements

The proposed approach requires procurement of a Technidata TD-NexLabs Laboratory Information Management System and electronic Order Communications System via OJEU procurement.

A Contract Notice was issued to the market via the Public Contracts Scotland (PCS) Portal on 22nd May 2017 for a single supplier to provide a Laboratory Information Management System and electronic Order Communications System with a deadline for responses of 26th July 2017. Seven suppliers responded.

6.2 Contract Length

Given that the replacement Laboratory Information Management System represents a substantial purchase, any procured system needs to have longevity. Consideration should also be given to the potential to align the wider Laboratory analyser/middleware MTS and the LIMS contracts with a view to these co-terminating at some point in the future. This would allow support for the laboratory services to be packaged together as part of a future procurement.

Costs have been based on a contract period of 7 years.

6.3 Summary

It is proposed that the Technidata TD-NexLabs LIS and OCS will replace the existing LIMS within NHS Lanarkshire, these being CliniSys at University Hospital Hairmyres and University Hospital Monklands and Technidata at University Hospital Wishaw and InterSystems LIMS across all three hospital sites with a single Laboratory Information Management System.

A Contract Notice placed as part of OJEU procurement confirmed that there were commercial off the shelf solutions (COTS) in the marketplace with the potential to meet the NHS Lanarkshire Laboratory Information Management System and electronic Order Communication System requirements. Seven suppliers responded to the advert and submitted proposals for consideration.

All supplier submissions have undergone a robust evaluation process. This established that five of the original seven proposals were unable to provide the required level of functionality without additional development and from an established, operational version of the proposed solution. Of the two remaining shortlisted option, the preferred replacement LIMS and OCS has been determined to be the Technidata TD-NexLabs LIMS and OCS. This was endorsed by the LIMS Project Board.

7 Management Case

7.1 Approach

The replacement Laboratory Information Management System and electronic laboratory Order Communications System procurement and implementation will move forward as part of the wider programme to establish a single Laboratory Information Management System across all laboratory disciplines and all three acute hospital sites within NHS Lanarkshire. This will ensure all systems and interfaces which will impact, or be impacted by the LIMS are coordinated to a common plan and timescale.

The approach will be to procure and implement the Technidata TD-NexLabs Laboratory Information Management System and Order Communications System following an OJEU Contract Notice and subsequent evaluation process to determine a preferred supplier.

7.2 Project Management Approach

The development of the project will be undertaken in line with Prince2 project management methodology. The following management products will be utilised in order to ensure successful deliver:

Controls:-

- Project Initiation Document.
- Project Board Approvals log.
- Risk, Issue and Assumption (RAID) log.
- Lessons learned log.

Plans:-

- Project Plan for the entire duration of the project.
- Detailed stage plans for individual stages.
- Plans will include the projects, milestones and dependencies of all supplier areas to the project such that all deliverables are committed to a single plan.

Quality Products:-

- Product descriptions as and when required.
- Agreed acceptance criteria.
- Configuration management plan.

Project Reports:-

- Fortnightly checkpoint reports.
- Monthly highlight reports.

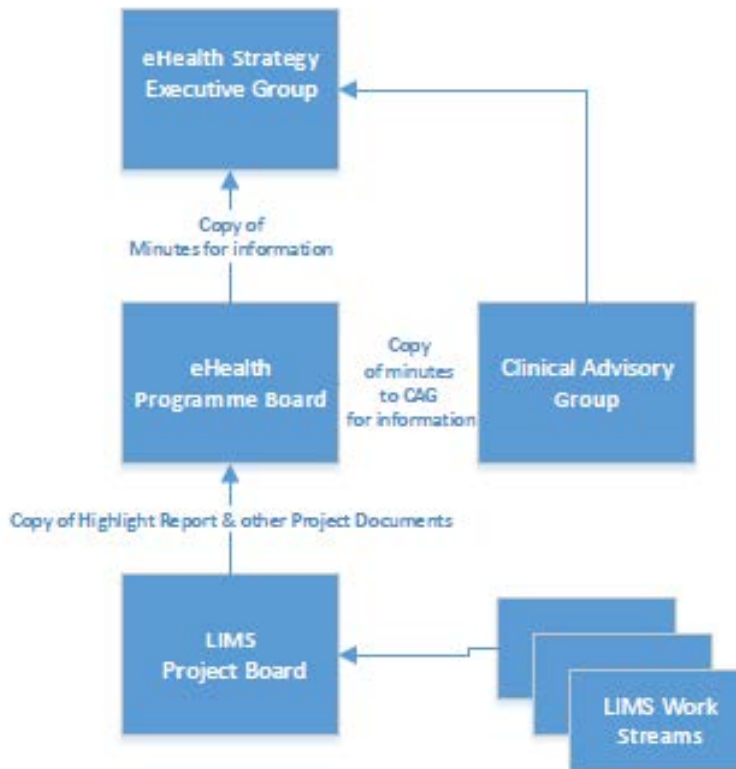
Key Activities

Key deliverables to support the procurement should include:-

- Approval of the Full Business Case.
- Confirm the project Governance Structure.
- Establishment of a Project Board
- Project Initiation Document confirming project approach, governance arrangements, scope, deliverables and timescales including project plan.

7.3 Project Governance

The proposed governance structure can be illustrated as follows:



The LIMS/OCS Project Board is accountable to the eHealth Programme Board for the successful delivery of the project. Its specific responsibilities are to:

- Approve the stages of the project including start up and closure
- Agree the Project Manager's responsibilities and provide direction throughout the lifecycle of the project
- Approve the Project Initiation Document and use this throughout to monitor progress and agree changes
- Review and approve other key documents such as Stage Plans, Exception Plans and End Project Report
- Link with eHealth structures throughout, providing reports to key groups as required

NHS Lanarkshire LIMS Project Board

| Name | Role/Job Title | Organisation |
|-----------------|-------------------------------|-----------------|
| Karen Aitchison | Service Manager | NHS Lanarkshire |
| Terry Dunthorne | General Manager Procurement | NHS Lanarkshire |
| Ian Godber | Consultant Clinical Scientist | NHS Lanarkshire |
| Liz McCulloch | Head of eHealth Programme | NHS Lanarkshire |
| Maureen McGinn | Project Manager | NHS Lanarkshire |
| Judith Park | Director of Access (Chair) | NHS Lanarkshire |

| Name | Role/Job Title | Organisation |
|---------------|----------------------------|-----------------|
| Donald Wilson | General Manager eHealth | NHS Lanarkshire |
| Derek Yuille | Deputy Director of Finance | NHS Lanarkshire |

Maureen McGinn, an experienced Project Manager has been assigned to oversee the day to day running of the project and ensure objectives are met. Expertise from Subject Matter Experts will be drawn into the team as and when required. The project manager will be responsible for:

- Working closely with suppliers and colleagues within NHS Lanarkshire
- Project delivery and progress reports to the Project Board
- Risk management and corrective actions that require to be taken

7.4 Project Plan

A proposed phased approach will be taken in relation to the implementation of the Technidata TD NexLabs LIMS and OCS. The proposed phases (subject to discussion prior to contract sign off) are set out below:

| | |
|------------------|---|
| January 2018 | Contract Awarded Infrastructure implementation and configuration |
| February 2018 | Software Installation complete |
| March/April 2018 | Architecture and workflow analysis |
| April/May 2018 | Training of NHS Lanarkshire implementation team |
| March 2018 | Phase 1 (Biochemistry, Haematology) implementation start |
| April 2018 | Phase 2 (Microbiology) implementation start |
| May 2018 | Phase 3 (Histopathology) implementation start |
| July 2018 | Phase 4 (Blood Transfusion) implementation start |
| November 2018 | Phase 1 implementation complete |
| December 2018 | Phase 2 implementation complete |
| January 2019 | Phase 3 implementation complete |
| March 2019 | Phase 4 implementation complete LIMS "GO LIVE" |
| April 2019 | Primary Care OCS implementation start |
| March 2020 | Primary Care OCS implementation complete (GO LIVE) |
| April 2020 | Acute Hospital OCS implementation start |
| March 2021 | Acute Hospital OCS implementation complete (GO LIVE) |

The project plan and delivery timescale will be determined as part of the next stage of the project. The plan will take account of supplier capacity, agreed roles and responsibilities and be influenced by advice from the clinical services involved as to how the Laboratory Information Management System and Order Communications System be implemented.

The delivery timescale will also be dependent on identification and appropriation of the required funding for the procurement of the Technidata LIMS and OCS.

7.5 Risks

The project risks will be determined as part of the project.

Risk and issue logs will be managed through the formal project governance process.

Appendix A – Key Stakeholders

NHS Lanarkshire Capital Investment Group (CIG)

| Name | Role/Job Title |
|------------------|---|
| Laura Ace | Director of Finance (Chair) |
| Craig Cunningham | South Lanarkshire Health & Social Care Partnership Representative |
| Terry Dunthorne | Chair of the Core Equipment Group |
| Heather Knox | Director of Acute Services |
| Colin Lauder | Deputy Director of Strategic Planning |
| John Paterson | Director, Property and Support Services Division |
| Colin Sloey | Director of Strategic Planning & Performance |
| Gordon Smith | Head of Finance (Corporate Services) |
| Owen Watters | North Lanarkshire Health & Social Care Partnership Representative |
| Donald Wilson | General Manager of eHealth/IM&T |
| Derek Yuille | Deputy Director of Finance (Acute & Corporate) |

NHS Lanarkshire LIMS Project Board

| Name | Role/Job Title | Organisation |
|-----------------|-------------------------------|--------------------------------|
| Karen Aitchison | Service Manager | NHS Lanarkshire |
| Val Borland | Senior eHealth Consultant | NHS National Services Scotland |
| Terry Dunthorne | General Manager Procurement | NHS Lanarkshire |
| Ian Godber | Consultant Clinical Scientist | NHS Lanarkshire |
| Liz McCulloch | Head of eHealth Programme | NHS Lanarkshire |
| Maureen McGinn | Project Manager | NHS Lanarkshire |
| Judith Park | Director of Access (Chair) | NHS Lanarkshire |
| Mark Salveta | Procurement Manager | NHS National Services Scotland |
| Donald Wilson | General Manager eHealth | NHS Lanarkshire |
| Derek Yuille | Deputy Director of Finance | NHS Lanarkshire |

Note:

Val Borland assumed temporary membership to support the development of this FBC

Core Evaluation Team

| Name | Role/Job Title | Role in Group |
|------------------|--------------------------------|---------------|
| Ian Godber | Consultant Clinical Scientist | Member |
| Maureen McGinn | Project Manager | Member |
| Betty Kyle | Technical Lead Haematology | Member |
| Ian McCormick | Technical Lead Microbiology | Member |
| Allan Wilson | Technical Lead Pathology | Member |
| Janice McNicol | Technical Lead Biochemistry | Member |
| Iain Singer | Consultant Haematology | Member |
| Stuart Thomas | Consultant Pathologist | Member |
| Tom Gillespie | Consultant Microbiologist | Member |
| Andy Fyfe | Consultant haematologist | Member |
| Brenda Madden | Laboratory IT Manager | Member |
| Kirsty Taggart | Transfusion Lead | Member |
| Lorraine Taggart | Head of Information Management | Member |
| Sharon Sempie | IM&T Applications Manager | Member |
| Stuart Graham | Head of Infrastructure | Member |

Co-opted Evaluation Team

| Name | Role/Job Title | Role in Group |
|--------------------|---------------------------------------|---------------|
| Louise Brown | Labs. Technical Manager | Member |
| Evelyn McEwan | Biomedical Scientist | Member |
| Jacqueline Clinton | Labs. Technical Manager | Member |
| Elizabeth Kilgour | Labs. Technical Manager | Member |
| Sandra Mitchell | BMS Microbiology | Member |
| Dr Sarah Whitehead | Consultant Microbiologist | Member |
| Stuart Leach | Information Governance | Member |
| Julie Howatt | PMO Application Support | Member |
| Iain McGinlay | Application Manager, Clinical Systems | Member |
| Gordon Young | Senior BMS Pathology | Member |
| Bruce Thomson | GP | Member |
| Andrew Cookman | Senior BMS Biochemistry | Member |

Benefit and Risk Evaluation Refresh

| Name | Role/Job Title | Organisation |
|-----------------|-------------------------------|-----------------|
| Karen Aitchison | Service Manager | NHS Lanarkshire |
| Ian Godber | Consultant Clinical Scientist | NHS Lanarkshire |
| Maureen McGinn | Project Manager | NHS Lanarkshire |

Appendix B – Semi Structured Interview Questions

Proposed questions for Bidder reference Conference Calls

| Reference Site Details | |
|------------------------|--|
| 1 | How long have you had the system? |
| 2 | What version of the system do you operate on? |
| 3 | Would you recommend this supplier to other organisations |
| 4 | What was the proposed timescale of the project plan from contract sign-off to project handover/completion? |
| 5 | Did the supplier provide a detailed project plan? |
| 6 | Did the supplier provide detailed guidance on how the implementation would be achieved e.g. qualification documents on installation, operation and performance? |
| 7 | What level of project management commitment in terms of time and resource did the supplier give to the project delivery? |
| 8 | Were you happy with the split between supplier team onsite working and remote working during implementation? |
| 9 | Did the supplier deliver all of the expected functionality as specified by your operational requirements? |
| 10 | To what extent were the requirements standard in the core product or did you require to purchase additional modules or options in order to achieve the functionality expected? |
| 11 | How much configuration was carried out by the supplier and was this carried out timeously? How much configuration was carried out locally and was this a satisfactory balance? |
| 12 | Where was the training carried out and what methodology and media was used? |
| 13 | Could you list the disciplines the system supports in your department? Microbiology - Pathology - Haematology - Biochemistry - Blood transfusion - |
| 14 | Do you have order comms within your Acute, GP and community settings? Acute – Do you use the supplier's own order comms product or is it an integrated 3 rd party product? Is your LIMS supplier the primary contractor? GP - – Do you use the supplier's own order comms product or is it an integrated 3 rd party product? Is your LIMS supplier the primary contractor? Can you take us step by step through the process, from the GP with the patient on screen? What do I do next? Community - – Do you use the supplier's own order comms product or is it an integrated 3 rd party product? Is your LIMS supplier the primary contractor? |
| 15 | Do you do order comms for all disciplines except Blood Transfusion? Microbiology Pathology Haematology Biochemistry |
| 16 | Has your system been upgraded since the implementation? |
| 17 | How has the supplier developed the product to ensure compliance with regulatory change? Who is the onus on to supply the change information? How quick is the supplier to respond to the change and does this incur |

| | |
|----|--|
| | additional costs? |
| 18 | Have you had further development since implementation e.g. any new analyser interfaces? How responsive was the supplier? Was this carried out timeously? Did this incur any or reasonable additional costs? |
| 19 | Can you describe the release cycles and the testing process? What would be the supplier/local resource requirement in order to test and implement a release? |
| 20 | Has the system performance been stable since implementation? How does the system perform in peak activity? |
| 21 | In terms of continued support post project completion, how responsive is the Help Desk? |
| 22 | How many priority 1 incidents have there been in the last 6 months and how responsive was the supplier? |
| 23 | How many priority 2 incidents have there been in the last 6 months and how responsive was the supplier? |
| 24 | How effective do you feel the system is in supporting the work of the department? |
| 25 | What would you consider to be your lessons learned from implementing and operating this system? |
| 26 | Is there anything you included in your requirements specification that the supplier did not deliver that had been expected to be delivered? |

Appendix C – Functionality Scoring Criteria

| Score | Rationale |
|-------|--|
| 0 | Contractor does not meet and Primary requirement in the scored section or Not answered or Very high risk |
| 1 | Contractor shows some understanding but Does not meet all of the Primary requirements in the scored section or High risk |
| 3 | Contractor shows no misunderstanding and meets all Primary requirements in the scored section to the minimum required level or Medium risk |
| 3 | Contractor meets all the Primary and Secondary requirements in the scored section demonstrating complete understanding or High risk |
| 3 | Contractor shows no misunderstanding and meets all Primary requirements in the scored section to the minimum required level or Medium risk |
| 5 | Contractor meets all Primary and Secondary requirements in the scored section demonstrating complete understanding or Low risk |

Where a score of 0, 1 or 5 is recorded, this must be accompanied by a comment outlining the justification for the decision.

Appendix D – Functionality Evaluation

The Tender Submissions were evaluated in line with the detail provided in the tender documentation and is summarised below:-

- 70% Functionality
- 30% Price

The Functionality Score was subdivided into the following sections:

| Section | Requirements | % |
|---------|--|-----|
| 3.1 | Core Requirements | 5% |
| 3.2 | Core Laboratory Requirements (All disciplines) | 20% |
| 3.3 | Biochemistry | 3% |
| 3.4 | Haematology | 3% |
| 3.5 | Blood Transfusion | 5% |
| 3.6 | Microbiology | 3% |
| 3.7 | Cellular Pathology | 3% |
| 3.8 | Management Reporting | 3% |
| 3.9 | Systems Administration and Configuration | 3% |
| 3.10 | Data Migration | 2% |
| 3.11 | IT Requirements | 3% |
| 4 | Order Communication System | 10% |
| 5 | Non- Functional | 7% |
| Total | | 70% |

Appendix E – Price Scoring Criteria

The Scoring of Price was undertaken by the Financial Advisor appointed by NSS. For the purpose of the evaluation, price was considered as the total cost for the seven year term. This price consists of supplier costs only.

| Value | Score (%) |
|--------------------------|-----------|
| Under £900,000 | 30 |
| £900,000 to £949,000 | 29 |
| £950,000 to £999,999 | 28 |
| £1,000,000 to £1,049,999 | 27 |
| £1,050,000 to £1,099,999 | 26 |
| £1,100,000 to £1,149,999 | 25 |
| £1,150,000 to £1,199,999 | 24 |
| £1,200,000 to £1,249,999 | 23 |
| £1,250,000 to £1,299,999 | 22 |
| £1,300,000 to £1,349,999 | 21 |
| £1,350,000 to £1,399,999 | 20 |
| £1,400,000 to £1,449,999 | 19 |
| £1,450,000 to £1,499,999 | 18 |
| £1,500,000 to £1,549,999 | 17 |
| £1,550,000 to £1,599,999 | 16 |
| £1,600,000 to £1,649,999 | 15 |
| £1,650,000 to £1,699,999 | 14 |
| £1,700,000 to £1,749,999 | 13 |
| £1,750,000 to £1,799,999 | 12 |
| £1,800,000 to £1,849,999 | 11 |
| £1,850,000 to £1,899,999 | 10 |
| £1,900,000 to £1,949,999 | 9 |
| £1,950,000 to £1,999,999 | 8 |
| £2,000,000 to £2,049,999 | 7 |
| £2,050,000 to £2,099,999 | 6 |
| £2,100,000 to £2,149,999 | 5 |
| £2,150,000 to £2,199,999 | 4 |
| £2,200,000 to £2,249,999 | 3 |
| £2,250,000 to £2,299,999 | 2 |
| £2,300,000 to £2,349,999 | 1 |
| £2,350,000 or over | 0 |