



FULL BUSINESS CASE

**DEVELOPMENT OF A MANAGED
SERVICE CONTRACT FOR THE
LABORATORY MEDICINE
UNIT**

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1.0 Executive Summary

1.1 Introduction

The Initial Agreement (IA) was approved by the Scottish Government Health and Social Care Directorate (SGHSCD) on 24 April 2017, and given the structure of the proposed procurement arrangement the Board was invited to proceed straight to Full Business Case. No specific conditions were outlined in the approval letter.

The Laboratory Medicine Unit is a component of Division 4, Acute Clinical Support Services, Support 1, a sub-sector of the NHS Grampian Acute Services Sector. It requires arrangements with specialist third party provider covering the procurement, maintenance and management of essential equipment utilised in the delivery of laboratory services. Managed service arrangements have been tendered; the proposed contract(s) have a ten year term and an annual value of £5 million.

This Full Business Case (FBC) provides the information required to demonstrate that the Project has put in place appropriate contractual, commercial and management arrangements to successfully deliver the project requirements, within the project's affordability limits, and that the project is ready to proceed to contract signature.

The Initial Agreement document approved by the Scottish Government Health Directorate in April 2017 clearly described the service arrangements and the associated need for change; it demonstrated the validity of the preferred way forward and illustrated the attendant funding model. The preferred way forward was to renew and widen the scope of the existing managed service contract for Laboratory Medicine Unit.

NHS Grampian has completed the evaluation of tenders for this contract and is ready to appoint the successful bidder following approval of this FBC, who is Abbott Laboratories UK Ltd.

The implementation of the proposed Managed Service Contract(s) will provide flexibility, along with an ability to expand to accommodate additional workload which may arise from redistribution under the Shared Services agenda.

1.2 Revisiting the Initial Agreement

This section outlines project detail and addresses whether the project is ready to proceed to contract signature. The strategic context and scope of the project is unchanged since the Initial Agreement.

The project described in this FBC has a number of unusual aspects which have necessitated adapting the SCIM process of moving directly from IA to FBC. These are:

- Due to the unique nature of the commercial arrangement, robust data on the financial implication of the Project can only be achieved by full market testing.
- The accelerated timeline is essential to avoid unintended repercussions of extending the current contract excessively beyond its 10 year options and to prevent the replacement of significant pieces of critical capital equipment not yet covered by a Managed Service Contract.

This adapted process maintains the SCIM overall objective of ensuring that a sound, robust analysis is undertaken to support effective decision-making.

The service risks associated with not changing existing arrangements have increased since the preparation of the IA due to the ageing of existing equipment and the expiration of the existing Managed Service Contract.

1.3 NHS Grampian Laboratory Medicine Unit

1.3.1 The Laboratory Medicine Unit

The Laboratory Medicine Unit provides 24hr comprehensive diagnostic and clinical services to primary and secondary care across NHS Grampian and tertiary services to colleague Boards including NHS Orkney, Highland, Western Isles and Shetland covering the following disciplines:

- Pathology
- Clinical Biochemistry
- Haematology
- Microbiology
- Virology
- Immunology
- Genetics

Services are delivered from two locations on the main acute site and several smaller satellite laboratories.

A full range of services is delivered from

- The Aberdeen Royal Infirmary Link Building at Foresterhill, Aberdeen, and

- The Polwarth Building, Aberdeen University Medical School also at Foresterhill.

Other limited or clinically specific services are available from:

- Dr Grays Hospital, Elgin,
- Sexual Health Service, Health Village, Frederick Street, Aberdeen,
- Diabetic Clinic, David Anderson Building Aberdeen,
- Cytology at Clinic E, Aberdeen Royal Infirmary.

The Unit delivers services to a wide range of users across primary care and secondary care, including the two acute hospitals in Grampian and around 73 GP practices.

The following table shows levels of activity for 2017/18.

Table 1: Laboratory Medicine Unit Activity Levels – 2017/18

Service	Requests	Tests
Biochemistry	1,128,643	8,565,058
Haematology	675,520	1,100,939
Immunology	41,132	83,835
Pathology (Histopathology)	33,729	49,192
Pathology (Cytopathology)	64,648	64,648
Microbiology	506,720	620,000

1.3.2. National Programme

The National Programme recognises that fundamental reform and change to the way our NHS delivers care is needed. There is an acceptance that by continuing to provide services as we have always done before will not address the sustainability challenge, and will not meet the Scottish Government's 2020 Triple Aim of quality of care, health of the population, and value and financial sustainability; better care, better health, better value.

Against this backdrop, the NHS Grampian Laboratory Medicine Unit is involved as part of a Managed Diagnostic Network across Scotland, to specifically address and engage with the process around developing the changes that are needed in future service provision to meet this Triple Aim. Whilst this is long term in strategic outlook, there has also been a focus to ensure opportunities for operational continuous improvement are exploited.

1.3.3. Regional Level and Current Arrangements

NHS Grampian was established in 1972 and provides health services for more than 500,000 people who live in the North East of Scotland and covering an area of more than 4,000 square miles. In total, NHS Grampian employs more than 17,000 staff.

In 2017/18 there were 64,797 acute elective and emergency in-patient admissions to NHS Grampian Hospitals and there are currently 2,076 inpatient beds operated by NHS Grampian. These include those at –

- Aberdeen Royal Infirmary (“ARI”) which is NHS Grampian's largest hospital, situated at Foresterhill, Aberdeen.
- The Matthew Hay Building (previously known as the Emergency Care Centre) brings together emergency and urgent care services into one building.
- Royal Aberdeen Children's Hospital.
- Aberdeen Maternity Hospital.
- Woodend Hospital caters for many patients, including the elderly.
- Royal Cornhill Hospital provides inpatient and community support for mental health services.
- Roxburgh House is a purpose-built unit providing palliative care for terminally ill patients.
- Dr Gray's Hospital is the district general hospital based in Elgin, Moray.
- The Oaks is another purpose-built unit which provides specialist care and support for people with cancer and other progressive illnesses in Moray.

These hospitals are also supported by a further 17 local Community Hospitals spread across the region. There are also 73 General Practitioner surgeries in Grampian, 8 of which are salaried practices.

The laboratories currently provide a range of regional services. For example, the Clinical Biochemistry Department provides Tumour Marker, QFIT and Myeloma Screening services for NHS Orkney and NHS Shetland as well as Sweat Testing Analysis for Cystic Fibrosis for NHS Highland. The Pathology Department also provides a comprehensive Histopathology and Cytopathology service to NHS Orkney and NHS Shetland. Cervical Cytology service for NHS Highland and the Western Isles is also provided by the department. The Microbiology service provides specialist bacteriology analysis and is the main provider of Virology testing for NHS Orkney and NHS Shetland. The Haematology Department fully participates in the AnteNatal Screening Programme for Haemoglobinopathies and Thalassaemia delivering the service for NHS Grampian, NHS Orkney and NHS Shetland. These laboratory services are provided solely at the ARI Laboratory Medicine Department.

In addition to supra-regional specialist diagnostic services for Lung and Hepatobiliary cancers and Paediatric Pathology, it is a nationally designated Regional Centre for the diagnosis and treatment of Bone and Soft tissue sarcomas.

NHS Grampian’s Laboratory Service operates within a highly complex arena; including the provision of a range of tertiary services to other NHS Boards. This history of successful multi Board cooperation is evidence of Grampian’s willingness to engage with a regional services agenda that is patient-focused without duplication of effort; that is able to meet the demands of increasingly localised communities while minimising variation and achieving economies of scale where possible. Service delivery strategies of which the Elective Care

Strategy is but one, have the potential to change both the scope and pattern of laboratory requesting and delivery. NHS Grampian's Laboratory Service has a proven track record in terms of its ability to meet these changing demands. The Grampian Clinical Strategy 2016 to 2021 sets out not only NHS Grampian's priorities, but also those shared priorities with Health and Social Care partners in the North and North East of Scotland. There is a high degree of connectivity related to the physical and mental health for children and adults spanning primary and acute care across the four overarching themes of prevention, self management, planned care and unscheduled care. NHS Grampian's Laboratory Medicine Unit plays a key role in each of these areas.

1.4. Need for change

The NHS Grampian Laboratory Medicine Unit will continue to build on providing a high quality, cost-effective service that meets the needs and demands of the people of Grampian for the next ten years and beyond.

There have been a number of drivers for change in the current contracted provision for the Laboratory Medicines Unit, ranging from the short term urgent need to renew items of specialist equipment (inclusive of Information Technology), to the maintenance provisions, to a longer term visioning of a future for the service in which it is best placed to meet the needs of service users in 2018/19 and beyond, across the North of Scotland.

A managed service contract arrangement has been in place since 2008 covering automated service elements of Clinical Biochemistry and Haematology and a small proportion of Immunology/Microbiology. The contract combines provision and access to key analysers and equipment, servicing and maintenance of that equipment and provision of associated reagents and other consumables within a single efficient contract. This 9 year contract expired on April 2018 and is currently operating under an agreed extension until April 2019. Many of these pieces of equipment are receiving critical end of life notifications. The risks associated with continuing to operate the current assets are significant and not conducive to the Unit's continuity, culture, vision and reputation and the ability to deliver the necessary essential service to NHS Grampian and the North of Scotland. Any replacement of the current equipment will require structural and service change, as the modern equivalent technology has advanced significantly since the procurement of the original assets and results in a quite different accommodation profile.

When put in place in 2008, the original managed service contract for Biochemistry and Haematology delivered an advanced level of automation; this offered a platform for real service transformation in local working practices and in service delivery. Changes and improvements were effected on workforce planning and skill mix, impacting on skill mix and roles, improved user access, faster turnaround times and new approaches to diagnosis and management of patients. Increased demand and complexity has exhausted the advantages achieved seven years ago and in order to maintain current service levels and be fit to meet future growth in diagnostics there is now a serious need for change.

Supporting the development of a distributive service model of laboratory services in the North Region, as envisaged by the Shared Services agenda, will be a key objective going forward.

1.4.1. Service Improvement

The rising workload for these services coupled with advances in methodology and requests for new testing, drives a need to transform the model of service delivery underpinned by modernised processes and equipment. The move towards Regional Working and Shared Services for laboratory services remains in its early stages across Scotland, and the planning of the new Laboratory Managed Service Contract for NHS Grampian aims to harmonise a common regional approach to data modelling, workload projection and contract management that will provide a consistent foundation for other laboratory services in the North Region. In addition the new Managed Service Contract would provide opportunities for existing staff in the training and use of cutting edge technologies and also assist NHS Grampian in recruiting trainee medical and scientific staff and retaining them on the completion of their training. New technology also offers opportunities to current service users to employ up to date methods that facilitate development and improvement in patient pathways for their services.

The IA, outlined the configuration of the NHS Grampian Laboratory Medicine Unit. This Initial Assessment remains valid. This project has been developed to secure a long term managed service contract with specialist third party provider covering the procurement, maintenance and management of essential equipment utilised in the delivery of Laboratory services from within NHS Grampian. The solution proposed will support continued service provision in a highly complex arena, where the service is best placed to meet the needs of service users in 2018 and beyond.

1.4.2. Investment Objectives

The following investment objectives were developed with key stakeholders during the development of the IA.

- To put in place arrangements for the robust and timely delivery of Laboratory Services, ensuring continuity of safe, sustainable and effective high quality services which maintain national accreditation standards
- To provide systems and service delivery models which can take advantage of Technological advances
- Support the service in preparedness to engage with regional working and the Shared Service Agenda
- To put in place service delivery arrangements and facilities that can accommodate the future demand and complexity of user needs and workload in a suitably responsive fashion and to deliver service resilience
- Improve safety/performance and effectiveness of equipment / data management and eliminate / mitigate risks around failure both temporary and permanent

- Ensure accommodation and equipment is efficient, safe and compliant with current legislation and accreditation standards
- Opportunity to develop the expertise that can be shared with and help support other Boards on a regional and National level.
- Opportunities for co-ordinated planning to manage future expenditure and enhance value for money
- Efficient allocation of risk for continuity of service

1.5 Option Appraisal

1.5.1 Appraisal Process

The Economic Case has revisited the Preferred Way Forward outlined within the IA and examined the relative value for money of the short-listed options by appraising the economic implications, risks and benefits associated with the options identified. The outcomes are summarised in Table 2 below.

Table 2: Evaluation of Options

	Option 1 (Do Minimum)	Option 2 (Renew MSC + extend Scope)
Net Present Cost (NPC) of the Project (£000's)	39,842	40,119
Non-Financial Weighted Benefit Score	173	444
NPC per Weighted Benefit Score	231	90
Rank	2	1

1.5.2 The Preferred Option

The Laboratory Medicine Unit has reviewed a range of potential options and considers that the preferred option is:

- Option 2 (previously 4a) Renew and widen scope of Managed Service Contract (Leasing).

This option is the extension of scope of the existing contract to include the cover of all Laboratory Medicine Unit disciplines, except Genetics, replacing the current contract which only covered Clinical Biochemistry and Haematology, and a small proportion of Immunology / Microbiology.

A Managed Service Contract including renewal of all critical equipment, periodic technical refresh of the equipment base, ongoing servicing and maintenance and supply of all consumables and reagents is the option that would best deliver the investment objectives.

1.5.3 Supporting Infrastructure Works

NHS Grampian has invested in reconfiguration works to ensure accommodation for the Virology service to meet Health and Safety Executive (HSE) and United Kingdom Accreditation Services (UKAS) requirements in advance of the award and implementation of the new Managed Service Contract.

Work to upgrade the roof structure and electrical infrastructure in the Laboratory Medicine Unit Link building at ARI is underway. This requirement was identified following receipt of the detailed technical specification of the new equipment and associated standalone air handling plant and all necessary work is expected to be complete by the proposed contract commencement date of 1 April 2019.

1.6 Commercial Arrangements

A Managed Service Contract was developed with the Central Legal Office (CLO). A bespoke approach was taken to reflect the Board's requirements but was based on a standard form contract that has been used by Health Boards across Scotland over the last 10 years and is known and understood by the industry. It includes a contract management structure, provisions for risk transfer and key performance requirements that encourage business continuity and quality whilst penalising failure.

The duration of the contract following implementation will be ten years, with an option to extend for two further years.

During the term of the Contract the managed service provider will be responsible for:

- Remedial and installation works
- Equipment supply and installation, including where necessary replacement
- Servicing and maintenance
- Reagent supply
- Supporting the effective management of the clinical Laboratory Medicine Unit to deliver key strategic benefits

The procurement was structured into different lots;

- Lot 1 – Biochemistry and Pathology (Histopathology and Cytopathology)
- Lot 2 – Haematology and Immunology
- Lot 3 – Bacteriology and Virology

The reason behind this structure is:

- The complexity of the contract meant that some contractors would not have been able to bid for haematology or microbiology if a single lot structure was employed. This might even have prevented them from bidding for the contract as a 3rd party.
- NHS Grampian viewed that the triple lot structure allowed each laboratory medicine discipline to obtain the best potential solution for their service.

- Within the triple lot structure, there was still the opportunity for any potential supplier to bid for any combination of lots via suspensive bids. This would also allow for NHS Grampian to potentially benefit from economies of scale and shared infrastructure such as IT support.

The procurement has been undertaken in accordance with European Procurement Regulations. The Invitation to Tender was issued on 20th September 2017 and responses have been received, clarified and scored and the preferred bidder identified for all 3 lots as Abbott Laboratories UK Ltd. Further details can be found in Appendix 9.

Following approval of this Full Business Case appointment will be made.

A summary of the procurement is set out below:

Table 3: Summary of Procurement

	Lot 1 – Biochemistry and Pathology (Histopathology and Cytopathology)	Lot 2 – Haematology and Immunology	Lot 3 – Bacteriology and Virology	Total
Contract Notice Responses (Nos)	3	6	7	16
Bidders (Nos)	3	4	4	11
Total Contract Value (£m)	21.72	14.50	14.36	50.58

The contractual structure will enable the Board to reclaim VAT on its maintenance, servicing and reagent costs under UK statute.

1.7 Financial Implication of Preferred Option

1.7.1. Enabling Costs

The enabling cost for the preferred option is £1.8 million. Table 4 below provides a breakdown of these costs.

Table 4: Summary of Initial Capital Investment

	FBC
	£000's
Enabling Works - Reconfiguration/Move services from Polwarth Building	776
Enabling Works – Roof structure and electrical Infrastructure	900
Project Development Costs	183
Total Enabling Costs	1,859

Sources of Funding	
NHS Grampian Infrastructure and Backlog Maintenance Programme	1,676
NHS Grampian Revenue Funding	183
Total Sources of Funding	1,859

1.7.2. Revenue Costs

The provision of a laboratory managed service will be delivered using a unitary charge funding model. The components of the unitary charge include fixed charges in relation to provision and installation of equipment, semi-fixed charges in relation to maintenance and management and variable costs in relation to reagents and consumables. Semi-fixed charges and variable cost will be subject to annual indexation (CPI) review. Table 5 set out these costs, in the first full year of operation.

Table 5: Summary of Revenue Implications - First Full Year of Operation (2020/21)

	FBC
	£000's
Revenue Costs	
Unitary Charge	XXXXXXXXXX
Building Related Running Costs	20
Total Costs	XXXXXXXXXX
Sources of Funding	
Depreciation	47
Unitary Charge - Existing MSC	XXXXXXXXXX
Other Revenue Costs - Transfer to New MSC	XXXXXXXXXX
Total Sources of Funding	XXXXXXXXXX

1.7.3. Affordability

NHS Grampian is committed to the Project and has provided for the enabling costs within its financial plans for 2018/19 and 2019/20 as appropriate. The revenue consequences of the proposed managed services contract arrangement fall within the existing revenue budget for this service.

1. 8 Project Programme

The procurement is nearing completion. The indicative milestones for the project are shown in table 6 below:

Table 6:

	Indicative Programme	Revised Date	Original Date
1	Submission of Initial Agreement	February 2017	February 2017
2	Instruct Enabling Work	February 2017	February 2017
3	Complete Enabling Work	August 2017	August 2017
4	Issue of Contract Notice and European Single Procurement Document	June 2017	February 2017
5	Issue of Invitation to Tender	September 2017	March 2017
6	Receipt and Evaluation of Tenders	September 2018	April 2017
7	Submission of Full Business Case	October 2018	May 2017
8	Consideration of Full Business Case by CIG	November 2018	-
9	Award of Contract	January 2019	May 2017
10	Commencement of Implementation Stage	January 2019	June 2017
11	Complete Further Enabling works	March 2019	
12	Final Acceptance (Full Implementation)	December 2019	March 2018

1.9 Confirmation of Project Management Arrangements

There has been extensive engagement with clinical stakeholders, IM&T and leads from each of the Laboratory Medicine Unit departments and disciplines. Staff are in support of the change and solutions which would be offered as part of the new Managed Service Contract, as this will provide a service which is best placed to meet the needs of the service users in 2018 and beyond. Further detailed work around the programme associated with the delivery of each lot, to cover the enabling works, procurements, delivery, installation and commissioning of equipment will progress post award. Engagement with the North Region, Laboratory Medicine Operational Group, has assisted the development of a long term strategic delivery plan. Regular communications between Laboratories across the North Region occur in multiple forums.

The common and specific roles and responsibilities for the project were established at the outset with the development of the Terms of Reference for the Laboratory Managed Service Contract Project Board. These Terms of Reference identified the role, remit and membership of the project.

A project governance structure was put in place using a project management approach.

These project management arrangements have led on the evaluation of bids in accordance with agreed scrutiny parameters.

These project management arrangements will require the development of a detailed programme from the successful bidder, to ensure the effective implementation of the Managed Service Contract.

1.10 Benefits Realisation Plan

An updated copy of the Benefits Realisation Plan has been developed as part of the FBC. This confirms which of the benefits are still appropriate and viable from the Initial Agreement and confirms how and by whom each of the benefits will be monitored and measured. These are attached as Appendices 1 and 2.

1.11 Risk Management

A robust risk management process was established at the outset as part of the project management arrangements for the Laboratory Managed Service Contract Project Board. The risk register has been reviewed regularly to reduce the likelihood of unmanaged risk affecting any aspect of the project. This is attached as Appendix 3.

1.12 Commissioning

The tendering process required that bidders submit detailed programmes of work following award of contract. Technical commissioning (preparedness to bring into operation) will be supported by the successful bidder, NHS Grampian Project Team and NHS Grampian Estates Team. Functional commissioning will be supported by the successful bidder and NHS Grampian Laboratory Medicines Unit. Final sign-off, acceptance and verification procedures will be undertaken by NHS Grampian Laboratory Medicines Unit.

1.13 Project Monitoring and Evaluation

The measurement methods identified in the benefits register (Appendix 1) will provide an indication as to how NHS Scotland Strategic Investment Priorities are being met by the establishment of the new Managed Service Contract. A final project monitoring report will be submitted to the Scottish Government shortly after project completion (expected 2021).

1.14 Conclusion

Against a backdrop of reducing staffing numbers, increasing costs, greater demand for services and rising ageing population, it is expected that the NHS Grampian Managed Service Contract will support the current and future delivery of laboratory services. Over

the course of the next ten years, the development of the Shared Services and Regional Working agendas will provide emerging ways of working, and the NHS Grampian Laboratory Medicine Unit is already engaged with this process from the outset. However in terms of the immediate timeframe, the Managed Service Contract will provide the solution for delivering improved and sustainable laboratory services in NHS Grampian now, whilst also allowing for opportunities for business generation, Regional laboratory integration and innovation.

It is anticipated that the Managed Service Contract procurement will facilitate NHS Grampian in continuing to provide a high quality, cost-effective service that meets the future needs of its users. A key benefit will be the establishment of modern, innovative and efficient equipment which will improve workflow and provide opportunities to meet increasing demand and in addition provide opportunities for Regional Working and the Shared Services agenda.

NHS Grampian has secured the best value commercial option for delivering the project requirements within the project's affordability limits and is financially sustainable over the long term.

2.0 Strategic Case

2.1. Introduction

This section of the Full Business Case confirms that there is still a need for investment, and the preferred option remains valid. In 2011 NHS Grampian produced Healthfit 2020 which set out a vision for how healthcare should be arranged to deliver optimal services to the population. Since then NHS Grampian has worked with partners in health and social care to produce the Grampian Clinical Strategy 2016-2021 which aims to;

- Confirm the direction for clinical services over the next five years and beyond,
- Identify the objectives across the health systems to improve patient outcomes
- Confirm the change that is required to support the health system to work more effectively,
- Outline areas of shared benefit across the system.

Since the approval of the Initial Agreement in April 2017, there have been no material changes to the case for investment in terms of changes to service, evolving business needs, or alterations to project scope.

The 2020 vision and the Grampian Clinical Strategy is underpinned by values that match the culture and ethos of the Laboratory Medicines Unit; an ambition to provide the best service possible for users and patients; to offer person centred services as locally and as timely as can be achieved; and to manage a high quality service efficiently within available resources.

Achieving these aims within the complex and demanding landscape of laboratory medicine is made more testing by a pattern of increasing demand; by volume and by the range of new tests requested by users. Advances in process and technique bring both an opportunity to achieve the vision of a modern service as well as challenges in managing service delivery to the required standard.

This outline proposal will contribute materially to the 2020 vision and the Grampian Clinical Strategy, as with the Managed Service Contract in place, the Laboratory Medicine Unit will be best placed to deliver diagnostic services to match key strategic benefits.

In Grampian there are demographic indicators of an increase in older people as there is elsewhere in Scotland; in Grampian the increase in the population of those aged 85yrs and above is the highest in Scotland. Generally people are living longer and there will be an increase in people living with multiple long term conditions. It is this population who tend to use the greater proportion of health service, and accordingly there will be an increased need for healthcare services in both hospital and community settings, where more than 80% of clinical decisions are informed by responsive, timely, accurate and high quality testing. If Grampian is to be able to respond to these increases it is essential that the delivery model has a secure foundation from which to provide its modern 24/7 service, and

this means there must be a change from the current situation as well as the capability and capacity to align to changing needs in the future.

Key factors of change are likely to include:

- a shift to more community based delivery. There is already a growth in the model of point of care testing being driven by the continually developing Health and Social Care Partnerships, enabling localised patient care and this is likely to extend and grow, with other models that will require a supportive and responsive laboratory service.
- New developments in NHS Grampian are also driving a need for a Laboratory Medicines Unit that is fit to meet the needs of a modern and forward looking healthcare provider. The Matthew Hay building has led to a transformation of many clinical pathways, increasing the need for more person-centered testing, with faster turnaround times. Developments such as the North of Scotland Major Trauma Centre programme, the forthcoming Baird Family Hospital and Anchor Centre, and the confirmation of future investment in developing Elective Care services for Grampian, all provide drivers for change for the Laboratory Medicine Unit.
- NHS Grampian is participating actively in the evolution of the Shared Services agenda and Regional Working. NHS Grampian has a positive track record for working in collaboration with other territorial Boards in the North and currently provides a laboratory medicine service to four such colleague Boards. Continuing to be able to work in such partnership and current regional working arrangements is a priority for the Unit. Addressing the need for change and ensuring Grampian has a modern service that is fit for the demands of the future and puts Grampian in the best possible position for operating as a fit partner with this agenda. It is planned that the preferred solution will offer an optimal foundation for taking forward the Regional Working and Shared Services agenda as it evolves.

2.2. Revisiting the Strategic Case

2.2.1. Strategic Background

The investment objectives set out in the Initial Agreement for the NHS Grampian Laboratories Managed Service Contract have been revisited and remain broadly the same for this Full Business Case but have been developed as the Shared Services agenda has unfolded. The strategic context and scope of the project is broadly unchanged since the Initial Agreement was approved.

The Initial Agreement was approved by SGHSCD in April 2017, (Appendix 4). No specific conditions were outlined in the approval letter. Stakeholder involvement continues to be core to the project.

A summary of the revisited strategic case is detailed in the following sections.

2.3 Case for Change

The case for change and outline of benefits to be gained from this investment proposal are identified through the following questions:

- Who is affected by this proposal?
- What are the current arrangements related to this proposal?
- What is the case for change?
- What is NHS Grampian seeking to achieve from this proposal?
- What measurable objectives will be gained from addressing these needs?
- What risks could undermine these benefits?

The NHS Grampian Laboratory Medicine Unit operates against a backdrop of reducing staffing numbers, increasing costs, greater demand for services and rising ageing population. Over the next ten years, with the increase in Regional Working and the development of the Shared Services agenda, the Laboratory Medicine Unit needs to be in a strong position to continue to excel in its delivery of a laboratory service.

2.4. Current Arrangements

2.4.1. Who is affected by this proposal?

NHS Grampian Board provides all healthcare services for around half-million people who live in Grampian, an area covering 3,000 square miles of city, town and village, and rural communities. The Health Board also provides specialist tertiary services for the North of Scotland, employing around 17,000 staff. As a teaching Board, it also has close links to the University of Aberdeen and Robert Gordon University. The Laboratory Medicine Clinical Unit provides laboratory services to primary and secondary care within Grampian and beyond, including providing Tertiary Care services to NHS Orkney and NHS Shetland. These services are currently delivered from the main Foresterhill Site. There is a satellite lab at Dr Gray's Hospital, Elgin, which provides much of the biochemistry, haematology and blood bank needs for the hospital at Dr Gray's.

There are 6 main laboratory disciplines (some with associated direct care clinical services), each headed by a consultant Service Clinical Director:

- i. Clinical Biochemistry (incorporating Toxicology, Adult Weight Management and Parenteral Nutrition)
- ii. Haematology (incorporating the ARI Phlebotomy service)
- iii. Immunology (incorporating Clinical Immunology)
- iv. Medical Genetics (comprising Cytogenetics, Molecular Genetics and Clinical Genetics)
- v. Medical Microbiology (comprising Microbiology and Virology)
- vi. Pathology (comprising Histopathology, Cytopathology and Mortuary services)

The Laboratory Medicine Unit has an annual budget of £23 million, employs over 400 staff and receives in excess of 2.3 million samples per year on which they perform over 12

million tests. Laboratories provide a 24/7 clinical and medical laboratory service (Clinical Biochemistry, Haematology and Medical Microbiology) and a comprehensive range of investigations including decentralised testing sites and some support for Point of Care Testing across Grampian.

The Unit provides a high quality, comprehensive and efficient analytical, clinical advisory and educational service accredited by United Kingdom Accreditation Services (UKAS) to ISO15189 standard. The Clinical Unit was the first in Scotland, in which all services attained unconditional accreditation status.

2.4.2. What are the current arrangements related to this proposal?

In order to provide the detail related to this proposal, this document has divided the detail around the Laboratory Medicines Unit under the following headings:

2.4.2.1. Current Location and Service

The laboratories are located in a mid 1960's built, single tower building of 5 floors that links ARI and the University. Each floor has a long narrow central corridor with rooms on each side. Microbiology is located on the lower ground and ground floors, Biochemistry on the 1st floor with Immunology & Haematology on the 2nd floor. Pathology occupies the 3rd and 4th floors. There is a connection to the adjacent NHS 'Specialist block' which houses the administrative function of Laboratory Medicine in addition to the existing clinical modalities, and there are links on the north of the building on the ground, 1st, 2nd and 3rd floors to the University of Aberdeen Polwarth Building. Genetics laboratories are located on the 2nd floor of the University Polwarth building. NHS Grampian has invested in reconfiguration works to ensure accommodation for the Virology service will meet HSE and UKAS requirements by creating new laboratory space in the main Microbiology corridor in the Links building. These works have been completed in advance of the award and implementation of the new Managed Service Contract. The Mortuary is situated at the back of the Polwarth building in a separate building.

The Link Building provides accommodation which has reached its maximum development potential and has itself become an impediment to modern laboratory redesign and function, preventing the uptake of new technology and working practices. The primary problem being a structure which incorporates its main structural support in the centre corridor spine of the building, limiting the maximum width of any laboratory redesign to 6m which is insufficient to accommodate modern tracked systems for unitary sample reception and blood sciences which modern technology allows.

To accommodate revised service arrangements, dry office type function has had to be moved out of the laboratory Link Building into refurbished accommodation in the adjacent Laboratory Administration Annex (old ward 3 and infection unit).

National Keele Benchmarking, performed annually for all laboratory services within Scotland, regularly demonstrates that NHS Grampian has the lowest cost per test metric compared to other comparable laboratories. In addition, it also shows that NHS Grampian

compares favourably to other teaching hospitals when considering laboratory service running costs. These statistics are testament to the high levels of managerial efficiency and governance exhibited within the unit, and the hard work of a much valued staffing cohort.

2.4.2.2. Exclusion of Genetics

Genetics has not been incorporated into the Laboratory Managed Service Contract process as its funding structures are separate from those of NHS Grampian.

Genetics in Scotland is operated and funded by National Services Division (NSD) as a consortium of 4 laboratory sites across the country providing services regionally and nationally. Typically each consortium laboratory is responsible for its regional workload whilst acting as national specialist centres for certain tests. There is the expectation that in times of stress, workload will be shared across the consortium, making common analyser platforms essential. Revenue funding to operate the services is allocated by NSD with the staff are employed by the host Health Boards.

2.4.2.3. Current Service Provision and Arrangements

NHS Grampian

The services that operate as part of the wider Laboratory Medicines Unit deliver to a wide range of service users across primary care and secondary care, including the two acute hospitals in Grampian; Aberdeen with 800 beds and Elgin with approximately 180 beds.

In 2017/18 there were 64,797 acute elective and emergency in-patient admissions to NHS Grampian and these include those at –

- Aberdeen Royal Infirmary (“ARI”) which is NHS Grampian's largest hospital, situated at Foresterhill, Aberdeen.
- The Matthew Hay Building (previously known as the Emergency Care Centre) brings together emergency and urgent care services into one building.
- Royal Aberdeen Children's Hospital.
- Aberdeen Maternity Hospital.
- Woodend Hospital caters for many patients, including the elderly.
- Royal Cornhill Hospital provides inpatient and community support for mental health services.
- Roxburgh House is a purpose-built unit providing palliative care for terminally ill patients.
- Dr Gray's Hospital is the district general hospital based in Elgin, Moray.
- The Oaks is another purpose-built unit which provides specialist care and support for people with cancer and other progressive illnesses in Moray.

These hospitals are also supported by a further 17 local Community Hospitals spread across the region. There are also 73 General Practitioner surgeries in Grampian, 8 of which are salaried practices.

Laboratory Medicine Unit

Point of Care testing is being developed as a service model to offer near patient testing in the community, often utilising the network of community hospitals across Grampian. This emerging service development seeks to reduce the need for acute admission and to support the delivery of localised care; however it is another area of growing demand for the Laboratory Medicine Unit.

A sense of scale may be offered by the following table showing levels of activity for 2017/18, with year on year workload increases being experienced by all disciplines.

Table 7: Laboratory Medicine Unit Activity Levels – 2017/18

Service	Requests	Tests
Biochemistry	1,128, 643	8,565,058
Haematology	675,520	1,100,939
Immunology	41,132	83, 835
Pathology (Histopathology)	33, 729	49,192
Pathology (Cytopathology)	64,648	64,648
Microbiology	506, 720	620,000

The Unit delivers its services from two locations on the main acute site and several smaller satellite laboratories. A full range of services is delivered from:

Aberdeen Royal Infirmary Link Building, Foresterhill, Aberdeen and the Polwarth Building, Aberdeen University Medical School, Foresterhill, Aberdeen.

Limited or specific services are available from:

- Dr Grays Hospital, Elgin
- Sexual Health Service, Health Village, Frederick Street, Aberdeen
- Diabetic Clinic, David Anderson Building, Aberdeen, and
- Cytology Clinic E, Aberdeen Royal Infirmary, Foresterhill, Aberdeen

As part of a recognised Teaching Hospital, the Laboratory Medicines Unit is actively involved in the training of medical students, clinical scientists and biomedical scientists. In doing this, the laboratories not only support the medical training at the University Medical School, but are also accredited laboratory training centres for the National School for Healthcare Science, NHS Education Scotland and the Institute of Biomedical Science The Laboratory Medicines Unit has well established training programmes in conjunction with other universities such as Robert Gordon University and is actively involved in the training of all groups of laboratory staff before and after their appointments to substantive posts.

It is a goal of the Laboratory Medicines Unit to support, undertake and promote high quality clinical research for the health benefits of our population and to play our part in enabling NHS Grampian to deliver world-class health outcomes.

The Unit is fully accredited by UKAS under the standard for Medical Laboratories – ISO 15189:2012. The ISO standard is divided into Management Requirements (15 clauses) and Technical Requirements (10 clauses), reference guidelines and UKAS publications which must be complied with for accreditation.

ISO 15189:2012 accreditation is extremely challenging for laboratories to comply with; each analytical method being assessed to include validation and verification, reagent preparation, staff competency and training, internal quality controls and external quality assurance. In addition, IT connectivity and post examination verifications are undertaken to ensure laboratory reports displayed on electronic stores are comparable with reports generated by the laboratories.

A Managed Service Contract arrangement has been in place since 2008 covering automated service elements of Clinical Biochemistry and Haematology and a small proportion of Immunology/Microbiology.

2.4.2.4 Current Estate Assessment

Availability of equipment provided through the existing Managed Service Contract since 2008 will expire in March 2019 following the agreed extension period. The current contract does not cover the full range of services – Pathology, Genetics and most of Microbiology and Immunology are excluded. The equipment base within and beyond the scope of the contract is degrading with many reaching end of life.

2.4.2.5. Enabling Works

The condition of the physical estate which houses the services described above must be factored into any plan for the unit's equipment. Such specialist equipment requires accommodation to be tailored to its specifications with enabling works to fit and install.

Essential enabling works have been identified by the project to support the delivery of the proposed arrangement. A required upgrade to the structural aspects and electrical infrastructure of the building has been programmed in, in advance of the expected contract commencement date and turnkey installation works to be undertaken by the successful bidder.

The standard of accommodation occupied by Virology in the Polwarth Building fell below the current standards required from HSE and therefore placed at risk the ability to retain UKAS accreditation. The completion of works to upgrade this Virology accommodation in September 2017 supports the laboratory estate in the realisation of the Managed Services Contract solution.

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2.5 Need for Change

There are a number of drivers for changing the current contracted provision for the Laboratory Medicines Unit; ranging from the short term and urgent need for renewing items of specialist equipment and maintenance provision to a longer term visioning of a future for

the service in which it is best placed to meet the needs of service users in 2018 and beyond.

The current Managed Service Contract came to an end in 2017, with an extant agreement to extend its cover for 12 months at an agreed cost to NHS Grampian. Any further extension is not believed to be a sustainable option as the equipment covered by the contract is beyond warranty and are now rapidly reaching end of life and urgently needs replacement. The risks associated with continuing to operate the current assets are significant and not conducive to the Unit's ability to provide the required critical service to NHS Grampian and the North of Scotland. Any replacement of the current equipment will require structural and service change, modern equivalent technology has advanced significantly since the procurement of the original assets and results in a significantly different accommodation profile.

2.5.1. Integration of Services

It is recognised that, with reducing staffing numbers, increasing costs, greater demand for services and rising ageing population, significant changes will need to be effected to address the sustainability challenge, whilst also meeting the expectations of patients. "Doing nothing" will not allow the different disciplines which make up the Laboratory Medicine Unit to deliver the increased demand. There is continual pressure to exploit current and future developments in analytical and knowledge management technologies. This will support the necessary development of the Laboratory Medicine Unit that underpin the current healthcare model. The new Managed Service Contract offers the opportunity to transform the model of service delivery, underpinned by modernised processes and equipment. In addition, delivering opportunities to train in modern, state of the art laboratory facilities will help attract and retain those staff undertaking their training within the Grampian Laboratory Medicines Unit and thus address service sustainability concerns.

2.5.2. Enhancement of Services

The delivery of an effective laboratory medicine service to the NHS Grampian and North of Scotland population requires a service which can provide the appropriate/comprehensive repertoire of testing, within the appropriate context and time frame. The outputs from those services underpin delivery of modern health care systems and have been stated by the Department of Health to represent involvement in 80% of clinical decision making.

The Managed Service Contract will support the current and future delivery of laboratory services. Through securing specialist third party providers covering the procurement, maintenance and management of essential equipment utilised in the delivery of laboratory services, the Laboratory Medicine Unit will continue to deliver the necessary clinical focus from within an appropriately configured infrastructure.

Through securing a long term Managed Service Contract, opportunities for business generation and innovation can be realised as systems with advanced levels of sophistication are put in place.

2.5.3. Delivery of Shared Services Agenda

The aim of the Shared Services approach is having a National and Whole System focus and working across existing regional boundaries, where the aspiration is to standardise and optimise the equitable delivery of services across Scotland, in order to enable equity of access, safety and delivery of the 2020 Triple Aim of quality of care, health of the population and value and financial sustainability.

The Shared Services agenda presents a number of challenges to Laboratory Medicines Unit, as historically, disciplines have been established and developed in response to demand and in line with available resource locally. Compliance with ISO 15189:2012 through UKAS accreditation visits, underpins the quality aspects of each of the laboratory disciplines. It is expected that the NHS Grampian Managed Service Contract will support the current and future delivery of laboratory services, and enable engagement in the development of Regional Working and the Shared Services agenda.

2.6 The Case for Investment

When put in place in 2008, the original Managed Service Contract for Biochemistry and Haematology delivered an advanced level of automation; this offered a platform for real service transformation in local working practices and in service delivery. Changes and improvements were effected on workforce planning, skill mix and roles, improved user access, faster turnaround times and new approaches to diagnosis and management of patients. Since then, increased demand and complexity has exhausted the advantages achieved nine years ago and in order to maintain current service levels and be fit to meet future growth in diagnostic there is now a serious need for change.

2.6.1. Investment Objectives

The rationale for investment should be reflected in the benefits gained from that investment. This provides both the evidence base that a proposal is worthwhile and that it presents value for money.

Potential options to support the delivery of these are developed in the Economic case.

Investment objectives as stated in the Initial Agreement remain valid. They have been discussed and clarified at a Stakeholder workshop. This workshop yielded clarity on what would be required from any investment, in order to meet the need for change as described in the preceding sections. NHS Grampian Laboratories comply with the requirements of 2 external registration / accreditation bodies, UKAS and Medicines and HealthCare products Regulatory Agency (MHRA) and hold full accreditation status with each. All discussions

and investment options were cognisant of ensuring current mandatory accreditation status are not compromised.

Each of these were then explored in more detail with further workshop sessions that focused on how proposed solutions might achieve the desired objectives and to what extent.

The finalised investment objectives are set out in the table below and include only those which are necessary and specific to the agreed need for change

Table 8: Investment Objectives

Effect of the need for change on the organisation	What has to be achieved to deliver the necessary change? (Investment Objectives)
An array of necessary and specialist equipment currently covered by an expiring service contract, upon which relies the continuity of a labs service covering the whole of Grampian as well as services to colleague Boards.	To put in place arrangements for the robust and timely delivery of Labs Services ensuring continuity of safe, sustainable and effective high quality services which maintain national accreditation standards.
Risk of an organisational inability to keep pace with modern procedures, methods and tests, failure to realise benefits from modernised equipment and work processes	To provide systems and service delivery models that can take advantage of Technological Advances
2008 service contract delivered benefits from advances in technology; current complexity and rate of demand for faster turnaround and for new tests is not deliverable with current array.	To put in place service delivery arrangements and facilities that can accommodate the future demand and complexity of user needs and workload in a suitably responsive fashion and to deliver service resilience
Delivering continuous quality and safety in the service is dependent upon effective equipment which can minimise errors, data management and machine/system failure.	Improve safety/performance and effectiveness of equipment /data management and eliminate/mitigate risks around failure both temporary and permanent.
Improving the staff working environment, storage capacity and suitability are all important aspects of the service vision as well as key to maintaining necessary legislative and accreditation compliance.	Ensure accommodation and equipment is efficient, safe and compliant with current legislation and accreditation standards
Grampian already works well in partnership with colleague Boards and is eager to be well placed to engage fully with regional working and shared services agenda.	Opportunity to develop the expertise that can be shared with and help support other Boards on a regional and National level.
Laboratory Medicine has a positive track record for financial efficiency, in line with Grampian's ongoing desire to maintain financial balance through effective financial	Opportunities for co-ordinated planning to manage future expenditure and enhance value for money

Effect of the need for change on the organisation	What has to be achieved to deliver the necessary change? (Investment Objectives)
planning.	
Laboratory Medicine is a highly complex and pressured environment; there is a desire to use management and staff time optimally and freeing up time otherwise spent on managing equipment risk supports this.	Efficient allocation of risk for continuity of service

2.6.2. Critical Success Factors

NHS Grampian's Laboratory Medicine Unit operates within a highly complex and pressured arena. Critical success factors include;

- a. The Unit's role includes the provision of a range of tertiary services to colleague Boards. This history of successful multi Board co-operation is evidence of Grampian's willingness to engage with a Regional Services agenda that is patient focused without duplication of effort; that is able to meet the demands of increasingly localised communities while minimising variation and achieving economies of scale where possible. This demonstrates that the Laboratory Medicine Unit is driven by the ambition to continually improve, to provide modern, flexible and fit for purpose services for patients on both a Grampian and Regional basis.
- b. The Managed Service Contract will provide a new solution which will allow for the service delivery model for all areas to be underpinned by modernised processes and equipment.
- c. This equipping and associated infrastructure works will contribute to planned and future enhancements to clinical services over the duration of the contract.
- d. The project delivers within the available funding envelope.
- e. The project is implemented without any significant disruption to existing clinical services.
- f. The project is delivered without any deviation from compliance of UKAS standards.
- g. The project increases staff morale and assists with recruitment and retention.

These critical success factors can be mapped to the Benefits Register (Appendix 1) and will be used as a framework against which the Managed Service Contract will be assessed.

2.7 Benefits Realisation

The realisation of the benefits outlined in the Benefits Register is the key to the successful delivery of the project. Benefits monitoring will be ongoing over the life of the project. Progress will be reported to the Project Board at regular intervals and will culminate in the Project Evaluation Report to be produced following project completion.

The Benefits Realisation Plan (Appendix 2) outlines the benefits, who will benefit, when benefits will be realised, and how they will be monitored on an ongoing basis.

2.8 What, if any, external factors are influencing this proposal

The NHS Grampian Clinical Strategy and the North Regional Clinical Strategy have the strategic theme of delivering high quality care in the right place through providing safer, effective and sustainable services at their core. There is a significant, reliance on a Laboratory Medicine Unit able to provide robust, efficient and effective clinical services.

The reliance on responsive, timely, accurate and high quality laboratory medicine to support clinical decisions is significant. This backdrop provides explanation to the circumstances in which the Laboratory Medicine Unit provides a service, for the significance of this proposal.

2.9 Key Service Risk

As could be expected from a unit delivering scientific test results, upon which 80% of clinical decision making relies on responsive, timely, accurate and high quality testing, the culture of the unit is very risk aware. Risk to specific and high level service provision is considered with business continuity as a prevalent part of everyday service delivery. (Appendix 3.)

2.10 Conclusion

This strategic case has been updated to reflect Regional Working plans, ageing infrastructure and confirms the need for investment.

The plans to secure an arrangement for NHS Grampian Laboratory Medicine Unit that is underpinned by values which match the culture and ethos of Laboratory Medicine; an ambition to provide the best service possible for users and patients; to offer person centred services as locally and as timely as can be achieved; and to manage a high quality service efficiently within available resources.

The plan will address the existing high level risk to analytical equipment (due to end of life notifications from existing contractors), which provide critical clinical services to NHS Grampian and the North of Scotland, and support the current and future delivery of laboratory services. The continued involvement in the evolution and vision of Regional Working and the Shared Services agenda will be complemented by the establishment of modern analytical systems and associated services, to support and ensure the future delivery of laboratory services.

3.0 The Economic Case

3.1 Introduction

The purpose of the Economic Case within this Full Business Case (FBC) is to undertake a detailed analysis of the costs, benefits and risks of a short list of options illustrating how NHS Grampian has selected the preferred option to be implemented. It demonstrates the relative value for money of the chosen options in delivering the required outcomes and services.

In addition it will seek to demonstrate that the preferred way forward identified at Initial Agreement stage remains valid.

Table 9 sets out a summary of the appraisal undertaken and demonstrates the changes since the preparation of the Initial Agreement do not materially change the outcome.

Table 9: Evaluation of Options

	Option 1	Option 2
(Out of 100)	Do minimum	Widen Scope of Managed Service Contract (Leasing)
Economic Appraisal	38.87	100.00
Risk Appraisal	48.67	78.00
Overall Ranking	2	1
Initial Agreement Ranking	2	1

3.1.1. Adaptation of SCIM IA to FBC

The project described in this FBC has a number of unusual aspects which have necessitated adapting the SCIM process, these are:

- Due to the unique nature of the commercial arrangement, robust data on the financial implication of the project can only be achieved by full market testing.
- The accelerated timeline is essential to avoid unintended repercussions of extending the current contract excessively beyond its 10 year options, and to prevent the replacement of significant pieces of critical capital equipment not yet covered by a Managed Service Contract.

This adapted process which combines the stages of the Outline Business Case (OBC) and FBC maintains the SCIM overall objective of ensuring that a sound, robust analysis is undertaken to support effective decision-making in relation to the Economic Case.

3.1.2 Approach to Revisiting the Assumptions in the Initial Agreement

The process to identify the preferred way forward was documented in the Initial Agreement. This work has been revisited by the Project Team.

The Initial Agreement (IA) was approved by Scottish Government Health and Social Care Directorate (SGHSCD) on 24 April 2017 and given the structure of the proposed procurement arrangement the Board was invited to proceed straight to Full Business Case. No specific conditions were outlined in the approval letter in relation to the Economic Case.

3.2 Revisiting the Preferred Way Forward – Short List of Options

This section details the Economic Case and considers:

- The identification process of short listing the options
- The monetary and non monetary costs and benefits of options
- The economic appraisal of the options
- The non financial risk appraisal of the options
- Value for Money Analysis (VFM) of the preferred option

This includes the final short list of option taken forward to implementation and the rationale for excluding the other options.

3.2.1. Identification of a Short List of Implementation Options

The development and refinement of a long list and short list of proposed solutions was completed with stakeholders at the Initial Agreement stage of the Project.

The development of the options focused on the full scope of laboratory services and delivery within a time period that will support service continuity.

The short list of options that emerged from this work are summarised as follows:

Table 10: Short List of Options at Initial Agreement

Option	Description
1	Do minimum
2	Widen Scope of Managed Service Contract (Leasing)
3	Widen Scope of Managed Service Contract (Capital Purchase)

The Initial Agreement presented Option 3 as a second preferred service solution. This included the proposed upfront purchase of equipment rather than procuring via a lease arrangement. The Project Team examined the relative advantages and disadvantages of this arrangement and confirmed not to pursue further, due to the complexities of the commercial arrangements associated. The output of this work forms Appendix 7.

The two remaining options are:

1. Option 1 – Do Minimum (Initial Agreement – Option 2)

The do minimum option would seek to renew the expiring Managed Service Contract by retaining its existing scope i.e. automated diagnostic testing workload within Biochemistry and Haematology, with all other testing workload including Pathology (Histopathology and Cytopathology); Immunology; Bacteriology and Virology being delivered using current arrangements.

This option assumes:

- no changes to the expected location for service delivery,
- growth will be limited to existing service users and accommodated within existing facilities and contractual arrangements,
- no new investment in the facilities or equipment, out with the scope of the existing contract with for the future investment would be subject to capital funds becoming available.

This option provides no opportunity for development of the workforce, trainees or employees through a programme of appropriate and satisfactory training.

This option is summarised in table 11 below:

Table 11: Option 1 – Do Minimum

Option 1	Description
Service provision	Current service arrangements continue with no service development
Service arrangements	Existing arrangements continue with renewed Managed Service Contract for some (Biochemistry and Haematology - major analysers) systems supporting automated diagnostic testing workload.
Service provider and workforce arrangements	Market testing completed with new Managed Service Contract supplier appointed. Internal resource for remaining automated diagnostic testing workload. No opportunity for workforce development with skills gap forecast.
Supporting assets	NHS Grampian owned equipment. Equipment under new contract lease arrangements. Existing facilities - Link Building
Public and service user expectations	Seamless provision of service would be challenging – as would consistent quality and timeliness.

2. Option 2 – Widen Scope of Existing Managed Diagnostic and Laboratory Services Contract (Leasing) (Initial Agreement – Option 4a)

Option 2 would seek to renew the expiring Managed Service Contract expanding its scope to include automated diagnostic testing workload for Biochemistry; Haematology; Pathology (Histopathology and Cytopathology); Immunology; Bacteriology and Virology. The supply, maintenance and refresh of all systems (equipment) associated with this arrangement will be the subject of an embedded lease.

This option assumes:

- minor service reconfiguration for the following services within existing service delivery locations in the Link Building: Biochemistry; Haematology; Pathology (Histopathology and Cytopathology); and Immunology,
- major service reconfiguration for the following services: Bacteriology and Virology
- substantial new investment in the facilities or equipment including provision for technology refresh of equipment.
- growth and technology advancement.

This option provides an opportunity for development of the workforce, trainees and employees through a programme of appropriate and satisfactory training within a modernised service. This option is summarised in table 12 below:

Table 12: Option 2 – Widen Scope of Existing Managed Diagnostic and Laboratory Services Contract (Leasing)

Option 2	Strategic scope of option
Service provision	Service provision is undertaken by the existing laboratory directorate but supported by a new Managed Service Contract which will deliver equipment refresh and reconfigured facilities
Service arrangements	Managed Service Contract covering automated diagnostic testing workload for Biochemistry; Haematology; Pathology (Histopathology and Cytopathology); Immunology; Bacteriology and Virology
Service provider and workforce arrangements	Market testing completed with new Managed Service Contract supplier appointed. Internal resource for overseeing automated diagnostic testing workload. Opportunity for workforce development and training/education.

Supporting assets	<p>NHS Grampian owned equipment transferred by nomination/adoption into the new Managed Service Contract.</p> <p>Equipment under new contract lease arrangements.</p> <p>Existing facilities - Link Building</p>
Public and service user expectations	Seamless provision of service – consistent quality and timeliness.

3.2.2. Identification and Quantification of Monetary Costs and Benefits of Options

3.2.2.1. Initial Cost Implications

Table 13 outlines the whole life capital costs that have been identified for each option. Whilst Option 2 will be financed by a Unitary Charge the economic appraisal considers the equivalent capital costs.

The following reflects the approach taken in the development of cost:

- Opportunity Costs - The facilities proposed for this project are already in use by the laboratory services and would continue to be used for that purpose therefore no opportunity cost has been identified.
- Turnkey Installation Costs - These costs relate to the installation and associated enabling works associated with implementation of the new equipment and analysers provided under the contract. These costs were high level estimates in the Initial Agreement and have been refined to reflect the solution proposed by potential suppliers.
- Enabling Costs –These costs relate to works necessary to upgrade the virology accommodation and associated service integration and the costs of upgrading the roof structure and electrical infrastructure to support delivery of the project.
- Initial Capital Costs – Equipment (inclusive of Information Technology): The level of investment in equipment has been updated to reflect information provided by the successful bidder.
- Revenue Project Development Cost: Project delivery has largely been met from within existing establishment for the Laboratory Medicine Unit supported as appropriate by the Boards Estates, Planning, Finance and Procurement teams. The NHS Grampian has procured additional building surveyor support.
- Revenue Commissioning Costs: Costs associated with the commissioning of the project will be met by the successful bidder, with NHS Grampian resource being the existing staff within the Laboratory Medicine Unit.
- Lifecycle Costs - Lifecycle replacement costs of assets during the appraisal period for each option have been provided by the successful bidder.

A 10 year appraisal period has been used because it reflects:

1. the expected life of the majority of equipment that forms part of the solution and
2. the initial term of the managed service contract associated with Option 2.

Whole life capital costs are set out in table 13 below.

Table 13: Whole Life Capital Cost Summary - Short Listed Options

	Option 1	Option 2
	£000's	£000's
Opportunity Cost	0	0
Enabling Costs	552	1,441
Turnkey Installation Cost (MSC)	500	XXXXXXXX
Initial Capital Costs – Equipment (MSC)	1,527	XXXXXXXX
Lifecycle Costs	1,537	510
Project Development	0	183
Optimism Bias	1,812	0
Total Initial Cost Implications	5,928	XXXXXXXX

3.2.2.2. Recurring Operating Cost Implications

Table 14 sets out recurring operating costs that have been identified for each option.

Table 14: Annual Recurring Operating Cost Implications

	Option 1	Option 2
	£000's	£000's
Clinical Service Costs	0	0
Non-Clinical Service Costs	4,362	XXXXXXXX
Building Related Running Costs	10	20
Total Recurring Revenue Cost Implications	4,372	XXXXXXXX

The following approach has been taken to develop this cost:

- Additional Clinical Operating Costs: None are anticipated.
- Non-Clinical Operating Costs: These costs have been based on the level of activity anticipated in the first year of operation and include: maintenance, 3rd party fees, IT systems and diagnostic consumables. These costs have been extracted

from both current costs incurred by the Board and the returns received from the preferred bidders.

- Transitional Costs: Transitional costs including double running costs have been reviewed and are considered to be immaterial.
- Monetary Benefits: The benefits to the Board associated with VAT recovery on a Managed Service Contract are noted but not included in the economic appraisal.
- Building Related Running Costs: Only running costs related with increase loading on the electrical supply have been included.
- Externality/Displacement Costs: None are anticipated.
- Net Income Contribution (income generated from non-public sector organisation): None is anticipated.

These whole life operating costs have been reflected in the economic appraisal.

3.2.2.3. Optimism Bias/Financial Risk

Optimism Bias has been calculated for the Do Minimum Option only, in accordance with HM Treasury's guidance as this option has not been developed following the initial approval. The preferred way forward option reflects the developing project costs which includes inherent risk provision. The Optimism Bias templates for the Do Minimum Option (1), is included as Appendix 5.

3.2.2.4. Monetary Benefits

No specific and material monetary benefit associated with the development of this service has been identified for inclusion within the costing of options. Minor efficiencies and income streams are expected to be realised and used to offset minor recurring revenue cost pressures arising from the delivery of the preferred service option, it is not practical to quantify these at this stage.

3.2.3. Non Monetary Costs and Benefits

It is not possible to monetise all cost and benefits associated with the options for this project, the following reflect those benefits identified in the benefits register that are not monetary:

- Modern and efficient equipment with improved process workflow is more able to meet increasing demand for number of tests
- Ability to offer new and more sensitive tests, providing more person-centred medicine inclusive of point of care activities
- Continued and improved employment opportunities locally; preferred employer for local graduates
- Mitigate risk around equipment failure, resulting in improved response time for repairs or failures and reduced equipment downtime
- Role for Grampian as partner in regional and shared services agenda by providing 'best in class' service, process and facilities
- Ability to comply with standards required for accreditations

- Put in place facilities to support robust hub service to improve sustainability of boards within the region whilst developing a distributive model under the Shared Services programme
- Modern and efficient equipment with improved process workflow is more able to meet demand for turnaround times, e.g. 1hr
- Improved built environment, including process workflow and layout as well as ventilation and storage,
- Risks associated with maintaining continuity of service transferred to contractor, releasing management time,
- Contractual arrangements that allow access to market expertise and the efficient allocation and management of risk for continuity of service.

To support the assessment of the options against the benefits these were identified and appraised at the workshop involving a range of stakeholders including clinicians, service managers and other stakeholders in December 2017. The workshop involved:

- Reviewing and agreeing a set of non-financial benefit criteria and weighting these to reflect the workshop group's view of the relative importance of each criterion
- Examining a short-list of options against the criteria and, following discussion, agreeing on how well each option could be expected to meet the criteria and then allocating a score (maximum 5 and minimum 1) for each option against each criterion
- Computing an overall weighted benefit score (summed scores x weight) for each option. This weighted benefit score is simply a measure of how well the workshop participants considered each option was likely to deliver the benefits required from the project
- Reviewing the weighted benefits scores from the appraisal and, following discussion, agreeing that they represented an accurate assessment of the group's views of how well each option is likely to perform in terms of delivering the benefits required from the investment in the project.

The Benefit Criteria agreed and weighted to reflect the workshop group's views on the relative importance of each criterion and the subsequent scoring is summarised in table 15.

Table 15: Scoring and Ranking Non Monetary Benefit Criteria against Options

	Weighting (%)	Option 1	Option 2
Modern and efficient equipment with improved process workflow is more able to meet increasing demand for number of tests	16.25	16.25	81.25
Ability to offer new and more sensitive tests, providing more person-centred medicine inclusive of point of care activities	7.50	7.50	30.00
Continued and improved employment opportunities locally; preferred employer for local graduates	5.00	5.00	25.00

Mitigate risk around equipment failure, resulting in improved response time for repairs or failures and reduced equipment downtime	7.50	7.50	30.00
Role for Grampian as partner in regional and shared services agenda by providing 'best in class' service, process and facilities.	8.75	26.25	43.75
Ability to comply with standards required for accreditations	10.00	20.00	50.00
Put in place facilities to support Robust hub service to improve sustainability of boards within the region whilst developing a distributive model under the Shared Services Programme.	10.00	10.00	40.00
Modern and efficient equipment with improved process workflow is more able to meet demand for turnaround times, e.g. 1hr	10.00	30.00	50.00
Improved built environment, including process workflow and layout as well as ventilation and storage	6.25	12.50	18.75
Risks associated with maintaining continuity of service transferred to contractor, releasing management time	10.00	20.00	40.00
Contractual arrangements that allow access to market expertise and the efficient allocation and management of risk for continuity of service	8.75	17.50	35.00
Total Weighted Score	100	172.50	443.75
Score out of 100		31.36	80.68
Rank		2	1

Applying the benefits criteria ranking demonstrates that Option 2 has the highest weighted score making it the preferred option using the non-financial benefits score.

3.2.4. Non Financial Risk Appraisal

The majority of risks associated with the short-listed options have been measured and quantified in monetary terms and included in the calculated Net Present Cost (NPC) of each option. Hence, the costs used in the economic appraisal have been risk adjusted to reflect the main business, operational and project implementation risks including:

- Commissioning risks
- Operational risks
- Service risks
- Business risks

Recognising that not all risks can be quantified in monetary terms, the non-financial risks associated with the short-listed options were identified and appraised. Those identified were:

This appraisal was similar to that used for the non-financial benefits and has been reviewed by the Project Team, involving:

- Reviewing each of the shortlisted options to identify potential non-financial risks
- Assessing each risk in terms of its likelihood and impact
- Computing a risk score for each option by multiplying the likelihood and impact scores

The results from the appraisal of non-financial risks are summarised in Table 16 that follows and demonstrate that the Do Minimum scores least with Option 1 scoring second lowest:

Table 16: Non Financial Risk Appraisal

	Option 1 The Do Minimum option			Option 2 Widen Scope of Existing Managed Diagnostic and Laboratory Services Contract (Leasing)		
	Impact	Likelihood	Risk Score	Impact	Likelihood	Risk Score
Significant equipment failure in one or more parts of the service	5	5	25	3	3	9
Ability access repair or maintenance of equipment necessary to deliver services	4	4	16	2	2	4
Significant error rate in tests due to out of date processes	4	3	12	4	1	4
HSE 'stop' notice on current working practices	4	3	12	4	1	4
Failure to attract a commercial interest in solution	0	0	0	3	2	6
The service solution does not support regional and strategic development in the service	3	4	12	3	2	6
Total Weighted Score			77.00			33.00
Score out of 100			48.67			78.00
Rank			2			1

3.2.5. Net Present Value of Options

The financial evaluation, calculating net present value, of each option is set in the context of the guidance provided in the Scottish Capital Investment Manual (SCIM). It incorporates a full analysis of the revenue and capital costs for each option.

A Generic Economic Model (GEM) has been applied to the monetary costs and benefits of the options to derive the comparative cost implications of each of the options in the form of Equivalent Annual Costs (EAC) and Net Present Costs (NPC). The output of the GEM model is set out in Appendix 6.

The appraisal process identifies the relevant costs and financial risks and benefits over the project development and the first 10 years of the asset lives associated with each of the short listed options.

Table 17 shows a summary of the cost implications together with net present costs for each of the short listed options.

In accordance with guidance, capital charges, inflation and VAT are excluded from the calculations. Capital and revenue costs are added together to calculate a net present cost for total expenditure.

Table 17: Summary Cost Implications Short List Options

	Option 1	Option 2
	£000's	£000's
Initial Cost Implications	5,928	XXXXXXXXXX
Additional Recurring Revenue Implications	4,372	XXXXXXXXXX
Net Present Cost (NPC)	39,842	XXXXXXXXXX

3.2.6. Assessing Uncertainty

Sensitivity analysis is fundamental to option appraisal since it is used to test the robustness of the ranking of options and the selection of a preferred option. It examines the vulnerability of options to changes in underlying assumptions and future uncertainties. For this project it has been undertaken by scenario analysis – examining the impact of changing scores, weights and net present costs through a number of scenarios

3.2.7. Sensitivity Analysis – Net Present Cost

The net present costs have been subjected to a range of sensitivity tests to check whether changes to any of the assumptions concerning capital or revenue costs have a significant impact on the option rankings. The tests undertaken were:

- Vary Demand +20%; and,
- Vary Capital Investment +20%.

The outcome of which are detailed in Table 18

Table 18: Sensitivity Testing– Net Present Cost

	Option 1		Option 2	
	NPC	Rank	NPC	Rank
	£000's		£000's	
Scenario 1: No Changes	39,842	1	40,119	2
Scenario 2: Increase Demand by 20%	46,631	1	46,957	2
Scenario 3: Increase Capital Investment by 20%	40,872	1	40,915	2

It has been demonstrated that there is little sensitivity arising from flexing these costs.

3.2.8. Sensitivity Analysis – Non Financial Benefits

This analysis has examined the impact arising from flexing the weighted benefit scores and is detailed in Table 19:

Table 19: Sensitivity Scenario - Non-Financial Benefits

	Option 1		Option 2	
	Score	Rank	Score	Rank
Scenario 1: No Changes	172.50	2	443.75	1
Scenario 2: Equal Weight	172.73	2	436.36	1
Scenario 3: Exclude Top Rank Score	156.25	2	362.50	1

It has been demonstrated in Table 19 that the ranking of options does not significantly change as a result of applying these scenarios as Option 2 remains superior in terms of expected non-financial benefits in all three scoring scenarios.

In conclusion, the option rankings show little sensitivity to amending the underlying assumptions.

3.2.9. Conclusion and Identifying the Preferred Option

Value for money in the Economic Case considers the optimum solution in terms of comparing qualitative benefits to costs. This analysis has been performed on an economic Net Present Cost basis in line with HM Treasury guidance and the results are shown in Table 20.

Table 20: Net Present Cost per Non-Monetary Benefit Score

	Option 1	Option 2
Net Present Cost (NPC) (£000's)	39,842	40,119
Non-Financial Weighted Benefit Score	173	444
NPC per Weighted Benefit Score	231	90
Score out of 100	38.87	100
Rank	2	1

A summary of the results of all the evaluation criteria of the economic and risk appraisals are presented together in Table 21 and affirms Option 1 to be the preferred option to be taken forward.

Table 21: Option Appraisal

	Option 1	Option 2
(Out of 100)	Do minimum	Widen Scope of Managed Service Contract (Leasing)
Economic Appraisal	38.87	100.00
Risk Appraisal	48.67	78.00
Overall Ranking	2	1
Initial Agreement Ranking	2	1

4.0 Commercial Case

4.1 Overview

This section outlines the commercial arrangements and implications for the project.

This is done by responding to the following questions:

- The procurement strategy and appropriate procurement route for the project,
- The scope and content of the proposed commercial arrangement,
- Risk allocation and apportionment between public and private sector,
- The payment structure and how this will be made over the lifetime of the project
- The commercial arrangements of the offer
- The contractual arrangements for the project.

The key commercial component of this project is the tendering of a Managed Service Contract in 3 lots:

- Lot 1 – Biochemistry and Pathology (Histopathology and Cytopathology)
- Lot 2 – Haematology and Immunology
- Lot 3 – Bacteriology and Virology

The scope of the Board's requirements are complex and the value of the contract will be in the region of £50 million (ex VAT) over its life.

The evaluation of this tender has been completed and preferred bidder identified. The preferred bidder for all 3 lots is Abbott Laboratories UK Ltd. Formal appointment will only be made following approval of this Full Business Case (FBC).

4.1.1. Reconfiguration enabling Works Delivered Outwith the Managed Service Contract

In addition to the main Managed Service Contract, NHS Grampian has invested £776,000 in reconfiguration works, to facilitate service moves from the Polworth Building. These have been delivered using an existing arrangement under the Frameworks Scotland 2 (FS2) Agreement and funded from the Board's infrastructure and backlog maintenance programme.

The scope of this work ensured that accommodation for the Virology service met HSE and UKAS requirements, and was in place in advance of the award and implementation of the new Managed Service Contract. It has the added clinical adjacency benefit of co-locating the other laboratory disciplines within the Laboratory Links Building at ARI, and allow any potential opportunities around clinical adjacencies to be realised.

Detailed design planning for further infrastructure works (electrical and structural upgrades) essential to support the new service arrangements is underway with all work expected to be complete by March 2019. This work has been procured using the Board's existing Measure Term contractual framework and the work will be funded through the Board's Infrastructure and Backlog Maintenance Programme.

These enabling works procurements are not considered further in the following sections of this case.

4.2 Procurement Strategy

4.2.1. Introduction

The purpose of this section is to specify the procurement strategy and it does this by setting out:

- Procurement Route
- Compliance with EU Regulations
- The Procurement Plan for the Project

4.2.2. Procurement Route

In identifying the procurement approach to be undertaken, the project team considered the following:

- Existing contracts or frameworks - no framework existed and the existing contracts weren't like for like, at the time of the project initiation.
- Contract Value - the contract is anticipated to be £50 million (£5 million per annum) therefore beyond OJEU thresholds.
- Scope of Contract – the contract is a mix of service, provision of equipment and works, reflecting the unique nature of the procurement requirement,
- Risk – the scope of the contract contains a number of high risk areas including: complex implementation, ongoing performance standards within a healthcare setting where continuity of high quality clinical service is imperative.

Route 3 of the Procurement Journey, which provides guidance on regulated activities above the OJEU threshold has been followed. Route 3 is compliant with the Public Contracts (Scotland) Regulations 2015 and the Procurement Reform (Scotland) Act 2014. The procurement strategy was developed with stakeholders and advisors. It included market engagement which supported consideration of the need to apply either the open or restricted procedure.

The scope of the tender, i.e. including all laboratory disciplines (apart from Genetics), would expose the procurement to the likelihood of large number of potential bidders for different parts of the service. To optimise the management of a complex procurement process, the restricted procedure procurement route was adopted which includes a selection stage, allowing the reduction of potential bidders invited to tender to those that met a minimum requirement.

The Managed Service procurement has been split into 3 lots to allow for optimal management of a complex programme of interlinked projects. The separation into 3 lots was the optimal risk mitigation strategy in light of the complexity arising from the number of likely bidders, the number of laboratory medicine disciplines involved alongside the scope of the Managed Service Contract which was to cover the works, procurement, delivery, installation and commissioning of equipment, supply of reagents and consumables, along with maintenance and repair of all components.

The 3 lots were structured as follows:

- Lot 1 – Biochemistry and Pathology (Histopathology and Cytopathology)
- Lot 2 – Haematology and Immunology
- Lot 3 – Bacteriology and Virology

The procurement allowed for the submission of suspensive bids. This will support securing the benefits that may arise where the winning bid for each lot relates to the same supplier.

4.2.3. EU Rules and Regulations

An OJEU compliant restricted procurement process has been followed, owing to:

- The potential value of the contract
- To adhere to the EU fundamental principle of equal treatment, non-discrimination, mutual recognition, proportionality and transparency.

4.2.4. Procurement Plan

An outline of the project's procurement plan is described below. This highlights the project's current procurement status, what has already been achieved and what still needs to be done.

The Procurement Plan included the following key pieces of work.

- Develop procurement strategy including stakeholder and market engagement
- Identification of the procurement route as set out in 4.2.2 above
- Development of procurement documents involved considerable work from each of the laboratory disciplines and including the following:
 - a. Contract Notice and European Single Procurement Document (ESPD)
 - b. Draft Managed Service Agreement
 - c. Invitation to Tender (ITT) inclusive of:
 - i. Detailed specification documents and information brief for each laboratory discipline. This contains detail specific to each laboratory discipline, operational aspects of each service, functionality of systems and ability to meet professional standards, high level timetable and implementation requirements, detail around how each laboratory discipline may interact with other disciplines, expectations on successful contractors, identification of costs, contract management, IT data management, support and software updates, with evidence of business management and innovation potential and any process improvement and redesign opportunities.
 - ii. Development of Evaluation Criteria inclusive of quality/price ratio of 60/40 and scoring.
- Establishment of Evaluation Panel to consider the returns from Bidders. Panel members are all employed by NHS Grampian and include experienced leads from all Laboratory Medicine Unit disciplines, Finance, Estates and Procurement Teams.
- Supplier selection as the first stage of the restricted procedure. This process involved publication of the contract notice in June 2017 and assessment of

interested parties' responses in relation to capability and capacity to deliver the contract.

- Issue of Invitation to Tender in September 2017 to those parties successful in the supplier selection stage.
- Receipt and evaluation of tender returns. This was an elongated process due to the complex nature of clarification issued.
- Identify winning bids for each lot and consider suspensive bids.
- Advise Bidders of evaluation outcome (and commencement of standstill period).
- Preparation of Business Case and Approval of the Intention to Award.

The Procurement Timetable from inception to operation is outlined below.

Table 22: Procurement Programme

Stage	Current Date	IA Date	Duration
Submission of Initial Agreement	February 2017	February 2017	
Instruct Enabling Works	February	February	
Complete specification of requirements for each Lab Discipline	April 2017	Not Applicable	16 months
Complete Commercial Contract detail	June 2017	Not Applicable	20 months
Issue of Contract Notice and European Single Procurement Document	June 2017	February 2017	60 days
Issue Invitation to Tender	20 September 2017	March 2017	54 days
Receipt of Tenders	28 November 2017	April 2017	7 months *
Complete Evaluation of Tenders	September 2018		
Advise bidders of evaluation outcome	January 2019		
Submission of Full Business Case (FBC)	October 2018	May 2017	17 months
Notification of award of contract	January 2019	May 2017	18 months
Standstill period	January 2019		12 days
Implementation of MSC, with definition of timescales, phasing, commissioning and commencement	January 2019	June 2017	18 months
Full Implementation Complete	December 2019	March 2018	21 months

The milestones associated with the project timetable have been subject to change since the Initial Agreement. The Contract Notice and European Single Procurement document was issued in June 2017, with the ITT issued in September 2017, evaluation has now been completed and appointment can be made following approval of this business case.

The elongation of the programme were due to (i) the additional time required to confirm the Boards complex requirements and (ii) the volume and nature of clarifications required during the evaluation process to confirm that bids met the Board's requirements. The initial tenders received from all bidders failed to address all of the requirements, and with support from the CLO and procurement colleagues, required a lengthy clarification process.

4.2.5. Advisors

Legal services have been provided by the NHS Scotland Central Legal Office (CLO). The CLO have contacted all suppliers and confirmed prices are held based on an Award of contract in January 2019.

External Advisors for Chartered Surveyors (WI Talbot) have been procured by NHS Grampian to assist the Project Team with the scoping and review of turnkey installation and reconfiguration works and standards. WI Talbot are a firm of Chartered Surveyors who were engaged by NHS Grampian to provide cost consultant support for the tendering stages of the project. WI Talbot undertook site visits and reviewed client based information to allow them to prepare output schedules of works that set out the general requirements for each of the work areas and lots. These were issues with the main tender elements of work.

WI Talbot carried out a tender check of each of the returns for the turnkey works and highlighted areas where there were omissions or discrepancies in what they would have expected to see returned by way of detail and cost. This level of challenge was used to ensure that further supporting information was provided by the tenderers where required to provide the necessary clarification to allow a more accurate comparison of bids for the turnkey works. WI Talbot provided commentary on the final submissions to allow the Lab Project Team to reach informed decisions on the award of works.

4.3 Scope and Content of Proposed Commercial Arrangements

4.3.1. Scope of Works / Services

The Managed Service Contract will cover all Laboratory Medicine Unit disciplines apart from Genetics, these are:

- Lot 1 – Biochemistry and Pathology (Histopathology and Cytopathology)
- Lot 2 – Haematology and Immunology
- Lot 3 – Bacteriology and Virology

The new Managed Service Contract will include renewal of all critical equipment, periodic technical refresh of the equipment base, ongoing servicing and maintenance, and supply of all consumables and reagents

The decision was made to structure the ITT into different lots as a result of a number of factors:

- The complexity of the contract meant that some contractors would not have been able to bid for haematology or microbiology if a single lot structure was employed. This might even have prevented them from bidding for the contract as a 3rd party.
- NHS Grampian viewed that the triple lot structure allowed each Laboratory medicine discipline to obtain the best potential solution for their service.
- Within the triple lot structure, there was still the opportunity for any potential supplier to bid for any combination of lots via suspensive bids. This would also allow for NHS Grampian to potentially benefit from economies of scale and shared infrastructure such as IT support.

The service arrangements associated with the scope of this procurement have an annual value of approximately £5 million. Given the scope of the arrangement, including installation of equipment, a contract period of 10 years following implementation has been included. The contract also makes provision for an extension, should the Board wish to take up this option.

The Central Legal Office (CLO) have provided procurement and legal advice throughout this procurement. A bespoke contract based on a standard form which is used for other managed service arrangements was developed following detailed preparation of technical requirements, assessment of asset registers, soft market testing and engagement with suppliers. The bespoke contract includes provision for risk transfer and key performance indicators that encourage business continuity and quality, whilst penalising failure.

It is anticipated that the Managed Service Contract procurement will facilitate NHS Grampian in continuing to provide a high quality, cost-effective service that meets the future needs of its users. A key benefit will be the establishment of modern, innovative and efficient equipment which will improve workflow and provide opportunities to meet increasing demand and in addition provide opportunities for regional working and the Shared Services agenda.

The successful bidder were required to identify how they would replace existing analysers and equipment, introduce new systems which would minimise manual intervention and deliver process improvements and operational efficiencies. Common instrumentation and middleware to facilitate contingency planning and cross-site transfer of work are anticipated as part of the final solution.

Responses describing bidder solutions to meeting a particular requirement or demonstrating how compliance is achieved is supported by detailed drawings/plans showing the layout of their proposed Managed Service Contract solution.

Following the decision and notification to award the contract for lot 1, lot 2 and lot 3, the successful bidder and NHS Grampian Board will have, within two months of the commencement date (or longer as agreed), discussed and agreed a detailed implementation plan. The implementation plans will show timescales within which NHS Grampian wishes the Managed Service Contract to be fully implemented and operational.

Turnkey installation works including any required accommodation changes within each laboratory discipline are the responsibility of the bidder's appointed Contractor, with detail around current establishment, equipment and accommodation having been provided as part of the detailed lot documentation, upon which the Contractor was invited to outline their solutions for, and resultant from site visits by potential suppliers. The services to be included in the commercial arrangements are for potential changes to layout of specific department disciplines, ensuring each site is ready for the delivery, installation, commissioning, testing and acceptance of all relevant components of the service, and ensuring that each site is left in an acceptable manner which will not compromise the smooth and efficient running of any of the Laboratory Medicine Unit disciplines.

The successful bidder will undertake all work required to prepare each laboratory discipline according to the lot detail. The successful bidder will procure, deliver, install, commission, maintain and repair all components of each solution. All reagents and consumables will be procured and delivered as required by NHS Grampian Board. Following commissioning, testing and acceptance, each system will have a go-live date in respect of the Managed Service Contract.

4.3.2. Project Information

The table below provides a checklist of Project information provided.

Table 23 Project Information

Project Information Requirements	Confirmation that information is available (Yes, No, n/a)
Developed brief	Yes. Outlined for each laboratory discipline as part of information pack, NHS Requirement for a Managed Service Contract, (lot1, lot2, lot 3).
Outlined design to include multi-discipline input, including but not limited to: Architecture, Building Services, Structural, Fire, including diagrams and sketches demonstrating the key proposals which bidders are expected to respond to.	Yes. Design and Information pack provided as part of the ITT information pack, further supported by additional detail as part of the further clarification process.
Laboratory discipline specific ISO documentation	Yes. Detail provided as part of the ITT information pack.

4.3.3. Risk Allocation

The key principle is that risk has been allocated to the party best able to manage it.

A key feature of the Managed Service Contract is transfer of Availability and Performance risk to the service provider. Table 24 outlines ownership of known key risks.

The spread of risk allocation was agreed at a workshop involving key members of the Laboratories team, eHealth, Finance and Procurement colleagues. The focus of the workshop was to use the extensive experience gained over the last 12 years operating the existing managed service arrangement, to inform a review of all available information regarding the commercial model and the associated arrangements for implementation and ongoing operation of the proposed new arrangements. Each risk category was scored individually and the results consolidated to derive the risk assessment in Table 24.

Table 24: Risk Allocation

Risk Category	Potential Allocation of Risk		
	Public	Private	Shared
Transition and Implementation (commissioning, migration, Board responsibility)	50	50	Y
Availability and Performance	-	100	N
Operating	25	75	Y
Revenue	10	90	Y
Termination	50	50	Y
Technology and Obsolescence	20	80	Y
Control	100	-	N
Financing	-	100	N
Change in Law	75	25	Y
Other Project Risks	100	-	N

A number of commercial risks will continue to be managed by the project team until final acceptance of the solution, these are:

- Procurement Challenge – Due to the scale and complexity of this procurement, the Board may receive procurement challenges from unsuccessful bidders. The project evaluation has been undertaken on the basis of best practice, with comprehensive document management, and regular advice from Legal Advisors have informed the actions taken by the Board during this procurement.
- Implementation Period Delays (Infrastructure) - a planned upgrade to possible structural works and electrical infrastructure of the building is programmed, delays would impact implementation. Detailed discussions will be progressed with the successful bidder as to how the infrastructure works can be best managed against the backdrop of the bidder turnkey installation works.
- Implementation Period Delays (Bidder) – there is a risk of an elongated implementation period because of the complexity associated with installing the new equipment and analysers in a continuously operating facility across different disciplines and sites. The successful bidder and NHS Grampian Board will have, within two months of the commencement date (or longer as agreed), discussed and agreed a detailed implementation plan. The implementation plans will show timescales within which NHS Grampian wishes the Managed Service Contract to be fully implemented and operational. This implementation plan will be resultant from detailed dialogue with the Managed Service Provider to ensure that the turnkey installation works are completed in a way that minimizes disruption to the ongoing operation of the service.

- Supply Chain Issues (Brexit) – the component of this contract including analysers and reagents have a supply chain which is highly depended on the EU and US. The Board recognises this risk and will work with the successful bidder to manage effectively.

4.4 Commercial Arrangements

The scope of the service requirements have been specified in a suite of documents including the ITT and contract form. This has been market tested and bidder' compliance with the Board's requirements has been established and evaluated Following approval of this Full Business Case appointment will be made.

The preferred bidder identified for all 3 lots is Abbott Laboratories UK Ltd. Further details of the evaluation can be found in Appendix 9.

A summary of the procurement is set out below:

Table 25: Summary of Procurement

	Lot 1 – Biochemistry and Pathology (Histopathology and Cytopathology)	Lot 2 – Haematology and Immunology	Lot 3 – Bacteriology and Virology	Total
Contract Notice Responses (Nos)	3	6	7	16
Bidders (Nos)	3	4	4	11
Total Contract Value (£m)	21.72	14.50	14.36	50.58

4.5 Payment Structure

4.5.1. Method of Payment

The provision of a Managed Service Contract will be delivered using a unitary charge funding model. The components of the unitary charge includes fixed charges in relation to provision and installation of equipment, semi-fixed charges in relation to maintenance and management and variable costs in relation reagents and consumables. Semi-fixed charges and variable cost will be subject to annual indexation (CPI) review. Following Final Acceptance, the Contractor shall charge the Unitary Charge to the Board for the Managed Services. The Unitary Charge shall be payable by the Board in four instalments quarterly in arrears. The final payment of the Unitary Charge shall be due on expiry of the Term and shall be pro- rata to reflect the fact that it relates to the period from the start of the last occurring Quarterly Period to expiry of the Term.

The annual Unitary Charge shall be the total of:

- The annual Fixed Charge;
- The annual Semi-Fixed Charge (as indexed); and
- The Annual Test/Variable Costs (as adjusted following annual reconciliation and indexed in each Contract Year).

The Contract also makes provision for appropriate payment during the implementation period.

4.6 Key Contractual Issues

4.6.1. Type of Contract

A Managed Service Contract was developed with the Central Legal Office (CLO). A bespoke approach was taken to reflect the Board's requirements but was based on a standard form contract that has been widely used by Health Boards across Scotland over the last 10 years, and is known and understood by the industry. The agreement for the Managed Service Contract for laboratory services will be in accordance with the specification and the Contract Agreement which formed part of the NHS Grampian Final Tender documents, and which will be signed by the successful bidder following award of contract. The Agreement is governed and construed according to Scots law. Appendix 10 sets out the structure of the Managed Service Contract Agreement.

4.6.2. Key Contractual Issues

The contract is required to support arrangements for the robust and timely delivery of laboratory services, ensuring continuity of safe, sustainable and effective high quality services which maintain national accreditation standards. The form of the contract reflects this with a contract management structure inclusive of performance standards. Recognising the scale of turnkey works, the contract has been amended to include appropriate arrangements for supporting the effective commissioning of these.

Some key contractual issues for this form of contract are:

Duration:

The contract is to include an implementation period, plus 10 years, and provision for extension for 2 years, should the Board choose to avail of this. The additional 2 x 1 year extensions should allow NHS Grampian a more flexible transition to the next MSC, mitigating the risks associated with an overrun. This is a critical clinical support service and it is essential that there is sufficient flexibility built into the arrangement to ensure that the service can continue operating should there be any delay in re-tendering the service in the future, for example, should agreement be reached to harmonise contractual periods across Boards as part of a future joint procurement exercise.

Implementation and Acceptance:

The contract places conditions on the service provider to manage the implementation with due regard to the operating environment. Acceptance will only occur following testing and sign-off by the Board, as per the standards set out in the contract.

Performance:

The service provider will be required to provide a high quality of service throughout the duration of the contract and key performance indicators set these requirements. Key performance indicators on analyser uptime, specimen turnaround time, engineer response times, have been incorporated into the Managed Service Contract, and will be reviewed on an ongoing basis to ensure the continuity of a quality service. Failure to achieve said standard will result in service deductions from payment. Equipment refresh is an inherent part of the contract performance.

Maintenance arrangements are set out in the contract.

Change Control:

The contract includes a mechanism to facilitate changes in the Board requirements as requirements and regulatory environment evolve over the life of the Project. Under the contract these can be funded by revenue or capital. The service will be required to produce a business case to be considered, in the first instance, by the Acute Senior Leadership Team and then by the Board's Asset Management Group and where planned investment would exceed the £1m, the NHS Grampian Board.

Termination:

Termination arrangements and associated remedies are set out in the contract. Ownership of equipment rests with service provider. These can be funded by revenue or capital following expiry of the contract.

4.6.3. Personnel Arrangements

There are no NHS Grampian employees who are wholly or substantially employed on services that will be transferred to the private sector under the proposals for this project, and therefore the Transfer of Undertakings (Protection of Employment) Regulations 1981 (TUPE) will not apply.

5.0 The Financial Case

5.1 Introduction

The Financial Case considers the financial implication of the proposed service arrangements and confirms its overall affordability in the context of the Board's financial plans. The proposed service arrangements are:

- Option 2 Widen Scope of Existing Managed Diagnostic and Laboratory Services Contract (Leasing) (Initial Agreement – Option 4a)

It does this by setting out:

- The financial model for the proposed service arrangements including revenue and capital implications;
- Arrangements for any outstanding financial issues and risks;
- The agreed accounting treatment;
- A statement on overall affordability and
- Confirming any external stakeholder support.

The Managed Service Contract will attract an annual unitary charge funded from the Board's revenue allocation. The enabling works – service reconfiguration, were delivered out with the Managed Service Contract and were funded from the Board's infrastructure and backlog maintenance programme in 2017/18. Further enabling works – roof structure and electrical infrastructure will similarly be funded from the Board's infrastructure and backlog maintenance programme in 2018/19. The Managed Service Contract is expected to include an implementation period, to have a term of 10 years, and provision for extension for 2 years, should the Board choose to avail of this.

The Managed Service Contract includes an embedded lease in relation to equipment; it has been evaluated in relation to accounting treatment and at this stage is anticipated to be a lease under IFRS 16 which will be the applicable accounting standard at inception.

In summary the investment required to deliver the project is set out in table 26 and the revenue implications in the first full year of operation are set out in table 27.

NHS Grampian is committed to the project and has incorporated the necessary funding increases for capital and revenue consequences in its financial plans for the coming years. Further details of the capital and revenue elements of the project and sources of funding are provided in the following sections.

Table 26: Summary of Initial Investment

	FBC
	£000's
Enabling Works - Reconfiguration/Move services from Polwarth Building	776
Enabling Works – roof structure and electrical infrastructure	900
Project Development Costs	183
Total Whole Life Capital Costs	1,859

Sources of Funding	
NHS Grampian Infrastructure and Backlog Maintenance programme	1,676
NHS Grampian Revenue Funding	183
Total Sources of Funding	1,859

Table 27: Summary of Revenue Implications - First Full Year of Operation (2020/21)

	FBC
	£000's
Revenue Costs	
Unitary Charge	XXXXXXXXXX
Building Related Running Costs	20
Total Costs	XXXXXXXXXX
Sources of Funding	
Depreciation	47
Unitary Charge - Existing MSC	XXXXXXXXXX
Other Revenue Costs - Transfer to New MSC	XXXXXXXXXX
Total Sources of Funding	XXXXXXXXXX

5.2 Revisiting the Finance Case

The Initial Agreement (IA) was approved by Scottish Government Health and Social Directorate (SGHSCD) on 24 April 2017 and given the structure of the proposed procurement arrangement the Board was invited to proceed straight to Full Business Case. No specific conditions were outlined in the approval letter in relation to the Finance Case. The Initial Agreement presented a second preferred service solution (Option 4b). This proposed the upfront purchase of equipment rather than procuring via a lease arrangement within the Unitary Charge. The Project Team examined the relative advantages and disadvantages of this arrangement and confirmed with not to pursue further. The output of this work forms Appendix 7.

5.3 Financial Model for the Proposed Service Arrangements

The provision of a Laboratory Managed Service will be delivered using a unitary charge funding model. Revenue budget will be required to meet this unitary charge. The components of the unitary charge includes fixed charges in relation to provision and installation of equipment, semi-fixed charges in relation to maintenance and management and variable costs in relation reagents and consumables.

Additional capital investment by NHS Grampian was required for enabling works with revenue resources invested in project development and commissioning costs.

The following sections set out how the key financial implications of the project have been identified and the assumptions influencing them.

5.3.1. Initial Investment

The total infrastructure costs that will be funded by the Board are set out in table 28.

Those capital costs that will be financed by the Managed Service provider and paid for by the Board through the annual unitary charge have a capital value of £4.4 million and are set out in table 31.

Table 28: Summary of Investment in Enabling Works

	FBC	IA	Variance
	£000's	£000's	£000's
Enabling - Reconfiguration/Move services from Polwarth Building	776	820	44
Enabling Works – Infrastructure	900	0	-900
Total Whole Life Costs	1,676	820	-856
Sources of Funding			
NHS Grampian Infrastructure and Backlog Maintenance Programme	1,676	820	-856
Total Sources of Funding	1,676	820	-856

5.3.1.1. Enabling Works – Service Reconfiguration

These works were subject to a separate procurement route. The costs associated with the enabling works are set out in table 29. These have been finalised as this work was completed in Autumn 2017. Funding was through NHS Grampian's Infrastructure and Backlog Maintenance Programme in 2017/18.

Table 29: Summary Enabling Works – Service Reconfiguration

	FBC	IA	Difference
	£000's	£000's	£000's
Reconfiguration/Move services from Polwarth Building	691	730	39
VAT 12.33%	85	90	5
Total Initial Investment	776	820	44
Sources of Funding			
NHS Grampian Infrastructure and	776		
Total Sources of Funding	776	820	44

5.3.1.2. Enabling Works – Roof Structure and Electrical Infrastructure

Following receipt of the proposed service solution and associated detailed equipment specifications from the bidders it became apparent that there are electrical capacity and

structural loading (roof) issues within the existing infrastructure, these could prevent successful implementation.

Detailed surveys were commissioned by the Board to assess these issues and identify any requirement needed. Remedial work undertaken included and are set out in table 30.

Table 30: Summary Enabling Works – Roof Structure and Electrical Infrastructure

	FBC	IA	Difference
	£000's	£000's	£000's
Investigation	60	0	-60
Remedial Work	707	0	-707
VAT	133	0	-133
Total Initial Investment	900	0	-900
Sources of Funding			
NHS Grampian Infrastructure and Backlog Maintenance Programme	900	0	-900
Total Sources of Funding	900	0	-900

5.3.1.3. New and Replacement Equipment

The new and replacement equipment will be procured through the Managed Service Contract, financed by the supplier and recharged as part of the Unitary Charge. The preferred bidder have provided detail of the capital costs for these items, detailed in table 31.

Table 31: New and Replacement Equipment

	FBC	IA	Difference
	£000's	£000's	£000's
Turnkey Installation and Implementation	XXXXXXXXXX	1,860	XXXXXXXXXX
Analysers and Equipment	XXXXXXXXXX	6,979	XXXXXXXXXX
Total Costs	XXXXXXXXXX	8,839	XXXXXXXXXX

All bidders provided indicative capital costs for their proposed solution, these were wide ranging. The movement in costs between IA and FBC reflect the preferred commercial model of the preferred bidder, whereby overhead and profit is recovered from other components of the managed service e.g. reagents and consumables.

5.3.2. Non-Recurring Revenue Costs

5.3.2.1. Project Development Costs

A Project Team consisting of multi disciplined NHS Grampian staff support this project, with legal advice provided by the Central Legal Office (CLO) and additional surveyor advice provided by a third party Talbot Chartered Surveyors. The majority of this work has been undertaken using existing resources, Table 32 sets out the additional project development costs.

Table 32: Additional Project Development Costs

	Total
	£000's
Project Development Costs	
Project Team	30
Project Advisors	108
Other Project Costs	45
Total Project Development Costs	183
Sources of Funding	
NHS Grampian Revenue Funding	183
Total Sources of Funding	183

5.3.2.2. Commissioning Costs

Commissioning activities will be led by the Managed Service provider, with the involvement of existing NHS Grampian resources; therefore no specific commissioning costs have been identified.

5.3.3. Summary of Revenue Implications- First Full Year of Operation (2020/21)

Table 33 details the anticipated annual recurring revenue costs that will be associated with the project in the first year of operation following commissioning. It details the projected unitary charge that will be charged through the contract.

Table 33: Summary of Revenue Implications - First Full Year of Operation (2020/21)

	FBC	IA	Movement from IA
	£000s	£000s	£000's
Revenue Costs			
Unitary Charge	xxxxxxxx	5,556	xxxxxxxx
Additional Depreciation	xxxxxxxx	0	xxxxxxxx
Additional Clinical Service Costs	xxxxxxxx	0	xxxxxxxx
Additional Non-Clinical Service Costs	xxxxxxxx	0	xxxxxxxx
Building Related Running Costs	xxxxxxxx	0	xxxxxxxx
Total Costs	xxxxxxxx	5,556	xxxxxxxx

Sources of Funding			
Net Depreciation	xxxxxxxx	88	xxxxxxxx
Unitary Charge - Existing MSC	xxxxxxxx	2,472	xxxxxxxx
Other Revenue Costs - Transfer to New MSC	xxxxxxxx	2,482	xxxxxxxx
Net Additional Revenue Costs	xxxxxxxx	514	xxxxxxxx
Total Sources of Funding	xxxxxxxx	5,556	xxxxxxxx

5.3.3.1. Movement in Recurring Revenue Costs

The anticipated recurring revenue cost associated with these facilities has reduced by xxxxxxxx compared with the IA figure. This reduction is as a result of market tension associated with competitive tendering and means the Board will benefit from an enhanced service arrangement that can be accommodated within the envelope of the existing revenue budget.

5.3.3.2. Unitary Charge (UC)

The predicted Unitary Charge and funding arrangements by lot are set out in table below.

Table 34: Unitary Charge - First Full Year of Operation (2020/21)

	Lot1	Lot 2	Lot 3	Total
	£000s	£000s	£000s	£000s
Fixed Costs	xxxxxxxx	xxxxxxxx	xxxxxxxx	xxxxxxxx
Semi Fixed	xxxxxxxx	xxxxxxxx	xxxxxxxx	xxxxxxxx
Variable	xxxxxxxx	xxxxxxxx	xxxxxxxx	xxxxxxxx
Total Costs	xxxxxxxx	xxxxxxxx	xxxxxxxx	xxxxxxxx
Sources of Funding				
Net Depreciation	xxxxxxxx	xxxxxxxx	xxxxxxxx	xxxxxxxx
Unitary Charge - Existing MSC	xxxxxxxx	xxxxxxxx	xxxxxxxx	xxxxxxxx
Other Revenue Costs - Transfer to New MSC	xxxxxxxx	xxxxxxxx	xxxxxxxx	xxxxxxxx
Total Sources of Funding	xxxxxxxx	xxxxxxxx	xxxxxxxx	xxxxxxxx

The components of the unitary charge include fixed charges in relation to provision and installation of equipment, semi-fixed charges in relation to maintenance and management and variable costs in relation reagents and consumables. Semi-fixed charges and variable cost will be subject to annual indexation (CPI) review. Approximately 12% of the UC will be fixed.

Prices for a number of additional service delivery options e.g. Point of Care blood gas analysis, tandem mass spectrometry etc. have been sought as part of this procurement, at this stage. Following appointment, work will be undertaken with the successful bidder to assess the value for money of these options. Those options that will be taken up early in the contract have an annual UC of approximately xxxxxxxx and have been included in the costs set out in this case. The Managed Service Contract includes a change control mechanism to allow for the implementation of these options as required.

5.3.3.3. Depreciation

The current service is operated using a combination of NHS Grampian owned equipment and equipment provided under the existing managed services contract. The scope of service under the new Managed Service Contract has been expanded to include service arrangement currently undertaken using NHS Grampian owned equipment. This equipment will transfer to the preferred Managed Service Providers and a saving (£47,000) in depreciation will accrue.

5.3.3.4. Building Related Running Costs

As this arrangement will be installed in existing facilities, the only increase identified in building related running costs is that associated with electrical load (£20,000 per annum).

5.3.3.5. Clinical Service Costs

The project will facilitate service re-design and potentially deliver of efficiencies through the automation of service. At this stage the impact cannot be quantified.

5.3.3.6. Non-Clinical Service Costs

None beyond those set out in relation to the Unitary Charge are anticipated.

The Unitary Charge together with the changes to annual depreciation charge and annual running costs are reflected in the Board's financial plans.

5.3.4. VAT

The contractual structure will enable the Board to reclaim VAT on its maintenance, servicing and reagent cost component of the Unitary Charge under UK statute. The proposed arrangement has been reviewed by the Board's VAT Advisor who has confirmed this assessment at this stage.

Anticipated VAT has been included within the costs presented.

- Enabling Works – Service Relocation : a rate of 12.33% has been applied this is net of the recoverable sums (38.35%) for this scheme agreed with HMRC;
- Enabling Works – Roof Structure and Electrical Infrastructure : - 100% recovery on professional fees has been assumed;
- Project Development Costs: where applicable VAT is assumed to be recoverable
- Recurring Running Cost – Unitary Charge – assumed recoverable as a Contract Out Service (Heading 3 Laboratory Services).
- Other Recurring Revenue Costs: where applicable VAT is assumed non

recoverable.

5.3.5. Financial Risk

All of the risks are identified within the Project Risk Register. Those risks that are financial in nature have been quantified. These are:

Table 35: Summary of Risk Provision

	£000s	%	Reason
Enabling Works – Infrastructure	200	25%	Detailed Design in Development
Unitary Charge (per annum)	120	2%	Tender Omissions

These financial risks are reflected in the in the Tables above. The residual risk will be managed by the Board within the funding requirements identified.

The financial risks carrying the greatest impact are those that relate the unknowns in site development and omission from the Board’s requirements during the tendering process.

The Project Team will continue to manage and monitor these and other financial risks and mitigate the impact.

5.3.6. Costs Not Included

Those clinical and non-clinical costs that relate to current service pressures or predicted growth in demand have not been reflected. However they are recognised by the Board and will be considered and managed through existing budgeting and financial management arrangements augmented by appropriate service re-design.

5.4 Statement of Overall Affordability

5.4.1. Provision in Financial Plans

In addition to the recurring revenue costs of the project from financial year 2020/21, there are also a number of non-recurring capital and revenue costs that have and will continue to be incurred directly by NHS Grampian during the implementation stage of the project.

NHS Grampian is committed to the project and has incorporated the requirement for the essential enabling works, as appropriate, in its infrastructure investment plans. The revenue consequences of this arrangement will be accommodated within the existing revenue budget for this service.

Table 36 and 37 consolidates the cash flows and funding requirements to support the project during development and the first full year of operation.

Table 36: Costs – Cashflow

	2017 /18 £000s	2018 /19 £000s	2019 /20 £000s	2020 /21 £000s	Total £000s
Enabling Costs	776	900	0	0	1,676
Total Infrastructure Costs	776	900	0	0	1,676
Project Development	41	62	80	0	183
Commissioning Costs	0	0	0	0	0
Unitary Charge	0	0	xxxxxxx	xxxxxxx	
Additional Depreciation	0	0	0	0	
Clinical Service Costs	0	0	0	0	
Non-Clinical Service Costs	0	0	0	0	
Building Related Running Costs			10	20	
Total Revenue Costs	41	62	xxxxxxx	xxxxxxx	
Total Costs	817	962	xxxxxxx	xxxxxxx	

Table 37: Funding – Cashflow

	2017 /18 £000s	2018 /19 £000s	2019 /20 £000s	2020 /21 £000s	Total £000s
NHS Grampian Infrastructure and Backlog Maintenance Investment plan	776	900			1,676
NHS Grampian Revenue	41	62	80		
NHS Grampian Depreciation (Equipment)			24	47	
NHS Grampian (Other Scheme Costs)			xxxxxxx	xxxxxxx	
Total Sources of Funding	817	962	xxxxxxx	xxxxxxx	

5.4.2 Sensitivity of Affordability

In assessing the affordability of the project consideration has been given to the impact of a 10% increase in costs in the following areas, as outlined in Table 38:

Table 38: Sensitivity Analysis

Area	Impact £000s	Management
Infrastructure Expenditure – Enabling Works	90	Structured processes of identifying and programming need and managing delivery are in place. This will be subject to and managed within a framework of competing priorities for funding.
Recurring Revenue Costs – Growth	500	Early identification, regular review and forms part of budget planning process.
Recurring Revenue Costs – Indexation	500	Early identification, regular review and forms part of budget planning process.

5.4.3. Value for Money

Extensive market engagement and planning was undertaken in developing and preparing the preferred service solution for market. The costs included within the business case have been subject to an extended period of competitive tendering and reflect value for money.

5.4.4. Agreed Accountancy Treatment

5.4.4.1. IFRIC 4 & IFRS 16

Where the contract would previously have been assessed as an operating lease under IAS 17, the timing of implementation (post 31 March 2019) will mean that the equipment (£4.4million) will require to be accounted for under IFRS 16, on NHS Grampian's balance sheet as a non current (fixed), right of use, asset with a corresponding liability shown as a finance lease creditor.

The project will be delivered under contract with an embedded lease over a minimum 10 year term. Throughout the term the Managed Service Provider will retain title for the assets, the contract provides for the transfer of title to NHS Grampian at the end of the term of the contract for an additional financial consideration, if required, the value of the financial consideration will be determined by both parties at that time. The contract has been assessed as an arrangement which contains a lease under International Financial Reporting Interpretation Committee Interpretation 4 ('IFRIC 4') and would be classified as an operating lease against the lease classification requirements of IAS 17 'Leases', however the arrangement will commence following 1 April 2019, and will be subject to the accounting requirements of IFRS 16

Accounting for Leases and “on balance sheet” in NHS Grampians accounts. See Appendix 8 for commentary on this assessment.

NHS Grampian Statement of Accounts are prepared under International Financial Reporting Standards (IFRS) and will recognise on its balance sheet the cost, at fair value, of the property, plant and equipment underlying the arrangement as a non current (tangible) fixed asset and record a corresponding long term liability associated with the financing arrangement. The asset’s carrying value will be determined in accordance with International Accounting Standards (IAS) 16 subsequent to final acceptance but for planning purposes fair value is assumed to be the capital values provided by the preferred bidder, (£4.4million).

The ‘lease rental’ paid on the long term liability will be derived by deducting all operating, maintenance and variable costs from the contract amounts paid to the preferred bidder. The ‘lease rental’ UC will be split between repayments of the liability, interest charged on the liability

The annual charge to the Statement of Comprehensive Net Expenditure (SOCNE) will consist of all operating, maintenance and variable costs, interest and depreciation calculated on a straight line basis.

On the expiry of the contract term the Net Book Value of the asset will be equivalent to the residual value assessed in accordance with IAS 16.

5.4.4.2. Enabling Works

The works with a value of £1,676,000 procured to enable the project, from NHS Grampian’s Infrastructure and Backlog Maintenance Programme, has/will be accounted for by NHS Grampian as capital or revenue expenditure as appropriate under IAS 16.

The recurring revenue costs of £5,003,000 will be covered from the existing revenue budget envelope for laboratory medicine.

5.5. Written Agreement of Stakeholder Support

No financial contributions are expected to be made by external partners, in relation to delivery of this arrangement.

6.0 The Management Case

6.1. The Management Case

This section will provide an update on all the arrangements in place to demonstrate that the organisation is ready to proceed to contract award and project implementation.

The Laboratory Medicine Unit, Acute Senior Leadership Team and NHS Grampian Board have been aware of the limitations of the current laboratory technology and physical infrastructure and its impact on working practices and existing activities. The Initial Agreement letter of approval from the Scottish Government Health and Social Care Directorate (SGHSCD) dated 24 April 2017 invited the Board of NHS Grampian to progress the Laboratory Medicine Unit Managed Service Contract Initial Agreement straight to Full Business Case.

This Management Case section will confirm the arrangements which are in place to successfully deliver the optimal solution for the Laboratory Medicine Unit. Option 2 Widen Scope of Existing Managed Diagnostic and Laboratory Services Contract (Leasing). The option developed in this Full Business Case will replace the previous contract and extend the scope of the new MSC, to include all Laboratory disciplines except Genetics. Genetics has not been included within the scope as it is not a service funded by NHS Grampian, but instead is funded on a cross Board consortium basis, agreed and allocated annually by NSD. NSD agree the work type to be performed and how that workload is to be allocated across the 4 consortium laboratories which cover Scotland. This therefore has a significant effect on the type of equipment each Laboratory has in its workplace. These unique arrangements covering funding, local/regional workload and equipment allocation, and, national workload, could only be dealt with at consortium level because of the potential for knock on consequences to the other Laboratories within the consortium. See page 24, section 2.4.2.2, Exclusion of Genetics.

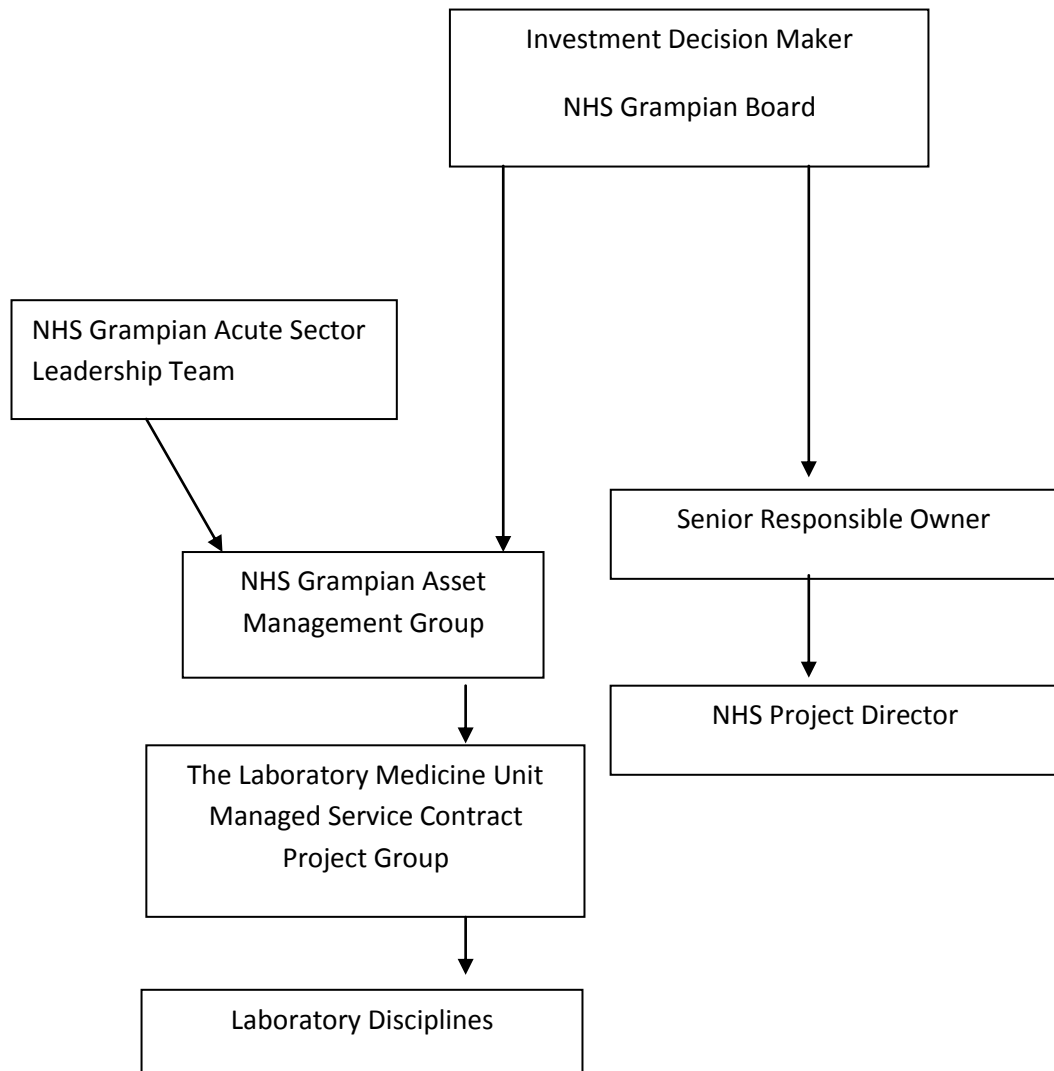
The new contract will secure long term managed services with a specialist third party provider. The contract will include renewal of all critical equipment, periodic technical refresh of the equipment base, ongoing servicing and maintenance and supply of all consumables and reagents utilised in the delivery of laboratory medicine services. This management case will demonstrate that the organisation is ready and capable of proceeding to contract award and project implementation.

6.2. Project Management Arrangements

In compliance with Scottish Capital Investment Manual, this project has deployed a programme and project management approach with a structure as shown in the diagram below.

Project Management Structure and Governance Arrangements

Figure (M1)



The reporting and governance arrangements outlined in figure above indicate the groups who will be involved in providing assurance to the NHS Grampian Board as part of the governance process for the project. Governance routes exist to the Acute Sector Leadership Team and to the Asset Management Group as well as to the NHS Grampian Board. The project governance has ensured that all key parts of the health economy are appropriately involved in the project as it progresses through each of the key stages.

Advice and any additional governance routes are supplied and accessible through the NHS Grampian organisational structure, offering strategic links with other developments and programmes such as the Baird Family Hospital, the Anchor Centre project and the Elective Care Programme.

The Board of NHS Grampian has invested significant financial and organisational resources in ensuring that it has sufficient capacity and capability to be able to effectively deliver and managed infrastructure projects across the organisation.

The Project Management structure was prepared from local experience, with guidance from Scottish Government and Central Legal Office. The cost of the project team over the life of the project, together with external advisors, will be met by NHS Grampian from its core revenue funding

6.2.1. The Managed Service Contract Project Group

The membership of the Laboratory Medicines Unit Managed Service Contract Project Group was established to oversee the process of assessment, planning and implementation necessary to secure the optimal solution for the Laboratory Medicines Unit.

The role and remit of the Laboratory Medicines Unit Managed Service Contract Project Group is as follows:

- To lead on the successful delivery of a solution to the expiration of the current Managed Service Contract for NHS Grampian Laboratories from 2019 to 2029.
- To assess, plan and deliver the specifications, documents and provide assurance to NHS Grampian Board that the solution delivers the aspects of a safe, efficient and patient centred service for the next 10 years. In addition that the preferred solution is affordable and the arrangements will represent value for money to NHS Grampian.
- To produce and recommend to the Board of NHS Grampian a Strategic Assessment, an Initial Agreement (IA) and a Full Business Case (FBC), to support the preferred solution to the expiry of the Laboratory Managed Service Contract.
- To produce the supporting Business Case process and documentation, particularly around the strategic case in the form of a strategic assessment of laboratory services in NHS Grampian.
- To lead on communicating with clinical teams, Senior Management in Acute and to the Executive team around progress.
- To agree any assessed bids in accordance with agreed scrutiny process.
- To develop the clinical and operational policies, where appropriate, related to the successful implementation of the successful solution.

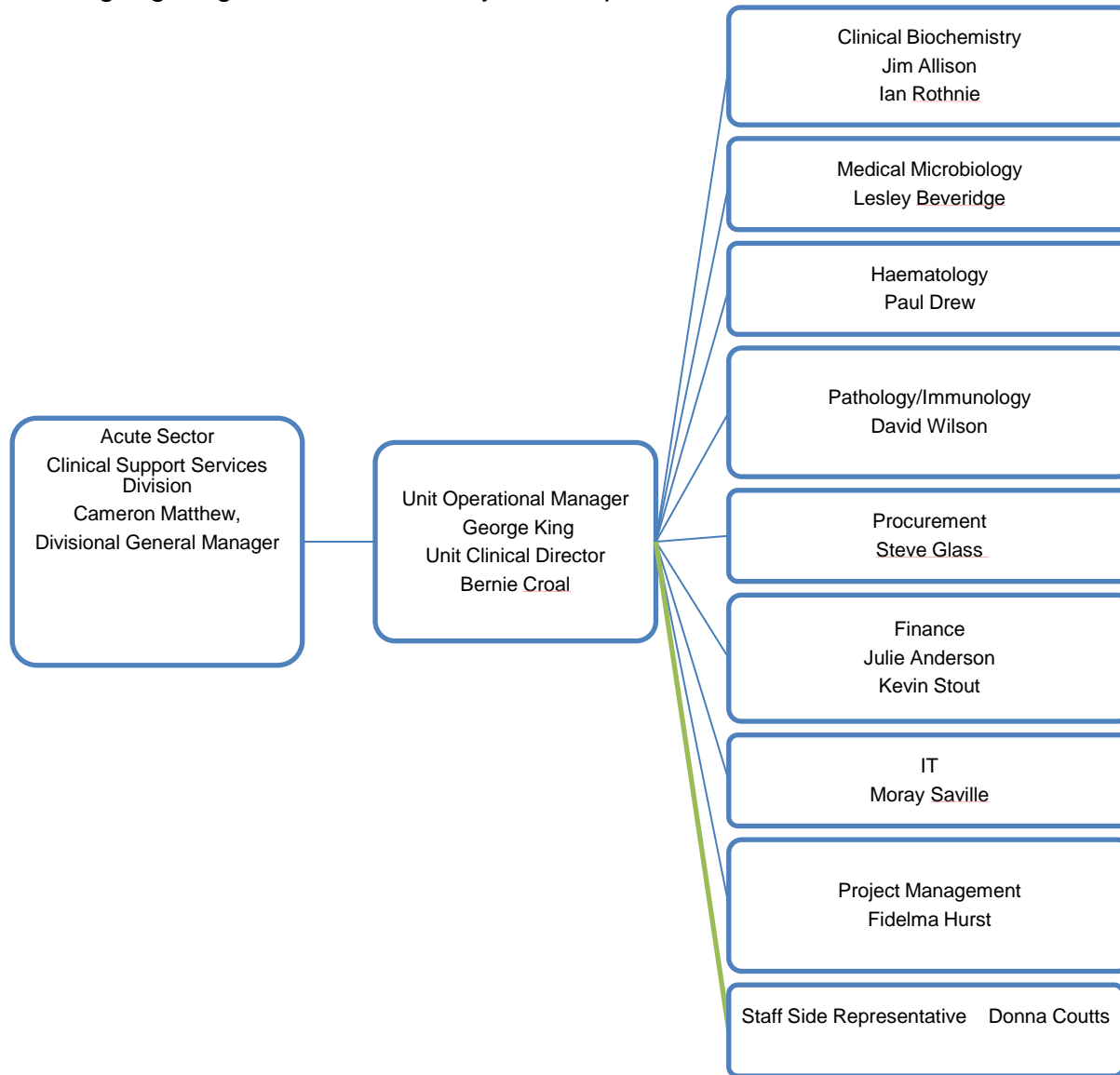
There are main 6 Laboratory disciplines (some with associated direct care clinical services), each headed by a Consultant Service Clinical Director.

Project Team Member	Role
Cameron Matthew	Divisional General Manager (Chair of Project Group)
George King	Unit Operational Manager Laboratory Services
Bernie Croal	Unit Clinical Director Laboratory Medicine
Jim Allison	Service Clinical Director Biochemistry
Ian Rothnie	BMS4/Laboratory Manager
Lesley Beveridge	BMS4/Laboratory Manager
Paul Drew	BMS4/Laboratory Manager
David Wilson	BMS4/Laboratory Manager
Moray Saville	Laboratory IT Manager
Donna Coutts	NHSG Staff Side Representative
Julie Anderson	Finance Manager
Kevin Stout	Finance Manager
Steven Glass	Head of Procurement and Logistics
Fidelma Hurst	Project Manager

Meetings:

- Administrative support is provided by DGM PA
- Meetings are held weekly, subject to review
- Meeting dates have been agreed and set in advance
- The business of the Project Group is recorded in an action note.

The following organogram details the Project Group.



6.2.2. Independent Client Advisors

The various parties noted below in Table 39 below have been appointed to provide specialist advice to NHS Grampian to support the delivery of the Laboratory Medicines Unit Managed Service Contract project.

Table: 39 Independent Client Advisors

Independent Client Advisors	
Project Role	Organisation and Named Lead
Quantity Surveyors	WI Talbot Chartered Surveyors Andrew Gove
Legal Advisor	Central Legal Office, NHS National Services Scotland. Joanne McCabe
Electrical Surveyor	CCDP Mr. K Scott
Structural Engineering	Ramsay Chalmers Mr. G Stewart

6.3. Change Management Arrangements

The Managed Service Contract was drawn up by the National Health Services Scotland Central Legal Office and formed a key part of the documentation shared at the outset as part of the procurement process.

In this contract, NHS Grampian confirmed detail around how the Laboratory Medicines Unit would get to where it wanted to be; how it will work with the successful bidder following award to implement the project.

There are main 6 Laboratory disciplines (some with associated direct care clinical services), each headed by a Consultant Service Clinical Director. The opportunities which will become available with the establishment of modern laboratory technology will enable the Laboratory Medicines Unit to function more efficiently as detailed below, but not limited to;

- Development in processes to allow for voice to text software to enable more efficient provision of clinical advice by Laboratory Consultants to clinical specialties.
- Automated Reagent Inventory reducing wastage.
- Analytical interface consolidation
- Improved workflow and a lean ergonomic working environment resulting in improved turnaround times e.g. introduction of rapid molecular PCR testing
- Consolidation of analytical platforms
- Future proofing Laboratory Services to be able to meet Regional Working and the Shared Services agenda

- Improved IT resilience; the Managed Service Provider will provide a solution which tolerates component failure, duplicates many LIMS functions within Middleware IT thus addressing risk of LIMS failure, and IT architecture which allows the IT service to be run from an alternative room, in the event of disaster. All these areas contribute to a significant improvement in contingency, compared to existing Laboratory IT systems.

The Managed Service Contract covers all aspects of the project from Award, Pre-installation, Development of Programme, Installation, Implementation and Acceptance, Training and Dispute Resolution. It stipulates monitoring arrangements throughout the programme, with key performance indicators. The development of this bespoke contract was to provide resilient contract management for the Managed Services Agreement, complimenting the extensive experience which already exists within each of the NHS Grampian laboratory disciplines.

The Laboratory Medicine Unit disciplines have been fully engaged with the whole process from service visioning and planning, through strategic assessments, workshops, and support for developing the Initial Agreement and Full Business Case.

Following appointment of the successful bidder, leadership will be provided from project group members to support smooth transition, successful implementation and commissioning, whilst maintaining an operational clinical service.

6.3.1. Implementation of Managed Service Contract

Following award of the contract to the successful bidder, the NHS Grampian laboratory discipline senior management and departmental leads will work with the bidder on the implementation programme, policies and working arrangements to support the successful commencement of the Managed Service Contract.

The delivery of the optimal solution will also involve the development of:

- Risk Register
- Communications Plan
- Governance Structure
- Transition Plan
- Contingency Planning
- Staff Training

The implementation period will be augmented by support from NHS Grampian Laboratory Medicine Unit, Estates, and E Health. The NHS Grampian laboratory discipline senior management and departmental leads will work with the successful bidder to co-ordinate the project through all of its stages, to ensure successful

completion of the facilities, and to bring into operation the solution which is consistent with the project objectives.

6.3.2. Project Programme

Table: 40 Project Programme

Key Milestones – NHS Grampian Laboratory Medicine Unit Managed Service Contract	Date	Completed
Issue of ITT	Sept 2017	Complete
Evaluation of ITT	Sept 2017 – Sept 2018	Complete
Finalise FBC Documentation	Oct 2018	Complete
Issue Report to Project Board / AMG / NHS Grampian	Oct 2018	Complete
Award of Contract	Jan 2019	
Enabling works and implementation	Jan 2019 – Dec 2019	

6.4. Benefits Realisation Plan

The rationale for the investment was demonstrated at Initial Agreement stage and a benefits register was developed to detail the benefits expected from the project. These have been set out in the Appendix 1. Significant work has been carried out as part of the project, to ensure that project benefits are still appropriate and viable. A benefits realisation plan has been developed and updated to confirm how and by whom each of the benefits will be monitored throughout the implementation stage, and then evaluated as part of the projects evaluation processes. All benefits within the Benefits Realisation Plan (Appendix 2) will be assessed as part of the Service Benefits Evaluation process.

6.5. Project Risk Register

Effective management of Project Risk is essential for the delivery of any project. A robust risk management process and risk register were developed at the outset of the project and monitored throughout by the Project Group, with implications on laboratory clinical service being regularly examined.

In developing the Project Risk Register, the initial activities of the Project Group focused on articulating the range of project risks, and the impact on the clinical service and the project itself. The risk registers included in the Initial Agreement were assessed to identify whether there was any change in the underlying assumptions. Assessment of each risk has been updated to reflect if they are financial or non-financial and any control measures which have been recorded.

A copy of the Updated Project Risk Register which is regularly monitored and reviewed by the Project Group is included as Appendix 3.

6.6 Commissioning

The award of the Managed Service Contract to a successful bidder will see the opportunity for establishment of modern laboratory technology to further enhance the clinical service provided. Tendered solutions for the Managed Service Contract identified a need for further enabling works in relation to electrical capacity in terms of what the current ageing electrical infrastructure can support, and structural load capacity in relation to air handling plant. These essential works will be undertaken prior to the implementation of the managed service arrangement. The commissioning actions and timetable needs to be planned and co-ordinated to ensure the success of bringing the new facilities and equipment into operation.

A programme will be developed by the successful bidder which will indicate enabling works, installation, technical commissioning, handover, functional commissioning and evaluation detail for each laboratory discipline. All bidders were given the opportunity to conduct site visits and are aware of the level and complexity of work required under each lot.

There are two separate streams of commissioning:

- Technical Commissioning
- Functional Commissioning

The Technical Commissioning will involve the physical change to departmental areas and handover of facilities back to NHS Grampian. Laboratory discipline senior management and departmental leads, with NHS Grampian Facilities and Estates key personnel, will work with the successful bidder's appointed contractors to ensure each laboratory discipline/facility is handed over in a state of readiness for the technical commissioning to commence.

Some of the activities included in the Technical Commissioning Plan are:

- Safety and security of facilities and staff
- IT enlivenment
- New equipment installation
-

The Functional Commissioning will commence following handover of the physical area / facility to NHS Grampian. This will involve the smooth transition to operation of new equipment infrastructure (the Equipment, period of “double-running”, pre and post analytical automation and the Solution Management System). The commissioning of each laboratory discipline will be managed, led and co-ordinated by departmental leads identified in advance.

Some of the activities included in the Functional Commissioning Plan are:

- Clinical clean
- Period of dual running and staff training

Commissioning will be led by each laboratory discipline departmental leads who will be part of and supported by NHS Grampian Operational Management, Facilities Management and the Managed Services Contract Project Team.

6.7. Monitoring and Evaluation Plan

The Laboratory departmental leads and project manager will be provided with full support from the wider project and operational management teams. Following appointment of the successful bidder, the Programme detail developed will indicate how stakeholder service requirements are to be met. Evaluation of the success in terms of ability to deliver to cost and programme will be evaluated by the Project Team.

6.8 Project Monitoring Report

A number of people are involved in the monitoring and evaluation process. The project monitoring will be led by the project manager, who will prepare reports for consideration by the Project Board over the life of the programme. Completion of this report will involve input from members of the project team, including finance manager, operational managers and laboratory departmental leads.

A final Project Monitoring report will be submitted to the Scottish Government shortly after project completion and will incorporate detail from each of the lots. An overview of achievement of the project's objectives and their delivery along with recommendations for any future improvements will be contained within this Project Monitoring Report.

The rationale for a project will have identified the potential benefits to be gained from the successful delivery of that project. All benefit within the Benefits Realisation Plan will be assessed as part of the Service Benefits Evaluation process.

Appendices

Available as separate Appendices Document.

