Step 1: Outline Business Case
Tool 1: Sample Outline Business Case
This tool is for use in conjunction with Step 1 of the Commissioning Toolkit document

[INSERT NAME OF COMMISSIONING BODY]

[INSERT NAME OF PROJECT]

Outline Business Case (OBC)

[INSERT DATE]

Revision history

Document Version Control			
Version	Date	Author	Change

Guide to this document

Using this template (the commissioner should remove the red text sections from the template prior to publishing the OBC, as they serve as drafting notes (DN) and do not form part of the template itself)

The purpose of this template document is to help commissioners in the creation of a Pathology Services OBC and steer them towards the supporting evidence required at the OBC stage. The template provides a set of proposed headings and text, drafting notes to provide additional direction to commissioners, as well as a number of samples from past OBCs where appropriate. The template is part of a set of documents provided within the Pathology Commissioning Toolkit and should be used in conjunction with the guidance provided in the toolkit.

It is important to note that the samples provided should be reviewed for their structure and format rather than content, as each commissioning project will require a tailored solution to match the commissioner's requirements. Given that the sample OBCs available at the time of writing this document refer to system-wide change, the solutions described in them may not be appropriate, for instance, to a local tender.

Finally, it should be noted that this document (and the wider Pathology Commissioning Toolkit) assumes the reader is seeking pathology-specific guidance rather than general advice. Links to general information which may be relevant to the user can be found in the guidance document itself, detailed in the "references" section of Step 1, "Produce Outline Business Case".

The structure and purpose of the OBC

This Business Case follows the HM Treasury 'five case' model, with the addition of a clinical case as follows:

The executive summary provides an overview of the six cases and the proposed preferred option (Section 1)

Strategic case – why is change necessary?
The strategic case outlines the strategic case for change, its context and goals of the project (Section 2)

Clinical case – what are the clinical reasons for change and expected clinical benefits?
The Clinical case (Section 3)

Economic case – what are the options for delivering the change, and which is the preferred one?
The Economic case details the critical success factors and the options for achieving the strategic goals (Section 4)

Commercial case – how will change be procured?
The Commercial case presents the procurement strategy, why changes are required, investment requirements, risk transfer and payment mechanisms (Section 5)

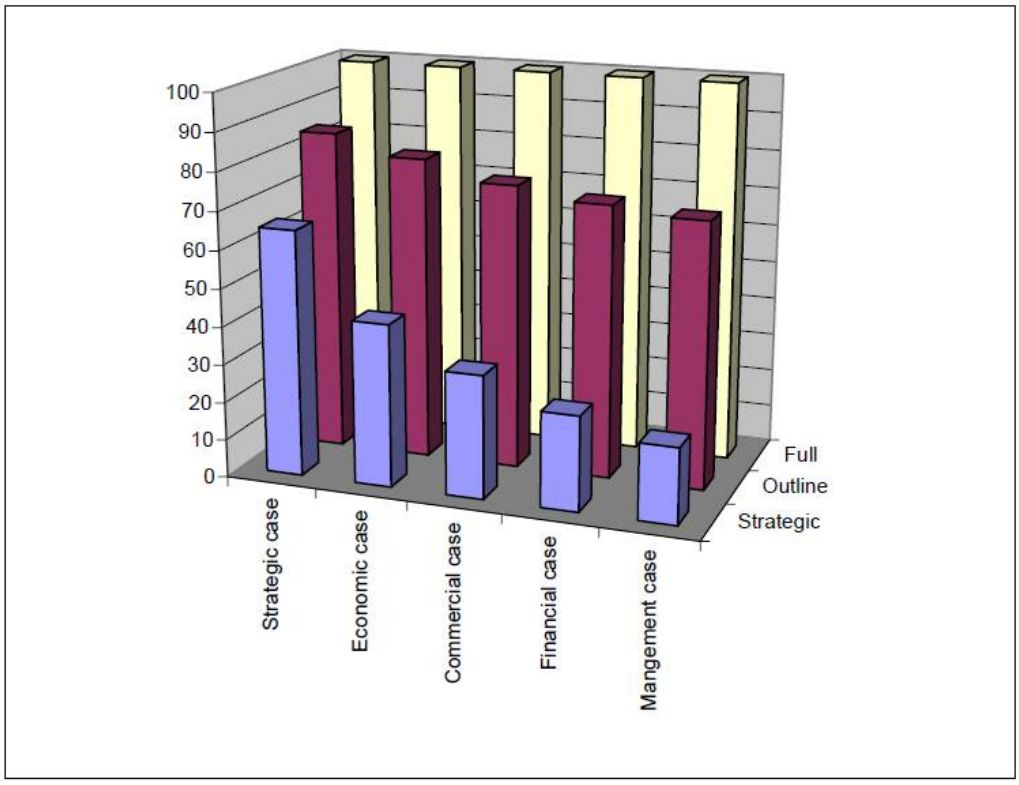
Financial case – how will change be funded?
The Financial case presents financial data and affordability of the project (Section 6)

Management case – how will the necessary change be managed successfully? The Management case reviews the arrangements for managing the project including risks, benefits realisation and post project evaluation methods. The management case also includes the governance requirements for joining up commissioners and governing across a system (Section 7)

The standard process of progression from Strategic Outline Case to Outline Business Case to Full Business Case (FBC) is available from the link found at the end of this section. It allows the strategic goals to be set first, followed by the identification and refinement of the options and blueprints for change within a structured framework (see below Diagram 1 for the proposed level of completion of each of the 5 cases during the 3 stages of the process). This process avoids abortive work on options which are not viable and ensures the full analysis is only undertaken on the option which is most likely to meet the goals of the project.

*Note that the Green Book Guide does not include a clinical case, which has been added to this template to provide space for the inclusion of clinical considerations which do not fit naturally in any of the generic 5 cases.

Diagram 1 – level of completeness (%) of the 5 cases in relation to the 3 stages of development of a business case (Source: Green Book Guide)



Approval of the OBC is sought in order to affirm that the assumptions made, and the options appraised, lead to the best available option being identified. The FBC then tests assumptions and affirms this option (or otherwise disproves it and sends the project for re-consideration).

Whilst every effort has been made to avoid repetition, the nature of the Five Business Cases (plus a clinical case) approach means that several of the themes may be discussed in more than one section, albeit from different perspectives.

A further guide to the HM Treasury five-case model is available in the Green Book guide. This is available from:

http://www.hm-treasury.gov.uk/data_greenbook_index.htm

Contents

Section: 1 Executive summary

[Drafting notes (DN): summarise the key reasons for change, linking to the complete pathology intervention cycle]

1.1 Introduction

[Insert text]

1.2 Key findings

The key findings of this Outline Business Case (OBC) are:

- [Insert text]

1.3 Recommendations

The recommendations in this OBC are:

- [Insert text]

1.4 Strategic case

[DN: The strategic case should set out, in the context of the scope of the Pathology commissioning intervention, the linkages between the commissioning strategy and desired future state of pathology services. The Strategic case should indicate if achieving the future state of pathology services requires a local negotiation with existing providers, tendering for services or a centrally-led system wide reconfiguration.

Key reasons for change should be summarised and should cover all of the aspects of proposed changes to the pathology services. See sample in KMPN OBC[1] p.8, the "pathology intervention process"]

1.5 Clinical case

[DN: The clinical case for change should be set out clearly to include the nature and scope of the existing pathology service supply, the key clinical drivers for change (e.g. poor quality or service outcome, lack of laboratory accreditation), the clinical and service benefits that can be attained as a consequence of the change. The scale of the benefits may be different depending on the approach chosen to implement the change (see Table 1 in the Guidance)

1.6 Economic case

1.6.1 The case for change and the long-list of options

The case for change is driven primarily by [DN: refer to the national, regional and local agenda, as appropriate]. The economic case demonstrates that options exist which will achieve value for money and provide cost efficiencies. The different options involve varying levels of change to the local provision of pathology service, ranging from a local negotiation,

[1] The KMPN OBC can be found at http://www.kmpathology.nhs.uk/home-page/pathology-publications/

through a retendering exercise to a system-wide reconfiguration programme. The pathology service improvement options identified were:

- Option 1:
- Option 2:
- …

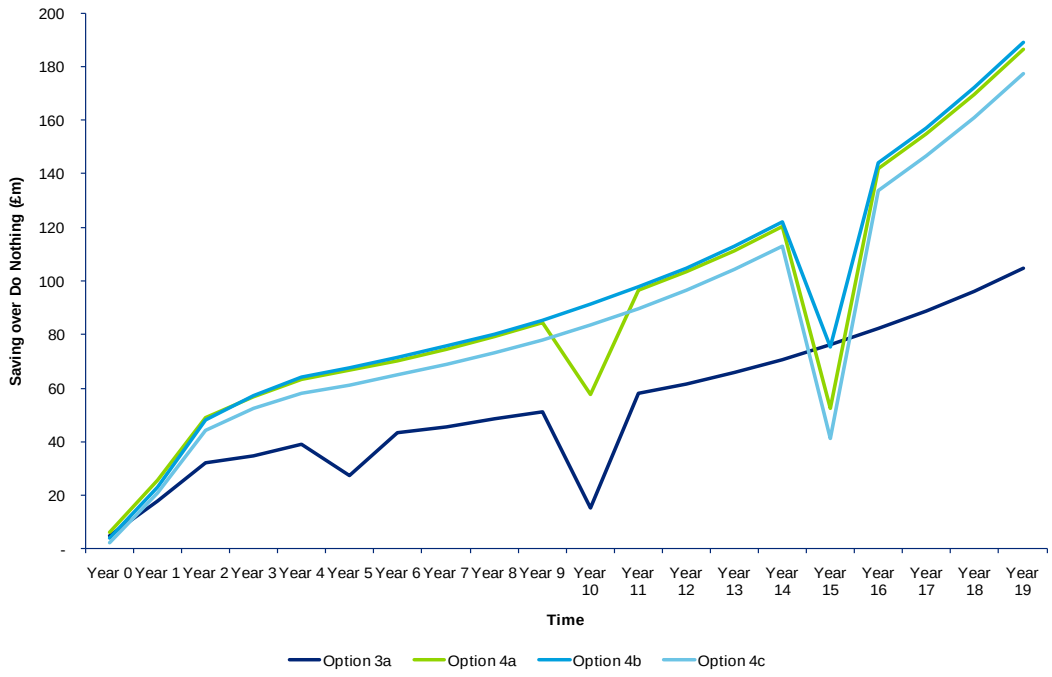
1.6.2 The short list of options and the preferred option

Further stakeholder engagement and scoring against the Critical Success Factors (CSFs)[2] resulted in a number of options being short listed to undergo the full economic analysis.

[DN: provide an overview of the short listed options, describing each and highlighting the strengths and weaknesses of each option, concluding by presenting the preferred option and the reasoning for the choice.

Consider including a graphical or table summary of the key features of the different options for quick comparison, see sample figure 1 below]

Sample figure 1: Sample savings over 'do nothing' (£m) of each short-listed option



[2] Critical success factors are elements that are vital for a strategy to be successful. These would depend on the specific circumstances of the project and the commissioner's healthcare region. Examples may include effective stakeholder management or the generation of interest in the wider pathology providers' market beyond the existing providers in the region.

1.7 Commercial case

1.7.1 How to structure the implementation of the preferred service provision

[DN: set out the approach to conduct a successful local negotiation, tendering or system-wide reconfiguration aimed at changing the provision of pathology services in the commissioners' healthcare region to deliver the benefits detailed in the strategic, clinical and financial cases. Provide an overview of how the process is expected to take place and the level of management the commissioner requires to achieve complete transition. Include consideration of how public sector and independent sector involvement could deliver benefits]

1.7.2 Charging mechanism

[DN: outline the principles of the planned charging mechanism, for example based on test volumes against a tariff card. If a level of price regulation is desired, identify the reasons for such price regulation and how it may be achieved]

1.7.3 Basis of contracting

[DN: The commitment of each of the GP commissioners involved needs to be proportionate to their individual responsibilities. It is expected that these commitments will be structured to be legally binding where appropriate, reflective of the significant and disparate distribution of costs between different entities.

Several examples of issues of where commitment from GP commissioners may be required are listed below:

- How the development cost of the programme will be split between involved parties;
- How to guarantee the transfer of activity from the involved parties, including providers where relevant, to the chosen service provider for a set period (eg circa 5 years), subject to acceptable pricing and service standards; and
- How the transitional costs and termination costs of the programme will be attributed between involved parties.]

1.7.4 Basis of collaborating

[DN: identify whether a formal commitment to collaboration is required in the shape of a contractual or corporate joint venture to support the transformation of the provision of pathology services in the commissioners' healthcare region.

Where tendering and/or reconfiguration of pathology services in the commissioners' healthcare region is planned as part of the project, a level of collaboration between provider and commissioner may be required. This may involve groups of providers and commissioners coming together to optimise benefits. This collaboration could be informal in the form of joint planning and coordination of implementation plans or formal in the form of a legal contract.

The preferred model will primarily depend on whether shared management responsibility for the operation of the new pathology contract is assessed as being more effective and will secure greater commitment than having a single entity responsible for management.

In all of the decisions, an appropriate balance needs to be struck between deliverability and the potential for achieving greater benefits through a more complex model. The estimated consequences of the 'do nothing' scenario provide a strong incentive to ensure that a deliverable structure for the preferred option is committed to by all parties.]

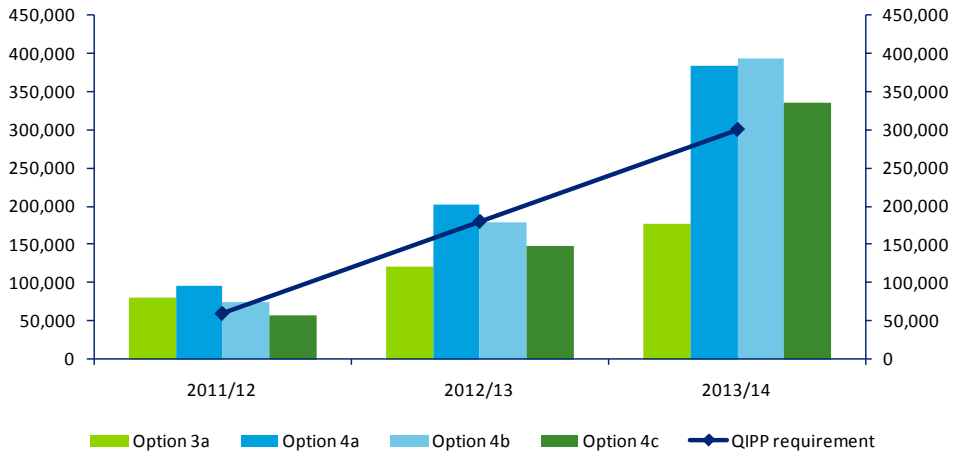
1.8 Financial case

[DN: ensure the text includes reference to the following elements out of the financial case:

- Affordability analysis;
- savings estimates for the preferred option;
- link to QIPP; and
- Assumptions.

Include graphical representation of savings, see sample below:]

Sample figure 2: Sample savings against QIPP - £100,000s



1.9 Management case

[DN: identify the different phases of the planned project taking account of the complexities of tendering and system wide change where relevant. Examples of phases could include the completion of the OBC, the procurement of services and the on-going management of future pathology services. For each phase identify the appropriate management approach including a description of relevant aspects of the chosen approach, such as stakeholders, the change process and governance]

1.10 Summary

[Insert text]

1.11 Next steps

[DN: detail next steps relating to the different phases of the planned project that are included in the management case. These steps should also include a reference to the quality assurance process, for example an internal review process or the use of an independent party. In addition describe how commissioners will be asked to confirm their approval to

progress the project and to demonstrate their support to the proposed changes to the provision of pathology services]

Section: 2 Strategic case

2.1 Introduction

[DN: outline the main reasons for change, linking the project to the local, regional and national recommendations described in QIPP and the Independent Review]

2.2 Overview

[DN: Provide a compelling overview of the strategic case]

2.3 The case for change

[DN: include motives for change, for example motives for improving the current service in terms of quality or cost. In addition, where relevant, include the reasons for considering the transformation of the provision of pathology services, for example to a model which is in line with the future shape of pathology services in England as outlined in the Independent Review. The motives taken into consideration should include both clinical and non-clinical elements]

2.4 Investment objectives: opportunities for pathology services

[DN: sample text below]

The Independent Review identified several opportunities to improve quality, increase efficiency and release considerable savings within the existing pathology services. Reviews and data collected within [insert the commissioners' healthcare regions] provided further evidence to support these conclusions. The areas where most benefit could be gained included [delete, add or amend as necessary]:

- Reducing cost variations;
- Avoiding waste from test duplication;
- Avoiding waste through inappropriate testing;
- Avoiding unnecessary capital investment;
- Improving quality;
- Procurement savings;
- Procuring community pathology services; and
- Redesigning services.

Any potential future service tender and/or reconfiguration option within [insert the commissioners' healthcare regions] should be able to capitalise from these opportunities.

2.5 Stakeholders

[DN: the term stakeholders covers all those who will be accountable, responsible, consulted or informed of the commissioning project. Discuss both the stakeholders who have been involved to-date and those which will be engaged in the commissioning process. These should include commissioners, clinicians and non-clinicians. A sample list for consideration is included below:]

Key professional stakeholders include:

- Commissioners including PCTs and practice based commissioning (PBC) groups;
- Pathology services providers, including all Trusts within the region;
- GP consortia;
- Requesting clinicians;
- Professional groups, including doctors and scientists;
- Pathology service and laboratory managers;
- Royal College of Pathologists and other academic bodies;
- Pathology staff groups and trade unions;
- Department of Health including the national pathology team; and
- NHS Trusts and other healthcare related organisations

Key external stakeholders include:

- Patients and the public;
- Pathology equipment suppliers;
- Local authorities, Health Overview and Scrutiny Committees;
- Opinion and community leaders, MPs, councillors; and
- Media.

Additional detail regarding stakeholder engagement is available in the management case below.

2.6 Project scope, risks, constraints and dependencies

[DN: consider the scope, risks, constraints and dependencies at strategic level. It is advisable to provide a reference to a more detailed register as an annex.]

2.7 Aims of the project

[DN: Develop the aims of the project which may be from a tender through to a wider system change]

The main aim of the Project is to ensure consistent, high quality and efficient pathology provision across [insert the commissioners' healthcare regions] to support improved health outcomes.

To meet this aim there are three key objectives for the Project. These are to:

- implement the quality recommendations of the Carter Report[3] within [insert the commissioners' healthcare regions]
- meet the pathology service needs of users, patients and commissioners; and

[3] Report of the Review of NHS Pathology Services in England' and 'Report of the Second Phase of the Review of NHS Pathology Services in England'

- gain the efficiency savings required to meet the recommendation of the Carter Report and the QIPP programme.

These have formed the basis of the critical success factors [add reference to the relevant section] that have been developed to appraise the long list of options in the economic case.

2.8 Conclusion

[Insert text]

Section: 3 Clinical case

3.1 Introduction

[DN: Outline the main elements of the clinical case for change. Sample text below]

3.2 Quality (standards, accreditation and audit)

The Independent Review recognised that quality measures were limited to the analytical process, and did not reflect the quality of the end-to-end service.

It was recommended that more suitable quality standards be developed and incorporated into a revised Accreditation Standard. All NHS pathology service providers should be required to be fully accredited, and to participate in audit processes, including point of contact testing (POCT).

[DN: Outline the quality of existing service providers in terms of the their accreditation, quality outcomes and service outcome]

Communication (IT connectivity)

The Independent Review found that limited IT connectivity contributed to wasteful duplicate testing and would inevitably contribute to the risk of errors by clinicians not having immediate access to relevant diagnostic information.

The review recommended that IT links should be developed as a matter of priority.

User responsiveness and information transparency

The Independent Review recommended that pathology services should be more responsive to the requirements of patients, especially with respect to phlebotomy and sample collection.

Consolidation (specialist services, networks and network management)

The Independent Review re-iterated that managed pathology networks offered the optimum model for service delivery.

It recommended that each acute hospital site should have a rapid response laboratory to meet the need for acute services such as emergency care, critical care, and maternity care. The remaining tests were described as ‘cold’ work and defined as tests that have a turnaround time greater than four hours. It suggested that this work should be centralised into a large sites providing services for several acute hospitals.

Workforce reform

The Independent Review recognised a requirement to reform the pathology workforce to meet the challenges arising from new methods of working and to manage the impending shortfall in skills and experience inherent in the demographic of the current staffing of the service.

[DN: Outline any workforce challenges with the local pathology service providers e.g. scientific and clinical skills shortages, vulnerable services such as those relying on single consultants and any potential optimisation of existing workforce]

Commissioning guidance (model contract and formulary)

The Independent Review recognised that commissioners would benefit greatly from clear commissioning guidance including a specification for pathology services for commissioners. It also recommended the development of a test formulary defining the utility and applicability of each pathology test.

Innovation

The Independent Review stated that innovation was a key factor for developing responsive high quality pathology services and recommended that the DH should seek ways to facilitate the adoption of innovation across the service.

The overall conclusion of the Independent Review suggested that transforming pathology services into managed networks offered maximum flexibility, operational and financial efficiency through significant economies of scale and improvements in quality.

3.3 The role of pathology in healthcare

[DN: discuss the role of pathology in the provision of the commissioners' healthcare services. A sample can be found in the KMPN OBC p.23-26]

3.4 The present state of pathology services

3.4.1 Completed reviews of pathology services (regional and/or local as appropriate)

[DN: include reference to previous reviews of pathology in the commissioners' healthcare regions and the relevance of their findings to this OBC. This reference will serve as context to the OBC as well as providing the full timeline for the tendering and/or transformation of pathology services in the commissioner's region]

3.4.2 Service configuration, including tests volumes breakdown

[DN: provide an overview of the current service provision configuration, covering both geographical location and the volume of tests in the different disciplines. Detail could also include the differing characteristics (e.g. urban vs. rural) of the population included in the commissioners' healthcare regions. Provide reference to a more detailed breakdown of tests if available (as an annex)]

Sample table 1: Sample breakdown of tests performed by discipline [DN: the split between total volume and GP Proportion may not be necessary pending on whether provider trusts are taking part in the tender]

Discipline	Total Volume	GP Proportion
Biochemistry		
Haematology		

Microbiology		
Immunology		
Cellular		
Cytology		
Genetics		
Other (add as required)		

3.4.3 End to end process

[DN: using evidence, underline any issues within the commissioners' healthcare regions relating to the full end-to-end pathology intervention process. These should go beyond the activity taking place in the laboratory and more specifically this should include reference to pre- and post-analytical services, support with uptake of point of care testing, measure to help with effective demand management and the ability to share patient results with all clinicians involved in their care]

3.4.4 Network and governance

[DN: identify the current governance arrangements, including clinical governance, within the local pathology provider or network, demonstrating clear lines of accountability.

Includes identifying potential opportunities such as improving demand management and capacity planning, as well as collaborative procurement]

3.4.5 Customer focus

[DN: customers of pathology services include patients, GPs and acute trusts. Identify, using evidence, the current level of the attention given to customer needs by the pathology service in its planning and development processes. Consider the potential for improvement during local negotiation or the tendering process]

3.4.6 Infrastructure and workforce

[DN: review the current state of both infrastructure (e.g. accommodation, IT, analysers) and the workforce (e.g. recruitment, retention, skills mix). Identify existing challenges that would be addressed through the re-commissioning process]

Section: 4 Economic case

4.1 Introduction

[DN: The economic case must also consider the wider impact of change on a system. For instance, what is the impact of removing Direct Access Services from a Trust and procuring these through another organisation. What residual costs remain and can be mitigated, how might these impact on the stability of the Trust, are benefits derived in the case subsequently creating opposite cost impacts elsewhere in the system, these should be considered within the economic case.]

[DN: see sample text below:]

The Economic Case assesses the priorities for improved service quality and the means for achieving them, documents the range of options for the tendering and/or reconfiguration of pathology services that have been identified, and explains how these options were assessed. It then explains how each of the short-listed options has been appraised, in terms of costs, benefits and risks. This appraisal has been conducted by reference to the requirements of HM Treasury's Green Book (a Guide to Investment Appraisal in the Public Sector).

The key steps within the business case are outlined in Figure 3. Broadly these steps can be grouped into:

- Defining and refining a short list of potential reconfiguration options.
- Quantifying relevant costs and benefits, and identifying non-quantifiable benefits.
- Further appraising the options based on risks and sensitivity analysis to reach the preferred option.

Sample figure 3: Sample economic case framework

[DN: additional optional text:] Whist no decision will have been taken on tendered services at the point of drafting the OBC, the commissioner should set out the cost and benefit estimates. These should be identified by option, and relevant assumptions on accuracy, and risks should be clearly documented. Such estimates will be further refined as the design of the tendered pathology services is finalised. Eg Estates assumptions may be difficult to assess and quantify until an option is tendered.

4.1.1 Stakeholder economic impact?

[DN: the economic benefits and requirements for investment that will be seen for each stakeholder group must be documented. For a sample see KMPN OBC p.38]

4.2 Critical Success Factors (CSFs)

[DN: identify the CSFs [4] that will be used to assess the long list of options in order to develop a short list of options for further assessment in the economic case.] The CSFs will have

[4] **Critical success factors are those few things that must go well to ensure success of the tender or the system change**

emerged from the review of pathology services, supported and informed by local evidence, stakeholders and in reference to the strategic guidance available from national and regional sources. The CSFs will depend also on the scope of the necessary changes identified by Commissioners and may cover a range of issues such a clinical quality factors, investment factors, governance arrangements and access requirements as well as maintaining services during potentially significant changes.

Category	CSF	Notes
Quality	Improve patient access	Improved access to phlebotomy or results
	Improved access to sub-specialised histopathology for cancer services	
Innovation	Enable improved pathways for long term conditions	Reduced consultations and improved outcomes for patients with established LTCs
Productivity	Providers have incentives to consolidate capacity to improve productive efficiency	
	Secure flexibility of pathology provision in support of wider reconfiguration plans	
	Improve contestability in the value chain providing pathology services to the population	A single lead provider may in practice support an ecosystem of suppliers and subcontractors which goes a long way to mitigate the risk of creating a complacent and inefficient local monopoly.
Prevention	Better alignment to NICE guidelines on use of diagnostics and screening	

4.3 The long-listed options

4.3.1 Description of the long list of options

[DN: describe the long list of possible options for the delivery of pathology services in a manner that will deliver the outcomes identified in the strategic and clinical cases. The options should also include the 'do nothing' option for benchmarking purposes. For a sample of options relating to pathology provision re-configuration see TPS OBC p.29]

4.3.2 Key dimensions of choice

[DN: identify the major characteristics of the options on the long list. See sample text below:]

The long list of options was generated based on the following key dimensions of choice for the end-state configuration of pathology services

- Collaboration: work with existing providers, for example to agree a new configuration and performance targets for pathology, based on mutual commitments regarding procurement and supply
- Competition: the extent to which services are market tested through procurement activity
- Scale: the scale at which any procurement or review takes place: whether regional or local
- Scope: whether procurement or other commissioning activity targets all pathology services or only certain disciplines, settings, or clinical contexts
- Commercial relationships and business models: whether to maintain direct relationships with laboratories or to transfer risk, for instance by contracting with a broker who secures best value pathology and interpretive services from a wide range of suppliers
- Performance management and incentives: choices about how suppliers are incentivised to deliver quality, what the metrics are, and the balance between fixed price and incentivised contractual arrangements

4.3.3 Assessment of long-listed options

[DN: using the CSF identified above, evaluate the long list of potential options to support the identification of the option demonstrating the greatest overall ability to achieve the objectives and outcomes desired. The evaluation should involve multiple stakeholders to increase buy-in to the outcomes. The evaluation could also involve assigning different weightings to individual CSFs to better represent the commissioner's priorities. The outcome should be analysed to inform the OBC of the reasoning behind the choice of the short-listed options. In addition to the text, a table should be created to provide an overview of the evaluation, see sample in the TPS OBC p.33]

4.4 Economic appraisal of short-listed options

[DN: provide an assessment of the costs and benefits associated with each of the short-listed options]

4.4.1 Identifying benefits

[DN: provide further detail regarding the benefits identified in section 4.1.1 in the context of the reasons for change listed in section 2.3 and create a matrix or 'map' of benefits to ensure all benefits are captured and quantified. This approach will help avoid duplication in the calculation of expected savings for each short-listed option. Samples of the table or 'map' can be found below and in the TPS OBC p.35-38]

Sample table 4: Sample summary benefits identification

Stakeholder	Behaviour (existing issue)	Lever (system change)	Output (improved system results)	Outcome (measures for quantifying benefits)
Patients				
Commissioners				
Requesting clinicians				
Acute trusts (providers)				
All trusts that use pathology				
Pathology services staff				

4.4.2 Quantifying benefits

[DN: describe the method used to quantify the benefits identified in section 4.4.1 in relation to each of the short-listed options to identify the preferred option in the conclusion of the economic case. See sample introductory text below and a detailed sample in TPS OBC p.38-48:]

The benefits of the retendering should result in positive changes to the key final outputs, for example: health outcomes, patient experience and value for money. Through the benefits table or 'map' in section 4.4.1, any impacts on the system can ultimately be traced through from a reconfiguration change to one of these final outputs. Therefore, focussing on ultimate outputs prevents double counting of benefits.

Sample table 5 below summarises our approach to estimating the final benefits. These have been divided into quantifiable and non-quantifiable benefits. However, it is challenging to define the precise impact on these metrics resulting from the pathology reconfiguration, particularly for patient and health outcome metrics. Sample table 4 (the benefits summary) illustrates that there is a great deal of interdependency and complexity in the chain between each change to the system and the resulting outcome. As the OBC is still being finalised there is insufficient detail to make robust assumptions about the magnitude of impact on the three outcomes listed in sample table 5. The exact configuration of new/changed services will emerge as the tendering progresses.

The task of estimating benefits was approached as follows:

- [DN: Note approaches used]

Sample table 5 below summarises the metrics which were selected to estimate the final outcome benefits. Benefits have been divided into quantifiable and non-quantifiable

benefits. For quantifiable benefits, the table shows the metrics that have been selected to capture each final outcome. There are many possible metrics available to measure the three final outcomes. We have selected a limited number on the basis of available data (academic studies and stakeholder discussions) and the extent to which the metrics capture changes attributed to the reconfigured system.

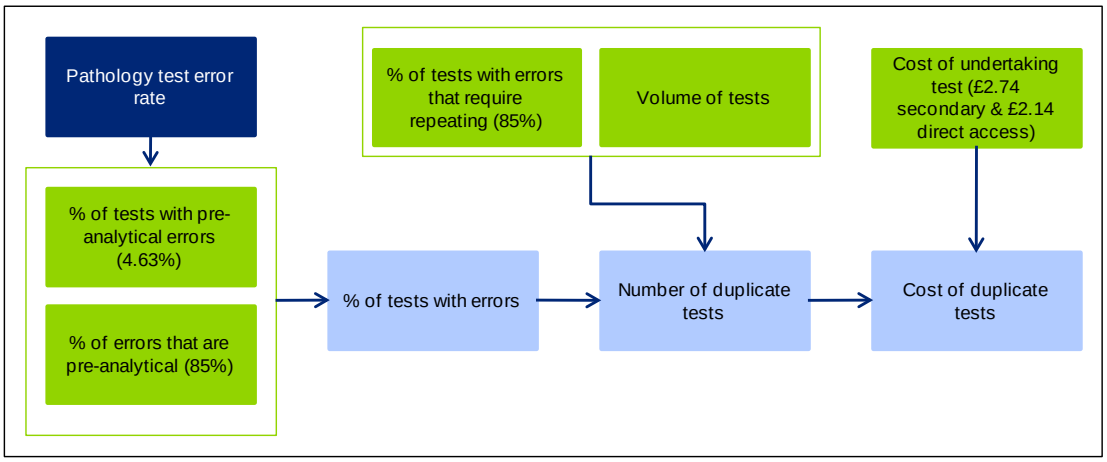
Sample table 5: Sample estimation of final outcome benefits

Benefit	Accruing to	Selected metrics to quantify
Quantifiable		
Improved health outcomes	Wider healthcare system/ patients	Reduction in preventable adverse inpatient events Reduction in preventable community/outpatient adverse drug events leading to hospital admission Reduction in likelihood of adverse public health episode Reduction in litigation costs from clinical negligence claims Improved management of long term conditions leading to reduced complications and death
Improved value for money	Commissioner/ Provider of pathology	Cost savings due to reconfiguration (expanded upon in the cost section of this OBC)
	Commissioner of all services	Cost savings across commissioning budgets arising from greater flexibility in choice of provider for pathways which are dependent on pathology services
	Provider of primary and secondary healthcare	Enhanced access to pathology reduces the number of appointments needed and improves the clinical effectiveness of appointments, by ensuring that the maximum clinical information is available
Non-quantifiable		
Patient experience	Wider healthcare system/ patients	Patient satisfaction surveys Access to care

Note: while there are a large number of qualitative metrics available, we have not attempted to capture all of these in this section.

[DN: provide a high level description of the method and assumptions used to estimate financial savings for each of the selected metrics as an appendix, see sample diagram below. Provide reference to the more detailed breakdown included in section 5 – the Financial Case. See sample in TPS OBC p.40-48:]

Sample figure 4: Sample estimation of benefits resulting from decreased test duplication



[DN: sample text informing the method of the analysis:] using the methodology outlined above, the following benefits have been quantified for each short-listed option. This is shown in sample table 6 below. The table also shows the specific assumptions relating to each option and outlines who the benefits would accrue to within the healthcare organisation. The reasonableness of these assumptions has been discussed with, and validated by, a range of [insert the commissioners' healthcare region] stakeholders. Annual benefits have been summed and discounted to give a Net Present Value ("NPV") in accordance with HMT Green Book principles over the 20 years of the reconfiguration. We used a discount assumption of [#]%.

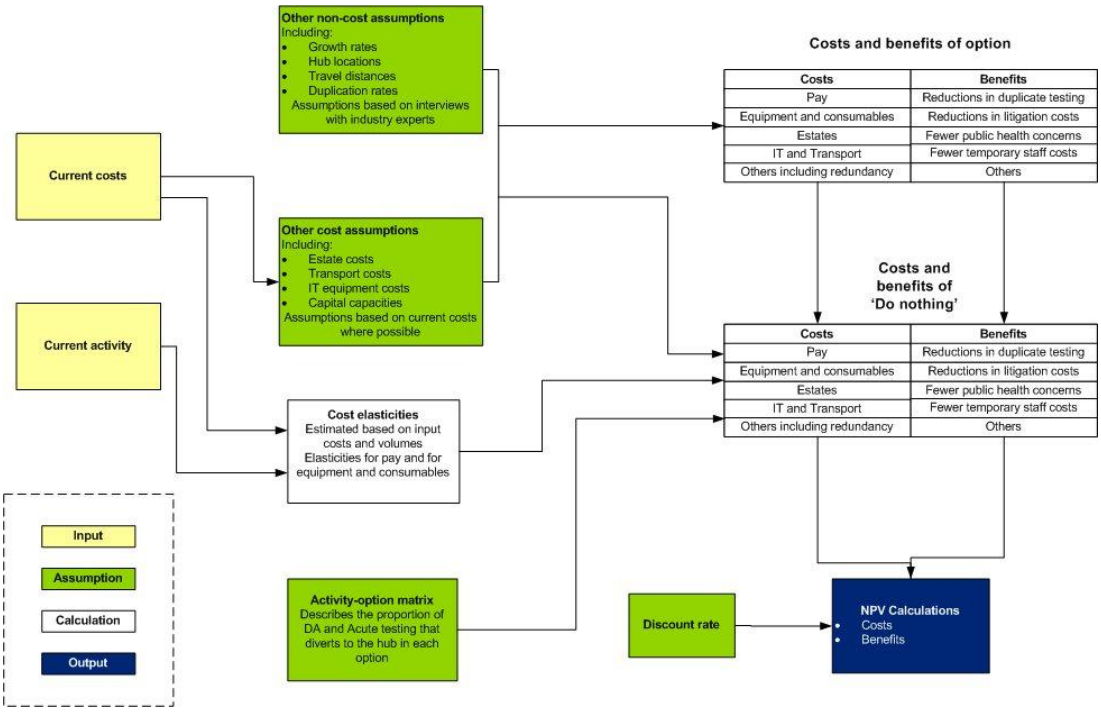
Sample table 6: Sample quantification of benefits (£'000)

	Option 1	Option 2	Option 3	Option 4
Benefit 1 – Reduction in preventable adverse inpatient events				
Assumption	[#]% of tests negatively impact patients	[#]% of tests negatively impact patients	[#]% of tests negatively impact patients	[#]% of tests negatively impact patients
Accruing to	Secondary care			
Net Present value (£'000)				
Net Present value (£'000)				

4.4.3 Estimating costs

[DN: provide an explanation of the economic model used to categorise and quantify costs. Also consider the benefits of avoided risk, such as risks discussed in the DH commissioning guidance. See sample in TPS OBC p.48-50:]

Sample figure 5: Sample economic model architecture



4.4.4 Net present cost findings

[DN: provide a Net Present Value ("NPV") model or appropriate analysis in accordance with HMT Green Book principles. See sample text below]

The following tables summarise the key results of the economic appraisal of each option. Costs and benefits for each year of the period between 2010/11 and 2029/30 have been estimated and expressed in real terms; that is, in 2010 pounds. Annual costs and benefits have then been summed and discounted to give a Net Present Value ("NPV") in accordance with HMT Green Book principles. We used a discount assumption of [#]%.

Sample table 7 shows total costs and quantified benefits. In both tables, the costs and benefits for each option are shown as a difference from the Do Nothing option.

Sample table 7: Sample Key results of economic appraisal (from a commissioner perspective)

Net Present Value (£'000)	Option 1	Option 2	Option 3	Option 4
Direct commissioning costs				
Project and transition costs				
IT				
Decommissioning costs				
Pathway integration				
Overheads				
Total costs				
Total savings against Do				

nothing				

Sample table 7a: Sample Key results of economic appraisal **(including a wider appraisal covering pathology providers. To be used where appropriate to the scope of the OBC)**

Net Present Value (£'000)	Option 1	Option 2	Option 3	Option 4
Pay				
Consumables and equipment				
IT				
Transport				
Estate costs				
Overheads				
Redundancy				
Staff travel costs				
Total costs				
Total savings against Do nothing				

[DN: analyse the data that forms the basis of tables 7 and 7a to highlight the implications of different NPVs or similar outcomes on the choice of the preferred option. Several sample graphs can be found in the TPS OBC p.52 - 53]

4.4.5 Options ranking

[DN: based on the quantitative economic costs and benefit analysis present the ranking of the short-listed options. A sample table is provided below]

Sample table 8: Sample option ranking

	Option 1	Option 2	Option 3	Option 4
Total cost savings against Do nothing (£'000)				
Total benefits savings (£'000)				
Rank				

4.4.6 Qualitative benefits appraisal

[DN: to complement the quantitative analysis of benefits undertaken in section 4.4.2, it is necessary to score the qualitative benefits identified in section 4.4.1 for each of the short-

listed options. A sample table for qualitative benefits scoring can be found in the TPS OBC p.55]

[DN: explain the mechanism by which numerical scoring was allocated for each benefit criteria. Whilst scoring of financially driven benefits is clear, non-financial benefits are more subjective and clear criteria are needed. A sample table for ranking qualitative benefits scoring is provided below:]

Sample table 9: Sample option ranking against qualitative benefits

Option	Total score	Rank
Option 1		
Option 2		
Option 3		
Option 4		

[DN: analyse the ranking information in sample table 9 and highlight the implications on the choice of the preferred option]

4.4.7 Risk appraisal – unquantifiable

[DN: describe the risk appraisal process used. Provide a summary of the risks that could impact the estimates of the costs and benefits in the OBC. These should include risks which are specific to the commissioners' healthcare region. A sample table is provided below with two samples of likely risks:]

Sample table 10: Sample key business and service risks affecting costs and benefits.

Risk	Risk description and impact	Possible mitigations
Higher than expected costs	• Transportation costs rise substantially with increase in fuel prices and staff mileage allowances • Issues around associated carbon footprint may adversely affect project • IT implementation costs too high to create standard IT platform for users and providers across the system to order tests and access results • Cost of reagents and testing equipment materially increases • Procurement savings and operational efficiencies are not realised • QIPP savings are not met, and long-term cost rise	• Ensure that contracts with the logistics providers have incentives to reduce fuel costs by minimising route distance and other cost over-runs. • Carbon footprint to be given due consideration during service reconfiguration (using full logistics analysis) • Ensure minimum standard for IT requirements set out with providers undertaking competitive tendering of IT services • Providers undertake competitive tendering with providers of reagents and testing equipment • Close management of baseline costs and costs each year are monitored against QIPP
Lack of adequate information to measure and challenge providers	• Without clearly defined metrics, written into contracts and agreed with providers, commissioners will be unable to monitor performance and challenge inefficiencies or quality disparities between providers • Commissioners may not have sufficient data analysis skills to evaluate and make use of indicators	• Rigid, enforceable quality and efficiency metrics , written into the contracts • Agreement of metrics with providers to avoid disputes relating to apparent poor performance • Development of commissioners data analysis capacity

[DN: identify the relevance of individual risks to each of the short-listed options. See sample table below:]

Sample table 11: Sample summary of the risk appraisal results

	Option 1	Option 2	Option 3	Option 4
Key: High risk ○ Low risk ●				
Higher than expected provider costs	◔	◑	◕	◕
Lack of adequate information to measure and challenge providers	◔	◑	◑	◑

[DN: explain the mechanism by which numerical scoring was allocated for each risk. A sample table for ranking risk appraisal results is provided below:]

Sample table 12: Sample risk appraisal results

	Option 1	Option 2	Option 3	Option 4
Score				
Rank (low to highest risk)				

4.5 The preferred option

[DN: summarise the quantifiable and non-quantifiable benefits and risks scoring for the different options in section 4.4 to a justified recommendation of a preferred option. A sample table is provided below:]

Sample table 13: Sample summary of overall results

	Option 1	Option 2	Option 3	Option 4
Economic appraisals (net cost, net benefits, NPV)				
Qualitative Benefits appraisal				
Risk appraisal				
Overall ranking				

4.6 Sensitivity analysis

[DN: produce a sensitivity analysis to determine the potential impact of both costs and the volume of activity on the savings each option will deliver due to increased economies of scale. See sample in the TPS OBC p.62-64]

Section: 5 Commercial case

5.1 Introduction

[DN: see sample text below. Note that the text is more relevant to a system-wide change and will have to be adapted for a local negotiation scenario:]

The commercial case sets out the principles behind the anticipated contracts and structures that will be used to implement the preferred service model, as identified in the economic case. Commercial considerations increase considerably as commissioners move from tendering services to a more encompassing system change. The preferred delivery structure is determined based on a combined assessment of efficiency and deliverability. The structure needs to achieve the following:

- Support the changes required to transition to the preferred service model;
- Deliver long term viability and efficiency of that model through the analysis period and thereafter;
- Allocate risks and rewards on an efficient and equitable basis; and
- Secure the requisite level of commitment from stakeholders.

The preferred structure has been identified by considering each of these requirements.

5.2 Scope of the required services

[DN: briefly summarise the scope of the pathology service in the preferred option, including a reference to the full service specification in section 5.14. Include a list of known commercial development targets (including stretch targets) based on the objectives identified in the strategic and clinical cases.]

5.3 Commercial implications of the preferred option

[DN: provide a detailed review of the commercial implications of the preferred option. Below is a list of headings which could be used when the preferred option involves a reconfiguration of the existing provision of pathology in the commissioners' healthcare region. See sample in the TPS OBC p.71-74. The list will have to be partially amended for projects that are pursuing a local negotiation instead of a system-wide change:]

5.3.1 Option [#]: [insert option's title/description]

5.3.2 Contract Management (including management of disputes and change control)

[Insert text]

5.3.3 Reporting

[Insert text]

5.3.4 Continuous Improvement

[Insert text]

5.3.5 Human Resources (including TUPE)

[Insert text]

5.3.6 Facilities

[Insert text]

5.3.7 Equipment (eg Analysers and associated technology)

[Insert text]

5.3.8 Information technology (eg Pathology LIMS)

[Insert text]

5.3.9 Logistics (eg Collections or samples)

[Insert text]

5.3.10 Further investment requirements

[Insert text]

5.3.11 Summary requirements of the preferred option

[Insert text]

5.4 The need for formal commitment to the collaborative model

[DN: this is an optional section, to be used where a formal structure for collaboration is deemed necessary in order to successfully deliver the preferred option. Provide information regarding the requirement for collaboration (such as delivering economies of scale and improving the quality of pathology services) and the levers that could be used to ensure commitment from the different stakeholder who are critical for the project's success. See sample introductory text below:]

The requirements of the NHS in general, and of the QIPP programme in particular, are that efficiencies be sustainable with scope to progressively achieve greater efficiency and contribution to healthcare benefits over time. The requirements of the pathology service are also likely to change over time as new testing becomes available and the technologies and working practices to deliver them develop.

The international comparison of diagnostic services in the second Independent Review shows the relatively low level of spend per capita on diagnostics in the UK. If the cost of healthcare is to be contained, then earlier diagnosis will be a key enabler, and the demands on the pathology service would increase considerably.

The structuring of the service across [insert the commissioners' healthcare region] needs to be designed to support sustainability and an ability to respond to change with the expectation of growth at rates higher than other services.

5.4.1 Commitment from stakeholders

[DN: identify the rational for obtaining commitment to the collaborative process from different stakeholder groups and the benefit this commitment will release. One example could be the need to guarantee commitment from users of pathology services within the commissioners' healthcare region to use central facilities prior to their construction to ensure economies of scale are delivered without creating excess capacity in the commissioner's region]

5.5 Governance arrangements

[DN: while the full description of governance is included in the management case, the commissioner should explain in the commercial case the importance of an effective governance framework within and between the commissioning organisations to ensure a sustained commitment from all stakeholders and provide an effective decision making mechanism. It is advisable to match the planned governance structure to the different stages of the project, for example differentiating between the governance requirement of the design phase and the implementation phase]

5.6 Promoting long term efficiency and ensuring contestability

[DN: identify the means by which competition and continual improvement to efficiency will be encouraged in a sustainable manner to enable the pathology provision within the commissioners' healthcare region to respond in an effective manner to the likely cost pressures on the NHS in the near future. Where a consolidation of provision across a commissioners' healthcare region is the preferred OBC option, include a consideration of how competition will be maintained. See sample in TPS OBC p.75]

5.7 Proposed charging mechanism

[DN: Produce a charging mechanism for the provision of pathology services that will encourage competition and a continuous drive for efficiency. In a system-wide transformation the charging mechanism will need to achieve the above, while guaranteeing the stability of providers over the relatively long period that will be necessary to pay for the investment in new capacity and capability during the transition period and beyond. While the charging mechanism itself can become quite complex it is important to remember the overall goal is to keep it as simple as possible]

5.7.1 Commercial mechanisms – high level principles

[DN: Define the high-level principles guiding the development of the charging mechanism, for example the creation of a standard pathology tariff across the commissioners' healthcare region. Note that these would depend on the level of collaboration between providers required by the project, where increased collaboration requires more protection of providers during the transition period to guarantee commitment to the process. See sample in the TPS OBC p.76]

5.7.2 Sharing of transition costs

[DN: Identify the transitional and transformational costs that will need to be shared across the collaboration and captured within the tariff. These could include the cost of new equipment and/or facilities, as well as the cost of shifting HR resources between organisations]

5.7.3 Sharing of 'profits' and the approach to trading

[DN: Identify the principles that will guide the sharing of savings across the commissioners' healthcare region to ensure financial benefits (savings and income) to both requesters and providers of pathology services in a manner promoting long term sustainability]

5.7.4 Optimising activity

[DN: Where a reconfiguration of the local NHS providers is required, highlight the ways in which users will be encouraged or required to send their activity to the consolidated facilities. In addition highlight the processes that may be put in place to manage demand]

5.8 Procurement strategy [DN: see Step 7 in the Pathology Services Commissioning Guidance for further information]

5.8.1 Procurement process – is a full OJEU process necessary?

[DN: Pathology services (as well as health and social services more generally) are currently classified as "Part B" services under the Regulations and are subject to a "lighter touch" regime than would be the case if they were fully-regulated (Part A) services, but this may be subject to change in the future]]

5.8.2 Engaging with the market

[DN: describe the planned approach to market that the procurement process should take to generate interest from a large enough range of providers to drive maximum competition and encourage innovative solutions. This approach should be tailored to scale (eg region, population) and context (commissioning vs. transformation) of the project. The information provided in this section should include a high level overview of the market's capacity and capability to support the requirements detailed in the specification. The information included in this section should provide sufficient details to illustrate that the market-related risks are manageable]

5.8.3 Policy on procurement

[DN: Commissioners should seek contact with the CCP and Monitor at an early stage of producing the OBC to identify where particular emphasis is needed from their respective views, and the level of visibility they would want. Include commentary on current procurement policy at the national and regional level. Examples could include DH "Procurement Guide for Commissioners of NHS Funded Services" and the CCP published Principles and Rules of Cooperation and Competition ("PRCC")]

5.9 Risk allocation and transfer

[DN: Provide guidelines and examples on the proposed approach to the management of risk, focusing on the extent to which risk will be transferred to providers. Information should include strategies for avoidance and mitigation of risks. One example of a risk could be the creation of excess capacity in the region. In this case an avoidance strategy might be the creation of modular facilities which allow for the fluctuation of capacity or seeking additional users outside the commissioner's healthcare region.

Note that it would not be appropriate to provide negotiation positions or specifics on individual providers at this stage, in the OBC. These could be detailed out in a separate negotiation planning document]

5.10 Proposed key contractual terms [DN: see Step 10 in the Pathology Services Commissioning Guidance for further information]

[DN: List the key contractual terms that are likely to be put in place as part of the procurement process. These could include service level agreements, governance and the tariff. See sample in TPS OBC p.78 for a wider list]

5.11 Creating a robust collaboration

[DN: Where collaboration between users and/or providers of pathology services is required to deliver the benefits outlined in the OBC, this section provides the commissioner with an opportunity to identify the mechanism to ensure such collaboration is efficient and effective. These could vary from governance and aspects of the charging mechanism to a legally binding contract on collaborating parties.

Where a contract is required identify the proposed length of the contract and the shape the relationship could take, for example a joint venture. The explanation of the different contractual models should include a review of their suitability to the characteristics of the commissioner's healthcare region. Consideration should also be given to the level of involvement in the provision of pathology services in the commissioner's region required from the independent sector]

5.12 Service specifications [DN: see Step 5 in the Pathology Services Commissioning Guidance for further information]

[DN: Include the pathology service specifications either as text in this section or as a reference to the relevant appendix]

5.13 Conclusions

[Insert text]

Section: 6 Finance case

6.1 Introduction

[Insert text]

6.2 Impact on the [insert the commissioners' healthcare region] income & expenditure (I&E) account

[DN: produce an analysis of the impact on the I&E account for the commissioners' healthcare region of implementing the short-listed options as required. Also include an analysis of the 'do nothing' option for benchmarking. The analysis should cover the affordability of the project in the context of the region's current budget and relevant savings targets, for example QIPP. The analysis should also include the savings potential against the current cost and the 'do nothing' option. See sample below and in the TPS OBC p.65-68]

Sample table 13: Do Nothing: Consolidated Statement of Comprehensive Income [DN: the sample table is modelled for a system-wide reconfiguration. If a local negotiation or tender is the preferred option, the row headings in the table will require updating]

Year ended 31 March	2010/11 £	2011/12 £	2012/13 £	2013/14 £	2014/15 £
Operating income					
Operating expenses					
Pay Costs					
Equipment and Consumables					
Estates Rental					
Overheads					
Transport					
IT					
Redundancy and Recruitment					
Operating surplus/(deficit)					
Depreciation					
Finance expense					
PDC dividends payable					
Surplus/(deficit) for the year					

6.3 Assumptions

[DN: detail the list of assumptions used to predict the financial impact of each of the short-listed options. These assumptions should be consistent with the information contained in the economic case. Assumptions should include but not be limited to, statements regarding inflation, VAT, analysis period, Baseline Year (ie 'Year 0') and likely changes to NHS funding over the life of the analysis period]

6.4 Impact on the balance sheet

[Insert text]

6.5 VAT and Tax treatments

[DN: assess the likely VAT implications, especially if private sector provision is a possible outcome. State whether professional tax advice would be required to ensure a VAT-efficient solution]

6.6 Overall affordability

[DN: state the overall affordability of the preferred option]

Section: 7 Management case

[DN: supporting notes for the completion of the management case beyond the limited information below can be found on http://www.hm-treasury.gov.uk/data_greenbook_business.htm (the Treasury's website on the 5 case model)]

7.1 Evidence of achievability

[DN: Set out the actions that will be required to ensure the successful delivery of the project in accordance with industry best practice. Information should include the identification of projects of a similar scale and level of complexity that have taken place in the UK or elsewhere and list the lessons learnt from those that will be incorporated into the management case to avoid a repeat of past mistakes and avoid known pitfalls.

In doing so, this section should highlight the aspects of the project which should be carefully managed to avoid issues during the remainder of the project. These could be divided by stages, for example design, implementation and operation. See sample in TPS OBC p.87]

7.2 Programme management arrangements

[DN: identify any links to overarching programmes being executed in the commissioners' healthcare region, for example QIPP. If such links exist identify the management links between the project and the overall programme to ensure alignment in goal and vision]

7.3 Project management arrangement

[Insert text]

7.3.1 Reporting structure

[Insert text]

7.3.2 Project roles and responsibilities

[Insert text]

7.3.3 Project plan

[Insert text]

7.3.4 The communication and engagement summary

[Insert text]

7.4 Use of specialist advisors

[Insert text]

7.5 Outline arrangements for change and project management

[Insert text]

7.6 Outline arrangements for benefits realisation

[The success of the benefits case is often very strongly reliant on the ability of the commissioner to manage the contract following successful procurement. This section should outline:

- What steps should be taken by commissioners in ensuring benefits are realised
- How the benefits outlined will be measured and tracked
- What incentives can be put in place, or exist, to achieve successful benefits delivery]

7.7 Quality

[Insert text. See sample text below]

Quality assurance and control are key disciplines of successful projects. For this Project, details of quality assurance control will be included in each group of tasks leading to a completed element of the project or work package. Examples of quality assessment include:

- Peer review
- Internal audit assessment
- Board approval - where appropriate
- OGC Gateway Review

7.7.1 OGC Gateway Review

Good governance of major projects usually includes an independent review of performance at key stages in the progress of the project. This ensures that the project is continuing to plan and is expected to deliver the desired outcomes. It also ensures that each stage has been properly completed before progressing too far with the next stage. It is proposed to use the Office of Government Commerce Gateway Review.

The Office of Government Commerce (OGC) developed an assessment tool[5] (Gateway Review) that whilst designed for new procurement projects in civil Central Government can equally be used in other like organisations eg the NHS where strategic partnering is central to its objectives.

The Gateway Process examines a project at critical stages in its lifecycle to provide assurance that it can progress successfully to the next stage. It is designed to be applied to projects that procure services, construction/property, IT-enabled business change projects and procurements utilising framework contracts. The process provides project teams with advice and guidance from fellow practitioners.

The review is carried out in six phases:

- Gateway Review 0 – Strategic Assessment reviews the Business Strategy and Need

[5] **http://webarchive.nationalarchives.gov.uk/20100503135839/http://www.ogc.gov.uk/what_is_ogc_gateway_review.asp**

- Review 1 – Business Justification reviews the Business Case its options appraisal and affordability
- Review 2 – Procurement Strategy reviews strategy and requirements and updates Business CASE
- Review 3 – Investment decision – evaluate bids and select Provider
- Review 4 – Readiness for service – award and readiness
- Review5 – Benefits realisation – service delivered benefits received.
- Subject to acceptance of the OBC Gateway Reviews 0 and 1 will be undertaken as a joint review immediately

7.8 Risk management strategy

[Insert text. See sample in TPS OBC p.95]

7.9 Contingency plan

[Insert text]

Section: 8 Conclusions and next steps

[Insert text]

Glossary

Abbreviation/word	Meaning
A&E	Accident and Emergency
ADR	Adverse Drug Reaction
The Independent Review	Lord Carter's Independent Review of NHS Pathology Services in England - 2005
CCP	Cooperation and Competition Panel
Cluster Models	A model of configuration of pathology service operations where several form a network of services with shared governance, development and delivery of services.
Cold work	Tests that have a turnaround time greater than four hours
CPA	Clinical Pathology Accreditation
Critical Success Factors	Elements that are necessary for a project to achieve its goal
CSF	Critical Success Factors (see above)
CQC	Care Quality Commission
DH	Department of Health
Direct Access	Pathology test requests made by primary health care services directly to a pathology laboratory.
EoE	East of England
EoE SPT	NHS East of England Strategic Projects Team.
EOI	Expression Of Interest
FBC	Full Business Case
FOIA	means the Freedom of Information Act 2000 and any subordinate legislation made under that Act from time to time together with any guidance and/or codes of practice issued by the Information Commissioner, the Department of Constitutional Affairs, the Office of Government Commerce and the NHS in relation to such legislation or relevant codes of practice to which the DH is subject
FT	Foundation Trust
Greenfield site	A new location for establishment of a building or facility, typically one not previously developed.
HMT	Her Majesty Treasury
HR	Human Resources
'hot' work	tests that have a turnaround time less than four hours
HRG Tariffs	The national tariff or price paid for a particular procedure or treatment

Abbreviation/word	Meaning
HPA	Health Protection Agency
IT	Information Technology
IM & T	Information Management and Technology
ITT	Invitation To Tender
ITN	Invitation to Negotiation
I&E Accounts	Invoice and Expenditure
JV	Joint Venture
LINk	National Health Services Local Involvement Network
Liberating the NHS	The Department of Health white paper "Equity and Excellence; Liberating the NHS" published 12 July 2010 - ISBN: 9780101788120
Levers	A pre-requisite or catalyst required for change to take place
MATRA	Multi Agency Threat and Risk Assessment
MHRA	Medicines and Healthcare products Regulatory Agency
NPV	Net Present value
OBC	Outline Business Case
OGC	Office of Government Commerce
OJEU	Official Journal of European Union
Options	Alternative approaches aimed at achieving desired goals or benefits
PBC	Practise Based Commissioning
PCT	Primary Care Trust and/or any successive commissioner
PDC	Public Dividend Capital
POCT	Point of Care Testing
PQQ	Pre Qualification Questionnaire
PRCC	Principles and Rules of Cooperation and Competition
Project	means the *[insert name]* Project
QIPP	Quality Innovation Prevention and Productivity
R&D	Research and Development
SHA	Strategic Health Authority
Treasury Rules	HM Treasury regulations and guidance as published from time to time
TUPE	The Transfer of Undertakings Protection of Employment Regulations 2006 (SI/2006/246).

Annexes

Annex A

A. Pathology Disciplines

Annex B

B. Volume of tests by discipline by provider

Annex C

C. Modelling

Annex D

D. Stakeholder Engagement