CLINICAL LABORATORY DIAGNOSTICS (Pathology)
Reconfiguration and Re-equipping under a Managed Service Contract
Summary of
BUSINESS CASE V4.4

August 2015
• EXECUTIVE SUMMARY

1.1 Introduction

This document is the full business case for the redevelopment of clinical laboratory diagnostics (CLD), commonly known as “pathology”, under a managed service contract.

The contract value, excluding capital costs to support enabling works, is up to a maximum of £17.8m over seven years (£18.6m assuming 3.5% inflation on consumables at CPI in years 4-7). The Trust has an option to extend for a further three years, subject to review as we reach the end of proposed contract. As such, it exceeds the threshold for NHS Trust Development Authority (TDA) approval and has been written with the TDA business case assessment checklist in mind in the standard HM Treasury “5 Case” format. A pre-procurement business case was thoroughly scrutinised and approved by the Finance & Investment Committee and the Trust Board in 2012, since when an OJEU compliant procurement process has been followed to select a managed service provider (MSP).

The outline version of this case was approved by the TDA for scrutiny and approval. This document will also be submitted for approval, upon which the contract can be signed and initiated.

1.2 Strategic Case

The clinical services that the Trust provides rely on a fast and effective CLD service for the rapid and reliable diagnosis of patients in hospital and primary care. However, the laboratory service is hampered by very old equipment, most of which is fully depreciated and beyond its economic life. This knocks on to high maintenance and reagent costs, and risk of business continuity failure. The lack of capital available for investment in the past has meant that many items are on costly leasing arrangements. At the same time, operating a full service on both of the Trust’s main hospitals at Eastbourne and Hastings causes unnecessary costs for disciplines within CLD that can easily be centralised.

At a national level, the Carter reports of the first decade of the 21st century recommended much wider regional collaboration between hospitals to drive up reliability and quality and drive down cost. In East Sussex, the county-wide exercise carried out by KPMG in 2011 yielded no options in this regard that could be implemented without major capital investment, time delays and risk. In this context, the Trusts in both East and West Sussex independently made the decision to adopt a more local strategy attuned to their specific needs.

The Trust has reconfigured its services to concentrate stroke care at Eastbourne with Hastings concentrating more on emergency surgical care. The temporary reconfiguration of Maternity and Paediatric services at Hastings has now been confirmed as permanent. To support this, the CLD service is planning to realign its services and bring all micro-biology under one roof at Eastbourne. In addition, the implementation of a larger laboratory for blood diagnostics, including large parts of haematology and clinical chemistry, at Eastbourne will assure rapid results for the emergency site as well as coping with the burgeoning demand from GPs.
However, the lack of capital for investment in the new equipment required means that alternative sources of capital are required. Managed service contracts are a common and accepted way of accessing investment in facilities while transferring significant risk to the private sector by contracting with a single organisation to manage all sub-contractor and supplier relationships. In addition there are VAT advantages which make it possible to secure investment and ensure maintenance and service regimes are adhered to, within the existing revenue budget envelope.

1.3 Economic case

The economic case is focused on identifying the most economically advantageous option for the Trust. A long-list of options was considered by the project team, which was whittled down to two practical options, with the do minimum option as a comparator. The options were:

1. Do minimum – keeping the service operational in its current configuration for as long as possible and replacing time-expired equipment funded through the Trust’s capital programme. It is estimated that about 20% of the replacement value of the current equipment would be required each year for the next five years. No capital funds to support this option have been identified.

2. Lease/reagent rental – this would effectively combine the lease and reagent cost of the equipment required for the reconfigured service, albeit it would entail multiple relationships with the individual suppliers, and the Trust would still bear the risk of service failure.

3. Managed service contract – this would bundle all the running costs of equipment in the reconfigured service with a single managed service provider (MSP). The MSP would bear the risk of equipment failure and would be able to upgrade or replace equipment in line with fluctuations in demand.

The managed service contract option was selected as the preferred way forward following a structured option appraisal scoring each shortlisted option against benefits weighted for their relative importance. Its key characteristics are:

- It would create the most reliable service, because it would result in the technology base being completely refreshed, and with a contractually guaranteed level of support and uptime, measured by key performance indicators (KPIs) and with contractual penalties for failure. Should an item of equipment fall below the acceptable level in terms of availability, it would be the responsibility of the MSP to rectify the situation. There would be no conflict of interest between lessor, supplier and service company for the Trust as these would be managed by the MSP.

- It would create faster and better clinical support, with no appreciable reduction in later years once initial guarantee and service contracts have expired.

- It will improve the quality of the patient experience, as the results will be quicker and fewer quality errors will be made.

- It would provide the framework to react flexibility to adapt to future developments in terms of changes in demand or new technology.
- It would be the easiest to implement, as it would be procured through a single process, and the contract would be with a single MSP. Implementation timescales would be specified in the contract and the MSP held to account for delivery.

A discounted cash flow analysis was carried out to identify the most economically favourable option in net present value (NPV) terms. This shows that the MSC, apart from the qualitative benefits identified above (and in section 4.10.1 below), also delivers the most economic benefit over its lifetime. This stems primarily from the reduced reagent costs under the MSC, which offer a substantial improvement on the current cost base, as well as further reductions in staffing costs. These will be achieved through a combination of surrendering currently vacant posts, reducing the numbers of supervisory posts, and review of skill mix as vacancies/turnover arise.

The preferred option has been compared to a “public sector comparator” (PSC) to establish whether it would be cheaper to deliver the scheme as planned in the preferred option from Exchequer funds, if these were made available. The PSC has three material disadvantages compared to the preferred option. Firstly, the capital figures available from MSC bidders indicate that direct purchase would be far more expensive than acquiring the assets through an MSC. Secondly the Trust would not be able to access the large discounts on reagent prices that the MSP routinely achieves. Thirdly, the significant doubts about timescale, procurement, contractual forms, availability of capital and implementation mean there is a large allowance for changes in scope and cost (referred to as “optimism bias”). Thus in capital, revenue and net present value terms the PSC is very disadvantageous. This is summarised below:

Table 1: Capital outlay and NPV comparisons for Capital Purchase (PSC) and MSC options.

<table>
<thead>
<tr>
<th>Measure</th>
<th>Reconfiguration - Managed Service Contract</th>
<th>Reconfiguration - Capital Purchase (Public Sector Comparator)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Capital (£000)</td>
<td>704</td>
<td>7,499</td>
</tr>
<tr>
<td>rank</td>
<td>1</td>
<td>3</td>
</tr>
<tr>
<td>Net present (cost)/value (£000)</td>
<td>6,012</td>
<td>(2,541)</td>
</tr>
<tr>
<td>rank</td>
<td>1</td>
<td>2</td>
</tr>
</tbody>
</table>

This demonstrates that the PSC is unaffordable in capital terms and uneconomic compared to the MSC.
The risks of each option have also been assessed, with the outcome that the MSP option has the lowest profile. This is largely because of significantly greater certainty about the availability of capital funding, timescale, project management, installation, service levels and costs.

1.4 Commercial case

The preferred option is being procured through an OJEU compliant procurement process that has been in train since March 2012. The restricted process adopted yielded 19 expressions of interest from potential suppliers, of whom five pre-qualified to bid, with 3 bids received. The intention to award the contract to Roche, an experienced provider of managed laboratory services, was published February 2015.

The evaluation process has been undertaken by over 30 staff including clinical, professional, technical, estates, finance and procurement staff from the Trust, working in small teams with the support of NHS Commercial Solutions. A contract has been prepared which includes provisions for risk transfer and key performance indicators that encourage business continuity and quality, while penalising failure. The contract will be let for a seven year period, with an option to extend for three further years, during which the MSP will be responsible for:

- Equipment supply and installation, including where necessary replacement.
- Servicing and maintenance
- Reagent supply.
- Supporting the effective management of the clinical laboratory diagnostic service to deliver key strategic benefits such as increasing productivity and maintaining/increasing market share, particularly GP work.

The contractual structure enables the Trust to reclaim VAT on its maintenance, servicing and reagent costs under UK statute.

The assessment of tenders was carried out in June and July 2014, using technical scores based on the views of assessment teams scrutinising the responses to 38 individual questions. In addition, financial scores were allocated, based on the global cost of the contract over 7 years.

Roche was deemed the bidder with the best combination of technical and financial scores, with a final score of 73%, some 5% ahead of its nearest rival. The second placed bid had the best financial score, but the worst technical score.

Further work up to contract commencement includes:

- Detailed specification of all equipment to install.
- Agreement of the detailed project plan for implementation.
- Agreement to the detailed penalties for late achievement of milestones.

The contract discussions are currently based on a final figure of £17.8m, showing a marginal improvement on the original tender values. The consumables element of this will be subject to inflation at CPI after the third year.
1.5 Financial case

The capital required to implement the MSC scheme amounts to some £700,000. £200,000 was allocated prior to FY14/15 and £500,000 was allocated to 2015/16, as project implementation continues.

The scheme makes a significant contribution to the Trust’s cost improvement programme, with a full year effect of £1.3m in the first full year (2017/18), rising to £1.8m by year seven. This comprises:

- VAT – the contract form means VAT will be reclaimable.
- Staff reductions enabled by new technology and reconfiguration of services.
- Lower consumables costs with the new equipment – particularly savings on reagents.
- Lower servicing and maintenance costs.
- Lower financing charges (lease element of MSC) compared to the PDC payable on the Trust’s own capital
- Increased income and margin on GP related income, which would otherwise be impeded. This would be because increased repertoires for modern equipment would be available and tests currently referred out of the Trust could be repatriated.

The assets used in the delivery of the MSC will not sit on the Trust’s balance sheet as a substantial proportion of risk will still reside with the provider for the life of the asset. The impact on the Financial Risk Ratio is positive. The sensitivity of the option to changes in a number of assumptions has been tested. These included:

- Loss of the VAT reclaim facility - £510,000 in 2018/19, assuming that earlier changes in legislation or HMRC rules are unlikely.
- Failure to reduce staffing levels in line with the plan - £100,000 from 2015/16.
- Increased prices due to failure to let the contract within the price guarantee period - £70,000 from 2015/16.
- Loss of GP activity in competitive tender - £700,000 (net effect) from 2017/18. The recent losses of some clinical services from the Trust has not impacted on the level diagnostics across Pathology activity.

While these factors in themselves are significant and could have an impact of several hundred thousand pounds none of them individually or even combined would make the other options appear more beneficial in financial or in overall economic cost/benefit terms, as the other options would largely be subject to equal or more risk, except for the VAT risk.
1.6 Management case

The project management arrangements are well established, with clear leadership and assurance arrangements. The project has had involvement from clinical and professional staff within the clinical laboratory staff from its inception. The project board meets fortnightly and is chaired by Michele Elphick, general manager for theatres and clinical support. The Senior Responsible Office is Richard Sunley, the Chief Operating Officer. The project manager is Hayley Barron, who is a member of the Programme Management Office. The programme for the project is summarised below:

Table 3: Project timeline

<table>
<thead>
<tr>
<th>Event</th>
<th>Date</th>
</tr>
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<tbody>
<tr>
<td>Pre-procurement business case approved</td>
<td>March 2012</td>
</tr>
<tr>
<td>OJEU Advert for restrictive procedure placed</td>
<td>April 2012</td>
</tr>
<tr>
<td>Pre-qualification questionnaire</td>
<td>June 2012</td>
</tr>
<tr>
<td>Invitation to tender</td>
<td>January 2014</td>
</tr>
<tr>
<td>Tenders received</td>
<td>April 2014</td>
</tr>
<tr>
<td>Tender evaluation and preferred supplier selected.</td>
<td>June 2014</td>
</tr>
<tr>
<td>Approval by Finance and Investment Committee and Trust Board</td>
<td>August 2014</td>
</tr>
<tr>
<td>Submission to Trust Development Authority</td>
<td>August 2014</td>
</tr>
<tr>
<td>Trust Development Authority approval</td>
<td>January 2015</td>
</tr>
<tr>
<td>Intention to award contract and stand still period</td>
<td>February 2015</td>
</tr>
<tr>
<td>Submission to Finance and Investment Committee</td>
<td>May 2015</td>
</tr>
<tr>
<td>Submission to Trust Board</td>
<td>June 2015</td>
</tr>
<tr>
<td>Trust Development Authority approval</td>
<td>June - September 2015</td>
</tr>
<tr>
<td>Contract signature</td>
<td>September 2015</td>
</tr>
<tr>
<td>Implementation</td>
<td>October 2015 – June 2016</td>
</tr>
<tr>
<td>Service Go Live &amp; Full Service Commencement</td>
<td>June 2016</td>
</tr>
</tbody>
</table>

The timetable is subject to final agreement with the TDA and will be finalised once transition planning with supplier is complete.

The keys risks to the project have been identified and avoiding or mitigating actions identified. The biggest single risk to the project relates to the potential for the statute or HMRC interpretation to change to remove the facility to reclaim VAT on consumables and other operating costs.

The Project Board has closely monitored guidance around VAT throughout the project to ensure that the original business case proposed was still valid in this regard. No indication has been given that such a change is likely to occur over the lifetime of the contract. However, this would not change the rankings of the options, and the Trust would still benefit from substantial reductions in reagent and other operating costs.
There is also a risk that implementation will take longer than planned, or that unforeseen obstacles surface during the implementation process. The implementation will be managed in detail by the project manager, Hayley Barron, and the staff of the Trust Programme Management Office. A final risk is that the prices offered by bidders were originally guaranteed for 120 days, which has now been exceeded although no amendments have been requested by the MSP. The contract will yield a full year benefit of £1.3m - £1.8m per annum compared to its current cost base.

The changes will affect most of the staff in CLD in some way. Although there will be a reduction of staff numbers against the baseline, it is anticipated that this will be achieved entirely through the management of vacancies. Notwithstanding this, the Trust will consult with staff and their official representatives on the planned changes in location and procedures, in accordance with the Trust’s staff consultation policy.

A benefits realisation plan has been developed. The majority of the benefits of the scheme are contractually guaranteed for the life of the contract, in the sense that the pricing schedule is fixed and monitoring arrangements and KPIs are included within the contract. The onus is therefore on the MSP to deliver and the Trust to monitor. To this end the Trust’s CLD manager will be responsible for both contract monitoring and agreeing any further measures to boost or safeguard the savings.

1.7 Conclusion

The ESHT Trust Board approved this business case at its June 2015 meeting, and it now submitted to the TDA for scrutiny and approval.