

Pathology collaboration full business case

[Trust names XXXXX]

Abstract

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Executive summary

Introduction

[XXXXXX]

Strategic case

[XXXXXX]

Economic case

[XXXXXX]

Financial case

[XXXXXX]

Commercial case

[XXXXXX]

Management case

[XXXXXX]

Summary recommendation for approval

Required approvals

- 1.
- 2.
- 3.
- 4.
- 5.

Strategic case

Case for change

Since we published the second phase of the Carter review in 2008, *Report of the second phase of the review of NHS pathology services in England*, more and more trusts have been looking at how they can change their pathology service and commercial models to increase efficiency and deliver cash savings while maintaining or improving quality. While some trusts have been successful, most initiatives in England have failed to implement or achieve the desired objectives for reasons including:

- protection of budgets
- lack of senior management support
- competing priorities
- lack of skills needed to execute the plans
- perceived need to retain full services on site
- difficulty accessing the capital required to move to new operating models
- lack of trust between potential partners
- lack of thorough commercial agreements that incentivise a win–win for the health economy.

Lord Carter's review *Operational productivity and performance in English NHS acute hospitals: Unwarranted variations*, published in 2016, evaluated whether the NHS gets the best value (defined here as the product of quality of care and the efficiency with which it is delivered) from its annual budget. It concluded the NHS could save £5 billion a year if the significant and unwarranted variation in costs and clinical practice was addressed. Of this, up to £2 billion could accrue through better use of clinical, scientific and technical staff, reducing agency spend and absenteeism and adopting good people management practices.

The report acknowledged there is exceptional practice in the NHS, but overall acute trusts in England are not delivering care of sufficiently high value. More should be done to raise poor performance to that achieved by the best providers, with employers, workforce leaders and their professional representative bodies playing a crucial role in achieving this.

The report looked for examples of good practice in the NHS and elsewhere and used data from these to develop the Model Hospital. Nine practices were identified as key to achieving the £5 billion in savings.

The report's 15 recommendations were all accepted by the Secretary of State for Health in March 2016. Recommendation 4 states that diagnostic services should introduce metrics to allow comparison of productivity – in terms of workforce and equipment – between departments.

Recommendation 4

Trusts should ensure their pathology and imaging departments achieve their benchmarks as agreed with NHS Improvement by April 2017, so that there is a consistent approach to the quality and cost diagnostic services across the NHS. If benchmarks for pathology are unlikely to be achieved, trusts should have agreed plans for consolidation with, or outsourcing to, other providers by January 2017.

Delivered by:

- (a) Trusts introducing the Pathology Quality Assurance Dashboard (PQAD) by July 2016 to assure themselves and others that the pathology service provided is and remains of appropriate quality and safety, with NHS Improvement hosting the dashboard.
- b) HSCIC [now NHS Digital] publishing a definitive list of NHS pathology tests and how they should be counted by October 2016, with NHS Improvement requiring trusts to adopt the definitions from April 2017.
- (c) NHS Improvement publishing guidance notes for forming collaborative joint ventures and specifying managed equipment service contracts for local adaptation by October 2016.
- (d) NHS Improvement introducing metrics that describe relative imaging departmental productivity related to the use of equipment and workforce activity by December 2016.

The productivity metrics now used to measure trust pathology departments measured on are available to all trusts through the Model Hospital. NHS Improvement will ensure that progress against benchmarks is monitored regularly and that trusts are exploring potential collaborations to achieve these benchmarks.

This environment has led NHS Improvement and NHS England to require providers and commissioners to work together to plan the delivery over the next three to five years of clinically and financially sustainable solutions within sustainability and transformation partnership (STP) boundaries, as well as across STPs where the clinical relationships (clinical tertiary referrals, patient flows, cancer networks, etc) warrant this. As part of this, the radical reconfiguration of pathology services needs to accelerate to realise the efficiencies from increasing the size of laboratories, adopting world-class technology, and better supporting preventative medicine, management of long-term conditions and management of deteriorating patients in primary care.

Drivers for change and consolidation

- **Strategic direction:** STPs are being asked to collaborate and consolidate pathology services across the STP footprint or across STP boundaries to save £200 million by 2019/2020.
- **Cost and price variation:** Across England the cost and price of pathology services varies significantly because not all laboratories are as efficient as each other, and because contractual arrangements between commissioners and trusts vary in relation to the provision of GP direct access pathology testing.
- **Variation in efficiency:** NHS laboratories vary significantly in operational efficiency and quality of customer service.
- **Technological requirements:** Many trusts have not been investing in technological advances. Manufacturers are developing smaller analysers and automated systems with higher capacity and accuracy. Advances in molecular techniques, personalised medicine and the revolution in microbiology all support the consolidation of pathology services as the square footage required for equipment is reduced and provision of more efficient and specialised services is supported. Also, with new point of care testing devices pathology laboratories can provide a wider range of tests outside the laboratory setting, while retaining control of the quality governance.
- **Estates capacity:** While some trusts have invested over the last few years in new pathology facilities (eg Gateshead, Severn Pathology and Frimley Park)

and others may be able to increase their capacity within current infrastructure, some are using all their available space. The latter group need to use their available capacity better and release estate for other clinical functions.

- **New ISO 15879 quality requirements:** The move from Clinical Pathology Accreditation (CPA) to the new International Organization for Standardization (ISO) standards increased the pressure on the service to maintain quality standards and accreditation. Staff need to spend more time on quality, and facilities and equipment need to be of a higher standard.
- **Market openness and competition:** New private (eg SPS, Pathology First, HSL, The Christie Partnership, Viapath) and public sector competitors (eg Gateshead Pathology, NHS Pathology – Frimley Park) are already using efficient consolidated service models that lower their costs. In addition, some new private organisations (eg Ribera Salud) are looking to exploit other pathology delivery models.
- **Increases in demand:** Service demands are increasing year on year because of changing demographics and long-term conditions. Laboratories need to be optimised to be able to do more with the same or even less.
- **Savings and access to capital:** All departments need to contribute toward improving the financial sustainability of their trust. For pathology departments this means controlling costs and operating within budgets. Access to capital for refurbishment or new builds is likely to be unavailable or severely restricted.
- **Staff issues:** The following need to be addressed through reconfiguration of pathology services:
 - ageing workforce
 - shortage of certain specialist biomedical staff such as blood transfusion practitioners
 - move from specialist staff to a greater skill mix working across disciplines
 - difficulty recruiting histopathology consultants
 - low staff morale as a result of failed and start/stop initiatives.

[Clinical lead to input clinical case for change for the trust or collaboration.]

Barriers to change

- **Differing trust objectives:** Trusts sometimes view pathology as a non-clinical service, and as such do not give it sufficient consideration to achieve change.
- **Protectionism:** Trusts can fear that losing pathology through centralisation will spiral into scaling down of their wider frontline clinical services.

- **Staff reluctance to change** to a new model of delivery of pathology services, particularly where this involves outsourcing.
- **Access to investment:** Consolidation business models have previously often been implemented with significant investment and sometimes with little increase in the geography served. New projects must be affordable or, if large investment is required, sources of capital must be clearly identified.
- **Resources required to develop new models:** Many pathology laboratories do not have enough staff, and make up the shortfall largely with agency staff. This coupled with ever increasing accreditation and regulatory requirements means that there is often insufficient time to effectively scope and plan for changes in service.
- **IT platforms:** Different IT platforms that cannot communicate with each other are a significant barrier to consolidation. Consolidated sites need to use the same IT platforms.
- **Equipment platforms:** The above applies equally to equipment platforms. The process of consolidation should include adoption of common equipment platforms.
- **Lack of engagement from clinical teams in drawing up the list of urgent tests that should remain available at each site:** Generally, moving tests off site is resisted and failing to help develop the urgent list can be part of this.
- **Agreement on commercial method to maintain trust external income:** Without agreement between the parties, consolidation cannot go ahead – external income is a significant part of the pathology service delivery.
- **Lack of local leadership and skills:** A large pathology consolidation project will require specialist skills (change management, IT, logistics, analysers), clinical skills and senior management engagement to develop the target operating model and agree the commercial terms between the parties.
- **Technical analysis:** Appraisal of the consolidation must include technical analysis to ensure that turnaround time and quality will be maintained in a consolidated hub model.

Trust background

- Sites service is provided on.
- Current financial commercial activities and clinical quality position of the trust in general.

Delivery of pathology services at the trusts

- Number of tests undertaken.
- Range of specialties.
- Details of any tests referred out.

Experience of consolidation or collaboration to date

- Details of any joint working, outsourcing or consolidation to date.
- Key barriers that have prevented consolidation to date.
- Within trust's STP or across STP boundaries.

Economic case

Consideration of options

Please indicate which of the options briefly described below you considered.

More detail on the specific models can be found in Appendix [X]. Appendix [X] provides a decision tree model to help with analysis and selection of options.

Outsourcing model

Under the full outsourcing model, the entire pathology delivery model is outsourced to a private sector provider, with a single contract or individual contracts covering facilities and analytics. All staff, assets and potentially estates are transferred to the private sector provider taking over the management, provision and control of the service delivery. As such the trust will only have to manage a contract for the delivery, and monitor the contract against the defined key performance indicators (KPIs). The current cost base is replaced by a single non-pay cost line, although some of the existing corporate overheads are likely to be trapped within the trust.

Note that this model does not require the outsourced provider to be a private sector provider as, depending on the location of the trust, NHS joint ventures may bid for the work.

Under this model, the trust no longer has control over the strategic direction or management of the service, other than those responsibilities defined in the contract.

Example: outsourcing of pathology by Chelsea and Westminster NHS Foundation Trust to Imperial College Healthcare NHS Trust.

[Insert local context and trust specific considerations.]

Thin joint venture

A thin joint venture involves the creation of a joint venture vehicle with the private sector for the strategic management of the pathology service. These services are then subcontracted to a private sector operator.

For example, the NHS and a private sector provider create a joint venture vehicle, with the NHS party maintaining majority control, to establish the strategic management of the service. From this, the individual pathology services are separately subcontracted. As the joint venture partner is likely to be a pathology service provider, it will be subcontracted the analytical service. Alternatively, only parts of the analytical service are outsourced – for example, specialist testing or specialties, to retain certain testing streams within the NHS. If the private sector provider runs all the pathology testing, NHS staff would transfer to the private sector provider under Transfer of Undertakings (Protection of Employment) regulations (TUPE).

Examples: Southwest Pathology Services, Pathology First Analytics/Pathology First Facilities and Health Services Laboratories (HSL).

[Insert local context and trust-specific considerations.]

Thick joint venture

A thick joint venture also involves the creation of a joint venture vehicle with the private sector, but this vehicle becomes the entity delivering the service and staff transfer into the joint venture under TUPE and existing contracts novating into it. The joint venture then becomes responsible for the delivery of the pathology service to the trust under a contract, and for the strategic direction and management of the service. As the trust is potentially the majority joint venture partner, it retains control.

Examples: Viapath and Christie Pathology Partnership.

[Insert local context and trust-specific considerations.]

NHS partnership

An NHS partnership is a pathology reconfiguration initiative between NHS parties, generally with the aim of creating a hub and spoke laboratory model across a number of trusts. This is enabled by one of the trust parties ‘hosting’ the venture, although a new legal entity may need to be created. The hub and spoke model transfers all ‘cold’ activity from the sites to a central laboratory, along with all GP activity. Each trust retains a small emergency services laboratory (ESL) for ‘hot’ testing.

This is an internal NHS model – NHS parties retain full operational control of the joint venture and service delivery is kept within the NHS. Savings and improvements are made through the consolidation of services in the hub and spoke arrangement.

Examples: These initiatives have seen varying success. Gateshead Pathology succeeded in consolidating services but attempts in the Brighton and Bristol areas disintegrated. Other examples of this model include North West London Pathology, South West London Pathology, and Berkshire and Surrey Pathology Services.

[Insert local context and trust-specific considerations.]

Capital investment joint venture

A capital investment joint venture is a form of NHS partnership in which pathology services are reconfigured between NHS parties to create a hub and spoke model across a number of trusts. This is enabled by one of the trust parties ‘hosting’ the venture, although a new legal entity may need to be created. The hub and spoke model transfers all ‘cold’ activity from the sites to a central laboratory, along with all GP activity. Each trust retains a small ESL for ‘hot’ testing.

This joint venture is responsible for delivering the pathology services. This is an internal NHS model as the NHS parties retain full operational control of the joint venture and service delivery remains within the NHS. Savings and improvements are made through the consolidation of services in the hub and spoke arrangement.

In these NHS partnerships a joint venture is set up with the private sector to manage facilities and the business, tapping into expertise and capital from the private sector.

Evaluation of options

[For the chosen options, please describe the evaluation process, including scoring.]

Table 1 below lists the evaluation criteria for the scoring exercise.

Table 1: Evaluation criteria for the scoring exercise

	Criteria	Description	Sub-weight	Weight
Patient and clinical quality				
1	Clinical quality	Allows clinical oversight to be retained to create a consultant-led service.	30%	40%
2	Patient safety	Minimises any potential risk to patient safety, eg the need to have some services within a certain proximity of the patient, necessary links with clinical staff and the patient are preserved (where appropriate).	20%	
3	Achievability	Addresses the national strategy and requirements, and can be implemented effectively in the shortest time. The operating model provides an optimal solution for the realisation of savings.	30%	
4	Facilities, IT and equipment systems	Allows state-of-the-art equipment platforms to be introduced, along with driving improvements in the IT solution. It also allows for any upgrading of the estates required.	20%	
General, financial and governance requirement				
5	Strategic fit	Aligns with recommendations from NHS Improvement and NHS England to achieve savings, quality and sustainability of the service.	30%	60%
6	Potential affordability and value for money	Provides the best opportunity to access funding, minimises the need for NHS capital and is likely to provide a high return on investment.	50%	
7	Control and governance	Allows trust to retain appropriate control and governance of the service.	20%	

Further detail on the evaluation criteria and the scoring against these is given in Appendix 2.

Target operating model

[For the chosen option, please describe the target operating model (TOM)]

[Expected consolidation model to be selected and described in detail in terms of level of consolidation by specialty with requirements for logistics, estates, equipment and IT].

[Please see Appendix X for a description of the TOM for consolidation through the definition of an ESL.].

Financial case

For the purpose of the financial model, the costs of the pathology service are considered for the whole health economy, ignoring where the benefits of consolidation should lie and whether these should be shared with customers, including clinical commissioning groups (CCGs).

Financial baseline

The financial baseline, also referred to as the As Is model (Table 2), is the current projected cost base for the pathology service at the trust assuming no further consolidation.

Table 2: Financial baseline for the laboratory service (As Is model) over 10 years

Start of period	01/04/2015	01/04/2016	01/04/2017	01/04/2018	01/04/2019	01/04/2020	01/04/2021	01/04/2022	01/04/2023	01/04/2024	01/04/2025
End of period	31/03/2016	31/03/2017	31/03/2018	31/03/2019	31/03/2020	31/03/2021	31/03/2022	31/03/2023	31/03/2024	31/03/2025	31/03/2026
Cost position											
Scientific staff	-	-	-	-	-	-	-	-	-	-	-
Medical staff	-	-	-	-	-	-	-	-	-	-	-
Admin and other staff	-	-	-	-	-	-	-	-	-	-	-
Total pay costs	-	-	-	-	-	-	-	-	-	-	-
Non-Pay Costs											
Equipment, reagents, and cons.	-	-	-	-	-	-	-	-	-	-	-
Tests Referred Out	-	-	-	-	-	-	-	-	-	-	-
Logistics	-	-	-	-	-	-	-	-	-	-	-
Estates	-	-	-	-	-	-	-	-	-	-	-
IT (licenses, support, maintenance etc)	-	-	-	-	-	-	-	-	-	-	-
Other costs and overheads	-	-	-	-	-	-	-	-	-	-	-
Total costs	-	-	-	-	-	-	-	-	-	-	-
One-off costs	-	-	-	-	-	-	-	-	-	-	-

[Please include any capital investment required to maintain the current service in the financial baseline.]

Financial benefits of target operating model (TOM)

Over the 10-year appraisal period, the nominal cost to the trust of the service under the TOM and the As Is model are compared (Table 3) to show that [X] can be saved with the TOM.

Table 3: Financial comparison of the TOM and As Is model (nominal over 10 years and on a net present cost basis)

Scenario	Savings	NPC
As Is Scenario	-	-
Target Operating Model	-	-

Table 3 also shows the net present cost (NPC) – that is, the discounted cost, of the laboratory service over the 10 years for both the As Is model and the TOM. On a discounted basis, the TOM represents a saving of [X] on a discounted basis over the As Is model.

In terms of the laboratory’s annual savings, Table 4 shows the annual nominal cost of providing the service in the first full year of steady-state service (the first year in which the service is fully transformed as per the TOM).

Table 4: Comparison of nominal run rate of the steady-state for the As Is model and TOM

	As Is Scenario	Target Operating Model
Cost position		
Scientific staff	-	-
Medical staff	-	-
Admin and other staff	-	-
Total pay costs	-	-
Non-Pay Costs		
Equipment, reagents, and cons.		
Tests Referred Out	-	-
Logistics	-	-
Estates	-	-
IT (licenses, support, maintenance	-	-
Other costs and overheads	-	-
Total non -pay costs	-	-

The outputs of the financial model indicate a clear financial benefit to the consolidation of services under the TOM.

Full details on the cost inputs into the financial model under the two scenarios are given in Appendix 3.

Investment required

[Please identify the investments – defined as one-off investments or transition costs – required to achieve the consolidated model, with particular focus on the following areas:

- equipment
- IT
- estates
- logistics
- transition costs
- other.]

Sources of funding

[For the funding above, please identify the sources and provide an analysis of their suitability and availability. Potential sources include finance through the trust cash positions, private sector financing or the Independent Trust Financing Facility (ITFF).]

[Highlight anticipated delays in the programme because of difficulties accessing finance. Estimate how much faster consolidation could be realised were financing immediately available to the trusts.]

Internally generated cash for investment

NHS trusts can use the following sources of internally generated cash to fund investment:

- unspent capital cash brought forward from previous years (unspent depreciation and receipts from asset disposals)
- cash associated with the charge for depreciation in the current financial year (excluding any IFRIC 12-related depreciation)
- receipts from asset disposals (up to delegated limits)
- income and expenditure surplus (both in-year and cash brought forward from earlier years)
- cash released from movement in debtor/creditor balances (although NHS trusts must take account of the Better Payment Practice Code).

Other potential capital routes for trusts to explore include:

- public dividend capital
- capital grants and loans
- charitable funding.

These are extra resources outside the normal course of business, and trusts should discuss should discuss their suitability as funding sources with NHS Improvement.

Independent Trust Financing Facility

The ITFF is a government organisation set up to independently advise the Secretary of State for Health on the financial assistance NHS trusts and foundation trusts require in the normal course of business for sustainability as part of a recovery process.

The ITFF can access extremely competitively priced capital for NHS trusts and is the recommended route for trusts requiring capital investment but having no internal trust funds.

Funding accessed via the ITFF is part of the capital designated limit (CDEL) for the Department of Health, and as the ITFF has limits set on the funding it can make available; however this is not a cash constraint. Therefore, where a trust has depreciation cover, investment can be funded with cash obtained from the ITFF as this will not count toward the CDEL.

[Insert specific information regarding the trust and its ability to approach the ITFF. If ITFF funding is to be sought, then trusts should discuss this with NHS Improvement as we will refer them to the ITFF where required.]

Private sector financing

[Please include any private sector involvement.]

The private sector can often provide ready access to capital for the NHS, and when the finance arrangement is structured correctly, may offer a route to realising capital without the need to account for the investment on the trust's balance sheet.

Note that rates are significantly higher with private sector investment than those incurred through the ITFF facility. There are also limits to the availability of funding from private sector parties.

[Insert specific detail about the private sector involvement in the joint venture and the investment that will be sought from the private sector. Also note whether this investment will be considered when calculating the ownership shares within the joint venture, as discussed in the Commercial case below.]

Commercial case

Clinical governance model

[Please detail the proposed clinical governance model.]

[Clinical lead to define the clinical steering group and governance structure.]

Operational governance model

[Please detail the proposed operational governance model.]

Commercial model

Description of the proposed commercial form is outlined below. For further detail, please see Appendix 1.

Outsource to an independent provider

Outsourcing to an independent provider represents the wish for the pathology service to be fully managed and delivered by another organisation, be they from the private sector or another NHS organisation. All assets, including staff and contracts, transfer to the outsourced provider and the trust only retains responsibility for management against the KPIs in the contract. It pays a single charge to the provider for the delivery of the service.

Private partner joint venture (thin joint venture)

Under the thin joint venture model, two joint venture vehicles are established with the private sector, one for managing the delivery of pathology services and one for managing the pathology support services, including estates, equipment and IT. Both joint ventures then outsource service delivery to the private sector partner. The trust retains management control but benefits from the private sector's delivery expertise.

Private partner joint venture (thick joint venture)

Under the thick joint venture model, two joint venture vehicles are established with the private sector, one for managing and delivering pathology services and the other for managing and delivering pathology support services, including estates, equipment and

IT. Under this model, the trust retains control of the delivery of the service, while gaining access to expertise from the private sector. Unlike in the thin joint venture model, the service continues to be delivered by the trust.

NHS partnership

In this model multiple NHS organisations form a partnership to consolidate pathology services. This model is 'hosted' by one of the NHS organisations to which all staff transfer under TUPE and all costs are allocated. Staff and costs are then shared between the parties based on their pre-agreed ownership shares.

Capital investment joint venture

The capital investment joint venture is a form of NHS partnership, but in addition to the above, a joint venture is formed with the private sector for the delivery of pathology support services, including estates, equipment, IT and transformation planning. This gives access to both private sector expertise and funding.

Key commercial terms

For the preferred option(s), commercial terms have been developed to provide a basis for the development of the commercial form. These are detailed in Appendix 4.

The commercial terms ensure that all trusts consolidating their services achieve gross savings net of investment and benefit from economies of scale, as well as share in the benefit of new activity from other trusts joining the venture. They also ensure that all organisations, be they NHS trusts or from the private sector, are fairly represented in the ownership share of the joint venture.

Table 5 below describes the main commercial terms for the TOM. More detail can be found in Appendix 4.

[Please delete the option not considered.]

Table 5: Commercial terms for the TOM

Key term	Description and issues	Outsourced option	Partnership options
Ownership shares	A method to calculate this based on the 'value' of each trust's contributions to the joint venture.	As the trust is outsourcing the management and delivery of pathology, it no longer retains an ownership share of the pathology service. This will be fully owned by the provider.	The proposed valuation method for defining ownership shares is given in Appendix [X].
Profit and loss	A method for distributing the profit and loss generated by the pathology service.	Annualised profits and losses are the responsibility of the provider of the pathology service.	Annualised profits are shared and losses underwritten by the owner organisations in proportion to their ownership shares.
Retention of revenue	A key concern for many trusts is the retention of their contracts with CCGs for GP direct access.	Contracts remain with the trust. The service provider delivers services to the trust(s) that in turn provide services to their CCGs.	All trusts in the partnership/joint venture can retain their own contracts with their CCGs. Contracts do not have to transfer to the host trust.
Exit arrangements	A method for the potential exit of an organisation.	Break clauses are determined in the contract with the outsourced provider and are subject to negotiation. The trust must be able to exit the contract if the provider repeatedly does not meet the KPIs in the contract.	Any organisation wishing to terminate its customer contract should give the joint venture at least 12 months' notice. If the contract is terminated before the first break period, the terminating organisation is responsible for any extra costs incurred by the joint venture in the

			12 months following termination.
Intellectual property (IP)	A method for using the IP of the organisations for the delivery of pathology services.	IP is retained by the provider of services.	The IP is owned by the partnership/joint venture and can be exploited by it on behalf of its owner organisations.
Hosting arrangements	Where the partnership model requires a host trust to ensure efficient management and consolidation.	If more than one trust is looking to collaborate to achieve economies of scale, a host trust can do the procurement for the other organisations.	Where NHS partners are to consolidate services, one organisation should act as the host, with staff, contracts and services transferring to the host to support more efficient management.
New contracts	Responsibility for signing contracts with new suppliers.	The outsourced service provider is responsible.	The host organisation hosts the contracts with liabilities shared with the other partners as per the ownership arrangements.
Capital investment	A method for the approval and financing of capital investments.	All capital investment is the responsibility of the provider.	<p>Any capital investment approved by the partnership/joint venture is 'called up' from the owner trusts per their ownership shares.</p> <p>All capital calls require a business case approved by the pathology management board. Capital calls above [£ million] require approval by the owner trusts per the scheme of delegation.</p> <p>If any potential owner trusts commit any capital investments (from which</p>

			the partnership/joint venture will benefit) within three months of the creation of the partnership/joint venture, this is included in the valuation of ownership shares.
Clinical governance	Description of clinical governance structure that allows consultant interaction and oversight of the laboratory.	Pathology services organisation is responsible for having the right clinical governance in place to ensure accreditation. In addition, a number of programmed activities (PAs) can be bought from trust consultants to ensure oversight and support.	A clinical governance committee can be set up, reporting straight to the partnership board on the clinical issues of the laboratory, such as quality, standard operating procedures (SOPs), demand management initiatives and introduction of new tests.

Staffing

TUPE transfers	A method for transfer of staff to the new provider of the service.	<p>All pathology staff from the trust will transfer to the provider under TUPE.</p> <p>Once the interview process is complete, appointed staff transfer from their current trust to the host trust under TUPE.</p> <p>[This option could be used for all staff or just for defined key posts to ensure the sustainability of the partnership/joint venture.]</p>	<p>All pathology staff from the owner trusts can apply for jobs in the new partnership/joint venture (per its agreed operating model).</p> <p>This applies to all clinical staff with the exception of staff who also have clinical (patient-facing) sessions. If clinical (patient-facing) time is greater than diagnostic pathology time, the latter service is recharged (and vice versa).</p>
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Management case

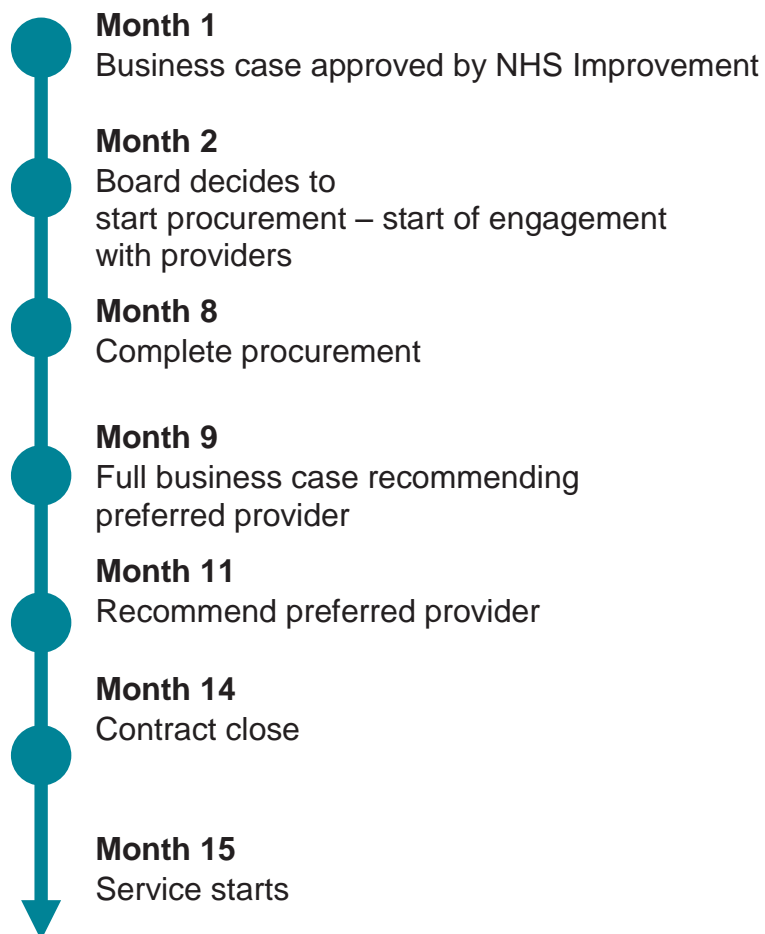
Timeline

[Please provide the timeline to implementation.]

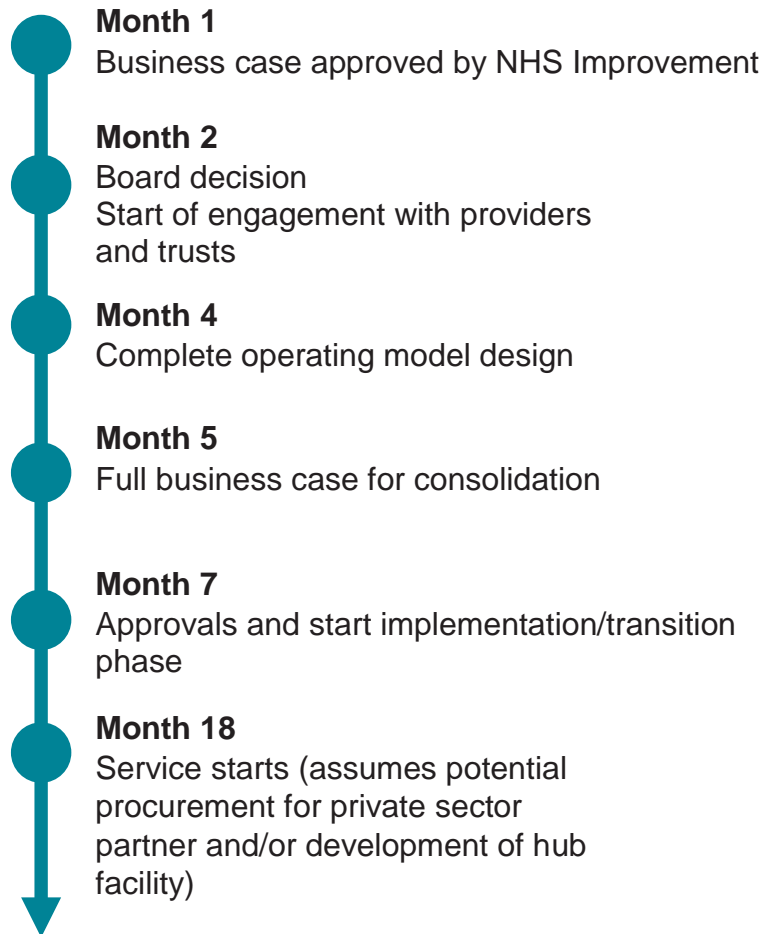
- Standard implementation timeline.
- Accelerated implementation timeline, based on access to capital [sources of capital must be clearly identified, described and agreed in principle] and skills.

[The following timelines are provided as guides. Please delete the timeline that does not apply to your chosen option(s), and indicate if you are part way through the process. Please also change the timeline if you believe it will be affected by your local situation.]

Outsourced model



Joint venture models



Constraints and risks

The predicted risk log for the preferred option is shown below. Impact and likelihood of risks are given an individual RAG rating, and these are then combined to give an overall RAG rating for each risk.

[Please tailor the examples below to your local situation.]

Outsourcing

Risk	Impact	Likelihood	Combined RAG rating	Mitigation measures
Inability to put together a network with partners	High	Low	Medium	Immediate engagement with partners to determine interest

Inability to implement	Medium	Medium	Medium	Detailed transition planning and testing
Strategic alignment and regulatory risk (pressure from DH and NHS Improvement)	High	Low	Medium	Continual discussions with DH and NHS Improvement to ensure strategic fit
Ability to meet ongoing CIPs	Medium	Low	Low	Private partner should be challenged to help identify ongoing CIP opportunities

Private partner joint venture (thick joint venture)

Risk	Impact	Likelihood	Combined RAG rating	Mitigation measures
Inability to put together a network with partners	High	Medium	Medium	Immediate engagement with partners to determine interest
Inability to implement	Medium	Medium	Medium	Detailed transition planning and testing
Strategic alignment and regulatory risk (pressure from DH and NHS Improvement)	High	Low	Medium	Continual discussions with DH and NHS Improvement to ensure strategic fit
Ability to meet ongoing CIPs	Medium	Low	Low	Private partner should be challenged to help identify ongoing CIP opportunities

NHS partnership

Risk	Impact	Likelihood	Combined RAG rating	Mitigation measures
Inability to put together a network with partners	High	Medium	Medium	Immediate engagement with partners to determine interest
Inability to implement	Medium	Medium	Medium	Detailed transition planning and testing
Strategic alignment and regulatory risk (pressure from DH and NHS Improvement)	High	Low	Medium	Continual discussions with DH and NHS Improvement to ensure strategic fit
Ability to meet ongoing CIPs	Medium	Low	Low	Private partner should be challenged to help identify ongoing CIP opportunities
Ability to access capital to re-organise the service	High	High	High	Effort should be given to seeking capital injections from the private sector, and minimising the capital requirement

Capital investment joint venture

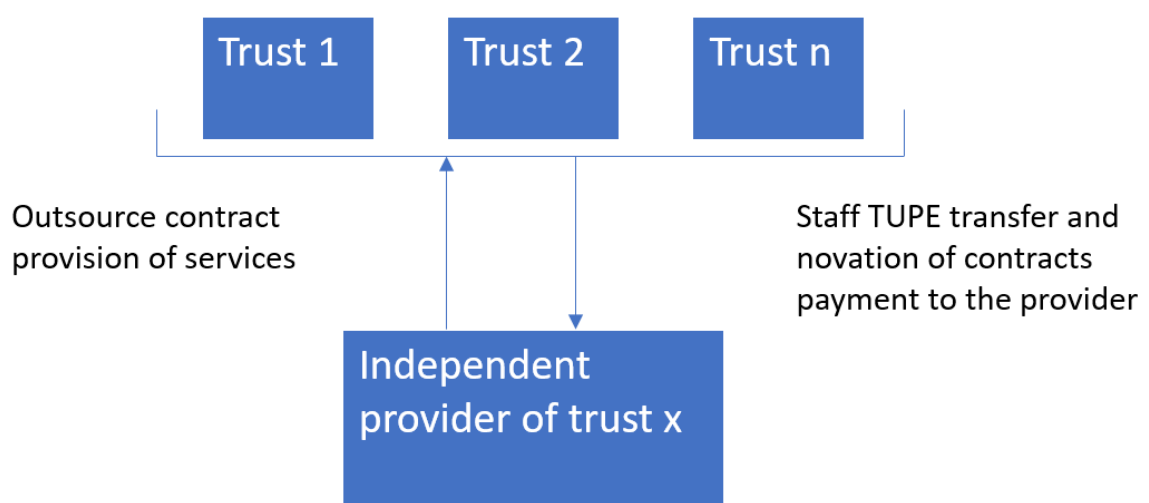
Risk	Impact	Likelihood	Combined RAG rating	Mitigation measures
Inability to put together a network with partners	High	Medium	Medium	Immediate engagement with partners to determine interest
Inability to implement	Medium	Medium	Medium	Detailed transition planning and testing

Strategic alignment and regulatory risk (pressure from DH and NHS Improvement)	High	Low	Medium	Continual discussions with DH and NHS Improvement to ensure strategic fit
Ability to meet ongoing CIPs	Medium	Low		Private partner should be challenged to help identify ongoing CIP opportunities

Appendix 1: Commercial models

This appendix describes the commercial models and for each summarises the relationship between the different organisations in a simple diagram.

Outsource to an independent provider



Under the option to outsource to an independent provider – whether in the private sector or another NHS organisation – a full outsourcing contract must be put in place. This covers all aspects of the service, including governance, equipment asset transfer, staff (staff transfer to the new provider under TUPE), logistics, access to facilities (required for the essential services laboratory), charges for services provided by the trust and any capital investment – that is, the current cost base of the laboratory transfers to the provider. The provider then delivers the pathology services to the trust in full, in return for a financial payment. The only control the trust has over the service is defined by the KPIs in the contract and the ability to re-tender at the end of the contract or at break.

The financial payment under the contract is usually based on cost per reportable, which retains the incentive for demand management with the trust. However, other countries are using new models such as ‘capitated payments’.

To award an outsourcing contract to the private sector, a trust needs to carry out a procurement process to select a preferred provider of the service. A collective of trusts can jointly procure the pathology services at all parties. A procurement process is not required if the contract goes to another NHS trust under a services-level agreement (SLA)

Example: this model has been implemented by Chelsea and Westminster Hospital with the outsourcing of its pathology service to Imperial College Healthcare NHS Trust.

Private partner joint venture (thin joint venture)

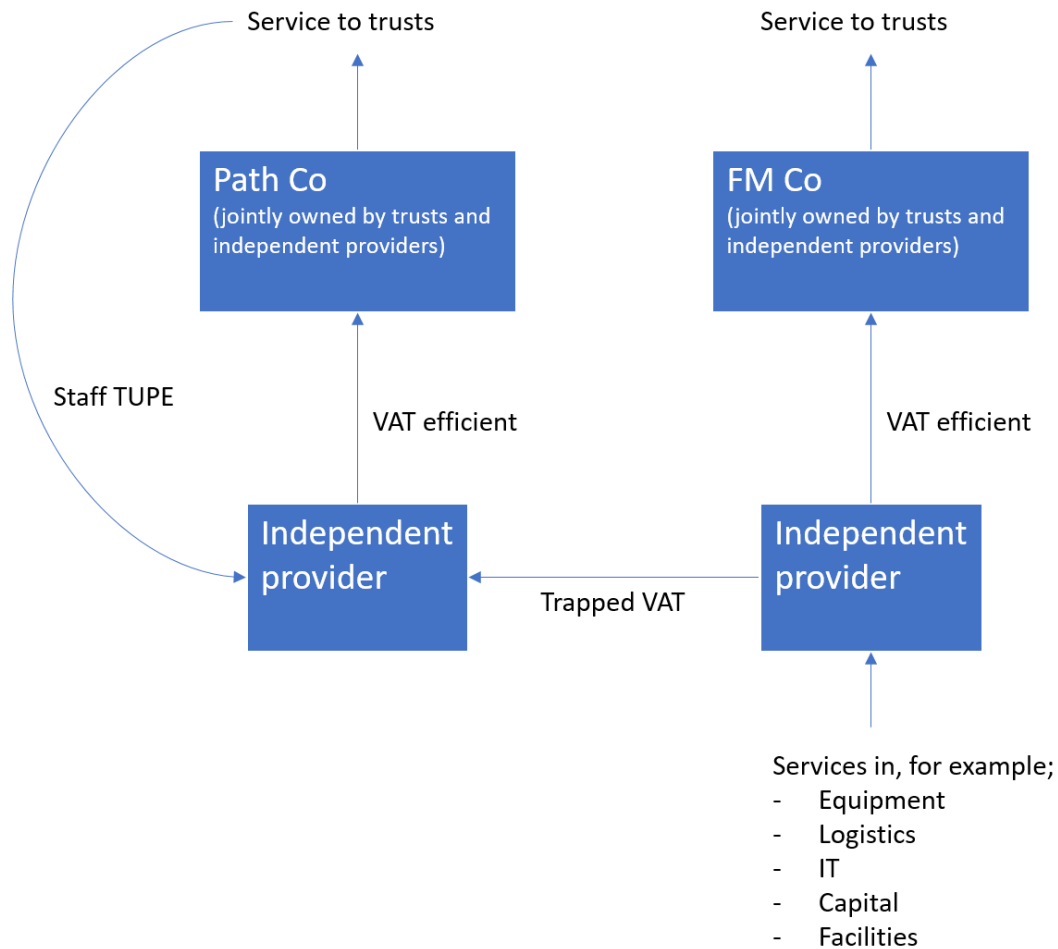
A thin joint venture is a partnership with an independent provider for the management of subcontracted pathology services, not for the provision of these services. These services are delivered by the independent provider – either a private sector provider or another NHS organisation (eg an existing collaboration). Traditionally one joint venture organisation owned by both the trusts and the private sector was created, but to maximise VAT efficiency and comply with HM Revenue & Customs (HMRC) rules, two separate legal entities are formed as joint ventures (see diagram below), jointly owned by both the partner trusts and the independent provider..

The two joint venture companies are:

- An **analytics joint venture** (represented by Path Co in the diagram below): responsible for the provision of analytical pathology services and all technical and laboratory staff transfer. This is a VAT zero-rated organisation.
- A **facilities management joint venture** (represented by FM Co): responsible for the provision of facilities, equipment, logistics, IT and other services. This is a VAT standard-rated organisation.

Both the analytical and facilities joint venture companies are responsible for the management of their own subcontracts with the pathology service providers. These joint ventures also provide strategic direction to the partnership and allow for new NHS partners to join. They do not make a profit (or loss) from the services provided to the founding partners. The joint ventures transfer all risks and liabilities to the independent provider providing the service.

Path Co is the company set up to manage the contract for the delivery of the pathology testing service. It subcontracts delivery of this service to the independent provider with all staff from the trusts' existing pathology services transfer into it under TUPE.



FM Co is separately established. This company is responsible for the management of the contract for facilities support for the pathology service, including estates, equipment, facilities management and logistics. Like Path Co, FM Co is only responsible for the management of the contract. It subcontracts delivery to the independent provider. FM Co does not provide its service to Path Co, but directly to the trusts. This maximises VAT efficiency. Some service have to be provided directly to Path Co – for example, finance and HR support, which is likely to trap some VAT (accountancy advice is required to establish VAT liabilities and efficiency under this structure).

Under this arrangement, consultants continue to be directly employed by the trusts. The independent pathology services provider can then buy a number of PAs from the trusts and support a clinical steering group that has an oversight of the clinical aspects of the laboratory.

New parties can be added to the joint venture in two ways:

- **As a customer of Path Co and FM Co.** Under this arrangement, profit transfers to the original trusts and independent provider that own Path Co and FM Co.
- **As a co-owner.** This involves the purchase of an ownership share from the existing partners.

Examples: Health Services Laboratories (a pathology joint venture between The Doctors Laboratory (TDL), University College London Hospitals NHS Foundation Trust and the Royal Free London NHS Foundation Trust) and Pathology First Analytics/Facilities LLPs (two joint ventures set up by Southend University Hospital NHS Foundation Trust, Basildon and Thurrock University Hospitals NHS Foundation Trust and iPP Analytics and iPP Facilities respectively).

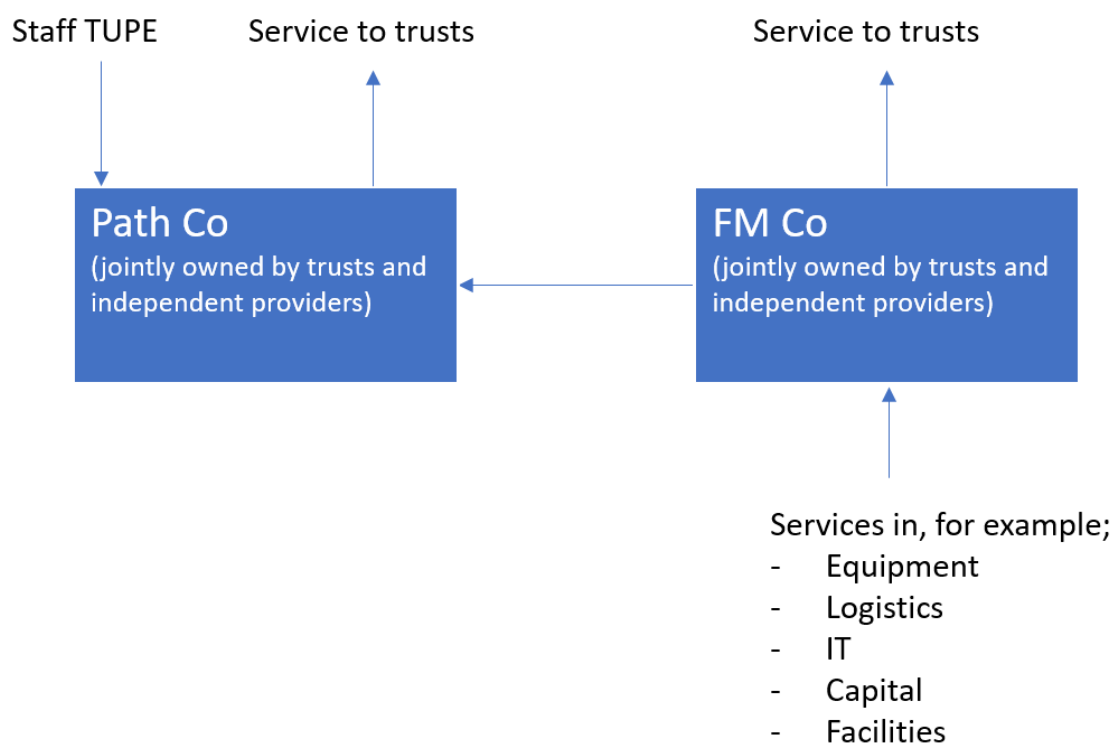
The selection of a private sector partner and supplier requires a procurement process.

Private partner joint venture (thick joint venture)

A thick joint venture is a partnership with an independent provider for the management and delivery of pathology services.

Two separate companies are formed as a joint venture and are jointly owned by the partner trusts and the independent provider – this maximises the structure’s VAT efficiency as per the thin joint venture model above. Its important difference from the thin joint venture model is that both of the formed companies employ staff and are responsible for both the management and delivery of the pathology service. They will make a profit (or loss). This structure implies that all risks and liabilities remain with the owners of the joint ventures.

The diagram shows a typical structure for this model: Path Co is the company set up to manage and deliver the pathology service. Staff from the trusts’ existing pathology services transfer into this company under TUPE.



FM Co is separately established. This company is responsible for the management and delivery of the support for the pathology service, including estates, equipment, facilities management and logistics. FM Co does not provide its service to Path Co, but directly to the trusts. This maximises VAT efficiency. Some services are provided directly to Path Co – for example, finance and HR support, which will trap VAT.

Under this arrangement, consultants continue to be employed directly by the trusts as per the thin joint venture model above.

New parties can be added to the joint venture in two ways.

- **As a customer of Path Co and FM Co.** Under this arrangement, profit transfers to the original trusts and independent provider that own Path Co and FM Co.
- **As a co-owner.** This would involve the purchase of an ownership share from the existing partners.

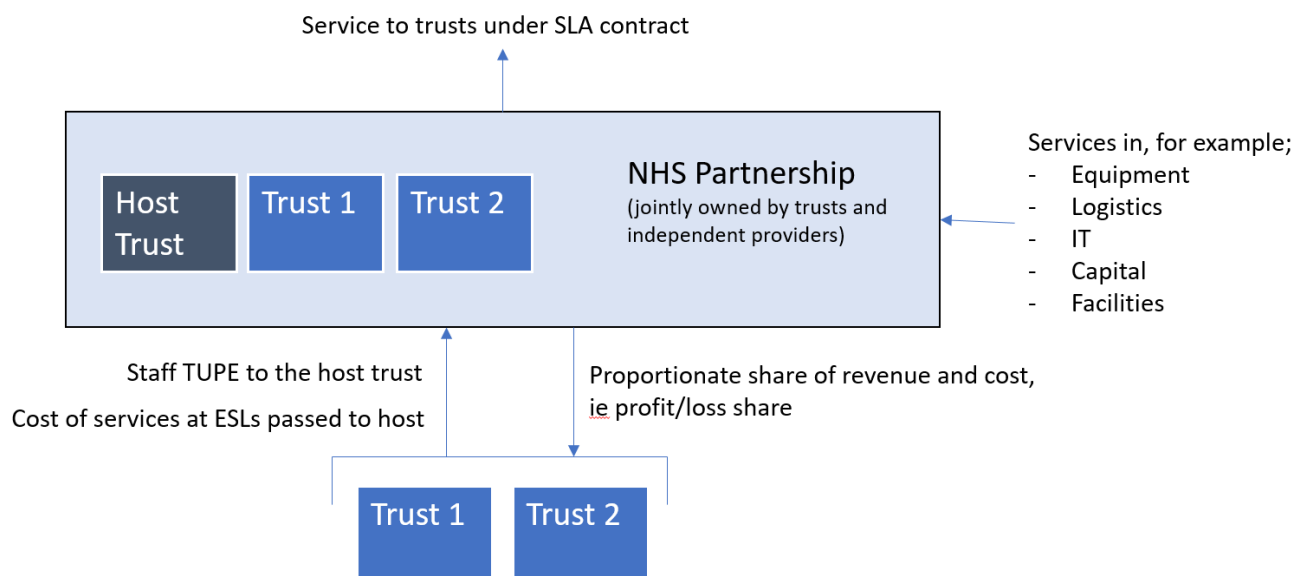
Examples: Viapath (joint venture between Guy’s and St Thomas’ Hospitals NHS Foundation Trust, King’s College Hospital NHS Foundation Trust and Serco) and The Christie Pathology Partnership LLP (joint venture between Christie Hospital NHS Foundation Trust and Synlab).

As with the thin joint venture above, this model is likely to require a procurement process for the appointment of a private sector partner

NHS partnership

The NHS partnership model is a partnership between NHS providers only for the management and delivery of pathology services, enabled by a 'host' trust.

The NHS partnership is not created as a separate company; instead it is 'hosted' by one of the trusts which incurs all costs and receives income for the service from the other trusts. This is also called a contractual joint venture. All partner trusts share the benefits, risks and liabilities in accordance with their agreed partnership stake (calculation of which is normally based on the testing volumes brought to the partnership).



Under this model, all staff from the trusts' existing pathology services transfer into the host under TUPE. Existing client contracts, equipment contracts, facilities, etc remain with the existing trusts and are recharged at cost to the host. Over time the host is likely to replace these contracts with a central contract for all trusts, to benefit from the economies of scale of joint procurement. As such, all costs for the delivery of the pathology service sit with the host. This cost is then charged back to the trusts according to the partnership stakes. If the host pathology service makes a profit (or loss) through this process, this is split between the trusts according to the partnership stakes.

The host delivers pathology services to the trusts under an SLA contract. Under this model, trusts are both customers and owners, which can create conflicts – for example, when seeking to minimise the cost they are charged as well as maximise the profit of the joint venture. The commercial and governance structures must be carefully considered to minimise this problem.

New trusts can join the venture in two ways:

- **As a customer.** The NHS joint venture, through the host trust, becomes the supplier of pathology services to the new trust under an SLA. As such, profit (or loss) under such a contract is split between the original owner trusts.
- **As an owner of the joint venture.** This requires the new trust to ‘purchase’ a shareholding in the joint venture from the other trusts, which dilutes the ownership shares of the existing owner trusts.

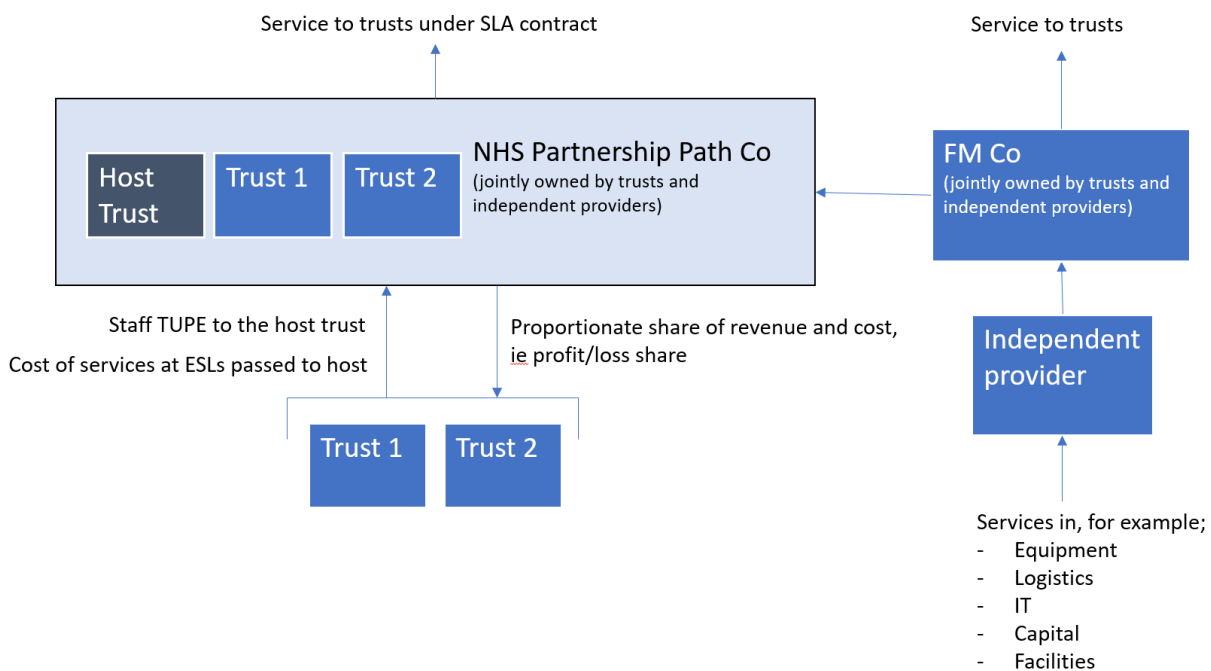
Examples: The Pathology Partnership (TPP) in the East of England and North West London Pathology. This is one of the most common models to have been adopted following the original Carter review.

Capital investment joint venture

This model is a variation of the NHS partnership model described above. However, it enables access to the private sector for capital investment and support service provision expertise.

Under this model, all staff from the trusts’ existing pathology services transfer into the host under TUPE. Existing client contracts, equipment contracts, facilities, etc remain with the existing trusts and are recharged at cost to the host. As such all costs for the delivery of the pathology service sit with the host and are then charged back to the trusts according to a pre-agreed formula. If the host pathology service makes a profit (or loss) through this process, this is split between the trusts according to the ownership shares.

The host delivers pathology services to the trusts under an SLA contract. Under this model, trusts are both customers and owners, which can create conflicts – for example, when seeking to minimise the cost they are charged as well as maximise the profit of the joint venture. The commercial and governance structures must be carefully considered to minimise this problem.



Alongside this, the joint venture sets up a separate company, co-owned by the trusts and an independent provider, for the provision of support services. FM Co will control and manage these services, and contract out their delivery to the independent provider. The support services include new equipment contracts, logistics, laboratory information management system (LIMS) and facilities, and can include additional services such as transition management and transformation. This model gives access to capital as FM Co incurs capital costs for new estates and similar projects, and recharges these to the trusts on an annual basis.

New trusts can join the venture in two ways:

- **As a customer.** The NHS joint venture, through the host trust, becomes the supplier of pathology services to the new trust under an outsourcing contract. As such, profit (or loss) under such a contract is split between the original owner trusts.
- **As an owner of the joint venture.** This requires the new trust to ‘purchase’ a shareholding in the joint venture from the other trusts, which dilutes the ownership shares of the existing owner trusts.

Appendix 2: Evaluation criteria

The evaluation criteria below score the options for consolidation in line with the strategic direction for pathology services, and the what trusts require of pathology services. This scoring mechanism helps with the selection of a preferred option(s).

Criteria	Description	Sub-weight	Weight	
Patients and clinical quality				
1	Clinical quality	Allows clinical oversight to be retained to create a consultant-led service.	30%	40%
2	Patient safety	Minimises any potential risk to patient safety, eg the need to have some services within a certain proximity of the patient, necessary links with clinicians, staff, and the patient are preserved (where appropriate).	20%	
3	Achievability	Addresses the national strategy and requirements, and can be implemented effectively in the shortest time. The operating model provides an optimal solution for the realisation of savings.	30%	
4	Facilities, IT and equipment systems	Allows state-of-the-art equipment platforms to be introduced, along with driving improvements in the IT solution. It also allows for any upgrading of the estates required.	20%	
General, financial and governance requirement				
5	Strategic fit	Aligns with recommendations from NHS Improvement and NHS England to achieve savings, quality and sustainability of the service.	30%	60%
6	Potential affordability and value for money	Provides the best opportunity to access funding, minimises the need for NHS capital and is likely to provide a high return on investment.	50%	
7	Control and governance	Allows the trust to retain appropriate control and governance of the service.	20%	

Each of these criteria is explained in more detail below.

Patient safety and clinical quality

Clinical quality

Allows clinical oversight to be retained to create a consultant-led service.

The scoring should focus on the ability of clinicians to retain clinical control of the service, to maintain or improve service standards of the service. Clinical control is separate from control of the service, and should focus on the input and control of clinicians in shaping service delivery, both initially and ongoing.

Patient safety

Minimises any potential risk to patient safety, eg the need to have some services within a certain proximity of the patient, necessary links with clinicians, staff and the patient are preserved (where appropriate).

The scoring should focus on the ability of the trust to maintain a service that matches its 'hot' testing requirements, and prevent service failures arising from the delivery of testing too far away from the trust location. It should also focus on how easy it is for trust clinicians and pathology staff to interact for the benefit of the patient.

Achievability

Addresses the national strategy and requirements, and can be implemented effectively in the shortest time. The operating model provides an optimal solution for the realisation of savings.

The scoring should reflect whether the solution matches the national strategy for consolidation of pathology service delivery, and whether it can be achieved in the shortest time. It should also reflect whether the option realises the maximum potential savings from consolidation of services.

Facilities, IT and equipment savings

Allows state-of-the-art equipment platforms to be introduced, along with driving improvements in the IT solution. It also allows for any upgrading of the estates required.

The scoring should reflect that, where required, the options allow new equipment platforms and new IT solutions to be introduced, to improve delivery of the service for patients and realise savings. It should also reflect that, where required, estates are invested in.

General, financial and governance requirements

Strategic fit

Aligns with recommendations from NHS Improvement and NHS England to achieve savings, quality and sustainability of the service.

The scoring should reflect alignment with the recommendations from NHS Improvement and NHS England regarding consolidation of pathology services.

Potential affordability and value for money

Provides the best opportunity to access funding, minimises the need for NHS capital and is likely to provide a high return on investment.

The scoring should focus on the ability of the option to maximise the return on the investment in consolidation, and achieve financial savings over the current delivery model. It should also reflect that the option minimises the required capital funding from central government, NHS Improvement or the trust, but not capital accessed from other sources, including private sector capital, or any financing for non-capital routes. Payment of these should be reflected in the return on investment.

Control and governance

Allows the trust to retain appropriate control and governance of the service.

The scoring should focus on the need for the trust to retain suitable control and governance of the service. This may not mean full control of the service, but control needs to be sufficient to prevent adverse impacts on patient care.

Appendix 3: Financial model assumptions

For the purpose of discounting values, an inflation rate of 2% and a cost of capital of 3% have been assumed, giving a compound discount rate of 5.06%.

Cost inputs for the financial model

Equipment, reagents and consumables

Equipment, reagents and consumables represent one of the largest cost areas for a laboratory. They are normally purchased through managed equipment service contracts, which are regularly extended beyond their initial life. Significant savings can be made in this market through better procurement of deals and consolidation of volumes. In addition, market prices have fallen by around 10% in recent years. This significant level of savings can be achieved simply by re-procuring contracts, and as such is reflected in the As Is model.

In addition, consolidation of volumes achieves savings through economies of scale in procurement. Discussion and soft-market testing have indicated that an additional 5% to 13% saving can be realised through group purchase of contracts, depending on the TOM.

Given the chosen TOM, it is predicted that a saving of [X]% can be realised on the current equipment contract spend.

Table A3.1: Real equipment, reagent and consumable values

	Current	As Is Scenario	Target Operating Model
Equipment, reagents, consumables (real)	.	.	.

Logistics

Consolidated solutions are likely to require additional logistics routes. The cost of a new trunk route – based on soft-market testing is estimated to be £50,000 per annum.

For the TOM, it is estimated that an additional [X] trunk routes are required, at a cost of [£X]. This is in addition to the current logistics costs of the laboratory.

Pay costs

[To be clarified with the team producing the numbers.]

Estates

Consolidation of testing between sites realises a net space across the sites. The volume of space saved depends on the level of consolidation. Under the TOM [delete as appropriate]:

- **Outsource model:** potential to reduce the estates footprint if the partner consolidates testing at its central laboratory.
- **Thin joint venture:** potential to reduce the estates footprint if the partner consolidates testing at its central laboratory.
- **Thick joint venture:** potential to reduce estates footprint (by 10% to 15%) if the trusts consolidate work across their laboratories. Alternatively, the trusts may decide to consolidate services at either an on-site or off-site hub location. Both are likely to save additional space, but this is likely to be greatest for the on-site hub option as it combines a hub location with an essential services laboratory (ESL).
- **NHS partnership:** as for the thick joint venture.
- **Capital investment joint venture:** as for the thick joint venture.

[Please provide information on potential plans for re-use of any space freed up as part of the process.]

Appendix 4: Ownership shares

The proposed method for calculating the ownership shares of each owner trust in a joint venture. This applies to the following commercial models:

- thin joint venture
- thick joint venture
- NHS partnership
- capital investment joint venture.

Where two companies are formed, the respective ownership shares must be calculated separately for each of the companies.

Rationale

The rationale for the method is to identify and value each organisation's contributions to the joint venture at its time of establishment. Value can be defined as contribution forgone for work transferred into the joint venture or via the exclusive use of key assets, be they staff or equipment.

Value is not intended to be attributed to those services used on an arm's length basis – for example, renting space from a trust as this obligation will pass to the joint venture at the time of establishment.

Respective contributions to be valued

The table below sets out the proposed contributions from each trust that are the basis of valuing the ownership shares.

Contribution	Description	Valuation method	Org X (£)	Org Y (£)
Key executive management staff	Value the contribution of existing senior managers (director level) from the organisations to both the creation of the joint venture and then as part of the executive team operating the new service.	Two elements to valuing this contribution: <ul style="list-style-type: none"> agree with the finance leads of the project who the key executive staff have been and their contribution to establishing the joint venture value the appointments to the joint venture executive management team from each trust. 		
Land or other assets	If any organisation contributes, for no cash consideration, any land or other asset for the exclusive use of the joint venture, this will be valued as attributed to the respective trust.	Any land or other asset made available in this way is valued at its existing book value.		
Capital investment	If any organisation agrees to a capital investment as part of the formation of joint venture this is attributed to the respective organisation. This includes any planned capital expenditure within the predicted lifespan of the joint venture as agreed by all parties at formation.	Any initial investment is valued at the current £ cost. Future capital investment is discounted by an agreed compound discount rate, taking into account the relevant inflation rate and cost of capital.		

Pathology equipment	Any pathology equipment required by the joint venture and made exclusively available to the new organisation will be valued.	Initially an estimate is based on the entire inventory (asset register) value of pathology equipment held by each organisation. This valuation is refined once the final pathology equipment requirements of the joint venture are agreed.		
IT equipment	As above but for IT equipment.	As above.		
Working capital	Any initial start-up working capital agreed to fund the joint venture by the organisation is valued and attributed to that organisation.	This is determined when the detailed three-year operating plan is developed by the joint venture and agreed by all organisations.		
Stranded costs	An organisation may have a stranded cost as a result of relocation of any laboratories. This will be considered as part of the valuation exercise given that the organisation will take on a liability in establishing the joint venture. Stranded costs are agreed with all organisations before the joint venture is formed.	Proposed that stranded costs are valued at the cost for the following 12 months when they become redundant. This gives the respective organisation time to redeploy, re-use or remove them.		
		Total (£'s)		
		Total (%)		

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