

Consolidated pathology network due diligence guide

December 2017

We support providers to give patients safe, high quality, compassionate care within local health systems that are financially sustainable.

Introduction

This document clearly defines those areas of due diligence that trusts consolidating their pathology services need to consider when developing and finalising network solutions and commercial terms. Due diligence is a vital part of any healthcare transformation but consolidations present inherent challenges for trusts, including the formation of the desired operating model and the governance to control it. There are also constraints around capital and the internal resources required to deliver the necessary changes. Networking failures have been traced back to inadequate due diligence.

About 130 NHS trusts and foundation trusts provide their own pathology services, often using outdated operating models that need investment in premises, IT and equipment. This also exacerbates competition for increasingly scarce staff. The Carter reports¹ into pathology optimisation have recommended the consolidation of pathology laboratories to maximise existing capacity and savings from economies of scale. This recommendation is endorsed by international and NHS evidence that the sustainable pathology services resulting from consolidation and modernisation increase both quality of service for patients and efficiency.

We are looking for an increase in ambition behind and speed of consolidation of pathology services across the NHS, The Carter reports propose consolidation by introducing a 'hub and spoke' model whereby high volume, non-urgent work is transferred to a central laboratory to maximise benefits through economies of scale. Spoke laboratories, referred to as essential service laboratories (ESL), then provide low volume urgent testing close to the patient.

We will update this guide regularly to reflect new information regarding commercial and governance structures in the context of consolidated pathology services.

Disclaimer

We provide guidance only and you should seek further advice on your proposed model's exact due diligence requirements.

¹ [Report of the Review of NHS Pathology Services in England](#) (DH 2006)
[Report of the Second Phase of the Review of NHS Pathology Services in England](#) (DH 2008)
[Operational productivity and performance in English NHS acute hospitals: Unwarranted variations](#) (DH 2016)

Effective due diligence for consolidation of services

This guidance has been compiled using laboratory management experience and expertise, review of several case studies of pathology consolidation and input from trust executives who have been through the consolidation process, both successfully and unsuccessfully. It has been reviewed and approved by the National Pathology Optimisation Delivery Group which has broad representation from the pathology industry, including the Royal College of Pathologists (RCPATH) and the Institute of Biomedical Scientists (IBMS).

Effective due diligence is necessary in any contracting transaction where service provision moves between legal entities or the delivery model changes. A clear and accurate baseline of operational performance, governance, risk and financial position is vital to success. The best due diligence is a process that involves substantial interactions and discussions. Reliance on each party fully disclosing its baseline position will find factors that support the project and reveal earlier in the process those that will be more challenging to overcome. Operational and financial transparency involving subject matter experts with board oversight is vital to keep the process focused on the aims of the change.

Due diligence in healthcare is complicated and extends beyond the usual financial framework of due diligence. When moving towards a networked pathology service the following areas need to be assessed:

- operational (including stakeholder relationships)
- financial
- commercial
- IT (where all the IT infrastructure and critical links are assessed)
- workforce
- integrity (exposure to legal, regulatory risk is assessed)
- values and behaviours (organisational culture).

Individual trust boards need to set out the data and other evidence that demonstrates the organisation has assessed the proposed network, understands the risks and has effective mitigation for these before transformational change.

Key steps

1. Start early – ideally before governance agreements are developed

Entering into a non-disclosure agreement (NDA) at an early stage allows the true organisational benefit to be identified. Where governance agreements need to be set before due diligence, you need to ensure caveats allow for this and that transaction terms are not locked until due diligence has concluded.

2. Engage with senior leadership and subject experts

Open and frank discussions with senior leadership and subject experts should explore the key concerns. Strong senior leadership can both focus attention where it is needed and empower others to be open and transparent. Subject experts are wider than the laboratory and operational teams; quality and governance (laboratory and trust level), procurement, finance, IT, logistics, legal and expert external consultants should all be engaged to support due diligence.

Communication and HR expertise should also be used to develop messages alongside the process to facilitate constructive dialogue.

3. Develop a review plan

A clear plan is needed, particularly because the due diligence process is complex and often presents resourcing issues for key members of the programme team. This plan should cover the entire service but allow time to explore issues as they are discovered. The following must be included (see also Table 1 below for more detail):

- legal
- financial
- assets
- regulatory
- quality
- environmental (estate, infrastructure and equipment)

- contracts
- workforce
- liabilities
- litigation
- identity.

4. Monitor progress against the plan

Progress should be monitored locally by the project team and at board level. Using a sub-board assurance structure can help with prompt escalation of key issues.

5. Understand the non-negotiable positions and critical path for patient-focused service delivery

The team commissioned to undertake the due diligence needs to be empowered and equipped to tackle issues as they arise. Due diligence can identify failings in current service delivery and board members need to be aware that some of these may need to be rectified before transformation can start. From the outset it should be recognised that there may not be a 'pass or fail' threshold for certain decisions; these should be flagged for more detailed contractual considerations and negotiations.

6. Maintain focus on the purpose of due diligence

Due diligence can be time consuming and by its nature is detail driven. The governance structure needs to allow the aims of the review to be met and met in a way that means the programme can proceed to its next phase. Due diligence should shape the operational target, key priorities and contractual model. It should not be used to expedite 'closing the deal'. What you learn from the due diligence process should be retained by including this in a baseline risk register for the future operating model.

7. Navigating politics

Due diligence can stir up sensitive issues for individuals and/or the organisation involved in the process. The timing of tackling the different elements (see Table 1 below) of the due diligence needs to be considered. A board sub-committee or a non-executive board member can give the process useful support at times of potential sensitivity or tension.

Table 1: Due diligence review plan

Element	Description	What to consider?
Legal	What/who is the transferring legal entity?	See Legal watchpoints guide in the NHS Improvement pathology toolkit
Financial	<p>To understand in detail the current operating costs and obligations</p> <p>To understand, agree and validate the baseline activity data</p> <p>To understand the revenue and funding sources</p>	<p>To understand in detail the current operating costs and obligations</p> <p>To understand in detail any future cost liabilities</p> <p>To understand length and term of ongoing liabilities, including revenue/income and outgoings</p> <p>To understand the scope of the service inclusion – that is, staff, equipment, logistics, portering, IT, infrastructure</p>
Regulatory	<p>To understand the current regulatory position</p> <p>To understand extant regulatory risks and issues</p> <p>To understand future regulatory requirements</p> <p>To review current monitoring process</p>	<p>To understand all requirements for the future operating model options</p> <p>To clarify the originating organisation’s regulatory risks and issues, and identify those that are mitigated and those that are not.</p> <p>To understand requirements from: Medicines and Healthcare products Regulatory Agency (MHRA), the Care Quality Commission (CQC), Human Tissue Authority (HTA), Health and Safety Executive (HSE), NHS Improvement and equivalent bodies (consider also, HM Revenue & Customs (HMRC) and Home Office for import and drug holding licences if the legal entity changes)</p> <p>To consider systems and processes outside the laboratory – for example, IT systems</p> <p>Gap analysis against published standards</p>

Quality	<p>To understand current quality and accreditation position</p> <p>To understand the extant quality risks and issues</p> <p>To understand future quality requirements</p> <p>To review current monitoring process</p>	<p>To understand all requirements for future operating model options</p> <p>To clarify originating organisation's quality and accreditation risks and issues, and identify those that are mitigated and those that are not</p> <p>To understand requirements from: MHRA, UKAS (the UK's national accreditation board), European Federation for Immunogenetics (EFI), HTA, RCPATH, IBMS, UK External Quality Assessment Services (UK NEQAS) and equivalent bodies</p> <p>To consider systems and processes outside the laboratory – for example, IT systems</p> <p>Gap analysis against published standards</p>
Assets	<p>To understand current asset and inventory baseline</p> <p>To understand current asset and inventory risks and issues</p> <p>To understand known future requirements</p> <p>To understand ownership of current assets and inventory</p>	<p>Clear, concise, detailed asset register – Have all organisations accounted for equipment in a consistent way (that is, using the same accounting standard)?</p> <p>Clear understanding of ongoing and future maintenance costs and requirements</p> <p>Life and life cycle requirements of current equipment</p> <p>Single points of service failure</p>
Environmental	<p>To understand current estate and laboratory environmental baseline</p> <p>To understand current estate and laboratory risks and issues</p> <p>To understand known future requirements</p>	<p>To understand liabilities of landlord and tenant</p> <p>To understand fixed estate infrastructure versus laboratory equipment</p> <p>To understand requirements for HSE – Category 3 containment units, autoclaves, etc</p> <p>To understand legal obligations in terms of waste disposal and</p>

	To understand ownership of estate	environmental agency licence holding (eg radioactive disposal licences)
Contracts	<p>To understand current terms of contract</p> <p>To understand scope and reach of contracts</p> <p>To understand current commissioning agents</p>	<p>To understand who the contracting authority is</p> <p>To understand tenure and termination clauses or penalties</p> <p>To understand who holds:</p> <ul style="list-style-type: none"> • primary care contracts • secondary care contracts • third-party contracts • nationally commissioned contracts • screening/Public Health England contracts
Workforce	<p>To understand current workforce, skill mix, number, contracts, working patterns, temporary resource</p> <p>To understand engagement and change process for all organisations</p>	<p>Local, regional and national workforce requirements. Identification of key skills or key requirements for the network</p> <p>Status of provider and operating model construct – public or private. If private, does it have provider status for pensions?</p>
Liabilities	To understand the liabilities, scope, tenure and reach of liabilities	Clear understanding of handover points of estates and equipment, processes and pathways
Litigation	To understand the position	Who owns the process or pathway?

Contact us:

NHS Improvement

Wellington House
133-155 Waterloo Road
London
SE1 8UG

0300 123 2257

enquiries@improvement.nhs.uk

improvement.nhs.uk

Follow us on Twitter [@NHSImprovement](https://twitter.com/NHSImprovement)

This publication can be made available in a number of other formats on request.