

MIDLANDS AND EAST 2 PATHOLOGY NETWORK STRATEGIC OUTLINE CASE

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Executive Summary

The purpose of this Strategic Outline Case (SOC) is to secure organisational Board support for the next steps in considering the optimisation of pathology services across the Midlands and East 2 (ME2) Pathology Network. It has been developed with the full support and input of the member organisations (and their stakeholders) and is the Network's response to NHS Improvement's expectation that further consolidation of pathology services, as heralded in the Carter Review of 2006, and later in the NHS Long Term Plan would take place across the NHS. NHSEI's expectations were communicated to NHS providers of pathology services in September 2017 and most recently reiterated in a letter to ICS and Trust Executive Teams in April 2022 which outlines target milestones for network development in line with NHSEI's Pathology Network Maturity Matrix. Midlands and East 2 (ME2) pathology network partners have been working collaboratively under a Memorandum of Understanding since 2019

Optimisation of pathology services across the Midlands and East 2 (ME2) pathology network may deliver financial benefits, however it offers other more significant and advantageous gains such as improving robustness and sustainability of clinical services, harmonising equity across the network, raising quality standards and providing opportunities for continuous improvement and learning.

Network discussions have resulted in the generation of five options, it is now proposed that three of those options are taken forward for further development and appraisal culminating in the production of an Outline Business Case (OBC).

Organisational Boards are asked to approve the Strategic Outline Case and confirm their support for development of the shortlisted options, including the modest investment set out in section 9 of this Strategic Outline Case, and to approve development of the Outline Business Case.

1. Introduction

The purpose of this strategic outline case is to describe the background, current context and proposals in respect of pathology services across the member Organisations of the Midlands and East 2 (ME2) Pathology Network, set out the drivers for change, including a summary of the challenges and opportunities that face the services in scope and, importantly, to seek member Trust Boards' approval for the development of an Outline Business Case.

The Network must now gain approval from member Trust Boards to develop an Outline Business Case for the rationalisation of pathology services across the Midlands and East 2 (ME2) Pathology Network. The reasons for delays in achieving this to date are multifactorial and considered as part of this Strategic Outline Case but can be summarised as the challenges presented by the Network's geography and size, the lack of resource to develop a strategic case and impacts attributable to the COVID-19 pandemic response. The commitment required from Boards to develop the Outline Business Case will include resourcing such a step and this is addressed through this proposal.

Oversight of the Strategic Outline Case development has been undertaken by the ME2 Pathology Network Implementation Board, Chaired by Tony Campbell, Deputy Chief Executive Officer of DHU Healthcare who is the Senior Responsible Officer (SRO) for the Strategic Outline Case. The Strategic Outline Case was considered by the Network Implementation Board at its 17th May 2022 meeting and the Network Executive Steering Group at its 28th March 2022 meeting and supported by all members.

2. Project rational and context

Nationally we do not have sufficient diagnostic provision to deliver the level of service desired by all service users. There are insufficient resources to invest in all Trusts to maintain world class pathology capability. The formal creation of the Midlands and East 2 Pathology Network will enable a more strategic and system level approach to delivering pathology services in an efficient and coordinated manner. The creation of a Pathology network spanning the East Midlands provides an exciting opportunity to not only future proof valuable services but save multiple

millions in procuring at scale together and developing new collaborative ways of working. The development of the network will aim to ensure we have well trained staff, appropriate resources, resilience and efficiency. The Midlands and East 2 Pathology Network has the potential to be the exemplar network to work for. It provides a depth and breadth of opportunity at both individual and organisational level to align clinical services from each partner Trust and to draw upon best practice for the benefit of all stakeholders within the network.

The Midlands and East 2 (ME2) Pathology Network is 1 of 29 within England, where the size and scope has already been agreed and for organisational purposes includes all Trusts summarised. NHSEI's expectations were communicated to NHS providers of pathology services in September 2017 including the view that for the Midlands and East 2 Pathology Network, financial modelling indicated that the Network could potentially release £11.4m in efficiency savings. The efficiency savings potential identified by NHSEI is based on data outputs from the Model Hospital. The collective pathology network workforce and non-pay costs for Midlands and East 2 (ME2) Pathology Network are circa £200m per year (**Table 1**).

Trust	Total cost (million) Pay and non-pay	Non pay cost (million)	Pay cost (million)
<i>National Median</i>	<i>17.75</i>	<i>8.57</i>	<i>9.18</i>
Chesterfield*	9.61	5.15	4.46
UHDB*	31.23	14.43	16.8
Kettering	12.93	7.32	5.61
Leicester	38.75	17.19	21.56
Northampton	17.01	9.73	7.28
Nottingham	43.27	21.64	21.63
Sherwood	14.13	8.2	5.93
Path Links:** ULHT NLAG	34.78	19.27	15.51
TOTALs	£201.71	£102.93	£98.78

Table 1: Current pay and non-pay costs (Model hospital whole service 2019):

*Derbyshire Pathology – Joint venture hosted by University Hospitals of Derby and Burton

**Path Links – Pathology service in Lincolnshire hosted by Northern Lincolnshire and Goole.

Pathology in the East Midlands delivers over 110 million tests a year from 15 laboratories in 9 Trusts and employs ~2400 staff (**Table 2**).

Trust	Number tests 19/20 (million)	No Requests (million)
<i>National Median</i>	9.26	1.56
Chesterfield*	6.84	1.33
UHDB*	25.07	3.59
Kettering	8.44	1.56
Leicester	21.71	3.32
Northampton	7.29	1.55
Nottingham	20.26	3.67
Sherwood	7.02	2.95
Path Links:**	23.86	4.08
ULHT	6.97	2.06
NLAG	16.89	2.02
TOTALs	113.65	20.72

Table 2: Number of tests and requests per year (Model hospital whole service 2019)

*Derbyshire Pathology – Joint venture hosted by University Hospitals of Derby and Burton

**Path Links – Pathology service in Lincolnshire hosted by Northern Lincolnshire and Goole.

The Pathology service provision across the East Midlands is complex. Past attempts to unify comparative services across the whole region have struggled to apply models which work elsewhere nationally. Significant variation across the network exists in terms of costs per test (**Table 3**) and opportunities exist to improve this situation.

Trust	Total cost (million) Pay and non-pay	Number tests 19/20 (million)	Cost per test 19/20- whole service (£)
<i>National Median</i>	17.75	9.26	1.97
Chesterfield*	9.61	6.84	1.40
UHDB*	31.23	25.07	1.25
Kettering	12.93	8.44	1.53
Leicester	38.75	21.71	1.79
Northampton	17.01	7.29	2.33
Nottingham	43.27	20.26	2.14
Sherwood	14.13	7.02	2.01
Path Links:**	34.78	23.86	1.46
ULHT		6.97	
NLAG		16.89	
TOTALs	£201.71	113.65	£1.77

Table 3: Cost per test – Whole service (Model hospital whole service 2019)

The Pathology service response to COVID-19 within the Midlands and East 2 region has provided a unique opportunity to work together, providing a blueprint to inform an operational model which best fits the complexities of the Midlands and East 2 region and the attendant stakeholder requirements.

The network has established four “clusters” who work under different governance models;

- **Derbyshire Pathology** (University Hospitals of Derby and Burton NHS FT & Chesterfield Royal Hospital NHS FT) has formed as a contractual joint venture between CRH & UHDB, hosted by UHDB.
- **Path Links** (Northern Lincolnshire & Goole NHS FT and United Lincolnshire Hospitals NHS Trust) is a single managed network hosted by Northern Lincolnshire & Goole NHS FT. It has been in place for over 20 years and is renowned nationally for its success in doing so.
- **Nottinghamshire** (Nottingham University Hospitals NHS Trust and Sherwood Forest Hospitals NHS FT) have a joint Pathology Board and Memorandum of Understanding.
- **LNR** (University Hospitals of Leicester, Northampton General Hospital NHS Trust and Kettering General Hospital NHS FT) has a joint Pathology Board and Memorandum of Understanding.

The aim of the network is to build upon these “clusters” as the emergent operating model so all sites can benefit from the rewards working as a combined network can provide. The response to the COVID-19 pandemic most clearly demonstrated how providers can work together effectively at scale and pace to achieve common objectives.

The four cluster arrangement aligns with ICS geographical footprints therefore making strategic sense and facilitates the network developing incrementally over time in order to overcome the complexities of forming a network of this size with a significant number of member organisations involved. The pandemic response from Pathology services has provided a unique opportunity for us to work through and develop plans based on evidence and experience, effectively testing the effectiveness and sustainability of the four cluster model we propose taking forward.

Collaborative working and shared objectives have been the driving forces behind our coordinated approach.

3. NHSEI Pathology Network Maturity Matrix – ‘When is a network a network’

The NHS Long Term Plan committed the NHS to establishing Pathology networks across England by December 2021. Realising the benefits of a Pathology Network will take time and, as networks adapt to the new way of working to deliver the expected transformation of Pathology services, they will need to progress along the maturity curve. To assist Networks, regions and the national team with this progression, the Pathology Network Maturity Matrix Tool was introduced as a means of objectively assessing maturity aligned to five progression stages; Pre-emerging, Emerging, Developing, Maturing and Thriving.

The tool identifies seven domains that characterise a Pathology Network formation and as networks develop through implementation, a description of indicative deliverables is offered in each matrix for the domain.

As such each matrix will;

- Provide networks with content to self-assess their current position
- Highlight key areas and topics for consideration at each stage of network development
- Support decision making within the network

The seven domains are;

- Governance
- Leadership
- Operational
- Quality
- IT and Digital
- Workforce
- Shared Supply Chain

Midlands and East 2 (ME2) pathology network completed the self-assessment and submitted its response to NHSEI in December 2021. All pathology networks were

expected to fall within the later 3 stages in their overall scoring by the end of 2021. The ME2 network scored 11 placing it within the 'Emerging' stage with an initial NHSEI challenge to achieve 'Developing' by the end of March 2022 and 'Maturing' by March 2023. Trusts were notified by NHSEI in April 2022 that these timescales have now been revised. The revised challenge is to achieve 'Developing' status no later than December 2022. In order to meet the 'Developing' status challenge the network needs to score a minimum of 15, of which development of this strategic outline case plays a fundamental part in order to secure points across multiple domains.

4. Strategic case for change

Pathology is an essential clinical service for all acute and primary care healthcare providers with 70-80% of clinical decisions requiring input from pathology and 95% of chronic disease pathways reliant upon pathology. As such it is critical to delivering a high quality clinical service which assists in patient flow in acute settings, reduces inappropriate bed occupancy, and helps to avoid unnecessary admissions and fewer secondary complications that meet the needs of patients and clinicians. One of the key purposes of the national pathology consolidation programme is to 'deliver the test, with the right advice at the right time, utilising the right approach and technology'

Operational Strategy

Reducing variation in operational practice facilitates;

- Consistency of method and standardisation of operating procedures
- Supports network based accreditation
- Reduces cost base

This work can be guided using information and data from GIRFT and model hospital.

One of the key aims of this strategy will be to ensure effective utilisation of resources and that each site has the benefits of accessing the wider network for support in service delivery. Optimising testing through rationalisation will be required, as not all laboratories will have the resources or the requirement to provide a full range of tests into the future. The scope of tests required will only widen, therefore laboratories will

have to consider what to optimise in order to have full access to the tests required to support the increasing diagnostic demands and complexities.

The development of Midlands and East 2 (ME2) Pathology Network requires a substantial development programme with the network achieving 'Developing' on the NHSEI Network Maturity Matrix no later than 31st December 2022 (an NHSEI challenge). A gap analysis detailing how the network will reach 'Maturing' by the end of 2024/2025 needs to be submitted to NHSEI by 30th June 2022. Progress reports and proposals for approval will be required to go to member Trust Boards on a regular basis.

Implementation of the Midlands and East 2 Pathology Network should be carried out incrementally to minimise operational risk. There is sufficient evidence of failure in other pathology consolidations so there will need to be clear and methodical transition planning. It should also be recognised that consolidation of pathology is a resource intensive project that requires a dedicated team working alongside management, clinical and operational teams to deliver a successful outcome. NHSEI has identified the following project resources as key enablers in developing a network. These roles, with the exception of the SRO and Clinical Director, should be full time roles:

- Senior responsible officer for the network
- Clinical Director/Lead
- Network Operations/ integration director
- Procurement Lead
- Programme Manager
- Quality Lead
- Workforce Lead
- Digital programme Manager
- Programme support officer
- Network Admin support
- Finance & analytical lead
- Communications lead

Currently many of these roles are covered on a voluntary basis, where existing senior leaders within the pathology network are undertaking multiple roles that are not sustainable. The total recurrent cost will be approximately £1,630,000 split proportionally across each member Trust.

Clinical Strategy

'Getting it right first time' (GIRFT)(NHSEI, 2021) is a national programme designed to improve the treatment and care of patients through in-depth review of services, benchmarking and presenting a data-driven evidence base to support change. The national Pathology GIRFT report was published in 2021 and makes 21 recommendations. The Midlands and East 2 (ME2) Pathology network Clinical Strategy is underpinned by those national programme recommendations with 8 listed below selected as our top clinical priorities;

- Urgently investigate acute kidney injury (AKI) flags to understand variation.
- Develop an integrated venous thromboembolism (VTE) pathway for network use.
- Interrogate all tests to ensure all are based on a valid clinical question, necessary, appropriate and sufficient to answer that question. Starting with urine sample requesting.
- Interrogate usage and wastage data for blood products, and address identified problems.
- Review and develop a robust Immunology service in the Network.
- Establish electronic requesting and messaging as standard in all labs and with all requestors.
- Embrace and support innovation in pathology, including digital pathology and improved decision support.
- Establish a proactive, integrated approach to ensure new technology can be adopted at speed, procuring as a network to deliver a standardised, high quality and cost effective service.

The Midlands and East 2 (ME2) pathology network clinical strategy focuses on ensuring the right test is available for the right patient at the right time with the right result. In order to attain this, the network first needs to ensure its clinical workforce is robust, removes duplication and works toward sustainability of its services. Particular

areas of focus are Cellular Pathology and Immunology where national staffing shortages exist and network optimisation provides opportunities for mutual aid and innovative ways of working to support each other. The network will define additional clinical priority areas as a means to work together and develop the network incrementally.

Procurement Strategy

The key aim of the Midlands and East 2 (ME2) procurement work stream is to identify opportunities for network procurements to deliver a standardised, high quality and cost effective service.

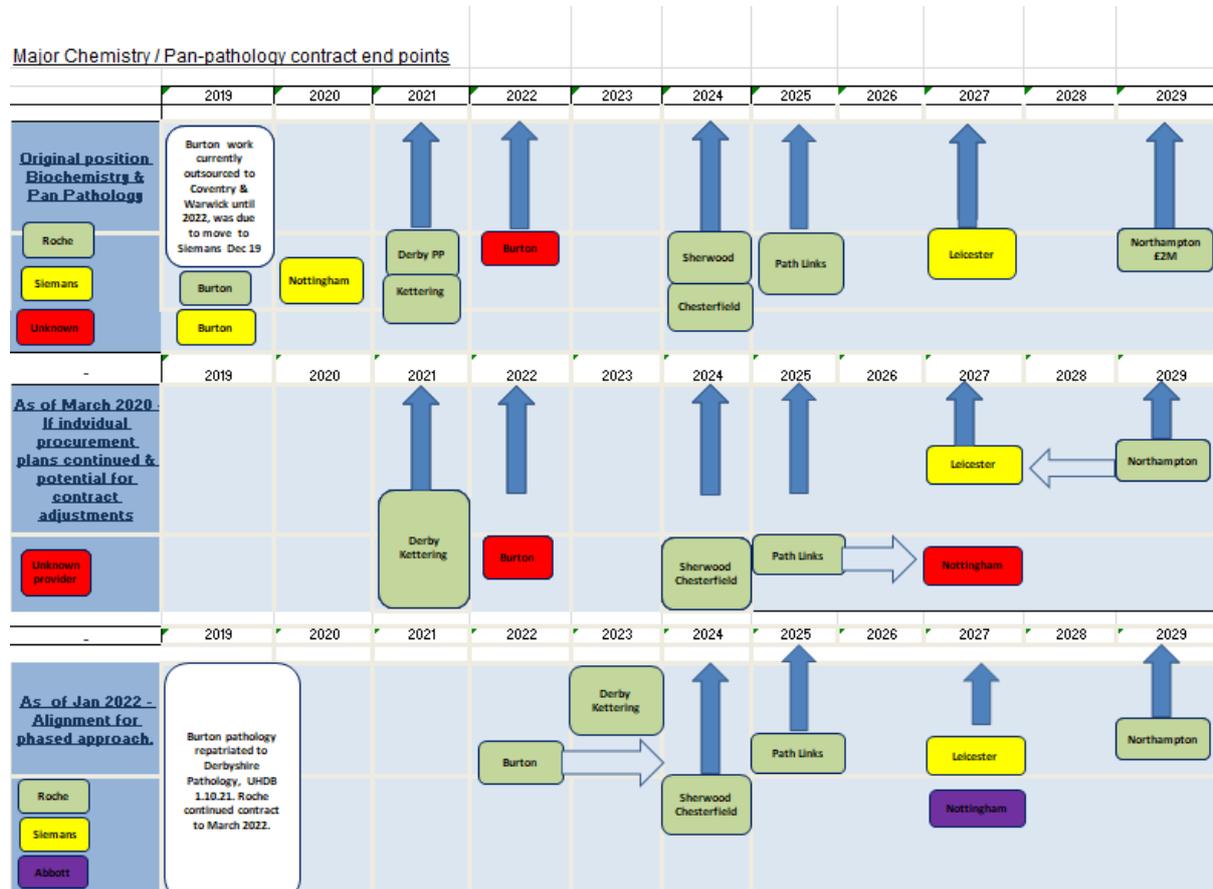
Whilst currently operating within an existing network or single site pathology service provider, the group aims to jointly procure as one network incorporating all Midlands and East 2 partner organisations.

The procurement work stream group aims to procure equipment and services on behalf of its ME2 network partners to support;

- Short, medium and long term alignment of major contracts.
- Standardisation of equipment platforms for resilience.
- Higher specification of equipment to improve the quality service across the network.
- Delivery of financial efficiencies associated with economies of scale and service reconfiguration.
- Value added contracts to improve service resilience (e.g. network engineer support)
- Reduction in variation of services to improve consistency of patient pathways across the network.
- Widening the scope of expertise through training/shared learning of standardised platforms.

Recognising the need to maintain service delivery during the early stages of the formation of the Midlands and East 2 network, some key major procurements have continued but the overarching vision is still in place.

Significant progress has been made in understanding the overall position of the major pathology contracts of the partner organisations. During the COVID pandemic a number of large scale procurements were paused and this presented opportunities for the group to work collaboratively to further align contracts as indicated below.



Taking learning points from the COVID pandemic and the associated challenges to the supply chain, a phased procurement approach is being proposed.

Phase 1 includes Derbyshire Pathology (Derby, Burton and Chesterfield), Kettering, Path Links and Sherwood but will not preclude other partners from joining the contract at a later date.

In the absence of delegated authority for financial decisions, the Trust boards of each Midlands and East 2 network partner will need to fully support the joint procurement approach in advance of the commencement of the procurement process.

All of the four main framework providers reviewed, have confirmed that it is possible to jointly procure equipment to achieve the aims of the procurement work stream whilst retaining separate contracts for individual Trusts or subnetworks within Midlands and East 2.

Digital Strategy

The ME2 digital strategy is focused on three levels:

- 1 Network development and opportunities for quality, efficiency, and affordability improvement
- 2 Making the best use of an extensive range of services and expertise within the network, providing patients and service users with access to enhanced, responsive, standardised and seamless pathology diagnostic services
- 3 Utilising digital resources to transform service delivery, collaborative working and resilience

Whilst recognising varying degrees of digital maturity across the network, all pathology network partners share a common vision and purpose to developing the described digital road map.

Close collaborative working established throughout the COVID pandemic not only highlighted the absolute need for wider integration and interoperability but also demonstrated gaps in service provision particularly in wider health community and social care settings

INTEROPERABILITY

The development of an ME2 Pathology Integration Engine (PIE) is fundamental to addressing both inter-provider operability and standardisation.

Capturing all network digital test request inputs, the PIE has the capacity and capability of translating all non-standardised inputs into a common standardised output. PIE routing algorithms will seamlessly distribute test requests to any network provider, irrespective of source location, creating a 'request anywhere & test anywhere' concept.

This will create an opportunity to maximise efficiency, improve standard practice and will support the development of an operating model for the network that is right for the East Midlands' patients and service users.

The construct of the PIE programme is shaped to deliver:

- Open access to the extended test repertoire of the network to all service users
- Wider access to (limited) electronic test requesting in community and social care settings, e.g. for the requesting of SARS-Cov-2 tests and their subsequent electronic result availability
- Full deployment of electronic test requesting in all settings
- A standardised approach to data management accelerating and facilitating network strategic design and data driven operational, workforce and quality improvements
- Infinite scalability with extended interoperability capability between pathology networks and other regional or national services e.g. genomics

There are four key elements and deliverables of the programme:

1. PIE Development

1.1. Single test pilot

- Proof of concept and testing/validation of PIE transformation and messaging flows (test order entry – LIMS result capture)

1.2. Low Capacity and Specialist Tests

- Extension of interoperability for specific test repertoire to underpin network clinical strategy, consolidation, and rationalisation, including repatriation of outsourced test activity
- Full system scalability to provide individual laboratory business continuity measures and further underpin network clinical strategy and consolidation of more common higher volume tests

2. 'Mini' Order Comms

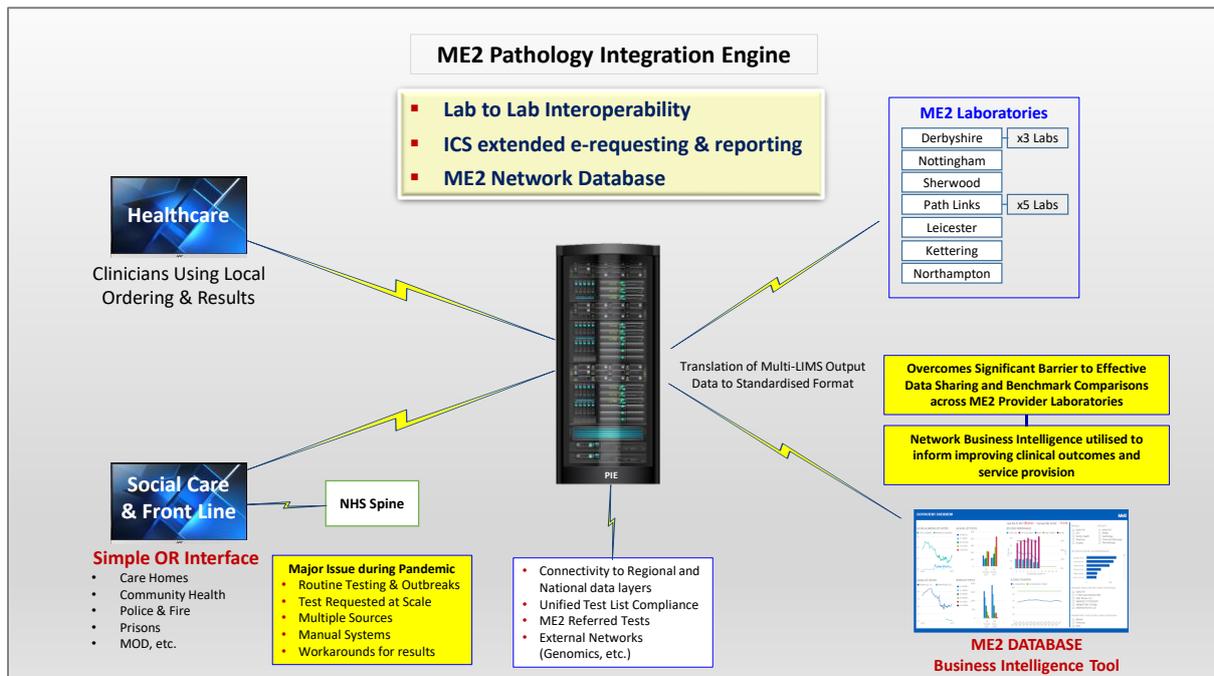
- Maximal utilisation of electronic test requesting to realise full potential of PIE and PIE database functionality
- Simple and intuitive 'limited test repertoire' system for extended use in community health and social care settings, opening service access and secure, timeliness of results reporting
- Extended test repertoire for acute healthcare setting with limited or no access to electronic requesting

3. PIE Database and Business Intelligence functions

- Multi-Trust database linkage to Business Intelligence tools to provide a standardised approach to network data management, feeding through to national data collection schemes, and driving forward network benchmarking and collaborative improvement opportunities

4. Clinical & Patient Portal

- Providing database accessibility to patients and service users at a local and regional level through the development of a user portal



The ME2 Pathology Network has been successful in receiving £1.1m national funding for the scheme. Timescale for delivery is Q3/Q4 2022-2023

DIGITAL HISTOPATHOLOGY

The ME2 Network vision is one of full digitisation of standard glass slide reporting across all providers. The plan is not only to secure the wider deployment of digital slide scanners but also to capitalise on novel digital infrastructure opportunities and artificial intelligence [AI] to transform histopathology service provision to an integrated regional model, by:

1. Full deployment of digital scanning equipment and reporting systems to all network histopathology services
2. Standardisation of digital systems and architecture to facilitate interoperability across the ME2 network, enabling and facilitating the development of WSI exchange and remote reporting
3. Developing and deploying a network digital solution allowing operational and working practice re-design, facilitating reporting anywhere (in the workplace, in any Trust, at home, etc.) and making best use of specialist and scarce clinical resource

The ME2 Network ambition is to, not only address interoperability issues between providers, but also to transform seven provider services into a single network offering

Supported by a national investment of over £8 million, all network histopathology laboratories will be digitally enabled from Q1/Q2 2022-2023

Progressing through an implementation and transformation phase, the ambition is to achieve a 'Leading' level of digital maturity by Q4 2022-2023 and progressing further thereafter.

Workforce Strategy

Staffing is a major constraint in service provision and extension of opening hours. A network workforce vision is required to meet the national aim of 'right role, right person'. There is significant variation in approach at Trust level to the modernisation of the pathology workforce and we are looking to develop a much more consistent and coherent approach together. There has always been significant staff movement around the region. Nationally we have excess equipment capacity yet increasing workforce shortages. Networking across wider geographies provides a solution to localised recruitment challenges and development of advanced scientific roles.

As a collective we can address some disparities by standardising the workforce. We want to be in a position where a band 6 has the same capability and responsibilities no matter which laboratory they are in. There is hidden talent and skills amongst our staff that could be harnessed and will ultimately improve morale and career progression. Consideration will also be given to a network wide strategy to support out of hours working.

The pathology workforce is said to be one of the most complex and heterogeneous in the NHS. This complicates service planning, particularly in relation to workforce. Advanced roles need to be part of the future operating model in order to fill the staffing gaps held by all Trusts

Training and education must complement both delivery of healthcare and sustainability of the future workforce. As a network, we hold a huge number of highly skilled, specialist and dedicated staff who could work across the network to deliver training and support in a coordinated and targeted approach.

The workforce strategy will encompass:

- Training and education
- Standardisation of roles
- Development of advanced roles

All of these areas will improve our workforce position but only if we do this as a large network approach. This work will not have longevity if done in silos.

Quality Strategy

The Midlands and East 2 (ME2) pathology network quality strategy aims to harmonise quality functions across the network to ensure user needs and requirements are met. Each partner Trust currently works to ISO15189 standards and are at varying places within their accreditation schedule. As a network we acknowledge that the road to a single quality management system encompassing all Trusts in the network is something that under several of the options under consideration is unachievable however in the longer term as the network progresses may be possible with comprehensive planning and implementation. Currently each Trust holds individual accreditation under a series of accreditation numbers **(Appendix C)**.

The key aim of the Midlands and East 2 (ME2) quality work stream is to ensure network quality inputs and outputs are standardised, resulting in high quality and cost effective services which meet user need and expectation.

Midlands and East 2 (ME2) pathology network currently operates multiple network and single organisation quality management systems with multiple software packages in use. The Quality Leads group aims to cohesively bring together QMS outputs from these systems to provide a network quality overview, identifying areas which can be harmonised immediately alongside developing a plan for aligning key functions and reporting mechanisms which align with the networks Quality Policy and overarching strategy.

Recognising the need to maintain accreditation status during the early stages of the formation of the Midlands and East 2 (ME2) pathology network, no changes to organisational legal entity have been made and individual organisations are continuing on their planned accreditation inspection schedules.

This status will remain until such a time that the network overarching quality vision is in place and sufficient elements have been harmonised to facilitate accreditation at cluster level.

A summary of the initial phased development of the strategy is outlined below;

Phase 1 – Delivered by March 2022

- Develop a network wide Quality Policy
- Develop a Quality Team structure led by a designated network quality lead
- Ensure PQAD is in use at all network sites with a review of inputs to provide standardisation and network benchmarking accuracy.
- Develop a network Quality Team meeting with formalised attendees, Terms of Reference and Agenda.

Phase 2 – Target March 2023

- Development of Network Mission, Vision and Values
- Development of network wide quality objectives and reporting mechanisms
- Review network quality management activities to reduce duplication

Phases 1 and 2 of the quality strategy are directly aligned to Domain 4 of NHSEI's Pathology Network Maturity Matrix in order to achieve 'Maturing' by March 2023.

Point of Care Strategy

The Midlands and East 2 (ME2) pathology network POCT Strategy is still in its infancy but will be developed further as part of the network outline business case.

To date the network has formed a POCT Committee which reports directly to the ME2 Clinical Reference Group and ultimately the ME2 Implementation Board. Representatives from each member Trust who hold POCT expertise attend the committee with the aim of defining ME2s POCT strategy and requirements.

Communications Strategy

The Midlands and East 2 (ME2) pathology network communications strategy has yet to be developed. Early discussions have focused on the networks identity and branding. This work stream will be developed further as part of the network outline business case. It is envisaged that staff within the network will be given the opportunity to participate in 'naming' the network to create a sense of involvement

and ownership as the network is formed. Consideration will need to be given to developing the networks vision, mission and values statements going forward.

Finance Strategy

The Midlands and East 2 (ME2) pathology network finance strategy has yet to be formally outlined. It is recognised that appointment to a network Finance Lead will be crucial in developing and implementing this work stream. Currently any funding received by the network is allocated to respective ICS' and drawn down by individual member Trusts. The finance work stream will feed into the ME2 Implementation Board and be overseen by the ME2 Executive Steering Group. As per the current working model, member Trust's retain individual autonomy and responsibility for capital to support their own service pending development of the outline business case.

5. Pathology Benchmarking

Pathology features within the 'Model Hospital', as an area of opportunity for removal of unwarranted variation. The model hospital is the key output of Lord Carter's earlier review of hospital efficiency and productivity, which identifies a potential for pathology to save £200m nationally. The NHS Long Term Plan confirms and builds on this approach. The delivery of the recommendations from the NHS Long Term Plan alongside realisation of the opportunities within the 'Model Hospital' is being led by NHSEI and there is growing expectation that the Midlands and East 2 Pathology Network makes progress on this agenda. Equally the COVID-19 pandemic has highlighted the weakness in the nation's diagnostic capability which has to be addressed.

The table below compares the cost per test per discipline for each site:

	Microbiology	Cellular Pathology	Blood Sciences
KGH	4.70	30.16	0.95
NGH	7.88	24.95	1.26
NUH	6.33	36.50	1.35
Path Links	2.19	19.19	0.61
SFH	2.37	21.59	0.88
UHDB	5.01	24.73	0.91
CRH	6.43	-	0.59
UHL	4.11	25.10	1.30
Group Median	4.70	24.92	1.30
National Median	4.57	26.46	1.14

Table 4: Cost per test by discipline for each Trust (Model Hospital; Latest published period 2019)

6. Current Position

The key milestone to moving the Midlands and East 2 region towards becoming a network is to define and agree its operating model. The emergent operating model within our network is that of a 4 “cluster” arrangement, aligned across relevant ICSs and underpinned by existing relationships, as follows;

- Derbyshire Pathology (Joint venture between Chesterfield Royal NHS FT and UHDB NHS FT)
- LNR - University Hospitals of Leicester, Kettering NHS FT and Northampton General Hospital.
- Nottinghamshire – Sherwood Forest Hospitals NHS FT and Nottingham University Hospitals
- Path Links – Northern Lincolnshire & Goole FT and United Lincolnshire Hospitals Trust – Legal entity hosted by NL&G)

Cluster	Number tests 19/20 (million)
Derbyshire	31.91
LNR	37.44
Nottinghamshire	27.28
Path Links	23.86
TOTALs	113.65

Table 5: Number of tests per Cluster

The Midlands and East 2 (ME2) pathology network is one of, if not the largest NHSEI proposed pathology network which presents a number of unique complexities.

Geographically the network encompasses nine individual acute hospital trusts over an extremely large geographical area spanning multiple ICS. The 4 cluster model we currently operate utilises existing working relationships to the networks advantage and works cohesively with the ICS footprint and patient flow.

The current network governance structure and its integration with the Midlands Pathology Board is depicted in **Appendices A** and **B**.

7. Consideration of Options

Midlands and East 2 (ME2) pathology network is the largest of the 29 consolidated pathology networks proposed by NHSEI in terms of geography, distance and proportion of tests undertaken which presents many unique challenges.

Reflecting the nature and location of pathology services in the Network area, members agreed that wholesale adoption of the NHSEI Hub and Essential Service Laboratories (ESL) or 'Spoke' recommended model was unlikely to meet the needs and aspirations of local providers and as such work was undertaken to scope and evaluate the options open to the Network which had the potential to realise the quality and financial benefits described in the Model Hospital. We recognise that while physical consolidation is important for some parts of the service, an integrated LIMS, digital histopathology, common equipment and shared procurement can deliver many of the Carter benefits through a virtual consolidation. Whichever model is chosen needs to be flexible and able to respond to new challenges. Hub and Spoke application may be considered on a bespoke basis within individual clusters or test type but not at wholesale network level.

When developing these proposals, particularly with a view to considering the long term sustainability of the arrangement, significant consideration needs to be given to the commercial model. There are 5 commercial models the network could choose to follow.

Option 1 - No change from current model

Main features: No change in overall service ownership. Individual trusts could continue to co-operate for mutual benefit on procurement etc. but would be under no obligation to do so.

Capital: Each Trust is responsible for raising the capital required or contracting with a private organisation to supply capital.

Profit and Liability: Each Trust holds their own accounts.

Autonomy: Each Trust retains individual autonomy.

Feasibility: Not feasible – Fails to develop a networked pathology service across ME2.

There is no option to not form a network; however, it is important to understand the risks of not formalising the Midlands and East 2 Pathology Network and capitalising on the excellent work already undertaken by the current member organisations;

- NHSEI has established a level of governance that would result in an inability to bid for national pathology funding streams as a result of failing to develop or under developing network strategies. In order to be in a strong position to ensure we are able to draw down from any investment coming into pathology services, we must operate in a coordinated approach.
- Continuing to operate under the existing Memorandum of Understanding (MOU) does not allow the network to mature and evolve sufficiently to realise the benefit of delegated authority from member Trusts.
- Eroding any of the cross network support that has emerged will decrease resilience and the resulting fragility of service could place individual Trusts in a precarious position with regards to their future pathology service provision.
- Business continuity and service sustainability risks sit with individual Trusts for resolution.
- Inability to benefit from economies of scale offered by potential service transformation initiatives.

Option 2 - Joint Venture / Community Interest Company

Main features: Full/Partial consolidation of pathology services. Configuration will be dependent on specialism. The incorporated organisation will have a memorandum (describing the members setting up the organisation) and articles of association (describing how the company is to be run and any benefits shared).

Capital: Through partners as per partnership agreement

Profit and Liability: Distributed to partners as per partnership agreement

Autonomy: Full autonomy

Feasibility: Potentially feasible – NHS Trusts and Foundation Trusts are free to enter into a joint venture, providing that the proposal meets competition requirements.

Joint ventures, or shared service agreements form a new structure with shared equity and governance to provide services. Risk and gain share is dependent on the partnership agreement put in place. Joint ventures between NHS organisations are comparatively rare when compared to the prevalence of the involvement of the private sector. Reasons for this are multiple, but the overarching one being that the independent sector can provide start-up capital, expertise and enterprise to accelerate the venture.

The option to form a joint venture is potentially feasible and will therefore be taken forward for detailed evaluation as part of the outline business case.

Option 3 - Outsourcing

Main features: Partnership with private provider to deliver pathology services for all providers on the same terms following a procurement process.

Capital: Each Trust is responsible for raising the capital required or contracting with a private organisation to supply capital

Profit and Liability: Each Trust holds their own accounts

Autonomy: Autonomy over outsourcing contract arrangements and KPIs only.

Feasibility: Feasible – Outsourced pathology services exist within England.

Potential pitfalls of an outsourced pathology network include;

- Clinical teams having a lack of control over the service
- Governance would be through a private company or neighbouring pathology network.
- Limited control of sample turnaround times which may impact patient flow
- Cost
- Inability to transform or improve services

Whilst feasible, the ME2 Executive Steering Group and thus network member Trusts have rejected this option as it presents unwarranted risks to services, destabilisation of patient pathways and limits development of clinical services, therefore outsourcing will not be taken forward for detailed evaluation as part of the outline business case (OBC).

Option 4 - A Hosted Organisation

Main features: Full consolidation into a single managed network hosted by a member organisation. Configuration will be dependent on specialism. This may involve the transfer of some staff from the non-host trusts to the host trust under Transfer of Undertakings (TUPE). All contracts, finance systems, liabilities and responsibilities transfer to the host trust. This structure allows for a responsive service that is well-defined commercially and where the operational management team has full control of operations at all sites. This means it has greater leverage to optimise the efficiency of the service and implement change.

Capital: Host trust is responsible for raising capital or contracting with a private organisation to supply capital.

Profit and Liability: To be shared in accordance with joint venture agreement.

Autonomy: Full autonomy as pathology operates as a division of the host trust under a delegated authority scheme.

Feasibility: Potentially Feasible – Any of the individual member Trusts could host the network. Clear operational and clinical governance structures would need to be defined.

The most common of commercial models found within networks. Midlands and East 2 is the biggest network in the country in terms of geography, patient population and staffing. Although this would be the option most likely supported by NHSEI, there are substantial barriers due to its scale that make this an unlikely achievable model. The TUPE transfer of 2333 staff, the financial obligations and HR risks associated for the host organisations are potentially too great and too distracting to reap the short terms benefits and there are no clear patient pathway flows between all locations.

Despite the risks above the option remains feasible and will therefore be taken forward for detailed evaluation as part of the outline business case.

Option 5 – Provider Collaborative

Main Features: Provider collaboratives are partnership arrangements involving at least two trusts (in this instance 9 acute Trusts) working at scale across multiple places, with a shared purpose and effective decision-making arrangements. By working effectively at scale; reduction in unwarranted variation, improved resilience and consolidation to provide better outcomes are key objectives of provider collaboratives.

Capital: Each trust is responsible for raising the capital required or contracting with a private organisation to supply capital

Profit and Liability: Each trust to hold their own accounts.

Autonomy: Decisions are subject to approval by all trusts, including clinical governance. Contracting can be utilised to support this.

Feasibility: Feasible – Requires common agreement between the Trusts.

There are 3 provider collaborative models. The models are not mutually exclusive; they can be combined or work in parallel, and one may evolve into another.

- **Provider Leadership Board Model** - Chief executives or other directors from participating trusts come together, with common delegated responsibilities from their respective boards (in line with their schemes of delegation), such that they can tackle areas of common concern and deliver a shared agenda on behalf of the collaborative and its system partners. To ensure effective oversight of the provider leadership board, trusts should consider how to involve their non-executive directors in providing scrutiny and challenge.
- **Lead Provider Model** - A single NHS trust or foundation trust takes contractual responsibility for an agreed set of services, on behalf of the provider collaborative, and then subcontracts to other providers as required.
- **Shared Leadership Model** - Members share a defined leadership structure in which the same person or people lead each of the providers involved, with at least a joint chief executive.

The provider collaborative model would formalise the current cluster arrangement, allowing those relationships to build and for teams to focus on current operational challenges.

All trusts providing acute and mental health services are expected to be part of one or more provider collaboratives by April 2022. Choosing to form a network provider collaborative realises this objective for all partner organisations involved.

Governance arrangements supporting provider collaboratives are under development as such if this option is selected the network will need to learn and evolve as information becomes available.

Option Appraisal overview:

Based on an initial feasibility appraisal it is recommended that Options; 2 (Joint Venture), 4 (A Hosted Organisation) and 5 (Provider Collaborative) be taken forward for detailed evaluation through an Outline Business Case (OBC).

8. Future Network Management Model

The purpose of any reconfiguration of activity will be to sustain quality over the long term whilst ensuring the best use of resources. The Network recognises that changes to delivery model may result in differential impact between organisational members. This is likely to require the network to describe partnership and governance arrangements that ensure an appropriate distribution of the resulting risks and benefits. The options for such arrangements will be explored at OBC phase for final conclusion in the Full Business Case (FBC).

Autonomy

Tight timelines prescribed in the NHSEI Network Maturity Matrix mean the network leadership team will seek a level of delegated authority to develop the network managed on Trust member organisations behalf through their nominated representatives via the ME2 Executive Steering Group. Examples of delegated authority in practice may include;

- Co-ordination of network level Cost Improvement Programmes (e.g. Procurement)
- Optimisation of referred test work stream

The network would also seek autonomy to allocate realised cost efficiencies toward recruitment of its network roles.

9. Project Structure and Resourcing

The resources outlined below are required in order to support development of the options appraisal in the form of the outline business case and to progress development of the network in order to adhere to the timescales set by NHSEI in terms of progress against the network maturity curve. Following completion of the OBC and FBC the recurrent resources will be required for the on-going co-ordination of the network.

Maturity Matrix Domain	Roles	Estimated Cost (£)	20% add on costs (£)
Leadership Team	Senior Responsible Officer (0.2 WTE)	25 - 30	5 - 6
	Programme Manager 8C (1 WTE)	66	13.2
	Programme Officer 6 (1 WTE)	35	7
	Admin Support 4 (1 WTE)	23	4.6
	Network Operational Lead 8C/D (1 WTE)	66 – 90	13.2 – 18
	Clinical/Medical Director	2 – 6 PAs	4 - 12
	Network Procurement Lead 8C/D (1 WTE)	66 – 90	13.2 – 18
	Network Digital/IT Lead 8C/D (1 WTE)	66 – 90	13.2 – 18
	Workforce Lead 8C/D (1 WTE)	66 – 90	13.2 – 18
	Communications Lead 8B (1 WTE)	64	12.8
	Finance Lead 8C/D (1 WTE)	66 – 90	13.2 – 18
Quality	Quality Lead 8C (1.0 WTE)	66	13.2
Digital	Programme Manager 8C (1 WTE)	66	13.2
Supply chain	Procurement Manager 8B (1 WTE)	64	12.8
	Category Manager 7 (1 WTE)	41	8.2
	Admin Support 4 (1 WTE)	23	4.6
Workforce	Project Manager 7 (1 WTE)	41	8.2
Clinical	Project Manager 7 (1 WTE)	41	8.2
	Data Analyst 7 (1 WTE)	41	8.2
	Admin Support 4 (1 WTE)	23	4.6
Total		£1.63m	£223k

Table 6: Proposed recurrent resource requirement

Year 1 resource requirement

Maturity Matrix Domain	Roles	Estimated Cost (£)	20% add on costs (£)
Leadership Team	Senior Responsible Officer (0.2 WTE)	25 - 30	5 - 6
	Programme Manager 8C (1 WTE)	66	13.2
	Programme Officer 6 (1 WTE)	35	7
	Network Operational Lead 8C/D (1 WTE)	66 – 90	13.2 – 18
	Clinical/Medical Director	2 – 6 PAs	4 – 12
	Communications Lead 8B (0.5 WTE)	32	6.4
	Finance Lead 8C/D (1 WTE)	66 – 90	13.2 – 18
	Information Analyst 7 (1 WTE)	41	8.2
Supply chain	Procurement Manager 8B (1 WTE)	64	12.8
	Category Manager 7 (1 WTE)	41	8.2
	Admin Support 4 (1 WTE)	23	4.6
Workforce	Project Manager 7 (1 WTE)	41	8.2
Total		£613k	£123k

Table 7: Proposed Year 1 resource requirement needed to progress OBC

Risk and Reward share

Midlands and East 2 (ME2) pathology network development has the capability to generate efficiency savings potential as a means to provide a return on investment of recurrent resources. It is proposed that rewards generated from efficiency savings produced by network activities are split as per Trust contribution for recurrent resource investment based on Pay/Non Pay costings (**Table 8**). It is not envisaged that all recurrent resources will be required in year 1, as such a revised split is offered (**Table 9**). A £1,000,000 investment in the Midlands and East 2 Pathology Network represents a 0.5% cost improvement target for the network in order for partner organisations to realise a return on their investment.

Trust	Split (%)	Cost (£)
Leicester	19%	309,700
UHDB	15.5%	252,650
Kettering	6.5%	105,950
Northampton	8.5%	138,550
Chesterfield	4.8%	78,200
Nottingham	21.5%	350,450
Sherwood	7%	114,100
Path Links: ULHT NLAG	17.2%	280,360

Table 8: Illustrative example of Trust contribution to total recurrent resource requirement based on Pay and Non Pay costings.

Trust	Split (%)	Cost (£)
Leicester	19%	116,470
UHDB	15.5%	95,015
Kettering	6.5%	39,845
Northampton	8.5%	52,105
Chesterfield	4.8%	29,424
Nottingham	21.5%	131,795
Sherwood	7%	42,910
Path Links: ULHT NLAG	17.2%	105,436

Table 9: Illustrative example of Trust contribution to Year 1 resource requirement based on Pay and Non Pay costings.

10. Network Successes to Date

Development of the network gives member organisations the opportunity to access various funding streams and business opportunities to enhance income. Some of the networks current successes are below;

Path Lake

Digital pathology is one of the Midlands and East 2 (ME2) network work streams and a regional business case was submitted at the end of November 2019 for the Innovate UK funding as part of the “Scaling up our Digital Pathology, Imaging and AI Centres of Excellence in England” initiative. Finance and service leads worked to tight timelines as part of an ME2 network bid. At the beginning of February 2020, the Regional Diagnostic Lead was informed that two Trusts within the ME2 network, UHDB and NUH had been approved to receive grant funding from Innovate UK. Working collaboratively, both UHDB and NUH have now successfully procured Digital Pathology equipment and are in the process of implementing this in line with the expectations of the PathLAKE+ project timelines.

Funding in support of digital strategy

In April 2022, the Digital Diagnostics Capability Programme issued its 2022-2025 roadmap and investment proposal for the midlands. The Midlands and East 2 (ME2) pathology network was successful in securing £8.83m for Digital Pathology, £880,000 for LIMS and £175,000 towards LIMS home reporting during 2021/2022, investments which would not have been attainable had the bid not been submitted as a network. Central funding proposals for 2022/2023 equate to further £1.76m investment and benefit the entire Midlands and East 2 network allowing development of individual Trust pathology digital service offerings.

Central funding requirements for the remainder of the roadmap can be seen below:

Area of Work	Description	Amount of Central Funding Required	Amount of Central Funding Required	Amount of Central Funding Required
		Capital 2022/23	Capital 2023/24	Capital 2024/25
LIMS Interoperability	Digital Interoperability		£10,250,000	£8,400,000
Digital Histopathology	Digital Histopathology – extend scope, capacity, and interoperability of existing multi-site digital systems	£744,000	£1,140,000	£2,400,000
Interoperability (Other)	Network shared resource management system	£142,000		
	Network Quality Management System (QMS)	£114,000		
	Training & Education	£114,000		
	Asset Management	£114,000		
	Development and commissioning of a Network User Digital Portal		£250,000	
Interoperability (POCT)	Network integrated POCT	£336,000		
ALL	Project management to support implementation and business change	£200,000	£210,000	£220,000

Table 10: Digital funding proposals for 2022-2025.

Analyser interfacing associated with COVID

The network was able to received funding to connect analysers to associated Middleware, enabling them to be connected to downstream systems such as ICE, and aid reporting of results to Point of Care generated Tests, CACTUS and the UKHSA SGSS system.

We have also received Digital Integration funding which we used to procure the PCR A.I software at Sherwood Forest Hospitals NHS Foundation Trust, which automates the interpretation and reporting of PCR test results.

The network attracted interface funding in excess of £37,000.

Equipment associated with COVID

The network was able to successfully secure several pieces of additional equipment to support the COVID-19 pandemic workload and subsequent replacements to replace equipment whose original lifespan had been shortened.

The network attracted funding in excess of £650,000.

Cancer Alliance Funding

The network has been successful in securing funding from the alliance over the last couple of years and a further £150,000 non-recurrent investment to support network development throughout 2022/23 from East Midlands Cancer Alliance has also been secured. The funding was awarded on the understanding that Network roles would need to be funded by network member Trusts from 2023/24 onwards as outlined in this strategic outline case in order for the network to be self-sustaining.

Learning Lessons Workshop

The Midlands and East 2 Pathology network has the opportunity to benefit enormously from the experience of its partner organisations, some of which are networks in their own right. In March 2021 the network held a learning lessons workshop to explore those experiences using them to inform initial decision making regarding network development. It was clear from that presentation that everyone could identify successes born of those experiences but also identify what didn't work as well as envisaged. Those views are summarised below;

Common key factors to support network development success;

- Trust board commitment and support
- Strong clinical and managerial leadership
- Understanding clinical need
- Access to financial resource
- Partner equity (risk and reward)

Common key enablers;

- IT connectivity
- Transport
- Sufficient resource
- Ensuring staff understand the need for change

Common difficulties;

- Communication with all staff regarding process
- Managing change

The networks response to the COVID-19 pandemic gave us further opportunity to identify what worked well. Similar principles were evident;

- Clear leadership with ability to make managerial decisions at local level
- Honest and open working
- Timely, responsive and adaptive working
- Business contingency through use of varying platforms
- I.T and logistics key to sharing work efficiently and effectively

11. Timetable and Next Steps

Subject to support of member Boards, it is proposed that the shortlisted options are developed further and evaluated through the production of an Outline Business Case (OBC), through which a preferred option will be identified for Final Business Case (FBC) development.

Through the presentation of the SOC, member organisations are asked to confirm that none of the short-listed options are unacceptable, in principle, remain committed to the current Memorandum of Understanding as the governance framework for the next phase of this programme and commit to the investment proposed in section 9 with regards to project structure and resourcing.

Key Milestones	Timing
SOC Approval – ME2	April – May 2022
SOC Approval – Member Trust Boards	May – June 2022
OBC Draft	June – September 2022
OBC Approval	September 2022 – March 2023

12. Key Risks

The primary risks to the OBC development and proposed mitigation measures are described below;

Risk	Mitigation Measures
Failure to secure support of member organisation boards	Senior representation from member organisations on Network Board and Executive representation from member organisations on Network Executive Steering Group to enable identification of concerns and barriers to approval.
Failure to secure investment to resource network roles	Secure commitment to resource through SOC approval
Failure to obtain NHSEI approval of OBC approach	SOC approval and early agreement of NHSEI for OBC approach and content. Involvement of key NHSEI personnel on Network Board and related activities
Failure to sustain clinical services	ME2 Clinical Reference Group in place chaired by network Clinical Director Clinical priorities developed as part of SOC
Insufficient capacity and expertise to develop OBC to required standard	Secure commitment to resource through OBC. Identify additional capacity and capability from member organisations and/or external sources.
Failure to align member organisation CIP activities compromising Network development	Senior representation from member organisations on Network Board and Executive representation from member organisations on Network Executive Steering Group to enable effective CIP discussion.
Recruitment to permanent network roles may create hard to fill vacancies at individual trust level	Expertise from those Trusts potentially retained within the network providing opportunity for recruitment and transitional phase Mutual aid from network partners
Failure to meet proposed timeline	Establish robust programme management and oversight arrangements including sufficient capacity and capability.

13. Recommendation

Trust Boards are asked to approve this Strategic Outline Case (SOC) and in doing so agree to:

1. The detailed development of the three shortlisted options to OBC level:
 - Joint Venture
 - Hosted Organisation
 - Provider Collaborative
2. Commitment to the proposed share of recurrent programme costs

14. Frequently Asked Questions

Question 1: Given that the formation of the 29 proposed Pathology Networks in England is a national directive, why is it not centrally funded?

Answer: NHSEI 'pump primed' development of the network by providing a non-recurrent investment of £310k to support recruitment of recommended network roles. Onus then falls on respective member Trusts to support development of the network and realise the potential efficiency savings that can be utilised to sustain the network.

Question 2: What happens if a member organisation declines approval of the Strategic Outline Case and development of the Outline Business Case?

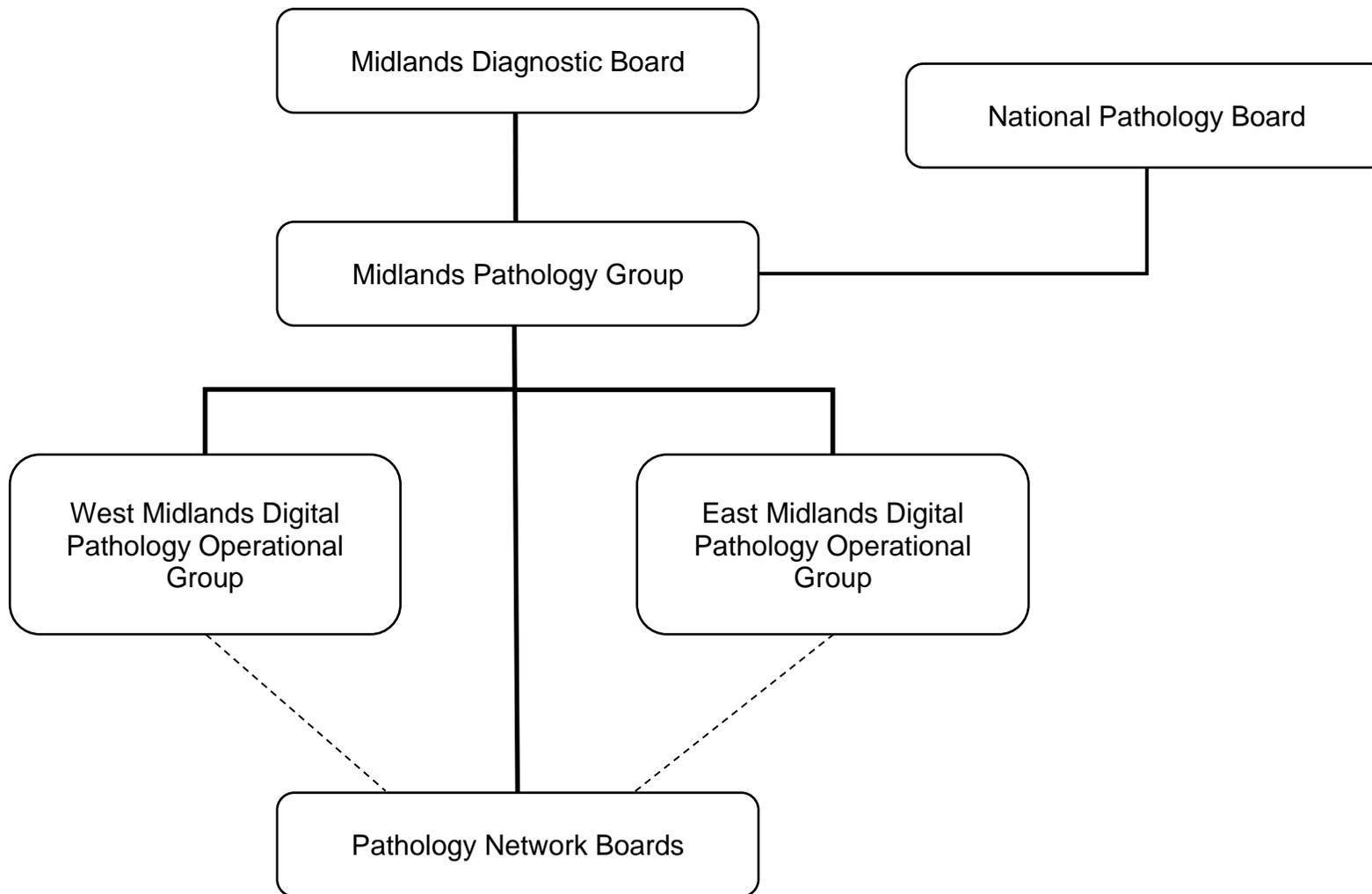
Answer: The development of the Midlands and East 2 (ME2) pathology network is a national directive. Failure to support its development will leave member Trusts accountable to NHSEI

15. References

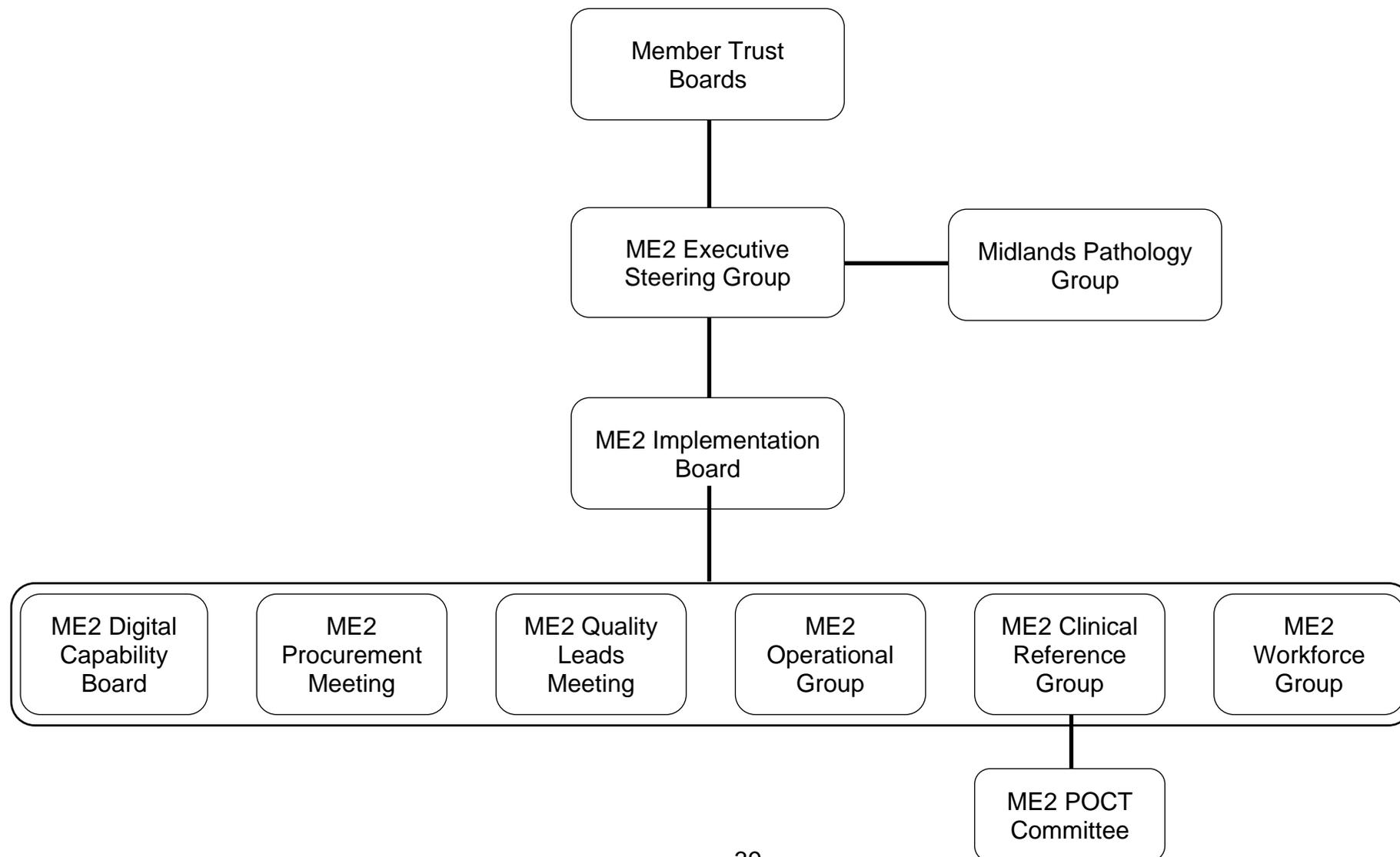
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NHS England and NHS Improvement (2021) *Working together at scale: guidance on provider collaboratives*. Available at: <https://www.england.nhs.uk/wp-content/uploads/2021/06/B0754-working-together-at-scale-guidance-on-provider-collaboratives.pdf> (Accessed: 25th March 2022).

Midlands Pathology Group Reporting Structure



Midlands and East 2 Pathology Network Reporting Structure



Appendix C.

Current configuration of Pathology Services within the Midlands and East 2 Pathology Network

Organisation	Pathology Service Provided	Accreditation Number
Path Links; <ul style="list-style-type: none"> • Northern Lincolnshire & Goole NHS Foundation Trust • United Lincolnshire Hospitals NHS Trust 	Blood Sciences Microbiology Cellular Pathology Andrology	8833
UHDB; <ul style="list-style-type: none"> • University Hospitals of Derby & Burton NHS Foundation Trust, • Chesterfield Royal Hospital NHS Trust 	Blood Sciences Microbiology Cellular Pathology	9308
	Blood Sciences	9807
	Microbiology	9096
Kettering General Hospital NHS Foundation Trust	Blood Sciences Microbiology Cellular Pathology	8118
University Hospitals of Leicester NHS Trust	Blood Sciences	8376
	Cellular Pathology	8608
	Microbiology	8605
	Cytogenetics	8069
Northampton General Hospital NHS Trust	Blood Sciences Microbiology Cellular Pathology	Unaccredited - ETS Unaccredited - ETS 8115
Nottingham University Hospitals NHS Foundation Trust	Cytogenetics	8031
	Molecular Genetics	8044
	Cellular Pathology	8162
	Clinical Pathology	8848
	Microbiology	8755
Sherwood Forest Hospitals NHS Foundation Trust	Microbiology	9356
	Haematology & Blood Transfusion	Unaccredited
	Biochemistry	8676
	Cellular Pathology	8705