Business Case

for the

National Medical Laboratory Information System (MedLIS) Project

Version 1.0

3rd June 2011

(following telecon with ND ISD and ND CSS 27th May, and Project Board meeting 2nd June)

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1.1 Introduction

This report documents the Business Case for purchasing and implementing new IT-based systems for the clinical laboratories in the HSE and Voluntary hospitals. These new systems are required to address the immediate and serious clinical risks associated with continued operation of current IT systems in these laboratories, or in some cases to provide IT systems for areas of laboratory work that don't have such systems.

Under the terms of the Department of Finance's Circulars 02/2009 and 02/2011 the HSE requires the sanction of the Department of Finance to the proposed expenditure on this project. Also, the level of expenditure involved in this project is such that the provisions of the Department of Finance's *Peer Review* process apply to it. This report serves to provide the Department of Finance with sufficient information to enable it to begin considering the project for sanction and for referral of the project to the first stage of the Peer Review process (Business Case Review).

1.2 Current Laboratory Services

The provision of high quality laboratory services is a critical component of patient care, involving diagnostic, monitoring and screening services. These clinical support services are vital for the day-to-day operation of all healthcare services - both acute and community based.

Laboratories that provide services for testing of patient samples are, in the main, located within acute hospitals. There are 44 such laboratories. The following table provides an analysis of the scale and range of services provided by these laboratories:

Analysis of Hospital Laboratories		
Number	**HSE Classification**	**Disciplines / Comment**
14	Small	These laboratories provide a limited level of service to the local hospital and to GPs.
21	Medium	These laboratories virtually all provide haematology, blood transfusion, biochemistry, microbiology and histopathology. 5 sites also have an immunology service.
9	Large	These laboratories have all disciplines and many sub-specialty disciplines and provide a large repertoire of investigations. In some of these laboratories they also provide national reference or *de facto* national reference laboratory services.

1.3 Laboratory Modernisation Process

A process of modernisation of laboratory medicine is underway, which will result in considerable change in the configuration of laboratories as outlined above. It is envisaged that the current fragmented configuration will, over time, be replaced by a single, coordinated laboratory medicine service, in which the routine tests will be processed through dedicated "cold" labs, tests from patients in acute hospitals will be processed through dedicated "hot" labs, and there will be increased use of "point-of-care" testing. Various models for delivery of the new service are under consideration and it is possible that some elements of the service will be provided externally under contract. In the event that some laboratory services fall to be provided externally the relevant contractor(s) will be required to interface to the proposed national laboratory information system[1].

1.4 Current Laboratory Information Systems (LIS)

LIS play a central role in the operational management of pathology laboratory workflow as well as providing the infrastructure to facilitate the electronic communication of patient test results to hospital clinicians, wards, OPDs, GP's, and other relevant healthcare providers.

Appendix 1 identifies the LIS deployed in each of the 44 laboratories. There are six different products in use, supplied by five different vendors.

1.5 LIS Issues/Risks

The LIS in use in all hospitals in Ireland are now quite dated. Some of them are quite inadequate, problematic and at serious risk of failure. Earlier attempts to procure new modern systems have not been successful and there is now an urgent need to establish a new project to define current requirements, run a procurement competition and implement a modern LIS. This new project will be given a new identity to reflect its different goals, objectives, scope, participants and context, and to improve clarity when re-engaging with stakeholders and the marketplace. In this general context priority must be given to those sites most poorly served by existing systems and those most at risk of failure of their existing systems.

The sites in greatest need of replacement LIS are as follows (in alphabetical order): -

- Beaumont Hospital, Dublin
- Connolly Hospital, Blanchardstown
- Mater Misericordiae Hospital, Dublin
- Midland Regional Hospital (all three sites – Tullamore, Portlaoise & Mullingar)
- Naas General Hospital
- North Eastern Hospitals Group (all four sites – Drogheda, Cavan, Louth and Navan)
- St. Columcille's Hospital, Loughlinstown
- St. James's Hospital, Dublin

[1] The current expectation is that HSE will progress an "insourced hub and spoke" model for the provision of "cold" testing however the National LIS system specified will be expected to be compatible with whatever model emerges.

The LIS in all the above sites passed their expected end-of-life several years ago. Interim upgrades and essential maintenance work have kept them operational but continuing to depend on them means continuation of the risk of failure and operating with a range of associated inadequacies.

Independent external risk advisors have rated the LIS in several of the above sites as having unacceptable clinical governance risks and of being in critical need of replacement.

The need for replacement LIS, however, is not confined to the list of sites above. All other sites have LIS whose contracts have run their full term and have been extended on an interim basis, pending commencement of a replacement project. In general these older systems do not meet the requirements of a modern laboratory service; they provide no integration of patient information across sites and they do not adequately support laboratory accreditation requirements.

In summary, the issues and risks associated with current operational LIS are as follows:-

- Unacceptable delays in the delivery of critical results to clinical areas with consequent delay in patient treatment
- Inability to maintain and securely store comprehensive patient information
- Some of our current LIS do not contain the functionality to adequately support the maintenance of patient records – namely, no functionality to merge records or audit changes to patient records. Lacking this functionality could have serious consequences for the issuing of laboratory results.
- Reduced access to patient history
- Dependency in some locations on paper-based records with all the inherent risks associated with such records, including transcription risks
- Inherent risks with faxing of patient information
- Inability to maintain/sustain a functioning laboratory service
- Specimen tracking problems could lead to patient mix-ups
- No system for monitoring turnaround times and alerting to delayed reporting of results (e.g. possible cancer diagnosis)
- Difficulty in supporting the HSE's Transformation Programme
- Difficulty in carrying out clinical audit
- Reliance on telephoned and written reports (accompanied by inherent transcription error)
- Inadequate IT support for ensuring compliance with the 2005 EU Directive on Blood Products
- Litigation risks
- Inefficient use of support staff
- Non-compliance with accreditation standards ISO 15189
- Continued variation in linkages with external agencies such as the National Cancer Registry of Ireland (NCRI), Computerised Infectious Disease Reporting (CIDR) and GP Messaging
- Impaired laboratory medicine expansion to meet new and emerging services to patients
- Some of the databases do not contain a data dictionary or any relevant documentation making it impossible to produce management reports which are required for day-to-day management of the laboratories or the provision of ad hoc reports requested by hospital management.
- Poor provision of management and financial data with no direct links to casemix data and patient/specialty costing

- Inadequate deployment of electronic communication systems for requests and results, particularly with Primary Care & Community Services

1.6 Organisational Context

This Business Case is put forward by the HSE on behalf of the laboratory services delivered within its own hospitals and those within the Voluntary hospitals that are funded directly by the HSE. An outline of the HSE organisational and management arrangements for acute hospitals, laboratory services and ICT services is set out later in the document. It is acknowledged that the organisational context set out reflects the current situation as at the date of this report and that the new Government's healthcare policy is expected to result in significant change in the organisational structures, ownership and funding of hospitals. The detailed implications of the new Government's policy cannot be set out at this time but it is expected that, in the main, the existing structures will continue in operation for the four-year lifetime of the National MedLIS Project. The new National LIS is required irrespective of the envisaged changes in healthcare organisation.

1.7 Strategic Context

The HSE is currently finalising a new ICT strategy document covering the period 2011 – 2016. The draft strategy has been approved by the HSE's Management Team and is being subjected to external review and validation prior to submission to the HSE Board in the coming months. While the strategy document will not be officially available until it is finalised and approved it may be made available in draft form in support of this Business Case, if required.

The Strategy maps out the vision and longer term goals that will direct and inform ICT decision-making. It identifies that in each acute hospital there will be a set of *core applications* to meet the specific needs of the institution. These applications will provide the required business functions and an integrated, electronic view of the patient/client information – i.e. in each case there will be an electronic version of the medical chart or an Electronic Patient Record (EPR). **The National LIS is included in the Strategy as one of the identified set of *core applications* that is required.**

The National MedLIS Project will directly support the achievement of the HSE's key service strategy and objectives including:

- laboratory modernisation;
- clinical strategy and care programmes, and
- integration of patient records.

The project will directly assist in achieving objectives set out in the HSE's Corporate Plan, National Service Plan and Transformation Programme.

The project will also support the phased introduction of electronic patient records as envisaged by the National Health Strategy ("Quality & fairness") and the move towards the development of the Electronic Health Care Record, proposed by the National Health Information Strategy.

1.8 Scope, Objectives & Benefits

The scope of this Business Case is the totality of the laboratory service delivered across all public hospitals' sites. Currently this comprises the laboratories in all the HSE and Voluntary hospitals, as listed in Appendix 1.

The deployment model for the proposed new National LIS will be based on a central single instance of the software and database. This model will facilitate the maximum sharing of information across sites, thereby ensuring that clinicians have access to the full laboratory diagnostic data on each patient. Market research has indicated that the mainline suppliers of LIS have implemented large scale projects based on this model, serving similar numbers of laboratories and similar workload to that proposed.

The strategic goal for the National MedLIS Project can be summarised as follows:

"***To ensure patients healthcare providers have rapid 24-hour access to complete and up-to-date accurate laboratory data across all sites".***

In order to execute this goal, the National LIS must:

- provide electronic storage of the entire patient laboratory record, integrated across all sites;
- provide real-time user-friendly access to this data throughout the agency;
- be a 'virtual' single, flexible, patient-centred information system with automatic tracking, routing and resulting of specimens;
- support "end-to-end" electronic communication of requests and results between hospital / primary care clinicians and the laboratory service, based on HIQA messaging standards;
- support automated interfaces with other relevant information systems, including Patient Administration, Clinical Portals and Clinical Information Systems, and
- ensure management information can be easily extracted to allow optimum management and planning of resources.

The successful implementation of the new National LIS across the laboratories will deliver significant benefits for both the patient and the organisations concerned, with some potential for Exchequer benefits also. The benefits include: -

- Improved quality of patient care
- Improved timeliness of service (faster turnaround of laboratory results)
- Improved security of patient information
- Reduced incidence of unnecessary repeat tests
- Reduced risk of hospital-wide system laboratory system failures
- Integration of information across multiple laboratory sites
- Streamlining of laboratory processes
- Improved ability to support increasing workload on existing infrastructure without the requirement for staff increases.

- Enabling interoperability through support for standardised messaging e.g. the Nationally adopted Health Level 7 messaging standard
- Providing support for Internationally Recognised coding systems e.g. LOINC (Logical Observation Identifiers Names and Codes), ICD 10 (International Classification of Disease), SNOMED (**S**ystematised **No**menclature of **Med**icine).
- Allowing compliance with accreditation standards ISO15189
- Reducing the risk of litigation
- Improved availability of management and clinical information

1.9 Costs

The estimated[2] once-off non-pay costs of the National MedLIS Project are set out in the following table: -

Summary of Once-off Costs (Non-Pay)	
Cost Element	**Cost**
Payable to LIMS Supplier	€ 25,241,746
Integration costs payable to other suppliers	€ 1,000,000
LAN & desktop equipment	€ 1,000,000
Additional wide-area network capacity	€ 250,000
Grand Total:	**€ 27,491,746**

The annual support and maintenance costs are estimated (see footnote) at **€2,778,413**, when all sites are fully implemented.

Assuming that a 7-year contract is awarded to the LIS supplier, and that the rollout period will be 3 years from date of that contract, the lifetime costs are as shown in the following table: -

Lifetime Costs (Non-Pay)	
Cost Element	**Cost**
Total once-off cost (non-pay)	€ 27,491,746
Annual cost X 5.5	€ 15,281,269
Grand Total:	**€ 42,773,015**

[2] Based on average of indicative prices ranging from €9.5m to €42m received from 4 of 5 suppliers contacted.

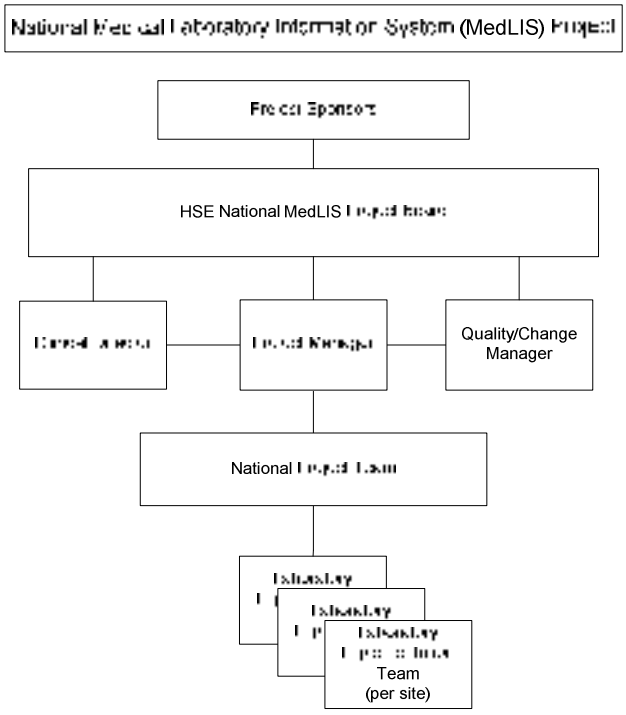
The project has been included in the ICT Capital Plan and there is sufficient funding available in the plan to cover the entire project's once-off, non-pay costs. The priority of the project is recognised and it is expected that funding for it will continue to be protected.

It is expected that the ongoing non-pay cost (estimated above at €2.778m per annum) will be similar to what's currently being paid for support and maintenance on the myriad of existing LIS used by laboratories. This is currently approximately €2.3m and while there may be no shortfall as the €2.778m is an estimate based on the average of a range of prices, the potential €400,000-€500,000 shortfall nationally in on-going costs should be seen in the context of the very significant savings expected from the lab modernization process which requires a National LIS to enable it. Individual hospital budgets will be reduced by these amounts upon termination of existing LIS contracts and these savings will go towards meeting the ongoing costs of the new National LIS, which will be paid centrally.

The payroll cost of staff required for the project, both at national level and in individual laboratories, will come from existing revenue budgets and there will be no additional net cost to the HSE. The assignment of staff to the project will be by means of redeployment. Hence the cost of project personnel represents an opportunity cost only and is not an additional cost.

1.10 Project Management & Control

The diagram below shows an outline of the proposed project management structure. The Project Board is in place and arrangements are being made to implement the various structures underneath. An identification and analysis of project risks has been undertaken and a Risk Management Plan for all medium and high risks has been developed.



1.11 Target Project Timetable

The timetable for this project is very difficult to determine at this point, having regard particularly to the number of stages that are outside the project's control – especially the approval and procurement stages. The overall target is to have the procurement process completed and a contract placed for the National LIS within 12 months of approval of this Business Case, followed by an implementation/ rollout period of 3 years. It is acknowledged that the achievement of these targets is dependent on rapid turnaround of the approval processes and minimal complications in the procurement and implementation phases.

2. Introduction

2.1 Purpose of this Report

This report documents the Business Case for purchasing and implementing new IT-based systems for the clinical laboratories in the HSE and Voluntary hospitals. These new systems are required to address the immediate and serious clinical risks associated with continued operation of current IT systems in these laboratories, or in some cases to provide IT systems for areas of laboratory work that don't have such systems.

Under the terms of the Department of Finance's Circulars 02/2009 and 02/2011 the HSE requires the sanction of the Department of Finance to the proposed expenditure on this project. Also, the level of expenditure involved in this project is such that the provisions of the Department of Finance's *Peer Review* process apply to it. This report serves to provide the Department of Finance with sufficient information to enable it to begin considering the project for sanction and for referral of the project to the first stage of the Peer Review process (Business Case Review).

2.2 Overview of the Current Laboratory Service

The provision of high quality laboratory services is a critical component of patient care, involving diagnostic, monitoring and screening services. These clinical support services are vital for the day-to-day operation of all healthcare services - both acute and community based. A recent National Health Service Pathology Review carried out in the UK identified that "70 – 80% of all healthcare decisions affecting diagnosis or treatment involve a pathology investigation, with individual treatment decisions and the monitoring of their response to treatment often dependent on a range of pathology based tests and investigations".

Laboratories that provide services for testing of patient samples are, in the main, located within acute hospitals. There are 44 such laboratories. There are a small number of laboratories outside of these hospitals, which mainly deal with other testing – e.g. Public Analyst Laboratories provide services for testing of samples from public water supplies. In addition, there are a small number of other specialist laboratories, including the Virus Reference Laboratory at University College, Dublin.

The following table provides an analysis of the scale and range of services provided by the 44 hospital laboratories:

Analysis of Hospital Laboratories		
Number	**HSE Classification**	**Disciplines / Comment**
14	Small	These laboratories provide a limited level of service to the local hospital and to GPs.
21	Medium	These laboratories virtually all provide haematology, blood transfusion, biochemistry, microbiology and histopathology. 5 sites also have an immunology service.
9	Large	These laboratories have all disciplines and many sub-specialty disciplines and provide a large repertoire of investigations. In some of these laboratories they also provide national reference or *de facto* national reference laboratory services.

Service delivery by the 44 laboratories continues to grow. Studies show an average increase of 10 – 12 % annually ([O'Moore et al 96] state "that the increase in workload in clinical laboratories has been in the order of up to 10% per annum since 1986".) and the number of parameters being measured on these samples has also increased.

A process of modernisation of laboratory medicine is underway, which will result in considerable change in the configuration of laboratories as outlined above. It is envisaged that the current fragmented configuration will be replaced over a number of years by a single, coordinated laboratory medicine service, in which:

- The large volumes of routine patient tests originating principally from the community care system will be processed through a dedicated "cold" lab stream. This would include automated and non-automated sections; would be supported by dedicated logistics solutions and IT, may be standalone and would have a fast turnaround time.
- Tests from patients in acute hospitals receiving acute "round-the-clock" care will be processed through dedicated "hot" lab streams. This will provide more access to clinical laboratory medical advice and more direct care of the complex patient. (A "hot" lab is a facility co-located with the emergency and complex acute services responsible for processing all urgent "hot" samples with an extremely fast turnaround time).;
- "Point-of-care" testing will be increased – where tests are carried out immediately: in acute hospitals, in local healthcare settings or in the patient's home - wherever it is clinically appropriate and cost effective. (Point of care involves tests performed by non laboratory staff at or near the site of patient care, e.g. GP office, clinic, home).

The laboratory medicine modernisation process is neither predicated on, nor dependant upon, the current ownership or funding model for hospitals. Hence, the new Government's proposed healthcare changes are not expected to impact significantly on the modernisation process. The efficiencies and quality improvements envisaged by the process will be equally applicable and beneficial under the new Government's proposed healthcare model as they are under the current model.

2.3 Overview of Current Laboratory Information Systems (LIS)

LIM play a central role in the operational management of pathology laboratory workflow as well as providing the infrastructure to facilitate the electronic communication of patient test results to hospital clinicians, wards, OPDs, GP's, and other relevant healthcare providers.

Appendix 1 identifies the LIS in each of the 44 laboratories. The following is a summary of the systems and the respective suppliers currently in place:

Supplier	Product	No. of Sites
iSOFT	i.LAB / Apex	20
Clinisys	Winpath	8
iSOFT	Telepath	6
C Rutter	Net Acquire	7
Sunquest	Sunquest Laboratory	2
Mediware Information Systems	Lifeline	1
	Total:	**44**

The existing LIS are deployed in a highly distributed manner. Generally, each laboratory operates its own independent LIS. This mirrors the existing general information systems deployment model in that each hospital generally operates its own independent IT systems. These include other major systems such as Hospital Information System and Radiology Information System. Over time, some of these independent deployments have been replaced with regional deployments covering a number of HSE hospitals, whereby a common database covers the population served by a group of hospitals within the same geographic area.

2.4 LIS Issues / Risks

The LIS in use in all hospitals in Ireland are now quite dated. Some of them are quite inadequate, problematic and at serious risk of failure. In some locations there is an extremely poor, or even non-existent, IT system in use for certain laboratory disciplines. Earlier attempts to procure new modern systems have not been successful and there is now an urgent need to establish a new project to define current requirements, run a procurement competition and implement a modern National LIS. This new project will be given a new identity to reflect its different goals, objectives, scope, participants and context, and to improve clarity when re-engaging with stakeholders and the marketplace. In this general context priority must be given to those sites most poorly served by existing systems and those most at risk of failure of their existing systems.

The sites in greatest need of replacement LIS are as follows (in alphabetical order): -

- Beaumont Hospital, Dublin
- Connolly Hospital, Blanchardstown
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- North Eastern Hospitals Group (all four sites – Drogheda, Cavan, Louth and Navan)
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- St. James's Hospital, Dublin

The LIS in all the above sites passed their expected end-of-life several years ago. Interim upgrades and essential maintenance work have kept them operational but continuing to depend on them means continuation of the risk of failure and operating with a range of associated inadequacies. Some of the known failures in these sites have included: -

- random deletion of the contents of histology records with permanent loss of data;
- inability to put normal ranges on report forms;
- complete reliance on paper reports;
- no ward or GP electronic look up of results;
- inability to recognise critical or urgent abnormalities electronically with consequent delay in alerting clinicians, and
- unpredictable 'crashing' of the entire system with subsequent loss of access to patient information for days.

Independent external risk advisors have rated the LIS in several of the above sites as having unacceptable clinical governance risks and of being in critical need of replacement.

The need for replacement LIS, however, is not confined to the list of sites above. All other sites have LIS whose contracts have run their full term and have been extended on an interim basis, pending commencement of a replacement project. In general these older systems do not meet the requirements of a modern laboratory service; they provide no integration of patient information across sites and they do not adequately support laboratory accreditation requirements.

In summary, the issues and risks associated with current operational LIS are as follows:-

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- Difficulty in supporting the HSE's Transformation Programme
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- Inefficient use of support staff
- Non-compliance with accreditation standards ISO 15189
- Continued variation in linkages with external agencies such as the National Cancer Registry of Ireland (NCRI), Computerised Infectious Disease Reporting (CIDR) and GP Messaging
- Impaired laboratory medicine expansion to meet new and emerging services to patients
- Some of the databases do not contain a data dictionary or any relevant documentation making it impossible to produce management reports which are required for day-to-day management of the laboratories or the provision of ad hoc reports requested by hospital management.
- Poor provision of management and financial data with no direct links to casemix data and patient/specialty costing
- Inadequate deployment of electronic communication systems for requests and results, particularly with Primary Care & Community Services

2.5 Future-proofing the Investment

It is acknowledged that this Business Case proposes a substantial investment in new systems at a time when considerable change is planned for the health service by the new Government that took office on 9th March 2011. The new Government's policy on healthcare, as articulated to-date, flags changes *inter alia* to the eligibility and funding arrangements for health services, to the ownership/governance arrangements for the public hospitals that are currently run directly by the HSE and to the role and function of the HSE itself. In light of these anticipated changes, assurance would be expected that the investment in the National LIS is future-proofed so that it continues to be the right solution irrespective of the future changes that are envisaged. The following points are put forward in support of this assurance: -

- The National LIS will be a transaction processing system, supporting routine operational processes that will continue to be performed at various hospital locations (the numbers may vary depending on the outcome of the laboratory modernisation process). The envisaged health service changes will not remove the need for laboratory diagnostic work and hence continued information systems support will be required.

- Existing LIS cannot continue to be used for the reasons outlined above. Hence, new LIS are required in any event.

- The alternative to a National approach is to allow individual hospital laboratories, or groups of them, to acquire individual replacement systems. Such an approach would carry the risk of continued fragmentation of patient records and of increased costs because of diseconomies of scale. Integrated care can best be provided by consolidation of information systems – clinicians may utilise various laboratories for different purposes and having each with an independent information system will make for greater complexity and cost in integrating records.

- The National LIS is compatible with the anticipated change in ownership and governance of the existing HSE hospitals – establishing them as not-for-profit trusts with their own boards. The project provides for delivery into the existing 17 public voluntary hospitals in any event.

3 Organisational Context

[It is acknowledged that the organisational context set out below reflects the current situation as at the date of this report and that the new Government's healthcare policy is expected to result in significant change in the organisational structures, ownership and funding of hospitals. The detailed implications of the new Government's policy cannot be set out at this time but it is expected that, in the main, the structures outlined below will continue in operation for the four-year lifetime of the National MedLIS Project. The new National LIS is required irrespective of the envisaged changes in healthcare organisation, and needs to be flexible enough to accommodate future organisational change.]

3.1 The Health Service Executive (HSE)

The Health Service Executive (HSE) was established in January 2005 as the single body responsible for meeting Ireland's health and social care needs. The establishment of the HSE was the beginning of the largest programme of change ever undertaken in the Irish public service. Prior to this, services were delivered through a complex structure of ten regional Health Boards, the Eastern Regional Health Authority and a number of other agencies. The HSE replaced all of these organisations and is now the single body responsible for ensuring that everybody can access cost effective and consistently high quality health and personal social services. The HSE is the largest employer in the State, with a WTE complement of 109,372. The net budget of the HSE for 2011 is €13.456 billion - the largest of any public sector organisation.

The HSE provides an extensive range of services to young and old, in hospitals, health facilities and in communities across the country. These services range from public health nurses treating older people in the community to caring for children with challenging behaviour; from educating people how to live healthier lives, to performing highly-complex surgery; from planning for major emergencies, to controlling the spread of infectious diseases.

3.2 HSE Organisational Structure

The HSE's organisational structure is set out in the diagram overleaf.

The core services are delivered through the Integrated Services Directorate, organised across four geographic regions. This directorate has responsibility for the delivery, reconfiguration, performance and financial management of all health and personal social services. Each of the four regions is headed up by a Regional Directors of Operations (RDO). The regions operate within nationally determined priorities and parameters.

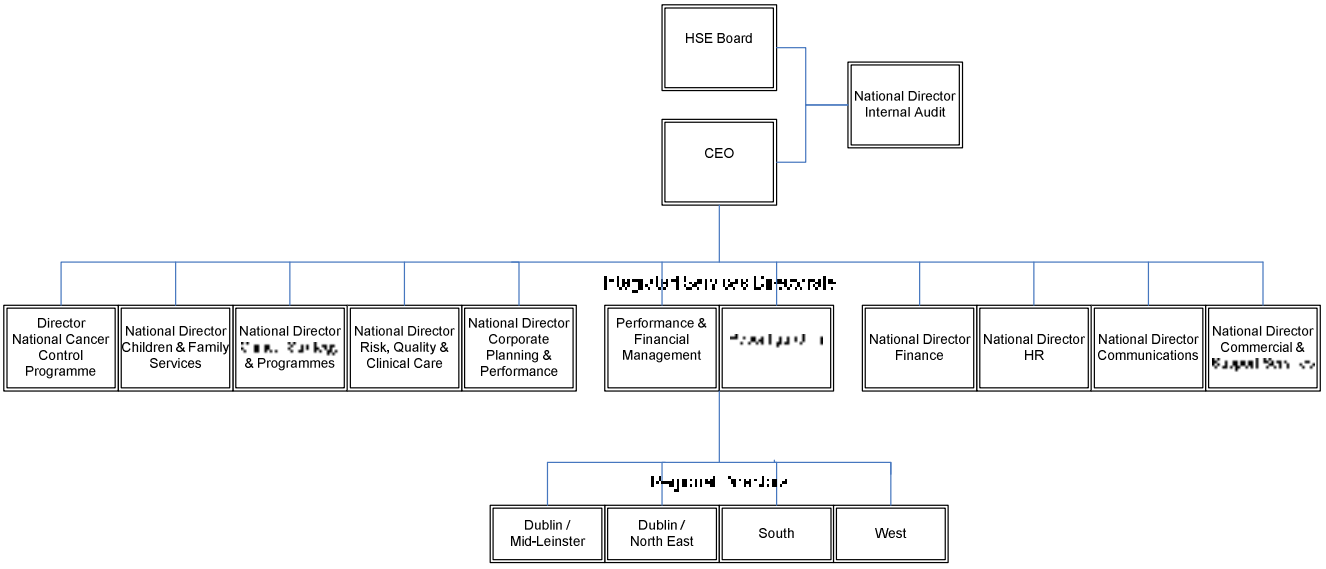
Some of the core services are delivered through National Programmes. For example, the National Cancer Control Programme (NCCP) is responsible for the provision of all cancer-related services, including Radiation Oncology, Community Oncology Services and the range of diagnostic and treatment services delivered through 8 Regional Major Cancer Centres. Similarly, the Children and Family Services are responsible for a range of child protection and child care services.

The Clinical Strategy and Programmes Directorate has been established to improve and standardise patient care throughout the organisation by bringing together clinical disciplines and enabling them to

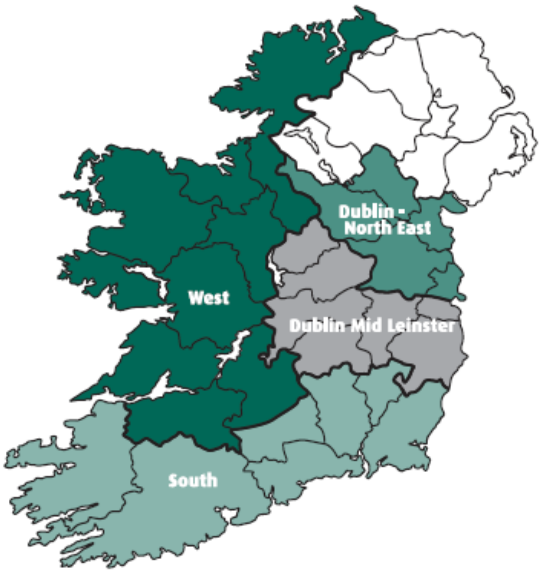
share innovative solutions to deliver greater benefits to every user of HSE services. This approach is expected to improve the quality of care delivered, improve access to all services and improve cost effectiveness. Various clinical programmes have been established under the direction of Lead Clinicians.

The remaining elements of the organisational structure provide a range of support functions to the core services and management.

HSE Organisational Structure:



HSE Regions



HSE West	Limerick, Tipperary North, Clare, Galway, Mayo, Sligo, Roscommon, Leitrim, Donegal
HSE South	Kerry, Cork, Waterford, Wexford, Carlow, Kilkenny, Tipperary South
HSE Dublin North East	Dublin North, Louth, Meath, Cavan, Monaghan
HSE Dublin Mid Leinster	Dublin South, Wicklow, Kildare, Laois, Offaly, Longford, Westmeath

3.3 Acute Hospitals

There are 50 acute hospitals in Ireland's public health system. These provide a range of assessment, diagnosis and treatment services. Designated national specialist services incorporate areas of care such as heart, lung and liver transplants, bone marrow transplants, spinal injuries, paediatric cardiac services, medical genetics, renal transplantation and haemophilia. Supra-regional services include neurosurgery and cardiac surgery, as well as complex cancer treatments and radiotherapy.

Acute hospitals also play a key role in undergraduate and post-graduate training and education for medical and health service professionals. Hospitals are also involved in clinical and related research activities, involving close links with universities and other third level institutions.

The organisation of hospital services is undergoing change at present, moving from structures that had hospitals separately organised from other services and reporting up through national lines into structures that have regional groups of hospitals integrated with other non-acute services within each Region. *Integrated Service Areas* are being established in various parts of the country but the process of transition is still underway. In most cases the acute hospitals are organised into groups within the four Regions with each having a separate manager responsible for them and reporting into the RDO.

Each hospital is managed by a Hospital General Manager/CEO who is directly responsible for the delivery of services within his/her hospital. 33 of the hospitals are directly owned and managed by the HSE. The remaining 17 hospitals are independent legal entities with which the HSE agrees an annual Service Plan and provides the revenue and capital funding required to supply the services specified in the Plan.

3.4 Independent ("Voluntary") Hospitals

As explained above, a number of acute hospitals are separate legal entities, which are independent of the HSE but are funded by the HSE. These hospitals have their own internal organisational structures, including their own ICT functions. The Mater Hospital St. James's Hospital and Beaumont Hospital are in this category. The HSE and these hospitals will work in partnership on the National MedLIS Project at the various levels required (management, ICT, laboratory, etc.). This partnership is reflected in the project governance and management structures, as outlined later in Section 7.

3.5 Laboratory Services

Laboratory services within the HSE proper are part of the acute hospital services within the regional structures. Within these structures a multi-hospital approach has increasingly been adopted to oversee laboratory services across all hospital sites. For example, a "Pathology Network" has been established in the North East, while in the Midlands a "Joint Pathology Committee" is in place.

Within the independent hospitals – such as the Mater Hospital, St. James Hospital and Beaumont – the laboratories are part of the relevant hospital management structure and are major departments in their own right. A variety of management models are in place but increasingly the laboratories are managed using a Clinical Directorate model within the hospital, reporting into the hospital's Chief Executive Officer.

3.6 ICT Services

The ICT Directorate is one of a number of key corporate support functions within the HSE. It is part of the Directorate of Commercial and Support Services and has full responsibility for all ICT projects and for the provision and support of all ICT operational systems within the HSE.

HSE senior management engagement on ICT matters is effected through the National Director of Commercial and Support Services, who is a member of the HSE Senior Management Team and reports directly to the Chief Executive Officer.

The ICT Directorate is organised along national lines and therefore is not part of regional structures, although staff are located at all the major centres across the country. The Directorate comprises 285 staff, which are organised into the major ICT sub-functions of Operations/Infrastructure, Applications Support, IS Implementation Projects, Corporate and Strategy/Planning.

In addition to the ICT Directorate proper the larger HSE acute hospitals each has a separate, relatively small ICT function reporting into the Hospital General Manager. These staff work in partnership with the ICT Directorate and comply with overall HSE ICT strategy. They provide local support to the hospital and resources for local IT projects.

Each of the major independent acute hospitals has a substantial ICT function which provides the full range of ICT services for the hospital.

4. Strategic Context

4.1 HSE ICT Strategy 2011 - 2016

The HSE is currently finalising a new ICT strategy document covering the period 2011 – 2016. The Strategy has been approved by the HSE's Management Team and will shortly go to the HSE Board for noting. While the strategy document will not be officially available until it is finalised and approved it may be made available in draft form in support of this Business Case, if required.

The Strategy maps out the vision and longer term goals that will direct and inform ICT decision-making. It identifies that in each acute hospital there will be a set of *core applications* to meet the specific needs of the institution. These applications will provide the required business functions and an integrated, electronic view of the patient/client information – i.e. in each case there will be an electronic version of the medical chart or an Electronic Patient Record (EPR). **The National LIMS is included in the Strategy as one of the identified set of *core applications* that is required.**

The Strategy specifies that these *core* applications be leveraged so as to achieve delivery of hospital based Electronic Patient Records (EPRs) and put in place the key building blocks required for a National *Electronic Health Record* (EHR). Where hospitals have already made significant progress in delivering site specific EPRs they will be supported in the completion of that work.

4.2 Modernisation of Laboratory Medicine

A major process of laboratory modernisation has been initiated by the HSE. This follows a review of laboratory medicine services carried out in 2007 by Teamwork Management Services Ltd. The Teamwork report recommended fundamental changes in the organisation of laboratory services including the separation of laboratories providing services to major acute hospitals from those providing services to other non-acute hospitals and Primary Care. The HSE Board accepted the Teamwork recommendations in May 2007 and discussions then commenced with the Department of Health & Children and other key stakeholders on its implementation. The Teamwork recommendations represent far reaching changes to the organisation of laboratory services and the process of their implementation is a very significant and complex undertaking. Governance structures have been established to give effect to the process.

Some service improvements have taken place since the completion of the Teamwork review. The number of individual accredited laboratory disciplines has increased significantly. Some reconfiguration of laboratory services has been achieved by transferring work undertaken in a number of small laboratories to larger laboratories. A number of laboratories have introduced improved processes employing the principles of Lean Six Sigma. There has also been downward pressure on pay and non pay costs through a combination of pay adjustments, improved efficiencies and implementation of cost containment strategies in individual locations.

Appendix 2 contains a short note on the up to-date situation vis-à-vis the implementation of the laboratory modernisation process. (This update was submitted by the HSE in January 2011 to the Department of Health & Children.)

The National MedLIS Project takes account of the significant changes proposed by the laboratory modernisation process. It is recognised that end-to-end connectivity in Pathology and Laboratory Medicine is the backbone to delivering the goals of the laboratory modernisation programme and in building efficiencies in all disciplines, whilst best serving patients in primary, secondary and tertiary care. The precise model of delivery has not yet been determined and it is not clear at this stage whether some laboratory services will ultimately be provided externally. Notwithstanding this, it is proposed that all laboratory test results will be recorded in the new National LIS so that a central repository of all patient laboratory diagnostic data will be available. In the event that some laboratory services fall to be provided externally[3] the relevant contractor(s) will be required to interface to the National LIS.

4.3 The National Recovery Plan 2011 - 2014

The National Recovery Plan 2011-2014 contains a commitment to introduce major change in medical laboratory services and associated work practices (para 4.6.2, page 69). The achievement of this is dependent on the implementation of a National LIS.

4.4 Public Service Agreement 2010 – 2014 ("*Croke Park Agreement*")

The Public Service Agreement 2010 – 2014 commits to achievement of efficiencies and cost savings throughout the public service. The change management climate that now exists under this Agreement is conducive to the effective implementation of the business and clinical service changes and the ICT deployment associated with the roll out of a National LIS.

4.5 Clinical Strategy & Programmes

The Clinical Strategy and Programmes Directorate has been established to improve and standardise patient care throughout the organisation by bringing together clinical disciplines and enabling them to share innovative solutions to deliver greater benefits to every user of HSE services.

The directorate has established a number of National Clinical Programmes. The Programmes are based on three main objectives:

- to improve the quality of care we deliver to all users of HSE services;
- to improve access to all services, and
- to improve cost effectiveness.

[3] The current expectation is that HSE will progress an "insourced hub and spoke" model for the provision of "cold" testing however the LIMS system specified will be expected to be compatible with whatever model emerges.

The flexibility of a modern LIS will allow HSE laboratories to support current and future Clinical Programme initiatives as they are developed in a way not currently practical with the existing systems. A modern LIS will enable optimum clinical access to relevant patient laboratory results, facilitate the establishment and monitoring of clinical guidelines as they pertain to the ordering of laboratory tests, interpretation of laboratory data and allow for more comprehensive clinical audit.

4.6 HSE Corporate Plan 2008 - 2011

The key HSE business/service strategy document is the HSE Corporate Plan 2008 – 2011. The strategic direction is informed by the needs of the population and builds on progress in meeting the objectives in the first HSE Corporate Plan (2005 – 2008). Governed by the policy directions outlined in the DoHC Statement of Strategy 2008 – 2011 and the Annual Output Statement for the Health Group of Votes, it reflects:

- the National Health Strategy 'Quality and Fairness';
- long term goals for each stage of the lifecycle framework in Towards 2016;
- the HSE Transformation Programme priorities;
- Key Result Areas, and
- various key strategic and policy documents relating to service provision.

The Corporate Plan has also been benchmarked against other international health care systems to ensure that the direction taken is in line with other worldwide health care strategies. The Plan articulates the three year direction for the HSE, incorporating both service delivery and supportive or enabling functions. In addition to the Corporate Plan and in line with stated aims and objectives of the Government's National Development Plan, a HSE Capital Plan 2008 – 2013 has also been developed to support the service planning agenda for the Irish health services.

The Plan flags the supporting role of ICT in the transformation of health services *(TP 10)* and states that the HSE will: -

- Implement an **information framework** based on the Health Information Bill, implementation of standards including the establishment of a patient / client index, provider index and professional index.
- Implement a series of **major strategic initiatives** in areas such as Cancer, Primary Care Teams, Electronic Blood Tracking, Laboratory Information Systems, Mental Health and Hospital Patient Record Systems.
- Continue to **support regional / local initiatives** that improve patient care.
- **Enhance our ICT Infrastructure** through, for example, implementation of a single National Health Network, establishment of a single data centre and consolidation of other ICT Infrastructure services, and
- **Strengthen ICT** capacity and capability. This will be achieved through implementation of the HSE's ICT strategy

4.7 HSE Transformation Programme

The HSE's Transformation Programme represents the organisation's ambition for the future. The programme was prepared following consultation among staff during 2006 and reflects the views expressed during a series of meetings and events across the organisation. It also reflects the views gathered from engagement with the Board of the HSE. Specifically this Transformation Programme states our purpose/mission *'To enable people live healthier and more fulfilled lives'* and provides us with a shared direction and focus that will enable us achieve our ambition/vision for the future which is that:

'Everybody will have easy access to high quality care and services that they have confidence in and staff are proud to provide'

Easy Access – Confidence – Staff Pride

The Transformation Programme sets out the following six main Transformation Priorities:

1. Simplified patient journeys
2. Easier access to primary care
3. Easier access to excellent hospitals
4. More programmes for chronic illness
5. More transparent and measurable standards
6. Greater staff involvement in transformation.

The HSE Transformation Programme provides for the review and reconfiguration of diagnostic services. Reforming diagnostic services will be underpinned by the following key principles: -

i. Services should be designed from the patient's point of view, and should focus not on primary or secondary care but patient care. Consideration must be given to ensuring equality of access and treatment especially for people who have learning difficulties or suffer from mental health problems.

ii. Patients should receive a consistent response, whenever, wherever and however they contact the service.

iii. Patients' needs should be met by the professional best able to deliver the service.

iv. Information obtained at each stage of the patient's journey should be shared with other professionals who become involved in their care.

v. Duplication of tests must be avoided, reducing delays in patient care, maximising scarce resources and reducing risks i.e. excessive exposure to radiation.

vi. Assessment or treatment should not be delayed through the absence of diagnostic and specialist advice.

vii. Core diagnostics should be delivered to clear and measurable standards.

4.8 HSE National Service Plan 2011

This National Service Plan 2011 (NSP2011) sets out the type and volume of service the HSE will provide directly, and through a range of HSE-funded agencies, during 2011, within the funding provided by Government and within the stipulated employment levels. The NSP2011 identifies the following high-level priorities: -

- Maintain the levels of service provided in 2010
- Deliver the cost reduction and restructuring programmes to enable the maintenance of these service levels on a total reduced budget basis of €962m (€683m net)
- Seek to ensure the delivery of high quality and safe services
- Accelerate our reform programme to reconfigure core services and in line with our strategy, deliver an appropriate balance between hospital and community services as well as best care models in childcare, disability, mental health and older person's services, and
- Implement the national clinical change programmes and new service developments.

The availability of modern, effective, integrated ICT systems is essential to achieving these objectives. There are many dimensions to this including supporting integration, efficiency, effectiveness and quality in acute hospital services. The National MedLIS project will contribute to the achievement of all these objectives in respect of laboratory services.

4.9 National Health Strategy 'Quality and Fairness'

The National Health Strategy recognises that a major development of information systems to support clinical practice is required.

Implementation of the new National LIS will address the overall quality objectives outlined in the National Health Strategy 'Quality and Fairness'

The strategy proposed that:-

- Information and Communications Technology would be fully exploited in service delivery (**Action point 117**).
- Information sharing and the use of electronic patient records would be introduced on a phased basis (**Action point 118**).
- Information system development will be promoted as central to the planning process (**Action point 120).**

The laboratory component constitutes approximately 60-80% of the electronic patient record (EPR). It is therefore a core component of any EPR initiative. It is vital to have a modern electronic laboratory module to allow us to build comprehensive EPR with the ability to share information between health agencies. The specifications developed for this project ensure that this will be able to take place.

4.10 National Health Information Strategy

The National Health Information Strategy recognised the following deficiencies in our current systems:-

- Barriers in accessing available data
- Limited analysis of available data
- Lack of coding of most health related information
- Uncertain quality of data
- Limited interoperability between information systems
- Underdevelopment of clinical information systems with key diagnostic data unavailable at all points
- Need to ensure confidentiality
- Limited electronic storage of health determinants and value for money data
- Lack of a unique patient identifier

The above issues will be specifically addressed in the National MedLIS project as pertaining to pathology diagnostic data.

4.11 Report of the Commission on Financial Management and Control

The Commission on Financial Management and Control Systems in the Health Service 2003 (The Brennan Report) stated that 'Clinicians need to have access to cost, performance and clinical outcome information in order to provide quality health care in an efficient manner. The international literature indicates that throughout the world countries/jurisdictions are striving to improve the quality of health care information.'

The report went on to state 'The case for increased investment is twofold. Firstly, at a health board/agency level, IT investment will deliver more process efficiency. IT facilitates the re-engineering of business processes from inefficient manual processes to the most efficient automated processes. A common system for the differing processes also allows the development of shared services to optimise efficiencies and concentrate expertise. Secondly, the real gain will be in the quality of information that becomes available to managers at all levels to enable more timely and effective decision making as well as benchmarking across similar hospitals, departments and services to deliver a more effective, optimum service.'

5. Project Scope, Objectives and Benefits

5.1 Scope

The scope of this Business Case is the totality of the clinical laboratory service delivered across all public hospitals' sites. Currently this comprises the laboratories in all the HSE and Voluntary hospitals, as listed in Appendix 1. Public Analyst laboratories are excluded from scope because the nature of their work is completely different.

It is acknowledged that the laboratory modernisation process may change the configuration of these laboratories. Notwithstanding this the National LIS will provide the essential information systems support for all directly provided laboratory services (i.e. hospital laboratories) irrespective of the configuration. In the event that some laboratory services are ultimately provided externally the relevant contractor(s) will be required to interface to the National LIS so that all patient diagnostic data is available in one central repository.

It is recognised that the need for replacement LIS varies across hospitals, depending on the situation with the existing LIS in use at each site. This factor, along with site readiness, will be considered when decisions fall to be made regarding the rollout sequence of the National LIS.

5.2 Deployment Model

The deployment model for the proposed new National LIS will be based on a central single instance of the software and database. This model will facilitate the maximum sharing of information across sites, thereby ensuring that clinicians have access to the full laboratory diagnostic data on each patient. The model will also achieve economies of scale in software licensing, implementation services, hosting and supporting infrastructure costs. The model will facilitate standardisation of processes and data and is consistent with the HSE's ICT Strategy for *core applications* in hospitals (refer section 4.1). This model is being followed in other existing major IS projects, including the National Integrated Medical Imaging System (NIMIS) and the Integrated Patient Management System (IPMS).

Market research has indicated that the mainline suppliers of LIS have implemented large scale projects based on this model, serving similar numbers of laboratories and similar workload to that proposed. The trend away from individual laboratories having their own separate systems to large multi-site deployments is now well established. In July 2010 the NHS in Wales awarded a single contract for its 18 laboratories, which is a scale not dissimilar to the eventual configuration of hot/cold laboratories in Ireland.

While it is expected that the software and database will be hosted internally in the HSE's contracted datacentre, the procurement process will allow vendors to put forward alternative cost-effective models. It is recognised that new models for delivery of computing facilities (e.g. cloud computing) are emerging and need to be considered by the HSE before placing substantial new IT business. Our market research has indicated that major LIS deployments use both in-house hosting arrangements and various forms of vendor-provided managed service arrangements. While the cost estimates set out in

this business case are based on the more traditional software procurement model – i.e. purchase of licences for in-house hosted software - other options will be explored at the procurement stage. Irrespective of licensing and hosting arrangements the capability to support a coherent patient record across all sites will be a mandatory requirement.

The data standardisation to be undertaken will include the adoption of standard codes for key entities such as clinicians, facilities and tests and will also cover the standardisation of how data is presented to other systems such as GP Practice Management systems. It is recognised that the project will need to work with other information systems projects and with external stakeholders (e.g. HIQA) so that maximum benefit can be obtained from this standardisation work.

5.3 Aims & Objectives

The primary objective of the National MedLIS Project is to address the immediate clinical risks of the current systems and lack thereof by procuring a modern laboratory information system to support the clinical and business needs of the laboratory medicine service, and secondly to support health service objectives in relation to laboratory services in the context of patient care for the next 5 – 10 years.

The strategic goal for the National MedLIS Project can be summarised as follows:

"***To ensure patients healthcare providers have rapid 24-hour access to complete and up-to-date accurate laboratory data across all sites".***

In order to execute this goal, the National LIS must:

- provide electronic storage of the entire patient laboratory record, integrated across all sites;
- provide real-time user-friendly access to this data throughout the agency;
- be a 'virtual' single, flexible, patient-centred information system with automatic tracking, routing and resulting of specimens;
- support "end-to-end" electronic communication of requests and results between hospital / primary care clinicians and the laboratory service, based on HIQA messaging standards;
- support automated interfaces with other relevant information systems, including Patient Administration, Clinical Portals and Clinical Information Systems, and
- ensure management information can be easily extracted to allow optimum management and planning of resources.

A more complete list of the attributes expected of the new LIS is shown below: -

- to store patient information in a robust and safe fashion;
- to allow efficient and real-time delivery of this information to relevant health care providers with more rapid decision making and more efficient treatment with subsequent reduction in costs;
- to shorten turnaround time of lab tests;
- to improve access to the results database;
- to improve accuracy of analysis, by eliminating transcription steps;

- to maximise the safe handling (sample tracking) and the information obtained from samples using system logic capabilities;
- to count and monitor resource utilisation;
- to allow accurate collection of data, workload and costs to allow for proper planning of services and resources;
- to standardise information so that accurate comparisons can be made between facilities;
- to exchange data and information both with analytical equipment and other healthcare information applications, and
- to improve productivity by automating processes and eliminating time consuming paperwork.

5.4 Expected Benefits

The deployment of a standardised National LIS will afford significant cost and performance management benefits by enabling optimisation and service improvement through better intelligence and availability of management information, and also facilitating appropriate electronic laboratory requests.

The tables below summarises the benefits that are expected following the implementing of a new National LIS. These are classified under the following headings - patient, organisation and exchequer - and are further defined as:

- Quantitative - cash releasing (CR) where existing expenditure can be identified and saved.
- Quantitative – non-cash releasing (NCR) where the benefit can be expressed in cash terms but is not directly cash releasing. For example, clinical time saved will normally be NCR because the time can be costed but the benefit will be realised in terms of improving efficiencies and service quality rather than reducing staff numbers.
- Qualitative – non-cash releasing and non measurable (Q) the implication being that these benefits in some way improve quality of care or the welfare of staff.

It is acknowledged that changes arising from the laboratory modernisation process will impact in the same time period as the National LIS rollout. While these changes should not impact negatively on achievement of the National MedLIS Project benefits, the change environment will be more complex and the realisation of these benefits will need careful monitoring and management. It is expected that the two projects will, in fact, be complementary in achievement of various improvements.

5.4.1 Patient Benefits

The following are the expected benefits from the patient's perspective:

Ref:	Expected Benefit	CR	NCR	Q
1.	Improved quality of patient care arising from: ▪ greater reliability of pathology results service; ▪ less dependency on manual processes with reduced risk of error; ▪ automated QA controls and rule-based processing; ▪ standardised SOPs integrated with the National LIS; ▪ integration of information across multiple laboratory sites; ▪ integration of pathology information with other clinical information, and ▪ improved facilities for clinicians to review current and historical results (better clinical decision-making).			X
2.	Improved timeliness of service (faster turnaround of laboratory tests)		X	
3.	Improved security of patient information (confidentiality, integrity & availability)			X
4.	Reduced incidence of unnecessary repeat tests (because of improved availability of previous test results)	X		
5.	Help reduce risk of hospital-acquired infections by providing improved, timely and specific diagnostic information to hospitals (appropriate action can be taken more quickly)	X		
6.	Improved access to hospital facilities (faster turnaround of laboratory results will result in greater throughput of patients)		X	

5.4.2 Organisational Benefits

The following are the expected benefits from the organisation's perspective:

Ref:	Expected Benefit	CR	NCR	Q
1.	Avert hospital wide laboratory system failures by replacing obsolete systems with a new modern National LIS and products that are reliable and robust.		X	
2.	For systems developed 'in-house', avert risk of system failures by transferring activities to a new National LIS where data can be held safely and securely.		X	
3.	Patient-centred data holding will enable safe sharing of relevant information across multiple sites. This is required to enable the changing model of service delivery.		X	
4.	Allow pathology processes to be streamlined so that samples can be analysed in a more efficient way.		X	
5.	Allow laboratory information support personnel and Medical Scientists to work more effectively (i.e. single system to deal with, cross site interaction and cover, less reliance on individual staff, critical mass in terms of out of hours provision, code maintenance etc.).		X	
6.	A modern system would allow future service developments (e.g. replacement analysers) to be implemented more easily and more efficiently.		X	
7.	Provide healthcare providers with information on investigations, profiles, sample types and turn-around times in an accurate and timely way through the use of web links.			X
8.	Allow urgent samples (e.g. A&E) to be fast-tracked with greater ease.			X
9.	Assist hospitals to manage infection outbreaks more effectively (particularly MRSA) through the provision of timely and highly specific information.	X		
10.	Assist hospitals to comply with new accreditation, licensing and regulatory requirements (e.g. ISO 15189). These requirements continue to evolve and a modern National LIS is essential for ensuring laboratories can continue to meet these new			X

Ref:	Expected Benefit	CR	NCR	Q
	requirements.			
11.	Allow best laboratory practice to be adopted in all disciplines once constraints associated with the current systems are eliminated.			X
12.	Allow an enhanced 'rules base' to be developed that will improve the quality and consistency of results and decrease turn-around times for tests and prevent unnecessary test duplication			X
13.	Allow SOPs to be adhered to in a more rigorous way by guiding staff through certain stages of the process.			X
14.	Allow staff to access other relevant health care data within the National LIS to assist in test interpretation (e.g. histology report of lymphoma when reviewing patient's bone marrow biopsy.)			X
15.	Reduces risk of litigation & loss of reputation		X	
16.	Allow management reports to be generated with greater ease and accuracy.		X	
17.	Allow clinically useful reports to be generated with greater ease and accuracy.			X
18.	Improve Clinical Governance by providing a comprehensive audit trail of system activities/transactions.			X
19.	Help pathology departments comply with recent EU legislation on Blood Tracking. (EU directive 2002/98/EC)			X
20.	Help pathology departments comply with National Guidelines & QA Standards – e.g. RCPI Faculty of Pathology Guidelines.			X
21.	Ensure better staff retention by deploying systems that are flexible, intuitive and easy to use. Assist in education & learning.		X	
22.	Allow changes in practice and method to be accommodated more easily.			X
23.	Greater efficiencies in 'laboratory to laboratory' links by enabling electronic data transfers (requests and results)		X	
24.	Enable interfaces to external systems to be built more easily (e.g. Hospital Information Systems, Order Communications GP systems etc). This will be particularly important in supporting the rollout of integrated clinical programmes of care involving, inter alia, structured care of chronic conditions between		X	

Ref:	Expected Benefit	CR	NCR	Q
	primary and acute hospital services.			
25.	Significantly reduce the number of interfaces that must be maintained.		X	
26.	Enable interoperability through support for standardised messaging e.g. the Nationally adopted Health Level 7 messaging standard.			X
27.	Provide support for Internationally Recognised coding systems e.g. LOINC (Logical Observation Identifiers Names and Codes), ICD 10 (International Classification of Disease), SNOMED (**S**ystematised **No**menclature of **Med**icine			X

5.4.3 Exchequer Benefits

The following are the expected benefits from the exchequer's perspective:

Ref:	Expected Benefit	CR	NCR	Q
1.	Generate revenue by allowing greater volumes of external work to be processed on existing infrastructures without the need for a pro-rata increase in staff.	X		
2.	Reduced incidence of unnecessary repeat tests (because of improved availability of previous test results)	X		
3.	Help reduce risk of hospital-acquired infections by providing improved, timely and specific diagnostic information to hospitals (appropriate action can be taken more quickly)	X		
4.	Reduce clerical/admin overheads via use of voice recognition technology for production of histopathology reports	X		
5.	More effective management of demand for laboratory resources via access to good quality, reliable and timely management information.	X		

5.5 Achieving the Benefits

The HSE's intention is to procure a proven LIS, which can be successfully referenced in a deployment setting similar to the HSE's context – i.e. similar scale, multiple separate laboratories, etc. The benefits will arise as a result of the successful implementation of such a LIS. A comprehensive benefits

realisation plan will be developed and put in place by the National MedLIS Project Board to ensure delivery of the opportunities afforded by the National LIS. This will include the assignment of clear responsibilities for achievement of benefits. The introduction of a modern integrated National LIS will bring immediate improvements in the quality and effectiveness of laboratory medicine service delivery to all partners involved in patient care.

Few LIS developments are immediately cost effective, however. On the contrary, the capital cost of the hardware, the on-going cost of hiring or developing computing expertise, the maintenance costs of the system, and the implementation costs of the changeover to a new system will almost certainly mean higher costs in the short-term. Over a period of years, however, the productivity payback in terms of cost-avoidance can be demonstrated as the laboratory service sustains major increases in workload without requiring pro-rata increases in staff and more efficient reporting of results enable system savings. Freeing staff from the current onerous task of maintaining paper based and standalone systems with inherent duplication will contribute to cost savings. Additional cost savings can be realised in other parts of the hospital by access to laboratory information in a timely manner (e.g. some systems do not allow "a copy to" additional report, which can have a bearing on follow up action), guidance on best use of services and analysing the use of services by clinicians through clinical audit.

Furthermore, as regulatory compliance and laboratory accreditation continue to demand more and more evidence of good validation and documentation, a modern LIS system may well become the only feasible and cost-effective way of documenting effective procedures, given the readily-identifiable problems of a paper system. (Storage, deterioration over time, availability etc,)

6. Financial Details

6.1 Project Costs (Non-Pay)

The main elements of non-payroll cost of the National MedLIS Project concern the application software licences, analyser interfaces, 3rd party software licences (e.g. database), integration, implementation services and hardware. In general these are the costs that are paid to the main LIS supplier. In order to determine these costs the HSE contacted five of the main suppliers of LIS systems to request budgetary costs. Four of the suppliers responded to the HSE's request and provided high-level budgetary figures.

6.1.1 Once-off Costs payable to LIS Suppliers

The average of the once-off costs provided by the four LIS suppliers (range €9.5m to €42m) is set out in the following table: -

Once-off Cost payable to LIS Supplier	
Application Software Licences	€ 15,511,555
Integration	€ 1,185,740
Laboratory Analyser Interfaces	€ 1,001,500
3rd party Software Licences	€ 713,125
Implementation Services	€ 1,636,375
Central Hardware (inc Systems Software)	€ 812,652
Sub-total:	**€ 20,860,947**
VAT:	€ 4,380,799
Grand Total:	**€ 25,241,746**

The supplier responses did not break down all the costs in the same way and hence the average cost for each element shown above is not that relevant. In some cases integration, analyser interfaces and 3rd party licences were included in the overall software cost. Therefore it is the overall total figure that is the most relevant – others should just be regarded as broadly indicative of the elemental costs involved.

6.1.2 Other once-off costs

Some once-off cost elements are not included in the budgetary cost estimates provided by the LIS suppliers. These are the integration costs payable to other vendors, local network and desktop equipment at each laboratory and additional wide-area network capacity.

Integration costs payable to other vendors

The new National LIS will require integration with all operational Patient Administration Systems (PAS), various national systems and any local clinical information systems that existing operational LIS solutions are integrated with. It will also require integration with Healthlink, the National Messaging Service. In all these cases either unidirectional or bidirectional interfaces will be required. The main national systems identifiable at present are: -

- Integrated Patient Management System (IPMS) – PAS
- IPMS – Clinical Manager
- Cancer Systems (incl. Screening & Audit)
- Computerised Infectious Disease Reporting (CIDR)
- National Cancer Registry of Ireland (NCRI)
- Electronic Blood Tracking System (EBTS)
- Kidney Disease Clinical Patient Management System (KDCPMS)

To varying degrees services will be required from the vendors of the systems that the National LIS integrates with. Some will be minimal – e.g. where an existing interface is being replaced on the labs side by the National LIS but there is no change or impact on the other system. Others will require implementation services and/or software development by the other vendors.

A sum of €1m is being allowed in the project estimates to cover these costs.

Local network and desktop equipment at each laboratory

Virtually all laboratories at present have substantial LAN and desktop equipment infrastructure in place. It is not anticipated that any significant upgrade of this infrastructure will be required to deploy the new National LIS. The total number of workstations in the laboratories is in the order of 2,000 and allowing for replacement of 25% of these, including an allowance for printers would cost ~ €0.5m. A further amount of €0.5m is being added to allow for upgrade of LAN switches and cabling, thereby giving a total of €1m under this heading.

Additional wide-area network capacity

Virtually all laboratories at present are on hospital sites that are connected on the National Health Network (NHN) or Government Network. The NHN is continuing to be rolled out for various other projects and the parallel network for resilience purposes – NHN2 – is planned. It is expected that all National LIS sites will be serviced with high-capacity links by NHN1 and NHN2 by virtue of other projects – e.g. IPMS and NIMIS. The incremental bandwidth requirement of the National LIS is expected to be relatively small and in most cases no upgrading of network capacity is expected to be required. However, a sum of €0.25m is being included in the overall cost estimate to cater for this eventuality at some sites, should it arise.

6.1.3 Summary of once-off costs

The total estimated once-off costs (non-pay), as outlined above, are:

Summary of Once-off Costs (Non-Pay)	
Cost Element	**Cost**
Payable to LIS Supplier	€ 25,241,746
Integration costs payable to other suppliers	€ 1,000,000
LAN & desktop equipment	€ 1,000,000
Additional wide-area network capacity	€ 250,000
Grand Total:	**€ 27,491,746**

6.2 Ongoing Costs (Non-Pay)

The average of the ongoing costs provided by the four LIS suppliers is set out in the following table: -

Summary of the Ongoing Costs (Non-Pay)	
Cost Element	**Supplier 1**
Software Licences & Support	€ 2,232,088
Hardware Maintenance	€ 147,774
Sub-total:	**€ 2,379,863**
VAT:	€ 148,550
Grand Total:	**€ 2,528,413**

A sum of €0.250m is being added to the above amount to allow for support/maintenance costs payable to other vendors – e.g. for interfaces – and for central hosting costs. The total annual support cost is therefore **€2,778,413.**

(No additional costs are being factored in for ongoing support/maintenance of new LAN or desktop equipment provided as part of this project as it is more likely that such equipment would replace existing equipment and would not attract additional costs.)

6.3 Lifetime Costs (Non-Pay)

The once-off and annual non-payroll costs associated with the purchase, deployment and operation of the new National LIS is shown above. The full lifetime costs of the project comprise the rolled up once-off and ongoing (annual) costs over the proposed duration (7 years) of the contract to be placed. These costs, however, cannot be accurately estimated until a rollout plan is agreed with the successful tenderer because it is not possible at this juncture to predict when individual elements of the costs will arise. It is expected that a rollout period of no more than 3 years can be achieved with sites migrating in groups onto the new National LIS. However, certainty about achieving this cannot be determined until the procurement process has been completed and a contract agreed with the successful tenderer.

The difficulty in accurately determining the full lifetime costs also arises from the fact that vendors have differing models for software licensing, subscriptions, upgrades and software maintenance. Additionally, they vary in areas such as software warranty, which impacts on when annual support charges commence (at a minimum the HSE would not expect to pay any software support charges until sites reach go-live stage at least).

Taking the above factors into account an estimate of lifetime cost has been determined using a factor of 5.5 times the full annual cost. This is based on a 7-year contract, allowing for a rollout period of 3 years, during which the annual charges will ramp up. Therefore, the final 4 years of the contract term will attract the full annual cost while an allowance of 50% is used for the first 3 years.

Lifetime Costs (Non-Pay)	
Cost Element	**Cost**
Total once-off cost (non-pay)	€ 27,491,746
Annual cost X 5.5	€ 15,281,269
Grand Total:	**€ 42,773,015**

6.4 Availability of Non-Pay Funding

The National MedLIS Project will require once-off and ongoing funding to cover non-pay cost elements.

The project has been included in the ICT Capital Plan and there is sufficient funding available in the plan to cover the entire project's once-off, non-pay costs. The priority of the project is recognised and it is expected that funding for it will continue to be protected.

It is expected that the ongoing non-pay cost (estimated above at €2.778m per annum) will be no more than what's currently being paid for support and maintenance on the myriad of existing LIS used by laboratories. Individual hospital budgets will be reduced by these amounts upon termination of existing LIS contracts and these savings will go towards meeting the ongoing costs of the new National LIS, which will be paid centrally.

6.5 Project Costs (Pay)

The once-off payroll cost of staff required for the project, both at national level and in individual laboratories, will come from existing revenue budgets and there will be no additional net cost to the HSE. The assignment of staff to the project will be by means of redeployment. Hence the cost of project personnel represents an opportunity cost only and is not an additional cost.

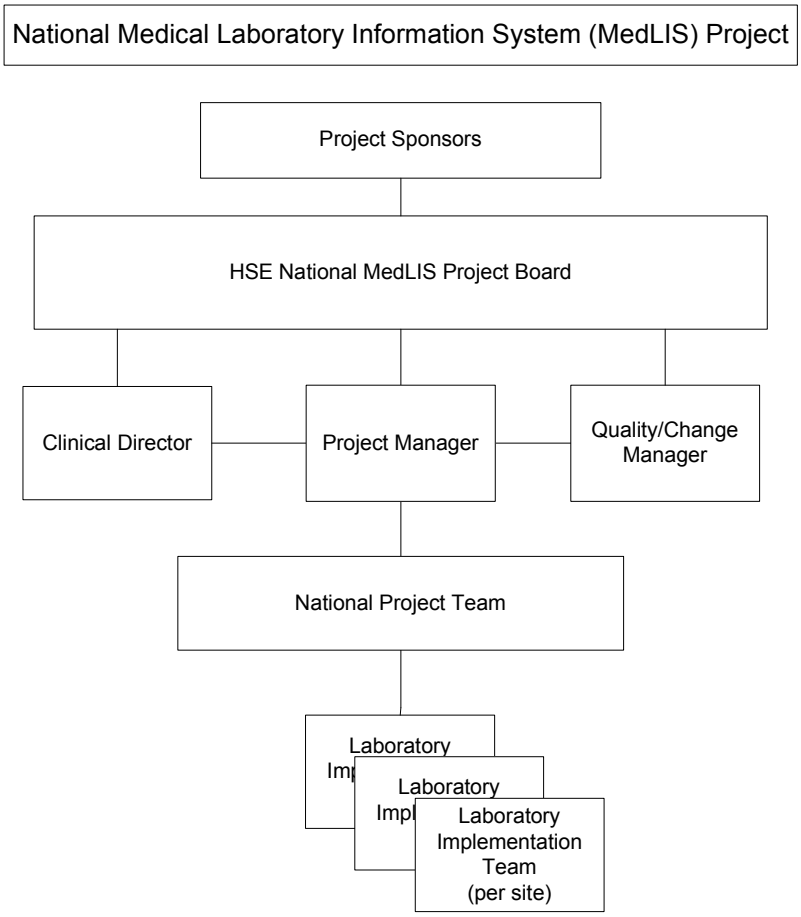
National project team costs will be borne by HSE nationally and funding will be prioritised within overall available resources in this regard.

Local project implementation costs will be borne by hospital labs and the necessary staffing and funding costs will be prioritised within overall available resources by hospital management in consultation with the 4 Regional Directors of Operations.

7. Project Management & Control

The proposed project will be managed openly and professionally through an identified project structure. Before commencing, a clear Terms of Reference will be drafted and agreed. The project will operate on a product-oriented basis producing a clearly defined set of discrete products to a planned timeframe and high standard of quality. Deliverables will be defined clearly and agreed at the outset. Resources required to produce the deliverables will also be identified and the project will not commence until these resources have been made available. Plans will also be drafted and agreed in order to plot resource allocation, identify dependencies and milestones and to highlight discrepancies and time slippage immediately should these occur. A Project Initiation Document (PID) will be produced and signed-off at the outset defining the project governance structures, products, resources, plans, quality mechanisms and controls.

7.1 Project Management Structure



7.2 Project Governance

Appropriate project governance structures will be established to control the project and provide strategic direction, steering, assistance and input. The project will be managed using PRINCE2 which is the standard methodology in place for ICT projects within the HSE.

7.2.1 Project Sponsors

The sponsorship of the project comprises two elements – business and ICT. The RDO for Dublin North East has been appointed by the HSE Management Team as the National Business Sponsor for the project. The Head of ICT will provide the ICT sponsorship.
The sponsors will provide the overall executive leadership for the project and ensure the provision of resources, both financial and personnel. In addition, the Head of ICT is the senior officer within the HSE who carries overall responsibility for the once-off, non-payroll expenditure on this project (i.e. for the capital expenditure).

(Payroll expenditure is the responsibility of the various line managers whose staff are assigned to the project.)

Responsibilities: The principal responsibilities of the Business Sponsor and the Head of ICT with respect to this project are: -

- To provide executive leadership for the project at the top level within the HSE, ensuring senior management ownership / buy-in
- To allocate resources in line with the importance of the project to the HSE
- To represent the project appropriately to the CEO, HSE Board, DoHC, Department of Finance (CMOD) and to any other parties at which representation at the most senior levels is required.

7.2.2 Project Board

The Project Board will provide the overall direction and management for the project. The Project Board is accountable for setting the scope of the project, and for overseeing its successful delivery, arbitrating on conflict wherever necessary. The Project Board will authorise any major deviation from agreed specifications or milestones.

The composition of the Project Board is as follows:

Title	Role	Nominee
Executive Sponsor (Chair)	Executive Sponsor :-to be ultimately responsible to the HSE Management Team for the delivery of the project	**Stephen Mulvany**, RDO DNE
ICT Sponsor (Deputy Chair)	Executive Sponsor: ICT responsible for ICT Capital expenditure sign off and compliance with the ICT strategy.	**Fran Thompson**, ICT Directorate
Pathology Clinical Director	1. To provide overall clinical sponsorship, 2. To provide the required clinical input to the project activities 3. Ensure that the project meets the needs and requirements of all Users. 4. To ensure that required clinical standards are implemented as part of the system	**Dr. Miriam Griffin**, Consultant Pathologist
ICT Assistant National Director	Representing the interests of those designing, developing, facilitating, procuring and implementing the project products.	**Seamus Butler**, ICT Directorate
Procurement	To advise the project on the procurement aspects of the project	**Brendan White** AND Procurement, Portfolio and Category Management
Cold Laboratory Reps	To provide linkages to the Cold Lab Project as part of the Lab Modernisation	**Pat O'Dowd** AND Contracts, Commercial & Support Services. Project Chair of Cold Lab Project Team **Denis Maher** ICT rep on Cold Lab Project Team
One Consultant from each laboratory discipline	Responsible for the approval of the specification of user needs, user liaison with the project team, the integrity of the desired outcome for their respective disciplines and for the monitoring that the solution	**Dr. Gerard Crotty**, Consultant Pathologist Tullamore - Haematology **Dr. Tony Dorman**, Laboratory Clinical Director Beaumont - Histopathology

	will meet those needs within the constraints imposed upon the project	**Dr Brian O'Connell,** Consultant Microbiologist St James's Hospital **Dr Maria Fitzgibbon** Consultant Bio-chemistry – Mater
Laboratory Managers X 3	Responsible for representing the interests of Laboratory managers and Laboratory services.	**Noel Brennan,** Laboratory Manager, Midland (to be confirmed) **John Gibbons**, Laboratory Manager, St James **Dr. Charlie O'Neill**, Pathology Manager, Children's University Hospital – NPH Rep
Customers of the Pathology Service	Responsible for the approval and specification of user needs user liaison with the project team, and the integrity of the desired outcome.	**Dr. Brian O'Mahony, GPIT Group** *Awaiting additional nominations from RCPI and the Clinical Strategy & Programmes Directorate*

Reporting to the Project Board (in attendance at all meetings)

Title	Role	Nominee
ICT Programme Manager	ICT Programme Manager	Willie Anderson, ICT Directorate
ICT Project Manager	Project Manager (Detailed Below)	Fergus Murray, ICT Directorate
Quality/Change Manager	Quality/Change Manager (Detailed Below)	Michael Nerney, Laboratory Manager

The Project Board has the overall authority for the project having specific ownership for the process, directing the project and taking responsibility for delivering the required outcome. It has ultimate authority within the project and is responsible for the initiation, direction, review and eventual closure of the project. To meet this function, project board members must have the authority required to commit resources and initiate new work. The following are the key responsibilities of the Project Board:

1. Provide management oversight of the project
2. Approve the establishment of project structures/groups and their Terms of Reference
3. Nominate membership of project structures/groups as appropriate
4. Agree resources required for the project and secure their assignment
5. Ensure commitment of Pathology Laboratory, ICT, Acute Hospital, Vendor and other personnel assigned to the project
6. Approve project plans and tolerances, and any deviations from them
7. Ensure that priority is given to project activities at all levels
8. Ensure that co-operation and ownership is achieved in the wider organisation
9. Ensure that an effective risk management plan is in place
10. Ensure project scope is clearly defined and understood
11. Ensure Benefits Realisation Plan is drawn up and implemented
12. Review project work plans submitted by the project team
13. Review major design decisions and/or design decisions referred to them for consideration and resolve design issues
14. Ensure project stays within scope
15. Hold regular status meetings to monitor progress
16. Review reported outcomes against expected business benefits
17. Review and sign-off documentation.

The chair of the Project Board was appointed by the HSE Management Team.

7.2.3 Clinical Director

The Clinical Director's role is to provide the required clinical input to project activities, to provide clinical sponsorship for the project and to ensure that the project meets the needs and requirements of clinicians. This is a role that is key to the success of the project, given that the IT solution will be used (and depended upon) extensively by clinical staff and will record patients' clinical information. The Clinical Director will: -

- Provide clinical input, as required, to project activities;
- Promote clinical user 'buy-in' to the introduction of improved work processes and supporting information systems and help motivate clinicians to adopt new systems/practices as part of the implementation process, and
- Act as the main liaison channel between the project and clinicians, representing clinicians and ensuring that adequate clinical perspective is maintained throughout the timeframe of the project.

7.2.4 Project Manager

The Project Manager will manage all aspects associated with the National LIS implementation on a day-to-day basis on behalf of the Project Board and will be accountable to it for its delivery.

The Project Manager's role is to:

- Manage the implementation of the project on a day-to-day basis on behalf of the Project Board
- Draft project plans, monitor progress and highlight exceptions and issues
- Monitor and manage all aspects of the risk management process from the procurement and implementation perspective
- Secure acceptance and approval of deliverables from the Project Board
- Manage Project Team tasks and deadlines
- Work closely with the Quality/Change Manager and support all change management tasks, as appropriate
- Ensure the project produces the required products to the predefined quality standard within the specified timeframe and cost constraints
- Ensure the Project Board are fully briefed on all implementation issues
- Be accountable to the Project Board for a successful implementation ensuring that the project is delivered on budget, on schedule and within scope.

7.2.5 Quality/Change Manager

The role of the Quality/Change Manager for this project recognises that successful change management requires the engagement and participation of all the people involved and that a framework is necessary for managing the people side of the required changes. The Quality/Change Manager will have the key role in facilitating the change associated with the National LIS implementation.

The Quality/Change Manager's role is to:

- Draft and implement the Change Management Strategy
- Establish Change Management Structures
- Formulate and agree policy, procedures and standard work practices to support the successful National LIS implementation
- Manage all change management tasks and deadlines
- Ensure that all change management outputs are produced to the predefined quality standard within the specified timeframe and cost constraints
- Implement the training and education programme
- Monitor and manage all change management aspects of the risk management process
- Implement relevant informatics standards to support the successful deployment of the National LIS.
- Support implementation of best practice protocols related to National LIS operation.
- Ensure that the Project Board are fully briefed on the change management elements of the project
- Work closely with the Project Manager to achieve the project's objectives.

7.2.6 National Project Team

The National Project Team will be established to carry out all project tasks including the specification of requirements, the EU procurement process, finalisation and agreement of contracts, and the build/configuration the new National LIS. The team will be responsible for developing a generic standard National LIS system that will be deployed in each site from a shared services environment. The discipline specific leads will, in turn, manage their own working groups and meet regularly to discuss issues and contribute to the national build.

The National Project Team will consist of the following personnel:-

- Project Manager
- Clinical Director
- Quality/Change Manager
- Discipline Specific Lead Blood Transfusion
- Discipline Specific Lead Microbiology
- Discipline Specific Lead Cellular pathology
- Discipline Specific Lead Biochemistry & Immunology
- Discipline Specific Lead Haematology
- ICT Programme Manager
- ICT Applications Specialist
- Procurement Specialist

The Clinical Director will make key decisions requiring clinical input during the development of the generic standard National LIS.

It is estimated that the development of a generic standard National LIS that will be deployed in each site from a shared services environment will take 6 - 8 months to configure from the date of contract.

7.2.7 Laboratory Implementation Teams

Laboratory Implementation Teams will be responsible for implementing the generic standard National LIS into their hospital(s). The Teams will comprise the following personnel:

- Pathology Implementation Manager
- Discipline Specific Lead Blood Transfusion
- Discipline Specific Lead Microbiology
- Discipline Specific Lead Cellular Pathology
- Discipline Specific Lead Biochemistry
- Discipline Specific Lead Haematology
- ICT Applications Specialist
- ICT Infrastructure Specialist

7.2.8 Stakeholders

The project organisation structure will also include involvement from all the stakeholders including:

- Region & Area Managers (Integrated Services Directorate)
- Hospital Managers / CEOs
- Pathology Clinical Directors
- Pathology Consultants
- Laboratory Managers
- Pathology Service users (Hospital and Community-based Clinicians)
- Directorate of Clinical Strategy and Programmes
- Directorate of Risk, Quality & Clinical Care
- ICT Directorate

In addition, it is recognised that relevant Colleges (and specific Faculties within them) are also stakeholders in the project and must be engaged with as appropriate during the lifetime of the project. The following are particularly relevant in this regard: -

- Royal College of Physicians in Ireland (Faculty of Pathology)
- Irish College of General Practitioners.

7.3 WTE Implications

As the assignment of staff to the project will be by means of redeployment without back-filling, there are no WTE implications.

7.4 Change Management & Training

The implementation of the National LIS will result in changes to current operational practices. The National LIS is a tool for staff to use to support them in their job and therefore to successfully implement the change it is imperative that staff use the system effectively and efficiently.

Change management needs effective communications in order to achieve the project goals. The Project Manager and the Quality/Change Manager will work with the HSE's Communications Department in order to deliver communication strategy for the project.

7.4.1 Training

The HSE recognises that all staff affected will require appropriate training to facilitate a smooth migration from their current LIS to the new system. A detailed staff training requirement plan will be developed for each laboratory as part of the implementation planning process.

The Laboratory Implementation Teams will be responsible for delivering the training programme and preparing users for User Acceptance Testing.

7.4.2 After Go-Live

For users to gain the most from the potential benefits of the system and for the project to achieve its business objectives, users will need ongoing support after go-live. User support groups will need to be established. There will be a requirement for on-going training for new recruits.

7.5 Target Project Timetable

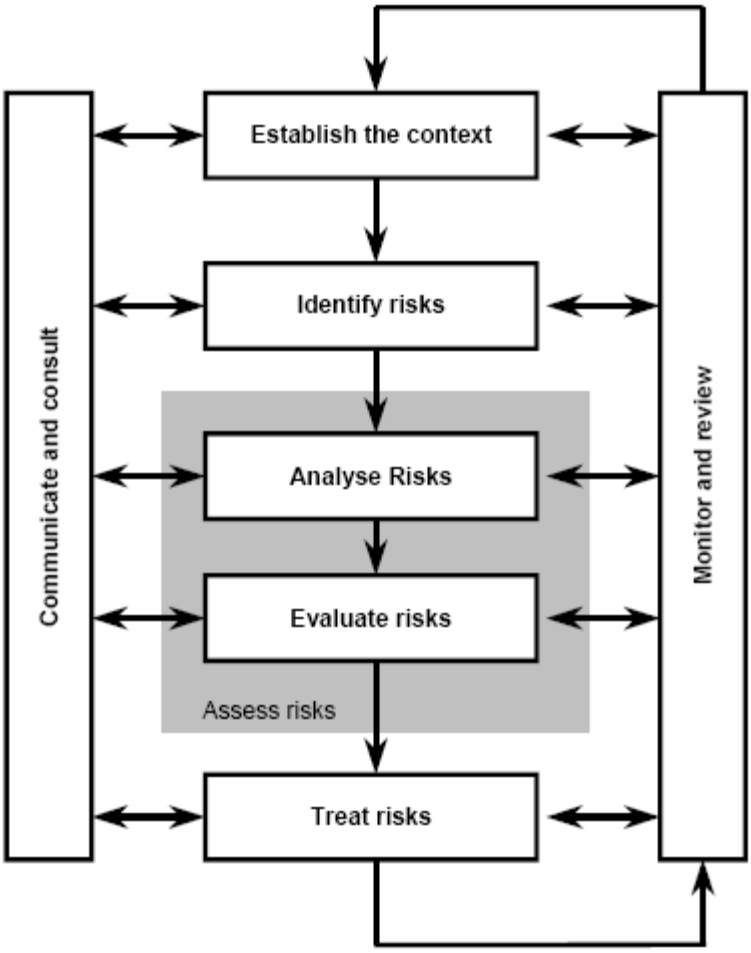
The timetable for this project is very difficult to determine at this point, having regard particularly to the number of stages that are outside the project's control – especially the approval and procurement stages. The overall target is to have the procurement process completed and a contract placed for the National LIS within 12 months of approval of this Business Case, followed by an implementation/ rollout period of 3 years. It is acknowledged that the achievement of these targets is dependent on rapid turnaround of the approval processes and minimal complications in the procurement and implementation phases.

7.6 Project Risks

The overall purpose of risk management is to ensure that issues that pose a threat to the successful completion of the project and/or the quality of its deliverables are properly managed so that their effect is minimised and the project successfully completed. It is recognised that risk management must be an iterative process, which is carried out throughout the lifetime of the project.

At the start of any project the number of possible risks can be very large. With leadership at HSE level, a strong and dedicated governance model, user ownership, experienced project management, a committed implementation team and contractual commitments from the supplier, it is possible to develop mitigation strategies for all risks.

The following diagram shows the generic methodology which will be used for risk management within the National MedLIS Project:

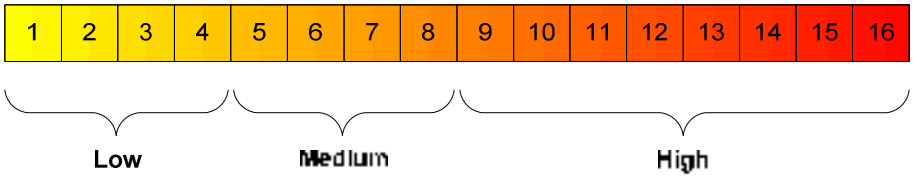


An identification and analysis of project risks has been carried out and is available in the pages which follow. A scoring system has been used to rate the impact and probability of each issue, with the product of these two scores giving the overall risk score for each issue. These scores serve to rank the risks in order to help determine the risk management strategy for each. Issues categorised as low risk were not deemed to require specific risk management strategies at this stage.

The Risk Management Plan (page 40) includes the following headings:

- Risk No
- Issue
- Associated Risk(s)
- Impact (scale of 1-4)
- Probability (scale of 1-4)
- Risk Score (Impact x Probability)
- Risk Management Strategy.

The following diagram shows how risks are classified as low, medium or high risks:



The risk management plan is for all medium and high risks. Issues that have been classified as low risk do not pose a threat to the project and don't require specific management. However, they will be reviewed throughout the project.

The Risk Management Plan will be maintained for the duration of the project and will be re-visited on a monthly basis when risks are re-evaluated. It should be possible to downgrade some of the medium or high risks where the corresponding risk management plan is effective. Although the Project Manager, Clinical Director and the Quality/Change Manager are the primary risk owners, many people involved in the project will have some responsibility for risk management including the Implementation Project Team and Laboratory Implementation Teams and it is important that they know what they are watching for and that reporting potential risks is a significant part of their role. Project risks will be reported to the Project Board on an agreed regular basis. Furthermore it is important that risk management is included within the project's communication strategy.

The Project Manager, Clinical Director and the Quality/Change Manager will work together in the monitoring and management of the risk management process although each will have responsibility for risks that are unique to their area. The risk management process includes: -

- The development of the Risk Management Plan
- The continual monitoring of the project to identify any new or changing risks
- Continual monitoring of the effectiveness of the Risk Management Plan
- Regular reports to the Project Board.

The Project Board has ultimate responsibility to ensure that an effective Risk Management Plan for the project is in place, that it is kept reviewed and updated and that the process for mitigation and treatment of risks is implemented effectively.

Risk No	Issue	Associated Risks	Impact[4]	Probability[5]	Risk Score[6]	Risk Management Strategy
1.	Consequent on the Government's recruitment moratorium and budgetary reductions, the HSE has imposed strict controls on expenditure and WTEs with consequential pressures throughout the organisations involved in the project. Additional pressures have also arisen from the requirement for extended working day and from early retirement incentives.	It may prove difficult to release personnel resources required to implement the National LIS as and when contracts are signed. It may prove difficult to obtain the level of buy-in and commitment required from the various staff groups to prepare for and to implement the National LIS.	4	4	16	▪ Secure commitment of required resources at the outset from the HSE and the Voluntary Hospitals concerned ▪ Postpone the National LIS implementation until the above commitment is made and the HSE and hospitals are able to absorb the overhead associated with the project. ▪ Monitor the impact of the strict financial controls on an ongoing basis and escalate any problems arising to relevant senior management at an early stage.
2	There may be delays in decision-making or other difficulties in getting key decisions made, having regard to general pressure of work and the fact that the project involves a number of separate organisations.	Delays in achievement of project objectives Risk that the project stalls	4	3	12	▪ Ensure strong links are maintained between the project and senior HSE personnel at Management Team level so that issues can be escalated and dealt with expeditiously ▪ Implement a formal regular reporting mechanism from the project to the HSE's senior management (both ICT and ISD)
3.	Project personnel are not very experienced in large-scale projects of this nature.	It may take longer to produce an implementation plan with the required level of detail Deficiencies may be discovered in the implementation plan as the project	4	3	12	▪ Assign an experienced project management coach or mentor to the project ▪ Due to the scale and complexity of the project, get external consultancy / input at key stages ▪ Put a strong quality assurance process in place to ensure the project is on the right track.

[4] Impact: 1 = Low; 4 = High
[5] Probability: 1 = Unlikely; 4 = Almost Certain
[6] Risk Score = Impact X Probability (1-16)

Risk No	Issue	Associated Risks	Impact[4]	Probability[5]	Risk Score[6]	Risk Management Strategy
		progresses with consequent need for re-working and redefinition of targets. There may be delays in delivering the project's objectives.				▪ Make sure the project deliverables are formally approved. ▪ Utilise strong team leaders and team members to bring additional experience to bear. ▪ Have a communications plan in place to ensure all project personnel know what is going on including whom to raise issues with and provide feedback to.
4.	The number of sites and departments within sites to implement is large, spread over a wide geographic area and within different organisations (e.g. voluntary hospitals)	There may be different requirements from the different sites/areas, resulting in difficulties in agreeing the common build. Individual sites/areas may seek short-term ineffective local solutions rather than agree to change. The project team may fail to engage with all the relevant stakeholders in all sites and this may impact negatively on the implementation and achievement of project objectives.	4	3	12	▪ Ensure that all sites/departments are fully aware of the expected benefits, workflow changes etc. at the earliest opportunity. ▪ Appoint the Pathology Implementation Managers at each of the sites/areas at an early stage to ensure full participation by them from the outset. ▪ Ensure comprehensive input from all sites on requirements ▪ Communicate with all relevant staff and provide forum to enable staff raise issues/concerns. ▪ Use the line management system to provide formal direction to staff in local sites/areas when necessary
5.	Organisational policy/process/procedure change – a reasonable level of workflow change may be required.	There may be confusion about new processes or staff may be unwilling to accept them There may be workload difficulties arising from new processes There may be operational service difficulties and data quality problems because of new processes	3	3	9	▪ Document all current policies and processes and ensure that they are correct. ▪ Ensure all relevant staff groups are involved in defining the policy and process/workflow changes. ▪ Communicate precisely how the new processes differ from the old ones. ▪ Have one person responsible for policy and process changes. ▪ Get Human Resources (HR) involved to deal with potential staff issues.
6.	The project impacts many staff disciplines (medical,	Failure by one or more of the staff disciplines involved to engage fully	3	3	9	▪ Include all relevant staff groups in the project governance structures including Laboratory

Risk No	Issue	Associated Risks	Impact[4]	Probability[5]	Risk Score[6]	Risk Management Strategy
	scientific, clerical/admin, nursing & allied)	may have a detrimental effect on the project's outcome.				Implementation Teams ▪ Put in place an effective communications plan ▪ Get Human Resources (HR) involved to deal with potential staff issues.
7.	The estimated project duration is long (4 years)	It may prove more difficult to manage the project plan / resources. The project team and relevant staff may lose focus. There is greater possibility of staff turnover in the project team and other relevant staff	4	3	9	▪ Break the project into smaller, shorter sub-groups. ▪ Identify clear milestones to check that the project is on schedule. ▪ Use formal change management procedures. ▪ Ensure all major deliverables are formally approved. ▪ Instill a sense of urgency from the start of the project.
8.	The number of interfaces to the National LIS is large across multiple sites, vendors and products, including a variety of laboratory analytical equipment	The amount of time and effort required to deliver the interfaces may be underestimated and may impact negatively on the system implementation / rollout. There may be continuing problems with some interfaces delaying go-live or causing post go-live problems	3	3	9	▪ Do comprehensive analysis and specification of all interfaces to ensure the needs of the interfaces are well understood. ▪ Apply rigorous QA process to interface specifications ▪ Test the interfaces as early in the project as possible in order to allow time for problem resolution ▪ Build in contingency for interface problems in project planning
9	The project is being initiated at a time of uncertainty about the future organisational arrangements for health services generally, and about the future configuration of lab services. (New Government also laboratory modernisation process not finalised.)	The project may stall, pending clarification of implications of potential new arrangements Specifications of requirements and other project deliverables may require re-working when implications of potential new arrangements are known Very low risk that the project would require substantial change or be terminated	4	2	8	▪ Project Sponsors to put in place effective communications with key personnel involved in new organisational arrangements so as to inform project at earliest opportunities ▪ Standing item on Project Board agenda so as to maintain management focus on the issue

Risk No	Issue	Associated Risks	Impact[4]	Probability[5]	Risk Score[6]	Risk Management Strategy
10	The project is being initiated at a time of uncertainty about the future industrial relations environment in the public service. There is considerable public speculation that the *Croke Park Agreement* may not hold and, if that happens, there may a sustained campaign of industrial action.	It may prove difficult to get staff co-operation for the project because of a negative IR environment. Staff may be instructed by their trades union not to participate in project activities.	4	2	8	▪ In the event that the IR environment becomes difficult the Project Sponsors will seek to arrange - through established IR communications structures - that the impact on the project is minimised.

The following table identifies the remaining items that were evaluated from a risk perspective. They are all considered as low risk and consequently are not further evaluated at this stage as they do not pose a threat to the project at this time. However they will be reviewed on an on-going basis throughout the duration of the project.

Table 5	**National MedLIS Project – Risk Management**	
Risk No.	**Risk Area**	**Current Status**
10.	Business Benefit	The business benefit is well defined.
11.	Project Scope	The scope of the project is well understood and defined at a high level.
12.	Project Governance	The project governance structure, including the Project Sponsor, is identified and the Project Board is in place
13.	Organisational Structure Change	There is little or no organisational structure change required for this project
14	Technical Requirements	The technical requirements are reasonably well understood and are in the course of being defined in detail.
15.	Data Requirements	The data requirements are reasonably well understood and are in the course of being defined in detail.
16.	Data Migration	Data take on is required only for two laboratory disciplines - Histopathology and Blood Transfusion – and is well understood. Other options are available in the event of data take-on difficulties for these disciplines.
17.	Availability of IT Solution	Market research indicates that there are likely to be several suppliers available with suitable solutions

7.7 Key External Impacts

The following are the key external impacts on the National MedLIS Project – i.e. factors which will influence the project and the extent of the benefits overall that the project can achieve.

7.7.1 National Client Index (NCI)

The National MedLIS Project is being initiated in advance of the introduction of a Unique Health Identifier (UHI). While it is expected that a UHI will be introduced in due course it requires new legislation to be enacted and there is no certainty about the timeline. A UHI is required to properly facilitate the integration of laboratory diagnostic data across multiple laboratories.

The National Client Index is a facility/service provided by the Primary Care Reimbursement Service (PCRS) within the HSE, to provide a means of linking disparate databases that contain client/patient data. The technology that underpins the NCI was originally used by the PCRS to link records for the same clients/patients across different schemes administered by the PCRS. The PCRS now provides these NCI services to a wider user base, including hospitals and other services. The NCI will be available to the National LIS to facilitate sharing of patient data across multiple laboratories by providing a common [background] identifier. It is expected that this solution will facilitate integration of patient records in advance of a UHI. However, the process implications of laboratories sharing data via use of NCI-provided linking mechanisms have not been fully explored and it is not clear as to the extent to which this will provide a successful solution. The National LIS can be deployed without the NCI solution being fully successful but the extent of cross-site integration may be incomplete.

7.7.2 *Clinical Portal* and Clinical Information Systems

The National LIS must support and enable end-to-end communication of test requests and results from/to all clinicians utilising medical laboratory services. However, the National LIS solution itself will not be the only one at play in this regard. Clinicians in various settings may utilise different IT solutions at the point of submitting requests and at the point of viewing results. This will range from GP Practice Management Systems to *Clinical Portals* to specific Clinical Information Systems in particular specialties – e.g. Renal. It is essential that the National LIS interfaces seamlessly with such systems and that it provides the underlying clinical decision support in a consistent way to these other systems. It is also essential that clinicians without any such systems are enabled for end-to-end electronic communication of laboratory tests and results by the National LIS itself. There is a wide range of clinicians who work in different settings – from ICUs in acute hospitals (with sophisticated Clinical Information Systems) to palliative care services delivered in patients' homes (utilising mobile devices) - and all must be catered for by the new National LIS solution.

The HSE has acquired various IT solutions that contain functionality to place laboratory test requests and view results, typically integrated with other patient data. This includes iSOFT's Clinical Manager product, which is being deployed by the Integrated Patient Management Programme (IPMS). It is not the intention that the National LIS will replace such solutions, more so that it will complement them. However, projects concerning these other solutions will potentially impact on the National MedLIS Project as, in some cases, the full achievement of end-to-end communications may be dependent on deployment of other solutions.

7.7.3 Primary Care Messaging

Primary Care Messaging concerns the electronic collection of test requests from GPs and the electronic delivery of test results. Healthlink has been established nationally to provide the messaging service to support 2-way communications between healthcare providers – typically between GPs and hospitals. This is based on the HIQA national messaging standards. It is expected that the National LIS will utilise the Healthlink messaging service for most communications with GP practices and, as such, will be dependent on it for end-to-end communications with GP practices.

7.7.4 National Health Network:

Wide-area data communications links have been greatly enhanced in recent years arising from the implementation of the National Health Network. These will need to be maintained and additional resilience provided. It is understood that a parallel network is planned, which when implemented will provide very high levels of service availability from the central hosting centre.

7.7.5 Data Sharing Protocols and Data Protection Compliance: The proposed sharing of patient data will require protocols and compliance with Data Protection legislation. The project will depend on these protocols and new arrangements being agreed. The project will not be acting independently in this regard because arrangements being put in place, or will be put in place, in respect of other projects and these will have a bearing on the National MedLIS Project. Additionally, within the HSE and the hospitals the responsibility for data protection matters – registration, compliance, etc, lie outside the scope of the project.

Appendix 1

Laboratory Information Systems (LIS) in Irish Hospitals					
Apex/iLAB	**Winpath – Clinisys (Woodard)**	**Telepath**	**NetAcquire – Custom Software (C Rutter)**	**Misys Healthcare System**	**Lifeline – Mediware Info Systems**
Waterford Regional Hospital	Our Lady of Lourdes, Drogheda	Mater Misericordiae University Hospital	Cavan General Hospital	Sligo General Hospital	Beaumont Hospital
St. Luke's General Hospital	Cappagh National Orthopaedic Hospital	Connolly Hospital, Blanchardstown	Midland Regional Hospital, Tullamore	Letterkenny General Hospital	
Wexford General Hospital	Our Lady's Hospital for Sick Children, Crumlin	St. Columcille's Hospital	Midland Regional Hospital, Mullingar		
South Tipperary General Hospital	National Maternity Hospital, Holles Street	St. James Hospital	Midland Regional Hospital, Portlaoise		
Cork University Hospital	Adelaide & Meath Incorporating the National Children's Hospital, Tallaght	Naas General Hospital	St. John's Hospital, Limerick		
Mallow General Hospital	Coombe Women's Hospital	Mercy University Hospital	South Infirmary Victoria University Hospital		
Kerry General Hospital	Portiuncula Hospital		St. Luke's Hospital, Rathgar		
Bantry General Hospital	Royal Victoria Eye & Ear Hospital				
Louth County Hospital					
Our Lady's Hospital, Navan					
Rotunda Hospital					
Children's University					

Laboratory Information Systems (LIS) in Irish Hospitals					
Apex/iLAB	**Winpath – Clinisys (Woodard)**	**Telepath**	**NetAcquire – Custom Software (C Rutter)**	**Misys Healthcare System**	**Lifeline – Mediware Info Systems**
Hospital, Temple Street					
St. Vincent's Hospital					
St. Michael's Hospital					
Mid Western Regional Hospital, Limerick					
Mid Western Regional Hospital, Nenagh					
Mid Western Regional Hospital, Ennis					
UCH, Galway					
Mayo General Hospital					
Roscommon County Hospital					

Appendix 2

Update on Laboratory Modernisation Process – 19.01.11

The HSE is currently progressing a process of significant reform of laboratory medicine services.

Background

The external review undertaken by Teamwork highlighted a number of limitations in the current system and recommended the implementation of a single coordinated system by:

- Processing the large volumes of routine patient tests generated from the community care system, outside the hospital, in dedicated "cold" labs. (A "cold" lab is a facility that is centralised and custom designed to process high volumes of routine "cold" samples, typically from primary care. It would include automated and non-automated sections; would be supported by dedicated logistics solutions and IT; may be standalone and would have a fast turnaround time);

- Processing tests from patients in regional hospitals receiving acute "round-the-clock" care through dedicated "hot" labs. This will provide more access to clinical laboratory medicine advice and more direct care of the complex patient. (A "hot" lab is a facility co-located with the emergency and complex acute services responsible for processing all urgent "hot" samples with an extremely fast turnaround time);

- Increasing "point-of-care" testing – where tests are carried out immediately: in acute hospitals, in local healthcare settings or in the patient's home - wherever it is clinically appropriate and cost effective. (Point of care involves tests performed by non laboratory staff at or near the site of patient care, e.g. GP practice, clinic, home);

- All laboratories would be fully accredited and supported with appropriate I.T. and transport / logistics infrastructures

Recent service improvements

Some service improvements have taken place since the completion of the external review. The number of individual accredited laboratory disciplines has increased significantly. Some reconfiguration of laboratory services has been achieved by transferring work undertaken in a number of small laboratories to larger laboratories. A number of laboratories have introduced improved processes employing the principles of Lean Six Sigma. There has also been downward pressure on pay and non pay costs through a combination of pay adjustments, improved efficiencies and implementation of cost containment strategies in individual locations.

Development of cold laboratory services

The HSE engaged The National Development Finance Agency and DKM Economic Consultants to assist in the preparation of an outline business case / cost/benefit analysis (OBC/CBA) for the development of cold laboratory services. This process is overseen by a Project Team which is chaired by Pat O'Dowd, Assistant National Director, Commercial and Support Services.

For the purposes of developing an OBC/CBA, a decision was taken that dedicated cold laboratory facilities would process biochemistry, haematology and immunoassay workload generated by the primary care sector. Further consideration could be given at a later stage to expanding the clinical scope of services to be provided at the facilities to include more laboratory disciplines, specialist or esoteric services. Thus, at present, microbiology, histopathology and other areas such as Public Analyst Laboratories and Public Health Laboratories are outside scope.

The OBC/CBA indicates that it would be viable to undertake a process of consolidation to create a national dedicated cold laboratory service. Rather than the current situation where the approximately 30 million tests generated by GP/primary care sector are processed in approximately 26 different laboratories throughout the country, the OBC/CBA considered the consolidation of that workload. It considers a number of different options, including 8, 3 and 2 site service configurations.

The OBC also identifies and analyses a number of options for financing the various cold laboratory site configurations including direct public provision, direct private provision and various public/private partnership models. These options are now under active consideration by the HSE.

Pre-competitive dialogue process

Given the range of complexities involved, the HSE undertook a formal pre-competitive process/market soundings exercise. This involved engagement with experienced and capable service providers – in the private and public sector - as a key input to reaching a definitive conclusion on (i) the service configuration option that will best deliver a consolidated and dedicated national cold laboratory service stream for the HSE and (ii) the most cost effective way of financing the preferred option.

The findings of that process will inform decisions to be taken in relation to the development of cold laboratory services

Hospital capacity for cold laboratory workload

A number of the larger hospital laboratories were requested in mid 2010 to make submissions in relation to their capacity to significantly expand the volume of laboratory workload which could be undertaken within existing resources. These submissions generally indicated that with the implementation of significant changes in work practices,

increased volumes / capacity growth could be facilitated either directly or through external partnerships. These submissions will also inform decision making.

Revised work practices within laboratories

The decision on the most appropriate way to develop cold laboratory services will also be informed by engagement in relation to the Public Service Agreement (PSA). The PSA recognises and acknowledges the advanced level of engagement of the relevant stakeholders *'to deliver major change to the medical laboratory services and associated work practices.'* (Paragraph 2.9.15 of the PSA refers). In this regard, MLSA, IMPACT and SIPTU representatives have been engaged in relation to the intention to introduce more cost effective work practices within existing laboratories as a precursor to national changes.

Discussions, conducted under the auspices of the Labour Relations Commission, concluded, without full agreement, on 14th January. The outstanding issues relating to the revised payments for emergency out of hours working and compensation for loss of earnings will be the subject of a Labour Court hearing on 28th January 2011.

Hospitals have been instructed to introduce extending working day arrangements from 1st February 2011. Rosters will initially be based on 8am – 8pm working on a 5/5 basis, in line with 2.9.12 of the Public Service Agreement.

The engagement in relation to the introduction of revised work practices will give a clear indication of the willingness and capacity of the public health service to provide laboratory services (including cold laboratory services) within the required efficiency / cost / quality parameters. This would mean significant changes in traditional practices, in skill mix and staffing, in technology utilisation and responsiveness.

Appendix 3

Examples of large-scale LIS deployments in other jurisdictions

The National LIS must be capable of scaling to support 44 pathology laboratories on a single instance database model, utilising a single hardware platform and deployed from a single datacentre. To ascertain the feasibility of fulfilling these requirements a number of international LIS suppliers were contacted and requested to submit a high level overview of their LIS implementations. The information provided by these suppliers, and various follow-up discussions with them, have given assurance that our proposed deployment model is feasible and appropriate.

Examples of large-scale LIS deployments that have already been undertaken, and which are in live operation, include the following: -

- London Health Sciences Centre, London, Ontario, Canada (18 labs)
- Adventist Health System, Lake Mary, Florida, USA (25 labs)
- Adventist Health, Glendale, California, USA (15 labs)
- Alegent Health, Omaha, Nebraska, USA (8 labs)
- Banner Health, Phoenix, Arizona, USA (24 labs)
- BJC Healthcare, St. Louis, Missouri, USA (6 labs)
- Billings Clinic, Billings, Montana, USA (12 labs)
- Clarian Health Partners, Indianapolis, Indiana, USA (12 labs)
- Memorial Hermann Health System, Houston, Texas, USA (8 labs)
- Tenet Health System, Dallas, Texas, USA (10 labs)
- Texas Health Resources, Dallas, Texas, USA (13 labs)
- St. John of God Laboratory Services in Western Australia (8 laboratories)
- All Northern Territory public laboratories in Australia
- The Echevane network, Barcelona (51 sites based on a central system)

Examples of large-scale LIS deployment projects that are in train include: -

- Eastern Ontario Regional Lab Association in Canada, (18 sites – 10M lab request orders)
- US Veterans Administration hospitals (158 sites – 75M lab request orders/annually)
- Universal Health Systems (23 sites – 7M lab request orders)
- Centralised LIS system based in Johannesburg to run all 258 public laboratories throughout South Africa (several thousand concurrent users and over 1,000 instruments interfaced).
- NHS Wales (18 laboratories - initial sites scheduled to go-live September 2011)