



## HSE Board Briefing Template

**Subject:** Proposal for Replacement of the Laboratory Facilities at University Hospital Galway: Strategic Assessment Report (Stage 1 of 6)

**Submitted for meeting on:** 13 December (EMT), 8 December (ARC), 16 December 2022 (Board)

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### Why is this information being brought to the Boards attention?

For consideration and approval to proceed. The total capital cost of this proposal is [REDACTED]. Projects of such scale and value require specific approvals at various stages of the project lifecycle in accordance with the current Public Spending Code. The first stage of the process involves the preparation and approval of a Strategic Assessment Report (SAR) for the project.

### Is there an action by the Board required, if so please provide detail?

This proposal was approved at EMT and ARC, it is recommended that the HSE Board consider the capital investment proposal as set out in this paper and in the attached SAR at Annex 1 and endorse the case that is being made to replace the existing laboratory facilities at University Hospital Galway (UHG). At this preliminary stage the initial cost estimate range for the proposal is [REDACTED] inclusive of VAT. Formal approval of the SAR (Decision Gate 0) will be requested from the Department of Health in order to proceed to the next stage of the process namely, the preparation of Preliminary Business Case for the project.

### Please indicate which of the Board's objectives this relates to;

- The development and implementing of an effective Corporate Governance Framework, incorporating clinical governance and a performance management and accountability system; **X**
- Developing a plan for building public trust and confidence in the HSE and the wider health service; **X**
- Ensuring the HSE's full support for and implementation of the Government's programme of health reform as set out in the Sláintecare Implementation Strategy; **X**
- Exercising effective budgetary management, including improving the value achieved with existing resources and securing target saving, with the objective of delivering the National Service Plan within Budget. **X**

### Brief summary of link to Board objectives.

This project aims to support the implementation of government health policy in the West of Ireland by providing key replacement infrastructure to enable ongoing laboratory services provision in Galway into the future. Capital investment of [REDACTED] will be required and it is a reserved function of the Board to approve any capital investment transactions above €10 million.

The HSE as Sponsoring Agency will have primary responsibility for evaluating, planning and managing this public investment project within the parameters of the Public Spending Code.

The latest Public Spending Code sets out the current process for the delivery of such major public investment projects. It sets out the roles and responsibilities for both Sponsoring Agencies such as the HSE and Approving

Authorities in that regard and provides detail on the requirements at each stage of the project lifecycle. There are now **six stages** and **four Decision Gates** in the project lifecycle, three ex ante and three ex post as follows;

**1. Strategic Assessment Report (SAR)**

- **Decision Gate 0 – Current Stage**

**2. Preliminary Business Case (PBC)**

- Decision Gate 1 – Approval in Principle

**3. Final Business Case (FBC), including design, procurement strategy and tendering**

- Decision Gate 2 – pre-tender Approval
- Decision Gate 3 – Approval to Proceed (Contract Award)

**4. Implementation**

**5. Review**

**6. Ex Post Evaluation**

This paper relates to the Strategic Assessment Report (SAR) – Decision Gate 0 (item 1 above).

As the project progresses through the project lifecycle it will be referred to ARC and the Board again for endorsement at three further stages in addition to this paper, namely for endorsement of the Preliminary Business Case (Decision Gate 1) and for endorsement of the Final Business Case which comprises two approval gates (Decision Gate 2 and Decision Gate 3).

**Background - provide context in order to ensure that the Board fully understand the issue.**

The primary objective of this proposal is to address serious risk and quality issues and spatial constraints associated with the facilities on the UHG campus, in use for the delivery of laboratory services. The current facilities consist of one concrete structure and a series of pre-fabricated buildings all of which have reached end of useful life and are seriously sub-standard for the needs of the laboratory services. Currently services operate from a range of individual laboratories accommodated in approximately 4,000sq m of space (including waste compounds and circulation space), comprising the original building constructed in 1958, and extensive prefabricated extensions mostly constructed 40 to 50 years ago. These are fragmented, necessitate duplication of resources and do not facilitate delivery of services to international best practice standards. The existing buildings are very clearly unfit for purpose as a modern efficient laboratory into the future. A number of specialist services are at significant risk due to the poor state of the buildings. In particular, the Blood and Tissue Establishment and Microbiology Category 3 laboratory, which is the only TB containment laboratory in the Saolta Group, are at a critical point as the facilities are nearing end of life, with technical deficits, and are facing the risk of loss of licence, accreditation and delivery ability. Contamination risks within molecular analysis are also a concern due to the current infrastructure.

The catchment population of UHG is approximately 350,000 people, drawn from the greater Galway and Roscommon areas, per the Central Statistics Office (CSO) 2022 Preliminary Population Census<sup>50</sup>. The *Saolta Group Strategy 2019-2023* indicates that it serves a population of 830,000 people, and provides acute and specialist hospital services to the west and north-west of Ireland, including counties Galway, Mayo, Sligo, Donegal, Roscommon, Leitrim and parts of adjoining counties, approximately one sixth of the national population spread across one third of the land area of the State. The national population has grown by 7.6% since the 2016 Census, and Saolta Group catchment population has grown by 6.3% in the same period. The labs also provide laboratory support for community / GP services for this catchment area.

The Laboratory Department undertook 14.6 million tests in 2019, across all disciplines. Some 59% of these originated in the acute hospital system and, of those, 90% originated in GUH, with the balance from other hospitals in the Saolta Group and nationwide

There have been a number of proposals over the years to deliver a new building to replace the existing accommodation for the laboratory services. A Cost Benefit Analysis was completed which supported new infrastructure provision as far back as 2008. More recently, in 2019, An Options Appraisal for Saolta Model 4 Hospital Services in Galway by KPMG rated the laboratory infrastructure at Grade D, in unacceptable condition, recommending a total rebuild.

The Laboratory Department on the UHG site encompasses the main specialties of Blood Transfusion, Clinical Biochemistry and Immunoassay, Clinical Immunology, Anatomic Pathology including Histopathology, Cytopathology and Molecular Pathology, Haematology, Medical Microbiology and Virology. The laboratory offers specialist technologies and expertise in Bacterial/Viral Whole Genome Sequencing, Endocrinology, Toxicology, Flow cytometry, Coagulation, Immunochemistry and Autoimmune disease.

Activities related to the Laboratory Medicine Service include infection control (both guidance and interpretation), epidemiology, occupational health screening, diagnostic aspiration cytology, post mortem examinations, direct clinical treatment of patients in certain circumstances, research and development, medical education and audit.

The Blood and Tissue Establishment is to provide both national and supra-regional services for Autologous Serum Tear Drops, Stem Cell Therapy, tissue supply and antibody screening. Supra-regional services include Mass Spectrometry (Clinical Biochemistry), Clinical Immunology, Direct Immuno-Fluorescent techniques (Histopathology). Within the Division Microbiology, GUH there are the Clinical Diagnostic sections of Microbiology and Virology; the Public Health Laboratory PHL (Food and Water analysis); and two National Reference Laboratories, the National Carbapenemase Producing Enterobacterales reference laboratory service and the National Salmonella, Shigella, and Listeria reference laboratory service.

A key feature of laboratory modernisation is the implementation of Managed Service Contracts (MSCs) for laboratory services, whereby the cost of the machine is rolled up into the cost of tests. This procurement process enables diagnostic laboratories to install the most innovative equipment and instrumentation without incurring major up-front equipping costs. However, without the availability of large open plan infrastructure, optimisation of such contracts is very difficult to achieve. Potential optimisation of workload capacity and reductions in Turn Around Times have fallen short of expectations in Galway due to a disjointed laboratory layout. Also, sample archiving, a common process in modern blood science laboratories is not ideally configured due to the current layout in Galway and so is currently done “off track” requiring staff to sort, archive and retrieve manually.

The objective of this proposal is to plan and build replacement laboratory infrastructure to meet projected future needs that would incorporate the following facilities:

**The central reception and automated laboratory:** To enable centralise sample processing and allow all easily automatable analytics on either a single consolidated platform or multiple platforms by the use of automated tracking linked with pre-analytical technology.

**Core Clinical Diagnostic laboratories:** An open plan layout for the core laboratories with demountable partitions and benches to allow for maximum flexibility. The initial footprint should factor in an expandability factor to allow for growth and changes in diagnostic practices, to future-proof the service.

**The Blood Tissue Establishment (BTE) Class II Clean laboratory:** Both Good Manufacturing Practice (GMP) and Tissue Licences are in place for the running of this specialised “Clean Laboratory” in order to undertake Adult Stem Cell Processing and the manufacture of Autologous Serum Eye drops. These services are expanding and require fit for purpose laboratory in order to maintain and develop specialist clean laboratory processing and research linkages.

**The molecular laboratory:** This will consolidate the molecular diagnostic and research platforms into a central specialised laboratory, with defined molecular areas (Area I: PCR preparation, Area II: Sample preparation, Area III: Amplification & Analysis).

**The flow cytometry laboratory:** This will consolidate the flow cytometry and research platforms into a central specialised laboratory, encompassing Immunology and Haematology.

**The Category 3 Laboratory:** This is the regional TB lab for all of Saolta and requires specialist facilities to undertake this service (sealed lab anteroom, negative pressure, etc.).

The SAR identifies a number of options to deliver on the vision for the replacement laboratory facilities. These options include a single replacement laboratory on the UHG campus as identified in the Development Control Plan for the site and an option to split the services into two facilities with a laboratory building solely for Acute Services and a separate facility for Community / GP services (hot lab + cold lab). The merits of the various options will be further considered at the next stage of the process i.e. development of the Preliminary Business Case.

This paper has been the subject of extensive consultation with operations and strategy colleagues. It is jointly recommended to the Board in support of an agreed position in relation to the future delivery of pathology services for the Saolta Group and its catchment population. The SAR includes in Appendix A letters of support from key stakeholders such as the National Clinical Pathology Programme (NCP) and the National Cancer Control Programme (NCCP). The project is also supported by the National Director of Acute Operations and the National Director for Change and Innovation. The project was included for progression in the HSE Capital Plan 2022 and the SAR has been prepared in that context.

This proposal is prioritised in the context of the poor conditions and capacity limitations of many existing facilities at University Hospital Galway (UHG) and the need for significant future capital investment in that site to address these matters. It is strategically aligned with overall plans to redevelop the site on a phased basis and in an orderly manner. It will deliver a solution for the entire laboratory service as required on the UHG campus.

An adjacent site on the UHG Campus has also been identified for the delivery of the proposed new Emergency Department and Women's & Children's development. On completion of the laboratory project, it is planned to remove the existing sub-standard single storey Laboratory buildings, which occupy a substantial site area at the rear of the hospital, and so free up critical space for further phases of development in line with the Development Control Plan for the UHG campus.

**Highlight any implications that the Board should be made aware of in its consideration such as;**

- **Current status**  
Awaiting HSE Board Approval of the Strategic Assessment Report (SAR)
- **Budget**  
The estimated total capital cost [REDACTED] inclusive of VAT. This cost includes construction costs, design fees, equipping, contingency and other costs associated with the project including VAT. This cost is subject to project delivery timelines, inflation and market conditions at time of tender. The project is largely a replacement project although some additional operational costs on the revenue side may also arise. Such costs will be considered in more detail in the Preliminary Business Case.
- **Resources**  
Existing WTE staffing will be available to open the new facilities, as it is a replacement laboratory project. The need for additional WTE staffing will be considered in developing the Preliminary Business Case (PBC).
- **Impact to delivery of services**  
The SAR concludes that the investment embodied in the proposal is necessary to address the significant infrastructural deficits in the Medical Laboratory Services at UHG. Such investment is required to enable future healthcare service delivery in the region in line with government policy.
- **Corporate Plan**  
Aligned with HSE Corporate Plan & Service Plan
- **Sláintecare**  
Sláintecare policy will build greater integration between the community and the acute healthcare sectors. Laboratories are an essential tool in this integration, providing a single point of access to the patient's laboratory diagnostic history. The workload from the community sector is currently a significant proportion, accounting for 40-50% in some laboratory departments. This is expected to grow with Sláintecare, so it is vital that the replacement laboratory services meet these demands.
- **Social factors**  
The provision of the new facilities all designed to modern standards will support but continuity and improvement in the quality of care for patients.
- **Technological factors**  
Replacement laboratory infrastructure will better enable use of new technologies and instrumentation and support the implementation of modern models of Laboratory Medicine service delivery.
- **Legal factors**  
The standard Public Works Contract for Building Works designed by the Employer (PW-CF1) is

Intended to be used should the project be approved to progress. Any relevant Legal factors will be considered in more detail throughout the project lifecycle should the project be approved to progress

**Sustainability:**

The Replacement Laboratories infrastructure will be designed to the latest standards for energy efficient design and the requirements will be set out in the detailed design documentation. An Energy Efficient Design (EED) specialist will be engaged as part of the design process for this specific purpose. Building(s) will be required to achieve the Nearly Zero – Energy Buildings (NZEB) standard in accordance with the revised Building Regulations Part L.

**Value for Money:**

The proposed works will be competitively tendered and this matter will be considered in more detail at the relevant stages throughout the project lifecycle should the project be approved to progress.

**Conclusion:**

The Strategic Assessment Report (SAR) has been completed by EY in accordance with the current Public Spending Code requirements for such reports. It is being submitted with this paper and presents the case for the Replacement of the Laboratory Facilities at University Hospital Galway (UHG). It sets out the scope of the project and the potential options considered. It also examines the cost and benefits arising. The SAR concludes that the investment embodied in the proposal is necessary. It recommends that the Approving Authority grant formal approval to progress to the next stage of the project lifecycle process.

**Recommendation:**

In the above context, the HSE Board are asked to approve the attached Strategic Assessment Report for submission to the Department of Health for formal review seeking approval to progress to the next stage of the project lifecycle.