



CYFARFOD BWRDD PRIFYSGOL IECHYD UNIVERSITY HEALTH BOARD MEETING

DYDDIAD Y CYFARFOD: DATE OF MEETING:	26 January 2023
TEITL YR ADRODDIAD: TITLE OF REPORT:	Aseptic Project – Business Justification Case – Approval to Submit to Welsh Government for Further Scrutiny
CYFARWYDDWR ARWEINIOL: LEAD DIRECTOR:	Jill Paterson, Director of Primary Care, Community and Long Term Care
SWYDDOG ADRODD: REPORTING OFFICER:	Jenny Pugh Jones, Clinical Director of Pharmacy and Medicines Management Rachel Stuart, Planning Project Manager

Pwrpas yr Adroddiad (dewiswch fel yn addas)

Purpose of the Report (select as appropriate)

Ar Gyfer Penderfyniad/For Decision

ADRODDIAD SCAA SBAR REPORT

Sefyllfa / Situation

This report provides an overview of the Aseptic Business Justification Case (BJC) and provides assurance that it has been taken through the Health Board's (HB) internal scrutiny business case review process to:

- Provide early scrutiny & challenge to the BJC;
- Improve the robustness of business case;
- Ensure that the evidence used is robust;
- Test the strategic fit.

The Board is asked to note that comments and amendments following this robust review have been incorporated into the BJC, which can be found at **Attachment 1** to this report.

The journey through the HB has been as follows:

- Key Leads review – complete;
- Strategic Development & Operational Delivery Committee (SDODC) review – complete;
- Transforming Access to Medicines (TrAMS) Board review – complete;
- Use of Resources Group review – complete;
- Executive Team review – complete.

The purpose of this paper is to seek Board approval for the:

- Onward submission of the BJC to Welsh Government (WG) in January 2023 for further scrutiny and approval of funding availability.
- Use of professional services/consultancy as appropriate to deliver the project.

Cefndir / Background

In 2018 the Clinical Pharmaceuticals and Technical Services (CPTS) group carried out an audit of all aseptic units in Wales. The University Health Board's three units at WGH, BGH and Glangwili General Hospital (GGH) were classified as 'high-risk critical'. The GGH unit closed in December 2018.

In 2019 the Health Board submitted a Business Justification Case (BJC) to Welsh Government (WG) for the consideration of securing capital funding in the region of £10m to establish a stand-alone Aseptic and Radiopharmacy Unit on the WGH site.

Since then WG has approved the TrAMS programme to transform the facilities in which NHS Wales procures, produces and delivers pharmaceutical aseptic and radiopharmacy products. Discussions between the Health Board and the Chief Pharmaceutical Officer for Wales, the Director for TrAMS and WG Capital Team concluded that an interim solution was required in advance of, and to be aligned to, the development of the South West Regional Aseptic Unit under the TrAMS Programme of work.

Asesiad / Assessment

The aim of the Aseptic Project is to deliver an interim solution for the University Health Board to continue to deliver safe, sustainable aseptic services in advance of the opening of the South West Regional Aseptic Unit under the TrAMS Programme by:

- Constructing a new demountable unit located close to the entrance of the Physiotherapy Unit of Withybush General Hospital (WGH).
- Refurbish the current aseptic unit at WGH as a cold storage area.
- Decommission the aseptic unit at Bronglais General Hospital (BGH) so that it can be refurbished as clinical pharmacy space;

Strategic Case:

Case for Change:

Both WGH and BGH units now no longer meet the required GMP standards for facilities. The number of items required to be prepared per annum in HDdUHB is expected to be around 20,000 by 2028, rising to around 23,000 by 2031; however, the facilities cannot meet this demand and the Health Board has significant concerns about external suppliers' ability to meet both demand and required quality standards. A solution is therefore required until the South West unit comes on-line under the TrAMS Programme which will meet the project's Spending Objectives.

There is an increasing demand for aseptically produced medicines due to:

- Our ageing population
- New medicines and technologies
- Reduction in capacity and capability to prepare medicine at the bedside

The business need is therefore an aseptic unit(s), compliant with current and anticipated future regulatory standards, until the South West Hub becomes operational under the TrAMS Programme. If this is not addressed and the current units at WGH and BGH fail, the University Health Board will need to outsource all aseptic requirements. This will have a significant

negative impact on patient care, due to the fragility of external providers, in addition to an estimated annual outsourcing cost of £1.82m with increased risk to service delivery.

The Project also provides the opportunity to meet a further business need for additional clinical pharmacy space, which can be provided by the repurposing of the BGH aseptic unit.

Drivers – Spending Objectives – Benefits:

Drivers	Spending Objective	Benefit	Expected Outcome
Effectiveness	Reduce the risk of negative impacts on patient care by providing a safe, sustainable aseptic service solution until services can be transferred to facilities to be provided under the TrAMS Programme.	Provision of sufficient in-house capacity to meet activity projections.	Improved quality of patient treatment. Reduced delivery times.
Efficiency	Consolidate aseptic services on one site to enable the early closure of the BGH aseptic unit, to provide efficiencies in service delivery and estate usage.	Refurbishment of the current BGH aseptic unit to provide additional clinical pharmacy space.	Increased pharmaceutical production.
Economy	Minimise the risk of negative financial impacts.	Reduction in the risk of failure of the aseptic estate.	Avoidance of the estimated annual cost of outsourcing of £1.82m.
Compliance	Put in place a new unit which will comply with Quality Assurance of Aseptic Preparation Services (QAAPS) standards and latest building guidelines.	To end the University Health Board's reliance on the WGH and BGH aseptic units, which both have 'highly critical' audit ratings.	Improved audit ratings and quality of service.
Replacement	Replace outdated equipment where possible to maximise the efficiency and compliance of the unit until the South West Hub becomes operational under the TrAMS Programme.	Improved equipment standards.	Reduced risk of service failure.

Key Project Business Risks:

Description	Mitigation
Reputational risk arising from failure to, for example: - Meet required timescales. - Achieve quality standards. - Meet patient needs.	Technical capability of the aseptic project group.
Non-compliance with QAAPS 2016 standards.	Technical capability of the aseptic project group. Annual audits by the Quality Assurance Lead Pharmacist for Wales.
Failure to deliver services in quantity / to quality required, resulting in need to outsource.	Effective recruitment and quality control.
Design does not meet regulatory standards.	Technical capability of the Aseptic Project Group.
Failure to secure capital funding in time and / or in entirety.	Engagement with WG.
Capital and / or revenue costs are higher than projected.	Technical capability of the Aseptic Project Group. Sensitivity analysis.
Project management costs over-run.	Effective project management through the Procurement Team
Failure to deliver an acceptable and timely solution will threaten the safe delivery / continued support of local cancer and neonatal services.	Technical capability of the Aseptic Project Group

Key Project Service Risks:

Description	Mitigation
Failure to achieve planning permissions and / or building regulations approvals	Engagement with local authorities as required
Risk to patient safety and access for emergency services at WGH during construction period (related to construction and moving of equipment).	Engagement with Emergency Services. Programme planning and management.
Noise pollution during construction	Noise reduction / abatement requirements to be detailed in tender specifications.
Tendered price is higher than costs estimated in this BJC	Estates team to follow the University Health Board's project approval process prior to tender for construction and engineering projects.
At present no tender is in place for procurement of the demountable and therefore no commitment given to any manufacturer. There is a risk that a factory slot may not be available when the unit is required.	20 weeks allowed for within project programme for mobilisation/manufacture stage – timelines have been advised to the framework suppliers – WPA
Lead times for procurement of equipment overshoot the project timeline.	Management through the project plan
Risk associated with potential reduction in parking spaces, including disabled spaces, during construction	Requirements to be detailed in tender specifications

Key Project Constraints:

Area	Constraint
Policy decisions	The Project is constrained by the scope and timescales of the TrAMS Programme, specifically delivery of the South West Hub. The new aseptic unit may therefore be required to be operational for a shorter or longer timescale than currently anticipated.
Regulations	The new aseptic unit must be compliant with QAAPS 2016 requirements and standards.
Timescales	The unit must be in place and operational within a constrained timescale to maintain integrity of supply.
Affordability – Capital / Revenue	The unit must be delivered within the affordability constraints shown in Section 5 (Funding and Affordability).
External factors	The Health Board's ability to outsource supply if the new aseptic unit is not capable of meeting demand will be constrained because supply is already known to be limited and the market is unlikely to be capable of supplying more than current levels.

Key Project Dependencies:

Area	Dependency
TrAMS Programme	The scope of the Project is dependent on decisions which may be made on the TrAMS Programme outside the influence of the University Health Board. If the scope and / or timeline of the TrAMS Programme were to change, in particular of the South West Hub, the University Health Board would need to rethink its solution and potentially enter into a new business case process.
Approvals	The Project will be dependent on internal approvals from the University Health Board and external approvals from WG.
Availability of capital	The Project will be dependent on capital funding from WG. This could be vulnerable to inflation and / or competing priorities at a national level.
Supply market availability	The Project will be dependent on the capacity of the supplier market to meet the Project's requirements.

Economic Case.

Critical Success Factors:

Critical Success Factors	Descriptor
Strategic Fit	Meets the project Drivers and Spending Objectives.
Business needs	Enhanced quality of service and improved outcomes. Equitable access to services. Equitable delivery of time critical products to patients based on location.
Value for Money (VfM)	Optimisation of costs and benefits. Minimises risks. Enables a timely solution. Provides flexibility for future use.
Affordability	Potential affordability (capital).
Achievability	Practicality of delivery. Site constraints or challenges. Supports functional requirements (design). Supply side capacity and capability (including clean room capability).

Options Analysis

Options considered and discounted:

Options	Rational for Discounting
1. Do Nothing	The option does not enable the Health Board to meet its Spending Objectives and Critical Success Factors.
2. Modular Build at WGH (aseptic and radiopharmacy)	Following the transfer of radiopharmacy services to SBUHB and the publication of the TrAMS programme, this option is no longer strategically, financially or operationally viable.
3. Do Minimum: Small Scale Refurbishment at WGH Aseptic Unit and Repurposing of BGH Aseptic Unit	<p>Closure of the WGH unit for at least 11 months would expose patients and the Health Board to unacceptable levels of risk and potential cost. The Health Board would continue to need to outsource supply, therefore this option will not address patients' and the Health Board's exposure to supply and cost risk.</p> <p>The Forecast Project Out-Turn Cost of the option is approximately 14.7% higher than that of Option 4 (preferred Option).</p>

Preferred Option:

Option	Rational
4. Demountable unit at WGH	<ul style="list-style-type: none"> • This option will not require any interruption to existing service and will provide the Health Board with a compliant and fully functional aseptic unit on a single site until the South West Hub becomes operational. • It will mitigate risk of the failure of the existing units and the consequent risk to patient care, and outsourcing costs estimated at up to £1.82m per annum. • The long life of the unit means that it will provide the University Health Board with premises suitable for future uses once the aseptic unit is decommissioned. The decommissioned unit could be used as office space, training space or storage. • Financial and operational risks are manageable. • The option will enable the BGH aseptic unit to be repurposed for other pharmaceutical use. • The Forecast Project Outturn Cost is lower than Option 3 and it carries lower risk; it therefore offers better VfM.

Commercial Case.

Procurement Route – Outputs

Demountable:

- Purchase and fit-out of a demountable unit to be located close to the entrance of the Physiotherapy Unit of WGH to house aseptic production and a cold room with the necessary equipment.
- The unit will consist of two 'Portakabin'-style buildings, a larger one designated for aseptic processes, and the smaller attached unit for clinical support and storage, this design will provide sufficient space for storage and segregation of products.
- There will be a glazed link to connect the two demountable buildings.

Construction:

- Enabling works at WGH for demountable and the existing WGH and BGH aseptic facilities to be reconfigured into clinical space, offices and storage.

Capital Cost Estimates:

Cost	Net cost (£)	VAT @ 20%	Gross cost (£)
Works cost	1,471,719	294,344	1,766,063
Fees *	336,697	33,114	369,811
Non-works costs	291,070	58,214	349,284
Equipment costs	142,953	28,591	171,543
Contingency	220,758	44,152	264,909
Forecast Project Out-turn Cost (pre VAT recovery)	2,463,197	458,414	2,921,611
Less recoverable VAT		(33,114)	(33,114)
Forecast Project Out-turn Cost	2,463,197	425,300	2,888,497

* It should be noted that not all Fees are subject to VAT

Procurement Route – Contracting Arrangements / Payment Terms:

Contracting Arrangements:

- The demountable requirement under the Recommended Option (and specific to the relevant Framework contract), the Health Board may be able to use any one of a range of standard forms of building contract or their own in-house agreement.
- For the isolators the Health Board will use the NHS Wales Standard Contract.
- For the enabling works the Health Board will use a Joint Contracts Tribunal (JCT) form of standard contract.

Payment Terms:

- For the demountable unit the University Health Board is likely to propose payment terms whereby a percentage is paid on delivery of the unit to site, with the remainder released once the unit has been fully commissioned.
- For the isolators and any other equipment procured separately. Part payment 30 days from receipt of the equipment and balance upon commissioning of the equipment.
- For the enabling work typical payment terms are monthly payment.

The lifespan of the demountable is 15 to 20 years, and one supplier has stated that the building will have a design life of 60 years and a building life of 30 years. The option therefore offers flexibility for future use, and following its decommissioning as an aseptic unit could be repurposed, for example, as dedicated cold storage, training space or support office accommodation.

Financial Case

Funding and Affordability – Capital and Operating Costs for Preferred Option:

Capital expenditure costs are aforementioned within the commercial case and total £2.673m. These costs are expected to be funded via the All Wales Capital Programme.

Revenue costs are £0.039m per annum due to the increased building footprint and transportation costs. This is expected to be funded within the current Aseptics budget due to economies of scale around the new service configuration.

The University Health Board anticipates that costs will be offset by efficiencies to be achieved by moving from two units to one, reducing outsourcing and being able to deliver a more robust service in a modern, compliant facility; however, these will need to be assessed over time.

Management Case

Delivery Arrangements:

Project management:

- The Project will be undertaken in line with NHS Infrastructure Investment Guidance and using established project management methodology.
- The University Health Board set up the Aseptic Project Group (the Project Group) on 23rd June 2022. The Project Group is responsible for good management and governance of the Project, to ensure its delivery within available resources, on time and to agreed service model specifications and that the Spending Objectives are met.
- The Project Group is accountable to the Senior Responsible Owner (SRO), being the Director of Primary Care, Community and Long Term Care; and the Project Director, being the Clinical Director of Pharmacy and Medicines Management.

Implementation - Milestones	Timeline
BJC HB Internal Scrutiny Process	28 January 2022 to 3 rd February 2023
BJC WG Scrutiny and Approval	6 th February 2023 to 31 st March 2023
Planning Approvals Received by	6 th January 2023
Appointment of project design team	28 th April 2023
Detailed technical design completed	21 st July 2023
Tender period	24 th July 2023 to 13 th October 2023
Contractor mobilisation and manufacture	16 th October 2023 to 1 st March 2024
repurpose the BGH aseptic unit	4 March 2024 to 7 th June 2024.
Demountable installation	4 th March 2024 to 24 th May 2024
Demountable commissioning	27 th May 2024 to 16 th August 2024
Demountable Operational go-live	2 nd September 2024
Repurpose the WGH aseptic unit	9 th September 2024 to 22 nd November 2024

Under the TrAMS Programme, the Health Board's aseptic production will transfer to the South West Hub; however, on current estimates, this will not be operational until sometime between 2028-30.

Argymhelliad / Recommendation

The Board is asked to **APPROVE** the:

- Onward submission of the Aseptic Project BJC to Welsh Government in January 2023 for further scrutiny and approval of funding availability.
- Use of professional services/consultancy as appropriate to deliver the project.

Amcanion: (rhaid cwblhau)

Objectives: (must be completed)

Cyfeirnod Cofrestr Risg Datix a Sgôr Cyfredol: Datix Risk Register Reference and Score:	A project risk register is held and managed by the Project Group. Risks are summarised under the assessment section of this SBAR.
Safon(au) Gofal ac Iechyd: Health and Care Standard(s):	1.1 Health Promotion, Protection and Improvement 2.1 Managing Risk and Promoting Health and Safety 2.6 Medicines Management
Amcanion Strategol y BIP: UHB Strategic Objectives:	3. Striving to deliver and develop excellent services 5. Safe sustainable, accessible and kind care
Amcanion Cynllunio Planning Objectives	5O_21 Fragile Services
Amcanion Llesiant BIP: UHB Well-being Objectives: Hyperlink to HDdUHB Well-being Objectives Annual Report 2018-2019	4. Improve Population Health through prevention and early intervention, supporting people to live happy and healthy lives

Gwybodaeth Ychwanegol:

Further Information:

Ar sail tystiolaeth: Evidence Base:	Compliance with Quality Assurance of Aseptic Preparation Service (QAAPS) 2016 standards.
Rhestr Termiau: Glossary of Terms:	Included in the body of the report
Partion / Pwyllgorau â ymgynhorwyd ymlaen llaw y Cyfarfod Bwrdd Iechyd Prifysgol: Parties / Committees consulted prior to University Health Board:	Aseptic Project Group Key Leads Senior Responsible Owner Project Director TrAMS Board Head of Health & Safety Principal Architect Director of Estates & Facilities Assistant Director of Finance Deputy Director of Operations Assistant Director of Workforce Assistant Director Strategic Planning + signature

	Strategic Development & Operational Delivery Committee Use of Resources Executive Team
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Effaith: (rhaid cwblhau) Impact: (must be completed)	
Ariannol / Gwerth am Arian: Financial / Service:	Mitigate the risk of negative financial impacts Included in the body of the report.
Ansawdd / Gofal Claf: Quality / Patient Care:	Reduce the risk of negative impacts on patient care by providing a safe, sustainable aseptic service solution until services can be transferred to facilities to be provided under the TrAMS Programme.
Gweithlu: Workforce:	No additional workforce costs are anticipated as a result of this development
Risg: Risk:	Included in the body of the report.
Cyfreithiol: Legal:	Not applicable.
Enw Da: Reputational:	Reputational risk arising from failure to, for example: <ul style="list-style-type: none"> • Meet required timescales. • Achieve quality standards. • Meet patient needs.
Gyfrinachedd: Privacy:	Not applicable.
Cydraddoldeb: Equality:	Equality Impact Assessment screening has been undertaken and, at this stage, does not indicate adverse impacts for protected groups.



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Hywel Dda University Health Board Aseptic Project

Business Justification Case – Medium value and risk

January 2023

SRO:	Jill Paterson, Director of Primary Care, Community and Long Term Care
Project Director:	Jenny Pugh-Jones, Clinical Director of Pharmacy and Medicines Management
Organisation:	Hywel Dda University Health Board

	Name	Date	Comments
Prepared by:	Greg Haddock, PwC	04 / 12 / 22	<ul style="list-style-type: none">Final draft for review and acceptance by the Hywel Dda University Health Board
Reviewed by:	Internal Scrutiny	05 / 01 / 23	<ul style="list-style-type: none">Various comments received.
Prepared by:	Greg Haddock, PwC	6 / 1 / 23	<ul style="list-style-type: none">Updated final draft which incorporates review comments received in December 2022 and January 2023
Approved by:	Hywel Dda University Health Board		<ul style="list-style-type: none">



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Glossary of Abbreviations

Abbreviation	Definition
AHMWW	A Healthier Mid and West Wales
AME	Annually Managed Expenditure
ASU	Aseptic Services Unit
BGH	Bronglais General Hospital
BJC	Business Justification Case
CPTS Group	Clinical Pharmaceuticals and Technical Services Group
CSF	Critical Success Factor
CSC	Capital Sub-Committee
GGH	Glangwili General Hospital
GMP	Good Manufacturing Practice (describes the minimum standard that a medicines manufacturer must meet in their production processes)
HVAC	Heating, Ventilation and Air Conditioning
HDUHB	Hywel Dda University Health Board
IAAP	Integrated Assurance and Approval Plan
JCT	Joint Contracts Tribunal
MHRA	Medicines & Healthcare products Regulatory Agency
MMC	Modern Methods of Construction
OBC	Outline Business Case
PBC	Programme Business Case
PCR	Project Closure Report
QAAPS	Quality Assurance of Aseptic Preparation Services
RPA	Risk Potential Assessment
SDODC	Strategic Development and Operational Delivery Committee
SAB	Sustainable Drainage Approval Body
SBUHB	Swansea Bay University Health Board
TrAMS	Transforming Access to Medicines
UHB	University Health Board
VfM	Value for Money
WG	Welsh Government



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WGH	Withybush General Hospital
WHBN	Welsh Health Building Note
WHTN	Welsh Health Technical Note
WPA	Welsh Procurement Alliance



Hywel Dda University Health Board Aseptic Project

1. Introduction

- 1.1 The purpose of this Business Justification Case (BJC) is to seek approval for Hywel Dda University Health Board (the University Health Board or HDUHB) to:
- construct a new demountable unit located close to the entrance of the Physiotherapy Unit of Withybush General Hospital (WGH), fire-rated within 3 metres of the main hospital; the unit will consist of two 'Portakabin'-style buildings, a larger one designated for aseptic processes, and the smaller attached unit for clinical support and storage; this design will provide sufficient space for storage and segregation of products; enabling works will need to be undertaken in the form of relocating portakabins which currently house Physiotherapy and two shipping containers, and the demolition of an outbuilding formerly utilised by laboratories;
 - refurbish the current aseptic unit at WGH as a cold storage area; and
 - decommission the aseptic unit at Bronglais General Hospital (BGH) so that it can be refurbished as clinical pharmacy space;
- as an interim solution for the University Health Board to continue to deliver safe, sustainable aseptic services in advance of the opening of the South West Regional Aseptic Unit under the Transforming Access to Medicines (TrAMS) Programme.
- 1.2 Under current TrAMS programme timelines, the South West Regional Aseptic Unit is expected to become operational between autumn 2028 and August 2030. It is anticipated that, following a transition period, production at the WGH aseptic unit will cease and the unit will be decommissioned. The demountable unit could then be used for alternative purposes, e.g. cold storage, training space or office accommodation.
- 1.3 The description above is termed 'the Project' throughout this BJC.
- 1.4 The Forecast Project Out-turn Cost of the Project, prior to going to tender and for approval by Welsh Government (WG), is £2,888,497 (post-VAT recovery). A detailed Development Cost Approval Form is attached at Appendix 1.
- 1.5 The total number of aseptic items consumed by the University Health Board is approximately 14,500, of which 71% are outsourced. Demand for aseptic items is projected to increase to 20,000 by 2028. In 2018 the Clinical Pharmaceuticals and Technical Services (CPTS) group classified the University Health Board's units at WGH and BGH as 'high-risk critical'. The units no longer meet the required Good Manufacturing Practice (GMP) standards for facilities. If this is not addressed and the units fail, the University Health Board will need to outsource all aseptic requirements. This will have a significant negative impact on patient care, due to the fragility of external providers, in addition to an estimated annual outsourcing cost of £1.82m with increased risk to service delivery. For these reasons this is a priority project for the University Health Board, and it is why the BJC is being submitted on the basis of an estimated capital cost.



- 1.6 Across the UK, demountable units have been used successfully to house aseptic services, as shown in the following examples:
- University Hospital Southampton has set up a modular Good Manufacturing Practice (GMP) oncology suite to provide services and treatment facilities for the oncology department of the hospital, licensed Grade D by the Medicines & Healthcare products Regulatory Agency (MHRA). A demountable unit was used to deliver these needs due to the urgency of the requirement, and a part of the unit was built off-site which enabled the project to be fast tracked and delivered within three months and a budget of £2m.
 - The Royal Marsden Hospital, Sutton has set up a support area, clean rooms and lab suites with a Grade B MHRA licence. The modularity of the structure and built in interior finishes have minimised the hard-to-clean areas, and have enabled the delivery of the new facility within sixteen months and a budget of £2m.
 - Singleton Hospital Swansea has set up a Good Manufacturing Practice (GMP) aseptic and radiopharmacy facility to prepare and manufacture chemotherapy and other critical medicines. The unit was partially manufactured off site, and the custom brick fascia crafting on site enabled the new extension to blend with the surrounding buildings. The unit enabled the hospital to achieve a Grade C and D MHRA licence within twelve months and a budget of £1.9m, including the supply of isolators.
- 1.7 Other relevant examples include pharmacy aseptic units constructed using a demountable unit at Royal Preston Hospital, Pilgrim Hospital Boston, the MAC plc Clinical Trials Facility within the Manchester Royal Infirmary campus, King's College Hospital London and Leighton Hospital Crewe.
- 1.8 Following a robust internal University Health Board scrutiny review, through Project Group, Strategic Development and Operational Delivery Committee (SDODC), Use of Resources group, Executive Team and the Board of the University Health Board, we are submitting the BJC at a relatively early stage in response to the urgency of the Project as described in paragraph 1.5, and to seek feedback from WG. Following receipt of tendered costs (anticipated in October 2023), the BJC will be revised and submitted for approval by the SDODC and the Board of the University Health Board, following which it will be submitted to WG for final approval. The University Health Board recognises that this approach carries a level of inflation risk, therefore an inflation contingency has been included within the Works Cost item of the Forecast Project Out-turn Cost.
- 1.9 An overview of the Sections of this BJC follows:

Section 2 – Strategic case: In 2018 the CPTS group carried out an audit of all aseptic units in Wales. The University Health Board's three units at WGH, BGH and Glangwili General Hospital (GGH) were classified as 'high-risk critical'. The GGH unit closed in December 2018. The WGH and BGH units however no longer meet the required GMP standards for facilities. The number of items required to be prepared per annum in HDUHB is expected to be around 20,000 by 2028, rising to around 23,000 by 2031, however the facilities cannot meet this demand and the University Health Board has significant concerns about external suppliers' ability to meet both demand and required quality standards. A solution is therefore required until the South West unit comes on-line under the TrAMS Programme which will meet the following Spending Objectives:



- **Effectiveness:** Reduce the risk of negative impacts on patient care by providing a safe, sustainable aseptic service solution until services can be transferred to facilities to be provided under the TrAMS Programme.
- **Efficiency:** Consolidate aseptic services on one site to enable the early closure of the BGH aseptic unit, to provide efficiencies in service delivery and estate usage.
- **Economy:** Minimise the risk of negative financial impacts.
- **Compliance:** Put in place a new unit which will comply with Quality Assurance of Aseptic Preparation Services (QAAPS) standards and latest building guidelines.
- **Replacement:** Replace outdated equipment where possible to maximise the efficiency and compliance of the unit until the South West Hub becomes operational under the TrAMS Programme.

Section 3 – Options Analysis: The University Health Board has identified four options:

- Option 1 – Do nothing / Business As Usual.
- Option 2 – Modular Build at WGH (aseptic production and radiopharmacy), as described in the Aseptic and Radiopharmacy Suite Strategic Outline Case (SOC), submitted to WG in December 2019 but not pursued.
- Option 3 – Do Minimum: Small Scale Refurbishment at the WGH Aseptic Unit and Repurposing of the BGH Aseptic Unit.
- Option 4 – Demountable unit at WGH.

The options have been assessed against Critical Success Factors (CSFs) of Strategic Fit, Business needs, Value for Money, Affordability, and Achievability. Option 4 has been identified as the Recommended Option.

Section 4 – Procurement: the University Health Board will procure:

- Purchase and fit out of two demountable units to facilitate Aseptic Processes under a Demountable Solution Contract.
- Enabling works at WGH for the new demountable units, reconfiguration of existing aseptic units at WGH and BGH under a Construction Framework Contract.

The Main Contract Procurement Methods are:

- The Welsh Procurement Alliance (WPA) framework for the Demountable units.
- The Hywel Dda Construction Framework for the enabling works and construction elements, including relocating existing containers on site and repurposing works for the existing aseptic units at WGH and BGH.
- The Joint Contracts Tribunal (JCT) Form of Contract.



The proposed start date on site is 4 March 2024, and proposed completion date is 25 November 2024. Subject to discussion with Shared Services, at this stage the University Health Board has based its approach for the Demountable on a single stage mini-competition using the WPA Framework, which is anticipated to take 8-9 weeks in total. To test market interest the University Health Board issued a call for expressions of interest from suppliers listed on the WPA Framework Agreement; five of the eight suppliers responded positively, confirming that they have suitable resources to complete the Project.

It is a requirement under the planning application criteria to incorporate biodiversity and enhancement measures, and the procurement will reflect this. The use of Modern Methods of Construction (MMC) to produce and install the demountable will minimise carbon emissions - this is set out in detail in paragraphs 4.3.2.10 – 12.

The existing isolators on site are nearing the end of their useful life and require replacement. Due to the extended lead-times for isolators, prior agreement was given that discretionary capital for their procurement would be allocated even though the BJC could be declined, as it is a critical need. An amount of £100,970 has been included within the Non-Works Costs element of the Forecast Project Out-turn Cost for the isolators (see p.4 of the Development Cost Approval Form attached at Appendix 1). A tender was issued on 21 September 2022 with a closing date of 19 October 2022. The University Health Board is in the process of evaluating the bids received with a view to appointing the successful contractor in early 2023.

Section 5 – Funding and affordability: Total Capital Costs are estimated at £2.889m. Total Revenue Costs are estimated at £208k, to cover additional maintenance costs associated with an increased building footprint, and additional transportation costs due to the closure of BGH Aseptic Unit. The University Health Board anticipates that costs will be offset by efficiencies to be achieved by moving from two units to one, reducing outsourcing and being able to deliver a more robust service in a modern, compliant facility, however these will need to be assessed over time.

The estimated depreciation charge is £192k per annum for the Recommended Option. It is assumed that additional depreciation charges will be funded by WG. It is estimated that the Recommended Option will impact the Balance Sheet of the University Health Board by increasing the value of fixed assets by £1.7m. The estimated impairment of this scheme on completion will be £1.1m. The University Health Board is assuming that Annually Managed Expenditure (AME) impairment on completion of the new build will be funded as AME funding via WG.

Section 6 – Delivery arrangements: The University Health Board set up the WGH Aseptic Project Group (the 'Project Group') on 23 June 2022, responsible for the management and governance of the Project. The Project Group is accountable to the Senior Responsible Officer (SRO), being the Director of Primary Care, Community and Long Term Care, and the Project Director, being the Clinical Director of Pharmacy and Medicines Management.



Recommendation

Based on the proposals outlined in this business case, approval is requested to commence the procurement of the preferred option.

Signed:

Senior Responsible Owner

Date:



2. Strategic case

2.1. Introduction

- 2.1.1. HDUHB is the planner and provider of NHS healthcare services for a population of approximately 385,000 in Carmarthenshire, Ceredigion, Pembrokeshire and bordering counties. The University Health Board delivers services through its four main hospital sites (Bronglais in Aberystwyth, Glangwili in Carmarthen, Prince Philip in Llanelli and Withybush in Haverfordwest) and through its community hospitals, minor injuries units, centres and clinics and mental health sites.
- 2.1.2. The strategic context within which the Project is being developed comprises:
- The overarching regulatory framework.
 - The University Health Board's 'A Healthier Mid and West Wales Strategy and Programme Business Case (PBC).
 - The TrAMS Programme.
 - The transfer of Radiopharmacy services to Swansea Bay University Health Board (SBUHB).

2.2. Regulatory framework

- 2.2.1. A number of regulatory frameworks govern the legal and professional standards against which all pharmacy services must be compliant. These include:
- Medicines Act (1968).
 - Misuse of Drugs Act (1971).
 - QAAPS: Professional Standards (2016).
 - The Royal Pharmaceutical Society document for the Professional Standards for Hospital Services – Optimising patient outcomes from medicines (England, Scotland and Wales) V3 (2017).
- 2.2.2. As a consequence, there are a number of external inspections which require significant evidence of compliance with the standards, including by the:
- General Pharmaceutical Council.
 - QAAPs 2016.
 - Home Office.
- 2.2.3. The design and operation of the new unit at WGH will comply with this regulatory framework, however it will operate under the section 10 exemption of the Medicines



Act 1968 and the University Health Board will not seek to attain a Manufacturing Specials licence from the MHRA.

2.3. A Healthier Mid and West Wales Strategy and PBC

- 2.3.1. In 2018, the University Health Board published 'A Healthier Mid and West Wales: Our Future Generations Living Well' (AHMWW)¹, a long term strategy for transforming health services and delivering quality care closer to home.
- 2.3.2. Following publication of the strategy, the University Health Board developed a PBC which describes how the strategy will be operationalised. The PBC sets out options for the construction of a new urgent and planned care hospital and improvements to the four main hospitals and community estate. As at the date of submission of this BJC, the PBC has been scrutinised by WG and the University Health Board has been instructed to progress to the next stage of the business case process.
- 2.3.3. The PBC describes a number of new build and refurbishment options at WGH which would see construction works taking place within a date range of 2026 (earliest estimated start date) and 2034 (latest estimated completion date), depending on the option chosen.
- 2.3.4. The University Health Board anticipates that, subject to receiving the necessary approvals from WG and at the appropriate time, it will produce an Outline Business Case (OBC) which will propose a preferred option for works at WGH. The preferred option will take the siting of the new aseptic unit into account.

2.4. Transforming Access to Medicines (TrAMS)

- 2.4.1. Set up by NHS Wales in 2021, the focus of the TrAMS Programme has been on increasing regional and national co-operation to improve the productivity and efficiency of the pharmacy supply chain and patient access to medicines in Wales. It has been developed in the following context:
 - There are fifteen aseptic units across Wales, many in a poor and deteriorating physical condition.
 - Units are subject to increasing regulatory requirements.
 - There is increasing demand for ready-to-use injectable medicines, leading units to increase the degree to which they outsource supplies from commercial suppliers.
 - The commercial sector is therefore also facing increasing demand.
 - Small teams in multiple locations lack sustainability.
 - The pandemic has exposed a lack of contingency.

¹ Available at <https://hduhb.nhs.wales/about-us/healthier-mid-and-west-wales/healthier-mid-and-west-wales-folder/documents/a-healthier-mid-and-west-wales-strategy/>



- There is a lack of space on acute hospital sites to facilitate the development of existing units.

2.4.2. The TrAMS PBC published in December 2020 makes the case for a transformational change. The vision of this change is for:

- A Medicines Preparation Service serving patients across Wales, in a way that is safe, high quality, equitable, sustainable and economically efficient.
- Meeting all current and future regulatory standards.
- Delivered through three regional medicines hubs, organised as a mutually supporting national service.
- Supporting patient pathway transformation and enabling clinical excellence.
- Transforming our workforce skills, roles, organisation, and productivity.
- Enabled by high quality, reliable, and efficient logistical service.
- Integration of digital prescribing, ordering, and planning solutions for a seamless workflow.
- Fit and ready for future automation, new therapies, and new ways of working.
- Centre of excellence for Quality Management and Medical Gas testing.
- Collaborates with our universities and sponsors to support trials and other research and development work.
- Creating and sustaining jobs and economic activity in Wales.

2.4.3. The PBC recommended the following preferred option:

- A hosted All Wales service, regionally delivered to give the best balance of resilience and efficiency delivered through:
 - Three integrated regional hubs – North, South West and South East.
 - Additional satellite units where geography requires.
 - A medicines logistics service.
 - A structured investment programme and migration from legacy facilities.
- Risk, quality and assurance to be addressed at a national level.
- Open book accounting which includes fair and sustainable allocation of discretionary capital and an operating budget that invests in people to save on medicines.



- Investments that deliver increased economic activity, resilience and prosperity in Wales, securing the wellbeing of future generations.

2.4.4. A SOC for the South West Hub was published in July 2022 and endorsed by the TrAMS Programme Board on 26 September 2022. The SOC indicates that construction may commence in May 2025.

2.5. Transfer of radiopharmacy services to SBUHB

2.5.1. Until October 2022 the WGH aseptic unit also provided a radiopharmacy service which manufactured and delivered approximately 660 critical diagnostic products to the nuclear medicine department per annum.

2.5.2. This activity was undertaken within the aseptic unit, however governance around nuclear medicine and pharmacy indicated that the arrangements were not robust and that, as a specialised area with a small number of staff, production lacked resilience. SBUHB has a fully licensed radiopharmacy unit and has often provided support when needed. The University Health Board and SBUHB therefore concluded a Service Level Agreement for HDUHB's radiopharmaceutical activity to transfer to the Radiopharmacy Unit at Singleton Hospital Swansea from October 2022. This move is fully aligned to the TrAMS service model.

2.5.3. This transfer of radiopharmaceutical activity from WGH to Singleton Hospital has facilitated the 'demountable' option – Option 4 – which is discussed in Section 3 (Options Analysis).

2.6. Case for change

2.6.1. This section sets out:

- Existing arrangements.
- Business needs.

2.6.2. Existing arrangements

2.6.2.1. Currently in 2022 the University Health Board operates two aseptic units, at WGH and BGH, both over fifteen years old. They operate under the section 10 Exemption of the 1968 Medicines Act, which permits the production of aseptic products without a licence provided certain conditions are adhered to. Executive Letter (97) 52 (NHS Executive 1997) introduced a requirement in England for the regular audit of unlicensed aseptic units by Regional Quality Assurance Specialists, to ensure that appropriate standards are achieved and maintained. This practice was adopted throughout Wales and unlicensed units are currently audited by the National Quality Assurance Lead for Wales according to the regulatory framework provided in QAAPS 2016. Until December 2018 the University Health Board also operated a third aseptic unit, at GGH.

2.6.2.2. The University Health Board has a slightly higher incidence of cancer than the Welsh average, as pockets of high economic deprivation are associated with increased incidence of all types of cancer. The University Health Board supports



diagnostic services and chemotherapy for most of the cancer sites. Oncology is supported by SBUHB, and all radiotherapy takes place in Singleton or Velindre Hospitals. A significant volume of specialist oncology surgery takes place in SBUHB and Cardiff and Vale UHB.

- 2.6.2.3. The Clinical Pharmaceuticals and Technical Services (CPTS) Group carried out an audit of all units in Wales in 2018. The facilities were judged against contemporaneous standards in the Rules and Guidance for Pharmaceutical Manufacturing (HMSO, 2017) and The Quality Assurance of Aseptic Pharmaceutical Services (Pharmaceutical Press, 5th Edition) and categorised under three risks:
- High-risk – action required in next 3 years.
 - Moderate-risk – review / action required in 3-6 years.
 - Low-risk – review in next 7-10 years.
- 2.6.2.4. Up to December 2018, the University Health Board operated three aseptic units at WGH, BGH and GGH. All three units were classified as 'high-risk critical'. Overall the audit found that, of the fifteen aseptic units in Wales, eight were high-risk (of which six were high-risk critical), three were moderate risk, and four were low risk.
- 2.6.2.5. In December 2018, following a succession of four water leaks in as many months, the University Health Board closed the aseptic unit at GGH due to the risk of providing contaminated products to patients as it was not possible to fully resolve the leak.
- 2.6.2.6. This meant that the WGH and BGH units then needed to provide chemotherapy to cancer patients across the whole of HDUHB.
- 2.6.2.7. Each site was operated by a single-handed pharmacist and cross-cover between the sites was not practicable.
- 2.6.2.8. This has caused significant challenges in coordinating chemotherapy treatment and ensuring that patients receive medication within acceptable timescales. To maintain continuity of service the University Health Board has found it essential to outsource products needing to be made aseptically, and this has resulted in additional financial and logistical pressures. The fragility of the existing small number of manufacturing units that are currently being commissioned to provide services for HDUHB has been highlighted for a number of years through audit reports and the risk register, and in recent months has resulted in some delays to patient treatment through failure to deliver products: for example, from January-June 2022 alone there were 75 instances of the Bath Aseptic Services Unit (ASU) missing their target delivery times to HDUHB, and 3 quality related issues with outsourced products (e.g. leaking bags). The table below highlights issues experienced by University Health Boards / Trusts in Wales with current suppliers over the last two years.



Table 1: Challenges with outsourcing for the period August 2020 – August 2022²

UHB / Trust	Total no. of reports submitted	Type of incident		Supplier			Impact on patients				
		Service	Quality	Bath ASU	Baxter	ITH Pharma	Inconvenience	Other	Treatment delayed	Treatment cancelled	Not stated
Aneurin Bevan UHB	22	18	4	19	0	3	17	3	2	2	0
Cardiff & Vale UHB	11	9	2	9	1	1	10	1	0	0	0
Cwm Taf UHB	9	8	1	6	3	0	4	3	1	1	0
Hywel Dda UHB	122	118	4	121	0	1	28	1	4	0	79
Swansea Bay UHB	21	19	2	18	1	2	19	1	1	0	0
Velindre NHS Trust	22	21	1	22	0	0	16	0	6	0	0

2.6.2.9. Furthermore, the WGH and BGH units underwent an external audit against QAAPS standards at the start of 2019 by the National Quality Assurance Lead for Wales. Critical concerns were highlighted, with urgent resolution required to enable the units to continue operating for the next 18 to 36 months and prior to any consideration of repatriation of outsourced activity from GGH. Minor refurbishment works were carried out in 2019, including resurfacing of floors and walls at the BGH unit, new office space at the WGH unit and new air units at both. However this can be described as a 'sticking plaster' approach which is not sustainable.

2.6.2.10. Table 2 below shows the current total annual output of aseptically prepared items (correct as at 10 October 2022). The total number of items produced is 14,538, of which 71% are outsourced. As noted above this presents a significant risk to service delivery. The annual financial pressure of a fully outsourced Aseptic service is estimated to be £1.82m.

² Information collated by the CPTS Group



Table 2: Current activity

Site	Number of workstations	Age of workstations (years)	Number of items manufactured on site p.a.	Number of items outsourced p.a.
BGH	2	17, 17	935	1,116
GGH	0	N / A	0	0
WGH	3	9, 9, 13	3,108	9,379
Total	5	-	4,043	10,495

- 2.6.2.11 The University Health Board is therefore operating within facilities which do not comply with the regulatory framework described in paragraphs 2.2.1 and 2.2.2. The University Health Board is seeking to mitigate risk to patients of service disruption through outsourcing, however the supplier market is not sufficiently stable to fully mitigate risk.

2.6.3. Business needs

- 2.6.3.1. There is an increasing demand for aseptically produced medicines due to:
- Our ageing population.
 - New medicines and technologies.
 - Reduction in capacity and capability to prepare medicine at the bedside.
- 2.6.3.2. Clinical advances and increasing regulatory demands are expected over the course of this decade which, in turn, will increase the demands on aseptic services. The TrAMS Production and Quality Assurance sub-group considers that comparisons can be made to the predictions for growth determined in the Pharmacy Aseptic Services Review in England 2017 / 2018, which state that the prescribing of chemotherapy is growing at a constant compound annual growth rate of 4.8%. Over time, products have also increased in complexity and require more time and skill to manipulate. Consequently, the NHS aseptic service's workload is increasing at a faster rate.
- 2.6.3.3. Using the 4.8% per annum predicted growth rate cited above, the number of items required to be prepared per year in HDUHB is expected to be around 20,000 by 2028, rising to around 23,000 by 2031.
- 2.6.3.4. Under the TrAMS Programme, the University Health Board's aseptic production will transfer to the South West Hub, however on current estimates this will not be operational until sometime between 2028-30. For the reasons stated above, a University Health Board position to await the opening of the South West Hub is untenable, and this position is supported by the National Quality Assurance Lead for Wales.
- 2.6.3.5. Discussions around potential options were therefore held between the University Health Board and the Chief Pharmaceutical Officer for Wales, the Director for the



TrAMS Programme and the WG Capital Team. These discussions concluded that an interim solution was required in advance of, and to be aligned to, the development of the South West Hub under the TrAMS Programme.

- 2.6.3.6. The University Health Board's business need is therefore an aseptic unit(s), compliant with current and anticipated future regulatory standards and which could help the University Health Board to reduce its requirement to outsource, until the South West Hub becomes operational under the TrAMS Programme. Given the critical nature of the service, the University Health Board does not consider that it is possible to describe 'core', 'desirable' and 'optional' levels of coverage.
- 2.6.3.7. The Project also provides the University Health Board with an opportunity to meet a further business need for additional clinical pharmacy space, which can be provided by the repurposing of the BGH aseptic unit (which occupies an area of approximately 20-30m²).

2.7. Spending Objectives

- 2.7.1. Our Spending Objectives are shown in Table 3 below. They build on the Spending Objectives stated in the December 2019 Aseptic and Radiopharmacy Suite SOC, and have been further debated by the WGH Aseptic Project Group described in section 5 (Delivery Arrangements). All are Specific, Measurable, Achievable, Realistic and Time-bound:

Table 3: Spending Objectives

	Driver	Spending Objective	Specific	Measurable	Achievable	Realistic	Time-bound
1	Effectiveness	Reduce the risk of negative impacts on patient care by providing a safe, sustainable aseptic service solution until services can be transferred to facilities to be provided under the TrAMS Programme.	✓	✓	✓	✓	✓
2	Efficiency	Consolidate aseptic services on one site to enable the early closure of the BGH aseptic unit, to provide efficiencies in service delivery and estate usage.	✓	✓	✓	✓	✓
3	Economy	Minimise the risk of negative financial impacts.	✓	✓	✓	✓	✓
4	Compliance	Put in place a new unit which will comply with QAAPS standards and latest building guidelines.	✓	✓	✓	✓	✓
5	Replacement	Replace outdated equipment where possible to maximise	✓	✓	✓	✓	✓



	Driver	Spending Objective	Specific	Measurable	Achievable	Realistic	Time-bound
		the efficiency and compliance of the unit until the South West Hub becomes operational under the TrAMS Programme.					

2.8. Main benefits

2.8.1. Anticipated benefits of the Project are shown in Table 4 below. Benefits have been classified by Beneficiary, Type and Class, as follows:

- Cash Releasing Benefits such as reductions in costs (CRB).
- Non-Cash Releasing Benefits such as staff time saved (Non-CRB).
- Quantifiable Benefits such as achievement of targets (QB).
- Qualitative Benefits such as improved staff morale (Qual).

Table 4: Main benefits

	Benefit	Expected outcome	Measures	Beneficiary	Benefit class
Driver – Effectiveness					
Spending Objective 1: Reduce the risk of any negative impacts on patient care, providing a safe, sustainable aseptic service solution until services can be transferred to facilities to be provided under the TrAMS Programme.					
1.	Provision of sufficient in-house capacity to meet activity projections.	Improved quality of patient treatment. Reduced delivery times.	Improved quality standards. Improved delivery times.	Direct- Patients, Carers, University Health Board	Non- CRB QB
Driver – Efficiency					
Spending Objective 2: Consolidate aseptic services on one site to enable the early closure of the BGH aseptic unit, to provide efficiencies in service delivery and estate usage.					
2.	Refurbishment of the current BGH aseptic unit to provide additional clinical pharmacy space.	Increased pharmaceutical production.	Completion of refurbishment. Increased pharmaceutical production.	Direct – Patients, University Health Board, Staff	Non-CRB



	Benefit	Expected outcome	Measures	Beneficiary	Benefit class
Driver – Economy					
Spending Objective 3: Minimise the risk of negative financial impacts.					
3.	Reduction in the risk of failure of the aseptic estate.	Avoidance of the estimated annual cost of outsourcing of £1.82m.	Spend on outsourcing.	Direct Patients, University Health Board	CRB
Driver – Compliance					
Spending Objective 4: Put in place a new unit which will comply with QAAPS standards and latest building guidelines.					
4.	To end the University Health Board's reliance on the WGH and BGH aseptic units, which both have 'highly critical' audit ratings.	Improved audit ratings and quality of service.	Audit ratings and quality measures.	Direct – Patients, University Health Board Indirect – Staff	Non-CRB
Driver – Replacement					
Spending Objective 5: Replace outdated equipment where possible to maximise the efficiency and compliance of the unit until the South West Hub becomes operational under the TrAMS Programme.					
5.	Improved equipment standards.	Reduced risk of service failure.	Improved equipment performance.	Direct – University Health Board Indirect – Patients, carers	Non-CRB

2.9. Main risks

- 2.9.1. Table 5 below shows the main business and service risks identified and proposed mitigations. Risks are managed through the Aseptic Project Group, and the approach to risk management is described in Section 6 (Delivery Arrangements).

Table 5: Main risks

No.	Risk categories	Counter measures
Business risks (retained by the University Health Board)		
1	Reputational risk arising from failure to, for example: <ul style="list-style-type: none"> Meet required timescales. Achieve quality standards. Meet patient needs. 	Technical capability of the aseptic project group.
2	Non-compliance with QAAPS 2016 standards.	Technical capability of the aseptic project group. Annual audits by the Quality Assurance Lead Pharmacist for Wales.



No.	Risk categories	Counter measures
3	Failure to deliver services in quantity / to quality required, resulting in need to outsource.	Effective recruitment and quality control.
4	Design does not meet regulatory standards.	Technical capability of the Aseptic Project Group.
5	Failure to secure capital funding in time and / or in entirety.	Engagement with WG.
6	Capital and / or revenue costs are higher than projected.	Technical capability of the Aseptic Project Group. Sensitivity analysis.
7	Project management costs over-run.	Effective project management through the Procurement Team.
8	Failure to deliver an acceptable and timely solution will threaten the safe delivery / continued support of local cancer and neonatal services.	Technical capability of the Aseptic Project Group.
Service Risks (may be shared with the supply side)		
10	Failure to achieve planning permissions and / or building regulations approvals.	Engagement with local authorities as required.
11	Risk to patient safety and access for emergency services at WGH during construction period (related to construction and moving of equipment).	Engagement with Emergency Services. Programme planning and management.
12	Noise pollution during construction.	Noise reduction / abatement requirements to be detailed in tender specifications.
13	Tendered price is higher than costs estimated in this BJC.	Estates team to follow the University Health Board's project approval process prior to tender for construction and engineering projects based on three key stages: Stage 1: Provisional cost estimate. Stage 2: Budget cost estimate. Stage 3: Pre-tender estimate. Development costs will be re-evaluated at each stage of this process.
14	As no tender is in place for procurement of the demountable and therefore no commitment given to any manufacturer, there is a risk that a factory slot may not be available when the unit is required.	20 weeks have been allowed within the project programme for the mobilisation / manufacture stage. Timelines have been advised to the WPA framework suppliers.
15	Lead times for procurement of equipment overshoot the project timeline.	Management through the project plan.
16	Risk associated with potential reduction in parking spaces, including disabled spaces, during construction.	Requirements to be detailed in tender specifications.

2.10. Constraints

- 2.10.1. Table 6 below shows the external conditions and parameters within which the Project must be delivered:

Table 6: Constraints



Area	Constraint
Policy decisions	The Project is constrained by the scope and timescales of the TrAMS Programme, specifically delivery of the South West Hub. The new aseptic unit may therefore be required to be operational for a shorter or longer timescale than currently anticipated.
Regulations	The new aseptic unit must be compliant with QAAPS 2016 requirements and standards.
Timescales	The unit must be in place and operational within a constrained timescale to maintain integrity of supply.
Affordability – Capital / Revenue	The unit must be delivered within the affordability constraints shown in Section 5 (Funding and Affordability).
External factors	The University Health Board's ability to outsource supply if the new aseptic unit is not capable of meeting demand will be constrained because supply is already known to be limited and the market is unlikely to be capable of supplying more than current levels.
Quality of build	The aseptic unit must be of sufficient quality to serve until the TrAMS Programme becomes operational.

2.11. Dependencies

- 2.11.1. Table 7 below sets out the dependencies outside the scope of the Project upon which successful delivery is dependent.

Table 7: Dependencies

Area	Dependency
TrAMS Programme	The scope of the Project is dependent on decisions which may be made on the TrAMS Programme outside the influence of the University Health Board. If the scope and / or timeline of the TrAMS Programme were to change, in particular of the South West Hub, the University Health Board would need to rethink its solution and potentially enter into a new business case process.
Approvals	The Project will be dependent on internal approvals from the University Health Board and external approvals from WG.
Availability of capital	The Project will be dependent on capital funding from WG. This could be vulnerable to inflation and / or competing priorities at a national level.
Supply market availability	The Project will be dependent on the capacity of the supplier market to meet the Project's requirements.



3. Options analysis

3.1 Critical Success Factors (CSFs)

- 3.1.1 The CSFs for the project are shown in Table 8 below. They build on the CSFs developed for the December 2019 Aseptic and Radiopharmacy Suite SOC, and have been further debated by the WGH Aseptic Project Group described in Section 6 (Delivery Arrangements).

Table 8: CSFs

CSF	Descriptor
1. Strategic Fit	Meets the Spending Objectives drivers of: <ul style="list-style-type: none">• Effectiveness.• Efficiency.• Economy.• Compliance.• Replacement.
2. Business needs	Enhanced quality of service and improved outcomes. Equitable access to services. Equitable delivery of time critical products to patients based on location.
3. Value for Money (VfM)	Optimisation of costs and benefits. Minimises risks. Enables a timely solution. Provides flexibility for future use.
4. Affordability	Potential affordability (capital).
5. Achievability	Practicality of delivery. Site constraints or challenges. Supports functional requirements (design). Supply side capacity and capability (including clean room capability).

3.2 Main options

- 3.2.1 The Economic Case of the Aseptic and Radiopharmacy Suite SOC described:
- The generation of a long list of fifteen options through a longlist option development workshop held on 18 March 2019. The workshop was attended by a wide range of stakeholders from within the University Health Board as well as external stakeholders.
 - The sifting of the long list of options against the CSFs identified.
 - A resulting shortlist of six options.
- 3.2.2 The WGH Aseptic Project Group established in May 2022 and described in full in Section 6 (Delivery Arrangements) has taken cognisance of this work, however the transfer of radiopharmacy services to SBUHB and the publication of the TrAMS Programme PBC has enabled the Group to consider an additional temporary demountable option which is less



complicated in terms of design and delivery and more cost-efficient than the options considered in the 2019 SOC.

3.2.3 Table 9 below sets out the options appraised.

Table 9: Summary of options appraisals

Option 1	Do Nothing: Business As usual (BAU)
Description	There will be no capital investment at WGH and BGH. Until new facilities are live under the TrAMS Programme, outsourcing of services and products will continue at current levels or higher to meet requirements.
Net Costs	No capital investment undertaken. It will be necessary to replace isolators, at an estimated cost of £100,970. The cost of outsourcing services and products is estimated at up to £35k per week / £1.82m per annum. ³
Advantages	4. Affordability <ul style="list-style-type: none"> The option would avoid the capital costs which would be incurred under Options 2, 3 and 4.
Disadvantages	1. Strategic fit <ul style="list-style-type: none"> The option will not enable the University Health Board to meet the Spending Objectives. The existing aseptic equipment is nearing the end of their usable life, and without an action plan to replace them, there is a high risk of the aseptic unit being unable to render quality services any longer while remaining compliant. Isolators need to be replaced regardless of the option chosen. 2. Business needs <ul style="list-style-type: none"> Both units have been categorised as high risk-critical due to non-compliance with QAAPS 2016 standards. There is therefore a high and increasing risk that both units will fail, therefore closure at short notice is a possibility despite mitigating actions. This would result in 100% reliance on private sector suppliers with estimated costs in excess of £1.82m per annum until the TrAMS hubs are operational. Increased reliance on the private sector could damage oncology services (see paragraph 2.2.27 for examples). 3. VfM <ul style="list-style-type: none"> The option does not minimise risk, as stated above. Although there would be no capital investment and no programme to implement, future capital costs to mitigate risks could be incurred and are unpredictable. The option would represent continuation of a 'sticking plaster' approach applied to date (see paragraph 2.2.2.8). Future revenue costs are also unpredictable. The option would not provide flexibility for future use. 4. Affordability <ul style="list-style-type: none"> The option may appear to be relatively affordable but this is likely to be illusory as future costs incurred to mitigate risk could be substantial and unpredictable. 5. Achievability <ul style="list-style-type: none"> Although the option may be achievable in the short term, it could impose future requirements and costs on the University Health Board which may be unachievable.
Conclusion	The option does not enable the University Health Board to meet its Spending Objectives and CSFs for the reasons stated above and is therefore unacceptable.

³ Based on a customised report from the Wellsky pharmacy system which looked at the Health Board's current spend on purchasing ready to administer products from commercial companies and the current spend on purchasing vials used to prepare products 'in-house' in the aseptic units for the period August 2021 – August 2022. Outsourcing from commercial companies is typically regarded as being 20-30% more expensive than preparing drugs in-house, therefore 30% has been added to the current spend on vials used to prepare products in the aseptic units to give an estimate of the additional spend if the products currently prepared in the aseptic units were outsourced from commercial companies.



Option 2	Modular Build at WGH (aseptic and radiopharmacy)
Description	<p>The Aseptic and Pharmacy Suite SOC submitted by the University Health Board to WG in December 2019 identified Option 6 as the emerging preferred option i.e, a new build facility on the Worthybush Hospital site which will allow consolidation of existing services into a single aseptic and radiopharmacy unit.</p> <p>The option would entail building a standalone modular unit housing both aseptic and radiopharmacy services, built to cater to current demand and future demand and fully compliant with QAAPS 2016 standards, including Centralised Intravenous Additive Service, intravenous chemotherapy and radiopharmacy.</p> <p>The unit would house a total of 4 isolators with a clean room each. Three of the isolators would cater to the current production level of 12,000 doses per year, and the additional isolator would allow the production to increase to 20,000 doses. The radiopharmacy services would additionally require 1 isolator and 1 clean room to produce 1,000 doses per year.</p> <p>The option was scoped as a permanent solution to the University Health Board's aseptic and radiopharmaceutical needs.</p>
Net Costs	Total costs (as at the date of the SOC) = £14.2m (Capital costs – £10.05m Radiopharmacy costs – £4.15m).
Advantages	<ol style="list-style-type: none"> Strategic Fit <ul style="list-style-type: none"> The option would partially meet Spending Objective 1, by providing a safe, sustainable aseptic service solution. It would fully meet Spending Objectives 2 and 3 by consolidating services on one site and minimising the risk of negative financial impacts. The new build would be accompanied by new equipment for the aseptic and radiopharmacy services, improving patient services and ensuring business continuity for the University Health Board, thereby meeting Spending Objective 5. Business needs <ul style="list-style-type: none"> The option would meet Business Needs by providing enhanced quality of service and improved outcomes, and equitable access and supply.
Disadvantages	<ol style="list-style-type: none"> Strategic Fit <ul style="list-style-type: none"> The option is now over-scoped as: <ul style="list-style-type: none"> The TrAMS Programme now means that services will transfer from the University Health Board to the South West Hub between 2028-31 (est.) and the unit will be decommissioned. Radiopharmaceutical services have transferred to SBUHB. VfM <ul style="list-style-type: none"> The option would not provide VfM, as it would incur a high level of capital expenditure which is no longer justified, given that aseptic services will transfer to the South West Hub under the TrAMS Programme and radiopharmacy services have transferred to SBUHB. Affordability <ul style="list-style-type: none"> The estimated capital expenditure identified in the SOC is no longer justified. Achievability <ul style="list-style-type: none"> The option would be achievable in terms of practicality of delivery, timescale for delivery, site constraints or challenges, design and supply side capacity and capability, however this consideration is redundant given the change in the strategic landscape.
Conclusion	Following the opportunity to transfer radiopharmacy services to SBUHB and the publication of the TrAMS programme, this option is no longer strategically, financially or operationally relevant and is therefore discounted.
Option 3	Do Minimum: Small Scale Refurbishment at WGH Aseptic Unit and Repurposing of BGH Aseptic Unit
Description	Under this option refurbishment of the existing aseptic unit at WGH would be undertaken over an estimated period of 11 months, involving the provision of a changing room, sufficient cold storage facilities and extensive heating, ventilation and air conditioning (HVAC) ducting and roof work to ensure adequate air flow to the air pressure room. Following refurbishment there would be consolidation of services on one site which would allow the early closure and repurposing of the BGH aseptic unit for other clinical / pharmaceutical / operational use. The closure period could be considerably longer – discussions with the National Quality Assurance Pharmacist have indicated that a comparable refurbishment at Glan Clwyd Hospital in Bodelwyddan (operated by Betsi Cadwaladr University Health Board) took approximately 18 months.
Net Costs	The University Health Board has produced a Development Cost Appraisal Form for this option (available on request), which shows a Forecast Project Out-Turn Cost of £3,065,766 (post-VAT Recovery). In addition the University Health Board will incur additional transport costs estimated at £19k pa as a result of the closure of the BGH aseptic unit.
Advantages	<ol style="list-style-type: none"> Strategic Fit



	<ul style="list-style-type: none"> The option would meet Spending Objective 1 ('providing a safe, sustainable aseptic service solution until services can be transferred to facilities to be provided under the TrAMS Programme'), however because this option would effectively be a continuation of the 'sticking plaster' approach used to date, there is a risk that any reduction in risk to patient care would be temporary (in addition to being outweighed by risk incurred during the 16-week closure of the WGH unit). The option would meet Spending Objective 2 (by consolidating services on one site at WGH). The option would meet Spending Objective 4 by bringing the WGH unit up to QAAPS 2016 standards, however compliance may also prove to be temporary only because of the 'sticking plaster' approach adopted. <p>5. Achievability</p> <ul style="list-style-type: none"> The option is achievable from a practical perspective.
Disadvantages	<p>1. Strategic Fit</p> <ul style="list-style-type: none"> The option would not encompass replacement of outdated equipment and therefore would not meet Spending Objective 5. <p>2. Business Needs</p> <ul style="list-style-type: none"> During the refurbishment period there would be no functional aseptic unit at WGH. The unit at BGH could be utilised to prepare some items, but nonetheless more outsourcing from commercial companies will be required. This is estimated to cost up to an additional £1.82m per annum and comes with a risk of patient treatment delays due to service issues. There are some drugs with very short expiries (4 hours) which cannot be outsourced, and the likelihood is that the University Health Board could not offer these drugs to patients during the refurbishment unless the patients were to travel to BGH. This could present difficulties to many patients. Quality and supply issues with outsourcing companies have been noted earlier (see paragraph 2.2.2.7), therefore this option would expose patients to quality and supply risks. The University Health Board has concluded that, were it to pursue this option, it would need to look to outsource from other specialist companies where costs would be far higher. This option poses a significant business continuity and service quality risk which should be avoided if possible. If the University Health Board were to continue to use its current suppliers, it would need to seek a total commitment service for the anticipated closure period, however the National Procurement Lead Pharmacist for Wales has indicated that it is unlikely that any of them would be in a position to commit currently, and if they did the costs would probably be a significant uplift on the current product costs to ensure they could deliver: it would require a robust forecast on your requirement line by line in order for them to engage and provide the costings. <p>3. VfM</p> <ul style="list-style-type: none"> The refurbishment would be relatively superficial in scope and further costs may be incurred subsequently. The closure of the WGH unit during refurbishment would expose the University Health Board to unpredictable costs from commercial suppliers. Risks to patient care are not minimised. The limited nature of the refurbishment is unlikely to provide flexibility for future use of the space. <p>4. Affordability</p> <ul style="list-style-type: none"> The Forecast Project Out-Turn Cost of the option is £177,269 higher than the cost of Option 4 (the Demountable unit at WGH – see below).
Conclusion	The Forecast Project Out-Turn Cost of the option is approximately 6.1% higher than that of Option 4 (see below). Furthermore the closure of the WGH unit for at least 11 months is an insurmountable problem, exposing patients and the University Health Board to unacceptable levels of risk and potential cost. The VfM of the option is therefore lower than Option 4 and it is discounted.
Option 4	Demountable unit at WGH
Description	This option would entail placement of a demountable unit on a suitable site at WGH with new equipment, capable of meeting all HDUHB requirements and compliant with QAAPS 2016 Standards. The existing aseptic unit at WGH would be decommissioned and the space utilised to create a larger walk-in cold room. The BGH unit would be repurposed for other pharmaceutical use. The demountable unit would be utilised until the South West Hub becomes operational under the TrAMS Programme at which point, following a transition period, it would be decommissioned and all activity transferred to the South West Hub.
Net Costs	The Forecast Project Out-turn Cost of the option is £2,888,497 (post-VAT recovery). (A detailed Development Cost Approval Form is attached at Appendix 1.) In addition the University Health Board will incur additional transport costs of £19k pa due to the closure of BGH Aseptic Unit. and additional premises costs associated with the increased size of the building footprint.
Advantages	<p>1. Strategic Fit</p> <ul style="list-style-type: none"> This option would address Spending Objective 1 as there would be no interruption to the provision of aseptic services until the TrAMS Programme becomes operational. Spending Objective 2 – consolidation on one site – is achieved.



	<ul style="list-style-type: none"> Spending Objective 3 – minimising risk of negative financial impacts – is met as the option is likely to enable the University Health Board to reduce expenditure on outsourcing. Spending Objective 4 – compliance – is met. By procuring new equipment, Spending Objective 5 is achieved. <p>2. Business Needs</p> <ul style="list-style-type: none"> The option will enable the University Health Board to mitigate the risk of failure of the existing estate; and the risk to patient care and estimated financial cost of up to £1.82m which would result from the need to fully outsource production. The option is expected to enable the University Health Board to repatriate production which is currently outsourced, however the level of repatriation achievable and the resulting cost efficiencies are difficult to estimate at this stage given the fragility of the service, and will therefore <p>3. Value for Money</p> <ul style="list-style-type: none"> The lifespan of the demountable is 15 to 20 years, and one supplier has stated that the building will have a design life of 60 years and a building life of 30 years. The option therefore offers flexibility for future use, and following its decommissioning as an aseptic unit could be repurposed, for example, as dedicated cold storage, training space or support office accommodation. There would be a functional aseptic unit at WGH throughout the entire implementation, mitigating the reliance on commercial companies during the decant to BGH which would be incurred in Option 3. As the option would involve repurposing the existing WGH facility as a cold storage unit, it would be possible to hold larger stocks, which would create a financial efficiency and reduce clinical risk. The option would enable closure of the BGH aseptic unit and conversion of the space to increased pharmaceutical production. <p>4. Affordability</p> <ul style="list-style-type: none"> The Forecast Project Out-Turn Cost of the option is approximately £177k lower than the cost of Option 3 (see above). <p>5. Achievability</p> <ul style="list-style-type: none"> The University Health Board has demonstrated, through the expression of interest process described at paragraph 1.8, that the supplier market is able to provide clean room capacity.
Disadvantages	<p>5. Achievability</p> <ul style="list-style-type: none"> As the placement of the unit will be implemented on a functioning hospital site, there is a risk of disruption related to noise and / or construction related activity on site. This will be managed contractually. There is some risk to lead times as the number of specialised demountable unit suppliers is limited.
Conclusion	<p>Option 4 will not require any interruption to existing service and will provide the University Health Board with a compliant and fully functional aseptic unit on a single site until the South West Hub becomes operational. It will mitigate risk of the failure of the existing units and the consequent risk to patient care, and outsourcing costs estimated at up to £1.82m pa. The long life of the unit means that it will provide the University Health Board with premises suitable for future uses once the aseptic unit is decommissioned. Financial and operational risks are manageable. The option will enable the BGH aseptic unit to be repurposed for other pharmaceutical use. The Forecast Project Outturn Cost is lower than Option 3 and the option carries lower risk; it therefore offers better VfM.</p>

- 3.2.4 The Financial Annex showing the financial appraisal of options 1, 3 and 4 is attached at Appendix 2. Please note that we have not included a financial appraisal of option 2 as this option is no longer available and is included for reference purposes only, to show the work previously done by the University Health Board in consideration of future aseptic products provision.

3.3 Recommended option

- 3.3.1 Based on the appraisal above, option 4 is the Recommended Option.
- 3.3.2 The University Health Board identified five possible sites ('Sites A-E') for the placement of the demountable unit at WGH. The relative advantages and disadvantages of each Site are shown in the document attached at Appendix 3 (Site Options Appraisal).
- 3.3.3 'Site B', located close to the entrance of the Physiotherapy Unit, was confirmed as the preferred Site at a meeting of the Aseptic Project Group held on 2 September 2022, and Sections 4 and 5 below reflect this decision.



3.3.4 Appendix 3 identifies a number of 'cons' in relation to Site B. These have been / will be addressed as follows:

- The Site B option will require the repositioning of two disabled car parking spaces. These will be moved to a suitable and easily accessible position directly opposite the Physiotherapy entrance by re-lining the existing 'standard' spaces. The lost 'standard' spaces will then be moved to the back of the hospital.
- There was some concern that Site B is further away than the originally-proposed location of Site A (Courtyard), therefore materials, supplies and products would have to be portered a further distance than originally envisaged: To address this, the demountable has been increased in size to facilitate a clinical support / storage function.
- Additional fire protection measures to structures within 3m of hospital: This will be mitigated as per the second bullet point above.
- Facilitating work involves removal of shipping containers and portacabin structures: This is a requirement under fire safety regulations in any case and will be organised by the WGH management team.
- Planning permission will be required and if larger than 100m² will require a SAB application: Planning permission will be required, however a SAB application will not be required as the building is under 100m².
- A unit larger than the standard 17.1m x 3.6m will require 2no. joined buildings: Construction-related risks will be managed through the Project Team.



4. Procurement Route

4.1. Introduction

4.1.1. This Section describes:

- The outputs to be procured (demountable unit, equipment and enabling works).
- The procurement route for the outputs.
- Payment terms.
- How the procurements will be contracted.
- Legal and personnel implications of the Recommended Option.

4.2. Outputs to be procured

4.2.1. The outputs which will be procured are:

4.2.1.1. Demountable: Purchase and fit-out of a demountable unit to be located close to the entrance of the Physiotherapy Unit of WGH to house aseptic production and a cold room with the necessary equipment. The unit will consist of two 'Portakabin'-style buildings, a larger one designated for aseptic processes, and the smaller attached unit for clinical support and storage, this design will provide sufficient space for storage and segregation of products. There will be a glazed link to connect the two demountable buildings. Site plans for the demountable unit are attached at Appendix 4 (Site Plans). The demountable unit will feature a 60 minute fire rated construction within 3m of the existing hospital building. This will be required to be addressed by the demountable building provider.

4.2.1.2. Construction: Enabling works at WGH Site B, existing WGH and BGH aseptic facilities to be reconfigured into clinical space, offices and storage.

4.2.2. A Development Approval Cost Form setting out the outputs to be procured and their estimated costs is provided at Appendix 1, and these are summarised below (please note that the table may include rounding effects):

Table 10: Estimated costs (£)

Cost	Net cost (£)	VAT @ 20%	Gross cost (£)
Works cost	1,471,719	294,344	1,766,063
Fees *	336,697	33,114	369,811
Non-works costs	291,070	58,214	349,284



Equipment costs	142,953	28,591	171,543
Contingency	220,758	44,152	264,909
Forecast Project Out-turn Cost (pre VAT recovery)	2,463,197	458,414	2,921,611
Less recoverable VAT		(33,114)	(33,114)
Forecast Project Out-turn Cost	2,463,197	425,300	2,888,497

* It should be noted that not all Fees are subject to VAT

4.3. Procurement route

4.3.1. Introduction and underlying principles

- 4.3.1.1. The procurement route for all goods, services and works pertaining to the WGH aseptic unit will comply with Hywel Dda Standing Orders and Standing Financial Instructions and ensure due regard to statutory requirements (including Public Contract Regulations), WG and central government policy and Audit Commission guidelines are followed.
- 4.3.1.2. The procurement process will strive to:
- Achieve VfM on behalf of NHS Wales, with VfM defined as the optimum combination of whole-life cost and quality (or fitness for purpose) to meet the user's requirement. Depending on the nature of the contract, whole-life cost may include implementation costs, ongoing operating costs, training and end-of-life disposal.
 - Ensure all suppliers compete on a fair and equal basis.
 - Ensure compliance and probity.
 - Ensure that all equipment and consumable products purchased are of appropriate specification for their intended purpose.
 - Ensure that key processes and procedures are in place to ensure the right quality, price, source, quantity and timing are achieved.
 - Monitor and manage contract performance to ensure the contract is being delivered as specified.
- 4.3.1.3. Where compliant frameworks exist, these will be explored to ensure they meet the University Health Board's requirements. However, if this approach is not available or acceptable, the procurement thresholds in the Hywel Dda Health Board Standing Orders will be followed, and where appropriate respective contracts will be advertised via www.sell2wales.gov.uk.
- 4.3.1.4. Irrespective of the procurement strategy approach, all contracts will be awarded on the basis of the most economically advantageous tender (MEAT), providing an opportunity to balance the quality of the goods, services and



works being procured against price and to frame specifications in a way which encourages innovation rather than defining the solution.

- 4.3.1.5. For all procurements, due regard will also be given to relevant WG and University Health Board organisational policies, for example, policies in relation to Modern Slavery and Equality, Social Value, Circular Economy and Decarbonisation. As a minimum a 15% weighting will be given for Carbon Footprint and Well Being and Future Generations criteria at the tender evaluation stages.

4.3.2. Demountable and enabling works

- 4.3.2.1. The University Health Board identified two possible procurement routes for the demountable unit and enabling works:

- A mini-competition under available framework agreement; or
- An open tender run directly by the University Health Board.

- 4.3.2.2. The potential advantages and disadvantages of each route are set out below:

Table 11: Possible procurement routes

Procurement route	Advantages	Disadvantages
Framework tender	<ul style="list-style-type: none">• Prequalification of suppliers has already been undertaken.• Suppliers have accepted contractual terms.• The University Health Board can be confident in suppliers' capability to deliver.• Risk attached to providing a complete turnkey solution would be transferred to the contractor.	<ul style="list-style-type: none">• No potential disadvantages identified.
Open tender	<ul style="list-style-type: none">• The University Health Board would be able to engage directly with suppliers who have clean room expertise.	<ul style="list-style-type: none">• It would be necessary to include a prequalification element in the tender process. This is likely to extend timelines by a minimum of 4 weeks in comparison with a framework tender.

- 4.3.2.3. To test market interest the University Health Board sought expressions of interest from suppliers listed on the WPA Framework Agreement. Suppliers were provided with the following information:

- (i) The project will be a full turnkey solution, from inception through to commissioning and will include (but not limited to) ground works, drainage, delivery and installation of demountable units.
- (ii) The proposed design must be compliant with appropriate British Standards, Welsh Health Building Notes (WHBNs), Welsh Health



Technical Memorandums (WHTMs), GMP guidelines and MHRA design requirements.

- (iii) The facility will be used to manufacture cytotoxic parenteral products under the section 10 Exemption of the Medicines Act 1968.
- (iv) The project will follow the principles of Qualification and Validation Rules and Guidance for Pharmaceutical Manufacturers.
- (v) All new equipment to be installed within the facility, including isolators, will be selected by the University Health Board.
- (vi) Specific requirements for these items must be considered as part of the facility design and installation. These include but are not limited to:
 - The impact of isolator air demand on cleanroom airflow.
 - Isolator extracts are to be vented directly to outside of the facility.
- (vii) All Fixtures and Fittings must be appropriate for use within a Classified Cleanroom Facility. All Fixtures and Fittings to be installed within the Cleanroom Areas, must be reviewed and approved by Hywel Dda University Health Board, prior to purchase/installation. This includes, but is not limited to, light fittings, filter boxes/diffusers, fire sounders, beacons, alarms.

4.3.2.4 Suppliers were also provided with the room details shown in Table 12 below:

Table 12: Room details

Room Name	Room GMP Classification	Notes
Outer support room	Unclassified	Function: storage and assembly of starting section 10 preparation of medicines prior to transfer into the inner support room and then the cytotoxic clean room. It should incorporate sufficient fridge space, clean room cupboards and movable benching space to allow for storage and assembly of section 10 starting materials. There should be a dedicated "in" and "out" transfer hatch between the outer support room and inner support room. There should be sufficient space for two computers. There should be a sink to allow hand washing. Occupancy: 4 operators.
First Change Room	D	The main change room should be designed to allow one operator to enter / exit the aseptic suite at any one time. Function of the room is to enable operators to change into / out of clean room garments before entering / exiting the inner support room. Space should be available for the housing of clean room garments and footwear and non-clean room clothes and items.
Materials in -Airlock	D	The materials airlock transfer hatch should be designed for the transfer of starting materials into the inner support room from the outer support room.



Room Name	Room GMP Classification	Notes
Finished Goods out - Airlock	D	The finished goods airlock transfer hatch should be designed for the transfer of finished goods from the inner support room to the outer support room.
Inner Support Room	D	Function: storage and assembly of starting section 10 preparation of medicines prior to transfer into the cytotoxic clean rooms. It should incorporate sufficient fridge space, clean room cupboards and movable benching space to allow for storage and assembly of section 10 starting materials. There should be dedicated transfer hatches in and out of the preparation room and in and out of the cytotoxic clean room. Occupancy: maximum 4 operators at any one time.
Second Change Room	D	The change room is intended to allow personnel to change clothing, gloves, footwear prior to entry into the cytotoxic clean room. Space should be available for the housing of clean room garments and footwear and other clean room items. Occupancy: 1 operator at any time.
Materials in - Airlock	C / D	The materials airlock transfer hatch should be designed for the transfer of starting materials into the cytotoxic clean room from the inner support room.
Finished Goods out - Airlock	C / D	The finished goods airlock transfer hatch should be designed for the transfer of finished goods from the cytotoxic clean room to the inner support room.
Cytotoxic Clean room	C	The cytotoxic cleanroom needs to be large enough to house two glove spray / wipe negative pressure isolators externally ducted to extract to atmosphere. The room will also need to accommodate three stainless steel trolleys and two clean room chairs for the clean room operators. Occupancy: 4 personnel working in room at any one time.

- 4.3.2.6 Five of the eight suppliers responded positively, confirming that they have suitable resources to complete the Project.
- 4.3.2.7 The University Health Board's preference is therefore to use the turnkey solution the WPA Framework has to offer. The University Health Board will issue tender documents once the BJC has been approved.
- 4.3.2.8 The mini-competition will be a single stage process and would take around 4 weeks for the tender documents to be issued and returned. We will need to allow an additional 4-5 weeks to score / evaluate (although this needs to be caveated depending on factors such as evaluation members' availability and number of bids received), obtain University Health Board approval and issue award and regret documents, with a 10 day voluntary standstill period between supplier award / regret letters and issue of purchase order.
- 4.3.2.9 The University Health Board will discuss this further with Shared Services to agree the most appropriate way forward so that this can be implemented once the BJC has been approved.
- 4.3.2.10 It is a requirement under the planning application criteria that the Project should incorporate biodiversity and enhancement measures. There will be wildflower planting and shrubbery to the perimeter of the structure, as well as bat/bird boxes on the relevant elevations to increase the opportunities for wildlife.



4.3.2.11 Use of Modern Methods of Construction (MMC), including pre-fabrication / off-site construction methods will bring the following advantages and minimise carbon emissions:

- Speed:
 - Less time on site due to fast installation, keeping project timelines to a minimum.
 - More reliable site deliveries, critical especially in locations - such as hospitals - where access and congestion are paramount.
 - Reduced dependency on good weather.
 - Greatly reduced crane time.
- Quality:
 - Improved quality and reliability due to factory-controlled Quality Control systems.
 - Less re-work on site: factories are typically 70%-80% efficient compared to efficiencies as low as 30% for some construction projects.
 - Reduced need for onsite labour.
- Safety:
 - Fewer site deliveries.
 - Less time spent on site and working at heights.
 - No working under a live load.
- Cost
 - Significant cash flow advantages over traditional build, due to earlier return on capital.
 - Encourages lightweight solutions, offering savings to foundation and structural design.
 - Cost certainty, helped by proven significant reductions in costly re-work.
- Environment:
 - Reduced CO² emissions due to fewer site deliveries.
 - Less waste to landfill.
 - Maximising the use of in house 'green' operations/processes.

4.3.2.12 In addition, new and energy efficient technologies (LED Lighting, Plant, Remote Building Monitoring) can all be incorporated as part of the proposals.

4.4. Equipment

- 4.4.1. Most of the existing equipment at WGH and BGH is dated and has limited further lifespan, therefore the University Health Board will not transfer it to the new aseptic unit. With the exception of isolators (see below), equipment will be procured as part of the Demountable Solution Contract.



- 4.4.2. Due to the extended lead-times for ordering new isolators and the urgency to replace the existing ones, prior agreement was given that discretionary capital would be allocated from 2023-24 to acquire two new isolators, even though the BJC could be declined. A tender was issued on 21 September 2022 with a closing date of 19 October 2022. The University Health Board is in the process of evaluating the bids with a view to appointing the successful contractor in early 2023. At the tender stage this would not bind the University Health Board to a contract, however the successful bidder will be expecting a purchase order and once this is issued this will form part of the contract.

4.5. Implementation plan

- 4.5.1. An implementation plan for the Recommended Option is provided at Appendix 5 (Project Programme – Recommended Option). Key dates are summarised below:

Table 13: Key dates

Implementation - Milestones	Timeline
BJC HB Internal Scrutiny Process	28 January 2022 to 3 rd February 2023
BJC WG Scrutiny and Approval	6 th February 2023 to 31 st March 2023
Planning Approvals Received by	6 th January 2023
Appointment of project design team	28 th April 2023
Detailed technical design completed	21 st July 2023
Tender period	24 th July 2023 to 13 th October 2023
Contractor mobilisation and manufacture	16 th October 2023 to 1 st March 2024
repurpose the BGH aseptic unit	4 March 2024 to 7 th June 2024.
Demountable installation	4 th March 2024 to 24 th May 2024
Demountable commissioning	27 th May 2024 to 16 th August 2024
Demountable Operational go-live	2 nd September 2024
Repurpose the WGH aseptic unit	9 th September 2024 to 22 nd November 2024

- 4.5.2. The timeline includes measures to address issues identified with regards to Site B, including the following:

- 4.5.2.1. The following items will need to be removed / decommissioned:
- Two stacked portacabins used for physiotherapy – these will be relocated by the WGH management team.
 - One shipping container containing notes / files – this will be moved off site as access to these is not required on a regular basis.



- One unused building – this will be decommissioned as part of the works.
- 4.5.2.2. The works will require the repositioning of two disabled car parking spaces to a suitable and easily accessible position directly opposite the Physiotherapy entrance by re-lining the existing 'standard' spaces. The lost 'standard' spaces will then be moved to the back of the hospital.
- 4.5.2.3. Facilitating works will be required for the removal of shipping containers and portacabin structures – this will be organised by the WGH management team and has been included in the Project costs.
- 4.5.2.4. Works to repurpose the BGH aseptic unit will take place between 4 March 2024 – 7 June 2024.
- 4.5.2.5. Works to repurpose the WGH aseptic unit will take place between 9 September 2024 – 22 November 2024.

4.6. Payment terms

- 4.6.1. Payment terms will be relevant to the procurement and will be determined by the terms and conditions. For example, the payment mechanism for the Demountable may be against the JCT Construction Contract Terms and Conditions and will differ to the payment terms for the procurement of the isolators, which will be procured via the NHS Wales Terms and Conditions for Goods.
- 4.6.2. For the demountable unit the University Health Board is likely to propose payment terms whereby a percentage is paid on delivery of the unit to site, with the remainder released once the unit has been fully commissioned.
- 4.6.3. Payment terms for isolators and any other equipment procured separately will include:
- Part payment 30 days from receipt of the equipment.
 - Balance upon commissioning of the equipment.
- 4.6.4. The University Health Board will also require whole life warranties for the demountable and equipment.
- 4.6.5. Typical payment terms for enabling works are monthly payment.

4.7. How the procurements will be contracted

- 4.7.1. The NHS Wales Terms and Conditions for Contract for Good or Services will normally form the basis of any contract entered into with suppliers unless otherwise agreed.
- 4.7.2. However, in relation to the demountable requirement under the Recommended Option (and specific to the relevant Framework contract), the University Health Board may be able to use any one of a range of standard forms of building contract including JCT / SBCC, NEC3 / NEC4, ACE, PPC, TPC, FAC1, or their own in-house agreement.



- 4.7.3. For the isolators the University Health Board will use the NHS Wales Standard Contract.
- 4.7.4. For the enabling works the University Health Board will use a JCT form of standard contract.

4.8. Legal and personnel implications of the Recommended Option

- 4.8.1. Planning permission for Site B will be required. However, as the building will be under 100m² in area, a Sustainable Drainage Approval Body (SAB) application will not be required.
- 4.8.2. Prior to any procurement all Health Boards are obliged to ensure that the procurement process is carried out in accordance with the public procurement rules, NHS Guidance and the instructions of the Auditor General's Office. Accordingly, employees / individuals will not be permitted to participate in any aspect of the procurement process or to make recommendations in respect of the procurement unless they confirm that they agree to be bound by those rules and instructions by signing a Declaration of Interest Form.
- 4.8.3. Our standard internal Human Resources processes will be followed to support staff who currently work at the BGH aseptic unit during the transfer. An Organisational Change Procedure is already in place to address this.
- 4.8.4. Longer term the University Health Board in collaboration with the TrAMS Programme will consider the implications for staff who will work at the WGH aseptic unit once the South West Hub opens under the TrAMS Programme, which is likely to be in 2028 at the earliest.



5. Funding and affordability

5.1. Capital and Operating Costs

The capital and operating costs of the Recommended Option are shown in the table below. The costs are also provided in the Financial Annex attached at Appendix 2.

Table 14: Cost of the Recommended Option (£'000s)

Costs	Total	Y1	Y2	Y3	Y4	Y5	Y6	Y7	Y8	Notes
Capital expenditure	Total	2023/24	2024/25	2025/26	2026/27	2027/28	2028/29	2029/30		
Works	1,766.00	530.00	1,236.00							
Fees	370.00	241.00	129.00							
Non Works	349.00	191.80	157.20							
Equipment Costs	172.00		172.00							
Contingency	265.00	25.00	240.00							
Less Recoverable VAT	- 33.00	- 21.50	- 11.50							VAT assessment will be undertaken with VAT advisers on approval of funding. VAT recovery % to be notified to WG.
Total Capital Costs	2,889.00	966.30	1,922.70							
Operating Expenditure										
Staff										
Premises	107.00	0	7.00	20.00	20.00	20.00	20.00	20.00		Additional costs associated with increased building footprint.
Outsourcing										
Transport	101.00	0	6.00	19.00	19.00	19.00	19.00	19.00		Additional transportation costs due to the closure of BGH Aseptic Unit.
Other Costs										
Total Operating Costs	208.00	0	13.00	39.00	39.00	39.00	39.00	39.00		
Total Project Costs	3,097.00	966.30	1,935.70	39.00	39.00	39.00	39.00	39.00		

5.2. Balance Sheet Treatment

- 5.2.1. The estimated depreciation charges are £192k per annum for the Recommended Option. It is assumed that additional depreciation charges will be funded by WG.



- 5.2.2. It is estimated that the Recommended Option will impact on the balance sheet of the University Health Board by increasing the value of fixed assets by £1.7m.
- 5.2.3. The estimated impairment of this scheme on completion will be £1.1m. The University Health Board is assuming that Annually Managed Expenditure (AME) impairment on completion of the new build will be funded as AME funding via WG.
- 5.2.4. The calculations underlying the above figures are attached at Appendix 6.



6. Delivery arrangements

6.1. Project management

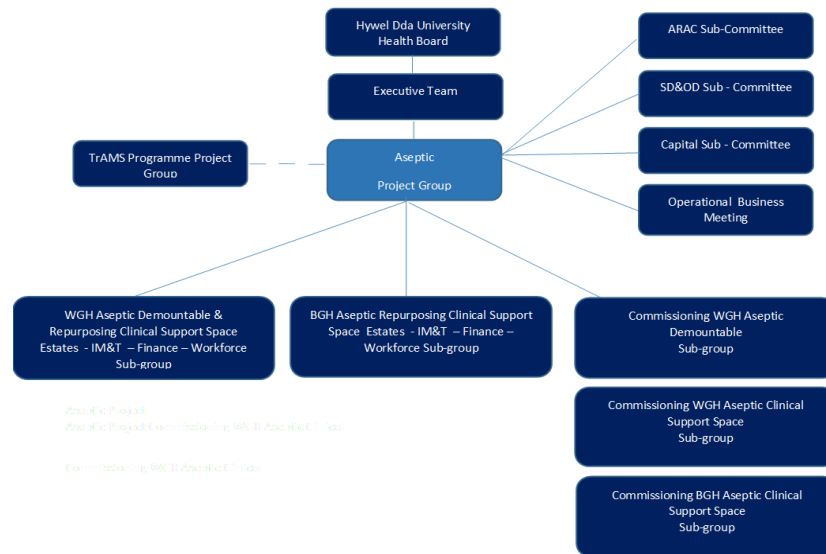
- 6.1.1. The Project will be undertaken in line with NHS Infrastructure Investment Guidance and using established project management methodology.
- 6.1.2. The University Health Board set up the Aseptic Project Group (the Project Group) on 23 June 2022. The Project Group is responsible for good management and governance of the Project, to ensure its delivery within available resources, on time and to agreed service model specifications and that the Spending Objectives are met. The Project Group's Terms of Reference are provided at Appendix 7.
- 6.1.3. The Project Group is accountable to the SRO, being the Director of Primary Care, Community and Long Term Care; and the Project Director, being the Clinical Director of Pharmacy and Medicines Management.
- 6.1.4. The Project Director will be supported by the Project Manager, whose role will be to work closely with the Project Director and the Project Group to enable the successful delivery of the Project and the Project's Management Case.

6.2. Principal duties

- 6.2.1. Following are some of the principal duties of the Project Group, a full list of which is detailed in the Terms of Reference:
 - To ensure the project plans are aligned to the TrAMS Programme of work.
 - To ensure that all activity is managed and monitored to ensure the safe, efficient and effective delivery of aseptic services, to include the decant and commissioning stages.
 - To ensure that all governance processes are in place to include the management of risks, issues, decisions, emerging opportunities and constraints.
 - To manage and oversee the development of an Equality Impact Assessment.

6.3. Governance structure

- 6.3.1. The Project Group is integrated within the University Health Board's governance structure as shown below:



6.3.2. As part of its principal duties, the Project Group's highlight reports are submitted to the Capital Sub Committee on a bi-monthly basis, drawing specific attention to any significant matter under consideration by the sub-groups.

6.3.3. No external specialist advisers have been brought in to assist in the implementation of the Project (other than some external business case writing support).

6.4. Project assurance

6.4.1. In order to ensure the quality delivery and management of the project, an Integrated Assurance and Approval Plan (IAAP) has been included at Appendix 8. In addition, various reports are created by the responsible sub-groups and discussed during the Project Group meetings. Furthermore, the bimonthly reports provided to the Capital Sub-Committee include a RAG status report.

6.4.2. The project reporting arrangements are summarised below:

Table 15: Reporting requirements

Forum	Requirement	Format
Committees of the Board: <ul style="list-style-type: none"> Strategic Development and Operational Delivery Committee (SDODC) Audit and Risk Assurance Committee 	Covering Situation-Background-Assessment-Recommendation (SBAR) (when required)	Written or verbal.
Executive Team	Update from SRO	Written or verbal.
Capital Sub-Committee (CSC)	Brief update or SBAR	Written or verbal
Project Group	<ul style="list-style-type: none"> CSC highlight reports 	Written or verbal



Forum	Requirement	Format
	<ul style="list-style-type: none">• Finance report• Workforce reports• Project timeline• Project risk register• Construction risk register• Action notes• Issues register• Decisions register• Change request register	

6.4.3. In addition to the above reporting, the Project Group may provide project status highlight reports to the TrAMS Programme Group, SDODC and the Board of the University Health Board as and when required.

6.4.4. Given the critical timeline for the Project, an independent and impartial review in addition to the internal project assurance structure described above will not be undertaken.

6.5. Communications and engagement

6.5.1. Engagement plan

6.5.1.1. The Project Manager will facilitate a communications and engagement plan in consultation with the Project Group. The plan will support delivery of the Project by ensuring stakeholders are consulted, including patients, WG and the TrAMS Programme.

6.5.1.2. An internal communication plan will ensure that staff are kept informed about the development of and rationale for the project and any concerns can be identified and addressed.

6.5.2. Change management

6.5.2.1. A relatively small number of staff will be impacted by the closure of the existing aseptic units at WGH and BGH and their decant to the new demountable unit, and the repurposing of the BGH unit for pharmaceutical purposes. The changes these individuals will experience will be managed directly with them.

6.6. Benefits realisation

6.6.1. A benefits realisation exercise will form part of the Project Closure Report (PCR), a key product in the post implementation and evaluation process (further detailed in section 6.9 below). This process will ensure that a robust analysis is carried out to understand whether the Project has achieved its Spending Objectives, through an assessment of the extent to which benefits have been realised.

6.6.2. The PCR, its contents and process will be informed by best practice guidance from project methodologies such as PRINCE2 and Better Business Case guidance.



6.7. Project risks

6.7.1. Risk management

6.7.1.1. The risk management process, conducted through the Project Group to date, has comprised the following steps:

- Completion of a Risk Potential Assessment (RPA) – attached at Appendix 9.
- Creating a register of perceived risks and updating it on a regular basis.
- Assigning / agreeing the ownership of risks.
- Actively managing the agreed actions to mitigate risk.

6.7.1.2. All risk actions are labelled as follows:

Table 16: Risk action labels

Avoid	Risks that can be managed out, usually by design.
Reduce / share	Risks that have a fairly high probability of occurring, which have some latitude in limiting the impact. There are few instances in construction where risk can be shared.
Transfer	Risks that can be transferred onto insurers or against contingencies.

6.7.1.3. Each risk is assigned an owner responsible for its management. The Project Manager assists the owners of the risks by monitoring and overseeing their progress in managing the risk.

6.7.2. Risk register

6.7.2.1. The risk register enables all risks – either project or construction related – to be captured.

6.7.2.2. The project risk register is a risks, issues and decisions register used to capture the organisational risks that sit outside of the construction programme, actions from the respective project groups, issues and key decisions made in the Project. It is a live document reviewed and updated on a regular basis by the Project Manager during the Project Group meetings. The Project Manager may also convene periodic workshops to review and update the risk register. During these reviews, new risks identified are added, and existing risks revisited to agree whether the risk factor should be altered and ensure that the agreed management action is being adequately undertaken by the risk owner.

6.7.2.3. The risks in the risk register are scored a factor of 1 to 5 in terms of likelihood and 1 to 5 for impact.



- 6.7.2.4. The construction risk register will be similar to the project risk register and created following the appointment of the Principal Contractor. All risks that the Principal Contractor can foresee at the outset of the Project will be included and updated at the monthly project review.

6.7.3. Risk reporting

- 6.7.3.1. The risk register forms an integral part of the monthly Project Group meetings. During the reviews new risks may be added and existing risks are revisited to agree whether the risk factor should be altered and ensure that the agreed management action is being adequately undertaken by the risk owner.
- 6.7.3.2. High risk items are included in the weekly Project Group agenda packs to ensure that mitigations are discussed and escalations can be agreed. The Executive Team as sponsoring group for the Project will be informed of risks which are of particular concern and / or do not have appropriate mitigation in place.

6.8. Contract management

- 6.8.1. Issues arising from the risk register and discussed with the Project Group will be assessed and appropriate contingency built into contracts with suppliers. Contingency has been included within the costs detailed in Section 4.

6.9. Project evaluation

- 6.9.1. The Project will be evaluated by the Project Manager one year post-implementation of the Recommended Option. This Post-Implementation Review will be undertaken to ensure that:
- The Project has achieved its Spending Objectives, mainly through assessing the extent to which benefits have been realised (see section 6.6 above).
 - Lessons are captured so that they can be absorbed into the Capital Planning Project Framework to aid the delivery of future capital projects.
 - A formal project closure can take place, with any outstanding risks and remaining benefits to be tracked and monitored identified.
 - Any outstanding audit recommendations are considered, addressed, reported on and closed.



Appendices

No.	Title	Paragraph reference	Description
1	Development Cost Approval Form (Recommended Option)	1.4 3.2.3 (Table 9, assessment of Option 4) 4.2.2	This document provides a Budget Cost Estimate for Capital Expenditure under the Recommended Option (Option 4). It has been used as the basis for the figures shown under Option 4 in the Financial Annex, and in Section 5.
2	Financial Annex	3.2.4 5.1	This appendix sets out projected Capital and Revenue Expenditure and Cost Savings (where applicable) for Options 1, 3 and 4.
3	Site Options Appraisal	3.3.2 3.3.4	This document was produced by the University Health Board's Design Team / Estates Department to facilitate the identification of the optimal location for the demountable at WGH under the Recommended Option. It identifies five possible sites ("Sites A-E") and sets out the relative advantages and disadvantages ("pro's and con's") of each. Site B was subsequently identified as the optimal location. Mitigations of the disadvantages identified are detailed in paragraph 3.3.4.
4	Site Plans	4.2.1.1	To provide an understanding of the current and future positioning, layout and external design of the demountable to be constructed at WGH under the Recommended Option, this Appendix contains the following site plans: 1. Existing Site Block Plan 2. Proposed Site Block Plan 3. Existing Site Layout 4. Proposed Site Layout 5. Proposed Floor Plan 6. Proposed Elevations (external design)
5	Project Programme (Recommended Option)	4.5.1	This appendix sets out the current (draft) anticipated Project Programme for the Recommended Option (Option 4). Key dates are summarised in paragraph 4.5.1.
6	DEL - AME Charges	5.2.4	This appendix sets out projected depreciation charges and balance sheet and impairment impacts for Options 3 and 4.
7	Project Group Terms of Reference	6.1.2	This document provides current Terms of Reference for the Project Group described in Section 6.



No.	Title	Paragraph reference	Description
8	Integrated Assurance Approval Plan	6.4.1	This appendix sets out the assurance activities that will be undertaken at portfolio, programme and project level, using pre-defined Gateway 0-5 and flexible Assurance Products (PAR, PVR, Critical Friend) as appropriate and proportionate.
9	Risk Potential Assessment	6.7.1.1	<p>This document follows WG Independent Assurance Hub guidance to provide a self-assessment of the Project's level of risk under the headings shown below. The University Health Board's self-assessment of the level of risk is also shown:</p> <ul style="list-style-type: none">• Strategic Alignment & Commitment (Medium).• Financial/funding impact (Low).• Stakeholder engagement (Low).• Governance (Low).• Programme/Project Dependencies (Low). <p>The University Health Board's overall self-assessment risk rating is Low.</p> <p>The document was signed by the SRO on 18 October 2022 and remains current.</p>



GIG
CYMRU
NHS
WALES

Bwrdd Iechyd Prifysgol
Hywel Dda
Hywel Dda University
Health Board

Development Approval Cost Forms

Status: Budget Cost Estimate

Health Board: : Hywel Dda University Health Board

Hospital/Site : Aseptic Units - WGH and BGH

Project Title : BJC Option 4 *Demountable Unit WGH, repurpose of former aseptic suite at WHG & BGH*

Client Unit : Pharmacy and Medicine

Supervising Officer : Ashley Wood

Project Allocation : Business Case

Project No : 1422 Cost Code : TBC

Prepared by : Ashley Wood Capital Support : Maggie Annison

Date & Revision : 30.06.2022 Version : v9

Reviews & Updates		
Version No:	Summary of Changes	Date Issued:
v2	Revised Site and Aseptics demountable layout cost	13.10.2022
v3	Revised Costs further to Project Group Meeting	20.10.2022
v4	Dates Typo.	01.11.2022
v5	Confirmed IT / Isolator Costs	24.11.2022
v6	VAT Removed on in House Fees	25.11.2022
v7	Updated Spend Profiles.	12.12.2022
v8	WG Inflationary Risk & VAT Split re-calculated.	20.12.2022
v9	Cashflow Split Amended - S. Welsby	21.12.2022

Project Title:
BJC Option 4

BASIS OF ESTIMATING

Healthcare Capital Investment document Version 2

Main Contract Procurement Method : WPA / Hywel Dda Construction Framework

Main Contract Standard Form and Option : WPA / JCT Form of Contract

Proposed start on site : 4th March 2024

Proposed completion date : 25th of November 2024

This estimate is based on current market costs and are valid for 90 days. Applications for revisions should be made after 90 days of this date if these works are being further considered.

Project Timescales (weeks):

Refer to Project Programme Gantt Chart v4

Capital Cost Summary

Ref	Cost Centre	Net £	VAT @ 20% £	Gross £
5	Works Cost (DAF2)	1,471,719.22	294,343.84	1,766,063.06
6	Fees (DAF3)	336,697.12	33,113.68	369,810.80
7	Non-works Costs (DAF3)	291,070.00	58,214.00	349,284.00
8	Equipment Costs (DAF2)	142,952.66	28,590.53	171,543.19
9	Contingency	220,757.88	44,151.58	264,909.46
10	Forecast Project Out-turn Cost (Pre VAT Recovery)	2,463,196.88	458,413.63	2,921,610.52
11	LESS RECOVERABLE VAT (DAF5)		33,113.68	33,113.68
12	FORECAST PROJECT OUT-TURN COST	2,463,196.88	425,299.95	2,888,496.84

- **Notes:-** 1) HDUHB's Development Approval Form does not account for VAT on Fees, as such are 100% recoverable.

Project Title:
BJC Option 4

CAPITAL COSTS: WORKS AND EQUIPMENT COSTS (cost breakdowns to be provided as separate documents)

Accommodation	Functional Size	Functional Unit m2/Nr etc	Gross Floor area (GFA) m2	Cost/m2 GFA £/m2	N/A/C	Works Cost £	Equipment Cost £
Demountable Solution Contract Purchase and fit out of 2No. Demountable units to facilitate Aseptics Processes. Glazed link to connect 2No. Demountable buildings; Aseptics facility and clinical support (10% Cost Indices uplift Inc.)	N/A	N/A	N/A	N/A		848,889.06	
Construction Framework Contract enablement works at Site B, located near Physiotherapy entrance. Withybush GH existing Aseptic facility to be reconfigured into offices & Storage. Bronglais GH existing Aseptic facility to be reconfigured into clinical support areas (10% Cost Indices uplift Inc.)	N/A	N/A	N/A	N/A		489,037.50	
WG Inflationary Risk	@		10%			133,792.66	
Overall Equipment Costs <i>Refer to Equipment Schedule BJC 4</i>	N/A	N/A	N/A	N/A			142,952.66

Total (gross) floor area

0

142,952.66

Less: Abatement for transferred equipment 0 %

0.00

1,471,719.22

142,952.66

Works Cost - to DAF1 Summary

1,471,719.22

Equipment Cost - to DAF1 Summary

142,952.66

Project Title:
BJC Option 4

CAPITAL COSTS: FEES AND NON-WORKS COSTS

1	Fees	£	% of Works Cost
NO VAT	a. In-House Design Fees & Project Management	154,530.52	10.50%
	b. Cost Advisor	44,151.58	3.00%
NO VAT	c. Capital Team Support	14,717.19	1.00%
	d. Planning Consultant	7,358.60	0.50%
	e. Civil and Structural Engineer	22,075.79	1.50%
	f. Building Services Engineer	44,151.58	3.00%
	g. Principal Designer	18,396.49	1.25%
	h. Supervisor	29,434.38	2.00%
	i. FM Advisor	0.00	0.00%
NO VAT	j. Other: - Time Charge	1,881.00	pro rata

Total Fees to DAF1 Summary

336,697.12	22.75%
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2 Non-Works Costs

	£	% of Works Cost
a. Other - Decant	10,000.00	0.68%
b. Business Case Support	25,000.00	1.70%
c. Planning and Building Control fees	5,000.00	0.34%
d. Other: - Asbestos Survey / Sampling / Removals	20,000.00	1.36%
- Informatics & Telecommunications	100,100.00	680.16%
- Other / Non Cost Items	10,000.00	0.68%
- Hotel Services / Contract Cleaning	5,000.00	0.34%
- In-House - Direct Labour Assistance	10,000.00	0.68%
- Life Cycle Costing	5,000.00	0.34%
- Isolators	100,970.00	6.86%
Total Non-Works Costs to DAF1 Summary	291,070.00	693.13%

Project Title:
BJC Option 4

PROJECT CASHFLOW FORECAST

Proposed start on site: 4th March 2023

Proposed completion date: 25th of November 2024

	Year	0	1	2	3	Total
	Financial year	2022/2023	2023/2024	2024/2025	200*/**	
Works Cost		0.00	441,515.77	1,030,203.45		1,471,719.22
Fees		0.00	218,853.13	117,843.99		336,697.12
Non-works Costs		30,000.00	130,535.00	130,535.00		291,070.00
Equipment Costs		0.00	0.00	142,952.66		142,952.66
Contingencies		0.00	22,075.79	198,682.09		220,757.88
VAT		6,000.00	145,728.73	306,684.90		458,413.63
Sub-total		36,000.00	958,708.42	1,926,902.10	0.00	2,921,610.52
Recoverable VAT		0.00	21,523.89	11,589.79		33,113.68
Total		36,000.00	937,184.52	0.00	0.00	2,888,496.83

Notes:- 1) HDUHB's Development Approval Form does not account for VAT on Fees, as such are 100% recoverable.

2) No VAT Assessment has been undertaken to date.

Project Title:
BJC Option 4

RECOVERABLE VAT CALCULATION

	a	b	c	d
	Cost Net of VAT	VAT at 20% (ie prior to recovery)	Percentage recoverable (% of col b)	Recoverable VAT (col b x col c)
	£	£	%	£
Works Cost	1,471,719.22	294,343.84	0.00%	0.00
Fees	336,697.12	33,113.68	100.00%	33,113.68
Non-works Costs	291,070.00	58,214.00	0.00%	0.00
Equipment Costs	142,952.66	28,590.53	0.00%	0.00
Total				£ 33,113.68

Notes:-

- 1) DAF does not account for VAT on Fees, as such are 100% recoverable.
- 2) No VAT Assessment has been undertaken to date.

ANCILLIARY PROJECT INFORMATION

Capital Commitment Charge @ 6%	175,296.63
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	Cost Net of VAT	
	£	
Change in Heating Volume (m3)	180.00	
Change in Floor Area (m2)	75.00	
Change in Energy Costs	2,250.00	
Change in Maintenance - Hard FM	2,250.00	
Change in Hotel Services - Soft FM	2,250.00	
Change in Waste	1,125.00	
Change in Rates (Provisional Sum)	12,000.00	
Change in Departmental Costs	0.00	< TBA
Change in Equipment Costs	0.00	< TBA
Total Revenue	20,130.00	

Note - Extra over Revenue Costs Per Annum

Project Title:
BJC Option 4
30.06.2022

RETENTION CALCULATION

	Project Allocation	Planned Expenditure	Retention	Released to DCP
Works Cost (inc VAT)	1,766,063.06		1,766,063.06	
Fees (Ex VAT)			0.00	
Internal	156,411.52		156,411.52	
External	165,568.41		165,568.41	
Non Works (inc VAT)				
Additional (to be named)	12,000.00		12,000.00	
Statutory & Local Authority Charges	30,000.00		30,000.00	
Planning & Building Control Fees	6,000.00		6,000.00	
Asbestos	24,000.00		24,000.00	
IT/Telecoms	120,120.00		120,120.00	
Other	12,000.00		12,000.00	
Hotel Services	6,000.00		6,000.00	
DLO	12,000.00		12,000.00	
Contingency (inc Vat)	264,909.46		264,909.46	
Total	2,575,072.45	0.00	2,575,072.45	0.00

INSTRUCTIONS

Complete
the
COSTS/RE
VENUE -
This
should
BENEFITS
- Specify
the
benefits
the option
RISKS -
Specify
the risks
that will

Version 1.2019

	Option 1	Option 3	Option 4
	Do nothing	Refurbishment	Demountable unit
Total Capital Expenditure	-	3,065.20	2,889.00
Total Revenue Expenditure	6,500.17	101.33	208.00
Total Cost Savings	586.25	-	-
Net Cost	5,913.92	3,166.53	3,097.00

OPTION 1 - Do Nothing: Business as Usual (BAU)

These represent the additional costs / savings only

COSTS	Total	Year 1	Year 2	Year 3	Year 4	Year 5	Year 6	Year 7
		2023/24	2024/25	2025/26	2026/27	2027/28	2028/29	2029/30
	£k	£k	£k	£k	£k	£k	£k	£k
Capital Expenditure								
Works	-							
Non Works	-							
Fees	-							
Equipment Costs	-							
Contingency	-							
Less Recoverable VAT	-							
Total Capital costs	-	-	-	-	-	-	-	-

Revenue Expenditure								
Staff	-							
Premises	-							
Outsourcing	6,500	1,058	1,814	1,814	1,814	1,814	1,814	1,814
Transport	0							
Other costs	0							
Total Revenue costs	6,500	0	1,058	1,814	1,814	1,814	1,814	1,814

Total Project Costs	6,500	0	1,058	1,814	1,814	1,814	1,814	1,814
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Cost Savings								
Staff Costs	542	57	97	97	97	97	97	97

Maintenance	45		5	8	8	8	8	8
Premises	0	0	0	0	0	0	0	0
Total Cost Savings	586	0	61	105	105	105	105	105

Net Cost	5,913.92	-	996.92	1,709.00	1,709.00	1,709.00	1,709.00	1,709.00
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Year 8	Source of Data	BENEFITS	
	(sources and assumptions)	Main Benefits	
		Benefit	
		1	Provision of sufficient in-house capacity to meet activity projections.
		2	Refurbishment of the current BGH aseptic unit to provide additional clinical pharmacy space.
		3	Cost efficiencies through reduced level of outsourcing.
		4	To end the University Health Board's reliance on the WGH and BGH aseptic units, which both have 'highly critical' audit ratings.
		5	Improved equipment standards.
-			
		Option Benefits	
		1	The University Health Board does not consider that this option carries any benefits.
1,814	Premium of 30% included on cost of in-sourcing for period September 2021 - August 2022 due to higher cost of outsourcing production. Assumed increased outsourcing will commence Sep 2024.		
1,814		RISKS	
		Main Risks	
		1	Capital and/or revenue costs are higher than projected.
		2	Failure to deliver services in quantity / to quality required, resulting in need to outsource.
		3	Unable to resource/recruit suitably qualified staff.
		4	Failure to achieve planning permissions and/or building regulations approvals.
		5	Risk to patient safety and access for emergency services at WGH during construction period (related to construction and moving of equipment).
1,814			
	Staff reduction due to outs-roucing production		

	No requirement for maintenance of equipment due to outsourcing	Option Risks	Risk Description
	Vacated premises would be re-purposed leading to no saving in premises costs		
0			
0			
1,814.00		1	The WGH and BGH units have been categorised as high risk-critical due to non-compliance with MHRA and QAAPS standards, and closure at short notice is a possibility despite mitigating actions. This would result in 100% reliance on private sector suppliers with estimated costs in excess of £1.82m per annum until the TrAMS hubs are operational.

OPTION 3 - Do Minimum: Small Scale Refurbishment at WGH Aseptic Unit and Repurposing of BGH Aseptic Unit

These represent the additional costs / savings only

COSTS	Total	Year 1	Year 2	Year 3	Year 4	Year 5	Year 6	Year 7	Year 8
Capital Expenditure		2023/24	2024/25	2025/26	2026/27	2027/28	2028/29	2029/30	
	£k	£k	£k	£k	£k	£k	£k	£k	
Works	636	254	382						
Fees	141	93	48						
Non Works	2,002	1,215	787						
Equipment Costs	205		205						
Contingency	96	38	58						
Less Recoverable VAT	-15	-10	-5						
Total Capital costs	3,065	1,590	1,474	0	0	0	0	0	-

Revenue Expenditure									
Staff	0	0	0	0	0	0	0	0	
Premises	0	0	0	0	0	0	0	0	
Outsourcing	0	0	0	0	0	0	0	0	
Transport	101	0	6	19	19	19	19	19	
Other Costs	0	0	0	0	0	0	0	0	
Total Revenue costs	101	0	6	19	19	19	19	19	-

Total Project Costs	3,167	1,590	1,481	19	19	19	19	19	-
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Cost Savings									
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Staff Costs	0								
Maintenance	0								
Premises	0								
Total Cost Savings	0	0	0	0	0	0	0	0	-

Net Cost	3,167	1,590	1,481	19	19	19	19	19	-
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Source of Data	BENEFITS	
(sources and assumptions)	Main Benefits	
Cashflow profile is not yet known. Arbitrary split of 50% in 2023/24 and 50% in 2024/25 utilised for illustration purposes on all capital costs		
	Benefit	
	1	Provision of sufficient in-house capacity to meet activity projections.
	2	Refurbishment of the current BGH aseptic unit to provide additional clinical
	3	Cost efficiencies through reduced level of outsourcing.
	4	To end the University Health Board's reliance on the WGH and BGH aseptic units,
VAT assessment would be undertaken with VAT advisors once more detailed design is available. VAT recovery % to be notified to WG	5	Improved equipment standards.
No additional costs anticipated for refurbishment option	Option Benefits	
As above	1	Services are consolidated onto one site at WGH (meeting Spending Objective 2).
As above	2	The option would meet Spending Objective 1 ("providing a safe, sustainable aseptic service solution until services can be transferred to facilities to be provided under the TrAMS Programme"), however there is a risk that any reduction in risk to patient care would be temporary.
Additional transportation costs due to the closure of BGH Aseptics Unit		
As above		
	Main Risks	
	1	Capital and/or revenue costs are higher than projected.
	2	Failure to deliver services in quantity / to quality required, resulting in need to outsource.
	3	Unable to resource/recruit suitably qualified staff.
	4	Failure to achieve planning permissions and/or building regulations approvals.

Option not expected to generate any efficiencies. Remain as status quo	5	Risk to patient safety and access for emergency services at WGH during construction period (related to construction and moving of equipment).
Option not expected to generate any efficiencies. Remain as status quo	Option Risks	Risk Description
Option not expected to generate any efficiencies. Remain as status quo		
	1	During the refurbishment period there would be no functional aseptic unit at WGH. The unit at BGH could be utilised to prepare some items, but nonetheless more outsourcing from commercial companies will be required.

OPTION 4 - Demountable unit at WGH

These represent the additional costs / savings only

COSTS	Total	Year 1	Year 2	Year 3	Year 4	Year 5	Year 6	Year 7
		2023/24	2024/25	2025/26	2026/27	2027/28	2028/29	2029/30
	£k	£k	£k	£k	£k	£k	£k	£k
Capital Expenditure								
Works	1,766.00	530.00	1,236.00					
Fees	370.00	241.00	129.00					
Non Works	349.00	191.80	157.20					
Equipment Costs	172.00		172.00					
Contingency	265.00	25.00	240.00					
Less Recoverable VAT	- 33.00	- 21.50	- 11.50					
Total Capital costs	2,889.00	966.30	1,922.70	-	-	-	-	-

Operating Expenditure								
Staff	-	-	-	-	-	-	-	-
Premises	107	0	7	20	20	20	20	20
Outsourcing	0							
Transport	101	0	6	19	19	19	19	19
Other Costs	0	0	0	0	0	0	0	0
Total Operating costs	208.00	-	13.00	39.00	39.00	39.00	39.00	39.00

Total Project Costs	3,097.00	966.30	1,935.70	39.00	39.00	39.00	39.00	39.00
----------------------------	-----------------	---------------	-----------------	--------------	--------------	--------------	--------------	--------------

Cost Savings								
Staff Costs	-							

Maintenance	-							
Premises	-							
Total Cost Savings	-	-	-	-	-	-	-	-

Net Cost	3,097.00	966.30	1,935.70	39.00	39.00	39.00	39.00	39.00
----------	----------	--------	----------	-------	-------	-------	-------	-------

[illegible]

	Efficiencies cannot be estimated at this stage.	Option Risks	Risk Description
	Efficiencies cannot be estimated at this stage.		
-			
		1	As the placement of the unit will be implemented on a functioning hospital site, there is a risk of disruption related to noise and/or construction related activity on site. This will be managed contractually.
		2	There is some risk to lead times as the number of specialised demountable unit suppliers is limited.
-			



GIG
CYMRU
NHS
WALES

Bwrdd Iechyd Prifysgol
Hywel Dda
University Health Board



Aseptics

Site Options Appraisal

Design Team / Estates Department

Contents

03 Introduction

04 Site Masterplan

05 Site Option A

06 Site Option B

07 Site Option C

08 Site Option D

09 Site Option E



Introduction

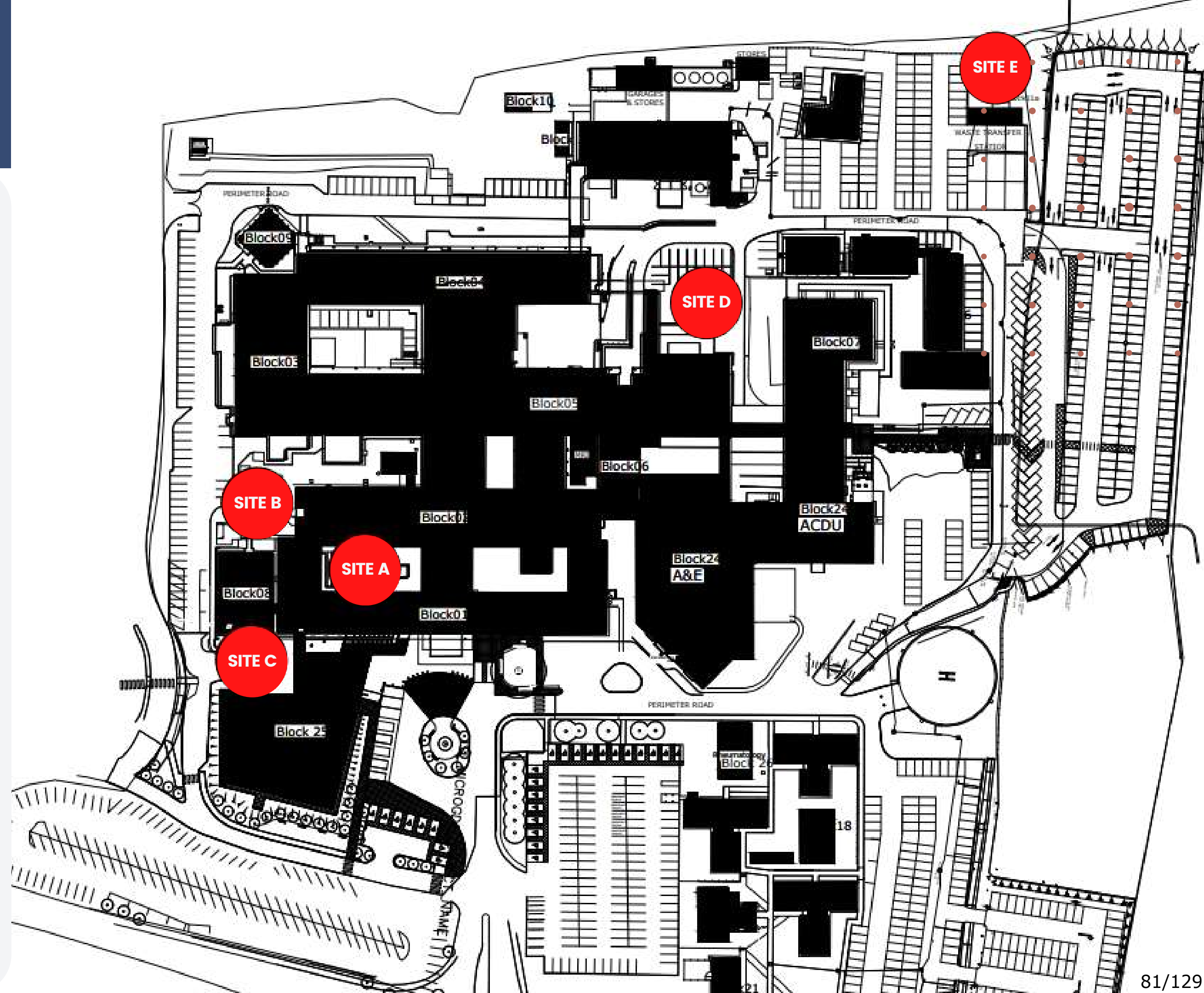
The aseptic facilities across Hywel Dda provide chemotherapy products to cancer patients and a radio pharmacy service delivering critical diagnostic products.

This document will outline the 5 possible options and their associated pro's and con's.

Masterplan

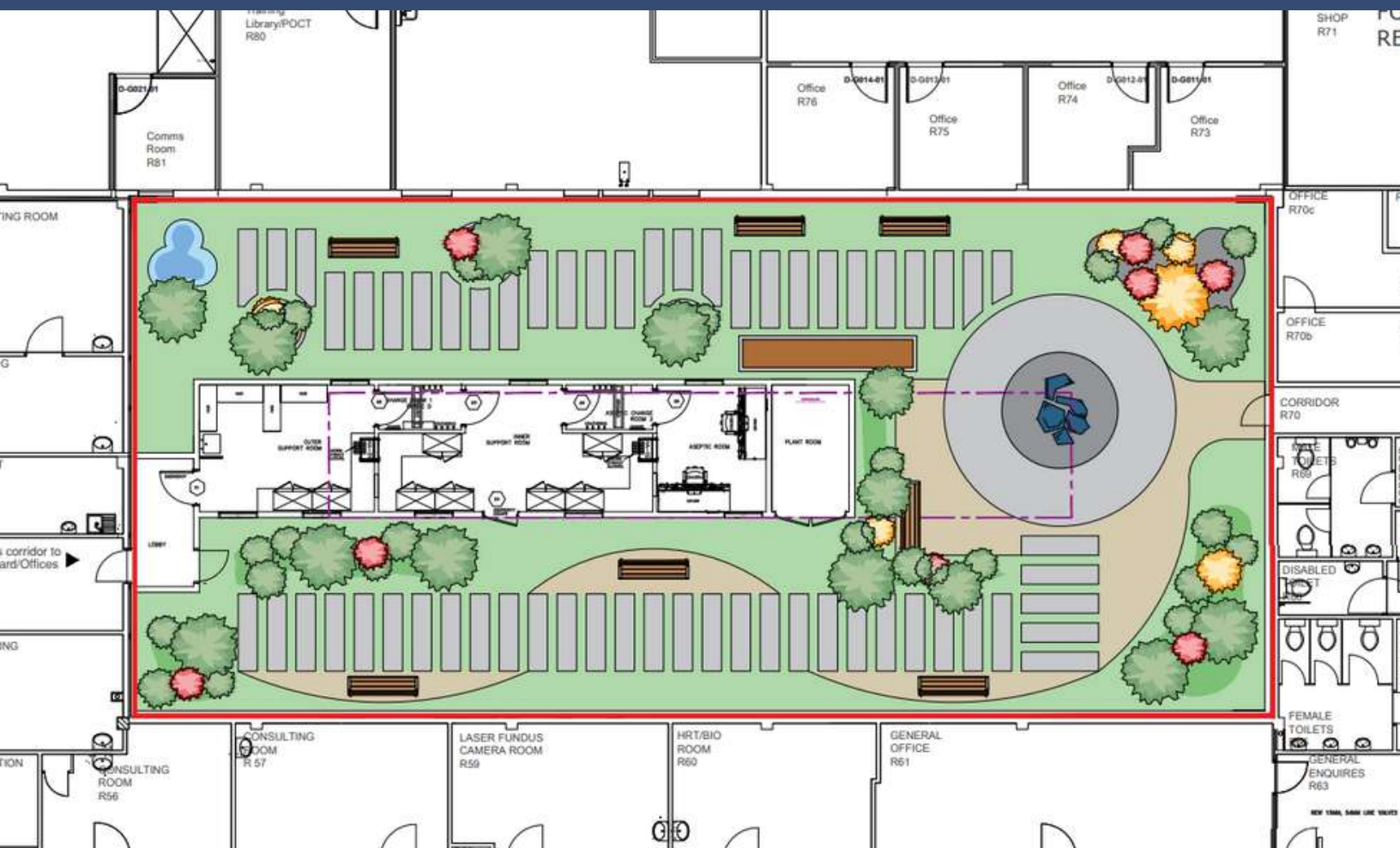
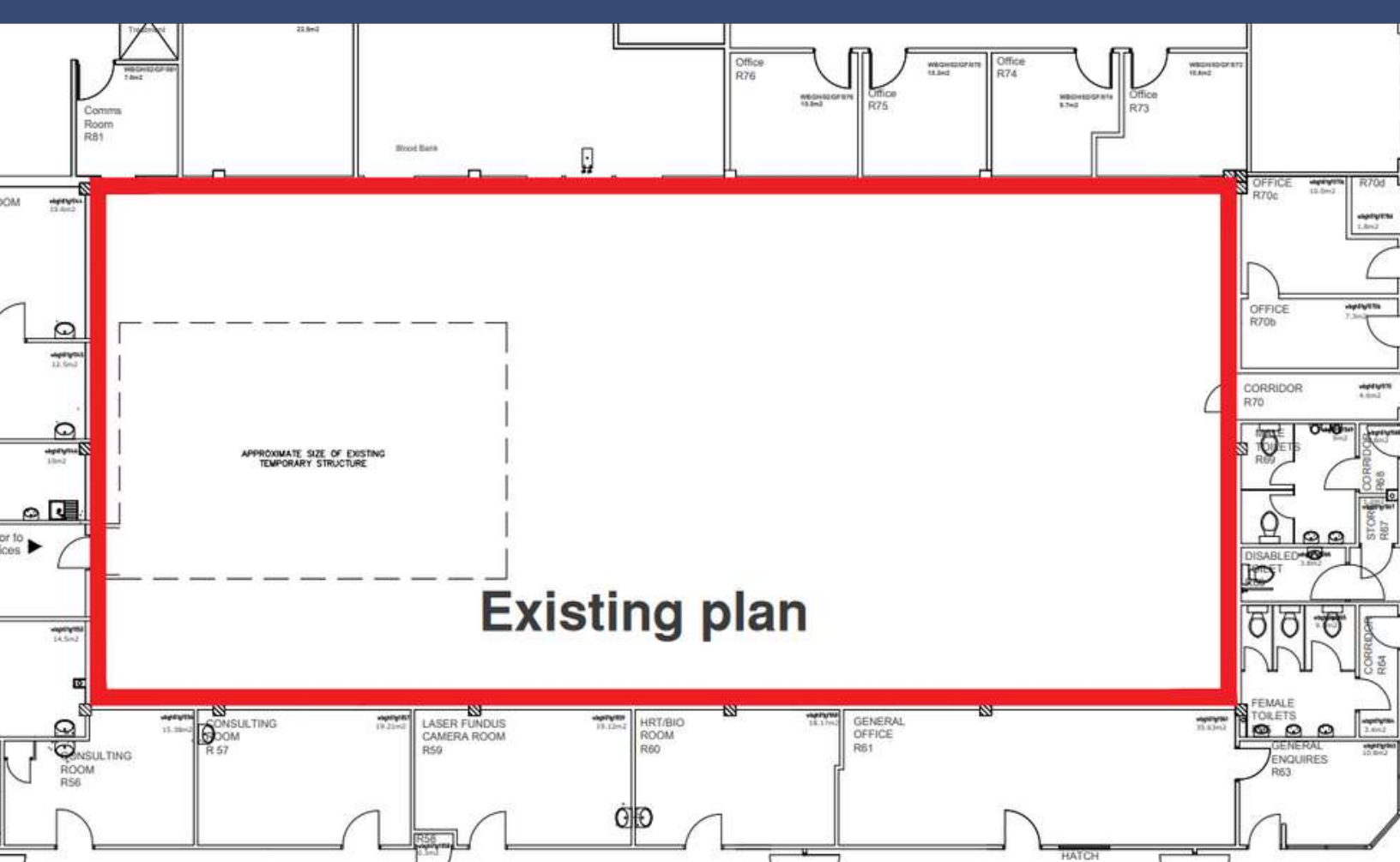
The attached site plan of Withybush General Hospital outlines the 5 potential sites for the Aseptics Service to be sited. These are as follows:

- Site A - Internal Courtyard between Block 1 and 2
- Site B - Grassed area adjacent to Physiotherapy Entrance
- Site C - Delivery Area adjacent to the Renal Unit
- Site D - Car Park near X-Ray Facility
- Site E - Waster Transfer Area





Site A

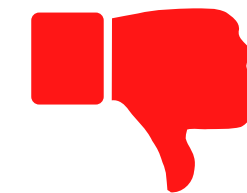


Site A

Site A is located within the courtyard between Block 1 & Block 2. The work would involve craning in a prefabricated demountable unit, pre-finished to allow continual Aseptic services.



1. Very good Aseptic services workflow and linkage to support areas
2. Very Good MHRA standards to meet compliance
3. Delivery route is very good due to close proximity of pharmacy stores
4. No removal of Car parking
5. No Revenue product transfer Implications



1. Existing Air handling unit noise
2. Loss of space for planned staff wellbeing area
3. Additional Pembrokeshire CC input on will be required on staff wellbeing designs
4. Impact on Clinicians offices & patient calls/OPD / CDU / Ward 12
5. Additional foot fall through other clinical areas as main access obtained through OPD twice daily
6. Pre-construction planning will be required for craning of materials and the building over live wards
7. Sprinkler system & 60min fire rating to building
8. Additional Revenue Costs for Demountable Building
9. Combination of Wellbeing Garden and Aseptics material and project planning



Site B

Block 28

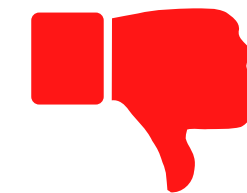
Site B

Site B is located at the entrance with the Physiotherapy Unit. The work would involve craning in a standard size prefabricated demountable unit, pre-finished to allow continual Aseptic services.



Pro's

1. Good Aseptic services workflow and linkage to support areas
2. Good MHRA standards to meet compliance
3. Construction related enabling work is very good due to open area, delivery drop off and no disruption to their services
4. Pharmacy Delivery route is good



Con's

1. Removal of disabled car parking spaces (2no. removed)
2. Possible revenue product transfer Implications as some cold storage disconnect with additional requirement for porters
3. Additional Fire Protection Measures to structures within 3m of hospital
4. Facilitating work involves removal of shipping containers and portakabins structures
5. Planning permission will be required and if larger than 100m2 will require a SAB application
6. A unit larger than the standard 17.1m x 3.6m will require 2no. joined buildings
7. Additional Revenue Costs for Demountable Building

Site C



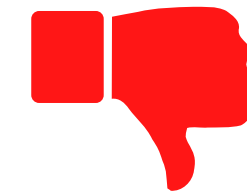
Site C

Site C is located in the delivery area of the Renal Unit. The work would involve craning in a prefabricated demountable unit, pre-finished to allow continual Aseptic services.



Pro's

1. Good Aseptic services workflow and linkage to support areas
2. Good MHRA standards to meet compliance
3. Construction related enabling work is good due to open area and delivery drop off's
4. Pharmacy Delivery route is good



Con's

1. Possible revenue product transfer Implications as some cold storage disconnect with additional requirement for porters
2. Area utilised for HGV turning which offers potential breach/damage to demountable
3. Relocation of Waste Unit will require additional separation due to WHTM/WHBN fire regulations.
4. Planning permission will be required and if larger than 100m2 will require a SAB application
5. Additional Revenue Costs for Demountable Building



Site D



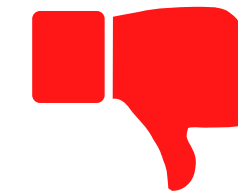
Site D

Site D is located in the adjacent to the X-Ray Unit The work would involve craning in a prefabricated demountable unit, pre-finished to allow continual Aseptic services.



Pro's

1. Good Aseptic services workflow and linkage to support areas
2. Good MHRA standards to meet compliance
3. Construction related enabling work is very good due to open area, delivery drop off and no disruption to their services
4. Pharmacy Delivery route is good

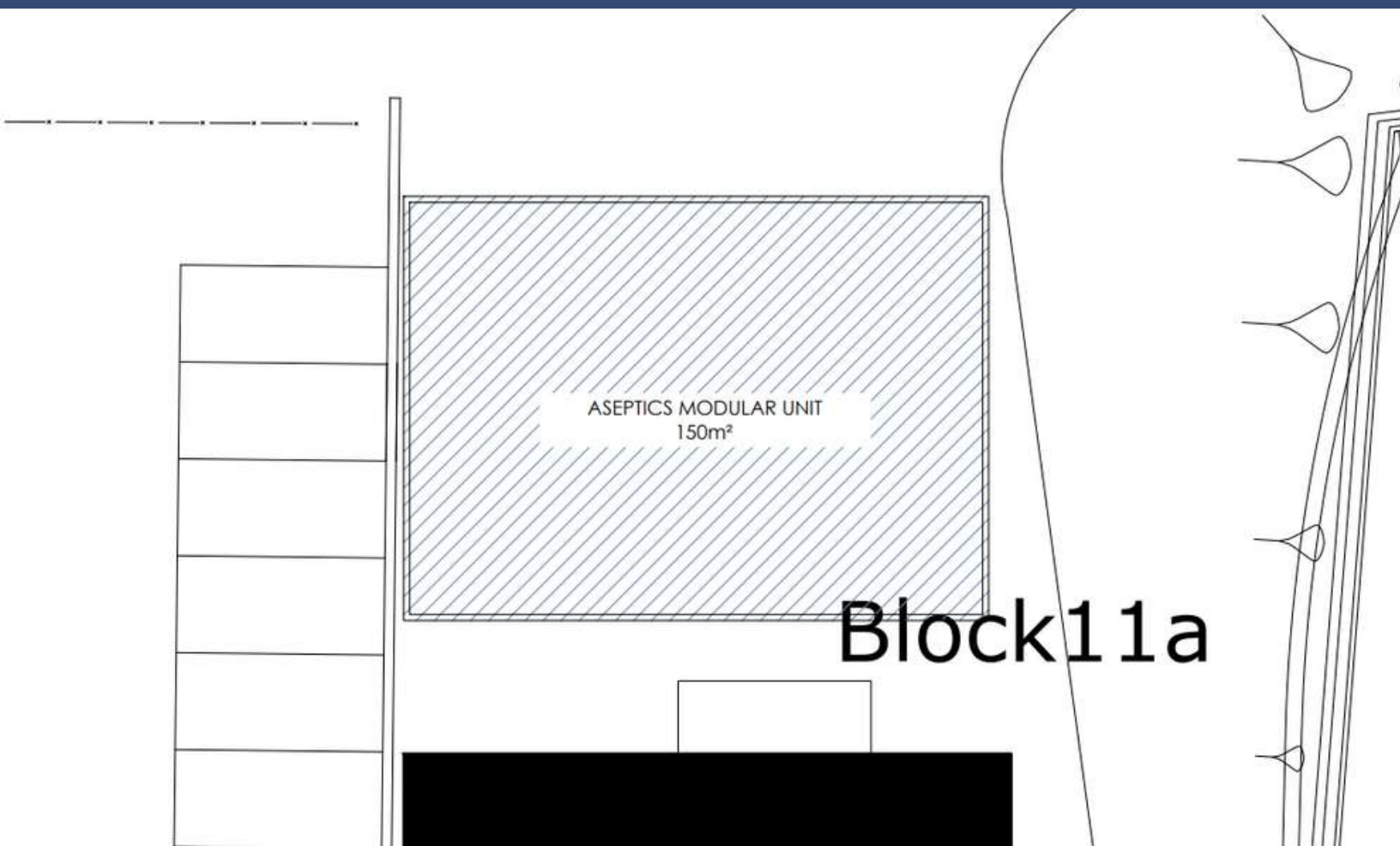
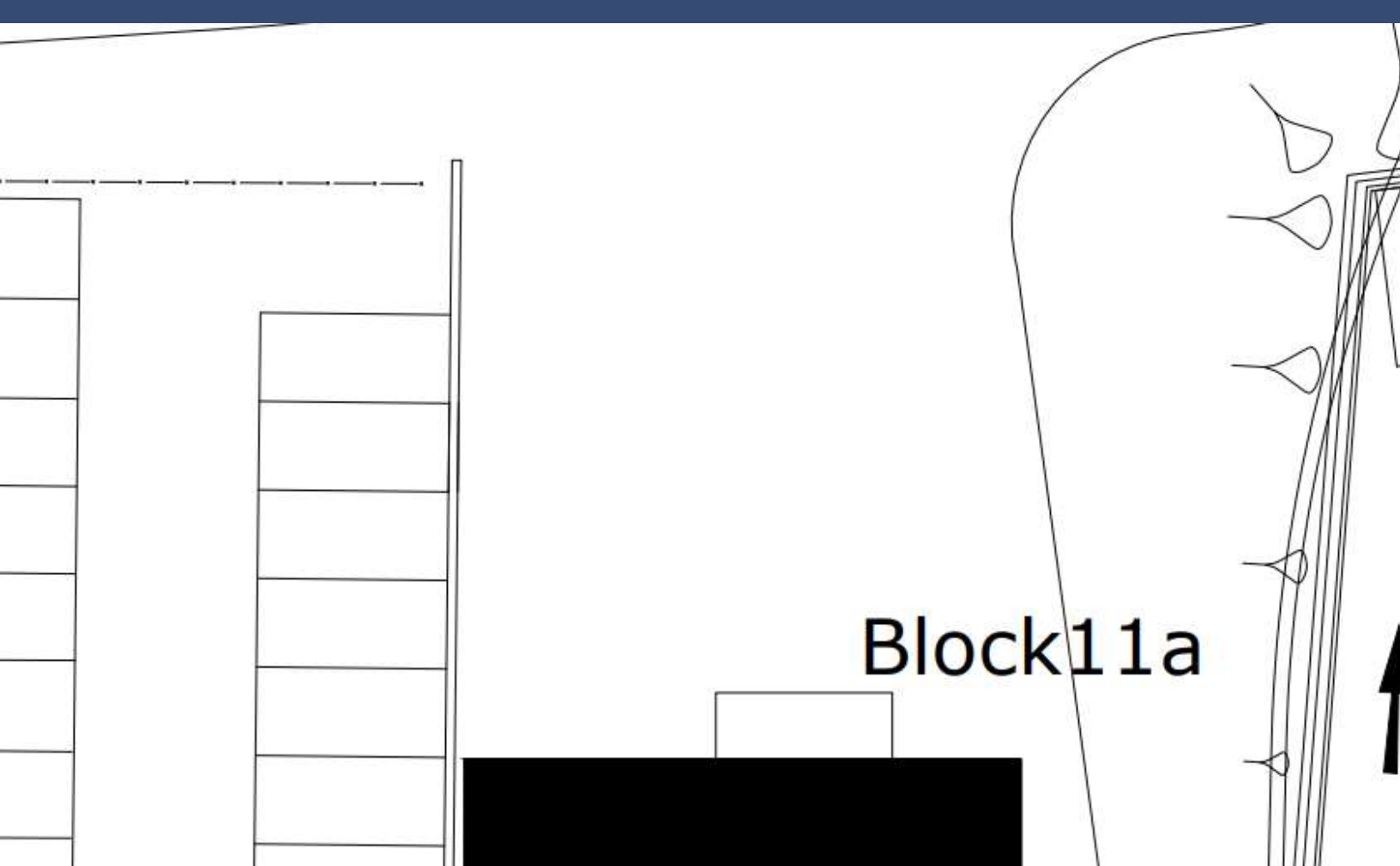


Con's

1. Approximately 5 car parking spaces will be lost as part of the proposals
2. Possible revenue product transfer Implications as some cold storage disconnect with additional requirement for porters
3. Planning Permission and SAB Application (size of Unit would be greater than 100m²)
4. Additional Revenue Costs for Demountable Building



Site E



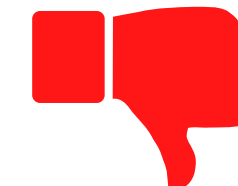
Site E

Site E is located in the adjacent to the Waste Transfer Area. The work would involve constructing a semi-independent modular unit, pre-finished to allow continual Aseptic services.



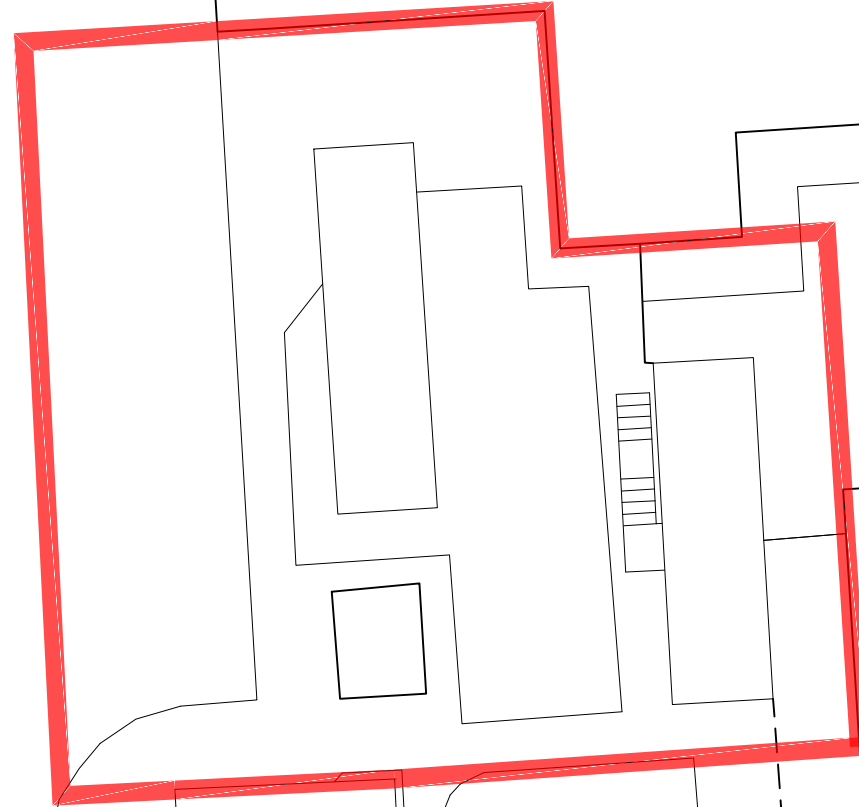
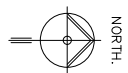
Pro's


1. Large Unit to deliver the a full Aseptic Service
2. Construction related enabling work is very good due to open area, delivery drop off and no disruption to their services

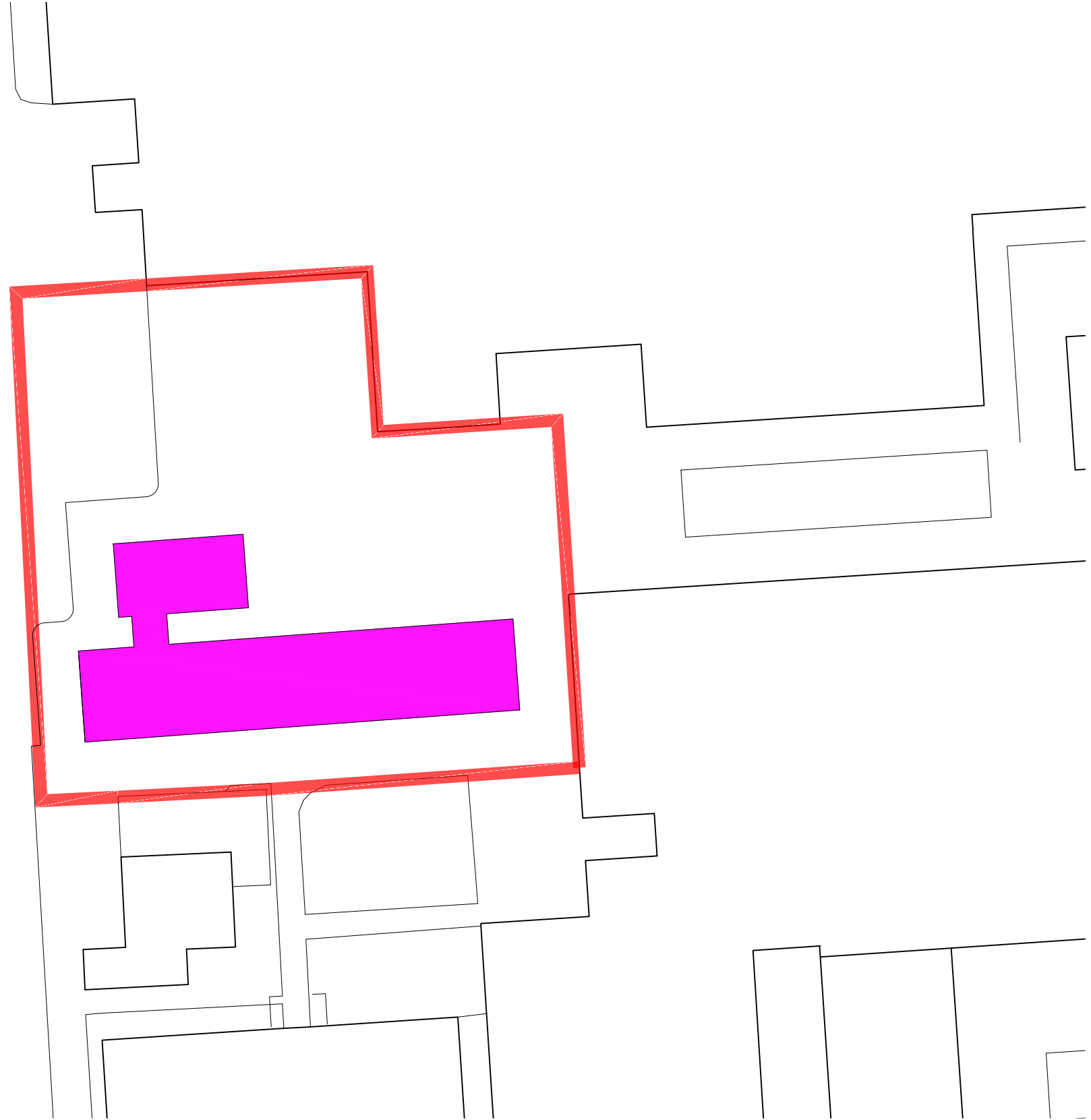
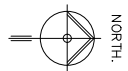



Con's

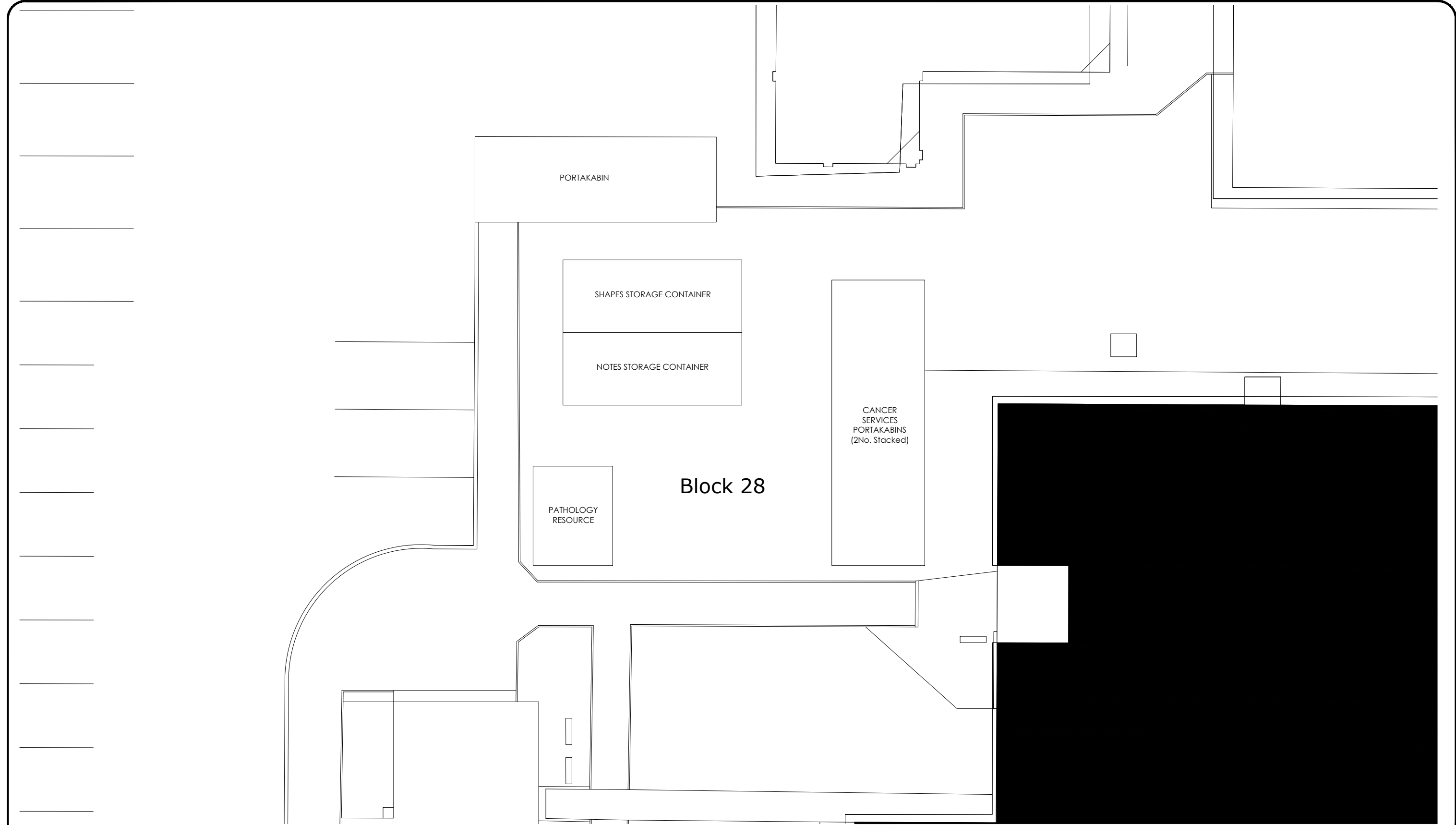
1. Aseptic services product flow - would potentially increase project size.
2. Possible revenue product transfer Implications as some cold storage disconnect with additional requirement for porters
3. MHRA Standards compliance. will be more difficult to achieve (clean down procedures)
4. Product security issues as the building will be semi-independent
5. Planning Permission and SAB Application as the size of Unit would be greater than 100m²
6. Additional construction cost due to building scale
7. Additional Revenue Costs for Demountable Building




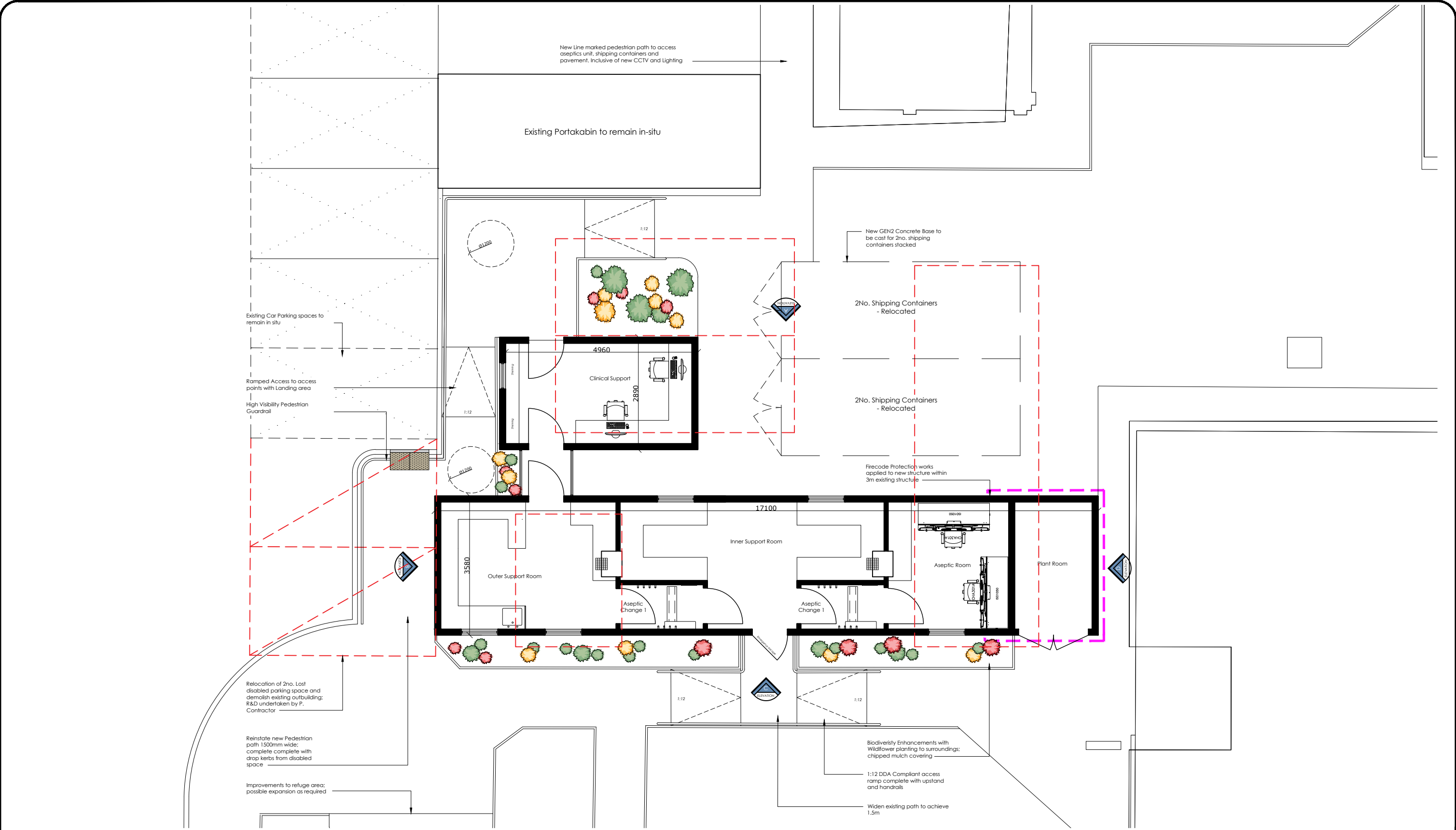
REVISION		DATE	PROJECT		TITLE		<div><div></div><div><div>GIG CYMRU NHS WALES</div><div>Bwrdd Iechyd Prifysgol Hywel Dda University Health Board</div></div></div> <div>A3</div>	
			Withybush General Hospital Haverfordwest SA61 2PZ		Physiotherapy Entrance (Site B) Demountable Option Existing Site Block Plan		DesignTeam.HDD@Wales.NHS.uk	
			DRAWN BY AW	CHECKED BY JWJ	SCALE 1:200 @ A3	DATE 06.09.2022	FILE Ref. 1422-HDD-DD-XX-DR-A-UNI-A002-S03-REVa-EXISTING SITE BLOCK PLAN	




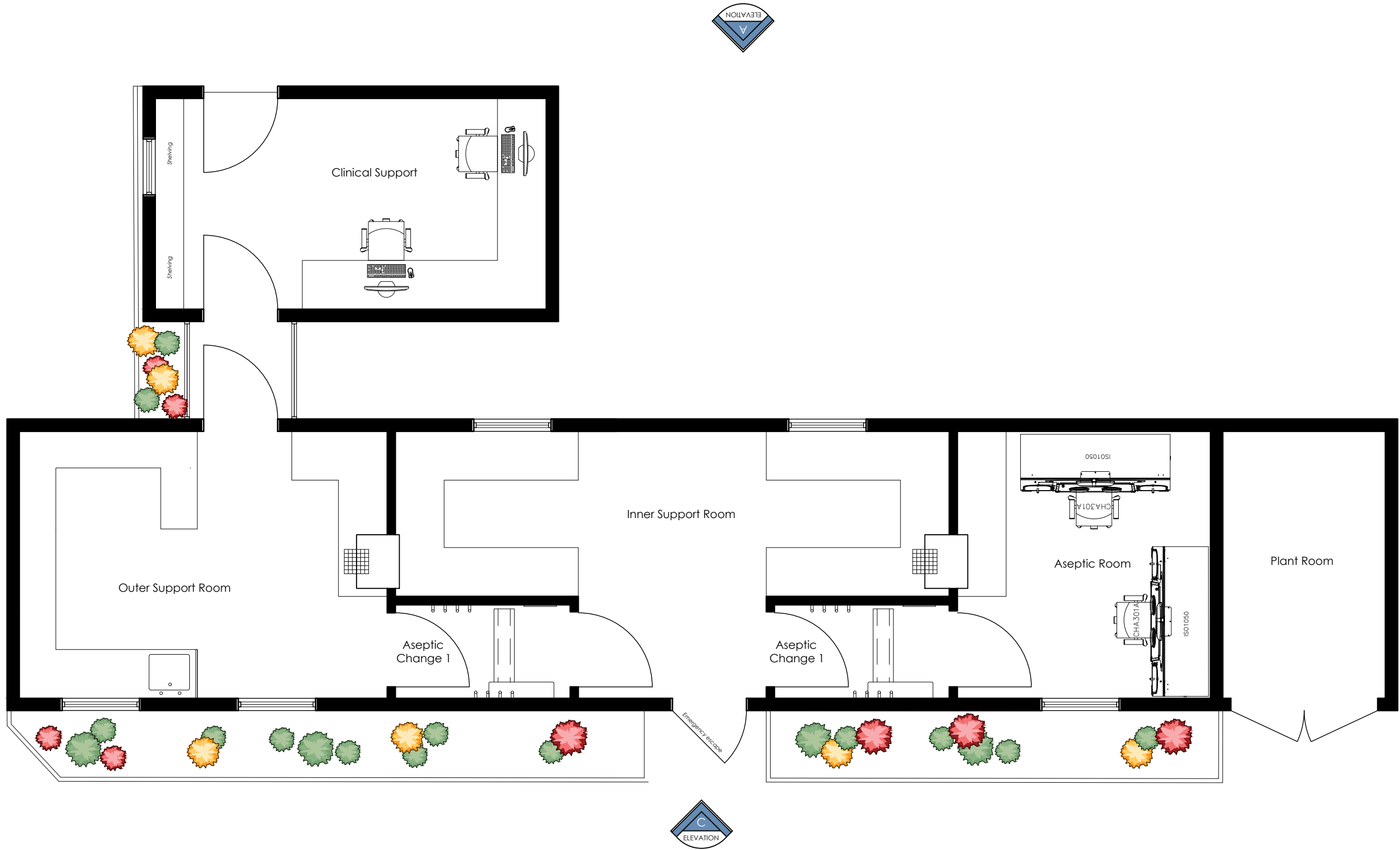
REVISION		DATE	PROJECT		TITLE		<div><div></div><div><div>GIG CYMRU NHS WALES</div><div>Bwrdd Iechyd Prifysgol Hywel Dda University Health Board</div></div></div> <div>A3</div>	
			Withybush General Hospital Haverfordwest SA61 2PZ		Physiotherapy Entrance (Site B) Demountable Option Proposed Site Block Plan		DesignTeam.HDD@Wales.NHS.uk	
			DRAWN BY AW	CHECKED BY JWJ	SCALE 1:200 @ A3	DATE 06.09.2022	FILE Ref. 1422-HDD-DD-XX-DR-A-UNI-A003-S03-REVa-PROPOSED SITE BLOCK PLAN	




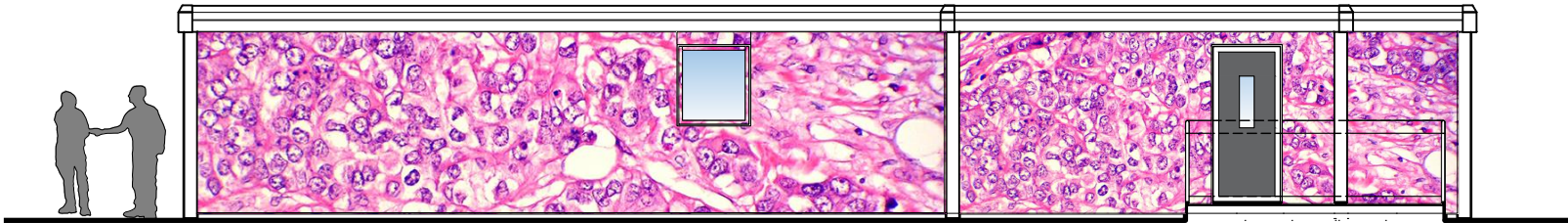
REVISION	DATE	PROJECT	TITLE	A3		
		Withybush General Hospital Haverfordwest SA61 2PZ	Physiotherapy Entrance (Site B) Demountable Option Existing Site Layout	 GIG CYMRU NHS WALES Bwrdd Iechyd Prifysgol Hywel Dda University Health Board		
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						FILE Ref. 1422-HDD-DD-XX-DR-A-UNI-A004-S03-REVa-EXISTING SITE LAYOUT



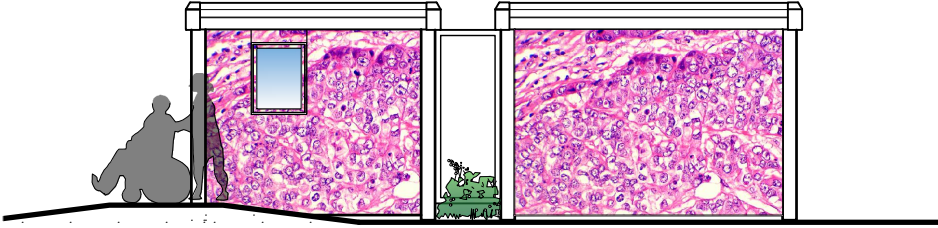
REVISION	DATE		PROJECT		TITLE		A3	
			Withybush General Hospital Haverfordwest SA61 2PZ		Physiotherapy Entrance (Site B) Demountable Option Proposed Site Layout		<div><div></div><div><div>GIG CYMRU NHS WALES</div><div>Bwrdd Iechyd Prifysgol Hywel Dda University Health Board</div></div></div>	
			DRAWN BY AW		CHECKED BY JWJ		SCALE NTS @ A3	DATE 06.09.2022
							FILE Ref. 1422-HDD-DD-XX-DR-A-UNI-A005-S03-REVa-PROPOSED SITE LAYOUT	



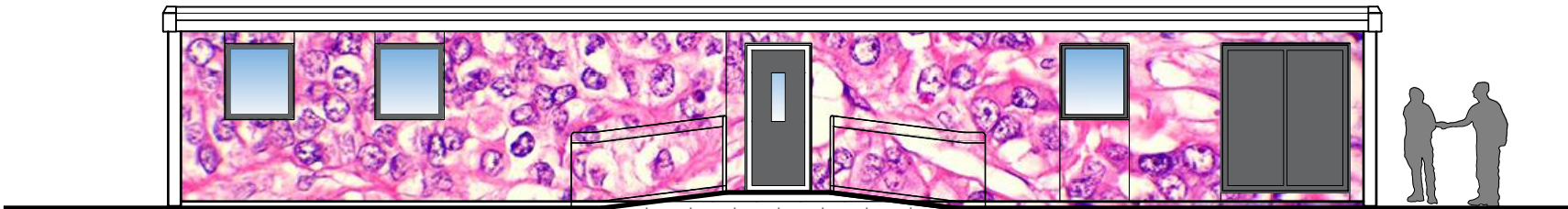
REVISION	DATE		PROJECT		TITLE		A3	
			Withybush General Hospital Haverfordwest SA61 2PZ		Physiotherapy Entrance (Site B) Demountable Option Proposed Floor Plan		<div> <div><div>Bwrdd Iechyd Prifysgol Hywel Dda University Health Board</div></div></div>	
			DRAWN BY AW		CHECKED BY JWJ		SCALE 1:100 @ A3	DATE 06.09.2022
							DesignTeam.HDD@Wales.NHS.uk	
							FILE Ref. 1422-HDD-DD-XX-DR-A-UNI-A101-S03-REVa-PROPOSED FLOOR PLAN	



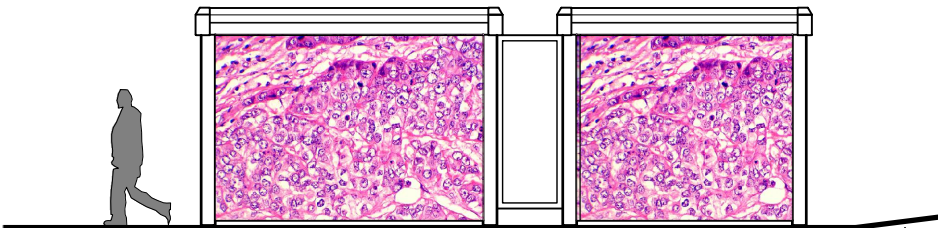
Proposed Elevation A



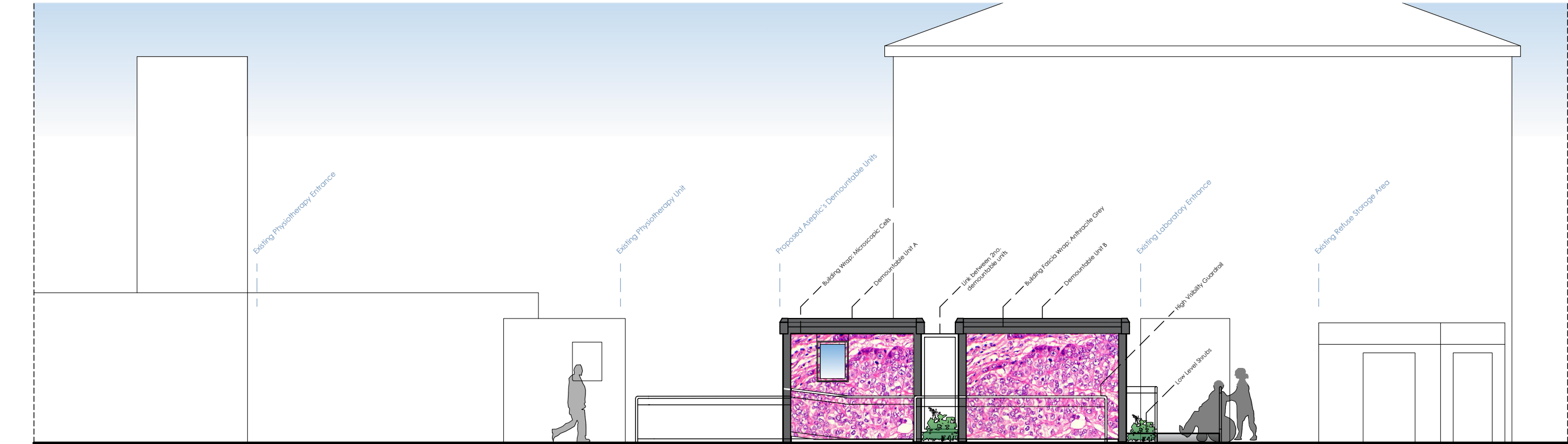
Proposed Elevation B



Proposed Elevation C



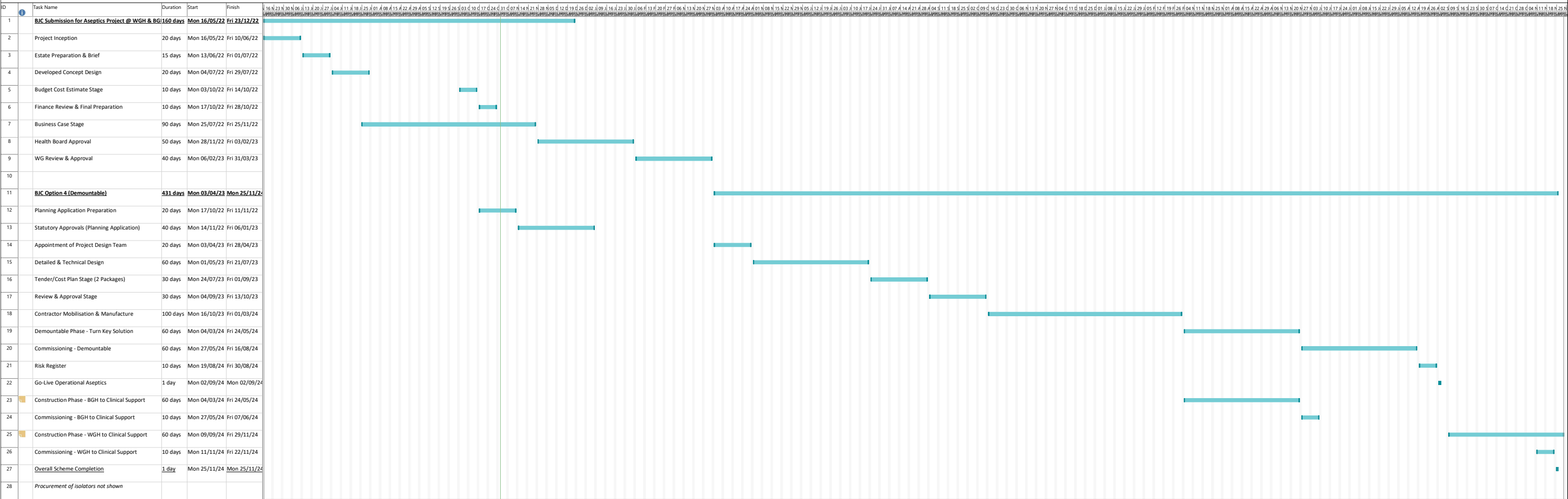
Proposed Elevation D



Street Scene - Elevation B

REVISION	DATE	PROJECT	TITLE	GIG CYMRU NHS WALES Bwrdd Iechyd Prifysgol Hywel Dda University Health Board		
		Withybush General Hospital Haverfordwest SA61 2PZ	Physiotherapy Entrance (Site B) Demountable Option Proposed Elevations	DesignTeam.HDD@Wales.NHS.uk		
		DRAWN BY AW	CHECKED BY JWJ	SCALE 1:100 @ A3	DATE 06.09.2022	FILE Ref. 1422-HDD-DD-XX-DR-A-UNI-A201-S03-REVA-PROPOSED ELEVATIONS

Withybush General Hospital Aseptic Project - Draft Project Programme Option 4



REVENUE COSTS

HB Name: Hywel Dda Health Board
Scheme Name: Aseptic Scheme
Project Stage: BJC

Summary		Capital Cost	Impairment	Additional Dep'n
		Based on BJC		
Option Names:				
Current Costs	N/A			
Fire Precaution Works Withybush	Option 3	3,065,766	2,295,140	55,816
Fire Precaution Works Withybush	Option 4	2,888,477	1,147,822	191,220

Note: Works on existing Hospital sites. No building sales

Aseptic Scheme

18/01/2023

CALCULATION OF CAPITAL CHARGE**Projected Capital Cost MIPS**

	Net	VAT	Gross
Building and Engineering	529,925	105,985	635,910
Fees			0
Planning Contingency	0	0	0
Inflation		0	0
Land			0
Furnishings(Donated)			0
Furnishings(NHS funded)			0
Equipment	171,361	34,272	205,633
Fees	126,413	14,812	141,226
Non Works Cost	1,668,686	333,737	2,002,423
Contingency	79,489	15,898	95,387
Recoverable VAT		(14,812)	-14,812
Total Cost	<u>2,575,874</u>	<u>489,892</u>	<u>3,065,766</u>

Allocation between building structure and engineering costs

	Structure	Engineering	Total
Percentage	60%	40%	100%
Building and Engineering	338,996	225,997	564,993
Fees			0
Total	<u>338,996</u>	<u>225,997</u>	<u>564,993</u>

	Value	Depreciation %	Annual Depreciation	Current Dep'n	Additional Dep'n
Annual Depreciation Costs					
Structure-60 years	338,996		5,650		5,650
Engineering-25 years	225,997		9,040		9,040
Furnishings(Donated) - 10years		10.00%	0		0
Furnishings(NHS)-10years	0	10.00%	0		0
Equipment	205,633	20.00%	41,127	0	41,127
	<u>770,626</u>		<u>55,816</u>		<u>55,816</u>

Impairment Impact

	Total	% Impairment	Impairment
Current Valuation		0	-
Land	0	0.00	-
New Build	731,297	0.23	- 166,303
Refurbishment	0	0.60	-
Fees	<u>2,128,837</u>	1	- 2,128,837
Estimated Impairment Impact	<u>2,860,133</u>		<u>- 2,295,140</u>
Equip	<u>205,633</u>		
	<u>3,065,766</u>		

New Valuation after impairment	564,993
Increase in Balance Sheet	770,626

Aseptic Scheme

CALCULATION OF CAPITAL CHARGE

Projected Capital Cost MIPS

	Net
Building and Engineering	1,471,719
Fees	
Planning Contingency	0
Inflation	
Land	
Furnishings(Donated)	
Furnishings(NHS funded)	
Equipment	142,953
Fees	336,697
Non Works Cost	291,070
Contingency	220,758
Recoverable VAT	
Total Cost	<u>2,463,197</u>

Allocation between building structure and engineering costs

	Structure
Percentage	60%
Building and Engineering	941,467
Fees	
Total	<u>941,467</u>

Value	Depreciation %
-------	-------------------

Annual Depreciation Costs

Structure-10 years (estimated life of demountable)	941,467	
Engineering-10 years (estimated life of demountable)	627,645	
Furnishings(Donated) - 10years		10.00%
Furnishings(NHS)-10years	0	10.00%
Equipment	171,543	20.00%
	<u>1,740,655</u>	

Impairment Impact

	Total	% Impairment
Current Valuation		0
Land	0	0.00
New Build	2,030,973	0.23
Refurbishment	0	0.60
Fees	685,961	1
Estimated Impairment Impact	<u>2,716,934</u>	
Equip	<u>171,543</u>	
	<u>2,888,477</u>	

New Valuation after impairment
Balance Sheet Impact

VAT	Gross
294,344	1,766,063
	0
0	0
0	0
	0
	0
	0
28,591	171,543
33,114	369,811
58,214	349,284
44,152	264,909
(33,134)	-33,134
425,280	2,888,477

Engineering	Total
40%	100%
627,645	1,569,112
	0
627,645	1,569,112

Annual Depreciation	Current Dep'n	Additional Dep'n
94,147		94,147
62,764		62,764
0		0
0		0
34,309	0	34,309
191,220		191,220

Impairment
-
-
- 461,861
-
- 685,961
- 1,147,822

1,569,112
1,740,655

CHECK
- Should = 0

TERMS OF REFERENCE

Aseptic

Project Group

Version	Date	Updated By	Update Detail
v.1	17 05 22	Rachel Stuart Capital Planning Project Manager	Initial Draft – For Approval
v.2	23 06 22	Rachel Stuart Capital Planning Project Manager	Inclusion of project scope, timeframe, options, amendment to membership and structure.
To be completed	Jan 23	Rachel Stuart Capital Planning Project Manager	Membership review and Structure Review



Aseptic Project ToRs



1. Introduction, Objective, Constitution, Scope, Timeframe, Reporting Structure.

Project Introduction:

The Aseptic Project Group was established in the on 23rd June 2022 with plans to develop a small scale capital refurbishment of aseptic facilities to allow the health board to meet the standards set out in the MHRA Good Manufacturing Practice Guidance and the Quality Assurance of Aseptic Preparation Services (QAAPS) standards.

Project Objective:

The aim of the project is to consolidate the Health Board's existing aseptic units to allow safe deliver of medicine, whilst ensuring the logistical provision of the aseptic service for the duration of the project and interim solution until the TrAMS programme of work is completed in SW- Wales.

Project Constitution:

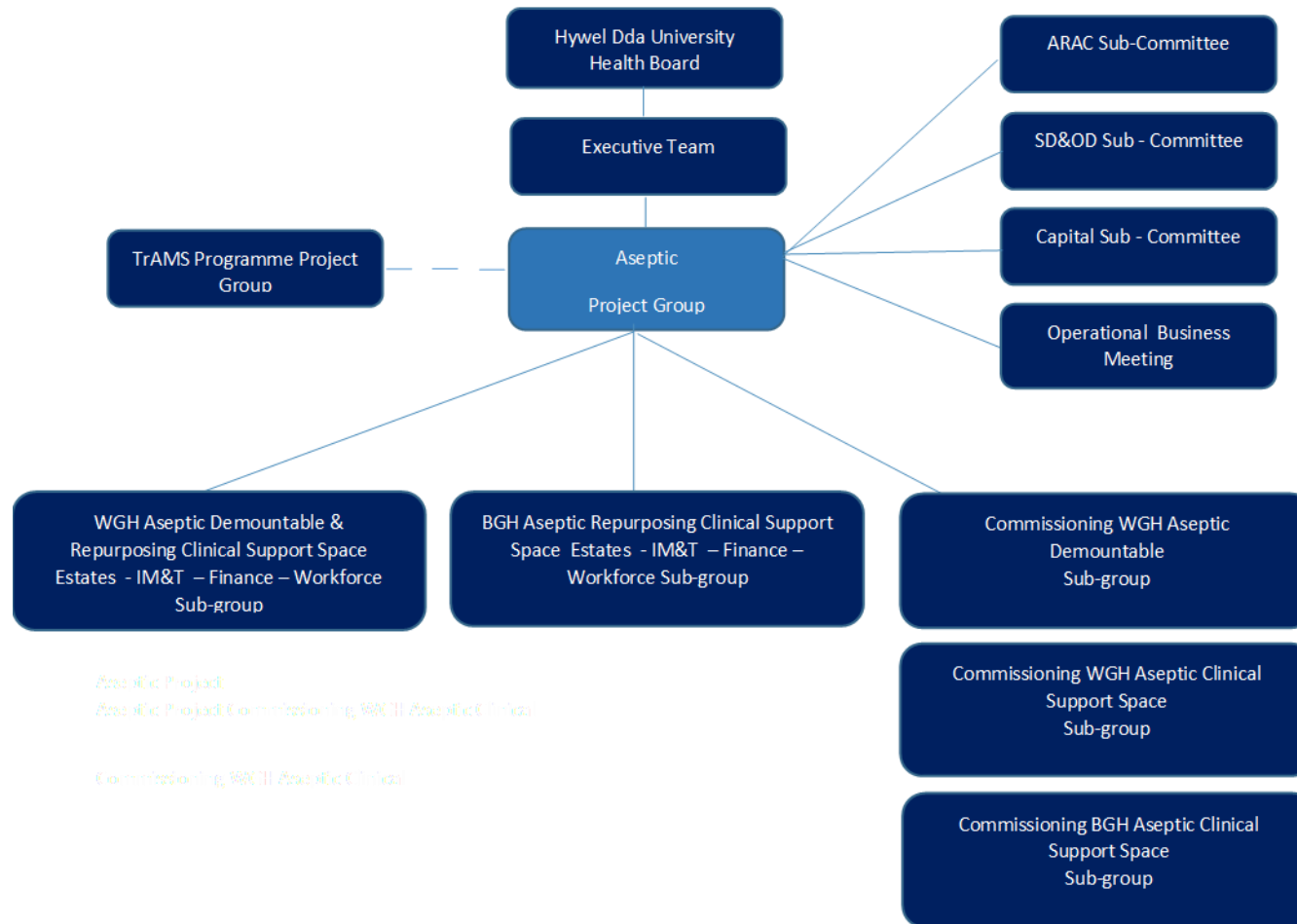
The Project Group operates in line with the principals of the 'NHS Wales Infrastructure Investment Guidance and will provide assurance that all planning and monitoring arrangements are robust to allow the Health Board to manage the successful delivery of the overall project.

Project Scope: Options analysis to be undertaken during the development of the Business Justification Case (BJC). The preferred option is:

- construct a new demountable unit located close to the entrance of the Physiotherapy Unit of Withybush General Hospital (WGH), fire-rated within 3 metres of the main hospital; the unit will consist of two 'Portakabin'-style buildings, a larger one designated for aseptic processes, and the smaller attached unit for clinical support and storage; this design will provide sufficient space for storage and segregation of products; enabling works will need to be undertaken in the form of relocating portakabins which currently house Physiotherapy and two shipping containers, and the demolition of an outbuilding formerly utilised by laboratories;
- refurbish the current aseptic unit at WGH as a cold storage area; and
- decommission the aseptic unit at Bronglais General Hospital (BGH) so that it can be refurbished as clinical pharmacy space.

Project Reporting Structure:

Aseptic Project ToRs



Aseptic Project

Aseptic Project Commissioning WGH Aseptic Clinical

Commissioning BGH Aseptic Clinical



Aseptic Project ToRs



2. Membership

The Senior Responsible Officer (SRO) for the scheme is Jill Paterson, Director of Primary Care, Community & Long Term Care and the Project Director is the Clinical Director of Pharmacy and Medicines Management. A detailed description of the roles of the SRO and PD is provided in Chapter 5.

Members are expected to nominate deputies to attend in instances of unavoidable absence. Deputies must be suitably briefed and have delegated authority to contribute and make decisions and share key messages and delegate tasks as appropriate within departments and wider networks.

The membership of the Project Group is split into two categories:

- Core membership requiring attendance at project meetings.
- Circulation group to keep key internal and external stakeholders informed with attendance at project group meetings as and when required.

Core membership:

Name/s	Designation/s	Role
Jill Paterson	Senior Responsible Officer (Chair)	<p>Defines the project objectives, ensuring that they are met to agreed time, cost and quality constraints;</p> <p>Represents the Health Board in defining what is required and oversees the effectiveness of the project group management team, ensuring the appropriate project management structure is in place to deliver the project objective and that the benefits are realized;</p> <p>Provides a broad specification of what the project should deliver and ensures that any change in circumstance affecting the project is evaluated and appropriate action taken.</p>
Jenny Pugh-Jones	Project Director / Director of Pharmacy and Medicines Management (Vice Chair)	<p>Provide project leadership, management and direction;</p> <p>Act as the lead reporting officer for Board, Committees and Sub-committees;</p> <p>Brief key stakeholders on the projects progress, benefits, risks and financial arrangements</p>

Aseptic Project ToRs

Name/s	Designation/s	Role
		Managing the Health Boards interest in the project, including co-ordination of and the production of the brief for the contractors.
Laura-Jayne Keating	All Wales QA Pharmacist	Provide effective clinical input to the project by providing advice and support to the Project Group on the schedule of accommodation, design, layout, decant arrangements, equipping, commissioning and the additional repurposing of BGH aseptic unit for pharmacy use. Ensure that consistencies and adherence to national standards with current and planned aseptic service provision are adhered to.
Paul Williams	Assistant Director of Strategic Planning	Ensure planning guidance is adhered to. If required to act as a conduit between the Health Board and Welsh Government via Welsh Government Capital Review Meetings.
Matthew Willis Rita Stuart (Rep)	BGH Interim General Manager BGH Service Delivery Manager	Provide effective input into the project by providing advice and support to the Project Group on consistency between BGH plans and overall site/service development.
Janice Cole-Williams Helen Johns (Rep)	WGH General Manager WGH Service Manager	Provide effective input into the project by providing advice and support to the Project Group on consistency between WGH plans and overall site/service development.
Cerith Morgan	Lead Technical Services Pharmacist (clinical lead)	Provide effective clinical input to the project by providing advice and support to the Project Group on the schedule of accommodation, design, layout, decant arrangements, equipping, commissioning and the additional repurposing of BGH aseptic unit for pharmacy use. Ensure that consistencies and adherence to national standards with current and planned aseptic service provision are adhered to.
Stuart Rees	PPH Clinical Lead Pharmacy (patient services lead)	Provide effective clinical input to the project by providing advice and support to the Project Group on the schedule of accommodation, design, layout, decant arrangements, equipping, commissioning and the additional repurposing of BGH aseptic unit for pharmacy use.

Aseptic Project ToRs

Name/s	Designation/s	Role
		Ensure that consistencies and adherence to national standards with current and planned aseptic service provision are adhered to.
Bleddyn Edwards	Lead Cancer Pharmacist	<p>Provide effective clinical input to the project by providing advice and support to the Project Group on the schedule of accommodation, design, layout, decant arrangements, equipping, commissioning and the additional repurposing of BGH aseptic unit for pharmacy use.</p> <p>Ensure that consistencies and adherence to national standards with current and planned aseptic service provision are adhered to.</p>
Jegadish Mathias	Clinical Lead Cancer Aseptic Services	<p>Provide effective clinical input to the project by providing advice and support to the Project Group on the schedule of accommodation, design, layout, decant arrangements, equipping, commissioning and the additional repurposing of BGH aseptic unit for pharmacy use.</p> <p>Ensure Cancer services guidance is adhered to regarding implementation.</p> <p>Ensure that consistencies and adherence to national standards with current and planned aseptic service provision are adhered to.</p>
Gina Beard	Lead Cancer Nurse	<p>Provide effective clinical input to the project by providing advice and support to the Project Group on the schedule of accommodation, design, layout, decant arrangements, equipping, commissioning and the additional repurposing of BGH aseptic unit for pharmacy use.</p> <p>Ensure Cancer services guidance is adhered to regarding implementation.</p> <p>Ensure that consistencies and adherence to national standards with current and planned aseptic service provision are adhered to.</p>
Donna Robson	BGH Pharmacy Site Manager	Provide effective clinical input to the project by providing advice and support to the Project Group on the schedule of accommodation, design, layout, decant arrangements,

Aseptic Project ToRs

Name/s	Designation/s	Role
		<p>equipping, commissioning and the additional repurposing of BGH aseptic unit for pharmacy use.</p> <p>Ensure consistency between plans and overall site/service development.</p> <p>Ensure that consistencies and adherence to national standards with current and planned aseptic service provision are adhered to.</p>
Dave Morgan	WGH Pharmacy Site Manager	<p>Provide effective clinical input to the project by providing advice and support to the Project Group on the schedule of accommodation, design, layout, decant arrangements, equipping, commissioning and the additional repurposing of BGH aseptic unit for pharmacy use.</p> <p>Ensure consistency between plans and overall site/service development.</p> <p>Ensure that consistencies and adherence to national standards with current and planned aseptic service provision are adhered to.</p>
Mel Jenkins Tracey Nicholas	Senior Infection Prevention Nurse Senior Infection Prevention Nurse WGH/BGH	Provide professional infection control input into all relevant aspects of the project.
Julian Wheeler-Jones Ashley Wood	Discretionary Capital Projects Manager Architectural Projects Officer	<p>Project architect and estates design lead;</p> <p>Preparation of the schedule of accommodation and Development Approval Form;</p> <p>Co-ordination of tender and contracting processes;</p> <p>Liaise between the contractor and the Project Group on technical matters and progress reports;</p> <p>Production and monitoring of the Project Execution Plan (estates implementation);</p>

Aseptic Project ToRs

Name/s	Designation/s	Role
		Provide leadership and support on estates matters relating to the decant and repurposing of BGH Aseptics for pharmacy use, ensuring alignment to the overall project plan.
Rachel Stuart	Capital Planning Project Manager	Co-ordinate the planning process, including facilitation of governance arrangements; business justification case; project execution plan; project risk register, issues register, decisions escalation register, capital highlight reports; equality impact assessment; reports to Committee/Board as required. Servicing meeting support.
Maggie Annison Sally Moses (Rep)	Facilities Information and Capital Management Capital Administrative Officer	Provide advice and support to the Project Group on equipping and commissioning for the project to including supporting aseptic services in the decant to BGH and the subsequent repurposing of BGH aseptic unit for pharmacy use; Establish relevant mechanisms to undertake the equipping necessary for the project; Liaise between the relevant services and Project Group to prepare a costed equipping schedule and co-ordinate the procurement as appropriate; Advise on room layouts and interior décor; Liaison between the services and IT to ensure effective communications are in place.
Paul Solloway	Deputy Digital Director	To lead on providing Information Management & Technology advice and support to the Project Group; To work closely with aseptic services and estates design lead.
Chris Hopkins Jan Bojanowski (rep)	Head of Clinical Engineering Agency Technologist	To lead on providing clinical engineering advice and support to the Project Group; To work closely with aseptic services and estates design lead.
Simon Chiffi Simon Day	Head of Estates Operations Head of Maintenance & Engineering	To provide estate operations support and advice to the project group.
Elfyn Jones	BGH Site Operations Manager	To lead on providing site operations advice and support to the Project Group;

Aseptic Project ToRs

Name/s	Designation/s	Role
Duncan Evans	WGH Site Operations Manager	To work closely with aseptic services and estates design lead.
Alun James Samantha Pennington	Head of Procurement NWSSP Deputy Hd of Sourcing Projects & Capital	To lead on providing stores management advice and support to the Project Group; To work closely with aseptic services and estates design lead.
Sarah Welsby Carwen Jarmen	Business Partner Planning & Major Projects Senior Finance Business Partner Scheduled Care	Provide finance advice and support to the Project Group; Monitor project finance stream, providing financial report updates to the Project Group; Provide finance support and input to the group relating to the temporary aseptic decant and the subsequent repurposing of BGH aseptic unit for pharmacy use; Preparing the financial case and monitoring project finances; Ensuring robust capital and revenue budgets; Reporting financial status to the Project Group and Welsh Government (as appropriate).
Elizabeth Merriman Shelly Dony	Assistant Head of Workforce Workforce Planning Project Manager	Provide leadership, direction and support to the Project Group on workforce planning.

Circulation Group:

Name/s	Designation/s	Role
Tom Sherman	Transforming Access to Medicines Service (TrAMS) Project Manager for SW Wales TRAMS Hub	Alignment to the TrAMS Programme of work.
Colin Powell	Transforming Access to Medicines Service (TrAMS) Service Director	Alignment to the TrAMS Programme of work.

Aseptic Project ToRs

As part of the BJC approval process the following members will be include in the circulation as necessary:

Name/s	Designation/s	Role
Sarah Perry	GGH General Manager	Consistency between plans and overall site/service development.
Stuart Bancroft	PPH General Manager	Consistency between plans and overall site/service development.
Debra Bennett	Cancer Services Service Delivery Manager	Ensure cancer guidance is adhered to regarding implementation.
Dylan Jones	Pathology Service Manager lead	Ensure cancer guidance is adhered to regarding implementation.
Elin Jones	Consultant Oncology	Ensure cancer guidance is adhered to regarding implementation.
Keith Jones	Director of Hospitals	Ensure cancer guidance is adhered to regarding implementation.
Rob Elliott	Director of Estates, Facilities and Capital Management	Ensure estate guidance is adhered to regarding implementation.
Lisa Humphrey	Interim General Manager Cancer Services	Ensure cancer services guidance is adhered to regarding implementation.
TBD	Community Health Council Representative	To undertake a scrutiny and advocacy role. Advise and support to the Project Group, providing an independent voice for people who use NHS services.

Sub-group Key Stakeholders: Addition members to be included following sub-group establishment as the project progresses:

Name/s	Designation/s	Role
Tim Harrison	Head of Health & Safety	To lead on providing Health & Safety advice and support to the Project Group;

Aseptic Project ToRs

Name/s	Designation/s	Role
		To work closely with aseptic services and estates design lead.
Daniel Dyer	Fire Safety Advisor WGH	To lead on providing fire safety advice and support to the Project Group;
		To work closely with aseptic services and estates design lead.
Sundeep Sehpal	Project Communications Manager	Provide communications leadership, direction and support to the Project Group and update the communications and engagement plan as appropriate.
Delyth Evans	Project Engagement Manager	Provide engagement leadership, direction and support to the Project Group and update the communications and engagement plan as appropriate.

3. Quoracy and Attendance

The membership of the Project Group shall be determined by the SRO and PD. A quorum shall consist of as a minimum the SRO/PD or delegated deputies and 1/3 membership. Should any member be unavailable to attend, they may appoint a fully briefed deputy who will have delegated authority to act on their behalf.

4. Principal Duties

- To ensure the project plans are aligned to the TrAMS Programme of work.
- To ensure that the logistical delivery of products are maintained as BAU throughout the project lifecycle.
- To ensure the workforce are kept engaged and informed and that any issues are raised with the Workforce lead and Project Director.
- To agree the services estate model solution for the interim period as per the project plan whilst awaiting the delivery of the TrAMS programme of work.
- To ensure that all activity is managed and monitored to ensure the safe, efficient and effective delivery of aseptic services, to include the decant and commissioning stages.
- To ensure all governance processes are in place to include the management of risks, issues, decisions, emerging opportunities and constraints.
- To ensure highlight reports are submitted to the Capital Sub Committee on a bi-monthly basis drawing specific attention to any significant matter under consideration by the projects sub-groups.
- Ensure appropriate escalation arrangements are in place to alert the Project Director/SRO of any urgent/critical matters that may compromise patient care or reputation of the Health Board.
- To manage and oversee the development Equality Impact Assessment.
- To agree and establish various sub-groups to oversee the implementation of the project.



Aseptic Project ToRs

- To formally carry out a Post Project Evaluation within one year of the service being operational to assess whether it has achieved its spending objectives and report the findings to the Capital Sub Committee.

Agenda, Papers, Frequency of Meetings.

There is no secretarial support for this project, the Capital Planning Project Manager will:

- Draft agendas in collaboration with the Project Director.
- The Project Group meeting will be held monthly for 1.5 hours. Additional meetings will be arranged as determined by the Project Director (Chair).
- Meetings will be held via Microsoft Teams unless otherwise required and agreed with the PD. Microsoft Teams protocols to be followed.
- Responsible for circulating papers three working days in advance of the meeting.
- Service the meeting and circulate minutes and action notes approved by the Project Director within 7 working days.
- Members must forward amendments to the Capital Planning PM within seven days.
- Meetings will be held monthly and reviewed periodically.

Standing Items to include:

- Status summary – Highlight Report to include project key deliverables / milestones in the Project Plan.
- Project Risk Register
- Project Issues Register
- Project Decisions Register
- Project Finance Report

5. Reporting, Accountability, Authority, Review

- The Project Group shall be accountable to the SRO and Project Director.
- The Project Group shall embed the Health Board's vision, standards, priorities and requirements, e.g. equality and human rights, through the conduct of its business.
- The Chair will report back into the Capital Sub-Committee on Project Groups activity, decisions, risks and issues.
- The Project Group shall contribute to the integration of good governance across the organisation, ensuring that all sources of assurance are incorporated into the Board's overall risk and assurance framework.
- Any urgent matters that may compromise patient care, affect the operation of the service and/or the reputation of the Health Board will be escalated to the SRO for the project via the Project Director.



Aseptic Project ToRs

- The Project Group will establish sub-groups or task and finish groups to carry out specific aspects of project business. The Project Group will receive written update reports following each meeting which details the business undertaken on its behalf.
- These Terms of Reference will be reviewed on a quarterly basis.

Senior Responsible Owner Shall:

- Defines the project objectives, ensuring that they are met to agreed time, cost and quality constraints;
- Represents the University Health Board in defining what is required and oversees the effectiveness of the project management team, ensuring the appropriate project management structure is in place to deliver the project objective and that the benefits are realized;
- Provides a broad specification of what the project should deliver and ensures that any change in circumstance affecting the project is evaluated and appropriate action taken.
- Report formally to Sub Committees on the Project Group's activities and progress.
- Ensure appropriate escalation arrangements are in place to alert the Health Board Chair, Chief Executive or Chairs of other relevant Committee of any urgent/critical matters that may compromise patient care and affect the operation and/or reputation of the Health Board.

The Project Director Shall:

- Responsible for project management;
- Managing the Health Boards interest in the project, including co-ordination of and the production of the brief for the contractors;
- Selecting and appointing consultants and contractors who will undertake the design and construction activity and ensuring they deliver according to the construction project programme;
- Acting as the point of contact in all dealings with contractors and other external organisations involved in the project and providing all decisions and directions on behalf of the University Health Board.

6. Links to Other Established Groups

TrAMS Programme Group. The Project Group will provide a project status highlight report as required.

Capital Sub-committee. Highlight reports on a bi-monthly basis.

Strategic Development and Operational Delivery Committee. As and when required.

HDdUHB – As and when require.

Integrated Assurance & Approval Plan

Name of Project	Aseptics		
Version Number	DRAFT - 1.0	Last Updated	01/11/2022
SRO Name	Jill Paterson		
Project Manager	Rachel Stuart	Project Director	Jenny Pugh-Jones
RPA - date submitted to IAH	01/02/2022	RPA - Outcome	Low
WG Major Portfolio/Programme/Project	Yes	IAH Ref	

Guidance

The Integrated Assurance and Approvals Plan (IAAP) sets out the assurance activities that will be undertaken at portfolio, programme and project level.

As part of the IAAP, assurance activities will take place across all levels of the Programme – programme and project. The Programme will utilise the pre-defined Gateway 0-5 and flexible Assurance Products (PAR, PVR, Critical Friend) as appropriate and proportionate.

The IAAP has been developed using a risk-based approach to ensure that the assurance provision is both proportionate and meets the needs of all those parties requiring assurance. It takes into account Portfolio/Programme/Project milestones and planned assurance activities. The Programme IAAP takes into account the assurance coverage of its constituent Projects.

1st Line Defence/Assurance will be provided by the Portfolio/Programme/Project itself through its Governance.

2nd Line Defence/Assurance refers to independent assurance such as Gateway Assurance.

3rd Line Defence/Assurance refers to scrutiny provided by 'external' organisations such as Audit.

This IAAP has been developed in line with the WG Integrated Assurance Strategy and is a live document. It will be periodically reviewed and updated and if appropriate, after each assurance review, change in scope, or risk potential of the Programme/Project. The IAAP will be maintained until the Programme/Project is closed and delivery responsibility passes to the operational business.

The milestones for governance, assurance and audit activity are based upon timescales included within the Current Portfolio and Programme Implementation Plans and will be updated should timetables change.

The Welsh Government Integrated Assurance Hub (IAH) have provided support in the completion of the IAAP and tailoring it to suit the specific needs of the Programme.

Glossary

AB - Accountable Body
 IA - Internal Audit
 IAH - Integrated Assurance Hub
 JC - Joint Committee
 JSC - Joint Scrutiny Committee
 LAs - Local Authorities
 NAO - National Audit Office
 OGC - Gateway (0 to 5)
 PAC - Public Accounts Committee
 PAR - Programme/Project Assessment Review
 PB - Programme Board
 PMO - Programme Management Office
 PVR - Programme/Project Validation Review
 RPA - Risk Potential Assessment
 SRO - Senior Responsible Owner
 WAO - Wales Audit Office



GIG
CYMRU
NHS
WALES

Bwrdd Iechyd Prifysgol
Hywel Dda
University Health Board

Canolbarth a Gorllewin Iachach

Cenedlaethau'r
dyfodol yn byw
bywydau iach



Risk Potential Assessment Form (RPA)

Asepsis Project



Llywodraeth Cymru
Welsh Government

Welsh Government Integrated Assurance

Risk Potential Assessment Form (RPA)

(IAH-RPA)

Version 2 – April 2022

April 2022

INTRODUCTION

About OGC Gateway™:

Programmes and projects provide an important vehicle for the efficient and timely delivery of government aims. Good and effective management and control of programmes and projects is therefore essential to the successful delivery of government objectives. The Welsh Government Assurance Process (consistent with the OGC Gateway) is the responsibility of the Integrated Assurance Hub (IAH) and authorised to deliver assurance under accredited licence from the Infrastructure and Projects Authority (IPA), which is part of the UK's Cabinet Office. This process is designed to provide independent guidance to Senior Responsible Owners (SROs), programme and project teams and to the departments who commission their work, on how best to ensure that their programmes and projects are successful

The OGC Gateway Process examines programmes and projects at 'key decision points' in their lifecycle, and looks ahead to provide assurance that they can progress successfully to the next stage. The OGC Gateway Process is regarded as best practice in central civil government throughout the UK, and applicable to a wide range of programmes and projects, including:

- policy development and implementation
- organisational change and other change initiatives
- acquisition programmes and projects
- property/construction developments
- IT-enabled business change
- procurements using or establishing framework arrangements.

Value of the OGC Gateway Process

OGC Gateway Reviews deliver a 'peer review', in which independent practitioners from outside the programme/project use their experience and expertise to examine the progress and likelihood of successful delivery of the programme or project. They are used to provide a valuable additional perspective on the issues facing the programme/project team, an external challenge to the robustness of plans and processes, and support to SROs in the discharge of their responsibilities to achieve their business aims, by helping to ensure:

- the best available skills and experience are deployed on the programme/project
- all the stakeholders covered by the programme/project fully understand the programme/project status and the issues involved
- there is assurance that the programme/project can progress to the next stage of development or implementation and is well managed in order to provide value for money on a whole life basis
- achievement of more realistic time and cost targets for programmes and projects
- improvement of knowledge and skills among government staff through participation in Reviews
- provision of advice and guidance to programme and project teams by fellow practitioners.

The Welsh Government's Risk Potential Assessment Form (IAH-RPA) is designed to provide a standard set of high-level criteria for assessing the **risk potential** of a programme/project in a strategic context.

The RPA enables a conversation to be had about the risks and responsibilities that the SRO has for delivery and that the programme/project in respect of visibility, reporting and assurance in a wider portfolio management context. The RPA can also help the programme/project to identify areas where specific skills sets, commensurate with the level of complexity, may be required.

The OGC Gateway Process offers an independent assurance for all potential high and medium risk programmes/projects within Welsh Government and Wider Welsh public sector. In order to determine the applicability of an OGC Gateway Review, the RPA **must** be completed by the SRO for the programme/project.

The RPA form is in five sections :

- Section 1 - (Programme/Project General Information) – gathers some basic information about the programme/project
- Section 2 - gathers a brief synopsis of the programme/project, its key objectives and the stage of the programme/project at the current time. This will provide context for the assessment by the IAH.
- Section 3 - is designed to build on information provided in Section 2, by capturing a standard set of high-level criteria for further assessing the **risk potential** of a proposed programme/project. This section is also used to determine if an Assessment Meeting with the SRO is appropriate to discuss whether an OGC Gateway Assurance might be of value to the programme/project. At the end of each question within this section the SRO is required to make a self assessment of the level of risk the programme/project carries. Further information and an explanatory note is required to support the self assessment.
- Section 4 – The SRO is required to provide an overall self assessment of the level of risk the programme/project is at.
- Section 5 – SRO sign off for the RPA form.

Completed forms must be sent directly for assessment to the Integrated Assurance Hub (IAH) Mailbox Assurance@gov.wales

SECTION 1 :	Programme/Project General Information
1. Is this a Portfolio/Programme or Project?	Project
2. Programme/Project name	Aseptics .
3. Your Division/Department	Capital Planning
4. Programme/Project Type	Capital Construction
5. SRO Contact Details (to include telephone number, mobile number and e-mail address)	Jill Paterson, Director of Primary Care, Community & Long Term Care Jill.Paterson@wales.nhs.uk
6. Programme/Project Manager details (to include telephone number, mobile number and e-mail address)	Jenny Pugh Jones Hywel Dda University Health Board Clinical Director of Pharmacy and Medicines Management. Jenny.Pugh-Jones@wales.nhs.uk
7. Primary contact point for administration of the OGC Gateway™ Review (to include telephone number, mobile number and e-mail address)	Eldeg Rosser Head of Capital Planning Hywel Dda university Health Board Eldeg.Rosser@wales.nhs.uk 07813769310
8. Finance Officer details: Review (to include telephone number, mobile number and e-mail address) <i>(N.B. review costs will initially be met by the Integrated Assurance Hub but will be recouped via journal at the end of the review)</i>	Sarah Welsby Business Partner, Planning and Major Projects Hywel Dda University Health Board Sarah.Welsby@wales.nhs.uk 01267283036
9. Date of previous Gateway Review if applicable – <i>please include previous Gateway Product & IAH unique number).</i>	Click here to enter a date. Choose an item.
10. Does the Programme/Project have an Integrated Assurance and Approvals Plan?	Yes

SECTION 2 : PROGRAMME / PROJECT DETAILS

Please provide a brief synopsis of the programme/project, the key objectives and at which stage the programme/project is currently at:

Following the closure of the aseptic suite at Glangwili General Hospital (GGH) and highly critical condition of the remaining facilities, the health board has been forced to outsource a significant proportion of aseptic products to provide the service and mitigate patient risk. This has come at a significant revenue cost to the health board. Therefore, given the high risk status of the remaining two 'Highly Critical' units, to avoid further disruption to patient care and significant financial pressures in an already fragile market place, the health board must pursue a local solution to address the short comings of the existing facilities. The current and short-term position indicates that there is, and will continue to be, insufficient capacity and resilience within the aseptic production services across Wales to support the needs of Hywel Dda patients until the TrAMS hubs are fully operational.

The TrAMS hub in the SW Wales is unlikely to be operational until the Autumn of 2028 at the earliest, notwithstanding the uncertainties in relation to MHRA licensing and workforce challenges. The proposed timelines for completion of TrAMS therefore far exceeds the projected life span of the current facilities within the health board. Consequently, a health board position to await the outcome of the TrAMS would leave the local patient population at an unacceptable risk. This position is supported by the National Quality Assurance Lead for Wales and the Leadership within NWSSP responsible for implementation of Trams on behalf of the Health Boards/Trust. This interim medium term solution is fully aligned to the National strategic direction set out in the TrAMS PBC.

Spending objectives:

	Driver	Spending Objective	Specific	Measurable	Achievable	Realistic	Time-bound
1	Effectiveness	Reduce the risk of negative impacts on patient care by providing a safe, sustainable aseptic service solution until services can be transferred to facilities to be provided under the TrAMS Programme.	✓	✓	✓	✓	✓
2	Efficiency	Consolidate aseptic services on one site to enable the early closure of the BGH aseptic unit, to provide efficiencies in service delivery and estate usage.	✓	✓	✓	✓	✓
3	Economy	Minimise the risk of negative financial impacts.	✓	✓	✓	✓	✓
4	Compliance	Put in place a new unit which will be MHRA licensed and comply with QAAP standards and latest building guidelines.	✓	✓	✓	✓	✓

5	Replacement	Replace outdated equipment where possible to maximise the efficiency and compliance of the unit until the South West Hub becomes operational under the TrAMS Programme	✓	✓	✓	✓	✓
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The project is at the Business Justification Case stage to seek approval for Hywel Dda University Health Board (HDUHB

or the University Health Board) to:

- Construct a new demountable unit located at the entrance with the Physiotherapy Unit of Withybush General Hospital (WGH) to house aseptic production and a cold room with the necessary equipment; the unit will be in an L-shaped configuration and will provide a total of 17.1m x 3.58m plus an additional 3.45m x 5.62m; this design will provide sufficient space for storage and segregation of products;
- Refurbish the current aseptic unit at WGH as a cold storage area; and
- Decommission the Aseptics unit at Bronglais General Hospital (BGH), so that it can be refurbished as clinical pharmacy space.

SECTION 3 : GUIDANCE

Section 3 of the RPA assesses the potential risk for the programmes/project. The overall RPA assessment process at this point is an **indicator** of risk potential and is not an exhaustive risk analysis model. However, it can be the starting point for a more exhaustive risk assessment of a programme/project.

This section is made up of a series of five key short assessments, which will determine the basic and initial risk rating of the programme/project. These assessments are made using the knowledge and judgement of the SRO and programme/project team and should be considered in the light of a programme/project's strategic context. Each question requires an answer using the drop down boxes, a self assessment of the level of risk and a short explanatory note of the reasoning for the self assessment mark. This will provide further detail for the IAH and an audit trail of the considerations.

After completion, the SRO should e-mail the RPA Form directly to the IAH for initial assessment. The IAH will then formally write to the SRO to notify them of the outcome.

The initial assessment will normally be used throughout the life of the OGC Gateway Review process. However, and even though the score might decline during the programme/project lifecycle, should the programme/project's risk assessment increase, the higher assessment may take precedent.

If you have further questions about the use or completion of this section, please contact the Integrated Assurance Hub on 0300 025 0149 or 0300 025 3901 or you can e-mail us on Assurance@gov.wales

SECTION 3.1 Strategic Alignment & Commitment

3.1.1: Does the programme/project satisfy a ministerial commitment?	Yes
If YES, please state who is the responsible minister(s)	Project aligns with the National Transforming Access to Medicines programme (TrAMS) Eluned Morgan
3.1.2: Does the programme/project cut across ministerial portfolios	No
3.1.3: Does the programme/project satisfy a major policy commitment?	Yes
If YES, Which policy?	

	Pharmacy: Delivering a Healthier Wales and aligns to Future Generations	
3.1.4: Does the Programme/Project impact Key Organisational Objectives?	Critical link to delivery of key strategic objectives /targets	
3.1.5: Does the Programme/Project impact Business Change?	Low impact	
Strategic Alignment & Commitment – Self assessed risk rating	Medium	
Further information & explanatory note: Following the closure of the Aseptic suite at GGH and highly critical condition of the remaining facilities, HDUHB has been forced to outsource a significant proportion of aseptic products to mitigate patient risk at significant cost. Therefore, HDUHB, must pursue a local solution for the replacement of aseptic facilities to allow regulatory compliance and provision of safe medicines. This is fully aligned to the National strategic direction set out in the TrAMS PBC.		

SECTION 3.2: Financial/funding impact	
3.2.1: How much is the projected budget for the programme/project? <i>N.B. when completing this part of the form, please take into account the whole-life costs of the programme/project (as defined by HM Treasury Green Book)</i>	£1M - £5M
3.2.2: How long is the programme/project expected to run?	Over 2 Years
3.2.3: Is funding secured and in place for the entire lifecycle of the programme/project?	No
3.2.4: Does the programme/project receive external funding?	Yes - Capital Revenue
3.2.5: How is the Programme/Project budget managed?	Budget within delegations and local control
Financial/Funding Impact – Self assessed risk rating	Low

Further information & explanatory note:

Project requires All Wales capital investment which will be via submission of a Business Justification Case.

SECTION 3.3 Stakeholder Engagement

3.3.1: Has the Programme/Project identified all stakeholders?	Yes - All stakeholders identified and engaged
3.3.2: How complex is stakeholder management?	several stakeholders across organisations
3.3.3: Impact on resources	resources yet to be identified
3.3.4: How many staff within the organisation will be affected by the programme/project?	10-25
3.3.5: Impact on Public	No impact
Stakeholder Engagement – Self Assessed Risk Rating	Low
Further information & explanatory note:	

SECTION 3.4 Governance

3.4.1: Has the programme/project undertaken a scoping exercise to ensure there is no duplication of work in any other part of the organisation?	Yes
3.4.2: Are the Programme/Project Governance arrangements in place?	Yes
3.4.3: Are the Programme/Projects Time & Quality Targets Achievable?	Yes
3.4.4: Has the Programmes/Projects benefits been identified?	Yes
3.4.5: Has the programme/project considered and implemented security standards in compliance with regulatory Acts e.g. GDPR?	Yes
3.4.6: Governance – Self Assessed Risk Rating	Low

Further information & explanatory note:
No further comments

SECTION 3.5 Programme/Project Dependencies

3.5.1: Is the Programme or Project dependant on or connected to wider initiatives?	standalone programme/project with no dependency
3.5.2: Does the programme/project depend on key components, consent or approvals which are outside the organisations direct control?	key component of programme/project objective requires consent or approval from external organisation
3.5.3: Does the programme/project key objective require new IT systems and/or the need to develop interfaces with existing IT systems?	No IT dependency
3.5.4: How complex are the commissioning/procurement arrangements for the programme/project	Single supplier required from existing commissioning/procurement framework
Programme/Project Dependencies – Self Assessed Risk Rating	Low

Further information & explanatory note:

The project is dependant on All Wales capital funding and is aligned to TrAMS in terms of achieving additional service sustainability.

Section 4: Programme/Project overall self assessment risk rating

Low

Section 5: SRO ENDORSEMENT

I am satisfied that the Risk Potential Assessment provides an accurate reflection of the programme/project at this stage of development.

Signed: Jill Paterson, Director of Primary Care, Community and Long Term Care
(Senior Responsible Owner)

Date 18/10/2022



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I will re-asses the programme/project if there is a significant change to the programme/project scope or budget or if significant changes emerge that may threaten successful delivery.

Signed: Jill Paterson, Director of Primary Care, Community and Long Term Care
(Senior Responsible Owner)



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