

Haematology Inpatients at University Hospital Wales (UHW)

Strategic Outline Case: Executive Summary

June 2026 – Final v8

TABLE OF CONTENTS

1.0	EXECUTIVE SUMMARY	5
1.1	Overview and Introduction	5
1.2	Strategic Case	6
1.3	Economic Case	21
1.4	Commercial Case	24
1.5	Financial Case	25
1.6	Management Case	26
1.7	Recommendation	28

TABLE OF TABLES

EXECUTIVE SUMMARY TABLE 1: SPENDING OBJECTIVES.....	10
EXECUTIVE SUMMARY TABLE 2: POTENTIAL SCOPE.....	17
EXECUTIVE SUMMARY TABLE 3: MAIN BENEFITS.....	20
EXECUTIVE SUMMARY TABLE 4: MAIN RISKS AND THEIR COUNTER MEASURES	21
EXECUTIVE SUMMARY TABLE 5: DEVELOPMENT OF OPTIONS / LONG LIST FRAMEWORK	22
EXECUTIVE SUMMARY TABLE 6: CAPITAL COSTS FOR THE PREFERRED WAY FORWARD	25
EXECUTIVE SUMMARY TABLE 7: PROJECT ROLES AND RESPONSIBILITIES	27
EXECUTIVE SUMMARY TABLE 8: INITIAL PROJECT PLAN	27

TABLE OF FIGURES

EXECUTIVE SUMMARY FIGURE 1: OVERARCHING NATIONAL POLICIES CONSIDERED WITHIN THE SOC	7
EXECUTIVE SUMMARY FIGURE 2: LOCAL POLICIES CONSIDERED WITHIN THE SOC	8
EXECUTIVE SUMMARY FIGURE 3: PROJECT REPORTING STRUCTURE	26

GLOSSARY / LIST OF ABBREVIATIONS

A&E	Accident and Emergency
AC	Ambulatory Care
ACT	Advanced Cell Therapy
ALL	Acute Lymphoblastic Leukaemia
AME	Annually managed expenditure
AT	Advanced Trials
ATMPs	Advanced Therapy Medicinal Products
AW	All Wales
AWMSG	All Wales Medicines Strategy Group
AXI-CEL	Axicabtagene Ciloleucel
BAU	Business as Usual
BCAG	Business Case Advisory Group
BCIS	Building Cost Information Service
BCR	Benefits Cost Ratio
BCSH	British Committee for Standards in Haematology
BCUHB	Betsi Cadwaladr University Health Board
BDP	Building Design Partnership (Architects)
BHNOG	Blood Health National Oversight Group
BHP	Blood Health Plan
BiTE	Bispecific T-cell Engager
BMT	Blood and Marrow Transplantation
BMTU	Bone Marrow Transplant Unit
BRP	Benefits Realisation Plan
BSBMTCT	British Society of Blood and Marrow Transplantation and Cellular Therapy
CAR-T	Chimeric Antigen Receptor T-Cell Therapy
CBI	Confederation of British Industry
CCRH	Cardiff Cancer Research Hub
CIA	Comprehensive Investment Appraisal
CMG	Capital Management Group
CNS	Clinical Nurse Specialists
CPD	Continuous Professional Development
CRB	Cash Releasing Benefits
CRest	Cancer Research Strategy
CRS	Cytokine Release Syndrome
CRUK	Cancer Research, United Kingdom
CSF	Critical Success Factors
CU	Cardiff University
CVUHB	Cardiff and Vale University Health Board
DEL	Departmental Expenditure Limits
ECMC	Experimental Cancer Medicines Centre
EME	Efficacy and Mechanism Evaluation
EOI	Expression of Interest
EP(C)T	Early Phase (Clinical) Trials
EU	European Union
FACT	Foundation for the Accreditation of Cellular Therapy
FBC	Full Business Case

FM	Facilities Management
GH	General Haematological Malignancy
GI	Gastrointestinal
GP	General Practice/ Practitioner
GTMP	Gene Therapy Medicinal Product
GVA	Gross Value Added
HA	Hereditary Anaemia
HCID	Highly Contagious Infectious Diseases
HCRW	Health and Care Research Wales
HCSW	Healthcare Support Worker
HDC	Haematology Day Centre
HDU	High Dependency Unit
HEPA	High Efficiency Particulate Air
HLA	Human Leukocyte Antigen
HM	His Majesty's
HSCT	Haematopoietic Stem Cell Transplantation
HTA	Human Tissue Authority
IAAP	Integrated Assurance and Approval Plan
IBI	Infected Blood Inquiry
ICANS	Immune Effector Cell Associated Neurotoxicity Syndrome
ICI	Immune Checkpoint Inhibitors
ICP	Integrated Commissioning Plan
IEC	Immune Effector Cell
IM&T	Information Management and Technology
IMTP	Integrated Medium Term Plan
IO	Immunotherapy Toxicity Service
IST	Immunosuppressive Therapy
ITP	Idiopathic Thrombocytopenic Purpura
ITU	Intensive Therapy Unit
JACIE	Joint Accreditation Committee - International Society for Cell & Gene Therapy (ISCT) and European Society for Blood and Marrow Transplantation (EBMT)
JCO	JACIE Central Office
KPIs	Key Performance Indicators
LBCL	Large B-cell Lymphoma
LHB	Local Health Board
LTAs	Long Term Agreements
MDT	Multi-Disciplinary Team
MECC	Making Every Contact Count
MMC	Modern Methods in Construction
MR	Magnetic Resonance
MRC	Medical Research Council
NAIT	Neonatal Alloimmune Thrombocytopenia
NCCP	National Clinical CAR-T Panel
NHS	National Health Service
NHSE	National Health Service England
NHSWSSP - SES	NHS Wales Shared Services Partnership – Specialist Estates Services
NICE	National Institute for Health and Care Excellence

NIHR	National Institute for Health and Care Research
NPC	Net Present Cost
NPSV	Net Present Social Value
NPV	Net Present Value
NWJCC	NHS Wales Joint Commissioning Committee
OBC	Outline Business Case
OPD	Outpatients Department
PBA	Project Bank Account
PERs	Project Evaluation Reviews
PICC	Peripherally Inserted Central Catheter
PIR	Post Implementation Review
PNH	Paroxysmal Nocturnal Haemoglobinuria
PPE	Post Project Evaluation
PPP	Public/ Private Sector Partnership
PRINCE2	PRojects IN Controlled Environments
QB	Quantifiable Benefits
QS	Quantity Surveyor
R&D	Research and Development
RPA	Risk Potential Assessment
RWE	Real-World Evidence
SACT	Systemic Anti-Cancer Therapy
SBS	Shared Business Services
SCPU	Stem Cell Processing Unit

SCTMP	Somatic Cell Therapy Medicinal Product
SE	South East (Wales)
SMART	Specific, Measurable, Achievable, Relevant, Time-bound
SO	Spending Objectives
SoA	Schedule of Accommodation
SOC	Strategic Outline Case
SOFW	Shaping Our Future Wellbeing
SRO	Senior Responsible Owner
SWBMT	South Wales Blood and Marrow Transplant
TCS	Transforming Cancer Services
TEP	Tissue Engineered Product
TILs	Tumour Infiltrating Lymphocytes
TTP	Thrombotic Thrombocytopenic Purpura
TUPE	Transfer of Undertakings (Protection of Employment)
UEL	Useful Economic Life
UHB	University Health Board
UHL	University Hospital Llandough
UHW	University Hospital Wales
VAT	Value Added Tax
VFM	Value for Money
WG	Welsh Government
WHC	Welsh Health Circular

1.0 EXECUTIVE SUMMARY

1.1 Overview and Introduction

To improve facilities for haematology inpatients and to ensure the continuation of the JACIE accreditation (Joint Accreditation Committee - International Society for Cell & Gene Therapy [ISCT] and European Society for Blood and Marrow Transplantation [EBMT]), the Cardiff and Vale Specialist Services Clinical Board recommends that a new building is to be developed along Academic Avenue at the University Hospital Wales (UHW), next to Tower Block 2, and some areas of Link Block A will also be refurbished to provide appropriate accommodation to meet the service and standard requirements.

This business case seeks to demonstrate the need for investment and to appraise the main options for service delivery with an aim to provide a preferred way forward for further analysis. Indicative costs suggest a capital investment of between £90.15m and £95.14m (including 20.43% optimism bias) dependent upon the chosen construction methodology to enable the Health Board to undertake the required works.

The facilities used by the Stem Cell Processing Unit (SCPU) are in a poor state of repair and are inadequate for the volume of work completed, for the equipment and for the staff in the department. This has been identified in a recent JACIE inspection. During the next stage further work will be completed regarding the element of works required for JACIE accreditation. A further investment will be required to relocate the Stem Cell Processing Unit from corridors B link and C on the upper ground floor of UHW to a refurbished area on the first floor where an opportunity has arisen in that Cardiff University (CU) has handed back a large room in the near vicinity of the labs, on the first floor B Block corridor. This room has been used as a laboratory teaching facility by CU. Further detail regarding this will be developed at the next stage of the business case process.

Meeting Standards

CVUHB is currently the sole provider of BMT and CAR-T services in Wales. Maintaining JACIE accreditation is a fundamental requirement of the NWJCC service specification, as well as a prerequisite for access to CAR-T therapies from pharmaceutical providers.

However, longstanding infrastructure limitations at the University Hospital of Wales site have been identified as a significant concern. The service has previously received adverse feedback from JACIE inspections in 2013 and 2019, particularly in relation to facilities and capacity.

The JACIE Inspectorate again heavily criticised the adult CVUHB facilities during the 2025 inspection, noting that previous commitments to rectify the deficiencies had not materialised. As a consequence, the JACIE Central Office (JCO) felt unable to recertify the service, despite ongoing excellent clinical results and now demands a credible, detailed plan to address the noted deficiencies before recertification could be entertained.

CVUHB is now required to submit a robust, costed, and time-bound corrective action plan by 8 July 2026. Failure to do so could result in complete loss of JACIE accreditation, with significant consequences, including the potential requirement for NHS Wales to commission these services from providers in England.

In short, if CVUHB is unable to retain JACIE accreditation, the potential impact on the service could result in steps being taken to decommission BMT and CAR-T therapies, which would fundamentally undermine the delivery of haematological cancer services for the population of South Wales.

To achieve and sustain compliance with JACIE standards, the service must address both quality and capacity requirements, with particular focus on infrastructure, workforce, and long-term service configuration.

1.2 Strategic Case

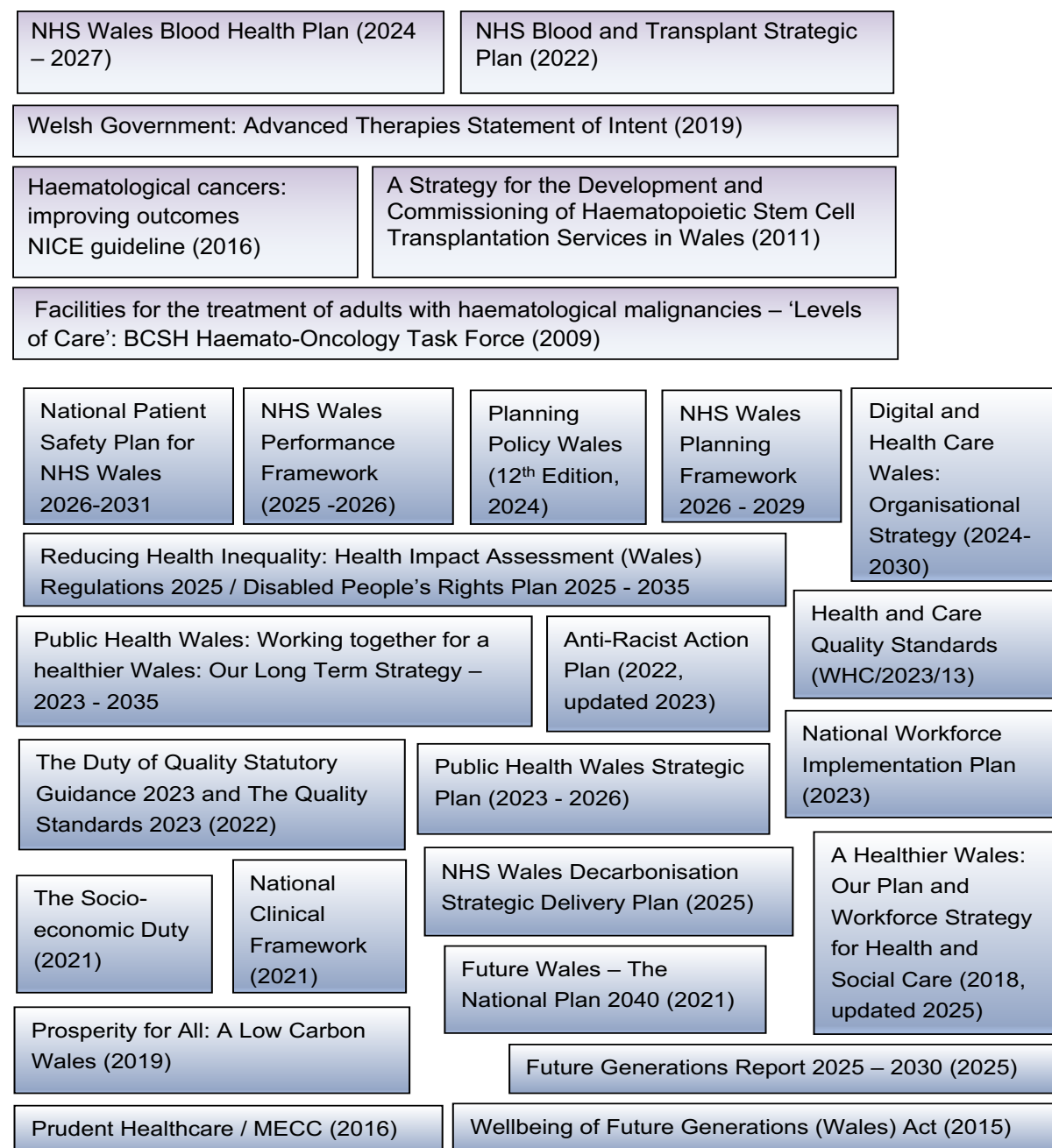
Cardiff and Vale University Health Board was established in October 2009 and is one of the largest NHS organisations in the UK.

Since its establishment, the Health Board's priority has been to provide safe, high quality and sustainable services that compare well with the best in the world, with a focus on developing centres of excellence that support the actions needed to progress and deliver the vision 'to reduce health inequalities and deliver outstanding services for the population we serve'.

The Health Board has the following strategic objectives:

- Putting People First – The Health Board will be a great place to train, work and live, where the organisation will listen to and empower people to live healthy lives. By 2035, colleagues will recommend the Health Board a great place to work, workforce will reflect the diversity of communities, and more people will be living healthier lives
- Providing Outstanding Care – The Health Board will provide outstanding services which are equitable, timely and safe, where people are treated with kindness and are supported to achieve the outcomes that matter to them. Inequities will be reduced in prevention, and there will be improved access to clinical services and clinical outcomes
- Delivering in the Right Places - By 2035 the Health Board will be using real time integrated data to inform joint decision making and multi-disciplinary team working, giving people access to and ownership of their data to enable them to manage their health and wellbeing. The organisation will be well on the journey to provide care in the right place, in facilities that are fit for purpose, flexible and promote recovery
- Acting for the Future – The Health Board will work to ensure that what is done today does not compromise the wellbeing of future generations. The Health Board will protect the environment and develop and use new technologies, treatments and techniques to provide the best possible health outcomes and sustainable health care into the future. By 2030 the Health Board's will have reduced its carbon footprint by 34% (currently under review) and will have increased research and clinical innovation activities.

The Health Board is confident that the strategic drivers for this investment and associated objectives, programmes and plans are consistent with national, regional and local strategy and policy documents. Some of the key policies that have shaped this SOC are:



Executive Summary Figure 1: Overarching National Policies considered within the SOC

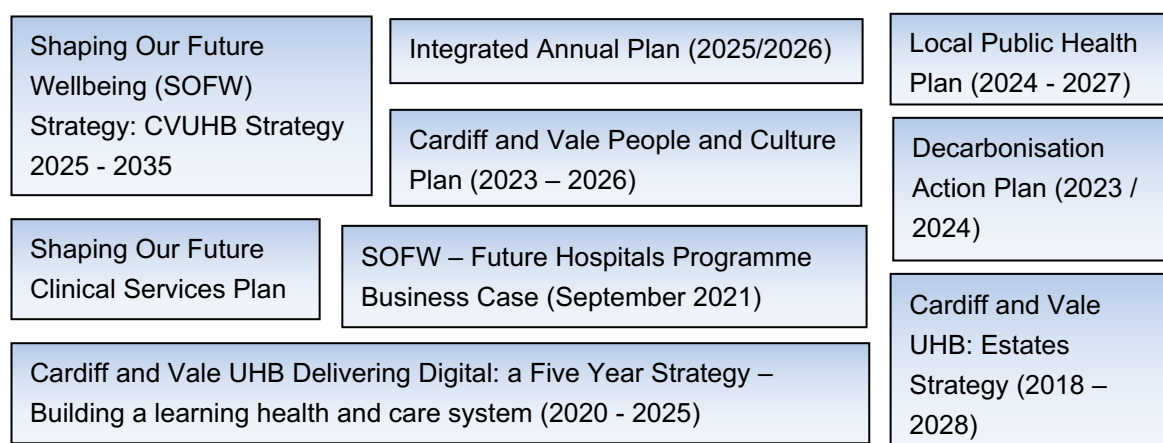
Haematology (including haemostasis and thrombosis) is the study of the blood and blood-forming tissues. A bone marrow transplant replaces damaged blood cells with healthy ones, detects and destroys residual malignant cells, restores normal bone marrow function including that of the immune system. It can be used to treat malignant conditions affecting the blood cells, such as leukaemia, lymphoma, myeloma and bone marrow failure syndromes such as aplastic anaemia and the myelodysplastic syndromes; inherited blood

disorders such as sickle cell disease and the thalassaemia syndromes; and non-malignant conditions such as immune deficiency syndromes and multiple sclerosis. Advanced therapies utilise the transplantation of human cells to replace, repair or reprogramme damaged tissue and/or cells. With new technologies, innovative products, and limitless imagination, many different types of cells may be used as part of a therapy or treatment for a variety of diseases and conditions.

This business case contributes to delivering these strategies through:

- Providing sufficient capacity to meet the clinical demand and ensure that all patients have equitable access to services across Mid, West and South Wales
- Ensuring the safety of patients, staff and visitors; and the requisite quality of care through provision of high-quality facilities that fully meet JACIE Standards
- Providing facilities for research and development to enable the introduction of new treatment modalities, ensuring state-of-the-art cancer care for patients in Wales
- Ensuring Cardiff and Vale Health Board (that is the only centre in Wales) has capacity to continue to deliver current high-risk Advanced Therapy Medicinal Products (ATMPs) via both commercial and clinical trial routes. It is envisaged that future demand for this type of therapy will increase as is proving the case in solid cancers and non-malignant conditions
- Providing advanced cellular and non-cellular products (e.g. *in vivo* gene therapies) to patients from across Wales within the haematology service. There is an urgent need for an expansion in facilities with designated beds co-located with the BMT service and with rapid access to intensive care unit (ITU) services
- Provide high-quality facilities to enable the Health Board to attract and retain specialist staff

The SOC also takes cognisance of the relevant local Health Board strategies:



Executive Summary Figure 2: Local policies considered within the SOC

The business case will contribute to delivering these strategies through:

- Emphasising a key area of the Integrated Annual Plan (2025/2026) which is to deliver exceptional specialist and tertiary services for local, regional, and national populations, and make a commitment for the redevelopment of haematology inpatient facilities to meet JACIE standards and to transform the patient experience in haematology and bone marrow transplant
- Addressing the compliance issues for BMT which is a key estates risk and therefore features as the top priority in the estate strategy
- Assist the Health Board to meet the themes set out in the workforce strategy for health and social care in relation to the CVUHB People and Culture Plan by improving the experience of staff working within the service
- Build upon the Shaping Our Future Wellbeing (SOFW) strategy and Shaping Our Future Clinical Services Plan in relation to providing a co-ordinated approach to transforming services for the future and delivery of improved outcomes and value-based healthcare whilst utilising innovative workforce models and introducing new technologies

The proposed facility outlined within the business case would unlikely be able to be linked to any new replacement for UHW due to the major rebuild of UHW2 for which there are no agreed timescales currently. However, much of the equipment would be suitable for transfer, dependent upon the timeframe for the delivery of any new facility proposed.

Spending Objectives

The specific spending objectives for the haematology strategic outline case include the following, along with how they will be measured:

Spending Objective 1: Quality and Safety of Services	
Specific	Services that deliver quality care and meet agreed clinical, quality and safety standards, including: ■ Compliance with legislation, regulations and accreditation standards / performance ■ Supports rapid adoption of best practice ■ Clinical effectiveness, including: ○ Delivering improved outcomes for patients ○ Supporting research & development ■ Improves consistency in clinical practice
Measurable	Evidenced by: ■ Continued Joint Accreditation Committee ISCT-EBMT (JACIE) accreditation ■ Elimination of environmental issues within haematology and bone marrow transplant facilities ■ Ensuring all services within the project have sufficient capacity to meet future demand in an area which is rapidly evolving ■ Adoption of currently commissioned services for which there is no capacity and for which patients are currently being referred to NHS England (e.g., autologous stem cell transplantation for multiple sclerosis and newer National Institute for Health and Care Excellence (NICE) - approved indications for CAR-T therapy)

Spending Objective 2: Provide a High Quality Environment	
Specific	To provide facilities that comply with statutory standards and best practice and enable the Health Board to deliver high quality care and provide clinical teams with the appropriate environments in which to care for patients
Measurable	Evidenced by: - Improved estate performance - Joint Accreditation Committee ISCT-EBMT (JACIE) accreditation - Meeting design and technical standards
Spending Objective 3: Access	
Specific	To ensure that the changing needs and expectations of a growing population are met in line with Health Board clinical strategies and national guidance standards and that the solution does not destabilise other clinical services/developments. Access to services is optimised with: - Service capacity that will meet demand in a timely way - Services delivered in an appropriate environment
Measurable	Evidenced by: - Reduced nosocomial infection rates within haematology and bone marrow transplant patients - Improved access to services through appropriate use of technologies - Access to new advanced therapy service to the population of Wales
Specific	To maximise the use of available resource and provide an environment that promotes improved service efficiency through improved productivity and improved patient flows
Measurable	Evidenced by: - Appropriate lengths of stay for inpatients - Reduction in staff turnover/increased staff retention through provision of better-quality facilities - Ability to deliver NICE approved treatments within the Health Board - Services provided within the identified revenue budget
Spending Objective 5: Sustainability/Flexibility	
Specific	To provide a solution that will enhance the reputation of the Health Board and will support the delivery of safe, sustainable and accessible services both in the short and medium term and with built-in resilience to adapt to changing needs
Measurable	Evidenced by: - Capacity to meet increased demand - Rooms to be generic and flexible to meet multiple uses wherever appropriate

Executive Summary Table 1: Spending Objectives

The spending objectives relate directly to the five generic drivers for intervention and spend, they also align with the NHS Infrastructure Investment Guidance objectives and criteria.

Existing Arrangements

Ward B4/C5 Haematology at UHW is a 27-bed ward over two areas providing inpatient services for the whole range of haematology disorders, both malignant and non-malignant,

for patients aged 25 years and older. Inpatient haematology care includes all inpatient chemotherapy, cellular therapy and complication management of disease or treatment consequences. Patients under 25 years are predominantly treated on the Teenage Cancer Trust Unit, however they often require stays on the B4/A4 footprint due to capacity or clinical requirement. As a result of the changing landscape of therapies for haematological cancers, the patients requiring inpatient treatment receive more complex therapies than a decade ago. This has resulted in a heavier burden to the nursing workforce and medical oversight.

Currently, there are six isolation single rooms (HEPA filtered with positive air pressure) and two 2-bed areas (HEPA filtered with positive air pressure and shared toilet facilities) in the transplant part of the ward; and there are two single rooms (no air handling or ensuite facilities), a 3-bedded area and three 4-bedded areas on the general side with shared toilet facilities. No cubicles on B4 haematology have ensuite facilities, meaning patients can be admitted for transplant requiring up to a four week stay with only a commode and wash basin for personal care, toileting and hygiene requirements. This falls below the acceptable standard for patients undergoing BMT who are in isolation.

Since the COVID-19 pandemic the service is currently based on C5, where only 3 acute admissions beds are in use. This segregated space has been essential to prevent and minimise the spread of infection, including but not limited to COVID-19. The service has seen a marked reduction in nosocomial infections since the introduction of the unscheduled care space. Prior to COVID-19 there were over 60 documented cases of potential or actual nosocomial infection which fell to zero after COVID-compliant measures were introduced during the first year of the pandemic. Given that 'COVID-compliant' measures are essentially the same as those of a JACIE-compliant service, this experience underscores the importance of routinely operating to JACIE standards. Nursing establishment for both areas remain the same, as such, a total of 27 inpatient beds is maintained across the two ward areas.

Due to increasing activity in all parts of the service, and particularly in BMT, there are frequently long delays for patients awaiting chemotherapy and patients frequently outlie on other non-haematology wards. Audit data from December 2025 to January 2026 highlights the ongoing pressure for general haematology beds which operate at 110% to 120% capacity.

The 10 NWJCC-commissioned beds within the 27 bed cohort (8 for BMT and 2 for CAR-T) are insufficient to accommodate patients requiring readmission due to complications (a JACIE standard). As a result, post-transplant patients are readmitted into general haematology beds, negatively impacting the capacity to admit general haematology patients for life-saving chemotherapy. Not only does this arrangement fall short of the JACIE standard to have patients readmitted to the transplant centre, but the extensive daily communication also required to safely manage patients "at a distance" adds a significant burden to consultant workload. Furthermore, during the past two years, 11 patients were

outsourced to centres in England for allogeneic BMTs due to lack of capacity with a further 3 being outsourced for autologous BMT for multiple sclerosis in the 2026/27 financial year to date. This latter outsourcing exemplifies that the service is unable to deliver commissioned activity for any new BMT indications including multiple sclerosis, immunodeficiency disorders and the recent (2023) expansion in NICE-approved CAR-T indications. Importantly, virtually all of these patients were repatriated to Wales well before the end of the contracted 100 days post-transplant period, leading to “double payment” by NHS Wales for these patients, with treatments already paid to centres in England now being delivered by the SWBMT Programme, without reimbursement of fees already paid to NHS England.

The haematology ambulatory care unit at UHW treats patients who would historically have been treated exclusively within an inpatient setting, however due to the increased activity and scope of service, the unit is already outgrowing its current accommodation and requires proper isolation facilities to maximise transplant activities within ambulatory care as well as managing those patients who present with symptoms of infection. Due to the isolation of the unit from other areas of the haematology service, additional staff are required to ensure patient safety. The JACIE Inspectorate declared that all but the isolation room was unfit for purpose affording the patient no privacy or requisite protection from nosocomial infection as demanded by JACIE standards.

The South Wales Blood and Marrow Transplant Programme (SWBMT) serves adults and children in the catchment area of mid, west and south Wales, accounting for nearly 80% of the Welsh population. It consists of a clinical programme supported by collection and processing facilities. The service is delivered across two Local Health Boards – Swansea Bay University Health Board (SBUHB) and Cardiff and Vale University Health Board. Industry qualification to deliver CAR-T therapy was achieved in December 2018 and in 2019 JACIE accreditation and human tissue authority (HTA) licensing were extended to include Immune Effector Cell (IEC) therapy to facilitate commissioning to deliver CAR-T therapy on behalf of its catchment area.

Demand for transplantation and general and malignant haematology has grown steadily over recent decades. In 2020 there was a decline in transplant activity internationally due to the impact of the COVID-19 pandemic with recovery to near pre-pandemic levels by 2023. It is projected that transplant activity will reach or surpass 2019 (pre-pandemic) levels. Exceptions to the pandemic decline were allogeneic transplantation given that this is largely undertaken in patients with aggressive haematological malignancies and CAR-T therapy which is reserved for patients not in remission and whose therapy cannot be successfully postponed.

It is anticipated that cellular therapy activity will continue to increase further due to continuously improving outcomes as a result of better supportive care, an increase in the range of treatment regimens available, the ability to deliver curative treatments to older patients (who bear the greatest burden of haematological cancer) and improved allogeneic

donor availability resulting from improvements in human leukocyte antigen (HLA) typing as well as the successful application of haploidentical family donors for patients lacking a conventional donor.

However, capacity to provide a timely service remains a challenge. This has resulted in increased waiting times for admission to the ward and delays in transplantation. To minimise the impact there are weekly planning meetings to review and triage patients on the waiting list. Although this has lessened the impact of the infrastructure deficiencies, it consumes inordinate amounts of senior clinician time and there are inevitable breakthrough relapses on the waiting list in some instances precluding transplantation and leading to premature death.

The introduction of a CAR-T programme has compounded the capacity issues.

As a result of deficiencies in the physical infrastructure the adult SWBMT Programme on the CVUHB site was severely criticised by the JACIE Inspectorate following the 2013 and 2019 inspections.

Following the most recent inspection in September 2025, JACIE deferred accreditation, pending a resubmission from the programme. This resubmission must address all identified areas of non-compliance and include a robust, fully costed, and time-bound corrective action plan for any outstanding issues. The deadline for submission is 8 July 2026, six months from receipt of the formal inspection report.

The Stem Cell Processing Unit is located on the upper ground floor of UHW, corridors B link and C and primarily serves the South Wales Blood and Marrow Transplant Programme, annually processing around 150 collections from adult patients (autologous donors), a few paediatric autologous donors, a few related normal donors collected by apheresis at UHW and around 50 donations (predominantly apheresis) from unrelated donors worldwide.

It has been known for some time that the facilities for the Stem Cell Processing Unit were poor, as there is only one clean room, limited lab and office space. A recent JACIE report has also highlighted this and, if not resolved, this may have implications to the service's accreditation.

Business Need

In addition to capacity constraints outlined above, the existing inpatient and ambulatory care facilities remain inadequate with regards to provision of hygiene facilities, triage, isolation and protection of patients from nosocomial (hospital-acquired) infection. This has resulted in unnecessary exposure of immunosuppressed patients to infection resulting in additional treatment, morbidity and mortality.

There is therefore a pressing need to provide an appropriate JACIE-compliant environment for BMT and CAR-T activity on the UHW site for the following reasons:

- International standards for cellular therapy services (transplantation and CAR-T) are defined by FACT-JACIE standards. There is published evidence demonstrating that clinical outcomes are better in JACIE-accredited centres when compared with non-accredited centres. Indeed, outcomes also improve in centres preparing for JACIE accreditation demonstrating that the discipline involved in becoming “JACIE-compliant” improves outcomes providing direct evidence that the adoption of quality standards improve clinical outcomes (Gratwohl et al, Haematologica 2014,908-915)
- Commissioning bodies in the UK made JACIE accreditation a prerequisite for providing BMT and CAR-T services and this is included in the NWJCC BMT and CAR-T Service Specifications. Therefore, lack of JACIE accreditation would necessitate closure of the BMT programme with the attendant loss of revenue and loss of reputation for Cardiff and Vale UHB, Welsh Government and for Wales.
- The JACIE Inspectorate in 2013 declared the physical infrastructure of the adult service on the CVUHB site “shabby and well behind the curve” compared with other UK centres. Following the 2019 inspection the feedback was even more scathing with the facilities described as “the worst ever seen”. Indeed, the Lead Inspector made it clear that had it not been for our excellent clinical outcomes the programme would have been recommended for closure. At the 2025 inspection the JACIE Lead Inspector made the wry but obvious comment that, “until the facilities are upgraded, the patient experience remains the same”, reflecting on the fact that promises made in the wake of the 2013 and 2019 inspections had not materialised. The JACIE report from the 2025 inspection was received in January 2026. It confirmed that none of the adult clinical facilities on the CVUHB site (inpatients, ambulatory care, haematology day centre, apheresis collection suite, outpatients) meets JACIE Standards. The Programme Director has to respond to the noted deficiencies by the deadline of 08 July 2026. Although acknowledging that capital deficiencies may not be remediable within the 6-month response deadline, JACIE has been clear that a “detailed response” is expected. Whilst we cannot speak for the JACIE Central Office (which makes the final decision), one would expect that this detail should include JACIE-compliant floor plans, a commitment to fund the development, and a clear timeline for completion. In contrast to previous inspections, JACIE has deferred making a decision regarding recertification pending our response
- Due to the existing design deficiencies affecting inpatient, day unit and outpatient facilities which prevents adequate triage and isolation, more than 60 instances of risk of nosocomial infection directly attributable to the lack of adequate facilities were documented in 2019. By contrast, in 2020, when strict COVID-compliant pathways were enforced, there was not a single incident of potential nosocomial infection proving that adequate facilities will protect patients and potentially save lives. Unfortunately, with BMT activity virtually at pre-pandemic levels, the same quality of isolation and patient distancing is no longer possible, and patients are again being put at risk of nosocomial infection.
- The lack of sufficient capacity to treat patients in a timely manner has resulted in patients breaching agreed waiting times for BMT, which can increase the risk of relapse whilst on the BMT waiting list. To minimise this relapse risk patients are often given additional (but unnecessary) chemotherapy which in turn can increase toxicities and complications

As a result of the above deficiencies, the physical fabric of the adult service on the UHW site was heavily criticised by the JACIE Inspectorate. Had it not been for the excellent clinical outcomes, the Programme would have been recommended for closure following the 2019 inspection. JACIE has deferred making a decision following the 2025 inspection due to the ongoing significant structural deficiencies on the CVUHB site and the lack of any material improvements following promises made after the 2013 and 2019 inspections.

Loss of JACIE accreditation would have far-reaching consequences:

1. The SWBMT Programme would be the only major UK programme, the 15th largest of 49 UK and Irish transplant centres, and centre to have had JACIE accreditation withdrawn
2. The SWBMT Programme would need to cease activity since it is the policy of all UK BMT commissioners, including NWJCC, to procure services only from JACIE-accredited centres. This would lead to significant political and reputational loss for Wales, Welsh Government, CVUHB and the SWBMT Programme
3. Patients in Wales would need to be referred to BMT centres in England where transplant costs are typically $\geq 50\%$ higher than in Wales. Welsh patients transplanted in England may not get the benefit of the comprehensive, award-winning prehabilitation programme that occurs in Cardiff, improving patient fitness prior to both transplantation and CAR-T therapy
4. In addition to the financial disbenefit to NHS Wales and the potential for a worse clinical outcome by referring patients to NHS England, such a move would contravene cancer standards which require patients to be treated as close to home as possible. The patient experience would be significantly worse since relatives would be able to visit less often and families would incur greater travel costs to visit patients in England.

The current facilities at UHW will likely again fail JACIE standards on triage, isolation and patient facilities given that no material improvement has occurred following earlier inspections. CVUHB therefore wish to pursue an integrated solution that might allow colocation of inpatients, day care, ambulatory care and outpatients across haematology services at the UHW site.

Any new physical infrastructure, including an expanded ambulatory model of treatment delivery, would meet current and projected future demand, offer insulation against uncertainties in future demand whilst addressing health and safety deficiencies. The vision is to provide safe, timely, compassionate and comprehensive care in an environment suited to the management of patients with leukaemia, myeloma, lymphoma, sickle cell disease, bleeding disorders and those who are having blood and marrow transplantation, CAR-T therapies or other ATMPs. This requires an increase in the number of beds, provision of isolation facilities in the ward, day centre, ambulatory care and outpatient settings, and separate, but neighbouring, facilities for patients with inherited bleeding disorders.

Without an urgent infrastructure upgrade, Welsh patients would potentially be denied access to effective therapies or may need to travel to England, falling foul of Welsh National Cancer standards.

Providing an adequate bed complement, with sufficient surge capacity, would reduce waiting times, obviate the need for “bridging” chemotherapy, and improve outcomes and patient experience.

The vision is to have a facility for the Stem Cell Processing Unit and Haematology which is fit for purpose and conforms to the JACIE, HTA, MHRA and UKAS standards and regulations.

The JACIE report for SCPU states:

“The Cell Processing Facility is aging. While it remains functional and adequate for the current workload, there are clear design and infrastructure limitations. For example, the Grade B change area opens into an unclassified area, and there are no locker or changing facilities for staff to prepare appropriately for gowning into the cleanroom space. The cleanroom itself is small and can only accommodate one cabinet. “

During the inspection, it was noted that the laboratory had recently acquired two additional rooms/spaces for expansion; however, these are not currently fitted to meet the needs of the processing facility. Consideration should be given to the level of investment required to future-proof the existing environment, and investment should also be considered to make the two newly acquired spaces fit for purpose.

As noted in the JACIE report, the current clean room does not meet the requirements for contamination control because it only has a single stage change and there is insufficient space in its current location to adapt the changing area into a dual stage change. This immediately precludes the use of the facility from future translational and advanced manufacturing activities.

Potential Scope

Welsh Government guidance assesses the scope against a continuum of need ranging from:

- A minimum – essential or core requirements/outcomes
- An intermediate – essential and desirable requirements/outcomes
- A maximum – essential, desirable and optional requirements/outcomes.

	Core	Desirable	Optional
Potential Scope	Services included: ▪ UHW Haematology/ BMT Inpatients ▪ UHW Advanced Therapies ▪ Stem Cell Processing Unit	Service included: ▪ UHW Haematology/ BMT Inpatients ▪ UHW Advanced Therapies ▪ UHW Haematology Outpatients ▪ Stem Cell Processing Unit	Services included: ▪ UHW Haematology/ BMT Inpatients ▪ UHW Haematology Day Centre ▪ UHW Haematology Outpatients ▪ UHW Cardiff Haemophilia Centre ▪ Stem Cell Processing Unit

Executive Summary Table 2: Potential Scope

Key service requirements are that there is a facility provided that meets minimum statutory requirements regarding environmental and care quality standards and capacity is sized to meet current demand. It must be noted that no future proofing to accommodate evolving indications are included in the project business case.

Main Benefits

This section describes the main outcomes and benefits associated with the implementation of the investment:

Spending Objective	Stakeholder Group	Main Benefits
Objective 1: Quality and safety of services	Patients	Non QB - High quality patient care QB – Improvements in health and safety (reduced incidents and specifically relating to toxicity) QB - Patient outcome maximised through treatment early in the course of the disease. For example, patients with acute myeloid leukaemia (AML) transplanted in first remission have a cure rate of 65% falling to 40% when done in second remission. Thus, earlier treatment avoids the costs of re-treatment (due to relapse) and results in a better long-term outcome QB - Providing patients in Cardiff and potentially South East Wales with access to high quality and safe solid tumour immunotherapies and immuno-oncology treatments QB - Significant improvement to the quality of care and expected patient outcomes (i.e., increase in curative treatments; improved 1 and 5 year survival rates) QB - High levels of safety which support increasing toxicity of treatments now and in future years i.e., reduced number of incidents relating to toxicity QB - Reduction of avoidable patient harm Non QB - Development of specialist toxicity management pathways with each organ specialist
	Staff	Non QB – Maintain continuity of services QB – Improvements in health and safety (reduced incidents) QB – Staff recruitment and retention will improve as investment in new facilities will help attract and retain high quality professional staff Non QB - Development of best practice clinical pathways with clinicians from the Health Board and Trust collaborating with on the management of complex patient toxicity
	Health Community	Non QB – High quality care given to all patients Non QB - Delivering high quality and research-led teaching at both undergraduate and postgraduate level, and to inspire others to pursue excellence in research, teaching and innovation Non QB - Supports the development of fundamental foundations (capacity/capability) to deliver advanced therapies/AMTPs

Spending Objective	Stakeholder Group	Main Benefits
Objective 2: Provide a high quality physical environment	Patients	Non QB – Provide safe and appropriate environments of care for patients and improving the patient experience, with improved patient satisfaction (patients have repeatedly complained about the lack of ensuite facilities during informal feedback) QB - An increase in capacity within inpatient facilities that will enhance patient flow and continuity of care with timely admission for therapy and reduced delays with documented increased risk of relapse Non QB – Maintaining appropriate privacy and dignity Non QB - Providing a supported environment for the delivery of EPCTs including, those utilising Advanced Therapies (ATs)
	Staff	Non QB – Provide a safe and appropriate environment for staff and be a better place to work Non QB – Improved clinical morale gained from improved access to modern equipment, technologies and facilities
	Health Community	QB – Compliance with statutory standards, including JACIE accreditation and maintenance of the HTA licence QB – Compliance with NHS guidance/best practice including NICE and All Wales Medicines Strategy Group requirements Non QB – Improved environments to enable productivity gains Non QB - Organisational reputation will be enhanced by providing high quality and safe care which supports the ability to provide new and novel treatments in South Wales
Objective 3: Access	Patients	Non QB – Provide suitable services and facilities sized to meet demand to ensure improved and optimised treatment pathways QB – Improved waiting times QB - Increasing research options for Welsh patients nearer to home QB – Improvements to patient aftercare: toxicity follow-ups provided for all patients with toxicity irrespective of tumour group QB - Improved survival and quality of life
	Staff	QB – Reduction in the non-availability of inpatient beds for Haematology/BMT patients
	Health Community	Non QB – Reduced pressures on other facilities and provides appropriate capacity for the population QB – Reduction in patients receiving extra ('holding') courses of chemotherapy (due to current waiting times). This will reduce patients' exposure to potential complications from unnecessary additional treatment Non QB - Provision of capacity and capability to deliver immunotherapies and advanced therapies/ATMPs will assist in establishing Cardiff and Wales as a global player new/emerging market
	Patients	QB – Improved waiting times QB - Reduced the current waiting times for BMT

Spending Objective	Stakeholder Group	Main Benefits
Objective 4: Effective use of resources	Staff	Non CRB – Reduced delays and cancellations maximise use of staff
	Health Community	Non QB - Maximise use of existing accommodation to enable estate rationalisation and improved utilisation Non CRB - Cost avoidance: if capacity and capability is not established patients may have to travel across the border for immunotherapies/ATMPs/advanced therapies and this will be more expensive CRB - Cost savings: there is a significant opportunity to delivery significant cost savings from reduced length of stay for patients with severe toxicity (grade 3 and 4)
Objective 5: Sustainability	Patients	Non QB – Services continue to be provided to meet patients' needs
	Staff	QB - Reduction in vacancy and turnover rates QB - Reduction in staff sickness rates Non QB - Improved job satisfaction
	Health Community	Non QB - Maximise flexibility of facilities QB - Provision of capacity and capability to deliver ATMPs in Cardiff will make it/Wales a more attractive place for strategic partners to invest in (in terms of infrastructure and financial investments)

Executive Summary Table 3: Main Benefits

Main Risks

The table below provides a summary of the key risks that might affect the delivery of the project along with counter measures:

Risk	Counter Measures
Service Risks	
Business case not endorsed by WG, impacting on progressing with the scheme to improve the existing facilities and meeting JACIE Accreditation as per the recommendations set out in the inspection. Risk of 'shutdown' by the regulatory board if improvements are not made to the patient environment as per the standard.	Demonstrate at Infrastructure Investment Board the importance of meeting JACIE Accreditation standards and improve the patient environment
Insufficient revenue resources to support the new facilities	Service model will be developed to support the service within the current revenue resource envelope or reduced costs where more optimal environments enable this
Design doesn't fully meet the operational requirements / JACIE Accreditation and provide the required clinical quality	Ensure appropriate review of plans during design development including clinical, infection prevention, clinical support and FM representatives

Risk	Counter Measures
Changes in demand – the anticipate demand for services is greater or less than has been projected within the case	Robust activity and capacity analysis has been undertaken. Design will be generic with the ability to adapt to different usage
Business Risks	
Financial Viability – capital cost of works is unaffordable, tenders exceed budget	Monitoring of costs during business case development. Robust financial analysis utilising established benchmarked norms to establish project budget
Changes in strategic context/policy direction	Non-political and strategic factors have been considered in developing the proposals
Design changes that are over and above the contingency allowances	Health Board to monitor and manage changes throughout the project
External Risks	
Failure to proceed – Contractor bankruptcy, development stalls due to lack of capital or failure to achieve business case approval	Appointment of established Contractor and liaison with Welsh Government to ensure available capital and approval of business case

Executive Summary Table 4: Main Risks and their Counter Measures

1.3 Economic Case

Critical Success Factors and Options Development

The critical success factors (CSFs) for the project were taken from the Welsh Government guidance and endorsed by the project team as follows:

- CSF 1 – Strategic Fit and Business Needs
- CSF 2 - Optimisation of Cost and Benefits (VFM)
- CSF 3 – Supplier Capacity and Capability
- CSF 4 – Potential Affordability
- CSF 5 – Potential Achievability

These CSFs have been used alongside the spending objectives for the project to evaluate a list of possible options. An infinite number of options and permutations are possible; however, within the broad scope outlined in the strategic case and utilising the Treasury Green Book and Infrastructure Investment Guidance options framework, the long list options findings are summarised overleaf:

Framework Options	Business as Usual (BAU)	Minimum	Intermediate	Maximum
Potential Service Scope Options – as outlined in the strategic case	Existing provision with no improvements	UHW Haematology/ BMT Inpatients UHW Advanced Therapies Stem Cell Processing Unit	UHW Haematology/ BMT Inpatients UHW Advanced Therapies UHW Haematology Outpatients Stem Cell Processing Unit	UHW Haematology /BMT Inpatients UHW Haematology Day Centre UHW Advanced Therapies UHW Haematology Outpatients UHW Cardiff Haemophilia Centre Stem Cell Processing Unit
	Discounted	Preferred Way Forward	Discounted	Discounted
Potential Service Solution Options – in relation to the preferred scope	Backlog maintenance is addressed	Backlog maintenance is addressed and refurbishment of the accommodation the services currently occupy	Backlog maintenance is addressed and refurbishment of other potentially available existing Health Board accommodation	New build provision plus refurbishment of existing areas
	Discounted	Discounted	Discounted	Preferred Way Forward
Potential Service Delivery Options - in relation to preferred scope and solution	3.1 In-house		3.2 Strategic Partnership	3.3 Outsource
	Preferred Way Forward		Discounted	Discounted
Potential Implementation Options – in relation to preferred scope, solution and method of service delivery		4.1 Phased		4.2 Big Bang (single phase)
		Discounted		Preferred Way Forward
Potential Funding Options – in relation to preferred scope, solution, method of service delivery and implementation		5.1 Public Funding		5.2 Private Funding
		Preferred Way Forward		Discounted

Executive Summary Table 5: Development of Options / Long List Framework

The drive of this project is to improve haematology inpatient facilities in order to meet the JACIE requirements and given the preferred scope identified above there is only one physical solution that will deliver the scope as there is insufficient space currently available on the UHW site, therefore, to provide the required accommodation, a combination of new build and refurbished accommodation on the UHW site is necessary.

Economic Appraisal

An economic appraisal has not been carried out as part of the development of the SOC; this will be completed during the next stage. Moving forwards, a comprehensive investment appraisal (CIA) will compare this preferred way forward against the business as usual option as a baseline.

Preferred Way Forward

A feasibility study has been undertaken to see how inpatient facilities for Haematology and BMT services could be developed on a site alongside UHW Academic Avenue, next to Tower Block 2. The building layout is shaped by existing site constraints, including Tower Block 2, the service tunnel, generators, and surrounding roads.

To connect effectively with the existing building, the first level of patient accommodation will be located on the first floor. Plant rooms will sit below at ground and first floor levels.

Around 812m² of existing first-floor space in Link Block A will be refurbished to form the entrance to the new department. This area will house the main entrance, reception, waiting area, consulting rooms, offices, and support spaces.

A further 232m² on the second floor of the existing building will be refurbished to provide additional support space, including staff facilities and offices.

The new building will connect to Tower Block 2 at first and second floor levels, providing approximately 1,280m² and 1,680m² of new accommodation respectively. The first floor will accommodate ambulatory care, three four-bed wards, and six single acute haematology wards, all with ensuite facilities. Twenty-two single-bed isolation wards will be located on the second floor around the perimeter of the plan. Each ward will include a lobby and an ensuite.

On both the first and second floors, support facilities will be centrally located so that wards, therapy rooms, offices, and other spaces benefit from external views. Escape stairs, accommodation stairs, and a bed lift will provide vertical circulation for staff and patients.

The proposed construction period is circa 15 to 18 months construction, dependent upon whether the solution is traditional or modular build, through to commissioning although the start date for this is dependent on the approvals process.

1.4 Commercial Case

The feasibility study provided in conjunction with the strategic outline case indicates that the required scope of works to support haematology and BMT inpatients and ambulatory care is to:

- Provide a new build along UHW Academic Avenue, next to Tower Block 2
- Refurbish Link Block A
- Refurbish part of the second floor of the existing building

Further work will also be undertaken in due course in relation to the relocation of the SCPU.

The procurement options considered by the Health Board include:

- Traditional tender process
- Single tender action to an individual contractor
- Utilising the Scape Built Environment Consultancy Services (“BECS”) Framework
- Using the Design for Life procurement framework

Due to the specialist nature of the scheme, the procurement route to be potentially utilised is an open market tendering process in conjunction with the NHS Wales Shared Services Partnership (NWSSP) procurement department to identify a suitable supply chain partner (SCP) for the works.

The quantity surveyor has been appointed via the Shared Business Services (SBS) Healthcare Planning, Construction Consultancy and Ancillary Services (HPCCAS) Framework Agreement.

The procurement strategies are expected to be in line with the procedures and practices as laid down in the varying frameworks. An open book approach to prices will be adopted and all costs closely scrutinised to ensure that the Health Board is getting the best value for money.

1.5 Financial Case

Capital Costs

The anticipated investment is between £90.15m and £95.14m (including 20.43% optimism bias) dependent upon the chosen construction methodology of the preferred way forward. A breakdown of the capital costs is summarised below:

	£000m Traditional Construction	£000m Modular Construction
Works costs	53.06	59.08
Fees	9.44	6.79
Non-works costs	2.50	2.62
Equipment	4.39	4.38
Planning Contingency	6.94	7.29
VAT Reclaim	-1.77	-1.40
Total Gross Project Cost	74.56	78.76
Optimism Bias	15.59	16.37
Total Gross Overall Cost Estimate	90.15	95.14

Executive Summary Table 6: Capital Costs for the Preferred Way Forward

MTX Contracts, a UK specialist in modular healthcare construction has provided the cost estimates that have been used for the modular option.

The £/m² rates for the traditional option can be benchmarked against the building cost information service (BCIS) average prices range results and compares similarly with the rates shown between the upper quartile and highest range for the new build and rehabilitation / conversion categories.

During the next stage further work will be completed regarding the Stem Cell Processing Unit element of works required for JACIE accreditation. A further investment will be required for this element of the works.

Depreciation and Impairment

Impairment will be calculated based on advice from the District Valuer. The asset value post impairment will be depreciated over the estimates useful economic life provided by the District Valuer.

The SOC assumes that the impairment charge will be funded by Welsh Government.

The total impact of impairment by year until the planned opening of the redeveloped accommodation will be included at the next stage.

Revenue Costs

There will be some additional revenue implications associated with main critical staffing infrastructure gaps identified by the JACIE inspection and a revenue case is being prepared by the Health Board for submission to the commissioners (NWJCC).

Overall Affordability

The anticipated capital spend, capital charges and depreciation profile for the project will be included at the next stage. All assets will be shown on the Health Board's balance sheet.

The asset will be valued on completion and recorded on the balance sheet at that value. Subsequently it will be treated as per the Health Board's capital accounting policy.

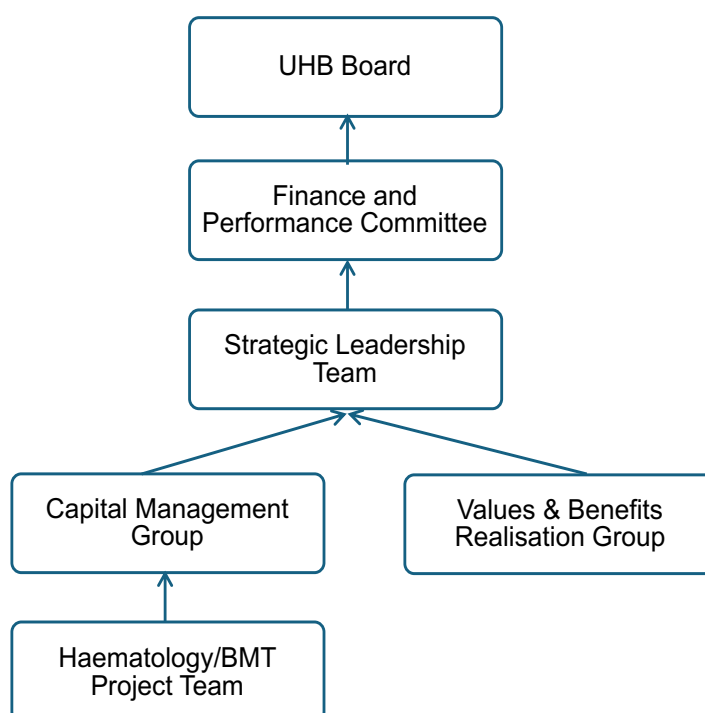
As highlighted above, it is assumed the impairment and recurrent charges for depreciation will be funded by WG and that revenue requirements associated with staffing infrastructure will be funded by the commissioners (NWJCC) through the established IMTP development route.

Further analysis regarding revenue funding and overall affordability will be undertaken at the next stage.

1.6 Management Case

Robust project management arrangements are vital to ensure the implementation of the overall project, and that effective control is maintained over the capital scheme.

The organisation and the reporting structure for the project is shown as follows:



Executive Summary Figure 3: Project Reporting Structure

Key project roles and responsibilities include:

Investment Decision Maker	CVUHB Board
Senior Responsible Owner	Director of Operations, Specialist Services Clinical Board, Jessica Castle
Project Director	Director of Capital, Estates and Facilities, Geoff Walsh

Executive Summary Table 7: Project Roles and Responsibilities

The purpose of the project team is to manage and co-ordinate, within the parameters set by the project board. The project team is responsible for the preparation of the strategic outline case for the project, which sets out the case for the proposed service and capital implications, providing then, additional supporting cases comprising the relevant other economic, commercial, financial and management information for the ongoing development.

The development of this project will also be supported by a range of corporate departments from within the Health Board including:

- Capital Planning
- Finance
- Strategic Clinical Engagement
- Workforce
- IM&T

Outline Project Plan

The dates detailed below highlight the proposed key milestones of the project:

Milestone Activity	Traditional Construction Date	Modular Construction Date
SOC submission to WG	June 2026	June 2026
Commencement of works	January 2028	May 2028
Construction completion	June 2029	October 2029

Executive Summary Table 8: Initial Project Plan

It must be noted however that the above milestones are subject to the Wesh Government business case approvals process.

Benefits Realisation and Risk Management

Benefits are anticipated when a change is conceived and there are measurable improvements that result from the outcome which is perceived as an advantage by the organisation and/or stakeholders. Benefit management and realisation therefore aim to identify, define, track, realise and optimise benefits within and beyond the project. A benefits realisation plan will be established during the development of the OBC and Full Business

Case (FBC) moving forwards and will provide a framework for this aim and will be overseen by the project board.

The risk management strategy for the scheme has been integrated into the project management procedures, with responsibility for implementation of the strategy resting with the project director. A project risk register has also been established and is subject to review and update on a regular basis.

Post Project Evaluation

The Health Board is committed to ensuring that a thorough and robust post-project evaluation (PPE) is undertaken at key stages in the process to ensure that positive lessons can be learnt from the project. The Health Board has identified a plan for undertaking post-PPE in line with current guidance, which is fully embedded in the project management arrangements of the project.

All processes will be managed by the project team and endorsed by the appropriate boards.

1.7 Recommendation

Failure to achieve business case approval at this stage would severely impact patients from across South Wales and those eligible as part of the SWBMT Programme. The Health Board would need to engage with NHS Wales Joint Commissioning Committee to decommission the Blood and Marrow Transplantation service provided by Cardiff and Vale UHB and commission activity from NHS England instead. This will inevitably lead to increased overall costs for NHS Wales and a poorer experience for patients from across South Wales who currently access these services in Wales.

This business case presents a compelling case for change for the development of a new build and the refurbishment of existing areas adjacent to Tower Block 2 at UHW for haematology inpatients in order to improve the physical and environmental facilities required to support the service and to ensure continued JACIE accreditation and the Health Board therefore recommends that WG approve this project business case in order to proceed to the next stage and to demonstrate steps are being made to support all standards and regulations associated with the service.