Transforming Access to Medicines Programme

South East Wales Hub Project

Outline Business Case

Change Control

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Approval Status

Body	Nature of Approval	Version	Date	Status
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Preface

The Transforming Access to Medicines (TRAMs) Programme was established in June 2021 following approval of the Programme Business Case (PBC) version 1.2 by the Shared Services Partnership Committee (SSPC) in January 2021, and Endorsement by the Cabinet Secretary for Health and Social Care, in March 2021.

Within the TRAMs Programme, a Project was established to select sites, prepare Business Cases and deliver the investment required in a Medicines Preparation Hub for South East Wales. Other projects within the Programme deal with Organisational Change, Education and Training, and Digital Systems, and the Programme is taking a national approach to developing its Supply Model and Scope of Service. The programme is transformational in terms of the delivery and workforce model for preparation of medicines in NHS Wales, and the provision of new capital facilities are only one aspect of the change.

In November 2023 Welsh Government directed that separate Business Cases were to be prepared for Radiopharmacy in South East Wales, due to the cessation of the service provided through Cardiff & Vale UHB, and for other aseptic injectable medicines in South East Wales. Subsequent to that an investment was approved for the Radiopharmacy for South East Wales, and this facility is currently being constructed. Concept Design for the remainder of the South East Wales Hub was funded at the same time as the Radiopharmacy, and this design work was completed to Royal Institute of British Architects (RIBA) Stage 02 by April 2024.

Over the winter of 2024/5 the project actively engaged with Health Board and Trust Finance and Pharmacy leads to define certain key aspects related to Scope of Service, Operational Pharmacy Supply Model, and Revenue Funding. On 15 March 2025 the members of the Finance Reference Group recognised in principle the methodology of a funding model as representative of the “Fair Shares” principle. For transparency this also set out the Velindre University NHS Trust commissioning shares that relate to the hub. The associated Scope of Service and Operational Pharmacy Supply Model has also been recognised by a reference group consisting of key service stakeholders, and the Directors of Pharmacy of the respective organisations.

The resources, equipment, and workload of the South East Hub as declared in this OBC currently does not include the preparation of materials for aseptic clinical trials. The Project Team need to evaluate and propose the future delivery model for aseptic preparation of clinical trials for South East Wales. This needs to be developed in partnership with Health Boards, Trusts and HCRW, recognising the considerable opportunity they represent and the ambition of the clinical services in this regard. Identified resources connected to clinical trials need to be added to the South East Hub Case at the FBC stage. Alternatively, a separate provision for preparing materials for clinical trials could be made in a separate Business Case within the TRAMs Programme, or elsewhere, once the best way forward for clinical trials is determined though this must align to the FBC timeline. Whilst clinical trials remain in scope for the South East Hub portfolio the workload and resources within this OBC does not consider clinical trials which represent 1.4% of the total current product output from the South East Hub acknowledging the ambition to grow clinical trials hosting in Wales. However, there is a need to determine a sustainable and regulatory compliant model for clinical trials provision, managing the current production risks relating to the NHS estate, given the increasing regulatory requirements, aging infrastructure, increasing complexity, short shelf lives of trials materials, and the distance of the hub from trials sites.

This Outline Business Case combines the estates deliverables from the concept stage with the revenue funding model and associated Service Scope and Operational Pharmacy Supply Model, so that the case as a whole can be formally approved via the mechanism of the Shared Services Partnership Committee (SSPC).

It is recognised that because the proposal involves a commitment in principle to a transfer of service and potential transfer of staff between NHS Organisations in Wales, and a commitment in principle to revenue funding of the new service, then the Health Boards and Trust impacted by the change will need to follow their own standing orders and governance processes in assessing how to review and consider this paper, in order that their own representative on SSPC can be empowered to approve it on their behalf.

The capital funding for the project is being sought directly from Welsh Government, and no capital or infrastructure approvals are being sought from SSPC members from their own capital allocations.

The following are **not included in this OBC**, and are or will be subject to separate approvals:

1. **South East Radiopharmacy** investment, which was subject to a separate Business Justification Case, which was approved by SSPC in July 2024.
2. **Classical Manufacture**, which remains part of Programme scope, and may in future be subject to separate Business Cases within the TRAMs Programme.
3. **Final Approval of Transfer of Service** including the transfer date, the number of staff to transfer, and any other impacts arising from the Organisational Change Process. Approval for these will be sought from the impacted organisations once these impacts are known, after the Organisational Change Consultation, and before the proposed transfer takes place.
4. **Final amount of the budget contributions** – This paper is based on Financial Actuals from the 2023/2024 financial year. Once the date of service transfer is known, the budget contributions will be recalculated using up to date actuals, in accordance with the methodology and principles requested for approval in this paper. This paper therefore asks for approval in principle of the method of calculation, and the figures provided are for illustration of that method.
5. **Clinical Trials -** An appropriate approach is being developed with key stakeholders to take into account their requirements with regard to clinical trials which may need to be delivered outside of the hub setting .

Executive Summary

The proposed Scope of Service constitutes a Technical and Professional Service, which falls within the competency of NWSSP to deliver.

The South East Wales Hub Project Board, the TRAMS Programme Board, and the Shared Services Partnership Committee are sequentially requested to **approve** the following:

1. That the concept designs for 15 Aseptic Isolators in 5 Classified Production Cleanrooms meet the service scope, and that investment should be sought from Welsh Government on that basis.
2. That in the event of Welsh Government funding the build of the TRAMS South East Wales Hub, with this scope, the Health Boards and Trusts will fund the revenue costs of the associated service on a "Fair Shares" basis according to the shares set out in table 4.5 and mechanism set out within Section 4.4 of this paper.
3. That once the service opens the participating Health Boards and Trust will purchase medicine in accordance with the Scope of Service contained in Appendix 2 of this paper, and as may be updated and modified to meet the needs of the service through the stated change control mechanisms.

The participating members of SSPC are further requested to take the necessary actions within their own organisation, to satisfy their own organisation's standing orders in respect of these approvals, such that they empower their representative to approve on behalf of their organisation, when SSPC meets.

Investment of £19.1m in a medicine's preparation facility in the IP5 Warehouse in Newport is sought from Welsh Government, without impact on the capital allocations of the member organisations of SSPC.

Future approvals will be sought at a later date in the form of:

- A **Full Business Case** combining the Revenue and Capital aspects of the proposal. This will be done once the detailed design has been completed to RIBA Stage 4.
- **Transfer of Service** Papers for each organisation, once the number of staff and date of transfer are known, which will be after OCP consultation has been carried out, and the site build is sufficiently advanced to confirm the transfer dates.

Executive Summary of Risk

On reviewing version 1.0 of this Outline Business Case, the regional stakeholder organisations (ABUHB, CAVUHB, CTMUHB, VUNHST) identified the following risks, and it has been agreed with the Project Team that these will be addressed within the Full Business Case, having been assessed, quantified, and mitigations designed by the Project Team, working in close partnership with the Health Boards and Trusts:

- **Retained Staff Risk**. The regional stakeholder organisations will all need to retain some staff on a planned basis, to order and receipt the product. This cost is currently not visible within the Economic Case. Initial estimates give a cost range (depending on how many staff are retained on each site) of between £1.1m - £1.6m for this cost. Further work is needed to validate and confirm what the cost will be, based on process design around the new digital system which will support ordering, and development of how each product will be ordered, received, and dispensed. This work will be carried out in partnership before FBC, and the outcome included in the Economic Case.

- **Residual Cost Risk.** The regional stakeholders will have the responsibility after service transfer to identify and eliminate costs associated with delivering the old service. Depending on how successful they are in doing this there may be elements of 'residual cost' that remain for a time and offset the benefits of the case until they can be resolved. In particular:

    - **Residual staff cost.** If some of the staff identified as in scope to transfer do not in fact move, and cannot be matched with either revised clinical or dispensary roles that are funded within their department, then there may be a cost pressure until these staff can be redeployed, or seek alternative employment themselves. The organisations will work in partnership with the Project Team to quantify this risk (what the estimated exposure is for each organisation) and review the Workforce Principles document to identify and optimise mitigations, which will be included within the FBC.

    - **Residual non pay cost.** This may relate to estate or service and maintenance costs that for contractual or other reasons cannot be 'turned off' immediately after the selected transfer date.

- **Evolution of the Baseline** from 2023/24 to 2024/25. The OBC is currently baselined on 2023/24 revenue figures. For the FBC the baseline will be rolled forward to 2024/25. If there were significant changes in any organisation in either the procurement of medicines or the staffing establishments, then these will need to be incorporated in the economic and financial cases. Depending on what is found, there may be an impact on benefits, including financial benefits.

- **Materials for Clinical Trial.** Further work is needed to identify the way forward for preparing materials for clinical trials, and potential synergies with the preparation of other Advanced Therapies, which although not in project scope, have similar requirements. Depending on the solutions proposed, and the funding model from Trials income, there is a potential for a cost impact on the case. This work needs to be completed and included in the FBC, and a working group is in place to undertake it.

All of the above risks have the potential to either add cost or undermine the benefits of the case, if not properly analysed and mitigated. There is one over-arching risk that acts in the counter direction:

- The Risk of not proceeding is that the NHS in Wales may become **unable to supply Anti-Cancer medicine to our patients**, impacting the time to treatment, and driving further cost into the service as we seek alternatives and mitigations for that. As established in the Programme Business Case improved quality and resilience are essential, and the operating environment has deteriorated significantly since the case was endorsed by the Cabinet Secretary for Health in March 2021.

This strategic risk needs to be borne in mind above all, and on that basis we recommend the Health Boards and Trusts to **approve** the case, to enable development work on the FBC to proceed.

1. Strategic Case

1.1 Strategic Context

The strategic context is as set out in the TRAMs Programme Business Case (PBC) v1.2, which has been approved by the Shared Services Partnership Committee and Endorsed by the Cabinet Secretary for Health and Social Care in March 2021

1.1.1 Patient Context

Pharmacy Technical Services are a Professional and Technical service that supports patient care by Health Boards and the Trust. From a strategic point this is a national service of which the South East Hub is only part of the intended overall service for the following areas of scope:

- Preparation of Injectable Systemic Anti-Cancer Therapy (SACT)
- Preparation of Intravenous Parenteral Nutrition (PN)
- Preparation of other Injectable Medicines (other CIVA)
- Expertise in Quality Assurance including testing and verifying medical gases

Accepted as a speciality within the pharmacy service, Technical Services are responsible for the development, preparation and supply of bespoke patient-centred medicines. This is undertaken in collaboration with traditional patient-facing clinical roles to ensure safe and efficacious medicines are supplied. As a collaborative partnership the clinician and clinical pharmacist provide therapeutic decision making and clinical verification of prescribed medicines, whilst technical services provide the requested medicines in a presentation verified to be of the highest quality and safety. This relationship provides clear delineation with regard to the clinical and technical responsibilities in relation to patient care. All clinical decisions with regard to patients will be made by an approved prescriber at the Health Board or Trust.

1.1.2 Professional Context

The traditional organisation has placed Technical Services within the Pharmaceutical Profession. The overall responsibility for medicines management and medicines safety in each Health Board and Trust lies with the Chief Pharmacist (or Director of Medicines Management or Directors of Pharmacy Services), and Technical Services lies within their professional responsibility. This is true even where the operations management responsibility sits elsewhere. For instance, Radiopharmacies report to Nuclear Medicine in some Health Boards, but the Professional responsibility for their medicine's preparation work remains with the Chief Pharmacist. Where local resource and capacity restraints require, some technical services products are outsourced from commercial suppliers. In this case the Chief Pharmacist (delegating to their staff), exercises their responsibilities as a responsible buyer, considering the MHRA License of the supplier to indicate the quality of the product.

While the contractual right of the buyer to audit the supplier's Quality System and procedures exists, it is in practice rarely exercised, both through the reluctance of commercial organisations to admit outsiders to their premises, and the absence of NHS resource to carry out such audits. Usually, the first notice of any problem with a supplier, is when the MHRA regulator imposes a constraint on their ability to supply. As noted in the case studies below, these unexpected constraints can have serious patient impacts.

There is a need for Technical Services to re-design its workforce to increasingly focus on recruiting and developing people with the necessary skill sets for Technical Services roles. This will move some recruitment away from Pharmacy professionals where legislation permits. The current training strategy for Pharmacy professionals is shifting to more patient facing roles, therefore, appropriate training programmes and qualifications will need to be developed, working in partnership with HEIW, to support this re-design of the workforce. Pharmacy professionals where appropriate should still have the opportunity to train and work in Technical Services roles.

Pharmacy Technical Services can be undertaken within an organisation under two distinct mechanisms.

1. Services operating under **Section 10 Exemption** of the Medicines Act 1968 are the responsibility of the Director of Pharmacy Services (previously known as Chief Pharmacist) and the Accountable Pharmacist, as these services lie within the Medicines Management portfolio. Where local Service capacity constraints apply, organisations can engage with commercial suppliers to procure outsourced items for patient supply. It is the responsibility of the Director of Pharmacy Services and Accountable Pharmacist to ensure suppliers adhere to regulatory licences and adherence to Good Manufacturing Practice (GMP). However, the Sec 10 ordering model of small quantities with short shelf lives leads to reactive management of quality issues, which can result in medicine shortages and a poor patient experience.
2. Alternatively Technical Services can operate under an **MS (Specials) license** issued by the Medicines and Healthcare products Regulatory Agency (MHRA). While this requires external inspections and imposes certain conditions on how the facility can be run, it also allows a wider range of staff to be recruited and employed, and for longer shelf lives to be assigned to the manufactured product. It also allows routine supply of product across organisational boundaries, and manufacture of product in batches in advance, not just for specific named patients.

1.1.3 Legislative framework

Below is a list of the core legal and professional standards that govern Pharmacy Technical services:

- Medicines Act 1968 – https://www.legislation.gov.uk/ukpga/1968/67
- Human Medicines Regulations 2012 – http://www.legislation.gov.uk/uksi/2012/1916/contents/made
- Misuse of Drugs Act 1971 – https://www.legislation.gov.uk/ukpga/1971/38/contents
- The supply of Unlicensed Medicinal Products (“Specials”) MHRA Guidance Note 14 – https://www.gov.uk/government/publications/supply-unlicensed-medicinal-products-specials
- Quality Assurance of Aseptic Preparation: Professional Standards 2016 – https://www.rpharms.com/Portals/0/RPS%20document%20library/Open%20access/Professional%20standards/Quality%20Assurance%20of%20Aseptic%20Preparation%20Services%20%28QAAPS%29/rps---qaaps-standards-document.pdf
- The Royal Pharmaceutical Society document for the Professional Standards for Hospital Services – Optimising patient outcomes from Medicine (England, Scotland and Wales) Version 3 December 2017 – https://www.rpharms.com/Portals/0/RPS%20document%20library/Open%20access/Professional%20standards/Professional%20standards%20for%20Hospital%20pharmacy/Hospital%20Standards-2017.pdf?ver=2017-12-21-132808-697

- **Duty of Quality** in Healthcare – introduced by the Health and Social Care (Quality and Engagement) (Wales) Act 2020, and Statutory Guidance 2023.
- **Wellbeing of Future Generations** Act 2015 – Places a duty on organisations to consider the long-term consequences of their investment decisions.

The resource requirements of maintaining compliance with these regulations, in the form of a Pharmaceutical Quality System (PQS) are ever increasing. The replication of multiple PQS across each hospital and organisation in Wales, while undoubtedly beneficial to patient safety, is an ever increasing administrative and financial burden on the service, and the service consequently needs to explore cost effective options for achieving the necessary standards

1.1.4 Regulatory agencies

The external inspection and audit requirement will depend on the specialist services provided from each site:

- Internal audit (NHS audit) WHC 2024/004 Sterile Preparation of Medicine in NHS Wales of Section 10 Units - https://www.gov.wales/sterile-preparation-medicine-nhs-wales-whc2024004
- General Pharmaceutical Council (GPhC)– if the Health Board or Trust has Registered Premises
- Medicines and Healthcare products Regulatory Agency (MHRA) – if the hospital holds a Manufacturing Licence (MIA), Specials Licence (MS) or Wholesaler Dealer Authorisation (WDA)
- Home Office – if Controlled drugs are supplied under a WDA.
- Health & Safety Executive for radiation safety (IRR & IRMER)
- Natural Resources Wales for environmental considerations including waste management
- Transport Regulations (Carriage of Dangerous Goods 2009)

All inspection visits require a significant evidential portfolio of compliance to the regulatory requirements and standards. The service needs to consider whether there is an opportunity to deliver fully compliant and high-quality medicines and associated pharmacy services in a more efficient and sustainable way with a strategic service redesign approach.

1.2 Strategic Case for Change

The underlying justification for the TRAMs Programme is based on service risks currently held within the existing Pharmacy Technical Services operated by the Health Boards and Trusts.

Mitigation of these risks is at the heart of the TRAMs Programme, and the proposed investment should be seen in the light that Business as Usual of each organisation seeking to mitigate its risks separately is not a sustainable option for any of the participating organisations.

The current service risks can be categorised as follows:

1.2.1 Rising Demand for Medicine

There is a rising trend in demand for all medicines, but in particular for Systemic Anti-Cancer Therapies (SACT), which before COVID (up to 2020) was increasing at 6% p/a, year on year. The demand for patient doses is driven by increasing numbers of patients presenting with cancer indications, and the expanding indications for use of existing therapies. Since 2020 the rate of growth is increasing with Welsh Cancer

Network and local aseptic services data suggesting **11% per annum increase**. These run rates continue to be monitored and will be updated in the FBC based on 2024/5 data.

The challenge to all the Health Boards and Trusts in Wales is how to meet this demand, which can be expected to continue increasing year on year. Sensitivity analysis within this paper will use the range of between 6% and 15% p/a for growth in demand for SACT, with the median of 11% growth being used in the core analysis. The current 'Business as Usual' product supply model lacks the capacity to grow to meet this demand and is evidenced by the quality reporting of local unit capacity from SE services into the National Lead for Pharmacy Quality Assurance. This results in a significant reliance on outsourcing to meet growth. In a number of Health Boards and Trust the service capacity is already fully committed, and it is anticipated that by the end of 26/27 service capacity will be reached nationally and that any future demand without service investment will need to be met by commercial suppliers, at a premium cost and with no certainty of ability to supply.

Meeting this projected demand growth, which is already causing challenges to the service today, is the key issue which this Business Case seeks to address. Put simply, if we cannot source sufficient cancer medication, then we will not be able to treat our patients.

1.2.2 Facilities

Facilities for Pharmacy Technical Services require replacement for a variety of reasons. Some are in poor structural condition due to age, some have electrical and mechanical defects, some have layouts that prevent them from complying with Quality and Regulatory standards. Some have already closed during the life of this project. As of April 2025, the position is as follows:

Site	Organisation	Products made	Regulatory model	Status
University Hospital Llandough	CAVUHB	SACT and other CIVAs	MHRA MS Specials & Sec 10 Exemption	Poor structural and M&E condition, due to close in 2025.
St Mary's Pharmaceutical Unit	CAVUHB	SACT and PN	Sec 10 Exemption	Poor layout, M&E deteriorating, water ingress
Royal Gwent Hospital	ABUHB	SACT	Sec 10 Exemption	Constrained by size
Royal Glamorgan Hospital	CTMUHB	SACT	Sec 10 Exemption	Poor layout, M&E deteriorating
Velindre Cancer Centre	VUNHST	SACT	Sec 10 Exemption	Constrained by size and capacity plan. Site due for closure. Plan to re-provide at same scale and capacity.
IP5 Medicines Unit	NWSSP	CIVAs	MHRA MS Specials	Constrained by capacity, no air extract for handling cytotoxic products

Overall, there are 21 isolators or work stations nominally available in existing units for preparing the products that are in scope. Each unit has a formal capacity plan as part of their quality and regulatory documentation, limiting the amount of medicine they can safely produce.

Existing plans and re-investments to address fabric or regulatory challenges make no change to staffing or the Operational Pharmacy Supply Model and will lead to no increase in capacity.

1.2.3 Staffing resilience

Each of the six facilities are separately managed and each must fill certain key roles with highly skilled highly graded staff (Typically band 8B), just in order to stay open. Each of these roles represents a single point of staffing fragility, and the pool available to cover within each organisation is very small. Where the Sec 10 Exemption is used it is limited only to certain Pharmacists and Pharmacy Technicians with relevant professional experience. The production staffing in each unit is equally fragile with small teams which become unable to manufacture if just one or two key personnel are absent.

1.2.4 Staffing Skill Mix

The project has undertaken resource mapping of the existing service in partnership with Health Boards and Trusts, in order to understand the existing staffing models. As a result of the resilience challenge outlined above, the teams become 'top heavy' in terms of grading, with high graded staff who need to be present for the facility to be open, actually spending large amounts of their time doing tasks that lower graded staff should do, just to balance out their working days and keep the unit's operating.

In terms of education and training the Pharmacy Profession is no longer producing Pharmacists or Pharmacy Technicians with the skills and experience to operate a Sec 10 Technical Services Unit. If no action is taken to broaden the scope of recruitment to include Health Scientists and Technicians, then the existing staffing construct will in time fail. This proposal has the "future proofing" of the appropriate staffing model at its core.

1.2.5 Outsourced Supply

The service across South East Wales has a heavy reliance on outsourced suppliers to supplement its in house manufacturing capacity.

Table 1.1 Percentage of Outsourced Supply, 2023/2024 data

	ABUHB	CAVUHB	CTMUHB	VUNHST	SOUTH EAST
Total Items Supplied	16,643	30,776	11,887	37,381	96,687
Medicines Made	7,196 (43%)	20,266 (65%)	3,157 (27%)	21,054 (56%)	51,633 (53%)
Medicines Outsourced	9,447 (57%)	10,510 (35%)	8,730 (73%)	16,327 (44%)	45,014 (47%)
Total Cost (£'000)	2,493	4,236	5,763	23,783	36,275
Medicines Made (£'000)	2,003	3,815	1,557	12,518	19.893
Medicines Outsourced (£'000)	490	421	4,206	11,265	16,382

The main outsource suppliers are:

- Bath ASU
- ITH Pharma
- Baxter
- Quantum Aseptic

In terms of cost exposure, the recent (24/25) All Wales Contract prices for Aseptic Medicine have been compared with the full costs of in-house production. Analysis on the products outsourced to commercial suppliers across Wales for the baseline 23/24 year indicate that with the adoption of efficient practices, utilisation of semi-automated processes, and the manufacture of campaigns/batches where shelf life allows, products can be manufactured on average 18% cheaper across Wales than commercial suppliers (20% cheaper if looking at South East Wales alone). This differential represents the commercial suppliers' overhead recovery, cost of capital and profit margins. The percentages above are an average, and sometimes the individual outsourced product can still be cheaper. The "make or buy" decision needs to be made in an agile way in response to market conditions and should ideally be done "Once for Wales" rather than repeated in each individual organisation or site procurement team.

There are several issues with reliance on these suppliers including:

- Issues with the quality of the product, with only a percentage being quality checked before leaving the supplier.
- Short notice inability to supply orders, resulting in poor patient experience, potential cancellation, or preparation within the local aseptic unit with little notice increasing risk of errors. The project is keeping a log of reported manufacturing errors by commercial suppliers, which will be used as a baseline for benefits measurement in the future.
- Cumulative effect of the cost of outsourcing compared to manufacture in house by the NHS.
- Suppliers selectively identifying products to manufacture based on profitability, therefore cannot be relied on to supply the products in demand if not part of profitability model.

With the anticipated trend growth of 11% p/a in SACT there remains serious doubt that the growth in the outsourced supply market will keep pace with demand. Unless the NHS also develops its capacity to manufacture, we risk being unable to source key products at critical times, the outcome being a poor patient experience and or delay in treatment with potentially life-threatening complications.

1.2.6 Regulatory

Supply of aseptically prepared medicines within the South East is subject to varying regulatory mechanisms specific to whether products are supplied under Section 10 Exemption of the Medicines Act 1968 or an MHRA "Specials" Licence. Regulatory guidance and standards, irrespective of regulatory mechanism, are constantly updated and developed to ensure that patients receive only the highest quality medicines. Services have a legal responsibility to these standards to ensure adherence to Good Manufacturing Practice, essential for patient safety. Regulatory requirements are evolving to require:

- Stringent requirements in relation to facilities design and utilisation.
- Increasing demands for physical and environmental monitoring of facilities
- An extensive programme of ongoing validation of people, process and equipment
- Regulatory cap on manufacturing capacity utilisation for the output of products

- Increasing minimum dedicated time requirements associated with setting up and operating the Pharmaceutical Quality System (PQS)

Although subject to different regulatory mechanisms both the Sec 10 Units and the MHRA Licensed Units are subject to ever increasing regulatory pressures, which have a common cause: the desire to mitigate risk to patients from contamination or errors with medicine.

This expresses itself through:

- Ever increasing requirements to validate equipment, processes, and people
- Ever more stringent requirements for layout, separation, and space
- Ever more demanding requirements for air plant, monitoring, recording, and review

The net effect of these regulatory demands are to place a functional ceiling on compliance in situations where:

- Physical site constraints in the existing service prevent addressing layout concerns, there is a lack of space for the creation of additional lobbies, rooms, and functional classified spaces
- Increasing the minimum viable size of a team, to cover separation of production and quality assurance roles, and to address the increasing requirement for quality management needed to support safe manufacture

Unless addressed these issues inevitably lead to unit closure, even where there is no accompanying issue of deteriorating or life expired fabric to be addressed.

It is important to emphasise that none of the existing units fully comply with the MHRA Annexe 1 and so cannot be licensed for MS Specials in their present condition. Addressing these issues just in the South East region will also add to national resilience, as the same issues of fragility and sustainability of the service are present nationally, and will be addressed by future cases within the Programme.

1.2.7 Product Supply Model

All of the factors above combine to make the current product supply model unsustainable.

The current supply model within the South East is based on traditional manual drawing up of injectable medicines on receipt of a prescription, for a specific patient, commonly to be delivered and injected the same day or the next. This is undertaken under Section 10 Exemption of the Medicines Act 1968. This Exemption places stringent controls on when and how medicines can be prepared and supplied. These are summarised below:

- Products must use sterile licensed starting materials only
- Preparation must only use “closed systems”
- Must occur under the supervision of an Accountable Pharmacist
- Finished products must have a **maximum of 8 days shelf life**
- Preparation must be carried out under NHS Standards as detailed in the Quality Assurance of Aseptic Preparation Services Handbook

In light of the regulatory and supply model pressures the local models of patient supply are driven by staffing, regulatory Section 10 Exemption restrictions and demand volume which drives increasing reliance on the commercial sector.

Staffing challenges within the South East services have multiple impacts on the model of supply. Quality data submitted to the National Lead for Pharmacy Quality Assurance via the iQAAPS reporting tool highlight services are frequently over the regulatory compliant cap on manufacturing/preparation capacity utilisation. The consequence of this is that less time is dedicated towards quality management activities that are essential for assurance of patient safety. Given the previously highlighted facilities restraints and the resultant inability to significantly grow the workforce, services are driven to engage the commercial sector for supply, increasing the costs of patient supply whilst reducing the quality of service and patient experience.

The decentralised nature of current aseptic services is not in line with the principles of prudent healthcare. The small quantities of medicines required locally do not allow batch or campaign manufacturing that reduce waste, the capped shelf life prevents forward planning and stock management, and by operating under Section 10 demand across organisations cannot be combined.

These issues were highlighted in the report by Lord Carter of Coles [Review of Operational Productivity in NHS Providers 2015], in which he recommended that Technical Services is among those services best consolidated at a regional level. There are several regional programmes currently underway across NHS England providing a similar solution to Aseptic services as is being proposed in our OBC

1.3 Spending Objectives

The main spending objectives, aligned to the PBC, are as follows:

- **Regulatory compliant provision of unlicenced medicines:** Supply of medicines from regulatory compliant MHRA licenced services will result in improved quality and safety. The creation of a suitable workforce model and "quality by design" manufacturing processes will ensure that regulatory compliance and patient safety is prioritised.
- **Service Continuity** – The manufacturing hub is designed to ensure there is resilience in both staffing and facilities to minimise supply chain issues inherent in commercial outsourced services. As an MHRA "Specials" manufacturer the service can provide extended shelf-life products, manufactured in batched to maximise resource utilisation and allow storage at stakeholder sites, closer to patients to facilitate agile supply.
- **Meeting Demand Growth –** Current demand growth for aseptic products is at 11%, meaning that by 25/26 current services within Wales will have reached capacity and rely solely on commercial providers for unlicenced aseptic medicines. The service model within this business case ensures we can meet the rising demand, in particular for Systemic Anti-Cancer Therapies (SACT), by providing a resilient workforce, regulatory compliant facilities capacity and by maximising the use of medicines.
- **Long Term sustainability -** especially of the staffing model, including skill mix, right grading, and ensuring a pipeline of future staff to key 'pinch point' roles. The current staffing model provides adequate resilience for approximately 5 years after hub opening and focuses investment on operational manufacturing staff.
- **Product Supply Model efficiency –** providing medicines from an MHRA licenced facility maximises the opportunity for benefits realisation. Centralised manufacture improves value and resource utilisation of medicines, offsetting potential medicines shortage issues, preserves capacity of the hub through modelling of medicines manufacturing schedules.

2. Economic Case

The Economic Case analyses the options that exist to address the issues identified in the Strategic Case, and analyses their costs and benefits, to identify a Preferred Way Forward.

2.1 Scope

The Scope as originally allocated to the South East Hub by the PBC included four elements:

- South East Radiopharmacy
- South East Aseptic Hub
- Wales Classical Manufacture
- Supporting Labs, Offices, Stores, and other ancillary spaces

An initial concept design cycle based on this Version 1 (V1) scope was carried out in 2021, with IP5 Warehouse as the emergent preferred site.

Based on the results of this work, Programme Board in 2022 authorised a refinement in Project Scope, with Classical Manufacturing being taken out of project scope, and retained at Programme Level for further review, which is ongoing.

In November 2023 Welsh Government requested Radiopharmacy for the South East be progressed in a separate Business Justification Case, which was approved by SSPC in July 2024, and for which the investment decision was made, and construction is ongoing.

The remaining project scope is therefore focussed on the Aseptic Preparation Hub, with a reduction in the overall square metres estimated for the project from the 5,000m2 studied in the first design cycle to 2,400m2, including ancillary spaces. This decision was based on considerations of value and affordability, in line with the overall Programme funding estimate endorsed in the PBC.

Because the regional product supply model was already selected as preferable by the PBC, site selection work has focussed around delivering this model. Accordingly, no sites have been selected, or site-specific capital costings developed, for reinvesting the Business-as-Usual Product Supply Model of separate provision by the Health Boards and Trusts. For the purposes of the Economic Case, a pro-rata re development cost has been assessed for BAU, and the process by which this was done is described below.

2.2 Critical Success Factors

The following critical success factors arise from both the Spending Objectives, and from the early survey and design work that has been completed in association with each candidate site:

- Location must be suitable for access for **logistic delivery** to the 9 major hospitals and cancer centres in South East Wales.
    - University Hospital Llandough
    - University Hospital Wales
    - Royal Gwent Hospital
    - Grange University Hospital
    - Nevill Hall Hospital
    - Royal Glamorgan Hospital

- Prince Charles Hospital
- Princess of Wales Hospital
- Velindre Cancer Centre

As a benchmark delivery times need to be kept **below 60 minutes** to these hospital sites. Practically this defines a locality centred along M4, between junctions 28 and 32, in order to meet the delivery constraint.

- The South East Hub site needs to be **accessible to existing staff.** Anonymised post code mapping has been carried out which reveals staff to be centred around Cardiff, Newport, and the South Wales valleys. Practically this drives the same locality constraint as logistic delivery for the central M4 corridor between J28 and J32. In the table 2.1 Summary site shortlist, below the two requirements are therefore combined.
- The site must have sufficient **electrical power** available. Many warehouse and office sites do not have the power margin available to accommodate air plant on the scale needed. Arising from the concept design cycle, a benchmark figure of 600KVA has been established for the Aseptic Hub cleanrooms.
- The site must have sufficient **indoor space** for the required clean room, storage areas, and production offices. This has been benchmarked as 2,400m2 for the purposes of site search.
- The site must have sufficient **outside space** for a service yard and car park. A benchmark figure of 3,000 sq metres of outside space has been used.
- Existing buildings must be in **good condition**, ideally not requiring major renewals or structural work. Subject to surveys, building life from 0-25 years is preferred.
- The site must have **vacant possession** and be otherwise ready to develop.
- The **commercial terms** must be acceptable
- **No other issues** including ecology, drainage, flood risk etc.

2.3 Site Search and Longlist

Site search was led by NWSSP Specialist Estates surveyors, and involved direct engagement both with land agents, and with other public sector bodies in South East Wales across an 18-month period from Jan 2022 – June 2023. A long list of sites was studied, and a selection workshop was held in May 2022 attended by key stakeholders from the service, which produced an initial long list. Since that date site research has continued and the long and short lists updated accordingly.

Longlisted sites analysed and discounted during the process included sites in

- Llanwern
- Port of Cardiff
- Newport Road Cardiff
- Merthyr Tydfil
- Adjacent to the Grange University Hospital

Reasons for discounting sites included: lack of sufficient power supply; insufficient space; inaccessible location for existing and future staff; unacceptable delivery time to major hospitals in the region.

2.3.1 Site Shortlist

Four sites were shortlisted, having been assessed as suitable to deliver the benefits assigned to the South East Hub under the PBC. Work on developing the benefits is reflected below. As these benefits are **not site specific**, they are not material to site selection.

The four sites shortlisted, are as follows:

Imperial Park Building 5 (IP5)

This building, for which NWSSP acquired in the name of VUHNST a 250-year lease in 2019, is a 30-year-old warehouse on the western edge of Newport, near Junction 28 of the M4.

The primary role of the building is as the NHS Wales National Distribution Centre. The 5,000 m2 at the eastern end of the building was initially allocated to TRAMS, and costings for the V1 scope were developed before development work was paused in November 2021. The site remains on the short list for the Scope V2, on which the Hub Design is now based. Around 2,400 sqm is now identified to the Hub concept design.

Office accommodation and lab space within the IP5 building have also been assigned to the TRAMS programme and have been developed and brought into use in a cost-effective way outside the scope of the South East Wales project, assisting with control of scope. This space will be retained regardless of which site is selected for the production facilities of the South East Wales Hub.

This site also enjoys an existing transport infrastructure as a main operating location for NHS Wales Health Courier Service, who have an existing expertise in medicines logistics connected to vaccine programmes and the NWSSP Medicines Unit.

Imperial Park Building 6 (IP6)

This site is adjacent to IP5 and is a new build opportunity. The park owner has indicated that he is prepared to assign the requested power margin as part of negotiating the new lease.

The site is offered as a straight lease for a bare warehouse which the owner proposes to build himself, for NHS led clean room fit out.

The size of the warehouse that the owner proposes to build is quoted as 50,000 square feet (4,671 m2).

The site is vacant and still available as at May 2025. As a square of mown grass on an active Business Park, it is not anticipated that there will be any issues of ecology or flooding to deal with, but surveys have not been commissioned.

Pioneer Coryton

This new build site in the Cardiff Edge Science Park appears suitable in principle and we negotiated actively to try and agree terms from July – December 2022. Although initially confident of success the park freeholder (Pioneer Group) was not able to secure vacant possession of the site. As such the decision was taken in February 2023 by the Programme SROs in consultation with Welsh Government not to proceed with site surveys.

The site owner talked positively about offering freehold transfer options as part of a lease agreement, but at the time of breaking off negotiations had not yet made a substantive offer. As such the indicative costings for this option are based on a straight lease.

Cytiva Coryton

This site is adjacent to Pioneer but has a different freeholder. The building, originally a warehouse and around 30 years old, was developed in 2021-2023 as a clean room facility by Cytiva, part of US based Danaher Group. In early 2023 due to a change of strategy by Danaher Group, the operation was closed and the staff made redundant.

The facility comprises of a complete set of clean rooms developed to ISO7 standard, which is aligned with the MHRA Grade C that our User Requirements demand, plus storage, staff support, and office areas. The clean rooms are however much larger than we would need and would have to be subdivided and reclassified in order to bring them into use, and to control operating cost. The facility would still need production equipment buying and commissioning, as well as clean room alterations, to meet our needs.

Negotiations took place with Danaher Group, and with the freeholder London Metric, from March to June 2023. London Metric were prepared in principle to sell the Freehold, but we were not able to agree terms with Danaher Group to assign the remaining 8 years of their lease. Accordingly, surveys of the site were not instructed. The main question to be resolved by surveys would be over the condition of the roof, which is the original one, but which was said to have been given a new covering with a 10-year guarantee in the 2022 refurbishment.

This site was the only freehold purchase option we had been able to identify for the shortlist but was effectively taken off the market by Danaher Group and cannot now be progressed.

Summary of Shortlist

The shortlisted sites were assessed against the Critical Success Factors with the outcomes summarised in the table below:

Table 2.1 Summary site shortlist

Site	Location	Power	Space	Condition	Vacant?	Commercial Terms
IP5 Newport	Yes	Yes	Yes	Roof	Stores	NWSSP long lease in place
IP6 Newport	Yes	Yes	Yes	New build	Yes	Lease discussed
Pioneer Coryton	Yes	Yes	Yes	New build	No	Lease discussed
Cytiva Coryton	Yes	Yes	Yes	Good tbc	No	No Longer available
Business As Usual	No sites studied					

Commentary on issues noted in the above table is as follows:

Power at IP5

The initial design cycle for IP5 raised concern over the power available to meet the requirements of the V1 Scope. In particular the requirement for electrically powered steam boilers for the Classical

Manufacturing Suite drove a high demand for power, which the site could not supply. When Programme Board removed the Classical Manufacturing suite from Project Scope (but retained it within the Programme for further review), this objection to the site was removed.

The power requirements for the V2 Scope were studied at the concept design phase and the Hub power requirement for 600KVA, can be met from the existing site margin as follows:

Table 2.2 Power at IP5

Usage	Power
Existing warehouse and vehicle charging	300KVA
Radiopharmacy per detail design to RIBA Stage 4	400KVA
Hub as per Concept Design to RIBA Stage 2	600KVA
Remaining Margin for growth and other projects	200KVA
Total for site	**1,500KVA**

(In addition, solar power developments on site are planned to mitigate the cost of power. But these do not impact on the maximum capacity required, which may be reached on a dark winter morning or evening when solar generation is zero.)

IP5 Newport: Condition: Roof

As part of the recent Radiopharmacy investment the roof over the whole TRAMs area, including the Hub development site, has been over clad with new panels. Work was completed in May 2025, and is now rated for a further 30 years, with a warranty from the roof system manufacturer

IP5 Newport: Vacant? Stores Rated Yellow

IP5 has been developed as NHS Wales National Distribution Centre. Development for TRAMs would now entail a reduction of pallet spaces for stores use and the dismantling and storing of 2-year-old racking. Liaison is ongoing to identify alternative locations for the stock and beneficial redeployment of the racking.

IP6 Newport: Commercial terms – Rated Yellow

No issues identified; no binding offer yet in place. Welsh Government directed that it was unlikely that a new lease would be approved, unless the already leased site at IP5 were categorically ruled out. Accordingly, no surveys were instructed.

Pioneer Coryton: Vacant? – Rated Red

This otherwise suitable site has an issue that part of it is leased to another tenant of the park. Although not currently in use by that tenant, the landlord has not been able to agree terms to secure vacant possession. In that circumstance, Programme Board chose not to proceed with surveys of the site, so there may be unknown factors associated with ecology, flood risk, etc.

Cytiva Coryton: Vacant?/Commercial terms – Rated Red

It has not been possible to agree commercially acceptable terms with Cytiva for the assignment of the remaining 8 years of their lease. In addition, they wish one of their group companies to remain as a sub tenant taking up around 10% of the building. This is acceptable in principle indeed it comes with

financial advantages to us, but Cytiva's proposed space allocation for them is not acceptable to us on operational and regulatory grounds. As such no fees have been expended on site surveys, leaving a question mark in particular over the roof, which is original at around 25 years of age.

The freeholder London Metric had indicated that they were prepared to sell us the freehold for a value we assessed as reasonable. However, the time taken to negotiate with Cytiva over the remaining 8 years of their lease, has led London Metric to accept in principle another offer for the freehold. The identity and intentions of the potential new freeholder are not known. There is however, limited value in pursing the freehold with anyone if terms with Cytiva to assign their lease cannot first be agreed.

2.4 Emergent Preferred Way Forward

Based on the above assessment against Critical Success Factors, and after discussion with Welsh Government Capital Team and Programme Board, two options are carried forward for Economic Assessment:

- The TRAMs Hub Option is IP5 Warehouse, Newport.
- The Business-as-Usual Option, for which no sites have been selected.

2.5 Economic & Financial Baseline

This section sets out the baseline financial position of how the NHS Organisations in the South East Region sourced and paid for the medicines that are in scope, during the financial year 2023/2024. The project continued to track costs, and these will be updated where appropriate in future iterations of the case.

The figures have been reviewed thoroughly by both members of the Pharmacy and Finance reference groups and recognised by them as an accurate representation of each organisation's position.

Table 2.3

Baseline Revenue Spend in Scope for the TrAMs Preferred Model – South East Wales Aseptic Services Only

Spend 2023/2024	ABUHB	CAVUHB	CTMUHB	VUNHST	NWSSP	Total
	£'000s	£'000s	£'000s	£'000s	£'000s	£'000s
Pay Costs	599	1,856	445	979	500	**4,379**
Non-Pay Costs	222	613	248	511	582	**2,176**
Medicines Made	2,003	3,815	1,557	12,518	-	**19,893**
Medicines Outsourced	490	421	4,206	11,265	-	**16,383**
Total	**3,314**	**6,706**	**6,456**	**25,273**	**1,082**	**42,830**

Notes to Table 2.3:

1. Agreed baseline financial year 2023/24, data provided by individual organisations via a spend questionnaire over three financial years.

2. The data is in relation to the South East Wales organisations only.
3. No inflation has been added to Non-Pay Costs.
4. Medicines data taken from Pharmacy Stock Management System (Careflow) for financial year 2023/24 and for Medicines within project scope.
5. Medicines split between made/manufactured in-house and outsourced from commercial provider.
6. Medicines made/manufactured in-house refers to medicines produced in the aseptic units of the organisations during 2023/24.

Supporting tables are contained in Appendix 1 covering:

- Baseline Medicines Cost
- Medicines breakdown by name
- Base Staff table by Pay Band
- Base Non-Pay Costs

2.5.1 Business As Usual

Table 2.4 below models projected revenue expenditure if each organisation continued to run its service separately, reinvesting its facilities to address fabric issues and mitigate regulatory pressure, but without addressing its staffing construct or product supply model based on the median 11% demand increase described in the Strategic Case for Change. The table also assumes that any investment in facilities is to maintain current business as usual capacity. Costs remain based in current rates to aid comparability.

Table 2.4

Revenue costs of Business as Usual with 11% demand growth

Business As Usual Scenario Spend	Base Year 23/24	24/25	25/26	26/27	27/28	28/29	29/30	30/31	31/32
	£'000s	£'000s	£'000s	£'000s	£'000s	£'000s	£'000s	£'000s	£'000s
Pay Costs (HB/T)	4,379	4,620	4,620	4,620	4,620	4,620	4,620	4,620	4,620
Non-Pay Costs (HB/T)	2,176	2,176	2,176	2,176	2,176	2,176	2,176	2,176	2,176
Medicines Made (HB/T capacity reached 25/26)	19,893	22,081	24,510	24,510	24,510	24,510	24,510	24,510	24,510
Additional Medicine Outsourcing (HB/T capacity reached 25/26)				2,696	5,689	9,011	12,698	16,791	21,334
On-Cost of Additional Medicine Outsourcing				554	1,170	1,853	2,612	3,453	4,388
Medicines Outsourced (Assume available growth capacity with Commercial Provider)	16,383	18,185	20,186	22,406	24,871	27,607	30,643	34,014	37,756
Total Revenue Spend	**42,830**	**47,062**	**51,491**	**56,962**	**63,035**	**69,775**	**77,258**	**85,563**	**94,782**

Notes to Table 2.4:

1. Pay cost projections for business as usual for South East organisations. There is no assumption of pay award from 2025/26 onwards.
2. Non-Pay cost projections. There is no inflation assumed.
3. Medicines made/manufactured in-house (aseptic services) until capacity has been reached at the South East units, currently estimated during 2025/26.
4. 2026/27 and onwards assume capacity reached at existing units and any further demand/growth would need to be met by outsourcing to commercial provider.
5. Additional outsourcing to commercial provider will incur an additional on-cost at an estimated premium of 20.567%.
6. Medicines outsourced to a commercial provider as in baseline year 23/24, continue to be outsourced with an 11% growth/demand expectation.

Table 2.4 above identifies the currently accepted scenario that BAU in-house capacity will be unable to meet demand by the end of 25/26. From this year onwards, demand increases can only be met by outsourcing to commercial suppliers, incurring commercial rate on-cost of those medicines (currently 20% for South East Wales). This assumes that commercial suppliers are able to absorb the demand increase.

It should be emphasised that this is not a "Do Nothing" scenario. Considerable capital investment would be needed to re-provide facilities, just to be able to "stand still" in service capacity terms.

Because the Programme Business Case has already selected the regional supply model as preferred, the project has not invested time and cost in selecting sites or preparing costings to recapitalise the Business-as-Usual service model.

For the purposes of the economic case, it is however necessary to estimate the capital cost of sustaining 5 separate manufacturing units and reinvesting in them. A pro-rata assessment has been made based on:

- The number of isolators or work stations in each unit, being the best indicator of productive capacity needed by the BAU Pharmacy Product Supply Model.
- The ratio of cleanroom and non-cleanroom square metres per isolator, as determined by the TRAMs Hub concept design. This is the best available indicator of the number of square metres required for modern and regulatory compliant design.
- The cost per square metre of the TRAMs Hub concept design.

Table 2.5

Comparison of Capital Costs Between Business as Usual or TrAMs South East Hub

Options	Service Model	Number of Isolators	Cleanroom Space (sq. m)	Developed Space (sq. m)	Capital Investment Net (£'000s)
Business As Usual	Existing	21	1,341	2,775	**22,679**
Preferred	TrAMs	15	958	1,982	**16,199**

A split of these costs per unit and per organisation is included in Appendix 1.

The aggregate capital cost of maintaining the Business-as-Usual supply model has been estimated by the project at £22.7m (plus VAT) over the next 5 years. We are not however aware of any viable alternative investment options being brought to maturity for this scenario, so whether the required capital could be invested in this timescale can be considered doubtful.

It should also be noted that the TRAMs Hub costing on which these pro-rata costs are developed does not include any provision for:

- Site acquisition (because a long lease is already in place)
- Building renovation (because the building has already been renovated under the SE Radiopharmacy case)
- Power reinforcement (because sufficient power is in place)
- Car Park or Yard works (because sufficient car parking and yard space exists)

It is therefore entirely possible that the costs of developing 5 actual sites for BAU could considerably exceed the estimate used in this analysis.

2.5.2 TRAMs Hub Option

This section models the revenue impact of the proposed service from the South East Wales Hub.

2.5.2.1 Capital Cost of the TRAMs Hub

The following table summarises the proposed costs of the TRAMs Hub investment:

Table 2.6

Capital Costs of the TRAMs Hub

	Capital Costs Net £'000s
Works Costs	**6,437**
Design Fees	699
Non-Works Costs	679
Equipment	6,271
Planning Contingencies	2,113
Sub Total	**16,199**
VAT	2,958
Total for Approval Purposes	**19,157**

Table 2.7

Capital Cashflow Requirements

	Capital Costs Cashflow Gross of Vat £'000s			
	2025/26	2026/27	2027/28	Total
Total Capital Cashflow	1,765	17,129	263	19,157

Further detail of the capital costs is available within the Estates Annexe.

2.5.3 Capacity and Staffing of the TRAMs Hub Option

South East Hub Staffing Establishment and Capacity Utilisation

In order to provide a skilled and sustainable workforce to deliver a regulatory compliant service to stakeholders, the TrAMS service must be staffed to meet the expected demand. With a view to the current Year 1 projected opening date of the South East Hub (27/28), the programme has identified a suitable staffing establishment (Reference Appendix 1).

Within this establishment is the necessary staff for delivery of operational, managerial and support services to deliver a compliant service that engages with stakeholders, develops staff and ensures regulatory compliance. The model also provides resilience in the staffing structure to meet current and future demand.

The calculation and validation of the staffing establishment within the OBC has been provided by undertaking an extensive review of the proposed product catalogue for Years 1-5 of the Hub operating and capacity utilisation this staffing establishment and product catalogue provides. This work was carried out by The TrAMS project team, with review by Pharmacy Reference Group, providing assurance that the approach is in line with current capacity assessment of current services and an acceptance that the capacity tool utilised in an accepted regulatory compliant method of capacity utilisation assessment. The product numbers have been projected forward as 11% annual growth from the baseline year 23/24.

The review has identified the types and numbers of products that will be made under the following categories.

- **Single item** "Specials" – Products with a low regional or national usage and shelf life of <96 hours.
- **Campaign Items** – Where regional or national use is >2 products per day at variable doses of the same medicine and there is a shelf life of <28 days.
- **Batch items** - where national or regional usage is high across several dose bands and the shelf life is >28 days.
- **Outsourced** – Products where there is no commercial value to manufacture when compared to commercial pricing.

Table 2.8 below highlights the breakdown of the above categories as a daily operating schedule within the South East Hub.

Table 2.8

Daily Output requirement in the first 3 years of operation

Manufacturing Type	27/28	28/29	29/30
SACT/Haem Batch	5 / day	5 / day	6 / day
SACT/Haem Campaign	13 / day	13 / day	13/ day
SACT Single Item	37 / day	41 / day	46 / day
CIVAS Batch	2 / day	2 / day	3 / day
CIVAS Campaign	2 / day	2 / day	2 / day
CIVAS Singles	4 / day	5 / day	5 / day
Compounded Parenteral Nutrition	31 / day	34 / day	37 / day
Neonatal Parenteral Nutrition Batch	1 / week	2 / week	3 / week
Outsourced Items	115 / day (As 6 transactions)	128 / day (As 6 Transactions)	142 / day (As 6 transactions)

The above data provides an example of an "average" daily manufacturing schedule within the hub for purposes of manufacturing capacity utilisation calculation. This is undertaken using the Pharmaceutical Aseptic Services Group capacity tool. This tool has been developed and approved by Heads of Pharmacy Technical Services, Production Leads and Regional/National Quality Assurance as a regulatory compliant method of calculating manufacturing capacity utilisation to demonstrate regulatory compliance and safe operating levels.

The tool assigns variable timings to different batch and campaigns depending on products made, with the timing data collected from around Wales as the benchmarked standard at present. Once the data in the table above has been populated into the capacity plan, we enter in the operational staffing numbers as whole-time equivalents available. Staff numbers entered were adjusted to remove time for Statutory & Mandatory training, annual leave and sickness plus time for quality management activities as is recommended in MHRA guidelines (Guidance Note 14 and Annexe 1).

For Year 1 the schedule above was calculated against the first-year staffing establishment and so on for the following two years. Years 4 & 5 capacity was calculated based on 11% growth but a steady state of staffing. Years 1 to 3 uplifting of staff was from 77 WTE in Year 1 to 98 WTE in Year 2 and 104 WTE in Year 3 ongoing.

The Capacity Utilisation of the TrAMS service is from Year 1 of operation is highlighted below

2.6 Repatriation of Outsourced Products

Whilst not a main driver for transformational change, there is a financial benefit to the repatriation of aseptic products into the South East Hub from the commercial suppliers.

This benefit can only be realised by increasing the capacity, contingency and model of provision of aseptic services within Wales. Current reporting from the Pharmacy Stock Management System (Careflow) identifies commercial suppliers of aseptic products and provides data on the medicines and doses ordered in response to aseptic unit capacity challenges as well as the unit price paid for each product.

To identify the cost to manufacture these items within the South East Hub, the project team have proposed a suitable method of manufacture (semi-automated or manual) for each product outsourced and where applicable campaign or batch sizes, this is used to determine the consumable cost associated with manufacture of the product.

From this assessment, a proposed "TrAMS" cost per product based on baseline year All Wales Contract Prices is identified, which is compared to the commercial price from the baseline year 23/24 (Example calculation below).

Table 2.9 Example of Cost Differential

Table 2.9 shows 23/24 outsourced data from the Pharmacy Stock Management System (Careflow) indicated the following ordered from commercial suppliers for Pembrolizumab 200mg Infusion:

Annual Outsourced Units Used	Annual Cost (£)	Average Cost per Unit
2663	£7,508,614	£2,819
Daily Outsourced Units Used	**Daily Cost (£)**	**Average Cost per Unit**
11	£28,768	£2,819

The All-Wales contract price for Pembrolizumab 100mg Vial is £1349.00, the final container is £3 and there is a daily cost of £85 to prepare the daily total campaign for Pembrolizumab.

Therefore, the cost to manufacture within the TrAMS hub is highlighted below:

Daily Units Manufactured	Number of vials required daily	Total cost of vials	Total cost of consumables and final containers	Total cost per Product	Projected Annual cost
11	22 vials	£29,678	(11 units daily x £3 final container) +(£85 batch cost) +(£29,678 cost of vials) = £29,796	£27,095/11 = £2708.72	£2708.72 x 2663 (Annual demand) = £7,213,398

Batching the above product with the available extended shelf life twice monthly would remove the cost from £85 per day batch cost to just £170 per month providing an additional £20,145 saving to the preparation of the product.

The annual saving opportunity is therefore:

Outsourced Annual Cost	Projected TrAMS Annual Cost	Batched Consumable Saving	Opportunity saving per annum
£7,508,614	£7,213,398	£20,145	£315,364

Outsourced Annual Cost – (Projected TrAMS Annual Cost + batched consumable saving)

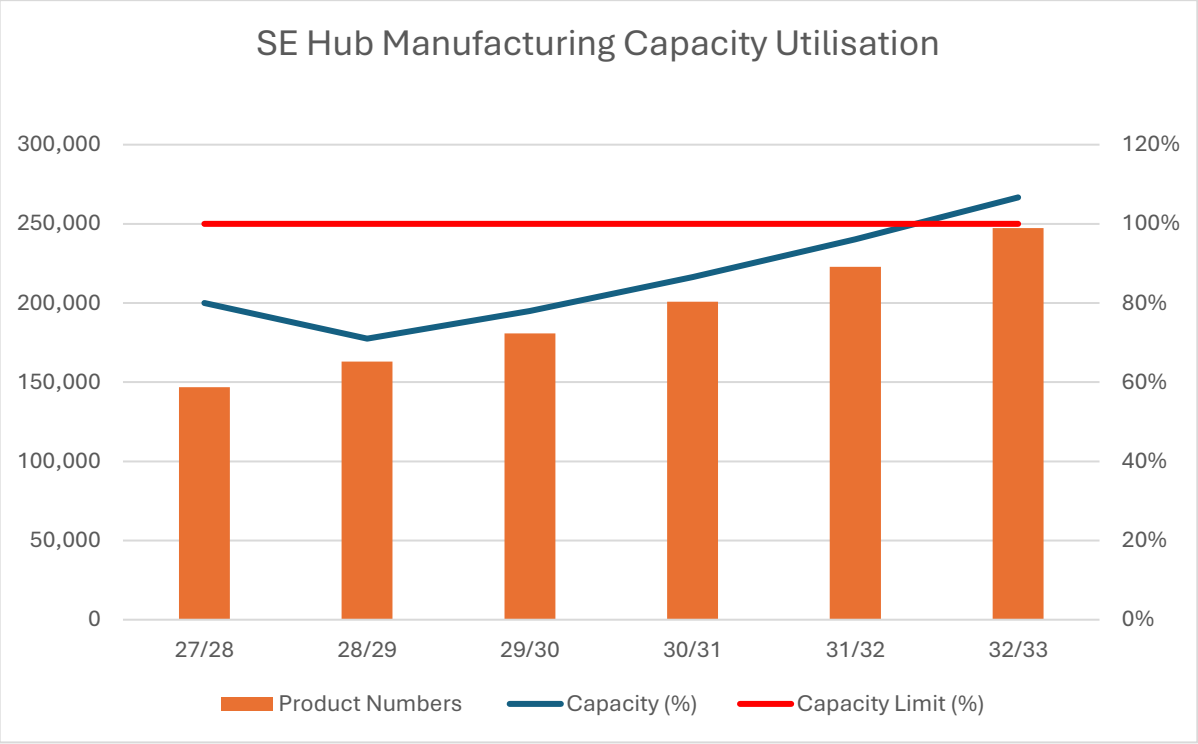
This calculation, applied to all outsourced products identified on the Pharmacy Stock Management System (Careflow) has identified a 20% "premium" paid by South East organisations across the outsourced range of products. Within the outsourced range of products, we have also identified the individual products where repatriation to the South East Hub confers a financial benefit to NHS Wales.

These items will be made in the South East Hub and are represented within the revenue tables as "outsourced savings opportunities".

Where products display a neutral or negative cost impact when made within the South East Hub, the service will assess the value of preparing these items within the hub or by outsourcing to a commercial supplier. Outsourcing these items would provide value by providing stakeholders with the best value product, whilst conserving manufacturing capacity within the hub for new products/services where value can be added.

The service will evaluate the commercial market annually to ensure that medicines supplied to stakeholder organisations provide the best value. Quality assurance of the outsourced items, whilst traditionally quality assured by organisations would now be assured by the TrAMS hub Quality Assurance team under service level agreement.

Table 2.10 Overall Hub Capacity versus Demand



This data firstly validates the staffing establishment as being appropriate for the level of activity projected to be required from the South East Hub at Y1 of operation. With subsequent additions of operational staff in Y2 and Y3 the data indicates that **no additional staff will be required to meet demand until mid-31/32 (Y5 of operation)**. The staffing establishment will be reviewed annually in line with demand to identify if further investment in staff is required to be brought forward or delayed.

2.7 Hub Manufacturing Methods

As described in the case for change, preparation of single products in the existing Section 10 aseptic units is completed using manual disinfection and aseptic processes, and under strict regulatory conditions. This model of preparation is time consuming, wasteful and restricts the capacity of units to operate safely and efficiently.

Assessing the agreed product portfolio in scope for the baseline year there are several mechanisms of manufacture that, under the benefits of holding an MHRA "Specials" licence, will allow prudent use of medicines, improve efficiency and output of the hub and also have a positive environmental impact on the use of single-use plastics. These are summarised below:

Table 2.11 Comparison of different methods of manufacture

Manufacturing Method	Description	Manufacturing Benefits
Manual - Single Product	This is using validated manual aseptic techniques undertaken by an operator to prepare a single product	Cost effective for single products
Manual – Campaign	Use of validated manual aseptic techniques however the operator combines multiple orders for multiple doses of the same medicine and presentation	Quicker assembly and transfer into manufacturing zones than making all items individually. Minimal waste of medicine through vial sharing Cost-effective
Manual – Batch	Use of validated manual aseptic techniques to prepare large numbers of the same product dose and presentation	Quicker assembly and transfer into manufacturing zones. Batch size designed for zero medicines waste Cost-effective Efficiency in QA assessment and release of batch
Semi-Automated - Single Product	Using validated semi-automated manufacturing techniques to prepare a single product	Only beneficial if needed for products where preparation is high in volume or complex in nature.
Semi-Automated – Campaign	Using validated semi-automated manufacturing techniques to prepare products for multiple orders for multiple doses of the same medicines and presentation	Quicker assembly and transfer into manufacturing zones than making all items individually. 2 minutes per product processing time compared to manual process 10 minutes Minimal waste of medicine through vial sharing

		Cost-effective Reduction in single use plastics
Semi-Automated - Batch		Quicker assembly and transfer into manufacturing zones than making all items individually. 2 minutes per product processing time compared to manual process 10 minutes. Batch size designed for zero medicines waste Efficiency in QA assessment and release of batch Cost-effective Reduction in single use plastics

The methods in table 2.11 summarise the manufacturing mechanisms to be utilised in the South East Hub and each mechanism is assigned to products within the portfolio based on shelf life, annual demand numbers and particular methods of manufacture stipulated within the product licence (Paclitaxel Infusion for example cannot be made using semi-automated technologies due to incompatibility with PVC tubing).

The table above does not detail other processing quality and efficiency measures. Manual disinfection of medicines and components into the critical zone is time consuming, however within the South East Hub, isolators and facilities will have the capability to utilise vaporised and ionised hydrogen peroxide technologies.

These technologies reduce the need for costly alcohol and detergent wipes used in manual disinfection processes. Not only does this technology improve disinfection and ultimately product quality, but the automated nature of disinfection releases staff to carry out ancillary and supportive tasks. It also reduces landfill waste of single use plastics by up to 85% in line with the NWSSP Decarbonisation Action Plan. There is also a reduction in the risk of product rejection, financial waste, and delay to patient treatment.

Currently validated semi-automated manufacturing methods have been developed in a number of aseptic facilities across Wales as part of a product development program.

NWSSP Medicines Unit, CAV St Marys Manufacturing Unit, and the Aseptic Unit in BCUHB have all contributed to process and timing data capture. The time attributed to these activities is discussed in the capacity section of the OBC but utilise baseline data provided by aseptic units across Wales.

2.8 Revenue costs of the TRAMs Hub Option

Based on the optimized manufacturing methods and the staffing establishment required to carry them out, the proposed revenue costs of the Hub are as follows:

Table 2.12

Recurring Revenue Spend Analysis for the Preferred Option (TrAMs Preferred Model South East Hub)

		SE Hub Go Live				
Preferred Option Spend (TrAMs)	**26/27**	**27/28**	**28/29**	**29/30**	**30/31**	**31/32**
	£'000s	**£'000s**	**£'000s**	**£'000s**	**£'000s**	**£'000s**
Pay (SE Hub)	472	4,888	6,200	6,589	6,589	6,589
Non-Pay (SE Hub)		2,008	2,008	2,008	2,008	2,008
Total Revenue Spend	**472**	**6,896**	**8,207**	**8,597**	**8,597**	**8,597**

In terms of a full year comparison of the hub proposal against the baseline, the following table compares the fully staffed Hub with the Service Baseline (both using 2023/4 rates):

Table 2.13

Comparison of Baseline and TrAMs South East Hub Pay and Non-Pay Spend

Baseline 2023/24 Costs vs South East Hub Operating Costs	**23/24 Baseline Costs (BAU)**	**South East Hub Costs 29/30**	**Increase on Baseline Costs**
	£'000s	**£'000s**	**£'000s**
Pay Costs	**4,379**	**6,589**	**2,210**
Non-Pay Costs			
Consumables & Equipment	763	726	(38)
Protective Clothing	263	200	(63)
Regulatory Costs	16	37	22
Software &Licensing	241	132	(109)
Office & Site Costs	522	518	(4)
Cleaning, Refuse & Waste	242	94	(147)
Staff Costs & Training	48	90	42
Transport Costs	82	211	129
Total Non-Pay Costs	**2,176**	**2,008**	**(168)**
Total Pay and Non-Pay Costs	**6,555**	**8,597**	**2,042**

Notes to Table 2.13:

1. Baseline costs for the South East organisations for financial year 2023/24.
2. South East hub costs relate to operating year 3 (2029/30) when the hub will be fully staff established.

As can be seen the operating costs of the Hub are higher than the baseline costs of the current service. This is because the Hub is resourced to manufacture medicine at a larger scale, both to meet clinical demand, and to achieve an **offsetting financial benefit** in the medicines spend, as will be shown in section 2.9 Benefits below.

2.9 Benefits

The Hub manufacturing model is inherently more efficient and productive than the current supply model of separate Health Board and Trust units supported by outsourcing.

This is because:

- The Hub consolidates demand from 9 major hospitals and cancer centres on one manufacturing site. This enables:
  - Efficient management of service demand
  - Improved asset utilisation with isolators in operation throughout the day
  - Batch and campaign manufacture rather than single items to improve efficiency, reduce waste and enhance agility of supply to patients
  - More planned manufacture for stock, rather than on demand
- The Hub will use semi-automated medicine pumps to enable large scale batch manufacture at pace. This technology provides enhanced accuracy and better yield output when compared to manual processes.
- The Hub will utilise Hydrogen Peroxide gassing technology for both room decontamination and product decontamination. This will reduce the failure rate and wastage of medicine during manufacture.
- The Hub staffing model will be more robust, with more staff available to be cross trained and provide better absence cover, compared to separate small teams.
- The Hub will be a 100% Licensed Service with MHRA MS Specials License. The Section 10 Exemption to the Medicines Act will not be used.
  - This will mean that all manufacturing activity can be right graded to staff with appropriate training, and Pharmacists and Health Scientists used on tasks appropriate to their higher skills and grade.
  - This also widens the recruitment pool, enabling Science Graduates of any suitable discipline to be employed in a wide variety of roles.
  - By being fully licensed we can also assign longer shelf lives to products, further supporting batching and making for stock, rather than making to order.
- Unlike a commercial outsourcer the Hub will not charge a profit margin or seek to recover its cost of capital. We estimate this as a 20% difference in price compared to the commercial sector, even where the manufacturing efficiency is the same.

The principal benefits of the Hub supply model are **capacity, contingency, and quality of medicine supply for our patients**, and the case is made on those grounds.

Other benefits accruing directly to the Health Boards and Trusts include:

- **Release of space** on Acute Hospital sites from the existing units to be redeveloped beneficially as each organisation sees fit
- **Release of nurse time** from preparing injections on the ward, to be redirected to towards patient care as each organisation sees fit.

Neither benefit has been treated as cashable in this case, but both are real and should be noted.

Modelling by the project team also shows considerable financial benefit to the Health Boards and Trusts from the manufacturing efficiencies referred to above, as set out in Table 2.14:

Table 2.14

Summary of Potential Annual Cash Releasing Opportunities Across All Wales Organisations for Baseline Year 2023/24

Medicines in scope that have manufacturing efficiencies	BAU Annual Cost	TrAMs Annual Cost	Total Opportunity	AB	CAV	CTM	VEL	HD	SB	Total
	£'000s	£'000s	£'000s	£'000s	£'000s	£'000s	£'000s	£'000s	£'000s	£'000s
Total	29,137	23,909	5,228	225	46	1,236	1,862	1,114	744	5,228

Notes to Table 2.14:

1. Total outsourced medicine spend across Wales for baseline year 2023/24.
2. Total estimated efficiency opportunities on outsourced activity across Wales is £5.2m.
3. Total South East **only** efficiency opportunities £3.4m (AB, CAV, CTM, VEL);
4. Total South East outsourced spend to commercial provider 2023/24 £16.4m;
5. Efficiency opportunity percentage of South East Hub as opposed to BAU is 20.567%.

This modelling has been undertaken by comparing commercial pricing of outsourced items with Welsh drug contract pricing and use of semi-automated technologies or manual processes to manufacture medicines in hub. This is only possible with the increased capacity the Regional Hub model provides and is unachievable in the current BAU picture. The methods of manufacture used within this modelling have been developed within the NWSSP Medicines Unit and are accepted and validated methods of aseptic manufacture

Only considering the opportunity to the South East Wales organisations, the savings opportunity on the Medicines spend, **offsets entirely the additional running costs** of the Hub by the end of Year 1 compared to Business As Usual.

2.10 Economic Evaluation of Preferred Way Forward

The economic evaluation compares the revenue spend under BAU against the Hub Option:

Table 2.15

Comparison of Business As Usual and TrAMS South East Hub Revenue Spend Analysis

BAU vs Preferred Option (SE Hub)	23/24	24/25	25/26	26/27	SE Hub Go Live 27/28	28/29	29/30	30/31	31/32
	£'000s	£'000s	£'000s	£'000s	£'000s	£'000s	£'000s	£'000s	£'000s
Business As Usual:-									
Pay Costs (HB/T)	4,379	4,611	4,611	4,611	4,611	4,611	4,611	4,611	4,611
Non-Pay Costs (HB/T)	2,176	2,176	2,176	2,176	2,176	2,176	2,176	2,176	2,176
Medicine Spend (HB/T)	36,276	40,266	44,695	50,166	56,239	62,980	70,462	78,768	87,987
BAU Total Spend	**42,830**	**47,053**	**51,482**	**56,953**	**63,026**	**69,767**	**77,249**	**85,554**	**94,773**
TrAMs SE Hub:-									
Pay (SE Hub)				472	4,888	6,200	6,589	6,589	6,589
Non-Pay (SE Hub)					2,008	2,008	2,008	2,008	2,008
Medicine Spend (SE Hub)					49,954	55,449	61,548	68,318	75,833
SE Hub Total Spend	**-**	**-**	**-**	**472**	**56,849**	**63,656**	**70,145**	**76,915**	**84,430**
Variance					**(6,176)**	**(6,111)**	**(7,104)**	**(8,639)**	**(10,343)**
Cumulative Variance					**(6,176)**	**(12,287)**	**(19,391)**	**(28,030)**	**(38,374)**

To put this at its simplest the Hub Option costs more to run because it has more staff. But the saving on medicine spend offsets the increase in staff cost. **The cumulative net benefit reaches £38m by the end of the period.**

It should also be stated that the total project cost of investing in the Hub, is lower than the estimated capital investment to re-invest in separate units. The project also assesses that the Hub investment can be made sooner, because the site is now investment ready, under an NHS long lease, and has planning permission in place, which we do not believe to be the case for separate unit options.

The assumptions above have been incorporated into a discounted cash flow for each of the options (BAU and TrAMs preferred option). The discounted cash flow has been prepared over a 25-year period, using a discount rate in line with the requirements of HM Treasury.
The key assumptions are summarised in table below.

- Costs are calculated over a 25-year appraisal period.

- Costs and benefits use real base year prices – all costs are expressed at 2023/24 prices in line with the baseline costs.
- The following costs are excluded from the economic appraisal:
    - Exchequer 'transfer' payments, such as VAT.
    - General inflation.
    - Sunk costs.
    - Non-cash items such as depreciation and impairments.
    - A discount rate of 3.5% has been applied to Years 1-25 in line with HM Treasury guidance.

The results of the economic appraisal are provided in the table below:

Table 2.16

Net Present Value analysis over 25 years

	Economic Model over 25 years £'000s	
	Business As Usual	**Preferred Model TrAMs**
Capital Costs excl Lifecycle	22,679	16,199
Revenue Costs	183,017	196,113
Direct Medicine Costs	2,111,596	2,111,596
Cash Releasing Benefits	-	(171,633)
Non-Cash Releasing Benefits	-	(93,008)
Total Costs and Benefits (undiscounted)	**2,317,292**	**2,059,267**
Risk	3,402	2,430
Total Costs and Benefits including Risk	**2,320,694**	**2,061,697**
Discounted Net Present Value (NPC)	**1,479,322**	**1,164,813**
Equivalent Annual Cost (EAC)	**59,173**	**46,593**

2.11 Sensitivity Analysis

The results of the economic appraisal above have been subject to a sensitivity analysis to examine the impact of potential changes to assumptions around future demand and growth of medicines and the potential to not realise outsource opportunities and cost avoidance.

The first part of this involves undertaking switching value analysis which has been applied to areas of material cash flows to identify the extent that costs and benefits must change in order for the Net Present Cost to move adversely in comparison to the Business-as-Usual model.

Based on this analysis, the TrAMs South East Wales Hub is the preferred option.

Table 2.17

Sensitivity Analysis summary

	Business As Usual £'000s	Preferred Model TrAMs £'000s	Difference in NPC £'000s
Baseline Net Present Costs (NPC)	1,479,322	1,164,813	(314,509)
Revised NPC after:			
Cost avoidance costs excluded	1,479,322	1,214,119	(265,203)
Annual demand/growth increased to 15%	1,877,760	1,481,255	(396,505)
Annual demand/growth decreased to 6%	1,098,309	861,260	(237,049)
No outsourced savings achieved	1,479,322	1,258,129	(221,192)

Based on the analyses above, the TRAMs South East Hub Option is therefore selected as Preferred Option on economic grounds.

3. Commercial Case

3.1 Commercial Approach

In July 2023 TRAMs Programme Board approved a contracting approach for the project based on separate contracts for building renovation and for cleanroom installation, with the two contractors occupying the site separately and sequentially. Movable equipment, principally the 15 Aseptic Gassing Isolators, will also be directly procured. This was determined to be the best value for money approach, and achieve the best control of change, with the cleanroom contractor as the biggest cost driver reporting directly to the NHS Project Team, including specialist pharmacists with direct knowledge of the relevant regulatory standards to be achieved.

The NHS Project Manager is in overall control, subject to the governance oversight set out in section 5.3 below, and supported by a team of specialist advisors amongst whom the Project Surveyor combines the advisory roles of Cost Advisor and Construction Management specialist. A spine of accountability runs from the Project Manager, the Programme Director, Project and Programme Boards, to the Programme SROs.

Suppliers have been engaged in multi-phase contracts with break clauses, and progression to the next stage being a contract option, dependent on satisfactory performance and funding awards. Where appropriate building industry template Terms and Conditions have been utilised.

This approach has facilitated the separate but closely related delivery of the Radiopharmacy and Hub projects, on adjacent parts of the same site. This also ensures that the designs are de-conflicted, ensuring fit both for space, utility use, and for commonality of key systems.

Procurement support is being provided through NWSSP Capital Team, with support from other procurement teams where appropriate.

A contract register is being kept of all contracted expenditures related to the project, their amounts, approvals, and expiry dates.

Specialist Estates advice is provided via NWSSP SES who have a representative on the Project and Programme Boards.

3.2 Commercial Position

Key contractors, roles, and status are as per the table below:

Table 3.1

Summary of Contractors and Advisors

Package	Contractor	Route to Market	Status
Enabling Works	TW Group (South Wales) Limited	Open Tender	Building renovation works enabling both the Radiopharmacy and the Hub were funded through the Radiopharmacy Case and will complete in May 2025.

Cleanroom Build	Angstrom Technology Limited	Open Tender	Has already delivered the Hub concept design to RIBA Stage 2. Engaged on multi-phase contract, with options to deliver Hub detailed design to RIBA stage 4, build, and validation.
Hub Isolator Supplier	Tbc	Open Tender	Tenders closed on 28 March 2025, with 5 bidders. Assessment is ongoing. Expected to be ready to award circa June 2025. Prices will be held for 6 months
Digital Stock Ordering, Workflow, and Control service	Tbc	Open Tender	Tender closes end of May 2025. Expected to be ready for awarding Sept 2025. Prices will be held for 6 months.
Cold Room build	Tbc	Open Tender	Will be tendered for post OBC.
Project Surveyor and Cost Advisor	Cooke & Arkwright	Framework award	In post and advising
Pharmaceutical Validation Specialist	Scitech	Open Tender	In post and advising

It should be noted that the enabling works contracted for the Radiopharmacy also enable the Hub Build, and no further building renovations will be required before the cleanroom build can commence on site. Enabling works include:

- Roof over sheeting of the whole 2,800 sq metres of the Radiopharmacy and Hub production zones
- Renovation of the dividing wall to provide 60-minute fire rated protection to both the Hub and the Warehouse.
- Demolition of various structures within the construction zone
- Drainage alterations and ground works for a new loading bay
- Renovation and reconfiguration of the toilets and staff mess rooms

In addition to these main contracts additional small expenditures are anticipated for:

- Data network commissioning
- Integration of new zones onto the building fire and security alarms and for access control
- Minor electrical works at times when no main contractor is mobilised on site
- Power Resilience study is currently out to tender, and will present options for improving the power resilience of the Radiopharmacy, Hub, and whole site.
- Structural Engineer advising the Project Team
- Building Control provider
- Planning Advisor and Ecology consultant (scope complete – planning permission covering the hub was granted in February 2025)

These were/are procured with the advice of NWSSP Procurement as and when required.

3.3 Risk Allocation

A paper was prepared for Programme Board analysing key risks arising from the contracting and delivery process, in particular around the decision not to use a single Supply Chain Partner (SCP), but instead to

contract directly with key specialist suppliers. The decision was taken that it was better for the NHS to own the risk of assembling the supply chain and managing key interfaces directly, rather than rely on a third party for this key task.

This is because the expertise in both cleanroom delivery and isolator performance lies with the NHS specialist Pharmacists and our contracted Advisors, not with a general building or multi-disciplinary company who might be engaged as SCP. The shorter the chain of accountability from the specialist delivery companies to the NHS Project Team the better control we will achieve over the specialist suppliers.

This structure is analogous to the fit out of a clinic or ward, where separate contracts will be used for building renovation, followed by a separate contract specialist equipment fit out by another directly contracted provider. The two contracts are separated by time, with each company occupying the site as Main Contractor sequentially. The Project Team's contracted construction management specialist ensures design alignment and overall control, as well as compliance with the Construction (Design and Management) Regulations 2015.

3.4 Charging Mechanism

The principal contracts are for construction, and charging is by a monthly assessment of work completed, certified by an employer's advisor, less a percentage retention for snagging, which is in line with construction industry best practice.

Equipment contracts are charged based on completion of key deliverables, typically:

1. Design Deliverables
2. Factory Acceptance Tests
3. Site Acceptance Tests
4. Full Documentation

Independent certification of completion of the deliverables has been arranged where necessary and appropriate.

3.5 Personnel Implications

The project has mobilised procurement support from within NWSSP to support assembly and management of the Supply Chain. The project has also mobilised capital accounting support to manage funding, cash flow, and payments, and to contribute financial analysis to the Business Cases.

The project is also supported by specialist contracted advisors, as noted in the table 3.1 above.

3.6 Accountancy Treatment

The Project has discussed the VAT treatment with our advisors, EY (Ernst & Young). There are no lease implications to be analysed under IFRS16, most of the expenditures being either capital purchases or capitalised resources associated with bringing the assets into use. Formal VAT assessment for the project is planned 2026/7.

The expenditure will be capitalised as either assets or assets under construction within the financial year when the expenditure is incurred.

3.7 Readiness status

Contracts are in place, and in general will be ready to start work within 4-6 weeks of funding being approved. Further detail is found in Appendices 4 and 5 of this document, and further estates related information is held by the Project Team for inspection by Welsh Government scrutineers if required.

Planning Permission was granted in Feb 2025 with no pre-commencement conditions, so there will be no delay to the works for this reason.

4. Financial Case

The financial case analyses the budgetary impacts of the preferred option, where the costs and benefits will fall, and proposes the funding arrangements to support the service.

4.1 Capital Costs

The table below summarises the £19.157m capital funding requirements of the preferred option.

Table 4.1

Capital Costs of the Preferred Option

	Capital Costs Net £'000s
Works Costs	**6,437**
Design Fees	699
Non-Works Costs	679
Equipment	6,271
Planning Contingencies	2,113
Sub Total	**16,199**
VAT	2,958
Total for Approval Purposes	**19,157**

It should be noted that the capital cost estimates are based on the TrAMs South East Hub preferred model, and the following assumptions have been made around the capital costs

- Works costs include the clean rooms build with the associated Environmental Monitoring System.
- Fees as outlined in Appendix A4 Estates Annexe and Cost Forms.
- Non works includes resource costs for validation testing of the hub.
- Equipment includes 15 aseptic isolators, digital solution costs and general equipment

The assumption in the Outline Business case is that VAT recovery will only be available on the professional fees. Although scope for further VAT recovery is expected to be limited, further work is planned with our VAT advisors as the Full Business Case is developed to ensure that VAT recovery is maximised.

Table 4.2

Capital Cash Flow

	Capital Costs Cashflow Gross of Vat £'000s			
	2025/26	2026/27	2027/28	Total
Total Capital Cashflow	**1,765**	**17,129**	**263**	**19,157**

Capital cash flow is dependent on the date of the investment decision and is estimated in table 4.2 based on a start on site in April 2026. Expenditure is shown in 2025/6 in relation to the opportunity for early expenditure on isolators and floor preparation, to be ready for the start of the main fit out.

It is proposed to seek all capital funding from Welsh Government. No commitment of capital is requested from SSPC member organisations. In order to allocate the capital Welsh Government does require to know whether the SSPC members will support the revenue costs of the proposed service.

The key impact on the balance sheet will be the addition of the new asset. The expected value will be reviewed further at FBC stage. Work will be undertaken with the District Valuer at FBC stage to assess any expected impairment.

The clean room build will be deemed to have a 20 year life for depreciation purposes and all other equipment including the Isolators a 10 year life.

4.2 Revenue Costs and Affordability

Regarding the revenue costs and affordability of the preferred option, the following should be noted:

- The revenue costs are mainly associated with ongoing pay costs and non-pay costs of operating the South East hub.
- The cash releasing revenue benefits are the efficiency savings of manufacturing at the Hub.
- The cost avoidance costs are associated with on costs of outsourcing to a commercial provider.
- The depreciation costs have been calculated across the useful lives of the assets.
- Any revenue consequence for the South East organisations will be apportioned on a 'Fair Shares' basis. The basis of the 'Fair Shares' assessment is described in section 4.3 below.

Table 4.3

Revenue Costs and Affordability		**SE Hub Go Live**				
	2026/27	**2027/28**	**2028/29**	**2029/30**	**2030/31**	**2031/32**
	£'000s	**£'000s**	**£'000s**	**£'000s**	**£'000s**	**£'000s**
Revenue Costs and Benefits:						
Revenue Staff Costs	472	4,888	6,200	6,589	6,589	6,589
Revenue Non-Pay Costs	-	2,008	2,008	2,008	2,008	2,008
Revenue Cash Releasing Benefits	-	(5,115)	(5,678)	(6,303)	(6,996)	(7,765)
Depreciation	-	1,321	1,334	1,334	1,334	1,334
Total	**472**	**3,102**	**3,864**	**3,628**	**2,935**	**2,166**
Funded By:						
Fair Shares basis	(472)	(1,781)	(2,530)	(2,294)	(1,601)	(832)
Depreciation	-	(1,321)	(1,334)	(1,334)	(1,334)	(1,334)

Total	**(472)**	**(3,102)**	**(3,864)**	**(3,628)**	**(2,935)**	**(2,166)**
Shortfall	-	-	-	-	-	-
Cumulative Shortfall	-	-	-	-	-	-

4.3 Funding Shares

While the benefits fall directly to the participating Health Boards, the operating costs of the Hub still require to be funded to enable it to open.

Based on the 2023/2024 medicine consumption figures for the participating organisations, the project team proposes the following funding shares for the Hub Operating costs:

Table 4.4

Summary of the Baseline and Preferred Option Revenue Spend in Scope for the TRAMS SE Hub

							FOR ILLUSTRATION ONLY			
Summary of Preferred Revenue Funding Model	**Service Model**	**AB**	**CAV**	**CTM**	**VEL**	**NWSSP**	**HD**	**SB**	**PT**	**Total**
		£'000s	**£'000s**	**£'000s**	**£'000s**	**£'000s**	**£'000s**	**£'000s**	**£'000s**	**£'000s**
Baseline Year 2023/24	BAU	13,233	13,957	13,487	-	1,082	382	149	541	42,830
Preferred Revenue Funding Model	TrAMs	13,172	13,614	12,568	-	1,082	373	146	529	41,484
Cost Variance of Models		**(61)**	**(343)**	**(919)**	**-**	**-**	**(8)**	**(3)**	**(12)**	**(1,346)**

Notes to Table 4.4:

1. A breakdown of the above summary table can be found in Appendix 1 Table 1e.
2. Total pay, non-pay and medicine spend for each organisation under both models for the medicines within the TrAMs South East Hub scope.
3. Velindre University NHS Trust costs under both models are fully passed on to the organisations.
4. NWSSP pay and non-pay contribution is their spend on Aseptic Services under both models.
5. NWSSP medicines spend is included within the organisations medicine spend.
6. HDUHB, SBUHB and PTHB are shown for illustration only. Their contract with Velindre University NHS Trust is out of scope for this project. The costs reflect the re-charge from Velindre University NHS Trust in accordance with historic % splits.

These figures have been reviewed by the participating Finance and Pharmacy representatives from the organisations concerned and are based on the "Fair Shares" principle, which has been calculated on the *finished goods volume share* basis.

Velindre University NHS Trust's share of the medicines spend has been re-allocated to the commissioning Health Boards based on an agreed *historic share basis*.

Table 4.5

Funding Commitment

Total Funding Commitment	ABUHB £'000s	CAVUHB £'000s	CTMUHB £'000s	VUNHST £'000s	NWSSP £'000s	HDUHB £'000s	SBUHB £'000s	PTHB £'000s	Total £'000s
Pay and non-pay costs based on fair shares	1,200	2,333	1,163	2,818	1,082				8,597
Velindre Recharge based on historic shares	1,106	809	784	(2,818)	-	43	17	60	-
Total	2,306	3,142	1,947	-	1,082	43	17	60	8,597

Table 4.5 shows the proposed annual funding commitment (stated at 2023/4 rates) sought from the Health Boards to meet the pay and non pay costs of operating the service, based on "fair shares".

The existing NWSSP Medicines Unit budget for aseptic activity is reassigned directly to the new service.

As noted in the economic case the funding requirements of the service are offset by the benefits opportunity.

Table 4.6

Breakdown of the financial benefits opportunity in the baseline year 2023/4

Medicines in scope that have manufacturing efficiencies	BAU Annual Cost	TrAMs Annual Cost	Total Opportunity	ABUHB	CAVUHB	CTMUHB	VELUNHST	HDUHB	SBUHB	Total
	£'000s	£'000s	£'000s	£'000s	£'000s	£'000s	£'000s	£'000s	£'000s	£'000s
Total	29,137	23,909	5,228	225	46	1,236	1,862	1,114	744	5,228

Notes to Table

1. Data based on baseline year 2023/24
2. Medicines identified within project scope whereby saving opportunities have been identified
3. Savings opportunities are recognised by bringing current medicine outsourced to a commercial provider into the TrAMs Suth East hub
4. A comparison of BAU manufacturing medicine costs versus TrAMS manufacturing medicine costs
5. Saving opportunities in relation to medicines identified, relate to across Wales
6. Only saving opportunities identified for the south east organisations have been recognised with the business case (total baseline year 23/24 =£3.37m)

This table demonstrates that the financial benefits opportunity in South East Wales exceeds the net cost of funding the new service.

It will be the responsibility of each organisation to secure their own benefits which may be achieved by a number of key actions:

- Ensuring that the costs of the legacy service are drawn down once the units close, by redeploying the staff into beneficial activity, and eliminating the supporting non pay spend.
- By ordering medicine in line with the new supply model, so as to benefit from the cost savings.
- By making beneficial use of the space released by the legacy units.

4.4 Funding Mechanism

In order to maintain the principle of "Fair Shares" in applying the shares set out in Table 4.5 it is proposed that:

- In Quarter 1 of each financial year the consumption of in scope medicines for the past financial year will be reviewed.
- Any requested change in the Scope of Service compared to that recorded in this paper will be analysed and the costs of meeting it determined.
- A Service Business Plan will be proposed to the SSPC in July of each year setting out:
    - Any change in funding shares proposed as a result of medicine consumption in the prior financial year
    - Any changes of Scope of Service proposed, and the impacts of meeting them
    - The proposed funding for the service in the following financial year, (prior to any % uplift for pay and inflation being applied)
- SSPC shall be responsible for reviewing, discussing, and approving this Business Plan, which will give annual certainty to the participating organisations as they enter the Budget setting process, while also provide a mechanism to manage and control any necessary change in the Scope, which may arise due to service need or market conditions.
- The final funding calculation including any pay and inflationary uplifts, and based on the most recent completed Calendar Year, will be calculated in January each year, and approved by SSPC in March prior to the start of the new financial year to which it applies.
- The costs will then be paid by SLA on the first day of each month, to give certainty to the operating Hub of the budgets and cashflow in place to run the service.

5. Management Case

5.1 Governance and Approvals

NWSSP is hosted by Velindre University NHS Trust and governed by all the Statutory Health Organisations in Wales acting equally through the mechanism of the Shared Services Partnership Committee (SSPC). NWSSP is not a statutory organisation in its own right. It operates within an established governance and accountability framework set out by Welsh Ministers. This framework, is designed to ensure that NWSSP operates in true partnership, owned and operated by the NHS in Wales operating under a hosting arrangement with Velindre University NHS Trust.

Decisions on NWSSP services are made on an all-Wales basis by the Shared Services Partnership Committee (SSPC). The SSPC was established in accordance with the Velindre National Health Service Trust Shared Services Committee (Wales) Regulations 2012 and the functions of managing and providing shared services (professional, technical, and administrative services) to the NHS in Wales is included within the Velindre National Health Service Trust (Establishment) (Amendment) Order 2012.

The proposed Service is a Technical and Professional service for the supply of medicines. There is no impact on the Patient Care Service Model and no requirement for a Quality Impact Assessment (QIA) on Patient Care. The proposed scope is analogous to that currently provided by commercial outsource suppliers, of whom QIA are not required. The Duty of Quality does apply, and the impact of the proposal on the quality of medicines preparation activity has been referenced throughout the case.

Approval of this OBC is sought from all members of SSPC.

Members should take note however that the revenue funding commitment at this stage falls on three Health Boards in particular, and the Scope of Service commitment applies to those three Health Boards and Velindre University NHS Trust. These four Organisation in South East Wales are therefore impacted to a greater degree than the other members of SSPC. While the internal governance of those four organisations may require them to seek approval through various internal boards and committees, the operative approval which the project is seeking is from SSPC as a whole, and therefore the individual organisations should work to empower their committee member to be able to approve the paper on their behalf.

The Health Boards and Trusts not directly impacted by this case should also consider that when the time comes to invest in the South West and North Hubs, similar funding methodology will be applied, for consistency and patient equity across Wales. Therefore they should review the methodology carefully and ensure they are happy to approve it on this occasion.

The capital for the project is being sought directly from Welsh Government, and no capital or infrastructure approvals are being sought from SSPC or its members.

5.2 Performance Management

The service will produce an extensive suite of performance indicators based around quality and compliance, which will be reported quarterly as part of the NWSSP Performance Management Framework. Performance will be scrutinised at every SSPC meeting and in more detail internally through quarterly reviews with the Division. Quarterly performance reports will also be provided to each individual organisation

In addition, specific measures will be put in place to measure productivity and efficiency including:

Throughput

- Measures production capabilities of a machine / line / product or plant
- Measured by the following
    - Throughput = # of units / time (min/hour/day etc)

Inventory Turns

- Calculates the time an inventory is sold over a time period
- Indicates resource effectiveness and inventory performance
- Low ratio indicates poor sales and high inventory
- High ratio indicates strong sales and low inventory
- Measured as
    - Inventory Turns = cost of goods sold / average inventory value

% On Time Delivery

- Reported late deliveries
    - %OTD = (# on time deliveries / # total deliveries)*100

Customer Returns

- Documented as complaints
- Need to assess current complaints reported in service PQS

Manufacturing Yield

- Calculated per batch then as a % of the service
- Industry standard is 90%
- Industry Excellence is 95%
    - Yield = total number of released good / batch or campaign size

Waste

- As a % of finished goods expired/damaged within Hub
    - Waste = (# wasted within hub / total manufactured products)

Isolator Utilisation

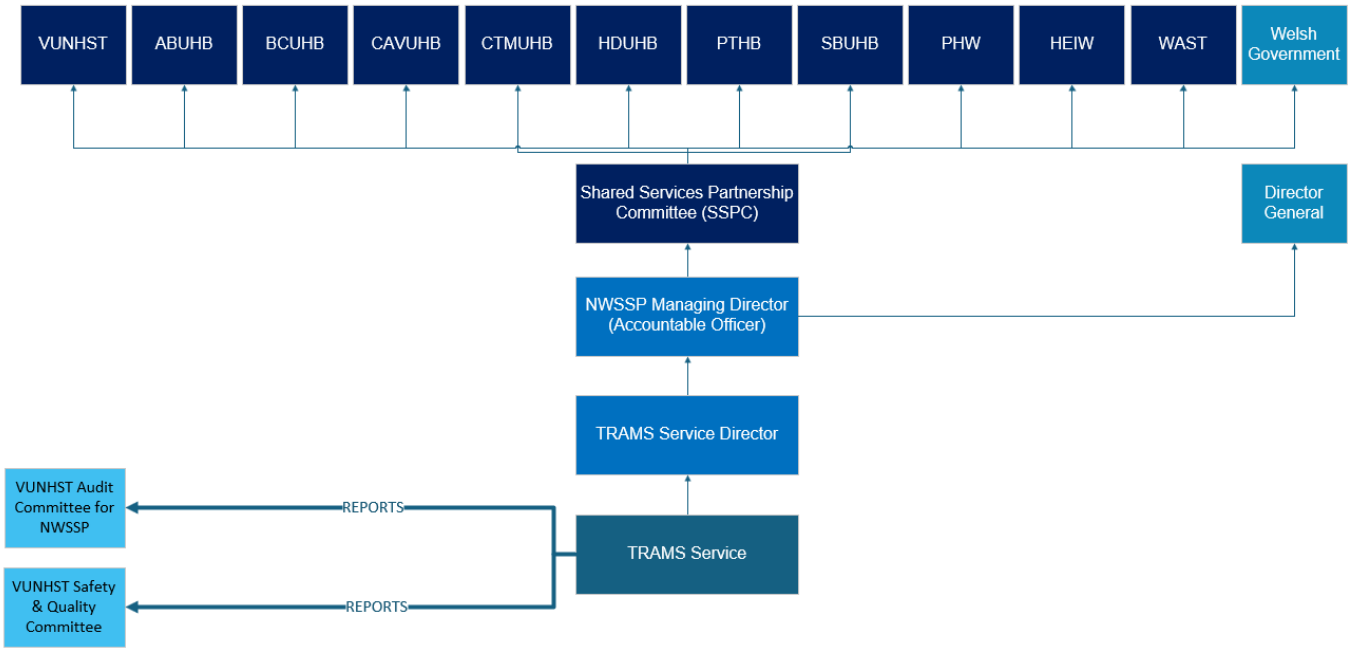
- Number of hours each isolator is in use to make medicine per week

(Hours available – Hours of work booked)/Hours Available

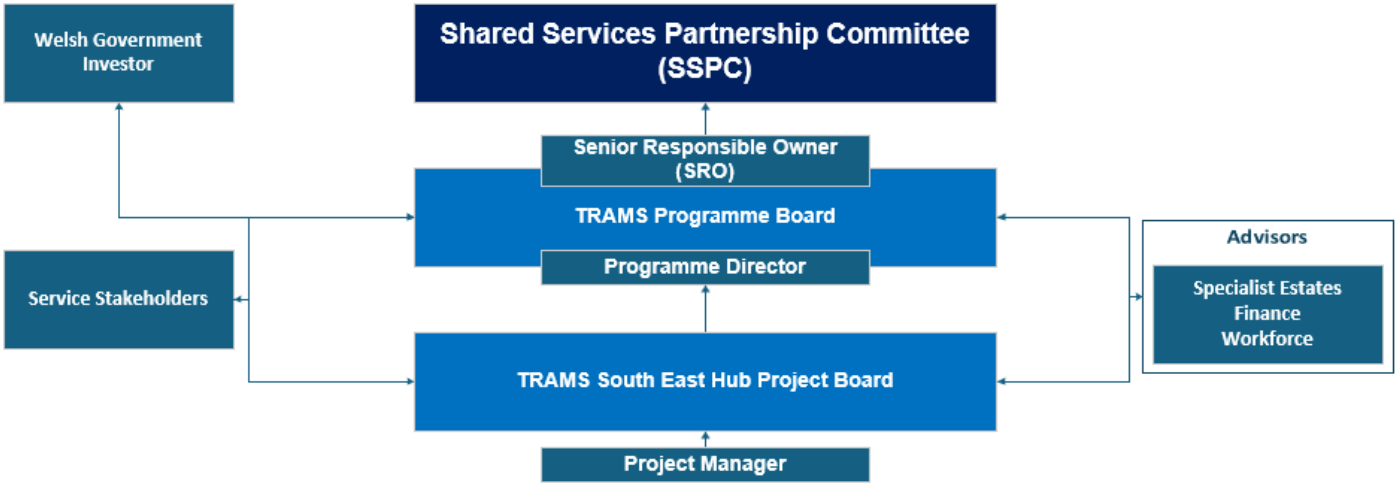
All of these measures are currently being baselined with the existing service, and current run rates will be presented in the FBC.

5.3 Project Governance

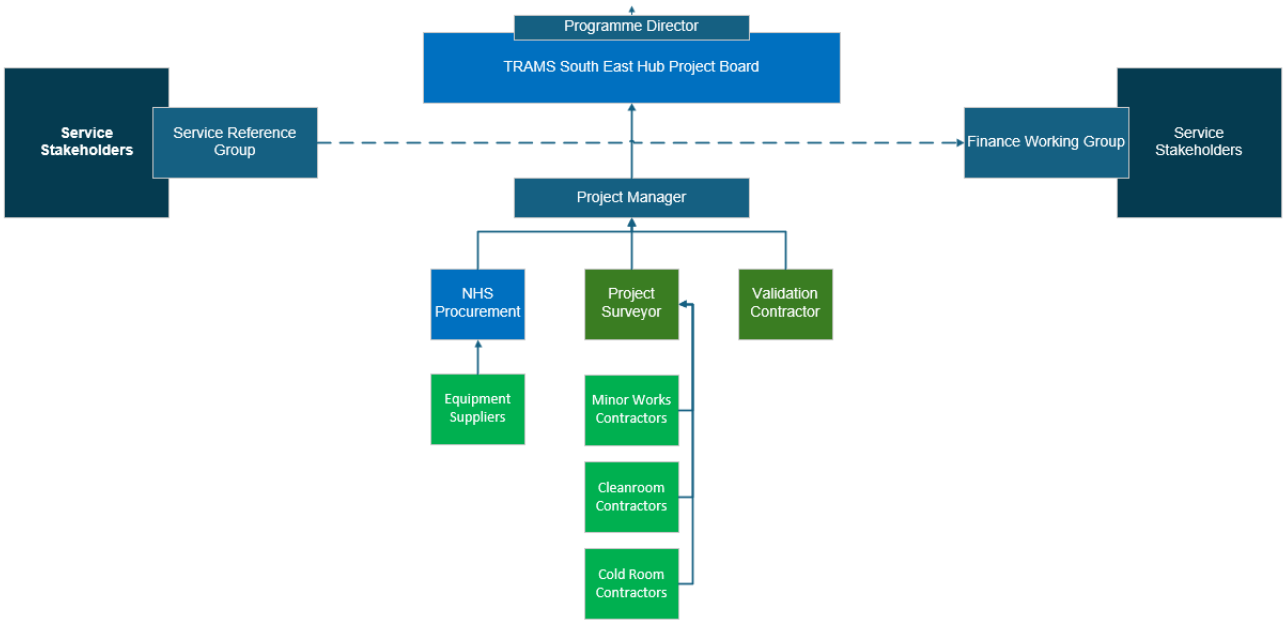
The Project is governed within the TRAMs Programme, which itself is subject to the oversight of the Health Boards and Trusts via the mechanism of SSPC.



The relationship of the South East Hub Project to the Programme is shown below:



Within the Project all the contractors and suppliers report to the Project Manager, who is supported by a team of professional advisors, and service and professional stakeholders:



The advisory reference groups which now include separate groups for **Finance, Pharmacy, Workforce, and Service Supply,** give an opportunity for key stakeholders to input into the development of the project and its key deliverables. This is in order that before formal proposals are escalated to SSPC for approval, the full spectrum of organisational and departmental priorities can have been considered, and any errors or omissions corrected.

Therefore, in order to obtain full assurance, each SSPC member should seek input from the members of these groups in their own organisation, to understand the extent to which the proposals meet their own service's needs. A full list of the membership of these stakeholder groups is included in Appendix 6.

5.4 Timelines

A project plan has been prepared that combines all the elements required from each contractor, advisor, supplier, NHS organisation, staff, and all the necessary validation, licensing and entry into service tasks.

Key high-level milestones from this plan include:

Milestone	Date
Planning Permission Granted	Feb 2025
OBC Approval	End July 2025
FBC Approval	End Dec 2025
Investment Decision	Jan 2026
Staff formal consultation commences	Feb 2026
Contractor on site	March 2026
Recruitment to vacancies commences	May 2026
Cleanroom practical completion	July 2026

Recruited staff deployed	Nov 2026
Validation of the SACT suite by	Dec 2026
Regulatory and Licensing approvals in place by	March 2027
Able to commence supplying SACT	April 2027
Transfer of existing staff begins	May 2027
Able to commence supplying CIVA and PN	Oct 2027
Transfer of existing staff concludes	Oct 2027

Planning Permission for change of elevations and change of use was granted in Feb 2025, with no pre-commencement conditions.

The plan is ambitious, includes considerable concurrent activity, and relies on all stakeholders treating the approval and deployment of this service as a matter of urgent need.

Progress against plan will be regularly reported on to Programme Board and via SSPC to service stakeholders, with issues raised for urgent resolution where required.

5.5 Risk Management

The Project is working under the TRAMs Programme Risk Management Approach, and has two risk registers in active use:

1. **Costed Construction Risk Register** – in use to validate the level of Project Contingency
2. **Project Management Risk Register** – in use to manage wider risks associated with the project.

In addition, the project has interfaces with other key risk registers:

3. **TRAMs Programme Risk Register** – this is the immediate escalation route from the Project Management Risk Register. Risk escalation is governed by the Programme Risk Approach and is based on either (a) Tolerances for Time, Cost or Quality being exceeded or (b) Any risk impacting on patient care, that must be escalated to Health Boards and Trusts via Programme Board and SSPC as soon as it may become known.
4. **NWSSP Pharmacy Service risk register** – covering the in-service risks to the existing Medicines Unit and will cover the in-service risks to the Radiopharmacy and Hub once they open.
5. **NWSSP Corporate Risk Register** – available for escalation of service risks if required.

Monthly Risk Workshops have been established, chaired by the Deputy Director of Pharmacy, and a risk report and project risk register are reviewed and approved monthly by the Project Board.

5.6 Organisational Change Process

If the Preferred Option is invested in, then this will impact on the employment rights of existing staff. A paper has been taken to Directors of People and OD group setting out the proposed approach which is:

1. The process set out in the All-Wales Organisational Change Policy will be utilised
2. Following the Investment decision the existing employers will consult their staff to establish who is impacted by the change:

a. While it is anticipated that the organisations who operate Pharmacy Technical Services in South East Wales (ABUHB, CAVUHB, CTMUHB, VUNHST, NWSSP) will be the main organisations involved, staff at any NHS Wales organisation will be able to liaise with their existing employer for inclusion in the consultation, if they believe that they are impacted by the change.
b. It should be noted that staff already deployed in Pharmacy Technical Services in NWSSP will be equally treated and subject to the same process as staff at the Health Boards and Trusts (This will include the staff planned to transfer from CAVUHB to NWSSP as part of Radiopharmacy mobilisation during 2025).

3. Those staff who are impacted will have their existing job descriptions matched against BOTH the job descriptions for the new service, and the revised roles that will be available in their existing employer after the change. This is important as there are staff on split roles at present, who spend some of their time working on Technical Services (impacted by the change) and some of their time of Clinical or Dispensary duties (not impacted by the change). Therefore, the numbers in scope for consultation are likely to be higher than the numbers identified to transfer, and some of the staff consulted will be matched with revised roles at their existing workplace and employer.
4. Those staff who match against the new service, and are willing and able to move, will be identified for a transfer to a specific role at the appropriate time. Terms and conditions will be protected, and all the protections applicable to the Transfer of Undertaking Protection of the Employment Act (TUPE) will apply.
5. A draft Equalities Impact Assessment (EQIA) has already been prepared. Once the staff to transfer have been identified, then the EQIA will be completed with reference to their particular needs and circumstances.
6. Once the number of staff identified for transfer has been confirmed, the remaining vacancies in the new service will be released for recruitment.
7. The transfer itself will be planned on a date based on service continuity and operational need and may take place sometime after the consultation ends.

There will be no budget attached to the transfer of personnel; the running costs of the new service will be met by the mechanism identified in the Financial Case. The redeployment of the staff not identified for transfer will be the responsibility of their existing employers.

A working group consisting of People & OD practitioners, and Staff Side representatives have been meeting approximately every 6 weeks since 2022 to discuss, plan, and prepare for this process. The names of the current members of this group are attached in Appendix 6 below.

5.7 Use of Specialist Advisors

A number of specialist advisors have been engaged, as detailed in the Commercial Case section 3.2.

5.8 Change and Contract Management Arrangements

Change is being managed in accordance with the arrangements set out in the relevant contracts and industry best practice, including:

- Use of Early Warning Notices (EWN) to identify emergent issues

- Use of Variation Orders (VO) by which the impacts of change can be assessed with the relevant contractors
- Review of EWN and VO with specialist advisors
    - Additional advice and support from NWSSP Specialist Estates Service as required
- Formal approval of variations that are within cost tolerance by the Project Manager, Finance Lead, and Project Executive.
- Escalation of recommended variations that exceed tolerance for formal approval in accordance with NWSSP Standing Financial Instructions (SFI).
- Formal Contract Change Control to revise Purchase Order amounts using documentation provided by NWSSP Procurement, following approval from the relevant person identified under SFI.

5.9 Benefits Realisation

The principal benefits of the case fall to the Health Boards and Trusts who purchase the medicine to be made by the new service, and who will automatically receive the benefits of continuity of supply, quality, and price advantage.

The new service includes key posts dedicated to benefits management in particular:

- Ongoing review of manufacturing efficiency against the baseline data from the existing service
- Ongoing review and comparison of the respective costs of:
    - Outsourced supply based on the All Wales contract price
    - Manufacture in house by the new service
    - Identification of new or emergent products which could be beneficially manufactured in house
    - Identification of products currently made in house that could be beneficially outsourced
    - A key benefit of the case is that these decisions will be made strategically Once for Wales, rather than ad hoc in each hospital's pharmacy purchasing team.
- The annual process of compiling and approving the Service Business Plan will give a mechanism for formally reviewing prior year performance and determining the best supply strategy for the forthcoming year, to maximise benefits for the service.

5.10 Post Implementation and Evaluation

After the closure of the South East Wales Hub Project, the TRAMs Programme will remain in operation for some time and will continue to monitor the benefits and support the embedding of outcomes as part of its ongoing work.

When the Programme finally closes a Service Management Board will remain in place, to monitor benefits delivery, under the overall governance of SSPC.

5.11 Arrangements and Plans

A key aspect of the Programme Business Case was identifying that 3 medicines preparation hubs are required for Wales, to support contingency in the event of a catastrophic failure at any one site (for instance a fire or a flood). It is essential for the long-term sustainability of the service that the Programme goes on to invest in the South West Region and North Region Hubs as planned.

It is unlikely that any of the existing units would be maintained in a condition to be able to contribute to contingency supply after they close. This is because:

1. The costs of keeping staff in post to maintain the units in 'warm standby' condition would be prohibitive
2. Their physical condition precludes their continuing use
3. The space on hospital sites is likely to have been re-allocated for alternative beneficial uses

In the interim there are two main sources of contingency for the South East of Wales:

1. The existing units in the South West and North, notably at Singleton Hospital and Wrexham Maelor Hospital. While these units are likely to be fully committed to supporting the Business As Usual services in their areas, in the event of a major and catastrophic shortage of medicine, some of their capacity could be diverted, as part of an overall prioritisation of demand under established arrangements.
2. In the short term an interruption in supply from the South East Hub would inevitably result in an increase in outsourced supply. While this would be financially challenging, it would enable continuity of medicine supply to patients to be maintained.

Appendix 1 Supporting table information in the Economic and Financial cases

Appendix 1a

Breakdown of Aseptic Services Only Staff by WTE and Spend for 2023/24 by South East Organisation

Organisation	AFC Band	Aseptic Chemotherapy Supply	Parenteral Nutrition Supply	CIVAS	Outsourced Aseptic Products	QC Lab	Technical Services Overhead	Total Hours	Total WTE	Total Pay Costs
		Hours	Hours	Hours	Hours	Hours	Hours	Hours	WTE	£'000s
ABUHB	2	15.00	15.00	1.00	0.00	0.00	3.25	34.25	0.91	25
	3	102.00	99.00	6.00	24.00	0.00	34.00	265.00	7.07	213
	4	10.00	7.00	0.00	7.00	0.00	40.85	64.85	1.73	54
	5	36.00	28.00	2.00	10.00	0.00	6.00	82.00	2.19	91
	6	7.00	4.00	0.50	8.00	0.00	14.15	33.65	0.90	41
	8a	9.50	4.00	0.50	6.00	0.00	16.80	36.80	0.98	67
	8b	7.50	4.00	0.50	7.00	0.00	34.35	53.35	1.42	107
CAVUHB	2	2.00	2.00	2.00	0.00	0.00	6.45	12.45	0.33	9
	3	77.00	54.00	154.00	0.00	15.00	34.10	334.10	8.91	266
	4	43.50	36.00	7.00	0.00	0.00	34.88	121.38	3.24	103
	5	116.50	105.00	102.00	5.00	37.30	34.45	400.25	10.67	444
	6	33.75	31.25	27.50	9.25	54.35	90.25	246.35	6.57	343
	7	29.75	20.00	21.00	5.00	0.00	52.06	127.81	3.41	206
	8a	12.50	10.25	14.25	9.00	0.00	51.54	97.54	2.60	177
	8b	5.25	1.00	1.75	0.00	0.00	69.15	77.15	2.06	174
	8c	0.00	0.00	0.00	0.00	0.00	30.64	30.64	0.82	85
	8d	0.00	0.00	0.00	0.00	0.00	17.10	17.10	0.46	49
CTMUHB	3	46.50	0.00	0.00	39.00	0.00	27.00	112.50	3.00	85
	4	15.50	0.00	0.00	13.00	0.00	8.50	37.00	0.99	31
	5	41.00	0.00	0.00	25.50	3.00	36.50	106.00	2.83	101
	6	10.00	0.00	0.00	13.00	0.00	43.50	66.50	1.77	79
	7	1.00	0.00	0.00	0.00	0.00	0.00	1.00	0.03	2
	8a	1.00	0.00	0.00	0.00	0.00	0.00	1.00	0.03	2
	8b	9.50	0.00	0.00	4.50	3.00	45.00	62.00	1.65	145
VUNHST	2	0.00	0.00	0.00	0.00	0.00	7.50	7.50	0.20	6
	3	297.50	0.00	0.00	0.00	0.00	22.50	320.00	8.53	250
	4	155.00	0.00	0.00	0.00	0.00	15.00	170.00	4.53	146
	5	210.00	0.00	0.00	0.00	0.00	52.50	262.50	7.00	296
	6	21.00	0.00	0.00	0.00	0.00	31.50	52.50	1.40	72

	7	30.00	0.00	0.00	0.00	0.00	0.00	30.00	0.80	48
	8a	7.50	0.00	0.00	0.00	0.00	41.25	48.75	1.30	93
	8b	1.50	0.00	0.00	0.00	0.00	33.50	35.00	0.93	68
NWSSP	3	0.00	0.00	70.00	0.00	0.00	77.50	147.50	3.93	118
	4	0.00	0.00	28.00	0.00	0.00	27.50	55.50	1.48	47
	5	0.00	0.00	19.00	0.00	0.00	6.00	25.00	0.67	26
	6	0.00	0.00	5.00	0.00	0.00	0.00	5.00	0.13	6
	7	0.00	0.00	0.00	0.00	0.00	6.00	6.00	0.16	9
	8a	0.00	0.00	5.00	0.00	0.00	32.50	37.50	1.00	73
	8b	0.00	0.00	0.00	0.00	0.00	37.50	37.50	1.00	88
	8c	0.00	0.00	0.00	0.00	0.00	37.50	37.50	1.00	90
	9	0.00	0.00	0.00	0.00	0.00	12.50	12.50	0.33	43
TOTAL		1,354	421	467	185	113	1,171	3,711	**98.96**	**4,379**

Notes to Appendix 1a:

1. Agreed baseline financial year 2023/24, data provided by individual organisations via a Spend Questionnaire over three financial years.
2. The data is in relation to the South East Wales organisations only.
3. Spend and WTE as reported by each organisation for aseptic services as of 31st March 2024.
4. Spend and WTE at point of scale on 31st March 2024.
3. WTE to be retained at each organisation to facilitate the receipt of medicines from the SE Hub.

Appendix 1b

Breakdown of Aseptic Services Non-Pay Spend for 2023/24 by South East Organisation

Non-Pay Baseline Spend 2023/2024	ABUHB	CAVUHB	CTMUHB	VUNHST	NWSSP	Total
	£'000s	£'000s	£'000s	£'000s	£'000s	£'000s
Consumables & Equipment	89	213	82	232	148	763
Protective Clothing	22	53	54	85	49	263
Regulatory Costs	1	4	1	-	10	16
Software & Licensing	7	100	39	51	44	241
Office & Site Costs	80	157	34	134	117	522
Cleaning, Refuse & Waste	14	70	-	10	148	242
Staff Costs & Training	6	2	26	-	13	48
Transport Costs	3	14	13	-	52	82
TOTAL Non-Pay Costs	**222**	**613**	**248**	**511**	**582**	**2,176**

Notes to Appendix 1b:

4. Agreed baseline financial year 2023/24, data provided by individual organisations via a Spend Questionnaire over three financial years.
5. The data is in relation to the South East Wales organisations only.
6. Total non-pay spend as per each organisation.

Appendix 1c

Total Baseline Medicine Spend for 2023/24 by Organisation for Medicines in Scope as per Pharmacy Stock Management System (Careflow) Data

In Scope - Baseline 2023/2024 Direct Medicine Spend	ABUHB	CAVUHB	CTMUHB	VUNHST	Total
	£'000s	£'000s	£'000s	£'000s	£'000s
Outsourced to commercial Provider Monthly Outsource Tracking Report 2023/24	490	421	4,206	11,265	16,383
Manufactured by Technical Services/Aseptic Units Balancing Figure	1,901	3,482	1,466	12,186	19,035
Sub-Total	2,392	3,903	5,673	23,451	35,418
Other Aseptic Direct Costs: Manufactured by Aseptic unit Consumables AMD (Aseptic Medical Devices reported expenditure)	101	334	90	333	858
Sub-Total	101	334	90	333	858
Total Direct Medicine Spend in Scope	**2,493**	**4,237**	**5,763**	**23,783**	**36,276**

Notes to Appendix 1c:

1. 2023/24 reported Outsourced to commercial providers tracking costs (Pharmacy Stock Management System (Careflow) report).
2. 2023/24 reported medicines made/manufactured within the South East Aseptic Services (Pharmacy Stock Management System (Careflow) report).
3. Manufactured medicines associated direct consumable costs based on AMD (Aseptic Medical Devices) reported expenditure received from Health Boards and Trust for 2023/24.

Appendix 1d

Breakdown of TrAMs South East Hub Non-Pay Estimated spend from Year 1 (2027/28)

Non-Pay South East Hub Costs	South East Hub Costs
	£'000s
Consumables & Equipment	726
Protective Clothing	200
Regulatory Costs	37
Software &Licensing	132
Office & Site Costs	518
Cleaning, Refuse & Waste	94
Staff Costs & Training	90
Transport Costs	211
TOTAL Non-Pay Costs	**2,008**

Appendix 1e

Staff Structure at South East Hub from Year 1 Go Live April 2027

Staff Structure South East Hub - AFC Band	Year 1 - Go Live April 2027/28 WTE	Year 2 2028/29 WTE	Year 3 2029/30 WTE	Year 1 - Go Live 2027/28 £'000s	Year 2 2028/29 £'000s	Year 3 2029/30 £'000s
Band 9	1.00			157		
Band 8D	4.00			524		
Band 8C	2.33		1.00	257		110
Band 8B	5.33	3.00	0.33	495	278	31
Band 8A	4.00	1.33		310	103	
Band 7	6.00	1.00		405	67	
Band 6	13.20	3.00		756	172	
Band 5	6.00	8.00	3.00	277	370	139
Band 4	37.00		3.00	1,355		110
Band 3	11.00	10.00		354	321	
TOTAL	**89.86**	**26.33**	**7.33**	**4,888**	**1,312**	**389**
Cumulative Total Establishment by Year 3 2029/30			**123.52**			**6,589**

Notes to Appendix 1e:

1. WTE staff establishment to be achieved within years one to three of South East Hub 'go live'.
2. Costs based on 2024/25 AFC rates.
3. Majority of the wte numbers are bands 7 to 3, which are described as operating roles or supervisory operating roles.

Appendix 1f

Comparison of Business as Usual and TrAMs South East Revenue Spend

					SE Hub Go Live				
BAU vs Preferred Option (SE Hub)	**23/24**	**24/25**	**25/26**	**26/27**	**27/28**	**28/29**	**29/30**	**30/31**	**31/32**
	£'000s	**£'000s**	**£'000s**	**£'000s**	**£'000s**	**£'000s**	**£'000s**	**£'000s**	**£'000s**
Business As Usual:-									
Pay Costs (HB/T)	4,379	4,611	4,611	4,611	4,611	4,611	4,611	4,611	4,611
Non-Pay Costs (HB/T)	2,176	2,176	2,176	2,176	2,176	2,176	2,176	2,176	2,176
Medicines Made (HB/T capacity reached 25/26)	19,893	22,081	24,510	24,510	24,510	24,510	24,510	24,510	24,510
Additional Medicine Outsourcing (HB/T capacity reached 25/26)				2,696	5,689	9,011	12,698	16,791	21,334
On-Cost of Additional Medicine Outsourcing				554	1,170	1,853	2,612	3,453	4,388
Medicines Outsourced (Assume available growth capacity with Commercial Provider)	16,383	18,185	20,186	22,406	24,871	27,607	30,643	34,014	37,756
BAU Total Spend	**42,830**	**47,053**	**51,482**	**56,953**	**63,026**	**69,767**	**77,249**	**85,554**	**94,773**
TrAMs SE Hub:-									
Pay (SE Hub)				472	4,888	6,200	6,589	6,589	6,589

Non-Pay (SE Hub)					2,008	2,008	2,008	2,008	2,008
Medicines Manufactured (SE Hub)					55,069	61,127	67,851	75,314	83,599
SACT/PN Opportunities (SE Hub)					(5,115)	(5,678)	(6,303)	(6,996)	(7,765)
SE Hub Total Spend	**-**	**-**	**-**	**472**	**56,849**	**63,656**	**70,145**	**76,915**	**84,430**

Variance					**(6,176)**	**(6,111)**	**(7,104)**	**(8,639)**	**(10,343)**
Cumulative Variance					**(6,176)**	**(12,287)**	**(19,391)**	**(28,030)**	**(38,374)**

Appendix 1g

Summary of Baseline Revenue Spend (including Velindre University NHS Trust shares)

						FOR ILLUSTRATION ONLY			
Baseline Year 23/24	**ABUHB**	**CAVUHB**	**CTMUHB**	**VUNHST**	**NWSSP**	**HDUHB**	**SBUHB**	**PTHB**	**Total**
	£'000s	**£'000s**	**£'000s**	**£'000s**	**£'000s**	**£'000s**	**£'000s**	**£'000s**	**£'000s**
Pay and Non-Pay Costs	821	2,469	693	1,490	1,082				6,555
Medicines Outsourced	490	421	4,206	11,265	-				16,383
Medicines Manufactured	1,901	3,482	1,466	12,186	-				19,035
Medicines Direct Consumable	101	334	90	333	-				858
Total Medicine Costs	2,493	4,237	5,763	23,783	-				36,276
Opportunities on Outsourced	**n/a**	**n/a**	**n/a**	**n/a**					**n/a**
Total Baseline Costs Per Organisation	**3,314**	**6,706**	**6,456**	**25,273**	**1,082**				**42,830**

Velindre Historic % Splits	**39.25%**	**28.69 %**	**27.82%**			**1.51%**	**0.59%**	**2.14%**	
Velindre Historic £ Splits	9,920	7,251	7,031	(25,273)		382	149	541	
Total Baseline Costs Per HB/T (including Velindre Historic Splits)	**13,233**	**13,957**	**13,487**	**-**	**1,082**	**382**	**149**	**541**	**42,830**

Notes to Appendix 1g:

1. Pay and non-pay costs as per baseline spend 2023/24.
2. All medicine costs as per baseline spend 2023/24.
3. Velindre University NHS Trust historic splits as reported by Velindre.
4. HDUHB, SBUHB and PTHB are shown for illustration only. Their contract with Velindre is out of scope for this project. The costs reflect the re-charge from Velindre in accordance with historic splits.

Appendix 1e

Summary of TrAMs South East Hub Revenue Spend (including Velindre University NHS Trust shares)

						FOR ILLUSTRATION ONLY			
SE Hub Year 3 29/30	**ABUHB**	**CAVUHB**	**CTMUHB**	**VUNHST**	**NWSSP**	**HDUHB**	**SBUHB**	**PTHB**	**Total**
	£'000s	**£'000s**	**£'000s**	**£'000s**	**£'000s**	**£'000s**	**£'000s**	**£'000s**	**£'000s**
PREFERRED OPTION Pay and Non-Pay Costs (apportioned by activity/usage)	1,197	2,327	1,161	2,811	1,082				8,578
Medicines Outsourced	490	421	4,206	11,265	-				16,383
Medicines Manufactured	1,901	3,482	1,466	12,186	-				19,035
Medicines Direct Consumable	101	334	90	333	-				858

Total Medicine Costs	2,493	4,237	5,763	23,783	-				36,276
Opportunities on Outsourced	**(225)**	**(46)**	**(1,236)**	**(1,862)**	**-**				**(3,370)**
Total Adjusted Medicine Costs	2,267	4,191	4,527	21,921	-				32,906
Total Costs Per Organisation	**3,465**	**6,518**	**5,687**	**24,732**	**1,082**				**41,484**
Velindre Historic % Splits	**39.25%**	**28.69%**	**27.82%**			**1.51%**	**0.59%**	**2.14%**	
Velindre Historic £ Splits	9,707	7,096	6,880	(24,732)		373	146	529	
Total Baseline Costs Per HB/T (including Velindre Historic Splits)	**13,172**	**13,614**	**12,568**	**-**	**1,082**	**373**	**146**	**529**	**41,484**

Notes to Appendix 1e:

1. Preferred option calculation of TrAMs SE Hub operating costs split on a 'fair shares' basis.
2. Full operating costs of the TrAMs South East Hub split by each organisation apportioned in accordance with unit activity/usage during baseline year 2023/24.
3. All medicine costs as per baseline spend 2023/24.
4. Saving Opportunities for each organisation from bringing commercial provider outsourced medicines into TrAMs South East Hub. Savings opportunities are in relation to baseline year 23/24 spend.
5. Velindre University NHS Trust historic splits as reported by Velindre.
6. HDUHB, SBUHB and PTHB are shown for illustration only. Their contract with Velindre is out of scope for this project. The costs reflect the re-charge from Velindre in accordance with historic splits.

Appendix 2 Service Scope and Product Delivery Model v 2.2

This service scope and Product delivery model are directly linked to the revenue financials shown above and constitute a baseline for future change control.

Transforming Access to Medicines

TRAMs Operational Pharmacy Supply Model

1. INTRODUCTION

This document outlines the comprehensive service model for the provision of ready-to-administer (RTA)products from the NWSSP Transforming Access to Medicines South-East National Hub. The product portfolio within scope of this document is highlighted in Appendix 1 and is a comprehensive list of all systemic anti-cancer therapy (SACT), parenteral nutrition and Centralised Intravenous Additives (CIVAS) based on 23/24 usage. Clinical Trials provision, although within scope of the TrAMS programme is not covered within this document and will be addressed separately owing to the complexities of clinical trial product provision

The service model described within this document has been developed in collaboration with the TrAMS Service Model Board and appropriate clinical subgroups chaired by the National Clinical Lead for TrAMS.

2. PRODUCT PORTFOLIO

Appendix 1 highlights the agreed TrAMS product portfolio as of 23/24, the baseline year used for the TrAMS OBC/FBC process. This is a comprehensive list of products agreed by the below clinical sub-groups. All new products will be developed using Pharmaceutical Quality System Change Control and New product processes in line with MHRA Guidance and Good Manufacturing Practice. Sub-groups involved in the approval of the portfolio include

- TrAMS Programme Team
- NHS Wales Technical Services Leads
- Directors of Pharmacy
- TrAMS Clinical Reference Group
- TrAMS Clinical Sub-groups (SACT/Haem, Parenteral Nutrition, Neonatal/Paediatric)

The Product Portfolio will be subjected to quarterly review and when required, updated based on:

- New products, identified via clinical horizon scanning, developed to meet NICE 60 day treatment targets
- Emergent changes to clinical demand outside of the annual planning cycle (noting that by Quarter 4 of a given year, the relevant Service Business Plan will be around 18 months old).
- Market changes in the availability or price of medicine
- Regulatory changes that have a material impact on the feasibility or cost of preparation
- Other unplanned events impacting on the organisations capacity to deliver the plan
- In aggregate these factors may result in a need to update the SLA for:
    - Decisions to add products

- Decisions to withdraw products
- Changes to the price of products
- Change to best value Route to Market for each product
- Changes to ordering or delivery cut off times

The Quarterly Review will be issued by the Service to the Commissioning Organisations, who will have the option to initiate a formal re-approval of the plan, if the changes are deemed by them to affect the overall stability of the service.

2.1. PRODUCT CLASSIFICATION

Products within the portfolio are classified into three separate categories

- Single item "Specials" – Products with a low regional or national usage and shelf life of <96 hours
- Campaign Items – Where regional or national use is >2 products per day at variable doses of the same drug and there is a shelf life of <28 days
- Batch items - where national or regional usage is high across several dose bands and the shelf life is >28 days

The purpose of this classification is to help identify those products within the portfolio that apply to the agreed ordering schedules and lead times within this document.

3. HUB / HOSPITAL SERVICE MODEL PROCESS

Procurement of ready-to-administer "Specials" from the TrAMS hubs will require dispensing within the purchasing organisation before supply to patients. As such the service interface process shown below removes the need for "patient-specific" ordering from the hubs, streamlining the ordering process, and removing risks from the process. Patient specific ordering will remain for those products where it is required for clinical purposes, this includes paediatric oncology and bespoke, compounded parenteral nutrition.

The process highlighted in Figures 1 and 2, have been developed by the TrAMS programme using Quality-by-Design principles to ensure efficiency and remove risk of errors from the process as highlighted by Failure Modes Effect Analysis of the process compared to the original service model within the Programme Business Case (PBC). This covers the process from ordering to dispensing to patient:

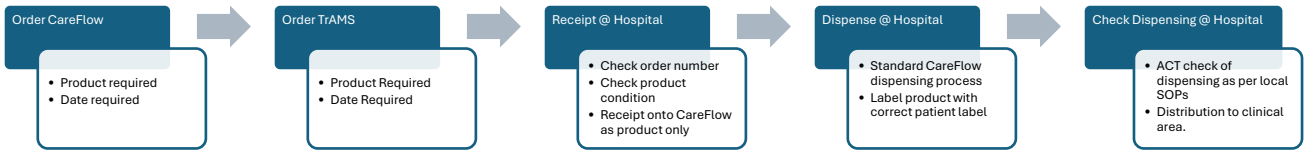


Figure 1: Service Model Hub / Hospital Interface – Standard Products

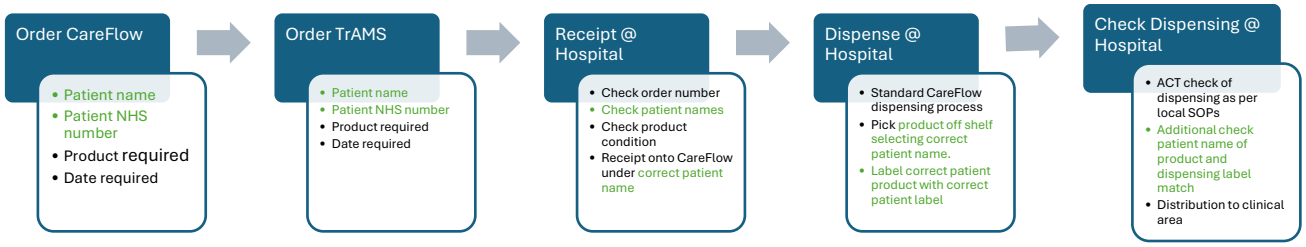


Figure 2: Service Model Hub / Hospital Interface – Paediatric Oncology and Bespoke PN

The transfer of ordering data from organisations to TrAMS hubs can be done via two processes, manually directly onto the TrAMS ordering portal or via digital interface of the TrAMS hub ordering system with Welsh Hospital Pharmacy Stock Management System (WHPSMS) -currently Careflow.

4. ORDERING SCHEDULES

Ordering of products from the TrAMS Hub, will adhere to the below:

- All the unlicensed medicine items on the product list will be ordered through the Service, at the listed price, regardless of whether insourced or outsourced.
- Licensed ready to administer SACT products are not included and will continue to be ordered locally direct from the suppliers
- All orders will be processed through the standard business systems. This means that:
    - Purchase Orders will be generated on the Pharmacy Stock System and sent digitally to the Service
    - The Service will make, check and dispatch the order to the requested location based on the PO containing all the necessary data
    - The Hospital or Cancer Centre receiving the product will receipt the order on its Pharmacy Stock system (WHPSMS)
    - Invoices (or recharges) will be generated by the Service and will be matched and recharged through the standard invoice matching and payment process.
    - There is no requirement to send prescriptions with orders. Prescriptions should remain in the hospital on the relevant e-Prescribing system.

4.1. Ordering Schedules for TrAMS Batch Items

Products within the TrAMS product portfolio assigned as “Batch” products will be prepared for stock at the hubs, and it is the expectation that these items are kept at appropriate stock levels locally where suitable to facilitate agile supply to patients. All batch products will have a 5-day lead time however items assigned as batch can be ordered as single items in exceptional circumstances as outlined in 4.6.

4.2. Ordering Schedules for Standard TrAMS Products

Items not assigned batch status within the portfolio will be classified as either campaign, or “Single item” products. These must be ordered by adhering to the ordering schedules outlined in Appendix 2. There is an expectation that a % of products be ordered prior to the 2pm cut-off KPI will be identified and agreed prior to approval of a Service Level Agreement between NWSSP and stakeholder organisations.

4.3. Ordering Schedules for Compounded Parenteral Nutrition

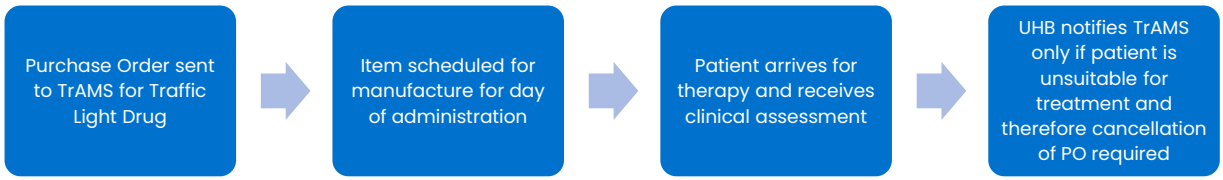
Due to the contemporaneous nature, and clinical risks of compounded parenteral nutrition Appendix 3 highlights the ordering schedule for compounded parenteral nutrition, which allow closer to manufacture ordering. Standardised presentations of Parenteral nutrition available as stock will be subject to the ordering schedules highlighted in 4.1 & 4.2, unless local usage numbers are sufficiently low for stock holding to be inefficient.

4.4. Ordering Schedules for Radiopharmaceuticals

The ordering schedules for radiopharmaceutical products is detailed in Appendix 3 and applies to all radiopharmaceutical products detailed within the product portfolio. These have been agreed by the SE Radiopharmacy sub-group previously.

4.5. Traffic Light High-Cost Drugs Authorisation to proceed

There are several products within the TrAMS portfolio that are high cost-low usage items, where stock is unlikely to be held locally or within the hub. These items are commonly prescribed and authorised in advance and can adhere to the ordering schedules outlined within Appendix 2. However, approval to proceed with patient treatment can occur on the day. To avoid wastage of these items, the portfolio will highlight (in green font within Appendix 1) the products where manufacturing will proceed upon receipt of a purchase order for single item products. These items can be cancelled upon notification from local clinical services. These products should be scheduled for PM administration where possible to allow adequate time for manufacture; however, we accept this is not always viable. An example of this process is below:



4.6. Exceptional Circumstances

There are scenarios where ordering of products from the hub with the outlined ordering schedule is not possible or clinically appropriate. These scenarios are:

- Patient presentation with a clinically urgent/life threatening need to initiate therapy.
- Blood results outside of acceptable limits for treatment requiring further tests on the day prior to treatment.
- Specific pre-administration tests required on the day prior to treatment that might require dose adjustment.

On the day, or 24-hour notice ordering will be accepted for agreed range of products provided the above scenarios are met. Patients who are admitted for second or subsequent courses of chemotherapy but have not had chemotherapy prescribed and confirmed within the ordering periods will not be eligible for on the day supply.

5. QUALITY ASSURANCE OF TRAMS "SPECIALS" & HOSPITAL RECEIPT

The Service Level Agreement between NWSSP and stakeholders will include the relationship relating to Quality Assurance of products. To improve efficiency at receipting sites, remove duplication of work the following elements of the service model will be in place:

- All items supplied by NWSSP will be given a Quality Assurance check prior to dispatch from the hub, each product and order will include documentation to confirm this check has occurred.
- Quality Assurance checks will comply with Good Manufacturing and Quality Assurance principles as set out in Medicines regulations and meeting Quality Assurance of Aseptic Preparation Services standards.
- Orders will be delivered by NHS Wales Health Courier Service by trained drivers, to the agreed delivery point for each building, in line with Technical Agreements and in compliance with Good Distribution Practice.
- Custody of the medicine will be handed over from NWSSP to the ordering organisation at point of delivery. Custody handover will be verified with a date and time stamped signature.

- It is the responsibility of the receipting organisation to ensure that a visual check for external packaging damage is undertaken on receipt. A full quality check is not required as this is the responsibility of the TrAMS Quality Control team as outlined in the service level agreement between NWSSP and stakeholder organisations.
- Any identified issues with the quality of medicines must be reported to the TrAMS hub within 24 hours of receipt to allow contemporaneous investigation of the issue and financial redress.
- Any quality issue identified prior to patient administration must be reported immediately to the TrAMS hub for investigation and MHRA/DMRC notification as appropriate.
- The responsibility for receipting the orders for financial purposes remains in the ordering organisation.
- Responsibility for dispensing orders against the original prescriptions remains in the ordering organisation.
- Responsibility for custody and storage of the order once delivered and accepted remains with the ordering organisation.
- Responsibility for distributing orders from the agreed delivery point, onward within the ordering organisation's building, remains with the ordering organisation.

6. DISPENSING TO PATIENTS / WARD STOCK

The products supplied by TrAMS to hospitals must be handled in accordance with the Human Medicines Regulations 2012. This requires one of the following two processes:

- Storage within pharmacy for dispensing to a patient
- Storage within pharmacy for issuing to stock in ward areas

Local handling of TrAMS products must also adhere to MHRA Guidance Note 14 pertaining to the supply of unlicensed specials. Audit of adherence to Medicines regulations and NHS best practice within hospital sites relating to the handling of unlicensed medicines is the remit of the National Lead for Pharmacy Quality Assurance.

7. ANNUAL REVIEW OF SERVICE MODEL

The service model described above will be reviewed annually in line with the appropriate technical and service level agreements. This is to ensure that TrAMS services adhere to contemporaneous regulatory requirements whilst meeting the changing demands of the service. This will be approved by the TrAMS Service Board and NWSSP Partnership Committee.

8. SERVICE MODEL BOARD ENDORSEMENT

The service model board members from each stakeholder organisation endorse in principle

the proposed TrAMS Service model subject to receipt and approval of the formal FBC through

internal organisation governance processes.

9. TrAMS PRODUCT PORTFOLIO – BASED ON 2023/24 BASELINE

ADULT Systemic Anti-Cancer Therapies (SACT) & Haematology
Abraxane (Paclitaxel Albumin) Intravenous Infusion

Alemtuzumab Subcutaneous Injection
Amsacrine Intravenous Infusion
Arsenic Trioxide Intravenous Infusion
Atezolizumab Intravenous Infusion
Avelumab Intravenous Infusion
Azacitidine Subcutaneous Injection
Belantumab Mafodotin Intravenous Infusion
Bendamustine Intravenous Infusion
Bevacizumab Intravenous Infusion
Bleomycin Injection – multiple routes
Blinatumumab Intravenous Infusion
Bortezomib Subcutaneous / Intravenous Injection
Brentuximab Intravenous Infusion
Busulfan Intravenous Infusion
Cabazitaxel Intravenous Infusion
Carboplatin Intravenous Infusion
Carfilzomib Intravenous Infusion
Carmustine Intravenous Infusion
Cemiplimab Intravenous Infusion
Cetuximab Intravenous Infusion
Cisplatin Hydration Fluid Intravenous Infusion
Cisplatin Intravenous Infusion
Cladribine Subcutaneous Injection / Intravenous Infusion
Clofarabine Intravenous Infusion
Cyclophosphamide Intravenous Infusion / Injection
Cytarabine Intravenous Infusion / Injection / Subcutaneous / Intrathecal
Dacarbazine Intravenous Infusion
Dactinomycin Intravenous Infusion
Daratumumab Intravenous Infusion
Daunorubicin Intravenous Infusion / Injection
Decitabine Intravenous Infusion
Dinutuximab beta Subcutaneous Injection / Intravenous Infusion
Dexrazoxone hydrochloride Intravenous Infusion
Docetaxel Intravenous Infusion
Dostarlimab Intravenous Infusion / Injection
Doxorubicin Intravenous Injection / Infusion / Chemoembolisation
Doxorubicin Pegylated-Liposomal Intravenous Infusion
Durvalumab Intravenous Infusion
Eculizumab Intravenous Infusion
Elranatamab Subcutaneous Injection
ENHERTU (Trastuzumab deruxtecan) Intravenous Infusion
Enfortumab Intravenous Infusion
Eribulin Intravenous Injection
Epirubicin Intravenous Injection/Infusion
EPOCH Intravenous Infusion
Etopophos Intravenous Infusion
Etoposide Intravenous Infusion / Intraventricular Injection

Fludarabine Intravenous Infusion
Fluorouracil Intravenous Infusion / Injection / intralesional / Ophthalmic application
Folinic Acid Intravenous Infusion
Gemcitabine Intravenous Infusion / Intravesical Instillation
Gemtuzumab Ozogamicin Intravenous Infusion
Glofitamab Intravenous Infusion
Idarubicin Intravenous Infusion
Ifosfamide / Mesna Intravenous Infusion
Ifosfamide Intravenous Infusion
Inotuzumab Ozogamicin Intravenous Infusion
Ipilimumab Intravenous Infusion
Irinotecan Hydrochloride Intravenous Infusion
Isatuximab Intravenous Infusion
KADCYLA (Trastuzumab emtansine) Intravenous Infusion
Loncastuximab Intravenous Infusion
Melphalan Intravenous Infusion
Mogamulizumab Intravenous Infusion
Mitomycin Intravesical Administration/Intravenous Infusion / Injection / Intraperitoneal
Mitoxantrone Hydrochloride Intravenous Infusion
Nelarabine Intravenous Infusion
Nivolumab Intravenous Infusion
Obinutuzumab Intravenous Infusion
Opdualag Intravenous Infusion
Oxaliplatin Intravenous Infusion
Paclitaxel Intravenous Infusion
Panitumumab Intravenous Infusion
Pembrolizumab Intravenous Infusion
Pemetrexed Intravenous Infusion
Pentamidine Intravenous Infusion / Nebuliser solution
Pentostatin Intravenous Infusion
Pertuzumab Intravenous Infusion
Pixantrone Intravenous Infusion
Polatuzumab Vedotin Intravenous Infusion
Raltitrexed Intravenous Infusion
Ramucirumab Intravenous Infusion
Ravulizumab Intravenous Infusion
Rituximab Intravenous Infusion
Sacituzumab Intravenous Infusion
Streptozocin Intravenous Infusion
Tagraxofusp Intravenous Injection
Talquetamab Subcutaneous Injection
Thiotepa Intravenous Infusion
Trabectedin Intravenous Infusion (Surefusor & IV bag)
Trastuzumab Intravenous Infusion
Topotecan Intravenous Infusion
Treosulfan Intravenous Infusion
Vinblastine Intravenous Infusion

Vincristine Intravenous Infusion
Vindesine Intravenous Infusion
Vinorelbine Intravenous Infusion
Vyxeos Intravenous Infusion

Paediatric SACT & Haematology
Bevacizumab Intravenous Infusion
Bleomycin Intravenous Infusion
Blinatumumab Intravenous Infusion
Bortezomib Injection
Busulfan Intravenous Infusion
Carboplatin Intravenous Infusion
Carmustine Intravenous Infusion
Cisplatin Intravenous Infusion
Clofarabine intravenous infusion??
Cyclophosphamide Intravenous Infusion / Injection
Dacarbazine Intravenous Infusion
Vincristine Intravenous Infusion
Vinblastine Intravenous Infusion??

ADULT CIVAS*
Alteplase Intravitreal Injection
Amphotericin B Intravenous Infusion
Amphotericin B Liposomal Intravenous Infusion
Avalglucosidase Infusion
Baclofen Intrathecal Injection
Belimumab Intravenous Infusion
Benzylpenicillin Intravenous Infusion
Calcium Folinate Infusion
Cefuroxime Eye Injection
Ceftazidime Intraperitoneal Injection
Cidofovir Intravenous Injection / Intravesical Instillation
Diamorphine Injection
Dobutamine Intravenous Infusion
Flucloxacillin IV Infusion
Flucloxacillin Elastomeric Intravenous Infusion
Fosaprepitant Intravenous Infusion
Foscarnet Intravenous Infusion
Furosemide Accufusor Intravenous Infusion
Ganciclovir Intravenous Infusion / Intravitreal injection
Gentamicin Intraperitoneal Injection
Hydrocortisone Intrathecal Injection
Infliximab Intravenous Infusion

Insulin Actrapid Intravenous Infusion
Levobupivacaine Infusion
Magnesium Sulphate Intravenous Infusion
Mesna Intravenous Infusion/Injection
Methotrexate Intramuscular / Intravenous / Intrathecal Injection / Infusion
Midazolam Intravenous Injection
Morphine Sulphate Intravenous Infusion/Injection / Intrathecal
Morphine and Clonidine Intrathecal Injection
Morphine Sulphate and Bupivacaine Intrathecal Injection
Natalizumab Intravenous Infusion
Piperacillin and Tazobactam Intravenous Infusion
Potassium Chloride Intravenous Infusion
Siltuximab Intravenous Infusion
Tocilizumab Intravenous Infusion
Tobramycin Injection
Ustekinumab Intravenous Infusion
Vancomycin Intravenous Infusion / Line Lock / Intrathecal Injection
Vedolizumab Intravenous Infusion

*work currently ongoing to standardise national presentations

NEONATAL AND PAEDIATRIC CIVAS*
Aciclovir Intravenous Infusion
Adrenaline Intravenous Infusion
Amphotericin B Intravenous Infusion
Dopamine Intravenous Infusion
Dobutamine Intravenous Infusion
Flucytosine
Fentanyl Intravenous Infusion / Injection
Ganciclovir Intravenous Infusion
Gentamicin Line Lock
Heparin Intravenous Infusion
Infliximab Intravenous Infusion
Insulin Actrapid Intravenous Infusion
Morphine Sulphate Intravenous Infusion / Injection
Midazolam Intravenous Infusion / Injection
Noradrenaline Intravenous Infusion
Pavilizumab Intravenous Infusion
Potassium Chloride Intravenous Infusion
Synacthen Low Dose Injection
Vancomycin Intravenous Infusion / Line Lock

10. ORDERING SCHEDULE FOR STANDARD TrAMS PRODUCTS*

Day	Administration Day	Ordering Cut-Off	Delivery Due	Ordering Cut-Off	Delivery Due
Standard Mon-Fri Weekday	Monday	14:00 Fri	7am Mon	17:00 Fri	12:00 Mon
	Tuesday	17:00 Fri	7am Tues	17:00 Fri	12:00 Tues
	Wednesday	14:00 Mon	7am Wed	17:00 Mon	12:00 Wed
	Thursday	14:00 Tues	7am Thurs	17:00 Tues	12:00 Thurs
	Friday	14:00 Wed	7am Fri	17:00 Fri	12:00 Wed
Bank Holiday Monday	As per normal working week: Xmas, New Year and Easter schedules will be released to organisations 3 months in advance to plan the annual change occurring with these BHs. These will be agreed in advance with Organisations before correspondence sent to clinical and procurement teams.				
Tuesday Post Bank Holiday					

***Batch products require a 5-day lead time**

11. ORDERING SCHEDULE FOR COMPOUNDED PARENTERAL NUTRITION

Day	Administration Day	Ordering Cut-Off	Delivery Due
Standard Mon-Fri Weekday	Monday	11am Fri	15:00pm Mon
	Tuesday	11am Mon	15:00pm Tues
	Wednesday	11am Tues	15:00pm Wed
	Thursday	11am Wed	15:00pm Thurs
	Friday/Sat/Sun	11am Thurs	15:00pm Fri
Bank Holiday Monday	As per normal working week: Xmas, New Year and Easter schedules will be released to organisations 3 months in advance to plan the annual change occurring with these BHs. These will be agreed in advance with Organisations before correspondence sent to clinical and procurement teams.		
Tuesday Post Bank Holiday			

12. ORDERING SCHEDULES FOR RADIOPHARMACEUTICAL PRODUCTS

Radiopharmaceutical products require a purchase order **received by 12:00 noon** on a working day for delivery by 9:00am the next working day.

Day	Prescription Cut Off	Ordering Cut Off	Delivery Due	Administration
Ordinary	10:00 Fri	12:00 Fri	09:00 Mon	10:00 Mon
Ordinary	10:00 Mon	12:00 Mon	09:00 Tues	10:00 Tues
Ordinary	10:00 Tues	12:00 Tues	09:00 Wed	10:00 Wed
Ordinary	10:00 Wed	12:00 Wed	09:00 Thurs	10:00 Thurs
Ordinary	10:00 Thurs	12:00 Thurs	09:00 Fri	10:00 Fri
Bank Holiday Monday	No Service			
Tuesday after Bank Holiday	10:00 Fri	12:00 Fri	09:00 Tues	10:00 Tues

Appendix 3 Hub Capacity Plan v 1.2

This Plan is also directly linked to the financial model for approval, and justifies the baseline staffing requirement for the Hub, to manufacture the stated number of medicine doses, aligned with the Service Scope and product Delivery Model:

Transforming Access to Medicines

Technical Service Model Capacity Utilisation Assessment for the South East TrAMS Hub

INTRODUCTION

This document outlines the projected hub capacity plan and staff modelling underpinning the South-East Hub staffing establishment. Capacity planning is a key component of Good Manufacturing Practice (GMP), and essential to meet anticipated demand whilst ensuring all regulatory compliant activities are maintained such as training, validation, planned preventative maintenance, quality management and staff-related factors such as annual leave and sickness.

MHRA Guidance for Specials Manufacturers requires a capacity plan to be in place, and that the utilisation of total staff for manufacturing activities should not exceed 70-80% to allow adequate resource for associated ancillary and quality management tasks outlined as part of Good Manufacturing Practice and Quality Assurance. Activities within this 20% include:

- Quality Management System activities
- Routine GMP training
- Planned and Unplanned Preventative Maintenance
- Training and Validation
- Quality and Performance meetings

It is worth noting that this exercise is using a tool designed for contemporaneous measurement of capacity utilisation in established technical services facilities where baseline data is available. However, in this document, the baseline data and projected demand data can be used to simulate the capacity utilised by the proposed staff numbers within the TrAMS SE Business case. This will be used to support the staffing establishment proposed.

1. TrAMS South East CAPACITY PLAN

To demonstrate the projected capacity resulting from the proposed staffing establishment within the TrAMS business case, the programme has utilised a nationally recognised and endorsed capacity plan, the PASG Capacity plan. This planning model has been developed by several Technical Services leads and has been endorsed by the PASG as a capacity planning tool that meets regulatory requirements.

This tool also allows the exclusion of essential non-production tasks such as Pharmaceutical Quality Management maintenance, whilst considering “traditional” production activities such as surface sanitisation, manufacturing activities, documentation completion and release activities. Once again this is in-line with MHRA Guidance to licensed “Specials” manufacturers. As such the 80% limit as imposed by the MHRA is represented as 100% within the PASG capacity plan.

2. CAPACITY PLAN MECHANISM

The capacity tool is a set of calculations and formulae that sit behind a Microsoft Access database. Using baseline data for product manufacturing timings, staff time taken for product preparation can be accounted for within the tool. By adding the times recorded as standard for each activity, the tool builds a capacity utilisation output. All that is required thus is for the projected or actual product demand to be entered to identify the percentage of hub capacity used.

3. STAFFING NUMBERS

The capacity plan allows for the entry of staffing numbers at each role and allows tasks to be adequately assigned to the appropriate level of staff, this allows us to assess the skill mix, as well as total numbers of staff available for operational activities including procurement, warehousing, order management. The staff numbers are detailed in Appendix 1 and relate to production related activities only. As detailed above there is a requirement for 20% of service activity to be ringfenced to meet regulatory compliance, and these have been removed from the plan***. As such 100% manufacturing capacity as represented within the capacity plan equates to 80% of the total service capacity.***

Within the staffing numbers for production activities, we have applied a factor of 0.4 to each w.t.e to account for the following:

- Statutory and mandatory training
- Annual Leave
- Sickness

This makes 0.6 of every 1 w.t.e available for production, however there are efficiencies within this model that can be made around the planning and completion of training and education activities that have not been considered at this stage.

4. BASELINE TIMING DATA

Baseline timing data is a key part of the capacity planning process. Given the breadth of data across all technical services within Wales, the baseline data has been entered into the capacity plan following the below principles:

- All batches/campaign items with a semi-automated method of manufacture will utilise capacity timings from the Medicines Unit within IP5
- All single product items or campaigns where manufacture follows manual processes will have a timing representing an average of those submitted by Technical Services across Wales.
- Compounded parenteral nutrition timing has been taken from Cardiff and Vale UHB.
- Process and Staff validations are assigned timings appropriate for the validation process required.
- Gassing decontamination timings are a worst-case scenario from commercial decontamination data

A table demonstrating the timings applied to each other activities described within this document are detailed in point 10 below.

5. PRODUCT PROJECTIONS & ANXILLIARY PRODUCTION TASKS

To calculate the daily timings, the capacity plan requires projected or contemporaneously accurate data entry of the products required. To provide accurate assessment of the staffing requirement against the projected demand the following principles have been applied:

- Baseline activity usage from 23/24 used
- Increased by 11% demand per annum up to 27/28 (projected year of hub opening)

These principles have been applied across the entire agreed product portfolio for each identified product. From this projected list there has been a projection of the daily number of products split into single item / campaign / batch as below:

Product Type	Quantity per Capacity Entry
Singe Item Batch	**1**
Single Item Batch	**5**
Single Item Batch	**10**
Campaign	**2-10**
Campaign	**11-20**
Campaign	**21-30**
Campaign	**31-40**
Batch	**10-20**
Batch	**21-40**
Batch	**41-50**
Batch	**51-60**
Batch	**120**
Compounded PN	**1**
Compounded PN	**5**
Adult Parenteral Nutrition + Additions	**1**
Neonatal Parenteral Nutrition + Additions	**1**
Dispensing of Outsourced Items	**10**

Additional tasks entered onto the capacity plan to ensure completeness include:

Task Type	Reference
Process Simulations	1/isolator/week
Gassing Transfer	3 sessions per day

Staff Validation	3/day
Cleaning	15 minutes per isolator per day

6. WEEKLY PRODUCTION SCHEDULE

Upon projection of the product demand, the workload has been spread evenly into daily demand based on the product splits identified in 2.3. This provided the daily demand data that can be placed into the capacity plan to give a projected capacity on any given day. The daily breakdown of products can be identified in Appendix 3. These figures will be entered into the capacity plan to identify the % staff capacity utilised to produce this number of items and assumes a six-day working schedule to mirror current practice within current technical services units

7. CAPACITY UTILISATION OUTCOME

Entering each of the daily production schedules within Appendix 2 into the PASG Capacity Tool provides us with an average weekly capacity utilisation of 81% to provide approximately 146,779 products per annum within 27/28. Figure 1 is a projection of how the 11% annual demand will impact on hub capacity in future years.

This projection identifies that the production staffing levels within the TrAMS SE Hub business case are sufficient to provide the anticipated product demand for 27/28. The projection also shows that with a 11% annual demand increase the hub can absorb demand up until 31/32 where additional staff investment will be required.

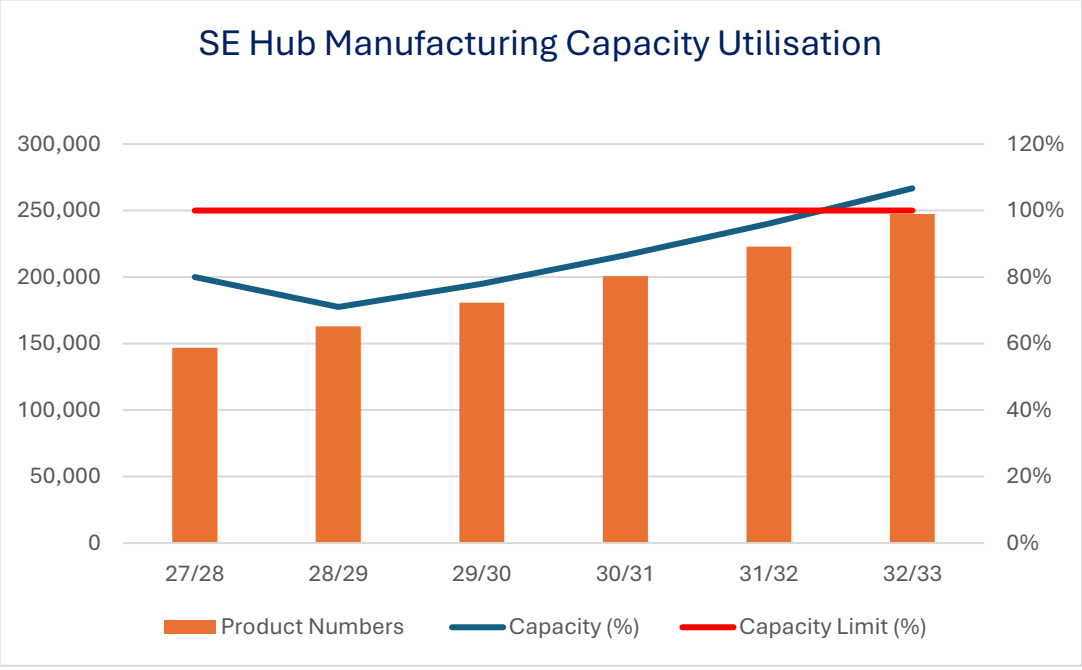


Figure 1: TrAMS Staffing Capacity Utilisation

8. OUTCOMES AND RECOMMENDATIONS

Assessment of the current staffing requirement and projected product demand has been undertaken using the nationally recognised UK PASG Capacity Utilisation tool.

Outcomes from this assessment indicates the following:

- Current staff costs and structure for the SE Hub is sufficient to provide the anticipated product demand for 27/28 (80% of capacity used).

- The staffing structure is capable of absorbing 5 years of currently anticipated demand growth post-opening before reinvestment in staff is required. This assumption can be reviewed if there are significant changes in clinical practice impacting the projected product demand.

- The assessment considers production capacity and all associated activities as an assumption of how the hub will operate. This may be subject to change as the hub construction takes place and detailed production processes are developed further.

- The UK PASG Capacity Utilisation Tool is reviewed annually prior to hub opening to provide updated projections on capacity and also during the transition period to, ensuring regulatory compliance during the onboarding of stakeholder services.

9. STAFF ROLE AND GRADE FOR SOUTH EAST HUB PRODUCTION ACTIVITIES

Hub Warehouse	Band	27/28
Responsible Person shared with QA	7	1.00
Warehouse Manager Deputy RP	6	1.00
Warehouse Supervisor	5	1.00
Warehouse Operatives	3	5.00
Hub QA		
QA Officer	7	2.00
Product Releaser/QA Officer	6	5.00
Hub Education & Training		
Education & Training Lead	8a	1.00
Senior Trainer	7	1.00
Trainer	6	5.00
Hub Production		
Head of Production	8c	1.00
Deputy Head of Production	8b	2.00
Production Manager	8a	2.00

Hub Production SACT/CIVAS/PN Patient Specific and Batch/Campaign	Band	27/28	28/29	29/30
Shift Lead Production Supervisor	7	2.00	1:00	
Senior Production Supervisor	6	2.20	3:00	
Production Supervisor	5	9.00	8:00	3:00
Senior Production Operatives	4	32.00		3:00
Production Operatives	3	10.00	10:00	
Order Receipt Admin	3	1.00		
Order Scheduling Admin	4	1.00		
Hub Procurement				
Procurement Manager	6	1.00		

Procurement Officer	5	1.00		
		27/28	**28/29**	**29/30**
Total		86.20	108.20	114.20

10. CAPACITY TIMING APPLIED TO ACTIVITIES (Requires NO) Timings

	Process	Processing order pre and post manufacture (mins)	Rx verf and stab / Prep of worksheet and label (mins)	Worksheet and label check (mins)	Assembly (mins)	Assembly check (mins)	Transfer (mins)	Transfer to work station (mins)	In Process Check (mins)	Compounding time for batch (mins)	Transfer out of work station (mins)	Transfer to support room (mins)	Labelling of products (mins)	Final Accuracy Check and approval (mins)	Number Items per batch
Batch Name	Proposed Staff ⇨	Order Admin / warehousing Staff	Production Operatives	Senior Production Operatives or Supervisors	Production Operatives	Senior Production Operatives or Supervisors	Production Operatives or Senior Production Operatives	Production Operatives or Senior Production Operatives	Production Operatives or Senior Production Operatives	Production Operatives or Senior Production Operatives	Production Operatives or Senior Production Operatives	Production Operatives or Senior Production Operatives	Production Operatives or Senior Production Operatives	Hub QA	
		Senior Production Personnel Support – Band 6 and higher													
Single Item Batch x 10		50	40	10	50	50	0	0	100	100	30	30	30	100	10
Campaign - 2-10		5	5	2	25	10	0	0	20	20	7.5	7.5	10	10	5
Campaign - 11-20		5	5	2	25	10	0	0	60	60	7.5	7.5	20	20	15
Campaign - 21-30		5	5	2	25	10	0	0	80	80	7.5	7.5	30	30	25
Campaign - 30-40		5	5	2	25	10	0	0	80	80	7.5	7.5	30	30	35
Batch 10-20		5	5	2	25	10	0	0	60	60	7.5	7.5	20	20	20
Batch 21-40		5	5	2	25	10	0	0	80	80	7.5	7.5	30	30	40
Batch 41-50		5	5	2	25	10	0	0	100	100	7.5	7.5	35	40	50
Batch 50-60		5	5	2	25	10	0	0	120	120	7.5	7.5	40	50	60
Batch 120		5	5	2	25	10	0	0	155	155	7.5	7.5	62	62	120
Adult PN - Standard + Addition		5	7	5	5	10	0	0	10	10	7.5	7.5	3	4	1
Neonatal PN - Standard + Additions		5	10	5	5	10	0	0	10	10	7.5	7.5	3	4	1
Compounded PN		5	10	5	15	15	0	0	45	45	7.5	7.5	3	10	1
Gassing Transfer		0	0	0	0	0	90	0	0	0	0	0	0	0	1
Process Simulation (1 per workstation/week = 5 per day)			5	2	25	10	0	0	300		300	7.5	20	20	75
Single Item Batch x 5		5	20	5	25	25	0	0	50	50	15	15	15	50	1
Compounding PN x 5		25	20	25	25	15	0	0	225	225	7.5	15	15	50	5
Cleaning (15 mins X 15)														75	
Compounder set up		0	0	0	0	0	0	0	0	200	0	0	0	0	

11. South East HUB DAILY DEMAND BREAKDOWN (based on 6 day working)

Monday						
	Single Item	Campaign 2-10	Campaign 11-20	Campaign 21-30	Campaign 30-40	Batch
SACT	37	8	5			5
CIVAS	4		2			2
PN - Compounded	31					
Outsourced	115					

Tuesday						
	Single Item	Campaign 2-10	Campaign 11-20	Campaign 21-30	Campaign 30-40	Batch
SACT	37	8	5			5
CIVAS	4		2			2
PN - Compounded	31					
Outsourced	115					

Wednesday						
	Single Item	Campaign 2-10	Campaign 11-20	Campaign 21-30	Campaign 30-40	Batch
SACT	37	8	5			5
CIVAS	4		2			2
PN - Compounded	31					
Outsourced	115					

Thursday						
	Single Item	Campaign 2-10	Campaign 11-20	Campaign 21-30	Campaign 30-40	Batch
SACT	37	8	5			5
CIVAS	4		2			2
PN - Compounded	31					
Outsourced	115					

Friday						
	Single Item	Campaign 2-10	Campaign 11-20	Campaign 21-30	Campaign 30-40	Batch
SACT	37	8	5			5
CIVAS	4		2			2
PN - Compounded	31					
Outsourced	115					

Weekend Day						
	Single Item	Campaign 2-10	Campaign 11-20	Campaign 21-30	Campaign 30-40	Batch
SACT	37					
CIVAS	3					
PN - Standard						1
PN - Compounded						
Outsourced	115					

Appendix 4 Estates Annexe and Cost Forms

Outline Business Case		
Trust/Health Board:		**NHS Wales Shared Services Partnership**
Hospital/Site	:	**IP5**
Project Title	:	**TrAMs Hub SACT & CIVAS**
Project No	:	
Prepared by	:	**Paul Beckett**
Date	:	**23-Apr-25**

Project Title **SACT & CIVAS TrAMs hub**

BASIS OF ESTIMATING

Healthcare Capital Investment document Version 2

Main Contract Procurement Method :

Main Contract Standard Form and Option :

Proposed start on site : Apr-26

Proposed completion date :

Date budget discussed with Estates Development*(ED) :

**Estates Development is a part of NHS Wales Shared Services, Specialist Estate Services , tel (029) 20904087/9*

Capital Cost Summary

Ref	Cost Centre	Net £	VAT @ 20% £	Gross £
5	Works Cost (BJC2)	6,437,110	1,287,422	7,724,532
6	Fees (BJC3)	698,993	51,604	750,597
7	Non-works Costs (BJC3)	679,432	29,774	709,206
8	Equipment Costs (BJC2)	6,270,702	1,254,140	7,524,842
9	Contingency at 15%	2,112,936	422,587	2,535,523
10	***Forecast Project Out-turn Cost***	16,199,172	3,045,528	19,244,700
11	LESS RECOVERABLE VAT (BJC5)		(87,604)	(87,604)
12	**FORECAST PROJECT OUT-TURN COST**	16,199,172	2,957,924	19,157,096

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Project Title **SACT & CIVAS TrAMs hub**

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

Accommodation	Function Size	Functional Unit m2/Nr net	Gross Floor area (GFA) m2	Cost/m2 GFA £/m2	N/A/C	Works Cost £	Equipment Cost £
Departmental costs			1549	4,156		5,610,944	6,270,702
On costs						826,166	
Total (gross) floor area			1549				6,270,702
Less: Abatement for transferred equipment 0 %							0
							6,270,702
Works Cost - to BJC1 Summary						6,437,110	
Equipment Cost - to BJC1 Summary							6,270,702

Comments and floor area relate to SACT & CIVAS
Total floor area total is for the clean room suites plus stores and offices

Project Title	**SACT & CIVAS TrAMs hub**		
CAPITAL COSTS: FEES AND NON-WORKS COSTS			
			% of Works
1	Fees	£	Cost
	a. Project Manager (C&A)	23,650	0.37%
	b. Cost Advisor (C&A)	37,840	0.59%
			0.00%
	Contractor design costs		0.00%
	d. Architect		0.00%
	e. Civil and Structural Engineer		0.00%
	f. Building Services Engineer		0.00%
	g. Planning Supervisor (Principal designer)	28,380	0.44%
	h. Supervisor (Scitec validation)	84,151	1.31%
	i. FM Advisor		0.00%
	j. Other (list and describe)		0.00%
	Radiation Protection		0.00%
	VAT advice	10,000	0.16%
	Power resilience report	74,000	1.15%
	NHS resource - legal and risk	12,500	0.19%
	NHS resource - audit & assurance	49,738	0.77%
	NHS resource - programme management	378,734	5.88%
	Total Fees to BJC1 Summary	**698,993**	10.86%
			% of Works
2	Non-Works Costs	£	Cost
	a. Land purchase costs and associated legal fees	0	0.00%
	b. Statutory and Local Authority charges		
	Phase 1 & 2		0.00%
	Section 106 25% contribution estimate		0.00%
	Licensing & regulation	41,974	0.65%
	Building reg fee		0.00%
	c. Planning and Building Control fees		
	Planning & Transport Asbri		0.00%
	d. Other		
	Carbon reports	12,150	0.19%
	Surveys eg environmental impact		0.00%
	Total Non-Works Costs to BJC1 Summary	54,124	0.84%
	d. Other (NHS & validation)		
	NHS resource		0.00%
	NHS resource -Validation	530,562	8.24%
	Consumables re validation	94,746	1.47%
	Total NHS & validation	625,308	9.71%
	Total Non-Works Costs inc NHS to BJC1 Summary	**679,432**	10.55%

Project Title **SACT & CIVAS TrAMs hub**

PROJECT CASHFLOW FORECAST

Proposed start on site:
Proposed completion date:

Year	0	1	2	3	Total
Financial year	2025/26	2026/27	2027/28	2028/29	
Works Cost	180,000	6,257,110	-		6,437,110
Fees	127,489	561,504	10,000		698,993
Non-works Costs	-	679,432	-		679,432
Equipment Costs	1,003,540	5,267,162			6,270,702
Contingencies	211,294	1,690,348	211,294		2,112,936
VAT	300,728	2,700,541	44,259		3,045,528
Sub-total	1,823,050	17,156,097	265,552	-	19,244,700
Recoverable VAT	(57,761)	(27,843)	(2,000)		(87,604)
Total	1,765,289	17,128,254	263,552	-	19,157,096

Project Title **SACT & CIVAS TrAMs hub**

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	6,437,110	1,287,422	2.8%	36,000
Fees	698,993	51,604	100.0%	51,604
Non-works Costs	679,432	29,774	0.0%	0
Equipment Costs	6,270,702	1,254,140	0.0%	0
Contingencies	2,112,936	422,587	0.0%	0
Total			£	87,604

Costed Risk Register TRAMS Hub

Version	1
Date	07/05/2025

Risk Descriptions				Post mitigation Score out of 5			Risk Cost Calculation					
No.	Risk	Consequence	Proposed mitigations	Severity	Likelihood	Proximity	Risk Score	RAG	Cost to Recitify	Risk Cost	Risk Owner	Mitigation Actionee
1	Damage to data cables in work area	Loss of connectivity to whole site	2 existing redundant cables at opposite sides of work area. Brief contractors, mark cables, monitor and manage.	2	1	4	6%		£28,612	**£1,831**	Project Manager	Project Surveyor
2	Damage to power boards in work area	Loss of power to IP5	Brief contractors and supervise as appropriate	3	2	4	19%		£28,612	**£5,493**	Project Manager	Project Surveyor
3	Damage to underground site power cable	Loss of power to whole park	Survey undertaken to locate cable. Brief contractors and supervise as appropriate	5	1	4	16%		£28,612	**£4,578**	Project Manager	Project Surveyor
4	Damage to sprinkler systems	Flood event	Drain sprinklers during relevant works. Establish location of isolator valve and brief contractors with actions on a flood.	4	1	4	13%		£28,612	**£3,662**	Project Manager	Project Surveyor
5	Damage/Blockage to site drainage	Loss of toilets	Call out drain contractor	2	2	4	13%		£14,306	**£1,831**	Project Manager	Builidng Manager
6	Failure of floor slab due to load exceeding strength	Redesign, dig out and recitfy footings.	Surveys and design calculations indicate low risk	5	1	3	12%		£1,452,057	**£174,247**	Project Manager	Cleanroom Contractor
7	Damage to roof during works. Either structural or damage to gutters and syphons.	Rework and delay to programme. Delay claims from other contractors	Ensure correct protections are in place, approval of RA/MS.	3	2	3	14%		£290,411	**£41,819**	Project Manager	Project Surveyor
8	Other damage to building fabric during constuction	Delay to programme, delay claims from other contractors	Monitor and manage contractors RA/MS effectively.	2	2	3	10%		£145,206	**£13,940**	Project Manager	Project Surveyor
9	Delay in isolator delivery	Delay to cleanroom validation and commissioning.	Monitor and manage isoator contractor.	3	3	2	14%		£145,206	**£20,910**	Project Director	Project Manager
10	Inflation Claims exceed expectations	Cost pressure to project	Good contract management. Proceed at pace to minimize duration of works	3	5	3	36%		£2,613,702	**£940,933**	Finance Lead	Project Manager
11	Unplanned design changes during construction	Change claims from contractors	Good procuement and project management controls	3	5	3	36%		£2,904,113	**£1,045,481**	Project Director	Project Manager
12	Cost of uncontracted works exceeds forecast (ie Data and Utility final connections, Security and Fire Alam integrations	Cost pressure to project	Good procuement and project management controls	3	4	2	19%		£290,411	**£55,759**	Project Manager	Procurement Lead
13	NHS IT costs exceed provisions	Cost pressure to project	Good procuement and project management controls	2	3	2	10%		£290,411	**£27,879**	Project Manager	IM&T Lead
14	NHS Capitalised staff costs exceed provisions due to programme delays.	Cost pressure to project	Good procuement and project management controls	3	3	1	7%		£2,734,706	**£196,899**	Finance Lead	Project Manager

Total Risk Provision	**£2,535,262**
Project Cost before Risks	**£16,853,572**
% of Costs	**15.0%**

Table of other Estates considerations

Consideration	Status	Rationale
Planning Permission	In Place	Permission for change of use and change in elevations was granted with no pre-commencement conditions in Feb 2025.
Ecology	In Place	Ecology considerations have also been addressed as part of the Radiopharmacy project (Bat and Swift boxes have been installed) and no further actions are required for the Hub.
BREEAM assessment	None	Renovations to the existing building shell were already completed by the Radiopharmacy project and no further external works are planned. All of the remaining work to deliver the project is internal fit out. In the circumstances the project assesses that there is limited value in conducting an BREEAM assessment.
AEDET	None	The facility is not open to the public and there will be no public or patient access. The layout and internal finishes are heavily dictated by regulatory requirements. In the circumstances the project assesses that there is limited value in carrying out an AEDET assessment
Project Bank Account	None	Construction period will not exceed 6 months and the main contractor proposes to carry out the main works themselves. In the circumstances the project assesses that a Project Bank Account is

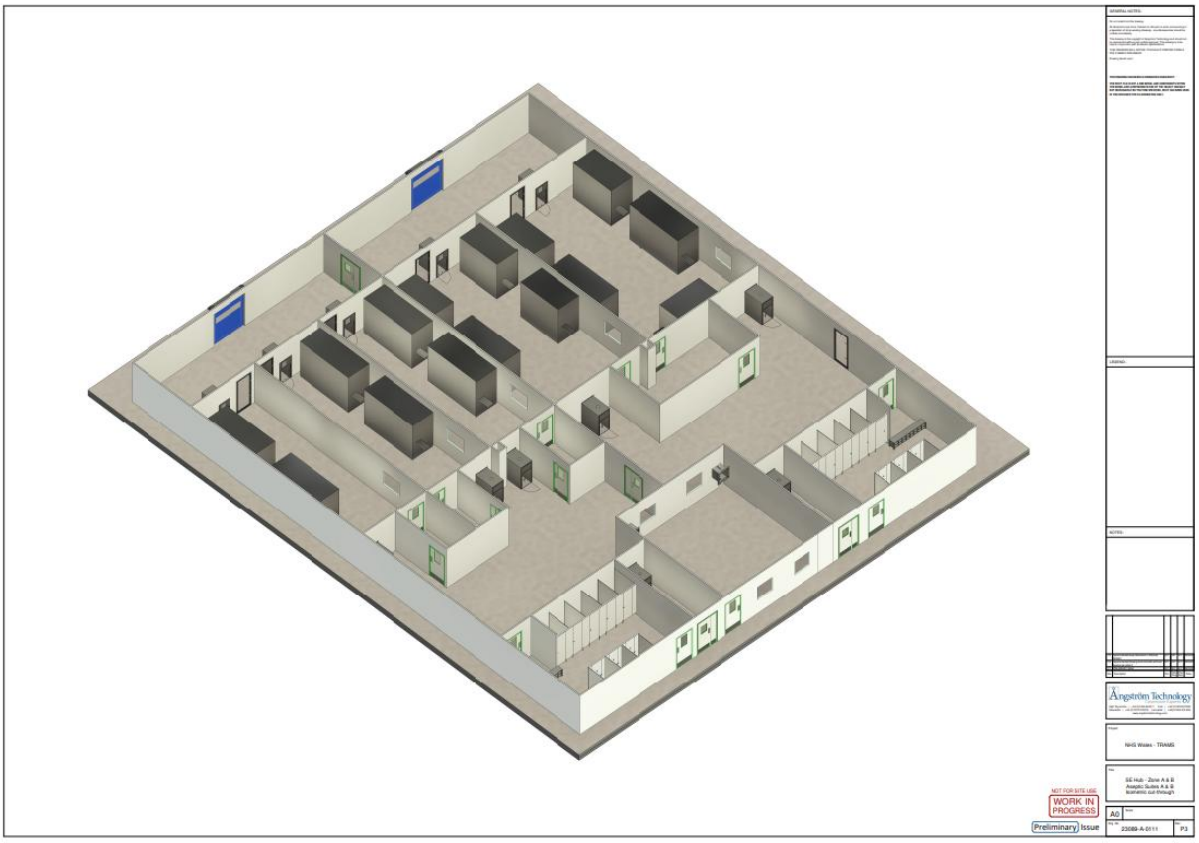
		not required, and no provision has been made for one.
Utilities	In Place	All utility supplies are in place, the main power cables from the IP5 power room to the works site have been tested as part of the Radiopharmacy project
Fire Strategy	In Place	The fire strategy prepared for the Radiopharmacy Project also covers the Hub Concept design. The compartmentation wall between the warehouse and the pharmacy zone has already been renovated.
Lifecycle costs	Under review	The lifecycle costs appropriate to a facility of this kind are under review, and will be included in the FBC.

Appendix 5 Concept Design drawings

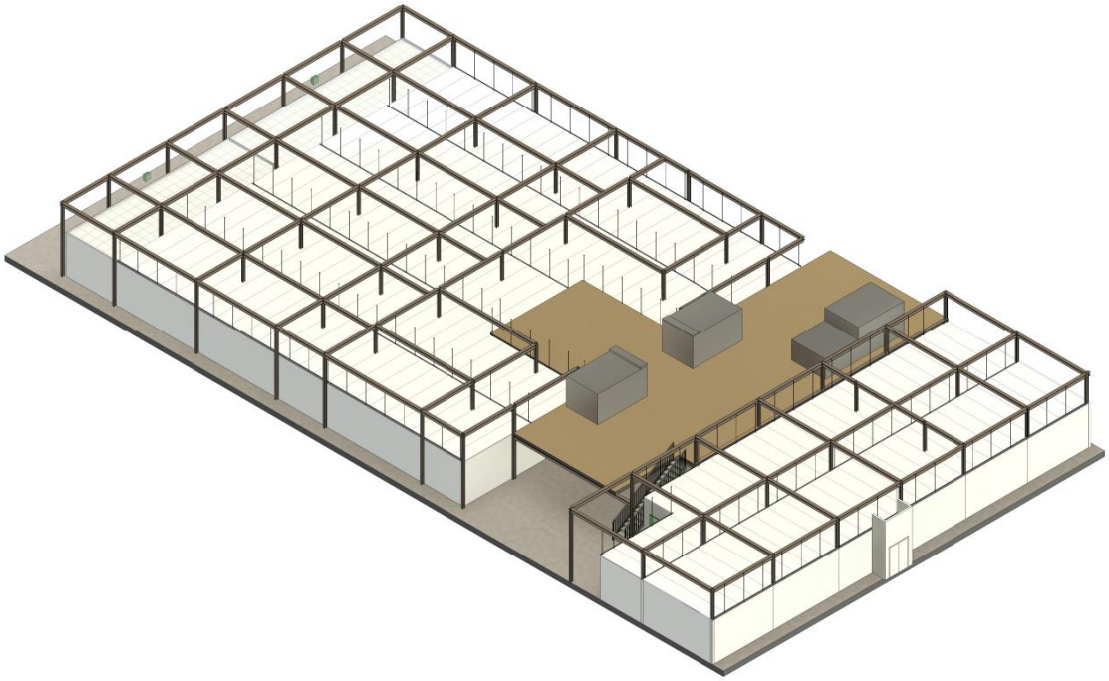
To note: Further details of the Mechanical & Electric concept design deliverabls and site utility connections are available for inspection on request.

Proposed layout of Hub (L) and Radiopharmacy (R) at the east end of IP5

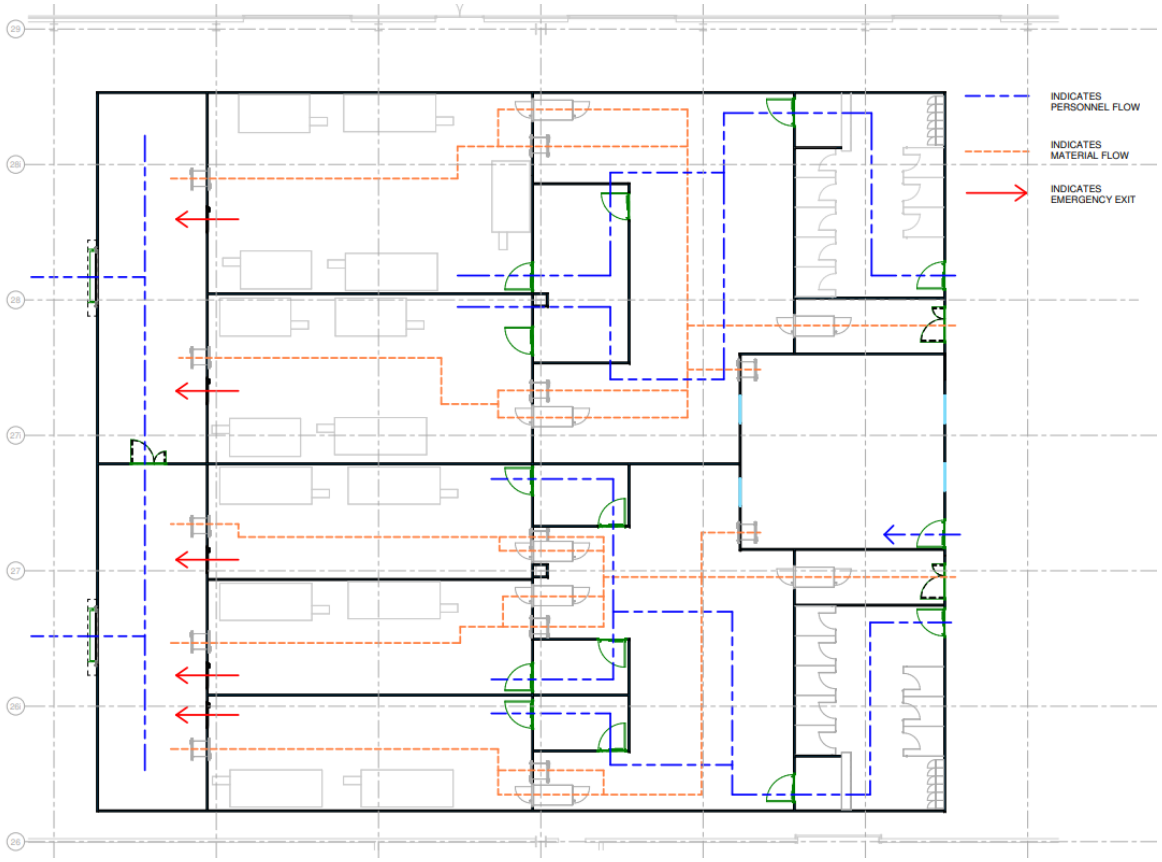
Proposed Hub interanal layout, isometric view



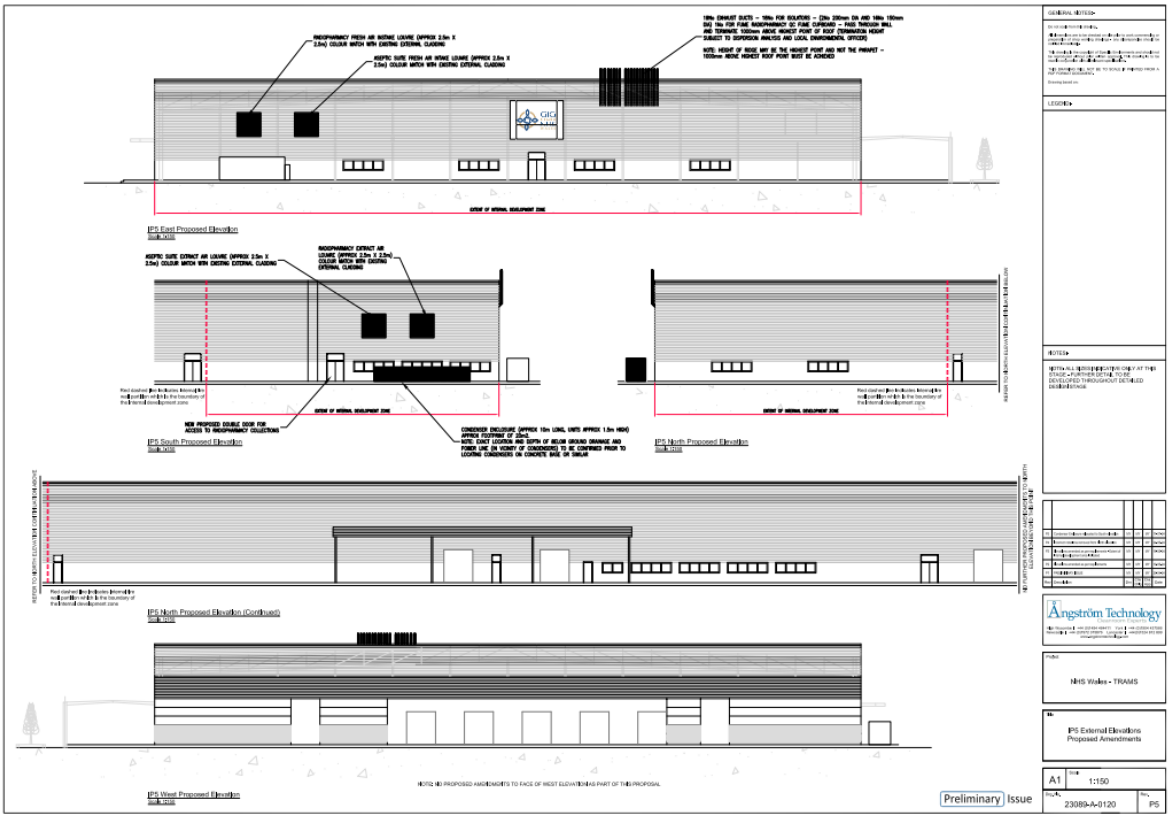
Proposed Hub and Radiopharmacy showing plant deck and walk on ceilings



Proposed material and personnel flows within the Hub cleanrooms



Proposed external elevations of IP5 showing the additional vents and stacks propsoed.



Appendix 6 Membership of Stakeholder Groups

TRAMs Programme Board

Post	Organisation	Programme Role	Current Occupant
Managing Director	NWSSP	Accountable Officer, and joint SRO	Neil Frow
Chief Pharmaceutical Officer	Welsh Government	Joint SRO, Professional Report for Service Director	Andrew Evans
TRAMS Service Director	NWSSP	TRAMS Programme Director and BCM	Colin Powell
Representative of CPG	SBUHB	Assurance Lead	Judith Vincent
Representative of CPG	VELUNHST	Board Member	Bethan Tranter
Nuclear Medicine Lead	SBUHB	Board Member	Neil Hartman
Assistant Director of Capital Funding	Welsh Government	Funding Stakeholder	Ian Gunney
Wales lead for Quality Assurance	NHS Wales	Quality Lead	Emma Davies
Director of Finance	ABUHB	Board Finance Lead	Robert Holcombe
NWSSP Finance Director	NWSSP	Board Member	Alison Ramsey
NWSSP Specialist Estates Lead	NWSSP	Board Member	Mike Travers
NWSSP Medical Director	NWSSP	Board Member	Ruth Alcolado
NWSSP Director of Workforce	NWSSP	Board Member	Gareth Hardacre
NWSSP Clinical Logistics Lead	NWSSP	Board Member	Tony Chatfield

Project Boards:

TrAMs Working Groups

Group Name	Name of Individual	Role	Organisation
TRAMs South East Hub Project Board			
	Colin Powell	Project Executive	NWSSP
	Peter Elliott	Project Manager	NWSSP
	Paul Beckett	Project Finance Lead	NWSSP
	Mike Travers	Estates Lead	NWSSP
	Tim Banner	Director of Pharmacy	CAVUHB
	Hannah Wilton	Director of Pharmacy	CTMUHB
	Jonathan Simms	Director of Pharmacy	ABUHB
	Bethan Tranter	Director of Pharmacy	VELUNHST
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	Martin Horton	Unison	ABUHB
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	Portia Rees-Jones	Dietetics	HDUHB
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	Anthony Cadogan	Deputy Chief Pharmacist	VUNHST
	Martin Rees-Milton	Principal Pharmacist Aseptics	VUNHST
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	Lois Lloyd	Chief Pharmacist	BCUHB
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	Lynne Herring	Lead Pharmacist Operational Services Manager	ABUHB
	Angharad Atkinson	Pharmacist	C&VUHB
	Kerry Crompton	Pharmacist	C&VUHB
	Tracey Parry	Lead Cancer Services Pharmacist	BCUHB
	Glesni Pritchard	Cancer Services Pharmacist	BCUHB
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	David Fox	Pharmacist Team Lead Aseptic Services	CTMUHB
	Owain Jones	Principal Pharmacist Clinical Trials	ABUHB / VUNHST
	Jatinder Parmer	Pharmacist	SBUHB
	Lucy Williams	Dietetics	CTMUHB
	Lucy Morgan	Critical Care Dietician	ABUHB
	Julie Regan	Clinical Lead Dietician	HDUHB
	Nokhuthula Nyoni	Dietician	VUNHST
	Karen Thomas	Joint Head of Dietetics	HDUHB
	Victoria Jones	Dietician	HDUHB
	Kathryn Francis	Adult Clinical Lead Dietician	HDUHB
	Rhys Hamer	Principal Pharmacist - Production and Aseptic Services	ABUHB
	Sarah Griffiths	Deputy Head of Pharmacy, Clinical Services Lead	CTMUHB
	Jane Powell	Deputy Head of Dietetics/Actue Team Lead	BCUHB
	Charlotte Thomas	Pharmacist	HDUHB
	Cerith Morgan	Lead Aseptic Pharmacist	HDUHB
	Stuart Rees	Clinical Pharmacy lead for Patient Services	HDUHB
	Linda Broomfield	Lead CNS Nutrition	HDUHB
	Zoe Hewitson	Registered Dietician	ABUHB
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	Lee Samuel	Head of Pharmacy Technical Services	SBUHB
	Alison Jones	Head of Pharmacy Technical Services	C&VUHB
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	Rosalind Bajjadar	Pharmacist	ABUHB
	Holly Breeze-Jones	Pharmacist	SBUHB
	Rebecca Owen	Clinical Pharmacist	CTMUHB
	Anwen Richards	Lead Pharmacist Women & Children's Health	HDUHN
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Clinical Trials:			
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Appendix 7 Glossary of Abbreviations

ABBREVIATION	DEFINITION
ABUHB	Aneurin Bevan University Health Board
BAU	Business as Usual
CAVUHB	Cardiff & Vale University Health Board
COVID	Coronavirus Disease
CTMUHB	Cwm Taf University Health Board
EWN	Early Warning Notice
FBC	Full Business Case
IFRS	International Financial Reporting Standards
IP5	Imperial Park Building 5
IP6	Imperial Park Building 6
MHRA	Medicines & Healthcare Products Regulatory Agency
NHS	National Health Service
NWSSP	NHS Wales Shared Services Partnership
OBC	Outline Business Case
OCP	Organisational Change Process
OTD	On Time Delivery
PASG	Pharmaceutical Aseptic Services Group
PBC	Programme Business Case
PO	Purchase Order
PQS	Pharmaceutical Quality System
QIA	Quality Impact Assessment
RIBA	Royal Institute of British Architects
SACT	Systemic Anti-Cancer Therapies

SCP	Supply Chain Partner
SE	South East
SES	Specialist Estates Services
SLA	Service Level Agreement
SQ	Square
SRO	Senior Responsible Officer
SSPC	Shared Services Partnership Committee
TRAMS	Transforming Access to Medicines
TUPE	Transfer of Undertaking Protection of the Employment Act
VAT	Value Added Tax
VO	Variation Orders
VUNHST	Velindre University NHS Trust
WHPSMS	Welsh Hospital Pharmacy Stock Management System
WTE	Whole Time Equivalent