Business Justification Case

South East Wales Radiopharmacy

Status	Issued for approvals
Version	2.2
Date	3 July 2024

Version	Date	Changes to content
1.0	17/11/23	First submission to Welsh Government
1.1	10/06/24	Re-drafted for second submission
1.2	11/06/24	Circulated for review, to become v2.0 once finalised
2.0	28/06/24	Updated explanatory text, and preferred funding option. Case now issued for approvals
2.1	01/07/24	Additions requested as per Programme Board minutes 1/7/24
2.2	03/07/24	Future year cost profile added as requested by Programme Board FD rep

Approvals	Version	Date	Decision
TrAMs SE Hub Project Board	1.0	17/11/23	Approved
TrAMs Programme Board (SRO)	1.0	17/11/23	Approved by SRO Action
Shared Services Partnership Committee	1.0	23/11/23	Approved
TrAMs SE Hub Project Board	2.0	27/06/24	Approved
TrAMs Programme Board	2.0	01/07/24	Planned
Shared Services Partnership Committee	2.0	18/07/24	Planned
TrAMs Programme Board	2.1	01/07/24	Approved

Contents

Executive Summary

This Business Justification Case (BJC) seeks approval for capital investment in preparative Radiopharmacy facilities in the South East Wales region.

The case is prepared in the context of:

- The urgent clinical need resulting from the forced closure of the old legacy Radiopharmacy facility.
- The provision of a safe and regulatory compliant facility of sufficient size to meet the expected future demand.
- Meeting the overarching Transforming Access to Medicines Programme (TrAMs), requirements outlined in the current endorsed TrAMs Programme Business Case.

Due to the points above it has been agreed with Welsh Government to submit a BJC with costs to the maturity of a Full Business Case (FBC) rather than an Outline Business Case (OBC) followed by an FBC.

The case recommends a total capital investment of £9.2m to be made through the TrAMs Programme, under the governance of the Shared Services Partnership Committee. The preferred option site is Imperial Park Building No.5, Newport.

Of this sum, £2.3m has already been funded in the development of the BJC together with the purchase of the key equipment requirements which have significant lead in times, so the net capital funding commitment requested from Welsh Government **is circa £6.9m to complete the project**. No capital funding is being sought from Health Boards and Trusts.

Contracts are in place to support delivery of the project, so the remaining expenditure is expected to be incurred within 6 months of the Investment Decision. Therefore, if the decision is taken by 1 Sept 2024, then the whole remaining balance is expected to be committed during the financial year 2024/25.

The revenue commitment to operate the service is also set out in this case.

Shared Services Partnership Committee is invited to **Approve the Business Justification Case together with the expected revenue consequences of the new service model.**

1. Strategic Case

1.1 Strategic Context

Radiopharmacy is a service that prepares radioactive injectables for patients, mostly for diagnostic purposes in support of Gamma Camera scans, but also a small number of therapeutic injections. Within South East Wales the service is currently managed by Cardiff and Vale University Health Board (CAVUHB) Nuclear Medicine department, with professional oversight and Quality Assurance support from the Health Board's Pharmacy department

The short shelf life of the product means that the injections take place on the same day as the medicine is prepared, usually within 1 to 4 hours

A number of regulators are involved in overseeing the preparative service including:

- Medicines Health Regulatory Authority (MHRA)
- Natural Resources Wales (NRW)
- Health and Safety Executive (HSE)
- Office of Nuclear Regulation (ONR)

The service is also supported by a contracted Radiation Protection Advisor (RPA) and Radioactive Waste Advisor (RWA). These are required by legislation.

The Transforming Access to Medicines (TrAMs) Programme Business Case which was endorsed by the Minister for Health and Social Care in March 2021 determined that the future reprovision of Radiopharmacy services would be in an All-Wales service, hosted within NHS Wales Shared Services Partnership (NWSSP) and delivered through 3 regional hubs. As at June 2024, the Outline Business Case for the first of these hubs, in South East Wales, is in preparation. Outline design work has been undertaken to test the fit of this Radiopharmacy development alongside the larger Hub investment in the Imperial Park 5 (IP5) building in Newport, owned and operated by NWSSP. A good fit has been established and the two developments aligned and deconflicted. It has been established by outline concept design that there is sufficient power for both.

Open issues within the TrAMs SE Wales Hub Project which have not yet been completed include:

- Planning Permission
    - A Planning Pre-Engagement process has been carried out based on the design concepts for the IP5 site.
    - It is intended to submit a planning application covering both the Radiopharmacy and the Hub in July 2024.
- Equipment Procurement including isolators
    - Pre-tender engagement was carried out in Oct 2021.
    - A further round to update costings was carried out in Nov 2023.
    - The tender for 15 Hub isolators is expected to be offered in Autumn 2024, aligned with the detailed design phase of this project.
- An Organisational Change Process (OCP) will identify if staff at C&V are impacted by TUPE regulations, and where TUPE applies, then they will transfer to NWSSP.
    - Planning for this is underway within the TrAMS Programme, working in partnership with Staff Side representatives, Health Boards and Trusts.

1.2 Strategic Case for Change

Radiopharmacy services in South East Wales have, until October 2023, been provided on a regional basis by CAVUHB, supporting patients in Aneurin Bevan University Health Board (ABUHB), Cwm Taf Morgannwg University Health Board (CTMUHB), and Velindre University NHS Trust (VELUNHST). The legacy unit is located within the University Hospital Wales and daily deliveries are made to nuclear medicine departments at the following sites:

- University Hospital Wales
- University Hospital Llandough
- Royal Glamorgan Hospital
- Royal Gwent Hospital
- Nevill Hall Hospital
- Velindre Cancer Centre

Deliveries are time critical and two dedicated vans and specially trained drivers are used for deliveries. This transport service is proposed to transfer to provision by NWSSP Health Courier Service in the near future.

9,028 individual patient doses were produced for the SE region in this period from October 2022 to September 2023 was:

- 230 for lung indications
- 875 for renal indications
- 1468 for cardiac indications
- 2014 for bone indications
- 2279 for cancer indications
- 2162 for other indications

Organisationally the split of patient doses for this period is:

- 3350 for CAVUHB
- 3380 for ABUHB
- 1028 for CTMUHB
- 1270 for VELUNHST

Patient doses are first prepared in multi dose vials, before being drawn up into individual syringes. The total demand for 9,028 doses is supplied by 4,012 vials, so on average 2.25 doses per vial. This ratio varies considerably depending on how many patients are booked into each clinic, giving both an efficiency challenge, and an opportunity for the service.

The existing service was staffed by 19 individuals, 18.2 WTE, but with a number of split role posts undertaking both technical and clinical work. Disaggregating the split roles, the work content for the existing CAVUHB Radiopharmacy unit standing alone is estimated at 13.2 WTE.

The legacy unit has been known to be at the end of its life for some time. Following an MHRA inspection in 2019, CAVUHB produced a Business Case in 2020 for a replacement, but this investment was deferred in favour of the TrAMs Programme alternative.

In October 2023 a further MHRA inspection took place, which identified a significant number of defects in the service which required immediate action. Following this inspection CAVUHB made the decision to close the legacy unit and examine alternative options.

Time limited service continuity measures have been put in place involving supply from outside the region, including by Swansea Bay University Health Board (SBUHB), Birmingham and Bristol NHS Trusts. These arrangements are temporary in nature and are not currently meeting the whole clinical demand.

On 24 October 2023 Paul Bostock, Chief Operating Officer, wrote on behalf of CAVUHB to Welsh Government and NWSSP, stating that CAVUHB's preference was for NWSSP to expedite the replacement service by means of the TrAMs programme.

On 25 October 2023 the government's Chief Pharmaceutical Officer Andrew Evans requested NWSSP to formulate an Option Appraisal to support an immediate investment in Radiopharmacy facilities under the TrAMs programme.

1.2.1 Impacts during the interim Service since shutdown

Analysis of the current interim service from SBUHB operating from one isolator, in one cleanroom, covering the whole of South and West Wales (12 major hospitals and cancer centres) has shown that while at this point the most harmful impacts on patient care have been successfully mitigated, there is still significant adverse impact:

- The last period for which CAVUHB was able to offer full uninterrupted service was May and June 2023, during which there were patient numbers of 1,371 and 1,374 respectively. It is noteworthy that even at full capacity the demands across the South East Wales region are not met. This is noted in the ABUHB impact section below.
- Service pattern from July-December 2023 was very unstable, with a number of shutdowns in CAVUHB culminating in closure, heavy rescheduling of patients, and short-term service support from a variety of providers including SBUHB, Birmingham and Bristol Trusts.
- Months January, February and March 2024 are reflective of the total capacity from Swansea with a shortfall of capacity of approximately 300 patient treatments per month compared to full production months in May and June 2023. This shortfall is reflected in the considerable increases in patient waiting times and 8-week breaches at individual health board nuclear medicine sites in "site impacts" sections below.
- April 2024 is significantly impacted by the SBUHB Radiopharmacy "firebreak" where there were a number of significantly reduced capacity days from 22nd April to 3rd May. The reduction in capacity was considered essential to ensure that quality and capacity aspects of the service were maintained particularly related to the greater than 100% increase in throughput through the SBUHB Radiopharmacy unit.

	Swansea hospitals					Cardiff & Vale hospitals												
	SING	MTON	POW	NPTH	WBUSH	RGWENT		RGLAM		LLAN		UHW		VELINDRE		NEVH		
Month	Patients	Patients	Patients	Patients	Patients	UHW Pts	Swa Pts	UHW Pts	Swa Pts	UHW Pts	Swa Pts	UHW Pts	Swa Pts	UHW Pts	Swa Pts	UHW Pts	Swa Pts	Monthly Total
Apr-23	184	49	60	9	75	123	0	58	0	58	0	154	0	103	0	114	0	987
May-23	300	79	77	15	142	134	0	84	0	76	0	197	0	101	0	166	0	1371
Jun-23	311	77	66	24	139	135	0	66	0	66	0	218	0	147	0	125	0	1374
Jul-23	262	40	82	9	147	57	14	15	26	14	36	38	4	20	100	19	0	883
Aug-23	286	0	99	17	136	73	0	34	11	37	23	109	6	84	57	58	0	1030
Sep-23	294	0	75	12	159	134	0	97	0	73	0	183	0	101	0	110	0	1238
Oct-23	324	0	118	12	164	45	23	15	29	20	33	35	7	24	0	19	0	868
Nov-23	311	2	116	7	170	11	46	0	2	0	74	0	41	0	0	0	1	781
Dec-23	250	61	129	10	143	0	39	0	0	0	56	0	61	0	0	0	12	761
Jan-24	254	81	105	7	180	0	43	0	34	0	80	0	148	0	98	0	110	1140
Feb-24	241	86	55	6	176	0	63	0	41	0	88	0	135	0	117	0	87	1095
Mar-24	219	66	34	14	140	0	49	0	27	0	75	0	113	0	89	0	92	918
Apr-24	170	62	80	2	156	0	0	0	47	0	57	0	65	0	102	0	111	852

Table: patient doses achieved per clinical site in South and West Wales across the last 12 months, source: Health Board records.

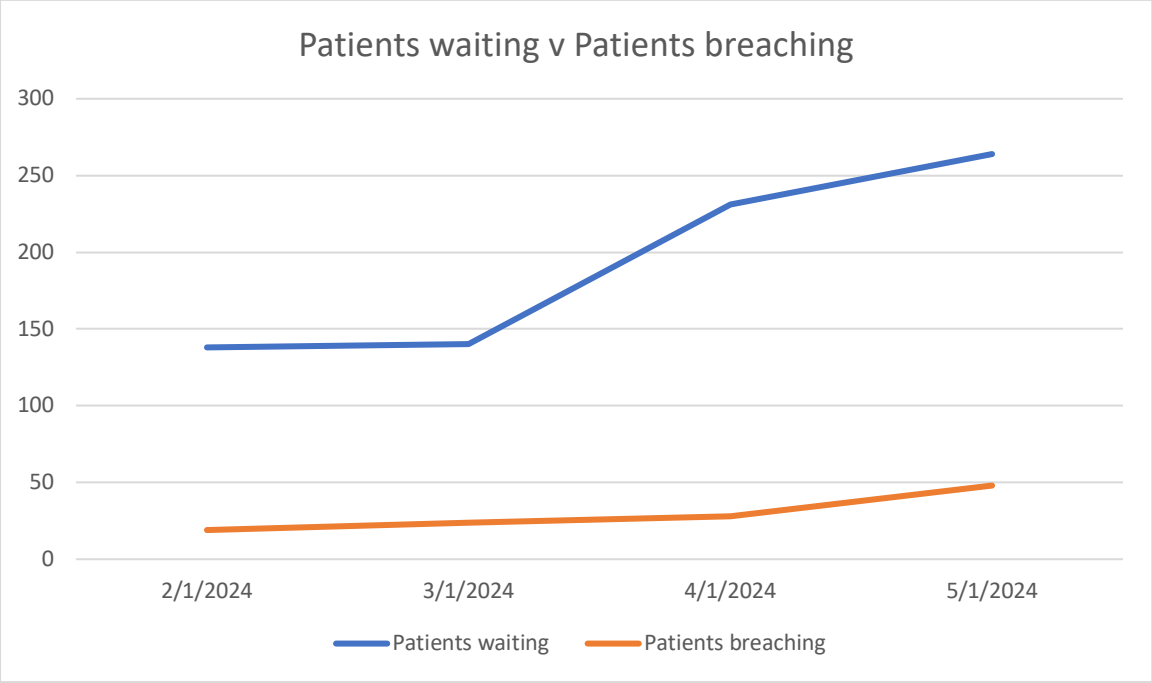
1.2.2 Individual Nuclear Medicine site impacts

The following section has been prepared by the CAVUHB Head of Radiopharmacy, and TrAMs national lead for Radiopharmacy. The data in the tables have been assembled from Health Board Nuclear Medicine department records.

Cardiff and Vale UHB impact

CAVUHB University Hospital Wales is the largest hospital in Wales with numerous specialities as well as being a major trauma centre and centre for kidney transplantation. There is therefore a significant demand for Nuclear Medicine scans. Nuclear Medicine scanning is carried out at the Llandough (UHL) and University Hospital of Wales (UHW) sites with the UHW site having two gamma cameras compared to one at UHL. The scanning capacity at UHW has been significantly impacted since the CAVUHB radiopharmacy closure with previous patient capacity at around 75 patients per week reduced to 25 patients per week. This means the numbers of patients waiting for treatment has climbed rapidly since the radiopharmacy closure. There is a time lag for the numbers of patients breaching the 8 weeks cut off starting from a position of zero in January that has now climbed to 50 patients. The numbers of patients breaching and waiting times for CAVUHB is shown below. Furthermore, the current waiting times broken down into scan time indicate around 41 days of scanning time to clear the back log. CAVUHB prioritise urgent and cancer pathways but as a result see patients for other studies waiting much longer meaning routine scans become much more urgent the longer they are left.

Much of the impact on capacity is based on the impact of delivery times to the CAVUHB sites. Typically, UHW received all their radiopharmaceuticals before 9am from the CAVUHB radiopharmacy but now receive radiopharmaceuticals from SBUHB at around 12 noon each day. The ability to extend scanning days is limited by the short shelf life of radiopharmaceuticals and the skill mix of the radiographer team who have multiple responsibilities across CAVUHB radiology as well as Nuclear Medicine.



Senior clinicians at CAVUHB have indicated their concerns at the significant drop in morale within the Nuclear Medicine team with fears of losing radiographer staff to other modalities. One Consultant Radiologist indicated their concerns via an e-mail on 21/05/2024.

> *"We had requests for 4 urgent transplant renograms yesterday, normally expected on the day or next day depending on clinical severity. The earliest date we could find was 5th June without cancelling other patients already booked and been waiting months! It's a dreadful situation at the moment, the team are really stretched trying to accommodate these emergencies."*

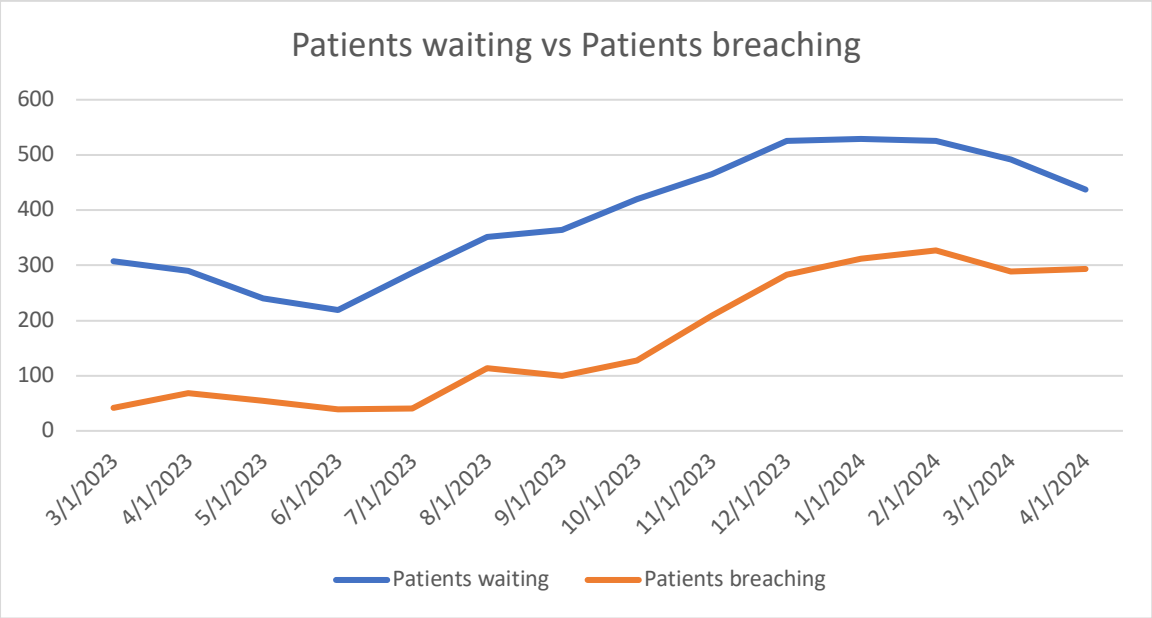
Aneurin Bevan UHB impact

ABUHB has two sites that carry out Nuclear Medicine scanning at Royal Gwent and Nevill Hall hospitals with each having one gamma camera for scanning. The two graphical presentations below indicate a considerable increase in patients waiting and breaching at 8 weeks post the CAVUHB radiopharmacy closure in October 2023. It is noticeable that there is some reduction in waiting and breach times in April 2024 which is in part due to improvement around delivery and hours worked from 9am-5pm to 10am-6pm. It is not expected that the waiting lists/breach times will decrease much more significantly due to later delivery times and limited capacity of supply from SBUHB radiopharmacy. The activity graph shows a clear downward trend in activity post closure of CAVUHB radiopharmacy.

Prior to the closure there is evidence that full demand was not being met via supply directly from CAVUHB. This is for a number of reasons:

1. The closure of the CAVUHB facility due to environmental control issues in July/August 2023.
2. The limitations on capacity at CAVUHB due to the small physical size of the radiopharmacy facilities / equipment and ongoing environmental control issues due to the condition of the aging facilities e.g. consistently requests were received from ABUHB for cardiac scanning clinics for which capacity did not exist.

The new radiopharmacy facility at IP5 in Newport will have state of the art isolator and gassing technology which will meet future MHRA requirements as well as having increased efficiency and capacity to meet all of the South East Wales demand. Delivery times will also be considerably improved for ABUHB and all South East Wales sites.



An e-mail from a Consultant Radiologist at ABUHB raised particular concerns around the current limitations on their service and impact on patients and staff.

> *"Disruption to front line services is very significant and I've described it as feeling like a constant struggle at the moment. I'm changing requests for radionuclide studies to other modalities (against our previous practice) as much as possible. I have had to respond to a number of understandably concerned/disgruntled clinicians. Our staff have agreed to some changes to their working patterns to try to compensate for the later delivery times but staff are understandably opposed to some of the proposals which have included even more unfavourable hours of working. I'm concerned that we could lose good members of staff to other modalities. Morale is generally low."*

Hywel Dda UHB impact

Hywel Dda UHB has one Nuclear Medicine site based at Withybush General hospital. This is a comparatively small service and forms part of the Swansea Radiopharmacy's usual service delivery arrangements after the closure of the Withybush radiopharmacy in October 2022.

The Nuclear Medicine team indicated that there had been a significant impact on their services during the SBUHB "firebreak" period which ran 22nd April to 3rd May 2024. This was a period of significantly reduced volume of production to enable rectification of quality issues exacerbated by the significant increase in required capacity at a greater than 100% increase. The firebreak disruption resulted in 64 patients being rescheduled. Prior to the firebreak there were 3 occasions where an order was unable to be fulfilled or was reduced due to the Swansea Radiopharmacy exceeding capacity. The bone cancer scan waiting list has now exceeded 4 weeks post fire break.

There are also significantly more occasions where receipt of radiopharmaceuticals has exceeded being 1 hour late since the closure of CAVUHB radiopharmacy.

Cwm Taf Morgannwg UHB impact

Following the closure of the CAVUHB radiopharmacy UUnit all patients were moved to Princess of Wales (POW) hospital site which meant demand was not met with a focus on bone cancer scans and urgent scan patients. The Royal Glamorgan (RGH) has since re-opened and capacity is now split again between the two sites.

Bone cancer scan patients waiting times have increased to 4 weeks and urgent scans increased to 8 weeks. Routines scans were placed on hold and the current longest wait for a routine scan is 48 weeks. For RGH there are currently 43 patients waiting over 8 weeks and for POW 24 patients waiting over 8 weeks. The delivery times for POW have not been significantly impacted but RGH delivery times have been much more unpredictable significantly impacting scanning days.

Impact on Clinically Urgent/Cancer patients

Initially the time increased for USC referrals from 10 days to 4 weeks. Urgents increased to 8 weeks and routines were placed on hold, but the waiting lists have decreased apart from routine patients.

Velindre Cancer Centre impact

The throughput of diagnostic radiopharmaceuticals for Velindre Cancer Centre is stable and relatively low in comparison to some other centres. The closure of the CAVUHB radiopharmacy has disrupted start and finish times which has caused issues in the workforce for those with longstanding commitments such as childcare. Whilst Velindre do not currently have a waiting list, they are having to inform referrers of delays in imaging / GFRs. The GFRs are probably the most impacted as they now group them, to prevent single dose requests. This might mean that ideal ‘need by’ dates are missed for this patient group.

Conclusions

- The closure of the CAVUHB radiopharmacy has put significant pressure on the remaining SBUHB Radiopharmacy requiring significant increase in staffing whilst supplying all of South Wales Nuclear Medicine sites via one production cabinet as opposed to the previous three cabinets. This means there is no contingency support in case of failure of the remaining production cabinet.
- Due to increased throughput, there is greater risk of environmental failure within the production facility and has resulted in very strict capacity controls to ensure sterility assurance of final products and patient safety.
- Due to capacity restrictions, it is estimated that the numbers of patients scanned in South Wales has reduced by at least 30% which equates to around 300 patients per month. This has impacted different sites to varying degrees with for example University Hospital of Wales having capacity reduced most significantly even though it is the largest Nuclear Medicine site, with often the most urgent and complex patients due to its patient specialities. Since the CAVUHB closure throughput of patients has reduced in the region of 66%.
- Across South Wales the numbers of patients awaiting Nuclear Medicine scans has increased significantly with 8-week limits being breached increasingly after an initial lag as the time since closure of the CAVUHB radiopharmacy extends. This is significantly impacting patients but also

Nuclear Medicine staffing morale and longer-term departmental resilience as the times since CAVUHB radiopharmacy closure extends.

- To meet capacity and provide resilience for Nuclear Medicine across South Wales it is vitally important that a new Radiopharmacy service is built at Imperial Park Newport. The new site will ensure sufficient operational cabinet support for South Wales as well as providing contingency capacity in case of failure of the Swansea Radiopharmacy. It is notable that Radiopharmacy resilience across the UK is stretched with many older and failing facilities as well as services that have been impacted by MHRA inspections including reductions in capacity or even closure.

1.3 Service Model

A future service model has been agreed in line with the recommended best practice whereby the new regional Radiopharmacy units will manufacture the medicine in ready to use vial kits. These will be delivered to Nuclear Medicine departments where the patient injections will be drawn up from the vials. Typically, around two to three injections are drawn up from each vial. This is also the service model being used during the current Service Continuity arrangements within SBUHB, Birmingham and Bristol NHS Trusts.

This approach gives maximum flexibility to the Nuclear Medicine department to ensure that the right level of radioactivity is injected to each patient, from the level available in the vial immediately prior to the injection being given. It also maximises Radiopharmacy operator safety by limiting their time exposure to the radioactive product during manufacture. Nuclear Medicine departments that have not previously utilised this service model are being supported with training and equipment to ensure safe and effective drawing up.

The service model will be underpinned by new Service Level Agreements and Technical Agreements between the respective organisations.

The service will operate on the basis of a core staff and non-pay budget allocated to NWSSP at the time of service transfer. The variable costs of the medicine will be recharged on a wholesale basis, with an equitable charge to all users per unit of medicine supplied, inclusive of the medicine, consumables, and transport.

Overall financial and service governance will rest with the Health Boards and Trusts, exercised jointly through the mechanism of the Shared Services Partnership Committee. The financial impacts of this model are analysed in Chapter 4, the Financial Case.

2. Economic Case

The economic case in this document is focussed on site selection for the reinvested Radiopharmacy service. This chapter has been reviewed but is unchanged from version 1 of the case submitted in November 2023.

2.1 Success Criteria

Success Criteria for site selection for the new service are:

1. Strategic Criteria
    a. The site should be available for development now
    b. The site selection should if possible, align strategically with the TrAMs Programme
2. Meets the capacity demands for service to patients
    a. Within the South East Wales region [9,000 doses p/a]
    b. Also offers contingency to support South West Wales when required [6,000 doses p/a]
    c. Also offers contingency to support other UK sites such as Birmingham and Bristol, when that capacity is not being required within Wales.
3. Meets all current and envisaged regulatory requirements
    a. Layout including room segregations
    b. Room air handling and filtration
    c. Equipment including isolators with Hydrogen Peroxide based decontamination
4. Provides a pleasant and functional work environment including
    a. Production clean rooms
    b. Supporting office, laboratory, storage, and ancillary spaces
    c. Staff facilities including toilets and mess rooms
5. Is accessible to current and future staff
    a. Including access to public transport, walking, cycling, and
    b. Car parking options
6. Facilitates reliable delivery to all major hospitals within the region within 60 minutes of setting out
    a. Good access to the trunk road network
    b. Limited exposure to known traffic bottlenecks
    c. Alternative route options in the event of disruption

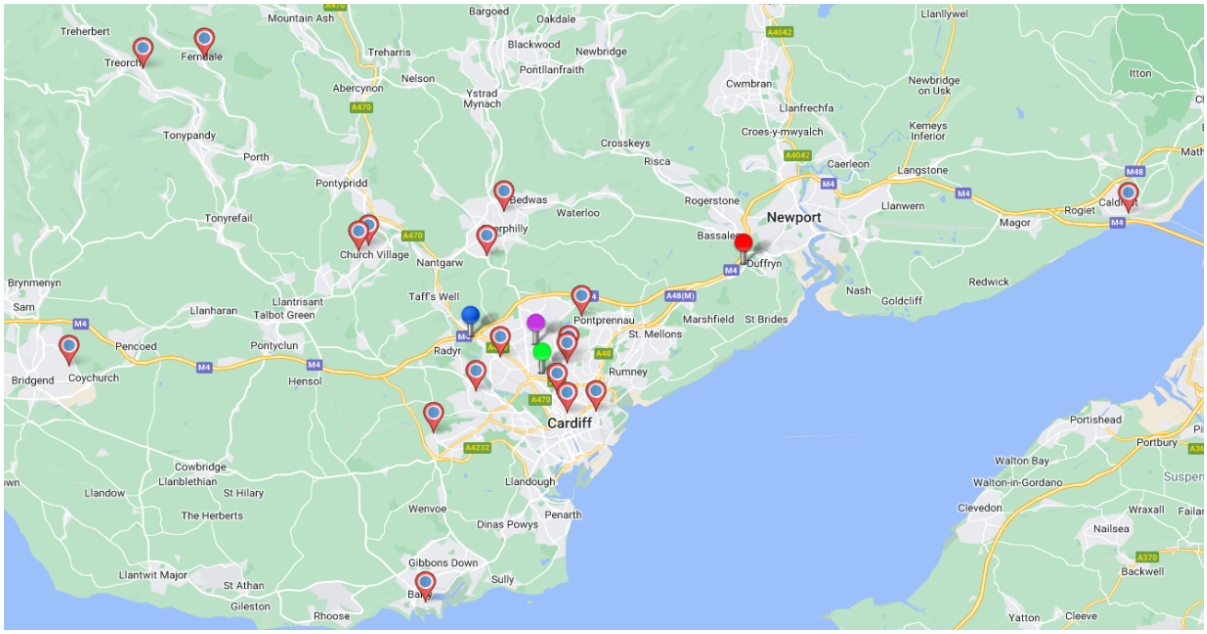
2.2 Investment options

The following investment options have been identified:

1. Re-investment of the unit in its current location, within the Nuclear Medicine department of UHW
2. Replacement Unit elsewhere on the UHW campus
3. Replacement Unit within the site footprint of St Mary's Pharmaceutical Unit (SMPU). This was the preferred option of the 2020 Business Case
4. Replacement Unit within the footprint of Imperial Park building 5 (IP5), Newport
5. Replacement Unit as part of a deliberate investment in the TrAMs South East Wales Hub, at a site other than IP5. The other candidate site is in Coryton.
6. Augmentation of the existing SBUHB unit at Singleton to provide capacity to serve the whole of South Wales

2.3 Staff Locations

Home addresses of the staff who work some or all of their duties within the existing legacy unit have been anonymised and mapped against the candidate site locations:



Option	Site	Postcode
1	**UHW Nuclear Medicine**	**CF14 4XW**
2	**UHW Other**	**CF14 4XW**
3	**SMPU**	**CF14 7HY**
4	**IP5**	**NP10 8BE**
5	**Coryton**	**CF14 7HY**
6	**Singleton (Not shown on map)**	**SA2 8 QA**

As expected, there is a concentration of staff within Cardiff, with a number also coming down the Taf and Rhondda Valleys, with outliers in Barry, Caldicot, and Bridgend.

If the existing unit at UHW is taken as being the reference point, and using google maps functionality the travel to work implications can be assessed as follows:

- Sites 1 and 2 – No change
- Sites 3 and 5 – Some increases and some decreases, neutral overall
- Site 4 – Net additional journey time of approx. 17 mins by car.
- Site 6 – Net additional journey time of approx. 67 mins by car.

These assessments are used to contribute to the scoring of question 5 in the next section.

2.4 Assessment of Options

All options are devised to provide a permanent solution, with a lifetime in excess of 20 years. Temporary build options were discussed but have been discounted because:

- In order to pass regulatory inspection, the unit has to be robust and finished to a high standard. Having scoped the unit on this basis, it will by default produce a solution able to last many years in service. The quality of the NWSSP Medicines Unit is an example of this.
- Where "temporary" units have been built in the past, they have ended up exceeding their design life anyway (e.g. the Aseptic Unit as UHL). Therefore, it makes sense to specify the build for a long life from the outset.
- TrAMs principles are intended to break the cycle of temporary, poor value, investment choices.

The options can be assessed against the success criteria as follows. All Items are scored out of 3, with 3 being the best score and 1 the lowest compliant score.

Scores of 0 can also be given and are red rated, as having the potential to be exclusionary for the option, if the factor is deemed sufficiently critical.

Option 1	**Existing CAVUHB Unit Refurbishment**	
Criteria	Narrative	Score out of 3
1.a Site Available Now	The site is available now. The site is however within a busy Medical Physics and Clinical Engineering (MPCE) department. Any development will therefore need to be carefully planned in collaboration with the Health Board to protect existing critical services.	2
1.b Alignment with TrAMs	This option for a regional preparative unit within a Clinical department is not aligned with the TrAMs Programme.	1
2.a Meets SE Wales Demand	The site has shown it can meet this level of demand based on past performance	3
2.b Contingency for SW Wales	Unclear the extent to which output could be increased, in combination with heavily revised layouts and processes	1
2.c Contingency for UK sites	Unclear the extent to which output could be increased, in combination with heavily revised layouts and processes	1
3.a Layout and Space	The square meterage available within the MPCE Department is not sufficient to achieve a compliant layout, ducted isolators, and air plant. This has been confirmed by external assessment. To create the floor space would require the decant of a number of other adjacent services.	0

3.b Room air handling	The height restriction within the building structure appears to preclude the installation of a compliant number of Fan Filter Units	0
3.c Gassing Isolators	The height restriction precludes the installation of ducted gassing isolators, as required to meet current regulatory needs	0
4.a Working Environment	Assessed as acceptable to the current staff	2
4.b Storage and Ancillary	Unlikely to be able to meet the full requirements within the available footprint	1
4.c Staff facilities	Staff facilities on the hospital site are generally assessed as good	3
5.a Accessibility Walk/Cycle/PT	The campus has good accessibility for current and future staff	3
5.b Car parking	Car parking on the site is difficult and likely to remain so	1
6.a Deliveries – Trunk Network	Traffic congestion when exiting the site can be a problem, with significant urban traffic to be negotiated before accessing the trunk network	2
6.b Congestion risk	Generally OK but delivery times not always achieved, particularly to Nevill Hall, being the furthest away of the daily deliveries	2
6.c Alternative Routes	Alternative routes out of Cardiff do exist, to Junctions 28, 30 and 32 of the M4	3
Total Score		**25**

Option 2	**New UHW site**	
Criteria	Narrative	Score out of 3
1.a Site Available Now	No site has yet been identified on the UHW Campus that is available to develop now, and can be protected from future redevelopments on the site. CAVUHB Execs have excluded this option, and it is scored "0" in this analysis as a result.	0
1.b Alignment with TrAMs	This option to develop on a clinical campus is not aligned with TrAMs	1
2.a Meets SE Wales Demand	If a site could be identified, there is no reason to doubt that unit could be built to sufficient capacity.	3
2.b Contingency for SW Wales	If a site could be identified, there is no reason to doubt that unit could be built to sufficient capacity.	3
2.c Contingency for UK sites	If a site could be identified, there is no reason to doubt that unit could be built to sufficient capacity.	3
3.a Layout and Space	As a new build design, the unit would be expected to comply with all requirements	3
3.b Room air handling	As a new build design, the unit would be expected to comply with all requirements	3
3.c Gassing Isolators	As a new build design, the unit would be expected to comply with all requirements	3
4.a Working Environment	As a new build design, the unit would be expected to comply with all requirements	3
4.b Storage and Ancillary	As a new build design, the unit would be expected to comply with all requirements	3
4.c Staff facilities	Staff facilities on the hospital site are generally assessed as good	3
5.a Accessibility Walk/Cycle/PT	The campus has good accessibility for current and future staff	3
5.b Car parking	Car parking on the site is difficult and likely to remain so	1
6.a Deliveries – Trunk Network	Traffic congestion when exiting the site can be a problem, with significant urban traffic to be negotiated before accessing the trunk network	2
6.b Congestion risk	Generally OK but delivery times not always achieved, particularly to Nevill Hall, being the furthest away of the daily deliveries	2
6.c Alternative Routes	Alternative routes out of Cardiff do exist, to Junctions 28, 30 and 32 of the M4	3
Total Score		**39**

Option 3	**St Marys Pharmaceutical Unit**	
Criteria	Narrative	Score out of 3
1.a Site Available Now	Although the 2021 Business Case recommended this option, there are significant concerns about the impact of a major building project on the rest of SMPU, with the proposal being to build on stilts over the loading bay. This building delivers critical medical supplies to the region, and itself has identified risks and fragilities. As such the readiness of the site for development must be questioned. This option was costed at £12m in 2021, and costs have likely increased by around 30% since then. Planning permission will need to be sought.	1
1.b Alignment with TrAMs	By co-locating the service with an existing Technical Services facility this option follows TrAMs principles to some extent. SMPU is however itself in need of re-investment, and has not been shortlisted for the TrAMs Hub, so this option is unlikely to remain aligned in the medium term.	2
2.a Meets SE Wales Demand	If a site were deemed suitable, there is no reason to doubt that unit could be built to sufficient capacity.	3
2.b Contingency for SW Wales	If a site were deemed suitable, there is no reason to doubt that unit could be built to sufficient capacity.	3
2.c Contingency for UK sites	If a site were deemed suitable, there is no reason to doubt that unit could be built to sufficient capacity.	3
3.a Layout and Space	If a site were deemed suitable, there is no reason to doubt that unit could be built to sufficient capacity.	3
3.b Room air handling	If a site were deemed suitable, there is no reason to doubt that unit could be built to sufficient capacity.	3
3.c Gassing Isolators	If a site were deemed suitable, there is no reason to doubt that unit could be built to sufficient capacity.	3
4.a Working Environment	If a site were deemed suitable, there is no reason to doubt that unit could be built to sufficient capacity.	3
4.b Storage and Ancillary	If a site were deemed suitable, there is no reason to doubt that unit could be built to sufficient capacity.	3
4.c Staff facilities	Existing staff rooms at SMPU are at capacity, in particular there is a shortage of toilet	1

	facilities for the number of staff employed. It might be possible to mitigate this by negotiating access to the adjacent café and toilets in Woodlands House, but these might not be available at the time when the Radiopharmacy Staff begin their shifts.	
5.a Accessibility Walk/Cycle/PT	The site has fair accessibility for current and future staff	3
5.b Car parking	Additional car parking on an adjacent lot could potentially be sourced, but this would be subject to a commercial negotiation and cannot currently be guaranteed.	1
6.a Deliveries – Trunk Network	Traffic congestion when exiting the site can be a problem, with significant urban traffic to be negotiated before accessing the trunk network	2
6.b Congestion risk	Can be an issue at peak times	2
6.c Alternative Routes	Alternative routes out of Cardiff do exist, to Junctions 28, 30 and 32 of the M4	3
Total Score		**39**

Option 4	**Imperial Park Building No 5 (IP5)**	
Criteria	Narrative	Score out of 3
1.a Site Available Now	The long lease to the site is owned, and an area of the warehouse has been identified as potentially suitable. Existing stock will need to be decanted to clear the area for development. Planning permission for change of use and modifications to the exterior elevation will need to be sought.	2
1.b Alignment with TrAMs	This site is one of the shortlisted proposals for the TrAMs SE Hub. Even if IP5 is not selected for the main hub investment, certain national functions such as Pharmacy Directorate and National Quality Team will remain based at the site, and so be able to contribute to the management and control of the radiopharmacy service.	3
2.a Meets SE Wales Demand	Sufficient space exists to allow a unit to be built to sufficient capacity.	3
2.b Contingency for SW Wales	Sufficient space exists to allow a unit to be built to sufficient capacity.	3
2.c Contingency for UK sites	Sufficient space exists to allow a unit to be built to sufficient capacity.	3
3.a Layout and Space	Sufficient space exists to allow a unit to be built to sufficient capacity.	3
3.b Room air handling	Sufficient space exists to allow a unit to be built to sufficient capacity.	3
3.c Gassing Isolators	Sufficient space exists to allow a unit to be built to sufficient capacity.	3
4.a Working Environment	The provisional location includes exterior windows to allow natural light into the clean rooms	3
4.b Storage and Ancillary	Sufficient space exists to allow a unit to be built to sufficient capacity.	3
4.c Staff facilities	Existing staff rooms and toilets allocated to CIVA@IP5 are large enough to absorb the expected increase of circa 10 staff. The opportunity would be taken to refurbish and upgrade the facility, as the finishes date from before NWSSP took possession of the building in 2019, and layouts could be improved with a view to further expansion in the future. There is currently no café for hot food on site.	2
5.a Accessibility Walk/Cycle/PT	The campus is accessible via bus and cycle routes along the A48. Depending on where	2

	staff currently live, this may be less accessible to them than the current site.	
5.b Car parking	Car parking at IP5 is good by comparison with hospital sites. Average journey time increase of 17 mins compared to UHW.	3
6.a Deliveries – Trunk Network	The site has good access to the trunk road network at junction 28 of the M4.	3
6.b Congestion risk	Congestion around the junction can be an issue at peak times	2
6.c Alternative Routes	Alternative routes do exist, via the A48 and A467.	3
Total Score		**44**

Option 5	**Coryton site**	
Criteria	Narrative	Score out of 3
1.a Site Available Now	The site is not yet in NHS Wales ownership, and a three cornered negotiation with a leaseholder and a freeholder will be needed to secure the site. On 15 Nov 2023 the Project Team was advised that the leaseholder was no longer offering their interest for sale.	0
1.b Alignment with TrAMs	This is one of the shortlisted sites for the TrAMs SE Hub. The investment in Radiopharmacy will only go ahead if the site is selected and purchased for the Hub. Alignment is therefore total.	3
2.a Meets SE Wales Demand	Sufficient space exists to allow a unit to be built to sufficient capacity.	3
2.b Contingency for SW Wales	Sufficient space exists to allow a unit to be built to sufficient capacity.	3
2.c Contingency for UK sites	Sufficient space exists to allow a unit to be built to sufficient capacity.	3
3.a Layout and Space	Sufficient space exists to allow a unit to be built to sufficient capacity.	3
3.b Room air handling	Sufficient space exists to allow a unit to be built to sufficient capacity.	3
3.c Gassing Isolators	Sufficient space exists to allow a unit to be built to sufficient capacity.	3
4.a Working Environment	The provisional location includes exterior windows to allow natural light into the clean rooms	3
4.b Storage and Ancillary	Sufficient space exists to allow a unit to be built to sufficient capacity.	3
4.c Staff facilities	Existing staff facilities are excellent	3
5.a Accessibility Walk/Cycle/PT	The campus is accessible via bus, cycle, and train routes.	3
5.b Car parking	Car parking is ample and segregated from the service yard.	3
6.a Deliveries – Trunk Network	The site has good access to the trunk road network at junction 32 of the M4.	3
6.b Congestion risk	Congestion around the junction can be an issue at peak times	2
6.c Alternative Routes	The site is on a cul-de-sac road accessed only from the Coryton gyratory. If that system is blocked then alternative access could be considered problematic. NWSSP HCS does have access in extremis to a blue light service in the event of threat to life.	2
Total Score		**43**

Option 6	**Singleton Hospital site**	
Criteria	Narrative	Score out of 3
1.a Site Available Now	The site is available now, and development work could in theory start immediately. The site is a working regional medicines distribution unit, currently providing planned services to three Health Boards (CTMUHB, SBUHB, and HDUHB) and contingency radiopharmacy support to CAVUHB, and is located on a busy hospital site. Any development will therefore need to be very carefully planned in collaboration with the Health Board to protect existing critical services.	2
1.b Alignment with TrAMs	As a regional Technical Services facility, investment here has some alignment with TrAMs principles. The site is however on a busy clinical campus, in a locality not shortlisted for the South West Hub, so this alignment is unlikely to persist in the medium term. If investment in this site precludes a radiopharmacy investment in the South East, then that is not in alignment with the Programme. If this investment is seen as part of service continuity mitigation while the South East investment is delivered, then there is strategic alignment. Scored “2” overall for this reason.	2
2.a Meets SE Wales Demand	The proposal is to convert the existing Blood Labelling room to prepare Technetium doses for South East Wales. Until this is scoped in detail, it is not possible to be certain that sufficient doses could be provided.	2
2.b Contingency for SW Wales	The unit cannot provide contingency for itself	0
2.c Contingency for UK sites	Probably too far away from Bristol or Birmingham to make any meaningful contribution	1
3.a Layout and Space	The “Blood suite” contains a layout dating from 2016, which is largely compliant, but would need careful planning to establish what the safe capacity for Technetium could be	2
3.b Room air handling	Designed for radioactive products and essentially compliant	3

3.c Gassing Isolators	Likely to be compliant, as a gassing isolator has been installed within the adjacent aseptic suite, of the same design	2
4.a Working Environment	No issues identified with the existing	3
4.b Storage and Ancillary	Potentially problematic as this would be shared with the other two existing suites, and has never been found fully sufficient by them since the site was developed	1
4.c Staff facilities	Fair for a hospital site, hot food canteen etc	3
5.a Accessibility Walk/Cycle/PT	The campus is accessible via bus, cycle routes, but is a long way away for existing Cardiff staff	1
5.b Car parking	Being a major regional hospital site, parking is problematic. Average staff journey time penalty of 67 mins compared to UHW.	1
6.a Deliveries – Trunk Network	Singleton hospital is on the wrong side of Swansea for access to the trunk network, and realistically will not be able to meet delivery times to the ABUHB hospitals. It is therefore a contingency for CTM, CAVUHB, and VELUNHST only.	1
6.b Congestion risk	Congestion on the waterfront road can be an issue at peak times	2
6.c Alternative Routes	It is possible to take alternative routes through Swansea if the waterfront road is blocked.	2
Total Score		**28**

Summary of Scores

	Site Investment Option					
Criterion	1 Existing	2 UHW	3 SPMU	4 IP5	5 Coryton	6 Singleton
1a	2	0	1	2	0	2
1b	1	1	2	3	3	2
2a	3	3	3	3	3	2
2b	1	3	3	3	3	0
2c	1	3	3	3	3	1
3a	0	3	3	3	3	2
3b	0	3	3	3	3	3
3c	0	3	3	3	3	2
4a	2	3	3	3	3	3
4b	1	3	3	3	3	1
4c	3	3	1	2	3	3
5a	3	3	3	2	3	1
5b	1	1	1	3	3	1
6a	2	2	2	3	3	1
6b	2	2	2	2	2	2
6c	3	3	3	3	2	2
Total	**25**	**39**	**39**	**44**	**43**	**28**

Evaluation of Preferred Way Forward

Options 1, 2, 5 and 6 are excluded as viable standalone investment options by having been scored "0" on key success factors.

Options 3 and 4 have been scored as viable, although some doubt remains about the practical viability of Option 3 for SMPU and the risk to the other services on the site of a major building project there. As the lower scoring of the compliant options, Option 3 is not taken forward in this case.

Option 5 scores higher than Option 3, and in the event that Option 5 were rescored as viable, the time risk of Coryton would need to be set against the Planning Permission risk of IP5. The investor needs to consider this also in the overall context of the TrAMs shortlist. If Coryton is not considered affordable as a Hub, then IP5 becomes the only investable option. If Coryton is affordable as the Hub, then it may still make sense to build the Radiopharmacy there too.

Option 6 in Swansea is not a viable long term option but could be considered as an interim contingency to boost supply while either Option 4 IP5 or Option 5 Coryton is built and commissioned. The staffing implication of this would need considerable further work, as only a small number of the existing staff may be able and willing to travel to Singleton, even on a temporary basis. Individual staff consultation would be needed to establish the viability of the option.

Preferred Way Forward

As of June 2024 the Coryton site is no longer being offered to the market.

The selected Preferred Way Forward based on the Economic Case is:

- Option 4 IP5

3. Commercial Case

3.1 Commercial Approach

The Commercial Case follows the procurement methodology developed to date for the TrAMs Programme. This can be summarised as follows:

- Utilise an existing building to minimise major construction works.
- Direct engagement of the **Clean Room contractor** by NWSSP, with the Clean Room contractor acting as Principal Contractor for their scope.
- Direct procurement of the major equipment (e.g. **Isolators**) by NWSSP capital teams, to avoid paying principal contractor's margin on these items.
- Any minor **building works** that are needed to be directly procured, segregated from the cleanroom works by either time or space, to maintain integrity of Construction Design and Management (CDM) and site management.
- Employer's side support to consist of
    - **Project Surveyor, Cost Advisor, and Principal Designer -** advisor to review contractor Risk Assessments and Method Statements, give advice, and maintain consistent approach to CDM.
    - **Specialist Validation** contractor to assist in drafting key pharmaceutical requirements documents and to support commissioning activity.
    - Specialist **Planning Advisor,** with supporting Transport Advisor and Environmental Advisor.
    - **Radiation Protection Advisor** and **Radioactive Waste Advisor.**
    - **Dangerous Goods Safety Advisor** to advise on delivery of the made product.
- Internal NWSSP support and resources not requiring to be contracted for consist of:
    - Project Management
    - Procurement Lead and resources
    - Finance Lead and resources
    - Legal Support if required during contract negotiations
    - Specialist Estates Services (SES) Surveyors and other resources including
        - Contract negotiations
        - Fire Advice
        - Specialist Mechanical & Electrical Advice
    - Health Courier Service for specialist transport of the medicines to hospital sites.

All contracts will be offered and awarded on a phased basis, giving contractual break points for 3 key project phases:

1. Outline Design Concepts to RIBA Stage 2
2. Detailed Design to RIBA Stage 4
3. Build, Validation, & Commissioning

The contracting authority will thus gain the benefit of having a warm supply chain ready to proceed, while not being committed to the delivery phase before funding is secured.

The contracts also include options for phases 4 and 5 related to the South East Hub Development, in the event that that case is funded.

3.2 Procurement Status

During the period December 2023 – February 2024 procurement processes were carried out with the support of NWSSP Capital Procurement team.

The fees to fund contract stages 1 and 2 were awarded in Dec 2023, so these contract phases have been committed to.

- Phase 1 for outline design to RIBA Stage 2 has now been completed.
- Phase 2 for detailed design to RIBA Stage 4 is in progress, forecast to complete in July 2024.
- Phase 3 for construction will not be committed to until the Investment Decision is made.

The only exception to this is the isolator supplier, who has been given early commitment to the full contract value, owing to the long lead time on these items. This decision was ratified by the Cabinet Secretary for Health and Social Care in May 2024.

The current commercial status of each major work package is:

Work Package	Contractor	Route to Market	Status
Project Surveyor	Cooke & Arkwright	SEWTAPS Framework	Mobilised and working on Phases 1 &2, ready to proceed with stage 3.
Cleanroom Contractor	Angstrom Technology	Open Tender	Mobilised and working on Phases 1 &2, ready to proceed with stage 3.
Isolator Supplier	Azbil Telstar	Open Tender	Early authorisation given to proceed with delivery due to long lead time.
Enabling building works	Tbc	SEWSCAP Framework	Currently in Procurement. Expected to be ready to proceed by Sept 2024
Validation Advisor	Scitech	Open Tender	Mobilised and working on Phases 1 &2, ready to proceed with stage 3.
RPA and RWA Advisor	RSK t/a Aurora	NOE Framework	Mobilised and working on Phases 1 &2, ready to proceed with stage 3.
Planning and Transport Advisor	Asbri Planning and Asbri Transport	Framework	Mobilised and working on Phases 1 & 2, ready to proceed with stage 3.

Out of the total Project Cost (excluding contingency), we estimate that by July 2024 75% of the Project costs will be secured by contract, rising to 85% by Sept 2024, once the enabling building works tender is awarded.

The remaining 15% represents movable fixtures and fittings, final utility connections, and modifications to the building security and fire alarms. These items will be contracted for during the remainder of the project. The price risk on these items is deemed low.

4. Financial Case

The financial case analyses the Preferred Option for an NWSSP operated service from a new unit in IP5, compared against Business As Usual scenarios based on a reinvestment of the legacy service model.

4.1 Capital Costs

The capital costs of the Preferred Option are as follows:

	Radiopharmacy		
	Phases 1 and 2 Design £'000	**Phase 3 Build & Validate £'000**	**Phases 1 to 3 Total £'000**
Works Costs	215	3,257	3,472
Fees	55	75	129
NHS Resource & Validation	234	889	1,123
Non-Works Costs	17	63	81
Equipment Costs	0	2,838	2,838
Contingency	78	1,548	1,626
VAT recovery	-54	-47	-101
Total costs	545	8,622	**9,168**
Less funding received :			
Fees phase 1 & 2 allocated	-500	0	-500
Equipment end of year monies 2023/24	0	-333	-333
Radiopharmacy isolators	0	-1,500	-1,500
BJC capital funding requirement	45	6,790	6,835

Note - all figures include VAT where relevant

Explanatory Notes

1. Works Cost

Design and build of the radiopharmacy cleanrooms and initial enabling works

2. Fees

Fees for cost advisor, building design and and validation supervisor

3. NHS Resource & validation

NHS salary costs for project management, validation and familiarisation. Also includes radiation protection advisor fees

4. Non-Works Costs

Local authority planning costs and carbon/environmental surveys

5. Equipment Costs

Radiopharmacy isolators (£1,504k) plus FMS and other radiopharmacy equipment

6. Contingency

Includes 15% contingency on costs plus provision for detailed design changes

7. VAT recovery

Expected VAT recovery on professional fees

Table 1 - Capital investment cost.

As a comparator, the proposed capital costs of CAVUHB's new Unit from their 2020 Outline Business Case were calculated at £12.8m.

The main differences are explained by the fact that the current preferred option is utilising an existing building that only requires minor renovations, and minimal external works, whereas the CAVUHB proposal included a whole new building shell and associated site development costs. It is also worth noting that the NWSSP proposal has been developed largely by an in-house team, with contractor input focussed on the technical design work and specialist advice only. Therefore, large fees for developing the supply chain and for external project management have been avoided. Significant NHS resources have been committed without additional charge in the areas of Procurement, Finance, and Project Management to develop the NWSSP case.

While the total project cost of £9.2m is shown, it is worth noting that investments of £2.3m have already been funded, therefore the remaining balance sought from Welsh Government to complete the project is only £6.9m. If committed by 1 Sept 2024, it is anticipated that the majority of these costs will be incurred in the financial year 2024/25, based on the supply chain already assembled by the project. If committed later than 1 September 2024, then elements of the spend will start to slip into the following financial year.

No capital funds are sought from the Health Boards and Trusts for this project. Any future significant capital for lifecycle requirements will be subject to further business cases from NWSSP to Welsh Government.

4.2 Revenue Commitments

The revenue costs of the new service, versus a baseline revenue costing provided by CAVUHB for the legacy service, are shown below:

Radiopharmacy operating costs

	CVUHB £'000	IP5 radio £'000	Increase on baseline £'000	IP5 post hub completion £'000	Increase on baseline post hub £'000
Pay	636	700	64	572	-64
Drugs	211	220	9	220	9
Generator Teckis 20 & consumables	141	141		141	
Transport in and out	97	143	47	86	-10
Equipment	13	116	103	116	103
Regulatory fees	10	36	27	36	27
PPE	31	35	3	35	3
IT	19	28	10	28	10
Site Costs	46	233	187	124	78
Cleaning	22	65	43	65	43
Refuse/waste disposal	3	8	5	8	5
Other	8	27	18	27	18
Total costs	**1,236**	**1,752**	**516**	**1,459**	**222**

Notes

CVUHB baseline costs based on 2022/23 final year of operation, adjusted for Datscan removal

Pay, CVUHB and IP5 radiopharmacy shown at 2023/24 rates

IP5 radiopharmacy staff costs will reduce by c. £128k post the Trams hub completion

Drugs cost based on raw material cost and future demand assessment following dialogue with all nuclear medicine sites in SE Wales

Teckis 20 generator costs unchanged as the process for preparing vials as opposed to syringes requires less consumables despite an increase in the number of patients treated

Transport costs include the costs associated with the receipt of raw materials inwards and the delivery of the final product to customers and HCS efficiency savings is expected with the hub opening

IP5 equipment includes isolator and general equipment maintenance and annual cleanroom validation costs

IP5 Regulatory fees includes Radiation Protection Advice & Support (RPAS)

IP5 site costs includes £173k energy costs, £26k for back up power generator hire and £17k for Environmental Monotoring system

Post Trams hub opening the energy costs will reduce by an estimated £83k as a result of a solar panel farm and the £26k power generator hire

IP5 cleaning includes specialist cleaning of the the units including the use of Steramist gassing

IP5 other includes staff training costs and office costs

No uplift for non pay inflation is included

Table 2 - Revenue cost of the new service

We have calculated two budgets for the future service. The initial budget of £1.752m is for a standalone Radiopharmacy service in IP5, which will be the position for at least the first 12-24 months of the new service. These costs are higher than the legacy CAVUHB cost because:

- Significant regulatory changes were made in the new “Annexe 1” from MHRA, this has significantly increased the costs of running a compliant service.

- The new unit is significantly larger than the old one, to accommodate regulatory requirements on layout, separations, and adjacencies. Lack of space to optimise the layout of the old unit was one of the reasons why it had to close.
- Modern regulatory requirements for 100% fresh filtered and enviromentally controlled air supply drive a requirement for a large air handling unit. This will require much more planned preventative maintenance and servicing than the ventilation in the old unit. Lack of space to install the ducting for a modern air plant was also one of the reasons why the old unit could not be cost effectively refurbished.
- Active air supply is now required to all transfer hatches, significantly increasing both plant costs and the costs of validation
- Two stage changing in separated rooms is also now required in all new units, driving an increase in classified clean room space
- The new unit will use Ionized Hydrogen Peroxide gassing for decontamination of both isolators and rooms. Gas decontamination is now the regulatory requirement for all new units. Again this technology has an annual servicing and maintenance requirement, and a consumable cost in purchasing the gas, which the legacy service did not.
- The new isolators costing around £0.5m each, required to provide a compliant service, compared to around £6,000 each for the old open fronted cabinets, generate a significant revenue tail of electricity, consumables, maintenance, and servicing costs.
- An additional transport cost is incurred because the unit is no longer co-located with the UHW Radiology service.
- In aggregate: the new service is planned to be compliant, reliable and sustainable, and the costs are calculated on that basis.

As a further comparator it is also worth noting that the 2020 CAVUHB Business case included revenue costs totalling £1.59m p/a offset by expected income of £1.18m p/a. So CAVUHB also anticipated that a modern and sustainable service would both cost more to run and would require an increase in cost to be passed on to customers.

An estimate of the recurrent costs of £1.459m has also been included showing the cost efficiencies that can be achieved once the South East Hub opens on the same site. These efficiencies include:

- Staffing – sharing senior management, Quality Assurance support, and staff absence cover in general across the whole hub. This process will be managed through the TRAMs Organisational Change Project, as described in the management case.
- Transport – the opportunity to share the cost of delivery drivers and vans (specified and approved for Radiopharmacy use) on a second daily run delivering other products.
- Power – the opportunity to deploy a more efficient backup power solution for the whole hub, and the planned solar photovoltaic (PV) installation at IP5.

We aim to achieve this long term recurring revenue position for the service from year 3 of operation onwards. The difference between the interim and recurrent annual cost of the service is £294k. The funding model proposed assumes that NWSSP will non-recurrently provide funding for this additional £294k until the recurrent operating solution can be implemented with the opening of the SE Wales hub.

Comparison of our identified service costs to assess value for money is difficult as there are no commercial suppliers operating in this market to provide any comparative costs. Product shelf life means that only nearby units can facilitate any supply. Cost comparisons were sought from both Bristol and Birmingham NHS Trusts, who have offered small scale incremental supply of between 2 and 6 vials per day at marginal cost prices over the past 2 years. Neither Trust was willing to commit to an enduring, supply at a robust level of reliability, at the scale requested of circa 20 vials per day, or to provide a full cost comparator.

University Hospital Bristol NHS Foundation Trust: *"We would not be able to supply an additional 20+ vials every day for the next few years."*

University Hospitals Birmingham NHS Foundation Trust: *"I'm afraid we wouldn't be able to assist with that level of service requirement. We are able to provide Welsh Nuclear Medicine departments with urgent contingency supplies only, so committing to such a large workload over such a long timeframe is not going to be possible. "*

4.3 Funding Models

Discussions have been held with the 4 major customers in the South East Region: CAVUHB, ABUHB, CTMUHB, and VUNHST, and an equitable funding model identified:

Option 1a: Recover costs based on demand share only with NWSSP contribution			
Costs to be recovered		1,752,249	
NWSSP contribution		-294,000	
Net costs to recover		1,458,249	
	2022/23 Baseline charge £	**Trams radio costs £**	**Increase £**
ABUHB	226,273	503,004	276,731
CVUHB	289,386	643,304	353,918
CTMUHB	70,720	157,209	86,490
Velindre	69,605	154,732	85,127
Total	655,984	1,458,249	802,265

The NWSSP annual contribution of £294k is a non-recurrent investment in the new service to bridge the cost efficiency gap until the full South East Hub opens.

The net figure of £1,458,249 therefore represents the recurrent revenue commitment for the service based on today's prices, to be funded as shown above based on an apportionment using historic demand levels for the service. Any increased cost to Velindre should be included as part of the normal future commissioning process with the relevant health boards.

The advantage of the selected funding model is that products will be procured at the same price, following an established "fair shares" principle recognised by all the participating organisations.

Based on an indicative start date of 1st July 2025 the IP5 Radiopharmacy operating charges would be profiled as follows:

	2025/26 from 1st July £	**2026/27 onwards £**
ABUHB	377,253	503,004
CVUHB	482,478	643,304
CTMUHB	117,907	157,209
Velindre	116,049	154,732
Total	**1,093,687**	**1,458,249**

Note: This funding model is for the Radiopharmacy BJC only and recognises that the funding model for the rest of the TrAMs Service will be assessed at the time those Business Cases are developed. This particular model DOES NOT set a precedent for the rest of the TrAMs business cases.

This revenue funding model is **recommended to SSPC for approval for the recurrent service provision of radiopharmacy services in South East Wales.**

4.5 Charging mechanism

It is recommended that the annual funding contributions sought above, will be applied as a per product charge, invoiced (or in the case of VELNHST recharged) monthly on the basis of actual usage.

The per unit price will be set on the baseline of demand from the 2022/23 financial year. At the time of writing this is assessed as being 3,633 vials p/a, leading to an average unit cost of:

£1,458,249 / 3,633 = £401 per vial

This business case is based on the historic level of demand. The total number of vials required to be manufactured needs to be kept under regular review, as efforts to improve the efficiency of the number of doses achieved from each vial are still underway. While it is likely that currently suppressed demand will increase once the full capacity of the new unit comes online, this may also result in an increase in vial to dose efficiency, as more patients can be booked into existing clinics.

The demand forecast will therefore continue to be refined and a detailed pricing model for the various different kinds of vial kit will be created over the next 12 months. This will be submitted for approval as part of Service Business Plan v2.0 which is due in May 2025, prior to the new service opening. The pricing will be calculated to achieve the approved levels of annual contribution from this case.

The unit prices will be kept under regular review thereafter and will be varied in future in order that:

- Costs incurred from any rise or fall in demand continue to be met.
- Any efficiencies in production that reduce costs are passed on equitably.
- Any unexpected cost pressures are also met equitably.
- As a guiding principle the service will continue to break even and will aim to run neither a deficit nor a surplus.

The detailed price model will be open book and will be shared with all participating organisations, as will the overall financial performance of the service.

As a participating element of the NWSSP financial operating model, any deficit or surplus that arises from the service will be owned jointly by the members of SSPC and will be handled under established NWSSP risk sharing arrangements.

4.6 Financial Summary

Capital costs have now reached a level of maturity where they can be proposed with confidence. The key cost lines are now supported by contracts, and the design concepts to support them have

been reviewed by specialist advisors. Progress with detailed design is underway. While the costs are stable, the project has made a modest provision to cover any further cost growth that may arise during the remainder of detailed design. It is anticipated that detailed design will be completed by August 2024, so a final assurance on this point can be given to the Welsh Government before the Investment Decsision is made.

The proposed project cost is lower than that for the CAVUHB New Build option. This reflects a site that is already in NHS ownership and operational management, with an existing building shell, car parking, and support facilities that require only minor remediation works.

The proposed operating costs of the new service are higher than the costs of the legacy service for the reasons explained above. Ultimately this is the price for a compliant, reliable and sustainable service, which is what our patients need and expect from NHS Wales. The proposed funding and charging mechanism is equitable, robust, and flexible to meet future as well as currrent need.

5. Management Case

5.1 Project Management Arrangements

It is proposed to manage the investment as a project within the TrAMs Programme.

A single Project Board was established to manage the South East Wales Hub within the Programme in July 2021. This Project Board is now managing both the Radiopharmacy investment and the closely related SE Hub investment. The project board reports to the TrAMs Programme Board, under the overall governance of the Shared Services Partnership Committee.

Project Management support will be provided by NWSSP Project Management Office (PMO), mobilising other resources from within NWSSP as may be required.

Key resource will be provided by the TrAMs Programme Workforce and Organisational Change Project, which will support the transfer and mobilisation of staff for the service, working in partnership with the current employer, CAVUHB.

The project is working to a multi-phase Business Case approach:

- An initial draft BJC for Radiopharmacy was submitted in Nov 2023 which secured the fees to develop the case to maturity, and to test the fit of the Radiopharmacy and SE Hub on the IP5 site.
- This second iteration of the Radiopharmacy BJC will be submitted in July 2024 for an Investment Decision.
- The Hub OBC is being targeted for submission in Sept 2024 to secure fees for hub detailed design.
- The Hub FBC is targeted for submission in March 2025 to secure funds to develop the hub in the financial year 2025/26.

5.2 Radiopharmacy Project Timeline

Provided an investment decision for the Radiopharmacy is made in Summer 2024, then the following timeline is proposed:

- Purchase Orders issued and contractors notified to proceed Sept 2024.
- Cleanroom contractor ordering materials and preparation Oct-Dec 2024.
- Enabling building works on site Oct-Dec 2024:
    - Removal of racking
    - Rectification of partition to become a fire wall
    - Roof repairs
    - External drainage and surfacing works
- Cleanroom build on site Jan-March 2025.
- Testing, commissioning, and seeking regulatory licenses April-June 2025.
- Service Go Live end of June 2025.

Throughout this process there will be a parallel development of documented processes, procedures, and documentation, all of which will support the final regulatory approvals and give assurance to the

accountable directors that the site is both safe to operate for staff and safe to supply medicine to patients.

Supporting digital infrastructure will need to be selected and deployed. It has been determined that the Radiopharmacy can be opened making selective use of existing digital systems, with any significant investment in new systems aligned with the main TrAMs Digital Project at a later date.

5.3 Staff Transfer

The staff from the legacy service have currently been seconded into a variety of roles supporting service delivery in CAVUHB, SBUHB, and NWSSP. They remain substantively employed by CAVUHB in the Nuclear Medicine department at University Hospital Wales. An Organisational Change Process (OCP) will identify if staff at C&V are impacted by TUPE regulations, and where TUPE applies, then they will transfer to NWSSP.

Once the revenue and capital funding arrangements are both confirmed by approval of this case, it is proposed that CAVUHB will consult the members of staff impacted by the change of location and employer. It is anticipated that where TUPE applies, they will transfer into directly comparable roles in the new service in NWSSP based at IP5. Any roles at IP5 not filled by this process will then be advertised and recruited by NWSSP on a timeline matched to completion of the build, to ensure sufficient staff are in place to validate and open the new service.

It is expected that all staff will remain with their substantive employer or take up a role within NWSSP, no financial provision for redundancy has been made. Given current vacancy rates, no cost pressure from displacement is anticipated and again no provision has been made.

When the TRAMs South East Hub investment decision has been made, a wider Organisational Change Project 2 will take place to fill the new hub structure.

Depending on the time between the two investment decisions, this may lead to a small number of the Radiopharmacy staff changing role twice in quick succession. This is an unavoidable consequence of splitting the business cases to meet the most urgent service need first. Relevant staff side representatives in both organisations are sighted on the process and staff will be supported throughout this change.

5.4 Risk Management

The Project will adopt the Risk Management Approach of the TrAMs Programme, this being directly applicable to the proposed investment and transfer of service.

Key risks and mitigations identified to date are:

Risk	Impact	Mitigation	Comment
Planning Permission at IP5	If not granted, would result in failure to bring the facility into use	Pre engagement letter with outline drawings and project description has been submitted (23 May 2024). Planning application will be submitted in July 2024, prior to the investment decision being sought. The project will submit timely updates to the investor on progress with Planning Permission.	Investment on the site should not be approved until a positive initial engagement with the Planning Authority has been conducted (due late June 2024). In the best case scenario, a positive response to the planning application will also have been received before Notice to Proceed with construction is given in Sept 2024.
Definition of costs at IP5	Detail design work is still ongoing, concurrent with the Business Case entering approvals.	The project will submit timely updates to the Investor on progress with detailed design, to give comfort that the project remains on track with the costings submitted in the case.	Costs are expected to be at full maturity before the Investment Decision is made.
Power at IP5	Concept design work has indicated that sufficient power is available at IP5. Work is still ongoing to confirm this by detailed design, and to determine the power resilience needs.	The project will hire a small temporary backup generator for the Radiopharmacy unit. A comprehensive backup power proposal will be submitted in the SE Hub Business Case.	We are now confident that there is sufficient power, it is just a question of managing the resilience aspect in partnership with other investments at IP5 e.g. Solar PV.
Service Risk at Singleton	Investments in Radiopharmacy compromise the viability of the existing	Proceed cautiously and with close engagement with the accountable	Singleton can only ever be a temporary contingency for South East Wales, and any

	Pharmacy Technical Services delivered on the site.	management of SBUHB, in particular the Clinical Director for Medicine and the Nuclear Medicine Lead.	investment must be evaluated in that context.
Delivery time for key equipment	Isolator delivery times being quoted at 8 – 12 months.	Isolator Award Letter was issued on 20th June 2024. Delivery on site expected March 2025.	Manageable risk, but needs careful handling to ensure the isolators arrive in the right place at the right time.
Staffing transfer	Any change of location and employer generates a staffing risk, that the existing staff may either decline the transfer for leave to seek other employment.	Engage actively with Workforce and Trades Unions to support the transfer process. Be prepared to go to open recruitment for unfilled roles.	Probably the biggest time risk on the project is having a workforce of the correct skills mobilised and ready to bring the new unit into use, wherever it is built, and however quickly.
Clinical Engagement	Nuclear Medicine departments may not have the skills to utilise multi dose vials to best effect.	Ensure clinicians understand and accept the proposed service model, and the right facilities and skills are in place within Nuclear Medicine departments to maximise utilisation of multi-dose vials.	Ongoing requirement for structured clinical liaison by the preparative service.

Estates Appendices will be added in Sept 2024, prior to the final Investment Decision by Welsh Government.