# Pathfinder updates:
## Wales & England

Quality Assurance & Technical Services Symposium

Leicester, 2026

# Transforming Access to Medicines

## TrAMs Programme – Wales

**Alison Jones, SE Wales Hub Lead**

*Delivering Value, Innovation and Excellence through Partnership*

GIG CYMRU NHS WALES
Partneriaeth Cydwasanaethau
Shared Services Partnership

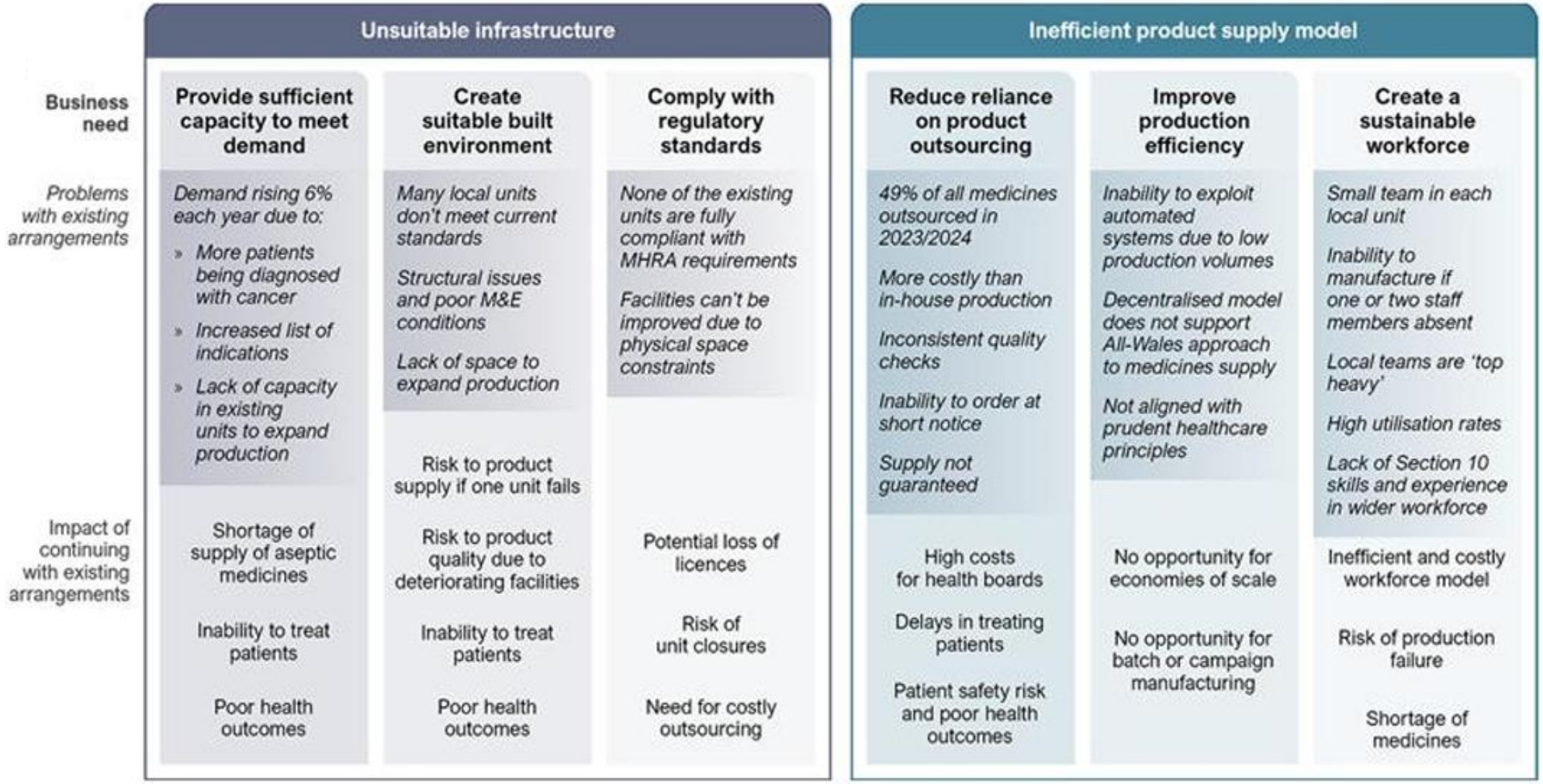
# TrAMs Programme Overview

- Programme established in June 2021

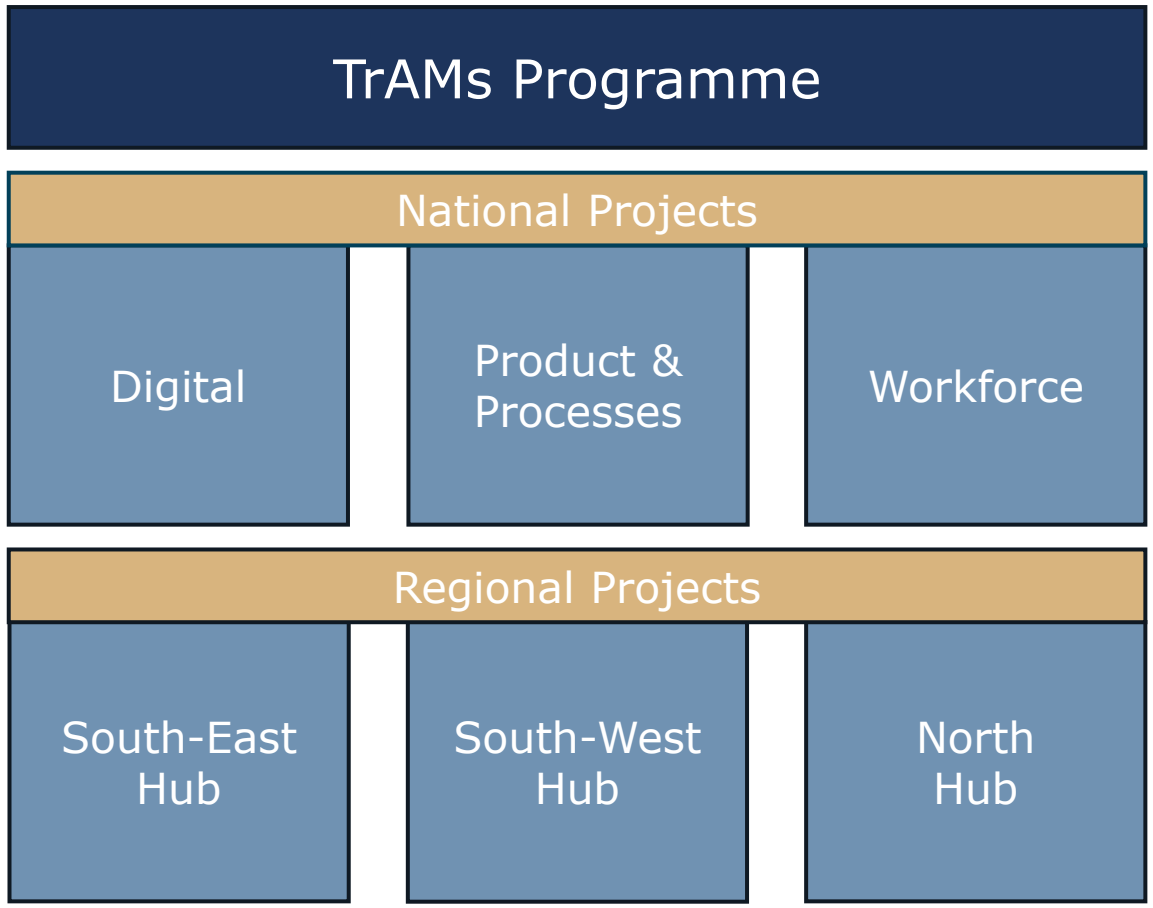
- Transformational All-Wales programme led by NWSSP to:
  - Consolidate Pharmacy Technical Services and manufacture medicines under aseptic conditions in three regions (North, South-West, South-East) on behalf of NHS Wales Health Boards and Trusts.
  - Manufacture and supply unlicenced “Specials” medicines to Wales

- Improve capacity, contingency and quality of medicines
- Improve patient experience

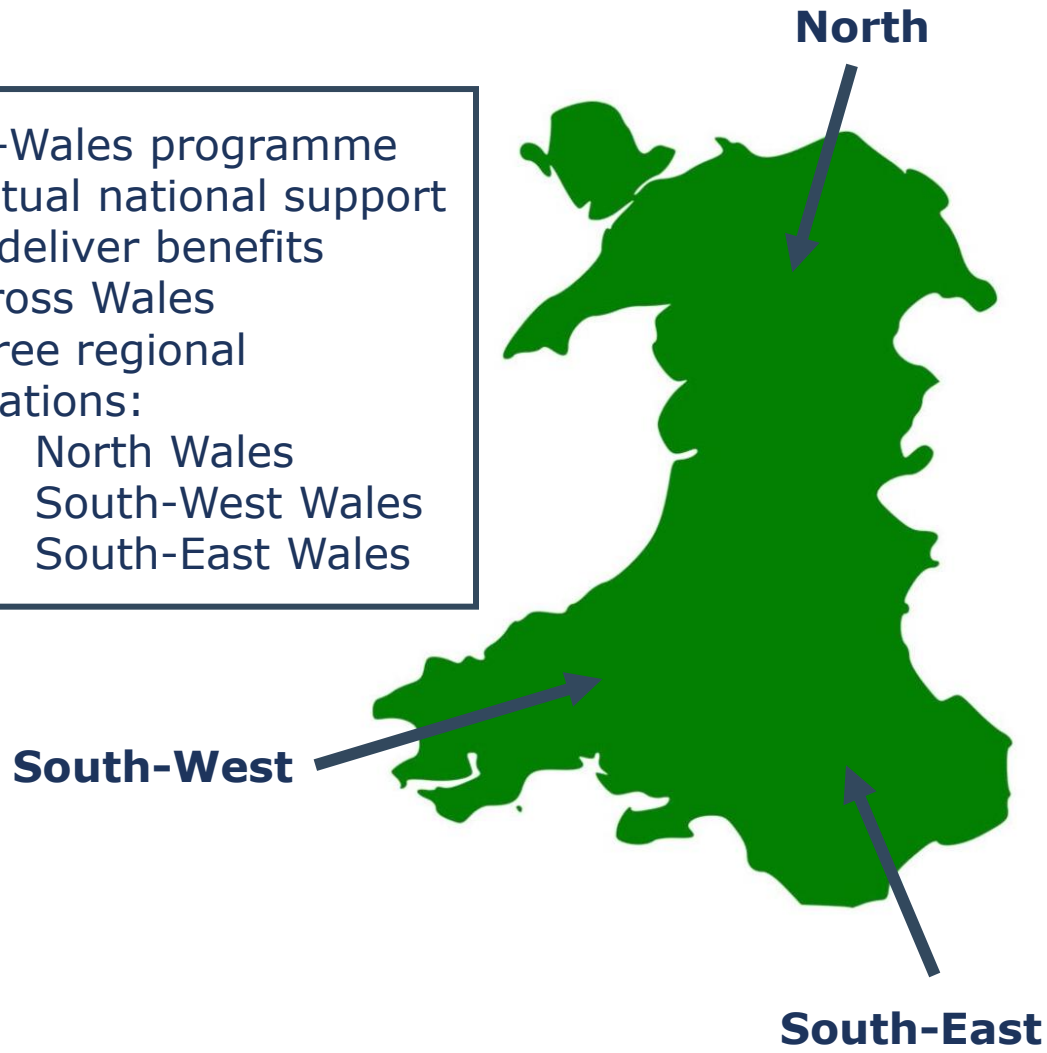
# TrAMs Programme – Case for Change



# TrAMs Programme Structure




- All-Wales programme
- Mutual national support to deliver benefits across Wales
- Three regional locations:
  - North Wales
  - South-West Wales
  - South-East Wales



# Meet the Team – TrAMs Programme

GIG CYMRU NHS WALES | Partneriaeth Cydwasanaethau Shared Services Partnership

## Senior Responsible Owners



**Neil Frow**
Managing Director
NWSSP



**Andrew Evans**
Chief Pharmaceutical Officer
Welsh Government

## Pharmacy Programme Delivery



**Laura-Jayne Keating**
TrAMs Programme Director
Director of Pharmacy Services



**Gareth Tyrell**
National Clinical Lead



**Emma Davies**
National Quality Lead



**Catherine Talbot**
National Workforce Lead

**Judith Vincent**
Pharmaceutical Advisor
Project Executive - TrAMs South-West



**Alison Jones**
Regional Hub Lead - South-East
CAVUHB Technical Services Lead



**Lee Samuel**
Regional Hub Lead - South-West
SBUHB Technical Services Lead

**Andrew Merriman**
Regional Hub Lead - North
BCUHB Technical Services Lead

## Programme & Project Management Finance & Workforce



**Sarah Ferrier**
TrAMs Programme Manager
Assistant Head of TMO



**Arial Desscan**
Project Manager
South-West, North Wales



**Will Brown**
Project Manager
South-East, Digital

**Paul Beckett**
Finance Lead

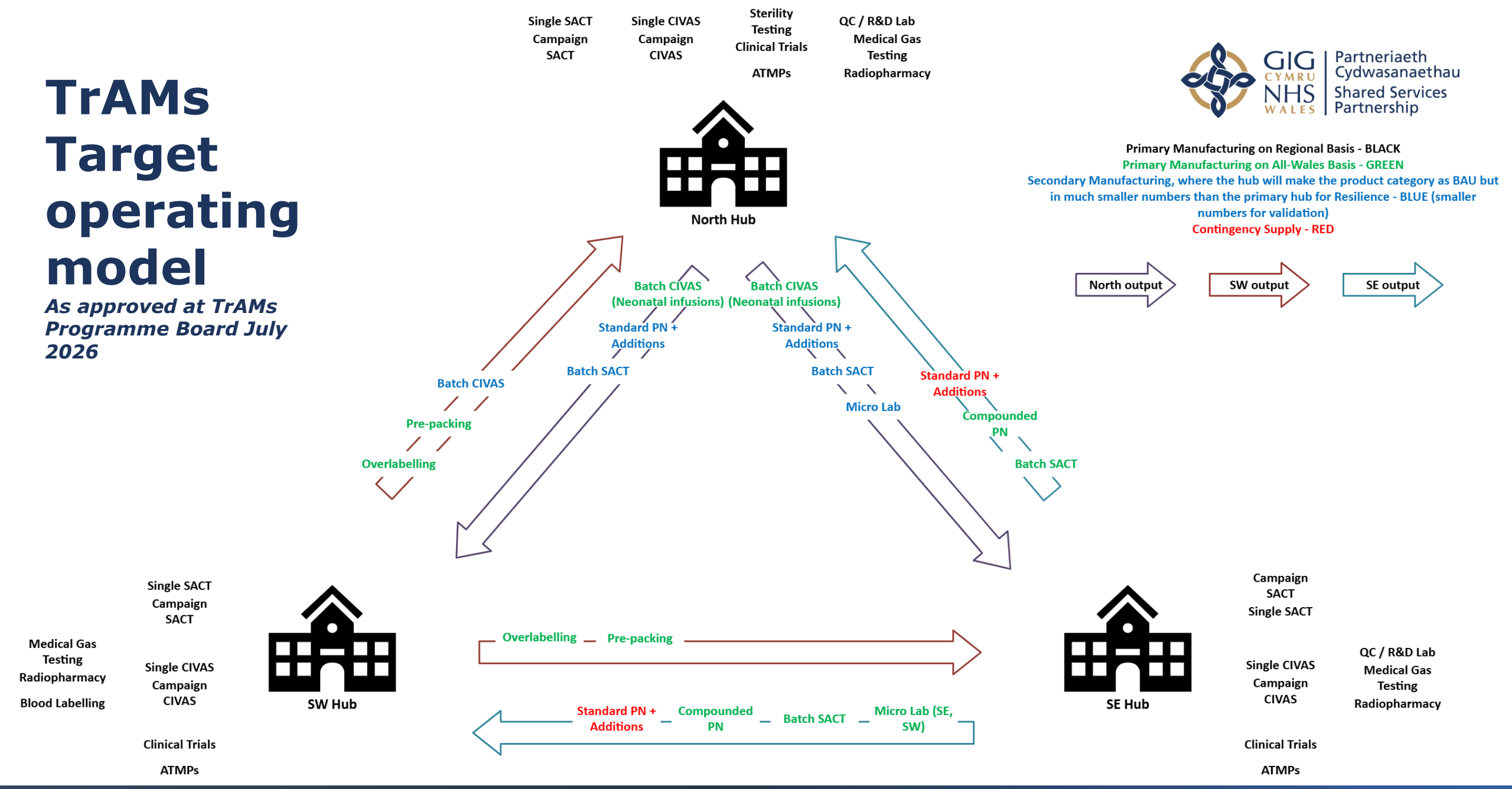
**Julie Coles**
Revenue Lead

**Gill Hughes**
Accountant

**Laura Rees**
Workforce

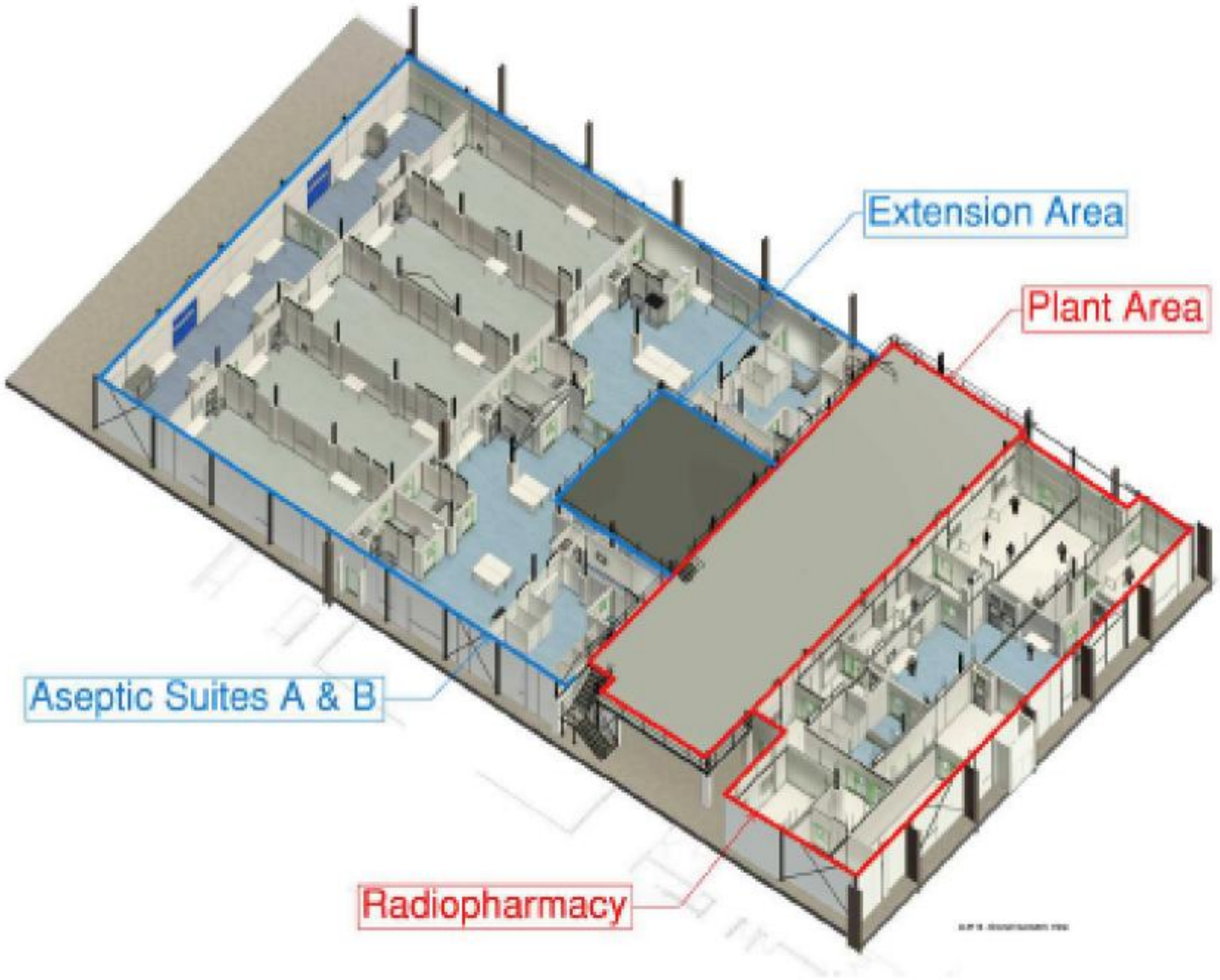
# TrAMs Target operating model

***As approved at TrAMs Programme Board July 2026***



GIG CYMRU NHS WALES | Partneriaeth Cydwasanaethau Shared Services Partnership

# South-East Hub Visuals












# TrAMs Programme - Benefits

GIG CYMRU NHS WALES | Partneriaeth Cydwasanaethau Shared Services Partnership

Contingency and standardisation to leverage economies of scale

Improved quality and regulatory compliance

Improved access to new and innovative treatments, greater clinical trial uptake

Reduced treatment waiting times and appointment delays

Greater facility capacity and adoption of innovative tech

Digital transformation – seamless interfacing across Wales

Reduced outsourcing and reliance on commercial suppliers

Robust, skilled workforce with defined career progression

# Any Questions?

**Email: TrAMs@Wales.nhs.uk**

**Write:** NHS Wales Shared Services Partnership  4-5 Charnwood Court
Heol Billingsley
Parc Nantgarw
Cardiff
CF15 7QZ

**Website:** nwssp.nhs.wales

# UHS Adanac Aseptics

Adanac Park Development Update

November 2026



# Adanac Park – location



- Our existing site (blue) is full and land locked on all sides by residential properties
- Adanac Park site (red) will provide new aseptic facilities.

UHS Adanac Aseptics | NHS University Hospital Southampton NHS Foundation Trust

# Adanac Aseptic Facility

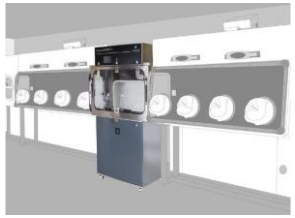
From construction and technical design to the completed production environment.

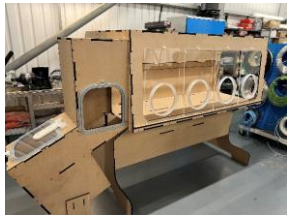
## FACILITY DELIVERY





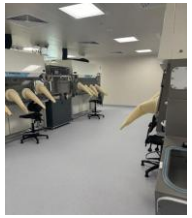
## DESIGN & MOCK-UP





## BUILT ENVIRONMENT





**FACILITY JOURNEY** Construction • Technical design and mock-up • Completed aseptic production environment

# Design Principles

## PRODUCT SEGREGATION BY SUITE

- Four dedicated cleanroom suites
- Dedicated AHUs per suite
- ATMP/Trials (out of scope)
- CIVAS
- SACT
- PN

## PROCESS SEGREGATION BY SPACE

- Product types grouped and processed on a campaign basis
- Dedicated equipment where possible
- Uni-directional process flows
- Separate MAL/PAL

## CLOSED PROCESSING

- Licensed starting materials
- Single-use consumables
- Closed systems
- Semi-automated processing in planning stages
- Fixed product types

## CONTAINMENT

- Uni-directional flow isolators
- Externally ducted
- Active filtered air pass-through hatches
- Automated decontamination of isolators (VHP)
- VHP transfer of individual batches into process chambers

# A purpose-built aseptic facility

Designed, built and qualified to the standards expected of a licensed manufacturing unit



*Inside one of the production suites*



*Construction*



*Completed building*

- Four dedicated cleanroom suites, each with its own air handling
- CIVAS, SACT and parenteral nutrition made in separate suites
- Closed processing, with automated decontamination of isolators
- 53 aseptic process simulation runs completed, December 2025 to July 2026

# What the hub will make

Four suites and 15 isolators, with each product line brought online once it is validated



### Oncology and monoclonals

Dedicated isolators for SACT. Brought on once CIVAS is stable.



### CIVAS

Ready-to-administer injectables. Our highest-volume line, and the first to validate and scale.



### Parenteral nutrition (TPN)

Dedicated isolators. UHS demand first, then wider supply.



### OPAT

Supports treatment at home. Each dose takes longer to make, so capacity is planned with care.



### Advanced therapies (ATMP)

Specialist, very low volume. Later in the sequence

**Proposed early portfolio:** batched chemotherapy, long-expiry CIVAS, ready-to-administer antibiotics and standard PN.

# Where we are now

A strong facility and team, with a clear package of regulatory work before we resubmit

1

## Facility ready

Purpose-built suites and equipment are in place. The CIVAS suite is fully validated. Oncology validation reports were awaiting final sign-off at the August visit.

2

## First MHRA assessment

The on-site assessment took place on 10 to 12 August. It recognised the quality of the facility and staff, and asked for further assurance on processes, documents and the quality system.

3

## Application reset

The application was withdrawn and the inspection case closed. Enabling a completely new inspection following recommended actions

4

## Preparing to resubmit

We are completing a detailed regulatory plan and strengthening the evidence pack before we resubmit.

**Planning assumption:** the unit comes online for licensed supply before the end of 2026/27, subject to completing the recovery plan and MHRA approval.

UHS Adanac Aseptics | NHS University Hospital Southampton NHS Foundation Trust

NHS University Hospital Southampton NHS Foundation Trust

# The Next Phase Moves from Readiness to Licensed Activity

Priorities focus on process optimisation and readiness, and the phased launch of CIV and ONC services under MS licence.

**EXECUTIVE FOCUS** — **Optimise readiness • Transition safely • Expand supply**

## 01 OPTIMISE READINESS

- Review QMS and validation packs
- Continue supply to UHS under S10
- Maintain facility readiness, operator qualification and APS status for licensing

## 02 PEOPLE & TRANSITION

- Continue recruitment against the phased plan.
- Phase Section 10 items into the CIV suite.

## 03 LAUNCH & SCALE

- MS licence submission and inspection
- Build the CIV OPAT portfolio.
- Secure final approval of ONC results.
- Start ONC lines for UHS spoke units and plan external-unit supply.
- Scale into semi-automation in PN suite

**CURRENT POSITION** — **Section 10 work started using ATU suite. Other suites staged validation for licensing**

**IMMEDIATE GATE** — **Ensure complete and clear all documentation for licensing**

# WYAAT Pharmacy Aseptics Hub

## QATS 2026: Project Update

Charlotte Cleveland – Programme Manager

**04th Nov 2026**



WYAATprogramme@nhs.net
wyaat.wyhpartnership.co.uk
@WYAAT_Hospitals

West Yorkshire
Association of Acute Trusts

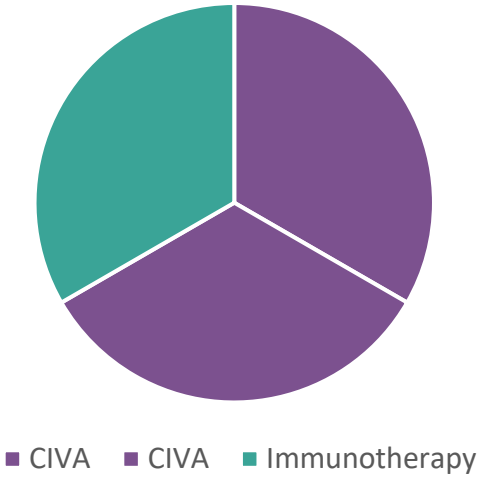
# Overview | Aseptic Manufacturing Hub

- The hub is hosted by Leeds Teaching Hospitals NHS Trust (LTHT).
- LTHT will transition all pharmacy services from their existing facility at Moor House, to the new site at Leeds Valley Park, this includes:
  - Pharmacy Manufacturing Unit – consisting of aseptic production unit and dispensary support unit (MS18166)
  - Pharmaceutical Store (WDA18166)
  - QA/QC services and laboratories
  - Pharmacy procurement, contracting and invoicing admin teams
  - NE&Y NHS Pharmaceutical Purchasing Consortium
- The aseptic unit will manufacture aseptic products for all six trusts in the provider collaborative.

West Yorkshire Association of Acute Trusts

# Product Scope

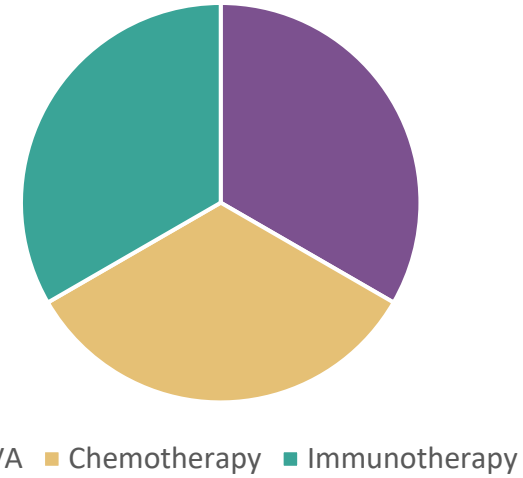
Original Room Configuration




Potential product volumes

- CIVAS – 400,000 doses
- Immunotherapy – 50,000 doses

Revised Room Configuration

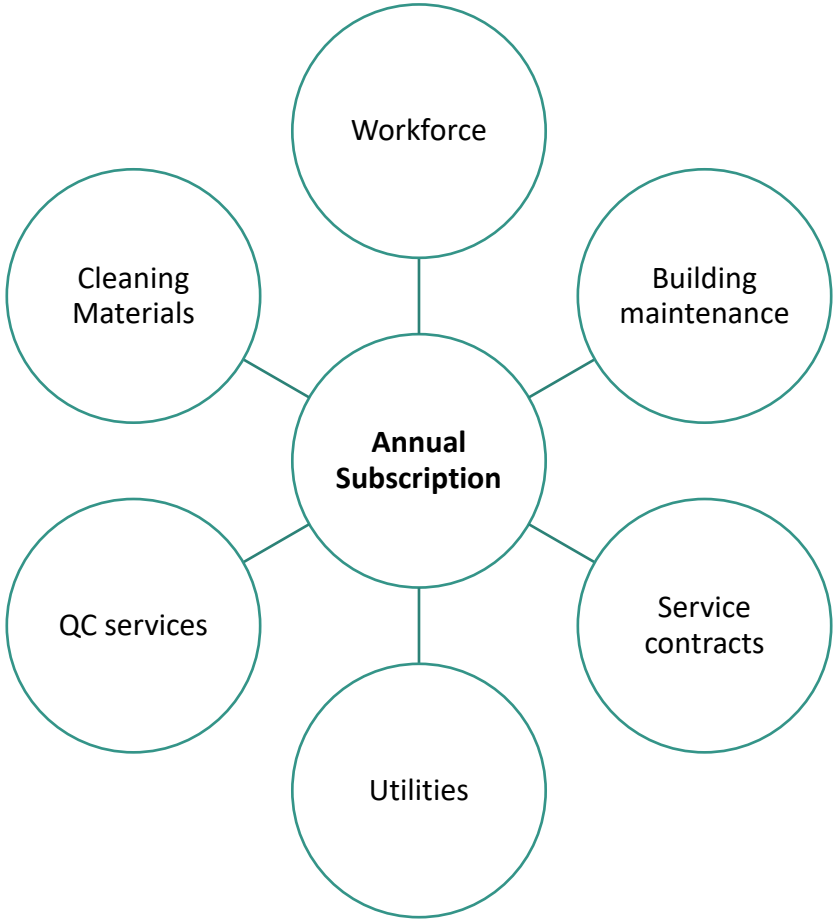


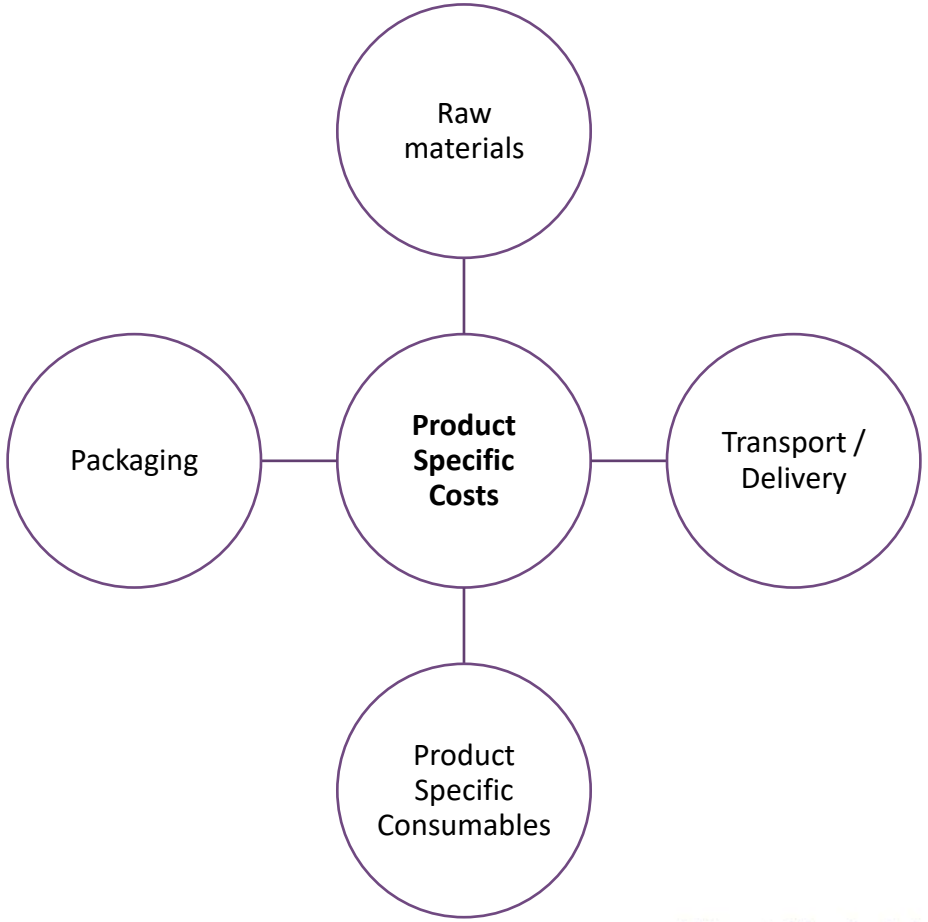

Revised potential product volumes

- Chemotherapy – 150,000 doses
- Immunotherapy – 100,000 doses
- CIVAS – 200,000 doses

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# Finance Model - Principles

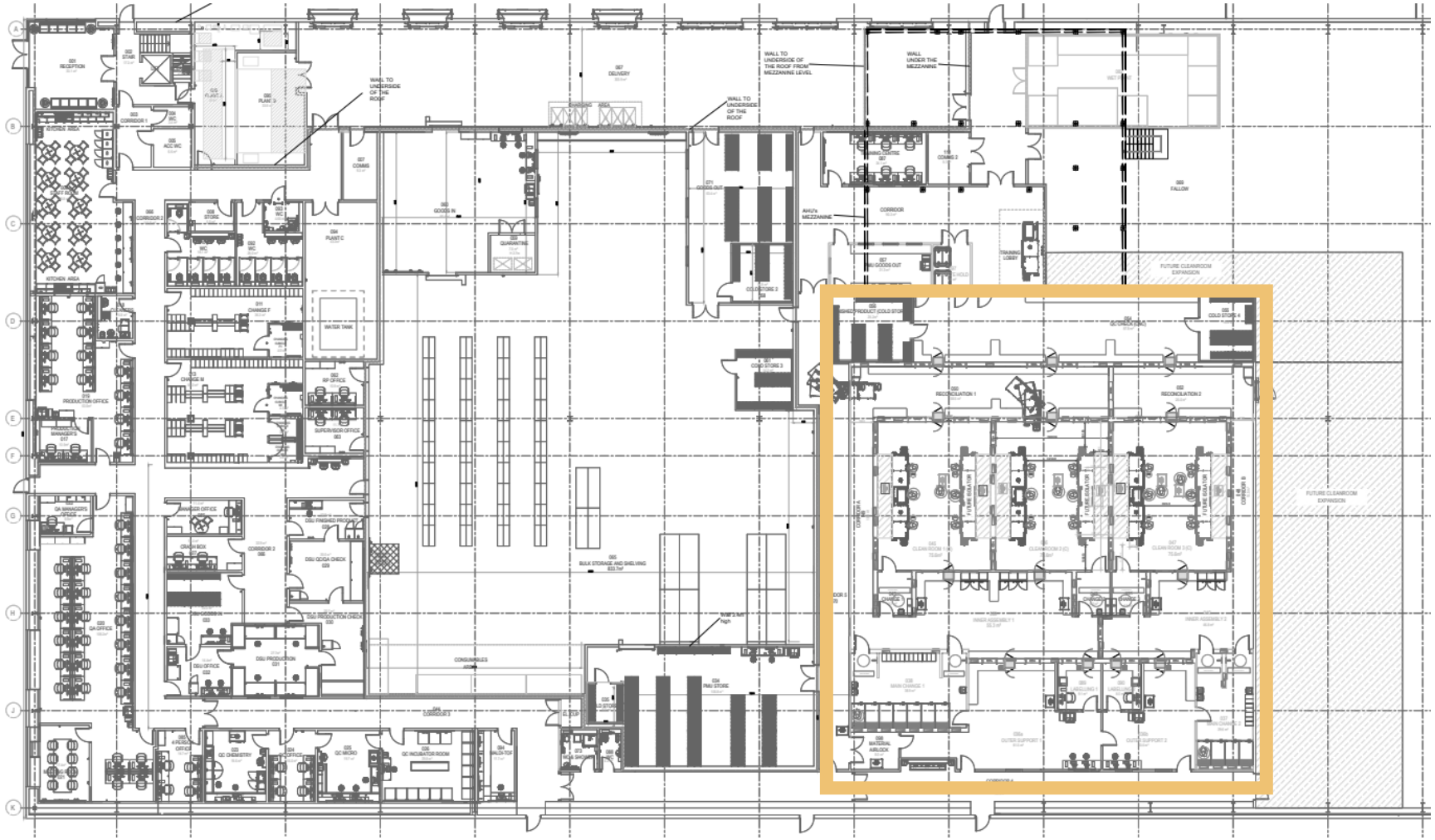


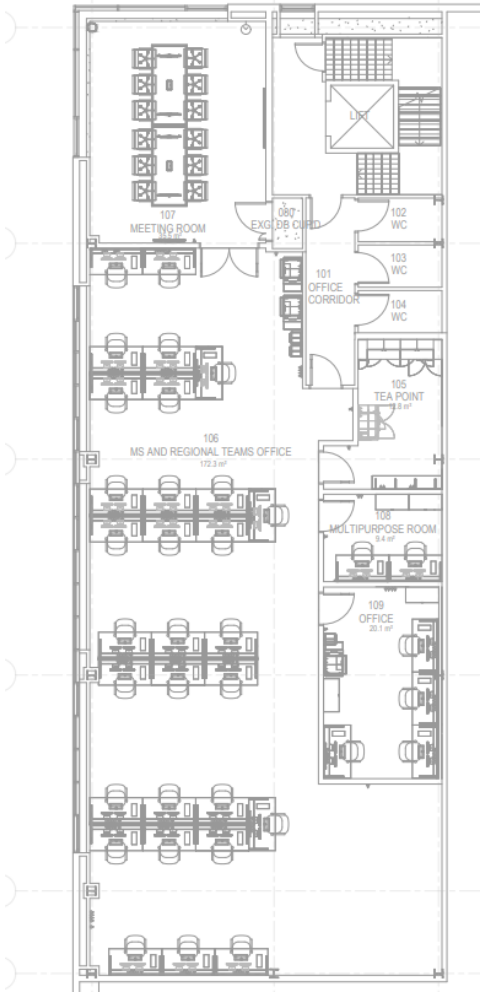

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# Building Design

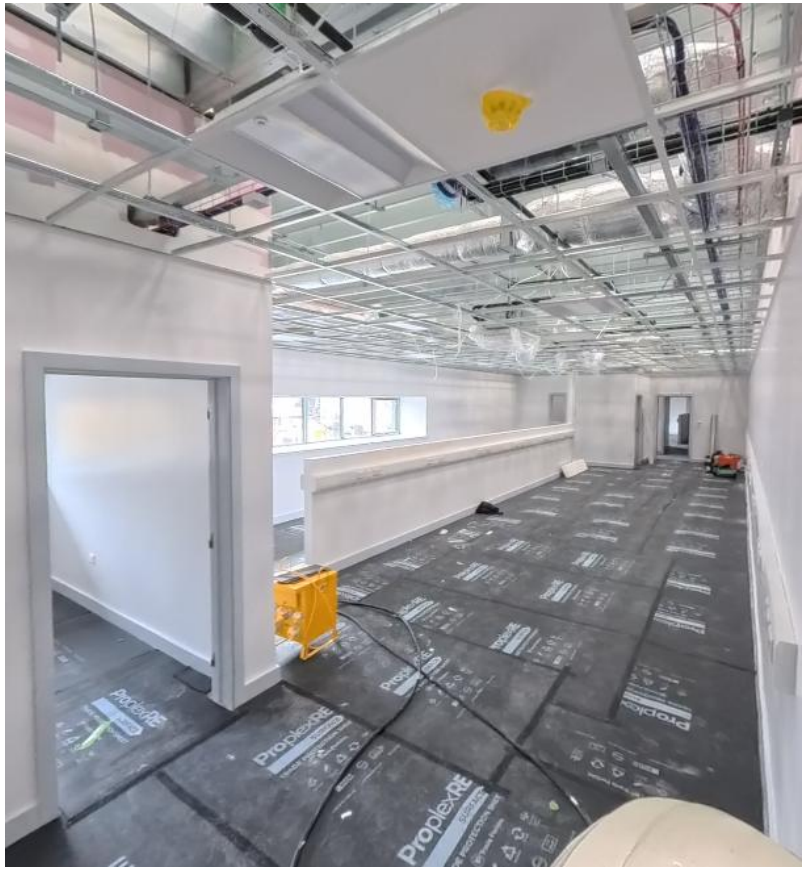
Ground Floor




First Floor









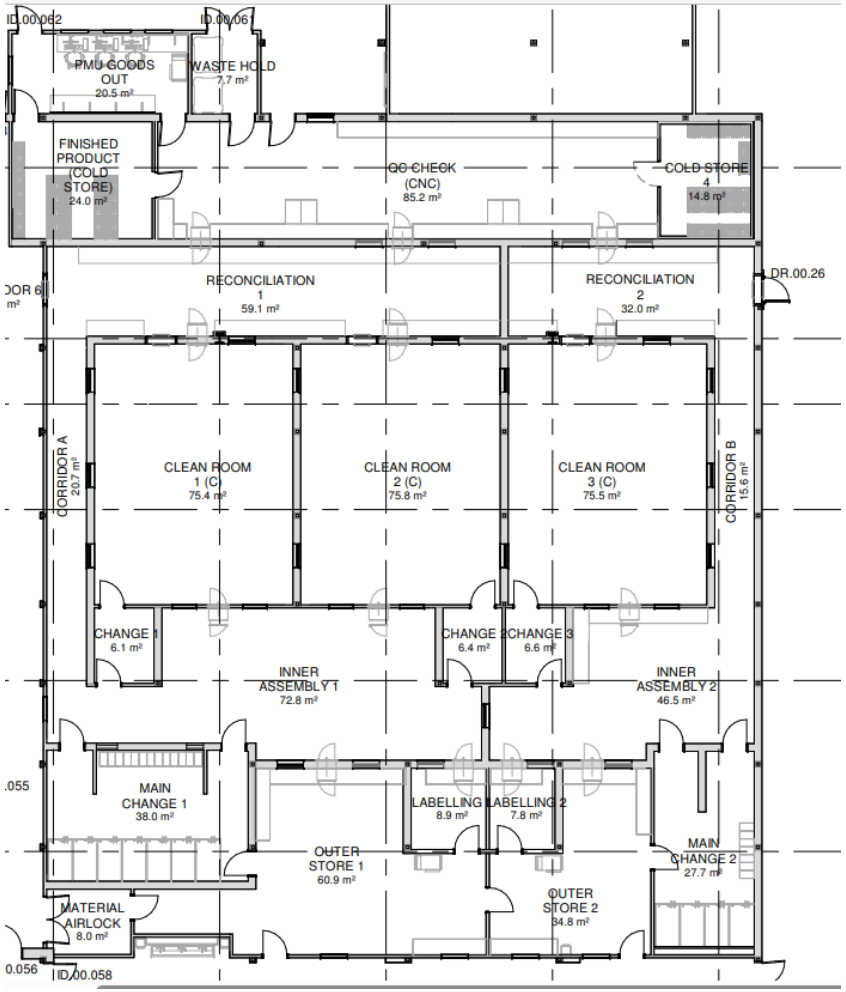


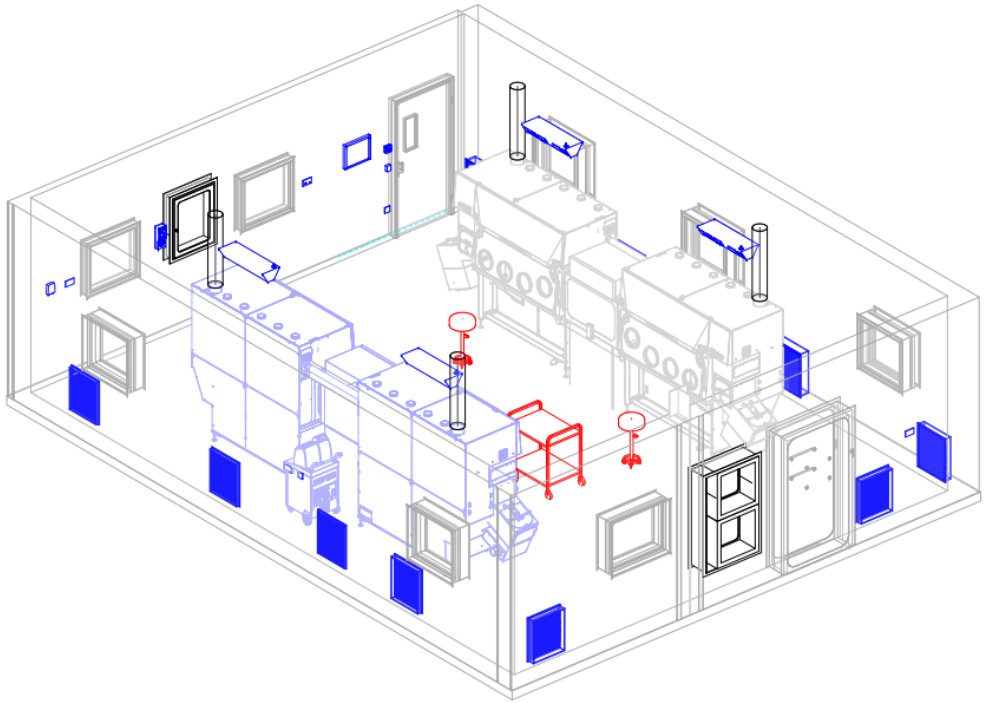





# Site Progress

# Cleanroom Suite



West Yorkshire Association of Acute Trusts
















# Site Progress

# Timeline

**Jan 26 - Dec 26**
Construction

**Dec 26 - Feb 27**
Contractor Commissioning & Validation

**March 27 – Jul 27**
Equipment Validation and MHRA Approvals

**April 27 – Jul 27**
Operational Transition

**Q2 2027**
Hub Go-live









WYAAT incorporates Airedale NHS Foundation Trust, Bradford Teaching Hospitals NHS Foundation Trust, Calderdale and Huddersfield NHS Foundation Trust, Harrogate and District NHS Foundation Trust, Leeds Teaching Hospitals NHS Trust, and Mid Yorkshire Teaching NHS Trust.

WYAATprogramme@nhs.net
wyaat.wyhpartnership.co.uk
@WYAAT_Hospitals

West Yorkshire
Association of Acute Trusts

# NENC MMC: build recovery

Progress over the last year




Cold room



Plant and building services

## Contractor transition

OPUS took on completion after Merit's administration. Extensive redesign and drawing rechecks added major pressure to the team.

## Funding for completion

Additional funding for the contractor to finish the build, commissioning and validation, reports, building testing and certificates.

**Learning: contractor changes require time for technical review and assurance.**



Medicines Manufacturing Centre

# Building the organisation and team

A standalone service, with no existing pharmacy department to inherit

**35**

staff now

**150**

planned workforce in 2027

## Recruitment and team culture

Induction, training plans and competencies alongside commissioning and qualification work.

## Governance and finance

Governance, banking and financial arrangements.

## Quality and operational systems

PQS, SOPs, policies and training systems.

## Everyday foundations

HR policies, uniforms, dress code, MMC branding and website development.

**Learning: operational readiness needs its own people and protected time.**



Medicines Manufacturing Centre

# Commissioning and equipment



## Commissioning

Testing, witnessing and evidence review underway.

## Equipment

Nearly all on site, with remaining deliveries awaiting fixed dates.

## Target: start PQ in December 2026

Subject to handover and readiness for the planned qualification work.



Medicines Manufacturing Centre

# Planning isolator cycle development



## Representative load and rack layout

Use the proposed gassing rack and bench simulation to assess loading and arrangement.

## BI/EI challenge strategy

Plan indicator locations and challenges for the cycle-development studies.

## Development before qualification

Use the studies to inform the cycle and load patterns taken forward for validation.

**Learning: cycle development needs its own time, materials and documented plan.**

# Regional support and next steps



## Eight Trusts remain supportive

## Proposed LLP transition

Move to the LLP once the legal agreements are signed and approved.

## Medicines procurement

Establish NHS procurement access and supply arrangements for the proposed LLP.

## Immediate focus

Complete commissioning and confirm handover and PQ readiness.

**Learning: plan legal, procurement and operational arrangements early.**



Medicines Manufacturing Centre

# Peninsula Aseptic Hub
# RDUH and UHP

Amanda Horton – Aseptic Services Manager (UHP)

Yvonne Palmer – Principal Pharmacist –Technical Services (RDUH)

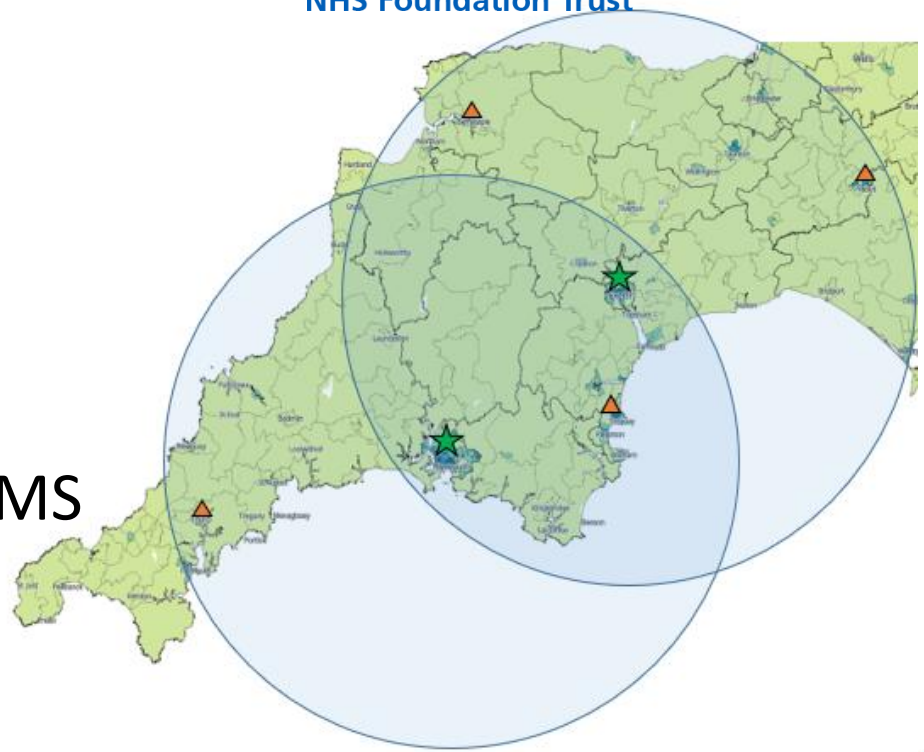


# Peninsula Aseptic Hub

- Part of the National NHS Aseptics Pathfinders.
- To operate as“1Hub – 2 Site” model of RDUH (Exeter) and UHP (Plymouth) for:
  - 1.8million people within the HUB location
  - 150 miles across the Peninsula
  - Capacity across the Hub: 670,000 items
- RDUH existing Aseptic Unit to be MHRA MS Licensed.
- UHP new Aseptic Unit to be MHRA MS Licensed
- Regional and National delivery capabilities
- Operational 2027/28

NHS
Royal Devon University Healthcare
NHS Foundation Trust

NHS
University Hospitals Plymouth
NHS Trust



We put people first
We take ownership
We respect and value each other
We are compassionate
We listen, learn and improve

# Peninsula Aseptic Hub – UHP Site

Amanda Horton – Aseptic Services Manager



# Current Unit

University Hospitals Plymouth NHS Trust

- Section 10 – Pharmacy Aseptic Unit.
- Located on Derriford Hospital site.
- Fabric and equipment at end-of-life (30+ years).
- QAAPS audit – Medium risk with service limitations.
- Trust Risk Register – 15 (at 25 for 5 years)
- Workload – *circa* 20,000 per annum (Cytotoxics, MABs, Clinical Trials)
- Staff – 40 WTE – across Production and QC



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# UHP Peninsula Aseptic Hub

University Hospitals Plymouth NHS Trust

- MS Licensed Aseptic Manufacturing Unit
- Option Appraisal, approved at Trust Board – Unit to be housed within existing Lighthouse Labs building (Estover Site)
- Capacity: 480,000 items – capacity to be stepped up incrementally
- Product Portfolio: Cytotoxic, CIVAS, Clinical Trials, TPN (supplemented standard bags)
- Expansion for future CGT and Radiopharmacy



# UHP Peninsula Aseptic Hub Unit Location

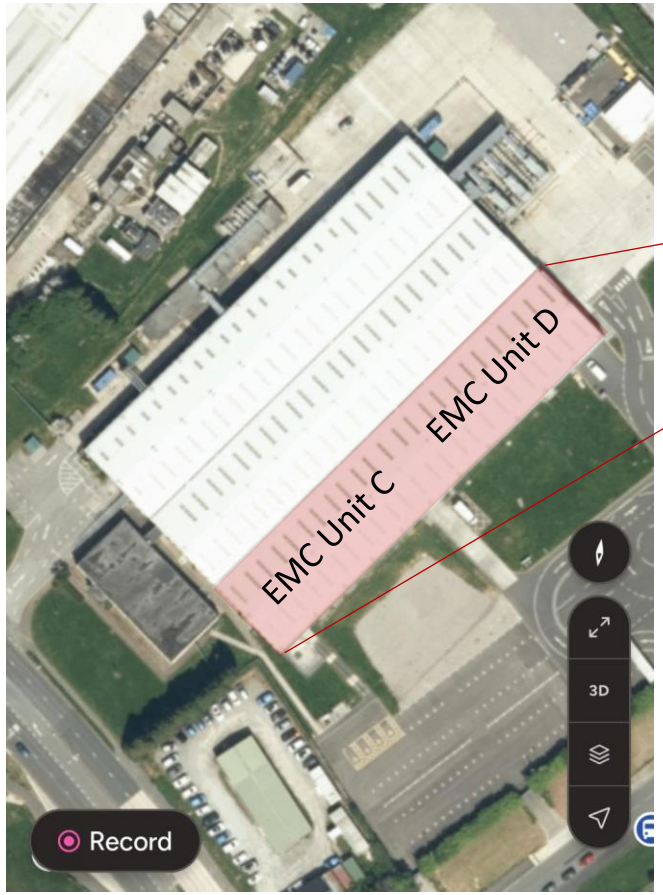
University Hospitals Plymouth NHS Trust

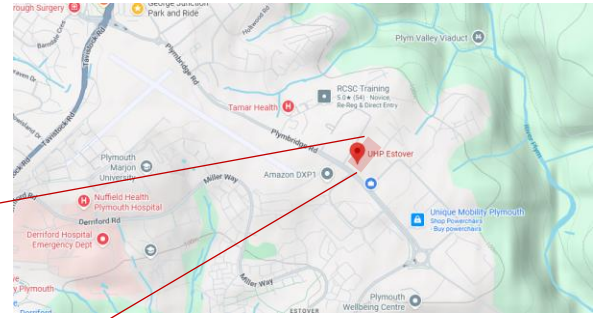
Extensively refurbished building located in the Estover area of Plymouth.

Aseptic Manufacturing Unit to be housed within Unit C.

Radiopharmacy and ATMP housed within Unit D.

UHP Pathology services to be housed within the same building, with shared welfare facilities.




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# Progress to date

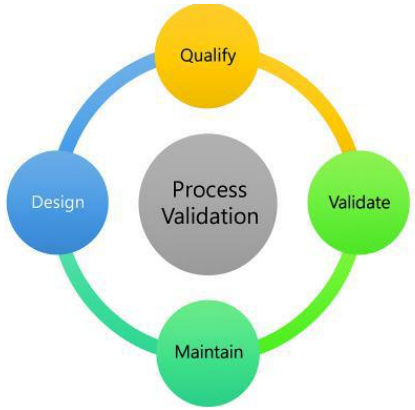
University Hospitals Plymouth NHS Trust

- Site location agreed
- Site quality documentation approved and distributed to suppliers.
- Isolators specified and ordered from Ortner Reinraumtechnik GmbH.
- Cleanroom contractor, Asgard Cleanroom Solutions Ltd engaged.
- Proposed site layout agreed to RIBA 4
- Engagement with the MHRA on designs and qualification.
- Commencement ceremony 19th November 2026.
- Expected build completion October/November 2027.
- Commissioning and qualification completion April 2028

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We are compassionate
We listen, learn and improve

# Asgard – Where are we now?

University Hospitals Plymouth NHS Trust




- Program baseline agreed and aligned with Asgard indicative program.
- Stage 4 design completed October 2026.
- Construction start programmed for November2026.
- Key focus: maintaining design sign-off dates to protect the October/November 2027 completion date.





We put people first
We take ownership
We respect and value each other
We are compassionate
We listen, learn and improve

# Commercial and Colleague Opportunities

University Hospitals Plymouth NHS Trust

Exploring opportunities for strategic commercial partnerships.

- Maximise value for the trust and wider NHS
- Support sustainable aseptic capacity
- Maximise the potential of the new facility

Opportunities for colleagues

- Innovative workforce solutions
- Creation of new roles and career pathways
- Development of specialist skills
- Adoption of new technology



NHS
Royal Devon
University Healthcare
NHS Foundation Trust

# Peninsula Aseptic Hub- RDUH site

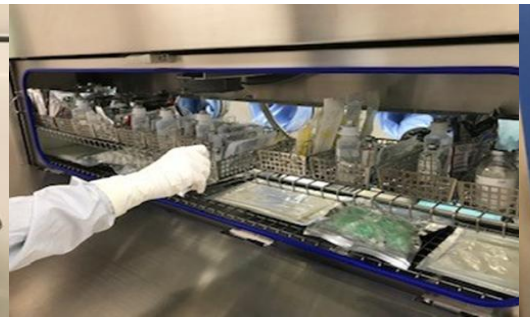
Yvonne Palmer
Principal Pharmacist Technical Services



# Two isolator rooms, Five VHP isolators, one dedicated aseptic team















# RDUH Site

- Standalone aseptic facility
- Aseptic Section 10 preparation since 2019 with microbial and process validation results available
- 5 Vaporised Hydrogen Peroxide isolators
- Unit original design was appraised by MHRA
- Trust approval for MS licence application process
- **Predicted capacity:** 160000 items; achieved by 20% yearly increase from current level in line with staffing level and efficient work processes

**SACT**

**OPIT**

**Increase of clinical trial items (under section 10) by moving Section 10 SACT into batch production**

# RDUH Challenges

- Time pressure : Project vs Service delivery and other Trust & Devon wide objectives (One Devon EPR)
- Different stage to Plymouth
- Unable to recruit qualified staff → increase number of training posts (additional 12 posts over last 3 years) → impacts on current capacity until qualified (SMT, STP, PTQA)
- Facility is now 10 years old. Refurbishment required (HEPA filter replacement, Vinyl upgrade, AHU equipment)
- Full revalidation of VHP cycles (empty & loaded) – alongside day-to-day service
- Isolator modification required (informed in October 2026)

# RDUH Challenge

- Time to develop Trust Business Case for additional staff to increase workload as per pathfinder business case in current financial climate
- Right time to engage with MHRA

## Any Questions?