Public Research, Development & Innovation Sub-Committee

Wed 12 March 2025, 02:00 PM - 04:00 PM

Trust Headquarters, 2 Charnwood Court, Parc Nantgarw, Cardiff. CF15 7QZ

Agenda

02:00 PM - 02:05 PM
5 min

1. PRELIMINARY MATTERS

1.1. Welcome and Introduction

Led by Professor Andrew Westwell, Research, Development & Innovation Sub-Committee Chair

1.2. Apologies

Led by Professor Andrew Westwell, Research, Development & Innovation Sub-Committee Chair

1.3. In Attendance

Led by Professor Andrew Westwell, Research, Development & Innovation Sub-Committee Chair

1.4. Declarations of Interest

Led by Professor Andrew Westwell, Research, Development & Innovation Sub-Committee Chair

02:05 PM - 02:15 PM
10 min

2. STANDARD BUSINESS

2.1. Minutes from the Public Research, Development & Innovation Committee held on the 10th December 2024

Led by Professor Andrew Westwell, Research, Development & Innovation Sub-Committee Chair

2.1 Public RDI Draft Minutes 10.12.2024 v2.pdf (8 pages)

2.2. Review of Action Log

Led by Dr Jacinta Abraham, Executive Medical Director and Research & Development Lead

2.2 Public RDI Action Log - 12.03.25.pdf (1 pages)

2.3. Matters Arising

Led by Professor Andrew Westwell, Research, Development & Innovation Sub-Committee Chair

02:15 PM - 02:45 PM
30 min

3. PRESENTATION AND GUEST ATTENDEES

3.1. Advanced Radiotherapy Cymru (ARC) Academy Update ^TO FOLLOW

Led by James Powell, Consultant Oncologist / Jennet Holmes, Head of Innovation

02:45 PM - 02:55 PM
10 min

4. KEY REPORT(S)

4.1. Executive Medical Director Briefing

Led by Dr Jacinta Abraham, Executive Medical Director and Research & Development Lead

4.1 Executive Medical Director Briefing.pdf (10 pages)

02:55 PM - 03:25 PM
30 min

5. QUALITY, SAFETY AND PERFORMANCE

5.1. Research, Development & Innovation Performance Report, Quarter 3, Financial Year 2024-25

Led by Sarah Townsend, Head of Research & Development and relevant leads as follows :

- ***Rhydian Owen, Research & Development Cancer Strategy Lead***
- ***Jennet Holmes, Head of Innovation***
- ***Dr Edwin Massey, Medical Director, Welsh Blood Service / Sian James, Head of Research, Development & Innovation, Welsh Blood Service***
- ***Amie Garwood-Pask, Deputy Head of Finance Business Partnering***

5.1 Cover Report RDI Performance Report FY2425 Q3.pdf (7 pages)
5.1 RDI Integrated Performance Report FY2425 Q3_With Risk Profile.pdf (54 pages)

03:25 PM - 03:35 PM
10 min

6. CONSENT ITEMS

The consent part of the agenda considers routine Committee business as a single agenda item. Members may ask for items to be moved to the main agenda if a fuller discussion is required.

6.1. Consent - For Approval / Endorsement

6.1.1. RD&I Intellectual Property Policy

Led by Sarah Townsend, Head of Research & Development

6.1 Cover Report Intellectual Property Policy.pdf (9 pages)
6.1 Intellectual Property (IP) Policy v7 February 2025 CLEAN VERSION.pdf (18 pages)
6.1 Intellectual Property (IP) Policy v7 February 2025 TRACKED CHANGES VERSION.pdf (25 pages)

6.2. Consent - For Information / Noting

6.2.1. Evaluation Report - Implementing the Cancer R&D Ambitions – An Integrated Business Case 2023-2026

Led by Rhydian Owen, Cancer R&D Strategy Lead

6.2.1 Annual Evaluation Integrated Bid Yr 2 04.02.2025.pdf (34 pages)

6.2.2. Summary from the Private Research, Development & Innovation Committee Meeting held on the 10th December 2024

Led by Professor Andrew Westwell, Research, Development & Innovation Sub-Committee Chair

6.2.2 Summary of Private RD&I Draft Minutes 10.12.2024 v2.pdf (4 pages)

03:35 PM - 03:40 PM
5 min

7. MEETING REFLECTIONS

Members to identify items to include in the Highlight / Assurance Report to the Trust Board in respect of the following areas:

- ***For Escalation***
- ***For Assurance***
- ***For Advising***

- *For Information*

03:40 PM - 03:40 PM
0 min

8. ANY OTHER BUSINESS

03:40 PM - 03:40 PM
0 min

9. DATE AND TIME OF THE NEXT MEETING

The Public Research, Development & Innovation Sub-Committee will next meet in June 2025, date to be confirmed.

03:40 PM - 03:40 PM
0 min

10. CLOSE

The Research, Development & Innovation Sub-Committee is asked to adopt the following resolution:

That representatives of the press and other members of the public be excluded from the remainder of this meeting having regard to the confidential nature of the business to be transacted, publicity on which would be prejudicial to the public interest in accordance with Section 1(2) Public Bodies (Admission to Meetings) Act 1960 (c.67).

03:40 PM - 03:40 PM
0 min

11. PRIVATE / PART B SESSION

The following item(s) will be discussed at the Private / Part B Session of the Research, Development & Innovation Sub-Committee:

- **Minutes from the Private Research, Development & Innovation Committee held on the 10th December 2024**
- **Business Case: Innovating Platelet Transfusion: HLA-Depleted Platelets to Overcome Refractoriness in Cancer Care**
- **Business Case: ARC Academy - “Prime-Pull” Immunotherapy: A Study in Cancer Patients Receiving Radiotherapy**

Minutes
Public Research, Development & Innovation Sub-Committee
Velindre University NHS Trust

Date 10/12/2024
Time 10.00-12.15pm
Location Trust Headquarters, 2 Charnwood Court, Parc Nantgarw, Cardiff
Chair Professor Andrew Westwell, Independent Member

PRESENT		
Professor Andrew Westwell	Independent Member and Research, Development & Innovation Sub-Committee Chair	**AW**
Professor Donna Mead	Professor Donna Mead, OBE Trust Chair	**DM**
Vicky Morris	Independent Member	**VM**
ATTENDEES		
Jacinta Abraham	Executive Medical Director and R&D Lead	**JA**
Matthew Bunce	Executive Director of Finance	**MB**
Anne Carey	Interim Chief Operating Officer	**AC**
Amie Garwood-Pask	Deputy Head of Finance Business Partnering	**AGP**
Chloe George	Head of Component Development, Welsh Blood Service	**CG**
Non Gwilym	Interim Director of Corporate Governance	**NG**
Jennet Holmes	Head of Innovation	**JH**
Sian James	Head of Research, Development & Innovation, Welsh Blood Service	**SJ**
Alan Prosser	Director, Welsh Blood Service	**AP**
Rhydian Owen	R&D Cancer Strategy Lead	**RO**
Professor Robert Jones	Associate Medical Director for Research, Development & Innovation	**RJ**
Nicola Williams	Director of Nursing, AHP's & Healthcare Scientists	**NW**
SECRETARIAT		
Sandra Cusack	Business Support Officer	**SMC**

1.0	**PRELIMINARY MATTERS**	
1.1	**Welcome and Introduction** *Led by Professor Andrew Westwell, Research, Development & Innovation Sub-Committee Chair*	
1.2	**Apologies Received From:** • Christopher Cotterill-Jones, Research Delivery Manager • Dr Edwin Massey, Medical Director, Welsh Blood Service • Sarah Townsend, Head of Research & Development	
1.3	**In Attendance** The Chair extended a warm welcome to the following attendees in support of specific agenda items: • Kate Cleary, R&D Cancer Strategy Programme Manager • Iestyn James, Clinical Business Support Manager (Observer) • Natasha McLaughlin, WBD RD&I Officer (Observer) • Helen Robertson, RD&I Communications & Engagement Officer (Observer)	
1.4	**Declarations of Interest** *Led by Professor Andrew Westwell, Chair of the Research, Development & Innovation Sub-Committee* No declarations of interest were raised.	
2.0	**STANDARD BUSINESS**	
2.1	**Draft Minutes from the meeting of the Public Research, Development & Innovation Committee held on the 17th September 2024** *Led by Professor Andrew Westwell, Chair of the Research, Development & Innovation Sub-Committee* Donna Mead raised a concern to Item 5.1 Finance Performance in the minutes of the last meeting, regarding compliance within the 30-day payment target, which is below the required 95%. Matt Bunce gave assurance that the overall compliance position is not significantly affected and that efforts will be made to improve compliance. There are also gaps within the finance team and the need for discussion with the R&D team to address this issue. A meeting will be arranged with the R&D team to ensure compliance within the 30-day payment target and improve the overall compliance rate will follow. Following the above action, the Research, Development & Innovation Sub-Committee **APPROVED** the Minutes of the Public Meeting held on 17th September 2024 as an accurate reflection of proceedings.	**APG/ ST**
2.2	**Review of Action Log**	

	Led by Dr Jacinta Abraham, Executive Medical Director and RD&I Lead The action log was discussed and Committee members confirmed that they were assured that all actions identified as closed had been fully instigated and could therefore be closed. The Research, Development & Innovation Sub-Committee **APPROVED** to **CLOSE** these actions.	
2.3	**Matters Arising** *Led by Professor Andrew Westwell, Chair of the Research, Development & Innovation Sub-Committee* There were no matters arising.	
3.0	**PRESENTATION AND GUEST ATTENDEES**	
3.1	**Developments within the Component Development and Research Laboratory** *Led by Chloe George, Head of Component Development, Welsh Blood Service* Chloe George, Head of Component Development at the Welsh Blood Service, presented an overview of the lab's activities, focusing on optimising blood components for patient transfusions and improving the efficiency of the blood supply chain. Key research areas include cold stored platelets for better hemostatic abilities, frozen platelets for extended shelf life, and whole blood for quicker transfusions in major hemorrhage cases. The lab is also addressing the upcoming ban on the plasticizer DEHP in blood packs and exploring ways to maximise blood donations. Collaborations with clinical and academic partners, including the military and emergency medical services, enhance research capabilities. The team has secured external funding, including a significant award in 2023, and is applying for larger grants to support ongoing and future research projects. AP emphasized the need for sustainable funding for research initiatives, suggesting that core business development should be supported by permanent funding rather than relying solely on grants. DM invited the Component Development and Research Laboratory Team to submit an application for funding to the Charitable Funds Committee. An open invitation to visit the Component Development and Research Laboratory at the Welsh Blood Service will be circulated to committee members. The visit will include a guided tour of the laboratory, live demonstrations such as observing the Microfluidics Microscope, and an opportunity to meet members of the research team. The visit is expected to last approximately one hour.	**CG**

	The Research, Development & Innovation Sub-Committee congratulated Chloe and the Team and **NOTED** the Component Development and Research Laboratory Presentation.	
4.0	**KEY REPORT(S)**	
4.1	**Executive Medical Director Briefing** *Led by Dr Jacinta Abraham, Executive Medical Director and R&D Lead* JA gave a brief overview of high-level activities relating to Research, Development and Innovation during Quarter 2, Financial Year 2024/25 along with noteworthy items from the RD&I environment since the last meeting. Key areas for discussion were as follows: **Health and Care Research Wales Initiatives** Following discussion, the Committee requested a paper be brought back to a future meeting of the Executive Management Board to demonstrate how Velindre can lead in the "once for Wales" delivery model for tackling cancer through research, aligning with Health and Care Research Wales' ambitious recruitment targets. Health and Care Research Wales has set an ambitious target to increase participant recruitment in cancer research by 500% by 2027, the plan also aims to diversify trial access across cancer types, demographics, and expand Phase III trials to over 50% of the cancer research portfolio. AW asked whether these figures quoted by HCRW were correct and RJ clarified that they were. **UK Clinical Trial Regulations – Proposals for legislative changes for clinical trials** Legislative changes proposed to make the UK more attractive for clinical trials, following the O'Shaughnessy report. **Medi Wales Innovation Awards** Four nominations from the organisation, with the BioNTech All-Wales collaboration receiving a commendation. **Microfluidic Modelling** The Welsh Blood Service has introduced a game-changing investment in microfluidic modelling technology, which recreates microvascular environments for advanced research applications, funded by a grant from the Welsh Government's SMART Capital Equipment Fund. **15 Step Visit** A visit to the Early Phase Clinical Trials Unit was conducted by Jacinta Abraham, Andrew Westwell and Sarah Townsend, which was overwhelmingly positive. There was interaction with several patients who expressed gratitude for the opportunity to participate in early-phase studies. The visit highlighted the unit's reach, including treating patients from North Wales, emphasizing	

	the importance of providing accommodation for those traveling long distances. The visit also identified areas for improvement, ensuring a better experience for all participants. The Research, Development & Innovation Sub-Committee **NOTED** the contents of the Executive Medical Director Briefing. Anne Carey, Interim Chief Operating Officer joined the meeting.	
5.0	**QUALITY, SAFETY AND PERFORMANCE**	
5.1	**Research, Development & Innovation Performance Report** *Led by Robert Jones, Associate Medical Director for Research, Development & Innovation and relevant leads* RJ presented an overview of the RD&I Performance Report for Quarter 2, Financial Year 2024-25, highlighting the Trust's portfolio, recruitment numbers, and the new dashboard format. He also mentioned the challenges in radiotherapy service capacity, pharmacy staffing, and access to biopsy samples. and the following key items were discussed further: **Financial Performance led by Amy Garwood-Pask Deputy Head of Finance Business Partnering as follows:** • Minor variances against the budget with a small overspend of £16,000. • Income slightly below target but expected to meet the annual target by year-end. • The need to improve the performance of paying invoices within 30 days with successful recruitment of a new finance team member to help address this issue (as discussed in item 2.1). **Rita Options Appraisal led by Jennet Holmes, Head of Innovation as follows:** The evaluation of the RITA chatbot presented four options for its future. The proposed option is to discontinue the current platform and seek alternative funding to explore further applications of the service. This approach involves looking for QA funding for a dedicated role to support the work, as the current AI platform is outdated and requires exploration of alternative platforms and costings. The Committee discussed at length and agreed that a strategic decision regarding the future of the Rita chatbot and the necessary resources to support it, is to be taken to January's Executive Management Board. **Risk Management** The Committee reviewed the risk profile, discussing ongoing issues with radiotherapy service capacity, pharmacy staffing, and access to biopsy samples for clinical trials, and the steps being taken to address these challenges. NG requested a meeting with R&D so that we can align processes for managing risks in accordance with the Trust's risk policy. The Committee:	**JH** **NG / ST**

	• **NOTED** the RDI Performance Report Quarter 2, Financial Year 2024-25. • **NOTED** the new dashboard, highlighting the work of RD&I in the Cancer Service, the Welsh Blood Service and Innovation. • **NOTED** the barriers to research and progress and ongoing efforts to address challenges in Pharmacy and Radiotherapy.	
6.0	**PLANNING AND STRATEGIC DEVELOPMENT**	
6.1	**Research & Development Cancer Ambitions Strategy & Cardiff Cancer Research Hub Update** *Led by Rhydian Owen, R&D Cancer Strategy Lead* RO gave an overview of the Research and Development Strategy, emphasising the need to update the strategy to reflect new opportunities and ensure alignment with the organisation's goals. Also provided, was an update on the Cardiff Cancer Research Hub, detailing its structure, ongoing trials, and the development of a partnership agreement to formalise collaboration between Velindre, Cardiff University, and Cardiff and Vale University Health Board There were discussions about the financial flows for trials, particularly how income from trials will be managed and distributed among the involved organisations. The Committee requested a meeting with the senior finance teams from the involved organisations to establish a clear and agreed-upon financial model for managing and distributing income from trials. JA discussed a new initiative involving collaboration between Velindre, Cardiff University, and Cardiff and Vale University Health Board. The first meeting of the Joint Academic Health Sciences Strategy (JAHSS) is scheduled for Friday 13th December 2024, with Jaz representing Velindre University NHS Trust. The strategy aims to enhance co-operation in education, innovation, and research across these organisations. The goal is to explore how the Cardiff Cancer Research Hub (CCRH) and other collaborative projects can fit into this broader strategy, leveraging strengths in life sciences, digital health, and other areas. The Committee agreed that this needs to be socialised and requested a paper to be presented at a future meeting of the Executive Management Board. The Bone Marrow Transplantation Unit is part of a broader infrastructure bid to the Welsh Government. There is a letter from Judith Paget to David Donegan regarding this bid, but specific details about the letter and the bid's status were not discussed in the meeting. Further information is needed to provide a comprehensive update on this topic. The Research, Development & Innovation Sub-Committee **NOTED** the Developments of the Cancer Ambitions Strategy and Cardiff Cancer Research Hub Update.	**RO/RJ /MB**

7.0	**INTEGRATED GOVERNANCE**	
	There are no items for Integrated Governance.	
8.0	**CONSENT AGENDA**	
8.1	**Consent - For Approval / Endorsement**	
	There were no items for approval / endorsement.	
8.2	**Consent - For Information / Noting**	
8.2.1	**Summary from the Private Research, Development & Innovation Committee Meeting held on the 17th September 2024** *Led by Professor Andrew Westwell, Research, Development & Innovation Sub-Committee Chair* The Research, Development & Innovation Sub-Committee **APPROVED** the Summary of the Private RD&I Sub-Committee minutes from the **17th September 2024**.	
9.0	**MEETING REFLECTIONS**	
	Members to identify items to include in the Highlight / Assurance Report to the Quality, Safety and Performance Committee / Strategic Development Committee in respect of the following areas: • **For Escalation** • **For Assurance** • **For Advising** • **For Information** AW requested a meeting to discuss the items to take forward in the highlight report.	**SMC**
10.0	**ANY OTHER BUSINESS**	
11.0	**DATE AND TIME OF THE NEXT MEETING**	
	The Public Research, Development & Innovation Sub-Committee will next meet on the **12th March 2025 from 2.00 - 4.00pm** at Trust Headquarters, 2 Charnwood Court, Parc Nantgarw, Cardiff.	
12.0	**CLOSE**	
	The Research, Development and Innovation Sub-Committee is asked to adopt the following resolution:	

	That representatives of the press and other members of the public be excluded from the remainder of this meeting having regard to the confidential nature of the business to be transacted, publicity on which would be prejudicial to the public interest in accordance with Section 1(2) Public Bodies (Admission to Meetings) Act 1960 (c.67).	
13.0	**PRIVATE / PART B SESSION**	
	The following item(s) will be discussed at the Private / Part B Session of the Research, Development & Innovation Sub-Committee: • FAKTION Investment Plan • RITA Options Appraisal - Determining the Future of RITA • ARF / ARC Project Briefing Paper • Radiation and Medical Physics MSc (RaMP) Bursary Programme Business Case	

ACTION LOG

MEETING DATE	AGENDA ITEM	Action number	ACTION	LEAD	DEADLINE DATE	UPDATE (including date)	STATUS	IF CLOSED WHAT ACTION WAS TAKEN
10/12/2024	**2.1**		**Minutes of the Last Meeting**					
			Under Item 5.1 RD&I Performance Report - Finance Performance; Concerns raised regarding compliance within the 30-Day Payment Target. Arrange meeting with the R&D team to ensure compliance and improve the overall compliance rate.	**Head of Research & Development**	**11/03/2025**	Update 11/12/2024 An amendment to the minutes were updated as requested.	**CLOSED**	
10/12/2024	**3.0**		**Component Development and Research Laboratory**					
			Circulate an invitation for committee members to visit the CDRL and see the research activities first hand.	**Head of Component Development**	**11/03/2025**	Update 11/12/2024 Email circulated to the RDI Committee, individuals to respond directly to Natasha McLaughlin to arrange a visit.	**CLOSED**	
10/12/2024	**5.1**		**RD&I Performance Report - Rita Options Appraisal**					
			A strategic decision required on the future outcome of the Rita chatbot and the necessary resources to support it. A paper to be presented to a future Executive Management Board.	**Head of Innovation**	**11/03/2025**	Update 05/03/2025 Date to be arranged with the CEO / Innovation Team.	**OPEN**	
10/12/2024	**5.1**		**RD&I Performance Report - Risk Management**					
			Arrange meeting with R&D so that we can align processes for managing risks in accordance with the Trust's risk policy.	**Interim Director of Corporate Governance**	**11/03/2025**	Update 28/02/2025 Following the meeting to discuss the RDI Risk Register - alignment of processes, ST clarified that the RDI risks are managed by the Trust risk management process, and is included in the performance report for the RDI Committee which was agreed at the meeting.	**CLOSED**	Any queries, Mel Findlay will contact Sarah Townsend.
10/12/2024	**6.1**		**R&D Cancer Ambitions Strategy & CCRH Update**					
			Arrange meeting with the finance teams to establish a clear and agreed-upon financial model for managing and distributing income from trials.	**Secretariat**	**11/03/2025**	Update 11/12/2024 Meeting scheduled with the RDI Team / Matt Bunce on 12/12/2024 to discuss the FAKTION Investment Plan and next steps, update to follow.	**CLOSED**	Since the meeting, a draft FAKTION investment plan has been created and is currently being refined following internal and external feedback.
			Following the first meeting of the Joint Academic Health Sciences Strategy (JAHSS), socialise a paper to Executive Management Board.	**Executive Medical Director**	**11/03/2025**	The first meeting of the Joint Academic Health Science Innovation Workshop was scheduled on the 03/03/2025, the purpose and workshop objectives were: •Identify key business outcomes across research, education, and clinical care •Prioritise workstreams that align with JAHS strategic goals •Develop actionable roadmaps for digital transformation initiatives	**CLOSED**	Discussion to take place at a future Executive Management Board.
10/12/2024	**9.0**		**RD&I Highlight Report**					
			Support the development of a draft Highlight Report for approval by the Research, Development & Innovation Sub-Committee Chair.	**Secretariat**	**11/03/2025**	Drafted and submitted to the Quality, Safety & Performance Committee.	**CLOSED**	Submitted on the Consent Agenda - For Noting to the Quality, Safety & Performance Committee 16/01/2025.

RESEARCH, DEVELOPMENT & INNOVATION SUB COMMITTEE

Executive Briefing to RD&I Sub-Committee

DATE OF MEETING	12 March 2025
PUBLIC OR PRIVATE REPORT	Public
IF PRIVATE PLEASE INDICATE REASON	NOT APPLICABLE - PUBLIC REPORT
REPORT PURPOSE	DISCUSSION
IS THIS REPORT GOING TO THE MEETING BY EXCEPTION?	NO
PREPARED BY	Sarah Townsend, Head of R&D Christopher Cotterill-Jones, Research Delivery Manager
PRESENTED BY	Jacinta Abraham, Executive Medical Director
APPROVED BY	Jacinta Abraham, Executive Medical Director
EXECUTIVE SUMMARY	This is the Executive Medical Director's briefing to the RD&I Sub-Committee. This briefing provides a summary and high-level update on the Research, Development, & Innovation activities taking place in Quarter 3 of Financial Year 2024/25, along with noteworthy items from the RD&I environment since the last meeting of the Sub-Committee. This briefing includes summarised updates on the following items:

	• Velindre Cancer Research & Development Strategic Ambitions. • Nursing & Interdisciplinary Research. • Velindre University NHS Trust VPAG submission. • Trust Medical Engagement Event. • Procurement of FLORENCE electronic Investigator Site File system. • Welsh Blood Service: What next for Dr Chloë George and her HSST project? • Innovation: Therapies Operational Lead selected for prestigious Bevan Exemplar Programme.

RECOMMENDATION / ACTIONS	The RD&I Sub-Committee are requested to note for **DISCUSSION** this Executive Medical Director's briefing summarising Research, Development & Innovation activity of Q3, FY2024/25 and noteworthy items occurring since the Sub-Committee's last meeting.

GOVERNANCE ROUTE	
List the Name(s) of Committee / Group who have previously received and considered this report:	**Date**
NOT APPLICABLE – This is the Executive Medical Director's briefing to the RD&I Sub-Committee.	
SUMMARY AND OUTCOME OF PREVIOUS GOVERNANCE DISCUSSIONS NOT APPLICABLE – This is the Executive Medical Director's briefing to the RD&I Sub-Committee.	

7 LEVELS OF ASSURANCE	
NOT APPLICABLE – This is the Executive Medical Director's briefing to the RD&I Sub-Committee.	
ASSURANCE RATING ASSESSED BY BOARD DIRECTOR/SPONSOR	Select Current Level of Assurance

APPENDICES	
None	

1. SITUATION

This is the Executive Medical Director's briefing to the RD&I Sub-Committee. This briefing provides a summary and high-level update on the Research, Development, & Innovation (RD&I) activities taking place in Quarter 3 of Financial Year 2024/25.

Additionally, this briefing includes any important or noteworthy information from the Research, Development, and Innovation environment since the previous RD&I Sub-Committee.

2. BACKGROUND

2.1 Velindre Cancer Research & Development Strategic Ambitions.

In FY2024/25, Q3 the Cardiff Cancer Research Hub (CCRH) Delivery Team notably excelled in the recruitment to the Monumental 6 trial, achieving the highest recruiting site in the UK – reaching the target recruitment ahead of the target deadline. This underscores the Trust's commitment to excel in meeting trial recruitment targets.

Progress continues on establishing the necessary legal and governance frameworks in drawing up a detailed contractual Partnership Agreement with NWSSP lawyers. In parallel, an external supplier has been commissioned to create a professional CCRH website to service as a virtual "front door" for industry and research partners, with a launch of the website planned for March 2025.

Collaborations with CCRH partners continue with:

- Identification of capacity building initiatives such as PhD studentships funded by the Myristica Trust.
- The CCRH's Discovery & Translational Research Group preparation of a large-scale NHS/academic research grant application to become an ATMP focused MRC Centre of Research Excellence.

2.2 Nursing & Interdisciplinary Research.

Nursing and Interdisciplinary care research achievements continues to grow with increasing recognition. This includes:

- **Excellence in Research Nursing:** The CCRH Research Nurse Lead has recently been awarded a Health & Care Research Wales training award. This accolade is a testament to the high standard of leadership and expertise in research nursing at Velindre, highlighting the critical role that research nurses play in driving forward clinical studies and ensuring high-quality patient care.
- **Recognition of Operational and Clinical Leadership:** The Therapies Operational Lead's selection for the prestigious Bevan Exemplar Programme further demonstrates the Trust's commitment to operational excellence and innovative therapeutic management. Such recognition underscores the seamless integration of research and clinical service delivery. Moreover, the Macmillan Lung Cancer Clinical Nurse Specialist has been awarded a PhD Fellowship, reflecting a commitment to continuous professional development and advanced research skills within the nursing workforce.
- **Interdisciplinary Collaborations Enhancing Clinical Outcomes:** The interdisciplinary approach is further strengthened by initiatives such as the work led by Jo Simpson at Velindre Cancer Centre. By tackling antimicrobial resistance, her research addresses one of the key challenges in modern cancer care—ensuring that infection control measures keep pace with evolving treatment modalities. This kind of cross-disciplinary collaboration enhances patient safety and exemplifies the holistic approach needed in today's healthcare landscape.

The recognition and awards achieved promotes a culture of excellence and innovation across the Trust. Their contributions ensure that research is deeply embedded in clinical practice, resulting in improved patient outcomes and a more resilient healthcare system.

2.3 Velindre University NHS Trust VPAG submission.

Velindre University NHS Trust has submitted a research funding request through the Wales Commercial Research delivery Centre (CRDC) Stream 1 VPAG investment programme. The funding is a critical opportunity to improve the Trust's capacity for commercial clinical trials, enhancing infrastructure, workforce, and digital capabilities to support Velindre's ambitions and being a national leader in oncology research.

The VPAG (Voluntary scheme for branded medicines Pricing, Access, and Growth) initiative is a government led programme aimed at increasing commercial research delivery in NHS Wales. The funding is designed to support NHS organisations in expanding their ability to conduct industry-sponsored trials, ensuring that Wales become a highly competitive location for pharmaceutical and biotechnology research and investment.

The VPAG investment is time-limited (5-years), and NHS organisations are expected to demonstrate long-term sustainability beyond the funding period through income generation, increased trial recruitment, and strengthened industry engagement.

Applications submitted from the NHS Wales organisations are currently going through the Welsh Government review process with decisions and funding allocation expected by the end of the financial year.

2.4 Trust Medical Engagement Event – 05 February 2025.

The Trust annual Medical Engagement Event took place on 05 February at Sophia Gardens, Cardiff. The event served as a key platform for medical professionals, researchers, and leadership to celebrate successes, showcasing strategic research direction and clinical trial achievements.

The event provided an opportunity to feature:

- Research successes and their impact on clinical care.
- Discussion of innovations in oncology, radiotherapy, and the Cardiff Cancer Research Hub.
- Enhancing engagement with research amongst the medical workforce.
- Encouraging future leaders in clinical and translational oncology research.

The event enhanced the positioning of research as a core pillar of clinical excellence and helped reinforce Velindre's leadership in NHS research ensuring continued engagement, innovation, and investment in clinical research.

2.5 Procurement of FLORENCE electronic Investigator Site File system.

Velindre University NHS Trust is actively progressing the procurement and implementation of the FLORENCE electronic Investigator Site File (eISF) system as part of a Wales-wide initiative for clinical research. The procurement is initially funded through the Voluntary scheme for branded medicines Pricing, Access, and Growth (VPAG) and aims to modernise clinical trial document management in Wales.

The FLORENCE eISF system is designed to digitise and streamline the management of clinical trial documents, providing secure digital infrastructure for research teams while ensuring compliance with regulatory requirements set by the Medicines and Healthcare products Regulatory Agency (MHRA) and Health Research Authority (HRA).

This also supports the Trust's commitment to digital transformation, aligning to NHS Wales and Trust digital strategies by enhancing capacity, efficiency, and security of clinical research delivery across Wales.

The procurement of FLORENCE is expected to deliver significant benefit to clinical research teams and investigators, improving compliance, operational efficiency and participant safety in clinical trials.

2.6 Welsh Blood Service: What next for Dr Chloë George and her HSST project?

In September 2024, Dr Chloë George successfully qualified as a Consultant Clinical Scientist, becoming the first in transfusion medicine at the Welsh Blood Service (WBS). This marks a significant advancement in the field of transfusion science, reinforcing the Trust's commitment to developing expertise in specialist scientific roles.

Dr George's Higher Specialist Scientist Training (HSST) project focused on platelet metabolism in cold-stored environments, a critical area of research that could transform transfusion medicine by extending shelf-life of platelet products and expanding their clinical applications

This work is crucial as it could enhance the availability of platelet transfusions in emergency and pre-hospital settings, where maintaining an adequate supply of platelets is challenging.

The next step is to evaluate cold-stored pooled platelets using combined platelets from four donors which is the usual process for manufacturing platelet donations.

It is hoped that in the future the WBS will head up a clinical trial to assess the use of cold-stored platelets in the pre-hospital environment in collaboration with the Emergency Medical Retrieval and Transfer Services (EMRTS).

2.7 Innovation: Therapies Operational Lead selected for prestigious Bevan Exemplar Programme

Velindre University NHS Trust is pleased to announce that Therapies Operational Lead Cathryn Lewis has been accepted into the Bevan Commission's prestigious Exemplar Programme. Her project, *Specialist Neuro-Oncology Community Therapy Services: Addressing Inequalities and Gaps in Service Provision*, aims to improve the availability and quality of specialist community-based therapy services for neuro-oncology patients in South-East Wales.

Neuro-oncology patients, particularly those with high-grade brain tumours, often face rapid disease progression and complex care needs. While Velindre's award-winning neuro-oncology therapy clinic supports approximately 150 patients annually during treatment, gaps remain in specialist community therapy services to support these patients at home.

Cathryn's project seeks to bridge this gap. She will map existing services, evaluate best practice guidelines, and gather insights from patients to identify their needs. The ultimate goal is to pilot a specialist occupational therapy and physiotherapy outreach service, starting in the final quarter of the project. This pilot will focus on improving patients' quality of life, maintaining independence, and reducing hospital admissions. Specialist therapists can prevent unnecessary deterioration at home, supporting patients and their carers.

The year-long programme will provide mentorship and resources, with the final project outcomes presented at the Senedd in December 2025.

3. ASSESSMENT

This briefing to the RD&I Sub-Committee summarises and provides an update of the activities of the Trust's Research, Development, and Innovation service for Quarter (Q) 3 of the Financial Year (FY) 2024/25 and other noteworthy items that the Executive Medical Director wishes to highlight to the RD&I Sub-Committee.

4. SUMMARY OF MATTERS FOR CONSIDERATION

The RD&I Sub-Committee is asked to note for **DISCUSSION** the summarised information of the Research, Development, and Innovation service's activity and other noteworthy items reported in this Executive Medical Director's briefing to the RD&I Sub-Committee.

5. IMPACT ASSESSMENT

TRUST STRATEGIC GOAL(S)	
Please indicate whether any of the matters outlined in this report impact the Trust's strategic goals: YES - Select Relevant Goals below	
If yes - please select all relevant goals:	
• Outstanding for quality, safety, and experience	☐
• An internationally renowned provider of exceptional clinical services that always meet, and routinely exceed expectations	☐
• A beacon for research, development, and innovation in our stated areas of priority	☒

• An established 'University' Trust which provides highly valued knowledge for learning for all. ☐ • A sustainable organisation that plays its part in creating a better future for people across the globe ☐	
RELATED STRATEGIC RISK - TRUST ASSURANCE FRAMEWORK (TAF) *For more information: STRATEGIC RISK DESCRIPTIONS*	10 - Governance
QUALITY AND SAFETY IMPLICATIONS / IMPACT	**Select all relevant domains below** Safe ☒ Timely ☐ Effective ☒ Equitable ☒ Efficient ☒ Patient Centred ☒ a) The Executive Medical Director's briefing summarises key Research, Development, and Innovation activities and other noteworthy research related items, demonstrating the Trust being a research supportive organisation. b) The Executive Medical Director's briefing demonstrates the Trust's commitment to undertaking research that is evidence based and appropriate, offering equal opportunities to all patients that is respectful and responsive to their treatment needs. c) The briefing also displays the Trust's dedication to conducting research in a safe and effective manner, making the best use skills and resources available.
SOCIO ECONOMIC DUTY ASSESSMENT COMPLETED: *For more information: https://www.gov.wales/socio-economic-duty-overview*	Not required NOT APPLICABLE – This is the Executive Medical Director's briefing to the RD&I Sub-Committee.

TRUST WELL-BEING GOAL IMPLICATIONS / IMPACT	A Healthier Wales - Physical and mental well-being are maximised and in which choices and behaviours that benefit future health
	If more than one Well-being Goal applies, please list below:
	If more than one wellbeing goal applies, please list below: **Click or tap here to enter text**
FINANCIAL IMPLICATIONS / IMPACT	Yes - please Include further detail below, including funding stream
	There is a potential financial impact in not demonstrating the Trust's commitment to the strategic goal "A beacon for research, development, and innovation in our stated areas of priority" as it could jeopardise the funding received from Health and Care Research Wales along with other non-commercial/commercial sources. No direct financial implications from this paper.
EQUALITY IMPACT ASSESSMENT *For more information:* *https://nhswales365.sharepoint.com/sites/VEL_Intranet/SitePages/E.aspx*	Yes - please outline what, if any, actions were taken as a result
	The Equality Impact of this Executive Briefing has been considered and there are no matters of concern to raise.
ADDITIONAL LEGAL IMPLICATIONS / IMPACT	There are no specific legal implications related to the activity outlined in this report.
	Click or tap here to enter text

6. RISKS

ARE THERE RELATED RISK(S) FOR THIS MATTER	No
WHAT IS THE RISK?	*[Please insert detail here in 3 succinct points].*
WHAT IS THE CURRENT RISK SCORE	Insert Datix current risk score
HOW DO THE RECOMMENDED ACTIONS IN THIS PAPER IMPACT THIS RISK?	*[In this section, explain in no more than 3 succinct points what the impact of this matter is on this risk].*
BY WHEN IS IT EXPECTED THE TARGET RISK LEVEL WILL BE REACHED?	Insert Date
ARE THERE ANY BARRIERS TO IMPLEMENTATION?	**Choose an item**
	[In this section, explain in no more than 3 succinct points what the barriers to implementation are].
All risks must be evidenced and consistent with those recorded in Datix.	

RESEARCH, DEVELOPMENT & INNOVATION SUB COMMITTEE

Research, Development, and Innovation -
Integrated Performance Report FY2024/25 Q3

DATE OF MEETING	12 March 2025
PUBLIC OR PRIVATE REPORT	Public
IF PRIVATE PLEASE INDICATE REASON	NOT APPLICABLE - PUBLIC REPORT
REPORT PURPOSE	DISCUSSION
IS THIS REPORT GOING TO THE MEETING BY EXCEPTION?	NO
PREPARED BY	Sarah Townsend, Head of Research & Development. Christopher Cotterill-Jones, Research Delivery Manager. Kate Cleary, Velindre Cancer R&D Strategy Business Support Manager. Sian James, Welsh Blood Service Head of Research, Development, and Innovation Services. Ross McLeish, Innovation Project Manager. Helen Robertson, RD&I Communications and Engagement Officer.
PRESENTED BY	Sarah Townsend, Head of Research & Development.
APPROVED BY	Jacinta Abraham, Executive Medical Director

EXECUTIVE SUMMARY	Trust Research, Development, & Innovation (RD&I) prepare an integrated performance report at the end of each financial year's quarter. This report summarises and provides an update of the activities of the Trust's Research, Development, and Innovation service during the financial year 2024/25, Q3.

RECOMMENDATION / ACTIONS	The RD&I Sub-Committee are requested to note for **DISCUSSION** the draft RD&I Integrated Performance Report for Financial Year 2024/25, Q3.

GOVERNANCE ROUTE

List the Name(s) of Committee / Group who have previously received and considered this report:	**Date**
RD&I Operational Management Group	28 January 2025
WBS Senior Leadership Team	12 February 2025
VCS Senior Leadership Team	19 February 2025
Executive Management Board	25 February 2025

SUMMARY AND OUTCOME OF PREVIOUS GOVERNANCE DISCUSSIONS

The governance cycle for this RD&I Integrated Performance Report was planned as follows:

Meeting	**Meeting Date**
WBS Senior Leadership Team	12 February 2025.
VCS Senior Leadership Team	19 February 2025.
RD&I Operational Management Group	28 January 2025.
Executive Management Board	25 February 2025.
RD&I Sub-Committee	12 March 2025.

Following the RD&I Operational Management Group, the report was updated to reflect changes to typographical errors, the inclusion of the risk profile and the inclusion of the abbreviation list.

No feedback had been received from WBS Senior Leadership Team, VCS Senior Leadership Team, or Executive Management Board prior to submission.

7 LEVELS OF ASSURANCE	
NOT APPLICABLE	
ASSURANCE RATING ASSESSED BY BOARD DIRECTOR/SPONSOR	**Select Current Level of Assurance**

APPENDICES	
1	Research, Development, and Innovation (RD&I): Integrated Performance Report

1. SITUATION

The RD&I Sub-Committee receives the Trust's RD&I Integrated Performance Report quarterly throughout the financial year.

For Quarters 1 through 3, the report covers the activities of the Trust's Research, Development, and Innovation service in the reported quarter.

For Quarter 4, an annual report incorporating Q1 through Q3 previously reported, plus Q4 activities, is provided covering the activities Trust's Research, Development, and Innovation service for the whole financial year.

2. BACKGROUND

The governance arrangements are that the Trust RD&I Integrated Performance Report is received for information or considered at the following groups and committees:

- Welsh Blood Service Senior Leadership Team.
- Velindre Cancer Centre Senior Leadership Team.
- Research, Development, and Innovation Operational Management Group.
- Executive Management Board.
- Research, Development, and Innovation Sub-Committee.

3. ASSESSMENT

The Trust RD&I Integrated Performance Report summarises and provides an update of the activities of the Trust's Research, Development, and Innovation service for Financial Year (FY) 2024/25, Q3.

The report provides an update of activities against the Trust's Research, Development, and Innovation service's strategic priorities:

- Strategic Priority 1: The Trust will drive forward the implementation of its Cancer Research & Development ambitions.
- Strategic Priority 2: The Trust will maximise the Research & Development ambitions of the Welsh Blood Service.
- Strategic Priority 3: The Trust will implement the Velindre Innovation Plan.
- Strategic Priority 4: The Trust will maximise collaborative opportunities locally, nationally & internationally.

Additionally, the activity of cross-cutting themes and corporate work areas supporting Research, Development and Innovation are reported.

4. SUMMARY OF MATTERS FOR CONSIDERATION

The Executive Management Board are requested to note for **DISCUSSION** the RD&I Integrated Performance Report for Financial Year 2024/25, Q3.

5. IMPACT ASSESSMENT

TRUST STRATEGIC GOAL(S)	
Please indicate whether any of the matters outlined in this report impact the Trust's strategic goals: YES - Select Relevant Goals below	
If yes - please select all relevant goals:	
• Outstanding for quality, safety, and experience	☐
• An internationally renowned provider of exceptional clinical services that always meet, and routinely exceed expectations	☐
• A beacon for research, development, and innovation in our stated areas of priority	☒
• An established 'University' Trust which provides highly valued knowledge for learning for all.	☐
• A sustainable organisation that plays its part in creating a better future for people across the globe	☐

RELATED STRATEGIC RISK - TRUST ASSURANCE FRAMEWORK (TAF) *For more information: STRATEGIC RISK DESCRIPTIONS*	10 - Governance
QUALITY AND SAFETY IMPLICATIONS / IMPACT	Yes -select the relevant domain/domains from the list below. Please select all that apply
	Safe ☒ Timely ☐ Effective ☒ Equitable ☒ Efficient ☒ Patient Centred ☒
	a) The Integrated Performance Report describes the Research, Development, and Innovation activities demonstrating the Trust being a research supportive organisation. b) The Integrated Performance Report demonstrates the Trust's commitment to undertaking research that is evidence based and appropriate, offering equal opportunities to all patients that is respectful and responsive to their treatment needs. c) The report also displays the Trust's dedication to conducting research in a safe and effective manner, making the best use skills and resources available.
SOCIO ECONOMIC DUTY ASSESSMENT COMPLETED: *For more information: https://www.gov.wales/socio-economic-duty-overview*	Not required
TRUST WELL-BEING GOAL IMPLICATIONS / IMPACT	A Healthier Wales - Physical and mental well-being are maximised and in which choices and behaviours that benefit future health

	If more than one Well-being Goal applies, please list below:
	If more than one wellbeing goal applies, please list below:
FINANCIAL IMPLICATIONS / IMPACT	Yes - please Include further detail below, including funding stream
	There is a potential financial impact in not demonstrating the Trust's commitment to the strategic goal "A beacon for research, development, and innovation in our stated areas of priority" as it could jeopardise the funding received from Health and Care Research Wales along with other non-commercial/commercial sources. No direct financial implications from this paper.
EQUALITY IMPACT ASSESSMENT *For more information:* *https://nhswales365.sharepoint.com/sites/VEL_Intranet/SitePages/E.aspx*	Yes - please outline what, if any, actions were taken as a result
	The Equality Impact of Trust RD&I Integrated Performance Report for FY2024/25, Q3 has been considered and there are no matters of concern to raise.
ADDITIONAL LEGAL IMPLICATIONS / IMPACT	There are no specific legal implications related to the activity outlined in this report.
	Click or tap here to enter text

6. RISKS

ARE THERE RELATED RISK(S) FOR THIS MATTER	No
WHAT IS THE RISK?	NOT APPLICABLE

WHAT IS THE CURRENT RISK SCORE	Insert Datix current risk score
HOW DO THE RECOMMENDED ACTIONS IN THIS PAPER IMPACT THIS RISK?	*[In this section, explain in no more than 3 succinct points what the impact of this matter is on this risk].*
BY WHEN IS IT EXPECTED THE TARGET RISK LEVEL WILL BE REACHED?	Insert Date
ARE THERE ANY BARRIERS TO IMPLEMENTATION?	**Choose an item**
	[In this section, explain in no more than 3 succinct points what the barriers to implementation are].
All risks must be evidenced and consistent with those recorded in Datix.	

APPENDIX 1. **Trust Research, Development, & Innovation (RD&I) Integrated Performance Report FY2024/25, Q3.**

GIG CYMRU NHS WALES
Ymddiriedolaeth GIG Prifysgol Felindre
Velindre University NHS Trust

2024/25

Q3

October 2024 to December 2024

Welsh Blood Service
Gwasanaeth Gwaed Cymru

Canolfan Ganser Felindre
Velindre Cancer Centre

Research, Development & Innovation

Integrated Performance Report

Velindre University NHS Trust
Research & Development
Velindre Cancer Centre
Velindre Road, Whitchurch
Cardiff, CF14 2TL

E-bost/Email: Velindre.R&DOffice@wales.nhs.uk
Ffôn/Tel: 029 2061 5888

Contents.

Abbreviations.

Abbreviation	Definition
ARC	Advancing Radiotherapy Cymru
ATMP	Advanced Therapy Medicinal Product
BAU	Business As Usual
BEST	Biomedical Excellence for Safer Transfusion
BICCC	Brief Intervention with Cyclophosphamide in Colorectal Cancer
BSI	British Standards Institution
C	Commercial
CAR-T	Chimeric Antigen Receptor T-cell
CCfLRI	Collaborative Centre for Learning, Research, and Innovation
CCRH	Cardiff Cancer Research Hub
CPO	Carbapenemase-Producing Organisms
CVUHB	Cardiff and Vale University Health Board
DEHP	Di (2 ethylhexyl) phthalate
DNA	Deoxyribonucleic acid
ECMC	Experimental Cancer Medicine Centres
EMA	European Medicines Agency
EMB	Executive Management Board
EMRTS	Emergency Medical Retrieval and Transfer Services
ESR	Electronic Staff Record
FDA	Food and Drug Administration (United States)
FY	Financial Year
HCRW	Health and Care Research Wales
HER	Human Epidermal growth factor Receptor
HSST	Higher Specialist Scientist Training
IMTP	Integrated Medium-Term Plan
ISO	International Organization for Standardisation
IV	Intravenous
KPI	Key Performance Indicators
MDT	Multi-Disciplinary Team
MHRA	Medicines and Healthcare products Regulatory Agency (United Kingdom)
MPM	Malignant Pleural Mesothelioma
MRC	Medical Research Council
mRNA	Messenger Ribonucleic acid
NC	Non-commercial
NHS	National Health Service
NIHR	National Institute for Health and Care Research
PhD	Doctor of Philosophy
Q	Quarter
QA	Quality Assurance
RAG	Red, Amber, Green
RD&I	Research, Development, Innovation
RIC	Regional Innovation and Communication
SACT	Systemic Anti-Cancer Therapy
SBRI	Small Business Research Initiative
SC	Sub-cutaneous

Abbreviation	Definition
TILs	Tumour Infiltrating Lymphocytes
UCL	University College London
UK	United Kingdom
USA	United States of America
VCC	Velindre Cancer Centre
VCS	Velindre Cancer Service
VEGF	Vascular endothelial growth factor
VUNHST	Velindre University NHS Trust
WBS	Welsh Blood Service
WCRC	Wales Cancer Research Centre
WG	Welsh Government
WGS	Whole Genome Sequencing
YTD	Year To Date

INTRODUCTION

The Trust Research, Development, and Innovation (RD&I) Integrated Performance Report summarises and provides an update of activities of the Trust's RD&I service for each quarter of the financial year.

The report reflects the RD&I strategic priorities published in the Velindre University NHS Trust's Integrated Medium-Term Plan (IMTP). These priorities support the Trust's strategic goal to be *"A beacon for research, development and innovation"* are as follows:

STRATEGIC PRIORTIES	
PRIORTIY 1	The Trust will drive forward the implementation of its Cancer Research and Development Ambitions 2022-2031.
PRIORITY 2	The Trust will maximise the Research and Development ambitions of the Welsh Blood Service.
PRIORITY 3	The Trust will implement the Velindre Innovation Plan.
PRIORITY 4	The Trust will maximise collaborative opportunities locally, nationally, and internationally.

The report provides an update of activities against the Trust RD&I service's strategic priorities, alongside the supporting work of cross-cutting themes and corporate functions that support research, development, and innovation.

The reports for quarters one through three summarise the work in that quarter, culminating in an annual report at the end of the financial year.

STRATEGIC PRIORITY 1

The Trust will drive forward the implementation of its Cancer Research and Development Ambitions.

1 Velindre Cancer Research & Development Strategic Ambitions.

1.1 Advance new treatments, interventions, and care.

From the Overarching Cancer Research and Development Ambitions Strategy 2021-31, **we said we would**: *'Advance new treatments, interventions and care'.*

And **we have:**

Achieved key milestones for the Cardiff Cancer Research Hub (CCRH)

The Cardiff Cancer Research Hub will bring bolder, more innovative approaches to solid tumour and haematology research to Wales. In the last quarter we have:

	The CCRH team have been doing excellent recruiting work on Monumental 6 and are the highest recruiter in the UK. They have also hit the recruitment target before the target deadline.
	The work to establish a legal and governance framework is progressing well. Following the approval of the Heads of Terms, a high-level partnership model has been agreed by all three partner organisations. A detailed, contractual Partnership Agreement is now being developed with NWSSP lawyers.
	An external supplier has been appointed to start work on a CCRH website with the aim to be live by March 2025. This will be a virtual front door, presenting our work in a professional and compelling manner to the pharmaceutical and other life sciences companies that are looking for partners to conduct cancer research, and to attract funders of cancer research.
	The CCRH is collaborating with other parts of Cardiff University to establish new collaborations and capacity building opportunities for Velindre clinicians (e.g. PhD studentships from the Myristica Trust are being made available to Velindre and CVUHB staff with the help of the CCRH).
	CCRH's Discovery & Translational Research Group is developing its first large, NHS/academic research grant, applying to become an ATMP-focused MRC Centre of Research Excellence. This has been approved as the sole bid representing Cardiff University, and involves CCRH, WCRC, ECMC and others. An initial bid is to be submitted to the MRC in February.
	**Trial portfolio overview:**

Stage	Study Name	Study Type	Funding	Cancer Type
Open to recruitment	MORAb-202	First in Human	Commercial	Solid - multi
	Monumental-6	Bi-specific	Commercial	Haem

	Trials in set up	IOV-MEL-301	TILS - ATMP	Commercial	Solid - Melanoma
		ATTR 01	Oncolytic virus vaccine - ATMP	Commercial	Solid Melanoma
	Closed	SOTIO	ATMP CAR-T Therapy	Commercial	Solid - multi

1.2 BioNTech vaccine trials within the CCRH trial portfolio.

We have also:

Continued to open BioNTech vaccine trials within the CCRH trial portfolio.

BioNTech trial portfolio overview:

Stage	Study Name	Study Type	Funding	Cancer Type
Open to recruitment	BNT327 -01	Anti-VEGF-A antibody candidate fused to a humanized anti-PD-L1 VHH being developed in collaboration with Biotheus	Commercial	Solid - Lung
	BNT113	ATMP mRNA vaccine	Commercial	H&N
Trials in set up	BNT116	First in Human - ATMP - BNT116 mRNA cancer vaccine	Commercial	Solid - Lung
	BNT 327-03	Next generation immune checkpoint modulators	Commercial	NSCLC 1L
	BNT327 -06	Next generation immune checkpoint modulators	Commercial	Solid - Lung
	DB-1303	Antibody drug conjugate	Commercial	Breast

2 Nursing & Interdisciplinary Research.

2.1 CCRH Research Nurse Lead awarded Health & Care Research Wales training award.

CCRH Research Nurse Lead awarded Health & Care Research Wales training award.

Kate Gilmour, Research Nurse Team Lead at the Cardiff Cancer Research Hub, has been awarded a Health and Care Research Wales Training Award. The funding will support Kate as she studies for a Master of Research (MRes) in Health Research at the University of Stirling, furthering her contributions to nurse-led research and patient care.

Kate's journey to this achievement is inspiring. After a career in social work, she retrained as a registered nurse and joined Velindre Cancer Centre three years ago. She began as a Systemic Anti-Cancer Therapy (SACT) nurse before transitioning to her current role with the Cardiff Cancer Research Hub (CCRH)—a partnership between Velindre, Cardiff University, and Cardiff and Vale University Health Board.

Promoted to Research Nurse Team Lead in May 2024, Kate's studies at Stirling will deepen her expertise in research methods, study design, and ethics. "I'm excited about how research can be adapted to Velindre to benefit patient care and our communities," Kate said.

Supported by Claire Lang, Senior Research Nurse Manager, and Sarah Townsend, Head of Research and Development, Kate's ambition is to advance nurse-led research and inspire others in her team to embrace innovation.

Professor Monica Busse, Faculty Director for Health and Care Research Wales, celebrated Kate and her fellow award recipients, stating, "We are committed to supporting researchers at all stages to advance their careers and make meaningful contributions."

Congratulations, Kate, on this well-deserved recognition!

2.2 Therapies Operational Lead selected for prestigious Bevan Exemplar Programme

Therapies Operational Lead selected for prestigious Bevan Exemplar Programme

Velindre University NHS Trust is pleased to announce that Therapies Operational Lead Cathryn Lewis has been accepted into the Bevan Commission's prestigious Exemplar Programme. Her project, *Specialist Neuro-Oncology Community Therapy Services: Addressing Inequalities and Gaps in Service Provision*, aims to improve the availability and quality of specialist community-based therapy services for neuro-oncology patients in South-East Wales.

Neuro-oncology patients, particularly those with high-grade brain tumours, often face rapid disease progression and complex care needs. While Velindre's award-winning neuro-oncology therapy clinic supports approximately 150 patients annually during treatment, gaps remain in specialist community therapy services to support these patients at home.

Cathryn's project seeks to bridge this gap. She will map existing services, evaluate best practice guidelines, and gather insights from patients to identify their needs. The ultimate goal is to pilot a specialist occupational therapy and physiotherapy outreach service, starting in the final quarter of the project. This pilot will focus on improving patients' quality of life, maintaining independence, and reducing hospital admissions. Specialist therapists can prevent unnecessary deterioration at home, supporting patients and their carers.

"This project is all about making a difference for patients with a devastating disease," Cathryn explained.

Kate Baker, Head of Therapies, praised Cathryn's commitment: "This initiative aligns strongly with Prudent Healthcare principles and has the potential to transform care for neuro-oncology patients."

The year-long programme will provide mentorship and resources, with the final project outcomes presented at the Senedd in December 2025.

Congratulations, Cathryn, on this well-deserved selection!

2.3 Macmillan Lung Cancer Clinical Nurse Specialist awarded PhD Fellowship.

Macmillan Lung Cancer Clinical Nurse Specialist awarded PhD Fellowship.

Alison Edwards, a Macmillan Lung Cancer Clinical Nurse Specialist, has been awarded a PhD Fellowship by Velindre Healthcare Cancer Research. Her groundbreaking research will explore the exercise needs of advanced lung cancer patients receiving immunotherapy or targeted treatments, as improvements in care allow them to live longer.

"I have a strong research background and have wanted to do a PhD for a long time. It has taken me time to find an area of interest from my clinical practice but now I have, I'm very excited to get started," Alison shared.

Recent advances shows exercise is safe for lung cancer patients and has many benefits including improvements in quality of life and symptoms such as fatigue and breathlessness.

"Treatments available for advanced stage lung cancer have grown rapidly in the past five years, resulting in patients living longer and being on these treatments for many months or years," Alison said, "In my role as a Macmillan Lung Cancer Clinical Nurse Specialist, I am working with increasing numbers of patients who are in this subgroup described as survivors of lung cancer, who talk about struggling to adapt to this 'new normal'."

Alison's study aims to find out about the needs of patients with advanced lung cancer around exercise, its role in their care and how best to provide information and support about exercise. By incorporating surveys, interviews, and group discussions, she aims to ensure patients' voices shape the development of services.

The Fellowship provides Alison with dedicated research time to make a lasting impact. Well-done, Alison!

2.4 Jo Simpson tackles antimicrobial resistance at Velindre Cancer Centre.

Jo Simpson tackles antimicrobial resistance at Velindre Cancer Centre.

Jo Simpson, an accomplished nurse at Velindre Cancer Centre, is embarking on an exciting new chapter as a Velindre Healthcare Research Fellow. Jo's one-year research project aims to improve screening compliance for Carbapenemase-Producing Organisms (CPOs)—a vital step in combating antimicrobial resistance.

CPOs are gut bacteria resistant to carbapenems, often referred to as the last line of antibiotic defence. These bacteria pose significant risks in hospital settings, particularly for vulnerable, immunocompromised patients. With patients sharing facilities on wards, the spread of CPOs can lead to infections that are challenging to treat.

Jo, who transitioned from Children's Nursing to Infection Prevention and Control in the past 18 months, is tackling this issue head-on. Her weekly audits reveal that CPO screening compliance is often around 50% or lower, falling short of the goal to screen patients within 48 hours of admission.

By exploring barriers to compliance and utilizing behaviour change research, Jo aims to develop sustainable solutions. She is working closely with the Velindre Healthcare Cancer Research team, including mentor Nick Courtier and Hayley Harrison Jeffreys, Head of Infection Prevention and Control.

"This research is key to improving early detection and ensuring patient safety," said Jo.

Congratulations, Jo, on this vital work advancing patient care and fighting antimicrobial resistance!

3 Velindre Cancer Service Research.

3.1 The APPROACH trial – First Welsh patient benefits from Proton Beam Therapy clinical trial.

Bethan Thomas is the first patient in Wales to take part in a PBT brain tumour clinical trial.

The APPROACH trial – First Welsh patient benefits from Proton Beam Therapy clinical trial.

A Velindre Cancer Centre patient has become the first from Wales to participate in the APPROACH clinical trial, which is investigating the potential benefits of proton beam therapy for brain tumours. Led by researchers at the University of Leeds, the trial focuses on patients with oligodendroglioma, a type of brain tumour.

Bethan Thomas, who joined the trial, shared her experience: "Being part of the trial meant even if I was randomised to receive radiotherapy, I would be closely monitored with regular visits with the consultant and regular scans for five years.Proton beam therapy isn't widely available to everybody, and it certainly isn't available in Wales so to have the potential to take part in the trial and have the best treatment, it was a bit of a no brainer for me!"

Standard radiotherapy for oligodendroglioma can cause long-term side effects, including memory issues and difficulties processing information. Proton beam therapy, an advanced form of radiotherapy, targets tumours more precisely, sparing healthy brain tissue and potentially reducing side effects.

The trial randomises patients into two groups: one receiving standard radiotherapy with chemotherapy, and the other receiving proton beam therapy with chemotherapy. Researchers, including Velindre co-investigator Dr James Powell, will evaluate side effects, quality of life, and survival rates over five years.

"This innovative trial has the potential to significantly improve care for patients with this type of brain tumour," said Dr Powell. Funded by the National Institute for Health and Care Research (NIHR) and Medical Research Council (MRC), the APPROACH trial represents an exciting step forward in advancing cancer care.

Velindre is also involved in the HIT-Meso trial, exploring proton beam therapy for lung cancer, further demonstrating its commitment to cutting-edge research.

3.2 Velindre leads the recruitment of the first UK patients into the Cardiff-led BICCC study.

Professor Rob Jones, Consultant in Medical Oncology. Velindre University NHS Trust.

Professor Andy Godkin, Chief Investigator from Cardiff University and CVUHB.

Velindre leads the recruitment of the first UK patients into the Cardiff-led BICCC study.

Velindre Cancer Centre has become the first site in the UK to recruit patients to the Cardiff-led BICCC study, a clinical trial investigating a novel approach to improving disease-free survival for colorectal cancer patients.

Colorectal cancer is one of the leading causes of cancer-related deaths worldwide. In the early stages of the disease, many patients can be cured with surgery. However, in the later stages, the cancer can return or progress even after surgery and chemotherapy. One potential way of preventing relapse is by making the patient's immune system better at detecting and destroying any cancer cells that might remain after removal of the cancer.

The Brief Intervention with Cyclophosphamide in Colorectal Cancer (BICCC) trial aims to test whether a low dose of cyclophosphamide—a chemotherapy drug—can enhance the immune system's ability to detect and destroy any remaining cancer cells after surgery and chemotherapy. The study focuses on stage 2–4 colorectal cancer patients and is being conducted across 10 UK sites, including Cardiff and Swansea.

Participants are randomly assigned to either standard care (active monitoring) or a four-week cyclophosphamide treatment spread over nine weeks. The primary goal is to assess whether the drug improves disease-free survival by kick-starting T cell activity against cancer cells. Recruited participants will be seen or sometimes phoned, five times over the course of 13 weeks for monitoring and receive their randomised treatment in the form of a tablet they take at home, with three years follow up.

Professor Rob Jones, Consultant in Medical Oncology and Associate Medical Director for RD&I at Velindre said, ""We have recruited five patients to this new Cardiff-led study, the first UK site to recruit. It has been great working with Professor Andy Godkin in the past and we hope this trial will be equally as successful as our previous collaboration. Patients in the previous study tolerated treatment very well with minimal side effects. Hopefully, this trial will demonstrate a brief intervention following definitive standard treatment will lead to additional patients who are cured."

Professor Andy Godkin, Chief Investigator from Cardiff University and Cardiff & Vale University Health Board, added ""It has been a fairly-long campaign to get this trial of the ground, and thanks to everyone for their patience, and for Cancer Research Wales for sticking with it. Velindre hospital has led the way, being the first of ten centres to open, and having already recruited several patients. Heartfelt thanks to Rob Jones and all the staff at Velindre, and of course, the patients."

The study is funded by Cancer Research Wales and represents an important step forward in colorectal cancer care.

3.3 Velindre University NHS Trust's research on show.

Velindre Involved in Two Highly Commended Projects at MediWales Innovation Awards 2024.

Two initiatives involving Velindre University NHS Trust were Highly Commended at the MediWales Innovation Awards 2024.

The BioNTech All Wales Research Collaboration was recognized as a runner-up in the Health and Social Care Research Partnership Award with Industry. This partnership with BioNTech, the global leader behind the first approved mRNA COVID-19 vaccine, has significantly enhanced Wales' ability to support cancer clinical trials. By recruiting clinicians, nurses, pharmacists, radiographers, and pathologists, the collaboration ensures equitable access to cutting-edge cancer treatments across the nation.

Additionally, Swansea-based medical device company Haemair's collaboration with the Welsh Blood Service was runner-up in the Partnership with the NHS Award. Together, they tested an innovative device designed to reduce harmful compounds like potassium and free iron in stored red cell components, helping to ensure safer blood transfusions.

These commendations highlight Velindre's commitment to advancing healthcare innovation through collaboration.

Velindre University NHS Trust's attends Health and Care Research Wales conference.

Our research was on show at the Health and Care Research Wales conference on 10 October 2024 at Sophia Gardens in Cardiff. This year we showcased two pieces of research that are important to the Trust to a steady stream of visitors - Welsh Blood Services research into cold-storing pre-hospital platelets and the breast cancer clinical trial FAKTION.

Visitors to our stand were able to see the difference between healthy platelets and 'bad' platelets that could no longer be used for transfusion as we explained the impact of the ability to store platelets on emergency vehicles for use in major trauma situations. You can find out more about this research on the Welsh Blood Service website [https://welsh-blood.org.uk/research-development-and-innovation-2/] .

FAKTION display chronicled the life cycle of the trial and how it progressed from a Phase 1 trial at Velindre to a drug treatment called Truqap getting FDA, EMA and MHRA approval for use in women with oestrogen receptor-positive, HER2-negative breast cancer. You can read more of the story on the Trust website [https://velindre.nhs.wales/news/latest-news/fda-approval-for-breast-cancer-drug-treatment-developed-at-velindre/].

Thanks to everyone who dropped by on the day including Trust Chair Donna Mead, the WBS research team who 'manufactured' the demonstration platelets (don't worry, they're not real……), and the WBS donor engagement team for the giveaways!

3.4 Velindre University NHS Trust Researchers publish in Clinical Oncology.

Dr Annabel Borley (top),
Dr Sophie Harding (bottom)

Velindre University NHS Trust Researchers publish in Clinical Oncology.

The Trust celebrates the publication of a study in the prestigious *Clinical Oncology* journal. Led by Dr Annabel Borley and Dr Sophie Harding, the research focuses on the successful implementation of a fixed-dose subcutaneous (SC) injection for treating HER2-positive breast cancer, transforming patient care and service efficiency.

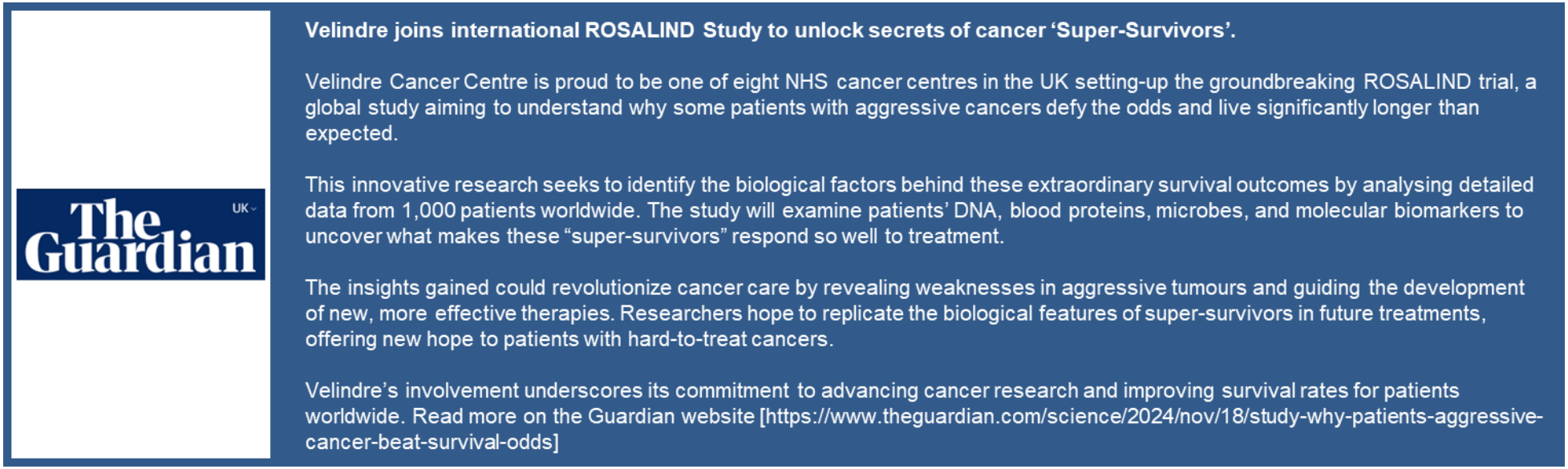
The study, titled *Switching to a Fixed-dose Combined Pertuzumab and Trastuzumab With Recombinant Human Hyaluronidase Subcutaneous Injection to Treat Human Epidermal Growth Factor Receptor 2-positive Breast Cancer in Real-world UK Clinical Practice*, highlights the significant benefits of switching from intravenous (IV) infusions to SC injections.

The project, initiated during the COVID-19 pandemic, reduced patient hospital visit times and minimized the risk of virus exposure while improving their overall treatment experience. Within just four weeks, 99% of eligible patients (97 out of 98) transitioned to the SC method.
From April 2021 to September 2022, the switch saved 3,062 hours in pharmacy preparation and 6,764 hours of patient chair time. This initiative also alleviated pharmacy workload pressures, enhancing operational efficiency.

Dr. Harding stated, “Great to see this collaborative project finally published to demonstrate the novel collaborative implementation approach we used to provide new SACT treatments for our patients at Velindre Cancer Centre. This approach can now be used to share best practice both within Wales and internationally to benefit the delivery of future oncology services for all patients”

Well-done to Dr Borley, Dr Harding, and the entire team on this publication!

3.5 Velindre joins international ROSALIND Study to unlock secrets of cancer 'Super-Survivors'.



Velindre joins international ROSALIND Study to unlock secrets of cancer 'Super-Survivors'.

Velindre Cancer Centre is proud to be one of eight NHS cancer centres in the UK setting-up the groundbreaking ROSALIND trial, a global study aiming to understand why some patients with aggressive cancers defy the odds and live significantly longer than expected.

This innovative research seeks to identify the biological factors behind these extraordinary survival outcomes by analysing detailed data from 1,000 patients worldwide. The study will examine patients' DNA, blood proteins, microbes, and molecular biomarkers to uncover what makes these "super-survivors" respond so well to treatment.

The insights gained could revolutionize cancer care by revealing weaknesses in aggressive tumours and guiding the development of new, more effective therapies. Researchers hope to replicate the biological features of super-survivors in future treatments, offering new hope to patients with hard-to-treat cancers.

Velindre's involvement underscores its commitment to advancing cancer research and improving survival rates for patients worldwide. Read more on the Guardian website [https://www.theguardian.com/science/2024/nov/18/study-why-patients-aggressive-cancer-beat-survival-odds]

3.6 Velindre leads the way in Mesothelioma research with the HIT Meso clinical trial.

Dr Paul Shaw, patient Haydn Povey and Senior Research Radiographer Emily Harris

Velindre leads the way in Mesothelioma research with HIT Meso clinical trial.

As part of Lung Cancer Awareness Month, Velindre Cancer Centre proudly highlights its role in the groundbreaking HIT Meso clinical trial, a Phase 3 study exploring the use of proton beam therapy to treat pleural mesothelioma. This incurable form of lung cancer affects the membrane surrounding the lungs, often caused by asbestos exposure in industries like shipbuilding, construction, and steel production.

Dr. Paul Shaw, Consultant Clinical Oncologist, explained the significance of the trial: “Malignant Pleural Mesothelioma (MPM) is a devastating and life limiting illness which impacts thousands of people and their families each year in the UK.”

The trial, sponsored by University College London and funded by Asthma + Lung UK, aims to determine whether proton beam therapy can become a new standard of care for patients with MPM, offering improved survival and quality of life.

Velindre recently recruited its first Welsh patient, Haydn Povey, who joined the trial with optimism: “My thinking is that I’ve got nothing to lose with this trial. This is the way people are going to find out the answers and if it helps people in the future then it’s worth it.”

Dr. Shaw emphasized, “If successful, proton beam therapy could become an upfront treatment option for patients with MPM. For certain patients, this might provide a new standard of care treatment that not only extends life but also enhance the quality of life for people living with this condition.

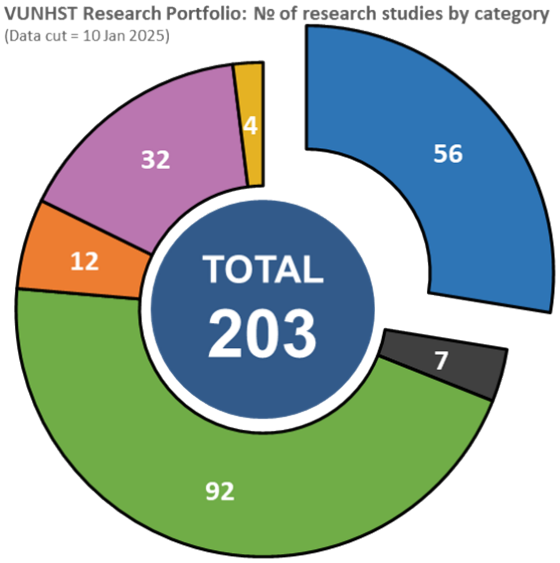
“Having alternative treatment options is especially important for patients of increasing age and co-morbidities, where SACT is often a high-risk option.

“Velindre has driven the design of this study from inception, and we have recently recruited the first Welsh patient,”

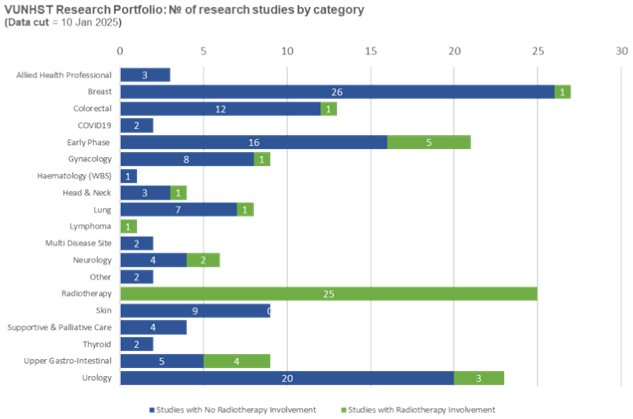
To be eligible for this trial, patients with MPM need to be suitable for active surveillance in advance of future SACT and will be randomised to one of two arms, active monitoring or immediate proton beam therapy over five weeks at UCL.

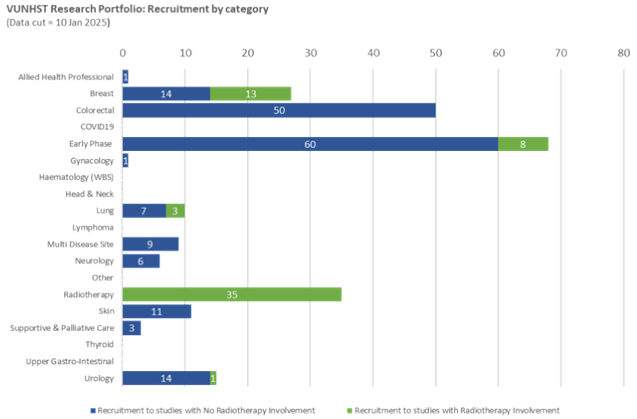
4 Velindre Research Performance Indicators.

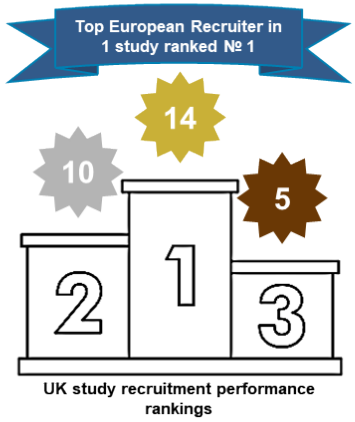
VUNHST Research Portfolio Dashboard



	Active (studies requiring participant consent)
	Active (support service or data collection only studies)
	Closed to recruitment, in follow up
	Closed to recruitment, no follow up
	In set-up
	Suspended







№ of studies opened

		CUMULATIVE	Quarter 1	Quarter 2	Quarter 3	Quarter 4
2024/25		22	7	4	11	-
	NC	12	6	2	4	-
	C	10	1	2	7	-
2023/24		31	7	9	7	8
	NC	17	3	4	3	7
	C	14	4	5	4	1
2022/23		35	5	9	6	15
	NC	19	2	6	3	8
	C	16	3	3	3	7

№ of participants recruited

		CUMULATIVE	Quarter 1	Quarter 2	Quarter 3	Quarter 4
2024/25		235	88	88	59	-
	NC	153	55	57	41	-
	C	82	33	31	18	-
2023/24		432	77	151	113	91
	NC	358	64	128	97	69
	C	74	13	23	16	22
2022/23		220	65	46	61	48
	NC	176	51	36	51	38
	C	44	14	10	10	10

Key: NC = Non-Commercial; C = Commercial

5 Health & Care Research Wales key indicators for Velindre University NHS Trust.

Health & Care Research Wales calculate the percentage of open studies recruiting to time and target as Red, Amber, Green (RAG).

The RAG rating is calculated as follows:

RAG rating = % recruitment - % time elapsed

Where $\%\ \boldsymbol{recruitment} = \frac{Total\ recruitment\ (at\ site)}{Site\ recruitment\ target}$

and $\%\ \boldsymbol{time\ elapsed} = \frac{Number\ of\ days\ open\ (at\ site)}{Number\ of\ days\ planned\ to\ be\ open}$

"RED"	=	% recruitment is 30% behind the % time elapsed (i.e. RAG rating = -30% or less).
"AMBER"	=	% recruitment is up to and including 30% behind % time elapsed (i.e. RAG rating = < -1% ≥ -29%).
"GREEN"	=	% recruitment is equal to or is greater than % time elapsed (i.e. RAG rating = ≥ 0%).

Health & Care Research Wales calculate the percentage of closed studies recruiting to target as Red, Green. Where, "Red" indicates the recruitment target was not met and "Green" indicates the recruitment target was met.

5.1 Open studies – recruitment to time and target (non-commercial).

	RAG	Rating	Comparison to previous Q	Comparison to previous FY	Narrative for RAG rating = "RED"
C3 Open: % of Open non-commercial HCRW Portfolio Studies Recruiting to Time & Target	R	47% 17 studies			The studies that are hosted by VUNHST are often of small number recruitment targets or long study duration. Therefore, it is possible for studies to be RAG rated "RED" for several years or fluctuate in RAG rating for the duration of the study. **List of studies with RAG rating = "RED"** • ACTOv [IRAS 1003954], target = 10; planned study end date = 01 Apr 2028. • ADAPT-P [IRAS 319805], target = 17; planned study end date = 01 Sept 2024 • APPROACH [IRAS 306432], target = 22; planned study end date = 05 Jan 2028 • BICCC [IRAS1004377], target = 50; planned study end date = 03 Jun 2025 • Cancer Vaccine Launchpad [IRAS 325291], target = 1; planned study end date = no end date • DETERMINE [IRAS 325291], target = 1; planned study end date = no end date • DOMENICA [IRAS 1006901], target = 20; planned study end date = 01 Apr 2026 • FAIM [IRAS 284870], target = 14; planned study end date = 30 Dec 2025 • HEPTARES [IRAS 1006164], target = 12; planned study end date = 30 Jun 2026 • Predicting cancer evolution in breast cancer (version 1) [310553]. Target = 20; planned study end date = 01 Oct 2025 • Rad-IO [IRAS 251669], target = 10; planned study end date = 03/06/2025 • **REFINE-Lung** [IRAS 1004165], target = 24; planned study end date = 01 Dec 2025. • **The role of the marrow macroenvironment in the pathogenesis of AML** [IRAS 231974], target = 50; planned study end date = 30 Nov 2024. *Study currently suspended.* • **TRAK-ER** [IRAS 286505], target = 20; planned study end date = 01 May 2024.
	A	11% 4 studies			
	G	42% 15 studies			

	RAG	Rating	Comparison to previous Q	Comparison to previous FY	Narrative for RAG rating = "RED"
					• **UKP3BEP Trial** [IRAS 182633], target = 5; planned study end date = 30 Nov 2024. • **342158** • **VISON** [IRAS 335269], target = 100; planned study end date = 30 Nov 2026

5.2 Open studies – recruitment to time and target (commercial).

	RAG	Rating	Comparison to previous Q	Comparison to previous FY	Narrative for RAG rating = "RED"
C4 Open: % of Open Commercial Studies Recruiting to Time & Target	R	43% 6 studies	↑	↑	The studies that are hosted by VUNHST are often of small number recruitment targets or long study duration. Therefore, it is possible for studies to be RAG rated "RED" for several years or fluctuate in RAG rating for the duration of the study. **<u>List of studies with RAG rating = "RED"</u>** • BO45217 (Krascendo 1) [IRAS 1009611], target = 3; planned study end date = 30/09/2025. • D6900C00001 (BlueStar) (AZD8205) [IRAS 1007820], target = 12; planned study end date = 31/03/2026 • MORAb-202-G000-201 [IRAS 292422], target = 2; planned study end date = 31/12/2024. • BNT327-01 [IRAS 1010045], target = 1; planned study end date = 31/03/2025 • **Tropion 04** [IRAS 1008502], target = 7; planned study end date =. 03/03/2026 • **Tropion 05** [IRAS 1007219], target = 3; planned study end date = 06/02/2025.
	A	7% 1 study	↓	↓	
	G	50% 7 studies	↓	↑	

5.3 Closed studies – recruitment to time and target (non-commercial).

	RAG	Rating	Comparison to previous Q	Comparison to previous FY	Narrative for RAG rating = "RED"
C3 Closed: % of Closed non-commercial HCRW Portfolio Studies Recruiting to Target	R	8% 1 study	↑	⇔	**List of studies with RAG rating = "RED"** • RANGO [IRAS 199009], target = 15; planned study end date = 01/03/2027. Note: We recruited 2 patients. The trial opened to recruitment December 2019. The Sponsor made the decision to pause recruitment during to the COVID19 pandemic in March 2020. Recruitment reopened in March 2022. The Sponsor then closed the trial to recruitment May 2023.
	G	92% 10 studies	↓	⇔	

5.4 Closed studies – recruitment to time and target (commercial).

	RAG	Rating	Comparison to previous Q	Comparison to previous FY	Narrative for RAG rating = "RED"
C4 Closed: % of Closed Commercial Studies Recruiting to Target	R	57% 8 studies	↓	↓	**List of studies with RAG rating = "RED"** • **Avanzar** [IRAS 1006036], target = 8; planned study end date = 30/11/2024**. Note:** Recruitment closed a year earlier than planned • **CAPItello-280** [IRAS 1005000], target = 2; planned study end date = 09/02/2025**. Note:** Recruitment closed a year earlier than planned. • **XB002 101 JEWEL** [IRAS 1005594], target = 5; planned study end date = 30/11/2025**. Note:** Recruitment was paused nationally due to safety concerns. The trial was only open for less than a week at Velindre. • **FIGHT-302** [IRAS255226], target =1 ; planned study end date =13/09/2024**. Note:** Recruitment was paused during the COVID 19 pandemic and never reopened. • **1403-0002 A study of a combination of BI drugs in Patients with Cancer** [IRAS 1005475], target = 3; planned study end date = 30 May 2026. **Note:** Velindre were only able to perform ultrasound biopsies due to capacity issues within the Cardiff and Vale Radiology Department. This had an impact on the number of patients we could recruit. • **CANC 48153** [IRAS 292846], target = 10; planned study end date = 01 Apr 2025**. Note:** Recruitment closed a year earlier than planned
	G	43% 6 studies	↑	↑	

	RAG	Rating	Comparison to previous Q	Comparison to previous FY	Narrative for RAG rating = “RED”
					• **MK1308A-008** 1003758, target = 7; planned study end date = 24 Oct 2024. **Note:** The Sponsor put recruitment on hold nationally in 2022 and the study never reopened to recruitment. This impacted our targets. Velindre is one of the top UK recruiters. • **MK3475-U03** [IRAS 1003378], target = 3; planned study end date = 21 May 2024. **Note:** The Sponsor put recruitment on hold nationally for a year which impacted our recruitment targets.

STRATEGIC PRIORITY 2

The Trust will maximise the Research & Development ambitions of the Welsh Blood Service.

6 Welsh Blood Service Research.

6.1 The Welsh Blood Service Evaluates New Technology for Sickle Cell Trait Screening

The Welsh Blood Service is testing new technology to improve how blood donations are screened for Sickle Cell Trait.

6.1.1 What is Sickle Cell Trait?

Sickle Cell Trait happens when a person inherits one normal haemoglobin gene and one abnormal haemoglobin S gene. Unlike Sickle Cell Disease, people with Sickle Cell Trait usually don't have symptoms and may not know they carry the gene.

However, it's important to identify this trait in blood donations. Blood containing haemoglobin S may not be suitable for certain patients, like newborns and people with Sickle Cell Disease. For these patients, even small amounts of haemoglobin S can affect their treatment. Screening for haemoglobin S helps ensure that every donation is safe and suitable for those who need it.

6.1.2 Improving the Screening Process

The Welsh Blood Service is testing new systems to detect haemoglobin S more quickly and efficiently. These tools are being tested to make the donor screening process faster and more efficient, while still ensuring the highest levels of safety.

The project is led by **Ann Jones** (pictured right), Automated Testing Operations Manager, alongside **Georgia Stephens**, **Dewi Reed** (pictured left). **Carol Ann Beer**, who recently retired, also contributed significantly to the team's efforts. Their work is helping to explore new ways to improve the blood screening process for Sickle Cell Trait.

"Having the opportunity to evaluate these systems has provided invaluable insight into how this testing can be integrated into the Automated Testing Laboratory to enable the provision of Haemoglobin S tested components from our donors in Wales for the patients we serve."

Ann Jones
Automated Testing Operations Manager at Welsh Blood Service

6.2 What next for Dr Chloë George and her HSST project?

In September, this year **Dr Chloë George** (pictured) qualified as a Consultant Clinical Scientist, the first in transfusion medicine at the Welsh Blood Service.

Her project looked at platelet metabolism in cold-stored environments and compared that to platelets stored at standard room temperature.

Platelets need energy to perform their function in the body and the idea was to see whether when they are stored at cold temperatures, the platelets go into a form of stasis where they are not using much energy which could facilitate longer storage periods.

This research was performed with platelets from apheresis donors, and corroborated research done by others around the world – bio-energetic profiles didn't show significant difference between cold-stored and room temperature stored platelets when taken from one donor, despite other metabolic markers suggesting that the cold slowed metabolism.

The next step is to test cold-stored pooled platelets using combined platelets from four donors which is the usual process for manufacturing platelet donations.

It is hoped that in the future the WBS will head up a clinical trial to test the use of cold-stored platelets in the pre-hospital environment in collaboration with the Emergency Medical Retrieval and Transfer Services (EMRTS).

"The clinical trial is a really exciting progression for the project - this would be the first clinical trial for the Welsh Blood Service and the first for cold-stored platelets in pre-hospital setting in the world.

"We are still at least 18 months away from being ready for a clinical trial as we gain funding, ethics approval, and all the other processes that go with setting up a trial."

As well as continuing on with her research role, Chloë has a clinical role within the organisation providing clinical patient advice alongside medical colleagues and taking part in the medical on call rota.

"I have been a scientist at WBS for 23 years and when working in the labs I didn't often get to see the effect the work we do has on the patient side, which is one of the things I love about my current post.

"Being in the position to give clinical advice for complex transfusion cases across Wales, advising on cross matching and compatible blood really brings home how life saving blood donation is.

My future ambitions are to continue to consolidate my clinical knowledge and to grow the Component Development Research Lab – after six years I think I can say I am definitely done with studying for now."

Dr Chloë George
Consultant Clinical Scientist (Head of Component Development & Research)
at Welsh Blood Service

6.3 WBS Investigating Innovative New Blood Packs

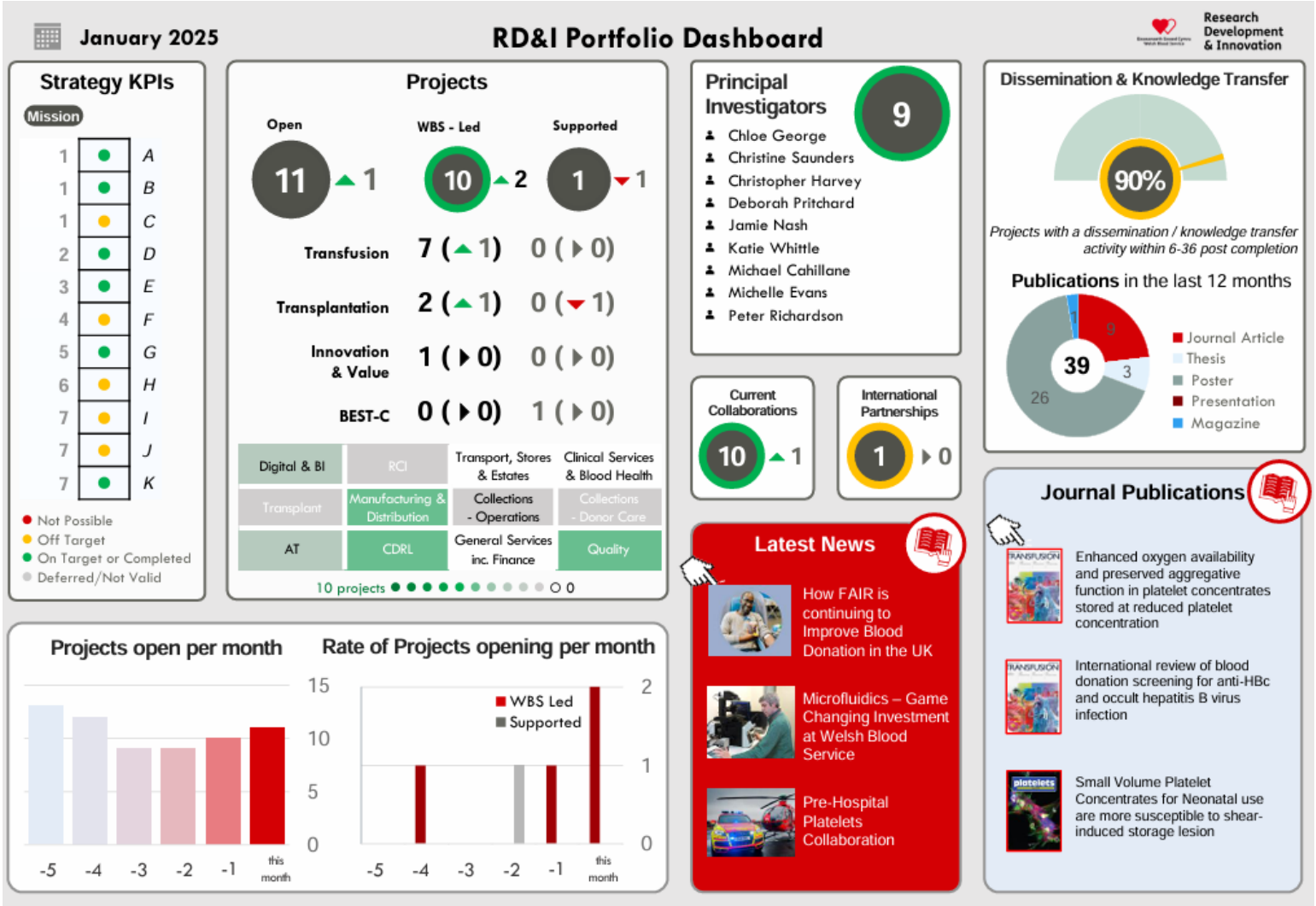
Blood services in Europe and around the world are researching the use of alternative plastics for taking donations and storing blood products, without limiting the shelf life of the blood products. We have recently started a new project looking at blood packs made from plastic that does not contain the plasticiser Di (2-ethylhexyl) phthalate or DEHP. The use of DEHP is being phased out globally and its removal marks a first step toward more environmentally sustainable practices in blood donation and storage.

An initial study was completed in November at four different donation clinics. We asked eligible donors if they would agree to their donation being used for research instead of transfusion on this occasion. Most were happy to be involved and we collected 16 donations in alternative blood packs made by supplier Macopharma.

Over the course of four days, the Collections teams played a crucial role in supporting this research project. It is a rare opportunity for research initiatives to be conducted directly within donation clinics, and the teams were exceptionally welcoming and supportive throughout the process.

Tracey Sullivan and her Education and Training team also made significant contributions, ensuring that all work carried out in the clinic adhered meticulously to the research protocol. The ongoing commitment to research and innovation continues to position the Welsh Blood Service at the forefront of safe and efficient transfusion services for patients across Wales. Currently, we are analysing the donations collected using the Macopharma pack. In the coming months, we will expand our testing to include blood packs from other manufacturers, enabling a comprehensive evaluation of options as we progress toward phasing out the current packs.

7 Welsh Blood Service Research Performance Indicators.



7.1 Open projects portfolio.

Project Name	WBS Project ID	Strategic Mission Link	WBS PI	Level of Involvement
Investigating the role of the bone marrow microenvironment in the pathogenesis of Acute Myeloid Leukaemia	96	Transfusion	*Head of WBMDR*	NHS Research
The use of legislation and regulation as a means of improving quality in public healthcare services	164	Innovation	Peter Richardson	WBS led RD&I
Improving Platelet Storage (PhD Cardiff Metropolitan University)	168	Transfusion	Christine Saunders	WBS led RD&I
Cold Stored Platelets for Pre-Hospital Use – Laboratory Testing	170	Transfusion	Jamie Nash	WBS led RD&I
Understanding and Investigating White Particulate Matter	175	Transfusion	Michael Cahillane	WBS led RD&I
Methodology Evaluation for Measuring Regulatory Cells in Kidney Transplant Recipients	178	Transplant	Deborah Pritchard	WBS led RD&I
Novel Cryoprotectants for Advancing Long-term Red Blood Cell and Platelet Storage	192	Transfusion	Chloe George	WBS led RD&I
Phase 0 Evaluation of non-DEHP Red Cell Storage Packs	194	Transfusion	Chloe George	WBS led RD&I
Comparison of haemolysis measurement of red cell components at the end of shelf life using a Spectrophotometric method and a Point of Care Test device HemoCue.	196	Transfusion	Michelle Evans	WBS led RD&I
Real-World Evaluation of Cytokine Dynamics using a Novel Flow Cytometry Assay	197	Transplantation	Katie Whittle	WBS led RD&I

7.2 The support of the Biomedical Excellence for Safer Transfusion (BEST) Collaborative.

Project Name	WBS Project ID	Mission Link	WBS Staff Lead	Involvement
BEST-C 183 Does Lipaemia Cause Red Cell Haemolysis? (DOLCE)	193	Transfusion	Chloe George	WBS support of others RD&I

7.3 Key Performance Indicators of the Welsh Blood Service RD&I Strategy.

These metrics reflect the implementation of the new RD&I strategy. In October we established Key Performance Indicators (KPIs) that align with the strategic goals of the updated RD&I strategy, which is currently progressing towards organisational approval. These KPIs are integrated into the organisation's reporting framework for planning and performance. For Apr to Sep 2024 performance, please refer to previous reporting of the former KPIs, as we have now ceased reporting for these outdated metrics.

✔	KPI On track
⚠	KPI requires attention

		A	M	J	J	A	S	O	N	D	J	F
Mission 1 – Improving Patient and Donor Care												
Number of WBS Led RD&I Projects	Sustain at least 10 open	See previous RD&I KPIs						⚠	⚠	✔		
Number of researchers	Sustain at least 10 annually							✔	✔	✔		
Percentage of WBS Departments involved in RD&I Projects	Ensure at least 80% of departments participate in RD&I activities previous year to date							⚠	⚠	⚠		
Mission 2 – Advancing Blood Components												
Number of Transfusion Research Projects Initiated	Sustain at least 4 open	See previous RD&I KPIs						✔	✔	✔		
Mission 3 – Leading Transplant Research in Wales												
Number of Transplant Research Projects Initiated	Sustain at least 2 open	See previous RD&I KPIs						✔	✔	✔		

Mission 4 - Use Innovation and Value Based Healthcare to Improve our Services and Performance												
Number of innovation Projects Successfully Implemented	Implement at least 5 new projects in the previous year to date	See previous RD&I KPIs					⚠	⚠	⚠		
Mission 5 – Use Collaboration to Sustain our RD&I												
Number of Collaborative Partnerships in RD&I	At least 8 projects per year that involve external party / collaborator (projects either ongoing or successfully completed)	See previous RD&I KPIs					✓	✓	✓		
Mission 6 – Serve the People of Wales by supporting international initiatives												
Number of international projects participated in	Participate in at least 5 international projects each year	See previous RD&I KPIs					⚠	✓	⚠		
Mission 7 – Enhance the Impact of RD&I and Celebrate Success												
Number of research papers published	Publish at least 10 papers	See previous RD&I KPIs					✓	✓	⚠		
The PI must describe a suitable dissemination / knowledge transfer activity	100% WBS Led projects must demonstrate how they achieved some type of dissemination activity						⚠	⚠	⚠		
Number of presentations at conferences (the WBS PMF KPI)	Present at 5 Conferences per year						✓	✓	✓		

7.4 RD&I KPI Narrative

Percentage of WBS Departments Involved in RD&I Projects: Currently, 75% of WBS departments are engaged in RD&I activity, with a target of 80%. The three departments not participating in RD&I activity are: Transport Stores, & Estates; Clinical Services & Blood Health and General Services -including Finance. Efforts are ongoing to encourage these departments to initiate or engage in RD&I activities to meet the target.

Number of Innovation Projects Successfully Implemented: No innovation projects have been implemented in the current reporting period, against a target of five per 12 months. One qualifying project is ongoing, while two supported projects concluded in Q2. Discussions at the WBS RD&I Group are ongoing to address this KPI.

Number of International Projects Participated In: There are four active international projects, compared to a target of five. However, the recently opened BEST-C project proposal is expected to bring this KPI to target by February.

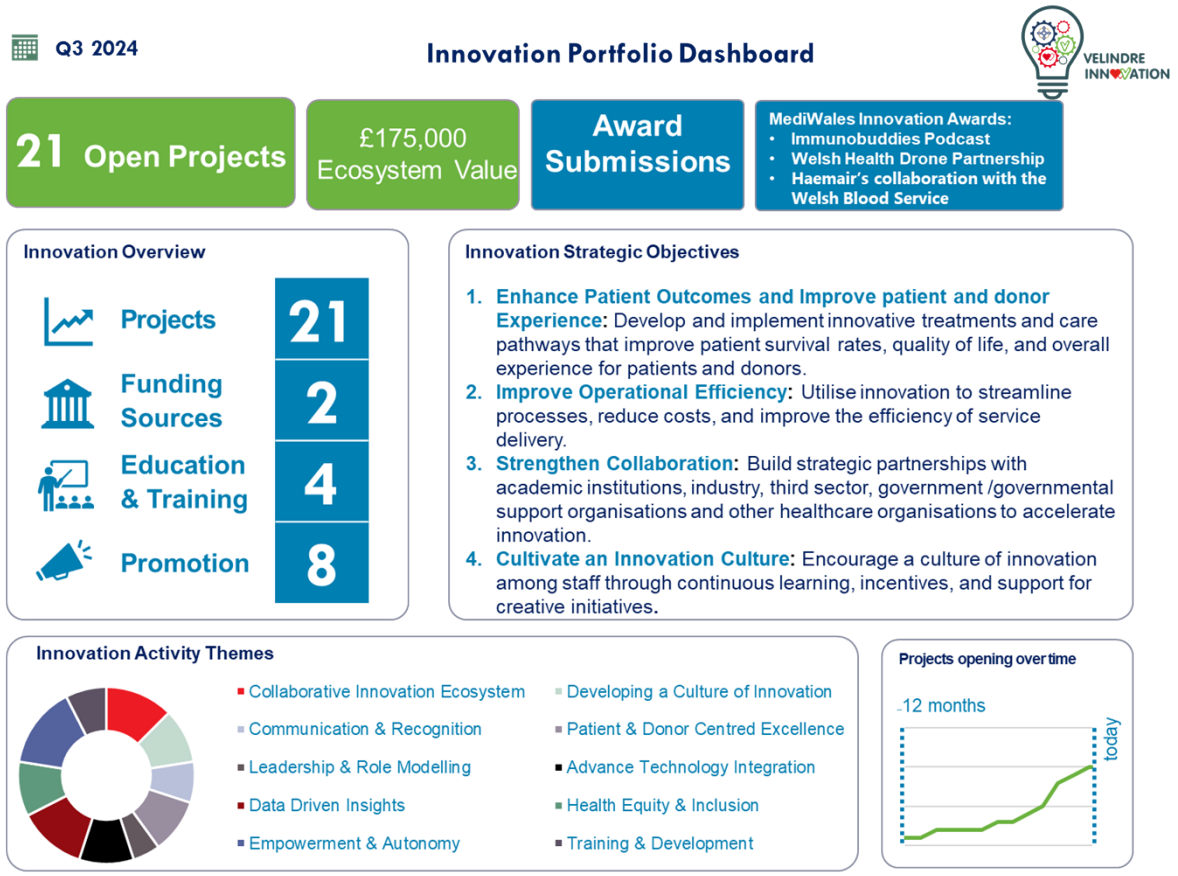
Number of Research Papers Published: Nine research papers (including journal articles, clinical guidelines, or theses) have been published in the last 12 months, just below the target of 10.

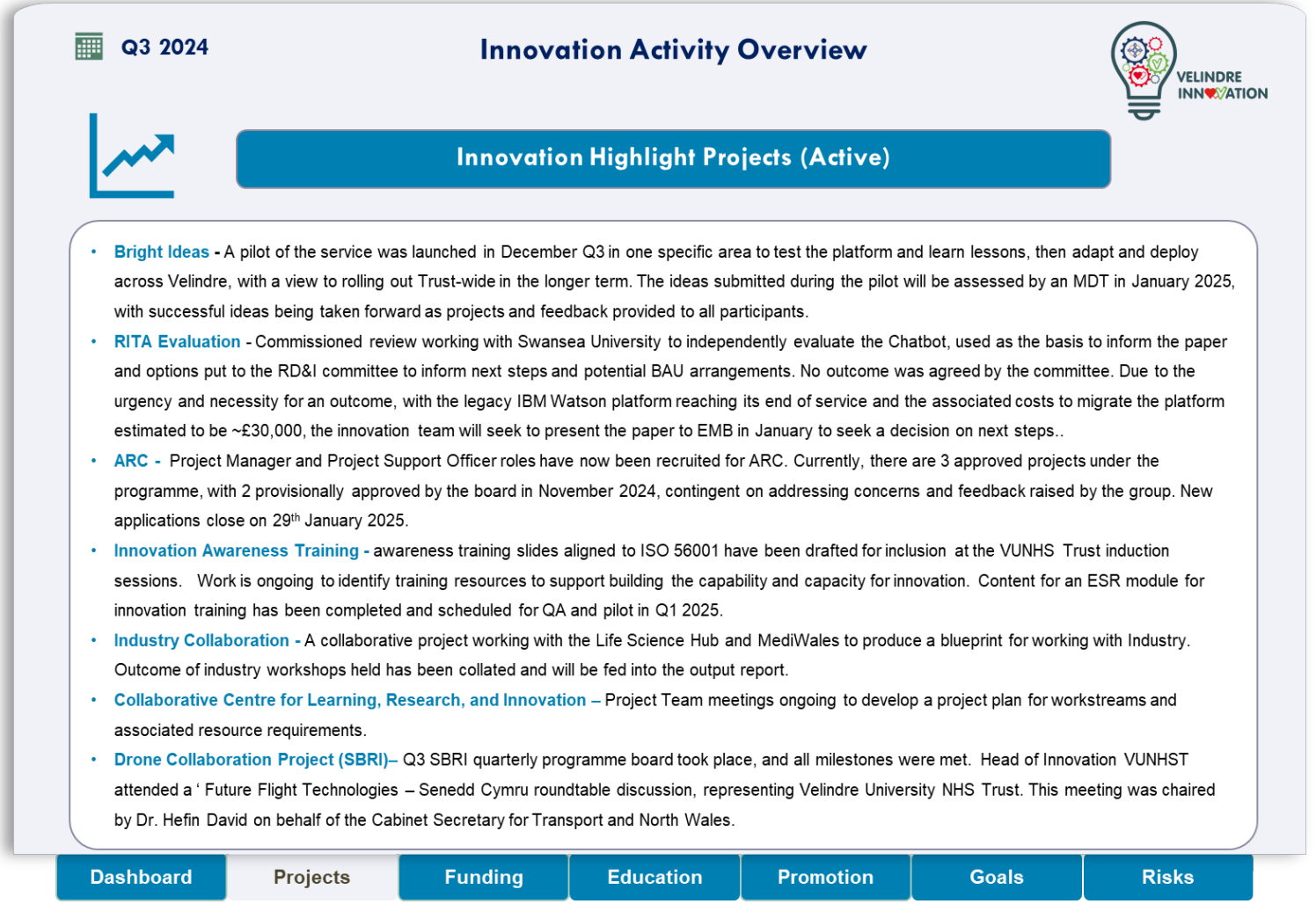
Principal Investigators must describe a suitable dissemination / knowledge transfer activity: PIs are required to perform a knowledge transfer activity within six months of completion of their project. This could include conference presentations, publications, or service improvement activities. Of the 30 eligible WBS-led projects, 28 have demonstrated knowledge transfer activities. PIs involved in the remaining two projects have been encouraged to accelerate their dissemination efforts to meet this requirement soon.

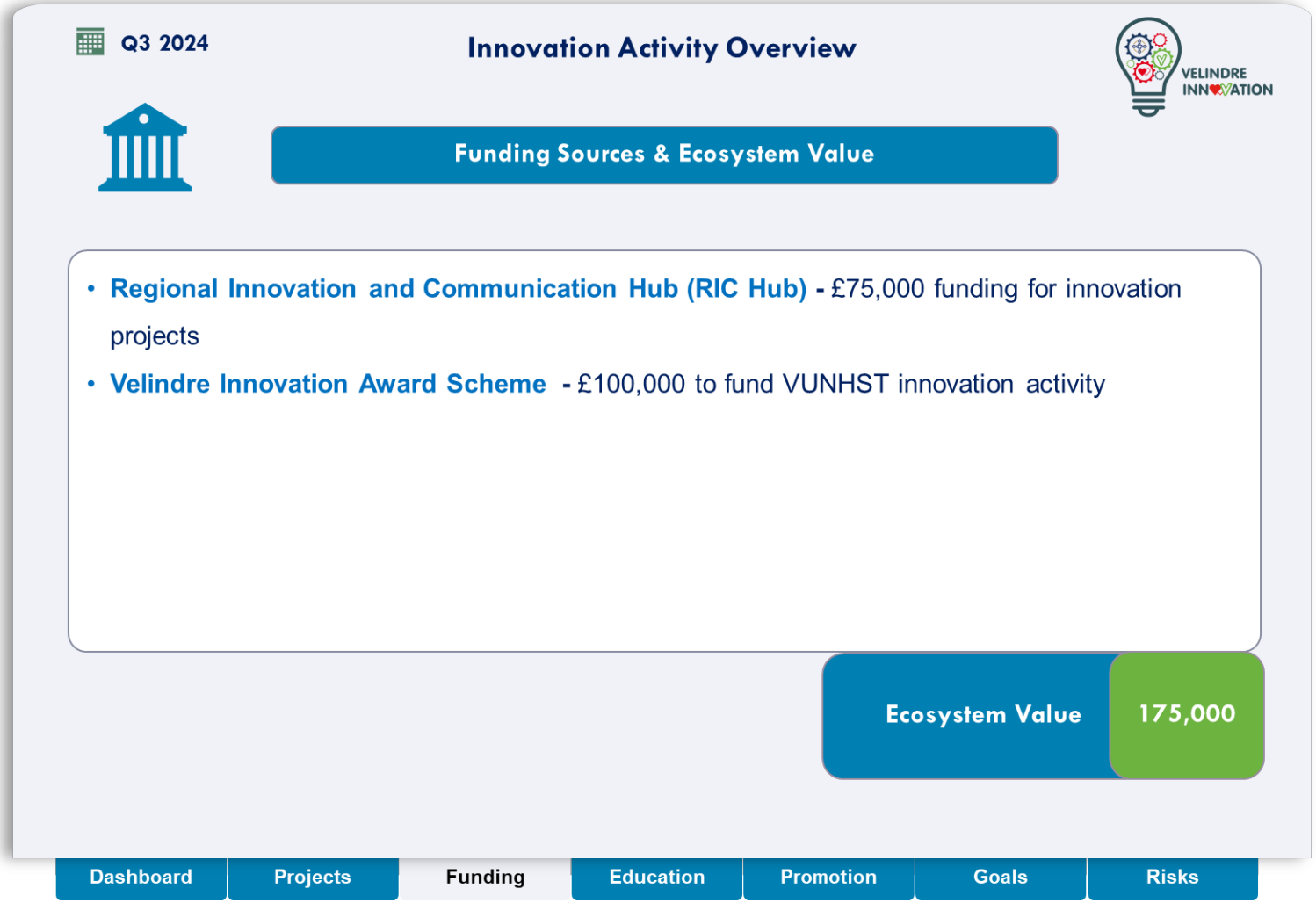
STRATEGIC PRIORITY 3

The Trust will implement the Velindre Innovation Plan.

8 Velindre Innovation Service.




Q3 2024
Innovation Activity Overview
VELINDRE INNOVATION
Innovation Highlight Projects (Active)
• Bright Ideas - A pilot of the service was launched in December Q3 in one specific area to test the platform and learn lessons, then adapt and deploy across Velindre, with a view to rolling out Trust-wide in the longer term. The ideas submitted during the pilot will be assessed by an MDT in January 2025, with successful ideas being taken forward as projects and feedback provided to all participants.
• RITA Evaluation - Commissioned review working with Swansea University to independently evaluate the Chatbot, used as the basis to inform the paper and options put to the RD&I committee to inform next steps and potential BAU arrangements. No outcome was agreed by the committee. Due to the urgency and necessity for an outcome, with the legacy IBM Watson platform reaching its end of service and the associated costs to migrate the platform estimated to be ~£30,000, the innovation team will seek to present the paper to EMB in January to seek a decision on next steps..
• ARC - Project Manager and Project Support Officer roles have now been recruited for ARC. Currently, there are 3 approved projects under the programme, with 2 provisionally approved by the board in November 2024, contingent on addressing concerns and feedback raised by the group. New applications close on 29th January 2025.
• Innovation Awareness Training - awareness training slides aligned to ISO 56001 have been drafted for inclusion at the VUNHS Trust induction sessions. Work is ongoing to identify training resources to support building the capability and capacity for innovation. Content for an ESR module for innovation training has been completed and scheduled for QA and pilot in Q1 2025.
• Industry Collaboration - A collaborative project working with the Life Science Hub and MediWales to produce a blueprint for working with Industry. Outcome of industry workshops held has been collated and will be fed into the output report.
• Collaborative Centre for Learning, Research, and Innovation – Project Team meetings ongoing to develop a project plan for workstreams and associated resource requirements.
• Drone Collaboration Project (SBRI)– Q3 SBRI quarterly programme board took place, and all milestones were met. Head of Innovation VUNHST attended a ' Future Flight Technologies – Senedd Cymru roundtable discussion, representing Velindre University NHS Trust. This meeting was chaired by Dr. Hefin David on behalf of the Cabinet Secretary for Transport and North Wales.
Dashboard
Projects
Funding
Education
Promotion
Goals
Risks


Q3 2024
Innovation Activity Overview
VELINDRE INNOVATION
Funding Sources & Ecosystem Value
• Regional Innovation and Communication Hub (RIC Hub) - £75,000 funding for innovation projects
• Velindre Innovation Award Scheme - £100,000 to fund VUNHST innovation activity
Ecosystem Value
175,000
Dashboard
Projects
Funding
Education
Promotion
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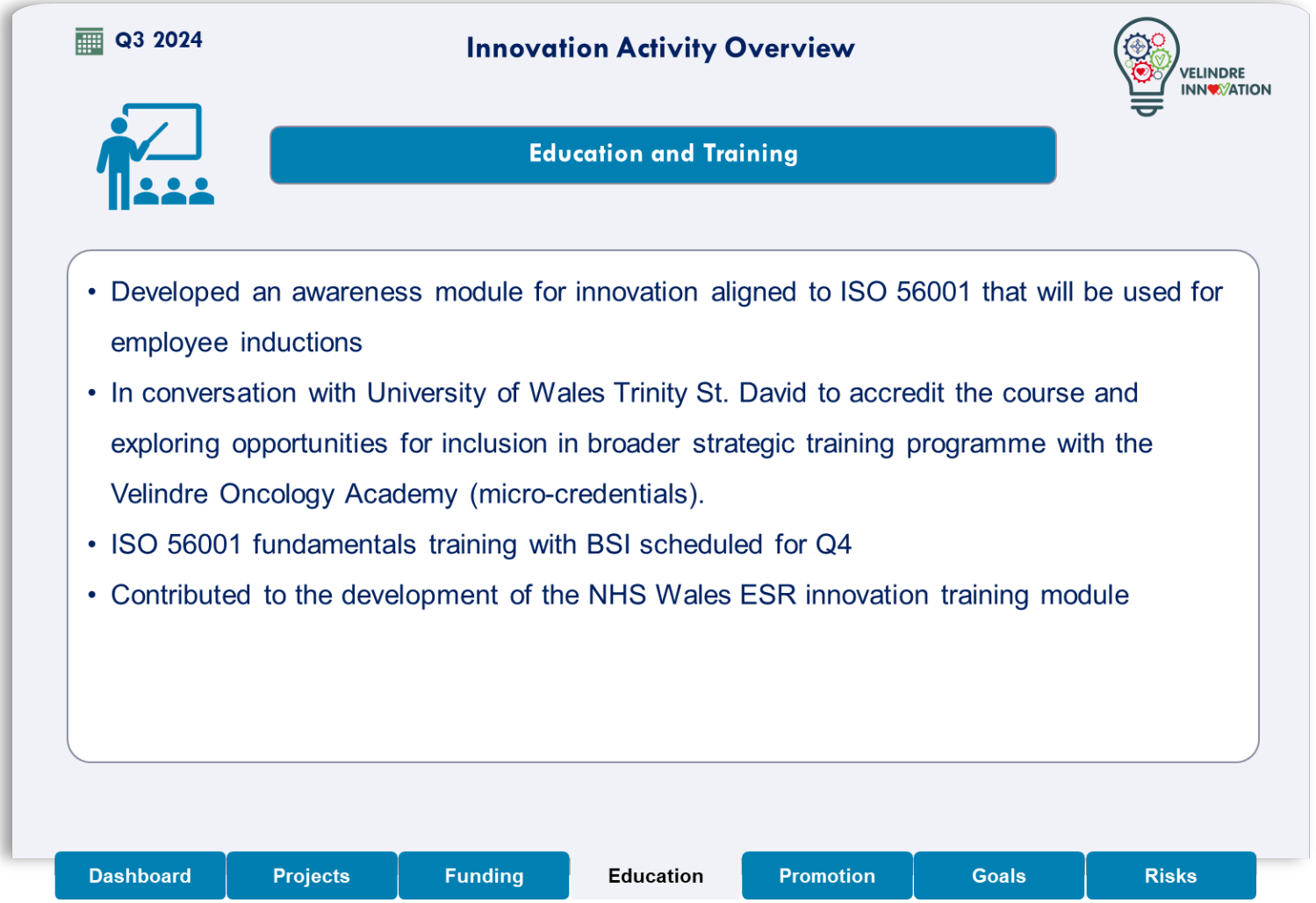
Risks


Q3 2024
Innovation Activity Overview
VELINDRE INNOVATION
Education and Training
• Developed an awareness module for innovation aligned to ISO 56001 that will be used for employee inductions
• In conversation with University of Wales Trinity St. David to accredit the course and exploring opportunities for inclusion in broader strategic training programme with the Velindre Oncology Academy (micro-credentials).
• ISO 56001 fundamentals training with BSI scheduled for Q4
• Contributed to the development of the NHS Wales ESR innovation training module
Dashboard
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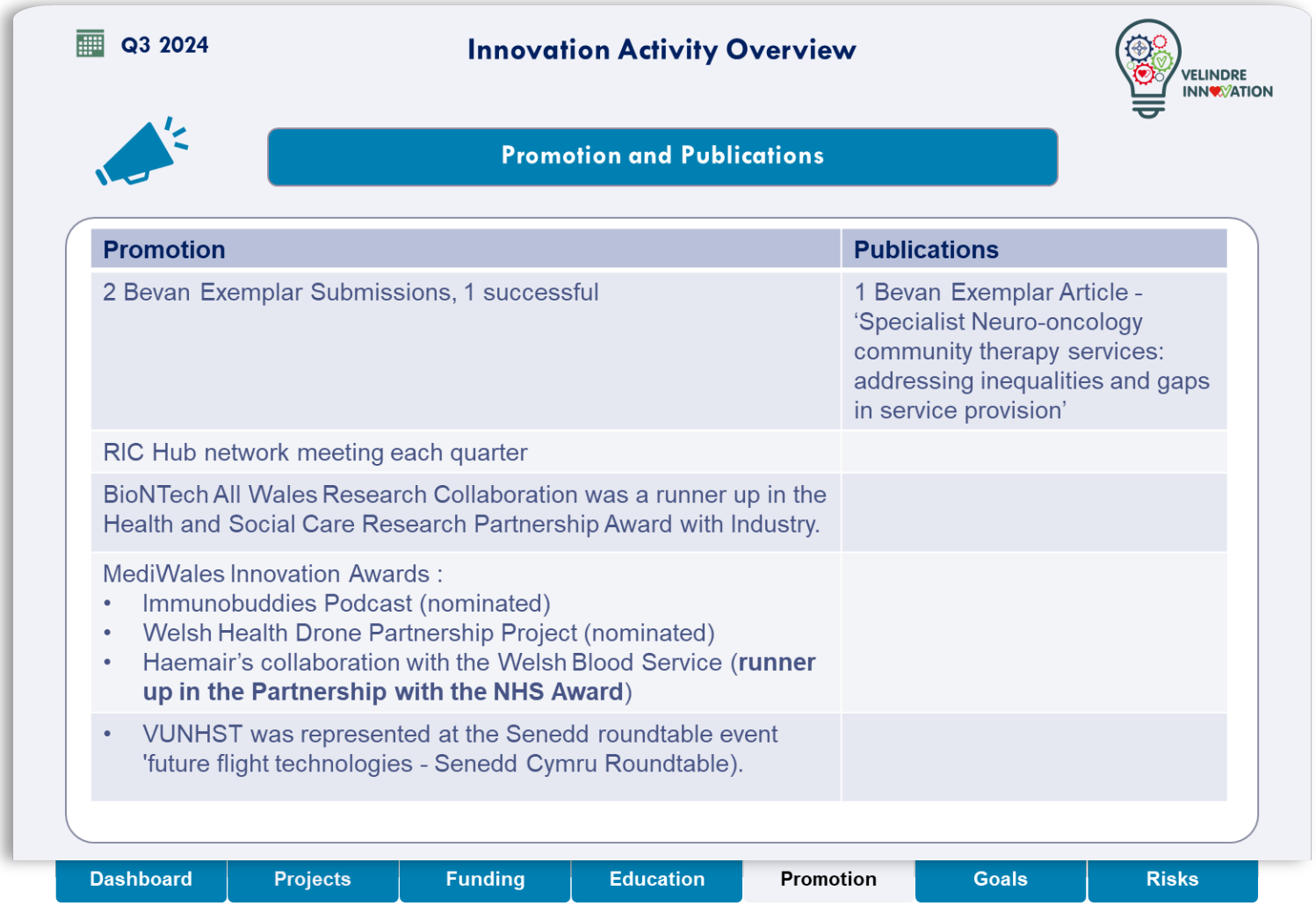
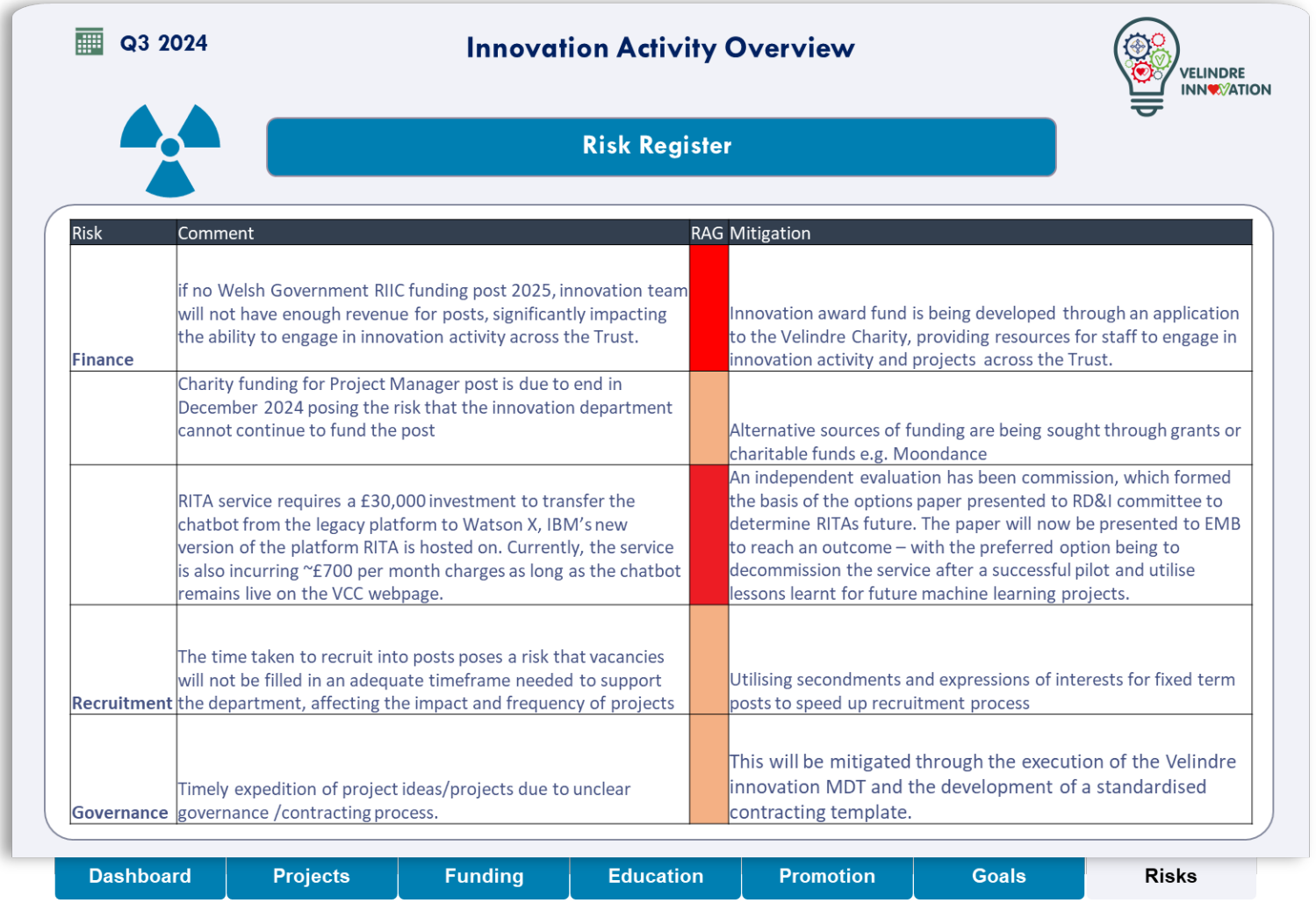

Q3 2024
Innovation Activity Overview
VELINDRE INNOVATION
Promotion and Publications
Promotion
Publications
2 Bevan Exemplar Submissions, 1 successful
1 Bevan Exemplar Article - 'Specialist Neuro-oncology community therapy services: addressing inequalities and gaps in service provision'
RIC Hub network meeting each quarter
BioNTech All Wales Research Collaboration was a runner up in the Health and Social Care Research Partnership Award with Industry.
MediWales Innovation Awards :
• Immunobuddies Podcast (nominated)
• Welsh Health Drone Partnership Project (nominated)
• Haemair's collaboration with the Welsh Blood Service (runner up in the Partnership with the NHS Award)
• VUNHST was represented at the Senedd roundtable event 'future flight technologies - Senedd Cymru Roundtable).
Dashboard
Projects
Funding
Education
Promotion
Goals
Risks


Q3 2024
Innovation Activity Overview
VELINDRE INNOVATION
Short-Medium Term Goals
• Implement ISO 56001 system and seek costs and plan for external verification
• Trained auditors in ISO system
• Funding sustainability
• Roll out induction training and staff training for innovation
• Accreditation of training course
• Implement the Bright Ideas platform, capture lessons learnt and begin the next phase of rollout.
• Complete branding survey and update guidance
• Reach outcome with EMB on RITA's future through options paper, produce a report for completion of the pilot project, successfully testing the feasibility of machine learning/ AI service.
• Agree governance approach for CCfLRI and develop a project plan for workstreams and associated resource requirements.
• Develop blueprint for collaborating with industry as an outcome of the workshops
Dashboard
Projects
Funding
Education
Promotion
Goals
Risks



Risk	Comment	RAG	Mitigation
Finance	if no Welsh Government RIIC funding post 2025, innovation team will not have enough revenue for posts, significantly impacting the ability to engage in innovation activity across the Trust.		Innovation award fund is being developed through an application to the Velindre Charity, providing resources for staff to engage in innovation activity and projects across the Trust.
	Charity funding for Project Manager post is due to end in December 2024 posing the risk that the innovation department cannot continue to fund the post		Alternative sources of funding are being sought through grants or charitable funds e.g. Moondance
	RITA service requires a £30,000 investment to transfer the chatbot from the legacy platform to Watson X, IBM's new version of the platform RITA is hosted on. Currently, the service is also incurring ~£700 per month charges as long as the chatbot remains live on the VCC webpage.		An independent evaluation has been commission, which formed the basis of the options paper presented to RD&I committee to determine RITAs future. The paper will now be presented to EMB to reach an outcome – with the preferred option being to decommission the service after a successful pilot and utilise lessons learnt for future machine learning projects.
Recruitment	The time taken to recruit into posts poses a risk that vacancies will not be filled in an adequate timeframe needed to support the department, affecting the impact and frequency of projects		Utilising secondments and expressions of interests for fixed term posts to speed up recruitment process
Governance	Timely expedition of project ideas/projects due to unclear governance /contracting process.		This will be mitigated through the execution of the Velindre innovation MDT and the development of a standardised contracting template.

STRATEGIC PRIORITY 4

The Trust will maximise collaborative opportunities locally, nationally, and internationally.

9 Velindre University NHS Trust Sponsored Research Performance Indicators.

The Trust sponsors research studies taking on the responsibility for the initiation, management, and financing (or arranging the financing) of those research studies.

9.1 VUNHST sponsored studies metrics

The following information shows the performance indicators for the Trust's sponsored studies

	FY2024/25			
	Q1	Q2	Q3	Q4
Number of New Projects Sponsored	1	0	1	
Number of Studies Opened	1	0	1	
Scope of Studies Opened	National	N/A	National	
Number of Sites Opened	1	0	1	
Number of Publications	0	1	1	
Number of Abstracts	3	1	0	
Number of Articles	1	1	1	
Recruitment	36	44	21	

9.2 VUNHST sponsored studies publications

The following information shows the publications, articles, and posters generated by the Trust's sponsored studies:

Conference / Journal / Website	Submitted by	Outcome	Title
SCOPE2			
Clinical Oncology	Helbrow J, Lewis G, Hurt C, *et al.*	Epub ahead of print.	Radiotherapy Quality Assurance in the SCOPE2 Trial: What Lessons can be Learned for the Next UK Trial in Oesophageal Cancer? https://www.sciencedirect.com/science/article/abs/pii/S0936655524005399 December 2024
PATHOS			
JAMA Otolaryngology – Head & Neck Surgery	O'Hara JT, Hurt CN, Ingarfield K, *et al.*	Epub ahead of print.	Transoral Laser or Robotic Surgery Outcomes for Oropharyngeal Carcinoma: Secondary Analysis of the PATHOS Randomized Clinical Trial. https://pubmed.ncbi.nlm.nih.gov/39388196/ October 2024

9.3 Genomics England partners with PATHOS clinical trial to advance Head & Neck Cancer Research.

Genomics England partners with PATHOS clinical trial to advance Head & Neck Cancer Research.

Velindre University NHS Trust is delighted to spotlight an exciting collaboration between Professor Tim Fenton and Genomics England, marking a significant milestone in cancer research. Genomics England has contributed double-depth whole genome sequencing (WGS) data from 343 tumour samples representing 88 patients enrolled in the PATHOS clinical trial. This extensive sequencing effort, provides one of the most comprehensive datasets for oropharyngeal cancer research globally.

The PATHOS trial focuses on oropharyngeal cancer, a type strongly associated with human papillomavirus (HPV) and representing a significant proportion of global head and neck cancer cases. By enriching the PATHOS WGS data and enabling DNA methylation profiling, this project aims to uncover new insights into the biology of this disease and drive forward clinically meaningful discoveries.

Genomics England's in-kind contribution also includes £10,000 to host and enable access to this invaluable dataset through their secure Research Environment for the next three years. This platform ensures researchers within the PATHOS analysis team can access and analyse the data securely, with membership to the Genomics England Research Network further enhancing collaboration opportunities.

The Research Network brings together over 1,300 genomic researchers and 30 life sciences companies from around the world, fostering partnerships and innovation. Through access to the National Genomic Research Library, which includes one of the largest cohorts of rare disease and cancer whole-genome sequencing data, Professor Fenton and his team are positioned to advance their work significantly.

This partnership exemplifies Velindre University NHS Trust's commitment to cutting-edge research and collaboration. By leveraging Genomics England's resources, PATHOS is set to generate breakthroughs that will not only benefit local patients but contribute to global cancer research.

10 Cross-cutting themes: progress.

Cross-cutting themes across Strategic Priorities 1 to 4.													
	FY2023/24				FY2024/25				FY2025/26				
Key Deliverables / Objectives	**Q1**	**Q2**	**Q3**	**Q4**	**Q1**	**Q2**	**Q3**	**Q4**	**Q1**	**Q2**	**Q3**	**Q4**	**Progress / Comments**
The implementation of programmes, complementing existing training opportunities that enable and support Trust staff to develop, deliver and manage research portfolios													
Continue the work to develop and implement a R&D/Trials training programme draws upon: - Trust developed internal training. - Training developed by other research partners and organisations such as Health and Care Research Wales. - Training from specialist non-commercial and commercial training providers to support Trust staff to develop, set-up and deliver, and manage portfolios of clinical trials/research studies.													**Training Programme & Opportunities** This work is an ongoing improvement of the RD&I Division's service. Work continues to develop and implement a R&D/Trials training programme that draws upon: - Trust developed internal training. - Training developed by other research partners and organisations such as Health and Care Research Wales. - Training from specialist non-commercial and commercial training providers. to support Trust staff to develop, set-up and deliver, and manage portfolios of clinical trials/research studies. Work continues into FY2024/25 with Trust Research Service staff contributing to the content of the Health and Care Research Wales training programme.
Further investment in the research delivery and governance teams to make sure that studies are optimised to facilitate effective and timely recruitment and delivery													
Continue the development and implementation of staffing plans for the research delivery and governance teams (previously identified) to facilitate timely recruitment.													**Reorganisation of Trust Research Delivery team** This work is an ongoing improvement of the RD&I Division's service. Considering the "Implementing the Cancer R&D Ambitions – an Integrated Business Case 2023-2026" work continues to keep under review and consolidate proposals and implementation of changes to the structure of the research set-up and delivery team structure.
Complete the appointment of senior staff in the research delivery team and to support the delivery of the Cardiff Cancer Research													

Cross-cutting themes across Strategic Priorities 1 to 4.													
	FY2023/24				FY2024/25				FY2025/26				
Key Deliverables / Objectives	**Q1**	**Q2**	**Q3**	**Q4**	**Q1**	**Q2**	**Q3**	**Q4**	**Q1**	**Q2**	**Q3**	**Q4**	**Progress / Comments**
Hub and other research priority areas for the Trust.													Work continues into FY2024/25 to reorganise the Trust's Research Service Delivery Team to improve service resilience.
Keep under review and consolidate proposals and implementation of changes to the structure of the research set-up and delivery team structure.													
The development and implementation of clinical information systems to identify donors/patients eligible to take part in research studies													
Having contributed to the Trust's implementation of the Digital Health & Care Record programme, continue to keep under review the input of, and use of information, making recommendations for improvement as appropriate.													The Trust Research Service staff, continue to keep under review the input of, and use of information, making recommendations for improvement as appropriate. The Trust Research Service staff are due to be involved the second phase of the Digital Health & Care Record programme during FY2024/25.
Contribute to the Welsh Government / Health & Care Research Wales "Digital agenda for research in Wales" including the work on: - The contribution and use of anonymised / pseudo-anonymised data research - The programme that seeks develop abilities to "find, recruit and follow-up" participants for research.													The Trust RD&I service continue to contribute to the Welsh Government/Health and Care Research Wales on the "Digital agenda for research in Wales" programme of work, as and when invited to provide input.

CORPORATE

11 Research, Development, and Innovation Finances.

11.1 Introduction

The purpose of this paper is to present the financial performance of the Research, Development & Innovation (RD&I) Division for the period to the end of December 2024 (Month 9 2024/25). The dashboard included within Appendix 1 provides an overview of the position.

11.2 Financial Plan September (Month 9)

The reported financial position for the RD&I Division at the end of December 2024 was an overspend of £72k. The 2024/25 financial plan for the division is consistent with previous years in so far that the overall plan comprises the following targets:

- **£4.6m spend on research activities**
- The majority (84%/£3.8m) of this relates to staff costs with the remaining £0.8m relating to non-pay costs including clinical supplies/services, education & development, travel and office equipment and consumables.

- **£4.8m of income from various sources:**
  - Health & Care Research Wales (26%)
  - Clinical Trial Income - Commercial & Non-Commercial (25%)
  - Support from Velindre Charity Integrated Bid & other individual business cases (44%)
  - Grant income & Velindre Lead sponsor income (5%)

Whilst there are variances against various budget areas, as shown within Appendix 1, there are currently no areas of concern.

11.3 Summary of Performance – Year to date December 2024

Key Financial Target 1: to remain within monthly budget expectations.

PERIOD		£000			
		PAY	NON-PAY	INCOME	TOTAL
MONTH 9	Budget	£286	£46	(£340)	(£8)
	Actual	£295	£67	(£395)	(£33)
	Variance	**£9**	**£21**	**(£55)**	**£24**
YEAR TO DATE	Budget	£2,632	£536	(£3,378)	(£210)
	Actual	£2,810	£487	(£3,435)	(£138)
	Variance	**£178**	**(£49)**	**(£57)**	**£72**

Performance during the period has been in line with the budget plan with a minimal overall variance.

Key Financial Target 2: to pay at least 95% of invoices within 30 days.

% Compliance	Current Month	Year to Date	Forecast Outturn
	64%	82%	>95%

Our PPP compliance target is to pay 95% of invoices within 30 days. In month 9 performance dropped to 64% due to unexpected staff absences which has also impacted on the year to date position – 82%. Recruitment is currently underway to ensure that ongoing performance is supported and through the task and finish group processes continue to be reviewed with measures and lessons resulting from the Group being cascaded to the team.

11.4 Analysis of Performance

Year to date performance (YTD) for RD&I as reported shows an adverse variance of £72k against the budget. This is primarily due to a charity income recovery issue relating to previous years and overspends against pay.

The overall position for RD&I has improved slightly since last month due to further non-pay savings.

The area of continued risk across the division is income. There is a significant income target of £4.8m for the 2024/25 financial year which includes an additional income target of £150k for increased commercial trials income. Whilst delivery is currently in line with target, this is an area that will continue to be closely monitored.

The trajectory of income received in year compared to historical trends is set out with Appendix 1. The year to date position has also been included below:

Income Analysis by category:

Cumulative to date			
£57k above budget			
INCOME SUBJECTIVE	**YTD Budget (£'000)**	**YTD Actual (£'000)**	**YTD Variance (£'000)**
Clinical Trial Income	(£856)	(£854)	£2
Charity Income	(£1,304)	(£1,233)	£71
Welsh Gov	(£864)	(£864)	-
WCRC & ECMC	(£139)	(£278)	(£138)
Grant/Lead sponsor income	(£214)	(£206)	£8
Total	**(£3,377)**	**(3,435)**	**(£57)**

Income for the period is slightly higher than budget and this pattern is expected to continue to the end of the year.

Work continues to further refine budget forecasts in readiness for year end preparation.

11.5 Delivery of savings

For the first time this year the deliverability of the establishment control savings could be at risk due to the division being close to full establishment. The table set out in Appendix 1 demonstrates that 12% of the 2024/25 savings plan could be at risk. Despite this, performance against current year savings target remains high. These areas will continue to be closely monitored.

Where it is anticipated that full delivery of savings is not possible, there is an expectation that mitigation will be identified as failure to manage this situation appropriately would have significant consequences on future years budgetary position.

11.6 IMTP

The process of reviewing and updating the Trusts 3-year plan (IMTP) is currently underway. This has been approved by Board and subsequently by WG earlier last year. Key to the refresh will be the

need to engage with internal and external stakeholders. IMTP planning guidance has been developed, and this has been based on:

- Welsh Government priorities and key policy requirements
- Trust priorities and key areas of work
- Trust core planning principles

In order to support this process, early engagement with Commissioners has begun. A schedule of prospective business cases has been developed for which it is hoped there will approval and funding to flow from Commissioners. These cases will be considered as part of Health Boards IMTP planning process and the outcome will be shared in due course.

The Division should be mindful that although the overall Trust IMTP position remains unknown there will be a requirement for the Division to deliver a package of targeted financial savings, development of workforce and associated capacity plans linked to performance and maximization of income opportunities. Until the quantum of the targeted savings is known for 2025/26, a target in the region of £230k should be planned for.

11.7 Conclusion/ Key Actions

Budget holders have a delegated responsibility to ensure that they manage within their budgets. As we approach the final quarter of the 2024/25 financial year it is important that robust forecasts accurately reflect the activity that will likely occur in the next few months. This will allow the Trust to make informed decisions and take the necessary action to ensure a balanced budget is delivered.

In order to retain a balanced position, the Division will be required to manage all current and new financial risks, deliver the agreed savings target, and mitigate or remove any cost pressures that may emerge over the course of the period.

11.8 RD&I Revenue Dashboard FY2024/25

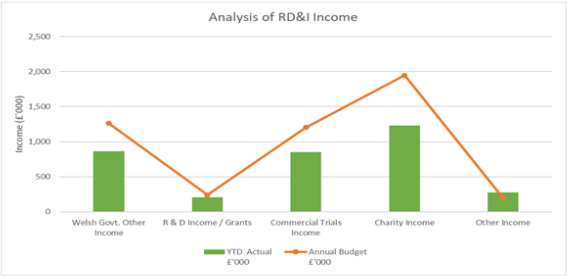
Appendix 1 - Research, Development & Innovation 2024-25 — Month 09 – December

The following tables, charts and figures give an indication of the financial performance *of the Directorate.*

Subjective	Annual Budget (£'000)	Cumulative Position M09 Budget £'000	Actual £'000	Variance £'000
Income	(4,847)	(3,378)	(3,436)	(57)
Pay	3,836	2,632	2,811	178
Non Pay	727	536	487	(49)
Grand Total	**(284)**	**(210)**	**(137)**	**72**

Income Summary

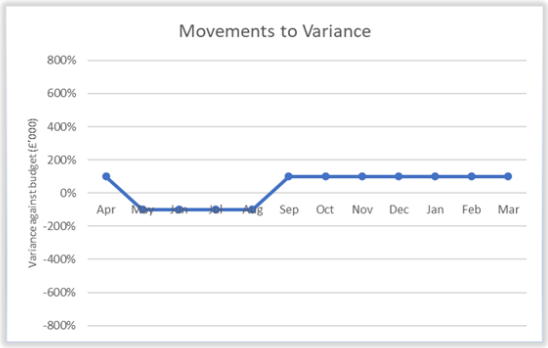
Sum of Amount £'s Subjective	Annual Budget £'000	YTD Budget £'000	YTD Actual £'000	YTD Var £'000
Welsh Govt. Other Income	1,260	864	864	(0)
R & D Income / Grants	240	215	207	8
Commercial Trials Income	1,203	856	855	2
Charity Income	1,946	1,304	1,233	71
Other Income	198	140	278	(138)
Grand Total	**4,847**	**3,378**	**3,436**	**(57)**



Recurring Budget Risks & Opportunities:

- Consider options to further explore commercial and other income in line with IMTP strategy
- Financial sustainability around level of posts funded via the charity – exit strategy to be developed
- Patient recruitment

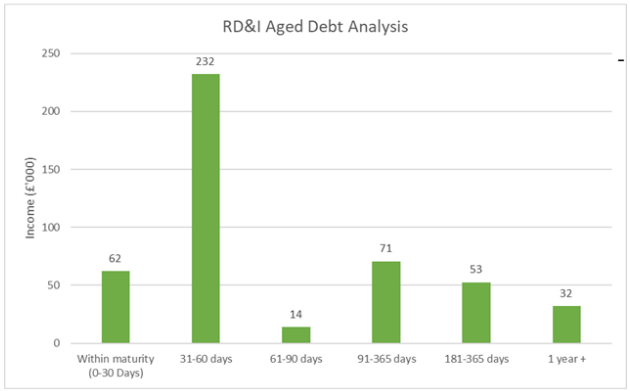
The figures and charts below highlight the performance against the 2024/25 targets.

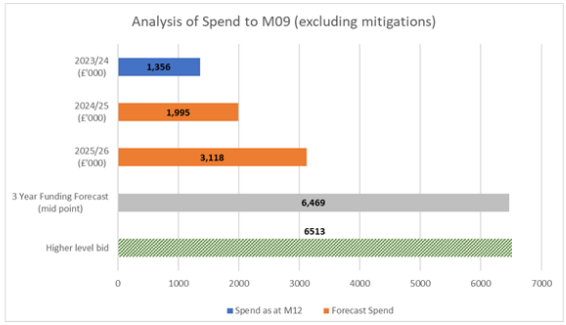


Payment of Invoices: to pay at least 95% of invoices within 30 days.

	Current Month	Year to Date	Forecast Outturn
% Compliance	95%	90%	>95%

Aged Debtors



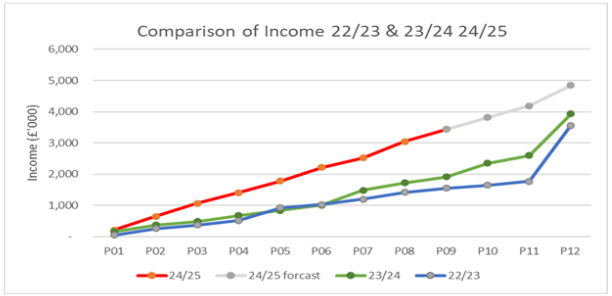


The figures and charts below highlight the medium-term position and will be key in determining a strategic approach to financial planning.

RD&I Saving Theme - Recurrent	Category	IMTP Target (£'000)	Savings Realised (£'000)	Variance (£'000)	Variation (%)
Commercial Income	Income	150	150	0	100%
Establishment Control	Pay	80	53	27	66%
Sub Total		**230**	**203**	**0**	

IMTP Considerations:

- Progress made against £150k increase in commercial trials income plus additional vacancy factor of £80k - £230k total. Overspending against pay highlights a risk
- Mitigation of financial pressures and risks



Appendix A: Summary of RD&I Risk Profile

The following table summarises the risks for Research & Development from 01 April 2023. Risks are reviewed through the RD&I governance route as appropriate and only escalated to a higher level where the Controls / Action Plan are unable to reduce the risk to an acceptable level. The escalation of a risk, based on the risk score once the controls / action plans have been applied, is as follows:

Risk Score	Escalation group
15 or above	Executive Management Board (EMB) and RD&I Sub-Committee. These risks are the responsibility of the EMB and RD&I Sub-Committee to ensure effective management and resolution. Risks are further escalated to Trust Board, if the RD&I Sub-Committee determines the risk to require Trust Board involvement or is a Trust-wide issue and so out of scope of the Research & Development Service.
8 to 14	Review action at Research, Development, and Innovation Operational Management Group and close within 6 months.
4 to 7	Review action at Research, Development, and Innovation Operational Management Group and close within 12 months.
1 to 3	If agreed no further action, risk can be closed and re-assessed if there is a recurrence of the risk.

Risk Summary Table (Open Risks)

№	Risk ID	Risk Description	Date opened	Inherent Risk Score	Controls / Action Plan & Progress	Current / Target Risk Score	Status	Level of control	Lead
1.	2200	The **RADIOTHERAPY SERVICE** risk (Risk ID 2200) was made visible in Datix to the Research Service in March 2024. The risk has been assessed for impact on the Research Service's ability to continue service delivery: 1. Capacity to meet the Trust's existing contractual requirements to deliver clinical trials requiring patients to receive radiotherapy treatment. 2. Capacity to offer patients opportunity to take part new clinical trials where they would receive radiotherapy treatment. The controls / action plans put in place to address the Research Service's aspects of this risk, and their progress are described in the "**Controls / Action Plan & Progress"** column. The RADIOTHERAPY SERVICE risk has an inherent risk score of 20 and has previously been escalated to the Trust Executive Management Board. The RADIOTHERAPY risk is owned by that service and is described below for reference: **RADIOTHERAPY CAPACITY** There is a risk to whole of Radiotherapy Performance and Service as a result of insufficient capacity within the current linear accelerator fleet, leading to the radiotherapy service being unable to meet the current and anticipated demand. The lack of sufficient capacity within the Radiotherapy service has had the following consequences:- Compliance risk - An inability to maintain waiting times compliance. - Creation of waiting lists. - Inability to meet RCR clinical guidelines. Patient safety risk	01 May 2011	12	**06 Aug 2024.** 1. The Research Service is in regular communication with the Radiotherapy Service to discuss their capacity in managing existing clinical trials with radiotherapy treatment and meet Trust contractual requirements. This is achieved through a number of mechanisms: a. Trust R&D Office representation on the Radiotherapy Trials Portfolio Group, which assess and discuss the impact of Radiotherapy Service changes on the delivery of existing clinical trials, allowing prioritisation discussions to take place. b. Regular meetings between the Head of R&D, Research Delivery Manager, and Superintendent Radiographer – R&D. Through these mechanisms, the existing clinical trials with radiotherapy have been assessed and the Trust is able to meet its contractual requirements. 2. The Research Service's Head of R&D and Research Delivery Manager are part of the established Radiotherapy Trials Solutions Group chaired by Dr Paul Shaw (Consultant Clinical Oncologist) that has made recommendations to improve the situation. Work is underway to implement and monitor these recommendations made by the group, to ensure that the Trust is able to set-up and deliver new clinical trials with radiotherapy treatment within the capacity constraints alongside the existing portfolio of trials; and aligned with the Radiotherapy's service re-design as part of the Integrated Radiotherapy Solutions (IRS). The above actions will allow the Trust to continue to deliver its current contracted portfolio of trials with radiotherapy treatment and offer patients opportunities to take part new trials aligned with the IRS development.	8	Open	Research / Trials = Adequate	Radiotherapy Services Manager

№	Risk ID	Risk Description	Date opened	Inherent Risk Score	Controls / Action Plan & Progress	Current / Target Risk Score	Status	Level of control	Lead
		- Patients will wait longer to start treatments resulting in possible poorer clinical outcomes, lack of symptom control and poor patient experience. Reputational risk - Limited service developments with a corresponding delay or inability to meet IMTP objectives. - Restricted ability to participate in clinical trials or research projects. - Issues with recruitment and retention of staff.			The Radiotherapy Service's IRS programme of work will see the implementation of a treatment and planning system supplied from a single vendor. Any changes resulting from the work that could affect the Trust's ability to deliver trials with radiotherapy treatment is considered through ongoing discussions with the Research Service and Clinical Teams.				
2.	3252	Cardiff & Vale University Health Board (CVUHB) unable to keep up with Velindre University NHS Trust's (VUNHST) support requests for research study radiological biopsies.	09 Nov 2023	20	1. Continuing to set-up research studies where biopsies are optional or can be undertaken at Velindre Cancer Centre (VCC) 2. Continuing to set-up research studies with mandatory biopsies using support requests to CVUHB on a case-by-case basis. 3. Work ongoing with CVUHB Joint Research Office & CVUHB Radiology to resolve issue. 4. VUNHST R&D commercial radiology sessions supporting the identification of radiological biopsy requirements as part of study set-up. 5. VUNHST exploring support service agreements with other organisations.	8	Open	Adequate	Head of R&D

Risk Summary Table (Closed Risks)

№	Risk ID	Risk Description	Date opened	Inherent Risk Score	Controls / Action Plan & Progress	Current / Target Risk Score	Status	Level of control	Lead
1.	3186	Recent vacancies in Velindre Cancer Centre's (VCC) means a possible slowing of research study set-up and patient recruitment is required, meaning a reduction in new studies opened and recruitment numbers. May also delay VCC Pharmacy's ability to support studies/service at Cardiff Cancer Research Hub (CCRH).	22 Aug 2023	15	**15 Oct 2024** 1. All vacancies have been recruited into. Progress to be reviewed in December 2024 following all staff being onboarded and training completed. 2. VCC Pharmacy and Trust R&D Office are collaborating on the prioritisation of research studies for set up and recruitment. **21 Aug 2024** 1. Additional Pharmacist resource in place (0.4WTE Band 7 from general Pharmacy budget); individual is new to trials and will take time to upskill. 2. Principal Pharmacist for Clinical Trials recruited with a start date 4th November 2024. 3. BioNTech funded posts in final stages of recruitment. 4. No material reduction in risk as throughput of new trials remains restricted and a backlog has developed. **23 Apr 2024** 1. VCC Pharmacy have made appointments to vacant posts, and staff have begun with the organisation during March/April 2024. 2. VCC Pharmacy are in the process of training new appointments to support trial setup and delivery. 3. VCC Pharmacy and Trust R&D Office meet weekly to discuss the priority trials and the progress in returning the pharmacy service to full capacity. 4. Trust R&D Office continue to work with the site-specific teams to compile trial prioritisation list to aid prioritise the work for VCC Pharmacy. 5. VCC Pharmacy and Trust R&D Office to review the core pharmacy team staffing to support study set up and recruitment at a future time point.	8	Closed	Adequate	Chief Pharmacist
2.	3251	Breach of confidential data when study participant data sent to Sponsor organisation via an unsecured electronic method.	18 Sep 2023	12	1. Staff ceased transmission of data until secure electronic portal in place and working. 2. Staff re-trained on Information Governance. 3. Staff training on use of secure electronic portal and importance of use. 4. Secure electronic transmission pathways to be set-up prior to recruitment of first participant for all future studies.	3	Closed	Adequate	Senior Research Nurse Manager

№	Risk ID	Risk Description	Date opened	Inherent Risk Score	Controls / Action Plan & Progress	Current / Target Risk Score	Status	Level of control	Lead
					5. Sponsor organisation informed, corrective and preventive action (CAPA) log completed with study file note shared with Sponsor and entered into Investigator Site File.				
3.	3250	Loss of minus-80 Celsius freezer integrity in Clinical Research Treatment Unit (CRTU).	28 Jun 2023	12	1. Immediate action to re-locate frozen samples to Welsh Blood Service (WBS) facilities. 2. Informed all sponsor organisations of freezer integrity loss and to arrange sample shipment. 3. Worked with freezer maintenance company on identifying fault and restarting freezer. 4. Updating sample management procedures, re-trained staff on processes, and ensuring timely shipment of samples to Sponsors, limiting numbers of samples on site. 5. Sponsor organisations informed, corrective and preventive action (CAPA) log completed with study file notes shared with Sponsors and entered into Investigator Site Files. 6. To collaborate with Welsh Blood Service (WBS) to implement a business continuity plan.	4	Closed	Adequate	Research Delivery Manager
4.	3249	Trial sub-investigator consented study participant without being signed off on delegation list or study training log.	11 Jul 2023	9	1. Having returned from maternity leave, Sub-Investigator re-instated on delegation logs and completing required training logs. 2. Principal Investigator(s) countersigning relevant delegation logs and training logs. 3. Sponsor organisation informed, corrective and preventive action (CAPA) log completed with study file note shared with Sponsor and entered into Investigator Site File. 4. Trust R&D Office regularly reminds all Principal Investigators of importance for all delegated staff to complete delegation logs and training logs. 5. Standard Operating Procedure to be updated to address re-instatement of delegation and study training on returning from extended leave.	3	Closed	Adequate	Research Delivery Manager

№	Risk ID	Risk Description	Date opened	Inherent Risk Score	Controls / Action Plan & Progress	Current / Target Risk Score	Status	Level of control	Lead
		-			6.				

RESEARCH, DEVELOPMENT & INNOVATION SUB COMMITTEE

Intellectual Property Policy

DATE OF MEETING	12 March 2025
PUBLIC OR PRIVATE REPORT	Public
IF PRIVATE PLEASE INDICATE REASON	NOT APPLICABLE - PUBLIC REPORT
REPORT PURPOSE	ENDORSE FOR APPROVAL
IS THIS REPORT GOING TO THE MEETING BY EXCEPTION?	NO
PREPARED BY	Sarah Townsend, Head of Research & Development. Rachel Granger, Senior Research Contracts Manager.
PRESENTED BY	Dr Jacinta Abraham, Executive Medical Director, and Board Lead for RD&I.
APPROVED BY	Jacinta Abraham, Executive Medical Director
EXECUTIVE SUMMARY	The Velindre University NHS Trust Intellectual Property (IP) Policy has undergone a scheduled review. Key changes to the policy include: • Updating the review period from two to three years. • The addition of Database rights to the definitions of Intellectual Property [IP] and Intellectual Property Rights [IPR].

	• Amendments to enhance the role of the Trust Research Service (i.e., Research & Development [R&D] Office) in contract negotiation. Additionally, references to outdated employment contract extracts have been removed, and various housekeeping amendment have been made to improve clarity. This revised Intellectual Property [IP] policy ensures the Trust's approach to IP management remains robust and compliant with the UK Policy Framework for Health and Care Research supporting innovations, protecting IP, and ensuring fair revenue sharing arrangements.

RECOMMENDATION / ACTIONS	Executive Management Board (EMB) is requested to review, discuss, and **ENDORSE FOR APPROVAL** this Policy.

GOVERNANCE ROUTE

List the Name(s) of Committee / Group who have previously received and considered this report:	**Date**
Executive Management Board	25 February 2025

SUMMARY AND OUTCOME OF PREVIOUS GOVERNANCE DISCUSSIONS

The governance cycle for this revised IP policy is planned as follows:

Meeting	**Meeting Date**
Executive Management Board	25 February 2025.
RD&I Sub-Committee	12 March 2025.

No feedback was received from the Executive Management Board prior to submission to RD&I Sub-Committee.

7 LEVELS OF ASSURANCE	
NOT APPLICABLE	
ASSURANCE RATING ASSESSED BY BOARD DIRECTOR/SPONSOR	Select Current Level of Assurance

APPENDICES	
1.	Intellectual Property [IP] policy with tracked changes.
2.	Intellectual Property [IP] policy.

1. SITUATION

The Executive Management Board is requested to discuss and endorse for approval the updated Intellectual Property (IP) Policy attached at Appendix 1. The policy ensures the Trust has a robust mechanism for identifying, protecting, and exploiting intellectual property arising from its employees' work, aligning with the UK Policy Framework for Health and Social Care Research.

2. BACKGROUND

Velindre University NHS Trust is committed to fostering innovation and protecting intellectual property arising from research, service delivery improvements, and training. Intellectual property [IP] includes novel ideas, discoveries, processes, and products that arise from the work of Trust employees, trainees, and collaborators. Protecting and managing IP is essential to ensure that innovations benefit patients, support the Trust's strategic goals, and foster partnerships with industry and academic institutions.

The UK Policy Framework for Health and Social Care Research requires NHS organisations to have appropriate mechanisms for identifying, protecting, and exploiting IP. This policy underpins the Trust's role as a leading research organisation and ensures that IP generated through research and innovation is managed effectively. The policy aligns with national and regional guidance on IP management and reflects the Trust's broader commitment to research, development, and innovation as outlined in the Trust's research strategies.

The review of the IP Policy was conducted to ensure continued alignment with evolving legal and regulatory frameworks, best practices, and the Trust's strategic priorities. The updated policy aims to provide clear guidance to staff, strengthen the role of the Trust Research Service (i.e., Research & Development [R&D] Office in IP management, and promote the fair distribution of revenue from the commercialisation of IP.

3. ASSESSMENT

The policy ensures the Trust has a robust mechanism for identifying, protecting, and exploiting intellectual property arising from its employees' work, aligning with the UK Policy Framework for Health and Social Care Research.

The policy was updated as it had reached the date for scheduled review.

The key revisions are:

- Review period extended from two to three years in accordance with Trust Policy on Policies.
- 'Database Right' added to definitions section and the explanatory appendix.
- Removal of outdated employment contract extract.
- References to R&D Department' replaced by RD&I Service or R&D Office as appropriate.
- Strengthened role of R&D Office in contract negotiation:
    - Non-Disclosure Agreements [NDAs] to be negotiated by the R&D Office.
    - Removed template Heads of Terms and language. Researchers must engage with R&D Office to ensure the negotiation of fair and reasonable IP arrangements with collaborators.
- Added further examples of activities where IP needs to be considered.
- Cross referencing of student IP provisions with the section on collaborative research projects.
- Updated the definition of 'Materials' to be more relevant to Trust researchers, including reference to donor blood and blood components.
- Clarification that Material Transfer Agreement [MTA] clauses can be incorporated into other agreements.
- Removal of references to AgorIP and All-Wales Intellectual Property Advisory Service.
- Housekeeping amendments to improve language clarity and presentation.

4. SUMMARY OF MATTERS FOR CONSIDERATION

The Executive Management Board are requested to review, discuss, and **ENDORSE FOR APPROVAL** the Policy.

5. IMPACT ASSESSMENT

TRUST STRATEGIC GOAL(S)	
Please indicate whether any of the matters outlined in this report impact the Trust's strategic goals: YES - Select Relevant Goals below	
If yes - please select all relevant goals: • Outstanding for quality, safety, and experience ☐ • An internationally renowned provider of exceptional clinical services that always meet, and routinely exceed expectations ☐ • A beacon for research, development, and innovation in our stated areas of priority ☒ • An established 'University' Trust which provides highly valued knowledge for learning for all. ☐ • A sustainable organisation that plays its part in creating a better future for people across the globe ☐	
RELATED STRATEGIC RISK - TRUST ASSURANCE FRAMEWORK (TAF) *For more information: STRATEGIC RISK DESCRIPTIONS*	10 - Governance
QUALITY AND SAFETY IMPLICATIONS / IMPACT	Yes -select the relevant domain/domains from the list below. Please select all that apply
	Safe ☐ Timely ☐ Effective ☐ Equitable ☐ Efficient ☐ Patient Centred ☐

	a) Research, development, and innovation are central to improving patient care and safety. Supporting innovation through robust Intellectual Property management ensures that new ideas, devices, and processes can be developed, protected, and translated into clinical practice. b) The implementation of an effective IP Policy supports staff in identifying and protecting IP, ensuring that innovations arising within the Trust contribute to improved treatment options, diagnostic tools, and patient outcomes, all while aligning with legal, ethical, and governance standards.
SOCIO ECONOMIC DUTY ASSESSMENT COMPLETED: *For more information:* *https://www.gov.wales/socio-economic-duty-overview*	Not required
	The Socio-economic Duty does not apply to this policy as it is an internal operational document concerning the management of intellectual property within the Trust. It does not involve a strategic decision that will significantly impact people experiencing socio-economic disadvantage. Neither does the policy directly affect patients, service users, or communities in terms of their socio-

TRUST WELL-BEING GOAL IMPLICATIONS / IMPACT	A Prosperous Wales - An innovative society that develops a skilled and well-educated population in an economy which generates wealth and provides employment opportunities
	If more than one Well-being Goal applies, please list below:
	The IP Policy supports the goal of A Prosperous Wales by fostering an innovative culture within the Trust, encouraging the development of a skilled workforce, and contributing to the wider economy through the protection and commercialisation of new ideas. It also aligns with A Healthier Wales by ensuring that innovative research and development lead to improved patient care and well-being.
	If more than one wellbeing goal applies, please list below: **Click or tap here to enter text**
FINANCIAL IMPLICATIONS / IMPACT	There is no direct impact on resources as a result of the activity outlined in this report.
	Source of Funding: **Choose an item** Please explain if 'other' source of funding selected: **Click or tap here to enter text** **Type of Funding:** **Choose an item** **Scale of Change** Please detail the value of revenue and/or capital impact: **Click or tap here to enter text** **Type of Change** **Choose an item** Please explain if 'other' source of funding selected:

	Click or tap here to enter text
EQUALITY IMPACT ASSESSMENT *For more information:* *https://nhswales365.sharepoint.com/sites/VEL_Intranet/SitePages/E.aspx*	Not required - please outline why this is not required
	Based on the information available on the Velindre University NHS Trust Intranet site (https://nhswales365.sharepoint.com/sites/VEL_Intranet/SitePages/E.aspx), the requirement for an EIA depends on whether the policy has the potential to impact individuals with protected characteristics under the Equality Act 2010, such as age, disability, gender, race, religion, sexual orientation, gender reassignment, pregnancy, and maternity. For the Intellectual Property (IP) Policy, the assessment is not required as there are no equality concerns because: 1. **Internal and Procedural Nature** – The policy primarily governs the internal management of intellectual property within the Trust. It does not directly affect service delivery to patients or public access to services. 2. **No Direct Impact on Individuals with Protected Characteristics** – The policy applies equally to all staff and is focused on processes for protecting and managing intellectual property arising from work undertaken within the Trust. 3. **Promotion of Fairness and Transparency** – The policy promotes fair recognition and revenue sharing for contributions made by staff members, regardless of their personal characteristics. The policy is operational in nature and applies equally to all staff, ensuring fairness, transparency, and support in the management and exploitation of intellectual property.

ADDITIONAL LEGAL IMPLICATIONS / IMPACT	There are no specific legal implications related to the activity outlined in this report.
	[In this section, explain in no more than 3 succinct points what the legal implications/ impact is or not (as applicable)].

6. RISKS

This section should indicate whether any matters addressed in the report carry a significantly increased level of risk for the Trust – and if so, the steps that will be taken to mitigate the risk - or if they will help to reduce a risk identified on a previous occasion.

ARE THERE RELATED RISK(S) FOR THIS MATTER	Choose an item
WHAT IS THE RISK?	*[Please insert detail here in 3 succinct points].*
WHAT IS THE CURRENT RISK SCORE	Insert Datix current risk score
HOW DO THE RECOMMENDED ACTIONS IN THIS PAPER IMPACT THIS RISK?	*[In this section, explain in no more than 3 succinct points what the impact of this matter is on this risk].*
BY WHEN IS IT EXPECTED THE TARGET RISK LEVEL WILL BE REACHED?	Insert Date
ARE THERE ANY BARRIERS TO IMPLEMENTATION?	Choose an item
	[In this section, explain in no more than 3 succinct points what the barriers to implementation are].
All risks must be evidenced and consistent with those recorded in Datix.	

APPENDIX 1. **Intellectual Property (IP) Policy – tracked changes version.**

APPENDIX 2. **Intellectual Property (IP) Policy – clean version.**

Ref: RD01

INTELLECTUAL PROPERTY (IP) POLICY

Executive Sponsor & Function:	Executive Medical Director and RD&I Board Lead
Document Author:	Head of Research & Development
Approved by:	Research, Development & Innovation Sub-Committee
Approval Date:	(TBA)
Date of Equality Impact Assessment:	27th February 2014
Equality Impact Assessment Outcome:	Approved
Review Date:	2028
Version:	07

Contents

1. INTRODUCTION

Intellectual Property (IP) is the term used to describe new ideas that result in the generation of some output such as a new device, diagnostic or therapeutic product document, design, or an improved way of working.

The core principles of the Policy relating to Intellectual Property is under pinned by the following three fundamental principles:

1. The management and exploitation of intellectual property must deliver benefits to patients and service users.
2. That industry has an important role to play in developing innovations.
3. That individuals who contribute intellectually to new ideas that generate an income to the Trust should be rewarded for their contributions.

2. POLICY STATEMENT

Velindre University NHS Trust recognises the importance of innovation and creativity as essential elements in the process of continual improvement. The UK Policy Framework for Health and Social Care Research https://www.hra.nhs.uk/planning-and-improving-research/policies-standards-legislation/uk-policy-framework-health-social-care-research/ places a duty on the Trust to have in place a mechanism for the exploitation of IP arising from its employees. Innovation in the NHS also occurs in the delivery of patient care and in the education and training of employees. The purpose of this document is to detail a policy for the effective management of IP within the Trust taking into account the principles referred to above and also arrangements with the Trust's academic and commercial partners.

3. SCOPE OF POLICY

This Policy applies to IP opportunities arising from activity involving:

- All staff that are full or part-time employees of the Trust where employment activity results in the generation of any form of IP either within the course of a working day or outside normal working hours and/or away from the place of work, where IP relates to their area of employment by the Trust. This includes IP generated in the course of education or training which is funded by the Trust, especially if the Trust also contributes towards creation of IP by, for example, acting as sponsor of the research in accordance with the UK Policy Framework for Health and Social care research.
- Staff with Trust contracts of employment whose payroll costs are partially or fully funded by another party (e.g. Academic Institution, Medical Charity and Government Department) unless the contract between the Trust and that party assigns ownership of the IP to that party.
- Academic staff of associated universities with honorary clinical contracts.
- Trainee professionals and students hosted by the Trust who are not also employees of the Trust who generate IP during the course of their training (IP

generated by students engaging in research for the Trust may be owned by the student, the institution with whom they are enrolled or the Trust, depending on the agreements between the student, the institution and the Trust.
- Independent providers of services who generate IP from research funded by the NHS are required to inform the appropriate party and share the benefits of its commercialisation. Where IP is assigned to the Trust, the Independent Provider of Services will benefit under the revenue sharing scheme of the Trust.

For individuals who hold an Honorary Contract with the Trust, the IP Policy of their substantive employer will take precedence over the Trust's policy unless circumstances (such as the Trust's or the Velindre University NHS Trust Charity's contribution to the creation of the IP for example where the honorary employee has utilised Velindre Charity funding, Trust equipment, consumables or the time during Trust funded sessions or of Trust-funded staff to create the IP) require negotiation to the contrary to ensure the Trust's contribution is fairly rewarded.

Trust staff seconded to another organisation or employees of another organisation hosted by the Trust under contract are subject to the terms defined in the contract between the Trust and that organisation.

Please note that the applicability of this IP Policy may be subject to a person's employment contract or any other terms upon which a person is engaged by the Trust.

4. AIMS & OBJECTIVES

In order to achieve its core objectives this Policy aims to ensure that:

- There is a good awareness and understanding of IP issues throughout the Trust.
- There is a process in place for disclosure, evaluation, management and exploitation of any IP generated by Trust employees which is timely, transparent and supportive.
- The responsibilities of staff and management are clear.
- The support role of the RD&I Service is clear.
- The ownership of IP related to the disclosure of an idea is established clearly at the outset by the RD&I Service.
- The ownership and management of IP arising from collaborative projects with other organisations, e.g. universities, is clear and supports innovation.
- There is a clear framework governing the ownership and management of the results and associated IP arising from collaborative research projects.
- The apportioning of revenue from any profits of commercialisation is clear and there is a process to implement revenue sharing.
- Potentially exploitable IP is protected appropriately.
- There is a transparent process to resolve any disputes.
- Income from IP owned by the Trust is used to improve patient care and service delivery.

5. ROLES AND RESPONSIBILITIES

5.1 Staff Responsibilities It is the responsibility of all Trust employees involved in the creation of IP to report any IP developments to the Trust's R&D Office in line with divisional policy and procedure and prior to any public disclosure outside the Trust (whether verbal or written)

Should employees fail to report any IP development to the Trust's R&D Office the key principles of this policy will apply retrospectively, unless public disclosure has invalidated the opportunity to protect IP. Potentially protectable IP should only be discussed outside the Trust within the strict confines of a reciprocal non-disclosure agreement which should be negotiated between the R&D Office and will be generally be between the Trust and the part to whom the IP, or idea which may generate IP, is to be disclosed.

5.2 The Executive Medical Director has the responsibility for IP Management and will keep the Trust's Board informed of all significant issues via the Research, Development & Innovation (RD&I) Sub-Committee or the Executive Management Board**.**

5.3 The Trust RD&I Sub-Committee undertakes the role of exploitation panel and is responsible for assessing newly identified IP and determining which exploitation route, if any, should be pursued. Recommendations from the exploitation panel will be passed to the Trust Board for approval.

5.4 The Trust Board has the final decision on which IP should be exploited based on the recommendations of the Trust RD&I Sub-Committee.

5.5 The Head of Research & Development is the nominated Trust IP manager. The post holder will be responsible for overseeing all IP projects and will act as the point of liaison between the Trust and any advisors engaged by the Trust and other stakeholders.

5.6 The Trust RD&I Service and R&D Office will provide advice and where appropriate signpost staff to other sources of information and support.

The role of the RD&I Service will be to:

- Maintain the Trust's IP policy.
- Ensure that new IP is recognised and treated appropriately with regard to confidentiality.
- Provide a contact point for Trust personnel seeking advice on IP.
- Increase the profile of IP and educate staff appropriately in the Trust, for example by facilitating awareness raising and training sessions for staff.
- Coordination with partners and national bodies in relation to IP management.
- Market and manage funding calls relating to innovation and IP.
- Where the RD&I Committee has identified an exploitation route the R&D Department will endeavour to secure the relevant resources to enable staff to develop their ideas and associated IP.

The role of the R&D Office will be to:

- Identify the most appropriate means of protecting the IP, determine the appropriate path to take advantage of the IP & raise awareness.
- Negotiate agreements where appropriate with third parties.

6. DEFINITION OF INTELLECTUAL PROPERTY (IP) AND INTELLECTUAL PROPERTY RIGHTS (IPR)

IP is intangible. It can be defined as the products of intellectual or creative activity in the form of novel ideas, innovation or research and development that can be given legal recognition of ownership. This ownership is a tradable commodity known as the intellectual property right (IPR). This can be a patent, copyright, database right, design rights, trademarks, know-how, as well as medical marketing authorisations and regulatory certifications (see Appendix 1). IPR can be assigned or licensed exclusively or non-exclusively. IP can be generated where R&D, innovation, delivery or management of care or other creative work is being undertaken.

During the application process for a patent, it is imperative that the invention documentation remains confidential. Prior disclosure of this information will render the invention non-patentable in almost all regions of the world.

While IP can and often does arise from formal research projects, it is not limited to the outputs of research studies and can be generated in many other ways. For example, IP may arise as a result of staff trying to find a solution to a problem, developing innovative teaching or training materials or designing a new device based on their experience while working with other staff and patients.

It should be noted that IP legislation is complicated and the scope of IP rights (what can be protected and what cannot be protected) is often a grey area. Members of staff are advised to contact the Trust RD&I Service at the earliest opportunity to discuss in more detail the relevance of IP protection to their ideas and any expression of those ideas. In order to ensure protection of the IP in your idea the idea must be recorded in permanent form.

More information about IP is available on the Intellectual Property Office website (www.ipo.gov.uk).

7. IMPLEMENTATION

This policy will be maintained by the R&D Office.

Please refer to section 5 further information in relation to the responsibilities in connection with this policy.

The policy will be available via the Trust Intranet Site and from the R&D Office. Where staff do not have access to the intranet their line manager must ensure that they have access to a copy of this policy.

The RD&I Sub-Committee will review the operation of this policy as required and at least every three years as set out in the Trust policy of Policies (GC01) https://nhswales365.sharepoint.com/sites/VEL_Intranet/SitePages/Governance-&-Communications.aspx.

8. POLICY COMPLIANCE

8.1 Identifying and Protecting IP

Staff at all levels need to be aware of the possibility that they may generate new IP during the course of their employment. The following are examples of activities where IP needs to be considered:

- A novel treatment
- A new diagnostic technique
- A new device
- A new drug or the new use of a drug
- Data, software, training material
- A treatment protocol
- New management system
- Research ideas
- A research protocol
- Guidelines, process maps and flowcharts, standard operating procedures and checklist

8.2 Ideas Disclosure

Velindre University NHS Trust RD&I Service has developed an “Ideas Disclosure Form” to be used by Velindre employees if they have an innovation that, as far as is known, is not in place elsewhere. A completed form should be submitted to the R&D Office for consideration by the RD&I Sub-Committee. The RD&I Sub-Committee will evaluate the potential of the IP and if appropriate create a plan for its management and exploitation.

The ideas disclosure form is attached in Appendix 2 and the general process for the disclosure of ideas in Appendix 3.

The Ideas Disclosure Form asks Velindre employees to provide information on their idea, explaining its originality/inventiveness, and how it can benefit the NHS and patients, either directly or indirectly.

In seeking to establish the originality/inventiveness of an idea, employees should review the overview of types of IP protection in Appendix 1 and, if the idea seems to fall into the category of a patentable invention, investigate current patents online before completing the Idea Disclosure Form. The following link will allow Velindre employees to do a preliminary patent search https://worldwide.espacenet.com/

Please note the RD&I Service is an official function of Velindre University NHS Trust. Therefore, any disclosure made to the RD&I Service including to its staff, e.g. through the Ideas Disclosure Form, is deemed as a confidential disclosure and will be kept confidential by the RD&I Service.

The Trust emphasises that staff should not disclose their idea to anyone apart from research collaborators with whom they are bound by a legally enforceable contract which includes provisions for confidentiality, as this might jeopardise subsequent IP protection.

Employees are urged to consult the Trust's R&D Office at the earliest possible stage if they have any questions about this and especially if they are uncertain about the implications of disclosing an idea to others.

8.3 Due diligence

When an idea or potential invention is notified to the RD&I Service, a process of due diligence will be carried out to identify all of the contributors, their employment status and their contribution to the idea/invention. Staff are asked to provide all records as necessary to facilitate this process. Incorrect identification of inventors may in some cases invalidate a patent, so it is important that all inventors are correctly identified.

8.4 Partnering with Universities or other organisations to develop IP

The Trust may partner with neighbouring universities' IP/commercialisation facilities to utilise their infrastructure and expertise. In this event both the inventor and the Trust will agree in clear terms the nature of the relationship with the partner university or other organisation. This agreement should be underpinned by three clear criteria:

- Where possible, Trust costs incurred in the development of the IP should be recovered before the benefits of commercialisation are shared with the inventor or other parties;
- That the development and commercialisation of the IP delivers benefits to patients/donors and the Trust;
- That the inventor(s) retain the rights to receive an appropriate level of income in the event that commercialisation of the IP generates downstream revenue..

8.5 Partnering with IP specialists

The Trust may also make use of external IP specialist's for advice on matters such as licensing, funding, legal, technical, spin-out to maximise new knowledge creation.

In the above circumstances, benefits to the licencing partner organisation will need to be agreed, for example a percentage of revenue in the event that the IP generates future revenues and/or profits. To achieve this a formal licensee partnership agreement will be put in place with the external specialist organisation if the Trust intends to use or commercialise the IP in partnership.

This can be useful in helping to build long-term, productive strategic relationships between the organisations concerned.

8.6 Ownership of IP

The Trust has right of ownership to all IP produced by Trust employees in the course of their normal duties. Employees have an obligation to inform the Trust about IP generated as a result of their activities and must not sell, assign or otherwise trade IP without Trust agreement.

Where the potential for new IP can be identified in advance, steps will be taken by the Trust to ensure that contracts/agreements contain appropriate terms and conditions to clearly indicate the assignment of intellectual property rights (IPR) and the distribution of benefits arising from the IP.

Where such agreements are not in place, or where organisations have differing agreements, the Trust will negotiate an appropriate share of benefit in accordance with the Trust procedure.

Where Velindre University NHS Trust chooses not to exploit IP arising from the work of its employees, it will, in most cases (subject to no outstanding claims such as from a funding body), assign the IP back to the inventor(s) who may wish to pursue its further development. In return for the assignment, the inventor(s) may be asked to share a small percentage of any income generated with the Trust. Additionally, the Trust will retain the right to use the work at no cost for its own non-commercial purposes.

Where IP is generated by students of higher education institutions the IP will be owned by the student or, if the student and the institution have agreed to this, by the institution. This agreement may occur, for example, by provision in the university regulations accepted by the student, or the terms of a particular funding scheme. Where Velindre University NHS Trust provides support for such research, and there is an opportunity to seek cost recovery or an appropriate share of benefit the Trust will do so. Where appropriate, any such agreement should be negotiated by the relevant parties at the outset.

8.7 Staff Rewards Policy

Velindre University NHS Trust wish to encourage full participation by our employees in the creation and commercial exploitation of IP when it has not been generated as part of their normal duties. This policy therefore lays out a set of conditions under which staff can receive tangible rewards as a result of the intellectual contributions to the generation of IP which is commercialised. This can be done in two ways:

1. To share revenue where the Trust receives any profits from IP exploitation.
2. To allow staff to participate in and hold equity in spin-out companies.

8.7.1 Revenue Sharing from IP Exploitation

In all cases the shared revenue will be the net income attributed [by the Trust] to an IP

right minus any costs incurred by the Trust in bringing the product to market. The Trust, exercising probity, will put robust systems in place to administer and calculate income arising from IP commercialisation. Revenue will be shared between the Trust and the inventor(s) according to the revenue sharing formula. In cases where several staff have been involved in generating the IP, the proportion of revenue allocated to inventors will be divided between them evenly unless it can be demonstrated and agreed that the contribution of individuals varies significantly.

The Trust will ensure that any profits arising from the exploitation of IP, which have been disclosed by and generated by a member of staff identified to the R&D Department, are shared on the following terms:

- In all cases the shared revenue will be the net of any remaining monies after reasonable protection and exploitation costs have been deducted e.g. the costs incurred by the researcher, the clinical directorate within which the research work took place, patenting fees or other legal costs, or marketing costs.
- Where the employee produces more than one item of IP, the income from subsequent IP - unless the subsequent IP is unrelated - will be aggregated with that from the first IP for the purpose of determining the employee's share according to the sliding scale of net revenue.
- Where there is a contracted agreement with a funding sponsor to share revenue from successful exploitation of IP arising from research funded by that sponsor, the cumulative net revenue to the Trust is the income from exploitation remaining after deduction of the sponsor's share and other costs as above.

8.7.2 Velindre University NHS Trust Revenue Sharing

Consideration has been given to the revenue sharing policies of University Health Boards/Trusts and Universities in Wales and is reflected in the following revenue sharing schedule:

Cumulative net income	Inventor	Department	R&D	Trust
First £10K	100%	0%	0%	0%
£10K-£20K	60%	20%	10%	10%
£20K-£100K	50%	20%	15%	15%
£100K-£250K	40%	20%	20%	20%
Over £250K	35%	20%	15%	30%

9. COLLABORATIVE RESEARCH PROJECTS

The Trust actively encourages its staff to work collaboratively with other organisations to promote research and innovation. It is widely recognised that the issue of IP in

collaborative research/innovation can be complex. The Trust aims to provide a framework whereby those that generate ideas are able to use them and are rewarded for their efforts whilst ensuring that the appropriate level of control is in place to ensure that any IP arising from collaborative research always benefits patients and donors and facilitates the collaborative process.

It is therefore important before embarking on a collaborative venture that all parties, the researchers, contract managers and funders, agree the principles of the collaboration. Researchers should engage with the R&D Office at the earliest opportunity to ensure that fair and reasonable IP arrangement which accord with this policy are negotiated.

10. SHARED MATERIALS

Materials are defined as biological materials, most often clinical biological samples derived from patients participating in research studies and donor blood and blood components. When such materials (whether or not they are “relevant material” as defined in the Human Tissue Act 2004) are distributed outside the Trust to researchers or for use in a research project they should be subject to a Material Transfer Agreement (MTA) which will be managed via the Trust’s R&D Office.

This agreement should define the limitations of use of the material and recognises the interest in the IP that may arise from its use. This agreement must be in place prior to distribution and use of the material. The use of trademarks and design rights associated with the aforementioned materials should also be the subject of this agreement. If the materials are intended to be used in a collaborative research project, including projects which require research approval via the Integrated Research Application System and consequently use the model agreements developed for use in such projects, material transfer clauses are likely to be incorporated into wider collaboration agreements.

11. RESOLUTION OF DISPUTES

Where there is dispute about the inventor(s) of IP, dated written records associated with the generation of the IP will be used to establish the inventor(s) of the IP and to determine their level of contribution/remuneration. In the absence of documentary evidence, the Chief Executive of the Trust shall decide, taking such professional advice as appropriate and this decision will be final.

12. NON COMPLIANCE

If any Trust employee fails to comply with this policy, the matter may be dealt with in accordance with the Trusts Disciplinary Policy. The action taken will depend on the individual circumstances and will be in accordance with the appropriate workforce and organisational development policies.

13. TRAINING

Whilst there are no formal training programmes in place to ensure implementation of this policy, each Executive Director/Divisional Director and General/Departmental Manager must ensure that managers and all staff, clinical and non-clinical, are made aware of the policy provisions and that they are adhered to at all times.

14. EQUALITY

The Trust is committed to ensuring that, as far as is reasonably practicable, the way it provides services to the public and the way it treats its Employees reflects their individual needs and does not discriminate against individuals or groups.

The Trust has undertaken an Equality Impact Assessment and received feedback on this policy and the way it operates. The Trust wanted to know of any possible or actual impact that this procedure may have on any groups in respect of gender (including maternity and pregnancy as well as marriage or civil partnership issues) race, disability, sexual orientation, Welsh language, religion or belief, transgender, age or other protected characteristics.

The assessment found that there was no impact to the equality groups mentioned. Where appropriate the Trust will make plans for the necessary actions required to minimise any stated impact to ensure that it meets its responsibilities under the equalities and human rights legislation

15. GETTING HELP

For further information on this Policy all Velindre University NHS Trust staff should contact the Velindre University NHS Trust R&D Department using the email address Velindre.R&DOffice@wales.nhs.uk.

16. REFERENCES

- Welsh Assembly Government, 'Intellectual Property and Innovation in Health care in Wales' – A Framework and Guidance on the Management of Intellectual Property in the NHS in Wales, February 2005
- The UK Policy Framework for Health and Social Care Research https://www.hra.nhs.uk/planning-and-improving-research/policies-standards-legislation/uk-policy-framework-health-social-care-research/
- GC01 Policy and Procedure for the Management of Trust Wide Policies and Other Trust Wide Written Control Documents
- https://nhswales365.sharepoint.com/sites/VEL_Intranet/SitePages/Governance-&-Communications.aspx

17. ACKNOWLEDGEMENTS

- Abertawe Bro Morgannwg University Health Board R&D Department

APPENDIX 1 - INTELLECTUAL PROPERTY (IP) PROTECTION

This appendix includes a very brief overview on some aspects of IP protection. For more detail please consult the Intellectual Property Office website "types of IP" section www.ipo.gov.uk/types.htm.

This information is provided for guidance purposes only and is not intended to constitute a definitive or complete statement of the law on IP, nor is any part of it intended to constitute legal advice for any specific situation.

Know-how

“Know how” rights arise automatically and do not require registration. Know-how (also known as a "trade secret") is any information that is not in the public domain which has an assumed value. Know-how is often the most valuable of all IP assets and rights arise automatically with no need for registration. For example, it can be the knowledge about how to perform a procedure or to create a product or process. Know-how can be identified and protected by a Non-Disclosure Agreement (NDA) agreement (also known as Confidential Disclosure Agreements, CDA). When working with other parties, NDAs can be reciprocal agreements whereby the boundaries of confidential information that is disclosed and received is identified and obligations on both receiving and disclosing parties are detailed. A template NDA may be obtained from the Trust R&D Department. Know-how and confidential information are not capable of assignment as property rights but a formal information transfer coupled with a non-use and secrecy agreement can have the same effect. They persist indefinitely, as long as they remain covered by the terms of a NDA.

Copyright

Copyright rights arise automatically and do not require registration. Copyright covers a wide range of works including written and graphical information such as leaflets, articles, assessment tools, training packs, databases, computer software, “Apps” and films/videos, drawings and the 2-D representation of 3-D structures. Copyright is an automatic unregistered right that subsists if the work is "original". The requirements for originality are low. Therefore it is best to assume that copyright will subsist in all written, graphic or photographic works generated by staff.

It is advisable to attach a statement to any works such as: Copyright Velindre University NHS Trust Date XX. All rights reserved. Not to be reproduced in whole or in part without the permission of the copyright owner. However, you may decide to designate certain areas of activity for which permission does not have to be obtained. For example "non-for-profit organisations such as NHS Health Boards and Trusts, may reproduce this work solely for the purposes of teaching or further non-commercial research. In all other circumstances the permission of the Trust must be obtained".

Patents

Patents need to be registered to attract protection. Patents can be used to protect "technical" inventions that are new and have a utility. The vast majority of ideas will have potential utility. In Europe and the majority of countries in the world "new" means that all of the features of the invention must not have been made available to the public in a single disclosure anywhere in the world prior to the patent filing date. A public disclosure can be written, verbal or by any other means (e.g. journals, internet, meetings, posters, etc) and could merely be the result of a conversation between friends. To qualify as a patentable invention the idea must also not be obvious. The assessment of what is obvious is a complex area of patent law and in the first instance staff are advised against concerning themselves with this criterion. In the UK, some inventions are specifically excluded from patenting where those inventions consist entirely of methods of treatment by surgery or therapy or diagnostic methods. However, these inventions are patentable in other countries, notably the USA.
Excluded inventions are also a complex area of patent law and staff are advised that if they think they have an invention which lies in an excluded category to please consult the Trust R&D Department in the first instance. However, it is best not to assume an invention is excluded in the first instance.

Design Rights

Design rights arise automatically and do not require registration. Design Rights protect against the copying of the shape or configuration of an article. Design Rights may exist in addition to other forms of protection offered by patents or copyright.

The "Design Right"

The "unregistered" Design Right as it is known, similar to copyright, is an automatic right and can last up to fifteen years. It can protect the 3D features of an article, internal and external features, but there are a number of exclusions for example where the article is dependent on another article the so-called “must-fit, must match" exclusion. A surgical instrument could be protected by this right. However, unregistered design rights are generally considered to be weak IP rights and often stronger rights such as patents are sought, at least to improve levels of protection. Given the particular requirement of this “niche” aspect of IP law it is best in the first instance not to assume that the design right will protect a given article.

Registered Design Rights

Both UK and European law provide for registered design rights which last up to 25 years. Registration is required to attract protection. Registered design rights protect the appearance of a product, for example its shape, colour or texture of materials. For example, a new design of surgical gown or a patient's pillow could be the subject of a registered design right.

Trade marks

A trademark is a sign or symbol that is used to distinguish a product or service of one undertaking (e.g. a company or organisation, such as an NHS organisation) from another undertaking. Trademarks need to be registered to attract protection. Trademarks can protect words, logos, shapes, colours and even smells (e.g. the name “Coca Cola” and also the shape of the Coca Cola bottle are registered trademarks). Trademarks are the IP right that protect brands. They can last forever, providing renewal fees are paid.

Database right

A database means a collection of independent works, data or other materials which are arranged in a systematic or methodical way and are individually accessible by electronic or other means. There are two types of intellectual property protection for databases: database right and copyright. Both are automatic, unregistered rights that allow the owner to control certain uses of their databases.

Copyright protects the selection or arrangement of material in a database where this is original (i.e. creative). Database right protects the contents of a database. A database does not have to be original for it to qualify for database right, but there needs to have been a substantial investment in obtaining, verifying or presenting the contents of the database.

Database right is based on the European Community Directive 96/9 on the legal protection of databases. This was implemented in the UK by the Copyright and Rights in Databases Regulations 1997, which remain in force as ‘retained EU law’ with amendments following the UK’s departure from the EU. The maker of a database must have a connection with the UK (or the European Economic Area if the right arose before 31 December 2020). Databases created from 2021 onwards are only protected under UK law.

Database right lasts for 15 years from the end of the calendar year in which the making of the database was completed. Any substantial change to the contents of a database which can be considered to be a substantial new investment qualifies the database resulting from that investment for its own term of protection.

Appendix 2 – Innovative Ideas Disclosure Form

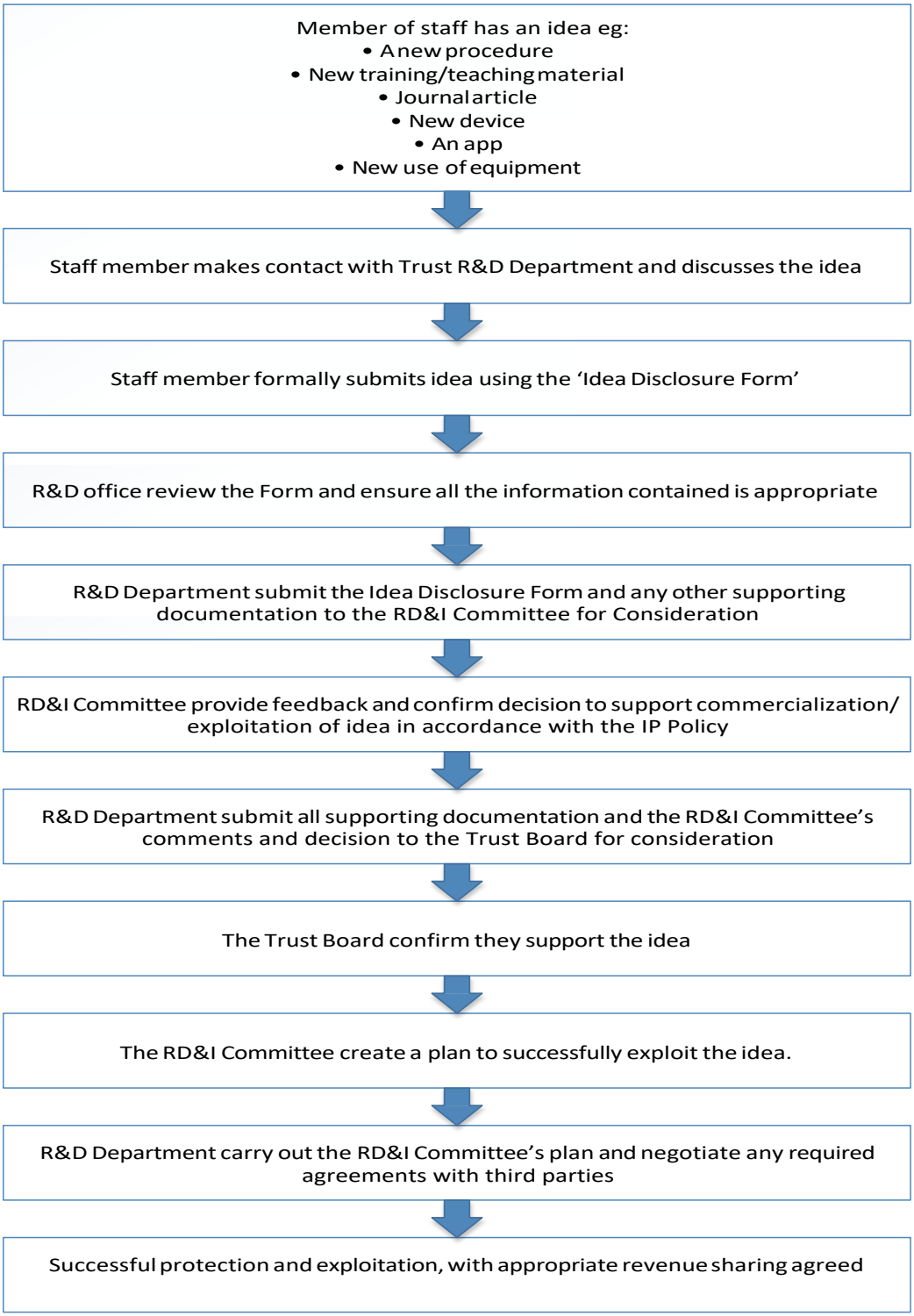
INNOVATIVE IDEAS DISCLOSURE FORM

Full Name	
Role	
Department	
Status of Employment	
The name of any collaborating individuals or parties	
Title of the project (max 60 characters)	
Idea Summary (Maximum 200 words)	
Summary of potential benefits to patients/health service (Maximum 200 words)	
What were the results of your preliminary patent	

search? A free patent search can be undertaken using the following link https://worldwide.espacenet.com/	
Any other relevant information (max 200 words)	

If applicable please include separately any supporting drawings or schematics to this application.

Appendix 3 - General Process for the Disclosure of Ideas



Ref: RD01

INTELLECTUAL PROPERTY (IP) POLICY

Executive Sponsor & Function:	Executive Medical Director and RD&I Board Lead
Document Author:	Head of Research & Development
Approved by:	Research, Development & Innovation Sub~~-~~ Committee
Approval Date:	~~28th February 2023~~ (TBA)
Date of Equality Impact Assessment:	27th February 2014
Equality Impact Assessment Outcome:	Approved
Review Date:	~~February~~ 2025~~8~~
Version:	0~~7~~6

Contents

1. INTRODUCTION

Intellectual Property (IP) is the term used to describe new ideas that result in the generation of some output such as a new device, diagnostic or therapeutic product document, design, or an improved way of working.

The core principles of the Policy relating to Intellectual Property is under pinned by the following three fundamental principles:

1. The management and exploitation of intellectual property must deliver benefits to patients and service users.
2. That industry has an important role to play in developing innovations.
3. That individuals who contribute intellectually to new ideas that generate an income to the Trust should be rewarded for their contributions.

2. POLICY STATEMENT

Velindre University NHS Trust recognises the importance of innovation and creativity as essential elements in the process of continual improvement. The UK Policy Framework for Health and Social Care Research https://www.hra.nhs.uk/planning-and-improving-research/policies-standards-legislation/uk-policy-framework-health-social-care-research/ places a duty on the Trust to have in place a mechanism for the exploitation of IP arising from its employees. Innovation in the NHS also occurs in the delivery of patient care and in the education and training of employees. The purpose of this document is to detail a policy for the effective management of IP within the Trust taking into account the principles referred to above and also arrangements with the Trust's academic and commercial partners.

3. SCOPE OF POLICY

This Policy applies to IP opportunities arising from activity involving:

- All staff that are full or part-time employees of the Trust where employment activity results in the generation of any form of IP either within the course of a working day or outside normal working hours and/or away from the place of work, where IP relates to their area of employment by the Trust. This includes IP generated in the course of education or training which is funded by the Trust, especially if the Trust also contributes towards creation of IP by, for example, acting as sponsor of the research in accordance with the UK Policy Framework for Health and Social care research.
- Staff with Trust contracts of employment whose payroll costs are partially or fully funded by another party (e.g. Academic Institution, Medical Charity and Government Department) unless the contract between the Trust and that party assigns ownership of the IP to that party.
- Academic staff of associated universities with honorary clinical contracts.
- Trainee professionals and students hosted by the Trust who are not also employees

of the Trust who generate IP during the course of their training (IP generated by students engaging in research for the Trust may be owned by the student, the institution with whom they are enrolled or the Trust, depending on the agreements between the student, the institution and the Trust.

- Independent ~~P~~providers of ~~S~~services who generate IP from research funded by the NHS are required to inform the appropriate party and share the benefits of its commercialisation. Where IP is assigned to the Trust, the Independent Provider of Services will benefit under the revenue sharing scheme of the Trust.

- For individuals who hold an Honorary Contract with the Trust, the IP Policy of their substantive employer will take precedence over the Trust's policy unless circumstances (such as the Trust's or the Velindre University NHS Trust Charity's contribution to the creation of the IP for example where the honorary employee has utilised Velindre Charity funding, Trust equipment, consumables or the time during Trust funded sessions or of Trust-funded staff to create the IP) require negotiation to the contrary to ensure the Trust's contribution is fairly rewarded.

- Trust staff seconded to another organisation or employees of another organisation hosted by the Trust under contract are subject to the terms defined in the contract between the Trust and that organisation.

Please note that the applicability of this IP Policy may be subject to a person's employment contract or any other terms upon which a person is engaged by the Trust.

4. AIMS & OBJECTIVES

In order to achieve its core objectives this Policy aims to ensure that:

- There is a good awareness and understanding of IP issues throughout the Trust.
- There is a process in place for disclosure, evaluation, management and exploitation of any IP ~~uncovered~~ generated by Trust employees which is timely, transparent and supportive.
- The responsibilities of staff and management are clear.
- The support role of the R~~&~~D&I Service ~~Departments~~ is clear.
- The ownership of IP related to the disclosure of an idea is established clearly at the outset by the R~~&~~D&I Service ~~Department~~.
- The ownership and management of IP arising from collaborative projects with other organisations, e.g. universities, is clear and supports innovation.
- There is a clear framework governing the ownership and management of the results and associated IP arising from collaborative research projects.
- The apportioning of revenue from any profits of commercialisation is clear and there is a process to implement revenue sharing.
- Potentially exploitable IP is protected appropriately.
- There is a transparent process to resolve any disputes.
- Income from IP owned by the Trust is used to improve patient care and service delivery.

5. ROLES AND RESPONSIBILITIES

~~5.~~ 5.1

5.1 **Staff Responsibilities** It is the responsibility of all Trust employees involved in the creation of IP to report any IP developments to the Trust's R&D ~~Department~~ Office in line with divisional policy and procedure and prior to any public disclosure outside the Trust (whether verbal or written)

Should employees fail to report any IP development to the Trust's R&D ~~Department~~ Office the key principles of this policy will apply retrospectively, unless public disclosure has invalidated the opportunity to protect IP. ~~Discussion of p~~Potentially protectable IP should only be discussed outside the Trust within the strict confines of a reciprocal non-disclosure agreement which should be negotiated between the R&D Office and will be generally be between the Trust and the part to whom the IP, or idea which may generate IP, is to be disclosed.

5.2

~~5.2~~ **The Executive Medical Director** has the responsibility for IP Management and will keep the Trust's Board informed of all significant issues via the Research, Development & Innovation (RD&I) Sub~~-~~Committee or the Executive Management Board**.**

~~5.3~~ 5.3 **The Trust RD&I Sub~~-~~Committee** undertakes the role of exploitation panel and is responsible for assessing newly identified IP and determining which exploitation route, if any, should be pursued. Recommendations from the ~~E~~exploitation ~~P~~panel will be passed to the Trust Board for approval.

~~5.4~~ 5.4 **The Trust Board** has the final decision on which IP should be exploited based on the recommendations of the Trust RD&I Sub~~-~~Committee.

~~5.5~~ 5.5 **The Head of Research & Development** is the nominated Trust IP manager. The post holder will be responsible for overseeing all IP projects and will act as the point of liaison between the Trust and any ~~All-Wales Intellectual Property Advisory Service~~advisors engaged by the Trust and other stakeholders.

~~• Ensure that new IP is recognised and treated appropriately with regard to confidentiality~~
~~• Identify the most appropriate means of protecting the IP determine the appropriate path to take advantage of the IP & raise awareness.~~

~~5.6~~ 5.6 **The Trust R~~&~~D&I Service and R&D Office ~~Department~~** will provide advice and where appropriate signpost staff to other sources of information and support.

The role of the R~~&~~D&I ~~Department~~Service will be to:

- Maintain the Trust's IP policy.
- Ensure that new IP is recognised and treated appropriately with regard to confidentiality.
- Provide a contact point for Trust personnel seeking advice on IP.
- Increase the profile of IP and educate staff appropriately in the Trust, for example by facilitating awareness raising and training sessions for staff.
- Coordination with partners and national bodies in relation to IP management.
- Market and manage funding calls relating to innovation and IP.
- Where the RD&I Committee has identified an exploitation route the R&D Department will endeavour to secure the relevant resources to enable staff to develop their ideas and associated IP.

The role of the R&D Office will be to:

- Identify the most appropriate means of protecting the IP, determine the appropriate path to take advantage of the IP & raise awareness.
- Negotiate agreements where appropriate with third parties.

6. DEFINITION OF INTELLECTUAL PROPERTY (IP) AND INTELLECTUAL PROPERTY RIGHTS (IPR)

IP is intangible. It can be defined as the products of intellectual or creative activity in the form of novel ideas, innovation or research and development that can be given legal recognition of ownership. This ownership is a tradable commodity known as the intellectual property right (IPR). This can be a patent, copyright, database right, design rights, trademarks, know-how, as well as medical marketing authorisations and regulatory certifications (see Appendix 1). IPR can be assigned or licensed exclusively

or non--exclusively. IP can be generated where R&D, innovation, delivery or management of care or other creative work is being undertaken.

During the application process for a patent, it is imperative that the invention documentation remains confidential. Prior disclosure of this information will render the invention non-patentable in almost all regions of the world.

While IP can and often does arise from formal research projects, it is not limited to the outputs of research studies and can be generated in many other ways. For example, IP may arise as a result of staff trying to find a solution to a problem, developing innovative teaching or training materials or designing a new device based on their experience while working with other staff and patients.

It should be noted that IP legislation is complicated and the scope of IP rights (what can be protected and what cannot be protected) is often a grey area. Members of staff are advised to contact the Trust R&D&I ServiceDepartment at the earliest opportunity to discuss in more detail the relevance of IP protection to their ideas and any expression of those ideas. In order to ensure protection of the IP in your idea the idea must be recorded in permanent form.

More information about IP is available on the Intellectual Property Office website (www.ipo.gov.uk).

7. IMPLEMENTATION

This policy will be maintained by the R&D Office.

Please refer to section 5 further information in relation to the responsibilities in connection with this policy.

The policy will be available via the Trust Intranet Site and from the R&D Office. Where staff do not have access to the intranet their line manager must ensure that they have access to a copy of this policy.

The RD&I Sub-Committee will review the operation of this policy as required and a. At least every two three years as set out in the Trust policy of Policies (GC01) https://nhswales365.sharepoint.com/sites/VEL_Intranet/SitePages/Governance-&-Communications.aspx.

8. POLICY COMPLIANCE

8.1 Identifying and Protecting IP

Staff at all levels need to be aware of the possibility that they may generate new IP during the course of their employment. The following are examples of activities where IP needs to be considered:

- A novel treatment

- A new diagnostic technique

- ~~A novel treatment~~
- ~~A new diagnostic technique~~

- A new device
- A new drug or the new use of a drug
- ~~Use of d~~Data, software, training material
- A treatment protocol
- New management system
- Research ideas
- A research protocol
- Guidelines, process maps and flowcharts, standard operating procedures and checklist

8.2 Ideas Disclosure

Velindre University NHS Trust R~~&~~D&I ~~Department~~Service has developed an "Ideas Disclosure Form" to be used by Velindre ~~E~~employees if they have an innovation that, as far as is known, is not in place elsewhere. A completed form should be submitted to the R&D ~~Department~~ Office for consideration by the RD&I Sub-Committee. The RD&I Sub-Committee will evaluate the potential of the IP and if appropriate create a plan for its management and exploitation.

The ideas disclosure form is attached in ~~a~~Appendix ~~3~~2 and the general process for the disclosure of ideas in ~~a~~Appendix ~~4~~3.

The Ideas Disclosure Form asks Velindre employees to provide information on their idea, explaining its originality/inventiveness, and how it can benefit the NHS and patients, either directly or indirectly.

In seeking to establish the originality/inventiveness of an idea, employees should review the overview of types of IP protection in Appendix 1 and, if the idea seems to fall into the category of a patentable invention, investigate current patents online before completing the Idea Disclosure Form. The following link will allow Velindre employees to do a preliminary patent search https://worldwide.espacenet.com/

Please note the R~~&~~D&I Service~~Department~~ is an official function of Velindre University NHS Trust. Therefore, any disclosure made to the R~~&~~D&I ~~Department~~Service including to its staff, e.g. through the Ideas Disclosure Form, is deemed as a confidential disclosure and will be kept confidential by the R~~&~~D&I Service~~Department~~.

The Trust emphasises that staff should not disclose their idea to anyone apart from research collaborators with whom they are bound by a ~~viable~~ legally enforceable contract which includes provisions for confidentiality, as this might jeopardise subsequent IP protection.

Employees are urged to consult the Trust's R&D ~~Department~~ Office at the earliest possible stage if they have any questions about this and especially if they are uncertain about the implications of disclosing an idea to others.

8.3 Due diligence

When an idea or potential invention is notified to the R~~&~~D&I ~~Department~~Service, a process of due diligence will be carried out to identify all of the contributors, their employment status and their contribution to the idea/invention. Staff are asked to provide all records as necessary to facilitate this process. Incorrect identification of inventors may in some cases invalidate a patent, so it is important that all inventors are correctly identified.

8.4 Partnering with Universities or other organisations to develop IP

The Trust may partner with ~~its~~ neighbouring universitiesy~~'s~~ IP/commercialisation facilitiesy~~s~~ to utilise their infrastructure and expertise. In this event both the inventor and the Trust will agree in clear terms the nature of the relationship with the partner university or other organisation. This agreement should be underpinned by three clear criteria:

- Where possible, Trust costs incurred in the development of the IP should be recovered before the benefits of commercialisation are shared with the inventor or other parties;
- That the development and commercialisation of the IP delivers benefits to patients/donors and the Trust;
- That the inventor(s) retain the rights to receive an appropriate level of income in the event that commercialisation of the IP generates downstream revenue..

8.5 Partnering with IP specialists

The Trust may also make use of external IP specialist's for advice on matters such as licensing, funding, legal, technical, spin-out to maximise new knowledge creation.

In the above circumstances, benefits to the licencing partner organisation will need to be agreed, for example a percentage of revenue in the event that the IP generates future revenues and/or profits. To achieve this a formal licensee partnership agreement will be put in place with the external specialist organisation if the Trust intends to use or commercialise the IP in partnership.~~..~~

This can be useful in helping to build long-term, productive strategic relationships between the organisations concerned.

8.6 Ownership of IP

The Trust has right of ownership to all IP produced by Trust employees in the course of their normal duties. Employees have an obligation to inform the Trust about IP generated as a result of their activities and must not sell, assign or otherwise trade IP without Trust agreement.
~~(see appendix 2 for an extract from the Trust Contract of Employment.)~~

Where the potential for new IP can be identified in advance, steps will be taken by the Trust to ensure that contracts/agreements contain appropriate terms and conditions to clearly indicate the assignment of intellectual property rights (IPR) and the distribution of benefits arising from the IP.

Where such agreements are not in place, or where organisations have differing agreements, the Trust will negotiate an appropriate share of benefit in accordance with the Trust procedure.

Commented [CC1]: Senior Research Contracts Manager: We have removed the reference to the contract of employment and the extract previously attached for several reasons:
1.The Trust's ownership is not dependent on the contract of employment but arises by operation of law.
2.The extract was out of date.
3. We run the risk of further amendments being made to the contract prior to the next review of this policy which would not come to the attention of the author.
4.Built in obsolescence is avoided.
5.The extract was from the AfC contract of employment - many staff not covered by this contract (ie medical staff) may create IP in the course of their duties.

Where Velindre University NHS Trust chooses not to exploit IP arising from the work of its employees, it will, in most cases (subject to no outstanding claims such as from a funding body), assign the IP back to the inventor(s) who may wish to pursue its further development. In return for the assignment, the inventor(s) may be asked to share a small percentage of any income generated with the Trust. Additionally, the Trust will retain the right to use the work at no cost for its own non-commercial purposes.

Where IP is generated by students of higher education institutions the IP will be owned by the student or, if the student and the institution have agreed to this, by the institution. This agreement may occur, for example, by provision in the university regulations accepted by the student, or the terms of a particular funding scheme. Where Velindre University NHS Trust provides support for such research, and there is an opportunity to seek cost recovery or an appropriate share of benefit the Trust will do so. Where appropriate, any such agreement should be negotiated by the relevant parties at the outset.

8.7 Staff Rewards Policy

Velindre University NHS Trust wish to encourage full participation by our employees in the creation and commercial exploitation of IP when it has not been generated as part of their normal duties. This policy therefore lays out a set of conditions under which staff can receive tangible rewards as a result of the intellectual contributions to the generation of IP which is commercialised. This can be done in two ways:

1. To share revenue where the Trust receives any profits from IP exploitation.
2. To allow staff to participate in and hold equity in spin-out companies.

~~8.7.1~~ 8.7.1 Revenue Sharing from IP Exploitation

In all cases the shared revenue will be the net income attributed [by the Trust] to an IP right minus any costs incurred by the Trust in bringing the product to market. The Trust, exercising probity, will put robust systems in place to administer and calculate income arising from IP commercialisation. Revenue will be shared between the Trust and the inventor(s) according to the revenue sharing formula. In cases where several staff have been involved in generating the IP, the proportion of revenue allocated to inventors will be divided between them evenly unless it can be demonstrated and agreed that the contribution of individuals varies significantly.

The Trust will ensure that any profits arising from the exploitation of IP, which have been disclosed by and generated by a member of staff identified to the R&D Department, are shared on the following terms:

- In all cases the shared revenue will be the net of any remaining monies after reasonable protection and exploitation costs have been deducted e.g. the costs incurred by the researcher, the clinical directorate within which the research work took place, patenting fees or other legal costs, or marketing costs.

- Where the employee produces more than one item of IP, the income from subsequent IP - unless the subsequent IP is unrelated - will be aggregated with that from the first IP for the purpose of determining the employee's share according to the sliding scale of net revenue.
- Where there is a contracted agreement with a funding sponsor to share revenue from successful exploitation of IP arising from research funded by that sponsor, the cumulative net revenue to the Trust is the income from exploitation remaining after deduction of the sponsor's share and other costs as above.

~~8.7.2~~ 8.7.2 Velindre University NHS Trust Revenue Sharing

Consideration has been given to the revenue sharing policies of University Health Boards/Trusts and Universities in Wales and is reflected in the following revenue sharing schedule:

Cumulative net income	Inventor	Department	R&D	Trust
First £10K	100%	0%	0%	0%
£10K-£20K	60%	20%	10%	10%
£20K-£100K	50%	20%	15%	15%
£100K-£250K	40%	20%	20%	20%
Over £250K	35%	20%	15%	30%

~~9~~9. COLLABORATIVE RESEARCH PROJECTS

The Trust actively encourages its staff to work collaboratively with other organisations to promote research and innovation. It is widely recognised that the issue of IP in collaborative research/innovation can be complex. The Trust aims to provide a framework whereby those that generate ideas are able to use them and are rewarded for their efforts whilst ensuring that the appropriate level of control is in place to ensure that any IP arising from collaborative research always benefits patients and donors and facilitates the collaborative process.

It is therefore important before embarking on a collaborative venture that all parties, the researchers, contract managers and funders, agree the principles of the collaboration. ~~These can be set out in a Heads of Terms (HoT) which allows research decision makers to identify in plain language what they regard as the key issues before instructing their lawyers to draw up a formal agreement (see Template Heads of Terms at Annex 5).~~ Researchers should engage with the R&D Office at the earliest opportunity to ensure that fair and reasonable IP arrangement which accord with this policy are negotiated.

Commented [CC2]: Senior Research Contracts Manager: Experienced research collaborators, whether universities or industry, and funders will have well developed expectations regarding IP issues and awareness of national template agreements. We have deleted these references to Heads of Terms because these are unlikely to be used in practice. The R&D Office has significant experience of negotiating IP arrangements which are fair, reasonable and in accordance with this policy.

~~10~~10. SHARED MATERIALS

Materials are defined as ~~equipment, reagents and~~ biological materials, most often clinical biological samples derived from patients participating in research studies and donor blood and blood components. ~~including cell lines, tissues, bacterial strains, plasmids and viruses.~~ When such materials (whether or not they are "relevant material" as defined in the Human Tissue Act 2004) are distributed outside the Trust to ~~other~~ researchers or for use~~d~~ in a research project they should be subject to a Material Transfer Agreement (MTA) which will be managed via the Trust's R&D ~~Department~~Office.

This agreement should define the limitations of use of the material and recognises the interest in the IP that may arise from its use. This agreement must be in place prior to distribution and use of the material. The use of trademarks and design rights associated with the aforementioned materials should also be the subject of this agreement. If the materials are intended to be used in a collaborative research project, including projects which require research approval via the Integrated Research Application System and consequently use the model agreements developed for use in such projects, material transfer clauses are likely to be incorporated into wider collaboration agreements.

~~11~~11. RESOLUTION OF DISPUTES

Where there is dispute about the inventor(s) of IP, dated written records associated with the generation of the IP will be used to establish the inventor(s) of the IP and to determine their level of contribution/remuneration. In the absence of documentary evidence, the Chief Executive of the Trust shall decide, taking such professional advice as appropriate and this decision will be final.

~~12~~12. NON COMPLIANCE

If any Trust employee fails to comply with this policy, the matter may be dealt with in accordance with the Trusts Disciplinary Policy. The action taken will depend on the individual circumstances and will be in accordance with the appropriate workforce and organisational development policies.

~~13~~13. TRAINING

Whilst there are no formal training programmes in place to ensure implementation of this policy, each Executive Director~~/, Divisional Director~~, and ~~Clinical Director, Divisional General/ Manager, Divisional Nurse, Departmental Manager, Head of Nursing and Head of Departments~~ must ensure that managers and all staff, clinical and non-clinical, are made aware of the policy provisions and that they are adhered to at all times.

Commented [CC3]: Senior Research Contract Manager: have brought this into line with the equivalent language used in policy GC03.

~~14~~14. EQUALITY

The Trust is committed to ensuring that, as far as is reasonably practicable, the way it

provides services to the public and the way it treats its Employees reflects their individual needs and does not discriminate against individuals or groups.

The Trust has undertaken an Equality Impact Assessment and received feedback on this policy and the way it operates. The Trust wanted to know of any possible or actual impact that this procedure may have on any groups in respect of gender (including maternity and pregnancy as well as marriage or civil partnership issues) race, disability,

sexual orientation, Welsh language, religion or belief, transgender, age or other protected characteristics.

The assessment found that there was no impact to the equality groups mentioned. Where appropriate the Trust will make plans for the necessary actions required to minimise any stated impact to ensure that it meets its responsibilities under the equalities and human rights legislation

~~15~~15. GETTING HELP

For further information on this Policy all Velindre University NHS Trust staff should contact the Velindre University NHS Trust R&D Department using the email address Velindre.R&DOffice@wales.nhs.uk.

~~AgorIP a company supported by Welsh Government, EU & Swansea University works with businesses, academics and NHS Wales providing IP advice and to bridge the gap between products and the market place www.agorip.com.~~

Commented [CC4]: Senior Research Contracts Manager: Funding for AgorIP ended in 2023 after the loss of European Regional Development Funding post-Brexit.

~~16~~16. REFERENCES

- Welsh Assembly Government, 'Intellectual Property and Innovation in Health care in Wales' – A Framework and Guidance on the Management of Intellectual Property in the NHS in Wales, February 2005
- The UK Policy Framework for Health and Social Care Research https://www.hra.nhs.uk/planning-and-improving-research/policies-standards-legislation/uk-policy-framework-health-social-care-research/
- GC01 Policy and Procedure for the Management of Trust Wide Policies and Other Trust Wide Written Control Documents
- https://nhswales365.sharepoint.com/sites/VEL_Intranet/SitePages/Governance-&-Communications.aspx

~~17~~17. ACKNOWLEDGEMENTS

- ~~-~~Abertawe Bro Morgannwg University Health Board R&D Department

APPENDIX 1 - INTELLECTUAL PROPERTY (IP) PROTECTION

This appendix includes a very brief overview on some aspects of IP protection. For more detail please consult the Intellectual Property Office website "types of IP" section www.ipo.gov.uk/types.htm.

This information is provided for guidance purposes only and is not intended to constitute a definitive or complete statement of the law on IP, nor is any part of it intended to constitute legal advice for any specific situation.

Know-how

“Know how” rights arise automatically and do not require registration. Know-how (also known as a "trade secret") is any information that is not in the public domain which has an assumed value. Know-how is often the most valuable of all IP assets and rights arise automatically with no need for registration. For example, it can be the knowledge about how to perform a procedure or to create a product or process. Know-how can be identified and protected by a Non-Disclosure Agreement (NDA) agreement (also known as Confidential Disclosure Agreements, CDA). When working with other parties, NDAs can be reciprocal agreements whereby the boundaries of confidential information that is disclosed and received is identified and obligations on both receiving and disclosing parties are detailed. A template NDA may be obtained from the Trust R&D Department. Know-how and confidential information are not capable of assignment as property rights but a formal information transfer coupled with a non-use and secrecy agreement can have the same effect. They persist indefinitely, as long as they remain covered by the terms of a NDA.

Copyright

Copyright rights arise automatically and do not require registration. Copyright covers a wide range of works including written and graphical information such as leaflets, articles, assessment tools, training packs, databases, computer software, “Apps” and films/videos, drawings and the 2-D representation of 3-D structures. Copyright is an automatic unregistered right that subsists if the work is "original". The requirements for originality are low. Therefore it is best to assume that copyright will subsist in all written, graphic or photographic works generated by staff.

It is advisable to attach a statement to any works such as: Copyright Velindre University NHS Trust Date XX. All rights reserved. Not to be reproduced in whole or in part without the permission of the copyright owner. However, you may decide to designate certain areas of activity for which permission does not have to be obtained. For example "non-for-profit organisations such as NHS Health Boards and Trusts, may reproduce this work solely for the purposes of teaching or further non-commercial research. In all other circumstances the permission of the ~~UHB~~ Trust must be obtained".

Patents

Patents need to be registered to attract protection. Patents can be used to protect "technical" inventions that are new and have a utility. The vast majority of ideas will have potential utility. In Europe and the majority of countries in the world "new" means that all of the features of the invention must not have been made available to the public in a single disclosure anywhere in the world prior to the patent filing date. A public disclosure can be written, verbal or by any other means (e.g. journals, internet, meetings, posters, etc) and could merely be the result of a conversation between friends. To qualify as a patentable invention the idea must also not be obvious. The assessment of what is obvious is a complex area of patent law and in the first instance staff are advised against concerning themselves with this criterion. In the UK, some inventions are specifically excluded from patenting where those inventions consist entirely of methods of treatment by surgery or therapy or diagnostic methods. However, these inventions are patentable in other countries, notably the USA.
Excluded inventions are also a complex area of patent law and staff are advised that if they think they have an invention which lies in an excluded category to please consult the Trust R&D Department in the first instance. However, it is best not to assume an invention is excluded in the first instance.

Design Rights

Design rights arise automatically and do not require registration. Design Rights protect against the copying of the shape or configuration of an article. Design Rights may exist in addition to other forms of protection offered by patents or copyright.

The "Design Right"

The "unregistered" Design Right as it is known, similar to copyright, is an automatic right and can last up to fifteen years. It can protect the 3D features of an article, internal and external features, but there are a number of exclusions for example where the article is dependent on another article the so-called “must-fit, must match" exclusion. A surgical instrument could be protected by this right. However, unregistered design rights are generally considered to be weak IP rights and often stronger rights such as patents are sought, at least to improve levels of protection. Given the particular requirement of this “niche” aspect of IP law it is best in the first instance not to assume that the design right will protect a given article.

Registered Design Rights

Both UK and European law provide for registered design rights which last up to 25 years. Registration is required to attract protection. Registered design rights protect the appearance of a product, for example its shape, colour or texture of materials. For example, a new design of surgical gown or a patient's pillow could be the subject of a registered design right.

Trade marks

A trademark is a sign or symbol that is used to distinguish a product or service of one undertaking (e.g. a company or organisation, such as an NHS organisation) from another undertaking. Trademarks need to be registered to attract protection. Trademarks can protect words, logos, shapes, colours and even smells (e.g. the name "Coca Cola" and also the shape of the Coca Cola bottle are registered trademarks). Trademarks are the IP right that protect brands. They can last forever, providing renewal fees are paid.

Database right

A database means a collection of independent works, data or other materials which are arranged in a systematic or methodical way and are individually accessible by electronic or other means. There are two types of intellectual property protection for databases: database right and copyright. Both are automatic, unregistered rights that allow the owner to control certain uses of their databases.

Copyright protects the selection or arrangement of material in a database where this is original (i.e. creative). Database right protects the contents of a database. A database does not have to be original for it to qualify for database right, but there needs to have been a substantial investment in obtaining, verifying or presenting the contents of the database.

Database right is based on the European Community Directive 96/9 on the legal protection of databases. This was implemented in the UK by the Copyright and Rights in Databases Regulations 1997, which remain in force as 'retained EU law' with amendments following the UK's departure from the EU. The maker of a database must have a connection with the UK (or the European Economic Area if the right arose before 31 December 2020). Databases created from 2021 onwards are only protected under UK law.

Database right lasts for 15 years from the end of the calendar year in which the making of the database was completed. Any substantial change to the contents of a database which can be considered to be a substantial new investment qualifies the database resulting from that investment for its own term of protection.

Appendix 2 - Extract from Velindre University NHS Trust Contract of Employment

26. Discoveries and Inventions

26.1 If at any time during your employment you alone or with others make or discover any invention, discovery, improvement or modification which relates to or which may relate to any products, site process, equipment, system or activity of the Trust or which are actually or partially useful to the activities of the Trust ("Invention") you shall forthwith disclose full particulars of the same including drawings and models to the Trust.

26.2 You hereby agree and acknowledge that all Inventions made in connection with the business of the Trust and all rights therein made in the course of your duties shall accordingly belong to the Trust.

26.3 You shall at the request and expense of the Trust execute on demand all such documents as the Trust may require and do all such other things as the Trust may consider to be necessary to enable the Trust to obtain the full benefit in such manner as the Trust may require of any Invention and the rights therein to which the Trust is entitled, to vest the rights arising there from fully in the name of the Trust or as it may direct and to secure such patent, utility, model, copyright or design registration or other similar protections for such Inventions in any part of the world as the Trust may consider appropriate.

26.4 You hereby irrevocably appoint the Trust to be your attorney in your name and on your behalf to execute all such documents and to do all such acts as may be necessary or desirable to give *effect* to the provisions of this Clause.

Appendix ~~3~~2 – Innovative Ideas Disclosure Form

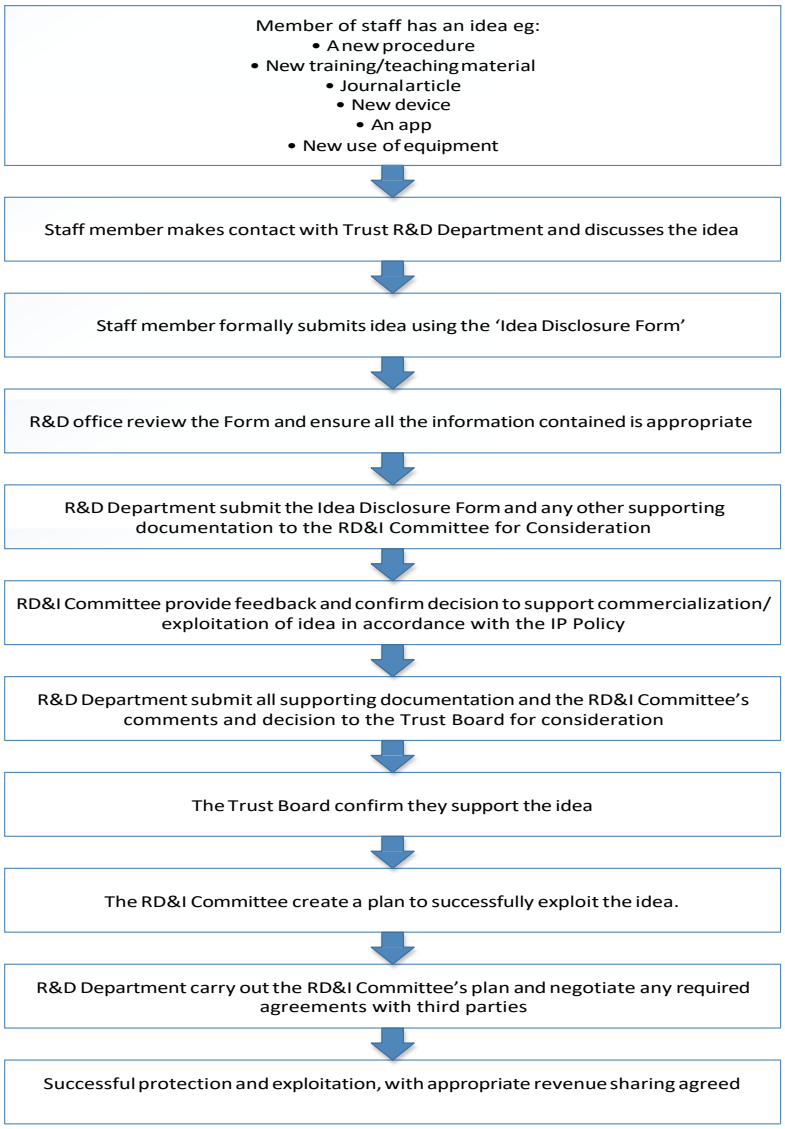
INNOVATIVE IDEAS DISCLOSURE FORM

Full Name	
Role	
Department	
Status of Employment	
The name of any collaborating individuals or parties	
Title of the project (max 60 characters)	
Idea Summary (Maximum 200 words)	
Summary of potential benefits to patients/health service (Maximum 200 words)	
What were the results of your preliminary patent	

search? A free patent search can be undertaken using the following link https://worldwide.espacenet.com/	
Any other relevant information (max 200 words)	

If applicable please include separately any supporting drawings or schematics to this application.

Appendix 43 - General Process for the Disclosure of Ideas



Appendix 5 - TEMPLATE HEADS OF TERMS (HoT)

It is important for Velindre staff engaged in research/ innovation and their managers to create the optimum conditions for a collaboration and to understand what it aims to achieve and the process for achieving it. The HoT should clearly set out the parties intentions expressly, such as "These HoT are not intended to be legally binding except as specifically set out in this letter".

HoT enable decision makers to identify the key issues surrounding a collaborative project in plain language. The very process of creating a HoT can be a very constructive and useful way for all parties to understand the needs and expectations of the other parties at the outset and may minimise disagreements and disputes later. In this way a project is more likely to be productive. It is important to consult lawyers after you have created your draft HoT but the process itself of creating the HoT should not be confined to lawyers. A template HoT is provided below.

- The Parties
- Purpose of project
- Scope of project
- Start date and main time points
- Resources provided by each party (e.g. financial, personnel, data, existing IP etc)
- Role of each of the Parties
- Ownership of IP in results
- Access rights to IP arising in the project
- Access rights to other parties' existing IP necessary for performing the project
- Confidentiality
- IP exploitation plan
- Management of project IP
- Decision making relating to IP exploitation
- Revenue/equity

- Dispute resolution
- Termination conditions

APPROVED BUSINESS CASES – ANNUAL EVALUATION REPORT

1. BUSINESS CASE TITLE	2. BUSINESS CASE REFERENCE NUMBER
Implementing the Cancer R&D Ambitions – An Integrated Business Case 2023-2026	2023-13
3. BUSINESS CASE PREPARED BY	**4. BUSINESS CASE SPONSORED BY**
Mererid Evans, Velindre Cancer R&D Strategy Clinical Lead Rob Jones, Associate Medical Director for RD&I, VUNHST Libby Batt, Velindre Cancer R&D Strategy Lead Sarah Townsend, Head of R&D VUNHST Jonathan Patmore, RD&I Finance Manager VUNHST David Osborne, Head of Finance Business Partnering, VUNHST Kate Cleary, Velindre Cancer R&D Strategy Project Support Manager Christopher Cotterill-Jones, Research Delivery Manager, VUNHST Jane Hopkinson, Velindre Professor of Nursing and Interdisciplinary Cancer Care Anthony Byrne, Velindre Lead for Cancer Palliative and Supportive Care research	Jacinta Abraham, Executive Medical Director
5. DATE APPROVED BY CFC	**6. DATE APPROVED BY RD&I SUB-COMMITTEE**
19/01/2023	15/11/2022

7. BRIEF SUMMARY OF THE BUSINESS CASE

The Trust has developed and endorsed its Cancer R&D Ambitions strategy for the 10 year period 2021-31 that builds on existing excellence and embraces new areas of research. The strategy aims to expand and balance the Trust's cancer research portfolio to increase recruitment into research studies led or supported by Velindre.

The enhanced clinical trial portfolio envisaged by the strategy includes Late Phase and higher-risk Early Phase and Advanced Therapy Medicinal Product (ATMP) clinical trials. It also aims to further develop the research portfolio to include different types of excellent research including Translational ('bench to bedside') research, Health Care Research (led by multi-professional groups), and other research that supports patient care when they need it most.

The funding provided by the Charity under the Integrated Business Case for 2023-26 aims to support the delivery of this Cancer R&D strategy. It included funding for:

- R&D support staff to enable and support increased trial delivery at Velindre (e.g. Research nurses, trial co-ordinators etc.).

- Clinical support staff to increase the Trust's capacity to deliver more trials (e.g. Pharmacy, Radiotherapy).
- Posts to increase the Trust's abilities to support different and new treatments (e.g. ATMPs, Drug-Radiation Combination Therapies).
- Increased capacity to conduct Health Care Research (e.g. PhDs for non-medical staff).
- Increased capacity to conduct research in Palliative Care, Radiotherapy and Cancer Immunology.
- Clinical Research Fellows and administrative staff to enable the establishment of the Cardiff Cancer Research Hub in partnership with CVUHB and Cardiff University. This provides the Trust with a capability to deliver higher-risk trials (utilising acute patient care facilities at UHW) and increased translational research (working with Cardiff University).
- A small grants scheme to provide more opportunities for staff across the Trust to participate in and lead research.
- Increase the Trust's capacity to attract and deliver commercially-funded research studies (e.g. via dedicated consultant sessional time)

8. PROJECT TERM – e.g. one year

The funding period is for 3 years, 1st April 2023 to 31st March 2026 and this report gives feedback on activities from 1 April 2023 - December 2024.

9. PLEASE INDICATE THE STAGE OF THE PROJECT THIS EVALUATION RELATES TO: (please tick)

Year 1	**y**
Year 2	**y**
Year 3	
End of project evaluation	

10. EXPENDITURE:

a) What was the value of the funding request?

CFC funding request over the three year period (to 2025/26) was up to £6.513m (higher level) and down to £4.484m (lower level). The different levels were dependent on cost savings and income from several sources.

The funding profile over the three years, along with the actual costs incurred as of December 2024 are as follows, using the higher level in the forecast:

	CFC Funding Approved (£'000)	Actual Spend (outturn/ YTD M9) (£'000)	Forecast Spend (£'000)	Forecast Variance (£'000)
2023/24	1,903	1,356	0	(547)
2024/25	2,217	1,232	762	(223)
2025/26	2,393	0	3,152	759
Total	**6,513**	**2,588**	**3,914**	**(11)**

b) Is expenditure on target? If no, explain why?
The bid is on target and we are anticipating full spend based on the higher level funding. A plan has been developed for finding alternatives funding sources for particular posts as per the exit strategy.

11. WILL THE PROJECT BE DELIVERED WITHIN THE AGREED TIME FRAME? IF NOT, FULLY LIST THE REASONS FOR THE DELAY AND WHAT ACTION YOU ARE TAKING TO RECTIFY/ PUT THE PROPOSAL BACK ON TRACK?

Yes

12. FULLY EVALUATE THE PROJECT BY COMPLETING THE TABLE BELOW. CONFIRM IF THE PROJECT IS DELIVERING/DELIVERED AGAINST ITS ORIGINAL OBJECTIVES AND HOW THIS IS BEING/HAS BEEN ACHIEVED. STATE THE AREAS WHERE YOUR PROJECT IS MAKING/HAS MADE A DIFFERENCE USING RELEVANT MEASURING TOOLS.

We are making progress towards the objectives stated within the bid and highlights of progress made towards specific objectives are listed below:

Original Business Case Objective	**Achieved (Y/N)***	**Explain how Achieved**
1.1 Research Delivery Teams		
Patients Increase research opportunities for patients to participate in research including: o Patients in South East Wales and beyond delivering research closer to patients' homes o Access to new cutting edge Early Phase Clinical Trials and Solid Tumour Advanced Therapies and Drug-RT combination trials (Velindre and the Cardiff Cancer Research Hub) o Access to Radiotherapy research both in VCC and ABUHB Radiotherapy Satellite Unit **Research Portfolio** Lead, and support high-quality Clinical Trials & other research studies. Ensure the right balance of the portfolio including: o Increase new studies led by local researchers in Wales	Y	Velindre continues to demonstrate a healthy and diverse research active ecosystem with the following highlights: A 70% increase of recruited patients from 2022/2023 to 2023/2024. (Please see appendix 2.1.) Velindre's partnership in the Cardiff Cancer Research Hub has enabled novel Early Phase Clinical Trials and Solid Tumour Advanced Therapies trials to open in Wales. (please see section 2.3.1 below) Discussions are ongoing between R&D staff and ABUHB, aligned with wider discussions between the Trust and ABUHB. The integrated bid has enabled the Trust to broaden its research portfolio e.g. see section 2.1.1 for Healthcare Research and 2.1.2 Palliative and Supportive Care Research. We have continued to deliver pioneering trials across our portfolio to improve patient treatments and outcomes. The Trust is a top European recruiter on many trials; please see appendix 2.2 for our recruitment performance rankings.

○ Improve the balance of the portfolio to include more observational and qualitative studies ○ Develop Early Phase Clinical Trial and ATMP portfolio ○ Expand the Early Phase Drug-Radiotherapy Combination Clinical Trials ○ Enhance the current commercial portfolio enabling commercial income for R&D reinvestment ○ Improve setup times of trial and patient recruitment to time and target		There has been an increase in the number of active Principal Investigators from 2023/2024 and 2024/2025 and an increase in active Chief Investigators in the same time period. (See appendix 2.3). During the period of the Integrated bid, there has been a 30% growth pa over the last 2 years in commercial income coming back into Velindre; please see appendix 2.4 for clinical trial income.	
○ Develop Knowledge exchange of expertise gained through research to the clinical service	Y	The Research Service's Senior Nursing Team undertook various benchmarking visits in 2023/24, visiting the Beatson, Institute for Cancer Research in Glasgow, the Christie Cancer Treatment Centre in Manchester and the Queen Elizabeth Hospital in Birmingham. Discussions have also been held in 2024/25 with other exemplars (e.g. Kings Health Partnership).	
Research Leadership ○ Seek research ringfenced time for a small number clinicians, that are generating significant commercial income	Y	A total of 4.5 Sessions have been awarded to PIs across lung, breast, melanoma and radiology. This has helped generate a 207% increase in commercial income in these specific SST between 22/23-23/24 (compared to 34% overall increase in commercial income). See appendix 2.5 for further details.	
1.2 R&D Governance			
○ Implement a tool, optimising a broad portfolio of high-quality studies that recruits to time and target ○ Support researchers with grant and protocol	Y	The R&D Governance office are developing a comprehensive study prioritization tool which takes into account how studies align with the Wales-wide priorities and the Trust's overarching cancer R&D ambitions. Support for grant and research submissions is embedded as standard within the R&D governance team.	

writing/ethics and research submissions ○ All trials/research is assessed in terms of utilisation of research resources. ○ Manage partnerships with Pharma including and seeking opportunities of new models for research income ○ Manage the reporting of research performance of the RD&I service including the business intelligence to inform senior research team decision making ○ Development of a financial strategy for all R&D		As part of a high quality portfolio, the R&D Governance office work with various departments to ensure that trial set up is to target. The R&D Governance office continue to work to a comprehensive annual operating plan, using UK study intensity and costing tools to ensure accurate research costs are charged. The CCRH is also using this study intensity tool to inform its demand & capacity planning. The R&D governance and strategy teams are working together to develop new industry relationships (e.g. initial discussions underway with Medsir[1],Boehringer Ingelheim and ThermoFisher). The R&D Governance team have developed a new R&D report for SSTs collating all SST R&D activity. This aim of this monthly report is to enhance data visibility and operational support for the SSTs and has been positively received by colleagues. R&D finance colleagues provide a quarterly update as part of the overarching RD&I Performance Report. The emphasis of this is to ensure sound financial management, modelling to support scenario planning and robust forecasting as well as assessing financial sustainability and ensuring appropriate exit strategies are in place to provide seamless transition between bid submissions. A key performance area is the level of commercial income being achieved and to what extent this has increased since the start of the current integrated bid. Please see appendix 2.4 for the clinical trial income data.	
○ Communicate the cancer portfolio opportunities ○ Communicate the impact of the Trusts RD&I	Y	Internally, R&D specific news stories on our intranet has increased dramatically since having a dedicated R&D Communications Officer: there has been a 1400% increase in R&D	

[1] https://www.medsir.org/, https://www.boehringer-ingelheim.com/, https://www.thermofisher.com/uk/en/home.html

		related news stories on the intranet (Aug 22-Mar 23 compared to Aug 23-Mar 24). Externally has also seen a rise in activity with news stories on the BBC and ITV as well as presence at conferences and events in the Senedd. All this will contribute to raising awareness of the Trust's research. A flavour of these stories have been included within appendix 4.	
2.1.1 Velindre Healthcare Research			
○ Developing a Health Care Research Community of Scholars ○ Partnership with a leading university to support research training necessary for healthcare research in Velindre Cancer Centre to become core business. ○ Development of a career framework to build capacity for research and innovation aligned with research competency frameworks ○ Nurse or Therapies Professorial Lead (providing mentorship and supervision for the Healthcare Fellowship award holders.)	Y	• The Velindre Healthcare Cancer Research Community has been established, which is a forum for seeking peer support, exploring research ideas and finding research collaborators. Since the start of the integrated bid, there have been 8 meetings of this Community. • The Velindre Healthcare Cancer Research Fellowship Scheme (delivering in partnership with Cardiff University, and a first for nurses and health professionals in Wales) has been established and is in its second year. It provides a career framework for Velindre staff to progress from clinical into clinical academic careers. There are now three Velindre Introduction to Research (ViR) award holders and three Velindre PhD award holders. This is led by the Professor of Interdisciplinary Cancer Care post, which is part funded by the Integrated Bid and has provided professorial leadership and mentorship. The postholder (Jane Hopkinson) recently retired; her successor has recently started and will ensure the continuation of this important leadership function. Velindre Fellows are also supported by the wider Velindre Healthcare Cancer Research Support Team, including 3 research-active Senior Lecturers who also provide mentorship and supervision. • Monica Busse, Director of Faculty, Health and Care Research Wales,	

○ Develop VUNHST's Advanced Practitioners to be research active Principal Investigators or Chief Investigators		has agreed that Velindre Fellows can become members of Faculty taking advantage of networking and training opportunities. This will increase visibility at national level for research and innovation in nurse and health professions practice informed by Velindre-led research. • There has been progress to achieving parity with other health providers across the UK: 3 Velindre Introduction to Research (ViR) award holders and 3 Velindre PhD award holders (median per health provider in England is 3 nurses and 4 allied health professionals with a research training (PhD). • Velindre healthcare clinical academics are driving the quality agenda for cancer care research through representation on both CAHPR (a UK wide network supporting Clinical Academics who are AHPs) and CARIN (a UK wide network supporting Clinical Academics who are nurses). • The Fellowship scheme is flexible and able to be adapted to provide a route for Advanced Practitioners to progress to PI or CI.	
2.1.2. Palliative and Supportive Care Research			
○ Assess how Velindre patients develop and utilize their knowledge about their condition, contextualise treatment decisions, effectively co-producing care and treatment plans aligned with their priorities ○ Use multi-methods research to develop patient-literate approaches to joint decision making and embedding a comprehensive understanding of the patient perspective at MDT meeting	Y	• The Pre-Agreed Supportive Care Escalation Plan (PASCEP) Study's leads include Elin Harding (integrated bid-funded post). This project looks to use QR code technology to improve communication between healthcare teams for patients with palliative conditions in an emergency situation. The team are collaborating on this project with the Welsh Ambulance Service Trust. The study is sponsored by Velindre with Cardiff University ethics in place and WAST R&D approval. Completed elements of project have generated publications, poster and abstract. Literature narrative review paper to be submitted. Update on the project and outcomes have been submitted to International conferences (e.g.	

○ Inform the processes of Advance and Future Care Planning (AFCP) Strategy within clinical practice and in particular look at requirements for patients to access their electronic AFCP directly ○ Open and recruit to complex palliative care pain control, cancer associated thrombosis and hydration at the end of life		European Association of Palliative Care, May 2025) • The team have been awarded funding from the CRW Brain Tumour Research Initiative (BATRI). The funding is a new departure for Cancer Research Wales to support palliative care research and this study will be an important focus for their brain cancer initiative. Anthony Byrne has collaborated with Steph Sivell, (Cardiff Uni.) and Ameeta Retzer (Uni. of Birmingham) on this brain tumour grant proposal - Core Outcome Measure clinical needs for people with primary Brain Tumours (COMBaT). The grant is for £241,041 and is for 22 months. • The team have submitted a proposal to the NIHR Cancer, for the support and rehabilitation for patients with brain tumour funding call (Stage 1 deadline January 2025). NIHR have also released a call for a national consortium to evaluate treatments for brain tumours. Currently collaborating on an application for this from a Cardiff/Wales perspective (Velindre, Marie Curie Research Centre, Cardiff (Sivell) and the Cancer Trials Unit, Cardiff University). • There is a secondary analysis of the qualitative data from the COBra project and a second paper (currently under peer review) reviewing the evidence of holistic needs assessment interventions implemented in cancer and their relevance for brain tumour patients in practice. Both of these pieces of work are helping to inform the above NIHR brain tumour bids. • Prof Taubert is working with PaCERS team at Marie Curie Research Centre (MCRC) and Steph Sivell on a rapid review of current AFCP literature to underpin a new definition and scope on behalf of Welsh Government. All part of a plan for the overall AFCP Strategy.	

		• Prof Taubert is developing and refining a virtual reality intervention that will help to manage pain for people living with advanced cancer. This is a NIHR funded Study with as Prof Taubert co-app and University College London leading. Velindre is in set up as a recruitment site. The Cochrane Protocol for this study has just been published.
2.2.1 Leading Cancer Immunology Research		
Clinical Academic 2.2.1		
○ Exploit research opportunities afforded by the current era of cancer immunotherapies, and to test new cancer vaccines, T- cell therapies and other Advanced Therapy Medicinal Products (ATMPs) in clinical trials ○ Work with partners to address the absence of a well-defined translational pipeline from laboratory to clinic in Wales (as identified by CRUK) ○ Bring precision immuno-therapeutics generated in Wales (T cell-based therapies and precision immuno-virotherapies) precision immuno- through to clinical trials for patients in Wales	Y	• A pipeline of ATMP trials has been setup and being expanded via the CCRH. • Two ATMP trials currently in setup (Iovance and ATTR-01) which are TILs and Vaccine trials respectively). • CCRH's Discovery & Translational Research Group established to develop a translational pipeline from Cardiff Uni. labs to trials at Velindre & CVUHB. • A translational ATMP Oncolytic virus vaccine study from CU (taking forward research led by Prof Alan Parker) is currently in setup. • A Clinical Senior Lecturer in Immuno-Oncology joined the team on 4 November 2024. We will therefore be able to provide a more extensive update at the next annual evaluation.
2.2.2 Maximising radiotherapy research opportunities @VCC		
Develop research academic leadership that drives (with others) Radiotherapy Research by: ○ Maximising opportunities for by investment in nVCC ensuring RD&I engagement in the Integrated Radiotherapy Solution (IRS) and Radiotherapy Research Bunker	Y	RD&I engagement in the IRS is ongoing. The following Varian-Velindre research grant application for £31,758 was submitted and approved: *"Does Surface Guided Radiotherapy (SGRT) improve set-up accuracy for prostate cancer patients receiving external beam radiotherapy (EBRT) in comparison to traditional tattoo-based alignment?"* The PI for this study is a therapeutic radiographer within the Radiotherapy

		Service. Further research opportunities are under development.
○ Seeking partnerships with Universities Pharma, IRS provider, 3rd Sector to build research opportunities	Y	A number of partnerships have been established (e.g. with AstraZeneca, Cardiff University and others). For example, the radiotherapy-led SABRE study is a commercial phase II interventional study sponsored by Boston Scientific Corporation. VCC were activated as a site in 12/2023, opening to recruitment with a target of 15 patients. The initial recruitment target of 15 was met in 03/2024 and a new recruitment target was requested by the PI (25-30 patients). The request was supported. The recruitment target was met in 07/2024 and an increased recruitment target was once again requested by the PI (30-50 patients). The request was supported. VCC are the highest recruiting site for this study as at Q3 2024. SABRE Newsletter Q3 2024.pdf
• Develop a new role of RT Research Data manager that works to support RT research radiographers	Y	This role was on-boarded in 01/2024. The Radiotherapy Data Manager is responsible for the timely data capture, data quality and maintenance of accurate and comprehensive RT R&D records. The Radiotherapy Data Manager works closely with the R&D office, Early Phase and Clinical Trials Unit Data Managers to ensure synergy of working practice. To strengthen working practice, the Radiotherapy Data Manager is currently based within the R&D office two days per week.
2.3.1 The Cardiff Cancer Research Hub		
○ Provide enhanced access to high risk trials Early Phase Clinical Trials and ATMPs ○ Advance collaborations with Cardiff University scientists,	Y	• The CCRH is live, with an active trial portfolio (2 trials open and 4 in setup) - see appendix 2.6 for an overview of the trial portfolio. So far 5 patients have been treated, giving the people of Wales access to trials

ECMC and WCRC and other partners ○ Develop a portfolio of clinical and technical translational research ○ Within 5 years - deliver at least one bench to bedside project with a Cardiff generated molecule/therapy. ○ Open one solid tumour non-cellular advanced therapy trial (e.g. an oncolytic virus) and one cellular advanced therapy trial annually. ○ Design and deliver 4 investigator-led Early Phase Clinical Trials with Cardiff Chief Investigators through interaction with Industry, Academic colleagues, CRUK and Cancer Research Wales.		that were previously not available to them. Many of these trials are 'firsts in Wales' and represent the evolving nature of these clinical trials. • A translational ATMP Oncolytic virus vaccine study, ATTEST/ATTR-01, (taking forward research which has been generated from Cardiff led by Prof Alan Parker) is currently in setup. Aim to open in Feb 25. • The work to establish a legal and governance framework and align processes, to enable the scaling collaboration between Velindre, Cardiff Uni. and CVUHB is progressing well. Heads of Terms and a high-level partnership model have been approved by all three partners. This is now being developed with NWSSP lawyers into a detailed, contractual Partnership Agreement. • CCRH's Discovery & Translational Research Group is established which will develop a translational pipeline from Cardiff Uni. labs to trials at Velindre & CVUHB. The group is advancing collaborations (e.g. it is developing its first large, NHS/academic research grant, applying to become an ATMP-focused MRC Centre of Research Excellence, which has been approved as the sole bid representing Cardiff Uni, and involves CCHR, WCRC, ECMC and others). • The CCRH is collaborating with other parts of Cardiff University to establish new collaborations and capacity building opportunities for Velindre clinicians (e.g. PhD studentships from the Myristica Trust are being made available to Velindre and CVUHB staff with the help of the CCRH).	
○ Generate commercial investment through grant income and commercial trial income - re-investing the income provide sustainability of existing	Y	• A Strategic Investment Case (SIC), was developed with an external management consultancy firm. Engaging with colleagues from VCC, CAVUHB and CU, the SIC holistically addressed how the Hub	

posts, and expansion of the workforce and infrastructure		will be financially sustainable for the future and provide a high-level roadmap for the mobilisation of the Hub. The team worked with the consultancy firm again on Market Engagement, developing a brochure to go to investors such as pharma, philanthropic organisations, charities etc. The exercise prioritised investors, collated key messages and drafted an investor pack with further guidance to make people 'pitch ready'.	
○ Develop an integrated working plan with our Haemato-oncology colleagues and driving plans to deliver Early Phase and ATMP Trials across both Velindre and UHW ○ Ensure the research team early phase trial and ATMPs are suitably trained, competent and adhere to Standard Operational Procedures	Y	To upskill the workforce, key milestones have been achieved: • Development of ATMP & Translational Research Training Package • Cross-site, multi-discipline CCRH nurse training and mentorship programme • Attendance at cell and gene therapy study days • Benchmarking exercise (see below) Further milestones embedded into the team are: • Joint assessment of EOI for trials • Sharing SOPs • Patient pathways developed per trial jointly Funding application submitted to Moondance for CCRH staff to visit other leading UK centres to learn how they are deploying ATMPs both within trials and as standard of care treatment (result awaited). This will inform Velindre and CCRH's SoPs and wider plans and processes to ensure ATMPs are developed into a larger trials portfolio and then into routine treatments.	
○ Ensure development of the new service is informed by other successful UK Cancer Centres delivering similar services	Y	• A cohort of medics, nurses and pharmacists from VCC and CAVUHB visited Cell Therapy centres in Newcastle, Christie and Guys. They brought back knowledge and built links with colleagues in the centres.	

Clinical Research Fellow 2.4.1			
○ Support clinicians to become future research leaders ○ Provide an opportunity for senior Velindre trainees to each pursue a laboratory-based research degree (MD) with a high-profile academic group ○ Provision of opportunities to gain higher degrees (MDs and PhDs) for research interested trainees ○ Enable Clinical research staff to be able to work flexibly across organisational boundaries, ○ Support to early career researchers at MSc and PhD level, mentoring them towards Fellowships, supporting their development by ensuring a Clinical Research Fellow career pathway	Y	**Clinical Research Fellow: RT Genomics & Immunology, Dr Ashley Poon-King,** started 1.7.23, has progressed to the 2nd year of her MD studies based in Professor Duncan Baird's, a CRUK grant holder, laboratory at Cardiff University, where she is researching the association between telomere length and structure and outcome in head and neck cancer patients. She is also continuing with ongoing work as clinical research fellow for Cardiff Cancer Research Hub (along with the other CRFs), organising and helping to develop pathway documents for management of acutely unwell patients for solid tumour patients. **Clinical Research Fellow: Clinical Trials / ATMPs, Jaya Vangara**, started 1.4.24, undertaking a research degree on "cancer models for preclinical potential of precision virotherapies" in Professor Alan Parker's group at Cardiff University with a project focussed on developing viral therapies and assessing their efficacy in a range of cancer types. **Clinical Research Fellow: Advanced RT, Jenny Golten,** started 1.9.24. This fellowship will focus on developing and performing advanced radiotherapy research in brain cancer and other tumour types, working with clinician researchers within Velindre and Cardiff University. **Clinical PhD (Lung) in Precision Oncology, Karam Aboud,** started 1.10.23. Completed first year of PhD project and passed first year internal viva. PhD project titled 'ctDNA markers of primary and secondary resistance in metastatic non-small cell lung cancer'. Through progressing their PhD research at AWMGS, this postholder is working on validating and	

		improving genomic tests which can directly improve standard of care testing. For example, they are currently working on validating a locally used genomic panel so it can also be used for MSI (micro satellite instability) in solid tumours. This can improve time efficiency of genomic testing for patients and reduce number of diagnostic tests required for each patient in the standard of care pathway. They are also working with collaborators in NHS, Cardiff University and at Birmingham University to research into cutting edge genomic technology (nanopore sequencing) in liquid biopsy to explore its use in non-small cell cancer research and potential improving standard of care testing in Wales. Active role as clinical fellow and sub investigator for early phase solid cancer and Haematology trials.
2.4.1 Developing the next generation of research leaders at Velindre		
○ Build capacity, capability and critical-mass within the research workforce ○ Providing opportunities for NHS staff to develop research skills, ○ Incorporate research professional development into staff education and workforce development strategies ○ More clinical researchers being Principal Investigators (PIs), allowing time in job plans for this activity ○ Ensure succession planning across the clinical workforce future proofing research activity ○ Work with our academic partners, targeting talented researchers and enabling Clinical Academic career pathways.	Y	• There has been an increase in the number of active Principal Investigators from 2023/2024 and 2024/2025 and an increase in active Chief Investigators in the same time period. See appendix 2.3 for further details. • There have been 72 publications and 70 conference abstracts during the funding period (a list of these are included within appendix 5) • As part of VUNHST's aim to build capacity, capability and a critical-mass within the research workforce, Katie Gilmour, CCRH Research Nurse, was awarded the Health and Care Research Wales Research Training Award to support her to study for a 2 year MRes Health Research at the University of Stirling. Further to this, Gabby Brutto, also a CCRH Research Nurse, has commenced her MSc Research Module at University of South Wales. • Velindre is working with Cardiff Uni (e.g. via Healthcare Research

		portfolio, joint working with WCRC and ECMC, and via CCRH's Discovery & Translational Group) to build and expand a pipeline of, and career pathway for, clinical academics. Velindre is also developing a plan to invest income from its FAKTION trial to build an increased capacity for consultant-level Chief Investigators, and a pipeline of more junior clinical academics, to help increase the supply of future Principal and Chief Investigators.	
2.5 Strategy Implementation Team			
○ Work with researchers and research teams to develop, managed and report progress including risks and risk mitigation ○ Maintenance of a secretariat function across the R&D ambitions to improve communications, information sharing enabling decision making and identifying cross cutting research ○ Seeks opportunities to align with nVCC developments and Velindre Futures work programmes to inform on cancer R and D ambitions and where appropriate better integrate research	Y	The Strategy Implementation Team have developed processes to capture and report progress against Velindre's Cancer R&D Ambitions strategy. Progress in implementing the strategy, as well as key achievements, risks and recommendations for mitigations and future work are now being fed to Velindre's RD&I Sub Committee, its R&D Senior Core Team and other groups within the Trust for discussion and decision making. The team's secretariat function is facilitating this information sharing, discussion and decision making process. This work also aligns the delivery of the Integrated Bid. The team link in with the research leads to identify key milestones and have developed action plans that demonstrate progress made. The team also link with TCS, Velindre Futures and other functions within Velindre (as well as external organisations such as CVUHB and ABUHB) to align the Trust's Cancer R&D ambitions with the nVCC, Velindre Futures and other programmes.	
○ Drive partnerships associated with the CCRH	Y	The Strategy Implementation Team also functions as the PMO for the CCRH. The team are leading the establishment, operational and growth of the CCRH. Action plans and risk management process have been developed to help manage this.	

		The team's work ensures that the partnership between Velindre, Cardiff Uni. and CVUHB is being deepened and formalised into a detailed partnership agreement. The team is also working with the wider R&D teams at Velindre and CVUHB to increase the number of partnerships with industry (e.g. Medsir) and ensure that existing partnerships are deepened. CCRH representatives also developed a bid for the VPAG investment to be invested in the CCRH. The VPAG fund is from HCRW with the aim of enabling commercial clinical trial delivery.
○ Strategic team supports the development of an investment Strategy and associated Outline Business Case and Full business cases	Y	The Strategic Investment Case (SIC) was completed in 2023. The Strategy Implementation team are now leading the development of a revenue Business Case for the CCRH. The team also supported the work of developing the case physical CCRH building into a Full Business Case (although Welsh Government approval of the Strategic Outline Case is still pending).

***If an objective is not being/was not achieved, provide details in section 13 below**

13. EXPLAIN WHERE THE PROPOSAL IS/DID NOT ACHIEVE AND WHY AND WHAT YOU WOULD DO DIFFERENTLY.

N/A

14. IN NO MORE THAN 100 WORDS EXPLAIN TO DONORS HOW YOU HAVE USED THEIR MONEY TO MAKE A DIFFERENCE?

The funding provided by the *Integrated Business Case 2023-2026* is enabling Velindre to deliver its key Cancer R&D Ambitions strategy. The funding is being used to build the Trust's capacity in key areas, to enable it to do more cancer research, support the development of new therapies and research in new areas, and increase the amount of commercial trials income generated for the Trust.

To read further on specific stories of research impact, click here for a patient story on a clinical trial that received funding from the Integrated bid. Click here to hear about an exciting, collaborative project, funded by the Integrated Bid, which uses QR code technology to improve communication for palliative patients in an emergency situation.

15. FEEDBACK? HOW HAS THE INTENDED USER COMMUNICATED THE DIFFERENCE THAT YOUR PROJECT HAS MADE?

We have received powerful feedback from our patients who have taken part in research. As well as having a positive personal experience, they have also recognised the importance role research plays. Click here to hear from four of our patients and their experience of taking part in a trial.
"Clinical trials are so important – without them we wouldn't have new drugs, new treatments. By taking part in the PEARL trial, I have played my part in getting better treatment for people with head and neck cancer," Bryan Webber.

The Integrated Bid has also increased Velindre's research capacity and capability: click here to listen to an Advanced Nurse Practitioner who has been awarded the Velindre Doctoral Studentship in Cancer Care.
"It's a myth that only certain types of people can do research – look at me. I have never seen myself as an academic, but I guess it takes all sorts and that is how it should be isn't it? I am nervous and excited in equal measure to start the PhD but so thankful for this amazing opportunity," Ceri Stubbs.

The investment in the Integrated Business Case has supported a demonstrable increase in the amount of clinical trials carried out at Velindre, and the number of patients that have accessed these trials. There has been a 70% increase of recruited patients from 2022/2023 to 2023/2024.

The additional capacity provided by the Integrated Business Case has also been critical in achieving an increase in amount of income from commercial (and non-commercial) trials flowing into the Trust. Commercial trials income has grown by 30% per annum since 2022/23 due to increased activity and improved tariffs.

The investment by the Integrated Business Case into the Cardiff Cancer Research Hub (CCRH) has enabled the CCRH to be established. The CCRH currently has 2 live trials (across both Velindre and CVUHB), with a further 2 in setup, and is working on its first multi-organisation translational research funding bid. This is increasing the scale and breadth of what Velindre can deliver by working in partnership with CVUHB and Cardiff University.

16. PROVIDE DETAILS OF LESSONS LEARNT

The Integrated Business Case has enabled the Trust to work much closer with its regional partners. This has generated learning at an operational level, which will be valuable to support a smooth increase in partnership working going forward. Lessons learned include:

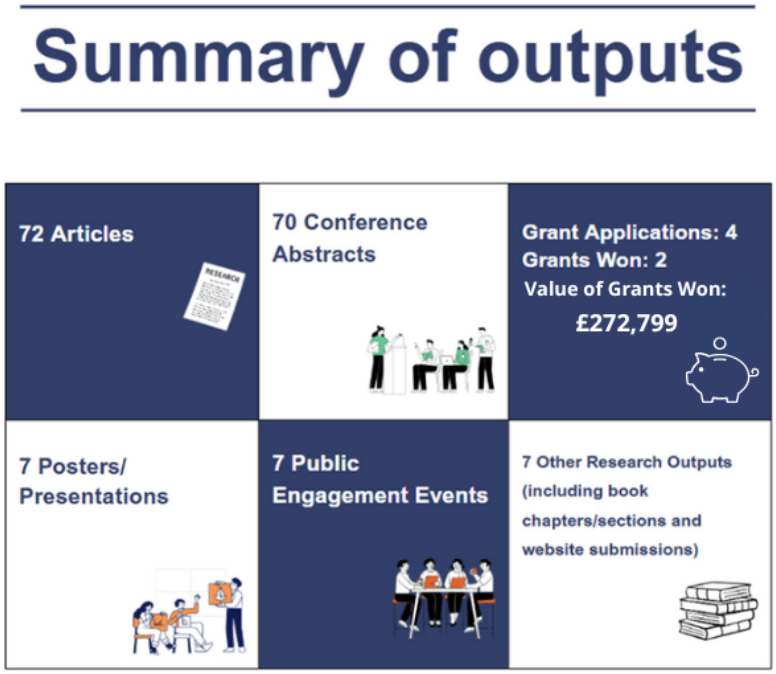
- Posts hosted by Cardiff University have higher pension contributions than Trust equivalent.
- The University is also unable to fund particular costs (e.g. NHS consultant commitment awards) for University-hosted posts that work across Velindre and/or CVUHB.

In addition, a number of examples of best practice have been provided by the work funded by the Integrated Business Case. For example, the multi-organisational, UK-wide approach taken by the Palliative Care researchers funded has proved highly successful, both to increase the impact and reach of the Velindre-funded posts, and the publications and other outputs generated. We will look to spread these lessons and utilise them in other areas wherever possible.

PLEASE NOTE: PUBLIC DOMAIN NOTICE
As part of the Trusts commitment to publicising committee papers on the internet, this report will be available to the public. The Charitable Funds Committee will assume unless explicitly stated here that the contents of this report has been agreed by all those involved and that it is ready for publication in the public domain.

Appendix

1. Further Outputs



Further detail on individual areas

Early Phase Trials Team

- 13 articles
- 5 conference abstracts

Late Phase Trials Team

- 10 articles
- 23 conference abstracts

Velindre Healthcare Research

- 18 nurse, AHP, and radiographer led publications
- 1 nurse-led book chapter, 1 nurse-led patient education pamphlet, 1 nurse-led online research based education tool developed
- 19 abstracts accepted for conference presentation, 2 invited international presentation
- No. of public engagement events & opportunities (e.g a public engagement panel meeting) - 2023/2024 2 events to promote Velindre Healthcare Research

Cancer Palliative & Supportive Care Research

- 25 publications
- 22 abstracts at conferences
- 1 book section, 1 website submission
- 2 grant submissions, 1 successful –
    - Core Outcomes to Measure clinical needs for people with primary Brain Tumours: COMBaT (Lead PIs: Dr Stephanie Sivell & Dr Ameeta Retzer). £241,041, 22 months
    - Cancer Research Wales, Brain Tumour Initiative (BATRI), aiming for follow on submission to NIHR

Developing the Next Generation of Researchers

- Publications (articles, conference posters) - Co-author of the 'immunotherapy' chapter in the upcoming new edition of practical clinical oncology book – chapter due for 2nd version submission to editors
- No. of public engagement events & opportunities - Raised £900 in charitable funds in for the Craig Maxwell VCC associated charity through the Wales coast path cancer challenge. 2 management and delivery of research community-building events
- No. of other events. Oral presentation at the DCG symposium at Cardiff University.

Radiotherapy

- **Education & accreditation:** A Radiotherapy Research Officer is the first in VCC to be accredited by the Academy for Healthcare Science (AHCS) as a clinical research practitioner (CRP).
- **Grants won:** A Varian-Velindre research grant for £31,758 approved with the PI being a therapeutic radiographer within the Radiotherapy Service.
- **Publications:** 2 posters presented, UKIO 2024. *"Educating and training undergraduate therapeutic radiographers: a collaborative approach to building research capability for NHS Wales"* and *"Therapeutic radiographer experiences of research capacity, capability and culture in NHS Wales: An evaluation study".*
- **Presentations:** Varian User Group Meeting, Nov 2024. *"Streamlining Radiotherapy; Insights and innovations from our integrated workflow journey so far"* and *"IDENTIFY SGRT system. Commissioning and user experience".*

R&D Communications Officer

Stall promoting VUNHST R&D at:

- HCRW Conference, October 2023 and October 2024
- Cross party group on Medical Research, Senedd, July 2024

Strategy Implementation team

- 4 articles
- 14 conference abstracts
- 1 grant application – Wales Commercial Research Delivery Centre Funding Requests VPAG, HCRW

2. Metrics

2.1 Patient recruitment

№ of participants recruited

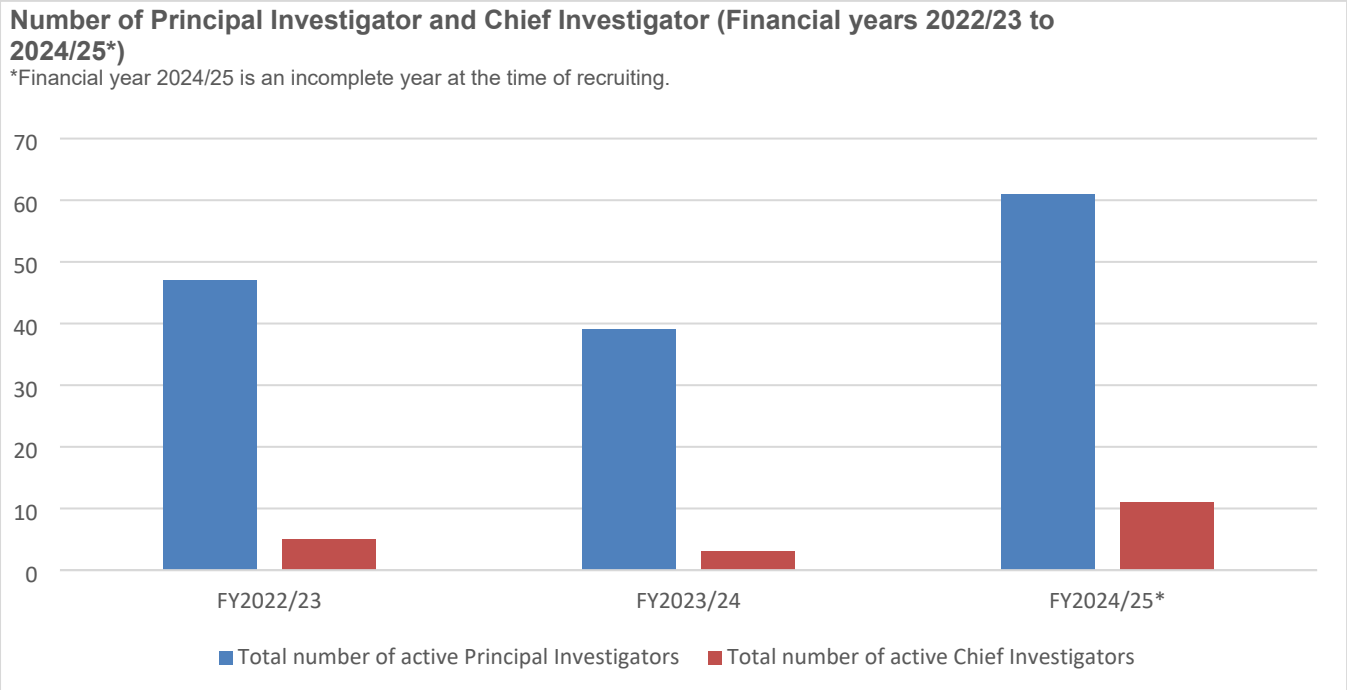
	CUMULATIVE	Quarter 1	Quarter 2	Quarter 3	Quarter 4
2024/25	235	88	88	59	-
	NC=112 / C=64	NC=55 / C=33	NC=57 / C=31	NC= 41 / C= 18	NC= - / C= -
2023/24	432	77	151	113	91
	NC=358 / C=74	NC=64 / C=13	NC=128 / C=23	NC=97 / C=16	NC=69 / C=22
2022/23	220	65	46	61	48
	NC=176 / C=44	NC=51 / C=14	NC=36 / C=10	NC=51 / C=10	NC=38 / C=10

Key: NC = Non-Commercial; C = Commercial

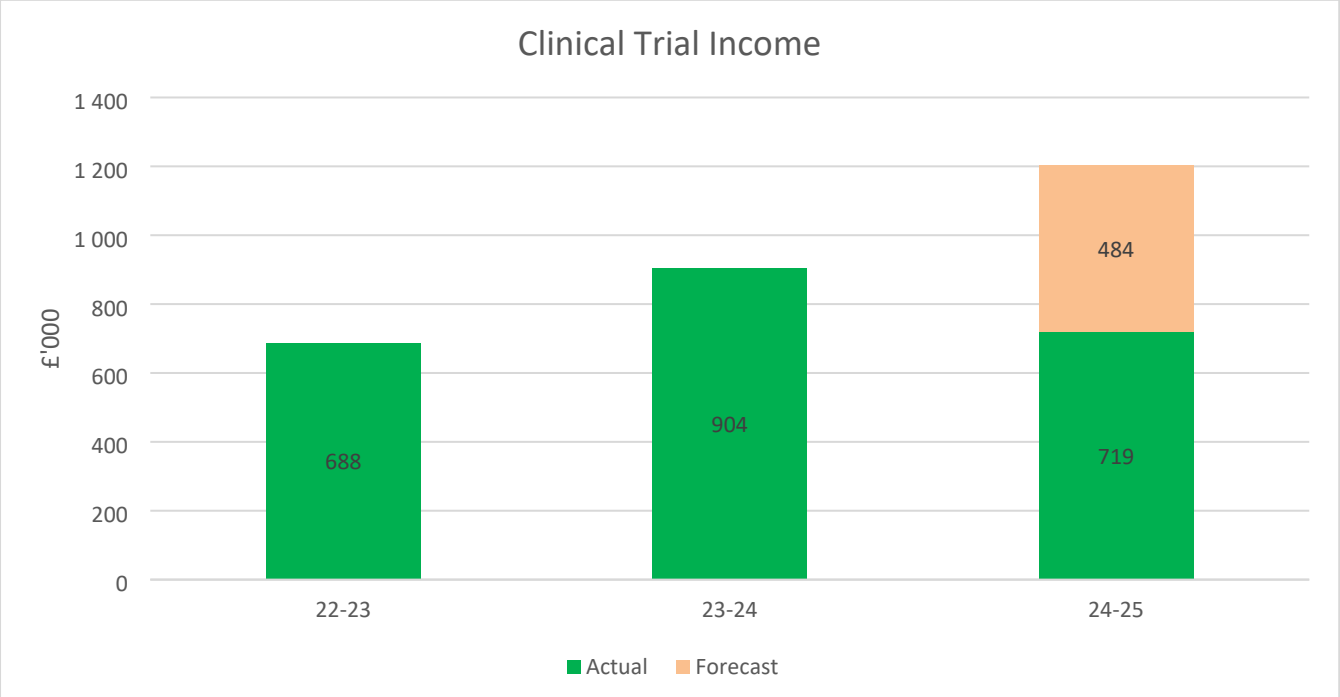
2.2 Study performance rankings

UK study recruitment performance rankings

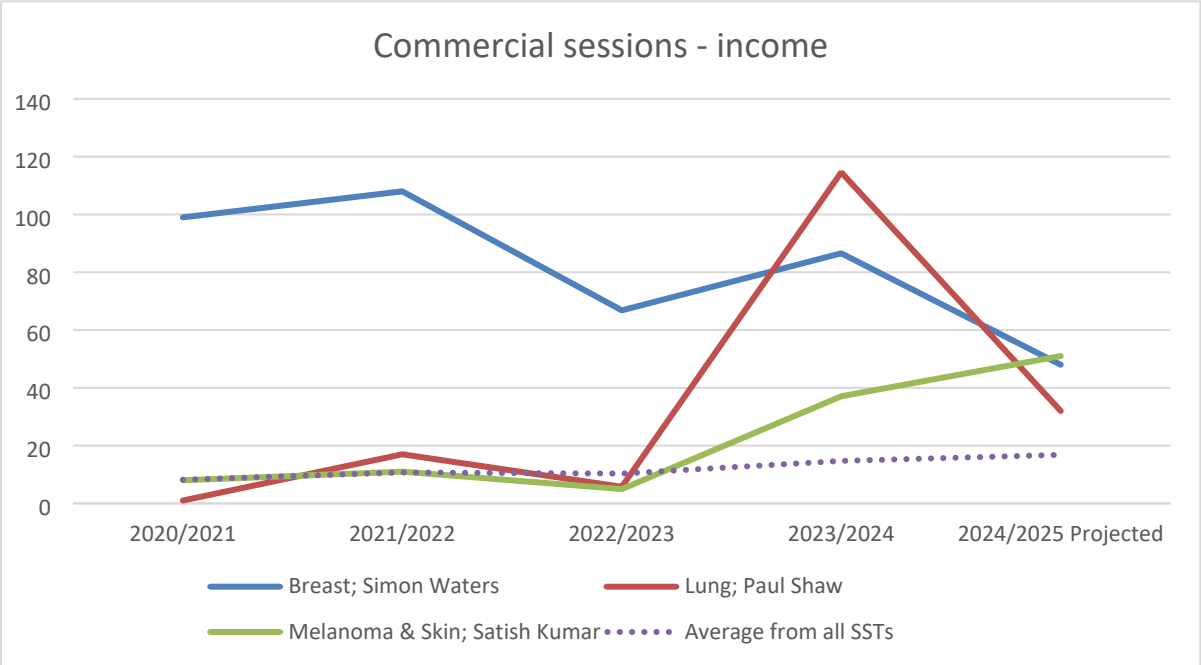
2.3 Numbers of Principal Investigators and Chief Investigators



2.4 Clinical trial income data



2.5 Commercial sessions



2.6 Cardiff Cancer Research Hub clinical trial portfolio

CCRH: Clinical Operations Group – is operational!

Open Trials	Drug Type	Lead Site	Nursing Teams	Delivery Clinical Area
Morab	Antibody Drug Conjugate	VCC – Solid Tumour	CCRH & CRF	CRF @ C&V
Monumental 6 **Top recruiter in the UK**	Bi-Specific	CVUHB - Haematology	CCRH & CRG	CRF, Haem B4 Ward @ C&V

Trials in Set up	Drug Type	Lead Site	Nursing Teams	Delivery Clinical Area
Iovance **Opening March 2025**	TILs	VCC – Solid Tumour	CCRH, CRF & CRG	CRTU, 1st floor @ VCS PACU @ UHW
ATTR-01 **Opening February 2025**	Oncolytic Virus Vaccine	VCC – Solid Tumour	CCRH & CRG	CRF @ C&V
BNT116 **Opening February 2025**	mRNA Cancer Vaccine	VCC – Solid Tumour	CCRH & CRF	CRF @ C&V
J&J 75276617ALE1001 **Opening Mar/Apr 2025**	Menin-KMT2A Inhibitor Bleximenib	C&V – Haematology	CCRH & CRF	CRF @ C&V

Claire Lang – Senior Nurse Manager, CCRH

Gabby Brutto – Research Nurse, CCRH

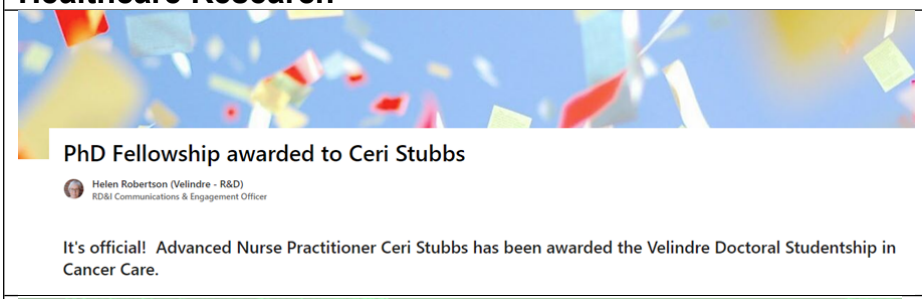
Dr Phil Savage – Medical Oncology Clinical Academic, CCRH

Dr Ashley Poon-King – 1 of 5 Clinical Research Fellows, CCRH

- Existing facilities being used – depending on CTIMP classification and risks (limited capacity, not cancer focused)
- 4 (of 5) Clinical Research Fellows in post and covering hub trials 1 day/week
- CCRH nursing team working across sites between Velindre and CAV.

3 Good News Stories

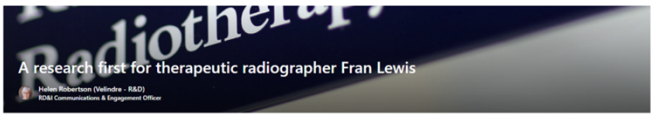
For further details on specific news stories that celebrate the achievements of some of the posts funded by the Integrated Bid, please see below -

Healthcare Research	
	Read the story here
	Read the story here
	Read the story here
Palliative and Supportive Care	
	Read the story here
	Read the story here

4 A snapshot of the internal and external stories generated by the dedicated R&D Communications post

Telling our stories to our people

A life changing six years of study brings success for Welsh Blood Service RD&I's Dr Felicity May.



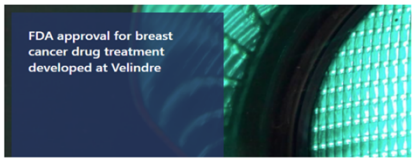
Congratulations to Fran Lewis who has been awarded the Research Capacity Building Collaboration Wales (RCBC Wales) First into Research fellowship.

Fran is the first therapeutic radiographer from Velindre Cancer Centre to have been awarded this highly competitive opportunity.

PhD Fellowship awarded to Ceri Stubbs

It's official! Advanced Nurse Practitioner Ceri Stubbs has been awarded the Velindre Doctoral Studentship in Cancer Care.

Two of our intrepid senior research nurses headed off to the Green Man Festival in the beautiful Bannau Brycheiniog last Sunday.



Welsh Blood Service partners with UK Defence Services

The Component Development & Research Laboratory (CDRL) is partnering with the Ministry of Defence to investigate a cutting-edge new development in blood components for military use.

Telling our stories to the world

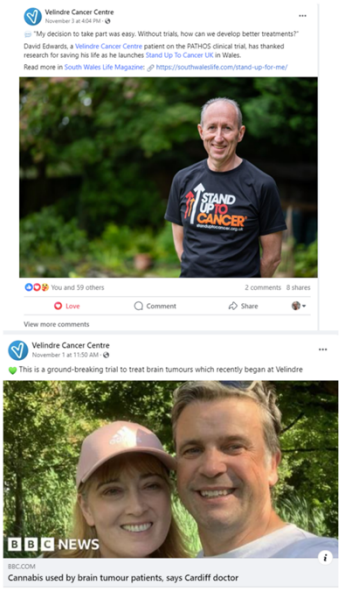
Velindre proud to be part of successful clinical trial

7 November 2023

The results of INTERLACE trial mark the biggest cervical cancer drug advance in 20 years.

The success of the INTERLACE clinical trial has recently been reported, bringing the promise of improvement in outcomes for women diagnosed with cervical cancer.

Treial i drin tiwmor yr ymennydd yn torri tir newydd



Joint Velindre and Cardiff University head and neck cancer trial passes incredible 1000 patient recruitment milestone!

6 September 2023

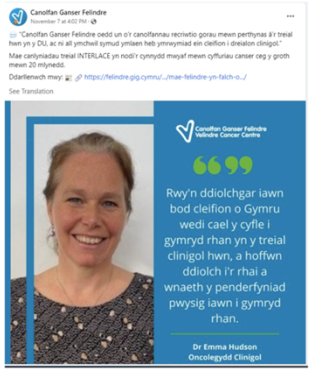
PATHOS, a Velindre University NHS Trust and Cardiff University co-sponsored clinical trial, is a Phase III, international trial aiming to develop a kinder treatment for patients with head and neck cancer.

It is looking at the role of less intensive treatment after minimally invasive surgery for people whose cancers have tested positive for Human Papilloma Virus (HPV). The 1000th patient was recruited in the last week of August 2023 at the Liverpool Head and Neck Centre.

Professor Mererid Evans, Consultant Oncologist, Cardiff University and Velindre University NHS Trust said:

"I am honoured to lead PATHOS, along with Professor Terry Jones from Liverpool University. Recruiting the 1000th patient to PATHOS is beyond all our expectations and is a tribute to all the hard work done by research teams at sites across the UK, as well as in France, Germany, Australia and the USA.

"We believe that by the time PATHOS completes recruitment next year, it will be the



5 List of publications and abstracts

Articles

Early Phase Trials Team

M. Beresford, A. Casbard, Z. Hudson, M. Carucci, K. Ingarfield, J. Gee, J. Smith, T. Kitson, F. Alchami, T. A. Madden, L. Hayward, D. Hwang, S. Spensley, S. Waters, D. Wheatley and R. H. Jones (2023). "Fulvestrant plus vandetanib versus placebo for the treatment of patients with metastatic breast cancer resistant to aromatase inhibitor therapy (FURVA): a multicentre, Phase 2, randomised controlled trial." BJC Reports 1(1): 13.

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Minutes
Private Research, Development & Innovation Sub-Committee
Velindre University NHS Trust

Date 10/12/2024
Time 12.30 – 1.30pm
Location Trust Headquarters, 2 Charnwood Court, Parc Nantgarw, Cardiff
Chair Professor Andrew Westwell, Independent Member

PRESENT		
Professor Andrew Westwell	Independent Member and Research, Development & Innovation Sub-Committee Chair	**AW**
Professor Donna Mead	Professor Donna Mead, OBE Trust Chair	**DM**
Vicky Morris	Independent Member	**VM**
ATTENDEES		
Jacinta Abraham	Executive Medical Director and R&D Lead	**JA**
Matthew Bunce	Executive Director of Finance	**MB**
Anne Carey	Interim Chief Operating Officer	**AC**
Non Gwilym	Interim Director of Corporate Governance	**NG**
Jennet Holmes	Head of Innovation	**JH**
Rhydian Owen	R&D Cancer Strategy Lead	**RO**
Professor Robert Jones	Associate Medical Director for Research, Development & Innovation	**RJ**
Nicola Williams	Director of Nursing, AHP's & Healthcare Scientists	**NW**
SECRETARIAT		
Sandra Cusack	Business Support Officer	**SMC**

1.0	**PRELIMINARY MATTERS**	
1.1	**Welcome and Introduction** *Led by Professor Andrew Westwell, Research, Development & Innovation Sub-Committee Chair*	
1.2	**Apologies Received From:** • Christopher Cotterill-Jones, Research Delivery Manager • Dr Edwin Massey, Medical Director, Welsh Blood Service • Sarah Townsend, Head of Research & Development	
1.3	**In Attendance** • Kate Cleary, R&D Cancer Strategy Programme Manager • Dr James Powell, Clinical Consultant Oncologist (for Item 3.3) • Helen Robertson, RD&I Communications & Engagement Officer (Observer)	
1.4	**Declarations of Interest** *Led by Professor Andrew Westwell, Chair of the Research, Development & Innovation Sub-Committee* No declarations of interest were raised.	
2.0	**STANDARD BUSINESS**	
2.1	**Minutes from the Private Research, Development & Innovation Committee held on the 17th September 2024** *Led by Professor Andrew Westwell, Chair of the Research, Development & Innovation Sub-Committee* AW requested a minor amendment made to Item 3.1 Innovation Small Grant Scheme, change the 'Advancing Radiotherapy Fund' to 'Advancing Radiotherapy Cymru'. Following the above amendment, the Research, Development & Innovation Sub-Committee **APPROVED** the Minutes of the Private Meeting held on the 17th September 2024 as an accurate reflection of proceedings.	**SMC**
2.2	**Review of Action Log** *Led by Dr Jacinta Abraham, Executive Medical Director* and RD&I Lead There were no outstanding actions for review.	
2.3	***Matters Arising*** *Led by Professor Andrew Westwell, Chair of the Research, Development & Innovation Sub-Committee*	

	There were no matters arising.	
3.0	**PRESENTATION AND GUEST ATTENDEES**	
3.1	**FAKTION Investment Plan Briefing** *Led by Professor Robert Jones, Associate Director of Research, Development & Innovation & Rhydian Owen, Cancer Research & Development Strategy Lead* RJ presented an overview of the FAKTION Investment Plan, outlining a draft proposal to invest the income generated from the Trust's sponsored non-commercial clinical trial FAKTION. The Committee: • **NOTED** the FAKTION Investment Plan Briefing • **NOTED** the development of a strategy for the wide distribution and management of the FAKTION funds	
3.2	**RITA Options Appraisal - Determining the Future of RITA** *Led by Jennet Holmes, Head of Innovation* The RITA chatbot was developed in 2023 as a proof of concept, with funding provided by the charity. It was designed to assist with the first visit to the Cancer Centre, but its usage remained limited. The funding for the project has ended, and the innovation team no longer have the resources to maintain it. The chatbot did not become a business-as-usual service, and its platform (IBM Watson) is now outdated. An independent evaluation was conducted, and four options were proposed. Following the Committee's discussion, it highlighted the need for a strategic approach involving key stakeholders, including digital and governance teams, to ensure any future AI-based services are effectively integrated and maintained. A strategic decision regarding the future of the Rita chatbot and the necessary resources to support it will be taken to a future Executive Management Board. The Research, Development & Innovation Sub-Committee **NOTED** the content of the report.	**JH**
3.3	**Radiation and Medical Physics MSc (RaMP) Bursary Programme** *Led by Dr James Powell, Consultant Clinical Oncologist* James Powell discussed the RaMP Bursary Program, a collaborative project led by Swansea University and Velindre Cancer Centre. The program aims to fund five predefined medical radiation physics projects for students enrolled in the MSC Radiation Physics Course at Swansea University. As this is a Swansea initiative, the business case has not gone through the Velindre ARC application process, however as the proposal has Velindre University NHS	

	Trust involvement, the ARC board is seeking to put the application through the RD&I governance process. The Research, Development & Innovation Sub-Committee **AGREED** to support the project in principle but emphasised the need for further detail on the funding breakdown.	**JP/JH**
3.4	**ARF / ARC Project Briefing** *Led by Jennet Holmes, Head of Innovation* The Committee would like to acknowledge Jennet Holmes for her significant contribution to the transition and structuring of the Advancing Radiotherapy Cymru (ARC) programme. Her efforts have been instrumental in creating a robust governance framework, recruiting a dedicated workforce, and ensuring the smooth operation of ARC. This has been particularly valuable given the previous lack of a stable home for the initiative. Jennet's work has been crucial in moving ARC in the right direction and ensuring its success. The Research, Development & Innovation Sub-Committee **NOTED** the reports providing key activities within the Advancing Radiotherapy Fund (ARF) and the Advancing Radiotherapy Cymru (ARC) programme.	
4.0	**CONSENT AGENDA**	
4.1	**Consent - For Approval / Endorsement**	
	There are currently no items for approval / endorsement.	
4.2	**Consent - For Information / Noting**	
	There are currently no items for information / noting.	
5.0	**ANY OTHER BUSINESS**	
	There were no additional items of business brought for discussion.	
6.0	**DATE AND TIME OF THE NEXT MEETING**	
6.1	The Private Research, Development & Innovation Sub-Committee will next meet on the **12th March 2025 from 4.15-5.00pm** at Trust Headquarters, 2 Charnwood Court, Parc Nantgarw, Cardiff.	
7.0	**CLOSE**	