

**November 2022**

- 0.0.0 10:00 - PRESENTATION : WELSH BLOOD SERVICE  
*Led by Professor Andrew Westwell, Chair of the Research, Development & Innovation Sub-Committee*
- 0.0.1 10:00 - WBS RD&I & PROD Study Update ^Slides Attached  
*Led by Sian James, RD&I Facilitation Lead and Felicity May, Clinical Specialist Histocompatibility & Immunogenetics Digital Lead, Welsh Blood Service*  
[0.0.1 WBS\\_RDI\\_-\\_Velindre\\_RDI\\_15\\_11\\_22.pdf](#)  
[0.0.1 PROD Study - Velindre RDI 15\\_11\\_22.pdf](#)
- 1.0.0 10:20 - STANDARD BUSINESS  
*Led by Professor Andrew Westwell, Chair of the Research, Development & Innovation Sub-Committee*
- 1.1.0 Apologies for Absence  
*Led by Professor Andrew Westwell, Chair of the Research, Development & Innovation Sub-Committee*
- 1.2.0 In Attendance  
  - *Felicity May, Clinical Specialist Histocompatibility & Immunogenetics Digital Lead, Welsh Blood Service (Item 0.0.1)*
  - *Christopher Cotterill Jones, Research Delivery Manager (Item 4.3)*
  - *Kate Cleary, Velindre Cancer R&D Strategy Project Support Manager (Observer)*
  - *Debbie Harvey, Project Lead, Life Sciences Hub Wales (Observer)*
- 1.3.0 Declarations of Interest  
*Led by Professor Andrew Westwell, Chair of the Research, Development & Innovation Sub-Committee*
- 1.4.0 Review of Action Log  
*Led by Dr Jacinta Abraham, Executive Medical Director & R&D Lead*  
[1.4.0 RDI PUBLIC ACTION LOG\\_21.07.2022.pdf](#)
- 2.0.0 10:25 - CONSENT ITEMS  
*Led by Professor Andrew Westwell, Chair of the Research, Development & Innovation Sub-Committee*
- 2.1.0 FOR APPROVAL  
*Led by Professor Andrew Westwell, Chair of the Research, Development & Innovation Sub-Committee*
- 2.1.1 Draft Minutes from the meeting of the Public Research, Development & Innovation Committee held on the 21st July 2022  
*Led by Professor Andrew Westwell, Chair of the Research, Development & Innovation Sub-Committee*  
[2.1.1 RDI Public Minutes 21.07.2022 DRAFT.docx](#)
- 2.2.0 10:35 - ITEMS FOR ENDORSEMENT  
*Led by Professor Andrew Westwell, Chair of the Research, Development & Innovation Sub-Committee*
- 2.2.1 RD&I Terms of Reference and Operating Arrangements  
*Led by Dr Jacinta Abraham, Executive Medical Director & R&D Lead and supported by Emma Stephens, Head of Corporate Governance*  
[2.2.1 RDI ToR\\_Cover Paper.docx](#)  
[2.2.1 \(1\) RDI ToR 2022-2023 - 'Clean' Version.docx](#)  
[2.2.1 \(2\) RDI ToR 2022-2023 - with Tracked Changes.docx](#)
- 2.3.0 FOR NOTING  
*Led by Professor Andrew Westwell, Chair of the Research, Development & Innovation Sub-Committee*
- 2.3.1 Draft Summary of the Minutes from the Private Research, Development & Innovation Committee held on the 21st July 2022  
*Led by Professor Andrew Westwell, Chair of the Research, Development & Innovation Sub-Committee*  
[2.3.1 Summary of RDI Private Minutes 21.07.2022 DRAFT \(v2\).docx](#)
- 2.3.2 Audit of Research & Development by NHS Wales Shared Services Partnership  
*Led by Sarah Townsend, Head of Research & Development*  
[2.3.2 R&D Final Internal Audit Report\\_Cover Paper.docx](#)  
[2.3.2 R&D Final Internal Audit Report.pdf](#)
- 3.0.0 10:45 - MAIN AGENDA  
*Led by Professor Andrew Westwell, Chair of the Research, Development & Innovation Sub-Committee*

- 3.1.0 10:45 - Executive Medical Director Briefing  
*Led by Dr Jacinta Abraham, Executive Medical Director & R&D Lead*  
3.1.0 Executive Briefing\_Cover Paper.docx  
3.1.0 Executive Briefing\_Slides.pptx
- 3.2.0 10:55 - Velindre HCARE Research Ambition Update  
*Led by Professor Jane Hopkinson, Velindre Professor of Nursing and Interdisciplinary Cancer Care*  
3.2.0 Velindre HCARE Research Ambition Update\_Cover Paper.docx  
3.2.0 Velindre HCARE Research Ambition Update.docx
- 3.3.0 11:05 - Trust RD&I Sub-Committee Risk Register Extract  
*\*There are no open risks recorded on Datix for escalation to the Research Development & Innovation Sub-Committee*  
*Led by Sarah Townsend, Head of Research & Development*
- 4.0.0 11:10 - STRATEGY, PERFORMANCE AND DELIVERY  
*Led by Professor Andrew Westwell, Chair of the Research, Development & Innovation Sub-Committee*
- 4.1.0 11:10 - Activity Data Benchmarking with other UK Cancer Centres  
*Led by Sarah Townsend, Head of Research & Development*  
4.1.0 Activity Data Benchmarking\_Cover Paper.docx  
4.1.0 Activity Data Benchmarking\_Slides.pptx
- 4.2.0 11:25 - Trust Research, Development and Innovation Performance Report  
*Led by Sarah Townsend, Head of Research & Development and supported by*  
  - Libby Batt, Head of R&D Strategy, Velindre Futures
  - Christopher Cotterill Jones, Research Delivery Manager
  - Peter Richardson, Welsh Blood Service
  - Jonathan Patmore, R&D Finance Manager4.2.0 RDI Performance Report Q2\_Cover Paper.docx  
4.2.0 RDI Performance Report Q2.docx
- 5.0.0 11:55 - HIGHLIGHT REPORTS TO QS&PC & SDC  
*Led by Professor Andrew Westwell, Chair of the Research, Development & Innovation Sub-Committee*  
*Members to identify items to include in the Highlight Report to the Trust Board:*  
*For Escalation*  
*For Assurance*  
*For Advising*  
*For Information*
- 6.0.0 12:00 - ANY OTHER BUSINESS  
*Prior Approval by the Chair Required*
- 7.0.0 12:00 - DATE AND TIME OF THE NEXT MEETING  
*The next meeting is arranged to be held on 28th February 2023 at 10:00am via Microsoft Teams.*
- 8.0.0 12:00 - CLOSE  
*The Committee is asked to adopt the following resolution in accordance with the Public Bodies (Admission to Meetings) Act 1960:*  
*The Committee hereby resolves that the remainder of the meeting be conducted 'In-Committee - Private Part B'.*

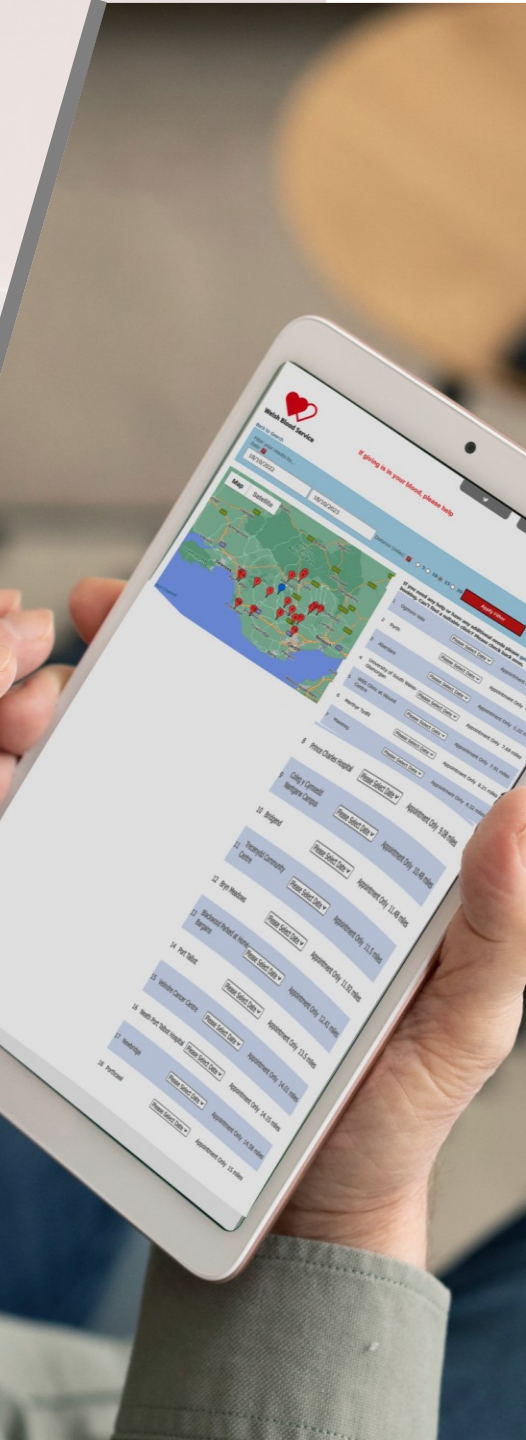
# Research, Development & Innovation



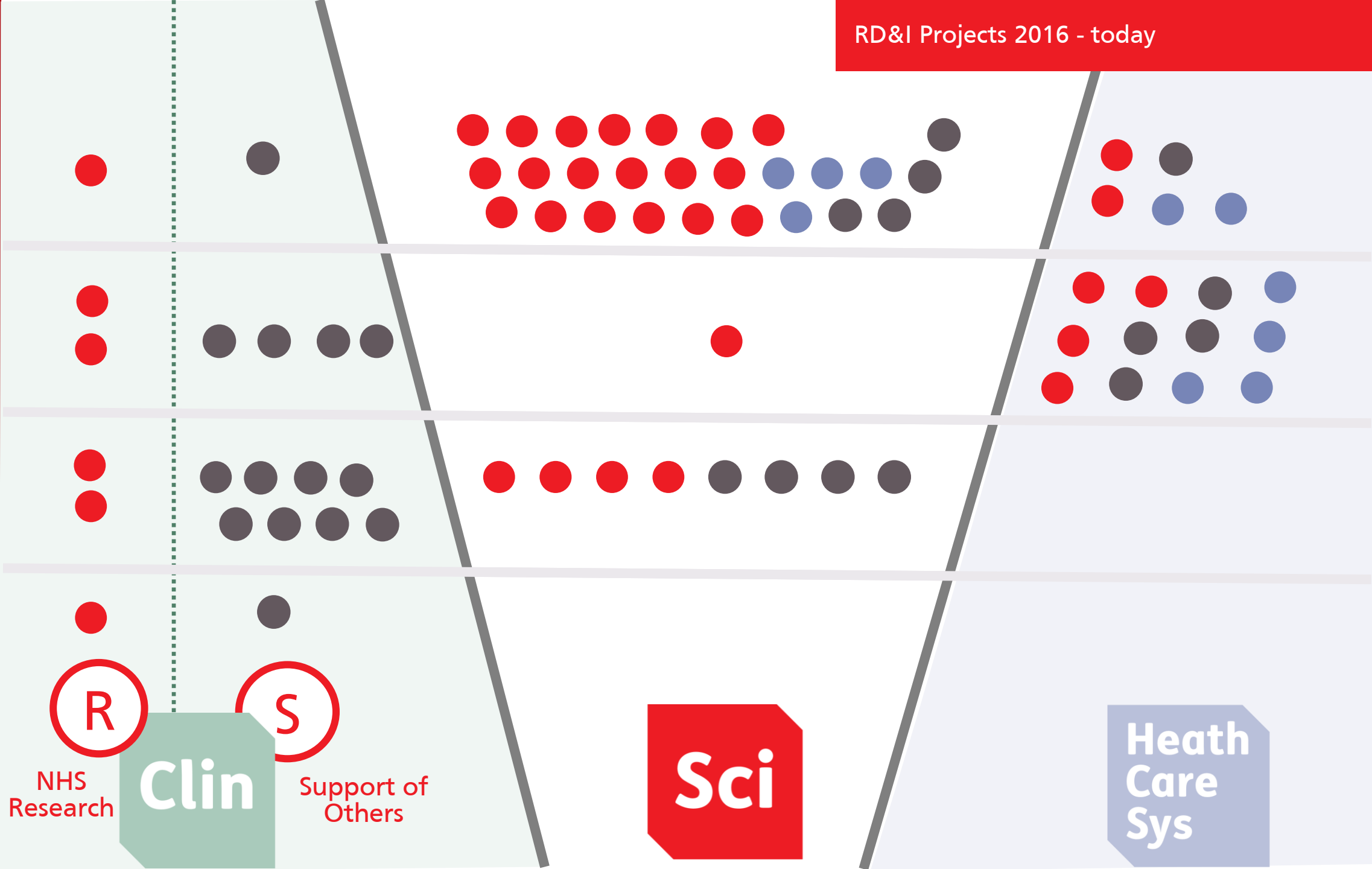
**Gwasanaeth Gwaed Cymru**  
**Welsh Blood Service**











NHS  
Research

Clin

Support of  
Others

Sci

Health  
Care  
Sys

# Updating the Research, Development & Innovation Strategy



# Stage 2

**Stakeholder Engagement  
& Ideas Capture  
Option Selection**

The  
Ask.

**Where are you going to place WBS?**

# Stakeholders

**WBS Researchers**

**WBS Management**

**Velindre RD&I Enablement**

**Velindre Management**

**Universities**

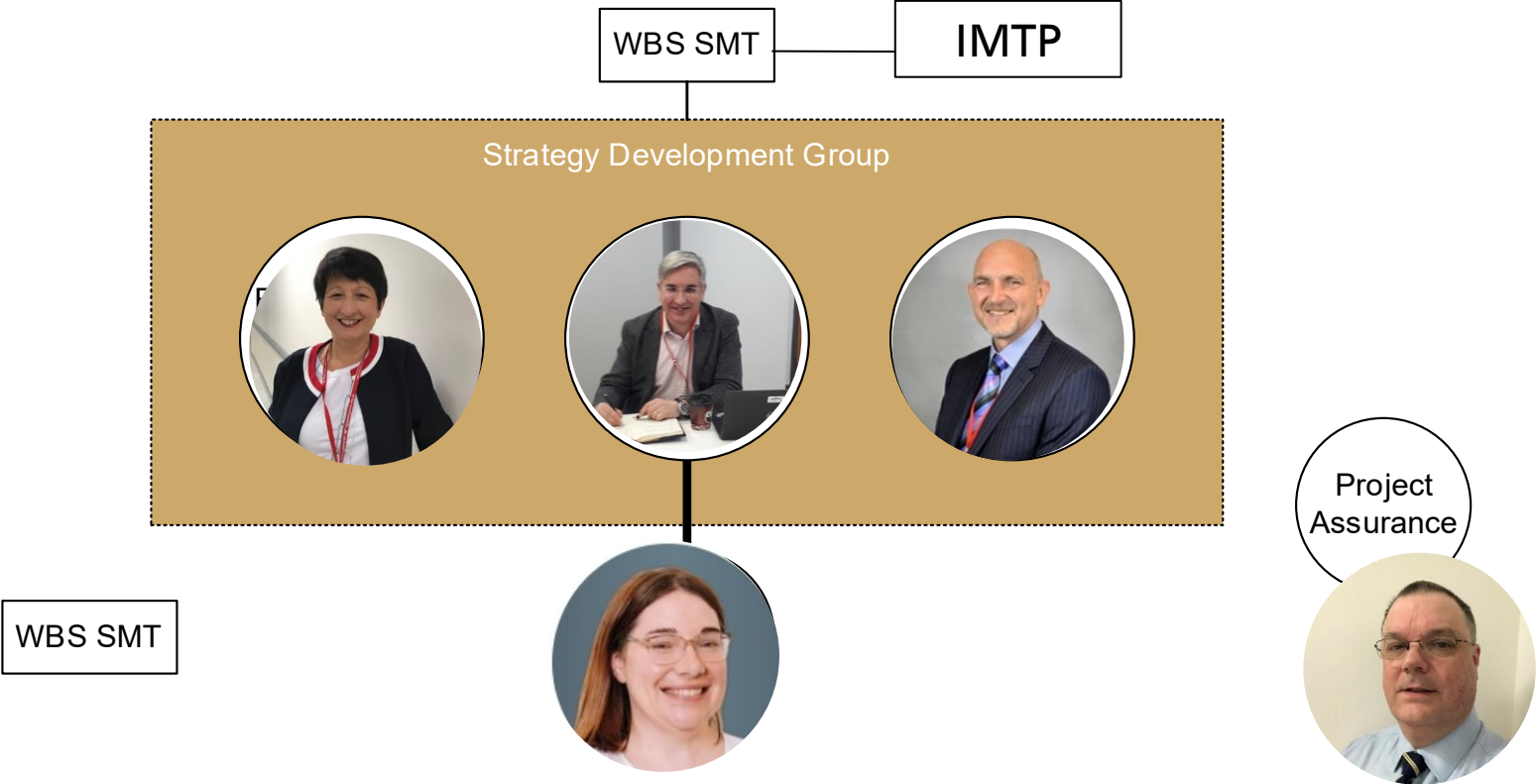
**Commercial Partners**

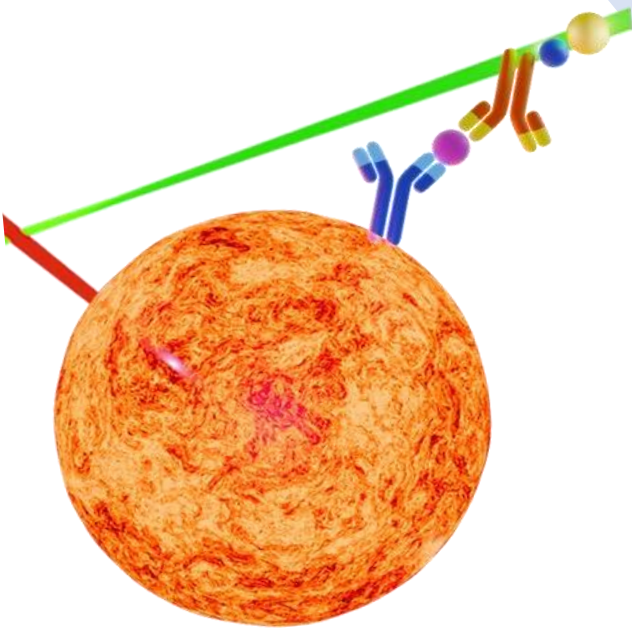
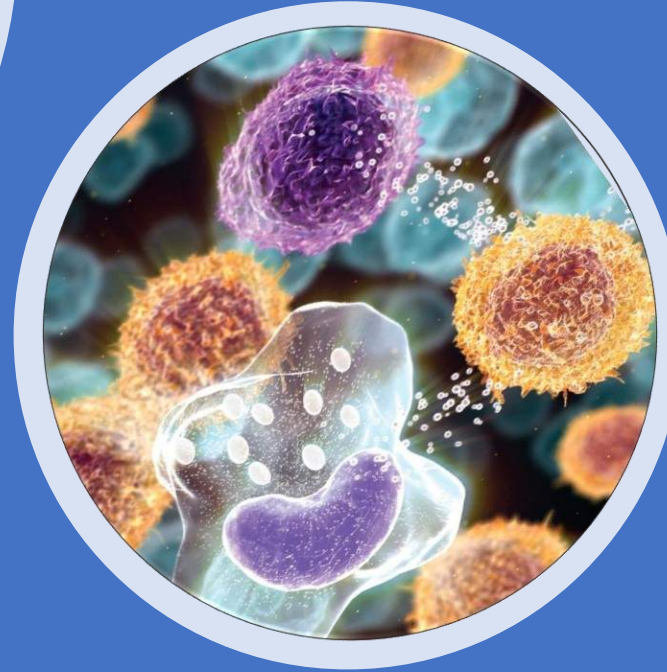
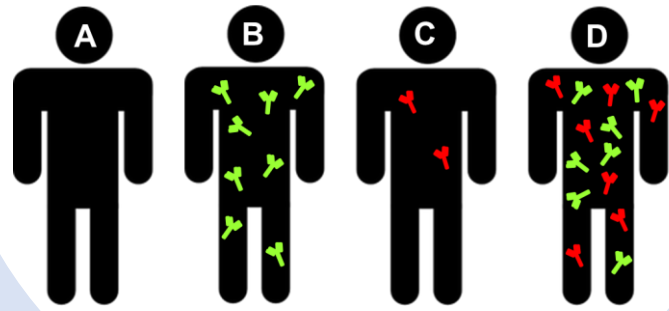
**Other Blood Establishments**

**Blood Institutions & Societies**

**Public input**







GIG  
CYMRU  
NHS  
WALES

Ymddiriedolaeth GIG  
Prifysgol Felindre  
Velindre University  
NHS Trust



GIG  
CYMRU  
NHS  
WALES

Bwrdd Iechyd Prifysgol  
Caerdydd a'r Fro  
Cardiff and Vale  
University Health Board

MANCHESTER  
1824

The University of Manchester

CARDIFF  
UNIVERSITY

PRIFYSGOL  
CAERDYDD

# PROD Study

PRedictive Biomarkers Of  
Response to Desensitisation



Gwasanaeth Gwaed Cymru  
Welsh Blood Service



# Overview

What is HSST?

DClinSci Project Overview

Research background and aims

What went well?

What was challenging?

Future Work

# My Story

2007

- Trainee Clinical Scientist
- Welsh Transplantation & Immunogenetics Laboratory (WTAIL)



2010

- Completed PG Diploma
- Histocompatibility and Immunogenetics (H&I)



2011

- Registered as Clinical Scientist

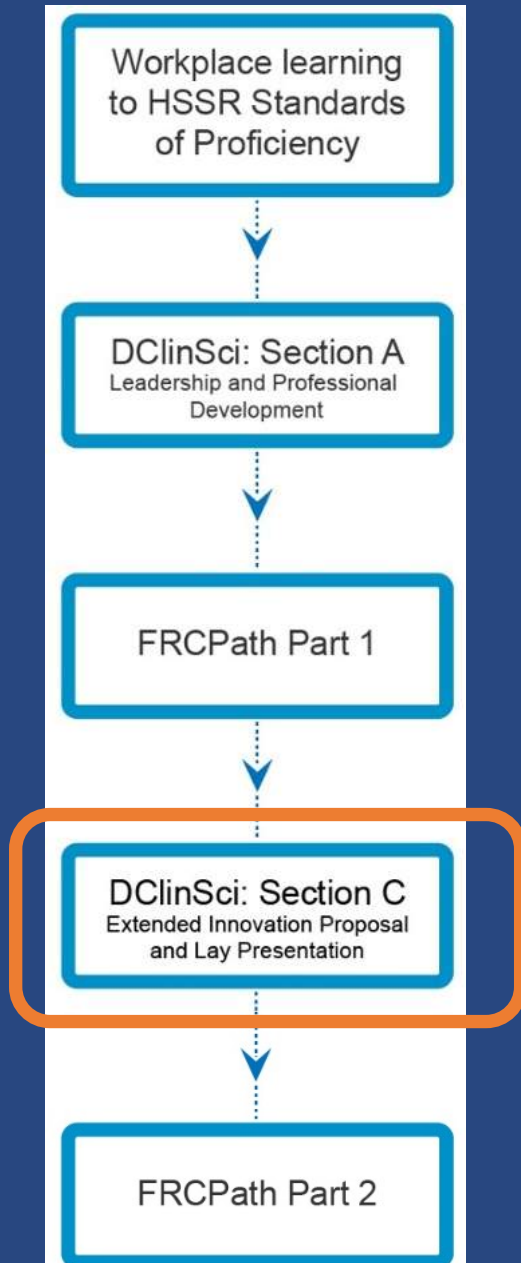


2017

- Started Higher Specialist Scientific Training (HSST)







# Higher Specialist Scientific Training

- 🔴 5 Year Professional Doctorate

  - 🔴 +1 year to complete viva and portfolio

- 🔴 Run by National School of Healthcare Science

- 🔴 Essential for consultant clinical scientist posts

- 🔴 Part time, vocational

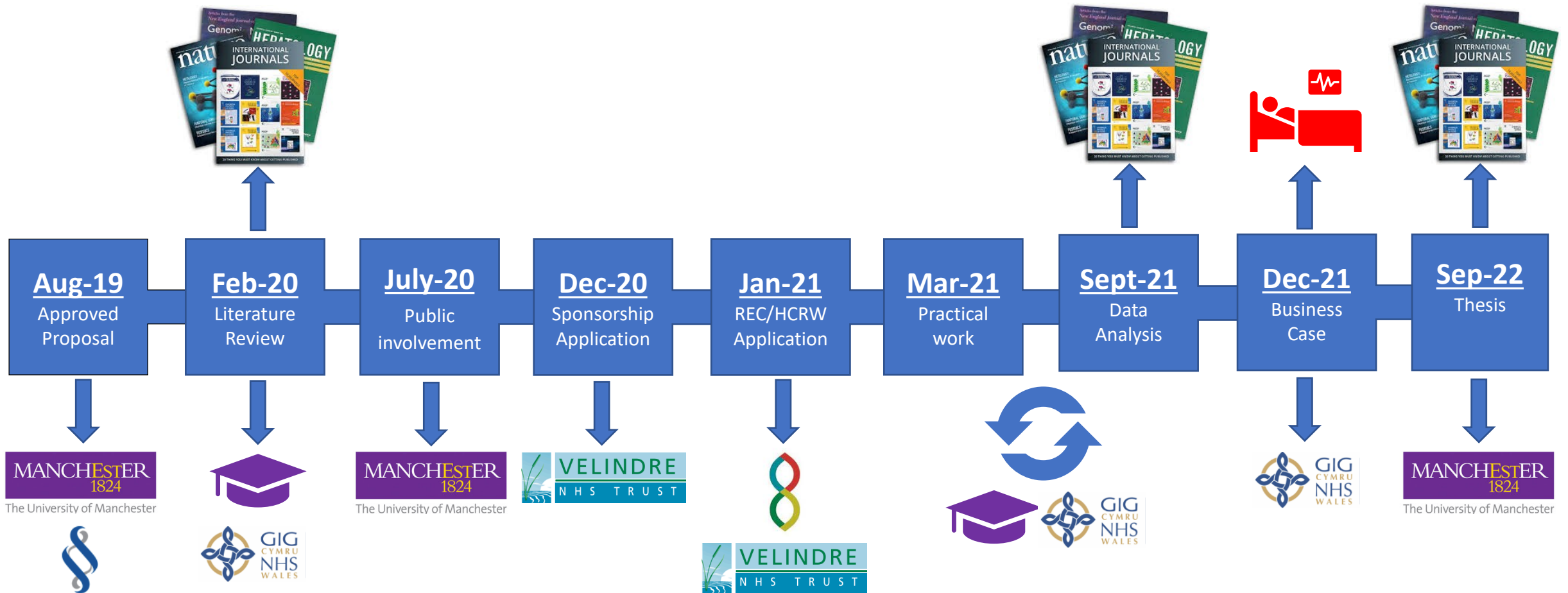
- 🔴 5 main elements


  - 🔴 Including PhD-level research project


- 🔴 Welsh Blood Service HSSTs

  - 🔴 First of x4 WBS HSSTs, Y6


# Research Project Plan



 = Academic supervisor (UoM)

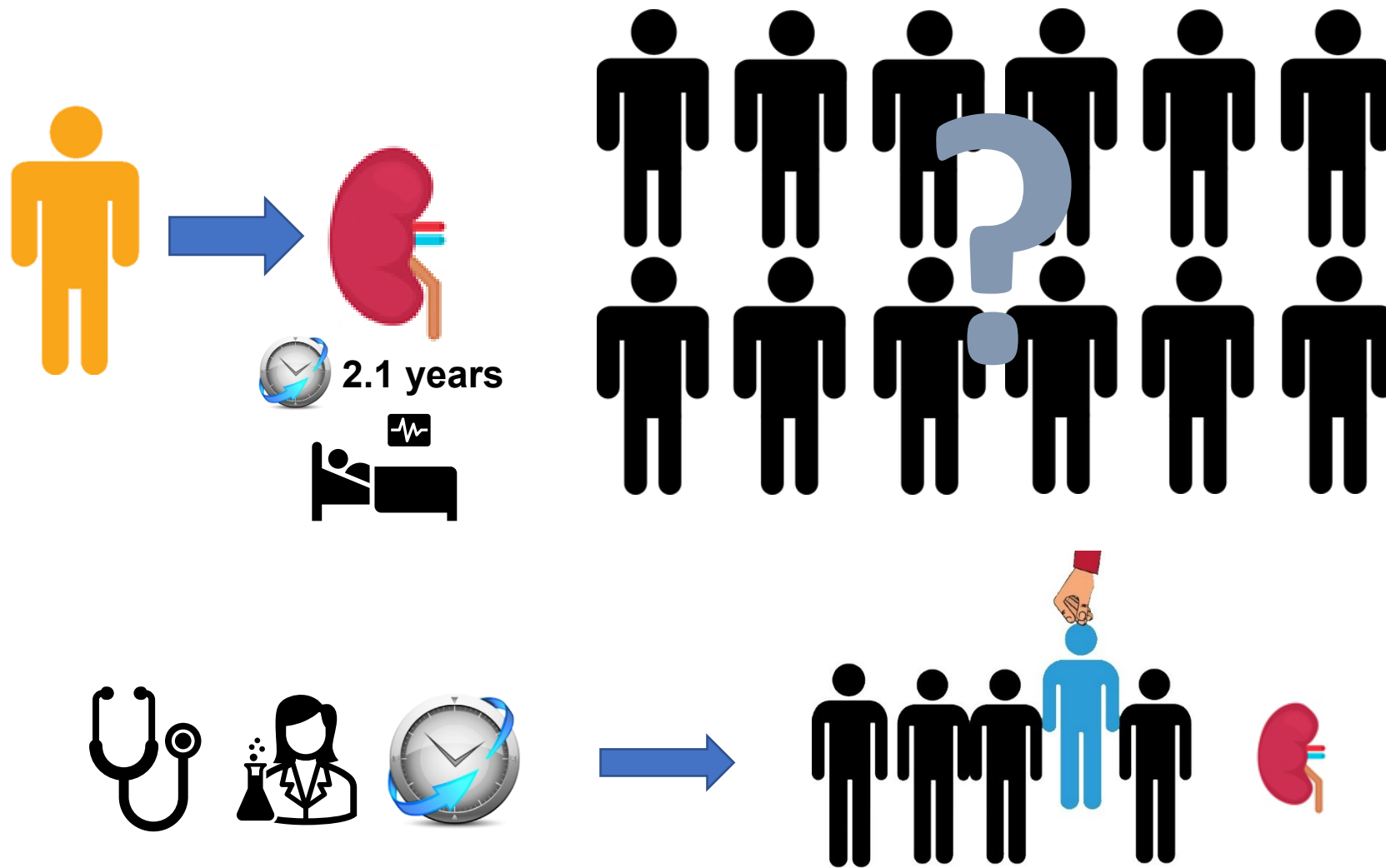
 = Workplace supervisor & NHS Collaborators

 = Royal College of Pathologists

 = Health & Care Research Wales

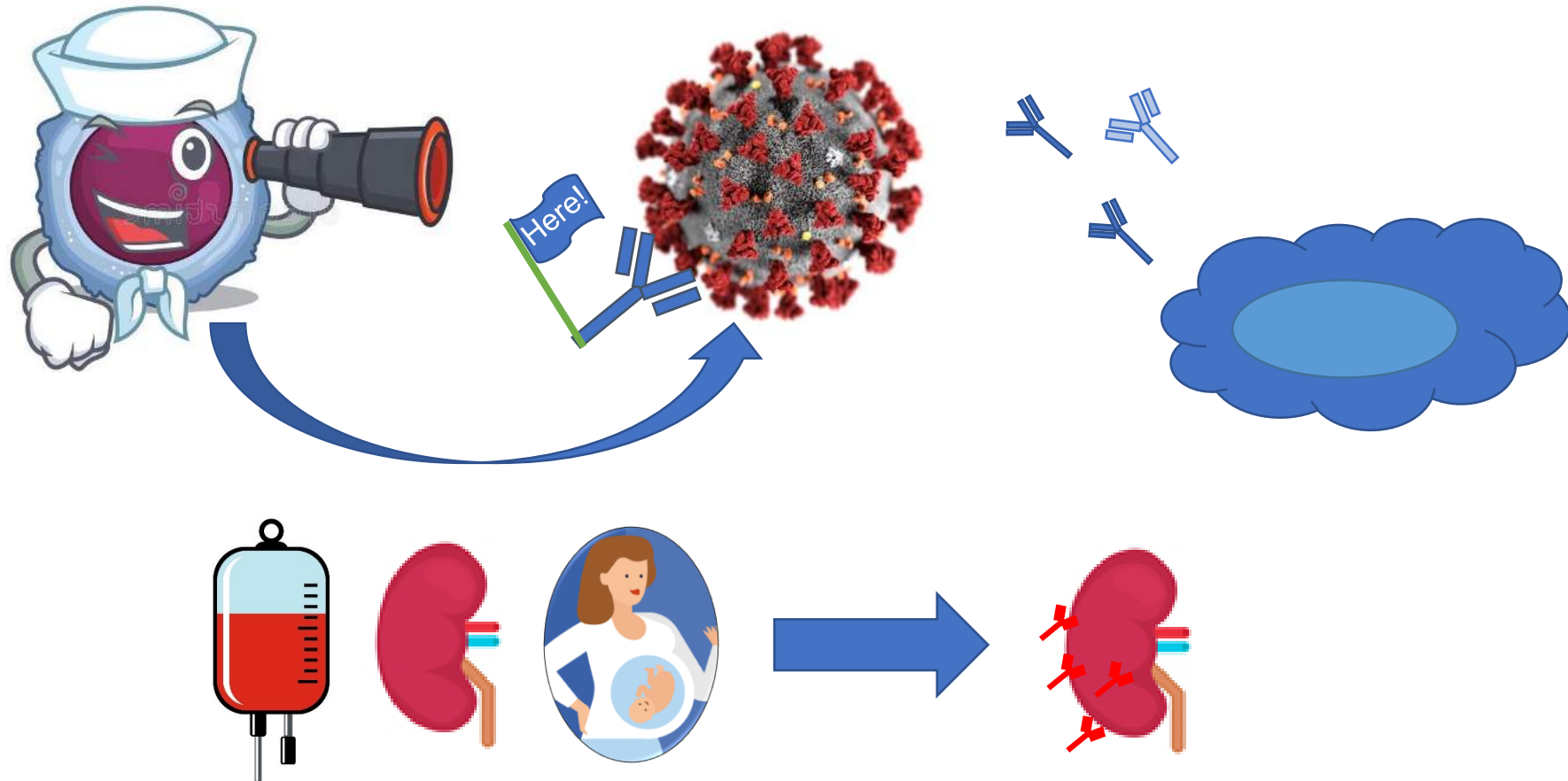
 = VUNHST RD&I

# Research Background

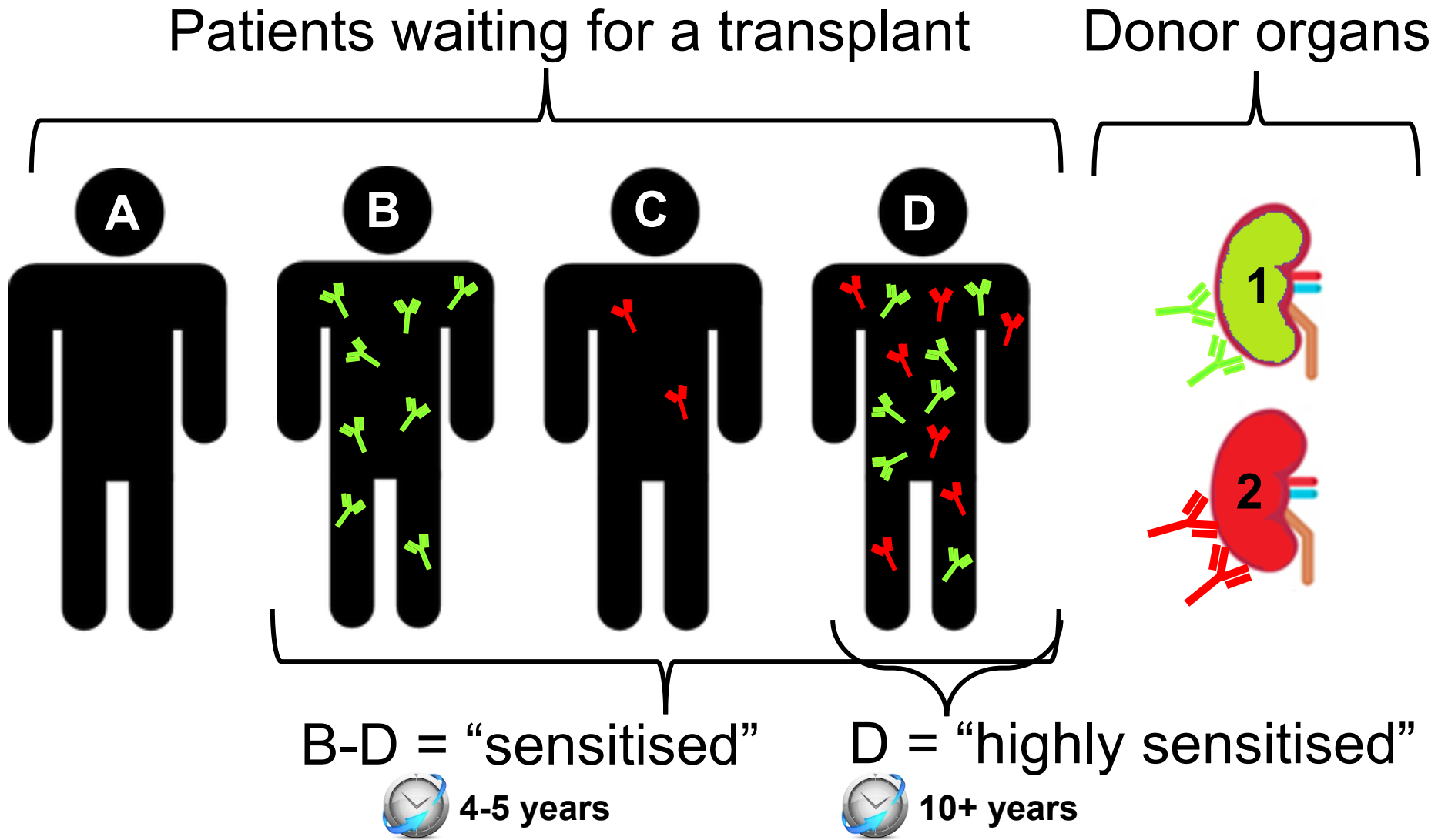




# Antibodies



# Sensitisation



# Desensitisation



# Variation in Patient Response



## ‘Desensitisation’

- > reduce antibody levels
- > increase donor options
- > reduce waiting/inequity



## Response to treatment known to vary



## Little known about:

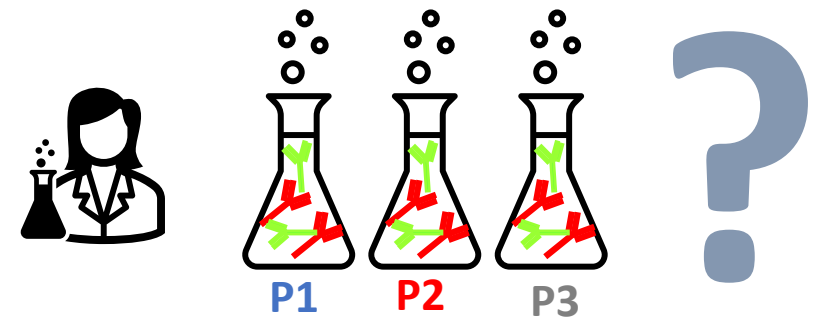
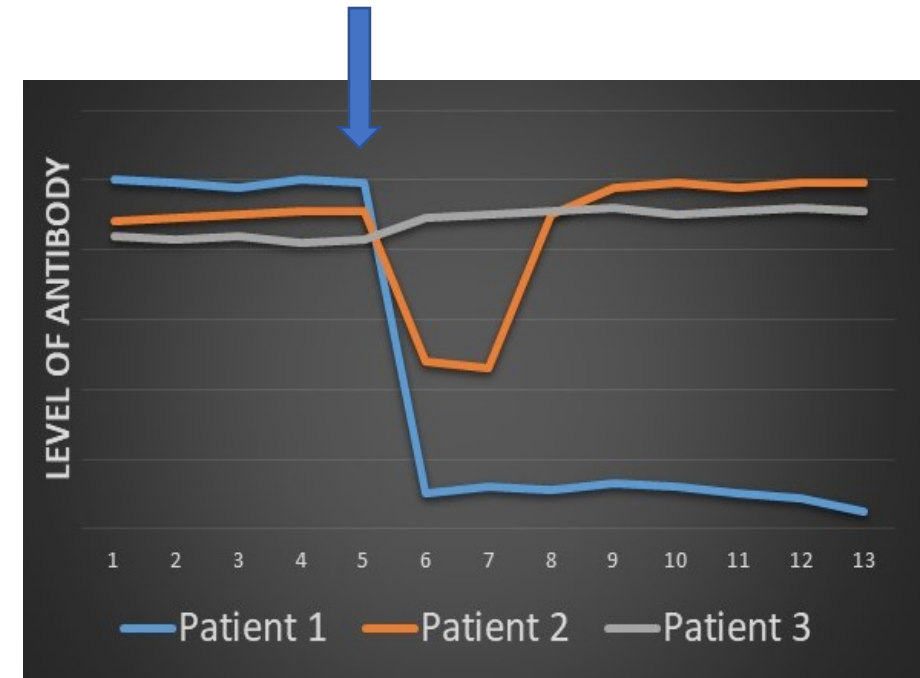
- > How treatment works
- > Why response varies
- > Underlying mechanisms



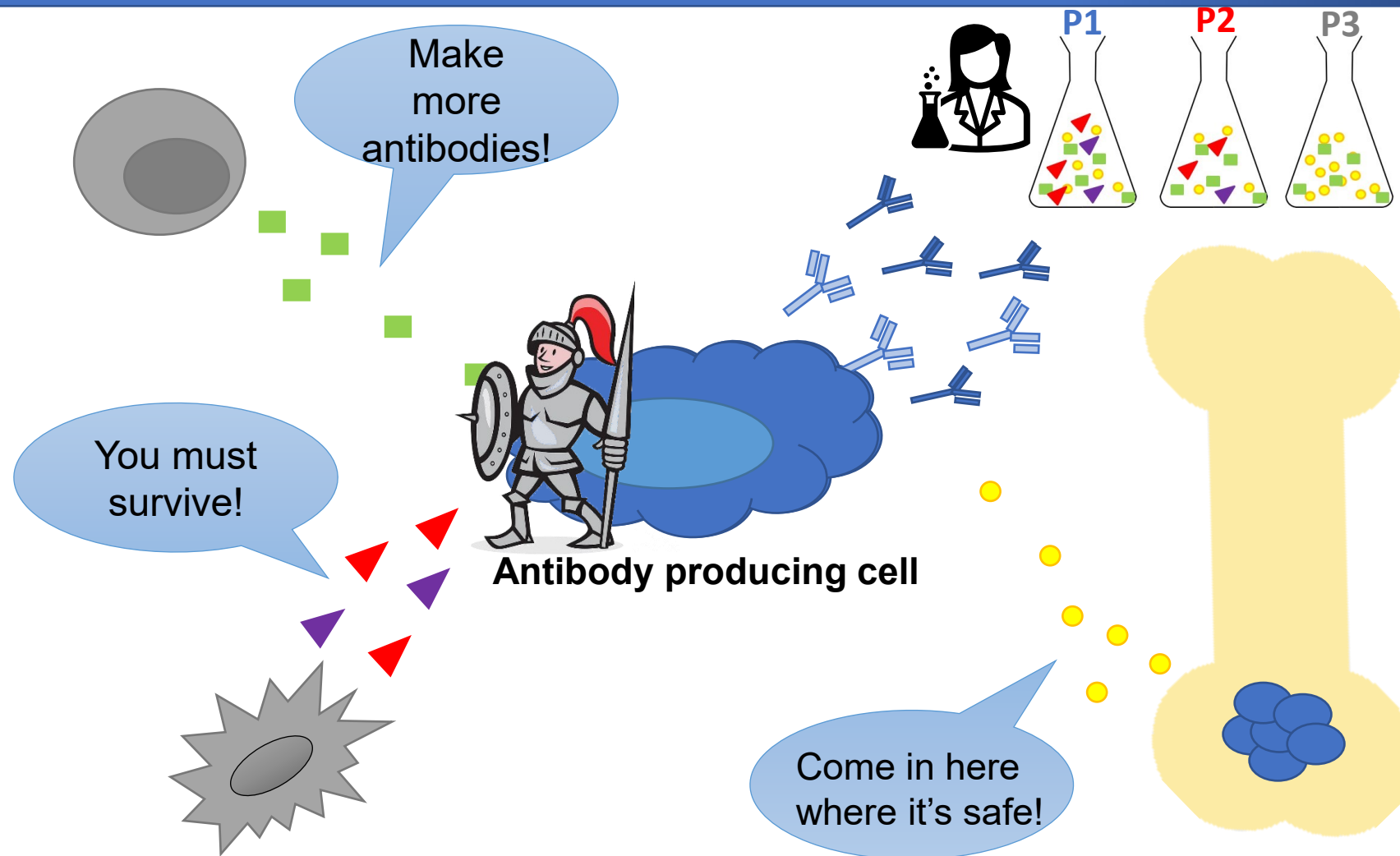
## How would predicting response help?

- > Avoid risks/side effects
- > Prevent waste (money/resource)
- > Alternative treatments

## Desensitisation

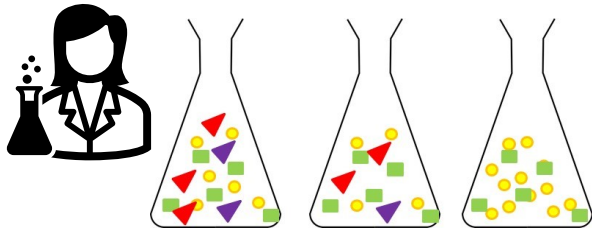


# Area of research: Biomarkers (Cytokines)

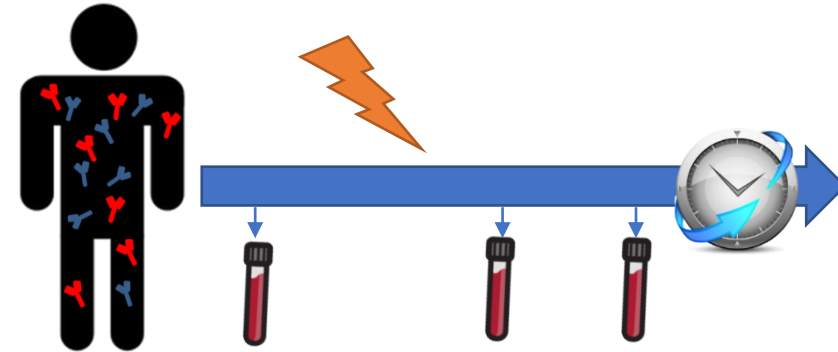




# Research Aim

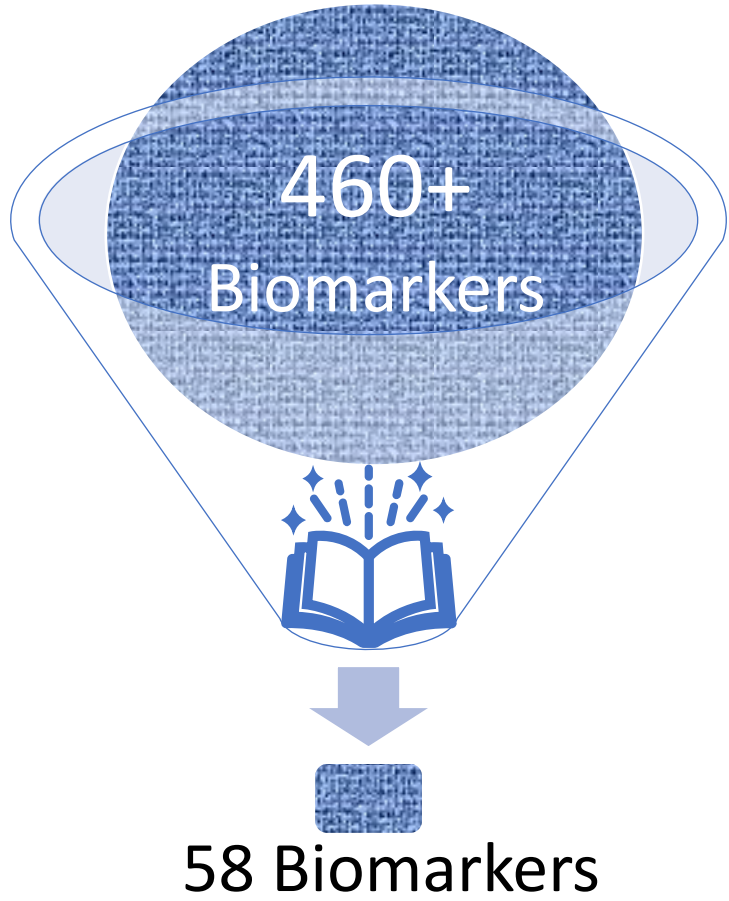


- Develop a test to detect biomarkers
- Test patients who have undergone treatment (before and after)



- Better understanding of the effects of desensitisation
- Compare patients who responded well with those that did not
- Identify a profile to predict response

# What went well?



**R&D SYSTEMS®**



## Collaboration



Bwrdd Iechyd Prifysgol  
Caerdydd a'r Fro  
Cardiff and Vale  
University Health Board



Uned Ymchwil Arennol Cymru  
Wales Kidney Research Unit

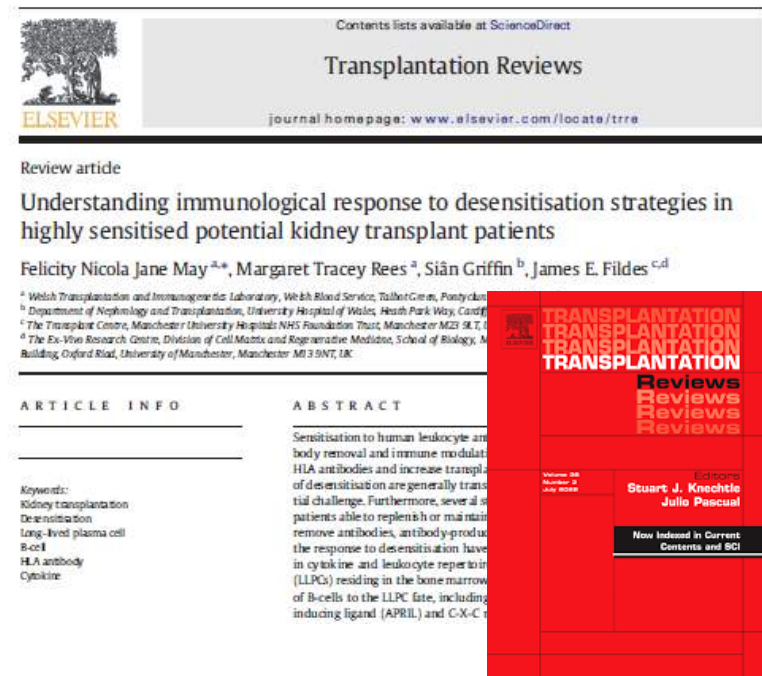


**James  
Lind  
Alliance**

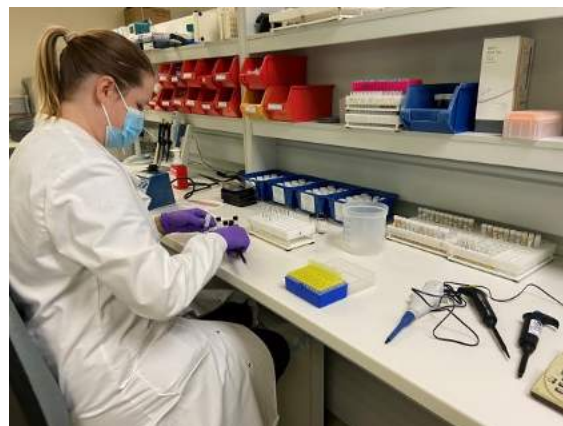
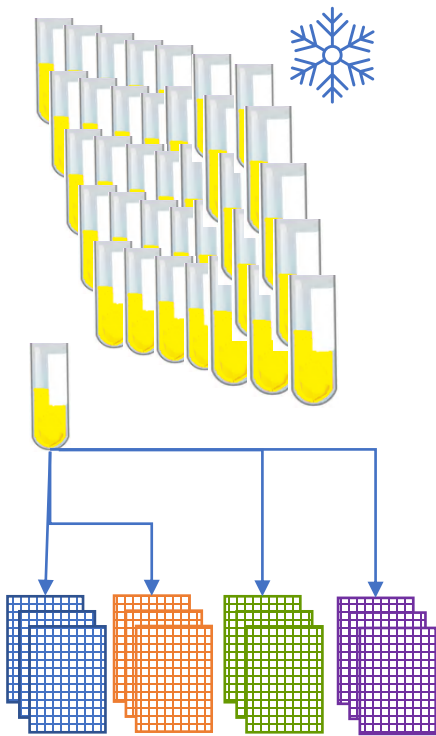
Priority Setting Partnerships



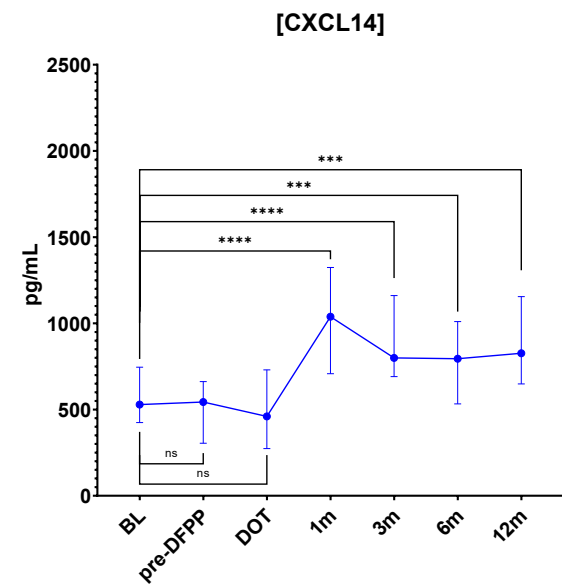
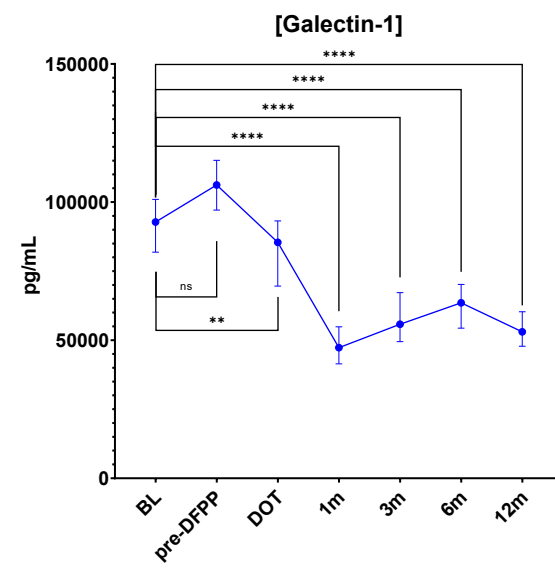
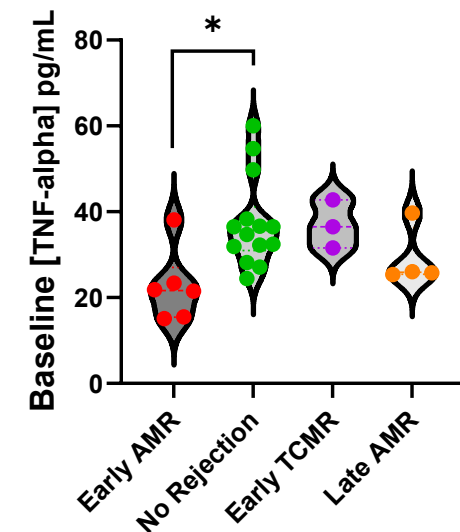
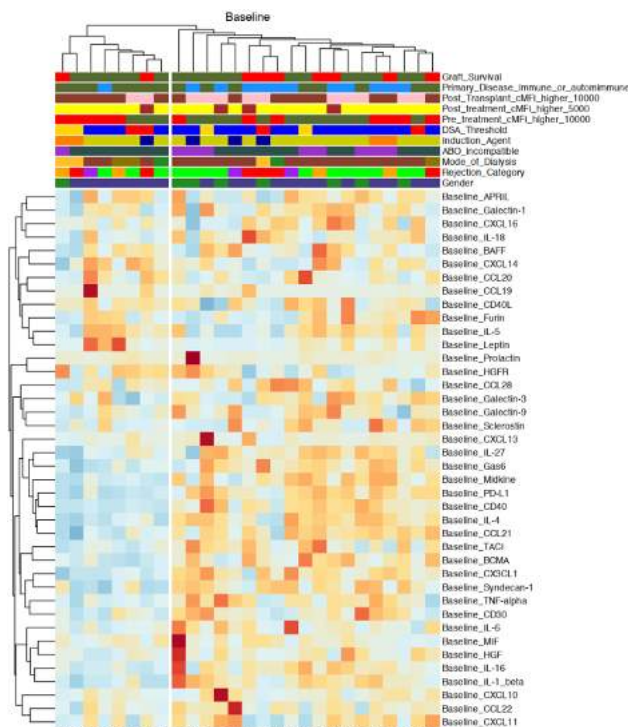
## Publication #1



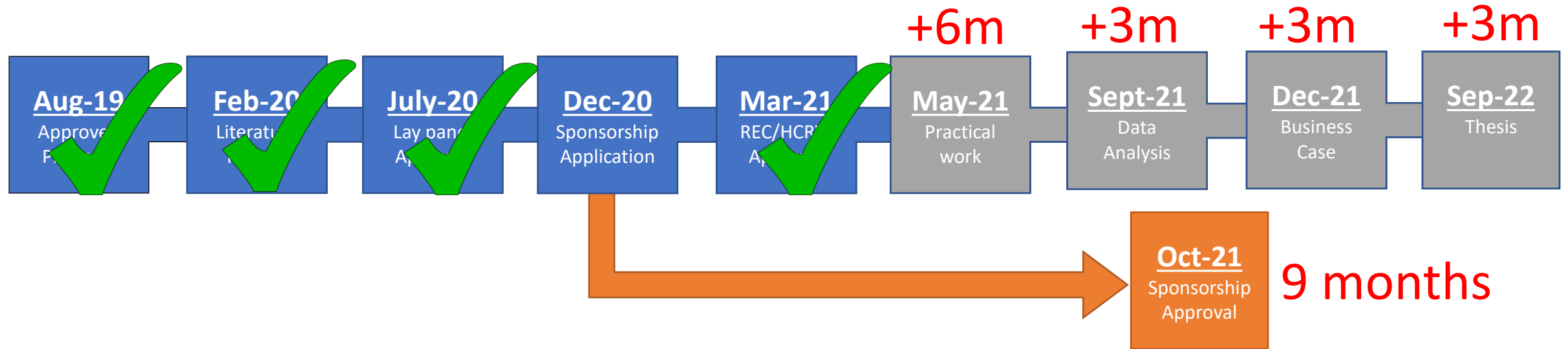
# What went well?



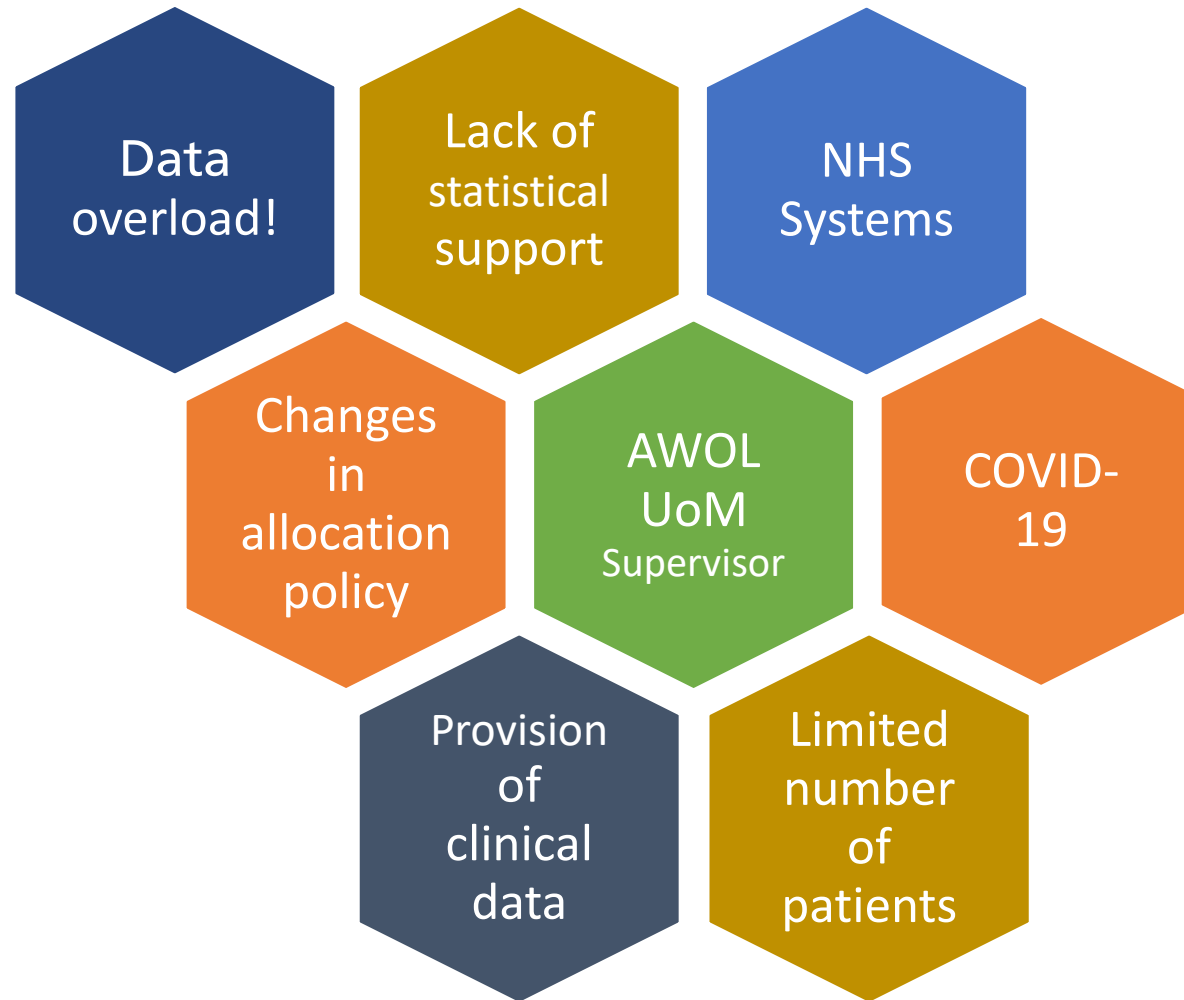
**28 (4 x 7) test kits**  
**=2688 tests, ~39,000 results!**  
**Results for all samples**  
**No run failures**  
**Good quality**



# What was challenging?



# What was challenging?





# Future Work



Publications from Thesis

Methodology

Patient outcomes

Cytokine results/findings



Publications from further analysis

ITOPS samples

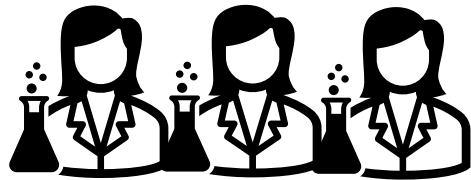
Effluent, additional timepoints



Future Studies

Replicate in other patient cohorts

Apply methodology to other clinical priority areas



Gwasanaeth Gwaed Cymru  
Welsh Blood Service



Future DClinSci  
Research Projects

PUBLIC RESEARCH, DEVELOPMENT & INNOVATION SUB-COMMITTEE ACTION LOG					
Minute Number	Action	Owner	Progress to Date	Target Date	Status (Open/Closed)
Actions agreed at the Committee on 28th April 2021					
5.1	Research Development & Innovation Intellectual Property Workshop - discuss and plan structure for a half-day workshop	Robyn Davies	<p><b>UPDATE 15/11/2022</b> - Confirmation received that Nia Roberts to present the IP Workshop at December's Board Development Session.</p> <p>21/07/2022 : Board Development date arranged for the 27/10/2022. Unfortunately the lead person in AgorIP has left and a replacement has not been made. However, RD has been in contact with a very engaging presenter and IP Attorney, Nia Roberts from Welsh Government, to ask if she would support this session. RD to include contact details and arrangements made in his handover arrangements. RD has also been involved with a small team from the innovation leads group to commission an All-Wales IP strategy from Grant Thorton – this report should be included in the development session.</p> <p>07/04/2022 Update - Workshop to be included on the 2022/2023 Trust Board Development Programme, scheduled date to be agreed.</p> <p>13/01/2022 Update - Meeting with AGORIP has taken place to arrange putting together a workshop.</p> <p>21/10/21 Update - This will now be taken forward following the commencement of Robyn Davies, Head of Innovation and it is planned to schedule the workshop for early 2022.</p> <p>22/07/2021 Update - Following the recent appointment of the new Head of Innovation plans have been initiated to take this forward.</p>		COMPLETED
Actions agreed at the Committee on 21st October 2021					
4.4	Explore potential for set-up of a Velindre Healthcare Fellowship Scheme	Jane Hopkinson	<p><b>UPDATE 15/11/2022</b> - This is included in the November Committee papers.</p> <p>21/07/2022 : JH confirms this is still in progress.</p> <p>07/04/2022 Update - Jane Hopkinson and Libby Batt met on the 17/02/2022 to discuss the Trust Fellowship Scheme. Libby described the fellowship set up for medics and the benefits for the individuals and VCC. A discussion followed with Libby Batt, Jane Darmanin and Sarah Townsend about the potential for set-up of a Velindre Healthcare Fellowship scheme.</p>		COMPLETED
Actions agreed at the Committee on 22nd July 2022					
2.1.1	Beatson West of Scotland Cancer Centre - Paper to be circulated and presented to the RD&I Sub-Committee when available. Idea is to scope out other centres and see what they are doing with research, what their setup and numbers are, as a way of seeing if there are any lessons to be learnt.	Sarah Townsend	<p><b>UPDATE 15/11/2022</b> - This is included in the November Committee papers.</p> <p>21/07/2022 : Draft report ready but have been unable to take it through the governance structure due to changes to EMB dates.</p> <p>07/04/2022 Update - Data to be presented to EMB in June, prior to the next Sub-Committee in July 2022.</p> <p>13/01/2022 Update - The project manager starts shortly and plans have been initiated to take this forward.</p> <p>21/10/2021 Update - Project on hold until the recently appointed Velindre Futures Project Manager is in post, who is currently working their notice period.</p>	15/11/2022	COMPLETED
Actions agreed at the Committee on the 21st July 2022					
2.2.1	Co-ordinate a meeting between JA, ES, ST to review the RD&I Sub-Committee Terms of Reference and Operating Arrangements to incorporate final amendments and present back to the November 2022 Committee meeting.	Sandra Cusack /Jacinta Abraham /Emma Stephens / Sarah Townsend	<p><b>UPDATE 15/11/2022</b> - Final amendments incorporated to the paper and included in the November Committee papers.</p>	15/11/2022	COMPLETED

<b>3.1</b>	Standard Agenda to include: Trust RD&I Sub-Committee Risk Register Extract, to formally note if any items are required to be escalated to the Sub-Committee, in line with the Trust Board Risk Appetite.	<b>Emma Stephens / Lauren Fear</b>	<b>UPDATE 15/11/2022</b> - This is included in the November Committee papers.	15/11/2022	<b>COMPLETED</b>
<b>3.1</b>	With regards to the Velindre Professor of Nursing and Interdisciplinary Cancer Care and Research Fellow, a programme of work to be addressed and brought back to the next meeting. The Report will be presented to the November 2022 Committee.	<b>Nicola Williams / Jane Hopkinson</b>	<b>UPDATE 15/11/2022</b> - This is included in the November Committee papers.	15/11/2022	<b>COMPLETED</b>
<b>4.1</b>	An update on the Integrated Radiotherapy Solution required at the next committee meeting. TCS Director / representative to be invited to the next committee meeting to facilitate a discussion in relation to the IRS. A summary paper will be presented to the November 2022 Committee.	<b>Huw Llewellyn</b>	<b>UPDATE 15/11/2022</b> - This is included in the November Committee papers.	15/11/2022	<b>COMPLETED</b>
<b>4.2</b>	Sub-Committee members to forward any suggestions/recommendations on the format and content of the quarterly RDI Performance Report before the next meeting. This will be presented to the November 2022 Committee.	<b>ALL</b>	<b>UPDATE 15/11/2022</b> - This is included in the November Committee papers.	15/11/2022	<b>COMPLETED</b>
<b>6.1</b>	A Legacy Report on all Innovation Activity to be handed over prior to the departure of Robyn Davies, Head of Innovation.	<b>Jacinta Abraham</b>	<b>UPDATE 15/11/2022</b> - This will now be taken forward following the commencement of the new Head of Innovation.	15/11/2022	<b>COMPLETED</b>
<b>7.0</b>	Support the development of a draft Highlight Report to the QS&P Committee for approval by the Committee Chair.	<b>Sarah Townsend</b>	<b>UPDATE 15/11/2022</b> - This has been drafted and submitted to the November 2022 Meeting of the Quality, Safety & Performance Committee.	15/11/2022	<b>COMPLETED</b>

## Minutes of the Velindre University NHS Trust

### Public Research, Development & Innovation Sub-Committee

**Date** 21/07/2022  
**Time** 10:00-12:30  
**Location** via Microsoft Teams  
**Chair** Professor Andrew Westwell, Independent Member

<b>PRESENT</b>		
Professor Andrew Westwell	Independent Member and Research, Development & Innovation Sub-Committee Chair	AW
Vicky Morris	Independent Member	VM
Professor Donna Mead	Trust Chair	DM
<b>ATTENDEES</b>		
Dr Jacinta Abraham	Executive Medical Director and R&D Lead	JA
Libby Batt	Head of Velindre Cancer R&D Strategy	LB
Christopher Cotterill Jones	Research Delivery Manager	CCJ
Sian James	RD&I Facilitation Lead, Welsh Blood Service	SJ
Dr Edwin Massey	Deputy Medical Director, Welsh Blood Service	EM
Christopher Moreton	Deputy Director of Finance	CM
Jonathan Patmore	RD&I Finance Business Partner	JP
Peter Richardson	SMT Lead RD&I , Welsh Blood Service	PR
Emma Stephens	Head of Corporate Governance	ES
Sarah Townsend	Head of Research & Development	ST
Nicola Williams	Executive Director of Nursing, AHPs and Health Science	NW
<b>SECRETARIAT</b>		
Sandra Cusack	Business Support Officer	SMC

0.0.0	PRESENTATIONS	
0.0.1	<p><b>SLIDE PRESENTATION: FAKTION; A phase 1b/randomised placebo-controlled phase II trial of Fulvestrant +/- (AKT inhibition) in patients with incurable breast cancer</b></p> <p><i>Led by Professor Robert Jones, Associate Medical Director for Research, Development &amp; Innovation</i></p> <p><i>Professor Robert Jones, Associate Medical Director for RD&amp;I</i> presented the data from the FAKTION Study and explained the background to the clinical trial that is led by Cardiff University, Velindre University NHS Trust and AstraZeneca that found a combination of drugs could help prolong the lives of patients with incurable disease. These findings were presented at the world's largest cancer conference – The American Society of Clinical Oncology Conference in Chicago in 2019 and most recently June 2022 and published simultaneously in the Lancet Oncology Journal.</p> <p>The latest research builds on the 2019 trial of capivasertib, a breast cancer drug developed by AstraZeneca. Capivasertib blocks the activity of the protein AKT which contributes to resistance to hormone therapy, one of the main forms of treatment for patients diagnosed with incurable disease.</p> <p>When the researchers combined capivasertib with hormonal treatment fulvestrant, it doubled the amount of time patients had their cancer under control (from five months to 10).</p> <p>In the latest phase of the FAKTION trial, patients who had a mutation in their cancer which activated the AKT protein (identified in around half of patients on the trial) lived for around 39 months when given this combination, compared to 20 months when given the hormone plus a placebo.</p> <p>Professor Jones who co-led the trial said that “this new data is very exciting, not only have we shown that capivasertib has the potential to give patients a very significant extension in their lifespan, but we may also be able to select out those patients who are most likely to benefit from the treatment by carrying out genetic tests on their cancer tissue. We are now very keen to see if this is confirmed in a larger phase three trial which has already completed recruitment.”</p> <p>This research is a 10-year partnership between Cardiff University, Velindre University NHS Trust and AstraZeneca. VUNHST was the</p>	



	<p>study sponsor and the University's Centre for Trials Research (CTR) coordinated the trial and its participating centres, involving approximately 150 patients across 19 hospitals in the UK. The CTR is core funded by Welsh Government through the Health and Care Research Wales and Cancer Research UK.</p> <p>The Chair and Sub-Committee members congratulated Professor Jones for his excellent presentation and the amazing results of the trial and commended the ongoing commitment of staff and the excellent work they are undertaking and look forward to hearing about a possible Phase 3 study.</p>	
<b>1.0.0</b>	<b>STANDARD BUSINESS</b>	
<b>1.1.0</b>	<p><b>Apologies</b></p> <ul style="list-style-type: none"> <li>• Matthew Bunce, Executive Director of Finance</li> <li>• Robyn Davies, Head of Innovation</li> <li>• Eve Gallop-Evans, VCC Clinical Director</li> <li>• Steve Ham, Chief Executive</li> <li>• Professor Jane Hopkinson, Velindre Cancer Centre Professor of Nursing and Interdisciplinary Cancer Care</li> <li>• Paul Wilkins, Interim Director of Velindre Cancer Service</li> </ul>	
<b>1.2.0</b>	<p><b>In Attendance</b></p> <ul style="list-style-type: none"> <li>• Kate Cleary, Velindre Cancer R&amp;D Strategy Project Support Manager (Observer)</li> <li>• Professor Robert Jones, AMD for RD&amp;I (Agenda Item 0.0.1)</li> <li>• Hannah Moscrop, Project Manager, TCS (Agenda Item 4.1)</li> <li>• Professor Peter Barrett-Lee &amp; Ross McLeish, Innovation Team (Agenda Item 4.2)</li> </ul>	
<b>1.3.0</b>	<p><b>Declarations of Interest</b></p> <p><i>Led by Professor Andrew Westwell, Chair of the Research, Development &amp; Innovation Sub-Committee</i></p> <p>No declarations of interest were raised.</p>	
<b>1.4.0</b>	<p><b>Matters Arising - Action Log</b></p> <p>Led by Dr Jacinta Abraham, Executive Medical Director</p>	

	<p>The Sub-Committee reviewed all actions identified as having closed since the previous meeting and those whose completion date was due or overdue.</p> <p>The Sub-Committee <b>APPROVED</b> the Action Log and further updates captured in the meeting for the record.</p>	
<b>1.4.1</b>	<p><b>Wales Cancer Industry Forum – an Introduction and Overview</b>  <i>Led by Professor Andrew Westwell, Chair of the Research, Development &amp; Innovation Sub-Committee</i></p> <p>Professor Andy Westwell gave a brief Introduction and Overview of the Wales Cancer Industry Forum.</p> <p>The Sub-Committee <b>NOTED</b> the presentation and looked forward to receiving further updates.</p>	
<b>2.0.0</b>	<p><b>CONSENT ITEMS</b></p> <p><b>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.</b></p>	
<b>2.1.0</b>	<b>FOR APPROVAL</b>	
<b>2.1.1</b>	<p><b>Minutes from the Meeting of the Research, Development &amp; Innovation Sub-Committee held on the 7th April 2022</b>  <i>Led by Professor Andrew Westwell, Chair of the Research, Development &amp; Innovation Sub-Committee</i></p> <p>The Sub-Committee <b>REVIEWED</b> and <b>APPROVED</b> the Minutes of the Public Meeting held on the 7th April 2022 as an accurate reflection of proceedings.</p>	
<b>2.2.0</b>	<b>ITEMS FOR ENDORSEMENT</b>	
<b>2.2.1</b>	<p><b><i>Item moved from CONSENT to MAIN Agenda to allow for further discussion.</i></b></p> <p><b>RD&amp;I Terms of Reference and Operating Arrangements</b>  <i>Led by Emma Stephens, Head of Corporate Governance</i></p> <p>The Sub-Committee were invited to review and propose any amendments required to the Terms of Reference as outlined in the content of the report. A number of additional changes were</p>	

	<p>requested by the Sub-Committee, it was agreed that these would be incorporated and brought back to the next meeting of the next Sub-Committee for Approval.</p> <p><b>ACTION:</b> Co-ordinate a meeting between JA, DM, ES, ST to review the RD&amp;I Sub-Committee Terms of Reference and Operating Arrangements to incorporate final amendments and present back to the November 2022 Committee meeting.</p>	<p><b>SMC/ JA/ DM/ ES/ST</b></p>
<b>2.3.0</b>	<b>FOR NOTING</b>	
<b>2.2.1</b>	<p><b>Draft Summary of the Minutes from the Private Research, Development &amp; Innovation Committee held on the 7th April 2022</b>  <i>Led by Professor Andrew Westwell, Chair of the Research, Development &amp; Innovation Sub-Committee</i></p> <p>The Sub-Committee <b>NOTED</b> the Summary Minutes of the Private Meeting held on the <b>7th April 2022</b></p>	
<b>3.0.0</b>	<b>MAIN AGENDA</b>	
<b>3.1.0</b>	<p><b>Executive Medical Director Briefing</b>  <i>Led by Dr Jacinta Abraham, Executive Medical Director</i></p> <p>The Executive Medical Director briefing reported high-level activities relating to Research, Development and Innovation that took place during quarter 1 of the financial year 2022/23.</p> <p>The following key highlights were reported:</p> <ul style="list-style-type: none"> <li>➤ <b>Welsh Blood Service</b></li> <li>➤ <b>Cancer Research Strategy for Wales (CRest)</b></li> <li>➤ <b>Joint Executive Team Meeting</b></li> <li>➤ <b>University Designation Status and Showcase Event</b></li> <li>➤ <b>Cardiff Cancer Research Hub</b></li> <li>➤ <b>One Site Wales</b></li> <li>➤ <b>MediWales Connects</b></li> <li>➤ <b>Moondance Cancer Awards</b></li> <li>➤ <b>Integrated Medium-Term Plan</b></li> <li>➤ <b>RD&amp;I Internal Audit</b></li> <li>➤ <b>Radiotherapy Research</b></li> </ul> <p>The Sub-Committee found it a really heartwarming and informative executive briefing and said it was a really good way of keeping</p>	

<p><b>3.1 (d)</b></p>	<p>focused on all of the activity that's going on in the Trust. JA thanked the Sub-Committee for the feedback and ST and CCJ for producing the paper and slides.</p> <p>The Sub-Committee <b>NOTED</b> the contents of the Executive Summary Highlights.</p> <p><b>RD&amp;I Sub-Committee Annual Report 2021</b>  <i>Led by Dr Jacinta Abraham, Executive Medical Director, supported by Emma Stephens, Head of Corporate Governance</i></p> <p>ES introduced the RD&amp;I Annual Report to the Sub-Committee for discussion and approval. This Annual Report summarises the key areas of business activity undertaken by the newly established RD&amp;I Sub-Committee in its first year of operation, encompassing the period from the 1 January 2021 up to and including the 31 December 2021.</p> <p>This Annual Report highlights some of the key issues which the RD&amp;I Sub-Committee intends to give further consideration to over the next 12 months, as well as the outcome of the 2021 RD&amp;I Sub-Committee Annual Effectiveness Survey, together with any opportunities for continuous improvement in the year ahead.</p> <p>ES reiterated that the primary purpose of the RD&amp;I Sub-Committee is to:</p> <ul style="list-style-type: none"> <li>• Provide strategy and policy oversight for RD&amp;I activities undertaken by the Trust feeding into its overarching Strategic Development Committee.</li> <li>• Provide assurance on the performance of Research and Development activity feeding into its overarching Quality, Safety &amp; Performance Committee.</li> <li>• Promote and encourage a RD&amp;I ethos and culture, integral to the Trust's vision, mission and values.</li> <li>• Provide assurance to the Board in relation to the Trust's arrangements for ensuring compliance with the UK Policy Frameworks for Health &amp; Social Care Research as amended from time to time.</li> <li>• Consider relevant matters with reference to the parameters identified for risk appetite in relation to RD&amp;I as set by the Board.</li> </ul>	
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	<p>AW thanked ES for including the Effectiveness Survey results in the report and suggested the graphs / charts could be condensed in future reports.</p> <p>VM questioned whether we should formally include bringing a Risk Register relevant to RD&amp;I to this Sub-Committee. JA confirmed that the risk register is managed by the Operational Management Group and if a RD&amp;I risk was identified that was to trigger a risk level that is high enough for the Sub-Committee, then it would automatically be included for presentation to this Sub-Committee. Discussions ensued that it would be good for future reports, just to make that reference so that we can see from an audit point of view, if you had to look back, that we are being very clear as an RD&amp;I Sub-Committee that there aren't any risks that have been triggered and that would be helpful in terms of ES going back to our recent discussions on the wider Risk Management Policy.</p> <p><b>ACTIONS:</b> Standard Agenda to include: <b>Trust RD&amp;I Sub-Committee Risk Register Extract</b>, to formally note if any items are required to be escalated to the Sub-Committee, in line with the Trust Board Risk Appetite.</p> <p>VM queried whether a programme of work for the Velindre Professor of Nursing and Interdisciplinary Cancer Care and Research Fellow is to be addressed and brought back to the next meeting. NW to Report back to the November 2022 Committee.</p> <p>The Sub-Committee reiterated their delight at seeing the publication list included in the Annual Report and asked if possible whether the VCC authors could be highlighted in the report going forward.</p> <p>The Sub-Committee commended the RD&amp;I Team on the huge amount achieved during the last year and personally thanked Sarah Townsend and Christopher Cotterill-Jones for all their help and support.</p> <p>The Sub-Committee <b>ENDORSED</b> the Annual Report <b>FOR COMMITTEE APPROVAL</b>.</p>	<p><b>SMC</b></p> <p><b>NW</b></p>
<b>4.0.0</b>	<b>STRATEGY, PERFORMANCE &amp; DELIVERY</b>	
<b>4.1.0</b>	<b>New Velindre Cancer Centre (nVCC) Research Development and Innovation Update</b>	



	<p><i>Led by Hannah Moscrop, Transforming Cancer Services</i></p> <p>In the absence of HL, Hannah Moscrop, Project Manager presented the nVCC Non-Clinical RD&amp;I Group Update. HM stated that the report was there for reference and invited any questions from the Sub-Committee that she was happy to address / facilitate.</p> <p>HM confirmed that the title of the Group was still to be addressed following previous comments and would report back to the next Sub-Committee Meeting.</p> <p>The report is an update to ensure visibility of this work and effective alignment across Trust and Project priorities.</p> <p>The update paper outlined the scope of this work, key activities, deliverables and dependencies, plus a high level timeline plan.</p> <p><b>ACTION:</b> Update on the Integrated Radiotherapy Solution (IRS) required at the next Sub-Committee meeting. TCS Director / representative to be invited to the next meeting to facilitate a discussion in relation to the IRS. A summary paper will be presented to the November 2022 Sub-Committee.</p> <p>The Sub-Committee <b>NOTED</b> the content of the New Velindre Cancer Centre (nVCC) Non-Clinical RD&amp;I Group Update.</p>	<p><b>SMC/ HL</b></p>
<p><b>4.2.0</b></p>	<p><b>Trust Research, Development and Innovation Performance Report</b></p> <p><i>Led by Sarah Townsend, Head of Research &amp; Development with input from the relevant leads :</i></p> <ul style="list-style-type: none"> <li>• <i>Libby Batt, Strategy Lead for Velindre Cancer R&amp;D Strategy</i></li> <li>• <i>Christopher Cotterill Jones, Research Delivery Manager</i></li> <li>• <i>Peter Richardson, SMT Lead RD&amp;I , Welsh Blood Service</i></li> <li>• <i>Robyn Davies, Head of Innovation</i></li> <li>• <i>Jonathan Patmore, RD&amp;I Finance Business Partner</i></li> </ul> <p>Following on from the last RD&amp;I Sub-Committee Meeting, a Task &amp; Finish Group was established to review the content of the quarterly RD&amp;I Integrated Performance Report. The purpose of the Task and Finish Group was to propose a new RD&amp;I Integrated Performance Report template for consideration by the Sub-Committee.</p>	

The Task & Finish Group agreed:

- To amend the Research, Development & Innovation (RD&I) Integrated Performance Report format to reflect the RD&I strategic priorities published in the Velindre University NHS Trust Integrated Medium-Term Plan (IMTP) that has been updated for 2022 to 2025.
- To prepare a quarterly report in line with the financial year, with highlights from each quarter to be included in the RD&I Sub Committee Annual Report.
- To present the first iteration of the new format to the RD&I Sub-Committee at the Committee meeting scheduled for 21 July 2022.
- The report would include progress of work and key achievements for each quarter demonstrating activity against the strategic priority areas, the cross-cutting themes that support these areas and Trust RD&I corporate work, for example Finance.

ST and the relevant leads presented the first iteration of the RD&I Integrated Performance Report for Quarter 1 of Financial Year 2022/23. The report now reflects the RD&I strategic priorities published in the Velindre University NHS Trust's Integrated Medium-Term Plan (IMTP) that has been updated for 2022 - 2025.

These priorities that support the Trust's strategic goal to be "A beacon for research, development and innovation" are as follows:

<b><u>STRATEGIC PRIORITIES</u></b>	
<b>Priority 1</b>	The Trust will drive forward the implementation of its Cancer Research and Development Ambitions 2021-2031.
<b>Priority 2</b>	The Trust will maximise the Research and Development ambitions of the Welsh Blood Service.
<b>Priority 3</b>	The Trust will implement the Velindre Innovation Plan.
<b>Priority 4</b>	The Trust will maximise collaborative opportunities locally, nationally, and internationally.

	<p>The report includes the progress of work and key achievements for Q1 of FY2022/23 demonstrating activity against these strategic priority areas, the cross-cutting themes that support these areas and Trust RD&amp;I corporate work, for example Finance.</p> <p>The Sub-Committee was asked to consider the following:</p> <ul style="list-style-type: none"> <li>a) Does the amended RD&amp;I Integrated Performance Report format and content reflect the expectations of the RD&amp;I Sub-Committee?</li> <li>b) This report format proposes that progress against each Strategic Priority is tabulated. These have not been completed for this first iteration of the amended RD&amp;I Integrated Performance Report. Would the completion of these tables address the RD&amp;I Sub-Committee's assessment and oversight of the work undertaken in respect of these strategic priorities?</li> <li>c) This Report receives section content from different contributors, that require sign off through the appropriate governance route prior to inclusion in the report. This can take time dependent on the cycle of business of the groups that are responsible for signing off the section content.</li> </ul> <p><b>ACTION:</b> Sub-Committee members to provide any suggestions / recommendations on the format and content of the RDI Performance Report before the next meeting. This will be presented at the Sub-Committee Meeting in November 2022.</p> <p>The Sub-Committee congratulated the RD&amp;I Team on a tremendous effort in collating this Report.</p> <p>The Sub-Committee <b>NOTED</b> the RD&amp;I Integrated Performance Report.</p>	<b>ALL</b>
<b>6.0.0</b>	<b>ANY OTHER BUSINESS</b>	
<b>6.1.0</b>	<p>Robyn Davies, Head of Innovation</p> <p>The Chair and Sub-Committee Members wanted to congratulate and say farewell to Robyn Davies for all his hard work over the last year as Head of Innovation and confirmed he would be sorely missed. Robyn is leaving the organisation on the 29th July 2022. Robyn</p>	

	<p>confirmed that he will provide a Legacy Report on all Innovation Activity prior to his departure.</p> <p><b>ACTION :</b> Legacy Report to be provided by RD on Innovation Activity.</p>	<b>RD</b>
<b>7.0.0</b>	<b>HIGHLIGHT REPORT TO THE TRUST QUALITY SAFETY &amp; PERFORMANCE COMMITTEE</b>	
	<p>Members to identify items to include in the Highlight Report to the Trust Board:</p> <p><b>For Escalation</b> Nil</p> <p><b>For Advising</b></p> <ul style="list-style-type: none"> <li>• TRUST Research, Development and Innovation Annual Report 2021</li> <li>• Congratulations and farewell wishes to Robyn Davies, Head of Innovation who is leaving the organisation on the 29th July 2022. Robyn will provide a Legacy Report on Innovation Activity prior to his departure.</li> </ul> <p><b>For Assurance</b></p> <ul style="list-style-type: none"> <li>• TRUST Research, Development and Innovation Performance Report 2021/2022</li> </ul> <p><b>For Information</b></p> <ul style="list-style-type: none"> <li>• FAKTION Update presented at The American Society for Clinical Oncology Annual Meeting (ASCO) which was held on the 3rd – 7th June 2022 in Chicago</li> <li>• Executive Summary Highlight Report</li> <li>• Wales Cancer Research Strategy (CreSt)</li> </ul> <p>The Sub-Committee <b>APPROVED</b> the above items to be included in the Highlight Report to the Quality Safety &amp; Performance Committee.</p> <p><b>ACTION:</b> ST to support the development of a draft Highlight Report for approval by the Sub-Committee Chair.</p>	<b>ST</b>
<b>8.0.0</b>	<b>DATE AND TIME OF THE NEXT MEETING:</b>	
	The next meeting is arranged to be held on <b><i>15th November 2022 at 10:00am via Microsoft Teams.</i></b>	

<b>9.0.0</b>	<b>CLOSE</b>	
	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).	

## RESEARCH, DEVELOPMENT AND INNOVATION SUB-COMMITTEE

### AMENDMENT TO STANDING ORDERS – SCHEDULE 3

<b>DATE OF MEETING</b>	15/11/2022
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<b>PUBLIC OR PRIVATE REPORT</b>	Public
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<b>IF PRIVATE PLEASE INDICATE REASON</b>	Not Applicable - Public Report
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<b>PREPARED BY</b>	Sarah Townsend, Head of Research & Development / Emma Stephens, Head of Corporate Governance
<b>PRESENTED BY</b>	Emma Stephens, Head of Corporate Governance
<b>EXECUTIVE SPONSOR APPROVED</b>	Jacinta Abraham, Executive Medical Director

<b>REPORT PURPOSE</b>	ENDORSE FOR BOARD APPROVAL
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#### COMMITTEE/GROUP WHO HAVE RECEIVED OR CONSIDERED THIS PAPER PRIOR TO THIS MEETING

COMMITTEE OR GROUP	DATE	OUTCOME

#### ACRONYMS

RD&I	Research, Development & Innovation
SO	Standing Orders
ToR	Terms of Reference



## 1. SITUATION / BACKGROUND

The Velindre University NHS Trust Standing Orders form the basis upon which the Trust's governance and accountability framework is developed and, together with the adoption of the Trust's Standards of Behaviour Framework Policy, is designed to ensure the achievement of the standards of good governance set for the NHS in Wales.

The purpose of this report is to outline the required changes to the Trust Standing Orders – **Schedule 3**, resulting from the Final Review of the **Terms of Reference and Operating Arrangements** in respect of the **Research, Development & Innovation Sub-Committee**, (ref. **Appendix 1 [no track changes] & Appendix 2 [with track changes]**), following the final amendments requested at the July 2022 Committee, and is seeking formal **ENDORSEMENT** by the **Research, Development & Innovation Sub-Committee** prior to submission to Trust Board.

## 2. ASSESSMENT /SUMMARY OF MATTERS FOR CONSIDERATION

### 2.1 Summary of Amendments

The final amendments requested at the July 2022 Committee to the Terms of Reference and Operating Arrangements for the Research, Development and Innovation Sub-Committee are set out in **Appendix 1 & 2** and include the following key changes summarised below:

Terms of Reference & Operating Arrangements	Summary of Amendments
Research, Development and Innovation Sub-Committee	<p><b>Section 3:</b></p> <ul style="list-style-type: none"> <li>- Inclusion of <b>role of Advancing Radiotherapy Fund Programme Board</b> in relation to the RD&amp;I Sub-Committee (<b>ref.3.2</b> &amp; Appendix 1 RD&amp;I Meeting Structure).</li> <li>- Removal of reference to the Chief Executive's Financial limit / delegated authority in the context of business cases that are received by the Committee (<b>ref.3.2</b>). More clearly articulated and clarified role of Committee in reviewing and scrutinising financial bids for approval.</li> </ul>

Terms of Reference & Operating Arrangements	Summary of Amendments
	<p><b>Section 4:</b></p> <ul style="list-style-type: none"> <li>- Membership revised to state a minimum of <b>3</b> members, including <b>2</b> Independent Members of the Board.</li> <li>- Staff Side Representative no longer listed as a Standard Attendee of the Committee.</li> <li>- Lay membership retained with a view to seek opportunities to further enhance.</li> </ul> <p><b>Appendix 1 - RD&amp;I Meeting Structure</b></p> <ul style="list-style-type: none"> <li>- Added <b>Advancing Radiotherapy Fund Programme Board</b> and <b>Charitable Funds Committee</b> to the organogram</li> </ul>

### 3. IMPACT ASSESSMENT

<b>QUALITY AND SAFETY IMPLICATIONS/IMPACT</b>	Yes (Please see detail below)
	The RD&I Sub-Committee provides evidence based, timely advice to the Board to assist in discharging its functions and meeting its responsibilities with regards to research, development and innovation activity. Assurance is also provided in relation to compliance with the Trust's regulatory responsibilities related to research, development and innovation.
<b>RELATED HEALTHCARE STANDARD</b>	Governance, Leadership and Accountability
<b>EQUALITY IMPACT ASSESSMENT COMPLETED</b>	Not required



GIG  
CYMRU  
NHS  
WALES

Ymddiriedolaeth GIG  
Prifysgol Felindre  
Velindre University  
NHS Trust

LEGAL IMPLICATIONS / IMPACT	There are no specific legal implications related to the activity outlined in this report.
FINANCIAL IMPLICATIONS / IMPACT	There is no direct impact on resources as a result of the activity outlined in this report.

#### 4. RECOMMENDATION

The Research, Development & Innovation Sub- Committee is asked to **ENDORSE** the amendments to the Trust Board Standing Orders – **Schedule 3** as outlined in section **2** of this report, and included in **Appendix 1 & 2**.

Subject to formal **ENDORSEMENT** by the RD&I Sub-Committee, the revised Terms of Reference will then be received at the next meeting of the Trust Board Audit Committee for formal **ENDORSEMENT** and recommendation to the Trust Board for **APPROVAL**.

# **Research, Development & Innovation (RD&I) Sub-Committee**

## **Terms of Reference & Operating Arrangements**

Reviewed:	November 2022
Approved:	
Next Review Due:	October 2023

## 1. INTRODUCTION

- 1.1 The Trust's standing orders provide that "The Board may and, where directed by the Assembly Government must, appoint Committees of the Trust either to undertake specific functions on the Board's behalf or to provide advice and assurance to the Board in the exercise of its functions. The Board's commitment to openness and transparency in the conduct of all its business extends equally to the work carried out on its behalf by Committees".
- 1.2 The Quality, Safety & Performance Committee, Strategic Development Committee and Charitable Funds Committee have been established by the Board to assist in discharging its functions and meeting its responsibilities with regards to the quality, safety and performance of healthcare, strategic and organisational development and to make and monitor arrangements for the control and management of the Trust's charitable funds.
- 1.3 As part of the aforementioned Committee functions, the **Research, Development & Innovation (RD&I) Sub-Committee** has been established to act as the "front door" for all RD&I business at Board level and will perform the following functions on their behalf:
- oversee and maintains oversight of the RD&I Strategy on behalf of the Strategic Development Committee.
  - oversee the development of an annual implementation plan that operationalises the Strategy and monitor the Division's performance and delivery on behalf of the Quality, Safety & Performance Committee.
  - review and approve business cases for alignment with strategy and funding on behalf of the Charitable Funds Committee.
- 1.4 Research, Development and Innovation are defined as follows:
- **Research and Development**, from a healthcare perspective - refers to systematic investigation and study to generate new knowledge and insight to drive improved patient care.
  - **Innovation**, from a healthcare perspective - refers to the application of original research into new or improved health policies, practices, systems, products and technologies, services or delivery methods for improved patient outcomes.

## 2. PURPOSE

- 2.1 The purpose of the RD&I Sub-Committee is to:
- Provide strategy and policy oversight for RD&I activities undertaken by the Trust reporting to the Strategic Development Committee.
  - Provide assurance on the performance of RD&I activity reporting to the Quality, Safety & Performance Committee.

- Promote and encourage a RD&I ethos and culture which is integral to the Trusts vision, mission and values including the identification of new and enhanced funding opportunities to grow the significance and reach of the Trust's RDI activities.
- Provide assurance to the Board in relation to the Trust's arrangements for ensuring compliance with the UK Policy Frameworks for Health & Social Care Research as amended from time to time.
- Consider relevant matters with reference to the parameters identified for risk appetite in relation to RD&I as set by the Board.
- The RD&I Sub-Committee is underpinned and informed through the work of a number of Management Groups and Assurance Processes as set out in **Appendix 1**.

### 3. DELEGATED POWERS AND AUTHORITY

With regards to its role in providing advice to the Board, the Committee will fulfil the following functions:

#### 3.1 Strategy & Policy Development

- Promote and encourage a RD&I ethos and culture within the Trust.
- Oversee the development of all RD&I strategies and implementation plans ensuring the conduct of good quality projects within the Trust's portfolio of RD&I activity.
- Consider the strategic implications for the Trust from the findings arising from national developments, review, audit and/or inspection, and monitor the successful implementation of any actions required resulting from these findings.
- Ensure that matters of strategic development are escalated as appropriate to the Trust Strategic Development Committee and on to Trust Board for assurance and approval as required.

#### 3.2 Strategy & Policy Approval

- Approve policies relevant to the business of the Committee as delegated by the Board.
- Scrutinise RD&I Business cases for any legal and / or ethical implications that need to be considered, access, finance and ensure alignment with the Trust overarching ten year strategy '**Destination 2032**' including the benefit / impact it will make for patients / donors / staff and service users. The Committee is also supported by the Advancing Radiotherapy Fund (ARF) Programme Board, (established to develop a programme of activity which will enable the development of stereotactic and other radiotherapy technology for the benefit of patients across Wales), in scrutinising bids for funding for business case proposals and will assess, review and advise as appropriate.



### 3.3 Monitoring and Review

- The Sub-Committee will, in respect of its assurance role, seek assurance that research governance and innovation arrangements are appropriately designed, implemented and are operating appropriately to ensure the provision of a high-quality RD&I service.
- To achieve this, the Sub-Committee will need assurance that the following aspects of RD&I are being effectively managed:
  - The safety, rights, dignity and wellbeing of participants in Innovation and Research development projects is above all other considerations.
  - There is clear, consistent strategic direction, strong leadership and transparent lines of accountability
  - The diversity of the organisation's patients, service users, donors and staff are valued and that their active involvement in the development of Research, Development and Innovation as appropriate.
  - There is close collaboration with partner Organisations in higher education to improve quality, promote joint working for best RD&I outcomes and avoid unnecessary duplication of functions. In this respect, the work of RD&I Sub-Committee will be reflected in the agenda and priorities of the Trust's Academic Partnership Board.
  - The organisation ensures compliance with appropriate legislation and regulation such as the, UK Policy Framework for Health and Social Care Research 2017 the EU Clinical Trials Directive 2004 as amended, Good Laboratory Practice, Good Manufacturing Practice in manufacturing products for clinical trials and Good Clinical Practice in the conduct of all clinical Research and Innovation activities as appropriate.
  - Systems are in place to monitor compliance with regulatory requirements of the Trust as well as organisational standards and to investigate complaints and deal with irregular or inappropriate behaviour in the conduct of Research and Innovation activity.
  - Research and Innovation investment and expenditure is accounted for and complies with audit requirements as well as the requirements of external funders or sponsors as appropriate.
  - The Committee will scrutinise research and/or innovation proposals and/or business cases that are seeking charitable funding PRIOR to submission to the Charitable Funds Committee, in order to provide assurance on the quality and safety of RD&I related activity.
  - When research or innovation findings have commercial potential, the Trust takes action to protect and exploit them in collaboration with its Research and Innovation partners and where appropriate commercial Organisations.

### 3.4 Access

The Chair of the RD&I Sub-Committee shall have reasonable access to Executive Directors and other relevant senior staff.

## **4. MEMBERSHIP**

### **Members**

4.1 A minimum of two (3) members to include:

Chair	Independent member of the Board (University) or delegated Independent Board member
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Two Independent Members of the Board

### **Attendees**

4.2 In attendance

- Executive Director with responsibility for RD&I currently Medical Director
- Executive Director of Finance or nominated officer with RD&I funding responsibilities
- Associate Medical Director with responsibility for R&D
- Clinical Director (or Nominated Deputy) – Velindre Cancer Centre
- Executive Director of Nursing AHP and Health Sciences
- Director of Corporate Governance
- Trust Head of Innovation
- Head of Velindre Cancer Research Strategy
- Trust Head of Research & Development
- Research Delivery Manager
- Research, Development and Innovation Finance Business Partner
- Representative - Velindre Cancer Centre Strategic Leadership Team
- Representative – Welsh Blood Service SMT Lead for RD&I
- Representative – Welsh Blood Service Lead Clinician for RD&I
- WBS RD&I Facilitation Lead
- Service User/Lay Representatives

4.3 **By invitation**

The Sub-Committee Chair may extend invitations as required to the following:

- Head of Information Governance (in advisory capacity)
- Divisional Directors
- Representatives of stakeholder organisations

As well as others internal or external to the Organisation who the Sub-Committee consider should be in attendance, taking account of the matters under consideration at each meeting.

4.4 **Secretariat**

As determined by the Director of Corporate Governance.

## 4.5 Member Appointments

Members shall be appointed for a maximum of 3 consecutive years before formally reviewing their role on the Committee. During this time a member may resign or be removed by the Board.

## 4.6 Support to Committee Members

The Director of Corporate Governance on behalf of the Committee Chair shall:

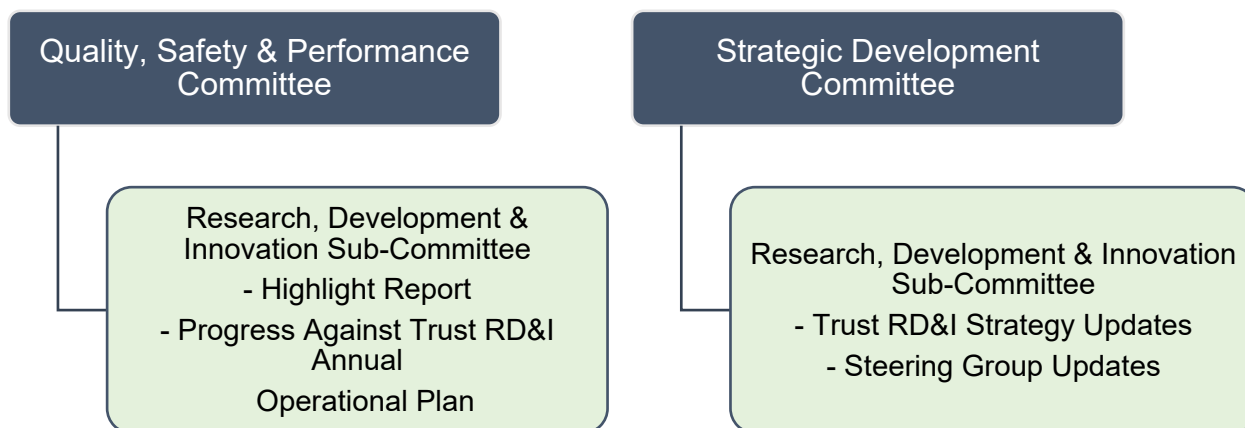
- Arrange the provision of advice and support to Committee members on any aspect related to the conduct of their role: and
- Ensure the provision of a programme of Organisational development for Committee members as part of the Trust's overall OD programme developed by the Director of Workforce and Organisational Development.

# 5. SUB-COMMITTEE MEETINGS

5.1 The Committee has, with approval of the Trust Board, established the:

- Research, Development & Innovation Sub-Committee

The Sub-Committee will have a dual reporting line to both the Quality, Safety and Performance Committee and the Strategic Development Committee as follows :



Although the Research, Development & Innovation Sub-Committee, is a sub-committee with dual reporting lines, it will both retain the delegated authority for decision making granted to the current committee by Trust Board. Further details regarding delegated powers and authority are set out in each of the Sub-Committee Terms of Reference.

The Research, Development & Innovation Sub-Committee is also accountable to the Trust Charitable Funds Committee in relation to ensuring business cases are aligned with RD&I strategy and Trust's strategic objectives. Further details are set out in each of the respective Terms of Reference. In addition, the wider governance and accountability reporting arrangements in place at a divisional level that feed upwards into the RD&I Sub-Committee structure are also summarised at **Appendix 1**.

## **5.1 Quorum**

At least two members must be present to ensure the quorum of the Committee, one of whom should be the Committee Chair. If the Chair is not present an agreement as to who will Chair from the Independent Members in their absence.

## **5.2 Frequency of Meetings**

Meetings shall be held no less than four times a year and otherwise as the Chair of the Committee deems necessary – consistent with the Trust's annual plan of Board Business.

## **5.3 Withdrawal of individuals in attendance**

The Committee may ask any or all of those who normally attend but who are not members to withdraw to facilitate open and frank discussion of particular matters.

# **6. RELATIONSHIPS & ACCOUNTABILITIES WITH THE BOARD AND ITS COMMITTEES/GROUPS**

6.1 Although the Board has delegated authority to the Sub-Committee for the exercise of certain functions as set out within these terms of reference, it retains overall responsibility and accountability for the safety, security and use of information to support the quality and safety of healthcare for its citizens through the effective governance of the Organisation.

6.2 The Sub-Committee is directly accountable to the Quality, Safety and Performance Committee, Strategic Development Committee and Charitable Funds Committee for its performance in exercising the functions set out in these terms of reference.

6.3 The Sub-Committee shall embed the Trust's corporate objectives, priorities, and requirements, e.g., equality and human rights through the conduct of its business.

# **7. REPORTING AND ASSURANCE ARRANGEMENTS**

7.1 The Committee Chair shall:

Report formally, to the:

- i. Quality, Safety & Performance Committee on the performance and delivery of RD&I quarterly.
- ii. Strategic Development Committee Board on strategic development and updates to the RD&I Strategy quarterly and
- iii. Charitable Funds Committee to recommend for approval business cases aligned with the RD&I Strategy and Trust's overarching strategic objectives.

7.2 The Sub-Committee shall receive:

- i. A briefing from the Executive Medical Director with responsibility for RD&I
- ii. A quarterly RD&I Integrated Performance Report (following presentation at EMB)
- iii. A quarterly Highlight Report from the Advancing Radiotherapy Fund Programme Board on the activity of the programme.

- 7.3 The Director of Corporate Governance, on behalf of the Board, shall oversee a process of regular and rigorous self-assessment and evaluation of the Committee's performance and operation including that of any Sub Committees established.

## **8. APPLICABILITY OF STANDING ORDERS TO COMMITTEE BUSINESS**

- 8.1 The requirements for the conduct of business as set out in the Trust's Standing Orders are equally applicable to the operation of the Sub-Committee.

## **9. REVIEW**

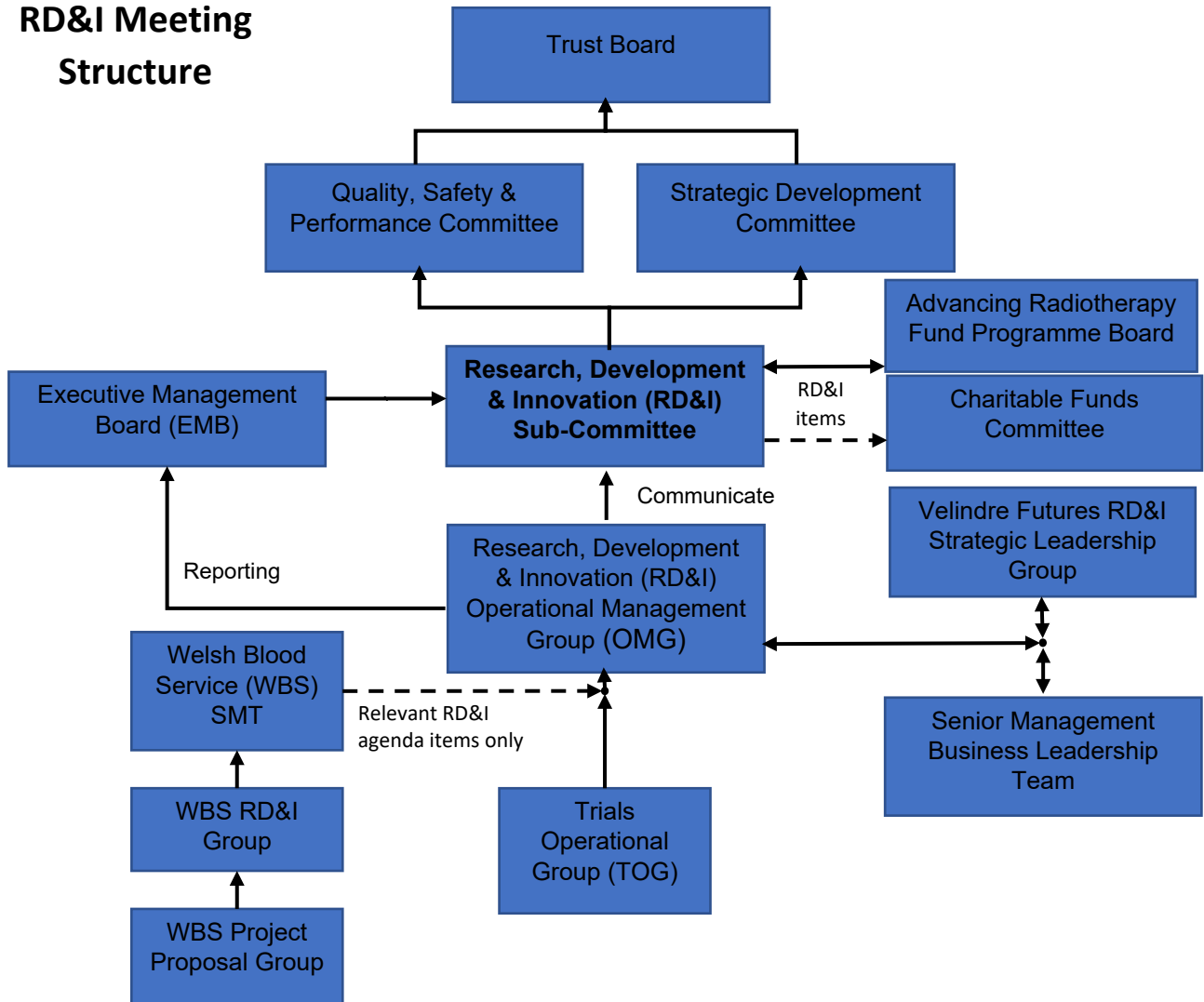
- 9.1 These terms of reference and operating arrangements shall be reviewed annually by the Sub-Committee with reference to the Board.

## **10. CHAIR'S ACTION ON URGENT MATTERS**

- 10.1 There may, occasionally, be circumstances where decisions which would normally be made by the Sub-Committee need to be taken between scheduled meetings. In these circumstances, the Sub-Committee Chair, supported by the Director of Corporate Governance as appropriate, may deal with the matter on behalf of the Board, after first consulting with two other Members of the Sub-Committee. The Director of Corporate Governance must ensure that any such action is formally recorded and reported to the next meeting of the Sub-Committee for consideration and ratification.
- 10.2 Chair's urgent action may not be taken where the Chair has a personal or business interest in the urgent matter requiring decision.

## APPENDIX 1

## RD&I Meeting Structure





# Research, Development & Innovation (RD&I) Sub-Committee

## Terms of Reference & Operating Arrangements

Reviewed:	<u>November 2022</u>
Approved:	
Next Review Due:	<u>October 2023</u>

## 1. INTRODUCTION

- 1.1 The Trust's standing orders provide that "The Board may and, where directed by the Assembly Government must, appoint Committees of the Trust either to undertake specific functions on the Board's behalf or to provide advice and assurance to the Board in the exercise of its functions. The Board's commitment to openness and transparency in the conduct of all its business extends equally to the work carried out on its behalf by Committees".
- 1.2 The Quality, Safety & Performance Committee, Strategic Development Committee and Charitable Funds Committee have been established by the Board to assist in discharging its functions and meeting its responsibilities with regards to the quality, safety and performance of healthcare, strategic and organisational development and to make and monitor arrangements for the control and management of the Trust's charitable funds.
- 1.3 As part of the aforementioned Committee functions, the **Research, Development & Innovation (RD&I) Sub-Committee** has been established to act as the "front door" for all RD&I business at Board level and will perform the following functions on their behalf:
- oversee and maintains oversight of the RD&I Strategy on behalf of the Strategic Development Committee.
  - oversee the development of an annual implementation plan that operationalises the Strategy and monitor the Division's performance and delivery on behalf of the Quality, Safety & Performance Committee.
  - review and approve business cases for alignment with strategy and funding on behalf of the Charitable Funds Committee.
- 1.4 Research, Development and Innovation are defined as follows:
- **Research and Development**, from a healthcare perspective - refers to systematic investigation and study to generate new knowledge and insight to drive improved patient care.
  - **Innovation**, from a healthcare perspective - refers to the application of original research into new or improved health policies, practices, systems, products and technologies, services or delivery methods for improved patient outcomes.

## 2. PURPOSE

- 2.1 The purpose of the RD&I Sub-Committee is to:
- Provide strategy and policy oversight for RD&I activities undertaken by the Trust reporting to the Strategic Development Committee.
  - Provide assurance on the performance of RD&I activity reporting to the Quality, Safety & Performance Committee.

- Promote and encourage a RD&I ethos and culture which is integral to the Trusts vision, mission and values including the identification of new and enhanced funding opportunities to grow the significance and reach of the Trust's RDI activities.
- Provide assurance to the Board in relation to the Trust's arrangements for ensuring compliance with the UK Policy Frameworks for Health & Social Care Research as amended from time to time.
- Consider relevant matters with reference to the parameters identified for risk appetite in relation to RD&I as set by the Board.
- The RD&I Sub-Committee is underpinned and informed through the work of a number of Management Groups and Assurance Processes as set out in **Appendix 1**.

### 3. DELEGATED POWERS AND AUTHORITY

With regards to its role in providing advice to the Board, the Committee will fulfil the following functions:

#### 3.1 Strategy & Policy Development

- Promote and encourage a RD&I ethos and culture within the Trust.
- Oversee the development of all RD&I strategies and implementation plans ensuring the conduct of good quality projects within the Trust's portfolio of RD&I activity.
- Consider the strategic implications for the Trust from the findings arising from national developments, review, audit and/or inspection, and monitor the successful implementation of any actions required resulting from these findings.
- Ensure that matters of strategic development are escalated as appropriate to the Trust Strategic Development Committee and on to Trust Board for assurance and approval as required.

#### 3.2 Strategy & Policy Approval

- Approve policies relevant to the business of the Committee as delegated by the Board.
- Scrutinise RD&I Business cases ~~which exceed the delegated limits of the Chief Executive to consider prior to formal Trust Board approval~~ for any legal and / or ethical implications that need to be considered, access, finance and ensure alignment with the Trust overarching ten year strategy '**Destination 2032**' including the benefit / impact it will make for patients / donors / staff and service users. The Committee is also supported by the Advancing Radiotherapy Fund (ARF) Programme Board, (established to develop a programme of activity which will enable the development of stereotactic and other radiotherapy technology for the benefit of patients across Wales), in scrutinising bids for funding for business case proposals and will assess, review and advise as appropriate.

### 3.3 Monitoring and Review

- The Sub-Committee will, in respect of its assurance role, seek assurance that research governance and innovation arrangements are appropriately designed, implemented and are operating appropriately to ensure the provision of a high-quality RD&I service.
- To achieve this, the Sub-Committee will need assurance that the following aspects of RD&I are being effectively managed:
  - The safety, rights, dignity and wellbeing of participants in Innovation and Research development projects is above all other considerations.
  - There is clear, consistent strategic direction, strong leadership and transparent lines of accountability
  - The diversity of the organisation's patients, service users, donors and staff are valued and that their active involvement in the development of Research, Development and Innovation as appropriate.
  - There is close collaboration with partner Organisations in higher education to improve quality, promote joint working for best RD&I outcomes and avoid unnecessary duplication of functions. In this respect, the work of RD&I Sub-Committee will be reflected in the agenda and priorities of the Trust's Academic Partnership Board.
  - The organisation ensures compliance with appropriate legislation and regulation such as the, UK Policy Framework for Health and Social Care Research 2017 the EU Clinical Trials Directive 2004 as amended, Good Laboratory Practice, Good Manufacturing Practice in manufacturing products for clinical trials and Good Clinical Practice in the conduct of all clinical Research and Innovation activities as appropriate.
  - Systems are in place to monitor compliance with regulatory requirements of the Trust as well as organisational standards and to investigate complaints and deal with irregular or inappropriate behaviour in the conduct of Research and Innovation activity.
  - Research and Innovation investment and expenditure is accounted for and complies with audit requirements as well as the requirements of external funders or sponsors as appropriate.
  - The Committee will scrutinise research and/or innovation proposals and/or business cases that are seeking charitable funding PRIOR to submission to the Charitable Funds Committee, in order to provide assurance on the quality and safety of RD&I related activity.
  - When research or innovation findings have commercial potential, the Trust takes action to protect and exploit them in collaboration with its Research and Innovation partners and where appropriate commercial Organisations.

### 3.4 Access

The Chair of the RD&I Sub-Committee shall have reasonable access to Executive Directors and other relevant senior staff.

## 4. MEMBERSHIP

### Members

4.1 A minimum of two (~~32~~) members to include:

Chair	Independent member of the Board (University) or delegated Independent Board member
-------	--

~~One~~ Two Independent Members of the Board

### Attendees

4.2 In attendance

- Executive Director with responsibility for RD&I currently Medical Director
- Executive Director of Finance or nominated officer with RD&I funding responsibilities
- Associate Medical Director with responsibility for R&D
- Clinical Director (or Nominated Deputy) – Velindre Cancer Centre
- Executive Director of Nursing AHP and Health Sciences
- Director of Corporate Governance
- Trust Head of Innovation
- Head of Velindre Cancer Research Strategy
- Trust Head of Research & Development
- Research Delivery Manager
- Research, Development and Innovation Finance Business Partner
- Representative - Velindre Cancer Centre Strategic Leadership Team
- Representative – Welsh Blood Service SMT Lead for RD&I
- Representative – Welsh Blood Service Lead Clinician for RD&I
- WBS RD&I Facilitation Lead
- Service User/Lay Representatives
- ~~Staff Side Representative~~

4.3 **By invitation**

The Sub-Committee Chair may extend invitations as required to the following:

- Head of Information Governance (in advisory capacity)
- Divisional Directors
- Representatives of stakeholder organisations

As well as others internal or external to the Organisation who the Sub-Committee consider should be in attendance, taking account of the matters under consideration at each meeting.

4.4 **Secretariat**

As determined by the Director of Corporate Governance.

## 4.5 Member Appointments

Members shall be appointed for a maximum of 3 consecutive years before formally reviewing their role on the Committee. During this time a member may resign or be removed by the Board.

## 4.6 Support to Committee Members

The Director of Corporate Governance on behalf of the Committee Chair shall:

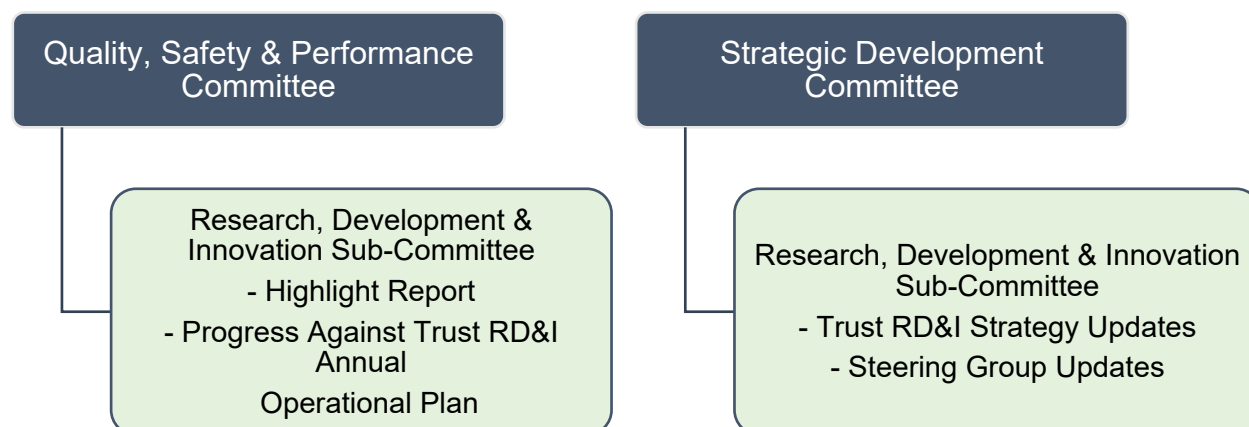
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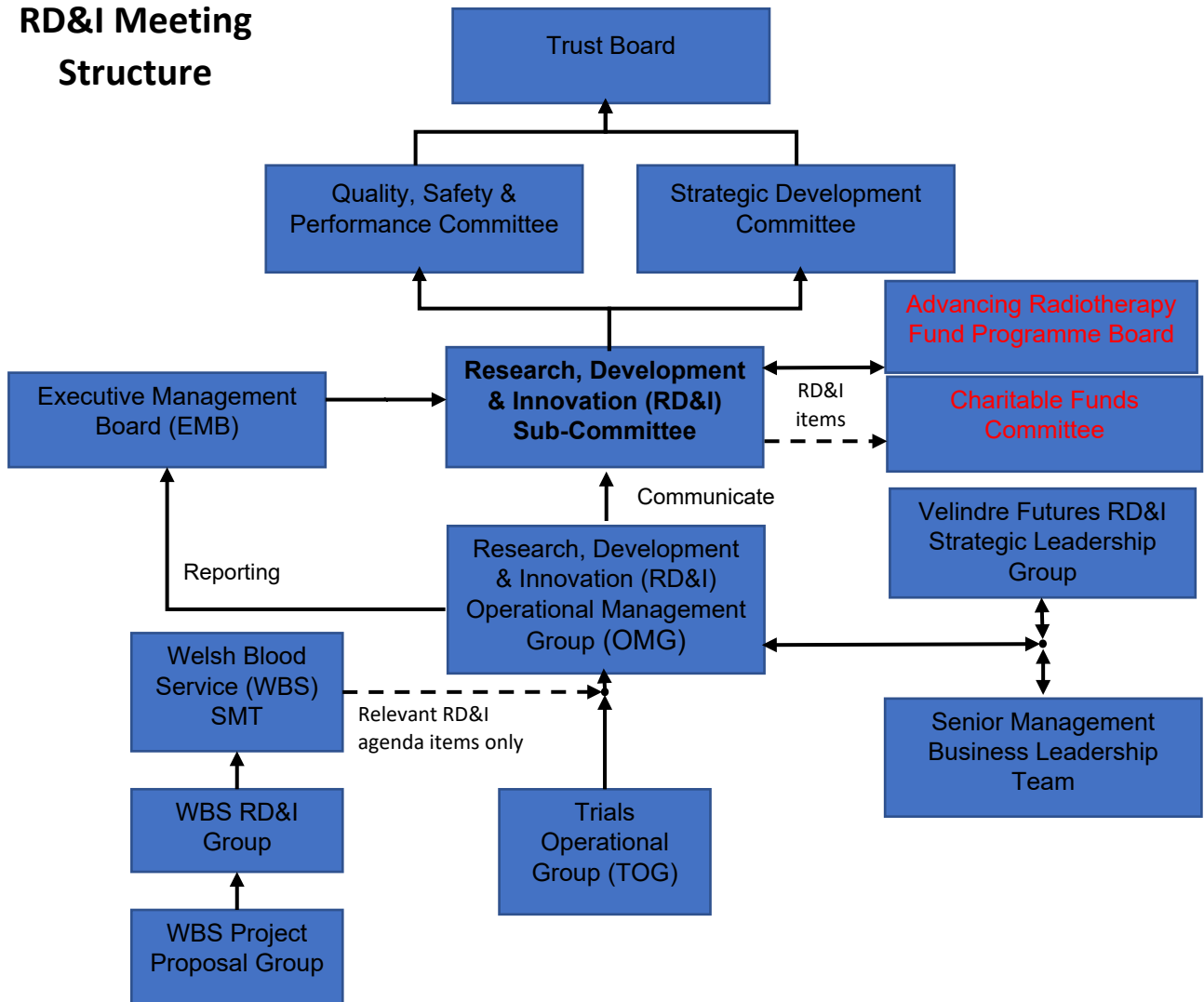
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## APPENDIX 1

### RD&I Meeting Structure



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

**Date** 21/07/2022  
**Time** 12:40-1:15pm  
**Location** via Microsoft Teams  
**Chair** Professor Andrew Westwell, Independent Member

<b>PRESENT</b>		
Professor Andrew Westwell	Independent Member and Research, Development & Innovation Sub-Committee Chair	AW
Vicky Morris	Independent Member	VM
<b>ATTENDEES</b>		
Dr Jacinta Abraham	Executive Medical Director and R&D Lead	JA
Libby Batt	Head of Velindre Cancer R&D Strategy	LB
Christopher Moreton	Deputy Director of Finance	CM
Jonathan Patmore	RD&I Finance Business Partner	JP
Peter Richardson	SMT Lead RD&I , Welsh Blood Service	AP
Emma Stephens	Head of Corporate Governance	ES
Sarah Townsend	Head of Research & Development	ST
<b>SECRETARIAT</b>		
Sandra Cusack	Business Support Officer	SMC

<b>1.0.0</b>	<b>STANDARD BUSINESS</b>	
<b>1.1.0</b>	<b>Apologies</b> <ul style="list-style-type: none"> <li>Professor Donna Mead, Trust Chair</li> <li>Steve Ham, Chief Executive</li> </ul>	

	<ul style="list-style-type: none"> <li>• Matthew Bunce, Executive Director of Finance</li> <li>• Nicola Williams, Executive Director of Nursing, AHPs and Health Science</li> <li>• Robyn Davies, Head of Innovation</li> <li>• Eve Gallop-Evans, VCC Clinical Director</li> <li>• Professor Jane Hopkinson, Velindre Cancer Centre Professor of Nursing and Interdisciplinary Cancer Care</li> <li>• Dr Edwin Massey, Deputy Medical Director, Welsh Blood Service</li> <li>• Paul Wilkins, Director of Cancer Services</li> </ul>	
<b>1.2.0</b>	<b>In Attendance</b> <ul style="list-style-type: none"> <li>• Kate Cleary, Velindre Cancer R&amp;D Strategy Project Support Manager (Observer)</li> <li>• Non Gwilym, VUNHST Assistant Director of Communications &amp; Libby Batt, Head of Cancer R&amp;D Strategy (for Item 3.1.1)</li> </ul>	
<b>1.3.0</b>	<b>Declarations of Interest</b> <i>Led by Professor Andrew Westwell, Chair of the Research, Development &amp; Innovation Sub-Committee</i>  No declarations of interest were raised.	
<b>1.4.0</b>	<b>Matters Arising – Action Log</b> <i>Led by Dr Jacinta Abraham, Executive Medical Director</i>  The Sub-Committee <b>APPROVED</b> the Action Log and the further updates captured in the meeting for the record.	
<b>2.0.0</b>	<b>CONSENT ITEMS</b> 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.	
<b>2.1.0</b>	<b>FOR APPROVAL</b>	
<b>2.1.1</b>	<b>Minutes from the last Private Research, Development &amp; Innovation Sub-Committee held on the 7th April 2022</b> <i>Led by Professor Andrew Westwell, Chair of the Research, Development &amp; Innovation Sub-Committee</i>	

	The Sub-Committee <b>REVIEWED</b> and <b>APPROVED</b> the Minutes of the Private Meeting held on the 7th April 2022 as an accurate reflection of proceedings.	
<b>3.0.0</b>	<b>MAIN AGENDA</b>	
<b>3.1.0</b>	<b>BUSINESS CASE EXPENDITURE PROPOSALS</b>	
<b>3.1.1</b>	<p><b>RD&amp;I Corporate Communications Co-ordinator Post</b></p> <p><i>Led by Non Gwilym, VUNHST Assistant Director of Communications &amp; Libby Batt, Head of Cancer R&amp;D Strategy</i></p> <p>This business case proposal is seeking funding from the Velindre Charity to support an <b>RD&amp;I Communications Co-ordinator Post</b> which will be part of the VUNHST Communications Team, that will support and coordinate communications with patients, public, staff and other stakeholders about RD&amp;I matters (including Welsh Blood Service (WBS) and Velindre Cancer Centre (VCC)). All RD&amp;I communications will be aligned with the Trust's strategies/RD&amp;I strategies set out by WBS and VCC and the Innovation Plan.</p> <p>The proposal is for 3 years of pump priming support, which would then cease. During the pump priming phase it is expected to be able to grow the RD&amp;I reach, including growing sources of income (to include commercial research activity) to strengthen the financial position and thereafter be in a position to fund this post recurrently.</p> <p>As described above, LB confirmed that the post would be working on 3 large emerging programmes of work:</p> <ol style="list-style-type: none"> <li>1. VUNHST's Cancer R and D Ambitions 2021-2031 include (and as recommended by the Nuffield Trust) a research network delivery approach to be taken across South East Wales, involving Velindre Cancer Centre, working in partnership with Aneurin Bevan UHB, Cardiff and Vale UHB and Cwm Taf UHB for research development and delivery. Linked with this is the development of a Tripartite (Cardiff University, Cardiff and Vale UHB and VUNHST) Cancer Research Hub based at the</li> </ol>	

University Hospital of Wales. This research work programme will require ongoing extensive communications.

2. Working closely with Health and Care Research Wales VUNHST will lead and coordinate an all-Wales research initiative known as “Once for Wales.” This will require communication across NHS Wales.
3. The Trust’s Innovation Plan for the next decade is in development, envisaging increasingly collaborative working with organisations on ventures that will deliver new opportunities for patients, public, staff and other stakeholders.

The postholder would support WBS communication as required and offer resilience and additional contingency support for the Trust when required.

Discussions were held about other leading NHS organisations that have achieved this outcome and therefore believe it is a realistic and achievable objective for our own Trust.

AW requested that perhaps the example of the Manchester Enterprise was included in the business case going forward to strengthen the case.

VM asked for assurance about the post and a clear plan that this post would not be drawn into other ongoing projects within the Trust. LB agreed and suggested that a Communication RD&I strategy and Implementation Plan should be put in place.

ES confirmed that an annual evaluation report is required for all business cases approved by the CFC. This could be shared to the Sub-Committee for transparency of reporting once it is received.

The Sub-Committee discussed and reviewed the proposal and made the following requests:

CM requested that prior to submission to the CFC, that the terms of the post should be looked at in particular that the length of time for pump priming should be reviewed as he considered that 3 years was too long, e.g. reduce to two years.

	<p>CM asked if NG and Team could review the Corporate budget in future with a view to making this a permanent post.</p> <p><b>ACTION:</b> LB/NG to liaise with Steve Coliandris to review and address terms of Corporate budget for the RD&amp;I Corporate Communications Co-ordinator Post with a view to making this a permanent post.</p> <p>The Sub-Committee <b>ENDORSED FOR SUBMISSION</b> to the Charitable Funds Committee this business case subject to the necessary revisions being incorporated and addressed to enable onward submission.</p>	<b>LB/NG</b>
<b>4.0.0</b>	<b>HIGHLIGHT REPORT TO TRUST BOARD</b>	
	<p>Members were asked to identify items for inclusion in the Highlight Report to the Trust Board:</p> <ul style="list-style-type: none"> <li>• <b>For Escalation</b></li> <li>• <b>For Advising</b></li> <li>• <b>For Assurance</b></li> <li>• <b>For Information</b></li> </ul>	
<b>5.0.0</b>	<b>ANY OTHER BUSINESS</b>	
	No other business was raised.	
<b>6.0.0</b>	<b>DATE AND TIME OF THE NEXT MEETING:</b>	
	The date of the next Private Research, Development & Innovation Sub Committee will be held on <b>15th November 2022 at 12:15 via Microsoft Teams.</b>	
<b>CLOSE</b>		

## RESEARCH, DEVELOPMENT AND INNOVATION SUB-COMMITTEE

### Audit of Research & Development by NHS Wales Shared Services Partnership

<b>DATE OF MEETING</b>	15/11/2022
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<b>PUBLIC OR PRIVATE REPORT</b>	Public
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<b>IF PRIVATE PLEASE INDICATE REASON</b>	Not Applicable - Public Report
--	--------------------------------

<b>PREPARED BY</b>	Sarah Townsend, Head of Research & Development Christopher Cotterill-Jones, Research Delivery Manager
<b>PRESENTED BY</b>	Sarah Townsend, Head of Research & Development
<b>EXECUTIVE SPONSOR APPROVED</b>	Jacinta Abraham, Executive Medical Director

<b>REPORT PURPOSE</b>	FOR NOTING
-----------------------	------------

COMMITTEE/GROUP WHO HAVE RECEIVED OR CONSIDERED THIS PAPER PRIOR TO THIS MEETING		
COMMITTEE OR GROUP	DATE	OUTCOME

ACRONYMS	
NWSSP	NHS Wales Shared Services Partnership
RD&I	Research, Development, & Innovation
R&D	Research & Development

## 1. SITUATION / BACKGROUND

The purpose of this paper is to inform the RD&I Sub-Committee of the recent review of Research and Development (R&D) that was undertaken by NHS Wales Shared Services Partnership (NWSSP) as part of the 2022/23 Internal Audit Plan.

## 2. ASSESSMENT / SUMMARY OF MATTERS FOR CONSIDERATION

The review sought to provide the Trust with assurance regarding the effective management of R&D within the Trust. The scope of the review was to provide assurance that there are effective systems, processes, and governance in place around the research and development function, including partnership working.

The NWSSP Audit fieldwork took place between July and September 2022, with an Audit Debrief meeting taking place in September 2022.

The Trust's R&D function received a "substantial" assurance classification as the Audit outcome.

## 3. IMPACT ASSESSMENT

<b>QUALITY AND SAFETY IMPLICATIONS / IMPACT</b>	There are no specific quality and safety implications related to the activity outlined in this report.
<b>RELATED HEALTHCARE STANDARD</b>	Governance, Leadership and Accountability
	<ul style="list-style-type: none"> <li>• Standard 3.3 Quality Improvement, Research and Innovation</li> <li>• Standard 3.4 – Information Governance and Communications Technology</li> <li>• Standard 3.5 – Record Keeping</li> </ul>
<b>EQUALITY IMPACT ASSESSMENT COMPLETED</b>	Not required
<b>LEGAL IMPLICATIONS / IMPACT</b>	There are no specific legal implications related to the activity outlined in this report.





**GIG**  
CYMRU  
**NHS**  
WALES

Ymddiriedolaeth GIG  
Prifysgol Felindre  
Velindre University  
NHS Trust

<b>FINANCIAL IMPLICATIONS / IMPACT</b>	There is no direct impact on resources as a result of the activity outlined in this report.

#### 4. RECOMMENDATION

It is recommended that Trust RD&I Sub-Committee note the NWSSP R&D Final Internal Audit Report dated September 2022.

# Research and Development Final Internal Audit Report September 2022

Velindre University NHS Trust

NWSSP Audit and Assurance



Partneriaeth  
Cydwasaethau  
Gwasanaethau Archwilio a Sicrwydd  
Shared Services  
Partnership  
Audit and Assurance Services



Ymddiriedolaeth GIG  
Prifysgol Felindre  
Velindre University  
NHS Trust



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Review reference:	VT- 2223-06
Report status:	Final
Fieldwork commencement:	17 <sup>th</sup> June 2022
Fieldwork completion:	23 <sup>rd</sup> August 2022
Draft report issued:	1 <sup>st</sup> September 2022
Debrief meeting:	24 <sup>th</sup> August 2022
Management response received:	13 <sup>th</sup> September 2022
Final report issued:	14 <sup>th</sup> September 2022
Auditors:	Simon Cookson, Director of Audit & Assurance Emma Rees, Deputy Head of Internal Audit Rhian Gard, Principal Auditor
Executive sign-off:	Jacinta Abraham, Medical Director
Distribution:	Edwin Massey, Deputy Medical Director Sarah Townsend, Head of Research & Development (Trust) Peter Richardson, Head of Quality & Assurance (WBS)
Committee:	Audit Committee



Audit and Assurance Services conform with all Public Sector Internal Audit Standards as validated through the external quality assessment undertaken by the Institute of Internal Auditors

## Acknowledgement

NHS Wales Audit & Assurance Services would like to acknowledge the time and co-operation given by management and staff during the course of this review.

## Disclaimer notice - please note

This audit report has been prepared for internal use only. Audit & Assurance Services reports are prepared, in accordance with the Service Strategy and Terms of Reference, approved by the Audit Committee.

Audit reports are prepared by the staff of the NHS Wales Shared Services Partnership – Audit and Assurance Services and addressed to Independent Members or officers including those designated as Accountable Officer. They are prepared for the sole use of Velindre University NHS Trust and no responsibility is taken by the Audit and Assurance Services Internal Auditors to any director or officer in their individual capacity, or to any third party.

## Executive Summary

### Purpose

To provide assurance that there are effective systems, processes and governance in place around the Velindre University NHS Trust (the Trust) research and development (R&D) function, including partnership working.

We focused on R&D falling under the Health and Care Research Wales definition of NHS research.

### Overview of key findings

No matters were identified for reporting during our review.

Full details of our findings can be seen in section 2.

### Report Classification

Substantial



Few matters require attention and are compliance or advisory in nature.

**Low impact** on residual risk exposure.

Assurance trend:



2017/18 (follow-up)  
Reasonable assurance



2017/18 (full scope)  
Limited assurance

### Assurance summary<sup>1</sup>

Assurance objectives	Assurance
1 Procedures, Processes and Strategy	Reasonable
2 Governance Framework	Substantial
3 R&D Organisational Arrangements	Substantial
4 R&D Projects	Substantial

The Trust's new Strategy – Destination 2032 – contains a strategic goal of being “a beacon for research, development and innovation” in the Trust's stated areas of priority. Significant effort has been made to transform R&D within the Trust in support of this goal, including:

- developing and implementing effective R&D procedures, including clearly defined roles and responsibilities;
- developing and implementing an effective R&D governance framework;
- good partnership working and engagement with stakeholders across many different organisations; and
- well-regulated and managed R&D projects which are monitored robustly.

The positive outcome of our review is a result of the focus and work undertaken by the Trust, in particular the Medical Director, Head of Research and Development, Head of Innovation and research and development staff throughout the Trust.

<sup>1</sup> The objectives and associated assurance ratings are not necessarily given equal weighting when formulating the overall audit opinion.

## 1. Introduction

- 1.1 Our review sought to provide the Trust with assurance regarding the effective management of R&D within the Trust, focusing on NHS research.
- 1.2 Research and development are essential for the advancement of healthcare and wealth creation through the development of intellectual property. All NHS R&D in Wales is overseen by Health and Care Research Wales (HCRW).
- 1.3 The Trust's R&D function is a corporate function. It takes a lead in ensuring that research falling under the HCRW definition of NHS research is conducted and managed to high scientific, ethical and financial standards. Additionally, it provides support for the non-NHS research led by the Welsh Blood Service (WBS).
- 1.4 The key risks considered in this review were:
  - the R&D function is not meeting the Trust's or HCRW's strategic objectives;
  - financial and reputational risk to the Trust if research projects are taking place without proper permission and authorisation;
  - a lack of governance arrangements resulting in poorly governed research; and
  - insufficient resource, training, knowledge and competency arrangements within the Trust resulting in poor quality R&D.

## 2. Detailed Audit Findings

**Audit objective 1: The trust has robust procedures, processes, including an appropriate strategy, which adheres to the principles of good practice in the management and conduct of Health and Social Care research set out by HCRW.**

- 2.1 The Trust has two R&D strategies, one for each division, aligned to the Trust Strategy and reflecting the differing nature of NHS and non-NHS research.
- 2.2 The Trust has a suite of R&D Standing Operating Procedures (SOPs). As part of the audit, we reviewed nine SOPs across the Trust's R&D function and WBS, a key management approval document and the WBS R&D Quality Manual.
- 2.3 Whilst we identified some SOPs were overdue for review, the underlying processes remain the same. We were informed that the review was intentionally delayed due to Covid-19 pressures and was underway during our audit (no matter arising has been included due to the review being underway, but the finding impacts the assurance rating for this objective). The R&D function is also writing a Quality Manual.

### Conclusion:

- 2.4 Noting the above, we have provided **reasonable assurance** over this objective.

**Audit objective 2: The trust has an appropriate governance framework in place for the management of the R&D function and within the Divisions in the Trust.**

- 2.5 The Trust has a robust R&D governance framework and reporting structure. We reviewed relevant agendas, papers and minutes over the last twelve months and could see detailed R&D reporting going to several forums (including QSPC, SDC, RD&I Sub Committee, RD&I Operational Management group, divisional meetings and Board).
- 2.6 There appears to be some duplication in reporting. However, the Trust is aware of this, and work is ongoing to develop a streamlined integrated R&D performance report with clear alignment to the strategies and IMTP.
- 2.7 There is strong stakeholder engagement and partnership working taking place throughout the Trust itself and with other NHS organisations and academia. This is evidenced by the awards won by the Trust for joint research projects.

**Conclusion:**

- 2.8 Noting the above, we have provided **substantial assurance** over this objective.

**Audit objective 3: There are appropriate organisational arrangements in place for the management of the R&D function and within the Divisions in the Trust.**

- 2.9 As part of the audit, we reviewed the organisational chart for the Trust's R&D function and the committee reporting structure and can confirm there is an appropriate level of scrutiny and challenge over R&D through the various forums it is reported to. We can confirm this from our review of Committee, group and Board minutes of the forums mentioned previously. Representatives from the R&D function and WBS regularly attend R&D forums to ensure there is joined up working and on-going communication between the two teams. This will be further enhanced by the appointment of the Head of Innovation for the Trust who will work closely with the Head of R&D in the Trust R&D function.
- 2.10 We were informed that the R&D function is in the process of undertaking a workforce review to identify the effectiveness of working arrangements and any improvements needed. The WBS R&D team works closely with the WBS Quality Assurance function to ensure good management of research and innovation.

**Conclusion:**

- 2.11 Noting the above, we have provided **substantial assurance** over this objective.

**Audit objective 4: All R&D Projects in the Trust are appropriately peer and risk reviewed, approved and comply with research governance standards and statutory requirements.**

- 2.12 At the time of our audit, there were 299 research projects registered on the HCRW/Trust portfolio management system and 12 non-NHS studies in WBS. We tested a sample of 23 NHS research projects across both divisions (22 for VCC and 1 for WBS).
- 2.13 As part of the testing, we reviewed evidence to demonstrate key aspects of the project approval process had been followed. We did not identify any exceptions in our testing.

**Conclusion:**

- 2.14 Noting the above, we have provided **substantial assurance** over this objective.

## Appendix A: Assurance opinion rating

We define the following levels of assurance that governance, risk management and internal control within the area under review are suitable designed and applied effectively:

	<b>Substantial assurance</b>	Few matters require attention and are compliance or advisory in nature. <b>Low impact</b> on residual risk exposure.
	<b>Reasonable assurance</b>	Some matters require management attention in control design or compliance. <b>Low to moderate impact</b> on residual risk exposure until resolved.
	<b>Limited assurance</b>	More significant matters require management attention. <b>Moderate impact</b> on residual risk exposure until resolved.
	<b>No assurance</b>	Action is required to address the whole control framework in this area. <b>High impact</b> on residual risk exposure until resolved.
	<b>Assurance not applicable</b>	Given to reviews and support provided to management which form part of the internal audit plan, to which the assurance definitions are not appropriate. These reviews are still relevant to the evidence base upon which the overall opinion is formed.





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## RESEARCH, DEVELOPMENT AND INNOVATION SUB-COMMITTEE

### Executive Briefing to RD&I Sub-Committee

<b>DATE OF MEETING</b>	15/11/2022
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<b>PUBLIC OR PRIVATE REPORT</b>	Public
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<b>IF PRIVATE PLEASE INDICATE REASON</b>	Not Applicable - Public Report
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<b>PREPARED BY</b>	Sarah Townsend, Head of Research & Development Christopher Cotterill-Jones, Research Delivery Manager
<b>PRESENTED BY</b>	Jacinta Abraham, Executive Medical Director
<b>EXECUTIVE SPONSOR APPROVED</b>	Jacinta Abraham, Executive Medical Director

<b>REPORT PURPOSE</b>	FOR NOTING
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COMMITTEE/GROUP WHO HAVE RECEIVED OR CONSIDERED THIS PAPER PRIOR TO THIS MEETING		
COMMITTEE OR GROUP	DATE	OUTCOME

ACRONYMS	
ASCO	American Society of Clinical Oncology
CAR-T	Chimeric Antigen Receptor T-Cells
CRO	Contract Research Organisation

CVUHB	Cardiff & Vale UHB
FY	Financial Year
HER	Human Epidermal growth factor Receptor
HLA	Human Leukocyte Antigen
HR	Hormone Receptor
NHS	National Health Service
NWSSP	NHS Wales Shared Services Partnership
OS	Overall Survival
PFS	Progression Free Survival
Q	Quarter
R&D	Research & Development
RD&I	Research, Development, & Innovation
UHB	University Health Board
UK	United Kingdom
WBMDR	Welsh Bone Marrow Donor Registry

## 1. SITUATION / BACKGROUND

The purpose of this paper is to report a high-level update on Research, Development & Innovation activities taking place in Quarter (Q) 2 of Financial Year (FY) 2022/23.

## 2. ASSESSMENT / SUMMARY OF MATTERS FOR CONSIDERATION

### 2.1. Welsh Blood Service

#### 2.1.1. COVID-19 Serosurveillance Scheme

*Executive Briefing Slides = slide 3*

*RD&I Integrated Performance Report FY2022/23, Q2 = page 45*

The Welsh Blood Service RD&I Facilitation Team were recent finalists in the NHS Wales Awards.

The COVID-19 Serosurveillance Scheme collaboration between Welsh Blood Service, Public Health Wales, Swansea Bay UHB and Cwm Taf Morgannwg UHB - A partnership approach to rapidly establishing COVID-19 surveillance during the pandemic was selected as a finalist for the NHS Wales award "Providing services in partnership across NHS Wales".

The scheme updates Welsh Government on the changes in infection and vaccine-mediated immunity to the COVID-19 virus in the adult Welsh population, month-on-month. The project, which began during the first wave in 2020, has processed over 66,000 samples to date. The scheme supports effective decision-making about Wales's vaccination programmes and public health measures.

Dr Siân James leads the project for the Welsh Blood Service, which involves a broad multidisciplinary approach across the organisation. This cross-department work, in tandem with the partnership between Public Health Wales, Cwm Taf Morgannwg University Health Board and Swansea Bay University Health Board, has been recognised for its efforts by the award nomination.

Alan Prosser, Director of the Welsh Blood Service, had the following to say on the project:

"This project is a great example of how the Welsh Blood Service can make a greater contribution to the health and wellbeing of the Welsh population. We have taken steps to integrate the use of samples for public health initiatives into our processes. This will allow the Welsh Blood Service to use the learning from this project in future collaborations.

We are extremely pleased to have our positive approach to collaboration and creating strong partnerships acknowledged. Being shortlisted for an award such as this is a testament to our staff professionalism in ensuring the success of this project."

### 2.1.2. **Welsh Bone Marrow Donor Registry**

*Executive Briefing Slides = slide 3*

*RD&I Integrated Performance Report FY2022/23, Q2 = page 45*

in its 33rd year of operation, the Welsh Bone Marrow Donor Registry (WBMDR) continues to be a mainstay of the Welsh Blood Service RD&I efforts.

- **International collaboration for cell therapy research**

The WBMDR are working alongside the South Wales Blood and Transplant Team at the University Hospital of Wales to support the provision of the "CAR-T" therapies. CAR-T or chimeric antigen receptor T-cells are an immunotherapy treatment that involves taking patients' cells and

engineering them to recognise infected cancer cells. These re-engineered cells are then returned to the patient with the hope the CAR-T cells will fight off cancer and restore health.

The scientific service and regulatory support of Welsh Histocompatibility & Immunogenetics Service (that WTAIL and WBMDR) are vital in supporting the use of CAR-T technology – e.g. Wales's Molecular Genetics stem cell transplant support is a WBS service. As immunology and transplant expertise provided to the clinical programmes come from WBS it important to be reminded of that enablement that WBS provide. As CAR-T is novel and delivered mainly in a trial setting, it is key to highlight that WBS support these trials also.

In addition, the registry is joining forces with international associates to support the Advanced Therapeutic Medicinal Products to international patients. Developing a new stem cell apheresis facility currently within Velindre Cancer Centre enables WBMDR to support various programmes, with the provision of tissue for transplant, and the provision of our vital service in the cell therapy supply chain.

- **Supporting Research**

The Welsh Bone Marrow Donor Registry has been participating in a research study led by Cardiff University since 2017, assisting in the care of patients with acute myeloid leukaemia that compares bone marrow samples from healthy volunteer donors with samples of patients with acute myeloid leukaemia to assess the role of the supporting cells in the bone marrow in the protection of leukaemia cells. The registry has recruited 34 bone marrow donors for the study to date.

WBMDR also looks at the unmet need surrounding patients of ethnic minority backgrounds. The challenge is to find suitable HLA-matched donors. The WBMDR's Communication and Engagement Co-ordinator will analyse existing recruitment materials to identify social marketing strategies that can develop the panel's diversity and tackle barriers to becoming a donor within underrepresented communities.

The acting Head of WBMDR also recently co-authored a paper published in the Bone Marrow Transplantation journal, and the effect of the COVID-19 pandemic on global unrelated stem cell donations.

- **What's in the research pipeline?**

The WBMDR would like to carry out a future study into the effect of storage on haematopoietic stem cells. This would review long-term liquid nitrogen storage and how fresh cells are shipped for immediate transplant. Cell quality will be assessed in terms of cell count and cell viability. This study would inform how we store haematopoietic stem cells following collection prior to transplantation.

## **2.2. Research and Development**

### **2.2.1. FAKTION and CAPItello-291**

*Executive Briefing Slides = slide 4*

Having previously reported the Trust sponsored FAKTION trial's data at American Society of Clinical Oncology (ASCO) conference on 04 June 2022 with a simultaneous publication in the prestigious Lancet Oncology journal, AstraZeneca's follow-up breast cancer study (CAPItello-291) has recently reported very positive results.

The CAPItello-291 Phase III trial showed that AstraZeneca's Capivasertib in combination with Fulvestrant demonstrated a statistically significant and clinically meaningful improvement in progression-free survival (PFS) versus placebo plus Faslodex in patients with hormone receptor (HR)-positive, human epidermal growth factor receptor 2 (HER2)-low or negative locally advanced or metastatic breast cancer, following recurrence or progression on or after endocrine therapy (with or without a CDK4/6 inhibitor).

The trial met both primary endpoints, improving PFS in the overall patient population and in a prespecified biomarker subgroup of patients whose tumours had qualifying alterations in the PIK3CA, AKT1 or PTEN genes. Although the overall survival (OS) data were immature at the time of the analysis, early data are encouraging. The trial will continue to assess OS as a key secondary endpoint.

The safety profile of Capivasertib plus Fulvestrant was similar to that observed in previous trials evaluating this combination.

The CAPItello-291 The global trial enrolled 708 adult patients, with Velindre University NHS Trust being the highest recruiting UK site.

AstraZeneca are likely to submit a marketing authorisation for Capivasertib in early 2023.

### **2.2.2. Research & Development Internal Audit**

*Executive Briefing Slides = slide 4*

*RD&I Integrated Performance Report FY2022/23, Q2 = page 42*

The Trust's R&D function received a "substantial" assurance classification following a recent internal audit

NHS Wales Shared Services Partnership (NWSSP) undertook an audit of Research & Development (R&D) as part of the 2022/23 internal Audit Plan

The review sought to provide the Trust with assurance regarding the effective management of R&D within the Trust. The scope of the review was to provide assurance that there are effective systems, processes, and governance in place around the research and development function, including partnership working.

The Audit fieldwork took place between July and September 2022, with an Audit Debrief meeting taking place in September 2022.

### **2.2.3. Charitable Funds Committee Integrated Bid**

*Executive Briefing Slides = slide 5*

The Research, Development & Innovation function are currently preparing a business case for submission to and consideration by the Charitable Funds Committee

The business case sets out a request for funding for Financial Years (FY) 2023/24 through 2025/26, to support the implementation of the Velindre Cancer Research & Development (R&D) ambitions. The business case application has two integrated and interdependent sections that supports the:

- Research infrastructure for Clinical Trial Delivery and Governance (this part includes a renewal of previous business case applications, with additional posts included)
- Implementation of the Cancer Research Ambitions to grow future research (this part includes existing and new posts, including posts agreed and co-funded with partners)

The funding is to allow the Trust to continue to support the thriving research infrastructure and ensure the flow of benefits for patients and research to continue to be delivered in line with the Trust's Cancer Research Ambitions.

The business case focuses on the Trust's ambition, over the next 3 years, to expand our cancer research portfolio to improve patient access to research and increase patient recruitment into research studies that Velindre leads and/or supports. This business case takes an integrated approach to ensure all funding requests are aligned with UK, Wales and Trust strategies including the Trusts' Overarching Cancer R&D Ambitions 2021-2031.

### **2.2.4. Oncacare**

*Executive Briefing Slides = slide 5*

Wales Cancer Research Centre introduced Oncacare to the Trust, and also to Cardiff and Vale University Health Board (CVUHB), in early 2021 and a Letter of Intent was signed by the Trust in July 2021 followed by a confidentiality agreement in November 2021. The Letter of Intent contained offerings to the Trust in the context of the NHS and its well-established four nations systems and processes specifically in the set-up of commercial clinical trials.

The Trust can expect to be offered interesting studies with a guarantee of acceptance as a site if we decided our patients would benefit from the trial on offer.

The Trust will continue to maintain and develop its current relationships with sponsors and other CROs and to manage delivery of its portfolio of commercial studies independently of Oncacare.

The Trust R&D office is working with the Joint Research Office at CVUHB to ensure that the terms of the collaboration are the same for both parties.

#### **2.2.5. Head of Innovation**

*Executive Briefing Slides = slide 6*

Robyn Davies, left the post of Head of Innovation within RD&I in July 2022.

The Head of Innovation post was advertised, with applicants being interviewed in August 2022. Unfortunately, an appointment was not made following the interviews.

The Trust is now currently considering the future appointment of the Head of Innovation post. In the meantime, arrangements are underway to support the Trust's ambitious Innovation agenda.

#### **2.2.6. Radiotherapy Research**

*Executive Briefing Slides = slide 6*

*RD&I Integrated Performance Report FY2022/23, Q2 = page 42*

It was reported at the RD&I Sub-Committee meeting of 21 July 2022, that currently there are capacity issues in the core Radiotherapy service that are having an impact on radiotherapy research, including:

- The types of research studies that can be conducted
- The number of patients that can be recruited to research studies
- The staff capacity for research

Delivery of the Radiotherapy and combination Drug/Radiotherapy research portfolio has been and continues to be a challenging resulting from the capacity limitations across the Radiotherapy service.

A Task & Finish group had been established to identify issues make recommendations.

In October 2022, a meeting took place with the following attendees:

- Clinical Director for Radiotherapy Research
- Interim Radiotherapy Services Manager
- Operational Superintendent Radiotherapy Department



- Head of Radiotherapy Physics
- Clinical Scientist, Medical Physics
- Senior Radiotherapy Treatment Planner
- Chair of the Radiotherapy Trials Portfolio Group
- Head of Research & Development
- Research Delivery Manager
- Clinical Director for Velindre Cancer R&D Strategy
- Strategy Lead for Velindre Cancer R&D Strategy
- Cancer R&D Strategy Project Manager

Work is underway to identify and implement mitigation strategies to improve the Radiotherapy service's capacity in terms of research studies and the wider service.

The findings and outcomes will be feedback to the RD&I Operational Management Group and RD&I Strategic Leadership Group.

A report will be made to the RD&I Sub-Committee in February 2023.

### 3. IMPACT ASSESSMENT

<b>QUALITY AND SAFETY IMPLICATIONS / IMPACT</b>	There are no specific quality and safety implications related to the activity outlined in this report.
<b>RELATED HEALTHCARE STANDARD</b>	Governance, Leadership and Accountability
	<ul style="list-style-type: none"> <li>• Standard 3.3 Quality Improvement, Research and Innovation</li> <li>• Standard 3.4 – Information Governance and Communications Technology</li> <li>• Standard 3.5 – Record Keeping</li> </ul>
<b>EQUALITY IMPACT ASSESSMENT COMPLETED</b>	Not required
<b>LEGAL IMPLICATIONS / IMPACT</b>	There are no specific legal implications related to the activity outlined in this report.



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NHS Trust

<b>FINANCIAL IMPLICATIONS / IMPACT</b>	There is no direct impact on resources as a result of the activity outlined in this report.

#### **4. RECOMMENDATION**

It is recommended that the RD&I Sub-Committee note for discussion the presentation and report.

# Research, Development & Innovation (RD&I) Sub-Committee 15 November 2022

Executive Lead Briefing

Dr. Jacinta Abraham, Executive Medical Director

# Content

- Welsh Blood Service
  - COVID-19 Serosurveillance Scheme
  - Welsh Bone Marrow Donor Registry
- Research & Development
  - FAKTION and CAPItello-291
  - Research & Development Internal Audit
  - Charitable Funds Committee Integrated Bid
  - Oncacare
  - Head of Innovation
  - Radiotherapy Research

# Velindre University NHS Trust: Welsh Blood Service

## COVID-19 Serosurveillance Scheme

- Welsh Blood Service's (WBS) RD&I Facilitation Team were recent finalists in the NHS Wales Awards
- The collaboration between WBS, Public Health Wales, Swansea Bay & Cwm Taf Morgannwg UHBs - A partnership approach to rapidly establishing COVID-19 surveillance during the pandemic was selected as finalists for NHS Wales award "Providing services in partnership across NHS Wales"
- The scheme, having processed over 66,000 samples updates Welsh Government on infection and vaccine mediated immunity changes in the Welsh population
- The scheme, led by Dr Siân James for WBS, involved broad multidisciplinary approaches across organisations.
- Alan Prosser, Director of WBS, said "Being shortlisted for an award such as this is a testament to our staff professionalism in ensuring the success of the project"

## Welsh Bone Marrow Donor Registry (WBMDR)

- In its 33<sup>rd</sup> year of operation the WBMDR is a mainstay of the WBS's RD&I efforts.
- WBMDR work alongside the South Wales Blood and Transplant Team to support the provision of "CAR-T" therapies
- The registry is joining international associates to support ATMPs to international patients
- Developing a new stem cell apheresis facility within VCC enables WBMDR to support programmes & provision of vital services in the cell therapy supply chain.
- Having participated in research for acute myeloid leukaemia, unmet needs of minority people and effects of COVID19 pandemic on stem cell donation, future work includes:
  - Effect of storage on haematopoietic stem cells reviewing long-term liquid nitrogen storage and how fresh cells are shipped for immediate transplant
  - Exploration of genetic profiles and donor characterisations for HLA matching

# Velindre University NHS Trust: Research & Development

## FAKTION and CAPItello-291

- The Trust sponsored FAKTION study and AstraZeneca's (AZ) follow on breast cancer study CAPItello-291 recently published very positive results.
- The CAPItello-291 Phase III trial showed that AZ's Capivasertib in combination with Fulvestrant demonstrated a statistically significant and clinically meaningful improvement in progression-free survival (PFS) versus placebo plus Fulvestrant in patients with hormone receptor (HR)-positive, human epidermal growth factor receptor 2 (HER2)-low or negative locally advanced or metastatic breast cancer, following recurrence or progression on or after endocrine therapy
- The trial met primary endpoints improving PFS in the overall patient population & in a prespecified biomarker subgroup
- VUNHST was highest UK recruiting site
- AZ are likely to submit an application for marketing authorisation for Capivasertib early in 2023

## Research & Development Internal Audit

- The Trust's R&D function received a "substantial" assurance classification following a recent internal audit
- NHS Wales Shared Services Partnership (NWSSP) undertook an audit of Research & Development (R&D) as part of the 2022/23 internal Audit Plan
- The review sought to provide the Trust with assurance regarding the effective management of R&D within the Trust. The scope of the review was to provide assurance that there are effective systems, processes, and governance in place around the research and development function, including partnership working.
- The Audit fieldwork took place between July and September 2022, with an Audit Debrief meeting taking place in September 2022.

# Velindre University NHS Trust: Research & Development

## Charitable Funds Committee Intergrated Bid

- Research, Development & Innovation (RD&I) are currently preparing a Business Case for submission and consideration by the Charitable Funds Committee
- The business case sets out a request for funding to support the implementation of the Velindre Cancer R&D Ambitions that supports:
  - Research infrastructure for Clinical Trial Delivery and Governance
  - Implementation of the Cancer Research Ambitions to grow future research
- The business case is to request funding for Financial Year 2023/24 to Financial Year 2025/26
- The business case is to allow the Trust to continue to support the thriving research infrastructure and ensure the flow of benefits for patients and research continue to be delivered in line with the Trust's Cancer Research Ambitions

## Oncacare

- The Trust aims to be an organisation synonymous with Research, Development & Innovation (RD&I) at a scale well beyond the current offering, and will seek to form strategic relationships with partners to achieve this
- Wales Cancer Research Centre introduced Oncacare to the Trust, and also to Cardiff and Vale University Health Board (CVUHB), in early 2021 and a Letter of Intent was signed by the Trust in July 2021 followed by a confidentiality agreement in November 2021
- The Trust is exploring a relationship with Oncacare.
- The Trust would be offered studies with a guaranteed acceptance as a site
- The Trust would continue to maintain & develop current Sponsor/CRO relationships to deliver a commercial study portfolio independently of Oncacare.
- The Trust is working with CVUHB to ensure that the terms of the collaboration are the same for both parties.

# Velindre University NHS Trust: Research & Development

## Head of Innovation

- Robyn Davies, left the post of Head of Innovation in July 2022
- Interviews for the Head of Innovation post took place in August 2022 but we did not appoint to this role
- Unfortunately, an appointment was not made
- The Trust is now currently considering an alternative arrangement for this post which is expected to be filled in the first quarter of 2023
- Existing arrangements continue to support the Trust's ambitious Innovation agenda.

## Radiotherapy Research

- Delivery of Radiotherapy and combination Drug/Radiotherapy research continues to be challenging due to limited capacity across the Radiotherapy service.
- In October 2022, a meeting took place to discuss the issues and identify possible mitigation strategies
- Work is underway to identify and implement mitigation strategies to improve the Radiotherapy service's capacity in terms of research studies and the wider service



## RESEARCH, DEVELOPMENT AND INNOVATION SUB-COMMITTEE

### Update on Multi-Professional Research Requirements

<b>DATE OF MEETING</b>	15/11/2022
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<b>PUBLIC OR PRIVATE REPORT</b>	Public
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<b>IF PRIVATE PLEASE INDICATE REASON</b>	Not Applicable - Public Report
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<b>PREPARED BY</b>	Jane Hopkinson, Velindre Professor of Nursing and Interdisciplinary Cancer Care
<b>PRESENTED BY</b>	Jane Hopkinson, Velindre Professor of Nursing and Interdisciplinary Cancer Care
<b>EXECUTIVE SPONSOR APPROVED</b>	Nicola Williams, Executive Director of Nursing, AHPs and Health Science

<b>REPORT PURPOSE</b>	FOR DISCUSSION / REVIEW
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#### COMMITTEE/GROUP WHO HAVE RECEIVED OR CONSIDERED THIS PAPER PRIOR TO THIS MEETING

COMMITTEE OR GROUP	DATE	OUTCOME
	(DD/MM/YYYY)	Choose an item.

#### ACRONYMS

VUNHST	Velindre University NHS Trust
HCARE	Healthcare Professionals (nurses, allied health professionals and radiographers)
R&I	Research and Innovation
MSc	Master of Science
PhD	Doctorate of Philosophy



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Velindre University  
NHS Trust

**1. SITUATION/BACKGROUND**

**2. ASSESSMENT / SUMMARY OF MATTERS FOR CONSIDERATION**

**3. IMPACT ASSESSMENT**

<b>QUALITY AND SAFETY IMPLICATIONS/IMPACT</b>	Yes (Please see detail below)
	The ambition is to enable nurses and therapists to lead on maintaining and improving the quality and safety of cancer care
<b>RELATED HEALTHCARE STANDARD</b>	Safe Care
	Leadership Staff and resources Effective care Individual care
<b>EQUALITY IMPACT ASSESSMENT COMPLETED</b>	Not required
	Not required at this stage
<b>LEGAL IMPLICATIONS / IMPACT</b>	There are no specific legal implications related to the activity outlined in this report.
<b>FINANCIAL IMPLICATIONS / IMPACT</b>	Yes (Include further detail below)
	Business case in development as part of the Trust Consolidated Research Bid: Research Support 2023 to 2026.

**4. RECOMMENDATION**

4.1 Note the ambition and discuss.

# **VELINDRE HEALTHCARE CANCER RESEARCH AND INNOVATION: THE AMBITION 2022-2026**

## **The situation now**

### **THE KNOWN BENEFITS OF RESEARCH AND INNOVATION**

Research active healthcare providers deliver higher quality services (safe, personalised, equitable, effective).

Research active clinicians analyse their practice seeking solutions to old and new problems. They are important to the development of the health professions and to improvements in cancer care.

Offering opportunity to influence patient care through research and innovation can be important to workforce recruitment and retention.

### **THE LIMITED VELINDRE RESEARCH AND INNOVATION CAPACITY**

Velindre has a small number of nurses and therapists who research their practice. The contribution of nurses and therapists to evidence-based quality improvement is limited. They are underserved in the education and training needed if they are to fulfil their potential contribution to an improvement culture.

Strategy and workplan are needed for sustained leadership and growth in healthcare research and innovation.

## **What we aim to achieve**

Our ambition is to establish a Velindre Healthcare Cancer Research and Innovation Centre of Excellence with a programme for transforming the safety and quality of cancer care.

The Velindre HCARE R&I Centre will be recognised nationally and internationally for service improvement informed by nurse and therapies led research and innovation.

## **How will we get there**

### **IMPROVEMENT AND INNOVATION CULTURE**

For Velindre to be a research active organisation then there is need for a culture change.

The contribution to quality improvement of social science (to inform service delivery and compassionate care practices), in addition to experimental science (to develop new treatments), needs to be recognised and valued.

We will identify the staff who have greatest potential to generate knowledge that can inform quality improvement in treatment, service organisation and care, and supported them in their personal ambitions. This should be independent of healthcare discipline but dependent on the personal ambition aligning with Velindre University NHS Trust Mission and Research and Innovation Strategy.

### **TRAINING AND EDUCATION**

Training and education in research methodologies and methods is needed by nurses and therapists to complement their professional qualifications.

We will develop a career framework to build capacity for research and innovation that can enable sustainable high-quality services resilient to the anticipated health challenges for the future NHS. This will comprise an introduction to research at MSc level for five healthcare staff annually, support for 2 healthcare staff to complete a PhD research training annually, and 1 member of healthcare staff to take up post-doctoral research annually. In this way, we will build capacity to have clinical-academic

leaders in cancer driving an agenda for evidence-based improvement in nursing and therapies practice.

## **What will success look like**

### **VELINDRE HEALTHCARE CLINICAL ACADEMIC CAREER PATHWAY**

- A step change in the quality and quantity of nurse and therapies led cancer research that benefits the health of the people of Wales and beyond. Aligned with research competency framework and career progression with all VUNHST Advanced Practitioners research active as PIs or CIs. Empowering Advanced Practitioners to work to the top of their license and enabling transformational leadership.
- An established partnership with a leading university to support research training necessary for research to become core business. The research training will span Velindre First into Research (MSc empirical project), Velindre Healthcare Clinical Academic Apprentice (PhD training in subject and methodological expertise), Velindre Healthcare Clinical Academic (Post-doc researcher generating and implementing new knowledge for practice), to disciplinary professorial lead.

### **HEALTHCARE RESEARCH LEADERS**

- A professorial lead for Velindre Allied Health Professional cancer research promoting Velindre R&I through publication and presentation at international level.
- A professorial lead for Velindre Nurse-led cancer research promoting Velindre R&I through publication and presentation at international level.

### **HEALTHCARE RESEARCH SUPPORT INFRASTRUCTURE**

- A portfolio of healthcare cancer research supported by infrastructure managed within the VUNHST Research and Development Office.

### **HEALTHCARE RESEARCH PROGRAMME**

- Projects aligned with Welsh cancer care priorities that demonstrate the special contribution nurses and allied health professionals make to cancer care.

### **QUALITY AND SAFETY**

- Integration of nurse and therapies led research into the VUNHST quality agenda

### **METRICS**

- Measured improvement in research maturity using the SORT tool.
- A database of outputs and events
- Examples of nurse and therapies research providing evidence to Chief Nursing Officer Wales and Chief Allied Health Professional Wales.
- Visibility at national level for an innovation in nursing practice informed by Velindre nurse-led research and an innovation in allied health professional practice informed by Velindre therapies-led research.
- Parity with other health providers across the UK with three nurses and 4 allied health professionals in the cancer centre who have a research training (PhD).
- Velindre clinical academics driving the quality agenda for cancer care through membership of one funding committee, one advisory panel, and one think tank.

### **VELINDRE HEALTHCARE RESEARCH REPUTATION**

- Success will be evidenced by awards, publication, and/or invitations to present at Welsh and UK meetings. We will celebrate success in Velindre healthcare research and innovation at a Velindre Healthcare Research and Innovation Annual Conference.

## RESEARCH, DEVELOPMENT AND INNOVATION SUB-COMMITTEE

### Activity Data Benchmarking with other UK Cancer Centres

<b>DATE OF MEETING</b>	15/11/2022
------------------------	------------

<b>PUBLIC OR PRIVATE REPORT</b>	Public
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<b>IF PRIVATE PLEASE INDICATE REASON</b>	Not Applicable - Public Report
--	--------------------------------

<b>PREPARED BY</b>	Sarah Townsend, Head of Research & Development Christopher Cotterill-Jones, Research Delivery Manager
<b>PRESENTED BY</b>	Sarah Townsend, Head of Research & Development
<b>EXECUTIVE SPONSOR APPROVED</b>	Jacinta Abraham, Executive Medical Director

<b>REPORT PURPOSE</b>	FOR NOTING
-----------------------	------------

<b>COMMITTEE/GROUP WHO HAVE RECEIVED OR CONSIDERED THIS PAPER PRIOR TO THIS MEETING</b>		
<b>COMMITTEE OR GROUP</b>	<b>DATE</b>	<b>OUTCOME</b>
Executive Management Board	15 Aug 2022	Recommendations were accepted

<b>ACRONYMS</b>	
AB UHB	Aneurin Bevan University Health Board
CTM UHB	Cwm Taf Morgannwg University Health Board
CV UHB	Cardiff & Vale University Health Board

FY	Financial Year
HD UHB	Hywel Dda University Health Board
LHB	Local Health Board
NIHR	National Institute and Care Research
ODP	Open Data Platform
R&D	Research & Development
SB UHB	Swansea Bay University Health Board
SE	South-East
SW	South-West

## 1. SITUATION / BACKGROUND

The purpose of this paper is to report the Activity Data Benchmarking with other UK Cancer Centres presentation.

The Nuffield Trust report – **Advice on the proposed model for non-surgical tertiary oncology services in South-East Wales** – published in December 2020, recommended that each LHB needs to develop and implement a coordinated plan for analysing and benchmarking cancer activity against other areas.

In striving to meet the Trusts' Strategic goal to be *"A beacon for research, development and innovation"*, the Trust's Integrated Medium-Term Plan (2022 to 2025) includes four main strategic priorities. Strategic Priority 1 is *"The Trust will drive forward the implementation of its Cancer Research & Development Ambitions 2021-2031"*. This strategic priority includes building research capacity and capability at Velindre and across South-East Wales.

To define a baseline the Trust can use to demonstrate improvements in Cancer Research & Development, an activity benchmarking exercise has been undertaken against five selected UK Cancer Centres.

These UK Cancer Centres were selected by the Trust's RD&I Senior Leadership Team, with data collection expanded to include data from South-West and South-East Wales.

The benchmarking exercise concentrated on considering three areas of investigation:

- a) Cancer Research Studies by Trial Phase
- b) Cancer Research Studies by Commercial Status
- c) Cancer Research Studies by Complexity

Data was collected from the National Institute for Health and Care Research (NIHR) Open Data Platform (ODP) – a national research data repository on 02 Aug 2022 and 03 Aug 2022 using the following criteria:

- The speciality was defined as “cancer”.
- The sub-specialities “Haematological Oncology” and “Children’s Cancer & Leukaemia” were excluded.
- Financial Year (FY) 2019/20 data was selected – as this is likely to be the most recent dataset least impacted by the COVID19 pandemic.

Each organisation’s catchment population figure is taken from their published data.

The data is presented in line with the following points:

- NIHR ODP trial phases categorised “N/A” or “-” are excluded.
- NIHR ODP trial phase categorisation anomalies not recognised in VUNHST are excluded.
- South-West Wales data represents, the combined data of:
  - Swansea Bay University Health Board (UHB), and
  - Hywel Dda University Health Board (UHB) only.
- South-East Wales data represents, the combined data of:
  - Aneurin Bevan UHB,
  - Cardiff & Vale UHB, and
  - Cwm Taf Morgannwg UHB only.
- The number of studies is presented as actual values, where studies are only counted once each in the South-West Wales and South-East Wales regional data even if the study is conducted in more than one UHB of that region.
- The number of participants is presented as actual values.

## **2. ASSESSMENT / SUMMARY OF MATTERS FOR CONSIDERATION**

In 2019/20 Velindre University NHS Trust:

- Could offer patients Phase I through to Phase IV studies, like the UK Cancer Centres selected for comparison. Whereas South-West Wales did not offer Phase I, Phase I/II nor Phase IV studies, and South-East Wales did not offer Phase I studies

- Could offer a greater number of studies from the study portfolio in terms of the Phase I through to Phase IV studies than South-West Wales [SB UHB & HD UHB] and South-East Wales (AB UHB, CV UHB & CTM UHB)

Study portfolios in all organisations comprised of more non-commercially sponsored studies than commercially sponsored studies with organisations recruiting more participants to those non-commercially sponsored studies than commercially sponsored studies.

Study portfolios of all organisations comprised of more interventional studies than observational studies or both (interventional & observational) studies.

This activity data benchmarking exercise enables the Trust to determine its performance against other UK Cancer Centres, and to help the Trust identify where to focus energy and resource.

The proposed next steps for consideration are:

- That the activity data benchmarking exercise is repeated annually in future financial years and reported to the RD&I Sub-Committee
- To undertake data capture and present the data for financial years 2020/21 and 2021/22 to determine the impact of COVID19 and compare this across the organisations (taking into consideration the ability to capture and present data for solid tumours only)
- To undertake a more detailed scoping exercise with each organisation to determine
  - Available facilities and equipment resource
  - Available staffing resource and any workforce planning utilised by the organisation
  - Any efficiencies that can be adapted for use in VUNHST
 with the findings of this detailed scoping exercise presented at a future meeting.

### 3. IMPACT ASSESSMENT

<b>QUALITY AND SAFETY IMPLICATIONS / IMPACT</b>	There are no specific quality and safety implications related to the activity outlined in this report.
<b>RELATED HEALTHCARE STANDARD</b>	Governance, Leadership and Accountability
	<ul style="list-style-type: none"> <li>• Standard 3.3 Quality Improvement, Research and Innovation</li> <li>• Standard 3.4 – Information Governance and Communications Technology</li> <li>• Standard 3.5 – Record Keeping</li> </ul>





**GIG**  
CYMRU  
**NHS**  
WALES

Ymddiriedolaeth GIG  
Prifysgol Felindre  
Velindre University  
NHS Trust

<b>EQUALITY IMPACT ASSESSMENT COMPLETED</b>	Not required
<b>LEGAL IMPLICATIONS / IMPACT</b>	There are no specific legal implications related to the activity outlined in this report.
<b>FINANCIAL IMPLICATIONS / IMPACT</b>	There is no direct impact on resources as a result of the activity outlined in this report.

#### 4. RECOMMENDATION

It is recommended that this paper and presentation is noted for discussion.

# Activity Data Benchmarking with other UK Cancer Centres

**RD&I Sub-Committee (15 November 2022)**

Sarah Townsend  
Head of Research & Development

# Content

- Background
  - Cancer Centres
  - Source data
  - Organisational population catchment area
  - No of studies by trial phase
  - Actual No of participants recruited by trial phase
  - No of studies by commercial status
  - Actual No of participants recruited by commercial status
  - No of studies by study complexity
  - Actual No of participants recruited by study complexity
  - Summary
  - Recommendations and Next steps
- This exercise has concentrated on considering three areas of investigation:
    - Studies by Trial Phase
    - Studies by Commercial Status
    - Studies by Complexity

# Background

- In striving to be “**A beacon for research, development and innovation**” its vital that the Trust benchmarks our research activity against other UK organisations.
- Currently, the Trust has:
  - 22 research studies in setup (both commercial and non-commercial studies)
  - 42 research studies in pre-set up (selected as a site, but awaiting the feasibility form from Velindre Trials Teams)
  - 109 research studies open to recruitment
  - 126 studies closed to recruitment and in follow-up
- The Nuffield report (December 2020) recommended:
  - “each LHB needs to develop and implement a coordinated plan for analysing and **benchmarking cancer activity** against other areas”
- Therefore an activity data benchmarking exercise was completed, using data taken from the National Institute for Health and Care Research (NIHR) Open Data Platform (ODP). The NIHR ODP output presents an overview of research performance data that was further interrogated to create the dataset used in this exercise
- The exercise defines the baseline activity that the Trust can use to demonstrate improvements in Cancer Research & Development (R&D) delivered by the Trust broadly conducted against selected UK Cancer Centres.

# Cancer Centres

- The UK Cancer Centres selected by Trust's RD&I Senior Leadership Team for comparison against Velindre University NHS Trust (VUNHST) were:
  - Royal Marsden NHS Foundation Trust [London and Surrey]
  - The Christie NHS Foundation Trust [Manchester]
  - Beatson West of Scotland Cancer Centre, NHS Greater Glasgow & Clyde [Glasgow]
  - University Hospitals Birmingham NHS Foundation Trust [Birmingham]
  - Leeds Teaching Hospitals NHS Trust [Leeds]
- The data collection was then expanded to include research performance data for:
  - South-West Wales [representing Swansea Bay University Health Board (SB UHB) and Hywel Dda University Health Board only]
  - South-East Wales [representing Aneurin Bevan University Health Board (AB UHB), Cardiff & Vale University Health Board (CV UHB) and Cwm Taf Morgannwg University Health Board (CTM UHB) only]

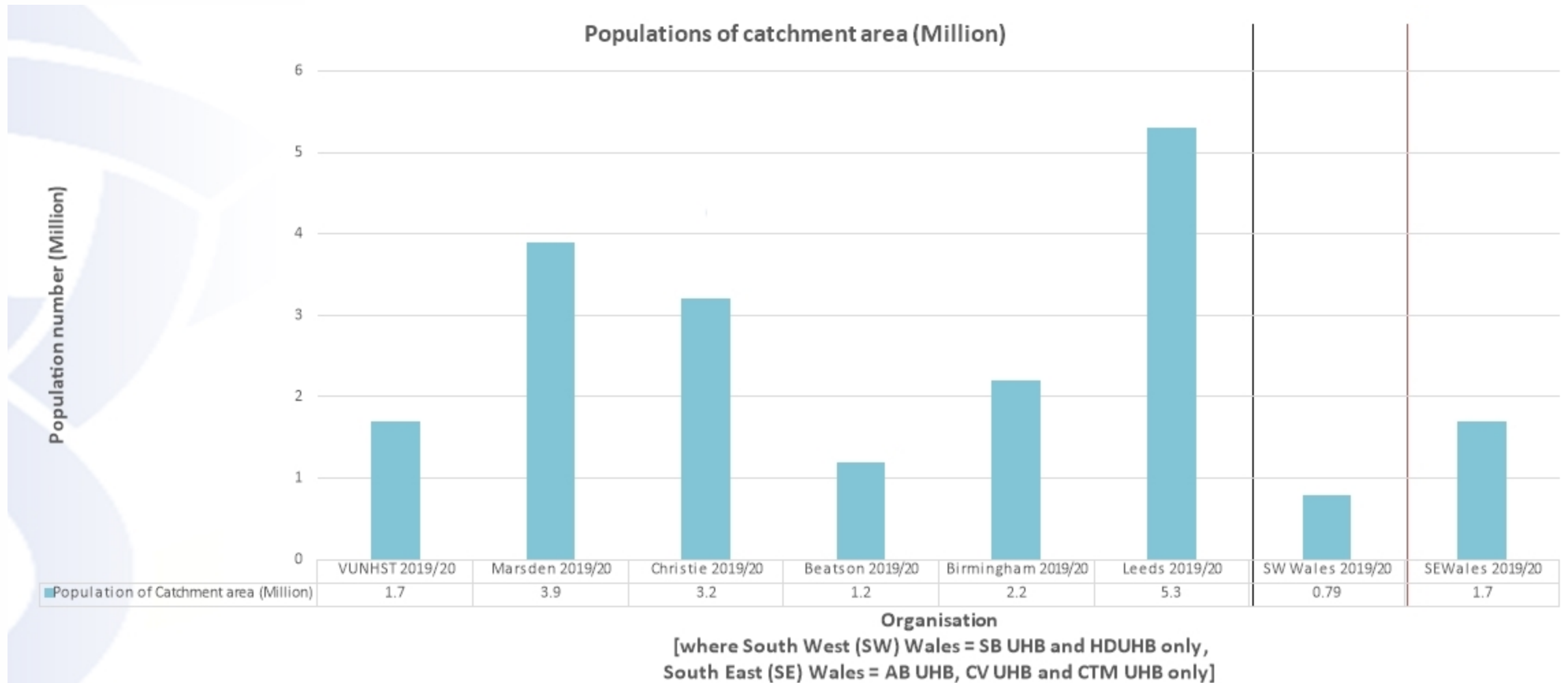
# Source data

- Data was collected from the NIHR ODP (a national research data repository), cut 02 Aug & 03 Aug 2022
- Financial year (FY) 2019/20 data was collected, as this is likely to be the most recent dataset least impacted by the COVID19 pandemic
- The data excludes:
  - Haematological Oncology studies
  - Children's Cancer & Leukaemia studies
  - NIHR ODP trial phases categorised as “N/A” or “-”
  - NIHR ODP trials phase categorisation anomalies that are not recognised in VUNHST
- Each organisation's catchment population figure was taken from their published data
- The number of studies and number of participants recruited are presented as actual values
- The data presented for commercial status and complexity is representative of each organisation's full cancer research portfolio

## Note:

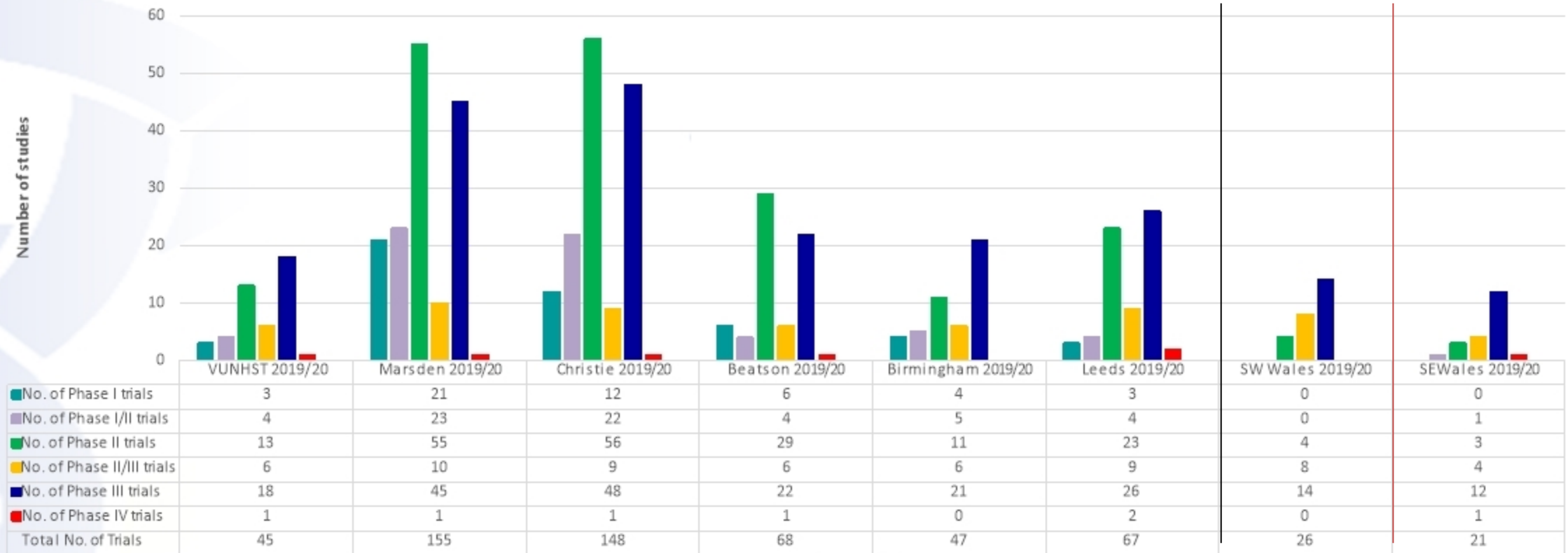
- Studies are led by VUHNST consultants at a University Health Board counts towards the total number of studies within that UHB, and therefor is included in the total study figures of the region where that UHB is located
- The recruitment of a participant to a VUNHST led study at a University Health Board counts towards the total recruitment of participants within that UHB, and therefore is included in the total recruitment figures of the region where that UHB is located

# Organisational population catchment area



# No of studies by trial phase

Number of studies by trial phase for FY2019/20 - excluding Haematological Oncology and Children's Cancer & Leukaemia studies  
[removing studies that categorised in ODP differently to those used in VUNHST]



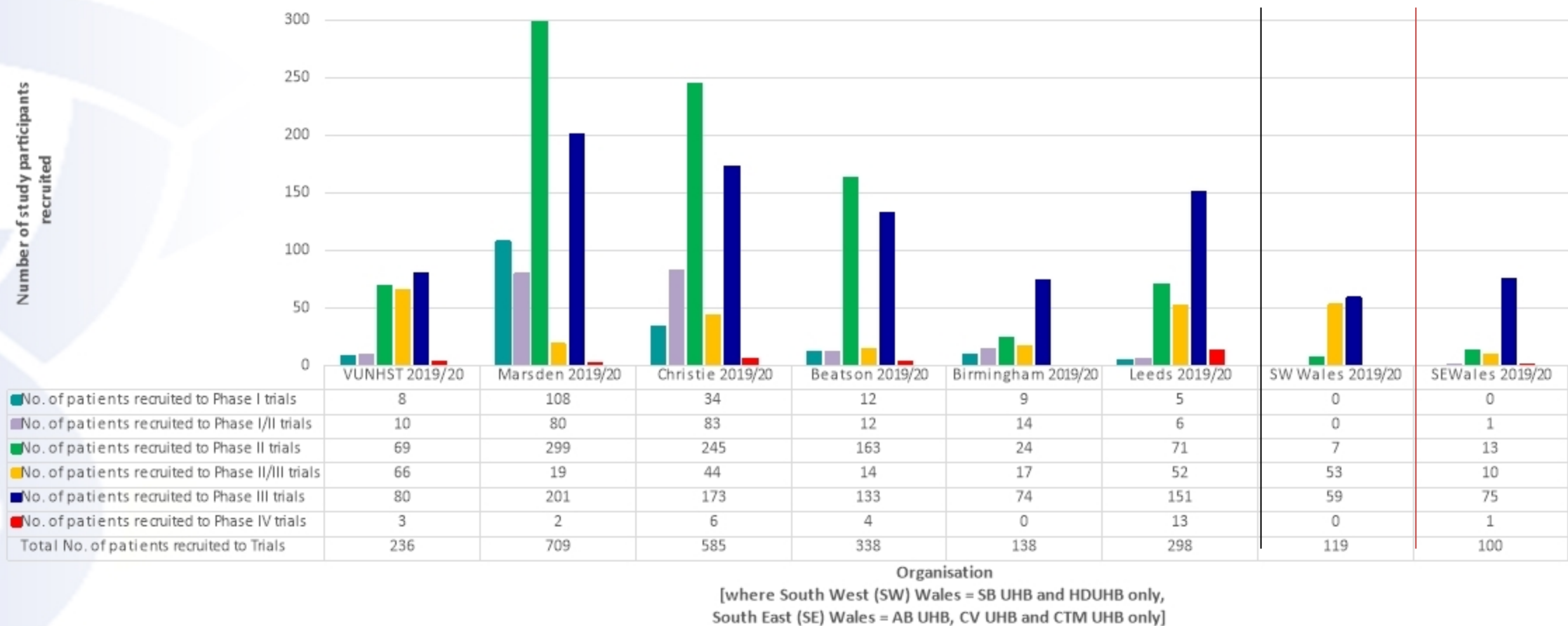
Organisation

[where South West (SW) Wales = SB UHB and HDUHB only,  
South East (SE) Wales = AB UHB, CV UHB and CTM UHB only]



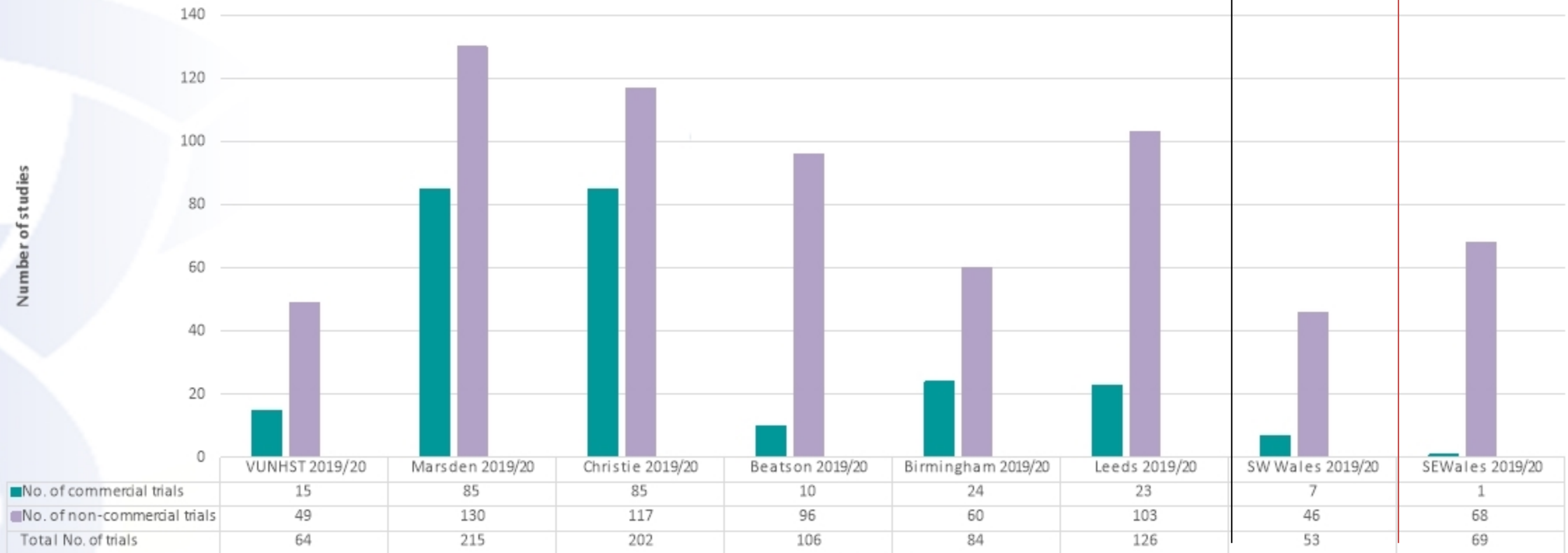
# Actual No of participants recruited by trial phase

Actual number of study participants by trial phase for FY2019/20 - excluding Haematological Oncology and Children's Cancer & Leukaemia studies [removing studies that categorised in ODP differently to those used in VUNHST]



# No of studies by commercial status

Number of studies by commercial status for FY2019/20 in the full cancer research portfolio  
[excluding Haematological Oncology and Children's Cancer & Leukaemia studies]

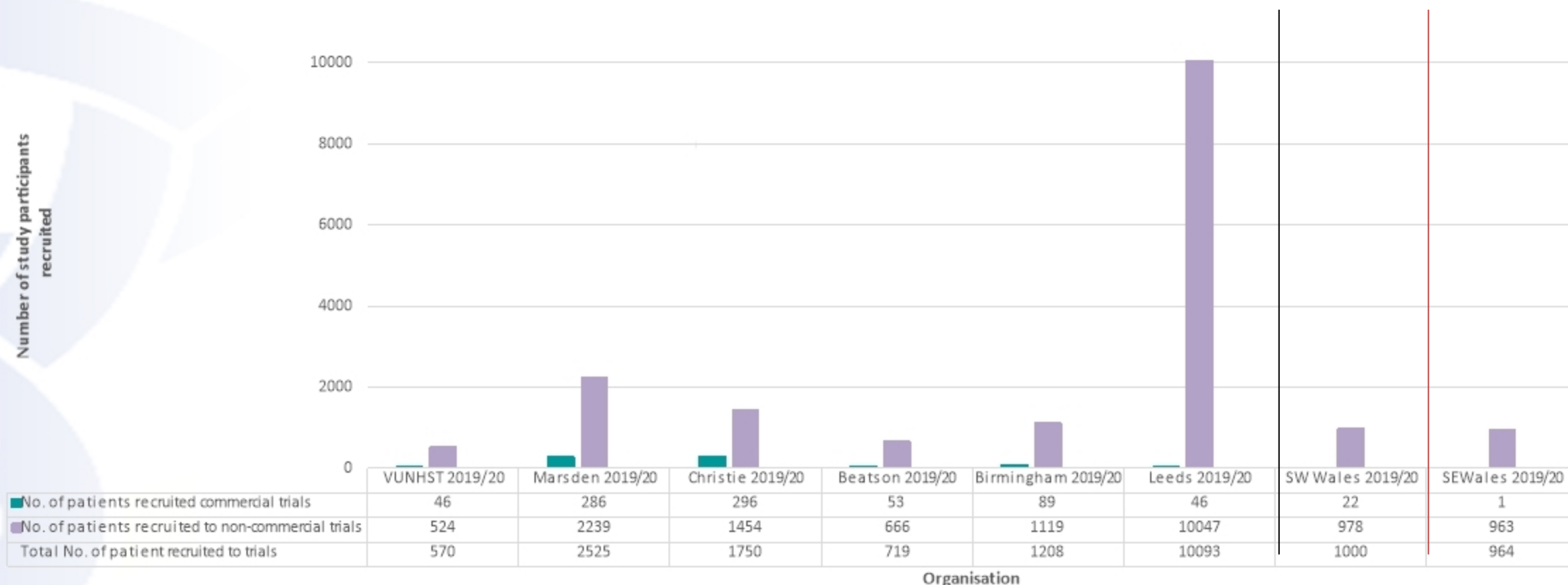


Organisation

[where South West (SW) Wales = SB UHB and HDUHB only,  
South East (SE) Wales = AB UHB, CV UHB and CTM UHB only]

# Actual No of participants recruited by commercial status

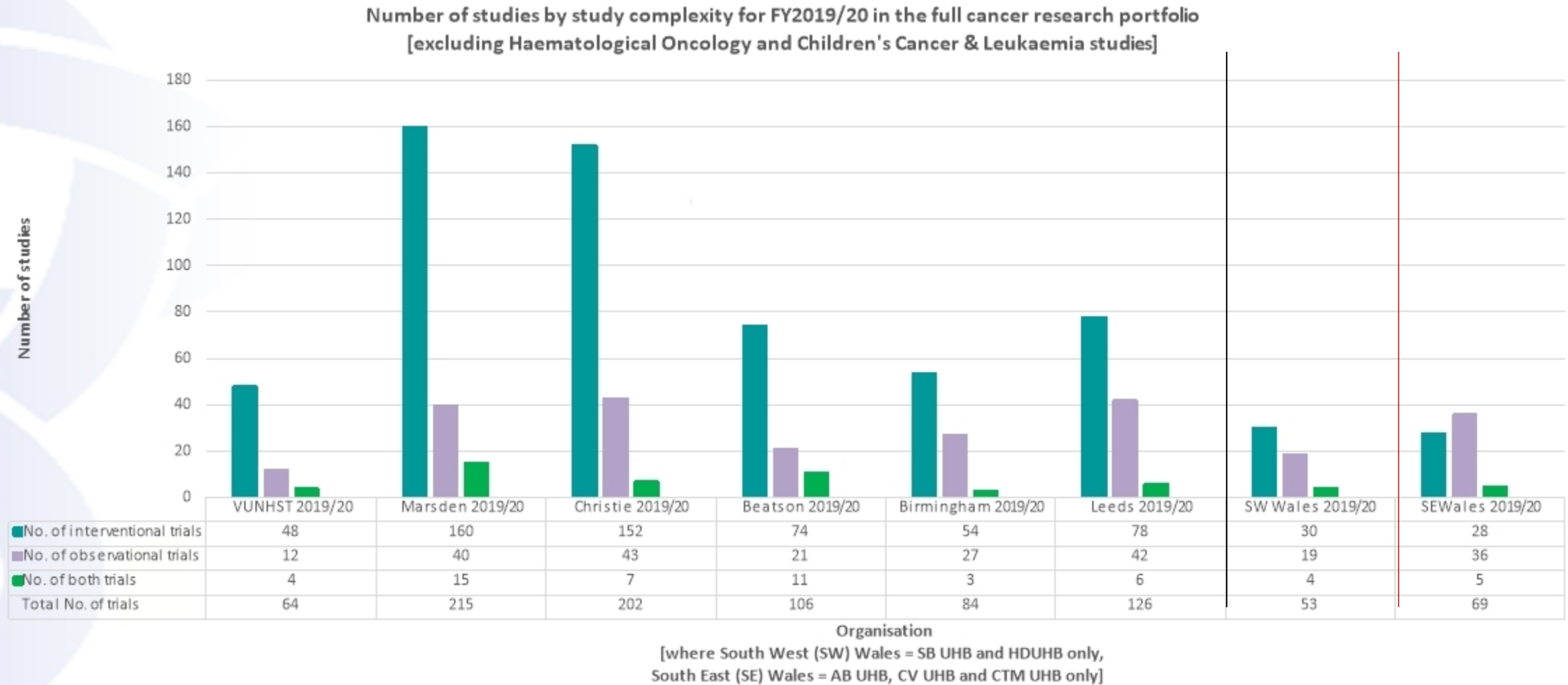
Actual number of study participants recruited by commercial status for FY2019/20 for the full cancer research portfolio  
[excluding Haematological Oncology and Children's Cancer & Leukaemia studies]



Organisation

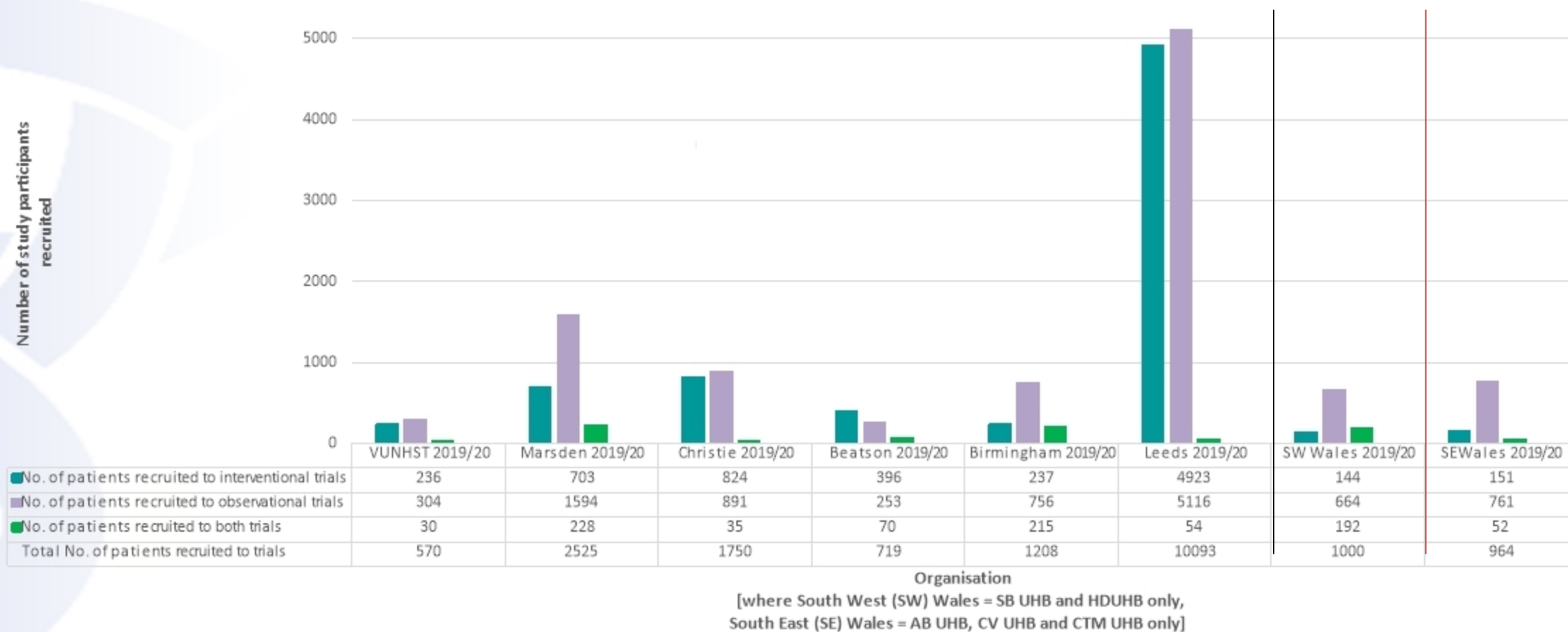
[where South West (SW) Wales = SB UHB and HDUHB only,  
South East (SE) Wales = AB UHB, CV UHB and CTM UHB only]

# No of studies by study complexity



# Actual No of participants recruited by study complexity

Actual number of study participants recruited by study complexity for FY2019/20 for the full cancer research portfolio  
[excluding Haematological Oncology and Children's Cancer & Leukaemia studies]



# Summary

- In 2019/20 Velindre University NHS Trust
  - Could offer patients Phase I through to Phase IV studies, like the UK Cancer Centres selected for comparison. Whereas South West Wales did not offer Phase I, Phase I/II nor Phase IV studies, and South East Wales did not offer Phase I studies
  - Could offer a greater number of studies from the study portfolio in terms of the Phase I through to Phase IV studies than South West Wales [SB UHB & HD UHB] and South East Wales [AB UHB, CV UHB & CTM UHB]
- Study portfolios in all organisations comprised of more non-commercially sponsored studies than commercially sponsored studies with organisations recruiting more participants to those non-commercially sponsored studies than commercially sponsored studies
- Study portfolios of all organisations comprised of more interventional studies than observational studies or both (interventional & observational) studies
- The activity data benchmarking exercise has enabled the Trust to determine its performance within the scope of other UK Cancer Centres, and to help the Trust identify where energy and resource should be focused.

# Recommendations and Next steps

- The following is recommended:
  - The activity data benchmarking exercise is repeated annually in future financial years and reported to EMB and through the RD&I reporting framework
  - Using the NIHR ODP repeat this exercise for financial years 2020/21 and 2021/22 to determine the impact of COVID19 and compare this across the organisations
  - Undertake a more detailed scoping exercise with each organisation to determine
    - Available facilities and equipment resource
    - Available staffing resource and any workforce planning utilised by the organisation
    - Any efficiencies that can be adapted for use in VUNHST
- The findings of the scoping exercise will be presented at a future meeting along with recommendations on service improvements

## RESEARCH, DEVELOPMENT AND INNOVATION SUB-COMMITTEE

### RD&I Integrated Performance Report for Quarter 2, Financial Year 2022/23

<b>DATE OF MEETING</b>	15/11/2022
------------------------	------------

<b>PUBLIC OR PRIVATE REPORT</b>	Public
---------------------------------	--------

<b>IF PRIVATE PLEASE INDICATE REASON</b>	Not Applicable - Public Report
--	--------------------------------

<b>PREPARED BY</b>	Sarah Townsend, Head of Research & Development Christopher Cotterill-Jones, Research Delivery Manager
<b>PRESENTED BY</b>	Sarah Townsend, Head of Research & Development
<b>EXECUTIVE SPONSOR APPROVED</b>	Jacinta Abraham, Executive Medical Director

<b>REPORT PURPOSE</b>	FOR NOTING
-----------------------	------------

COMMITTEE/GROUP WHO HAVE RECEIVED OR CONSIDERED THIS PAPER PRIOR TO THIS MEETING		
COMMITTEE OR GROUP	DATE	OUTCOME

ACRONYMS	
FY	Financial Year
Q	Quarter
RD&I	Research, Development, & Innovation



## 1. SITUATION / BACKGROUND

At the meeting convened on 21 July 2022 the RD&I Sub-Committee received the Research, Development, & Innovation (RD&I) Integrated Performance Report for Financial Year (FY) 2022/23, Quarter (Q) 2.

## 2. ASSESSMENT / SUMMARY OF MATTERS FOR CONSIDERATION

The RD&I Integrated Performance Report summarises the activities of the Trust's Research, Development, & Innovation function during quarter 2 of financial year 2022/23.

## 3. IMPACT ASSESSMENT

<b>QUALITY AND SAFETY IMPLICATIONS / IMPACT</b>	There are no specific quality and safety implications related to the activity outlined in this report.
<b>RELATED HEALTHCARE STANDARD</b>	<p>Governance, Leadership and Accountability</p> <ul style="list-style-type: none"> <li>Standard 3.3 Quality Improvement, Research and Innovation</li> <li>Standard 3.4 – Information Governance and Communications Technology</li> <li>Standard 3.5 – Record Keeping</li> </ul>
<b>EQUALITY IMPACT ASSESSMENT COMPLETED</b>	Not required
<b>LEGAL IMPLICATIONS / IMPACT</b>	There are no specific legal implications related to the activity outlined in this report.
<b>FINANCIAL IMPLICATIONS / IMPACT</b>	There is no direct impact on resources as a result of the activity outlined in this report.

## 4. RECOMMENDATION

It is recommended that the Trust RD&I Sub-Committee note for discussion RD&I Integrated Performance Report for quarter 2 of the financial year 2022/23.



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Quarter 2  
2022/23

**Research, Development  
& Innovation**

**Integrated Performance  
Report**

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# ABBREVIATIONS

BEST	Biomedical Excellence for Safer Transfusion
BMTU	Bone Marrow Transplant Unit
BYS	By Your Side
CAR-T	Chimeric Antigen Receptor T-Cell
CCTH	Cardiff Cancer Research Hub
CVUHB	Cardiff & Vale University Health Board
DRD	DNA repair Deficiency
FDA	Food and Drug Administration
FY	Financial Year
HLA	Human Leukocyte Antigen
IMTP	Integrated Medium-Term Plan
IRS	Integrated Radiological Services
JRO	Joint Research Office
LIP	Local Information Pack
mUBC	Metastatic Urothelial Bladder Cancer
NDA	New Drug Application
NHS	National Health Service
NIHR	National Institute for Health and Care Research
NSCLC	Non-Small Cell Lung Cancer
PDUFA	Prescription Drug User Fee Amendments
PFS	Progression Free Survival
Q	Quarter
R&D	Research & Development
R&I	Research & Innovation
RD&I	Research, Development, & Innovation
RfPB	Research for Public Benefit
SACT	Systemic Anti-Cancer Therapy
SCCHN	Squamous Cell Carcinoma of Head and Neck
SERD	Selective Estrogen Receptor Degradar
SOC	Standard Of Care
TKET	Transfer Knowledge Exchange and Training
TLWC	This is Living with Cancer
UHW	Univeristy Hospital of Wales
UK	United Kingdom
VCC	Velindre Cancer Centre
VHCR	Velindre Healthcare Research
VUNHST	Velindre University NHS Trust
WBMDR	Welsh Bone Marrow Donor Registry
WBS	Welsh Blood Service
WCAT	Wales Clinical Academic Track

# INTRODUCTION

The Research, Development & Innovation (RD&I) Integrated Performance Report format has been amended. The report now reflects the RD&I strategic priorities published in the Velindre University NHS Trust's Integrated Medium-Term Plan (IMTP) that has been updated for 2022 to 2025.

These priorities that support the Trust's strategic goal to be "A beacon for research, development and innovation" are as follows:

<b>STRATEGIC PRIORITIES</b>	
<b>Priority 1</b>	The Trust will drive forward the implementation of its Cancer Research and Development Ambitions 2021-2031.
<b>Priority 2</b>	The Trust will maximise the Research and Development ambitions of the Welsh Blood Service.
<b>Priority 3</b>	The Trust will implement the Velindre Innovation Plan.
<b>Priority 4</b>	The Trust will maximise collaboratively opportunities locally, nationally, and internationally.

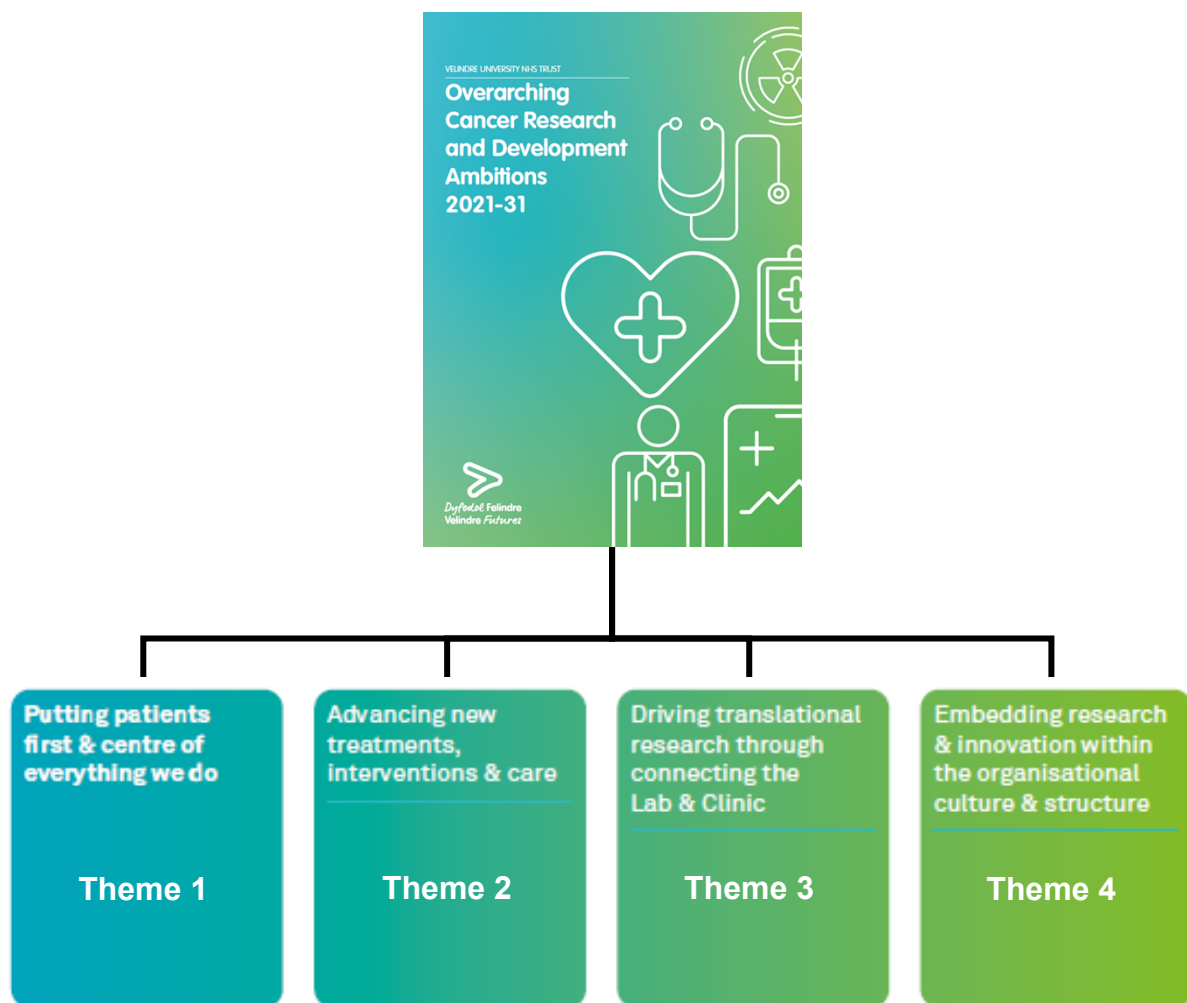
The report includes the progress of work and key achievements for Q2 of FY2022/23 demonstrating activity against these strategic priority areas, the cross-cutting themes that support these areas and Trust RD&I corporate work, for example Finance.

# **STRATEGIC PRIORITY 1:**

## **The Trust will drive forward the implementation of its Cancer Research & Development Ambitions**



# 1 Velindre Cancer R&D Ambitions



## 1.1 Overarching Theme

Key progress/updates for this period
<p><b>Overarching Ambitions Action Plan</b></p> <p>Alongside an Action Plan with key deliverables and timelines, the team are developing documents setting out the critical success factors and mapping out the dependents across the scope of the strategy.</p> <p>The team are working with the RD&amp;I Senior Management Business Team to develop the integrated bid that will be submitted to Velindre Charitable funds subject to endorsement by the different governance processes.</p>

## 1.2 Theme 1: Putting patients first and centre of everything we do

*Included in this theme is Palliative and Supportive Care and Nursing and Allied Health Professional and Clinical Scientists Research*

Key progress/updates for this period
<p><b>Palliative and Supportive Care</b></p> <p>The Marie Curie bid went in over the summer and an interview took place on the 9<sup>th</sup> September. The full outcome is due at the end of October. Positive feedback was received on the day from the external panel and the bid has two internal committees to now go through.</p> <p>There are two palliative care studies:</p> <ul style="list-style-type: none"> <li>• HIDDEN 2 - Hospital Deep Vein Thrombosis Detection Study in Cancer Patients Receiving Palliative Care</li> <li>• Chelsea II - A cluster randomised trial of clinically-assisted hydration in patients in the last days of life</li> </ul> <p>The first WCAT Palliative care trainee has been appointed.</p>

### 1.3 Theme 2: Advancing new treatments, interventions, and care

Key progress/updates for this period
<p><b>UK Research Leadership</b></p> <p>Success for Dr James Powell who will be UK Co-Investigator on a trial called 'Analysis of Proton vs Photon Radiotherapy in Oligodendroglioma &amp; Assessment of Cognitive Health (APPROACH)' which looks at comparing Photons and Protons.</p> <p>Dr Paul Shaw is currently working with University College London designing a study to examine hemi-thoracic proton beam therapy in malignant pleural mesothelioma with a primary outcome of survival improvement and reduction in treatment toxicity.</p> <p><b>IRS Radiotherapy Bunker</b></p> <p>A Radiotherapy R&amp;D Group has been established to oversee activities and membership will include all key internal stakeholders. One of the responsibilities of this group will be to consider and prioritise all proposals for submission to the IRS Joint R&amp;D Committee that will be formed, in partnership with Varian, post contract signature.</p> <p><b>Radiotherapy Research</b></p> <p>A task and finish group has been set up to discuss capacity issues in the core Radiotherapy service that is negatively impacting on radiotherapy research. The aim is to define (as a group) what and where the issues are and the possible solutions. The group includes senior colleagues from medical physics, radiography, and medics. Please see the report included on this meeting for further details.</p>

### 1.4 Theme 3: Driving translational research through connecting the Lab & Clinic

Key progress/updates for this period
<p><b>ATMP trials</b></p> <p>A bid has been submitted to The Translational Knowledge Exchange and Training (TKET) Award to fund a multidisciplinary team (medics, nurses, pharmacists) to visit</p>

Key progress/updates for this period
<p>to 3 Cell Therapy centres in the UK: Christie NHS Foundation Trust, Guy's Hospital and Newcastle upon Tyne Hospital. Whilst we are awaiting the funding result, the next steps will be to clarify as a team the outputs from the visits and formalise how the knowledge will be shared with the wider group. The aim will be to bring back learning from these visits which will be shared across the research teams and supporting departments across Velindre and UHW to further inform delivery of solid tumour ATMP trials within the Hub.</p> <p><b>Cardiff Cancer Research Hub</b></p> <ul style="list-style-type: none"> <li>• The shared cancer research priorities have now been agreed by all Tripartite partners. These priorities act as the building blocks of the Hub, providing a clear direction when applying for grants and developing further partnerships:             <ul style="list-style-type: none"> <li>○ Attract, Train, and Retain a diversity of clinical scientists to embed within and enhance the translational activities of cancer research labs across Cardiff.</li> <li>○ <u>Action</u>: Develop and instigate an agreed clinical academic training pathway with mentorship, excellence, and sustainability at its core.</li> <li>○ Create a Multidisciplinary Think Tank to optimise grant capture, including large scale centre bids.</li> <li>○ <u>Action</u>: Employ Grant Officer(s) to coordinate and develop a range of funding bids, increasing collaboration across industry, government, and charities.</li> <li>○ Harmonise Regulations to facilitate a “can-do” research culture which maximises research activity and outputs.</li> <li>○ <u>Action</u>: Create and manage a harmonised biorepository to modernise patient consent and to enable sample and data sharing.</li> </ul> </li> <li>• The CCRH Project Board's brief and terms of reference has been approved, providing direction to the team and to the project's governance structure.</li> <li>• Following comments from VUNHST's Board, branding of this initiative has been extensively discussed in the Project Board. There was a strong consensus that the title of the Hub should reflect the Tripartite partnership and location. This was further discussed at the CVUHB, VUNHST and Cardiff University Executive Partnership Board with a consensus decision that the name will be 'The Cardiff Cancer Research Hub - A partnership between Velindre, Cardiff and Vale and Cardiff University'. Funds have been secured from VCC's R&amp;D budget to work with a local design agency to design the Hub branding and logo.</li> <li>• Regarding the Investment Strategy for CCRH, there has been engagement with other organizations to establish lessons learnt regarding investment funding, with pre-market engagement undertaken for the development of the investment strategy. Support from VUNHST has been secured to help take forward this work.</li> <li>• There has been slow progress in securing appropriate infrastructure at UHW. This is now being addressed and the appointment of a joint planning role between CVUHB and VUNHST will enable this work programme to move forward. Service specifications have now been compiled for the Hub and, also on dependent projects: Acute Oncology Service and Haematology (BMTU). A co-located request is currently being worked through.</li> </ul>

Key progress/updates for this period
<ul style="list-style-type: none"> <li>• Trial portfolio is gathering pace with MOAT, MORAb and MAGE in set up as well as SOTIO which is the first Solid tumour CAR-T trial to be delivered on the UHW site. <ul style="list-style-type: none"> <li>○ <b>MOAT – Mode of Action Transgene Study</b> - A multicentre, open label, dose escalating, phase 1b, neoadjuvant study of intravenous dosing of NG-641, an oncolytic adenoviral vector expressing a fibroblast activation protein-directed bi-specific T-cell activator antibody fragment (FAP-Tac) and an immune enhancer module (CXCL9/CXCL10/interferon alpha2), as monotherapy or in combination with pembrolizumab in patients with surgically resectable squamous cell carcinoma of the head and neck.</li> <li>○ <b>MORAb-202-G000-201</b> - A Multicenter, Open-Label Phase 1/2 Trial Evaluating the Safety, Tolerability, and Efficacy of MORAb-202, a folate receptor alpha (FR<math>\alpha</math>)-targeting antibody-drug conjugate (ADC) in Subjects With Selected Tumour Types</li> <li>○ <b>MAGE</b> - A Cancer Research UK Phase I/IIa trial of Chimpanzee Adenovirus Oxford 1 (ChAdOx1) and Modified Vaccinia Ankara (MVA) vaccines against MAGE-A3 and NY-ESO-1 with standard of care treatment (chemotherapy and an immune checkpoint inhibitor).</li> <li>○ <b>SOTIO</b> - A First-in-Human, Phase 1/2, Dose Escalation Study of BOXR1030</li> <li>○ T cells in Subjects With Advanced GPC3-Positive Solid Tumors</li> </ul> </li> <li>• A Senior Operational Team has been established that has oversight of the operational delivery of high and intermediate Early phase and ATMP trials. This multi-professional team includes Haematological Oncology and Solid tumour representatives and have an agreed work plan to develop operational policies and supporting documentation.</li> <li>• A Senior nurse has been appointed and will come into post on 31 October 2022 who will lead a scoping exercise with other UK centres that conduct EPT and ATMP trials. A Clinical Research Fellow post is also currently being advertised.</li> <li>• The Head of R&amp;D and her team continue to work with the Joint Research Office (JRO) on the Heads of Terms which is now in its final draft. They are establishing where in the organisation the document needs to be signed off as well as clarifying details such as commencement and duration of collaboration and how the parties will collaborate to appoint the Hub senior management team. The JRO's Partnership and Business Manager is due commence in mid-October and will meet the Head of R&amp;D as a priority to finalize the Heads of Terms. This document will be presented at the next Project Board in November.</li> </ul>

## 1.5 Theme 4: Embedding research innovation within the organisational culture and structure

Key progress/updates for this period
<b>Velindre @Aneurin Bevan</b>

Key progress/updates for this period
<p>Dialogue around building on research opportunities continues between the two sites with a key meeting scheduled on 10 November 2022 where increasing trial activity and developing collaborative working will be discussed.</p> <p><b>Building Capacity and Capability –</b></p> <p><b>Nurse and Therapies</b></p> <p><b>Training and Education</b> The team are developing a 'Dragons Den' workshop for an upcoming Velindre Nurse conference to be held in March 2023. The workshop will address a specific research proposal and the panel will raise questions to highlight areas researchers need to address such as governance and ethics.</p> <p><b>RD&amp;I Communications</b> The business case for a Communications Coordinator has been written. The role will be part of the corporate team with a remit to support and coordinate RD&amp;I communications with patients, public, staff and other stakeholders about RD&amp;I matters (Welsh Blood Service (WBS) and Velindre Cancer Centre (VCC)). This business case will now be included in the Integrated RD&amp;I Business case to Velindre Charitable Funds.</p>

## 2 Nursing & Interdisciplinary Research

The now established Velindre Healthcare Research Support Team has update the nurse and therapies research and innovation ambition statement, in line with the VUNHST R&I Strategy and in preparation for submission of a business case entitled Velindre R&I Integrated Research

### VELINDRE HEALTHCARE CANCER RESEARCH AND INNOVATION: THE AMBITION 2022-2026

#### The situation now:

- THE KNOWN BENEFITS OF RESEARCH AND INNOVATION

Research active healthcare providers deliver higher quality services (safe, personalised, equitable, effective).

Research active clinicians analyse their practice seeking solutions to old and new problems. They are important to the development of the health professions and to improvements in cancer care.

Offering opportunity to influence patient care through research and innovation can be important to workforce recruitment and retention.

- **THE LIMITED VELINDRE RESEARCH AND INNOVATION CAPACITY**

Velindre has a small number of nurses and therapists who research their practice. The contribution of nurses and therapists to evidence-based quality improvement is limited. They are underserved in the education and training needed if they are to fulfil their potential contribution to an improvement culture.

Strategy and workplan are needed for sustained leadership and growth in Velindre healthcare research and innovation.

**What we aim to achieve:**

Our ambition is to establish a Velindre Healthcare Cancer Research and Innovation (R&I) Centre of Excellence with a programme for transforming the safety and quality of cancer care.

The Velindre Healthcare R&I Centre will be recognised nationally and internationally for service improvement informed by nurse and therapies led research and innovation.

**How will we get there:**

- **IMPROVEMENT AND INNOVATION CULTURE**

For Velindre to be a research active organisation then there is need for a culture change.

The contribution to quality improvement of social science (to inform service delivery and compassionate care practices), in addition to experimental science (to develop new treatments), needs to be recognised and valued.

We will identify the staff who have greatest potential to generate knowledge that can inform quality improvement in treatment, service organisation and care. We will support them in their personal ambitions. This support should be independent of healthcare discipline but dependent on the personal ambition aligning with Velindre University NHS Trust Mission and Research and Innovation Strategy.

- **TRAINING AND EDUCATION**

Training and education in research methodologies and methods is needed by nurses and therapists to complement their professional qualifications.

We will develop a career framework to build capacity for research and innovation that can enable sustainable high-quality services resilient to the anticipated health challenges for the future NHS. This will comprise an introduction to research at MSc level for 3 healthcare staff annually, support for 1 healthcare staff member to commence a PhD research training annually, and 1 member of healthcare staff to take up post-doctoral research

annually. In this way, we will build capacity to have clinical-academic leaders in cancer driving an agenda for evidence-based improvement in nursing and therapies practice.

**What will success look like:**

- **VELINDRE HEALTHCARE CLINICAL ACADEMIC CAREER PATHWAY**

A step change in the quality and quantity of nurse and therapies led cancer research that benefits the health of the people of Wales and beyond. It will align with a research competency framework and career progression with all VUNHST Advanced Practitioners research active as PIs or CIs. It will empower Advanced Practitioners to work to the top of their license and enable transformational leadership.

An established partnership with a leading university to support research training necessary for research to become core business. The research training will span Velindre First into Research (MSc empirical project), Velindre Healthcare Clinical Academic Apprentice (PhD training in subject and methodological expertise), and Velindre Healthcare Clinical Academic (Post-doc researcher generating and implementing new knowledge for practice). The award scheme will have a nurse or therapies professorial lead.

- **HEALTHCARE RESEARCH LEADERS**

A professorial lead for Velindre healthcare cancer research promoting Velindre R&I through publication and presentation at international level. The person will be a role model who will supervise and mentor Velindre Healthcare Fellowship award holders.

- **HEALTHCARE RESEARCH SUPPORT INFRASTRUCTURE**

A portfolio of healthcare cancer research supported by infrastructure managed within the VUNHST Research and Development Office.

- **HEALTHCARE RESEARCH PROGRAMME**

Projects aligned with Welsh cancer care priorities that demonstrate the special contribution nurses and therapists make to cancer care.

- **QUALITY AND SAFETY**

Integration of nurse and therapies led research into the VUNHST quality agenda

- **VELINDRE HEALTHCARE RESEARCH REPUTATION**

Success will be evidenced by awards, publication, and/or invitations to present at Welsh and UK meetings. We will celebrate success in Velindre healthcare research and innovation at a Velindre Healthcare Research and Innovation Annual Conference.

*Progress to,*

- *Build healthcare research capacity*

*Velindre healthcare research (VHCR) support team established:*

- *Jane Darmanin, Head of VHCR,*
- *Jodie Sherburn, Research Nurse,*
- *Lenira Semedo, Research Associate,*
- *Manasi Patil, Research Assistant (Small Grants),*
- *Ross McLeish, Data Manager,*
- *Mike Morgan, R&D Officer,*
- *Gwyneth Cole, Administrator*

*Edwards A, Clinical Nurse Specialist (lung), developing an application for a Healthcare Research Wales Clinical Research Time Award.*

*Education and training to build research capacity*

- *Jane Darmanin leading on development of resources and coordinating one-to-one support to include a 'Dragons Den.'*
- *VHCR support team planning a research education needs survey*
- *Jane Hopkinson has joined CARIN a UK network for building nurse and allied health professional clinical-academic research capacity. This gives access to benchmarking data.*

*Sue Tranker, Chief Nursing Officer Wales, is in support of establishing a clinical-academic career pathway and research competencies and standards for clinical nurses in Wales. An Assistant Director is sought to act on behalf of Nurse Execs Wales in progressing clinical-academic careers with Velindre offering to take on this role.*

- *Programme of funded work*

- *Semedo L, Roberts R, Investigating nurses' knowledge and confidence to educate patients and carers pre-IV SACT*
- *Hull R, Semedo L, Roberts R, Closed system devices for SACT administration*
- *Coffey C, Soldon J, Holiday S, Patil, M. Psychology Triage, Small Grant Scheme*
- *Mathlin J, Measure of taste change during radiotherapy for H&N cancer, Small Grant Scheme*
- *Hopkinson J, BeTR-C digital, Cardiff University Innovation for All Award*
- *Ashley L, Hopkinson J, et al. Cancer and dementia in the community, RfPB England*

- *Raising the profile of Velindre healthcare research and innovation nationally and internationally*



- *Edwards A, Mickleburgh B, Hopkinson J (July 2022) The impact of a Lung Cancer Clinical Nurse Specialist role on person-centered and equitable care: a service improvement and evaluation project. Cardiff FRCR Research, Improvement and Innovation Award competition. joint 2nd Prize*
- *Semedo L (September 2022) A systematic review and narrative synthesis investigating the contribution of the family carer in cancer treatment adherence in ambulatory (outpatient) settings. RCN International Nursing Research Conference 2022.*
- *Hopkinson J (June 2022) Education needs and disparities in cancer cachexia care. MASCC/ISOO 2022 Annual Meeting. Toronto, Canada.*
- *Sherburn J (October 2022) RiTA project. UKONS.*
- *Semedo L, Coles B, Hopkinson J (submitted) The contribution of the family carer to cancer treatment adherence in ambulatory settings: A systematic review and thematic synthesis. European Journal of Oncology Nursing.*
- *Ashley L, Surr C, Hopkinson J, et al. (In revision) Cancer care for people with dementia: literature overview and recommendations for practice and research. CA: A Cancer Journal for Clinicians*
- *Hopkinson J, Strasser F (In press) Psychosocial aspects of nutrition. In: Jatoi A, Kaasa S, Strijbos M. ESMO Handbook of Nutrition and Cancer (2nd ed).*
- *Koji A, Hopkinson J, Baracos V (In press) Psychological symptoms of illness and emotional distress in advanced cancer cachexia Current Opinion in Nutrition and Metabolism.*
- *Hopkinson J, Amano K, Baracos V (In press) Eating Issues in Palliative Cancer Patients: a source of cachexia-related distress. In, Chochinov H, Schulman L (Eds) 3rd Edition of the Handbook of Psychiatry in Palliative Medicine: Psychosocial Care of the Terminally Ill. Oxford University Press.*
- *Hopkinson J, Courtier N, Reagon C, Csontos J, Pengelly M, Burbidge B (in review) Cancer Memory Mate implementation: qualitative research to evaluate an innovation to support cancer treatment in people with dementia or mild cognitive impairment. European Journal of Oncology Nursing.*

## **Nursing and Healthcare Therapies**

The Velindre Futures Cancer R&D Strategy team are meeting with Velindre's Professor of Nursing and Interdisciplinary Research, the Operational Lead in Nursing and Interdisciplinary Research & Innovation and the Head of Research & Development to develop and define a programme for healthcare research. This will set out the investment needed and set out key performance metrics to inform the trajectory of progress.

### 3 Performance Indicators

#### 3.1 Summary of performance indicators

The following is a summary of the indicators used by Health and Care Research Wales as part of their delivery framework for performance management.

METRIC	Health & Care Research Wales Data <sup>1</sup>		Velindre University NHS Trust Data <sup>2</sup>	
	Non-Commercial	Commercial	Non-commercial	Commercial
<b>Key Indicator Metrics</b>				
<b>C3/C4 Open:</b> % of Open Studies Recruiting to Time & Target	30%	16%	*	*
<b>C3/C4 Closed:</b> % of Closed Studies Recruiting to Target	100%	0%	*	*
<b>Non Key Indicator Metrics</b>				
Median No of days to first recruited participant	(Blank)	(Blank)	420	455
% of Non-Recruiting Studies	0%	0%	0%	(Blank)
Number of Open and Recruiting Studies	16	9	44	35
Number of Participants Recruited	47	12	91	25

#### Notes:

1	=	Health and Care Research Wales Data only includes those research studies that are part of the Health and Care Research Wales portfolio.
2	=	Velindre University NHS Trust Data includes all research studies that are part of the Trust's study portfolio
*	=	The Trust is working on the calculation of this data for presentation in the RD&I Integrated Performance Report
(Blank)	=	There is no data to report in the period covered by the RD&I Integrated Performance Report

## 3.2 Health & Care Research Wales indicators

### 3.2.1 C3 OPEN: Percentage of Health and Care Research Wales non-commercial Portfolio studies recruiting to target

Metric:	C3 OPEN: Percentage of Health and Care Research Wales Portfolio studies recruiting to time and to target at NHS organisations in Wales.					Target/Measure:	100%		HCRW Performance Indicator:	YES	
How is metric measured:			<p>Health and Care Research Wales use data from the Local Portfolio Management System (LPMS) and the Open Data Platform (ODP) to measure against this key indicator.</p> <p>Open studies are measured using a RAG rating system as follows:</p> <ul style="list-style-type: none"><li>RED: % recruitment is 30% behind the % time elapsed (e.g., RAG Rating = -30% or less)</li><li>AMBER: % recruitment is up to and including 30% behind % time elapsed (e.g., RAG Rating = &lt; -1% ≥ -29%)</li><li>GREEN: % recruitment is equal to or is greater than % time elapsed (e.g., RAG Rating = ≥ 0%)</li></ul> <p>Calculation</p> <p><b>RAG rating</b> = % recruitment – % time elapsed</p> <p>Where: % <b>recruitment</b> = <math>\frac{\text{total recruitment (at organisation)}}{\text{site recruitment target}}</math>      % <b>time elapsed</b> = <math>\frac{\text{Number of days open (at organisation)}}{\text{Number of days planned open}}</math></p>								
Previous Financial Year	Overall		Current Financial Year	Quarter 1		Quarter 2		Quarter 3		Quarter 4	
	Red	63%		Red	61%	Red	42%	Red		Red	
	Amber	14%		Amber	10%	Amber	14%	Amber		Amber	
	Green	23%		Green	29%	Green	23%	Green		Green	
	Black	-		Black	-	Black	-	Black		Black	
	Silver	-		Silver	-	Silver	-	Silver		Silver	
	Purple	-		Purple	-	Purple	-	Purple		Purple	
	White	-		White	-		White	21%		White	
Previously Identified Issues				Previous Action Plan(s) to Improve					Target Date	Status	
<p>The Health and Care Research Wales 2021/22 dataset included 35 studies (R = 22 studies, A = 5studies, G = 8 studies).</p> <p>The Health and Care Research Wales performance dashboard does not allow the data to be filtered by cancer research studies only. This means that the data presented in the Health and Care Research Wales Performance Dashboard does not allow a direct comparison of cancer research studies between VUNHST and other NHS Wales Organisations.</p>				<ul style="list-style-type: none"><li>- Discuss improvements to the dataset used to prepare their metrics, specifically considering:<ul style="list-style-type: none"><li>o Study narrative to give context and reasons for underperformance</li><li>o The measurement of the metric where recruitment targets are small and the study has a long recruitment period.</li></ul></li><li>- Discuss improvements to the newly developed Wales Cancer Dashboard, to allow direct comparison of cancer research studies between VUNHST and other NHS Wales Organisations.</li></ul>					Quarter 2	Ongoing	

The studies hosted by VUNHST are usually small number recruitment targets of long time periods. It is possible for a VUNHST hosted study to be RAG rated red for a number of years or fluctuate in its RAG rating.	<p>Health and Care Research Wales made some changes to the reporting of this metric, including additional ratings:</p> <ul style="list-style-type: none"> <li>- <b>BLACK:</b> studies missing data required to measure Recruitment to Time &amp; Target</li> <li>- <b>SILVER:</b> Suspended studies</li> <li>- <b>PURPLE:</b> Primary Care Studies</li> <li>- <b>WHITE:</b> Non-recruiting studies</li> </ul> <p>Further work is underway to make improvements to the Wales Cancer Dashboard</p>		
See issues listed above.	<p>VUNHST R&amp;D Office:</p> <ul style="list-style-type: none"> <li>- Work continues to interrogate the Trust's study portfolio to determine if to continue to support studies and identify potential barriers to study delivery and develop mitigation strategies to overcome these barriers.</li> </ul> <p>Work to incorporate the recent changes to Health and Care Research Wales changes for reporting this metric will be needed</p>	Quarter 2	Ongoing
Discussion of Issues	Action Plan(s) to Improve Performance	Target Date	
	<p>Upon completion of the interrogation of the Trust's study portfolio the R&amp;D Office will</p> <ul style="list-style-type: none"> <li>- Work with SSTs and Associate Medical Director (AMD) for R&amp;D to identify studies that are non-recruiting or under-performing with a possible view to closing these research studies.</li> <li>- Review the recruitment targets of active studies and request reductions in recruitment targets from the Sponsor, where appropriate.</li> </ul>	Quarter 3	

## 3.2.2 C4 OPEN: Percentage of Health and Care Research Wales Portfolio commercially sponsored studies recruiting to target

Metric:	C4 OPEN: Percentage of Commercially sponsored studies recruiting to time and to target at NHS organisations in Wales.				Target/Measure:	100%		HCRW Performance Indicator:	YES		
How is metric measured:			<p>Health and Care Research Wales use data from the Local Portfolio Management System (LPMS) and the Open Data Platform (ODP) to measure against this key indicator.</p> <p>Open studies are measured using a RAG rating system as follows:</p> <ul style="list-style-type: none"><li>RED: % recruitment is 30% behind the % time elapsed (e.g., RAG Rating = -30% or less)</li><li>AMBER: % recruitment is up to and including 30% behind % time elapsed (e.g., RAG Rating = &lt; -1% ≥ -29%)</li><li>GREEN: % recruitment is equal to or is greater than % time elapsed (e.g., RAG Rating = ≥ 0%)</li></ul> <p>Calculation</p> <p><b>RAG rating</b> = % recruitment — % time elapsed</p> <p>Where: % <b>recruitment</b> = <math>\frac{\text{total recruitment (at organisation)}}{\text{site recruitment target}}</math>      % <b>time elapsed</b> = <math>\frac{\text{Number of days open (at organisation)}}{\text{Number of days planned open}}</math></p>								
Previous Financial Year	Overall		Current Financial Year	Quarter 1		Quarter 2		Quarter 3		Quarter 4	
	Red	79%		Red	77%	Red	63%	Red		Red	
	Amber	-		Amber	6%	Amber	11%	Amber		Amber	
	Green	21%		Green	16%	Green	11%	Green		Green	
	Black	-		Black	-	Black	-	Black		Black	
	Sliver	-		Sliver	-	Sliver	-	Sliver		Sliver	
	Purple	-		Purple	-	Purple	-	Purple		Purple	
	White	-		White	-	White	14%	White		White	
Previously Identified Issues				Previous Action Plan(s) to Improve				Target Date	Status		
<p>The Health and Care Research Wales 2021/22 dataset included 29 studies (R = 23 studies, A = No Value; G = 6 studies).</p> <p>The Health and Care Research Wales performance dashboard does not allow the data to be filtered by cancer research studies only. This means that the data presented in the Health and Care Research Wales Performance Dashboard does not allow a direct comparison of cancer research studies between VUNHST and other NHS Wales Organisations.</p> <p>The studies hosted by VUNHST are usually small number recruitment targets of long time periods. It is possible for a VUNHST hosted study to be RAG rated red for a number of years or fluctuate in its RAG rating.</p>				<p>VUNHST met with Health and Care Research Wales to:</p> <ul style="list-style-type: none"><li>Discuss improvements to the dataset used to prepare their metrics, specifically considering:<ul style="list-style-type: none"><li>Study narrative to give context and reasons for underperformance</li><li>The measurement of the metric where recruitment targets are small and the study has a long recruitment period.</li></ul></li><li>Discuss improvements to the newly developed Wales Cancer Dashboard, to allow direct comparison of cancer research studies between VUNHST and other NHS Wales Organisations.</li></ul>				Quarter 2	Ongoing		

	<p>Health and Care Research Wales made some changes to the reporting of this metric, including additional ratings:</p> <ul style="list-style-type: none"> <li>- <b>BLACK:</b> studies missing data required to measure Recruitment to Time &amp; Target</li> <li>- <b>SILVER:</b> Suspended studies</li> <li>- <b>PURPLE:</b> Primary Care Studies</li> <li>- <b>WHITE:</b> Non-recruiting studies</li> </ul> <p>Further work is underway to make improvements to the Wales Cancer Dashboard</p>		
See issues listed above.	<p>VUNHST R&amp;D Office:</p> <ul style="list-style-type: none"> <li>- Work continues to interrogate the Trust's study portfolio to determine if to continue to support studies and identify potential barriers to study delivery and develop mitigation strategies to overcome these barriers.</li> </ul>	Quarter 2	Ongoing
Discussion of Issues	Action Plan(s) to Improve Performance	Target Date	
	<p>Upon completion of the interrogation of the Trust's study portfolio the R&amp;D Office will</p> <ul style="list-style-type: none"> <li>- Work with SSTs and Associate Medical Director (AMD) for R&amp;D to identify studies that are non-recruiting or under-performing with a possible view to closing these research studies.</li> <li>- Review the recruitment targets of active studies and request reductions in recruitment targets from the Sponsor, where appropriate.</li> </ul>	Quarter 3	

## 3.2.3 C3 CLOSED: Percentage of Health and Care Research Wales non-commercial Portfolio studies recruiting to target

Metric:	C3 CLOSED Percentage of Health and Care Research Wales Portfolio studies recruiting to target at NHS organisations in Wales.				Target/Measure:	100%		HCRW Performance Indicator:	YES		
How is metric measured:		Health and Care Research Wales use data from the Local Portfolio Management System (LPMS) and the Open Data Platform (ODP) to measure against this key indicator.									
		Closed studies are measures using a RAG rating system as follows: <ul style="list-style-type: none"><li>RED: % recruitment is &lt; 100%</li><li>GREEN: % recruitment ≥ 100%</li></ul>									
		Calculation <b>RAG rating</b> = % recruitment									
		<i>Where: % recruitment</i> = $\frac{\text{total recruitment}}{\text{target recruitment}}$									
Previous Financial Year	Overall		Current Financial Year	Quarter 1		Quarter 2		Quarter 3		Quarter 4	
	Red	77%		Red	-	Red	50%	Red		Red	
	Green	23%		Green	100%	Green	50%	Green		Green	
Previously Identified Issues				Previous Action Plan(s) to Improve					Target Date	Status	
The Health and Care Research Wales 2021/22 dataset included 13 studies (R = 10 studies, G = 3 studies). A review of the Red RAG rated studies showed that for several studies the recruitment was stopped by the sponsor for differing reasons.				VUNHST met with Health and Care Research Wales to: <ul style="list-style-type: none"><li>- Discuss improvements to the dataset used to prepare their metrics, specifically considering:<ul style="list-style-type: none"><li>o Study narrative to give context and reasons for underperformance</li><li>o How to note where stopping of recruitment is outside VUNHST control (i.e. sponsor puts recruitment on hold due to COVID19 and never reopens the study, or study stopped for safety reasons).</li></ul></li><li>- Discuss improvements to the newly developed Wales Cancer Dashboard, to allow direct comparison of cancer research studies between VUNHST and other NHS Wales Organisations.</li></ul>					Quarter 2	Ongoing	
Discussion of Issues				Action Plan(s) to Improve Performance					Target Date		

## RD&I - Integrated Performance Report

The 50% Red RAG rated studies accounts for 1 study. VUNHST was one of the top recruiters for this study, but recruitment nationally had been harder than expected due to changes in treatment.	Continue discussions with Health and Care Research Wales relating to improving the preparation of their metrics specifically where the stopping of recruitment is outside the control of VUNHST.	Ongoing
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## 3.2.4 C4 CLOSED: Percentage of Health and Care Research Wales Portfolio commercially sponsored studies recruiting to target

Metric:	C3 CLOSED Percentage of Commercially sponsored studies recruiting to target at NHS organisations in Wales.				Target/Measure:	100%		HCRW Performance Indicator:	YES		
How is metric measured:			Health and Care Research Wales use data from the Local Portfolio Management System (LPMS) and the Open Data Platform ODP to measure against this key indicator.								
			Closed studies are measures using a RAG rating system as follows: <ul style="list-style-type: none"><li>RED: % recruitment is &lt; 100%</li><li>GREEN: % recruitment ≥ 100%</li></ul>								
			Calculation <b>RAG rating</b> = % recruitment								
			<i>Where:</i> % <b>recruitment</b> = $\frac{\text{total recruitment}}{\text{target recruitment}}$								
Previous Financial Year	Overall		Current Financial Year	Quarter 1		Quarter 2		Quarter 3		Quarter 4	
	Red	83%		Red	-	Red	100%	Red		Red	
	Green	17%		Green	-	Green	0%	Green		Green	
Previously Identified Issues				Previous Action Plan(s) to Improve				Target Date	Status		
The Health and Care Research Wales 2021/22 dataset included 12 studies (R = 10 studies, G = 2 studies). A review of the Red RAG rated studies showed that for several studies the recruitment was stopped either due to the study being a rare cancer and more difficult to recruit to or by the sponsor for differing reasons.				VUNHST met with Health and Care Research Wales to: <ul style="list-style-type: none"><li>Discuss improvements to the dataset used to prepare their metrics, specifically considering:<ul style="list-style-type: none"><li>Study narrative to give context and reasons for underperformance</li><li>How to note where stopping of recruitment is outside VUNHST control (i.e. sponsor puts recruitment on hold due to COVID19 and never reopens the study, or study stopped for safety reasons).</li></ul></li></ul> Discuss improvements to the newly developed Wales Cancer Dashboard, to allow direct comparison of cancer research studies between VUNHST and other NHS Wales Organisations.				Quarter 2	Ongoing		
Discussion of Issues				Action Plan(s) to Improve Performance				Target Date			
The 100% Red RAG rated studies accounts for 3 studies.				Continue discussions with Health and Care Research Wales relating to improving the preparation of their metrics				Ongoing			

## RD&I - Integrated Performance Report

<ul style="list-style-type: none"><li>- One study was harder to recruit participants to than anticipated. The study had screened 13 patients for only two patients to go onto treatment</li><li>- Two studies were as a rare cancer with only a small cohort of potential patients.</li></ul>	specifically relating to the narrative entered into to give context for underperforming and how it can better utilised when presenting the metrics.	
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### 3.2.5 C1: Time taken from receipt of Local Information Pack (LIP) to recruitment of first participant into Health and Care Research Wales non-commercial Portfolio studies

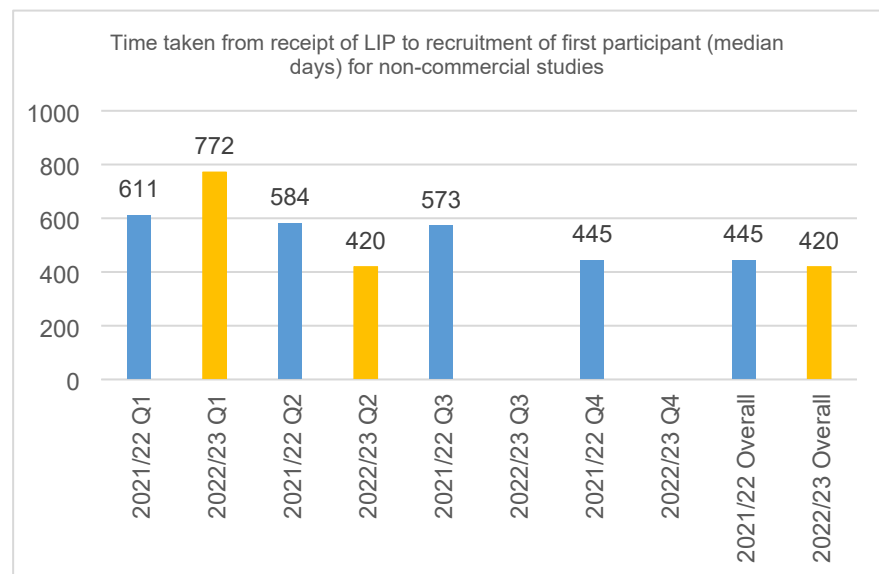
Metric:	C1: Time taken from receipt of Local Information Pack (LIP) to recruitment of first patients into Health and Care Research Wales Portfolio studies				Target/Measure:	Median № of days		HCRW Performance Indicator:	NO		
How is metric measured:		Health and Care Research Wales use data from the Local Portfolio Management System (LPMS) and the Open Data Platform ODP to measure against this key indicator.									
		Calendar days have been adopted to measure this time period consistently across the UK.									
		The start date of this measure is the date the Local Information Pack (LIP) is shared with the NHS organisation by the Sponsor. The end date for this measure is the date the first participant was recruited to the study at the NHS organisation.									
		<b>Note:</b> Any study that is planning to recruit less than one participant per month is not counted within this measure.									
Previous Financial Year	Overall		Current Financial Year	Quarter 1		Quarter 2		Quarter 3		Quarter 4	
	Median days	203		Median days	Blank	Median days	Blank	Median days		Median days	
Previously Identified Issues				Previous Action Plan(s) to Improve					Target Date	Status	
The Health and Care Research Wales 2021/22 dataset included 3 studies (Range =193 to 243 days; Median = 203 days). This dataset only includes studies where the planned recruitment target is more than one participant per month.				VUHNST met with Health and Care Research Wales to: - To discuss improvements to the newly developed Wales Cancer Dashboard, that will allow direct comparison of cancer research studies between VUNHST and other NHS Wales Organisations for number of median days from receipt of Local Information Pack to: o Recruitment of first participant o Confirmation of Capacity and Capability  Work is ongoing in relation to the improvements to the Wales Cancer Dashboard.					Quarters 2/3	Ongoing	
				Work is ongoing by the VUNHST R&D Office to: - Review research study set-up and delivery process to determine where barriers / bottle necks are occurring in the process. - Identify the internal and external support departments where delays may be occurring and work with those departments to improve the timeline for review.					Quarters 2/3	Ongoing	

	<ul style="list-style-type: none"> <li>- Work with Site Specific Teams (SSTs) and study Principal Investigators to review barriers / bottle necks that potentially delay the recruitment of studies' first participants after the Trust has issued Confirmation of Capacity and Capability.</li> <li>- Identify potential mitigation strategies to reduce and improve the number of median days from receipt of Local Information Pack to: <ul style="list-style-type: none"> <li>o Recruitment of first participant</li> <li>o Confirmation of Capacity and Capability</li> </ul> </li> <li>- Implement the agreed mitigation strategies that aim to reduce and improve the number of median days from receipt of Local Information Pack to: <ul style="list-style-type: none"> <li>o Recruitment of first participant</li> <li>o Confirmation of Capacity and Capability</li> </ul> </li> </ul>		
Discussion of Issues	Action Plan(s) to Improve Performance	Target Date	
<p>This dataset only includes studies where the planned recruitment target is more than one participant per month. The 'Blank' presented by Health and Care Research Wales Performance Dashboard for Quarter 1 and 2 of 2022/23 indicates that VUNHST did not have any studies that fit the criteria for inclusion in the Health and Care Research Wales dataset those quarters of the financial year 2022/23.</p> <p><b>The following data is taken from the VUNHST study portfolio for non-commercial studies in quarter 2 of financial year 2022/23.</b></p>	Work described "Previous Action Plan(s) to Improve" above is ongoing	Quarter 2 and 3	

## RD&I - Integrated Performance Report

The data for time take from receipt of Local Information Pack to recruitment of first participants (median days) for all non-commercial studies is as follows:

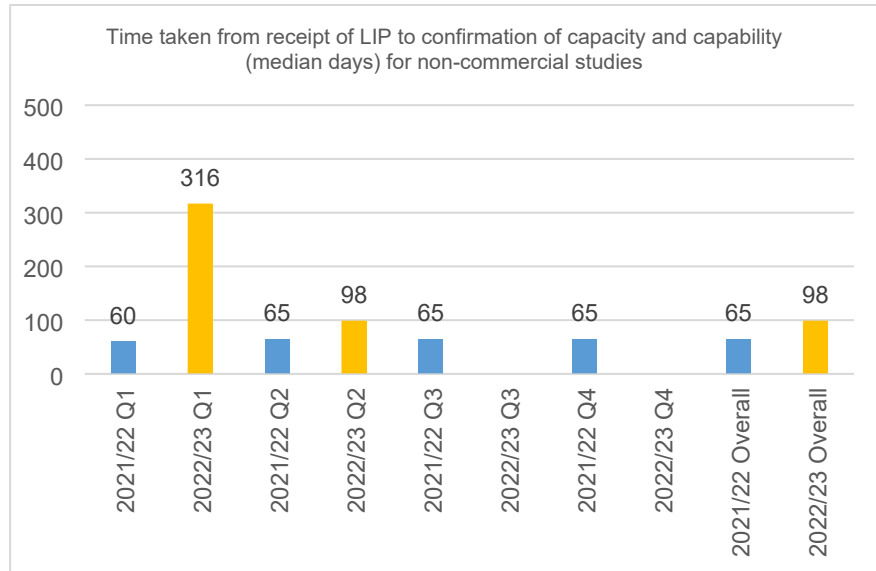
FY	Q1	Q2	Q3	Q4	Overall	Range
2021/22	611	584	573	445	444	104 to 1231
2022/23	772	420			772	346 to 1197



## RD&I - Integrated Performance Report

The data for time taken from receipt of Local Information Pack to Confirmation of Capacity and Capability (median days) for all non-commercial studies is as follows:

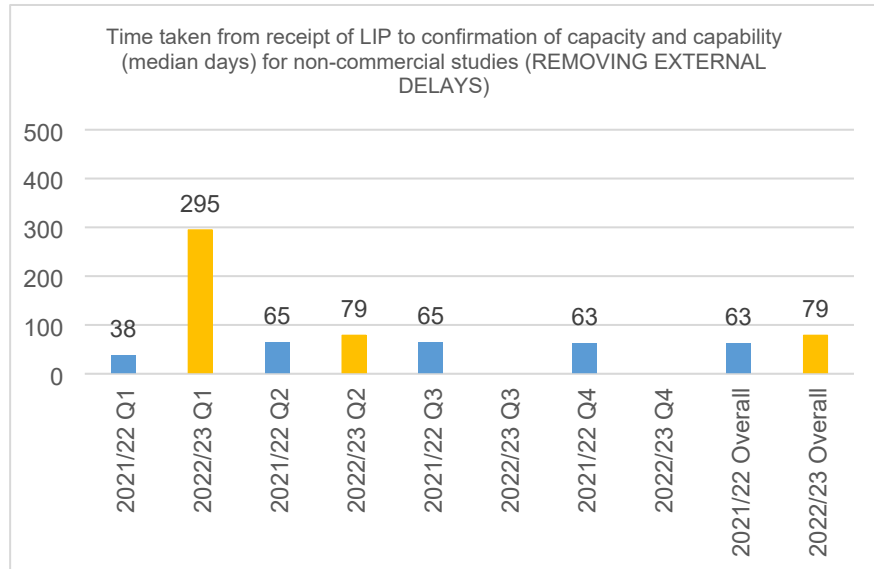
FY	Q1	Q2	Q3	Q4	Overall	Range
2021/22	60	65	65	65	65	0 to 427
2022/23	316	98			316	5 to 327



## RD&I - Integrated Performance Report

The data for time taken from receipt of Local Information Pack to Confirmation of Capacity and Capability (median days) **[Removing external delays]** for all non-commercial studies is as follows:

FY	Q1	Q2	Q3	Q4	Overall	Range
2021/22	38	65	65	63	63	1 to 300
2022/23	295	79			295	5 to 295



### 3.2.6 C2: Time taken from receipt of Local Information Pack (LIP) to recruitment of first participant into Health and Care Research Wales Portfolio commercially sponsored studies

Metric:	C2: Time taken from receipt of Local Information Pack (LIP) to recruitment of first patients into Commercially sponsored studies				Target/Measure:	Median № of days		HCRW Performance Indicator:	NO		
How is metric measured:		Health and Care Research Wales use data from the Local Portfolio Management System (LPMS) and the Open Data Platform ODP to measure against this key indicator.									
		Calendar days have been adopted to measure this time period consistently across the UK.									
		The start date of this measure is the date the Local Information Pack (LIP) is shared with the NHS organisation by the Sponsor. The end date for this measure is the date the first participant was recruited to the study at the NHS organisation.									
		Note: Any study that is planning to recruit less than one participant per month is not counted within this measure.									
Previous Financial Year	Overall		Current Financial Year	Quarter 1		Quarter 2		Quarter 3		Quarter 4	
	Median days	Blank		Median days	Blank	Median days	Blank	Median days		Median days	
Previously Identified Issues				Previous Action Plan(s) to Improve					Target Date	Status	
The Health and Care Research Wales 2021/22 dataset was 'Blank' due to VUNHST not having any studies that fit the criteria for inclusion in the Health and Care Research Wales dataset for financial year 2021/22. This dataset only includes studies where the planned recruitment target is more than one participant per month.				VUHNST met with Health and Care Research Wales to: - To discuss improvements to the newly developed Wales Cancer Dashboard, that will allow direct comparison of cancer research studies between VUNHST and other NHS Wales Organisations for number of median days from receipt of Local Information Pack to: o Recruitment of first participant o Confirmation of Capacity and Capability  Work is ongoing in relation to the improvements to the Wales Cancer Dashboard.					Quarters 2/3	Ongoing	
				Work is ongoing by the VUNHST R&D Office to: - Review research study set-up and delivery process to determine where barriers / bottle necks are occurring in the process. - Identify the internal and external support departments where delays may be occurring and work with those departments to improve the timeline for review.					Quarters 2/3	Ongoing	

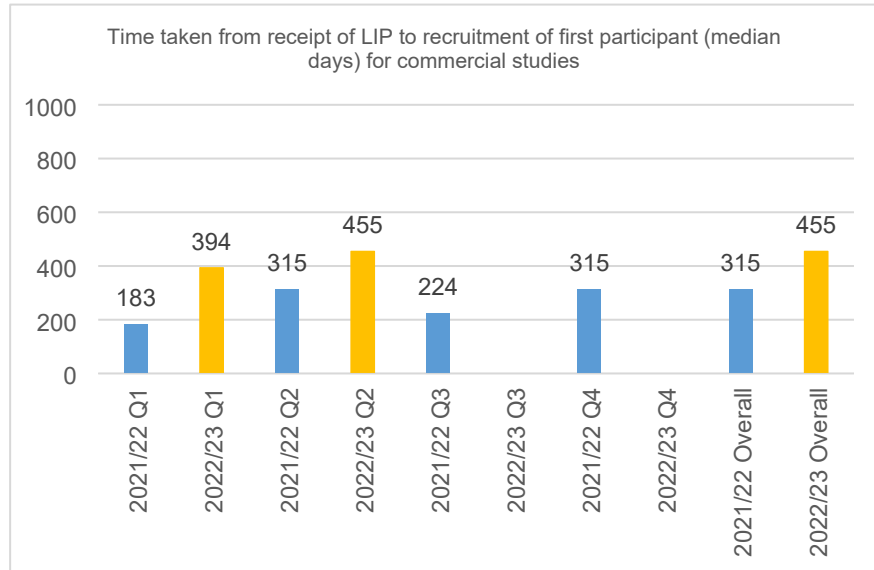


	<ul style="list-style-type: none"> <li>- Work with Site Specific Teams (SSTs) and study Principal Investigators to review barriers / bottle necks that potentially delay the recruitment of studies' first participants after the Trust has issued Confirmation of Capacity and Capability.</li> <li>- Identify potential mitigation strategies to reduce and improve the number of median days from receipt of Local Information Pack to: <ul style="list-style-type: none"> <li>o Recruitment of first participant</li> <li>o Confirmation of Capacity and Capability</li> </ul> </li> <li>- Implement the agreed mitigation strategies that aim to reduce and improve the number of median days from receipt of Local Information Pack to: <ul style="list-style-type: none"> <li>o Recruitment of first participant</li> <li>o Confirmation of Capacity and Capability</li> </ul> </li> </ul>		
Discussion of Issues	Action Plan(s) to Improve Performance	Target Date	
<p>This dataset only includes studies where the planned recruitment target is more than one participant per month. The 'Blank' presented by Health and Care Research Wales Performance Dashboard for Quarter 1 and 2 of 2022/23 indicates that VUNHST did not have any studies that fit the criteria for inclusion in the Health and Care Research Wales dataset those quarters of the financial year 2022/23.</p> <p><b>The following data is taken from the VUNHST study portfolio for non-commercial studies in quarter 2 of financial year 2022/23.</b></p>	Work described "Previous Action Plan(s) to Improve" above is ongoing	Quarter 2 and 3	

## RD&I - Integrated Performance Report

The data for time take from receipt of Local Information Pack to recruitment of first participants (median days) for all commercial studies is as follows:

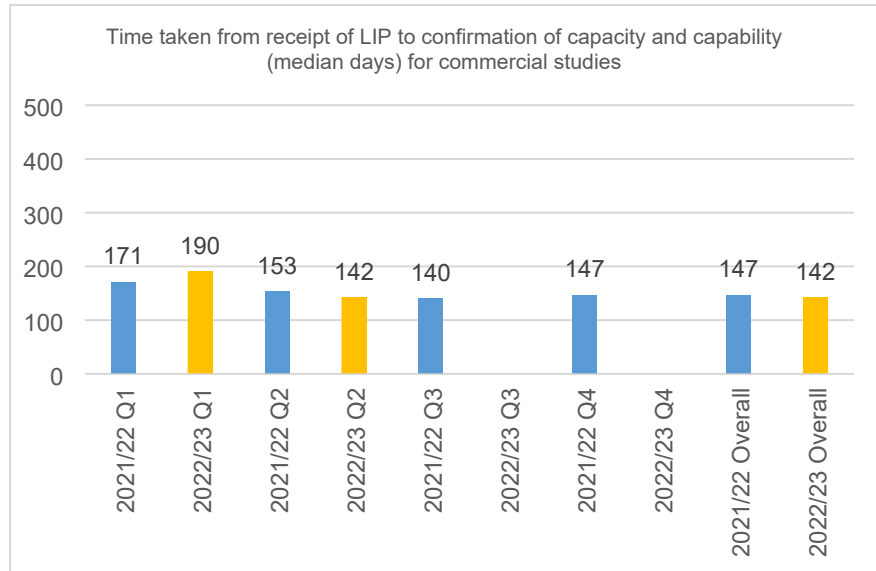
FY	Q1	Q2	Q3	Q4	Overall	Range
2021/22	183	315	224	315	315	81 to 748
2022/23	394	455			394	215-913



## RD&I - Integrated Performance Report

The data for time taken from receipt of Local Information Pack to Confirmation of Capacity and Capability (median days) for all commercial studies is as follows:

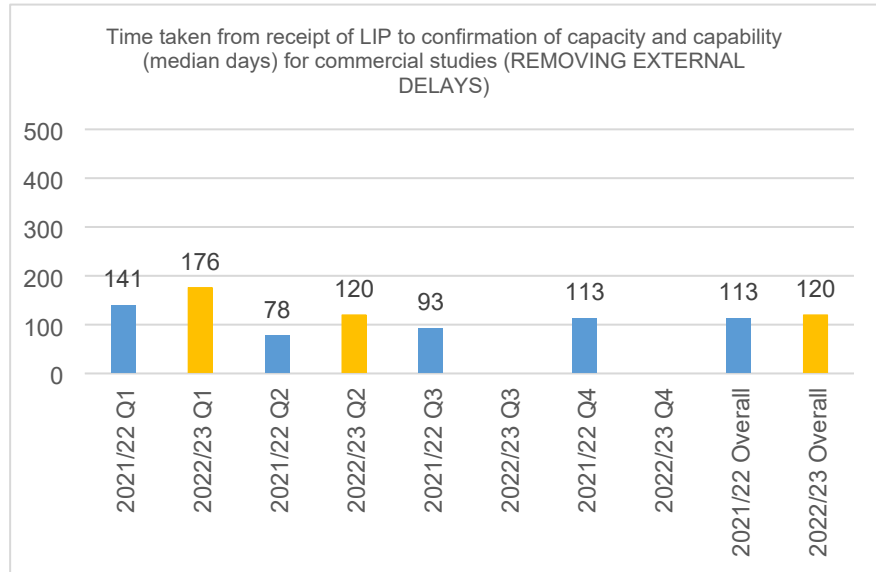
FY	Q1	Q2	Q3	Q4	Overall	Range
2021/22	171	153	140	147	147	56 to 469
2022/23	190	142			190	176 to 243



## RD&I - Integrated Performance Report

The data for time taken from receipt of Local Information Pack to Confirmation of Capacity and Capability (median days) **[Removing external delays]** for all commercial studies is as follows:

FY	Q1	Q2	Q3	Q4	Overall	Range
2021/22	141	78	93	113	113	13 to 284
2022/23	176	120			176	100-575



### 3.2.7 C5: Percentage of non-recruiting Health and Care Research Wales non-commercial Portfolio studies within NHS organisations

Metric:	C5: Percentage of non-recruiting Health and Care Research Wales Portfolio studies within NHS organisations in Wales				Target/Measure:		0%		HCRW Performance Indicator:		NO	
How is metric measured:			Health and Care Research Wales use data from the Local Portfolio Management System (LPMS) and the Open Data Platform ODP to measure against this key indicator.  This key indicator measures all Health and Care Research Wales non-commercial Portfolio studies that have been open to recruitment but have closed to recruitment during the reporting period and have not recruited a participant throughout the duration of the study recruitment period.									
Previous Financial Year	Overall		Current Financial Year	Quarter 1		Quarter 2		Quarter 3		Quarter 4		
	%	8%		%	0%	%	0%	%		%		
Previously Identified Issues				Previous Action Plan(s) to Improve						Target Date		Status
The Health and Care Research Wales 2021/22 dataset included 13 studies.  An 8% Non-recruiting Health and Care Research Wales Portfolio studies represented 1 study where the research left VUNHST before starting the project, and the Sponsor put recruitment on hold due to the pandemic. Recruitment never reopened.				VUHNST met with Health and Care Research Wales to discuss where recruitment is outside the control of VUNHST how this information is captured in this metric.  Work on this is ongoing.								Ongoing
Discussion of Issues				Action Plan(s) to Improve Performance						Target Date		

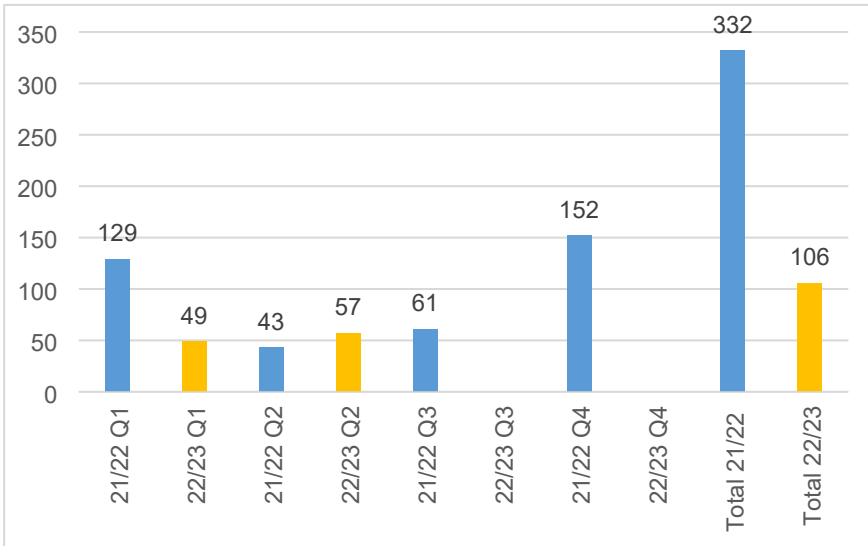
### 3.2.8 C6: Percentage of non-recruiting Health and Care Research Wales Portfolio commercially sponsored studies within NHS organisations

Metric:	C6: Percentage of non-recruiting Commercially sponsored studies within NHS organisations in Wales					Target/Measure:	Median № of days		HCRW Performance Indicator:	NO	
How is metric measured:			Health and Care Research Wales use data from the Local Portfolio Management System (LPMS) and the Open Data Platform ODP to measure against this key indicator.  This key indicator measures all Commercially sponsored studies that have been open to recruitment but have closed to recruitment during the reporting period and have not recruited a participant throughout the duration of the study recruitment period.								
Previous Financial Year	Overall		Current Financial Year	Quarter 1		Quarter 2		Quarter 3		Quarter 4	
	%	50%		%	Blank	%	33%	%		%	
Previously Identified Issues					Previous Action Plan(s) to Improve					Target Date	Status
The Health and Care Research Wales 2021/22 dataset included 12 studies, with 50% representing 6 studies. The reasons for non-recruitment were: - study was for rare cancer and recruitment was more difficult than expected - study had issues with recruitment due to COVID19 - studies were not given 'greenlight' by the Sponsor due to safety concerns with the investigational medicinal product. - studies were closed early by the Sponsor.					VUHNST met with Health and Care Research Wales to discuss where recruitment is outside the control of VUNHST how this information is captured in this metric.  Work on this is ongoing.						Ongoing
Discussion of Issues					Action Plan(s) to Improve Performance					Target Date	
The Health and Care Research Wales 2022/23 Q2 dataset reporting 33% non-recruiting relates to 1 study. This study was a study in rare cancer with a small cohort of potential patients											

## 3.2.9 Number of studies opened

Metric:	Number of studies opened in Velindre University NHS Trust		Target/Measure:	Not Applicable		HCRW Performance Indicator:	NO	
How is metric measured:		Velindre University NHS Trust use data from the Local Portfolio Management System (LPMS) to measure against this indicator. This indicator measures the number of research studies opened in Velindre University NHS Trust.						
Previous Financial Yea	Total	Current Financial Year	Quarter 1	Quarter 2	Quarter 3	Quarter 4	Year to date	
	33		5	9			14	
Graph			Discussion					
			<p>In the graph the blue bars represent the number of studies opened in Velindre University NHS Trust quarter by quarter (and cumulative total) for financial year 2021/22. The yellow bars represent the number of studies opened in Velindre University NHS Trust quarter by quarter (and cumulative total) for financial year 2022/23.</p> <p>The data shows that for quarter 2 of 2022/23 Velindre University NHS Trust opened 9 research studies, this is down 7 compared to the 16 opened research studies in quarter 2 of the previous financial year 2021/22.</p>					

## 3.2.10 Number of participants recruited into studies

Metric:	Number of participants recruited to studies open in Velindre University NHS Trust		Target/Measure:	Not Applicable		HCRW Performance Indicator:	NO	
How is metric measured:		Velindre University NHS Trust use data from the Local Portfolio Management System (LPMS) to measure against this indicator.  This indicator measures the number of participants recruited into research studies int Velindre University NHS Trust.						
Previous Financial Yea	Total	Current Financial Year	Quarter 1	Quarter 2	Quarter 3	Quarter 4	Year to date	
	332		49	57			106	
Graph			Discussion					
			<p>In the graph the blue bars represent the number of participants recruited to studies in Velindre University NHS Trust quarter by quarter (and cumulative total) for financial year 2021/22 The yellow bars represent the number of number of participants recruited to studies in Velindre University NHS Trust quarter by quarter (and cumulative total) for financial year 2022/23.</p> <p>The data shows that for quarter 2 of 2022/23 Velindre University NHS Trust recruited 57 participants into research studies, this is up 14 patients compared to the 43 participants recruited to research studies in quarter 2 of the previous financial year 2021/22.</p>					



## 4 Velindre Cancer Centre hosted research – key achievements

### 4.1 EMERALD

**Study Title: Elacestrant Monotherapy vs Standard of Care for the Treatment of Patients with ER+/HER2- Advanced Breast Cancer Following CDK4/6 inhibitor Therapy: A Phase 3 Randomised, Open-Label, Active Controlled, Multicentre Trial**

The U.S. Food and Drug Administration (FDA) has accepted the Menarini Group's New Drug Application (NDA) for elacestrant, an investigational selective estrogen receptor degrader (SERD), for patients with ER+/HER2- advanced or metastatic breast cancer.

The FDA has granted the application Priority Review and assigned a PDUFA date of February 17, 2023. The FDA grants Priority Review designation to medicines that it considers have the potential to provide significant improvements over current standard of care in the safety and effectiveness of the treatment, diagnosis, or prevention of serious conditions. The FDA granted Fast Track designation for elacestrant in 2018.

- Elacestrant, if approved, would be the first oral selective estrogen receptor degrader (SERD) to be available for patients suffering from 2L and 3L ER+/HER2- advanced or metastatic breast cancer
- Submission supported by results from the pivotal Phase 3 EMERALD study of elacestrant showing statistically significant efficacy over current standard-of-care (SOC) medications for both the overall study population and patients whose tumors harbor an ESR1 mutation

Velindre University NHS Trust was the UK's top recruiter to the EMERALD Trial.

### 4.2 ATLANTIS

**Study Title: An adaptive multi-arm phase II trial of maintenance targeted therapy after chemotherapy in metastatic urothelial cancer**

Dr. Jim Barber, Consultant in Clinical Oncology (Urology) has contributed an article published in the Journal of Clinical Oncology titled: "*A Randomized, Double-Blind, Biomarker-Selected, Phase II Clinical Trial of Maintenance Poly ADP-Ribose Polymerase Inhibition with Rucaparib Following Chemotherapy for Metastatic Urothelial Carcinoma.*"

The publication is available online at: <https://ascopubs.org/doi/pdf/10.1200/JCO.22.00405>

The study was a randomised comparison within the ATLANTIS trial. The ATLANTIS trial is an adaptive, multicomparison, clinical trial platform. It tests multiple, biomarker-selected switch maintenance therapies for patients with metastatic urothelial carcinomas (mUC), and without disease progression after completing four to eight platinum-based

chemotherapy cycles, in a series of parallel, randomized, double-blind, phase II comparisons.

Maintenance rucaparib, following platinum-based chemotherapy, extended progression free survival (PFS) in DNA repair Deficiency (DRD) biomarker-selected patients with mUC and was tolerable.

### **4.3 Velindre University NHS Trust tops recruitment**

**Study title: A Phase II Multi-Arm (basket) Trial Investigating the Safety and Efficacy of IO102-IO103 in Combination with Pembrolizumab, as First-line Treatment for Patients with Metastatic Non-Small Cell Lung Cancer (NSCLC), Squamous Cell Carcinoma of Head and Neck (SCCHN), or Metastatic Urothelial Bladder Cancer (mUBC)**

Velindre University NHS Trust was the first site worldwide to recruit a participant to the IO102-IO103-022 trial, that aims to investigate the efficacy of IO102-IO103 in combination with pembrolizumab in the frontline treatment in each of the different metastatic solid tumour indications.

The Trust is currently the top recruiter to this trial in the world.

**Study title: A Phase III Double-blind Randomised Study Assessing the Efficacy and Safety of Capivasertib + Fulvestrant Versus Placebo + Fulvestrant as Treatment for Locally Advanced (Inoperable) or Metastatic Hormone Receptor Positive, Human Epidermal Growth Factor Receptor 2 Negative (HR+/HER2-) Breast Cancer Following Recurrence or Progression On or After Treatment with an Aromatase Inhibitor (CAPItello – 291)**

The purpose of this research study is to find out if a medication called capivasertib given with fulvestrant (a standard of care medication) will work more effectively than fulvestrant alone in treating patients with locally advanced (inoperable) or metastatic hormone receptor positive, human epidermal growth factor receptor 2 negative (HR+/HER2-) breast cancer. Capivasertib is not approved by any health authority, except for use in research studies.

The Trust is the top recruiter to this trial in the UK.

**Study Title: Validation of Tie2 as the first tumour vascular response biomarker for VEGF inhibitors: Optimising the design of a subsequent randomised discontinuation trial (VALTIVE1)**

Initial studies in ovarian and bowel cancer, led to the discovery of the first biomarker that confirms whether a VEGFi is working. The test involves measuring a protein in the blood

called Tie2, which can be measured from routine blood tests. When Tie2 decreases in the blood, that tumour blood vessels are blocked by VEGFi and the treatment is working; when the level increases, that the blood vessels have escaped the control of VEGFi and treatment should be changed.

However, further research is required to establish the test in the NHS to support clinical decision making.

The VALTIVE1 study, collects blood samples from patients with advanced ovarian cancer who are receiving a specific type of VEGFi called bevacizumab as part of their standard of care. The aim of VALTIVE1 is to generate a comprehensive biomarker data set that describes how Tie2 responds to treatment with bevacizumab.

The data set will be used to design VALTIVE2, which will be a randomised trial with the aim of proving conclusively the value of Tie2 test.

The Trust is the top recruiter to this trial in the UK.

#### **4.4 Velindre University NHS Trust's Research & Development Internal Audit**

A review of Research and Development (R&D) was undertaken by NHS Wales Shared Services Partnership (NWSSP) as part of the 2022/23 Internal Audit Plan.

The review sought to provide the Trust with assurance regarding the effective management of R&D within the Trust. The scope of the review was to provide assurance that there are effective systems, processes, and governance in place around the research and development function, including partnership working.

The Audit fieldwork took place between July and September 2022, with an Audit Debrief meeting taking place in September 2022.

The Trust's R&D function received a "substantial" assurance classification as the Audit outcome.

## **5 Velindre Cancer Centre hosted research – Action Plan(s)**

### **5.1 Radiotherapy**

Delivery of the Radiotherapy and combination Drug/Radiotherapy research portfolio has been and continues to be a challenging resulting from the capacity limitations across the Radiotherapy service.

The Radiotherapy service has not been able to deliver the required full capacity to meet the research demand and growth for a variety of reasons.

In October 2022, a meeting took place with the following attendees:

- Clinical Director for Radiotherapy Research
- Interim Radiotherapy Services Manager
- Operational Superintendent Radiotherapy Department
- Head of Radiotherapy Physics
- Clinical Scientist, Medical Physics
- Senior Radiotherapy Treatment Planner
- Chair of the Radiotherapy Trials Portfolio Group
- Head of Research & Development
- Research Delivery Manager
- Clinical Director for Velindre Cancer R&D Strategy
- Strategy Lead for Velindre Cancer R&D Strategy
- Cancer R&D Strategy Project Manager

Work is underway to identify and implement mitigation strategies to improve the Radiotherapy service's capacity in terms of research studies and the wider service.

## 5.2 Oncacare

Wales Cancer Research Centre introduced Oncacare to the Trust, and also to Cardiff and Vale University Health Board (CVUHB), in early 2021 and a Letter of Intent was signed by the Trust in July 2021 followed by a confidentiality agreement in November 2021. The Letter of Intent contained offerings to the Trust in the context of the NHS and its well-established four nations systems and processes specifically in the set-up of commercial clinical trials.

The Trust can expect to be offered interesting studies with a guarantee of acceptance as a site if we decided our patients would benefit from the trial on offer.

The Trust will continue to maintain and develop its current relationships with sponsors and other CROs and to manage delivery of its portfolio of commercial studies independently of Oncacare.

The Trust R&D office is working with the Joint Research Office at CVUHB to ensure that the terms of the collaboration are the same for both parties.

## **STRATEGIC PRIORITY 2:**

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

## 6 COVID-19 Serosurveillance Scheme shortlisted for NHS Wales Award

Wales's national serosurveillance of COVID-19, in which the Welsh Blood Service is a partner, has been nominated for an NHS Wales Award.

The COVID-19 serosurveillance scheme is set up in partnership with four NHS Wales organisations. Our role at Welsh Blood is to provide blood samples and demographic information to the scheme for epidemiological analysis. The scheme updates Welsh Government on the changes in infection and vaccine-mediated immunity to the COVID-19 virus in the adult Welsh population, month-on-month. The project, which began during the first wave in 2020, has processed over 66,000 samples to date. The scheme supports effective decision-making about Wales's vaccination programmes and public health measures. It has won its nomination for 'Providing Services in Partnership Across NHS Wales'.

Dr Siân James leads the project for the Welsh Blood Service, which involves a broad multidisciplinary approach across the organisation. This cross-department work, in tandem with the partnership between Public Health Wales, Cwm Taf Morgannwg University Health Board and Swansea Bay University Health Board, has been recognised for its efforts by the award nomination.

The scheme has been featured in our previous reports and continues to be a mainstay of our Donor research theme. On the project's first anniversary, we gave a token of thanks to our colleagues who continue to provide this project. We recently celebrated this project's second anniversary and shared an update on the project and our plans for the future with colleagues. Our donors, who make this project possible were fully recognised in our submission to the awards.

Alan Prosser, Director of the Welsh Blood Service, had the following to say on the project:

"This project is a great example of how the Welsh Blood Service can make a greater contribution to the health and wellbeing of the Welsh population. We have taken steps to integrate the use of samples for public health initiatives into our processes. This will allow the Welsh Blood Service to use the learning from this project in future collaborations. We are extremely pleased to have our positive approach to collaboration and



creating strong partnerships acknowledged. Being shortlisted for an award such as this is a testament to our staff professionalism in ensuring the success of this project. Well done to the team, and the best of luck with the awards in October 2022.'

## 7 Welsh Bone Marrow Donor Registry

Now in its 33<sup>rd</sup> year of operation, the Welsh Bone Marrow Donor Registry (WBMDR) continues to be a mainstay of the Welsh Blood Service RD&I efforts.

The WBMDR is a panel of donors who have volunteered to donate their stem cells if they match with a patient needing a transplant. Stem cell transplants can treat certain types of cancer and other blood and immune system diseases.

The WBMDR processes around 1,000 requests per month. Requests can be for patients in Wales, the UK and globally to look for a donor that closely matches the intended recipient's tissue type.

In the UK, around 2,000 allogeneic stem cell transplants are performed each year, and demand is increasing.

### **WBMDR are key players in our Cellular Therapies theme**

Recently, we have refined the name of this theme to Cellular Therapies. It is a refocus for this theme on the increase in of stem cell product use, cell transplantation settings and the specialities of operating a donor registry, cell retrieval and logistical operations. It also means that we can more easily make known that the Welsh Blood Service is interested in this area, drawing parallels with blood establishments and the groups that use this term.

We have updated all of our documents to reflect this change, but we wanted to ensure that you were also aware of it. The theme is now working on the increasing use of cell therapies in a variety of settings.

### **International collaboration for cell therapy research**

The WBMDR are working alongside the South Wales Blood and Transplant Team at the University Hospital of Wales to support the provision of the "CAR-T" therapies. CAR-T or chimeric antigen receptor T-cells are an immunotherapy treatment that involves taking patients' cells and engineering them to recognise infected cancer cells. These re-engineered cells are then returned to the patient with the hope the CAR-T cells will fight off cancer and restore health.

*In addition, the registry is joining forces with international associates to support the Advanced Therapeutic Medicinal Products to international patients. Developing a new stem cell apheresis facility within Velindre Cancer Centre enables WBMDR to support various programmes and the provision of our vital service in the cell therapy supply chain.*



*The WBMDR 1400th donation took place in the WBMDR's flagship collection centre within the Velindre Cancer Centre.*



### **Supporting Research**

The Welsh Bone Marrow Donor Registry has been participating in a research study led by Cardiff University since 2017, assisting in the care of patients with acute myeloid leukaemia.

The study compares bone marrow samples from healthy volunteer donors with samples of patients with acute myeloid leukaemia to assess the role of the supporting cells in the bone marrow in the protection of leukaemia cells. The registry has recruited 34 bone marrow donors for the study to date.

WBMDR also looks at the unmet need surrounding patients of ethnic minority backgrounds. The challenge is to find suitable HLA-matched donors. The WBMDR's Communication and Engagement Co-ordinator will analyse existing recruitment materials to identify social marketing strategies that can develop the panel's diversity and tackle barriers to becoming a donor within underrepresented communities.

The acting Head of WBMDR also recently co-authored a paper published in the Bone Marrow Transplantation journal, and the effect of the COVID-19 pandemic on global unrelated stem cell donations.

### **What's in the research pipeline?**

The WBMDR would like to carry out a future study into the effect of storage on haematopoietic stem cells. This would review long-term liquid nitrogen storage and how fresh cells are shipped for immediate transplant. Cell quality will be assessed in terms of cell count and cell viability. This study would inform how we store haematopoietic stem cells following collection prior to transplantation.

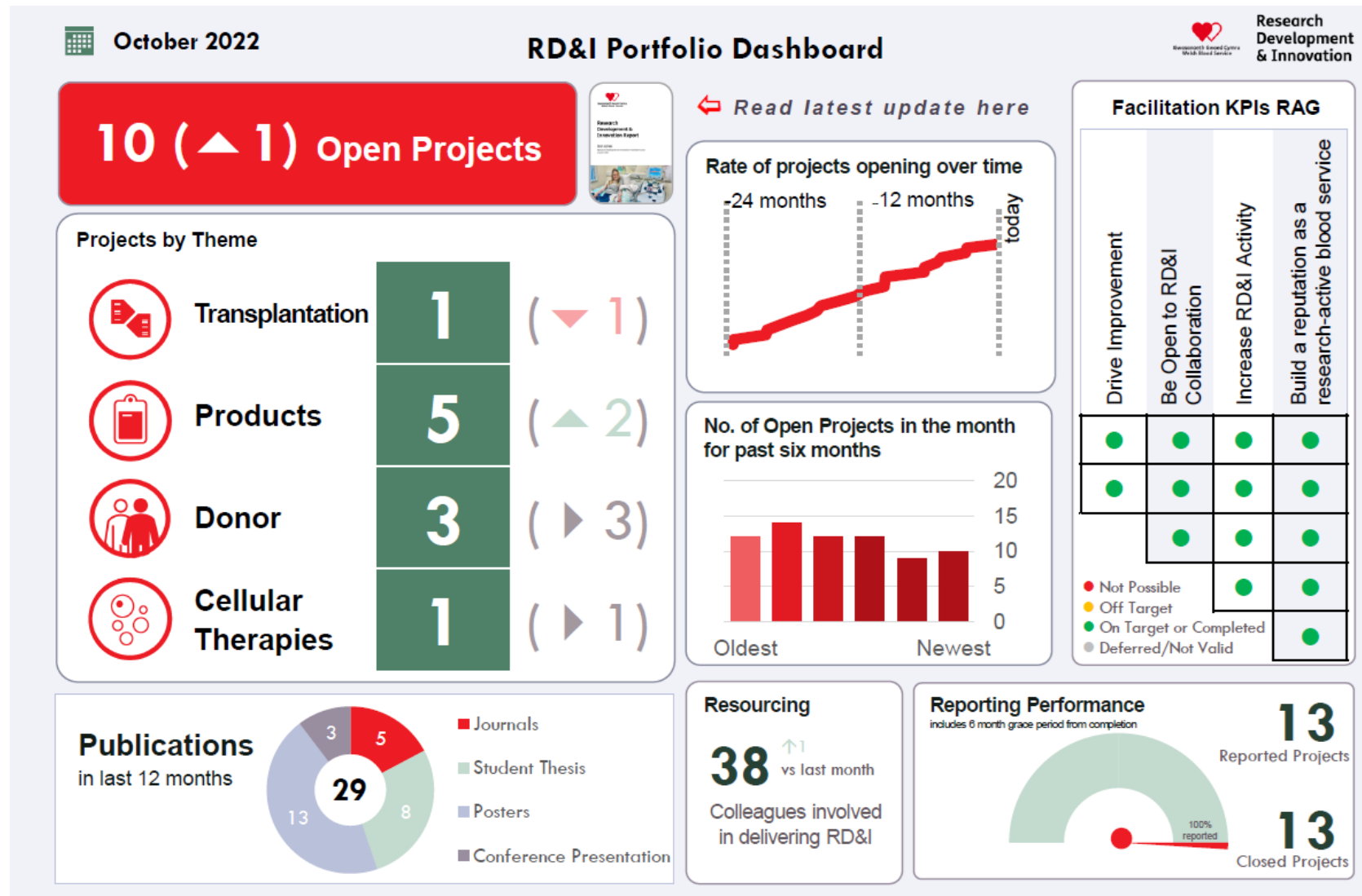


Additionally, it is speculated that the HLA profile of younger people may be changing from the historic population HLA characterisation. It would be beneficial to the Registry to explore these genetic profiles and donor characterisations as it will affect the diverse requirements of a donor registry service.

The WBMDR Collection Co-ordinator will also be undertaking an academic project commencing early 2023.



## 8 Welsh Blood Service RD&I Dashboard



## 9 Open Projects Portfolio

Welsh Blood Service's open projects (as of 19 October 2022)

Project Name	WBS Project ID	WBS Research Theme	WBS Staff Lead	Involvement
Titre scores: An alternative to continuous flow analysis for monitoring antenatal patients in the Welsh Blood Service?	165	Products	Avi Brick	WBS led RD&I
The use of legislation and regulation as a means of improving quality in public healthcare services	164	Donor Care and Public Health	Peter Richardson	WBS led RD&I
Proof of Concept of Method to Remove Extracellular Harmful Agents from Stored Red Cell Units	163	Products	Chloe George	WBS led RD&I
Bioenergetic Profiles of Platelets in Storage as an Indicator of Platelet Viability & Function	162	Products	Chloe George	WBS led RD&I
What donor contact method gives us the best return?	160	Donor Care and Public Health	Kate Satherley	WBS led RD&I
BEST- C 157 Project: We Keep Getting Aggregates in Platelets. Let's GET AGGRIP on Aggregates	159	Products	Nicola Pearce	BEST-C
BEST-C 142 Project: A comparison of anti-D titres using gel and tube technologies	157	Products	Chloe George	BEST-C
Sero-surveillance for SARS-CoV-2 infection in blood donors in Wales	127	Donor	Sian James	WBS led RD&I
Effect of Different Sensitisation Events on HLA Antibody Stability in Kidney Transplant Candidates	145	Transplantation	Maria Burton	WBS led RD&I
Investigating the role of the bone marrow microenvironment in the pathogenesis of Acute Myeloid Leukaemia (AML)	96	Cellular Therapies	Emma Cook	NHS Research

## 10 Key Performance Indicators of the Welsh Blood Service RD&I Strategy

Objective	Activity	Indicator or KPI	Facilitation Target	Co-dependant on	Target	Month by Month Status											
Drive Improvement						A	M	J	J	A	S	O	N	D	J	F	M
Ensure our research efforts are of the highest quality	Applications for NHS Research approval will adhere to NHS Permissions Performance metrics	Velindre NHS Trust to national KPI for NHS Permissions	✓	Velindre Trust R&D	100% Compliance	✓	✓	✓	✓	✓	✓						
Obtaining sustainability for RD&I activities	The utilisation of the RD&I funding	WBS RD&I spend per fiscal year		WBS Finance		✓	✓	✓	✓	✓	✓						
Be Open to RD&I Collaboration																	
Embed a positive culture around RD&I activity / Actively seek collaborative partners to develop appropriate RD&I projects	Maintain an active media presence for RD&I to highlight our achievements	Deliverables described in Communicating Achievements	✓	WBS Donor Engagement Communication	100% delivery	✓	✓	✓	✓	✓	✓						

## RD&I - Integrated Performance Report

Actively seek collaborative partners to develop appropriate RD&I projects	Participation in all applicable BEST-Collaborative projects, as invited	Project invitations as received by our BEST-C members and actioned appropriately.		BEST C Member Rep	100%	✓	✓	✓	✓	✓	✓						
Actively seek collaborative partners to develop appropriate RD&I projects	An inviting RD&I presence on WBS Internet Webpage	All website content must be bilingual. Minimally the RD&I Strategy, contact details will be added to the webpage.	✓		Refreshed annually	✓	⚠	⚠	✓	✓	✓						
<b>Increase RD&amp;I Activity</b>																	
Ensure our research efforts are of the highest quality / Embed an RD&I positive culture in WBS	Provision of the Learning Zone, ensuring that it is in line with the RD&I strategy and current and future needs of the Service.	A service provision for users of the Learning Zone, adapting and meeting needs.	✓			✓	✓	✓	✓	✓							

## RD&I - Integrated Performance Report

Organise and co-ordinate our research activity / Obtaining sustainability for RD&I activities	A pipeline of planned RD&I activity across the organisation.	A planned, continuous programme of RD&I projects in each of the four RD&I themes.			Achieved in this document	✓	✓	✓	✓	✓							
Developing our workforce capability/ Embed an RD&I positive culture in WBS	Maintain and promote membership of ISBT, AABB and the BEST-Collaborative	Ongoing membership; Signposting to membership resources, funding opportunities, and learning events.	✓		At least ten	✓	✓	✓	✓	✓	✓						
Organise and co-ordinate our research activity	Adequate planning and resourcing of RD&I Projects before commencement and correct modification to resourcing of RD&I projects.	Projects reporting to green project status (ongoing as planned).			Green status for 70% of projects and 70% of the project with a Time Index of 1	✓	✓	✓	✓	✓	✓						

Build a reputation as a research-active blood service																
Build a reputation as a research-active blood service	Our RD&I findings will be disseminated to the healthcare field through publication and publicity. (Related activity RD&I to fund delegations (which can occur including our external collaborators) to a conference, with an encouragement to contribute to conference proceedings)	A suitable dissemination activity (e.g., conference proceedings/ publication) for every completed WBS-led RD&I project			100% of WBS-led projects need to demonstrate how they have achieved this dissemination activity.	✓	⚠	⚠	✓	✓	✓					
Measuring and defining Progress and Success	WBS's publication output needs to be of high scholarly level as a marker of the work's high quality. When appropriate, the PI of the RD&I project will be asked to seek a peer-reviewed publication to disseminate its findings	# of peer-reviewed publication outputs			80% of completed RD&I projects achieve a peer-reviewed publication	✓	⚠	✓	✓	⚠	✓					

## RD&I - Integrated Performance Report

<b>Build a reputation as a research-active blood service</b>	An RD&I Event with WBS showcasing our work.	Half-day or evening event, possible co-produced with another organisation. Showcasing RD&I	✓		Event due late 2022	✓	✓	✓	✓	✓	✓						
<b>Measuring and defining Progress and Success</b>	We will disseminate our RD&I findings to others.	Number of scholarly publications * (scholarly is a peer-reviewed publication and is to include the publication of conference proceedings)			Maintain current output	✓	✓	✓	✓	✓	✓						
<b>Measuring and defining Progress and Success</b>	A quarterly report is produced and published to promote the achievement of the previous three months and present the current status of the WBS RD&I portfolio	a quarterly report delivered to WBS RD&I Group and elsewhere	✓		Every three months	✓	✓	✓	✓	✓	✓						



## **STRATEGIC PRIORITY 3:**

### **The Trust will implement the Velindre Innovation Plan**

## 11 RITA Virtual Assistant Project

RITA has now been deployed on the trust website VCC page with a soft launch, allowing us to continue to engage with our patients and obtain feedback for the ongoing direction and development of the virtual assistant. This will also enable us to identify any areas where there are glitches or incorrect intent



identification and provide access to evaluation and analytical tools. These tools will provide data on how many users are engaging with RITA, along with useful insights as to the most common questions our services users are asking. We will then use this data to build upon on the work already done and make sure we are continuing to develop RITA with a patient-centric approach.

With RITA launched the innovation team is working in conjunction with Velindre Comms to deploy a communication strategy, raising awareness of the service to our patients and staff. We will be utilising internal comms, social media, and physical media such as flyers and posters around the hospital.

### Welsh language translator

We have created a separate version of RITA that will translate Welsh text into English, search its repository for an answer based on the intent or area of questioning it identifies and then translate this back into Welsh to provide the same service to our Welsh speaking service users. We have tested this with Welsh language colleagues and third-party Welsh speakers, and the feedback has been positive.

However, there is work to be done to make this truly conversational in Welsh by creating a separate Welsh specific version, translating over 1000 original dialogue responses through a translation service. We are currently searching for appropriate funding/grant applications to explore this.

This can be accessed here:

<https://velindre.nhs.wales/about-us/research-development-and-innovation/innovation/rita/rita-cymraeg/>

### Deployment support

With RITA now deployed on the VCC website, the Innovation team will still be involved in improving the system by using the analytics and feedback from the launch to create additional content and features for service users and fixing any issues to performance.

David Mason-Hawes from the Digital Services department has confirmed they will take on the ongoing maintenance and support of RITA once the project has finished. The

innovation project manager will provide training and credentials to Digital Services to enable a smooth transition.

### **Talking Heads Sub-Project**

Talking Heads” is an exciting new project within RITA Chatbot to produce a series of two-minute ‘Talking Head’ videos that will introduce individual Clinical & Healthcare staff and their roles. These videos will then be available as embedded media within the virtual assistant when a patient asks a question relating to that clinical area.

We will also be integrating the videos onto the Trust website.

These clips will allow patients, family, and carers to understand the role of their key workers and clinicians and help ease the anxiety of attending Velindre.

Initial filming took place on 10<sup>th</sup>, 13<sup>th</sup> & 14<sup>th</sup> October where we filmed 38 clinicians. We have a further 1.5 days filming left to cover all clinical departments and disease sites.

## **12 By-Your-Side – Localising Pfizer’s Global Cancer App**

The Patient Solutions Team at Pfizer was looking to improve their cancer ‘By Your Side’ website and mobile app. This is a digital solution that supports patients with cancer in managing their health, wellness and everyday life.

‘This is Living With Cancer (TLWC)’ known as By Your Side (BYS) in the UK is an existing application available for all cancer patients to help their general well-being and daily tasks. TLWC/BYS aims to be a one-stop repository of support for cancer patients, but to be more effective, it could better tailor its content to patient need. The challenge is to localise web and app content to be most useful for each patient using the app. The longer-term aim could be to offer a simple and personalized connector solution to empower cancer patients to live the best lives they can.

The combined Velindre and Pfizer team had a sprint project that they delivered in three months (by July 2022). The project aimed to have piloted a new localisation concept for BYS and evaluate it for consideration of larger programme scaling to geographical areas with other partners. Pfizer’s objective with the new concept is to offer a simple personal experience to patients looking for day-to-day support utilising a digital platform for their health management and ability to connect easily to local specialised support when expert follow-up is needed.

Velindre was the first project in the UK selected by Pfizer and the project was delivered to budget and time. The project was supported by input from healthcare professionals and cancer patients and included:

- A new tailored and fit for purpose contract – led by Rachel Granger
- An agree Project Methodology
- Defined functional requirements
- Four design workshops including patients, carers and Subject Matter Experts (SMEs)
- Incorporated user metrics
- Delivery of Patient and HCP insights and recommendations for scalability

## **Phase 2**

Following the success of this project, Pfizer has approached Velindre to conduct a Phase 2 of BYS localization, with a view to implement the suggestions and feedback given by VCC patients during the initial workshops and make the app available to all our service users.

Discussions are due to take place at the end of the month to provide an overview of the project outcomes and requirements for both Velindre and Pfizer before we proceed with the project.

## **STRATEGIC PRIORITY 4:**

**The Trust will maximise  
collaborative opportunities  
locally, nationally &  
internationally**

## 13 Trust Sponsored Research

Sponsored research is the research where the Velindre University NHS Trust takes the legal responsibility for the design, management and conduct of the research. Sponsored research may be hosted by the Trust and/or hosted by other healthcare organisations and research institutions across the UK, Europe and World-wide. The number of Trust sponsored studies may be relatively small, but the Research & Development team commit a significant amount of resource to ensure that the Trust's sponsor responsibilities are met.

The Trust may delegate some sponsor responsibilities to a clinical trials unit to manage larger research studies hosted by other healthcare organisations and research institutions.

Up to the end of Quarter 2 of Financial Year 2022/23, the Trust sponsored research portfolio is as follows:

Metric Description	Year to date
Number of new sponsored research studies (Total)	0
• Number of sponsored research studies that are Trust-wide	N/A
• Number of sponsored research studies that are UK-wide	N/A
• Number of sponsored research studies that are Europe-wide	N/A
• Number of sponsored research studies that are World-wide	N/A
Number of research sites opened for sponsored research studies	4

Metric Description	Year to date
Number of publications from sponsored research studies	3
• Journal article	1
• Abstracts	2
Number of participants recruited to sponsored research studies	63

## 14 Welsh Blood Service collaborations

The mainstay of the Welsh Blood Services research vision is that we collaborate with others to maximise the quality, outcome and reach of our research efforts.

Being open to collaboration and delivering these collaboratives is achieved through dedicated key performance indicators that we can celebrate here.

The Welsh Blood Service strongly supports the international and UK industry through our collaborative partnerships. Current industrial partnerships include working with the local SME HeamAir, who with the Component Development and Research Laboratory are investigating a novel device around blood safety testing. We work alongside to support several incubation businesses they have spent up from academia.

The WBS's links with academia are extensive, as described in our opening chapter alongside the two recently completed studentships; we continue this with our research collaboration with Cardiff Metropolitan University and the investigation of platelet storage conditions.

We work alongside NHS organisations' clinical delivery and enjoy ongoing support with haematology services in Cardiff and Vale University Health board and the Royal Navy. Our work supports the provision of renal transplant research through our strong links with the nephrology service at Cardiff and Vale University Health board. We currently have ongoing and proposed long-term collaborative projects looking at the frontiers of tissue and organ transplantation.

We continue with international blood services through our membership in various international research consortiums, including the BEST Collaborative, European Blood Alliance Special Interest Groups, Blood transfusion Genomics Consortium and the International HLA Workshop.

Ultimately our collaborations are activity reflected in the WBS RD&I portfolio activity and our vital publication records, which are recorded in the previous chapter and our quarterly update, which is published on the WBS website.

## **CROSS CUTTING THEMES: across Strategic Priorities 1 to 4**



## 15 Cross-cutting themes: progress

Cross-cutting themes across Strategic Priorities 1 to 4.													
Key Deliverables / Objectives	FY2022/23				FY2023/24				FY2024/25				Progress / Comments
	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4	
<ul style="list-style-type: none"> <li>The implementation of programmes, complementing existing training opportunities that enable and support Trust staff to develop, deliver and manage research portfolios</li> </ul>													
<ul style="list-style-type: none"> <li>Complete the review of existing training opportunities (identified in 2021/22) to develop an implementation plan for a complementary programme that enables Trust staff to develop, deliver and manage research portfolios.</li> </ul>			X										<b>Training Programme &amp; Opportunities</b> <ul style="list-style-type: none"> <li>Work continues to identify existing training and develop an implementation plan to ensure the Trust can provide/promote a staff training programme for research &amp; development</li> </ul>
<ul style="list-style-type: none"> <li>Complete the implementation of a programme that enables Trust staff to develop, deliver and manage research portfolios</li> </ul>								X					
<ul style="list-style-type: none"> <li>ongoing review and improvement of the programme that enables Trust staff to develop, deliver and manage research portfolios.</li> </ul>												X	
<ul style="list-style-type: none"> <li>Further investment in the research delivery and governance teams to make sure that studies are optimised to facilitate effective and timely recruitment and delivery</li> </ul>													
<ul style="list-style-type: none"> <li>Continue the development and implementation of staffing plans for the research delivery and governance teams (identified in 2021/22) to facilitate effective and timely recruitment and delivery.</li> </ul>	X												<b>Reorganisation of Trust Research Delivery team</b> <ul style="list-style-type: none"> <li>Work continues on plans to improve/change the administrative structure, roles and responsibilities of the research delivery team is ongoing with support from Trust Workforce &amp; Organisational Development, as appropriate.</li> </ul>
<ul style="list-style-type: none"> <li>Complete the appointment of senior staff in the research delivery team and to support the delivery of the Cardiff Cancer Research Hub</li> </ul>		X											
<ul style="list-style-type: none"> <li>Complete the implementation of changes to the structure of the research delivery team administrative structure.</li> </ul>			X										
<ul style="list-style-type: none"> <li>Keep under review the investment in the research delivery and governance teams supporting research studies, identifying target investment areas as appropriate.</li> </ul>					X	X	X	X	X	X	X	X	

## Cross-cutting themes across Strategic Priorities 1 to 4.

Key Deliverables / Objectives	FY2022/23				FY2023/24				FY2024/25				Progress / Comments
	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4	
<ul style="list-style-type: none"> <li>The development and implementation of clinical information systems to identify donors/patients eligible to take part in research studies</li> </ul>													
<ul style="list-style-type: none"> <li>Complete the R&amp;D contribution to the Trust's implementation of the Digital Health &amp; Care Record in line with the Trust's project schedule.</li> </ul>		X											<b>Delivery of the Digital Health and Care Record system</b> <ul style="list-style-type: none"> <li>The R&amp;D delivery staff continue to support the Trust's Digital Health and Care Record development programme. Although delayed the system is expected to go live in November 2022. Staff continue to contribute to the design of the dataset for the capture of research study data in line with regulatory body and study Sponsor requirements.</li> </ul>
<ul style="list-style-type: none"> <li>Complete a review of clinical information systems available (in conjunction with partner stakeholders, i.e. DHCW and HCRW) to identify research study participants.</li> </ul>				X									
<ul style="list-style-type: none"> <li>Complete the implementation of a clinical information system that identifies donors/patients eligible to take part in research studies.</li> </ul>					X	X	X	X					

CORPORATE

## 16 RD&I Finances

### 16.1 Background / context

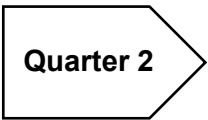

The RD&I Division has a financial ledger comprising all research budgets it directly manages. This comprises a large majority of the Trust's research and innovation income and expenditure and is the subject of this finance report. In addition, some activities managed outside the RD&I Division, e.g., pharmacy and radiotherapy research staff, are reported as part of the relevant Divisional reports.

For 2022/23 the RD&I Divisional Financial Plan has been set at similar levels to the previous year. In summary this is to:

- Secure income of **£3,190k** from multiple sources, most significantly:
  - Health & Care Research Wales (£1,085k)
  - Reimbursements from commercial clinical trials (£733k)
  - Support from the Velindre charity (£846k)
- Spend **£2,805k**, of which £2,683k (£93%) is salary costs, including:
  - Management, trial support, data, and administrative staff (£1,187k)
  - Nursing staff (£1,002k)
  - Medical staff (£380k)
- Manage a further **c. £500k**, held in grant funding from external bodies, such as Cancer Research UK, for specific research trials led by VUNHST.

### 16.2 Summary of Performance against Key Financial Targets: Quarter 2

#### 16.2.1 Key Financial Target 1: to remain within monthly budget expectations

£000					
		PAY	NON-PAY	INCOME	TOTAL
 <b>Quarter 2</b>	Budget	739	47	-725	61
	Actual	675	45	-659	61
	Variance	-64	-2	66	0
 <b>Year to Date</b>	Budget	1,347	70	-1,128	289
	Actual	1,239	77	-1,028	289
	Variance	-108	7	100	0
	Annual Budget	2,683	183	-3,190	-323

<b>Forecast Outturn</b>	Forecast Outturn	2,503	228	-3,054	-323	
	Variance	-180	45	136	0	<i>Forecast Variance</i>

Performance in Quarter 2 was in line with the Budget Plan with £0 overall variance.

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

	Quarter 2	Year to Date	Forecast Outturn
<b>NHS Invoices</b>	86%	83%	95%
<b>Non-NHS Invoices</b>	95%	90%	95%

Performance fell below target in Q1 and improved for Q2. To date, 22 out of 194 invoices missed the target. Several process changes have been made to help improve performance, which is expected to return to target in the remaining quarters.

#### 16.2.3 Analysis of Performance to Date and Forecast Outturn

Performance through the second quarter has been in line with the Budget Plan, with a £0 overall variance being recorded. Within that total figure:

- higher than expected vacancies due to staff turnover has created a £108k underspend.
- in turn, this has allowed the Division to reduce the expectation of funding support from sources such as Innovation and Velindre Charitable Funds.

The forecast outturn for the Division is to achieve the Budget Plan with £0 variance. The primary risks to achieving this outturn are:

- Securing income from participating in commercial and other fee-paying trials (Budget = £750k). Quarter 1& 2 were both on target to achieve this budget, however the timing and value of trial income is difficult to predict with certainty and therefore a risk remains that income will slow in the second half of the year.
- Attracting income streams to support Innovation (Budget = £170k). A “self-funding” target was instigated for 2022/23 to secure income from various sources to cover Innovation Team costs. A temporary vacancy in the Head of Innovation role means only a proportion of this income will be achieved, although the vacancy itself results in some offsetting underspend. Wider underspends from vacancies in other teams are expected to offset much of the remaining sum.

## 16.2.4 Pay Analysis by Staff Group

PAY GROUP	Cumulative Q2		
	£108k less than budget		
	YTD	YTD	YTD
	Budget (£'000)	Actual (£'000)	Variance (£'000)
Professional Scientific & Technical	0	0	0
Additional Clinical Services	41	38	-3
Administrative & Clerical	598	516	-82
Allied Health Professionals	26	26	0
Healthcare Scientists	84	84	0
Medical	189	180	-9
Nursing	469	396	-74
Vacancy Factor	-61	0	61
<b>Total</b>	<b>1,347</b>	<b>1,239</b>	<b>-108</b>

Pay underspends are the result of temporary vacancies arising across several areas. These are more than the estimated “Vacancy Factor” planned. They are due to a mixture of staff turnover, internal secondments of staff moving to VCC temporarily, as well as from longer than usual vacancy periods due to the current challenges of recruiting suitable staff into the roles. This trend is forecast to continue, albeit at a reduced rate due to recruitment activities.

## 16.2.5 Non-Pay Analysis by Category

NON-PAY CATEGORY	Cumulative Q2		
	£7k more than budget		
	YTD	YTD	YTD
	Budget (£'000)	Actual (£'000)	Variance (£'000)
Clinical/General Services/Supplies	50	36	-14
Maintenance & Repairs	0	0	0
Transport (inc. patients)	0	4	4
Printing / Stationary / Postage	0	3	3
Travel & Subsistence	0	3	3
Education & Development	0	8	8
Equipment & Consumables	0	3	3
Computer Maintenance & Supplies	19	19	0
<b>Total</b>	<b>70</b>	<b>77</b>	<b>7</b>

The Division holds modest non-pay budgets. At Quarter 2 a small overspend is due to budget timing and does not reflect an underlying trend. An overspend is forecast at the year end, however this will be matched with project income, with no overall impact.

## 16.2.6 Income Analysis by Category

INCOME CATEGORY	Cumulative Q2		
	£100k less than budget		
	YTD	YTD	YTD
	Budget (£'000)	Actual (£'000)	Variance (£'000)
<b>HCRW Income</b>	-263	-263	<b>0</b>
<b>Trial Reimbursements</b>	-338	-338	<b>0</b>
<b>Charitable Income - Infrastructure</b>	-211	-183	<b>27</b>
<b>Innovation Income</b>	-71	-17	<b>54</b>
<b>Other Income</b>	-245	-227	<b>19</b>
<b>Total</b>	<b>-1,128</b>	<b>-1,028</b>	<b>100</b>

Income recovery has proceeded to plan in Quarter 2 except for Innovation income, which has not reached its target due, in part, to the temporary vacancy with the Head of Department position. Other variances reflect deliberate reductions, e.g., in charity funding, to match reduced expenditure due mainly to vacancies. These trends are expected to continue for the second half of the year.