Public Research, Development & Innovation Sub-Committee

Thu 20 July 2023, 10:00 - 12:00

Trust Headquarters, 2 Charnwood Court, Parc Nantgarw, Cardiff

Agenda

10:00 - 10:20
20 min

1. PRESENTATION

1.1. PROD Study

Led by Felicity May, Clinical Scientist, Welsh Blood Service

1.1 PROD Study.pdf (26 pages)

1.2. Measuring the Immune Response after Kidney Transplantation

Led by Deborah Pritchard, Welsh Transplantation and Immunogenetics Lab Manager, Welsh Blood Service

1.2 Immune Response after Kidney Transplantation.pdf (11 pages)

10:20 - 10:25
5 min

2. STANDARD BUSINESS

2.1. Apologies

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

- ***Dr Eve Evans, Clinical Director, Velindre Cancer Services***
- ***Steve Ham, Chief Executive***
- ***Professor Donna Mead, Trust Chair***

2.2. In Attendance

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

- ***Felicity May, Clinical Scientist, Welsh Blood Service (Item 1.1)***
- ***Deborah Pritchard, Welsh Transplantation and Immunogenetics Lab Manager, Welsh Blood Service (Item 1.2)***
- ***Christopher Cotterill-Jones, Research Delivery Manager (Item 4.1)***
- ***Dr James Powell, Consultant Clinical Oncologist (Item 4.2)***
- ***Libby Crumpton, Advancing Radiotherapy Fund Manager (Item 5.3.2)***
- ***Kate Cleary, Velindre Futures Cancer R&D Strategy Project Manager (Observer)***
- ***Debbie Harvey, Life Sciences Hub Cardiff (Observer)***

2.3. Declarations of Interest

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

2.4. Minutes from the Public Research, Development & Innovation Committee held on the 28th February 2023

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

2.4 Public RDI Minutes 28.02.23 (Draft).pdf (13 pages)

2.5. Action Log

Led by Dr Jacinta Abraham, Executive Medical Director & R&D Lead

2.5 Public RDI Action Log 28.02.23.pdf (1 pages)

2.6. Matters Arising

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

10:25 - 10:40
15 min

3. MAIN AGENDA

3.1. Executive Medical Director Briefing

Led by Dr Jacinta Abraham, Executive Medical Director & R&D Lead

3.1a Executive Briefing Cover Report.pdf (8 pages)
3.1b Executive Briefing.pdf (7 pages)

3.2. TRUST Research, Development & Innovation Sub-Committee Risk Register Extract

Led by Sarah Townsend, Head of Research & Development

There are no open risks on Datix for escalation to the Research Development & Innovation Sub-Committee in line with the Trust Board Risk Appetite

10:40 - 11:40
60 min

4. STRATEGY, PERFORMANCE AND DELIVERY

4.1. TRUST Research, Development & Innovation Performance Report

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

- ***Christopher Cotterill-Jones, Research Delivery Manager***
- ***Libby Batt, Velindre Futures Cancer R&D Strategy Lead***
- ***Peter Richardson, Head of Quality & Assurance, Welsh Blood Service & Dr Sian James, R&D Facilitation Lead, Welsh Blood Service***

4.1a RDI Performance Report FY2022-23 Cover Report.pdf (3 pages)
4.1b RDI Performance Report FY2022-23.pdf (108 pages)

4.2. Option appraisal for the research bunker in nVCC - Update

Oral Update by Dr James Powell, Consultant Clinical Oncologist

4.3. Welsh Blood Service Research, Development & Innovation Strategy Project Update

Led by Dr Sian James, R&D Facilitation Lead, Welsh Blood Service

4.3 WBS RDI Project Board Update.pdf (16 pages)

11:40 - 11:45
5 min

5. CONSENT AGENDA

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.

5.1. Consent - For Approval

There are currently no items for approval.

5.2. Consent - For Endorsement

There are currently no items for endorsement.

5.3. Consent - For Noting

5.3.1. Draft Summary of the Minutes from the Private Research, Development & Innovation Committee held on the 28th February 2023

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

5.3.1 Private Summary RDI Minutes 28.02.2023.pdf (5 pages)

5.3.2. Advancing Radiotherapy Fund (ARF) Highlight Report

Led by Libby Crumpton, Advancing Radiotherapy Fund Manager

5.3.2 ARF Highlight Report.pdf (4 pages)

11:45 - 11:50
5 min

6. ANY OTHER BUSINESS

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

Announcement from NIHR: Researchers in Scotland, Wales and Northern Ireland to access further NIHR research funding.

6.0 NIHR Announcement.pdf (1 pages)

11:50 - 11:55
5 min

7. HIGHLIGHT REPORT

Members to identify items to include in the Highlight Report:

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

11:55 - 12:00
5 min

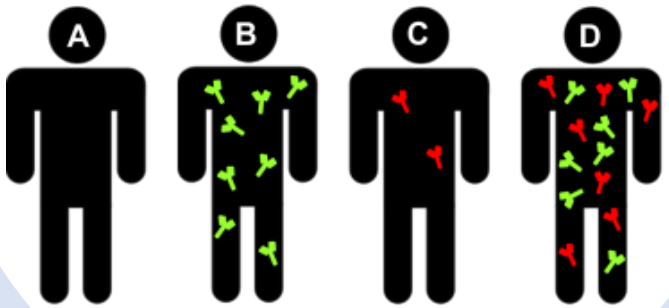
8. DATE AND TIME OF THE NEXT MEETING

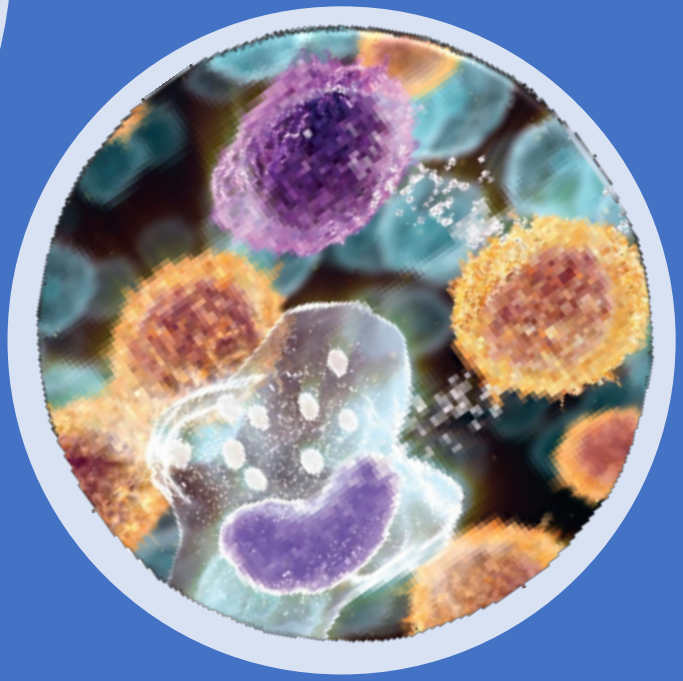
The Public Research, Development & Innovation Sub-Committee will next meet on the 19th September 2023 from 10:00-12.00pm at Trust Headquarters, Nantgarw.

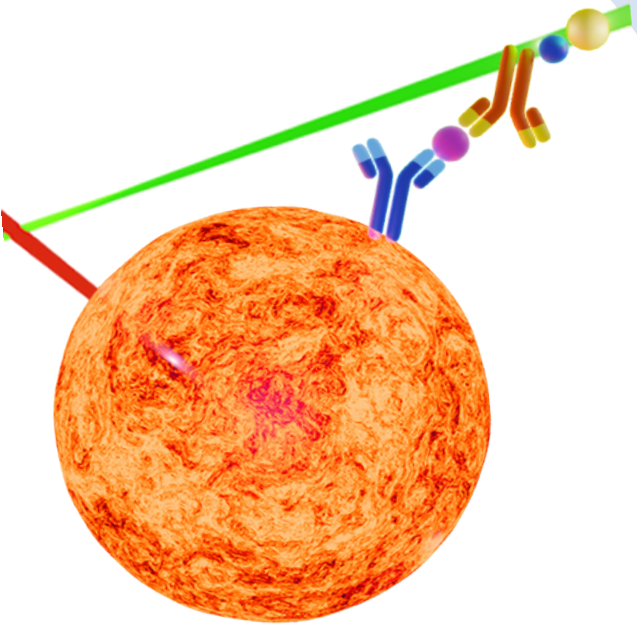
12:00 - 12:00
0 min

9. CLOSE

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







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

Felicity May – Clinical Scientist, WBS

Presentation Overview

Introduction

- Research context

Chapter 1 – Literature Review

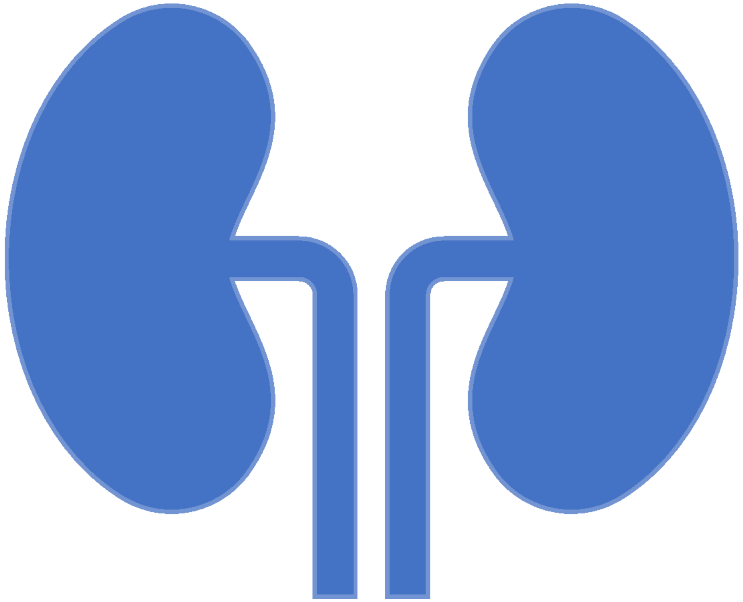
- Aims & Objectives

Chapter 2 - Methodology

Chapter 3 – Patient Analysis

Chapter 4 – Biomarker Analysis

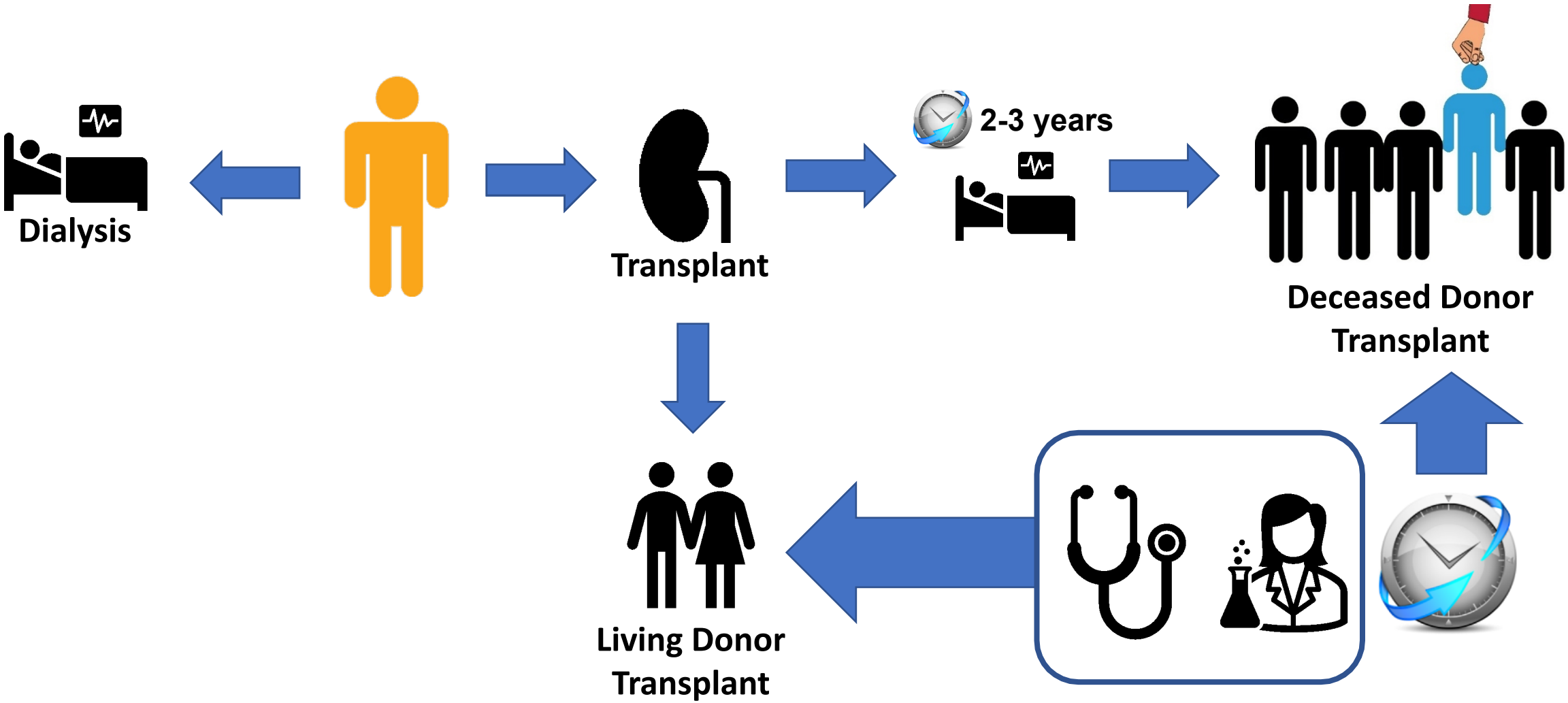
Chapter 5 - Discussion



Research Context

Introduction

Renal Replacement for ESRD



HLA and Transplantation

Normal role of HLA

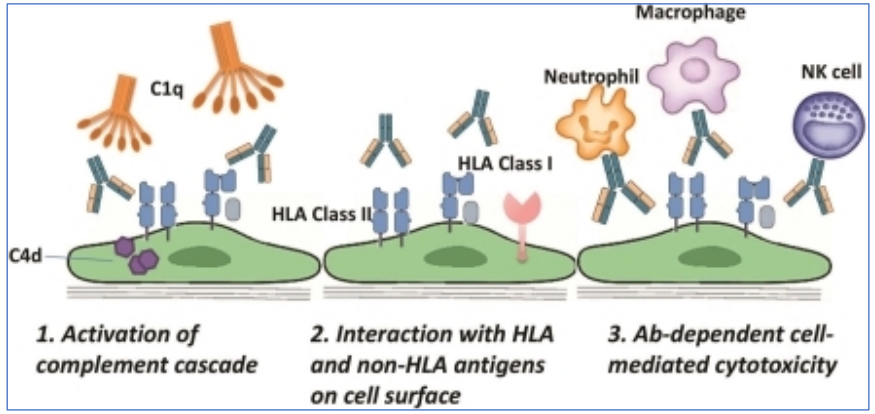
- MHC antigens expressed on cell surface
- Highly polymorphic (>30,000 variants!)
- Immunity - distinguish 'self' from 'non self' (e.g., infection)

Transplant Rejection

- Patient's immune system recognises HLA on the donor cells as 'non self'
- Cellular/antibody response to attack graft

HLA Sensitisation

- Prior exposure to non-self HLA increases risk
- Pregnancy, transfusion or previous transplant
- Circulating HLA antibodies = measure of immunological risk
  - ➢High level DSA → risk of hyperacute rejection (HAR) → veto
  - ➢Med- Low level DSA → risk of rejection episodes → advise



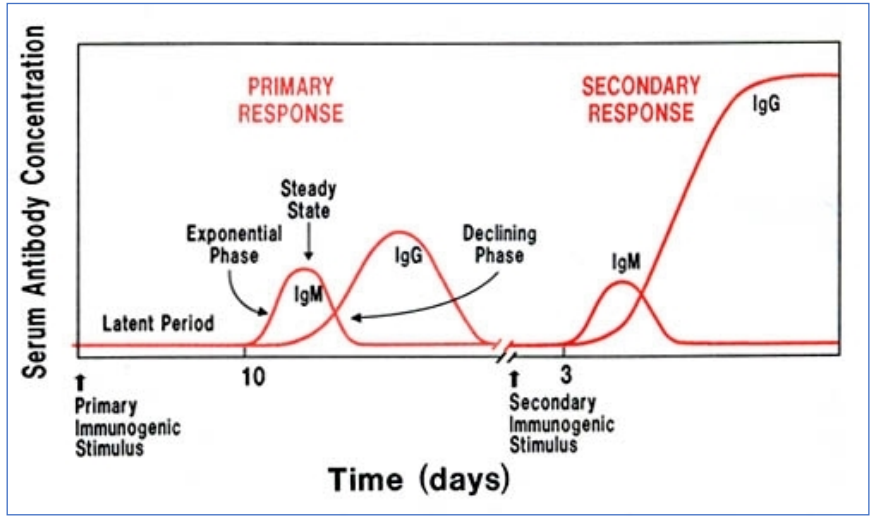


Image source: Wang et al. 2019

Inequity of Access

- Priority on national waiting list (2019 KOS)
- UK Living Kidney Sharing Scheme (UKLKSS)
- HLA Incompatible Transplantation

Understanding Immunological Response to Desensitisation Strategies in Highly Sensitised Potential Kidney Transplant Patients

Transplant Reviews 2021; 35(2):100596. doi: 10.1016/j.trre.2021.100596.

Literature Review

Chapter 1

Variation in HLAi Transplant Outcome

‘Desensitisation’

-> Reduce antibody levels

->Improve access to transplantation

->Minimise risk of AMR

Known variation in outcome

-> Antibody response

-> Early/late rejection

-> Graft survival

Gaps in understanding:

-> Why response varies

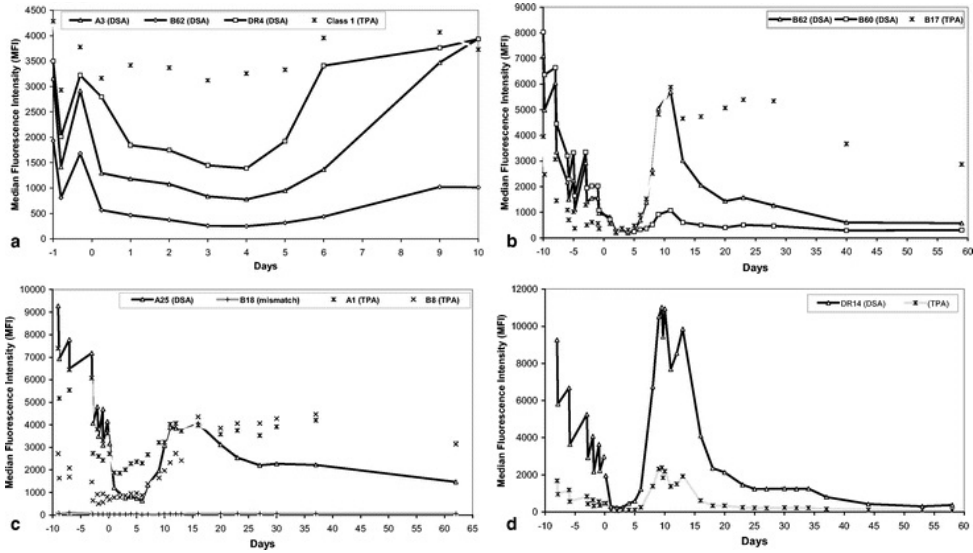
-> Effects/mechanism of treatment

-> No established “optimal” protocol

How would predicting outcome help?

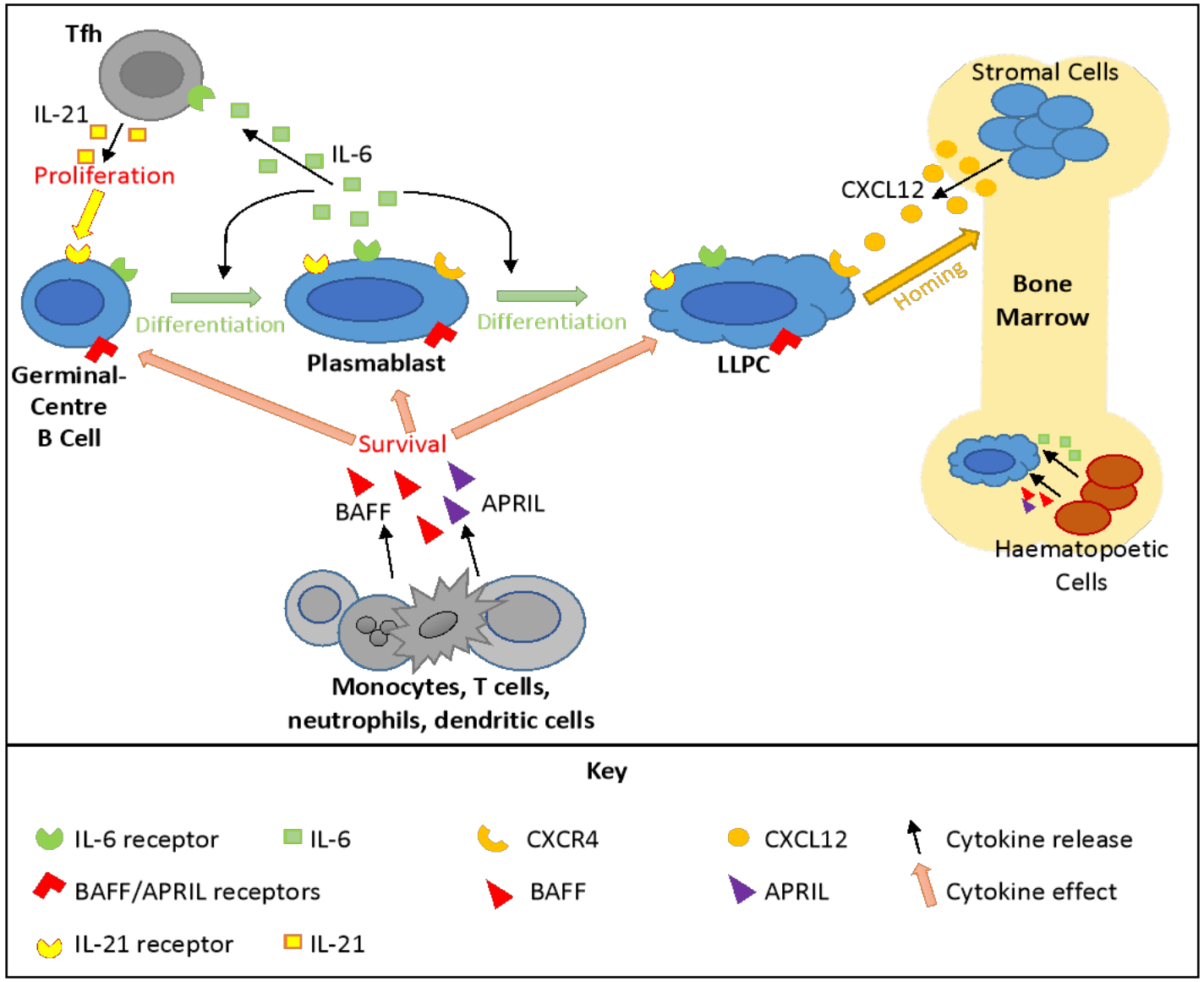
-> Avoid use of ineffective treatment
- unnecessary risks/side effects
- wasted money/resource

-> Inform alternative treatments



Ko et al. Transplant International 2017; 30: 1215–1225

Long-Lived Plasma Cells



Long-lived plasma cells (LLPCs)

- Main source of HLA antibodies in HSPs
- Reside in the bone marrow
- Secrete antibodies for up to a lifetime
- May evade desensitisation

Cytokines, chemokines & immune factors

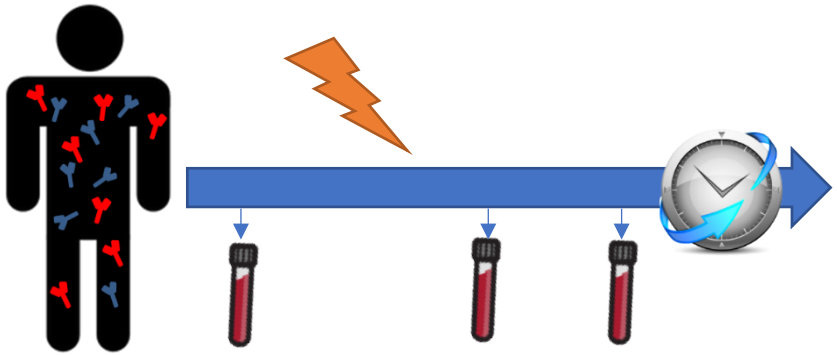
- Support generation, survival and homing of LLPCs
- Relatively understudied in transplant recipients
- Elevated levels of sCD30, BAFF and IL-6 associated with risk of AMR

(Banham et al., 2013, Jordan et al., 2017; Schaefer et al., 2016, Thaunat et al., 2008; Wilson et al., 2016).

Research Aims and Objectives

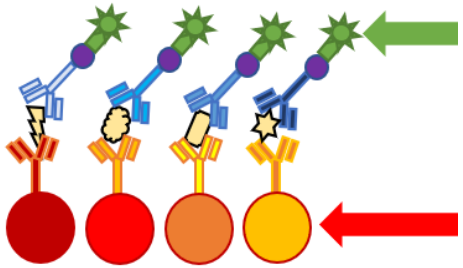
Aim

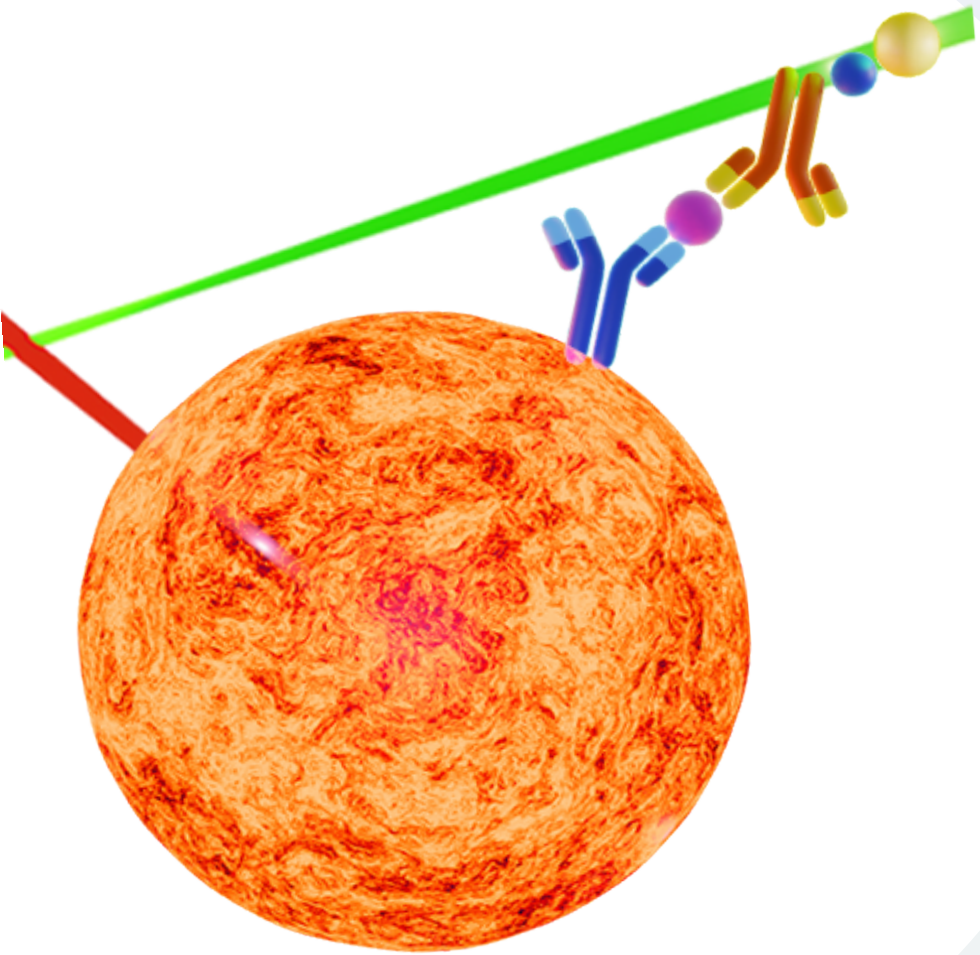
Characterise immunological factors involved in **plasma cell generation, homing, and survival** in desensitised patients.



Objectives

- ❑ Design a Luminex Multiplex panel to quantify analytes of interest.
- ❑ Source longitudinal serum samples from patients who have been desensitised and transplanted
- ❑ Identify effects of treatment on the immunological factors.
- ❑ Determine if a profile at baseline can predict outcome





Selection of potentially informative biomarkers of immunological memory response in renal transplantation.

Methodology

Chapter 2

Study Design

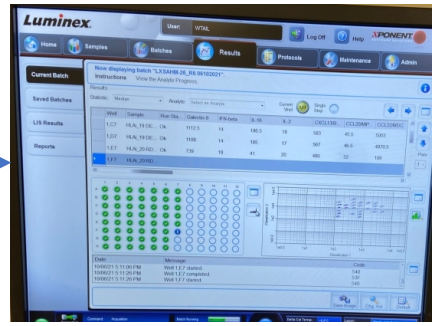
459
Analytes

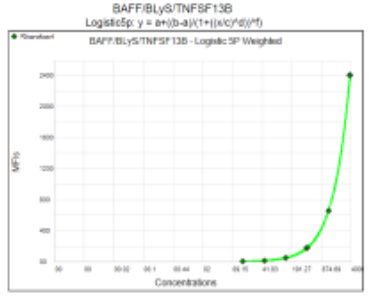
58 Analytes

R&D SYSTEMS

ITOPS

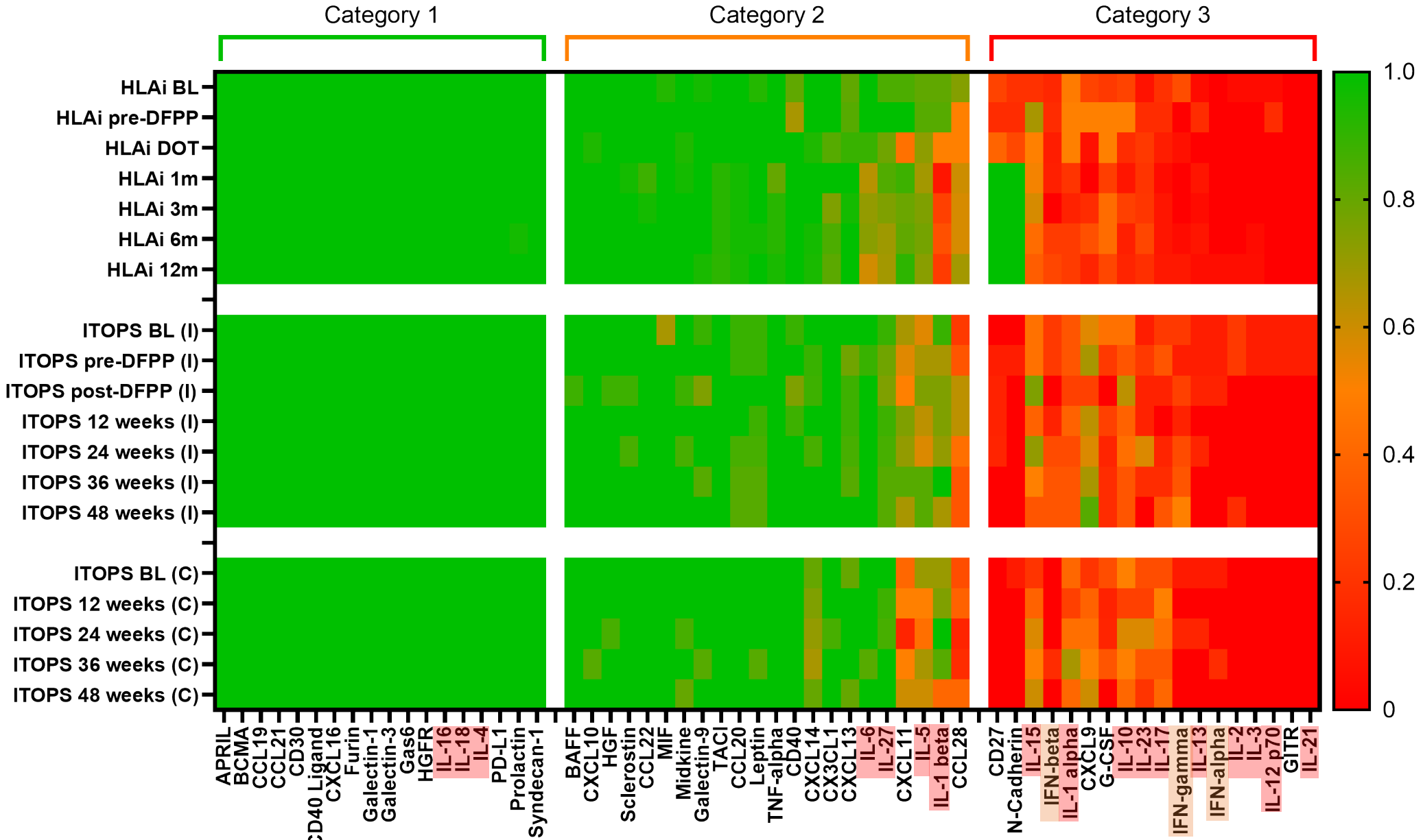
HLAi

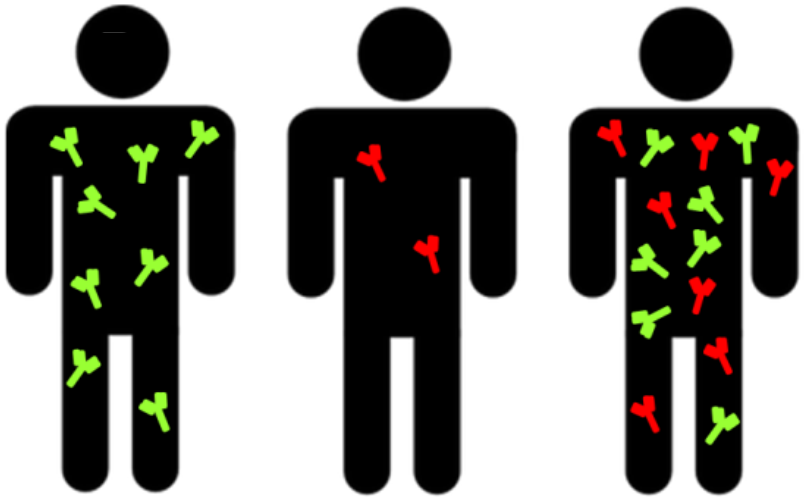




237 samples (x2)
58 markers
= 27,492 results
Results for all samples
No run failures

Assay Performance





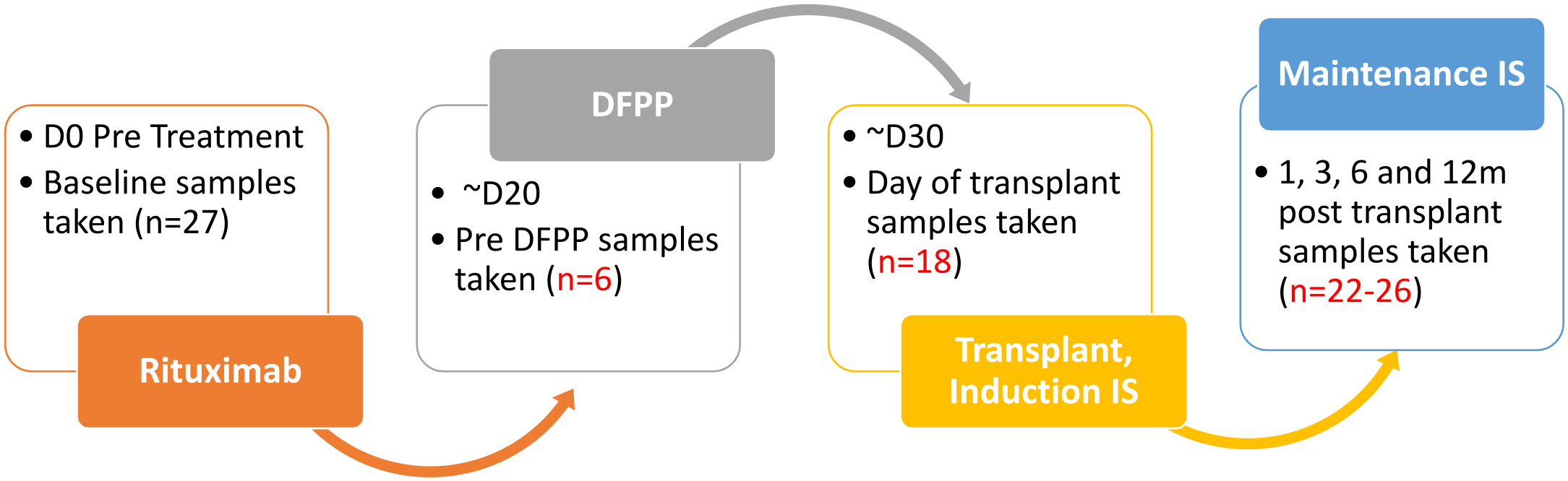
Patient Factors Associated with Clinical Outcome following HLA-incompatible living kidney transplantation: a single centre study of 27 incompatible transplants.

Patient Factors

Chapter 3

HLAi Patient Cohort

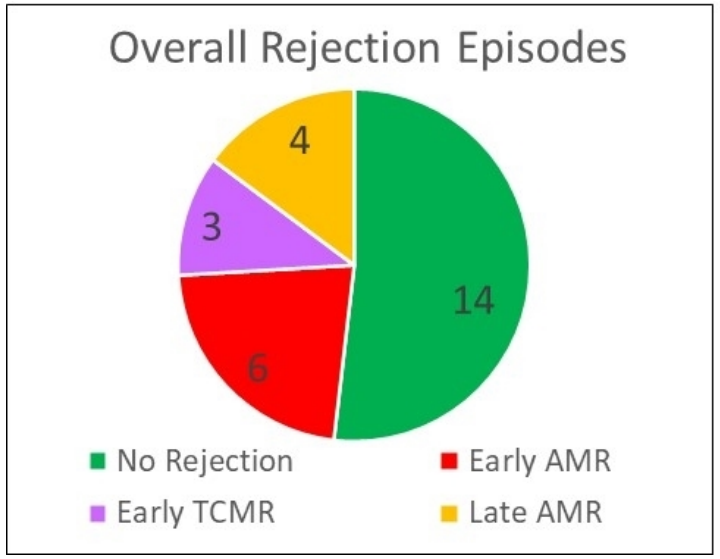
- n=27 patients transplanted with HLA incompatible living kidney donors in UHW 2008 – 2016
- Overall follow-up: 5.2-13.2 years
- All received pre-transplant desensitisation (single dose of rituximab followed by cycles of DFPP)
- Routine serum samples collected for HLA antibody testing – stored in WTAIL (-80°C)
- Samples missing from archive



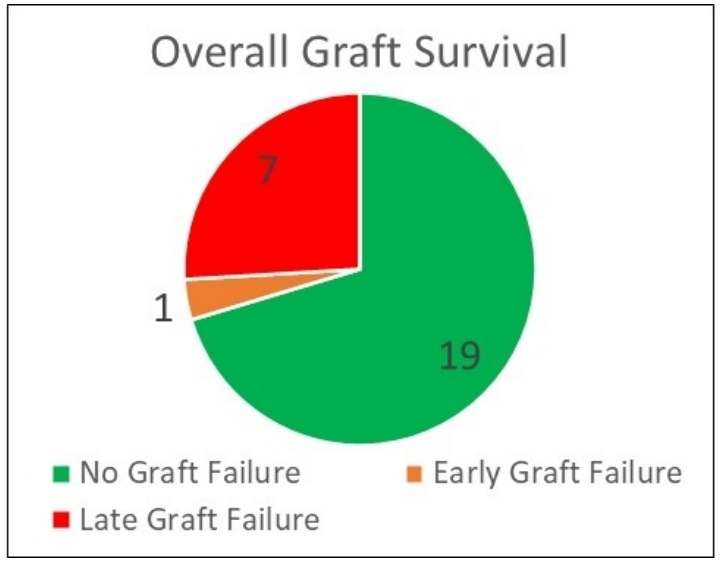
The timing of induction varied, depending on the agent used: alemtuzumab was administered on the day of transplant; basiliximab was administered in two doses (one on the day of transplant, the second at 4-days post-transplant); rATG was administered daily for 5-days from the day of transplant.

Transplant Outcome

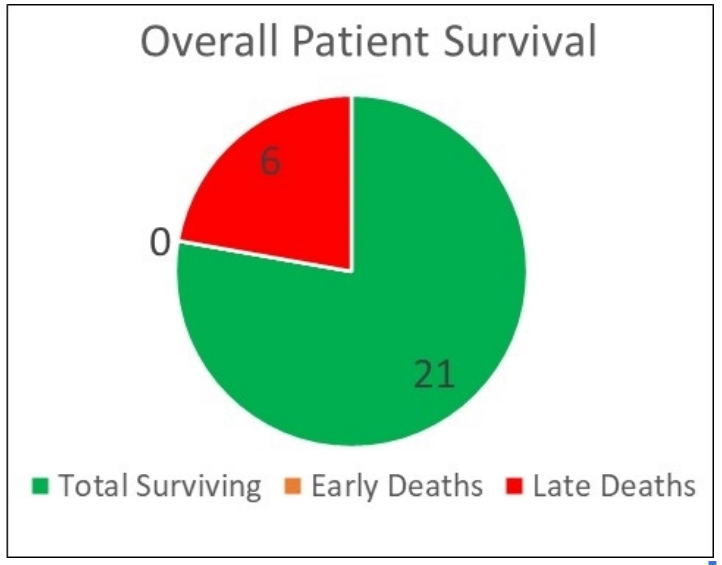
51.9% Rejection-Free Survival

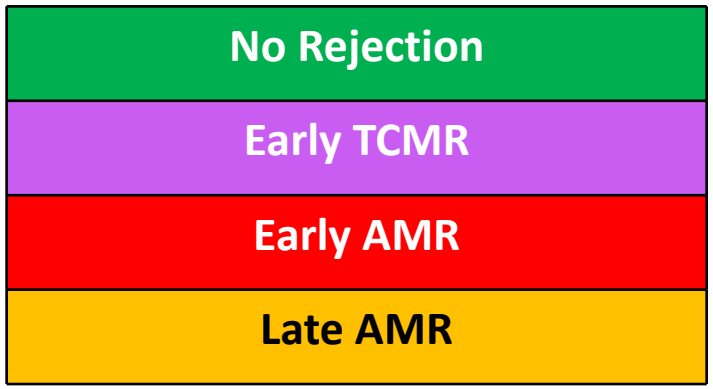


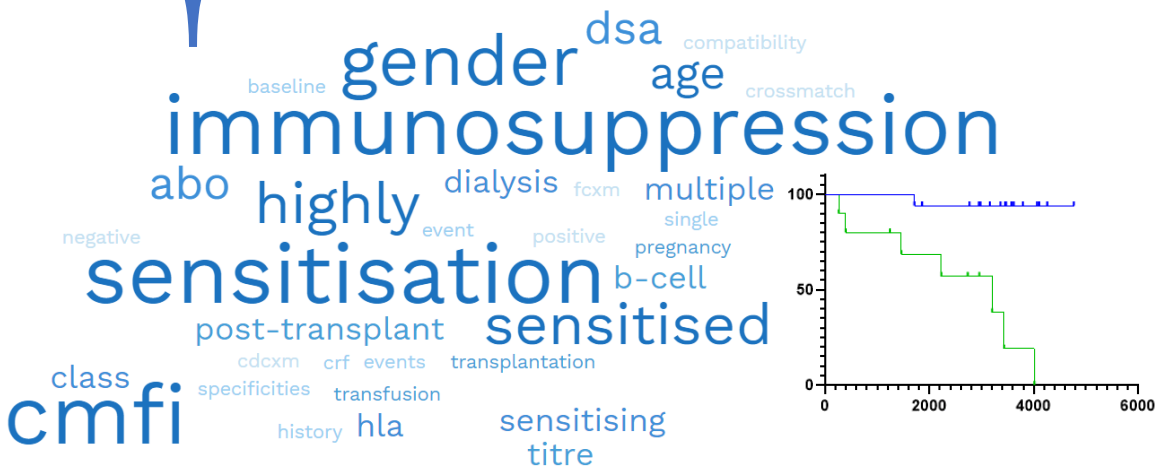
70.4% Graft Survival



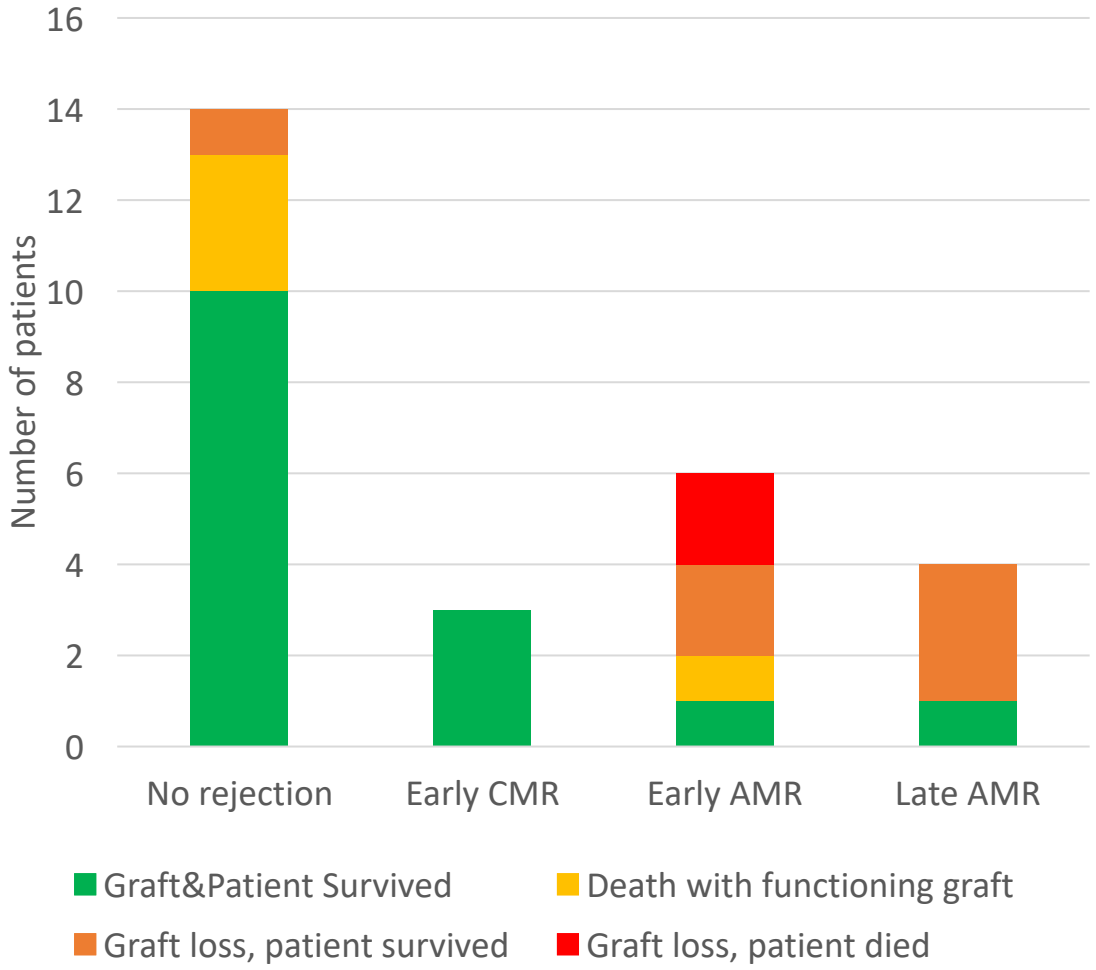
77.8% Patient Survival

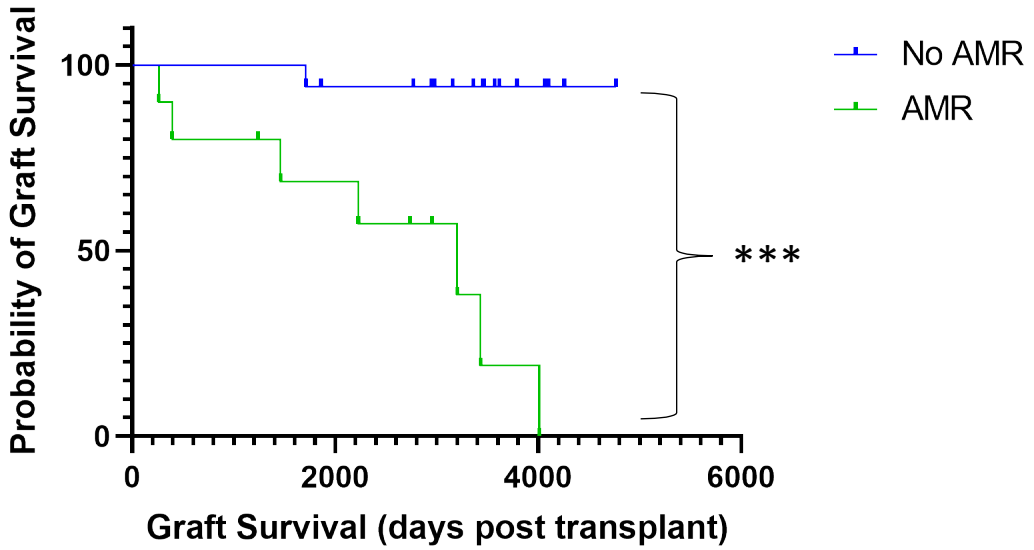


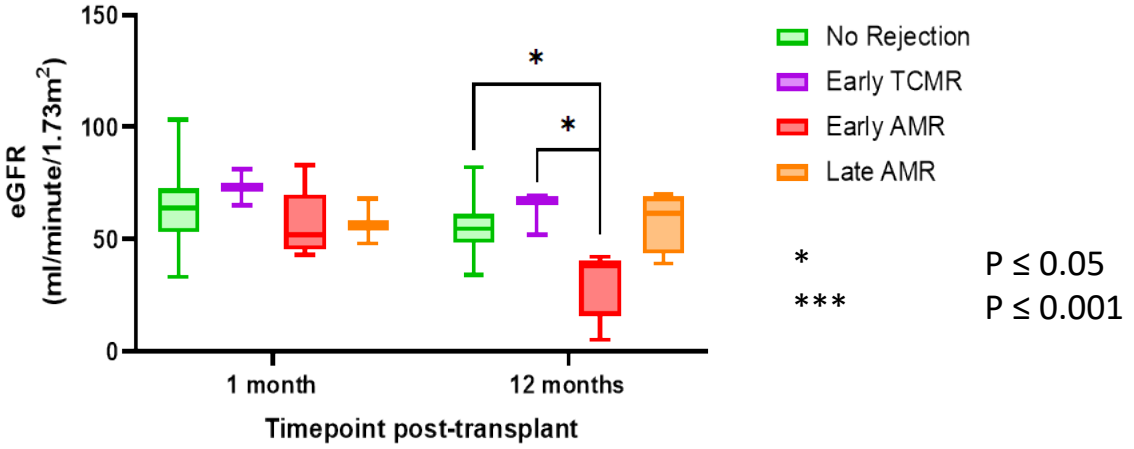




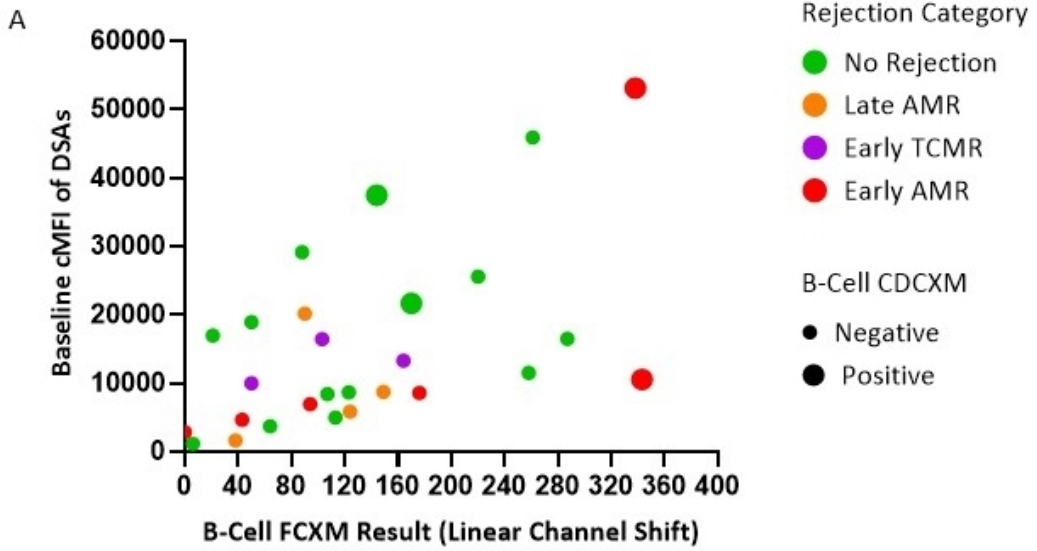
AMR associated with poor graft survival and function

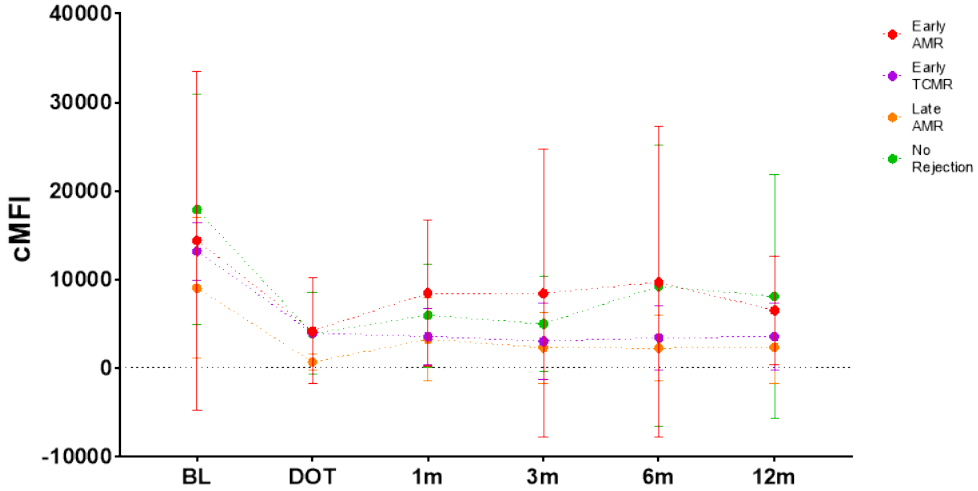


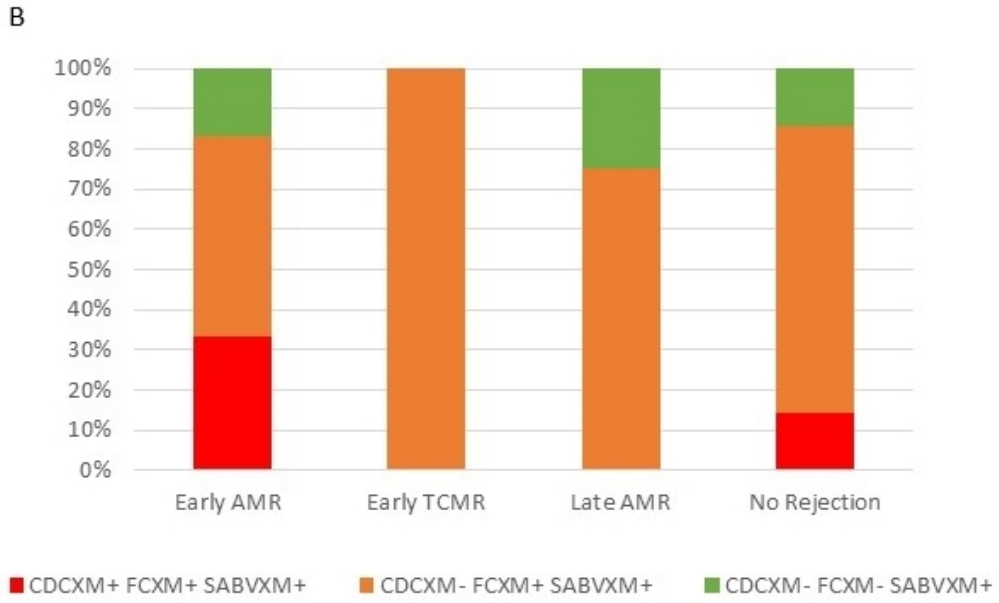


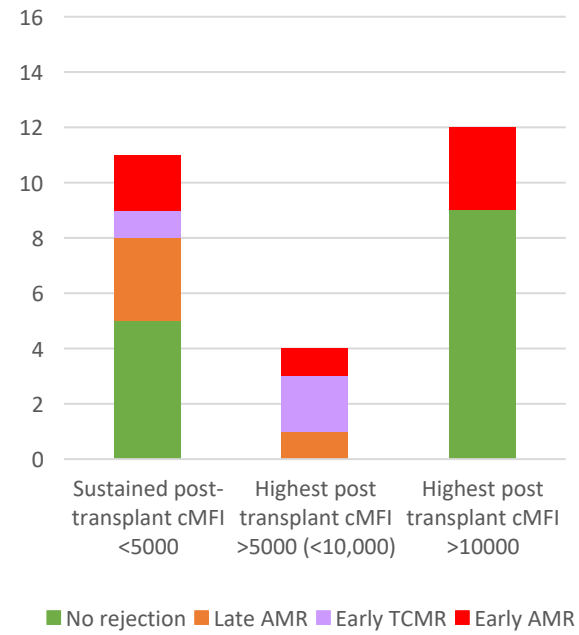


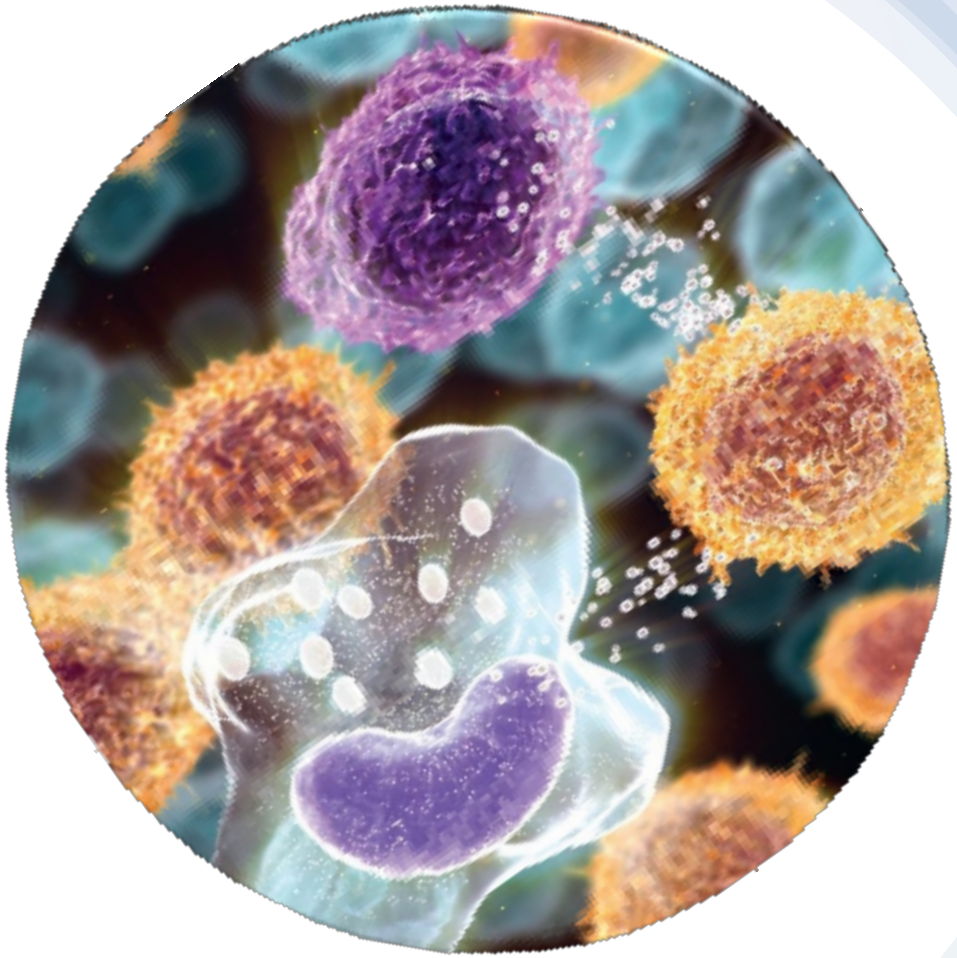
DSA is a poor predictor of outcome









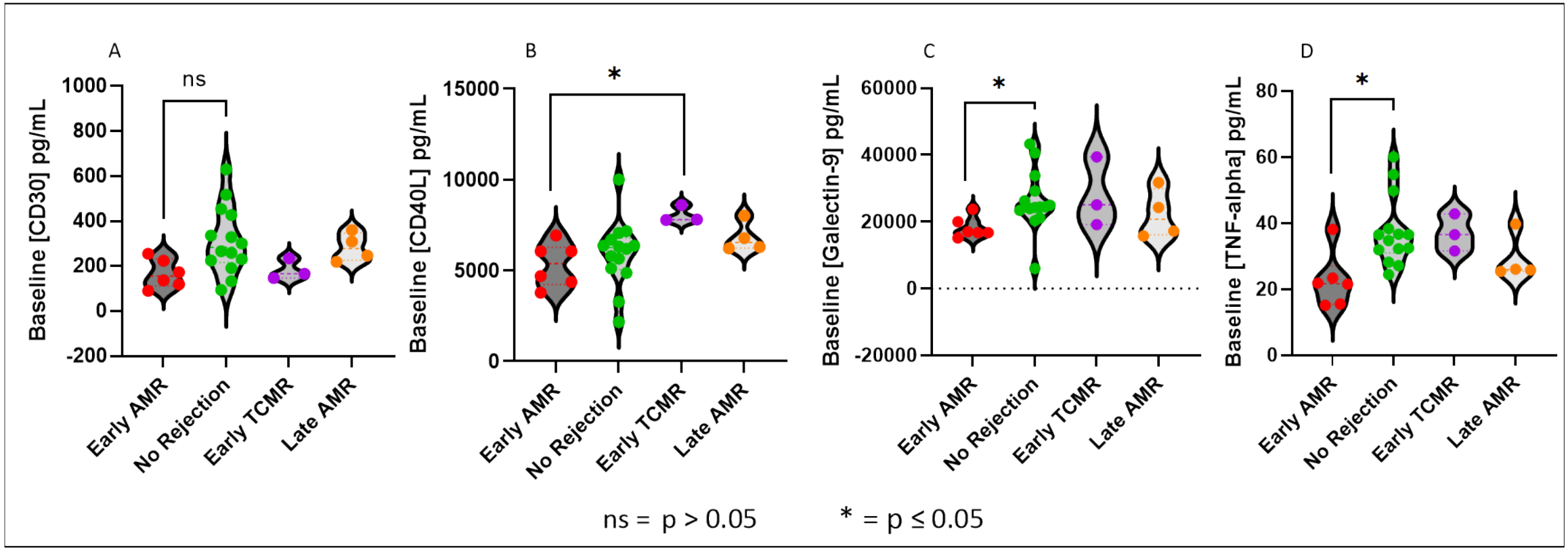


Immune profiles associated with Response to Desensitisation and Clinical Outcome following HLA Incompatible Transplantation

Immune Factors

Chapter 4

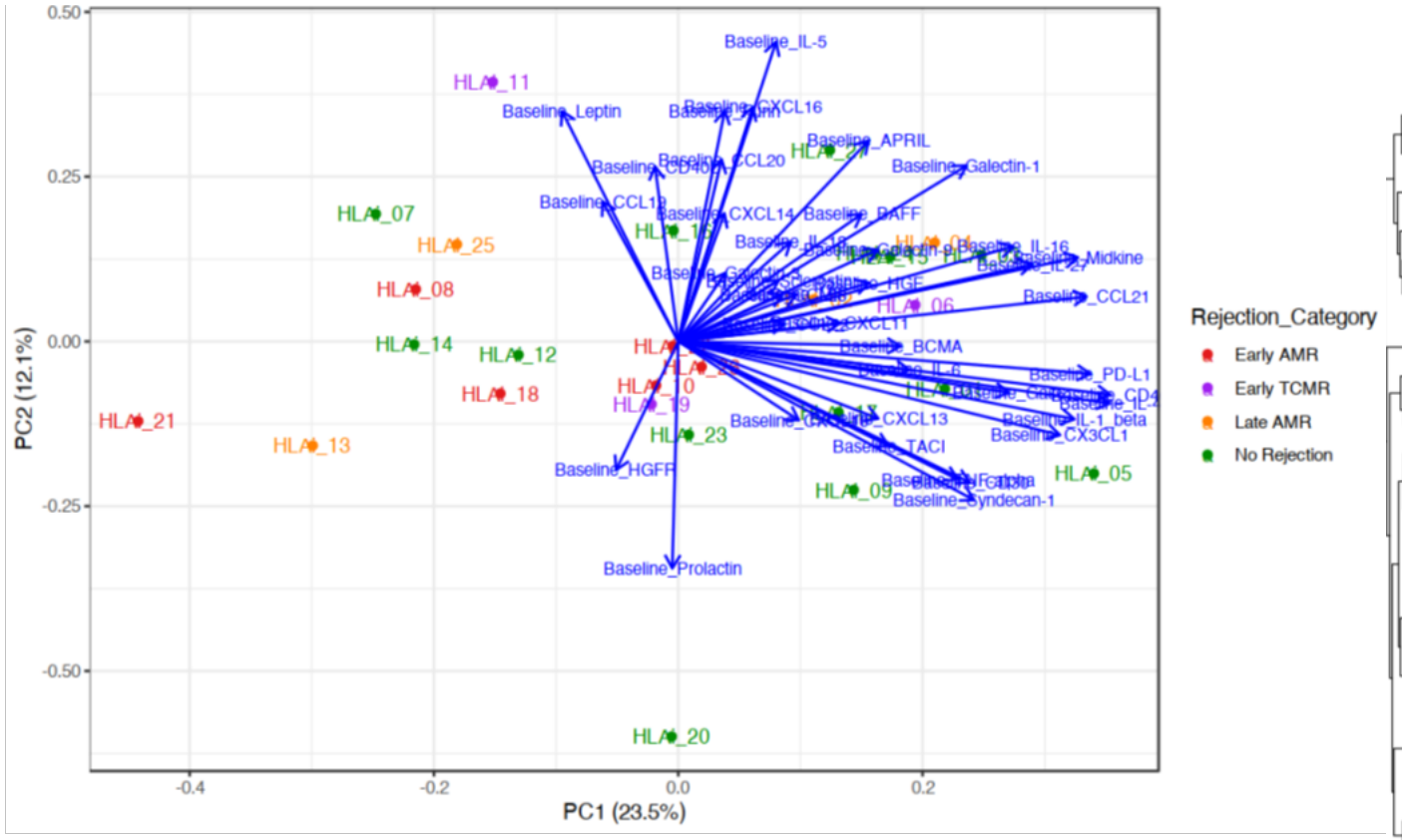
Baseline – Predictive Profile? – Univariate

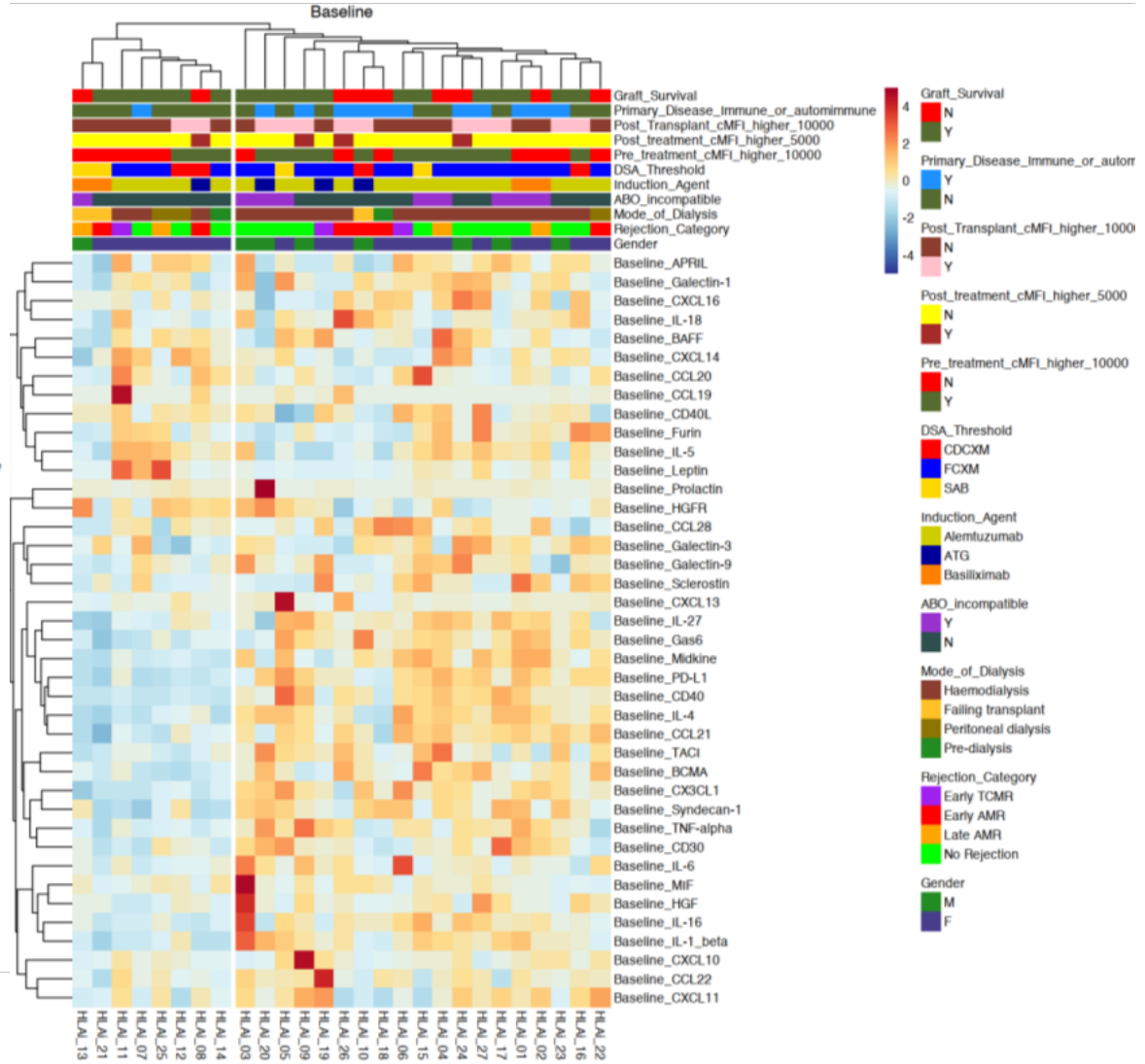


Earlier AMR patients had significantly lower levels of:

- CD30 → marker of T/B-cell activation
- CD40 ligand → proinflammatory B-cell activator
- Galectin-9 → suppressor of T/B-cell responses
- TNF-alpha → proinflammatory B-cell growth factor

Baseline – Predictive Profile? – Multivariate



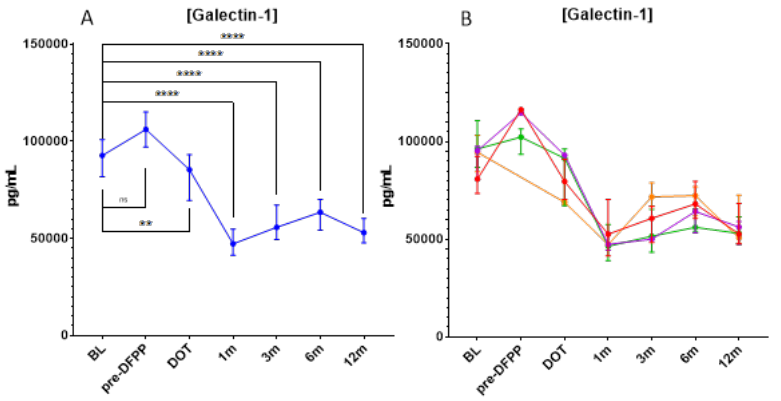


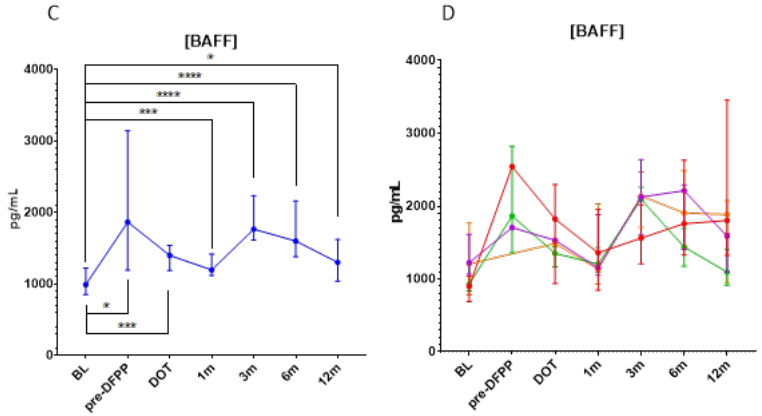
Longitudinal Effects

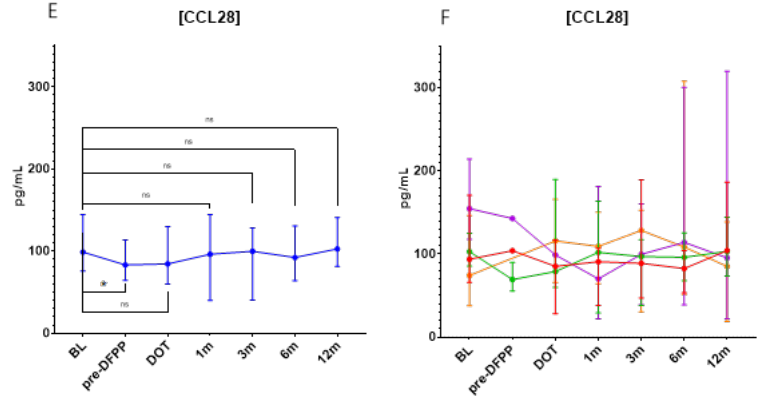
Reduction
n=22, 55.0%

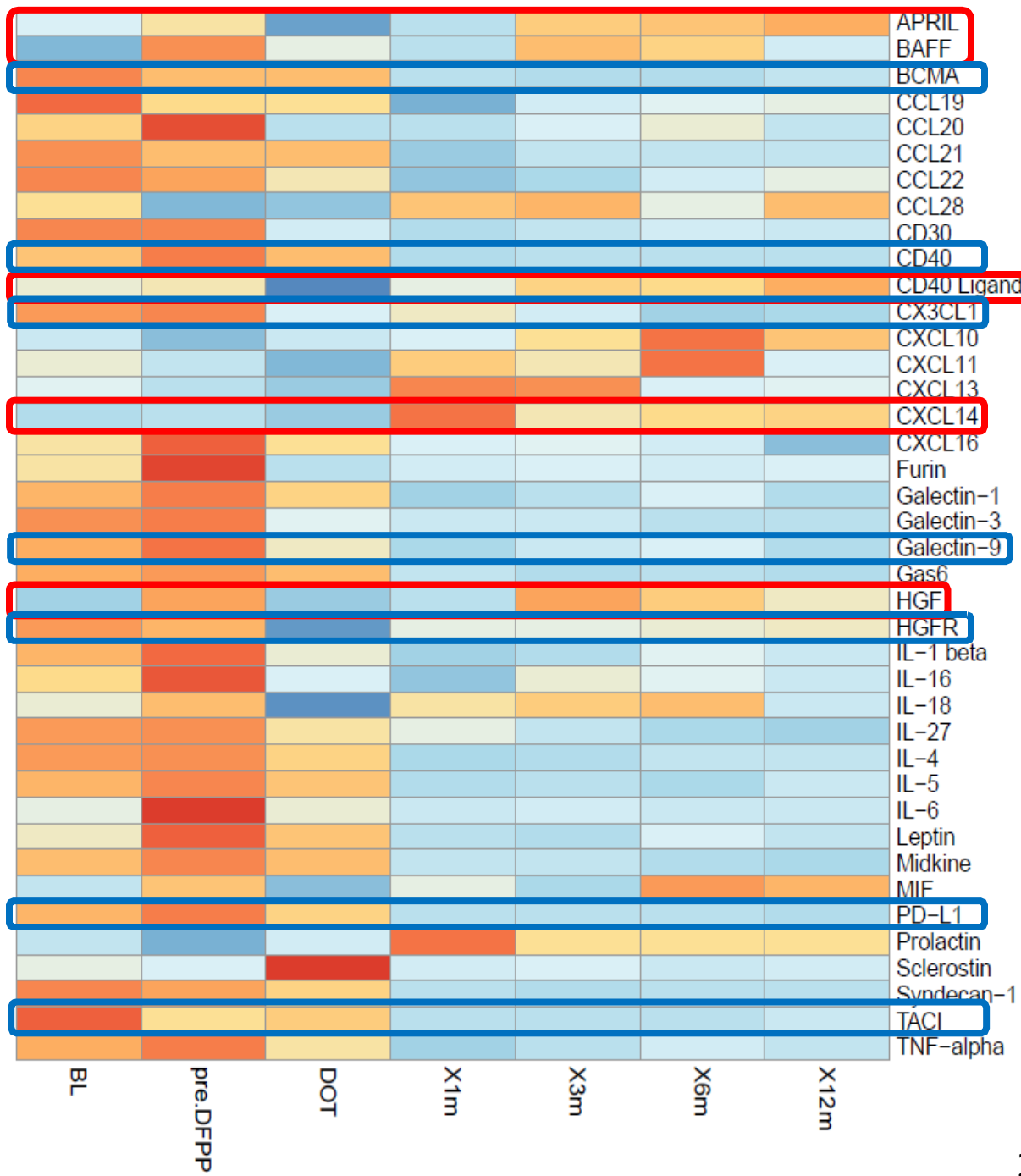
Increase
n=5, 12.5%

No sig difference
n= 13, 32.5%









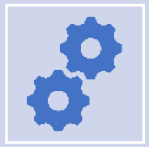
Discussion

Chapter 5

Critical Evaluation

Selection of samples and patient population

- Small sample size, multiple samples/timepoints missing
- Use of sera, collected under non-standardised conditions
- lack of control group
- lack of standardisation in treatment protocols
- Subjective diagnosis of rejection



Panel Design

- Laborious analyte selection process
- Selection based on individual merit rather than networks
- Independent validation of results
- Waste - multiple analytes <LLOD

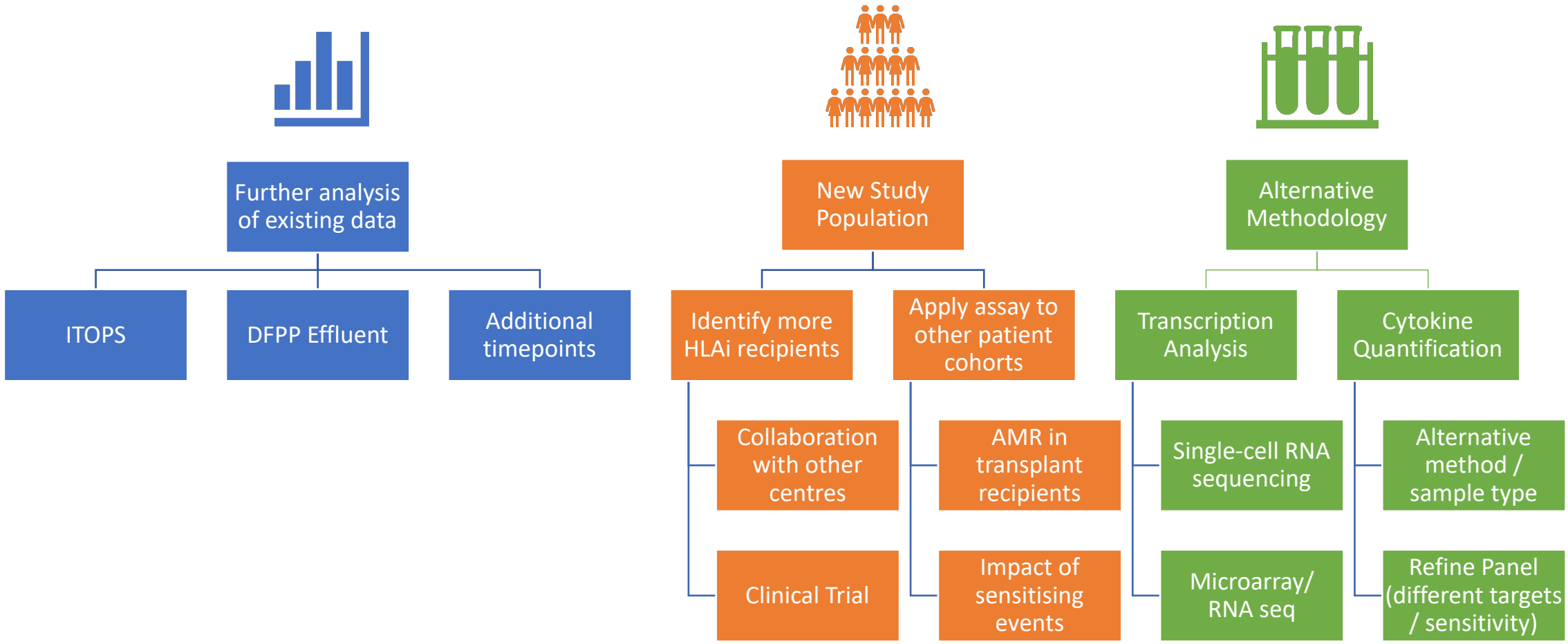
Peripheral cytokine measurement

- Analyte variations - stability/half-life, low peripheral concentration
- Assay variations - storage, freeze thaw, temperatures, timings
- Patient variables – treatment, physiology etc.

Conclusions

- Much to be understood to inform selection of treatment
- No predictive biomarkers identified in this study.
- Desensitisation and transplantation profoundly alters immune signals
- Unintended effects = upregulation of pro-survival signals

Future Work


Further analysis of existing data
ITOPS
DFPP Effluent
Additional timepoints
New Study Population
Identify more HLAi recipients
Apply assay to other patient cohorts
Collaboration with other centres
Clinical Trial
AMR in transplant recipients
Impact of sensitising events
Alternative Methodology
Transcription Analysis
Cytokine Quantification
Single-cell RNA sequencing
Microarray/ RNA seq
Alternative method / sample type
Refine Panel (different targets / sensitivity)

Thank You!

Acknowledgements

Patients

Dr Siân Griffin - Consultant Nephrologist (C&V)

Dr Madhvi Menon – Academic Supervisor (UoM)

Prof Tracy Hussell - Academic Co-Supervisor (UoM)

Syed Murtuza Baker – Biostatistician (UoM)

Chantal Colmont - CU Wales Kidney Research Unit

Dr Tracey Rees – Workplace Supervisor

Dr Siân James – WBS RD&I

Welsh Transplantation and Immunogenetics Laboratory

Support from VUNHST, C&V and WBS SMT

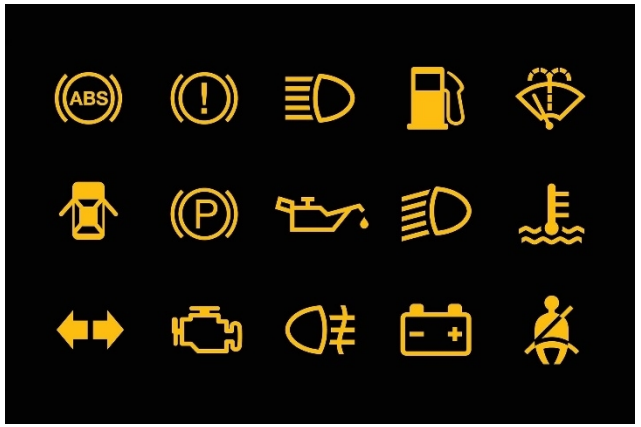
Measuring The Immune Response After Kidney Transplantation

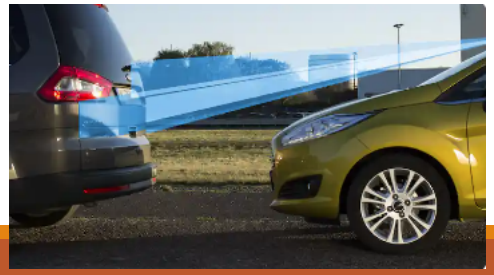
DEBORAH PRITCHARD
CLINICAL SCIENTIST

WELSH TRANSPLANT LABORATORY
LABORATORY MANAGER

HIGHER SPECIALIST SCIENTIST TRAINING (HSST) DOCTORAL RESEARCH PROJECT

25 Years





Kidney Transplants

2800 patients received a kidney transplant last year

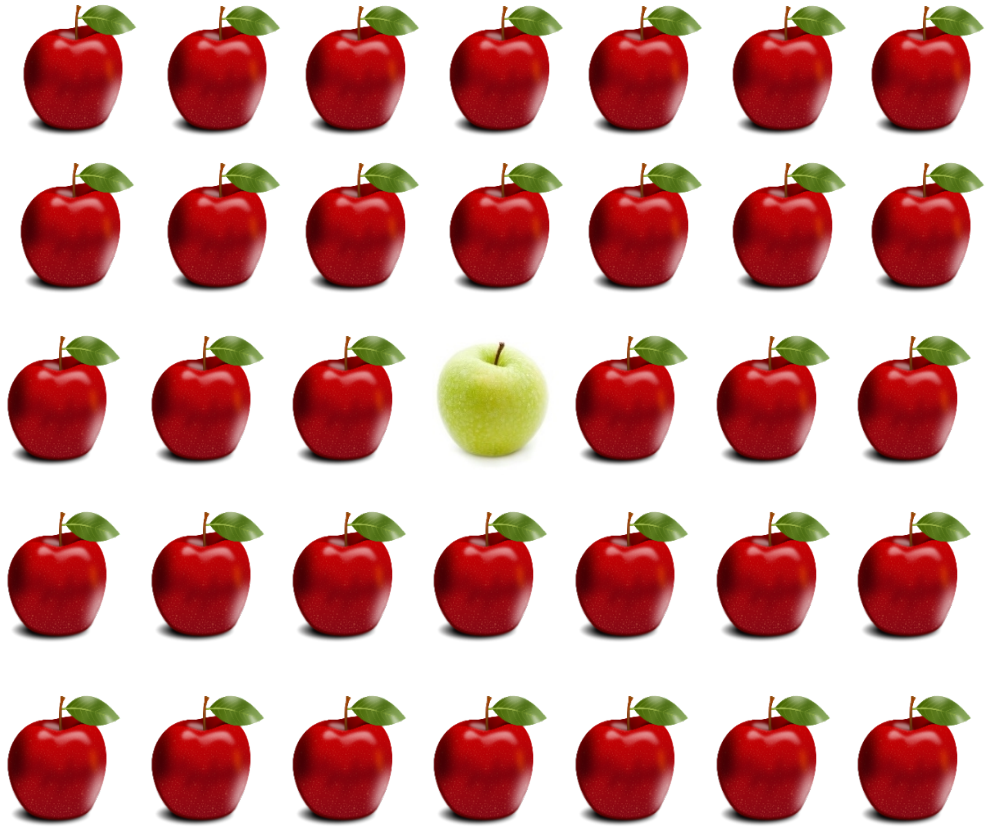
Kidney transplants work for ~15 years

If the transplant stops working = dialysis

Major goal in transplantation is to increase the time a transplant works for

- Patient benefits compared to dialysis
- Health economy benefits
- Demand for transplant – over 5000 patients waiting

Immune System

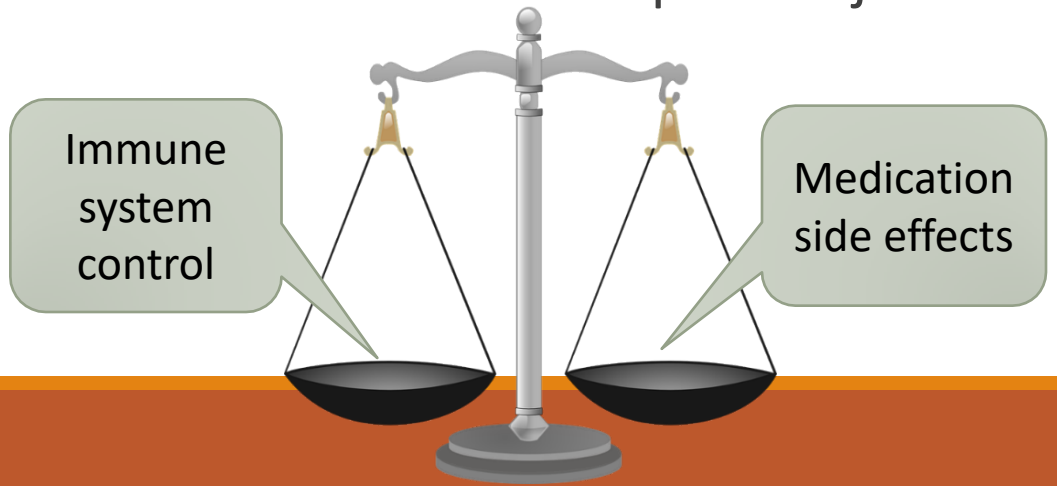


Normal role = detect & fight infections

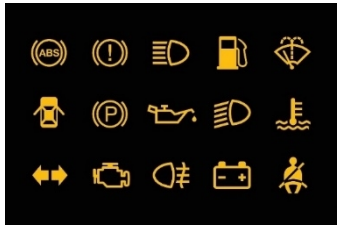
Kidney transplant identified as different

Medication to supress immune system

Immune attack = transplant rejection



Patient Testing After Transplantation



Rejection diagnosed & anti-rejection treatment started

Blood/ urine tests

Patients with rejection have poorer transplant outcome

Test

Transplant

Kidney function impacted

immune damage to transplant

Existing damage to transplant

Routine appointments and blood/urine tests

time after transplant

Test immune system

My research project

High risk of rejection

Low risk of rejection

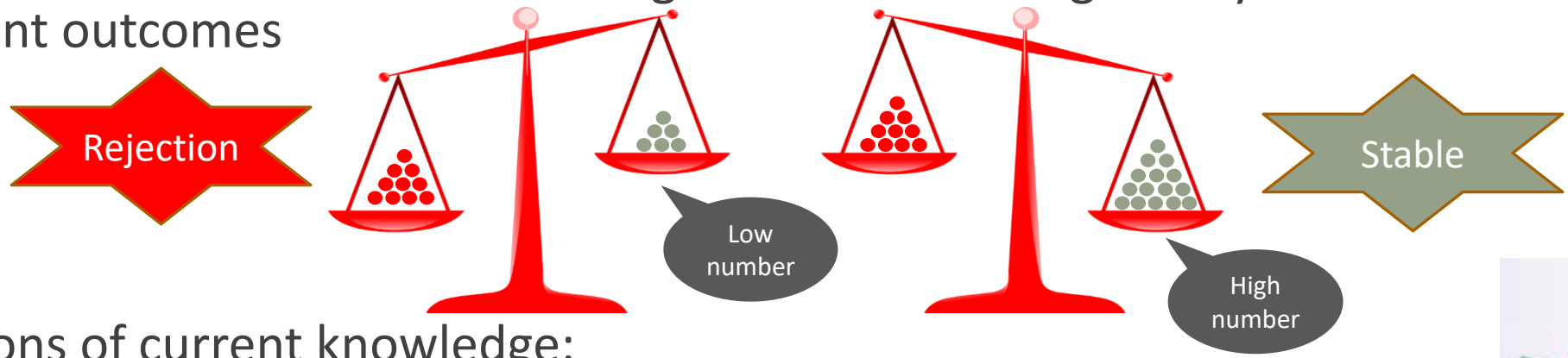
Personalise monitoring/treatment based on test results

Regulatory Immune Cells

Immune system is complex, made up of lots of different cell types, and varies by person

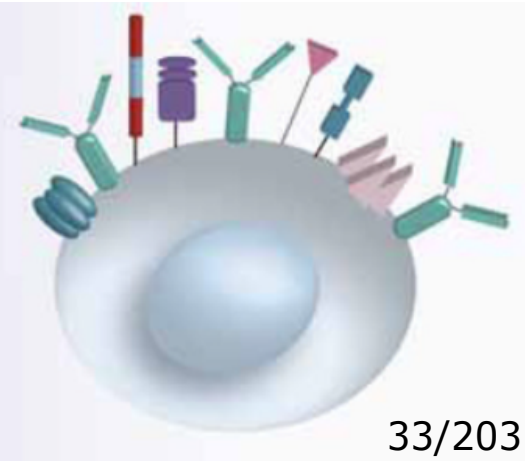
- Attack cells
- Regulatory cells

Previous research indicates measuring the amount of regulatory cells is correlated with transplant outcomes



Limitations of current knowledge:

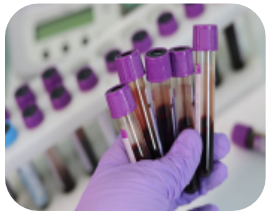
- Limited number of studies performed in transplant patients
- Tests used in research setting not transferrable to the NHS
- Makers to identify regulatory cells not well defined



Research Project

Measure regulatory cells in kidney transplant patients

Set up laboratory test to look at several markers associated with regulatory cells (informed by literature review)



Test blood samples from consented patients after kidney transplant (from sample repository patients with and without rejection)

Result analysis to determine if any of the markers alone, or in combination, can differentiate between patients with and without rejection

Findings will be published and communicated

Research Overview

LIMITATIONS

Initial, single centre study

Method is limited by the number of markers that can be combined

Not proving that the cells identified can supress other cells

- Using markers from other groups that have shown this link and applying to a different patient population

STRENGTHS/BENEFITS

Test combination of markers not previously tested

Add data to limited studies available in transplantation

Using methodology that can be easily transferred to other NHS labs

Test may be applicable to other organ transplants

Summary

Rejection is the immune system attacking a transplanted kidney

Medication needed to supress the immune system, but rejection can still occur

Immune cells with regulatory function can help prevent rejection

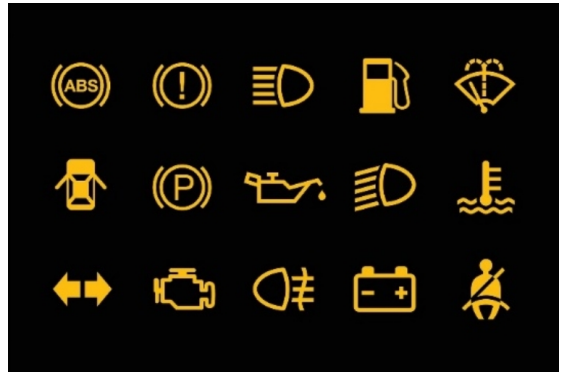
Measuring regulatory cells may identify patients at risk of rejection and those that are stable

Set up laboratory test to measure the amount of regulatory cells in transplant patients

- Using unique combination of markers

Opportunity to personalise monitoring/treatment based on test results

- improve transplant outcome



Any Questions?

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

Date 28/02/2023
Time 10:00-12:00pm
Location via Microsoft Teams
Chair Professor Andrew Westwell, Independent Member

PRESENT		
Professor Andrew Westwell	Independent Member and Research, Development & Innovation Sub-Committee Chair	AW
Vicky Morris	Independent Member	VM
Professor Donna Mead OBE	Trust Chair	DM
ATTENDEES		
Dr Jacinta Abraham	Executive Medical Director and R&D Lead	JA
Libby Batt	Head of Velindre Cancer R&D Strategy	LB
Matthew Bunce	Executive Director of Finance	MB
Christopher Cotterill Jones	Research Delivery Manager	CCJ
Rachel Hennessey	Interim Head of Operation & Service Delivery	RH
Professor Jane Hopkinson	Velindre Cancer Service Professor of Nursing and Interdisciplinary Cancer Care	JH
Sian James	RD&I Facilitation Lead, Welsh Blood Service	SJ
Dr Edwin Massey	Medical Director, Welsh Blood Service	EM
Jonathan Patmore	RD&I Finance Business Partner	JP
Peter Richardson	Head of Quality & Assurance & Regulatory Compliance, 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
SECRETARIAT		
Sandra Cusack	Business Support Officer	SMC

1.0	**PRESENTATIONS**	
1.1	**Palliative and Supportive Care Research…. Building On Success** Led by Professor Anthony Bryne, Consultant in Palliative Medicine Professor Andrew Westwell welcomed and introduced Professor Anthony Byrne, Consultant in Palliative Medicine who provided a short presentation on Palliative and Supportive Care Research, Building on Success and the contribution this will make to the Velindre Cancer Strategy. The presentation was well received from the RD&I Sub-Committee. **ACTION:** Post meeting discussion to be arranged with DM/AB/Palliative Care Team around the portfolio research methods adopted and how to take forward. ***Edwin Massey joined the meeting at 10.30am***	**Secretariat**
2.0	**STANDARD BUSINESS**	
2.1	**Apologies** received from: • Eve Gallop-Evans, Clinical Director, Velindre Cancer Services • Steve Ham, Chief Executive • Paul Wilkins, Interim Director, Velindre Cancer Services	
2.2	**In Attendance** • Professor Anthony Bryne, Consultant in Palliative Medicine (Item 1.1) • Christopher Cotterill Jones, Research Delivery Manager (Item 4.1) • Ross McLeish, Innovation Project Manager (Item 4.1) • Kate Cleary, Velindre Futures Cancer Research & Development Strategy Project Manager (Observer)	
2.3	**Declarations of Interest** *Led by Professor Andrew Westwell, Chair of the Research, Development & Innovation Sub-Committee* No declarations of interest were raised.	
2.4	**Review of Action Log** *Led by Dr Jacinta Abraham, Executive Medical Director* and R&D Lead The Research, Development & Innovation Sub-Committee reviewed all actions identified as **COMPLETE** since the previous meeting and **APPROVED** to **CLOSE**. The remaining **OPEN** actions were reviewed and the following was agreed:	

	4.1.0 (15.11.2022) Activity Data Benchmarking with other UK Cancer Centres : R&D to undertake a more detailed scoping exercise with each organisation to determine resources, staff, equipment and present findings at a future meeting. Update - Benchmarking work has commenced in line with the research ambitions and the Cardiff Cancer Research Hub. This data will be included in an annual presentation and to be received at December 2023 RD&I Sub-Committee. ***4.2.1 (15.11.2022) RDI Performance Report - Radiotherapy Research :*** 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, a report to be made available at the next RDI Sub-Committee Meeting. Update - Radiotherapy Trials Research Group has been established to identify issues and implement potential solutions. A Radiotherapy Research Portfolio Group has also been established to oversee the radiotherapy portfolio. Outcomes from the Radiotherapy Trials Research Group will be presented and to be received at December 2023 RD&I Sub-Committee.	**ST** **ST**
3.0	**MAIN AGENDA**	
3.1	**Executive Medical Director Briefing** *Led by Dr Jacinta Abraham, Executive Medical Director* and R&D Lead The Executive Medical Director Summary reported high-level activities relating to Research, Development and Innovation that took place during Quarter 3, Financial Year (FY) 2022/23. The following key highlights were reported : **Welsh Blood Service (WBS)** • Chloe George, Head of Component Development at WBS has been awarded 'Healthcare Scientist of the Year' at the Advancing Healthcare Awards Cymru. Chloe impressed judges with her ground-breaking work into the cold storage of platelets, for a longer shelf life and safer transfusions. Chloe and her team in the Component Development & Research Laboratory are also investigating new treatments for a range of haematological illnesses, improving transfusion outcomes and minimising risk to patients. • Welsh Blood Service would also like to congratulate the Vaccine Distribution Project Team, who were deservedly shortlisted for the 'Improving Public Health Outcomes' Award. **Research & Development (R&D)** • Charitable Funds Committee RD&I Integrated Bid • Cardiff Cancer Research Hub • Oncacare	

	• Research Study Data & Performance Measures The Research, Development & Innovation Sub-Committee would like to personally congratulate Chloe and the Team on this outstanding achievement and the recognition of their hard work and commitment to the Welsh Blood Service. The Research, Development & Innovation Sub-Committee **NOTED** the contents of the Executive Medical Director Briefing.	
3.2	**Trust Research, Development and Innovation Sub-Committee Risk Register Extract** *Led by Sarah Townsend, Head of Research & Development* ST reported that there were no open risks recorded on Datix for escalation to February 2023 Research, Development & Innovation Sub-Committee, in line with the Trust Board Risk Appetite. The Committee referenced that it will be important as we develop the implementation plans for the Cardiff Cancer Research Hub (CCRH), identifying potential risk and mitigating strategy to be an agenda item going forward. **ACTION:** Post meeting discussion to be arranged with ST/LB/AW/JA around the CCRH going forward. The Research, Development & Innovation Sub-Committee **NOTED** the update.	**Secretariat**
4.0	**STRATEGY, PERFORMANCE & DELIVERY**	
4.1	**Trust Research, Development and Innovation Performance Report** *Led by Sarah Townsend, Head of Research & Development* with support from the relevant leads: ST provided an introduction on the Trust Research, Development & Innovation Performance Report for the Financial Year 2021-22 on the four strategic priorities that are also published within the Integrated Medium Term Plan (IMTP). This reports information on the Trust's national and global achievements and compliance against Health and Care Research Wales (HCRW) key performance indicators, including the following : **VELINDRE R&D AMBITIONS *led by Libby Batt, Head of Cancer R&D Strategy, Velindre Futures*** **RADIOTHERAPY RESEARCH** Several groups have been established to ensure Radiotherapy Research continues to be a core function within Velindre with focused objectives and clear aims. The Radiotherapy Research Working Group has been set up to	

	bring representatives from the three departments in Radiotherapy together, along with representatives from Transforming Cancer Services (TCS). This collaborative group will share information with oversight of the Research Bunker in the new Velindre Cancer Centre (nVCC) as well as relevant bids going into Charitable Funds and Advancing Radiotherapy Funds (ARF). From this group, a subgroup has been formed and led by Professor John Staffurth to identify the preferred type of machine to go into the bunker that will facilitate and enhance the status of the nVCC/VCS/Trust as a UK/International research leader. Professor Staffurth has mentioned that he would be very happy to come and present the options appraisals at the next meeting of the Research, Development & Innovation Sub-Committee. DM asked for clarification as to why JS was involved in doing an options appraisal for the regular research therapy and how does this align with the fact that we already have a have a research strategy with our current contract with Varian? LB/JA assured DM that it links in with the Integrated Radiotherapy Solution (IRS) and that JS is looking at the wider aspect of machinery to go into the Research Bunker, they are looking at all options and this does not compromise the relationship with Varian. JA also reiterated the need for keeping the Committee sited on all the ongoing work, and informed the Committee that JS has recently presented to Executive Management Board (EMB) and will come and present this information to the Research, Development & Innovation Sub-Committee. Alongside this, the task and finish group are looking at capacity issues within the core Radiotherapy service continues to work together to identify solutions and next steps to collectively best address this topic. **ACTION:** A representative from IRS to present at the next Private RD&I Sub-Committee on where they are up to in terms of the research strategy that was agreed with Varian. **CELL THERAPY SITE VISIT** The bid submitted to The Translational Knowledge Exchange and Training (TKET) Award was successful. This will fund a multidisciplinary team (medics, nurses, pharmacists) to visit Cell Therapy centres in Christie NHS Foundation Trust, Guy's Hospital and Newcastle upon Tyne Hospital. The Hub Senior Nurse is now leading on coordinating the visits and will collate learning from all staff groups that go on placements to be circulated and presented via workshops, training and webinar sessions within the Trust and with the Cardiff Cancer Research Hub partners. **CARDIFF CANCER RESEARCH HUB** • The tender for the development of an investment strategy closed at the end of September, but the bid was higher than the budget available. The wider feedback from the market was that more funding would be required to complete this piece of work. Further discussion is continuing with colleagues from the Project Board to further refine the scope of work and ensure this key piece of work is completed.	**Secretariat**

	• Work on securing appropriate infrastructure at University Hospital of Wales (UHW) is continuing and the Hub will be included alongside other infrastructure development @UHW. This is now being led by Cardiff and Vale University Health Board (CVUHB) and they will merge the three sets of clinical specifications from the Hub, Haematology and Acute Oncology Service (AOS) into one master document (ensuring the space planned avoids duplication and maximises best use of space). The intention is that the strategic outline case will be completed by the end of March 2023, allowing time to channel via CVUHB and Welsh Health Specalised Services Committee (WHSSC) boards, before submission to Welsh Government (WG) in May 2023. • The draft Heads of Terms are being finalized and will set out the governance principles between the organisations. This piece of work has been carried out between the R&D teams in VUNHST and the Joint Research Office (JRO), CU and CVUHB. The next step is a more detailed Memorandum of Understanding (MOU) which would cover all R&D activities between the three organisations. • One of the three Research Priorities for the Hub is to 'Harmonise Regulations to facilitate a "can-do" research culture which maximises research activity and outputs.' To facilitate this piece of work, the Hub Senior Nurse has made links with Wales Cancer Bank (WCB) to identify how WCB could support and work with the Cardiff Cancer Research Hub on sample collection. • A local agency to design the Hub branding and logo has now been appointed and are starting to collate colleagues' thoughts from across the three organisations to begin the design process. **NURSING & INTERDISCIPLINARY RESEARCH** ***led by Jane Hopkinson, Velindre Cancer Service Professor of Nursing and Interdisciplinary Cancer Care*** The Velindre **ambition** for nurse and therapies cancer research 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. Progress with achievement of the ambition includes infrastructure to support nurse and therapies led research. The following appointments have been made, • Head of Healthcare Cancer Research (0.4wte) • Healthcare Cancer Research Trials Nurse (0.2wte) • Therapies Healthcare Cancer Research Data Manager (1wte) • Velindre Research Associate (1wte) • Velindre Research Assistant, Small Grants Award (0.8wte)	

	• Administrative support DM questioned whether these were new appointments or whether this was existing staff undertaking these roles and responsibilities. DM stated that this was one of the reasons that they were keen to support the Integrated bid and this component of it, to stop people squeezing in extra responsibilties over and above their role. JH asked whether to look at the previous model that they have been working on during the last two years, which is to support clinical staff with research assistant time, it was agreed for further discussions to take place outside of the Committee Meeting. NW assured the Committee that this is in discussion at the Healthcare Science Forum and it is an area of priority and is in-line with their advanced practise framework development for dedicated time for research. **ACTION:** Post discussion meeting with DM/NW/JH to discuss the new appointments and the funding of fellowship schemes. **WELSH BLOOD SERVICE UPDATE** ***led by Peter Richardson, Head of Quality & Assurance, Welsh Blood Service & Dr Sian James, RD&I Facilitation Lead*** • Healthcare Scientist of the Year - congratulations to Chloe and the Component Development Lab team along with Sian James and her team and the Finance Team. • Vaccine Distribution Project Team, who were deservedly shortlisted for the 'Improving Public Health Outcomes' Award. • Welsh Blood Service RD&I Dashboard – Sero-surveeillance project • WBS RDI Strategy Project Update – invitations now all circulated can you please engage in this. • The support of the Biomedical Excellence for Safer Transfusion (BEST) Collaborative • Key Performance Indicators of the Welsh Blood Service RD&I Strategy ***11.25am Peter Richardson left the Committee*** **CHARITABLE FUNDS COMMITTEE RD&I INTEGRATED BID** ***led by Christopher Cotterill Jones, Research Delivery Manager*** CCJ reported progress against work and key achievements for Q3 of FY 2022/23 demonstrating activity against these strategic priority areas, the cross-cutting themes that support these areas and Trust RD&I corporate work, for example Finance. CCJ gave a brief update on the following: • **Summary of performance indicators** • **Health and Care Research Wales Performance Dashboard** • **Velindre Cancer Centre hosted research – key achievements** - **OPTIMA** - **TROPION 02**	**Secretariat**

VELINDRE UNIVERSITY NHS TRUST TRIAL TOP RECRUITERS!

The Trust continues to be the top recruiter to this trial in the world - 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 was the top recruiter to this trial in the UK - 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.

ONCACARE

- The Trust aims to be an organisation synonymous with RD&I at a scale beyond the current offering and seeks to form strategic relationships with partners to achieve this.
- The Trust continues to work with Oncacare to explore the benefits of a collaboration.
- The Trust together with Cardiff & Vale University Health Board continues to negotiate a master collaboration agreement with Oncacare.

RESEARCH STUDY DATA & PERFORMANCE MEASURES

In Quarter 3, FY 2022/23 it was identified that there were some anomalies in the research study data measures captured by the Trust and the data captured by Health and Care Research Wales (HCRW).

From 01 April 2022, the only key indicators measured by HCRW are:

- Percentage of open studies recruiting to time and target
- Percentage of closed studies recruiting to target

The Trust's Head of Research & Development and Research Delivery Manager met with HCRW's Senior Research Performance Manager in February 2023.

The anomalies and discrepancies were discussed in detail. A plan for further investigation and actions to rectify the issues was agreed. Actions that could be taken immediately have taken place.

BY YOUR SIDE APP – Localising Pfizer's Global Patient Cancer App
led by Ross McLeish, Innovation Project Manager

The Patient Solutions Team at Pfizer are 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, this 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. 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
- An Agile 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 Proposal
Following the success of the project, Pfizer has approached Velindre to conduct a Phase 2 of BYS localisation, with a view to implement the

	suggestions and feedback given by Velindre Cancer Centre patients during the initial workshops and make the app available to all our service users. Successful implementation of this Phase will provide Velindre with a ready-made patient app that has centralised, and localised information pulled directly from the Trust website, available to our users within its own 'My Centre' section. Velindre will be the first Trust in the UK to have this feature available to our patients. Discussions took place in January 2023 between the Innovation Project Manager, Executive Lead for Innovation and Chief Digital Officer to provide an overview of the project outcomes and requirements for both Velindre and Pfizer before the Trust proceeds with the project. Following this, a paper was presented to EMB and SLT. Pfizer provided a draft report of the pilot project for review. DM explored whether the execution of a commercialisation agreement between the Trust and Pfizer is required for the use of Velindre data? JA confirmed that EMB discussed the same issues but also to address the data, in terms of being an asset function. **ACTION:** RMcL to explore and address these issues and provide assurance to the Committee in due course. **HEAD OF INNOVATION (occurred following the RDI Sub-Committee)** Dr Jacinta Abraham, Executive Medical Director and R&D Lead would like to confirm that Jennet Holmes has been appointed as Head of Innovation and will take up position at the end of June / early July 2023. **RD&I FINANCE UPDATE *led by Jonathan Patmore, R&D Finance Manager*** The Finance Report outlined the financial position and performance for Quarter 3, FY 2022/23. The following was highlighted by JP: The RD&I Division includes the R&D Office, Research Nursing Delivery Teams, Early Phase Team, Innovation Team and administrative staff such as Trials Coordinators and Data Managers. Along with a significant number of individual study budgets, this comprises most of the Trust's research and innovation activity and is the subject of this finance report. Outside of this report, some staff managed outside the RD&I Division, e.g. pharmacy and radiotherapy research staff, are reported as part of the relevant Divisional reports (e.g. VCS). For 2022/23 the overall RD&I Financial Plan comprises targets to: • Spend **£3.0m on research activities**, of which 93% (£2.8m) is salary costs, including: o Management, trial support, data, and administrative staff (40%) o Nursing staff (33%) o Medical staff (13%)	**RMcL/ST**

	• Secure income of **£3.25m** from multiple sources, most significantly:
	  ○ Health & Care Research Wales (34%)
	  ○ Reimbursements from commercial clinical trials (22%)
	  ○ Support from the Velindre charity (26%)
	
	• Manage a further **c. £500k**, held in grant funding from external bodies, such as Cancer Research UK, for specific research trials led by VUNHST.
	
	The Research, Development & Innovation Sub-Committee **NOTED** the RD&I Integrated Performance Report for Quarter 3 of the Financial Year 2022/23.	

5.0	**CONSENT AGENDA** **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.**	
5.1	**CONSENT - FOR APPROVAL**	
5.1.1	**Draft Minutes from the Public Research, Development & Innovation Committee held on the 15th November 2022** *Led by Professor Andrew Westwell, Chair of the Research, Development & Innovation Sub-Committee* The Research, Development & Innovation Sub-Committee **APPROVED** the Minutes of the Public Meeting held on the **15th November 2022** as an accurate reflection of proceedings.	
5.1.2	**Intellectual Property Policy** *Led by Sarah Townsend, Head of Research & Development* The Intellectual Property Policy was circulated to the Committee for comments and an updated version was submitted with tracked changes and a clean version as in Appendix 1 & 2. A summary of the key changes below: • Clarification of the scope of the policy in relation to staff who generate IP while studying and hosted students who are not employees • Clearer flagging of public disclosure issues • Minor changes of language to improve accuracy and clarity • Removal of outdated references Appendix 1 Intellectual Property (IP) Policy_v6 with Tracked Changes	

	Appendix 2 Intellectual Property (IP) Policy_v6 Clean Version The Research, Development & Innovation Sub-Committee **APPROVED** the Trust Intellectual Property Policy. The IP policy will be on the Trust Board agenda on the 30th March 2023 in the Policies Approved Update Report and will be reviewed in one year from the date of approval.	
5.2	**CONSENT - FOR ENDORSEMENT**	
	No Items for Endorsement.	
5.3	**CONSENT - FOR NOTING**	
5.3.1	**Draft Summary of the Minutes from the Private Research, Development & Innovation Committee held on the 15th November 2022** *Led by Professor Andrew Westwell, Chair of the Research, Development & Innovation Sub-Committee* The Research, Development & Innovation Sub-Committee **NOTED** the Summary Minutes of the Private Meeting held on the 15th November 2022.	
6.0	**ANY OTHER BUSINESS**	
6.1	Prior Approval by the Chair Required No prior items have been raised for consideration under Any Other Business.	
7.0	**HIGHLIGHT REPORT TO THE TRUST QUALITY SAFETY & PERFORMANCE COMMITTEE**	
	Members to identify items to include in the Highlight Report to the Trust Board: **For Escalation** • Nil **For Advising** • Radiotherapy Research • Head of Innovation **For Assurance** • Trust RD&I Sub-Committee Risk Register Extract • TRUST Research, Development, and Innovation Performance Report 2021/2022 • Intellectual Property (IP) Policy **For Information**	

	• Palliative and Supportive Care Research, Building On Success Presentation • Executive Medical Director Briefing • WBS Healthcare Scientist of the Year The RD&I Sub-Committee **APPROVED** the above items to be included in the Highlight Report to the Quality Safety & Performance Committee. **ACTION:** ST to support the development of a draft Highlight Report for approval by the Research, Development & Innovation Sub-Committee Chair.	**ST**
8.0	**DATE AND TIME OF THE NEXT MEETING:**	
	The next meeting of the Research, Development and Innovation Sub-Committee will be held in person on the **4th July 2023 at 2.00pm at Trust Headquarters, Nantgarw.**	
9.0	**CLOSE**	
	The Research, Development and Innovation Sub-Committee is asked to adopt the following resolution: That representatives of the press and other members of the public be excluded from the remainder of this meeting having regard to the confidential nature of the business to be transacted, publicity on which would be prejudicial to the public interest in accordance with Section 1(2) Public Bodies (Admission to Meetings) Act 1960 (c.67).	

PUBLIC RESEARCH, DEVELOPMENT & INNOVATION SUB-COMMITTEE ACTION LOG					
Minute Number	**Action**		**Progress to Date**	**Target Date**	**Status (Open/Closed)**
Actions agreed at the Committee on the 28th February 2023					
1.1	Palliative and Supportive Care Research, Building On Success Presentation : Post meeting discussion to be arranged with DM/ AB/Palliative Care Team around the portfolio research methods adopted and how to take forward.	**AB / SMC**	**UPDATE 04/07/2023** Currently liaising with Professor Anthony Byrne to secure meeting date.	04/07/2023	**OPEN**
3.2	Trust RD&I Sub-Committee Risk Register Extract : Post meeting discussion to be arranged with ST/LB/AW/JA around the CCRH going forward.	**SMC**	**UPDATE 04/07/2023** Post discussion meeting held on the 23/05/23 to discuss the visibility of RD&I risks and future reporting of risks on datix for escalation to the RD&I Sub-Committee in line with the Trust Board Risk Appetite. **I**t will be important as we develop the implementation plans for the Cardiff Cancer Research Hub (CCRH), identifying potential risk and mitigating strategy to be an agenda item going forward.	04/07/2023	**CLOSED**
4.1(a)	Nursing & Interdisciplinary Research : Post discussion meeting with DM/ NW/JH to discuss the new appointments and the funding of fellowship schemes.	**NW / JH**	**UPDATE 04/07/2023** Discussion meeting held and funding agreed as part of overarching research bid. Velindre Healthcare Cancer Research Fellowships currently advertised.	04/07/2023	**CLOSED**
4.1(b)	BY YOUR SIDE App : Explore whether the execution of a commercialisation agreement between the Trust and Pfizer is required for the use of Velindre data.	**ST / RMcL**	**UPDATE 04/07/2023** Currently liaising with the Research Contracts Manager and will report back to the RD&I Sub-Committee in due course. We have received from Pfizer a "donation agreement" which provides for Pfizer to make the functionality of the App available to the Trust. It is recommended that the Trust seeks advice from NWSSP Legal and Risk on the suitability of this agreement.	04/07/2023	**OPEN**
Actions agreed at the Committee on the 15th November 2022					
4.1.0	Activity Data Benchmarking with other UK Cancer Centres : R&D to undertake a more detailed scoping exercise with each organisation to determine resources, staff, equipment and present findings at a future meeting.	**ST**	**UPDATE 04/07/2023** Benchmarking work has commenced in line with the research ambitions and the Cardiff Cancer Research Hub. This data will be included in the annual presentation and be received at December's RD&I Sub-Committee.	07/12/2023	**OPEN**
4.2.1	RDI Performance Report - Radiotherapy Research : 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, a report to be made available at the next RDI Sub-Committee Meeting.	**ST**	**UPDATE 04/07/2023** Radiotherapy Trials Research Group has been established to identify issues and implement potential solutions. A Radiotherapy Research Portfolio Group has also been established to oversee the radiotherapy portfolio. Outcomes from the Radiotherapy Trials Research Group will be presented and be received at December's RD&I Sub-Committee.	07/12/2023	**OPEN**

Research, Development & Innovation Sub-Committee

Executive Briefing to RD&I Sub-Committee

DATE OF MEETING	20/07/2023

PUBLIC OR PRIVATE REPORT	Public

IF PRIVATE PLEASE INDICATE REASON	Not Applicable - Public Report

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

REPORT PURPOSE	FOR NOTING

COMMITTEE/GROUP WHO HAVE RECEIVED OR CONSIDERED THIS PAPER PRIOR TO THIS MEETING		
COMMITTEE OR GROUP	**DATE**	**OUTCOME**
Not applicable		

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) 4 of Financial Year (FY) 2022/23.

2. ASSESSMENT / SUMMARY OF MATTERS FOR CONSIDERATION

2.1. Welsh Blood Service

2.1.1. Advancing Kidney Transplant Treatments

Executive Briefing Slides = slide 3

Felicity May has been awarded her Doctor of Clinical Science after fulfilling the five-year rigorous demands of NHS's Higher Specialist Scientist Training programme. Felicity undertook an NHS Research study during the programme, looking at improving desensitisation treatments for renal patients.

Sensitisation is a complex clinical problem that greater effect transplant suitability in some patient groups. Felicity's project is a step towards understanding why some transplant patients do not respond to desensitisation treatment. Felicity's research will aid further studies which hope to minimise unnecessary treatment for kidney transplant patients and inform alternative treatments.

Felicity's achievement placed her at the forefront of histocompatibility and immunogenetics field.

2.2. Research and Development

2.2.1. Joint Executive Team meeting

Executive Briefing Slides = slide 4

Welsh Government have regular engagements and monitoring meetings to assure themselves that an NHS organisation's Integrated Medium-Term Plan delivery is on track. This includes Joint Executive Team meetings to discuss progress against IMTP delivery.

The Trust's Joint Executive Team (JET) meeting was convened on 19 May 2023, where the Trust's Executive Team presented on the Trust's progress against planned delivery.

Dr Jacinta Abraham presented on the work of the Trust's RD&I Division covering the work of:

- Welsh Blood Service

- Research & Development
- Innovation
- Trust performance against Health & Care Research Wales key indicators for research

The Trust's RD&I activity received positive interest at the JET meeting. There was recognition of the award given to Healthcare scientist Chloe George. Also, it was noted that Velindre Cancer centre were leading globally by being the first to recruit into a lung study as well as being a top recruiter of international studies.

2.2.2. **Cardiff Cancer Research Hub(CCRH)**

Executive Briefing Slides = slide 4

A Translational Knowledge Exchange and Training (TKET) Award (funded via Cardiff University) supported successful visits, by multi-disciplinary teams, to benchmark against three UK Cancer Centres of Excellence:

- The Christie NHS Foundation Trust
- Guy's and St. Thomas' NHS Foundation Trust
- Newcastle Hospitals NHS Foundation Trust

The CCRH Senior Research Nurse led the coordination of the visits and will collate the learning from all staff groups to be circulated and presented. These visits have built excellent links and shared learning. This is a real success story of a collaborative effort driven by Cardiff Cancer Research Hub.

The CCRH has seen real measurable progress over the last 12 months. Highlights include:

The draft Heads of Terms setting out the governance principles between the organisations are being finalised. This piece of work has been carried out between the R&D teams in VUNHST and the Joint Research Office CU and CVUHB

Funds have been secured to commission external experts to develop a Strategic Investment Case to holistically address how the Hub will be financially sustainable for the future. Moorhouse Consulting has been commissioned to lead this initiative. It is envisaged that a more detailed Memorandum of Understanding (MOU) which would cover the leadership arrangements and financial model for the Hub, to follow this piece of work.

The team are already developing the CCRH trials portfolio. At the end of March 2023, one trial was open, and four trials were in set up.

2.2.3. **First in the World and Europe**

Executive Briefing Slides = slide 5

STUDY TITLE: I0102-I0103-022. 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 was the first worldwide site to randomise a patient into a study investigating a new drug in Patients with Metastatic Non-Small Cell Lung Cancer (NSCLC), Squamous Cell Carcinoma of Head and Neck (SCCHN), or Metastatic Urothelial Bladder Cancer (mUBC), and remains the world's highest recruiter.

STUDY TITLE: TROPION 03. A Phase 3 Open-label, Randomised Study of Datopotamab Deruxtecan (Dato-DXd) With or Without Durvalumab Versus Investigator's Choice of Therapy in Patients With Stage I-III Triple-negative Breast Cancer Who Have Residual Invasive Disease in the Breast and/or Axillary Lymph Nodes at Surgical Resection Following Neoadjuvant Systemic Therapy

Velindre was the first site in Europe to randomise a patient into a study in patients with Stage I-III Triple-negative Breast Cancer and remains top UK recruiter and is the fourth highest recruiter in the world.

2.2.4. **OnCovid Publications**

Executive Briefing Slides = slide 5

STUDY TITLE: OnCovid - Natural history and outcomes of cancer patients during COVID19 epidemic.

The Trust supported the OnCovid: natural history and outcomes of cancer patients during the COVID19 epidemic study. The overarching purpose of this retrospective, non-interventional study is to describe the features of COVID-19 infection in cancer patients, investigate its severity in this population and evaluate long-term outcomes.

The trial findings highlighted a consistent reduction of COVID-19 severity in patients with breast cancer during the Omicron outbreak in Europe. The study also

demonstrated that even in this population, a complete severe acute respiratory syndrome coronavirus 2 vaccination course is a strong determinant of improved morbidity and mortality from COVID-19.

The Trust's Research Nurse Team Lead, Amanda Jackson, and Head of Research Development, Sarah Townsend, have been listed as authors in a paper published in the Lancet Oncology journal. Amanda Jackson has also been listed in author in a paper published in Journal of Clinical Oncology.

Velindre were also recognised as a contributing organisation in a meeting abstract at the 2022 ASCO Annual Meeting.

2.2.5. **Health and Care Research Wales: Research Framework**

Executive Briefing Slides = slide 6

During winter/spring 2023, Health and Care Research Wales (HCRW) facilitated the co-creation of an NHS Research & Development (R&D) framework with key stakeholders through a series of workshops asking delegates what was needed enable NHS organisations to integrate research into healthcare and the next steps to ensure successful framework development and delivery.

The draft framework document outlining what 'research excellence looks like' within NHS organisations in Wales where research is embraced, integrated into services and is a core part of the organisation's culture was published for consultation in May 2023.

Trust representatives attended the workshops that informed the key themes of the framework document.

The Trust submitted comments in response to the consultation of the draft NHS R&D Framework by the required deadline of 01 June 2023.

2.2.6. **BioWales 2023, London**

Executive Briefing Slides = slide 6

BioWales 2023 took place in London on 14 March 2023. The event is a flagship event for the thriving and dynamic life sciences sector in Wales.

BioWales 2023 provided a platform to discuss:

- Significant developments around clinical innovation, medical technology and diagnostics.
- Exciting new innovations and companies looking for investment and collaborations, including presentations from Welsh companies at various stages in their investor journey
- Highlights from NHS innovation and research collaboration opportunities.

The event also included a session on “Working with the Welsh NHS” discussing clinical access, adoption, and clinical trials.

Trust delegates attended this successful event.

2.3. Innovation

2.3.1. Wales Innovation Strategy

Executive Briefing Slides = slide 7

Welsh Government launched a new Innovation Strategy “Wales Innovates: Creating a Stronger, Fairer, Greener Wales” in February 2023.

The new Innovation Strategy:

- Sets out aspiration for Wales to be a leading, innovation-based nation.
- Focuses on ensuring innovative new technologies are developed to help solve the biggest challenges facing communities, ensuring those solutions reach every part of society.
- Through collaboration, the aim is to bring about better healthcare, tackling the climate and nature emergencies and creating better jobs and prosperity for businesses, universities, and local communities.

The strategy adopts a “mission based” attitude and will work with government’s Health and Wellbeing agenda to see the health and social care sector collaborate with industry, academia and the third sector to deliver new ways of working that deliver greater value and impact for citizens.

2.3.2. Innovation Lead

Executive Briefing Slides = slide 7

The new Head of Innovation, Jennet Holmes, will be joining the Trust on 30 June 2023, from Welsh Government where she was Head of Innovation and Collaborative Partnerships.

Jennet will take the lead on the implementation of the Trust's innovation strategy and ensure alignment with the Wales Innovation Strategy.

2.3.3. **Wales Innovation Strategy**

Executive Briefing Slides = slide 7

https://www.gov.wales/innovation-strategy-wales

2.3.4. **VCC Talking Heads**

The "Talking Heads" sub-project is an exciting new piece of work to produce a series of two-minute videos to introduce individual Clinical & Healthcare staff and their roles. The videos will be embedded within the RITA Chatbot virtual assistant when a patient asks a question relating to that clinical area. The videos will also be available on the Trust website.

These videos will help and give patients, family, and carers opportunity to:

- understand the role of their key clinicians and healthcare staff,
- view clinical areas and the cancer centre site before their visit,

hopefully easing and reducing their anxiety of having to attending Velindre Cancer Centre.

3. IMPACT ASSESSMENT

QUALITY AND SAFETY IMPLICATIONS/IMPACT	There are no specific quality and safety implications related to the activity outined in this report.
RELATED HEALTHCARE STANDARD	Governance, Leadership and Accountability
	• Standard 3.3 Quality Improvement, Research and Innovation • Standard 3.4 – Information Governance and Communications Technology

	• Standard 3.5 – Record Keeping
EQUALITY IMPACT ASSESSMENT COMPLETED	Yes
	We have considered the importance of equality impact in the writing of this report and there are no matters of concern to raise.
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

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

Research, Development & Innovation (RD&I) Sub-Committee
20th July 2023

Executive Lead Briefing

Dr. Jacinta Abraham, Executive Medical Director

Content

- Welsh Blood Service
  - Advancing Kidney Transplant Treatments
- Research & Development
  - Joint Executive Team Meeting
  - Cardiff Cancer Research Hub
  - First in the World and Europe
  - OnCovid Publications
  - Health and Care Research Wales: Research Framework
  - BioWales 2023, London
- Innovation
  - Wales Innovation Strategy
  - Innovation Lead
  - RITA – “Talking Heads” Sub-project

Velindre University NHS Trust RDI: Welsh Blood Service

Advancing Kidney Transplant Treatments

- Felicity May has been awarded her Doctor of Clinical Science after fulfilling the five-year NHS Higher Specialist Scientist Training programme.
- Felicity's achievement placed her at the forefront of histocompatibility and immunogenetics field.
- A research study undertaken during the programme, looking at improving desensitisation treatments for renal patients.
- Sensitisation is a complex clinical problem that greater effect transplant suitability in some patient groups.
- The project is a step towards understanding why some transplant patients do not respond to desensitisation treatment. Felicity's research will aid further studies which hope to minimise unnecessary treatment for kidney transplant patients and inform alternative treatments.

Velindre University NHS Trust RDI: Research & Development

Joint Executive Team meeting

- The Trust's Joint Executive Team (JET) meeting with Welsh Government was convened on 19 May 2023.
- Dr. Jacinta Abraham presented on the work of the Trust's RD&I Division covering the work of:
  - Welsh Blood Service
  - Research & Development
  - Innovation
  - Trust performance against Health & Care Research Wales key indicators for research
- The Trust's RD&I activity received positive interest at the JET meeting.

Cardiff Cancer Research Hub

- A Translational Knowledge Exchange and Training (TKET) Award supported successful visits to:
  - Christie NHS Foundation Trust
  - Guy's & St.Thomas' NHS Foundation Trust
  - Newcastle Hospitals NHS Foundation Trust
- This knowledge sharing/learning has built excellent links with the outputs shaping further Trust developments.
- At end of March 2023, 1 "Hub" trial was open, with another 4 in set-up

Velindre University NHS Trust RDI: Research & Development

First in the World and Europe

- Velindre was the first worldwide site to randomise a patient into a study investigating a new drug in Patients with Metastatic Non-Small Cell Lung Cancer (NSCLC), Squamous Cell Carcinoma of Head and Neck (SCCHN), or Metastatic Urothelial Bladder Cancer (mUBC), and remains the world's highest recruiter.
- Velindre was the first site in Europe to randomise a patient into a study in Patients With Stage I-III Triple-negative Breast Cancer, and remains top UK recruiter.

OnCovid Publications

- The Trust supported the "OnCovid: natural history and outcomes of cancer patients during the COVID19 epidemic" study.
- The Trust's Research Nurse Team Lead, Amanda Jackson, and Head of Research Development, Sarah Townsend, have been listed as authors in a paper published in the Lancet Oncology journal. Amanda Jackson has also been listed in author in a paper published in Journal of Clinical Oncology.

Velindre University NHS Trust RDI: National Context

Health and Care Research Wales: Research Framework

- Health and Care Research Wales (HCRW) facilitated the co-creationcreation of an NHS Research & Development (R&D) framework with key stakeholders through a series of workshops.
- The draft framework document outlining what ‘research excellence looks like’ within NHS organisations in Wales was published for consultation in May 2023.
- The Trust submitted comments in response to the consultation of the draft NHS R&D Framework by the required deadline of 01 June 2023.

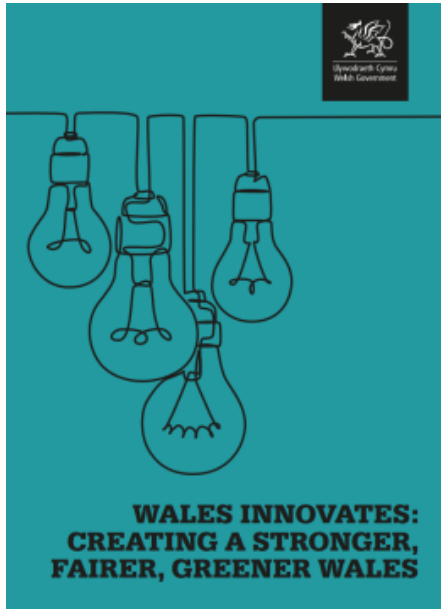
BioWales 2023, London

- BioWales 2023 - London took place on 14 March 2023, a flagship event for the thriving and dynamic life sciences sector in Wales.
- Providing a platform to discuss clinical innovations, medical technology and diagnostics, the event highlights NHS innovation and research collaboration opportunities.
- The event included a “Working with the Welsh NHS” session discussing clinical access, adoption and clinical trials.

Velindre University NHS Trust RDI: Innovation

Wales Innovation Strategy

- Welsh Government launched a new Innovation Strategy “Wales Innovates: Creating a Stronger, Fairer, Greener Wales” in February 2023.
- The new Innovation Strategy Sets out aspiration for Wales to be a leading, innovation based nation.
- The strategy adopts a “mission based” attitude and will work with the government’s Health and Wellbeing agenda, collaborating with various stakeholders to deliver greater value and impact for citizens.



Innovation Lead

- The new Head of Innovation, Jennet Holmes, will be joining the Trust on 30 June 2023, from Welsh Government where she was Head of Innovation and Collaborative Partnerships.

RITA – “Talking Heads” VCC Sub-project

- A series of two-minutes “Talking Head” videos introducing Velindre staff and their roles are being produced to giving patients opportunity to view clinical areas and the site before attending any appointments.

Research, Development & Innovation Sub-Committee

RD&I Integrated Performance Report – Annual Report (including Q4 update) FY2022/23

DATE OF MEETING	20/07/2023

PUBLIC OR PRIVATE REPORT	Public

IF PRIVATE PLEASE INDICATE REASON	Not Applicable - Public Report

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

REPORT PURPOSE	FOR NOTING

COMMITTEE/GROUP WHO HAVE RECEIVED OR CONSIDERED THIS PAPER PRIOR TO THIS MEETING		
COMMITTEE OR GROUP	**DATE**	**OUTCOME**
RD&I Operational Management Group	30/05/2023	Discussed and updated
Executive Management Board	05/06/2023	Discussed and updated

1. SITUATION / BACKGROUND

At the meeting convened on 28 February 2023 the RD&I Sub-Committee received the Research, Development, & Innovation (RD&I) Integrated Performance Report for Financial Year (FY) 2022/23, Quarter (Q) 3.

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

2. ASSESSMENT / SUMMARY OF MATTERS FOR CONSIDERATION

This RD&I Integrated Performance Annual Report (including Quarter 4 update) summarises the activities of the Trust's Research, Development, & Innovation function during the financial year 2022/23.

3. IMPACT ASSESSMENT

QUALITY AND SAFETY IMPLICATIONS/IMPACT	There are no specific quality and safety implications related to the activity outined in this report.
RELATED HEALTHCARE STANDARD	Governance, Leadership and Accountability
	• Standard 3.3 Quality Improvement, Research and Innovation • Standard 3.4 – Information Governance and Communications Technology • Standard 3.5 – Record Keeping
EQUALITY IMPACT ASSESSMENT COMPLETED	Not required
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

It is recommended that the RD&I Sub-Committee note for discussion the RD&I Integrated Performance Annual Report (including Quarter 4 update) for the financial year 2022/23.

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

Annual Report (including Q4 update)
2022/23

Welsh Blood Service
Gwasanaeth Gwaed Cymru

Canolfan Ganser Felindre
Velindre Cancer Centre

Research, Development & Innovation Integrated Performance Report

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

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

Contents

ABBREVIATIONS

A&E	Accident & Emergency
AHP	Allied Health Professionals
AHW	A Healthier Wales
ASCO	American Society of Clinical Oncology
ATMP	Advanced Therapy Medicinal Product
BVLS	Beyond Visual Line of Sight
BYS	By Your Side
C&V	Cardiff & Vale
CARIN	Clinical Academic Roles Implementation Network
CCRH	Cardiff Cancer Research Hub
CEO	Chief Executive Officer
CI	Chief Investigator
CIU	Chemotherapy Inpatient Unit
CT	Computerised Tomography
CU	Cardiff University
CVUHB	Cardiff & Vale University Health Board
DGH	District General hospital
DHCW	Digital Health & Care Wales
DRD	DNA Repair Deficiency
EMB	Executive Management Board
EMRTS	Emergency Medical Retrieval and Transfer service
FDA	Food and Drug Administration
FY	Financial Year
HCP	Healthcare Professional
HCRW	Health and Care Research Wales
HS&DR	Health and Social Care Delivery Research
IMTP	Integrated Medium-Term Plan
KPI	Key Performance Indicator
LPMS	Local Portfolio Management System
MOU	Memorandum of Understanding
MSc	Master of Science
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
vcc	New Velindre Cancer Centre
ODP	Open Data Platform
OMG	Operational Management Group
PCIP	Planned Care Innovation Programme
PDUFA	Prescription Drug User Fee Act
PFS	Progression Free Survival
PhD	Doctor of Philosophy

PI	Principal Investigator
Q	Quarter
R&D	Research & Development
R&I	Research & Innovation
RAG	Red, Amber, Green
RD&I	Research, Development & Innovation
RfPB	Research for Patient Benefit
RIC	Regional Innovation Coordination
RICH	Regional Innovation Coordination Hubs
RIIC	Research, Innovation, Improvement Coordinating
RT-TPG	Radiotherapy Trial Portfolio Group
SAC	Snowdonia Aerospace
SACT	Systemic Anti-Cancer Treatment
SCCHN	Squamous Cell Carcinoma of Head and Neck
SERD	Selective Estrogen Receptor Degrader
SOC	Standard Of Care
TCS	Transforming Cancer Services
TKET	Translational Knowledge Exchange and Training
TLWC	This is Living With Cancer
UHW	University Hospital of Vales
UK	United Kingdom
US	United States
USA	United Stated of America
VCC	Velindre Cancer Centre
VUNHST	Velindre University NHS Trust
WAST	Welsh Ambulance Service NHS Trust
WBS	Welsh Blood Service
WTE	Whole time Equivalent

INTRODUCTION

This report 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:

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

The report includes the progress of work and key achievements for Financial Year(FY) 2022/23 including Quarter(Q) 4 update 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 Research & Development Ambitions

1.1 Implementing the Velindre Cancer Research & Development (R&D) Ambitions – An Integrated Business Case 2023-2026

The team led with the RD&I Senior Management Business Team a successful R&D integrated bid that was approved by Velindre Charitable Funds in January 2023. The bid was ambitious in its scope, embedding different areas of research and generating new and exciting key posts within R&D. Charitable funds commended the fact that the bid brought R&D together in one integrated bid and was supportive of its ambition. The bid funds 118.7WTE (of which 49.9WTE are new, includes co-funded posts) which financially equates from £6.513m over 3 years down to £4.484m (dependent on cost savings and income from several sources). There was key advice from the Charitable Funds Committee to ensure non staff costs are also factored in. There is ongoing discussion around non-staff costs and the governance arrangements surrounding the bid. A date has been set to meet with VUNHST's Chair.

The Integrated bid includes Late Phase and Early Phase and ATMP clinical trials, Radiotherapy research. New areas of research include Translational Research, Health Care Research (led by multi-professional groups), and Palliative and Supportive Care research. It also focuses on building capacity and capability across the organisation's workforce, addressing how we can develop a sustainable and robust workforce that embraces research.

Next steps are to bring in all of these new posts which includes an RD&I Communications and Engagement Officer. This key role will be part of the corporate team with a remit to support and coordinate RD&I communications with patients, public, staff and other stakeholders about RD&I matters (Welsh Blood Service (WBS) and Velindre Cancer Centre (VCC).

The Implementation team are also working with each research area on developing Action Plans, integrating the objectives from the R&D strategy with the objectives from the integrated bid, to enable each area to demonstrate measurable progress. All the objectives from the bid and the strategy have strong alignment with obvious crossover and will provide a clear roadmap for R&D for the next 10 years.

1.2 Radiotherapy Research

In the last year, a number of groups have been set up within Radiotherapy Research to ensure Radiotherapy Research continues to be a core function within Velindre with focused objectives and clear aims.

The Radiotherapy Research Working Group has been set up to bring representatives from the three departments in Radiotherapy together, along with representatives from TCS. This collaborative group will share information with oversight of the Research Bunker in nVCC as well as relevant bids going into Charitable Funds and Advancing Radiotherapy Funds. From this group, a Task and Finish Subgroup has been formed to conduct an options appraisal, identifying the preferred type of machine to go into the research bunker that will facilitate and enhance the status of the nVCC/VCC/Trust as a UK/International research leader.

The Radiotherapy Trials Research Solutions Group is a collaborative task and finish group seeking to identify and address capacity issues within the core Radiotherapy service. With representation across the three departments within Radiotherapy, the group has identified short-, medium- and long-term issues and is collectively looking at the best ways to provide solutions. This group is starting to deliver real traction and aim to provide more details on the changes they are making to the department later this year.

1.3 Cardiff Cancer Research Hub (CCRH)

Cell Therapy Site Visits

The bid submitted to The Translational Knowledge Exchange and Training (TKET) Award (funded via Cardiff University) was successful. This has funded a multidisciplinary team (medics, nurses, pharmacists) to visit Cell Therapy centres in Christie NHS Foundation Trust, Guy's Hospital and Newcastle upon Tyne Hospital. The CCRH Senior Research Nurse has led on coordinating the visits and will collate the learning from all staff groups to be circulated and presented via workshops, training and webinar sessions within the Trust and with the Cardiff Cancer Research Hub partners. Organising these visits has resulted in building excellent links with the centres and has shown that there is a real appetite for this shared knowledge. These visits and the resulting shared learning are a fantastic output from the bid and is a real success story of a collaborative effort driven by Cardiff Cancer Research Hub.

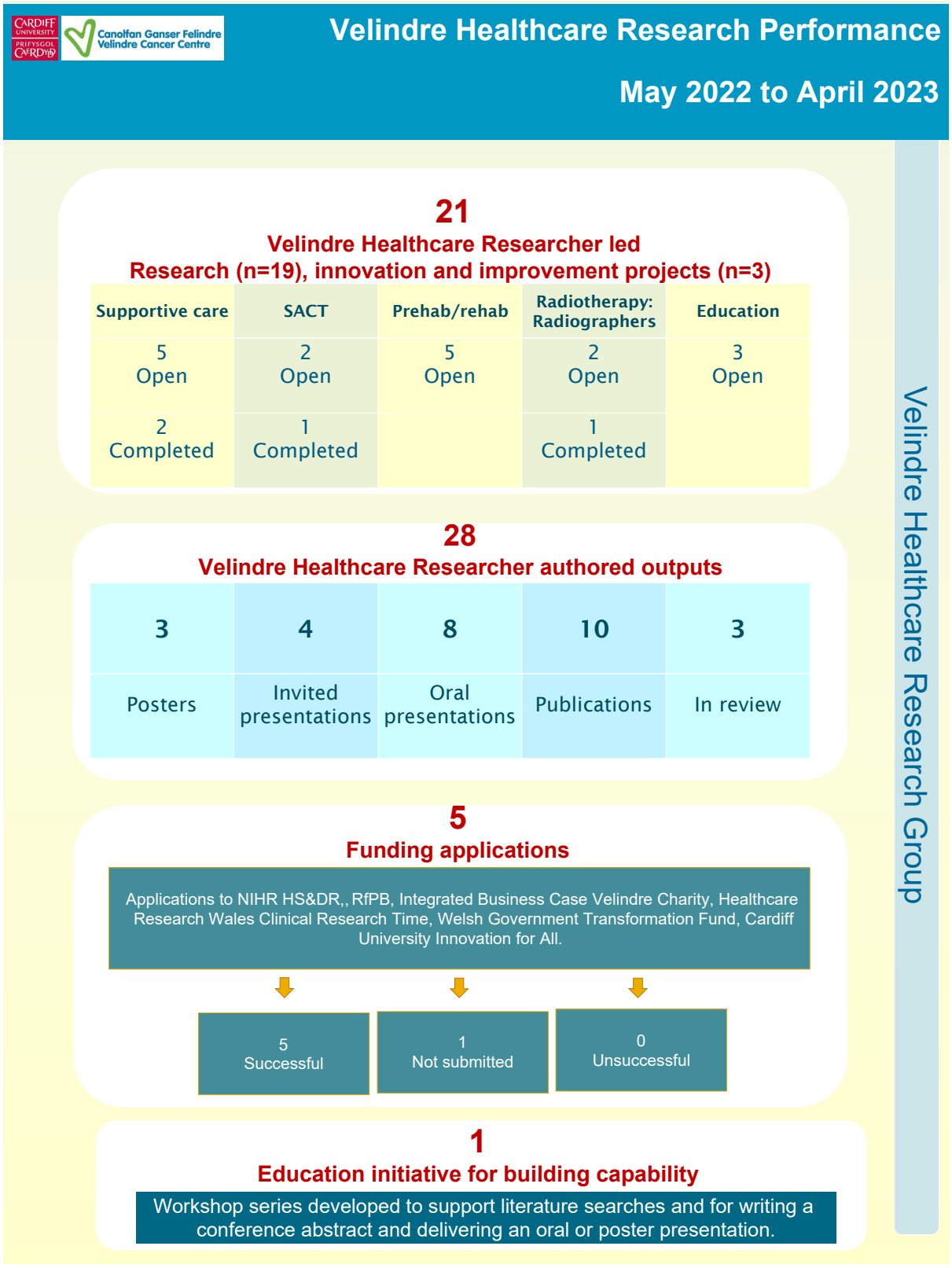
The CCRH has seen real measurable progress over the last 12 months. All teams from the three organisations have been driving it forward and showing true commitment to bringing this innovative Hub, with cutting edge treatment, to the people of Wales. Highlights include:

- A project of this size and complexity will take time to embed but whilst key pieces of work are being developed to get the Hub officially opened, the team are already developing the trials portfolio. At the end of March 2023, one trial was open, and four trials were in set up: all of these trials are only able to open due to the Hub so represent new opportunities for patients.
- The workforce for the Hub is moving forward with key roles already in post including the Senior Research Nurse and Trial Coordinator. Adverts for other

important roles will be opening soon including 2 x Research Nurses, 4 x Clinical Research Fellows and 1 x Clinical Academic.

- Site for the CCRH is still under discussion with UHW: the plan will be to develop an Outline Business Case, currently Cardiff and Vale is scoping out space options.
- Funds have been secured from Velindre Charitable Funds to commission external experts to develop a Strategic Investment Case that will holistically address how the Hub will be financially sustainable for the future. Moorhouse Consulting has been commissioned to lead this initiative.
- A Senior CCRH Operational Team is established that has oversight of the operational delivery of high and intermediate Early Phase and ATMP trials. This multi-professional team includes Haem-Onc and Solid tumour representatives and have an agreed work plan to develop operational policies and supporting documentation.
- The draft Heads of Terms are being finalised and will set out the governance principles between the organisations. This piece of work has been carried out between the R&D teams in VUNHST and the Joint Research Office CU and CVUHB. We are awaiting feedback from Cardiff University and CVUHB. The next step is a more detailed Memorandum of Understanding (MOU) which would cover all R&D activities between the three organisations.
- A branding agency are designing a logo and branding that will give the Hub a strong identity to reflect a partnership that the people of Wales can be proud of.
- The shared cancer research priorities have now been agreed by all three partners. These priorities act as the building blocks of the Hub, providing a clear direction when applying for grants and developing further partnerships:
    1. Attract, Train and Retain a diversity of clinical scientists to embed within and enhance the translational activities of cancer research labs across Cardiff.
        - Action: Develop and instigate an agreed clinical academic training pathway with mentorship, excellence and sustainability at its core.
    2. Create a Multidisciplinary Think Tank to optimise grant capture, including large scale centre bids.
        - Action: Employ Grant Officer(s) to coordinate and develop a range of funding bids, increasing collaboration across industry, government and charities.
    3. Harmonise Regulations to facilitate a “can-do” research culture which maximises research activity and outputs.
        - Action: Create and manage a harmonised biorepository to modernise patient consent and to enable sample and data sharing.

2 Nursing & Interdisciplinary Research



2.1 Velindre Health Care Research

2.1.1 Work in progress

- Dissemination of the new Healthcare Research Wales (HCRW) education and training offer for clinical staff.
- In house workshops about writing and presenting a conference abstract, led by Lenira Semedo, Velindre Healthcare Research Associate.
- Bernadette Coles and the Velindre Library Team support for Velindre healthcare staff literature reviews
- Jane Hopkinson and Lenira Semedo to lead a 'how to research' workshop at the Velindre University NHS Trust Celebration of Nursing 2023 at the All Nations Centre, Cardiff, on 12 May 2023.
- 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 advanced practitioners and consultant 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.
- Velindre healthcare clinical academic career pathway, which will align with a research competency framework and career progression with all VUNHST Advanced Practitioners research active as Principal Investigators (PIs) or Chief Investigators (Cis). It will empower Advanced Practitioners to work to the top of their license and enable transformational leadership. The successful Velindre Integrated Business Care will support research training that spans 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.

2.1.2 Next steps for building Velindre healthcare research capacity:

The Velindre Futures Cancer Research and Innovation Strategy team is meeting with Velindre's Professor of Nursing and Interdisciplinary Research to agree the workplan for delivery of the Velindre Healthcare Cancer Research Fellowship Scheme and to set out key performance metrics to monitor progress.

The aim is to develop a plan that will increase the number of Velindre nurses and therapists who are Chief Investigators enabling a step change improvement in the quality and quantity of multi-disciplinary and multi-partner innovation to achieve our Trust's purpose to improve lives.

2.2 Research and Innovation Survey

A survey for nurses, therapists, and healthcare scientists, which was sent out across the Trust, to establish baseline information regarding the understanding of Research and Innovation, involvement in Research and Innovation, educational and training needs to become involved in Research and Innovation.

The departments where staff who responded worked is per below table. Not every respondent declared their department of work.

Department	Number
Nursing	5
Therapies	6
Radiographer	2
Administrative	1
ANP	2
Clinical Scientist	4
Manager	1

The survey was sent out via the Trust comms newsletter, for completion electronically. Support in producing the survey in electronic format was provided by the Innovation Project Manager. There was also a targeted issue of the electronic survey employed by the Research Nurse to clinical leads.

The initial response was poor, with only around 20 responders. Discussions held with senior nurses who indicated that paper format would result in a better response. Again, these paper copies were targeted as had been requested. This only increased the response rate to a total of 31.

The results however give an insight into the projects taking place, what education and training is needed to encourage future involvement.

- The most motivated to respond appear to be band 6 & 7.
- 71% of respondents already taking a higher degree therefore more aware of research
- 78% felt they had a good understanding of R&I
- When asked if Velindre prioritised R&I, 55% said Velindre was good at that, and 45% said not so good to poor.
- In terms of educational needs, 62% wanted training in writing a grant application, 62% wanted training in publication, 55% wanted to learn how to navigate ethics application, and 51% wanted to learn about R&D application, how to write up a research project and how to write abstracts.

The full survey results can be seen in sections 12. Workforce Innovation & Research Survey.

2.2.1 Education and Training

Based on initial face to face discussions with staff, around their educational needs, some training sessions have been delivered via the library service and other sessions are planned for delivery by the Research Associate.

Training information boards have also been set up for nurses and AHP`s based on Rhosyn day unit, and Chemotherapy Inpatient Unit (CIU). These boards include contact details, training and funding opportunities, events, and new publications. There is also information re internal processes and how to access for the set-up of a research study. They are regularly updated by the Research Nurse.

The facilitation of the library training sessions included the discussion of content and linking with the nurse education department to identify most appropriate times to deliver and advertise the sessions. The first sessions took place August 2022. They included:

- An introduction to Library Resources.
- Defining your Research Question.
- Designing your Research Strategy.
- Introduction to Critical Appraisal.
- Practical Critical Appraisal.
- Specific Resource Training.

Training session to be delivered April 2023 by Research Associate include

- Introduction to Abstract Writing.
- Writing and Reviewing Abstracts.
- Oral and Poster Presentations.

Much of the content of these sessions is echoed in the survey as required training. It does however need to go further, with more in-depth information about Research and Development, and Ethics submissions. Discussions are underway in relation to the delivery of these requested sessions.

3 Performance Indicators

3.1 Summary of performance indicators

Overall, there has been marked improvement in the Trust run number of studies that have been RAG rated “GREEN” for the Health and Care Research Wales (HCRW) key indicators:

- OPEN studies – Percentage of studies recruiting to time and to target at NHS organisations in Wales with open studies being up 21% for non-commercial studies and up 11% for commercial studies
- CLOSED studies – Percentage of studies recruiting to target at NHS organisations in Wales with closed studies being up 37% for non-commercial studies; up 21% for commercial studies.

The HCRW key indicators for Velindre University NHS Trust are shown in the tables that follow, where:

R = Red, Recruitment less than 70% of expected (based on site target and time elapsed).
A = Amber, Recruitment between 70% and 100%.
G = Green, Recruitment greater than 100% of expected.
W = White, Non-recruiting studies – i.e., those active studies that do not intend recruit participants. Non-recruiting studies are identified as:

- The 'Site Recruitment Target' is set as zero.
- The site is a non-recruiting site (i.e., the 'Location Type' is set as 'Unknown' or 'Shared-care site').
- The Site Status is set as 'Open - No Recruitment Activity'.
- The 'Recruitment Activity Upload Method' is set as 'N/A', meaning that the way participants join the study does not meet the definition of recruitment (i.e., participant provides informed consent and is counted towards the sample size of the study).

The Trust R&D Office have met with the HCRW Performance Team to discuss:

- Datasets for HCRW Key Indicators and contribute to how these can be best presented to better represent Velindre's unique position in the research infrastructure in Wales.
- How the narrative entered in the Local Portfolio Management System can give context and be better utiliised in presenting these measures.

Further work on the above points is underway.

The Trust R&D Office, with oversight from the RD&I Operational Management Group (OMG) regularly:

- Interrogates the Trust's study portfolio to determine the potential barriers to delivers and develop mitigation strategies to overcome these barriers.
- Reviews all studies to identify underperformance and target these studies for action, developing mitigating strategies in collaboration with the Sponsors.

The following tables describe the Health and Care Research Wales (HCRW) key indicators and local performance measures used to manage the Trust's research portfolio:

- HCRW key indicator: Percentage of Health and Care Research Wales Portfolio studies recruiting to time and to target at NHS organisations in Wales for open studies.

- HCRW key indicator: Percentage of Commercially sponsored studies recruiting to time and to target at NHS organisations in Wales for open studies.
- HCRW key indicator: Percentage of Health and Care Research Wales Portfolio studies recruiting to time and to target at NHS organisations in Wales for open studies for closed studies.
- HCRW key indicator: Percentage of Commercially sponsored studies recruiting to time and to target at NHS organisations in Wales for open studies for closed studies.

- Local performance measure: Time taken from receipt of Local Information Pack (LIP) to recruitment of first participant into Health and Care Research Wales non-commercial Portfolio Studies.
- Local performance measure: Time taken from receipt of Local Information Pack (LIP) to recruitment of first participant into Health and Care Research Wales commercially sponsored Studies.
- Local performance measure: Percentage of non-recruiting Health and Care Research Wales non-commercial Portfolio studies within NHS organisations (Velindre University NHS Trust)
- Local performance measure: Percentage of non-recruiting Health and Care Research Wales Portfolio commercially sponsored studies within NHS organisations (Velindre University NHS Trust)
- Local performance measure: Number of studies opened (Velindre University NHS Trust)
- Local performance measure: Number of participants recruited into studies (Velindre University NHS Trust)

3.2 Health & Care Research Wales indicators for Velindre University NHS Trust

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

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:

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.

Open studies are measured using a RAG rating system as follows:

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

Calculation

$$\textbf{RAG rating} = \%\ \text{recruitment} - \%\ \text{time elapsed}$$

Where: $\%\ \textbf{recruitment} = \frac{\text{total recruitment (at organisation)}}{\text{site recruitment target}}$ $\%\ \textbf{\textit{time elapsed}} = \frac{\text{Number of days open (at organisation)}}{\text{Number of days planned open}}$

Previous Financial Year	Overall		Current Financial Year	Quarter 1		Quarter 2		Quarter 3		Quarter 4	
	Red	63%		**Red**	61%	**Red**	42%	**Red**	NR[1]	**Red**	34%
	Amber	14%		**Amber**	10%	**Amber**	14%	**Amber**	NR[1]	**Amber**	8%
	Green	23%		**Green**	29%	**Green**	23%	**Green**	NR[1]	**Green**	44%
	Black	-		**Black**	-	**Black**	-	**Black**	NR[1]	**Black**	-
	Silver	-		**Silver**	-	**Silver**	-	**Silver**	NR[1]	**Silver**	-
	Purple	-		**Purple**	-	**Purple**	-	**Purple**	NR[1]	**Purple**	-
	White	-		**White**	-	**White**	21%	**White**	NR[1]	**White**	14%

Previously Identified Issues	Previous Action Plan(s) to Improve	Target Date	Status
The Health and Care Research Wales (HCRW) 2022/23 dataset included 50 studies (R = 17 studies, A = 4 studies, G = 22 studies, W = 7 studies). 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	Having met with HCRW, further work is underway to improve: • Datasets for HCRW Key Indicators and contribute to how these can be best presented to better represent Velindre's unique position in the research infrastructure in Wales.	Ongoing	

[1] NR = Not reported. The data was not reported in Q3 FY2022/23 due to concerns with the completeness and accuracy of the source 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.	• How the narrative entered in the Local Portfolio Management System can give context and be better utiliised in presenting these measures.		
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.	HCRW have made some changes to the reporting of this metric, including additional ratings. Further work is underway to improve how the indicators can better represent Velindre's unique position in the research infrastructure in Wales	Ongoing	
Discussion of Issues	**Action Plan(s) to Improve Performance**	**Target Date**	
	The Trust R&D Office, with oversight from the RD&I Operational Management Group (OMG) regularly: • Interrogates the Trust's study portfolio to determine the potential barriers to delivers and develop mitigation strategies to overcome these barriers. • Reviews all studies to identify underperformance and target these studies for action, developing mitigating strategies in collaboration with the Sponsors.	Ongoing	

3.2.2 C4 OPEN: Percentage of Health and Care Research Wales Portfolio Commercially sponsored studies recruiting to target (VUNHST)

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:

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.
Open studies are measured using a RAG rating system as follows:

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

Calculation

$$\textbf{RAG rating} = \%\ \text{recruitment} - \%\ \text{time elapsed}$$

Where: $\%\ \textbf{recruitment} = \frac{\text{total recruitment (at organisation)}}{\text{site recruitment target}}$ $\%\ \textbf{\textit{time elapsed}} = \frac{\text{Number of days open (at organisation)}}{\text{Number of days planned open}}$

Previous Financial Year	Overall		Current Financial Year	Quarter 1		Quarter 2		Quarter 3		Quarter 4	
	Red	79%		**Red**	77%	**Red**	63%	**Red**	NR[2]	**Red**	47%
	Amber	-		**Amber**	6%	**Amber**	11%	**Amber**	NR[2]	**Amber**	8%
	Green	21%		**Green**	16%	**Green**	11%	**Green**	NR[2]	**Green**	32%
	Black	-		**Black**	-	**Black**	-	**Black**	NR[2]	**Black**	-
	Sliver	-		**Sliver**	-	**Sliver**	-	**Sliver**	NR[2]	**Sliver**	-
	Purple	-		**Purple**	-	**Purple**	-	**Purple**	NR[2]	**Purple**	-
	White	-		**White**	-	**White**	14%	**White**	NR[2]	**White**	13%

Previously Identified Issues	Previous Action Plan(s) to Improve	Target Date	Status
The Health and Care Research Wales (HCRW) 2022/23 dataset included 38 studies (R = 18 studies, A = 3 studies, G = 12 studies, W = 5 studies). 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	Having met with HCRW, further work is underway to improve: • Datasets for HCRW Key Indicators and contribute to how these can be best presented to better represent Velindre's unique position in the research infrastructure in Wales.	Ongoing	

[2] NR = Not reported. The data was not reported in Q3 FY2022/23 due to concerns with the completeness and accuracy of the source data.

not allow a direct comparison of cancer research studies between VUNHST and other NHS Wales Organisations.	• How the narrative entered in the Local Portfolio Management System can give context and be better utiliised in presenting these measures.		
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.	HCRW have made some changes to the reporting of this metric, including additional ratings. Further work is underway to improve how the indicators can better represent Velindre's unique position in the research infrastructure in Wales	Ongoing	
Discussion of Issues	**Action Plan(s) to Improve Performance**	**Target Date**	
	The Trust R&D Office, with oversight from the RD&I Operational Management Group (OMG) regularly: • Interrogates the Trust's study portfolio to determine the potential barriers to delivers and develop mitigation strategies to overcome these barriers. • Reviews all studies to identify underperformance and target these studies for action, developing mitigating strategies in collaboration with the Sponsors.	Ongoing	

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

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: • RED: % recruitment is < 100% • GREEN: % recruitment ≥ 100% Calculation **RAG rating** = % recruitment *Where*: % **recruitment** = $\frac{\text{total recruitment}}{\text{target recruitment}}$				

Previous Financial Year	Overall		Current Financial Year	Quarter 1		Quarter 2		Quarter 3		Quarter 4	
	Red	77%		**Red**	-	**Red**	50%	**Red**	NR[3]	**Red**	40%
	Green	23%		**Green**	100%	**Green**	50%	**Green**	NR[3]	**Green**	60%
	White	-		**White**	-	**White**	-	**White**	NR[3]	**White**	-

Previously Identified Issues	Previous Action Plan(s) to Improve	Target Date	Status
The Health and Care Research Wales 2022/23 dataset included 10 studies (R = 4 studies, G = 6 studies). A review of the 4 "RED" rated studies showed that the reasons for not achieving the target were: • 1 study, recruitment nationally was more difficult due to changes in treatment. VUNHST was one of the top recruiters for the study. • 1 study, rare cancer patient cohort of small numbers. Recruitment to study was more difficult than expected. • 1 study, sponsor organisation went into administration and recruitment to the study ceased two years earlier than planned.	Having met with HCRW, further work is underway to improve: • Datasets for HCRW Key Indicators and contribute to how these can be best presented to better represent Velindre's unique position in the research infrastructure in Wales. • How the narrative entered in the Local Portfolio Management System can give context and be better utiliised in presenting these measures.	Ongoing	

[3] NR = Not reported. The data was not reported in Q3 FY2022/23 due to concerns with the completeness and accuracy of the source data.

• 1 study, sponsor organisation closed the study to recruitment early having met national recruitment target early.			
Discussion of Issues	**Action Plan(s) to Improve Performance**	**Target Date**	
The HCRW Performance Dashboard does not clearly reflect where the stopping of recruitment to a research study is outside the control of VUNHST	Continue work with HCRW to improve how narrative in the Local Portfolio Management System can give context and be better utilised in presenting these measures	Ongoing	

3.2.4 C4 CLOSED: Percentage of Health and Care Research Wales Portfolio Commercially sponsored studies recruiting to target (VUNHST)

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:

- RED: % recruitment is < 100%
- GREEN: % recruitment ≥ 100%

Calculation

RAG rating = % recruitment

Where: % **recruitment** $= \frac{\text{total recruitment}}{\text{target recruitment}}$

Previous Financial Year	Overall		Current Financial Year	Quarter 1		Quarter 2		Quarter 3		Quarter 4	
	Red	83%		**Red**	-	**Red**	100%	**Red**	NR[4]	**Red**	50%
	Green	17%		**Green**	-	**Green**	0%	**Green**	NR[4]	**Green**	38%
	White	-		**White**	-	**White**	-	**White**	NR[4]	**White**	13%

Previously Identified Issues	Previous Action Plan(s) to Improve	Target Date	Status
The Health and Care Research Wales 2022/23 dataset included 10 studies (R = 4 studies, G = 3 studies, W = 1 study). A review of the 4 "RED" rated studies showed that the reasons for not achieving the target were: • 1 study, recruitment was more difficult than expected. VUNHST screened 13 patients for only 2 patients to be entered into the trial. • 1 study, recruitment was more difficult than expected. • 1 study, rare cancer patient cohort of small numbers. Recruitment to study was more difficult than expected. • 1 study, rare cancer patient cohort of small numbers. VUNHST planned to recruit 3 patients prior to closure in 2026. Sponsor closed the study three	Having met with HCRW, further work is underway to improve: • Datasets for HCRW Key Indicators and contribute to how these can be best presented to better represent Velindre's unique position in the research infrastructure in Wales. • How the narrative entered in the Local Portfolio Management System can give context and be better utiliised in presenting these measures.	Ongoing	

[4] NR = Not reported. The data was not reported in Q3 FY2022/23 due to concerns with the completeness and accuracy of the source data.

years earlier having met their global total of 900 patients, despite being a rare cancer.			
Discussion of Issues	**Action Plan(s) to Improve Performance**	**Target Date**	
The HCRW Performance Dashboard does not clearly reflect where the stopping of recruitment to a research study is outside the control of VUNHST	Continue work with HCRW to improve how narrative in the Local Portfolio Management System can give context and be better utilised in presenting these measures	Ongoing	

3.3 Local Performance Measures for Velindre University NHS Trust

3.3.1 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 (VUNHST)

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. **Note:** This measure only includes studies where the planned target is more than one participant per month (unless this has been achieved within 70 calendars days of site activation).				

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**	NR[5]	**Median days**	61

Previously Identified Issues	**Previous Action Plan(s) to Improve**	**Target Date**	**Status**
The Health and Care Research Wales 2022/23 dataset includes 1 study. This dataset only includes studies where the planned target is more than one participant per month (unless this has been achieved within 70 calendars days of site activation).	Having met with HCRW, further work is underway to improve: • Datasets for HCRW Key Indicators and contribute to how these can be best presented to better represent Velindre's unique position in the research infrastructure in Wales.	Ongoing	

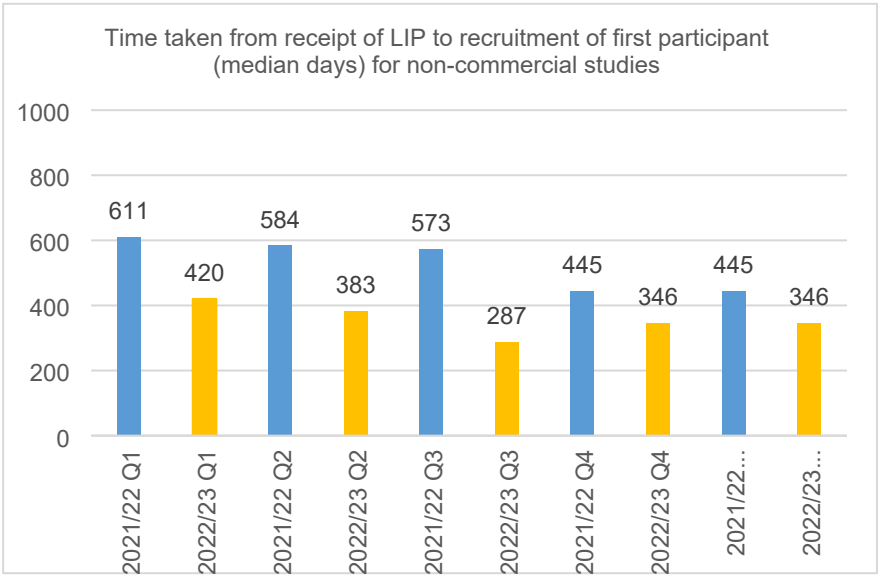
Discussion of Issues	**Action Plan(s) to Improve Performance**	**Target Date**
This dataset only includes studies where the planned target is more than one participant per month (unless this has been achieved within 70 calendars days of site activation). The "Blank" presented for Q1 and Q2 in the HCRW Performance Dashboard indicates that VUNHST did not have any studies that fit the criteria for inclusion in the HCRW dataset	Work described "Previous Action Plan(s) to Improve" above is underway	Ongoing

[5] NR = Not reported. The data was not reported in Q3 FY2022/23 due to concerns with the completeness and accuracy of the source data.

The following data is taken from the VUNHST study portfolio for non-commercial studies in financial year 2022/23.

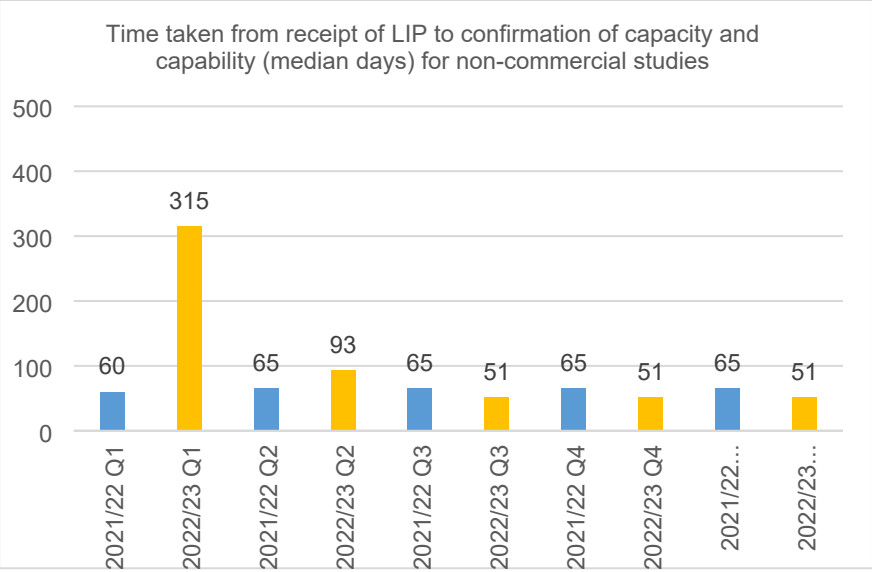
The data for time take from receipt of Local Information Pack to recruitment of first participants (median days) for all non-commercial studies is as follows:

FY	Q1	Q2	Q3	Q4	Overall	Range
2021/22	611	584	573	445	445	0 to 910
2022/23	420	383	287	346	346	61 to 894



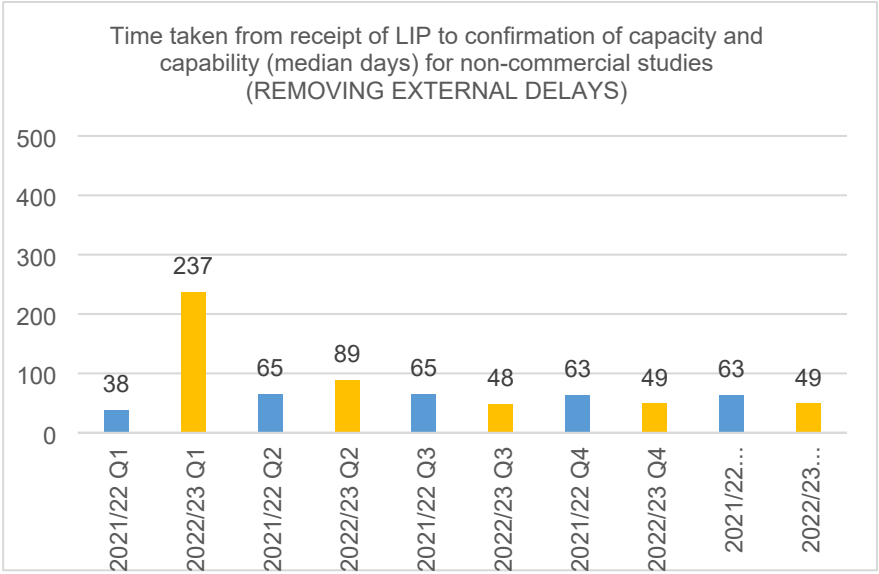
The data for time taken from receipt of Local Information Pack to Confirmation of Capacity and Capability (median days) for all non-commercial studies is as follows:

FY	Q1	Q2	Q3	Q4	Overall	Range
2021/22	60	65	65	65	65	0 to 427
2022/23	315	93	51	51	51	0 to 327



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	237	89	48	49	49	0 to 295



3.3.2 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 (VUNHST)

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:** This measure only includes studies where the planned target is more than one participant per month (unless this has been achieved within 70 calendars days of site activation).				

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**	NR[6]	**Median days**	57

Previously Identified Issues	Previous Action Plan(s) to Improve	Target Date	Status
The Health and Care Research Wales 2022/23 dataset includes 2 studies. This dataset only includes studies where the planned target is more than one participant per month (unless this has been achieved within 70 calendars days of site activation).	Having met with HCRW, further work is underway to improve: • Datasets for HCRW Key Indicators and contribute to how these can be best presented to better represent Velindre's unique position in the research infrastructure in Wales.	Ongoing	

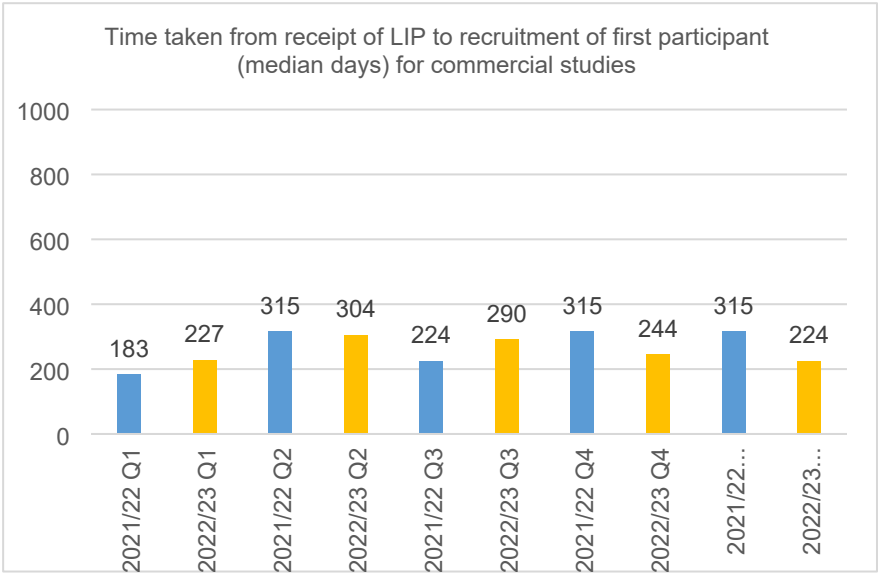
Discussion of Issues	Action Plan(s) to Improve Performance	Target Date
This dataset only includes studies where the planned target is more than one participant per month (unless this has been achieved within 70 calendars days of site activation). The "Blank" presented for Q1 and Q2 in the HCRW Performance Dashboard indicates that VUNHST did not have any studies that fit the criteria for inclusion in the HCRW dataset.	Work described "Previous Action Plan(s) to Improve" above is underway	Ongoing

[6] NR = Not reported. The data was not reported in Q3 FY2022/23 due to concerns with the completeness and accuracy of the source data.

The following data is taken from the VUNHST study portfolio for commercial studies in financial year 2022/23.

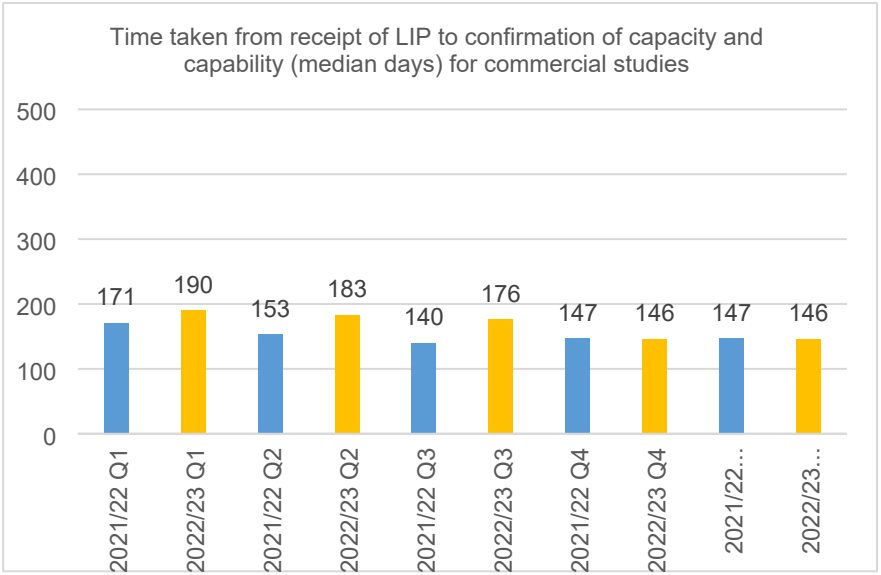
The data for time take from receipt of Local Information Pack to recruitment of first participants (median days) for all commercial studies is as follows:

FY	Q1	Q2	Q3	Q4	Overall	Range
2021/22	183	315	224	315	315	81 to 748
2022/23	227	304	290	244	224	43 to 933



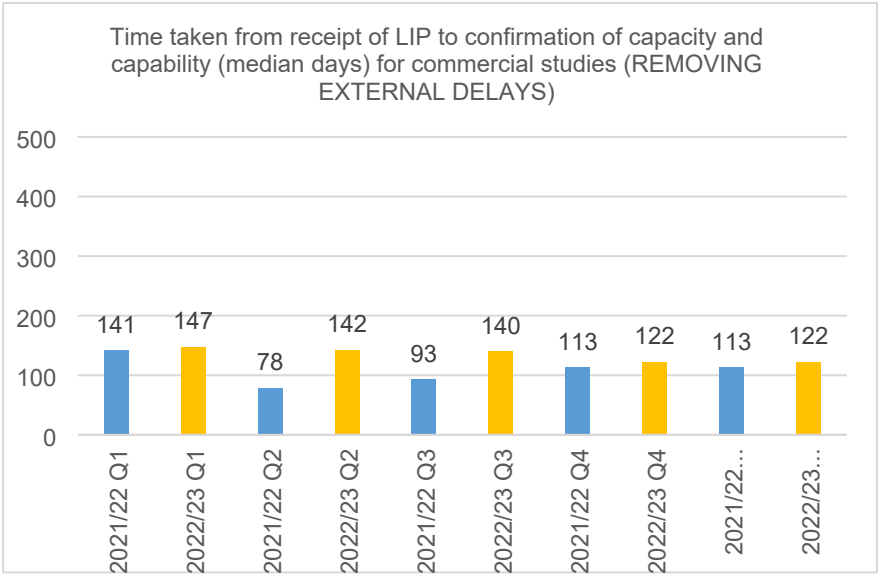
The data for time taken from receipt of Local Information Pack to Confirmation of Capacity and Capability (median days) for all commercial studies is as follows:

FY	Q1	Q2	Q3	Q4	Overall	Range
2021/22	171	153	140	147	147	56 to 469
2022/23	190	183	176	146	146	40 to 707



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	147	142	140	122	122	18 to 179



3.3.3 C5: Percentage of non-recruiting Health and Care Research Wales non-commercial Portfolio studies within NHS organisations (VUNHST)

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%	%	NR	%	10%

Previously Identified Issues	Previous Action Plan(s) to Improve	Target Date	Status
The Health and Care Research Wales 2022/23 dataset included 10 studies. A 10% Non-recruiting Health and Care Research Wales Portfolio studies represented 1 study where the Sponsor organisation closed the study to recruitment early having met national recruitment target early.	Having met with HCRW, further work is underway to improve: • Datasets for HCRW Key Indicators and contribute to how these can be best presented to better represent Velindre's unique position in the research infrastructure in Wales • Where study recruitment is outside the control VUNHST, how this information is captured in this measure .	Ongoing	

Discussion of Issues	Action Plan(s) to Improve Performance	Target Date
The HCRW Performance Dashboard does not clearly reflect where the stopping of recruitment to a research study is outside the control of VUNHST.	Work described "Previous Action Plan(s) to Improve" above is underway.	

3.3.4 C6: Percentage of non-recruiting Health and Care Research Wales Portfolio commercially sponsored studies within NHS organisations (VUNHST)

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%	%	NR	%	43%

Previously Identified Issues	Previous Action Plan(s) to Improve	Target Date	Status
The Health and Care Research Wales 2022/23 dataset included 7 studies. A 43% Non-recruiting Health and Care Research Wales Portfolio studies represented 3 studies where: • 1 study, Recruitment was more difficult than expected. • 1 study, Rare cancer patient cohort of small numbers. Recruitment to study was more difficult than expected. • 1 study, Rare cancer patient cohort of small numbers. VUNHST planned to recruit 3 patients prior to closure in 2026. Sponsor closed the study three years earlier having met their global total of 900 patients, despite being a rare cancer.	Having met with HCRW, further work is underway to improve: • Datasets for HCRW Key Indicators and contribute to how these can be best presented to better represent Velindre's unique position in the research infrastructure in Wales • Where study recruitment is outside the control VUNHST, how this information is captured in this measure .	Ongoing	

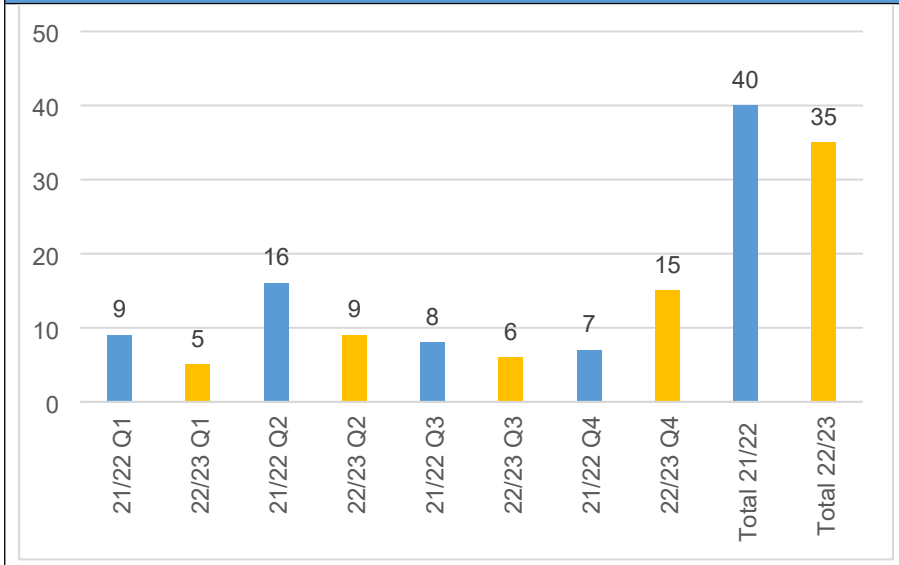
Discussion of Issues	Action Plan(s) to Improve Performance	Target Date

3.3.5 Number of studies opened (VUNHST)

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	6	15	35

Graph



Discussion

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.

The data shows that for financial year 2022/23 Velindre University NHS Trust opened 35 research studies, this is down 5 compared to the 40 opened research studies in the previous financial year 2021/22.

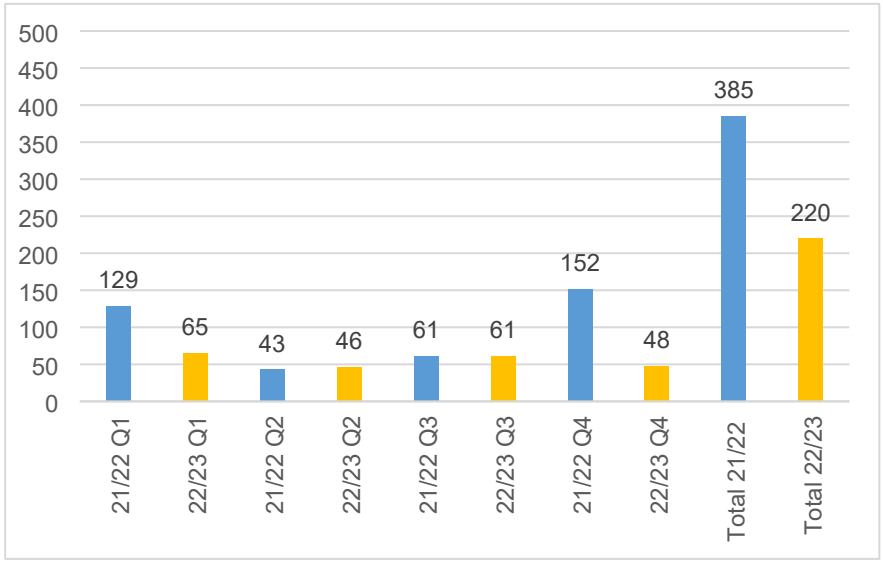
Despite a reduction in number of studies opened the income from research studies received by the Trust for FY2022/23 was £750K which is up from the income of £650K for FY2021/22.

3.3.6 Number of participants recruited into studies (VUNHST)

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		65	46	61	48	220

Graph



Discussion

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.

The data shows that for financial year 2022/23 Velindre University NHS Trust recruited 220 participants into research studies, this is down 165 patients compared to the 385 participants recruited to research studies in the previous financial year 2021/22.

The recruitment numbers of 129 and 152 in Q1 and Q4 of FY2021/22 results from retrospective data collection and observation studies.

Despite a reduction in number of participants recruited into research studies, the income from research studies received by the Trust for FY2022/23 was £750K which is up from the income of £650K for FY2021/22.

4 Velindre Cancer Centre hosted research – key achievements

4.1 FAKTION

Study Title: A phase 1b/2 randomised placebo-controlled trial of fulvestrant +/- AZD5363 in postmenopausaul women with advanced breast cancer previously treated with a third generation aromatase inhibitor.

Prof Rob Jones

Patients with incurable breast cancer could potentially benefit from new Welsh-led research, latest evidence suggests.

The research, carried out by Velindre University NHS Trust, in partnership with AstraZeneca and Cardiff University over 10 years was presented at the world renowned American Society of Clinical Oncology conference on 04 June 2022 in Chicago and published simultaneously in the prestigious Lancet Oncology journal.

The latest research builds on the 2019 FAKTION trial based on the use of capivasertib, an investigational breast cancer drug developed by AstraZeneca that blocks the activity of a protein called AKT that has been shown to contribute to resistance to hormone therapy. The 2019 research found that, by combining capivasertib with a standard hormonal treatment, in this instance fulvestrant, patients may expect their cancer to be controlled for more than 10 months rather than under five months with the current standard care.

New evidence from the FAKTION trial looks primarily at how long patients can expect to live for and if the genetic makeup of their cancer influences this.

Over half of patients in the trial were identified as having a specific mutation in their cancer specimen which activated the AKT pathway. Patients in this group who were treated with the combination of capivasertib and fulvestrant lived for around 39 months compared to 20 months if given fulvestrant and a placebo.

Professor Rob Jones, the Assistant Medical Director for Research at Velindre and Professor of Medical Oncology at Cardiff University, said: "***These new data are very exciting. Not only have we shown that capivasertib has the potential to give patients a very significant extension in their life-span, 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 3 trial which has already completed recruitment.***"

Professor Kieran Walshe, Director of Health and Care Research Wales said: "***It's encouraging to see these further results from the FAKTION study, which build on the previous findings and offer potential hope for millions of breast cancer patients. This partnership is a great example of the collaborative research taking place in Wales, which is aiming to make a real difference to people's lives.***"

The preliminary data from FAKTION which was reported three years ago triggered a larger Phase 3 trial called CAPItello 291 which aims to evaluate the potential benefit of capivasertib in combination with fulvestrant to prolong survival in ER+/HER2– advanced breast cancer patients.

4.2 SYMPLIFY

Study Title: Observational study to assess a multi-cancer early detection test in individuals referred with signs and symptoms of cancer

The SYMPLIFY study team collected the award for ***Innovation in early detection and diagnosis*** in the Pioneering Innovation category at the Moondance Cancer Awards 2022 on 16 June 2022.

L-R: *Jason Mohammad, Christopher Cotterill-Jones, Chris Norman, Sarah Townsend and Judi Rhys*

Judi Rhys, CEO of Tenovus Cancer Care presented the award and said "***This was a world class shortlist, with 6 fantastic nominations for us to consider but the panel did feel like one stood out …***"

Sarah Townsend, Health of Research & Development and Christopher Cotterill-Jones, Research Delivery Manager, along with a colleague from Health and Care Research Wales, accepted the award on behalf of all who took part in the SYMPLIFY study.

Dr Nicola Williams, Director of Support and Delivery at Health and Care Research Wales said: "***Congratulations to all the research staff in all health boards across Wales rolling out this study on an enormous scale, using the One Site Wales approach. SYMPLIFY is a brilliant example of how we can work together contributing to life-saving cancer research.***"

Sarah also took part in a MediWales Connects 2022 parallel session on 29 June 2022 discussing the Trust's experience in using and adapting the "One Site Wales" approach for delivery of the SYMPLIFY study.

The session looked at how a One Wales approach to research delivery that has allowed sponsors, researchers, NHS staff and patients to collaborate to achieve research excellence with tangible patient benefit throughout the COVID-19 pandemic. The delivery model has since been adapted and applied beyond the pandemic context, for example in cancer diagnostics and it continues to provide an ambitious blueprint for research delivery that meets the UK vision and reaches patients and participants throughout Wales, with each panel member gave feedback on their experiences of using the One Wales approach.

4.3 CHARIOT

STUDY TITLE: A Phase I does escalation safety study combining the ATR inhibitor VX-970 with chemoradiotherapy in oesophageal cancer using time to event continual reassessment method.

The sponsor nominated Dr Paul Shaw and his team for a special OCTO award. Awards are usually based on the organisation's core values of respect, integrity, collaboration, equality, and excellence.

The Sponsor provided the following reason for our nomination: "***we have been so impressed with the team's dedication to the study. It's always a treat to work with a team that is so diligent and that has been evident throughout the trial.***

The data team got a particular mention because you consistently had the lowest number of outstanding CRFs and data queries, and you have always been the most responsive of the sites we had on board."

Dr Paul Shaw

Dr Shaw's contribution to the CHARIOT trial had been noted as both a site Principal Investigator and an engaged member of the Trial Management Group. Dr Shaw's leadership has encouraged the site team to be highly engaged throughout and with everyone (clinical, research, pharmacy, and data teams) being responsive and communicative. The Sponsor's trial team at OCTO were delighted to be working with such a dedicated and hardworking team of individuals and thanked them for making running CHARIOT that much easier."

4.4 ONCOVID

STUDY TITLE: OnCovid - Natural history and outcomes of cancer patients during COVID19 epidemic.

The Trust supported the OnCovid: natural history and outcomes of cancer patients during the COVID19 epidemic study. The overarching purpose of this retrospective, non-interventional study is to describe the features of COVID-19 infection in cancer patients, investigate its severity in this population and evaluate long-term outcomes.

The trial findings highlighted a consistent reduction of COVID-19 severity in patients with breast cancer during the Omicron outbreak in Europe. The study also demonstrated that even in this population, a complete severe acute respiratory syndrome coronavirus 2 vaccination course is a strong determinant of improved morbidity and mortality from COVID-19.

The Trust's Research Nurse Team Lead, Amanda Jackson, and Head of Research Development, Sarah Townsend, have been listed as authors in a paper published in the Lancet Oncology journal. Amanda Jackson has also been listed in author in a paper published in Journal of Clinical Oncology.

Velindre were also recognised as a contributing organisation in a meeting abstract at the 2022 ASCO Annual Meeting.

4.5 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.

4.6 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 cardinomas (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.

4.7 FOXTROT

Study Title: Fluoropyrimidine Oxaliplatin & Targeted Receptor pre-operative therapy for colon cancer. A randomised trial assessing whether preoperative chemotherapy and/or an anti-EGFR monoclonal antibody improve outcome in high-risk operable colon cancer.

The FOxTROT trial was funded by Cancer Research UK and led from the Universities of Birmingham and Leeds. The trial involved patients from 85 hospitals across Europe, with Velindre University NHS Trust contributing 25 participants.

The trial found that patients with early-stage colon cancer benefit from six weeks of chemotherapy before surgery, cutting the risk of cancer returning within two years by 28%.

Associate Professor at the Birmingham Clinical Trials Unit at the University of Birmingham, Dr Laura Magill, said:
"Up to 1 in 3 colon cancer patients can see their cancer come back after surgery. That figure is far too high, and we need new treatment strategies to stop colon cancer coming back. The standard approach has been to give chemotherapy after surgery to eradicate any cancer cells that might have spread before surgery. But our research shows that giving some of that chemotherapy before surgery increases the chances that all cancer cells will be killed.

A growing body of evidence is showing the value of pre-operative chemotherapy in several other cancers, and we believe that our results could transform how we approach colon cancer in the clinic."

The study's results were published in the Journal of Clinical Oncology's article, "Preoperative chemotherapy for operable colon cancer: mature results of an international randomised controlled trial". The publication is available online at: https://ascopubs.org/doi/full/10.1200/JCO.22.00046

4.8 STAMPEDE

Study Title: Systemic Therapy in Advancing or Metastatic Prostate Cancer: Evaluation of Drug Efficacy

The STAMPEDE trial closed to recruitment in March 2023 having run for eighteen years and recruiting 11,992 participants, with 452 patients from Velindre, making this the largest trial ever completed in advanced prostate cancer.

STAMPEDE revolutionised the way that trials can be done, having incorporated ten primary research questions into one platform trial infrastructure and the data collected leading to the publication of a considerable number of articles across multiple journals. The findings have changed the standard of care four times for men living with prostate cancer with both cancer and survival outcomes being improved beyond initial expectations back in 2005.

Chief Investigator Nick James said:
"*It's been an honour and a pleasure to lead STAMPEDE from inception back in 2005 to final completion of recruitment today. Over the 18 years almost 12,000 men have taken part in the trial which has tested 10 different approaches to advanced prostate cancer and has led to multiple changes to the standard of care for men with the disease, extending typical survival times by many years. In addition, the design of the trial itself, a multi-arm platform which we have used to test all these different treatments is itself ground-breaking. Multi-arm platform trials have been used in a range of diseases including COVID as well as cancer. Linked to the trial is a tissue bank and an image bank collected from the biopsies and patient imaging. This is yielding invaluable insights into our understanding of*

the disease behaviour. This huge and unique resource will continue to improve our knowledge of the disease for many years. STAMPEDE will continue via a rebooted platform as STAMPEDE2, initially with three new comparisons"

4.9 First in the World and Europe

4.9.1 IO102-IO103

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)

This trial is investigating the efficacy of the drug IO102-IO103 in combination with pembrolizumab in the frontline treatment in each of the different metastatic solid tumour indications.

Velindre University NHS Trust was the first site worldwide to recruit a participant to the IO102-IO103-022 trial, which 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.

4.9.2 TROPION 03

Study Title: A Phase 3 Open-label, Randomised Study of Datopotamab Deruxtecan (Dato-DXd) With or Without Durvalumab Versus Investigator's Choice of Therapy in Patients With Stage I-III Triple-negative Breast Cancer Who Have Residual Invasive Disease in the Breast and/or Axillary Lymph Nodes at Surgical Resection Following Neoadjuvant Systemic Therapy

This trial is comparing datopotamab deruxtecan with chemotherapy for triple negative breast cancer patients without pathological complete response at the time of surgery following neoadjuvant therapy.

Velindre University NHS Trust was the first European site to randomise a patient into the study and were also the first site to open in the UK. Velindre is currently the top UK recruiter and 4th highest recruiter in the world.

4.10 Other news and study performance rankings

4.10.1 TROPION 02

Study Title: A Phase 3, Open-label, Randomised Study of Datopotamab Deruxtecan (Dato-DXd) Versus Investigator's Choice of Chemotherapy in Patients who are not

Candidates for PD-1/PD-L1 Inhibitor Therapy in First-line Locally Recurrent Inoperable or Metastatic Triple-negative Breast Cancer

This trial is comparing datopotamab deruxtecan with chemotherapy for triple negative breast cancer. It is open to people with triple negative breast cancer that:

- has come back in the same place and it cannot be removed by surgery
- or has spread to another part of the body

Velindre University NHS Trust was the first UK site to randomise a patient and are currently the UK's top recruiter.

4.10.2 CAPItello - 291

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.

4.10.3 OPTIMA

Study Title: Optimal Personalised Treatment of early breast cancer using Multi-parameter Analysis

OPTIMA is a study trying to find out if a test called Prosigna can effectively and safely identify whether a patient is likely to benefit from chemotherapy or not.

Velindre University NHS Trust was the second UK site to recruit 100 participants.

4.10.4 Study performance rankings

Ranking	Study Title	Summary
Top Worldwide Recruiter	IO102-IO103-022	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)

Ranking	Study Title	Summary
Top UK Recruiter and 4th Highest Worldwide Recruiter	Tropion 03	A Phase 3 Open-label, Randomised Study of Datopotamab Deruxtecan (Dato-DXd) With or Without Durvalumab Versus Investigator's Choice of Therapy in Patients With Stage I-III Triple-negative Breast Cancer Who Have Residual Invasive Disease in the Breast and/or Axillary Lymph Nodes at Surgical Resection Following Neoadjuvant Systemic Therapy
Top UK Recruiter	CAPItello - 291	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
Top UK Recruiter	Tropion 02	A Phase 3, Open-label, Randomised Study of Datopotamab Deruxtecan (Dato-DXd) Versus Investigator's Choice of Chemotherapy in Patients who are not Candidates for PD-1/PD-L1 Inhibitor Therapy in First-line Locally Recurrent Inoperable or Metastatic Triple-negative Breast Cancer
Top UK Recruiter	VALTIVE-1	Validation of tie2 as the first tumour vascular response biomarker for vegf inhibitors: optimising the design of a subsequent randomised discontinuation
2nd Highest UK Recruiter	CUPCOMP	Carcinoma of Unknown Primary Site (CUP): A comparison across tissue and liquid biomarkers
2nd Highest UK Recruiter	OPTIMA	Optimal Personalised Treatment of early breast cancer using Multi-parameter Analysis
Joint 2nd Highest UK Recruiter	CYPIDES	Safety and pharmacokinetics of ODM-208 in patients with metastatic castration-resistant prostate cancer II trial for patients with a poor early response using positron emission tomography (PET)
3rd Highest UK Recruiter	CONCORDE	A platform study of DNA damage response inhibitors in combination with conventional radiotherapy in non-small cell lung cancer
3rd Highest UK Recruiter	TRITON 3	A Multicenter, Randomized, Open-label Phase 3 Study of Rucaparib versus Physician's Choice of Therapy for Patients with Metastatic Castration-resistant Prostate Cancer Associated with Homologous Recombination Deficiency
Joint 3rd Highest UK Recruiter	Cardiac Care	A multicentre prospective randomised open-label blinded end-point controlled trial of high-sensitivity cardiac troponin I-guided combination angiotensin receptor blockade and beta blocker therapy to prevent cardiac toxicity in breast cancer patients receiving anthracycline adjuvant therapy.
Joint 3rd Highest UK Recruiter	ATLANTIS	An adaptive multi-arm phase II trial of maintenance targeted therapy after chemotherapy in metastatic urothelial cancer
Joint 4th Highest UK Recruiter	NET-02	A non-interventional, multicenter, multiple cohort study investigating the outcomes and safety of atezolizumab under real-world conditions in patients treated in routine clinical practice

Ranking	Study Title	Summary
5th Highest UK Recruiter	TRAP	Targeted Radiotherapy in Androgen-suppressed Prostate cancer patients

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

5.1 Radiotherapy research

5.1.1 Radiotherapy Trials Research Solutions

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.

A Radiotherapy Trials Research Solutions group has been established to review the situation, identify, and implement mitigation strategies to improve to improve the Radiotherapy service's capacity in terms of research studies and the wider service.

5.1.2 Radiotherapy Trial Portfolio Group (RT-TPG)

The Radiotherapy Trial Portfolio Group (RT-TPG) has been re-established to monitor the portfolio and Radiotherapy service position by bringing together required parties.

- **Communication** – the group continues to build communication and interaction between VCC research teams to improve the provision and delivery of both Radiotherapy and combination Drug/Radiotherapy clinical trial research.
- **Reporting** – Governance processes are being developed to improve accurate and timely reporting of operational and strategic issues to the Trust's R&D service and tri-partied Radiotherapy Management Group (RMG).
- **Radiotherapy Clinical Trial Risks** – The process for documenting Radiotherapy clinical trial risks and subsequent mitigating strategies is under review.
- **Assessment Tool** – The development of an assessment tool to aid evaluation of clinical trial requirements alongside the service position is in operation. Whilst this is multifaceted and complex, the purpose is to acknowledge the likelihood of successful study set-up prior to undertaking the feasibility process, helping to mitigate against increasing study timelines.

5.2 Oncacare

Having been introduced to the Trust in 2021 by WCRC, the Trust has signed a Letter of Intent and Confidentiality Agreement with Oncacare. The Letter of Intent contained Oncacare's offering to the Trust in the context of the NHS and its well-established four

nations systems and processes in the set-up of commercial clinical trials. The Trust has been leading on this initiative for Velindre University NHS Trust working with the research leads at Cardiff & Vale University Health Board to develop an agreement that will allow them to also establish a relationship with Oncacare.

Through Oncacare, Velindre will be offered studies with a guarantee of being a research site should the Trust decide these studies would be beneficial for our patients. This arrangement does not exclude the Trust from maintaining and developing its current relationships with Sponsors and other CROs and to manage delivery of its portfolio of commercial studies independent of Oncacare.

During 2022/23, in accordance with its ambition to seek and accelerate relationships with commercial organisations, the Trust's Head of R&D has:

- Sought to draft a Master Collaboration Agreement with input from NHS Wales Legal and Risk Services in readiness for the Trust's execution once agreed.
- Negotiated with Oncacare, the terms of a business plan, financial provisions and funding to support and deliver these and other studies.

This work is expected to conclude in financial year 2023/24, with the Trust executing an agreement with Oncacare.

STRATEGIC PRIORITY 2:
The Trust will maximise the Research & Development ambitions of the Welsh Blood Service

6 Advancing Kidney Transplant Treatments

We celebrate our colleague Felicity May completing her Higher Specialist Scientist Training after five years of study.

In 2020 Felicity embarked on the research phase by leading an NHS Research Study entitled “Development of a predictive biomarker profile to stratify the response of potential kidney recipients to antibody reduction and immune modulation (IRAS 292042).” This study investigated the response to desensitisation treatment in patients awaiting a kidney transplant.

Pictured: Felicity May, picking up patient samples from University Hospital of Wales.

Felicity conducted her research with academic support from the University of Manchester and in collaboration with the Nephrology and Transplant Department clinicians at the University Hospital of Wales, Cardiff. Later, we explain the clinical impact of this study.

This original research contribution to knowledge generation in healthcare science and satisfying the Royal College of Pathologists academic examinations led to Felicity being awarded her Doctorate of Clinical Science in February 2023.

Here we explain the importance of this research and how it can help patients with kidney disease.

6.1 Improving transplantation outcomes

On average, a patient waits over two years for a kidney transplant. There is a far greater demand for kidney transplants than available organ donors. Not every organ is safe for every patient. When a kidney becomes available for transplantation, many clinical and laboratory factors determine which patient receives the donated kidney.

Felicity investigated the immune system of kidney transplant patients to help address a significant inequity issue.

6.2 A barrier to successful transplantation

The immune system makes molecules called antibodies to help fight off illness. However, antibodies cause problems for potential transplant recipients because they can lead to the rejection of transplanted organs. Most patients on the transplant waiting list have high levels of antibodies. High antibody levels reduce the likelihood of successful transplantation. Patients with high antibody levels wait longer for a compatible organ or may never be eligible for a kidney transplant.

6.3 What can be done?

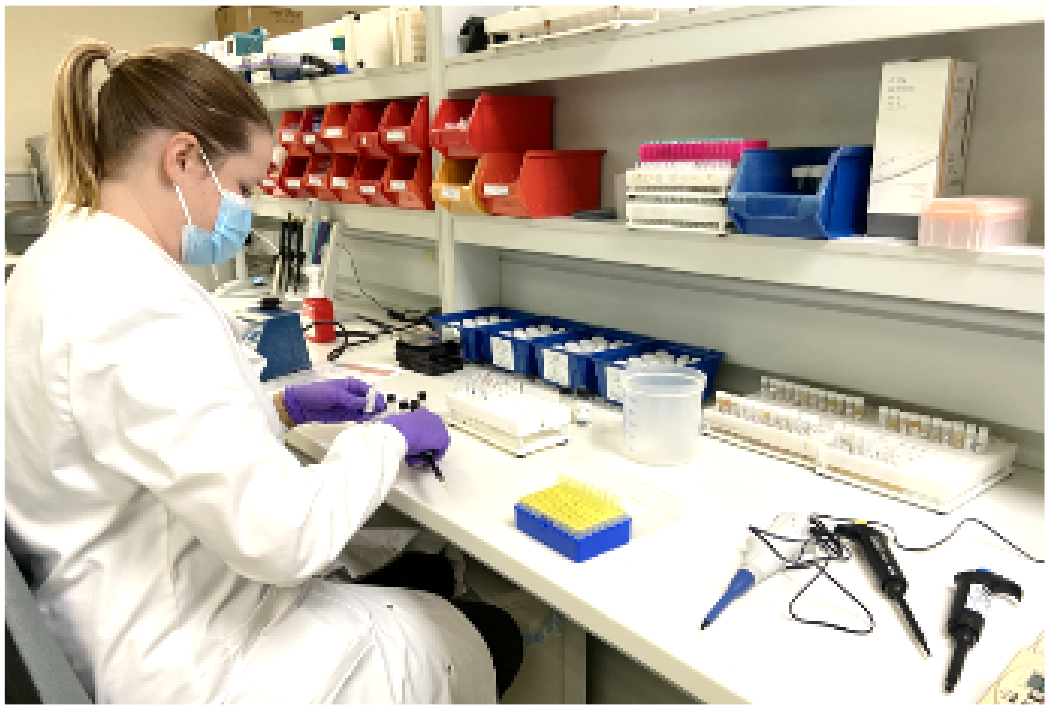
Treatments are available to reduce antibody levels in patients awaiting a kidney transplant. The treatment is desensitisation and allows patients to be successfully transplanted with otherwise ‘incompatible’ organs.

Desensitisation describes a range of treatments used to remove antibodies from donor patients. Some treatments target the cells that generate antibodies, and some target the antibodies themselves. However, desensitisation is not an effective treatment for all patients. The response to desensitisation treatment can vary. The treatment works effectively in some patients, but others do not respond as hoped.

Giving patients desensitisation treatment exposes them to unnecessary side effects if the treatment does not work. Due to this knowledge gap, clinicians cannot predict whether a transplant patient will respond to desensitisation treatment.

6.4 Felicity's Research Impact

Felicity designed and conducted a research project to address this knowledge gap. Felicity investigated twenty-seven transplant patients who underwent desensitisation treatment before transplantation. The research examined serum samples collected from patients at different time points before and after treatment. It is not possible to predict patient response to desensitisation treatment using antibodies alone. Therefore, Felicity looked at levels of cell signalling molecules, which have rarely been studied in transplant patients.

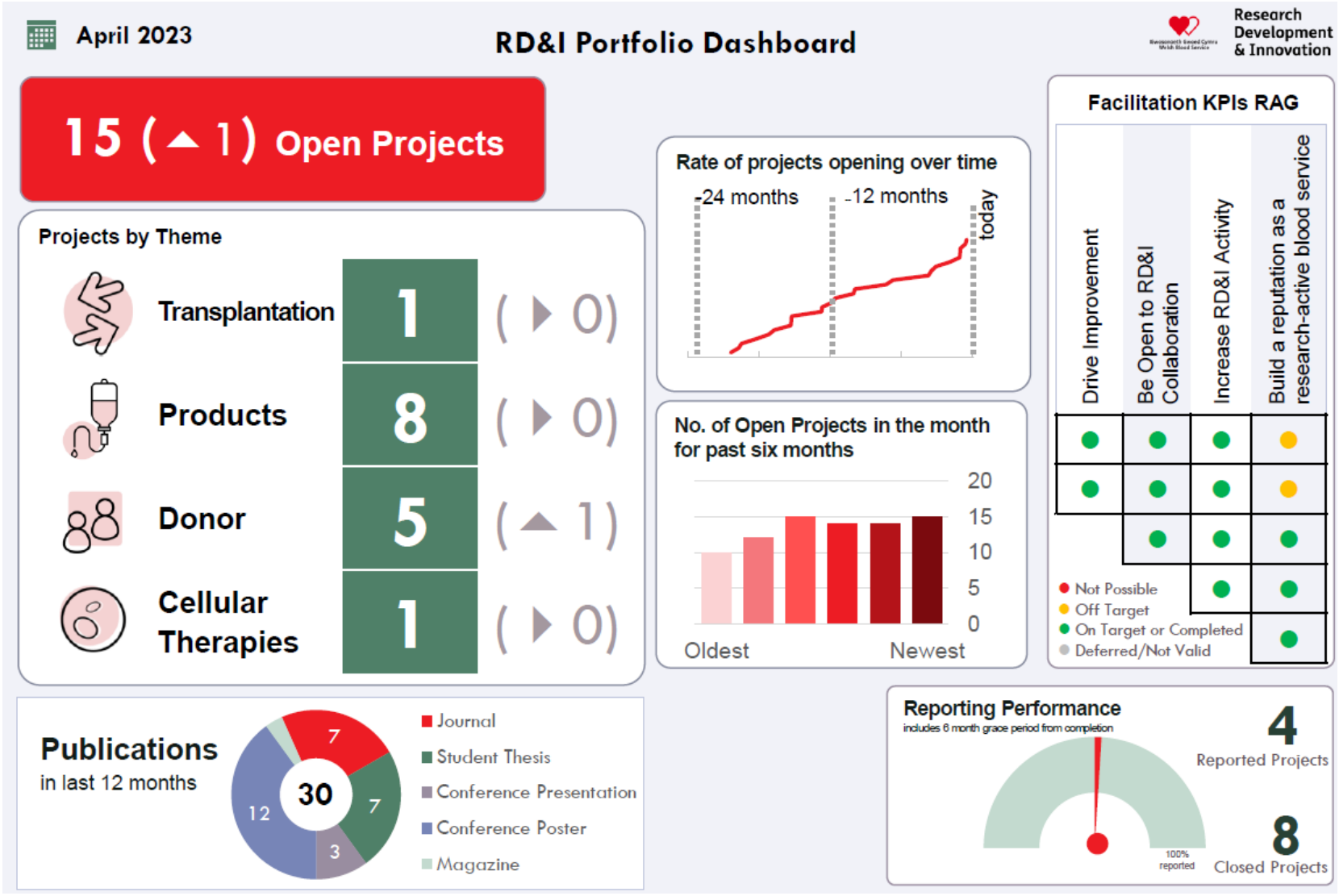


Pictured Testing in the WBS's Welsh Transplantation & Immunogenetics Laboratory

Felicity discovered some unintended effects of desensitisation treatment. In some patients, the treatment increased cell signalling for antibody production! This is a surprising discovery that needs further exploration.

Felicity's project is a step towards understanding why some transplant patients do not respond to desensitisation treatment. Felicity's research will aid further studies which hope to minimise unnecessary treatment for kidney transplant patients and inform alternative treatments.

7 Welsh Blood Service RD&I Dashboard



8 Open Projects Portfolio

The Welsh Blood Services RD&I Portfolio of open project as of 01 Jan 2023.

Project Name	WBS Project ID	WBS Research Theme	WBS Staff Lead	Involvement
Investigating the role of the bone marrow microenvironment in the pathogenesis of Acute Myeloid Leukaemia (AML)	96	Cellular Therapies	Emma Cook	NHS Research
Sero-surveillance for SARS-CoV-2 infection in blood donors in Wales	127	Donor	Sian James	WBS led RD&I
What donor contact method gives us the best return?	160	Donor	Kate Satherley	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
The use of legislation and regulation as a means of improving quality in public healthcare services	164	Donor	Peter Richardson	WBS led RD&I
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
Use of Global Haemostasis Assays for the Evaluation of Thawed Plasma for Clinical Use	166	Products	Michael Cahillane	WBS led RD&I
Use of Haemostasis Assays for the Evaluation of Five-Day Thawed Plasma for Clinical Use	167	Products	Elisabeth Davies	WBS led RD&I
Improving Platelet Storage (PhD Cardiff Metropolitan University)	168	Products	Christine Saunders	WBS led RD&I
The effect of digital technology on blood donor engagement and its impact on levels of engagement in South Wales	169	Donor Care & Public Health	Andrew Paramore	WBS led RD&I
Cold Stored Platelets for Pre-Hospital Emergency Resuscitation (CoPPER): Laboratory Testing	170	Products	Jamie Nash	WBS led RD&I
Service Support of the Role of donor derived cell free DNA (DD cfDNA), islet derived exosomes and proinsulin in diagnosing pancreas graft acute rejection (EMPAR) study	171	Transplantation	Emma Burrows	The WBS support of others RD&I

Project Name	WBS Project ID	WBS Research Theme	WBS Staff Lead	Involvement
Effect of mixing on the quality of red cells at time expiry	172	Products	Nicola Pearce	WBS led RD&I
Established a reliable and sustainable blood donation and blood quality system to support the nationalization of manufacturing of plasma fractionation in the Kingdom of Saudi Arabia (IRAS: 271608)	173	Donor Care & Public Health	Edwin Massey	NHS Research

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

The Welsh Blood Services BEST-C as of 01 Apr 2023.

Project Name	WBS Project ID	WBS Research Theme	WBS Staff Lead
BEST-C 142 Project: A comparison of anti-D titres using gel and tube technologies	157	Products	Chloe George

9 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	✔	✔	✔	✔	✔	✔	✔	✔	⚠	⚠	⚠	✔
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.	✔		Refreshed annual	✔	⚠	⚠	✔	✔	✔	✔	✔	✔	✔	✔	✔

Increase RD&I Activity						A	M	J	J	A	S	O	N	D	J	F	M
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.	✔			✔	✔	✔	✔	✔	✔	✔	✔	✔	✔	✔	✔
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						A	M	J	J	A	S	O	N	D	J	F	M
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 disseminatio n activity (e.g., conference proceedings/ publication) for every completed WBS–led RD&I project			100% of WBS-led projects need to demonstr ate how they have achieved this dissemin ation 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 complete d RD&I projects achieve a peer-reviewed publicati on	✔	⚠	✔	✔	⚠	✔	✔	✔	✔	⚠	⚠	⚠
Build a reputation as a research-active blood service	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	✔	✔	✔	✔	✔	✔	✔	✔	✔	✔	⚠	⚠

Measuring and defining Progress and Success	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	✔	✔	✔	✔	✔	✔	✔	✔	✔	✔	✔	✔
Measuring and defining Progress and Success	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

10 RITA – a Chatbot powered by Artificial Intelligence

RITA has now been deployed successfully on the Trust website since February 2023, both on the Velindre Cancer Centre main page and the dedicated RITA Project page. Performance measures and usage data are continuing to be collected to measure the number of users compared to the soft launch figures and calculate the average number of users per month (currently at 29). Analytics show the current most popular areas of questioning relate to support, facilities, department locations and definitions of medical terminology. The RITA project team meets weekly to review performance, make amendments to any questions not answered and update content as needed.

The ”Plus” package provided by IBM is due for renewal in June 2023 and the Innovation Project Manager is currently in discussion with both the innovation and IBM team to evaluate whether another year should be purchased.

10.1 RITA – “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. Velindre 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 in October 2022 having filmed 38 clinicians. There is a further one and half day’s filming left to cover all internal footage of VCC departments and external drone footage of the site.

We have now received all the clips from the production company and will be integrating them into RITA over the coming weeks, while also being utilised as separate media on the Trust website and the BYS Localisation project, giving patients the opportunity to view clinical areas and the site before attending.

11 ByYourSide – Localising Pfizer’s Global Patient Cancer App

The Patient Solutions Team at Pfizer were 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. 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.

Phase 2 Proposal
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 Velindre Cancer Centre patients during the initial workshops and make the app available to all our service users.

Successful implementation of this Phase will provide Velindre with a ready-made patient app that has centralised, and localised information pulled directly from the Trust website, available to our users within its own 'My Centre' section. Velindre will be the first Trust in the UK to have this feature available to our patients.

The Innovation Project Manager presented this proposal to the EMB on 20th February 2023 and received a positive outcome to pursue contracting for the next phase. A working project team is currently being formed to evaluate content options, while a DPIA is in the process of being completed to ensure the correct governance procedures are followed prior to launch.

12 Workforce Innovation & Research Survey

Research and innovation are vital parts of improving Cancer services at Velindre University NHS Trust. The Trust therefore strive to improve the Research, Development & Innovation service, to support clinical teams in advancing their professional areas of care.

The Innovation Team have produced a short survey as a baseline to assess innovation understanding and uptake of innovation and research projects within Velindre. This has been disseminated to Velindre Cancer Centre staff in the hope that will also help us understand what their needs and understanding are, in terms of education and support in becoming involved in Research, Development & Innovation to the benefit of our patients.

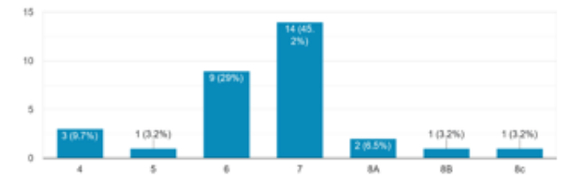
The survey saw 31 responses to the online survey – the results can be seen here:

Nurse, AHP and Clinical Scientists Staff Research & Innovation Survey

Response Summary

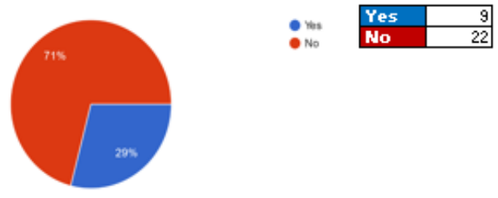
Band

31 responses



Undertaking a higher degree

31 responses

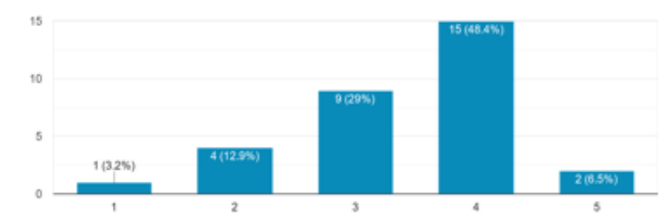


Yes	9
No	22

Department	Numbe
Nursing	5
Therapies	6
Radiographe	2
Administrati	1
ANP	2
Clinical Scie	4
Manager	1

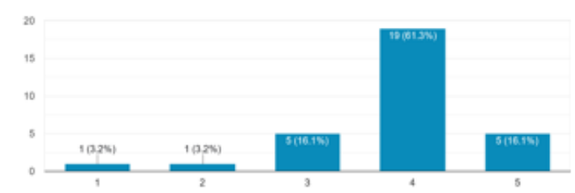
How well does your organisation understand and prioritise research and innovation?

31 responses



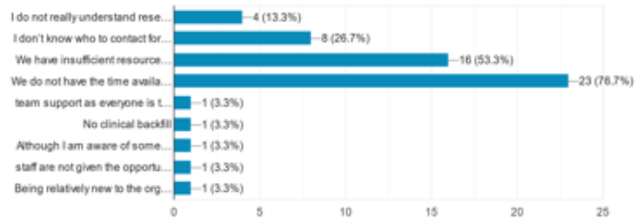
How well do you understand research and innovation?

31 responses



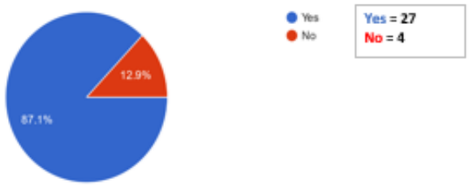
What are the biggest challenges you face with respect to research and innovation? please tick all that apply

30 responses



Have you ever participated (or do you plan to participate) in Research or Innovation in your current role?

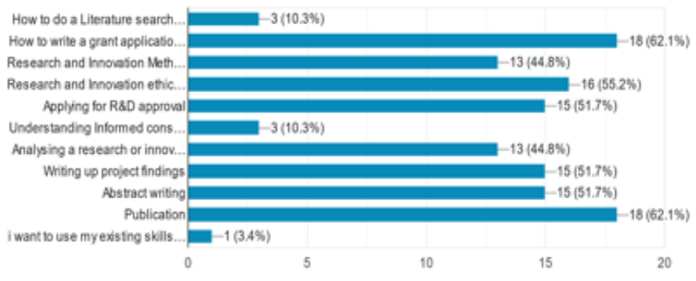
31 responses



Yes = 27
No = 4

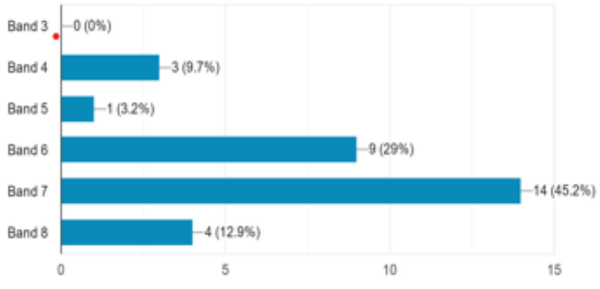
What are your educational & training needs to become involved in research and innovations Tick all that apply

29 responses



What do you think your role is in research and innovation? Please select your band first:

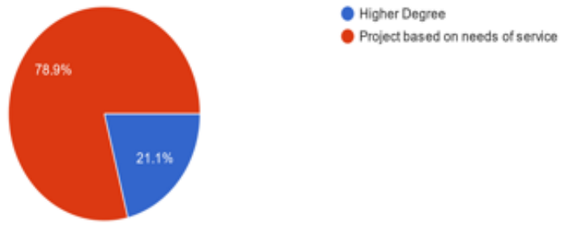
31 responses



Supporting others to carry this out / cascade information / embark on RD&I myself
I feel it is a key part of my role, both as a clinician and clinical lead for the service.
participate in sponsored studies. participation in SST IT / digital project
I should be involved in the development of service and innovation with new evidence that comes out. I believe I should play an active part in team research, but that my Band 7 would typically be the leader for this, unless delegated
Promotion and looking for ways to improve
it is one of the four pillars of practice and is vital to supporting evidenced based care
To progress innovation within the service to ensure up to date treatments and side effect management
To develop, take part in and lead true research and innovation projects within Radiotherapy at Velindre.
participate and promote research activities withing RT
Senior member of treatment planning section, so supporting developments as assigned. Recent focus on Non-Medical Target definition and associated / wider arena of workforce development and advanced clinical
Proposing and supervising research projects.
To provide practical experience and expertise in the development of new projects and their incorporation into clinical practice.
to lead and promote participation in both
to contribute ideas/ provide feedback
MY role is entirely involved in research
One of the 4 Pillars of Practice which is essential for my Advanced Practice role
Promotion, conducting research and innovation
I think research and innovation should transcend roles as we all have ideas and new ways of approaching projects, or seeing gaps in services.
supporting and encouraging junior staff to explore their own questions/ VCC service needs/ patients needs
Don?t really understand the previous question
providing an effective change in service, measuring the effectiveness with robust data, analysing it and presenting it

Please state whether part of a higher degree or purely a project based on the needs of the service

19 responses



	4
	15

13 Pan-Wales patient centred Radiotherapy Services for Advanced Cancer Symptoms

With the current difficulties in delivering radiotherapy for advance cancer and with increasing demand coupled with a worsening workforce crisis in clinical oncology, Consultant Oncologist Mick Button and Radiotherapy Planning Radiographer, Steven Hill are undertaking a Bevan Commission project through the Planned Care Innovation Programme (PCIP) to improve the Palliative Radiotherapy pathway.

The vision is to deliver a high-quality, sustainable, efficient service for patients needing radiotherapy for cancer symptom control – wherever in Wales they live.

This has 3 components:

- High-quality clinical care
- High-quality communication and decision making
- High-quality training

Across Wales, roughly 150 patients a month have radiotherapy with the aim of urgently minimising their cancer symptoms and improving their quality of life. This is over a quarter of all radiotherapy courses delivered.

Currently, patients needing such radiotherapy can only be seen and assessed by senior clinical oncologists, who also are required to plan and prescribe the treatments. It requires multiple pre-arranged hospital visits (clinical assessment, CT planning and then treatment) – but is usually a very effective, well-tolerated and cost-effective way of improving patients' quality of life and reducing symptoms due to advanced cancer.

The project is drawing to a close and a hybrid showcase event was held at the National Imaging Academy Wales on 3rd May 2023, with representatives from across all 3 cancer centres presenting their work along with contributions from Canada and the Clatterbridge. This event saw 50 in-person and 15 online attendees, with the roundtable discussion resulting in an agreement to develop more detail about the way forward, working with attendees at a future date to produce a national proposal with locally developed detail prior to September 2023.

13.1 ACTAH Project

Due to an approach by a C&V emergency medicines consultant, Velindre has initiated the ACTAH project with the goal of developing a new service that utilises home visits to manage acute oncology patients experiencing an acute episode in collaboration with Cardiff and Vale Health Board. Management in this way could help prevent unnecessary hospital admissions and there is a particular focus on avoiding A&E admissions if it is safe to do so. Furthermore, the ACTAH project aims to manage these cancer patients with

acute issues in the community for better experience and outcomes. For the initial pilot deployment, this will be rolled out in the Cardiff area only.

Objectives:

1. Reduce admissions to VCC and A&E & DGH.
2. Treating oncology patients at home if it is safe to do so.
3. Subsequent continued care of the patient at home if safe.
4. For patients that will require admission, stabilise at home and arrange the most appropriate admission pathway.
5. Create better experiences and outcomes for patients with acute episodes.

We are in the very early stages of this project, with a preliminary meeting taking place to discuss clinical leads for the project and identify pathways. A subsequent meeting is due to be held at the Life Sciences Hub in the coming weeks.

14 Welsh Blood Service (WBS) Drone Project

The purpose of this foundation study is to:

- establish the potential for drone-based delivery services to support the Welsh NHS, including specific use cases for the Welsh Blood Service.
- test the basic premise with the Civil Aviation Authority
- identify the roadmap and critical tasks that will allow us to realise the longer-term vision.

The organisations involved in this partnership are the Welsh Ambulance Service NHS Trust (WAST), The Welsh Blood Service (WBS), Snowdonia Aerospace (SAC) SLiNKTECH Ltd. (SLiNK), The Welsh Air Ambulance and the Welsh Emergency Medical Retrieval and Transfer service (EMRTS), collectively referred to as the Welsh Health Drone Innovation Partnership.

Following completion of a requirements gathering exercise and an initial assessment of the clinical, technical, and regulatory feasibility, a report is available, and will be shared with a wider group of senior stakeholders with a view to arranging a launch event in the Spring of 2023.

In the meantime, given the success of the foundation study a further application for funding support to explore a proof of concept of Beyond Visual Line of Sight (BVLS) drone flights is being prepared for the Welsh Government Innovation team to consider by the above partnership.

15 Regional Innovation Coordination Hubs (RICH)

The Velindre Research, Innovation, Improvement Coordinating (RIIC) Hub has helped to raise the profile and the importance of RD&I within and without the Trust and has had a

significant impact on the development of innovation infrastructure. This is reflected in the Velindre University NHS Trust's new ten-year Strategy that fully aligns with the principles set out in 'A Healthier Wales' (AHW). Importantly the Trust's strategic goal 3 is to be "a beacon for research, development and innovation in our stated areas of priority."

Through partnership working, the Trust is committed to building its national and international reputation through the successful development and delivery of a high impact RD&I activity that:

- Delivers the best possible interventions that improve survival and enhance the lives of patients who will remain, "at the centre of all that we do."
- Attracts and retains the best staff and make RD&I a core part of their roles.

The Trust's new Strategic Goal 4 also supports the previous RIIC ambitions to be an established 'University' Trust which provides highly valued knowledge and learning for all.

The work of the RIIC hub is facilitated in Velindre by the organisational structure aligning research, development, and innovation into one division, led by the Executive Medical Director. During year 3 of the RIIC Hub, an integrated quarterly report has been developed that comprehensively covers the whole Trust, including the Cancer Centre and Welsh Blood Service.

The significant achievements of the hub include:

- Developing a strong collaborative network with the other Trusts through fortnightly meetings. Developing key themes to launch collaborative projects.
- Contributing to the All-Wales RIIC Network
- Supporting developments across RD&I, including the:
    - Cardiff Cancer Research Hub and programme
    - New Cancer Hospital including the combined learning and Innovation centre – supporting the ambition to develop the smartest and greenest hospital in the country. This is part of an ambitious Regional Cancer Transformation Programme
    - New component lab in WBS
    - Healthcare Professionals R&I portfolio
    - New innovation infrastructure and plan

Despite the continuing implementation of Covid restrictions and the pressure this creates, particularly on clinical staff, the Velindre RIIC hub has provided much needed capacity funding to raise the profile of R&I and importantly develop the infrastructure for innovation with the refocus to Regional Innovation Coordination (RIC) Hubs. The refocus of the RIIC hubs in this 4th year will help to strengthen innovation to deliver higher impact collaborative projects.

STRATEGIC PRIORITY 4:
The Trust will maximise collaborative opportunities locally, nationally & internationally

16 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 Financial Year 2022/23, the Trust sponsored research portfolio is as follows:

Metric Description	Year to date
Number of new sponsored research studies (Total)	1
• 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	7

Metric Description	Year to date
Number of publications from sponsored research studies	10
• Journal article	2
• Abstracts	8
Number of participants recruited to sponsored research studies	231

17 Service improvement recognition at Welsh Blood Service

The Welsh Blood Service RD&I Facilitation Team has been awarded a Spotlight on Service Improvement Bronze Award, recognising their implementation of Microsoft Power Platform into business processes.

An electronic form has been developed to record Publication requests and authorisation, replacing the previous paper-based method. The automation allows proposal manuscript capture, approver's notification and review outcome, and integration with Microsoft Office and SharePoint suite. The programming then tailors the process based on submitted responses leading to a streamlined approval.

The award reflects the implementation of a modern, efficient operation and recommends that colleagues using paper-based processes for internal approvals consider moving to this innovation.

18 Enabling patients with haemochromatosis to donate their blood

The Blood Health Team of the Welsh Blood Service have placed the initiative to enable Haemochromatosis patients to be treated via blood donation has been successfully included in the Bevan Commission's Bevan Exemplar Programme.

Haemochromatosis is an inherited condition where iron levels in the body slowly build up over many years. This build-up of iron, known as iron overload, can cause unpleasant symptoms. If it is not treated, this can damage parts of the body such as the liver, joints, pancreas and heart.

Treatment is regular venesection, which removes one unit of whole blood. Currently, most Haemochromatosis patients in Wales are treated by their NHS Health Boards, where units of blood are disposed of. However, blood from the venesection procedure can be utilised for donation by the Welsh Blood Service, as venesection and blood donation are similar medical procedures.

This 'Enabling patients with Haemochromatosis to donate their blood' project has been designed to offer an accessible and equitable service to patients with Haemochromatosis by standardising and optimising the referral pathways into blood donation at the WBS. This aim aligns with the strategic objectives of the Welsh Government's Blood Health Plan, which is to improve general blood health.

Considering an ongoing national blood stock shortage and in line with prudent healthcare benefits, WBS and NHS Wales organisations offer resilience to the blood supply chain, reduced clinical healthcare spending, and a sense of altruism for the Haemochromatosis patients.

The project will be led by Elisabeth Davies, a Clinical Scientist at WBS through its Blood Health Team. The project encompasses the education of Healthcare Professionals (HCPs) on patient empowerment, establishing standards in 'All Wales' clinical referral pathways and influencing donation clinic planning in WBS.

This project continues through 2023 in to early 2024.

CROSS CUTTING THEMES:
across Strategic Priorities 1 to 4

19 Cross-cutting themes: progress

Cross-cutting themes across Strategic Priorities 1 to 4.													
	FY2022/23				FY2023/24				FY2024/25				
Key Deliverables / Objectives	**Q1**	**Q2**	**Q3**	**Q4**	**Q1**	**Q2**	**Q3**	**Q4**	**Q1**	**Q2**	**Q3**	**Q4**	**Progress / Comments**
• The implementation of programmes, complementing existing training opportunities that enable and support Trust staff to develop, deliver and manage research portfolios													
○ 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.			x										**Training Programme & Opportunities** This work is an ongoing improvement of the RD&I Division's service. Work continues to develop and implement a R&D/Trials training programme draws upon: • Trust developed internal training • Training developed by other research partners and organisations such as Health and Care Research Wales • Training from specialist non-commercial and commercial training providers • to support Trust staff to develop, set-up and deliver, and manage portfolios of clinical trials/research studies.
○ Complete the implementation of a programme that enables Trust staff to develop, deliver and manage research portfolios								x					
○ Ongoing review and improvement of the programme that enables Trust staff to develop, deliver and manage research portfolios.												x	
• Further investment in the research delivery and governance teams to make sure that studies are optimised to facilitate effective and timely recruitment and delivery													
○ Continue the development and implementation of staffing plans for the research delivery and governance teams (identified in 2021/22) to facilitate effective and timely recruitment and delivery.	x												**Reorganisation of Trust Research Delivery team** This work is an ongoing improvement of the RD&I Division's service. Work continues to keep under review and consolidate proposals and implementation of changes to the
○ Complete the appointment of senior staff in the research delivery team and to support the delivery of the Cardiff Cancer Research Hub		x											

Cross-cutting themes across Strategic Priorities 1 to 4.													
	FY2022/23				FY2023/24				FY2024/25				
Key Deliverables / Objectives	**Q1**	**Q2**	**Q3**	**Q4**	**Q1**	**Q2**	**Q3**	**Q4**	**Q1**	**Q2**	**Q3**	**Q4**	**Progress / Comments**
○ Complete the implementation of changes to the structure of the research delivery team administrative structure.			x										structure of the research set-up and delivery team structure.
○ Keep under review the investment in the research delivery and governance teams supporting research studies, identifying target investment areas as appropriate.					x	x	x	x	x	x	x	x	
• The development and implementation of clinical information systems to identify donors/patients eligible to take part in research studies													
○ Complete the R&D contribution to the Trust's implementation of the Digital Health & Care Record in line with the Trust's project schedule.		x											**Delivery of the Digital Health and Care Record system** Having contributed to the Trust's implementation of the Digital Health & Care Record programme, implemented in November 2022, continue to keep under review the input of, and use of information, making recommendations for improvement as appropriate.
○ Complete a review of clinical information systems available (in conjunction with partner stakeholders, i.e., DHCW and HCRW) to identify research study participants.				x									
○ Complete the implementation of a clinical information system that identifies donors/patients eligible to take part in research studies.					x	x	x	x					

CORPORATE

20 RD&I Finances

20.1 Background / context

The RD&I Division manages all income and expenditure relating to the R&D Office, Research Nursing Delivery Teams, Early Phase Team, Innovation Team and administrative staff such as Trials Coordinators and Data Managers. Along with a significant number of individual project and trial budgets, this comprises most of the Trust's research and innovation activity and is the subject of this finance report. Outside of this report are those staff managed outside the RD&I Division, e.g., pharmacy and radiotherapy research staff, who are reported as part of the relevant Divisional reports (e.g., VCC).

For 2022/23 the overall RD&I Financial Plan comprised targets to:

- **Spend £3.6m on research activities**, of which most (80%, £2.9m) is salary costs, including:
  - Management, trial support, data, and administrative staff (35%)
  - Nursing staff (28%)
  - Medical staff (10%)

- **Secure income of £3.7m** from multiple sources, most significantly:
  - Health & Care Research Wales (30%)
  - Reimbursements from commercial clinical trials (20%)
  - Support from the Velindre charity (19%)
  - Funding for trials where Velindre is the lead sponsor (13%)

20.2 Summary of Performance against Key Financial Targets

20.2.1 Key Financial Target 1: to remain within budget expectations

Key financial performance figures for Quarter 4 and the Outturn for the year are summarised in the following table:

		£000			
		Pay	Non-Pay	Income	Total Variance
Quarter 4	Budget	862	65	1,573	
	Actual	703	175	1,527	
	Variance	**-159**	**110**	**46**	**-3**
Full Year Outturn	Budget	2,865	700	3,713	
	Actual	2,576	827	3,556	
	Variance	**-288**	**127**	**157**	**-4**

20.2.2 Analysis of Performance in Quarter 4 and End of Year Outturn

Performance through the fourth quarter has been in line with the Budget Plan, with a £3k positive overall variance being recorded. Within that total figure are some notable trends, where the main features are:

- higher than expected vacancies due to staff turnover, maternity and difficulties recruiting to posts has meant a further underspend on pay costs, adding a further £159k underspend to the total; and
- in turn, this has allowed the Division to:
    - reduce the expectation of income from sources such as Velindre Charitable Funds, as well as:
    - undertake some limited investment activities, including replacement of minor equipment, support for staff attendance to present Velindre research papers at conferences, and providing support for research sites where Velindre is the lead Sponsor.

Once all income and expenditure was fully accounted for, **the outturn for the Division was a minor variance of £4k underspent for the year**. This followed the same pattern in each quarter, with significant staff underspends due to vacancies, maternity leave etc. meaning that income expectations from sources such as the Velindre Charity could be reduced, and non-pay expenditure could be increased where justified to do so.

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

In the year, 50 out of 468 invoices missed the 30-day payment target, which meant the overall target was missed. This was mainly due to the unusual situation in RD&I where patient research records need to be investigated by the research team before confirming invoices can be paid for support services such as pathology and imaging. For 2023/24 a R&D Office project will determine whether this process can be streamlined further within RD&I.

	Quarter 4	Outturn
NHS Invoices	78%	91%
Non-NHS Invoices	87%	89%

20.2.4 Pay Analysis by Staff Group

	2022/23 Outturn		
	£288k less than budget		
PAY GROUP	Budget (£'000)	Actual (£'000)	Variance (£'000)
Professional Scientific & Technical	0	0	0
Additional Clinical Services	82	81	-1
Administrative & Clerical	1195	1088	-107
Allied Health Professionals	53	52	0
Healthcare Scientists	160	176	17
Medical	363	363	0
Nursing	1040	815	-225
Vacancy Factor	-27	0	28
Total	2,865	2,576	**-288**

Pay expenditure was 90% of the planned budget. Underspends, particularly in the nursing and administration teams, were due to a mixture of factors including staff turnover, long term sickness, maternity leave, internal secondments of staff moving to VCC temporarily, as well as from longer than usual vacancy periods due to the ongoing challenges being experienced of recruiting staff into roles.

20.2.5 Non-Pay Analysis by Category

	2022/23 Outturn		
	£127k more than budget		
NON-PAY CATEGORY	Budget (£'000)	Actual (£'000)	Variance (£'000)
Clinical/General Services/Supplies	680	720	**40**
Maintenance & Repairs	0	1	**1**
Transport (inc. patients)	0	11	**11**
Printing / Stationary / Postage	0	28	**28**
Travel & Subsistence	1	21	**20**
Education & Development	0	17	**17**
Equipment & Consumables	0	8	**8**
Computer Maintenance & Supplies	19	21	**3**
Total	700	827	**127**

The Division holds modest non-pay budgets, with £473k (68%) of the total in the table above relating to sponsored studies where VUNHST is the lead and funding is distributed to other participating organisations. Key expenditure is on contracts for clinical services such as cardiology and pathology services needed to support research, as well as expenditure to support research staff with training and the running costs of a department with furniture and equipment.

20.2.6 Income Analysis by Category

	2022/23 Outturn		
	£157k less than budget		
INCOME CATEGORY	Budget (£'000)	Actual (£'000)	Variance (£'000)
HCRW Income	-1,048	-1,098	**-50**
Trial Reimbursements	-734	-688	**46**
Charitable Income	-931	-691	**241**
Innovation Income	-189	-194	**-5**
Sponsored Study Income	-473	-473	**0**
Other Income	-338	-412	**-74**
Total	-3,713	-3,556	**157**

Income recovery has proceeded largely to plan through the year except for deliberate reductions, e.g., in charity funding requirements. Trial reimbursements were modestly (£46k) below plan, which had been set a stretch target (increase of £100k) from the previous year. A small excess of income was received from HCRW (£50k), however this related to a change in the funding mechanism for pay awards. Innovation secured significant funding as planned from Welsh Government's RICH Hub funding (£56k), as well as the Cardiff University Accelerate programme (£121k) before it closed, which funded the Rita chatbot programme and the staff who worked on it.

Appendix A: Publications

A1. Velindre Cancer Centre

BREAST

Articles

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C1. Nursing & Interdisciplinary Research

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Semedo L, Coles B, Hopkinson J (In review) The contribution of the family carer to cancer treatment adherence in ambulatory settings: A systematic review and thematic synthesis.

Invited Presentations

Hopkinson J. Nurse-led holistic multimodal care for cancer cachexia. 2023.
Japanese Society for Palliative Medicine, Kobe, Japan.

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Matthams C, Mundy L. The undergraduate therapeutic radiographers research program Velindre Cancer Centre, developed in collaboration with Cardiff University.
Health & Care Research Wales Support & Delivery Conference. 2023.

Hurdley R, **Hopkinson J.** 'Memory Mate' as boundary object in cancer treatment for patients with dementia.
British Sociological Association, South-West Regional Medical Sociology Group Day Event. 2023.

Semedo L, Roberts R, Seddon K, Kumar R, Radley L, **Hopkinson JB.** A protocol for the development of a brief educational intervention to improve nurse knowledge and confidence to educate patients and carers pre-intravenous systemic anti-cancer therapy (SACT) in one cancer centre in Wales (UK).
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Edwards A, Mickleburgh B, Hopkinson J. The impact of a Lung Cancer Clinical Nurse Specialist role on person-centered and equitable care: a service improvement and evaluation project.
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Williams K. The role of the AHP in AOS.
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Posters

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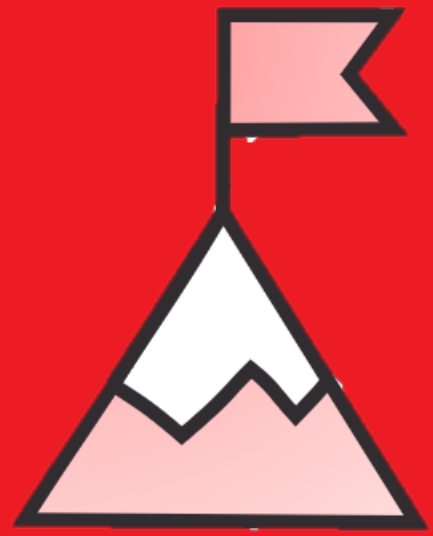
Research, Development and Innovation

Gwasanaeth Gwaed Cymru
Welsh Blood Service

Updating the Welsh Blood Service's **Research, Development & Innovation Strategy**



A new WBS Research Development and Innovation Strategy

The WBS performs this strategy

Focus on patient outcomes, and financial governance is robust.

Deliverable 1

A written document in English and Welsh

Deliverable 2

Key Performance Indicators to evidence the progress of this strategy

Deliverable 3

Update of the relevant electronic webpages

Deliverable 4

The strategy is approved as an organisational policy on the quality management system. Together with any update of associated documents (e.g. Terms of Reference, standard operating procedures)

Deliverable 5

The KPI statuses are reached and monitored.

Deliverable 6

Projects and Delivery plans focused on means to improve the care of patients.

Deliverable 7

The strategy's financial impact is assessed, and a financial arrangement and delivery considerations are defined (and appended to the strategy).

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The strategy's financial impact is assessed, and a financial arrangement and delivery considerations are defined (and appended to the strategy).

Strategy Development Board

WBS Researchers

Corporate

Supplier

Strategy Development Board

WBS Researchers

Corporate

Supplier

Stakeholders

WBS's Researchers
Heads of Department
Velindre Research
Velindre Executives
University Investigators
Commercial Partners (existing and unknown)
Commercial suppliers
Medical Investigators
Public input
Donor Expectations
Patient Expectations
Research Funders
Welsh Government and Infrastructur
Other Blood Services
Unknown and many more . . .

Stage 1

Initiate the Strategy Development Group Planning

Stage 2

Stakeholder Engagement & Ideas Capture

Option Selection

Stage 3

Scrutiny
Approval
and Dissemination

Stage 3

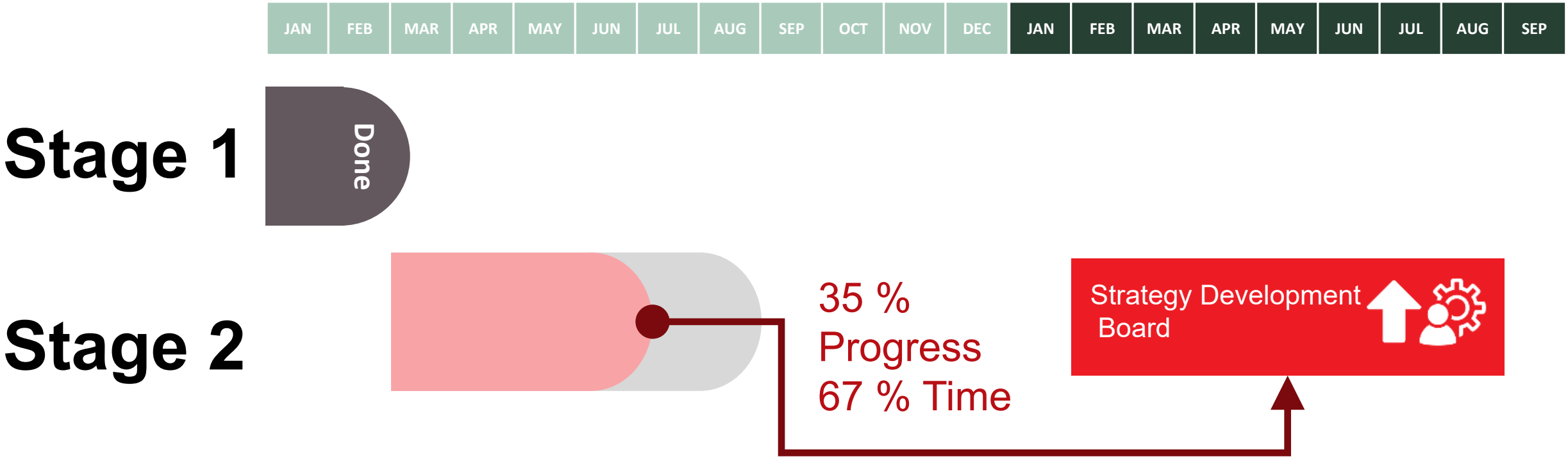
Scrutiny
Approval
and Dissemination

Stage 2

Stakeholder Engagement & Ideas Capture

Option Selection

Stage 2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Stage 1
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Stage 2
35 %
Progress
67 % Time
Strategy Development
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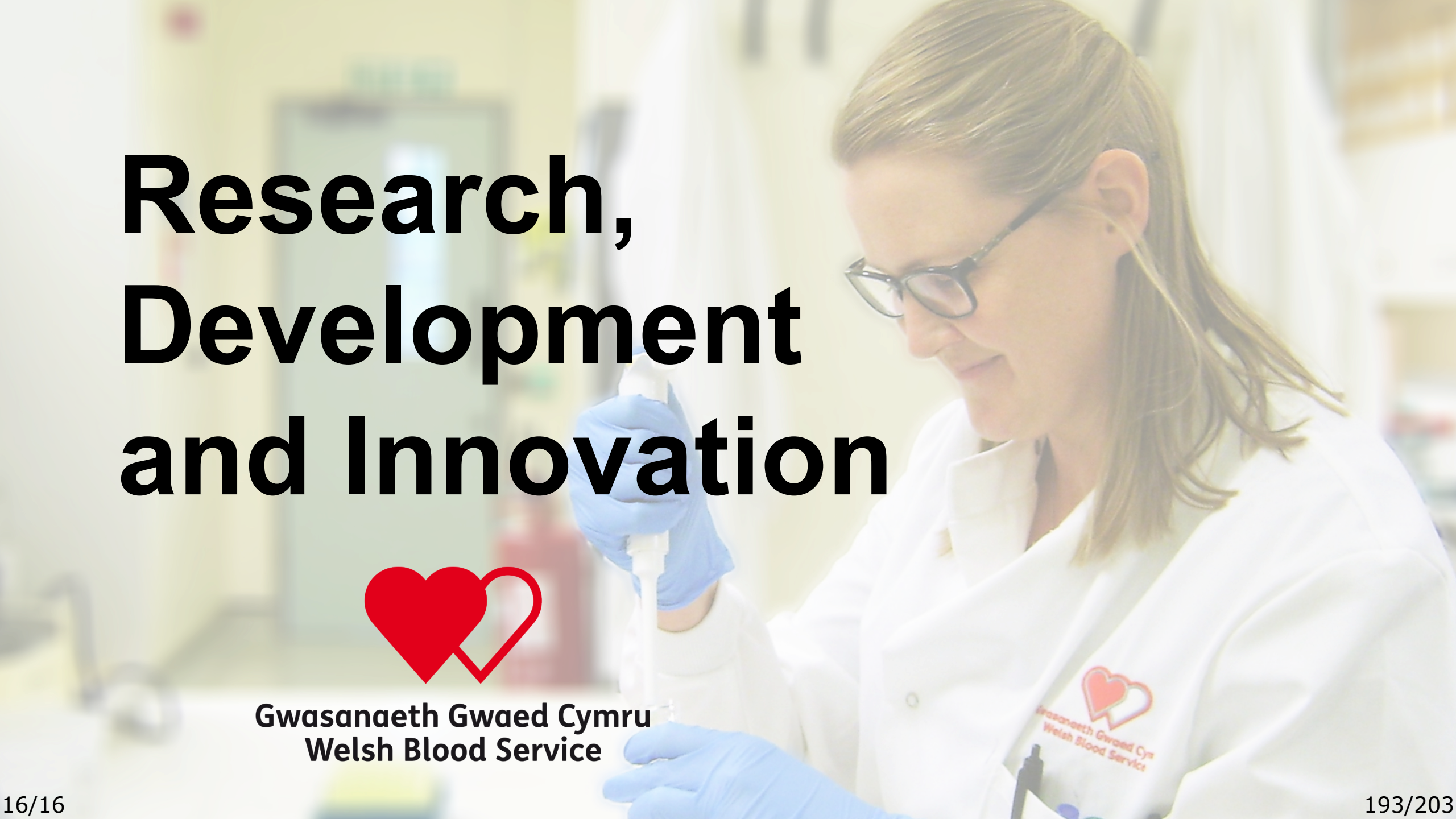
Stage 2
35%

- **Time issue**
- **Time issue addressed by resource and increasing deadline**
- **Internal Stakeholder engagement ongoing**
- **External Stakeholder engagement late summer**
- **Stage Two completion expected on end of year**

Research, Development and Innovation



Gwasanaeth Gwaed Cymru
Welsh Blood Service

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

Date 28/02/2023
Time 12:15-1:30pm
Location via Microsoft Teams
Chair Professor Andrew Westwell, Independent Member

PRESENT		
Professor Andrew Westwell	Independent Member and Research, Development & Innovation Sub-Committee Chair	AW
Vicky Morris	Independent Member	VM
Professor Donna Mead OBE	Trust Chair	DM
ATTENDEES		
Dr Jacinta Abraham	Executive Medical Director and R&D Lead	JA
Libby Batt	Head of Velindre Cancer R&D Strategy	LB
Matthew Bunce	Executive Director of Finance	MB
Rachel Hennessey	Interim Head of Operation & Service Delivery	RH
Professor Jane Hopkinson	Velindre Cancer Centre Professor of Nursing and Interdisciplinary Cancer Care	JH
Dr Edwin Massey	Medical Director, Welsh Blood Service	EM
Jonathan Patmore	RD&I Finance Business Partner	JP
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
SECRETARIAT		
Sandra Cusack	Business Support Officer	SMC

1.0	**STANDARD BUSINESS**	
1.1	**Apologies** received from: • Eve Gallop-Evans, Clinical Director, Velindre Cancer Services • Steve Ham, Chief Executive • Paul Wilkins, Interim Director, Velindre Cancer Services	
1.2	**In Attendance** • Kate Cleary, Velindre Futures Cancer Research & Development (R&D) Strategy Project Manager (Item 2.1)	
1.3	**Declarations of Interest** *Led by Professor Andrew Westwell, Chair of the Research, Development & Innovation Sub-Committee* No declarations of interest were raised.	
1.4	**Review of Action Log** *Led by Dr Jacinta Abraham, Executive Medical Director* and R&D Lead The Research, Development & Innovation Sub-Committee **APPROVED** the Action Log and further updates captured in the meeting for the record.	
2.0.0	**MAIN AGENDA**	
2.1	**Cardiff Cancer Research Hub – Name and Branding** Led by Libby Batt, Velindre Futures Cancer R&D Strategy Lead & Kate Cleary, Velindre Futures Cancer R&D Strategy Project Manager LB / KC presented the background on the decision of the Name and Branding on the Cardiff Cancer Research Hub (CCRH) was agreed: The Hub comprises three organisations working together with shared identity, so needs a name demonstrating collaboration, being memorable and easily remembered. Needs to be accessible to stakeholders such (i.e. patients; partners). Needs to be confident, focusing on research but also on business as well. The strapline under the Cardiff Cancer Research Hub, represents a partnership between Velindre, Cardiff and Vale (C&V) and Cardiff University (CU). **Cardiff Cancer Research Hub Timeline** • Extensive discussions have taken place between the three partner organisations about the name of the Hub.	

	• The Velindre University NHS Trust (VUNHST)/Cardiff and Vale University Health Board (CAVUHB), Bi-lateral Executive Partnership Board, (Cardiff University (CU) attends), recognised Velindre's substantial contribution. That group agreed the strap line will be "A partnership between Velindre, Cardiff & Vale and Cardiff University". • Recently EMB SHAPE endorsed the direction of travel. The name was confirmed as the ***Cardiff Cancer Research Hub***. KC presented the process, plans and next steps for the Branding: **Next steps – spreading the word** • The Trust Communications team will contribute to Hub generated good news stories, promoting the collaborative work to progress delivery of highly complex and cutting-edge trials, promoting the Hub as an important initiative for the Trust. DM requested with the branding exercise, it be made clear that Velindre is a prime partner and requested the Sub-Committee have sight of the branding designs prior to other Committes e.g., Executive Management Board (EMB), so there is clear opportunity to have input / comment. **ACTION :** LB/KC agreed to bring the branding designs to the Research, Development & Innovation Sub-Committee via out of committee or the next formal committee meeting in July. The Research, Development & Innovation Sub-Committee **DISCUSSED** and **NOTED** the presentation on the Cardiff Cancer Research Hub Branding.	**KC**
2.2	**Cardiff Cancer Research Hub - Heads of Terms** Led by Sarah Townsend, Head of Research & Development ST reported on the current status of the CCRH Heads of Terms : The Heads of Terms document summarises how the three organisations will work together and draws upon the agreed CCRH Proposal to outline: • The objectives of the collaboration (paragraph 1); • The physical resources that will be required (paragraph 6); • The workforce required to set up, develop and operate the hub safely and effectively (paragraph 9). Further Information is required from the stakeholder organisations in order to finalise the document. This information has been requested and is currently awaited. The document sign off route for each organisation is also being considered.	

	The Research, Development & Innovation Sub-Committee **DISCUSSED** and **NOTED** the current status of the Heads of Terms as described in the paper and the proposed strategy for review.	
2.3	**Oncacare Collaboration Agreement Update** Led by Sarah Townsend, Head of Research & Development ST updated the committee on the following: Oncarcare has signed a Master Collaboration Agreement (MCA) with an NHS Foundation Trust in England. The Trust is currently setting up two Oncacare introduced studies, outside the proposed MCA. This helps Oncacare establish credibility in the market place and also tests the model of delivery ahead of a more formal arrangement. Whilst this joint working was welcomed, the Trust cannot access Oncacare's delivery resources without executing the MCA. Oncacare is currently working with six other NHS organisations in the same way. Upon the Trust's execution of the MCA, Oncacare propose to provide funding for key posts via a grant award letter referencing the MCA. An operational management group will be established with Trust and Oncacare membership to oversee this initiative. The Research, Development & Innovation Sub-Committee **NOTED** the update regarding Oncacare Agreement and the proposed next stages in the process as discussed.	
2.4	**BedRace Game Commercialisation Agreement** Led by Sarah Townsend, Head of Research & Development During 2022, the Head of Innovation and the game inventor, Dr Clea Atkinson, worked with AgorIP and Focus Games Ltd ("Focus") to obtain the trademark and further develop the game. In the absence of a Head of Innovation, the Head of R&D has taken responsibility, after discussion with the Executive Medical Director, for progressing the game's commercialisation in accordance with the previous Sub-Committee approval, and the Senior Research Contracts Manager has engaged with Dr Atkinson and Focus to negotiate the commercialisation agreement's terms. The Research, Development & Innovation Sub-Committee **DISCUSSED** and **NOTED** the commercialisation agreement between the Trust and Focus Games Ltd., subject to the satisfactory resolution	

	of any issues raised as a result of the receipt of the legal opinion of NWSSP Legal & Risk Services.	
3.0	**CONSENT AGENDA**	
3.1	***Consent – For Approval***	
3.1.1	**Minutes from the last Private Research, Development & Innovation Committee held on the 15th November 2023** Led by Professor Andrew Westwell (Chair) The Research, Development & Innovation Sub-Committee **REVIEWED** and **APPROVED** the Minutes of the Private Meeting held on the 15th November 2022 as an accurate reflection of proceedings.	
3.2	**Consent – For Endorsement**	
	No Items for Endorsement.	
3.3	**Consent – For Noting**	
	No Items for Noting.	
4.0	**ANY OTHER BUSINESS**	
	No other business was raised.	
5.0	**DATE AND TIME OF THE NEXT MEETING**	
	The next meeting of the Research Development and Innovation Sub-Committee will be held in person on **4th July 2023 at 4.15pm at Trust Headquarters.**	
CLOSE		

Research, Development & Innovation Sub-Committee

Highlight Report from the Advancing Radiotherapy Fund (ARF)

DATE OF MEETING	20/07/2023

PUBLIC OR PRIVATE REPORT	Public

IF PRIVATE PLEASE INDICATE REASON	Not Applicable - Public Report

PREPARED BY	Libby Crumpton, Advancing Radiotherapy Fund Project Manager
PRESENTED BY	Libby Crumpton, Advancing Radiotherapy Fund Project Manager
EXECUTIVE SPONSOR APPROVED	Jacinta Abraham, Executive Medical Director

REPORT PURPOSE	FOR NOTING

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

ACRONYMS	
ARF	Advancing Radiotherapy Fund
RD&I	Research, Development and Innovation
PM	Project Manager
CFC	Charitable Funds Committee

1. PURPOSE

1.1 This paper had been prepared to provide the RD&I Sub-Committee with details of key issues considered by the Advancing Radiotherapy Fund (ARF) Board at its meeting held on 26th April 2023.

1.2 Key highlights from the meeting are reported in section 2.

1.3 The Committee is requested to **NOTE** the contents of the report and actions being taken.

2. HIGHLIGHT REPORT

ALERT / ESCALATE	There were no items identified for **ALERT** or **ESCALATION** to the Research, Development & Innovation Sub-Committee.
ADVISE	The Trust sponsored **PEARL** trial has experienced delays which resulted in the need for an extension to the trial agreed by the sponsor and both funders ARF and Cancer Research Wales: - A lack of capacity in the VCC radiotherapy department to support the study (VCC is the biggest recruiter to the study) - COVID pandemic suspending then reducing patient recruitment - Lower recruitment at Guys and St Thomas has been lower than anticipated due to competition from the PATHOS study - The Principal Investigator (PI) at the Beatson being on long term sick leave, which resulted in considering other candidates for the role. *The PI has since returned to work and the centre is recruiting* - PET replacement program at PETIC has halted recruitment in Velindre Cancer Centre (VCC), Swansea and Bristol over summer months. Due to the Covid pandemic, saliva swabs were unable to be taken forming the basis of PhD work within the initial proposal. The trial team are requesting the unused funds are used to further support PEARL trial team costs, to ensure efficient completion of the trial.

	Update from **PATHOS** Clinical Fellow / lead to be obtained on the status of this trial.
ASSURE	Due to the Advancing Radiotherapy Fund (ARF) Research and Development (R&D) Lead sessions being vacant, and a period of leave for the ARF PM, project updates were paused. This has meant no formal updates to RD&I Sub Committee. The ARF Project Administrator Hannah Fox has maintained links with projects and their leads, and the ARF Board. Project meetings will be resumed with leads / project teams, following the appointment of the R&D Lead and the PM returning. Appendix A shows projects updates submitted to the ARF Board in the April 2023 meeting. Points of note: - Dr Kieran Foley, Consultant Radiologist received confirmation that an application to the National Institute for Health and Care Research (NIHR) for a £250,00 grant (Research for Patient Benefit, RfPB) has been successful. This is in collaboration with Southampton, and Prof Tim Underwood, who is co-CI with Dr Foley: Understanding the variation of modern endoscopic ultrasound use in patients with oesophageal cancer (VALUE): a multi-methods study. - Patient recruitment for EHRT only an EHRT and SpaceOAR completed. EHRT patients have completed two follow up, data being reviewed. EHRT business case developed for submission to commissioners this year. - Funding for the x2 research radiographer roles has ended. An end of project report will be requested. VCC finance colleagues have confirmed the roles have formed part of the radiotherapy ~~w~~workplan / budget.
INFORM	Dr James Powell was appointed R&D Lead for the ARF, commencing this role in autumn 2022 replacing Prof. Mererid Evans who had previously stepped down. Elizabeth Crumpton (Libby), ARF Project Manager (PM) returned from a period of maternity leave in May 2023. There was not cover for the PM role during this period. Both ARF Project Manager and Project Administrator roles, have been extended to March 2024.

	As a reminder, an ARF Strategy (2022-2025) was developed by Prof. Evans and shared with members of the RD&I community in 2022. The ARF Board led a grant submission to The Moondance Foundation, for £1.5 million over a five-year period, £300,000 per year. This application was successful and has since been match funded by the Trust Charitable Funds Committee (CFC). Driving innovation in radiotherapy treatment to deliver better outcomes and improve quality of life and patient experience, whilst providing equitable care to cancer patients across Wales, are key objectives of the Advancing Radiotherapy Cymru (ARC) Academy. An all-Wales programme with ambitions to deliver best practice in radiotherapy by supporting clinical service developments, workforce recruitment, development and training, and research for the benefit of all patients receiving radiotherapy in Wales. Governance and the structure of the ARC are to be determined, but will include updates where appropriate to RD&I.
APPENDICES	YES - (Please Include Appendix Title in Box Below)
	Advancing Radiotherapy Fund: Project Updates *some amendments have been made, since these were submitted to the ARF Board in April 2023. ARF Project Highlight Report Ap

Researchers in Scotland, Wales and Northern Ireland to access further NIHR research funding

This is a significant expansion of NIHR research funding into devolved nations.

Please note this recent announcement from NIHR:
https://www.nihr.ac.uk/news/researchers-in-scotland-wales-and-northern-ireland-to-access-further-nihr-research-funding/33914