Public Research, Development & Innovation Sub-Committee

Tue 28 February 2023, 10:00 - 12:30

via Microsoft Teams

Agenda

10:00 - 10:20
20 min

1. PRESENTATION

1.1. " Palliative and Supportive Care Research…. Building On Success"

Led by Dr Anthony Bryne, Consultant in Palliative Medicine

1.1 Palliative and Supportive Care Research. Building on Success.pdf (18 pages)

10:20 - 10:35
15 min

2. STANDARD BUSINESS

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

2.1. Apologies

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

2.2. In Attendance

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

- ***Dr 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 R&D Strategy Project Manager (Observer)***

2.3. Declarations of Interest

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

2.4. Review of Action Log

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

2.4 RDI PUBLIC ACTION LOG_15.11.22 FINAL.pdf (1 pages)

10:35 - 10:50
15 min

3. MAIN AGENDA

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

3.1. Executive Medical Director Briefing

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

3.1 Cover Paper_Executive Briefing.pdf (7 pages)
3.1 Executive Briefing.pdf (5 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

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10:50 - 11:20
30 min

4. STRATEGY, PERFORMANCE AND DELIVERY

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

4.1. Trust Research, Development & Innovation Performance Report

Led by Sarah Townsend, Head of Research & Development with support from the relevant leads:

- ***Libby Batt, Velindre Futures Cancer R&D Strategy Lead***
- ***Christopher Cotterill Jones, Research Delivery Manager***
- ***Ross McLeish, Innovation Project Manager***
- ***Jonathan Patmore, R&D Finance Manager***
- ***Peter Richardson, Head of Quality & Assurance, Welsh Blood Service & Dr Sian James, RD&I Facilitation Lead, Welsh Blood Service***

4.1 Cover Paper_RDI Performance Report Q3.pdf (3 pages)
4.1 RDI Integrated Performance Report Q3.pdf (45 pages)

11:20 - 11:35
15 min

5. CONSENT AGENDA

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

5.1. CONSENT - FOR APPROVAL

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

5.1.1. Minutes from the Meeting of 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

5.1.1 DRAFT RDI Public Minutes 15.11.22 v3 FINAL.pdf (13 pages)

5.1.2. Intellectual Property Policy

Led by Sarah Townsend, Head of Research & Development

5.1.2 (a) Cover Paper_Intellectual Property Policy updated.pdf (3 pages)
5.1.2 (b) Appendix 1 Intellectual Property (IP) Policy_v6 with Tracked Changes.pdf (22 pages)
5.1.2 (c) Appendix 2 Intellectual Property (IP) Policy_v6 Clean Version.pdf (20 pages)

5.2. CONSENT - FOR ENDORSEMENT

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

No Items for Endorsement

5.3. CONSENT - FOR NOTING

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

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

5.3.1 DRAFT Summary of RDI Private Minutes 15.11.22 2022 v3 FINAL.pdf (6 pages)

11:35 - 11:35
0 min

6. ANY OTHER BUSINESS

Prior Approval by the Chair Required

11:35 - 11:45
10 min

7. HIGHLIGHT REPORTS

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

7.1. Highlight Report to Strategic Development Committee

Members to identify items to include in the Highlight Report:
For Escalation
For Assurance
For Advising
For Information

7.2. Highlight Report to Quality, Safety and Performance Committee

Members to identify items to include in the Highlight Report:
For Escalation
For Assurance
For Advising
For Information

11:45 - 11:50
5 min

8. DATE AND TIME OF THE NEXT MEETING

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

Date and time of next meeting to be confirmed

11:50 - 11:55
5 min

9. CLOSE

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

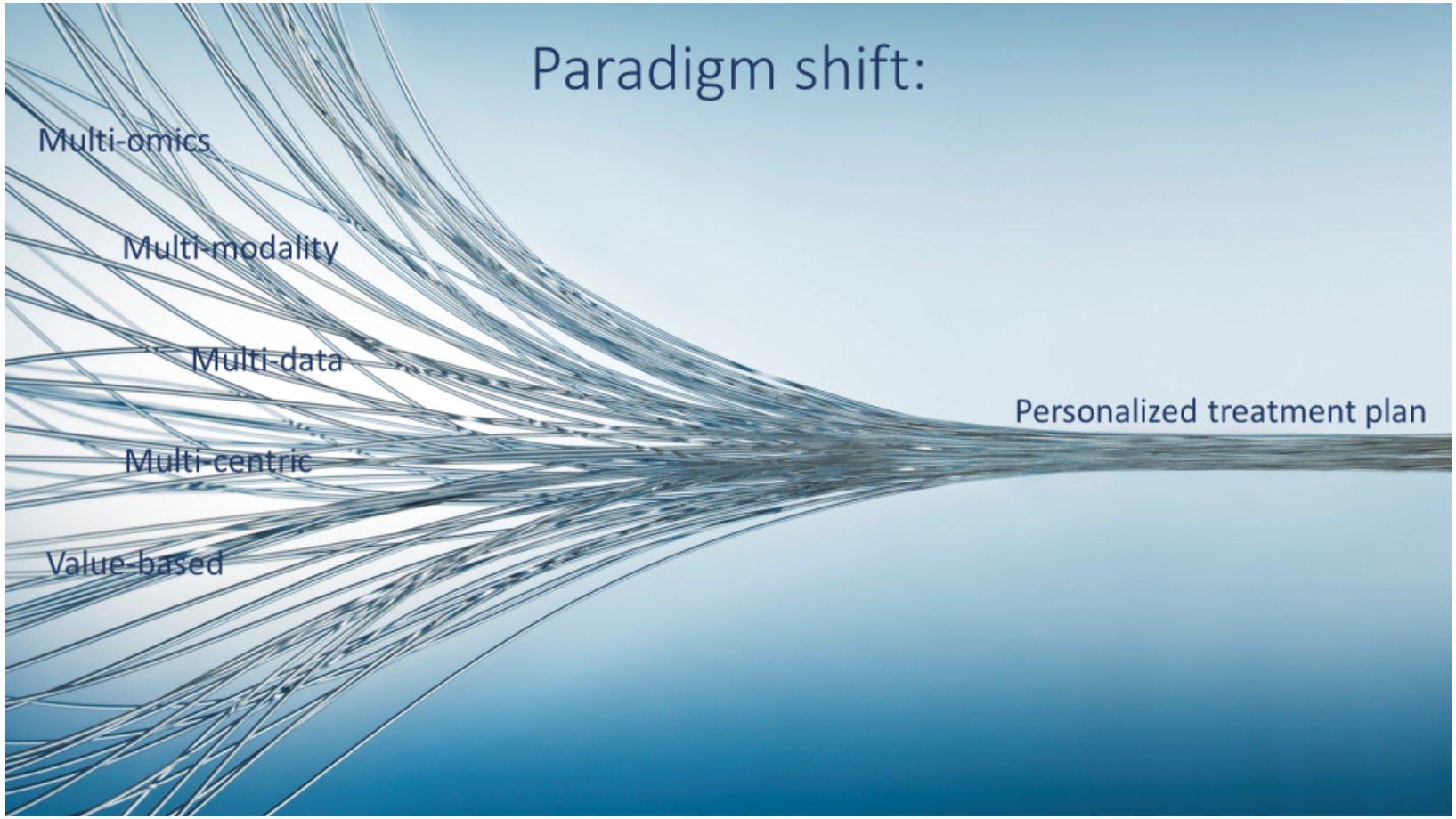
The Research, Development and Innovation Sub-Committee is asked to adopt the following resolution:

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).

PALLIATIVE AND SUPPORTIVE CARE RESEARCH

BUILDING ON SUCCESS

VELINDRE CANCER R&D AMBITIONS



PATIENT AT THE CENTRE: CROSS CUTTING AMBITION

CAPACITY, IMPACT AND ADDED VALUE:

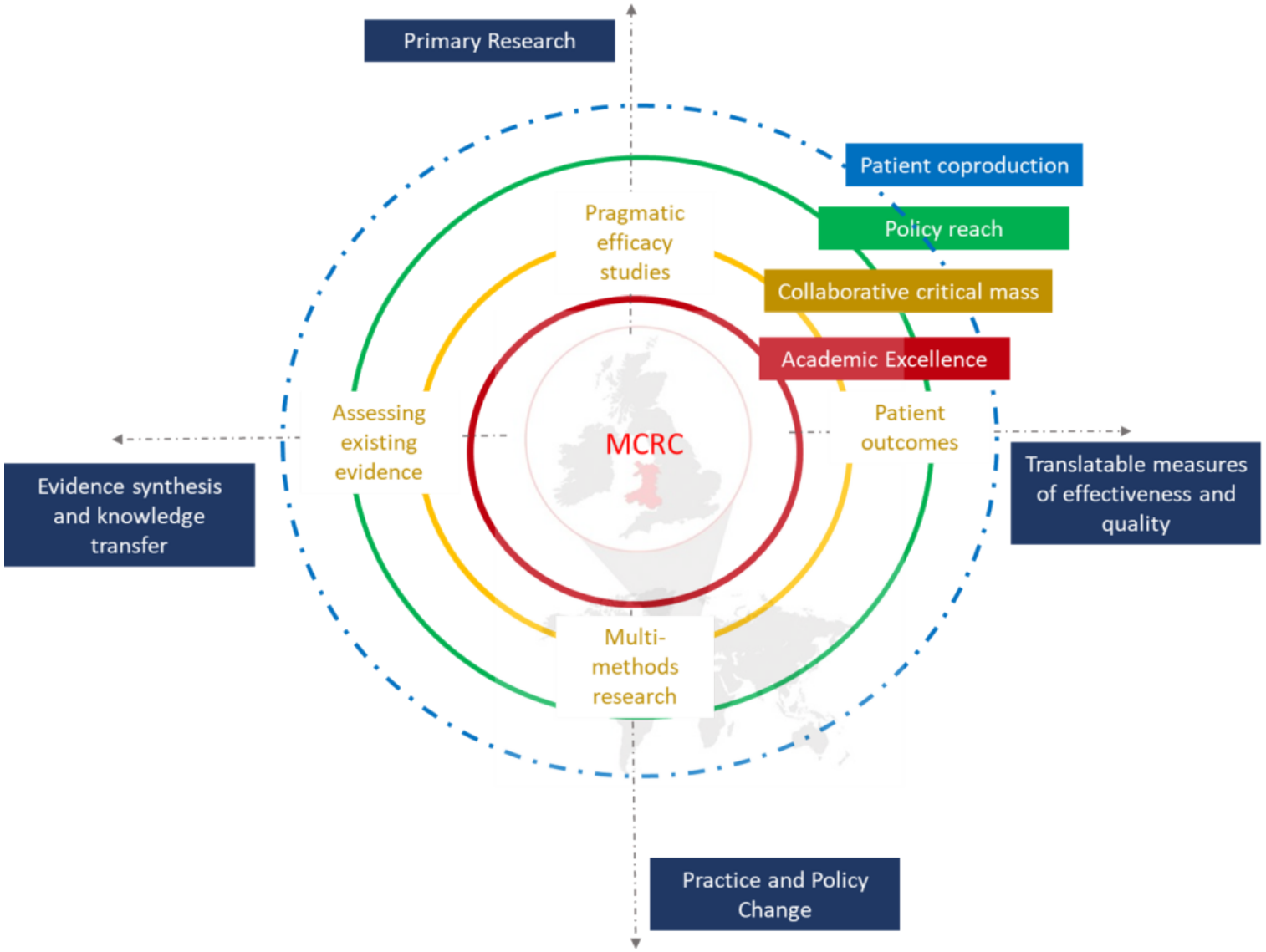
MARIE CURIE RESEARCH CENTRE

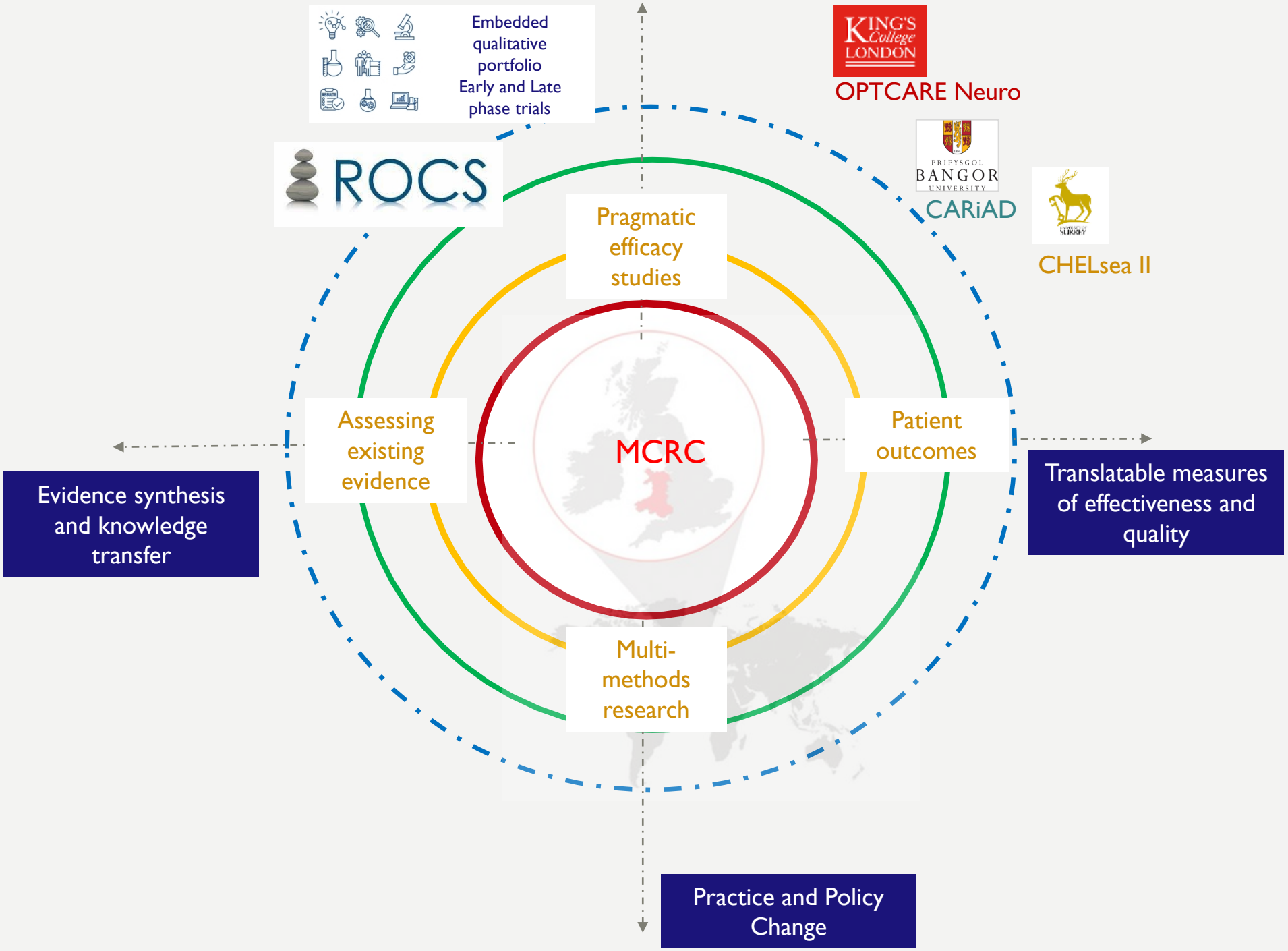
CENTRE AIMS

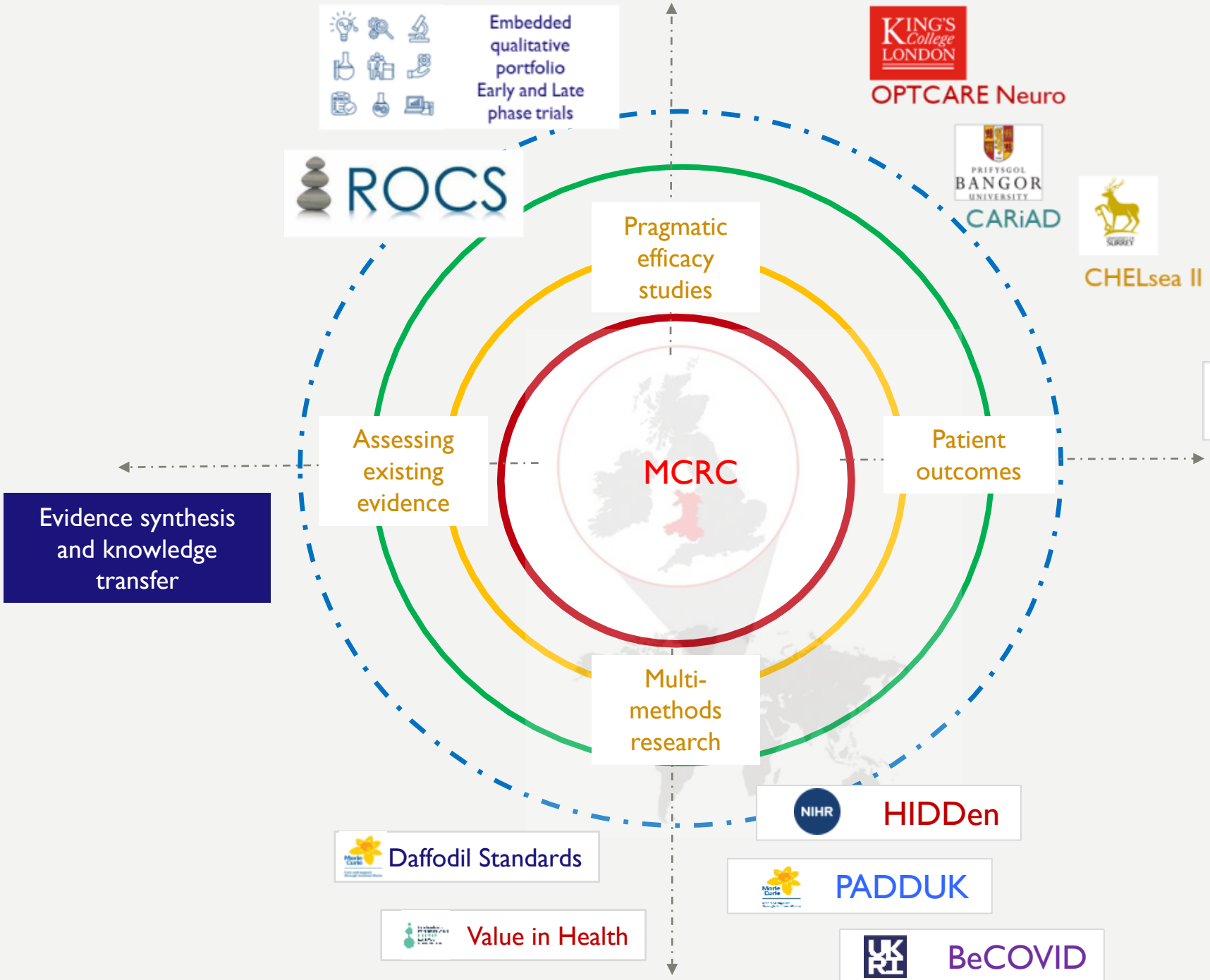
- Undertaking high quality research of national priority, which is directly relevant to patient and carer needs.
- Demonstrating impact through knowledge transfer and mobilization, effecting the translation of research findings into clinical practice and policy implementation.

INTEGRATED PORTFOLIO: 2017-2022

Marie Curie
Palliative Care Research Centre
CARDIFF




Embedded qualitative portfolio Early and Late phase trials
ROCS
KING'S College LONDON
OPTCARE Neuro
PRIFYSGOL BANGOR UNIVERSITY
CARiAD
CHELsea II
Pragmatic efficacy studies
Assessing existing evidence
MCRC
Patient outcomes
Multi-methods research
Evidence synthesis and knowledge transfer
Translatable measures of effectiveness and quality
Practice and Policy Change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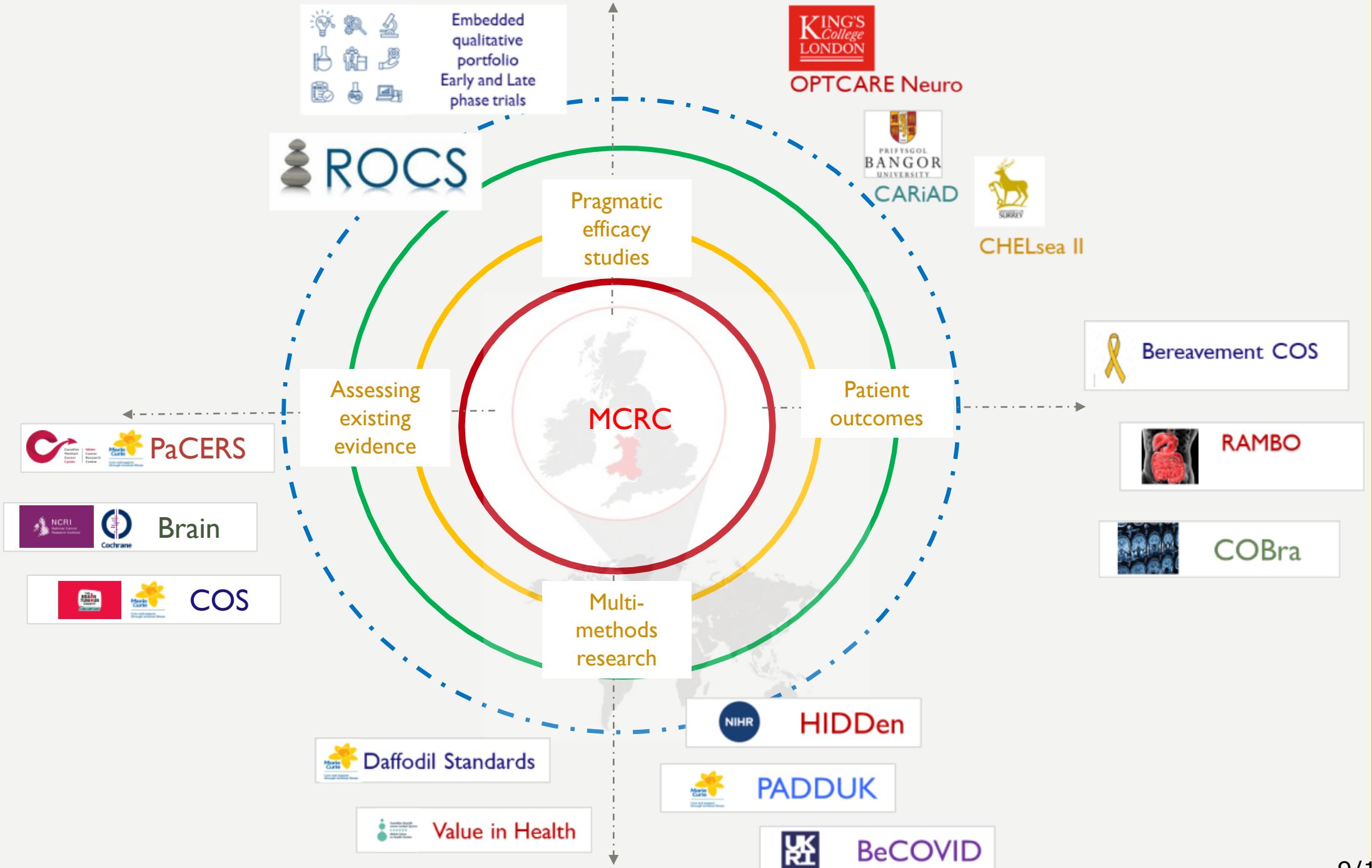
Bereavement COS
RAMBO
COBra
NIHR
HIDDen
Daffodil Standards
PADDUK
Value in Health
UKRI
BeCOVID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Multi-methods research
Bereavement COS
RAMBO
COBra
PaCERS
Brain
COS
NIHR
HIDDen
PADDUK
BeCOVID
Daffodil Standards
Value in Health

OUTPUTS

£11.6M Lead App funding

£11.2M co-App funding

37 funded studies

For every **£1** of Marie Curie investment we generated **£4.14** in lead applicant funding alone

10,000 + participants in studies

110 peer reviewed papers

99 conference abstracts

Marie Curie
Care and support through terminal illness

IMPACTS

NICE National Institute for Health and Care Excellence

6 NICE Guidelines

2 WHO Guidelines

2 international Covid 19 Guidelines

ASH & ISTH Guidelines

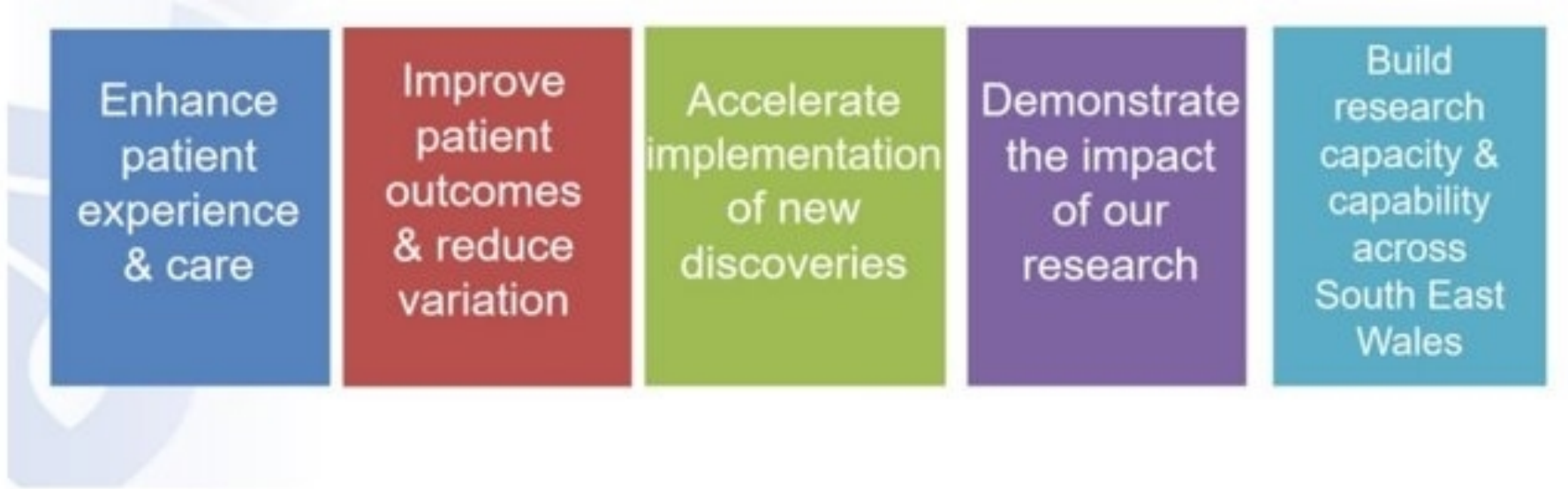
Primary legislation

UK Bereavement Commission

DoH Guidance

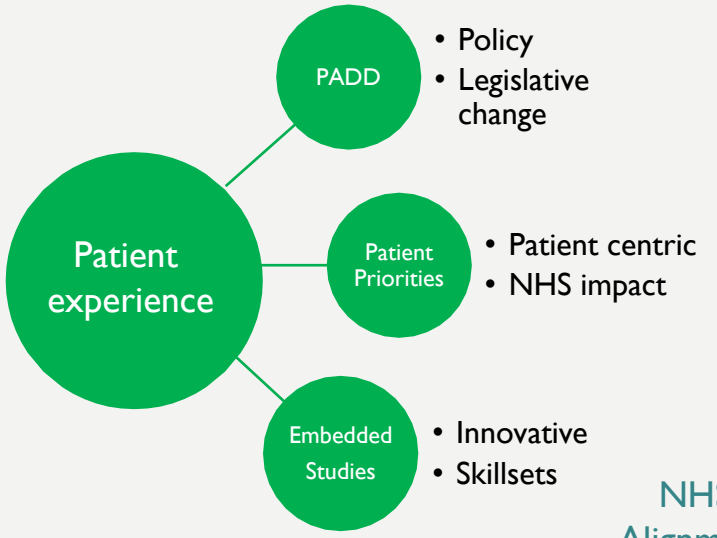
NHS Wales Exec Guidance

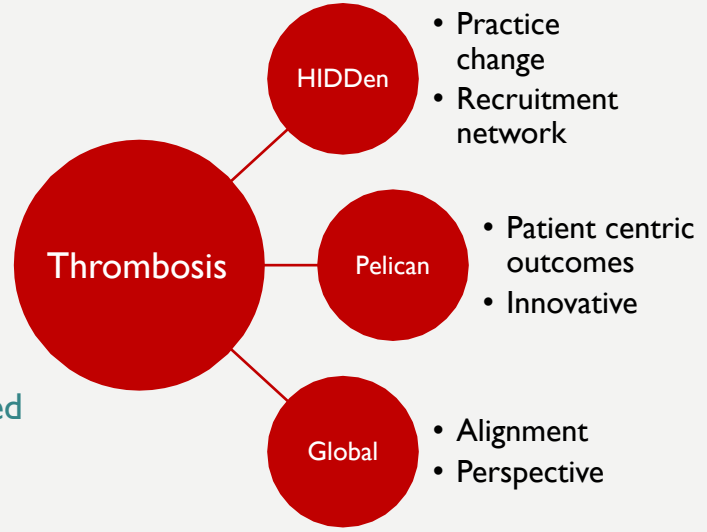
Marie Curie
Care and support through terminal illness

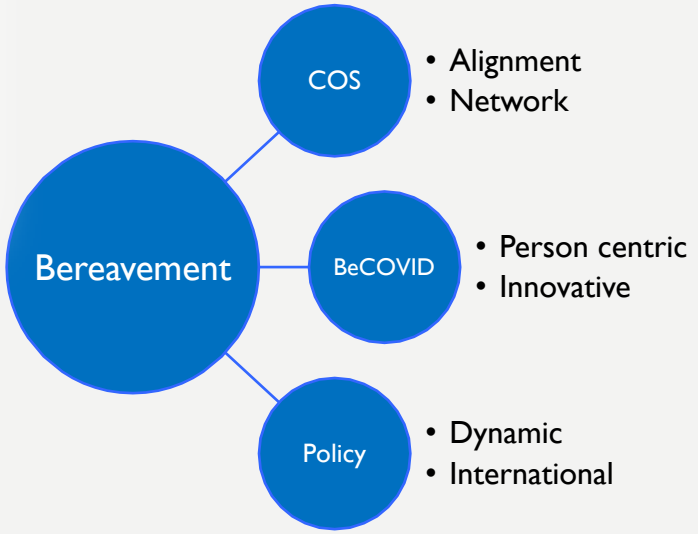


CAPACITY, IMPACT AND ADDED VALUE

FUTURE VALUE







PRIORITIES, PREFERENCES AND OUTCOMES THAT MATTER

PATIENT EXPERIENCE AND PREFERENCES

Health literacy and the activated patient. Patient frames the consultation

Route map. Working with NOP format. Defined palliative care pathway.

Challenge and equip patients to take control of own care. Question prompt lists per consultation.

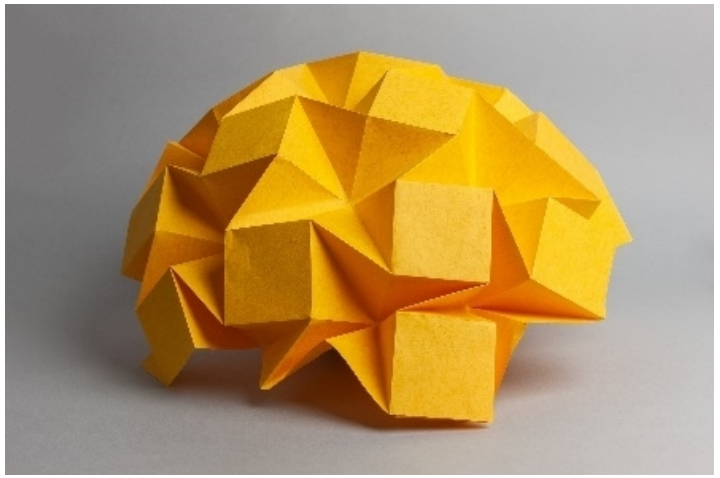
Frame consultation by patient, not treatment – 'my preference is' campaign. Offer all reasonable treatment options including do nothing, not just MDT recommendation.

Formal and recorded inclusion of patient priorities/social context.

IT solutions for documenting and sharing patient priorities – clinical coding and pop up windows.

COBra Study

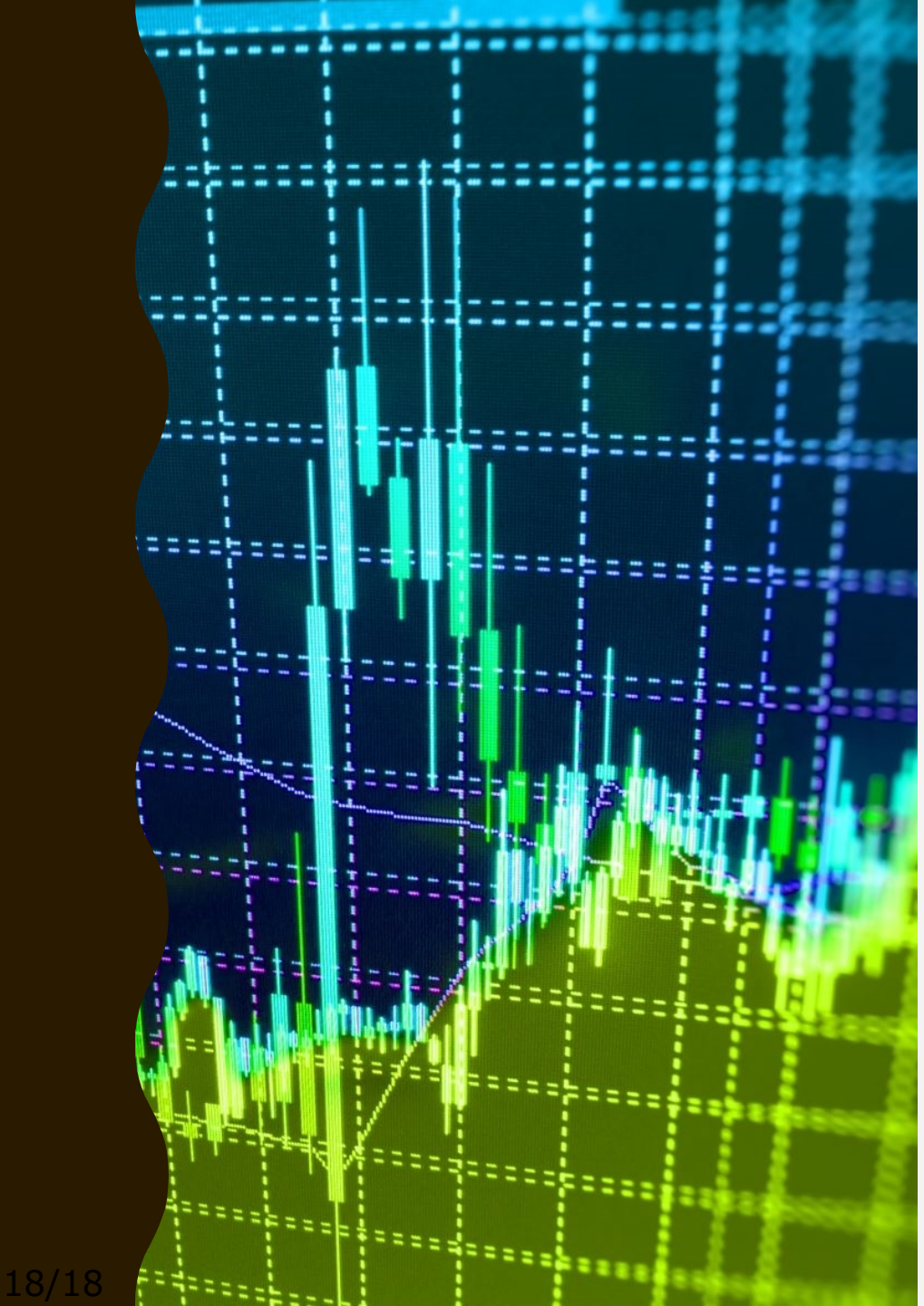
Patient Reported Core Outcomes in Brain Tumour Trials



OUTCOMES THAT MATTER

VALUE BASED AND REDUCING VARIATION

- Multi-perspective approach
- Data driven
- Impact focus
- Policy-clinical-academic alignment



CAPACITY

- Multiple Velindre staff supported across disciplines
- Cross-cutting collaborations
- Shared funding and critical mass

PUBLIC RESEARCH, DEVELOPMENT & INNOVATION SUB-COMMITTEE ACTION LOG					
Minute Number	**Action**	**Owner**	**Progress to Date**	**Target Date**	**Status (Open/Closed)**
Actions agreed at the Committee on the 15th November 2022					
0.0.1	WBS RD&I Strategy Engagement Event : JA, AP, EM to discuss the requirements for the engagement event that will inform the WBS RD&I Strategy Update. This is a programme of work in three planned stages.	Jacinta Abraham	**UPDATE 28/02/2023** WBS RD&I Strategy Event calendar invitations have been issued to Stakeholders. Dr Sian James as Project Manager will be responsible for updating this Sub-Committee on progress of the Project.	28/02/2023	**CLOSED**
2.1.1	RDI Annual Report : Minor amendement to the Minutes of 21/07/22 Item 4.2 To add, formal thanks to both Divisions.	Sandra Cusack	**UPDATE 15/11/2022** Minutes amended to reflect formal thanks to both Divisions.	15/11/2022	**CLOSED**
2.2.1	RDI Terms of Reference : Amendments to be made reflecting the Advancing Radiotherapy Fund (ARF) relationship to the Research, Development and Innocation Sub-Committee (RDI) and the Charitable Funds Committee (CFC), accurately reflect the changes to allow onward submission to the Audit Committee.	Emma Stephens	**UPDATE 31/01/2023** The Terms of Reference have been updated to reflect the amendments requested and will now proeceed for onward submission to Trust Audit Committee for formal endorsement and Trust Board for formal approval through the March 2023 governance cycle.	31/01/2023	**CLOSED**
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.	Sarah Townsend	**UPDATE 28/02/2023** 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 to the 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.	Sarah Townsend	**UPDATE 28/02/2023** Radiotherapy Trials Research Group has been establish 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 at a future meeting of the RDI Sub-Committee.	07/12/2023	**OPEN**
6.0	Support the development of a draft RDI Highlight Report to the December 2022 Meeting of the Strategic Development Committee, for approval by the Committee Chair.	Sandra Cusack	**UPDATE 28/02/2023** This has been drafted and submitted to the December 2022 Meeting of the Strategic Development Committee.	02/12/2022	**CLOSED**
6.0	Support the development of a draft Highlight Report to the January 2023 Meeting of the Quality, Safety & Performance Committee, for approval by the Committee Chair.	Sandra Cusack	**UPDATE 28/02/2023** This has been drafted and submitted to the January 2023 Meeting of the Quality, Safety & Performance Committee.	19/12/2022	**CLOSED**

RESEARCH, DEVELOPMENT AND INNOVATION SUB-COMMITTEE

Executive Briefing to RD&I Sub-Committee

DATE OF MEETING	28th February 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**

ACRONYMS	
AOS	Acute Oncology Service
BMTU	Bone Marrow Transplant Unit

CROs	Contract Research Organisations
CU	Cardiff University
CVUHB	Cardiff & Vale University Health Board
FY	Financial Year
HCRW	Health and Care Research Wales
MOU	Memorandum of Understanding
NHS	National Health Service
Q	Quarter
R&D	Research & Development
RD&I	Research, Development & Innovation
UHW	University Hospital of Wales
UK	United Kingdom
VUNHST	Velindre University NHS Trust
WCB	Wales Cancer Bank
WG	Welsh Government
WHSSC	Welsh Health Specialised Services Committee

1. SITUATION / BACKGROUND

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

2. ASSESSMENT / SUMMARY OF MATTERS FOR CONSIDERATION

2.1. Welsh Blood Service

2.1.1. **Healthcare Scientist of the Year**

Executive Briefing Slides = slide 3

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.

The Advancing Healthcare Awards recognise and celebrate the work of health professionals, healthcare scientists and those who work alongside them in support roles, leading innovative healthcare practice across the UK. The awards have been running for 20 years and have both UK-wide and regional award programmes.

Welsh Blood Service would also like to congratulate our Vaccine Distribution Project Team, who were deservedly shortlisted for the 'Improving Public Health Outcomes' Award.

2.2. **Research and Development**

2.2.1. **Charitable Funds Committee Integrated Bid**

Executive Briefing Slides = slide 4

The Research, Development & Innovation function submitted a business case for consideration by the Charitable Funds Committee at their meeting convened on 19 January 2023.

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

- Research infrastructure for Clinical Trial Delivery and Governance (this part includes a renewal of previous business case applications, with additional posts included)

- Implementation of the Cancer Research Ambitions to grow future research (this part includes existing and new posts, including posts agreed and co-funded with partners)

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

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

The business case was approved at the Charitable Funds Committee meeting.

2.2.2. **Cardiff Cancer Research Hub**

Executive Briefing Slides = slide 4

Work on the development of a strategic investment case to support the development of the Cardiff Cancer Research Hub is expected to start under contract on 1 March 2023 for a period of 4 months.

Work on securing appropriate infrastructure ad University Hospital of Wales (UHW) continues with the Hub being included alongside other infrastructure development at UHW. This is now being led by Cardiff & Vale University Health Board (CVUHB) and they will merge the three sets of clinical specifications from the Hub, Haematology – Bone Marrow Transplant Unit (BMTU), 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 Specialised Services Committee (WHSSC) boards before submission to Welsh Government (WG) in May 2023.

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 Velindre University NHS Trust (VUNHST) and the Joint Research Office,

Cardiff University (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.

2.2.3. **Oncacare**

Executive Briefing Slides = slide 5

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.

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

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

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

The Trust R&D office continues to work with the Joint Research Office at CVUHB to ensure that the terms of the master collaboration agreements with Oncacre are the same for both parties.

2.2.4. **Research Study Data & Performance Measures**

Executive Briefing Slides = slide 5

In quarter 3 FY2022/23 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.

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	No (Include further detail below)
	In line with the requirements of the UK Policy Framework for Health and Social Care

	Research, no specific issues have been identified.
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 Research, Development & Innovation Sub-Committee **DISCUSS** and **NOTE** for the presentation and report.

Research, Development & Innovation (RD&I) Sub-Committee
28 February 2023

Executive Lead Briefing

Dr. Jacinta Abraham, Executive Medical Director

Content

- Welsh Blood Service
  - Healthcare Scientist of the Year

- Research & Development
  - Charitable Funds Committee Integrated Bid
  - Cardiff Cancer Research Hub
  - Oncacare
  - Research Study Data & Performance Measures

Velindre University NHS Trust: Welsh Blood Service

Healthcare Scientist of the Year

- Chloe George, Head of Component Development at WBS has been awarded ‘Healthcare Scientist of the Year’ at the Advancing Healthcare Awards Cymru.
- The judges were impressed with Chloe’s 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.
- The Advancing Healthcare Awards recognise and celebrate the work of health professionals, healthcare scientists and those who work alongside them in support roles, leading innovative healthcare practice across the UK.

- Welsh Blood Service would also like to congratulate their Vaccine Distribution Project Team, who were deservedly shortlisted for the ‘Improving Public Health Outcomes’ Award.

Velindre University NHS Trust: Research & Development

Charitable Funds Committee Integrated Bid

- Research, Development & Innovation (RD&I) submitted a Business Case for consideration by the Charitable Funds Committee.
- The bid set out a request for funding to implement the Velindre Cancer R&D Ambitions that supports:
  - Research infrastructure for Clinical Trial Delivery and Governance
  - Implementation of the Cancer Research Ambitions to grow future research
- The business case is to request funding for Financial Year 2023/24 to Financial Year 2025/26.
- The business case allows the Trust to continue to support the thriving research infrastructure and ensure the flow of benefits for patients and research continue to be delivered in line with the Trust's Cancer Research Ambitions.
- The Charitable Funds Committee review took place in January 2023, with the committee granting approval for the business case.

Cardiff Cancer Research Hub

- Work will commence on the Investment Strategy development in March 2023.
- Being led by CV UHB, work continues to secure appropriate infrastructure at UHW, with the Hub being included alongside other initiatives in the development of a clinical specification.
- The draft Heads of Terms that set out the governance principles between the organisations are being finalised by the three organisations. (For discussion in today's private meeting).
- An agency has been appointed to develop the Hub branding and logo, and are beginning to collect input from stakeholders across the three organisations.

Velindre University NHS Trust: Research & Development

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. (This will be discussed in today's private meeting)

Research Study Data & Performance Measures

- In quarter 3 FY2022/23 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.

RESEARCH, DEVELOPMENT AND INNOVATION SUB-COMMITTEE

RD&I Integrated Performance Report for Quarter 3, Financial Year 2022/23

DATE OF MEETING	28th February 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 DISCUSSION / REVIEW

COMMITTEE/GROUP WHO HAVE RECEIVED OR CONSIDERED THIS PAPER PRIOR TO THIS MEETING		
COMMITTEE OR GROUP	**DATE**	**OUTCOME**
RD&I Operational Management Group	24 Jan 2023	DISCUSSED & REVIEWED
Executive Management Board	20 Feb 2023	NOTED

ACRONYMS	
FY	Financial Year

Q	Quarter
RD&I	Research, Development, & Innovation

1. SITUATION / BACKGROUND

At the meeting convened on Tuesday 15 November 2022 the RD&I Sub-Committee received the Research, Development, & Innovation (RD&I) Integrated Performance Report for Financial Year (FY) 2022/23, Quarter (Q) 2.

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 Report summarises the activities of the Trust's Research, Development, & Innovation function during quarter 3 of 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	No (Include further detail below)

	In line with the requirements of the UK Policy Framework for Health and Social Care Research, no specific issues have been identified.
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 Research, Development & Innovation Sub-Committee **DISCUSS** and **REVIEW** the RD&I Integrated Performance Report for quarter 3 of the financial year 2022/23.

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

Quarter 3

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

AOS	Acute Oncology Service
BEST	Biomedical Excellence for Safer Transfusion
BVLS	Beyond Visual Line of Sight
BYS	By Your Side
CI	Chief Investigator
CRO	Contract Research Organisation
CT	computerised tomography
CU	Cardiff University
CVUHB	Cardiff & Vale University Health Board
EMB	Executive Management Board
EMRTS	Emergency Medical Retrieval and Transfer service
FY	Financial Year
HCP	Health Care Professional
HCRW	Health Care Research Wales
HLA	Human Leukocyte Antigen
IMTP	Integrated Medium Term Plan
MOU	Memorandum of Understanding
NHS	National Health Service
nVCC	New Velindre Cancer Centre
PCIP	Planned Care Innovation Programme
PI	Principal Investigator
Q	Quarter
R&D	Research & Development
R&I	Research & Innovation
RAG	Red, Amber, Green
RD&I	Research, Development & Innovation
RIC	Regional Innovation Coordination
RICH	Regional Innovation Coordination Hubs
RIIC	Research, Innovation, Improvement Coordinating
RTT	Recruitment to Time and Target
SACT	Systemic Anti Cancer Therapy
SLT	Senior Leadership Team
TCS	Transforming Cancer Services
TKET	Translational Knowledge Exchange and Training
TLWC	This is Living With Cancer
UHB	University Health Board
UHW	University Hospital of Wales
UK	United Kingdom
VCC	Velindre Cancer Centre

VUNHST	Velindre University NHS Trust
WHSSC	Welsh Health Specialised Services Committee

INTRODUCTION

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

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

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 Q3 of FY2022/23 demonstrating activity against these strategic priority areas, the cross-cutting themes that support these areas and Trust RD&I corporate work, for example Finance.

STRATEGIC PRIORITY 1: The Trust will drive forward the implementation of its Cancer Research & Development Ambitions

1 Velindre Cancer R&D Ambitions

1.1 Key progress / updates for this period

1.1.1 Implementing the Cancer R&D Ambitions – An Integrated Business Case 2023-2026

The team led with the RD&I Senior Management Business Team the R&D integrated bid, due to be presented to Velindre Charitable funds in January. The bid covered funding for the Research Delivery Team as well as posts to implement the Ambitions strategy and was the first time that an integrated bid has been submitted, reflecting the scope of the team's aspirations and commitment to delivering high quality research.

1.1.2 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 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 subgroup has been formed to identify the preferred type of machine to go into the bunker that will would facilitate and enhance the status of the nVCC/VCC/Trust as a UK/International research leader.

Alongside this, the task and finish group 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.

1.1.3 Cell Therapy site visits

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.

1.1.4 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.
- Work on securing appropriate infrastructure at UHW is continuing and the Hub will be included alongside other infrastructure development @UHW. This is now being

led by CVUHB and they will merge the three sets of clinical specifications from the Hub, Haem and 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 WHSSC boards, before submission to 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 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.

2 Nursing & Interdisciplinary Research

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

The Velindre Library Team are supporting the development of an on-line training offer relating to library services available to healthcare staff. Design work is in progress on Velindre Healthcare Cancer Research web pages. The Velindre Healthcare Cancer

Research Group is progressing work led by Head of Healthcare Cancer Research to address education and training needs, for example a three-session package focusing on abstract submission and presentation at local and national conferences. The upcoming Velindre Nurse Conference 2023 will include a Dragons Den workshop on getting research active.

Clinical services where there is one or more research and/or innovation active nurse or therapist,

- SACT team
- Radiographer team
- Clinical Trials Nurse team
- Therapies (allied health professional) team
- Psychology team
- Clinical Nurse Specialist team
- Infection Control team
- Supportive Care team

3 Performance Indicators

3.1 Summary of performance indicators

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

METRIC	Health & Care Research Wales Data[1]		Velindre University NHS Trust Data[2]	
Key Indicator Metrics	Non-Commercial	Commercial	Non-commercial	Commercial
C3/C4 Open: % of Open Studies Recruiting to Time & Target	29%	17%	*	*
C3/C4 Closed: % of Closed Studies Recruiting to Target	50%	0%	*	*
Non Key Indicator Metrics				
Median № of days to first recruited participant	(Blank)	(Blank)	420	304
% of Non-Recruiting Studies	0%	33%	17%	29%
Number of Open and Recruiting Studies	23	12	41	34
Number of Participants Recruited	86	24	126	32

Notes:

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

3.2 Health and Care Research Wales Performance Dashboard

At the time of writing, the 2022/23 Health and Care Research Wales (HCRW) Performance Dashboard notes state that studies that are planning to recruit less than one participant a month are excluded from the measures.

However, having spoken to the HCRW Senior Research Performance Manager, this relates only to the measure of Time taken from receipt of Local Information Pack (LIP) to the recruitment of the 1st participant – and this is no longer a key indicator.

It does not apply to the Key indicators of Recruitment to Time and Target, there are different exclusions for those studies that contribute to that Key Indicator and other measures on the HCRW Performance dashboard.

Despite this, the HCRW performance dashboard is still not reflecting the Trust's set-up and delivery work. As of a data cut of 11 Jan 2023, according to Trust data, the Velindre has:

- **73 studies** open to recruitment
  - (**31 commercial** studies, **42 non-commercial** studies)
- **15 studies** open with no recruitment activity
  - (**4 commercial** studies, **11 non-commercial** studies)
- **109 studies** closed and in follow-up
  - (**35 commercial** studies, **74 non-commercial** studies)
- **24 studies** in set-up
  - (**10 commercial** studies, **14 non-commercial** studies)

The HCRW Performance Dashboard data (data cut = 13 Jan 2023) reports, when filtered for the Trust, **39 open and recruiting** studies (**14 commercial** studies, **25 non-commercial** studies).

This apparently only shows studies that are open to recruitment AND have recruited at least one participant in the financial year since 01 April 2022.

Many of the Trust's cancer research studies have low recruitment target numbers over long study durations. Many of Velindre's studies may not recruit a participant in this financial year, therefore those would be excluded on that basis.

The total number of studies used to calculate Recruitment to Time & Target from the HCRW dashboard = **68 open studies.**

The breakdown is:
- The HCRW dashboard that reports the RAG rating for Recruitment to Time & Target (RTT) for non-commercial studies = **38 open studies** in total
- The HCRW dashboard that reports the RAG rating for Recruitment to Time & Target (RTT) for commercial studies = **30 open studies** in total

This apparently only shows those studies that are open to recruitment AND have recruited at least one participant to the study since the study has opened. Again, many of the Trust's cancer research studies have low recruitment target numbers over long study durations. Many of Velindre's studies may not recruit the first participant for some time after 'greenlight', therefore those would be excluded on that basis.

None of these reasons for exclusion are explained in the "Notes" page of the HCRW Performance Dashboard. It is these unexplained exclusions that has caused the confusion in thinking studies that are planning to recruit less than one participant a month are excluded from the measures. The HCRW Senior Research Performance Manager has agreed that the "Notes" need to be updated with this information and will instruct their team to do that.

The Head of Research & Development and Research Delivery Manager are due to meet with HCRW Senior Research Performance Manager in February 2023, to review the Health and Care Research Wales performance data for the Trust, with a view to improving the dashboard information to better reflect the Trust's status regarding research.

4 Velindre Cancer Centre hosted research – key achievements

4.1 OPTIMA

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

OPTIMA is a national, NHS-funded clinical study. It is 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.

The aim of OPTIMA is to:

- personalise treatment
- target chemotherapy to patients most likely to benefit from it
- identify patients who may be better treated by moving directly to hormone therapy

Velindre was the second UK site to recruit 100 participants to the OPTIMA study.

4.2 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.

The aims of the trial are to find out:

- whether Dato-DXd is better than chemotherapy
- more about the side effects of Dato-DXd
- how Dato-DXd affects quality of life

Velindre was the first UK site to randomise a participant to the study and continues to be the top UK recruiter to the study.

4.3 Velindre University NHS Trust tops recruitment

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

Carcinoma of Head and Neck (SCCHN), or Metastatic Urothelial Bladder Cancer (mUBC)

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

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

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

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

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

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

5.1 Radiotherapy

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

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

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

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

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

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

A further meeting is expected to take place in Quarter 4 of FY2022/23 to review the work and potential improvements.

5.2 Oncacare

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

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

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

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

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

6 Welsh Blood Service

6.1 Healthcare Scientist of the Year

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.

Commenting on her incredible achievement Chloe said: “I am absolutely delighted to have won this award and to have received recognition for the work I do as a Healthcare Scientist within NHS Wales, it means a lot to me.

“I would like to thank the Welsh Blood Service who have supported me throughout my 20-year career and in particular, my now retired mentor Joan Jones, who saw potential in me and provided me with opportunities to develop.

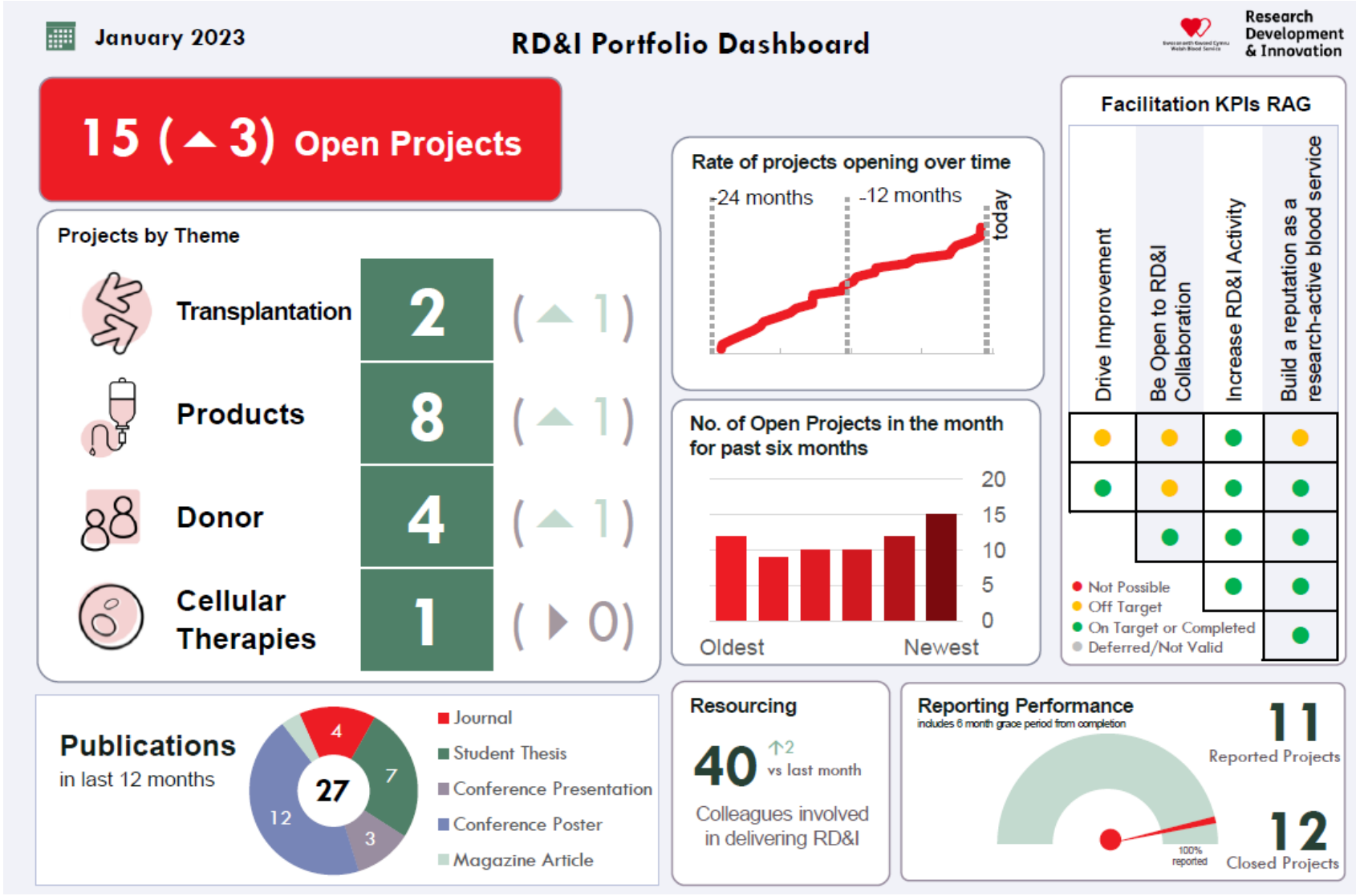
“I strive to be a role model for other scientists and in particular women in the workforce and hope that I can help others to develop and stretch themselves during their careers.

“I would of course also like to thank my husband and two children who tirelessly put up with me talking about science and support me in everything that I do!”

The Advancing Healthcare Awards recognise and celebrate the work of health professionals, healthcare scientists and those who work alongside them in support roles, leading innovative healthcare practice across the UK. The awards have been running for 20 years and have both UK-wide and regional award programmes.

Welsh Blood Service would also like to congratulate our Vaccine Distribution Project Team, who were deservedly shortlisted for the ‘Improving Public Health Outcomes’ Award.

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
Effect of Different Sensitisation Events on HLA Antibody Stability in Kidney Transplant Candidates	145	Transplantation	Maria Burton	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
Proof of Concept of Method to Remove Extracellular Harmful Agents from Stored Red Cell Units	163	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	170	Products	Jamie Nash	WBS led RD&I

Project Name	WBS Project ID	WBS Research Theme	WBS Staff Lead	Involvement
Resuscitation (CoPPER): Laboratory Testing				
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

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

The Welsh Blood Services BEST-C as of 01 Jan 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
BEST- C 157 Project: We Keep Getting Aggregates in Platelets. Let's GET AGGRIP on Aggregates	159	Products	Nicola Pearce

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. Minimally the RD&I Strategy, contact details will be added to the webpage.	✔		Refreshed annual	✔	⚠	⚠	✔	✔	✔	✔	✔	✔			
Increase RD&I Activity																	
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																	
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 completed RD&I projects achieve a peer-reviewed publication	✔	⚠	✔	✔	⚠	✔	✔	✔	✔			
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 Innovation Update

10.1 RITA – a chatbot powered by artificial intelligence

RITA has now been deployed successfully on the Trust website since November 2022 on Velindre Cancer Centre page with a soft launch, allowing us to continue to engage with our patients and obtain feedback for the ongoing direction and development of the virtual assistant.

This has enabled us to identify any areas where there are glitches or incorrect intent identification and provide access to evaluation and analytical tools. These tools provided data on how many users are engaging with RITA, along with useful insights as to the most common questions our services users are asking. The innovation team has used this data to build upon the work already done and to make sure we are continuing to develop RITA with a patient-centric approach.

With the soft launch period complete, the innovation team is working in conjunction with Velindre Communications to deploy a communication strategy, using external and internal communications, social media, and physical media, e.g., flyers and posters, to raise awareness of the service to our patients and staff and the wider innovation network.

The full launch is due to coincide with World Cancer Day on 4th February 2023, with a week of communications being deployed in the run-up to this date which will feature video media and quotes from the project team and patients to generate interest and awareness of the project launch. Performance measures and usage data will be collected to measure the impact of the strategy on the number of users compared to the soft launch figures.

10.1.1 RITA - Welsh Language Translator

Velindre have created a separate version of RITA that will translate Welsh text into English, search its repository for an answer based on the intent or area of questioning it identifies and then translate this back into Welsh to provide the same service to our Welsh-speaking service users. This has been tested with Welsh language colleagues and third-party Welsh speakers, and the feedback has been positive with some minor errors in complete translation due to the platform utilising the English language base, meaning some clickable button labels are unable to be changed.

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

10.1.2 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. These clips will be used in the editing process, while also being utilised as separate media for use within RITA and the Trust website, giving patients the opportunity to view clinical areas and the site before attending.

10.2 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. 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 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.

Discussions have taken place in January 2023 between 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. A planned paper submission to the EMB and SLT has been targeted for end of February 2023 and discussions are ongoing with Pfizer who have provided a draft report of the pilot project for review.

10.3 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 is ongoing with the Innovation Team continuing to collect responses and based on feedback we have produced physical copies to ensure we maximise the response rate amongst clinical staff.

10.4 Pan-Wales Patient Centred Radiotherapy Service 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 planning is currently underway and will involve 3 centres across Wales.

10.5 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.

10.6 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

11 Trust Sponsored Research

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

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

Up to the end of Quarter 3 of Financial Year 2022/23, the Trust sponsored research portfolio is as follows:

Metric Description	Year to date
Number of new sponsored research studies (Total)	0
• Number of sponsored research studies that are Trust-wide	N/A
• Number of sponsored research studies that are UK-wide	N/A
• Number of sponsored research studies that are Europe-wide	N/A
• Number of sponsored research studies that are World-wide	N/A
Number of research sites opened for sponsored research studies	6

Metric Description	Year to date
Number of publications from sponsored research studies	
• Journal article	2
• Abstracts	5
Number of participants recruited to sponsored research studies	163

12 Welsh Blood Service collaborations

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

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

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

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

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

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

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

CROSS CUTTING THEMES: across Strategic Priorities 1 to 4

13 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** • Work continues to identify existing training and develop an implementation plan to ensure the Trust can provide/promote a staff training programme for research & development
○ 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** • Work continues on plans to improve/change the administrative structure, roles and responsibilities of the research delivery team is ongoing with support from Trust Workforce & Organisational Development, as appropriate.
○ Complete the appointment of senior staff in the research delivery team and to support the delivery of the Cardiff Cancer Research Hub		x											
○ Complete the implementation of changes to the structure of the research delivery team administrative structure.			x										
○ 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	

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 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** • The cutover from using CaNISC to using the Digital Health and Care Record (DHCR) solution took place on 14 Nov 2022. The DHCR solutions consists of Wales Patients Administration System (WPAS) and Welsh Clinical Portal (WCP). The R&D team are now working to update the records of patients taking part in clinical trials with the appropriate information.
○ 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

14 RD&I Finances

14.1 Background / context

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. VCC).

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:
  - Management, trial support, data, and administrative staff (40%)
  - Nursing staff (33%)
  - Medical staff (13%)

- 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.

14.2 Summary of Performance against Key Financial Targets: Quarter 3

14.2.1 Key Financial Target 1: to remain within budget expectations

Key financial performance figures are summarised in the following table:

		£000			
		Pay	Non-Pay	Income	Total Variance
Quarter 3	Budget	656	97	-545	
	Actual	634	98	-524	
	Variance	**-22**	**1**	**21**	**0**
Year to Date	Budget	2,002	167	-1,672	
	Actual	1,874	176	-1,552	
	Variance	**-129**	**9**	**120**	**0**

		£000			
		Pay	Non-Pay	Income	Total Variance
Forecast Outturn	Annual Budget	2,778	232	-3,250	
	Forecast Outturn	2,490	279	-3,009	
	Variance	-288	47	241	0

14.2.2 Analysis of Performance to Date and Forecast Outturn

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

- higher than expected vacancies due to staff turnover has created a £129k underspend; and
- in turn, this has allowed the Division to reduce the expectation of funding support from sources such as Innovation and Velindre Charitable Funds.

The forecast outturn for the Division is to achieve the Budget Plan with £0 variance. This includes pay award funding, which has been received, however is allocated to Q4 and explains the increase in Pay variance in the outturn forecast. The primary risk to achieving this outturn is:

- Securing income from participating in commercial and other fee-paying trials. Income in Quarters 1-3 has remained on target to achieve this budget; however, the timing and value of trial income is difficult to predict with certainty and therefore a risk remains that income will slow in the final quarter of the year.

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

	Quarter 3	Year to Date	Forecast Outturn
NHS Invoices	98%	98%	95%
Non-NHS Invoices	87%	89%	95%

To date, 33 out of 352 invoices missed the 30-day target. These are mainly where patient research records need to be investigated by the nursing team before confirming invoices can be paid. For Q4 a further effort will be made to increase the efficiency of this process.

14.2.4 Pay Analysis by Staff Group

Cumulative Q3

	£129k less than budget		
PAY GROUP	YTD Budget (£'000)	YTD Actual (£'000)	YTD Variance (£'000)
Professional Scientific & Technical	0	0	**0**
Additional Clinical Services	61	59	**-2**
Administrative & Clerical	897	778	**-118**
Allied Health Professionals	39	39	**0**
Healthcare Scientists	126	127	**1**
Medical	273	263	**-11**
Nursing	704	608	**-97**
Vacancy Factor	-99	0	**99**
Total	2,002	1,874	**-129**

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

14.2.5 Non-Pay Analysis by Category

	Cumulative Q3		
	£9k more than budget		
NON-PAY CATEGORY	YTD Budget (£'000)	YTD Actual (£'000)	YTD Variance (£'000)
Clinical/General Services/Supplies	148	127	**-21**
Maintenance & Repairs	0	0	**0**
Transport (inc. patients)	0	6	**6**
Printing / Stationary / Postage	0	8	**8**
Travel & Subsistence	0	6	**6**
Education & Development	0	6	**6**
Equipment & Consumables	0	3	**3**
Computer Maintenance & Supplies	19	19	**0**
Total	167	176	**9**

The Division holds modest non-pay budgets. At Quarter 3 a small overspend is due to budget timing and does not reflect an underlying trend. An overspend is forecast at the year end, however this will be matched with project income, with no overall impact.

14.2.6 Income Analysis by Category

Cumulative Q3
£120k less than budget

INCOME CATEGORY	YTD Budget (£'000)	YTD Actual (£'000)	YTD Variance (£'000)
HCRW Income	-263	-263	**0**
Trial Reimbursements	-550	-523	**27**
Charitable Income	-431	-300	**130**
Innovation Income	-113	-156	**-43**
Other Income	-315	-310	**6**
Total	-1,672	-1,552	**120**

Income recovery has proceeded to plan in Quarter 3 except for deliberate reductions, e.g. in charity funding, to match reduced expenditure due mainly to vacancies, and a modest over-achievement of Innovation income from the RITA project. This overall trend is expected to continue for Q4.

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

Date 15/11/2022
Time 10:00-12:15pm
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	Deputy Medical Director, Welsh Blood Service	EM
Jonathan Patmore	RD&I Finance Business Partner	JP
Alan Prosser	Director, Welsh Blood Service	AP
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

0.0.0	**PRESENTATIONS**	
0.0.1	**PROD Study Update** *Led by Felicity May, Clinical Specialist Histocompatibility & Immunogenetics Digital Lead of the Welsh Blood Service* The RD&I Sub-Committee received a presentation on Predictive biomarkers response to desensitisation by Felicity May, Clinical Specialist Histocompatibility & Immunogenetics Digital Lead of the Welsh Blood Service. **WBS RD&I Strategy Update** *Led by Dr Sian James, RD&I Facilitation Lead, Welsh Blood Service* Dr Sian James, RD&I Facilitation Lead presented an update on a refresh of the WBS Research Development & Innovation Strategy and intends to perform stakeholder engagement through an in-person event at WBS HQ. The stakeholder engagement will commence around March 2023. **ACTION:** From a Trust perspective, JA to be involved in discussions in how to take this forward. Meeting to be arranged with AP, ED, JA in the first instance.	**JA**
1.0.0	**STANDARD BUSINESS**	
1.1.0	**Apologies** • Eve Gallop-Evans, VCC Clinical Director • Steve Ham, Chief Executive • Peter Richardson, Head of Quality & Assurance, Welsh Blood Service	
1.2.0	**In Attendance** • Felicity May, Clinical Specialist Histocompatibility & Immunogenetics Digital Lead, Welsh Blood Service *(Item 0.0.1)* • Christopher Cotterill Jones, Research Delivery Manager *(Item 4.3)* • Debbie Harvey, Project Lead, Life Sciences Hub *(Observer)*	
1.3.0	**Declarations of Interest** *Led by Professor Andrew Westwell, Chair of the Research, Development & Innovation Sub-Committee* No declarations of interest were raised.	
1.4.0	**Matters Arising - Action Log** *Led by Dr Jacinta Abraham, Executive Medical Director* The RD&I Sub-Committee reviewed all actions identified as having closed and updated received since the previous meeting.	

	The RD&I Sub-Committee **APPROVED** the Action Log.	
2.0.0	**CONSENT ITEMS** **The consent part of the agenda considers routine Committee business as a single agenda item. Members may ask for items to be moved to the main agenda if a fuller discussion is required.**	
2.1.0	**FOR APPROVAL**	
2.1.1	**Minutes from the Meeting of the Research, Development & Innovation Sub-Committee held on the 21st July 2022** *Led by Professor Andrew Westwell, Chair of the Research, Development & Innovation Sub-Committee* **ACTION :** Amendment to Item 4.2 RDI Annual Report, to formally thank both Divisions and note this in the minutes. Subject to the minor amendment outlined above, the RD&I Sub-Committee **REVIEWED** and **APPROVED** the Minutes of the Public Meeting held on the **21st July 2022** as an accurate reflection of proceedings.	**SMC**
2.2.0	**ITEMS FOR ENDORSEMENT**	
2.2.1	***Item moved from CONSENT to MAIN Agenda to allow for futher discussion.*** **RD&I Sub-Committee Terms of Reference and Operating Arrangements** *Led by Dr Jacinta Abraham, Executive Medical Director & R&D Lead and supported by Emma Stephens, Head of Corporate Governance* DM requested a number of further amendments to the RD&I Sub-Committee Terms of Reference following the conclusion of the consultation period. It was agreed that these will be addressed outside of the committee. DM requested that the Advancing Radiotherapy Fund (ARF) Programme Board relationship to the Research, Development and Innovation Sub-Committee (RDI) and the Charitable Funds Committee (CFC) needs to accurately reflect the following : i. The ARF Prorgamme Board is authorised to approve projects which apply to this fund as long as there is funding available and therefore to approve business cases. ii. The ARF Programme Board formally reports to the CFC and, within this accountability governance relationship has its own advisory board which is comprised of experts in the field who review research related and other bids to the ARF. Bids are assessed for	

	science, ethics, funding, and quality; and recommendations are made to the ARF Programme Board who then have delegated authority to approve the bids. iii. The equality impact assessment section be completed fully to reflect the role of the RD&I Sub-Committee. iv. Clarification of approval arrangements under item 4.5 Member Appointments. v. MB will liaise with ES regarding re-wording of item 3.2 Strategy & Policy Approval out of committee. **ACTION: Subject to the above** amendments, the RD&I Sub-Committee **ENDORSED** the Terms of Reference for onward submission to the Trust Audit Committee for formal Endorsement and recommendation to the Trust Board for Approval.	**ES/MB**
2.3.0	**FOR NOTING**	
2.3.1	**Draft Summary of the Minutes from the Private Research, Development & Innovation Committee held on the 21st July 2022** *Led by Professor Andrew Westwell, Chair of the Research, Development & Innovation Sub-Committee* The RD&I Sub-Committee **NOTED** the Summary Minutes of the Private Meeting held on the **21st July 2022**	
2.3.2	**Audit of Research & Development by NHS Wales Shared Services Partnership** *Led by Sarah Townsend, Head of Research & Development* NHS Wales Shared Services Partnership (NWSSP) undertook an audit of Research & Development (R&D) as part of the 2022/23 internal Audit Plan. The review sought to provide the Trust with assurance regarding the effective management of R&D within the Trust. The Trust's R&D function received a "substantial" assurance classification. DM would like to add, that following an internal audit meeting, the audit team were very impressed with R&D and singled this out to the Chair. The RDI Sub-Committee formally thanked the following staff: • Sarah Townsend, Head of Research & Development • Christopher Cotterill-Jones, Research Delivery Manager • Peter Richardson, Head of Quality & Assurance & Regulatory Compliance (WBS) • Sian James, RD&I Facilitation Lead (WBS) The RD&I Sub-Committee **NOTED** the NWSSP R&D Final Internal Audit Report.	
3.0.0	**MAIN AGENDA**	

3.1.0	**Executive Medical Director Briefing** *Led by Dr Jacinta Abraham, Executive Medical Director* The Executive Summary Briefing reported high-level activities relating to Research, Development and Innovation that took place during Quarter (Q) 2 of Financial Year (FY) 2022/23. The following key highlights were reported : **Welsh Blood Service** ➢ COVID-19 Serosurveillance Scheme ➢ Welsh Bone Marrow Donor Registry **Research & Development** ➢ FAKTION and CAPItello-291 ➢ Research & Development Internal Audit ➢ Charitable Funds Committee Integrated Bid ➢ Oncacare ➢ Head of Innovation ➢ Radiotherapy Research The RD&I Sub-Committee **NOTED** the contents of the Executive Medical Director Briefing.	
3.2.0	**Velindre HCARE Research Ambition Update** *Led by Professor Jane Hopkinson, Velindre Professor of Nursing and Interdisciplinary Cancer Care* JH gave a brief update on the Velindre HCARE Research Ambition as this also formed part of the RDI Integrated Bid which was to be presented at the Private RDI Sub-Committee. Velindre has a small number of nurses and therapists who research as part of their practice. The contribution of nurses and therapists to evidence-based quality improvement is limited. They are underserved in the education and training needed, if they are to fulfil their potential contribution to an improvement culture. Strategy and workplan are needed for sustained leadership and growth in Velindre Healthcare Research and Innovation. The ambition is to establish a Velindre Healthcare Cancer Research and Innovation (R&I) Centre of Excellence with a programme for transforming the safety and quality of cancer care. The Velindre Healthcare R&I Centre will be recognised nationally and internationally for service improvement informed by nurse and therapies led research and innovation. Training and education in research methodologies and methods is needed by nurses and therapists to complement their professional qualifications. We will develop a career framework to build capacity for research and innovation that can enable	

	sustainable high-quality services resilient to the anticipated health challenges for the future NHS. This will comprise an introduction to research at MSc level for 3 healthcare staff annually, support for 1 healthcare staff member to commence a PhD research training annually, and 1 member of healthcare staff to take up post-doctoral research annually. In this way, we will build capacity to have clinical-academic leaders in cancer driving an agenda for evidence-based improvement in nursing and therapies practice. Further context about the Velindre Healthcare Research plans is included in the RD&I Integrated Bid held at the Private RDI Sub-Committee Meeting. The RD&I Sub-Committee **NOTED** the contents of the Velindre HCARE Research Ambition Update which forms part of the Trust Consolidated Research Bid - Implementing the Cancer R&D Ambitions – An Integrated Business Case 2023-2026.	
3.3.0	**Trust RD&I Sub-Committee Risk Register Extract** *Led by Sarah Townsend, Head of Research & Development* At the last Sub-Committee meeting, it was requested to make this a standard agenda item to formally note, if any, items that are required to be escalated to the Sub-Committee, in line with the Trust Board Risk Appetite. It was reported that there were no open risks recorded on Datix for escalation to November's RD&I Sub-Committee in line with the Trust Board Risk Appetite. The RD&I Sub-Committee **NOTED** this update.	
4.0.0	**STRATEGY, PERFORMANCE & DELIVERY**	
4.1.0	**Activity Data Benchmarking with other UK Cancer Centres** *Led by Sarah Townsend, Head of Research & Delivery* ST presented the Activity Data Benchmarking with other UK Cancer Centres. The Nuffield Trust report – **Advice on the proposed model for non-surgical tertiary oncology services in South-East Wales** – published in December 2020, recommended that each LHB needs to develop and implement a coordinated plan for analysing and benchmarking cancer activity against other areas. In striving to meet the Trusts' Strategic goal to be *"A beacon for research, development and innovation"*, the Trust's Integrated Medium-Term Plan (2022 to 2025) includes four main strategic priorities. Strategic Priority 1 is *"The Trust will drive forward the implementation of its Cancer Research & Development Ambitions 2021-2031"*. This strategic priority includes	

building research capacity and capability at Velindre and across South-East Wales.

To define a baseline the Trust can use to demonstrate improvements in Cancer Research & Development, an activity benchmarking exercise has been undertaken against five selected UK Cancer Centres.
These UK Cancer Centres were selected by the Trust's RD&I Senior Leadership Team, with data collection expanded to include data from South-West and South-East Wales.

The benchmarking exercise concentrated on considering three areas of investigation:

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

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

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

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

The data is presented in line with the following points:

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

	In 2019/20 Velindre University NHS Trust:
	• Could offer patients Phase I through to Phase IV studies, like the UK Cancer Centres selected for comparison. Whereas South-West Wales did not offer Phase I, Phase I/II nor Phase IV studies, and South-East Wales did not offer Phase I studies
	• Could offer a greater number of studies from the study portfolio in terms of the Phase I through to Phase IV studies than South-West Wales [SB UHB & HD UHB] and South-East Wales (AB UHB, CV UHB & CTM UHB)
	
	Study portfolios in all organisations comprised of more non-commercially sponsored studies than commercially sponsored studies with organisations recruiting more participants to those non-commercially sponsored studies than commercially sponsored studies.
	
	Study portfolios of all organisations comprised of more interventional studies than observational studies or both (interventional & observational) studies.
	
	The activity data benchmarking exercise enabled the Trust to determine its performance against other UK Cancer Centres, and to help the Trust identify where to focus energy and resource.
	
	ACTION: The proposed next steps for consideration are:
	• That the activity data benchmarking exercise is repeated annually in future financial years and reported to the RD&I Sub-Committee
	• To undertake data capture and present the data for financial years 2020/21 and 2021/22 to determine the impact of COVID19 and compare this across the organisations (taking into consideration the ability to capture and present data for solid tumours only)
	• To undertake a more detailed scoping exercise with each organisation to determine
	  o Available facilities and equipment resource
	  o Available staffing resource and any workforce planning utilised by the organisation
	  o Any efficiencies that can be adapted for use in VUNHST with the findings of this detailed scoping exercise presented at a future meeting.
	
	The RD&I Sub-Commitee thanked ST for a positive report and **NOTED** the contents of the Activity Data Benchmarking with other UK Cancer Centres.	

4.2.0	**Trust Research, Development and Innovation Performance Report** *Led by Sarah Townsend, Head of Research & Development and supported by*	

	• *Libby Batt, Head of Cancer R&D Strategy, Velindre Futures* • *Christopher Cotterill Jones, Research Delivery Manager* • *Peter Richardson, Head of Quality & Assurance, Welsh Blood Service* • *Jonathan Patmore, R&D Finance Manager* The newly formatted Research, Development & Innovation (RD&I) Integrated Performance Report form has been amended. The report now reflects the RD&I strategic priorities published in the Velindre University NHS Trust's Integrated Medium-Term Plan (IMTP) that has been updated for 2022 to 2025. These priorities that support the Trust's strategic goal to be "A beacon for research, development and innovation" are as follows: • **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 included the progress of work and key achievements for Quarter 2 of Financial Year 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. **Overarching Cancer R&D Ambitions** The Research, Development & Innovation (RD&I) Team have prepared a Business Case for submission and consideration by the Charitable Funds Committee. The business case sets out a request for funding to support the implementation of the Velindre Cancer R&D Ambitions that includes : • Research infrastructure for Clinical Trial Delivery and Governance • Implementation of the Cancer Research Ambitions to grow future research The business case requests funding for Financial Year 2023/24 to Financial Year 2025/26. The business case will allow the Trust to continue to support the thriving research infrastructure, ensure the flow of benefits for patients and research continue to be delivered in line with the Trust's Cancer Research Ambitions. **Cardiff Cancer Research Hub** The shared cancer research priorities have now been agreed by all Tripartite partners. These priorities act as the building blocks of the Hub, providing a clear direction when applying for grants and developing further partnerships. • The CCRH Project Board's brief and terms of reference has been approved, providing direction to the team and to the project's governance structure.	

	• Following comments from VUNHST's Board, branding of this initiative has been extensively discussed in the Project Board. There was a strong consensus that the title of the Hub should reflect the Tripartite partnership and location. This was further discussed at the CVUHB, VUNHST and Cardiff University Executive Partnership Board with a consensus decision that the name will be 'The Cardiff Cancer Research Hub - A partnership between Velindre, Cardiff and Vale and Cardiff University'. Funds have been secured from VCC's R&D budget to work with a local design agency to design the Hub branding and logo. • Regarding the Investment Strategy for CCRH, there has been engagement with other organizations to establish lessons learnt regarding investment funding, with pre-market engagement undertaken for the development of the investment strategy. Support from VUNHST has been secured to help take forward this work. • There has been slow progress in securing appropriate infrastructure at UHW. This is now being addressed and the appointment of a joint planning role between CVUHB and VUNHST will enable this work programme to move forward. Service specifications have now been compiled for the Hub and, also on dependent projects: Acute Oncology Service and Haematology (BMTU). A co-located request is currently being worked through. • Trial portfolio is gathering pace with MOAT, MORAb and MAGE in set up as well as SOTIO which is the first Solid tumour CAR-T trial to be delivered on the UHW site. • A Senior Operational Team has been established that has oversight of the operational delivery of high and intermediate Early phase and ATMP trials. This multi-professional team includes Haematological Oncology and Solid tumour representatives and have an agreed work plan to develop operational policies and supporting documentation. • A Senior nurse has been appointed and will come into post on 31 October 2022 who will lead a scoping exercise with other UK centres that conduct EPT and ATMP trials. A Clinical Research Fellow post is also currently being advertised. • The Head of R&D and team continue to work with the Joint Research Office (JRO) on the Heads of Terms which is now in its final draft. They are establishing where in the organisation the document needs to be signed off as well as clarifying details such as commencement and duration of collaboration and how the parties will collaborate to appoint the Hub senior management team. The JRO's Partnership and Business Manager is due commence in mid-October and will meet the Head of R&D as a priority to finalize the Heads of Terms. This document will be presented at the next Project Board in November. **Oncacare** Wales Cancer Research Centre introduced Oncacare to the Trust, and also to Cardiff and Vale University Health Board (CVUHB), in early 2021 and a Letter of Intent was signed by the Trust in July 2021 followed by a confidentiality agreement in November 2021. The Letter of Intent	

	contained offerings to the Trust in the context of the NHS and its well-established four nations systems and processes specifically in the set-up of commercial clinical trials. The Trust can expect to be offered interesting studies with a guarantee of acceptance as a site if we decided our patients would benefit from the trial on offer. The Trust will continue to maintain and develop its current relationships with sponsors and other CROs and to manage delivery of its portfolio of commercial studies independently of Oncacare. The Trust R&D office is working with the Joint Research Office at CVUHB to ensure that the terms of the collaboration are the same for both parties. **Radiotherapy Research** Delivery of Radiotherapy and combination Drug/Radiotherapy research continues to be challenging due to limited capacity across the Radiotherapy service. In October 2022, a meeting took place to discuss the issues and identify possible mitigation strategies. Work is underway to identify and implement mitigation strategies to improve the Radiotherapy service's capacity in terms of research studies and the wider service. The findings and outcomes will be reported to the RD&I Operational Management Group and RD&I Strategic Leadership Group. **ACTION:** A report of this work will be made to the RD&I Sub Committee in February 2023 **Welsh Blood Service : COVID-19 Serosurveillance Scheme** The Welsh Blood Service RD&I Facilitation Team were recent finalists in the NHS Wales Awards. This cross-department work, in tandem with the partnership between Public Health Wales, Cwm Taf Morgannwg University Health Board and Swansea Bay University Health Board, has been recognised for its efforts by the award nomination. The scheme updates Welsh Government on the changes in infection and vaccine-mediated immunity to the COVID-19 virus in the adult Welsh population, month-on-month. The project, which began during the first wave in 2020, has processed over 66,000 samples to date. The scheme supports effective decision-making about Wales's vaccination programmes and public health measures. **Welsh Bone Marrow Donor Registry (WBMDR)** • In its 33rd year of operation the WBMDR is a mainstay of the WBS's RD&I efforts. • WBMDR work alongside the South Wales Blood and Transplant Team to support the provision of "CAR-T" therapies • The registry is joining international associates to support ATMPs to international patients • Developing a new stem cell apheresis facility within VCC enables WBMDR to support programmes & provision of vital services in the cell therapy supply chain.	**ST**

	• Having participated in research for acute myeloid leukaemia, unmet needs of minority people and effects of COVID19 pandemic on stem cell donation, future work includes:
	  • Effect of storage on haematopoietic stem cells reviewing long-term liquid nitrogen storage and how fresh cells are shipped for immediate transplant
	  • Exploration of genetic profiles and donor characterisations for HLA matching
	
	The RD&I Sub-Committee questioned whether the use of a 'dashboard' style of reporting would be better suited to the reporting of this item.
	
	The RD&I Sub-Committee **NOTED** the RD&I Integrated Performance Report.	

5.0.0	**ANY OTHER BUSINESS**	
5.1.0	Prior Approval by the Chair Required No prior items have been raised for consideration under Any Other Business.	
6.0.0	**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** • Head of Innovation • RD&I Terms of Reference and Operating Arrangements • Radiotherapy Research **For Assurance** • Trust RD&I Sub-Committee Risk Register Extract • TRUST Research, Development, and Innovation Performance Report 2021/2022 **For Information** • PROD Study Update • WBS RD&I Strategy Update • Executive Summary Highlight Report 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 RD&I Sub-Committee Chair.	**ST**
7.0.0	**DATE AND TIME OF THE NEXT MEETING:**	
	The Research, Development and Innovation Sub-Committee will next meet on the **28th February 2023 from 10.00 – 12.30pm via Microsoft Teams**.	
8.0.0	**CLOSE**	
	That representatives of the press and other members of the public be excluded from the remainder of this meeting having regard to the confidential nature of the business to be transacted, publicity on which would be prejudicial to the public interest in accordance with Section 1(2) Public Bodies (Admission to Meetings) Act 1960 (c.67).	

RESEARCH, DEVELOPMENT AND INNOVATION SUB-COMMITTEE

Intellectual Property Policy

DATE OF MEETING	28th February 2023

PUBLIC OR PRIVATE REPORT	Public

IF PRIVATE PLEASE INDICATE REASON	Not Applicable - Public Report

PREPARED BY	Sarah Townsend, Head of R&D and Rachel Granger, Senior Contracts Manager
PRESENTED BY	Sarah Townsend, Head of R&D
EXECUTIVE SPONSOR APPROVED	Jacinta Abraham, Executive Medical Director

REPORT PURPOSE	FOR APPROVAL

COMMITTEE/GROUP WHO HAVE RECEIVED OR CONSIDERED THIS PAPER PRIOR TO THIS MEETING		
COMMITTEE OR GROUP	**DATE**	**OUTCOME**
Executive Management Board	20 Feb 2023	ENDORSED FOR COMMITTEE APPROVAL

ACRONYMS	
RD&I	Research, Development and Innovation
RD&I OMG	Research, Development and Innovation Operational Management Group
VUNHST	Velindre University NHS Trust
VCC	Velindre Cancer Centre
WBS	Welsh Blood Service

1. SITUATION

1.1 The revised Trust Intellectual Property Policy (Reference RD01) is provided to the Research, Development & Innovation Sub Committee for **APPROVAL** following Endorsement at the Executive Management Board of 20 February 2023.

2. BACKGROUND

2.1 The UK Policy Framework for Health and Social Care Research 2017 places a duty on the Trust to have in place a mechanism for the exploitation of IP arising from its employees. This mechanism is described in the attached Intellectual Property Policy.

2.2 The current Policy was extensively reviewed via the Trust governance framework as well as by legal services and was amended in line with advice received.

3. ASSESSMENT / SUMMARY OF MATTERS FOR CONSIDERATION

3.1 This Policy is due for review and has been circulated widely for consideration in line with the Trust Policy approval process. All comments and suggestions during the consultation process have been included within the final policy as appropriate. Please refer to **Appendix 1** for the track change copy for ease of reference and **Appendix 2** for the final updated policy.

3.2 The key changes are summarised 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

4. IMPACT ASSESSMENT

QUALITY AND SAFETY IMPLICATIONS/IMPACT	There are no specific quality and safety implications related to the activity outined in this report.
	(Policy)
RELATED HEALTHCARE STANDARD	Governance, Leadership and Accountability

	If more than one Healthcare Standard applies please list below:
EQUALITY IMPACT ASSESSMENT COMPLETED	Yes
	As this Policy is only a revision to an existing Policy a new EQIA is not required
LEGAL IMPLICATIONS / IMPACT	Yes (Include further detail below)
	This policy has been reviewed by Legal services and minor revision has been made to the Policy in line with the recommendations
FINANCIAL IMPLICATIONS / IMPACT	There is no direct impact on resources as a result of the activity outlined in this report.

5. RECOMMENDATION

The Research, Development & Innovation Sub-Committee is requested to **APPROVE** the Trust Intellectual Property Policy.

Ref: RD01

INTELLECTUAL PROPERTY (IP) POLICY

Executive Sponsor & Function:	Executive Medical Director and RD&I Board Lead
Document Author:	Head of Research & Development
Approved by:	Research, Development & Innovation Sub Committee ~~Trust Board~~
Approval Date: ~~2021~~	28th February 2023 (TBA)~~25th March~~
Date of Equality Impact Assessment:	27th February 2014
Equality Impact Assessment Outcome:	Approved
Review Date:	February 2025~~January 2023~~
Version:	06~~05~~

Contents

1. INTRODUCTION

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

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

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

2. POLICY STATEMENT

Velindre University NHS Trust recognises the importance of innovation and creativity as essential elements in the process of continual improvement. The UK Policy Framework for Health and Social Care Research (https://www.hra.nhs.uk/planning-and-improving-research/policies-standards-legislation/uk-policy-framework-health-social-care-research/) ~~2017~~ places a duty on the Trust to have in place a mechanism for the exploitation of IP arising from its employees. Innovation in the NHS also occurs in the delivery of patient care and in the education and training of employees. The purpose of this document is to detail a policy for the effective management of IP within the Trust taking into account the principles referred to above and also arrangements with the Trust's academic and commercial ~~Academic~~ partners.

3. SCOPE OF POLICY

This Policy applies to IP opportunities arising from activity involving:

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

employees of the Trust who are not also employees of the Trust who generate IP during the course of their training (IP generated by students engaging in research for the Trust may be owned by the student, the institution with whom they are enrolled or the Trust, depending on the agreements between the student, the institution and the Trust~~Trust unless there is an agreement to the contrary~~).

- Independent Providers of Services who generate IP from research funded by the NHS are required to inform the appropriate party and share the benefits of its

commercialisation. Where IP is assigned to the Trust, the Independent Provider of Services will benefit under the revenue sharing scheme of the Trust.

- For individuals who hold an Honorary Contract with the Trust, the IP Policy of their substantive employer will take precedence over the Trust's policy unless circumstances (such as the Trust's contribution to the creation of the IP for example where the honorary employee has utilised Trust equipment, consumables or the time of Trust-funded staff to create the IP) require negotiation to the contrary to ensure the Trust's contribution is fairly rewarded.
- Trust staff seconded to another organisation or employees of another organisation hosted by the Trust under contract are subject to the terms defined in the contract between the Trust and that organisation.

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

4. AIMS & OBJECTIVES

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

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

5. ROLES AND RESPONSIBILITIES

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

Should employees fail to report any IP development to the Trust's R&D Department the key principles of this policy will apply retrospectively, unless

public disclosure has invalidated the opportunity to protect IP. Discussion of potentially protectable IP should only be discussed outside the Trust within the strict confines of a reciprocal non-disclosure agreement.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

7. IMPLEMENTATION

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

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

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

The RD&I Committee will review the operation of this policy as required. At least every two years.

8. POLICY COMPLIANCE

8.1 Identifying and Protecting IP

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

- A novel treatment
- A new diagnostic technique

- A new device
- A new drug or the new use of a drug
- Use of data, software, training material
- A treatment protocol
- New management system

8.2 Ideas Disclosure

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

The ideas disclosure form is attached in appendix 3 and the general process for the disclosure of ideas in appendix 4.

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

In seeking to establish the originality/inventiveness of an idea, employees should investigate current patents online before completing the Idea Disclosure Form. The following link will allow Velindre employees to do a preliminary patent search https://worldwide.espacenet.com/

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

The Trust emphasises that staff should not disclose their idea to anyone apart from research collaborators with whom they are bound by a viable contract which includes provisions for confidentiality, as this might jeopardise subsequent IP protection. Employees are urged to consult the Trust’s R&D Department at the earliest possible stage if they have any questions about this and especially if they are uncertain about the implications of disclosing an idea to others.

8.3 Due diligence

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

8.4 Partnering with Universities or other organisations to develop IP

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

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

8.5 Partnering with IP specialists

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

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

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

8.6 Ownership of IP

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

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

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

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

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

8.7 Staff Rewards Policy

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

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

8.7.1 Revenue Sharing from IP Exploitation

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

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

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

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

8.7.2 Velindre University NHS Trust Revenue Sharing

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

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

9 COLLABORATIVE RESEARCH PROJECTS

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

It is therefore important before embarking on a collaborative venture that all parties, the researchers, contract managers and funders, agree the principles of the collaboration. These can be set out in a Heads of Terms (HoT) which allows research decision makers to identify in plain language what they regard as the key issues before instructing their lawyers to draw up a formal agreement (see Template Heads of Terms at Annex 5).

10 SHARED MATERIALS

Materials are defined as equipment, reagents and biological materials, including cell lines, tissues, bacterial strains, plasmids and viruses. When such materials are distributed to other researchers or used in a project they should be subject to a Material Transfer Agreement (MTA) which will be managed via the Trust's R&D Department. This agreement should define the limitations of use of the material and recognises the interest in the IP that may arise from its use. This agreement must be in place prior to distribution and use of the material. The use of trademarks and design rights associated with the aforementioned materials should also be the subject of this agreement.

11 RESOLUTION OF DISPUTES

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

12 NON COMPLIANCE

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

13 TRAINING

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

14 EQUALITY

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

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

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

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

15 GETTING HELP

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

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

16 REFERENCES

- ~~Excellence and Opportunity: A science and Innovation White Paper for the 21st Century~~
- ~~www.dti.gov.uk/ost/abouitost/dtiwhite/~~
- ~~Government Response to the Baker Report~~
- ~~www.hm-treasury.gov.uk/documents/eterpriseand productivity/research and enterprise/ent sme baker.cfm~~
- Welsh Assembly Government, 'Intellectual Property and Innovation in Health care in Wales' – A Framework and Guidance on the Management of Intellectual Property in the NHS in Wales, February 2005
- The UK Policy Framework for Health and Social Care Research (https://www.hra.nhs.uk/planning-and-improving-research/policies-standards-legislation/uk-policy-framework-health-social-care-research/)

17 ACKNOWLEDGMENTS

- ~~NISCHR template IP policy for NHS Health Boards in Wales (NISCHR NHS IP Policy January 2013).~~
- ~~Innovation in Wales~~
- ~~An Intellectual Property (IP) policy for activities funded by NISCHR~~

- Abertawe Bro Morgannwg University Health Board R&D Department

APPENDIX 1 - INTELLECTUAL PROPERTY (IP) PROTECTION

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

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

Know-how

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

Copyright

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

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

Patents

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

Design Rights

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

The "Design Right"

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

Registered Design Rights

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

Trade marks

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

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

26. Discoveries and Inventions

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

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

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

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

Appendix 3 – Innovative Ideas Disclosure Form

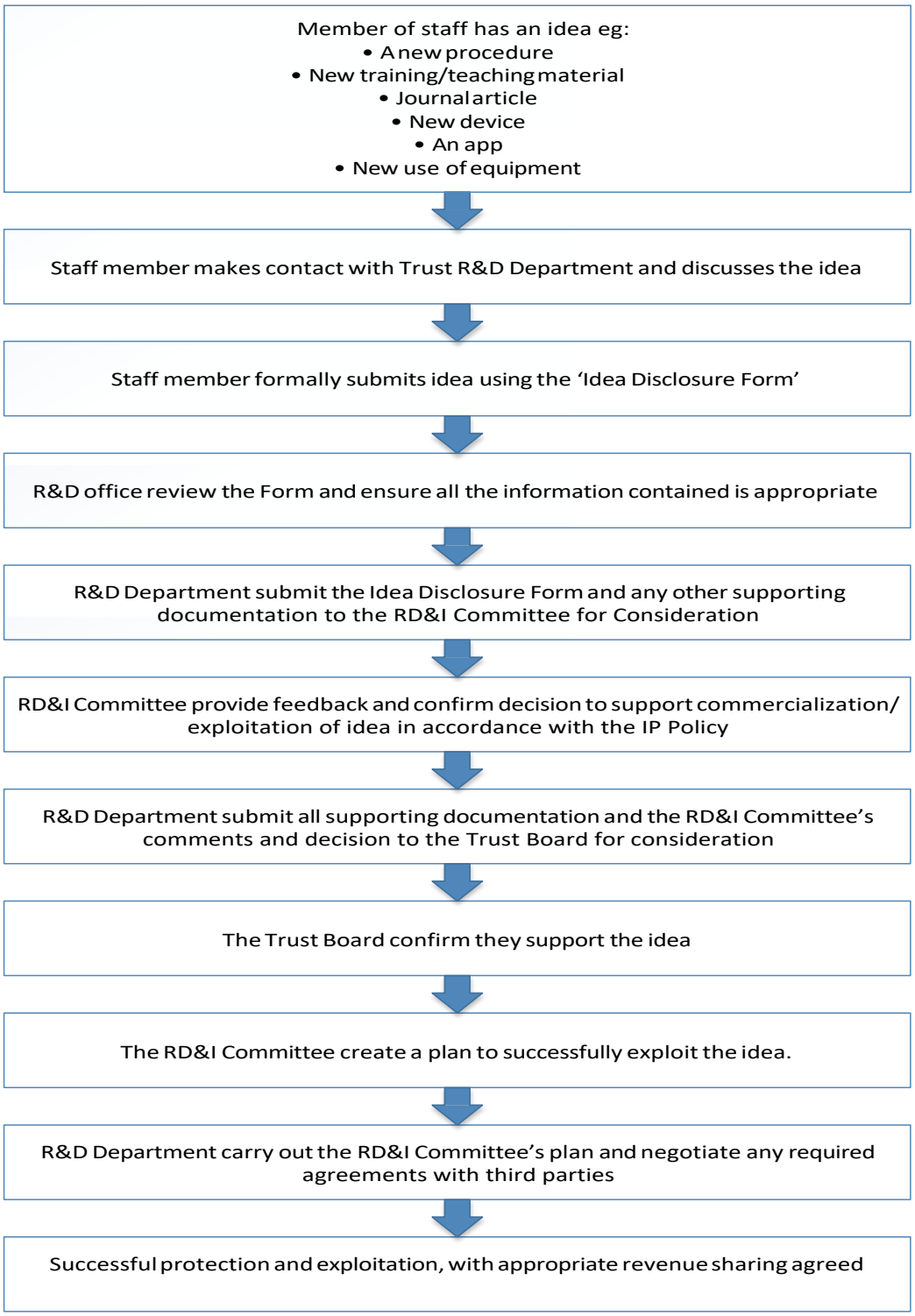
INNOVATIVE IDEAS DISCLOSURE FORM

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

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

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

Appendix 4 - General Process for the Disclosure of Ideas



Appendix 5 - TEMPLATE HEADS OF TERMS (HoT)

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

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

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

- Dispute resolution
- Termination conditions

Ref: RD01

INTELLECTUAL PROPERTY (IP) POLICY

Executive Sponsor & Function:	Executive Medical Director and RD&I Board Lead
Document Author:	Head of Research & Development
Approved by:	Research, Development & Innovation Sub Committee
Approval Date:	28th February 2023 (TBA)
Date of Equality Impact Assessment:	27th February 2014
Equality Impact Assessment Outcome:	Approved
Review Date:	February 2025
Version:	06

Contents

1. INTRODUCTION

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

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

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

2. POLICY STATEMENT

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

3. SCOPE OF POLICY

This Policy applies to IP opportunities arising from activity involving:

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

generated by students engaging in research for the Trust may be owned by the student, the institution with whom they are enrolled or the Trust, depending on the agreements between the student, the institution and the Trust.

- Independent Providers of Services who generate IP from research funded by the NHS are required to inform the appropriate party and share the benefits of its commercialisation. Where IP is assigned to the Trust, the Independent Provider of Services will benefit under the revenue sharing scheme of the Trust.
- For individuals who hold an Honorary Contract with the Trust, the IP Policy of their substantive employer will take precedence over the Trust's policy unless circumstances (such as the Trust's contribution to the creation of the IP for example where the honorary employee has utilised Trust equipment, consumables or the time of Trust-funded staff to create the IP) require negotiation to the contrary to ensure the Trust's contribution is fairly rewarded.
- Trust staff seconded to another organisation or employees of another organisation hosted by the Trust under contract are subject to the terms defined in the contract between the Trust and that organisation.

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

4. AIMS & OBJECTIVES

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

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

5. ROLES AND RESPONSIBILITIES

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

Should employees fail to report any IP development to the Trust's R&D Department the key principles of this policy will apply retrospectively, unless public disclosure has invalidated the opportunity to protect IP. Discussion of potentially protectable IP should only be discussed outside the Trust within the strict confines of a reciprocal non-disclosure agreement.

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

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

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

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

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

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

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

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

develop their ideas and associated IP.
- Negotiate agreements where appropriate with third parties.

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

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

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

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

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

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

7. IMPLEMENTATION

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

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

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

The RD&I Committee will review the operation of this policy as required. At least every two years.

8. POLICY COMPLIANCE

8.1 Identifying and Protecting IP

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

- A novel treatment
- A new diagnostic technique
- A new device
- A new drug or the new use of a drug
- Use of data, software, training material
- A treatment protocol
- New management system

8.2 Ideas Disclosure

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

The ideas disclosure form is attached in appendix 3 and the general process for the disclosure of ideas in appendix 4.

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

In seeking to establish the originality/inventiveness of an idea, employees should investigate current patents online before completing the Idea Disclosure Form. The following link will allow Velindre employees to do a preliminary patent search (https://worldwide.espacenet.com/)

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

The Trust emphasises that staff should not disclose their idea to anyone apart from research collaborators with whom they are bound by a viable contract which includes

provisions for confidentiality, as this might jeopardise subsequent IP protection. Employees are urged to consult the Trust's R&D Department at the earliest possible stage if they have any questions about this and especially if they are uncertain about the implications of disclosing an idea to others.

8.3 Due diligence

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

8.4 Partnering with Universities or other organisations to develop IP

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

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

8.5 Partnering with IP specialists

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

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

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

8.6 Ownership of IP

The Trust has right of ownership to all IP produced by Trust employees in the course of their normal duties. Employees have an obligation to inform the Trust about IP generated as a result of their activities and must not sell, assign or otherwise trade IP

without Trust agreement (see appendix 2 for an extract from the Trust Contract of Employment.)

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

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1. To share revenue where the Trust receives any profits from IP exploitation.
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In all cases the shared revenue will be the net income attributed [by the Trust] to an IP right minus any costs incurred by the Trust in bringing the product to market. The Trust, exercising probity, will put robust systems in place to administer and calculate income arising from IP commercialisation. Revenue will be shared between the Trust and the inventor(s) according to the revenue sharing formula. In cases where several staff have been involved in generating the IP, the proportion of revenue allocated to

inventors will be divided between them evenly unless it can be demonstrated and agreed that the contribution of individuals varies significantly.

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

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

8.7.2 Velindre University NHS Trust Revenue Sharing

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

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

9 COLLABORATIVE RESEARCH PROJECTS

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

and facilitates the collaborative process.

It is therefore important before embarking on a collaborative venture that all parties, the researchers, contract managers and funders, agree the principles of the collaboration. These can be set out in a Heads of Terms (HoT) which allows research decision makers to identify in plain language what they regard as the key issues before instructing their lawyers to draw up a formal agreement (see Template Heads of Terms at Annex 5).

10 SHARED MATERIALS

Materials are defined as equipment, reagents and biological materials, including cell lines, tissues, bacterial strains, plasmids and viruses. When such materials are distributed to other researchers or used in a project they should be subject to a Material Transfer Agreement (MTA) which will be managed via the Trust's R&D Department. This agreement should define the limitations of use of the material and recognises the interest in the IP that may arise from its use. This agreement must be in place prior to distribution and use of the material. The use of trademarks and design rights associated with the aforementioned materials should also be the subject of this agreement.

11 RESOLUTION OF DISPUTES

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

12 NON COMPLIANCE

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

13 TRAINING

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

14 EQUALITY

The Trust is committed to ensuring that, as far as is reasonably practicable, the way it provides services to the public and the way it treats its Employees reflects their

individual needs and does not discriminate against individuals or groups.

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

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

15 GETTING HELP

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

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

16 REFERENCES

- Welsh Assembly Government, 'Intellectual Property and Innovation in Health care in Wales' – A Framework and Guidance on the Management of Intellectual Property in the NHS in Wales, February 2005
- The UK Policy Framework for Health and Social Care Research (https://www.hra.nhs.uk/planning-and-improving-research/policies-standards-legislation/uk-policy-framework-health-social-care-research/)

17 ACKNOWLEDGMENTS

- Abertawe Bro Morgannwg University Health Board R&D Department

APPENDIX 1 - INTELLECTUAL PROPERTY (IP) PROTECTION

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

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

Know-how

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

Copyright

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

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

Patents

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

Design Rights

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

The "Design Right"

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

Registered Design Rights

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

Trade marks

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

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

26. Discoveries and Inventions

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

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

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

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

Appendix 3 – Innovative Ideas Disclosure Form

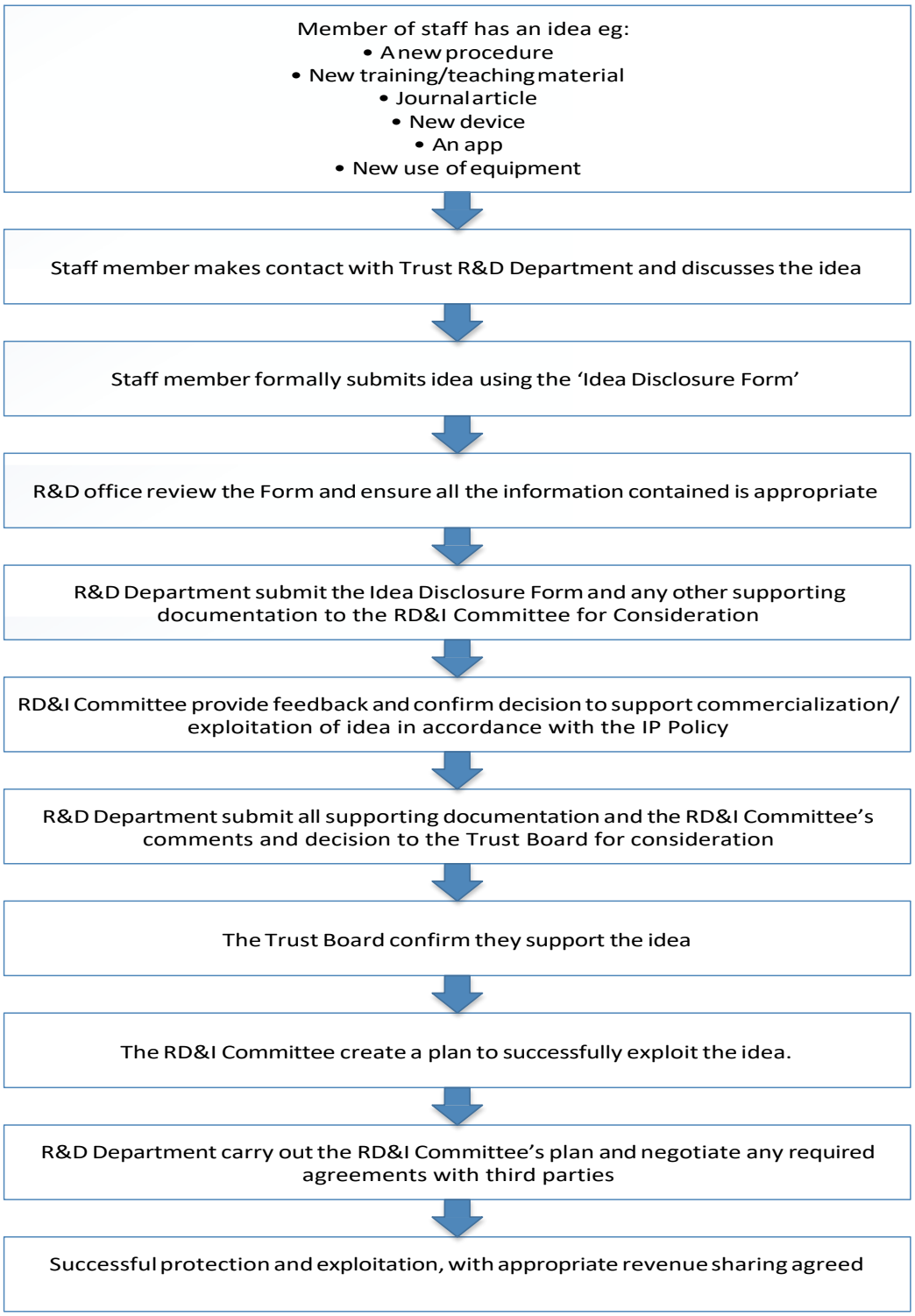
INNOVATIVE IDEAS DISCLOSURE FORM

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

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

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

Appendix 4 - General Process for the Disclosure of Ideas



Appendix 5 - TEMPLATE HEADS OF TERMS (HoT)

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

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

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

- Dispute resolution
- Termination conditions

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

Date 15/11/2022
Time 12:30-1:30pm
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
Christopher Cotterill Jones	Research Delivery Manager	CCJ
Dr Robert Jones	Associate Medical Director for RD&I	RJ
Rachel Hennessey	Interim Head of Operation & Service Delivery	RH
Professor Jane Hopkinson	Velindre Cancer Centre Professor of Nursing and Interdisciplinary Cancer Care	JH
Sian James	RD&I Facilitation Lead, Welsh Blood Service	SJ
Dr Edwin Massey	Deputy Medical Director, Welsh Blood Service	EM
Jonathan Patmore	RD&I Finance Business Partner	JP
Alan Prosser	Director, Welsh Blood Service	AP
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

1.0.0	**STANDARD BUSINESS**	
1.1.0	**Apologies** • Eve Gallop-Evans, VCC Clinical Director • Steve Ham, Chief Executive • Peter Richardson, Head of Quality & Assurance & Regulatory Compliance (WBS)	
1.2.0	**In Attendance** • Professor Mererid Evans, Velindre Cancer R&D Strategy Clinical Lead *(Item 3.1.1)* • Dr Anthony Byrne, Consultant Palliative Medicine *(Item 3.1.1)* • Kate Cleary, Velindre Cancer R&D Strategy Project Support Manager *(Observer)*	
1.3.0	**Declarations of Interest** *Led by Professor Andrew Westwell, Chair of the Research, Development & Innovation Sub-Committee* No declarations of interest were raised.	
1.4.0	**Matters Arising – Action Log** *Led by Dr Jacinta Abraham, Executive Medical Director* The Sub-Committee **APPROVED** the Action Log and the further updates captured in the meeting for the record.	
2.0.0	**CONSENT ITEMS** The consent part of the agenda considers routine Committee business as a single agenda item. Members may ask for items to be moved to the main agenda if a fuller discussion is required.	
2.1.0	**FOR APPROVAL**	
2.1.1	**Minutes from the last Private Research, Development & Innovation Sub-Committee held on the 21st July 2022** *Led by Professor Andrew Westwell, Chair of the Research, Development & Innovation Sub-Committee* The Sub-Committee **REVIEWED** and **APPROVED** the Minutes of the Private Meeting held on the **21st July 2022** as an accurate reflection of proceedings.	
2.2.0	**For Noting** Led by Professor Andrew Westwell (Chair)	
2.2.1	**FAKTION Licence Agreement** Led by Sarah Townsend, Head of Research & Development The Sub-Committee **NOTED** the FAKTION Licence Agreement.	

3.0.0	**MAIN AGENDA**	
3.1.0	**BUSINESS CASE EXPENDITURE PROPOSALS**	
3.1.1	**Implementing the Cancer R&D Strategy – An Integrated Research and Development Bid** *Led by Professor Mererid Evans, Dr Robert Jones and Supported by Professor Jane Hopkinson, Dr Anthony Byrne* **BACKGROUND:** The Trust has developed and endorsed Cancer R&D Ambitions for the next 10 years (2021-31), that builds on existing excellence and embraces new areas of research. On a strategic level within VUNHST, there is a clear organisational commitment to research, identified by: • The Trust's Strategy Destination 2032 which includes goals to be: "A beacon for RD&I in our stated areas of priority" and "An established University Trust which provides highly valued knowledge and learning for all" • The Trust's Overarching Cancer R&D Ambitions/Strategy (2021-2031) • The Trust's Integrated Medium-Term Plan (2022-2025) Over the next 3 years, our focus will be to expand and balance the cancer research portfolio to increase recruitment into research studies led or supported by Velindre. The clinical trial portfolio will include Late Phase and higher-risk Early Phase and Advanced Therapy Medicinal Product (ATMP) clinical trials. In addition, we will further develop the research portfolio to include different types of excellent research including, Translational ('bench to bedside') research, Health Care Research (led by multi-professional groups), and Palliative and Supportive Care research that support patients when they need it most. In developing this business case to the Charitable Funds Committee (CFC), we have taken an integrated approach to ensure all funding requests are aligned with national and our organisation's strategies. We have conducted a business and workforce planning exercise where we have reviewed and justified each post. This includes both existing posts (currently funded) and new posts related to the new areas of research. The attached business case details a narrative of the financial ask and the justification. The attached appendices which include: Appendix 1: Justification of posts – provides a detailed justification for each of the posts included in the business case. Appendix 2: Case stories of success – provides examples of cancer R&D successes over the last 3 years.	

	Appendix 3: Further context and justification – provides further information on the research themes and posts in Section 2 of the bid. Appendix 4: Business case objectives – provides detailed business case objectives and tools by which success will be measured. Appendix 5: Financial Tables– provides detailed financial breakdown for each of the over the 3-year funding period, including co-funding sources and likely cost savings. This business case has been supported by the **Executive Management Board** on the 26th October 2022 for onward endorsement to the RDI Sub-Committee for approval at the Charitable Funds Committee. **ACTION:** Circulate the slide set to RDI Committee Members. The Sub-Committee **ENDORSED FOR SUBMISSION** to the Charitable Funds Committee this business case, subject to a series of meetings with key leads to support and incorporate the necessary revisions.	**SMC**
3.1.2	**Oncacare Collaboration** *Led by Dr Robert Jones, Consultant Oncologist & Sarah Townsend, Head of Research & Development* This collaboration is an opportunity to increase commercial trials activity with its benefits of wider patient access to clinical trials, possibly on favourable commercial terms. It will involve commitment by the Trust to work towards improving its study set up timelines and recruitment figures for which plans to achieve this are underway. Oncacare currently has no track record in the UK for collaborating with the NHS in the set up and delivery of research studies. However, they are progressing collaborative relationships with a number of research active NHS research organisations across the UK. This is a bold and dynamic initiative, the feasibility of which the RD&I senior leadership team wish to explore with the intention of managing the Oncacare collaboration independent of the delivery of the Trust's current portfolio **ACTION:** The recommendation is that the Trust, in accordance with its ambition to seek to accelerate strategic relationships with commercial entities should: • Continue to explore whether it is feasible for the Trust to become an ongoing member of the Oncacare global site network. • Agree to consider execution of the final draft of the Master Collaboration Agreement that has been negotiated with	

	Oncacare Ltd by R&D leads from the Trust and C&VUHB subject to the resolution of any legal issues identified in the course of review of the terms according to Trust process. The RD&I Sub-Committee agreed to the **RECOMMENDATIONS** set out in this Report.	
3.1.3	**WBS Drone Project** *Led by Alan Prosser, Director, Welsh Blood Service* The RD&I Sub-Committee **NOTED** the work carried out to date by the Welsh Health Drone Innovation Partnership and the potential for future service improvements, which may result from the use of this technology and also **NOTED** the support from EMB to support the continued involvement by WBS in this project, subject to appropriate funding being awarded.	
3.1.4	**nVCC Non-Clinical RD&I Group – Integrated Radiotherapy Solution (IRS) Update (Research Element)** *Led by Gavin Bryce, Transforming Cancer Services Programme Manager* GB presented an IRS Research Update to the RDI Sub-Committee, focussing on the procurement and the winning bid from the IRS Competitive Dialogue Procedure. During the dialogue they set out: • Key Radiotherapy Research themes relating to the core solution. • Three potential Varian options for the Research Bunker – (the Trust could still look to procure a non-Varian machine) and a Trust team are looking into this. • Alignment of Research themes, but flexibility to prioritise areas of research. • An agreed governance structure for the Joint Research Committee (JRC). • Funding linked to the IRS machines and upgrades – can be rolled over (relating to the core solution). • Bid support and other coaching and mentoring. • Discount off list price for the research machine (optional), discount on list capital price (global price) and discount on revenue. • The Trust will own Intellectual Property (IP) / jointly share in agreement and will have the opportunity for Gain Share of commercial profits arising from said IP. The agreement and development of research themes will be jointly owned by a Joint Research Committee (JRC).	

	ACTION: • Provide Terms of Reference for this Committee • Develop first meeting with Varian	**GB**
4.0.0	**ANY OTHER BUSINESS**	
	No other business was raised.	
5.0.0	**DATE AND TIME OF THE NEXT MEETING**	
	The Research Development and Innovation Sub-Committee will next meet on the 28th February 2023 from 12.00–1.30pm via Microsoft Teams.	
CLOSE		