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Cardiff and Vale University Health Board

Research and Development Strategy 2020-2023

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1.0 Executive Summary

This Strategy sets out clear aims on how Research and Development activities will be supported, promoted and implemented within C&V UHB. It provides strategic direction within the context of local and national developments including the organisation's IMTP and C&V UHB Shaping Our Future Wellbeing Strategy 2015-2025. This Strategy closely reflects the aims of the Health and Care Research Wales (HCRW) Strategic Plan (2015-2020) which demonstrates Wales' commitment to creating a dynamic research environment for the health and wealth of the people of Wales. The five high level strategic aims will be underpinned at Clinical Board level by more detailed R&D Implementation plans.

This document also outlines how the Strategy has been developed, and the roles and responsibilities required at individual organisational levels for its successful delivery.

2.0 Introduction

2.1 How the Strategy has been developed

The Strategy has been developed in full consultation with the Clinical Boards through the Clinical Board R&D Leads at the Research Delivery Management Board, involving senior finance, R&D Office, and research and delivery staff representation.

2.2 Strategy approval and review mechanism

The Strategy has been approved by the Executive Management Board. Welsh Government requires an annual review process to ensure the document remains fit for purpose. Each Clinical Board will review their individual strategic aims and objectives on an annual basis.

3.0 National Context

3.1 National Funding Structure

The Welsh Government's Research and Development Division sits within the Health and Social Services Group. It leads on strategy, policy, commissioning, funding, contract management and governance of health and social care R&D in Wales.

HCRW is a national, multi-faceted virtual organisation comprising several distinct elements of infrastructure and funding schemes, to support and build capacity in Research and Development. The Support and Delivery Service, which is part of this, includes a Support Centre to provide

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centralised functions and services at a national level, and local R&D functions via NHS R&D departments at each organisation.

In order to provide a range of local R&D services, each NHS organisation is in receipt of Local Support and Delivery Funding.

The Welsh Government set a national objective to ensure the effective provision of an NHS research infrastructure, to develop research capacity through the appropriate use of R&D allocations, as well as investment of other R&D income that the NHS organisation generates. The key indicator set to achieve this national objective is for NHS organisations to have a current 'in use' finance policy.

HCRW has produced a NHS R&D Finance Policy Template which covers the details and mechanisms necessary for the management, accountability and distribution of NHS research funding and income.

3.2 HCRW strategy

HCRW' vision is for Wales to be internationally recognised for its excellent health and social care research that has a positive impact on the health, wellbeing and prosperity of the people in Wales.

The Local Support and Delivery Funding is underpinned by the [Delivery Framework - Performance Management of Local Support and Delivery Services 2019/20](#).

The Delivery Framework sets out how the Welsh Government will performance manage the NHS organisations in Wales in relation to R&D, including the use of their local support and delivery funding, performance against national objectives, key indicators and targets. It also sets out the enablers of research aligned to the IMTPs (Integrated Medium Term Plans) of NHS organisations in Wales.

3.3 Working with the HCRW Support Centre to realise the 'One Wales' vision

The vision of the Support and Delivery Service is to realise a 'One Wales Seamless Service' for supporting and delivering high quality health and social care research. As part of the Support and Delivery Service, C&V UHB needs to be responsive to the 'One Wales' aims of increasing opportunities for patients and the public to participate in, and benefit from, safe ethical research, regardless of geographical location. This will enable Industry and Chief Investigators to set-up studies in multiple sites across Wales in a single-access, streamlined and efficient way; whilst attracting

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and deploying appropriately skilled, qualified and experienced staff in a consistent way across HCRW, embedding shared values and behaviours.

4.0 Local Context

4.1 Consistency with C&V UHB Integrated Medium Term Plan (IMTP)

The Integrated Medium Term Plans (IMTPs) play a fundamental role in the planning and delivery of high quality care to the population of Wales.

The R&D Division, Welsh Government therefore expects each NHS organisation to purposefully support research and, through the IMTP, demonstrate how the patients of Wales will be offered increased opportunities to participate in high quality research within their locality.

The R&D Division of Welsh Government, in its review of IMTPs, will particularly focus on identifying how NHS R&D Directors have aligned themselves and their R&D departments to other parts of the NHS to promote R&D and maximise the potential for the uptake of findings across their organisations, including, as appropriate, primary care.

The core actions identified in C&V UHB IMTP 2019-2022 have been fully integrated into the aims section of this R&D Strategy document

4.2 Core business with R&D embedded in strategic goals

C&V UHB Shaping Our Future Wellbeing Strategy 2015-2025 outlines as part of its 'Vision of Care' statement that we will focus on working better together across the care sectors, valuing people and harnessing innovation, and research to make this a great place for patients and staff

4.3 Clinical Board structure and R&D Implementation plans to support the delivery of the Strategy

C&V UHB has a management structure based around 7 Clinical Boards supported by corporate organisational functions. Each Clinical Board has endorsed the overall strategic aims and objectives of the C&V UHB R&D Strategy and have summarised their own individual high level strategic aims and objectives. Each Clinical Board is required to have an up to date R&D Implementation Plan which underpins how they will meet their strategic aims and objectives. The Clinical Board R&D Implementation Plans will inform discussions at biannual R&D review meetings with the Medical Director, R&D Director and R&D Performance Manager. R&D representation on each Clinical Board 'Board' meeting, with R&D as a standing agenda item, with the presentation of key R&D metrics, would also be considered as good practice.

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5.0C&V UHB R&D Strategic Aims

AIM 1 Maximise patient access to high quality care through participation in safe, ethical research

- Monitor and manage all key indicators set out in the Delivery Framework for Performance management of NHS R&D, promoting Clinical Board ownership of targets relating to increasing numbers of non-commercial and commercial studies and recruitment to them, and the elimination of non-recruiting studies, as well as recruiting to time and target
- Ensure a more refined risk-based approach to Capacity and Capability, and Sponsorship assessments with the aim of decreasing study set-up times
- Provide support to research teams to navigate the regulatory review processes to help reduce set up times
- Encourage a balanced portfolio of study types to include observational and complex interventional studies

AIM 2 Ensure a culture that places research at the core of clinical service delivery and the prevention, and population health, agendas

- The Executive Board will be provided with R&D reports through the Medical Director
- Clinical Boards will facilitate a joined up approach between Boards for R&D funding proposals to share costs and associated benefits from revenue
- Directorate and Clinical Board R&D leads together with the R&D office will performance manage ring fenced Directorate R&D budgets
- Clinical Boards will consider the full benefits of R&D studies including the potential for significant drug/device savings
- The UHB will hold an Annual R&D day to promote research and the message that it is at the core of clinical service delivery
- R&D will feature strongly in the UHB annual report
- R&D Communication through web pages, newsletters, social media and other means will be reviewed and strengthened to improve dissemination and engagement in R&D related issues
- Links between Continuous Service Improvement and the research community will be strengthened to facilitate research into practice initiatives and innovation opportunities, and to strengthen the culture of Research, Innovation and Improvement becoming a core function of daily practice.

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- The Clinical Board R&D Lead role will be strengthened through membership of the Research Delivery Management Board

AIM 3 Build research infrastructure and capacity

- The Research Delivery Management Board will approve budgetary allocations to Clinical Boards/Directorates on an annual basis ensuring research infrastructure and capacity continues to be built in alignment with Clinical Board Strategic aims.
- Support services will be invested in appropriately, to align with Clinical Board strategic aims
- Funding will be identified to support the set-up of a Research Nursing Bank to increase the ability to cover research nurse maternity, sickness and study leave
- The Clinical Research Facility will be utilised to prioritise early phase studies and those that require a specialist environment, also carrying out later phase studies, to ensure it operates at maximum capacity with good utilisation of the endoscopy suite
- Establish research beds within the critical care footprint using the current PACU (which will become a larger purpose built enhanced care unit in late 2020) for patients at risk of serious toxicities and organ failures from new biologic agents such as CAR-T therapy, which would be unsuitable for the Clinical Research Facility. MHRA phase 1 accreditation will be sought providing a unique selling point, for not only Cardiff, but the UK.
- The physical build capacity of the Clinical Research Facility will be further developed to allow a safe and appropriate environment for the placement of a larger number of studies
- The Children and Young Adult Research Unit will be supported and fully utilised providing further opportunities for children across Wales to participate in clinical studies
- The UHB will support high quality applications for Centre or Unit bids, alone or in collaboration with local HEIs, to major funders
- The UHB will explore a range of possibilities to support investigator-led complex studies (both UHB Sponsored and where the UHB wishes to act as a National Co-ordinating centre) where a Clinical Trials Unit is required
- The UHB will support new investigators where the appointment has been made specifically to boost the UHB R&D agenda
- The UHB will support a balanced range of studies, including portfolio and pathway to portfolio that have real potential to be developed into future portfolio studies.

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- The UHB will increase commercial income by ensuring it focuses resources on studies where recruitment targets are realistic, and the study is judged as likely to facilitate future service enhancement.
- The UHB will look to expand commercial activities via direct meetings with global pharmaceutical companies.
- The Primary Care 'Hub and Spoke' model will be supported through the pilot phase in the UHB to provide more research opportunities for participants in GP practices which are not traditionally research active.

AIM 4 Develop workforce capability and satisfaction by providing a learning environment which actively promotes research

- Providing equal access to structured, high quality training opportunities for all staff involved in research in the UHB. This includes staff working in core research delivery roles, staff supporting research activity in their department and staff carrying out their own research.
- Providing a needs based annual training programme responding to identified research governance trends, regular audit and evaluation of staff training requirements, and in line with the HCRW aims and objectives.
- Providing support and guidance for research staff with their development and career progression, in line with organisational and national standards.
- Providing educational learning opportunities for undergraduate nursing, midwifery and allied health professional students and medical trainees within the UHB that raise awareness of research and clinical trials in the NHS, and the roles research staff have within the wider disciplinary team.
- Providing research teams with a dedicated educational oversight, linked to the Learning, Education and Development Department, ensuing training standards meet local policy and procedure, as well as national and international regulatory requirements.
- Encourage and support non-medical staff to take on the role of Principal Investigator for suitable studies
- Having a point of contact and hub for information sharing for up to date, relevant research specific communication throughout the UHB
- Setting up a small education and training budget to be available for eligible Cardiff and Vale UHB research staff wanting to apply for funding to support short courses, study days and conferences.
- Providing Clinical Boards with access to £10k per annum to utilise for training events either at Board or individual level

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AIM 5 Enter into strategic collaborations and engagements to enhance joint working across Wales, the UK and internationally.

- The agreement to establish a Joint Research Office between C&V UHB and Cardiff University (CU) will be realised to:
 - support the delivery of a shared research strategy, with clear priorities and outcomes;
 - maximise our joint potential in the delivery of research and impact for patients;
 - establish a unified service by bringing together people, processes and systems;
 - create a positive environment for all of our staff to collaborate;
 - encourage and support researchers to engage and inform patients and the public;
 - develop connections which will enable growth in research activity, income and output.
- C&V UHB will facilitate joint working with CU Biobank under the terms of the Collaborative Material Transfer Agreement
- C&V UHB will work closely with Welsh Government through HCRW Support Centre to help realise the One Wales initiative by fully engaging in working groups tasked at looking at the various aspects of this agenda
- C&V UHB will explore the possibility of acting as Sponsor/Joint Sponsor of multicentre European studies
- C&V UHB will be the clinical lead for Wales for the Advanced Therapy Treatment Centre (ATCC) working under the terms of the successful collaborative award from Innovate UK with Swansea, Birmingham and Nottingham, with the aim of enabling pioneering therapies for the people of Wales.
- C&V UHB will continue to develop its relationships with other Higher Education Institutes in Wales and beyond, and other NHS organisations to maximise potential for joint working and reciprocal beneficial relationships

6.0 Roles and Responsibilities

6.1 Chief Executive

The Chief Executive, as Accountable Officer, is responsible for ensuring C&V UHB delivers on its R&D Strategy and implements effective Research Governance to meet applicable legislative standards. Responsibility for delivery is delegated through the reporting line as defined below.

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6.2 Medical Director

The Medical Director is the C&V UHB Executive Lead for R&D, reporting to the Chief Executive on the delivery and implementation of the R&D Strategy and Policy

6.3 Assistant Medical Director for Research and Development

The Medical Director is supported by an Assistant Medical Director (AMD) with specific responsibility for R&D. The AMD for R&D is required to coordinate strategically all aspects of research delivery within C&V UHB, providing expert advice and support to the Medical Director and Chief Executive, The AMD for R&D will oversee the allocation and management of the R&D Budget and will chair the Research Delivery Management Board

6.4 Clinical Board Research and Development Leads

Each Clinical Board will appoint a Clinical Board R&D Lead (refer to Job description – JDR-RD-002) who is responsible for attending the Research Delivery Management Board (RDMB) and Research Governance Group (RGG). RDMB is responsible for strategic decisions on the following:

- Management of UHB R&D income streams through Welsh Government (currently called Activity Based Funding), commercial income and grant funding.
- Allocation of Activity Based Funding to Clinical Boards (CB) including support services, Delivery staff, Clinical Research Facility and R&D Office.

The role of the RGG is to oversee the operational management of Research Governance and provide assurance of robust Research Governance arrangements within the UHB.

The Clinical Board R&D lead is also responsible for ensuring there is appropriate input into the C&V UHB R&D Strategy and that this is underpinned by a robust Clinical Board R&D Implementation Plan.

6.5 Research and Development Office

The R&D Office is headed by the R&D Manager reporting to the AMD for R&D, within the Medical Director's Office. The R&D Office provides the operational support and assurance to C&V UHB that all R&D operates within a framework of effective governance consistent with Wales and UK R&D specific legislation and guidance. The R&D Office is responsible for providing administrative support for drafting and reviewing the R&D Strategy.

6.6 Research Delivery Team

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The Research Delivery team is headed by the Head of Research Delivery –South East Wales, reporting to the AMD (R&D) within the Medical Director’s Office. The Research Delivery Team oversees performance in terms of delivering studies to time and target and is responsible for supporting the Medical Director and R&D Director at biannual performance meetings where the Clinical Board Implementation Plans together with overall performance at study level will be discussed.

7.0 C&VUHB’s SMART Objectives

- 7.1** Increase the total number of open and recruiting commercial and non-commercial portfolio studies from 264 in 2018/19 by 10% by 2023
- 7.2** Improve recruitment to time and target metrics from the current 51% to 75% by 2023
- 7.3** Reduce time taken from receipt of Local Information Pack to recruitment of first patient from a median of 128 days for non-commercial and 90 days for commercial to 60 days by 2023
- 7.4** Increase commercial income from £1.7m in 2018/9 by 20% by 2023
- 7.5** Increase the number of UHB Sponsored studies from 18 in 2018/19 by 30% by 2023
- 7.6** A Joint Research Office to be physically established by September 2020 with continuing progress towards integration of all relevant functions by 2023
- 7.7** Clinical Board/Directorate R&D budgets to be appropriately managed in terms of income and expenditure from Welsh Government Activity Based Funding by April 2020, to include Commercial and non-commercial trial income and expenditure by April 2021 measurable by simplified population of quarterly spending plans, quarterly returns and annual reports to Welsh Government.

8.0 References

NHS R&D Finance Policy Template
<https://www.healthandcareresearch.gov.wales/nhs-randd-funding-policy/>

Delivery Framework – Performance Management of Local Support and Delivery Services 2019/20

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https://www.healthandcareresearch.gov.wales/uploads/About/Delivery_Frame_work-2019-20.pdf

C&V UHB Integrated Medium Term Plan (IMTP)

<http://www.cardiffandvaleuhb.wales.nhs.uk/sitesplus/documents/1143/Cardiff%20and%20Vale%20UHB%20IMTP%202019%20to%202022.pdf>

C&V UHB Shaping Our Future Wellbeing Strategy 2015-2025

<http://www.cardiffandvaleuhb.wales.nhs.uk/sitesplus/documents/1143/10%20-%20UHB%20Shaping%20Our%20Future%20Wellbeing%20Strategy%20Final.pdf>

Clinical Board R&D Lead Job Description (JDR-RD-002) (link once available)