



**AGENDA ITEM**

2.2.8

**QUALITY & SAFETY COMMITTEE**

**RESEARCH AND DEVELOPMENT (R&D) UPDATE**

<b>Date of meeting</b>	18/05/2021
<b>FOI Status</b>	Open/Public
<b>If closed please indicate reason</b>	Not Applicable - Public Report
<b>Prepared by</b>	Professor John Geen, Assistant Director for R&D, Mrs Rhian Beynon, R&D Manager
<b>Presented by</b>	Mrs Rhian Beynon R&D Manager
<b>Approving Executive Sponsor</b>	Executive Director of Public Health
<b>Report purpose</b>	FOR NOTING

**Engagement (internal/external) undertaken to date (including receipt/consideration at Committee/group)**

<b>Committee/Group/Individuals</b>	<b>Date</b>	<b>Outcome</b>
(Insert Name)	(DD/MM/YYYY)	Choose an item.

**ACRONYMS**

ABF	Activity Based Funding
CRP	Clinical Research Portfolio
HCRW	Health and Care Research Wales
UPH	Urgent Public Health (Research Studies)

## 1. SITUATION/BACKGROUND

The R&D department has the responsibility to provide the leadership, co-ordination, support, promotion, networking, dissemination, resources, infrastructure and oversight of all multi-professional, multi-disciplinary commercial and non-commercial research that takes place in Secondary / Primary / Community and Population Health research settings. It is also essential that all research be fully integrated into Cwm Taf Morgannwg UHB (CTMUHB's) R&D agenda, priorities and strategy. To deliver this, CTMUHB's R&D department requires the necessary infrastructure to support all research activity from study concept through to patient recruitment and dissemination of research findings. Taking a fully integrated approach to research support and delivery across the Health Board will help ensure that researchers and the population are fully engaged in commercial and non-commercial research and will have equitable access to research opportunities, new therapeutics, treatments, pathways and technologies. Undertaking high quality co-produced research will serve to inform future value based service improvements in health, social care and third sector. It is also important to note that a high quality, fully integrated collaborative research portfolio is essential for the Health Board to achieve and maintain its University Health Board (UHB) status.

Between 2011/12 and 2019/20, R&D Local Support and Delivery funding from the R&D Division, Welsh Government was allocated to NHS organisations' utilizing the Activity Based Funding formula (ABF), predominantly predicated on a rolling 3-year average of research activity (Clinical Research Portfolio (CRP) studies open, number of participants recruited onto CRP studies, number of Chief Investigators / Clinical Research fellows within each NHS organization). The Assistant Director for R&D within CTMUHB is accountable for the funding allocation and its expenditure by the R&D Division, Welsh Government. Funding has been allocated with consideration for the local R&D agenda and strategy and in line with R&D Division, Welsh Government's policy and guidance to ensure appropriate use of the ring fenced funding. The R&D Division, Welsh Government and HCRW Support and Delivery Centre performance manage the Health Board's R&D funding allocations by monitoring and scrutinising the expenditure through the submission of quarterly financial reports and an annual face-to-face performance management meeting.

In April 2020, a new expenditure based funding model was introduced by the R&D Division, Welsh Government, whereby funding is distributed to each NHS Organisation based on the actual resource required to support study delivery needs. 2020/2021 and 2021/2022 have been deemed transitional periods whereby NHS Organisations' funding is dependent on committed expenditure based on the previous year's spending plan. As part of the new funding model, any re-distribution of expenditure within the budget can only be made

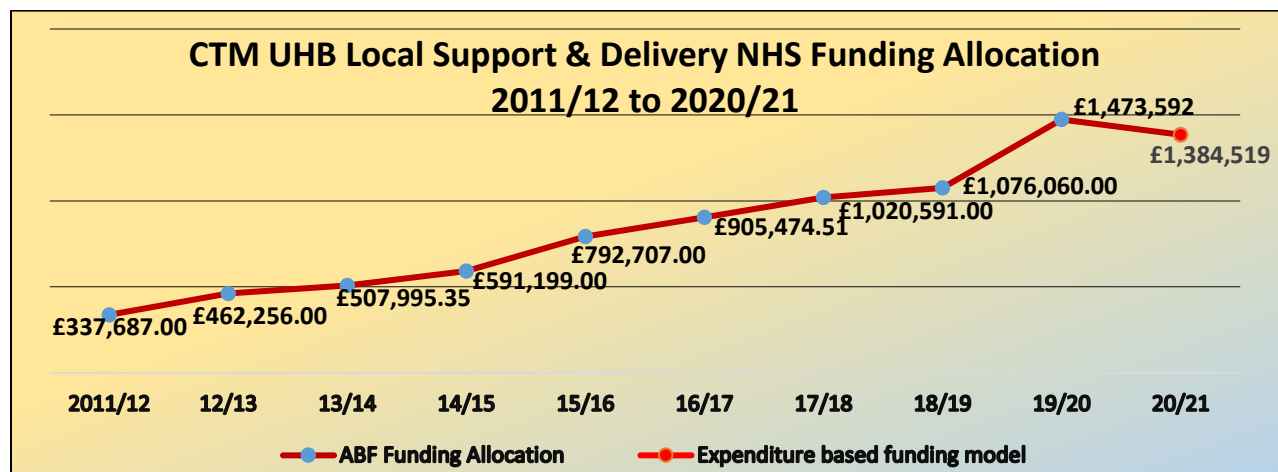
following discussion with HCRW, whereby the use of delivery resources is considered in a national context, determining whether current committed staffing is justified by the research activities undertaken by the organisation i.e. by reviewing the workforce agreed in the spending plan against the actual delivery undertaken. Financial reporting requirements through submission of expenditure and face to face meetings (virtual) have increased from quarterly to monthly.

Each NHS organisation in receipt of this funding is performance managed against key performance indicators set by the R&D Division, Welsh Government.

## 2. SPECIFIC MATTERS FOR CONSIDERATION BY THIS MEETING (ASSESSMENT)

### 2.1 Local Support and Delivery Funding

Through the Activity Based Funding model, CTMUHB increased the amount of funding received by the R&D Division, Welsh Government each year, which reflects the considerable efforts of the R&D team, Health Board research active professionals, academic and industry collaborators, to increase the high quality research undertaken across the UHB. The figure below demonstrates the significant increase in funding received by the Health Board from 2011-12 to 2019-20. CTMUHB's allocation for 2020-21 decreased by £104792 from the previous year with the implementation of the new expenditure based funding model. The NHS R&D funding would have increased had the "Activity Based Funding" model still been in existence.



## NHS R&D FUNDING FROM ALL SOURCES 2020/2021

### NHS Research & Development Local Support and Delivery Funding

**2020/2021= £1,368,800**



**£16,464 Cancer Research UK Funding** to cover 0.4 Whole Time Equivalent (WTE) existing Band 6 Research Nurse post to support cancer studies at CTM UHB. HCRW have confirmed that they will cover this funding from April 2021.

**£99,000 CTM UHB Primary Care Funding** to cover Band 5 Primary Care Facilitator 1.0WTE, Band 7 Post-Doctoral Principal Researcher 1.0WTE and Academic GP Research Lead 0.2 WTE.

### **NHS R&D FUNDING FROM ALL SOURCES 2021/2022**

#### **NHS Research & Development Local Support and Delivery Funding 2021-2022= TBC**

The total funding requested from each of the Welsh NHS Organisations has exceeded the total 2021/2022 budget for Local Support & Delivery and discussions are underway with each R&D Department to confirm agreed costs, unfunded costs and those which are yet to be decided. CTMUHB R&D has requested funding for an additional research midwife, research nurse, stroke research nurse (0.5wte) clinical trials pharmacist, pharmacy technician (0.5wte) and research therapist. The decision is awaited.

**£99,000 CTMUHB Primary Care Funding** to fund Band 5 Primary Care Facilitator 1.0WTE, Band 7 Post-Doctoral Principal Researcher 1.0WTE and Academic GP Research Lead 0.2 WTE.

### **2.2 External Funding**

Another mechanism by which research funding can be brought into the Health Board is through grant funding. Securing external funding through a competitive process also enables the research project to be adopted onto the CRP, although it no longer attracts the Chief Investigator affiliation premium or the associated activity premium in the Health Boards R&D funding. **£150,916.73** grant funding has been awarded to CTMUHB in the last 3 years to enable the set up and delivery of research in stroke, respiratory medicine, public health, CAMHS, paediatrics, cancer, pharmacy, occupational health and speech and language therapy.

Income can also be generated through undertaking commercial research, whereby research studies are sponsored by pharmaceutical and medical device companies. These can fund all necessary costs for the study to be undertaken, to include overheads and capacity building costs that can be re-invested into research, in accordance with the All-Wales R&D Finance Policy. This allows further research capacity to be developed, enabling more research to be undertaken, with the associated benefits to the workforce and most importantly patients.

Between April 2014-2015 and 2020-2021, a total of **£165,619.74** commercial income has been generated through research activity (cost recovery for staff time and investigations, overheads and set up fees).

Between 2013-2014 and 2020-2021, a total of **£164,376.67** cost savings have been made in Medicines Management as a direct result of undertaking pharmaceutical related commercial and non-commercial research.

### **2.3 Research Performance & Activity**

The R&D team continue to prioritize the strategic objective of increasing portfolio research and commercial activity by circulating the details of potential studies across primary, secondary and community care, providing support to clinicians in completing feasibility questionnaires, attending site selection visits and the study set up and delivery. Please see Appendix 1 for graphs outlining the increase in CRP and commercial activity over the previous 6 years. It is important to note that the research priorities for much of 2021 to the current day have been focused on the Covid response and this is reflected in the metrics displayed in the graphs of appendix 1.

R&D Division, Welsh Government has confirmed that "recruitment to time and target" is the key performance metric of research activity and not the number of studies or participants. A key priority for the R&D team is to ensure that the appropriate research nurse/officer/assistant support is allocated to studies in order to meet the recruitment targets and ensuring that recruitment targets are agreed with the study team that are achievable.

### **2.4 Development of a Clinical Research Centre for CTM UHB**

A key strategic objective for CTMUHB for several years to develop and increase the commercial and non-commercial research agenda across CTMUHB has been the creation of a Clinical Research Facility to provide the necessary infra-structure and space to undertake high quality research. A bid was submitted to the R&D Division, Welsh Government for funding from the UK Covid 19 Vaccine Taskforce Fund (VTF) in the autumn of 2020 to develop a Clinical Research Facility and provide a facility that could be used to deliver Covid-19 vaccine and other Covid related clinical trial(s) during 2021. The funding submission was successful and £155k capital funding was awarded and a further £50k capital funding was provided directly by the UHB for the required building works. Through collaborative discussions, the UHB agreed that the clinical skills unit at Royal Glamorgan Hospital could undergo the required re-purposing works to develop a designated research facility and provide the best environment for future research activity during and beyond the Covid 19 response. Following completion of the building, the Clinical Research Centre opened in February 2021, which includes office space for the R&D team, a reception area and 3 clinic rooms for research participants.

### **2.5 Research and Development Infrastructure**

During the last 18 months, there has been significant development in the R&D infrastructure for research support and delivery. An R&D Officer, Research

Officer, Research Nurse and Research Assistant have been appointed to provide support for the set up and delivery of research across Bridgend. A Research Midwife has been appointed to support the set up and delivery of research projects in obstetrics and gynaecology with two additional Research Nurses and Research Assistant appointed to provide further capacity to support the delivery of research across the Health Board.

The R&D spending plan for 2021-2022 has been submitted to HCRW and discussions taken place to describe the proposed changes required in the CTMUHB R&D infra-structure to help the service continue to increase the research activity across the organisation. The R&D team are currently awaiting the response from HCRW.

## 2.6 CTMUHB R&D Response to the Covid-19 Pandemic

Due to the COVID-19 pandemic, the majority of active research studies were suspended in March 2020 and urgent public health (UPH) research was prioritized across the UK to gather the necessary clinical and epidemiological evidence to inform national policy and enable new diagnostic tests, treatments and vaccines to be developed and tested. The National Institute for Health Research released the "Restart Framework" to restore the research paused at the beginning of the pandemic whilst continuing to support Covid-19 research, outlining 3 levels of prioritization. The table below outlines the number of active studies within CTMUHB during 2020-21 based on priority level:

Level	No. of studies 2020-21	No. of recruits 2020-21
<b>Level 1a</b> COVID-19 UPH vaccine and prophylactic studies as prioritised by the Vaccines Task Force. Platform therapeutics trials (RECOVERY; PRINCIPLE; REMAP CAP)	4	329
<b>Level 1b</b> Other COVID-19 UPH studies	12	3,956
<b>Level 2</b> Research protocol includes urgent treatment or intervention without which patients could come to harm. E.g. studies providing access to life-preserving/ life-extending treatment not otherwise available	38	121
<b>Level 3</b> All other studies (including new Covid-19 studies not in Level 1)	102	1,165
<b>Total</b>	<b>156</b>	<b>5,5571</b>

Discussions are ongoing with the All-Wales Vaccine Research Delivery Group with regard to the potential set up and delivery of a COVID-19 booster vaccine clinical trial at CTMUHB during 2021. Details of the study are to be confirmed.

## 2.7 Triennial Review (University Health Board Status)

The triennial review process to maintain UHB status has been developed to an annual review looking to build on the organisations current relationships with



its academic partners and set future priorities in the key areas of research, innovation and training and education, having impact both on the NHS and academia. A series of workshops were undertaken with each of the six academic partners, chaired by the Assistant Director for R&D, (Cardiff University, Cardiff Metropolitan University, University of South Wales, Swansea University, University of Wales Trinity Saint David, Open University) to discuss current relationships and explore potential opportunities for strengthening collaboration and partnership with outputs linked to the key strategic documents of Welsh Government. The UHB representatives attended an expert panel review session with Welsh Government on 18 March 2021 and the outcome of the review is currently awaited.

## **2.8 Dissemination and Impact of Research**

It is important that research findings are translated through knowledge mobilization to ensure that the impact of research is maximized; informing patient care, outcomes and experience. The R&D team are collating research publications from the work that has been developed/undertaken in CTMUHB. A number of press releases have been made focusing on work developed within CTMUHB and these can also be promoted within the Health Board through the Health Board's communications team. The impact and evidence base provided by research is also an important metric for maintaining University Health Board status. The annual CTMUHB R&D Conference also provides a mechanism by which research outputs can be shared to a wide range of delegates from the NHS, academia, industry and the public. The last R&D Conference was held on 19 November 2019 at the Vale Resort, Hensol and was attended by 201 delegates.

## **3. KEY RISKS/MATTERS FOR ESCALATION TO BOARD/COMMITTEE**

**3.1** The R&D Department continues to seek support from the Health Board through the appropriate channels, to enable the organisation to continue to develop the infrastructure required to meet the targets and metrics set and performance managed by the R&D Division, Welsh Government and the Health Board's own R&D strategy, delivery plan and ambition. This includes the further development of its commercial research portfolio and scope for increasing the Health Board's income generation and re-investment into research activities. Increasing this income will serve to compliment the income currently provided from the NHS R&D funding from WG and successful grant applications. Failure to invest / re-invest in the research infra-structure and maintain or increase the research activity, will result in decreasing R&D income through grant funding and commercial studies and will be a risk to the success of the Health Board's R&D ambitions and evidence based improvements in patient care. The recent identification and donation of the

estate and provision of £50K to allow the development of a Clinical Research Centre, demonstrates the UHB’s commitment to supporting research.

**3.2** The introduction of the expenditure based funding model in 2020/2021 has removed the autonomy of NHS organisations’ to decide how the Local Support and Delivery funding is allocated, based on its own R&D strategy and agenda, in line with the national R&D agenda and strategic objectives. The increased bureaucracy in having to discuss any re-purposing of funding with HCRW has removed the level of flexibility, agility and responsiveness to our organisation’s research needs. It is important to note that significant reductions in NHS R&D funding from WG could destabilize the Health Boards R&D infra-structure and the ability to support research and other consequences such as R&D team morale. The new funding model does not allow for funding to cover Principal Investigator’s time for medical, nursing, health care scientist, therapist and allied health professionals and consultant research sessions to support and promote research in clinical specialties will not be funded beyond 31 August 2021.

The Assistant Director for R&D prepared a briefings paper on the Welsh Royal College of Physicians “Time for Research Report”, which was presented to the Executive team by the Executive lead for R&D. The document emphasised the need to invest in research, notably through increasing capacity, as this will deliver long-term gains for patients and public health but the organisation as a whole. R&D activity could be increased if the capacity of the workforce could be optimized to ensure that research is central to their roles. This could be facilitated by the inclusion of research sessions in Consultant job plans notably through SPA and the inclusion of research and provision of time to undertake research in non-medical job descriptions. This would increase the research capacity considerably across the UHB, contributing to the improved quality of patient care, but also staff morale, recruitment and retention. With support from the Executives, Human Resources, Workforce and Organisational Development and Line Management this is achievable. However this does require a change in culture and the recognition that time spent supporting / undertaking research is time well invested and a function of all health care workers.

## IMPACT ASSESSMENT

<b>Quality/Safety/Patient Experience implications</b>	There are no specific quality and safety implications related to the activity outlined in this report.
<b>Related Health and Care standard(s)</b>	Governance, Leadership and Accountability
	Staff & Resources
	Safe Care Effective Care





<b>Equality Impact Assessment (EIA) completed - Please note EIAs are required for <u>all</u> new, changed or withdrawn policies and services.</b>	No (Include further detail below)  If yes, please provide a hyperlink to the location of the completed EIA or who it would be available from in the box below.  If no, please provide reasons why an EIA was not considered to be required in the box below.
	Not required
<b>Legal implications / impact</b>	There are no specific legal implications related to the activity outlined in this report.
<b>Resource (Capital/Revenue £/Workforce) implications / Impact</b>	There is no direct impact on resources as a result of the activity outlined in this report.
<b>Link to Strategic Well-being Objectives</b>	Provide high quality, evidence based, and accessible care

#### 4. RECOMMENDATION

**4.1** The Committee is asked to **NOTE** and **SUPPORT** the content of this report to ensure the on-going delivery of the HB's R&D strategy.