



AGENDA ITEM

3.2.10

QUALITY & SAFETY COMMITTEE

RESEARCH AND DEVELOPMENT (R&D) UPDATE

Date of meeting	22/11/21
FOI Status	Open/Public
If closed please indicate reason	Not Applicable - Public Report
Prepared by	Professor John Geen, Assistant Director for R&D, Mrs Rhian Beynon, R&D Manager
Presented by	Mrs Rhian Beynon R&D Manager
Approving Executive Sponsor	Executive Director of Public Health
Report purpose	FOR NOTING

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

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

ACRONYMS

CRP	Clinical Research Portfolio
HCRW	Health and Care Research Wales
R&D	Research and Development
UPH	Urgent Public Health (Research Studies)



1. SITUATION/BACKGROUND

CTM UHB's R&D department continues to oversee, coordinate and support all research activity from all multi-professional, multi-disciplinary commercial and non-commercial research that takes place in Secondary / Primary / Community and Population Health research settings, ensuring equitable access to research opportunities, new therapeutics, treatments, pathways and technologies.

R&D Local Support and Delivery Funding from the R&D Division, Welsh Government is allocated to each NHS Organisation to provide the necessary workforce to support and deliver Clinical Research Portfolio and commercial studies, in line with the R&D Division, Welsh Government policy and guidance. The NHS Organisation's funding allocations are monitored through the submission of monthly financial reports and an annual performance management meeting. 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 NHS Research Local Support and Delivery Funding 2021/22

The Local Support and Delivery funding confirmed to date for 2021/22 is broken down as follows:

Recurrent Funding: £1,215,256

Non-Recurrent Funding: £202,043

Total: £1,417,299

CTM UHB R&D has recently requested permanent funding for an additional Band 6 research nurse x 2, Band 5 research officer and funding to provide career progression for a Band 5 Research Officer to and Band 6 Clinical Studies Officer. The decision is awaited from the HCRW Support and Delivery Centre.

The Spending plan for 2022/23 has been submitted to HCRW and a request for permanent funding has been made for all posts outlined in this year's plan. The total funding requested amounts to **£1,558,460**. The R&D team are currently awaiting the response from HCRW.

2.2 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 CRP and commercial activity over the previous 6 years. Increasing primary care, population health and commercial research is a priority for the team. There are currently 2 open commercial trials and 3 further commercial trials due to open shortly.

CTM UHB has been successful in achieving top recruiting site status for a number of studies during the last 12 months and this is a reflection of the R&D team's hard work in the support and delivery of the research portfolio. This is demonstrated in the table below.

Study	No. of Participants	Wales Recruitment Position	UK Recruitment Position
RAPTOR C-19 – Expanding national RAPid community Test evaluation FOR C-19	222	1 st	1 st
FALCON C-19 Facilitating Accelerated CLinical evaluation Of Novel diagnostic tests for COVID-19 (Lumira Dx Arm)	286	1 st	4 th
Chief PD CHolinesterase Inhibitor to prEvent Falls in Parki Mailbox	5	1 st	7 th
PHOSP - Post-hospitalisation COVID-19 study: a national consortium to understand and improve long-term health outcomes (Tier 1)	190	Joint 1 st	8 th
ISARIC Clinical Characterisation Protocol for Severe Emerging Infection	3285	1 st	14 th
PIMCO Psychological impact of Covid-19	21	1 st	18 th
GENOMICC genetics of susceptibility and mortality in critical care	197	1 st	19 th
SYMPLIFY (GRAIL Study) Observational study to assess a multi-cancer early detection test in individuals presenting with signs and symptoms of cancer	228	2 nd	TBC

“Recruitment to time and target” is currently the key performance metric of research activity confirmed by the R&D Division, by Welsh Government and not the number of studies or participants. A UK Task and Finish group on metrics, measures and incentives is in the process of being set up and HCRW have confirmed that this will help support the thinking around the refresh of the current Delivery Plan.

2.3 Research and Development Infrastructure

During the last 6 months, there has been further development in the R&D infrastructure for research support and delivery. Non-recurrent funding from HCRW has been secured for an additional 1.0 Research Midwife (job share appointment made), 1.0 Research Officer (recruitment in process) and 0.5 Research Physiotherapist (in post) until March 2022 to provide additional support for the set up and delivery of research across CTMUHB. Permanent funding (11k of this non-recurring) for an additional 0.8wte Clinical Trials Pharmacist has also been secured (recruitment in process) to help develop commercial research activity.

Moondance funding has been awarded to CTM UHB to cover 0.2 wte Research Champion (Consultant) and 1.0 Band 6 Senior Clinical Studies Officer for a period of 18 months to further develop and increase the colorectal research portfolio across the Health Board. The Health Board has confirmed that it will continue to fund 0.2 wte Research Champion from April 2023 and permanent funding for the Band 6 Senior Clinical Studies Officer beyond the grant term is currently being sought from the Health Board.

2.4 Clinical Research Centre

The Clinical Research Centre was opened at the Royal Glamorgan Hospital site in February 2021, which includes a reception area and 3 clinic rooms for research participants and office space for the R&D team and researchers to use, along with hot desking facilities for NHS academic and industry partners. The Chief Executive had a tour of the Centre in July 2021 with the Executive Director for R&D and Assistant Director for R&D.

The Centre study is currently being used for the SIREN study, an urgent public health Covid-19 study tracking the Covid-19 antibody status of healthcare staff through two weekly swabs and quarterly bloods. The CERM (Chronic Endometriosis and Recurrent Miscarriage) Trial is due to open shortly at the Centre, investigating whether doxycycline administered prior to conception improves pregnancy outcomes in women with recurrent miscarriage associated with chronic endometriosis. CTMUHB has also been shortlisted to



undertake a booster vaccine trial in late autumn and confirmation of site selection is awaited.

Administrative offices are also located at the Princess of Wales Hospital, Prince Charles Hospital and Keir Hardie University Health Park to ensure that equitable research support is provided across CTMUHB and further clinic space is currently being explored at Prince Charles Hospital.

2.5 CTMUHB R&D Response to the Covid-19 Pandemic

The R&D team continue to support Covid-19 research, along with the non-Covid-19 portfolio in line with 3 levels of prioritisation outlined in the National Institute for Health Research "Restart Framework". The table below outlines the number of active studies within CTM UHB during 2021-22 (up to October 2021):

Level	No. of studies 2021-2022	No. of recruits 2021-22
Level 1a UPH 1a Vaccine: Current active Covid-19 Vaccine trials	Awaiting site selection for booster vaccine	Awaiting site selection for booster vaccine
Level 1a UPH 1a Other: Covid-19 interventional trials	2	26
Level 1b UPH 1b: includes all other UPH Covid-19 studies	6	940
Non UPH Covid-19 Non-UPH: all non-UPH Covid-19 studies	5	136
Level 2 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	8	36
Level 3 All other studies	15	309
Total	36	1447



2.6 HCRW Infrastructure

The Assistant Director for R&D has recently been appointed as Vice Chair for the HCRW NHS R&D Leadership Group. The R&D Manager is a member of HCRW Research Delivery Operational Group and HCRW Research Management Operational Group.

2.7 Research with our Academic Partners

CTMUHB continues to work with its academic partners in the development of collaborative research projects and grant applications. This increases the available research capacity and strengthens the partnerships with academic collaborators, which in turn supports the organisation in maintaining University Health Board status. Securing external funding through a competitive process also enables the research project to be adopted onto the Clinical Research Portfolio. The table below illustrates the collaborative work currently ongoing or in development.

Study Title	Academic Partnership	Grant Funder	Collaboration
SPLAC / PPLAC II : Prescribing Lifestyle Adjustments for Cardiovascular Health	University Of South Wales	KESS	Primary Care Secondary Care
Antibiotic Guardian Study: Establishing rapid <i>Gonococcus</i> and <i>M.genitalium</i> diagnosis with antimicrobial resistance screening in Wales, to combat increasingly untreatable STIs	Cardiff University	KESS	Sexual Health Services
Visualisation of Hypertension: A Novel Communication Approach to Support Adherence to Medication	Cardiff Metropolitan	KESS	Community Pharmacies
DESTINY: D-Dimer Testing in Primary Care; a feasibility study	University of South Wales	KESS	GP Practices
MOMA: Measurement of mouthwash anti-viral activity against Covid-19	Cardiff University	Venture Life Group plc	Critical Care / Wards
Predict EV: A study of the predictive nature of extracellular vesicles in stroke progression	Cardiff Metropolitan	British Heart Foundation	Stroke / Clinical Biochemistry



Mapping the lipid envelope composition of SARS-CoV2 for reducing transmission, thrombosis and inflammation (AVECO)	Cardiff University	BBSRC (Biotechnology and Biological Sciences Research Council)	Covid-19 / Clinical Biochemistry
Identifying and Prioritising Diagnostic Imaging Training: a national training needs assessment in Emergency Medicine	University of South Wales	Research Capacity Building Collaboration Wales	National Imaging Academy Wales / Radiology
A Pilot qualitative crossover study: To understand the patients, parents /guardians and mental health professionals' views and feedback on implementing a mobile application (BCAMHS) within mental health services, compared to the standard pathway.	Cardiff Metropolitan	Innovate UK	Mental Health
Lung Modelling for Covid-19	Swansea University	UKRI	Critical Care
The impact of death and associated bereavement during the Covid-19 pandemic in Wales/Welsh Valleys	Open University	TBC	Bereavement services (Pathology)

The Research Capacity Building Collaboration Wales has released a call for the First into Research Fellowships, which enables nurses, midwives, pharmacists or allied health professionals to spend one day per week undertaking a research project for a period of 12 months. The closing date for eligibility applications is 19th November, 2021. CTMUHB have submitted collaborative bids for the HCRW Research for Patient and Public funding scheme and a submission has been made for the HCRW Clinical Research Time Award.

3.0 KEY RISKS/MATTERS FOR ESCALATION TO BOARD/COMMITTEE

3.1 CTMUHB needs to continue developing the infrastructure required to meet both its own R&D ambitions and the expectations set and performance managed by the Welsh Government. This includes the further development of its commercial research portfolio and scope for increasing the HB'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



allocation and successful grant applications. Failure to invest / re-invest in the research infra-structure and maintain or increase 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 HB's R&D ambitions and evidence based improvements in patient care. Internal discussions with Finance Leads will be scheduled to discuss the HB continuing resourcing of R&D.

3.2 The introduction of the expenditure based funding model in 2020/21 has significantly reduced 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 inherent 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 since August 31st, 2021 consultant research sessions to support and promote research in clinical specialties are no longer funded.

3.3 A proposal has been put forward by HCRW that funding for R&D Directors at each NHS Organisation will be removed from April 2022. The proposal indicates intention to reinvest the funds released from this into strengthening the NHS R&D infrastructure. Due to the pivotal nature of the role in setting the local R&D strategy and delivery plan, having responsibility for the management of the R&D budget and performance metrics, alternative funding will need to be sourced if the funding is removed. A communication is currently being drafted by HCRW to be circulated to the Executive Leads for R&D, Executive Directors of Finance and R&D Directors.

3.4 Non-recurrent Local Support and Delivery funding from R&D Division, Welsh Government only enables the recruitment of short fixed term/secondment posts which are difficult to recruit to and does not allow sufficient planning beyond the end of each financial year. The strategic plan to increase our CRP and commercial portfolio provides another mechanism by which funding can be brought into the Health Board to provide further stability to the infrastructure.



IMPACT ASSESSMENT

Quality/Safety/Patient Experience implications	There are no specific quality and safety implications related to the activity outlined in this report.
Related Health and Care standard(s)	Governance, Leadership and Accountability If more than one Healthcare Standard applies please list below: Staff and Resources Safe Care Effective Care
Equality Impact Assessment (EIA) completed - Please note EIAs are required for <u>all</u> new, changed or withdrawn policies and services.	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
Legal implications / impact	There are no specific legal implications related to the activity outlined in this report.
Resource (Capital/Revenue £/Workforce) implications / Impact	There is no direct impact on resources as a result of the activity outlined in this report.
Link to Strategic Goals	Improving Care

4. RECOMMENDATION

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