





Meeting Date	26 <sup>th</sup> July 2018 Agenda Item							
Report Title	Research & Innovation Update Report							
Report Author	Jemma Hughes, R&D Manager							
	Professor Steve Bain, Assistant Medical Director (R&D)							
Report Sponsor	Professor Hamish Laing – Executive Medical Director							
Presented by	Professor Hamish Laing – Executive Medical Director							
Freedom of Information	Open							
Purpose of the Report	To update the Board on R&I activity. The Board is asked to note its content.							
Key Issues	Comparison of ABMU R&I activity to other HBs within Wales.							
	Updates on recent key Research & Innovations for the HB.							
	Integration of Health and Care Research Wales delivery team.							
	Outline of risk of centralisation of contract review.							
Specific Action	Information	Discussion	Assurance	Approval				
Required			<b>√</b>					
(please ✓ one only)								
Recommendations	Members are asked to:     Note the contents of this report							

### Research & Innovation (R&I)

#### 1. INTRODUCTION

The R&I report is provided to offer insight & assurance to the Board on current research activity levels and an update on recent key innovation projects. The report provides business intelligence on research performance and activity compared against other HBs in Wales. It also describes issues for integrating Health and Care Research Wales delivery staff within the corporate R&D team who have been TUPE'd to ABMU. The Board is asked to note the content of the report and endorse further discussion on effective integration of research delivery.

#### 2. BACKGROUND

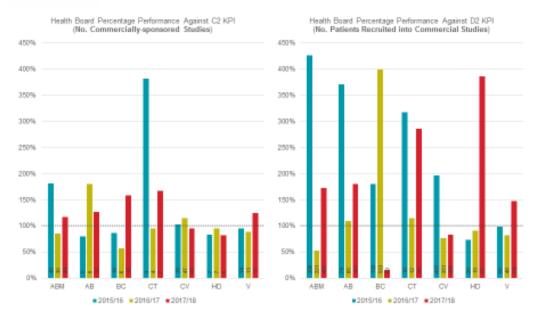
### **Business Intelligence:**

As noted in previous reports, Welsh Government (WG) research targets for the Health Board (HB) relate to numbers of non-commercial Portfolio studies (studies funded by a set list of main research funding bodies) and commercially sponsored studies open to recruitment in the HB and the number of patients of recruited to such studies. The R&D budget from Welsh Government is adjusted each year by activity according to an activity-based funding formula that applies tariffs & weighting depending on study complexity.

Whilst there is an overall trend in Wales for research targets to be just underattained for non-commercial studies (95% target met for number of studies) and (84% for number of patients recruited) the number of commercial studies has been achieved at 112% however the number of patients recruited into commercial studies was missed at 84%. Within this national context, the graphs below demonstrate that ABMU has performed strongly when compared to all HBs in Wales. The difficulty with meeting the research targets is universal to all HBs. Numbers in non-commercial have seen a particular downturn since 2015/16 as a trend across all HBs. ABMU is particularly strong in relation to our commercial research activity, especially in achieving 1<sup>st</sup> patient recruitment within the 30 day target.



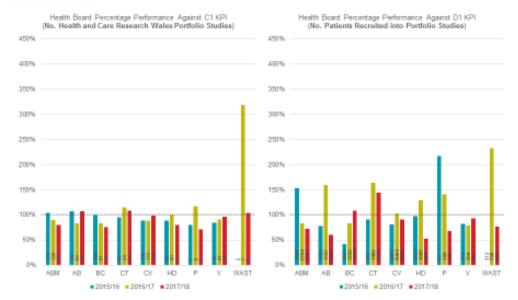
## No. commercial studies and No. participants recruited



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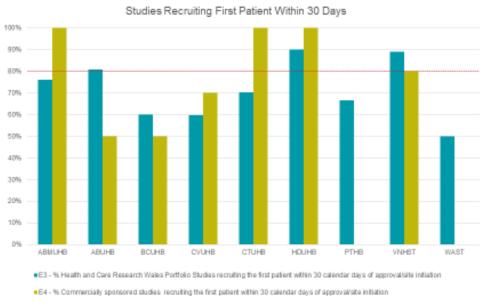


# No. non commercial portfolio studies and No. participants recruited





### Recruitment of first participant within 30 days of initiation/activation 2017/18



### Integration of TUPE'd staff:

The research nurse workforce were successfully TUPE'd from Welsh Government to ABMU at the beginning of the financial year 2017-18. The plan to integrate them with the ABMU R&D team, the Cancer R&D nursing staff and those nurses employed in Joint Clinical research Facility is progressing. The intention is to have a fully integrated single research function to ensure best value and effectiveness.

Progress has been delayed by contractual issues relating to the transferred staff and continuing involvement from Health & Care Research Wales (HCRW) in the posts that they have transferred. This is an area where ABMU is in active discussion with HCRW to ensure contracts and line management of these staff are aligned and congruent with our other research staff.

### Key Research Achievements in the current period:

# 1. Respiratory Innovation Centre (Prof Keir Lewis/Dr Gwyneth Davies) ABMU is partner to the recently announced £2.5m Respiratory Innovation Centre, led by Prof Keir Lewis, Hywel Dda University Health Board and Swansea University.

### 2. Sanofi Centre of Excellence for Diabetes (Prof Steve Bain/Kathie Wareham)

ABMU Health Board's Joint Clinical Research Facility and the Diabetes Research Unit Cymru have been selected by Global Pharma company Sanofi to be their UK Centre of Excellence in Diabetes – this strategic alliance

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provides ABMU JCRF with first access to Sanofi pipeline of clinical research trials.

### 3. ABMU Consultant Physiotherapist named as Critical Care Research Lead for Wales.

Dr Ceri Battle has been named as the Research Lead for Critical Care in Wales. Dr Battle is the first non-medical consultant elected into the role.

### 4. ABMU named as a partner to the Midlands-Wales Advanced Therapy Treatment Centre Project.

Funded by Innovate UK, the MW-ATTC project spans regionally across the Midlands and South Wales, including Cardiff and Swansea to deliver advanced therapies. As part of the collaboration, ABMU JCRF facility will be involved in running advanced gene therapy trials as part of the network of clinical facilities funded under the project.

### 5. ABMU Consultants Prof Alex Chase & Dr Dave Smith authors on latest complex angioplasty trial publication.

Prof Alex Chase and Dr Dave Smith were authors in a trial that was presented as a late breaking trial at the EuroPCR meeting in Paris on May 24th 2018. ABMU were the fourth largest recruiters for a complex angioplasty trial that was conducted in large cardiac centres throughout the UK and Ireland. The trial manuscript was simultaneously published online in the Euro-intervention journal.

### 6. Family Resilience Assessment Instrument tool (FRAIT).

ABMU Health Visiting team (led by Jane O'Kane) have been working collaboratively with the University of South of Wales on the development of a Family Resilience Assessment Instrument tool (FRAIT). In recognition of the know-how the ABMU HV team have provided to the development of FRAIT, a formal Intellectual Property assignment was executed between the HB & University on May 3<sup>rd</sup> 2018, ensuring formal recognition of the HB to the development of FRAIT with revenue sharing options if the tool is successfully spun out by the University.

#### 7. AgorIP

The Health Board currently has 9 innovation ideas under assessment with the *AgorIP*, based at Swansea University. The purpose of *AgorIP* is to support the HB in assessing the potential of innovative ideas and manage effectively the associated intellectual property thereafter, to maximise exploitation.

### 8. JCRF Diabetes studies (Bain & Wareham)

Diabetes studies performed in the JCRF are being presented at symposia during the European Cardiology Society meeting (Munich, August 2018 (and European Association for the Study of Diabetes meeting (Berlin, September 2018) and also published in high-ranking journals (such as Circulation, impact factor 19.3).

### 9. Partnership with Pfizer

Pfizer have established a significant strategic partnership with Swansea University and are seeking to undertake several studies in the ARCH region through the JCRF and the Data Science Team in Swansea University. ABMU's R&D team are exploring some immediate opportunities for research trials and are actively involved in planning for longer term collaboration.

#### 3. GOVERNANCE AND RISK ISSUES

### Activity levels & associated impact on Budget.

The Q4 performance report for the Health Board (17/18) indicates that all commercial targets were met by the Health Board (5% target increase. Actual 14% increase achieved in numbers and 33% increase in patients recruited) but the targets for non-commercial portfolio studies were not met. The target is to increase number of studies and patients recruited by 10%. Actual figures were -12% for number of studies and

-21% for number of patients recruited. These figures will impact on the research budget level set for the HB to be allocated in the next financial year and will be discussed with HCRW at the annual performance review in July.

In 17/18 the budget was reduced by £127,000 due to a similar trend in 16/17. The additional pay costs from the staff transferred has resulted in less scope to invest in other research areas within the HB. Therefore, the issue of successful integration to ensure effective utilisation of all staffing resource available will be critical to manage the budget pressures. The Department of Health have adjusted the Activity Based Funding formula in England to include a tariff for commercial studies. Wales have now adopted the same approach, which may help re-stabilise the R&D budget over the coming years.

#### Risk of centralisation of contract reviews

Currently, Welsh Government & Health and Care Research Wales Support & Delivery service are proposing to create central oversight of contract and costings review in line with an 'One Wales' approach – offering a single "door" to Wales for global pharmaceutical industry partners. ABMU are contributing to the development of the models of oversight to ensure there is no adverse impact on our local efficiency for study set up and contract reviews.

In our judgement there needs to be a balance between 'central oversight' and 'central co-ordination' and the most commercially research active HBs in Wales are concerned that a 'central co-ordination' model does not recognise fully the way global pharma select sites for research trials. In our experience sites are chosen on efficiency of study set up and a proven track record of the Primary Investigator and clinical team to recruit to target. There is global competitive recruitment and so any delays can seriously impact upon the reputation of a clinical site.

Through our JCRF, ABMU and Swansea University have developed a highly efficient contract review process resulting in the JCRF holding preferred site status with many

global Pharma companies, most recently being named a UK Centre of Excellence for Diabetes with Sanofi. The Board is asked to note the ongoing discussion about centralisation and the need to ensure that ABMU is not disadvantaged by the model proposed. Further updates will be provided to the Board through the JCRF Board.

### 4. FINANCIAL IMPLICATIONS

None quantified

### 5. RECOMMENDATION

**6.** The Board is asked to note the contents of this report

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Quality, Safety and Patient Experience										
N/A										
Financial Implications										
N/A										
Legal Implications (including equality and diversity assessment)										
N/A										
Staffing Implica	Staffing Implications									
Further discussion is required with Health and Care Research Wales and ABMU HR										
to agree staffing integration.										
Long Term Implications (including the impact of the Well-being of Future Generations (Wales) Act 2015)										
N/A										
Report History	September 2017 – R&D Report.									

Appendices	R&D Activity report.