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Bwrdd Iechyd Prifysgol  
Bae Abertawe  
Swansea Bay University  
Health Board



<b>Meeting Date</b>	<b>07 October 2021</b>	<b>Agenda Item</b>	<b>6.3(i)</b>
<b>Report Title</b>	<b>Research &amp; Development Annual Report 2020/21</b>		
<b>Report Author</b>	Anne-Claire Owen, Acting R&D Manager		
<b>Report Sponsor</b>	Dr Richard Evans, Medical Director		
<b>Presented by</b>	Dr Richard Evans, Medical Director		
<b>Freedom of Information</b>	Open		
<b>Purpose of the Report</b>	<p>The purpose of this report is to provide the Board with an update on R&amp;D activity within the Health Board. Our objectives for 2020/21 were to promote research throughout the Health Board and to engage more directorates in clinical research trials. We planned do this by representation at Directorate meetings, offering expert research assistance where required, and by promoting research trials that wish to engage with Welsh Health sites.</p> <p>The majority of research studies were halted at the outset of the pandemic for safety reasons and to ensure Swansea Bay contributed to urgent Public Health (UPH) priority Covid-19 studies. Staff were committed to recruit patients and SBU HB was one of the top UK recruiters for many of these complex trials.</p> <p>This report also considers the impact of the Vacutainer shortages and the measures in place to continue research along with the new Health and Care Research Wales (HCRW) Needs Based Funding (NBF) model.</p>		
<b>Key Issues</b>	<p>The national priority for research and key target is to increase the quantity of high quality research, providing patients with the opportunity to participate and benefit.</p> <p>Halted studies have been re-commenced in a safe manner as well as new studies, and the Health Board continues to support UPH COVID-19 studies.</p> <p>We had anticipated a normal year for research in 2021/22, quickly reopening suspended trials and expressing interest</p>		

	<p>in new trials, but have now been affected by the lack of vacutainer blood sample bottles in the UK. As most research trials need regular blood samples for both analysis and for safety measures, this could have a significant effect on our ability to conduct trials. In a worst case scenario, this could reduce income generation during this period by £180,000. This will be mitigated since most pharmaceutical trials provide their own vacutainers, and they may be able to source these from outside the UK.</p> <p>We expect Health and Care Research Wales to fully fund our non-commercial portfolio commitments, so this should not have a negative impact on our income</p>			
<b>Specific Action Required</b> <i>(please choose one only)</i>	<b>Information</b>	<b>Discussion</b>	<b>Assurance</b>	<b>Approval</b>
	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<b>Recommendations</b>	<p>Members are asked to:</p> <ul style="list-style-type: none"> <li>• <b>Note the content of the report.</b></li> </ul>			

## **Research & Development Annual Report 2020-21**

### **1. INTRODUCTION**

This report seeks to inform the Board on the current state of R&D activity within the Health Board, with a focus on the impact of the Covid-19 pandemic, the impact of the Vacutainer shortages and the Needs Based Funding (NBF) model.

Appended to this report are two comprehensive performance data reports for 2021/22 – data cut 06/09/2021- provided by Health and Care Research Wales, which offer an overview of activity by each Health Board across Wales and compares Wales' performance to England. SBUHB compares favourably, reflecting the excellent commitment to R&D that Health Board staff continue to demonstrate (Appendix 1).

There are a number of areas where activity could be improved and we working closely with the clinical teams to support research aligned to the local population. During the pandemic and the increase in Covid-19 studies, we have been able to build connections with the clinical teams, in particular the intensive care unit (ITU).

Appendix 2 highlights the number of Covid-19 studies across Wales and a comparison of the activity of each Health Board.

### **2. BACKGROUND**

The arrival of the Covid-19 pandemic saw an abrupt halt to R&D activity across the Health Board. At the outset of the outbreak, the Health Board suspended 217 studies. As of 7 September 2021, 61 of those studies remain suspended as the teams continue the re-start process ensuring necessary adaptations are being made to conduct the studies in line with Covid-19 secure measures. There are currently 22 open and recruiting Covid-19 studies that includes non-portfolio, commercial and primary care.

In April 2021, Swansea Bay UHB together with Public Health Wales opened the first study to test a plant-derived Covid-19 vaccine candidate that sought to evaluate the efficacy and safety of the Coronavirus-Like Particle Covid-19 Vaccine (CoVLP). Staff conducting the study recruited 61 participants and were the highest recruiting site in the UK.

In light of the global Vacutainer blood bottle shortage, all ongoing studies have been reviewed and those that use NHS stock of Vacutainer tubes have been put on immediate hold pending re-stocking.

### **3. GOVERNANCE AND RISK ISSUES**

The shortage of storage bottles for blood samples could see some studies suspended for two to three months. The shortage has the potential to affect trial income over the next 2-3 months but is unlikely to affect commercial income since the pharma companies supply their own stock specifically for use in their studies.

The potential reputational risk is mitigated in that study sponsors do not intend to hold the Health Board to targets set prior to both the worldwide pandemic and Vacutainer shortage.

The Health Board is currently managing a backlog in Radiology and current waiting times mean that the Department does not have the capacity to support research activity at this time. There is a potential reputational risk if studies requiring Radiology support cannot be supported. Transfer of R&D imaging capacity to the MRI and CT scanners in the Institute of Life Sciences 2 (ILS2) suite on the Singleton site should resolve the delays.

#### **4. FINANCIAL IMPLICATIONS**

Although a significant shortfall in research income was predicated due to the pandemic, this was ultimately wholly mitigated. Of the research grants held during 2020/21 we either received full funding for these schemes which have been deferred in the Health Board books until they can be used in 2021/22, or we negotiated with the grant holder for a 'no-cost extension' so that income has been delayed until we are in a position to resume the grant work. There has been no financial impact due to these measures (Appendix 3).

SB UHB research was commended for its application of the new Needs Based Funding model (NBF) in submitting its 2021/22 Spending Plan.

#### **5. RECOMMENDATION**

The Board is asked to note the contents of the report and endorse the re-opening of research activity across the Health Board, subject to appropriate safeguarding measures being in place along with the full agreement of any supporting services.

<b>Governance and Assurance</b>		
<b>Link to Enabling Objectives</b> (please choose)	<b>Supporting better health and wellbeing by actively promoting and empowering people to live well in resilient communities</b>	
	Partnerships for Improving Health and Wellbeing	<input checked="" type="checkbox"/>
	Co-Production and Health Literacy	<input checked="" type="checkbox"/>
	Digitally Enabled Health and Wellbeing	<input checked="" type="checkbox"/>
	<b>Deliver better care through excellent health and care services achieving the outcomes that matter most to people</b>	
	Best Value Outcomes and High Quality Care	<input checked="" type="checkbox"/>
	Partnerships for Care	<input checked="" type="checkbox"/>
	Excellent Staff	<input checked="" type="checkbox"/>
	Digitally Enabled Care	<input checked="" type="checkbox"/>
	Outstanding Research, Innovation, Education and Learning	<input checked="" type="checkbox"/>
<b>Health and Care Standards</b>		
(please choose)	Staying Healthy	<input type="checkbox"/>
	Safe Care	<input checked="" type="checkbox"/>
	Effective Care	<input checked="" type="checkbox"/>
	Dignified Care	<input type="checkbox"/>
	Timely Care	<input type="checkbox"/>
	Individual Care	<input type="checkbox"/>
	Staff and Resources	<input type="checkbox"/>
<b>Quality, Safety and Patient Experience</b>		
Improved patient experience through access to new treatments offered under research programmes.		
<b>Financial Implications</b>		
Improved financial position through re-start of commercially funded studies and re-start of grant-funded studies.		
<b>Legal Implications (including equality and diversity assessment)</b>		
Enabling compliance with UK Policy on Research Governance.		
<b>Staffing Implications</b>		
N/A.		
<b>Long Term Implications (including the impact of the Well-being of Future Generations (Wales) Act 2015)</b>		
N/A		
<b>Report History</b>	Board Report 24 September 2020.	
<b>Appendices</b>	<b>Appendix 1: Health and Care Research Wales NHS Wales Performance Report 2021/22</b>  <b>Appendix 2: COVID-19 Research Swansea Bay UHB</b>  <b>Appendix 3: R&amp;D Finances 2020-21</b>	