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Iechyd Cyhoeddus  
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Public Health  
Wales

**Name of Meeting**  
Knowledge, Research and  
Information Committee  
**Date of Meeting**  
10th March 2022  
**Agenda item:**  
3.2

## Update on COVID-19 Vaccine Trials in Wales

|                        |  |
|------------------------|--|
| <b>Executive lead:</b> | Iain Bell, Director of Public Health Data, Knowledge and Research, Knowledge Directorate |
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| <b>Approval/Scrutiny route:</b> | Considered at the Business Executive Team Meeting on 1 <sup>st</sup> March 2022 for KRIC on 9 <sup>th</sup> March 2022. |
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### Purpose

This paper provides an overview of the success of Public Health Wales’s recent role in providing strategic oversight of COVID-19 vaccine and drug PANORAMIC trials and the evolution of PHW’s role in the ‘One Wales’ approach, in partnership with Health and Care Research Wales (HCRW).

The paper also asks the committee to consider and support further work to develop the future of role PHW in relation supporting with HCRW trials in a ‘Once Wales’ approach.

### Recommendation:

|  |   |                                       |                                   |                                       |
|--|---|---------------------------------------|-----------------------------------|---------------------------------------|
| APPROVE<br><input checked="" type="checkbox"/> | CONSIDER<br><input checked="" type="checkbox"/> | RECOMMEND<br><input type="checkbox"/> | ADOPT<br><input type="checkbox"/> | ASSURANCE<br><input type="checkbox"/> |
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The committee is asked to:

1. **Consider and Recognise** the progress to date and the contribution from PHW teams, particularly coordination role of PHW Research and Development Office in relation to successful role PHW has played in delivery of COVID-19 vaccine and drug trials in Wales to date.
2. **Consider** and **Approve** the strategic direction and requirement for work to identify implications to embed PHW role as a hub for oversight and coordination of future trials

3. **Note** - This is an ongoing piece of work and further updates will be provided to the Knowledge, Research and Information Committee once there is more clarity from HCRW on the future direction of the 'One Wales' approach to clinical trial delivery and strategic future of vaccine and antiviral trials is assessed.

**Link to Public Health Wales [Strategic Plan](#)**

Public Health Wales has an agreed strategic plan, which has identified seven strategic priorities and well-being objectives.

This report contributes to the following:

|  |  |
|--|--|
| <b>Strategic Priority/Well-being Objective</b> | 7 - Building and mobilising knowledge and skills to improve health and well-being across Wales |
| <b>Strategic Priority/Well-being Objective</b> | All Strategic Priorities/Well-being Objectives   |

**Summary impact analysis**

|  |   |
|--|---|
| <b>Equality and Health Impact Assessment</b> | Equality or Health Impact Assessment has not been undertaken alongside this report, as this programme of work is primarily led by Health and Care Research Wales alongside Health Boards who are undertaking the trial. |
| <b>Risk and Assurance</b>                    | One of the strategic risks relates to protecting the public from COVID-19   |
| <b>Health and Care Standards</b>             | This report supports and/or takes into account the <a href="#">Health and Care Standards for NHS Wales</a> Quality Themes   |
| <b>Financial implications</b>                | Financial implications are not addressed in this report.  |
| <b>People implications</b>                   | The Research and Development Office are working in partnership with Health and Care Research Wales to oversee and monitor vaccine trials and PANORAMIC in Wales.  |

## **1. Purpose / situation**

This paper provides an overview of the success of Public Health Wales's recent role in providing strategic oversight of COVID-19 vaccine and drug PANORAMIC trials and the evolution of PHW's role in the 'One Wales' approach, in partnership with Health and Care Research Wales (HCRW). The paper also asks the group to consider and support further work to develop the future of role PHW in relation supporting with HCRW trials in a 'Once Wales' approach.

## **2. Background**

Public Health Wales (PHW) lead by the Research and Development Office has been instrumental in supporting the delivery of COVID-19 Vaccine Clinical Trials across Wales and is providing a 'One Wales' response and strategic oversight for all COVID-19 trials delivered, in partnership with HCRW.

In December 2021, PHW took an oversight role of a clinical trial to test novel antiviral COVID-19 treatments in the community setting for adults with recently confirmed COVID-19 and those who are at higher risk of complications (the PANORAMIC Trial). PANORAMIC is designed as a 'platform clinical trial', meaning it can rapidly evaluate several antiviral treatments over time. The first treatment to be investigated through the trial is Molnupiravir, a COVID antiviral pill already licensed by the MHRA.

PHW has featured in several communications released for the successful delivery of the PANORAMIC trial, including a recent BBC Wales Article (13<sup>th</sup> January 2022); [Covid: Hundreds in Wales take antiviral tablets - BBC News](#)

### **The PHW 'One Wales' Approach and benefits so far**

The PHW 'One Wales' approach to COVID-19 vaccine trials was extended to include the anti-viral PANORAMIC trial, which commenced in December 2021. The model for the PANORAMIC study, is different to the one used for COVID-19 vaccine trials.

PHW is working with HCRW and the Centre for Trials Research at Cardiff University to provide a 'Hub' for the trial. PHW is an investigator site and directly contracting with the sponsor, Oxford University. To deliver the trial, PHW has issued six General Practitioners across Wales with honorary contracts and an SLA have set up with GP Practice in North Wales. PHW Informatics team provide PCR and LFT results to the HCRW centralised booking team. This model has been successful, with PHW being the highest

recruiting site for the Trial with over 1025 participants recruited (accounting for 13% of the overall recruitment to the Trial).

### **Governance and Risk**

The Public Health Wales Vaccine Trials Oversight Group currently provides strategic oversight and governance, to monitor the set-up and management of COVID-19 Vaccine Trials and PANORAMIC in Wales.

The group of which the membership includes PHW Executive Directors, representation from across PHW teams as relevant, PHW Research and Development representation and HCRW. The group meets monthly.

HCRW and PHW produce an Exception Update Report for each meeting, which includes an update on trial safety. The group also review a risk register.

The PHW Research and Development Office are providing the link between PHW and HCRW to assist with monitoring and oversight at the trial sites.

### **3. Description/Assessment**

#### **Impact and Future Context**

As above, the model utilised within the latest PANORMANIC study with PHW acting as a 'Hub' for the trial has been successful; with high levels of recruitment to the trial. There is an opportunity to utilise the learning from this hub and spoke model, for PHW to work with HCRW to develop PHW's strategic role in supporting vaccine and drug trial programmes in the future. PHW as an organisation is well placed to take a 'One Wales' approach and maximise the benefits of this. In the immediate this approach offers the ability to respond to:

- the evolving trial landscape to mitigate against the impact of further COVID-19 variants
- the emergence of trials delivered in community settings looking at combined Flu and COVID-19 vaccines

The PHW role leading on and providing strategic oversight and coordination for future trials under the 'One Wales' model would also continue to support the Welsh Government's commitment to ensure that the people of Wales are able to access vaccine research opportunities.

This hub and spoke model led by PHW offers a new approach to delivery of future vaccine research across Wales however in order to ensure sustainability there would need to be consideration of the following:

- **PHW resource capability and capacity:** PHW will need to work in partnership with HCRW to understand the full implications of embedding the model for PHW to provide the continued oversight and leadership for multiple trials.
- **Review of laboratory capacity/access to expertise:** An increase in trial activity could require support from the microbiology service, if testing is required in scenario. Without agreed resource and support or access to expert advice for a trial there is a risk of trial setup delays.
- **Review of PHW governance and risk management:** to ensure ability provide assurance that clinical governance practice, policies and procedures are in place where honorary contracts are issued to clinicians to deliver the study on behalf of PHW. PHW will contract directly with the sponsor of trials, therefore work will be required to understand and ensure appropriate procedures in relation to liability.

#### 4. Recommendation

The Committee is asked to:

1. **Consider and Recognise:** the progress to date and the contribution from PHW teams in relation to successful role PHW has played in delivery of COVID-19 vaccine and drug trials in Wales to date.
2. **Consider and Approve:** the strategic direction and requirement for work to identify implications to embed PHW role as a hub for oversight and coordination of future trials
3. **Note:** This is an ongoing piece of work and further updates will be provided to the Knowledge, Research and Information Committee once there is more clarity from HCRW on the future direction of the 'One Wales' approach to clinical trial delivery and strategic future of vaccine and antiviral trials is assessed.

## Annex 1

On the 19 August 2020, Public Health Wales entered into a formal partnership with HCRW to provide strategic oversight and monitoring of COVID-19 research trials delivered in Wales. Public Health Wales has set up a Vaccine Trials Oversight Group to provide strategic oversight and governance and to monitor the set-up and management of COVID-19 Vaccination Trials in Wales.

Public Health Wales's roles and responsibilities include:

- Providing a 'once for Wales' approach by being the investigator site for all COVID-19 vaccine research; set out in a Service Level Agreement (SLA) with the relevant Health Board to deliver the trial;
- Monitoring the set-up and delivery of COVID-19 vaccine trials in Wales as managed by HCRW;
- Providing honorary contracts to the Principal Investigators (PIs) on the trial and managing clinical oversight of their roles;
- Oversight of strategic risk and escalation of risk through Public Health Wales structures;
- Overseeing laboratory capacity to deliver the vaccines programme;
- Providing media and communications support to the vaccines programme in partnership with HCRW; and
- Supporting the links between Public Health Wales's Vaccination Preventable Disease Programme and the Wales Vaccine Trial Delivery Programme.

### 4.1.1 COVID-19 Vaccine Trial pipeline: 2020-2021

| Trial     | Type                  | Location                        | Start date | Status | Target | Recruited | Update   |
|-----------|-----------------------|---------------------------------|------------|--------|--------|-----------|--|
| Novavax   | New vaccine (Phase 3) | Wrexham                         | 2/11/20    | Closed | 400    | 490       |  |
| Janssen   | New vaccine (Phase 3) | Cardiff                         | 23/11/20   | Closed | 333    | 234       |  |
| Medicago  | New vaccine (Phase 3) | Swansea                         | 26/4/21    | Closed | 50     | 60        | 1 <sup>st</sup> Europe participant was recruited by Wales. |
| ComFluCoV | Dose 2 Covid19 + Flu  | Cardiff Mass Vaccination Centre | 13/05/21   | Closed | 126    | 126       |  |
| COV-Boost | Booster combinations  | Wrexham                         | 07/06/21   | Closed | 148    | 148       | AZ participants  |

|                             |                                   |                                      |                 |        |     |     |  |
|-----------------------------|-----------------------------------|--------------------------------------|-----------------|--------|-----|-----|--|
|                             |                                   |                                      |                 |        |     |     | under recruited.   |
| Com-Cov3                    | 2 <sup>nd</sup> dose young people | Cardiff (Children's Hospital, Heath) | 14/09/2021      | Closed | 15  | 40  | Phase 1 complete, phase 2 recruitment suspended due to change in guidance from JCVI for adolescents. |
| COV-Boost (fractional dose) | Fractional booster study          | Wrexham                              | From 21/02/2022 | Open   | 148 | N/A |  |
| Moderna                     | 4th dose                          | Llantrisant                          |                 | Set-up | TBC | -   |  |
| Janssen                     | Omicron variant (Phase 2)         | Wrexham                              |                 | TBC    | TBC | -   |  |

**Novavax Trial:** Public Health Wales signed the first trial site agreement on the 27 October 2020 with Novavax; with Betsi Cadwaladr University Health Board (BCUHB) delivering the trial in Wrexham. BCUHB exceeded the recruitment target set and have vaccinated almost 500 patients. This trial is now closed. Wrexham are also delivering the COV-Boost trial, the COV-Boost (fractional dose) trial and are due to deliver the Janssen (Omicron variant) trial.

**Medicago Trial:** The site agreement was signed on the 08 April 2021 with Medicago with Swansea Bay UHB delivering the trial. Due to the rapid roll-out of deployed vaccines in Wales the agreed recruitment was challenging to achieve and this trial closed early.

**Moderna Trial (4<sup>th</sup> dose):** The site for this trial is due to be in Cwm Taf UHB (Llantrisant) and the trial is currently in set-up.

#### 4.1.2 COVID-19 antiviral trial

| Trial     | Type   | Location  | Start date | Status | Target | Recruited                         | Update   |
|-----------|--|-----------|------------|--------|--------|-----------------------------------|--|
| PANORAMIC | Platform (MSD Molnupiravir and PaxlovidPfizer) | All-Wales | 12/2022    | Open   | -      | 1025 (~ 13% of total recruitment) | Over 1,000 trials participated (highest recruiting site) |



The Public Health Wales One-Wales approach to COVID-19 vaccine trials was extended to include the anti-viral PANORAMIC trial (sponsor Oxford University) which commenced in December 2021. Public Health Wales are working with Health and Care Research Wales (HCRW) and the Centre for Trials Research at Cardiff University to provide a 'Hub' for the trial.

PANORAMIC is a clinical trial to test novel antiviral COVID-19 treatments for use early on in the illness by people (18+) in the community with COVID-19 and those who are at higher risk of complications. PANORAMIC is designed as a 'platform clinical trial', meaning it can rapidly evaluate several antiviral treatments over time. The first treatment to be investigated through the trial is Molnupiravir, a COVID antiviral pill already licensed by the MHRA.