

Llywodraeth Cymru Welsh Government

Ein cyf/Our ref: WQ81049 and WQ81050

Hefin David MS Welsh Parliament Cardiff Bay Cardiff CF99 1SN

29 September 2020

Dear Hefin,

I am writing in response to WQ81049 and WQ81050 regarding vaccine clinical research trials in Wales.

WQ81049 - Does the Welsh Government keep a record of how many people domiciled in Wales have volunteered for the COVID-19 vaccine trials at the University of Oxford and Imperial College London?

The vaccine trial was sponsored by the University of Oxford, the study was established to test the immune response to the vaccine and protection in people of different ages, including healthcare workers. The Welsh Government does not hold data related to clinical trials as governance arrangements for clinical trials are the responsibility of the sponsor and underpinned by strict confidentiality agreements. As you will be aware, not every patient is eligible for a clinical trial. Once a patient consents to participate, screening is undertaken to assess patient eligibility. Once the screening process is complete, the clinical trial team can determine if a patient is eligible for the trial. The subjects volunteered for the Oxford study through a specific pre-screening website. Of these, a proportion went on to the screening stage of the study. A detailed breakdown on the volunteering and screening stage of the study will be available when the data is published in full.

The Imperial trial, Wales has not yet participated in the current early phases of this study, but through the coordinated efforts of Health and Care Research Wales, Wales intends to take part in later phases of this trial.

WQ81050 - How many people domiciled in Wales and from vulnerable groups, were successfully chosen to take part in COVID-19 vaccine trials at the University of Oxford and at imperial College London?

As I mentioned above, not every patient is eligible for a clinical trial and screening processes are put in place to assess patient eligibility. Wales successfully recruited to the study and also met the sponsor requirements to recruit a significant proportion of health

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Rydym yn croesawu derbyn gohebiaeth yn Gymraeg. Byddwn yn ateb gohebiaeth a dderbynnir yn Gymraeg yn Gymraeg ac ni fydd gohebu yn Gymraeg yn arwain at oedi.

care workers, but due to the governance arrangements for clinical trials, I am unable to provide further information on this. A full breakdown of the data will be available in the final published report.

In relation to the involvement of vulnerable groups, this is an important consideration for research both planned and underway. As Wales prepares to participate in other vaccine studies, a vaccine research delivery group overseen by Health and Care Research Wales has been established and includes patient and public involvement to ensure that specific communities and groups are considered within the requirements of the trial protocol. This includes older age groups, those with comorbidities, and in ethnically and geographically diverse populations. There is also specific focus in all of the vaccine research protocols to include proportionate representation from all vulnerable groups and those from Black, Asian and Minority Ethnic (BAME) groups

The Welsh Government fully understands that all members of the public in Wales should have the opportunity to participate in vaccine research. To assist with this, a new NHS service has been launched helping people to sign up for information on the new COVID-19 vaccine trials. Researchers are looking for people from all backgrounds, ages and parts of the UK, including people with or without existing health conditions, to make sure that any vaccines developed will work for everyone.

This registry has been established to provide people with more information on vaccine research and to help them register their interest in potential studies. As with the governance arrangements around clinical trials, screening for eligibility into vaccine trials will continue. Further information on this work is available on the Health and Care Research Wales website: <u>https://www.healthandcareresearch.gov.wales/news/new-nhs-service-for-covid-19-vaccine-studies/</u>

Finally, Wales has not had any involvement in the current early phases of the Imperial vaccine trial but, intends to take part in later phases of this study.

Yours sincerely,

Jethy

Vaughan Gething AS/MS Y Gweinidog lechyd a Gwasanaethau Cymdeithasol Minister for Health and Social Services