



By email

request-713347-c3eb0290@whatdotheyknow.com

Our ref: 16/12/kl/2165

18 January 2021

Dear J Grove,

Re: Freedom of Information request - Species and strains used for safety testing of the Pfizer-BioNTech COVID-19 "vaccine"

Thank you for your request received on 16 December 2020 addressed to Public Health England (PHE). In accordance with Section 1(1)(a) of the Freedom of Information Act 2000 (the Act), I can confirm that PHE does not hold the information you have specified.

Request

Elliot Colburn MP in a recent parliamentary debate has said that the current COVID-19 vaccine is safe because of the safety testing including "in vivo testing often using mice".

What preclinical species and the strain of each species (e.g. C57BL/6 mouse, BALB/c mouse, Sprague Dawley rat and cynomolgus monkey) have been recorded as being used for safety studies (i.e. all safety studies including "Antibody Dependent Enhancement" (ADE) and effects on female fertility) that the Pfizer-BioNTech COVID-19 vaccine has been tested in?

Response

PHE can confirm that it does not hold the information as specified in your request.

PHE is an executive agency of the Department of Health and Social Care (DHSC) and a distinct organisation with operational autonomy. PHE provide government, local government, the NHS, Parliament, industry and the public with evidence-based professional, scientific expertise and support. While PHE is providing scientific expertise and support in relation to COVID-19 vaccines, the Medicines and Healthcare products Regulatory Agency (MHRA) is responsible for the regulation of medicine and medical devices, including vaccines.

Under section 16, a public authority has a duty to provide advice and assistance. Accordingly, you may wish to contact the MHRA for further information. You may be

interested in the following MHRA decision “Information for Healthcare Professionals on Pfizer/BioNTech COVID-19 vaccine”. This decision mentions the use of animals in section 5.3 (Preclinical safety data). This can be accessed at:

<https://www.gov.uk/government/publication/regulatory-approval-of-pfizer-biontech-vaccine-for-covid-19/information-for-healthcare-professionals-on-pfizerbiontech-covid-19-vaccine>

For your convenience, I have located the trial data has been published at the links below:

<https://www.nejm.org/doi/full/10.1056/NEJMoa2034577>

[https://www.thelancet.com/journals/lancet/article/PIIS0140-6736\(20\)32661-1/fulltext](https://www.thelancet.com/journals/lancet/article/PIIS0140-6736(20)32661-1/fulltext)

If you have any queries regarding the information that has been supplied to you, please refer your query to me in writing in the first instance. If you remain dissatisfied and would like to request an internal review, then please contact us at the address above or by emailing foi@phe.gov.uk.

Please note that you have the right to an independent review by the Information Commissioner’s Office if a complaint cannot be resolved through the PHE complaints procedure. The Information Commissioner’s Office can be contacted by calling the ICO’s helpline on 0303 123 1113, visiting the ICO’s website at www.ico.org.uk or writing to the ICO at Wycliffe House, Water Lane, Wilmslow, Cheshire, SK9 5AF.

Yours sincerely
FOI Team