FOI 23-332 - Clinical Study Report of the Trial registered as C4591015 and assessment report by MHRA

REQUEST
6 May 2023

This request is related to the regulatory submission for the Pfizer vaccine, would you be able to provide the Clinical Study Report of the Trial registered as C4591015 and the assessment report done by the MHRA ?

MHRA RESPONSE
19 May 2023

All clinical data submitted for the authorisation of the Pfizer vaccine is available through the EMA clinical repository, linked below:

https://clinicaldata.ema.europa.eu/web/cdp/home

The non-confidential parts of the assessment reports for all authorised vaccines are available through the MHRA Products Portal (link provided below):
https://products.mhra.gov.uk/

If you disagree with how we have interpreted the Freedom of Information Act 2000 in answering your request, you can ask for an internal review. Please reply to this email, within two months of this reply, specifying that you would like an Internal Review to be carried out.

Please remember to quote the reference number above in any future communications.

If you were to remain dissatisfied with the outcome of the internal review, you would have the right to apply directly to the Information Commissioner for a decision. Please bear in mind that the Information Commissioner will not normally review our handling of your request unless you have first contacted us to conduct an internal review. The Information Commissioner can be contacted at:

Information Commissioner's Office
Wycliffe House
Water Lane
Wilmslow
Cheshire
SK9 5AF

Yours sincerely

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