

FOI 22/1190 Pfizer / BioNTech Covid 19 vaccine - infants and children aged 6 months to 4 years

REQUEST

9 December 2022

Details and results of the clinical trial involving 4,526 participants referred to in the press release.

MHRA RESPONSE

6 January 2023

Dear

Thank you for your email.

The data will have been added to the European Medicines Agency (EMA) clinical data repository at the following link of the EMA website below:

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

If you disagree with how we have interpreted the Freedom of Information Act 2000 with regards to your request, you can ask for the decision to be reviewed. The review will be carried out by a senior member of the Agency who was not involved with the original decision.

If you have a query about the information provided, please reply to this email.

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

MHRA Customer Service Centre

Medicines and Healthcare products Regulatory Agency
10 South Colonnade, Canary Wharf, London E14 4PU