## FOI 24/161 - Freedom of Information request - Unblinding of vaccine trials

MHRA Customer Services <MHRACustomerServices@mhra.gov.uk>
Thu 14/03/2024 10:34
To [redacted]
FOI 24/161

Dear [redacted]

Regarding your Freedom of Information Act (FOIA) enquiry, dated 18 February 2024:

'Dear MHRA Customer Services,
1. For the trials Pfizer PL GB 53632/ 0002 and PL GB 53632/0003 can you give me the date of unblinded and how long this was from the start of the trial.
2. For Moderna PL GB 53720/0002 and PLGB 53720/0004 the same information please.
3. For Astrazeneca PL 17901/0355 the same information please.'

Unfortunately, MHRA estimate that compliance with this request would exceed the appropriate limit under Section12 Freedom of Information (FOI) Act 2000, which is set at 24 working hours per request. Public authorities are not obliged to work past the appropriate limit under Section 12(1) of the FOI Act 2000 and we are, therefore, refusing your request.

In calculating the time taken to determine whether we hold the information, locate and compile that information, we tried to find the date of unblinding and how long it was from the start of the trial for one study that was submitted for the authorisation of the Pfizer vaccine, Study C4591001.

Please be aware that there are different levels of unblinding during a clinical trial and circumstances under which breaking a blind may be necessary at different timepoints. For example, the main study data submitted for the authorisation of Comirnaty concentrate for dispersion for injection COVID-19 mRNA Vaccine (nucleoside modified), Study C4591001, shows that Sponsor staff, investigators and participants were blinded at different periods during the study. For participants, the blind could be broken for pre-defined reasons specified in the protocol. For any remaining participants whose blind had not been broken during the blind-phase study, they would be unblinded up to approximately 5 months after receiving their second dose of vaccine. The date of unblinding for each participant would differ depending on what date they received their second dose of vaccine, however, unblinding started on 14 December 2020. As the blinding and unblinding of Sponsor staff, investigators and study participants is not as simple as providing one date and one period of time from dosing, it takes approximately 4 hours of reading through the study documents in order to be able to provide only partial information on when unblinding took place.

We therefore calculate that to do this for all clinical trial data submitted for all the vaccines you have stated, and provide all information, would take over 24 working hours, which is why Section 12 of the FOI Act 2000 is engaged.

We recommend that you refine your request to ask for details of unblinding for a specific study, and also be specific about whether you want information about the unblinding of participants, sponsor staff or investigators.

We think it may also be useful for you to know that some information on unblinding for these clinical studies is available in the public domain, please see the below links for examples of where this can be accessed for the Pfizer vaccine.

https://www.ema.europa.eu/en/documents/variation-report/comirnaty-h-c-5735-ii-0067-epar-assessment-report-variation_en.pdf
https://www.cdc.gov/vaccines/acip/meetings/downloads/slides-2021-08-30/02-COVID-perez-508.pdf

Additional resources where this information could be accessed include the European Medicines Agency Medicines Finder and their Clinical Repository. Linked to these are provided below:
https://clinicaldata.ema.europa.eu/web/cdp/home
https://www.ema.europa.eu/en/medicines

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

If you are dissatisfied with the handling of your request, you have the right to ask for an internal review. Internal review requests should be submitted within two months of the date you receive this response and addressed to: info@mhra.gov.uk

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 Experience Centre
Communications and engagement team
Medicines and Healthcare products Regulatory Agency
10 South Colonnade, Canary Wharf, London E14 4PU

-----Original Message-----
From: [redacted]
Sent: Sunday, February 18, 2024 4:01 PM
To: MHRA Customer Services <MHRACustomerServices@mhra.gov.uk>
Subject: FOI 24/161 - Freedom of Information request - Unblinding of vaccine trials

Dear MHRA Customer Services,
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Yours sincerely,

[redacted]

-----Original Message-----

[redacted]

Thank you for your email.

Please find attached the response to your FOI request.

Kind Regards

MHRA Customer Experience Centre
Communications and engagement team
Medicines and Healthcare products Regulatory Agency
10 South Colonnade, Canary Wharf, London E14 4PU

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Please use this email address for all replies to this request:
request-1012788-40a838a2@whatdotheyknow.com

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https://eur01.safelinks.protection.outlook.com/?url=https%3A%2F%2Fwww.whatdotheyknow.com%2Fhelp%2Fofficers&data=05%7C02%7CMHRACustomerServices%40mhra.gov.uk%7C4335977aea9541c08dc608dc309adaa5%7Ce527ea5c62584cd2a27f8bd237ec4c26%7C0%7C0%7C638438688887681305%7CUnknown%7CTWFpbGZsb3d8eyJWIjoiMC4wLjAwMDAiLCJQIjoiV2luMzIiLCJBTiI6Ik1haWwiLCJXVCI6Mn0%3D%7C0%7C%7C%7C&sdata=NTDusaDs57ZjteTb1xnkiTI5n%2Fkyynujh4HSl7158JI%3D&reserved=0

For more detailed guidance on safely disclosing information, read the latest advice from the ICO:
https://eur01.safelinks.protection.outlook.com/?url=https%3A%2F%2Fwww.whatdotheyknow.com%2Fhelp%2Fico-guidance-for-authorities&data=05%7C02%7CMHRACustomerServices%40mhra.gov.uk%7C4335977aea9541c08dc608dc309adaa5%7Ce527ea5c62584cd2a27f8bd237ec4c26%7C0%7C0%7C638438688887689237%7CUnknown%7CTWFpbGZsb3d8eyJWIjoiMC4wLjAwMDAiLCJQIjoiV2luMzIiLCJBTiI6Ik1haWwiLCJXVCI6Mn0%3D%7C0%7C%7C%7C&sdata=nkN06Cd5bXGyZNIrFWGNf9GvaOD2eJL5JfBf%2FPmZ2Kg%3D&reserved=0
https://eur01.safelinks.protection.outlook.com/?url=https%3A%2F%2Fwww.whatdotheyknow.com%2Fhelp%2Fico-anonymisation-code&data=05%7C02%7CMHRACustomerServices%40mhra.gov.uk%7C4335977aea9541c08dc608dc309adaa5%7Ce527ea5c62584cd2a27f8bd237ec4c26%7C0%7C0%7C638438688887694664%7CUnknown%7CTWFpbGZsb3d8eyJWIjoiMC4wLjAwMDAiLCJQIjoiV2luMzIiLCJBTiI6Ik1haWwiLCJXVCI6Mn0%3D%7C0%7C%7C%7C&sdata=1bPWe%2BG21jNDm2cd%2F8VBkyinzLIcGaj5vjghDmXyy84%3D&reserved=0

Please note that in some cases publication of requests and responses will be delayed.

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