FOI 23/972 - RE: FOI request regarding subject 10841470 male 65, in the Pfizer trial.

MHRA Customer Services <MHRACustomerServices@mhra.gov.uk>
Mon 15/01/2024 10:32
To [redacted]
FOI 23/972

Dear [redacted]

Thank you for your request for information dated, Tuesday December 12, 2023, where you asked:

"I would be grateful if you would send me all of the information you hold on the following Pfizer trial participant. He is the placebo group participant who died on 11.1.2021 after having one dose of Moderna COVID-19 vaccine on 23.12.2020, via his employer.
Please include any tables that his death is recorded in. His death was one of the 38 deaths that occurred between dose 1 and the data cutoff of 13.3.2021 and one of the 29 deaths that occurred during the blinded, placebo-controlled part of the study, so please include any tables relating to these deaths.

Participant……10841470 male 65

Study sponsor……BioNTech
Study conducted by……Pfizer
Study intervention number…..PF07302048
Study intervention name……..RNA-Based COVID-19 Vaccine Protocol number……C4591001
Phase……1/2/3
Short title:
A Phase 1/2/3 Study to Evaluate the Safety, Tolerability and Efficacy of RNA Vaccine Candidates Against COVID-19 in Healthy Individuals."

Our response:
We wish to inform you that we want to be as open as possible in answering requests or information. We can confirm that MHRA does hold some information within scope of your request. However, your request is very broad primarily due to the terminology used 'all information' … about a specific trial participant. After preliminary searches we have established that gathering all the information we hold on this participant, as per the requirements of the FOIA, would exceed the limits under Section 12 of the FOIA. We have reached this conclusion because:

- The term 'all' would require us to conduct an expansive search through the clinical study report, associated annexes, possibly assessment reports, and also any other material where this participant may be cross-referred to.
- Two members staff have spent significant amounts of time locating information in preliminary searches.
- While the participants death will be recorded in tables in the clinical study report this will be not be linked with the subject number—which in this document will appear on a separate page. Therefore, the cause/s of death and other details would need to be manually cross-referenced to other relevant tables in the clinical study report.
- Clinical trial information has been submitted in tranches throughout the lifecycle of the vaccine.

Section 12(1) of the FOIA allows MHRA to refuse a request for information if we estimate that the cost of complying with the request would exceed the appropriate fees limit for determining whether

we hold the information, and in locating, retrieving and extracting the information. Whilst we have located some of information within scope of your request, it has become clear that the cost limit would be exceeded by a complete search as set out in section 12(1) of the FOIA and we have therefore ceased any further searches. Section 16 of the Freedom of Information Act requires MHRA to provide advice and assistance to the requestor, and this is provided below.

Advice and assistance
If you wish to submit a narrowed request, we would suggest requesting the participant's narrative of death which in the adjacent pages is accompanied by tables of the participants biometric information. However, we would like to advise that FOI is a disclosure to the world and on receipt of a narrowed request, we will need to consider whether any exemptions under the FOI apply - we'd therefore like to make you aware that health information relating to deceased individuals may be covered by section 41 (information provided in confidence).

If you wish, it may be an option for you to approach the Marketing Authorisation Holder (MAH) with your enquiry directly: Contact Information for Healthcare Professionals | Pfizer Medical Information - UK

We trust that you will find our response acceptable. However, if you disagree with how we have interpreted the Freedom of Information Act 2000 in answering your request, you can ask us to review our actions and decisions by writing to: info@mhra.gov.uk, and requesting an internal review.

Please note that your internal review request must be in a recordable format (email, letter, audio tape etc.), and that you have 40 working days upon receipt of this letter to ask for a review. We aim to provide a full response to your review request within 20 working days of its receipt. Please quote the reference number above in any future communications.

If you are not content 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 online via an electronic form: https://ico.org.uk/make-a-complaint/foi-and-eir-complaints/foi-and-eir-complaints/

Or in writing to:
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: Tuesday, December 12, 2023 1:36 PM
To: MHRA Customer Services <MHRACustomerServices@mhra.gov.uk>
Subject: FOI request regarding subject 10841470 male 65, in the Pfizer trial.

[redacted]

Dear Sir or Madam,

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Many thanks for your help
Yours faithfully
[redacted]