From: Dr [redacted]
Sent: 05 July 2021 10:37
To: MHRA Customer Services <MHRACustomerServices@mhra.gov.uk>
Subject: Re: FOI 21/632 CSC 53240 Freedom of Information Request

Dear MHRA,

Thank you for your response to my simple request for documentation which falls short of the required standard for response to a freedom of information request.

I will quote the contentious statements below which are either inaccurate or failed to answer the question sent. I would be grateful if you could address these as requested in the original FOI request and in response to false statements made.

(1) We can confirm that the clinical trials were performed in accordance with Good Clinical Practice (GCP) and that the sponsor had access to the raw data (patient-level anonymised data or equivalent patient-level data).
This was not the answer to the question provided which was a request for documents that showed that the MHRA requested the raw (patient level) data from the sponsor. **Please reply as requested "no request for raw data from the sponsor was made"**

(2) We can confirm that the MHRA is permitted access to any pertinent raw data (patient-level anonymised data or equivalent patient-level data). Raw data may be held in different formats and are usually supplied to the MHRA electronically, but on rare occasions this could be via hard copy.
This was not an answer to the question provided which was whether the MHRA holds the patient data. The MHRA clearly does not have a copy of the patient data. **Please reply "the MHRA does not have a copy of the patient level data"**

(3) We can confirm that the clinical trial data were analysed as they would be for any marketing authorisation application for a new medicinal product.
This was not an answer to the question which was to show that the MHRA conducted a process to analyse the patient level data. Please reply **"the MHRA did not review the patient level data from Pfizer"**

(4) To provide a fuller answer to this question exceeds the FOI time limit of 24 working hours and so would be exempt under Section 12 (Unnecessary use of resources) of the FOI Act. Section 12 of the Act allows public authorities to refuse requests
This is clearly not true as you have confirmed that there was no request made to analyse the patient-level data by the MHRA. Please either confirm your claim that there is a volume of documents showing that the MHRA analysed the patient-level data from Pfizer (that they do not hold) in contravention to the above points, or rephrase your answer to confirm that the MHRA has not analysed the patient-level data.

(5) We hope that as these vaccines have now been approved by many regulatory agencies around the world this should reassure you that a thorough assessment of the clinical trial data has been performed.
This is not a true statement as there is no approval to my knowledge in any country in the world that has an internationally recognised drug regulator. All approvals have been provisional because the phase 3 studies involved are still ongoing. Please clarify this statement with correct usage of "approved". (The current conditional EMA status is here)

(6) In the CHM minutes you have referenced, there is a statement that PHE have commissioned an independent analysis of the raw (patient-level) data of the Pfizer Comirnaty study. Assuming this to be true please confirm the above statements as requested. If this is not true please clarify who you believe has investigated or verified the raw (patient-level) data from Pfizer.

Thank you for your help in answering these document requests truthfully to the best of your ability and for clarifying the concerns raised by your initial response.

[redacted]