FOI 22/1080

MHRA RESPONSE
21 April 2023

Dear

Thank you for your request under the Freedom of Information Act, please accept our apologies for the long delay in response.

We have replicated the questions from your email in italics and listed our responses beneath each of these.

1. ***Study Design Concept (11 Dec 2020), Protocol (28 Jan 2021), and first interim report Q3 2021. Please provide copies of these documents as well as confirmation that the study began on 8 June 2021.***

A: Please find the requested documents attached. This study started on 01 March 2021.

2. ***"Detailed analyses on breakthrough cases and validated data on correlates of protection: 31 January 2022" . I would be grateful if you could point me to, or supply, these analyses or provide an explanation for any delay.***

A. These data have been submitted in a draft literature/journal manuscript, which is expected to be published by an online journal / publisher. We are therefore, exempting these analyses under Section 22 (Information intended for future publication and research information) of the FOI Act.

On principal the usual process which follows creation of a draft manuscript, is onward publication in the scientific literature and we have interpreted this to be a clear intent of publication in due course, thus satisfying one of the main criteria of Section 22. A consideration of the public interest is also required under Section 22; the primary factor considered in favour of release was: access to information and data that could help inform on healthcare choices i.e. COVID-19 vaccination, however the impact of this factor was considered to be limited because this particular COVID-19 vaccine is currently only available to a very small pool of patients—those in which mRNA vaccines are contraindicated. Given that we fully expect these data to be published in due course we see no overall advantage to the public interest by providing a draft manuscript at this juncture.

3. ***I requested the publication plans for the final Clinical Study Reports (due date 30 September 2022) on the trial subjects after they had been followed for 1 year post second dose for the randomised, controlled,***

COV001, COV002, COV003 and COV005. You informed me this date had slipped to 31 December 2022. Why has this date slipped?

A. Due to the complexities within clinical development programmes, delays can often occur, consequently extensions to due dates by which to meet conditions can be necessary; such extensions are agreed with MHRA assessment teams.

4. ***Thank you for providing an undated, revised list of conditions, you stated that this is due to be published online shortly. Where have you published these new conditions?***

A. The revised list of conditions is available on Conditions of Authorisation for Vaxzevria - GOV.UK (www.gov.uk). In terms of the new updates these will also be published on this site, most likely, at the next renewal.

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