Medicines & Healthcare products Regulatory Agency

MHRA Central Freedom of Information Team
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MHRA Website

[redacted]

Our Ref: **FOI2025/01203**

15 December 2025

Dear [redacted]

Thank you for your Freedom of Information (FOI) request received on 14 November 2025. You wrote:

> *I am contacting you to see if you can help me to establish the publication date of three phase III clinical trial protocols on the EudraCT public website following their approval by MHRA acting as the National Competent Authority (NCA) for GB.*
>
> *In particular, the three trials in question have the Sponsor Protocol Number: C13006, C13007 and C13008. The product name is VEDOLIZUMAB.*
>
> *The links to the respective trials are as follows:*
>
> *https://www.clinicaltrialsregister.eu/ctr-search/trial/2008-002784-14/GB*
> *https://www.clinicaltrialsregister.eu/ctr-search/trial/2008-002782-32/GB*
> *https://www.clinicaltrialsregister.eu/ctr-search/trial/2008-002783-33/GB*
>
> *I note that each trial reports: a date on which this record was first entered in the EudraCT database; a date of the NCA decision; a date of ethics committee opinion; and a date of the global end of the trial. However, it is not clear to me which (if any) of these dates represents the date on which the clinical trial protocols would have been accessible to view by a member of the public.*
>
> *I spoke with the European Medicines Agency directly, and they explained to me that the "Publication of an EudraCT Clinical Trial Application (CTA) related information was done automatically in our EU CTR when the National Competent Authority updates the information regarding their approval and approval date, as well as of the Ethics Committee opinion and opinion date, on EudraCT database".*
>
> *Thus, it appears that it is possible that MHRA (as the NCA for GB) might know when the protocols were made publicly available on EudraCT public website (or your own national databases).*
>
> *Is it possible to confirm on which date each of the above protocols was publicly available via the EudraCT database, or otherwise made publicly available?*

**MHRA Response**

Please note that because the EU clinical trial register is automatically updated, we hold no dates of when these would have been updated with the specific protocols stated in your request. We do hold the dates of regulator approval and approval by the relevant ethics committee, however, this information is already available to you through the EU clinical trials register links you have provided in your request.

If you have any queries about this letter, please contact us quoting the reference number above.

Yours sincerely,

MHRA Central Freedom of Information Team
Medicines & Healthcare products Regulatory Agency

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**Your right to complain under the Freedom of Information Act**

If you are not happy with this response you may request an internal review by e-mailing foi.request@mhra.gov.uk or by writing to: MHRA Central Freedom of Information Team, 10 South, Colonnade, Canary Wharf, London, E14 4PU
Any request for an internal review must be received by us within 40 working days of the date of this letter. Please note we are not obliged to provide a review if it is requested after more than 40 working days.

If you are not content with the outcome of the internal review you may apply directly to the Information Commissioner's Office for a decision. Generally, the Commissioner cannot make a decision unless you have exhausted our own complaints procedure. The Information Commissioner can be contacted at: The Information Commissioner's Office, Wycliffe House, Water Lane, Wilmslow, Cheshire SK9 5AF.
Website: ICO FOI and EIR complaints or telephone 0303 123 1113.

**Re-use of our information**