



Medicines & Healthcare products
Regulatory Agency

MHRA Central Freedom of
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[MHRA Website](#)

Our Ref: **FOI2026/00327**

22 May 2026

Dear [REDACTED]

Thank you for your Freedom of Information (FoI) request received on 25 July. You wrote:

Hi,

I would like to request the following information under the Freedom of Information Act.

1. How many times has the MHRA previously reassessed approved protocols since 1st January 2021?
2. With reference to your response to question 1, how many times has the MHRA reassessed approved protocols within 6 months of initial approval?
3. With reference to questions 1 and 2, how often was this on the basis of "representations" rather than new emerging scientific evidence?
4. With reference to this letter recently published here:
<https://assets.publishing.service.gov.uk/media/6998b06d047739fe61889efb/Sponsor-letter110226.pdf>, could you clarify what is meant by the term "representations"?
5. With reference to the same letter, could you clarify which individuals or organisations made these representations?

MHRA Response

We can confirm we hold information requested, but it is exempt from disclosure under section 12(1) of the Freedom of Information Act.

This is because we estimate the cost of searching for and identifying the requested information would exceed the cost limit of £600 specified in the Freedom of Information and Data Protection (Appropriate Limit and Fees) Regulations 2004. This represents the estimated cost of at least one person spending 3½ working days (equivalent to 24 staff-hours) in determining whether the Agency holds the information, and locating, retrieving and extracting it.

The information you have requested in question 1, 2 and 3 will require a full review of the case files for all Clinical Trial applications received since 01 January 2021 as our database does not have a field we can search against which would show where we have "reassessed approved protocols". Since 01 January 2021 the Agency has received 5007 clinical trial applications. We have undertaken a sampling exercise, and our estimate is that it would take approximately 12 minutes to review each of these cases, giving a total of 60,084 minutes

(1001 hours) to fulfil your request. This far exceeds the 24 hours specified in the Act and is why we consider that Section 12 (1) is engaged.

Under Section 16 of the Freedom of Information Act, we have a duty to assist you in refining your request so that it falls within the applicable cost limit. However, we are unable to suggest a way to bring Question 4 within the statutory cost threshold. As such, we recommend that you focus your request on the remaining questions submitted.

Please note that our consideration has been limited to Question 4 and 5 at this stage. Once it was evident that responding to this part alone would exceed the cost limit, we applied Section 12 to the request as a whole and did not proceed further. Consequently, we have not assessed whether any additional cost limits or exemptions may apply to the other parts of your request should they be resubmitted.

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

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 Contact Information](#) or telephone 0303 123 1113.

Re-use of our information

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<https://www.nationalarchives.gov.uk/doc/open-government-licence/version/3/>