



Medicines & Healthcare products  
Regulatory Agency

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Our Ref: **FOI2026/00419**

18 May 2026

Dear [REDACTED]

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

Before proceeding any further, I should make it quite clear that I do not have any doubts about the integrity of Professor George or anyone else at the MHRA. However, I know that when humans act, they are not necessarily guided by conscious rational reasoning; hence the occurrence of the current and previous recusals to which the CEO refers. If humans were always consciously rational, life would be a lot simpler – and a lot less interesting!

Given all that it seems obvious to me to ask "what changed", between the original approval and the discovery of the "new concerns".

At one point, the MHRA agreed the KCL Pathways trial in the form in which it was recruiting. Then at a later point, the MHRA felt the need to question some aspect of this. Between those two points something occurred. Either the original team who gave approval thought further and identified new concerns, or the team changed by the arrival of Professor George or possibly others (I don't know your rate of staff turnover).

Now, I cannot see that the new contact with KCL arose in a vacuum, and that one MHRA person took it upon themselves to make that contact. There must have been some prior discussion at the MHRA, and on an issue as important as a clinical trial, there must have been a note made of the participants in that discussion and what was said in the process in which the "new concerns" arose.

Question 3. You ask for some clarification about this. I was, and am, trying to find the details of what occurred before KCL was newly contacted about the PATHWAYS trial.

Question 3: So, if I may now modify my question 3: please send me details of who discussed what with whom in the process that led to KCL being contacted about the Pathways Trial after the trial was initially approved. I assume that these details may be in the form of emails, memoranda, minutes (informal or formal) or anything other form that has not occurred to me.

Question 4: I would also like to clarify my question 4.

The CEO says in the internal email "scientific dialogue that is going on...is not so unusual. It is not uncommon for complex clinical trials to go through stages of iteration." What the email does not say is how common it is for this dialogue and iteration to occur after the trial was approved.

Therefore, I am interested in other such cases of dialogue after the trial was approved.

I will redraft my Q4:

Question 4 Please may I have the following details for the last three trials in which the MHRA intervened after the trial was approved.

a) the name of the trial and the nature of the intervention, bearing in mind that for the

PATHWAYS trial we were told that the “MHRA has now raised new concerns”,  
b) how long after each trial was approved did the intervention take place, and  
c) what press releases were published about the intervention.

Question 5. My original Question 5 has now been subsumed into Qn 4.

I have a final comment on the internal email sent by the CEO. In it the CEO says “Jacob is an ethical man...”, rather than an “ethical person”

As I said at the start I have no doubts about the integrity of anyone at the MHRA. But I am quite unable to see what Prof George’s gender has to do with his integrity or character or role. The use of the phrase ‘an ethical man’ shows how naturally our culture still weaves the irrelevance of gender into our linguistic framework, so long after most of us have given up on the ‘chairman/woman’ usage, and more than a century, I believe, after ‘doctress’ was proposed and abandoned.

## **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 4 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 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](mailto: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.

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