



Medicines & Healthcare products Regulatory Agency

MHRA Central Freedom of
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[MHRA Website](https://www.mhra.gov.uk)

Our Ref: **FOI2025/00324**

30 April 2025

Dear [REDACTED]

Thank you for your Freedom of Information (Fol) request received on 31 March. You wrote:

- 1. Before the MHRA outsourced the decisions about whether a scientific experiment on humans with drugs/substances/IMPs is a clinical trial (CTIMP) or not a clinical trial (non-CTIMP) to universities and other bodies, the MHRA used to make these decisions. For 30 of the most recent applications, could you please release a summary of the proposed study (e.g. abstract) and your decision on whether it is a CTIMP or a non-CTIMP, before the MHRA outsourced the decision-making process.*
- 2. How do you monitor the universities that make these decisions and ensure that they are correctly categorising studies as clinical trials, and non-CTIMPs? I'm especially interested to know how you ensure that universities are not unnecessarily, *over*-categorising studies as CTIMPs.*
- 3. Would this hypothetical experiment be a CTIMP or a non-CTIMP: a well known, GMP-manufactured drug is given at a safe dose in a one-off dose, double-blind, placebo-controlled RCT experiment to patients with a mental health condition to study the effects of this drug on an experimental behavioural measure (i.e. not clinical or safety outcome) in the lab.*
- 4. Should the university regulatory bodies who make these decisions now be transparent and publish (1) applications and results; (2) the minutes/ways they make the decisions about specific studies.*

MHRA Response

Under Section 14(2) of the Fol Act, public authorities are not obliged to comply with a repeat request.

Where a public authority (in this case MHRA) has previously responded to a request for information which was made by any person, it is not obliged to comply with a subsequent identical or substantially similar request from that person unless a reasonable interval has elapsed between compliance with the previous request and the making of the current request.

In this case, the Agency has already responded to a similar request from you, FOI2025/00319 on 30 April 2025 and so, under section 14(2) of the FoI Act will not be responding further.

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 FOI and EIR complaints](#) or telephone 0303 123 1113.

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