



Medicines & Healthcare products Regulatory Agency

MHRA Central Freedom of
Information Team
10 South Colonnade
Canary Wharf
London
E14 4PU

foi.request@mhra.gov.uk

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

Our Ref: **FOI2025/00319**

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 you received before the change in policy, could you please release a summary of the proposed study (e.g. abstract) and your decision on whether it was a CTIMP or a non-CTIMP.*
- 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. What requirements do you put on universities who now make these CTIMP/non-CTIMP decisions about their transparency of decision-making to researchers? Do you require them to publish previous decisions and how they came to them, if they are asked?*

MHRA Response

We confirm that we hold some of the information you have requested and provide it below. We are not able to provide information regarding Q1 and outline our reasons below.

- 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 you received before the change in policy, could you please release a summary of the proposed study (e.g. abstract) and your decision on whether it was a CTIMP or a non-CTIMP.**

Section 12(4) of the FoI Act and also the Freedom of Information and Data Protection (Appropriate Limit and Fees) Regulations 2004 provides that requests can be aggregated for the purpose of estimating whether the cost limit applies, providing they relate to any extent to the same or similar information and the requests are received from the same individual or different persons who appear to the public authority to be acting in concert or in pursuance of a campaign.

We estimate that the cost of complying with your aggregated requests would exceed the appropriate limit for central Government, set by regulations at £600. 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.

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.

As part of the MHRA's routine inspections, the Sponsors list of Clinical Trials may be questioned and investigated as needed.

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.

Based on the limited information provided, the MHRA are not able to provide confirmation. As of October 2021, the MHRA has stopped the SCOPE advice process, and the enquirer is advised to refer to the website algorithm located here for further information:

<https://www.gov.uk/guidance/clinical-trials-for-medicines-apply-for-authorisation-in-the-uk#when-a-clinical-trial-authorisation-cta-is-needed>

4. What requirements do you put on universities who now make these CTIMP/non-CTIMP decisions about their transparency of decision-making to researchers? Do you require them to publish previous decisions and how they came to them, if they are asked?

The MHRA does not require the Sponsors to publish their decision-making outcome on whether a Clinical Trial is considered a CTIMP or not.

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