UK Research and Innovation

[redacted]

20 December 2024

Dear [redacted]

Freedom of Information request: FOI2024/01201

Thank you for your Freedom of Information request received on the 2 December in which you requested the following:

Your request:

Under the FOI Act, I would like to ask some questions about oncology clinical trial approvals and excess costs.

1. *Please provide a copy of your manual or standard approach for approving clinical trials in oncology. (For example, how they are scored and evaluated to secure funding).*

2. *Please provide a copy of the standard process for approving clinical trials in oncology that exceed costs above £2 million. (Including whether there is ministerial involvement, or whether they have the power to overrule decisions.)*

3. *Please provide me a copy of all correspondence you have received relating to excessive oncology clinical trial costs and getting them approved in the last 12 months.*

4. *Please could you tell me how many clinical trials in oncology with excessive costs you have approved in the 12 months up to this request, versus the 5 years before it. And how many have not been approved. (e.g. 2024 = 20 yes, 10 no| 2023 = 15 yes, 5 no... etc.)*

Our response

I can confirm that UK Research and Innovation (UKRI) does not hold information relevant to your request.

MRC has no role in approving clinical trials; this is the role of the Clinical Trials Regulator, the Medicines and Healthcare products Regulatory Agency[1] (MHRA). MRC reviews applications for research funding for clinical trials through the developmental pathway funding scheme (DPFS), where research funding is provided by MRC the necessary regulatory approval from the MHRA is then required before the study can start.

We have interpreted the reference to excessive costs as Excess Treatment Costs (ETC), and we would recommend contacting the National Institute for Health and Care Research[2][3] (NIHR) for further information. Briefly, ETC should be identified as part of the research funding application to MRC, and, if the research study is successful in receiving MRC funding, ETC payments for the study are paid for by the NHS. There are caps in place relating to the threshold of ETC that are not automatically paid by the NHS; the high cost threshold is £1 million per study and/or an average per patient ETC of £20,000. MRC would only be contacted if we had agreed to fund a trial in which the NHS subsequently refused to cover the ETC. This has not occurred since the high cost threshold was established in 2018, therefore, we do not hold any relevant correspondence in scope of question 3.

[1] https://www.gov.uk/government/organisations/medicines-and-healthcare-products-regulatory-agency
[2] https://www.nihr.ac.uk/research-funding/responsibilities-after-funding/excess-treatment-costs
[3] https://www.nihr.ac.uk/excess-treatment-costs-etc-process-chart-supporting-information

Regarding question 4, as stated above, MRC can fund clinical trials but has no role in approving clinical trials. Most of the clinical trials that the MRC funds are likely to have ETC associated with them. However, the presence or absence of ETC would not be a reason for MRC to reject a funding application for a clinical trial. Both funded and unfunded trials may contain ETCs, as every cancer patient put on a trial would be under NHS clinical care. We cannot provide any data that would answer this question, given that ETC are not a determining factor in the MRC's decision-making process and MRC has no role in approving clinical trials.

If you have any queries regarding our response please do let us know. If you are dissatisfied with the handling of your request, you have the right to ask for an internal review, explaining which elements of this decision you disagree with and why. Internal review requests should be submitted within 40 working days of the date of our response and should be addressed to:

Head of Information Governance
Email: foi@ukri.org

Please quote the reference number above in any future communications.

If you are still not content with the outcome of the internal review, you may apply to refer the matter to the Information Commissioner for a decision. Generally, the ICO cannot make a decision unless you have exhausted the review procedure provided by UKRI. The Information Commissioner can be contacted at: www.ico.org.uk.

If you wish to raise a complaint regarding the service you have received or the conduct of any UKRI staff in relation to your request, please see UKRI's complaints procedure[4].

Yours sincerely,

[redacted]
Information Governance
Information Rights Team
UK Research and Innovation
foi@ukri.org | dataprotection@ukri.org

[4] https://www.ukri.org/who-we-are/contact-us/make-a-complaint/#skipnav-target