



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: **FOI2026/00482**

02 June 2026

Dear [REDACTED]

Thank you for your Freedom of Information (Fol) request received on 01 May. You wrote:

We request copies of, or summaries of, inspection findings from GCP inspections conducted by MHRA between 01/01/2018 and 30/03/2026, where the clinical trial documentation (including protocol or title) contains the term 'basket trial'.

We are happy to receive this information in summary form where full reports cannot be disclosed.

If this request is likely to exceed the cost limit, we would be grateful for advice on how it could be refined.

MHRA Response

We can confirm we hold the 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.

Under Section 12(1) of the Fol Act the Agency is not therefore obliged to comply with your request and we will not be processing it further.

In order to identify any inspection findings where the trial inspected was a 'basket trial', we would have to locate, open and manually review the content of over 350 inspection reports. It is estimated that it would take approximately 5 minutes per report and so would exceed the cost limit. Only the study title is included in the inspection report, so if 'basket trial' wasn't specified in the study title, we would need to undertake further checks of potential basket studies to determine if they are in scope of the request.

Under Section 16 of the Fol Act we should help you narrow your request so that it may fall beneath the cost limit.

To help you make a refined request which may fall within the FOI cost limit, we have searched our clinical trials database for all 'basket' clinical trials that have been approved by MHRA since 2020. We cross checked the names of these studies against our inspection reports and located one inspection where a basket trial was included.

The inspection was of a non-commercial organisation and took place in 2024. We have identified two findings which relate specifically to the basket trial.

If you wish to request the extracts from the inspection report that relate to the basket trial, please submit a refined request for this information.

We would be happy to consider any revised request you may wish to make based on the information above.

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

The MHRA information supplied in response to your request is subject to Crown copyright. Information created by the MHRA which is disclosed under the Freedom of Information Act is made available for re-use under the Open Government Licence (OGL) v3.0, except where this is otherwise stated. There are some restrictions on re-use under the OGL and these can be viewed here:

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