



Medicines & Healthcare products  
Regulatory Agency

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[MHRA Website](#)

Our Ref: **FOI2024/00469**

29 August 2024

Dear [REDACTED]

Thank you for your Freedom of Information (Fol) request received on 14 August. You wrote:

***“This mail is enquiring about availability of clinical investigation and observations online which is available publicly though FOIA. Any particular website to find the company particular investigation reports.”***

### MHRA Response

Following discussions with relevant subject matter experts, we have established that the information you requested is not held in the form that it has been requested i.e. in a publicly available repository online.

However, we do hold clinical investigation reports in our internal records. If report/s were requested through FOI it would be most likely that the reports would be exempt under Section 43(2) of the FOIA. However, each request would be handled based on the particulars of the specific request.

Our responses to previous FOI requests received by MHRA since ~2019 are available [online](#). However, it is not currently possible to search this archive by key terms and we have not been able to locate any past clinical investigation report releases.

#### *Advice and assistance*

Because your request was very brief and so to help eliminate any potential confusion of terms. Clinical investigation reports are the final reports after clinical investigations have been completed, but these are not routinely released. We would also like to clarify that we are not aware of what the following relates to 'clinical investigation and observations online'.

We wish to make you aware that MHRA also holds clinical study reports (CSRs), and good clinical practice (GCP) inspection reports. MHRA also holds clinical trial applications (CTA) for clinical trials based in the UK, however, details of clinical trials based in the UK and conducted abroad are populated to publicly available registries such as the [ISRCTN Registry](#).

If you wish to make a new request, please be as specific as possible about the document or document/s requested.

Please also bear in mind the cost limit for processing FOI requests, if we estimate the cost of checking if we hold 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 request would be refused and where possible a refined request suggested to you.

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

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

### **Re-use of our information**

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