



Medicines & Healthcare products  
Regulatory Agency

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[gov.uk/mhra](http://gov.uk/mhra)

[REDACTED]

23 May 2023

**FOI 23/271**

Dear [REDACTED]

Thank you for your information request, dated 11 April 2023, where you asked:

‘Can you confirm how long it should take MHRA to approve a CTA application?’

The standard time for the initial response is 30 days from the date of receipt of a valid request for authorisation of a clinical trial where the MHRA will have to give written notice to the sponsor.

<https://www.legislation.gov.uk/uksi/2004/1031/regulation/18/made>

<https://www.legislation.gov.uk/uksi/2004/1031/regulation/19/made>

The MHRA now publish performance data for clinical trial applications which is updated by the 15<sup>th</sup> day of every month. This link is provided below:

<https://www.gov.uk/government/publications/mhra-performance-data-for-assessment-of-clinical-trials-and-established-medicines>

‘Are there currently unusual problems or delays at MHRA in approving CTA applications?’

A combination of factors is resulting in queued cases in some of our services. These include increased demand for the services, low-quality applications received into services and reduced capacity while we increase our resources.

Therefore, customers may currently experience extended timelines when submitting initial clinical trial applications or when requesting amendments.

Our staffing levels have now returned to normal, and most vacancies have been filled, including key leadership posts. Four new assessors have joined the MHRA’s Clinical Trials Unit over the last 12 months with 3 more due to start between May – July; their training is being prioritised. Moreover, the MHRA is supplementing new assessor capacity with an additional fixed term resource of appropriately experienced and qualified specialists to support the training and supervision of new staff.

Since July 28, 2022 'How many applications have been made to MHRA for CTA approval?'  
Between July 28, 2022 and April 26, 2023 - A total of 723 applications were received; 651 of which were valid applications for assessment.

'How many have been accepted?'

Between July 28, 2022 and April 26, 2023 – 252 applications were approved

'How many have been rejected?'

Between July 28, 2022 and April 26, 2023 – 14 applications were rejected

'How many are in limbo awaiting further information?'

Between July 28, 2022 and April 26, 2023 – 346 applications were pending, where the MHRA had not issued a final decision.

I am pleased to provide you with all the information requested.

These documents are provided with any personal information redacted as well as any information considered commercially sensitive, under section 40 and 43 of the Freedom of Information Act.

The Freedom of Information Act only entitles you access to information – the information supplied is subject to Crown copyright, and there are some restrictions on its re-use. For information on the reproduction or re-use of MHRA information, please visit <https://www.gov.uk/government/publications/reproduce-or-re-use-mhra-information/reproduce-or-re-use-mhra-information>.

If you disagree with how we have interpreted the Freedom of Information Act 2000 with regards to your request, you can ask for the decision to be reviewed. The review will be carried out by a senior member of the Agency who was not involved with the original decision.

If you are dissatisfied with the handling of your request, you have the right to ask for an internal review. Internal review requests should be submitted within two months of the date you receive this response and addressed to: [info@mhra.gov.uk](mailto:info@mhra.gov.uk)

Please remember to quote the reference number above in any future communications.

If you were to remain dissatisfied with the outcome of the internal review, you would have the right to apply directly to the Information Commissioner for a decision. Please bear in mind that the Information Commissioner will not normally review our handling of your request unless you have first contacted us to conduct an internal review. The Information Commissioner can be contacted at:

Information Commissioner's Office  
Wycliffe House  
Water Lane  
Wilmslow  
Cheshire  
SK9 5AF

Yours sincerely,

Clinical Investigations and Trials  
(Science, Research and Innovation Group)