

FOI 23/343

Dear

Thank you for your information request, dated 14th May 2023, we apologise for the delay in this response. You asked for:

- *What is the total number of clinical trial applications that have not yet been reviewed (Phase 1-4).*
- *What is the longest time from application rec'd to being reviewed (Phase 1-4).*
- *What is the current average turnaround time of clinical trials (Phase 1-4).*

We are pleased to provide you with the response, see below:

The MHRA is addressing delays and backlogs in clinical trial applications as our highest priority.

We have focused considerable resources within the agency to deliver accelerated improvements to timescales for clinical trial assessments and eliminate backlogs. As a result the backlog is reducing significantly, at pace, and the data provided in response to your enquiry is only reflective of a specific point.

At the time of response, there were 311 clinical trials applications pending assessment in our system.

The longest time taken to review an application from 01/01/2023 was 237 days.

Regarding your third question, we would like you to refer to MHRA performance data which is published monthly. This includes data on average times for clinical trial responses and was updated on August 15th.

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

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
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

MHRA Customer Experience Centre

Communications and engagement team

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