



Medicines & Healthcare products  
Regulatory Agency

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United Kingdom  
[gov.uk/mhra](https://www.gov.uk/mhra)

[REDACTED]  
[REDACTED]

20 May 2024

MHRA reference: FOI2024/00098

Dear [REDACTED],

Thank you for your information request, which we received on 27 April. You asked for:

*Subject: Overhaul of Trial Regulations*

*I refer to the above subject and to correspondence to date as summarised in Annex 1 below.*

*As over a year has elapsed since your press release - dated 21 March 2023 - I would appreciate a progress update. Is a copy of the completed RIA now available?*

We have dealt with your request under the Freedom of Information Act 2000 (FOIA).

We confirm that we hold the information you have asked for, and we are disclosing this information in full.

An update is provided below.

Since publishing the government response on clinical trials, we have been drafting the legislation to implement the new proposals. Alongside drafting the legislation we are analysing the impacts, this assessment is still in draft so not yet ready to share. We will share the final version when this happens.



## Medicines & Healthcare products Regulatory Agency

We hope this information is useful for you.

This concludes our response to your request.

If you have a query about this response, please contact us at

Please remember to quote the reference number at the top of this letter in any future communications. Details of your appeal rights are below.

Yours sincerely,

Partnership Group

**Medicines and Healthcare products Regulatory Agency**

### **Appeal rights**

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

If you remain dissatisfied with the outcome of the internal review, you 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 a request unless the requester has first asked us to conduct an internal review.

The Information Commissioner can be contacted through their online webform at: <https://ico.org.uk/make-a-complaint/foi-and-eir-complaints/foi-and-eir-complaints/>

Or in writing to: Information Commissioner's Office, Wycliffe House, Water Lane, Wilmslow, Cheshire, SK9 5AF

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