FOI 23-215 – Regulatory Impact Assessment for clinical trial regulation

REQUEST
22 March 2023

“MHRA to streamline clinical trial approvals in biggest overhaul of trial regulation in 20 years”

I refer to the above subject and attach hereto MHRA Press Release dated 21 March 2023.

I have noted the content and would be grateful if you could arrange to provide me with a copy of the **"Regulatory Impact Assessment [RIA]"** undertaken by MHRA to support the overhaul of trial regulations.

MHRA RESPONSE
1 May 2023

Dear

Thank you for your email.

Drafting of the Impact Assessment is in progress, as we prepare the statutory instrument to implement the clinical trials reforms. The Impact Assessment will be completed before the legislation to is made and we can share a copy once completed. The Impact Assessment will also be made publicly available and published alongside the statutory instrument, when the legislation is laid.

If you disagree with how we have interpreted the Freedom of Information Act 2000 in answering your request, you can ask for an internal review. Please reply to this email, within two months of this reply, specifying that you would like an Internal Review to be carried out.

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
Medicines and Healthcare products Regulatory Agency
10 South Colonnade, Canary Wharf, London E14 4PU
Telephone 020 3080 6000