



Medicines & Healthcare products
Regulatory Agency

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

[REDACTED]

31st January 2024

FOI 24/020

Dear [REDACTED]

Thank you for your information request, dated 04.01.2024, where you asked for:

“Further to my email below, I would like to submit a request under the Freedom of Information Act 2000 for the following document:

The study protocol entitled: Controlled, Double-Blind, Randomized, Dose-ranging Study of once-daily regimen of BAY59-7939 in the Prevention of VTE in Patients Undergoing Effective Total Hip Replacement – the “ODIXaHIP-OD” Study

It is our understanding that this document has already been the subject of an FOI request and that a copy has been provided to the firm ratiopharm GmbH.

Should you require anything further from me please do not hesitate to contact me. Please could you also let me know (roughly) how long this request will take?”

Section 21 – Information accessible by other means: the information you have requested is already in the public domain.

<https://www.gov.uk/government/publications/freedom-of-information-responses-from-the-mhra-week-commencing-7-november-2022/freedom-of-information-request-foi-221025>

https://assets.publishing.service.gov.uk/media/659ea9763308d2000d1fbdbf/FOI_22-1025_PDF_attachment_1_.pdf



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https://assets.publishing.service.gov.uk/media/659ea977e8f5ec000f1f8b26/FOI_22-1025_PDF_attachment_3.pdf

The Act's section 21 exemption states that there is no right of access to information via FOI if it is reasonably available to the applicant by another route.

If you have a query about the information provided, please reply to this email.

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