FOI 22/1208 – OdiXahip – a Phase IIa Dose Escalating Proof of Principle Trial

MHRA RESPONSE
23 January 2023

Dear

Thank you for your information request, dated 19 December 2022, where you asked for

'Pursuant to the Freedom of Information Act 2000, in relation to the clinical trial titled "Oral Direct Factor Xa Inhibitor BAY 59-7939 in the Prevention of VTE in Patients Undergoing Total Hip Replacement. ODiXahip - a Phase IIa Dose Escalating Proof of Principle Trial", which has NCT reference NCT00839826, please provide copies of:

1. **The Investigator's Brochure ('IB');**
2. **The "Informed Consent Document" or "Informed Consent Form" (the 'ICD'/'ICF'); and**
3. **The trial protocol as approved by the MHRA.**

The study start date was December 2002 and the primary completion date was November 2003. The unique protocol ID is 10942. The sponsor was Bayer Healthcare AG.'

I am pleased to provide you with some of the information requested, attached to this email.

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.

I can confirm that we do not hold the information to the other application documentation that you have requested.

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 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,

MHRA Customer Service Centre

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