

Freedom of Information Request

Ref: 22-193

14 April 2022

By Email

Dear Sir/Madam

Thank you for your request for information under the Freedom of Information Act 2000. The Trust's response is as follows:

- We can confirm that we do hold the information you are requesting

Under the Freedom of Information Act 2000, please provide me with all of the following:

1) Details of all parties that have contributed funding to the trust in relation to the Xtandi (Enzalutamide) trial NCT00974311 being conducted at your site/s.

Medivation Inc.

2) A list of all sites within your trust that Xtandi (Enzalutamide) trials have been conducted at.

Bristol Royal Infirmary (BRI)

Bristol Haematology and Oncology Centre (BHOC)

3) Numbers of Xtandi (Enzalutamide) trial participants at each trial location, for the NCT00974311 trial.*

Please note: Where the figures are between 1 and 5, this has been denoted by *. Due to the low numbers, we have considered that there is the potential for individuals to be identified from the information provided, when considered with other information that may also be in the public domain. In our view disclosure of these low figures would breach one of the Data Protection Principles set out in Schedule 1 of the Data Protection Act, namely Principle 1. The Trust therefore finds that the Section 40(2) exemption contained within the Freedom of information Act 2000 is engaged. (Section 40 is the exemption for personal information).

4) Number of staff involved in conducting the trial at each trial location, listing their roles, for the trial, NCT00974311

For both sites, Bristol Royal Infirmary (BRI) and Bristol Haematology and Oncology Centre (BHOC):

Clinical Oncologist and Principal Investigator

Clinical Fellow in Oncology and Sub-Investigator

Research Nurse x 2

5) What costs were incurred by the trust in order to conduct the Xtandi (Enzalutamide) trial, NCT00974311? If a document does not state the total budget or cost of a trial, but lists the actual or expected costs of any aspect of the trial, it would also be subject to this request. If a document states the yearly budget for a clinical trial, that would be pertinent as well. This includes per-patient costs in conducting the trial. The simplest response would be to provide the cost in GBP of either the budget for the trials or the actual outlays, and both if that is possible.*

*This is commercially sensitive information and will not be shared at an organisational level. Section 43 of the FOI Act provides that information is exempt if its disclosure would, or would be likely to prejudice the commercial interests of any person. Therefore we are withholding this information at this time.

6) A breakdown of any funding received from internal and external sources in order to conduct the Xtandi (Enzalutamide) trial, NCT00974311. Please break funding down into i) funding from public (governmental) bodies, ii) private entities, and iii) philanthropies/charitable bodies. Please include the full name of the funding body. Please specify amounts in GBP. (Please provide this as an excel spreadsheet)*

*This is commercially sensitive information and will not be shared at an organisational level. Section 43 of the FOI Act provides that information is exempt if its disclosure would, or would be likely to prejudice the commercial interests of any person. Therefore we are withholding this information at this time.

7) A record of all expenses incurred in conducting the Xtandi (Enzalutamide) trial, NCT00974311.

This may include: unit costs of test, fees to central laboratories, investigator fees, data management costs.*

*This is commercially sensitive information and will not be shared at an organisational level. Section 43 of the FOI Act provides that information is exempt if its disclosure would, or would be likely to prejudice the commercial interests of any person. Therefore we are withholding this information at this time.

This concludes our response. We trust that you find this helpful, but please do not hesitate to contact us directly if we can be of any further assistance.

If, after that, 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 of receipt of the response to your original letter and should be addressed to:

Data Protection Officer
University Hospitals Bristol and Weston NHS Foundation Trust

Trust Headquarters
Marlborough Street
Bristol
BS1 3NU

Please remember to quote the reference number above in any future communications.

If you are not content with the outcome of the internal review, you have the right to apply directly to the Information Commissioner for a decision. The Information Commissioner can be contacted at: Information Commissioner's Office, Wycliffe House, Water Lane, Wilmslow, Cheshire, SK9 5AF

Publication

Please note that this letter and the information included/attached will be published on our website as part of the Trust's Freedom of Information Publication Log. This is because information disclosed in accordance with the Freedom of Information Act is disclosed to the public, not just to the individual making the request. We will remove any personal information (such as your name, email and so on) from any information we make public to protect your personal information.

To view the Freedom of Information Act in full please click [here](#).

Yours sincerely

Freedom of Information Team
University Hospitals Bristol and Weston NHS Foundation Trust