

Freedom of Information Request

Ref: 21-189

27 April 2021

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

1. What steps is your institution currently taking to make the results of these clinical trials public on the European trial registry?

The analysis and publication of the trial results for CoolXenon2 will be done concurrently with a subsequent linked trial. End of Study (all data queries resolved and database lock) is currently scheduled for September 2021 and trial results should be available early 2022. We have confirmation from the MHRA that this approach is acceptable.

2. By when does your institution plan to have made public the results of all due trials on the registry?

At the time of receipt of the FOI request, UHBW had seven sponsored 'due trials' listed in the registry (excluding CoolXenon 2). Of these, four have been published in peer reviewed journals and the results of a further study have recently been posted on EudraCT. For the remaining two studies, we are working closely with the research teams to make the results publicly available and we aim to resolve this by 31st August.

3. What steps has your institution taken to ensure that in future, all clinical trial results will be made public on trial registries within 12 months of trial completion?

Our current process is that we ensure that investigators are aware of their obligations and we have systems in place to review the status of trials monthly and specifically for individual trials on completion via our sponsor study closure checklist.

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:

Director of Corporate Governance
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