

FOI 24/187 - Freedom of Information request - Ethics Committee report for CLCZ696B2228 (A multicenter, randomized, double-blind, parallel group study to assess the safety and tolerability of initiating LCZ696 in heart failure patients)

MHRA Customer Services <MHRACustomerServices@mhra.gov.uk>

Wed 28/02/2024 08:31

To [REDACTED]

FOI 24/187

Dear [REDACTED]

Thank you for your request of 23 February where you have asked.

Please could you provide copies of the correspondence between the sponsor and the Ethics Committee concerning the approval of clinical trial CLCZ696B2228.

Despite searching in various locations I have been unable to find a copies of these correspondence in the public domain.

<https://www.clinicaltrialsregister.eu/ctr-search/trial/2013-001835-33/GB#N>

We have dealt with your request under the Freedom of Information Act (FOIA).

The MHRA are the licensing authority for the UK and does not hold data with regards to the communication or review conducted by Research Ethics Committees (RECs) on Clinical Trials. Therefore, we do not hold the information you've requested.

We can advise that the Health Research Authority (HRA) are responsible for the overview of the RECs across the UK. You may wish to contact them at the following <https://www.hra.nhs.uk/about-us/governance/freedom-information/>

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](mailto: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 Experience Centre**  
Communications and engagement team  
Medicines and Healthcare products Regulatory Agency  
10 South Colonnade, Canary Wharf, London E14 4PU

---

From: [REDACTED]

Sent: Friday, February 23, 2024 4:35 PM

To: MHRA Customer Services <[MHRACustomerServices@mhra.gov.uk](mailto:MHRACustomerServices@mhra.gov.uk)>

Subject: FOI 24/187 Freedom of Information request - Ethics Committee report for CLCZ696B2228 (A multicenter, randomized, double-blind, parallel group study to assess the safety and tolerability of initiating LCZ696 in heart failure patients)

You don't often get email from [REDACTED]

Dear MHRA,

Please could you provide copies of the correspondence between the sponsor and the Ethics Committee concerning the approval of clinical trial CLCZ696B2228.

Despite searching in various locations I have been unable to find a copies of these correspondence in the public domain.

<https://www.clinicaltrialsregister.eu/ctr-search/trial/2013-001835-33/GB#N>

Thank you in advance for your help.

Kind regards,  
[REDACTED]