Medicines & Healthcare products Regulatory Agency

MHRA Central Freedom of Information Team
10 South Colonnade
Canary Wharf
London
E14 4PU

foi.request@mhra.gov.uk.

MHRA Website

[redacted]

Our Ref: **FOI2025/00185**

28 April 2025

Dear [redacted]

Thank you for your Freedom of Information (FoI) request received on 26 February. You wrote:

> *Dear Medicines & Healthcare products Regulatory Agency*
>
> *Pursuant to the Freedom of Information Act 2000, in relation to the clinical trial titled "A Phase 1/2a Dose Escalation and Cohort Expansion Study of the Safety, Tolerability, and Efficacy of Anti-LAG-3 Monoclonal Antibody (BMS-986016) Administered Alone and in Combination with Anti-PD-1 Monoclonal Antibody (Nivolumab, BMS-936558) in Advanced Solid Tumors", which has the EudraCT number 2014-002605-38, please provide copies of:*
>
> 1. *A copy of Revised Protocol 7 (dated 20 December 2016).*
> 2. *A copy of Revised Protocol 8 (dated 31 July 2017).*
> 3. *A copy of the Investigator's Brochure.*
> 4. *A copy of the patient informed consent forms.*
> 5. *Copies of any minutes or decisions relating to the approval of the trial and/or amendments to the trial protocol.*
>
> *The MHRA approved the protocol on 21 November 2016. The sponsor was Bristol-Myers Squibb International Corporation.*
>
> *Please let us know if you require any further information from us.*

MHRA Response

We are able to confirm we hold most of the information you have requested. Of what we are able to provide we will be exempting some of the information. For ease we will address the first 3 questions together and the final 2 separately.

1. ***A copy of Revised Protocol 7 (dated 20 December 2016).***
2. ***A copy of Revised Protocol 8 (dated 31 July 2017).***
3. ***A copy of the Investigator's Brochure.***

We are unable to provide you with some of the information requested as it constitutes personal data of someone other than yourself and as such, it is being withheld in accordance with section 40(2) of the Freedom of Information Act.

Section 40(2) exempts information in response to a request if it is personal data belonging to an individual other than the requester and it satisfies one of the conditions listed in the legislation. In this case the condition contained in section 40(3A)(a) applies - that disclosure would breach one of the data protection principles, specifically that “Personal data shall be processed lawfully, fairly and in a transparent manner...”.

We do not consider that disclosing this information is necessary or justified in order to satisfy your information request and the requirements of the FoI Act. In relation to this request, we consider that there is no strong legitimate interest that would override the prejudice to the rights and freedoms of the data subject.

Personal data are subject to UK General Data Protection Regulation (UK GDPR) and the Data Protection Act 2018

MHRA maintains the following policy on disclosure of personal information:

"All personal information held in MHRA records is regarded as confidential. Information will not normally be disclosed to third parties without the consent of the person concerned. Information may normally be disclosed without consent to meet statutory requirements; to comply with a court order; to prevent duplication of payments from public funds; or where there is a compelling public interest in making the disclosure."

All disclosures made by MHRA, in order to be considered authorised must be able to demonstrate that at least one of the above criteria apply.

Please see attached of what we are able to provide as part of this response.

4. A copy of the patient informed consent forms.

We can confirm that the MHRA does not hold this information.

5. Copies of any minutes or decisions relating to the approval of the trial and/or amendments to the trial protocol.

The initial Clinical Trial Authorisation (CTA) application was approved on the 21 November 2016. There have been ten subsequent substantial amendments to the Protocol since the initial CTA approval date. These are listed below:

- Protocol 1, dated 20 December 2016 - the substantial amendment was approved.
- Protocol 8, dated 10 October 2017 - the substantial amendment was approved.
- Protocol 9, dated 18 April 2018 - the substantial amendment was approved.
- Protocol 10, dated 11 June 2019 - the substantial amendment was approved.
- Protocol 11, dated 18 February 2020 - the substantial amendment was approved.
- Protocol 12, dated 1 May 2020 - the substantial amendment was approved.
- Protocol 13, dated 13 August 2021 - the substantial amendment was approved.
- Protocol 14, dated 19 June 2023 - the substantial amendment was approved.
- Protocol 15, dated 28 April 2024 - the substantial amendment was approved.
- Protocol 02UK, dated 16 September 2024 - the substantial amendment was approved.

If you have any queries about this letter, please contact us quoting the reference number above.

Yours sincerely,

MHRA Central Freedom of Information Team
Medicines & Healthcare products Regulatory Agency

Your right to complain under the Freedom of Information Act

If you are not happy with this response you may request an internal review by e-mailing foi.request@mhra.gov.uk or by writing to: MHRA Central Freedom of Information Team, 10 South, Colonnade, Canary Wharf, London, E14 4PU

Any request for an internal review must be received by us within 40 working days of the date of this letter. Please note we are not obliged to provide a review if it is requested after more than 40 working days.

If you are not content with the outcome of the internal review you may apply directly to the Information Commissioner's Office for a decision. Generally, the Commissioner cannot make a decision unless you have exhausted our own complaints procedure. The Information Commissioner can be contacted at: The Information Commissioner's Office, Wycliffe House, Water Lane, Wilmslow, Cheshire SK9 5AF.
Website: ICO FOI and EIR complaints or telephone 0303 123 1113.

Re-use of our information