Medicines & Healthcare products Regulatory Agency

MHRA Central Freedom of Information Team
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MHRA Website

Peter Selley
[redacted]

Our Ref: **FOI2026/01427**

5 November 2026

Dear **Peter Selley,**

Thank you for your Freedom of Information (FoI) request received on 18 October. You wrote:

> *My request concerns the Moderna products mRNA-1345 and mRNA-1365.*
>
> *These products were approved by NHS HRA for a Phase 1 clinical trial in children 5-23 months of age (NCT05743881) IRAS ID 1006997.*
>
> *You previously informed me on 21 March 2025 (ref IR2025/00170) that the MHRA held nine Suspected Unexpected Serious Adverse Drug Reactions (SUSARs) reports arising from this clinical trial. In September 2025 (ref FOI2025/00887) you informed me there had been one further SUSAR report as of 31 August 2025.*
>
> *Please inform me:*
>
> *1) Since 31 August 2025, how many additional Suspected Unexpected Serious Adverse Drug Reactions (SUSARs) arising in this trial have been notified to MHRA?*
>
> *2) Throughout this trial what is the total number of SUSARs reported a) for mRNA-1345 and b) for mRNA-1365?*
>
> *3) Throughout this trial what is the number of SUSARs reports of enhanced respiratory disease a) for mRNA-1345 and b) for mRNA-1365?*
>
> *If it is not possible to provide the information requested due to the information exceeding the cost of compliance limits identified in Section 12, please provide advice and assistance, under the Section 16 obligations of the Act, as to how I can refine my request.*
> *If you can identify any ways that my request could be refined, I would be grateful for any further advice and assistance.*
> *If you have any queries, please don't hesitate to contact me via email and I will be very happy to clarify what I am asking for and discuss the request.*

MHRA Response

Thank you for your request for information. Following a search of our electronic records, we have established that we hold some of the information you have requested.

In accordance with Section 1(1) of the Freedom of Information Act 2000 we confirm we hold information you requested for questions 1 and 2(a), 2(b) and this is provided below.

For question 3(a) and 3(b), under Section 1(1)(a) of the Act, we confirm we do not hold the information requested.

We have provided our replies beneath each of your questions below:

1. *Since 31 August 2025, how many additional Suspected Unexpected Serious Adverse Drug Reactions (SUSARs) arising in this trial have been notified to MHRA?*

Our response:
There have been a further three SUSARs reported to us from this trial since 31st August 2025.

2. *Throughout this trial what is the total number of SUSARs reported*

    a) *for mRNA-1345 and*

Our response:
There has been one SUSAR reported for the investigational medicinal product (IMP) mRNA-1345.

    b) *for mRNA-1365?*

Our response:
There have been twelve SUSARs reported for the IMP mRNA-1365

3. *Throughout this trial what is the number of SUSARs reports of enhanced respiratory disease*

    a) *for mRNA-1345 and*

Our response:
We have searched for enhanced respiratory disease and confirm that we do not hold the requested information; there are no SUSAR reports for enhanced respiratory disease for mRNA-1345.

    b) *for mRNA-1365?*

Our response:
We have searched for enhanced respiratory disease and confirm that we do not hold the requested information; there are no SUSAR reports for enhanced respiratory disease for mRNA-1365.

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.

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