



foi.request@mhra.gov.uk.

[MHRA Website](#)

Our Ref: **FOI2026/00416**

18 May 2026

Dear [REDACTED]

Thank you for your Freedom of Information (Fol) request received on 20 April. You wrote:

For the years from April 2021 to present, the last 5 years

- 1. how many suspected unexpected serious adverse reactions have there been in human participants in clinical trials in the UK and*
- 2. how many people have died?*

MHRA Response

We confirm that we hold the information you have requested and provide it below:

1. From 1 April 2021 to 20 April 2026 8,028 suspected unexpected serious adverse drug reactions (SUSARs) have been reported in UK clinical trials
2. From 1 April 2021 to 20 April 2026 497 SUSARs with a fatal outcome have been reported in UK clinical trials

Advice and assistance

Please note, we would caution against making any interpretation of the above raw figures for the reasons outlined below:

- Without context such as the total number of trials, the nature of those trials and the factors such as the health of the participants on entry to a trial, for example, some trials will be in patient populations where the patient's prognosis is already poor, the figures alone can provide very few insights.
- The report of a SUSAR does not always equate to a potential safety signal, as some adverse events may be anticipated to occur based on the established safety profile of the investigational drug.
- The number of SUSARs alone does not represent the confirmed safety profile of a drug. These should be placed in the context of the full benefit-risk profile of the associated indications studied in clinical trials and the associated number of patients treated with the products.
- Even if these figures were requested for a specific trial, rather than all UK registered trials across five years, the insights that could be gained would be limited.

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

The MHRA information supplied in response to your request is subject to Crown copyright. Information created by the MHRA which is disclosed under the Freedom of Information Act is made available for re-use under the Open Government Licence (OGL) v3.0, except where this is otherwise stated. There are some restrictions on re-use under the OGL and these can be viewed here:

<https://www.nationalarchives.gov.uk/doc/open-government-licence/version/3/>