Medicines & Healthcare products Regulatory Agency

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Our Ref: **FOI2026/00582**

24 June 2026

Dea[redacted]

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

> *Thank you very much indeed for the information. Is it possible please to break the figures down to the SUSARS and deaths for Phase 1, 2 and 3 trials please? Sane dates please.*

MHRA Response

We can neither confirm nor deny we hold information falling within the description specified in your request under section 12(2) of the Freedom of Information Act, as to do so would exceed the cost limit.

This is because we estimate the cost of checking if we hold the requested information or not would exceed the cost limit of £600 specified in the Freedom of Information and Data Protection (Appropriate Limit and Fees) Regulations 2004. This represents the estimated cost of at least one person spending 3½ working days (equivalent to 24 staff-hours) in determining whether the Agency holds the information, and locating, retrieving and extracting it.

Under Section 12(2) of the FoI Act the Agency is not therefore obliged to comply with your request and we will not be processing it further. The reasons being:

As per your request, to obtain a breakdown of trial phases for each of the 8,000+ SUSARs reported over the 5- year period, the protocol number for each trial* will have to be extracted from the SUSAR search results then manually pasted to a search function of the software platform we use to establish the trial identifier (IRAS ID) of each trial. This software package can only determine trial phases from the - IRAS ID. Protocol numbers present formatting issues when used to search. Further, when searching for the requested information IRAS IDs are more reliable than protocol numbers.

When establishing the trial phases, the search is based on initial clinical trial applications (rather than the subsequent modifications otherwise incorrect/duplication of trial phases would occur). Additionally, protocol numbers are not always listed in initial applications hence why IRAS IDs are imperative.

*Background: With SUSAR reporting, each field is referred to as E2B R3 data elements (patient name, suspect drug, sponsor protocol code) that are stringently governed by the International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH) guidelines. Trial identifiers IRAS ID and EudraCT number are not valid, ICH E2B R3 data elements. Protocol numbers are (and mandatory) based on the report type being from a study, and the study type being from a clinical trial. Trial phases are not ICH E2B R3 data elements either, this is why another software package is required to determine them from IRAS IDs.

Problems encountered:

- ***Conversion of protocol numbers to their respective IRAS IDs***

  The protocol numbers for each SUSAR report are recorded in a column in the search results. There is a need to convert this data into a paragraph by using a specific function. The reformatted information is then in a form that can be entered into the search window of the software platform. A report of IRAS IDs can then be generated.

- Some SUSAR reports are not aligning with the correct protocol number; either additional characters or incorrect values. An example of an incorrect protocol number is an entry of 'STUDY ID NOT AVAILABLE', or 'Partner 2.0, 6 January 201'. As a result, these are not identified in the search for IRAS IDs – raising the issue of the trials that have been excluded, and therefore the exact number of different trial phases is not correctly captured.

- An issue of disappearing trials was encountered during searching trial phases, another issue identified was of phases not being identified even if our internal clinical trial application case folders cited these phases.

- Another factor is that it is not possible to isolate solely phase 1, 2, 3, or 4 trials. There is a mixture of combination phased trials (phase 1-2, 1-3, 2-3, 3-4, 1-4) in addition to these solitary phased trials. Trying to establish metrics for each combination will take longer than 24 hours especially considering the SUSARs that do not cite correct protocol numbers will need to be referred to again, and their case narratives examined to try to identify the correct trial and IRAS ID.

  - To add to the complexities, trials have the tendency to change their phases throughout their programme for example, from phase 1 to a phase 1-3, or a phase 3 to a phase 4. There is no guarantee that the trial phases will be the same in a month's time.

- Each SUSAR cites the trial protocol number and therefore there are several SUSARs over that 5-year period that whilst each relate to a different patient, they collectively originate from the same trial, entering the same protocol number several times in the search will only yield one result so it is currently not feasible to separate the 8,000+ SUSARs and 400+ fatal SUSARs into the varying trial phases. For example, when the 497 fatal SUSARs were tested using protocol numbers rather than IRAS IDs, there was a notable mismatch in the total which reduced to 211. Incorrect protocol numbers failed to yield a result and duplicate protocol numbers (relating to different patients/different SUSARs) reduced the number to the one IRAS ID (of the same trial). Completing this single aspect of a preliminary search required 2 days.

We have estimated that to determine if held, locate, extract and retrieve the requested information, it would take longer than 24 hours i.e.to be able to go through each of the

12,000~ SUSARs to cross check each SUSAR with each trial phase and considering the complexities outlined above.

Under Section 16 of the FoI Act where possible we should help you narrow your request so that it may fall beneath the cost limit. However, as your request is reliant on trial identifiers that are not recognised as valid E2B R3 data elements, not found on SUSAR reports, and these require extensive conversion using a separate software platform, we have not been able to identify a viable manner by which you could narrow or refine your request, we are therefore unable to provide more specific advice under Section 16 of the FoI Act.

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 Contact Information or telephone 0303 123 1113.

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