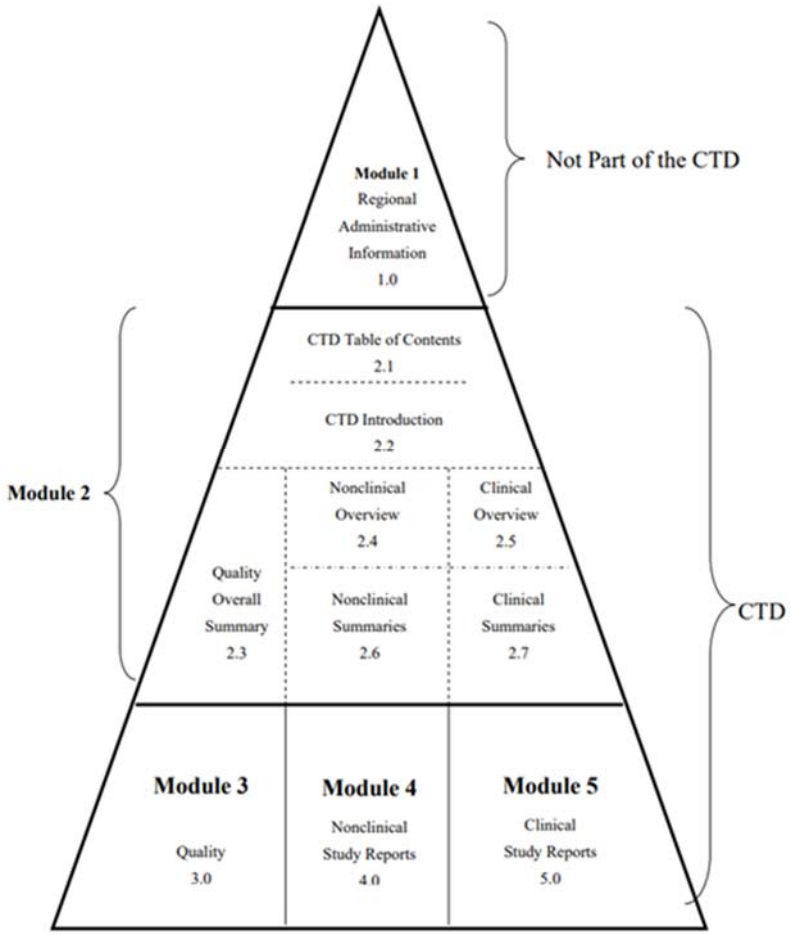
FOI 23/789

Dear

Thank you for your follow-up request of 16 October 2023, where you asked the following:

Do you have a listing of all records in the file related to the safety module?

We do not hold the information that you have requested. Please note that in relation to Quality, Safety and Efficacy of a medicinal product, the dossier is not structured such that modules are presented for each of these criteria. Rather the modules are as below.



The majority of the pre-authorisation safety data will be in the form of information from clinical trials which are located in module 5 of the dossier, pre-clinical testing also covers aspects of safety (module 4). Module 3 which concentrates on the quality of the product is in a sense inseparable from safety; if the quality controls in place are appropriate a quality product is manufactured; thus contributing to safety. Module 2 includes overall summaries of quality, clinical, and non-clinical information.

In addition to the above, new information can be provided in the form of responses to questions, and these would generally be located in the administrative module (module 1), however, new addenda and updated documents will also be included in the aforementioned modules. Module 6 includes post-marketing data, which can be present if a product has been marketed in another geographical location prior to authorisation in GB, NI, or the UK.

In addition to the dossiers that MHRA hold for medicinal products described above, MHRA also hold assessment reports, these comment and assess the content of the dossier. In due course, a public assessment report is then generated based on the internal assessment report.

We hope that this helps with regards to submitting a request in the future. Please confirm that we can close FOI 23/789. Any new request will be logged under a new reference number and the timeline/process will restart.

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

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
HQ&A FOI Team