

FOI 23/380 – SKYConvion trial dates and PAR

Dear

Thank you for your email of 28 May where you have asked “I attach hereto News Story published by MHRA 26 May 2023, confirming clinical evidence for authorising the new "SKYConvion" Covid 19 inoculations is based on data from two clinical trials on approximately 3,100 individuals aged 18 to 84 years.

I would be grateful if you could arrange to provide me with the following information from MHRA records.

- 1. Start and end date of the two clinical trials referred to, and**
- 2. A copy of the trial findings used to inform MHRA decision to authorise use of "SKYConvion" Covid 19 inoculations.”**

The dates for each study (date of first enrolment – date of completion) are as follows:
GBP510-001: 20 Jan 2021 – 30 Jul 2021
GBP510-002: 03 Feb 2021 – 28 Jul 2021

Regarding “the trial findings used to inform MHRA decision to authorise use of "SKYConvion" Covid 19 inoculations” we are exempting this under Section 22 of the FOIA (information intended for future publication) as we intend to publish the PAR for SKYConvion suspension and emulsion for emulsion for injection, COVID-19 vaccine (PLGB 33611/0029) in the near future.

If you disagree with how we have interpreted the Freedom of Information Act 2000 in answering your request, you can ask for an internal review. Please reply to this email, within two months of this reply, specifying that you would like an Internal Review to be carried out.

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

MHRA Customer Experience Centre
Communications and engagement team
Medicines and Healthcare products Regulatory Agency
10 South Colonnade, Canary Wharf, London E14 4PU Telephone 020 3080 6000