FOI 23/519

Dear

Thank you for your email of 17 July when you requested under the Freedom of Information Act the following related to **the Moderna's 'NextCove' clinical trial mRNA-1283-P301 (clinical trials ID: NCT05815498):**

"a) MHRA quantitative assessment of the "foreseeable benefits" to the younger individuals involved in the trial and those affected by the condition under investigation
b) MHRA's assessment of the clinical trial's compliance with UK Law
c) a list of any other clinical trials of mRNA Covid vaccines involving trials participants aged 0-17yrs which have been approved by MHRA since 1 January 22."

I am pleased to provide you with the following response:

a. *MHRA quantitative assessment of the "foreseeable benefits" to the younger individuals involved in the trial and those affected by the condition under investigation*

As with all Clinical Trial Authorisation (CTA) applications the risk/benefit balance for the study population was carefully evaluated based on the submitted information, but this does not necessarily include a quantitative assessment.

The foreseeable benefits include potential direct benefits (current and future) to the study participants as well as indirect benefits in relation to future evolution/developments and supporting science. These are carefully weighed against the identified risks and potential risks of study participation. For all approved clinical trials, the overall risk/benefit balance was considered to be favourable for the entire study population.

b. *MHRA's assessment of the clinical trial's compliance with UK Law*

This trial and all clinical trials are regulated by the Clinical Trials Regulations 2004, which implement Directive 2001/20/EC on the conduct of clinical trials (Clinical Trials Directive) and Directive 2005/28/EC on good clinical practice for medicinal products for human use (GCP Directive). The Medicines and Healthcare products Regulatory Agency conduct their assessment in accordance with The Medicines for Human Use (Clinical Trials) Regulations 2004, which includes Schedule 1 Conditions And Principles Of Good Clinical Practice And For The Protection Of Clinical Trial Subjects and all approved clinical trials are deemed to be in compliance with UK law.

c. *a list of any other clinical trials of mRNA Covid vaccines involving trials participants aged 0-17yrs which have been approved by MHRA since 1 January 22.*

Section 21 – Information accessible by other means: the information you have requested is already in the public domain, and can be found at **https://www.clinicaltrialsregister.eu/ctr-search/search** and https://classic.clinicaltrials.gov/ct2/home
The Act's section 21 exemption states that there is no right of access to information via FOI if it is reasonably available to the applicant by another route.

Below link is for another UK trial related to mRNA COVID-19 vaccines involving children:

A Study to Evaluate the Immunogenicity and Safety of Omicron Variant Vaccines in Comparison With mRNA-1273 Booster Vaccine for COVID-19 - Full Text View - ClinicalTrials.gov

We can suggest you search public registers such as ISRCTN, clinicaltrials.gov and Be part of research:

https://www.isrctn.com/
https://www.clinicaltrialsregister.eu/ctr-search/search
https://bepartofresearch.nihr.ac.uk/
COVID-19 Studies from the World Health Organization Database - ClinicalTrials.gov

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
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