FOI 23/228 - total incidence of first SARS-CoV-2 symptomatic or asymptomatic infection occurring prior to 15 days post dose 2 in participants seronegative at baseline

MHRA RESPONSE
17 May 2023

Dear

Thank you for your request under the Freedom of Information Act, we apologise for the delay in reply.

In your email you requested:

I wish to know the total incidence of first SARS-CoV-2 symptomatic or asymptomatic infection occurring ***prior to 15 days post dose 2*** *in participants seronegative at baseline.*

1. Please provide the numbers broken down between the Control group and the AZD1222 group.

2. Please also provide the numbers as between the 2 groups broken down as per table 9 above, namely:

- *Symptomatic – Primary*
- *Symptomatic – Non-primary*
- *Asymptomatic*

(the reference to table 9 was to the MHRA Public Assessment Report for Vaxzevria).

We confirm that we hold some of the information you have requested.

Table 9 is based on one single study (COV002) where weekly PCR tests were done so that asymptomatic cases could be detected. We do not have data before full effect of 2 doses.

However, we have data in the whole efficacy cohort where all studies were aggregated, but this only describes the primary endpoint of symptomatic cases.

Summary of First SARS-CoV-2 Virologically-confirmed COVID-19 Occurring Post First Dose of Study Intervention (Any Dose for Efficacy Analysis Set)

Category	Participants with events, n (%)	
	AZD1222 (N=10014)	Control (N=10000)
First occurrence after dose 1	108	227
Post Dose 1 and before Dose 2	68	105
From Dose 2 through Dose 2 + 14 days	10	20
≥ 15 days after Dose 2	30	102

You may wish to note that all clinical data for Vaxzervria are published by the European Medicines Agency in their clinical repository, which you can access via this link: https://clinicaldata.ema.europa.eu/web/cdp/home

We hope this information is helpful to you.

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
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Yours sincerely
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