Medicines & Healthcare products
Regulatory Agency

10 South Colonnade
Canary Wharf
London
E14 4PU
United Kingdom
gov.uk/mhra

[redacted]

20 December 2023

Dear [redacted]

RE: FOI 23/905

Thank you for your email of 24 October 2023, where you requested the following information under the Freedom of Information Act:

MHRA's CPRD database includes the protocols for the Post-Authorisation Safety Studies (PASS) relating to the Covid vaccines used in the UK :
· AstraZeneca : https://cprd.com/protocol/post-authorisation-post-marketing-observational-study-using-existing-secondary-health-data
· Pfizer : https://cprd.com/protocol/post-conditional-approval-active-surveillance-study-among-individuals-europe-receiving
· Moderna : https://cprd.com/post-authorization-active-surveillance-safety-study-using-secondary-data-monitor-real-world-safety
The protocols include the timetables for those MAHs' submission of their Interim/Progress and Final reports. I have only found one of those online; namely, the AstraZeneca 'Interim Report 1' here
: https://www.encepp.eu/encepp/viewResource.htm?id=104913

Q1. Please can you send me the other AstraZeneca, Pfizer and Moderna Covid vaccine PASS studies which MHRA holds (all versions: ie Interim/Progress and Final)

Q2. For those Interim/Progress and Final PASS reports which have not yet been submitted by the MAHs, please can you tell me the corresponding planned submission dates.

Which you then clarified on 22 November as:

Interim, progress and final reports defined in the following PASS study protocols :
- PFIZER : *'Pfizer-BioNTech COVID-19 vaccine C4591021 NON-INTERVENTIONAL STUDY PROTOCOL'*

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- ASTRAZENECA : *'PASS Protocol AstraZeneca AZD1222, D8111R00006'*
- MODERNA: *'Post-marketing safety study for COVID-19 mRNA-1273 vaccine Protocol mRNA-1273-P904'*

Please find attached the following documents:

COVID-19 Vaccine	**Report**
Pfizer/BioNTech	C4591021 interim1 report body
	C4591021 interim2 report body
	C4591021 interim3 report body
	C4591021 interim4 report body
AstraZeneca	D8111R00006 Progress report 1
Moderna	P904 interim report update1 report
	P904 eu pass second interim update
	P904 eu pass third interim update
	P904 eu pass fourth interim update

Some information is withheld in the reports provided, in accordance with section 40(2).

Section 40(2) applies when personal data relates to individuals. This information is withheld as it falls under the exemption in sections 40(2) and 40(3)(a)(i) of the FOIA, which relates to the personal data of which the applicant is not the data subject. Section 40(2) of the FOIA provides that personal data relating to other persons is exempt information if disclosure would breach the Data Protection Act 1998 (DPA). We consider that disclosure of this information is likely to breach the first data protection principle in Schedule 1 to the DPA, which relates to the fair and lawful processing of personal data. Therefore, we have concluded that this information is exempt from disclosure under section 40(2) read in conjunction with section 40(3)(a)(i) of the FOIA.

As previously advised, information on the study milestones can be found on the European Medicines Agency Website:

comirnaty-epar-risk-management-plan_en.pdf (europa.eu) (see pages 159-160, C4591021)
spikevax-previously-covid-19-vaccine-moderna-epar-risk-management-plan_en.pdf (europa.eu) (see page 117, mRNA-1273- P904)
vaxzevria-previously-covid-19-vaccine-astrazeneca-epar-risk-management-plan_en.pdf (europa.eu) (see page 62-63, D8111R00006)

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I hope this information is helpful. 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

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