FOI 23/113

12th February 2023

Dear

Thank you for your information request dated 9th February 2023, where you asked the following information:

Post-Conditional Approval Active Surveillance Study Among Individuals in Europe Receiving the Pfizer-BioNTech Coronavirus Disease 2019 (COVID-19) Vaccine Date of Approval : 04-10-2021 Application Number : 21_000535

donc *[sic]* on the CPRD (Clinical Practice Research Datalink) provided by the MHRA with the support of the NIHR involving :

- Saad Shakir - Chief Investigator - Drug Safety Research Unit
- Debabrata Roy - Corresponding Applicant - Drug Safety Research Unit
- Catherine Fry - Collaborator - Drug Safety Research Unit
- Hai Nguyen - Collaborator - Drug Safety Research Unit
- Miranda Davies - Collaborator - Drug Safety Research Unit
- Samantha Lane - Collaborator - Drug Safety Research Unit
- Sandeep Dhanda - Collaborator - Drug Safety Research Unit

Would you be able to provide all records related to this project, including :

- All versions of the protocol
- All contracts / reports / preliminary reports
- All numerical / statistical tables
- All correspondences (including emails) associated to those tables and reports

Responding to each point in turn

- **All versions of the protocol**

  This information is exempt under Section 43 of the FOIA 'Commercial interests' disclosure would be likely to prejudice the commercial interests of any person and Section 41 of the FOIA 'Information provided in confidence' where information is provided to the Agency in confidence, the release of which would likely result in legal action.
  You may wish to contact Saad Shakir at saad.shakir@dsru.org as they may be able to provide the information you requested

  CPRD publishes a summary of studies using CPRD data on its website - Approved studies using CPRD Data | CPRD

- **All contracts**

This information is exempt under Section 43 of the FOIA 'Commercial interests' disclosure would be likely to prejudice the commercial interests of any person

- **/ reports / preliminary reports**

  I can confirm that we do not hold the information that you requested. You may wish to contact Saad Shakir at saad.shakir@dsru.org as they may be able to provide the information you requested

- **All numerical / statistical tables**

  I can confirm that we do not hold the information that you requested. You may wish to contact Saad Shakir at saad.shakir@dsru.org as they may be able to provide the information you requested

- **All correspondences (including emails) associated to those tables and reports**

  I can confirm that we do not hold the information that you requested. As these tables are part of the study and held by the study team, there is no correspondence between CPRD and the study team relating to these.

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

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