

Ensuring clarity and transparency in COVID-19 vaccine research

AstraZeneca made a request to **access health datasets through NHS Digital's TRE to assess the real-world effectiveness of the Oxford/AstraZeneca COVID-19 vaccine** among people who receive one or two doses of the vaccine. These include a range of datasets including vaccination status, hospital admissions information and COVID-19 tracking data.

IGARD welcomed the application and recognised the importance and timeliness of the study. However, they noted that the application stated that AstraZeneca were a joint data controller, with the other sponsor listed located in the United States of America. IGARD sought to clarify whether this USA organisation had any data controllership responsibility and asked that the researchers updated their application to highlight that no US entity would have data controller responsibilities. They also requested a **special condition be added to the data use to ensure that it was to be used within England and Wales only.**

Within the information about data privacy, IGARD highlighted that the process for patients and the public opting out of their data being used for this research was unclear and that this posed not only a legal risk to the data controllers, but a significant reputational risk to NHS Digital, if not explained clearly. They recommended this be **clarified to ensure transparency**, and also suggested that further consideration should be given to **patient and public involvement and engagement in the study**, due to the significant amount of data flowing and the public interest in the topic.

Read the full IGARD minutes where they discussed this access request [here](#)