EMA/124534/2022
Stakeholders and Communication

Dear Mr Lach,

Subject: **PROLIFIC2020 study ASK-105382 Letter to the requester; document not held by the Agency**

Thank you for your request for access to documents received on 21st January 2022, for which the procedure was initiated on 23rd February 2022, in which you apply for a copy of the following document, in particular:

- Results of the PROLIFIC2020 study from 2020.

Your request has been handled in accordance with Article 7 of Regulation (EC) No 1049/2001 regarding public access to European Parliament, Council and Commission documents (the Regulation)[1] and Section 3 of the Annex to the "*European Medicines Agency policy on access to documents - POLICY/0043*"[2].

The Agency regrets to inform you that the document you requested is not held by the Agency. We are therefore not in a position to provide you with access to this document.

Please note that the PROLIFIC2020 study has been suspended. Therefore, at this stage no information has been submitted to the EMA related to the study. For further details, please refer to the following link: https://cambridgebrc.nihr.ac.uk/prolific/.

For your information, EMA has conducted a literature review of observational studies on the use of chloroquine and hydroxychloroquine in COVID-19 patients which is published on the EMA website: https://www.ema.europa.eu/en/documents/other/list-references-observational-studies-chloroquine-hydroxychloroquine-covid-19-patients_en.pdf.

In addition, you can find in the EMA' Public-health advice during COVID-19 pandemic webpage, a section related to the use of use of chloroquine and hydroxychloroquine medicines in particular in patients with or at risk of COVID-19 infection: https://www.ema.europa.eu/en/human-regulatory/overview/public-health-threats/coronavirus-disease-covid-19/public-health-advice-during-covid-19-pandemic#use-of-chloroquine-and-hydroxychloroquine-medicines-section.

As provided for in Article 2(3) of the Regulation, the right of access, as defined in that Regulation, applies only to existing documents that are held by the Agency.

1 OJ L 145, 31.5.2001, P. 43-48
2 EMA/729522/2016 "*European Medicines Agency policy on access to documents - POLICY/0043*" of 4 October 2018, available at https://www.ema.europa.eu/documents/other/policy/0043-european-medicines-agency-policy-access-documents_en.pdf.

In light of the above, the Agency is not in a position to satisfy your request.

Should you wish to avail yourself of the remedies available under Union law against this decision, please be informed that you can bring a complaint before the European Ombudsman, pursuant to Article 228 of the Treaty on the Functioning of the European Union (TFEU). Alternatively, you can institute legal proceedings before the General Court of the European Union in accordance with Article 263 of the TFEU.

If you have any queries on the enclosed, please do not hesitate to contact the Access to Documents Service, by submitting an online request form as mentioned above or by sending your request to AskEMAATD@ema.europa.eu. Please use the ASK Procedure Number mentioned in the subject line in any correspondence related to this request.

Yours sincerely,

Head of Access to Documents Service
Documents Access and Publication Department
(Signature on file)

Legal Administrator
Legal Department
(Signature on file)