Medicines & Healthcare products Regulatory Agency

MHRA

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[redacted]
UNIVERSITY OF OXFORD
OXFORD VACCINE GROUP, CENTRE FOR CLINICAL VACCINOLOGY AND TROPICAL MEDICINE,
CHURCHILL HOSPITAL, OLD ROAD, HEADINGTON
OXFORD
OX3 7LE
UNITED KINGDOM

12/02/2021

Dear [redacted]

THE MEDICINES FOR HUMAN USE (CLINICAL TRIALS) REGULATIONS 2004 S.I. 2004/1031

Our Reference:	CTA 21584/0441/001-0001
Eudract Number:	2020-005765-13
Product:	ChAdOx1 nCoV-19, Bexsero
Protocol number:	COV006

NOTICE OF ACCEPTANCE

I am writing to inform you that the Licensing Authority accepts your request for a clinical trial authorisation (CTA), received on 05/02/2021.

MEDICAL
TOXICOLOGY
PHARMACEUTICAL

The authorisation is effective from the date of this letter although your trial may be suspended or terminated at any time by the Licensing Authority in accordance with regulation 31. You must notify the Licensing Authority within 90 days of the trial ending.

You are reminded that a favourable opinion from the Ethics Committee is also required before this trial can proceed.

Any favourable opinion given by a research ethics committee is subject to the condition that the clinical trial is registered on a publicly accessible database. If your trial registry number has not already been provided, you should email this to both MHRA (clintrialhelpline@mhra.gov.uk) and HRA (study.registration@hra.nhs.uk) with subject line "Clinical Trial Registration" before the first participant is recruited and no later than six weeks after recruitment of the first participant. If a deferral granted by HRA exists, then this should also be communicated.

Yours sincerely,

Clinical Trials Unit
MHRA

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