



MHRA

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

Dr Frances Hall
CAMBRIDGE UNIVERSITY HOSPITALS NHS FOUNDATION TRUST
P O BOX 194, ADDENBROOKE'S HOSPITAL,
HILLS ROAD
CAMBRIDGE
CB2 0QQ
UNITED KINGDOM

26/05/2020

Dear Dr Frances Hall

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

Our Reference:	CTA 12854/0250/001-0002
Eudract Number:	2020-001354-22
Product:	Olumiant (Baricitinib), Ultomiris (Ravulizumab)
Protocol Number:	TACTIC-R
Substantial Amendment Code Number:	Code Number: Substantial Amendment 1 Version: Protocol v2.0 Date: 2020/05/20

ACKNOWLEDGEMENT OF AMENDMENT

Thank you for your notice of amendment, received on 22/05/2020. The information you provided to support your request is complete and therefore your request is valid.

Your request will be assessed and you will be notified of the Licensing Authority's decision within 35 days.

Please quote the EudraCT number, CTA number and your amendment code in any further communications relating to this submission.

Yours sincerely,

Submissions
MHRA