Medicines & Healthcare products Regulatory Agency

MHRA

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27/05/2020

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

NOTICE OF ACCEPTANCE OF AMENDMENT

I am writing to inform you that the Licensing Authority accepts the proposed amendment to your clinical trial authorisation (CTA), received on 22/05/2020.

This amendment may therefore be made.

You are reminded that where it is appropriate, the Ethics Committee should also be notified of amendments.

Yours sincerely,

Clinical Trials Unit
MHRA