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Dr Frances Hall  
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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**