



Medicines & Healthcare products
Regulatory Agency



MHRA

10 South Colonnade
Canary Wharf
London
E14 4PU
United Kingdom

gov.uk/mhra

Ms W van Bentum-Puijk
UNIVERSITY MEDICAL CENTRE UTRECHT
HEIDELBERGLAAN 100,
UTRECHT
NL-3584 CX
NETHERLANDS

08/01/2025

Dear Ms W van Bentum-Puijk,

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

Our Reference:	CTA 30913/0006/001-0038
Eudract Number:	2015-002340-14
Product:	ceftriaxone, levofloxacin, piperacilin-tazobactam, hydrocortisone, amoxicillin-clavulanate, azithromycin, clarithromycin, moxifloxacin, ceftaroline, hydroxychloroquine, Tocilizumab, Sarilumab, Heparin, Sarilumab unlicensed, Kaletra 80mg/20mg Oral Solution, interferon beta-1a, anakinra, Lopinavir/Ritonavir Mylan, Ascorbic Acid, simvastatin, Ramipril, Lisinopril, Perindopril, Enalapril, Captopril, losartan, Valsartan, Candesartan, Irbesartan, Repagermanium, cysteamine bitartrate, Clopidogrel, Prasugrel, Aspirin, ticagrelor, Pascorbin, Casirivimab / imdevimab (Ronapreve), Pascorbin / Ascorbic Acid, Dexamethasone, Xofluza, Tamiflu, Baricitinib
Protocol number:	n/a
Substantial Amendment Code Number:	AM042

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 13/12/2024.

PHARMACEUTICAL

SCIENTIFIC - Remarks: Clinical conditions of approval.

*Authorisation of your trial is subject to the following condition(s) and to be submitted by one month from the receipt of the decision letter at the latest:

- Clarification is required whether the section 4.4 to 4.8 has been updated to any of the SmPC submitted in this package. If yes, please summarise and submit these in a separate document.
- Clarification is required that any safety updates in the SmPC does have an impact in the protocol document.



•Clarification is required whether any RSI document previously considered as the IB has been now replaced by the SmPC and thus submitted in this application package for the first time.

If your trial does not meet these conditions your trial does not have authorisation and therefore you cannot proceed with the trial. You must inform the MHRA immediately if this is the case. All changes to the terms and conditions of this trial must be made as a request for a substantial amendment to this clinical trial authorisation.

If you have a query on these comments, please contact Rebecca Smith on rebecca.smith@mhra.gov.uk

This amendment may therefore be made.

If applicable, you should ensure your trial details have been updated on the database where you have registered your trial.

You are reminded that from 1 January 2022 you will need to comply with the requirements specified in the following guidance, where applicable:

o Import of IMPs from listed countries to GB:

<https://www.gov.uk/government/publications/importing-investigational-medicinal-products-into-great-britain-from-approved-countries>

o Supply of IMPs to Northern Ireland:

<https://www.gov.uk/guidance/supplying-investigational-medicinal-products-to-northern-ireland>

o Substantial amendments to clinical trials:

<https://www.gov.uk/guidance/guidance-on-substantial-amendments-to-a-clinical-trial>

Any required substantial amendment to your Clinical Trial Authorisation should be submitted and approved as soon as possible and before 1 January 2022.

Yours sincerely,

**Clinical Trials Unit
MHRA**