



Medicines & Healthcare products
Regulatory Agency



MHRA

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

29/01/2024

Dear Ms W van Bentum-Puijk,

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

Our Reference:	CTA 30913/0006/001-0035
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:	AM040

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 22/12/2023.

MEDICAL - Remarks: Condition:

Authorisation of your clinical trial is subject to the following condition:

For both the domain-specific protocols in this application, in the UK tocilizumab is not to be used in pregnant participants.

If this condition is met, the trial is authorised and you do not need to respond to this letter. If your trial does not meet this condition, your trial does not have authorisation and therefore you can not proceed with the trial. You must inform the MHRA immediately if the trial does not meet the above condition. 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. For further information on the above, please contact Dr Andrew Ruddick (andrew.ruddick@mhra.gov.uk).

PHARMACEUTICAL

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**