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

09/05/2022

Dear Ms W van Bentum-Puijk,

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

Our Reference:	CTA 30913/0006/001-0027
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
Protocol number:	n/a
Substantial Amendment Code Number:	AM035

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 12/04/2022.

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:

- ***Import of IMPs from listed countries to GB:***

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

- ***Supply of IMPs to Northern Ireland:***

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

- ***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