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12th December 2024

Re: Study Title: Randomized, Embedded, Multi-factorial, Adaptive Platform Trial for Community-Acquired Pneumonia (REMAP-CAP)
REC reference: 18/LO/0660
EudraCT number: 2015-002340-14
IRAS project ID: 237150

Substantial Amendment 42 (AM42)

I am submitting substantial amendment AM042 for the REMAP-CAP study. It involves:

1. Changes to the Summary of Product Characteristics (SmPC) for REMAP-CAP Investigational Medicinal Products (IMPs)

Submission of updated SmPCs for the antibiotic, macrolide, corticosteroid, influenza antiviral, and influenza immune modulation domains.

2. Submission of Tocilizumab labels

This involves changes to the MHRA CTA for Tocilizumab stock to be used within REMAP-CAP. Supply will be sourced from Roche's clinical trial stock which will have clinical trial labelling.

The QP releasing site will be Roche Pharma AG, Emil Barell-Strasse 1, Grenzach-Whylen, 79639. The QP declaration for Tocilizumab is also attached.

3. Submission of SoECAT V1.0 & V2.0

We are submitting both versions of the SoECAT, which should have been submitted in previous amendments but was missed as an oversight.

4. Submission of the Regulatory Compliance Confirmation (RCC) letter and QP declaration for Baloxavir paediatric formulation and labels

This involves changes to the MHRA CTA for Baloxavir (as an oral solution) stock to be used within REMAP-CAP for paediatric patients. Supply will be sourced from Roche's clinical trial stock which will have clinical trial labelling.

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The QP releasing site will be Roche Pharma AG, Emil Barell-Strasse 1, Grenzach-Whylen, 79639.

5. Updates to all versions of the patient/legal representative information sheets, consent forms, and privacy notice

All information sheets and consent forms and the privacy notice have been updated according to the new European Master ICF as requested by the EU sponsor - University Medical Center (UMC) Utrecht.

Admin changes have been made across all IS/CFs and the privacy notice to correct typographical errors, make the language more lay, ensure consistency in wording/detail, and the addition of a QR code to view our study video/animation.

Please also see attached a letter from the DSMB showing that there were no safety concerns.

There are also new IS/CFs: These are for telephone/remote consent for children, video consent for children, ProLR consent for children, and a summary IS/CF for patients (as we have one for PerLR).

The below documents are included in this submission:

REMAP-CAP-Child 16-17-Video-CF-v1.0-20.11.2024
REMAP-CAP-Child 0-15-Video-CF-v1.0-20.11.2024
REMAP-CAP-Child 0-17 Tel-CF-v1.0-20.11.2024
REMAP-CAP-Child 0-17-ProLR-Sum-ICF-v1.0-13.11.2024
REMAP-CAP-Child 0-9-PIS-ICF-v1.5-13.11.2024 clean
REMAP-CAP-Child 0-9-PIS-ICF-v1.5-13.11.2024 TC
REMAP-CAP-Child 10-15-PIS-ICF-v1.6-13.11.2024 clean
REMAP-CAP-Child 10-15-PIS-ICF-v1.6-13.11.2024 TC
REMAP-CAP-Child 16-17-PIS-ICF-v1.4-13.11.2024 clean
REMAP-CAP-Child 16-17-PIS-ICF-v1.4-13.11.2024 TC
REMAP-CAP-Patient-Video-CF-v1.2-13.11.2024 clean
REMAP-CAP-Patient-Video-CF-v1.2-13.11.2024 TC
REMAP-CAP-PerLR-Video-CF-v1.2-13.11.2024 clean
REMAP-CAP-PerLR-Video-CF-v1.2-13.11.2024 TC
REMAP-CAP-Tel-CF-v2.1-13.11.2024 clean
REMAP-CAP-Tel-CF-v2.1-13.11.2024 TC
REMAP-CAP-ProLR-Sum-ICF-v1.11-13.11.2024 clean
REMAP-CAP-ProLR-Sum-ICF-v1.11-13.11.2024 TC
REMAP-CAP-PerLR-Sum-ICF-v1.7-13.11.2024 clean
REMAP-CAP-PerLR-Sum-ICF-v1.7-13.11.2024 TC
REMAP-CAP-PerLRIS-ICF-v1.19-13.11.2024 clean
REMAP-CAP-PerLRIS-ICF-v1.19-13.11.2024 TC
REMAP-CAP-PIS-ICF-UK-v1.19-13.11.2024 clean
REMAP-CAP-PIS-ICF-UK-v1.19-13.11.2024 TC
REMAP-CAP-PIS-Sum-ICF-v1.0-20.11.2024
REMAP-CAP-Privacy-Notice-v1.2-25.11.2024
REMAP-CAP_SmPC_Amoxicillin-Clavulanate_20200303_current
REMAP-CAP_SmPC_Azithromycin powder_20220622_current
REMAP-CAP_SmPC_Azithromycin tablet_20220519_current
REMAP-CAP_SmPC_Baloxavir_20230615_tablets
REMAP-CAP_SmPC_Baloxavir_20210107_granules
REMAP-CAP_SmPC_Ceftriaxone_20230221_current

REMAP-CAP_SmPC_Baricitinib (Olumiant)_20230925_current
REMAP-CAP_SmPC_Ceftriaxone_20230221_current
REMAP-CAP_SmPC_Clarithromycin powder_20230127_current
REMAP-CAP_SmPC_Clarithromycin tablet_20230715_current
REMAP-CAP_SmPC_Dexamethasone Injection_20220225_current
REMAP-CAP_SmPC_Dexamethasone Tablet_20220814_current
REMAP-CAP_SmPC_Erythromycin powder_20220622_current
REMAP-CAP_SmPC_Erythromycin tablet_20230702_current
REMAP-CAP_SmPC_Hydrocortisone_20230607_current
REMAP-CAP_SmPC_Levofloxacin_20221102_current
REMAP-CAP_SmPC_Moxifloxacin_20201109_current
REMAP-CAP_SmPC_Oseltamivir (Tamiflu)_20210525_current
REMAP-CAP_SmPC_Piperacillin-Tazobactam_20221219_current
REMAP-CAP_SmPC_Roxithromycin_202005XX_current
REMAP-CAP_SmPC_Tocilizumab (RoActemra)_20221122_current
FM-0061 Regulatory Compliance Confirmation Letter CTR switch MV43976_Baloxavir
GxP-0566740_MV43976_QP_Baloxavir_2MG_719-1686/F08-01 Secondary packaging
MV43976_BALO_2G_40MG_20ML_BX_39030769
MV43976_BALO_2G_40MG_20ML_BX_39030769_BFP
MV43976_BALO_2G_40MG_20ML_VL_39030770
MV43976_BALO_2G_40MG_20ML_VL_39030770_BFP
GxP-0556697_MV43976_TOCI_200MG_10ML_BX_39029772
GxP-0556698_MV43976_TOCI_200MG_10ML_BX_39029772_BFP
GxP-0556699_MV43976_TOCI_200MG_10ML_VL_39029773
GxP-0556700_MV43976_TOCI_200MG_10ML_VL_39029773_BFP
QP Declaration Tocilizumab GxP-0370888[60]
MhraProductsForm
REMAP-CAP SoECAT V1.0
REMAP-CAP SoECAT V2.0
REMAP-CAP_DSMB Letter_20241107

Many Thanks
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