

London - Surrey Borders Research Ethics Committee

Research Ethics Committee (REC) London Centre
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**Please note: This is an
acknowledgement letter from
the REC only and does not
allow you to start your study
at NHS sites in England until
you receive HRA Approval**

30 April 2018

Professor Anthony Gordon
UK Chief Investigator
Imperial College London
11th floor Intensive Care Unit
Charing Cross Hospital
Fulham Palace Road
w6 8rf

Dear Professor Gordon

| | |
|-------------------------|---|
| Study title: | Randomized, Embedded, Multifactorial, Adaptive Platform trial for Community-Acquired Pneumonia |
| REC reference: | 18/LO/0660 |
| EudraCT number: | 2015-002340-14 |
| IRAS project ID: | 237150 |

Thank you for your letter of 30 April 2018. I can confirm the REC has received the documents listed below and that these comply with the approval conditions detailed in our letter dated 26 April 2018

Documents received

The documents received were as follows:

| <i>Document</i> | <i>Version</i> | <i>Date</i> |
|---|----------------|---------------|
| Participant information sheet (PIS) [UK REMAP-CAP Information for participants and Consent Form] | 2.0 | 19 April 2018 |
| Participant information sheet (PIS) [UK REMAP-CAP Retrospective Information for participants and Consent Form] | 2.0 | 19 April 2018 |
| Participant information sheet (PIS) [UK REMAP-CAP Information for PerLR and Consent Form] | 2.0 | 19 April 2018 |
| Response to Additional Conditions Met | | 30 April 2018 |

Approved documents

The final list of approved documentation for the study is therefore as follows:

| <i>Document</i> | <i>Version</i> | <i>Date</i> |
|---|----------------|------------------|
| Copies of advertisement materials for research participants | VERSION 1 | 21 December 2017 |
| Copies of advertisement materials for research participants | VERSION 1 | 21 December 2017 |
| Covering letter on headed paper [REC covering letter from CI] | | 20 March 2018 |
| Evidence of Sponsor insurance or indemnity (non NHS Sponsors only) | | 16 January 2018 |
| HRA Schedule of Events [HRA Schedule of Events Validated] | Version 1 | 07 February 2018 |
| HRA Statement of Activities [HRA Statement of Activities Validated] | Version 1 | 19 March 2018 |
| Initial Assessment for REC [Initial Assessment for REC] | | 16 April 2018 |
| IRAS Application Form [IRAS_Form_23032018] | | 23 March 2018 |
| IRAS Application Form XML file [IRAS_Form_23032018] | | 23 March 2018 |
| Letter from sponsor | | 13 March 2018 |
| Other [REMAP-CAP Protocol Amendment Summary] | version 2 | 13 December 2017 |
| Other [REMAP-CAP European Region-Specific Appendix] | version 2 | 14 December 2017 |
| Other [REMAP-CAP Macrolide Duration Domain-Specific Appendix] | version 2 | 12 December 2017 |
| Other [REMAP-CAP Statistical Analysis Appendix] | version 2 | 12 December 2017 |
| Other [REMAP-CAP Synopsis] | version 2 | 15 January 2018 |
| Other [REMAP-CAP Antibiotic Domain-Specific Appendix] | version 2 | 12 December 2017 |
| Other [REMAP-CAP Corticosteroid Domain-Specific Appendix] | version 2 | 12 December 2017 |
| Other [Levofloxacin SPC] | version 1 | 14 February 2018 |
| Other [Moxifloxacin SPC] | version 1 | 14 February 2018 |
| Other [Pip-tazo SPC] | version 1 | 14 February 2018 |
| Other [Azithromycin SPC] | version 1 | 14 February 2018 |
| Other [Ceftaroline SPC] | version 1 | 14 February 2018 |
| Other [Ceftriaxone SPC] | version 1 | 14 February 2018 |
| Other [Clarithromycin SPC] | version 1 | 14 February 2018 |
| Other [Co_amoxi_clav SPC] | version 1 | 14 February 2018 |
| Participant information sheet (PIS) [ProLR ICF] | version 1 | 07 March 2018 |
| Participant information sheet (PIS) [UK REMAP-CAP Information for participants and Consent Form] | 2.0 | 19 April 2018 |

| | | |
|---|-----------|------------------|
| Participant information sheet (PIS) [UK REMAP-CAP Retrospective Information for participants and Consent Form] | 2.0 | 19 April 2018 |
| Participant information sheet (PIS) [UK REMAP-CAP Information for PerLR and Consent Form] | 2.0 | 19 April 2018 |
| Research protocol or project proposal [Core Protocol] | version 2 | 12 December 2017 |
| Response to Additional Conditions Met | | 30 April 2018 |
| Summary CV for Chief Investigator (CI) [Prof Gordon CV] | | 01 February 2018 |
| Summary of product characteristics (SmPC) [Hydrocortisone SMPC] | | 14 February 2018 |
| Summary, synopsis or diagram (flowchart) of protocol in non technical language [Protocol summary] | version 2 | 15 January 2018 |

You should ensure that the sponsor has a copy of the final documentation for the study. It is the sponsor's responsibility to ensure that the documentation is made available to R&D offices at all participating sites.

18/LO/0660

Please quote this number on all correspondence

Yours sincerely



Barbara Cuddon
REC Manager

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Copy to: *Dr Farah Al-Beidh*
Mrs Gisela / M Pereira Barreto, Imperial College London Healthcare Trust