

**RE: IRAS PROJECT ID 237150, REC Reference 18/LO/0660 expedited approval AM026**

Surrey Borders <surreyborders.rec@hra.nhs.uk>

Tue 03/08/2021 16:37

To: ukremap-cap <ukremap-cap@icnarc.org>; Ashley Totenhofer <Ashley.Totenhofer@hra.nhs.uk>

Cc: Surrey Borders <surreyborders.rec@hra.nhs.uk>

Dear Farah

I've had a quick look into this amendment in Ashley's absence and it looks like AM27 documents were incorporated into AM26 as they were related. AM26 therefore covers approval for both.

Many thanks

Maeve

**Maeve Groot Bluemink** (she/her and they/them)  
**Approvals Manager**  
**Health Research Authority**  
W. [www.hra.nhs.uk](http://www.hra.nhs.uk)

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**From:** ukremap-cap <ukremap-cap@icnarc.org>

**Sent:** 02 August 2021 11:03

**To:** Ashley Totenhofer <Ashley.Totenhofer@hra.nhs.uk>

**Cc:** Surrey Borders <surreyborders.rec@hra.nhs.uk>

**Subject:** Re: IRAS PROJECT ID 237150, REC Reference 18/LO/0660 expedited approval AM026

**Study Title: Randomized, Embedded, Multi-factorial, Adaptive Platform Trial for community -Acquired Pneumonia**

**REC reference: 18/lo/0660**

**EudraCT number: 2015-002340-14**

**IRAS project ID: 237150**

**Substantial amendment 27 (AM027) Expedited Approval**

Hello Ashley,

I hope you are well and had a lovely weekend. I know you had previously indicated that your REC approval would cover both AM026 and AM027, however the approval letter and email only covers AM026. Can you confirm that REC / HRA approval is not required for AM027

**Farah Al-Beidh PhD**

UK REMAP-CAP Trial Manager

Imperial College London / ICNARC

**Tel: 02075949725**

**Mobile: 07714051401 / 07956132684**

Email: [ukremap-cap@icnarc.org](mailto:ukremap-cap@icnarc.org)

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**From:** Ashley Totenhofer <[Ashley.Totenhofer@hra.nhs.uk](mailto:Ashley.Totenhofer@hra.nhs.uk)>  
**Sent:** 29 July 2021 10:58  
**To:** ukremap-cap <[ukremap-cap@icnarc.org](mailto:ukremap-cap@icnarc.org)>  
**Cc:** Surrey Borders <[surreyborders.rec@hra.nhs.uk](mailto:surreyborders.rec@hra.nhs.uk)>  
**Subject:** RE: IRAS PROJECT ID 237150, REC Reference 18/LO/0660 expedited approval AM026

Dear Farah

Please see attached.

Kind regards

Ashley

**Ashley Totenhofer** (he/him)  
**Workflow Monitoring Manager**  
**Health Research Authority**

3<sup>rd</sup> Floor Barlow House | 4 Minshull Street | Manchester | M1 3DZ

**T.** 0207 104 8017

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**From:** ukremap-cap <[ukremap-cap@icnarc.org](mailto:ukremap-cap@icnarc.org)>  
**Sent:** 28 July 2021 11:59  
**To:** Ashley Totenhofer <[Ashley.Totenhofer@hra.nhs.uk](mailto:Ashley.Totenhofer@hra.nhs.uk)>; ukremap-cap <[ukremap-cap@icnarc.org](mailto:ukremap-cap@icnarc.org)>  
**Cc:** Surrey Borders <[surreyborders.rec@hra.nhs.uk](mailto:surreyborders.rec@hra.nhs.uk)>  
**Subject:** Re: IRAS PROJECT ID 237150, REC Reference 18/LO/0660 expedited approval AM026

Hello, please see MHRA approval letter for AM027, Just received.  
It would be great if we can have HRA approval for AM026/AM027 ASAP.  
Thanks  
Farah

**Farah Al-Beidh PhD**

UK REMAP-CAP Trial Manager

Imperial College London / ICNARC

**Tel: 02075949725****Mobile: 07714051401 / 07956132684**Email: [ukremap-cap@icnarc.org](mailto:ukremap-cap@icnarc.org)

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**From:** Ashley Totenhofer <[Ashley.Totenhofer@hra.nhs.uk](mailto:Ashley.Totenhofer@hra.nhs.uk)>  
**Sent:** 05 July 2021 13:17  
**To:** ukremap-cap <[ukremap-cap@icnarc.org](mailto:ukremap-cap@icnarc.org)>  
**Cc:** Surrey Borders <[surreyborders.rec@hra.nhs.uk](mailto:surreyborders.rec@hra.nhs.uk)>  
**Subject:** RE: IRAS PROJECT ID 237150, REC Reference 18/LO/0660 expedited approval AM026

Hi Farah

Yes, you will get a single Approval which covers AM026 and AM027.

Kind regards

Ashley

**Ashley Totenhofer** (he/him)  
**Workflow Monitoring Manager**  
**Health Research Authority**

3<sup>rd</sup> Floor Barlow House | 4 Minshull Street | Manchester | M1 3DZ**T.** 0207 104 8017**E.** [ashley.totenhofer@hra.nhs.uk](mailto:ashley.totenhofer@hra.nhs.uk)**W.** [www.hra.nhs.uk](http://www.hra.nhs.uk)Sign up to receive our newsletter [HRA Latest](#).For information on the HRA's work on Covid19 please visit this link: <https://www.hra.nhs.uk/about-us/news-updates/research-nhs-during-covid-19-pandemic/>

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**From:** ukremap-cap <[ukremap-cap@icnarc.org](mailto:ukremap-cap@icnarc.org)>  
**Sent:** 05 July 2021 13:16  
**To:** Ashley Totenhofer <[Ashley.Totenhofer@hra.nhs.uk](mailto:Ashley.Totenhofer@hra.nhs.uk)>  
**Cc:** Surrey Borders <[surreyborders.rec@hra.nhs.uk](mailto:surreyborders.rec@hra.nhs.uk)>  
**Subject:** Re: IRAS PROJECT ID 237150, REC Reference 18/LO/0660 expedited approval AM026

Hello Ashley,

Just to be clear. Once the MHRA provide approval for AM027 you will be able to approve AM026?

Thanks

Farah

**Farah Al-Beidh PhD**

UK REMAP-CAP Trial Manager

Imperial College London / ICNARC

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**From:** Ashley Totenhofer <[Ashley.Totenhofer@hra.nhs.uk](mailto:Ashley.Totenhofer@hra.nhs.uk)>

**Sent:** 05 July 2021 13:13

**To:** ukremap-cap <[ukremap-cap@icnarc.org](mailto:ukremap-cap@icnarc.org)>

**Cc:** Surrey Borders <[surreyborders.rec@hra.nhs.uk](mailto:surreyborders.rec@hra.nhs.uk)>

**Subject:** RE: IRAS PROJECT ID 237150, REC Reference 18/LO/0660 expedited approval AM026

Dear Farah

I can see you have now submitted the updated IB's. Once we have a copy of the4 MHRA Approval letter we can issue HRA Approval.

Kind regards

Ashley

**Ashley Totenhofer** (he/him)  
**Workflow Monitoring Manager**  
**Health Research Authority**

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**From:** ukremap-cap <[ukremap-cap@icnarc.org](mailto:ukremap-cap@icnarc.org)>

**Sent:** 01 July 2021 09:45

**To:** Ashley Totenhofer <[Ashley.Totenhofer@hra.nhs.uk](mailto:Ashley.Totenhofer@hra.nhs.uk)>

**Cc:** Catherine Adams <[Catherine.Adams@hra.nhs.uk](mailto:Catherine.Adams@hra.nhs.uk)>

**Subject:** Re: IRAS PROJECT ID 237150, REC Reference 18/LO/0660 expedited approval AM026

AM027 only needs MHRA approval, and so has not been submitted to the REC /HRA, the changes the MHRA need to the IB do not need REC approval. I will send you the updated document and approval when they come through.

Thanks

Farah

**Farah Al-Beidh PhD**

UK REMAP-CAP Trial Manager

Imperial College London / ICNARC

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**Mobile: 07714051401 / 07956132684**

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**From:** Ashley Totenhofer <[Ashley.Totenhofer@hra.nhs.uk](mailto:Ashley.Totenhofer@hra.nhs.uk)>

**Sent:** 01 July 2021 09:01

**To:** ukremap-cap <[ukremap-cap@icnarc.org](mailto:ukremap-cap@icnarc.org)>

**Cc:** Catherine Adams <[Catherine.Adams@hra.nhs.uk](mailto:Catherine.Adams@hra.nhs.uk)>

**Subject:** RE: IRAS PROJECT ID 237150, REC Reference 18/LO/0660 expedited approval AM026

Dear Farah

Thank you for your email. Has AM027 been submitted to us as I can't see this on our system? If the changes the MHRA need don't require REC review you can forward me the updated documents together with the MHRA Approval. However if they need review by the REC AM027 would need to be submitted for REC review as normal.

Kind regards

Ashley

**Ashley Totenhofer** (he/him)  
**Workflow Monitoring Manager**  
**Health Research Authority**

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**From:** ukremap-cap <[ukremap-cap@icnarc.org](mailto:ukremap-cap@icnarc.org)>

**Sent:** 30 June 2021 17:05

**To:** Surrey Borders <[surreyborders.rec@hra.nhs.uk](mailto:surreyborders.rec@hra.nhs.uk)>; Surrey Borders <[surreyborders.rec@hra.nhs.uk](mailto:surreyborders.rec@hra.nhs.uk)>; Catherine Adams <[Catherine.Adams@hra.nhs.uk](mailto:Catherine.Adams@hra.nhs.uk)>; ukremap-cap <[ukremap-cap@icnarc.org](mailto:ukremap-cap@icnarc.org)>

**Subject:** Re: IRAS PROJECT ID 237150, REC Reference 18/LO/0660 expedited approval AM026

**Study Title: Randomized, Embedded, Multi-factorial, Adaptive Platform Trial for community -Acquired Pneumonia**

**REC reference: 18/lo/0660**

**EudraCT number: 2015-002340-14**

**IRAS project ID: 237150**

**Substantial amendment 26 (AM026) Expedited Approval**

Dear REC / HRA,

The MHRA have rejected AM026, as indicated below, as they could not approve the IB without the safety information. They have now requested that the IB and the IMP specific information is submitted as AM027. This has now been done.

Would the HRA be able to approve the:  
Information sheets  
Study funding document and extension  
Closure of the Antiplatelet domain

I hope that is clear, please let me know if you need anything further from me  
Many Thanks  
Farah

**Farah Al-Beidh PhD**

UK REMAP-CAP Trial Manager

Imperial College London / ICNARC

**Tel: 02075949725****Mobile: 07714051401 / 07956132684**Email: [ukremap-cap@icnarc.org](mailto:ukremap-cap@icnarc.org)

---

**From:** ukremap-cap <[ukremap-cap@icnarc.org](mailto:ukremap-cap@icnarc.org)>**Sent:** 25 June 2021 12:14**To:** [gram.nrspcc@nhs.scot](mailto:gram.nrspcc@nhs.scot) <[gram.nrspcc@nhs.scot](mailto:gram.nrspcc@nhs.scot)>; Researchgw Amendments <[Research.Amendments@hscni.net](mailto:Research.Amendments@hscni.net)>; [research-permissions@wales.nhs.uk](mailto:research-permissions@wales.nhs.uk) <[research-permissions@wales.nhs.uk](mailto:research-permissions@wales.nhs.uk)>; Surrey Borders <[surreyborders.rec@hra.nhs.uk](mailto:surreyborders.rec@hra.nhs.uk)>; Surrey Borders <[surreyborders.rec@hra.nhs.uk](mailto:surreyborders.rec@hra.nhs.uk)>; undefined <[catherine.adams@hra.nhs.uk](mailto:catherine.adams@hra.nhs.uk)>**Subject:** Re: IRAS PROJECT ID 237150, REC Reference 18/LO/0660 expedited approval**Study Title:** Randomized, Embedded, Multi-factorial, Adaptive Platform Trial for community -Acquired Pneumonia**REC reference:** 18/lo/0660**EudraCT number:** 2015-002340-14**IRAS project ID:** 237150**Substantial amendment 26 (AM026) Expedited Approval**

Dear REC / HRA,

The MHRA have rejected AM026, as they could not approve the IB without the safety information. They have now requested that the IB and the IMP specific information is submitted as AM027.

Would the REC / HRA be able to approve the:

Information sheets

Study funding document and extension

Closure of the Antiplatelet domain

I will then continue to submit the IMP documentation for MHRA approval as part of AM027 later today.

I hope that is clear, please let me know if you need anything further from me

Many Thanks

Farah

**Farah Al-Beidh PhD**

UK REMAP-CAP Trial Manager

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---

**From:** ukremap-cap <[ukremap-cap@icnarc.org](mailto:ukremap-cap@icnarc.org)>

**Sent:** 25 June 2021 11:03

**To:** [gram.nrspcc@nhs.scot](mailto:gram.nrspcc@nhs.scot) <[gram.nrspcc@nhs.scot](mailto:gram.nrspcc@nhs.scot)>; Researchgw Amendments <[Research.Amendments@hscni.net](mailto:Research.Amendments@hscni.net)>; [research-permissions@wales.nhs.uk](mailto:research-permissions@wales.nhs.uk) <[research-permissions@wales.nhs.uk](mailto:research-permissions@wales.nhs.uk)>; Surrey Borders <[surreyborders.rec@hra.nhs.uk](mailto:surreyborders.rec@hra.nhs.uk)>; Surrey Borders <[surreyborders.rec@hra.nhs.uk](mailto:surreyborders.rec@hra.nhs.uk)>

**Cc:** ukremap-cap <[ukremap-cap@icnarc.org](mailto:ukremap-cap@icnarc.org)>

**Subject:** Re: IRAS PROJECT ID 237150, REC Reference 18/LO/0660 Confirmation of favourable opinion for substantial amendment

**Study Title:** Randomized, Embedded, Multi-factorial, Adaptive Platform Trial for community -Acquired Pneumonia

**REC reference:** 18/lo/0660

**EudraCT number:** 2015-002340-14

**IRAS project ID:** 237150

**Substantial amendment 26 (AM026) Expedited Approval**

Hello REC/HRA teams,

Just to keep you updated, the MHRA requested an updated DMX-200 IB that included an RSI section. This has just been submitted for MHRA approval, but i wanted to provide you with the updated cover letter provided to the MHRA.

I also wanted to notify you that the REMAP-CAP Antiplatelet domain has formally closed.

*On the 22<sup>nd</sup> of June 2021 the REMAP-CAP International Trial Steering Committee (ITSC) received correspondence from the REMAP-CAP DSMB notifying us of Platform Conclusions arising from an adaptive analysis.*

*This adaptive analysis revealed that for patients with COVID-19 who are receiving organ support in an ICU, antiplatelet therapy, either with aspirin or P2Y12 inhibitor (which were found to be equivalent), was ineffective when compared to no antiplatelet therapy (OR = 0.99 [95% CrI 0.82 – 1.19], probability of OR < 1.2 = 98%). The unanimous recommendation of the DSMB was that this domain be closed for patients with severe COVID-19 (i.e. patients receiving organ support in an ICU). This recommendation has been accepted by the ITSC.*

*In addition, in light of the recent publication of [results from the RECOVERY trial, which found that treatment with aspirin did not improve 28-day mortality](#), the REMAP-CAP ITSC have decided to also close the Antiplatelet Domain to patients with moderate COVID-19 (i.e. hospitalised patients not receiving organ support in an ICU). These data are reflective of high-quality evidence from a large randomised trial, which further suggest that antiplatelet therapy is not associated with improved outcomes for patients with COVID-19.*

Many Thanks for your help and support with this trial  
Farah



**Farah Al-Beidh PhD**

UK REMAP-CAP Trial Manager

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**From:** Farah Al-Beidh <[Farah.Al-Beidh@icnarc.org](mailto:Farah.Al-Beidh@icnarc.org)>**Sent:** 05 June 2021 08:50**To:** ukremap-cap <[ukremap-cap@icnarc.org](mailto:ukremap-cap@icnarc.org)>**Subject:** Fw: IRAS PROJECT ID 237150, REC Reference 18/LO/0660 Confirmation of favourable opinion for substantial amendment

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**From:** [surreyborders.rec@hra.nhs.uk](mailto:surreyborders.rec@hra.nhs.uk) <[noreply@harp.org.uk](mailto:noreply@harp.org.uk)>**Sent:** Friday, June 4, 2021 3:27 PM**To:** [anthony.gordon@imperial.ac.uk](mailto:anthony.gordon@imperial.ac.uk) <[anthony.gordon@imperial.ac.uk](mailto:anthony.gordon@imperial.ac.uk)>; Farah Al-Beidh <[Farah.Al-Beidh@icnarc.org](mailto:Farah.Al-Beidh@icnarc.org)>**Cc:** [gram.nrspcc@nhs.scot](mailto:gram.nrspcc@nhs.scot) <[gram.nrspcc@nhs.scot](mailto:gram.nrspcc@nhs.scot)>; [research.amendments@hscni.net](mailto:research.amendments@hscni.net) <[research.amendments@hscni.net](mailto:research.amendments@hscni.net)>; [research-permissions@wales.nhs.uk](mailto:research-permissions@wales.nhs.uk) <[research-permissions@wales.nhs.uk](mailto:research-permissions@wales.nhs.uk)>**Subject:** IRAS PROJECT ID 237150, REC Reference 18/LO/0660 Confirmation of favourable opinion for substantial amendment

Dear Prof Gordon

|   |   |
|---|---|
| <b>IRAS project ID:</b>                             | 237150  |
| <b>REC reference:</b>                               | 18/LO/0660  |
| <b>Short Study title:</b>                           | REMAP-CAP [COVID-19] [UPH]  |
| <b>Date complete amendment submission received:</b> | 02 June 2021  |
| <b>Amendment No./ Sponsor Ref:</b>                  | AM026   |
| <b>Amendment Date:</b>                              | 02 June 2021  |
| <b>Amendment Type:</b>                              | <b>Substantial</b>  |
| <b>Outcome of HRA Assessment</b>                    | <b>HRA and HCRW Approval for the amendment is pending – HRA and</b> |

|  |
|--|
| HCRW Approval for the amendment will be separately confirmed by email. |
|--|

I am pleased to confirm that this amendment has been reviewed by the Research Ethics Committee and has received a Favourable Opinion. Please find attached a copy of the Favourable Opinion letter.

### HRA and HCRW Approval Status

As detailed above, **HRA and HCRW Approval for this amendment is pending.** HRA and HCRW Approval for the amendment will be separately confirmed by email. You should not implement this amendment at participating NHS organisations in England and/or Wales until HRA and HCRW Approval is issued.

If you require further information, please contact me.

Kind regards

**Chelsea Phillips**

**Approvals Administrator**

The Old Chapel | Royal Standard Place | HRA | NG1 6FS

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