
Fw: CEC 214784 : REMAP-CAP SA042 approval pending

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

Date Thu 03/04/2025 13:03

To ukremap-cap <ukremap-cap@icnarc.org>

From: Clinical Trial Helpline <ctdhelpline@mhra.gov.uk>

Sent: 01 April 2025 09:46

To: ukremap-cap <ukremap-cap@icnarc.org>

Subject: CEC 214784 : REMAP-CAP SA042 approval pending

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Dear Aisha,

Thank you for your email.

We have reviewed your request and can provide the following advice from expert.

We have reviewed the Sponsors response and can confirm the conditions have been met and no further action is required.

Please advise for future amendment applications with updates to the trial RSI, a summary of changes document is provided in that amendment application to support the changes.

Our opening hours are Mon – Fri 08:30am – 4:30pm (excluding UK Public Holidays)

With regards

Rajesh

MHRA Customer Experience Centre

Medicines and Healthcare products Regulatory Agency

10 South Colonnade, Canary Wharf, London E14 4PU

Telephone 020 3080 6456

Email: clintrialhelpline@mhra.gov.uk

[gov.uk/mhra](https://www.gov.uk/mhra)

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From: Clinical Trial Helpline <ctdhelpline@mhra.gov.uk>

Sent: 27 March 2025 12:34

To: ukremap-cap <ukremap-cap@icnarc.org>

Subject: FW: CEC 214784 : REMAP-CAP SA042 approval pending

Dear Aisha

Thank you for your email re **REMAP-CAP SA042 approval pending**.

This has now been resolved by our experts.

Our assessor is still reviewing the documentation. Unfortunately they have competing priorities but we will endeavour to get the response back to you as soon as we can.

We trust that this resolves your request.

Our opening hours are Mon – Fri 08:30am to 4:30pm (excluding UK Public Holidays).

With regards

Leonard

MHRA Customer Experience Centre

Clinical Investigations Trials

Medicines and Healthcare products Regulatory Agency

10 South Colonnade, Canary Wharf, London E14 4PU

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Medicines & Healthcare products
Regulatory Agency

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

Sent: 25 March 2025 12:02

To: Clinical Trial Helpline <ctdhelpline@mhra.gov.uk>

Cc: ukremap-cap <ukremap-cap@icnarc.org>

Subject: RE: CEC 214784 : REMAP-CAP SA042 approval pending

Hello,

Do you know how long before we should receive an approval letter?

Kind regards

Aisha

From: Clinical Trial Helpline <ctdhelpline@mhra.gov.uk>

Sent: 21 March 2025 15:21

To: ukremap-cap <ukremap-cap@icnarc.org>

Subject: RE: CEC 214784 : REMAP-CAP SA042 approval pending

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Dear Aisha

Thank you for your follow up email dated **21 March 2025** re **REMAP-CAP SA042 approval pending**.

We have redirected your query to our experts for a response.

Our opening hours are Mon – Fri 08:30am to 4:30pm (excluding UK Public Holidays).

Kind regards

Leonard

MHRA Customer Experience Centre

Clinical Investigations Trials

Medicines and Healthcare products Regulatory Agency

10 South Colonnade, Canary Wharf, London E14 4PU

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Privacy Notices: [MHRA](#), [CPRD](#) and [NIBSC](#).



Medicines & Healthcare products
Regulatory Agency

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

Sent: 21 March 2025 11:34

To: Clinical Trial Helpline <ctdhelpline@mhra.gov.uk>

Cc: ukremap-cap <ukremap-cap@icnarc.org>

Subject: RE: CEC 214784 : REMAP-CAP SA042 approval pending

Hello,

Thank you for confirming the letter had conditions.

Could you confirm that our response to the conditions which I attached in my previous email is being processed?

When should we expect a further letter from your team confirming conditions have been met?

Kind regards

Aisha

USEFUL LINKS:

[Training for staff – Remapcap-UK](#)

[REMAP-CAP eCRF Data Completion Guidelines V14 – Remapcap-UK](#)

[FAQ – Remapcap-UK](#)



UK REMAP-CAP Team
Imperial College London / ICNARC
Email: ukremap-cap@icnarc.org
Web: www.remapcap.co.uk

Janis Best-Lane - Senior Trial Manager - 020 7594 5906 / 07714 051680
Aisha Anjum - Trial Manager - 07956 800722
Beren Barklam - Trial Coordinator/Monitor - 020 4513 6242
Lucy Stronach - Trial Monitor
Tina Reetun - Trial Monitor
Lindsay Jack - Trial Monitor

From: Clinical Trial Helpline <ctdhelpline@mhra.gov.uk>
Sent: 21 March 2025 11:21
To: ukremap-cap <ukremap-cap@icnarc.org>
Subject: FW: CEC 214784 : REMAP-CAP SA042 approval pending

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Dear Aisha

Thank you for your email dated **19 March 2025** re **REMAP-CAP SA042 approval pending**.

This has now been resolved by our experts.

The Notice of Acceptance of Amendment letter that you provided is the same letter that we have on record that was provided to you. This letter includes conditions. We apologise for any confusion.

We trust that this resolves your request.

Our opening hours are Mon – Fri 08:30am to 4:30pm (excluding UK Public Holidays).

With regards

Leonard
MHRA Customer Experience Centre
Clinical Investigations Trials
Medicines and Healthcare products Regulatory Agency
10 South Colonnade, Canary Wharf, London E14 4PU
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From: ukremap-cap <ukremap-cap@icnarc.org>
Sent: 19 March 2025 14:26
To: Clinical Trial Helpline <ctdhelpline@mhra.gov.uk>
Cc: ukremap-cap <ukremap-cap@icnarc.org>
Subject: RE: CEC 214784 : REMAP-CAP SA042 approval pending

Dear Team,

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

CTA 30913/0006/001-0038 & submission ID: 100839402

I just called in and have been told that SA042 was 'closed' on the system with evidence of an acceptance letter with no conditions.

We're a little confused – I've attached confirmation of our submitted response on 4Feb25 following the acceptance with conditions received on 8Jan25, also attached.

We chased via email on 24Feb25 and heard nothing back once 14 days passed until I called today.

I have attached a zip file of the documents we submitted to meet the conditions (cover letter + 8x SoC for SmPCs), we'd be very grateful if you could please look into this.

Many thanks

Kind regards

Aisha

USEFUL LINKS:

[Training for staff – Remapcap-UK](#)

[REMAP-CAP eCRF Data Completion Guidelines V14 – Remapcap-UK](#)

[FAQ – Remapcap-UK](#)



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Aisha Anjum - Trial Manager - 07956 800722

Beren Barklam - Trial Coordinator/Monitor - 020 4513 6242

Lucy Stronach - Trial Monitor

Tina Reetun - Trial Monitor

Lindsay Jack - Trial Monitor

From: Clinical Trial Helpline <ctdhelpline@mhra.gov.uk>
Sent: 25 February 2025 16:16
To: ukremap-cap <ukremap-cap@icnarc.org>
Subject: CEC 214784 : REMAP-CAP SA042 approval pending

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Dear Aisha,

Thank you for your email.

We have forwarded your email to CT Submission for an update.

If you have not heard from us within 14 calendar days, please contact us.

Our opening hours are Mon – Fri 08:30am – 4:30pm (excluding UK Public Holidays)

With regards

Rajesh
MHRA Customer Experience Centre
Medicines and Healthcare products Regulatory Agency
10 South Colonnade, Canary Wharf, London E14 4PU
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From: ukremap-cap <ukremap-cap@icnarc.org>
Sent: 24 February 2025 11:45
To: Submissions <Submissions@mhra.gov.uk>
Cc: ukremap-cap <ukremap-cap@icnarc.org>
Subject: RE: REMAP-CAP SA042 approval pending

You don't often get email from ukremap-cap@icnarc.org. [Learn why this is important](#)

Dear MHRA,

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

Please could we have an update following our response to SA042 conditional approval submitted on 4th Feb 2025? Many thanks

Kind regards
Aisha

USEFUL LINKS:

[Training for staff – Remapcap-UK](#)

[REMAP-CAP eCRF Data Completion Guidelines V14 – Remapcap-UK](#)

[FAQ – Remapcap-UK](#)



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Aisha Anjum - Trial Manager - 07956 800722

Beren Barklam - Trial Coordinator/Monitor - 020 4513 6242

Lucy Stronach - Trial Monitor

Tina Reetun - Trial Monitor

Lindsay Jack - Trial Monitor

From: No Reply

Sent: 04 February 2025 11:32

To: l.stronach@imperial.ac.uk

Subject: UK (MHRA) Delivery Notification - MHRA_Submission_100852386.xml has been uploaded to UK (MHRA)

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This message was sent to you automatically by MHRA.GOV.UK

Your submission MHRA_Submission_100852386.xml has been uploaded/submitted to UK (MHRA).

Details of your Submission:

Submission ID: 100852386

First Name: Lucy

Surname: Stronach

Email:

ukremap-cap@icnarc.org

elizaveta.malkova@ecraid.eu

EU.remapcap@umcutrecht.nl

Company number: 19174

Comments: Response to MHRA for the REMAP-CAP study AM42 (CTA 30913/0006/001-0038 & submission ID: 100839402)

Department Type: Human Medicines

Regulatory Activity Type: Clinical Trial

Regulatory Sub-activity type: Response

Procedure Type: National

Submission Type: eCTD

Agency: UK(MHRA)

Products:

Reference Number	Product Name
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Technically Validated: No
Validation Tool:
Other Validation Tool:
Covid Submission: No

Regards,

MHRA Submissions Support Team.

Email: submissions@mhra.gov.uk

For further guidance on submitting your application, please take time to read our FAQs and Submissions Guidance.

For technical issues, please raise a ticket via the Help and Support.

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