
RE: MHRA: Substantial Modification Approval: CTA 30913/0006/001-0040 and EudraCT Number: 2015-002340-14

From Ganguly, Hedwig <hedwig.ganguly@mhra.gov.uk>

Date Mon 10/08/2026 17:18

To ukremap-cap <ukremap-cap@icnarc.org>; Anjum, Aisha <a.anjum@imperial.ac.uk>; Clinical Trial Helpline <ctdhelpline@mhra.gov.uk>

Cc EU.remapcap <eu.remapcap@umcutrecht.nl>

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Dear Lucy

You do not need to await for a final response from us as we made a note of what you mentioned earlier and it is acceptable for now.

Kind Regards,

Hedwig

Mrs Hedwig Ganguly

Scientific Assessor

Clinical Investigation and Trial

Innovation and Compliance Group

MHRA

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E: hedwig.ganguly@mhra.gov.uk

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

Sent: 10 August 2026 13:31

To: Ganguly, Hedwig <hedwig.ganguly@mhra.gov.uk>; Anjum, Aisha <a.anjum@imperial.ac.uk>; Clinical Trial Helpline <ctdhelpline@mhra.gov.uk>

Cc: EU.remapcap <eu.remapcap@umcutrecht.nl>; ukremap-cap <ukremap-cap@icnarc.org>

Subject: Re: MHRA: Substantial Modification Approval: CTA 30913/0006/001-0040 and EudraCT Number: 2015-002340-14

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Hi Hedwig,

Thank you for your email.

No problem, please could you confirm whether we need to await a final response from you for this amendment?

Many thanks,
Lucy

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UK REMAP-CAP Team
Imperial College London / ICNARC
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Lucy Stronach - Trial Monitor - 07714051401
Janis Best-Lane - Senior Trial Manager - 07714 051680
Millie Parke - Trial Coordinator
Tina Reetun - Trial Monitor
Lindsay Jack - Trial Monitor
Ashley Alexander - Trial Monitor

From: Ganguly, Hedwig <hedwig.ganguly@mhra.gov.uk>
Sent: 10 August 2026 12:08
To: ukremap-cap <ukremap-cap@icnarc.org>; Anjum, Aisha <a.anjum@imperial.ac.uk>; Clinical Trial Helpline <ctdhelpline@mhra.gov.uk>
Cc: EU.remapcap <eu.remapcap@umcutrecht.nl>
Subject: RE: MHRA: Substantial Modification Approval: CTA 30913/0006/001-0040 and EudraCT Number: 2015-002340-14

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Dear Aisha

Sincere apologies for the delay in responding to your email.

Thank you for the response.

Kind Regards,

Hedwig

Mrs Hedwig Ganguly

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Innovation and Compliance Group

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

Sent: 07 August 2026 15:17

To: Anjum, Aisha <a.anjum@imperial.ac.uk>; Ganguly, Hedwig <hedwig.ganguly@mhra.gov.uk>; Clinical Trial Helpline <ctdhelpline@mhra.gov.uk>

Cc: EU.remapcap <eu.remapcap@umcutrecht.nl>; ukremap-cap <ukremap-cap@icnarc.org>

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Hello,

I just wanted to check if the below sufficed or if we should be waiting for a final response from you before going on to request HRA approval and implementing the amendment?

Kind regards

Aisha

From: Anjum, Aisha <a.anjum@imperial.ac.uk>

Sent: 31 July 2026 15:36

To: hedwig.ganguly@mhra.gov.uk; clintrialhelpline@mhra.gov.uk

Cc: ukremap-cap <ukremap-cap@icnarc.org>; EU.remapcap <eu.remapcap@umcutrecht.nl>

Subject: MHRA: Substantial Modification Approval: CTA 30913/0006/001-0040 and EudraCT Number: 2015-002340-14

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Dear Mrs Hedwig Ganguly,

I hope you are well.

I am emailing in response to the Notice of Acceptance of Substantial Modification received yesterday for SA044, with the following Scientific remark:

A statement made in the cover letter “planned protocol changes to the REMAP-CAP trial. We then proceeded to submit Am44 to the REC and believed also to have submitted to the MHRA at the same time” – Clarification is required if MHRA were to receive any updated protocol document as there were no such documentation been submitted in this application.

Apologies for any confusion, by ‘planned protocol changes’ we refer to the protocol design whereby treatments are planned to be stopped if statistical triggers are reached. We did not submit a protocol document with changes as part of the amendment.

I hope that clarifies.

Kind regards

Aisha



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