

RE: Substantial amendment 26 (AM02) / EudraCT 2015-002340-14

Campbell, Lisa <Lisa.Campbell@mhra.gov.uk>

Fri 11/06/2021 18:15

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

Cc: Jones, David <David.Jones@mhra.gov.uk>; Lewis, Dr Simon <Simon.Lewis@mhra.gov.uk>; Waterson, Ian <Ian.Waterson@mhra.gov.uk>; Campbell, Lisa <Lisa.Campbell@mhra.gov.uk>

Dear Farah

The DMX-200 IB is not approvable as it does not contain a reference safety information section. As there is no option for a GNA with substantial amendments the substantial amendment submission is rejected.

For guidance on RSI please refer to the link provided;

http://www.hma.eu/fileadmin/dateien/Human_Medicines/01-About_HMA/Working_Groups/CTFG/2017_11_CTFG_Question_and_Answer_on_Reference_Safety_Information_2017.pdf

Please email me a draft RSI section if you would like me to pre-assess the modified IB prior to formal submission. We will of course expedite review of your re-submission. Please note that all submitted documents should be listed in the cover letter and the MHRA do not assess patient facing documents (these are for ethics only), as such the latter do not need to be submitted for review.

Kind Regards

Lisa

Lisa Campbell MD MBBCh BSc

Senior Medical Assessor

Clinical Trials Unit

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More information can be found [here](#).

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

Sent: 07 June 2021 12:40

To: Campbell, Lisa <Lisa.Campbell@mhra.gov.uk>












Cc: Jones, David <David.Jones@mhra.gov.uk>; Lewis, Dr Simon <Simon.Lewis@mhra.gov.uk>



















Subject: Re: Substantial amendment 26 (AM02)

Hello Lisa,

I hope you are well and thank you for the update and the support in processing this amendment.

The below documentation was provided for review

-  DIL2501 REMAP CAP label Proof english & dutch 20210505
-  DMX-200 ARDS IB v3.0 SIGNED
-  DMX-200 COVID-19 IMPD v2.0 April 2021
-  DMX-200_REMAP_CAP_label_proof_Part_2_sign_of 20210506
-  Grant Agreement-101003589-RECoVER_FE
-  MIA_Fisher_DE_BW_01_MIA_2021_0022_DE+ EN
-  QP Declaration REMAP CAP_27May2021
-  REMAP-CAP AM026 cover letter 010621
-  Site GMP Certificate FDA EU and Registration Database Reference 2020 Signed
-  IRASEudractExport
-  MhraProductsForm AM026

-  UK REMAP CAP COVID19 PerLR ICF V1.7 2021.06.01 Scotland CLEAN
-  UK REMAP CAP COVID19 PerLR ICF V1.7 2021.06.01 Scotland TC
-  UK REMAP CAP COVID19 PerLRIS ICF v1.8 2021.06.01 NI CLEAN
-  UK REMAP CAP COVID19 PerLRIS ICF v1.8 2021.06.01 NI TC
-  UK REMAP CAP COVID19 PerLRIS ICF v1.9 2021.06.01 CLEAN
-  UK REMAP CAP COVID19 PerLRIS ICF v1.9 2021.06.01 TC
-  UK REMAP CAP COVID19 PIS ICF V1.7 2021.06.01 Scotland CLEAN
-  UK REMAP CAP COVID19 PIS ICF V1.7 2021.06.01 Scotland TC
-  UK REMAP CAP COVID19 PIS ICF V1.8 2020.06.01 NI CLEAN
-  UK REMAP CAP COVID19 PIS ICF V1.8 2020.06.01 NI TC
-  UK REMAP CAP COVID19 PIS v1.9 2021.06.01 CLEAN
-  UK REMAP CAP COVID19 PIS v1.9 2021.06.01 TC
-  UK REMAP CAP COVID19 Retro PIS ICF V1.7 2021.06.01 Scotland CLEAN
-  UK REMAP CAP COVID19 Retro PIS ICF V1.7 2021.06.01 Scotland TC
-  UK REMAP CAP COVID19 Retro PIS ICF V1.8 2020.06.01 NI CLEAN
-  UK REMAP CAP COVID19 Retro PIS ICF V1.8 2020.06.01 NI TC
-  UK REMAP CAP COVID19 Retro PIS ICF v1.9 2021.06.01 CLEAN
-  UK REMAP CAP COVID19 Retro PIS ICF v1.9 2021.06.01 TC

The ACE2-RAS domain specific was not submitted , as this has not changed and was approved as part of AM025.

The IB for DMX-200 has not previously been submitted to the MHRA for review, as this is the 1st time that the DMX-200 intervention itself is being submitted to the MHRA for approval.

I now have access to the MHRA submissions portal and moving forward i will always include a list of submitted documentation for MHRA approval as part of the cover letter.

Please let me know if you need any further information

Many Thanks

Farah

Farah Al-Beidh PhD

UK REMAP-CAP Trial Manager

Imperial College London / ICNARC

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From: Campbell, Lisa <Lisa.Campbell@mhra.gov.uk>

Sent: 07 June 2021 12:10

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

Cc: Jones, David <David.Jones@mhra.gov.uk>; Lewis, Dr Simon <Simon.Lewis@mhra.gov.uk>; Campbell, Lisa <Lisa.Campbell@mhra.gov.uk>

Subject: Substantial amendment 26 (AM02)

Dear Farah Al-Beidh

The CTU have started assessing your recent substantial amendment to add DMX-200 to REMAP-CAP.

As you are aware this will need review by the Expert Advisory Committee and their decision will be available towards the latter part of next week.

In the meantime please can you confirm that there is no updated protocol (we would normally expect a list of documents submitted as part of the submission cover letter for clarity and to ensure no documents are missed, moving forward please ensure this is done for future applications). I note you have submitted the IB for DMX-200 (version 3.0, dated 23rd March 2021) and understand you also previously submitted this as part of SA25.

Kind regards

Lisa

Lisa Campbell MD MBBCh BSc

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Clinical Trials Unit

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