Amendment Tool

v1.5 25 Mar 2021

For office use

QC: No

Section 1: Project information

Short project title*:	REMAP-CAP
IRAS project ID* (or REC reference if no IRAS project ID is available):	237150
Sponsor amendment reference number*:	AM029
Sponsor amendment date* (enter as DD/MM/YY):	22 September 2021
Briefly summarise in lay language the main changes proposed in this amendment. Explain the purpose of the changes and their significance for the study. If the amendment significantly alters the research design or methodology, or could otherwise affect the scientific value of the study, supporting scientific information should be given (or enclosed separately). Indicate whether or not additional scientific critique has been obtained (note: this field will adapt to the amount of text entered)*:	I am submitting substantial amendment AM029 for the REMAP-CAP study. Much of this documentation was submitted as part of AM028, however the MHRA required additional information be provided within the IB and so provided a notice of non-acceptance for AM028. The IMP documentation, supplied as part of AM028, plus the updated IB (and summary of track changes) is now being resubmitted as AM029 for review and approval by the MHRA and HRA. All patient facing documentation remains as part of AM028 for review and approval by the REC / MHRA We added 1 IMP product to the MHRA CTA Cysteamine Bitartrate For AM029 I have submitted the below documents: Amendment_Tool_v1_5_25Mar21 REMAP-CAP AM029 22.09.21 Locked Cysteamine_Nylexa IMPD_V1.0_18 Aug 2021 Nylexa clincial label_Version4.0_13 Jul 2021 REMAP-CAP - Domain Specific Appendix - Cysteamine - V1.0 - 21 June 2021 REMAP-CAP pharmacy guide - Version 3 - 18 August 2021_CLEAN MhraProductsForm_AM028 200821 IRASEudractExport Cysteamine_Nylexa IB_Version1.1_22 Sep 2021 Track changed Cysteamine_Nylexa IB_Version1.1_22 Sep 2021 clean

Project type (select):	◉ Specific study ○ Research tissue bank ○ Research database			
Has the study been reviewed by a UKECA-recognised Research Ethics Committee (REC) prior to this amendment?:	◉ Yes		○ No	
What type of UKECA-recognised Research Ethics Committee (REC) review is applicable? (select):	◉ NHS/HSC REC ○ Ministry of Defence (MoDREC)			
Is all or part of this amendment being resubmitted to the Research Ethics Committee (REC) as a **modified amendment** (i.e. a substantial amendment previously given an unfavourable opinion)?	○ Yes		◉ No	
Where is the NHS/HSC Research Ethics Committee (REC) that reviewed the study based?:	England	Wales	Scotland	Northern Ireland
	◉	○	○	○
Was the study a clinical trial of an investigational medicinal product (CTIMP) OR does the amendment make it one?:	◉ Yes		○ No	
EudraCT number*:	2015-002340-14			
Was this clinical trial of an investigational medicinal product (CTIMP) processed under the Combined Ways of Working (CWoW) pilot?:	◉ Yes		○ No	
Did the study receive Pharmacy Assurance?:	◉ Yes		○ No	
Was the study a clinical investigation or other study of a medical device OR does the amendment make it one?:	○ Yes		◉ No	
Did the study involve the administration of radioactive substances, therefore requiring ARSAC review, OR does the amendment introduce this?:	○ Yes		◉ No	
Did the study involve the use of research exposures to ionising radiation (not involving the administration of radioactive substances) OR does the amendment introduce this?:	○ Yes		◉ No	
Did the study involve adults lacking capacity OR does the amendment introduce this?:	○ Yes		◉ No	
Did the study involve access to confidential patient information outside the direct care team without consent OR does the amendment introduce this?:	◉ Yes		○ No	
Did the study involve prisoners OR does the amendment introduce this?:	○ Yes		◉ No	

Did the study involve children OR does the amendment introduce this?:	○ Yes		◉ No	
Did the study involve NHS/HSC organisations prior to this amendment?:	◉ Yes		○ No	
Did the study involve non-NHS/HSC organisations OR does the amendment introduce them?:	○ Yes		◉ No	
	England	Wales	Scotland	Northern Ireland
Lead nation for the study:	◉	○	○	○
Which nations had participating NHS/HSC organisations prior to this amendment?	☑	☑	☑	☑
Which nations will have participating NHS/HSC organisations after this amendment?	☑	☑	☑	☑

Section 2: Summary of change(s)

What do you want to update?:	○ Chief Investigator ○ Sponsor ○ Administrative ◉ Project information

Please note: Each change being made as part of the amendment must be entered separately. For example, if an amendment to a clinical trial of an investigational medicinal product (CTIMP) involves an update to the Investigator's Brochure (IB), affecting the Reference Safety Information (RSI) and so the information documents to be given to participants, these should be entered into the amendment tool as three separate changes. A list of all possible changes is available on the "Glossary of Amendment Options" tab. To add another change, tick the "Add another change" box.

Change 1	
Area of change (select)*:	CTIMP IMP
Specific change (select - only available when area of change is selected first)*:	IMP being added to the study for the first time
Further information (free text - note that this field will adapt to the amount of text entered):	Much of this documentation was submitted as part of AM028, however the MHRA required additional information be provided within the IB and so provided a notice of non-acceptance for AM028. The IMP documentation, supplied as part of AM028, plus the updated IB (and summary of track changes) is now being resubmitted as AM029 for review and approval by the MHRA and HRA. All patient facing documentation remains as part of AM028 for review and approval by the REC / MHRA We added 1 IMP product to the MHRA CTA Cysteamine Bitartrate For AM029 I have submitted the below documents: Amendment_Tool_v1_5_25Mar21 REMAP-CAP AM029 22.09.21 Locked Cysteamine_Nylexa IMPD_V1.0_18 Aug 2021 Nylexa clincial label_Version4.0_13 Jul 2021 REMAP-CAP - Domain Specific Appendix - Cysteamine - V1.0 - 21 June 2021 REMAP-CAP pharmacy guide - Version 3 - 18 August 2021_CLEAN MhraProductsForm_AM028 200821 IRASEudractExport Cysteamine_Nylexa IB_Version1.1_22 Sep 2021 Track changed Cysteamine_Nylexa IB_Version1.1_22 Sep 2021

Applicability:	England	Wales	Scotland	Northern Ireland
Where are the participating NHS/HSC organisations located that will be affected by this change?*:	☑	☑	☑	☑
Will all participating NHS/HSC organisations be affected by this change, or only some? (**please note** that this answer may affect the categorisation for the change):	◉ All		○ Some	

Add another change: ☐

Section 3: Declaration(s) and lock for submission

Declaration by the Sponsor or authorised delegate

- I confirm that the Sponsor takes responsibility for the completed amendment tool
- I confirm that I have been formally authorised by the Sponsor to complete the amendment tool on their behalf

Applicant identification:	◉ Sponsor ○ Legal representative of the sponsor ○ Person or organisation authorised by the sponsor

Organisation:	RA
Name [first name and surname]:*	Clementina Okundaye
Address:	Heidelberglaan 100, 3584 CX, Utrecht, The Netherlands
Telephone number:	0031 88 755 5196
Fax number:	NA
Purchase Order (PO) number for MHRA invoicing:	R5418.70
Email address:*	eu.remapcap@umcutrecht.nl

Lock for submission

Please note: This button will only become available when all mandatory (*) fields have been completed. When the button is available, clicking it will generate a locked PDF copy of the completed amendment tool which must be included in the amendment submission. Please ensure that the amendment tool is completed correctly before locking it for submission.

Lock for submission

After locking the tool, proceed to submit the amendment online. The "Submission Guidance" tab provides further information about the next steps for the amendment.

Section 4: Review bodies for the amendment

Please note: This section is for **information only**. Details in this section will complete automatically based on the options selected in Sections 1 and 2.

	Review bodies																	
	UK wide:						England and Wales:				Scotland:				Northern Ireland:			
	REC	Competent Authority MHRA - Medicines	Competent Authority MHRA - Devices	ARSAC	Radiation Assurance	UKSW Governance	REC (MCA)	CAG	HMPPS	HRA and HCRW Approval	REC (AWIA)	PBPP	SPS (RAEC)	National coordinating function	HSC REC	HSC Data Guardians	Prisons	National coordinating function	Category:
Change 1:	Y	Y				Y				Y				Y				Y	A
Overall reviews for the amendment:																			
Full review:	Y	Y				Y				Y				Y				Y	
Notification only:	N	N				N				N				N				N	
Overall amendment type:	Substantial for review																		
Overall Category:	A																		

This amendment relates to:	
Part 1:	Yes
Part 2:	No
Notification for authorisation to the competent authority (MHRA - Medicines):	Yes
Notification for an opinion to the ethics committee (REC):	Yes