

Amendment Tool

v1.6 06 December 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*:	AM031			
Sponsor amendment date* (enter as DD/MM/YY):	13 December 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)*:	<p>As part of AM031 i am submitting updated documentation 1. IMPD v2.0 dated 13 Dec 2021_track changed 2. IMPD v2.0 dated 13 Dec 2021_Final 3. Cysteamine label v5.0 dated 20 Aug 2021 – Expiry date extended up to Jun 2022</p> <p>The main changes in the revised IMPD include:</p> <ol style="list-style-type: none"> 1. Change of AMRI name to Curia (Scotland) Limited – page 101 2. Inclusion of 18m stability report for non-GMP batch and 6month stability report for GMP batch : Section 2.1.P.& Stability – p 171 onwards. This data supports extension of expiry date to Jun 2022 3. Shelf-life extension plan – page 177-178 			
Project type (select):	Specific study			
	<div>Research tissue bank</div> <div>Research database</div>			
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
	Yes	No	No	No
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 CTIMP combined review service (formerly known as 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 young offenders who are in custody or supervised by the probation service 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:	Yes	No	No	No

Which nations had participating NHS/HSC organisations prior to this amendment?	Yes	Yes	Yes	Yes
Which nations will have participating NHS/HSC organisations after this amendment?	Yes	Yes	Yes	Yes

Section 2: Summary of change(s)

What do you want to update?:	Project information			
	New site/PI only			

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, click the "Add another change" box.

Change 1				
Area of change (select)*:	Study Documents			
Specific change (select - only available when area of change is selected first)*:	IMPD - Substantial changes (including IMP labels, GMP documents, MIA (IMP), QP declarations)			
Further information (free text - note that this field will adapt to the amount of text entered):	Updated IMPD and labels. The main changes in the revised IMPD include: 1. Change of AMRI name to Curia (Scotland) Limited – page 101 2. Inclusion of 18m stability report for non-GMP batch and 6month stability report for GMP batch : Section 2.1.P.& Stability – p 171 onwards. This data supports extension of expiry date to Jun 2022 3. Shelf-life extension plan – page 177-178			
Applicability:	England	Wales	Scotland	Northern Ireland
Where are the participating NHS/HSC organisations located that will be affected by this change?*	Yes	Yes	Yes	Yes
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 <ul style="list-style-type: none">I confirm that the Sponsor takes responsibility for the completed amendment toolI 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:	University Medical Centre Utrecht
Name [first name and surname]*:	Clementina Okundaye
Address:	Heidelberglaan 100, 3584 CX, Utrecht, The Netherlands
Telephone number:	0031 (0)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																		Category:
	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	
Change 1:		Y																	N/A
Overall reviews for the amendment:																			
Full review:		Y																	
Notification only:		N																	
Overall amendment type:	Substantial for information																		
Overall Category:	N/A																		