Amendment Tool

v1.6 06 December 2021

For office use

QC: Yes

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*:	AM035
Sponsor amendment date* (enter as DD/MM/YY):	12 April 2022
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)*:	Addition of releasing site information to section D9 of the MHRA CTA for licensed cysteamine. This involves changes to the MHRA CTA for the Cysteamine stock for use within REMAP-CAP. Addition of UK Releasing site:Catalent CTS (Edinburgh) Limited ,Unit 1, Inchwood Park, Bathgate,West Lothian, EH48 2FY, United Kingdom Marketing Authorisation holder: Catalent CTS (Edinburgh) Limited , MIA(IMP)number: 25274 Extension of study insurance until June 2023 Significant changes to the IMPD

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
	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)*:	CTIMP IMP			
Specific change (select - only available when area of change is selected first)*:	Other - Please specify in the free text below			
Further information (free text - note that this field will adapt to the amount of text entered):	The addition of UK releasing site: Catalent CTS (Edinburgh) Limitied, Unit 1 Inchwood Park, Bathgate, West Lothian, EH48 2FY, United Kingdom			
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	
			Remove all changes below	

Change 2				
Area of change (select)*:	Study Management			
Specific change (select - only available when area of change is selected first)*:	Insurance - Renewal with no change to the level or breadth of cover			
Further information (free text - note that this field will adapt to the amount of text entered):	The insurance for the study has been exteded till June 2023			
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	
			Remove all changes below	

Change 3				
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):	1. Page 103: Section 1.1.P.2.2 Manufacturer(S): Added new clinical trial supplier {CatalentCTS(Edinburgh)Limited} details, their responsibilities and QP release under the QP-to-QP agreement 2. Page 168: Primary packaging: added that the new clinical trial supplier will carry out labelling & packaging for unlabelled vials from lot no.P04620 3. Page 222 to 246: Added GMP manufacturing authorisation certificate of Catalent CTS (Edinburgh)Limited 4. Page 247 to 251: Added GMP compliance certificate of Catalent CTS (Edinburgh) Limited 5. Page 252 to 253: Added GDP compliance certificate of Catalent CTS (Edinburgh) Limited			
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	
			Remove all changes below	

Change 4	
Area of change (select)*:	Study Documents
Specific change (select - only available when area of change is selected first)*:	IMPD - Non-substantial changes
Further information (free text - note that this field will adapt to the amount of text entered):	1. Page8: Corrected the section number for the alternative stability testing laboratory 2. Page 28 &34: Added lot number for the new reference standard & the CoA for the reference standard 3. Page 86 to 88: Section2.1.S.7 Stability: added more information on the alternative stability testing laboratory, included stability protocol, stability testing time points and post-approval stability protocol and stability commitment by Cambrex Profarmaco Milano for the drug substance 4. Page178: Added 9m stability results for the GMP batch P04620

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

- 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:	Univeristy Mendical 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:	N/A
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
Change 2:	N	N				N				N				N				N	N/A
Change 3:	N	Y				N				N				N				N	N/A
Change 4:	N	N				N				N				N				N	N/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																		