

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*:	AM040			
Sponsor amendment date* (enter as DD/MM/YY):	17 November 2023			
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>I am submitting AM040 for the REMAP-CAP study, which involves:</p> <ol style="list-style-type: none"> 1. Submission of the Immune modulation domain DSA 2. Updates to the adult and childrens' PIS documents 3. Update to allow for consent forms to be posted to patients who have been discharged from hospital 4. Closure of the fixed course hydrocortisone intervention 5. Closure of the Anticoagulation Domain 6. Closure of the Antiplatelet Domain 			
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)*:	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):	Tocilizumab and baricitinib will be added to the study as an intervention for influenza patients.			
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 Documents			
Specific change (select - only available when area of change is selected first)*:	Protocol - Substantial changes (e.g. affecting safety or the scientific value of the trial)			
Further information (free text - note that this field will adapt to the amount of text entered):	Submission of the Immune modulation domain specific appendix			
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)*:	IB, SmPC - Substantial changes (e.g. affecting the risk/benefit assessment)			
Further information (free text - note that this field will adapt to the amount of text entered):	Submission of the SmPCs for tocilizumab and baricitinib			
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)*:	Other significant change to study documents (e.g. information sheets, consent forms, questionnaires, letters) that can be implemented within existing resource in place at participating organisations - Please specify in the free text below			
Further information In particular, please describe why this change can be implemented within the existing resource in place at the participating organisations (free text - note that this field will adapt to the amount of text entered)*	Both adult and childrens' PIS documents have been updated to include the interventions for the immune modulation domain (tocilizumab & baricitinib). The telephone consent form has been updated so it can be used for both personal legal representatives and patients. Hydrocortisone has been removed from the childrens' PIS as it is not an option for paediatric participants. Fixed course hydrocortisone has been removed from the adult PIS as the intervention has been closed. There are minor corrections across all PIS documents.			
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 5				
Area of change (select)*:	Participant Procedures			
Specific change (select - only available when area of change is selected first)*:	Recruitment - Change in identification, approach, recruitment or consent of participants			
Further information (free text - note that this field will adapt to the amount of text entered):	We would like to include the option that sites can post the consent form to patients who have been discharged promptly, prior to providing their written retrospective consent. Once the patient has been discharged home, sites will call the patient (using the updated and submitted telephone agreement form) and explain the study and ask if the consent can be posted. Sites will then arrange a time to call the patient again and explain the consent and allowing the patient to ask any questions. If the patient is happy they can sign and return the consent form which will then be countersigned by the person who discussed the study with the patient.			
Applicability:	England	Wales	Scotland	Northern Ireland
Where are the participating NHS/HSC organisations located that will be affected by this change?*	No	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 6				
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):	We have closed recruitment to the 'fixed-course hydrocortisone' intervention of the Corticosteroid Domain as it has reached a prespecified statistical trigger for futility. The anticoagulation and antiplatelet domains have also been closed due operational futility.			
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:	
Name [first name and surname]*:	Elizaveta Malkova
Address:	
Telephone number:	
Fax number:	
Purchase Order (PO) number for MHRA invoicing:	
Email address*:	elizaveta.malkova@ecraid.eu

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	Y				Y				Y				Y				Y	A
Change 2:	Y	Y				Y				(Y)				(Y)				(Y)	A
Change 3:	N	Y				(Y)				(Y)				(Y)				(Y)	C
Change 4:	Y	N				Y				Y				Y				Y	C
Change 5:	Y	N				Y				Y				Y				Y	B
Change 6:	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																		