

# 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*:	AM042			
Sponsor amendment date* (enter as DD/MM/YY):	12 December 2024			
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)*:	1. Changes to the Summary of Product Characteristics (SmPC) for REMAP-CAP Investigational Medicinal Products (IMPs) 2. Submission of Tocilizumab labels 3. Submission of SoECAT V1.0 & V2.0 4. Submission of the Regulatory Compliance Confirmation (RCC) letter and QP declaration for Baloxavir paediatric formulation and labels 5. Updates to all versions of the patient/legal representative information sheets, consent forms, and privacy notice			
Project type (select):	<b>Specific study</b>			
	Research tissue bank Research database			
Has the study been reviewed by a UKECA-recognised Research Ethics Committee (REC) prior to this amendment?:	<b>Yes</b>		No	
What type of UKECA-recognised Research Ethics Committee (REC) review is applicable? (select):	<b>NHS/HSC REC</b>			
	Ministry of Defence (MoDREC)			
Is all or part of this amendment being resubmitted to the Research Ethics Committee (REC) as a <b>modified amendment</b> (i.e. a substantial amendment previously given an unfavourable opinion)?	Yes		<b>No</b>	
Where is the NHS/HSC Research Ethics Committee (REC) that reviewed the study based?:	England	Wales	Scotland	Northern Ireland
	<b>Yes</b>	No	No	No
Was the study a clinical trial of an investigational medicinal product (CTIMP) OR does the amendment make it one?:	<b>Yes</b>		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		<b>No</b>	
Did the study receive Pharmacy Assurance?:	<b>Yes</b>		No	
Was the study a clinical investigation or other study of a medical device OR does the amendment make it one?:	Yes		<b>No</b>	
Did the study involve the administration of radioactive substances, therefore requiring ARSAC review, OR does the amendment introduce this?:	Yes		<b>No</b>	
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		<b>No</b>	
Did the study involve adults lacking capacity OR does the amendment introduce this?:	<b>Yes</b>		No	
Did the study involve access to confidential patient information outside the direct care team without consent OR does the amendment introduce this?:	Yes		<b>No</b>	
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		<b>No</b>	
Did the study involve children OR does the amendment introduce this?:	<b>Yes</b>		No	
Did the study involve NHS/HSC organisations prior to this amendment?:	<b>Yes</b>		No	
Did the study involve non-NHS/HSC organisations OR does the amendment introduce them?:	Yes		<b>No</b>	
	England	Wales	Scotland	Northern Ireland
Lead nation for the study:	<b>Yes</b>	No	No	No
Which nations had participating NHS/HSC organisations prior to this amendment?	<b>Yes</b>	<b>Yes</b>	<b>Yes</b>	<b>Yes</b>
Which nations will have participating NHS/HSC organisations after this amendment?	<b>Yes</b>	<b>Yes</b>	<b>Yes</b>	<b>Yes</b>

## Section 2: Summary of change(s)

What do you want to update?:	<b>Project information</b>
	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)*:	IB, SmPC - Non-substantial changes (e.g. that do not affect risk/benefit assessment)			
Further information (free text - note that this field will adapt to the amount of text entered):	Updated SmPCs for the antibiotic, macrolide, corticosteroid, influenza antiviral, and influenza immune modulation domains. These are updated annually, and the update does not affect the risk/benefit assessment.			
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? ( <b>please note</b> that this answer may affect the categorisation for the change):	All		Some	
Remove all changes below				

Change 2				
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):	Clinical trial labelling for tocilizumab in the immune modulation domain.			
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? ( <b>please note</b> that this answer may affect the categorisation for the change):	All		Some	
Remove all changes below				

Change 3				
Area of change (select)*:	Study Management			
Specific change (select - only available when area of change is selected first)*:	Funding arrangements - Changes to the payments, benefits or incentives to be received by researchers/sites			
Further information (free text - note that this field will adapt to the amount of text entered):	The SoECATs (v1.0 & v2.0) were not included in previous amendment submissions in error.			
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? ( <b>please note</b> that this answer may affect the categorisation for the change):	All		Some	
Remove all changes below				

Change 4				
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):		Regulatory Compliance Confirmation (RCC) letter and QP declaration for Baloxavir paediatric formulation and labels			
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? ( <b>please note</b> that this answer may affect the categorisation for the change):		All		Some	
Remove all changes below					

  

Change 5					
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)*		<p>All information sheets and consent forms and the privacy notice have been updated according to the new European Master ICF as requested by the EU sponsor - University Medical Center (UMC) Utrecht.</p> <p>Admin changes have been made across all IS/CFs and the privacy notice to correct typographical errors, make the language more lay, ensure consistency in wording/detail, and the addition of a QR code to view our study video/animation.</p> <p>There are also new IS/CFs: These are for telephone/remote consent for children, video consent for children, ProLR consent for children, and a summary IS/CF for patients (as we have one for PerLR).</p>			
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? ( <b>please note</b> that this answer may affect the categorisation for the change):		All		Some	
Add another change					

<b>Section 3: Declaration(s) and lock for submission</b>	
<b>Declaration by the Sponsor or authorised delegate</b> <ul style="list-style-type: none"> <li>I confirm that the Sponsor takes responsibility for the completed amendment tool</li> <li>I confirm that I have been formally authorised by the Sponsor to complete the amendment tool on their behalf</li> </ul>	
<i>Applicant identification:</i>	<b>Sponsor</b>
	Legal representative of the sponsor
	Person or organisation authorised by the sponsor
<i>Organisation:</i>	UMC Utrecht
<i>Name [first name and surname]*:</i>	Elizaveta Malkova
<i>Address:</i>	Heidelberglaan 100, 3584CX Utrecht, The Netherlands
<i>Telephone number:</i>	3188555196
<i>Fax number:</i>	N/A
<i>Purchase Order (PO) number for MHRA invoicing:</i>	R5861.70
<i>Email address*:</i>	eu.remapcap@umcutrecht.nl

  

<b>Lock for submission</b> <p><b>Please note:</b> 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.</p> <div style="text-align: center;"> <div style="background-color: #92d050; padding: 5px 20px; display: inline-block;">Lock for submission</div> </div> <p>After locking the tool, <a href="#">proceed to submit the amendment online</a>. The "Submission Guidance" tab provides further information about the next steps for the amendment.</p>
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#### 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:	N	N				(Y)				(Y)				(Y)				(Y)	C
Change 2:	Y	Y				Y				Y				Y				Y	A
Change 3:	Y	N				Y				Y				Y				Y	A
Change 4:	Y	Y				Y				Y				Y				Y	A
Change 5:	Y	N				Y				Y				Y				Y	C
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																		