

Modification Tool

v2.1 24 April 2026

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 modification reference number*:	SA044			
Sponsor modification date* (enter as DD/MM/YY):	22 June 2026			
Briefly summarise in lay language the main changes proposed in this modification. Explain the purpose of the changes and their significance for the project. If the modification 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)*:	We would like to inform you about the recommendation that we received from our independent DSMB; to close recruitment to the oseltamivir interventions (5 and 10 days) as these have been reported as inferior in critically ill adult patients. This was originally submitted to REC on 1st April 2026 (Am44 - Amendment tool) and thought to have been submitted to MHRA too, however there appears to have been an error and it was not received by the MHRA, which came to light on 15th June 2026. After discussing with the MHRA they have requested this be submitted as a modification at present.			
Project type (select):	Specific project			
	Research tissue bank			
	Research database			
Has the project been reviewed by a UKECA-recognised Research Ethics Committee (REC) prior to this modification?:	Yes		No	
What type of UKECA-recognised Research Ethics Committee (REC) review is applicable? (select):	NHS/HSC REC			
	Ministry of Defence (MoDREC)			
Where is the NHS/HSC Research Ethics Committee (REC) that reviewed the project based?:	England	Wales	Scotland	Northern Ireland
	Yes	No	No	No
Was the project a clinical trial of an investigational medicinal product (CTIMP) OR does the modification make it one?:	Yes		No	
EudraCT number* (if the project has a EudraCT number enter it here. If the project does not have a EudraCT number enter "N/A"):	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 project receive Pharmacy Assurance?:	Yes		No	
Was the project a clinical investigation or other study of a medical device OR does the modification make it one?:	Yes		No	
Was the project a performance evaluation study of an In Vitro Diagnostic (IVD) medical device^ (including as a companion diagnostic in a clinical trial of an investigational medicinal product)?:	Yes		No	
Does the modification make the project a performance evaluation study of an In Vitro Diagnostic (IVD) medical device^ (including as a companion diagnostic in a clinical trial of an investigational medicinal product)?:	Yes		No	
^ IVD medical devices are tests used on biological samples, such as tissues, blood or urine, to determine the status of a person's health. This may be a reagent, reagent product, calibrator, control material, kit, instrument, apparatus, equipment or system, whether used alone or in combination				
Did the project involve the administration of radioactive substances, therefore requiring ARSAC review, OR does the modification introduce this?:	Yes		No	
Did the project involve the use of research exposures to ionising radiation (not involving the administration of radioactive substances) OR does the modification introduce this?:	Yes		No	
Did the project involve adults lacking capacity OR does the modification introduce this?:	Yes		No	
Does the project involve access to confidential patient information outside the direct care team without consent OR does the modification introduce this?: (e.g. the project relies upon section 251 support in England and Wales, or equivalent in Scotland to set aside the common law duty of confidentiality)	Yes		No	
Does the project involve prisoners or young offenders who are in custody or supervised by the probation service OR does the modification introduce this?:	Yes		No	
Does the project involve children OR does the modification introduce this?:	Yes		No	
Did the study involve NHS/HSC organisations prior to this modification?:	Yes		No	
Did the study involve non-NHS/HSC organisations OR does the modification 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 modification?	Yes	Yes	Yes	Yes
Which nations will have participating NHS/HSC organisations after this modification?	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 modification must be entered separately. For example, if a modification 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 modification tool as three separate changes. A list of all possible changes is available on the "Glossary of Options" tab. To add another change, click the "Add another change" box.

Change 1				
Area of change (select)*:	CTIMP safety			
Specific area of change (select - only available when area of change is selected first)*:	Data - new data or interpretation affecting risk/benefit assessment			
Further information: explain what the change is, why the change is being made and any possible impact on participants/carers (free text - note that this field will adapt to the amount of text entered):	The DSMB's recommendation is to close recruitment to the oseltamivir interventions (5 and 10 days) as these have been reported as ineffective in critically ill adult patients. The International Trial Steering Committee (ITSC) have agreed with this recommendation, and we have now closed these interventions in the severe state only (critically ill adults) As per the attached letter, the ITSC recommends that for participants in the severe state who have been allocated to one of these interventions, administration should discontinue. We are working to analyse and report the full data as soon as possible. Although our results have shown monotherapy of oseltamivir in severe patients is ineffective, until we have more information, we also propose that we pause the combination interventions in severe state adult patients (critically ill). Separate to this, as 10 days of Oseltamivir is not a typical treatment for moderate adults on the ward, as they do not remain in hospital long enough to receive this, we believe this option is redundant, and we would like to continue to pause this in moderately ill adults. We have currently paused recruitment to the whole antiviral domain while we update our patient information sheets. After discussion with our PPI group, they fed back to us that it was important that we should include this emerging information as part of our consent process. See change 2.			
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)*:	Project documents
Specific area of change (select - only available when area of change is selected first)*:	Other significant change to project documents that can be implemented within existing resource in place at participating organisations - please specify in the free text below
Further information: explain what the change is, why the change is being made and any possible impact on participants/carers. 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)*	PIS/CF changes: >Addition of emerging information to full versions of PIS for adults and paediatrics, in the section regarding side effects and other important information. >Change in format of IMPs listed in PIS from text to table, for ease. >Removal of tickboxes and need to delete/change text, to reduce burden of localising treatment info everytime interventions change at a site and to reduce chance of errors. Relevant domains can be circled on the CF. >Addition of statement in all CFs regarding use of data for future research (applicable to patients going forwards) >Merging of PIS/CFs for different paediatric age groups into one PIS/CF suitable for all ages, for each type of consent >Addition of a clarifying instruction to the Telephone CFs for adults/paediatrics

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 modification tool
- I confirm that I have been formally authorised by the Sponsor to complete the modification tool on their behalf

Applicant identification:	Sponsor
	Legal representative of the sponsor Person or organisation authorised by the sponsor
Organisation:	University Medical Center Utrecht
Name [first name and surname]*:	Mina Jafarzadeh
Address:	Heidelberglaan 100, 3584CX Utrecht, The Netherlands
Telephone number:	0031 6 51717055
Fax number:	N/A
Purchase Order (PO) number for MHRA invoicing:	R5861.70
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 modification tool which must be included in the modification submission. Please ensure that the modification tool is completed correctly before locking it for submission.

Lock for submission

After locking the tool, [proceed to submit the modification online](#). The "Submission Guidance" tab provides further information about the next steps for the modification.

Section 4: Review bodies for the modification

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	N				Y				Y				Y				Y	C
Overall reviews for the modification:																			
Full review:	Y	Y				Y				Y				Y				Y	
Notification only:	N	N				N				N				N				N	
Overall modification type:	Substantial modification																		

UKSW Governance:	NHS/HSC review is required
Overall Category:	A

Please note: The modification tool has been revised to provide updated classifications in line with the new regulations. However, IRAS has not been updated and will still require you to submit using the old classifications. This section provides guidance on which option to select in order to ensure the modification is processed correctly:

Your modification should be submitted as a **substantial amendment**