

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*:	NSA07			
Sponsor amendment date* (enter as DD/MM/YY):	19 October 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 non-substantial amendment 07 for the REMAP-CAP study. This involves:</p> <ol style="list-style-type: none"> 1. Update to the antiviral domain specific appendix - minor clarification to wording relating to paediatric participants 2. Update to the corticosteroid domain specific appendix - minor clarification to wording relating to paediatric participants 			
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?	No	Yes	Yes	Yes
Which nations will have participating NHS/HSC organisations after this amendment?	No	Yes	Yes	Yes

Section 2: Summary of change(s)

What do you want to update?:	Project information
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What do you want to update:

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)*:	Protocol - Non-substantial changes (e.g. not 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):	<p>In the Corticosteroid Domain Specific Appendix there are the following changes:</p> <ol style="list-style-type: none"> 1. Clarification that age for infants refers to corrected gestational age. 2. Clarification that the rationale for evaluating the use of corticosteroids applies to both adult and paediatric populations, including the ability to evaluate differential responsiveness to systemic corticosteroid therapy by age. 3. Background section updated to provide greater context regarding the use of corticosteroids in paediatric populations. It has also been updated to make reference to the current standard of care for paediatric patients (as well as adults) with COVID-19 4. Updates to reflect available safety information regarding the use of systemic corticosteroids in young paediatric patients. 5. Minor clarification that the fixed duration of dexamethasone is for a maximum of 10 days (while the patient remains admitted to hospital) 6. Minor additions to explain that the expected course of corticosteroids is likely to be less than 10 days. This is important in the context of the recommendation that prolonged courses of corticosteroids should be avoided in young infants. <p>In the Influenza Antiviral Domain Specific Appendix there are the following updates:</p> <ol style="list-style-type: none"> 1. The eligibility criteria were updated to incorporate corrected gestational age 2. The dosing recommendations for children were updated to incorporate variable dose practices. 3. The unit-of-analysis was updated to incorporate age-strata. 			
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	
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

Name [first name and surname]*:

Sanne van Rooij

Email address*:

eu.remcap@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)	A
Overall reviews for the amendment:																			
Full review:						N				N				N				N	
Notification only:						Y				Y				Y				Y	
Overall amendment type:	Non-substantial, no study-wide review required																		
Overall Category:	A																		