

Amendment Tool

v1.8 30 April 2025

For office use

QC: No

Section 1: Project information

Short project title*:	SepTiC		
IRAS project ID* (or REC reference if no IRAS project ID is available):	1005848		
Sponsor amendment reference number*:	AM010		
Sponsor amendment date* (enter as DD/MM/YY):	13 August 2025		
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>We would like to make the following changes:-</p> <ol style="list-style-type: none"> 1. Update the protocol to v2.0 12.08.2025 2. Submit a renewed insurance certificate for the trial 		
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
	Yes	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* (if the study has a EudraCT number enter it here. If the study does not have a EudraCT number enter "N/A"):	N/A		
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	
Was the study 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 amendment make the study 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 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	
Does the study involve access to confidential patient information outside the direct care team without consent OR does the amendment introduce this?: (e.g. the study 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 study involve prisoners or young offenders who are in custody or supervised by the probation service OR does the amendment introduce this?:	Yes	No	
Does 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?:	Chief Investigator
	Sponsor Group
	Administrative
	Project information

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: explain what the change is, why the change is being made and any possible impact on study participants/carers (free text - note that this field will adapt to the amount of text entered):	We have reviewed our recruitment and screening rates, and in conjunction with discussion and feedback from our TMG we would like to amend the inclusion and exclusion criteria of the trial. Therefore we would like to submit an updated protocol v2.0. Both a clean and tracked changed version are included in the amendment.			
Applicability:	England	Wales	Scotland	Northern Ireland
Where are the participating NHS/HSC organisations located that will be affected by this change?*	Yes	No	No	No
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: explain what the change is, why the change is being made and any possible impact on study participants/carers (free text - note that this field will adapt to the amount of text entered):	We would also like to submit a renewed insurance certificate for the trial			
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 Design
Specific change (select - only available when area of change is selected first)*:	Inclusion/exclusion criteria - Minor change unlikely to affect safety or scientific value of study

Further information: explain what the change is, why the change is being made and any possible impact on study participants/carers (free text - note that this field will adapt to the amount of text entered):		Additional inclusion criteria for the GM-CSF trial, clarification in 'or requiring two organ support' to include (i.e. two of vasopressors, renal replacement therapy, or non-invasive ventilation / continuous positive airway pressure / high flow nasal oxygen respiratory support) The following exclusion criteria for the trial have been removed:- o Not expected to survive 90 days, due to pre-existing chronic (end-stage) disease o Removing the following wording – 'A source of infection that will require a prolonged course of antibiotics, for greater than 21 days' and amending this to :- 'Being treated for infective endocarditis, osteomyelitis, hepatic or cerebral abscess, tuberculosis'			
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 4					
Area of change (select)*:		Study Documents			
Specific change (select - only available when area of change is selected first)*:		Other minor 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: explain what the change is, why the change is being made and any possible impact on study 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)*		Removing the MOCA-Blind questionnaire at 6 months from the secondary endpoint for the trial as discussed and agreed by the Trial Management Committee.			
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	
<ul style="list-style-type: none"> 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]*:	Amalia Ndoutoumou
Email address*:	a.ndoutoumou@imperial.ac.uk

<p>Lock for submission</p> <p>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.</p> <div style="text-align: center;"> <div style="background-color: #90EE90; padding: 5px; display: inline-block;">Lock for submission</div> </div> <p>After locking the tool, amendments to trials processed under the combined review service should be made using the new part of IRAS. Further information can be found on the "Submission Guidance" tab.</p>

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:				
								approval				function				function

	REC	Competent Authority MHRA - Medicines	Competent Authority MHRA - Devices	ARSAC	Radiation Assurance	UKSW Governance	REC (MCA)	CAG	HMPPS	HRA and HCRW Api	REC (AWIA)	PBPP	SPS (RAEC)	National coordinating	HSC REC	HSC Data Guardians	Prisons	National coordinating	Category:
Change 1:						(Y)				(Y)				N				N	B
Change 2:						N				N				N				N	N/A
Change 3:						(Y)				(Y)				(Y)				(Y)	B
Change 4:						(Y)				(Y)				(Y)				(Y)	C
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:	B/C																		