Modification Tool

v2.1 24 April 2026

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 modification reference number*:	AM013
Sponsor modification date* (enter as DD/MM/YY):	25 August 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)*:	1.Protocol updates, please see main changes listed below:- •Change the sample size from 3758 for the diagnostic and fluid trials to 1300 •Change the sample size from 1300 for the GM-CSF trial to 400 •Update the statistical analysis and rationale for the sample size change detailed in section 9. Statistical Analysis. •Update to the archiving duration from 10 to 25 years. 2.We would like to update the end date to the trial to 31st August 2028. 3.We would like to make a change to our privacy notice regarding international transfer of data.

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"):	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 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?:	Chief Investigator Sponsor Group Administrative **Project information**

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)*:	Project documents			
Specific area of change (select - only available when area of change is selected first)*:	Protocol - non-significant changes that do not affect safety or the scientific value			
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):	Update to archiving duration and other formatting corrections			
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 design			
Specific area of change (select - only available when area of change is selected first)*:	Participant numbers - significant change to sample size			
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 sample size has been reduced from 3758 to 1300 for the diagnostic and fluid trials, and from 1300 to 400 for the GM-CSF trial. The full justification for this can be found in the statistical section of the updated protocol. The sample size was initially calculated based on 90-day mortality alone. The power of the trial was increased when the primary outcome included both 90-day mortality and clinical state (in-hospital without organ support, in-ICU with organ support, discharged) over 90 days, thus allowing us to reduce the sample size and still answer the research questions.			
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)*:	Project design			
Specific area of change (select - only available when area of change is selected first)*:	Change to project duration (no change to project end definition, treatment or interventions, or monitoring arrangements) that will not have any additional resource implications for 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 (free text - note that this field will adapt to the amount of text entered):	Extend project duration. New end of study date is 31st August 2028			
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)*:	Project documents			
Specific area of change (select - only available when area of change is selected first)*:	Other non-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)*	Update to international transfer section of privacy notice. Incoroporating changes in relation to Sponsor updated wording.			
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

Name [first name and surname]:*	Nkemjika Abiakam
*Email address**:	rgit.ctimp.team@imperial.ac.uk

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, modifications 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.

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																	
	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:	N	N				(Y)				(Y)				(Y)				(Y)	A
Change 2:	Y	N				(Y)				(Y)				(Y)				(Y)	A
Change 3:	(Y)	(Y)				(Y)				(Y)				(Y)				(Y)	C
Change 4:	N	N				(Y)				(Y)				(Y)				(Y)	C
Overall reviews for the modification:																			
Full review:	Y	N				N				N				N				N	
Notification only:	N	Y				Y				Y				Y				Y	
Overall modification type:	Substantial modification																		
UKSW Governance:	NHS/HSC review is not 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 - project information amendment**