

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*:	AM012		
Sponsor modification date* (enter as DD/MM/YY):	01 May 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 make the following changes to the trial: - 1. Submit a new vial label to comply with part of Regulation 46(1) of the Medicines for Human Use (Clinical Trials) Regulations 2004, as amended. Please see new label justification attached:- SepTiC vial labels v2.0 01.05.2026_Clean SepTiC vial labels v2.0 01.05.2026_Tracked		
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
	Yes	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)*:	IMPD - non-significant changes			
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):	1.Submit a new vial label to comply with part of Regulation 46(1) of the Medicines for Human Use (Clinical Trials) Regulations 2004, as amended. Please see new label justification attached:- SepTiC vial labels v2.0 01.05.2026_Clean SepTiC vial labels v2.0 01.05.2026_Tracked The part to which we are not able to comply refers to the inclusion of the Sponsor name on the vial labels. Due to space limitation on the label, we are not able to add this information. We would like to note that the Sponsor name is included in the address of the Chief Investigator, 'Imperial College' and, the IMP will only be administered and handled solely by qualified site personnel who are trained on the trial and who is the Sponsor of 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	
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]*:	Amalia Ndoutoumou
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																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/A
Overall reviews for the modification:																			
Full review:																			
Notification only:																			
Overall modification type:	Non-notifiable																		
UKSW Governance:	NHS/HSC review is not required																		
Overall Category:	N/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 is classed as **non-notifiable**, meaning there is no need to make an online modification submission

Please note: Whilst this is a **non-notifiable** modification, meaning that there is no need to make an online submission for review, it may still need to be shared with participating organisations. See the "Submission Guidance" tab for further information.