

# Amendment Tool

v1.6 06 December 2021

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*:	AM002			
Sponsor amendment date* (enter as DD/MM/YY):	22 December 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>We would like to make two changes to the study:-</p> <ol style="list-style-type: none"> <li>Updated the IRAS (CWOW form) to clarify Victoria Pharmaceuticals (our labeller and distributor) as part of our manufacturing process and providing the finished IMPs to site. Tanner Pharma UK Limited are an importer site. The IMP is imported to Tanner UK, then to Victoria Pharmaceuticals for labelling and final release to sites.</li> <li>Add a non-NHS site to the study</li> </ol>			
Project type (select):	<b>Specific study</b>			
	Research tissue bank			
	Research database			
Has the study been reviewed by a UKECA-recognised Research Ethics Committee (REC) prior to this amendment?:	<b>Yes</b>		No	
What type of UKECA-recognised Research Ethics Committee (REC) review is applicable? (select):	<b>NHS/HSC REC</b>			
	Ministry of Defence (MoDREC)			
Is all or part of this amendment being resubmitted to the Research Ethics Committee (REC) as a <b>modified amendment</b> (i.e. a substantial amendment previously given an unfavourable opinion)?	Yes		<b>No</b>	
Where is the NHS/HSC Research Ethics Committee (REC) that reviewed the study based?:	England	Wales	Scotland	Northern Ireland
	<b>Yes</b>	No	No	No
Was the study a clinical trial of an investigational medicinal product (CTIMP) OR does the amendment make it one?:	<b>Yes</b>		No	
EudraCT number*:	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)?:	<b>Yes</b>		No	
Did the study receive Pharmacy Assurance?:	Yes		<b>No</b>	
Was the study a clinical investigation or other study of a medical device OR does the amendment make it one?:	Yes		<b>No</b>	
Did the study involve the administration of radioactive substances, therefore requiring ARSAC review, OR does the amendment introduce this?:	Yes		<b>No</b>	
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		<b>No</b>	
Did the study involve adults lacking capacity OR does the amendment introduce this?:	<b>Yes</b>		No	
Did the study involve access to confidential patient information outside the direct care team without consent OR does the amendment introduce this?:	Yes		<b>No</b>	
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		<b>No</b>	
Did the study involve children OR does the amendment introduce this?:	Yes		<b>No</b>	
Did the study involve NHS/HSC organisations prior to this amendment?:	<b>Yes</b>		No	
Did the study involve non-NHS/HSC organisations OR does the amendment introduce them?:	<b>Yes</b>		No	
	England	Wales	Scotland	Northern Ireland
Lead nation for the study:	<b>Yes</b>	No	No	No
Which nations had participating NHS/HSC organisations prior to this amendment?	<b>Yes</b>	<b>Yes</b>	<b>Yes</b>	<b>Yes</b>
Which nations will have participating NHS/HSC organisations after this amendment?	<b>Yes</b>	<b>Yes</b>	<b>Yes</b>	<b>Yes</b>

Which nations had participating non-NHS/HSC organisations prior to this amendment?	No	No	No	No
Which nations will have participating non-NHS/HSC organisations after this amendment?	Yes	No	No	No

## 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)*:	CTIMP IMP			
Specific change (select - only available when area of change is selected first)*:	Other - Please specify in the free text below			
Further information (free text - note that this field will adapt to the amount of text entered):	Updated the IRAS (CWOW form) to clarify Victoria Pharmaceuticals (our labeller and distributor) as part of our manufacturing process and providing the finished IMPs to site. Tanner Pharma UK Limited are an importer site. The IMP is imported to Tanner UK, then to Victoria Pharmaceuticals for labelling and final release to sites.			
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? ( <b>please note</b> that this answer may affect the categorisation for the change):	All		Some	
Where are the participating non-NHS/HSC organisations located that will be affected by this change?*	Yes	No	No	No
				Remove all changes below

Change 2				
Area of change (select)*:	Participating Organisations			
Specific change (select - only available when area of change is selected first)*:	Addition of sites undertaking the same activities as existing sites			
Further information (free text - note that this field will adapt to the amount of text entered):	We would like to add a non-NHS site to the study:- Cleveland Clinic London with PI - Prof Luigi Camporota			
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? ( <b>please note</b> that this answer may affect the categorisation for the change):	All		Some	
Where are the participating non-NHS/HSC organisations located that will be affected by this change?*	Yes	No	No	No
				Add another change

## Section 3: Declaration(s) and lock for submission

Declaration by the Sponsor or authorised delegate	
<ul style="list-style-type: none"> <li>I confirm that the Sponsor takes responsibility for the completed amendment tool</li> <li>I confirm that I have been formally authorised by the Sponsor to complete the amendment tool on their behalf</li> </ul>	
Applicant identification:	Sponsor
	Legal representative of the sponsor
	Person or organisation authorised by the sponsor

Organisation:	
Name [first name and surname]*:	Rinat Ezra
Address:	
Telephone number:	
Fax number:	
Purchase Order (PO) number for MHRA invoicing:	4731623
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 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, 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.

#### 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															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)	New site
Overall reviews for the amendment:																			
Full review:	Y	Y				Y				Y				Y				Y	
Notification only:	N	N				N				N				N				N	
Overall amendment type:	Substantial for review																		
Overall Category:	A																		