

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*:	AM001		
Sponsor amendment date* (enter as DD/MM/YY):	21 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>1. Updated labels – providing more detail and format changes to the already approved labels- new labels included in the submission.</p> <p>2. Consent forms for PerLR – typographical error we need to change from 'England/Wales' to 'England/Wales/Northern Ireland' – see tracked version attached</p> <p>2a Telephone consent – after feedback from sites, due to this patient group (critical care) patients/families may not have access to email and so have requested a telephone form which allows sites to explain the study via telephone used in previous studies:- BLING III and REMAP-CAP.</p> <p>2b Postal consent – similar to the point above, The REC for advice on this and they agreed we should submit this as an amendment. This will be used in circumstances where the patient is discharged before the site obtains written retrospective consent, the site will call the patient to explain the study and send the consent by post. Points 2a and 2b are linked here.</p> <p>4. We will add another 7 NHS sites and PIs to the study, and change the PIs at 4 sites</p> <p>5. Non-substantial changes to the IMPD</p>		
Project type (select):	Specific study		
	<p>Research tissue bank</p> <p>Research database</p>		
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*:	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	
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?	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)*:	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 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)*	Updated labels – providing more detail and format changes to the already approved labels			
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)*:	Study Documents			
Specific change (select - only available when area of change is selected first)*:	Correction of typographical errors			
Further information (free text - note that this field will adapt to the amount of text entered):	<p>1. Consent forms for PerLR – typographical error we need to change from 'England/Wales' to 'England/Wales/Northern Ireland'</p> <p>2. Telephone agreement – eConsent is no longer available for this Type B study. After feedback from sites, due to this patient group (critical care) patients/families may not be able to visit the hospital in person and provide written consent prior to randomisation but are available to provide their wishes via the telephone. A telephone agreement form allows sites to explain the study via telephone and has been used successfully in previous studies:- BLING III and REMAP-CAP. The telephone agreement is taken first and when the PerLR visits the hospital written consent is obtained. If the PerLR is not available to provide written consent then the telephone agreement prevails.</p> <p>3. Postal consent – similar to the point above, we have spoken to the REC for advice on this and they agreed we should submit this as an amendment. We would like to include the option that sites can post the consent form to patients who have been discharged promptly, prior to providing their written retrospective consent. Once the patient has been discharged home, sites will call the patient (using the submitted telephone agreement form) and explain the study and ask if the consent can be posted. Sites will then arrange a time to call the patient again and explain the consent and allowing the patient to ask any questions. If the patient is happy they can sign and return the consent form which will then be countersigned by the person who discussed the study with the patient.. Points 2 and 3 are linked here.</p>			
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)*:	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):	<p>We will add another 7 NHS sites and PIs to the study:-</p> <ol style="list-style-type: none"> 1. The Royal Bournemouth Hospital, PI is Dr Henrik Reschreiter 2. Bristol Royal Infirmary, PI is Dr Jeremy Bewley 3. Royal Free Hospital, PI is Dr Clare Morkane 4. King's Mill Hospital, PI is Dr Sandaruwan Herath 5. Torbay Hospital, PI is Dr Adam Revill 6. Royal Oldham Hospital, PI is Dr Redmond Tully 7. St George's Hospital, PI is Dr Rhodri Hanslip <p>We would like to change the PIs at the following sites:-</p> <ol style="list-style-type: none"> 1. Royal Victoria Belfast from Dr Jon Silversides to Dr Chris Nutt 2. Belfast City from Dr Jon Silversides to Dr Chris Nutt 3. Russell's Hall, Dudley from Dr Mike Reay to Dr Faiuna Haseeb 4. King's College Hospital, from Dr Philip Hopkins to Reena Mehta 								
Applicability:	<table border="1"> <tr> <td>England</td> <td>Wales</td> <td>Scotland</td> <td>Northern Ireland</td> </tr> <tr> <td>No</td> <td>Yes</td> <td>Yes</td> <td>Yes</td> </tr> </table>	England	Wales	Scotland	Northern Ireland	No	Yes	Yes	Yes
England	Wales	Scotland	Northern Ireland						
No	Yes	Yes	Yes						
Where are the participating NHS/HSC organisations located that will be affected by this change?*									
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								
Remove all changes below									

Change 4									
Area of change (select)*:	Study Documents								
Specific change (select - only available when area of change is selected first)*:	IMPD - Non-substantial changes								
Further information (free text - note that this field will adapt to the amount of text entered):	<p>We are submitting a tracked and clean version of the IMPD for Leukine and placebo. The changes include the following:-</p> <ol style="list-style-type: none"> 1. Clarifications in the stability protocol and corrections of minor mistakes in the manufacturing process for the both the IMPD and placebo. 2. The addition and clarification of the manufacturers in the process. Patheon who are manufacturing Leukine and placebo including primary and secondary packaging. Victoria Pharmaceuticals who are providing the storage, primary and secondary labelling, assembly, QP release and distribution of the IMP and placebo. The revisions are considered editorial. <p>Note:- the previously approved version was Leukine v2.0 and placebo v1.0, we are now submitting Leukine v5.0 and Placebo v2.0. To clarify the changes from v2.0 to v5.0 for Leukine were internal changes and subject to automatic versionning. All tracked changes are highlighted in the documentation.</p>								
Applicability:	<table border="1"> <tr> <td>England</td> <td>Wales</td> <td>Scotland</td> <td>Northern Ireland</td> </tr> <tr> <td>Yes</td> <td>Yes</td> <td>Yes</td> <td>Yes</td> </tr> </table>	England	Wales	Scotland	Northern Ireland	Yes	Yes	Yes	Yes
England	Wales	Scotland	Northern Ireland						
Yes	Yes	Yes	Yes						
Where are the participating NHS/HSC organisations located that will be affected by this change?*									
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								
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]*:

Rinat Ezra

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)	C
Change 2:						N				N				N				N	N/A
Change 3:						(Y)				(Y)				(Y)				(Y)	New site
Change 4:						N				N				N				N	N/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:	C																		