

Amendment Tool

v1.6 06 December 2021

For office use

QC: No

Section 1: Project information

Short project title*:	PhEAST			
IRAS project ID* (or REC reference if no IRAS project ID is available):	304658			
Sponsor amendment reference number*:	21068 SA_11_24			
Sponsor amendment date* (enter as DD/MM/YY):	04 November 2024			
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)*:	Veranex (formerly "Medidee") will act as the trial sponsor's new Legal Representative in the EU.			
Project type (select):	Specific study			
	<input type="checkbox"/> Research tissue bank <input type="checkbox"/> 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			
	<input type="checkbox"/> 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	Northern Ireland
	Yes	No	No	No
Was the study a clinical trial of an investigational medicinal product (CTIMP) OR does the amendment make it one?:	Yes	No		
Was the study a clinical investigation or other study of a medical device OR does the amendment make it one?:	Yes		No	
Does this clinical investigation or other study of a medical device require a Notice of No Objection from MHRA Devices?:	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 have Radiation Assurance OR is Radiation Assurance being sought for the first time because of this amendment?:	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	
Lead nation for the study:	England	Wales	Scotland	Northern Ireland
	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)

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 Management			
Specific change (select - only available when area of change is selected first)*:	Sponsor - Change of Sponsor's legal representative			
Further information (free text - note that this field will adapt to the amount of text entered):	<p>Veranex (formerly "Medidee") will act as the trial sponsor's new Legal Representative in the EU, for the purposes of the EU medical devices legislation following Brexit. Details below:</p> <p>Veranex Germany GmbH, Landsbergerstrasse 302, DE-80687 Munich. Contact details: EU-clinical@veranex.com Telephone: 0046 725 568 059</p> <p>Veranex are also acting in the capacity as the manufacturer's authorised representative in the EU, details as below:</p> <p>Veranex Germany GmbH Landsbergerstrasse 302 DE-80687 Munich mdd-ec-rep@veranex.com</p>			
Applicability:	England	Wales	Scotland	Northern Ireland
Where are the participating NHS/HSC organisations located that will be affected by this change?*	No	No	No	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 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]*:	Alison Thorpe
Email address*:	sponsor@nottingham.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, [proceed to submit the amendment online](#). The "Submission Guidance" tab provides further information about the next steps for the amendment.

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:	
UKCA Authority medicines	UKCA Authority devices	Assurance	Veranex		(A)		HCRA Approval	(A)	(C)	coordinating function	Guardians		coordinating function

	REC	Compete MHRA - M	Compete MHRA - D	ARSAC	Radiation	UKSW Gc	REC (MC)	CAG	HMPPS	HRA and J	REC (AW)	PBPP	SPS (RAE)	National c	HSC REC	HSC Data	Prisons	National c	Category:	
Change 1:	Y					(Y)													(Y)	C
Overall reviews for the amendment:																				
Full review:	Y					N													N	
Notification only:	N					Y													Y	
Overall amendment type:	Substantial																			
Overall Category:	C																			