Amendment Tool

v1.5 25 Mar 2021

For office use

QC: No

Section 1: Project information

Short project title*:	PACKMAN
IRAS project ID* (or REC reference if no IRAS project ID is available):	1003404
Sponsor amendment reference number*:	Amendment 04
Sponsor amendment date* (enter as DD/MM/YY):	18 June 2021
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)*:	An error was corrected in the drug dosing tables on pages 30 and 31 of the protocol - the text regarding the timing intervals for subsequent doses now matches the descriptive text in the main body of the protocol. The formatting of the table has also been changed slightly to improve clarity. The explantory text included on the e-consent form design has been amended to make it clearer to participants and legal representatives how to identify their trial number. In addition, the post-submission text has been amended to clarify that the research paramedic will provide the patient/legal representative with a copy of the signed consent form as soon as possible, rather than within the next 24 hours.

Project type (select):	◉ Specific study ○ Research tissue bank ○ 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 ○ 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
	○	○	◉	○
Was the study a clinical trial of an investigational medicinal product (CTIMP) OR does the amendment make it one?:	◉ Yes		○ No	
EudraCT number*:	2020-000154-10			
Was this clinical trial of an investigational medicinal product (CTIMP) processed under 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 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:	◉	○	○	○
Which nations had participating NHS/HSC organisations prior to this amendment?	☑	☐	☐	☐
Which nations will have participating NHS/HSC organisations after this amendment?	☑	☐	☐	☐

Section 2: Summary of change(s)

What do you want to update?:	○ Chief Investigator ○ Sponsor ○ 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, tick 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)*:	Protocol - Non-substantial changes (e.g. not affecting safety or the scientific value of the trial)			
Further information (free text - note that this field will adapt to the amount of text entered):	Correction of error in dosing tables. Update of Trial Manager details			
Applicability:	England	Wales	Scotland	Northern Ireland
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		◉ Some	

Add another change: ☑

Change 2				
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 (free text - note that this field will adapt to the amount of text entered):	Minor amendments on the e-consent form designs to the post-submission text to clarify that participants will receive a copy of the signed consent form from the research paramedic as soon as possible, and to the explantory text to help participants identify their trial number on the e-consent forms. Please see changes highlighted in orange in the attached documents.			
Applicability:	England	Wales	Scotland	Northern Ireland
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		◉ 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]:*	Mathew Gane
Email address:*	sponsorship@warwick.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:			
	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:						(Y)				(Y)									B
Change 2:						(Y)				(Y)									C
Overall reviews for the amendment:																			
Full review:						N				N									
Notification only:						Y				Y									
Overall amendment type:	Non-substantial, no study-wide review required																		
Overall Category:	B/C																		

Please note: As this is a non-substantial amendment to a CTIMP under the CWoW pilot, this amendment should **not** be processed via online submission. Please see the "Submission Guidance" tab for further information.