

# Amendment Tool

v1.8 30 April 2025

For office use

QC: No

## Section 1: Project information

Short project title*:	PANTHER		
IRAS project ID* (or REC reference if no IRAS project ID is available):	1008743		
Sponsor amendment reference number*:	NSA01		
Sponsor amendment date* (enter as DD/MM/YY):	11 August 2025		
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 the following changes:-</p> <ol style="list-style-type: none"> <li>1. Correction to sample collection dates in the Master Protocol</li> <li>2. Correction to safety reporting flowchart in the UK Region Specific Appendix</li> <li>3. Amending current questionnaire from MOCA-Blind to MOCA-Mini</li> <li>4. Adding renewed insurance certificate</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
	<b>Yes</b>	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* (if the study has a EudraCT number enter it here. If the study 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)?:	<b>Yes</b>	No	
Did the study receive Pharmacy Assurance?:	<b>Yes</b>	No	
Was the study a clinical investigation or other study of a medical device OR does the amendment make it one?:	Yes	<b>No</b>	
Was the study a performance evaluation study of an In Vitro Diagnostic (IVD) medical device <sup>^</sup> (including as a companion diagnostic in a clinical trial of an investigational medicinal product)?:	Yes	<b>No</b>	
Does the amendment make the study a performance evaluation study of an In Vitro Diagnostic (IVD) medical device <sup>^</sup> (including as a companion diagnostic in a clinical trial of an investigational medicinal product)?:	Yes	<b>No</b>	
<sup>^</sup> 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 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	
Does the study involve access to confidential patient information outside the direct care team without consent OR does the amendment introduce this?: (e.g. the study relies upon section 251 support in England and Wales, or equivalent in Scotland to set aside the common law duty of confidentiality)	Yes	<b>No</b>	
Does 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>	
Does 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?:	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
	<b>Project information</b>

**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)*:	Protocol - Non-substantial changes (e.g. not affecting safety or the scientific value of the trial)			
Further information: explain what the change is, why the change is being made and any possible impact on study participants/carers (free text - note that this field will adapt to the amount of text entered):	<p>1. We would like to make a correction in the PANTHER Master protocol, the previous version detailed the sample collection points as 'baseline, day 3 and day 7' this has been updated to 'baseline day 2 and day 6'. This detail has been amended in the visit schedule 6.4 and research samples 6.8. Both tracked and clean versions are available:-</p> <p>a. PANTHER Master Protocol V2.1 30.07.2025_Tracked</p> <p>b. PANTHER Master Protocol V2.1 30.07.2025_Clean</p> <p>2. We would like to make a correction to the PANTHER_UK_Region Specific Appendix, the previous flow chart containing reporting information related to medical devices 'report SAEs to the MHRA in 7 days' this is not applicable to PANTHER which is deemed as an IMP trial, not a device trial, therefore this detail has been removed. Both tracked and clean versions are available:-</p> <p>a. PANTHER_UK_Region Specific Appendix_v1.1_20250805_TC</p> <p>b. PANTHER_UK_Region Specific Appendix_v1.1_20250805_Clean</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? ( <b>please note</b> 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)*:	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: explain what the change is, why the change is being made and any possible impact on study participants/carers. 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)*	We would like to amend our current questionnaire of the MOCA-Blind to the MOCA-Mini. We have received feedback from our PPI group and collaborators who have deemed the MOCA-Mini as less burdensome on patients and just as scientifically equivalent to the MOCA-Blind.			
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	
Remove all changes below				

Change 3				
Area of change (select)*:	Study Management			
Specific change (select - only available when area of change is selected first)*:	Insurance - Renewal with no change to the level or breadth of cover			
Further information: explain what the change is, why the change is being made and any possible impact on study participants/carers (free text - note that this field will adapt to the amount of text entered):	We would like to submit a renewed insurance certificate for 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? ( <b>please note</b> 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]*:	Amalia Ndoutoumou
Email address*:	a.ndoutoumou@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)	A
Change 2:						(Y)				(Y)				(Y)				(Y)	C
Change 3:						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:	A																		

