Amendment Tool

v1.8 30 April 2025

For office use

QC: No

Section 1: Project information

Short project title*:	PROTECT-AEGIS
IRAS project ID* (or REC reference if no IRAS project ID is available):	1011239
Sponsor amendment reference number*:	Substantial amendment 2
Sponsor amendment date* (enter as DD/MM/YY):	23 March 2026
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)*:	Changes to the following: 1. Update to reference safety information for trial IMP - ibuprofen tablet 400mg

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
	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	
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)?:	**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**	
Was the study a performance evaluation study of an In Vitro Diagnostic (IVD) medical device^ (including as a companion diagnostic in a clinical trial of an investigational medicinal product)?:	Yes		**No**	
Does the amendment make the study a performance evaluation study of an In Vitro Diagnostic (IVD) medical device^ (including as a companion diagnostic in a clinical trial of an investigational medicinal product)?:	Yes		**No**	
^ 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		**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**	
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		**No**	
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		**No**	
Does 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**	No	**Yes**	No
Which nations will have participating NHS/HSC organisations after this amendment?	**Yes**	No	**Yes**	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)*:	Study Documents
Specific change (select - only available when area of change is selected first)*:	IB, SmPC - Substantial changes (e.g. affecting the risk/benefit assessment; changing Reference Safety Information)
Where a substantial change is being made to the IB or SmPC (e.g. affecting the risk/benefit assessment), it would normally be expected that this would be accompanied by a significant change to study documents (e.g. information sheets) to notify participants about the updated risk/benefit assessment. Please enter a separate change in the amendment tool for a significant change to study documents or provide a justification in the free text below setting out why the study documents are not being updated:	
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)*:	Update to the reference safety information (section 4.8) for Ibuprofen 400 mg tablets. The version dated 22.10.2024 will now be used to monitor any adverse reactions for participants administered ibuprofen orally. The following is a brief summary of the sections that were updated: i.Section 4.4: Addition to the renal category: renal tubular acidosis and hypokalaemia and clarifications/change of wording to the dermatological section ii.Section 4.6: Further risks of ibuprofen use in pregnancy iii.Section 4.8: Addition of Kounis syndrome, exfoliative dermatitis, sever cutaneous adverse reactions, renal insufficiency, renal tubular acidosis and hypokalaemia as adverse reactions. iv.Section 4.9: Addition of symptoms and reactions with prolonged usage of a higher than recommended dose of ibuprofen The above is a change to the reference safety information only. A risk assessment benefit has been completed and the above changes do not require a change to any trial documents.

Applicability:	England	Wales	Scotland	Northern Ireland
Where are the participating NHS/HSC organisations located that will be affected by this change?*:	**Yes**	No	**Yes**	No
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

Applicant identification:	**Sponsor** Legal representative of the sponsor Person or organisation authorised by the sponsor

Organisation:	
Name [first name and surname]:*	Mays Jawad
Address:	
Telephone number:	
Fax number:	
Purchase Order (PO) number for MHRA invoicing:	Paid with credit card, please see attached proof of payment
Email address:*	research.amendments@qmul.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																	
	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)				(Y)				(Y)					C
Overall reviews for the amendment:																			
Full review:		Y				N				N				N					
Notification only:		N				Y				Y				Y					
Overall amendment type:	Substantial for information																		
Overall Category:	C																		