

Amendment Tool

v1.8 30 April 2025

For office use

QC: No

Section 1: Project information

Short project title*:	The TYPHOON Study			
IRAS project ID* (or REC reference if no IRAS project ID is available):	345168			
Sponsor amendment reference number*:	NSA02			
Sponsor amendment date* (enter as DD/MM/YY):	30 October 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)*:	Data collection period changed to 01.08.2025 to 31.07.2026. Project end date changed to 01.10.2026. New dates updated on Protocol (Planned Study Period, Patient Identification, Inclusion Criteria) New study sites added Minor changes to other study documents, including information on data protection to the Patient Information Summary Organisation Information Document updated			
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
	No	No	Yes	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	
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:	No	No	Yes	No
Which nations had participating NHS/HSC organisations prior to this amendment?	Yes	Yes	Yes	No

Which nations will have participating NHS/HSC organisations after this amendment?	Yes	Yes	Yes	No
---	-----	-----	-----	----

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 Design			
Specific change (select - only available when area of change is selected first)*:	Extension to study duration that will not have any additional resource implications for 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)*	1. Delaying study duration as previously held up by DPIA which is now approved. 2. Extension of end date to enable sites to complete their local Research and Development processes to start the project. Data collection period changed to 01.08.2025 to 31.07.2026. Project end date changed to 01.10.2026.			
Applicability:	England	Wales	Scotland	Northern Ireland
Where are the participating NHS/HSC organisations located that will be affected by this change?*	Yes	Yes	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	
				Remove all changes below

Change 2				
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):	Protocol updated to reflect the change in Planned Study Period (Patient Identification, Inclusion Criteria)			
Applicability:	England	Wales	Scotland	Northern Ireland
Where are the participating NHS/HSC organisations located that will be affected by this change?*	Yes	Yes	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	
				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: explain what the change is, why the	<div>Study now open to recruitment. Current existing sites and their Principle Investigators (PIs) include: 1.Royal Devon and Exeter Hospital, Royal Devon University NHS Trust– PI: Ms Clair Saxby 2.Royal Free London NHS Foundation Trust – PI: Dr. Zahra Nawaz 3.Medway NHS Foundation Trust – PI: Dr. Haran Devakumar 4.Sandwell and West Birmingham NHS Trust – PI: Mr Yohanna Takwoingi 5.NHS Tayside – PI: Mr Spielmann 6.James Cook University Hospital, South Tee’s NHS Trust - PI: Mr Mohammed Bahgat 7.Queen Elizabeth University Hospital, NHS Greater Glasgow and Clude- PI: Mr Thomas Milner 8.Somerset NHS Foundation Trust - PI: Mr Christ Burgess 9.University Hospitals Coventry and Warwickshire NHS Trust - PI: Mr Dimitrios Voliotidis 10.Wrightington, Wigan and Leigh Teaching Hospitals NHS Foundation Trust - PI: Mr Nirmal</div>

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):	Kumar 11.Freeman Hospital, Newcastle upon Tyne Hospitals NHS Foundation Trust PI: - Mr James O'Hara 12.Royal Cornwall Hospital Trust - PI: Mr Venkat Reddy 13.Stockport NHS Trust - PI: Mr Sudhakar Ramachandran 14.Wrexham Maelor Hospital, Betsi Cadwaladr University Health Board - PI: Mr Todd Kanzara 15.Sunderland Hospital, South Tyneside and Sunderland NHS Foundation Trust - PI: Ms Nashreen Oozeer 16.Royal Bolton Hospital, Bolton NHS Foundation Trust- PI: Mr Vikas Malik 17.Warrington and Halton NHS Trust – PI: Mr Sri Bathala 18.William Harvey Hospital, East Kent University Hospitals University NHS Foundation Trust – PI: Mr Graeme Crossland 19.Ipswich Hospital, East Suffolk and North Essex NHS Foundation Trust Update outline OID.			
Applicability:	England	Wales	Scotland	Northern Ireland
Where are the participating NHS/HSC organisations located that will be affected by this change?*	Yes	Yes	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	
			Remove all changes below	

Change 4				
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)*	Participant information sheet - additional information on data protection, minimal changes to wording, space for contact details highlighted for each site to populate Consent form - updated to reflect change in PIS version New project poster			
Applicability:	England	Wales	Scotland	Northern Ireland
Where are the participating NHS/HSC organisations located that will be affected by this change?*	Yes	Yes	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

Name [first name and surname]*:

Adam Wade

Email address*:

Adam.Wade@nhs.scot

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																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)					C
Change 2:						(Y)				(Y)				(Y)					A
Change 3:						(Y)				(Y)				(Y)					New site
Change 4:						(Y)				(Y)				(Y)					C
Overall reviews for the amendment:																			
Full review:						N				N				N					
Notification only:						Y				Y				Y					
Overall amendment type:	Non-substantial, no study-wide review required																		
Overall Category:	A																		