

Modification Tool

v2.1 24 April 2026

For office use

QC: No

Section 1: Project information

Short project title*:	COLLABORATE			
IRAS project ID* (or REC reference if no IRAS project ID is available):	337660			
Sponsor modification reference number*:	Minor Modification 2			
Sponsor modification date* (enter as DD/MM/YY):	28 April 2026			
Briefly summarise in lay language the main changes proposed in this modification. Explain the purpose of the changes and their significance for the project. If the modification 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)*:	Translation of the Parent Information Sheet Part 1 and 2, and the Mechanistic Sub-Study Parent Information Sheet and Consent Form			
Project type (select):	Specific project			
	Research tissue bank			
	Research database			
Has the project been reviewed by a UKECA-recognised Research Ethics Committee (REC) prior to this modification?:	Yes		No	
What type of UKECA-recognised Research Ethics Committee (REC) review is applicable? (select):	NHS/HSC REC			
	Ministry of Defence (MoDREC)			
Where is the NHS/HSC Research Ethics Committee (REC) that reviewed the project based?:	England	Wales	Scotland	Northern Ireland
	Yes	No	No	No
Was the project a clinical trial of an investigational medicinal product (CTIMP) OR does the modification make it one?:	Yes		No	
Was the project a clinical investigation or other study of a medical device OR does the modification make it one?:	Yes		No	
Was the project 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 modification make the project 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 project involve the administration of radioactive substances, therefore requiring ARSAC review, OR does the modification introduce this?:	Yes		No	
Did the project involve the use of research exposures to ionising radiation (not involving the administration of radioactive substances) OR does the modification introduce this?:	Yes		No	
Did the project involve adults lacking capacity OR does the modification introduce this?:	Yes		No	
Does the project involve access to confidential patient information outside the direct care team without consent OR does the modification introduce this? (e.g. the project 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 project involve prisoners or young offenders who are in custody or supervised by the probation service OR does the modification introduce this?:	Yes		No	
Does the project involve children OR does the modification introduce this?:	Yes		No	
Did the study involve NHS/HSC organisations prior to this modification?:	Yes		No	
Did the study involve non-NHS/HSC organisations OR does the modification 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 modification?	Yes	Yes	Yes	Yes

Which nations will have participating NHS/HSC organisations after this modification?

Yes

Yes

Yes

Yes

Section 2: Summary of change(s)

Please note: Each change being made as part of the modification must be entered separately. For example, if a modification 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 modification tool as three separate changes. A list of all possible changes is available on the "Glossary of Options" tab. To add another change, click the "Add another change" box.

Change 1				
Area of change (select)*:	Project documents			
Specific area of change (select - only available when area of change is selected first)*:	Translated versions of participant information			
Further information: explain what the change is, why the change is being made and any possible impact on participants/carers (free text - note that this field will adapt to the amount of text entered):	The Parent Information Sheet (Part 1 and Part 2) has been translated into 10 languages: Polish; Romanian; Punjabi; Urdu; Portuguese; Spanish; Arabic; Bengali; Gujarati; Italian. These languages were selected due to being the most common UK languages after English. COLLABORATE PIS Part 1 V2.1_12_12_2025_Arabic; COLLABORATE PIS Part 1 V2.1_12_12_2025_Bengali; COLLABORATE PIS Part 1 V2.1_12_12_2025_Gujarati; COLLABORATE PIS Part 1 V2.1_12_12_2025_Italian; COLLABORATE PIS Part 1 V2.1_12_12_2025_Polish; COLLABORATE PIS Part 1 V2.1_12_12_2025_Portuguese; COLLABORATE PIS Part 1 V2.1_12_12_2025_Punjabi; COLLABORATE PIS Part 1 V2.1_12_12_2025_Romanian; COLLABORATE PIS Part 1 V2.1_12_12_2025_Spanish; COLLABORATE PIS Part 1 V2.1_12_12_2025_Urdu COLLABORATE PIS Part 2 & Privacy Notice V2.0_22102025_Arabic; COLLABORATE PIS Part 2 & Privacy Notice V2.0_22102025_Bengali; COLLABORATE PIS Part 2 & Privacy Notice V2.0_22102025_Gujarati; COLLABORATE PIS Part 2 & Privacy Notice V2.0_22102025_Italian; COLLABORATE PIS Part 2 & Privacy Notice V2.0_22102025_Polish; COLLABORATE PIS Part 2 & Privacy Notice V2.0_22102025_Portuguese; COLLABORATE PIS Part 2 & Privacy Notice V2.0_22102025_Punjabi; COLLABORATE PIS Part 2 & Privacy Notice V2.0_22102025_Romanian; COLLABORATE PIS Part 2 & Privacy Notice V2.0_22102025_Spanish; COLLABORATE PIS Part 2 & Privacy Notice V2.0_22102025_Urdu The mechanistic sub-study Parent Information Sheet and the Informed Consent form have been translated to Polish only. Polish was selected based on advice from the mechanistic sub-study lead. COLLABORATE Sub-Study ICF_V1.1 15.12.2025_Polish; COLLABORATE Sub-Study PIS V1.0_15.08.2025_Polish Translations were first conducted with Google Translate, and then were back translated by a first-language speaker, who confirmed the translations were correct and final.			
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? (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 modification tool
- I confirm that I have been formally authorised by the Sponsor to complete the modification tool on their behalf

Name [first name and surname]*:

becky.ward@imperial.ac.uk

Email address*:

becky.ward@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 modification tool which must be included in the modification submission. Please ensure that the modification tool is completed correctly before locking it for submission.

Lock for submission

After locking the tool, [proceed to submit the modification online](#). The "Submission Guidance" tab provides further information about the next steps for the modification.

Section 4: Review bodies for the modification

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:																			N/A
Overall reviews for the modification:																			
Full review:																			
Notification only:																			
Overall modification type:	Non-notifiable																		
UKSW Governance:	NHS/HSC review is not required																		
Overall Category:	N/A																		

Please note: The modification tool has been revised to provide updated classifications in line with the new regulations. However, IRAS has not been updated and will still require you to submit using the old classifications. This section provides guidance on which option to select in order to ensure the modification is processed correctly:

Your modification is classed as **non-notifiable**, meaning there is no need to make an online modification submission

Please note: Whilst this is a **non-notifiable** modification, meaning that there is no need to make an online submission for review, it may still need to be shared with participating organisations. See the "Submission Guidance" tab for further information.