

Amendment Tool

v1.8 30 April 2025

For office use

QC: No

Section 1: Project information

Short project title*:	Indigo		
IRAS project ID* (or REC reference if no IRAS project ID is available):	324034		
Sponsor amendment reference number*:	SA_03		
Sponsor amendment date* (enter as DD/MM/YY):	27 June 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 added a longer version of an already REC-approved text message to contact eligible participants to the trial.</p> <p>To increase participation by people with English as a second language we have added an option for them to read a short explanation of the study in their preferred language. It describes the trial, the current situation around full translation of the questionnaire and that they can ask people they trust to help them complete the questionnaire if they find written English difficult.</p> <p>We have performed an interim analysis on approximately 30,000 responses. This has shown a significant difference in one of the outcome measures so we would like to remove one of the randomisations. This randomisation was between showing a participant a question either at the start or end of the survey. The question related to consent for linkage to their NHS records. The null hypothesis can be rejected as showing participants the question at the start of the survey performs better than at the end.</p> <p>The following documents have been edited: - Indigo - survey flow_2025.06.27 - v1.3.pptx - Indigo - protocol - 2025.06.27_v1.6.docx - Indigo - full initial questionnaire - 2025.06.27_v1.9.2.docx - Indigo Community - Adverts (overall) - 2025.07.31 - v1.5.docx</p> <p>The following documents are new: - Indigo - introduction translated_2025.06.27 - v0.1.docx - Indigo - Instagram description - 2025.07.02 - v0.1.png</p>		
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
	Yes	No	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:	Yes	No	No	No
Which nations had participating NHS/HSC organisations prior to this amendment?	Yes	No	No	No
Which nations will have participating NHS/HSC organisations after this amendment?	Yes	No	No	No
Was this a "single site, self sponsored" study in England or Wales prior to this amendment?	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)*:	Other minor change to study design 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)*	<p>As per our protocol, we assessed the effect of randomisation on the question about linking participants' answers to their NHS records. We can reject the null hypothesis on the basis of analysis to date. It is clear that the best moment to ask them this question is at the beginning of the questionnaire instead of at the end.</p> <p>This change is reflected on the following documents: - Indigo - survey flow_2025.06.27 - v1.3.pptx - Indigo - full initial questionnaire - 2025.06.27_v1.9.2.docx</p>			
Applicability:	England	Wales	Scotland	Northern Ireland
Where are the participating NHS/HSC organisations located that will be affected by this change?*	Yes	No	No	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 - Substantial changes (e.g. 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>Following Change 1, we updated the protocol to remove the randomisation of the linkage questions in the questionnaire.</p> <p>The following document reflects these changes: - Indigo - protocol - 2025.06.27_v1.6.docx</p>			
Applicability:	England	Wales	Scotland	Northern Ireland

Where are the participating NHS/HSC organisations located that will be affected by this change?*	Yes	No	No	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)*:	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)*	<p>Following conversations with GP surgeries and secondary care sites, we have added a longer template for mail out. This can be used in email to eligible patients as the current shorter text suits SMS rather than email.</p> <p>Following analyses of the free text boxes filled in by participants, we have added options to the answers covering the cancer diagnosis and have removed the free text boxes in the questions asking about marital status (and we have added the option "Prefer not to say"), sex recorded at birth and gender.</p> <p>Furthermore, as per our protocol, we have set an Instagram profile where we hope to recruit more eligible participants. The link to recruit sits in the profile description and nowhere else.</p> <p>The following documents reflect these changes: - Indigo Community - Adverts (overall) - 2025.07.31 - v1.5.docx - Indigo - Instagram description - 2025.07.02 - v0.1.png</p>			
Applicability:	England	Wales	Scotland	Northern Ireland
Where are the participating NHS/HSC organisations located that will be affected by this change?*	Yes	Yes	No	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)*:	Translations - Addition of translated versions of participant-facing documentation			
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>Although the translations of the questionnaire are not ready yet, we wish to acknowledge that we are working on this issue by explaining the study in participants' preferred language. Languages based upon census and cancer prevalence data. Text allows people to read a little about the trial, it tells them that they can have someone they trust help them, to take part if they wish and if they are not confident with reading and / or writing English. It also allows people to register that language they would have preferred the study to be available in so we can quantify demand for translations.</p> <p>The following documents reflect these changes: - Indigo - introduction translated_2025.06.27 - v0.1.docx - Indigo - full initial questionnaire - 2025.06.27_v1.9.2.docx</p>			
Applicability:	England	Wales	Scotland	Northern Ireland
Where are the participating NHS/HSC organisations located that will be affected by this change?*	Yes	No	No	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]*:	Ruth Nicholson
Email address*:	r.nicholson@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, [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:	N					(Y)				(Y)									C
Change 2:	Y					Y				(Y)									A
Change 3:	N					(Y)				(Y)									C
Change 4:	N					N				N									N/A
Overall reviews for the amendment:																			
Full review:	Y					Y				N									
Notification only:	N					N				Y									
Overall amendment type:	Substantial																		
Overall Category:	A																		