

Amendment Tool

v1.6 06 December 2021

For office use

QC: No

Section 1: Project information

Short project title*:	The UK-Irish Atopic eczema Systemic TherApy Register (A-STAR)			
IRAS project ID* (or REC reference if no IRAS project ID is available):	237309			
Sponsor amendment reference number*:	SA-04			
Sponsor amendment date* (enter as DD/MM/YY):	08 August 2024			
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>This amendment updates the Protocol with new site information, contact details and changes the participants visit time windows. Updates have been made to two PIS documents: 'A-STAR Adult Biorepository PIS-ICF - V3.2' and 'A-STAR Parents_Guardians Biorepository PIS-ICF - V3.2'. This amendment can be implemented within the existing resource as the changes are only to provide additional information for recruiting sites & participants. Changes are in line with the original intentions of the study as set out in the protocol.</p> <p>There are no changes in this amendment that will affect the scientific value of the study.</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	Northern Ireland
	No	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	
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	
Did the study involve access to confidential patient information outside the direct care team without consent OR does the amendment introduce this?:	Yes		No	
Did 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	
Did 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	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 Documents			
Specific change (select - only available when area of change is selected first)*:	Other significant 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 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>Slight changes to the wording in both PIS have been made throughout the documents & are visible in the tracked changes. These changes were made for clarity in consultation with our patient representative.</p> <p>The amount of blood required has been reduced to reflect what is required for the current analyses.</p> <p>Tape strips have been mentioned in the section 'What are the risks of taking part' section. This is for clarity. They are not a new sample.</p> <p>Additional information has been included in the section 'What will happen to my blood and skin samples?' This is to provide additional information to the patients on genetic testing that will be carried out on the sample. This is in line with the original plan for the study and has been included for clarity. Again, this was written in close consultation with our patient representative who advised on the level of detail required. Text in this section has also been changed to make it clear who is collaborating on the project (Universities and industrial partners) and that samples will be sent to a number of different research centres. This is not a change to the original plan for the study. The change has been made for clarification. Clarification has also been made to the final paragraph in this section, to let a patient know what will happen to their samples and data.</p> <p>The section 'What will happen to my data?' has been changed to 'Information on the Use of Data'. Text in this section has been completely reworded line with the recommended HRA transparency wording used by KCL/GSTT as sponsor. In addition to this, new text has been added under the subheading 'Further information on the use of your data'. This is to provide additional information about the genetic data that will be generated, how and where this will be used.</p> <p>The consent form section of the PIS has been updated to include specific opt in/out for: use of DNA/RNA, use of data/samples by consortium including industrial partners, samples sent within and outside the UK, willing to be contacted for participation in future research. These changes are all in line with the original intention of the project as detailed in the protocol and have been submitted for clarification only.</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	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 (free text - note that this field will adapt to the amount of text entered):	<p>The time window for study visits 2 & 3 have been reduced for patients enrolled in the Bioresource sub-study. The reduction is from +/- 2 weeks to +/- 1 week in visit 2. The visit 3 window has been reduced from +/- 4 weeks to +/- 1 week with +/- 2 weeks in exceptional circumstances.</p> <p>Sites are now required to complete the A-STAR Bioresource CRF on the same day as the collection of biological material. This change only affects sites undertaking the optional Bioresource sub-study.</p> <p>Sheffield Teaching Hospital and Sheffield Children's Hospital are no longer participating in the Bioresource sub-study and have been removed from the protocol.</p> <p>Pharmacokinetic analysis of Ciclosporin and Azathioprine levels has been removed from the protocol.</p> <p>A typo has been corrected: cellutape to Sellotape and Nick Reynolds' contact details have been updated.</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	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]*:

p.p. Chiara Ellis; Professor Bashir Al-Hashimi

Email address*:

R&D@gstt.nhs.uk; vpri@kcl.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:	Y					Y				Y				Y					C
Change 2:	N					(Y)				(Y)				(Y)					A
Overall reviews for the amendment:																			
Full review:	Y					Y				Y				Y					
Notification only:	N					N				N				N					
Overall amendment type:	Substantial																		
Overall Category:	A																		