Amendment Tool

v1.5 25 Mar 2021

For office use

QC: No

Section 1: Project information

Short project title*:	Biomarker-guided duration of antibiotic treatment for sepsis
IRAS project ID* (or REC reference if no IRAS project ID is available):	209815
Sponsor amendment reference number*:	NSA-12
Sponsor amendment date* (enter as DD/MM/YY):	26 April 2021
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)*:	Trial contacts updated to include current members of the team Trial summary - removal of project timetable Section 7.6 Removal of reference to study timelines Reporting SAEs - Route of reporting SAEs has been updated from fax to email - SAE form amended to reflect this Monitoring section in protocol updated to remove reference to timeline and be less prescriptive. Section 4.1 Updating the protocol with some clarity added to the adverse event reporting section- suggested changes, (just removed the repeated sections and made it more concise and easy to follow The patient information sheets have been updated to remove reference to ethnicity data collection as this data is no longer required- it was added as part of the UPH badging the trial received on 19th Oct 2020 and ceased on the 1st June 2021 and because we no longer require this data we have removed this from the information sheets according to GDPR.

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
	◉	○	○	○
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 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:	◉	○	○	○
Which nations had participating NHS/HSC organisations prior to this amendment?	☑	☑	☑	☑
Which nations will have participating NHS/HSC organisations after this amendment?	☑	☑	☑	☑

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, tick the "Add another change" box.

Change 1				
Area of change (select)*:	Administrative details for the project			
Specific change (select - only available when area of change is selected first)*:	Contact details - CI or other project staff			
Further information (free text - note that this field will adapt to the amount of text entered):	Trial contacts updated to include current members of the team- Trial Manager Nicola McGowan has left the trial and Uzma Manazar appointed as new Trial Manager. Statistician Dipesh Mistry has left and new statistician appointed is Anower Hossain			
Applicability:	England	Wales	Scotland	Northern Ireland
Where are the participating NHS/HSC organisations located that will be affected by this change?*:	☑	☑	☑	☑
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: ☑

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):	Trial summary - removal of project timetable Section 7.6 Removal of reference to study timelines			
Applicability:	England	Wales	Scotland	Northern Ireland
Where are the participating NHS/HSC organisations located that will be affected by this change?*:	☑	☑	☑	☑
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: ☑

Change 3				
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):	Reporting SAEs - Route of reporting SAEs has been updated from fax to email Section 4.1 -Updating the protocol with some clarity added to the adverse event reporting section- suggested changes, (just removed the repeated sections and made it more concise and easy to follow			
Applicability:	England	Wales	Scotland	Northern Ireland
Where are the participating NHS/HSC organisations located that will be affected by this change?*:	☑	☑	☑	☑
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: ☑

Change 4				
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):	Section 8.2 Updated to be less prescriptive and extra details removed from here as it isn't necessary to be included in the protocol when it is already included in the monitoring plan.			
Applicability:	England	Wales	Scotland	Northern Ireland
Where are the participating NHS/HSC organisations located that will be affected by this change?*:	☑	☑	☑	☑

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: ☑

Change 5				
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 (free text - note that this field will adapt to the amount of text entered):	ADAPT Sepsis PIS commencement, ADAPT Sepsis PIS Recovery, ADAPT Sepsis CIS Consultee - all updated to remove reference to ethnicity data collection and now reads: The data collected from your medical records will include information about your health.			
Applicability:	England	Wales	Scotland	Northern Ireland
Where are the participating NHS/HSC organisations located that will be affected by this change?*:	☑	☑	☑	☑
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: ☑

Change 6				
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 (free text - note that this field will adapt to the amount of text entered):	The SAE forms have been amended to remove the word fax and replace with email in line with change in protocol			
Applicability:	England	Wales	Scotland	Northern Ireland
Where are the participating NHS/HSC organisations located that will be affected by this change?*:	☑	☑	☑	☑
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]:*	Mohammed Zubair
Email address:*	Mohammed.Zubair@manchester.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																
UK wide:						England and Wales:				Scotland:				Northern Ireland:			
	thority nes	thority s		rance	ance				/V Approval				nating function				nating function

	REC	Competent Aut MHRA - Medici	Competent Aut MHRA - Device	ARSAC	Radiation Assu	UKSW Governa	REC (MCA)	CAG	HMPPS	HRA and HCR\	REC (AWIA)	PBPP	SPS (RAEC)	National coordi	HSC REC	HSC Data Gua	Prisons	National coordi	Category:
Change 1:	(Y)					Y				(Y)				(Y)				(Y)	C
Change 2:	N					(Y)				(Y)				(Y)				(Y)	A
Change 3:	N					(Y)				(Y)				(Y)				(Y)	A
Change 4:	N					(Y)				(Y)				(Y)				(Y)	A
Change 5:	N					(Y)				(Y)				(Y)				(Y)	C
Change 6:	N					(Y)				(Y)				(Y)				(Y)	C
Overall reviews for the amendment:																			
Full review:	N					Y				N				N				N	
Notification only:	Y					N				Y				Y				Y	
Overall amendment type:	Non-substantial																		
Overall Category:	A																		

For national coordinating function office use:	
Update HARP:	This amendment may involve an update to contact details, project end date, or other project details. Ensure that HARP is updated with the current details. If this is the only change, no further study-wide review is required.