Amendment Tool

v1.2 11 Jun 2020

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-10
Sponsor amendment date* (enter as DD/MM/YY):	09 November 2020
Summary of amendment including justification*:	Addition of special category data to be collected added to the PIS - special category data added is ethnicity data

Project type:	◉ 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?:	◉ 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?	○ 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 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 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 Changes" tab. To add another change, tick 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 minor document change that can be implemented within existing resource in place at participating organisations - Please specify in the free text below
Further information (free text):	The trial is UPH badged, following the NICE guidelines requirement the additional wording has been added to all Patient information sheets for data transparency- 'The data collected from your medical records will include information about your health and your ethnicity. This data is considered to be special category data and will be collected so that the relevance of the patient population to the NHS patient population can be evaluated'.

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?:	◉ 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]:*	Stephanie Edwards
Email address:*	Stephanie.Edwards@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 PDF copy of the completed amendment tool that can 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, refer to the "Submission Guidance" tab for 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:				
petent Authority A - Medicines	petent Authority A - Devices	AC	ation Assurance	W Governance	(MCA)		PS	and HCRW Approval	(AWIA)	P	(RAEC)	onal coordinating function	REC	Data Guardians	ons	onal coordinating function

	REC	Com MHR	Com MHR	ARS	Radi	UKSI	REC	CAG	HMP	HRA	REC	PBPI	SPS	Natio	HSC	HSC	Priso	Natio	Category:
Change 1:						(Y)				(Y)				(Y)				(Y)	C
Overall reviews for the amendment:																			
Full review:						N				N				N				N	
Notification only:						Y				Y				Y				Y	
Overall amendment type:	Non-substantial, no study-wide review required																		
Overall Category:	C																		