Amendment Tool

v1.6 06 December 2021

For office use

QC: No

Section 1: Project information

Short project title*:	MAPS-2
IRAS project ID* (or REC reference if no IRAS project ID is available):	290474
Sponsor amendment reference number*:	MA_04_22
Sponsor amendment date* (enter as DD/MM/YY):	29 June 2022
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)*:	1) The inclusion criteria in the protocol has been slightly amended as per feedback from sites that are struggling to recruit. Patients must now have an NIHSS 10≥, OR NIHSS 6≥ and a failed bedside assessment of swallowing (instead of having an NIHSS 10≥ AND a failed bedside assessment of swallowing). The sentence "...unless this is more than 12 h from last known well." (in relation to the recruitment time window) has been removed, as this was found to confuse research staff. The CI and TSC agreed the above protocol changes and that this sentence was redundant. 2) University Hospital Coventry and Royal United Hospital Bath have withdrawn from setting up the study. 3) There has been a change in PI at University Hospital of North Tees. 4) Friarage Hospital (South Tees Hospitals NHS Foundation Trust) and Redcar Primary Care Hospital (South Tees Hospitals NHS Foundation Trust) have been added as repatriation sites (No PIs). Stepping Hill Hospital (Stockport NHS Foundation Trust) has been added as a new recruiting site: PI: Dr. Appukuttan Suman. 5) A protocol amendment table has been added to the final page of the protocol, which will document and summarise all protocol changes going forward in the trial.

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
	Yes	No	No	No
Was the study a clinical trial of an investigational medicinal product (CTIMP) OR does the amendment make it one?:	**Yes**		No	
EudraCT number*:	2021-003853-40			
Was this clinical trial of an investigational medicinal product (CTIMP) processed under the CTIMP combined review service (formerly known as the Combined Ways of Working (CWoW) pilot)?:	Yes		**No**	
Did the study receive Pharmacy Assurance?:	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 have Radiation Assurance OR is Radiation Assurance being sought for the first time because of this amendment?:	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**	**Yes**
Which nations will have participating NHS/HSC organisations after this amendment?	**Yes**	**Yes**	**Yes**	**Yes**

Section 2: Summary of change(s)

What do you want to update?:	**Project information**
	New site/PI only

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)*:	Inclusion/exclusion criteria - Minor change unlikely to affect safety or scientific value of study
Further information (free text - note that this field will adapt to the amount of text entered):	The inclusion criteria has been amended to include patients with an NIHSS >=10 OR NIHSS >=6 AND a failed bedside assessment of swallowing. Patients are no longer required to have both to be eligibile for trial entry. Changing from AND to OR for dysphagia and NIHSS>=10 will not affect the scientific validity of the trial, as both NIHSS>=10 and dysphagia independently predict pneumonia and mortality. Therefore the frequency of outcomes (death, pneumonia) will not be affected by the change in patietns with stroke. As a further safeguard we added NIHSS>=6 to dysphagia. While dysphagia itself is suffifficient in definite strokes, some patients present with dysphagia and non-stroke conditions. Adding a minimum NIHSS will exclude these. Additionally, The sentence in the inclusion criteria #2 "...unless this is more than 12 h from last known well." (in relation to the recruitment time window) has been removed, as the CI and TSC agreed this was not required and risked confusing the investigators at sites.

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	
			Remove all changes below	

Change 2	
Area of change (select)*:	Participating Organisations
Specific change (select - only available when area of change is selected first)*:	Early closure or withdrawal of research sites
Further information (free text - note that this field will adapt to the amount of text entered):	The following two recruiting sites are no longer able to participate in MAPS-2 and have thus withdrawn from study set-up: University Hospital Coventry and Royal United Hospital Bath.

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	
			Remove all changes below	

Change 3	
Area of change (select)*:	Researchers
Specific change (select - only available when area of change is selected first)*:	PI - New PI, or temporary arrangements to cover the absence of a PI

Further information (free text - note that this field will adapt to the amount of text entered):	Dr. Sarah Whitehouse has replaced Dr. Ijaz Anwar at University Hospital of North Tees (North Tees and Hartlepool Hospitals NHS Foundation Trust).

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	

Remove all changes below

Change 4	
Area of change (select)*:	Participating Organisations
Specific change (select - only available when area of change is selected first)*:	Addition of sites undertaking the same activities as existing sites
Further information (free text - note that this field will adapt to the amount of text entered):	Two new repatriation sites have been added: Redcar Primary Care Hospital and Friarage Hospital (both South Tees Hospitals NHS Foundation Trust). It has already been confirmed that repatriation sites do not require Pis in MAPS-2. Stepping Hill Hospital (Stockport NHS Foundation Trust) has been added as a new recruiting site - the PI is Dr. Appukuttan Suman.

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 5	
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):	A protocol amendment table has been inserted into the final page of the protocol. This table will document and summarise all protocol changes going forward.

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]:*	Angela Shone
Email address:*	sponsor@nottingham.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:			
	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	Category:
Change 1:						(Y)				(Y)				(Y)				(Y)	A
Change 2:						(Y)				(Y)				(Y)				(Y)	A
Change 3:						(Y)				(Y)				(Y)				(Y)	A
Change 4:						(Y)				(Y)				(Y)				(Y)	New site
Change 5:						(Y)				(Y)				N				N	B
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:	A																		