# **Amendment Tool**

v1.6 06 December 2021

QC: No

Short project title*:	DASH									
IRAS project ID* (or REC reference if no IRAS project ID										
is available):	233744									
Sponsor amendment reference number*:	MA_12_22									
Sponsor amendment date* (enter as DD/MM/YY):	20 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)*:	trial. In the original E (VWF) antigen, VWI  We would like to ma assess ADAMTS13 microparticles and c  These tests would b and factor VIII assay be destroyed after e assays. The tests w Desborough (deput) Haemophilia and Th separately to the ma	We have collected matched pre-/post-IMP plasma samples from 25/54 patients in the Dritial. In the original DASH protocol, these samples were to measure Von Willebrand Fact (VWF) antigen, VWF activity and factor VIII to assess the effects of the IMP.  We would like to make an amendment to the protocol to add additional tests. We intend assess ADAMTS13 activity (an enzyme responsible for cleaving VWF), VWF-bearing microparticles and coagulation tests related to VWF and microparticles.  These tests would be performed on any plasma remaining after the VWF antigen, VWF and factor VIII assays. No further blood or plasma is required from patients. The samples be destroyed after experiments are complete. No further funding will be required for these assays. The tests will be run by Dr Arthur Disegna under the supervision of Dr Michael Desborough (deputy chief-investigator of the DASH trial) and Prof Nikki Curry at the Oxford Haemophilia and Thrombosis Centre. The results of these additional tests would be publicated by the main DASH trial.  This amendment has the support of the DASH trial steering committee, the sponsor of the and our patient representatives.								
				Specific s	tudy					
Project type (select):		Research tissue bank								
J				Research	datahasa					
Has the study been reviewed by a UKECA-recognised Res	search Ethics		/os	Nescarcii						
Has the study been reviewed by a UKECA-recognised Res Committee (REC) prior to this amendment?:	search Ethics	Y	es es		No					
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Yes

Did the study involve NHS/HSC organisations prior to this amendment?:

No

Did the study involve non-NHS/HSC organisations OR does the amendment introduce them?:	Y	es	ı	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	Yes	No		
Which nations will have participating NHS/HSC organisations after this amendment?	Yes	No	Yes	No		

# Section 2: Summary of change(s)

What do you want to update?:	Project information
what do you want to update:.	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)*:	of Samples - minor changes (e.g. to the logistical arrangements for transporting or samples)								
Further information (free text - note that this field will adapt to the amount of text entered):	We have collected m trial. In the original D/ (VWF) antigen, VWF  We would like to mak assess ADAMTS13 a microparticles and co  These tests would be and factor VIII assays be destroyed after ex assays. The tests will Desborough (deputy Haemophilia and Thr separately to the mail This amendment has and our patient representations.	ASH protocol, thes activity and factor e an amendment to tivity (an enzyme agulation tests related by performed on any so that the support of	e samples were to VIII to assess the to the protocol to a responsible for cleated to VWF and not plasma remaining or plasma is requirablete. No further fur Disegna under to the DASH trial) a he results of these	measure Von Will effects of the IMP.  dd additional tests eaving VWF), VWI nicroparticles.  g after the VWF an red from patients. unding will be required by the supervision of I and Prof Nikki Currel additional tests will effects of the supervision of the additional tests will effect the IMP.	lebrand Factor  . We intend to F-bearing  tigen, VWF activ The samples wil irred for these Dr Michael y at the Oxford ould be publishe				
Applicability:		England	Wales	Scotland	Northern Irela				
Where are the participating NHS/HSC organisations locat by this change?*:	ed that will be affected	Yes	No	Yes	No				
Will all participating NHS/HSC organisations be affected b some? ( <b>please note</b> that this answer may affect the cates change):	, , ,	Į.	All	So	ome				
	<del></del>			Remove all o	hongoo holow				

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):	Protocol amended to	Protocol amended to include the above change								
Applicability:		England	Wales	Scotland	Northern Ireland					
Where are the participating NHS/HSC organisations locate by this change?*:	ed that will be affected	Yes	No	Yes	No					
Will all participating NHS/HSC organisations be affected by some? (please note that this answer may affect the categorange):	A	All	Some							
				Add anot	her 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.

Please note: This section is for info		,						•	Review		•								]
		UK wide:				Eng	gland a			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)	РВРР	SPS (RAEC)	National coordinating function	4SC REC	HSC Data Guardians	Prisons	National coordinating function	Category:
Change 1:						(Y)				(Y)				(Y)					С
Change 2:						(Y)				(Y)				(Y)					А
Overall reviews for the amendm	ent:	•																	
Full review:						N				N				N					
Notification only:						Υ				Υ				Υ					
Overall amendment type:	N	on-sub	stantia	ıl, no s	tudy-v	vide re	view r	equire	d										
Overall Category:	А																		