Amendment Tool

v1.5 25 Mar 2021

For office use 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_08_21						
Sponsor amendment date* (enter as DD/MM/YY):	13 September 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)*:	Site 005, Derby, willl	close to recruitmer	nt on 30th Septemi	ber 2021.			
		(Specific study	′			
Project type (select):			Research tiss	ue bank			
		O Research database					
Has the study been reviewed by a UKECA-recognised Res	search Ethics			1			
Committee (REC) prior to this amendment?:	Sourch Eurice		Yes		O No		
What type of UKECA-recognised Research Ethics Commit	ttee (REC) review	(NHS/HSC RE	C			
is applicable? (select):		O Ministry of Defence (MoDREC)					
Is all or part of this amendment being resubmitted to the R Committee (REC) as a modified amendment (i.e. a subst amendment previously given an unfavourable opinion)?	() Yes		No			
Where is the NHS/HSC Research Ethics Committee (REC	that reviewed	England	Wales	Scotland	Northern Irela		
the study based?: Was the study a clinical trial of an investigational medicinal product (CTIMP)		•	0	0	0		
OR does the amendment make it one?:	product (CTIVIII)	(Yes		○ No		
EudraCT number*:		2018-001904-1	12				
Was this clinical trial of an investigational medicinal processed under the Combined Ways of Working (CV			O Yes		No		
Did the study receive Pharmacy Assurance?:			O Yes		No		
Was the study a clinical investigation or other study of a modoes the amendment make it one?:	edical device OR	() Yes		No		
Did the study involve the administration of radioactive substrequiring ARSAC review, OR does the amendment introdu		() Yes		No		
Did the study involve the use of research exposures to ioni (not involving the administration of radioactive substances) amendment introduce this?:		() Yes	,	No		
Did the study involve adults lacking capacity OR does the a introduce this?:	amendment	(Yes		○ No		
Did the study involve access to confidential patient informa direct care team without consent OR does the amendment		(Yes		No		
Did the study involve prisoners OR does the amendment in	ntroduce this?:	() Yes		No		
Did the study involve children OR does the amendment int	roduce 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 doe introduce them?:	es the amendment	() Yes		No		
minoduce them:		England	Wales	Scotland	Northern Irel		
Lead nation for the study:		•	0	0	0		
Which nations had participating NHS/HSC organisations p amendment?	rior to this	V		V			

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Section 2: Summary of change(s)

What do you want to undate?

Project information

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Area of change (select)*: Participating Organisations Early closure or withdrawal of research sites Centre 005, Royal Derby Hospital, will close to recruitment on 30th September 202! 1 dadget to the amount of text entered): Centre 005, Royal Derby Hospital, will close to recruitment on 30th September 202! 1 DASH trial. The reason for this, given by the site, is that the research nurse is moving and there is lack of capacity until her replacement is in post. Applicability. Applicabili	dicinal product (CTIMP) involves tents to be given to participants,	s an update to the In these should be en	nvestigator's Bro Itered into the ai	chure (IB), affe mendment tool	ecting the Refer as three separ	ence Safety Information at the changes. A list of a	on (RSI) and so the			
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Non-substantial, no study-wide review required

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Overall reviews for the amendment:

Change 1:

Full review:

Notification only:

Overall amendment type:

Overall Category: