Amendment Tool

v1.6 06 December 2021

For office use

QC: Yes

Section 1: Project information

Short project title*:	MicroGuide-2
IRAS project ID* (or REC reference if no IRAS project ID is available):	295323
Sponsor amendment reference number*:	DRC #8614
Sponsor amendment date* (enter as DD/MM/YY):	06 May 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)*:	Study timescales modified due to pandemic. Sample size calculations updated to reflect latest knowledge of primary outcome trends in NHS hospitals. Administrative corrections. Supplier Contact Information – Chief Investigator profile and contact information updated; Director of Research profile information updated Protocol Summary – Supplier's details updated; changed wording to clarify on sample size calculation and redefined study population 3.1. Summary of Study Design – Timescales extended due to pandemic impacts. 3.2. Study Population – redefined to include all NHS Trusts that use MicroGuide, 3.3 Inclusion Criteria – For inclusion criteria: Demonstrating carbapenem class antimicrobial consumption within a middle band for NHS Trusts in England; added wording to optimize study power 5 Study Flow Chart – Trial Design Overview added 6.1.1.1 Protection of Human Subjects – Site recruitment methods expanded. 8.3. Sample Size and Power Calculations – changed percentage of change in primary outcomes (from 15% to 20%) and number of Trusts (from 9 to 8) to achieve study power of 80%; study power of 90% has been removed. Protocol changes have been reviewed within the study team and by MSD global review group.

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**	
Was the study a clinical investigation or other study of a medical device OR does the amendment make it one?:	**Yes**		No	
Does this clinical investigation or other study of a medical device require a Notice of No Objection from MHRA Devices?:	**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 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**	No	No	No
Which nations will have participating NHS/HSC organisations after this amendment?	**Yes**	No	No	No
Was this a "single site, self sponsored" study in England or Wales prior to this amendment?	Yes		**No**	

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, click 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 - Sponsor or representative			
Further information (free text - note that this field will adapt to the amount of text entered):	Supplier Contact Information – Chief Investigator profile and contact information updated; Director of Research profile information updated. Protocol Summary – Supplier's details updated.			
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 2				
Area of change (select)*:	Study Design			
Specific change (select - only available when area of change is selected first)*:	Participant numbers - Minor change to sample size			
Further information (free text - note that this field will adapt to the amount of text entered):	Changed wording to clarify on sample size calculation and redefined study population. 8.3. Sample Size and Power Calculations – changed percentage of change in primary outcomes (from 15% to 20%) and number of Trusts (from 9 to 8) to achieve study power of 80%; study power of 90% has been removed.			
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 3				
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):	3.2. Study Population – redefined to include all NHS Trusts that use MicroGuide, 3.3 Inclusion Criteria – For inclusion criteria: Demonstrating carbapenem class antimicrobial consumption within a middle band for NHS Trusts in England; added wording to optimize study power. 5 Study Flow Chart – Trial Design Overview added			
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 4				
Area of change (select)*:	Study Design			
Specific change (select - only available when area of change is selected first)*:	Extension to study duration that will not have any additional resource implications for participating organisations - Please specify in the free text below			
Further information In particular, please describe why this change can be implemented within the existing resource in place at the participating organisations (free text - note that this field will adapt to the amount of text entered)*	3.1. Summary of Study Design – Timescales extended due to pandemic impacts.			
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 Design			
Specific change (select - only available when area of change is selected first)*:	Other significant change to study design that can be implemented within existing resource in place at participating organisations - Please specify in the free text below			
Further information In particular, please describe why this change can be implemented within the existing resource in place at the participating organisations (free text - note that this field will adapt to the amount of text entered)*	6.1.1.1 Protection of Human Subjects – Site recruitment methods expanded.			
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]:*	Edita Custic Weguelin
Email address:*	edita.custic@msd.com

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)									C
Change 2:	N		Y			(Y)				(Y)									B
Change 3:	N		Y			(Y)				(Y)									B
Change 4:	N		Y			(Y)				(Y)									C
Change 5:	Y		Y			Y				Y									C
Overall reviews for the amendment:																			
Full review:	Y		Y			Y				Y									
Notification only:	N		N			N				N									
Overall amendment type:	Substantial																		
Overall Category:	B/C																		

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.