Amendment Tool

v1.6 06 December 2021

For office use

QC: No

Section 1: Project information

Short project title*:	EVIS
IRAS project ID* (or REC reference if no IRAS project ID is available):	307862
Sponsor amendment reference number*:	SA_10
Sponsor amendment date* (enter as DD/MM/YY):	13 February 2025
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)*:	Following the submission of SA09 (on 20/12/2024), the HRA requested all PIS/ICFs to include the HRA's transparent wording for GDPR. All PIS/ICFs were updated in response. However, due to an administrative error, these updated documents were not incorporated into the REC's favourable opinion for SA09. The REC advised the submission of another amendment in order to address this. The changes submitted in this amendment are; 1). Minor updates to the study documentation to incorporate the HRA's transparent wording for the; EVIS Main PIS/ICF, PIS Summary, Welfare Attorney/Guardian, Professional Legal Rep (Scotland & England), Recovered Capacity (Scotland & England), Personal Legal Rep PIS/ICFs and EVIS Sub-Study Consent Form & PIS (V3.0) 2). Changes to the EVIS GP Letter (V2.0) to update the GP letter to; (A) reflect the revised primary outcome (B) Update the specified follow up period to match the protocol changes submitted in SA09. 3). Changes to the EVIS Trial Protocol (V5.0): (A) Administrative updates: versioning. (B) Correction of identified errors in time points for various end points. (C) Updated the description of the health economics evaluation (D) Revised time point of evaluation for the Health outcomes

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
	No	No	**Yes**	No
Was the study a clinical trial of an investigational medicinal product (CTIMP) OR does the amendment make it one?:	**Yes**		No	
EudraCT number*:	2021-006886-39			
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 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:	No	No	**Yes**	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?:	Chief Investigator Sponsor Group Administrative **Project information**

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 Documents			
Specific change (select - only available when area of change is selected first)*:	Other minor change to study documents (e.g. information sheets, consent forms, questionnaires, letters) 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)*	1). Minor updates to the study documentation to incorporate the HRA's transparent wording for the; EVIS Main PIS/ICF, PIS Summary, Welfare Attorney/Guardian, Professional Legal Rep (Scotland & England), Recovered Capacity (Scotland & England), Personal Legal Rep PIS/ICFs and EVIS Sub-Study Consent Form & PIS (V3.0)			
Applicability:	England	Wales	Scotland	Northern Ireland
Where are the participating NHS/HSC organisations located that will be affected by this change?*:	**Yes**	No	**Yes**	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 Documents
Specific change (select - only available when area of change is selected first)*:	Other significant change to study documents (e.g. information sheets, consent forms, questionnaires, letters) 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	2) Changes to the EVIS GP Letter (V2.0) (A). To update the GP letter to provide the revised primary outcome as the way in which clinical effectiveness is measured. (B). To update the specified follow up period to match the protocol changes submitted in SA09. 3). Changes to the EVIS Trial Protocol (V5.0): (A) Correction of identified errors in time points for various end points. Updated the Schedule of Assessments, Study Visits, Objectives and Outcome Measures and Appendix C to ensure

that this field will adapt to the amount of text entered)*	Assessments, Study Visits, Objectives and Outcome measures and Appendix C to ensure consistency in each section in regard to the time points specified for data collection for each end point. (B) Updated the description of the health economics evaluation to provide further information regarding the data used, and how this is being collected. (C) Revised time point of evaluation for the Health outcomes i.e. the collection of re-admission data 30 & 90 days post randomisation instead of post discharge.

Applicability:	England	Wales	Scotland	Northern Ireland
Where are the participating NHS/HSC organisations located that will be affected by this change?*:	**Yes**	No	**Yes**	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 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):	3). Changes to the EVIS Trial Protocol (V5.0): (A) Administrative updates: versioning.

Applicability:	England	Wales	Scotland	Northern Ireland
Where are the participating NHS/HSC organisations located that will be affected by this change?*:	**Yes**	No	**Yes**	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]:*	Louise Ner
Email address:*	louise.ner@nhs.net

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, amendments to trials processed under the combined review service should be made using the new part of IRAS. Further information can be found on the "Submission Guidance" tab.

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:			
									roval				function				function

	REC	Competent Authority MHRA - Medicines	Competent Authority MHRA - Devices	ARSAC	Radiation Assurance	UKSW Governance	REC (MCA)	CAG	HMPPS	HRA and HCRW App	REC (AWIA)	PBPP	SPS (RAEC)	National coordinating	HSC REC	HSC Data Guardians	Prisons	National coordinating	Category:
Change 1:	N					(Y)				(Y)				(Y)					C
Change 2:	Y					Y				Y				Y					C
Change 3:	N					(Y)				(Y)				(Y)					A
Overall reviews for the amendment:																			
Full review:	Y					Y				Y				Y					
Notification only:	N					N				N				N					
Overall amendment type:	Substantial for review																		
Overall Category:	A																		