Amendment Tool

v1.6 06 December 2021

For office use

QC: No

Section 1: Project information

Short project title*:	BADBIR
IRAS project ID* (or REC reference if no IRAS project ID is available):	32990
Sponsor amendment reference number*:	Substantial Amendment 13
Sponsor amendment date* (enter as DD/MM/YY):	01 August 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)*:	Changes to protocol have been made to accommodate changes in the British Association of Dermatologists Biologics & Immunomodulators Register (BADBIR): • Extension to the duration study participants complete questionnaires. Existing protocol includes collection of patient-report outcome measures from patients up to year 3 of the study only. After this, clinical follow-up continues but data not collected from participants directly. This amendment alters schedule for a once annual collection of questionnaire data from participants after year 3 of participation. • Addition of two new disease severity measures for patients with Generalised Pustular Psoriasis diagnosis (GPPGA & GPPASI) • Change to Biologic Exposed Cohort eligibility criteria to allow entry of biologic-experienced patients commencing new Small Molecule therapies

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**	
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**	**Yes**	**Yes**	**Yes**
Which nations will have participating NHS/HSC organisations after this amendment?	**Yes**	**Yes**	**Yes**	**Yes**

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)*:	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):	Sections 6 and 8.7 of the Protocol detail the questionnaires completed by BADBIR participants at study follow-ups. In prior Protocol, patient-completed data was not collected after FUP6 of the study (year 3). This has been amended and participants will be requested to complete questionnaires once annually after year 3 (FUP7+) until study end. The rationale for this change is to capture more patient-reported severity and outcomes data in later follow-up years for each participant. With successful recruitment since 2007, BADBIR now has many thousands of patients in long-term follow-up. In clinic, many patients are switching between different psoriasis therapies following their initial registration into BADBIR. This extension of questionnaire collection will provide significantly more patient-reported data on a more psoriasis treatments providing the study with more comprehensive data for analysis. It is not anticipated this will have significant impact on participating research sites. Participants are able to enter questionnaire data directly through a dedicated online portal.

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)*:	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):	The core physician-assessed disease severity measures in the BADBIR protocol are the Psoriasis Area and Severity Index (PASI) and the Physician Global Assessment (PGA). These measures are used extensively in dermatology outpatients clinics for patients with generalised chronic plaque psoriasis diagnosis. The BADBIR protocol allows registrations of patients with varied psoriasis phenotypes at baseline. Patients with a diagnosis of Generalised Pustular Psoriasis cannot have disease accurately measure with PASI and PGA. There are two disease-specific severity measures more appropriate: Generalised Pustular Psoriasis Physician Global Assessment (GPPGA) & Generalised Pustular Psoriasis Area and Severity Index (GPPASI). Both have been added to the data collection at baseline and all follow-ups.

Applicability:	England	Wales	Scotland	Northern Ireland
Where are the participating NHS/HSC organisations located that will be affected by this change?*:	**Yes**	**Yes**	No	**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)*:	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 Small Molecule study cohort was introduced to BADBIR in 2018 to reflect new additions to the psoriasis drug market in the real world. At this time, the new small molecule treatments were anticipated to be used pre-biologic therapy to treat psoriasis. The original eligibility criteria thus instructed patients joining this cohort must be naive to biologic therapy. In 2022, there are further Small Molecule drugs upcoming in the pipeline to treat psoriasis. The newer products are anticipated to be used as alternative to or following a biologic treatment for psoriasis. To reflect real-world use of all new Small Molecule products, the eligibility criteria has been changed to allow registrations of biologic-experienced patients. If patient commencing new Small Molecule drug is naive to biologics, they will enter the Small Molecule cohort. If patient has been treated with a biologic previously, they will enter the Biologic-Exposed cohort.

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)*:	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)*	Minor changes made to the Clinical Questionnaires to accommodate changes 1-3 within data collection. Minor updates to consent and patient information materials to reflect new study Chief Investigator (see change 5 below) Consent and PIS Materials: • Patient Information Sheet v5.3 • Patient Consent Form v5.3 • Patient Assent Form v5.3 • Parent or Guardian Consent Form v5.3 • BADBIR Children's Information Sheet v2.2 • BADBIR Young Persons Information Sheet v2.2 • BADBIR Very Young Children's Information Sheet v2.2 Questionnaires: • Clinical Baseline Questionnaire v11 • Clinical Follow-up Questionnaire v11 • Patient Baseline Questionnaire v6 • Patient Follow-up Questionnaire v7 • Under 16 Patient Baseline Questionnaire v2 Patient Portal Documentation: • Patient Portal Invitation Letter v1 N.B. This is a new document and a variation on the existing Participant Invitation letter used by local sites to contact eligible patients in advance of consent. The Portal Invitation letter is for optional use by sites to contact previously-consented study participants to request they join the online Portal to record questionnaires as alternative to completing in-clinic. Reasonable changes are permitted to reflect local practice.

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 5	
Area of change (select)*:	Researchers

Specific change (select - only available when area of change is selected first)*:	CI - New CI, or temporary arrangements to cover the absence of a CI
Further information (free text - note that this field will adapt to the amount of text entered):	Named Chief Investigator for BADBIR study will change from Professor Chris Griffiths to Professor Richard Warren.

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 6	
Area of change (select)*:	Researchers
Specific change (select - only available when area of change is selected first)*:	Changes to the research team (other than CIs or PIs)
Further information (free text - note that this field will adapt to the amount of text entered):	The Steering Committee appointed by BADBIR funder has changed. This has been updated on page 1 of the Protocol.

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 7	
Area of change (select)*:	Participant Procedures
Specific change (select - only available when area of change is selected first)*:	Participant procedures - minor change that can be implemented within existing resource 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)*	In line with Change 1 described above, participants after year 3 in the study are now requested to complete questionnaires about their health once annually. Participants will be encouraged to do this directly through the online Patient Portal applications thus impact on participating organisations is limited.

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	

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]:*	Lynne MacRae
Email address:*	FBMHethics@manchester.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:	N					(Y)				(Y)				(Y)				(Y)	A
Change 2:	N					(Y)				(Y)				N				(Y)	B
Change 3:	N					(Y)				(Y)				(Y)				(Y)	A
Change 4:	N					(Y)				(Y)				(Y)				(Y)	C
Change 5:	Y					Y				(Y)				(Y)				(Y)	C
Change 6:	N					N				N				N				N	N/A
Change 7:	N					(Y)				(Y)				(Y)				(Y)	C
Overall reviews for the amendment:																			
Full review:	Y					Y				N				N				N	
Notification only:	N					N				Y				Y				Y	
Overall amendment type:	Substantial																		
Overall Category:	A																		

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.