

Modification Tool

v2.1 24 April 2026

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 modification reference number*:	Substantial Amendment 15			
Sponsor modification date* (enter as DD/MM/YY):	19 March 2026			
Briefly summarise in lay language the main changes proposed in this modification. Explain the purpose of the changes and their significance for the project. If the modification 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)*:	The British Association of Dermatologists Biologics and Immunomodulators Register (BADBIR) study has been open since 2007. This amendment principally covers two significant changes: 1) Extend Study End Date by 10-years from July 2028 to July 2038 2) Introduce a new type of Data Linkage from national healthcare data providers including NHS England. To date, the study has benefitted from linkage on mortality, malignancy and episodes of inpatient admission. This amendment has the addition of Prescriptions datasets to protocol in order to obtain the most comprehensive data available on treatment exposure.			
Project type (select):	Specific project			
	Research tissue bank Research database			
Has the project been reviewed by a UKECA-recognised Research Ethics Committee (REC) prior to this modification?:	Yes		No	
What type of UKECA-recognised Research Ethics Committee (REC) review is applicable? (select):	NHS/HSC REC			
	Ministry of Defence (MoDREC)			
Where is the NHS/HSC Research Ethics Committee (REC) that reviewed the project based?:	England	Wales	Scotland	Northern Ireland
	Yes	No	No	No
Was the project a clinical trial of an investigational medicinal product (CTIMP) OR does the modification make it one?:	Yes		No	
Was the project a clinical investigation or other study of a medical device OR does the modification make it one?:	Yes		No	
Was the project a performance evaluation study of an In Vitro Diagnostic (IVD) medical device [^] (including as a companion diagnostic in a clinical trial of an investigational medicinal product)?:	Yes		No	
Does the modification make the project a performance evaluation study of an In Vitro Diagnostic (IVD) medical device [^] (including as a companion diagnostic in a clinical trial of an investigational medicinal product)?:	Yes		No	
[^] IVD medical devices are tests used on biological samples, such as tissues, blood or urine, to determine the status of a person's health. This may be a reagent, reagent product, calibrator, control material, kit, instrument, apparatus, equipment or system, whether used alone or in combination				
Did the project involve the administration of radioactive substances, therefore requiring ARSAC review, OR does the modification introduce this?:	Yes		No	
Did the project involve the use of research exposures to ionising radiation (not involving the administration of radioactive substances) OR does the modification introduce this?:	Yes		No	
Did the project involve adults lacking capacity OR does the modification introduce this?:	Yes		No	
Does the project involve access to confidential patient information outside the direct care team without consent OR does the modification introduce this?: (e.g. the project relies upon section 251 support in England and Wales, or equivalent in Scotland to set aside the common law duty of confidentiality)	Yes		No	

Does the project involve prisoners or young offenders who are in custody or supervised by the probation service OR does the modification introduce this?:	Yes	No		
Does the project involve children OR does the modification introduce this?:	Yes	No		
Did the study involve NHS/HSC organisations prior to this modification?:	Yes	No		
Did the study involve non-NHS/HSC organisations OR does the modification 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 modification?	Yes	Yes	Yes	Yes
Which nations will have participating NHS/HSC organisations after this modification?	Yes	Yes	Yes	Yes

Section 2: Summary of change(s)

Please note: Each change being made as part of the modification must be entered separately. For example, if a modification 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 modification tool as three separate changes. A list of all possible changes is available on the "Glossary of Options" tab. To add another change, click the "Add another change" box.

Change 1	
Area of change (select)*:	Project design
Specific area of change (select - only available when area of change is selected first)*:	Change to project duration (no change to project end definition, treatment or interventions, or monitoring arrangements) that will not have any additional resource implications for participating organisations - please specify in the free text below
Further information: explain what the change is, why the change is being made and any possible impact on participants/carers (free text - note that this field will adapt to the amount of text entered):	*Study End Extended to 2038* BADBIR's current study end date is July 2028. It is proposed to extend this by ten years to July 2038. The original date in 2028 was estimated on time required to acquire enough person years follow-up data on new treatments for psoriasis to power a question on malignancy risk. In the 19 years since BADBIR was established, multiple new types of biologic and small molecule treatments for psoriasis have become available on the NHS. With this, there has been some fragmentation to treatment exposure across the disease population. Each new class of treatment introduced is taking additional time to now acquire power for a drug safety analysis. This is particularly the case for the latest classes of biologic therapies released to market (IL-23 inhibitors and IL-17AF inhibitors). A date of 2038 will allow sufficient time to gather appropriate person years follow-up on newer treatments to best evidence a statistically-significant safety analysis to take place. As well as comparing biologic therapies to conventional systemics, section 11.3 of protocol has stated it will be additionally possible to make comparisons between the distinct modes-of-action within the biologic treatment group. A new appendix 2 has been added to the Protocol to profile the power needed for these comparisons. The figure in appendix 2 demonstrates that the proposed 10-year extension would be essential to power intra-biologic comparisons. Without this extension, key comparisons, particularly those involving IL-17 and IL-23 inhibitors, will remain underpowered and unable to provide definitive evidence on long-term malignancy risk. Additional benefits of extending study end date are: (1) To acquire greater follow-up duration on the paediatric recruits into the study (i.e. those exposed on systemic treatments before the age of 16). (2) To understand more about any potential affect of cumulative exposure to multiple systemics / modes-of-action. The earliest patients recruited into BADBIR have received biologic therapies for almost 20 years with many exposed to multiple treatments with. (3) BADBIR also has established itself as a leading resource for research in moderate-to-severe psoriasis since inception in 2007. This extension will further strengthen the long-term utility of this dataset to explore the natural progression of disease.

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)*:	Confidential patient information			
Specific area of change (select - only available when area of change is selected first)*:	Data items			
Further information: explain what the change is, why the change is being made and any possible impact on participants/carers (free text - note that this field will adapt to the amount of text entered):	*Data Linkage Services on Prescriptions Added to Protocol* BADBIR has benefited from data linkage since inception in 2007 (Malignancy & Mortality). A subsequent amendment added in services on episodes of inpatient admission. BADBIR continues to benefit from this linkage to ensure the most comprehensive data possible is informing study outcome. In 2026, new services from NHS England are to be introduced on Secondary care electronic prescribing and medicine administration (ePMA). Equivalent services are available from other providers including Public Health Scotland. Linkage services covering prescriptions will help collect best possible data on treatments exposure for individual patients. For the primary outcome of safety in BADBIR, this will strengthen accuracy in attribution of risk on adverse event outcomes. Section 3.3 of the protocol has been amended to profile the study's additional linkage category of "Prescriptions". Changes to information sheet and consent form documentaiton are described below as Change 3. Please note BADBIR has applied for amendment to existing S251 approval with the Confidentiality Advisory Group (CAG) in parallel with this NHS Ethics submission. It is the intention to link on prescriptions data for existing study participants as well as those newly consenting.			
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 3	
Area of change (select)*:	Project documents
Specific area of change (select - only available when area of change is selected first)*:	Other non-significant change to project documents that can be implemented within existing resource in place at participating organisations - please specify in the free text below
Further information: explain what the change is, why the change is being made and any possible impact on participants/carers. 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)*	*Updated Consent Materials* The 'Prescriptions' category of Linkage services has been added to the Information Sheet and Consent Form to inform participants of how data will be used. Please note the named services and providers in each region of the UK detailed on page 5 of the informaiton sheet are periodically updated as these may be subject to change. Up-to-date information of these services is available on BADBIR's website. An additional consent statement has been added to all consent form variants enabling the participant to indicate their willingness (or otherwise) to be contacted by the University of Manchester about similar studies. The statement clarifies that this is optional and that the participant can participate in the study without agreeing to this. We are now collecting patient

participant can participate in the study without agreeing to this. We are now collecting patient email address on the Baseline CRF to enable this contact (please see change 8).				
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)*:	Project documents			
Specific area of change (select - only available when area of change is selected first)*:	Protocol - non-significant changes that do not affect safety or the scientific value			
Further information: explain what the change is, why the change is being made and any possible impact on participants/carers (free text - note that this field will adapt to the amount of text entered):	*Summary of Protocol Updates* Minor changes to Protocol to reflect above plus change to how address data is requested. Tracked changes version submitted as part of this amendment: i) Steering Committee and Study Team members ii) Section 2.4 "Summary of Current Position" added iii) Section 3.2.1 updated to include Prescriptions data linkage iv) Section 3.4 updated to extend study end date to 2038 v) Section 9.1.2 updated to clarify how postcode data will be collected and used vi) Section 9.5 updated with additional systemic psoriasis products available since last protocol update vii) Appendix 2 Statistical Power for Biologic-class Comparison added			
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)*:	Key project roles			
Specific area of change (select - only available when area of change is selected first)*:	Changes to the research team			
Further information: explain what the change is, why the change is being made and any possible impact on participants/carers (free text - note that this field will adapt to the amount of text entered):	The Programme Manager has changed from Ms Danielle Bowerbank to Ian Evans. The Assistant Study Manager role has been renamed to Lead Study Coordinator and has changed from Ms Samantha Pacynko to Mr Andrew Smith. This is due to staff turnover and will not have any foreseeable impact on participants.			
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)*:	Project design			
Specific area of change (select - only available when area of change is selected first)*:	Other non-significant change to project design that will have additional resource implications for participating organisations - please specify in the free text below			
Further information: explain what the change is, why the change is being made and any possible impact on participants/carers. In particular, please describe the additional resource arrangements that participating organisations will need to have in place to implement this change (free text - note that this field will adapt to the amount of text entered)*:	Since the introduction of biologic therapies for psoriasis, several academic studies have researched safety outcomes using real world data. BADBIR data were used to compare rates of serious infection between patients receiving biologic and non-biologic systemic therapies, to assess the risk of major adverse cardiovascular events (MACE) in patients receiving biologics compared with conventional therapies and also to conduct research into malignancy risk. Collectively, the resultant findings have improved understanding of the real-world safety profile of first-generation biologics, including TNF inhibitors (TNFi) and IL-12/23 inhibitors. As a result, emerging research is increasingly focused on comparisons between different classes of biologics, rather than solely against conventional systemic therapies. Further details are included in the protocol (2.4 Summary of Current Position). A summary of the statistical power required for such comparisons between modes of action is provided in Appendix 2 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)*:	Project documents			
Specific area of change (select - only available when area of change is selected first)*:	CRF or project data records - changes to documentation used			
Further information: explain what the change is, why the change is being made and any possible impact on participants/carers (free text - note that this field will adapt to the amount of text entered):	The Clinician Baseline CRF and Clinician Follow-up CRFs have been updated to reflect the addition of 'Oral or SC (subcutaneous)' data item to provide additional treatment information. Clinician Baseline CRF: We are now collecting patient email address on the Baseline CRF to enable us to contact patients about additional studies that may be of interest. We are now collecting postcode instead of address as this is all we require to enable linkage to the Index of Multiple Deprivation (IMD). Clinician Follow-up CRF: We have also updated the categories of Serious Adverse Events (SAEs) and Event Specific Questions (ESQs) to reflect the latest version of our Pharmacovigilance Standard Operating Procedure (SOP). Please see enclosed Clinician Baseline CRF and Clinician Follow-up CRF for details.			
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 modification tool
- I confirm that I have been formally authorised by the Sponsor to complete the modification tool on their behalf

Name [first name and surname]*:	Lynne MacRae
Email address*:	UoMRGT@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 modification tool which must be included in the modification submission. Please ensure that the modification tool is completed correctly before locking it for submission.

Lock for submission

After locking the tool, [proceed to submit the modification online](#). The "Submission Guidance" tab provides further information about the next steps for the modification.

Section 4: Review bodies for the modification

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																		Category:
	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	
Change 1:	(Y)					(Y)		(Y)		(Y)		N		(Y)		N		(Y)	C
Change 2:	Y					Y		Y		Y		Y		Y		Y		Y	A
Change 3:	N					(Y)		(Y)		(Y)		N		(Y)		N		(Y)	C
Change 4:	N					(Y)		(Y)		(Y)		N		(Y)		N		(Y)	A
Change 5:	N					N		N		N		N		N		N		N	N/A
Change 6:	N					(Y)		(Y)		(Y)		N		(Y)		N		(Y)	A
Change 7:	N					(Y)		(Y)		(Y)		N		(Y)		N		(Y)	A
Overall reviews for the modification:																			
Full review:	Y					Y		Y		Y		Y		Y		Y		Y	
Notification only:	N					N		N		N		N		N		N		N	
Overall modification type:	Substantial modification																		
UKSW Governance:	NHS/HSC review is required																		
Overall Category:	A																		

Please note: The modification tool has been revised to provide updated classifications in line with the new regulations. However, IRAS has not been updated and will still require you to submit using the old classifications. This section provides guidance on which option to select in order to ensure the modification is processed correctly:

Your modification should be submitted as a **substantial amendment**

