Amendment Tool

v1.6 06 December 2021

For office use

QC: Yes

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 14
Sponsor amendment date* (enter as DD/MM/YY):	26 September 2024
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 the protocol have been made to accommodate changes in the British Association of Dermatologists Biologics and Immunododulators Register (BADBIR) 1) Steering Group Mambers and Study Team 2) Changes to bring the protocol upto date with current biologic and small molucule treatments currently licensed in UK and ROI. (Page 3, Section 2) 3) Section 3 methods updated to provide clarification and update on study team procedures. Section 3.3 End of the study added. (Page 5, Section 3) 4) Study Participant section - Conventional cohort reduced to methotrexate. Patients with Generalised Pustular Psoriasis eligible if starting Acitertin and ciclosporin, these patient will also not be required to meet the PASI and DLQI score criteria. (Page 8, section 4) 6) Section 4.4 Paediatric Patients added - Amendment 8 (01/07/2015) removed the minimum age limit for new registrations was approvedthis added to protocol. Removal of the requirement of a DLQI score to be above 10 from the eligibility criteria. (Section 4, page 10) 7) Addition of Section 5 Recruitment- to document postal consent process included in Amendment 5 on 05/05/2011. (Section 5, page 10) 8) Updates to section 7 to update current study team procedures. (Section 7 page 13) 9) Update to summary study flow chart to include paediatric recruitment. (Page 14, Section 8) 10) Update to section 9 Baseline data to add additional fields that have been approved in previous amendments. (Page 15, Section 9) 11) Additional data fields at baseline for patients diagnosed with Generalised Pustular Psoriasis (Page 16, section 9) 12)Updated patient documents in order to promote the use of the patient portal where patients are able to complete their questionnaires online: Patient Portal Invitiation Letter (version 2) Patient Poster to include details of patient portal (version 2)

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):	Updates to study protocol to incude updates to study team preceduces and to add information which has been approved in previous amendments, these inculde: 1) Changes to Steering Group Mambers and Study Team 2) Changes to bring the protocol upto date with current biologic and small molucule treatments currently licensed in UK and ROI. (Page 3, Section 2) 3)Protocol section 4.4 has been added to the protocol to outline the prcedures for consenting patients under the age of 16. Patients under 11 consent form from parent/guardian is required. Patients between ages 11-16 an Assent form and parent / guardian consent will be required. Patients will be required to complete an adult consent form at their next dermatology clinic appointment once turning 16. Protocol section 4.4 Paediatric Patients - On guidance from paediatric clinicians it has been noted that there are patients under the age of 16 who are considered to have moderate to severe psoriasis but do not meet the eligibility criteria for the conventional cohort due to having a low Child Dermatology Life Quality Index Score (cDLQI) therefore we would like to alter the eligibility criertia for patients under the age of 16 and who are starting on a conventional therapy, so these patients can be recruited to BADBIR without meeting cDLQI score 10 or above. 5) Section 3 methods updated to provide clarification and update on study team procedures. Section 3.3 End of the study added. (Page 5, Section 3) 6) Addition of Section 5 Recruitment- to document postal consent process which was included in Amendment 5 on 05/05/2011. (Section 5, page 10) 7) Updates to section 7 Auditing the conduct of the study and rsearch governance to update current study team procedures. (Section 7 page 13) 8) Update to summary study flow chart to include paediatric recruitment approved in amendment 8 (01/07/2015). (Page 14, Section 8) 9) Update to section 9 Baseline data to add additional fields that have been approved in previous amendments. (Page 15, Section 9)

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)*:	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 that this field will adapt to the amount of text entered)*	Updated patient documents in order to promote the use of the patient portal where patients are able to complete their questionnaires online: Patient Portal Invitiation Letter (version 2) Patient Poster to include details of patient portal (version 2)			
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)*:	Study Design			
Specific change (select - only available when area of change is selected first)*:	Other minor 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)*	Section 4.3 Traditional Systemic Therapy Comparator cohort: Change to recruit Methotrexate only in the conventional cohort. Patients who are diagnosed with Generalised Pustular Psoriasis: additional data fields at baseline for patients diagnosed with Generalised Pustular Psoriasis (Page 16, section 9) This includes: Has the patient recently been hospitalised for a Generalised Pustular Psoriasis Flare? Yes/No If Yes Date of admission: GPPGA on admission: Time to pustular clearance: GPPGA/GPPASI at Week 1, Week 2 and Week 3 Possible trigger for flare:			
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 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):	Protocol section 4.4 Paediatric Patients - On guidance from paediatric clinicians it has been noted that there are patients under the age of 16 who are considered to have moderate to severe psoriasis but do not meet the eligibility criteria for the conventional cohort due to having a low Child Dermatology Life Quality Index Score (cDLQI) therefore we would like to alter the eligibility criertia for patients under the age of 16 and who are starting on a conventional therapy, so these patients can be recruited to BADBIR without meeting cDLQI score 10 or above. Section 4.3 Traditional Systemic Therapy Comparator cohort:

	Section 4.3 Traditional Systemic Therapy Comparator cohort: Generalised Pustular Psoriasis they will be eligible if starting methotrexate, acitertin and ciclosporin. Patients with Generalised Pustular Psoriasis are not required to meet the PASI and DLQI eligibility criteria for the conventional cohort. (Page 8, section 4)

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

Overall Category:	A