NHS
Health Research Authority

ANNUAL PROGRESS REPORT TO MAIN RESEARCH ETHICS COMMITTEE
(For all studies except clinical trials of investigational medicinal products)

To be completed in typescript and submitted to the main REC by the Chief Investigator. For questions with Yes/No options please indicate answer in bold type.

1. Details of Chief Investigator

Name:	Professor Christopher EM Griffiths
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2. Details of study

Full title of study:	British Association of Dermatologists Biologic and Immunomodulators Register
Name of main REC:	North West England
REC reference number:	07/MRE08/9
Date of favourable ethical opinion:	14/11/2007
Sponsor:	University of Manchester

3. Commencement and termination dates

Has the study started?	*Yes*
If yes, what was the actual start date?	16/08/2007
If no, what are the reasons for the study not commencing? What is the expected start date?	
Has the study finished? *If yes, complete and submit "Declaration of end of study" form, available at http://www.nres.npsa.nhs.uk/applications/after-ethical-review/endofstudy/*	*No*

If no, what is the expected completion date? *If you expect the study to overrun the planned completion date this should be notified to the main REC for information.*	31/07/2028
If you do not expect the study to be completed, give reason(s)	

4. Registration

Is the study a 'clinical trial'? (Defined as first 4 categories on the IRAS filter page) (For CTIMP please use CTIMP progress reporting template)	*No*
Is the study registered on a publically accessible database? (Registration of clinical trials is a condition of approval for studies approved after 30 September 2013)	No
If yes, please provide the name of the database and the registration number Database: Registration number:	
If no: a. What is the reason for non-registration? b. What are your intentions for registration?	

5. Site information

Do you plan to increase the total number of sites proposed for the study? If yes, how many sites do you plan to recruit?	*Yes* Unknown

6. Recruitment of participants

In this section, "participants" includes those who will not be approached but whose samples/data will be studied.

Number of participants recruited:	**18,275** Overall Registrations: 12,356 Biologic Cohort 5,610 Conventional Cohort 309 Small Molecule Cohort
Number of participants completing trial:	*Actual number completed to date:* None as follow up ongoing

Number of withdrawals from study to date due to: (a) withdrawal of consent - **118** (b) loss to follow-up - **483** *(61 emigrated, 118 withdrawn consent, 446 deceased)* (c) death (where not the primary outcome) - **446** Total study withdrawals: **625**	
*Number of treatment failures to date (prior to reaching primary outcome) due to: (a) adverse events *Not applicable* (b) lack of efficacy *Not applicable* Total treatment failures: * Applies to studies involving clinical treatment only	
Have there been any serious difficulties in recruiting participants?	No
If Yes, give details:	
Do you plan to increase the planned recruitment of participants into the study? *Any increase in planned recruitment should be notified to the main REC as a substantial amendment for ethical review.*	No

7. Safety of participants

Have there been any related and unexpected serious adverse events (SAEs) in this study?	*Not applicable*
Have these SAEs been notified to the Committee? *If no, please submit details with this report and give reasons for late notification.*	*Not applicable*
Have any concerns arisen about the safety of participants in this study? *If yes, give details and say how the concerns have been addressed.*	*Not applicable*

8. Amendments

Have any substantial amendments been made to the trial during the year?	*Yes*
If yes, please give the date and amendment number for each substantial amendment made.	Substantial Amendment Number 11 Dated 13 July 2019

	REC Approval: 25 September 2018

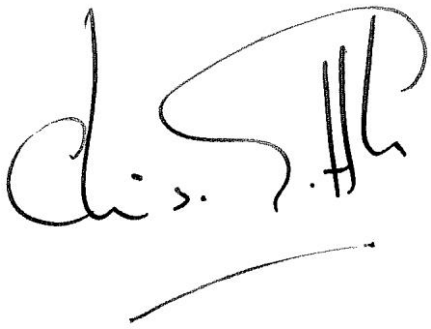
9. Serious breaches of the protocol

Have any serious breaches of the protocol occurred during the year? *If Yes, please enclose a report of any serious breaches not already notified to the REC.*	*No*

10. Other issues

Are there any other developments in the study that you wish to report to the Committee? Are there any ethical issues on which further advice is required? *If yes to either, please attach separate statement with details.*	*No* *No*

11. Declaration

Signature of Chief Investigator:	
Print name:	Professor Chris Griffiths
Date of submission:	17/06/2019