Health Research Authority

Annual Progress Report to Research Ethics Committee

For all studies except clinical trials of investigational medicinal products

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

1. Details of the 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
IRAS ID:	32990
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** / No
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 on the HRA website	Yes / **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 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)	Yes / **No**
Is the study registered on a publicly accessible database? (Registration of clinical trials is a condition of approval for studies approved after 30 September 2013)	Yes / **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? Not applicable b) What are your intentions for registration?

5. 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:	Proposed in original application: Estimated 2000−4000 patients for each biologic therapy and 4000 for comparison cohort Actual number recruited to date: Overall Registrations: 20581 Biologic Cohort: 14130 Conventional Cohort: 6042 Small Molecule Cohort: 409
Number of participants completing trial:	Actual number completed to date: None as follow up ongoing
Number of withdrawals from study to date due to: Total study withdrawals:	a) withdrawal of consent: 172 b) loss to follow-up: 1123 (172 withdrawn consent, 68 emigrated, 883 deceased) c) death (where not the primary outcome) 883 Total study withdrawals: 1123
*Number of treatment failures to date (prior to reaching primary outcome) due to: Total treatment failures:	a) adverse events – Not applicable b) lack of efficacy – Not applicable

*Applies to studies involving clinical treatment only	
Have there been any serious difficulties in recruiting participants?	Yes / **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 REC as a substantial amendment for ethical review.	Yes / **No**

6. Safety of participants

Have there been any related and unexpected serious adverse events (SAEs) in this study?	Yes / **No**
Have these SAEs been notified to the Committee? If no, please submit details with this report and give reasons for late notification.	Yes / No /**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. This information will be considered by the Committee when reviewing the report.	Yes / **No**

7. Amendments

Have any substantial amendments been made to the trial during the year?	**No**
If yes, please give the date and amendment number for each substantial amendment made.	

8. 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.	Yes / **No** Yes / **No**

9. Other issues

Are there any other developments in the study that you wish to report to the Committee? If yes, please attach separate statement with details.	Yes / **No** Yes / No

10. Declaration

Signature of Chief Investigator:	
Print name:	Professor Chris Griffiths
Date of submission:	23/05/2022