NHS

National Patient Safety Agency

National Research Ethics Service

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
Address:	Dermatology Centre Hope Hospital Stott Lane Salford
Telephone:	0161 206 4392
Email:	christopher.griffiths@manchester.ac.uk
Fax:	0161 206 1095

2. Details of study

Full title of study:	British Association of Dermatologists Biological Interventions 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?	*No* *If yes, complete and submit "Declaration of end of study" form, available at www.corec.org.uk*

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. Site information

Is this a study requiring site-specific assessment (SSA) and ethical approval of each site and local Principal Investigator? If yes, how many UK research sites have been recruited Has the Site Specific Information Form (SSIF)* been submitted to the local REC for each local Principal Investigator? **or Part C or Annex D of the former MREC application form if submitted prior to 1 March 2004*	*Yes* *Proposed in original application: 200* *Actual number recruited to date:158 sites have been recruited* *Yes up until change in April 2009 then Trust R & D only*
Is this study "SSA-exempt"? * If yes, how many UK sites are currently involved in facilitating this research? ** or was previously designated as a "no local investigator" or "no local researcher" study*	*No* *158 sites currently have local R & D approval (134 in England, 10 in Scotland, 4 in Northern Ireland, 10 in Wales)* *156 sites have recruited at least one participant* *153 sites are actively recruiting*
Do you plan to increase the total number of UK sites proposed for the study? If yes, how many sites do you plan to recruit? *In the case of studies requiring SSA, all sites must be approved by the main REC as part of the favourable opinion.*	*No*

5. Recruitment of participants

*Number of participants recruited:	*7546 biologic cohort and 4155 controls – UK* *414 biologic cohort and 197 controls - Eire*
*Number of participants completing trial:	*None as follow up extended in amendment 9 to end date 31st July 2028*
*Number of withdrawals due to: (a) lack of efficacy (b) adverse events (c) self-withdrawal (d) non-compliance Total number of withdrawals:	 N/A N/A 42 N/A 284 (218 deaths, 42 withdrawal of consent, 24 emigrated)
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.*	

** In the case of international trials, please provide separate figures for UK and non-UK participants.*

6. 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*

7. 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.	*Amendment 8 - 01 July 2015* *Amendment 9 – 01 December 2015*

8. 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?	*No* *No* *If yes to either, please attach separate statement with details.*

9. Declaration

Signature of Chief Investigator:	
Print name:	CEN GRIFFITHS.
Date:	27.6.16.