

**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

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| Name: | Professor Christopher EM Griffiths |
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2. Details of study

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| 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

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|---|---|
| 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 <i>If yes, complete and submit "Declaration of end of study" form, available at www.corec.org.uk</i> |

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| If no, what is the expected completion date? <i>If you expect the study to overrun the planned completion date this should be notified to the main REC for information.</i> | 31/07/2018 |
| If you do not expect the study to be completed, give reason(s) | |

4. Site information

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| 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 | Yes <i>Proposed in original application: 200 Actual number recruited to date:153</i> |
| Has the Site Specific Information Form (SSIF)* been submitted to the local REC for each local Principal Investigator? <i>*or Part C or Annex D of the former MREC application form if submitted prior to 1 March 2004</i> | <i>Yes up until change in April 2009 now submitted to local Trust R & D departments</i> |
| Is this study "SSA-exempt"? * If yes, how many UK sites are currently involved in facilitating this research? <i>* or was previously designated as a "no local investigator" or "no local researcher" study</i> | No <i>155 currently have local R & D Actual number recruited to date – 144 (121 in England, 4 in Northern Ireland, 9 in Scotland, 10 in Wales)</i> <i>146 currently have local R&D approval</i> |
| 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? <i>In the case of studies requiring SSA, all sites must be approved by the main REC as part of the favourable opinion.</i> | No |

5. Recruitment of participants

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| *Number of participants recruited: | <i>6544 biologic cohort and 3733 controls</i> |
| *Number of participants completing trial: | <i>Proposed in original application: 4,000 per biologic drug and 4,000 controls Actual number completed to date: No patients have completed follow-up Amendment 7, extended the follow-up to 2018 all patients registered remain in follow up until then.</i> |
| *Number of withdrawals due to: | |
| (a) lack of efficacy | N/A |
| (b) adverse events | N/A |
| (c) self-withdrawal | 14 |
| (d) non-compliance | N/A |
| Total number of withdrawals: | 158 (134 deaths, 14 withdrawal of consent, |

| | |
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| | 10 emigrated) |
| Have there been any serious difficulties in recruiting participants? | <i>Competition from other studies which has meant research time on this study</i> |
| If Yes, give details: | |
| Do you plan to increase the planned recruitment of participants into the study? <i>Any increase in planned recruitment should be notified to the main REC as a substantial amendment for ethical review.</i> | No |

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

6. Safety of participants

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| Have there been any related and unexpected Serious Adverse Events (SAEs) in this study? | <i>Not applicable</i> |
| Have these SAEs been notified to the Committee? <i>If no, please submit details with this report and give reasons for late notification.</i> | <i>Not applicable</i> |
| Have any concerns arisen about the safety of participants in this study? <i>If yes, give details and say how the concerns have been addressed.</i> | <i>Not applicable</i> |

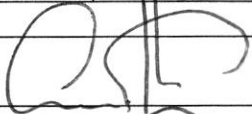
7. Amendments

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| 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. Other issues

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

9. Declaration

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| Signature of Chief Investigator: |  |
| Print name: | Q. E. R. Griffiths |
| Date: | 18. May 2015. |