COVER LETTER

Subject:	**End of Trial Notification**
Compound Number:	Not Applicable
Trademark (if applicable):	
EudraCT Number:	2007-000593-24
Protocol Number/Version:	PP20899 F
Ethics Reference Number	[redacted]
Protocol Title:	An Open-Label Study to Investigate the Effects Of Anti-TNF Therapy on Peripheral Blood and Synovial Biomarkers in Patients with Active Rheumatoid Arthritis

Dear Sir/Madam

Please find enclosed an End of Trial Notification for the above study.

The trial has been terminated early as the objectives that were hoped to be addressed have been superseded by information available in the scientific literature from other research. No patients had been recruited into the study. Accordingly, no study report will be prepared.

If you require any clarification or further documentation then please do not hesitate to contact me.

Yours sincerely,

[redacted]

[redacted]

Declaration of the end of trial form

NOTIFICATION OF THE END OF A CLINICAL TRIAL OF A MEDICINE FOR HUMAN USE TO THE COMPETENT AUTHORITY AND THE ETHICS COMMITTEE

For official use

Date of receipt:	Competent authority registration number: Ethics committee registration number:

To be filled in by the applicant

A MEMBER STATE IN WHICH THE DECLARATION IS BEING MADE: UK

B TRIAL IDENTIFICATION

B.1 EudraCT number:	**2007-000593-24**
B.2 Sponsor's protocol code number:	**PP20899**
B.3 Full title of the trial:	**An open-label study to investigate the effects of anti-TNF therapy on peripheral blood and synovial biomarkers in patients with active rheumatoid arthritis.**

C APPLICANT IDENTIFICATION (please tick the appropriate box)

C.1	**DECLARATION FOR THE COMPETENT AUTHORITY**	☐
C.1.1	Sponsor	☐
C.1.2	Legal representative of the sponsor	☐
C.1.3	Person or organisation authorised by the sponsor to make the application.	☐
C.1.4	**Complete below**:	
C.1.4.1	Organisation:	
C.1.4.2	Name of person to contact:	
C.1.4.3	Address:	
C.1.4.4	Telephone number:	
C.1.4.5	Fax number:	
C.1.4.6	E-mail	

C.2	**DECLARATION FOR THE ETHICS COMMITTEE**	☒
C.2.1	Sponsor	☐
C.2.2	Legal representative of the sponsor	☐
C.2.3	Person or organisation authorised by the sponsor to make the application.	☒
C.2.4	Investigator in charge of the application if applicable[1]:	
•	Co-ordinating investigator (for multicentre trial):	☐
•	Principal investigator (for single centre trial):	☐
C.2.5	**Complete below**:	
C.2.5.1	Organisation:	Roche Products Limited
C.2.5.2	Name:	[redacted]
C.2.5.3	Address:	6 Falcon Way, Shire Park Welwyn Garden City Hertfordshire UK, AL7 1TW
C.2.5.4	Telephone number:	[redacted]
C.2.5.5	Fax number:	
C.2.5.6	E-mail:	[redacted]

[1] According to national legislation

D END OF TRIAL

D.1	**Is it the end of the trial in this Member State?**	yes ☒	no ☐
D.1.1	If yes, give date (YYYY/MM/DD):	2009/07/10	

D.2	**Is it the end of the complete trial in all countries concerned by the trial?**	yes ☒	no ☐
D.2.1	If yes, give date (YYYY/MM/DD):	2009/07/10	

D.3	**Is it a premature ending of the trial?**	yes ☒	no ☐
D.3.1	If yes, give date (YYYY/MM/DD):	2009/07/10	
D.3.2	What is (are) the reason(s) for the premature ending?	Objectives that were hoped to be addressed by this protocol are now out of date and superceded by literature and research previously conducted. No patients were recruited into the trial.	
D.3.2.1	Safety	yes ☐	no ☒
D.3.2.2	Lack of efficacy	yes ☐	no ☒
D.3.2.3	The trial has not commenced	yes ☒	no ☐
D.3.2.4	Other	yes ☐	no ☒
D.3.3	If yes to any of the above questions, briefly describe in an annex (free text):		
D.3.3.1	The justification for premature ending of the trial:	Due to the delay in starting the trial, the objectives that were hoped to be addressed by this protocol are now out of date and have been superceded by information in the literature and other previously conducted research.	
D.3.3.2	Number of patients still receiving treatment at time of premature termination in the MS concerned by the declaration and their proposed management:	No patients had been recruited into the trial at the time of the premature termination. Therefore there is no consequence for proposed management.	
D.3.3.3	The consequences of early termination for the evaluation of the results and for overall risk benefit assessment of the investigational medicinal product:	none - no patients had been recruited to the trial.	

E SIGNATURE OF THE APPLICANT IN THE MEMBER STATE

E.1 I hereby confirm that/confirm on behalf of the sponsor that (delete which is not applicable):

- The above information given on this declaration is correct; and
- That a summary of the clinical trial report will be submitted to the competent authority and ethics committee concerned as soon as available and within a 1 year deadline after the end of the trial in all countries.

E.2	**APPLICANT TO THE COMPETENT AUTHORITY** (as stated in C.1)	☐
E.2.1	Date :	
E.2.2	Signature :	
E.2.3	Print name:	

E.3	**APPLICANT TO THE ETHICS COMMITTEE** (as stated in C.2) **:**	☒
E.3.1	Date :	16th July 2009
E.3.2	Signature :	[redacted]
E.3.3	Print name:	