

Declaration of the End of Trial Form (cf. Section 4.2.1 of the *Detailed guidance on the request to the competent authorities for authorisation of a clinical trial on a medicinal product for human use, the notification of substantial amendments and the declaration of the end of the trial*¹)

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 :	2007-002084-27
B.2 Sponsor's protocol code number:	07/H0801/119
B.3 Full title of the trial :	The pharmacokinetics and anti-inflammatory effects of prednisolone in severe asthma

C APPLICANT IDENTIFICATION (please tick the appropriate box)

C.1 DECLARATION FOR THE COMPETENT AUTHORITY	X
C.1.1 Sponsor	<input type="checkbox"/>
C.1.2 Legal representative of the sponsor	<input type="checkbox"/>
C.1.3 Person or organisation authorised by the sponsor to make the application.	X
C.1.4 Complete below:	
C.1.4.1 Organisation : Imperial College London	
C.1.4.2 Name of person to contact : Professor Kian Fan Chung	
C.1.4.3	
Address : Department of Thoracic Medicine, National Heart and Lung Institute Dovehouse Street, London SW3 6LY	
C.1.4.3 Telephone number : 020 7594 7959	
C.1.4.4 Fax number : 020 7351 8126	
C.1.4.5 E-mail f.chung@imperial.ac.uk	

C.2 DECLARATION FOR THE ETHICS COMMITTEE	X
C.2.1 Sponsor	<input type="checkbox"/>
C.2.2 Legal representative of the sponsor	<input type="checkbox"/>
C.2.3 Person or organisation authorised by the sponsor to make the application.	X
C.2.4 Investigator in charge of the application if applicable ² :	
• Co-ordinating investigator (for multicentre trial):	<input type="checkbox"/>
• Principal investigator (for single centre trial):	<input type="checkbox"/>
C.2.5 Complete below :	
C.2.5.1 Organisation: Imperial College London	
C.2.5.2 Name : Professor Kian Fan Chung	
Address : Department of Thoracic Medicine National Heart and Lung Institute Dovehouse Street London SW3 6LY	
C.2.5.3 Telephone number : 020 7594 7959	
C.2.5.4 Fax number : 020 7351 8186	
C.2.5.5 E-mail : f.chung@imperial.ac.uk	

¹ OJ, C82, 30.3.2010, p. 1; hereinafter referred to as 'detailed guidance CT-1'.

² According to national legislation.

D END OF TRIAL**D.1 Date of the end of the complete trial in all countries concerned by the trial?**

D.1.1 (2013/11/12):

D.2 Is it an early termination?³yes ☒ no ☐

D.2.1 If yes, give date (2013/11/12):

D.2.2 Briefly describe in an annex (free text):

D.2.2.1 The justification for early termination of the trial;

We were only been able to recruit five participants to the study as a result of staff shortages and patients not being keen to take prednisolone for two weeks. Furthermore, the clinical research fellow who undertook the study has now returned to clinical practice and presently we do not have the funding to replace her and continue with the study.

D.2.2.2 Number of patients still receiving treatment at time of early termination in the MS concerned by the declaration and their proposed management;
N/A

D.2.2.3 The consequences of early termination for the evaluation of the results and for overall risk benefit assessment of the investigational medicinal product.


D.2.2.4 As a result of the small number of patients recruited only limited conclusions will be drawn from the trial results.
There are no consequences for overall risk benefit assessment of the investigational medicinal product.

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 the clinical trial summary report will be submitted within the applicable deadlines in accordance with the applicable guidance by the Commission.⁴

E.2 APPLICANT TO THE COMPETENT AUTHORITY (as stated in C.1)


X

E.2.1 Date : 13th November 2013E.2.2 Signature : 

E.2.3 Print name: Professor Kian Fan Chung

E.3 APPLICANT TO THE ETHICS COMMITTEE (as stated in C.2) :

X

E.3.1 Date : 13th November 2013E.3.2 Signature : 

E.3.3 Print name: Professor Kian Fan Chung

³ Cf. Section 4.2. of the detailed guidance CT-1.⁴ Section 4.3. of the detailed guidance CT-1.