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 :

B TRIAL IDENTIFICATION

B.1 EudraCT number: 2007-000936-21
B.2 Sponsor's protocol code number: 2007LF004B
B.3 Full title of the trial: The Effect on Alveolar Nitric Oxide of Salmeterol, Fluticasone, and in combination, in stable Bronchiectasis.

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: Royal Brompton and Harefield NHS Foundation Trust	
C.1.4.2	Name of person to contact: Dr Robert Wilson	
C.1.4.3	Address: Royal Brompton Hospital, Respiratory Medicine, Fulham Road, London SW3 6NP	
C.1.4.4	Telephone number: 0207 351 8837	
C.1.4.5	Fax number:	
C.1.4.6	E-mail: r.wilson@rbht.nhs.uk	

C.2	**DECLARATION FOR THE ETHICS COMMITTEE**	√
C.2.1	Sponsor	☐
C.2.1	Legal representative of the sponsor	☐
C.2.2	Person or organisation authorised by the sponsor to make the application.	☐
C.2.3	Investigator in charge of the application if applicable[2]:	
	• Co-ordinating investigator (for multicentre trial):	√
	• Principal investigator (for single centre trial):	☐
C.2.4	**Complete below** :	
C.2.4.1	Organisation:	
C.2.4.2	Name :	
C.2.4.3	Address :	
C.2.4.4	Telephone number :	
C.2.4.5	Fax number :	
C.2.4.6	E-mail :	

D END OF TRIAL

D.1	**Date of the end of the complete trial in all countries concerned by the trial**?
D.1.1	(YYYY/MM/DD): 2015/04/20

D.2	**Is it an early termination?**[3]	yes √	no ☐

1 OJ, C82, 30.3.2010, p. 1; hereinafter referred to as 'detailed guidance CT-1'.
2 According to national legislation.
3 Cf. Section 4.2. of the detailed guidance CT-1.

D.2.1 If yes, give date (YYYY/MM/DD): 2014/04/10
D.2.2 Briefly describe in an annex (free text):
D.2.2.1 The justification for early termination of the trial;

Trial has always been a challenge to recruit for because patients are concerned about stopping their inhaled steroid. Poor recruitment considered to be partly due to lack of a dedicated nurse for the study. Machine to measure Nitric Oxide (NO) also broke down and other machines in the hospital that are working cannot measure bronchial NO. Purchase of a new machine prohibitively expensive, it is not clear if the old machine can be fixed; this is the only study in which bronchial NO is measured.

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;

All patients have completed the study and returned to their regular management.

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.

The message of the study is clear: some patients with bronchiectasis are able to stop inhaled steroid without any change in their symptoms, a small proportion of patients have increased symptoms on stopping inhaled steroid. However some of the patients who stop are less well during a future infection with increased symptoms. Some of these patients are able to use inhaled steroid during the infections only. Terminating early is likely to mean the analysis will lack power to make definitive recommendations. We have not yet broken the code to analyse bronchial NO.

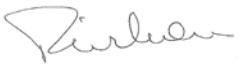
E SIGNATURE OF THE APPLICANT IN THE MEMBER STATE

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) √

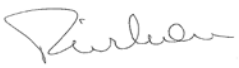
E.2.1 Date: 29th April 2015
E.2.2 Signature:



E.2.3 Print name: Dr Rob Wilson

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

E.3.1 Date: 29th April 2015
E.3.2 Signature:



E.3.3 Print name: Dr Rob Wilson

[4] Section 4.3. of the detailed guidance CT-1.