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: United Kingdom

B TRIAL IDENTIFICATION

B.1 EudraCT number:	**2007-001645-17**
B.2 Sponsor's protocol code number:	**2007OE003B**
B.3 Full title of the trial:	**Patients with Fibrotic Lung Disease at High Risk for Pulmonary Hypertension: a randomised, placebo-controlled trial with Bosentan Therapy**

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 Trust
C.1.4.2	Name of person to contact:	Mrs Wendy Butcher, Head of R&D
C.1.4.3	Address:	Research and Development Office Chelsea Wing, Level 2 Sydney Street London SW3 6NP
C.1.4.4	Telephone number:	02073518109
C.1.4.5	Fax number:	02073518578
C.1.4.6	E-mail	w.butcher@rbht.nhs.uk

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:	Royal Brompton and Harefield NHS Trust
C.2.5.2	Name:	Mrs Wendy Butcher, Head of R&D
C.2.5.3	Address:	Research and Development Office Chelsea Wing, Level 2 Sydney Street London, SW3 6NP
C.2.5.4	Telephone number:	02073518109
C.2.5.5	Fax number:	02073518578
C.2.5.6	E-mail:	w.butcher@rbht.nhs.uk

[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):	N/A -This study never commenced.

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):	N/A -This study never commenced.

D.3	**Is it a premature ending of the trial?**	yes ☐ no ☒
D.3.1	If yes, give date (YYYY/MM/DD):	
D.3.2	What is (are) the reason(s) for the premature ending?	
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:	
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:	
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:	

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 : 24/4/09	
E.2.2	Signature : Wendy Butcher	
E.2.3	Print name: WENDY BUTCHER	

E.3	**APPLICANT TO THE ETHICS COMMITTEE** (as stated in C.2) **:**	☒
E.3.1	Date : 24/4/09	
E.3.2	Signature : Wendy Butcher	
E.3.3	Print name: WENDY BUTCHER	