

Annex 3: 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:
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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:	2007-007877-22
B.2 Sponsor's protocol code number:	2007IC013H
B.3 Full title of the trial:	<i>A prospective blinded randomised placebo controlled trial investigating whether oxycodone modified release reduces parenteral opioid use following intermediate thoracic surgery (OxyPATs Project)</i>

C APPLICANT IDENTIFICATION (please tick the appropriate box)

C.1 DECLARATION FOR THE COMPETENT AUTHORITY	<input checked="" type="checkbox"/>
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.	<input checked="" type="checkbox"/>
C.1.4 Complete below:	
C.1.4.1 Organisation:	<i>Royal Brompton & Harefield NHS Foundation Trust.</i>
C.1.4.2 Name of person to contact:	<i>Dr Chris Walker</i>
C.1.4.3 Address:	<i>Harefield Hospital Hill End Road Harefield Middlesex UB9 6JH</i>
C.1.4.4 Telephone number:	<i>01895828538</i>
C.1.4.5 Fax number:	
C.1.4.6 E-mail	<i>c.walker@rbht.nhs.uk</i>

C.2 DECLARATION FOR THE ETHICS COMMITTEE	<input type="checkbox"/>
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.	<input checked="" type="checkbox"/>
C.2.4 Investigator in charge of the application if applicable ¹ :	
• Co-ordinating investigator (for multicentre trial):	<input type="checkbox"/>
• Principal investigator (for single centre trial):	<input checked="" type="checkbox"/>
C.2.5 Complete below:	
C.2.5.1 Organisation:	<i>Royal Brompton & Harefield NHS Foundation Trust.</i>
C.2.5.2 Name:	<i>Dr Chris Walker</i>
C.2.5.3 Address:	<i>Harefield Hospital Hill End Road Harefield Middlesex UB9 6JH</i>
C.2.5.4 Telephone number:	<i>01895828538</i>
C.2.5.5 Fax number:	
C.2.5.6 E-mail:	<i>c.walker@rbht.nhs.uk</i>

D END OF TRIAL

¹ According to national legislation

D.1	Is it the end of the trial in this Member State?	yes <input checked="" type="checkbox"/> no <input type="checkbox"/>
D.1.1	If yes, give date (YYYY/MM/DD):	2011/12/13

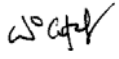
D.2	Is it the end of the complete trial in all countries concerned by the trial?	yes <input checked="" type="checkbox"/> no <input type="checkbox"/>
D.2.1	If yes, give date (YYYY/MM/DD):	2011/12/13

D.3	Is it a premature ending of the trial?	yes <input checked="" type="checkbox"/> no <input type="checkbox"/>
D.3.1	If yes, give date (YYYY/MM/DD):	2011/12/13
D.3.2	What is (are) the reason(s) for the premature ending?	<i>The Sponsor decided to terminate this study because it failed to recruit and it has been difficult to communicate with the Chief Investigator.</i>
D.3.2.1	Safety	yes <input type="checkbox"/> no <input checked="" type="checkbox"/>
D.3.2.2	Lack of efficacy	yes <input type="checkbox"/> no <input checked="" type="checkbox"/>
D.3.2.3	The trial has not commenced	yes <input type="checkbox"/> no <input checked="" type="checkbox"/>
D.3.2.4	Other	yes <input type="checkbox"/> no <input checked="" type="checkbox"/>
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:	0 (Zero)
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:	<i>In practice no complications as no patient is recruited.</i>

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):
	<ul style="list-style-type: none"> The above information given on this declaration is correct

E.2	APPLICANT TO THE COMPETENT AUTHORITY (as stated in C.1)	<input checked="" type="checkbox"/>
E.2.1	Date :	2011/12/29
E.2.2	Signature :	
E.2.3	Print name:	Dr J Fatukasi

E.3	APPLICANT TO THE ETHICS COMMITTEE (as stated in C.2) :	<input checked="" type="checkbox"/>
E.3.1	Date :	2011/12/29
E.3.2	Signature :	
E.3.3	Print name:	Dr J Fatukasi