

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 no

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 no

D.2.1 If yes, give date (YYYY/MM/DD): 2011/12/13

D.3 Is it a premature ending of the trial? yes no

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? *The Sponsor decided to terminate this study because it failed to recruit and it has been difficult to communicate with the Chief Investigator.*

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: 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: *In practice no complications as no patient is recruited.*

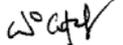
E SIGNATURE OF THE APPLICANT IN THE MEMBER STATE

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

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

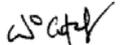
E.2.1 Date : 2011/12/29

E.2.2 Signature : 

E.2.3 Print name: Dr J Fatukasi

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

E.3.1 Date : 2011/12/29

E.3.2 Signature : 

E.3.3 Print name: Dr J Fatukasi