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 :	**2009-014491-21**
B.2 Sponsor's protocol code number:	**Current Version 17, 10/05/2011**
B.3 Full title of the trial : Neoadjuvant docetaxel prior to radical prostatectomy for high risk localised prostate cancer. Evaluation of biological and functional imaging surrogates of therapy efficacy.	

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 : Cambridge University Hospitals NHS Trust	
C.1.4.2	Name of person to contact : Dr. Danish Mazhar	
C.1.4.3	Address : Oncology Centre,Box 193, Addenbrookes Hospital, Hills road, Cambridge CB2 0QQ	
C.1.4.4	Telephone number : 01223 216525	
C.1.4.5	Fax number : 01223 274409	
C.1.4.6	E-mail : danish.mazhar@addenbrookes.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[2]:	
	• Co-ordinating investigator (for multicentre trial):	☐
	• Principal investigator (for single centre trial):	☑
C.2.5	**Complete below :**	
C.2.5.1	Organisation: Cambridge University Hospitals NHS Trust	
C.2.5.2	Name : Dr. Danish Mazhar	
C.2.5.3	Address : Oncology Centre,Box 193, Addenbrookes Hospital, Hills road, Cambridge CB2 0QQ	
C.2.5.4	Telephone number : 01223 216525	
C.2.5.5	Fax number : 01223 274409	
C.2.5.6	E-mail : danish.mazhar@addenbrookes.nhs.uk	

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): 2013/06/06

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): 2013/06/06
D.2.2	Briefly describe in an annex (free text):
D.2.2.1	The justification for early termination of the trial; The justification for early termination of the trial; **Insufficient patient recruitment**
D.2.2.2	
D.2.2.3	Number of patients still receiving treatment at time of early termination in the MS concerned by the declaration and their proposed management; **nil**
D.2.2.4	The consequences of early termination for the evaluation of the results and for overall risk benefit assessment of the investigational medicinal product. **Insufficient patients recruited for evaluation of risk benefit if IMP.**

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 : 20/6/13	
E.2.2	Signature :	
E.2.3	Print name: Dr. Danish Mazhar	

E.3	**APPLICANT TO THE ETHICS COMMITTEE** (as stated in C.2) :	☑
E.3.1	Date : 20/6/13	
E.3.2	Signature :	
E.3.3	Print name: Dr. Danish Mazhar	

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