

**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*<sup>1</sup>)**

**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>B.1 EudraCT number :</b>	<b>2009-014491-21</b>
<b>B.2 Sponsor's protocol code number:</b>	<b>Current Version 17, 10/05/2011</b>
<b>B.3 Full title of the trial :</b>	<b>Neoadjuvant docetaxel prior to radical prostatectomy for high risk localised prostate cancer. Evaluation of biological and functional imaging surrogates of therapy efficacy.</b>

**C APPLICANT IDENTIFICATION (please tick the appropriate box)**

<b>C.1 DECLARATION FOR THE COMPETENT AUTHORITY</b>	<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 <b>Complete below:</b>	
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	

<b>C.2 DECLARATION FOR THE ETHICS COMMITTEE</b>	<input checked="" 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 type="checkbox"/>
C.2.4 Investigator in charge of the application if applicable <sup>2</sup> :	
• Co-ordinating investigator (for multicentre trial):	<input type="checkbox"/>
• Principal investigator (for single centre trial):	<input checked="" type="checkbox"/>
C.2.5 <b>Complete below :</b>	
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**

<b>D.1 Date of the end of the complete trial in all countries concerned by the trial?</b>
D.1.1 (YYYY/MM/DD): 2013/06/06

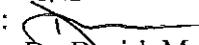
<b>D.2 Is it an early termination?<sup>3</sup></b>	yes <input checked="" type="checkbox"/> no <input type="checkbox"/>
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<sup>1</sup> OJ, C82, 30.3.2010, p. 1; hereinafter referred to as 'detailed guidance CT-1'.  
<sup>2</sup> According to national legislation.  
<sup>3</sup> 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.<sup>4</sup>

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 : 20/6/12  
 E.3.2 Signature :   
 E.3.3 Print name: Dr. Danish Mazhar

<sup>4</sup> Section 4.3. of the detailed guidance CT-1.