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 :

B TRIAL IDENTIFICATION

B.1 EudraCT number : 2006-005816-29
B.2 Sponsor's protocol code number: 2006-002-0201-ONC
B.3 Full title of the trial : Taxotere in palliative therapy. (TInPaT). A pilot study of Taxotere Cisplatin and 5FU in the palliative treatment of squamous call carcinoma of the head and neck

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 : The Royal Wolverhampton Hospitals NHS Trust.	
C.1.4.2	Name of person to contact : Dr Caroline Brammer	
C.1.4.3	Address : New Cross Hospital, Wednesfield Road, Wolverhampton WV10 0QP	
C.1.4.4	Telephone number : 01902 695201	
C.1.4.5	Fax number : 01902 695624	
C.1.4.6	E-mail: caroline.brammer@nhs.net	

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:	
C.2.5.2	Name of person to contact :	
C.2.5.3	Address :	
C.2.5.4	Telephone number :	
C.2.5.5	Fax number :	
C.2.5.6	E-mail :	

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): 2011/02/15

1 OJ, C82, 30.3.2010, p. 1; hereinafter referred to as 'detailed guidance CT-1'.

2 According to national legislation.

D.2	**Is it an early termination?**[3]	Yes ☒ no ☐
D.2.1	If yes, give date (YYYY/MM/DD): 2011/02/15	
D.2.2	Briefly describe in an annex (free text):	
D.2.2.1	The justification for early termination of the trial; The toxicity of the treatment did not appear to be justified in light of the response rate. A data monitoring committee was called who agreed that the study should close on the grounds of futility.	
D.2.2.2	Number of patients still receiving treatment at time of early termination in the MS concerned by the declaration and their proposed management: Nil	
D.2.2.3	The consequences of early termination for the evaluation of the results and for overall risk benefit assessment of the investigational medicinal product: The study results will be reported with the advice that the regimen not be recommended for further study.	

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 : 17/02/2011	
E.2.2	Signature :	
E.2.3	Print name: Dr C Brammer	28/2/11

E.3	**APPLICANT TO THE ETHICS COMMITTEE** (as stated in C.2) :	☐
E.3.1	Date :	
E.3.2	Signature :	
E.3.3	Print name:	

[3] Cf. Section 4.2. of the detailed guidance CT-1.

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