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 trial¹)

For official use

Date of receipt:

NOTIFICATION OF THE END OF A CLINICAL TRIAL OF A MEDICINE FOR HUMAN USE TO THE COMPETENT AUTHORITY AND THE ETHICS COMMITTEE

Competent authority registration number: MREC ref 13/LO/0214

	1	Ethics committee registration number: IS	SRCTN79949827
To be	filled in by the applicant		
A M	EMBER STATE IN WHICH THE DE	CLARATION IS BEING MADE:	
в ті	RIAL IDENTIFICATION		
	draCT number: 2012-002623-15		
	onsor's protocol code number: Univers		- 11
		aoperative Lymph node staging for Stratific	ed colon cancer surgery
C AI	PPLICANT IDENTIFICATION (please	e tick the appropriate box)	
C.1	DECLARATION FOR THE COMP	ETENT AUTHORITY	0
C.1.1	Sponsor		
C.1.2	Legal representative of the sponsor		
C.1.3	Person or organisation authorised by the	e sponsor to make the application.	√ □
C.1.4	Complete below:		
	Organisation: St James's University Ho		
	Name of person to contact: Miss Helen		7TE
		lding, St James's University Hospital, LS9	/11
	Telephone number: +44 (0)7966087652	2	
	Fax number: E-mail: h.andrew@leeds.ac.uk		
C.1.4.0	E-mail: n.andrew@ieeds.ac.uk		
C.2	DECLARATION FOR THE ETHIC	S COMMITTEE	
C.2.1	Sponsor		
C.2.2	Legal representative of the sponsor		ā
C.2.3	Person or organisation authorised by th	e sponsor to make the application	<i>_</i>
C.2.4	Investigator in charge of the application		
•	Co-ordinating investigator (for multicer		
	Principal investigator (for single centre		
	Complete below:		_
	Organisation: St James's University Ho	osnital	
	Name: Miss Helen Andrew	,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,	
		lding, St James's University Hospital, LS9	7TF
	Telephone number:	, , ,	
	Fax number:	-	
	E-mail: h.andrew@leeds.ac.uk		
D EN	ND OF TRIAL		
D.1	Date of the end of the complete trial i	in all countries concerned by the trial?	
D.1.1	(2015/08/07):	in an education content and by the trust	
D.11.1	(2013/00/07).		
D.2	Is it an early termination? ³		yes □ no 🗸 □
1 2	OJ, C82, 30.3.2010, p. 1; hereinafter referre	ed to as 'detailed guidance CT-1'.	
2	According to national legislation.		

Cf. Section 4.2. of the detailed guidance CT-1.

- D.2.1 If yes, give date (YYYY/MM/DD):
- D.2.2 Briefly describe in an annex (free text):
- D.2.2.1 The justification for early termination of the trial;
- 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;
- 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.

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		
E.2.2		
E.2.3		
E.3	APPLICANT TO THE ETHICS COMMITTEE (as stated in C.2):	
E.3.1		
E.3.2		

Section 4.3. of the detailed guidance CT-1.