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 :	**(2013-002457-30)**
B.2 Sponsor's protocol code number:	**(13.0099)**
B.3 Full title of the trial :	**Effects of Donepezil on regional cerebral blood flow following aneurysmal subarachnoid haemorrhage**

C APPLICANT IDENTIFICATION (please tick the appropriate box)

C.1	**DECLARATION FOR THE COMPETENT AUTHORITY**	x
C.1.1	Sponsor	x
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 : St George's University of London	
C.1.4.2	Name of person to contact : Debbie Rolfe	
C.1.4.3	Address : JREO, Cranmer Terrace, Tooting, London. SW17 0RE	
C.1.4.4	Telephone number : 020 8725 5013	
C.1.4.5	Fax number : 020 8725 0794	
C.1.4.6	E-mail: drolfe@sgul.ac.uk	

C.2	**DECLARATION FOR THE ETHICS COMMITTEE**	**x**
C.2.1	Sponsor	x
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: St Georges University of London	
C.2.5.2	Name : Debbie Rolfe	
C.2.5.3	Address : JREO, Cranmer Terrace, Tooting, London SW17 0RE	
C.2.5.4	Telephone number : 020 8725 5013	
C.2.5.5	Fax number : 020 8725 0794	
C.2.5.6	E-mail : drolfe@sgul.ac.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	(2016/11/10):

D.2	**Is it an early termination?**[3]	yes x 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 (2016/Nov/10)
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.

The trial centre has installed a new CT scanner which is not compatible with the Xenon analysis software (despite reassurances from the CT manufacturer to the contrary). It is not possible to recruit any further subjects as we can no longer acquire primary endpoint data.
No participants are receiving treatment at the time of this notice.
100 participants were proposed in the original application however only 19 participants were recruited of which 18 have completed follow up visits. 1 participant was withdrawn.
Analysis of data obtained is underway – a report will follow

E SIGNATURE OF THE APPLICANT IN THE MEMBER STATE

E.1 I hereby confirm that/:

- 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 : 10th November 2016
E.2.2 Signature :
E.2.3 Print name: Debbie Rolfe

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

E.3.1 Date : 10th November 2016
E.3.2 Signature :
E.3.3 Print name: Debbie Rolfe

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