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 :	**(2010-024552-28)**
B.2 Sponsor's protocol code number:	**(Protocol Version 14 July 2nd 2010; UK Final Version 3, 22nd July 2012)**
B.3 Full title of the trial :	**BRidge or continUe coumadIn for device SurgEry randomized CONTROLled Trial**

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 : Oxford University Hospitals NHS Trust	
C.1.4.2	Name of person to contact : Heather House	
C.1.4.3	Address : Joint Research Office, Block 60, Churchill Hospital, Oxford OX3 7LE	
C.1.4.4	Telephone number : 01865 572236	
C.1.4.5	Fax number : 01865 572242	
C.1.4.6	E-mail ; heather.house@ouh.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: Oxford University Hospitals NHS Trust	
C.2.5.2	Name : Kim Rajappan	
C.2.5.3	Address : Cardiac Department, John Radcliffe Hospital, Oxford OX3 9DU	
C.2.5.4	Telephone number : 01865 220454	
C.2.5.5	Fax number : 01865 740409	
C.2.5.6	E-mail : kim.rajappan@ouh.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	(2013/03/04):

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 (2013/03/04):
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 was concluded because the Data Safety Monitoring Board (DSMB) reviewed the data at the planned second interim analysis and suggested that the data are highly convincing at this stage and would not profit from addition of further patients.
There are no patients in the UK still receiving treatment. In fact the study had not started to recruit in the UK before it was terminated.
As stated already there are no adverse consequences of early termination and it was actually felt by the DSMB that carrying on was unnecessary.

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 : 06/04/13	
E.2.2	Signature :	
E.2.3	Print name: Heather House	

E.3	**APPLICANT TO THE ETHICS COMMITTEE** (as stated in C.2) **:**	☐
E.3.1	Date : 27th March 2013	
E.3.2	Signature :	
E.3.3	Print name: Kim Rajappan	

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