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 : BELGIUM

B TRIAL IDENTIFICATION

B.1 EudraCT number : 2009-016094-16

B.2 Sponsor's protocol code number: AGO/2009/008

B.3 Full title of the trial : Sevoflurane-Remifentanil interaction: Multiple response surfaces, validation of calibration stimuli, validation of the intraperative isobole concept and investigating remifentanil induced opioid tolerance.

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 :	
C.1.4.2	Name of person to contact :	
C.1.4.3	Address :	
C.1.4.4	Telephone number :	
C.1.4.5	Fax number :	
C.1.4.6	E-mail	

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: University Hospital Ghent	
C.2.5.2	Name : Dr. Hugo Vereecke	
C.2.5.3	Address : De Pintelaan 185 , 9000 Gent	
C.2.5.4	Telephone number : 09/332 32 81	
C.2.5.5	Fax number : 09/332 49 87	
C.2.5.6	E-mail : hugo.vereecke@ugent.be	

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): 2010/12/15

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.

D.2.1	If yes, give date (YYYY/MM/DD): 2012/12/15
D.2.2	Briefly describe in an annex (free text): cfr. infra
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	Date :	
E.2.2	Signature :	
E.2.3	Print name:	

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: Dr. Hugo Vereecke	

Annex to D.2.2 :

The trial was terminated prematurely due to the need of a change to the protocol.
As the Principal Investigator has left the University Hospital Ghent end 2010; the change of protocol was never submitted, and the study was stopped.
Since the start of the study, only 4 of the planned 40 patients could be included.
The last patient was included on May 27th 2010, and is not under treatment anymore.

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

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