

27/16/12/20

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 : <i>CTA 2013-00078-55</i> Ethics committee registration number: <i>2013-012</i>
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To be filled in by the applicant

A MEMBER STATE IN WHICH THE DECLARATION IS BEING MADE :

B TRIAL IDENTIFICATION

B.1 EudraCT number :	<i>2013-00078-55</i> (..)
B.2 Sponsor's protocol code number:	(..)
B.3 Full title of the trial :	<i>Supramax dose finding study for reversal of deep anaesthesia induced neuromuscular block</i>

C APPLICANT IDENTIFICATION (please tick the appropriate box)

C.1 DECLARATION FOR THE COMPETENT AUTHORITY	<input type="checkbox"/>
C.1.1 Sponsor	<input type="checkbox"/>
C.1.2 Legal representative of the sponsor	<input type="checkbox"/>
C.1.3 Person or organisation authorised by the sponsor to make the application.	<input type="checkbox"/>
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	<input type="checkbox"/>
C.2.1 Sponsor	<input type="checkbox"/>
C.2.2 Legal representative of the sponsor	<input type="checkbox"/>
C.2.3 Person or organisation authorised by the sponsor to make the application.	<input type="checkbox"/>
C.2.4 Investigator in charge of the application if applicable ² :	
• Co-ordinating investigator (for multicentre trial):	<input type="checkbox"/>
• Principal investigator (for single centre trial): <i>Dr. Denis Glessner</i>	<input type="checkbox"/>
C.2.5 Complete below :	
C.2.5.1 Organisation: <i>UZ Brussel</i>	<i>Dr. O. Detuche</i>
C.2.5.2 Name: <i>Dienst Anesthesiologie</i>	<i>Prof. Dr. P. Foucart</i>
C.2.5.3 Address: <i>Herestraat 49 3000 Leuven</i>	
C.2.5.4 Telephone number: <i>02/476.35.80</i>	
C.2.5.5 Fax number: <i>/</i>	
C.2.5.6 E-mail: <i>Direc.anesth@uzbrussel.be</i>	

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):
D.2 Is it an early termination? ³ yes <input checked="" type="checkbox"/> no <input type="checkbox"/>

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 (YYYY/MM/DD): 16/Nov/23.
- D.2.2 Briefly describe in an annex (free text):
- D.2.2.1 The justification for early termination of the trial: Due to logistic problems.
- 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. ✓

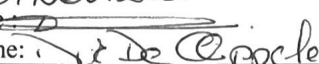
E SIGNATURE OF THE APPLICANT IN THE MEMBER STATE

- 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 : 16/Nov/23.
- E.3.2 Signature: 
- E.3.3 Print name: S. de C. de C.