

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:
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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 :	2018-003687-31
B.2 Sponsor's protocol code number:	AGO/2018/005
B.3 Full title of the trial :	Influence of continuous administration of phenylephrine versus dobutamine on spinal oxygen saturation, measured with near-infrared spectroscopy (NIRS).

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 checked="" 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):	<input checked="" type="checkbox"/>
C.2.5 Complete below :	
C.2.5.1 Organisation: Ghent University Hospital	
C.2.5.2 Name : Dr. Caroline Vanpeteghem	
C.2.5.3 Address : Corneel Heymanslaan 10, 9000 Ghent, Belgium	
C.2.5.4 Telephone number : +32 (0)9 332 56 25	
C.2.5.5 Fax number : +32 (0)9 332 49 87	
C.2.5.6 E-mail : caroline.vanpeteghem@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): 2021-05-22

D.2 Is it an early termination?³	yes <input type="checkbox"/> no <input checked="" type="checkbox"/>
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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):
- 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 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 : 16.07.2024

E.3.2 Signature :

E.3.3 Print name: Dr. Caroline Vanpeteghem