

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*<sup>1</sup>)

# **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>B.1 EudraCT number :</b>	(..) 2021 - 001425 - 48
<b>B.2 Sponsor's protocol code number:</b>	(..) blueberry.
<b>B.3 Full title of the trial :</b>	Dexamethasone and postoperative bleeding following tonsillectomy in children

**C APPLICANT IDENTIFICATION** (please tick the appropriate box)

<b>C.1 DECLARATION FOR THE COMPETENT AUTHORITY</b>	<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 checked="" type="checkbox"/>
C.1.4 <b>Complete below:</b>	
C.1.4.1 Organisation : UZ Brussel	
C.1.4.2 Name of person to contact : Nadia Nagaji	
C.1.4.3 Address : Laarbeeklaan 101, 1050 Jette	
C.1.4.4 Telephone number : 02 476 3128	
C.1.4.5 Fax number :	
C.1.4.6 E-mail : Nadia.nagaji@uzbrussel.be	

<b>C.2 DECLARATION FOR THE ETHICS COMMITTEE</b>	<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 <sup>2</sup> :	
• Co-ordinating investigator (for multicentre trial):	<input checked="" type="checkbox"/>
• Principal investigator (for single centre trial):	<input type="checkbox"/>
C.2.5 <b>Complete below :</b>	
C.2.5.1 Organisation: UZ Brussel	
C.2.5.2 Name : Nadia Nagaji	
C.2.5.3 Address : Laarbeeklaan 101, 1050 Jette	
C.2.5.4 Telephone number : 02 476 3128	
C.2.5.5 Fax number :	
C.2.5.6 E-mail : Nadia.nagaji@uzbrussel.be	

**D END OF TRIAL**

<b>D.1 Date of the end of the complete trial in all countries concerned by the trial?</b>
D.1.1 (YYYY/MM/DD): 17 apr 2024
<b>D.2 Is it an early termination?</b> <sup>3</sup> yes <input checked="" type="checkbox"/> no <input type="checkbox"/>

<sup>1</sup> OJ, C82, 30.3.2010, p. 1; hereinafter referred to as 'detailed guidance CT-1'.

<sup>2</sup> According to national legislation.

<sup>3</sup> Cf. Section 4.2. of the detailed guidance CT-1.

- D.2.1 If yes, give date (YYYY/MM/DD): 17 Apr 2024
- D.2.2 Briefly describe in an annex (free text):
- D.2.2.1 The justification for early termination of the trial; lack of financial, administrative & scientific support
- 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; 0, 10 patients were included in Belgium
- 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.

evaluation can still be done for sponsor with less subjects.

#### 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.<sup>4</sup>

#### E.2 APPLICANT TO THE COMPETENT AUTHORITY (as stated in C.1) ☐

E.2.1 Date: 28 APR 2024

E.2.2 Signature:

E.2.3 Print name: Nadia Najaji

*N. Najaji*

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

E.3.1 Date: 28 APR 2024

E.3.2 Signature:

E.3.3 Print name: Nadia Najaji

*N. Najaji*