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: EC-2021-030

To be filled in by the applicant

A MEMBER STATE IN WHICH THE DECLARATION IS BEING MADE :

B TRIAL IDENTIFICATION

B.1 EudraCT number :	(..) 2020 - 004723 - 17
B.2 Sponsor's protocol code number:	(..)
B.3 Full title of the trial :	Clinical usefulness and influence on esophageal motility of pyridostigmine for dysphagia in systemic sclerosis

C APPLICANT IDENTIFICATION (please tick the appropriate box)

C.1	**DECLARATION FOR THE COMPETENT AUTHORITY**	☒
C.1.1	Sponsor U2 Brussel	☐
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 : U2 Brussel	
C.1.4.2	Name of person to contact : Sébastien Kindt	
C.1.4.3	Address : Laarbeeklaan 101, 1090 Jette	
C.1.4.4	Telephone number : 0032 2477 6011	
C.1.4.5	Fax number :	
C.1.4.6	E-mail sebastien.kindt@u2brussel.be	

C.2	**DECLARATION FOR THE ETHICS COMMITTEE**	☒
C.2.1	Sponsor U2 Brussel	☐
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): Prof. Dr. S. Kindt	☐
C.2.5	**Complete below** :	
C.2.5.1	Organisation: U2 Brussel	
C.2.5.2	Name : Sébastien Kindt	
C.2.5.3	Address : Laarbeeklaan 101, 1090 Jette	
C.2.5.4	Telephone number : 0032 477 6011	
C.2.5.5	Fax number :	
C.2.5.6	E-mail : sebastien.kindt@u2brussel.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):

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 (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; Unable to recruit more patients.
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; zero
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 : 06/05/24
E.2.2 Signature :
E.2.3 Print name: Prof. Dr. Sébastien Kindt

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

E.3.1 Date : 06/05/24
E.3.2 Signature :
E.3.3 Print name: Prof. Dr. Sébastien Kindt

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