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 :	**(2015-000053-21)**
B.2 Sponsor's protocol code number:	**(FLUI-2014-134)**
B.3 Full title of the trial :	
Placebo controlled study to assess the effect of Roflumilast in hyperinflated COPD patients in addition to LABA/LAMA therapy using Functional Respiratory Imaging	

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 : FLUIDDA nv	
C.1.4.2	Name of person to contact : Jan De Backer	
C.1.4.3	Address : Groeningenlei 132 2550 Kontich	
C.1.4.4	Telephone number : 0032 3 450 87 20	
C.1.4.5	Fax number :	
C.1.4.6	E-mail: jan.debacker@fluidda.com	

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: FLUIDDA nv	
C.2.5.2	Name : Jan De Backer	
C.2.5.3	Address : Groeningenlei 132 2550 Kontich	
C.2.5.4	Telephone number : 0032 3 450 87 20	
C.2.5.5	Fax number :	
C.2.5.6	E-mail : jan.debacker@fluidda.com	

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

2 According to national legislation.

D END OF TRIAL

D.1	**Date of the end of the complete trial in all countries concerned by the trial?**
D.1.1	(2017/12/15):

D.2	**Is it an early termination?**[3]	yes ☒ no ❑
D.2.1	If yes, give date (2017/12/15):	
D.2.2		

D.2.2.1 The justification for early termination of the trial;
The trial was terminated early, because the sponsor received the notification that AstraZeneca will not deliver new investigational products (expire date) whereby it is not possible for the Sponsor to perform the necessary steps (iniation of new Site, shipment of medication, etc,), according to ICH-GCP, to include new patients in this 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;
There were no patients still receiving treatment at the time of early termination

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.
There is a significant impact of early termination on the evaluation of the results due to the small sample size included in this study. The overall risk benefit assessment of the investigational medicinal product will be reported in accordance to ICH-GCP

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 : 15/12/2017	
E.2.2	Signature :	
E.2.3	Print name: Jan De Backer	

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:	

3 Cf. Section 4.2. of the detailed guidance CT-1.
4 Section 4.3. of the detailed guidance CT-1.