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 :

B TRIAL IDENTIFICATION

B.1 EudraCT number :	2013-003357-17
B.2 Sponsor's protocol code number:	Ketamin_SST01
B.3 Full title of the trial : An open-label prospective trial of S-ketamine for pain treatment in chronic pancreatitis (RESET trial)	

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.	X
C.1.4	**Complete below**:	
C.1.4.1	Organisation : Mech-Sense, Department of Gastroenterology, Aalborg University Hospital	
C.1.4.2	Name of person to contact : Anne Estrup Olesen	
C.1.4.3	Address : Mølleparkvej 4, 4.sal, 9000 Aalborg	
C.1.4.4	Telephone number : 9760535	
C.1.4.5	Fax number :	
C.1.4.6	E-mail: aneso@rn.dk	

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):	X
C.2.5	**Complete below** :	
C.2.5.1	Organisation: Mech-Sense, Department of Gastroenterology, Aalborg University Hospital	
C.2.5.2	Name : Anne Estrup Olesen	
C.2.5.3	Address : Mølleparkvej 4, 4.sal, 9000 Aalborg	
C.2.5.4	Telephone number : 97660535	
C.2.5.5	Fax number :	
C.2.5.6	E-mail : aneso@rn.dk	

D END OF TRIAL

D.1	**Date of the end of the complete trial in all countries concerned by the trial**?
D.1.1	(2018/02/28):

D.2	**Is it an early termination?**[3]	yes X 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 (2016/10/21):
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 : 31.10.16
E.3.2	Signature : Anne Estrup Olesen
E.3.3	Print name: Anne Estrup Olesen

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

We have determined to make an early termination to the RESET study. This is due to difficulty in recruiting study subjects. We have been trying to recruit patients since the start of the study in 2013, and has so far only reached seven. Four have completed the study and the last three are only in the planning phase. Therefore, no patients are currently being treated with the medication or the corresponding placebo.

The recruitment has despite of great effort been difficult and we must now conclude that the goal of recruiting 40 patients is not feasible. We therefore find it unethical to proceed with the last three subjects, when the results probably will not be able to produce any significant difference, as the participation number will be too small.