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 : France

B TRIAL IDENTIFICATION

B.1 EudraCT number : (2013-002996-16)
B.2 Sponsor's protocol code number: (ANRS SHS155 STIMAGO)
B.3 Full title of the trial : Etude pilote pour l'évaluation des bénéfices et des risques du méthylphénidate pour la prise en charge de la dépendance à la cocaïne

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 : Institut National de la Santé et de la Recherche Médicale – Agence Nationale de Recherches sur le Sida et les Hépatites virales (Inserm – ANRS)	
C.1.4.2	Name of person to contact : Ben Mechlia	
C.1.4.3	Address : 101 rue de Tolbiac 75013 Paris France	
C.1.4.4	Telephone number : +33 (0)1 44 23 61 38	
C.1.4.5	Fax number : +33 (0)1 53 94 60 01	
C.1.4.6	E-mail: mohamed.ben-mechlia@anrs.fr	

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.	X
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: Institut National de la Santé et de la Recherche Médicale – Agence Nationale de Recherches sur le Sida et les Hépatites virales (Inserm – ANRS)	
C.2.5.2	Name : Ben Mechlia	
C.2.5.3	Address : 101 rue de Tolbiac 75013 Paris France	
C.2.5.4	Telephone number : +33 (0)1 44 23 61 38	
C.2.5.5	Fax number : +33 (0)1 53 94 60 01	
C.2.5.6	E-mail : mohamed.ben-mechlia@anrs.fr	

D END OF TRIAL

D.1	**Date of the end of the complete trial in all countries concerned by the trial**?
D.1.1	(2018/06/30):

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

D.2	**Is it an early termination?**[3]	yes X no ☐
D.2.1	If yes, give date: (2018/06/30)	
D.2.2	Briefly describe in an annex (free text): Lettre jointe à la demande.	
D.2.2.1	The justification for early termination of the trial; faisabilité de l'étude.	
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; L'étude a été arrêtée avant l'inclusions du premier participant.	
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. Non applicable	

E SIGNATURE OF THE APPLICANT IN THE MEMBER STATE

E.1 I hereby confirm on behalf of the sponsor that:

- 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)	X
E.2.1	Date : 2018/07/13	
E.2.2	Signature :	
E.2.3	Print name: Mohamed Ben Mechlia	

E.3	**APPLICANT TO THE ETHICS COMMITTEE** (as stated in C.2) **:**	X
E.3.1	Date : 2018/07/13	
E.3.2	Signature :	
E.3.3	Print name: Mohamed Ben Mechlia	

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

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

A Marseille, le 13 juillet 2018

Madame, monsieur,

Après les nombreux rebondissements que l'essai ANRS-Stimago a connus, nous avons pris la décision d'interrompre cette étude. En effet, le manque d'expérience dans la coordination d'essais cliniques du SESSTIM et la complexité de l'étude ne nous permettent pas de démarrer le recrutement des patients dans des conditions optimales. Pour un essai aussi sensible, tous ces aspects nous semblent importants à assurer.

Par ce courrier, nous rendons officiel l'arrêt de l'essai ANRS-Stimago depuis le 30 juin 2018.

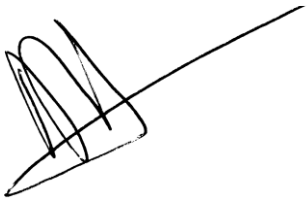
Merci pour votre compréhension,

Bien cordialement,

Pr Amine Benyamina,

Investigateur principal, PU-PH,

Hôpital Paul Brousse, AP-HP



Perrine Roux, responsable scientifique, CR Inserm,

SESSTIM, UMR1252