

**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> 2014-000182-45
<b>B.2 Sponsor's protocol code number:</b> 2013AT001B
<b>B.3 Full title of the trial:</b> A pilot study into health pre and post treatment with intravenous Aminophylline and Hydrocortisone in severe asthmatics (SARAH)

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

<b>C.1 DECLARATION FOR THE COMPETENT AUTHORITY</b>	<input checked="" type="checkbox"/>
C.1.1 Sponsor	<input checked="" 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 type="checkbox"/>
C.1.4 <b>Complete below:</b>	
C.1.4.1 Organisation :	
C.1.4.2 Name of person to contact :	
C.1.4.3 Address :	
C.1.4.4 Telephone number :	
C.1.4.5 Fax number :	
C.1.4.6 E-mail	

<b>C.2 DECLARATION FOR THE ETHICS COMMITTEE</b>	<input checked="" 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 type="checkbox"/>
• Principal investigator (for single centre trial): Dr Andrew Menzies-Gow	<input checked="" type="checkbox"/>
C.2.5 <b>Complete below :</b>	
C.2.5.1 Organisation:	
C.2.5.2 Name :	
C.2.5.3 Address :	
C.2.5.4 Telephone number :	
C.2.5.5 Fax number :	
C.2.5.6 E-mail :	

**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 (2015/02/26):

<b>D.2 Is it an early termination?<sup>3</sup></b>	yes <input checked="" type="checkbox"/> no <input type="checkbox"/>
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<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 (2015/02/26):

D.2.2 Briefly describe in an annex (free text):

This trial was set up as the dissertation project for our one of our staff as part of their Allergy MSc. Unfortunately they have left our employment before the trial was completed.

D.2.2.1 The justification for early termination of the trial;

There are no other staff members available to complete this pilot study.

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

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.

The consequences of early termination are that no meaningful data will be available to instruct future prescribing. However, this was a pilot study to evaluate novel outcome measures using what is considered standard of care therapy for patients with chronic severe asthma and its early termination will have no impact on the routine care of these patients.

### 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: 05<sup>th</sup> March 2015

E.2.2 Signature :

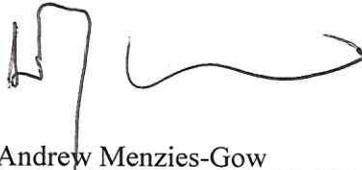


E.2.3 Print name: Ms Ira Jakupovic

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

E.3.1 Date: 05<sup>th</sup> March 2015

E.3.2 Signature :



E.3.3 Print name: Dr Andrew Menzies-Gow