

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 : 23.06.2015

Competent authority registration number :

Ethics committee registration number: 755/2009

To be filled in by the applicant

A MEMBER STATE IN WHICH THE DECLARATION IS BEING MADE : Austria

B TRIAL IDENTIFICATION

B.1 EudraCT number : (.KP 2009-015516-18.)

B.2 Sponsor's protocol code number: (.001.)

B.3 Full title of the trial : Microstructural morphological changes of the macula after intravitreal microplasmin for non-surgical treatment of vitreomacular traction syndrome

C APPLICANT IDENTIFICATION (please tick the appropriate box)

C.1 DECLARATION FOR THE COMPETENT AUTHORITY	X
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 Complete below:	
C.1.5 Organisation : Medical University of Vienna, Department of Ophthalmology	
C.1.5.1 Name of person to contact : Univ. Prof. Dr. Ursula Schmidt-Erfurth	
C.1.5.2 Address : Waehringer Guertel 18-20, A-1090 Vienna, Austria	
Telephone number : Tel. +43 1 40400 48470	
Fax number : Fax +43 1 40400 78890	
C.1.5.3 E-mail: Christina.laschitz@gmail.com	

C.2 DECLARATION FOR THE ETHICS COMMITTEE	<input 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 ² :	
• Co-ordinating investigator (for multicentre trial):	<input type="checkbox"/>
• Principal investigator (for single centre trial):	<input type="checkbox"/>
C.2.5 Complete below :	
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

D.1 Date of the end of the complete trial in all countries concerned by the trial?
D.1.1 :
D.1.2

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 <input checked="" type="checkbox"/> no <input type="checkbox"/>
D.2.1 If yes, give date (2011/12/16):	
D.2.2 Briefly describe in an annex (free text):	
D.2.2.1 The justification for early termination of the trial; No sponsor was found for this 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. 0	

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):
	<ul style="list-style-type: none"> 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 : 03-JUL-15	
E.2.2	Signature :	
E.2.3	Print name: UNIV.PROF.DR. URSULA SCHMIDT-ERFURTH	

E.3	APPLICANT TO THE ETHICS COMMITTEE (as stated in C.2) :	<input type="checkbox"/>
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.