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  $trial^{I}$ )

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				
	f 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: ()				
B.2 Sponsor's protocol code number: ()				
	ll title of the trial :			
C APPLICANT IDENTIFICATION (please tick the appropriate box)				
<b>C.1</b>	DECLARATION FOR THE COMPE	TENT 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:			
C.1.4.2	Name of person to contact:			
	Address:			
C.1.4.4	Telephone number :			
C.1.4.5	Fax number:			
C.1.4.6	E-mail			
<b>C.2</b>	DECLARATION FOR THE ETHICS	S 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 <sup>2</sup> :		
•	Co-ordinating investigator (for multicen	tre trial):		
•	Principal investigator (for single centre	trial):		
C.2.5	Complete below:			
	Organisation:			
	Name:			
C.2.5.3	Address:			

C.2.5.4 Telephone number: C.2.5.5 Fax number: C.2.5.6 E-mail:

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

<sup>&</sup>lt;sup>2</sup> According to national legislation.

## D END OF TRIAL

rned by the			
risk benefit			
E SIGNATURE OF THE APPLICANT IN THE MEMBER STATE			
eadlines in			

If the national and global end dates coincide in a concerned Member State, the form shall be submitted only once to the National Competent Authority of this Member State with both sections D1.1. and D2.1 complete.

<sup>&</sup>lt;sup>3</sup> In case of a multi-country trial, if the national and global end of trial dates are different in a given Member State, the sponsor shall submit this form two times :

<sup>1)</sup> At the <u>end of the trial in the individual Member State</u>, section D1.1. shall be completed and submitted to the respective National Competent Authority.

<sup>2)</sup> At the <u>global end of the trial</u>, the sponsor shall complete section D.2.1. with the global trial end date and the completed form shall be submitted <u>to all participating Member States</u> in order to allow the sponsor to prepare the trial result summary within the 12-months (or 6-months in case of paediatric trials) timeframe.

<sup>&</sup>lt;sup>4</sup> Cf. Section 4.2. of the detailed guidance CT-1.

<sup>&</sup>lt;sup>5</sup> Section 4.3. of the detailed guidance CT-1.