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 : Belgium.

B TRIAL IDENTIFICATION

B.1 EudraCT number : EudraCT 2007-003114-34
B.2 Sponsor's protocol code number: NA
B.3 Full title of the trial : The impact of oral curcumin (Curcuma longa) on mycophenolic acid and metabolite pharmacokinetics in stable renal allograft recipients: exploratory investigation of the role of intestinal uridine-diphosphate-glucoronosyltransferases (UGTs) in in vivo mycophenolic acid disposition.

C APPLICANT IDENTIFICATION (please tick the appropriate box)

C.1	**DECLARATION FOR THE COMPETENT AUTHORITY**	X
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 : KU Leuven	
C.1.4.2	Name of person to contact :	
C.1.4.3	Address : Herestraat 49, 3000 Leuven	
C.1.4.4	Telephone number :	
C.1.4.5	Fax number :	
C.1.4.6	E-mail:	

C.2	**DECLARATION FOR THE ETHICS COMMITTEE**	X
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: KU Leuven	
C.2.5.2	Name :	
C.2.5.3	Address : Herestraat 49, 3000 Leuven	
C.2.5.4	Telephone number :	
C.2.5.5	Fax number :	
C.2.5.6	E-mail :	

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

D END OF TRIAL

D.1 Date of the end of the trial in this Member State ?[3]	yes X no ☐
D.1.1. (2007/12/31): The trail was never started, no patients were screened or included in the study. The reason for not starting the study was insufficient quality control data for stability of content of the available curcumin formulations to be tested in a scientific study. Therefore the decision was made not to pursue the study as the results could not have been generalized for all curcumin products available for human consumption.	

D.2	**Date of the end of the complete trial in all countries concerned by the trial**?[3] yes ☐ no X
D.2.1	(YYYY/MM/DD):

D.3	**Is it an early termination?**[4]	yes ☐ no X
D.3.1	If yes, give date :	
D.3.2	Briefly describe in an annex (free text):	
D.3.2.1	The justification for early termination of the trial;	
D.3.2.2	Number of patients still receiving treatment at time of early termination in the MS concerned by the declaration and their proposed management;	
D.3.2.3	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.[5]

E.2	**APPLICANT TO THE COMPETENT AUTHORITY** (as stated in C.1) ☐
E.2.1	Date : 18-10-2012
E.2.2	Signature :
D.2.1.1	Print name: Dirk Kuypers

E.3	**APPLICANT TO THE ETHICS COMMITTEE** (as stated in C.2) **:** ☐
E.3.1	Date : 18-10-2012
E.3.2	Signature :
D.2.1.2	Print name: Dirk Kuypers

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[3] 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 :

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

2) At the global end of the trial, the sponsor shall complete section D.2.1. with the global trial end date and the completed form shall be submitted to all participating Member States 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.

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.

[4] Cf. Section 4.2. of the detailed guidance CT-1.

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

Note to file S50646:

EudraCT number : EudraCT 2007-003114-34

Sponsor's protocol code number: NA

Full title of the trial : *The impact of oral curcumin (Curcuma longa) on mycophenolic acid and metabolite pharmacokinetics in stable renal allograft recipients: exploratory investigation of the role of intestinal uridine-diphosphate-glucoronosyltransferases (UGTs) in in vivo mycophenolic acid disposition.*

Ethical committee approval for this study was obtained on 26/06/2007.

The trail was never started, no patients were screened or included in the study. The reason for not starting the study was insufficient quality control data for **stability of content of the available curcumin formulations** to be tested in a scientific study. Therefore the decision was made not to pursue the study as the results could not have been generalized for all curcumin products available for human consumption.

18-10-2022

Dirk Kuypers