

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:
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To be filled in by the applicant

A MEMBER STATE IN WHICH THE DECLARATION IS BEING MADE : United Kingdom

B TRIAL IDENTIFICATION

B.1 EudraCT number :	2010-021515-17
B.2 Sponsor's protocol code number:	REC 10/H0711/58
B.3 Full title of the trial : RiFL: Rifaximin in Fatty Liver Disease: Does Modulation of Gut Microbiota Reduce Hepatic Inflammation in Non-Alcoholic Steatohepatitis (NASH)?	

C APPLICANT IDENTIFICATION (please tick the appropriate box)

C.1 DECLARATION FOR THE COMPETENT AUTHORITY	<input type="checkbox"/>
C.1.1 Sponsor	<input 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.	X
C.1.4 Complete below:	
C.1.4.1 Organisation : Imperial College London	
C.1.4.2 Name of person to contact : Dr Jeremy Cobbold	
C.1.4.3 Address : Translational Gastroenterology Unit, John Radcliffe Hospital, Oxford University Hospitals NHS Trust, Headley Way, Headington, Oxford, OX3 9DU, UK	
C.1.4.4 Telephone number : +44 1865 228756	
C.1.4.5 Fax number : +44 1865 228763	
C.1.4.6 E-mail: jeremy.cobbold@ndm.ox.ac.uk	

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):	X
C.2.5 Complete below :	
C.2.5.1 Organisation: Imperial College London	
C.2.5.2 Name : Dr Jeremy Cobbold	
C.2.5.3 Address : Translational Gastroenterology Unit, John Radcliffe Hospital, Oxford University Hospitals NHS Trust, Headley Way, Headington, Oxford, OX3 9DU, UK	
C.2.5.4 Telephone number : +44 1865 228756	
C.2.5.5 Fax number : +44 1865 228763	
C.2.5.6 E-mail : jeremy.cobbold@ndm.ox.ac.uk	

D END OF TRIAL

D.1 Date of the end of the complete trial in all countries concerned by the trial?
D.1.1 (2012/09/17):

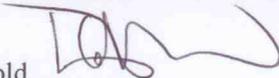
¹ OJ, C82, 30.3.2010, p. 1; hereinafter referred to as 'detailed guidance CT-1'.

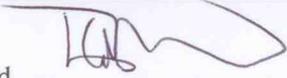
² According to national legislation.

D.2	Is it an early termination? ³	yes no X
D.2.1	If yes, give date :	
D.2.2	Briefly describe in an annex (free text):	
D.2.2.1	The justification for early termination of the trial	
D.2.2.2	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):
	<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)	<input type="checkbox"/>
E.2.1	Date : 9 th April 2015	
E.2.2	Signature : 	
E.2.3	Print name: Dr Jeremy Cobbold	

E.3	APPLICANT TO THE ETHICS COMMITTEE (as stated in C.2) :	<input type="checkbox"/>
E.3.1	Date : 9th April 2015	
E.3.2	Signature : 	
E.3.3	Print name: Dr Jeremy Cobbold	

³ Cf. Section 4.2. of the detailed guidance CT-1.
⁴ Section 4.3. of the detailed guidance CT-1.