

Cancer Research UK & UCL Cancer Trials Centre
University College London
90 Tottenham Court Road
London W1T 4TJ
website: <http://www.ctc.ucl.ac.uk/>

Director: Professor J A Ledermann

Medicines & Healthcare products Regulatory Agency
151 Buckingham Palace Road
Victoria
SW1W 9SZ

Thursday, 26 May 2016

Dear Sir/Madam ,

Trial Title: A Phase II Single Arm Study of the use of CODOX-M/IVAC with Rituximab (R-CODOX-M/IVAC) in the treatment of patients with Diffuse Large B-Cell Lymphoma (DLBCL) or Burkitt's Lymphoma (BL) of International Prognostic Index High or High – Intermediate Risk

Short Title: R-CODOX-M/IVAC
Ethics Committee: East of England – Cambridgeshire and Hertfordshire
REC Ref No: 05/Q0201/81
EudraCT number: 2005-003479-19
Sponsor: University College London
Sponsor's Project ID #: UCL/05/134
Chief Investigator: Dr Andrew McMillan

Please find enclosed the Declaration of the End of Trial Form for the above trial, which reached its end of trial as defined by the trial protocol at 3 years after the last patient was recruited.

Please do not hesitate to contact me if you have any queries or require any further information.

With best wishes,
Yours sincerely

A handwritten signature in blue ink, appearing to read 'Kwan'.

Katharina Wanek
Trial Coordinator
Haematology & Brain Tumour Trials Group

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 :

B TRIAL IDENTIFICATION

B.1 EudraCT number :	2005-003479-19
B.2 Sponsor's protocol code number:	UCL/05/134
B.3 Full title of the trial :	A Phase II Single Arm Study of the use of CODOX-M/IVAC with Rituximab (R-CODOX-M/IVAC) in the treatment of patients with Diffuse Large B-Cell Lymphoma (DLBCL) or Burkitt's Lymphoma (BL) of International Prognostic Index (IPI) High or High Intermediate Risk

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.	<input checked="" type="checkbox"/>
C.1.4 Complete below:	
C.1.4.1 Organisation : CR UK & UCL Cancer Trials Centre	
C.1.4.2 Name of person to contact : Katharina Wanek	
C.1.4.3 Address : 90 Tottenham Court Road, W1T 4TJ, London	
C.1.4.4 Telephone number : 0207 679 9116	
C.1.4.5 Fax number : 0207 679 9861	
C.1.4.6 E-mail: k.wanek@ucl.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):	<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 (2016/04/02):

D.2 Is it an early termination?³	yes <input type="checkbox"/> no <input checked="" type="checkbox"/>
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¹ OJ, C82, 30.3.2010, p. 1; hereinafter referred to as 'detailed guidance CT-1'.

² According to national legislation.

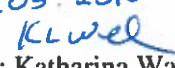
³ Cf. Section 4.2. of the detailed guidance CT-1.

- D.2.1 If yes, give date (YYYY/MM/DD):
- 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 Number of patients still receiving treatment at time of early termination in the MS concerned by the declaration and their proposed management;
- 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.

E SIGNATURE OF THE APPLICANT IN THE MEMBER STATE

- E.1 I hereby 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.⁴

E.2 APPLICANT TO THE COMPETENT AUTHORITY (as stated in C.1)

- E.2.1 Date : 26.05.2016
- E.2.2 Signature : 
- E.2.3 Print name: Katharina Wanek

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

- E.3.1 Date :
- E.3.2 Signature :
- E.3.3 Print name:

⁴ Section 4.3. of the detailed guidance CT-1.