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

East of England – Cambridgeshire and Hertfordshire

Thursday, 26 May 2016

Dear Ms Copeland,

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 attached 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.

At Royal Devon and Exeter Hospital, the PI changed from Dr Malcolm Hamilton to Dr Claudius Rudin. The site informed the UCL CTC of this change of PI on 10th of May 2016, which was after the end of trial was reached on 2nd April 2016. The Ethics Committee East of England – Cambridgeshire and Hertfordshire was consulted concerning the need to submit an amendment for the change of PI, and the committee decided that no amendment needs to be submitted for the change of PI because this would have no use at this point as this cannot be approved retrospectively.

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

With best wishes,
Yours sincerely

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:

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**	❑
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 :	
C.1.4.3	Address :	
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**	❑
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[2]:	
	• Co-ordinating investigator (for multicentre trial):	❑
	• Principal investigator (for single centre trial):	❑
C.2.5	**Complete below :**	
C.2.5.1	Organisation: CR UK & UCL Cancer Trials Centre	
C.2.5.2	Name : Katharina Wanek	
C.2.5.3	Address : 90 Tottenham Court Road, W1T 4TJ, London	
C.2.5.4	Telephone number : 0207 679 9116	
C.2.5.5	Fax number : 0207 679 9861	
C.2.5.6	E-mail : k.wanek@ucl.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	(2016/04/02):	

D.2	**Is it an early termination?[3]**	yes ❑ no ✓

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 :	
E.2.2	Signature :	
E.2.3	Print name:	

E.3	**APPLICANT TO THE ETHICS COMMITTEE** (as stated in C.2) **:**	✓
E.3.1	Date : 26/05/2016	
E.3.2	Signature : kwanek	
E.3.3	Print name: Katharina Wanek	

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