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CANCER RESEARCH UK &
UCL CANCER TRIALS CENTRE
Lymphoma Trials Office
222 Euston Road
London NW1 2DA

LTO Director: Professor DC Linch
Centre Director: Dr J A Ledermann

17th October 2005

Dear Competent Authority,

EudraCT Number 2005-003479-19
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) (Age-Adjusted International Prognostic Index (IPI) High or High-Intermediate Risk)

I am requesting clinical trial authorisation for the above trial.

Please find enclosed:

Receipt of confirmation of EudraCT number
Application form
Trial protocol

Please note that the informed consent form, subject information leaflet and the arrangements for recruitment of subjects are included as appendices in the protocol.
All of the above is provided in electronic format on disk supplied.
This study has been simultaneously submitted to the research ethics committee for approval.

I have been informed by the Clinical Trial helpline of the MHRA that
'the Investigator's Brochure is not required for studies using marketed products. Where the products are licensed in the EU so then no IMP dossier required, only a copy of the Summary of Product Characteristics (SmPC) translated into English if obtained from another Member State. If the product is on the UK market then it is not necessary to provide a copy of the SmPC provided that the product licence number is clearly included in the application form and its omission is discussed in the covering letter. It is only necessary to provide the manufacturer's authorisation number where licensed products are undergoing further manufacturing steps such as blinding.'

I hope this application is to your satisfaction. I look forward to your response.

Yours sincerely,

Dr. Catherine Burton
Clinical Research Fellow, University College London