NHS
Health Research Authority

DECLARATION OF THE END OF A STUDY

(For all studies except clinical trials of investigational medicinal products)

To be completed in typescript by the Chief Investigator and submitted to the Research Ethics Committee (REC) that gave a favourable opinion of the research within 90 days of the conclusion of the study or within 15 days of early termination.

For questions with Yes/No options please indicate answer in bold type.

1. Details of Chief Investigator

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2. Details of study

Full title of study:	A Phase III multicentre randomized clinical trial comparing rituximab with CHOP given every 14 days and rituximab with CHOP given every 21 days for the treatment of patients with newly diagnosed diffuse large B cell non-Hodgkin's lymphoma.
Research sponsor:	University College London
Name of REC:	London - Hampstead
REC reference number:	07/Q0501/49

3. Study duration

Date study commenced:	14/03/2005
Date study ended:	02/02/2017
Did this study terminate prematurely?	***Yes*** / ~~*No*~~ *If yes, please complete sections 4, 5, 6, & 7.* *If no, please go direct to section 8.*

4. Recruitment

Number of participants	1236

recruited	
Proposed number of participants to be recruited at the start of the study	1086
If different, please state the reason or this	Recruitment was extended for the registration phase to allow a further 200 patients to be recruited for the PET sub-study. This was approved by REC on 18/09/2008.

5. Circumstances of early termination

What is the justification for this early termination?	The trial protocol stated that patients would be followed up until death but the decision has now been made by the trial management group to close the trial early as no further data analysis will be done.

6. Temporary halt

Is this a temporary halt to the study?	~~*Yes*~~ ***No***
If yes, what is the justification for temporarily halting the study? When do you expect the study to re-start?	*e.g. Safety, difficulties recruiting participants, trial has not commenced, other reasons.*

7. Potential implications for research participants

Are there any potential implications for research participants as a result of terminating/halting the study prematurely? Please describe the steps taken to address them.	There are no potential implications for research participants as a result of ending the trial early. All trial treatment has been completed and the results were published in *The Lancet* (2013, 25; 381 (9880):1817-26). No further data analysis will be done and no further involvement will be requested from patients.

8. Final report on the research

Is a summary of the final report on the research enclosed with this form?	~~*Yes*~~ ***No*** *If no, please forward within 12 months of the end of the study.* The results of the study were published in *The Lancet* (2013, 25; 381 (9880):1817-26) - paper enclosed with this end of study declaration).

9. Declaration

Signature of Chief Investigator:	
Print name:	Professor David Cunningham
Date of submission:	3rd February 2017