A Phase III multicentre randomised clinical trial of R-CHOP14 vs R-CHOP21 in newly diagnosed diffuse large B-cell lymphoma

Patient initials		Date of birth	(dd/mm/yyyy)	
Centre		Consultant		
Trial number		Sex		1=M, 2=F

Please complete and return to the Lymphoma Trials Office, 90 Tottenham Court Road, London W1T 4TJ , within 6 weeks of end of cycle.

Treatment form (1 of 4)

Cycle number ☐ **Date at start of cycle** _____(dd/mm/yyyy)

Before start of cycle

Haematology

Date of haematology		(dd/mm/yyyy)
	Value	**Units**
Haemoglobin		g/dl
Platelets		$x10^9$/l
White blood cells		$x10^9$/l
Neutrophils		$x10^9$/l
Lymphocytes		$x10^9$/l

Biochemistry

Date of biochemistry		(dd/mm/yyyy)
	Value	**Units**
Sodium		mmol/l
Potassium		mmol/l
Creatinine		µmol/l
Urea		mmol/l
Albumin		g/l
Total protein		g/l
Calcium		mmol/l
Phosphate		mmol/l
LDH		IU/l
Bilirubin		µmol/l
Alkaline phosphatase		IU/l
AST		IU/l
ALT		IU/l

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Patient initials		Date of birth	(dd/mm/yyyy)	
Centre		Consultant		
Trial number		Sex		1=M, 2=F

Treatment form – R-CHOP^{14} (Page 2 of 4)

BSA (m^2) ☐

Drug	Dose (mg/m2)	Route	Total dose (mgsxbody surface area)	Reduction[1]	Delay[1]
Cyclophosphamide	**750**	IV			
Doxorubicin	**50**	IV			
Vincristine	**2**	IV			
Prednisolone (day 1)	**100**	PO			
Prednisolone (day 2)	**100**	PO			
Prednisolone (day 3)	**100**	PO			
Prednisolone (day 4)	**100**	PO			
Prednisolone (day 5)	**100**	PO			
Rituximab	**375**	IV			

[1] 0= No delay/reduction, 1=Haematological Toxicity, 2=Other Toxicity 3=Patient choice, 4=clinician choice, 5=Administrative, 6= other (specify below)

Please confirm G-CSF schedule for administration

Day of cycle	Date (dd/mm/yyyy)	Route	Dose
4		s.c.	
5		s.c.	
6		s.c.	
7		s.c.	
8		s.c.	
9		s.c.	
10		s.c.	
11		s.c.	
12		s.c.	

A Phase III multicentre randomised clinical trial of R-CHOP14 vs R-CHOP21 in newly diagnosed diffuse large B-cell lymphoma

Patient initials		Date of birth	(dd/mm/yyyy)	
Centre		Consultant		
Trial number		Sex		1=M, 2=F

Treatment form – R-CHOP^{21} (Page 2 of 4)

BSA (m^2) ☐

Drug	Dose (mg/m2)	Route	Total dose (mgsxbody surface area)	Reduction[1]	Delay[1]
Cyclophosphamide	**750**	IV			
Doxorubicin	**50**	IV			
Vincristine	**1.4**	IV			
Prednisolone (day 1)	**40**	PO			
Prednisolone (day 2)	**40**	PO			
Prednisolone (day 3)	**40**	PO			
Prednisolone (day 4)	**40**	PO			
Prednisolone (day 5)	**40**	PO			
Rituximab	**375**	IV			

[1] 0= No delay/reduction, 1=Haematological Toxicity, 2=Other Toxicity 3=Patient choice, 4=clinician choice, 5=Administrative, 6= other (specify below)

Was G-CSF given? ☐ 0=No, 1=Yes,

If G-CSF was given please confirm the schedule for administration

Day of cycle	Date (dd/mm/yyyy)	Route	Dose
4		s.c.	
5		s.c.	
6		s.c.	
7		s.c.	
8		s.c.	
9		s.c.	
10		s.c.	
11		s.c.	
12		s.c.	

A Phase III multicentre randomised clinical trial of R-CHOP14 vs R-CHOP21 in newly diagnosed diffuse large B-cell lymphoma

Patient initials		Date of birth	(dd/mm/yyyy)	
Centre		Consultant		
Trial number		Sex		1=M, 2=F

Please record all toxicities occurring during this cycle of therapy. Use Common Toxicity Criteria grading and report worst grade experienced (if toxicity not experienced enter '0')

Treatment form (Page 3 of 4)

Toxicity	**CTC grade**	**Related to Cyclophosphamide** Y=Yes N=No	**Related to Doxorubicin** Y=Yes N=No	**Related to Vincristine** Y=Yes N=No	**Related to Prednisolone** Y=Yes N=No	**Related to Rituximab** Y=Yes N=No	**Related to G-CSF** Y=Yes N=No
Neutropenia							
Thrombocytopenia							
Infection							
Nausea							
Vomiting							
Neurological							
Cardiac							
Fatigue							
Mucositis							
Alopecia							
Haematuria							
Insomnia							
Constipation							
Diarrhoea							
Indigestion							
Mood disturbance							
Fever							

A Phase III multicentre randomised clinical trial of R-CHOP14 vs R-CHOP21 in newly diagnosed diffuse large B-cell lymphoma

Patient initials		Date of birth	(dd/mm/yyyy)	
Centre		Consultant		
Trial number		Sex		1=M, 2=F

Treatment form (Page 4 of 4)

Toxicity	**CTC grade**	**Related to Cyclophosphamide** Y=Yes N=No	**Related to Doxorubicin** Y=Yes N=No	**Related to Vincristine** Y=Yes N=No	**Related to Prednisolone** Y=Yes N=No	**Related to Rituximab** Y=Yes N=No	**Related to G-CSF** Y=Yes N=No
Chills							
Mucosal swelling							
Headache							
Bronchospasm							
Aching muscles & joints							
Itching							
Skin rash							
Hypotension							
Bone pain							
Other – specify							
Other – specify							

Form completed by: _____ Date of completion: _____

Signature: _____

A Phase III multicentre randomised clinical trial of R-CHOP14 vs R-CHOP21 in newly diagnosed diffuse large B-cell lymphoma

Patient initials		Date of birth	(dd/mm/yyyy)	
Centre		Consultant		
Trial number		Sex		1=M, 2=F

To be completed after 4 cycles of treatment. Please return to Lymphoma Trials Office, 90 Tottenham Court Road, London W1T 4TJ , within 6 weeks of completion of 4th cycle.

Restaging Form - After 4 Cycles (Page 1 of 2)

Sites of nodal disease

Site	**Involved** Y=Involved N= not involved	**Investigation** 1=clinical 2=x-ray 3=CT scan 4=other	**Response** 1=CR, 2=Cru, 3=PR, 4=SD, 5=PD/Relapse
Left cervical			
Right cervical			
Left supraclavicular			
Right supraclavicular			
Waldeyer's ring			
Left axillary			
Right axillary			
Paratracheal			
Mediastinal			
Hilar			
Retrocrural			
Para-aortic			
Coeliac axis			
Mesenteric			
Splenic			
Portal			
Left iliac			
Right iliac			
Left inguinal			
Right inguinal			
Left femoral			
Right femoral			
Other, specify			
Other, specify			
Other, specify			
Other, specify			

A Phase III multicentre randomised clinical trial of R-CHOP14 vs R-CHOP21 in newly diagnosed diffuse large B-cell lymphoma

Patient initials		Date of birth	(dd/mm/yyyy)	
Centre		Consultant		
Trial number		Sex		1=M, 2=F

Restaging Form - After 4 Cycles (Page 2 of 2)

Sites of extranodal disease

Site	**Involved** Y=Involved N= not involved	**Investigation** 1=clinical 2=x-ray 3=CT scan 4=other	**Response** 1=CR, 2=Cru, 3=PR, 4=SD, 5=PD/Relapse
Spleen			
Liver			
Lungs			
Bone marrow			
Kidney			
Pericardium			
Pleura			
Skin			
Testis			
Other, specify			
Other, specify			

Response ☐ Date of assessment ☐ (dd/mm/yyyy)

1= CR
2= Cru
3= PR
4= SD
5= PD/Relapse (If so, please complete progression form)

Form completed by: _____ Date of completion: _____

Signature: _____

A Phase III multicentre randomised clinical trial of R-CHOP14 vs R-CHOP21 in newly diagnosed diffuse large B-cell lymphoma

Patient initials		Date of birth	(dd/mm/yyyy)	
Centre		Consultant		
Trial number		Sex		1=M, 2=F

Completed on completion or discontinuation of protocol treatment. Return the form to Lymphoma Trials Office, 90 Tottenham Court Road, London W1T 4TJ, within 6 weeks of assessment.

Treatment Summary Form (Page 1 of 1)

1) Number of cycles of chemotherapy completed ☐

2) Date of last cycle of protocol treatment _____(dd/mm/yyyy)

3) Reason for terminating protocol treatment ☐

1= Full protocol treatment completed

2= Disease Progression (complete disease progression form)

3= Death (complete death form)

4= Toxicity (please specify below)

_____

5= Patient refusal

6= Other medical conditions

7= None of the above (please specify below)

Form completed by: _____ Date of completion: _____

Signature: _____

A Phase III multicentre randomised clinical trial of R-CHOP14 vs R-CHOP21 in newly diagnosed diffuse large B-cell lymphoma

Patient initials		Date of birth	(dd/mm/yyyy)	
Centre		Consultant		
Trial number		Sex		1=M, 2=F

To be completed after the end of treatment. Please return to Lymphoma Trials Office, 90 Tottenham Court Road, London W1T 4TJ, within 6 weeks of assessment.

Restaging at End of Treatment Form (Page 1 of 3)

Haematology

Date of haematology		(dd/mm/yyyy)
	Value	**Units**
Haemoglobin		g/dl
Platelets		$x10^9$/l
White blood cells		$x10^9$/l
Neutrophils		$x10^9$/l
Lymphocytes		$x10^9$/l

Biochemistry

Date of biochemistry		(dd/mm/yyyy)
	Value	**Units**
Sodium		mmol/l
Potassium		mmol/l
Creatinine		µmol/l
Urea		mmol/l
Albumin		g/l
Total protein		g/l
Calcium		mmol/l
Phosphate		mmol/l
LDH		IU/l
Bilirubin		µmol/l
Alkaline phosphatase		IU/l
AST		IU/l
ALT		IU/l

Patient initials		Date of birth	(dd/mm/yyyy)	
Centre		Consultant		
Trial number		Sex		1=M, 2=F

Restaging at End of Treatment Form (Page 2 of 3)

Sites of Nodal Disease

Site	**Involved** Y=Involved N= not involved	**Investigation** 1=clinical 2=x-ray 3=CT scan 4=other	**Response** 1=CR, 2=Cru, 3=PR, 4=SD, 5=PD/Relapse
Left cervical			
Right cervical			
Left supraclavicular			
Right supraclavicular			
Waldeyer's ring			
Left axillary			
Right axillary			
Paratracheal			
Mediastinal			
Hilar			
Retrocrural			
Para-aortic			
Coeliac axis			
Mesenteric			
Splenic			
Portal			
Left iliac			
Right iliac			
Left inguinal			
Right inguinal			
Left femoral			
Right femoral			
Other, specify			
Other, specify			
Other, specify			
Other, specify			

A Phase III multicentre randomised clinical trial of R-CHOP14 vs R-CHOP21 in newly diagnosed diffuse large B-cell lymphoma

Patient initials		Date of birth	(dd/mm/yyyy)	
Centre		Consultant		
Trial number		Sex		1=M, 2=F

Restaging at End of Treatment Form (Page 3 of 3)

Sites of extranodal disease

Site	**Involved** Y=Involved N= not involved	**Investigation** 1=clinical 2=x-ray 3=CT scan 4=other	**Response** 1=CR, 2=Cru, 3=PR, 4=SD, 5=PD/Relapse
Spleen			
Liver			
Lungs			
Bone marrow			
Kidney			
Pericardium			
Pleura			
Skin			
Testis			
Other, specify			
Other, specify			

Final Response [ ] Date of assessment [ ] (dd/mm/yyyy)

1= CR
2= Cru
3= PR
4= SD
5= PD/Relapse (If so, please complete progression form)

Form completed by: _____ Date of completion: _____

Signature: _____

A Phase III multicentre randomised clinical trial of R-CHOP14 vs R-CHOP21 in newly diagnosed diffuse large B-cell lymphoma

Patient initials		Date of birth	(dd/mm/yyyy)	
Centre		Consultant		
Trial number		Sex		1=M, 2=F

Please complete at 3, 6, 9, 12, 18 and 24 months after completion of protocol treatment, and annually thereafter. Return to Lymphoma Trials Office, 90 Tottenham Court Road, London W1T 4TJ, within 6 weeks of assessment

Follow up form (page 1 of 1)

Patient status

Date of Assessment _____ (dd/mm/yyyy)

☐ 1=Alive without progression
2=Alive with progression/ relapse — Please complete disease progression form
3=Dead — Please complete death form

Any further anti cancer therapy given (since last follow up) ☐ 0= No, 1=Yes

If yes, what treatment given? _____

Reason for therapy
a) Progression ☐
b) Other ☐ please specify _____

Form completed by: _____ Date of completion: _____

Signature: _____

A Phase III multicentre randomised clinical trial of R-CHOP14 vs R-CHOP21 in newly diagnosed diffuse large B-cell lymphoma

Patient initials		Date of birth	(dd/mm/yyyy)	
Centre		Consultant		
Trial number		Sex		1=M, 2=F

Complete after any disease progression. Please return to Lymphoma Trials Office, 90 Tottenham Court Road, London W1T 4TJ as soon as possible after confirmation of disease progression.

Disease progression form (page 1 of 3)

Date of first progression (dd/mm/yyyy)	

Please specify nature of disease progression (1=Yes, 0=No)

Development of new lymph nodes/mass	
≥ 50% increase in size of lymph nodes/mass	
Enlarging liver or spleen	
The development of B symptoms or severe pruritis	
Reappearance of bone marrow disease	

A Phase III multicentre randomised clinical trial of R-CHOP14 vs R-CHOP21 in newly diagnosed diffuse large B-cell lymphoma

Patient initials		Date of birth	(dd/mm/yyyy)	
Centre		Consultant		
Trial number		Sex		1=M, 2=F

Disease progression form (page 2 of 3)

Sites of Nodal Disease

Site	**Involved** Y=Involved N= not involved	**Investigation** 1=clinical 2=x-ray 3=CT scan 4=other	**Measurable** M=measurable E=evaluable	**Size** Bidimensional measurements (mm x mm)
Left cervical				
Right cervical				
Left supraclavicular				
Right supraclavicular				
Waldeyer's ring				
Left axillary				
Right axillary				
Paratracheal				
Mediastinal				
Hilar				
Retrocrural				
Para-aortic				
Coeliac axis				
Mesenteric				
Splenic				
Portal				
Left iliac				
Right iliac				
Left inguinal				
Right inguinal				
Left femoral				
Right femoral				
Other, specify				
Other, specify				
Other, specify				
Other, specify				

A Phase III multicentre randomised clinical trial of R-CHOP14 vs R-CHOP21 in newly diagnosed diffuse large B-cell lymphoma

Patient initials		Date of birth	(dd/mm/yyyy)	
Centre		Consultant		
Trial number		Sex		1=M, 2=F

Disease progression form (page 3 of 3)

Sites of Extranodal Disease

Site	**Involved** Y=Involved N= not involved	**Investigation** 1=clinical 2=x-ray 3=CT scan 4=other	**Measurable** M=measurable E=evaluable	**Size** Bidimensional measurements (mm x mm)
Spleen				
Liver				
Lungs				
Bone marrow				
Kidney				
Pericardium				
Pleura				
Skin				
Testis				
Other, specify				
Other, specify				

Form completed by: _____ Date of completion: _____

Signature: _____

A Phase III multicentre randomised clinical trial of R-CHOP14 vs R-CHOP21 in newly diagnosed diffuse large B-cell lymphoma

Patient initials		Date of birth	(dd/mm/yyyy)	
Centre		Consultant		
Trial number		Sex		1=M, 2=F

Please complete at the time of the patient's death. Please return as soon as possible to the Lymphoma Trials Office, 90 Tottenham Court Road, London W1T 4TJ.

Death form (1 of 1)

Date of death (dd/mm/yyyy)	

Cause of Death ☐

1=Non-Hodgkin's lymphoma

2=Treatment related toxicity

3=Secondary malignancy, please specify

Date confirmed (dd/mm/yyyy)	
Type of malignancy	

4=Cardiac death

5=Other, please specify

Form completed by: _____ Date of completion: _____

Signature: _____