A Phase II Single Arm Study of the use of R-CODOX-M/IVAC in the treatment of DLBCL or BL

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

Rituximab Treatment form (Page 1 of 1)

Days	Dose (mg/m^2)	Route	Date	Total dose (mgs x BSA)	Reduction[1]	Delay[1]
21	375	IV				
42	375	IV				

[1] 0= No delay/reduction, 1=Haematological Toxicity, 2=Non-Haematological Toxicity, 3=Other Toxicity, 4=Patient choice, 5=clinician choice, 6=Administrative, 7= other **(specify in box below)**

Form completed by: _____ Date of completion: _____

Signature: _____

A Phase II Single Arm Study of the use of R-CODOX-M/IVAC in the treatment of DLBCL or BL

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

Treatment Summary Form (Page 1 of 1)

Did the Patient receive full protocol treatment? ☐ 1=Yes 2=No

If no please complete the rest of the form

How many cycles of CODOX-M were received? ☐

How many cycles of IVAC were received? ☐

Were the final 2 doses of Rituximab given according to Protocol? ☐ 1=Yes 2=No

Please specify date protocol treatment terminated ____/____/____ (dd/mm/yyyy)

Reason for terminating protocol treatment ☐

1= Disease Progression (complete disease progression form)
2= Death (complete death form)
3= Toxicity (please specify below)
4= Patient refusal
5= Other medical conditions
6= None of the above (please specify below)

Form completed by: _____ Date of completion: _____

Signature: _____

A Phase II Single Arm Study of the use of R-CODOX-M/IVAC in the treatment of DLBCL or BL

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

End of Treatment Assessment Form (1 of 4)

Haematology

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

Biochemistry

	Value	Units
Date of Biochemistry	/ /	(dd/mm/yyyy)
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
β2 microglobulin		mg/l

A Phase II Single Arm Study of the use of R-CODOX-M/IVAC in the treatment of DLBCL or BL

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

End of Treatment Assessment Form (Page 2 of 4)

Pre-treatment assessment

Investigation	**Date** (dd/mm/yyyy)	**Result** 1=Normal 2=Abnormal 3= Not done
CT scan neck	/ /	
CT scan thorax	/ /	
CT scan abdomen	/ /	
CT scan pelvis	/ /	
Echocardiogram	/ /	
LVEF		**%**
Specify abnormality		
Bone marrow aspirate	/ /	
Specify abnormality		
Bone marrow trephine	/ /	
Specify abnormality		

Investigation	**Date** (dd/mm/yyyy)	**Result** 1=Minimal residual uptake 2=Positive disease, 3=Not Done
PET scan (if applicable)	/ /	

A Phase II Single Arm Study of the use of R-CODOX-M/IVAC in the treatment of DLBCL or BL

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

End of Treatment Assessment Form (Page 3 of 4)

Sites of nodal disease

Site	**Involved** Y=Involved N= Not involved	**Investigation** 1=Clinical 2=X-ray 3=CT scan 4=PET scan, 5=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 II Single Arm Study of the use of R-CODOX-M/IVAC in the treatment of DLBCL or BL

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

End of Treatment Assessment Form (Page 4 of 4)

Sites of extranodal disease

Site	**Involved** Y=Involved N= Not involved	**Investigation** 1=Clinical 2=X-ray 3=CT scan 4=PET scan, 5=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				

Overall Response

Date of Assessment _____ (dd/mm/yyyy)

Response ☐

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 II Single Arm Study of the use of R-CODOX-M/IVAC in the treatment of DLBCL or BL

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

Please complete monthly for the first 4 months, 2 monthly for the remainder of the first year, 3 monthly during year 2, 4 monthly during year 3, 6 monthly during year 4, and annually thereafter.

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 II Single Arm Study of the use of R-CODOX-M/IVAC in the treatment of DLBCL or BL

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

Disease progression/ relapse form (page 1 of 3)

Date of first progression or relapse _____ (dd/mm/yyyy)

Please specify nature of disease progression

0 = No
1 = Yes

≥50% increase from nadir in the SPD of any previously identified abnormal node for PRs or non-responders.	
Appearance of any new lesion during or at the end of therapy.	

Please specify nature of disease relapse

0 = No
1 = Yes

Appearance of any new lesion or increase by ≥50% in the size of previously involved sites	
≥50% increase in the greatest diameter of any previously identified node greater than 1cm in its short axis or in the SPD of more than one node.	

A Phase II Single Arm Study of the use of R-CODOX-M/IVAC in the treatment of DLBCL or BL

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

Disease progression/ relapse 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=PET scan, 5=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 II Single Arm Study of the use of R-CODOX-M/IVAC in the treatment of DLBCL or BL

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

Disease progression/ relapse 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=PET scan, 5=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 II Single Arm Study of the use of R-CODOX-M/IVAC in the treatment of DLBCL or BL

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

Death form (Page 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: _____

A Phase II Single Arm Study of the use of R-CODOX-M/IVAC in the treatment of DLBCL or BL

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

Please send completed form Lymphoma Team, UCL CTC, 90 Tottenham Court Road, 6th Floor, London W1T 4TJ. For queries please call the Trials Centre on 0207 679 9860.

Withdrawal of Consent form - Page 1 of 1

	0=No 1=Yes	Date of withdrawal
Has the patient withdrawn consent from receiving trial treatment?		/ / (dd/mm/yyyy)
Has the patient withdrawn consent from the trial completely?		/ / (dd/mm/yyyy)

Form completed by: _____ Date of completion: _____

Signature: _____