

**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		Cycle Number		Cycle start date	

**Treatment form – CODOX-M (1 of 4)**

**Before start of cycle**

**Haematology**

	<b>Value</b>	<b>Units</b>
Date of haematology	/ /	(dd/mm/yyyy)
Haemoglobin		g/dl
Platelets		x10 <sup>9</sup> /l
White blood cells		x10 <sup>9</sup> /l
Neutrophils		x10 <sup>9</sup> /l
Lymphocytes		x10 <sup>9</sup> /l

**Biochemistry**

	<b>Value</b>	<b>Units</b>
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

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**Treatment form – CODOX-M (2 of 4)**

BSA (m<sup>2</sup>)

Drug	Days	Dose (mg/m <sup>2</sup> )	Route	Total dose (mgs x BSA)	Reduction <sup>1</sup>	Delay <sup>1</sup>
Rituximab	1	375	IV			
	11	375	IV			
Cyclophosphamide	1	800	IV			
	2	200	IV			
	3	200	IV			
	4	200	IV			
	5	200	IV			
Vincristine (a max. of 2mg for each day)	1	1.5	IV			
	8	1.5	IV			
Doxorubicin	1	40	IV			
Cytarabine	1	70	INTRATHECAL			
	3	70	INTRATHECAL			
Cytarabine (proven or suspected CNS disease patients - Cycle 1 Only)	5	70	INTRATHECAL			
Methotrexate	10	3000	IV			
Leucovorin*	11	15*	IV			
Pegylated G-CSF (Neulasta)	13	6	SC			
Methotrexate	15	12	INTRATHECAL			
Methotrexate (proven or suspected CNS disease patients - Cycle 1 Only)	17	12	INTRATHECAL			
<b>Commence IVAC on the day that the unsupported absolute granulocyte count is &gt; 1.0x10<sup>9</sup>/l, with an unsupported platelet count of &gt;75x10<sup>9</sup>/l</b>						

<sup>1</sup> 0= No delay/reduction, 1=Haematological Toxicity, 2=Other Toxicity, 3=Patient choice, 4=clinician choice, 5=Administrative, 6= low granulocyte count, 7=low platelet count, 8=Non-Haematological Toxicity, 9=other (specify in box below)

\* 15 mg/m<sup>2</sup> given at hour 36, every 3hrs between 36-48hrs, then every 6 hours until methotrexate level is <5 x10<sup>-8</sup>M

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Consultant		Cycle Number		Cycle start date	

**Treatment Form CODOX-M (3 of 4)**

Adverse Event	Severity Grade <sup>a</sup> <small>(Grades 0-5)</small>	Dates of Onset & Resolution <small>dd mm yy (e.g. 01 JAN 09)</small>	Related to Cyclophosphamide <sup>b</sup>	Related to Vincristine <sup>b</sup>	Related to Doxorubicin <sup>b</sup>	Related to Rituximab <sup>b</sup>	Related to Methotrexate <sup>b</sup>	Related to Leucovorin <sup>b</sup>	Related to Cytarabine <sup>b</sup>	Related to Neulasta <sup>b</sup>	Outcome <sup>c</sup>	Was the event serious? <sup>d</sup> <small>0 = No 1 = Yes</small>
Neutropenia	<input type="checkbox"/>	Start <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> End <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Thrombocytopenia	<input type="checkbox"/>	Start <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> End <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Infection	<input type="checkbox"/>	Start <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> End <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Nausea	<input type="checkbox"/>	Start <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> End <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>	Start <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> End <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Neurological	<input type="checkbox"/>	Start <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> End <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Cardiac	<input type="checkbox"/>	Start <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> End <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
a) Tick worst grade observed during reporting period / Use CTCAE v3.0 unless stated otherwise						c) 0 = Fatal; 1 = Not resolved; 2 = Resolved; 3 = Resolved with sequelae; 4 = Resolving; 5 = Unknown						
b) 0 = Not related; 1 = Unlikely; 2 = Possibly; 3 = Probably; 4 = Definitely						d) Ensure a completed SAE report has been submitted to the LTO, UCL CTC						

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Consultant		Cycle Number		Cycle start date	

**Treatment Form CODOX-M (4 of 4)**

Adverse Event	Severity Grade <sup>a</sup> <small>(Grades 0-5)</small>	Dates of Onset & Resolution <small>d d m m m y y (e.g. 01 JAN 09)</small>	Related to Cyclophosphamide <sup>b</sup>	Related to Vincristine <sup>b</sup>	Related to Doxorubicin <sup>b</sup>	Related to Rituximab <sup>b</sup>	Related to Methotrexate <sup>b</sup>	Related to Leucovorin <sup>b</sup>	Related to Cytarabine <sup>b</sup>	Related to Neulasta <sup>b</sup>	Outcome <sup>c</sup>	Was the event serious? <sup>d</sup>
												<small>0 = No 1 = Yes</small>
Mucositis	<input type="checkbox"/>	Start <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> End <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Haematuria	<input type="checkbox"/>	Start <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> End <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Fever	<input type="checkbox"/>	Start <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> End <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Other - Specify	<input type="checkbox"/>	Start <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> End <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Other - Specify	<input type="checkbox"/>	Start <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> End <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Other - Specify	<input type="checkbox"/>	Start <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> End <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Other - Specify	<input type="checkbox"/>	Start <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> End <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

a) Tick worst grade observed during reporting period / Use CTCAE v3.0 unless stated otherwise  
b) 0 = Not related; 1 = Unlikely; 2 = Possibly; 3 = Probably; 4 = Definitely  
c) 0 = Fatal; 1 = Not resolved; 2 = Resolved; 3 = Resolved with sequelae; 4 = Resolving; 5 = Unknown  
d) Ensure a completed SAE report has been submitted to the LTO, UCL CTC

<b>FORM COMPLETED BY:</b>	<b>Print name:</b> _____	<b>Signature:</b> _____	<b>Date:</b> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <small>d d m m m y y</small>
<b>FOR CTC USE ONLY:</b>	Date received: _____ <small>(stamp)</small>	Date entered on database: <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <small>d d m m m y y</small>	Entered on database by: _____

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### Adverse Events Completion Instructions

- Record all adverse events (AEs) that occur from informed consent until 30 days post last protocol treatment whether related to the treatment or not.
- Provide different dates for different episodes of the same event (i.e. if an event resolves to grade 0 or baseline and starts again, a new entry is required with start date, grade etc).
- Pre-existing events do not qualify as AEs unless they worsen.

1) Severity Grade

- Enter worst grade observed since last cycle
- Use CTCAE v3.0
- If no AE occurred enter "0"

2) Related to

- Use the following options: 0 = Not related; 1 = Unlikely; 2 = Possibly; 3 = Probably; 4 = Definitely

3) Outcome

- Use the following options: 0 = Fatal; 1 = Not resolved; 2 = Resolved; 3 = Resolved with sequelae; 4 = Resolving; 5 = Unknown

4) Was the event serious?

- Ensure a completed SAE Report has been submitted to UCL CTC (this must be done within 1 business day of becoming aware of the SAE)

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**Treatment form – IVAC (1 of 4)**

**Before start of cycle**

**Haematology**

	<b>Value</b>	<b>Units</b>
Date of haematology	/ /	(dd/mm/yyyy)
Haemoglobin		g/dl
Platelets		x10 <sup>9</sup> /l
White blood cells		x10 <sup>9</sup> /l
Neutrophils		x10 <sup>9</sup> /l
Lymphocytes		x10 <sup>9</sup> /l

**Biochemistry**

	<b>Value</b>	<b>Units</b>
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

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**Treatment form – IVAC (2 of 4)**

BSA (m<sup>2</sup>)

Drug	Days	Dose (mg/m <sup>2</sup> )	Route	Total dose (mgs x BSA)	Reduction <sup>1</sup>	Delay <sup>1</sup>
Rituximab	1	375	IV			
Etoposide	1	60	IV			
	2	60	IV			
	3	60	IV			
	4	60	IV			
	5	60	IV			
Ifosfamide	1	1500	IV			
	2	1500	IV			
	3	1500	IV			
	4	1500	IV			
	5	1500	IV			
Mesna	1	1200	IV			
	2	1200	IV			
	3	1200	IV			
	4	1200	IV			
	5	1200	IV			
Cytarabine	1	4000	IV			
	2	4000	IV			
Methotrexate	5	12	INTRACTHECAL			
Pegylated G-CSF (Neulasta)	7	6	SC			
Cytarabine (High Risk Only- Cycle 1 Only)	7	70	INTRACTHECAL			
	9	70	INTRACTHECAL			

<sup>1</sup> 0= No delay/reduction, 1=Haematological Toxicity, 2=Other Toxicity, 3=Patient choice, 4=clinician choice, 5=Administrative, 6= low granulocyte count, 7=low platelet count, 8=Non-Haematological Toxicity, 9=other (specify in box below)

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**Treatment form – IVAC (3 of 4)**

Adverse Event	Severity Grade <sup>a</sup> <small>(Grades 0-5)</small>	Dates of Onset & Resolution  <small>d d m m m y y (e.g. 01 JAN 09)</small>	Related to Rituximab <sup>b</sup>	Related to Etoposide <sup>b</sup>	Related to Ifosfamide <sup>b</sup>	Related to Mesna <sup>b</sup>	Related to Cytarabine <sup>b</sup>	Related to Methotrexate <sup>b</sup>	Related to Neulasta <sup>b</sup>	Outcome <sup>c</sup>	Was the event serious? <sup>d</sup> <small>0 = No 1 = Yes</small>
Neutropenia	<input type="checkbox"/>	Start <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> End <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Thrombocytopenia	<input type="checkbox"/>	Start <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> End <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Infection	<input type="checkbox"/>	Start <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> End <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Nausea	<input type="checkbox"/>	Start <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> End <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>	Start <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> End <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Neurological	<input type="checkbox"/>	Start <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> End <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Cardiac	<input type="checkbox"/>	Start <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> End <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
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**Treatment form – IVAC (4 of 4)**

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											<small>0 = No 1 = Yes</small>
Mucositis	<input type="checkbox"/>	Start <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> End <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Haematuria	<input type="checkbox"/>	Start <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> End <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Fever	<input type="checkbox"/>	Start <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> End <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Other - Specify	<input type="checkbox"/>	Start <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> End <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Other - Specify	<input type="checkbox"/>	Start <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> End <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Other - Specify	<input type="checkbox"/>	Start <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> End <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Other - Specify	<input type="checkbox"/>	Start <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> End <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

a) Tick worst grade observed during reporting period / Use CTCAE v3.0 unless stated otherwise  
b) 0 = Not related; 1 = Unlikely; 2 = Possibly; 3 = Probably; 4 = Definitely

c) 0 = Fatal; 1 = Not resolved; 2 = Resolved; 3 = Resolved with sequelae; 4 = Resolving; 5 = Unknown  
d) Ensure a completed SAE report has been submitted to the LTO, UCL CTC

<b>FORM COMPLETED BY:</b>	<b>Print name:</b> _____	<b>Signature:</b> _____	<b>Date:</b> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <small>dd mm yy</small>
<b>FOR CTC USE ONLY:</b>	Date received: _____ <small>(stamp)</small>	Date entered on database: <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <small>dd mm yy</small>	Entered on database by: _____

## 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		Cycle Number		Cycle start date	

### Adverse Events Completion Instructions

- Record all adverse events (AEs) that occur from informed consent until 30 days post last protocol treatment whether related to the treatment or not.
- Provide different dates for different episodes of the same event (i.e. if an event resolves to grade 0 or baseline and starts again, a new entry is required with start date, grade etc).
- Pre-existing events do not qualify as AEs unless they worsen.

1) Severity Grade

- Enter worst grade observed since last cycle
- Use CTCAE v3.0
- If no AE occurred enter "0"

2) Related to

- Use the following options: 0 = Not related; 1 = Unlikely; 2 = Possibly; 3 = Probably; 4 = Definitely

3) Outcome

- Use the following options: 0 = Fatal; 1 = Not resolved; 2 = Resolved; 3 = Resolved with sequelae; 4 = Resolving; 5 = Unknown

4) Was the event serious?

- Ensure a completed SAE Report has been submitted to UCL CTC (this must be done within 1 business day of becoming aware of the SAE)