R-CODOX-M/IVAC Trial - Serious Adverse Event (SAE) Reporting Form

Please complete all sections with details of any SAE occurring from the time of informed consent until 30 days post trial adminstration (and later if the event is felt to be a long term side effect).
For guidance on which events to report please see section 15 of the R-CODOX-M/IVAC trial protocol & 'Guidelines for reporting Serious Adverse Events'.
Please fax this form to the Haematology Trials Group on 020 7679 9861 within 1 business day of notification of the event.

Trial details	**EudraCT number** 2005-003479-19		
Study title	A Phase II Single arm study of the use of CODOX-M/IVAC with Rituximab in the treatment of patients with Diffuse Large B-Cell or Burkitt's Lymphoma.	**Study acronym**	R-CODOX-M/IVAC

1) Patient details

Patient initials	☐☐☐	**Gender:**	☐ Male ☐ Female	**Patient trial number:**	RCM ☐☐☐
Date of birth	☐☐ ☐☐☐ ☐☐ (dd mmm yy)	**Height**	☐☐☐ cm	**Weight**	☐☐☐.☐ kg
Site name		**Type of report**	☐ First ☐ Update ☐ Final	**Treating clinician**	

2) Trial treatment – please give information on most recent cycles

Treatment/Drug name	Brand	Dose	Unit	Frequency	Is this full dose?	Route	Start date (d d m m m y y)	Ongoing?	End date (d d m m m y y)
Rituximab	Mabthera		mg		☐ Y ☐ N	IV	☐☐ ☐☐☐ ☐☐	☐ Y ☐ N	☐☐ ☐☐☐ ☐☐
Cyclophosphamide			mg		☐ Y ☐ N	IV	☐☐ ☐☐☐ ☐☐	☐ Y ☐ N	☐☐ ☐☐☐ ☐☐
Vincristine			mg		☐ Y ☐ N	IV	☐☐ ☐☐☐ ☐☐	☐ Y ☐ N	☐☐ ☐☐☐ ☐☐
Doxorubicin			mg		☐ Y ☐ N	IV	☐☐ ☐☐☐ ☐☐	☐ Y ☐ N	☐☐ ☐☐☐ ☐☐
Methotrexate (IV)			mg		☐ Y ☐ N	IV	☐☐ ☐☐☐ ☐☐	☐ Y ☐ N	☐☐ ☐☐☐ ☐☐
Methotrexate (IT)			mg		☐ Y ☐ N	Intrathecal	☐☐ ☐☐☐ ☐☐	☐ Y ☐ N	☐☐ ☐☐☐ ☐☐
G-CSF	Neulasta		mg		☐ Y ☐ N	SC	☐☐ ☐☐☐ ☐☐	☐ Y ☐ N	☐☐ ☐☐☐ ☐☐
Cytarabine (IT)			mg		☐ Y ☐ N	Intrathecal	☐☐ ☐☐☐ ☐☐	☐ Y ☐ N	☐☐ ☐☐☐ ☐☐
Cytarabine (IV)			mg		☐ Y ☐ N	IV	☐☐ ☐☐☐ ☐☐	☐ Y ☐ N	☐☐ ☐☐☐ ☐☐
Etoposide			mg		☐ Y ☐ N	IV	☐☐ ☐☐☐ ☐☐	☐ Y ☐ N	☐☐ ☐☐☐ ☐☐
Ifosfamide			mg		☐ Y ☐ N	IV	☐☐ ☐☐☐ ☐☐	☐ Y ☐ N	☐☐ ☐☐☐ ☐☐

Most recent cycle number	☐	**Date last drug given prior to SAE:** (d d m m m y y)	☐☐ ☐☐☐ ☐☐	**What was the last drug given prior to SAE?**	

R-CODOX-M/IVAC Trial - Serious Adverse Event (SAE) Reporting Form

3) Event summary description *Give a concise medical description of the event including all relevant symptoms and complete* ***Q4*** *for each SAE (i.e any event that meets the definition of serious).*

RCM ☐☐☐

No. of Q4 (SAEs) included in this report: ☐

If hospitalisation, pls provide: Admission date ☐☐ ☐☐ ☐☐☐☐ (d d m m y y) Discharge date ☐☐ ☐☐ ☐☐☐☐ (d d m m m y y)

R-CODOX-M/IVAC Trial - Serious Adverse Event (SAE) Reporting Form

4) Serious Adverse Event (SAE)	**Patient trial number**	**RCM** ☐☐☐

COMPLETE A SEPARATE Q4 PAGE FOR EACH EVENT THAT MEETS THE DEFINITION OF SERIOUS (Photocopy blank Q4 as required)

Name of event (use CTCAE version 3)	*Grade*	*Date of onset*	*Ongoing?*	*Date resolved*
	☐	☐☐ ☐☐ ☐☐☐☐ (d d m m m y y)	☐ Y ☐ N	☐☐ ☐☐ ☐☐☐☐ (d d m m m y y)

Why was this event serious? *(choose most serious)*	***Outcome of this event***
☐ Resulted in death	☐ Resolved
☐ Life-threatening	☐ Resolved with sequelae
☐ Required new or prolonged hospitalisation	☐ Persisting
☐ Resulted in persistent or significant disability/incapacity	☐ Worsened
☐ Resulted in congenital anomaly/birth defect	☐ Fatal (*please tick PERSISTING unless THIS event caused patient's death)*
☐ Other *(specify)* _____	☐ Not assessable

Was this event expected in view of patient's medical history?	☐ ***Y***	☐ ***N***	If patient has died, please give date of death: ☐☐ ☐☐ ☐☐☐☐ (d d m m m y y)

SAE Assessment *(This section must be completed by a clinician approved to do so by the PI at site and listed for this responsibility on the Site Staff Responsibilities log)*

Trial Drug name	**Causal relationship to event** *(Enter one code only)* 0 = None 1 = Unlikely 2 = Possibly 3 = Probably 4 = Definitely	**Action taken** *(Enter one code only)* 0 = None 1 = *Dose reduction 2 = * Treatment delayed 3 = * Treatment delayed and reduced 4 = Treatment permanently stopped	*** Length of delay / how much dose was reduced by** *(for dose reduction / treatment delay only)*	**OFFICE USE ONLY** **Event expected for the trial drug / regimen?** **1 = Expected 2 = Not Expected**
Rituximab	☐	☐		
Cyclophosphamide	☐	☐		
Vincristine	☐	☐		
Doxorubicin	☐	☐		
Methotrexate (IV)	☐	☐		
Methotrexate (IT)	☐	☐		
G-CSF (Neulasta)	☐	☐		
Cytarabine (IT)	☐	☐		
Cytarabine (IV)	☐	☐		
Etoposide	☐	☐		
Ifosfamide	☐	☐		

R-CODOX-M/IVAC Trial - Serious Adverse Event (SAE) Reporting Form

Is the Serious Adverse Event (SAE) being reported within 1 business day of becoming aware of the event?	☐ *Y* ☐ *N* ***(if No, please give reasons for the delay in reporting below)***

Office use only		
Event No ***RCM -*** ☐☐☐-☐☐☐-☐☐☐-☐☐		
Date SAE was received ☐☐ ☐☐ ☐☐ (d d m m m y y)	*Was the event a SUSAR?* ☐ **Y* ☐ *N*	*Date SAE entered on database* ☐☐ ☐☐ ☐☐ (d d m m m y y)
**Date reported to MHRA* ☐☐ ☐☐ ☐☐ (d d m m m y y)	**Date reported to theREC* ☐☐ ☐☐ ☐☐ (d d m m m y y)	**Reported to Principal Investigators* ☐ *Y*
Form checked by	*Date checked by central reviewer* ☐☐ ☐☐ ☐☐ (d d m m m y y)	*Date checked by clinical reviewer* ☐☐ ☐☐ ☐☐ (d d m m m y y)
	(signature)	*(signature)*

R-CODOX-M/IVAC Trial - Serious Adverse Event (SAE) Reporting Form

5) Management of SAE

Patient trial number	RCM ☐☐☐

Treatment for SAE ☐ *Y* ☐ *N* *(If yes, please specify below)*

Drug Name	Brand	Indication	Dose	Units	Frequency	Route	Start date (d d m m m y y)	Ongoing?	End date (d d m m m y y)
							☐☐☐☐☐☐☐☐	☐ Y ☐ N	☐☐☐☐☐☐☐☐
							☐☐☐☐☐☐☐☐	☐ Y ☐ N	☐☐☐☐☐☐☐☐
							☐☐☐☐☐☐☐☐	☐ Y ☐ N	☐☐☐☐☐☐☐☐
							☐☐☐☐☐☐☐☐	☐ Y ☐ N	☐☐☐☐☐☐☐☐
							☐☐☐☐☐☐☐☐	☐ Y ☐ N	☐☐☐☐☐☐☐☐

Concomitant medications? ☐ *Y* ☐ *N* *(Only include drugs given within the last **30 days** excluding treatment for SAEs. Continue on separate sheet if necessary)* ***Continued on a separate sheet*** ☐ *Y* ☐ *N*

Drug Name	Brand	Indication	Dose	Units	Frequency	Route	Start date (d d m m m y y)	Ongoing?	End date (d d m m m y y)
							☐☐☐☐☐☐☐☐	☐ Y ☐ N	☐☐☐☐☐☐☐☐
							☐☐☐☐☐☐☐☐	☐ Y ☐ N	☐☐☐☐☐☐☐☐
							☐☐☐☐☐☐☐☐	☐ Y ☐ N	☐☐☐☐☐☐☐☐
							☐☐☐☐☐☐☐☐	☐ Y ☐ N	☐☐☐☐☐☐☐☐
							☐☐☐☐☐☐☐☐	☐ Y ☐ N	☐☐☐☐☐☐☐☐

Any relevant tests / laboratory data? ☐ *Y* ☐ *N* *(If yes, please specify below)*

Test date (d d m m m y y)	Test	Results	(pending)
☐☐☐☐☐☐☐			☐ *Y*
☐☐☐☐☐☐☐			☐ *Y*
☐☐☐☐☐☐☐			☐ *Y*
☐☐☐☐☐☐☐			☐ *Y*

Any relevant medical history / concurrent conditions? ☐ *Y* ☐ *N* *(If yes, please specify below and continue on separate sheet if necessary)*

Signature *(Form must be signed by a clinician approved by the PI at site and listed for this responsibility on the Site Staff Delegation log)*		***Print name***		***Date of report***	☐☐☐☐☐☐☐☐ *d d m m m y y*

R-CODOX-M/IVAC Trial - Serious Adverse Event (SAE) Reporting Form

Concomitant medications *(continued)* *(Only include drugs given within the last **30 days** excluding treatment for SAEs. Continued from Q5 previous sheet)*	**Patient trial number** **RCM**

Drug Name	**Brand**	**Indication**	**Dose**	**Units**	**Frequency**	**Route**	**Start date** d d m m m y y	**Ongoing?**	**End date** d d m m m y y
								Y N	
								Y N	
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R-CODOX-M/IVAC Trial - Serious Adverse Event (SAE) Reporting Form

Additional Information *(use for event summary description and relevant medical history/concurrent conditions as required)*	**Patient trial number**	**RCM** ☐☐☐