RCM GUIDELINES FOR REPORTING SERIOUS ADVERSE EVENTS

- Please follow the field by field instructions below when completing your SAE forms.
- **ALL FIELDS MUST BE COMPLETED** on the original form (either at the first submission or when the original form is amended as an update or final form).
- Please initial and date all amendments to the form.
- **If any data is unobtainable, please put NK (Not Known). All empty fields will be queried.**
- Please complete the page number and total number of pages on each page of the form.
- SAE forms should be faxed to CTC on 0207 679 9861 (**within 1 business day of site becoming aware of SAE for the original submission**).
- CTC will follow up all SAEs to resolution/death and until all queries are answered.
- If you have any queries about completing the form, please contact the R-CODOX-MIVAC Trial Coordinator at CTC (r-codox-mivac@ctc.ucl.ac.uk, 0207 679 9538).

1) Patient details

Field	Comment
Patient initials	
Patient trial #	RCMxxx
Date of birth	dd-mmm-yy
Gender	Please tick
Height	In cm
Weight	In Kg
Site Name	
Treating clinician	
Type of Report	**First** – initial notice to trials centre **Update** – any further follow-up information for the trials centre; i.e. progression of symptoms **Final** – the event is resolved/fatal **N.B** updated information should be completed/amended on the original form and all amendments should be initialled and dated

2) Trial treatment ***(please give information for the first cycle(s)until treatment completed for each drug given)***

Field	Comment
Brand	Brand of IMP (please contact pharmacy for information)
Dose	dose in mgs
Unit	mgs
Frequency	Frequency of dose
Is this full dose?	Please tick Y or N
Start date	Treatment drugs: The date of the first administration of the IMP on the trial
Ongoing	Treatment should be considered ongoing until patient has completed all cycles of treatment or has been withdrawn from trial treatment. The end dates of treatment should only be provided if patient has completed the 3rd cycle of CODOX and/or the 4th cycle of IVAC, or if treatment with IMP(s) has been permanently discontinued. If treatment with a particular IMP has been completed or permanently stopped then 'Ongoing?' should be marked 'N' and an end date should be provided.

End date	This must be left blank if 'Y' is marked for 'Ongoing' BUT must be completed if 'N' has been marked for 'Ongoing'
Most recent cycle number	Number of chemotherapy cycles completed prior to SAE
Date of last drug given prior to SAE	Date of last IMP given prior to SAE occurring. If more than one IMP drug is given at the time of the SAE, please give the date of the final day of last treatment administered.
What was the last drug given prior to SAE?	The name of the last IMP given prior to SAE

3) Event summary description

Event summary description	Give a concise medical description of the event including all relevant symptoms and complete 1 x Q4 for each SAE (i.e any event that meets the definition of serious). Continue on an Additional Information sheet if necessary.
No. of Q4 (SAEs) included in this report	Indicate the number of SAEs (and corresponding Q4s) included in the report.
If hospitalisation provide:	Date of admission
	Date of discharge (if/when known)
Page___of___	Please complete the page number (1) and the total number of pages

4) Serious Adverse Event (SAE) - Complete a separate Q4 page for each event that meets the definition of serious

Patient trial #	Please put the Patient trial # (RCMXXX) at the top of all Q4 pages
Name of event	CTCAE version 3 short names **must** be used. Please ask the Haematology Trials Group if you would like a copy.
Grade	Please use CTCAE v3.0 to identify grade of event. (1 = mild, 2 = moderate, 3 = severe, 4 = life-threatening, 5 = fatal)
Date of onset	Please indicate the date of onset of the SAE
Ongoing?	If the SAE is currently ongoing tick 'Y' to 'Ongoing?' and do not enter an end date. If the event is no longer ongoing tick 'N' to 'Ongoing?' you must then enter and end date.
Date resolved	This must be left blank if 'Y' is marked for 'Ongoing' BUT must be completed if 'N' has been marked for 'Ongoing'
Why was this event serious	The definition of seriousness is in section 12 of the R-CODOX-MIVAC protocol. Please only tick one – the most serious.
Outcome	An outcome of fatal should only be recorded for an event being reported if that event caused the patient's death. Any other event which was ongoing at the time the patient died should have the outcome left as 'persisting'.
Was this event expected in view of patient's medical history?	Please tick Yes or No
If patient has died, please give date of death	
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 Delegation log

Causal relationship to event	For each trial treatment enter one code only from those provided to indicate whether it was related to or caused the event (please see section 12 of the R-CODOX-MIVAC protocol).
Action taken	Enter one code only from those provided for each trial treatment to indicate the action taken.
*Length of delay/how much dose was reduced by	Please give details only for those marked 1/2/3 in action taken (dose reduction/treatment delayed/treatment delayed and reduced)
Is the SAE being reported within 1 business day of becoming aware of the event?	Please indicate here if the SAE is being to the CTC within the specified time.
Office use only	Please leave blank
Page___of___	Complete the appropriate page number and the total number of pages

5) Management of SAE

Patient trial #	Please put the Patient trial # (RCMXXX) at the top of the page
Treatment for SAE	Please tick Yes or No If Y, all details must be provided. If N, all details should be left blank.
If Y: for only those treatments used to address the SAE, indicate:	Drug Name, Brand, Indication, Dose, Units, Frequency & Route Treatment such as physiotherapy, surgery, referral to other specialists / teams etc can be listed under 'any other relevant information'
Start date	Start date of each treatment
Ongoing?	If the treatment is currently ongoing and will continue after event is resolved tick 'Y' to 'Ongoing?' and do not enter an end date. If the patient has completed treatment or treatment is to be permanently discontinued tick 'N' to 'Ongoing?' and enter date of last treatment.
End date	This must be left blank if 'Y' is marked for 'Ongoing' BUT must be completed if 'N' has been marked for 'Ongoing'
Concomitant medications	Please tick Yes or No If Y, all details must be provided. If N, all details should be left blank. Please record all concomitant medications taken in the last 30 days.
Continued on a separate sheet	Tick Y or N as required.
If Y: concomitant medications taken in the last 30 days (excluding treatment for SAEs):	Drug Name, Brand, Indication, Dose, Units, Frequency & Route Only include drugs given within the last 30 days excluding treatment for SAEs, which must be included in the section above.
Start date	Start date of each treatment
Ongoing?	If the treatment is currently ongoing and will continue after event is resolved tick 'Y' to 'Ongoing?' and do not enter an end date. If the patient has completed treatment or treatment is to be permanently discontinued tick 'N' to 'Ongoing?' and enter date of last treatment.
End date	This must be left blank if 'Y' is marked for 'Ongoing' BUT must be completed if 'N' has been marked for 'Ongoing'
Any relevant tests/laboratory data?	Please tick Yes or No If Y, details must be provided. If N, all details should be left blank.
If Y: Test information	Provide Test date, type of test & results (tick Y for pending if required)
Any relevant medical history/concurrent conditions	Please tick Yes or No If Y, details must be provided. If N, all details should be left blank.

If Y:	Was there anything in the patient's history that might be relevant to the event? Any other information that might be relevant to the event, which has not been stated elsewhere on SAE form?
Signature	The form must be signed by a clinician approved to do so by the PI at site and listed for this responsibility on the Site Staff Delegation log.
Date of report	Date signed. The first report should be completed and faxed to the Haematology Trials Group at the Cancer Trials Centre within 24 hours of the date of site becoming aware of event and updates should be sent with anonymised copies of investigation results where applicable.
Page___of___	Complete the appropriate page number and the total number of pages

Additional pages:

Patient trial #	Please put the Patient trial # (RCMXXX) at the top of each page
Concomitant Medications	As above
Additional Information	Use for event summary description and relevant medical history/concurrent conditions as required
Page___of___	Complete the appropriate page number and the total number of pages