UKALL14

SAE Form Guidance Notes

For use with SAE report form v4.0 21 Jan 16

General points	
Check the SAE is reportable	- Before you start completing the SAE report, please check that the SAE is reportable. - The UKALL14 protocol contains details of SAE reporting windows and exemptions from SAE reporting. - If you are unsure whether event needs to be reported as an SAE, please email or call the UKALL14 CTC team for advice.
Cover sheet	- Please include a fax cover sheet and provide contact details in case of any queries about the report. - The person submitting the SAE report should be listed on the site delegation log and assigned the duty of SAE reporting.
Trial number	- Complete the patient's trial number on all pages.
Page number	- Complete the page number (x of y) on all pages. - If further pages are added, please remember to update the page numbering.
Test results	- Test results should only be provided if they are relevant to the SAE event(s). - Results should be transcribed onto the report wherever possible; please avoid sending print-outs from hospital reporting systems unless absolutely necessary. If sending reports: • Ensure that all patient identifiers are obscured – refer to the patient by initials and trial number only • Highlight the relevant results
Making changes to the SAE report	- Any amendments or updates to the report should be made on the initial report. - Initial and date all changes, and strike through information that is incorrect or superseded - See the CRF completion guidelines for further information about good practise in form completion
Acknowledgement	- UCL CTC will acknowledge receipt of SAEs by email within 1 business day of receipt of the SAE. - If you do not receive an acknowledgement within 1 day of sending in an SAE report, please contact the CTC.
Shared care / transfer of care	If the patient's care is transferred to another site before SAE resolution, the reporting site remains responsible for updates to the SAE. The local study team at the new site should facilitate this by providing updates on the patient's condition and additional data (e.g. test results) to the reporting site.
Finalisation of reports	The site that submits the SAE report is responsible for providing updates until UCL CTC confirms the report is final and there are no further queries.

Page 1 – patient details

UKALL14
Serious Adverse Event (SAE) Report

Please complete all sections with details of any SAE occurring during the reporting windows outlined in protocol section 12.2.2 (and outside these timeframes if the event is felt to be a long term side effect). For guidance on which events to report please see trial protocol.
Please fax this form to the UKALL14 Co-ordinator at the CR UK & UCL Cancer Trials Centre on 020 7679 9861 within 24 hours of becoming aware of the event.

Trial details			
Trial title	A randomised trial for adults with newly diagnosed acute lymphoblastic leukaemia		
Trial acronym	UKALL14	EudraCT number	2009-012717-22

Patient details			
Patient initials	☐☐☐	Patient trial number	14 - ☐ - ☐☐☐
Sex	☐ Male ☐ Female	Date of birth	☐☐ ☐☐ ☐☐ (d d m m y y)
Hospital		Treating Clinician	
Type of report	☐ First ☐ Update ☐ Final	Height ☐☐☐ cm	Weight ☐☐☐.☐ kg
Trial arm	B Randomisation: ☐ 0=N/A 1=B1 2=B2 T Randomisation: ☐ 0=N/A 1=T1 2=T2 P Randomisation: ☐ 0=N/A 1=P1 2=P2		

Field	How to complete
Hospital	The trial site responsible for the patient's care at the time of SAE onset.
Treating Clinician	The clinician responsible for the patient's care. NB: Another investigator can assess causality and sign off the report.
Type of report	Tick "first" for initial reports. For follow-up reports, cross out "first" and tick "update" or "final"
Weight & Height	Enter most recent weight and height prior to onset of SAE. If not measured recently, enter ND.
Trial arm	Enter the relevant code for each of the three randomisations (B, T and P). Enter 0 if not applicable

Page 1 – treatment details

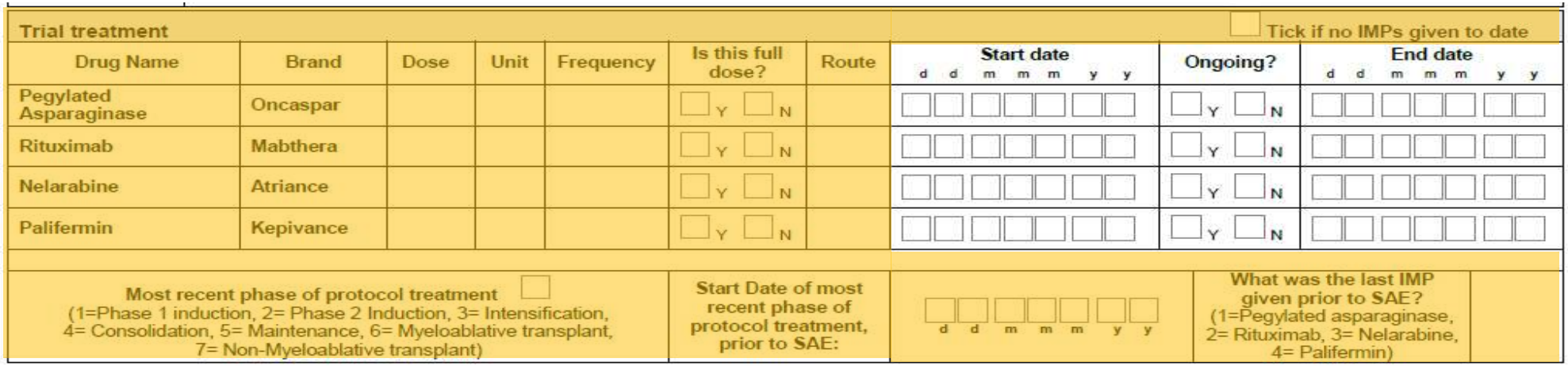
Trial treatment ☐ Tick if no IMPs given to date

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)
Pegylated Asparaginase	Oncaspar				☐ Y ☐ N		☐☐☐☐☐☐☐☐	☐ Y ☐ N	☐☐☐☐☐☐☐☐
Rituximab	Mabthera				☐ Y ☐ N		☐☐☐☐☐☐☐☐	☐ Y ☐ N	☐☐☐☐☐☐☐☐
Nelarabine	Atriance				☐ Y ☐ N		☐☐☐☐☐☐☐☐	☐ Y ☐ N	☐☐☐☐☐☐☐☐
Palifermin	Kepivance				☐ Y ☐ N		☐☐☐☐☐☐☐☐	☐ Y ☐ N	☐☐☐☐☐☐☐☐

Most recent phase of protocol treatment ☐ (1=Phase 1 induction, 2= Phase 2 Induction, 3= Intensification, 4= Consolidation, 5= Maintenance, 6= Myeloablative transplant, 7= Non-Myeloablative transplant)	Start Date of most recent phase of protocol treatment, prior to SAE:	☐☐☐☐☐☐☐☐ (d d m m m y y)	What was the last IMP given prior to SAE? (1=Pegylated asparaginase, 2= Rituximab, 3= Nelarabine, 4= Palifermin)	

Field	How to complete
Trial treatment details	- Complete for every IMP the patient has received – even if not in the most recent phase of treatment. - If a patient has not received an IMP they were randomised to receive, explain why in the event summary. - If the patient has not received any IMPs (e.g. not due yet, or Philadelphia positive patient on arm B1), tick the "no IMPs given" box .
Dose & units	The actual dose given to the patient *e.g. if the patient was dosed at 1000 IU/m^2 and the patient has a BSA of 2m^2, the dose entered would be 2000, and units would be IU* - If an infusion was interrupted and not completed, enter the actual dose that was delivered, not the planned dose
Frequency	The days of the treatment phase on which the drug was given
Is this full dose?	- Tick yes if the patient received the correct protocol dose - Tick no if patient was given a reduced dose of the IMP, and provide reason in the event summary - Tick no if the patient received an overdose, and provide further information in the event summary
Route	Follow standard conventions: PO/oral = oral, IV = intravenous, SC = subcutaneous etc.

Page 1 – treatment details - continued



Trial treatment — ☐ Tick if no IMPs given to date

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)
Pegylated Asparaginase	Oncaspar				☐ Y ☐ N		☐☐☐☐☐☐☐☐	☐ Y ☐ N	☐☐☐☐☐☐☐☐
Rituximab	Mabthera				☐ Y ☐ N		☐☐☐☐☐☐☐☐	☐ Y ☐ N	☐☐☐☐☐☐☐☐
Nelarabine	Atriance				☐ Y ☐ N		☐☐☐☐☐☐☐☐	☐ Y ☐ N	☐☐☐☐☐☐☐☐
Palifermin	Kepivance				☐ Y ☐ N		☐☐☐☐☐☐☐☐	☐ Y ☐ N	☐☐☐☐☐☐☐☐

Most recent phase of protocol treatment ☐
(1=Phase 1 induction, 2= Phase 2 Induction, 3= Intensification, 4= Consolidation, 5= Maintenance, 6= Myeloablative transplant, 7= Non-Myeloablative transplant)

Start Date of most recent phase of protocol treatment, prior to SAE: ☐☐☐☐☐☐☐☐ (d d m m m y y)

What was the last IMP given prior to SAE? (1=Pegylated asparaginase, 2= Rituximab, 3= Nelarabine, 4= Palifermin)

Field	How to complete
Start date	The date of the first dose given during the most recent phase in which the drug was administered prior to SAE onset. *e.g. if a patient had received pegylated asparaginase during induction and intensification, and an SAE occurred during intensification, the date of the day 2 intensification dose would be entered.*
Ongoing?	- This should accurately represent the situation at the time of report submission. - Update as necessary on follow-up reports. - Tick 'no' if IMP treatment had been completed for the treatment phase - Tick 'no' if drug was withdrawn due to SAE onset - Tick 'yes' if the patient was planned to receive / did receive more of the IMP after SAE onset. - Amend to 'no' if a decision was taken to withdraw the IMP after SAE onset
End date	If the patient did not receive any more of the IMP after SAE onset, enter the date of the last dose given.

Page 1 – treatment details - continued

Trial treatment ☐ Tick if no IMPs given to date

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)
Pegylated Asparaginase	Oncaspar				☐ Y ☐ N		☐☐☐☐☐☐☐	☐ Y ☐ N	☐☐☐☐☐☐☐
Rituximab	Mabthera				☐ Y ☐ N		☐☐☐☐☐☐☐	☐ Y ☐ N	☐☐☐☐☐☐☐
Nelarabine	Atriance				☐ Y ☐ N		☐☐☐☐☐☐☐	☐ Y ☐ N	☐☐☐☐☐☐☐
Palifermin	Kepivance				☐ Y ☐ N		☐☐☐☐☐☐☐	☐ Y ☐ N	☐☐☐☐☐☐☐

Most recent phase of protocol treatment ☐ (1=Phase 1 induction, 2= Phase 2 Induction, 3= Intensification, 4= Consolidation, 5= Maintenance, 6= Myeloablative transplant, 7= Non-Myeloablative transplant)	Start Date of most recent phase of protocol treatment, prior to SAE:	☐☐☐☐☐☐☐ (d d m m m y y)	What was the last IMP given prior to SAE? (1=Pegylated asparaginase, 2= Rituximab, 3= Nelarabine, 4= Palifermin)	

Field	How to complete
Most recent phase of protocol treatment	- This field must be completed even if patients have never received an IMP. - Enter the code for the most recent treatment phase started **at the time of SAE onset**. - If a patient is undergoing consolidation, please state which cycle they were on at time of SAE onset in the event summary.
Start date of most recent phase	- This field must be completed even if patients have never received an IMP. - Enter the date of day 1 of the treatment phase, or the first day of transplant conditioning - For transplant patients, please also state the date of transplant day 0 in the event summary.
What was the last IMP given prior to SAE?	Enter only one code, even if the patient has received more than one IMP during the most recent phase of treatment. *e.g. if a patient received pegylated asparaginase 5 days before SAE onset and rituximab 1 day before, you would enter "2" (Rituximab)*

Page 2 - event summary description

UKALL14
Serious Adverse Event (SAE) Report

Patient trial number: 14- ☐ - ☐☐☐

Event summary description	*(Give a concise medical description of the event including all relevant symptoms and complete page overleaf for each event that meets the definition of serious)*	Continued on a separate sheet:	☐ Y	☐ N

What to include in the event summary

The event summary should provide a clear account of the event from onset through to resolution.

- The event summary should expand on the information elsewhere in the report – its primary purpose is to allow the team at UCL CTC to verify that the information on the event page(s) is correct.
- It can also be used to expand on information elsewhere in the SAE report (e.g. treatment reductions/overdoses, treatment delays).
- The event summary should be updated with additional information as it becomes available.
- Before you submit update reports, check the narrative for consistency. If new information renders previous content incorrect, the superseded information should be crossed out, initialled and dated.

Verification of event onset date	- List the presenting signs/symptoms, and when they were first noted. - Confirm the date on which the event became serious and why.
Verification of event term	Ensure that enough information is given to demonstrate that the event term is appropriate, e.g. if the event term is given as "lung infection" ensure that the event summary describes the symptoms and investigations that led to the diagnosis
Verification of seriousness criteria	- Ensure enough information is given to demonstrate that the seriousness criterion selected on the event page is correct. For example: - If hospitalisation was prolonged, include planned discharge date. - If life-threatening, provide evidence of ITU admission or equivalent seriousness. - If deemed "medically significant", provide details of why this was felt to be significant (e.g. local investigator's decision, AE of special interest).

Page 2 - event summary description - continued

UKALL14
Serious Adverse Event (SAE) Report

Patient trial number: 14-☐-☐☐☐

Event summary description	(Give a concise medical description of the event including all relevant symptoms and complete page overleaf for each event that meets the definition of serious)	Continued on a separate sheet:	☐ Y	☐ N

What to include in the event summary	
Verification of grade	- Refer to tests performed – results should be listed in the 'relevant tests/laboratory data' section on page 5 - If the definition of grade in CTCAE v4.03 is based on clinical features and/or management, ensure the event summary includes enough information to demonstrate that the definition was met.
Verification of actions with regard to trial treatment	- Tell us how the event impacted on the patient's trial treatment (IMP and non-IMP), for example dose delays, dose reductions or withdrawal of drugs. - If an IMP is withdrawn because of an SAE, make sure the "action taken" on the event page and the IMP treatment information on page 1 are updated accordingly to ensure consistency of information.
Verification of treatment for SAE	Tell us how the event was managed – make sure that any drugs that were given to treat the SAE are also detailed in the "treatment for SAE" section on page 5. *For example, if the narrative says "patient was treated with IV antibiotics" we would expect to see at least one IV antibiotic drug listed on page 5.*
Verification of outcome & end date	Tell us how and when the event was resolved – for example: - If the patient dies, provide the date and certified cause of death - If resolved, how was this determined? (e.g. resolution of symptoms, test results returned to baseline, treatment stopped etc.) - If resolved with sequelae, what were the long term sequelae? (e.g. long term prophylactic treatment needed)

Date site became aware of SAE: d d m m m y y	If aware more than 24 hours before submission, reason for late reporting:
No. of events included in this report: ☐	If hospitalisation, please provide: Admission date d d m m m y y Discharge date d d m m m y y

SAE Report Template v4 05.10.07 *[modified for UKALL14 on 21Jan2016, v4.0]*

Page ___ of ___

Field	How to complete
Date site became aware of SAE	- Enter the first date on which the local study team became aware of the SAE. - If there is a delay in the site becoming aware (i.e. a large time elapsed between event onset and awareness date), please explain why in the event summary. You may also be asked to complete an incident report.
Reason for late reporting	- Provide a brief explanation if the team became aware of the SAE more than 24 hours before reporting. - If reported within 24 hours of becoming aware, enter N/A.
Number of events:	- Ensure this number is consistent with the number of event pages completed. - Amend in update reports if events are added or cancelled.

Admission / discharge date	- Only need to be completed if the patient was hospitalised or hospitalisation was prolonged due to the SAE.
	- If the patient was already an inpatient at the time of onset:
	  - Enter the initial hospitalisation date.
	  - Make a note in the event summary explaining that patient was already hospitalised.
	- If the discharge date and resolution date are not the same:
	  - Check whether there is a further event prolonging admission, and if so, add another event page
	  - Add an explanation to the event summary

Page 3 - Event page – **complete and even page for each event meeting the criteria of serious**

UCL

UKALL14
Serious Adverse Event (SAE) Report

CANCER RESEARCH UK

Patient trial number: 14- ☐ - ☐☐☐

Serious Adverse Event (SAE)				
COMPLETE A SEPARATE PAGE FOR EACH EVENT THAT MEETS THE DEFINITION OF SERIOUS (photocopy this page as necessary for each event)				
Name of event (use CTCAE version 4.0)	**Grade**	Date of onset	Ongoing?	Date resolved
	☐	d d m m m y y	☐ Y ☐ N	d d m m m y y

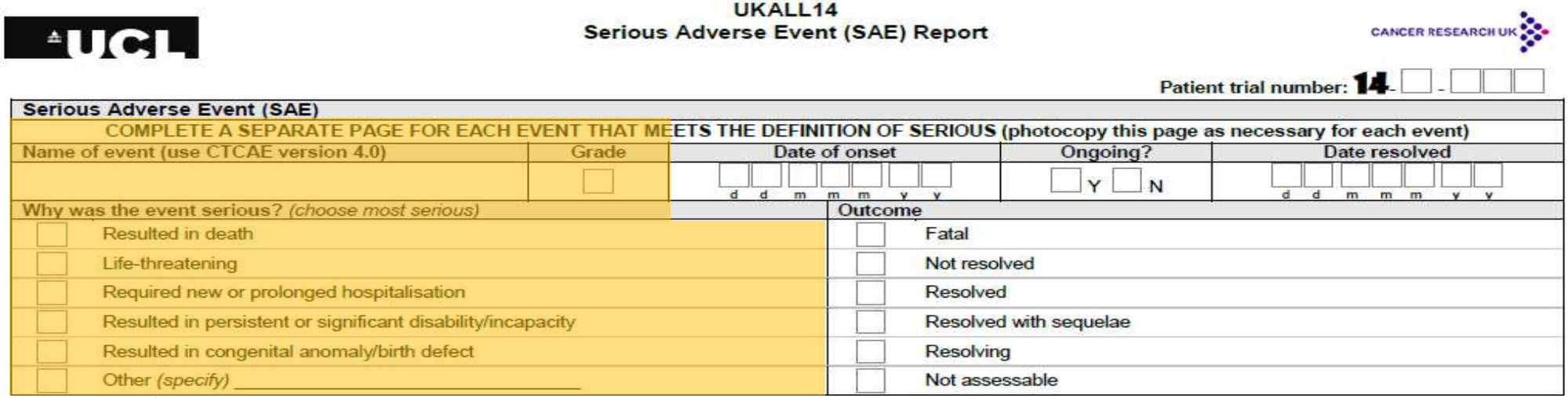
Why was the event serious? *(choose most serious)*		**Outcome**	
☐	Resulted in death	☐	Fatal
☐	Life-threatening	☐	Not resolved
☐	Required new or prolonged hospitalisation	☐	Resolved
☐	Resulted in persistent or significant disability/incapacity	☐	Resolved with sequelae
☐	Resulted in congenital anomaly/birth defect	☐	Resolving
☐	Other *(specify)* _____	☐	Not assessable

Field	**How to complete**

Name of event	- Select a term from CTCAE v4.03.
	- Only use "other" if there is no appropriate event term. Enter as *[system organ class] other: [event term]*
	- Please note that for UKALL14 we ask sites to follow the following conventions:
	  - For infections with no clear source (e.g. positive blood cultures only): *Infections & infestations other: unknown source*
	  - For line infections: *Device related infection: Hickman/PICC line*

Grade	- Should be consistent with description in CTCAE v4.03, and verifiable via test results/information in the event summary - Should reflect the grade at maximum severity - Amend in update reports if the event worsens
Why was the event serious?	- Should accurately reflect the situation at the time of reporting - Amend in update reports if the event worsens - Ensure consistency with grade (e.g. if event is life threatening, grade should be 4; if event is fatal, grade should be 5) - Only tick "life threatening" if an event is immediately life threatening (typically requiring ITU admission) - Only the direct cause of death should be classified as resulting in death. CTC will check for consistency between the SAE report and the death CRF.

Page 3 - Event page – **complete and even page for each event meeting the criteria of serious**



UKALL14
Serious Adverse Event (SAE) Report

CANCER RESEARCH UK

Patient trial number: 14- ☐ - ☐☐☐

Serious Adverse Event (SAE)

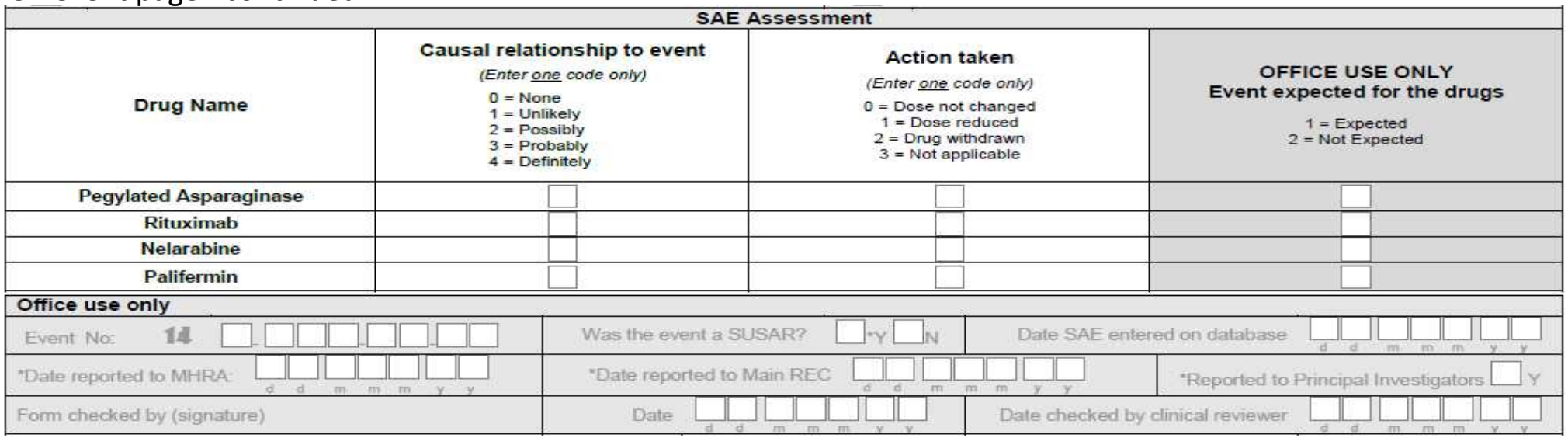
COMPLETE A SEPARATE PAGE FOR EACH EVENT THAT MEETS THE DEFINITION OF SERIOUS (photocopy this page as necessary for each event)

Name of event (use CTCAE version 4.0)	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 the event serious? *(choose most serious)*	Outcome
☐ Resulted in death	☐ Fatal
☐ Life-threatening	☐ Not resolved
☐ Required new or prolonged hospitalisation	☐ Resolved
☐ Resulted in persistent or significant disability/incapacity	☐ Resolved with sequelae
☐ Resulted in congenital anomaly/birth defect	☐ Resolving
☐ Other *(specify)* _____	☐ Not assessable

Field	How to complete
Date of onset	- Typically this will be the date the event became serious. - For events that prolong hospitalisation, onset date should be the date on which the event was diagnosed, or the grade requiring prolongation was reached. - Ensure a rationale is given for the date of onset in the event summary description
Ongoing/date resolved	- Should accurately reflect situation at time of submitting report. - Amend as necessary in update reports - A resolution date should be entered if 'ongoing' is answered 'no'.
Outcome	- Should accurately reflect the situation at the time of reporting - Amend in update reports as necessary until the final outcome of the SAE is known - Ensure consistency with ongoing/date resolved (if event is 'resolved'/'resolved with sequelae', the ongoing field must be answered 'no' and a resolution date must be provided) - Only the direct cause of death should be classified as having a fatal outcome. Other events that were ongoing at the time of death should be classed as 'not resolved'. The date of death should be documented in the event summary.

Page 3 - event page - continued



SAE Assessment

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 = Dose not changed 1 = Dose reduced 2 = Drug withdrawn 3 = Not applicable	OFFICE USE ONLY Event expected for the drugs 1 = Expected 2 = Not Expected
Pegylated Asparaginase	☐	☐	☐
Rituximab	☐	☐	☐
Nelarabine	☐	☐	☐
Palifermin	☐	☐	☐

Office use only

Event No: 14 ☐☐☐☐☐☐☐☐	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 Main REC ☐☐ ☐☐ ☐☐☐☐ (d d m m m y y)	*Reported to Principal Investigators ☐ Y
Form checked by (signature)	Date ☐☐ ☐☐ ☐☐☐☐ (d d m m m y y)	Date checked by clinical reviewer ☐☐ ☐☐ ☐☐☐☐ (d d m m m y y)

Field	How to complete
Causal relationship to event	- Assessment must be performed by the PI or a coinvestigator. They should also sign the report. - The assessor must be delegated duty "K" on the delegation log (send updated log to UCL CTC with the report if necessary) - Assessment must be performed for every IMP the patient has received - If the investigator changes the causality assessment, please explain the rationale in the event summary - Causality assessment must be reassessed if the event term changes. If there is no change, the investigator should initial and date next to the entry to confirm it has been reviewed
Action taken	- Should reflect the situation at the time of submitting the report - Amend in update reports if necessary – give rationale for changes in the event summary - If action not known at the time of reporting, write NK and update when known - If a dose is delayed, this should be mentioned in the event summary. The 'action taken' code should reflect whether the patient was dose-reduced on restarting the drug. Enter "1" if dose reduced or "0" if not dose reduced - If treatment with an IMP has been completed, action taken should be "3" (N/A) - If a patient is never intended to receive a drug (e.g. patients on B1 will not receive rituximab or nelarabine), enter "3" (N/A)

Page 4 – Concomitant medications

UKALL14
Serious Adverse Event (SAE) Report

Patient trial number: 14- ☐ - ☐☐☐

Concomitant Medications

- *List non-IMP drugs given within the 30 days prior to SAE onset, including non-IMP treatment for ALL.*
- *Do not list IMP treatments or treatment for SAE, as these are recorded elsewhere on the form.*
- *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	

What counts as a concomitant medication?

Concomitant medications (or 'con meds') are non-IMP drugs given within the 30 days prior to SAE onset.
We collect them to see if there are other drugs that may have contributed to an SAE.
We also use them to check with compliance to the protocol with regard to correct administration of backbone chemotherapy and supportive care.

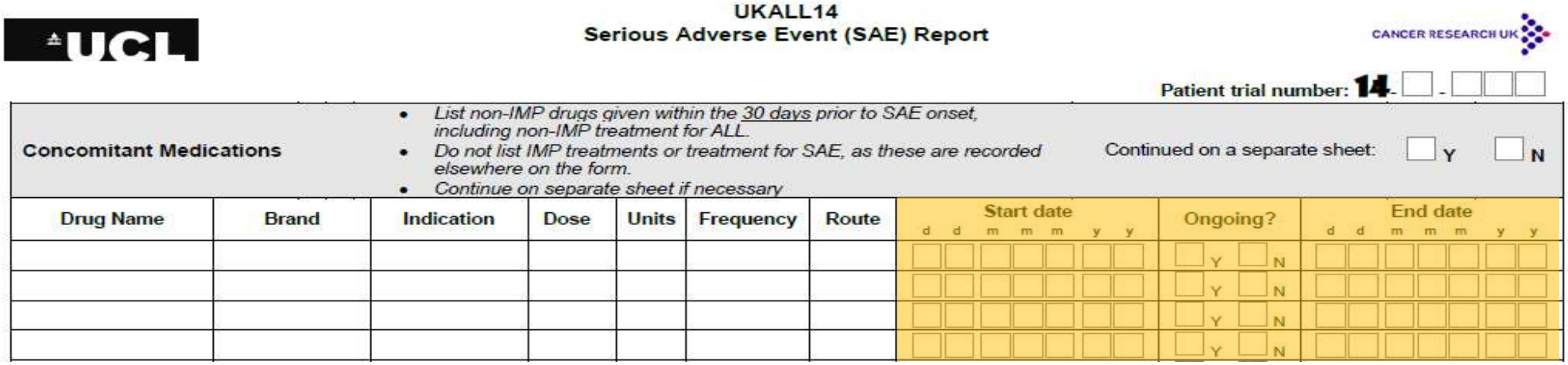
Con meds include the following:

- ✓ Any non-IMP treatment given for ALL in the 30 days prior to SAE onset (e.g. 'backbone' chemotherapy and steroids, transplant conditioning, etc.) – remember to check whether any drugs from the previous treatment phase fall into the 30 day timeframe
- ✓ Any supportive care drugs given within the 30 days prior to onset
- ✓ Treatments given to treat existing conditions and AEs within the 30 days prior to onset

The following are not classed as con meds:

- × IMPs (rituximab, pegylated asparaginase, nelarabine, palifermin) – details for these drugs should be listed on page 1
- × Treatments for the SAE – these should be listed in the 'Treatment for SAE' section on page 5
- × Non-drug treatments – if any non-drug treatments were given that may have contributed to the event, please add details to the event summary
- × Drugs that were stopped more than 30 days prior to SAE onset

Page 4 – Concomitant medications



UKALL14
Serious Adverse Event (SAE) Report

Patient trial number: 14- ☐ - ☐☐☐

Concomitant Medications

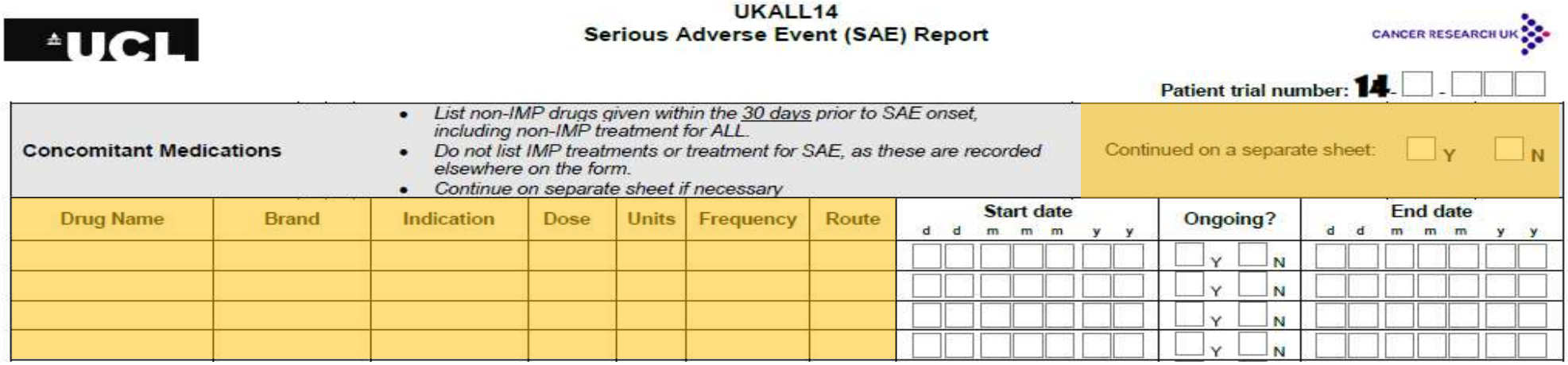
- *List non-IMP drugs given within the 30 days prior to SAE onset, including non-IMP treatment for ALL.*
- *Do not list IMP treatments or treatment for SAE, as these are recorded elsewhere on the form.*
- *Continue on separate sheet if necessary*

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	

Field	How to complete
Continued on a separate sheet?	Tick yes or no. If you continue to a separate sheet please use the same format (an extension page is provided).
Drug name	Enter the generic name.
Brand	Either the brand name or the manufacturer. If not known, enter NK.
Indication	The reason why the drug was given. This should be either prophylaxis or the symptom/condition for which the drug was given.
Dose/units	Enter for all treatments, do not leave fields blank. If not applicable, enter N/A.
Frequency	Follow standard conventions: OD = once a day, BD = twice a day, TDS = 3 times a day, QDS = 4 times a day, PRN = as needed, stat = once only.
Route	Follow standard conventions: PO/oral = oral, IV = intravenous, SC = subcutaneous etc.

Page 4 – Concomitant medications - continued



UKALL14
Serious Adverse Event (SAE) Report

CANCER RESEARCH UK

Patient trial number: 14- ☐ - ☐☐☐

Concomitant Medications

- *List non-IMP drugs given within the 30 days prior to SAE onset, including non-IMP treatment for ALL.*
- *Do not list IMP treatments or treatment for SAE, as these are recorded elsewhere on the form.*
- *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	☐☐☐☐☐☐☐☐

Field	How to complete
Start date	- The first date on which the treatment was given at this dose. - If given on same day as event onset but before the onset of the event, clarify in event summary.
Ongoing / end date	- Should accurately reflect situation at time of submitting the report. - An end date should be provided if 'ongoing' is answered 'no'. - If con meds are stopped while the SAE is ongoing, amend 'ongoing' to 'no' and provide the end date

UKALL14
Serious Adverse Event (SAE) Report

Patient trial number: 14- ☐ - ☐☐☐

Did the patient receive any treatment for this SAE? ☐ Y ☐ N *(If yes, please specify below)* *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	

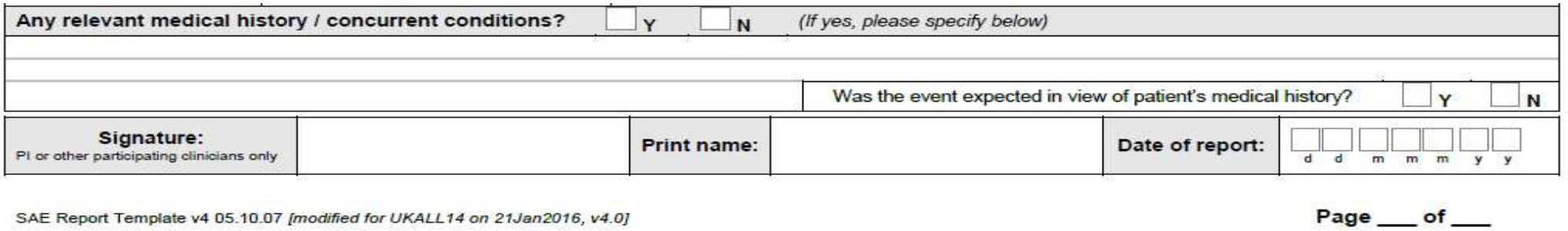
Field	How to complete
Did the patient receive any treatment?	Tick yes or no, and provide details as necessary.
Continued on a separate sheet?	Tick yes or no. If you continue to a separate sheet, follow the same structure as the 'treatment for SAE' table.
Drug name	Enter the generic name
Brand	Either the brand name or the manufacturer. If not known, enter NK
Indication	The reason why the drug was given. This should be the symptom/condition for which the drug was given
Dose/units	Enter for all treatments, do not leave fields blank. If not applicable, enter N/A
Frequency	Follow standard conventions: OD = once a day, BD = twice a day, TDS = 3 times a day, QDS = 4 times a day, PRN = as needed, stat = once only.
Route	Follow standard conventions: PO/oral = oral, IV = intravenous, SC = subcutaneous etc.
Start date	The first date on which the treatment was given at this dose. If before event onset, clarify in event summary.
Ongoing / end date	- Should accurately reflect situation at time of submitting report. Update as necessary in update reports - An end date should be provided if 'ongoing' is answered 'no'.

Page 5 – continued – Relevant tests & lab data

Any relevant tests / laboratory data? ☐ Y ☐ N *(If yes, please specify below)*		
Date (d d m m m y y)	Test	Results
		Results pending: ☐ Y
		Results pending: ☐ Y
		Results pending: ☐ Y
		Results pending: ☐ Y
		Results pending: ☐ Y
		Results pending: ☐ Y

Field	How to complete
Any relevant tests/lab data?	Tick either yes or no, and provide details where necessary
Date / Test / Results	Only enter details of tests that are directly relevant to the SAE event(s)
	Please state the normal range in brackets next to the result (where applicable).
	We are particularly interested in being able to verify the following: - Diagnosis/event term is correct - Date of onset - Grade at maximum severity - Date of resolution
	- If any results are pending at the time of reporting, remember to check regularly to see if the result has been reported. - When the result is available, send an update report.

Page 5 – continued – Relevant medical history and investigator sign-off



Fields	How to complete
Any relevant medical history/concurrent conditions?	- Tick yes or no, and provide details where necessary. - We recommend seeking input from the PI/co-investigator regarding the relevance of any past medical history and/or comorbidities
Was the event expected in view of the patient's medical history?	- Only needs to be completed if the answer to "any relevant medical history/concurrent conditions" is "yes". - PI/co-investigator input should be sought about whether event expected in light of the patient's medical history. Tick yes or no as appropriate.
Signature / print name / date	- The report must be signed by the PI or a co-investigator - The person who signs the report must be assigned duty "K" on the delegation log. - This should be the investigator who assesses causality on the event page. - The report should be counter-signed if new events are added or causality assessment is changed

Contact details
SAE reports should be submitted by fax to UCL CTC: Fax: 0207 679 9861
If you have any questions about SAE reporting for UKALL14, please contact the study team at UCL CTC: ctc.ukall14@ucl.ac.uk Tel: 0207 678 9860

We hope that these guidelines have been helpful, and welcome feedback from sites on how our guidance documents can be improved.
Please contact the CTC team at the email address above if you have any comments on this document or suggestions for improvements.

Author: Pip Patrick, Senior Trial Coordinator
February 2017