OPTIMAL SAE Reporting Form 12

Patient Initials	Date of Birth	Site Number	Trial Number
	d d - m m - y y y y	0	0

- **Please complete the form, sign and then fax immediately (within one day of awareness) to: OPTIMAL Clinical Trial Coordinator: 01865 572035**
- **If late, give reason for lateness on fax cover sheet**
- **Refer to the SAE reporting form completion guidelines for guidance**

PI:		Reported by:		Randomising Site:	
Email address:		Tel No:		Fax No:	

1. Report type:

☐ **Initial** ☐ **Follow up** → **If follow up, SAE reference: (supplied by sponsor)**

2. Criteria for definition of SAE (tick one)

☐ Subject died

☐ Life threatening

☐ In-patient hospitalisation Or prolongation of existing hospitalisation →

Admission Date	d d m m y y y y
Discharge Date	d d m m y y y y

☐ Persistent or significant disability

☐ Congenital anomaly/birth defect

☐ Other medically important event

Date of awareness: d d - m m - y y y y

Start date and time of SAE: d d - m m - y y y y h h . m m **(24 hr clock)**

Stop date and time of SAE: d d - m m - y y y y h h . m m **(24 hr clock)**

OR Ongoing (tick if applicable) ☐

3. Details of Event —

Please provide an account of the event including i) subject's state of health prior to SAE, ii) diagnosis and iii) treatment for SAE. Include any relevant lab data or diagnostic tests in the table provided. If needed please use the continuation form.

Current status of study participation *(please tick appropriate box)*	Withdrawn due to SAE		Continuing in study		Continuation sheet used?		No. of pgs. Used?	

For Office use Only: Date for Received: d d - m m - y y y y SAE Reference Number:

3. (contd.) [Lab data / Diagnostic tests]

Test (units)	Normal range	Date (ddmmyyyy)	Result

Site Number 0 _ _ Trial Number 0 _ _

Patient date of birth d d - m m - y y y y

Adverse event (CTCAE term v4.03) *(Exactly as stated in the CTCAE document)*	**CTCAE Grade:**

4. Evaluation of Event

i) Severity (tick one) Mild ☐ Moderate ☐ Severe ☐

ii) SAE Resolved? (tick one) Resolved ☐ Unresolved ☐ (please complete follow up report as appropriate)

iii) Outcomes (tick one)

- Recovered no sequelae ☐
- Recovered with sequelae ☐
- Patient died ☐
- Continuing ☐
- Unknown ☐

Date of resolution: d d m m y y y y

→ Date of Death : d d m m y y y y *please complete notification of death form*

Cause of death Disease Progression? **Yes** ☐ **No** ☐

If no please state cause:_____

iv) Caused obtained from (tick one)

- Working diagnosis ☐
- Coroners inquest ☐
- Death Certificate ☐

5. Subject details

Age at SAE onset (yrs)	**Sex (M or F)**	**Height (m)**	**Weight (Kg)**
		_ . _ _	_ _ _ . _

Race

Caucasian ☐ Black ☐ Hispanic ☐ Asian ☐ Other Specify

6. Study Drugs

Please give details of most recent dose(s) ☐ **No study drugs received (go straight to Section 8)**

MOST RECENT

Study Drug *(Tick and complete for those received)*	Product Form	Cycle No (e.g. 1,2,3)	Day of Cycle (e.g. 1,2,3)	Start Date and Time if applicable	Stop Date and Time if applicable	Dose	Units	Frequency	Batch No.	Expiry Date	Causality Could event have been caused by study drug?	Expectedness If related, was the event expected?
☐ Bortezomib	☐ SC ☐ IV			d d m m y y y y h h m m **24 hr**	d d m m y y y y h h m m **24 hr**					d d m m y y y y	☐ **Related** ☐ **Unrelated**	☐ **Expected** ☐ **Unexpected**
☐ Bendamustine	IV			d d m m y y y y h h m m **24 hr**	d d m m y y y y h h m m **24 hr**					d d m m y y y y	☐ **Related** ☐ **Unrelated**	☐ **Expected** ☐ **Unexpected**
☐ Dexame-thasone	Tablet			d d m m y y y y	d d m m y y y y					d d m m y y y y	☐ **Related** ☐ **Unrelated**	☐ **Expected** ☐ **Unexpected**
☐ Thalidomide	Capsules			d d m m y y y y	d d m m y y y y					d d m m y y y y	☐ **Related** ☐ **Unrelated**	☐ **Expected** ☐ **Unexpected**

7. Action Taken as a Result of SAE

Study Drug	**Action Taken**										
(Tick and complete for those received)	None	Dose Reduction	Dose Increase	Withheld Transiently	If withheld transiently: Date withheld	If withheld transiently: Reason withheld	If withheld transiently: Date restarted	Discon-tinued	Date discontinued	Event abated after study drug withheld / discontinued	Event reappeared after study drug reintroduced
☐ Bortezomib	☐	☐	☐	☐ →	d d m m y y y y		d d m m y y y y	☐ →	d d m m y y y y	☐ Yes ☐ No ☐ N/A	☐ Yes ☐ No ☐ N/A
☐ Bendamustine	☐	☐	☐	☐ →	d d m m y y y y		d d m m y y y y	☐ →	d d m m y y y y	☐ Yes ☐ No ☐ N/A	☐ Yes ☐ No ☐ N/A
☐ Dexamethasone	☐	☐	☐	☐ →	d d m m y y y y		d d m m y y y y	☐ →	d d m m y y y y	☐ Yes ☐ No ☐ N/A	☐ Yes ☐ No ☐ N/A
☐ Thalidomide	☐	☐	☐	☐ →	d d m m y y y y		d d m m y y y y	☐ →	d d m m y y y y	☐ Yes ☐ No ☐ N/A	☐ Yes ☐ No ☐ N/A

8. Concomitant Therapies

Include treatments received for SAE: **NONE** ☐ **UNKNOWN** ☐

Therapy (drug/procedure)	**Cycle** (at time of therapy)	**Dose** (write N/A if not applicable)	**Start date** (dd/mm/yyyy)	**Stop date** (dd/mm/yyyy)	**Route**	**Indication for use**	**Ongoing (Y/N)**

9. Relevant Medical History

Include medical conditions, e.g. tumour history, allergies, previous drug reactions, alcohol/drug abuse, etc. Specify disease/syndrome for each concomitant therapy listed.

NONE ☐ **UNKNOWN** ☐

Disease/Syndrome *(specify)*	**Date of Onset** (dd/mm/yyyy)	**Ongoing** Yes/No	**Date of resolution** (dd/mm/yyyy)	**Pertinent details** *including surgical procedures and dates*
		Y ☐ N ☐ →		
		Y ☐ N ☐ →		
		Y ☐ N ☐ →		
		Y ☐ N ☐ →		

Reporting/Treating Clinician (print name):	***(Please note: Your name must be on the delegation log)***	
Signature ***(By signing this you are confirming you have assessed causality and expectedness)*:**	**Date signed:**	d d m m y y y y
Form completed by (print name):		
Signature	**Date signed:**	d d m m y y y y

OPTIMAL SAE Reporting Form 12 Continuation Form

Patient Initials	Date of Birth	Site Number	Trial Number
	d d - m m - y y y y	0	0

This report relates to the SAE dated:	d d m m y y y y			
Linked to:		Initial Report		Follow-up report

SAE form Section Number	Additional information (according to section)

Reporting/Treating Clinician (print name):	***(Please note: Your name must be on the delegation log)***							
Signature ***(By signing this you are confirming you have assessed causality and expectedness)*****:**	**Date signed:**	d	d	m	m	y	y	y	y
Form completed by (print name):								
Signature	**Date signed:**	d	d	m	m	y	y	y	y