OPTIMAL Treatment Form 8

Cycle No 5

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

COMPLETION INSTRUCTIONS

SECTION A - To be completed on day 1 of the cycle. **SECTION B - To be completed at the end of the cycle.**

SECTION A

8.1 Clinical Assessment

Date of Clinical Assessments (d d m m y y y y)

1. Is Patient Alive Yes ☐ No ☐ → **Please complete Death Form 18**

2. Weight (kg) ☐☐☐.☐

3. ECOG performance status ☐ **0** ☐ **1** ☐ **2** ☐ **3** ☐ **4**

4. Pregnancy Test (*if applicable*)

Result
1=Negative
2=Positive
3=Not applicable

☐ → Date (d d m m y y y y)

5. Is patient on dialysis? **Yes** ☐ **No** ☐ → *If dialysis was started or stopped since patient's last trial visit please enter date:* (d d m m y y y y)

6. Has the patient completed an EQ-5D-3L Quality of Life Questionnaire? **Yes** ☐ **No** ☐ *If no please give reason below:*

Date Questionnaire completed: (d d m m y y y y)

7. Have any Adverse Events or Adverse Reactions occurred since last treatment cycle?

No ☐ **Yes** ☐ If yes please provide details in section 8.4

8. Select treatment diary card(s) given to patient ☐ **Thalidomide** ☐ **Dexamethasone**

9. Please record details of current concomitant medications in section 8.3

Completed by: (Print) _____

Signature: _____

CRFs should only be completed by appropriately qualified personnel detailed on the site delegation log

Date completed: D D M M Y Y Y Y

For Office use only
Date form received: _____ Date form entered: _____ Initials: _____

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

SECTION B

8.2 Treatment - *Please provide details of treatment received*

Date cycle started (dd/mm/yyyy) (d d m m y y y y) *Date cycle finished (dd/mm/yyyy)* (d d m m y y y y)

Treatment Codes:

a: **0**=No change **2**=Automatic neuropathy **4**=Clinician decision **6**=Administrative **8**=SAE/AE*

1=Haematological toxicity **3**=Peripheral neuropathy **5**=Patient decision **7**=Other (specify below or attach additional information CRF)

b: If patient has stopped treatment completely, please continue to collect central lab samples and follow patient up at 30 days post discontinuation as per 1 month follow up

*: For each adverse event please complete further details (grade, causality, etc.) in section 8.4. Please consult protocol for SAE definitions - if an SAE has occurred and requires reporting, please submit an SAE form.

Study drugs - tick and complete for those received		No. of capsules/ tablets given	No. of capsules/ tablets returned	Treatment dose given (mg)	Delay [a] (see codes above - if no delay, enter 0)	Reduction [a] (see codes above - if not reduction enter 0)	Omission [a] (see codes above - if not omitted enter 0)	Discontinuation [a,b] (see codes above - if not discontinued, enter 0)
☐ **Thalidomide**	Week 1							
	Week 2							
	Week 3							
☐ **Dexamethasone**	Week 1							
	Week 2							
	Week 3							

Thalidomide treatment diary card attached? ☐ **Yes** ☐ **No** - If no, please state reason: _____

Dexamethasone treatment diary card attached? ☐ **Yes** ☐ **No -** If no, please state reason: _____

Study drugs - tick and complete for those received	Route *(Velcade only)* **1=SC 2=IV**	**Day** (state cycle day given)	Treatment dose given (mg)	Delay [a] (see codes above - if no delay, enter 0)	Reduction [a] (see codes above - if not reduction enter 0)	Omission [a] (see codes above - if not omitted enter 0)	Discontinuation [a,b] (see codes above - if not discontinued, enter 0)
☐ **Bortezomib (Velcade)**							
☐ **Bendamustine (Levact)**							

Completed by: (Print) _____

Signature: _____

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Date completed: D D M M Y Y Y Y

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Date form received: _____ Date form entered: _____ Initials: _____

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

8.3 Concomitant Medication(s) - *Please provide details of all concomitant medications taken during this cycle.*

Therapy (drug/procedure)	Dose	Start date (dd/mm/yyyy)	Stop date (dd/mm/yyyy)	Route	Indication for use	Ongoing (Y/N)

8.4 Adverse Events (AE) and Adverse Reactions (AR)

AE & AR key:

Severity Scale: 1. Mild, 2. Moderate, 3. Severe.

Outcome: 1. Resolved no sequelae, 2. Resolved with sequelae, 3. Death, 4. Continuing, 9. Not known.

Adverse Events (please use one line per AE)

AE Description (incl. CTCAE terms)	CTCAE Grade	Dates (dd/mm/yyyy)	Ongoing Y/N	Severity (*use key above*)	Outcome (*use key above*)
		Start Stop			
		Start Stop			
		Start Stop			

Adverse Reactions (please use one line per AR)

AR Description (incl. CTCAE terms)	CTCAE Grade	Dates (dd/mm/yyyy)	Ongoing Y/N	Severity (*use key above*)	Outcome (*use key above*)
		Start Stop			
		Start Stop			
		Start Stop			

Completed by: (Print) _____

Signature: _____

CRFs should only be completed by appropriately qualified personnel detailed on the site delegation log

Date completed: D D M M Y Y Y Y

For Office use only

Date form received: _____ Date form entered: _____ Initials: _____