

Patient Initials

Grid for Patient Initials

Date of Birth

Grid for Date of Birth (dd-mm-yyyy)

Site Number

Grid for Site Number (0)

Trial Number

Grid for Trial Number (0)

COMPLETION INSTRUCTIONS

SECTION A - To be completed on day 1 of cycle.

SECTION B - To be completed as central samples are collected.

SECTION C - To be completed at the end of the cycle.

SECTION A

6.1 Clinical Assessment

Date of Clinical Assessments

- 1. Weight (kg)
2. ECOG performance status
3. Pregnancy Test
4. Is patient on dialysis?
5. Has the patient completed an EQ-5D-3L Quality of Life Questionnaire?
6. Have any Adverse Events or Adverse Reactions occurred since last treatment cycle?
7. Select treatment diary card(s) given to patient
8. Please record details of current concomitant medications in section 6.7

LOCAL LABORATORY TEST RESULTS

6.2 Haematology

Date of test (dd/mm/yyyy)

- 1. Haemoglobin
2. Platelets
3. White Blood cell (WBC count)
4. Haematocrit
5. Neutrophil Count
6. Lymphocytes
7. Monocytes

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

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Date form received:

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Date of Birth

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**6.3 Biochemistry**

Date of test (dd/mm/yyyy)

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Date if different from above OR tick box if same as above

	Test Result				
1. Sodium	[ ][ ] [ ][ ]	mmol/L	[ ][ ] [ ][ ] [ ][ ] [ ][ ] [ ][ ] [ ][ ]	[ ]	[ ]
2. Potassium	[ ][ ] . [ ][ ]	mmol/L	[ ][ ] [ ][ ] [ ][ ] [ ][ ] [ ][ ] [ ][ ]	[ ]	[ ]
3. Total Protein	[ ][ ] [ ][ ]	G/L	[ ][ ] [ ][ ] [ ][ ] [ ][ ] [ ][ ] [ ][ ]	[ ]	[ ]
4. Albumin	[ ][ ] [ ][ ]	G/L	[ ][ ] [ ][ ] [ ][ ] [ ][ ] [ ][ ] [ ][ ]	[ ]	[ ]
5. Bicarbonate	[ ][ ] [ ][ ] . [ ][ ]	mmol/L	[ ][ ] [ ][ ] [ ][ ] [ ][ ] [ ][ ] [ ][ ]	[ ]	[ ]
6. Adjusted Calcium	[ ][ ] [ ][ ] . [ ][ ] [ ][ ]	mmol/L	[ ][ ] [ ][ ] [ ][ ] [ ][ ] [ ][ ] [ ][ ]	[ ]	[ ]
7. Phosphate	[ ][ ] [ ][ ] . [ ][ ] [ ][ ]	mmol/L	[ ][ ] [ ][ ] [ ][ ] [ ][ ] [ ][ ] [ ][ ]	[ ]	[ ]
8. Serum Urea	[ ][ ] [ ][ ] . [ ][ ] [ ][ ]	mmol/L	[ ][ ] [ ][ ] [ ][ ] [ ][ ] [ ][ ] [ ][ ]	[ ]	[ ]
9. Serum Creatinine	[ ][ ] [ ][ ] [ ][ ]	µmol/L	[ ][ ] [ ][ ] [ ][ ] [ ][ ] [ ][ ] [ ][ ]	[ ]	[ ]
10. Uric Acid	[ ][ ] [ ][ ] [ ][ ]	µmol/L	[ ][ ] [ ][ ] [ ][ ] [ ][ ] [ ][ ] [ ][ ]	[ ]	[ ]
11. Creatinine Clearance	[ ][ ] [ ][ ] . [ ][ ] [ ][ ] [ ][ ]	ml/min	[ ][ ] [ ][ ] [ ][ ] [ ][ ] [ ][ ] [ ][ ]	[ ]	[ ]
12. LDH	[ ][ ] [ ][ ] [ ][ ]	IU/L	[ ][ ] [ ][ ] [ ][ ] [ ][ ] [ ][ ] [ ][ ]	[ ]	[ ]
13. Bilirubin	[ ][ ] [ ][ ] [ ][ ]	µmol/L	[ ][ ] [ ][ ] [ ][ ] [ ][ ] [ ][ ] [ ][ ]	[ ]	[ ]
14. Glucose	[ ][ ] [ ][ ] . [ ][ ]	mmol/L	[ ][ ] [ ][ ] [ ][ ] [ ][ ] [ ][ ] [ ][ ]	[ ]	[ ]
15. C-Reactive Protein	[ ][ ] [ ][ ] [ ][ ] . [ ][ ]	mg/L	[ ][ ] [ ][ ] [ ][ ] [ ][ ] [ ][ ] [ ][ ]	[ ]	[ ]

**Completed by:** \_\_\_\_\_  
(Print)

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**Signature:** \_\_\_\_\_

**Date completed:**

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## 6.4 Immunology

Date of test (dd/mm/yyyy) 

d	d	m	m	y	y	y	y
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### Disease assessment

Date of test if different from above (dd/mm/yyyy)

#### Quantitative Immunoglobulin Results

1. IgA (g/L)  1=Measureable, please complete result → 

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 2=Un-measureable
2. IgM (g/L)  1=Measureable, please complete result → 

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 2=Un-measureable
3. IgG (g/L)  1=Measureable, please complete result → 

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 2=Un-measureable
4. Sflc Kappa (mg/l)  1=Done, please complete result → 

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 2=Not done
5. Sflc Lambda (mg/l)  1=Done, please complete result → 

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 2=Not done
6. Sflc Kappa/Lambda ratio  1=Done, please complete result → 

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 2=Not done

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d	d	m	m	y	y	y	y
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d	d	m	m	y	y	y	y
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d	d	m	m	y	y	y	y
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d	d	m	m	y	y	y	y
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d	d	m	m	y	y	y	y
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#### Protein Electrophoresis Results

8. Beta-2 microglobulin (mg/L) 

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7. Specify Paraprotein type (g/L) 

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↓  
 1=Measureable, please complete result 

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 2=Immunofixation only
8. Specify Paraprotein type (g/L) (if more than one type) 

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↓  
 1=Measureable, please complete result 

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 2=Immunofixation only
10. If paraprotein cannot be measured please give monoclonal protein plus beta region (g/L): 

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**OR**  Not required
11. If 24 hour urine collection performed please give light chain load (g/L): 

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**OR**  Not done

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d	d	m	m	y	y	y	y
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d	d	m	m	y	y	y	y
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d	d	m	m	y	y	y	y
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**SECTION B**

**6.5 Central Lab samples (Birmingham)**

**WEEK 3** Tick all samples collected

	Date Collected	Sample Sent?	Date Sent	OR	Reason not sent:
<input type="checkbox"/> 5ml blood (EDTA) →	d d m m y y y y	<input type="checkbox"/> No <input type="checkbox"/> Yes →	d d m m y y y y		
<input type="checkbox"/> 10ml clotted blood →	d d m m y y y y	<input type="checkbox"/> No <input type="checkbox"/> Yes →	d d m m y y y y		
<input type="checkbox"/> 20ml urine →	d d m m y y y y	<input type="checkbox"/> No <input type="checkbox"/> Yes →	d d m m y y y y		

Is sample from 24 hour collection?  No  Yes → Total vol. collected     ml

**SECTION C**

**6.6 Treatment - Please provide details of treatment received**

Date cycle started (dd/mm/yyyy)

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

d	d	m	m	y	y	y	y
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**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 6.8. 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 <sup>a</sup> (see codes above - if no delay, enter 0)	Reduction <sup>a</sup> (see codes above - if not reduction enter 0)	Omission <sup>a</sup> (see codes above - if not omitted enter 0)	Discontinuation <sup>a,b</sup> (see codes above - if not discontinued, enter 0)
<input type="checkbox"/> <b>Thalidomide</b>	Week 1						
	Week 2						
	Week 3						
<input type="checkbox"/> <b>Dexamethasone</b>	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 <sup>a</sup> (see codes above - if no delay, enter 0)	Reduction <sup>a</sup> (see codes above - if not reduction enter 0)	Omission <sup>a</sup> (see codes above - if not omitted enter 0)	Discontinuation <sup>a,b</sup> (see codes above - if not discontinued, enter 0)
<input type="checkbox"/> <b>Bortezomib (Velcade)</b>							
<input type="checkbox"/> <b>Bendamustine (Levact)</b>							

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(Print)

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### 6.7 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)

### 6.8 Adverse Events (AE) and Adverse Reactions (AR)

AE &amp; 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 <table border="1" style="display: inline-table; width: 100px; height: 15px;"></table> Stop <table border="1" style="display: inline-table; width: 100px; height: 15px;"></table>			
		Start <table border="1" style="display: inline-table; width: 100px; height: 15px;"></table> Stop <table border="1" style="display: inline-table; width: 100px; height: 15px;"></table>			
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#### 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 <table border="1" style="display: inline-table; width: 100px; height: 15px;"></table> Stop <table border="1" style="display: inline-table; width: 100px; height: 15px;"></table>			
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Signature: \_\_\_\_\_

Date completed:

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