

Patient Initials

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Date of Birth

d	d	-	m	m	-	y	y	y	y
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Site Number

0		
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Trial Number

0		
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### 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

#### 4.1 Clinical Assessment

Date of Clinical Assessments

1. Weight (kg) 

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2. ECOG performance status 

0
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1
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2
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3
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4
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3. Pregnancy Test (if applicable)   

Result
1=Negative
2=Positive
3=Not applicable

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 → Date 

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4. Is patient on dialysis? Yes 

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 No 

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 → *If dialysis was started or stopped since patient's last trial visit please enter date:*

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5. Has the patient completed an EQ-5D-3L Quality of Life Questionnaire? Yes 

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 No 

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*If no please give reason below:*
6. Have any Adverse Events occurred since screening?  

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 No 

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 Yes 

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 If yes please provide details in section 4.8
7. Select treatment diary card(s) given to patient 

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 Thalidomide 

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 Dexamethasone
8. Please record details of current concomitant medications in section 4.7

### LOCAL LABORATORY TEST RESULTS

#### 4.2 Haematology

Date of test (dd/mm/yyyy)

d	d	m	m	y	y	y	y
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Date if different from above OR tick box if same as above

- |                                 | Test Result   |  |  |  |   |  |  |  |  |  |  |  |  |   |  |
|---------------------------------|---|--|--|--|---|--|--|--|--|--|--|--|--|---|--|
| 1. Haemoglobin                  | <table border="1" style="display: inline-table; width: 40px; height: 20px;"><tr><td style="width: 20px;"></td><td style="width: 20px;"></td></tr></table> . <table border="1" style="display: inline-table; width: 20px; height: 20px;"><tr><td style="width: 20px;"></td></tr></table> g/dL                |  |  |  | <table border="1" style="display: inline-table; width: 60px; height: 20px;"><tr><td style="width: 15px;"></td><td style="width: 15px;"></td><td style="width: 15px;"></td><td style="width: 15px;"></td><td style="width: 15px;"></td><td style="width: 15px;"></td><td style="width: 15px;"></td><td style="width: 15px;"></td></tr></table> |  |  |  |  |  |  |  |  | <table border="1" style="display: inline-table; width: 20px; height: 20px;"><tr><td style="width: 20px;"></td></tr></table> |  |
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|                                 |   |  |  |  |   |  |  |  |  |  |  |  |  |   |  |
| 2. Platelets                    | <table border="1" style="display: inline-table; width: 60px; height: 20px;"><tr><td style="width: 20px;"></td><td style="width: 20px;"></td><td style="width: 20px;"></td></tr></table> x10 <sup>9</sup> /L   |  |  |  | <table border="1" style="display: inline-table; width: 60px; height: 20px;"><tr><td style="width: 15px;"></td><td style="width: 15px;"></td><td style="width: 15px;"></td><td style="width: 15px;"></td><td style="width: 15px;"></td><td style="width: 15px;"></td><td style="width: 15px;"></td><td style="width: 15px;"></td></tr></table> |  |  |  |  |  |  |  |  | <table border="1" style="display: inline-table; width: 20px; height: 20px;"><tr><td style="width: 20px;"></td></tr></table> |  |
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|                                 |   |  |  |  |   |  |  |  |  |  |  |  |  |   |  |
| 3. White Blood cell (WBC) count | <table border="1" style="display: inline-table; width: 40px; height: 20px;"><tr><td style="width: 20px;"></td><td style="width: 20px;"></td></tr></table> . <table border="1" style="display: inline-table; width: 20px; height: 20px;"><tr><td style="width: 20px;"></td></tr></table> x10 <sup>9</sup> /L |  |  |  | <table border="1" style="display: inline-table; width: 60px; height: 20px;"><tr><td style="width: 15px;"></td><td style="width: 15px;"></td><td style="width: 15px;"></td><td style="width: 15px;"></td><td style="width: 15px;"></td><td style="width: 15px;"></td><td style="width: 15px;"></td><td style="width: 15px;"></td></tr></table> |  |  |  |  |  |  |  |  | <table border="1" style="display: inline-table; width: 20px; height: 20px;"><tr><td style="width: 20px;"></td></tr></table> |  |
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| 4. Haematocrit                  | <table border="1" style="display: inline-table; width: 20px; height: 20px;"><tr><td style="width: 20px;"></td></tr></table> . <table border="1" style="display: inline-table; width: 40px; height: 20px;"><tr><td style="width: 20px;"></td><td style="width: 20px;"></td></tr></table> L/L                 |  |  |  | <table border="1" style="display: inline-table; width: 60px; height: 20px;"><tr><td style="width: 15px;"></td><td style="width: 15px;"></td><td style="width: 15px;"></td><td style="width: 15px;"></td><td style="width: 15px;"></td><td style="width: 15px;"></td><td style="width: 15px;"></td><td style="width: 15px;"></td></tr></table> |  |  |  |  |  |  |  |  | <table border="1" style="display: inline-table; width: 20px; height: 20px;"><tr><td style="width: 20px;"></td></tr></table> |  |
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| <b>Differential</b>             |   |  |  |  |   |  |  |  |  |  |  |  |  |   |  |
| 5. Neutrophil Count             | <table border="1" style="display: inline-table; width: 40px; height: 20px;"><tr><td style="width: 20px;"></td><td style="width: 20px;"></td></tr></table> . <table border="1" style="display: inline-table; width: 20px; height: 20px;"><tr><td style="width: 20px;"></td></tr></table> x10 <sup>9</sup> /L |  |  |  | <table border="1" style="display: inline-table; width: 60px; height: 20px;"><tr><td style="width: 15px;"></td><td style="width: 15px;"></td><td style="width: 15px;"></td><td style="width: 15px;"></td><td style="width: 15px;"></td><td style="width: 15px;"></td><td style="width: 15px;"></td><td style="width: 15px;"></td></tr></table> |  |  |  |  |  |  |  |  | <table border="1" style="display: inline-table; width: 20px; height: 20px;"><tr><td style="width: 20px;"></td></tr></table> |  |
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|                                 |   |  |  |  |   |  |  |  |  |  |  |  |  |   |  |
| 6. Lymphocytes                  | <table border="1" style="display: inline-table; width: 40px; height: 20px;"><tr><td style="width: 20px;"></td><td style="width: 20px;"></td></tr></table> . <table border="1" style="display: inline-table; width: 20px; height: 20px;"><tr><td style="width: 20px;"></td></tr></table> x10 <sup>9</sup> /L |  |  |  | <table border="1" style="display: inline-table; width: 60px; height: 20px;"><tr><td style="width: 15px;"></td><td style="width: 15px;"></td><td style="width: 15px;"></td><td style="width: 15px;"></td><td style="width: 15px;"></td><td style="width: 15px;"></td><td style="width: 15px;"></td><td style="width: 15px;"></td></tr></table> |  |  |  |  |  |  |  |  | <table border="1" style="display: inline-table; width: 20px; height: 20px;"><tr><td style="width: 20px;"></td></tr></table> |  |
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| 7. Monocytes                    | <table border="1" style="display: inline-table; width: 40px; height: 20px;"><tr><td style="width: 20px;"></td><td style="width: 20px;"></td></tr></table> . <table border="1" style="display: inline-table; width: 20px; height: 20px;"><tr><td style="width: 20px;"></td></tr></table> x10 <sup>9</sup> /L |  |  |  | <table border="1" style="display: inline-table; width: 60px; height: 20px;"><tr><td style="width: 15px;"></td><td style="width: 15px;"></td><td style="width: 15px;"></td><td style="width: 15px;"></td><td style="width: 15px;"></td><td style="width: 15px;"></td><td style="width: 15px;"></td><td style="width: 15px;"></td></tr></table> |  |  |  |  |  |  |  |  | <table border="1" style="display: inline-table; width: 20px; height: 20px;"><tr><td style="width: 20px;"></td></tr></table> |  |
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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

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Date of Birth

d	d	-	m	m	-	y	y	y	y
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Site Number

0		
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Trial Number

0		
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### 4.3 Biochemistry

Date of test (dd/mm/yyyy)

d	d	m	m	y	y	y	y
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Date if different from above OR tick box if same as above

	Test Result				
1. Sodium	<input style="width: 30px; height: 20px;" type="text"/>	mmol/L	<input style="width: 30px; height: 20px;" type="text"/>	<input style="width: 30px; height: 20px;" type="text"/>	<input style="width: 30px; height: 20px;" type="text"/>
2. Potassium	<input style="width: 30px; height: 20px;" type="text"/> . <input style="width: 30px; height: 20px;" type="text"/>	mmol/L	<input style="width: 30px; height: 20px;" type="text"/>	<input style="width: 30px; height: 20px;" type="text"/>	<input style="width: 30px; height: 20px;" type="text"/>
3. Total Protein	<input style="width: 30px; height: 20px;" type="text"/>	G/L	<input style="width: 30px; height: 20px;" type="text"/>	<input style="width: 30px; height: 20px;" type="text"/>	<input style="width: 30px; height: 20px;" type="text"/>
4. Albumin	<input style="width: 30px; height: 20px;" type="text"/>	G/L	<input style="width: 30px; height: 20px;" type="text"/>	<input style="width: 30px; height: 20px;" type="text"/>	<input style="width: 30px; height: 20px;" type="text"/>
5. Bicarbonate	<input style="width: 30px; height: 20px;" type="text"/> . <input style="width: 30px; height: 20px;" type="text"/>	mmol/L	<input style="width: 30px; height: 20px;" type="text"/>	<input style="width: 30px; height: 20px;" type="text"/>	<input style="width: 30px; height: 20px;" type="text"/>
6. Adjusted Calcium	<input style="width: 30px; height: 20px;" type="text"/> . <input style="width: 30px; height: 20px;" type="text"/>	mmol/L	<input style="width: 30px; height: 20px;" type="text"/>	<input style="width: 30px; height: 20px;" type="text"/>	<input style="width: 30px; height: 20px;" type="text"/>
7. Phosphate	<input style="width: 30px; height: 20px;" type="text"/> . <input style="width: 30px; height: 20px;" type="text"/>	mmol/L	<input style="width: 30px; height: 20px;" type="text"/>	<input style="width: 30px; height: 20px;" type="text"/>	<input style="width: 30px; height: 20px;" type="text"/>
8. Serum Urea	<input style="width: 30px; height: 20px;" type="text"/> . <input style="width: 30px; height: 20px;" type="text"/>	mmol/L	<input style="width: 30px; height: 20px;" type="text"/>	<input style="width: 30px; height: 20px;" type="text"/>	<input style="width: 30px; height: 20px;" type="text"/>
9. Serum Creatinine	<input style="width: 30px; height: 20px;" type="text"/>	µmol/L	<input style="width: 30px; height: 20px;" type="text"/>	<input style="width: 30px; height: 20px;" type="text"/>	<input style="width: 30px; height: 20px;" type="text"/>
10. Uric Acid	<input style="width: 30px; height: 20px;" type="text"/>	µmol/L	<input style="width: 30px; height: 20px;" type="text"/>	<input style="width: 30px; height: 20px;" type="text"/>	<input style="width: 30px; height: 20px;" type="text"/>
11. Creatinine Clearance	<input style="width: 30px; height: 20px;" type="text"/> . <input style="width: 30px; height: 20px;" type="text"/>	ml/min	<input style="width: 30px; height: 20px;" type="text"/>	<input style="width: 30px; height: 20px;" type="text"/>	<input style="width: 30px; height: 20px;" type="text"/>
12. LDH	<input style="width: 30px; height: 20px;" type="text"/>	IU/L	<input style="width: 30px; height: 20px;" type="text"/>	<input style="width: 30px; height: 20px;" type="text"/>	<input style="width: 30px; height: 20px;" type="text"/>
13. Bilirubin	<input style="width: 30px; height: 20px;" type="text"/>	µmol/L	<input style="width: 30px; height: 20px;" type="text"/>	<input style="width: 30px; height: 20px;" type="text"/>	<input style="width: 30px; height: 20px;" type="text"/>
14. Glucose	<input style="width: 30px; height: 20px;" type="text"/> . <input style="width: 30px; height: 20px;" type="text"/>	mmol/L	<input style="width: 30px; height: 20px;" type="text"/>	<input style="width: 30px; height: 20px;" type="text"/>	<input style="width: 30px; height: 20px;" type="text"/>
15. C-Reactive Protein	<input style="width: 30px; height: 20px;" type="text"/> . <input style="width: 30px; height: 20px;" type="text"/>	mg/L	<input style="width: 30px; height: 20px;" type="text"/>	<input style="width: 30px; height: 20px;" type="text"/>	<input style="width: 30px; height: 20px;" type="text"/>

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

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Patient Initials

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Date of Birth

d	d	-	m	m	-	y	y	y	y
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Site Number

0		
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Trial Number

0		
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## 4.4 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

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

d	d	m	m	y	y	y	y
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Completed by: \_\_\_\_\_  
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Signature: \_\_\_\_\_

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Trial Number

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## SECTION B

### 4.5 Central Lab samples (Birmingham)

#### WEEK 1 Tick all samples collected

	<u>Date Collected</u>	<u>Sample Sent?</u>	<u>Date Sent</u>	<u>OR</u>	<u>Reason not sent:</u>																
<input type="checkbox"/> 5ml blood (EDTA) →	<table border="1" style="width: 100%; height: 20px; border-collapse: collapse;"><tr><td style="width: 22px; text-align: center;">d</td><td style="width: 22px; text-align: center;">d</td><td style="width: 22px; text-align: center;">m</td><td style="width: 22px; text-align: center;">m</td><td style="width: 22px; text-align: center;">y</td><td style="width: 22px; text-align: center;">y</td><td style="width: 22px; text-align: center;">y</td><td style="width: 22px; text-align: center;">y</td></tr></table>	d	d	m	m	y	y	y	y	<input type="checkbox"/> No <input type="checkbox"/> Yes →	<table border="1" style="width: 100%; height: 20px; border-collapse: collapse;"><tr><td style="width: 22px; text-align: center;">d</td><td style="width: 22px; text-align: center;">d</td><td style="width: 22px; text-align: center;">m</td><td style="width: 22px; text-align: center;">m</td><td style="width: 22px; text-align: center;">y</td><td style="width: 22px; text-align: center;">y</td><td style="width: 22px; text-align: center;">y</td><td style="width: 22px; text-align: center;">y</td></tr></table>	d	d	m	m	y	y	y	y		<table border="1" style="width: 100%; height: 20px;"></table>
d	d	m	m	y	y	y	y														
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<input type="checkbox"/> 10ml clotted blood →	<table border="1" style="width: 100%; height: 20px; border-collapse: collapse;"><tr><td style="width: 22px; text-align: center;">d</td><td style="width: 22px; text-align: center;">d</td><td style="width: 22px; text-align: center;">m</td><td style="width: 22px; text-align: center;">m</td><td style="width: 22px; text-align: center;">y</td><td style="width: 22px; text-align: center;">y</td><td style="width: 22px; text-align: center;">y</td><td style="width: 22px; text-align: center;">y</td></tr></table>	d	d	m	m	y	y	y	y	<input type="checkbox"/> No <input type="checkbox"/> Yes →	<table border="1" style="width: 100%; height: 20px; border-collapse: collapse;"><tr><td style="width: 22px; text-align: center;">d</td><td style="width: 22px; text-align: center;">d</td><td style="width: 22px; text-align: center;">m</td><td style="width: 22px; text-align: center;">m</td><td style="width: 22px; text-align: center;">y</td><td style="width: 22px; text-align: center;">y</td><td style="width: 22px; text-align: center;">y</td><td style="width: 22px; text-align: center;">y</td></tr></table>	d	d	m	m	y	y	y	y		<table border="1" style="width: 100%; height: 20px;"></table>
d	d	m	m	y	y	y	y														
d	d	m	m	y	y	y	y														
<input type="checkbox"/> 20ml urine →	<table border="1" style="width: 100%; height: 20px; border-collapse: collapse;"><tr><td style="width: 22px; text-align: center;">d</td><td style="width: 22px; text-align: center;">d</td><td style="width: 22px; text-align: center;">m</td><td style="width: 22px; text-align: center;">m</td><td style="width: 22px; text-align: center;">y</td><td style="width: 22px; text-align: center;">y</td><td style="width: 22px; text-align: center;">y</td><td style="width: 22px; text-align: center;">y</td></tr></table>	d	d	m	m	y	y	y	y	<input type="checkbox"/> No <input type="checkbox"/> Yes →	<table border="1" style="width: 100%; height: 20px; border-collapse: collapse;"><tr><td style="width: 22px; text-align: center;">d</td><td style="width: 22px; text-align: center;">d</td><td style="width: 22px; text-align: center;">m</td><td style="width: 22px; text-align: center;">m</td><td style="width: 22px; text-align: center;">y</td><td style="width: 22px; text-align: center;">y</td><td style="width: 22px; text-align: center;">y</td><td style="width: 22px; text-align: center;">y</td></tr></table>	d	d	m	m	y	y	y	y		<table border="1" style="width: 100%; height: 20px;"></table>
d	d	m	m	y	y	y	y														
d	d	m	m	y	y	y	y														

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

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 ml

#### WEEK 2 Tick all samples collected

	<u>Date Collected</u>	<u>Sample Sent?</u>	<u>Date Sent</u>	<u>OR</u>	<u>Reason not sent:</u>																
<input type="checkbox"/> 5ml blood (EDTA) →	<table border="1" style="width: 100%; height: 20px; border-collapse: collapse;"><tr><td style="width: 22px; text-align: center;">d</td><td style="width: 22px; text-align: center;">d</td><td style="width: 22px; text-align: center;">m</td><td style="width: 22px; text-align: center;">m</td><td style="width: 22px; text-align: center;">y</td><td style="width: 22px; text-align: center;">y</td><td style="width: 22px; text-align: center;">y</td><td style="width: 22px; text-align: center;">y</td></tr></table>	d	d	m	m	y	y	y	y	<input type="checkbox"/> No <input type="checkbox"/> Yes →	<table border="1" style="width: 100%; height: 20px; border-collapse: collapse;"><tr><td style="width: 22px; text-align: center;">d</td><td style="width: 22px; text-align: center;">d</td><td style="width: 22px; text-align: center;">m</td><td style="width: 22px; text-align: center;">m</td><td style="width: 22px; text-align: center;">y</td><td style="width: 22px; text-align: center;">y</td><td style="width: 22px; text-align: center;">y</td><td style="width: 22px; text-align: center;">y</td></tr></table>	d	d	m	m	y	y	y	y		<table border="1" style="width: 100%; height: 20px;"></table>
d	d	m	m	y	y	y	y														
d	d	m	m	y	y	y	y														
<input type="checkbox"/> 10ml clotted blood →	<table border="1" style="width: 100%; height: 20px; border-collapse: collapse;"><tr><td style="width: 22px; text-align: center;">d</td><td style="width: 22px; text-align: center;">d</td><td style="width: 22px; text-align: center;">m</td><td style="width: 22px; text-align: center;">m</td><td style="width: 22px; text-align: center;">y</td><td style="width: 22px; text-align: center;">y</td><td style="width: 22px; text-align: center;">y</td><td style="width: 22px; text-align: center;">y</td></tr></table>	d	d	m	m	y	y	y	y	<input type="checkbox"/> No <input type="checkbox"/> Yes →	<table border="1" style="width: 100%; height: 20px; border-collapse: collapse;"><tr><td style="width: 22px; text-align: center;">d</td><td style="width: 22px; text-align: center;">d</td><td style="width: 22px; text-align: center;">m</td><td style="width: 22px; text-align: center;">m</td><td style="width: 22px; text-align: center;">y</td><td style="width: 22px; text-align: center;">y</td><td style="width: 22px; text-align: center;">y</td><td style="width: 22px; text-align: center;">y</td></tr></table>	d	d	m	m	y	y	y	y		<table border="1" style="width: 100%; height: 20px;"></table>
d	d	m	m	y	y	y	y														
d	d	m	m	y	y	y	y														
<input type="checkbox"/> 20ml urine →	<table border="1" style="width: 100%; height: 20px; border-collapse: collapse;"><tr><td style="width: 22px; text-align: center;">d</td><td style="width: 22px; text-align: center;">d</td><td style="width: 22px; text-align: center;">m</td><td style="width: 22px; text-align: center;">m</td><td style="width: 22px; text-align: center;">y</td><td style="width: 22px; text-align: center;">y</td><td style="width: 22px; text-align: center;">y</td><td style="width: 22px; text-align: center;">y</td></tr></table>	d	d	m	m	y	y	y	y	<input type="checkbox"/> No <input type="checkbox"/> Yes →	<table border="1" style="width: 100%; height: 20px; border-collapse: collapse;"><tr><td style="width: 22px; text-align: center;">d</td><td style="width: 22px; text-align: center;">d</td><td style="width: 22px; text-align: center;">m</td><td style="width: 22px; text-align: center;">m</td><td style="width: 22px; text-align: center;">y</td><td style="width: 22px; text-align: center;">y</td><td style="width: 22px; text-align: center;">y</td><td style="width: 22px; text-align: center;">y</td></tr></table>	d	d	m	m	y	y	y	y		<table border="1" style="width: 100%; height: 20px;"></table>
d	d	m	m	y	y	y	y														
d	d	m	m	y	y	y	y														

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

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 ml

#### WEEK 3 Tick all samples collected

	<u>Date Collected</u>	<u>Sample Sent?</u>	<u>Date Sent</u>	<u>OR</u>	<u>Reason not sent:</u>																
<input type="checkbox"/> 5ml blood (EDTA) →	<table border="1" style="width: 100%; height: 20px; border-collapse: collapse;"><tr><td style="width: 22px; text-align: center;">d</td><td style="width: 22px; text-align: center;">d</td><td style="width: 22px; text-align: center;">m</td><td style="width: 22px; text-align: center;">m</td><td style="width: 22px; text-align: center;">y</td><td style="width: 22px; text-align: center;">y</td><td style="width: 22px; text-align: center;">y</td><td style="width: 22px; text-align: center;">y</td></tr></table>	d	d	m	m	y	y	y	y	<input type="checkbox"/> No <input type="checkbox"/> Yes →	<table border="1" style="width: 100%; height: 20px; border-collapse: collapse;"><tr><td style="width: 22px; text-align: center;">d</td><td style="width: 22px; text-align: center;">d</td><td style="width: 22px; text-align: center;">m</td><td style="width: 22px; text-align: center;">m</td><td style="width: 22px; text-align: center;">y</td><td style="width: 22px; text-align: center;">y</td><td style="width: 22px; text-align: center;">y</td><td style="width: 22px; text-align: center;">y</td></tr></table>	d	d	m	m	y	y	y	y		<table border="1" style="width: 100%; height: 20px;"></table>
d	d	m	m	y	y	y	y														
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<input type="checkbox"/> 10ml clotted blood →	<table border="1" style="width: 100%; height: 20px; border-collapse: collapse;"><tr><td style="width: 22px; text-align: center;">d</td><td style="width: 22px; text-align: center;">d</td><td style="width: 22px; text-align: center;">m</td><td style="width: 22px; text-align: center;">m</td><td style="width: 22px; text-align: center;">y</td><td style="width: 22px; text-align: center;">y</td><td style="width: 22px; text-align: center;">y</td><td style="width: 22px; text-align: center;">y</td></tr></table>	d	d	m	m	y	y	y	y	<input type="checkbox"/> No <input type="checkbox"/> Yes →	<table border="1" style="width: 100%; height: 20px; border-collapse: collapse;"><tr><td style="width: 22px; text-align: center;">d</td><td style="width: 22px; text-align: center;">d</td><td style="width: 22px; text-align: center;">m</td><td style="width: 22px; text-align: center;">m</td><td style="width: 22px; text-align: center;">y</td><td style="width: 22px; text-align: center;">y</td><td style="width: 22px; text-align: center;">y</td><td style="width: 22px; text-align: center;">y</td></tr></table>	d	d	m	m	y	y	y	y		<table border="1" style="width: 100%; height: 20px;"></table>
d	d	m	m	y	y	y	y														
d	d	m	m	y	y	y	y														
<input type="checkbox"/> 20ml urine →	<table border="1" style="width: 100%; height: 20px; border-collapse: collapse;"><tr><td style="width: 22px; text-align: center;">d</td><td style="width: 22px; text-align: center;">d</td><td style="width: 22px; text-align: center;">m</td><td style="width: 22px; text-align: center;">m</td><td style="width: 22px; text-align: center;">y</td><td style="width: 22px; text-align: center;">y</td><td style="width: 22px; text-align: center;">y</td><td style="width: 22px; text-align: center;">y</td></tr></table>	d	d	m	m	y	y	y	y	<input type="checkbox"/> No <input type="checkbox"/> Yes →	<table border="1" style="width: 100%; height: 20px; border-collapse: collapse;"><tr><td style="width: 22px; text-align: center;">d</td><td style="width: 22px; text-align: center;">d</td><td style="width: 22px; text-align: center;">m</td><td style="width: 22px; text-align: center;">m</td><td style="width: 22px; text-align: center;">y</td><td style="width: 22px; text-align: center;">y</td><td style="width: 22px; text-align: center;">y</td><td style="width: 22px; text-align: center;">y</td></tr></table>	d	d	m	m	y	y	y	y		<table border="1" style="width: 100%; height: 20px;"></table>
d	d	m	m	y	y	y	y														
d	d	m	m	y	y	y	y														

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

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 ml

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

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Date of Birth

d	d	-	m	m	-	y	y	y	y
---	---	---	---	---	---	---	---	---	---

Site Number

0		
---	--	--

Trial Number

0		
---	--	--

## SECTION C

### 4.6 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 of treatment as per 1 month follow up, unless participant or clinician requests otherwise

\*: For each adverse event please complete further details (grade, causality, etc.) in section 4.8. 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"/> <u>Thalidomide</u>	Week 1						
	Week 2						
	Week 3						
<input type="checkbox"/> <u>Dexamethasone</u>	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"/> <u>Bortezomib</u> (Velcade)							
<input type="checkbox"/> <u>Bendamustine</u> (Levact)							

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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For Office use only  
 Date form received: \_\_\_\_\_ Date form entered: \_\_\_\_\_ Initials: \_\_\_\_\_

Patient Initials

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Date of Birth

d	d	-	m	m	-	y	y	y	y
---	---	---	---	---	---	---	---	---	---

Site Number

0		
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Trial Number

0		
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### 4.7 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)

### 4.8 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>			
		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>			

#### 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>			
		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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 Completed by: \_\_\_\_\_  
 (Print)

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

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

Date completed:

D	D	M	M	Y	Y	Y	Y

**For Office use only**

Date form received: \_\_\_\_\_

Date form entered: \_\_\_\_\_

Initials: \_\_\_\_\_