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

7.1 Clinical Assessment

Date of Clinical Assessments

1. Weight (kg) ☐☐☐ . ☐   d d m m y y y y

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

3. Pregnancy Test (if applicable)   Result 1=Negative 2=Positive 3=Not applicable ☐ → Date d d m m y y y y

4. 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

5. 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

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

No ☐ **Yes** ☐ If yes please complete the relevant table in section 7.8

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

8. Please record details of current concomitant medications in section 7.7

LOCAL LABORATORY TEST RESULTS

7.2 Haematology

Date of test (dd/mm/yyyy) d d m m y y y y

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

#		Test Result			Date	
1.	Haemoglobin	☐☐ . ☐	g/dL		d d m m y y y y	☐
2.	Platelets	☐☐☐	x10^9/L		d d m m y y y y	☐
3.	White Blood cell (WBC count)	☐☐ . ☐	x10^9/L		d d m m y y y y	☐
4.	Haematocrit	☐ . ☐☐☐	L/L		d d m m y y y y	☐
	Differential					
5.	Neutrophil Count	☐☐ . ☐	x10^9/L		d d m m y y y y	☐
6.	Lymphocytes	☐☐ . ☐	x10^9/L		d d m m y y y y	☐
7.	Monocytes	☐☐ . ☐	x10^9/L		d d m m y y y y	☐

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 ☐☐☐☐☐☐☐☐

Patient Initials

Date of Birth

d d - m m - y y y y

Site Number

0 [ ][ ]

Trial Number

0 [ ][ ]

7.3 Biochemistry   Date of test (dd/mm/yyyy)   d d m m y y y y

Test Result

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

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

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
[ ][ ] [ ][ ] [ ][ ][ ][ ]

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Patient Initials	Date of Birth	Site Number	Trial Number

Date of Birth: d d - m m - y y y y

Site Number: 0 [ ] [ ]

Trial Number: 0 [ ] [ ]

7.4 Immunology   Date of test (dd/mm/yyyy) [d d m m y y y y]

Disease assessment

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

Quantitative Immunoglobulin Results

1. IgA (g/L) [ ] 1=Measureable, please complete result 2=Un-measureable → [ ][ ] . [ ][ ]   [d d m m y y y y]

2. IgM (g/L) [ ] 1=Measureable, please complete result 2=Un-measureable → [ ][ ] . [ ][ ]   [d d m m y y y y]

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

4. Sflc Kappa (mg/l) [ ] 1=Done, please complete result 2=Not done → [ ][ ][ ] . [ ][ ]   [d d m m y y y y]

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

6. Sflc Kappa/ Lambda ratio [ ] 1=Done, please complete result 2=Not done → [ ][ ][ ] . [ ][ ]   [d d m m y y y y]

Protein Electrophoresis Results

8. Beta-2 microglobulin (mg/L) [ ][ ] . [ ][ ]   [d d m m y y y y]

7. Specify Paraprotein type (g/L) [ ]
   ↓
   [ ] 1=Measureable, please complete result 2=Immunofixation only   [ ][ ] . [ ][ ]   [d d m m y y y y]

8. Specify Paraprotein type (g/L) *(if more than one type)* [ ]
   ↓
   [ ] 1=Measureable, please complete result 2=Immunofixation only   [ ][ ] . [ ][ ]   [d d m m y y y y]

10. If paraprotein cannot be measured please give monoclonal protein plus beta region (g/L):   [ ][ ][ ] . [ ]   [d d m m y y y y]

    OR [ ] Not required

11. If 24 hour urine collection performed please give light chain load (g/L):   [ ][ ] . [ ][ ]   [d d m m y y y y]

    OR [ ] Not done

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: _____

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

SECTION B

7.5 Central Lab samples (Birmingham)

WEEK 3 Tick all samples collected

	Date Collected	Sample Sent?	Date Sent	OR	Reason not sent:
☐ 5ml blood (EDTA) →	d d m m y y y y	☐ No ☐ Yes →	d d m m y y y y		
☐ 10ml clotted blood →	d d m m y y y y	☐ No ☐ Yes →	d d m m y y y y		
☐ 20ml urine →	d d m m y y y y	☐ No ☐ Yes →	d d m m y y y y		

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

---

SECTION C

7.6 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 as per 1 month follow up

*****: For each adverse event please complete further details (grade, causality, etc.) in section 7.8. 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 [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) _____	*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 ☐☐☐☐☐☐☐☐

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

7.7 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)

7.8 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) _____

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Signature: _____

Date completed: D D M M Y Y Y Y ☐☐☐☐☐☐☐☐

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

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