OPTIMAL Treatment Form 5

Cycle No 2

Patient Initials | Date of Birth (dd-mm-yyyy) | Site Number (0) | 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

5.1 Clinical Assessment

Date of Clinical Assessments (dd/mm/yyyy)

1. Weight (kg) ___ . ___
2. ECOG performance status ☐ 0 ☐ 1 ☐ 2 ☐ 3 ☐ 4
3. Pregnancy Test (*if applicable*) Result (1=Negative 2=Positive 3=Not applicable) ☐ → Date (dd/mm/yyyy)
4. Is patient on dialysis? **Yes** ☐ **No** ☐ → *If dialysis was started or stopped since patient's last trial visit please enter date:* (dd/mm/yyyy)
5. Has the patient completed an EQ-5D-3L Quality of Life **Yes** ☐ **No** ☐ *If no please give reason below:*

   Date Questionnaire completed: (dd/mm/yyyy)
6. Have any Adverse Events or Adverse Reactions occurred since last treatment cycle?

   No ☐ **Yes** ☐ If yes please provide details in section 5.8
7. Select treatment diary card(s) given to patient ☐ **Thalidomide** ☐ **Dexamethasone**
8. Please record details of current concomitant medications in section 5.7

LOCAL LABORATORY TEST RESULTS

5.2 Haematology

Date of test (dd/mm/yyyy)

		Test Result		Date if different from above OR tick box if same as above
1.	Haemoglobin	___ . ___	g/dL	(dd/mm/yyyy) ☐
2.	Platelets	___	$x10^9$/L	(dd/mm/yyyy) ☐
3.	White Blood cell (WBC count)	___ . ___	$x10^9$/L	(dd/mm/yyyy) ☐
4.	Haematocrit	___ . ___	L/L	(dd/mm/yyyy) ☐
	Differential			
5.	Neutrophil Count	___ . ___	$x10^9$/L	(dd/mm/yyyy) ☐
6.	Lymphocytes	___ . ___	$x10^9$/L	(dd/mm/yyyy) ☐
7.	Monocytes	___ . ___	$x10^9$/L	(dd/mm/yyyy) ☐

Completed by: (Print) _____

Signature: _____

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Date completed: D D M M Y Y Y Y

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Patient Initials | Date of Birth (dd-mm-yyyy) | Site Number | Trial Number

Site Number: 0 | Trial Number: 0

5.3 Biochemistry

Date of test (dd/mm/yyyy)

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

Signature: _____

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

5.4 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) _____

Signature: _____

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

SECTION B

5.5 Central Lab samples (Birmingham)

WEEK 1 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

WEEK 2 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

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

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)

SECTION C

5.6 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 5.8. 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) _____

Signature: _____

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

5.7 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)

5.8 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) _____

Signature: _____

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Date completed: D D M M Y Y Y Y

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