OPTIMAL 12 Month Follow-up Form 11

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

To be completed at 12 months from trial randomisation date

11.1 DATE OF FOLLOW-UP APPOINTMENT (dd/mm/yyyy) d d – m m – y y y y

11.2 DISEASE STATUS

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

2. Is the patient on anti-myeloma therapy for active disease? ☐ No ☐ Yes

If Yes was therapy commenced after trial induction therapy? ☐ No ☐ Yes

4. Please give details of all anti-myeloma treatment for active disease given since the one month follow-up (continue on additional information CRF, if required)	Start date (dd/mm/yyyy)	Stop date (dd/mm/yyyy)

11.3 PERFORMANCE STATUS:

ECOG performance status: 0 ☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐

Completed by:
(Print)

Signature:

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

Date completed (ddmmyyyy): 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)

11.4 CLINICAL ASSESSMENT:

Patient's general condition: ☐ Improving ☐ Stable ☐ Worsening

11.5 Has the patient been an inpatient in hospital since the last trial visit

☐ No ☐ Yes → *Please give the admission & discharge dates for each hospital episode below starting with the most recent. If there has been more than 5 admissions, please continue on an Additional Information Form*

Reason for Admission	Admission date (ddmmyyyy)	Discharge date (ddmmyyyy)

If there have been more than 5 admissions, please continue on an Additional Information form

11.6 LOCAL laboratory Test Results *(please provide most recent local results)*

1. Creatinine — Date of this sample (dd/mm/yyyy) ☐☐☐☐☐☐☐☐ Result ☐☐☐ µmol/L

2. eGFR for this trial visit: Date of this sample (dd/mm/yyyy) ☐☐☐☐☐☐☐☐ Result ☐ >50ml/min ☐ 20-50ml/min ☐ <20ml/min

Completed by:
(Print)

Signature:

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Date completed (ddmmyyyy): D D M M Y Y Y Y

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OPTIMAL 12 Month Follow-up Form 11

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

11.7 Have any Adverse Events or Adverse Reactions occurred since last trial follow-up?

No ☐ **Yes** ☐ **If yes please complete section 11.8 (AE) and/or 11.9 (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, **5**=Not known.

11.8 Adverse Events (please use one line per AE)

AE Description	CTCAE Grade	Date (dd/mm/yyyy)	Ongoing Y/N	Severity	Outcome
		Start Stop			
		Start Stop			
		Start Stop			

11.9 Adverse Reactions (please use one line per AR)

AR Description	CTCAE Grade	Date (dd/mm/yyyy)	Ongoing Y/N	Severity	Outcome
		Start Stop			
		Start Stop			
		Start Stop			

Completed by:
(Print)

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

Signature:

Date completed (ddmmyyyy): D D M M Y Y Y Y

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

Completion Guidelines for CRF 11 - 12 Month Follow-up Form

12.1 DATE OF FOLLOW-UP APPOINTMENT:

Please provide the date the patient attended for their scheduled 12 month follow-up for OPTIMAL

12.2 DISEASE STATUS:

Please indicate the status which best describes the patient 12 months on from starting their trial treatment

8.5 LOCAL HAEMATOLOGY & BIOCHEMISTRY:

Please insert the results for the local haematology and biochemistry results nearest to this time point