

Carfilzomib/Cyclophosphamide/Dexamethasone with maintenance carfilzomib in untreated transplant-eligible patients with symptomatic MM to evaluate the benefit of upfront ASCT

# **1st Progression/Relapse Form**

Patient Initials	
Trial Number	

#### (This form has 7 pages including cover sheet)

Please send forms to:

Cardamon Trial Coordinator CR UK & UCL Cancer Trials Centre 90 Tottenham Court Road London W1T 4TJ

General enquires: **020 7679 9860** Randomisations: **020 7679 9860** between 9.00am and 5.00pm Fax: **020 7679 9861** E-mail: <u>ctc.cardamon@ucl.ac.uk</u>



Cancer Research UK and UCL Cancer Trials Centre





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## Additional instructions for completing forms

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The 1st progression/Relapse Form should be completed at the time of first relapse.

#### Completing forms

- Ensure all entries are clear, legible and written in black ink
- Avoid the use of abbreviations and acronyms
- Do not leave any fields blank. In case of missing data
  - ND (not done) if a test has not been performed or a measure not taken. If applicable state the reason
  - NA (not applicable) if a measure is not applicable
  - NK (not known) if data is unknown. This should only be used once every effort to obtain the data has been exhausted.
- CRFs may only be completed by an appropriately qualified individual delegated as responsible by the PI on the site delegation log
- CRF Footer section
  - The "completed by" Name should be legible
  - Each CRF should be signed and dated by the person completing the form
  - Do not complete the UCL CTC Use only section
- The CRF should be sent/faxed to the Cancer Trials Centre (CTC) with a copy retained at the Site (ensure when photocopying the page that the copy is added to the CRF booklet in the same place where the original was stored)

If you have any questions about how to complete this form please contact the Cardamon Trial Coordinator on: 020 7679 9860



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Trial

Number

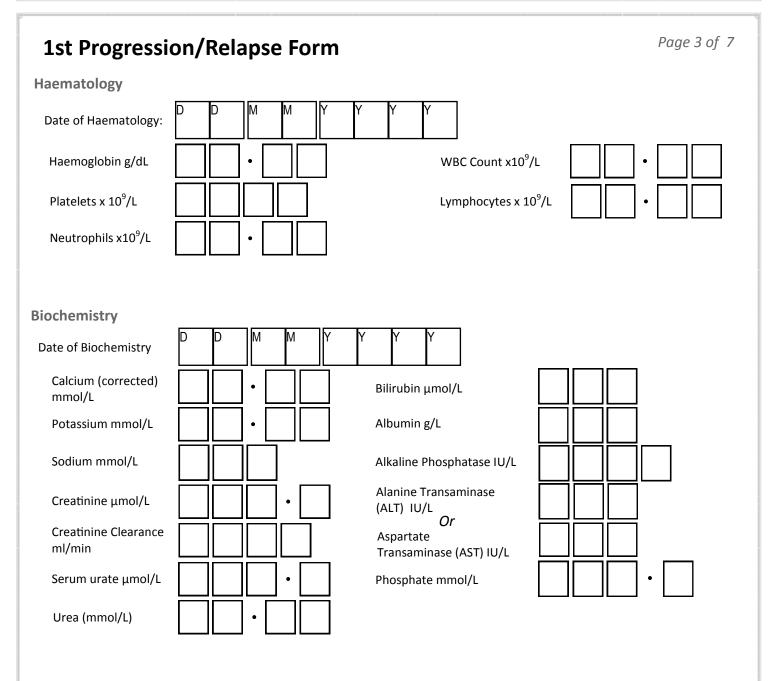
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Patient Initials

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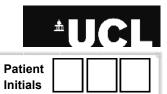
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1st Progression/Relapse Form	Page 4 of 7
Bone marrow biopsies	
Bone marrow aspirate Date of sample D D M M Y Y Y Y	
1= Present, complete % of plasma cells: 2= Present , not measured 3= Absent 4= Not done 1 = Present , not measured 4 = Not done	
Bone marrow trephine Date of sample D D M M Y Y Y Y	
1= Present, complete % of plasma cells: 2= Present , not measured 3= Absent 4= Not done %	
Bone marrow aspirate and peripheral blood samples must also be sent to the UCL Cancer Institute Myeloma Lab at relap N.B: Sites unable to perform cytogenetics/FISH must send an additional 4-8ml of BM aspirate to the UCL Cancer Institute	
Sent? 1=Yes 2= No Date sample sent to lab	
1=Yes 2= No     Date sample sent to lab       BM aspirate for genomic analyses (8ml) to the     D       UCL Cancer Institute Myeloma Lab     D	Y Y
Peripheral blood sample for genomic analyses (8ml) to the DDMMMYYY UCL Cancer Institute Myeloma Lab	Y Y
If No to any of the above, specify a reason:	
Soft tissue plasmacytoma/Extramedullary lesions	
Does the patient have any soft tissue plasmacytomas/ Extramedullary lesions?	each site involved
If yes, date of test D D M M Y Y Y Y L	g axis Short axis
Site involved: Bidimensional measurements (cm):	x
Site involved: Bidimensional measurements (cm):	x
Site involved: Bidimensional measurements (cm):	x



Cancer Research UK and UCL Cancer Trials Centre

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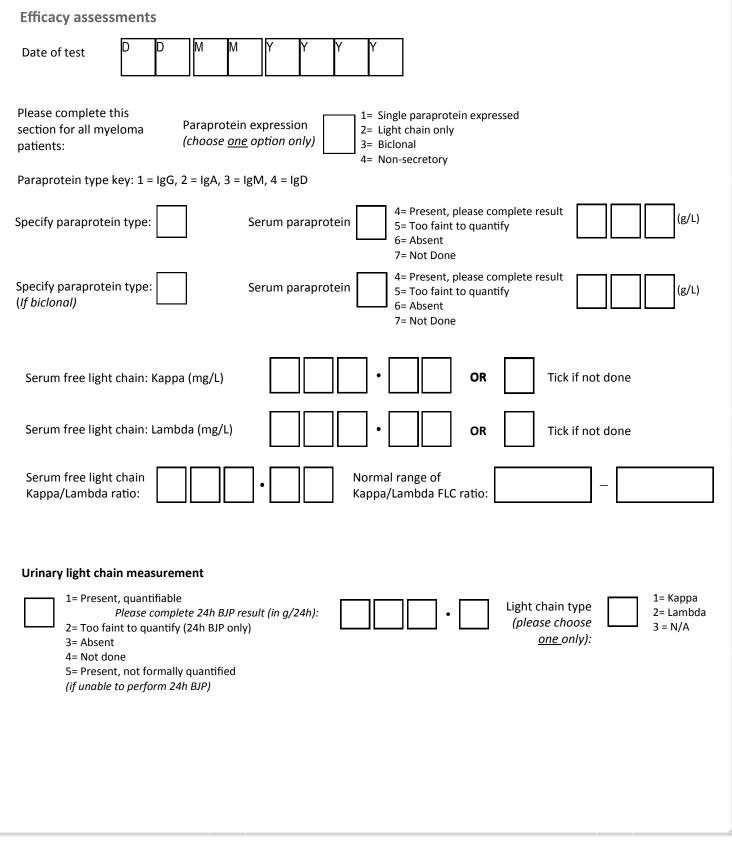
Trial Number

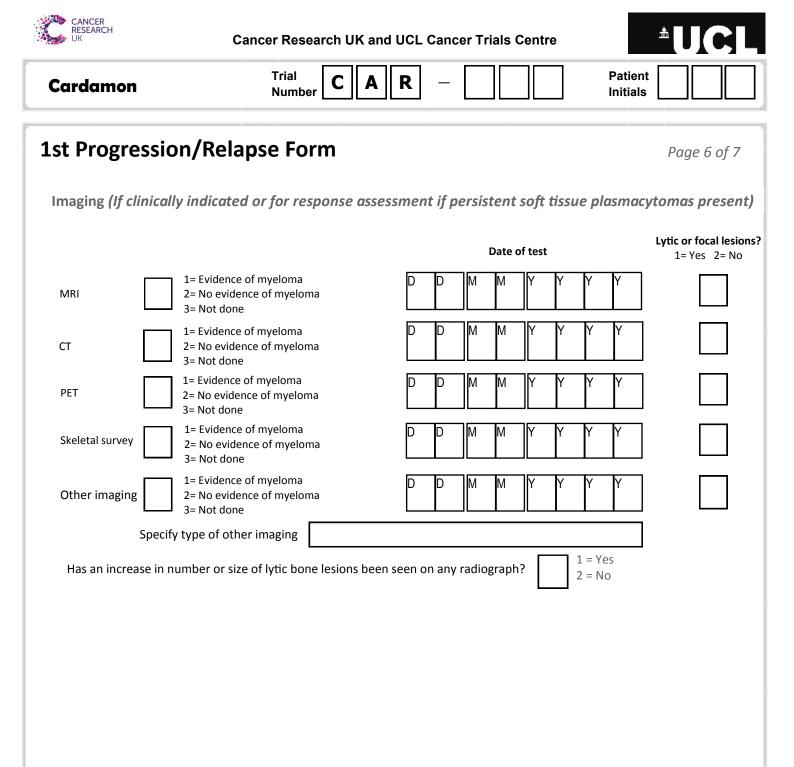
Patient Initials

## 1st Progression/Relapse Form

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To be completed upon first disea	se progression/relapse.
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Cardamon	Trial CAR – Patient Initials	
Lst Progression/Rela	ose Form	Page 7 of 2
Date of <u>first</u> Progression/Relapse	D M M Y Y Y Y	
Has progression been confirmed by cytogenetics/FISH?	1=Yes 2= No; please provide reason cytogenetics/FISH not performed:	
Please specify the nature of disease (Se	progression in the table below: 1=Yes e Appendix 3 for further details) 2=No	
≥25% increase in serum paraprotei	(absolute increase ≥5g/l)	
≥25% increase in urine light chain e	ccretion (absolute increase ≥200mg/24h)	
≥25% increase in the difference bet	ween involved and uninvolved light chains (absolute increase ≥100mg/l)	
≥25% increase in bone marrow plas	ma cell percentage (absolute increase ≥10%)	
Development of new lytic bone lesi		
	ng bone lesions or soft tissue plasmacytomas	
	2.8mmol/l) attributed solely to myeloma	
Other, please specify below:		
Further Treatment Plan: Is further myeloma treatment planned? (choose one option only) If Yes, please specify the treatment:	1= Yes (please complete treatment details and start date below) 2= Palliation/no further treatment 3= Watch and wait or not known at present	
and provide the start date :	D D M M Y Y Y Y	
Is Salvage ASCT planned for this patient i second remission?	1= Yes 2= No, please complete below 3= Not known at this time, please amend this form once this inform	ation is availab
If <b>No</b> , please specify a reason for not planning to proceed to salvage ASCT:		
Please ensure that in the case of t	reatment-related disease progression, an SAE form is completed and faxed/emaile within 1 business day of the site becoming aware.	d to UCL CTC
ame of person completing form:	Signature of person completing form: Date completed:	
	D D M M Y	YYY

The site PI or delegated investigator must sign to confirm that information within the CRF is accurate

Investigator name: Inv	nvestigator signature:	Date completed:							
		D	D	М	М	Y	Y	Y	Y

Please return to: Cardamon Trial Coordinator, CR UK & UCL Cancer Trials Centre, 90 Tottenham Court Road, London, W1T 4TJ CRF Template V1 – 19 Oct 2010 Modified for **Cardamon** on 04 Jul 2019, v3.2 UCL CTC Use only: Form received: \_\_\_\_\_ Date form entered: \_\_\_\_\_ Initials: \_\_\_\_\_