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

CASE REPORT FORMS

Patient Initials	
Site	
Trial Number	

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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General instructions for completing Case Report Forms (CRFs)

Schedule of Forms

The schedule of forms below is designed to help you track patient visits. (This form does not need to be sent to the CTC).

- When a patient is registered fill in the Anticipated Date of visits according to the protocol
- When a CRF has been completed fill in the Completed Date
- When a CRF has been checked and sent fill in the Date Sent to UCL CTC date

CRF Name	Schedule	Anticipated Date (DD/MM/YYYY)	Completed Date (DD/MM/YYYY)	Date Sent to UCL CTC (DD/MM/YYYY)				
Preliminary Registration Form		/ /	/ /	/ /				
Full Registration Form + QoL		/ /	/ /	/ /				
Demographics Form		/ /	/ /	/ /				
Induction Form Cycle 1		/ /	/ /	/ /				
Induction Form Cycle 2		/ /	/ /	/ /				
Induction Form Cycle 3		/ /	/ /	/ /				
Induction Form Cycle 4		/ /	/ /	/ /				
End of Induction Form		/ /	/ /	/ /				
PBSCH, Post-PBSCH and Randomisation Forms + QoL		/ /	/ /					
Consolidation Form Cycle 1		/ /	/ /	/ /				
Consolidation Form Cycle 2		/ /	/ /	/ /				
Consolidation Form Cycle 3		/ /	/ /	/ /				
Consolidation Form Cycle 4		/ /	/ /	/ /				
Post-Consolidation Form + QoL		/ /	/ /	/ /				
Transplant Form		/ /	/ /	/ /				
Day 100 Post-ASCT Form + QoL		/ /		/ /				
Treatment Summary Form			/ /	/ /				
Maintenance Form (repeating up to 18 cycles)		/ /	/ /	/ /				
6 Month Post-start of Maintenance Form + QoL		/ /	/ /	/ /				
End of Maintenance Form		/ /	/ /	/ /				
Maintenance Summary Form		/ /	/ /	/ /				
Follow-up/Long Term Follow up Form		/ /	/ /	/ /				
Withdrawal/Lost to Follow Up Form	As required	N/A	/ /	/ /				
Serious Adverse Event (SAE) Report	As required	N/A	/ /	/ /				
Urgent Event (TMA) Form	As required	N/A	/ /	/ /				
Pregnancy Report	As required	N/A	/ /	/ /				
Lactational Exposure Report	As required	N/A	/ /	/ /				
1st Progression/Relapse Form	As required	N/A	/ /	/ /				
2nd Progression/Relapse Form	As required	N/A	/ /	/ /				
Death Form	As required	N/A	/ /	/ /				



General instructions for completing Case Report Forms (CRFs)

Registration Procedure

- To register a patient
 - All inclusion/exclusion criteria must be met
 - All required tests/scans must be completed as per the protocol
 - The registration form should be completed
- Once the above are completed you should fax the completed form to the CTC on 020 7679 9861
- A member of the CTC trials team will check the eligibility criteria and register the patient if all criteria are met
- Upon successful registration a trial number will be allocated to the patient and the Case Report Forms will be sent by email

Completing Forms

- Ensure all entries are clear, legible and written in black ink
- Avoid the use of abbreviations and acronyms
- The CRF should be completed as soon as possible after the scheduled visit
- The Principal Investigator (PI) is responsible for the accuracy of the data reported on the CRF
- Please ensure that all adverse events are recorded on the adverse event form and the form is attached
- 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 clearly 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 UCL 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)
- Serious Adverse Events (SAEs) must be faxed within 24 hours of the site being aware of the event to **020 7679 9861**
- If you have any queries or require clarification about completing a CRF please contact a member of the CARDAMON Trial Team on **020 7679 9860**
- Completed CRFs should be sent to the CTC within **30** days of the scheduled visit at the address below:

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

Corrections to entries

- If an error is made draw a single line through the item, then write the correct entry on an appropriate blank space near the original data point on the CRF and initial and date the change
- Do NOT
 - Obscure the original entry by scribbling it out
 - Try to correct/modify the original entry
 - Use Tippex or other correction fluid



General instructions for completing Case Report Forms (CRFs)

Review of CRF

Before sending the CRF to the CTC please review it by:

- Checking the legibility of the form entries
- Checking all corrections have been appropriately made
- Checking that all appropriate fields have been updated
 - If a test has not been performed or a measure not taken enter ND (Not Done), if applicable state the reason.

- If a measure is not applicable enter NA (Not Applicable)
- If data is unknown enter NK (Not Known). This should only be used once every effort to obtain the data has been exhausted

CRF Queries

- When the form is received at the CTC it will undergo various checks and the information added onto a trial database by CTC data management staff
- Query sheets may be generated which will detail a description of the data being queried, there will be a section to comment on the query
- A query may require an update to a CRF or just a clarification on the query sheet
- The query sheet must be signed and dated and the original sent to the CTC with a copy retained with the patient's CRF
- Data that is likely to be queried includes missing values, ambiguous entries, illogical data and out of range values

Patients stopping treatment

- In the event a patient stops trial treatment during Induction/ASCT/Transplant/ Consolidation please complete the Treatment Summary Form and continue to follow up the patient
- In the event a patient stops trial treatment during Maintenance please complete the Maintenance Summary Form and continue to follow up the patient
- If the patient withdraws consent or is lost to follow-up please complete the Withdrawal/Lost to Follow Up Form
- If the patient dies at any point after registration please complete the Death Form

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

Preliminary Registration Form

Patient Initials	
Site	
Date sent	D D M M Y Y Y Y
Sent by	
Phone number	
Research contact email address	

(This form has 2 pages including cover sheet)

Please fax form to Cardamon Trial Coordinator

<u>0207 679 9861</u>

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

Trial Number		To be completed by the UCL CTC
Date of Preliminary Registra	tion D D M M Y Y Y Y	
Registered by		
CANCER RESEARCH UK	Cancer Research UK and UCL Cancer Trials Centre	[±] UCL



Date of Birth

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Preliminary Registration form

Patient

Initials

Page 1 of 1

Preliminary Registration Patient Information
Sex: Male Female
Consultant
NHS Number
Informed Consent
Main trial consent form signed? 1= Yes 1= Yes 2= No 2= No
Version number of consent form signed $\begin{tabular}{ccc} \bullet \end{tabular}$ Date consent form signed $\begin{tabular}{cccc} D & D & M & M & Y & Y & Y \\ \end{tabular}$
Version number of patient information sheet • Has patient initialled all boxes? $1 = Yes$ 2 = No
Has patient signed and personally dated? 2= No Has person taking consent signed and 1= Yes dated (on same day as patient)? 2= No
Name of person taking consent:
Optional PET-CT sub-study consent form 1= Yes — please complete details below: signed? 2= No or not applicable — please skip to Patient Information section below
Version number of consent form signed $\begin{tabular}{ c c c c c } \hline & & & & & & & & & & & & & & & & & & $
Version number of patient information sheet Has patient initialled all boxes? $1 = Yes$ 2 = No
Has patient signed and personally dated? 1= Yes Has person taking consent signed and 1= Yes Z= No dated (on same day as patient)? 2= No
Name of person taking consent:
Treatment plan
Anticipated start of treatment
Has the patient's bone marrow biopsy Date scheduled D D M M Y Y Y Y Y A Bate scheduled? (1= Yes; 2= No)
Section to be completed by the PI or a co-investigator delegated the responsibility on the site delegation log
Based on peripheral blood and radiology results performed to date, does the patient 1= Yes provisionally meet the eligibility criteria for the Cardamon study? 2= No
Investigator name Investigator (print):
Date signed:
Preliminary registration does not guarantee study entry, and trial treatment must not start until full registration is complete

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 20.07.2017 Preliminary Registration Form v3.0 UCL CTC Use only: Form received: Date form entered: Initials: ___

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

Full Registration form

Patient Initials	
Site	
Date sent	D D M M Y Y Y Y
Trial Number (if known)	
Sent by	
Phone number	
Research contact email address	
Pharmacy contact email address	

(This form has 12 pages including cover sheet)

Please fax form to:

Cardamon Trial Coordinator 0207 679 9861

Or email form to:

*if sending by email please ensure DOB and NHS number are redacted

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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Full Registration form

Patient

Initials

An	swers to the following questions must be Yes (or N/A for Q11, if appropriate)			
	Inclusion Criteria	Yes	No	N/A
1	Age ≥ 18 years			
2	Life expectancy \geq 3 months			
3	Eastern Cooperative Oncology Group (ECOG) performance status 0–2			
4	 Previously untreated patient with symptomatic MM, with the exception of the following treatments: local radiotherapy to relieve bone pain and/or spinal cord compression bisphosphonates corticosteroids within the last 3 months. Within 14 days prior to study entry the maximum permitted dose is 160mg (i.e. 4 days at 40mg, or equivalent) unless otherwise agreed by the TMG) 			
5	 Measurable disease as defined by one of the following: Secretory myeloma: Monoclonal protein in the serum (≥10g/L) or monoclonal light chain in the urine (Bence Jones protein ≥200mg/24hours), or serum free light chain (SFLC, involved light chain ≥100mg/L provided the FLC ratio is abnormal) Non-secretory myeloma: Either ≥30% clonal plasma cells in bone marrow (aspirate or trephine) Or 10-30% clonal plasma cells in the marrow and >1 soft tissue or extra-osseous plasmacytoma ≥ 2 cm that is measurable for response assessment by CT or MRI 			
6	Suitable for high dose therapy and ASCT			
7	Adequate hepatic function, with serum ALT \leq 3.5 times the upper limit of normal and serum direct bilirubin \leq 2 mg/dL (34 µmol/L) within 14 days prior to registration			
8	 Adequate blood counts within 14 days prior to registration with: Absolute Neutrophil Count (ANC) ≥ 1.0 × 10⁹/L and patient has not received any growth factor support within 7 days of testing or ≥ 0.8 x 10⁹/L for patients with racial neutropenia Haemoglobin ≥ 8 g/dL (80 g/L) Platelet count ≥ 75 × 10⁹/L (≥ 50 × 10⁹/L if myeloma involvement in the bone marrow is > 50%) and patient has not received any platelet transfusions within 7 days prior to testing 			
9	Creatinine clearance (CrCl) \geq 30 mL/minute within 14 days prior to registration, either measured or calculated using a standard formula (e.g. Cockcroft and Gault)			
10	Written informed consent			
11	If female of childbearing potential (FCBP): has agreed to ongoing pregnancy testing and to prac- tice contraception (if female is not of childbearing potential, tick N/A) If male, patient has agreed to practice contraception			

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 17 Sep 2018, v4.0 UCL CTC Use only: Form received: _____ Date f Date form entered: _ Initials: _





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Full Registration form

Patient

Initials

-	<i>bility Checklist</i> wers to the following questions must be No												
Ans	Exclusion Criteria	Yes	No										
1	Pregnant or breast-feeding female (lactating women may participate if breastfeeding ceases for the dura- tion of trial treatment and until 12 months after last treatment)												
2	Previous systemic chemotherapy for myeloma, with the exception of steroids, as defined in the inclusion criteria												
3	3 Any major surgery within 21 days prior to registration which in the investigator's opinion would compro- mise trial treatment and/or the patient's ability to comply with trial visits. Surgery to relieve spinal cord compression or for treatment of bone fractures is permitted												
4	Acute active infection requiring treatment (systemic antibiotics, antivirals, or antifungals) 7 days prior to planned start of treatment, unless otherwise agreed by the TMG												
5	Known HIV infection or active Hepatitis B or C infection												
6	Unstable angina or myocardial infarction within 4 months prior to registration, NYHA Class III or IV heart failure, uncontrolled angina, history of severe coronary artery disease, severe uncontrolled ventricular ar- rhythmias, sick sinus syndrome, or electrocardiographic evidence of acute ischemia or Grade 3 conduction system abnormalities unless patient has a pacemaker												
7	Uncontrolled hypertension or uncontrolled diabetes within 14 days prior to registration												
8	 Non-haematologic malignancy within the past 3 years with the exception of: a) adequately treated basal cell carcinoma, squamous cell skin cancer, or thyroid cancer b) carcinoma in situ of the cervix or breast c) prostate cancer of Gleason Grade 6 or less with stable prostate-specific antigen levels d) cancer considered cured by surgical resection or unlikely to impact survival during the duration of the study, such as localized transitional cell carcinoma of the bladder or benign tumours of the adrenal or pancreas 												
9	Significant neuropathy (Grades 3–4, or Grade 2 with pain) within 14 days prior to registration												
10	Known history of allergy to Captisol [®] (a cyclodextrin derivative used to solubilize carfilzomib)												
11	Contraindication to any of the required concomitant drugs or supportive treatments, including hypersensi- tivity to all anticoagulation and antiplatelet options, antiviral drugs, or intolerance to hydration due to pre- existing pulmonary, renal or cardiac impairment												
12	Patient with pleural effusion(s) requiring thoracentesis or ascites requiring paracentesis within 14 days prior to registration												
13	Any other clinically significant medical disease or condition that, in the Investigator's opinion, may inter- fere with protocol adherence or a subject's ability to give informed consent												
	esult 2 = Positive Date of pregnancy test	To be perfo within 14 c to registrat bingector	lays pric tion										

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 17 Sep 2018, v4.0 UCL CTC Use only: Form received: _____ Date f Date form entered: _



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Full	Regi	istrat	ion	form

Patient

Initials

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Registration
Has the patient been allocated a trial number? Yes—please enter trial number and skip to pre-treatment assessments on page 4
No-please complete section
Informed Consent below:
Main trial consent form signed? 1= Yes 2= No 1= Yes 2= No 2= No
Version number of consent form signed Date consent form signed D D M M Y Y Y Y
Version number of patient information sheet • Has patient initialled all boxes? 1= Yes 2= No
Has patient signed and personally dated?1= Yes 2= NoHas person taking consent signed and dated (on same day as patient)?1= Yes 2= No
Name of person taking consent:
Optional PET-CT sub-study consent form 1= Yes — please complete details below: signed? 2= No or not applicable — please skip to Patient Information section below
Version number of consent form signed Date consent form signed D D M M Y Y Y Y
Version number of patient information sheet • Has patient initialled all boxes? 1= Yes 2= No
Has patient signed and personally dated?1= Yes 2= NoHas person taking consent signed and dated (on same day as patient)?1= Yes 2= No
Name of person taking consent:
Patient Information
Consultant name
Sex Male Female
NHS Number
Anticipated start of treatment D D M M 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 17 Sep 2018, v4.0 UCL CTC Use only: Form received: ______ Date form entered: _____





Cardamon	Patient Initials	Patient Date of Birth	D	D	М	М	Y	Y	Y

Full Registration form

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Pre-treatment ass	essments													
Date of Assessment	D D	М	MY	Y	Y	Y								
Height (cm)			•		Bloo (mm	d Pressure Hg) ¹				/				
Weight (kg)			•		Pulse	e rate (bpm)								
Temperature (⁰ C)			•		-	iratory Rate oths per								
ECOG Performance Status	con	st be <u><</u> 2 un nplications eloma			minu	¹ If patient (delete as a								
Date ECOG D performed	D M	Μ	Y Y	Y	Y	Investigato name (prin								
	ι] Ι			₽		Investigato signature:	r							
						Date signed	d: D	D	M	Λ	Y Y	ŕ	Y	Y
Quality of Life Que Has the Quality of Life			ted?	2= No	; to be c	e send to the completed a please prov	ind sent p	orior to a	day 1 of	^r cycle	1			
Haematology														
Date of sample	D D	М	M Y	Y	Y	withii	performed n 14 days pr jistration	rior						
	Test Resu	lt												
Haemoglobin g/dL		•		<u>></u> 8 g/dL (8	80 g/L)	² If pai	tient has ra	acial neu	tropenia	a, the i	nvestig	ator n	nav co	onfirm
Platelets x 10 ⁹ /L					′L (<u>></u> 50 x10 a in marro	⁹ /L eligibili ow is Invest	ty below: igator						,	
Neutrophils x10 ⁹ /L ²		•		<u>></u> 1.0 x 10 ^s due to rac)/L (<u>></u> 0.8 x1 cial neutro _l	name 10 ⁹ if penia) Invest signat								
White Blood Cell (WBC) Count x10 ⁹ /L			•			Date s	igned:) 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 17 Sep 2018, v4.0 UCL CTC Use only: Form received: _____ Date f Date form entered: _



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Full Registration form Biochemistry Μ M To be performed within 14 Date of sample days prior to registration* Calcium (corrected) mmol/L Potassium mmol/L • Sodium mmol/L Creatinine µmol/L **Creatinine Clearance** <u>></u>30 mL/minute ml/min Serum urate µmol/L Urea (mmol/L) • Bilirubin must be <u><</u>2 Bilirubin µmol/L mg/dL (34 µmol/L) Albumin g/L Alkaline Phosphatase IU/L Alanine Transaminase ALT must be ALT upper limit of normal <3.5 x ULN (IU/L) (ALT) IU/L Aspartate Transaminase (AST) IU/L Phosphate mmol/L Total Protein g/L Lactate dehydrogenase *Within 6 weeks (LDH) IU/L prior to registration *Within 6 weeks B2 microglobulin mg/L prior to registration

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 17 Sep 2018, v4.0 UCL CTC Use only: Form received: Date form entered:

Initials:



Patient

Initials

Patient



Date of Birth

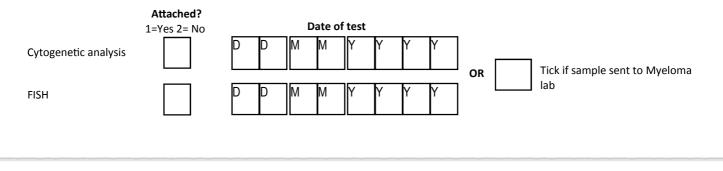
M

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Full Registration form Bone marrow biopsies Bone marrow aspirate Date of sample: 1= Present, complete % of plasma cells: % 2= Present, not measured 3= Absent 4= Not done M Date of sample: Bone marrow trephine 1= Present, complete % of plasma cells: % 2= Present, not measured 3= Absent 4= Not done 3 bone marrow samples must be taken and sent to the central labs prior to starting trial treatment (see details below) 1 peripheral blood sample must also be taken and sent to the central lab (see details below) N.B. Sites unable to perform cytogenetics/FISH must send an additional 4-8ml of BM aspirate to the UCL Cancer Institute Myeloma Lab Sent? Date sample sent to lab 1=Yes 2= No Μ BM aspirate for MRD (2ml) to HMDS, Leeds BM aspirate for genomic analyses (8ml) to the UCL Cancer Institute Myeloma Lab Peripheral blood sample for genomic analyses (8ml) to the UCL Cancer Institute Myeloma Lab BM trephine block (or slides) for immunohistochemistry to M UCL Department of Research Pathology If No to any of the above, specify a reason: Molecular tests Baseline molecular tests are being reviewed centrally on the Cardamon trial, please attach a copy of the anonymised report sheet

to the registration form when it is faxed.

N.B: Sites unable to perform cytogenetics/FISH must send an additional 4-8ml of BM aspirate to the UCL Myeloma Lab



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 17 Sep 2018, v4.0



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Full Registration form

Patient

Initials

Soft tissue plasmacytoma/Extramedullary lesions
Does the patient have any soft tissue plasmacytomas/ Extramedullary lesions? 1= Yes, complete date of test and a separate line for each site involved 2= No
If yes, date of test D D M M Y Y Y Y L Long axis Short axis
Site involved: Bidimensional measurements (cm): X
Site involved: Bidimensional measurements (cm): X
Site involved: Bidimensional measurements (cm): X
PET-CT sub-study: Baseline scan details (please complete for patients participating in the PET-CT sub-study only)
Date of baseline D D M M Y Y Y Y Date images transferred D D M M Y Y Y Y P Date images transferred to PET-CT scan:
Myeloma diagnosis
D D M M Y Y Y Y
Stage of disease (ISS stage): 1= I 2= II 3= III Type of myeloma: 1= Secretory 2= Non-secretory
Paraprotein expression: (choose <u>one</u> option only) 1= Single paraprotein expressed 2= Light chain only 3 = Biclonal 4 = N/A, non-secretory patient
Date of test
Paraprotein type key: 1 = IgG, 2 = IgA, 3 = IgM, 4 = IgD 4= Present, please complete result
Specify paraprotein type: Serum paraprotein: 5= Too faint to quantify 6= Absent 7= Not Done (g/L)
Specify 2nd paraprotein : (If biclonal) Serum paraprotein: 5= Too faint to quantify 6= Absent (g/L) 7= Not Done
Serum free light chain: Kappa (mg/L)
Serum free light chain: Lambda (mg/L)
Serum free light chain Kappa/Lambda ratio:

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 17 Sep 2018, v4.0 UCL CTC Use only: Form received: _____ Date f



Patient

Initials

Cancer Research UK and UCL Cancer Trials Centre

Date of Birth

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Full Registration form	Page 9 of 12
Urinary light chain measurement 1= Present, quantifiable Please complete 24h BJP result (in g/24h): 2= Too faint to quantify (24h BJP only) 3= Absent 5= Present, not formally quantified (if unable to perform 24h BJP)	1= Kappa 2= Lambda 3 = N/A
Immunofixation 1= Positive Date of test D M M Y Y Immunofixation Serum 2= Negative Date of test D D M M Y Y	Y Y
Immunofixation Urine 1= Positive Date of test D D M M Y Y 2= Negative	Y Y
Imaging (as per local policy) By if patient is participating in PET-CT sub study please also complete section on page 3 MRI 1 = Evidence of myeloma 3 = Not done 1 = Not done 1 = Not outere 1 = Son outere of myeloma 3 = Not done 1 = Son outere of myeloma 3 = Not done 1 = Son outere of myeloma 3 = Not done 1 = Son outere of myeloma 3 = Not done 1 = Son outere of myeloma 3 = Not done 1 = Son outere of myeloma 3 = Not done 1 = Son outere of myeloma 3 = Not done 1 = Son outere of myeloma 3 = Not done 1 = Son outere of myeloma 3 = Not done 1 = Son outere of myeloma 3 = Not done 1 = Son outere of myeloma 3 = Not done 1 = Son outere of myeloma 3 = Not done 1 = Son outere o myeloma 3 = Not done 1 = Son outere o myeloma 3 = Not done 1 = Son outere o myeloma 3 = Not done	Lytic or focal lesions? 1= Yes 2= No
Other imaging 1= Evidence of myeloma 2= No evidence of myeloma 3= Not done D D M M Y Y Y Y Y Specify type of other imaging	
Creatinine Clearance (EDTA) ml/min OR tick if not done	

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 17 Sep 2018, v4.0 UCL CTC Use only: Form received: _____ Date form entered: _____ Initials: ___



Patient

Initials

Full Registration form



Patient Date of Birth D

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HCV Hepatitis B surface antibody HIV Hepatitis B core antibody ¹ Hepatitis B surface antigen HBV DNA (if indicated, otherwise enter ND) Note: Active hepatitis B / C infection and / or known HIV infection mere exclusion criteria. ¹ If patient has previous Hep B infection, the investigator may confirm eligibility below (see Appendix 4 of protocol for full details): Investigator name (print): Investigator signature: Date signed: D M M M <	rology		A 1	
Test Result Test Result HCV Hepatitis B surface antibody Hepatitis B core antibody ¹ HIV Hepatitis B core antibody ¹ Hepatitis B core antibody ¹ Hepatitis B surface antigen HBV DNA (if indicated, otherwise enter ND) Intere exclusion criterio. ¹ If patient has previous Hep B infection, the investigator may confirm eligibility below (see Appendix 4 of protocol for full details): Investigator name (print): Investigator Investigator name (print): Date signed: Date signed: D MIGA scan 1= Normal ECG 1= Normal 2= Abnormal, specify: Date of D MIGA 2= Abnormal, specify:	Date of Serology:			
HCV Hepatitis B surface antibody HIV Hepatitis B core antibody ¹ Hepatitis B surface antigen HBV DNA (if indicated, otherwise enter ND) Note: Active hepatitis B / C infection and / or known HIV infection are exclusion criteria. ¹ If patient has previous Hep B infection, the investigator may con- firm eligibility below (see Appendix 4 of protocol for full details): Investigator name (print): Investigator Investigator signature: Date signed: D MM Y Y Y Investigator Investigator signature: Date signed: D MM Y Y Y Investigator signature: Date signed: Date signed: D MICA scan Investigator signature: Investigator Date of test: Date of concordiogram 2 = Abnormal, specify: Date of test: Date of 2 = Abnormal, specify: Date of test: Date of test: D MM Y Y Y ECG 1= Normal 2 = Abnormal, specify:	Result Codes (please enter below	v): 1 = Positive 2 = Negative		
HIV Hepatitis B core antibody 1 Hepatitis B surface antigen HBV DNA (if indicated, otherwise enter ND) Wote: Active hepatitis B / C infection and / or known HIV infection are exclusion criteria. 1 If patient has previous Hep B infection, the investigator may con- firm eligibility below (see Appendix 4 of protocol for full details): Investigator name (print): Investigator and (print): Investigator signature: Date signed: Date signed: D MM Y Y Y MUGA 1= Normal 2= Abnormal, specify: Date of test: D ECG 1= Normal 2= Abnormal, specify: Date of test: D M	Test	Result		Result
Hepatitis B surface antigen HBV DNA (if indicated, otherwise enter ND) Vote: Active hepatitis B / C infection and / or known HIV infection in exclusion criteria. If patient has previous Hep B infection, the investigator may confirm eligibility below (see Appendix 4 of protocol for full details): Investigator Investigator Investigator Investigator Signature: Date signed: Date signed: D MUGA scan I = Rormal ECHO / I = Normal Becomplexity: Date of Date of D MUGA scan Date of ECHO / I = Normal Becomplexity: Date of Date of D MUGA scan Date of ECG I = Normal 2 = Abnormal, specify: Date of Date of D MUGA I = Normal 2 = Abnormal, specify: Date of Date of D MUGA I = Normal 2 = Abnormal, specify: Date of D M Y Y	HCV		Hepatitis B surface antibody	
whete: Active hepatitis B / C infection and / or known HIV infection are exclusion criteria. Inf patient has previous Hep B infection, the investigator may confirm eligibility below (see Appendix 4 of protocol for full details): Investigator name (print): Investigator signature: Date signed: D MM Y Y Y P M M Y Y Y Date signed: D MM Y Y Y	HIV		Hepatitis B core antibody ¹	
are exclusion criteria. ¹ If patient has previous Hep 8 infection, the investigator may confirm eligibility below (see Appendix 4 of protocol for full details): Investigator Investigator name (print): Investigator Investigator Date signed: Date signed: D P M M Y Y Y Y ardiac function Date signed: be of scan performed: 1 = Echocardiogram 2 = MUGA scan ECHO / 1 = Normal 2 = Abnormal, specify: Date of Date of Date of Date of Date of D M M Y Y Y Y Y Y	Hepatitis B surface antigen			
Investigator name (print): Investigator signature: Date signed: Date s		nd / or known HIV infection		
signature: Date signed: Date signed: Date signed: Date signed: Date of Scan performed: 1 = Echocardiogram 2 = MUGA scan ECHO / 1 = Normal 2 = Abnormal, specify: ECG 1 = Normal 2 = Abnormal, specify: Date of D M M Y Y Y Y To be performed within 6 weeks prior to registration ECG 1 = Normal 2 = Abnormal, specify: Date of D M M Y Y Y Y			Investigator	
Date signed: Image: Constraint of the second seco				
be of scan performed: 1 = Echocardiogram 2 = MUGA scan ECHO / 1 = Normal 2 = Abnormal, specify: Date of Date of 2 = Abnormal, specify: Date of Date of 2 = Abnormal, specify: Date of Date of 2 = Abnormal, specify: Date of 2 = Abnormal, specify: Date of 1 = Normal 2 = Abnormal, specify: Date of 0 0 0 0 0 0 0			Date signed:	M Y Y Y
be of scan performed: 1 = Echocardiogram 2 = MUGA scan ECHO / 1 = Normal 2 = Abnormal, specify: Date of Date of 2 = Abnormal, specify: Date of Date of 2 = Abnormal, specify: Date of Date of 2 = Abnormal, specify: Date of 2 = Abnormal, specify: Date of 1 = Normal 2 = Abnormal, specify: Date of 0 0 0 0 0 0 0				
1= Echocardiogram 2= MUGA scan ECHO / MUGA 1= Normal 2= Abnormal, specify: Date of test: Date of test: Date of test: To be performed within 6 weeks prior to registration ECG 1= Normal 2= Abnormal, specify: Date of test: Date of test: Date of test: Date of test:	rdiac function			
2= MUGA scan ECHO / MUGA 1= Normal 2= Abnormal, specify: Date of test : D Date of test : D MUGA 1= Normal 2= Abnormal, specify: ECG 1= Normal 2= Abnormal, specify:	pe of scan performed:			
MUGA 2= Abnormal, specify: test: To be performed within 6 weeks prior to registration ECG 1= Normal 2= Abnormal, specify: Date of test: D M M Y Y Y Y	1= Echocardiogram 2= MUGA scan			
2= Abnormal, specify:		specify:	test :	
To be performed within 14 days prior registration		specify:	[] [I M Y Y Y Y
			To be performed w	vithin 14 days prior registration

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 17 Sep 2018, v4.0 UCL CTC Use only: Form received: _____ Date f





Patient Date of Birth n

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1= Yes

2= No

Full Registration form

Patient

Initials

Page 11 of 12

Medical History

Enter details of all significant conditions past or present, e.g. hypertension, allergies, malignancies, details of any recent surgery, etc. Where a condition is continuing and symptomatic (e.g. uncontrolled hypertension), please insert the CTCAE grade If condition is ongoing enter C (Continuing) as End Date.

Does the patient have a significant medical history or baseline symptoms?

No	Condition or Procedure please record all significant conditions or procedures. Use the CTCAE adverse event name where applicable	Status Resolved/ Asymptomatic = 0 Continuing = 1	Onset Date (DD/MM/YYYY)	End Date (DD/MM/YYYY)	Specify grade of Adverse Event	Treatment Ongoing 1=Yes 2=No
1			/ /	/ /		
2			/ /	11		
3			/ /			
4			/ /	/ /		
5			/ /			
6			/ /			
7						
8			/ /			
9			/ /	/ /		
10			/ /	/ /		
11			/ /	/ /		
12			/ /	/ /		

NOTE: please refer to the exclusion criteria for a full list of excluded conditions / procedures





Patient Date of Birth D

1= Yes—please specify below

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Page 12 of 12

Full Registration form

Patient

Initials

Concomitant Treatment of Interest

1= Yes—please specify below Has the patient received any local radiotherapy treatment? 2= No **Treatment Site** Total Dose (Gy) **Treatment Start Date Treatment End Date Number of Fractions** (DD/MM/YYYY) (DD/MM/YYYY) / / / / / / / / / / /

Has t	he patient received any bisphosphonate	1= Yes—please sp 2= No	ecity below	
	Generic Drug Name	Start Date (DD/MM/YYYY)	End Date (DD/MM/YYYY)	Treatment Ongoing (1 = Yes; 2 = No)
1		/ /	/ /	
2		/ /	/ /	

	(DD/MM/YYYY)	End Date (DD/MM/YYYY)	Dose	Unit	Total days given	Treatment Ong (1 = Yes; 2 = N
	/ /	/ /				
	/ /	/ /				_
ovestigator must sign to co				ate com	pleted:	
	Investigator signatur	e:		ate comp	oleted:	
	Investigator signatur	e:		ate comp		

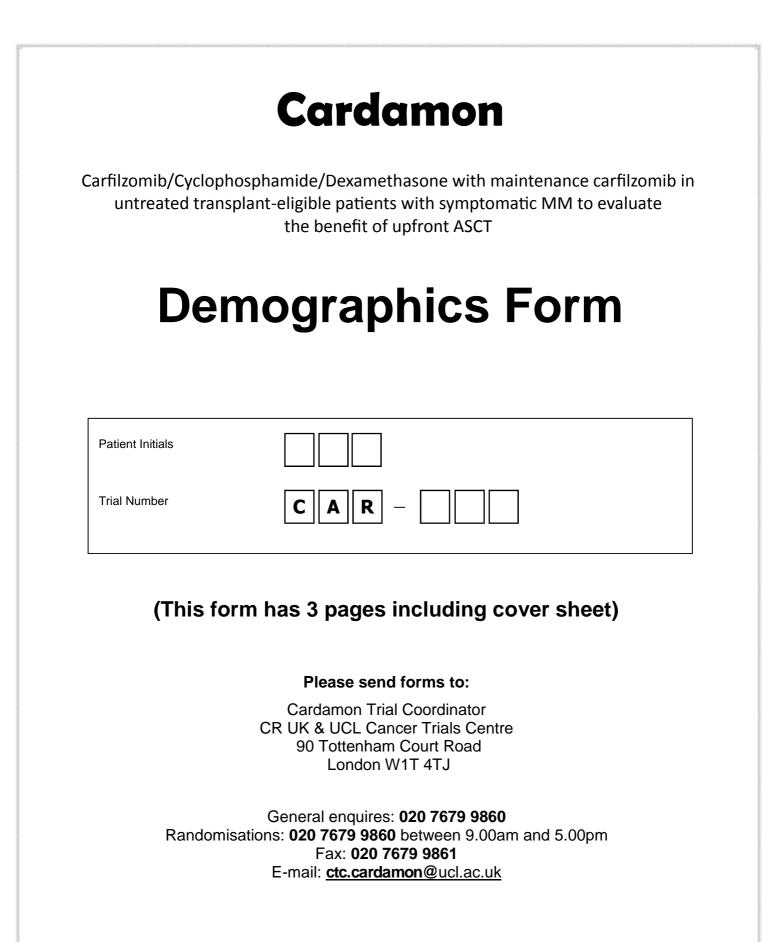
Please return to: Cardamon Trial Coordinator, CR UK & UCL Cancer Trials Centre, 90 Tottenham Court Road, London, W1T 4TJ
CRF Template V1– 19 Oct 2010 Modified for Cardamon on 17 Sep 2018, v4.0

Registered by:

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Date of Registration





Cancer Research UK and UCL Cancer Trials Centre







Additional instructions for completing forms

Demographics Form

The Demographics Form is used to capture demographic information about the patient.

Completing the form

- For new patients, this form should be completed and submitted at baseline with the registration form and after the patient has provided informed consent.
- For existing patients, this form should only be completed after re-consent to v7.0 of the PIS and consent form, or later.

Specific Fields

- Ethnicity
 - Only one ethnicity box should be ticked
 - Other, please specify- If ethnicity is not detailed please enter it in the box provided

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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Cardamon

Patient Initials

Demographics Form
Informed Consent
Main trial consent form signed? 1= Yes 2= No
Version number of consent form signed NOTE: Ethnicity should only be provided if patient has
Version number of patient information sheet
Date consent form signed D D M M Y Y Y Y
Ethnicity
Please tick one of the following options
White: White - British 1 White - European 2 White - Other* 3
Mixed Race: White and Black 4 White and Black 6 White and Asian 6
Asian or Asian British: Indian 7 Pakistani 8 Bangladeshi 9 Asian - Other* 10
Black or Black British: Caribbean 11 African 12 Black - Other*: 13
Chinese 14 Arab 15 Any other ethnic group* 16 Any other mixed / multiple ethnic background* 17
*Other, please specify
Name of person completing form: Signature of person completing form: Date completed: D D M Y Y

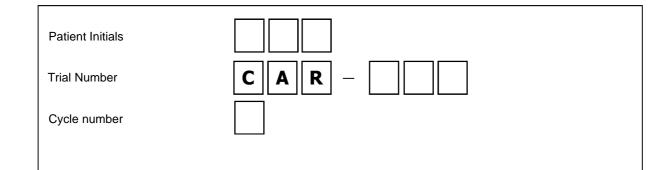
Please return to: Cardamon Trial Coordinator, CR UK & UCL Cancer Trials Centre, 90 Tottenham Court Road, London, W1T 4TJ

CRF Template V3 06/Jan/2017 Modified for Cardamon on 17 Sep 2018, v1.0 Date form entered: Date form received: ____ Initials: _____ Initials: __ __ Initials: _____ Date entered: __ For UCL CTC use only: Date Checked: ____



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

Induction form



(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







Page 2 of 7

Additional instructions for completing forms

The Induction Form is used to record the first 4 cycles of CarCyDex treatment for the Patient.

- Please ensure that you are using the correct units (i.e. haemoglobin in g/dL). If your local report uses different units please convert these before entering them on the form
- Omission/Reduction/Delay: Please do not leave these blank, if there were no omissions, reductions or delays please ensure that you have entered "0" in each box. A discrepancy will be raised for all fields left blank
- If the patient has non-secretory or light chain only myeloma, there is no need to answer the paraprotein and immunofixation questions in the efficacy section (page 1). Please simply enter N/A in these fields
- Disease responses must be confirmed by the local investigator and done on day 1 of each cycle. The response assessment section for cycle 1 should be left blank, however, paraprotein, serum free light chain and urinary Bence Jones protein levels must be recorded if available
- Disease response assessment should be based on blood and/or urine tests performed at the start of each cycle (day 1, ± 7 days), this must be assessed by the PI or delegated investigator (see appendix 3 of protocol).
- Disease response for each cycle must be assessed according to the paraprotein/BJP/SFLC results of tests performed at the beginning of the subsequent cycle, for example, response to cycle 1 would be assessed on cycle 2, day 1, and documented on the cycle 2 CRF.
- At the end of induction, disease assessment must be performed within 14 days of the last treatment and prior to PBSCH. This should be reported on the end of induction CRF
- Please ensure that the patient diary card has been completed and returned
- Pregnancy tests should be performed in each cycle prior to the first dose being given
- Please ensure a progression/relapse form is submitted for patients with progressive disease
- If the response is not yet confirmed, please send the CRF regardless and re-send the amended page when the response is confirmed

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.
- The Principal Investigator (PI) is responsible for the accuracy of the data reported on the CRF
- Please ensure that all adverse events are recorded on the adverse event form and the form is attached
- 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 clearly 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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Cardamon

Patient

Initials

Induction Form

Page 3 of 7

Cycle No:



Haematology

Test	Day 1 result	Day 2 result	Day 8 result	Day 9 result	Day 15 result	Day 16 result
Date (dd/mm/yyyy)						
Haemoglobin (g/dL)						
WBC (x10 ⁹ /L)						
Platelets (x 10 ⁹ /L)						
Neutrophils (x10 ⁹ /L)						
Lymphocytes (x 10 ⁹ /L)						
Blood pressure (mmHg)						

- Patients must have FBC and biochemistry tests prior to days 1, 8, & 15 of each cycle •
- These are to be repeated on days 2, 9 & 16 if clinically indicated •
- The validity period for FBC is 48 hours, and for biochemistry it is 72 hours •



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Patient

Initials

Induction Form

Page 4 of 7

Cycle No:

Biochemistry

Test	Day 1 result	Day 8 result	Day 15 result
Date (dd/mm/yyyy)			
Calcium (corrected) (mmol/L)			
Potassium (mmol/L)			
Phosphate (mmol/L)			
Urea (mmol/L)			
Sodium (mmol/L)			
Serum Urate (µmol/L)			
Creatinine (µmol/L)			
Creatinine clearance (ml/min) if clinically indicated, otherwise enter ND			
Albumin (g/L)			
Bilirubin (μmol/L)			
Alkaline Phosphatase (IU/L)			
Aspartate Transaminase (IU/L)			
Alanine Transaminase (IU/L)			

Adverse events

Has patient returned their diary card?

1 = Yes 2 = No

Did the patient experience any adverse events?

1 = Yes (please ensure adverse event form is submitted) 2 = No

Pregnancy test (for females of child bearing potential only)

Result:1= Negative 2 = Positive 3= Not applicableDate of pregnancy test	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 17 Sep 2018, v4.0 UCL CTC Use only: Form received:

Date form entered: _



Cancer Research UK and UCL Cancer Trials Centre



Cardamon	Trial Number	CA	R	- [Patient Initials			
Induction Form								Pag	e 5 of	⁻ 7
Cycle No:]									
Efficacy assessments										
Date of test D D	M M Y	Y Y	Y							
Intervence	Paraprotein expressi (choose <u>one</u> option o		-	it chain o	rotein expre nly	essed				
Paraprotein type key: 1 = IgG,	2 = IgA, 3 = IgM, 4 = I	gD								
Specify paraprotein type:	Serum p	araprotein			aint to quar nt	complete res	ult		(g/L)
Specify paraprotein type:] Serum pa	araprotein			aint to quar nt	complete res ntify	ult		(g/L)
Serum free light chain: Kappa	i (mg/L)]•[OR	Т	ïck if not don	e		
Serum free light chain: Lamb	da (mg/L)].[OR	Т	ick if not don	e		
Serum free light chain Kappa/Lambda ratio:				range of .ambda I	- FLC ratio:		[
Urinary light chain measurem	ient									
1= Present, quantifiable Please comple 2= Too faint to quantify 3= Absent 5= Present, not formally (if unable to perform 24	quantified	24h):]	•	Light cha <i>(please</i> <u>on</u>		2:	= Kappa = Lamb = N/A	
Immunofixation (only to	-									
Immunofixation Serum	1= Positive 2= Negative 3= Not done	Date c	of test	DD) M	MY	Y Y Y			
Immunofixation Urine	1= Positive 2= Negative 3= Not done	Date o	of test	D C) M	MY	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 17 Sep 2018, v4.0 UCL CTC Use only: Form received: ______ Date for



Cancer Research UK and UCL Cancer Trials Centre

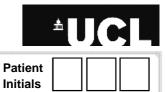
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Number



Induction Form	Page 6 of 7
Cycle No: Please note: this page should not be completed in cycle	1
Response assessment This section must be completed and signed by the local principal investigator / del day 1 of each cycle (from cycle 2 onwards)	egated investigator and done on
Date of response assessment	Y
	nent—to be followed up as per protocol on and treatment summary form)
Investigator name (print): Investigator signature: D Date signed: D	M M Y Y Y Y
 Disease response assessment should be based on blood and/or urine tests performed a days), this must be assessed by the PI or delegated investigator (see appendix 3 of protoc) Disease response for each cycle must be assessed according to the paraprotein/BJP/SF beginning of the subsequent cycle, for example, response to cycle 1 would be assessed o the cycle 2 CRF. At the end of induction, disease assessment must be performed within 14 days of the lass should be reported o the end of induction CRF 	col) FLC results of tests performed at the on cycle 2, day 1, and documented on

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 17 Sep 2018, v4.0 UCL CTC Use only: Form received: ______ Date for Date form entered: _ Initials:



Cancer Research UK and UCL Cancer Trials Centre

Cardamon nduction Form		Trial Number	CAR		Patier	·· I II II
nduction Form						*
						Page 7 of 7
ycle No: D Date cycle started: D Patient BSA •		M M Y m ² Patients w	vith a BSA >2.2m ² sh	Y nould receive dose base	ed on BSA of 2.2m ²	
Did the patient receive pro hydration in line with prot		IV 1 = Yes 2 = No	Any delays redu during this cycle	ictions or omissions e of induction?	2 - No belo	ase complete all boxes in tal ow (if no delay / reduction / ission, please enter = 0)
Drug	Day	Dose given	Route (PO or IV)	Omission (see codes below)	Reduction (see codes below)	Delay (see codes below)
Dexamethasone	1	mg				
(40mg PO or IV)	8	mg				
	15	mg				
	22	mg				
Carfilzomib	1	mg				
(56mg/m ² * IV)	2	mg				
*except cycle 1 days 1 & 2	8	mg				
(20mg/m ²)	9	mg				
	15	mg				
	16	mg				
Cyclophosphamide	1	mg				
(500mg PO Or 375mg IV)	8	mg				
	15	mg				
D=No delay/reduction/omissic 5=Allergic reaction/hypersensi specify below), 13=Protocol a 12 = OTHER Reduction	itivity 7 pprove	=Infection, 8=Patient d reduction/omission	Choice, 9=Clinician			
Name of person completing form:		Signature	of person completing	form: Da	ite completed:	
				D	D M M	YYYY
The site PI or delegated investige	ator mu	st sign to confirm that in	nformation within the	CRF is accurate		
nvestigator name:		Investigato	or signature:	Da	ite completed:	
				D	D M M	<u> </u>

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 17 Sep 2018, v4.0 UCL CTC Use only: Form received: _____ Date form entered: _____

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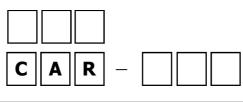


Carfilzomib/Cyclophosphamide/Dexamethasone with maintenance carfilzomib in untreated transplant-eligible patients with symptomatic MM to evaluate the benefit of upfront ASCT

End of Induction Form

Patient Initials

Trial Number



(This form has 6 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







Additional instructions for completing forms

Page 2 of 6

The End of Induction Form should be used to collect patient data once they have completed their first 4 cycles of CarCyDex treatment. The End of Induction Form should be completed within 14 days of the completion of the 4th cycle of CarCyDex Induction and prior to PBSCH.

Specific Fields

- Please ensure that you are using the correct units (i.e. haemoglobin in g/dL). If your local report uses different units please convert these before entering them on the form.
 - Please ensure that you have answered the regarding adverse events
 - If no adverse events occurred, then simply answer "no" and there is no need to attach an adverse event form
 - If an adverse event is still ongoing from the previous cycle <u>you must provide an adverse</u> <u>event</u> form and enter these AEs, using the original start date of the AE
- For tests which are only required if clinically indicated (e.g. 24hr BJP) please indicate if they were not done by completing the boxes with ND
- Disease responses must be confirmed by the local investigator
- Please ensure a progression/relapse form is submitted for patients with progressive disease

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.
- The Principal Investigator (PI) is responsible for the accuracy of the data reported on the CRF
- Please ensure that all adverse events are recorded on the adverse event form and the form is attached
- 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 clearly 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



Cancer Research UK and UCL Cancer Trials Centre



Cardamon	Trial CAR - Patient Initials
End of Induct	tion Form Page 3 of 6
Date of Haematology:	D D M M Y Y Y Y
Haemoglobin g/dL	• •
Platelets x 10 ⁹ /L	Lymphocytes x 10 ⁹ /L
Neutrophils x10 ⁹ /L	
Biochemistry	
Date of Biochemistry	
Calcium (corrected) mmol/L	Bilirubin μmol/L
Potassium mmol/L	Albumin g/L
Sodium mmol/L	Alkaline Phosphatase IU/L
Creatinine μ mol/L	Alanine Transaminase (ALT) IU/L
Creatinine Clearance ml/min	Or Aspartate Transaminase (AST) IU/L
Serum urate µmol/L	Phosphate mmol/L
Urea (mmol/L)	
Adverse events	
Has patient returned the	eir diary card? 1 = Yes 2 = No
Did the patient experien between their last cycle post-induction assessme	of induction and their 1 = Yes (please ensure adverse event form is submitted)
Soft tissue plasmacyto	ma/Extramedullary lesions (if present at registration)
Does the patient have any soft Extramedullary lesions?	tissue plasmacytomas/ 1= Yes, complete date of test and a separate line for each site involved 2= No
If yes , date of test	D D M M Y Y Y Y Long axis Short axis
Site involved:	Bidimensional measurements (cm):
Site involved:	Bidimensional measurements (cm):
Site involved:	Bidimensional measurements (cm):

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 17 Sep 2018, v4.0 UCL CTC Use only: Form received: ______ Date for



Cancer Research UK and UCL Cancer Trials Centre



Cardamon	Trial Number CAR		Patient Initials
End of Induction For	m		Page 4 of 6
Efficacy assessments			
Date of test D D M	M Y Y Y Y		
invelonia, piedse	2 = L	ingle paraprotein expressed ight chain only biclonal	
Paraprotein type key: 1 = IgG, 2 = IgA,	3 = IgM, 4 = IgD		
Specify paraprotein type:	Serum paraprotein	4= Present, please complete resu 5= Too faint to quantify 6= Absent 7= Not Done	ult (g/L)
Specify paraprotein type:	Serum paraprotein	4= Present, please complete resu 5= Too faint to quantify 6= Absent 7= Not Done	ult (g/L)
Serum free light chain: Kappa (mg/L)	•	OR Ti	ck if not done
Serum free light chain: Lambda (mg/	L)	OR Ti	ck if not done
Serum free light chain Kappa/Lambda ratio:		al range of a/Lambda FLC ratio:	_
Uningen, light chain magazurgenant			
Urinary light chain measurement 1= Present, quantifiable Please complete 24h BJ 2= Too faint to quantify (24h BJP) 3= Absent 5= Present, not formally quantified (if unable to perform 24h BJP)	only)	Light chair (please cl one	
Immunofixation (only to confirm	n CR)		
Immunofixation Serum 2=	Positive Negative Date of test Not done	D D M M Y Y	Y Y
Immunofixation Urine 2=	Positive Negative Date of test Not done	D D M M Y Y	YY

 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 17 Sep 2018, v4.0

 UCL CTC Use only:
 Form received: ______

 Date form entered: ______
 Initials: ______

CANCER RESEARCH UK	Cancer Research UK and UCL Cancer Trials Centre	UC
Cardamo	on Trial CAR - Patient Initials	
End of In	nduction Form	Page 5 of 6
Imaging (Or	Only if clinically indicated, or if soft tissue plasmacytomas present at registration)	Lytic or focal lesions
	Date of test	1= Yes 2= No
MRI	1= Evidence of myelomaDDMMYYYY2= No evidence of myeloma3= Not doneDDMMYYY	
СТ	1= Evidence of myeloma2= No evidence of myeloma3= Not done	
PET	1= Evidence of myeloma D D M M Y Y Y 2= No evidence of myeloma 3= Not done D D M M Y Y Y	
Skeletal surve	/ey 1= Evidence of myeloma 2= No evidence of myeloma 3= Not done D D M M Y Y Y Y	
Other imagir	ting 1= Evidence of myeloma 2= No evidence of myeloma 3= Not done D D M M Y Y Y Y	
	Specify type of other imaging	
Cardiac func Type of scan per 1=		
ECHO / MUGA	1= Normal 2= Abnormal, specify:	Y Y Y
MUGA	2= Abnormal, specify:	
ECG	1= Normal Date of test D D M M	YYYY



Cancer Research UK and UCL Cancer Trials Centre

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End of Induction Form					Pc	ige 6	of 6
Response post-induction							
This section must be completed and signe	d by the local princip	al investigator or deleg	ated investi	gator			
Date of response assessment	D D	M M Y Y	Y Y				
Patient's response to inductic (choose <u>one</u>	on treatment:	1= sCR 2= CR 3= VGPR 4= PR		ceed to pe	ripheral	blood s	stem
		5= MR 6= SD } Patient off µ protocol (Pla					
		7= PD — Patient off pro protocol (Please con summary form)					
Is this response confirmed? (<i>(refer to IMWG criteria/protocol</i> Investigator name (print):		Date confirmed: D	D M D M	M Y	/ Y ///////////////////////////////////	Y	Y
Name of person completing form:	Signature of person co	mpleting form:	Date comple	· · ·			
			DD	M M	Y Y	Y	Y
The site PI or delegated investigator must sign to	 confirm that information v	vithin the CRF is accurate			JL		
Investigator name:	Investigator signature:		Date comple		<u>.</u>		
			DD	ММ	Y Y	Y	Y
						ļ	

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 17 Sep 2018, v4.0 UCL CTC Use only: Form received: ______ Date for Date form entered: ____

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

PBSCH, Post-PBSCH and Randomisation forms

Site	
Name of sender	
Contact email address	
Contact phone number	
Contact fax number	
Pharmacy contact	
Pharmacy email address	
Pharmacy fax number	
Date	

Please fax forms (9 pages in total) to Cardamon Trial Coordinator 0207 679 9861

The forms will be checked for accuracy and eligibility and the trial arm allocation faxed/emailed back to the site & pharmacy contacts

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







Additional instructions for completing forms

Page 2 of 9

The 'Peripheral Blood Stem Cell Harvest (PBSCH) Form' should be used to collect patient data on the patient's stem cell harvest and randomisation, if applicable.

The 'Post-Peripheral Blood Stem Cell Harvest (PBSCH) and Randomisation Form' should be used to collect patient data once they have completed their first 4 cycles of CarCyDex treatment and PBSCH. Assessments should be performed within 14 days after PBSCH.

Specific Fields

- Please ensure that you are using the correct units (i.e. haemoglobin in g/dL). If your local report uses different units please convert these before entering them on the form
- Please ensure you complete the drug details for both the original mobilisation and subsequent remobilisations if applicable
- Patients achieving a response of <PR will not proceed to randomisation and should be followed up in line with the protocol
- Disease responses must be confirmed by the local investigator
- Please ensure a progression/relapse form is submitted for patients with progressive disease

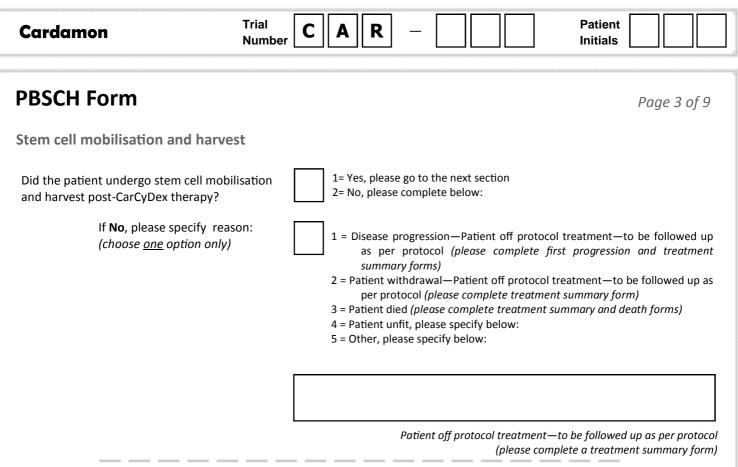
Completing forms

- 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.
- The Principal Investigator (PI) is responsible for the accuracy of the data reported on the CRF
- Please ensure that all adverse events are recorded on the adverse event form and the form is attached
- 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 clearly 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







Mobilisation

Drug	Total dose given (mg)	Start date (DD/MM/YYYY)	End date (DD/MM/YYYY)			
		/ /	/ /			
		/ /	/ /			
		/ /	/ /			
		/ /	/ /			

Date of first stem cell collection	D	D	М	М	Y	Y	Y	Y	
Number of harvest days:]								
Number of stem cells collected]•[x10 ⁶	CD34+	+ cells/ŀ	g
Did the patient undergo remobi	lisatio	on?							ection (Remobilisation) on page 4 Itcome section of page 4

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Trial R С Α Number

Page 4 of 9

Re-Mobilisation

PBSCH Form

Drug	Dose given (mg)	Start date (DD/MM/YYYY)	End date (DD/MM/YYYY)
		/ /	/ /
		/ /	/ /
		/ /	/ /
Date of stem cell collection D D	M M Y Y Y	Y Number of harvest d	ays:
Number of stem cells collected	• x10 ⁶ C	D34+ cells/kg	
Harvest Outcome			
Was the peripheral blood stem cell harves	st successful?	1= Yes, please complete belo 2= No—Patient off protocol up as per protocol (p summary form)	
End of successful harvest	M Y Y Y	Y Number of harvest of	days:
Total number of stem cells	•	034+ cells/kg	





Trial Patient R Cardamon С Number Initials Post-PBSCH and Randomisation form Page 5 of 9 Haematology М M Date of Haematology: Haemoglobin g/dL WBC Count x10⁹/L Platelets x 10⁹/L Lymphocytes x 10⁹/L Neutrophils x10⁹/L **Biochemistry** M M Date of Biochemistry Calcium (corrected) Bilirubin µmol/L . mmol/L Albumin g/L Potassium mmol/L . Sodium mmol/L Alkaline Phosphatase IU/L Alanine Transaminase Creatinine µmol/L Note: Please con-(ALT) IU/L OR firm ND if only AST **Creatinine Clearance** or ALT assessed. Aspartate Transaminase ml/min (AST) IU/L Serum urate µmol/L Phosphate mmol/L Urea (mmol/L) Adverse events Did the patient experience any adverse events 1 = Yes (please ensure adverse event form is submitted) between their post-induction assessment until 2 = No post-PBSCH? **Quality of Life Questionnaire** 1 = Yes; please send to the CTC as soon as possible Has the Quality of Life (QoL) been completed? 3 = Not done; please provide reason in box below:

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 17 Sep 2018, v4.0 UCL CTC Use only:



Cardamon

Cancer Research UK and UCL Cancer Trials Centre

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Trial

Number



Post-PBSCH and Randomisation form	Page 6 of 9
Bone marrow biopsies	
Bone marrow aspirate Date of sample D D M M Y Y Y 1= Present, complete % of plasma cells: 2= Present, not measured % 3= Absent 3= Absent	
Bone marrow trephine Date of sample D M M Y Y Y 1= Present, complete % of plasma cells: 2= Present, not measured % 3= Absent 4bsent %	
Bone marrow aspirate sample must be sent to HMDS, Leeds following the PBSCH Sent? 1=Yes 2= No Date sample sent to lab:	
BM aspirate for MRD (2ml) sent to HMDS, Leeds?	Y
If No, please specify a reason:	
Soft tissue plasmacytoma/Extramedullary lesions Does the patient have any soft tissue plasmacytomas/ 1= Yes, complete date of test and a separate light 2= No	ine for each site involved
If yes, date of test	Long axis Short axis
Site involved: Bidimensional measurements (cm):	x
Site involved: Bidimensional measurements (cm):	x
Site involved: Bidimensional measurements (cm):	x

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 17 Sep 2018, v4.0 UCL CTC Use only: Form received: ______ Date for Date form entered: _





Cardamon	Trial Number C A R		Patient Initials
Post-PBSCH and Rand	omisation form		Page 7 of 9
Efficacy assessments			
Date of test D D M	M Y Y Y Y		
	one option only) 2= Li	ngle paraprotein expressed ght chain only iclonal	
Paraprotein type key: 1 = IgG, 2 = IgA, 3	B = IgM, 4 = IgD		
Specify paraprotein type:	Serum paraprotein	4= Present, please complete resul 5= Too faint to quantify 6= Absent 7= Not Done	t (g/L)
Specify paraprotein type:	Serum paraprotein	4= Present, please complete resul 5= Too faint to quantify 6= Absent 7= Not Done	t (g/L)
Serum free light chain: Kappa (mg/L)		OR Tic	k if not done
Serum free light chain: Lambda (mg/L)	OR Tic	k if not done
Serum free light chain Kappa/Lambda ratio:		al range of /Lambda FLC ratio:	_
Urinary light chain measurement			
1= Present, quantifiable Please complete 24h BJ 2= Too faint to quantify (24h BJP of 3= Absent 5= Present, not formally quantifie (if unable to perform 24h BJP)	only)	Light chain (please ch	
Immunofixation (only to confirm	n CR)		
Immunofixation Serum 2=	Positive Negative Date of test Not done	D D M M Y Y	Y Y
Immunofixation Urine 2=	Positive Negative Date of test Not done	D D M M Y Y	Y Y

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CANCER RESEARCH UK Cancer Research UK and UCL Cancer Trials Centre							
Cardamon	Trial C A R – Patient Initials						
Post-PBSCI	and Randomisation form	Page 8 of 9					
Imaging (If clin	cally indicated or for response assessment if persistent soft tissue plasmacy	tomas presei					
	Date of test	Lytic or focal lesion 1= Yes 2= No					
MRI	1= Evidence of myeloma D D M M Y Y Y 2= No evidence of myeloma 3= Not done D D M M Y Y Y						
ст	1= Evidence of myeloma D D M M Y Y Y 2= No evidence of myeloma 3= Not done D D M M Y Y Y Y						
PET	1= Evidence of myeloma D D M M Y Y Y Y 2= No evidence of myeloma 3= Not done D D M M Y Y Y Y						
Skeletal survey	1= Evidence of myelomaDDMMYYY2= No evidence of myeloma3= Not done						
Other imaging	1= Evidence of myeloma D D M M Y Y Y Y 2= No evidence of myeloma 3= Not done D D M M Y Y Y Y						
Sp	ecify type of other imaging						
Has an increase	in number or size of lytic bone lesions been seen on any radiograph? $1 = Yes$ 2 = No						





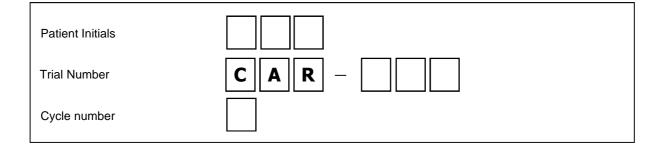
Cardamon	Trial CAR - Patient Initials
Post-PBSCH and F Response post-PBSCH	Randomisation form Page 9 of 9
This section must be completed	and signed by the local principal investigator or delegated investigator
Date of response assessment	
Disease response post PBSCH Choose <u>one</u> option only	1= sCR 2= CR 3= VGPR 4= PR Patient should proceed to Randomisation
	5= MR 6= SD } Patient off protocol treatment—to be followed up as per pro- tocol (Please submit treatment summary form)
	7= PD — Patient off protocol treatment—to be followed up as per protocol (Please complete first progression and treatment summary form)
Is this response confirmed? (1=y (refer to IMWG criteria/protocol	
Investigator name (print):	Investigator signature:
	Date signed:
Name of person completing form:	Signature of person completing form: Date completed:
The site PI or delegated investigator	must sign to confirm that information within the CRF is accurate
Investigator name:	Investigator signature: Date completed:
Randomisation Details (C	ΓC USE ONLY)
Patient eligible for randomisati	ion? Yes No
Trial arm allocated?	Consolidation ASCT
Randomised by	
Date of randomisation	

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

Consolidation Form



(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>



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Additional instructions for completing forms

The Consolidation Form is used to record the 4 cycles of CarCyDex treatment for the patients randomised to the consolidation arm.

Page 2 of 7

Specific Fields

- Cycle number—please take cycle number from the start of consolidation not all treatment i.e. the first cycle after randomisation will be cycle 1 not cycle 5
- Omission/Reduction/Delay: Please do not leave these blank, if there were no omissions, reductions or delays please ensure that you have entered "0" in each box. A discrepancy will be raised for all fields left blank
- If any efficacy tests have not been done because they are not clinically indicated, please ensure that you complete the boxes with ND to confirm that the tests were not done. A discrepancy will be raised for those fields left completely blank
- Please ensure that you are using the correct units (i.e. haemoglobin in g/dL). If your local report uses different units please convert these before entering them on the form
- Disease response assessment should be based on blood and/or urine tests performed at the start of each cycle (day 1, ± 7 days), this must be assessed by the PI or delegated investigator (see appendix 3 of protocol)
- Disease response for each cycle must be assessed according to the paraprotein/BJP/SFLC results of tests performed at the beginning of the subsequent cycle, for example, response to cycle 1 would be assessed on cycle 2, day 1, and documented on the cycle 2 CRF
- At the end of consolidation, disease assessment must be performed within 14 days of the last treatment and prior to starting maintenance. This should be reported on the end of consolidation CRF
- Please ensure that the patient diary card has been completed and returned
- Pregnancy tests should be performed in each cycle prior to the first dose being given
- Please ensure a progression/relapse form is submitted for patients with progressive disease

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.
- The Principal Investigator (PI) is responsible for the accuracy of the data reported on the CRF
 - Please ensure that all adverse events are recorded on the adverse event form and the form is attached
- 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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Cardamon

Patient

Initials

Consolidation Form

Page 3 of 7

Cycle No:



Haematology

Test	Day 1 result	Day 2 result	Day 8 result	Day 9 result	Day 15 result	Day 16 result
Date (dd/mm/yyyy)						
Haemoglobin (g/dL)						
WBC (x10 ⁹ /L)						
Platelets (x 10 ⁹ /L)						
Neutrophils (x10 ⁹ /L)						
Lymphocytes (x 10 ⁹ /L)						
Blood pressure (mmHg)						

- Patients must have FBC and biochemistry tests prior to days 1, 8, & 15 of each cycle •
- These are to be repeated on days 2, 9 & 16 if clinically indicated •
- The validity period for FBC is 48 hours, and for biochemistry it is 72 hours .





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Trial		D	
Number	A	ĸ	

Patient Initials

Consolidation Form

Page 4 of 7

Cycle No:

Biochemistry

Test	Day 1 result	Day 8 result	Day 15 result
Date (dd/mm/yyyy)			
Calcium (corrected) (mmol/L)			
Potassium (mmol/L)			
Phosphate (mmol/L)			
Urea (mmol/L)			
Sodium (mmol/L)			
Serum Urate (μmol/L)			
Creatinine (µmol/L)			
Creatinine clearance (ml/min) if clinically indicated, otherwise enter ND			
Albumin (g/L)			
Bilirubin (μmol/L)			
Alkaline Phosphatase (IU/L)			
Aspartate Transaminase (IU/L)			
Alanine Transaminase (IU/L)			

Adverse events

Has patient returned their diary card?

1 = Yes 2 = No

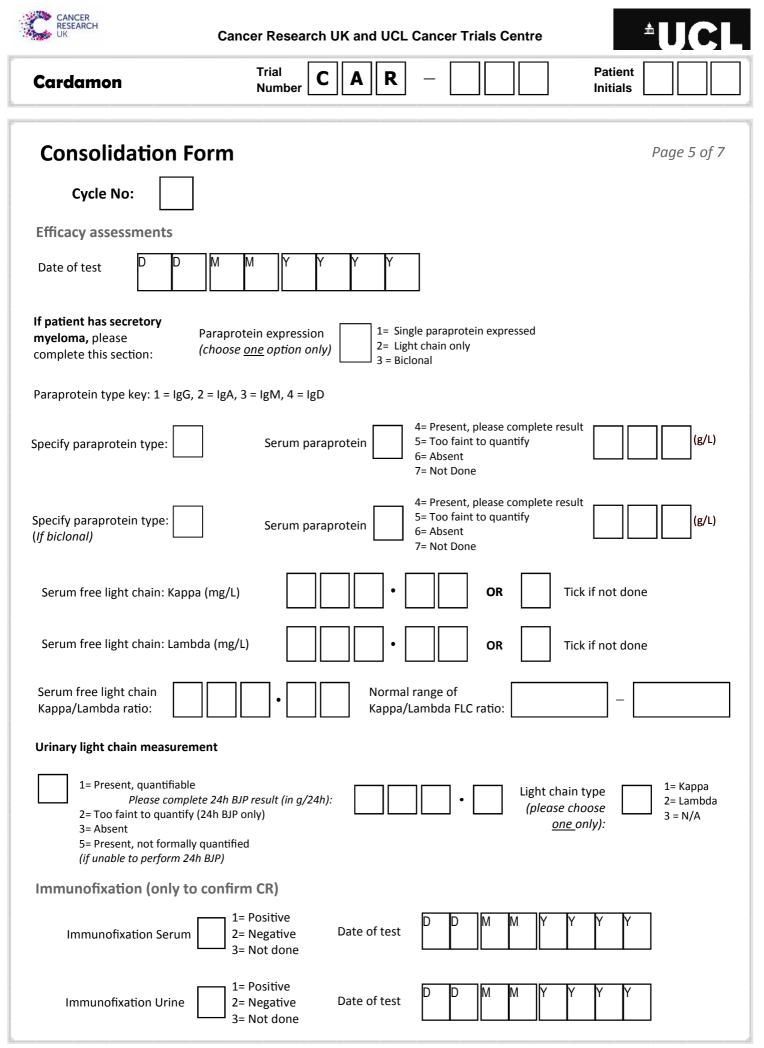
Did the patient experience any adverse events?

1 = Yes (please ensure adverse event form is submitted) 2 = No

Pregnancy test (for females of child bearing potential only)

Result: 1= Negative 2 = Positive 3= Not applicable	Date of pregnancy test	D	D	М	М	Y	Y	Y	Y
--	------------------------	---	---	---	---	---	---	---	---

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Cancer Research UK and UCL Cancer Trials Centre

Trial



Patient

Num		
Consolidation Form Cycle No: Please note: th	this page should not be completed in cycle 1	Page 6 of 7
day 1 of each cycle (from cycle 2 onwards	ned by the local principal investigator / delegated investig ds) P P M M Y Y Y Y	ator and done on
Date of response assessment Patient's response to consolidation treatment (choose <u>one option only</u>) (e.g. this is the response to last cycle receiv i.e. cycle 1 would be assessed on cycle 2, da and documented on the cycle 2 CRF)	ived, 2= CR 3= VGPR	
Investigator name (print):	Investigator signature: Date signed: D D M M Y	Y Y Y

- Disease response assessment should be based on blood and/or urine tests performed at the start of each cycle (day 1, ± 7 days), this must be assessed by the PI or delegated investigator (see appendix 3 of protocol)
- Disease response for each cycle must be assessed according to the paraprotein/BJP/SFLC results of tests performed at the beginning of the subsequent cycle, for example, response to cycle 1 would be assessed on cycle 2, day 1, and documented on the cycle 2 CRF
- At the end of consolidation, disease assessment must be performed within 14 days of the last treatment and prior to starting maintenance. This should be reported on the end of consolidation CRF

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 17 Sep 2018, v4.0 UCL CTC Use only: Form received:





Cardamon		Trial Number	CAR	-	Patie Initia			
Consolidatio	n Fo	rm				Page 7 of 7		
Cycle No:								
Date cycle starte	ed:	D M M	Y Y Y	Y				
Patient BSA • m^2 Patients with a BSA >2.2 m^2 should receive dose based on BSA of 2.2 m^2								
Any delays reductions or omissions during this cycle of consolidation? $\begin{bmatrix} 1 = Yes \\ 2 = No \end{bmatrix}$								
Drug	Day	Dose given	Route (IV or PO)	Omission (see codes below)	Reduction (see codes below)	Delay (see codes below)		
Dexamethasone (20mg PO or IV)	1	mg						
	8	mg						
	15	mg						
	22	mg						
Carfilzomib (56mg/m²)	1	mg						
	2	mg						
	8	mg						
	9	mg						
	15	mg						
	16	mg						
Cyclophosphamide	1	mg						
(500mg PO or 375mg IV)	8	mg						
	15	mg						
0=No delay/reduction/om 6=Pancreatitis 7=Patient ((specify below), 13=Protoc	Choice, 8	3=Clinician Choice, 9=	=Administrative, 10=					
12 = OTHER Reducti	on/Dela	ay/Omission Reason	n					
					Data ann datad			
Name of person completing for	orm:	Signatur	re of person completing	torm:	Date completed:	YYY		
The site PI or delegated inve	stigator ı		t information within the ator signature:		Date completed:			
					D D M M	YYYY		

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

Post-Consolidation Form

Patient Initials

Trial Number

С	Α	R	_	

(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







Additional instructions for completing forms

Page 2 of 7

The Post-Consolidation form collects details of the patient's response to consolidation treatment. Assessments are to be performed within 14 days of completing the last cycle of consolidation

Specific Fields

- Please ensure that you are using the correct units (i.e. haemoglobin in g/dL). If your local report uses different units please convert these before entering them on the form.
- If any efficacy tests have not been done because they are not clinically indication, please ensure that you complete the boxes with ND to confirm that the tests were not done. A discrepancy will be raised for those fields left completely blank.
- Disease response should be confirmed by a local investigator
- Please ensure a progression/relapse form is submitted for patients with progressive disease

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.
- The Principal Investigator (PI) is responsible for the accuracy of the data reported on the CRF
- Please ensure that all adverse events are recorded on the adverse event form and the form is attached
- 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





Trial Patient R Cardamon С Number Initials **Post-Consolidation Form** Page 3 of 7 Haematology М Date of Haematology: Haemoglobin g/dL WBC Count x10⁹/L Platelets x 10⁹/L Lymphocytes x 10⁹/L Neutrophils x10⁹/L **Biochemistry** M M Date of Biochemistry Calcium (corrected) Bilirubin µmol/L mmol/L Potassium mmol/L Albumin g/L . Sodium mmol/L Alkaline Phosphatase IU/L Alanine Transaminase Creatinine µmol/L (ALT) IU/L OR **Creatinine Clearance** Aspartate ml/min Transaminase (AST) IU/L Serum urate µmol/L Phosphate mmol/L Urea (mmol/L) **Adverse events** 1 = YesHas patient returned their diary card? 2 = No Did the patient experience any adverse events 1 = Yes (please ensure adverse event form is submitted) between their last cycle of consolidation and their 2 = No post-consolidation assessment? 1=Yes; please ensure the form is attached Has the Quality of Life (QoL) been completed? 3=No, please provide reason if not done: Μ D N Date of QoL completion:

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 17 Sep 2018, v4.0 UCL CTC Use only:





Caraamon	ial CAR –	Patient Initials
Post-Consolidation For	n	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 ce 2= Present , not measured 3= Absent 4= Not done	ls: 6	
Bone marrow trephine Date of sample	D D M M Y Y Y Y	
1= Present, complete % of plasma ce 2= Present , not measured 3= Absent 4= Not done	ls: 6	
	o HMDS, Leeds after 4 cycles of consolidation treatment samples must also be sent to the UCL Cancer Institute Myelomo	a Lab at this time point
	Sent? 1=Yes 2= No Date sample sent	to lab
BM aspirate for MRD (2ml) to	HMDS, Leeds	Y Y Y Y
BM aspirate for genomic analythe UCL Cancer Institute Myel		Y Y Y Y
Peripheral blood sample for g the UCL Cancer Institute Myel		Y Y Y Y
If No to any of the above, specify a reaso		
Soft tissue plasmacytoma/Extrame	dullary lesions	
Does the patient have any soft tissue plasmacyt Extramedullary lesions?	bmas/ 1= Yes, complete date of test and a sep 2= No	parate line for each site involved
If yes, date of test	M Y Y Y Y	Long axis Short axis
Site involved:	Bidimensional measurements ((cm): X
Site involved:	Bidimensional measurements ((cm): X
Site involved:	Bidimensional measurements ((cm): X

 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 17 Sep 2018, v4.0

 UCL CTC Use only:
 Form received: ______

 Date form entered: ______
 Initials: ______





Cardamon	Trial Number C A R	-	Patient Initials
Post-Consolidation Fo	orm		Page 5 of 7
PET-CT sub study: Post-Consolid (please complete for patients participating			
Date of PET-CT:		M Y Y Y Y	
Date images transferred to	PET core lab: D D M	MYYYY	
Efficacy assessments			
Date of test D D M	M Y Y Y Y		
		gle paraprotein expressed nt chain only Ional	
Paraprotein type key: 1 = IgG, 2 = IgA, 3	s = IgM, 4 = IgD		
Specify paraprotein type:	Serum paraprotein	 4= Present, please complete resul 5= Too faint to quantify 6= Absent 7= Not Done 	t (g/L)
Specify paraprotein type:	Serum paraprotein	4= Present, please complete resul 5= Too faint to quantify 6= Absent 7= Not Done	t (g/L)
Serum free light chain: Kappa (mg/L)		OR Tic	k if not done
Serum free light chain: Lambda (mg/L)	OR Tic	k if not done
Serum free light chain Kappa/Lambda ratio:		l range of Kappa/ a FLC ratio:	-
Urinary light chain measurement			
1= Present, quantifiable <i>Please complete 24h BJ</i> 2= Too faint to quantify (24h BJP 3= Absent 5= Present, not formally quantifie <i>(if unable to perform 24h BJP)</i>	only)	• Iight chain (please ch <u>one</u>	
Immunofixation (only to confirm	n CR)		
Immunofixation Serum 2=	Positive Negative Date of test Not done	D D M M Y Y	Y Y
Immunofixation Urine 2=	Positive Negative Date of test Not done	D D M M 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 17 Sep 2018, v4.0 UCL CTC Use only: Form received: ______ Date for

Post-Consolidation Form Imaging (if clinically indicated or for response assessment if persistent soft fissue plasmacytomat plasmacytoma plas					Patie nitia										R	Α	C		Tria Nun			imon	arda
WB: If patient is participating in PET-CT sub study please complete section at the end of this page Lytic of fa Image: Date of test 1 = Evidence of myeloma Image: Display for the first of the fi	-	-	-	асу	sma	pla	ue	tiss	oft	nt s	ster	ersi	if p	nt	sme	asses	onse						
MRI 1 = Evidence of myeloma D D M M Y<	ocal lesi	or foc	ic o	-		-			-														
CT 2= No evidence of myeloma 3= Not done PET 1= Evidence of myeloma 2= No evidence of myeloma 3= Not done Skeletal survey 1= Evidence of myeloma 3= Not done Other imaging 1= Evidence of myeloma 3= Not done D D M M Y Y Y Y CT 2= No evidence of myeloma 3= Not done D D M M Y Y Y Y CT 2= No evidence of myeloma 3= Not done D D M M Y Y Y Y CT 2= No evidence of myeloma 3= Not done D D M M Y Y Y Y CT 3= No evidence of myeloma 3= Not done Specify type of other imaging 1= Yes			1-		Y	(Y	Y	Y			М)		D				lence of mye	2= No evide			MRI
PET 2= No evidence of myeloma 3= Not done Skeletal survey 1= Evidence of myeloma 2= No evidence of myeloma 3= Not done Other imaging 1= Evidence of myeloma 2= No evidence of myeloma 3= Not done Other imaging 1= Evidence of myeloma 3= Not done Specify type of other imaging					Y	(Y	Y	Y		М	М	D		D				lence of mye	2= No evide			СТ
Skeletal survey 2= No evidence of myeloma 3= Not done Other imaging 1= Evidence of myeloma 2= No evidence of myeloma 3= Not done D M M Y Y Y Specify type of other imaging					Y	ſ	Y	Y	Y		М	М	D		D				ence of mye	2= No evide			PET
Other imaging 2= No evidence of myeloma 3= Not done Specify type of other imaging Has an increase in number or size of lytic hone lesions been seen on any radiograph? 1 = Yes					Y	(Y	Y	Y		М	М)		D				lence of mye	2= No evide		l survey	Skeletal
Has an increase in number or size of lytic hone lesions been seen on any radiograph? $1 = Yes$					Y	(Y	Y	Y		М	М)		D				lence of mye	2= No evide		imaging	Other ir
Has an increase in number or size of lytic hone lesions been seen on any radiograph?																		3	her imaginį	type of oth	Specif		
										oh?	ogra	radio	any	on	seen	been	esions	one l	ize of lytic b	umber or siz	ase in r	n increa	Has an



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Post-Consolidation Fo	rm	Page 7 of 7
Response post-consolidation This section must be completed and sig	ned by the local principal investigator or delegated investigator	
Date of response assessment	D D M M Y Y Y Y	
Patient's response to consolidation trea (choose <u>one</u> option only)	tment: 1= sCR 2= CR 3= VGPR 4= PR 5= MR 6= SD	
	7= PD — Patient off protocol treatment—to be follow (Complete first progression and treatment s 8= Unable to assess— Specify reason:	
Is this response confirmed? (1=yes, 2=nd (refer to IMWG criteria/protocol append		Y Y Y
Investigator name (print):	Investigator signature:	
	Date signed: D D M M Y	Y Y Y
Name of person completing form:	Signature of person completing form: Date completed:	
		Y Y Y
The site PI or delegated investigator must sign to Investigator name:	o confirm that information within the CRF is accurate Investigator signature: Date completed:	
		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 17 Sep 2018, v4.0 UCL CTC Use only: Form received: ______ Date for Date form entered: _



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

Transplant Form

Patient Initials

Trial Number

(This form has 3 pages including cover sheet)

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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







Additional instructions for completing forms

Page 2 of 3

The transplant form collects details of the patient's transplant for those patients randomised to the ASCT arm of the trial. Patients should proceed to transplant as soon as possible after randomisation and high dose Melphalan should be given no more than 4 weeks after randomisation.

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 if not required
 - 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 UCL 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)

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





Cardamon	Trial Number CAR	- 🗌		Patien Initials		
Transplant Form					Pc	age 3 of 3
Did the patient receive an autologo	bus stem cell transplant?	1= Yes 2 = No				
lf no	, please give the reason:		progression unfit to proc specify)			
	Specify:					
Admission date: D D	MMYYYY					
Date of transplant: D D	M M Y Y Y					
Melphalan dose:	mg					
Have neutrophils recovered?	1 = Yes 2 = No					
Date of 1st of three consecutive days Neu after first po	utrophils ≥ 0.5x10 ⁹ /L D D ost-transplant nadir:	M M Y	Y Y	Y		
Have platelets recovered?	1 = Yes 2 = No					
Date of 1 st of three consecutive days	platelets ≥20x10 ⁹ /L D D (unsupported):	M M Y	Y Y	Y		
Was the patient admitted to ITU or HDU during their transplant?	1 = Yes 2 = No					
If yes, he	ow many days?	days	5			
Date of discharge from hospital: D	D M M Y Y	Y Y				
Name of person completing form:	Signature of person completing fo		Date completed			
			D D M	MY	ľ	
The site PI or delegated investigator must sign to Investigator name:	o confirm that information within the one of		Date completed	ł:		
			D D M	MY	Y	Y Y

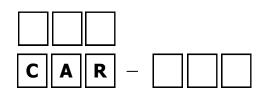


Carfilzomib/Cyclophosphamide/Dexamethasone with maintenance carfilzomib in untreated transplant-eligible patients with symptomatic MM to evaluate the benefit of upfront ASCT

Day 100 Post-ASCT 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







Additional instructions for completing forms

Page 2 of 7

The Day 100 post-ASCT form collects details of the patient's response to transplant for those patients randomised to the ASCT arm of the trial.

Specific Fields

- If any efficacy tests have not been done because they are not clinically indicated, please ensure that you complete the boxes with ND to confirm that the tests were not done. A discrepancy will be raised for those fields left completely blank.
- Please ensure that you are using the correct units (i.e. haemoglobin in g/dL). If your local report uses different units please convert these before entering them on the form.
- Disease response should be confirmed by a local investigator
- Please ensure a progression/relapse form is submitted for patients with progressive disease

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





Cancer Research UK and UCL Cancer Trials Centre Trial Patient R Cardamon С Number Initials Day 100 post-ASCT Form Page 3 of 7 Haematology М Date of Haematology: WBC Count x10⁹/L Haemoglobin g/dL Platelets x 10⁹/L Lymphocytes x 10⁹/L Neutrophils x10⁹/L **Biochemistry** Μ M Date of Biochemistry Calcium (corrected) Bilirubin µmol/L mmol/L Potassium mmol/L Albumin g/L • Sodium mmol/L Alkaline Phosphatase IU/L Alanine Transaminase Creatinine µmol/L (ALT) IU/L Or **Creatinine Clearance** Aspartate ml/min Transaminase (AST) IU/L Serum urate µmol/L Phosphate mmol/L Urea (mmol/L) **Adverse events** Did the patient experience any adverse events 1 = Yes (please ensure adverse event form is submitted) between PBSCH and their day 100 post-ASCT as-2 = No sessment? 1 = Yes; please ensure the form is attached Has the Quality of Life (QoL) been completed?

3 = No, please provide reason if not done:

M Μ Date of QoL completion:

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 31.10.2017 Version 3.1 UCL CTC Use only: Form received:





Cardamon	Trial Number	CA	R –				Patient nitials		
Dav 100 post-A Bone marrow biopsies		- I		- 1 - 1 -		_	P	age 4	l of 7
Bone marrow aspirate	Date of sample	D M	MY	Y Y	Y				
1= Present, complete 2= Present , not mea 3= Absent 4= Not done] %						
Bone marrow trephine	Date of sample	D M	MY	Y Y	Y				
1= Present, complete 2= Present , not mea 3= Absent 4= Not done] %						
Bone marrow aspirate samp Bone marrow aspirate and p						oma Lab d	at this time po	oint	
			Sent? L=Yes 2= No	Date	sample so	ent to lab			
BM aspirate f	or MRD (2ml) to HMDS, I	_eeds		D D	М	MY	Y Y	Y	
	or genomic analyses (8m er Institute Myeloma Lab			D D	М	MY	Y Y	Y]
	ood sample for genomic a er Institute Myeloma Lab		0	D D	М	MY	Y Y	Y]
If No to any of the above	, specify a reason:]
Soft tissue plasmacytor	na/Extramedullary	/ lesions							
Does the patient have any soft t Extramedullary lesions?	tissue plasmacytomas/		1= Yes, compl 2= No	ete date of t	est and a	separate	line for each	site inv	olved
If yes , date of test	D D M M	Y Y Y	Y				Long axis	Sł	nort axis
Site involved:			Bidim	ensional me	asuremei	nts (cm):		x	
Site involved:			Bidim	ensional me	asuremei	nts (cm):		x	
Site involved:			Bidim	ensional me	asuremei	nts (cm):		x	

 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 31.10.2017 Version 3.1

 UCL CTC Use only:
 Form received:

 Date form entered:
 Initials:





Cardamon	Trial Number CAR	-	Patient Initials
Day 100 post-ASCT Fo	orm		Page 5 of 7
PET-CT sub study: Post-Consoli (please complete for patients participatin			
Date of PET-CT:		M Y Y Y Y	
Date images transferred to	PET core lab: D D M I	M Y Y Y Y	
Efficacy assessments		_	
Date of test D D M	M Y Y Y Y		
inycionia , picase		le paraprotein expressed t chain only onal	
Paraprotein type key: 1 = IgG, 2 = IgA, 3	= IgM, 4 = IgD		
Specify paraprotein type:	Serum paraprotein	4= Present, please complete resul 5= Too faint to quantify 6= Absent 7= Not Done	t (g/L)
Specify paraprotein type:	Serum paraprotein	4= Present, please complete resul 5= Too faint to quantify 6= Absent 7= Not Done	t (g/L)
Serum free light chain: Kappa (mg/L)		OR Tic	k if not done
Serum free light chain: Lambda (mg/L		OR Tic	k if not done
Serum free light chain Kappa/Lambda ratio:	Normal ra Kappa/La	ange of ambda FLC ratio:	_
Urinary light chain measurement			
1= Present, quantifiable Please complete 24h BJ 2= Too faint to quantify (24h BJP of 3= Absent 5= Present, not formally quantifie (if unable to perform 24h BJP)	only)	• light chair (please cl one	/= Lamnda
Immunofixation (only to confirm	n CR)		
Immunofixation Serum 2=	Positive Negative Date of test Not done	D D M M Y Y	Y Y
Immunofixation Urine 2=	Positive Negative Date of test Not done	D D M M 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 31.10.2017 Version 3.1

 UCL CTC Use only:
 Form received:

 Date form entered:

 Initials:

ardamon		Trial Number	CAR] –						Patient Initials		
maging (If cl		ed or for respo				tent	soft	tissu	ie pla	smacy	-	e 6 of 7 prese l
B: If patient is par	icipating in PET-CT s	ub study please compl	ete section at the en	nd of this p		Date o	of test				Lytic or 1 1= Ye	focal lesi es 2= N
MRI		ce of myeloma dence of myeloma one	D	D	М	М	Y	Y	Y	Y		
СТ		ce of myeloma dence of myeloma ne	D	D	М	Μ	Y	Y	Y	Y		
PET		ce of myeloma dence of myeloma ne	D	D	М	М	Y	Y	Y	Y		
Skeletal survey		ice of myeloma dence of myeloma one	D	D	Μ	М	Y	Y	Y	Y		
Other imaging		ce of myeloma dence of myeloma me	D	D	Μ	М	Y	Y	Y	Y		
	Specify type of o				un di a		<u>- Г</u>		1 = Ye	S		
nas an increa	se in number or s	size of lytic bone le	esions been seen	i on any	rauic	grapn	ŗ		2 = No	1		





Cardamon	Trial CAR –	Patient Initials
Day 100 post-ASCT Fe	orm	Page 7 of 7
Response day 100 post-ACST		
Date of response assessment	D D M M Y Y Y	Y
Patient's response to ASCT and Melphalan tr (choose <u>one</u> op	eatment: 2= CR	to maintenance treatment (please en- nary form is submitted)
		nent—to be followed up as per protocol n and treatment summary form)
Is this response confirmed? (1=yes, 2=r (refer to IMWG criteria/protocol appen		M M Y Y Y Y
Investigator name (print):	Investigator signature:	
	D D Date signed:	M M Y Y Y Y
Name of person completing form:	Signature of person completing form: Date	e completed:
The site PI or delegated investigator must sign Investigator name:	to confirm that information within the CRF is accurate Investigator signature: Date	e completed:
		D M M 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 31.10.2017 Version 3.1

 UCL CTC Use only:
 Form received:

 Date form entered:

 Initials:

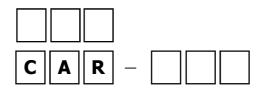


Carfilzomib/Cyclophosphamide/Dexamethasone with maintenance carfilzomib in untreated transplant-eligible patients with symptomatic MM to evaluate the benefit of upfront ASCT

Treatment Summary Form

Patient Initials

Trial Number



(This form has 3 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







Additional instructions for completing forms

Page 2 of 3

The treatment summary form collects details of the patient's treatment up until the start of maintenance.

Specific fields:

• Total number of cycles should include all treatment cycles regardless of whether the cycle was completed —even if a patient completed only 1 day of a cycle, it is considered a cycle.

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 if not required
 - 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



Cardamon

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Trial

Number

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Treatment Summary Form	Page 3 of 3
<u>To be completed for all patients</u>	
Did patient receive full protocol treatment?	1= Yes, please complete this section only 2= No, please complete both sections
Date treatment stopped/completed:	D D M M Y Y Y
Total number of CarCyDex treatment received: (Induction + Consolidation)	
Did patient have a Melphalan conditioned ASCT?	1= Yes 2= No
Will the patient start maintenance Carfilzomib?	1= Yes 2= No
(This includes Induction, Consolidation, PBSCH and ASC 1 = Disease Progression / Relapse (Please comp 2 = Death (Please complete a Death form)	
3 = Toxicity , please specify: (Please complete an AE/SAE form as appropriat	re)
4 = Lost to follow up (Please complete a Withdr	rawal/Lost to Follow up form
5 =Intercurrent illness preventing further treat	ment, please specify:
6 = Inadequate harvest	
7 =Other, please specify:	
Name of person completing form: Signature of	person completing form: Date completed:
The site PI or delegated investigator must sign to confirm that info	rmation within the CRF is accurate
Investigator name: Investigator s	signature: Date completed:
	D D M M Y Y Y

 Please return to: Cardamon Trial Coordinator, CR UK & UCL Cancer Trials Centre, 90 Tottenham Court Road, London, W1T 4TJ

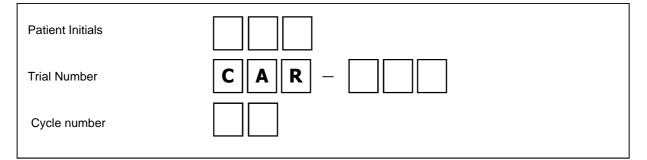
 CRF Template V1– 19 Oct 2010 Modified for Cardamon on 17 Sep 2018, v4.0

 UCL CTC Use only:
 Form received: ______ Date form entered: ______ Initials: _____



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

Maintenance Form



(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







Additional instructions for completing forms

Page 2 of 7

The Maintenance Form collects details of the patient's maintenance treatment; in the absence of PD, a patient may receive up to 18 cycles of maintenance.

Specific Fields

- Cycle number—please take cycle number from the start of maintenance not all treatment i.e. for patients on the consolidation arm the first cycle will be cycle 1 not cycle 9
- Omission/Reduction/Delay: Please do not leave these blank, if there were no omissions, reductions or delays please ensure that you have entered "0" in each box. A discrepancy will be raised for all fields left blank
- Please ensure that you are using the correct units (i.e. haemoglobin in g/dL). If your local report uses different units please convert these before entering them on the form.
- Response assessments should be only be carried out by the principal investigator or coinvestigator
- The response assessment section for cycle 1 should be left blank, however, paraprotein, serum free light chain and urinary Bence Jones protein levels must be recorded if available
- Disease response assessment should be based on blood and/or urine tests performed at the start of each cycle (day 1, ± 7 days), this must be assessed by the PI or delegated investigator (see appendix 3 of protocol)
- Disease response for each cycle must be assessed according to the paraprotein/BJP/SFLC results of tests performed at the beginning of the subsequent cycle, for example, response to cycle 1 would be assessed on cycle 2, day 1, and documented on the cycle 2 CRF
- At the end of maintenance, disease assessment must be performed within 14 days of the last treatment. This should be reported on the maintenance summary CRF
- Please ensure a progression/relapse form is submitted for patients with progressive disease

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
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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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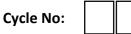
Cardamon	Ì
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Patient

Initials

Maintenance Form

Page 3 of 7





Haematology

Test	Day 1 result	Day 8 result	Day 15 result
Date (dd/mm/yyyy)			
Haemoglobin (g/dL)			
WBC (x10 ⁹ /L)			
Platelets (x 10 ⁹ /L)			
Neutrophils (x10 ⁹ /L)			
Lymphocytes (x 10 ⁹ /L)			
Blood pressure (mmHg)			

Trial

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- Patients must have FBC and biochemistry tests prior to days 1, 8, & 15 of each cycle •
- The validity period for FBC is 48 hours, and for biochemistry it is 72 hours •



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Trial

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Patient

Initials

Maintenance Form

Page 4 of 7

Cy	cie	INC):



Biochemistry

Test	Day 1 result	Day 8 result	Day 15 result
Date (dd/mm/yyyy)			
Calcium (corrected) (mmol/L)			
Potassium (mmol/L)			
Phosphate (mmol/L)			
Urea (mmol/L)			
Sodium (mmol/L)			
Serum Urate (µmol/L)			
Creatinine (µmol/L)			
Creatinine clearance (ml/min) if clinically indicated, otherwise enter ND			
Albumin (g/L)			
Bilirubin (μmol/L)			
Alkaline Phosphatase (IU/L)			
Aspartate Transaminase (IU/L)			
Alanine Transaminase (IU/L)			

Adverse events

Did the patient experience any adverse events?

1 = Yes (please ensure adverse event form is submitted) 2 = No

Pregnancy test (for females of child bearing potential only)

Result:

1 = Negative 2 = Positive 3 = Not applicable

Date of pregnancy test

D	D	М	М	Y	Y	Y	Y	

CANCER RESEARCH UK C	ancer Researcl	n UK and	d UCL	Cance	er Trial	ls Cen	itre		ħ		RL
Cardamon	Trial Number		R	_				Patie Initia			
Maintenance Form									Po	age !	5 of 7
Cycle No:											
Efficacy assessments											
Date of test D D M	M Y Y	Ý	Y								
	protein expression ose <u>one</u> option onl			gle para nt chain Ional		express	ed				
Paraprotein type key: 1 = IgG, 2 = Ig	A, 3 = IgM, 4 = IgD)									
Specify paraprotein type:	Serum para	aprotein			faint to ent		nplete re Y	esult			(g/L)
Specify paraprotein type:	Serum para	aprotein			faint to ent		nplete re y	esult			(g/L)
Serum free light chain: Kappa (mg	/L)].[OR		Tick if not c	lone		
Serum free light chain: Lambda (m	g/L)].[OR [Tick if not c	lone		
Serum free light chain Kappa/Lambda ratio:				range d Lambda		tio:					
Urinary light chain measurement											
1= Present, quantifiable Please complete 24h 2= Too faint to quantify (24h B 3= Absent 5= Present, not formally quant (if unable to perform 24h BJP)	JP only)	n):			•		(please	ain type e choose <u>ne only</u>):		1 = Ka 2 = La 3 = N/	mbda
Immunofixation (only to con	firm CR)										
Immunofixation Serum	1= Positive 2= Negative 3= Not done	Date o	f test	D	DN	1 M	Y	Y Y	Y		
Immunofixation Urine	1= Positive 2= Negative 3= Not done	Date c	f test	D	DN	1 M	Y	Y Y	Y		

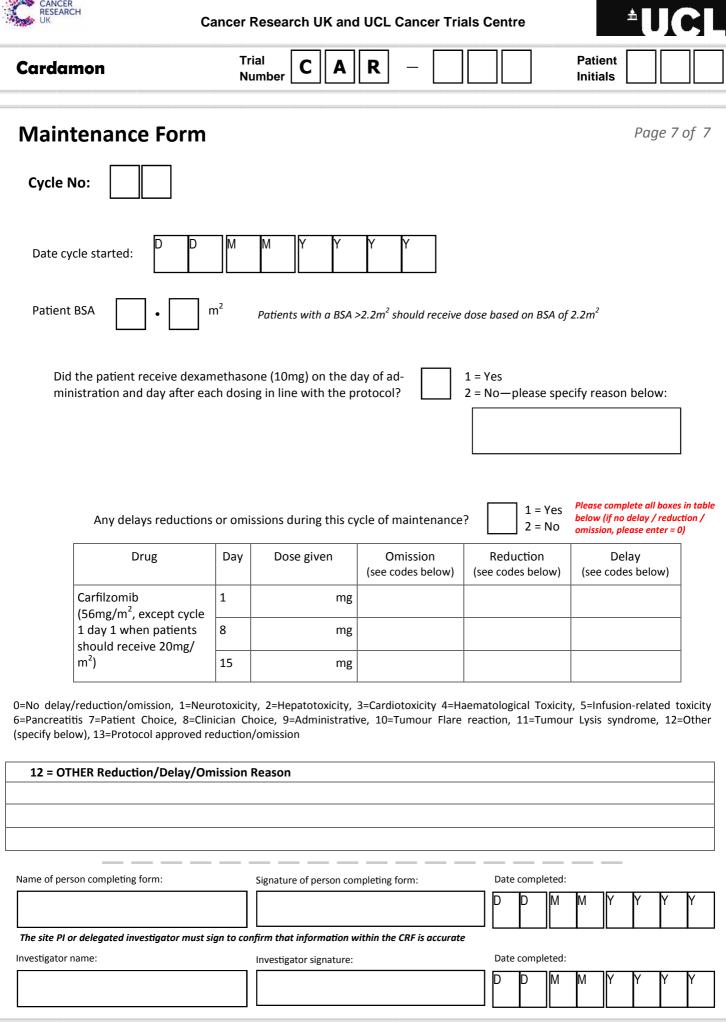




Cardamon	Trial Numbe	er C A	R –			Patient Initials
Maintenance Cycle No:	Form Please note: this	page shoul	d not be cor	npleted in o	cycle 1	Page 6 of 7
day 1 of each cycle (fro	ompleted and signed i m cycle 2 onwards)	by the local	principal in	vestigator ,	/ delegated	investigator and done on
Date of response assessn Patient's response to mai (choose <u>one</u> option only) (e.g. this is the response i.e. cycle 1 would be ass and documented on the o	ntenance treatment: e to last cycle received, essed on cycle 2, day 1	4= Pl 5= N 6= SI 7= Pl	२ GPR २ IR D D — Patient o	te first progr ss—		be followed up as per protocol eatment summary form)
Investigator name (print):			Investi signati Date s	ure:	DM	M Y Y Y Y

- Disease response assessment should be based on blood and/or urine tests performed at the start of each cycle (day 1, ± 7 days), this must be assessed by the PI or delegated investigator (see appendix 3 of protocol)
- Disease response for each cycle must be assessed according to the paraprotein/BJP/SFLC results of tests performed at the beginning of the subsequent cycle, for example, response to cycle 1 would be assessed on cycle 2, day 1, and documented on the cycle 2 CRF.
- At the end of maintenance, disease assessment must be performed within 14 days of the last treatment. This should be re-• ported on the maintenance summary CRF





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

6 Month Post-Start of Maintenance Form

Patient Initials

Α

Trial Number

(This form has 6 pages including cover sheet)

R

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>









Additional instructions for completing forms

Page 2 of 6

The 6 Month Post-Start of Maintenance Form should be completed after the patient has completed 6 months of maintenance, and sent along with Maintenance cycle 6

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)





Cardamon	Trial CAR - Patient Initials						
6 Month Doct Start	of Maintenance Form						
Visit date	Page 3 of 6						
Has the Quality of Life (QoL) been completed?	1=Yes; please ensure the form is attached 3=No, please provide reason if not done:						
Date of QoL completion: D D	M M Y Y Y Y						
Bone marrow biopsies							
Bone marrow aspirate Date of sa	mple D D M M Y Y Y Y						
1= Present, complete % of plasm 2= Present , not measured 3= Absent 4= Not done	na cells: %						
Bone marrow trephine Date of sar	nple D D M M Y Y Y Y						
1= Present, complete % of plasm 2= Present , not measured 3= Absent 4= Not done	a cells: %						
Bone marrow aspirate sample must be se	nt to HMDS, Leeds 6 months post-start of maintenance						
	Sent? 1=Yes 2= No Date sample sent to lab						
	RD (2ml) to HMDS, Leeds						
If No to the above, specify a reason:							
Soft tissue plasmacytoma/Extramedullary lesions							
Does the patient have any soft tissue pla Extramedullary lesions?	smacytomas/ 1= Yes, complete date of test and a separate line for each site involved 2= No						
If yes, date of test	M M Y Y Y Y Long axis Short axis						
Site involved:	Bidimensional measurements (cm):						
Site involved:	Bidimensional measurements (cm):						
Site involved:	Bidimensional measurements (cm):						

 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 31.10.2017 Version 3.1

 UCL CTC Use only:
 Form received:

 Date form entered:

 Initials:





Cardamon	Trial Number C A R –	Patient Initials
6 Month Post-Start of	Maintenance Form	Page 4 of 6
PET sub study: 6 month post-sta (please complete for patients participating		
Date of PET-CT:	D D M M Y Y Y Y	
Date images transferred to PET core lab:		
Efficacy assessments		
Date of test D D M N	M Y Y Y Y	
Invelorita , preuse	ein expression <u>one</u> option only) 1= Single paraprotein expressed 2= Light chain only 3 = Biclonal	
Paraprotein type key: 1 = IgG, 2 = IgA, 3	= IgM, 4 = IgD	
Specify paraprotein type:	Serum paraprotein 4= Present, please complete result 5= Too faint to quantify 6= Absent 7= Not Done	(g/L)
Specify paraprotein type:	Serum paraprotein 4= Present, please complete result 5= Too faint to quantify 6= Absent 7= Not Done	(g/L)
Serum free light chain: Kappa (mg/L)	OR Tick i	if not done
Serum free light chain: Lambda (mg/L)	OR Tick i	if not done
Serum free light chain Kappa/Lambda ratio:	Normal range of Kappa/ Lambda FLC ratio:	_
Urinary light chain measurement		
1= Present, quantifiable Please complete 24h BJP 2= Too faint to quantify (24h BJP o 3= Absent 5= Present, not formally quantified (if unable to perform 24h BJP) Immunofixation (only to confirm	only) <u>one</u> on	$ose \qquad \qquad 3 = N/A$
Immunofixation Serum 2=	Positive Negative Date of test Not done	Y Y
Immunofixation Urine 2=	Positive Negative Date of test D D M M Y Y Not done	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 31.10.2017 Version 3.1

 UCL CTC Use only:
 Form received:

 Date form entered:

 Initials:

ardamon		Trial Number	С	A	R							Patient Initials		
maging (If clin	ost-Start or ically indicated c	or for resp	onse	asses	ssmen	t if p	ersis	stent	soft	tissı	ie pl	asmac	-	e 5 of 6 preser
vB: If patient is partic	ipating in PET-CT sub stu	uay piease com	piete se	εςτιοπ α	t the end	of this	page	Date o	of test					focal lesi es 2= No
MRI	1= Evidence of 2= No evidence 3= Not done				D	D	Μ	М	Y	Y	Y	Y		
ст	1= Evidence of 2= No evidence 3= Not done				D	D	М	М	Y	Y	Y	Y		
PET	1= Evidence of 2= No evidence 3= Not done				D	D	М	М	Y	Y	Y	Y		
Skeletal survey	1= Evidence of 2= No evidence 3= Not done				D	D	М	М	Y	Y	Y	Y		
Other imaging	1= Evidence of 2= No evidence 3= Not done				D	D	Μ	М	Y	Y	Y	Y		
	ecify type of other i in number or size o		esion	s been	seen o	n any	radio	ograph	?		1 = Ye 2 = N			
									L					





Cardamon	Trial Number CAR	Patient Initials
6 Month Post-Start o	of Maintenance Form	Page 6 of 6
Response 6 months post-start o	f maintenance	
Date of response assessment	D D M M Y Y Y Y	
Patient's response to maintenance (choose <u>one</u> c		
	7= PD — Patient off protocol treatment— (Complete first progression and t 8= Unable to assess— Specify reason:	
Investigator name (print):	Investigator signature: Date signed:	M Y Y Y Y
Name of person completing form: The site PI or delegated investigator must sig Investigator name:	gn to confirm that information within the CRF is accurate Investigator signature: Date comple	M M 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 31.10.2017 Version 3.1

 UCL CTC Use only:
 Form received:

 Date form entered:
 Initials:

 Initials:



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

End of Maintenance Form

Patient Initials

Trial Number

C	A	R	_	

(This form has 5 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>









Additional instructions for completing forms

Page 2 of 5

The End of Maintenance form collects details of the patient's response to maintenance treatment. Assessments are to be performed within 14 days of completing the last cycle of maintenance.

Specific Fields

- Please ensure that you are using the correct units (i.e. haemoglobin in g/dL). If your local report uses different units please convert these before entering them on the form
- If any efficacy tests have not been done because they are not clinically indication, please ensure that you complete the boxes with ND to confirm that the tests were not done. A discrepancy will be raised for those fields left completely blank
- Disease response should be confirmed by a local investigator
- Please ensure a progression/relapse form is submitted for patients with progressive disease

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
- The Principal Investigator (PI) is responsible for the accuracy of the data reported on the CRF
- Please ensure that all adverse events are recorded on the adverse event form and the form is attached
- 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)





Cardamon		atient hitials
End of Maintenance	Form	Page 3 of 5
Adverse events		
Did the patient experience any adver between their last cycle of maintena their end of maintenance assessmen	nce and 1 = Yes (please ensure adverse event form i	is submitted)
Pregnancy test (for females of	child bearing potential only)	
Result: 1 = Negative 2 = Positive 3 = Not applicable	Date of pregnancy D D M M Y Y Y test	Y
Bone marrow biopsies (to conf	irm CR only)	
Bone marrow aspirate Date of sar	nple D D M M Y Y Y Y	
1= Present, complete % of plasm 2= Present , not measured 3= Absent 4= Not done	a cells:	
Bone marrow trephine Date of sar	nple D D M M Y Y Y Y	
1= Present, complete % of plasm 2= Present , not measured 3= Absent 4= Not done	a cells: %	
If No to the above, specify a reason:		
Soft tissue plasmacytoma/Extra	nedullary lesions	
Does the patient have any soft tissue plasma Extramedullary lesions?	acytomas/ 1= Yes, complete date of test and a separate 2= No	line for each site involved
If yes, date of test D D	M M Y Y Y Y	Long axis Short axis
Site involved:	Bidimensional measurements (cm):	x
Site involved:	Bidimensional measurements (cm):	x
Site involved:	Bidimensional measurements (cm):	x

 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 31.10.2017 Version 3.1

 UCL CTC Use only:
 Form received:

 Date form entered:

 Initials:





Cardamon		atient itials
End of Maintenance	Form	Page 4 of 5
Efficacy assessments		
Date of test D D M	M Y Y Y Y	
inveronia , piedse	totein expression 1 = Single paraprotein expressed 2 = Light chain only 3 = Biclonal	
Paraprotein type key: 1 = IgG, 2 = IgA,	, 3 = IgM, 4 = IgD 4= Present, please complete result	
Specify paraprotein type:	Serum paraprotein Serum paraprotein 5= Too faint to quantify 6= Absent 7= Not Done	(g/L)
Specify paraprotein type:	Serum paraprotein 4= Present, please complete result 5= Too faint to quantify 6= Absent 7= Not Done	(g/L)
Serum free light chain: Kappa (mg/L	.) • OR Tick if no	ot done
Serum free light chain: Lambda (mg/	/L) OR Tick if no	ot done
Serum free light chain Kappa/Lambda ratio:	Normal range of Kappa/Lambda FLC ratio:	-
Urinary light chain measurement		
1= Present, quantifiable Please complete 24h B 2= Too faint to quantify (24h BJF 3= Absent 5= Present, not formally quantif (if unable to perform 24h BJP)	P only) <u>one</u> only):	3 = N/A
Immunofixation (only to confi	rm CR)	
Immunofixation Serum 2	1= Positive 2= Negative Date of test 3= Not done	Y
Immunofixation Urine 2	1= Positive 2= Negative Date of test D D M M Y Y Y 3= Not done	Y
		r.

 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 31.10.2017 Version 3.1

 UCL CTC Use only:
 Form received:

 Date form entered:
 Initials:

 Initials: ____

Cardamon Trial Number C A R - Patient - End of Maintenance Form Page 5 of 5 Imaging (If clinically indicated or for response assessment if persistent soft tissue plasmacytomas present) Date of text Difference Difference MRI 1 = Evidence of myeloma Difference Difference Difference Cr 1 = Evidence of myeloma Difference Difference Difference Difference PET 1 = Evidence of myeloma Difference Difference </th <th>CANCER RESEARCH UK</th> <th>Cancer Research</th> <th>UK and UCL Cancer Trials</th> <th>Centre</th> <th>⁺UCL</th>	CANCER RESEARCH UK	Cancer Research	UK and UCL Cancer Trials	Centre	⁺UCL
Imaging (If clinically indicated or for response assessment if persistent soft tissue plasmacytomas present) Date of text Interview of the interview of myeloma Imaging (If clinically indicated or formeloma Imaging (If clinically indininin the indicated indicate)	Cardamon				
MRI 1 = Evidence of myeloma 0 0 M Y Y Y CT 2 = No evidence of myeloma 0 0 M Y Y Y CT 2 = No evidence of myeloma 0 0 M M Y Y Y CT 2 = No evidence of myeloma 0 0 M M Y Y Y PET 1 = Evidence of myeloma 0 0 M M Y Y Y 3 = Not done 0 0 M M Y Y Y I I Evidence of myeloma 0 0 M M Y Y I I S Not done 0 I M Y Y I I S Not done 0 I Y Y I I S No evidence of myeloma I Y Y I I S No evidence of myeloma I I No No No No No No No No No No <td< th=""><th></th><th></th><th></th><th></th><th>asmacytomas present) Lytic or focal lesions?</th></td<>					asmacytomas present) Lytic or focal lesions?
CT 2 - No evidence of myeloma 3 - Not done PET 1 - Evidence of myeloma 2 - No evidence of myeloma 3 - Not done Skeletal survey 1 - Evidence of myeloma 3 - Not done Other imaging 2 - No evidence of myeloma 3 - Not done Specify type of other imaging 3 - Not done Specify type of other imaging A - No evidence of myeloma 3 - Not done Specify type of other imaging - D - M M M Y Y Y - D - M M M Y Y Y - D - M M M Y Y Y - D - M M M Y Y Y - D - M M M Y Y Y - D - M M M Y Y Y - D - M M M Y Y Y - D - M M M Y Y Y - D - M M M Y Y Y - D - M M M Y Y Y - D - M M M Y Y Y - D - N M M Y Y Y - D - N M M Y Y Y Y - D - N M M Y Y Y Y - D - N M M Y Y Y Y - D - N M M Y Y Y Y - D - N M M Y Y Y Y - D - N M M Y Y Y Y - D - N M M Y Y Y Y - D - N M M Y Y Y Y - D - N M M Y Y Y Y	MRI	2= No evidence of myeloma		Y Y Y	Y
PET 2 = No evidence of myeloma 3 = Not done 2 = No evidence of myeloma 2 = No Response at the end of maintenance Date of response assessment P P M M Y Y Y Patient's response to maintenance treatment: 2 = CR 3 = VGPR 4 = PR 5 = MR 6 = 5D 7 = D 8 = Unable to assess-Specify reason: Investigator name Investigator name D M M Y Y Y Name of person completing form:	СТ	2= No evidence of myeloma	D D M M	Y Y Y	Y
Skeletal survey 2 = No evidence of myeloma 3 = Not done Other imaging 1 = Evidence of myeloma 2 = No evidence of myeloma 3 = Not done Specify type of other imaging Has an increase in number or size of lytic bone lesions been seen on any radiograph? 1 = Evidence Date of response at the end of maintenance Date of response at the end of maintenance Date of response to maintenance treatment: 1 = SCR (choose one option only) 2 = CR 3 = WOR 4 = PR 5 = MR 6 = SD 7 = PD 8 = Unable to assess—Specify reason: Investigator name Investigator name Signature: Date signed: D M M Y Y Y Y Name of person completing form: Signature of person completing form: Date completed: Date completed: Date P or delegated investigator must sign to confirm that information within the CRF is accurate Investigator signature: Date completed:	PET	2= No evidence of myeloma	D D M M	Y Y Y	Y
Other imaging 2 = No evidence of myeloma 3 = Not done Specify type of other imaging Has an increase in number or size of lytic bone lesions been seen on any radiograph? 1 = Yes 2 = No Response at the end of maintenance Date of response assessment 0 P M Y Y Patient's response to maintenance treatment: 1 = SCR 2 = CR 3 = VGPR 4 = R 5 = MR 6 = SD 7 = PD 8 = Unable to assess—Specify reason: Investigator name Investigator Investigator name 1 = gens Investigator name Signature of person completing form: Date completed: Date of person completing form: Signature of person completing form: Date completed: D M Y Y Y The site PI or delegated investigator mast sign to confirm that information within the CRF is accurate Date completed: Date completed:	Skeletal survey	2= No evidence of myeloma	D D M M	Y Y Y	Y
Has an increase in number or size of lytic bone lesions been seen on any radiograph? 1 = Yes 2 = No Response at the end of maintenance Date of response assessment P M Y Y Y Patient's response to maintenance treatment: (choose <u>one</u> option only) 1 = sCR 2 = CR 3 = VGPR 4 = PR S = MR 6 = SD 7 = PD 8 = Unable to assess—Specify reason: Investigator name (print): Investigator signature: Date signed: P M Y Y Y Y Name of person completing form: Signature of person completing form: D = M Date completed: D = M D = M M Y Y Investigator name: Investigator signature: Investigator signature: D = M D = M M Y Y	Other imaging	2= No evidence of myeloma	D D M M	Y Y Y	Y
Has an increase in number or size of lytic bone lesions been seen on any radiograph? 2 = No Response at the end of maintenance Date of response assessment D Date of response to maintenance treatment: 1 = sCR 2 = CR 3 = VGPR 4 = PR 5 = MR 6 = SD 7 = PD 8 = Unable to assess—Specify reason: Investigator name Investigator signature: Date of person completing form: Signature of person completing form: Date of person completing form: Signature of person completing form: Date of person completing form: Interstigator must sign to confirm that information within the CRF is accurate Investigator name: Investigator signature: Date completed:	Spec	ify type of other imaging			
Date of response assessment D D M Y Y Y Y Patient's response to maintenance treatment: 1 = sCR 2 - CR 3 = VGPR 4 = PR 5 = MR 6 = SD 7 = PD 8 = Unable to assess - Specify reason: Investigator name Investigator Investigator investigator investigator Date signed: D M Y Y Y Y Name of person completing form: Signature of person completing form: Date completed: D M Y <t< td=""><td>Has an increase in</td><td>number or size of lytic bone lesio</td><td>ons been seen on any radiograp</td><td>hri i -</td><td></td></t<>	Has an increase in	number or size of lytic bone lesio	ons been seen on any radiograp	hri i -	
Date of response assessment 1 = sCR Patient's response to maintenance treatment: 1 = sCR 2 = CR 3 = VGPR 4 = PR 5 = MR 6 = SD 7 = PD 8 = Unable to assess—Specify reason: Investigator name Investigator (print): Investigator Signature of person completing form: Date completed: D M Mame of person completing form: Signature of person completing form: Date signed: D M Y Y Y	-	D			
(choose <u>one</u> option only) 2 = CR 3 = VGPR 4 = PR 5 = MR 6 = SD 7 = PD 8 = Unable to assess—Specify reason: Investigator name (print): Date signed: Date signed: Date completed: Date completed:	Date of response asse	ssment			
(print): linvestigator name: linvestigator name: linvestigator signature: linvestigator sign	Patient's response		2= CR 3= VGPR 4= PR 5= MR 6= SD 7= PD	reason:	
(print): linvestigator name: linvestigator name: linvestigator signature: linvestigator sign					
Date signed:			-		
The site PI or delegated investigator must sign to confirm that information within the CRF is accurate Investigator name: Investigator signature: Date completed:			Date signed:	D M M	Y Y Y Y
The site Pl or delegated investigator must sign to confirm that information within the CRF is accurate Investigator name: Investigator signature: Date completed:	Name of person completing	g form: Signature of p	person completing form:	Date completed:	
Investigator name: Date completed:				DDM	MYYYY
	Investigator name:	Investigator s	signature:		MYYYY

 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 31.10.2017 Version 3.1

 UCL CTC Use only:
 Form received:

 Date form entered:
 Initials:

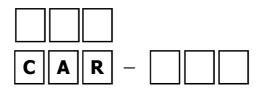


Carfilzomib/Cyclophosphamide/Dexamethasone with maintenance carfilzomib in untreated transplant-eligible patients with symptomatic MM to evaluate the benefit of upfront ASCT

Maintenance Summary Form

Patient Initials

Trial Number



(This form has 3 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>









Additional instructions for completing forms

Page 2 of 3

The maintenance summary form collects details of the patient's maintenance treatment.

Specific Fields

- Total number of Maintenance cycles should be entered—even if a patient completed only 1 day of a cycle, it is considered a cycle
- Maintenance summary form should be completed at the end of the Maintenance treatment phase. If a patient withdraws at any time during maintenance, the maintenance form detailing the last cycle the patient received should be submitted to the UCL CTC concurrently with this form

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 if not required
 - 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)



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Trial

Number



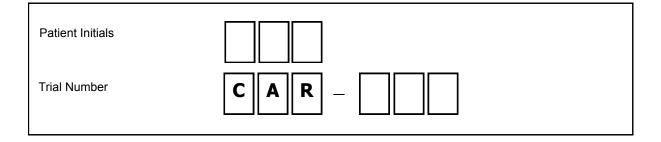
Maintenance Summary	/ Form	Page 3 of 3
To be completed for all patie	<u>ents</u>	
Did patient receive full maintenance t	reatment? 1= Yes, please complete this section only 2= No, please complete both sections	
Total number of Carfilzomib maintena	nce treatment cycles received:	
Date treatment stopped/completed:		
		_
Specify a reason for discontinuation or	not completing maintenance treatment: (choose <u>one</u> option only from below)	
1 = Disease Progression / Relapse (Pleas	e complete a Progression/Relapse form)	
2 = Death (Please complete a Death forr	71)	
	···/	
3 = Toxicity , please specify: (Please complete an AE/SAE form as app	aropriata	
(Please complete an AE/SAE Jorn as app	propriate)	
4 = Lost to follow up (Please complete a	Lost to Follow up/ Withdrawal form)	
5 =Intercurrent illness preventing furthe	er treatment please specify:	
6 =Other, please specify:		
Name of person completing form:	Signature of person completing form: Date completed:	
		' l' l' l' l
The site PI or delegated investigator must sign to co	onfirm that information within the CRF is accurate	
Investigator name:	Investigator signature: Date completed:	
		YYYY

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 20.07.2017 Version 3.0 Date form entered: UCL CTC Use only: Form received: Initials:



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



(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>









Additional instructions for completing forms

Page 2 of 7

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)



Α

R

Trial

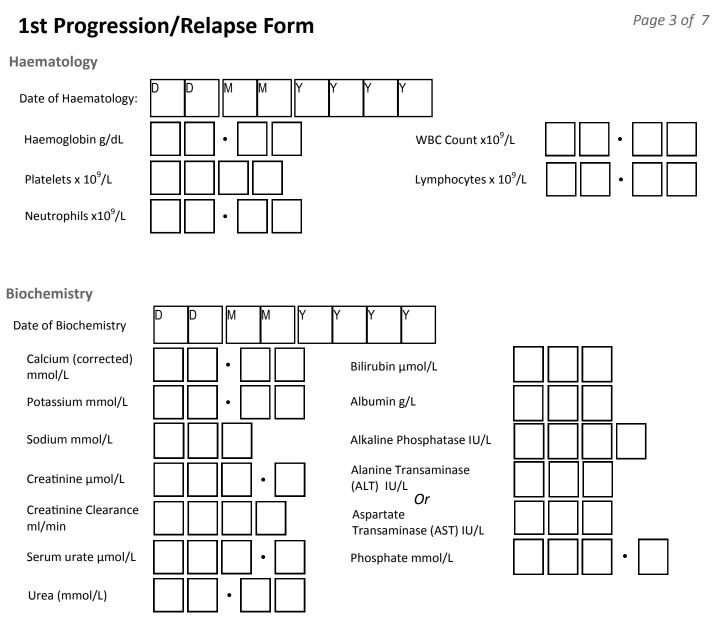
Number

С



Cardamon

Patient Initials





Α

С

R

Trial

Number



1st Progression/Relapse Form	Page 4 of 7
Bone marrow biopsies	
Bone marrow aspirate Date of sample	
1= Present, complete % of plasma cells: 2= Present , not measured 3= Absent 4= Not done $\begin{pmatrix} 1 \\ 2 \\ 3 \\ 4 \\ 4 \\ 4 \\ 3 \\ 4 \\ 4 \\ 5 \\ 5 \\ 6 \\ 6 \\ 7 \\ 6 \\ 7 \\ 7 \\ 7 \\ 7 \\ 7 \\ 7$	
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 1 = Present, complete % of plasma cells: $2 = Present, not measured %$	
Bone marrow aspirate and peripheral blood samples must also be sent to the UCL Cancer Institute Myeloma Lab at r N.B: Sites unable to perform cytogenetics/FISH must send an additional 4-8ml of BM aspirate to the UCL Cancer Inst	
Sent? 1=Yes 2= No Date sample sent to lab BM aspirate for genomic analyses (8ml) to the D D M M Y	YYY
UCL Cancer Institute Myeloma Lab	
Peripheral blood sample for genomic analyses (8ml) to the DDMMMY UCL Cancer Institute Myeloma Lab	Y 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?	e for each site involved
If yes, date of test D D M M Y Y Y Y	Long axis Short axis
Site involved: Bidimensional measurements (cm):	x
Site involved: Bidimensional measurements (cm):	x
Site involved: Bidimensional measurements (cm):	x

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 UCL CTC Use only:
 Form received:

 Date form entered:
 Initials:

 Form received: Date form entered: _____ Initials: ___





Cardamon		itient
1st Progression/R To be completed upon fi	Relapse Form Tirst disease progression/relapse.	Page 5 of 7
Efficacy assessments Date of test D D	M M Y Y Y Y	
complete this section: (cl	araprotein expression 1= Single paraprotein expressed choose one option only) 2= Light chain only 3 = Biclonal	
Paraprotein type key: 1 = IgG, 2 = Specify paraprotein type:	= IgA, 3 = IgM, 4 = IgD Serum paraprotein 4= Present, please complete result 5= Too faint to quantify 6= Absent 7= Not Done	(g/L)
Specify paraprotein type:	Serum paraprotein 4= Present, please complete result 5= Too faint to quantify 6= Absent 7= Not Done	(g/L)
Serum free light chain: Kappa (r	(mg/L) OR Tick if no	ot done
Serum free light chain: Lambda	a (mg/L) • OR Tick if no	ot done
Serum free light chain Kappa/Lambda ratio:	Normal range of Kappa/Lambda FLC ratio:	-
Urinary light chain measuremer	nt	
1= Present, quantifiable <i>Please complete</i> 2= Too faint to quantify (24 3= Absent 5= Present, not formally qu (<i>if unable to perform 24h E</i>	juantified	3 = N/A

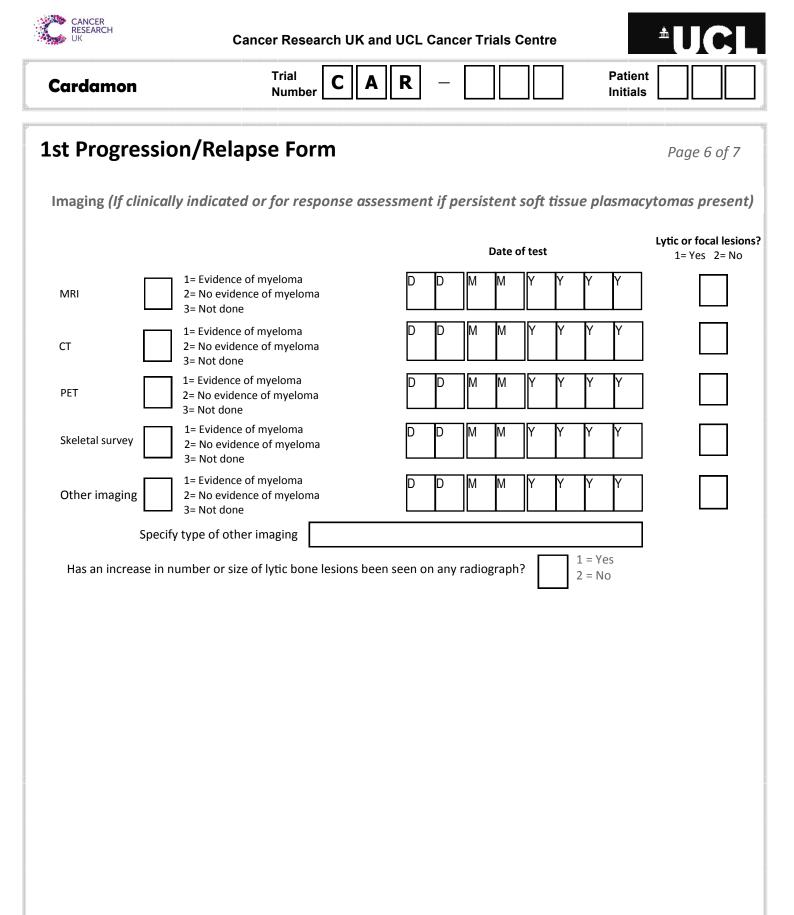
 Please return to: Cardamon Trial Coordinator, CR UK & UCL Cancer Trials Centre, 90 Tottenham Court Road, London, W1T 4TJ

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 UCL CTC Use only:
 Form received:

 Date form entered:
 Initials:

 Initials:



CANCER RESEARCH WK Ca	ancer Research UK and UCL Cancer Trials Centre	
Cardamon	Trial C A R – Patient Initials	
1st Progression/Rela	apse Form Page 7 d	of .
Date of <u>first</u> Progression/Relapse	D D M M 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 diseas (.	se progression in the table below: 1=Yes See Appendix 3 for further details) 2=No	
≥25% increase in serum paraprot	ein (absolute increase ≥5g/l)	
≥25% increase in urine light chain	n excretion (absolute increase ≥200mg/24h)	
≥25% increase in the difference b	etween involved and uninvolved light chains (absolute increase ≥100mg/l)	
≥25% increase in bone marrow pl	lasma cell percentage (absolute increase ≥10%)	
Development of new lytic bone le	esions or soft tissue plasmacytomas	
Definite increase in the size of ex	isting bone lesions or soft tissue plasmacytomas	
Development of hypercalcaemia	(>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: and provide the start date :	? 1= Yes (please complete treatment details and start date below) 2= Palliation/no further treatment 3= Watch and wait or not known at present D M M Y Y Y	
Is Salvage ASCT planned for this patien second remission?	t in 1= Yes 2= No, please complete below 3= Not known at this time, please amend this form once this information is avail	lab
If No , please specify a reason for not planning to proceed to salvage ASCT:		
lame of person completing form:	Signature of person completing form: Date completed:	(
The site PI or delegated investigator must si	ign to confirm that information within the CRF is accurate	
ivestigator name:	Investigator signature: Date completed:	

 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 31.10.2017 Version 3.1

 UCL CTC Use only:
 Form received:

 Date form entered:

 Initials:



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

2nd Progression/Relapse Form

Patient Initials	
Trial Number	

(This form has 4 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>









Additional instructions for completing forms

Page 2 of 4

The 2nd Progression/Relapse Form should be completed at the time and in the event of a second 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 if not required
 - 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)



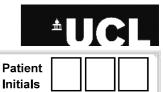
Α

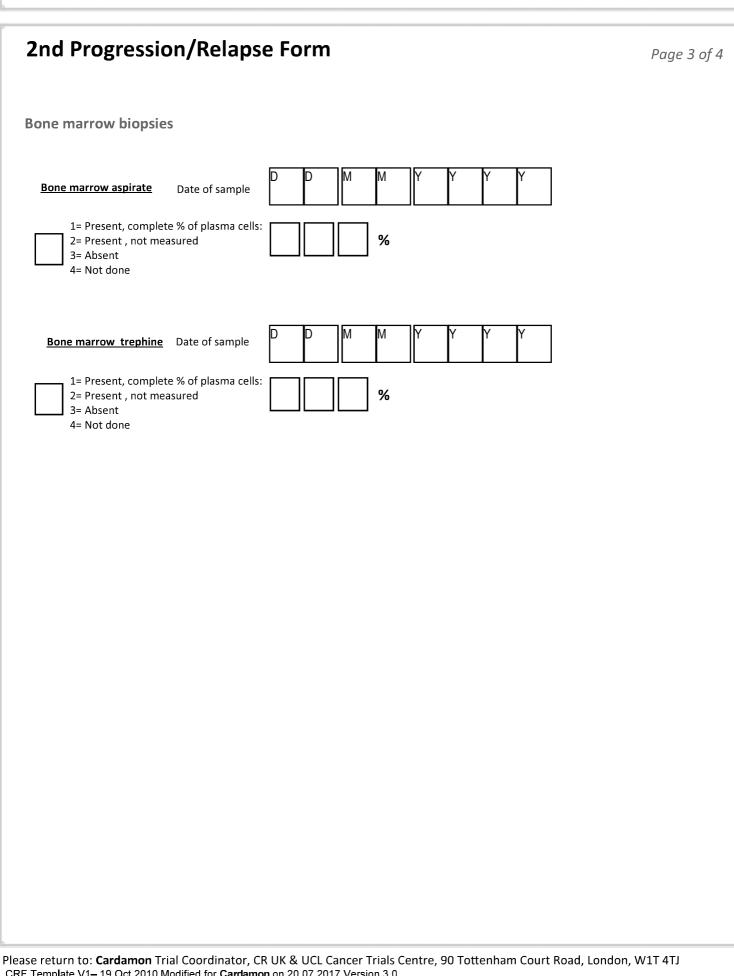
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R

Trial

Number







Α

С

R



Page 4 of 4

2nd Progression/Relapse Form

To be completed upon second disease progression/relapse.

Trial

Number

Date of <u>second</u> Progression/ Relapse

D	D	М	М	Y	Y	Y	Y

Please specify the nature of disease progression in the table below: 1= Yes

2=No

≥25% increase in serum paraprotein (absolute increase ≥5g/l)*		
≥25% increase in urine light chain excretion (absolute increase ≥200mg/24h)*		
≥25% increase in the difference between involved and uninvolved light chains (absolute increase ≥100mg/l)*		
≥25% increase in bone marrow plasma cell percentage (absolute increase ≥10%)*		
Development of new lytic bone lesions or soft tissue plasmacytomas		
Definite increase in the size of existing bone lesions or soft tissue plasmacytomas		
Development of hypercalcaemia (>2.8mmol/l) attributed solely to myeloma		
Other, please specify below:		

*with respect to nadir values after first progression

Further Treatment Plan

1= Yes (please complete treatment details and start date below)2= Palliation/no further treatment3= Watch and wait/not known at present (please provide update when known)
D D M M Y Y Y Y
Signature of person completing form: Date completed:
nfirm that information within the CRF is accurate
Investigator signature: Date completed:

 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 20.07.2017 Version 3.0

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 Form received:

 Date form entered:
 Initials:

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

Follow Up form / Long Term Follow Up Form

Patient Initials

Trial Number



R

Α

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>









Additional instructions for completing forms

Page 2 of 3

The Follow up/Long Term Follow up Form is used to follow up all patients registered to the trial (provided they have not withdrawn consent) and to monitor overall and progression free survival. See section 9.7 of the protocol for further details.

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.
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- 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)
- •
- Follow Up / Long Term Follow Up Schedule (see section 9.7 of the protocol)
- Patients who complete all trial treatment (induction, consolidation/ASCT and maintenance) or discontinue study treatment for any reason other than progression/inadequate response/ inadequate bone marrow harvest should be followed up 3 monthly for 12 months post last trial treatment. After 12 months, patients should enter long term follow-up—see section 9.9 of protocol for further details
- Patients who progress at any point during the study treatment, achieve <PR after induction treatment, or have an inadequate stem cell harvest should continue to be followed up for survival and subsequent treatment information at 6 monthly intervals from the date of progression as per long-term follow-up
- Patients on long term follow up should be seen according to routine clinical practice, though not less than every 6 months
- A progression/relapse form should be submitted as soon as possible in the case of a relapse, regardless of the time until the next follow up visit

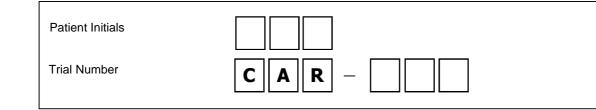
CANCER RESEARCH W	Cancer Research UK and UCL Cancer Trials Centre
Cardamon	Trial C A R – Patient Initials
[:] ollow Up / Lonរ្	g Term Follow Up Form Page 3 of
Date of Visit: D D N	1 M Y Y Y Follow up month: Months post treatment / relapse (delete as applicated ble)
Since the patient's last follo patient's partner become p	
Has the patient developed a since last visit?	a secondary malignancy 1 = Yes 2 = No
If yes please give details:	
Patient status:	E = Alive without progression = Alive with progression/relapse (<i>Please complete disease progression form for 1st or 2nd relapse</i> = Deceased (<i>Please complete death form</i>) = Alive, in second remission = Alive, in third or later remission
If progressed, enter date of progression:	
Has the patient had any further myeloma treatment since last visit?	1 = Yes 2 = No
If yes, start date of further myeloma treatment?	
Type of myeloma treatment:	1 = Chemotherapy 2 = Radiotherapy 4 = Biological therapy 5 = Combination therapy 6 = Other
Please specify the treatme	ent regimen given:
Best response to t treatment (choose <u>on</u>	given: 2= CR 6= SD
ame of person completing form:	Signature of person completing form: Date completed:
The site PI or delegated investigator vestigator name:	must sign to confirm that information within the CRF is accurate Investigator signature: Date completed:
	Investigator signature: Date completed:

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 17 Sep 2018, v4.0 UCL CTC Use only: Form received: _____ Date form entered: _____ Initials: ____



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

Withdrawal/Lost to Follow Up Form



(This form has 3 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>









Additional instructions for completing forms

Page 2 of 3

The Withdrawal/Loss to Follow Up Form is used to record details of a patient's withdrawing from the trial, or those lost to follow up

 In addition to this form, if the patient withdraws before they have started their first cycle of maintenance then sites should complete the <u>Treatment Summary Form</u>. For all withdrawals or losses to follow up after the patient has started maintenance treatment please complete the <u>Maintenance Summary Form</u>

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
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- CRF Footer section
 - The "completed by" Name should be legible Each CRF should be signed and dated by the person completing the form
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	Ca	incer Researd	ch UK and L	JCL Cance	r Trials	Centre				9
Cardamon		Trial Number	CA	R] – [Patient Initials		
Vithdrawa	I/Lost to	o Follow	v Up Fo	orm					Page	3 of
Please specify p	atient's status:		ost to Follow lease complet		& C			l rawn co e comple	nsent te Section	ns B &
A: Lost to Follow	— — — — Up									
Date the patien	t was last known	to be alive (DD)/MM/YYYY)	D D	М	М	Y Y	Y	Y	
Reason patient	was lost to follow	w up								
	Moved Away		Emigrated		Lost (Contact			Discharge	d to G
	Other (specify re	ason)			-					
B: Withdrawn										
Date patient with	ndrew (DD/MM/Y	YYY)		Γ						
Please specify v	which aspects of	the trial the na	tient has with	drawn from (even tho	uah they	cannot l		nally	
2. Future Data C Patient has with GP. <u>3. Future Data C</u> Patient has with from the NHS In	drawn consent f ollection: NHS Ir drawn consent	for collection of <u>information Serv</u> for collection o	ice					2 =	Yes No Yes No	
4. Biological Sar Patient withdraw future research	nples	-	lected tissue/b	blood sample	es to be u	sed in			Yes No	
C: Contact Detai										
If available, pleas patient's future he								f data reç	garding	
Contact Nar	ne:				t's Role urse etc):					
Contact Add	Iress:									
lame of person completir	ng form:	Signature	of person compl	eting form:		Date con				
						DD	Μ	MY	Y Y	Y
The site PI or delegated i	nvestigator must sig			in the CRF is ac	curate	Data con	nletod			
The site PI or delegated in nvestigator name:	nvestigator must sig		information with	in the CRF is ac	curate	Date con		MY	YY	Y

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 CRF Template V1– 19 Oct 2010 Modified for Cardamon on 17 Sep 2018, v4.0

 UCL CTC Use only:
 Form received: ______ Date form entered: ______ Initials: _____

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

Death Form

Patient Initials

Trial Number



(This form has 3 pages including cover sheet)

Please send forms to:

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

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Additional instructions for completing forms

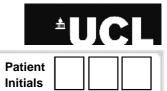
Page 2 of 3

The Death Form is used to record the patient's cause of death

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
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Cardamon	Trial CAR				Patient Initials			
Death Form						Рс	nge 3	of 3
To be completed upon pa	tient's death							
Date of Death	И М Ү Ү Ү Ү							
<u>Primary</u> cause of Death* (choose <u>one</u> option only from	m below)							
1= Dis	ease Progression							
2= Tre	eatment related toxicity, please specify:							
3= Inf	ection							
4= Ca	rdiac event							
5= Re	nal failure							
6= Ot	her malignancy, please complete below: Date confirmed	D D M I	И	Y	Y Y			
	Type of cancer:							
7= Ot	her, please specify:							
*Please ensure that in co	ase of a death due to treatment related to. and faxed to UCL CTC within 1 busine.							
Name of person completing form:	ing form:	Date cor	npleted:					
			D D	М	M Y	Y	Y	Y
	or must sign to confirm that information within	the CRF is accurate][_]
Investigator name:		Date cor	mpleted:	MY		Y		
						_	ľ	'
	Coordinator, CD LIK & LICL Concer Tria	la Cantra 00 Tattan				\A/4T	471	

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 20.07.2017 Version 3.0 UCL CTC Use only: Form received: _ Initials: ___