Cancer Research UK & UCL Cancer Trials Centre **CARDAMON** **ADVERSE EVENT FORM**

Trial No: CAR - ☐☐☐ **Initials:** ☐☐☐ **Date of assessment:** ☐☐☐☐☐☐☐☐ (d d m m y y y y) **Site:** _____

Visit this CRF applies to

I = Induction
C = Consolidation
M = Maintenance
☐ **Cycle no.** ☐☐

OR

1 = End of Induction | 2 = Post-Consolidation
3 = Post-PBSCH
4 = Day 100 Post-ASCT
5 = 6 Months Post Start Maintenance
6 = End of Maintenance
☐

Adverse Event *(If possible, use term as listed in CTCAE v4.03)*	**Severity Grade** [1] *(Grades 0-5) For grade 0 AEs, do not complete the columns to the right*	**Seriousness Criteria** [2]	**SAE Report Submitted** *0 = No 1 = Yes* [3]	**Dates of Onset** d d m m y y y y *(e.g. 01 – 01 – 2011)*	**Outcome** [4]	**Causal relationship with Carfilzomib**[5]	**Causal relationship with Cyclophosphamide**[5] (0 in Maintenance unless long term effect)	**Causal relationship with Dexamethasone**[5] (0 in Maintenance unless long term effect)
Neutrophil count decreased				Start ☐☐☐☐☐☐☐☐ End ☐☐☐☐☐☐☐☐				
Platelet count decreased				Start ☐☐☐☐☐☐☐☐ End ☐☐☐☐☐☐☐☐				
Anemia				Start ☐☐☐☐☐☐☐☐ End ☐☐☐☐☐☐☐☐				
Peripheral motor neuropathy				Start ☐☐☐☐☐☐☐☐ End ☐☐☐☐☐☐☐☐				
Peripheral sensory neuropathy				Start ☐☐☐☐☐☐☐☐ End ☐☐☐☐☐☐☐☐				
Diarrhea				Start ☐☐☐☐☐☐☐☐ End ☐☐☐☐☐☐☐☐				
Nausea				Start ☐☐☐☐☐☐☐☐ End ☐☐☐☐☐☐☐☐				
Vomiting				Start ☐☐☐☐☐☐☐☐ End ☐☐☐☐☐☐☐☐				
Fatigue				Start ☐☐☐☐☐☐☐☐ End ☐☐☐☐☐☐☐☐				
Dizziness				Start ☐☐☐☐☐☐☐☐ End ☐☐☐☐☐☐☐☐				
Hypertension				Start ☐☐☐☐☐☐☐☐ End ☐☐☐☐☐☐☐☐				

1) Enter worst grade observed during reporting period / Use CTCAE v4.03 where possible
2) Enter code: 0 = not serious; 1 = resulted in death; 2 = life threatening; 3 = required hospitalisation; 4 = resulted in disability/ incapacity; 5 = congenital anomaly or birth defect; 6 = other medically significant
3) If yes, ensure a completed SAE Report has been submitted to the UCL CTC, unless stated in the protocol as exempt and it is not related to a trial treatment, including maintenance treatment. COVID-19 is an AESI and must be reported as an SAE even if it did not cause hospitalisation and was not life-threatening
4) Enter code: 0 = Fatal; 1 = Not resolved; 2 = Resolved; 3 = Resolved with sequelae; 4 = Resolving; 5 = Unknown
5) Enter code: 0 = Not related (no reasonable possibility) 1 = Related (reasonable possibility)

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Adverse Event *(If possible, use term as listed in CTCAE v4.03)*	**Severity Grade** [1] *(Grades 0-5) For grade 0 AEs, do not complete the columns to the right*	**Seriousness Criteria** [2]	**SAE Report Submitted** *0 = No 1 = Yes* [3]	**Dates of Onset** d d m m y y y y *(e.g. 01 – 01 – 2011)*	**Outcome** [4]	**Causal relationship with Carfilzomib**[5]	**Causal relationship with Cyclophosphamide**[5] (0 in Maintenance unless long term effect)	**Causal relationship with Dexamethasone**[5] (0 in Maintenance unless long term effect)
Dyspnea				Start / End				
Acute kidney injury				Start / End				
Lung infection				Start / End				
Infections and infestations - Other, specify: COVID-19		6		Start / End				
				Start / End				
				Start / End				
				Start / End				
				Start / End				
				Start / End				
				Start / End				
				Start / End				

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FORM COMPLETED BY: **Print name:** ____________________ **Signature:** ____________________ **Date:** ☐☐/☐☐/☐☐☐☐ (d d m m y y y y)

Please return to: Cardamon Trial Co-ordinator, CR UK & UCL Cancer Trials Centre, 90 Tottenham Court Road, London, W1T 4TJ, United Kingdom

For UCL CTC use only: Date form received: ____________ Date form checked: ____________ Date form entered: ____________ Initials: ________

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Trial No: CAR - ☐☐☐ **Initials:** ☐☐☐ **Date of assessment:** ☐☐ ☐☐ ☐☐☐☐ (d d m m y y y y) **Site:** ____________________

Adverse Event *(If possible, use term as listed in CTCAE v4.03)*	**Severity Grade** 1 *(Grades 0-5) For grade 0 AEs, do not complete the columns to the right*	**Seriousness Criteria** 2	**SAE Report Submitted** *0 = No 1 = Yes* 3	**Dates of Onset** d d m m y y y y *(e.g. 01 – 01 – 2011)*	**Outcome** 4	**Causal relationship with Carfilzomib**5	**Causal relationship with Cyclophosphamide**5 (0 in Maintenance unless long term effect)	**Causal relationship with Dexamethasone**5 (0 in Maintenance unless long term effect)
				Start ☐☐ ☐☐ ☐☐☐☐ End ☐☐ ☐☐ ☐☐☐☐				
				Start ☐☐ ☐☐ ☐☐☐☐ End ☐☐ ☐☐ ☐☐☐☐				
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				Start ☐☐ ☐☐ ☐☐☐☐ End ☐☐ ☐☐ ☐☐☐☐				

1) Enter worst grade observed during reporting period / Use CTCAE v4.03 where possible
2) Enter code: 0 = not serious; 1 = resulted in death; 2 = life threatening; 3 = required hospitalisation; 4 = resulted in disability/ incapacity; 5 = congenital anomaly or birth defect; 6 = other medically significant and it is not related to a trial treatment, including maintenance treatment. COVID-19 is an AESI and must be reported as an SAE even if it did not cause hospitalisation and was not life-threatening
3) If yes, ensure a completed SAE Report has been submitted to the UCL CTC, unless stated in the protocol as exempt
4) Enter code: 0 = Fatal; 1 = Not resolved; 2 = Resolved; 3 = Resolved with sequelae; 4 = Resolving; 5 = Unknown
5) Enter code: 0 = Not related (no reasonable possibility) 1 = Related (reasonable possibility)

FORM COMPLETED BY: **Print name:** ____________________ **Signature:** ____________________ **Date:** ☐☐ ☐☐ ☐☐☐☐ (*d d m m y y y y*)

Please return to: Cardamon Trial Co-ordinator, CR UK & UCL Cancer Trials Centre, 90 Tottenham Court Road, London, W1T 4TJ, United Kingdom

For UCL CTC use only: Date form received: ____________ Date form checked: ____________ Date form entered: ____________ Initials: ________

Trial No: CAR - ☐☐☐ **Initials:** ☐☐☐ **Date of assessment:** ☐☐/☐☐/☐☐☐☐ (d d m m y y y y) **Site:** _____

Completion Instructions

- **Record all adverse events (AEs) that occur from informed consent until 30 days post last trial treatment administration whether related to the trial treatment or not.**
- **Events that began before the date of registration do not qualify as AEs unless they worsen.**
- **All AEs added to the form (not pre-printed) must be added to subsequent forms until they have resolved.**
- **Page 3 does not need to be completed or printed if the AEs experienced fit in the first 2 pages. If page 3 is required after submitting pages 1 and 2, re-submit the entire form with page 3. Page 4 never needs to be printed.**

1) Severity Grade

- Enter worst grade observed since last cycle
- Use CTCAE v4.03 where possible. Provide CTCAE v4.03 System Organ Class where it is not, in addition to the non-CTCAE term
- If no AE occurred enter "0" and do not complete the columns to the right

2) Seriousness Criteria

- Use the following options: **0 = not serious; 1 = resulted in death; 2 = life threatening; 3 = required hospitalisation; 4 = resulted in disability/ incapacity; 5 = congenital anomaly or birth defect; 6 = other medically significant**

3) SAE Report Submitted

- Ensure a completed SAE Report has been submitted to the UCL CTC, unless stated in the protocol as exempt and it is not related to a trial treatment, including maintenance treatment.
- Positive cases of COVID-19 must be reported as an **Adverse Event of Special Interest** under the seriousness criteria of **6 = other medically significant** even if it was not life-threatening and did not cause or prolong hospitalisation.

4) Outcome

- Use the following options: **0 = Fatal; 1 = Not resolved; 2 = Resolved; 3 = Resolved with sequelae; 4 = Resolving; 5 = Unknown**

5) Causal relationship with

- Use the following options: **0 = "Not related (no reasonable possibility)" 1 = "Related (reasonable possibility)"**

Note: The expression *'reasonable suspected causal relationship'* is meant to convey in general that there is reason (e.g. facts, evidence or arguments) to suggest a causal relationship. Therefore, if you consider an AE to be either *Definitely*, *Probably* or *Possibly* related to the IMP, select *1= Related (reasonable possibility) to a trial treatment*. AEs considered to fall within the *Unlikely* or *None* categories map to *Not related (no reasonable possibility) to a trial treatment*.