MRC Clinical Trials Unit

Smarter studies
Global impact
Better health

RAMPART

SAE CRF - Form 13
Version 2.0 03 February 2020

Patient Initials [ ][ ][ ][ ] Date of Birth [d d]/[m m m]/[y y y y] Trial Number [R][ ][ ][ ][ ][ ][ ][ ]

Date of Receipt [d d]/[m m m]/[y y y y] *(For MRC CTU use only)* AE number (as specified in AE log) [ ][ ]

This CRF should be completed and faxed to the CTU (0207 670 4818) within 24 hours of becoming aware of an SAE.

A. Details of Report

1 **Type of report**
- ☐ Initial
- ☐ Follow-up, # .....

2 **Trial arm**
- ☐ Arm A (active monitoring)
- ☐ Arm B (durvalumab only)
- ☐ Arm C (durvalumab & tremelimumab)

3 **Gender**
- ☐ Female
- ☐ Male
- ☐ Other, please specify:.....

4 [ ][ ][ ] cm **Height**

5 [ ][ ][ ].[ ] kg **Weight**

B. Details of Event

1 **Why was the event serious?**
- ☐ Resulted in death — *please complete a Death CRF (Form 12)*
- ☐ Life-threatening
- ☐ Required inpatient hospitalisation/prolongation of existing hospitalisation
- ☐ Persistent or significant disability/incapacity
- ☐ Congenital anomaly/birth defect
- ☐ Overdose
- ☐ Other important medical condition

2 **Where did the SAE take place?**
- ☐ Hospital
- ☐ Outpatient clinic
- ☐ Home
- ☐ Nursing home
- ☐ Other, please specify: .....

3 **Main diagnosis/symptom** Enter the main event in the first row, followed by any associated symptoms. If the main diagnosis changes after investigation then please update on a follow-up CRF.	4 **Grade** CTCAE v4.03 (please ✓ one) 1	2	3	4	5	5 **Date of onset** dd/mmm/yyyy	6 **SAE status** If ongoing please leave blank: Resolved	Resolved with sequelae	Worsened	Fatal	7 **Date resolved** dd/mmm/yyyy
						d d m m m y y y y					d d m m m y y y y
8 **Associated symptoms**											
						d d m m m y y y y					d d m m m y y y y
						d d m m m y y y y					d d m m m y y y y
						d d m m m y y y y					d d m m m y y y y

C. Trial Medications

SKIP IF PATIENT ON ACTIVE MONITORING ARM A

1 [ ][ ] **Cycle number**

		Trial Drug: Durvalumab	Trial Drug: Tremelimumab
2 **Date of first administration** dd/mmm/yyyy		d d m m m y y y y	d d m m m y y y y
3 **Actual dose given at most recent administration**		[ ][ ][ ][ ] mg	[ ][ ][ ][ ] mg
4 **Date of most recent administration** dd/mmm/yyyy		d d m m m y y y y	d d m m m y y y y
5 **Causal relationship to SAE** (please ✓ one)	Definitely	☐	☐
	Probably	☐	☐
	Possibly	☐	☐
	Unlikely	☐	☐
	Not related	☐	☐
	Administration route	☐	☐
6 **Expectedness** (please ✓ one)	Expected	☐	☐
	Unexpected	☐	☐
7 **Action taken due to SAE** (please ✓ one)	None	☐	☐
	Dose reduction	☐	☐
	Treatment delayed	☐	☐
	Dose reduction and treatment delayed	☐	☐
	Treatment stopped	☐	☐

Signature | Printed Name | Date Completed [d d]/[m m m]/[y y y y]

Please return a copy to RAMPART Trial, MRC Clinical Trials Unit at UCL, 90 High Holborn, 2nd Floor, London WC1V 6LJ

For office use only

Date form received at CTU dd / mmm / yyyy

Date form entered onto database dd / mmm / yyyy

Initials of data enterer [ ][ ][ ][ ]

Patient Initials | Date of Birth d d / m m m / y y y y | Trial Number R

Date of Receipt d d / m m m / y y y y *(For MRC CTU use only)* | AE number (as specified in AE log)

D. Other Treatments (Exclude any therapy given for management of SAE; include any concomitant medication, radiotherapy and palliative care from the last 3 months . If more than 3 treatments, please print another copy of this page to fill in.

1 **Is the patient taking any other treatments?** (see definition above)
☐ No — ☞ *go to Section E*
☐ Yes

2 **Treatment** (use generic name)				
3 **Total daily dose** (please give units)		result / unit	result / unit	result / unit
4 **Route** (please ✓ one)	Oral	☐	☐	☐
	Intravenous	☐	☐	☐
	Subcutaneous	☐	☐	☐
	Other, please specify:	.....	.....	.....
5 **Start date** dd/mmm/yyyy		d d m m m y y y y	d d m m m y y y y	d d m m m y y y y
6 **Ongoing** (please ✓ one)	No	☐	☐	☐
	Yes	☐	☐	☐
7 **End date** dd/mmm/yyyy		d d m m m y y y y	d d m m m y y y y	d d m m m y y y y
8 **Causal relationship to SAE** (please ✓ one)	Definitely	☐	☐	☐
	Probably	☐	☐	☐
	Possibly	☐	☐	☐
	Unlikely	☐	☐	☐
	Not related	☐	☐	☐
	Administration route	☐	☐	☐
9 **Action taken due to SAE** (please ✓ one)	None	☐	☐	☐
	Dose reduction	☐	☐	☐
	Treatment delayed	☐	☐	☐
	Dose reduction and treatment delayed	☐	☐	☐
	Treatment stopped	☐	☐	☐

E. Event Description

1 **Was this event deemed to be related to progression?** ☞ *If yes, complete Form10 - Progression.*
☐ No
☐ Yes

2 **Describe serious adverse event** (include manifestation and progression of event, any treatments given in response to the event, and any relevant tests carried out e.g. WBC, neutrophil count. Continue on a separate sheet if necessary)

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Signature	Printed Name	Date Completed
		d d / m m m / y y y y

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E. Event Description — *continued*

3 **Did the patient undergo any diagnostic tests in relation to the SAE?**
☐ No — ☞ *go to question E8*
☐ Yes

Diagnostic Tests

4 **Test name**							
5 **Date** dd/mmm/yyyy	d d m m m y y y y	d d m m m y y y y	d d m m m y y y y	d d m m m y y y y
6 **Normal range**				
7 **Result + units**	result	unit	result	unit	result	unit	result	unit

8 d d / m m m / y y y y **What date did you become aware of the SAE?**

9 **Do you consider this event likely to have been caused by anything other than the treatment listed previously on this form?**
☐ No
☐ Yes, please specify (include medical history, drug/alcohol abuse, family history, findings from special investigation):

.....

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.....

.....

Signature	Printed Name	Date Completed
		d d / m m m / y y y y

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For CTU clinical reviewer use ONLY

☐ **7 day SUSAR** ☐ **15 day SUSAR**
☐ **SAR** ☐ **SAE** ☐ **Not SAE**

System Organ Class:.....
Preferred term:.....
Lower level term:.....
MedDra code:.....
Comments: .....

.....

.....

.....

.....

.....

Reviewer's signature: .....

d d / m m m / y y y y **Date checked by clinical reviewer**

For MRC CTU staff use ONLY

☐☐☐☐☐☐☐☐ **Event no.**

d d / m m m / y y y y **If SUSAR, date sent to MHRA & MREC**

d d / m m m / y y y y **Date form checked and ready to file**

MRC CTU staff signature: .....

For office use only

Date form received at CTU dd / mmm / yyyy

Date form entered onto database dd / mmm / yyyy

Initials of data enterer