MRC Clinical Trials Unit

Smarter studies
Global impact
Better health

RAMPART

SAE CRF - Form 13
Version 1.0 29 Oct 2018

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? -** *Tick one only*
- ☐ 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)	4 **Grade** CTCAE v4.03 (please ✓ one) 1 2 3 4 5	5 **Date of onset** dd/mmm/yyyy	6 **SAE status** (please ✓ one) Resolved / Resolved with sequelae / Ongoing / 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

		Trial Drug: Durvalumab	Trial Drug: Tremelimumab
1 ☐☐ **Cycle number**			
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**

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 (dd/mmm/yyyy)

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For CTU clinical reviewer use ONLY

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

Preferred term:.....
Lower level term:.....
MedDra code:.....
Comments: .....

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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 ☐☐☐☐