MRC Clinical Trials Unit

Smarter studies
Global impact
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RAMPART

Adverse Events Log - Form06
Version 1.0 25 June 2018

UCL

Patient Initials	☐☐☐☐	Date of Birth	dd/mmm/yyyy	Date of Consent	dd/mmm/yyyy	Trial Number	R☐☐☐☐☐☐☐☐

ⓘ Record any adverse events, symptoms, clinical findings and new primary cancers the patient experiences from the date of consent to 120 days after the recorded date of last infusion.
ⓘ Any **SARs/SUSARs** should be reported on this log for the duration of the study.
ⓘ If treatment is ended early, adverse events should still be collected for 120 days after the recorded date of last infusion.
ⓘ If no adverse events were experienced since the date of consent for a day 1 visit, question A1 should be answered no and returned to MRC CTU.
ⓘ Adverse event grading should be according to the CTCAE v4.03 grading system i.e. 1-5 depending on severity of adverse event.
ⓘ Any abnormal lab values should be reported as an AE in accordance to CTCAE 4.03. Consult the CTCAE 4.03 document for further information.

A 1 **Has the patient experienced any adverse events since the date of consent (if day 1 visit)?** No ☐ Yes ☐

Initials and date: ☐☐☐☐ dd/mmm/yyyy

B **AE Number**	C **Event Name**	D **Highest Grade (CTCAE v4.03)** (1-5)	E **Date of Onset**	F **Date Resolved**	G **Is it an AESI?**	H **Is it a serious AE? (if yes, complete SAE CRF)**	I **Outcome** (1-5) *	J **Is the AE an immune-related reaction?**	K **Is there reasonable possibility AE was caused by Durvalumab infusion?**	L **Is there reasonable possibility AE was caused by Tremelimumab infusion?**	**Initials and date of row completion**
☐☐		☐	dd/mmm/yyyy	dd/mmm/yyyy	☐ No ☐ Yes	☐ No ☐ Yes		☐ No ☐ Yes	☐ No ☐ Yes	☐ No ☐ Yes	
☐☐		☐	dd/mmm/yyyy	dd/mmm/yyyy	☐ No ☐ Yes	☐ No ☐ Yes		☐ No ☐ Yes	☐ No ☐ Yes	☐ No ☐ Yes	
☐☐		☐	dd/mmm/yyyy	dd/mmm/yyyy	☐ No ☐ Yes	☐ No ☐ Yes		☐ No ☐ Yes	☐ No ☐ Yes	☐ No ☐ Yes	
☐☐		☐	dd/mmm/yyyy	dd/mmm/yyyy	☐ No ☐ Yes	☐ No ☐ Yes		☐ No ☐ Yes	☐ No ☐ Yes	☐ No ☐ Yes	
☐☐		☐	dd/mmm/yyyy	dd/mmm/yyyy	☐ No ☐ Yes	☐ No ☐ Yes		☐ No ☐ Yes	☐ No ☐ Yes	☐ No ☐ Yes	

If adverse events continue on an additional page, please tick box. ☐

***Outcome** 1= Resolved, 2=Resolved with sequelae, 3=Ongoing, 4=Worsened, 5=Fatal

For office use only
Date form received at CTU dd / mmm / yyyy
Date of data entry dd / mmm / yyyy
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Patient Initials [ ][ ][ ][ ] Date of Birth d d / m m m / y y y y Date of Consent d d / m m m / y y y y Trial Number R [ ][ ][ ][ ][ ][ ][ ][ ]

B AE Number	C Event Name	D Highest Grade (CTCAE v4.03) (1-5)	E Date of Onset	F Date Resolved	G Is it an AESI?	H Is it a serious AE? (if yes, complete SAE CRF)	I Outcome (1-5) *	J Is the AE an immune-related reaction?	K Is there reasonable possibility AE was caused by Durvalumab infusion?	L Is there reasonable possibility AE was caused by Tremelimumab infusion?	Initials and date of row completion
[ ][ ]		[ ]	d d / m m m / y y y y	d d / m m m / y y y y	☐ No ☐ Yes	☐ No ☐ Yes		☐ No ☐ Yes	☐ No ☐ Yes	☐ No ☐ Yes	
[ ][ ]		[ ]	d d / m m m / y y y y	d d / m m m / y y y y	☐ No ☐ Yes	☐ No ☐ Yes		☐ No ☐ Yes	☐ No ☐ Yes	☐ No ☐ Yes	
[ ][ ]		[ ]	d d / m m m / y y y y	d d / m m m / y y y y	☐ No ☐ Yes	☐ No ☐ Yes		☐ No ☐ Yes	☐ No ☐ Yes	☐ No ☐ Yes	
[ ][ ]		[ ]	d d / m m m / y y y y	d d / m m m / y y y y	☐ No ☐ Yes	☐ No ☐ Yes		☐ No ☐ Yes	☐ No ☐ Yes	☐ No ☐ Yes	
[ ][ ]		[ ]	d d / m m m / y y y y	d d / m m m / y y y y	☐ No ☐ Yes	☐ No ☐ Yes		☐ No ☐ Yes	☐ No ☐ Yes	☐ No ☐ Yes	
[ ][ ]		[ ]	d d / m m m / y y y y	d d / m m m / y y y y	☐ No ☐ Yes	☐ No ☐ Yes		☐ No ☐ Yes	☐ No ☐ Yes	☐ No ☐ Yes	
[ ][ ]		[ ]	d d / m m m / y y y y	d d / m m m / y y y y	☐ No ☐ Yes	☐ No ☐ Yes		☐ No ☐ Yes	☐ No ☐ Yes	☐ No ☐ Yes	
[ ][ ]		[ ]	d d / m m m / y y y y	d d / m m m / y y y y	☐ No ☐ Yes	☐ No ☐ Yes		☐ No ☐ Yes	☐ No ☐ Yes	☐ No ☐ Yes	

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