Royal Brompton & Harefield NHS
NHS Foundation Trust

Serious Adverse Events (SAEs) Reporting Form for RB&HFT sponsored CTIMPs

Fax number: 020 7351 8578
E-mail: safetyreporting@rbht.nhs.uk

1. Study details						
Study title:						
EudraCT number:			**REC Reference:**			
RO R&D number:			**Principal Investigator (PI):**			
2. Reporting personnel contact details						
Person sending report:			**Trial site:**			
Job title:			**Email:**		**Phone:**	
Type of report:	□ Initial	□ Follow-up	**Has the CI/PI been made aware of the event prior to form being completed?**		□ Yes	□ No
3. Patient details						
Patient trial/study ID:			**Patient initials:**		**Patient DOB:**	dd/mm/yyyy
Gender:	□ Male	□ Female	**Was study drug un-blinded?**	□ Yes	□ No	□ N/A

4. Study/trial treatment details

IMP(s) patient was receiving at time of SAE (if applicable)	**Dose (mg)**	**Route of administration**	**Date of dose initiated**	**End Date** (if applicable)	**Ongoing?**		**Dose reduction**		**Specify:**
			dd/mm/yyyy	dd/mm/yyyy	□ Y	□ N	□ Y	□ N	
			dd/mm/yyyy	dd/mm/yyyy	□ Y	□ N	□ Y	□ N	
			dd/mm/yyyy	dd/mm/yyyy	□ Y	□ N	□ Y	□ N	
			dd/mm/yyyy	dd/mm/yyyy	□ Y	□ N	□ Y	□ N	
			dd/mm/yyyy	dd/mm/yyyy	□ Y	□ N	□ Y	□ N	
			dd/mm/yyyy	dd/mm/yyyy	□ Y	□ N	□ Y	□ N	

Date of last treatment given prior to SAE occurrence?	dd/mm/yyyy	**Was treatment given at full dose prior to event?**	□ Y	□ N	Please specify below:
Most recent cycle (if					

applicable)								
Did reaction abate after stopping drug?	□ Yes	□ No	□ N/A	**Did reaction reappear after reintroduction?**			□ Yes	□ No	□ N/A

4.1. Has patient received any additional treatment for management of SAE?				□ Y	□ N	If yes, please specify below:		
Treatment (please specify)**:**	**Total daily dose (mg):**	**Route of administration**	**Start Date**	**Date initiated**		**Ongoing?**		**End Date** (if applicable)
			dd/mm/yyyy	dd/mm/yyyy		□ Y	□ N	dd/mm/yyyy
			dd/mm/yyyy	dd/mm/yyyy		□ Y	□ N	dd/mm/yyyy

4.2 Any concomitant medication?				□ Y	□ N	If yes, please specify below:		
Treatment (please specify)**:**	**Total daily dose (mg):**	**Route of administration**	**Start Date**	**Date initiated**		**Ongoing?**		**End Date** (if applicable)
			dd/mm/yyyy	dd/mm/yyyy		□ Y	□ N	dd/mm/yyyy
			dd/mm/yyyy	dd/mm/yyyy		□ Y	□ N	dd/mm/yyyy

4.3 Any relevant tests/laboratory data?	□ Y	□ N	*If yes, please specify below:*
Please use separate sheet if necessary:			

4.4 Any relevant medical history/concurrent conditions?	□ Y	□ N	*If yes, please specify below:*
Please use separate sheet if necessary:			

4.5 Any other relevant information?	□ Y	□ N	*If yes, please specify below:*
Please use separate sheet if necessary:			

5. Serious Adverse Event (SAE) details must be completed for each SAE:

Date of onset:	**Date PI/CI became aware:**	**Ongoing?**		**Severity/Intensity**			**Date resolved**
dd/mm/yyyy	dd/mm/yyyy	□ Y	□ N	□ Mild	□ Moderate	□ Severe	dd/mm/yyyy

Expectedness:	□ Expected	□ Unexpected	Please indicate if the event is listed in the reference document (i.e. protocol, SmPC, Investigator's Brochure)?	□ Y	□ N

Why was the event classified as serious? (tick the most appropriate)	**Where did the event take place?**			**Outcome**
□ Resulted in death	□ Home			□ Resolved
□ Resulted in persistent or significant disability/incapacity	□ Out-patient clinic			□ Resolved with sequelae
□ Life-threatening	□ Hospital	Admission date:	dd/mm/yyyy	□ Ongoing

□ Required inpatient or prolonged existing hospitalisation		Discharge date:	dd/mm/yyyy	□ Unresolved
□ Resulted in congenital anomaly/birth defect	□ Nursing Home			□ Worsened
□ Other Important Medical Event (IME)	□ Hospice			□ Fatal *(please specify date)*
Please specify any other IME:	□ Other	*Please specify:*		dd/mm/yyyy

5.1 Casual relationship to event (Is the event related to the subject's involvement in the study)?

Trial drug (IMP)	*Definitely related	*Possibly related	*Probably related	Not related	Unlikely	Not assessable
	☐	☐	☐	☐	☐	☐
	☐	☐	☐	☐	☐	☐
	☐	☐	☐	☐	☐	☐

**Please note – definitely, possibly and probably qualifies an AE as an AR*

5.2 Action taken to address the above:

Trial drug (IMP)	None	*Dose reduction	*Treatment delayed	Treatment delayed and reduced	Treatment permanently stopped	Name of person making a decision
	☐	☐	☐	☐	☐	☐
	☐	☐	☐	☐	☐	☐

**Please specify details of dose reduction and/or treatment delay, if any:*

6. Summary Description of the event:

Please give a concise medical description of the event including all relevant symptoms (please specify the grade):

7. Outcome

Please provide details of how you conducted the assessment of causality for expectedness and relatedness and/or why you reached decisions highlighted above (i.e. reasons for the outcome):

Whom did you discuss your judgment of assessment with:

Reporting death:

- *Was it expected? If yes, please state reasons (i.e. disease progression)?*

8. Signatures					
Signature of person making the assessment Authorised health professional		**Print name**		**Date of assessment**	dd/mm/yyyy
Signature of person completing the form if different to person above		**Print name**		**Date of assessment**	dd/mm/yyyy

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Date SAE report received:	dd/mm/yyyy		**Date SAE reviewed:**	dd/mm/yyyy	**SAE number:**			
RO confirmation of assessment:	□ Yes	□ No	**Date entered on database:**	dd/mm/yyyy	Please indicate if the event is listed in the reference document (i.e. protocol, SmPC, Investigator's Brochure)?		□ Yes	□ No
Was the event a SUSAR?	□ Yes	□ No	**Date SUSAR reported to MHRA:**	dd/mm/yyyy	**Date SUSAR reported to the main REC:**	dd/mm/yyyy		
Date SUSAR reported to GTAC *(if applicable)*:	dd/mm/yyyy		**Date SUSAR reported to all PIs:**	dd/mm/yyyy	**Date RO acknowledged receipt of the form:**	dd/mm/yyyy		
RO Comments:								
Signature of person reviewing/checking the form:			**Print name**		**Date of assessment**	dd/mm/yyyy		