NERO Serious Adverse Event Report Form

Please email ctu@soton.ac.uk within 24 hours of identification of event FAO: Quality & Regulatory Team

If you do not receive confirmation of receipt within 1 working day from SCTU, please call/re-send the report.

University of Southampton

A) SITE DETAILS

1. Name of Site

2. Name of Principal Investigator

B) WHY WAS THE EVENT SERIOUS?

3. *Please select from the list below*

1 = Resulted in death
2 = Life-threatening
3 = Required inpatient hospitalisation or prolongation of existing hospitalisation
4 = Persistent or significant disability/incapacity
5 = Congenital anomaly/birth defect
6 = Other, Important medical event

C) PATIENT DETAILS

Sponsor number: RHMCAN1682 REC No.: **22/LO/0281** Country: UK

4. Patient Initials | **5. Patient ID** | **6. Year of Birth** (Y Y Y Y) | **7. Height** (cm) | **8. Weight** (kg)

9a. Gender
1 = Male
2 = Female

9b Arm
1 = Experimental: Active Symptom Control (ASC) + Niraparib
2 = Control arm: ASC only

D) DETAILS OF SAE

10. Date SAE was identified by site (D D M M M Y Y Y Y)

11. Date SAE sent to SCTU (D D M M M Y Y Y Y)

12. Main adverse event diagnosis / symptom - Please record medical term

13. Grade (CTCAE v5.0)	14. Date of SAE onset	15. SAE status	16. Date SAE resolved	17. Corresponding AE No.
1 = Mild 2 = Moderate 3 = Severe 4 = Life-threatening 5 = Death related to AE	*dd- mmm-yyyy*	1 = Resolved 2 = Resolved with sequelae 3 = Ongoing 4 = Worsened 5 = Fatal	*dd-mmm-yyyy*	As recorded on the AE eCRF

Associated Symptoms (if applicable) - *If associated symptoms meet the serious criteria in their own right, a separate SAE will need to be initiated (e.g. if associated symptom is life-threatening or caused prolongation of hospitalisation)*

E) TRIAL MEDICATIONS

18. Cycle No:

19. Trial Treatment name	20. Date of first administration	22. Date of most recent administration prior to SAE onset	21. Dose given at most recent administration	23. Action taken due to SAE 0 = None 1 = Dose reduction 2 = Treatment delayed 3 = Dose reduced & Treatment delayed 4 = Treatment stopped	***Investigator's Opinion*** 24. *Causal relationship to SAE* *Is this event causally related to the trial treatment?*		25. *PI signature* *Please provide signature of the PI/delegate who carried out the assessment and date of assessment*
Niraparib	DD-MMM-YYYY	DD-MMM-YYYY			***Related*** ☐	***Unrelated*** ☐	*PI Signature*
Active Symptom Control	DD-MMM-YYYY	DD-MMM-YYYY			***Related*** ☐	***Unrelated*** ☐	*Date*

25a. If the event is deemed related to 'Active symptom control' please define the active symptom control in table 'F' below.

25b. Is the event thought to be due to an interaction between the Niraparib and the Active Symptom control? Yes☐ No ☐ N/A ☐

Patient ID _ _ _ - _ _ _ _ _ _ _ _

26. **Did symptoms abate after stopping drug?** Yes ☐ No ☐ N/A ☐	**27.** **Did symptoms reappear after reintroduction of drug?** Yes ☐ No ☐ N/A ☐

F) OTHER TREATMENTS - do not include therapy given for management of SAE *(If none please tick N/A)* **N/A** ☐

Investigator's Opinion

28. **Treatment** *(*Give generic name) - *Please include concomitant medication, radiotherapy, surgery and palliative care.*	**Is this treatment considered 'Active Symptom Control'? Y/N**	**29.** **Total daily dose**	**30.** **Route** 1 = Oral 2 = Intravenous 3 = Subcutaneous 4 = Other	**31.** **Start date** *dd-mmm-yyyy*	**32.** **Ongoing** 0 = No 1 = Yes	**33.** **End date** *dd-mmm-yyyy*	**34.** **Action taken** 0 = None 1 = Dose reduction 2 = Treatment delayed 3 = Dose reduced & treatment delayed 4 = Treatment stopped	**35.** **Causal relationship** 1 = Related 2 = Unrelated	**36.** **Sign off** Please provide PI (or delegate) signature to confirm they agree with all information listed in section F.
									Signature
									Date (dd-mmm-yyyy)

G) CAUSALITY NOT RELATED TO TREATMENT

37. If you do not consider the main event to be caused by the trial treatment or concomitant medications please **specify any other possible cause** (e.g. medical history, drug or alcohol abuse, family history, findings from special investigations)

☐ N/A

H) DIAGNOSTIC TESTS *(details of any tests or procedures carries out to diagnose or confirm the SAE)* – If none please tick N/A ☐ **N/A**

Test name						
Date						
Normal range						
Results (+ units)						

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I) DESCRIPTION OF SAE & RELEVANT MEDICAL HISTORY

Patient ID: | | | | - | | | | | | | |

38. Describe serious adverse event *(include manifestation & progression of event and any treatments given in response to the event).*

J) SIGN OFF

Form completed by: _____ *Signature* _____ *Print Name* **Date:** _____ *dd-mmm-yyyy*

Contact E-mail: _____ **Contact Telephone No:** _____

Principal Investigator or delegate: _____ *Signature* _____ *Print Name* **Date:** _____ *dd-mmm-yyyy*

Clinical Reviewer Opinion **Related** – SAR/SUSAR **Unrelated** – SAE

SCTU Event No. | | | | |

Assessment against: *Please tick the most appropriate status*	***Related***	***Unrelated***
Niraparib	☐	☐
Active Symptom Control	☐	☐

Do you think the SAE is due to an interaction between the Niraparib and the Active Symptom Control?

Yes ☐ **No** ☐ **N/A** ☐

CR comments: _____

Signature: _____ **Date of Review:** D D M M M Y Y Y Y