STATEC Trial

A randomised trial of non-Selective versus selective adjuvant Therapy in high risk Apparent sTage 1 Endometrial Cancer

Trial Sponsor reference: UCL/13/0630	Clinicaltrials.gov no: NCT02566811

FOR UCL CTC USE ONLY	SAE ID : STA– ☐☐☐☐ — ☐☐☐ *(file SAE Report with SAE Sponsor Review Form)*

CANCER RESEARCH UK

UCL

SERIOUS ADVERSE EVENT (SAE) REPORT

Please email this form within 24 hours of becoming aware of the SAE to the STATEC Trial Coordinator at the CR UK & UCL Cancer Trials Centre to ctc.statec@ucl.ac.uk

Patient details

Patient Trial Number: STA–☐☐☐☐ **Patient initials:** ☐☐☐ **Age at onset:** ☐☐☐ Years **Sex:** Female

Height: ☐☐☐ cm **Weight:** ☐☐☐ . ☐ kg **Site name:** _____ **Country:**

Type of report: ☐ Initial *d d m m y y y y* — *Date report completed by the site*

☐ **Follow-up**

For all follow-up reports, please:

- **initial & date all changes throughout the report.**
- **fax to the trials centre within 24 hours of becoming aware of significant new information.**

FOR INITIAL REPORTS ONLY:

Date site notified of SAE: ☐☐ ☐☐ ☐☐☐☐ *d d m m y y y y*

If reported to the CTC after 24 hours of becoming aware of SAE, provide reason:

- Patient admitted to another hospital ☐
- Patient admitted to another dept at site ☐
- Other reasons ☐ *specify* _____

SURGERY:

Hysterectomy and BSO (dd/mm/yyyy): ☐☐ ☐☐ ☐☐☐☐ **Surgery not performed** ☐

Lymphadenectomy (dd/mm/yyyy): ☐☐ ☐☐ ☐☐☐☐ **Surgery not performed** ☐

☐ **Same date as hysterectomy and BSO**

Serious Events *(list serious events only)* — *Continued on a separate sheet?* ☐ Y — **Total No. of Events** ☐☐

Event No.	Event Term (refer to CTCAE v4.03)	Severity Grade (CTCAE v4.03)	Dates of Onset & Resolution (dd/mm/yyyy)	Outcome of Event[1]	Causal relation to surgery[2]: *(enter one code)*
1		☐	*Onset* ☐☐ ☐☐ ☐☐☐☐ *Resolution* ☐☐ ☐☐ ☐☐☐☐	☐	☐
2		☐	*Onset* ☐☐ ☐☐ ☐☐☐☐ *Resolution* ☐☐ ☐☐ ☐☐☐☐	☐	☐
3		☐	*Onset* ☐☐ ☐☐ ☐☐☐☐ *Resolution* ☐☐ ☐☐ ☐☐☐☐	☐	☐
4		☐	*Onset* ☐☐ ☐☐ ☐☐☐☐ *Resolution* ☐☐ ☐☐ ☐☐☐☐	☐	☐
5		☐	*Onset* ☐☐ ☐☐ ☐☐☐☐ *Resolution* ☐☐ ☐☐ ☐☐☐☐	☐	☐

Codes: **(1) Outcome of Event** (enter one code per event)**: 0 = Fatal 1 = Not Resolved 2 = Resolved 3 = Resolved with Sequelae**
(2) Causal Relationship (enter one code)**: 0 = "Not related (no reasonable possibility)" 1 = "Related (reasonable possibility)"**

STATEC Trial SAE Report

Patient Trial Number: STA– ☐☐☐☐ **Initials** ☐☐☐

Why was the SAE serious? *(please refer to the Pharmacovigilance section of the protocol for details)*		
Resulted in death	☐	
Life threatening	☐	
Required new or prolonged hospitalisation	☐	**For new hospitalisations only:** Date of admission: ☐☐ ☐☐ ☐☐☐☐ (*d d m m y y y y*) Date of discharge: ☐☐ ☐☐ ☐☐☐☐ (*d d m m y y y y*)
Resulted in persistent or significant disability/incapacity	☐	
Resulted in congenital anomaly or birth defect	☐	
Other medically significant *(e.g. non-serious adverse events of special interest)*	☐	*specify* _____

If patient has died: **Date of death:** ☐☐ ☐☐ ☐☐☐☐ (*d d m m y y y y*) **Cause of death:** *(specify)* _____ **Autopsy report available?** *(this may be requested by UCL CTC if required)* ☐ N ☐ Y

Any tests/laboratory data applicable to this SAE? ☐ N ☐ Y *If yes, specify below* | *Continued on a separate sheet?* ☐ Y

Date *(dd/mm/yyyy)*	**Test** *(specify)*	**Results** *(specify, to include reference ranges as appropriate)*	**Results Pending** *(check box if result has not been provided)*
☐☐ ☐☐ ☐☐☐☐			☐
☐☐ ☐☐ ☐☐☐☐			☐
☐☐ ☐☐ ☐☐☐☐			☐
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☐☐ ☐☐ ☐☐☐☐			☐

Any non-serious events relevant to this case? ☐ N ☐ Y *If yes, list adverse Event Term below*

Any relevant medical history/concurrent conditions? ☐ **N** ☐ **Y** *(If yes, specify below)*

STATEC Trial SAE Report

Patient Trial Number: STA– ☐☐☐☐ **Initials** ☐☐☐

Treatment for SAE? ☐ N ☐ Y *If yes, specify below, include: drug name, brand, indication, formulation, dose (including unit), route, start and end dates*	
	Continued on a separate sheet? ☐ Y

Concomitant medications? ☐ N ☐ Y *Only include drugs given within the 30 days prior to SAE onset excluding treatment for SAE. Use continuation page if necessary.* — *Continued on separate page?* ☐ Y

Drug Name	Brand	Indication	Dose (include units)	Frequency	Route	Ongoing?	Treatment Dates (dd/mm/yyyy)
						☐ Y ☐ N	*Start* ☐☐ ☐☐ ☐☐☐☐ *End* ☐☐ ☐☐ ☐☐☐☐
						☐ Y ☐ N	*Start* ☐☐ ☐☐ ☐☐☐☐ *End* ☐☐ ☐☐ ☐☐☐☐
						☐ Y ☐ N	***Start*** ☐☐ ☐☐ ☐☐☐☐ *End* ☐☐ ☐☐ ☐☐☐☐
						☐ Y ☐ N	***Start*** ☐☐ ☐☐ ☐☐☐☐ *End* ☐☐ ☐☐ ☐☐☐☐
						☐ Y ☐ N	*Start* ☐☐ ☐☐ ☐☐☐☐ *End* ☐☐ ☐☐ ☐☐☐☐
						☐ Y ☐ N	*Start* ☐☐ ☐☐ ☐☐☐☐ *End* ☐☐ ☐☐ ☐☐☐☐

Were any SAEs listed on this form related to a concomitant medication? ☐ N ☐ Y *If yes, give details of adverse event term, drug name and if there was an interaction with surgery*

Event No.	Event Term	Concomitant Medication (list which concomitant medication is related to adverse event)	Was the AE as a result of an interaction between surgery and concomitant medication?
State Event No. and Term as given in Serious Events section			
			☐ N ☐ Y
			☐ N ☐ Y
			☐ N ☐ Y
			☐ N ☐ Y
			☐ N ☐ Y

Case Narrative

(Give a concise medical description of the events including all relevant signs and symptoms, body systems, and any additional information deemed relevant to the case. State the rationale for causal relationship between the event and trial treatment, include medical judgement considering all relevant factors.)

Continued on a separate sheet? ☐ Y

Investigator Assessment: *(must be authorised on staff delegation log to review SAEs and perform evaluations of causal relationship)*

Print Name: _____ **Signature:** _____ **Date of Assessment:** ☐☐ ☐☐ ☐☐☐☐ *d d m m y y y y*

Form(s) completed by: *(must be authorised on staff delegation log to complete CRFs and report SAEs)*

Print Name: _____ **Signature:** _____ **Date of Completion:** ☐☐ ☐☐ ☐☐☐☐ *d d m m y y y y*

Concomitant medications (Continuation page)

Only include drugs given within the 30 days prior to SAE onset <u>excluding</u> treatment for SAE.

Drug Name	Brand	Indication	Dose (include units)	Frequency	Route	Ongoing?	Treatment Dates (dd/mm/yyyy)
						☐ Y ☐ N	*Start* ☐☐ ☐☐ ☐☐☐☐ *End* ☐☐ ☐☐ ☐☐☐☐
						☐ Y ☐ N	*Start* ☐☐ ☐☐ ☐☐☐☐ *End* ☐☐ ☐☐ ☐☐☐☐
						☐ Y ☐ N	*Start* ☐☐ ☐☐ ☐☐☐☐ *End* ☐☐ ☐☐ ☐☐☐☐
						☐ Y ☐ N	*Start* ☐☐ ☐☐ ☐☐☐☐ *End* ☐☐ ☐☐ ☐☐☐☐
						☐ Y ☐ N	*Start* ☐☐ ☐☐ ☐☐☐☐ *End* ☐☐ ☐☐ ☐☐☐☐
						☐ Y ☐ N	*Start* ☐☐ ☐☐ ☐☐☐☐ *End* ☐☐ ☐☐ ☐☐☐☐