POISE Serious Adverse Event Form

1. Study Information

Study Title	Premature Ovarian Insufficiency Study of Effectiveness of hormonal therapy (POISE)		
Sponsor ref no	121197	**EudraCT no**	2020-002589-15

2. Site Information

Site Name/Number		**Country**	United Kingdom
Name of person reporting this SAE			
Contact details	**Phone:**	**Email:**	

3. Type of report

Initial	☐	**Follow-up**	☐
Date of Report	dd-mmm-yyyy	**If follow-up report enter NCTU SAE reference number supplied for initial report**	

4. Participant Information

Participant ID number		**Sex**	**Female**
Initials		**Date of Birth**	dd-mmm-yyyy

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5. Details of Event

Event Name: *SAE in medical terms (diagnosis if possible)*				
Description of Event: *Please provide any additional relevant information e.g. signs and symptoms and any relevant tests/results.* ***DO NOT*** *use abbreviations*				
Serious Criteria			***Yes***	***No***
	Death		☐	☐
	Life-threatening		☐	☐
	Hospitalisation/prolongation of hospitalisation		☐	☐
	Persistent/significant disability or incapacity		☐	☐
	Congenital anomaly or birth defect		☐	☐
	Other significant medical event – specify _____		☐	☐
Date of onset of event	**dd-mmm-yyyy**	**Date event met "Serious criteria"**	**Dd-mmm-yyyy**	

6. Relevant Medical History

Does the participant have any *relevant* medical history?	☐ **Yes**	☐ **No**
Name of condition	**Tick if ongoing**	
	☐	
	☐	
	☐	
	☐	
	☐	

7. Event Outcome

Outcome of event *(tick one box only)*	☐ **Fatal** Give cause of death if known, in event description (above)	**Date of death:** **dd-mmm-yyyy**
	☐ **Recovered/Resolved without sequelae**	**Date of recovery:** **dd-mmm-yyyy**
	☐ **Recovered/Resolved <u>with</u> sequelae** describe in event description (above)	
	☐ **Ongoing** (ensure follow-up is sent when available)	
	☐ **Unknown at time of report** (ensure follow-up is sent as soon as possible)	

8. Cause of Event

Cause of Event (Detail all possible and suspected causes including relevant medical history)	

9. Medications – IMP(s)

COC or HRT						
Has the Participant received any of this IMP?		☐ **Yes** (provide details below)		☐ **No** (indicate why not (e.g. screening period)		
Name of Medication	**Indication for use**	**Dose & units**	**Dose form**	**Route of Administration**	**Date of first administration**	**Date of last administration**
	POI					
In the Investigator's opinion, is the SAE related to this IMP? (tick one only)		**Definitely related** ☐	**Probably related** ☐	**Possibly Related** ☐	**Unlikely to be related** ☐	**Unrelated** ☐
Action taken as a result of this SAE		**None** ☐	**Dose changed** ☐	**IMP temporarily discontinued** ☐	**IMP permanently discontinued** ☐	**Unknown at time of report** ☐

10. Concomitant Medication

Was the participant receiving any concomitant medication (within the 14 days prior to this SAE)	☐ **Yes** (record details below or attach copy of up-to-date concomitant medication log)		☐ **No**	
Name of medication (generic name where possible)	**Dose**	**Units**	**Start Date**	**Stop Date or ongoing**

11. Additional Information

Additional relevant information	

12. Completion Details

Report Completed by (You must have signed the delegation log)	Name:	Signature:	Date: dd-mmm-yyyy
Investigator review (if not reporter) (You must have signed the delegation log)	*By signing below I confirm the seriousness, causality and outcome of this report*		
	Name:	Signature:	Date: dd-mmm-yyyy

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13. Clinical Evaluation (Medical Monitor/Chief investigator)

Causality Assessment:	☐ **Unrelated**		
	☐ **Related**	**Expectedness Assessment:** Only required if "related"	
		☐ **Expected**	☐ **Unexpected***

Assessment completed by:	Name:	Signature:	Date: dd-mmm-yyyy

**SAEs that are considered to be related to trial intervention and are unexpected (as per the current trial-specific Reference Safety Information) are subject to expedited reporting to the MHRA and/or REC.*

Completed SAE forms must be emailed to nctu-sae@nottingham.ac.uk within 24 hours of the participant reporting the SAE to the research team.