Liverpool Women's NHS
NHS Foundation Trust

SAE / AE Report Form

Complete sections 1-5

Section 1: Research participant (complete all sections)	
Participant study number	
Participant initials	
Weight:	Height (not required for neonates):

Section 2: Research study (complete all sections)			
Title of the Study:			
		Medication/intervention	Mode of administration:
EudraCT number of trial		Dose	Frequency

Section 3: Adverse event

Description of event (please provide sufficient detail for independent review of causality where the event is deemed to be serious)

Check all appropriate to adverse event

Resulted in death* ☐

Life threatening at time of event* ☐

Requires inpatient hospitalisation* or extension of existing hospitalisation* ☐

Resulted in persistent or significant disability/incapacity* ☐

Is a congenital anomaly/defect* ☐

May lead to one of the above outcomes or require treatment to prevent one of the above outcomes ☐

** event is a **SUSAR‡** if it is serious, not expected and if it is possible, probable or highly probable to be in relation to the study intervention*

Relation with study intervention

Highly probable* ☐

Probable* ☐

Possible* ☐

Unlikely (remote) ☐

None (inter-current event) ☐

See Managing and reporting adverse events SOP for definitions of causality

Onset of event (date - dd/mm/yy and time - 24 hour clock):

Event stopped (date - dd/mm/yy and time - 24 hour clock):

Ongoing at time of report?
Yes ☐ No ☐

Date event cleared completely:

Severity
Mild ☐
Moderate ☐
Severe ☐
Life-threatening ☐
Death ☐

Was the event expected on the basis of what is known about the study intervention?

Yes ☐ No* ☐

Frequency
Event occurred only once and cleared in 24 hours ☐
Event occurred episodically between onset and clearance dates ☐
Event was present for the entire time between onset and clearance dates ☐

Outcome
Resolved ☐
Resolved with sequelae ☐
Not resolved/ongoing ☐
Ongoing at death ☐
Fatal ☐

Action taken
None ☐
Dose reduced ☐
Dose increased ☐
Temporarily interrupted ☐
Permanently discontinued ☐

‡ If the event is a SUSAR it requires expedited reporting as detailed in LWFT SAE procedure guideline – contact Liverpool Women's R&D office (tel: 0151 702 4346 / 4241)

Section 4: Other medication (at the time of onset and for duration of event)			
Name	Dose	Route	IMP/NIMP/Concomitant medication

Section 5: Reporter of adverse event (complete all sections)		
Name:	Position:	Report Date:
Tel No:	Email:	Report type (please tick): Initial ☐ Follow up to telephone.☐
Verification of assessment by study Principal Investigator*	**Name:**	**Signature:** **Date:**

* Causality and severity assessed and agreed

Reporting Procedure

All SAEs must be reported **within 24 hours** of the investigator becoming aware of them to the Sponsor (this should be via the R&D office). SAEs from Commercial Clinical Trials should be reported to the Sponsor and a copy sent to R&D. **Phone 0151 702 4346 / 4241 to report, leaving a message if unanswered or fax this form to 0151 702 4299.**

Please submit a copy of this report to the Trust R&D office situated on the second floor of the hospital.

R&D should acknowledge receipt of your report via e-mail within 24 hours – if you have not been notified of receipt, you must follow this up with R&D to ensure the department has received notification and that appropriate reporting has been undertaken.

For use by R&D Office

Section 6: Informing Sponsor		
Is LWFT Sponsor / Co-sponsor with responsibility for pharmacovigilance	Yes / No	If no: date Sponsor informed: If yes: complete sections 7 & 8.

Section 7: Sponsor assessment (complete all sections if LWFT has responsibility for pharmacovigilance)		
Name:	Position*:	Date report received:
Date of sponsor's assessment		
People involved in sponsor's assessment		
Sponsor's assessment of causality, with summary of justification:		
Sponsor's assessment of seriousness, with summary of justification		

*Please note independent assessment can be conducted on behalf of the Sponsor by an independent clinician at the site the participant was recruited. Confirmation of independent assessment can be documented via email correspondence with the Sponsor R&D office (to be kept on file with this completed form).

Section 8: Actions to be taken by Sponsor (delete those that do not apply):			
Requires un-blinding	Yes / No	**Un-blinding indicates need for expedited reporting**	Yes / No
Expedited report to MHRA within 7 days	Date initial report made: Date detailed report made:	**Expedited report to MHRA within 15 days**	Date initial report made: Date detailed report made:
Report to LREC	Date initial report made: Date detailed report made:	**Inform investigators**	Date investigators informed
Inform marketing authorisation holders	Date M.A. holders informed	**Review of trial risk management plan**	Date of review: Date of actions:
Inform co-sponsors:	Name of co-sponsor and date informed:	Name of co-sponsor and date informed:	