ADVERSE EVENT REPORTING FLOWCHART

Adverse Event (AE)

"Any untoward medical occurrence in a participant to whom a medicinal product has been administered."

Is the event already captured on the outcome form?

NO

Adverse Event (AE)

- Record on the paper Adverse Event form in the CRF booklet (Sections 11 for the Mother, Sections 12 or 13 for the baby(ies)
- Report this to the CTU by entering into the WOMAN-PharmacoTXA database within **24 hours**

YES

*You do **not** need to report this as an Adverse Event*

Does the event fulfil any of the following seriousness criteria?

- *Results in death*
- *Is life threatening*
- *Requires in-patient hospitalisation or prolongation of existing hospitalisation*
- *Results in persistent or significant disability/incapacity*
- *Other, medically important*

YES

Serious Adverse Event (SAE)

- Complete a paper Serious Adverse Event report form (copies in Investigator Site File, Section 4)
- Report this to the CTU by entering into the WOMAN-PharmacoTXA database within **24 hours**

CAUSALITY

Does the reporting investigator believe with reasonable probability that the event is due to the intervention?

YES

Serious Adverse Reaction (SAR)

Is the SAR expected?

CTU to assess against Reference Safety Information

NO

NO

Serious Adverse Event (SAE)

All SAEs, SARs and SUSARs are reported through an annual report to the relevant Regulatory Authorities and Ethics Committees.

Report includes:

- List of SAEs, SARs and SUSARs
- Data Monitoring Committee report

Reported annually on the anniversary of the first Regulatory agency approval.

Suspected Unexpected Serious Adverse Drug Reaction (SUSAR)

"A serious adverse reaction, the nature and severity of which is not consistent with the information about the medicinal product in question set out in the reference safety information."

If fatal or life threatening CTU must ensure

- Reporting of event to:
  - Regulatory authorities of all countries where the trial is being conducted, and
  - The relevant ethics committees

WITHIN 7 DAYS OF LEARNING OF THE SUSAR

- Follow-up information must be provided within a further eight days

If not fatal or life threatening

CTU will report to the above bodies within 15 days of learning of the SUSAR

- CTU also informs all investigators and LSHTM Quality Assurance Manager and presents the data for Data Monitoring Committee review

The Site File contains:

- Guidance on AE Reporting for the WOMAN-PharmacoTXA trial (Trial Procedures File, Section 8)
- Additional copies of AE CRF (from CRF booklet) and blank SAE report forms (Investigator Site File (ISF), Section 8)
- Completed AE and SAE report forms should be filed, together with the participant's Case Report Form booklet in ISF Box File 1
- CTU will coordinate the reporting to all relevant Ethics Committees, Regulatory Authorities and other investigators.

IF URGENT ADVICE REQUIRED: CTU emergency number +44(0)7768 707500

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