VIEDOC eLearning

15. AE / SAE Reporting

1 General

- AEs should be carefully monitored and reported during the entire survey (from the "ACROSTUDY start date" to the date of ”Exit ACROSTUDY”).
- AEs classified by the physician as possibly related to Somavert should be followed until the AE has resolved or is assessed by the physician as ”chronic” or ”stable”.

2 Pregnancy

- If a patient becomes or is found to be pregnant while receiving Somavert or within 30 days of discontinuing Somavert medication, the physician is to submit an AE report form that includes the anticipated date of birth or pregnancy termination. The patient is then to be followed by the physician until completion of the pregnancy. If the pregnancy ends for any reason before the anticipated date provided, the physician should notify the Local Pfizer Monitor. If the outcome of the pregnancy meets the criteria for immediate classification as a serious AE (i.e., spontaneous abortion, stillbirth, neonatal death, or congenital anomaly [including that in an aborted fetus]), the physician should follow the procedures for reporting serious AEs.
- Note that ”spontaneous abortion” includes miscarriage and missed abortion.
- All neonatal deaths that occur within one month of birth should be reported, without regard to causality, as serious AEs. In addition, any infant death after one month that the physician assesses as possibly related to the in utero exposure to Somavert should also be reported.
- In case of a live birth, the ”normality” of the newborn can be assessed at time of birth (i.e., there is no required minimum follow-up of a presumably normal infant before the Exposure in Utero form can be completed.
- The ”normality” of an aborted fetus can be assessed by gross visual inspection unless there are preabortion laboratory findings suggestive of a congenital anomaly.
- The same assessment and reporting procedures apply for a **male ACROSTUDY patient**, whose partner becomes pregnant during his participation in ACROSTUDY.

3 Report within 24 hours

- All Serious Adverse Events must be reported within 24 hours to the Local Safety department.
- A completed, signed Serious Adverse Event follow-up report for above types of Serious Adverse Event should be sent to the Pfizer Local Safety Department **within 5 calendar days**.
- All dated and signed original SAE reports should be submitted to the Pfizer Local Safety Department **within 3 months**.