VIEDOC eLearning

14. Adverse Event Definitions

1 Criteria

- An Adverse Event (AE) is any untoward medical occurrence in a patient participating in ACROSTUDY; the event does not necessarily have a causal relationship with Somavert.
- AEs include the following:
  - Abnormal test findings.
  - Clinically significant symptoms and signs.
  - Changes in physical examination findings.
  - Hypersensitivity.
  - Progression/worsening of underlying disease.
  - Lack of effect.
- Additionally, they may include the signs or symptoms resulting from:
  - Drug overdose
  - Drug withdrawal
  - Drug abuse
  - Drug misuse
  - Drug interactions
  - Drug dependency
  - Extravasation
  - Exposure in utero
- Lack of or insufficient clinical response, benefit, efficacy, or therapeutic effect should be recorded as an adverse event.

2 Seriousness (gravity)

- A serious adverse event or serious adverse drug reaction is any untoward medical occurrence at any dose that:
  - Results in death
  - Is life-threatening
  - Requires in-patient hospitalization or prolongation of existing hospitalization
  - Results in persistent or significant disability/incapacity
  - Results in congenital anomaly/birth defect
- Medical and scientific judgment should be exercised in determining whether an event is an important medical event. An important medical event may not be immediately life-threatening and/or result in death or hospitalization. However, if it is determined that the event may jeopardize the patient and may require intervention to prevent one of the other outcomes listed in the definition above, the important medical event should be reported as serious.

3 Relatedness

- This criterion is a determination of whether or not there is a reasonable possibility that the AE may have been related to Somavert treatment.
- Note that the term ”reasonable possibility” does not include cases where there is only a remote or unlikely possibility that

the AE may have been caused by Somavert.