Date: October 15, 2008

Topic: CTCAE v3.0 Help Desk Tickets – WG # 11 SOC: Respiratory, thoracic and mediastinal disorders

From: Ann Setser

Voice Changes - Grade 5 - Can voice change toxicity cause Death?

CTEP – Consider for CTCAE v3.0 Revision

One of our Pulmonology groups does a procedure to biopsy the upper nasal tissue to look at the cilia. To do this they have a procedure called nasal scrape.

The current pain category of the CTCAE v 3 does not have a location for nose. Would your editorial board consider adding nose to the select locations under pain? The implication is that it is internal nose pain (vs. dermalogic).

Setser comment: Nasal pain is MedDRA LLT for PT Rhinalgia

Suggestions for addition in CTCAE v4.0:

* MedDRA: Pulmonary veno-occlusive disease -- SOC Respiratory, thoracic and mediastinal disorders
* MedDRA: Bronchiolitis obliterans with organizing pneumonia -- SOC Respiratory, thoracic and mediastinal disorders
* MedDRA: Asthma
* hemoptysis/haemoptysis
  + Hemoptysis is LLT for PT Haemoptysis
* pulmonary oedema
  + Pulmonary edema is LLT for PT Pulmonary oedema
* sinus problems – not in MedDRA
  + MedDRA PT Sinus disorder

all clinical studies for accurate reporting of safety profiles and the comparability among publications.  We observed inconsistencies of reporting among international investigators.  To better follow CTCAE, I would like to confirm with you several common AE reporting practices and post some questions.

1. if a diagnosis can be established, diagnosis is preferred over signs and symptoms.  For example, coughing, fever, dyspnea are the symptoms of pneumonia.  Only pneumonia should be reported unless complications are not normally associated it, e.g. septic shock.

In my view, CTC is grading system, but not a dictionary.  CTC should be carefully followed when reporting cancer-treatment related toxicities.  Other events should be reported and coded by MedDra.  Training on CTC should be given to promote good reporting

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