Date: October 15, 2008

Topic: CTEP CTCAE v3.0 Help Desk Tickets : WG # 2 SOC Cardiac disorders

From: Ann Setser

Requests for inclusion in CTCAE v4.0 – MedDRA LLTs:

* Cardiomegaly
* Acute coronary syndrome (Added in Draft 1)
* Cardiac failure/insufficiency
  + Cardiac insufficiency is LLT for PT Cardiac failure
    - Heart failure; Left ventricular failure (Both terms added in Draft 1)
* Ventricular hypokinesia – is not a MedDRA term. Options (all LLTs for PT Ventricular hypokinesia):
  + Diffuse ventricular hypokinesia
  + Left ventricular hypokinesia
  + Regional ventricular hypokinesia
  + Right ventricular hypokinesia
* Cardiac tamponade – MedDRA LLT & PT
* Cardiogenic shock – MedDRA LLT & PT
* Cardiac asthma – MedDRA LLT & PT

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Myocarditis:  add grade 2: description would be something like “clinical evidence of myocarditis ( lab, imaging, EKG, etc) without physiological sequelae.”

Hypertension: Underline the headings for Pediatric (for consistent formatting with other AEs)

Hypertension.  With the new antiangiogenic drugs, hypertension needs more clinical /more detailed examples in CTCAE to better reflect patient status.

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**Hypertension** Grade 1 states '..(<24 hrs)' Grade 2 states '... (>24hrs)’ what happens at = 24 hours, which grade should this be incorporated into?

To be discussed:

THIS IS WHAT WE HAVE PREVIOUSLY SAID ABOUT THE '24-HOUR ISSUE R/T HOSPITALIZATION.

Hospitalization and Prolongation of Hospitalization

Hospitalization includes any overnight stay in a healthcare facility, including the so-called "23 hour observation" status often used because of reimbursement issues. It does not include extended infusions or treatments in an outpatient facility. Evaluation and treatment in an emergency medical department is not per-sea hospitalization, but investigators should use good judgment when considering reporting guidelines and definitions for a patient treated for extended periods of time in emergency departments. Prolongation of hospitalization (longer than expected) is either the result of the AE itself or intervention or potential complications from the AE, including prevention and/or monitoring

DOES THE SAME APPLY FOR DURATION OF AES?

Consider GRADE 1 = LESS THAN 24 HRS AND GRADE 2 = EQUAL TO OR GREATER THAN 24 HOURS.

**Hot flashes/flushes** - Grade 3 - misspelling of 'interferring' should be changed to 'interfering'.

CTEP Response: YES, THIS IS A TYPO AND SHOULD BE INTERFERING

Suggestion for addition to CTCAE v4.0 Oncology emergency:

* MedDRA LLT Superior vena caval syndrome for PT Superior vena caval occlusion
* MedDRA: LLT & PT Venoocclusive disease