



**MedDRA Coding Quality:  
Focus on Soft Coding**  
**MedDRA User Group**  
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# Why FDA Evaluates Manufacturer-submitted MedDRA Coding

- FDA depends on many different firms to submit accurate and complete MedDRA coded reports
  - Rely on coded data to perform analyses and generate important safety signals
- Inaccurate and/or incomplete coding results in delayed, misdirected or missed safety concerns

# FDA-defined Mfr. Coding “Errors”

- **Missed Concepts**

- All medical concepts described after the product is taken should be coded
- Concepts not captured in coding are “missed”

Examples:

*“The patient took drug X and developed alopecia, increased LFTs and pancreatitis.” The manufacturer codes only alopecia and increased LFTs (misses the concept of pancreatitis).*

*“The patient took drug X and developed interstitial nephritis which later deteriorated into renal failure.” The manufacturer codes only interstitial nephritis (missed renal failure concept).*

# FDA-defined Mfr. Coding “Errors”

- **“Soft Coding”**
  - MedDRA terms that most accurately reflect the reporter’s words should be selected.
  - Selecting a term which is both less specific and less severe than another term that exists in MedDRA is “soft coding”

# Soft Coding Example 1

- 2 months after starting drug, pt developed leg edema; hepatic function tests were abnormal. Over the next month, pt developed worsening of symptoms, including ascites, flapping tremor and hepatic encephalopathy and died of hepatic failure.

# Soft Coding Example 1

- Soft Coded as
  - *Hepatic function abnormal*
- Should have coded
  - *Hepatic failure*

# Soft Coding Example 2

- 2 days after drug started pt experienced dyspnea. Chest CT scan one week later revealed bilateral pleural effusions. Respiratory failure occurred. Pt was placed on a respirator and treated; drugs were DC'd; pt recovered. Lung damage due to drugs was suspected.

# Soft Coding Example 2

- Soft Coded as
  - *Lung disorder*
- Should have coded
  - *Respiratory failure*
  - *(Pleural effusion)*

# Soft Coding Example 3

- Patient experienced general muscle soreness, dark urine and urine volume decreased while being treated with Drug X. Lab test results confirmed rhabdomyolysis, liver and renal function impairment. Drug X was stopped immediately. Hemofiltration was administered. Over the next two weeks, myalgia and debilitation improved, CPK and urine volume returned to normal and liver function became normal.

# Soft Coding Example 3

- Soft Coded as
  - *Myalgia*
  - *Asthenia*
  - *Urine colour abnormal*
  - *Urine output decreased*
  - *Hepatic function abnormal*
- Should have coded
  - *Rhabdomyolysis*
  - *Renal impairment*
  - *Hepatic function abnormal*

# Soft Coding Example 4

- Patient was hospitalized with multiple infections after receiving drug. X-ray showed pneumonia. Treatment included mechanical ventilation, antibiotic and antifungal therapy. A blood culture was positive for *Enterococcus cloacae*. Patient expired due to sepsis.

# Soft Coding Example 4

- Soft Coded as
  - *Infection*
- Should have coded
  - *Pneumonia*
  - *Enterococcal bacteraemia*
  - *Sepsis*
  - *(Mechanical ventilation)*



# **Soft Coding Implications for Searching / Data Retrieval**

## **Audience Discussion**

# FDA Recommendations

- Organizations should take advantage of MedDRA's specificity to avoid soft coding errors
  - Critical for later retrieval / signal generation
- FDA encourages firms to follow *ICH MedDRA Term Selection Points to Consider*

[www.meddramso.com/MSSOWeb/activities/PTC.htm](http://www.meddramso.com/MSSOWeb/activities/PTC.htm)

  - Firms should establish their own coding guidelines based on, and not conflicting with, the ICH PTC document



# Questions / Discussion