

Frequent Coding Related Challenges in MedDRA Coding

- Comment problems in MedDRA coding
- Comment questions from study team

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Comment problems in MedDRA coding – More than one diagnosis in an AE record

	Verbatim	Query / Resolution	LLT
1	APPEARANCE OF PAPILLARY SKIN ERUPTION OVER BILAT LOWER LEGS <INNER ASPECT> WITH MILD ITCHING	Query: Whether the diagnosis was <u>Eruption</u> or <u>Itching</u> or <u>both</u> ? Resolution: Both diagnosis were existing.	Two AEs: (1) Eruption fixed (2) Itchy legs
2	DERMATITIS AND OTHER ECZEMA	Query: Whether the diagnosis was <u>Dermatitis</u> or <u>Eczema</u> ? Resolution: Eczema	Eczema
3	ABDOMEN FULLNESS AND DIARRHEA	Query: Abdomen Fullness and Diarrhea are two symptoms. Please confirm whether the symptom was Abdomen Fullness or Diarrhea or both or caused by a diagnosis? Resolution: The diagnosis is Acute Gastritis.	Acute gastritis
4	URINE PROTEIN/CREATININE RATIO ABNORMAL	Query: (1) Divided into two AEs. (2) The ration compared to last result was higher or lower? Resolution: The values compared to previous ones almost the same. This AE should be deleted.	----- AE deleted
5	HEADACHE AND BACK PAIN	Query: (1) Divided into two AEs. (2) Provide the completed information for both AEs. Resolution: (1) AE:Headache & AE:Back Pain (with completed information)	Two AEs: (1) Headache (2) Back pain

Comment problems in MedDRA coding
– Incomplete information

	Verbatim	Query / Resolution	LLT
1	TOTAL CHOLESTEROL 224MG/DL	Query: (1) Was this value significant higher or lower compared to last visit's value? (2) If this is not significant, should this AE be deleted? Resolution: (1) Higher than previous value but NOS. (2) please delete it.	-----AE deleted
2	OTHER DISTURBANCES OF ORAL EPITHELIUM INCLUDING TONGUE	Query: What does 'Disturbance' mean in medical description in this AE? Resolution: Left buccal mucosal ulcer	Oral ulceration
3	SERVERAL PIN SIZE SKIN	Query: Please confirm the diagnosis on those 'Pin Size Skin'. Resolution: Those pin size skin looked different from normal skin but no exact diagnosis and medicine treatment.	Skin disorder
4	SLEEP WELL	Query: Sleep well is not a medical concept AE term. Please confirm if the subject's sleep quality was changed from last visit. Resolution: The subject told the Dr. he felt 'sleep well' after taking study drug.	Uncoded term.

Comment questions from study team

- Do all AE terms must be exactly as same as MedDRA dictionary terms?
 - Why AE recorded directly from Medical Chart will be query issued?
- Why MedDRA not ICD-9 or ICD-10?
- *CTCAE v3. & MedDRA dictionary mapping ?*
- *Different languages' coding data exchange methods?*

Thank you for The attention