Use of MedDRA in Data Analysis – MedDRA® MSSO Point of View

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MedDRA Structure

System Organ Class (SOC) (26)

High Level Group Term (HLGT) (335)

High Level Term (HLT) (1,710)

Preferred Term (PT) (19,086)

Lowest Level Term (LLT) (69,019)

MedDRA Version 14.0

Use of MedDRA Grouping Terms

- HLGTs and HLTs provide clinically relevant groupings
  - HLGT *Cardiac arrhythmias*
    - HLT *Cardiac conduction disorders*
    - HLT *Rate and rhythm disorders NEC*
    - HLT *Supraventricular arrhythmias*
    - HLT *Ventricular arrhythmias and cardiac arrest*

Use of MedDRA Grouping Terms (cont)

- Caution - ensure all terms are relevant to output
  - HLT *Vascular tests NEC (incl blood pressure)*
    - PT *Blood pressure decreased*
    - PT *Blood pressure increased*
- Caution - related PTs in different locations in SOC
  - HLT *Bullous conditions*
    - PT *Stevens-Johnson syndrome*
  - HLT *Exfoliative conditions*
    - PT *Dermatitis exfoliative*

Which Level? – SOC *Investigations*

Adverse Event (MedDRA v14.0)	25 mg MyDrug (N=44)	Placebo (N=15)
SOC Investigations	13 (29.5%)	2 (13.3%)
PT Aspartate aminotransferase increased	6	0
PT Alanine aminotransferase increased	5	0
PT Gamma-glutamyltransferase increased	4	0
PT Blood creatine phosphokinase increased	2	1
PT Blood alkaline phosphatase increased	2	0
PT Blood glucose increased	1	1
PT Blood lactate dehydrogenase increased	2	0
PT Lipase increased	2	0
PT White blood cell count decreased	2	0
PT Blood amylase increased	1	0
PT Faecal fat increased	0	1

Patients may have more than one event reported

Which Level? – SOC *Investigations* (cont)

Adverse Event (MedDRA v14.0)	25 mg MyDrug (N=44)	Placebo (N=15)
SOC Investigations	13 (29.5%)	2 (13.3%)
PT Blood pressure increased	1	0
PT Blood urea increased	1	0
PT Occult blood positive	1	0
PT Liver function test abnormal	1	0
PT Monocyte count decreased	1	0
PT Protein urine present	1	0

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Which Level? – SOC *Investigations* (cont)

Adverse Event (MedDRA v14.0)	25 mg MyDrug (N=44)	Placebo (N=15)
SOC Investigations	13 (29.5%)	2 (13.3%)
HLT Liver function analyses	16	0
HLT Tissue enzyme analyses NEC	4	0
HLT Digestive enzymes	3	0
HLT White blood cell analyses	3	0
HLT Skeletal and cardiac muscle analyses	2	1
HLT Carbohydrate tolerance analyses (incl diabetes)	1	1
HLT Faecal analyses NEC	1	1
HLT Vascular tests NEC (incl blood pressure)	1	0
HLT Renal function analyses	1	0
HLT Urinalysis NEC	1	0

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Which Level? – SOC *Investigations* (cont)

Adverse Event (MedDRA v14.0)	25 mg MyDrug (N=44)	Placebo (N=15)
SOC Investigations	13 (29.5%)	2 (13.3%)
HLGT Hepatobiliary investigations	16	0
HLGT Enzyme investigations NEC	6	1
HLGT Gastrointestinal investigations	4	1
HLGT Haematology investigations (incl blood groups)	3	0
HLGT Renal and urinary tract investigations and urinalyses	2	0
HLGT Metabolic, nutritional and blood gas investigations	1	1
HLGT Cardiac and vascular investigations (excl enzyme tests)	1	0

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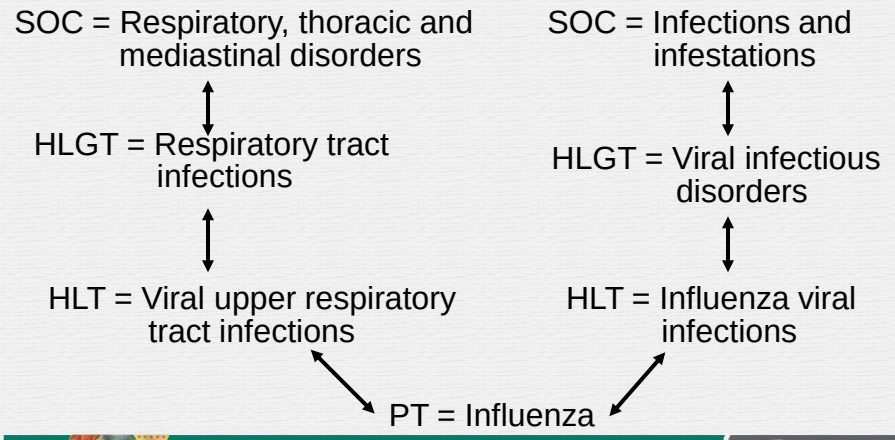
MedDRA Multi-Axiality in Data Analysis

MedDRA Multi-Axiality



MedDRA Multi-Axiality (cont)

PTs in the following SOCs only appear in that particular SOC and not in others; i.e., they are not multi-axial:

- *Investigations*
- *Surgical and medical procedures*
- *Social circumstances*

Primary SOC Analysis – SOC *Infections and infestations*

Adverse Event (MedDRA v14.0)	25 mg MyDrug (N=44)	Placebo (N=15)
SOC Infections and infestations	14 (31.8%)	4 (26.7%)
PT Upper respiratory tract infection	5	2
PT Sinusitis	3	0
PT Urinary tract infection	2	1
PT Ear infection	2	0
PT Viral infection	2	0
PT Bronchitis	1	0
PT Influenza	1	0
PT Localised infection	0	1
PT Lower respiratory tract infection	1	0
PT Pneumonia	1	0
PT Tooth abscess	1	0

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Secondary SOC Analysis – SOC *Infections and infestations*

Adverse Event (MedDRA v14.0)	25 mg MyDrug (N=44)	Placebo (N=15)
SOC Respiratory, thoracic and mediastinal disorders		
PT Upper respiratory tract infection	5	2
PT Sinusitis	3	0
PT Bronchitis	1	0
PT Influenza	1	0
PT Lower respiratory tract infection	1	0
PT Pneumonia	1	0
SOC Infections and infestations		
PT Viral infection	2	0
PT Localised infection	0	1

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Secondary SOC Analysis – SOC *Infections and infestations* (cont)

Adverse Event (MedDRA v14.0)	25 mg MyDrug (N=44)	Placebo (N=15)
SOC Renal and urinary disorders		
PT Urinary tract infection	2	1
SOC Ear and labyrinth disorders		
PT Ear infection	2	0
SOC Gastrointestinal disorders		
PT Tooth abscess	1	0

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MedDRA Data Retrieval and Presentation: Points to Consider

MedDRA Data Retrieval and Presentation: Points to Consider

- An ICH-Endorsed Guide for MedDRA users on Data Output
- Developed by an ICH Expert Working Group
  - Same WG that composed the “Term Selection” PTC
- Provides data retrieval and presentation options for industry or regulatory purposes

MedDRA Data Retrieval and Presentation: Points to Consider (cont)

- Objective is to promote understanding of implications that various options for data retrieval have on accuracy and consistency of final output
- Updated with each MedDRA release
  - **User feedback encouraged!**
- Current version available on MedDRA MSSO Web site (http://www.meddramsso.com/subscriber_library_ptc.asp)

Data Retrieval PTC: Points Addressed

- General Principles
  - Quality of Source Data
  - Documentation of Data Retrieval and Presentation Practices
  - Do Not Alter MedDRA
  - Organization-Specific Data Characteristics
  - Characteristics of MedDRA that Impact Data Retrieval and Analysis
  - MedDRA Versioning
- General Queries and Retrieval
- Standardised MedDRA Queries
  - Applications, modifications, version changes, change requests, etc.
- Customized Searches

Thank You