MedDRA and Safety Signals

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Agenda

- MedDRA overview
- MedDRA and identifying safety signals
  - Positive aspects
  - Challenges
Identify Safety Risks

• Step 1: Collect adverse event data
• Step 2: Organize ADR/AE data
• Step 3: Analyze ADR/AE data
• Step 4: Identify Safety Issues

• MedDRA is used in step 2, 3, and 4

• Why do we need MedDRA?
What is MedDRA?

• Stands for Medical Dictionary for Regulatory Activities

• It is a tool to
  – Organize/classify ADR/AE and other patient data
  – Retrieve and analyze

• Standardization
  – Mandated in EU and Japan
  – Used by US FDA
  – Recommended terminology in Canada

MedDRA Structure

• Blood and lymphatic system disorders
• Cardiac disorders
• Congenital, familial and genetic disorders
• Ear and labyrinth disorders
• Endocrine disorders
• Eye disorders
• Gastrointestinal disorders
• General disorders and administration site conditions
• Hepatobiliary disorders
• Immune system disorders
• Infections and infestations
• Injury, poisoning and procedural complications
• Investigations
• Metabolism and nutrition disorders
• Musculoskeletal and connective tissue disorders
• Neoplasms benign, malignant and unspecified (incl cysts and polyps)
• Nervous system disorders
• Pregnancy, puerperium and perinatal conditions
• Psychiatric disorders
• Renal and urinary disorders
• Reproductive system and breast disorders
• Respiratory, thoracic and mediastinal disorders
• Skin and subcutaneous tissue disorders
• Social circumstances
• Surgical and medical procedures
• Vascular disorders
MedDRA Structure (cont)

System Organ Class (SOC)

High Level Group Term (HLGT)

High Level Term (HLT)

Preferred Term (PT)

Lowest Level Term (LLT)

SOC = Cardiac disorders

HLGT = Cardiac arrhythmias

HLT = Supraventricular arrhythmias

PT = Sinus arrhythmia

LLT = Sinus arrhythmia

LLT (Non-current) Arrhythmia sinus

Sinoatrial node dysfunction
**Multi-axiality**

- **SOC** = Respiratory, thoracic and mediastinal disorders
- **HLGT** = Respiratory tract infections
- **HLT** = Viral upper respiratory tract infections
- **PT** = Influenza

**Single Axial SOCs**

- SOC *Investigations*
- SOC *Surgical and medical procedures*
- SOC *Social circumstances*
Advantages of Using MedDRA

• Standard used by regulatory authorities within ICH regions and beyond
  – EU, Japan, US, Canada, Australia
• ICH-endorsed user guides
  – MedDRA term selection: PTC
  – MedDRA data retrieval and presentation: PTC
• User responsive, actively maintained

Advantages of Using MedDRA (cont)

• MedDRA’s wide variety of information
  – Diseases, signs/symptoms, diagnoses
  – Laboratory tests and qualitative test result
  – Surgical and medical procedures
  – Social, family history
• MedDRA PT primary and secondary SOC assignments
Advantages of Using MedDRA (cont)

• Five levels of hierarchy
  – HLT, HLGT, and SOC groupings for data gathering
  – Flexibility of grouping specificity

• Standardised MedDRA Queries (SMQs)
  – Developed and tested by PV experts from industry and regulatory authorities
  – Maintained by the MSSO

Challenges of Using MedDRA

• Single axial SOCs isolate
  – Test results
  – Procedures
  – Social information

• Granularity

• Limitations of HLT and HLGT groupings
Challenges of Using MedDRA (cont)

- Versioning
  - Version of coded data
  - Version of SMQs
- Large terminology requires software tools
- MedDRA training is strongly recommended for optimal use

Signal Detection in Real Time

- How signal detection is conducted using MedDRA as the standard coding dictionary
  - From FDA perspective
  - From MHRA perspective
  - From industry perspective
Thank you 谢谢