MedDRA Workshop
42th Annual Meeting of Representatives of National Pharmacovigilance Centres participating in the WHO PIDM
Bogotá, Colombia
1 November 2019
Dr. Carol-Ann Wilson - MSSO
MedDRA background, structure and scope
General coding principles
How to use the MedDRA browser
MedDRA Term Selection: Points to Consider document
Hands-on coding exercises
Data Retrieval and Analysis of MedDRA Coded Data/ Standardised MedDRA Queries
Useful resources
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MedDRA Background, Structure and Scope
MedDRA was developed under the auspices of the International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH). The activities of the MedDRA Maintenance and Support Services Organization (MSSO) are overseen by an ICH MedDRA Management Committee, which is composed of the ICH parties, the Medicines and Healthcare products Regulatory Agency (MHRA) of the UK, Health Canada, and the WHO (as Observer).
What is MedDRA?

**Med** = Medical

**D** = Dictionary for

**R** = Regulatory

**A** = Activities
MedDRA is a clinically-validated international medical terminology used by regulatory authorities and the regulated biopharmaceutical industry. The terminology is used through the entire regulatory process, from pre-marketing to post-marketing, and for data entry, retrieval, evaluation, and presentation.
Scope of MedDRA

IN

Medical conditions
Indications
Investigations (tests, results)
Medical and surgical procedures
Medical, social, family history
Medication errors
Product quality issues
Device-related issues
Product use issues
Pharmacogenetic terms
Toxicologic issues
Standardized queries

OUT

Not a drug dictionary
Patient demographic terms
Clinical trial study design terms

Frequency qualifiers
Numerical values for results
Severity descriptors
Not an equipment, device, diagnostic product dictionary

000281
MedDRA Structure

System Organ Class (SOC) (27)
High Level Group Term (HLGT) (337)
High Level Term (HLT) (1,737)
Preferred Term (PT) (23,708)
Lowest Level Term (LLT) (80,262)
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
Product issues
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
Non-Current Terms

- Flagged at the LLT level in MedDRA
- Not recommended for continued use
- Retained to preserve historical data for retrieval and analysis
- Terms that are vague, ambiguous, outdated, truncated, or misspelled
- Terms derived from other terminologies that do not fit MedDRA rules
MedDRA Codes

• Each MedDRA term assigned an 8-digit numeric code starting with “1”
• The code is non-expressive
• Codes can fulfill a data field in various electronic submission types (e.g., E2B)
• New terms are assigned sequentially
Codes and Languages

10019211

Cefaleia
Portuguese

Kopfschmerz
German

Hoofdpijn
Dutch

Headache
English

Céphalée
French

Bolest hlavy
Czech

Fejfájas
Hungarian

Cefalea
Italian

Cefalea
Spanish

头痛
Chinese

Головная боль
Russian

Electronic Submission

Version 22.1

두통
Korean
• Multi-axial = the representation of a medical concept in multiple SOCs
  – Allows grouping by different classifications
  – Allows retrieval and presentation via different data sets
• All PTs assigned a primary SOC
  – Determines which SOC will represent a PT during cumulative data outputs
  – Prevents “double counting”
  – Supports standardized data presentation
  – Pre-defined allocations should not be changed by users
SOC = Respiratory, thoracic and mediastinal disorders (Secondary SOC)

HLGT = Respiratory tract infections

HLT = Viral upper respiratory tract infections

PT = Influenza

SOC = Infections and infestations (Primary SOC)

HLGT = Viral infectious disorders

HLT = Influenza viral infections
Rules for Primary SOC Allocation

• PTs represented in only one SOC are automatically assigned that SOC as primary
• PTs for diseases, signs and symptoms are assigned to prime manifestation site SOC
• Congenital and hereditary anomalies terms have SOC Congenital, familial and genetic disorders as Primary SOC
• Neoplasms terms have SOC Neoplasms benign, malignant and unspecified (incl cysts and polyps) as Primary SOC
  – Exception: Cysts and polyps have prime manifestation site SOC as Primary SOC
• Infections and infestations terms have SOC Infections and infestations as Primary SOC
If a PT links to more than one of the exceptions, the following priority will be used to determine primary SOC:

1\textsuperscript{st}: Congenital, familial and genetic disorders

2\textsuperscript{nd}: Neoplasms benign, malignant and unspecified (incl cysts and polyps)

3\textsuperscript{rd}: Infections and infestations
<table>
<thead>
<tr>
<th>PT</th>
<th>HLT</th>
<th>HLGT</th>
<th>SOC</th>
</tr>
</thead>
<tbody>
<tr>
<td>Congenital HIV infection</td>
<td>Viral infections congenital</td>
<td>Infections and infestations congenital</td>
<td>Congenital, familial and genetic disorders</td>
</tr>
<tr>
<td>Congenital neonatal infections</td>
<td>Neonatal and perinatal conditions</td>
<td>Pregnant, puerperium and perinatal conditions</td>
<td></td>
</tr>
<tr>
<td>Retroviral infections</td>
<td>Viral infectious disorders</td>
<td>Infections and infestations</td>
<td></td>
</tr>
<tr>
<td>Acquired immunodeficiency syndromes</td>
<td>Immunodeficiency syndromes</td>
<td>Immune system disorders</td>
<td></td>
</tr>
</tbody>
</table>
Non-multiaxial SOCs

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*
General Coding Principles
Why is Coding Important?
Why is Coding Important?

Coding quality
• Standardization
• Accuracy
• Consistency
• Transparency

Efficient, effective and reproducible data retrieval, presentation and evaluation of safety data

Patient safety!
Select the closest matching LLT to capture all the reported information

<table>
<thead>
<tr>
<th>VT</th>
<th>Pneumonia after bypass surgery</th>
</tr>
</thead>
<tbody>
<tr>
<td>LLT</td>
<td>Post procedural pneumonia</td>
</tr>
<tr>
<td>PT</td>
<td>Post procedural pneumonia</td>
</tr>
</tbody>
</table>
Do not add information, interpret or diagnose

<table>
<thead>
<tr>
<th>VT</th>
<th>Blood pressure measurement was 160/100 mmHg</th>
</tr>
</thead>
<tbody>
<tr>
<td>LLT</td>
<td>Blood pressure reading high</td>
</tr>
<tr>
<td>PT</td>
<td>Blood pressure increased</td>
</tr>
</tbody>
</table>
Do not add information, interpret or diagnose

- **VT**: Patient took more pills than prescribed during last week
- **LLT**: Extra dose administered
- **PT**: Extra dose administered
Use medical judgment and references

- VT: Metralgia
- LLT: Uterine pain
- PT: Uterine pain
Check the MedDRA hierarchy

- VT: Cervical spasm during IUD insertion
- LLT: Spasm uterine cervix
- PT: Uterine spasm
Know how to handle combination terms

- VT: Joint inflammation caused by rubella infection
- LLT: Arthritis due to rubella
- PT: Arthritis rubella
Know how to handle combination terms

VT
Sepsis due to purulent cholecystitis

LLT
• Cholecystitis suppurative
• Biliary sepsis

PT
• Cholecystitis infective
• Biliary sepsis
Seek clarification if vague or ambiguous verbatims are reported

- VT: Patient with global insufficiency
- LLT: Ill-defined disorder
- PT: Ill-defined disorder
How to Use the MedDRA Browser

WBB training credentials (temporary)
https://tools.meddra.org/wbb
Login: training
PWD: @MEDDRA22
MSSO’s MedDRA Browsers

• MedDRA Desktop Browser (MDB)
  – Download MDB and release files from MedDRA website

• MedDRA Web-Based Browser (WBB)
  – [https://tools.meddra.org/wbb/](https://tools.meddra.org/wbb/)

• Features
  – Both require MedDRA ID and password
  – View/search MedDRA and SMQs
  – Support for all MedDRA languages
  – Language specific interface
  – Ability to export search results and Research Bin to local file system
MedDRA Browser Demonstration
SOC View
Assessing the Reported Information

• Consider what is being reported. Is it a:
  – Clinical condition - Diagnosis, sign or symptom?
  – Indication?
  – Test result?
  – Injury?
  – Procedure?
  – Medication error?
  – Product use issue?
  – Product quality issue?
  – Social circumstance?
  – Device issue?
  – Procedural complication?

  – Is it a combination of these?

The type of report will influence the way you search for a suitable LLT. It may indicate in which SOC you expect to find the closest match.
MedDRA Browsing Tips

• First, try using actual words from reporter
• Use “top-down” and “bottom-up” approaches
• Look at the “neighbors” and check the hierarchy
• Consider synonyms, e.g., “Liver” and “Hepatic”
• Use word stems, e.g., “Pancrea”
• Use available resources for difficult verbatim terms (web search, medical dictionaries and textbooks, colleagues)
• Become familiar with the MedDRA Concept Descriptions
Two days old boy developed anemia and jaundice.

____________________ LLT → ______________________ PT
____________________ LLT → ______________________ PT
Exercise

The infusion solution was contaminated with Staphylococcus.

___________________ LLT → _____________________ PT
Enlargement of right breast in male patient.

____________________ LLT → ____________________ PT
MedDRA Term Selection: Points to Consider Document
MedDRA Term Selection: Points to Consider (MTS:PTC)

- Provides term selection advice for industry and regulatory purposes
- Objective is to promote accurate and consistent term selection to facilitate a common understanding of shared data
- Recommended to be used as basis for individual organization’s own coding conventions
MedDRA Term Selection: PTC (cont)

- Developed by a working group of the ICH Management Committee
- Updated twice yearly with each MedDRA release
- Available on MedDRA and JMO websites
  - English and Japanese
  - Word (“clean” and “redlined”), PDF, HTML formats
  - “Redlined” document identifies changes made from previous to current release of document
• In some cases with more than one option for selecting terms, a “preferred option” is identified but this does not limit MedDRA users to applying that option. Organizations should be consistent in their choice of option.

• Section 4.1 – Versioning (Appendix)
  – 4.1.1 Versioning methodologies
  – 4.1.2 Timing of version implementation
General Term Selection Principles

- Quality of Source Data
- Quality Assurance
- Do Not Alter MedDRA
- Always Select a Lowest Level Term
- Select Only Current Lowest Level Terms
- When to Request a Term
- Use of Medical Judgment in Term Selection
- Selecting More than One Term
- Check the Hierarchy
- Select Terms for All Reported Information, Do Not Add Information
Term Selection Points

- Diagnoses and Provisional Diagnoses with or without Signs and Symptoms
- Death and Other Patient Outcomes
- Suicide and Self-Harm
- Conflicting/Ambiguous/Vague Information
- Combination Terms
- Age vs. Event Specificity
- Body Site vs. Event Specificity
- Location-Specific vs. Microorganism-Specific Information
- Modification of Pre-existing Conditions
- Exposures During Pregnancy and Breast Feeding
- Congenital Terms
- Neoplasms
- Medical and Surgical Procedures
- Investigations
Term Selection Points (cont)

- Medication Errors, Accidental Exposures and Occupational Exposures
- Misuse, Abuse and Addiction
- Transmission of Infectious Agent via Product
- Overdose, Toxicity and Poisoning
- Device-related Terms
- Drug Interactions
- No Adverse Effect and “Normal” Terms
- Unexpected Therapeutic Effect
- Modification of Effect
- Social Circumstances
- Medical and Social History
- Indication for Product Use
- Off Label Use
- Product Quality Issues
## Diagnoses and Provisional Diagnoses

<table>
<thead>
<tr>
<th><strong>SINGLE DIAGNOSIS</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>DEFINITIVE DIAGNOSIS</strong></td>
</tr>
<tr>
<td>Single diagnosis without signs and symptoms</td>
</tr>
<tr>
<td>• Diagnosis (only possible option)</td>
</tr>
<tr>
<td>Example: “Myocardial infarction” → select “Myocardial infarction”</td>
</tr>
</tbody>
</table>

Similar principles apply for multiple diagnoses

MTS: PtC Section 3.1
### SINGLE DIAGNOSIS

<table>
<thead>
<tr>
<th>DEFINITIVE DIAGNOSIS</th>
<th>PROVISIONAL DIAGNOSIS</th>
</tr>
</thead>
<tbody>
<tr>
<td>Single diagnosis with signs/symptoms</td>
<td>Single provisional diagnosis with signs/symptoms</td>
</tr>
<tr>
<td>•Preferred: Diagnosis only</td>
<td>•Preferred: Provisional diagnosis and signs/symptoms</td>
</tr>
<tr>
<td>Example: “Anaphylactic reaction with rash, dyspnoea, hypotension, and laryngospasm”</td>
<td>Example: “Possible myocardial infarction with chest pain, dyspnoea, diaphoresis”</td>
</tr>
<tr>
<td>→ select “Anaphylactic reaction”</td>
<td>→ select “Myocardial infarction” “Chest pain”, “Dyspnoea”, and “Diaphoresis”</td>
</tr>
</tbody>
</table>

Similar principles apply for multiple diagnoses.
### SINGLE DIAGNOSIS

<table>
<thead>
<tr>
<th>DEFINITIVE DIAGNOSIS</th>
<th>PROVISIONAL DIAGNOSIS</th>
</tr>
</thead>
<tbody>
<tr>
<td>Single diagnosis with signs/symptoms</td>
<td>Single provisional diagnosis with signs/symptoms</td>
</tr>
<tr>
<td>• Alternate: Diagnosis and signs/symptoms</td>
<td>• Alternate: Signs/symptoms only (as provisional diagnosis may change)</td>
</tr>
</tbody>
</table>

Similar principles apply for multiple diagnoses
Always include signs/symptoms not associated with diagnosis

<table>
<thead>
<tr>
<th>Reported</th>
<th>LLT Selected</th>
</tr>
</thead>
<tbody>
<tr>
<td>Myocardial infarction, chest pain, dyspnoea,</td>
<td>Myocardial infarction</td>
</tr>
<tr>
<td>diaphoresis, ECG changes and jaundice</td>
<td>Jaundice (note that jaundice is not typically associated with myocardial</td>
</tr>
<tr>
<td></td>
<td>infarction)</td>
</tr>
</tbody>
</table>

Combination Terms

- One condition is more specific than the other

<table>
<thead>
<tr>
<th>Reported</th>
<th>LLT Selected</th>
</tr>
</thead>
<tbody>
<tr>
<td>Arrhythmia due to atrial fibrillation</td>
<td>Atrial fibrillation</td>
</tr>
<tr>
<td>Hepatic function disorder (acute hepatitis)</td>
<td>Hepatitis acute</td>
</tr>
</tbody>
</table>

- A MedDRA combination term is available

<table>
<thead>
<tr>
<th>Reported</th>
<th>LLT Selected</th>
</tr>
</thead>
<tbody>
<tr>
<td>Retinopathy due to diabetes</td>
<td>Diabetic retinopathy</td>
</tr>
<tr>
<td>Rash with itching</td>
<td>Itchy rash</td>
</tr>
</tbody>
</table>
• If splitting provides more clinical information, select more than one term
• In all cases of combination terms, apply medical judgment

<table>
<thead>
<tr>
<th>Reported</th>
<th>LLT Selected</th>
</tr>
</thead>
<tbody>
<tr>
<td>Diarrhoea and vomiting</td>
<td>Diarrhoea Vomiting</td>
</tr>
<tr>
<td>Wrist fracture due to fall</td>
<td>Wrist fracture Fall</td>
</tr>
</tbody>
</table>
In most cases MedDRA terms capture both infectious agent and affected site.

The preferred option is to select terms for both the microorganism-specific infection and the anatomic location.

Alternatively, select a term that reflects the anatomic location or select a term that reflects the microorganism-specific infection. Medical judgment should be used in deciding whether anatomic location or the microorganism-specific infection should take priority.

<table>
<thead>
<tr>
<th>Reported</th>
<th>LLT Selected</th>
<th>Preferred Option</th>
<th>Comment</th>
</tr>
</thead>
<tbody>
<tr>
<td>Haemophilus respiratory infection</td>
<td>Haemophilus infection</td>
<td>✓</td>
<td>Represents both microorganism-specific infection and anatomic location</td>
</tr>
<tr>
<td></td>
<td>Respiratory infection</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Respiratory infection</td>
<td></td>
<td>Represents location-specific infection</td>
</tr>
<tr>
<td></td>
<td>Haemophilus infection</td>
<td></td>
<td>Represents microorganism-specific infection</td>
</tr>
</tbody>
</table>
DVT with pulmonary embolism

Chronic renal insufficiency with anemia, hypertension and interstitial pulmonary edema

Blood culture positive/ Salmonella blood infection

Hypothyreosis with depressive symptoms, weight gain, constipation and aphasia
Coding Exercises

How to join

1. Go to PollEv.com
2. Enter MEDDRA174
3. Respond to activity
Suicide attempt with an overdose of sleeping and pain pills

a) Suicide attempt
b) Overdose
c) Intentional overdose
d) Suicide attempt AND Multiple drug overdose intentional
e) Multiple drug overdose
Suicide attempt with an overdose of sleeping and pain pills

- Suicide attempt
- Overdose
- Intentional overdose
- Suicide attempt AND Multiple drug overdose intentional
- Multiple drug overdose
Pharmacist dispensed wrong drug due to confusion of drug names. Patient took the drug for 5 days before the error was detected.

a) Wrong drug dispensed
b) Confusion
c) Wrong drug dispensed AND Drug name confusion AND Wrong drug administered
d) Wrong drug dispensed AND Confusion
e) Wrong drug dispensed AND Wrong drug administered
Pharmacist dispensed wrong drug due to confusion of drug names. Patient took the drug for 5 days before the error was detected.

<table>
<thead>
<tr>
<th>Wrong drug dispensed</th>
<th>Confusion</th>
</tr>
</thead>
<tbody>
<tr>
<td>Wrong drug dispensed AND Drug name confusion AND Wrong drug administered</td>
<td></td>
</tr>
<tr>
<td>Wrong drug dispensed AND Confusion</td>
<td></td>
</tr>
<tr>
<td>Wrong drug dispensed AND Wrong drug administered</td>
<td></td>
</tr>
</tbody>
</table>
Patient accidentally swallowed Nitroglycerin (instead of correct sublingual administration)

a) Incorrect route of drug administration
b) Swallowing disorder
c) Accident
d) Accidental ingestion of drug
Patient accidentally swallowed Nitroglycerin (instead of correct sublingual administration)

Incorrect route of drug administration

Swallowing disorder

Accident

Accidental ingestion of drug
The ointment had a different consistency and the consumer reported severe skin irritation at site of administration

a) Product quality issue AND Poor quality drug administered

b) Product physical consistency issue AND Poor quality drug administered AND Application site irritation

c) Poor quality drug administered AND Skin irritation

d) Product physical consistency issue AND Skin irritation
The ointment had a different consistency and the consumer reported severe skin irritation at site of administration

- Product quality issue AND Poor quality drug administered
- Product physical consistency issue AND Poor quality drug administered AND Application site irritation
- Poor quality drug administered AND Skin irritation
- Product physical consistency issue AND Skin irritation
Fetal heart rate irregular while mother was on drug X

a) Fetal exposure during pregnancy AND Fetal arrhythmia

b) Fetal exposure during pregnancy AND Fetal heart rate abnormal

c) Maternal exposure during pregnancy AND Fetal heart rate abnormal

d) Drug exposure during pregnancy AND Fetal arrhythmia
Fetal heart rate irregular while mother was on drug X

Fetal exposure during pregnancy AND Fetal arrhythmia

Fetal exposure during pregnancy AND Fetal heart rate abnormal

Maternal exposure during pregnancy AND Fetal heart rate abnormal

Drug exposure during pregnancy AND Fetal arrhythmia
Bump on leg

a) Skin mass
b) Mass
c) Lower extremity mass
d) Local swelling
e) Lower limb deformity
f) Unilateral leg swelling
Bump on leg

Skin mass

Mass

Lower extremity mass

Lower limb deformity

Unilateral leg swelling
How to Code?

Viral carditis

a) Viral infection
b) Carditis
c) Cardiac infection
d) Viral infection AND Cardiac infection
e) Viral myocarditis
Viral carditis

Viral infection

Carditis

Cardiac infection

Viral infection AND Cardiac infection

Viral myocarditis
Cardia insufficiency

a) Cardiac insufficiency  
b) Ill-defined disorder  
c) Unevaluable event  
d) Incompetent cardia
Cardia insufficiency

Cardiac insufficiency

Ill-defined disorder

Unevaluable event

Incompetent cardia
Pain in hand, severe pain in leg and toe

a) Pain
b) Musculoskeletal pain
c) Pain in hand AND Pain in leg AND Pain in toe
d) Pain in extremity
e) Pain in hand AND Pain in leg
Pain in hand, severe pain in leg and toe

Musculoskeletal pain

Pain in hand AND Pain in leg AND Pain in toe

Pain in extremity

Pain in hand AND Pain in leg
Left foot and left ankle swelling
  a) Swelling of feet AND Ankle swelling
  b) Peripheral swelling
  c) Unilateral leg swelling
  d) Local swelling
Left foot and left ankle swelling

- Swelling of feet
  AND Ankle swelling

- Peripheral swelling
- Unilateral leg swelling
- Local swelling
How to Code?

Asplenia after previous spleen resection

a) Asplenia AND Splenectomy
b) Asplenia
c) Splenectomy
d) Acquired asplenia
Asplenia after previous spleen resection

Asplenia AND Splenectomy

Asplenia

Splenectomy

Acquired asplenia
Myocardial infarction leading to sudden death

a) Sudden death
b) Cardiac death
c) Acute myocardial infarction
d) Sudden cardiac death AND Myocardial infarction
Myocardial infarction leading to sudden death

- Sudden death
- Cardiac death
- Acute myocardial infarction
- Sudden cardiac death AND Myocardial infarction
Data Retrieval and Analysis of MedDRA Coded Data
What is a Query?

Clinical Trial Database
Safety Database

Case
LLT1
LLT2
LLT3

"Hit"

Query
SMQ
PT
LLT
LLT
LLT 1
PT
LLT
LLT
LLT
MedDRA Data Retrieval and Presentation: Points to Consider (DRP:PTC)

- Provides data retrieval and presentation options for industry or regulatory purposes
- Most effective when used in conjunction with MedDRA Term Selection: PTC document
- Recommended to be used as basis for individual organization’s own data retrieval conventions
MedDRA Data Retrieval and Presentation: PTC (cont)

- Developed by a working group of the ICH Management Committee
- Updated twice yearly with each MedDRA release
- Available on MedDRA and JMO websites
  - English and Japanese
  - Word (“clean” and “redlined”), PDF, HTML formats
  - “Redlined” document identifies changes made from previous to current release of document
Data Retrieval PTC

Points Addressed

• General Principles
  – Quality of Source Data
  – Documentation of Data Retrieval and Presentation Practices
  – Do Not Alter MedDRA
  – Organisation-Specific Data Characteristics
  – Characteristics of MedDRA that Impact Data Retrieval and Analysis
  – MedDRA Versioning

• General Queries and Retrieval
• Standardised MedDRA Queries
• Customised Searches
Standardised MedDRA Queries (SMQs)

• Collaboration between CIOMS (Council for International Organizations of Medical Sciences) and ICH (MSSO)
• Groupings of terms from one or more MedDRA SOCs related to medical condition or area of interest
• Terms relate to signs/symptoms, diagnoses, syndromes, physical findings, laboratory and other test data, etc.
• Intended to aid in case identification
SMQ Benefits and Limitations

• Benefits
  – Application across multiple therapeutic areas
  – Validated reusable search logic
  – Standardized communication of safety information
  – Consistent data retrieval
  – Maintenance by MSSO/JMO

• Limitations
  – Do not cover all medical topics or safety issues
  – Will evolve and undergo further refinement even though they have been tested during development
• Clinical trials
  – Where safety profile is not fully established, use multiple SMQs on routine basis as screening tool
  – Selected SMQs to evaluate previously identified issue (pre-clinical data or class effect)

• Post-marketing
  – Selected SMQs to retrieve cases for suspected or known safety issue
  – Signal detection (multiple SMQs employed)
  – Single case alerts
  – Periodic reporting (aggregate cases for safety and other issues, e.g., lack of efficacy)
SMQ in Production - Examples

As of Version 22.0, a total of 104 level 1 SMQs in production

- Agranulocytosis
- Anaphylactic reaction
- Cerebrovascular disorders
- Convulsions
- Depression and suicide/self-injury
- Hepatic disorders
- Hypersensitivity
- Ischaemic heart disease
- Lack of efficacy/effect
- Medication errors
- Osteonecrosis
- Peripheral neuropathy
- Pregnancy and neonatal topics
- Pseudomembranous colitis
- Rhabdomyolysis/myopathy
- Severe cutaneous adverse reactions
- Systemic lupus erythematosus
SMQ Data Characteristics

- MedDRA term inclusion
- Broad/narrow
- Algorithms
- Hierarchy
- SMQ status/term status within an SMQ
- SMQ files and documents
• SMQs are constructed at MedDRA PT level
• LLTs that are subordinate to an included PT are also included
Narrow and Broad Searches

• “Narrow” scope – specificity (cases highly likely to be condition of interest)
• “Broad” scope – sensitivity (all possible cases)
• “Broad search” = All broad + all narrow terms
SMQ *Lactic acidosis*

**Definition**
Lactic acidosis is a form of high anion gap metabolic acidosis - Intrinsic cardiac contractility may be depressed, but inotropic function can be normal because of catecholamine release. Peripheral arterial vasodilatation and central vasoconstriction can be present - Central nervous system function is depressed, with headache, lethargy, stupor, and, in some cases, even coma. Glucose intolerance may occur - Characterized by an increase in plasma L-lactate. Acidosis is seldom significant unless blood lactate exceeds 5 mmol/l. Clinical presentation in type B lactic acidosis: o Symptoms: hyperventilation or dyspnea, stupor or coma, vomiting, drowsiness, and abdominal pain. o Onset of symptoms and signs is usually rapid accompanied by deterioration in the level of consciousness.

**Source**

**Note**
Testing in two regulatory databases confirmed that the term list is adequate; in one regulatory database, the term “acidosis” identified cases, but this may be a phenomenon of the database characteristics (coding of verbatim to terms of an old terminology or other coding conventions).
Algorithmic SMQs

• Some SMQs are designed to utilize algorithms

• Better case identification among broad search terms may result if cases are selected by a defined combination of selected terms
Algorithmic SMQ Example

- Anaphylactic reaction (SMQ):
  - A case with any of the following PTs:
    - Anaphylactic reaction
    - Anaphylactic shock
    - Anaphylactic transfusion reaction
    - Anaphylactoid reaction
    - Anaphylactoid shock
    - Circulatory collapse
    - Dialysis membrane reaction
    - Kounis syndrome
    - Procedural shock
    - Shock
    - Shock symptom
    - Type I hypersensitivity

(Narrow search terms = Category A)
Algorithmic SMQ Example (cont)

<table>
<thead>
<tr>
<th>Category B – Upper airway/Respiratory</th>
<th>Category C – Angioedema/Urleticaria, etc.</th>
<th>Category D – Cardiovascular/Hypotension</th>
</tr>
</thead>
<tbody>
<tr>
<td>Acute respiratory failure</td>
<td>Allergic oedema</td>
<td>Blood pressure decreased</td>
</tr>
<tr>
<td>Asthma</td>
<td>Angioedema</td>
<td>Blood pressure diastolic decreased</td>
</tr>
<tr>
<td>Bronchial oedema</td>
<td>Erythema</td>
<td>Blood pressure systolic decreased</td>
</tr>
</tbody>
</table>

- Case = A (Narrow terms)
- Or Term from Category B and term from Category C
- Or Term from either Category B or Category C plus Term from Category D
Hierarchical SMQs

- Some SMQs may develop as a set of queries related to one another in a hierarchical relationship.
- Not related to MedDRA standard hierarchy.
- One or more subordinate SMQs combined to create a superordinate, more inclusive SMQ.
Haematopoietic cyberopenias

- Haematopoietic cytopenias affecting more than one type of blood cell
- Haematopoietic erythopenia
- Haematopoietic leukopenia
- Haematopoietic thrombocytopenia
• Each SMQ has a status (Active/Inactive)
• Similar in concept to MedDRA currency
• Terms assigned to an SMQ also have a status flag
  – Once a term is added to an SMQ, it will always be included in the SMQ but the status may be inactive
MedDRA Browser Demonstration
SMQ View
SMQ Files and Documents

• MedDRA distributed files unchanged by inclusion of SMQ files
• SMQ Introductory Guide
  – Recommended reading for optimal use of SMQs
  – Details of individual SMQs
  – Notes for implementation and/or expectation of results
• Production SMQ Spreadsheet
  – SMQs and included terms, SMQ summary
• SMQ changes: “What’s New” document, Version Report, MVAT
• Original CIOMS Working Group documentation
Useful Resources
Useful Resources

• MedDRA Concept Descriptions
• MedDRA Introductory Guide
• MedDRA Term Selection: Points to Consider
• MedDRA Points to Consider Companion Document
• Introductory Guide for Standardised MedDRA Queries (SMQs)
• MedDRA Data Retrieval and Presentation: Points to Consider
• MedDRA Website
• MedDRA Version Reports
Concept Descriptions

• Descriptions of how a concept is interpreted, used, and classified in MedDRA
• Not a definition
• Intended to aid accurate and consistent use of MedDRA in coding and retrieval
• Overcome differences in medical practice worldwide
  – Descriptions aim to be broadly consistent with definitions across different regulatory regions
• See Appendix B of MedDRA Introductory Guide
• Accessible in MSSO’s Browsers
MedDRA CONCEPT DESCRIPTIONS

This appendix provides a list of MedDRA concept descriptions. A concept description is a description of how a concept is interpreted, used, and classified within the MedDRA terminology and is not a definition. The concept descriptions are intended to aid the consistent and accurate use of MedDRA in coding, retrieval, and analysis and to overcome the differences of medicine practice worldwide. The MSSO expects this appendix to be a working document and grow as subscribers request additional concepts to be documented.

A B C D E F G H I J K L M N O P Q R S T U V W X Y Z

Abuse

For the purposes of term selection and analysis of MedDRA-coded data, abuse is the intentional, non-therapeutic use by a patient or consumer of a product – over-the-counter or prescription – for a perceived reward or desired non-therapeutic effect including, but not limited to, “getting high” (euphoria). Abuse may occur with a single use, sporadic use or persistent use of the product.
• New document providing details, examples and further guidance on specific topics
• “Living” document that is updated based on users needs
• Detailed guidance on coding of medication errors
Welcome to MedDRA

In the late 1990s, the International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH) developed MedDRA, a rich and highly specific standardised medical terminology to facilitate sharing of regulatory information internationally for medical products used by humans... (more)

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Thank you!
Further questions?