Introduction to MedDRA: Coding and Data Analysis

Jane Knight

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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.
MedDRA’s Purpose

• Facilitate the exchange of clinical information through standardization
• Important tool for product evaluation, monitoring, communication, electronic records exchange, and oversight
• Supports coding (data entry) and retrieval and analysis of clinical information about human medical products including pharmaceuticals, biologics, vaccines, and drug-device combination products
MedDRA and the MSSO

• International support and development of terminology
• Foster use of MedDRA through communications and educational offerings
• “Custodians”, not owners, of the terminology
• JMO (partner organization for Japanese-language MedDRA)
• Governed by a Management Committee (industry, regulators, multi-national, other interested parties)
Where MedDRA is Used

Regulatory Authority and Industry Databases
Individual Case Safety Reports and Safety Summaries

Clinical Study Reports
Investigators’ Brochures
Core Company Safety Information
Marketing Applications
Publications
Prescribing Information
Advertising
As of January 2019
- 5,700 Subscribing organizations (MSSO+J MO)
- 122 Countries

Graph shows types of subscribing organizations
MedDRA Users by Region

- **Europe**: 38%
- **Americas**: 32%
- **JMO (Japan)**: 14%
- **Asia**: 13%
- **Africa**: 1%
- **Oceania**: 2%

### Users by Country

<table>
<thead>
<tr>
<th>Country</th>
<th>Count</th>
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</thead>
<tbody>
<tr>
<td>United States</td>
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<td>Japan</td>
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<td>Russian Federation</td>
<td>37</td>
</tr>
<tr>
<td>Czechia</td>
<td>36</td>
</tr>
</tbody>
</table>
MedDRA Data Sharing

- Subscription grants access to MedDRA for one year
- Subscriber cannot grant any sublicense, publish or otherwise distribute MedDRA to a third party
- Data may be freely exchanged between current MedDRA subscribers
  - Sponsor-sponsor, sponsor-CRO, vendor-user, etc.
  - Use Self-Service Application to check organization’s subscription status
- Sharing MedDRA with a non-subscribing organization is a violation of the MedDRA license
Scope of MedDRA

IN

Out

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

Frequency qualifiers
Numerical values for results
Severity descriptors
Not a drug dictionary
Patient demographic terms
Clinical trial study design terms
Not an equipment, device, diagnostic product dictionary
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)
### MedDRA in Use

<table>
<thead>
<tr>
<th>Lowest Level Term</th>
<th>Preferred Term</th>
<th>High Level Term</th>
<th>High Level Group Term</th>
<th>System Organ Class</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>English</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Asthmatic wheezing</td>
<td>Wheezing</td>
<td>Bronchospasm and obstruction</td>
<td>Bronchial disorders (excl neoplasms)</td>
<td>Respiratory, thoracic and mediastinal disorders</td>
</tr>
<tr>
<td><strong>Russian</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Астматическое свистящее дыхание</td>
<td>Свистящее дыхание</td>
<td>Бронхоспазм и обструкция</td>
<td>Бронхиальные нарушения (искл. новообразования)</td>
<td>Нарушения со стороны дыхательной системы, органов грудной клетки и средостения</td>
</tr>
</tbody>
</table>

**Coding** – Applied to individual events  
**Analysis** – Grouping of multiple events for signal detection
Codes and Languages

- Cefaleia (Portuguese)
- Kopfschmerz (German)
- Hoofdpijn (Dutch)
- Headache (English)
- Céphalée (French)
- Bolest hlavy (Czech)
- Fejfájás (Hungarian)
- Cefalea (Italian)
- Headache (Chinese)
- Cefalea (Spanish)
- Головная боль (Russian)

Electronic Submission
A Multi-Axial Terminology

- 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
A Multi-Axial Terminology (cont)

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:

1st: Congenital, familial and genetic disorders
2nd: Neoplasms benign, malignant and unspecified (incl cysts and polyps)
3rd: Infections and infestations
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*
<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></td>
<td>Pregnancy, puerperium and perinatal conditions</td>
</tr>
<tr>
<td>Retroviral infections</td>
<td>Viral infectious disorders</td>
<td></td>
<td>Infections and infestations</td>
</tr>
<tr>
<td>Acquired immunodeficiency syndromes</td>
<td>Immunodeficiency syndromes</td>
<td></td>
<td>Immune system disorders</td>
</tr>
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</table>
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 users have access, as part of their subscription, to a range of powerful computer tools which help to get the most out of the database in addition to the different guides and training available which support implementation and use of MedDRA.

Help Yourself
Get answers to some of your immediate questions via the MedDRA Self-Service Application

Related Documents:
- Facilitating MedDRA Use
- Related Links:
  - Download the Desktop Browsers (MSSO and JMO)
  - Open the Web-Based Browser
  - Open the MWAT
  - Training Materials
  - Submit Change (WebCR)
• MedDRA Mobile Browser for use on phones and tablets

• Accessed at: mmb.meddra.org

• Requires your organisation’s MedDRA ID and Password
• Requires MedDRA ID and Password
### MedDRA Version Releases:

#### MedDRA Version 22.0 March 2019

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<tr>
<th>Release package</th>
<th>Language</th>
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<tbody>
<tr>
<td>MedDRA 22.0 版 中文</td>
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<td>MedDRA Версия 22.0 Русский Март 2019 г</td>
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<tr>
<td>Version 22.0 de MedDRA Español</td>
<td>Spanish</td>
<td>7.3 MB</td>
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Accessing MedDRA Content

- MedDRA content files are a series of ASCII files
- Folder is unzipped by a version-specific unzip password
- Files can be imported into the MedDRA Desktop Browser
- Files may also be incorporated into company database

- Release package contains documents, including:
  - MedDRA Introductory Guides
  - MedDRA Distribution File Format Document
  - Other support documents all available in Russian
• Users can send change requests (CRs) to MSSO for consideration
  – Organizations allowed 100 CRs/month
  – For simple changes (PT and LLT levels), response within 7-10 working days
  – Complex changes (above PT level) posted for comments mid-year

• Two MedDRA updates/year
  – 1 March X.0 (Complex release)
  – 1 September X.1 (Simple release)
MedDRA Version Analysis Tool (MVAT)

- Web-based (https://tools.meddra.org/mvat)
- Free to all users
- Features
  - Version Report Generator (produces exportable report comparing any two versions)
  - Data Impact Report (identifies changes to a specific set of MedDRA terms or codes uploaded to MVAT)
  - Search Term Change (identifies changes to a single MedDRA term or code)
- User interface and report output available in all MedDRA languages
<table>
<thead>
<tr>
<th>PtC Category</th>
<th>PtC Document</th>
<th>Purpose</th>
<th>Languages</th>
<th>Release Cycle</th>
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</thead>
<tbody>
<tr>
<td>Term Selection</td>
<td>MedDRA Term Selection: Points to Consider</td>
<td>Promote accurate and consistent coding with MedDRA</td>
<td>English and Japanese</td>
<td>Updated with each MedDRA release</td>
</tr>
<tr>
<td></td>
<td>MedDRA Term Selection: Points to Consider Condensed Version</td>
<td>Shorter version focusing on general coding principles to promote accurate and consistent use of MedDRA worldwide</td>
<td>All MedDRA languages (except English and Japanese)</td>
<td>Update as needed</td>
</tr>
<tr>
<td>Data Retrieval and Presentation</td>
<td>MedDRA Data Retrieval and Presentation: Points to Consider</td>
<td>Demonstrate how data retrieval options impact the accuracy and consistency of data output</td>
<td>English and Japanese</td>
<td>Updated with each MedDRA release</td>
</tr>
<tr>
<td></td>
<td>MedDRA Data Retrieval and Presentation: Points to Consider Condensed Version</td>
<td>Shorter version focusing on general retrieval and analysis principles to promote accurate and consistent use of MedDRA worldwide</td>
<td>All MedDRA languages (except English and Japanese)</td>
<td>Update as needed</td>
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<tr>
<td>General</td>
<td>MedDRA Points to Consider Companion Document</td>
<td>More detailed information, examples, and guidance on specific topics of regulatory importance. Intended as a “living” document with frequent updates based on users’ needs. First edition covers data quality and medication errors.</td>
<td>English and Japanese</td>
<td>Updated as needed</td>
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MedDRA® TERM SELECTION: POINTS TO CONSIDER
ICH-Endorsed Guide for MedDRA Users

Release 4.17
Based on MedDRA Version 22.0

1 March 2019

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• 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
• 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
Quality of Source Data Quality Assurance

- Quality of original information impacts quality of output
- Obtain clarification of data
- Can be optimized by careful design of data collection forms and proper training of staff
- Organizations’ coding guidelines should be consistent with MTS:PTC
- Review of term selection by qualified individuals
- Human oversight of automated coding results
• MedDRA is a standardized terminology with a pre-defined term hierarchy
• Users must not make *ad hoc* structural alterations, including changing the primary SOC allocation
• If terms are incorrectly placed, submit a change request to the MSSO
Always Select a Lowest Level Term
Select Only Current LLTs

• Lowest Level Term that most accurately reflects the reported verbatim information should be selected

• Degree of specificity may be challenging
  – Example: “Abscess on face” → select “Facial abscess,” not simply “Abscess”

• Select current LLTs only
  – Non-current terms for legacy conversion/historical purposes
When to Request a Term
Use of Medical Judgment

• Avoid company-specific “work-arounds” for MedDRA deficiencies. If concept not adequately represented in MedDRA, submit Change Request to MSSO.

• If no exact match in MedDRA, use medical judgment to match to an existing term that adequately represents the concept.
Selecting More than One Term
Check the Hierarchy

- Can select more than one LLT to represent reported information. Document procedures.
  - Selecting one term may lead to loss of specificity
  - Selecting more than one term may lead to redundant counts

- Check the hierarchy above a selected LLT (PT, HLT, HLGT, SOC) to ensure placement accurately reflects meaning of reported term
Select Terms for All Reported Information

• Select terms for every AR/AE reported, regardless of causal association
• Select terms for device-related events, product quality issues, medication errors, medical and social history, investigations and indications as appropriate
Do not make diagnosis if only signs/symptoms reported

<table>
<thead>
<tr>
<th>Reported</th>
<th>LLT Selected</th>
<th>Comment</th>
</tr>
</thead>
<tbody>
<tr>
<td>Abdominal pain, increased serum amylase, and increased serum lipase</td>
<td>Abdominal pain</td>
<td>It is inappropriate to assign an LLT for diagnosis of “pancreatitis”</td>
</tr>
<tr>
<td></td>
<td>Serum amylase increased</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Lipase increased</td>
<td></td>
</tr>
</tbody>
</table>
• Missed Concepts
  – All medical concepts described after the product is taken should be coded
  – Example: “The patient took drug X and developed alopecia, increased LFTs and pancreatitis”. Manufacturer only codes alopecia and increased LFTs (missed concept of pancreatitis)
  – Example: “The patient took drug X and developed interstitial nephritis which later deteriorated into renal failure”. Manufacturer only codes interstitial nephritis (missed renal failure concept)
Important Coding Errors (cont)

• “Soft Coding”
  – Selecting a term which is both less specific and less severe than another MedDRA term is “soft coding”
  – Example: “Liver failure” coded as hepatotoxicity or increased LFTs
  – Example: “Aplastic anemia” coded as unspecified anemia
  – Example: “Rash subsequently diagnosed as Stevens Johnson syndrome” coded as rash
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.
Narrative vignette

A 75-year-old male receiving Drug X for rheumatoid arthritis developed symptomatic aortic valve stenosis. The patient’s medical history is significant for colon cancer and cigarette smoking. He underwent an aortic valve replacement and developed a sternal wound infection three days post-surgery.
Specificity

The patient suffered from an allergic reaction to an antibiotic
Symptoms

The patient states she has been experiencing cold sweats
Lab results indicate the patient has increased troponin and increased CPK-MB.
Medication errors

Patient accidentally took **drug Y** instead of **drug X** and became **short of breath**
Patient demographics

A 2 day old baby was noted to have a mild fever
Indications

A 35 year old woman was taking Drug X to prevent relapses of multiple sclerosis
Specificity

Following the procedure, the patient experienced several days of constipation.
Death and other patient outcomes

The 66 year old man died from a ruptured aortic aneurysm
Product quality issues

It was determined that the product was counterfeit
Social circumstances

The patient was **confined to a wheelchair**
Medication errors/Product use errors and issues

The pharmacist made a **mistake in compounding** the medication.
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

### SINGLE DIAGNOSIS

<table>
<thead>
<tr>
<th>DEFINITIVE DIAGNOSIS</th>
<th>PROVISIONAL DIAGNOSIS</th>
</tr>
</thead>
<tbody>
<tr>
<td>Single diagnosis without signs and symptoms</td>
<td>Single provisional diagnosis without signs and symptoms</td>
</tr>
<tr>
<td>• Diagnosis (only possible option)</td>
<td>• Provisional diagnosis (only possible option)</td>
</tr>
<tr>
<td>Example: “Myocardial infarction” → select “Myocardial infarction”</td>
<td>Example: “Possible myocardial infarction” → select “Myocardial infarction” (select term as if definitive diagnosis)</td>
</tr>
</tbody>
</table>

Similar principles apply for multiple diagnoses
# Diagnoses and Provisional Diagnoses (cont)

## 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>
</tbody>
</table>

Example: “*Anaphylactic reaction with rash, dyspnoea, hypotension, and laryngospasm*” → select “Anaphylactic reaction”

Example: “*Possible myocardial infarction with chest pain, dyspnoea, diaphoresis*” → select “Myocardial infarction” “Chest pain”, “Dyspnoea”, and “Diaphoresis”

Similar principles apply for multiple diagnoses.
Diagnoses and Provisional Diagnoses (cont)

<table>
<thead>
<tr>
<th>SINGLE DIAGNOSIS</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>DEFINITIVE DIAGNOSIS</strong></td>
</tr>
<tr>
<td>Single diagnosis with signs/symptoms</td>
</tr>
<tr>
<td>•Alternate: Diagnosis and signs/symptoms</td>
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</table>

Example: “Anaphylactic reaction with rash, dyspnoea, hypotension, and laryngospasm” → select “Anaphylactic reaction”, “Rash”, “Dyspnoea”, “Hypotension”, and “Laryngospasm”

Example: “Possible myocardial infarction with chest pain, dyspnoea, diaphoresis” → select “Chest pain”, “Dyspnoea”, and “Diaphoresis”

Similar principles apply for multiple diagnoses
Diagnoses and Provisional Diagnoses (cont)

- Always include signs/symptoms not associated with diagnosis

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

- First, try to obtain more specific information

<table>
<thead>
<tr>
<th>Reported</th>
<th>LLT Selected</th>
<th>Comment</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hyperkalaemia with a serum potassium of 1.6 mEq/L</td>
<td>Serum potassium abnormal</td>
<td>LLT <em>Serum potassium abnormal</em> covers both of the reported concepts (note: serum potassium of 1.6 mEq/L is a low result, not high)</td>
</tr>
<tr>
<td>GU pain</td>
<td>Pain</td>
<td>“GU” could be either “genito-urinary” or “gastric ulcer”. If additional information is not available, then select a term to reflect the information that is known, i.e., LLT <em>Pain</em></td>
</tr>
</tbody>
</table>
Vague Information

• First, try to obtain more specific information

<table>
<thead>
<tr>
<th>Reported</th>
<th>LLT Selected</th>
<th>Comment</th>
</tr>
</thead>
<tbody>
<tr>
<td>Turned green</td>
<td>Unevaluable event</td>
<td>“Turned green” reported alone is vague; this could refer to a patient condition or even to a product (e.g., pills)</td>
</tr>
<tr>
<td>Patient had a medical problem of unclear type</td>
<td>Ill-defined disorder</td>
<td>Since it is known that there is some form of a medical disorder, LLT <em>ill-defined disorder</em> can be selected</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>
Combination Terms (cont)

• 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>
### Investigations

**Medical condition vs. investigation result**

<table>
<thead>
<tr>
<th>Reported</th>
<th>LLT Selected</th>
<th>Comment</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hypoglycaemia</td>
<td>Hypoglycaemia</td>
<td>LLT Hypoglycaemia links to SOC Metabolism and nutrition disorders</td>
</tr>
<tr>
<td>Decreased glucose</td>
<td>Glucose decreased</td>
<td>LLT Glucose decreased links to SOC Investigations</td>
</tr>
</tbody>
</table>
**Investigations (cont)**

- **Unambiguous investigation result**

<table>
<thead>
<tr>
<th>Reported</th>
<th>LLT Selected</th>
<th>Comment</th>
</tr>
</thead>
<tbody>
<tr>
<td>Glucose 40 mg/dL</td>
<td>Glucose low</td>
<td>Glucose is clearly below the reference range</td>
</tr>
</tbody>
</table>

- **Ambiguous investigation result**

<table>
<thead>
<tr>
<th>Reported</th>
<th>LLT Selected</th>
<th>Comment</th>
</tr>
</thead>
<tbody>
<tr>
<td>His glucose was 40</td>
<td>Glucose abnormal</td>
<td>No units have been reported. Select LLT <em>Glucose abnormal</em> if clarification cannot be obtained.</td>
</tr>
</tbody>
</table>
Investigations (cont)

- Investigation results consistent with diagnosis

<table>
<thead>
<tr>
<th>Reported</th>
<th>LLT Selected</th>
<th>Comment</th>
</tr>
</thead>
<tbody>
<tr>
<td>Elevated potassium, K 7.0 mmol/L, and hyperkalaemia</td>
<td>Hyperkalaemia</td>
<td>It is not necessary to select LLT Potassium increased</td>
</tr>
</tbody>
</table>

- Grouped investigation result terms

<table>
<thead>
<tr>
<th>Reported</th>
<th>LLT Selected</th>
<th>Comment</th>
</tr>
</thead>
<tbody>
<tr>
<td>Increased alkaline phosphatase, increased SGPT, increased SGOT and elevated LDH</td>
<td>Alkaline phosphatase increased SGPT increased SGOT increased LDH increased</td>
<td>Select four individual terms. A single term such as LLT Liver function tests abnormal should not be selected.</td>
</tr>
</tbody>
</table>
MedDRA Coding Exercise
Instructions

• Open the MedDRA Web-Based Browser (WBB)
  – https://tools.meddra.org/wbb/
• Open an excel workbook
• Look up the MedDRA dictionary and select the most suitable LLT match for each of the reported verbatims
• Note the LLT, PT and SOC of your selection in your excel workbook against each verbatim
• Observe the MedDRA dictionary hierarchy
Which LLT Would You Select for the following terms?

1. Mild skin itching
2. Prolapse L5 surgery
3. Feeling of numbness in throat
4. Mass in ear
5. COPD with shortness of breath
6. Warm feeling in face after infusion
7. Fractured femur from tripping over
8. Increased fatigue
9. Perinephric abscess due to Proteus
10. Recurring C. difficile infection with diarrhoea
11. Using 2 mg tablets thinking they were 0.5 mg
12. Pulled out her IUD so she could get pregnant
<table>
<thead>
<tr>
<th>Verbatim</th>
<th>LLT</th>
<th>PT</th>
<th>SOC</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mild skin itching</td>
<td>Itchy skin</td>
<td>Pruritus</td>
<td>Skin and subcutaneous tissue disorders</td>
</tr>
<tr>
<td>Prolapse L5 surgery</td>
<td>Prolapsed disc repair</td>
<td>Intervertebral disc operation</td>
<td>Surgical and medical procedures</td>
</tr>
<tr>
<td>Feeling of numbness in throat</td>
<td>Numbness throat</td>
<td>Pharyngeal hypoaesthesia</td>
<td>Respiratory, thoracic and mediastinal disorders</td>
</tr>
<tr>
<td>Mass in ear</td>
<td>Mass</td>
<td>Mass</td>
<td>General disorders and administration site conditions</td>
</tr>
<tr>
<td>COPD with shortness of breath</td>
<td>COPD</td>
<td>Chronic obstructive pulmonary disease</td>
<td>Respiratory, thoracic and mediastinal disorders</td>
</tr>
<tr>
<td>Warm feeling in face after infusion</td>
<td>Feeling of warmth facial</td>
<td>Feeling hot</td>
<td>General disorders and administration site conditions</td>
</tr>
<tr>
<td>Fractured femur from tripping over</td>
<td>Fracture femur</td>
<td>Femur fracture</td>
<td>Injury, poisoning and procedural complications</td>
</tr>
<tr>
<td>Falls</td>
<td>Fall</td>
<td>Fall</td>
<td>Injury, poisoning and procedural complications</td>
</tr>
<tr>
<td>Increased fatigue</td>
<td>Fatigue aggravated</td>
<td>Fatigue</td>
<td>General disorders and administration site conditions</td>
</tr>
<tr>
<td>Perinephric abscess due to Proteus</td>
<td>Perinephric abscess</td>
<td>Perinephric abscess</td>
<td>Infections and infestations</td>
</tr>
<tr>
<td>Recurring C. difficile infection with diarrhoea</td>
<td>Proteus infection</td>
<td>Proteus infection</td>
<td>Infections and infestations</td>
</tr>
<tr>
<td>Using 2 mg tablets thinking they were 0.5 mg</td>
<td>C.difficile diarrhoea</td>
<td>Clostridium difficile colitis</td>
<td>Infections and infestations</td>
</tr>
<tr>
<td>Pulled out her IUD so she could get pregnant</td>
<td>Intentional medical device removal by patient</td>
<td>Intentional medical device removal by patient</td>
<td>Injury, poisoning and procedural complications</td>
</tr>
</tbody>
</table>
Verbatim: “Man with decreased fertility.”

A. Infertility
B. Fertility decreased male
C. Infertility male
D. Fertility decreased
Which LLT Would You Select?

Verbatim: “Became color blind in adolescence”

A. Color blindness
B. Blindness color
C. Colour blindness acquired
D. Color blindness acquired
Which LLT Would You Select?

Verbatim: “Turned very greasy”

A. Ill-defined disorder
B. Unevaluable event
C. Skin greasy
D. Unevaluable reaction
Which LLT Would You Select?

Verbatim: “Deliberately took an overdose”

A. Intentional overdose
B. Overdose NOS
C. Deliberate overdose
D. Overdose
Which LLT Would You Select?

Verbatim: “Patient reported medical problem”

A. Adverse event
B. Unevaluable event
C. Unevaluable reaction
D. Ill-defined disorder
Which LLT Would You Select?

**Verbatim:** “Toddler accidentally took his mother’s medication”

A. Accidental overdose
B. Accidental exposure to product by child
C. Accidental drug intake by child
D. Accidental ingestion
Which LLT Would You Select?

Verbatim: “Infection after surgery”

A. Infection
B. Postoperative wound infection
C. Surgical wound infection
D. Postoperative infection
Which LLT Would You Select?

Verbatim: “He sold his father’s medication”

A. Drug diversion
B. Intentional product misuse
C. Drug use for unapproved indication
D. Intentional drug misuse
Which LLT Would You Select?

**Verbatim:** “Had MI”

A. Myocardial infarction  
B. Ill-defined disorder  
C. MI  
D. Unevaluable event
Which LLT Would You Select?

**Verbatim:**
“Hypernatraemia (Serum sodium = 115 mEq/L)”

A. Serum sodium abnormal
B. Hypernatraemia
C. Hyponatraemia
D. Serum sodium decreased
Which LLT Would You Select?

Verbatim: “Took intramuscular drug by mouth”

A. Wrong route of administration
B. Drug administered via inappropriate route
C. Medication error
D. Intramuscular formulation administered by other route
Which LLT Would You Select?

Verbatim: “Death from cerebral haemorrhage”

A. Sudden death
B. Death
C. Cerebral haemorrhage
D. Brain death
Which LLT Would You Select?

Verbatim: “Patient was found dead”

A. Death from natural causes
B. Death
C. Died in sleep
D. Found dead
Which LLT Would You Select?

Verbatim: “The doctor mistakenly prescribed the wrong drug; the pharmacist noticed the error before dispensing the drug”

A. Wrong drug dispensed
B. Medication error
C. Intercepted drug prescribing error
D. Intercepted drug dispensing error
Which LLT Would You Select?

**Verbatim**: “Died as a result of a suicide attempt”

A. Suicide gesture
B. Attempted suicide
C. Completed suicide
D. Death
Which LLT Would You Select?

Verbatim: “Dose taken was below the minimum recommended dose in the product label”

A. Underdose
B. Drug administration error
C. Accidental underdose
D. Incorrect dosage administered
Which LLT Would You Select?

Verbatim: “Abused by her husband”

A. Physical abuse
B. Battered wife
C. Spousal abuse
D. Victim of spousal abuse
Verbatim: “After taking an antihistamine along with her prescribed proton pump inhibitor, a 53-year-old woman developed vertigo.”

A. Drug interaction NOS
B. Vertigo subjective
C. Vertigo
D. Drug interaction
Which LLT Would You Select?

Verbatim: “The medication was stored at room temperature instead of in the refrigerator where it belonged.”

A. Incorrect storage of drug
B. Improper storage of unused product
C. Intercepted medication error
D. Product storage error temperature too high
Verbatim: “Because the label on the package was missing the wording on dosing information, the patient took the drug twice daily instead of once daily, resulting in the administration of an overdose.”

A. Product label issue
B. Product label missing
C. Product label missing text

D. Wrong dose administered
E. Once daily dose taken more frequently
F. Inappropriate schedule of drug administration

G. Overdose
H. Accidental overdose
<table>
<thead>
<tr>
<th>PtC Category</th>
<th>PtC Document</th>
<th>Purpose</th>
<th>Languages</th>
<th>Release Cycle</th>
</tr>
</thead>
<tbody>
<tr>
<td>Term Selection</td>
<td>MedDRA Term Selection: Points to Consider</td>
<td>Promote accurate and consistent coding with MedDRA</td>
<td>English and Japanese</td>
<td>Updated with each MedDRA release</td>
</tr>
<tr>
<td></td>
<td>MedDRA Term Selection: Points to Consider Condensed Version</td>
<td>Shorter version focusing on general coding principles to promote accurate and consistent use of MedDRA worldwide</td>
<td>All MedDRA languages (except English and Japanese)</td>
<td>Update as needed</td>
</tr>
<tr>
<td>Data Retrieval and Presentation</td>
<td>MedDRA Data Retrieval and Presentation: Points to Consider</td>
<td>Demonstrate how data retrieval options impact the accuracy and consistency of data output</td>
<td>English and Japanese</td>
<td>Updated with each MedDRA release</td>
</tr>
<tr>
<td></td>
<td>MedDRA Data Retrieval and Presentation: Points to Consider Condensed Version</td>
<td>Shorter version focusing on general retrieval and analysis principles to promote accurate and consistent use of MedDRA worldwide</td>
<td>All MedDRA languages (except English and Japanese)</td>
<td>Update as needed</td>
</tr>
<tr>
<td>General</td>
<td>MedDRA Points to Consider Companion Document</td>
<td>More detailed information, examples, and guidance on specific topics of regulatory importance. Intended as a “living” document with frequent updates based on users’ needs. First edition covers data quality and medication errors.</td>
<td>English and Japanese</td>
<td>Updated as needed</td>
</tr>
</tbody>
</table>
• 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
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
Legacy Data Conversion

• Method 1 - Data converted from legacy terminology terms to MedDRA

<table>
<thead>
<tr>
<th>Reported</th>
<th>Legacy Term</th>
<th>MedDRA Term</th>
</tr>
</thead>
<tbody>
<tr>
<td>Gastrointestinal ischaemia</td>
<td>Gastrointestinal disorder</td>
<td>Gastrointestinal disorder</td>
</tr>
</tbody>
</table>

- Results reflect specificity of legacy terminology
- Benefits of greater specificity of MedDRA not attained
• Method 2 - Data converted from original reported terms (verbatim terms) to MedDRA

<table>
<thead>
<tr>
<th>Reported</th>
<th>Legacy Term</th>
<th>MedDRA Term</th>
</tr>
</thead>
<tbody>
<tr>
<td>Gastrointestinal ischaemia</td>
<td>Gastrointestinal disorder</td>
<td>Gastrointestinal ischaemia</td>
</tr>
</tbody>
</table>

-Specificity of reported term reflected by MedDRA term
MedDRA Versioning

- MedDRA is updated twice a year
  - 1 March X.0 release (all levels)
  - 1 September X.1 release (LLT and PT levels only)

- Version used in data retrieval and presentation should be documented

- Resources:
  - “What’s New” document
  - Version report
  - MedDRA Version Analysis Tool (MVAT)

- Terms used for queries should be in same version as data being queried
<table>
<thead>
<tr>
<th></th>
<th>MedDRA Version 18.1</th>
<th>Number of Events at PT Level</th>
</tr>
</thead>
<tbody>
<tr>
<td>Metastatic pain (PT)</td>
<td></td>
<td>15</td>
</tr>
<tr>
<td>Cancer pain</td>
<td></td>
<td>5</td>
</tr>
<tr>
<td></td>
<td>MedDRA Version 19.0</td>
<td>Number of Events at PT Level</td>
</tr>
<tr>
<td>Metastatic pain (no longer a PT)</td>
<td></td>
<td>0</td>
</tr>
<tr>
<td>Cancer pain</td>
<td></td>
<td>20</td>
</tr>
</tbody>
</table>
### MedDRA Versioning (cont):
**Effect of Primary SOC Change**

<table>
<thead>
<tr>
<th>SOC</th>
<th>Number of Events</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>MedDRA Version 18.0</strong></td>
<td></td>
</tr>
<tr>
<td>Vascular disorders</td>
<td></td>
</tr>
<tr>
<td>Intra-abdominal haematoma</td>
<td>20</td>
</tr>
<tr>
<td><strong>MedDRA Version 18.1</strong></td>
<td></td>
</tr>
<tr>
<td>Vascular disorders</td>
<td>0</td>
</tr>
<tr>
<td>Gastrointestinal disorders</td>
<td></td>
</tr>
<tr>
<td>Intra-abdominal haematoma</td>
<td>20</td>
</tr>
</tbody>
</table>
Overview by Primary SOC

• Use Internationally Agreed Order of SOCs when applicable, e.g., the EU SPC guideline
  – See MedDRA Introductory Guide, ASCII files
• Consider use of HLTs and HLGTs
• Line listings, tables, graphs
• Benefits - Broad overview, PTs displayed only once
• Limitations - Incomplete groupings due to SOC allocation rules, lengthy output
Primary SOC Graphical Display Example

- **Ear**: 1.9%
- **Eye**: 1.3%
- **Gastr**: 13.2%
- **Genit**: 3.7%
- **Immun**: 0.3%
- **Infec**: 12.8%
- **Inj&P**: 1.5%
- **Inv**: 3.0%
- **Metab**: 1.5%
- **Musc**: 1.9%
- **Nerv**: 10.7%
- **Preg**: 0.3%
- **Psych**: 0.6%
- **Repro**: 1.5%
- **Resp**: 8.8%
- **Skin**: 3.0%
- **Surg**: 0.9%

Relative frequency of any event (%)
What is a Query?

Clinical Trial Database
Safety Database

Query

Case
LLT1
LLT2
LLT3

SMQ
PT
LLT
LLT
LLT 1
PT
LLT
LLT
LLT

"Hit"
Query Strategy Tips

- Define the condition
- Develop inclusion/exclusion criteria
- Good browser is key component
- Search “non multi-axial” and “other/support” SOCs
- Search a term’s “neighbors”, including secondary locations
- Use grouping terms where applicable
- Avoid using LLTs (Exception: species information at LLT level in SOC Infections and infestations)
- Store for future use
- Review for impact of new MedDRA versions
Complete the Circle (Connect the DOTSSS!)

- Diagnosis/disease terms
- Operations (Surgical and medical procedures)
- Tests (Investigations)
- Support SOCs (Other...)
- Signs & symptoms
- Social circumstances
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 Applications

• 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 Benefits and Limitations

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

• Limitations
  – Do not cover all medical topics or safety issues
  – Will evolve and undergo further refinement even though they have been tested during development
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
• SMQs are constructed at MedDRA PT level
• LLTs that are subordinate to an included PT are also included
It is recommended that organizations use the SMQs with data coded with the same version of MedDRA

- Match the MedDRA version of the SMQ with the MedDRA version of the coded data
- Mismatches of SMQ and MedDRA coded data could produce unexpected results
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
**Narrow vs. Broad Example**

**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 verbatims to terms of an older 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
• **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/ Urticaria, 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.
Hierarchical SMQ Example

- Haematopoietic cytopenias
  - Haematopoietic erythropenia
  - Haematopoietic leukopenia
  - Haematopoietic thrombocytopenia
IT Considerations

• Software tools support the use of MedDRA
  – Several are free with MedDRA subscription
    • Two browsers (Desktop and Web-Based)
    • MedDRA Version Analysis Tool (MVAT)
  – Software tools need driven by the volume of data
    • With small amounts, users can use simple software tools (e.g., free MSSO browsers, spreadsheets)
    • Larger implementations may need commercial data management products
    • List of third-party software tools on MedDRA website
MedDRA Training Opportunities – Available for Users

• Free Face-to-Face (F2F) training
  – Coding with MedDRA
  – Safety Data Analysis and Standardised MedDRA Queries
  – Getting Started with MedDRA

• Free webinars
  – Getting Started with MedDRA
  – MedDRA Overview
  – MedDRA Coding Basics
  – Advanced MedDRA Coding
  – Data Analysis and Query Building with MedDRA
  – Standardised MedDRA Queries
  – What’s New with MedDRA (with each MedDRA release)
Registration for Training

MedDRA - Medical Dictionary for Regulatory Activities

Schedule / Training /

The description, training materials and online registration form for each training event are available from the schedule below by clicking on the convenient event.

Note: Face-to-Face classes are posted under the Face-to-Face training tab. Webinars are posted under the Webinars tab.

MSSO Cancellation Policies:

Courses: The MSSO reserves the right to cancel any scheduled training event. The MSSO is not responsible for expenditures made for travel arrangements. It is recommended that travel arrangements not be made prior to two weeks before the scheduled event.

Registration: If an individual's cancellation notification is not received in advance, the MSSO will consider revising an individual's access to future face training sessions.

For comprehensive training in MedDRA application in coding and analysis, we recommend users attend both the Coding with MedDRA and MedDRA Safety Data Analysis and SMQs courses.

Waiting List Status for MedDRA Training Events:

If you register for a MedDRA training course and are placed on the waiting list for that course, you will be contacted if space becomes available. If space is not available, your registration will not roll over to a future course. You must re-register for each subsequent course.

Training Certificates:

Attendees of the face-to-face training sessions receive a certificate of course completion. This certificate can be downloaded and printed from the MedDRA Self-Service Application. Certificates are not provided for participation in MedDRA training webinars.

MedDRA Training

Click Here for Face to Face Training
Click Here for Webinars

May 22, 2019
Face-to-Face Training - Coding with MedDRA
Sunnyvale, California, USA

May 23, 2019
Face-to-Face Training - MedDRA Safety Data Analysis and SMQs
Sunnyvale, California, USA

May 28, 2019
Face-to-Face Training - Coding with MedDRA
Chaozhou District, Shenzhen, China

May 29, 2019
Face-to-Face Training - Coding with MedDRA
Chaozhou District, Shenzhen, China

Training Statistics for 2018:
71 face-to-face classes attended by 2,753 attendees from 10 countries.
29 webinars with 2,584 connections from 57 countries.

Help Yourself:
Get answers to some of your immediate questions via the MedDRA Self-Service Application

User Comments on MedDRA Training:

"I thoroughly enjoyed the coding course and having both lectures and hands-on exercises was a fantastic way to learn." - [Comment]

"A really informative course, presented in an accessible and cogent way. I would highly recommend both the course and the instructor." - [Comment]
Training Scheduled in Moscow

September 24th 2019 - Coding with MedDRA
September 25th 2019 - MedDRA Data Analysis and SMQs

Marco Polo Presnja Hotel
Spiridonyevsky Pereulok 9
Presnensky
123104 Moscow
Russia

Марко Поло Пресня Отель
Спиридоньевский переулок 9
Пресненский, Москва, Россия
MedDRA Training Opportunities – Available to All

- Free resources on MedDRA website
  - Slides for all F2F courses and webinars
  - Short videocasts on MedDRA-related topics
    - Available in several languages
    - Can be downloaded or viewed directly on website
    - Help trainees prepare for F2F courses
- Webinars and videocasts available on new MedDRA MSSO YouTube Channel
More Resources for MedDRA Users

- MedDRA website
  - Help Desk
  - Subscriptions
  - News and Events
  - MedDRA Best Practices document
  - Points to Consider documents
  - Terminology downloads
  - Training
  - Tools
  - MedDRA publications
  - User group meetings
  - Expert meetings
MSSO Contacts

• Website
  – www.meddra.org

• Email
  – mssohelp@meddra.org

• Frequently Asked Questions
  – www.meddra.org/faq