Data Analysis and Query Building with MedDRA

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).
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Course Overview

- Discuss topics in the MedDRA Data Retrieval and Presentation: Points to Consider document
- Discuss applications of MedDRA in data retrieval, presentation, and analysis
- Discuss and demonstrate the use of MedDRA for developing queries
- Conclude with a question and answer session
- Appendix - MedDRA's scope, structure, and characteristics
MedDRA Data Retrieval and Presentation: Points to Consider Document

ICH M1 Points to Consider Working Group (PtC WG)

- Regulators and industry from EU, US, and Japan
- Health Canada, Canada
- MFDS, Republic of Korea
- ANVISA, Brazil
- NMPA, China
- MSSO
- JMO
- WHO (Observer)

November 2017, Geneva, Switzerland
<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 &quot;living&quot; 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>

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**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
Quality of Source Data

• High quality data output is dependent on maintaining quality of original information reported by using consistent and appropriate term selection (Refer to MedDRA Term Selection: Points to Consider document)

• Method of conversion of data into MedDRA might impact retrieval and presentation - legacy data conversion using verbatims or coded terms

Documentation of Data Retrieval and Presentation Practices

• Organisation-specific guidelines
  – Consistent with Points to Consider documents
  – Coding conventions
  – Data retrieval and output strategies (including SMQs)
  – Quality assurance procedures
  – MedDRA version used for search
  – Search strategy methods
  – Version update processes
  – Processes for customised MedDRA queries
Do Not Alter MedDRA

• 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

Impact of MedDRA’s Characteristics
– Grouping Terms

• HLGTs and HLTs provide clinically relevant groupings
  – HLGТ Cardiac arrhythmias
    • HLT Cardiac conduction disorders
    • HLT Rate and rhythm disorders NEC
    • HLT Supraventricular arrhythmias
    • HLT Ventricular arrhythmias and cardiac arrest
Impact of MedDRA’s Characteristics – 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

Multi-Axiality

• Primary SOC allocation rules affect the way data are distributed across the terminology
• Impact on frequencies of medical condition of interest should be considered
• Example: for hepatic abnormality search in SOC Hepatobiliary disorders, SOC Investigations (laboratory test terms), SOC Surgical and medical procedures (e.g., PT Liver transplant)
Multi-Axiality (cont)

- Main presentation is by Primary SOC
- Secondary SOCs used for alternate views and presentation of data

Which Level? – SOC Investigations

<table>
<thead>
<tr>
<th>Adverse Event (MedDRA v18.0)</th>
<th>25 mg MyDrug (N=44)</th>
<th>Placebo (N=15)</th>
</tr>
</thead>
<tbody>
<tr>
<td>SOC Investigations</td>
<td>13 (29.5%)</td>
<td>2 (13.3%)</td>
</tr>
<tr>
<td>PT Aspartate aminotransferase increased</td>
<td>6</td>
<td>0</td>
</tr>
<tr>
<td>PT Alanine aminotransferase increased</td>
<td>5</td>
<td>0</td>
</tr>
<tr>
<td>PT Gamma-glutamyltransferase increased</td>
<td>4</td>
<td>0</td>
</tr>
<tr>
<td>PT Blood creatine phosphokinase increased</td>
<td>2</td>
<td>1</td>
</tr>
<tr>
<td>PT Blood alkaline phosphatase increased</td>
<td>2</td>
<td>0</td>
</tr>
<tr>
<td>PT Blood glucose increased</td>
<td>1</td>
<td>1</td>
</tr>
<tr>
<td>PT Blood lactate dehydrogenase increased</td>
<td>2</td>
<td>0</td>
</tr>
<tr>
<td>PT Lipase increased</td>
<td>2</td>
<td>0</td>
</tr>
<tr>
<td>PT White blood cell count decreased</td>
<td>2</td>
<td>0</td>
</tr>
<tr>
<td>PT Amylase increased</td>
<td>1</td>
<td>0</td>
</tr>
<tr>
<td>PT Faecal fat increased</td>
<td>0</td>
<td>1</td>
</tr>
</tbody>
</table>

Patients may have more than one event reported.
### SOC Investigations (cont)

#### Adverse Event (MedDRA v18.0)

<table>
<thead>
<tr>
<th>Adverse Event</th>
<th>25 mg MyDrug (N=44)</th>
<th>Placebo (N=15)</th>
</tr>
</thead>
<tbody>
<tr>
<td>SOC Investigations</td>
<td>13 (29.5%)</td>
<td>2 (13.3%)</td>
</tr>
<tr>
<td>PT Blood pressure increased</td>
<td>1</td>
<td>0</td>
</tr>
<tr>
<td>PT Blood urea increased</td>
<td>1</td>
<td>0</td>
</tr>
<tr>
<td>PT Occult blood positive</td>
<td>1</td>
<td>0</td>
</tr>
<tr>
<td>PT Liver function test abnormal</td>
<td>1</td>
<td>0</td>
</tr>
<tr>
<td>PT Monocyte count decreased</td>
<td>1</td>
<td>0</td>
</tr>
<tr>
<td>PT Protein urine present</td>
<td>1</td>
<td>0</td>
</tr>
</tbody>
</table>

Patients may have more than one event reported

#### SOC Investigations (cont)

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

Patients may have more than one event reported
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

MedDRA Versioning (cont): Effect of PT Demotion

<table>
<thead>
<tr>
<th>MedDRA Version 18.1</th>
<th>Number of Events at PT Level</th>
</tr>
</thead>
<tbody>
<tr>
<td>Metastatic pain (PT)</td>
<td>15</td>
</tr>
<tr>
<td>Cancer pain</td>
<td>5</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>MedDRA Version 19.0</th>
<th>Number of Events at PT Level</th>
</tr>
</thead>
<tbody>
<tr>
<td>Metastatic pain (no longer a PT)</td>
<td>0</td>
</tr>
<tr>
<td>Cancer pain</td>
<td>20</td>
</tr>
</tbody>
</table>
MedDRA Versioning (cont): Effect of Primary SOC Change

<table>
<thead>
<tr>
<th>SOC Vascular disorders</th>
<th>Number of Events</th>
</tr>
</thead>
<tbody>
<tr>
<td>PT Intra-abdominal haematoma</td>
<td>20</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>SOC Gastrointestinal disorders</th>
<th>Number of Events</th>
</tr>
</thead>
<tbody>
<tr>
<td>PT Intra-abdominal haematoma</td>
<td>20</td>
</tr>
</tbody>
</table>

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
Use of MedDRA in Data Retrieval, Presentation and Analysis

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**

SOC

Ear
Eye
Gastro
Gastroint
Immun
Infect
Inj&I
e
Inv
Metab
Mus
e
Nerv
Preg
Psych
Repro
Resp
Skin
Surg

0 5 10 15
Relative frequency of any event (%)

**Primary SOC Output Listing Example**

SOC Nervous system disorders

HLGT Mental impairment disorders

HLT Mental impairment (excl dementia and memory loss) 1
PT Disturbance in attention

HLGT Movement disorders (incl Parkinsonism)

HLT Dyskinesias and movement disorders NEC 2
PT Psychomotor hyperactivity

HLT Tremor (excl congenital) 3
PT Tremor

HLGT Neurological disorders NEC

HLT Disturbances in consciousness NEC 1
PT Somnolence

HLT Neurological signs and symptoms NEC
PT Dizziness 1
Focused Searches

Useful when further investigating concepts of interest

• Secondary SOC assignments
  – Programming required if database does not allow automated output by secondary SOC
  – Benefits - more comprehensive view of medically related events
  – Limitations - display by primary and secondary SOC could lead to double counting

• Grouping terms (HLGT/HLT)

• SMQ

• Customized search
  – Modified SMQ
  – Ad hoc query

How Many Cases of Autoimmune Diseases?

<table>
<thead>
<tr>
<th>Adverse Event (MedDRA v22.0)</th>
<th>No. of cases</th>
</tr>
</thead>
<tbody>
<tr>
<td>SOC Blood and lymphatic system disorders</td>
<td></td>
</tr>
<tr>
<td>PT Anaemia</td>
<td>5</td>
</tr>
<tr>
<td>PT Autoimmune neutropenia</td>
<td>5</td>
</tr>
<tr>
<td>PT Evans syndrome</td>
<td>1</td>
</tr>
<tr>
<td>PT Platelet anisocytosis</td>
<td>1</td>
</tr>
<tr>
<td>PT Platelet toxicity</td>
<td>2</td>
</tr>
<tr>
<td>SOC Cardiac disorders</td>
<td></td>
</tr>
<tr>
<td>PT Autoimmune myocarditis</td>
<td>4</td>
</tr>
<tr>
<td>PT Myocardial infarction</td>
<td>1</td>
</tr>
<tr>
<td>PT Myocarditis</td>
<td>2</td>
</tr>
</tbody>
</table>
### How Many Cases of Autoimmune Diseases? (cont)

<table>
<thead>
<tr>
<th>Adverse Event (MedDRA v22.0)</th>
<th>No. of cases</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>SOC Endocrine disorders</strong></td>
<td></td>
</tr>
<tr>
<td>PT Polyglandular autoimmune syndrome type I</td>
<td>2</td>
</tr>
<tr>
<td>PT Thyroid disorder</td>
<td>1</td>
</tr>
<tr>
<td><strong>SOC Eye disorders</strong></td>
<td></td>
</tr>
<tr>
<td>PT Birdshot chorioretinopathy</td>
<td>2</td>
</tr>
<tr>
<td>PT Autoimmune uveitis</td>
<td>3</td>
</tr>
<tr>
<td><strong>SOC Hepatobiliary disorders</strong></td>
<td></td>
</tr>
<tr>
<td>PT Primary biliary cholangitis</td>
<td>3</td>
</tr>
<tr>
<td>PT Hepatitis toxic</td>
<td>1</td>
</tr>
<tr>
<td>PT Hepatocellular injury</td>
<td>1</td>
</tr>
<tr>
<td><strong>SOC Immune system disorders</strong></td>
<td></td>
</tr>
<tr>
<td>PT Autoimmune disorder</td>
<td>4</td>
</tr>
<tr>
<td><strong>SOC Musculoskeletal and connective tissue disorders</strong></td>
<td></td>
</tr>
<tr>
<td>PT Arthritis</td>
<td>1</td>
</tr>
<tr>
<td>PT Muscular weakness</td>
<td>2</td>
</tr>
<tr>
<td>PT Polymyalgia rheumatica</td>
<td>1</td>
</tr>
<tr>
<td>PT Rheumatoid arthritis</td>
<td>3</td>
</tr>
<tr>
<td><strong>SOC Skin and subcutaneous tissue disorders</strong></td>
<td></td>
</tr>
<tr>
<td>PT Alopecia</td>
<td>1</td>
</tr>
<tr>
<td>PT Skin haemorrhage</td>
<td>1</td>
</tr>
<tr>
<td>PT Vitiligo</td>
<td>2</td>
</tr>
</tbody>
</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 Desktop Browser (MDB) and Web-Based Browser (WBB) Update

- **New functionality for users**
  - Preview upcoming (supplemental) changes in next release*
  - View primary and secondary link information
  - Upload terms to run against SMQs
  - Advanced search options (e.g., NOT, OR)

*Supplemental view not available on MDB*
In my dataset, which terms are autoimmune disorders?

My system only shows the primary SOC hierarchy. How do I view secondary SOC links for a set of terms?

Option 1: Export search results
- Example: search for “headache”
- Export with primary and secondary SOC hierarchies (default setting)
• Option 2: Use the Research Bin
  – Add terms to Research Bin
  – Export with primary and secondary SOC hierarchies

• Option 3: Hierarchy Analysis feature
  – Upload terms in spreadsheet
  – Export with primary and secondary SOC hierarchies
  – No need for programming
Secondary SOC Analysis Example (cont)

- Output sorted by secondary SOCs – there are 10 autoimmune disorders

<table>
<thead>
<tr>
<th>HLGT Autoimmune disorders</th>
<th>SOCImmune system disorders</th>
<th>No. of cases</th>
</tr>
</thead>
<tbody>
<tr>
<td>PT Autoimmune disorder</td>
<td>Autoimmune disorder</td>
<td>4</td>
</tr>
<tr>
<td>PT Autoimmune myocarditis</td>
<td>Autoimmune myocarditis</td>
<td>4</td>
</tr>
<tr>
<td>PT Autoimmune neutropenia</td>
<td>Autoimmune neutropenia</td>
<td>5</td>
</tr>
<tr>
<td>PT Primary biliary cholangitis</td>
<td>Primary biliary cholangitis</td>
<td>3</td>
</tr>
<tr>
<td>PT Birdshot chorioretinopathy</td>
<td>Birdshot chorioretinopathy</td>
<td>2</td>
</tr>
<tr>
<td>PT Evans syndrome</td>
<td>Evans syndrome</td>
<td>1</td>
</tr>
<tr>
<td>PT Polyglandular autoimmune syndrome type I</td>
<td>Polyglandular autoimmune syndrome type I</td>
<td>2</td>
</tr>
<tr>
<td>PT Polymyalgia rheumatica</td>
<td>Polymyalgia rheumatica</td>
<td>1</td>
</tr>
<tr>
<td>PT Rheumatoid arthritis</td>
<td>Rheumatoid arthritis</td>
<td>3</td>
</tr>
<tr>
<td>PT Autoimmune uveitis</td>
<td>Autoimmune uveitis</td>
<td>3</td>
</tr>
<tr>
<td>PT Vitiligo</td>
<td>Vitiligo</td>
<td>2</td>
</tr>
</tbody>
</table>

Adverse Event (MedDRA v22.0)

<table>
<thead>
<tr>
<th>SOC Immune system disorders</th>
<th>No. of cases</th>
</tr>
</thead>
<tbody>
<tr>
<td>HLGT Autoimmune disorders</td>
<td>30</td>
</tr>
<tr>
<td>PT Autoimmune disorder</td>
<td>4</td>
</tr>
<tr>
<td>PT Autoimmune myocarditis</td>
<td>4</td>
</tr>
<tr>
<td>PT Autoimmune neutropenia</td>
<td>5</td>
</tr>
<tr>
<td>PT Primary biliary cholangitis</td>
<td>3</td>
</tr>
<tr>
<td>PT Birdshot chorioretinopathy</td>
<td>2</td>
</tr>
<tr>
<td>PT Evans syndrome</td>
<td>1</td>
</tr>
<tr>
<td>PT Polyglandular autoimmune syndrome type I</td>
<td>2</td>
</tr>
<tr>
<td>PT Polymyalgia rheumatica</td>
<td>1</td>
</tr>
<tr>
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<td>3</td>
</tr>
<tr>
<td>PT Autoimmune uveitis</td>
<td>3</td>
</tr>
<tr>
<td>PT Vitiligo</td>
<td>2</td>
</tr>
</tbody>
</table>
Developing Queries Using MedDRA

What is a Query?

Clinical Trial Database
Safety Database

Query

Case
LLT1
LLT2
LLT3

"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

Example – Cardiac Arrhythmias

• Obvious starting point – HLGT *Cardiac arrhythmias* (“Top-down” search)
• Also use “Arrhythmia” terms as starting point of “Bottom-up” search
• What about non-multi-axial SOCs?
• **SOC Investigations**
  – PTs subordinate to HLT *ECG investigations* and HLT *Heart rate and pulse investigations* should be reviewed
    • Example: PT *Heart rate irregular*

• **SOC Surgical and medical procedures**
  Important to review:
  – PTs subordinate to HLT *Cardiac device therapeutic procedures* *
    • Example: PT *Implantable defibrillator insertion*
  – PTs subordinate to HLT *Cardiac therapeutic procedures NEC* *
    • Example: PT *Cardioversion*

*Note: Pacemaker and other cardiac therapeutic procedure terms were not included in SMQ *Cardiac arrhythmias*
Example – Cardiac Arrhythmias (cont)

• Because arrhythmias may produce various signs and symptoms, you may wish to review PTs subordinate to the following HLTs:
  – HLT *Disturbances in consciousness NEC*
  – HLT *Neurological signs and symptoms NEC*
  – HLT *Cardiac disorders NEC*
  – HLT *Cardiac signs and symptoms NEC*
  – HLT *Dyspnoeas*

• Lastly...
  – PTs subordinate to HLT *Death and sudden death* (under SOC *General disorders and administration site conditions*) should be reviewed
    • Example: PT *Cardiac death*
# Cardiac Arrhythmias – Identifying Cases

<table>
<thead>
<tr>
<th>Patient ID</th>
<th>Patient Events (PTs)</th>
<th>Primary SOC</th>
<th>Case of interest?</th>
</tr>
</thead>
<tbody>
<tr>
<td>01</td>
<td>Nausea, Vomiting</td>
<td></td>
<td>Unlikely</td>
</tr>
<tr>
<td>02</td>
<td>Sudden death</td>
<td>General disorders and administration site conditions</td>
<td>Potential case. Needs review.</td>
</tr>
<tr>
<td>03</td>
<td>Electrocardiogram abnormal, Dyspnoea, Cardiorespiratory arrest</td>
<td>Investigations, Respiratory, thoracic and mediastinal disorders</td>
<td>Cardiac disorders</td>
</tr>
<tr>
<td>04</td>
<td>Breast cancer, Postmenopause</td>
<td></td>
<td>Unlikely</td>
</tr>
<tr>
<td>05</td>
<td>Syncope, Palpitations</td>
<td>Nervous system disorders, Cardiac disorders</td>
<td></td>
</tr>
<tr>
<td>06</td>
<td>Pacemaker generated arrhythmia</td>
<td>General disorders and administration site conditions</td>
<td></td>
</tr>
<tr>
<td>07</td>
<td>Atrial fibrillation, Cardioversion</td>
<td>Cardiac disorders, Surgical and medical procedures</td>
<td></td>
</tr>
<tr>
<td>09</td>
<td>Cerebrovascular accident, Prostate cancer</td>
<td></td>
<td>Unlikely</td>
</tr>
<tr>
<td>10</td>
<td>Cardiac assistance device user</td>
<td>Social circumstances</td>
<td></td>
</tr>
</tbody>
</table>

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# Search Demonstration

**Topic: Cardiac failure**

- Build a query with a set of PTs relevant to this condition
- **Consider:**
  - Diagnosis terms
  - Signs and symptoms
  - Investigations
  - Surgical and medical procedures
  - Other...
- Can you identify cases of interest in a dataset?
Developing Queries – Lessons Learned

- MedDRA is a potentially powerful tool for data retrieval, BUT it requires:
  - Solid medical knowledge
  - Solid MedDRA knowledge
- Size and complexity of MedDRA overcome lack of specificity of other terminologies, but may require a more “creative” approach to data retrieval
- WELL WORTH THE EFFORT to develop, share, and store in-house queries

Summary

In this course, we:

- Discussed topics in the MedDRA Data Retrieval and Presentation Points to Consider document
- Discussed applications of MedDRA in data retrieval, presentation, and analysis
- Discussed and demonstrated the use of MedDRA for developing queries
MSSO Contacts

• Website
  – www.meddra.org
• Email
  – mssohelp@meddra.org
• Frequently Asked Questions
  – www.meddra.org/faq

Question and Answer Session
Appendix – MedDRA’s Scope, Structure, and Characteristics/Browsers

MedDRA Definition

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

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

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)
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

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

Primary SOC Priority

If a PT links to more than one of the exceptions, the following priority will be used to determine primary SOC:

1\(^{st}\): **Congenital, familial and genetic disorders**
2\(^{nd}\): **Neoplasms benign, malignant and unspecified (incl cysts and polyps)**
3\(^{rd}\): **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*