# Creating Customized MedDRA® Queries

**Workshop**

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## Learning Objectives

- Understand how the features of MedDRA affect safety data retrieval
- Learn about the principles of constructing MedDRA-based queries to retrieve data relevant to safety issues or medical conditions

## Workshop Overview

- MedDRA refresher
- "MedDRA Data Retrieval and Presentation: Points to Consider" document
- Principles of creating queries
- Practical examples of building queries
- Modified MedDRA query based on an SMQ
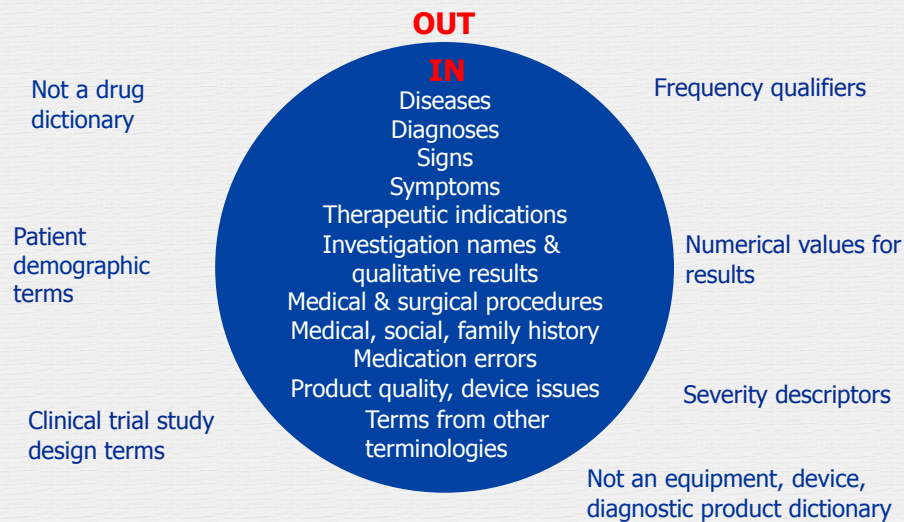- Create your own queries
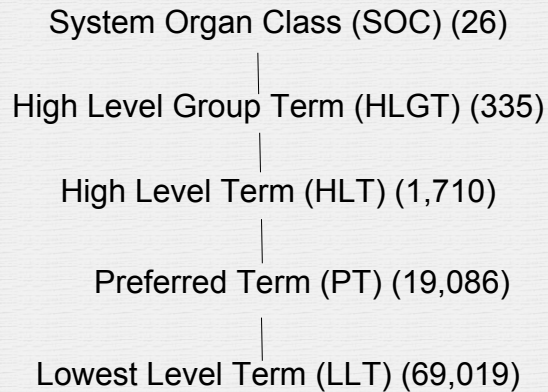
## MedDRA Definition

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.

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## Scope of MedDRA

**OUT**

**IN**

Not a drug dictionary

Patient demographic terms

Clinical trial study design terms

Diseases
Diagnoses
Signs
Symptoms
Therapeutic indications
Investigation names & qualitative results
Medical & surgical procedures
Medical, social, family history
Medication errors
Product quality, device issues
Terms from other terminologies

Frequency qualifiers

Numerical values for results

Severity descriptors

Not an equipment, device, diagnostic product dictionary

# MedDRA Structure

System Organ Class (SOC) (26)

High Level Group Term (HLGT) (335)

High Level Term (HLT) (1,710)

Preferred Term (PT) (19,086)

Lowest Level Term (LLT) (69,019)

MedDRA Version 14.0

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# System Organ Classes

- Blood and lymphatic system disorders
- Cardiac disorders
- Congenital, familial and genetic disorders
- Ear and labyrinth disorders
- Endocrine disorders
- Eye disorders
- Gastrointestinal disorders
- General disorders and administration site conditions
- Hepatobiliary disorders
- Immune system disorders
- Infections and infestations
- Injury, poisoning and procedural complications
- Investigations
- Metabolism and nutrition disorders

- Musculoskeletal and connective tissue disorders
- Neoplasms benign, malignant and unspecified (incl cysts and polyps)
- Nervous system disorders
- Pregnancy, puerperium and perinatal conditions
- Psychiatric disorders
- Renal and urinary disorders
- Reproductive system and breast disorders
- Respiratory, thoracic and mediastinal disorders
- Skin and subcutaneous tissue disorders
- Social circumstances
- Surgical and medical procedures
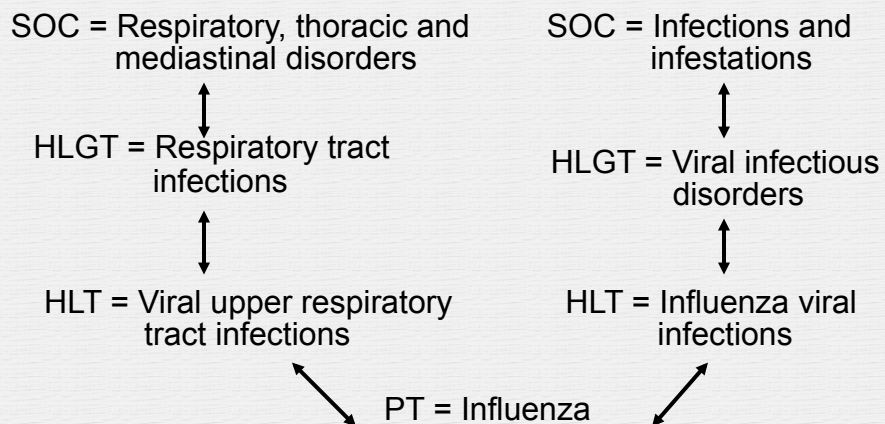- Vascular disorders

## 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
- Purpose of Primary SOC
  - Determines which SOC will represent a PT during cumulative data outputs
  - Is used to support consistent data presentation for reporting to regulators

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## A Multi-Axial Terminology (cont)

SOC = Respiratory, thoracic and mediastinal disorders

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HLGT = Respiratory tract infections

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HLT = Viral upper respiratory tract infections

SOC = Infections and infestations

↕

HLGT = Viral infectious disorders

↕

HLT = Influenza viral infections

PT = Influenza

# A Multi-Axial Terminology (cont)

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

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

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# Rules for Primary SOC Allocation

- 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*

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## No One-Stop Shopping



Vs.

# MedDRA Desktop Browser Demonstration

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# MedDRA Data Retrieval and Presentation: Points to Consider

- An ICH-Endorsed Guide for MedDRA users on Data Output
- Developed by an ICH Expert Working Group
- Provides data retrieval and presentation options for industry or regulatory purposes
- Objective is to promote understanding of implications that various options for data retrieval have on accuracy and consistency of final output
- Current version available on MedDRA MSSO Web site (http://www.meddramsso.com/subscriber_library_ptc.asp)

## Data Retrieval PTC
## Points Addressed

- General Principles
  - Quality of Source Data
  - Documentation of Data Retrieval and Presentation Practices
  - Do Not Alter MedDRA
  - Organization-Specific Data Characteristics
  - Characteristics of MedDRA that Impact Data Retrieval and Analysis
  - MedDRA Versioning
- General Queries and Retrieval
- Standardised MedDRA Queries
- Customized Searches
  - Modified MedDRA Query Based on an SMQ
  - Customized Queries

## Standardised MedDRA Queries (SMQs)

- Result of cooperative effort between CIOMS and ICH (MSSO)
- Groupings of terms from one or more MedDRA System Organ Classes (SOCs) related to defined medical condition or area of interest
- Included terms may relate to signs, symptoms, diagnoses, syndromes, physical findings, laboratory and other physiologic test data, etc., related to medical condition or area of interest
- Intended to aid in case identification

# SMQs in Production - Examples

- As of Version 14.0, a total of 85 in production (One is inactive)

- Agranulocytosis
- Anaphylactic reaction
- Cerebrovascular disorders
- Convulsions
- Depression and suicide/self-injury
- Hepatic disorders
- Ischaemic heart disease
- Lack of efficacy/effect

- Peripheral neuropathy
- Pregnancy and neonatal topics
- Pseudomembranous colitis
- Rhabdomyolysis/myopathy
- Severe cutaneous adverse reactions
- Systemic lupus erythematosus

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# General Principles of Query Construction

- Define the medical condition
- Develop inclusion/exclusion criteria
  - Risk factors typically excluded
- Know your data, e.g., how specific coding conventions impact retrieval strategy
- Good browser is key component
  - Flexible search capabilities
  - Ability to view secondary SOC assignments

## Query Strategy Tips

1. ALWAYS search the "non-multi-axial" SOCs

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

## Query Strategy Tips (cont)

2. Consider looking at the following SOCs

   - *General disorders and administration site conditions*
   - *Congenital, familial and genetic disorders*
   - Remaining "Other/Support" SOCs as needed

## Query Strategy Tips (cont)

3. Take your time and do a broad, inclusive search. If you find a term you like, go up and down the hierarchy and consider the term's "neighbors," including the term's multi-axial linkages. ("Top-down" and "Bottom-up" searches).

## Query Strategy Tips (cont)

4. Use the "grouping terms" in the hierarchy (HLGTs, HLTs) when applicable. If all PTs in an HLT are pertinent except for one, use the HLT and "exclude" that particular PT.

## Query Strategy Tips (cont)

5. Avoid the use of LLTs in queries. These terms were designed to be the "entry-level" into the terminology and NOT designed for useful data retrieval

NOTE: SOC *Infections and infestations* is an exception to this tip: specific species information is found at the LLT level

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## Query Strategy Tips (cont)

6. When you think you're done, you're NOT – always recheck your work…
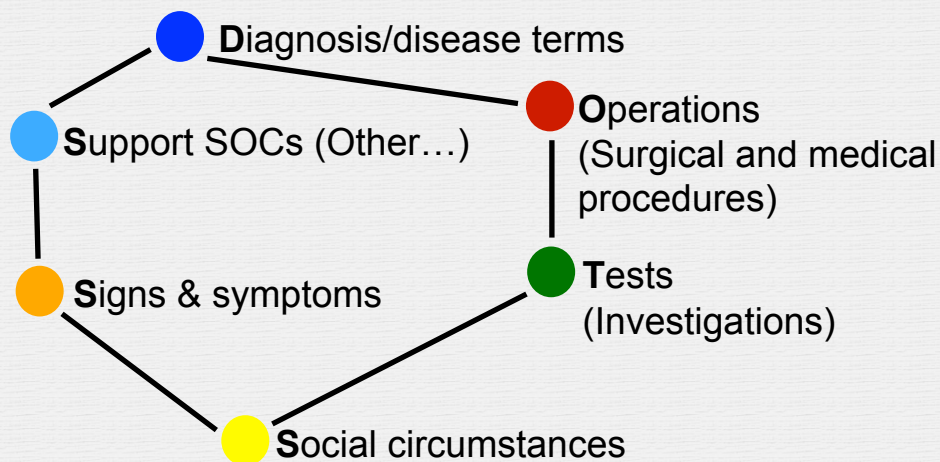
## Additional Points About Query Development

- Need medical knowledge and MedDRA knowledge
- Maintenance for MedDRA version changes, e.g., PT demotions, LLT currency changes, etc.
- A thorough, well-constructed query takes time, but it is well worth the effort
- Recycle, share, and store!
- Consider submitting to MSSO as a Change Request for possible SMQ development

## Connect the DOTSSS!

**D**iagnosis/disease terms

**O**perations (Surgical and medical procedures)

**S**upport SOCs (Other…)

**T**ests (Investigations)

**S**igns & symptoms

**S**ocial circumstances

# Query Building Example

- Identify relevant PTs for chronic renal failure
- Consider:
  - **D**iagnosis/disease terms (Obvious starting place? Top down, bottom up)
  - **O**perations (Surgical and medical procedures)
  - **T**ests (Investigations)
  - **S**igns and symptoms
  - **S**upport SOCs (Other…)
  - **S**ocial circumstances

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# Cardiac Failure Query Exercise

- Build a query with a set of PTs relevant to this condition
- Can you identify cases of interest in a dataset?

# Customized Searches – Modified SMQs

- Do not modify SMQ unless there is a compelling reason – makes it non-standard
- "**Modified MedDRA query based on an SMQ**"
  - To be used to refer to an SMQ that has been modified
  - All modifications must be documented
  - Version updates and maintenance are responsibility of organization that created it

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# Modifying an SMQ - Exercise

- SMQ *Lack of efficacy/effect* often needs to be modified based on the particular characteristics of a product
- Consider how you would create a Modified MedDRA Query based on SMQ *Lack of efficacy/effect* for:
  - An inhaled bronchodilator indicated for use in asthma
- Remember to document changes!

## Create Your Own Queries

- Suggestions for topics?

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## Summary

In this workshop we:
- Learned how the characteristics of MedDRA affect data retrieval
- Were introduced to the "MedDRA Data Retrieval and Presentation: Points to Consider" document
- Learned the principles of constructing MedDRA-based queries
- Performed practical query building exercises
- Constructed queries based on our own topics of interest