



Standardised MedDRA Queries (SMQs)



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Course Overview

- Review the MedDRA Data Retrieval and Presentation: Points to Consider document
- Discuss and demonstrate the use of MedDRA for developing queries
- Discuss features of SMQs including:
 - Background and data characteristics
 - Analysis of a data set using SMQs
 - SMQ applications
 - SMQ browser view demonstration

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Course Overview (cont)

- Discuss the creation of customized searches
- Conclude with question and answer session
- Appendix - MedDRA's scope, structure, and characteristics

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MedDRA Data Retrieval and Presentation: Points to Consider

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ICH M1 Points to Consider Working Group (PtC WG)



November 2017, Geneva, Switzerland

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

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PtC Documents

PtC Category	PtC Document	Purpose	Languages	Release Cycle
Term Selection	MedDRA Term Selection: Points to Consider	Promote accurate and consistent coding with MedDRA	English, Japanese, and other selected languages	Updated annually with the March release of MedDRA (starting with MedDRA Version 23.0)
	MedDRA Term Selection: Points to Consider Condensed Version	Shorter version focusing on general coding principles to promote accurate and consistent use of MedDRA worldwide	All MedDRA languages (except English, Japanese, and other languages with an available translation of the full MTS:PTC document)	Update as needed
Data Retrieval and Presentation	MedDRA Data Retrieval and Presentation: Points to Consider	Demonstrate how data retrieval options impact the accuracy and consistency of data output	English, Japanese, and other selected languages	Updated annually with the March release of MedDRA (starting with MedDRA Version 23.0)
	MedDRA Data Retrieval and Presentation: Points to Consider Condensed Version	Shorter version focusing on general retrieval and analysis principles to promote accurate and consistent use of MedDRA worldwide	All MedDRA languages (except English, Japanese, and other languages with an available translation of the full DRP:PTC document)	Update as needed

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PtC Documents (cont)

PtC Category	PtC Document	Purpose	Languages	Release Cycle
General	MedDRA Points to Consider Companion Document	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. New section on product quality is being drafted.	English and Japanese	Updated as needed

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MedDRA Data Retrieval and Presentation: Points to Consider (DRP:PTC)

MedDRA® DATA RETRIEVAL AND PRESENTATION: POINTS TO CONSIDER

ICH-Endorsed Guide for MedDRA Users on Data Output

Release 3.19
Based on MedDRA Version 23.0

1 March 2020

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MedDRA® trademark is registered by ICH

- 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

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MedDRA Data Retrieval and Presentation: PTC (cont)

- Developed by a working group of the ICH Management Committee
- Updated annually in step with the March release of MedDRA (starting with MedDRA Version 23.0)
- Available on MedDRA and JMO websites
 - English, Japanese, and other selected languages
 - Word (“clean” and “redlined”), PDF, HTML formats
 - “Redlined” document identifies changes made from previous to current release of document

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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

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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

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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)

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MedDRA Version Analysis Tool (MVAT) (cont)

- User interface and report output available in all MedDRA languages
- Ability to run reports on supplemental changes
- Option to run reports on secondary SOC changes

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Developing Queries Using MedDRA

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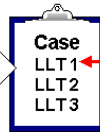
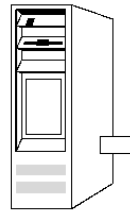
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What is a Query?

Clinical Trial Database
Safety Database



Query

SMQ
PT
LLT
LLT
LLT 1
PT
LLT
LLT
LLT

"Hit"

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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

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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

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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

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Standardised MedDRA Queries (SMQs)

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Standardised MedDRA Queries (SMQs)

- 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

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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

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SMQs in Production - Examples

- As of Version 23.0, a total of 106 level 1 SMQs in production
 - Agranulocytosis
 - Anaphylactic reaction
 - Central nervous system vascular 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

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SMQ Data Characteristics

- MedDRA term inclusion
- Broad/narrow
- Algorithms
- Hierarchy
- SMQ status/term status within an SMQ
- Term versioning in an SMQ

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MedDRA Term Inclusion

- SMQs are constructed at MedDRA PT level
- LLTs that are subordinate to an included PT are also included

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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 Search ←


Narrow Terms

Broad Terms

}

Broad Search

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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
1. Braunwald E, Fauci A, Kasper D. Harrison's Principles of Internal Medicine. 15th Edition, 2001 pp 285-9 2. Weatherall D, Ledingham J and Warrell D. Oxford Textbook of Medicine. Third edition, 1996; volume 2 pp 1541-44

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).

Narrow Terms
Blood lactic acid increased
Hyperlactacidaemia
Lactic acidosis

Broad Terms
Acid base balance abnormal
Acidosis
Anion gap abnormal
Anion gap increased
Blood alkalisation therapy
Blood bicarbonate abnormal
Blood bicarbonate decreased
Blood gases abnormal
Blood lactic acid abnormal
Blood pH abnormal
Blood pH decreased
Carbon dioxide combining power abnormal
Carbon dioxide combining power decreased
Coma acidotic
Kussmaul respiration
Metabolic acidosis
PCO2 abnormal
PCO2 decreased
Urine lactic acid increased

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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

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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)

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Algorithmic SMQ Example (cont)

Category B – Upper airway/Respiratory	Category C – Angioedema/ Urticaria, etc.	Category D – Cardiovascular/ Hypotension
Acute respiratory failure	Allergic oedema	Blood pressure decreased
Asthma	Angioedema	Blood pressure diastolic decreased
Bronchial oedema	Erythema	Blood pressure systolic decreased

- 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

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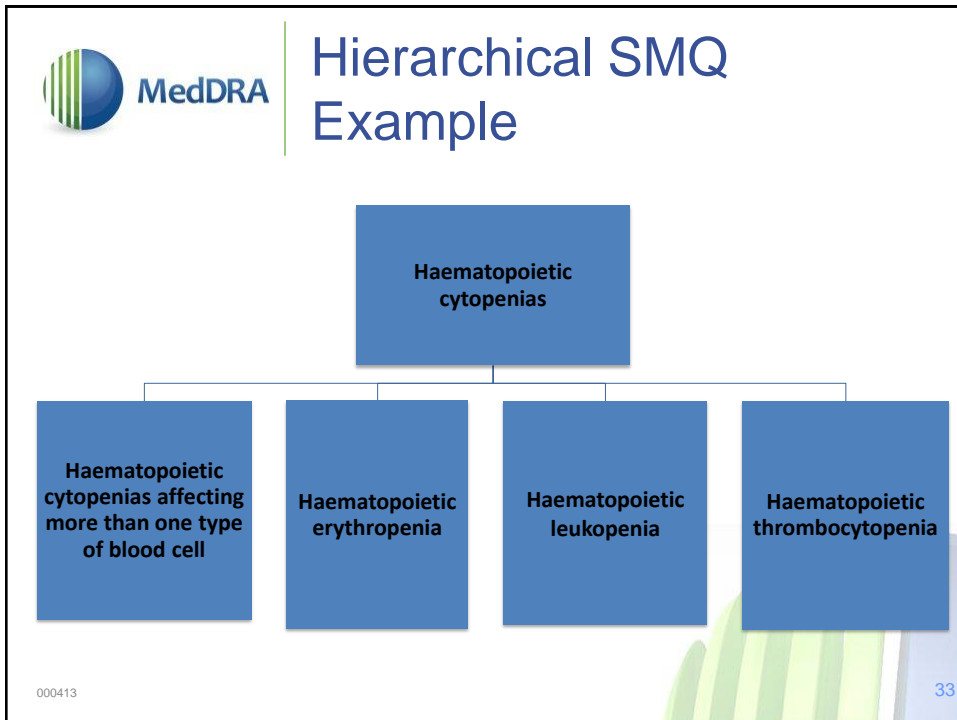
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Hierarchical SMQs

- Some SMQs may develop as 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

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SMQ Status/Term Status

- 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

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SMQ Versioning

- 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

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SMQ Versioning (cont)

- Example of PT added to SMQs in MedDRA Version 23.0:
 - PT *Hormone receptor positive breast cancer* in SMQ *Breast malignant tumours*
- Using version 22.1 SMQs which do not contain these PTs would fail to identify cases coded to these terms in a database using MedDRA Version 23.0

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Browser Demonstration SMQ View

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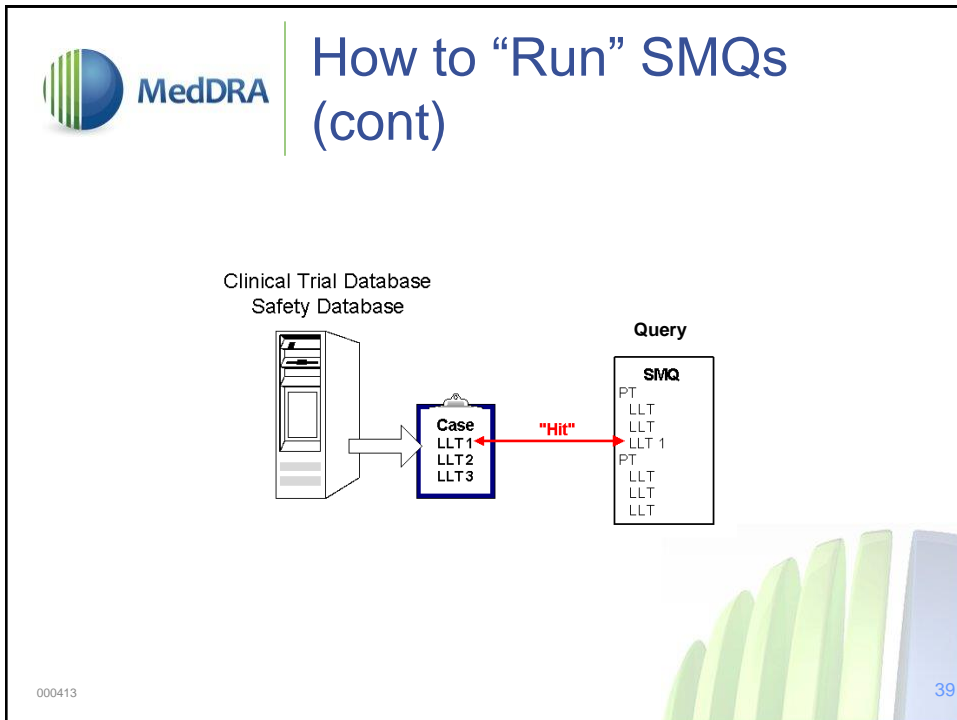


How to "Run" SMQs

- IT perspective of SMQs = stored queries
- Code at LLT level; most organizations store coded data as LLTs
- SMQ ASCII files include PTs and LLTs
- Load SMQs into a query tool; run query against coded MedDRA terms in safety or clinical trial database for "Hits"
- Use SMQ options, if applicable
 - Narrow/broad search
 - Algorithms
 - Hierarchy

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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/>
- Mobile MedDRA Browser (MMB)
 - <https://mmb.meddra.org>
- Features
 - Each 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 (MDB and WBB only)

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MDB and WBB Special Features

- 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

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Standardised MedDRA Query (SMQ) Analysis

- In my dataset, which cases are "hits" for SMQs (potential cases of interest)?

Row ID	Term	Code	Case ID
1	Amylase abnormal	10072327	1
2	Abdominal distension	10000060	1
3	Acute kidney injury	10069339	2
4	Blood creatinine increased	10005483	2
5	Status asthmaticus	10041961	3
6	Gout	10018627	4
7	Joint effusion	10023215	4
8	Major depression	10057840	5
9	Suicidal ideation	10042458	5
10	Cataract operation	10063797	6
11	Abdominal pain	10000081	7
12	Diarrhoea	10012735	7
13	Palpitations	10033557	8
14	Atrial flutter	10003662	8
15	Pancreatitis acute	10033647	9
16	Dementia Alzheimer's type	10012271	10
17	Hypertension	10020772	10
18	Anaphylactic shock	10002199	11
19	Bronchospasm	10006482	12
20	Swelling face	10042682	12
21	Rash	10037844	12
22	Hypotension	10021097	12
23	SLE arthritis	10040968	13
24	Haemolysis	10018910	14
25	Autoimmune nephritis	10077087	14
26	Double stranded DNA antibody positive	10069907	14
27	Photodermatosis	10051246	15
28	Pleural effusion	10035598	15
29	Epilepsy	10015037	15
30	Disease progression	10061818	16
31	Exercise tolerance decreased	10051301	16

Input

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SMQ Analysis (cont)

- SMQ Analysis feature
- Apply SMQs to user's MedDRA-coded data
 - Narrow/broad
 - Hierarchical
 - Algorithmic (separate search option to apply algorithm)

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Standardised MedDRA Query (SMQ) Analysis

- Run broad search on all SMQs

Row ID	Term	Code	Case ID
1	Amylase abnormal	10072327	1
2	Abdominal distension	10000060	1
3	Acute kidney injury	10069339	2
4	Blood creatinine increased	10005483	2
5	Status asthmaticus	10041961	3
6	Gout	10018627	4
7	Joint effusion	10023215	4
8	Major depression	10057840	5
9	Suicidal ideation	10042458	5
10	Cataract operation	10063797	6
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28	Pleural effusion	10035598	15
29	Epilepsy	10015037	15
30	Disease progression	10061818	16
31	Exercise tolerance decreased	10051301	16

Input

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SMQ Analysis (cont)

- Results of broad search on all SMQs
 - Includes narrow search
 - Includes hierarchical SMQs
 - Algorithmic SMQ analysis not shown

Row ID	LLT/PT Term	LLT/PT Code	PT	SMQ Matched	Scope	Category	Weight	Status	Case ID	SMQ Level 1
1	Amylase abnormal	10072327	Amylase abnormal	Acute pancreatitis (SMQ)	Broad	B	0	Active	1	Acute pancreatitis (SMQ)
2	Abdominal distension	10000060	Abdominal distension	Gastrointestinal nonspecific symptoms and therapeutic procedures (SMQ)	Broad	A	0	Active	1	Gastrointestinal nonspecific inflammation and dysfunctional conditions (SMQ)
3	Abdominal distension	10000060	Abdominal distension	Acute pancreatitis (SMQ)	Broad	C	0	Active	1	Acute pancreatitis (SMQ)
4	Acute kidney injury	10069339	Acute kidney injury	Tumour lysis syndrome (SMQ)	Broad	C	0	Active	1	Tumour lysis syndrome (SMQ)
5	Acute kidney injury	10069339	Acute kidney injury	Toxic septic shock conditions (SMQ)	Broad	A	0	Active	1	Shock (SMQ)
6	Acute kidney injury	10069339	Acute kidney injury	Torsade de pointes, shock associated conditions	Broad	A	0	Active	1	Shock (SMQ)
7	Acute kidney injury	10069339	Acute kidney injury	Shock associated (cardiac or cardiac conditions (excl torsade de pointes) (SMQ)	Broad	A	0	Active	1	Shock (SMQ)
8	Acute kidney injury	10069339	Acute kidney injury	Rhabdomyolysis/myopathy (SMQ)	Broad	A	0	Active	1	Rhabdomyolysis/myopathy (SMQ)
9	Acute kidney injury	10069339	Acute kidney injury	Hypovolaemic shock conditions (SMQ)	Broad	A	0	Active	1	Shock (SMQ)
10	Acute kidney injury	10069339	Acute kidney injury	Hypoglycaemic and neurogenic shock conditions	Broad	A	0	Active	1	Shock (SMQ)
11	Acute kidney injury	10069339	Acute kidney injury	Drug reaction with eosinophilia and systemic symptoms syndrome (SMQ)	Broad	B	0	Active	1	Drug reaction with eosinophilia and systemic symptoms syndrome (SMQ)
12	Acute kidney injury	10069339	Acute kidney injury	Dehydration (SMQ)	Broad	A	0	Active	1	Dehydration (SMQ)
13	Acute kidney injury	10069339	Acute kidney injury	Anaphylactic/anaphylactoid shock conditions (SMQ)	Broad	A	0	Active	1	Shock (SMQ)
14	Acute kidney injury	10069339	Acute kidney injury	Acute renal failure (SMQ)	Narrow	A	0	Active	1	Acute renal failure (SMQ)
15	Blood creatinine increased	10005483	Blood creatinine increased	Tumour lysis syndrome (SMQ)	Broad	C	0	Active	1	Tumour lysis syndrome (SMQ)
16	Blood creatinine increased	10005483	Blood creatinine increased	Rhabdomyolysis/myopathy (SMQ)	Broad	A	0	Active	1	Rhabdomyolysis/myopathy (SMQ)
17	Blood creatinine increased	10005483	Blood creatinine increased	Retropertoneal fibrosis (SMQ)	Broad	A	0	Active	1	Retropertoneal fibrosis (SMQ)
18	Blood creatinine increased	10005483	Blood creatinine increased	Drug reaction with eosinophilia and systemic symptoms syndrome (SMQ)	Broad	B	0	Active	1	Drug reaction with eosinophilia and systemic symptoms syndrome (SMQ)
19	Blood creatinine increased	10005483	Blood creatinine increased	Chronic kidney disease (SMQ)	Broad	A	0	Active	1	Chronic kidney disease (SMQ)
20	Blood creatinine increased	10005483	Blood creatinine increased	Acute renal failure (SMQ)	Broad	A	0	Active	1	Acute renal failure (SMQ)
21	Status asthmaticus	10041961	Status asthmaticus	Hyperaerobilia (SMQ)	Broad	A	0	Active	1	Hyperaerobilia (SMQ)
22	Status asthmaticus	10041961	Status asthmaticus	Eosinophilic pneumonia (SMQ)	Broad	C	0	Active	1	Eosinophilic pneumonia (SMQ)
23	Status asthmaticus	10041961	Status asthmaticus	Asthma/bronchospasm (SMQ)	Narrow	A	0	Active	1	Asthma/bronchospasm (SMQ)

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SMQ Analysis (cont)

- Results of algorithmic SMQ analysis

Row ID	LLT/PT Term	LLT/PT Code	PT	SMQ Matched	Scope	Category	Weight	Status	Case ID	SMQ Level 1
1	Amylase abnormal	10072327	Amylase abnormal	Acute pancreatitis (SMQ)	Broad	B	0	Active	1	Acute pancreatitis (SMQ)
2	Abdominal distension	10000060	Abdominal distension	Acute pancreatitis (SMQ)	Broad	C	0	Active	1	Acute pancreatitis (SMQ)
3	Anaphylactic shock	10002159	Anaphylactic shock	Anaphylactic reaction (SMQ)	Narrow	A	0	Active	1	Anaphylactic reaction (SMQ)
19	Bronchospasm	10006482	Bronchospasm	Anaphylactic reaction (SMQ)	Broad	B	0	Active	1	Anaphylactic reaction (SMQ)
20	Swelling face	10042682	Swelling face	Anaphylactic reaction (SMQ)	Broad	C	0	Active	1	Anaphylactic reaction (SMQ)
21	Rash	10037844	Rash	Anaphylactic reaction (SMQ)	Broad	C	0	Active	1	Anaphylactic reaction (SMQ)
22	Hypotension	10021097	Hypotension	Anaphylactic reaction (SMQ)	Broad	D	0	Active	1	Anaphylactic reaction (SMQ)
23	SLE arthritis	10040968	SLE arthritis	Systemic lupus erythematosus (SMQ)	Narrow	A	0	Active	1	Systemic lupus erythematosus (SMQ)
25	Autoimmune nephritis	10077087	Autoimmune nephritis	Systemic lupus erythematosus (SMQ)	Broad	F	1	Active	1	Systemic lupus erythematosus (SMQ)
24	Haemolysis	10018910	Haemolysis	Systemic lupus erythematosus (SMQ)	Broad	H	3	Active	1	Systemic lupus erythematosus (SMQ)
26	Double stranded DNA antibody positive	10069907	Double stranded DNA antibody positive	Systemic lupus erythematosus (SMQ)	Broad	I	3	Active	1	Systemic lupus erythematosus (SMQ)
29	Epilepsy	10015037	Epilepsy	Generalised convulsive seizures following immunisation (SMQ)	Narrow	A	0	Active	1	Generalised convulsive seizures following immunisation (SMQ)
15	Pancreatitis acute	10033647	Pancreatitis acute	Acute pancreatitis (SMQ)	Narrow	A	0	Active	9	Acute pancreatitis (SMQ)

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SMQ Applications

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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)

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EMA: Signal Detection Analysis

- ICSR coding at LLT level, analysis at PT level (medical concept):
 - ✓ It may be important to conduct analysis at **higher level** of hierarchy: SOC, HLG, HLT
 - When doing so, impact of axial and non multi-axial SOCs needs to be taken into account: relevant PTs in more than 1 SOC
 - ✓ It may be important to conduct analysis at **SMQ** level to maximise likelihood that all terms related to a specific medical condition of interest are identified
- **Challenge: strike the correct balance**
 - ✓ Too narrowly focused search (specificity): exclude events of potential relevance
 - ✓ Too broad search (sensitivity): difficult to identify a trend or signal that may require further analysis (incl. case review)



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Acknowledgement: Dr. Aniello Santoro, EMA

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Use of SMQs at FDA – Reviewing Prescribing Information

- Proposed Prescribing Information:
- Warnings & Precautions:
 - Dizziness/Somnolence
 - Withdrawal of Antiepileptic Drugs
 - Suicidal Behavior and Ideation (class labeling)
- Final Prescribing Information
- **Boxed Warning:**
 - **Serious Psychiatric and Behavioral Reactions**
- Warnings & Precautions:
 - Falls
 - Dizziness & somnolence
 - Withdrawal of Antiepileptic Drugs
 - Suicidal Behavior and Ideation (class labeling)

SMQ (Narrow Search)	RR
(1) Hostility/aggression	4.4
(2) Vestibular disorders	4.258
(1) Hearing and vestibular disorders	4.088
(1) Hyponatraemia/SIADH	3.832
(2) Hearing impairment	3.832
(1) Dyslipidaemia *	2.555
(1) Biliary disorders	2.135
(2) Functional, inflammatory and gallstone related biliary disorders	2.135

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Customized Searches

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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
 - SMQ *Lack of efficacy/effect* often modified based on particular product

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Customized Searches – *Ad Hoc* Queries

- Need medical knowledge
- Need knowledge of structure and characteristics of MedDRA and of your data
- Refer to the *MedDRA Data Retrieval and Presentation: Points to Consider* document for query construction tips
- Save query for future use; maintenance needed for MedDRA version changes
- Consider submitting *ad hoc* query to MSSO via change request for possible development as an SMQ

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Summary

In this course, we:

- Reviewed the MedDRA Data Retrieval and Presentation: Points to Consider document
- Reviewed use of MedDRA for developing queries
- Discussed Standardised MedDRA Queries (SMQs)
- Discussed the creation and use of customized searches

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MedDRA

MSSO Contacts

- Website
 - www.meddra.org
- Email
 - msohelp@meddra.org
- Frequently Asked Questions
 - www.meddra.org/faq
- MedDRA Browsers
 - <https://www.meddra.org/meddra-desktop-browsers>
(Desktop Browser)
 - <https://tools.meddra.org/wbb/> (Web-Based Browser)
 - <https://mmb.meddra.org> (Mobile Browser)

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MedDRA

MSSO Contacts (cont)

- Self-Service Application
 - <https://www.meddra.org/meddra-self-service-application>
- Training Schedule
 - <https://www.meddra.org/training/schedule>
- Change Request Submission
 - <https://www.meddra.org/how-to-use/change-requests>
- MedDRA Support Documentation
 - <https://www.meddra.org/how-to-use/support-documentation>

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Question and Answer Session

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Appendix – MedDRA’s Scope, Structure, and Characteristics

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MedDRA

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.

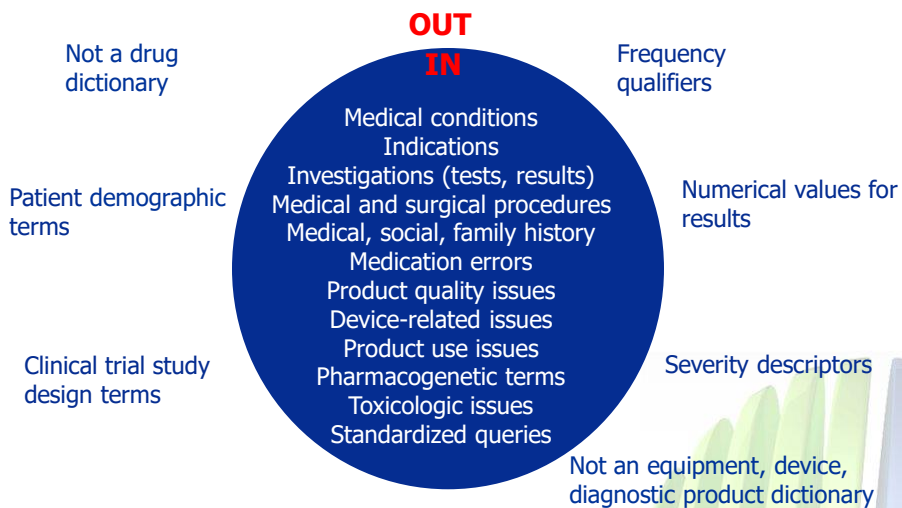
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MedDRA

Scope of MedDRA



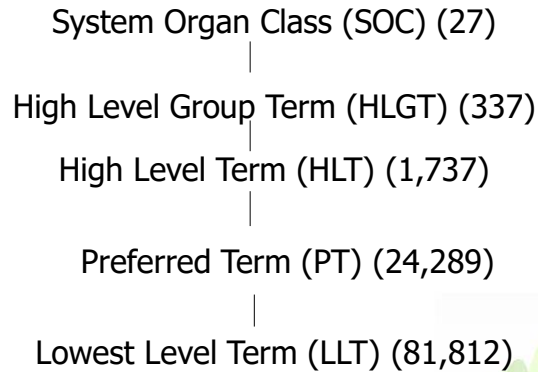
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MedDRA

MedDRA Structure



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MedDRA Version 23.0

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MedDRA

A Multi-Axial Terminology

- Multi-axial = the representation of a medical concept in multiple SOC
 - 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

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MedDRA

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



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