



Advanced MedDRA Coding



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 six ICH parties (EU, EFPIA, MHLW, JPMA, FDA, PhRMA), the Medicines and Healthcare products Regulatory Agency (MHRA) of the UK, Health Canada, and the WHO (as Observer).



MedDRA

Disclaimer and Copyright Notice

- This presentation is protected by copyright and may, with the exception of the MedDRA and ICH logos, be used, reproduced, incorporated into other works, adapted, modified, translated or distributed under a public license provided that ICH's copyright in the presentation is acknowledged at all times. In case of any adaption, modification or translation of the presentation, reasonable steps must be taken to clearly label, demarcate or otherwise identify that changes were made to or based on the original presentation. Any impression that the adaption, modification or translation of the original presentation is endorsed or sponsored by the ICH must be avoided.
- The presentation is provided "as is" without warranty of any kind. In no event shall the ICH or the authors of the original presentation be liable for any claim, damages or other liability arising from the use of the presentation.
- The above-mentioned permissions do not apply to content supplied by third parties. Therefore, for documents where the copyright vests in a third party, permission for reproduction must be obtained from this copyright holder.

000141

3



MedDRA

Course Overview

- Discuss important principles in the MedDRA Term Selection: Points to Consider document
- Demonstrate some features of a MedDRA browser
- Discuss coding examples using a MedDRA browser
- Present some MedDRA coding "pearls"
- Conclude with a question and answer session
- Appendix – MedDRA's scope, structure, and characteristics/Browsers

000141

4



MedDRA Term Selection: Points to Consider Document

000141

5



MedDRA Term Selection: Points to Consider (MTS:PTC)

MedDRA® TERM SELECTION: POINTS TO CONSIDER ICH-Endorsed Guide for MedDRA Users

Release 4.15
Based on MedDRA Version 21.0

1 March 2018

Disclaimer and Copyright Notice

This document is protected by copyright and may, with the assent of the MedDRA and ICH logos, be used, reproduced, incorporated into other works, adapted, modified, translated or distributed under a public license provided that ICH's copyright in the document is acknowledged at all times. In case of any adaption, modification or translation of the document, reasonable steps must be taken to clearly label, demarcate or otherwise identify that changes were made to or based on the original document. Any impression that the adaption, modification or translation of the original document is endorsed or sponsored by the ICH must be avoided.

The document is provided "as is" without warranty of any kind. In no event shall the ICH or the authors of the original document be liable for any claim, damages or other liability arising from the use of the document.

The above-mentioned permissions do not apply to content supplied by third parties. Therefore, for documents where the copyright vests in a third party, permission for reproduction must be obtained from this copyright holder.

MedDRA® trademark is registered by IFPMA on behalf of ICH

000141

6

- Provides term selection advice for industry and regulatory purposes
- Objective is to promote accurate and consistent term selection to facilitate a common understanding of shared data
- Recommended to be used as basis for individual organization's own coding conventions



MedDRA Term Selection: PTC (cont)

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

000141

7



ICH M1 Points to Consider Working Group (PtC WG)



- Regulators and industry from EU, US, and Japan
- Health Canada
- MSSO
- JMO
- WHO (Observer)

New members 2017/2018

- MFDS, Republic of Korea
- ANVISA, Brazil
- CFDA, China

Meeting 13-15 November 2017, Geneva, Switzerland

000141

8



MedDRA

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

000141

9



MedDRA

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

000141

10



MedDRA

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

000141

11



MedDRA

Diagnoses and Provisional Diagnoses

SINGLE DIAGNOSIS	
DEFINITIVE DIAGNOSIS	PROVISIONAL DIAGNOSIS
Single diagnosis without signs and symptoms •Diagnosis (only possible option)	Single provisional diagnosis without signs and symptoms •Provisional diagnosis (only possible option)
Example: " <i>Myocardial infarction</i> " → select " <i>Myocardial infarction</i> "	Example: " <i>Possible myocardial infarction</i> " → select " <i>Myocardial infarction</i> " (select term as if definitive diagnosis)

Similar principles apply for multiple diagnoses

000141

12



MedDRA

Diagnoses and Provisional Diagnoses (cont)

SINGLE DIAGNOSIS	
DEFINITIVE DIAGNOSIS	PROVISIONAL DIAGNOSIS
Single diagnosis with signs/symptoms •Preferred: Diagnosis only	Single provisional diagnosis with signs/symptoms •Preferred: Provisional diagnosis and signs/symptoms
Example: " <i>Anaphylactic reaction with rash, dyspnoea, hypotension, and laryngospasm</i> " → select " <i>Anaphylactic reaction</i> "	Example: " <i>Possible myocardial infarction with chest pain, dyspnoea, diaphoresis</i> " → select " <i>Myocardial infarction</i> " " <i>Chest pain</i> ", " <i>Dyspnoea</i> ", and " <i>Diaphoresis</i> "

000141

Similar principles apply for multiple diagnoses

13



MedDRA

Diagnoses and Provisional Diagnoses (cont)

SINGLE DIAGNOSIS	
DEFINITIVE DIAGNOSIS	PROVISIONAL DIAGNOSIS
Single diagnosis with signs/symptoms •Alternate: Diagnosis and signs/symptoms	Single provisional diagnosis with signs/symptoms •Alternate: Signs/symptoms only (as provisional diagnosis may change)
Example: " <i>Anaphylactic reaction with rash, dyspnoea, hypotension, and laryngospasm</i> " → select " <i>Anaphylactic reaction</i> ", " <i>Rash</i> ", " <i>Dyspnoea</i> ", " <i>Hypotension</i> ", and " <i>Laryngospasm</i> "	Example: " <i>Possible myocardial infarction with chest pain, dyspnoea, diaphoresis</i> " → select " <i>Chest pain</i> ", " <i>Dyspnoea</i> ", and " <i>Diaphoresis</i> "

000141

Similar principles apply for multiple diagnoses

14



MedDRA

Diagnoses and Provisional Diagnoses (cont)

- Always include signs/symptoms not associated with diagnosis

Reported	LLT Selected
Myocardial infarction, chest pain, dyspnoea, diaphoresis, ECG changes and jaundice	Myocardial infarction Jaundice (note that jaundice is not typically associated with myocardial infarction)

000141

15



MedDRA

Conflicting/Ambiguous Information

- First, try to obtain more specific information

Reported	LLT Selected	Comment
Hyperkalaemia with a serum potassium of 1.6 mEq/L	Serum potassium abnormal	LLT <i>Serum potassium abnormal</i> covers both of the reported concepts (note: serum potassium of 1.6 mEq/L is a low result, not high)
GU pain	Pain	"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 <i>Pain</i>

000141

16



MedDRA

Vague Information

- First, try to obtain more specific information

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

000141

17



MedDRA

Investigations

- Medical condition vs. investigation result

Reported	LLT Selected	Comment
Hypoglycaemia	Hypoglycaemia	LLT <i>Hypoglycaemia</i> links to SOC <i>Metabolism and nutrition disorders</i>
Decreased glucose	Glucose decreased	LLT <i>Glucose decreased</i> links to SOC <i>Investigations</i>

000141

18



MedDRA

Investigations (cont)

- Unambiguous investigation result

Reported	LLT Selected	Comment
Glucose 40 mg/dL	Glucose low	Glucose is clearly below the reference range

- Ambiguous investigation result

Reported	LLT Selected	Comment
His glucose was 40	Glucose abnormal	No units have been reported. Select LLT <i>Glucose abnormal</i> if clarification cannot be obtained.

000141

19



MedDRA

Investigations (cont)

- Investigation results consistent with diagnosis

Reported	LLT Selected	Comment
Elevated potassium, K 7.0 mmol/L, and hyperkalaemia	Hyperkalaemia	It is not necessary to select LLT <i>Potassium increased</i>

- Grouped investigation result terms

Reported	LLT Selected	Comment
Increased alkaline phosphatase, increased SGPT, increased SGOT and elevated LDH	Alkaline phosphatase increased SGPT increased SGOT increased LDH increased	Select four individual terms. A single term such as LLT <i>Liver function tests abnormal</i> should not be selected.

000141

20



MedDRA Browser Demonstration

000141

21



Coding Exercises

000141

22



MedDRA

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.

000141

23



MedDRA

Which LLT Would You Select?

Verbatim: "Man with decreased fertility."

- A. Infertility
- B. Fertility decreased male
- C. Infertility male
- D. Fertility decreased

000141

24



MedDRA

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

000141

25



MedDRA

Which LLT Would You Select?

Verbatim: "Turned very greasy"

- A. Ill-defined disorder
- B. Unevaluable event
- C. Skin greasy
- D. Unevaluable reaction

000141

26



MedDRA

Which LLT Would You Select?

Verbatim: "Deliberately took an overdose"

- A. Intentional overdose
- B. Overdose NOS
- C. Deliberate overdose
- D. Overdose

000141

27



MedDRA

Which LLT Would You Select?

Verbatim: "Patient reported medical problem"

- A. Adverse event
- B. Unevaluable event
- C. Unevaluable reaction
- D. Ill-defined disorder

000141

28



MedDRA

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

000141

29



MedDRA

Which LLT Would You Select?

Verbatim: "Infection after surgery"

- A. Infection
- B. Postoperative wound infection
- C. Surgical wound infection
- D. Postoperative infection

000141

30



MedDRA

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

000141

31



MedDRA

Which LLT Would You Select?

Verbatim: "Had MI"

- A. Myocardial infarction
- B. Ill-defined disorder
- C. MI
- D. Unevaluable event

000141

32



MedDRA

Which LLT Would You Select?

Verbatim:

"Hypernatraemia (Serum sodium = 115 mEq/L)"

- A. Serum sodium abnormal
- B. Hypernatraemia
- C. Hyponatraemia
- D. Serum sodium decreased

000141

33



MedDRA

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

000141

34



MedDRA

Which LLT Would You Select?

Verbatim: "Death from cerebral haemorrhage"

- A. Sudden death
- B. Death
- C. Cerebral haemorrhage
- D. Brain death

000141

35



MedDRA

Which LLT Would You Select?

Verbatim: "Patient was found dead"

- A. Death from natural causes
- B. Death
- C. Died in sleep
- D. Found dead

000141

36



MedDRA

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

000141

37



MedDRA

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

000141

38



MedDRA

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

000141

39



MedDRA

Which LLT Would You Select?

Verbatim: "Abused by her husband"

- A. Physical abuse
- B. Battered wife
- C. Spousal abuse
- D. Victim of spousal abuse

000141

40



MedDRA

Which LLT Would You Select?

Verbatim: "A 27-year-old woman took a 2-week course of antibiotics during her second trimester of pregnancy. She did not experience any side effects."

What is the preferred option for the LLT(s) to be selected?

- A. Maternal exposure during pregnancy
- B. No adverse effect
- C. Normal pregnancy

000141

41



MedDRA

Which LLT Would You Select?

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

000141

42



MedDRA

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

000141

43



MedDRA

Which LLTs Would You Select?

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

000141

44



Some MedDRA Coding “Pearls”

000141

45



Remember That MedDRA Can Be Used to Code More Than AEs

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.

000141

46



MedDRA

MedDRA Coding “Pearls”

- First, try using reporter’s actual words
- Be aware of MedDRA’s specificity
- Exploit MedDRA’s hierarchy – if an LLT is close to what you need, look at its “siblings” and “parent”
- Check where the LLT lies in MedDRA (i.e., check the hierarchy above to be sure it represents the verbatim term accurately)

000141

47



MedDRA

MedDRA Coding “Pearls” (cont)

- Use “top-down” and “bottom-up” navigation
- Try synonyms → if it’s not “renal” try “kidney”, etc.
- Use word stems, e.g., “Pancrea”
- Use available resources for difficult verbatim terms (web search, medical dictionaries, colleagues)

000141

48



MedDRA

MedDRA Coding “Pearls” (cont)

- And most important of all... get more coding training!

000141

49



MedDRA

Summary

- Discussed important principles presented in the MedDRA Term Selection: Points to Consider document
- Demonstrated some features of a MedDRA browser
- Discussed coding examples using a MedDRA browser
- Presented some MedDRA coding “pearls”

000141

50



MedDRA

MSSO Contacts

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

000141

51



MedDRA

Question and Answer Session

000141

52



Appendix: MedDRA's Scope, Structure, and Characteristics/Browsers

000141

53

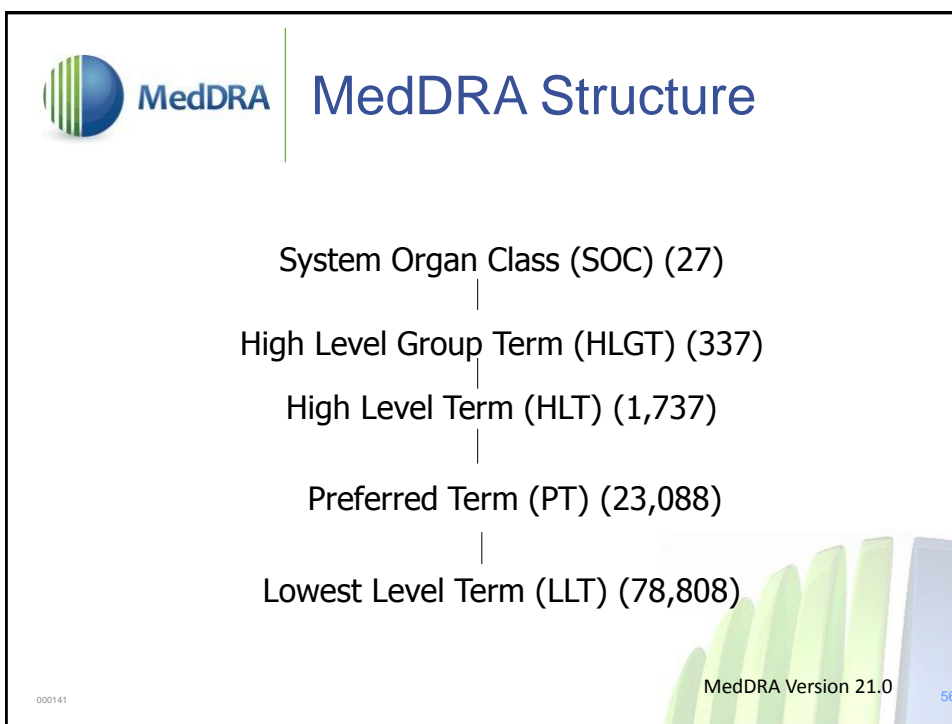
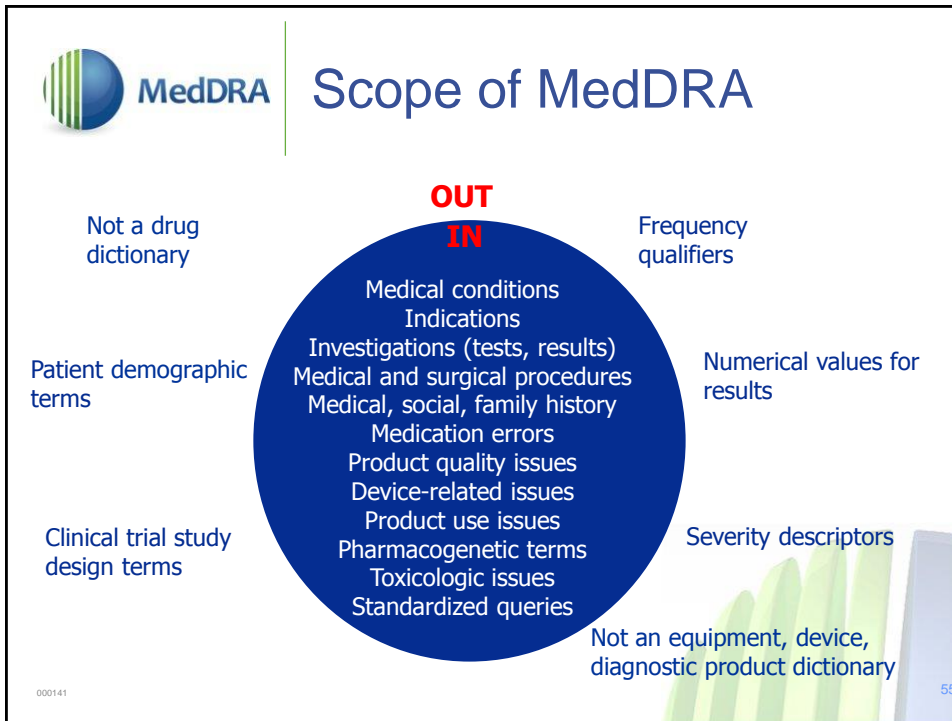


MedDRA Definition

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.

000141

54





MedDRA

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
- Product issues
- Psychiatric disorders
- Renal and urinary disorders
- Reproductive system and breast disorders
- Respiratory, thoracic and mediastinal disorders
- Skin and subcutaneous tissue disorders
- Social circumstances
- Surgical and medical procedures
- Vascular disorders

000141

57



MedDRA

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

000141

58



MedDRA

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

000141

59



MedDRA

Primary SOC Priority

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*

000141

60



MedDRA

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*

000141

61



MedDRA

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/>
- 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

000141

62