

Rules for MedDRA Terms Search and MedDRA Report

MedDRA Terms Search (see [pg.4](#) for detailed instructions)

- Search MedDRA lowest level terms (LLTs) or preferred terms (PTs) across labeling or within labeling section(s)
 - The drop-down menu in MedDRA Terms search is based on the 'Labeling Section(s)' search menu in FDALabel (Full Prescribing Information and Over-the-Counter only)
 - Select labeling section from drop-down menu or search entire document (Labeling Full Text as default)

MedDRA Report

- Extract all MedDRA LLTs and mapped PTs for a labeling document
- MedDRA Report is located in the last column of the Results table (Expanded View) and can be downloaded in Excel/csv format
- MedDRA Report is only available for human prescription and biological drug labeling

MedDRA Rules for Natural Language Processing (NLP)

Insignificant Characters (replaced with spaces in both MedDRA terms and SPL text)

- any kind of whitespace or invisible separator (space, tab, carriage return, newline, form feed, etc.)
- any invisible control character(s)
- punctuation (@ * # % periods, commas, semicolon, double quotes, etc.)
 - excludes minus/hyphen (-), plus (+), and apostrophe/single-quote (')
- apostrophe following an "s" at the end of a word
- symbols: ~ \$ ^ = < > /
- minus/hyphen (-) when surrounded by alphabetical characters
 - except when leading word is "non", "not", "anti", "not", "un" (considered significant in these cases)

Significant Characters (match exactly, in sequence, against what's in the labeling text)

- letters and digits
- apostrophe/single-quote (') except following an "s" at end of word
- curly apostrophe/"smart single quote" considered equivalent to regular (keyboard) apostrophe (') (to match MedDRA)
- plus (+)
- minus/hyphen (-) when not surrounded by alphabetical characters or when leading word is "non", "not", "anti", "not", "un"
- period immediately surrounded by alphabetical characters

Non-current MedDRA Terms (MedDRA version 25.0)

Non-current MedDRA terms (e.g., High, Cap, Hot) can cause an increase in false positive adverse even (AE) results. These terms have been removed from FDALabel MedDRA Terms search and the MedDRA Report.

Case-sensitive Matched MedDRA Terms

MedDRA LLTs from MedDRA v25.0 that must match by letter case are listed below; the letter case is significant to the meaning of these terms. Other MedDRA terms do not have to match by letter case.

ADD	GH	PAT
AF	GIFT	PE
AIDS	GOT	PEEP
ALL	GU	PET
ALT	HAM	PET/MRI
ARC	HT	Pb
ARIA	K	pH
BP	K+	QTc
BUN	LA	RA
Br	LH	SAP
Br-	LOC	SIRS
CAD	LP	SOB
CAT	MAC	Se
CK	MAP	T3
CO	ME	T4
CT	MERS	TB
Ca	MI	TG
Cl	MS	TEN
Cl-	Na	THRIVE
Cu	Na+	TIA
DIOS	O/A	TOP
DOE	OA	UC
DU	O/C	URI
ELISA	OC	VC
EM	P	VD
ENG	P+	VF
Fe	PANDA	VT
GA	S	

Description of MedDRA Report

15 Columns in MedDRA Report

- 1) Section
- 2) Occurring LLT
- 3) Occurrences
- 4) PT
- 5) Section Code
- 6) LLT Code
- 7) PT Code
- 8) SPL Set ID
- 9) SPL Eff Date
- 10) SPL Ver
- 11) Trade Name
- 12) Product Names
- 13) Product NDCs
- 14) FDALabel URL
- 15) DailyMed URL

MedDRA Report Column Description

Section: Labeling section where LLT occurred

Occurring LLT: LLT that occurs in the labeling document

Occurrences: Number of times LLT occurs in the labeling section or subsection

PT: Mapped Preferred Term (PT) of the extracted LLT that occurs in the labeling document

Section Code: Labeling section (LOINC[†])

LLT Code: LLT MedDRA code^{†‡}

PT Code: PT MedDRA code^{†‡}

SPL Set ID: Unique identification for each SPL document

SPL Eff Date: Most recent SPL date

SPL Ver: Revision number of SPL

Trade Name: Trade name of product

Product Names:

- Obtained directly from SPL (not including generic name), in the order they appear in the SPL document
- Name duplicates are not removed from the results and directly correspond with the list of NDCs (products)

Product NDCs: Individual product codes

FDALabel URL: Link to SPL document in FDALabel

DailyMed URL: Link to SPL document in DailyMed

Abbreviations: LLT (Lowest Level Term); PT (Preferred Term); LOINC (Logical Observation Identifiers Names and Codes); SPL (Structured Product Labeling); NDC (National Drug Code)

[†]LOINC and MedDRA codes are standardized codes that are primarily used for machine processing

[‡]The LLT and PT codes are the same when the LLT is also the PT

Occurrences of LLT in MedDRA Report (Sections: Labeling Sections and Subsections)

A MedDRA LLT will be listed and counted twice when it occurs in a subsection, once for the subsection and again for the main section. For example, the term “birth defect” occurring in subsection 8.1 “PREGNANCY SECTION” will be counted once for 8.1 “PREGNANCY SECTION” section and again for 8.0 “USE IN SPECIFIC POPULATIONS SECTION” section, but only appears once within the main section.

SPL Document	Results
8.0 USE IN SPECIFIC POPULATIONS	“birth defect” occurs in 8.0 USE IN SPECIFIC POPULATIONS (1)
↳ 8.1 PREGNANCY	“birth defect” occurs in 8.1 PREGNANCY (1)
↳ • “birth defect” (1)	

Example: MedDRA term “birth defect” only occurs in the SPL one time in 8.0 USE IN SPECIFIC POPULATIONS (within subsection 8.1 PREGNANCY SECTION), but is counted two times in the Results, once for occurring within 8.0 USE IN SPECIFIC POPULATIONS and again for occurring within the 8.1 PREGNANCY subsection.

Instructions for the MedDRA Terms Search Feature: The MedDRA Terms search option is listed in “Add more criteria” located at the bottom of the FDALabel tool interface.

1. Enter a MedDRA term by typing 3 or more letters in the text box.

- a. A list of suggested terms (both LLTs and PTs) will auto-generate after 3 letters
2. Select a term from the list to add to your search query (preferred terms are indicated with a blue 'PT' icon).
3. Left click the term to see a list of additional options:
 - a. "Insert Preferred Term" adds the PT to your search query
 - b. "Insert Lowest Level Terms Having Same Preferred Term"/ "Insert Lowest Level Terms" adds all LLTs, that map to the same PT, to your search query (recommended option)
 - c. "Show Lowest Level Terms Having Same Preferred Term"/ "Show Lowest Level Terms" displays all the LLTs that maps to the same PT
4. Search with unlimited number of LLT/PT terms by repeating steps 1-3. An "OR" logic is embedded between each term in the same MedDRA Terms search box.
5. Multiple MedDRA Terms search boxes can be added; use "AND"/ "OR" logic option among the search boxes to further customize your query.
6. By default, the MedDRA term search will auto-generate a list with both LLTs and PTs present in labeling, for selection. Select one of the options for additional filters:
 - a. "list preferred terms only" narrows the list to only show PTs
 - b. "list terms not appearing in any labeling" expands the list to show MedDRA terms with zero counts in labeling

FDALabel Disclaimer: MedDRA Terms Search and Report

The Medical Dictionary for Regulatory Activities ([MedDRA](#)) is a standardized medical terminology developed by the International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH). The MedDRA features developed in FDALabel are intended to facilitate the study of adverse event (AE) occurrences in product labeling. It should be noted that MedDRA version updates, which occur on a biannual basis, may affect search results due to changes in mapping or promotion/demotion of MedDRA terms. FDALabel updates MedDRA at least once a year during a new version release. The FDA does not require AEs to be described with MedDRA terminology in labeling. Thus, a MedDRA term search or report in FDALabel may not represent all AE concepts represented in labeling. Furthermore, the presence of a MedDRA term in labeling may not necessarily refer to an AE (e.g., MedDRA terms may correspond to indications or patient comorbidities). During the application of the MedDRA features in FDALabel, specific rules (see above) were defined for applying Natural Language Processing (NLP) using MedDRA. Labeling documents (SPL: Structured Product Labeling) are indexed by MedDRA Lowest Level Terms (LLTs) following the predefined MedDRA rules. MedDRA LLTs, extracted from a SPL, are mapped to Preferred Terms (PTs) for the MedDRA report.