



---

# MedDRA Distribution File Format Document Version 16.0

---

**MSSO-DI-6281-16.0.0**

**March 2013**



### ACKNOWLEDGEMENTS

MedDRA® trademark is owned by IFPMA on behalf of ICH. COSTART Thesaurus Fifth Edition, Copyright © 1995 US Food and Drug Administration (FDA). Hoechst Adverse Reaction Terminology System (HARTS), Copyright © 1992 Aventis Pharma. ICD-9-CM, International Classification of Diseases, Ninth Revision, Clinical Modification, Copyright© 1998 Medicode, Inc. ICD-10, Source: World Health Organization. WHO Adverse Reaction Terminology (WHO-ART), Copyright © 1998 World Health Organization Collaborating Centre for International Drug Monitoring. Japanese Adverse Reaction Terminology (J-ART) is a product of the Ministry of Health, Labour and Welfare (MHLW).

### Disclaimer and Copyright Notice

This document is protected by copyright and may 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.

## Table of Contents

---

### TABLE OF CONTENTS

1.	INTRODUCTION.....	1
2.	GENERAL FILE INFORMATION.....	2
3.	MedDRA SCHEMA.....	4
4.	TABLE DEFINITION.....	9
5.	TABLE JOINS.....	12
6.	DATA MODEL.....	13
7.	CONSECUTIVE FILE INFORMATION.....	14
8.	MedDRA CONSECUTIVE FILE DESCRIPTIONS.....	15
9.	CONSECUTIVE FIELD DEFINITIONS.....	19

### LIST OF FIGURES

Figure 6-1.	MedDRA Data Model.....	13
-------------	------------------------	----

### LIST OF TABLES

Table 2-1.	MedDRA Files.....	2
Table 2-2.	MedDRA History File: meddra_history.asc.....	3
Table 2-3.	MedDRA Release File: meddra_release.asc.....	3
Table 3-1.	1_low_level_term Derived from MedDRA file: llt.asc.....	4
Table 3-2.	1_pref_term Derived from MedDRA file: pt.asc.....	4
Table 3-3.	1_hlt_pref_term Derived from MedDRA file: hlt.asc.....	5
Table 3-4.	1_hlt_pref_comp Derived from MedDRA file: hlt_pt.asc.....	5
Table 3-5.	1_hlgt_pref_term Derived from MedDRA file: hlgt.asc.....	5
Table 3-6.	1_hlgt_hlt_comp Derived from MedDRA file: hlgt_hlt.asc.....	6
Table 3-7.	1_soc_term Derived from MedDRA file: soc.asc.....	6
Table 3-8.	1_soc_hlgt_comp Derived from MedDRA file: soc_hlgt.asc.....	6
Table 3-9.	1_md_hierarchy Derived from MedDRA file: mdhier.asc.....	7
Table 3-10.	1_soc_intl_order Derived from MedDRA file: intl_ord.asc.....	7
Table 3-11.	1_smq_list Derived from MedDRA file: smq_list.asc.....	7

## Table of Contents

---

Table 3-12. 1_smq_Content Derived from MedDRA file: smq_content.asc .....	8
Table 4-1. Field Definitions in MedDRA Files .....	11
Table 7-1. MedDRA Consecutive Files.....	14
Table 8-1. MedDRA Consecutive File: llt.seq .....	15
Table 8-2. MedDRA Consecutive File: pt.seq.....	16
Table 8-3. MedDRA Consecutive File: hlt.seq.....	16
Table 8-4. MedDRA Consecutive File: hlt_pt.seq.....	16
Table 8-5. MedDRA Consecutive File: hlgt.seq.....	17
Table 8-6. MedDRA Consecutive File: hlgt_hlt.seq .....	17
Table 8-7. MedDRA Consecutive File: soc.seq .....	17
Table 8-8. MedDRA Consecutive File: soc_hlgt.seq.....	18
Table 8-9. MedDRA Consecutive File: mdhier.seq.....	18
Table 8-10. MedDRA Consecutive File: intl_ord.seq.....	18
Table 9-1. Field Definitions in Consecutive Files .....	22

### 1. INTRODUCTION

The MedDRA Distribution File Format Document contains information regarding the MedDRA file schema and the Consecutive files which may be used to upgrade an existing installation to the current version of MedDRA. This document will support the user in creating and populating a relational database with the MedDRA and Consecutive files. Users of this document should have some knowledge of relational databases to successfully import the MedDRA data to a usable database format.

The first section of this document contains the following information about the MedDRA files:

- General File Information – Overview of the MedDRA files included in this package
- The MedDRA Schema – Information on the structure and attributes of the MedDRA tables to be imported to the relational database
- MedDRA Table Definition – Definition of each field in the MedDRA database tables
- MedDRA Table Joins – Definition of the table joins necessary to associate the MedDRA database tables with each other
- MedDRA Data Model – The complete data model for the MedDRA database.

The second section of this document contains information about the MedDRA Consecutive files including:

- General File Information – overview of the MedDRA consecutive files
- The MedDRA Consecutive File Description – information on the structure and attributes of the consecutive files
- Field Definitions – definitions of each field in each consecutive file.

Note: The SMQ files (smq\_list and smq\_content) contain data elements within the \*.asc files that identify changes resulting from MedDRA version updates. See Section 3 MedDRA Schema for more details.

Prior to MedDRA Version 16.0, this document was named the “ASCII and Consecutive File Documentation”. The name was changed to the “MedDRA Distribution File Format Document” to better reflect the contents of the document as not all translations of MedDRA are encoded with the extended ASCII format.

**2. GENERAL FILE INFORMATION**

This section lists the MedDRA data files in this package. Each MedDRA file is in extended ASCII format for English and the Western European language translations. The remaining supported languages including Czech, Hungarian, and Chinese use UTF-8 file format. Table 2-1 lists the MedDRA files, associated tables, and number of records contained in each file.

<b>File Name</b>	<b>MedDRA Table</b>	<b>Number of Records in Table</b>
hlgt.asc	1_hlgt_pref_term	334
hlgt_hlt.asc	1_hlgt_hlt_comp	1735
hlt.asc	1_hlt_pref_term	1717
hlt_pt.asc	1_hlt_pref_comp	28307
llt.asc	1_low_level_term	71326
meddra_history_english.asc	N/A*	111863
meddra_release.asc	N/A*	1
mdhier.asc	1_md_hierarchy	29840
pt.asc	1_pref_term	20057
soc.asc	1_soc_term	26
soc_hlgt.asc	1_soc_hlgt_comp	351
intl_ord.asc	1_soc_intl_order	26
smq_list.asc	1_smq_list	206
smq_content.asc	1_smq_content	64381

**Table 2-1. MedDRA Files**

Data fields in the files appear in the same order as indicated in the MedDRA Schema (Section 3) for each table. Data is delimited by “\$.” There is no ”\$“ at the beginning of the first field, however, there is a “\$“ after the last field.

\* The meddra\_history\_english.asc and meddra\_release.asc files are optional files for use with the MedDRA Desktop Browser (MDB) release 3.0.2 Beta and up. These files are not part of the MedDRA schema.

The meddra\_history\_english.asc file contains information that allows the MDB to display the history of term addition, term deletion, term level change, term name change, and LLT currency change in MedDRA. When new versions of MedDRA are released, the history data may be used to update the MDB to keep up with new changes. The history function is available in MDB Beta 3.0.2 for English MedDRA only. Newer MBD versions support all available languages. The history file contains a field for the MedDRA code, the term name, what version (e.g., 10.1) the term was added, the type of term (e.g., PT, HLGT), its currency status if it is an LLT, and an action code. The action code can be either A (Add), U (Update), or D (Delete). See the table below.

## General File Information

---

Field Name	Field Attributes
term_code	long integer, not null
term_name	char (100), not null
term_addition_version	char(5), not null
term_type	char (4), not null
llt_currency	char (1)
action	char (1), not null

**Table 2-2. MedDRA History File: meddra\_history.asc**

The meddra\_release.asc file contains version and language information for the accompanying set of files that allows the MDB (Beta version 3.0.2 and up) to identify a specific version and language when loading the files. Specifically, there is a field for the MedDRA version (e.g., 13.1), one for the language (e.g., English, German, etc.) and three null fields reserved for future use. See the table below.

Field Name	Field Attributes
version	char (100), not null
language	char (100), not null
null_field	char (100)
null_field	char (100)
null_field	char (100)

**Table 2-3. MedDRA Release File: meddra\_release.asc**

### 3. MedDRA SCHEMA

This section presents table and field information used for importing the MedDRA data to a relational database. Table Name, Field Names, Field Attributes, and Table Indexes are provided for each MedDRA table. When importing the MedDRA data to a relational database, create each table listed below and assign all field names and attributes indicated. Field names should be applied in the order in which they appear in the file. Indexes are also provided but may not be necessary depending on the software package used.

Field Name		Field Attributes
llt_code		long integer, not null
llt_name		char (100), not null
pt_code		long integer
llt_whoart_code <sup>+</sup>		char (7)
llt_harts_code <sup>+</sup>		long integer
llt_costart_sym <sup>+</sup>		char (21)
llt_icd9_code <sup>+</sup>		char (8)
llt_icd9cm_code <sup>+</sup>		char (8)
llt_icd10_code <sup>+</sup>		char (8)
llt_currency		char (1)
llt_jart_code <sup>+</sup>		char (6)
Index Name	Table Name	Field(s) to Index
ix1_pt_llt01	1_low_level_term	llt_code
ix1_pt_llt02	1_low_level_term	llt_name
ix1_pt_llt03	1_low_level_term	pt_code

**Table 3-1. 1\_low\_level\_term Derived from MedDRA file: llt.asc**

<sup>+</sup>Note: As of MedDRA v15.0 these fields contain no data. See section 4 for details.

Field Name		Field Attributes
pt_code		long integer, not null
pt_name		char (100), not null
null_field		char (1)
pt_soc_code		long integer
pt_whoart_code <sup>+</sup>		char (7)
pt_harts_code <sup>+</sup>		long integer
pt_costart_sym <sup>+</sup>		char (21)
pt_icd9_code <sup>+</sup>		char (8)
pt_icd9cm_code <sup>+</sup>		char (8)
pt_icd10_code <sup>+</sup>		char (8)
pt_jart_code <sup>+</sup>		char (6)
Index Name	Table Name	Field(s) to Index
ix1_pt01	1_pref_term	pt_code
ix1_pt02	1_pref_term	pt_name
ix1_pt03	1_pref_term	pt_soc_code

**Table 3-2. 1\_pref\_term Derived from MedDRA file: pt.asc**

<sup>+</sup>Note: As of MedDRA v15.0 these fields contain no data. See section 4 for details.



## MedDRA Schema

---

Field Name		Field Attributes
hlt_code		long integer, not null
hlt_name		char (100), not null
hlt_whoart_code <sup>+</sup>		char (7)
hlt_harts_code <sup>+</sup>		long integer
hlt_costart_sym <sup>+</sup>		char (21)
hlt_icd9_code <sup>+</sup>		char (8)
hlt_icd9cm_code <sup>+</sup>		char (8)
hlt_icd10_code <sup>+</sup>		char (8)
hlt_jart_code <sup>+</sup>		char (6)
Index Name	Table Name	Field(s) to Index
ix1_hlt01	1_hlt_pref_term	Hlt_code
ix1_hlt02	1_hlt_pref_term	Hlt_name

**Table 3-3. 1\_hlt\_pref\_term Derived from MedDRA file: hlt.asc**

\*Note: As of MedDRA v15.0 these fields contain no data. See section 4 for details.

Field Name		Field Attributes
hlt_code		long integer, not null
pt_code		long integer, not null
Index Name	Table Name	Field(s) to Index
ix1_hlt_pt01	1_hlt_pref_comp	Hlt_code,pt_code
ix1_hlt_pt02	1_hlt_pref_comp	Pt_code, hlt_code

**Table 3-4. 1\_hlt\_pref\_comp Derived from MedDRA file: hlt\_pt.asc**

Field Name		Field Attributes
hlgt_code		long integer, not null
hlgt_name		char (100), not null
hlgt_whoart_code <sup>+</sup>		char (7)
hlgt_harts_code <sup>+</sup>		long integer
hlgt_costart_sym <sup>+</sup>		char (21)
hlgt_icd9_code <sup>+</sup>		char (8)
hlgt_icd9cm_code <sup>+</sup>		char (8)
hlgt_icd10_code <sup>+</sup>		char (8)
hlgt_jart_code <sup>+</sup>		char (6)
Index Name	Table Name	Field(s) to Index
ix1_hlgt01	1_hlgt_pref_term	Hlgt_code
ix1_hlgt02	1_hlgt_pref_term	Hlgt_name

**Table 3-5. 1\_hlgt\_pref\_term Derived from MedDRA file: hlgt.asc**

\*Note: As of MedDRA v15.0 these fields contain no data. See section 4 for details.

## MedDRA Schema

---

Field Name		Field Attributes
hlgt_code		long integer, not null
hlt_code		long integer, not null
Index Name	Table Name	Field(s) to Index
ix1_hlgt_hlt01	1_hlgt_hlt_comp	Hlgt_code, hlt_code
ix1_hlgt_hlt02	1_hlgt_hlt_comp	Hlt_code, hlgt_code

**Table 3-6. 1\_hlgt\_hlt\_comp Derived from MedDRA file: hlgt\_hlt.asc**

Field Name		Field Attributes
soc_code		long integer, not null
soc_name		char (100), not null
soc_abbrev		char(5), not null
soc_whoart_code <sup>+</sup>		char (7)
soc_harts_code <sup>+</sup>		long integer
soc_costart_sym <sup>+</sup>		char (21)
soc_icd9_code <sup>+</sup>		char (8)
soc_icd9cm_code <sup>+</sup>		char (8)
soc_icd10_code <sup>+</sup>		char (8)
soc_jart_code <sup>+</sup>		char (6)
Index Name	Table Name	Field(s) to Index
ix1_soc01	1_soc_term	Soc_code
ix1_soc02	1_soc_term	Soc_name

**Table 3-7. 1\_soc\_term Derived from MedDRA file: soc.asc**

<sup>+</sup>Note: As of MedDRA v15.0 these fields contain no data. See section 4 for details.

Field Name		Field Attributes
soc_code		long integer, not null
hlgt_code		long integer, not null
Index Name	Table Name	Field(s) to Index
ix1_soc_hlgt01	1_soc_hlgt_comp	Soc code, hlgt_code
ix1_soc_hlgt02	1_soc_hlgt_comp	Soc_code
ix1_soc_hlgt03	1_soc_hlgt_comp	Hlgt_code, soc_code

**Table 3-8. 1\_soc\_hlgt\_comp Derived from MedDRA file: soc\_hlgt.asc**

## MedDRA Schema

---

Field Name		Field Attributes
pt_code		long integer, not null
hlt_code		long integer, not null
hlgt_code		long integer, not null
soc_code		long integer, not null
pt_name		char (100), not null
hlt_name		char (100), not null
hlgt_name		char (100), not null
soc_name		char (100), not null
soc_abbrev		char (5), not null
null_field		char (1)
pt_soc_code		long integer
primary_soc_fg		char (1)
Index Name	Table Name	Field(s) to Index
ix1_md_hier01	1_md_hierarchy	Pt_code
ix1_md_hier02	1_md_hierarchy	Hlt_code
ix1_md_hier03	1_md_hierarchy	Hlgt_code
ix1_md_hier04	1_md_hierarchy	Soc_code
ix1_md_hier05	1_md_hierarchy	Pt_soc_code

**Table 3-9. 1\_md\_hierarchy Derived from MedDRA file: mdhier.asc**

Field Name		Field Attributes
intl_ord_code		long integer, not null
soc_code		long integer, not null
Index Name	Table Name	Field(s) to Index
ix1_intl_ord01	1_soc_intl_order	intl_ord_code, soc_code

**Table 3-10. 1\_soc\_intl\_order Derived from MedDRA file: intl\_ord.asc**

Field Name		Field Attributes
smq_code		Long integer, not null
smq_name		Char(100), not null
smq_level		Integer, not null
smq_description		VarChar*, not null
smq_source		VarChar*
smq_note		VarChar*
MedDRA_version		Char(5), not null
status		Char(1), not null
smq_algorithm		VarChar, not null
Index Name	Table Name	Field(s) to Index
ix1_smq_list01	1_smq_list	smq_code

**Table 3-11. 1\_smq\_list Derived from MedDRA file: smq\_list.asc**

\*Note: The maximum field length of the variable character (VarChar) field is 2000 characters.

## MedDRA Schema

---

Field Name		Field Attributes
smq_code		Long integer, not null
term_code		Long integer, not null
term_level		Integer, not null
term_scope		Integer, not null
term_category		Char(1), not null
term_weight		Integer, not null
term_status		Char(1), not null
term_addition_version		Char(5), not null
term_last_modified_version		Char(5), not null
Index Name	Table Name	Field(s) to Index
ix1_smq_content01	1_smq_content	smq_code
ix1_smq_content02	1_smq_content	term_code

**Table 3-12. 1\_smq\_Content Derived from MedDRA file: smq\_content.asc**

## Table Definition

### 4. TABLE DEFINITION

This section defines the fields in each MedDRA table.

Table Name	Field Name	Description
1_low_level_term	llt_code	8-digit code to identify the Lowest Level Term
	llt_name	Full name of the Lowest Level Term
	pt_code	8-digit code to identify the Preferred Term
	llt_whoart_code <sup>+</sup>	Code allocated by the WHO-ART <sup>®</sup> terminology
	llt_harts_code <sup>+</sup>	Code allocated by the HARTS <sup>®</sup> terminology
	llt_costart_sym <sup>+</sup>	Symbol allocated by the COSTART <sup>®</sup> terminology
	llt_icd9_code <sup>+</sup>	Code allocated by the 9 <sup>th</sup> Revision of the International Classification of Diseases, ICD-9
	llt_icd9cm_code <sup>+</sup>	Code allocated by the 9 <sup>th</sup> Revision of the International Classification of Diseases, Clinical Modification, ICD-9-CM <sup>®</sup>
	llt_icd10_code <sup>+</sup>	Code allocated by the 10 <sup>th</sup> Revision of the International Classification of Diseases, ICD-10 <sup>®</sup>
	llt_currency	Indicates whether the Lowest Level Term is current or non-current
1_pref_term	llt_jart_code <sup>+</sup>	Code allocated by the J-ART terminology
	pt_code	8-digit code to identify the Preferred Term
	pt_name	Full name of the Preferred Term
	null_field	This field is null
	pt_soc_code	The primary System Organ Class to which the Preferred Term is linked
	pt_whoart_code <sup>+</sup>	Code allocated by the WHO-ART terminology
	pt_harts_code <sup>+</sup>	Code allocated by the HARTS terminology
	pt_costart_sym <sup>+</sup>	Symbol allocated by the COSTART terminology
	pt_icd9_code <sup>+</sup>	Code allocated by the 9 <sup>th</sup> Revision of the International Classification of Diseases
	pt_icd9cm_code <sup>+</sup>	Code allocated by the 9 <sup>th</sup> Revision of the International Classification of Diseases, Clinical Modification
1_hlt_pref_term	pt_icd10_code <sup>+</sup>	Code allocated by the 10 <sup>th</sup> Revision of the International Classification of Diseases
	pt_jart_code <sup>+</sup>	Code allocated by the J-ART terminology
	hlt_code	8-digit code to identify the High Level Term
	hlt_name	Full name of the High Level Term
	hlt_whoart_code <sup>+</sup>	Code allocated by the WHO-ART terminology
	hlt_harts_code <sup>+</sup>	Code allocated by the HARTS terminology
	hlt_costart_sym <sup>+</sup>	Symbol allocated by the COSTART terminology
	hlt_icd9_code <sup>+</sup>	Code allocated by the by the 9 <sup>th</sup> Revision of the International Classification of Diseases
	hlt_icd9cm_code <sup>+</sup>	Code allocated by the 9 <sup>th</sup> Revision of the International Classification of Diseases, Clinical Modification
	hlt_icd10_code <sup>+</sup>	Code allocated by the 10 <sup>th</sup> Revision of the International Classification of Diseases
1_hlt_pref_comp	hlt_jart_code <sup>+</sup>	Code allocated by the J-ART terminology
	hlt_code	8-digit code to identify the High Level Term
	pt_code	8-digit code to identify the Preferred Term

## Table Definition

Table Name	Field Name	Description	
1_hlgt_pref_term	hlgt_code	8-digit code to identify the High Level Group Term	
	hlgt_name	Full name of the High Level Group Term	
	hlgt_whoart_code <sup>+</sup>	Code allocated by the WHO-ART terminology	
	hlgt_harts_code <sup>+</sup>	Code allocated by the HARTS terminology	
	hlgt_costart_sym <sup>+</sup>	Symbol allocated by the COSTART terminology	
	hlgt_icd9_code <sup>+</sup>	Code allocated by the 9 <sup>th</sup> Revision of the International Classification of Diseases	
	hlgt_icd9cm_code <sup>+</sup>	Code allocated by the 9 <sup>th</sup> Revision of the International Classification of Diseases, Clinical Modification	
	hlgt_icd10_code <sup>+</sup>	Code allocated by the 10 <sup>th</sup> Revision of the International Classification of Diseases	
	hlgt_jart_code <sup>+</sup>	Code allocated by the J-ART terminology	
1_hlgt_hlt_comp	hlgt_code	8-digit code to identify the High Level Group Term	
	hlt_code	8-digit code to identify the High Level Term	
1_soc_term	soc_code	8-digit code to identify the System Organ Class	
	soc_name	Full name of the System Organ Class	
	soc_abbrev	System Organ Class abbreviation	
	soc_whoart_code <sup>+</sup>	Code allocated by the WHO-ART terminology	
	soc_harts_code <sup>+</sup>	Code allocated by the HARTS terminology	
	soc_costart_sym <sup>+</sup>	Symbol allocated by the COSTART terminology	
	soc_icd9_code <sup>+</sup>	Code allocated by the 9 <sup>th</sup> Revision of the International Classification of Diseases	
	soc_icd9cm_code <sup>+</sup>	Code allocated by the 9 <sup>th</sup> Revision of the International Classification of Diseases, Clinical Modification	
	soc_icd10_code <sup>+</sup>	Code allocated by the 10 <sup>th</sup> Revision of the International Classification of Diseases	
1_soc_hlgt_comp	soc_code	8-digit code to identify the System Organ Class	
	hlgt_code	8-digit code to identify the High Level Group Term	
1_md_hierarchy	pt_code	8-digit code to identify the Preferred Term	
	hlt_code	8-digit code to identify the High Level Term	
	hlgt_code	8-digit code to identify the High Level Group Term	
	soc_code	8-digit code to identify the System Organ Class	
	pt_name	Full name of the Preferred Term	
	hlt_name	Full name of the High Level Term	
	hlgt_name	Full name of the High Level Group Term	
	soc_name	Full name of the System Organ Class	
	soc_abbrev	System Organ Class abbreviation	
	null_field	This field is null	
	pt_soc_code	The primary System Organ Class to which the Preferred Term is linked	
	primary_soc_fg	Flag set to Y/N to indicate Primary SOC	
	1_soc_intl_order	intl_ord_code	Serial code for international System Organ Class sort order
		soc_code	8-digit code to identify the System Organ Class Term
	1_smq_list	smq_code	Eight-digit numeric code assigned to the SMQ, which starts with "2"
smq_name		Name for the SMQ, each SMQ carries "(SMQ)" at	

## Table Definition

Table Name	Field Name	Description
		the end of the name
	smq_level	Value between 1 and 5 identifying the level of the SMQ within the hierarchy of SMQs; 1 is the most general, 5 is the most narrow
	smq_description	Description of the SMQ
	smq_source	Source for the development of the SMQ (e.g., medical references)
	smq_note	Note for users to better understand the scope and development process for the SMQ. The description of the algorithm used is included (if applicable), as well as the definition of categories
	MedDRA_version	MedDRA version to use in conjunction with this SMQ
	status	Status of the SMQ. "A" = An active SMQ; "I" = An inactive SMQ
	smq_algorithm	If the SMQ was developed for use with an algorithm, the Boolean expression of the algorithm is included. "N" if the SMQ does not utilize an algorithm
1_smq_content	smq_code	Eight-digit code assigned to the SMQ
	term_code	Subordinate term code; it could be a code for MedDRA PT, LLT, or child SMQ
	term_level	MedDRA hierarchy level of the term (4=PT, 5=LLT) or 0 (zero) for a child SMQ
	term_scope	Defines the MedDRA term as a member of the broad scope (1), narrow scope (2) of the SMQ search, or a child SMQ (0) (zero)
	term_category	The category is assigned a single alphabetical letter depending upon the algorithm applied. If the SMQ does not use algorithms, then all Term_category values are assigned "A." For a child SMQ, this field is assigned "S."
	term_weight	Term weight is used for some SMQ algorithms. "0" is used as default
	term_status	Identifies a term as active within this SMQ or inactive within this SMQ. When a term is added to an SMQ, the value is set to "A" for Active. The term can be flagged as "I" for inactive if the term is no longer used in the SMQ.
	term_addition_version	Identifies the version of MedDRA in which this term was added to the SMQ
	term_last_modified_version	Identifies the version of MedDRA in which this term was last modified in this SMQ

**Table 4-1. Field Definitions in MedDRA Files**

\*Note: As of MedDRA v15.0, the data in the legacy code fields (i.e., COSTART, WHO-ART, ICD-9, ICD-9-CM, ICD-10, HARTS, and J-ART) have been removed from the MedDRA files. No MedDRA term names or MedDRA codes have been modified or removed and the structure of the MedDRA files has not changed. The removal of the codes is reflected in the consecutive files for MedDRA v15.0. A list of MedDRA terms with the these removed codes is available on the [MSSO Web site](#) (login required) for reference by MedDRA users.

## 5. TABLE JOINS

This section describes the table joins for the MedDRA tables developed using the MedDRA Schema. In the database, join the field listed for Table 1 to the field listed for Table 2.

<b>Join Table 1</b>	<b>Join Table 2</b>	<b>Table 1 Field Name</b>	<b>Table 2 Field Name</b>
1_hlt_pref_comp	1_pref_term	pt_code	pt_code
1_md_hierarchy	1_low_level_term	pt_code	pt_code
1_pref_term	1_low_level_term	pt_code	pt_code
1_hlgt_hlt_comp	1_hlt_pref_term	hlt_code	hlt_code
1_hlgt_hlt_comp	1_hlgt_pref_term	hlgt_code	hlgt_code
1_soc_hlgt_comp	1_hlgt_pref_term	hlgt_code	hlgt_code
1_soc_term	1_soc_hlgt_comp	soc_code	soc_code
1_md_hierarchy	1_pref_term	pt_code	pt_code
1_hlt_pref_comp	1_hlt_pref_term	hlt_code	hlt_code
1_soc_term	1_pref_term	soc_code	pt_soc_code
1_soc_intl_order	1_soc_term	soc_code	soc_code
1_smq_list	1_smq_content	smq_code	smq_code
1_smq_list	1_smq_content	smq_code	term_code
1_pref_term	1_smq_content	pt_code	term_code

**Table 5-1. Joins between each of the files**



## 6. DATA MODEL

The MedDRA Data Model shows all tables and table joins for a complete MedDRA database. Compare this model to the relational database created from the MedDRA Schema and Table Joins to ensure accuracy.

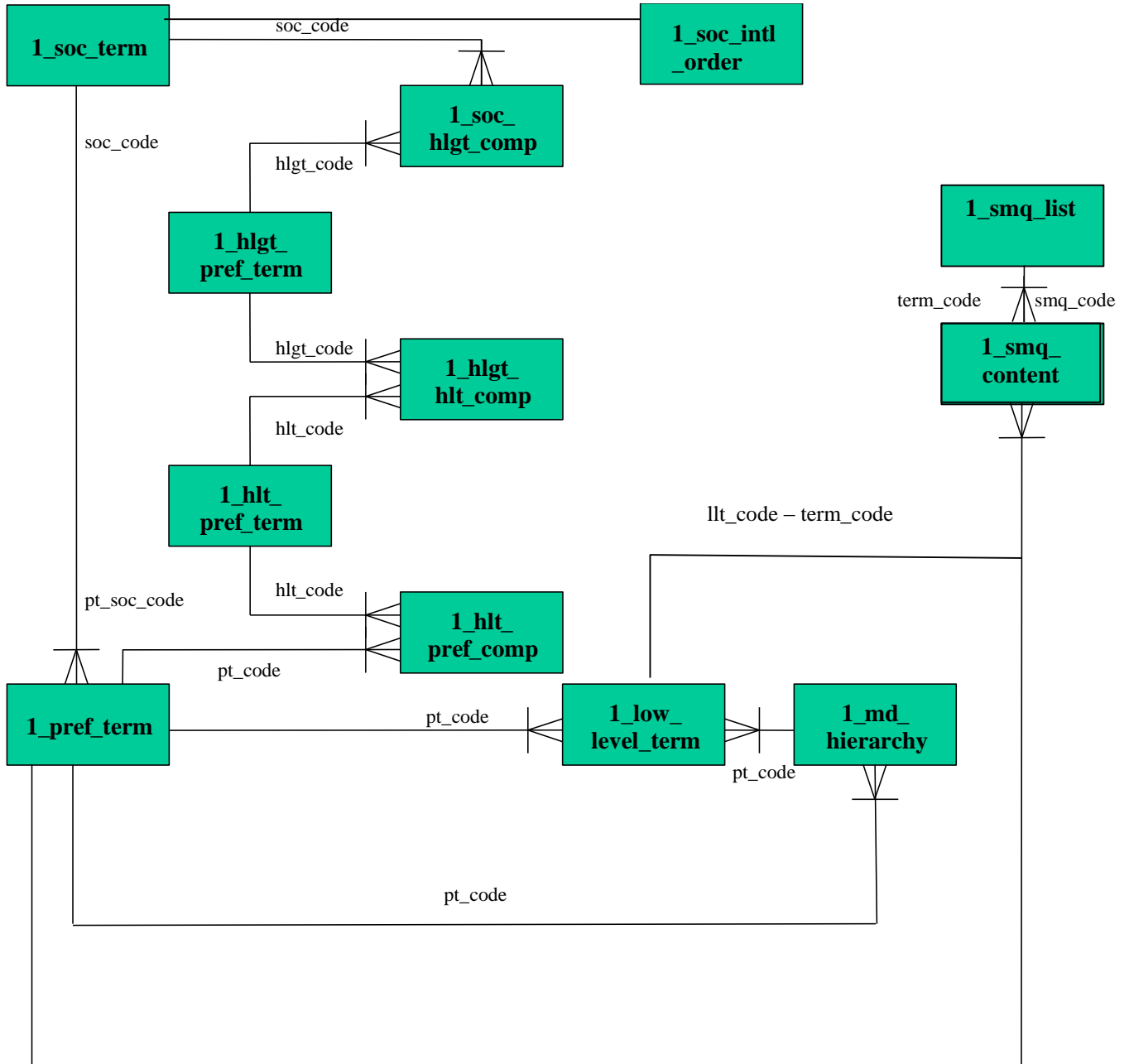


Figure 6-1. MedDRA Data Model

## 7. CONSECUTIVE FILE INFORMATION

This section lists the MedDRA consecutive files. Each consecutive file is in extended ASCII format for English and the Western European language translations. The remaining supported languages including Czech, Hungarian, and Chinese use UTF-8 file format. Table 7-1 lists the consecutive files, associated MedDRA tables and the number of records contained in each consecutive file. A zero indicates that the file has not changed since the prior consolidated MedDRA release.

<b>File Name</b>	<b>MedDRA Table</b>	<b>Number of Records in Table</b>
hlgt.seq	1_hlgt_pref_term	3
hlgt_hlt.seq	1_hlgt_hlt_comp	60
hlt.seq	1_hlt_pref_term	28
hlt_pt.seq	1_hlt_pref_comp	1504
llt.seq	1_low_level_term	2020
mdhier.seq	1_md_heirarchy	1804
pt.seq	1_pref_term	656
soc.seq	1_soc_term	0
soc_hlgt.seq	1_soc_hlgt_comp	3
Intl_ord.seq	1_soc_intl_order	0

**Table 7-1. MedDRA Consecutive Files**

## **8. MedDRA CONSECUTIVE FILE DESCRIPTIONS**

This section describes the MedDRA consecutive files. MedDRA consecutive release files contain only records that have changed since the last MedDRA release. Each file consists of records containing a version date for the new release and an action code designating that the record was either “A” – added, “D” – removed, or “M” – modified. Consecutive files can be identified by the \*.seq extension to the file name. The file names match the regular consolidated MedDRA data files that are also distributed with the \*.asc extension.

The "mod\_fld\_num" field, in the third position of each record, indicates which field(s) was modified. Only records with an action code of “M” have this field populated. For records that do not contain "M" in the action field, the “mod\_fld\_num” field is left empty (\$\$). Records with multiple modified fields have multiple numbers in this new field separated by a space such as (\$5 7\$).

File name, field names, and field attributes for each MedDRA consecutive file are provided below. Field definitions are provided in the next section of this document. Data fields are delimited by “\$.” There is no “\$” at the beginning of the first field, however, there is a “\$” after the last field. Field names are listed in the order in which the data appears in the file. With the exception of the first three fields per file, these files have the same structure as the MedDRA data files (see Section 3. MedDRA SCHEMA in this document for more information).

<b>Field Names</b>	<b>Field Attributes</b>
llt_version_date	date, not null, dd/mm/yyyy
llt_action_code	char(1), not null
llt_mod_fld_num	char (20)
llt_code	long integer, not null
llt_name	char (100), not null
pt_code	long integer
llt_whoart_code	char (7)
llt_harts_code	long integer
llt_costart_sym	char (21)
llt_icd9_code	char (8)
llt_icd9cm_code	char (8)
llt_icd10_code	char (8)
llt_currency	char (1)
llt_jart_code	char (6)

**Table 8-1. MedDRA Consecutive File: llt.seq**

## MedDRA Consecutive File Descriptions

---

Field Names	Field Attributes
pt_version_date	date, not null, dd/mm/yyyy
pt_action_code	char(1), not null
pt_mod_fld_num	char (20)
pt_code	long integer, not null
pt_name	char (100), not null
null_field	char (1)
pt_soc_code	long integer
pt_whoart_code	char (7)
pt_harts_code	long integer
pt_costart_sym	char (21)
pt_icd9_code	char (8)
pt_icd9cm_code	char (8)
pt_icd10_code	char (8)
pt_jart_code	char (6)

**Table 8-2. MedDRA Consecutive File: pt.seq**

Field Names	Field Attributes
hlt_version_date	date, not null, dd/mm/yyyy
hlt_action_code	char (1), not null
hlt_mod_fld_num	char (20)
hlt_code	long integer, not null
hlt_name	char (100), not null
hlt_whoart_code	char (7)
hlt_harts_code	long integer
hlt_costart_sym	char (21)
hlt_icd9_code	char (8)
hlt_icd9cm_code	char (8)
hlt_icd10_code	char (8)
hlt_jart_code	char (6)

**Table 8-3. MedDRA Consecutive File: hlt.seq**

Field Names	Field Attributes
h_p_version_date	date, not null, dd/mm/yyyy
h_p_action_code	char (1), not null
h_p_mod_fld_num	char (20)
hlt_code	long integer, not null
pt_code	long integer, not null

**Table 8-4. MedDRA Consecutive File: hlt\_pt.seq**

## MedDRA Consecutive File Descriptions

---

Field Names	Field Attributes
hlgt_version_date	date, not null, dd/mm/yyyy
hlgt_action_code	char (1)
hlgt_mod_fld_num	char (20)
hlgt_code	long integer, not null
hlgt_name	char (100), not null
hlgt_whoart_code	char (7)
hlgt_harts_code	long integer
hlgt_costart_sym	char (21)
hlgt_icd9_code	char (8)
hlgt_icd9cm_code	char (8)
hlgt_icd10_code	char (8)
hlgt_jart_code	char (6)

**Table 8-5. MedDRA Consecutive File: hlgt.seq**

Field Names	Field Attributes
h_h_version_date	date, not null, dd/mm/yyyy
h_h_action_code	char (1), not null
h_h_mod_fld_num	char (20)
Hlgt_code	long integer, not null
hlt_code	long integer, not null

**Table 8-6. MedDRA Consecutive File: hlgt\_hlt.seq**

Field Names	Field Attributes
soc_version_date	date, not null, dd/mm/yyyy
soc_action_code	char (1), not null
soc_mod_fld_num	char (20)
soc_code	long integer, not null
soc_name	char (100), not null
soc_abbrev	char (5), not null
soc_whoart_code	char (7)
soc_harts_code	long integer
soc_costart_sym	char (21)
soc_icd9_code	char (8)
soc_icd9cm_code	char (8)
soc_icd10_code	char (8)
soc_jart_code	char (6)

**Table 8-7. MedDRA Consecutive File: soc.seq**

## MedDRA Consecutive File Descriptions

---

Field Names	Field Attributes
s_h_version_date	date, not null, dd/mm/yyyy
s_h_action_code	char (1), not null
s_h_mod_fld_num	char (20)
soc_code	long integer, not null
hlgt_code	long integer, not null

**Table 8-8. MedDRA Consecutive File: soc\_hlgt.seq**

Field Names	Field Attributes
md_version_date	date, not null, dd/mm/yyyy
md_action_code	char (1), not null
md_mod_fld_num	char (20)
pt_code	long integer, not null
hlt_code	long integer, not null
hlgt_code	long integer, not null
soc_code	long integer, not null
pt_name	char (100), not null
hlt_name	char (100), not null
hlgt_name	char (100), not null
soc_name	char (100), not null
soc_abbrev	char (5), not null
null_field	char (1)
pt_soc_code	long integer
primary_soc_fg	char (1)

**Table 8-9. MedDRA Consecutive File: mdhier.seq**

Field Names	Field Attributes
Intl_ord_version_date	date, not null, dd/mm/yyyy
Intl_ord_action_code	char(1), not null
Intl_ord_mod_fld_num	char (20)
Intl_ord_code	long integer, not null
soc_code	long integer, not null

**Table 8-10. MedDRA Consecutive File: intl\_ord.seq**

## Consecutive Field Definitions

### 9. CONSECUTIVE FIELD DEFINITIONS

This section defines the fields in each MedDRA consecutive file.

File Names	Field Names	Description
llt.seq	llt_version_date	Date when MedDRA version was released, dd/mm/yyyy
	llt_action_code	Indicates record was added, deleted, or modified
	llt_mod fld_num	Indicates a field number for each field that is modified when the record contains an "M" in the action field of the record. Records that do not contain "M" in the action field will be left empty. See Section 8 for more information.
	llt_code	8-digit code to identify the Lowest Level Term
	llt_name	Full name of the Lowest Level Term
	pt_code	8-digit code to identify the Preferred Term
	llt_whoart_code	Code allocated by the WHO-ART <sup>©</sup> terminology
	llt_harts_code	Code allocated by the HARTS <sup>©</sup> terminology
	llt_costart_sym	Symbol allocated by the COSTART <sup>©</sup> terminology
	llt_icd9_code	Code allocated by the 9 <sup>th</sup> Revision of the International Classification of Diseases, ICD-9 <sup>©</sup>
	llt_icd9cm_code	Code allocated by the 9 <sup>th</sup> Revision of the International Classification of Diseases, Clinical Modification, ICD-9-CM <sup>©</sup>
	llt_icd10_code	Code allocated by the 10 <sup>th</sup> Revision of the International Classification of Diseases, ICD-10 <sup>©</sup>
	llt_currency	Indicates whether the Lowest Level Term is current or non-current
	llt_jart_code	Code allocated by the J-ART terminology
pt.seq	pt_version_date	Date when MedDRA version was released, dd/mm/yyyy
	pt_action_code	Indicates record was added, deleted, or modified
	pt_mod fld_num	Indicates a field number for each field that is modified when the record contains an "M" in the action field of the record. Records that do not contain "M" in the action field will be left empty. See Section 8 for more information.
	pt_code	8-digit code to identify the Preferred Term
	pt_name	Full name of the Preferred Term
	Null_field	This field is null
	pt_soc_code	The primary System Organ Class to which the Preferred Term is linked
	pt_whoart_code	Code allocated by the WHO-ART terminology
	pt_harts_code	Code allocated by the HARTS terminology
	pt_costart_sym	Symbol allocated by the COSTART terminology
	pt_icd9_code	Code allocated by the 9 <sup>th</sup> Revision of the International Classification of Diseases
	pt_icd9cm_code	Code allocated by the 9 <sup>th</sup> Revision of the International Classification of Diseases, Clinical Modification
	pt_icd10_code	Code allocated by the 10 <sup>th</sup> Revision of the International Classification of Diseases
	pt_jart_code	Code allocated by the J-ART terminology

## Consecutive Field Definitions

File Names	Field Names	Description
hlt.seq	hlt_version_date	Date when MedDRA version was released, dd/mm/yyyy
	hlt_action_code	Indicates record was added, deleted, or modified
	hlt_mod fld_num	Indicates a field number for each field that is modified when the record contains an "M" in the action field of the record. Records that do not contain "M" in the action field will be left empty. See Section 8 for more information.
	hlt_code	8-digit code to identify the High Level Term
	hlt_name	Full name of the High Level Term
	hlt_whoart_code	Code allocated by the WHO-ART terminology
	hlt_harts_code	Code allocated by the HARTS terminology
	hlt_costart_sym	Symbol allocated by the COSTART terminology
	hlt_icd9_code	Code allocated by the 9 <sup>th</sup> Revision of the International Classification of Diseases
	hlt_icd9cm_code	Code allocated by the 9 <sup>th</sup> Revision of the International Classification of Diseases, Clinical Modification
	hlt_icd10_code	Code allocated by the 10 <sup>th</sup> Revision of the International Classification of Diseases
	hlt_jart_code	Code allocated by the J-ART terminology
	hlt_pt.seq	h_p_version_date
h_p_action_code		Indicates record was added, deleted, or modified
h_p_mod fld_num		Indicates a field number for each field that is modified when the record contains an "M" in the action field of the record. Records that do not contain "M" in the action field will be left empty. See Section 8 for more information.
hlt_code		8-digit code to identify the High Level Term
pt_code		8-digit code to identify the Preferred Term
hlgt.seq	hlgt_version_date	Date when MedDRA version was released, dd/mm/yyyy
	hlgt_action_code	Indicates record was added, deleted, or modified
	hlgt_mod fld_num	Indicates a field number for each field that is modified when the record contains an "M" in the action field of the record. Records that do not contain "M" in the action field will be left empty. See Section 8 for more information.
	hlgt_code	8-digit code to identify the High Level Group Term
	hlgt_name	Full name of the High Level Group Term
	hlgt_whoart_code	Code allocated by the WHO-ART terminology
	hlgt_harts_code	Code allocated by the HARTS terminology
	hlgt_costart_sym	Symbol allocated by the COSTART terminology
	hlgt_icd9_code	Code allocated by the 9 <sup>th</sup> Revision of the International Classification of Diseases
	hlgt_icd9cm_code	Code allocated by the 9 <sup>th</sup> Revision of the International Classification of Diseases, Clinical Modification
	hlgt_icd10_code	Code allocated by the 10 <sup>th</sup> Revision of the International Classification of Diseases
hlgt_jart_code	Code allocated by the J-ART terminology	
hlgt_hlt.seq	h_h_version_date	Date when MedDRA version was released,



## Consecutive Field Definitions

File Names	Field Names	Description
		dd/mm/yyyy
	h_h_action_code	Indicates record was added, deleted, or modified
	h_h_mod fld_num	Indicates a field number for each field that is modified when the record contains an "M" in the action field of the record. Records that do not contain "M" in the action field will be left empty. See Section 8 for more information.
	hlgt_code	8-digit code to identify the High Level Group Term
	hlt_code	8-digit code to identify the High Level Term
soc.seq	soc_version_date	Date when MedDRA version was released, dd/mm/yyyy
	soc_action_code	Indicates record was added, deleted, or modified
	soc_mod fld_num	Indicates a field number for each field that is modified when the record contains an "M" in the action field of the record. Records that do not contain "M" in the action field will be left empty. See Section 8 for more information.
	soc_code	8-digit code to identify the System Organ Class
	soc_name	Full name of the System Organ Class
	soc_abbrev	System Organ Class abbreviation
	soc_whoart_code	Code allocated by the WHO-ART terminology
	soc_harts_code	Code allocated by the HARTS terminology
	soc_costart_sym	Symbol allocated by the COSTART terminology
	soc_icd9_code	Code allocated by the 9 <sup>th</sup> Revision of the International Classification of Diseases
	soc_icd9cm_code	Code allocated by the 9 <sup>th</sup> Revision of the International Classification of Diseases, Clinical Modification
	soc_icd10_code	Code allocated by the 10 <sup>th</sup> Revision of the International Classification of Diseases
	soc_jart_code	Code allocated by the J-ART terminology
soc_hlgt.seq	s_h_version_date	Date when MedDRA version was released, dd/mm/yyyy
	s_h_action_code	Indicates record was added, deleted, or modified
	s_h_mod fld_num	Indicates a field number for each field that is modified when the record contains an "M" in the action field of the record. Records that do not contain "M" in the action field will be left empty. See Section 8 for more information.
	soc_code	8-digit code to identify the System Organ Class
	hlgt_code	8-digit code to identify the High Level Group Term
md_hier.seq	md_version_date	Date when MedDRA version was released, dd/mm/yyyy
	md_action_code	Indicates record was added, deleted, or modified
	md_mod fld_num	Indicates a field number for each field that is modified when the record contains a "M" in the action field of the record. Records that do not contain "M" in the action field will be left empty. See Section 8 for more information.
	pt_code	8-digit code to identify the Preferred Term
	hlt_code	8-digit code to identify the High Level Term
	hlgt_code	8-digit code to identify the High Level Group Term
	soc_code	8-digit code to identify the System Organ Class

## Consecutive Field Definitions

---

File Names	Field Names	Description
	pt_name	Full name of the Preferred Term
	hlt_name	Full name of the High Level Term
	hlgt_name	Full name of the High Level Group Term
	soc_name	Full name of the System Organ Class
	soc_abbrev	System Organ Class abbreviation
	null_field	This field is null
	pt_soc_code	The primary System Organ Class to which the Preferred Term is linked
	primary_soc_fg	Flag set to Y/N to indicate Primary SOC
Intl_ord.seq	intl_ord_verson_date	Date when MedDRA version was released, dd/mm/yyyy
	Intl_ord_action_code	Indicates record was added, deleted, or modified
	Intl_ord_mod fld_num	Indicates a field number for each field that is modified when the record contains an "M" in the action field of the record. Records that do not contain "M" in the action field will be left empty
	intl_ord_code	Serial code for international SOC sort order
	soc_code	8-digit code to identify the System Organ Class

**Table 9-1. Field Definitions in Consecutive Files**