

MedDRA Distribution File Format Document Version 28.0

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ACKNOWLEDGEMENTS

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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 most of the Western European language translations. All other supported languages use UTF-8 file format. Table 2-1 lists the MedDRA files and associated tables. The record counts for the files in Table 2-1 for a given release may be found in the corresponding "What's New" document for that release.

| File Name ¹ | MedDRA Table | |
|----------------------------|------------------|--|
| hlgt.asc | 1_hlgt_pref_term | |
| hlgt_hlt.asc | 1_hlgt_hlt_comp | |
| hlt.asc | 1_hlt_pref_term | |
| hlt_pt.asc | 1_hlt_pref_comp | |
| Ilt.asc | 1_low_level_term | |
| meddra_history_english.asc | N/A* | |
| meddra_release.asc | N/A* | |
| mdhier.asc | 1_md_hierarchy | |
| pt.asc | 1_pref_term | |
| soc.asc | 1_soc_term | |
| soc_hlgt.asc | 1_soc_hlgt_comp | |
| intl_ord.asc | 1_soc_intl_order | |
| smq_list.asc | 1_smq_list | |
| smq_content.asc | 1_smq_content | |

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 MDB 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.

¹Record counts for the files above may be found in the "What's New" document.

| 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 |
| Ilt_currency | char (1) |
| action | char (1), not null |

Table 2-2. MedDRA History File: meddra_history_english.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 | |
| Ilt_name | | char (100), not | null |
| pt_code | | long integer | |
| llt_whoart_code⁺ | | char (7) | |
| Ilt_harts_code⁺ | | long integer | |
| llt_costart_sym⁺ | | char (21) | |
| Ilt_icd9_code ⁺ | | char (8) | |
| Ilt_icd9cm_code ⁺ | | char (8) | |
| Ilt icd10 code⁺ | | char (8) | |
| Ilt_currency | | char (1) | |
| Ilt jart code ⁺ | | char (6) | |
| Index Name Table Name | | | Field(s) to Index |
| ix1_pt_llt01 | 1_low_level_te | rm | Ilt_code |
| ix1_pt_llt02 | 1_low_level_te | rm | Ilt_name |
| ix1_pt_llt03 | | rm | pt_code |

Table 3-1. 1_low_level_term Derived from MedDRA file: Ilt.asc

*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 ⁺ | | 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) | |
| 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

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

| Field Name | | Field Attribute | s |
|------------------------------|------------|------------------|-------------------|
| hlt_code | | long integer, no | ot 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) | |
| Index Name | Table Name | | Field(s) to Index |
| ix1_hlt01 1_hlt_pref_term | | 1 | Hlt_code |
| ix1_hlt02 | | 1 | 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_com | ıp | Hlt_code,pt_code |
| ix1_hlt_pt02 | 1_hlt_pref_com | ıp | 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 ⁺ | | 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) | |
| Index Name Table Name | | | Field(s) to Index |
| ix1 hlgt01 1 hlgt pref ter | | m | Hlgt_code |
| ix1_hlgt02 1_hlgt_pref_teri | | m | 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.

| Field Name | Field A | ttributes | |
|----------------|-----------------|------------------------|--|
| hlgt_code | long int | eger, 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 Attribute | es |
|------------------------------|------------|------------------------|-------------------|
| 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) | |
| Index Name | Table Name | | Field(s) to Index |
| ix1_soc01 | 1_soc_term | | Soc_code |
| ix1_soc02 | 1_soc_term | <u>-</u> | Soc_name |

Table 3-7. 1_soc_term Derived from MedDRA file: soc.asc

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

| Field Name | | Field Attribute | s |
|----------------|-----------------|------------------------|---------------------|
| soc_code | | long integer, no | t 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

| Field Name | | Field Attribute | s |
|----------------|---------------|----------------------|-------------------|
| pt_code | | long integer, no | t null |
| hlt_code | | long integer, no | t null |
| hlgt_code | | long integer, no | |
| soc_code | | long integer, no | |
| pt_name | | char (100), not | |
| hlt_name | | char (100), not | |
| hlgt_name | | char (100), not | |
| 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_hierarch | | Pt_code |
| ix1_md_hier02 | | | Hlt_code |
| ix1_md_hier03 | | | Hlgt_code |
| ix1_md_hier04 | 1_md_hierarch | y | Soc_code |
| ix1_md_hier05 | 1_md_hierarch | y | Pt_soc_code |

Table 3-9. 1_md_hierarchy Derived from MedDRA file: mdhier.asc

| Field Name | | Field Attribute | s |
|----------------|------------------|------------------|-------------------------|
| intl_ord_code | | long integer, no | t null |
| soc_code | | long integer, no | t 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 Attri | butes |
|-----------------|------------|-------------|-------------------|
| smq_code | | Long integ | er, not null |
| smq_name | | Char (100) | , not null |
| smq_level | | Integer, no | t null |
| smq_description | | VarChar*, | not null |
| smq_source | | VarChar* | |
| smq_note | | VarChar* | |
| MedDRA_version | | Char (5), n | ot null |
| status | | Char (1), n | ot null |
| smq_algorithm | | VarChar, n | ot null |
| Index Name | Table Name | | Field(s) to Index |
| ix1_smq_list01 | 1_smq_list | <u> </u> | 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.

| Field Name | | Field Attri | butes |
|-----------------------------|---------------|-------------|-------------------|
| smq_code | | Long integ | er, not null |
| term_code | | Long integ | er, not null |
| term_level | | Integer, no | ot null |
| term_scope | | Integer, no | ot null |
| term_category | | Char (1), n | ot null |
| term_weight | | Integer, no | ot null |
| term_status | | Char (1), n | ot null |
| term_addition_version | | Char (5), n | ot null |
| term_last_ modified_version | | Char (5), n | ot 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

4. TABLE DEFINITION

This section defines the fields in each MedDRA table.

| Table Name | Field Name | Description |
|------------------|------------------------------|---|
| 1 low level term | Ilt_code | 8-digit code to identify the Lowest Level Term |
| | Ilt name | Full name of the Lowest Level Term |
| | pt code | 8-digit code to identify the Preferred Term |
| | Ilt whoart code ⁺ | Code allocated by the WHO-ART© terminology |
| | Ilt harts code⁺ | Code allocated by the HARTS© terminology |
| | Ilt costart sym ⁺ | Symbol allocated by the COSTART© terminology |
| | Ilt icd9 code+ | Code allocated by the 9 th Revision of the |
| | | International Classification of Diseases, ICD-9 |
| | Ilt_icd9cm_code+ | Code allocated by the 9 th Revision of the |
| | | International Classification of Diseases, Clinical |
| | | Modification, ICD-9-CM© |
| | Ilt_icd10_code⁺ | Code allocated by the 10 th Revision of the |
| | | International Classification of Diseases, ICD-10© |
| | Ilt_currency | Indicates whether the Lowest Level Term is current |
| | | or non-current |
| | llt_jart_code⁺ | Code allocated by the J-ART terminology |
| 1_pref_term | 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 th Revision of the |
| | | International Classification of Diseases |
| | pt_icd9cm_code+ | Code allocated by the 9 th Revision of the |
| | | International Classification of Diseases, Clinical |
| | | Modification |
| | pt_icd10_code ⁺ | Code allocated by the 10 th Revision of the |
| | | International Classification of Diseases |
| 4 1 14 6 4 | pt_jart_code ⁺ | Code allocated by the J-ART terminology |
| 1_hlt_pref_term | 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 by the 9 th Revision of the |
| | Into the document of the | International Classification of Diseases |
| | hlt_icd9cm_code+ | Code allocated by the 9 th Revision of the |
| | | International Classification of Diseases, Clinical Modification |
| | hlt_icd10_code⁺ | Code allocated by the 10 th Revision of the |
| | | International Classification of Diseases |
| | hlt_jart_code ⁺ | Code allocated by the J-ART terminology |
| 1_hlt_pref_comp | hlt_code | 8-digit code to identify the High Level Term |
| | pt_code | 8-digit code to identify the Preferred Term |
| 1_hlgt_pref_term | hlgt_code | 8-digit code to identify the High Level Group Term |

Table Definition

| Table Name | Field Name | Description |
|------------------|-------------------------------|--|
| - | 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 th Revision of the |
| | 19 | International Classification of Diseases |
| | hlgt icd9cm code⁺ | Code allocated by the 9th Revision of the |
| | | International Classification of Diseases, Clinical |
| | | Modification |
| | hlgt_icd10_code⁺ | Code allocated by the 10 th Revision of the |
| | | International Classification of Diseases |
| | hlgt_jart_code⁺ | 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+ | 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 th Revision of the |
| | 000_1040_0040 | International Classification of Diseases |
| | soc icd9cm code+ | Code allocated by the 9 th Revision of the |
| | | International Classification of Diseases, Clinical |
| | | Modification |
| | soc_icd10_code+ | Code allocated by the 10 th Revision of the |
| | | International Classification of Diseases |
| | soc_jart_code ⁺ | Code allocated by the J-ART terminology |
| 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 |
| | | |
| 1_smq_list | smq_code | |
| | sma name | |
| | Jinq_name | |
| 1_smq_list | smq_code smq_name | Term Eight-digit numeric code assigned to the SMQ, which starts with "2" Name for the SMQ, each SMQ carries "(SMQ)" at the end of the name |

| Table Name | Field Name | Description |
|---------------|--------------------------------|--|
| | 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_versi on | 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 removed codes is available on the MedDRA 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.

| Join Table 1 | Join Table 2 | Table 1 Field Name | Table 2 Field Name |
|------------------|------------------|--------------------|--------------------|
| 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 |
| 1_low_level_term | 1_smq_content | Ilt_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.

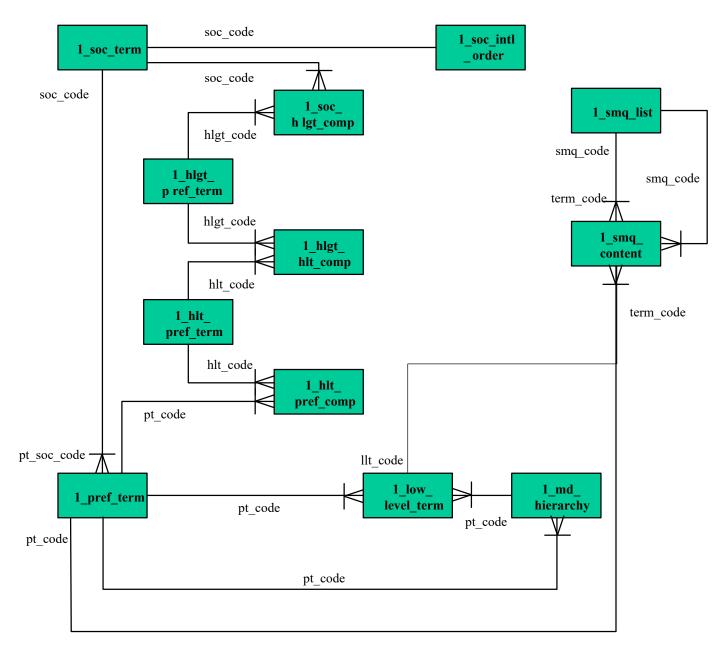


Figure 6-1. MedDRA Data Model

7. CONSECUTIVE FILE INFORMATION

This section lists the MedDRA consecutive files. Each consecutive file is in extended ASCII format for English and most of the Western European language translations. All other supported languages use UTF-8 file format. Table 7-1 lists the consecutive files and associated MedDRA tables. The record counts for the files in Table 7-1 for a given release may be found in the corresponding "What's New" document for that release.

| File Name ¹ | MedDRA Table |
|------------------------|------------------|
| hlgt.seq | 1_hlgt_pref_term |
| hlgt_hlt.seq | 1_hlgt_hlt_comp |
| hlt.seq | 1_hlt_pref_term |
| hlt_pt.seq | 1_hlt_pref_comp |
| Ilt.seq | 1_low_level_term |
| mdhier.seq | 1_md_hierarchy |
| pt.seq | 1_pref_term |
| soc.seq | 1_soc_term |
| soc_hlgt.seq | 1_soc_hlgt_comp |
| intl_ord.seq | 1_soc_intl_order |

Table 7-1. MedDRA Consecutive Files

¹Record counts for the files above may be found in the "What's New" document.

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).

| Field Names | Field Attributes | |
|------------------|----------------------------|--|
| Ilt_version_date | date, not null, dd/mm/yyyy | |
| Ilt_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) | |
| Ilt_harts_code | long integer | |
| llt_costart_sym | char (21) | |
| Ilt_icd9_code | char (8) | |
| Ilt_icd9cm_code | char (8) | |
| Ilt_icd10_code | char (8) | |
| Ilt_currency | char (1) | |
| llt_jart_code | char (6) | |

Table 8-1. MedDRA Consecutive File: Ilt.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

9. CONSECUTIVE FIELD DEFINITIONS

This section defines the fields in each MedDRA consecutive file.

| File Names | Field Names | Description |
|------------|----------------------------|---|
| llt.seq | Ilt_version_date | Date when MedDRA version was released, |
| | | dd/mm/yyyy |
| | Ilt_action_code | Indicates record was added, deleted, or modified |
| | <pre>Ilt_mod_fld_num</pre> | 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. |
| | Ilt_code | 8-digit code to identify the Lowest Level Term |
| | Ilt_name | Full name of the Lowest Level Term |
| | pt_code | 8-digit code to identify the Preferred Term |
| | <pre>Ilt_whoart_code</pre> | Code allocated by the WHO-ART© terminology |
| | Ilt_harts_code | Code allocated by the HARTS© terminology |
| | Ilt_costart_sym | Symbol allocated by the COSTART© terminology |
| | Ilt icd9 code | Code allocated by the 9 th Revision of the |
| | | International Classification of Diseases, ICD-9© |
| | Ilt_icd9cm_code | Code allocated by the 9 th Revision of the |
| | | International Classification of Diseases, Clinical |
| | | Modification, ICD-9-CM© |
| | Ilt icd10 code | Code allocated by the 10 th Revision of the |
| | | International Classification of Diseases, ICD-10© |
| | Ilt_currency | Indicates whether the Lowest Level Term is current |
| | _ , | or non-current |
| | Ilt_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 th Revision of the |
| | | International Classification of Diseases |
| | pt_icd9cm_code | Code allocated by the 9 th Revision of the |
| | | International Classification of Diseases, Clinical |
| | | Modification 40th Decisions of the |
| | pt_icd10_code | Code allocated by the 10 th Revision of the |
| | | International Classification of Diseases |
| | pt_jart_code | Code allocated by the J-ART terminology |

| Field Names | Description |
|-------------------|--|
| 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 th Revision of the |
| | International Classification of Diseases |
| hlt_icd9cm_code | Code allocated by the 9 th Revision of the |
| | International Classification of Diseases, Clinical |
| | Modification |
| hlt_icd10_code | Code allocated by the 10 th Revision of the |
| | International Classification of Diseases |
| | Code allocated by the J-ART terminology |
| h_p_version_date | Date when MedDRA version was released, |
| | dd/mm/yyyy |
| | 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. |
| _ | 8-digit code to identify the High Level Term |
| | 8-digit code to identify the Preferred Term |
| hlgt_version_date | Date when MedDRA version was released, dd/mm/yyyy |
| hlgt action code | Indicates record was added, deleted, or modified |
| <u> </u> | Indicates a field number for each field that is |
| Ingr_mod_md_nam | 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. |
| hlat code | 8-digit code to identify the High Level Group Term |
| · · · - | Full name of the High Level Group Term |
| | Code allocated by the WHO-ART terminology |
| | Code allocated by the HARTS terminology |
| <u> </u> | Symbol allocated by the COSTART terminology |
| | Code allocated by the 9 th Revision of the |
| 3 _ 3 | International Classification of Diseases |
| hlat icd9cm code | Code allocated by the 9 th Revision of the |
| | International Classification of Diseases, Clinical |
| | Modification |
| hlat icd10 code | Code allocated by the 10 th Revision of the |
| 9 | International Classification of Diseases |
| 1 | |
| | hlt_version_date hlt_action_code hlt_mod_fld_num hlt_code hlt_name hlt_whoart_code hlt_harts_code hlt_costart_sym hlt_icd9_code hlt_icd9cm_code |

| File Names | Field Names | Description |
|--------------|------------------|---|
| hlgt_hlt.seq | h_h_version_date | Date when MedDRA version was released, |
| | | 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 th Revision of the |
| | | International Classification of Diseases |
| | soc_icd9cm_code | Code allocated by the 9 th Revision of the |
| | | International Classification of Diseases, Clinical Modification |
| | soc_icd10_code | Code allocated by the 10 th 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 |

| File Names | Field Names | Description |
|--------------|-----------------------|--|
| | 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 |
| Intl_ord.seq | intl_ord_version_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