SMQ SAS® Dataset Macro

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ABSTRACT

A Standardized MedDRA Query (SMQ) is a grouping of terms from one or more SOCs that relate to a defined medical condition or area of interest. SMQs are created to standardize identification and retrieval of safety data. SMQs are part of each new MedDRA release, which is maintained by MSSO and JMO, and correspond to the terms present in that version of MedDRA. SMQs have been applied in safety and medical reviews, focused searches, signal detections, case alert, and periodic updates for clinical trials and post-marketing analyses and reports.

At each new MedDRA release, we will have MedDRA and SMQ ASCII files downloaded from MedDRA dictionary. These ASCII files are with a well-defined hierarchy structure. However, SMQs with child SMQs may not directly link to Preferred Term (PT)/Lower Lever Term (LLT) codes. These files cannot be utilized directly in SAS® programming for queries. It is necessary to covert the original SMQ files to SAS® datasets with a user-friendly structure.

The SAS® macro introduced in this paper will covert SMQ ASCII files to SAS® datasets. The SMQ SAS® dataset is re-structured so that the parent and child SMQs are directly linked to their corresponding PT/LLT codes. The macro produces a single SAS® dataset including all SMQ definitions for one MedDRA version. The SMQ dataset will be used to support medical and safety reviews, to generate CDISC compliant datasets, and to support clinical study analysis.

INTRODUCTION

Standardized MedDRA Queries (SMQs) are created to standardize identification and retrieval of safety data.

SMQs are a joint effort of the Council for International Organizations of Medical Sciences (CIOMS), ICH (including Maintenance and Support Services Organization (MSSO) and Japanese Maintenance Organization (JMO)) representing both industry and regulatory authorities. An SMQ is a grouping of terms from one or more SOCs that relate to a defined medical condition or area of interest. The terms included relate to signs, symptoms, diagnoses, syndromes, physical findings, laboratory and other physiologic test data, etc. that are associated with the medical condition or area of interest. SMQs are part of each new MedDRA release, which is maintained by MSSO and JMO, and correspond to the terms present in that version of MedDRA.

Changes to SMQs that can occur with each MedDRA version include (but are not limited to) the following:

- Addition of PTs

- Inactivation of a PT (i.e., effectively "removing" a PT from an SMQ)

- Change of term scope (e.g., a narrow term becomes a broad term)

- Restructuring of an SMQ (e.g., change in the hierarchical position of an SMQ)

- Creation of a new SMQ

During Medical query, the MedDRA version of the SMQ and the coded clinical data being searched have to be the same. Mismatch version could produce unexpected results.

(MedDRA® DATA RETRIEVAL AND PRESENTATION: POINTS TO CONSIDER, ICH-Endorsed Guide for MedDRA Users on Data Output, Release 3.13, Based on MedDRA Version 20.0, 1 March 2017, http://www.mssotools.com/mssoweb/PTC/drp_ptc_r313.html)

SMQs have been applied in safety and medical reviews, focused searches, signal detections, case alert, and periodic updates for clinical trials and post-marketing analyses and reports.

SMQ SAS® DATASET GENERATION

PROCESS

Figure 1 is a flowchart to show the process of the generation from SMQ ASCII files to a SMQ SAS® dataset.
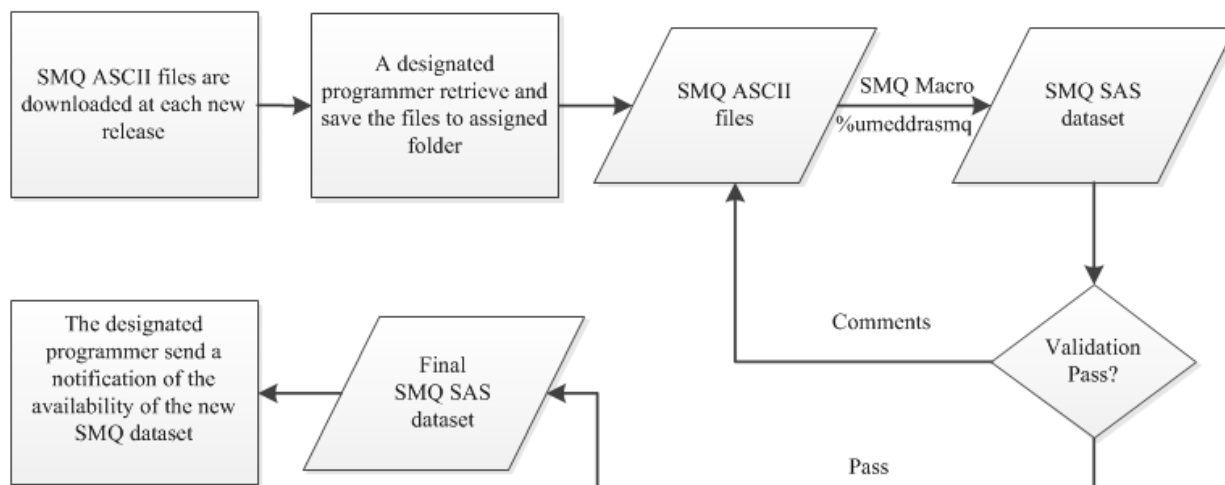

Figure 1. Flowchart

REQUIRED COMPONENTS

The following components are required to generate the SMQ SAS® dataset:

- SMQ ASCII package transferred from PVRM, which contains:
  - Two SMQ ASCII files
    - smq_list.asc
    - smq_content.asc
  - Two MedDRA ASCII files
    - pt.asc
    - llt.asc
  - Guidance and information on the updates in the newer version
- SAS® macro: %medrasmq.

MEDDRA AND SMQ ASCII FILES

SMQ ASCII files

The following are the two original SMQ ASCII files, which are '$' delimited:

- smq_list.asc   : List of Standardized MedDRA Queries (SMQs)
- smq_content.asc   : Map the SMQs to a standard MedDRA hierarchy

Table 1 below shows the detailed description of all columns included in the smq_list.asc. smq_list.asc contains one observation per SMQ.

Column Name	Description
smq_code	Unique SMQ identifier; used to link smq_content.asc
smq_name	Name of SMQ
smq_level	Reference to the value within the hierarchy of SMQs. e.g. MedDRA version 21.0 has 102 SMQs with level 1, and 120 subordinate SMQs with level 2, 3, 4 or 5.
smq_description	Description of SMQ
smq_source	Medical references for SMQ
smq_note	Additional information of SMQ
MedDRA_version	Associated MedDRA version. * Must match with the MedDRA version of the coding in the clinical data that will be queried.
status	Status of SMQ: A = Active, I = Inactive. * Only active SMQs may be used in queries.
smq_algorithm	Boolean expression if SMQ was developed for use with an algorithm

Table 1. smq_list.asc

Display 1 is a screenshot of smq_list.asc when opened in NotePad.
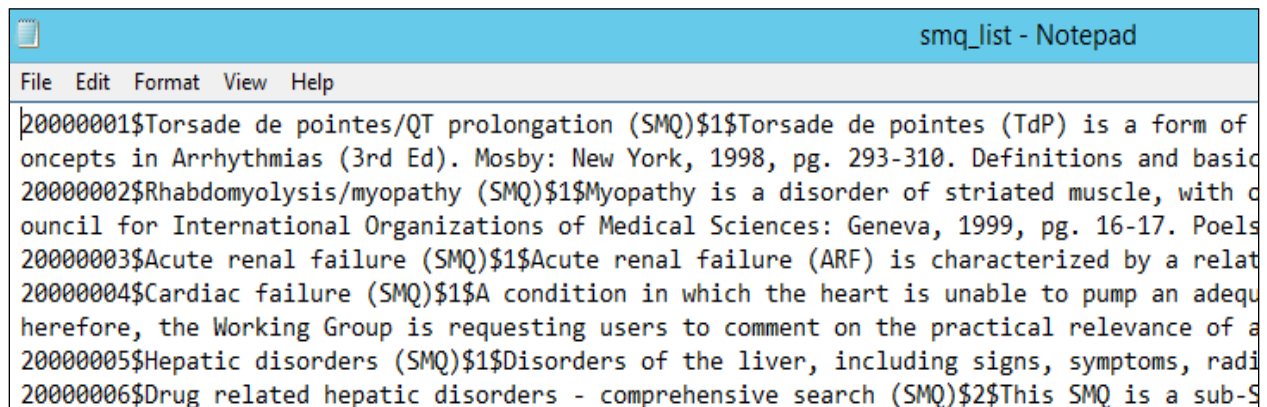
Display 1. A screenshot of smq_list.asc opened in NotePad

Display 2 is a screenshot of smq_list SAS® dataset.

| smq_code	smq_name	smq_level	smq_description	smq_source	smq_note	meddra_version	status	smq_algorithm
20000001	Torsade de poi...	1	Torsade de pointes...	Zipes DP. Spe...	1. Includes sud...	21.0	A	N
20000002	Rhabdomyolysi...	1	Myopathy is a diso...	Basic requirem...	1. Renal impair...	21.0	A	N
20000003	Acute renal fail...	1	Acute renal failure...	The Merck Ma...		21.0	A	N
20000004	Cardiac failure...	1	A condition in whic...	Council for Inte...	The CIOMS W...	21.0	A	N
20000005	Hepatic disord...	1	Disorders of the liv...	Harrison's Prin...		21.0	A	N
20000006	Drug related he...	2	This SMQ is a sub-...			21.0	A	N
20000007	Drug related he...	3	This SMQ is a sub-...			21.0	A	N
20000008	Liver related in...	3	This SMQ is a sub-...			21.0	A	N
20000009	Cholestasis an...	3	This SMQ is a sub-...			21.0	A	N
20000010	Hepatitis, non-i...	4	This SMQ is a sub-...			21.0	A	N
20000011	Liver neoplasm...	4	This SMQ is a sub-...			21.0	A	N
20000012	Liver neoplasm...	4	This SMQ is a sub-...			21.0	A	N
20000013	Hepatic failure,...	4	This SMQ is a sub-...			21.0	A	N
20000014	Congenital, fa...	2	This SMQ is a sub-...			21.0	A	N
20000015	Liver-related co...	3	This SMQ is a sub-...			21.0	A	N
20000016	Liver infections...	2	This SMQ is a sub-...			21.0	A	N
20000017	Hepatic disord...	2	This SMQ is a sub-...			21.0	A	N
20000018	Pregnancy-rela...	2	This SMQ is a sub-...			21.0	A	N
20000019	Haemolytic dis...	1	Hemolytic anemia i...	Reporting Adve...		21.0	A	N
20000020	Severe cutane...	1	This SMQ was dev...	Roujeau JC an...		21.0	A	N
20000021	Anaphylactic re...	1	Anaphylaxis is an...	1 The Merck M...	The following a...	21.0	A	A or (B and C) or...
20000022	Acute pancreat...	1	Drug-induced panc...	1. Anonymous...	To apply algorit...	21.0	A	A or (B and C)
20000023	Agranulocytosi...	1	Agranulocytosis ca...	1. Reporting A...	If possible, full...	21.0	A	N
20000024	Angioedema (S...	1	Urticaria: o Many p...	1. Bankowski Z...		21.0	A	N
20000025	Asthma/bronch...	1	Asthma is a chroni...	1. CIOMS publi...		21.0	A	N
20000026	Dyslipidaemia (...	1	Altered, most often...	1. Harrison's Pr...		21.0	A	N
20000027	Haematopoieti...	1	In the CIOMS publi...	CIOMS publica...	Cases with no l...	21.0	A	N
20000028	Haematopoieti...	2	In the CIOMS publi...	CIOMS publica...	Cases with no l...	21.0	A	N
20000029	Haematopoieti...	2	In the CIOMS publi...	CIOMS publica...	Cases with no l...	21.0	A	N

Display 2. A screenshot of smq_list data after imported to SAS®

Table 2 below shows the detailed description of all columns included in the smq_content.asc. smq_content.asc can contain multiple entries per SMQ including MedDRA PT/LLT codes as well as subordinate SMQs.

Column Name	Description
smq_code	Unique SMQ identifier; used to link smq_list
term_code	contain MedDRA PT, LLT, or child SMQ
term_level	Level of terms: 4 = PT, 5 = LLT, 0 = child SMQ. Note: a child SMQ points to other SMQs. If a child SMQ is in the list, all of the Preferred Terms and Lowest Level Terms from the child SMQ must be included.
term_scope	Scope of terms: broad scope=1, narrow scope = 2, child SMQ scope= 0
term_category	Use with Algorithms in smq_list. If child SMQ - S. A, B, C, D, …. See the Note for the details below.
term_weight	Used with some algorithms, applicable only for algorithmic search that uses weighing. 0 = default.
term_status	Status of teams: A = Active. I = Inactive.
term_addition_version	The version of MedDRA when the term was added to the SMQ
term_last_modified_version	The version of MedDRA when the term was last modified in this SMQ.

Table 2. smq_content.asc

Display 3 is a screenshot of smq_content.asc when opened in NotePad.
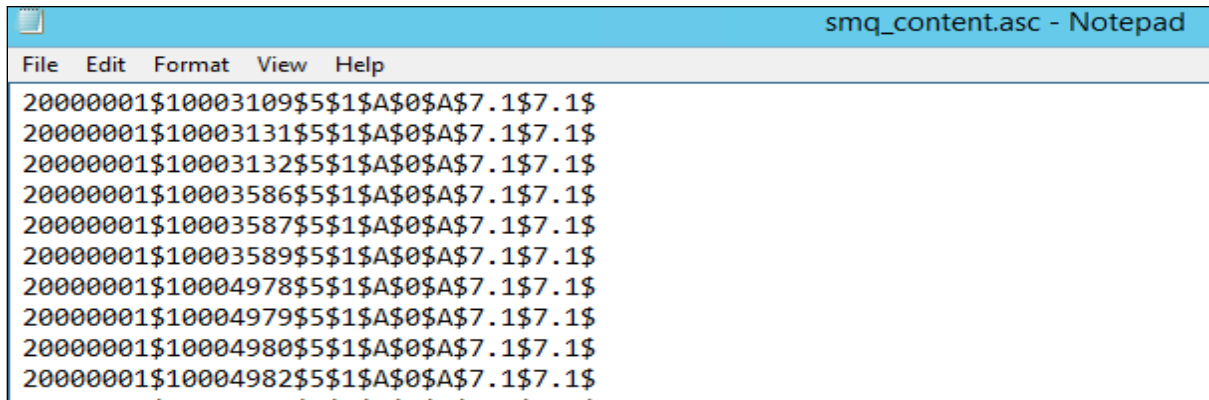
Display 3. A screenshot of smq_content.asc opened in NotePad

Display 4 is a screenshot of smq_content SAS® dataset.

smq_code	term_code	term_level	term_scope	term_category	term_weight	term_status	term_addition_version	term_last_modified_version
20000001	10003109	5	1	A	0	A	7.1	7.1
20000001	10003131	5	1	A	0	A	7.1	7.1
20000001	10003132	5	1	A	0	A	7.1	7.1
20000001	10003586	5	1	A	0	A	7.1	7.1
20000001	10003587	5	1	A	0	A	7.1	7.1
20000001	10003589	5	1	A	0	A	7.1	7.1
20000001	10004978	5	1	A	0	A	7.1	7.1
20000001	10004979	5	1	A	0	A	7.1	7.1
20000001	10004980	5	1	A	0	A	7.1	7.1
20000001	10004982	5	1	A	0	A	7.1	7.1
20000001	10004983	5	1	A	0	A	7.1	7.1
20000001	10007515	4	1	A	0	A	7.1	7.1
20000001	10007517	5	1	A	0	A	7.1	7.1
20000001	10007565	5	1	A	0	A	7.1	7.1
20000001	10007617	4	1	A	0	A	7.1	7.1
20000001	10007644	5	1	A	0	A	7.1	7.1
20000001	10010683	5	1	A	0	A	7.1	7.1
20000001	10010766	5	1	A	0	A	7.1	7.1
20000001	10010771	5	1	A	0	A	7.1	7.1
20000001	10010772	5	1	A	0	A	7.1	7.1
20000001	10011915	5	1	A	0	A	7.1	7.1
20000001	10011938	5	1	A	0	A	7.1	7.1

Display 4. A screenshot of smq_content data after imported to SAS®

In smq_content file, SMQ structure is like the following:

- When term_level = 4, the term_code represents the PT code. All PTs related to the defined SMQ are included.

- When term_level = 5, the term_code contains the LLT code. Only LLTs associated with PTs used in the SMQ are included.

- When term_level = 0, the term_code includes child SMQ codes. SMQs can have multiple levels.

Term_code starts with digit 1 when term_level is 4 or 5. Term_code starts with digit 2 when term_level is 0. The term_category and term_weight columns are only used for algorithmic SMQs (i.e. developed for use with an algorithm search).

Note:

For those SMQs that are algorithmic, the broad search terms are divided into various categories so that a defined combination of terms may be applied. In algorithmic SMQs, narrow search terms are always Category A, and broad search terms are always Categories B, C, D, etc. For example, in Acute pancreatitis (SMQ), the broad search terms are grouped into two categories: Category B is a list of laboratory values and Category C is a list of signs and symptoms. The algorithm for Acute pancreatitis (SMQ) Introduction defines a case of interest as a record coded with one of the Category A (narrow scope) terms OR a record coded with one of the Category B AND one of the Category C terms. Display 5 is an example of algorithm SMQs.

smq_code	smq_name	smq_level	smq_descri...	smq_source	smq_note	meddra_version	status	smq_algorithm
20000022	Acute pancreatitis (SMQ)	1	Drug-induced p...	1. Anonymous...	To apply algorit...	21.0	A	A or (B and C)

smq_name='Acute pancreatitis (SMQ)'

Display 5. Acute pancreatitis (SMQ) algorithm

For SMQ 'Anticholinergic syndrome (SMQ)', the categories are defined as following:

- Category A (narrow scope) : Cases encoding to PT Anticholinergic syndrome

- Category B (broad scope)   : Nervous system-related PTs

- Category C (broad scope)   : Psychiatric-related PTs

- Category D (broad scope)   : Other relevant anticholinergic syndrome-related PTs

Display 6 is an example on how to expand to LLTs and PTs when term_level is 0:

SMQ 20000005 is part of hierarchical SMQs with term_level=0. Each row that has term_level 0 has to be replaced with the rows of the child SMQ whose code is given in term_code. A child SMQ can have its own child SMQs. See the figure below. SMQ 20000005 includes 5 separate SMQs (20000006, 20000014, 20000016, 20000017 and 20000018). And, one of the child SMQs (20000006) has its own child SMQs (20000007, 20000008, 20000009, and 20000015). Again, child SMQ 20000007 has its own child SMQs (20000010, 20000011, 20000012, and 20000013). Finally, child SMQ 20000011 has its own child SMQs (20000208, 20000209).

smq_code	term_code	term_level	term_scope	term_catego...	term_weight	term_status
20000005	20000006	0	0	S	0	A
20000005	20000014	0	0	S	0	A
20000005	20000016	0	0	S	0	A
20000005	20000017	0	0	S	0	A
20000005	20000018	0	0	S	0	A
20000006	20000007	0	0	S	0	A
20000006	20000008	0	0	S	0	A
20000006	20000009	0	0	S	0	A
20000006	20000015	0	0	S	0	A
20000007	20000010	0	0	S	0	A
20000007	20000011	0	0	S	0	A
20000007	20000012	0	0	S	0	A
20000007	20000013	0	0	S	0	A
20000011	20000208	0	0	S	0	A
20000011	20000209	0	0	S	0	A

Display 6. SMQ 20000005 of hierarchical SMQs

Different version of MedDRA SMQs may contain different levels, e.g. MedDRA version 21.0 contains 5 hierarchical levels, and MedDRA 17.0 contains 4 hierarchical levels. Display 7 is a tree chart to show the SMQ hierarchical structure.
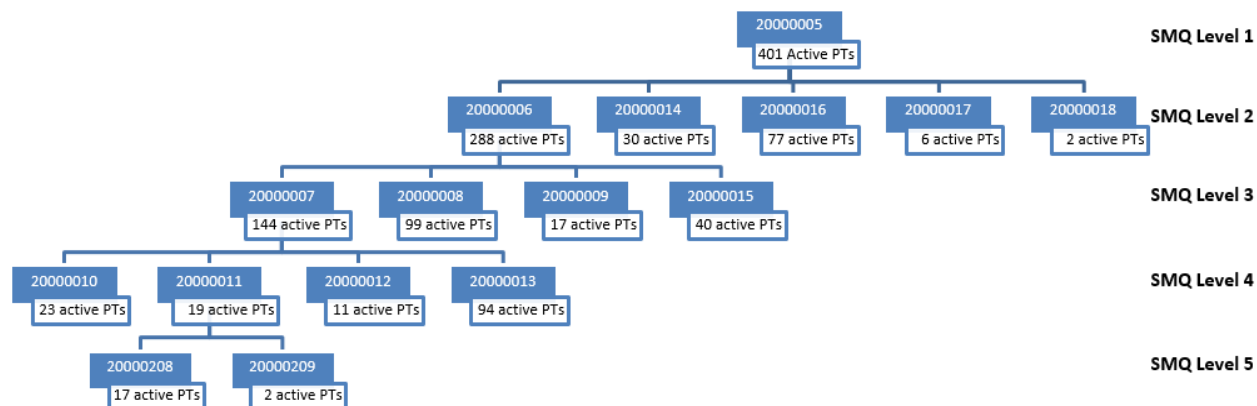
Display 7. Example of SMQ structure

Thus, SMQ 20000005 includes all PTs from its child SMQs 20000006, 20000014, 20000016, 20000017, and 20000018, whereby in turn SMQ 20000006 includes all PTs from its child SMQs 20000007, 20000008, 20000009 and 20000015. In the same way, SMQ 20000007 includes all PTs from its child SMQs 20000010, 20000011, 20000012, and 20000013. Also, SMQ 20000011 includes all PTs from its child SMQs 20000208 and 20000209.

It could easily be assumed that the number of PTs in one SMQ should be the sum of the number of PTs in its child SMQs. However it may not always be sure. For example, the 19 active PTs (of SMQ 20000011) equal to the sum of 17 active PTs (of SMQ 20000208) + 2 active PTs (of SMQ 20000209). But the number (144) of active PTs in SMQ 20000007 does not equal to the sum (147) of the number of PTs in its child SMQs (20000010, 20000011, 20000012, and 20000013). This is because SMQs 20000010, 20000011, 20000012, and 20000013 are not mutually exclusive: three PTs (10019772, 10053219, and 10076331) are included in both SMQs 20000010 and 20000013. Display 8 is a screenshot to show three PTs linked to two different SMQs.

smq_code	term_code	term_level	term_scope	term_catego...	term_weight	term_status
20000010	10019772	4	2	A	0	A
20000013	10019772	4	2	A	0	A
20000010	10053219	4	2	A	0	A
20000013	10053219	4	2	A	0	A
20000010	10076331	4	2	A	0	A
20000013	10076331	4	2	A	0	A

Display 8. Three PTs linked to two different SMQs

In the final SMQ SAS® dataset, for SMQ 20000005, all PTs and LLTs under its child SMQs and sub-child SMQs of all hierarchical levels will be presented in a row (record). Since one PT code usually is linked to multiple LLT codes, there may be many more records after LLT codes are added.

Display 9 shows some examples. For SMQ 20000005, one PT code 10000746 linked to multiple LLT codes 10000745 and 10000746. This is similar for PT code 10000804, 10001547, and 10001551.

smq_code	smq_name	smq_level	meddra_version	status	smq_algorit...	ptcd	lltcd
20000005	Hepatic disorders (SMQ)	1	21.0	A	N	10000028	10000028
20000005	Hepatic disorders (SMQ)	1	21.0	A	N	10000746	10000745
20000005	Hepatic disorders (SMQ)	1	21.0	A	N	10000746	10000745
20000005	Hepatic disorders (SMQ)	1	21.0	A	N	10000746	10000746
20000005	Hepatic disorders (SMQ)	1	21.0	A	N	10000804	10000804
20000005	Hepatic disorders (SMQ)	1	21.0	A	N	10000804	10017469
20000005	Hepatic disorders (SMQ)	1	21.0	A	N	10000804	10049844
20000005	Hepatic disorders (SMQ)	1	21.0	A	N	10001547	10001547
20000005	Hepatic disorders (SMQ)	1	21.0	A	N	10001547	10001548
20000005	Hepatic disorders (SMQ)	1	21.0	A	N	10001547	10058473
20000005	Hepatic disorders (SMQ)	1	21.0	A	N	10001551	10001550
20000005	Hepatic disorders (SMQ)	1	21.0	A	N	10001551	10001551
20000005	Hepatic disorders (SMQ)	1	21.0	A	N	10001551	10001845
20000005	Hepatic disorders (SMQ)	1	21.0	A	N	10001551	10018455
20000005	Hepatic disorders (SMQ)	1	21.0	A	N	10001551	10018456
20000005	Hepatic disorders (SMQ)	1	21.0	A	N	10001551	10018457
20000005	Hepatic disorders (SMQ)	1	21.0	A	N	10001551	10018643
20000005	Hepatic disorders (SMQ)	1	21.0	A	N	10001551	10018644
20000005	Hepatic disorders (SMQ)	1	21.0	A	N	10001551	10018645

Display 9. PT code linked to multiple LLT codes

MedDRA ASCII files

The following are the two original MedDRA ASCII files for expanding PTs and LLTs.

- pt.asc   : Preferred Term Derived from MedDRA file
- llt.asc   : Lowest Level Term Derived from MedDRA file

The pt.asc file contains PT codes and names. Table 3 shows the detailed description of all columns included in pt.asc:

Column Name	Description
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 9th Revision of the International Classification of Diseases
pt_icd9cm_code	Code allocated by the 9th Revision of the International Classification of Diseases, Clinical Modification
pt_icd10_code	Code allocated by the 10th Revision of the International Classification of Diseases
pt_jart_code	Code allocated by the J-ART terminology

Table 3. pt.asc

The llt.asc file contains LLT codes and names. Table 4 shows the detailed description of all columns included in llt.asc:

Column Name	Description
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 terminology
llt_harts_code	Code allocated by the HARTS terminology
llt_costart_sym	Symbol allocated by the COSTART terminology
llt_icd9_code	Code allocated by the 9th Revision of the International Classification of Diseases, ICD-9
llt_icd9cm_code	Code allocated by the 9th Revision of the International Classification of Diseases, Clinical Modification, ICD-9-CM
llt_icd10_code	Code allocated by the 10th Revision of the International Classification of Diseases, ICD-10
llt_currency	Indicates whether the Lowest Level Term is current or non-current
llt_jart_code	Code allocated by the J-ART terminology

Table 4. llt.asc

In pt.asc file, only pt_code is required for SMQ dataset. In llt.asc file, both pt_code and llt_code is required to link with the pt.asc file.

SAS® MACRO

Function:

Macro, %medrasmq, is designed to generate a SMQ dataset from the ASCII files of a given MedDRA version. Table 5 shows the description of parameters and the default value at SAS® macro %medrasmq.

Definition:

%medrasmq(version=, inpath=, outpath=);

Parameter	Default	Description
version		Numeric version of MedDRA
inpath		Full server path for MedDRA and SMQ ASCII files
outpath		Full server path for SMQ SAS® dataset

Table 5. SAS® macro %medrasmq

Sample call:

```
%medrasmq(version=21.0
          ,inpath=%str(/SAS®data/Data/Production/BDM/Tools/MedDRA/ MedDRA_dictionary/
          Extract/21_0/MedASCII)
          ,outpath=%str(/SAS®data/Data/Development/BDM/ToolsDev/Macros/Utility/MedDRA/
          SMQ/raw_data/other/21_0)
          );
```

Sample output:

smq_code	smq_name	smq_level	meddra_ver ...	status	smq_algorit...	ptcd	lltcd	ptscope	ptstat	ptaddv	ptmodv
20000001	Torsade de poi...	1	21.0	A	N	10007515	10003109	Broad	Active	7.1	7.1
20000001	Torsade de poi...	1	21.0	A	N	10007515	10003586	Broad	Active	7.1	7.1
20000001	Torsade de poi...	1	21.0	A	N	10007515	10003587	Broad	Active	7.1	7.1
20000001	Torsade de poi...	1	21.0	A	N	10007515	10003589	Broad	Active	7.1	7.1
20000001	Torsade de poi...	1	21.0	A	N	10007515	10007515	Broad	Active	7.1	7.1
20000001	Torsade de poi...	1	21.0	A	N	10007515	10007517	Broad	Active	7.1	7.1
20000001	Torsade de poi...	1	21.0	A	N	10007515	10010683	Broad	Active	7.1	7.1
20000001	Torsade de poi...	1	21.0	A	N	10007515	10019249	Broad	Active	7.1	7.1
20000001	Torsade de poi...	1	21.0	A	N	10007515	10021145	Broad	Active	7.1	7.1
20000001	Torsade de poi...	1	21.0	A	N	10007515	10041914	Broad	Active	7.1	7.1
20000001	Torsade de poi...	1	21.0	A	N	10007515	10078323	Broad	Active	7.1	7.1
20000001	Torsade de poi...	1	21.0	A	N	10007617	10007617	Broad	Active	7.1	7.1
20000001	Torsade de poi...	1	21.0	A	N	10007617	10007644	Broad	Active	7.1	7.1
20000001	Torsade de poi...	1	21.0	A	N	10014387	10014383	Narrow	Active	7.1	7.1
20000001	Torsade de poi...	1	21.0	A	N	10014387	10014387	Narrow	Active	7.1	7.1
20000001	Torsade de poi...	1	21.0	A	N	10014387	10024802	Narrow	Active	7.1	7.1
20000001	Torsade de poi...	1	21.0	A	N	10014387	10036887	Narrow	Active	7.1	7.1
20000001	Torsade de poi...	1	21.0	A	N	10014387	10037700	Narrow	Active	7.1	7.1

Display 10. SAS® output from macro %medrasmq

SMQ SAS® DATASET

The SMQ SAS® dataset is generated by running SAS® macro *%medrasmq* with input of original MedDRA and SMQ ASCII files. Table 6 shows the detailed description of all variables in the SMQ SAS® dataset.

Variable Name	Variable Label	Description
smqcd	SMQ code	Unique SMQ identifier. An 8-digit number starting with digit 2.
smqname	SMQ name	The name of SMQ
smqlvl	SMQ level	Reference to value within the hierarchy of SMQs
smqvers	SMQ version	Identifies the associated MedDRA version
smqstat	SMQ status	Active or Inactive
smqalgo	SMQ Algorithm	If SMQ was developed for use with an algorithm, contains the Boolean expression.
ptcd	Preferred Term Code	MedDRA PT code
ptscope	Term scope (PT)	Broad or Narrow
ptcat	Term category (PT)	Use with Algorithms. If child SMQ - S. If no algorithm - A.
ptwgt	Term weight (PT)	Used with some algorithms. 0 = default.
ptstat	Term status (PT)	Active or Inactive
ptaddv	Term Addition Version (PT)	The version of MedDRA where PT was added to the SMQ
ptmodv	Term Last modified Version (PT)	The version of MedDRA where PT was last modified in this SMQ.
lltcd	Lowest Level Term Code	MedDRA LLT code
lltscope	Term scope (LLT)	Broad or Narrow

Variable Name	Variable Label	Description
lltcat	Term category (LLT)	Use with Algorithms. If child SMQ - S. If no algorithm - A.
lltwgt	Term weight (LLT)	Used with some algorithms. 0 = default.
lltstat	Term status (LLT)	Active or Inactive
lltaddv	Term Addition Version (LLT)	The version of MedDRA where LLT was added to the SMQ
lltmodv	Term Last modified Version (LLT)	The version of MedDRA where LLT was last modified in this SMQ.
dictv	Dictionary Version	The version of MedDRA Dictionary

Table 6. Variables in SMQ SAS® dataset

SMQ code	SMQ name	SMQ level	SMQ version	SMQ status	SMQ Algorithm	Preferred Term Code	Term scope (PT)	Term category (PT)	Term weight (PT)	Term status (PT)	Term Addition Version (PT)	Term Last modified Version (PT)	Lowest Level Term Code	Term scope (LLT)	Term category (LLT)
20000001	Torsade de pointes/QT prolongation (SMQ)	1	20.1	Active	N	10007515	Broad	A	0	Active	7.1	7.1	10003109	Broad	A
20000001	Torsade de pointes/QT prolongation (SMQ)	1	20.1	Active	N	10007515	Broad	A	0	Active	7.1	7.1	10003586	Broad	A
20000001	Torsade de pointes/QT prolongation (SMQ)	1	20.1	Active	N	10007515	Broad	A	0	Active	7.1	7.1	10003587	Broad	A
20000001	Torsade de pointes/QT prolongation (SMQ)	1	20.1	Active	N	10007515	Broad	A	0	Active	7.1	7.1	10003589	Broad	A
20000001	Torsade de pointes/QT prolongation (SMQ)	1	20.1	Active	N	10007515	Broad	A	0	Active	7.1	7.1	10007515	Broad	A
20000001	Torsade de pointes/QT prolongation (SMQ)	1	20.1	Active	N	10007515	Broad	A	0	Active	7.1	7.1	10007517	Broad	A
20000001	Torsade de pointes/QT prolongation (SMQ)	1	20.1	Active	N	10007515	Broad	A	0	Active	7.1	7.1	10010683	Broad	A
20000001	Torsade de pointes/QT prolongation (SMQ)	1	20.1	Active	N	10007515	Broad	A	0	Active	7.1	7.1	10019249	Broad	A
20000001	Torsade de pointes/QT prolongation (SMQ)	1	20.1	Active	N	10007515	Broad	A	0	Active	7.1	7.1	10021145	Broad	A
20000001	Torsade de pointes/QT prolongation (SMQ)	1	20.1	Active	N	10007515	Broad	A	0	Active	7.1	7.1	10041914	Broad	A
20000001	Torsade de pointes/QT prolongation (SMQ)	1	20.1	Active	N	10007515	Broad	A	0	Active	7.1	7.1	10078323	Broad	A
20000001	Torsade de pointes/QT prolongation (SMQ)	1	20.1	Active	N	10007617	Broad	A	0	Active	7.1	7.1	10007617	Broad	A
20000001	Torsade de pointes/QT prolongation (SMQ)	1	20.1	Active	N	10007617	Broad	A	0	Active	7.1	7.1	10007644	Broad	A
20000001	Torsade de pointes/QT prolongation (SMQ)	1	20.1	Active	N	10014387	Narrow	A	0	Active	7.1	7.1	10014383	Narrow	A
20000001	Torsade de pointes/QT prolongation (SMQ)	1	20.1	Active	N	10014387	Narrow	A	0	Active	7.1	7.1	10014387	Narrow	A
20000001	Torsade de pointes/QT prolongation (SMQ)	1	20.1	Active	N	10014387	Narrow	A	0	Active	7.1	7.1	10024802	Narrow	A
20000001	Torsade de pointes/QT prolongation (SMQ)	1	20.1	Active	N	10014387	Narrow	A	0	Active	7.1	7.1	10036887	Narrow	A
20000001	Torsade de pointes/QT prolongation (SMQ)	1	20.1	Active	N	10014387	Narrow	A	0	Active	7.1	7.1	10037700	Narrow	A

Display 11. A screenshot of SMQ SAS® dataset

CONCLUSION

The SMQ macro will convert MedDRA and SMQ ASCII files to a SAS® dataset at each new MedDRA release. The SMQ SAS® dataset will be used in performing standardized MedDRA queries for active SMQs only. The generated SMQ SAS® dataset will also be used in creating CDISC compliant analysis data in clinical trials.

REFERENCES

Gary Chen, Shire Pharmaceuticals and David Shen, Independent Consultant. Paper HO02 "Practice of SMQs for Adverse Events in Analysis of Safety Data and Pharmacovigilance" PharmaSUG 2013, Chesterbrook, PA: https://www.pharmasug.org/proceedings/2013/HO/PharmaSUG-2013-HO02.pdf

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