MedDRA® DATA
RETRIEVAL AND PRESENTATION:
POINTS TO CONSIDER

Release draft
Based on MedDRA version 7.1

ICH-Endorsed Guide for MedDRA Users on
Data Output

18 November 2004
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1 INTRODUCTION

The Medical Dictionary for Regulatory Activities (MedDRA)\(^1\) was designed for the specific use of sharing regulatory information for human medical products. However, unless consistency can be achieved in the selection of terms for reported symptoms, signs, and diseases, etc. or in the methods used to retrieve data for evaluation, the terminology will yield little improvement over the divergent practices of the past.

The MedDRA terminology was developed as a medically validated medical terminology for utilization throughout the regulatory process\(^2\). MedDRA has a large number of very specific terms called Lowest Level Terms (LLTs) in order to accurately capture the reporter’s words (verbatim term). This large number of LLTs results in a correspondingly large number of Preferred Terms (PTs), a concept that is sometimes referred to as “granularity” and/or “specificity.”

A highly granular terminology minimizes the need for interpretation at data entry. However, classification of data received is only one part of the data management process that attempts to retrieve, sort and present data in the most understandable and reproducible way for the benefit of drug development, pharmacovigilance and risk management. Therefore, the developers of the terminology designed a structure that facilitates data retrieval in the form of grouping terms called High Level Terms (HLT) and High Level Group Terms (HGLT), which group very specific terms used for coding into broader medical concepts. Moreover, MedDRA’s feature of multi-axiality, in which PTs can be assigned to more than one SOC, allows flexibility in data retrieval via different routes. While these features of MedDRA allow a reasonable "first approach" to data retrieval, the complexity of MedDRA calls for guidance to optimize the results. The MedDRA Data Retrieval and Presentation: Points to Consider document is an ICH-endorsed guide for MedDRA users. It is designed to be updated based on MedDRA changes, and is a companion document to the MedDRA terminology. The principles described in this document are most effective when the user has followed the principles of the MedDRA Term Selection: Points to Consider document for data entry (i.e., coding).

This document was developed and is maintained by a working group charged by the ICH Steering Committee. Members of the working group include regulatory and industry representatives of the European Union, Japan and the United States, as well as representatives from Canada, the MedDRA Maintenance and Support Services Organization (MSSO), and Japanese Maintenance Organization (JMO). (See Appendix 1 for working group members.)

This document is intended to provide data retrieval and presentation options for either industry or regulatory purposes. The examples contained in this document are based on MedDRA version 7.1 and are intended to facilitate reader comprehension.

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1 MedDRA refers to all sequential and translated versions of the terminology, which are maintained by either the Maintenance and Support Services Organization (MSSO) or the Japanese Maintenance Organization (JMO).

2 From MedDRA 7.1 Introductory Guide
The examples presented are not intended to imply regulatory requirements. This document reflects a broad range of experience. It is expected that as experience with data retrieval and presentation of MedDRA-encoded data increases, there will be additions and perhaps changes to this document.

1.1 Objective

The objective of the MedDRA Data Retrieval and Presentation: Points to Consider document is to provide assistance and understanding of the implications that the various options for data retrieval have on the accuracy and consistency of the final output. For example, certain drugs and/or therapeutic areas might need a customized approach for data output. One should take into consideration the options for data input that are described in the MedDRA Term Selection: Points to Consider document or in company specific coding practices.

For reproducibility and understanding, organizations are encouraged to document their data retrieval and output strategies, methods and quality assurance procedures in organization–specific guidelines, which should be consistent with this document.

1.2 Applications of MedDRA

- To aggregate reported terms in medically meaningful groupings for the purpose of reviewing and/or analyzing safety data
- To facilitate identification of common data sets for evaluation of clinical and safety information
- To facilitate consistent retrieval of specific cases or medical conditions from a database
- To improve consistency in comparing and understanding safety signals and aggregated clinical data
- To facilitate electronic data interchange of clinical safety information
- To report adverse drug reaction/adverse event (ADR/AE) terms via individual case safety reports
- To report ADR/AEs in tables, analyses, and line listings
- To identify frequency of medically similar ADR/AEs
- To capture and present product indications, investigations, medical history and social history data

1.3 Background

This Points to Consider document has been prepared to help all MedDRA users begin on common ground, as the MedDRA terminology itself does not contain specific guidelines for its use. The document provides a framework to foster consistent use of MedDRA for data retrieval and presentation, with the goal of allowing medically meaningful review and analysis of clinical data.

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2 For ADR/AE definitions, refer to ICH Guidelines and CIOMS publications.
The intent of this document is to describe the possibilities of MedDRA and to highlight the impact of the structure, rules and conventions of MedDRA on data output. It is written to address principles only. The examples and options for use that are provided are not intended to communicate specific regulatory reporting requirements or address database issues. As this document cannot address every situation, medical judgment should always be applied.

This document is not a substitute for MedDRA training. It is considered essential that users have knowledge of the complexity and content of MedDRA. The reader should also refer to the MedDRA Introductory Guide and the MedDRA Term Selection: Points to Consider document.

1.4 Scope

The principles described in this document apply to all data encoded with MedDRA. The focus is on aggregated data. This document does not address the use of MedDRA for:

- Single case reporting
- Labeling
- Medical evaluation
- Statistical methodology

2 GENERAL PRINCIPLES

2.1 Quality of Source Data

High quality data output is dependent upon maintaining the quality of the information originally reported by using consistent and appropriate term selection. Organizations are encouraged to pursue continuous oversight of data quality. Data quality issues are also addressed in MedDRA Term Selection: Points to Consider.

Special consideration should be given to the methodology used for the conversion of data from other terminologies into MedDRA. The manner in which data were converted might impact retrieval and presentation strategies. For example, when data are converted directly from legacy terms to MedDRA terms, the results typically reflect only the specificity of the previous terminology; there is no benefit gained from the greater specificity of MedDRA.

**Example:**

Reported term: Bowel ischaemia
Legacy term: Gastrointestinal Disorder
MedDRA term: Gastrointestinal disorder

In contrast, data re-coded from the reported term to the MedDRA term retains the specificity of the reported term.
Example:
Reported term: Bowel ischaemia
Legacy term: Gastrointestinal Disorder
MedDRA term: Bowel ischaemia

It is important to clearly describe the data sets and to document the conversion process(es).

Consequences for data retrieval
Keep in mind that interpretation of the data output can be affected if the two methods described above are combined. For example, if legacy data have been converted directly from legacy terms to MedDRA terms and newly acquired data are coded in MedDRA, the difference in resulting specificities could be problematic.

When designing a search strategy, it might be appropriate to look at the verbatim terms for data converted using the first conversion method because if the query is based on specific MedDRA terms, the cases previously coded to a non-specific term might be overlooked. For example, if searching on bowel ischaemia, cases of bowel ischaemia that had been coded under the legacy term gastrointestinal disorder would be missed.

Should there be a need to conduct a search requiring this level of detail, it might be necessary to review or re-code the source data.

2.2 Quality Assurance of the Process of Data Retrieval and Presentation
Careful documentation of the coding conventions used for data entry is essential for understanding and reproducing results. Organizations are encouraged to document their data retrieval and presentation strategies, methods, and quality assurance procedures in organization-specific guidelines, which should be consistent with this document.

The MedDRA terminology is multi-axial and more complex than common terminologies previously used. Therefore, an individual with a medical background who is also trained in the use of MedDRA should review the data retrieval and presentation strategy.

MedDRA is a standardized terminology and the assignment of terms across System Organ Classes (SOCs) is pre-determined within the terminology; therefore, users should not alter it in any way. If users believe that term(s) are inappropriately placed in the hierarchy, they should inform the MedDRA MSSO via the change request process.

2.3 Organization-Specific Data Characteristics
Although MedDRA is intended to be a standardized terminology, there are variations in the way that implementation has been conducted. It is important to understand the organization-specific characteristics of both the data and the implementation strategies.

Each organization should have access to a MedDRA specialist who can provide
expert advice on MedDRA and has knowledge of the following characteristics of the database:

- Database structure (i.e., how hierarchy is stored and used)
- Data storage (e.g., level of term, synonym/reported term)
- Data migration from other terminologies to MedDRA
- Coding practices over time
- Limitations/restrictions (e.g., inability to view secondary SOCs or retrieve cases by secondary assignments)

Knowledge of term selection principles used by an organization for coding is also critical. The following term selection points (which are discussed in detail in *MedDRA Term Selection: Points to Consider* document) illustrate some of the factors to keep in mind when planning retrieval and presentation of data:

- Selecting more than one term when coding a medical condition increases counts of terms.
- Conversely, selecting a diagnosis term only (without also selecting terms for signs and symptoms) reduces the counts of terms.

This is very important to consider when reviewing adverse event profiles. The profile obtained when both diagnosis and signs and symptoms have been coded will appear very different than the profile obtained when only a diagnosis has been coded. An organization’s coding conventions should always be considered whenever the data from other databases (e.g., co-developing or co-marketing partners, regulators) are used and/or compared.

### 2.4 Impact of MedDRA’s Characteristics on Data Retrieval and Presentation

The structure, rules and conventions of MedDRA are detailed in the *MedDRA Introductory Guide*. The following characteristics of MedDRA need to be kept in mind for data retrieval and presentation:

**Grouping Terms - HLGTs and HLTs**

The hierarchy of MedDRA, in particular the HLGT and HLT levels, should be viewed as an additional tool to aid in data retrieval and presentation, as it provides clinically relevant groupings of terms.

**Example:**

<table>
<thead>
<tr>
<th>HLGT</th>
<th>Cardiac arrhythmias</th>
</tr>
</thead>
<tbody>
<tr>
<td>HLT</td>
<td>Cardiac conduction disorders</td>
</tr>
<tr>
<td>HLT</td>
<td>Rate and rhythm disorders NEC</td>
</tr>
<tr>
<td>HLT</td>
<td>Supraventricular arrhythmias</td>
</tr>
<tr>
<td>HLT</td>
<td>Ventricular arrhythmias and cardiac arrest</td>
</tr>
</tbody>
</table>

However, the user should review the terms within the HLGT or HLT of interest to ensure that all terms are suited for the purpose of the output. Note in the example below that terms describing changes in blood pressure in both
“directions” are grouped under a common HLT.

**Example:**

<table>
<thead>
<tr>
<th>HLT</th>
<th>Preferred Terms</th>
</tr>
</thead>
<tbody>
<tr>
<td>Vascular tests NEC (incl blood pressure)</td>
<td>Blood pressure decreased</td>
</tr>
<tr>
<td>Blood pressure increased</td>
<td>Blood pressure</td>
</tr>
<tr>
<td>Blood pressure abnormal</td>
<td></td>
</tr>
</tbody>
</table>

This HLT also includes many other PTs for parameters such as pulmonary arterial pressure, vascular resistance, haemodynamic tests, etc.

Clinically related PTs in MedDRA might be overlooked or not recognized as belonging together as they might exist in different locations within a single SOC.

**Example:**

<table>
<thead>
<tr>
<th>HLGT</th>
<th>Epidermal and dermal conditions</th>
</tr>
</thead>
<tbody>
<tr>
<td>HLT</td>
<td>Bullous conditions</td>
</tr>
<tr>
<td>PT</td>
<td>Stevens-Johnson syndrome</td>
</tr>
<tr>
<td>Blood pressure decreased</td>
<td></td>
</tr>
<tr>
<td>Blood pressure increased</td>
<td></td>
</tr>
<tr>
<td>Blood pressure abnormal</td>
<td></td>
</tr>
</tbody>
</table>

Hence, the overall frequency of a medical concept might be underestimated if the above points are not taken into consideration, possibly impacting the interpretation of the data.

### 2.5 Granularity

Unique medical concepts (PTs) in MedDRA are considerably more specific (i.e., “granular”) than terms on a comparable level of hierarchy in other terminologies. As a consequence of this specificity, related events that might have been represented by a single term in other terminologies might now be represented among more than one MedDRA PT. This can compromise signal detection.

The following table illustrates how data coded to a single PT from another terminology may be expressed by several PTs in MedDRA.

<table>
<thead>
<tr>
<th>OTHER TERMINOLOGY PREFERRED TERMS</th>
<th># SUBJ.</th>
<th>MEDDRA VERSION7.1 PREFERRED TERMS</th>
<th># SUBJ.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Infection</td>
<td>12</td>
<td>Upper respiratory tract infection</td>
<td>7</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Nasopharyngitis</td>
<td>2</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Infection</td>
<td>1</td>
</tr>
</tbody>
</table>
2.6 Multi-axiality

MedDRA is a multi-axial terminology, which means that a PT may be assigned to more than SOC. Multi-axiality allows terms to be grouped in different ways (e.g., by etiology or body system/site). Each PT is assigned to one primary SOC; assignments of that PT to other SOCs are considered secondary. Assignment of a single primary SOC prevents multiple counting.

MedDRA users should be aware of primary SOC assignment rules that will affect the way data are distributed across the terminology. Because MedDRA placement rules allow for terms related to a particular medical condition to reside in more than one SOC, users should be familiar with the general content and structure of all MedDRA SOCs to ensure that data are not overlooked.

Example:

All terms reflecting congenital events are primary to the SOC Congenital, familial and genetic disorders.

Example:

The primary assignment for PT Enterocolitis infectious is SOC Infections and infestations (with a secondary assignment to SOC Gastrointestinal disorders) whereas the primary assignment for PT Enterocolitis is SOC Gastrointestinal disorders.

Clinically related PTs in MedDRA could be overlooked or not recognized as belonging together because they might be distributed among two or more SOCs.

Example:

PT Thrombocytopenia is in SOC Blood and lymphatic system disorders
PT Platelet count decreased is in SOC Investigations

MedDRA’s 26 SOCs address anatomical locations and etiology, as well as purposes or other concepts; therefore, data might reside in SOCs that are not anticipated by the user. Thus, the impact of multi-axiality on frequencies of the medical condition of interest should be considered.

Example:

PT Post procedural haemorrhage has the primary SOC assignment of SOC Injury, poisoning and procedural complications
PT Chest pain has the primary SOC assignment of SOC General disorders and administration site conditions
Example:

For hepatic abnormality, SOC *Investigations*, should be searched (in addition to SOC *Hepatobiliary disorders*) to identify related laboratory test terms. Furthermore, SOC *Surgical and medical procedures* should be searched for related terms such as PT *Liver transplant*.

All possible secondary SOC assignments for any given concept may not exist in MedDRA. However, MedDRA is an evolving terminology and new or revised SOC assignments can be created in the future as a result of the change request process.

Users should also be aware that the following three SOCs do not have multi-axial assignments for any of their terms (i.e., terms assigned to these SOCs do not appear in any other SOC):

SOC *Investigations*
SOC *Surgical and medical procedures*
SOC *Social circumstances*

When designing retrieval strategies, one should not overlook terms in these SOCs.

Laboratory test results are not linked via multi-axiality to a corresponding medical condition. For example, PT *Blood glucose increased* is in SOC *Investigations* (its only SOC assignment) but PT *Hyperglycaemia* is in SOC *Metabolism and nutrition disorders* and has no link to SOC *Investigations*.

Tables or other views of the data need to take into account the impact of SOC *Investigations*. As illustrated in the table below, multiple MedDRA terms might be used to code very similar medical conditions and might be included in a “disorder SOC” while its associated laboratory finding is displayed in SOC *Investigations*.

<table>
<thead>
<tr>
<th>Reported Event (% subjects)</th>
<th>Coded Term (% subjects)</th>
<th>Body System/SOC (% subjects)</th>
<th>PT (% subjects)</th>
<th>SOC (% subjects)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hyperglycaemia (4.1)</td>
<td>Hyperglycaemia (10.5)</td>
<td>Metabolism &amp; nutritional disorders (10.5)</td>
<td>Hyperglycaemia (4.1)</td>
<td>Metabolism &amp; nutritional disorders (4.1)</td>
</tr>
<tr>
<td>Increased blood sugar (2.7)</td>
<td></td>
<td></td>
<td>Blood glucose increased (6.4)</td>
<td>Investigations (6.4)</td>
</tr>
<tr>
<td>Glucose increased (2.2)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Blood glucose high (1.0)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Increasing glucoses (0.5)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

### 2.7 Special Search Categories

As with other terminologies, some clinical conditions and syndromes cannot be fully represented in one MedDRA SOC. For example, anaphylaxis is manifested in various parts of the body at the same time and terms for related signs and symptoms are spread over more than one SOC; they are not completely grouped by one HLT or HLGT. MedDRA provides Special Search
Categories (SSCs) comprised entirely of PTs, which group terms relevant to a particular condition together across SOCs.

2.8 Standardized MedDRA Queries

Standardised MedDRA Queries (SMQs) are a joint effort of the Council for International Organizations of Medical Sciences (CIOMS) SMQ Working Group and ICH (MSSO/JMO). SMQs are groupings of terms from one or more SOCs that relate to a defined medical condition or area of interest. The terms included could 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 differ from SSCs in several ways:

- SMQs can contain grouping terms (HLTs and HLGTs) as well as PTs, whereas SSCs only contain PTs
- Development of SMQs is focused on highly relevant drug safety topics
- SMQs can have usage options such as “narrow” and “broad” sub-searches, hierarchical relationships between related SMQs and algorithmic design

2.9 MedDRA Versioning

The MedDRA terminology is updated twice per year. It is important to consider the impact of the changes (e.g., new terms or changes in primary SOC assignment) on retrieval and presentation strategies. Users should read the documentation provided with each MedDRA release, especially the What’s New document that lists the changes in detail. When planning or performing data retrieval and presentation, the version of MedDRA used should be documented.

The terms used for queries should be in the same MedDRA version as the data being queried. For example, new terms might have been included in a query built on MedDRA version 7.1 that might not be represented in stored data coded in MedDRA version 5.0; this could lead to search results that are incomplete. On the other hand, a search built on an earlier MedDRA version (e.g., from a closed study), might not detect all of the relevant data in an integrated safety summary (ISS) coded in a later version of MedDRA. Any queries stored in an organization’s system should be updated to the appropriate version of MedDRA prior to use on new data.

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4 [http://www.cioms.ch/frame_meddra_queries_oct_2004.htm](http://www.cioms.ch/frame_meddra_queries_oct_2004.htm) Contains an introduction to SMQs but the full publication is available only as a paper copy.
Publication = SMQs: Development and Rational use of Standardised MedDRA Queries (SMQs)
3 QUERIES and RETRIEVAL

3.1 General Principles:

Data retrieval is performed for summary and analysis of clinical trial data, pharmacovigilance, medical information queries and for a number of other purposes. The search strategies, methods and tools applied to retrieve the data might be different depending on the intended use of the output.

The user should be aware of particular database characteristics, organization-specific data entry conventions, data sources, and the size of the database. In addition, archives of previously used searches might be available, particularly for pharmacovigilance purposes; with updating, these may be suitable for reuse. The user should be aware of the version of MedDRA used in coding all data.

During the course of data retrieval, it is important that the user develop a clear understanding of the important safety issues as early in the search process as possible. Information from pre-clinical trials, the ADR/AE profile from clinical trials, knowledge of ADR/AE profiles of similar products, and regulatory queries can be useful in identifying areas of possible focus. Understanding some of these issues might affect the strategy for aggregation of search terms.

Capturing related adverse events into categories can be difficult; a search that is defined with parameters that are too narrow might exclude events of potential relevance, whereas parameters that are too broad might make it difficult to identify a trend or signal. The grouping of terms that describes a potential effect, whether or not it can be regarded as a syndrome, requires medical judgment and the results of the analysis should be carefully interpreted. For complex queries, it is advisable to create a data analysis plan.

In presenting adverse events, it is important to display and to group related events (i.e., events that represent the same condition of interest) so that the true occurrence rate of an event is not obscured. Search strategies should be documented and retrieved data should be adjudicated.

The following are examples of the types of searches for which these principles might apply:

- Overview of safety profile in a summary report, Periodic Safety Update Report (PSUR), ISS, etc.
- Comparison of the frequency of ADR/AE (reporting rates for spontaneous reports or incidence for studies)
- Analysis of a specific safety concern
- Identification of patient subpopulations at risk
3.2 Overall Presentation of Safety Profiles

The aim of an overall presentation of the safety profile is to highlight the distribution of ADR/AEs and to identify areas where more in depth analysis should be conducted. The data should be presented in a way that allows ready recognition of patterns of terms potentially associated with relevant medical conditions.

Historically, the standard approach has been to present data by "Body System" or "System Organ Class" and “Preferred Term” corresponding to SOCs and PTs in MedDRA. However, due to the unique characteristics of MedDRA previously described (granularity, multi-axiality, etc.), this type of presentation alone might not optimally represent the frequency of events and can even be misleading. For example, if a number of reports describe a similar medical condition, they could be represented under various specific PTs, thereby diluting the signal.

3.2.1 Overview by Primary System Organ Class

As a first look, one should display all data. This assures that all events will be seen and the overview might be useful in identifying clusters, perhaps in an HLT or HLGT. For a small data set, this might be all that is required.

Objectives:
- To display all the data in the entire MedDRA structure
- To include all events (as this approach is all-inclusive, no events are omitted)

It is recommended that this overview be undertaken as the first step in data retrieval and for planning further analyses.

Method:

The primary SOC view of the data including HLGTs, HLTs, and PTs can be used for standard tables (clinical trial and post-marketing data) and cumulative summaries (post-marketing data). Line listings (both clinical and post-marketing data) can also be displayed by primary SOC and PT. It might be sufficient to use the primary SOC and PT display only for small data sets, but it might be preferable to display data by SOC as well as by grouping terms (HLGTs and HLTs) and PTs for more complex data.

The Internationally Agreed Order of SOCs was developed to facilitate consistency irrespective of language or alphabet. The order of the SOCs was based upon the relative importance of each SOC in ADR/AE reports. Whenever suitable, organizations should consider the use of Internationally Agreed Order of SOCs (see the MedDRA Introductory Guide and MedDRA ASCII files) rather than alphabetical order or frequency. However, organizations exchanging data should discuss and agree on the order of SOCs when preparing data for presentation.
### MedDRA 7.1 English Alphabetical Order vs. MedDRA 7.1 Internationally Agreed Order

<table>
<thead>
<tr>
<th>English Alphabetical Order</th>
<th>Internationally Agreed Order</th>
</tr>
</thead>
<tbody>
<tr>
<td>Blood and lymphatic system disorders</td>
<td>Infections and infestations</td>
</tr>
<tr>
<td>Congenital, familial and genetic disorders</td>
<td>Neoplasms benign, malignant and unspecified (incl cysts and polyps)</td>
</tr>
<tr>
<td>Ear and labyrinth disorders</td>
<td>Blood and lymphatic system disorders</td>
</tr>
<tr>
<td>Endocrine disorders</td>
<td>Immune system disorders</td>
</tr>
<tr>
<td>Eye disorders</td>
<td>Endocrine disorders</td>
</tr>
<tr>
<td>Gastrointestinal disorders</td>
<td>Metabolism and nutrition disorders</td>
</tr>
<tr>
<td>General disorders and administration site conditions</td>
<td>Nervous system disorders</td>
</tr>
<tr>
<td>Hepatobiliary disorders</td>
<td>General disorders and administration site conditions</td>
</tr>
<tr>
<td>Immune system disorders</td>
<td>Eye disorders</td>
</tr>
<tr>
<td>Infections and infestations</td>
<td>Ear and labyrinth disorders</td>
</tr>
<tr>
<td>Injury, poisoning and procedural complications</td>
<td>Vascular disorders</td>
</tr>
<tr>
<td>Investigations</td>
<td>Cardiac disorders</td>
</tr>
<tr>
<td>Metabolism and nutrition disorders</td>
<td>Respiratory, thoracic and mediastinal disorders</td>
</tr>
<tr>
<td>Musculoskeletal and connective tissue disorders</td>
<td>Hepatobiliary disorders</td>
</tr>
<tr>
<td>Neoplasms benign, malignant and unspecified (incl cysts and polyps)</td>
<td>Skin and subcutaneous tissue disorders</td>
</tr>
<tr>
<td>Nervous system disorders</td>
<td>Musculoskeletal and connective tissue disorders</td>
</tr>
<tr>
<td>Pregnancy, puerperium and perinatal conditions</td>
<td>Renal and urinary disorders</td>
</tr>
<tr>
<td>Psychiatric disorders</td>
<td>Pregnancy, puerperium and perinatal conditions</td>
</tr>
<tr>
<td>Renal and urinary disorders</td>
<td>Reproductive system and breast disorders</td>
</tr>
<tr>
<td>Reproductive system and breast disorders</td>
<td>Congenital, familial and genetic disorders</td>
</tr>
<tr>
<td>Respiratory, thoracic and mediastinal disorders</td>
<td>General disorders and administration site conditions</td>
</tr>
<tr>
<td>Skin and subcutaneous tissue disorders</td>
<td>Investigations</td>
</tr>
<tr>
<td>Social circumstances</td>
<td>Injury, poisoning and procedural complications</td>
</tr>
<tr>
<td>Surgical and medical procedures</td>
<td>Surgical and medical procedures</td>
</tr>
<tr>
<td>Vascular disorders</td>
<td>Social circumstances</td>
</tr>
</tbody>
</table>

**Graphical display might facilitate understanding by the viewer. This can include histograms, bar charts, pie charts etc.**

**Benefits:**

- Provides a broad overview of the distribution of data and helps to identify areas of special interest that might call for more in-depth analysis.
- Grouping terms help to aggregate related PTs to facilitate the identification of medical conditions of interest. An individual PT will be displayed only once, preventing over counting of terms.
- The primary SOC overview might be the only form of analysis appropriate for a small data set.

In-depth analysis will require medical expertise in order to define terms that should be aggregated.

**Limitations:**

Because it is based on primary PT-to-SOC assignment, there might be incomplete groupings of terms that relate to a particular medical condition/syndrome because they might be distributed among different SOCs. Due to certain MedDRA rules, events might not be found where the user expects...
them to be. Another potential limitation is a very lengthy output.

### 3.2.2 Focused Searches

**Objectives:**

In certain situations such as those listed below [Note: this list is not all inclusive], users might wish to design a specific search in addition to the Overview by Primary System Organ Class (section 3.2.1).

- Further examination of clusters seen in Primary SOC output
- Previously identified safety concerns (e.g., known class effects, results from toxicology and animal studies, etc.)
- Monitoring events of special interest
- Responding to regulatory and other queries

It is recommended that the initial focused search augment the “Overview by Primary System Organ Class” (section 3.2.1) by exploiting the secondary SOC assignments available in MedDRA.

**Method:**

- Display the SOC or the HLGT/HLT relevant to the search with all the primary and secondary terms. Using this method, displaying more than one SOC leads to double counting of terms.
- If applicable, link relevant PTs from the three non-multi-axial SOCs (i.e., SOC Investigations, SOC Surgical and medical procedures, and SOC Social circumstances).

**Benefits:**

The multi-axial links enhance the meaningfulness of the grouping terms. In other words, this method overcomes the limitations described under 2.6.

**Limitations:**

- Covers only conditions that are confined under one SOC or HLGT/HLT.
- For medical conditions that involve terms in more than one SOC, users should consider using an SMQ.
4 Appendices:

4.1 Current members of the ICH Points to Consider working group:

**Rapporteur:**
Reinhard Fescharek

**Japan:**
Ministry of Health, Labour and Welfare:
Tatsuo Kishi
Kenichi Tamiya
Manabu Yamamoto
Japan Pharmaceutical Manufactures Association
Takayoshi Ichikawa
Yo Tanaka
Japanese Maintenance Organization
Reiji Tezuka
Yasuo Sakurai
Akemi Ishikawa

**European Union:**
Commission of the European Communities
Dolores Montero
Carmen Kreft-Jais
European Federation of Pharmaceutical Industries Associations
Reinhard Fescharek
Christina Winter

**Canada:**
Health Canada
Bill Wilson

**United States:**
US Food and Drug Administration
John (Jake) Kelsey
Toni Piazza-Hepp
Pharmaceutical Research and Manufacturers of America
Susan M. Lorenski
JoAnn Medbery
MedDRA MSSO
Patricia Mozzicato
4.2 Past members/affiliations of the ICH Points to Consider working group:

**Japan:**
Ministry of Health, Labour and Welfare  
Tamaki Fushimi  
Kazuhiro Kemmotsu  
Chie Kojima  
Emiko Kondo  
Kemji Kuramochi  
Kaori Nomura  
Takashi Yasukawa

Japan Pharmaceutical Manufacturers Association  
Akemi Ishikawa  
Satoru Mori  
Yasuo Sakurai  
Kunikazu Yokoi

Japanese Maintenance Organization  
Yuki Tada

**Canada:**
Health Canada  
Heather Morrison

**European Union:**  
European Federation of Pharmaceutical Industries Associations  
Barry Hammond – past Rapporteur

**United States:**
US Food and Drug Administration  
Miles Braun  
Brad Leissa  
Andrea Feight  
Pharmaceutical Research and Manufacturers of America  
David Goldsmith  
Sidney Kahn  
Margaret M. Westland – past Rapporteur

MedDRA MSSO  
JoAnn Medbery