



MESSENGER

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Data Conversion...

A step toward MedDRA implementation

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One of the obvious steps toward MedDRA implementation is the conversion of an organization's existing data to MedDRA.

Many related questions are involved with this issue. Typically, they involve scope (what data should be converted) and method (existing legacy code or verbatim). This article discusses these issues.

SCOPE

Because the proposed rules or guidance published by regulators address post-market safety reporting, many organizations have decided to begin MedDRA implementation with their drug safety or pharmacovigilance groups.

Most organizations have also decided to implement MedDRA for clinical trials, but usually on a different, later timetable. They believe it makes sense to use a single terminology throughout the product lifecycle and that it would be too difficult to convert data if multiple terminologies were used.

The issue of scope then leads to several different questions, including what data should be converted (i.e., adverse events only, or should medical history, physical examinations, and lab data be included as well?).

In many cases, medical history, physical examinations, and lab data may be recorded in systems today but could be "lost" in text data fields that do not have controlled input and are

difficult to search.

The scope of the conversion may be limited to data that is reasonably available for conversion. If a large effort is required to extract other data (e.g., medical history, physical examinations, and lab data), these data may not be a good candidate for conversion and should stay in its current form. On the other hand, if these data are available and can be clearly identified, the MSSO recommends that they be converted as well.

The idea is not merely to have a large database of MedDRA-coded data, but rather to take advantage of coded data and perform better, more precise analyses with these data.

User Group Meetings 2002

5 MARCH 2002

0800 - 1200

In conjunction with the DIA Euro Meeting Basel 2002
Convention Center, Basel, Switzerland

JUNE 2002

In conjunction with the DIA 38th Annual Meeting
The New Lakeside Center at McCormick Place
Chicago, Illinois, USA

check www.meddramsso.com
for information regarding the User Group meetings.

The next scope question is how far back in time the data to be converted should reach. The MSSO recommends that organizations convert all post-market data they plan to utilize in analyses. Otherwise, a mix of data coded to a legacy terminology (e.g., COSTART or WHO-ART) and MedDRA may yield results that are difficult or impossible to fully analyze.

The scope decision for clinical trial data is more difficult. Factors in the decision include the phase of the clinical trial, the future intentions (e.g., line extensions) for the compound, and the value of the data to the organization.

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Data conversion

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If an organization is about to complete a large Phase III trial, it is not likely to be the proper time to convert the data. This is also dependent upon the number of terms to be converted.

Organizations should select data to be converted based on the future value of the data.

METHOD

Having determined the scope of their conversion, organizations must decide upon their method. The choices are either to utilize existing legacy terms and codes or to utilize the original verbatim or "as-reported term" as a basis of conversion.

Terms and codes from several legacy terminologies are included within the data distributed with MedDRA. For instance, all COSTART terms and COSTART symbols are included in MedDRA. One approach to conversion is simply to find the existing legacy term in MedDRA and consider the task complete.

The MSSO does not recommend this approach for two reasons. MedDRA is more rich, specific, and granular than the legacy terminologies. In many cases, when coding with the legacy terminologies, coders had to accept a much more general term than what is available in MedDRA. Simply mapping into MedDRA with the legacy codes perpetuates this loss of information.

A second, possibly more compelling reason, is that those conducting search strategies and data analysis will have to be cognizant of the dramatic differences in level of detail between the mapped legacy data and the data coded to the full extent of MedDRA. A mix of legacy mapped data and data coded to the full extent of MedDRA may yield results that are difficult to analyze properly.

The other approach, which is recommended by the MSSO, is to use the original verbatim or "as-reported term" as the input for conversion and then determine the appropriate MedDRA term. The existing legacy term can serve as a reference, but it should not be a limiting factor in the final decision

<u>Verbatim</u>	<u>COSTART</u>	<u>MedDRA 4.0 PT</u>
Acute hepatitis A	Hepatitis	Hepatitis A
Osteomyelitis due to salmonella	Osteomyelitis	Osteomyelitis salmonella
Acute Meniere's disease	Vestibular disorder	Meniere's disease
Thanatophoric dwarf	Dwarfism	Thanatophoric dwarfism

on the appropriate MedDRA term.

This process, while more time consuming and expensive, will certainly yield better results. The examples above in the blue shaded box are provided to illustrate this point.

Several benefits derived from the conversion process may not be obvious. These include better understanding the true nature of the data an organization has stored, developing MedDRA coding conventions, and providing examples to the organization's personnel of the impact of MedDRA on the data.

In working with several groups within the organization to convert data to MedDRA, the entire organization can gain an understanding of the quality of the data in its database and insights into better methods of data collection.

One of the key outcomes of a data conversion task is the development of coding conventions. These conventions include rules for converting legacy data and are used in production when coding with MedDRA.

Some of the coding conventions developed during legacy conversion only apply to legacy data (e.g., how to deal with multiple medical concepts contained in a single verbatim) and are not to be used in future MedDRA coding. Other conventions apply to both legacy data conversion and production MedDRA coding.

The goals of the coding conventions are to provide a written record of the data conversion decisions and to support consistency of coding.

The conversion to MedDRA also provides examples of MedDRA coding to the organization that are based on its own data. It is not unusual for an organization to use examples from the con-

version process as examples in organization-specific training (see table above).

In conclusion, the data conversion process is one of the first and more obvious steps toward MedDRA implementation. In addition to data converted to MedDRA, it can yield production coding conventions, a better understanding of the data in an organization's system, and a better understanding of MedDRA.

TRANSLATION UPDATE

What is the status of MedDRA translation to French, German, Portuguese, and Spanish?

Translations of MedDRA will be available starting March 2002 with the release of MedDRA 5.0.



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MedDRA subscription price increase

Dear MedDRA Subscribers:

Last year there were several contract changes regarding your MedDRA subscription price.

One change to the MSSO contract was the inclusion of a 3% increase to MedDRA subscriptions for year 2002. Effective January 1, 2002, there will be a 3% price adjustment for the MedDRA subscription. Pricing approved by the International Federation of Pharmaceutical Manufacturers Associations (IFPMA) for the MedDRA Subscription is listed below.

Basic Subscription, \$3,090 USD

Developer license, \$5,150 USD

Core 1 - Less than \$10 million in annual revenue, \$7,210 USD

Core 2 - From \$10 million to \$500 million, \$12,360 USD

Core 3 - From \$500 million to \$1 billion, \$23,690 USD

Core 4 - From \$1 billion to \$5 billion, \$63,860 USD

Core 5 - Greater than \$5 billion, \$84,460 USD

The basic subscription level is only available to non-profit medical libraries, educational institutions, and direct patient care providers, i.e., non-profit hospitals. A developer license is available for those software development/integration companies who are trying to integrate MedDRA with other applications and tools. If your organization does not fall into one of the above-mentioned categories, your subscription fee will be determined on a sliding scale based upon your company's total sales.

All MedDRA subscribers are invited and encouraged to attend our user group meetings. There are three user group meetings being planned in 2002; one in Europe, one in the US and one in Japan.

All core subscribers receive a PIN number and general SIN number for web access. An additional change request SIN allows you to submit 100 change requests per month to TRW/MSSO.

During 2001, we processed over 7,000 change requests for MedDRA subscribers. We distributed a major release, v4.0 of MedDRA which was the result of a comprehensive review of each System Organ Class (SOC) for completeness and consistency. There is a scheduled updated release, v4.1, for November of 2001.

We look forward to working with each of you in providing a terminology, MedDRA, that is standardized throughout the healthcare and pharmaceutical community.



We want your feedback! Please contact us:

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MSSO adds field

Change to .seq file format for Release 4.1

Based on subscriber comments, the MSSO is adding an additional field to the .seq file structures as of MedDRA release 4.1 (1 November 2001).

A new field will be inserted after the date and action field

putting this new field in the third position of each record. The new field will be called "mod_fld_num", and will contain a field number for each field that is modified; that is, when the record contains an "M" in the action (second) field of the record.

Records that do not contain an "M" in the action field will be left empty (\$\$). Records with multiple modified fields will have multiple numbers in this new field separated by a space (\$5 7\$).

MSSO adopts original field length

In the documentation of MedDRA release 4.1, the MSSO is reverting back to the original term field length of 100 characters.

This field length had been increased when the ICD-9 issues of truncated and missing terms had been identified. At that time, the increase in size was believed necessary in order to correct these problems and to allow adequate space for translations of these impacted terms.

Since then, the MedDRA management board decided not to make these corrections, and it decided that the MSSO should provide the future ICD-10-CM mapping as an external cross walk, and not as an integration into the MedDRA terminology itself.

At the same time, the MSSO had received many complaints about the new field size being too big for systems to easily handle, while complicating print reports with wasted spaces.

2002 MedDRA TRAINING CALENDAR

FULL SCOPE OF MEDDRA

4-5 December 2001 – Durham, NC USA
15-16 January 2002 – New Orleans, LA USA
12-13 February 2002 – Las Vegas, NV USA
26-27 March 2002 – Dallas, TX USA
9-10 April 2002 – Dublin, Ireland
23-24 April 2002 – Chicago, IL USA
14-15 May 2002 – Reston, VA USA
16-17 July 2002 – Culver City, CA USA

CODING

5 December 2001 – Paris, France
February 2002 – Europe
March 2002 – Europe
May 2002 – Europe

ADVANCED MEDDRA

6 December 2001 – Durham, NC USA
14 February 2002 – Las Vegas, NV USA
16 May 2002 – Reston, VA USA

IMPACT OF MEDDRA ON INFORMATION TECHNOLOGY

7 December 2001 – Durham, NC USA
15 February 2002 – Las Vegas, NV USA
17 May 2002 – Reston, VA USA

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