Multilingual MedDRA

How is Interoperability Achieved?

MedDRA has a multiaxial structure with 5 levels of terms. Forming the foundation of the terminology are over 70,000 “Lowest Level Terms” (LLTs) each linked to one of more than 20,000 “Preferred Terms” (PTs), at the second level. The PTs are grouped into over 1,700 “High Level Terms” (HLTs) which in turn are further grouped in over 330 “High Level Group Terms” (HLGTs). Finally, HLGTs are grouped into 27 “System Organ Classes” (SOCs).

Each term at every level is assigned a unique 8 digit numeric code. When information is exchanged the unique numeric code for a MedDRA term is used. This code is the key to the translations. To demonstrate this, the following table shows the code and its meaning in English and Japanese for several clinical concepts.

<table>
<thead>
<tr>
<th>Preferred Term Code</th>
<th>English</th>
<th>Japanese</th>
</tr>
</thead>
<tbody>
<tr>
<td>10022000</td>
<td>Influenza</td>
<td>インフルエンザ</td>
</tr>
<tr>
<td>10047470</td>
<td>Viral myocarditis</td>
<td>ウイルス性心筋炎</td>
</tr>
<tr>
<td>10027599</td>
<td>Migraine</td>
<td>片頭痛</td>
</tr>
</tbody>
</table>

Thus, the PT code 10022000 always represents the clinical concept of “influenza”, no matter the language used. Therefore, an English user can assign the code and a Japanese user (for example) would understand the same clinical concept, even though neither user is likely fluent in the other’s language.

Because of the way MedDRA is constructed and maintained, interoperability is possible, making MedDRA, when combined with electronic data exchange, an extremely powerful tool.
Support is also Multilingual

The MedDRA Management Committee recognises that it is not enough to have the MedDRA files available in many languages. All users must also be able to have the same understanding of MedDRA and its use. Therefore documents and electronic tools are available in all the MedDRA languages. These include items such as:

- MedDRA Introductory Guide;
- Introductory Guide for Standardised MedDRA Queries (SMQs);
- MedDRA Distribution File Format Document;
- Single Case Reporting Using Semi-annual Version Control Recommendations;
- Implementation of MedDRA Supplemental Terms Recommendations;
- Primary System Organ Class (SOC) Allocation in MedDRA Recommendations;
- MedDRA Implementation and Versioning for Clinical Trials Recommendations;
- MedDRA Desktop and Web-based Browsers;
- A multilingual access welcome page on the MedDRA website.

All release documents are updated with each new version of MedDRA using rules designed to ensure consistency within and amongst translations and can be found on the MedDRA website. Users can also submit change requests related to any of the translated versions of MedDRA. A variety of training sessions and videocasts are also available in several different languages.

Future Translations

The MedDRA Management Committee is open to adding additional languages based upon demand and regulatory needs as well as the willingness of interested regulators to support the initial translation work and consult later on the maintenance of the translations. Once the intellectual rights to the translations have been transferred to ICH, the MSSO would maintain the new languages and assure coordination of updates with all other translations.

Interest in a new language can be raised to the MedDRA Secretariat for the attention of the Committee.

Useful Links

MedDRA Website: www.meddra.org
MSSO Help Desk: mssohelp@meddra.org
JMO Help Desk: helpdesk.jmo@pmrj.jp
MedDRA Secretariat: admin@ich.org

MedDRA is a product of the International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH). ICH brings together the regulatory authorities and pharmaceutical industry to standardise and streamline scientific and technical aspects of the drug regulatory process.