Multilingual MedDRA

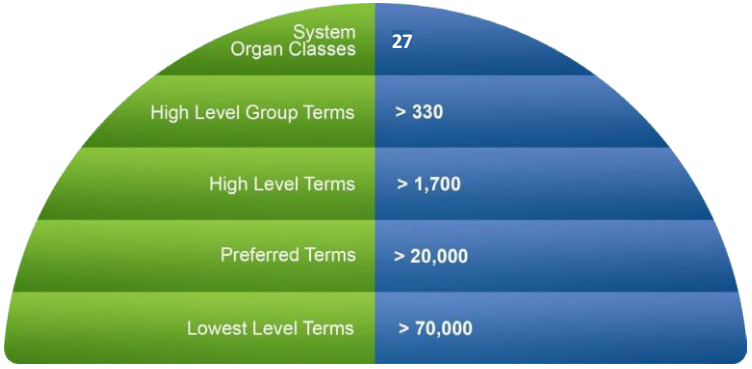
Designed to Improve Communication

The primary intent of the ICH in developing the Medical Dictionary for Regulatory Activities (MedDRA) was to improve communication among and between industry and regulators by facilitating electronic communication. This objective was supported by having the terminology available in multiple languages. The first version of MedDRA was released in 1999 in English and Japanese.

The terminology is now available in multiple languages thanks largely to individual Regulatory Authorities who initially translated MedDRA into their local language. The intellectual rights to all translations have been transferred to ICH.
The Maintenance and Support Services Organization (MSSO) with the help of various regulators and the Japanese Maintenance Organization (JMO) maintain all translations of MedDRA to ensure consistency, inclusion of new medical concepts, and quality. Unlike some other terminologies, there are no regional extensions of MedDRA. There is only one version of MedDRA in all languages. This makes full interoperability between languages possible. This feature facilitates many important uses of MedDRA, including electronic data exchange, reproducibility of search results and communication between/among: industry and regulators; industry partners; and regulatory partners. In addition the multilingual approach allows most users to operate in their native language and that promotes accuracy and precision in assigning codes.

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.

Preferred Term Code	English	Japanese
10022000	Influenza	インフルエンザ
10047470	Viral myocarditis	ウイルス性心筋炎
10027599	Migraine	片頭痛

Thus, the MedDRA 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.

FACTSHEET 2

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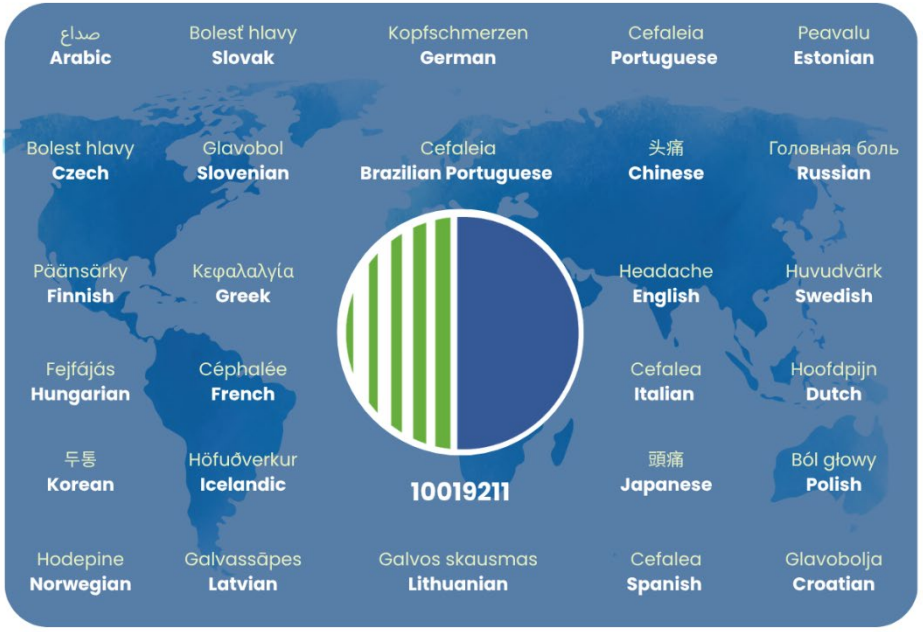
Support is also Multilingual

The MedDRA Steering Committee recognises that it is not enough to have the MedDRA files available in many languages. Users must also be able to have the same understanding of MedDRA and its use. Therefore documents and electronic tools are available in many of 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, Mobile, 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 to propose update to the translation of any translated versions of MedDRA. A variety of training sessions and videocasts are also available in several different languages.

Future Translations

The MedDRA Steering 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.

About ICH

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.

Useful Links

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