Accessing MedDRA

Why a Subscription Fee?

ICH developed the Medical Dictionary for Regulatory Activities (MedDRA) to help standardise and streamline communication of medical information between regulators and pharmaceutical companies. MedDRA is now an integral part of regulatory activities and is used extensively by industry to manage clinical trial and post-marketing safety data.

The ICH MedDRA Steering Committee has worked to ensure that MedDRA is accessible to all those who need it. The Committee has also ensured MedDRA is maintained in multiple languages and updated in line with medical developments. The provision of extensive documentation, tools and training are key to supporting users. These enable MedDRA to be used in a consistent and standardised manner. The Committee has tasked a Maintenance and Support Services Organization (MSSO) with providing this support to users. Keeping MedDRA up-to-date with new medical developments, disseminating new versions routinely, and providing extensive support requires a full-time and qualified MSSO with both medical expertise and IT resources. MedDRA is updated twice yearly with changes to the data files for all languages, documentation and translation from English to many supported languages.

This scale of support requires funding. The only funding is through subscription fees. Even so, many subscribers actually receive a MedDRA subscription free of charge (for example, in the case of regulators) or at nominal cost. As more organisations have subscribed to MedDRA, the MedDRA Steering Committee has been able to reduce or maintain subscription fees.

Unlike some software licences and other subscriptions, only one enterprise-wide subscription to MedDRA is required for a commercial organisation. Thus, multinational organisations only need one subscription no matter how many users or sites they have.

Access to MedDRA

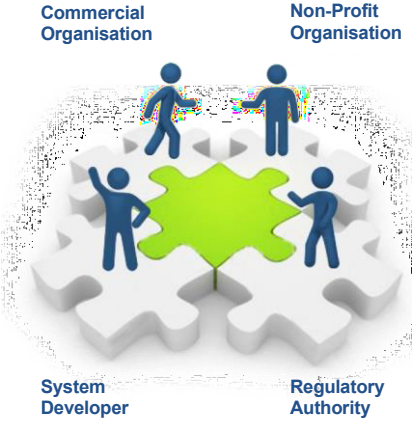
There are two methods of obtaining access to MedDRA. Organisations may either obtain their own subscription to MedDRA or in the case of some smaller organisations, access MedDRA via a special license.

How to Obtain a Subscription?

MedDRA is available to individuals and organisations. The MedDRA MSSO is responsible for supplying subscriptions worldwide (except Japan where the Japanese Maintenance Organization [JMO] provides support). Interested parties may contact the MSSO or JMO via the relevant Help Desk.

Four types of subscription are available from the MSSO:

- RegulatoryAuthority;
- Non-Profit/Non-Commercial (such as medical library, educational institution, organisation engaged in not for profit activities);
- Commercial;
- System Developer (developer of software products that utilise MedDRA).



What are the Roles of MSSO and JMO?

The MSSO is responsible to manage the development and maintenance of the English version of MedDRA, including the documentation. It is also responsible for maintaining all translations of MedDRA except Japanese. The JMO manages the Japanese translation of MedDRA, change requests from Japan, and support of Japanese subscribers.
JMO fees are based on a sliding scale, similar to the MSSO, and are approved annually by the Japanese Management Board. The JMO fee scale can be found on the JMO website.

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Subscriptions for Regulatory Authorities and Non-Profit / Non-Commercial organisations are available without charge. Subscription rates for Commercial subscribers are on a sliding scale based upon annual revenue. Subscriptions for System Developers are available for a flat fee.

Details of the MSSO fee scale, which is approved each year by the ICH MedDRA Steering Committee, can be found on the MedDRA website.

A subscription is not just electronic files

To support the standardised use of MedDRA, subscription includes tools, extensive documentation and support services:

- MedDRA in English and 26 supported languages
- Help Desk support (Email and Online);
- MedDRA Desktop, Mobile, and Web-based Browsers;
- MedDRA Version Analysis Tool (MVAT);
- MedDRA Application Programming Interfaces (APIs)
- Mappings to other terminologies
- User group membership;
- Access to free in-person training sessions, webinars, videocasts, and the MedDRA Learning Management System;
- Participation in the MedDRA change request process (for all subscribers with the exception of System Developers);
- Extensive documentation including:
  - MedDRA Introductory Guide;
  - Introductory Guide for Standardised MedDRA Queries (SMQs);
  - ICH-endorsed Points to Consider and Companion documents that provide advice on the use of MedDRA for coding and data analysis.

Special Licence Example

The European Medicines Agency (EMA) provides to organisations with less than 10 million Euros annual revenue access to non-downloadable MedDRA in its web-based "EudraVigilance" applicati to report pharmacovigilance informati in a format that conforms to ICH standards.

How to Obtain a Special Licence

Some regulatory authorities have obtained special licences from the MedDRA Steering Committee to allow non-commercial and small commercial organisations with low revenue and often limited IT support access to MedDRA. Special licences allow MedDRA's use *without charge* in a non-downloadable format within a Regulatory Agency's electronic tools designed to allow companies to meet their regulatory reporting requirements.

The MedDRA Steering Committee will consider requests for special licences from any regulator worldwide.
Easy access is an important goal. Requests for special licences may be forwarded 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: **contact@ich.org**

ICH harmonisation for better health

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.

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