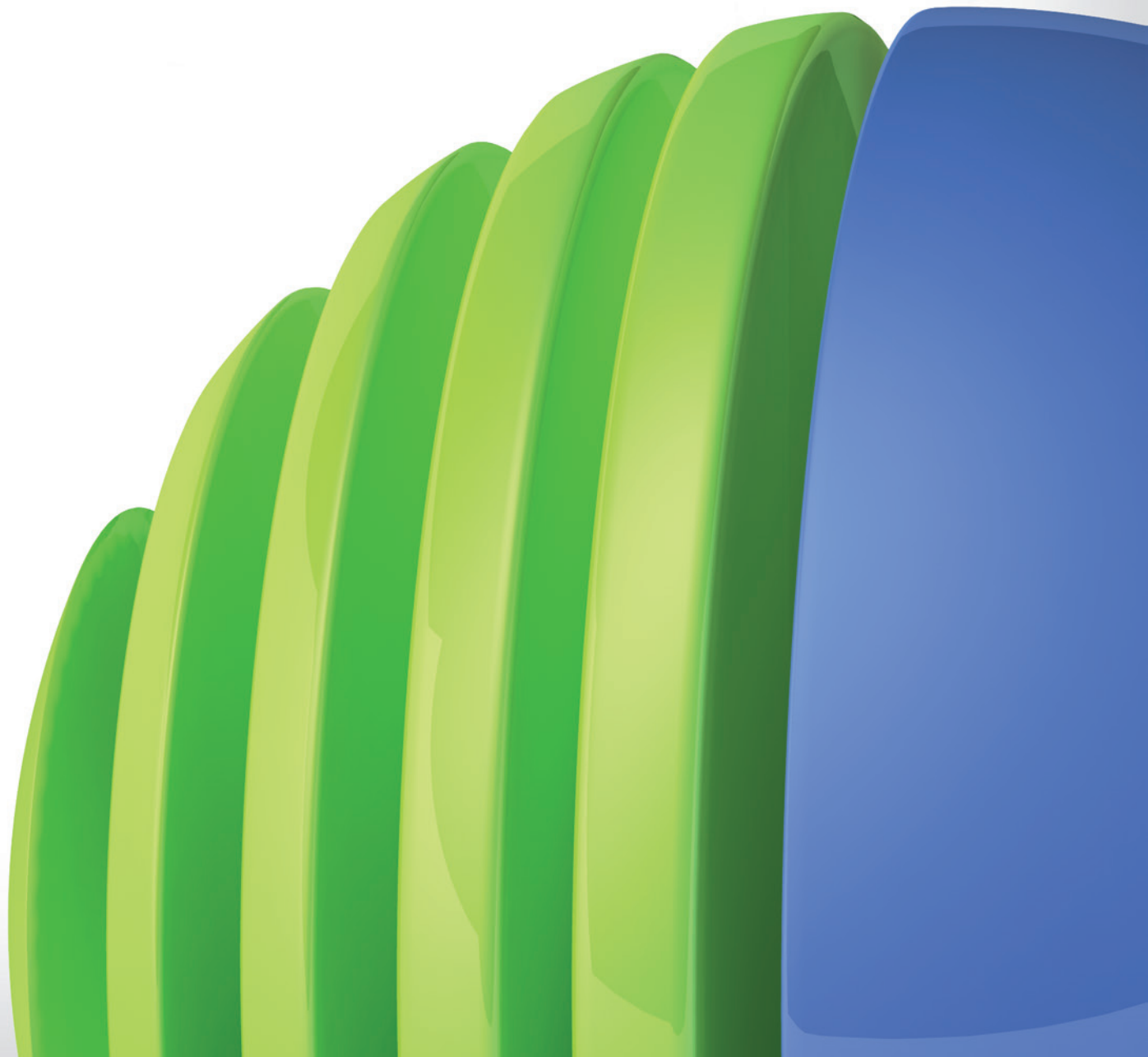# Understanding **MedDRA**

The Medical Dictionary for Regulatory Activities

What is ICH?

The International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH) (www.ich.org) is an initiative by regulators and research-based pharmaceutical industry organisations to standardise and streamline scientific and technical aspects of the drug regulatory process. Its purpose is to achieve greater harmonisation of technical guidelines and requirements for pharmaceutical product registration.

Founding members are:

- In Europe, European Union (EU) and European Federation of Pharmaceutical Industries and Associations (EFPIA);

- In Japan, Ministry of Health, Labour and Welfare (MHLW) and the Japan Pharmaceutical Manufacturers Association (JPMA);

- In USA, Food and Drug Administration (FDA) and Pharmaceutical Research and Manufacturers of America (PhRMA);

- Additional members include Observers from the European Free Trade Association (EFTA), Health Canada, and the World Health Organization (WHO).

ICH activities now also include participation from other countries and regions (Drug Regulatory Authorities/Departments of Health from Australia, Brazil, China, Chinese Taipei, India, Republic of Korea, Russia and Singapore, and Regional Harmonisation Initiatives from APEC – Asia-Pacific Economic Cooperation, ASEAN – Association of Southeast Asian Nations, EAC – East African Community, GCC – Gulf Cooperation Council, PANDRH – Pan American Network for Drug Regulatory Harmonization, and SADC – Southern African Development Community).

ICH Products:

The ICH has produced numerous guidelines in the areas of quality, safety and efficacy. Several multidisciplinary guidelines and standards have also been developed. MedDRA is a leading example of an ICH multidisciplinary standard. In developing MedDRA, a medical dictionary for regulatory activities, the ICH endeavoured to provide a single standardised international medical terminology.

Contents

Key Acronyms

CIOMS	Council for International Organizations of Medical Sciences		**MSSO**	Maintenance and Support Services Organization
ICH	International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use		**MVAT**	MedDRA Version Analysis Tool
			PtC WG	Points to Consider Working Group
ICSR	Individual Case Safety Report		**SMQ**	Standardised MedDRA Query
JMO	Japanese Maintenance Organization		**WHO-ART**	WHO Adverse Reaction Terminology
MedDRA	Medical Dictionary for Regulatory Activities			

MedDRA:
An Overview

Collaboration is a fundamental pillar of medical research. From the inception of a drug to its placement on the market and beyond, teams from across the medical community come together to develop and test the best possible medical products for patient use. These products are extensively reviewed by regulatory authorities before general release and closely monitored thereafter.

ICH recognised that the use of different terminologies at different stages in the course of developing medicines made it difficult to cross-reference and analyse data. Converting data from one terminology to another cost time, resources and resulted in the inevitable loss or distortion of data. In view of these challenges, ICH created the Medical Dictionary for Regulatory Activities (MedDRA) to facilitate the exchange of information through standardisation.

Used by regulators and industry for more than a decade, MedDRA is an important tool for product evaluation, monitoring, communication, electronic records exchange and oversight. MedDRA was created to manage clinical information about pharmaceuticals, biologics, vaccines and drug-device combinations for the entire lifespan of products. It is a rich, highly specific, hierarchical, medically oriented, and rigorously maintained terminology designed to meet the needs of drug regulators and the pharmaceutical industry as a shared international standard.
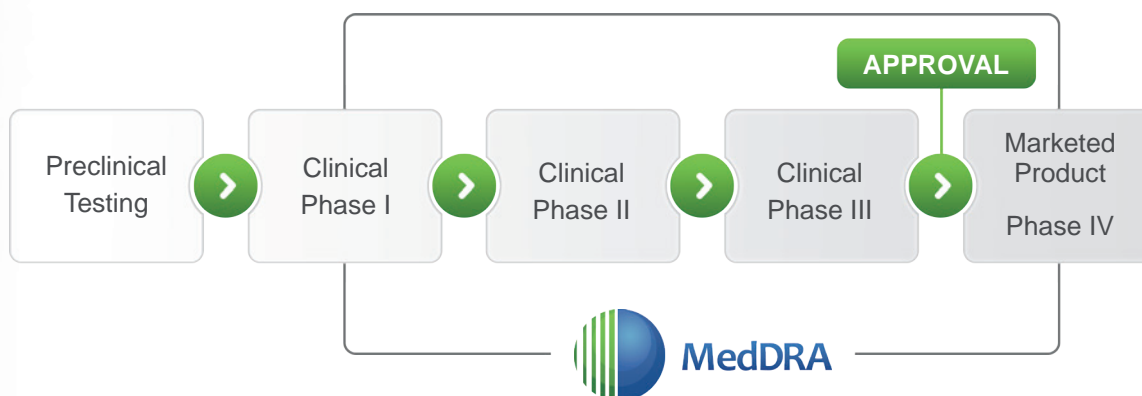
> "MedDRA has its origins in regulatory pharmacovigilance and has developed into the complete terminology for all medicines regulation in Europe and beyond. The granularity and usability of MedDRA, coupled with new technologies, has enabled pharmacovigilance signal detection to now look across large volumes of data and identify the most important public health issues. Knowing that MedDRA continues to be maintained and developed to the highest standards means that we can be assured it will continue to be the terminology that underpins our pharmacovigilance activities."
>
> **Mick Foy,** *Vigilance and Risk Management of Medicines, UK MHRA*
> *UK MHRA MedDRA Management Board Representative*

For example, clinical trials are increasingly conducted internationally. Much of the clinical information gathered in trials – such as disease and disorders present; medical, social and family history; signs and symptoms observed; as well as adverse events and adverse drug reactions – can be accurately and efficiently communicated using MedDRA. This allows such data to be pooled, compared and analysed across trials, regardless of linguistic barriers.

ICH's powerful tool, MedDRA, is available worldwide for monitoring medical products. Because MedDRA is already widely used, integration of information among regulators and business partners, both domestic and international, is facilitated.

Tried and trusted by experts around the world, MedDRA is an investment for drug regulators and pharmaceutical companies to protect patients, and an important tool for researchers and health professionals.

"Targeted monitoring strategies using MedDRA coded data are effective methods for identification of potential signals."

Heather Sutcliffe
Canada Vigilance Programme, Health Canada

Health Canada MedDRA
Management Board Representative

MedDRA at a Glance

MedDRA is an extensive medical terminology with a unique architecture and features that support public health monitoring, data analysis, communication (both electronic and traditional) and data management. This terminology is hierarchical, multiaxial, multilingual, regularly-updated, and strictly maintained. Since it has been in widespread use for more than a decade, it is stable and mature with extensive supporting materials.

MedDRA: An Investment for Regulatory Activities

This section provides an overview of MedDRA features, benefits and uses. A more in-depth view can be found in the section entitled "MedDRA: Network and Infrastructure".

MedDRA was developed by ICH in the late 1990s after decades of using other or no terminologies. ICH envisioned that the adoption of MedDRA as a single standardised terminology would offer a number of clear advantages for regulators and industry:

- Improvements in the ease, quality and timeliness of data available for analysis, exchange and decision making;
- Facilitation of the electronic exchange of data relating to medical products;
- Long-term savings in resources, due to substantial time saved converting data from one terminology to another.

Organised for analysis

"Coding" data into a standardised terminology facilitates its analysis. A critical benefit of MedDRA is in its support of straightforward as well as sophisticated analyses. Whether one is a drug regulator, or works within a pharmaceutical company, or is a medical researcher or a public health official, information is critical to making decisions that affect the well-being of people covered by your area of responsibility. With MedDRA, the information is organised to be of greatest value so that data can be examined from multiple points of view whilst ensuring that the method of organisation is valid, thereby allowing detailed as well as high level analyses. It must also be robust enough to stand up to new challenges and changing needs whilst allowing others to reproduce the results using the same tools.

Drug Regulator

Drug Industry Employee

Public Health Official

Medical Researcher

Tried and tested

The organisational structure of MedDRA has been proven through a decade of usage in ICH regions to fulfil these needs. MedDRA is constantly maintained by experts allowing it to remain valid and current, even as new medical concepts arise. Its structure means it is robust and flexible. MedDRA has a hierarchical structure and can be used to analyse a particular medical event (e.g., *Migraine*) or an issue involving a whole system or organ (e.g., *Nervous system*). Thanks to its multiaxiality and a special feature known as Standardised MedDRA Queries (SMQs), MedDRA can be used to examine medical conditions which affect more than one organ or system.

SMQs also support signal detection and the retrieval of data for safety analyses. As over 90 SMQs have already been created to date, covering the major events of interest (e.g., *Cardiac failure* and *Anaphylactic reaction*), this is a very powerful feature. Because these queries are standardised, the confirmation of a finding is facilitated, potentially saving valuable time. Additional SMQs are created as the need arises.
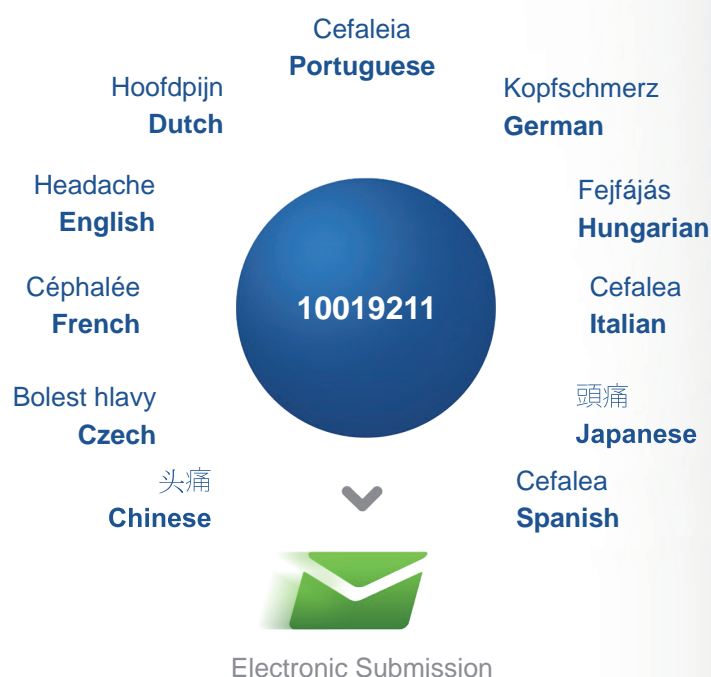
> 66 99
> *"MedDRA has made a great contribution to safety measures in Japan. This is especially due to its high quality and the fact that it is standardised across its translations, which include Japanese – MedDRA/J. This standardisation and ease of interoperability through the eight-digit numeric code enables us to take advantage of safety information from all over the world without any language barriers."*
>
> **Makoto Hirose**, *Safety Division, MHLW MHLW MedDRA Management Board Representative*

Multilingual to maximise data sharing

The users of MedDRA have found it to be such an important tool that in addition to the English Master, it has been translated into Chinese, Czech, Dutch, French, German, Hungarian, Italian, Japanese, Portuguese and Spanish. Each MedDRA term has an associated numerical code which remains the same irrespective of the language. Thus, for example, a user of the French version can understand the results from the user of the Japanese version through their identical numerical codes.

This multilingual approach allows most users to operate in their native language which promotes accuracy and precision of assigning codes. Interoperability is very powerful and allows easy multinational sharing of data. Essential supporting documentation is available in all the languages.

Cefaleia
Portuguese

Hoofdpijn
Dutch

Kopfschmerz
German

Headache
English

Fejfájás
Hungarian

Céphalée
French

10019211

Cefalea
Italian

Bolest hlavy
Czech

頭痛
Japanese

头痛
Chinese

Cefalea
Spanish

Electronic Submission

Electronic communication connecting regulators & the regulated

One of the important visions of ICH is the exchange of electronic documents and records. To achieve this vision, MedDRA was created along with specifications for the content needed to exchange electronic Individual Case Safety Reports (ICSRs). MedDRA is used within the ICSR for medical history (diagnoses, surgical procedures), reported cause of death, reactions/events, laboratory terms and indication for drug use. MedDRA and the ICSR accelerate exchange of information and increase the efficiency with which important regulatory information is shared. MedDRA is an essential tool for those engaged in regulating, monitoring, marketing, or researching the use of pharmaceutical products.

In the ICH regions, Europe and Japan require the use of MedDRA by pharmaceutical companies, while in the United States, although not required, it is the *de facto* standard. Other regulators also either recommend the use of MedDRA (including Australia, Canada and Singapore) or require it (Saudi Arabia). MedDRA and the ICSR can also be used for regulator-to-regulator and company-to-company (licence agreements or co-development) communication.

MedDRA is already in wide usage with more than 3,700 subscribing organisations around the world including numerous regulators. Many subscribing organisations are outside of the ICH regions.

Free for regulators, affordable for all

A MedDRA subscription is available without charge to each governmental regulator, while non-profit organisations conducting non-commercial work, direct patient care providers, educational institutions and non-profit medical libraries can have access to MedDRA at either a nominal cost or no cost at all. The cost for commercial users increases as the subscriber's revenue increases.

Special Licences are also available allowing MedDRA's use by smaller commercial users without charge in non-downloadable format within electronic systems designed to allow companies to meet their regulatory reporting requirements. One such system for which a Special Licence has been granted is the European Medicines Agency's EudraVigilance system. This allows certain small and micro-sized enterprises to enter data using MedDRA without the need for a MedDRA subscription.

Robust Oversight by Experts

MedDRA remains very much an ICH initiative. Each of the six ICH members name representatives to the MedDRA Management Board, as do Health Canada and the Medicines and Healthcare products Regulatory Agency of the UK (MHRA). The Board works under the ICH Steering Committee. It is responsible for ensuring that subscriber needs are met, through continuous development and maintenance that meets the highest standards. The Board is also responsible for overseeing the activities of the organisation that acts as the Maintenance and Support Services Organization (MSSO). Oversight consists of frequent meetings with MSSO personnel, clinical audits and financial audits.

The MSSO is tasked with maintenance of the terminology, including the addition of new terms, updating the hierarchy, distributing the new versions of MedDRA (including SMQs), training of users and managing subscriptions. Each year, there are two updates to MedDRA.

A Japanese Maintenance Organization (JMO) has also been established to support users in Japan and works closely with the MSSO to provide Japanese user input into MedDRA and to translate MedDRA into Japanese. The JMO reports to a Japanese Management Board (JMB) which includes representation from the Japanese drug regulatory authority and pharmaceutical industry. The JMB in turn reports to the ICH MedDRA Management Board.

MedDRA

ICH
harmonisation for better health

 " *"As a powerful and truly international terminology, MedDRA is core to protect public health. By providing a multilingual and routinely maintained extensive medical coding standard, safety data can be analysed faster and consistently throughout the life cycle of a medicinal product. This allows for improved decision making, timely information of healthcare professionals and to better safeguard patients."*

Sabine Brosch, *Pharmacovigilance and Risk Management Sector, EMA*
EU MedDRA Management Board Representative

WHO

EU

IFPMA

UK MHRA

PhRMA

EFPIA

Health Canada

MHLW

FDA

JPMA
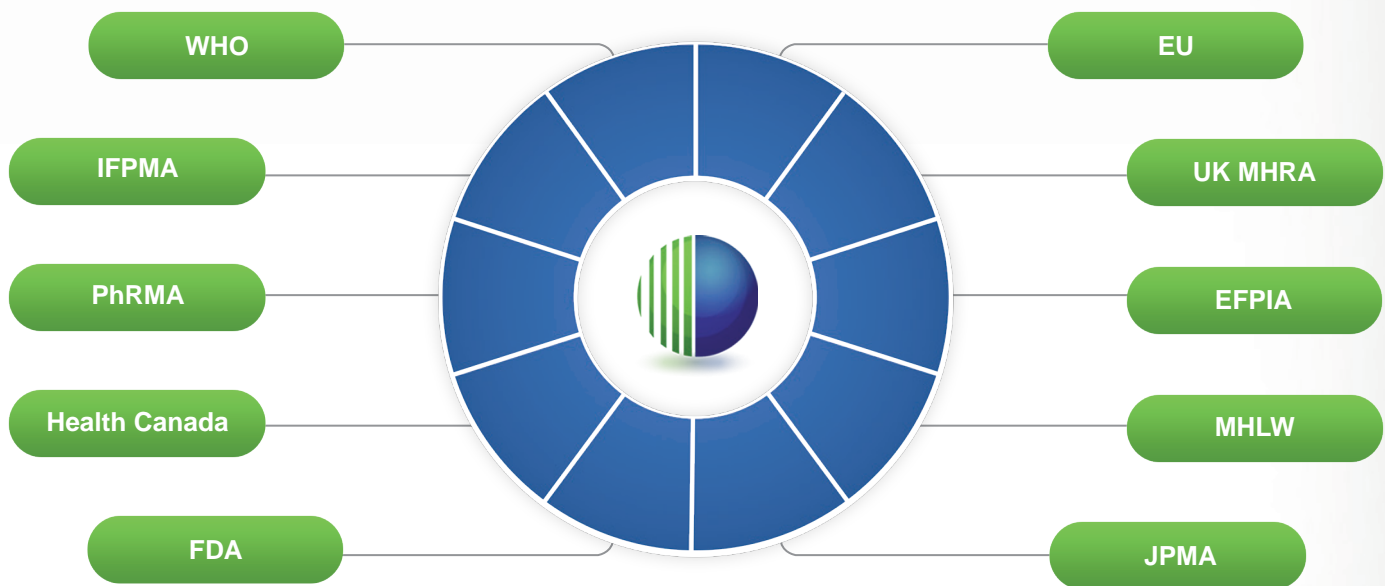
MedDRA is an important ICH product for the communication of clinical information. It is mature, current and available in many languages. Use of MedDRA allows information exchange and analysis among many partners over the entire lifespan of products in an efficient manner with accuracy and reproducibility.

MedDRA: Network and Infrastructure

This section is intended for those who need an in-depth understanding of MedDRA and provides a detailed description about how MedDRA is structured, maintained, and supported, as well as highlighting the materials available to MedDRA subscribers.

Structure of MedDRA

The most important reason to "code" data into a standardised terminology is to analyse it. A benefit of MedDRA is in its support of straightforward as well as sophisticated analyses. MedDRA can be used to analyse individual medical events (e.g., *Influenza*) or issues involving a system, organ or etiology (e.g., *Infections*) using its hierarchical structure. MedDRA can be used for signal detection and monitoring of clinical syndromes whose symptoms encompass numerous systems or organs using its multiaxial hierarchy or though the special feature of Standardised MedDRA Queries (SMQs).

Glossary of MedDRA Terms

SOC	System Organ Class
HLGT	High Level Group Term
HLT	High Level Term
PT	Preferred Term
LLT	Lowest Level Term
SMQ	Standardised MedDRA Query

Hierarchical system

At first, the structure of MedDRA sounds complicated. However, the structure is very logical. There are five levels to the MedDRA hierarchy, arranged from very specific to very general.

System Organ Classes	26
High Level Group Terms	> 330
High Level Terms	> 1,700
Preferred Terms	> 20,000
Lowest Level Terms	> 70,000

Over 70,000 "Lowest Level Terms" (LLTs) parallel how information is communicated, reflecting how an observation is reported in practice. This level directly supports assigning MedDRA codes within a user database.
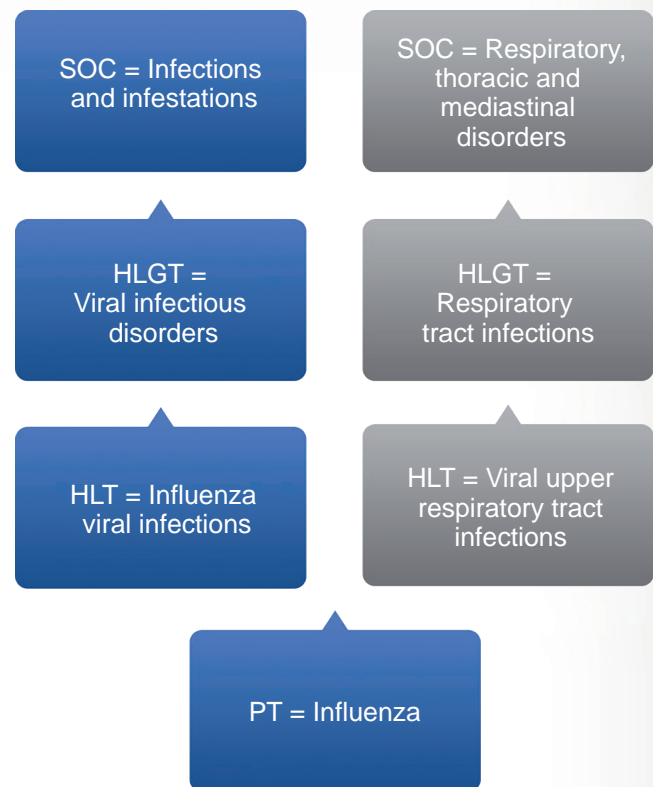
Over 20,000 "Preferred Terms" (PTs) are single concepts for symptoms, signs, disease diagnoses, therapeutic indications, investigations, surgical or medical procedures, and medical, social or family history characteristics.

Related PTs are grouped together into over 1,700 "High Level Terms" (HLTs) based upon anatomy, pathology, physiology, etiology or function. HLTs are in turn linked to over 330 "High Level Group Terms" (HLGTs).

Finally, HLGTs are grouped into 26 "System Organ Classes" (SOCs) which are grouped by etiology (e.g., *Infections and infestations*), manifestation site (e.g., *Gastrointestinal disorders*) or purpose (e.g., *Surgical and medical procedures*). There is also a SOC accounting for social circumstances.

Multiaxial structure

Even a single medical concept can be examined from several points of view. For example, the PT *Influenza* represents an important respiratory tract problem as well as an infection. For this reason, each PT is assigned to a primary SOC, but may also be assigned to one or more secondary SOCs. The multiaxial structure of MedDRA supports signal detection and signal monitoring. The PT *Influenza* is primary to the SOC *Infections and infestations*, but this PT is also secondary to the SOC *Respiratory, thoracic and mediastinal disorders.*

SOC = Infections and infestations

SOC = Respiratory, thoracic and mediastinal disorders

HLGT = Viral infectious disorders

HLGT = Respiratory tract infections

HLT = Influenza viral infections

HLT = Viral upper respiratory tract infections

PT = Influenza

"In co-licensing, MedDRA enables faster and more accurate review of the safety profile of another company's product. I have experienced due diligence efforts pre and post MedDRA and can attest to the vast difference that this common terminology has made when there are tight timelines."

Christina Winter, *Global Clinical Safety & Pharmacovigilance, GlaxoSmithKline R&D*
EFPIA MedDRA Management Board Representative

SMQs assist with signal detection

SMQs may also be used to further support signal detection and monitoring. SMQs are validated, pre-determined sets of MedDRA terms grouped together after extensive review, testing, analysis and expert discussion. A SMQ can be wide in reach, such as *Taste and smell disorders*, or specific, such as the SMQ on *Agranulocytosis*. Currently, more than 90 SMQs have been created. Additional SMQs are created as the need arises.

SMQs are complex and varied in concept. Some SMQs are a simple set of PTs while other SMQs are hierarchical containing subordinate SMQs. SMQs can include "narrow" and "broad" terms. Narrow terms are those that are highly likely to represent the condition of interest. For example, the PTs *Pancreatitis acute* and *Pancreatitis haemorrhagic* are narrow terms for the *Acute pancreatitis (SMQ)* whereas the PT *Blood bilirubin increased* is a broad term. Not all instances of increased blood bilirubin are indicative of acute pancreatitis. SMQ retrievals may be limited to narrow terms if desired.

All SMQs have been validated for sensitivity and specificity and are actively maintained to reflect changes in MedDRA. The Council for International Organizations of Medical Sciences (CIOMS) Working Group, in collaboration with ICH, has been instrumental in the development and maintenance of SMQs. The CIOMS Working Group on SMQs is composed of senior scientists from several drug regulatory authorities, international pharmaceutical companies, the MSSO, the JMO, the WHO, and other institutions.

> *"MedDRA is an excellent and unique medical terminology. It enables us to communicate safety data of medicines easily and globally, not only with healthcare companies, but also with regulators. We can also contribute to the continual enhancement of MedDRA through the change request process, since MedDRA is a "live" terminology. Working in the MedDRA world is really wonderful!"*
>
> **Yo Tanaka,** *Chugai Clinical Research Center, Chugai Pharmaceutical Co., Ltd.*
> *JPMA MedDRA Management Board Representative*

A collaborative standardisation project

MedDRA was based on a terminology belonging to the Medicines and Healthcare products Regulatory Agency (MHRA) of the UK and was developed by the ICH partners, including the WHO. The intention was to establish a standardised terminology which would eliminate the use of different terminologies through the different stages of the development of medicines, such that separate terminologies for subjects like patient diagnoses and adverse reactions are not needed. This required the development of a terminology that was clinically correct, highly structured, rich in available terms, and could be standardised across regulatory bodies and the pharmaceutical industry. Further important aims were to have a terminology to transmit electronic data files and that could support multiple languages. MedDRA meets these goals.

Language neutral to maximise data sharing

All MedDRA data are stored using numerical codes for each term. While these codes have no inherent meaning, they allow efficient database management. These codes also allow easy use of multiple languages. Each code is unique to a single MedDRA term and can be displayed (decoded) in the desired language in an efficient manner. Thus, an Individual Case Safety Report (ICSR) from one country can be easily understood in all the other countries, and is another important public health benefit of MedDRA.

MedDRA Facilitates Electronic Communication

MedDRA is an important component of the CTD whereby pharmaceutical companies assemble all quality, safety and efficacy information into one format for all ICH regulatory authorities. In addition, MedDRA is a necessary part of the electronic submission of ICSRs using the ICH E2B standard. This is beneficial to everyone as information can be quickly and efficiently exchanged, allowing more resources to be expended on the content of the ICSR and less on data management.

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

Compatible with other terminologies

The MedDRA Management Board recognises that there is a need for interoperability with other terminologies. For example, a collaborative effort has been undertaken between the ICH and the Uppsala Monitoring Centre (UMC) of the WHO to develop a mapping between WHO Adverse Reaction Terminology (WHO-ART) and MedDRA to make the WHO Vigibase™ database compatible with both MedDRA and WHO-ART. This allows access to over 7 million ICSRs in either terminology, making it a powerful tool for public health and signal detection. This mapping, available from UMC, can be used to convert legacy data from WHO-ART to MedDRA. Another example involves compatibility across cancer research. Since CTCAE version 4.0, all the terms in the Common Terminology Criteria for Adverse Events (CTCAE), used and maintained by the US National Cancer Institute (NCI) of the National Institutes of Health (NIH), are themselves LLTs of MedDRA.

Governance ensures the integrity of updates

MedDRA is an extensive and highly organised terminology. Experience with previously used terminologies demonstrated that terminologies must change as new medical knowledge develops. Thus, one of the ICH requirements was that MedDRA be maintained. That is, terms must be added or updated as knowledge grows, with careful review so that changes are medically correct and the logical structure and consistency are retained. To meet this requirement, ICH created a governance structure, the MedDRA Management Board, to nurture and protect the integrity of MedDRA.
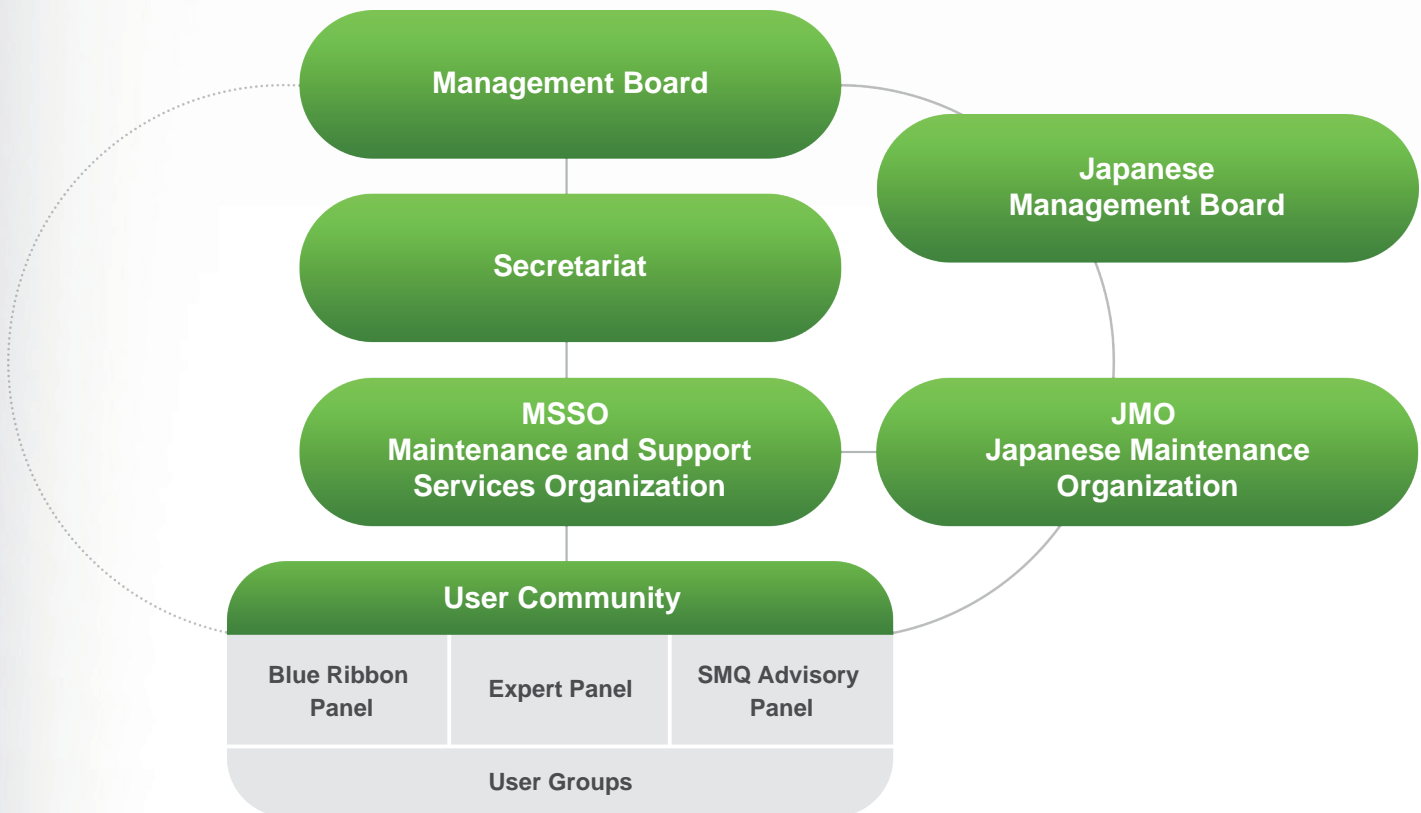
The professionals who are members of the Board use MedDRA in their daily work. Therefore, there is strong interest in ensuring that subscriber needs are met. The Board has created initiatives to improve MedDRA, such as expanding the original scope to include the creation of SMQs and clinical events associated with vaccines and drug-device combinations.

The MedDRA Management Board has supported the convening of expert groups, called Blue Ribbon Panels to examine such scope changes.

An ICH Expert Working Group, the MedDRA Points to Consider Working Group (PtC WG), has also been established to create and maintain guiding principles on the use of MedDRA (how to select MedDRA terms and retrieve and present MedDRA coded data). When appropriate, the Board works with independent organisations, such as CIOMS which has established a Working Group that helps manage SMQ creation, updating and documentation.

Maintenance and support

Maintenance of the terminology and support for users are key components of MedDRA's success.

Maintenance and continuous development

Part of the responsibility of the MedDRA Management Board is oversight of the MSSO. The MSSO's responsibilities include: addition of new terms and changes to existing terms; placement of terms in the hierarchy; review of the hierarchy as medical concepts change; coordination of translations; coordination of changes in documentation; updating SMQs as terms are added or updated; creation of tools to help users (browsers, MedDRA Version Analysis Tool (MVAT), change request system); and release and distribution of new versions of MedDRA. Since all of this must also protect the clinical integrity of MedDRA, personnel at MSSO include a number of international medical doctors as well as computer experts. Subscription fees cover these extensive services.

> *"MedDRA has been designed for long term use – since no Lowest Level Terms are ever deleted, it ensures no events are "lost" even when searching for information originally coded in a much earlier version."*
>
> **Hilary Vass,** *Medical Coding, Biogen Idec Ltd.*
> *EFPIA MedDRA Management Board Representative*

Support from experts

The MedDRA Management Board is continuously working to ensure that subscribers have the support they need. Every subscriber has access to the MedDRA website (www.MedDRA.org) that offers extensive information, help and resources. All support materials are available on this website and the MSSO/JMO can be directly contacted for further support.

The MedDRA Management Board is continuously working to ensure that subscribers have the support they need

Since MedDRA has been in wide use for more than a decade, considerable expertise is available to support those who wish to use it. This support includes documentation, help from the MSSO/JMO, training, electronic tools and knowledgeable peers.

Written support

MedDRA is always current with two releases annually. The first annual release in the spring includes changes to all levels in MedDRA (if any occur). The second release in the autumn is minor and only includes changes to terms at the PT and LLT levels (e.g., new terms, spelling changes, non-current LLTs). With both releases, there are easily understood documents detailing the changes (listings, explanations, version reports, SMQ spreadsheets).
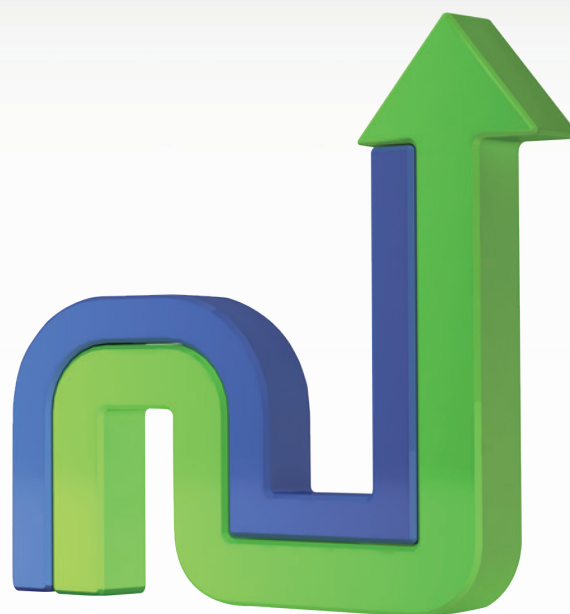
*With both releases,
there are easily understood
documents detailing the changes
(listings, explanations, version reports, SMQ spreadsheets)*

Each new version of MedDRA has updated guides for MedDRA itself and the SMQs. These guides are available as PDF files in all 11 MedDRA languages and can be easily shared:

- The "MedDRA Introductory Guide" includes the rules and conventions used for spelling, abbreviations, word order, punctuation, naming conventions for terms at all levels, anatomical considerations and an explanation and rationale of what is included in each SOC;

- The "SMQ Introductory Guide" details such information as design concepts, the definition of "narrow" and "broad" terms, and how to take full advantage of each SMQ. Each SMQ is given a definition of its intent as well as inclusion and exclusion criteria;

- Guidance for use of the electronic files with explanations of the file structure is described in the document entitled "MedDRA Distribution File Format Document".

Two "Points to Consider" (PtC) documents – "MedDRA Term Selection" and "MedDRA Data Retrieval and Presentation" are available in English and Japanese and provide invaluable advice on the use of MedDRA. Both documents are updated, as needed, with the release of each new version of MedDRA, by members of the ICH MedDRA PtC WG who are expert users.

Direct support and helpdesk

Direct support can be obtained from the MSSO/JMO and a helpdesk is available. Subscribers may submit change requests to MedDRA using the WebCR tool, by e-mail or via the helpdesk. Change requests are a way for subscribers to contribute to keeping MedDRA current. As new medical knowledge evolves, subscribers are likely to encounter the new medical concept first. By making a request for a change to MedDRA, subscribers bring this new knowledge into the terminology in a timely manner.

MedDRA User Group meetings are also organised and provide an opportunity to discuss MedDRA-related topics and network with other MedDRA users.

Training and electronic tools

Extensive training on MedDRA is available in a variety of languages in addition to a range of powerful computer tools which help users to get the most out of the terminology.

- Free face-to-face training sessions are conducted at locations around the globe.

- Virtual training sessions (webinars) and recorded videocasts/webinars are available on the MedDRA website.

- Browsers are available to help navigate MedDRA.

- MVAT is another available tool which allows subscribers to assess the impact of any changes in their data due to version changes in MedDRA. The user can see changes in MedDRA terms between any two versions, find how these changes may impact their data and search specific terms for changes.

MedDRA Browsers

Two types of MedDRA "browsers" are available to subscribers. One is intended for your personal computer and one is accessible via the internet. The browsers include the entire hierarchy of MedDRA terms and allow examination in detail from various points of view. They can be used as aides to assigning MedDRA codes to data or to create search strategies. All levels of MedDRA can be searched for specific words or combinations of words or searches can be limited to specific levels of MedDRA terms. Synonyms are available. For example, using the synonym function, a search for the word "skin" also retrieves the word "derm". Using the browsers, one can view all terms within a hierarchy. You can also view the available SMQs, their content, and a term's scope (narrow versus broad).

MedDRA has become the standard medical terminology for drug regulators and pharmaceutical companies in the ICH region. MedDRA allows easy communications with others and is a powerful tool for public health monitoring. Availability in multiple languages makes it accessible to the widest numbers of users. After more than a decade of use, MedDRA has a wealth of experience around it with a strong maintenance programme to keep it current and numerous tools to support subscribers.

www.meddra.org

Contact MSSO at mssohelp@meddra.org

**International Conference on Harmonisation of Technical Requirements
for Registration of Pharmaceuticals for Human Use**

2013
ICH Secretariat
e-mail: admin@ich.org
www.ich.org