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Medical Dictionary MedDRA - used in over 60 countries, among which is Montenegro

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SUMMARY

Introduction: Medical Dictionary for Regulatory Activities (MedDRA) is a medical coding dictionary which is designed in order to be used by regulatory authorities, pharmaceutical companies, clinical research organizations and health care professionals, i.e. all participants in the system of medicines safety monitoring.
Methods: This article describes process which is used for medical coding in clinical data management and, in brief, most commonly used medical dictionary MedDRA. The purpose of this paper is a modest contribution to easier and more successful understanding of the encoding process in clinical data management in the field of pharmacovigilance.
Topic: MedDRA Development, structure, multi-axiality, availability of foreign languages, as well as common problems faced by medical coding expert while coding were presented.
Conclusion: MedDRA has become the standard medical terminology for drug regulators and pharmaceutical companies in Montenegro. Training should be provided to all coders in order to achieve the optimum level of coding and to ensure that all the parameters for quality are achieved. Coding should be treated as one of the most important function in clinical research.

Keywords: medical dictionary, drug safety, pharmacovigilance

INTRODUCTION

There are numerous dictionaries used for classifying medicines, adverse reactions, and medical conditions, but Medical Dictionary for Regulatory Activities (MedDRA) is important and commonly used dictionary in the field of medicines safety monitoring,too MedDRA is a medical coding dictionary developed by Maintenance and Support Services Organisation (MSSO)[1]. MedDRA is supported by International Conference on Harmonisation (ICH) on Technical Requirements for Registration of Pharmaceuticals for Human use. ICH's powerful tool, MedDRA is available to all for use in the registration, documentation and safety monitoring of medical products both before and after a product has been authorised for sale. Products covered by the scope of MedDRA include pharmaceuticals, biologics, vaccines and drug-device combination products. Today, its growing use worldwide by regulatory authorities, pharmaceutical companies, clinical research organisations and health care

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professionals allows better global protection of health of a patient[2].

MeDRA is available to anyone who is willing to use it, although in 1999, when it was initially implemented, most users were from Europe, Japan and USA[2]:

- Medical terms generated during all phases of clinical trial, excluding animal toxicology, as well as post-marketing and pharmacovigilance data
- Therapeutic indications (including signs, symptoms, diseases, diagnosis, or prophylaxis of disease, and modification of functions)
- Coding names and quantitative results of investigations, surgical procedures and medical/social/family history.

The terminology is used through the entire regulatory process, from pre-marketing to post-marketing, and for data entry, retrieval, evaluation, and presentation[3][4].

METHODOLOGY

This article describes process which is used for medical coding in clinical data management and, in brief, most commonly used medical dictionary MedDRA. The purpose of this paper is a modest contribution to easier and more successful understanding of the encoding process in clinical data management in the field of pharmacovigilance.

TOPIC

MedDRA Development

Prior to development of MedDRA, there was no internationally accepted medical terminology for biopharmaceutical regulatory purposes. Most organizations dealing with regulatory affairs, has used some of international terminology for adverse drug reactions in combination with the terminology of morbidity. Therefore, for example in Europe, the *World Health Organization's Adverse Reaction Terminology* (WHO-ART) in combination with International Classification of Diseases Ninth Revision (ICD-9) was used. In the USA *Coding Symbols for a Thesaurus of Adverse Reaction Terms* (COSTART) in combination with modified ICD-9 was used, while in Japan *Japanese Adverse Reaction Terminology* (J-ART) was developed. Additionally, many organizations have modified this terminology, in order to adapt it to their own needs. Hence, the use of different terminology in various stages of the life cycle of a drug complicate the data analysis[5]. For example, data relating to safety in clinical trials are the most commonly classified using ICD terminology, while J-ART, WHO ART or COSTART were used during post-marketing surveillance[1]. The need for a standardised medical terminology was identified by the ICH in the 1990s, since there was not a standard terminology available that provided the scope and level of granularitys needed by regulatory authorities and industry[6]. In the past, the terminologies in use, such as the FDA's COSTART, WHO-ART, J-ART, H-ARTS, ICD-9 and ICD-9CM were updated so infrequently that individual users created their own version and standardisation was lost. MedDRA was based on a terminology belonging to the Medicines and Healthcare products Regulatory Agency (MHRA) of UK (*Medicines and Healthcare products Regulatory Agency* - MHRA)[7]. In October 1994 ICH adopted MEDDRA Version 1.0 as basis for international terminology. An ICH M1 Expert Working Group was formed to further develop the terminology. Version 1.0 was released for alpha testing by pharmaceutical companies and regulatory authorities. In February 1996, ICH agreed to the Version 2.0 and renamed the terminology MedDRA for Medical Dictionary for Regulatory Activities in July 1997[8].

Maintenance and Support Services Organization

Under the oversight of the ICH MedDRA Management Board, the key function of the MSSO is to maintain, distribute, and support MedDRA on behalf of MedDRA users[9]. The MSSO staff includes[9]:

- Physicians and support personnel that participate in the review of proposed changes submitted by MedDRA users
- Highly skilled, multi-lingual (Chinese, English, French, German, Spanish) MedDRA trainers with industry experience and in depth knowledge of regulatory reporting requirements
- Dedicated, full-time quality assurance personnel to ensure compliance to the MSSO's ISO 9001:2008 certification
- IT staff to develop and maintain software tools for MedDRA users
- Project Management to provide oversight and direction.

The MedDRA MSSO staff ensures that daily operational processes and medical reviews of the MedDRA terminology are performed utilizing the highest quality standards in the industry.

MedDRA is used in over 60 countries, among which is Montenegro. MedDRA global success is reflected in continuing development in order to adapt to the new scientific knowledge and requirements of the regulator.

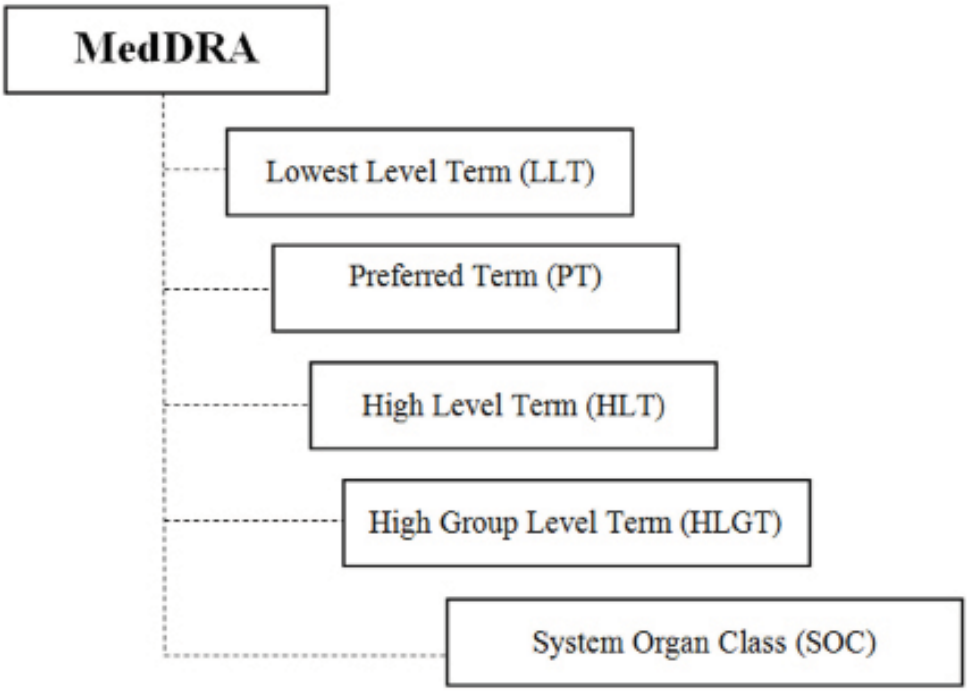

Figure 1. Structural Hierarchy of the MedDRA Terminology

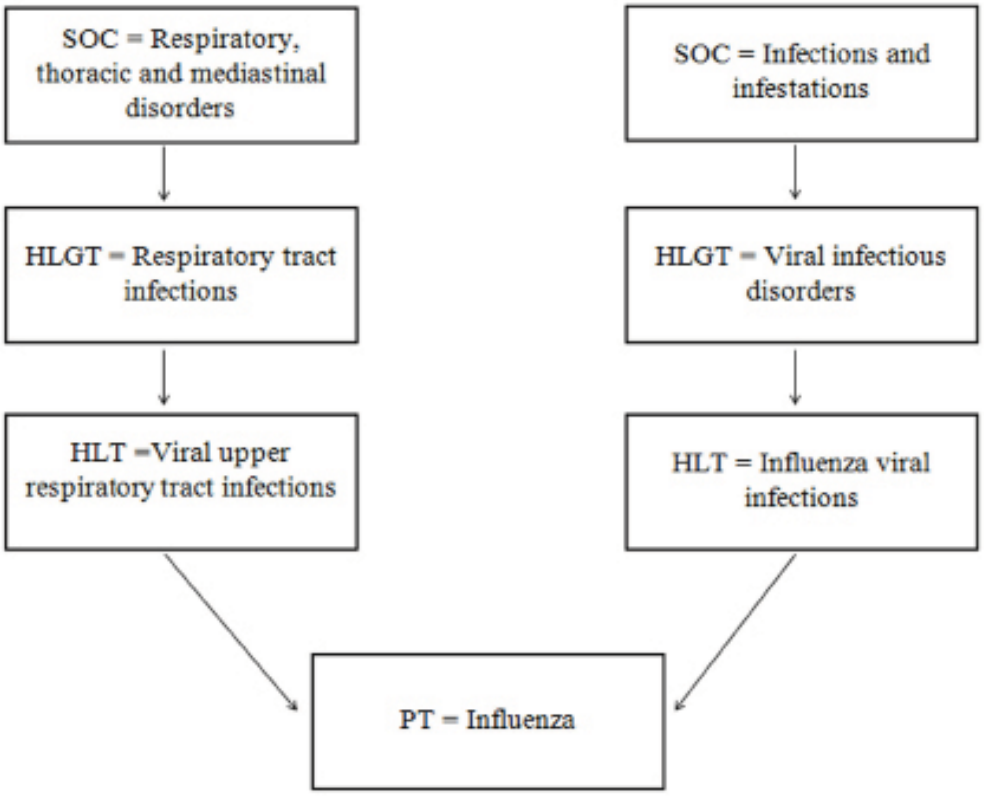

Figure 2.
MedDRA Multi-axiality

MedDRA releases 2 versions in a year – one in March and the second in September. One can obtain access to the MedDRA terminology annually, by renewable subscription. Each subscription brings all MedDRA updates that incorporate approved changes and additions. The current version is 18.0, from March 2015.

MedDRA Structure

The structure of MedDRA is very logical. There are five levels (Fig. 1) of hierarchy in the structure of MedDRA. *System Organ Class* (SOC) as the highest level is followed by the *High Level Group Term* (HLGT), *High Level Term* (HLT), *Preferred Term* (PT) and *the Lowest Level Term* (LLT). There are 72637 terms at the most specific level (LLT). They are grouped in 20559 *Preferred Terms*. Further, *Preferred Terms* make 1720 *High Level Terms* for a symptom, sign, disease diagnosis, therapeutic indication, investigation, surgical or medical procedure, and medical social or family history characteristic. *High Level Terms* are related to 334 *High Level Group Terms*. Finally, *High Level Group Terms* are grouped into 26 *System Organ Class* (SOC) based on etiology (e.g., Infections and infestations), the place of origin (e.g. Gastrointestinal disorders), or purpose, or purposes (e.g., Surgical or medical procedures). There is also a SOC relating to social conditions or circumstances.

MedDRA Multi-axiality

MedDRA is a multi-axial terminology meaning that a Preferred Term (PT) may be linked to more than one SOC.[10] For example, PT *influenza* has a link to both SOC *Respiratory, thoracic and mediastinal disorders* (its organ system of manifestation) and to SOC *Infections and infestations* (Fig. 2). Each PT is assigned a primary SOC to avoid "double counting" while retrieving information from all SOCs (i.e., a cumulative SOC-by - SOC data output). The other SOCs to which a multi- axial PT is linked are called "secondary" SOCs[11].

MedDRA available in foreign languages

In addition to the original English master and Japanese translation, MedDRA has been translated and is maintained in the following languages: Chinese, Czech, Dutch, French, German, Hungarian, Italian, Portuguese and Spanish. Each MedDRA term has an associated 8-digit numerical code which remains the same irrespective of the language. Multiple languages allow a large number of users to operate in their native language which promotes accuracy and precision in assigning codes. This interoperability is very powerful and allows easy sharing of data internationally[1].

Common problems faced by medical coding expert while coding

While coding, medical coding expert may face with the following problems[12]:
- Illegible verbatim term
- Spelling errors
- Use of abbreviations
- Multiple signs and symptoms recorded as separate events which may lead to some diagnosis (for example: signs and symptoms recorded as running nose, cough and fever, may lead to diagnosis of Pneumonia)
- Multiple medical concepts recorded together. In order to code it is needed to split the terms.
- Event is recorded without mentioning the site, e.g. ulcer is recorded without additional information like moth ulcer, leg ulcer, etc.
- Multiple medical concepts recorded which had surgical procedure and reason for injury. However the reason or cause or site of injury is not clear.
- A medication term reported however allergy due to the medication or outcome of the allergy is not specified.

CONCLUSION

MedDRA has become the standard medical terminology for drug regulators and pharmaceutical companies in over 60 countries, among which is Montenegro. 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. Guidelines for investigators, coding rules and medical validation should be provided to all coders in order to achieve the optimum level of coding and to ensure that all the parameters for quality are achieved[13], [14]. Since the coding should be treated as one of the most important function in clinical research, it is necessary to minimize the problems faced by medical coding expert when coding.

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Medicinski rečnik MedDRA – koristi se u više od 60 država, među kojima je Crna Gora

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KRATAK SADRŽAJ

Uvod: Medicinski rečnik za regulatorne poslove (MedDRA) je sistematični rečnik standardizovane medicinske terminologije namenjen regulatornim autoritetima, industriji, istraživačkim organizacijama, kao i zdravstvenim radnicima, odnosno svim učesnicima u sistemu praćenja bezbedne primene lekova.
Metodologija: U ovom radu objašnjen je najčešće korišćeni rečnik MedDRA, kao i process kodiranja ukratko. Svrha rada je skroman doprinos lakšem i uspješnijem razumevanju procesa kodiranja u obrađivanju kliničkih podataka iz oblasti farmakovigilance.
Tema: Prikazan je razvoj, sruktura, multiaksijalnost, dostupnost MedDRA-e na stranim jezicima, kao i najčešći problemi sa kojima se susreću eksperti za kodiranje u svom radu.
Zaključci: Rečnik MedDRA je postao standardna medicinska terminologija za regulatorne organe u oblasti lekova i farmaceutske kompanije u Crnoj Gori i drugim zemljama. U cilju postizanja optimalnog nivoa kodiranja potrebno je organizovati treninge za sve koji se bave kodiranjem, kako bi se osigurali svi parametri kvaliteta u tom procesu. Kodiranje se smatra jednim od najvažnijih procesa u kliničkim istraživanjima.

Ključne reči: medicinski rečnik, bezbednost primene lekova, farmakovigilansa

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