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Identification of Medicinal Products: Providing an Educational Framework

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Abstract. The ISO standards for the Identification of Medicinal Products (IDMP) prove to be difficult to implement. Guidance needs to be provided to those using and further developing IDMP-related standards and terminologies. Providing fitting and structured education would be a step forward. This article describes research of current education and certification on IDMP and the creation of an educational framework for targeted IDMP knowledge transfer. This framework indicates the required level of knowledge for the various identified roles within the organizations working with IDMP. Based on a combination of desk research, a questionnaire, and individual interviews, relevant roles were identified covering the various organizations (Users, Educators, Medicine Authorities, Standard Developing Organizations, and IT-suppliers) and five levels of required knowledge were determined, including applicable roles and educational components. Furthermore, this article lists several recommendations that should be taken into consideration whilst developing content and implementing educational modules for IDMP.

Keywords. IDMP, standards, education, medication, patient safety, interoperability

Introduction

Increased usage of structured terminologies and standards in the domain of Identification of Medicinal Products (IDMP) and the exchange of its data is expected to improve patient safety and increase efficiency of development, use and monitoring of medicinal products. While relevant ISO standards have been available since 2012[1], the impact of these norms can be considered as sub-optimal. Organizations make use of local/national standards or have developed their own system to classify and identify medicinal products. To prevent issues due to mistakes in translation and to facilitate interoperability and cooperation, such complexity should be prevented. This article aims to provide a concrete educational framework by answering the following questions what level of knowledge is expected of people and how do they acquire that knowledge, now and in the future? An educational framework would create common understanding among users, provide flexibility for distinct roles and could function as a first step for the further adoption and development of the set standards on IDMP. The end goal is providing users with an education framework to adopt IDMP related standards and terminologies. The expected growth in the number of new medicinal products seeking market authorization should also function as a motivator to use of the set of IDMP standards.

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1. Methodology and Findings

Information was gathered from both existing documentation as well as experts and industry users. The *e-Competence Framework*[2] describes 41 competences and roles relevant in an ICT environment. From this list, the relevant roles on the topic of IDMP were drafted which also provided input for a set of questions to be used in a questionnaire. The questionnaire was sent to industry professionals and experts, who were contacted over a period of two months and based on their UNICOM[3] involvement.

In two months, 82 individuals have replied to the questionnaire. The distribution across the various types of organizations was the following Users (41.5%), Educators (17.1%), Medicine Authorities (15.9%), Standard Developing Organizations 13.4%), and IT-suppliers (12.2%). Nearly all respondents indicated that the current situation was not ideal (93.9%); the lack of uniformity, unclear guidance and the lack of governance has led to variation. Note that none of the respondents that considered the current situation as ideal originated from the group of educators and the Standard Developing Organizations. Furthermore, 24.4% of the respondents required certification on IDMP from their staff but a majority referred to publicly available information or internal knowledge transfer even though 78.8% indicated that specific groups in their organization focus on IDMP. The variation in answers indicated that there are many different specializations and professionals working with IDMP. They also indicated that required knowledge was dependent on their role and engagement. Dividing those into groups of technical, business, clinical and regulatory was a first step.

Individual interviews with a number of industry users and experts on the topic of IDMP, were conducted to validate the outcomes of the questionnaire and provide more details on the current issues. The interviewees indicated that the lack of coherent education together with the great variation in used terminologies and standards, as the main thresholds for efficient exchange of data and increased patient safety.

1.1. Definition and Scope

In context of this study, an educational framework[4] is defined as the following: “An instructional framework provides a cohesive structure made up of proven components, but it is adaptable so as to work with varying teaching styles, content areas, and student needs (while maintaining the core structure of the framework)”[5]. Furthermore, an educational framework should adhere to the following objectives[6]:

- Promote a consistent view of body of knowledge worldwide;
- Specify its scope;
- Be publicly accessible;
- Enable the identification of role specific competencies;
- Provide a foundation for (health informatics) course and curriculum design;

Development and accreditation.

2. The Educational Framework

Based on the input, relevant roles and applicable levels could be identified. Below, five levels of understanding and specialization have been identified to create a curriculum with a clearly defined purpose in mind. The levels start with basic information and build

up to specialized understanding. Using these levels, fitting educational goals or topics could be defined, enabling educators.

2.1. Informative Level

The first level of education should be considered informative and isaimed at spreading awareness and a basic understanding of the standards and terminologies of IDMP. It is recommended that use cases and guidance on the ISO documents should be available to the public as a basic means of education to achieve a broad basic understanding.

2.2. Foundation Level:

Users are familiar with the basics of IDMP and are familiar with publicly available information. They understand the status quo and the main drivers for IDMP. Operational users should be able to integrate IDMP-libraries in their environment and import data. Strategic users are expected to have a high-level understanding of IDMP,its benefits and an overview of relevant stakeholders.
Relevant roles: IT Account manager, CIO/CTO, Database Administrator.

2.3. Intermediate Level

Users should be able to understand the logic of IDMP and its implementation. Furthermore, the relevant terminology should be clear to them in such a way that they grasp the relevance of terms in discussions. Business users should be able to propose new uses of IDMP in their organization while overseeing the impact on the processes in combination with stakeholders.
Relevant roles: Analyst, Product Owner, Information Manager, Medical Coder.

2.4. Advanced Level – Clinical and Regulatory

Users should be able to understand the terminology of IDMP fully. Furthermore, they should be able to scrutinize the standardsand make suggestions for improvement that will be beneficial for the general population of users. Users should be proficient in understanding terms and concepts and *their* applicability. They should proactively assist in the implementation of IDMP.
Relevant roles: Medication Compliance Officer, Pharmacovigilance Professional, Authors of medication related information (e.g., CDS or MPD), Medication Information Analyst, Regulatory Information Analyst.

2.5. Advanced Level – Technical

Users possess detailed knowledge on the structure of IDMP and its relevance in a technical sense. They should keep up to date with ongoing changes on a technical level and be aware of the impact of adjustments. Implementationsand changes can be carried out with little preparation time including the connection to external reference databases/services.
Relevant roles: Innovation Manager, Data modeler and Interface Specialist,Standard Specialists (participating in standard development).

3. Discussion and Conclusions

The construction of an educational framework would be a means to promote the adoption and usage of IDMP and its corresponding terminology. During the construction of the framework, its objectives were taken into consideration but it needs to be discussed further in order to refine the levels and content of the modules. Subsequently, pilot educational modules could be developed and expanded upon. Below a number of recommendations are listed.

Currently, the curricula are determined by a diverse group of professionals across various types of organizations. Centralized guidance on such a curriculum at a higher level would be preferred. Input for the curriculum should come from all users, while education could be provided by (non-)commercial organizations. Coordination and supervision could be done by independent organizations, such as medicine authorities.

It is noted that the various ISO documents, including several implementation guides, do not provide a generic overview regarding the usage and the step-by-step approach required for familiarizing or implementing IDMP. Therefore it is advisable to provide a roadmap that provides guidance getting familiar with the standards. This will clarify the necessary steps and logic to new and existing users. It will also lower the threshold for individuals and organizations that are new to IDMP. By keeping the threshold low, the awareness and basic understanding of this topic will grow resulting in effective implementation of IDMP.

Standards tend to grow organically to vast systems. By actively limiting new additions, the size of IDMP can be kept at a manageable level without the loss of important nuances. This keeps the threshold low for new users.

This article has focused on the creation of an educational framework leading to the education and certification of individuals. However, a certification could also be used to mark organizations as IDMP compliant. A similar approach as being used for other ISO norms such as ISO 9001 could be attained.

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