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Working paper

Report on education and certification programs

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Main author(s):

Robert Stegwee

CEN

Other author(s):

Christian Hay

ISO/GS1

Esther Peelen

Nictiz

Statement of originality

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Working paper abstract

The UNICOM project, financed under Horizon 2020, is about improved patient safety and better healthcare for all. It supports the implementation of Identification of Medicinal Products (IDMP) in the EU, wants to make sure that appropriate education is available for the people engaged in the implementation of IDMP and that a trusted level of knowledge and understanding of IDMP-related standards and terminologies can be requested from the people that engage with future development and maintenance of IDMP implementations.

WP 1 (Task 1.4) carries out research of current education and certification on IDMP and the creation of an educational framework for IDMP-related standards and terminologies. This framework should facilitate the required level of knowledge, beyond a general understanding, for the various relevant organisations and for the identified roles within these organisations. Based on desk research, a questionnaire and individual interviews, relevant roles were identified covering the various organisations (Users, Educators, Medicine Authorities, Standard Developing Organisations, and IT-suppliers). Based on gathered input, five levels of required knowledge were determined, including applicable roles, possible means of education, instruction and certification. Furthermore, this working paper lists a number of prerequisites and recommendations which should be taken into consideration whilst developing the content and implementing educational modules.

Keywords: IDMP, standards, education, certification, medication, patient safety

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TABLE OF CONTENTS

Working paper abstract	2
List of abbreviations	4
1 Executive summary	5
2 Introduction, structure and objectives	6
3 Methodology	7
3.1 Research methodology	7
3.2 Construction methodology	8
4 Findings	9
4.1 Defining an educational framework	9
4.2 Current challenges	9
4.3 Usefulness of an educational framework	10
4.4 Relevant roles and levels for the educational framework	10
4.5 Relevant organisations for implementation and execution	11
5 Framework	12
5.1 Knowledge levels and relevant roles	12
5.2 Overview of the framework	14
6 Prerequisites and recommendations	16
7 Appendices	18
7.1 Appendix I – Content of the questionnaire	18
7.2 Appendix II – Interview guideline	19
7.3 Appendix III – Initial framework, interviewee leaflet including introduction	20
7.4 Appendix IV – Interviews professionals	24
8 Used external sources	25

LIST OF FIGURES

Figure 1. Distribution of respondents	7
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LIST OF TABLES

Table 1. Educational Framework Overview for IDMP-related standards and terminologies	14
Table 2. Questionnaire questions	18
Table 3. Initial Knowledge matrix	21
Table 4. Overview of interviewees, roles and organisations	24

List of abbreviations

Abbreviation	Term
CDA	Clinical Document Architecture
eD	eDispensing
EMA	European Medicines Agency
eP	ePrescription
FDA	Food and Drug Administration of the United States
FHIR	Fast healthcare interoperability resources
HL7	Health Level Seven
IDMP	Identification of medicinal products
ISO	International Organisation for Standardization
NCA	National competent authority
PhPID	Pharmaceutical product identifier
PS	Patient summary
RA	Regulatory authorities
SDO	Standards developing organisation
SPOR	Substances, products, organisations and referentials
XEVMPD	Extended EudraVigilance medicinal product dictionary

1 Executive summary

This UNICOM working paper aims to provide the basis for an educational framework addressing the topic of IDMP-related standards and terminologies. The construction of an educational framework, providing suggestions and guidelines for curricula, aims to support the appropriate usage and support of widely applicable and used standards resulting in safer healthcare. It tries to achieve these results by ensuring that appropriate education is available for the people engaged in the implementation of IDMP and that a trusted level of knowledge and understanding of IDMP-related standards and terminologies can be requested from the people that will engage with this work.

Based on desk research, it was determined to make use of a so-called backwards design to draft the educational framework based on the desired outcome. By backtracking from the desired outcome to the means of instruction, the fitting methods and technologies could be identified. A public questionnaire together with conducted interviews with subject matter experts, led to the construction of five levels of education and relevant roles. These levels are:

1. Informative level;
2. Foundation level;
3. Intermediate level;
4. Advanced clinical and regulatory;
5. Advanced technical.

In order to keep the framework up to date and relevant, further expansion on these levels is encouraged to cater for specialisation and domain expertise.

Constructing the actual curriculum for these five levels should be done in a joint effort by all organisations involved (Users of standards, Educators, Medicine Authorities, Standard Developing Organisations and IT-suppliers). Due to the fact that industry organisations are likely to be most advanced in the implementation of IDMP, they are able to provide valuable input for the content of the curriculum. The constructed educational modules could be provided by not-for-profit (public) organisations and commercial educators while (international) independent organisations could be overseeing and safeguarding the quality of the education.

For a successful implementation and adoption of this educational framework and the related curricula, a number of prerequisites and recommendations were formulated. Firstly, lowering the threshold for obtaining basic information and use cases would significantly help in creating a widespread understanding of the standards and their usage. Such basic information should be made available freely and accessible for those interested in IDMP or working with the standards and terminologies. Furthermore, standards and terminologies have a tendency to grow to a size that is no longer properly manageable. By actively limiting new additions and constantly scrutinizing the existing body of the standards and terminologies, the size of the IDMP-related standards and terminologies can be kept at a manageable level without the loss of important nuances. This will help in keeping the size of IDMP and therefore the threshold to engage with this topic low for new users who are not familiar with IDMP and its usage.

2 Introduction, structure and objectives

Currently, the standards and terminologies in the domain of Identification of Medicinal Products (IDMP) are not being used consistently across the various types of organisations and industries that are working with medicinal products on a daily basis. Despite the ISO standards and implementation guidelines being available since 2012ⁱ, the adoption of IDMP is still incomplete. The lack of coherent education and certification on the use of IDMP-related standards and terminologies (in short IDMP) is regarded as a contributing factor to this undesirable variation across implementations.

[The UNICOM project](#), financed under Horizon 2020, is about improved patient safety and better healthcare for all. It supports the implementation of IDMP in the EU, wants to make sure that appropriate education is available for the people engaged in the implementation of IDMP and that a trusted level of knowledge and understanding of IDMP can be requested from the people that will be engaging with this work.

Work Package 1 of the UNICOM project (Task 1.4) is responsible for the creation of an educational framework for IDMP-related standards and terminologies. This framework identifies the required level of knowledge, beyond a general understanding, for the various relevant organisations and for the different roles people have within these organisations. Corresponding certifications could be a means to ensure that the appropriate level of knowledge is attained, either in internal educational programs or when contracting external expertise for IDMP-related projects.

By providing Educators (e.g., universities, not-for-profit organisations, and commercial providers) with an educational framework, they can create a fitting curriculum to provide courses and subsequently certifications matching the needs of organisations that make use of IDMP. This covers the preferred means of instruction and examination as well. The end goal is providing experts and users with the opportunity to adopt the IDMP-related standards and terminologies in such a consistent manner that information is interoperable and all organizations spare resources and increase patient safety.

In this working paper, we have chosen to focus on the description of the educational framework itself rather than providing detailed (scientific) report and analysis of all gathered data. By combining desk research with a questionnaire and individual in-depth interviews, this working paper aimed to provide concrete guidance and recommendations for further development and the creation of the subsequent curriculum. This pragmatic approach will become evident via the structure of this working paper.

After discussing the used methodology for the research and the used methodology for constructing the framework, the results of the Desk Research, questionnaire and interviews will be discussed together per relevant aspect. The concluding section of this working paper presents the proposed educational framework as well as recommendations. Relating to the latter, we also identify a few topics that are not part of the educational framework per se but could be considered as prerequisites for a successful usage of the educational framework or relevant for the use of IDMP in general terms. These additional remarks are presented as a final section of the working paper.

In order to create a fitting framework, this working paper aims to achieve the following:

- Define the various relevant organisational roles in demand of knowledge of IDMP-related standards and terminologies;
 - Differentiate between business, technical and clinical roles;
- Define the level of knowledge required per role;
- Create insight in the current situation regarding available education and certification across relevant organisations;
- Provide handholds for determining fitting methods of instruction and certification;
- Publish a publicly available overview regarding the needs for education and certification on IDMP for various types of organisations and roles; this would guide future development of targeted service offerings on education and certification.

3 Methodology

3.1 Research methodology

In order to obtain input for the educational framework, information was gathered from both existing documentation as well as from the developers and regular users of IDMP-related standards and terminologies. This section briefly describes the methods used and the role of formal guiding documents, such as the *e-Competence Framework*. The e-Competence Framework lists an overview of 41 competences and roles relevant in a (professional) ICT working environment.

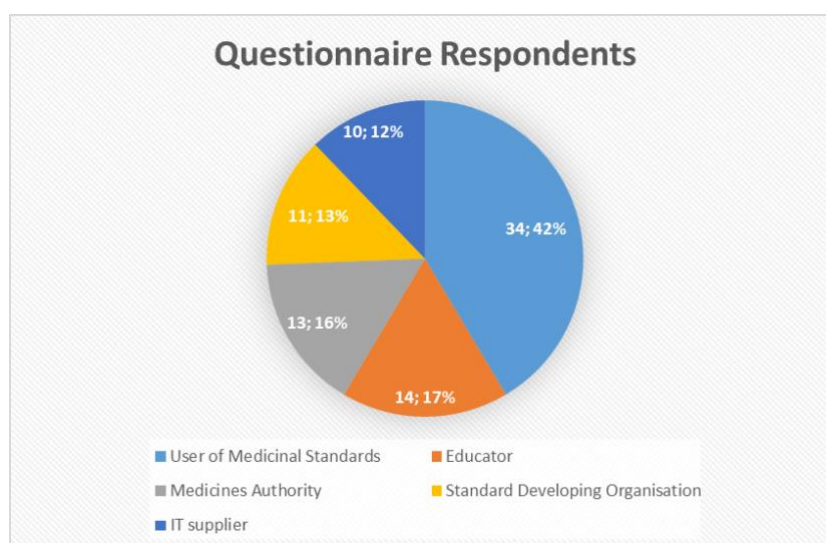
The main stages of the research consisted of desk research, followed by a questionnaire, sent both to members of the consortium as well as external stakeholders, and concluded with individual interviews to provide more detail where needed.

A questionnaire was chosen to assess the current state and gather the needs for education and certification across the landscape of users of IDMP, as well as the developers of the standards. The desk research provided the basis for an initial set of questions to be used in the questionnaire whereas the e-Competence Framework provided input for the relevant roles. At first instance, the questionnaire was sent out for initial validation to the participants of work package 1. Next it was distributed among all work package leads in the consortium in order to gather feedback on the questions themselves and their phrasing. Based upon this input we decided to structure the questionnaire according to the type of organisation of the respondent.

The questionnaire was then distributed among the members of the UNICOM consortium, as well as the participants in the UNICOM Community of Expertise. The type of organisation determined the flow of questions within the questionnaire. The question formats consisted of both multiple choice, Likert scales as well as free text answers. The final question of the survey was the request to share the contact details of potential other organisations/individual experts that could be interested in participating in the survey. This was designed to create a snowball effect in recruiting respondents to the questionnaire.

The questionnaire was made using Google Forms under a Google Mail account specifically created for the purpose of this survey. A complete overview of the questions (per type of organisation) and the created Google Mail account can be found in Appendix I at the end of this document. The sent-out questionnaire provided the necessary insights regarding the use of IDMP-related standards and terminologies, current education plans, curricula, and the level of understanding in the various types of organisations. Over a period of 2 months 82 individuals, both within and outside the consortium, have replied to the questionnaire providing valuable input. The distribution across the various types of organisations can be found below:

Figure 1. Distribution of respondents



The desk research in combination with the results of the questionnaire led to the creation of an initial version of the educational framework. This initial version was included into a leaflet for means of documentation as well as input for the follow-up interviews (see Appendix III). The leaflet was sent to the interviewees in advance to provide insight in the proposed framework. These interviews were conducted with a small distinct group of professionals and aimed to validate the initial version of the framework and to provide more details in particular areas. Furthermore, the required level of knowledge for the various roles was discussed during the interviews, as well as its applicability in their setting. Furthermore, it was discussed which type of organisation should be in control in providing education, assessing knowledge and establishing the curriculum.

3.2 Construction methodology

Because the desired framework aims to facilitate education and certification, the framework could be constructed with a clear end result in mind. Therefore, we chose to make use of the so-called backwards design method when constructing the initial framework and recommend the use of the 5E-methodology to keep the framework up to date. Due to the complexity of the field and the wide range of involved actors and roles, it is not realistic to aim for a definitive framework from the start. Therefore, we position our work as the initial iterations in line with the 5E-methodologyⁱⁱ of educational design, as elaborated below. Adding new levels, roles or shifting with the knowledge domains will be necessary based on implementation results.

Backwards Design

The Backwards Design methodology for a framework starts off with the identification of the desired results; what is the final goal of constructing the framework?ⁱⁱ After determining the goal of the framework (the desired level of knowledge for the various roles and the recommended education methods), the content of the curriculum can be determined and at the final stage the methods of instruction can be selected. By following this backwards methodology, the initial and foremost focus of developing the framework covers the desired results.

5E methodology

The complexity of IDMP and its widespread usage in the future requires recurring evaluation and adjustments. In order to keep the educational framework up to date and fit to its purpose, the so-called 5E methodology could be used. This method of constructing and maintaining an educational framework describes a continuous process of engagement, exploration, explanation, elaboration, and evaluation. Input from all relevant organisations such as industry users, regulatory authorities, and (commercial) educators is crucial for its further development and practical applicability.

4 Findings

4.1 Defining an educational framework

The desk research helped to clarify the definition, goal and to outline the intended scope of an educational frameworkⁱⁱⁱ. An educational or instructional framework should cater to the teachings of a set curriculum fitting to the level of knowledge required with the intended end results in mind. The methods of instruction and corresponding examination should be tailored to the present level of knowledge among the subjects participating in the educational framework. The citation below nicely summarizes this definition:

“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).”^{iv}

Whereas an educational framework covers the outline of an instructional module, the corresponding processes and the level of knowledge, a syllabus is a descriptive list of topics discussed during the course or training. A curriculum often combines both of these aspects in a single document including a detailed overview of the coursework, its examination and a description of the goals and content offered by the educational institution^v. The educational framework, described in this working paper, presents a structure and a definition of desired outcomes which helps (commercial) educators in developing their own appropriate curriculum including instruction and examination methods.

4.2 Current challenges

Nearly all the respondents to the questionnaire considered the current situation as sub-optimal. According to them, the level of both national and international consensus on standard and definitions is too low and to some extent even non-existent. This lack of consensus causes inefficient collaboration and undermines the potential benefit of standardization. The fact that, according to one of the respondents, the EMA is not consistent in its strategy on the topic of standardization is not advantageous. Recurring revisions and a lack of a long-term strategy on the implementation and usage of IDMP has led to little support of IDMP among professionals.

Suggestions for improvements include the construction of an educational framework for the various required levels of knowledge, to set a global standard as the norm and create a team of experts to assist in mapping to locally used definitions and terminologies. The various levels of knowledge should start off with a generic informative level and culminate in an in-depth understanding of the material and its applicability. A suggestion mentioned multiple times is to really integrate the use of IDMP as a global/enterprise standard encouraged and/or enforced by National Healthcare Authorities. This would include the use of IDMP as an integral part in medication related processes and not just as an addition to already existing processes. By acknowledging the use of IDMP as a best practice, its impact on patient safety will continue to grow.

Furthermore, differentiation within organisations also creates complexity. Interviewees have indicated that even within their organisations the used terms and concepts vary per department. This significantly complicates the implementation of a general standard and terminology. Currently, nearly all education is organised by the departments or internal experts themselves, in accordance with their specific needs and interest. This ad hoc approach is caused by the vast size of the ISO related documentation and the lack of a clear understanding of how to implement – let alone use – the set standards. Their observation is that many people claim to know IDMP and its data model, but few people really understand its functionality and applicability.

Challenges regarding curriculum, education, and certification

In general, the respondents of the survey indicated that there is no concrete level of education or certification required on the topic of IDMP by their organisations. Some respondents refer to UNICOM deliverables, such as [IDMP in a Capsule](#), as means of instruction. This implies that no methods of

instruction were in place in their organisation, before this working paper was published as part of the UNICOM project. Other respondents referred to a general level of understanding for substance experts in their organisation without specifying how to achieve this required level of knowledge. Some respondents indicate that they require a general level of education, such as Bachelor, Master or even PhD in order to understand the topic of IDMP-related standards and terminologies. However, such a degree does not necessarily cover IDMP at the required level, if the topic is covered at all.

Almost none of the respondents indicated that certifications on the topic of IDMP were required by policies or regulations within their organisation, whereas others mentioned the lack of existing official certifications on this topic. ISO standards have been published since 2012 and are maintained on the topic of IDMP but at this moment, no official examination and certification has been introduced. One specific respondent was even a bit wary about the implementation of official certifications because those might provide a false sense of understanding or perceived support for standardization in this domain achieved via IDMP. A certification on the topic of IDMP should not just be required top down from the EU or some national authorities but should really be seen as added value and a desirable certification for personnel in all types of organisations.

4.3 Usefulness of an educational framework

Both respondents to the questionnaire as well as the individual interviewees encouraged the creation of an educational framework and the corresponding implementation. The construction of an educational framework would create a degree of uniformity across the full spectrum of users while providing enough freedom in the distinct curricula for the required levels of knowledge and distinct roles. Furthermore, an educational framework should aim to lower the threshold to learn and invest into obtaining knowledge of IDMP; in the current situation people do not have a clearly defined development path in this regard, resulting in an unstructured method of self-learning. An educational framework would be useful if it provides organisations and users of IDMP with a clear roadmap which allows them to get educated with a structured and (internationally) recognized method of instruction and corresponding certification. Through this, the credibility of such educational modules will be improved as well. However, those certifications must be organised properly in order to preserve their value and credibility.

Additionally, one of the interviewees remarked the exponential growth of applications for new products and medicine. In order to streamline the growing number of applications, the use of the same language will be of great help. A framework to cater to the creation of curricula for education on this common language will facilitate the usage of this same language.

4.4 Relevant roles and levels for the educational framework

To provide an overview of the relevant roles for IDMP-related standards and terminologies the *EN 16234-1 e-Competence Framework* was used as a basis. The overview in the document is not exhaustive so by providing the respondents to the questionnaire and interviewees with the opportunity to list specific roles that deal with IDMP within their organisation, this provisional list of relevant roles could be expanded upon.

Almost all respondents to the questionnaire, coming from all types of organisations, have indicated that there are specific groups in their respective organisation that are responsible for IDMP. The great variation in answers indicates that there are many different specialisations and professionals working with IDMP-related standards and terminologies. They also indicated that the need to obtain specific knowledge was heavily reliant on the role of the professional and their engagement in the working field. Therefore, a generic distinction between technical, clinical, regulatory and business users was a good first step which is also included in the initial and definitive version of the educational framework.

In order to structure the large number of roles and specialisations, a number of levels are defined. These levels build up from basic information up to a specialised level of understanding relevant for experts. By dividing the large number of roles into these levels, fitting educational goals or topics could be defined. The levels combined with the educational goals and topics make it possible for educators, both not-for-profit as well as commercial, to create a curriculum with a clearly defined purpose in mind. Based on the

desk research and the questionnaire an initial framework was set up which was validated during the individual interviews by sending it out beforehand via a leaflet. See Appendix III for the leaflet and the initial framework.

In general, the drafted levels and the corresponding roles in the initial framework were considered as a solid basis for the educational framework by the interviewees. They had some small recommendations in order to increase its applicability and its support across the users of IDMP, such as including a basic informative level and creating overview documentation for all applicable ISO and related documentation. Furthermore, regarding the identified levels, the division into business, clinical, regulatory and technical users was considered logical but the Advanced specializations ('Clinical and Regulatory' and 'Technical') were considered too broad due to the various roles relevant for those levels and the complexity of the domains. The interviewees understood that not all specialisations could have their own certification but creating more specializations, such as substance or dosage experts, while keeping the distinction between business, clinical and technical intact, will be desirable soon after the first implementation. Such additional specializations and corresponding education will be covered by the recurring feedback and improvement model used in the 5E-methodology meant to keep the framework up to date.

4.5 Relevant organisations for implementation and execution

In the current situation, the provided education is mainly driven by internal experts within the organisations and is based on a best effort approach. Therefore, the interval and organisation of such education is often inconsistent and focussed on specific domains of IDMP. Subsequently, the curricula regarding this topic are determined by a diverse group of professionals ranging from University's lecturers to legal departments in other types of organisations. It would be preferred to centralize the organisation of such a curriculum on an international level while offering specific modules that are relevant for distinct roles, responsibilities, and domains. Multiple interviewees indicated that the education should preferably be provided by a not-for-profit organisation to limit the potential for conflict of interest, but this was not a hard requirement. However, input for the curriculum should be coming from users of IDMP-related standards and terminologies such as industry organisations.

As one interviewee commented, industry users are likely to be more aware of such standards and further in their implementation than regulatory or not-for-profit organisations. Therefore, it is recommended to consult industry users about their requirements regarding the actual content of the curriculum. A joint approach might be most feasible due to the combination of theoretical and practical knowledge required on this complex topic.

The National Competent Authorities (NCAs) also play an important role in the successful implementation of an educational framework. However, they should not engage in drafting the curriculum but could take a regulatory role in which they guard the qualifications and the quality. Beware, variations across the national NCAs (e.g., budget and focus) might complicate international efforts so, for example, the EMA could take on a supporting or advisory role.

Including sections on IDMP-related standards and terminologies in Bachelor or Master Programs would also be supported by all the interviewees, but this would only cater to students starting their career and exclude active professionals. To cater to active professionals, a publicly accessible minor or semester at a university would be a great way to provide education on IDMP. Universities are located across countries and have a proven track record of high quality education. In order to include these topics in existing curricula, other organisations such as industry users or regulatory organisations should make its relevance for students clear.

5 Framework

Based on the findings discussed in Chapter 4, a definitive version of the educational framework is presented here. Firstly, this section will describe the five levels that have been defined together with a description pertaining to its applicability for the relevant roles. These roles will be listed after each of the descriptions, except on the informative level because this first level does not have a target audience with distinct roles. After discussing all the identified levels and relevant roles, a matrix style presentation of the framework is provided to present the information in a structured manner. In the next chapter, recommendations and prerequisites are identified that are relevant to make the implementation and use of this framework a success.

5.1 Knowledge levels and relevant roles

The actual content for each of the identified knowledge levels should be fitting for the related roles and their daily operations in regard to IDMP. Below, five basic levels of understanding and specialisation, that serve as the basis for the educational framework, have been identified. This structure also leaves room for further specialisation modules as desired by the interviewees. For example, a user on the Advanced Technical level might have an interest in specializing in the IDMP domain of substances or dose forms.

Informative level

The first level of education should be considered informative and is aimed at spreading awareness and a basic understanding of the standards and terminologies of IDMP. Some other initiatives in this regard have chosen to limit access to documentation and information to those having obtained a basic informative certificate. It is recommended that use cases and guidance on the ISO documents should be available to the general public as a basic means of education to achieve a broad basic understanding. By lowering the threshold as early as possible, implementation of IDMP and its success will gain traction. This informative level should provide a structured overview of all relevant ISO documentation and guidance for an implementation roadmap providing best practices for all relevant organisations. By offering access to such information, people might be persuaded to invest more time and resources in IDMP. [IDMP in a Capsule](#) is a good example of an easily accessible educational product fitting for this informative purpose. This level should focus on answering the questions “*Why is this relevant and what is the next step for myself and my organisation?*”.

This level of education is relevant for all persons working with or those who have an interest in IDMP-related standards and terminologies. Therefore, no specific roles have been identified.

Foundation level

In general, on the foundation level it is expected that users are familiar with the basic principles of IDMP and have seen/read the publicly available information such as described above. They should be able to understand the status quo and the main drivers to strive for standardisation and an implementation of IDMP. It is not expected that users on this level keep up to date with minor changes, but they should be aware of major updates. Actors acting within an operational role, such as IT developers, should know the basics of implementing IDMP related libraries to their technology stack and importing necessary data. On the strategic level, such as Chief Information/Technology Officer, users are expected to have a high-level understanding of IDMP, the benefits and which stakeholders are making use of the standards as well. Understanding the internal processes of their own organisation is important, although outside the scope of this educational framework.

Relevant roles:

1. IT Account manager;
2. Chief Information/Technology Officer;
3. Database Administrator;

4. IT developer;
5. Project Manager;
6. User (Regulatory, Clinical, Supply chain).

Intermediate level

Users looking to be certified on the Intermediate level should be able to understand the logic of IDMP and its desired implementation. Furthermore, the relevant terminology should be clear to them in such a way that they grasp the relevance of terms in discussions. Business Analysts and Product Owners should be able to propose new ways in which IDMP can be used in their organisation while users such as Information Managers are able to oversee the impact on the processes in combination with stakeholders. Medical coders should be proficient in using the IDMP standards and terminologies in their internal systems and processes, in combination with local data structures and vocabularies. By obtaining this level of understanding, the users should be able to understand the workings of IDMP and its relation to internal processes and departments. Emphasizing that implementation of such standards within a large organisation also entails significant alignment is therefore very important.

Relevant roles:

1. Business Analyst;
2. IT/IS Product Owner;
3. Information Manager;
4. Medical Coder.

Advanced – Clinical and Regulatory level

Those certified on the Advanced – Clinical and Regulatory level, should be able to understand the terminology of IDMP to the fullest extent. Furthermore, they should be able to scrutinize the set standards and be able to make suggestions for improvement that will be beneficial for the general population of users. Furthermore, users at this level should be proficient in understanding the differentiation of terms and concepts and its applicability in their domain. They should proactively assist in the implementation of IDMP-related standards and terminologies across their organisation by providing expert insights.

Relevant roles:

1. Medication Compliance Officer;
2. Pharmacovigilance Professional;
3. Authors of medication related information (e.g., CDS or MPD);
4. Medication Information Analyst;
5. Regulatory Information Analyst.

Advanced – Technical level

Users aiming to achieve the Advanced – Technical certification, possess detailed knowledge on the structure of IDMP-related standards and terminologies 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 such adjustments. Implementations and changes can be carried out with little preparation time. If an organisation chooses to make use of an external reference database instead of internal implementation, users with this level of knowledge should be able to oversee such a referencing method.

Relevant roles:

1. Innovation Manager;
2. Data modeller and Interface Specialist;
3. Standard Specialists (participating in standard development);

5.2 Overview of the framework

The matrix below provides a structured overview of the levels and roles. This overview also includes a breakdown of the required knowledge per level as discussed on the previous pages. This will provide the educators with more concrete guidance for the creation of the actual curricula and determining fitting means of instruction and examination.

Table 1. Educational Framework Overview for IDMP-related standards and terminologies

Level	Roles	Basic principles and why it is important	Main drivers for IDMP	Basic know-how on implementation	Overview of stakeholders	Logic of IDMP and its role in the industry	Suggest uses for IDMP in their organisation	Overview of impact on the existing situation	Mapping IDMP to internal systems	Detailed knowledge of IDMP concepts	Scrutinize and suggest improvements	Assist implementation with expert insights	Understand medical relevance	In-depth knowledge on IDMP structure	Able to oversee and guide implementations
Informative level	<ul style="list-style-type: none"> Everyone 	X	X												
Foundation	<ul style="list-style-type: none"> IT Account Manager Chief Information/Technology Officer; Database Administrator; IT developer; Project Manager; User: 	X	X	X	X										
Intermediate	<ul style="list-style-type: none"> Business Analyst; IT/IS Product Owner; Information Manager; Medical Coder. 	X	X	X	X	X	X	X	X						
Advanced – Clinical and Regulatory	<ul style="list-style-type: none"> Medication Compliance Officer; Pharmacovigilance Professional; Authors of medication related information (e.g., CDS or MPD); Medication Information Analyst. Regulatory Information Analyst 	X	X	X	X	X	X	X	X	X	X	X	X		

Level	Roles	Basic principles and why it is important	Main drivers for IDMP	Basic know-how on implementation	Overview of stakeholders	Logic of IDMP and its role in the industry	Suggest uses for IDMP in their organisation	Overview of impact on the existing situation	Mapping IDMP to internal systems	Detailed knowledge of IDMP concepts	Scrutinize and suggest improvements	Assist implementation with expert insights	Understand medical relevance	In-depth knowledge on IDMP structure	Able to oversee and guide implementations
Advanced – Technical	<ul style="list-style-type: none"> Innovation Manager; Data Modeller and Interface Specialist; Standards Specialists (participating in development). 	X	X	X	X	X	X	X	X	X	X			X	X

6 Prerequisites and recommendations

This chapter provides a number of recommendations to make the implementation and use of the constructed educational framework successful. A distinction among these recommendations is made between those that are prerequisites for an effective usage of the framework and those that are more general recommendations for the success of IDMP as a whole.

Prerequisites:

Inclusion in BSc., MSc., continuing education and certification programs

It has been mentioned a number of times that including a small module on IDMP-related standards and terminologies in BSc. and MSc. curricula would be beneficial for its renown. In the current situation, little attention is provided to such standards and the use of those standards in the daily work of both industry, clinical and regulatory professionals. Usually, the persons that draft the curriculum for BSc or MSc program have not been working in their field of expertise for some time so it might require some degree of external momentum (e.g., from industry users or regulatory organisations) to include IDMP in the curriculum. Of course, the module on IDMP should be fitting in with the rest of the educational material, the lecturers should have sufficient knowledge on the topic and the students should be interested or engaged.

Follow-up

As mentioned a number of times in this working paper, the implementation and use of the described educational framework would only be feasible if it is broadly supported throughout the whole supply chain and working field. Therefore, it would be sensible to keep all relevant organisations actively engaged in order to create broad support and aim for a universal usage of the IDMP-related standards and terminologies. Active engagement of the target audience and relevant organization is also an important prerequisite for keeping the educational framework and subsequent curricula up to date and fitting.

Roadmap

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. By providing a roadmap that functions as guidance when delving into the contents of the standards, the order of the necessary steps and logic will be made clear to new and existing users. This roadmap can be presented in a single overarching document that discusses the aim of all the separate standards and terminologies and their relation to one another. This overarching roadmap should also be made part of the informative/foundation level education listing a step-by-step approach to IDMP.

Recommendations

Lowering the threshold

As touched upon at the “Informative level”, it is important to lower the threshold for new individuals and organisations interested in IDMP. By keeping the threshold as low as possible, the awareness and basic understanding of this topic will grow resulting in a more effective implementation of the educational framework as a whole. Making information publicly available for all those who are interested is one concrete example of a way of lowering the threshold.

Active branding and promotion

In order to create sufficient support for the adoption of IDMP-related standards and terminologies, the potential of active branding and promotion should not be underestimated. By an ongoing presence on media such as LinkedIn and by proactively providing information on the topic, support and knowledge of IDMP will grow. Of course, this links to recommendation of lowering the threshold described above. One prime example of successful branding and promotion is HL7 FHIR.

Manageable size

Some standards have a tendency to grow organically to vast systems with extended terminology and concepts. This organic growth might lead to ambiguity and an unclear connection between the used terminology and the relevant concepts. By actively limiting new additions and constantly scrutinizing the existing body of the standards and terminologies, the size of the IDMP-related standards and terminologies can be kept at a manageable level without the loss of important nuances. This will help in keeping the threshold low for new users who are not familiar with IDMP and its usage.

Certifying organisations and services

This working paper has focussed on the creation of an educational framework leading to the education and certification of individuals working for the various types of organisations. However, one of the interviewees made the remark that a certification could also be used to mark organisations as IDMP compliant. By attaining the same approach as being used for other ISO norms such as ISO 9001, organisations may receive a certification that they are attaining a minimal percentage of compliance with the standards. The same can be applied to the certification of data providers that conform to the set standards and terminologies.

Keeping certifications up to date

Due to the complexity of the domain, the content of the educational framework and the corresponding curricula will be subject to ongoing improvement and changes. In order for professional industry wide certificates to stay relevant and credible, it is important to keep the certified population knowledgeable. Therefore, it is necessary that individuals who are certified are motivated to keep their knowledge up to date. By providing ongoing refresher courses and promoting its use, the certified population will be motivated to keep their knowledge at the required level.

7 Appendices

7.1 Appendix I – Content of the questionnaire

In the diagram below, the questions used in the questionnaire are listed. On the right hand side, the X's indicate the relevance for each of the questions for the types of organisations. The questionnaire has been created by the use of Google Forms due to its functionality and ease of use. For this purpose, a specific Gmail account has been created: idmp.unicom@gmail.com. Its login credentials are known to the creators of this working paper. The questionnaire can be accessed via [this link](#). The distribution of the questionnaire has been via multiple emails as well as posts by the UNICOM account on LinkedIn.

Table 2. Questionnaire questions

Question	SDO's	Educators	Authorities	Users of IDMPs	IT suppliers
What type of organisation are you working for?	X	X	X	X	X
How would you describe your role?	X	X	X	X	X
Are there specific groups in your organisation that focus on IDMP?	X	X	X	X	X
What types of education and certification on IDMP do require from your (temporary) staff?	X	X	X	X	X
Do you notice variety among (temporary) staff and to what extent does this complicate their work?	X	X	X	X	X
To what extent are IDMP-related certifications required by policies or regulations within your organisation?	X	X	X	X	X
What types of education and certification on IDMP do you already provide?	X				
Regarding the types of education you offer; do you differentiate between standard developers and users of the standards?	X	X			
Regarding the types of education you require; do you differentiate between standard developers and users of the standards?				X	X
To your knowledge, are IDMP-related standards and terminologies part of the curriculum?	X	X		X	X
If so, do you know who determined such a curriculum and is it revised on a regular basis?	X	X		X	X
Would you consider the current situation as the ideal situation?	X	X	X	X	X
What would you like to see changed regarding the use of IDMP?	X	X	X	X	X

7.2 Appendix II – Interview guideline

Questions for interviewees

1. Are you familiar with UNICOM and its objectives?
 - a. If not, provide a brief introduction.
 - b. If so, continue with next question.
2. What is the name of the organisation you are working for?
3. How would you classify your organisation in regard to IDMP?
 - a. SDO;
 - b. Educator;
 - c. Authority;
 - d. User of IDMP;
 - e. IT supplier;
4. How would you describe your role?
5. In your daily activities, are you working with IDMP-related standards and terminologies?
6. Which challenges do you encounter on the topic of IDMP? E.g., lack of knowledge/understanding or little standardization?
7. Would the provisioning of educational standards function as a solution to these issues?
8. Follow-up: Would providing the options for education lead to greater support and usage of the IDMP-related standards and terminologies?
9. Part of the UNICOM project is drafting an educational framework on the topic of IDMP, could you define the different levels of understanding required for various roles?
10. Would you agree with 4 educational levels based on the required level of knowledge? Any remarks?
 - a. Share matrix with the identified roles and knowledge levels (currently being drafted).
11. In broad terms, what methods of instruction/education should be used to achieve such a level of understanding?
 - a. Instructional texts;
 - b. Educational videos;
 - c. (online) classroom instruction;
 - d. Interactive assignments;
 - e. examinations.
12. Should such education be included in the curriculum of specific Bachelor or Master programs or should it be offered by commercial providers? Please motivate.
13. Should the curriculum of the course/module be determined by a single actor after consulting the users and educational providers?
14. Follow-up: Which organisation should be responsible?
15. Which role should National Authorities have in this regard?
16. Are there any other (ongoing) initiatives which might be interesting for UNICOM?
17. Would you be willing to support in the implementation of IDMP within your organisation or be willing to provide us with the contact details of persons within your organisation that might be interested?

7.3 Appendix III – Initial framework, interviewee leaflet including introduction

Introduction

The UNICOM project is in the process of creating an educational framework for IDMP-related standards and terminologies. This framework should facilitate the identification of the required level of knowledge, beyond a general understanding, for the various relevant organisations and for the different roles people have within these organisations. Corresponding examinations and certifications could be a means to ensure that the appropriate level of knowledge is attained and kept up to date.

In an attempt to make as efficient use of your time as possible during the interview, we would like to provide you with some information beforehand. This includes the goal of the interviews as well as the interview structure and the processing of results. In order to provide you with insight on the current version of the educational framework, this document also contains a matrix with the (preliminary) drafted levels of required knowledge and identified roles.

Goal of the interviews

Recently, a questionnaire has been sent out to gather input from professionals who work with IDMP on a regular basis. The results of this questionnaire are used as input for the educational framework. To be more specific, the various identified roles and the applicable levels of required knowledge have been drafted on the basis of this input. During the interview we would like to gather additional insights in the roles, knowledge levels and also on the topic of means of education and certification.

Interview structure and processing of results

The interviews will be conducted in a semi-structured format in which a predetermined set of questions will be discussed and at the same time leaving plenty of room for a conversation-like setting. This interview structure is aimed to provide the UNICOM working paper with the best results and well-founded conclusions.

With your permission, we would like to include your full name, role and organisation in the final report to be as transparent as possible regarding the source of data. This will also benefit the credibility of the results due to the fact that distinguished domain professionals have contributed to the creation of the educational framework.

Current version of identified roles and levels

On the following pages you will find an overview of the various roles and level identified via desk research and based on the answers received on the questionnaire. Note that this is a draft version so during the interview we encourage you to scrutinize the roles, levels and corresponding descriptions. Any suggestions regarding the topics of certification and examination are also highly appreciated.

Structured overview of the identified levels and roles:
Table 3. Initial Knowledge matrix

Level	Roles (Regulatory, clinical or supply chain)	Basic principles	Basic know-how on implementation	Main drivers for IDMP	Overview of Landscape and stakeholders	Logic of IDMP its role in the industry	Suggest uses for IDMP in their organisation	Overview of impact on the existing situation	Mapping IDMP to internal systems.	Detailed knowledge of all concepts	Scrutinize and suggest improvements	Assist implementation with expert insights	Understand Medical relevance	In-depth knowledge on IDMP structure	Able to oversee and guide implementations
Foundation	<ul style="list-style-type: none"> Account manager; Chief Information/ Technology Officer; Database Administrator; IT developer; Project Manager; User: 	X	X	X	X										
Intermediate	<ul style="list-style-type: none"> Business Analyst; IT/IS Product Owner; Information Manager; Medical Coder 	X	X	X	X	X	X	X	X						
Advanced – Clinical	<ul style="list-style-type: none"> Medication Compliance Officer; Pharmacovigilance Professional; Authors of medication related information (e.g., CDS or MPD) Medication Information Analyst 	X	X	X	X	X	X	X	X	X	X	X	X		
Advanced – Technical	<ul style="list-style-type: none"> Innovation Manager; Database and Interface Specialist Standards Specialists (participating in standard development; Substance Experts. 	X	X	X	X	X	X	X	X	X		X		X	X

Overview and elaboration:

1. Foundation (basic knowledge for those working in the area/on projects):

- a. Account manager;
- b. Chief Information/Technology Officer;
- c. Database Administrator;
- d. IT developer;
- e. Project Manager;
- f. User;

In general, on the foundation level it is expected that users are familiar with the basic principles of IDMP. They should be able to understand the status quo and the main drivers to strive for such a form of standardisation. It is not expected that users on this level keep up to date with minor changes. Actors acting on the operational level, such as IT development, users should know the basics of implementing IDMP related libraries to their technology stack and importing necessary data. On the strategic level, such as Chief Information/Technology Officer, users are expected to have a high level understanding of IDMP, the benefits and which stakeholders are making use of the standards as well.

Required knowledge:

- Basic principles;
- Basic know-how on implementation;
- Main drivers;
- Overview of stakeholders.

2. Intermediate (knowledge on the added value of processes and know-how on the implementation in their organisation):

- a. Business Analyst;
- b. IT/IS Product Owner;
- c. Information Manager;
- d. Medical Coder.

Users looking to be certified on the Intermediate level should be able to understand the logic of IDMP and its desired implementation. Furthermore, the relevant terminology should be clear to them in such a way they grasp the relevance of terms in discussions. Business Analysts and Product Owners should be able to propose new ways in which the IDMP standards and related terminologies can be used in their organisation while users such as Information Managers are able to oversee the impact on the processes in combination with stakeholders. Medical coders should be proficient in mapping the IDMP standard to their internal systems and processes.

Required knowledge:

- Understand the logic of IDMP its role in the industry;
- Suggest uses for IDMP in their organisation;
- Overview of impact on the existing situation;
- Mapping IDMP to internal systems.

3. Advanced - Clinical (more advanced training for those authoring drug dictionaries, formularies on the clinical impact/opportunities of IDMP compliance);

- a. Medication Compliance Officer;
- b. Pharmacovigilance Professional.
- c. Authors of medication related information (e.g., CDS or MPD);
- d. Medication Information Analyst.

Those certified on the Advanced – Clinical level, should be able to understand the terminology of IDMP to the fullest extent. Furthermore, they should be able to scrutinize the set standards and be able to make suggestions for improvement that will be beneficial for the general population of users. They should proactively assist in the implementation of IDMP related standards across their organisation by providing expert insights.

Required knowledge:

- Foundation + Intermediate domains;
- Detailed knowledge on all concepts and terminology;
- Scrutinize and suggest improvements on set standards;
- Pro-actively assist implementation by expert insights;
- Medicinal relevance.

4. Advanced – Technical (more advanced training for those working on the technical implementation of IDMP standards to existing and new medication databases/lists)

- a. Innovation Manager;
- b. Database and Interface Specialist;
- c. Standard Specialists (participating in standard development);
- d. Substance Experts.

Users aiming to achieve the Advanced – Technical certification, possess detailed knowledge on the structure of IDMP related standards 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 such adjustments. Implementations and changes can be carried out with little preparation time.

Required knowledge:

- Foundation + Intermediate domains;
- Detailed knowledge on all concepts and terminology
- Detailed knowledge on the structure of IDMP related standards;
- Able to oversee implementations

7.4 Appendix IV – Interviews professionals

Interviewees were identified based upon the need for detailing certain aspects of the initial framework and receiving feedback on our work so far. They were not meant to be representative of the full stakeholder spectrum of IDMP-related standards and terminologies.

Table 4. Overview of interviewees, roles and organisations

Name	Role	Organisation	Organisation type
Craig Anderson	Director Information Management;	Pfizer, Canada	Industry user
Martin Ingvar	Professor of Integrative Medicine	Karolinska Institute, Sweden	Educator
Remco Munnik	Data consultant	IPERION/Deloitte, Netherlands	Commercial educator
Anne Bourrelly	Director Regulatory Information Management	Roche, Switzerland	Industry user
Philipp Weyermann	Head of Regulatory Assessment	SwissMedic, Switzerland	Regulatory organisation

8 Used external sources

- i [Data on medicines \(ISO IDMP standards\): Overview | European Medicines Agency \(europa.eu\)](#)
- ii [Teaching and Learning Frameworks | Poorvu Center for Teaching and Learning \(yale.edu\)](#)
- iii [Het Format voor een opleidingskader - PDF Gratis download \(docplayer.nl\)](#)
- iv [Instructional Framework 101: What It Is & Why Every School Needs One \(learningfocused.com\)](#)
- v [Difference Between Curriculum and Syllabus \(pediaa.com\)](#)