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Statement of originality

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Deliverable abstract

Work Package 1 focuses on IDMP-related standards and terminologies; its second deliverable is deepening the needs and requirements for an IDMP logical model.

This deliverable references existing ISO standards, as well as existing HL7 version 3 specifications and HL7 FHIR resources, and acknowledges existing logical models which have been developed by actors in their IDMP implementation programme. It further considers findings from the first Work Package 1 deliverable (D1.1 Gap analysis about existing and new standards and profiles) which pointed out the need to develop several logical models, addressing and connecting specific domains.

Keywords: IDMP, logical model, implementation, Standards Developing Organisations, community of expertise

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Executive Summary

UNICOM is about improved patient safety and better healthcare for all. To contribute to this vision, this European Commission supported Innovation Action focuses on implementing the International Organization for Standardization (ISO) suite of IDMP (IDentification of Medicinal Products) standards. Work involves their further development, testing, implementation, and diffusion. UNICOM partners include national medicines authorities across Europe, healthcare organisations, standardisation bodies, health ICT companies, SMEs and research institutes. They are working together to enable the many existing databases and products that include medicines information to be adapted towards and incorporate IDMP compatible data fields and attributes, so that all sources of medicines information become semantically interoperable, may be accurately cross-referenced with each other, integrated and analysed nationally, European-wide and at the global level.

Work Package 1 focuses on IDMP-related standards and terminologies; its first document was concerned with gaps in existing standards and profiles, and the arising need for adapted and new ones, all aligned with each other. That document confirmed that an IDMP logical model is needed to facilitate implementation with as little divergences as possible

This second document raises requirements for the development of a new IDMP logical model, to serve as a reference to implementers and developers of specific data models. It presents what is meant by a "logical model", provides several references which document logical models and their conceptual, standardised framework. This document builds on the first deliverable mentioned above, by using its domain structure and the cross-domain dimension of the required new IDMP logical model.

When developing this document, Work Package 1 experts invested their experience and specific expertise to deliver a commonly agreed report, supporting homogeneous standards developments and implementations within the UNICOM project and beyond.

The present document is meant to serve as a source of information for the ISO expert group within ISO Technical Committee 215 Health Informatics. This expert group, under supervision of ISO Working Group 6 Pharmacy and Medication Business, is going to develop a new international standard, in full collaboration with CEN (in accordance with the "Vienna Agreement" between ISO and CEN) and considering the inputs from other standards developing organizations as represented in Work Package 1 of UNICOM.

1   Scope and objectives

1.1   Purpose

The purpose of this document is to provide motivated background information to be considered when developing the international standard for the IDMP logical model. Such development work will be carried out by a team of experts from WG6 on Pharmacy and Medication Business within ISO/TC 215 Health Informatics. The work is expected to start shortly after the preliminary work item is accepted at the plenary meeting of ISO/TC 215 in November 2020. It can be expected that the work will need 24 months to make it through the ballot and publication process for an official CEN ISO Technical Specification.

Given the process within ISO, this document is targeted primarily at the members of ISO/TC 215 WG6 and the experts undertaking the work on the IDMP logical model. As such, they will be very much aware of the current status and developments in the of IDMP. However, in order for the wider stakeholder community to also be able to understand the objectives and the requirements presented in this document, we have included some very limited background on IDMP where necessary.

The new standard shall address the logical model's usability, not only for regulatory processes, but as well for clinical, supply chain and public health processes. It may even be the case that certain details from the current IDMP standards are left out of the IDMP logical model, as they are specific **only** to the regulatory processes and do not need to carry over to other implementation domains. This idea of a "reference" logical model for IDMP to be adopted and incorporated in domain or process specific logical models is further elaborated in chapter 3.

After this introduction, chapter 2 provides a description of the methodology followed in eliciting the requirements for an IDMP logical model. Chapter 3 details the scope of the logical model and its relations to other models and artefacts relevant to the use of IDMP. These discussions already give rise to generic requirements for the IDMP logical model, which will be provided in coloured frames in chapter 3. These generic requirements will be reiterated in full in chapter 4, augmented by the specific requirements which follow from the analysis of the relevant processes within the domain of IDMP. Readers that are well versed in the domain of logical modelling may jump directly to chapter 4, as it holds the full specification of requirements as developed within this specific task of UNICOM WP 1. The document ends with a conclusion in chapter 5 and a few annexes for further reference.

Value of logical models

The purpose of the IDMP logical model is to shift IDMP's current data architecture to one that is implementation agnostic so that implementers can easily "plug" IDMP into any system for automatic connectivity. With an IDMP logical model and, for example, an ePrescription logical model, conformant implementations can be achieved more easily and efficiently.

1.2   Work Package 1

The UNICOM project has been separated into different "Work Packages." The first Work Package (WP 1) involves the standard developing organisations (SDOs) and provides an excellent opportunity to encourage collaborations so that the best, usable and efficient standards are provided to the community.

WP 1 is focused on the universal use of IDMP and its related standards and terminologies. This focus provided WP 1's first deliverable, namely the "*Gap Analysis about Existing and New standards and Profiles*" which is currently under review by the European Commission. WP 1 is further delivering opportunities for education and a "*community of expertise*" platform, where users may access first-hand information and discuss or clarify issues which they encounter in their implementation projects.

This second document "*Requirements for a new ISO logical model, platform independent*" follows requests captured in the gap analysis. This new standard should facilitate the implementer's activity and resolve a number of identified ambiguities.

WP 1 has other documents which will serve the UNICOM project and support IDMP implementation across Europe.

1.3 The stated need for an IDMP logical model

The set of IDMP specifications consists of five standards and four implementation guides. The IDMP standards provide a high-level conceptual model while the implementation guides give a fragmented, physical implementation using HL7 SPL and other HL7 version 3 CDA specifications. There is a clear intent with a number of stakeholders to no longer use HL7 version 3 for future implementations and move to HL7 FHIR instead. In order to guide coherent implementation of IDMP, an intermediate logical model is needed to provide an implementation independent model. Current implementation experience has shown that, for instance, some attributes are implicitly included in the HL7 implementation, but are not in the conceptual model. The IDMP logical model shall therefore provide a detailed specification of all data elements that are fundamental to using IDMP in real-world systems. The logical model should provide a solid basis for technical implementation, whether it is in the form of a database or a technical exchange format (such as HL7).

The IDMP logical model shall be positioned between the IDMP standards (in particular EN ISO 11615) and the IDMP implementation guides (in particular CEN ISO/TS 20443). It should build upon the high-level conceptual model and partial logical data models already provided in the standards. In addition, it should take into account the implementation experience embedded in the implementation guides and underlying HL7 specifications. Care should be taken not to develop the IDMP logical model as an independent entity, but to keep it fully aligned with the existing IDMP standards and implementation guides.

1.4 Background

IDMP was initially written from a regulatory and pharmacovigilance perspective. It has become apparent over the last few years that there is a need for IDMP to be able to cover additional use cases that need high quality medicinal product information. Our first deliverable 1.1 "Gap Analysis about Existing and New standards and Profiles" explored these new use cases.

There are no less than 11 references to logical models in this gap analysis. The logical models do not all focus on Regulatory Affairs as pointed to in § 6.2.5 and 6.3.7 (the gaps noted in § 6.3.6 for data exchange and § 6.4.3.2 for adverse event are closely bound to this group), but also include other business processes which shall benefit from an IDMP logical model. They illustrate that a considerable gap is revealed and should be taken into consideration by standards developers. One can aggregate these requirements as follows:

- Logical models for ePrescription (§ 6.3.6 and § 6.5.2.1.2), eDispensing (§ 6.4.1)
- Logical model for Patient Summary (§ 6.3.6)
- Logical model for recording medication errors (§ 6.4.2.3) and adverse events (§ 6.4.3.2)
- Logical model for Supply Chain (§ 6.3.6)
- Logical model for medicinal product dictionaries (in addition to the gap analysis)

This background helps standard developers considering business use cases to which the IDMP logical model standard will have to be connected. These business use cases all belong the IDMP landscape as described in the UNICOM WP 1 gap analysis, as reproduced in figure 1.

**3
Application
fields
for IDMP**

Marketing Authorization and Pharmacotherapeutic
Surveillance of Medicinal Products

Effective Clinical Use of Medicinal Products

Controlled Supply Chain
of Medicinal Product Packages

**5
Implementation
domains
for IDMP**

| Development and Production | Regulation and Authorization | Dissemination and Information | Prescription and Dispensation | Utilization and Outcome Assessment |

**Combining
the perspectives**

| Development and Production | Regulation and Authorization | Dissemination and Information | Prescription and Dispensation | Utilization and Outcome Assessment |

Marketing Authorization and Pharmacotherapeutic
Surveillance of Medicinal Products

Effective Clinical Use of Medicinal Products

Controlled Supply Chain
of Medicinal Product Packages

| Development and Production | Regulation and Authorization | Dissemination and Information | Prescription and Dispensation | Utilization and Outcome Assessment |

Pharmacotherapeutic Drug Class Identifiers

International Nonproprietary Names

Global Identification of Medicinal Products

National Identification of Medicinal Products and Packages

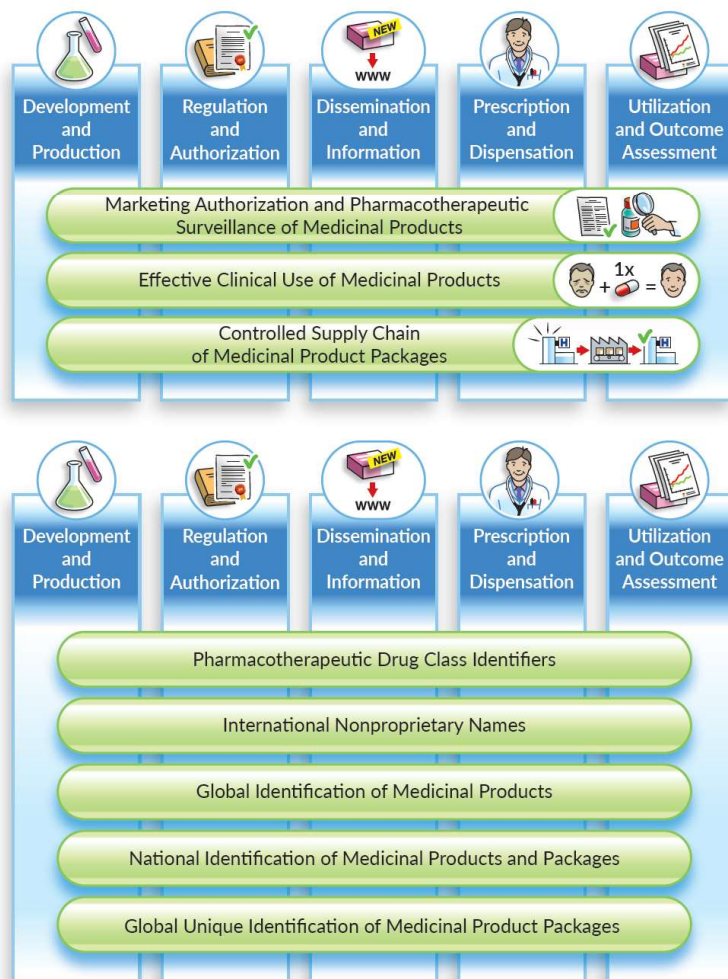Global Unique Identification of Medicinal Product Packages

Figure 1 – IDMP landscape from UNICOM WP 1 gap analysis

2 Methodology

2.1 Introduction

This work starts by identifying what logical models we are addressing.

IDMP is an information model standard; the related standards that have been addressed in the gap analysis expose specific data needs. While some of the standards have process models, the goal is to facilitate harmonised IDMP implementations; as a consequence, the scope of this document is to provide a base for an IDMP logical data model, and not for a business process model, or for an architecture model.

The document formalises the scope of the model, both in terms of the breadth (functional and data scope) and depth (the representation and management requirements). In other words, the document identifies the functional requirements (what the logical model should cover) and operational requirements (how the logical model shall be managed and used in operations).

IDMP logical model characterized

The IDMP logical model is characterized as a logical data model that represents the detailed data requirements of IDMP in an implementation independent manner.

It is important to acknowledge the purpose of logical models: logical models, like all models, contain a representation of a certain perspective on reality. A model is not supposed to represent the entire universe. A single logical model that encompasses the three application fields (market authorization and pharmacotherapeutic surveillance, effective clinical use, and the controlled supply chain) across the five implementation domains (development and production, regulation and authorization, dissemination and information, prescription and dispensation, and utilization and outcome assessment) would likely be a complex endeavour. This is taken into consideration by limiting the breadth of this work to the common overarching elements.

Logical models will exist with other models – either previous versions, or models from other organisations, or clinical models from other areas. Thus, an important part of the work is to address the lifecycle and the differences and compatibility issues with existing logical models. Alignment with the existing IDMP standards and implementation guides is clearly within scope for ISO. But one also knows IDMP is being implemented by different organisations such as, FDA, EMA, individual NCAs and industry, and presumably those organisations will be having their own logical models as part of their internal information systems design.

This will bring a set of important requirements, since it is not expected that one logical model replaces all others, for all purposes. The challenge is to define how different logical models may be related and articulated in a consistent manner in order to achieve the objectives of IDMP implementation.

The operational requirements for a logical model are also highlighted. More than being just a visual diagram, logical models need to be usable as a reference in implementing and validating systems and other standards, so they should be managed and documented in a reusable, computable manner.

From these considerations, the following methodology steps are defined:

1. Scoping the work on IDMP logical model in terms of functional breadth and the required depth of the model – taking into account the three application fields and five implementation domains mentioned.
2. Identify the usage and impact of the IDMP logical model, namely the relation to conceptual models, relation to other (existing or previous) models and to implementation specifications, and relation to terminologies.
3. Define the maintenance of the logical model, and identify the requirements to properly capture, share, describe, update, use, maintain and evolve the IDMP logical model.

The following paragraphs will provide more detail on the first two steps of the methodology. Chapter 3 will provide the outcome of the scoping discussions carried out as part of the steps 1 and 2. The detailed requirements are then provided in Chapter 4.

2.2   Setting the functional scope of the model

Any logical model shall be clearly scoped, which may help determine its content and other requirements.

The fundamental scope is determined by the primary and secondary business processes that the logical model is intended to cover. These business processes and details are present in IDMP itself, and in projects like UNICOM. The gap analysis in UNICOM shall also be considered for the scope, and especially the description of the landscape as referenced in figure 1 in this document.

Some requirements are independent of any model, or any scope. Those generic requirements are considered first, and pertinent international standards are referenced, then specific models are identified. Ultimately, the requirements of the logical model shall validate this initial scope.

2.3   Identifying linkage to other models

Given the impact of IDMP in regulatory activities, and the expectation that IDMP will be used in further domains, the requirements shall consider the interaction between the initial regulatory domain and the evolving use in adjacent domains like prescription, dispense, etc. This does not mean that the IDMP logical model should cover the full clinical space, rather it should link to the logical models that are already available there.

For example, when using a product description in a clinical document (e.g., a prescription) it is important to ensure that it is compatible with the IDMP logical model. Elements in the clinical document logical model should be linked to the IDMP logical model, meaning that the definitions and terminologies are compatible. Context specificities may justify the use of elements in certain models that are not semantically equivalent to the elements in the IDMP logical model. Linking of these elements is then established through the formal representation of an associative relation between the two concepts in the respective logical models. In order to fully understand the notion of (semantic) linking or mapping we refer to section 3.2 and to ISO 17115 and ISO/TS 21564.

Ignoring this need for linking to other models will likely cause islands in interoperability, where an IDMP specification may work for regulatory purposes, but is unusable or impractical for clinical purposes, which would defeat the very purpose of IDMP.

3 Scoping the requirements for the IDMP logical model

In this section, we present the logical models – their content, etc., and specifically the IDMP logical model; we also describe the generic requirements for the logical model in the context of IDMP. These generic requirements will be supplemented by the context specific requirements in section 4.

Note: in this chapter we use the keywords shall, should, may, can, must, according to ISO/IEC Directives Part 2, tables 3, 4, 5, 6, 7).

3.1 Logical model – definition and context

This paragraph aims to summarize and put in perspective the relevant terms and definitions as used in the health informatics domain with respect to the modelling of information. This is not a systematic review of all terms and definitions used either within ISO or in the scientific literature, but rather a deliberate choice from the available ISO definitions to illustrate the way of thinking that underlies the purpose of the IDMP logical model, and hence this document. Each reference also provides the link to the specific definition in the context of the quoted standard in the ISO Online Browsing Platform.

The aim of this document is to provide a set of requirements for the logical model of identification of medicinal products (IDMP), so we should start with the definition of the term logical model and take it from there.

logical model (ISO/TS 18864:2017)
information model that specifies the structures and relationships between data elements but is independent of any particular technology or implementation environment

information model (ISO/IEC 19763-12:2015)
graphical and textual representation of entities and the relationships between them

> *Note 1 to entry: Can also be known as a data model, a conceptual data model, a logical data model, an entity relationship model, an object class diagram, or a database definition.*

This is where the confusion may arise: what is the relationship between the logical (information) model for which we aim to provide a set of requirements and the data model for IDMP.

As mentioned in the stated purpose of the IDMP logical model, it is to provide a complete but implementation independent specification, based on the high-level conceptual model specified by the five IDMP standards.

We turn to a well-known three-layer approach for data modeling, with the conceptual model representing the real-world understanding, the logical model representing the more detailed data requirements, and the physical model representing the implementation in a specific technology, e.g. database management system.
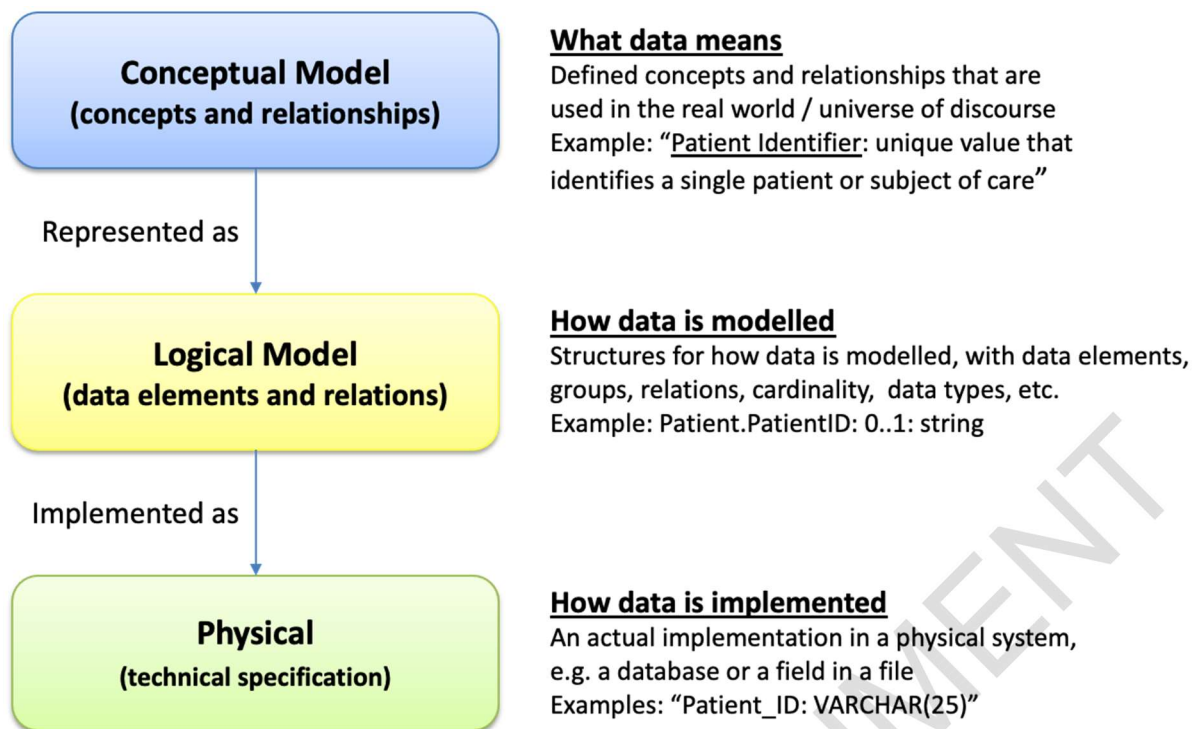
Figure 2 – Relation between information and data models - conceptual, logical and physical

In terms of definitions, we'll continue our journey with the conceptual model.

conceptual model (ISO/IEC 11179-1:2015)
data model that represents an abstract view of the real world

But it is not the whole real world that we want to model, so we need to focus and limit the scope of the model to a specific part of the real world.

conceptual model (ISO 19101-1:2014)
model that defines concepts of a universe of discourse

universe of discourse (ISO 15531-1:2004)
the collection of concrete or abstract things that belong to an area of the real world, selected according to its interest for the system to be modelled and for its corresponding environment

It is not just the concepts that need to be modeled, but also the relationships between those concepts that are of interest within the universe of discourse, or domain.

conceptual model (ISO/TS 18864:2017)
description of common concepts and their relationships, particularly in order to facilitate exchange of information between parties within a specific domain of healthcare

Now we have definitions for a conceptual model and a logical model as the top two layers of information models for a specific universe of discourse. These two need to be connected of course, as the IDMP logical model needs to fully specify the high-level conceptual model in the IDMP standards. A few other definitions are helpful to establish the connection.

The textual descriptions and definitions of the concepts, relationships and data elements, as used in the combination of conceptual and logical model, are usually combined in a glossary.

glossary ([ISO/IEC/IEEE 31320-2:2012](#))
The collection of the names and narrative descriptions of all terms that may be used for defined concepts (views, classes, subject domains, relationships, responsibilities, properties, and constraints) within an environment.

As this definition of glossary was taken from yet another ISO standard, you may notice that the use of concept, relationship and data element (or property) is not consistent with some of the other definitions. This will happen a lot, as the way things are called depends on the modeling language or methodology that is being used.

The difference between the conceptual model and the logical model is basically the fact that the logical model contains an elaborate description of the data elements, groups, and relations, reflecting the concepts and relationships already defined by the conceptual model.

data element, data attribute, data item ([ISO/TS 21089:2018](#))
single unit of data that in a certain context is considered indivisible

For the "certain context" one can of course read the universe of discourse or the system for which the logical model is being developed. It is considered indivisible in the sense that, within this context, it is not useful to further break up this element in its constituting parts.

In information systems, data elements are often bound to a specific data type.

data type ([ISO/IEC 9075-1:2016](#))
set of representable values

Often data types are interpreted as simple value domains, for example string, integer, decimal, boolean, etc. Alternatively, they can take the form of complex data types, grouping together a predefined set of data elements, such as person name or address. However, from a conceptual and logical perspective circumstances may require to further specify the domain or value set that this data element can be populated with, e.g., diagnosis or procedure codes. This may lead to the need to specify a binding to a specific terminology (e.g., SNOMED CT) or a specific set of identifiers (e.g., social security number as defined and maintained by the US Government) in order to ensure common understanding of the data element. This is especially relevant in the case of information exchange (as identified in the conceptual model definition in ISO/TS 18864). Therefore, in many cases rich data type descriptions, including terminology bindings, are required to achieve semantic interoperability.

While some terminological constraints are strictly attached to the technical implementation, others (perhaps most) are actually defined at the functional level, sometimes they are even external, legally binding references. For example, the value sets for language codes are defined in an ISO standard, and it is normally relevant – from the functional level – to adhere to that standard, instead of leaving it to the technical implementation. This is especially important to make sure systems are interoperable and contain quality data. Therefore, a description of the data type using a reference terminology or value set will often be necessary. For example, using SNOMED CT, a value set of substances can be designated as ingredients in a particular medicinal product would be described as: all descendants of the SNOMED CT concept 105590001|Substance (substance)|. Looking at the purpose of the IDMP logical model, it is easy to see that a terminology binding will be required for quite a number of the data elements at the logical level.

The representation of a logical model can make use of any (standardized) methodology. To illustrate this, two examples are provided from the IDMP domain. The first is a UML Class Diagram taken from EN ISO 11615:2017 for the unique identification and exchange of *regulated medicinal product information*. Note that, although part of one of the conceptual IDMP standards, this diagram represents a partial logical model for the specification of a medicinal product.
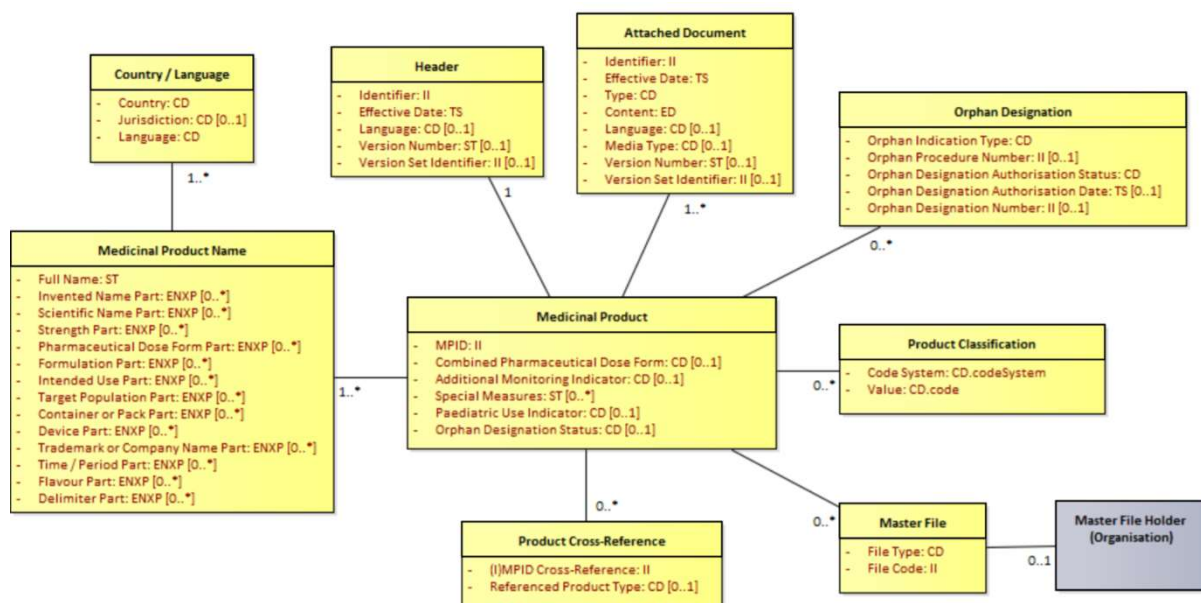
Figure 3 – IDMP partial logical model - UML representation from EN ISO 11615

This representation is a standard UML Class Diagram representation. It shows the different entities (e.g. Medicinal Product) and their attributes e.g. "Special Measures" and respective characteristics like type and cardinality (ST [0..1], i.e. an optional string with maximum 1 occurrence).

The second example is an HL7 FHIR representation. Please note the difference between a FHIR Logical Model representation, used for capturing requirements, and a fully detailed and implementable FHIR profile.

Figure 4 – FHIR-based representation of Medication in the context of the IPS

Existing tools to produce and maintain a logical model include:

▓ Microsoft® Visio ®
▓ MagicDraw ®
▓ Sparx® Enterprise Architect ®
▓ Visual Paradigm – https://online.visual-paradigm.com/

In order for implementers to directly use the IDMP logical model, the computable representation of it shall be in an open format. The following computable, open representations are examples of good practice:

▓ Forge FHIR representation of logical models – https://simplifier.net/guide/profilingacademy/Logicalmodels
▓ Eclipse Modeling Framework – https://www.eclipse.org/modeling/emf

It is beyond the scope of this document to prescribe a specific modelling methodology and related toolset to specify and document the IDMP logical model in a computable format. However, the requirement to make such a choice is clear.

Requirements for definition and context

A. The IDMP logical model shall describe the structure of and the relations between the data elements that are pertinent to the exchange of information related to medicinal products
B. The IDMP logical model shall be independent of any particular technology or implementation environment
C. The IDMP logical model should be expressed using a standardized method of representation
D. The IDMP logical model should be published as an open computable representation
E. The IDMP logical model should be linked to a conceptual model of the IDMP universe of discourse – whether this conceptual model will in itself be an ISO IDMP standard is outside the scope of this document
F. The IDMP logical model shall specify the data types for the data elements
G. The IDMP logical model shall specify the cardinality of the relations between (groups of) data elements
H. The definition of elements in the IDMP logical model shall be linked to a single glossary of terms; this glossary is part of (or referenced by) the conceptual model
I. The definition of data elements in the IDMP logical model should include a rich definition of the data type including the set of representable values, when applicable
J. Each set of representable values in the IDMP logical model should be described using a reference terminology

3.2 Logical model – linkage to other models

As mentioned in section 2.3, having the IDMP logical model serve as a common reference for other more detailed models makes the identification of proper linkage between these models very important. In this section we discuss several different forms of linkage. Understanding the nature of the linkage is necessary to achieve alignment between models and interoperability between systems implementing the models.

Linkage is used in this document as a broad term, encompassing different forms of relationships between the items that are being linked. To illustrate this, the following types of linkage may be discerned:

- Identical items – the items being linked are fully identical in terms of definition, structure, value set, etc.
- Semantically equivalent items – the items have an overlapping domain of meaning and their definitions are interpreted as identical
- Generically related items – where one item is a generalization of the other item, indicating a 'parent-child' or 'is-a' relation between the items
- Partitively related items – where one item is identified as being part of the other item, indication a 'whole-part' composition relation between the items
- Associated items – the items are neither equivalent, nor hierarchically related, but do have a relevant association in a certain context
- Mapped items – an index from one item to one or more other items, indicating the nature of the linkage provided by the mapping

This illustration is based on the work that has been done within ISO on categorial structures of terminology (ISO 17115:2020) and terminology mappings (ISO/TS 21564:2019).

Having an overview of the linkage between two models, preferably as a full set of mapped items, also allows to carry out a proper comparison of the two models and to identify gaps. Gaps will be identified as part of the comparison, for example, when items in one model cannot be mapped to corresponding items in the other model or where an equivalence relation between two items is needed but not provided.
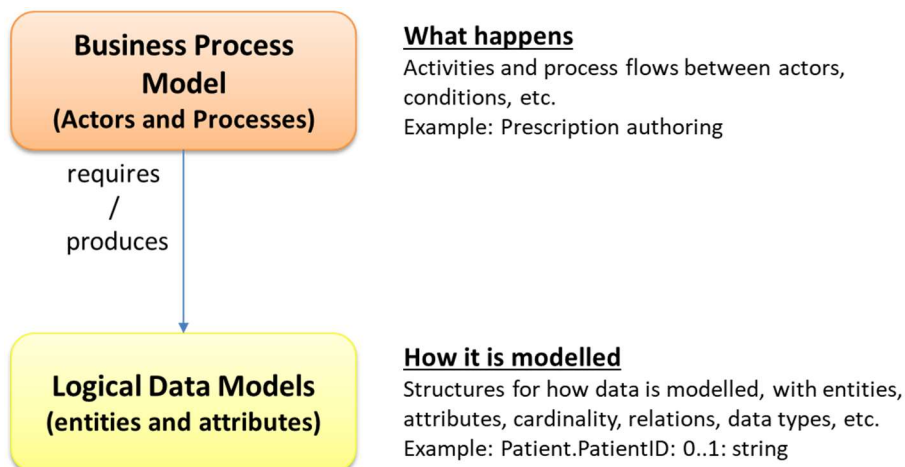
3.2.1 **Linking logical data models and process models**

Business Process Model
(Actors and Processes)

requires / produces

Logical Data Models
(entities and attributes)

What happens
Activities and process flows between actors, conditions, etc.
Example: Prescription authoring

How it is modelled
Structures for how data is modelled, with entities, attributes, cardinality, relations, data types, etc.
Example: Patient.PatientID: 0..1: string

Figure 5 – Logical data models - linkage to business process models

The process models are used here to determine the scope (see next section)

Requirement for linkage to process models

K. There shall be a relation between a logical model and the business process(es) it serves, already when defining the logical model

3.2.2 **Linking IDMP overall and process-specific data models**

It is important to note that the functional scope of the IDMP logical model is aimed at the common use of IDMP in health and care, irrespective of the field of application (market authorization and pharmacotherapeutic surveillance, effective clinical use, and the controlled supply chain) or the domain of implementation (development and production, regulation and authorization, dissemination and information, prescription and dispensation, and utilization and outcome assessment). The targeted ISO standard may provide a common IDMP logical model as a reference for all domains, with more specialized logical models to capture the specific needs identified for any of the individual domains.

The picture below demonstrates schematically that the IDMP logical model has a given scope that overlaps or shall connect with other models in other domains. In that sense it is a reference model with more or less direct overlap with the domain specific models: the regulatory area is very much in the scope of IDMP for all matters related to product identification; the prescription, however, has some attributes that shall be inherited from IDMP and others which have different sources. Thus, the overlap may not be as strong.
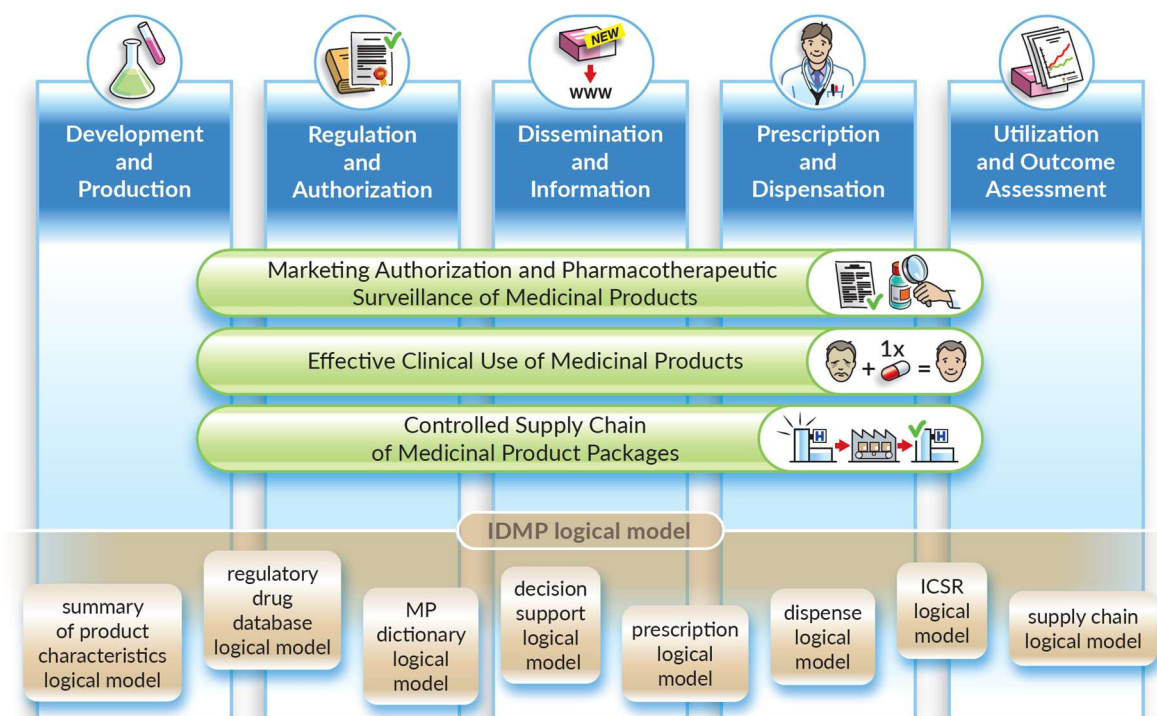
Figure 6 – IDMP logical model across application fields, implementation domains, and linkage with other models

Following from this notion, the linkage with the prescription can be analysed as an example. In the picture below, the connections mean simply "linked" – without describing exactly what kind of linkage is established (identical, semantic equivalence, etc.). Some attributes in the Prescription are linked to the prescribed product, and as such can be on any level – substance, pharmaceutical product, etc – or as a combination of elements. Other attributes are about how the medication is to be prepared or given to the patient, and some of those attributes may be linked to attributes that are defined in IDMP.
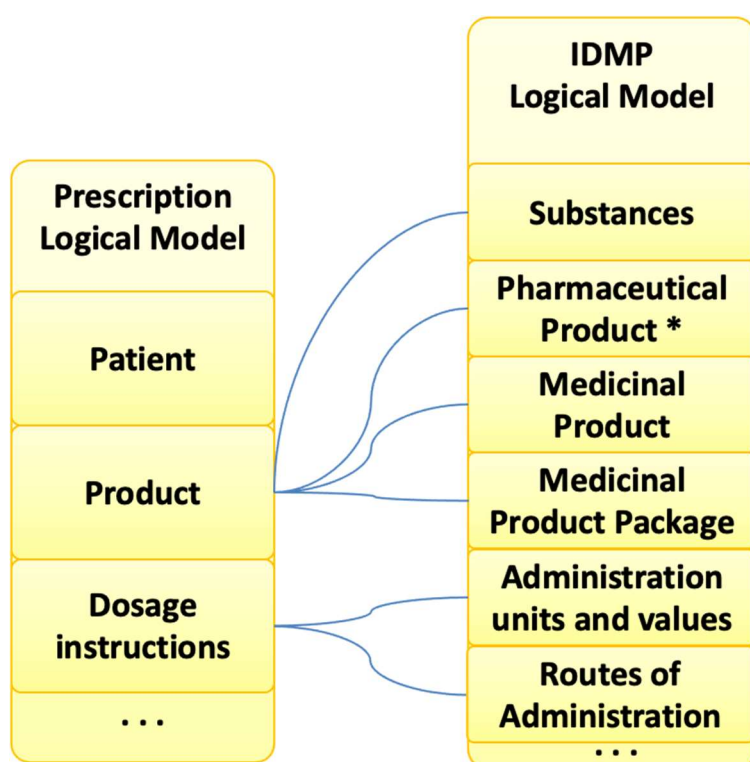
Figure 7 – Linkage between Prescription and IDMP logical models (overview)

This linkage can be used to carry out a gap analysis. In the prescription model, for example, we may see that the notion of Product identifier may be any of the IDMP identifiers, but may also be another identifier, such as the national product code. This shows that compatibility and mapping to the current prescriptions may need more than the IDMP identifiers – for example, one may need to use other IDMP attributes.

Another important example would be to identify the differences between the partial logical models in EN ISO 11615:2017 and the new IDMP logical model. Those that have invested heavily in IDMP compliant systems for market authorization can then easily see how their systems map to the new standard.

It is not the intention to require the IDMP logical model to be linked to all existing process-specific data models that might be relevant. Some existing models, as mentioned above, may be linked in order to assure the alignment of the IDMP logical model to other artifacts in the IDMP set of standards. In general, the IDMP logical model should make it possible, and preferably easy, for the developers of other models to link the elements in their own models to the IDMP logical model.

Requirement for relating to process-specific data models

L. The IDMP logical model may be used to link the elements in one model to the elements in another model

3.2.3 Linking IDMP and other logical models

Clearly, there are other logical models outside the domain of IDMP, being an international ISO standard. These may be other global drug models, such as used in SNOMED CT, or national drug models, such as the British dm+d and the Belgian SAM models, the Dutch G-Standaard and its related Health and Care Information Model for Pharmaceutical Product, and many others. In order to provide clarity on the linkage between any two logical models, a mapping needs to be established between the concepts and data elements contained in each of them. These are depicted below.
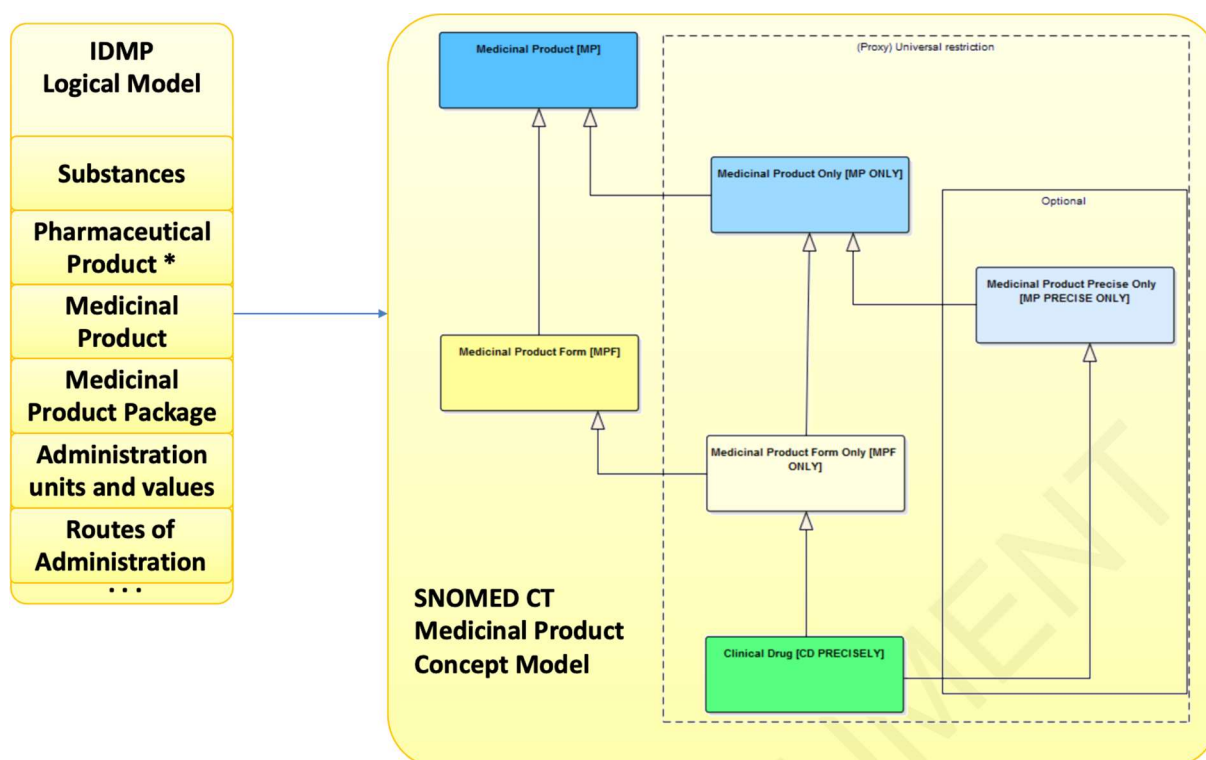
Figure 8 – Linking the IDMP model with the SNOMED CT Medicinal Product Concept Model
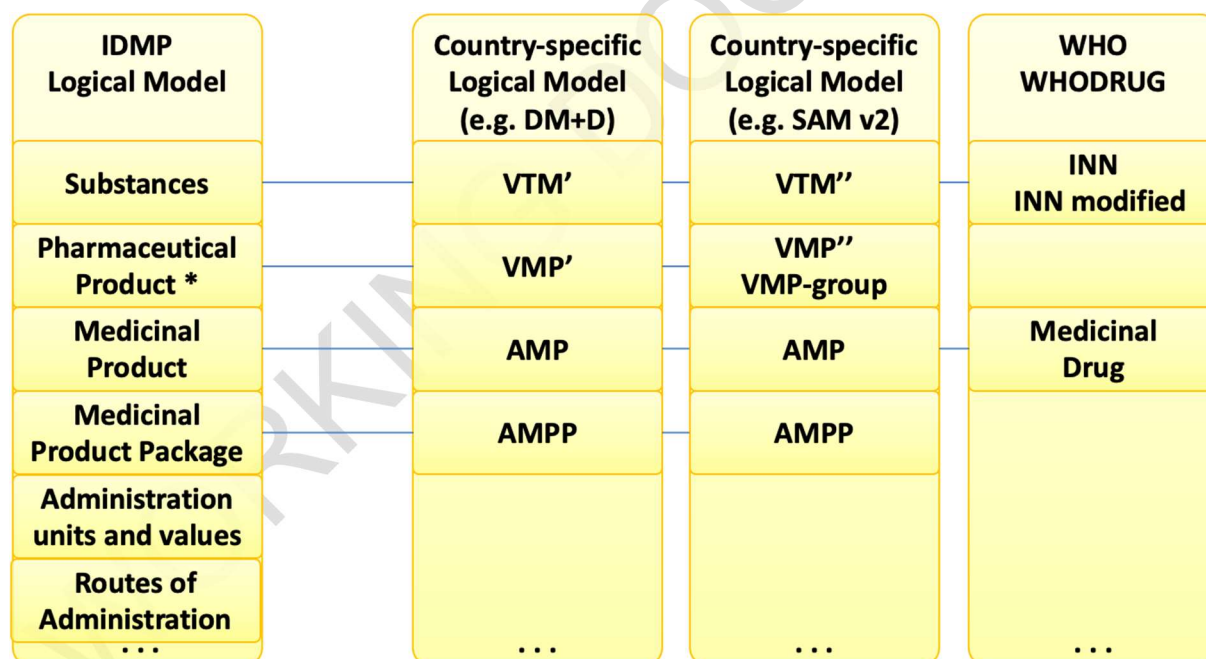

Figure 9 – Linking the IDMP logical model with national models: the British dm+d model and the Belgian SAM model & WHODrug

This linkage can also be used to perform a gap analysis between models to check any potential issues when migrating between models. Some of them are already indicated above:

- where * indicates modified substance and EDQM dose form;
- the ' with Virtual Therapeutic Moiety (VTM) and Virtual Medicinal Product (VMP) indicates that they are based on modified substance;
- the '' with the same indicates that they are based on the International Nonproprietary Name (INN) as represented in the WHODRUG model of the World Health Organisation;

- o the Actual Medicinal Product (AMP) and Product Package (AMPP) do not have such distinctions.

A possible conclusion from this analysis may be that the ISO definition of a Pharmaceutical Product is not semantically equivalent to the definition of VMP in dm+d or SAM v2, nor to the SNOMED CT definition of Medicinal Product.

Ultimately, the IDMP logical model shall be used to enable or facilitate such a rich and full analysis – ideally automatic analysis rather than just passive "alignment". Obviously, it is not the intention that such analyses are all carried out by the developers of the IDMP logical model. The requirements are that the IDMP logical model is documented in such a way as to enable the developers of other models to carry out their relevant analysis.

Requirements for relating to other logical models

M. The IDMP logical model shall be mappable to other logical models
N. Ideally, one should be able to automate the comparison or mapping logical models and discover the gaps.
O. The IDMP logical model should be computable in a way that automatic gap analysis can be done

4 Requirements for an IDMP logical model

4.1 Generic requirements

Note: in this section we use the keywords shall, should, may, can, must, according to ISO/IEC Directives Part 2, tables 3, 4, 5, 6, 7).

4.1.1 Generic requirements for logical models

In the development of a proper scope for the requirements, we came across a number of generic requirements on the basis of the intended understanding of the IDMP logical model and its relations to other models. These requirements are reiterated below, with reference to the numbered requirements (A-O) in the coloured boxes in chapter 3.

On the content and representation on the IDMP logical model itself:

1) The IDMP logical model shall describe the structure of and the relations between the data elements that are pertinent to the exchange of information related to medicinal products (see A)
2) The IDMP logical model shall be independent of any particular technology or implementation environment (see B)
3) The IDMP logical model should be expressed using a standardized method of representation (see C)
4) The IDMP logical model shall specify the data types for the data elements (see F)
5) The IDMP logical model shall specify the cardinality of the relations between (groups of) data elements (see G)
6) The definition of data elements in the IDMP logical model should include a rich definition of the data type including the set of representable values, when applicable (see I)
7) Each set of representable values in the IDMP logical model should be described using a reference terminology (see J)
8) Examples should be included to illustrate the use of the identified (groups of) data elements and their relations in complex real-world situations
9) The IDMP logical model should be published as an open computable representation (see D)

On the linkage between the IDMP logical model and other (process or data) models:

10) There shall be a relation between a logical model and the business process(es) it serves, already when defining the logical model (see K)
11) The IDMP logical model may be used to link the elements in one model to the elements in another model (see L)
12) The IDMP logical model shall be mappable to other logical models (see M)
13) Ideally, one should be able to automate the comparison or mapping logical models and discover the gaps (see N)
14) The IDMP logical model should be computable in a way that automatic gap analysis can be done (see O)

4.1.2 Requirements for linkage with conceptual model and definitions

In terms of the association of the IDMP logical model with a conceptual model or glossary, a few additional requirements should be added. The IDMP logical model shall recover, as much as possible, the underlying definitions from the current EN ISO IDMP standards, because the essence of the IDMP logical model is already described in the base of the existing standards. Some of these definitions may not be explicit at this time.

It is important to consider that not all definitions may need to be formalized: Given the wide scope of IDMP, there may be a need to provide definitions only for "key" data elements, leaving as optional the definition for elements that may be less critical. Also, the same term with the same name may have different meanings in some of the domains that IDMP covers. For instance, the term "indication" may be used differently in the context of prescribing medication for a patient than as part of a regulatory submission.

While changes in definitions are expected to be rare, changes and their impact shall be tracked – when a definition becomes broader or narrower, it is important to see if the logical model elements for that concept are still in line with the new definition.

15) The IDMP logical model should be linked to a conceptual model of the IDMP universe of discourse – whether this conceptual model will in itself be an ISO IDMP standard is outside the scope of this document (see E)

16) The definition of elements in the IDMP logical model shall be linked to a single glossary of terms; this glossary is part of (or referenced by) the conceptual model (see H)

17) The existing IDMP definitions shall be exposed as part of a conceptual model or simple glossary to be referenced by the IDMP logical model

18) If the glossary contains concepts with the same name but with a different meaning or definition, it shall be clear which definition is associated with a term in the logical model

19) The glossary or conceptual model should be expressed in a computable format for maintenance, and analysis of the associations with the IDMP logical model

Having a single common (computable) glossary for IDMP may help in maintaining consistency across all IDMP related standards and terminologies.

4.1.3 Requirements for evolution and backward compatibility

It's important to support the evolution of the logical model(s) and the conceptual model(s). For example, when a definition is changed, it is important to know if the logical model relates to the previous version or to the new version.

20) The IDMP logical model shall have a change process defined – which may be included in the IDMP standard change process itself.

21) The IDMP logical model shall be versioned, i.e. each different iteration shall have a unique version identifier

22) There should be a formal mapping of changes – e.g. when an attribute is replaced by another in a subsequent version, or when an attribute is deprecated

23) New gaps that are identified in the logical model shall be added to a new candidate version of the logical model

24) The logical model and their attributes and elements shall have a status

Also, the content of the IDMP standards themselves may evolve, requiring the logical model to follow that evolution.

25) There shall be a logical model version that reflects the current official version of IDMP publication

26) There shall be a logical model version for any subsequent version of the IDMP publication

27) The version of the IDMP publication that the logical model is based upon shall be clearly identified

28) Each data element, group of data elements, and each relation in the logical model shall have a version

29) Every data element, group of data elements, and each relation shall have a date of last modification

30) One version of a data element, group of data elements, or relation shall be associated with at least one version of the logical model

4.2 Specific requirements for the IDMP logical model

The specific requirements in this section are not as strictly formulated as the generic requirements. They are more exemplary and indicative, awaiting further refinement of business process models and their related logical models in each of the identified application fields (see also Figure 6). Therefore, the keywords used in the previous section are not used here in the same fashion. Full requirements can only be specified when detailed logical models within each of the application fields are available and agreed upon. Some of these models have already been identified in the WP 1 gap analysis and have been listed in section 1.4.

The IDMP logical model needs to provide the relevant (groups of) data elements and their relationships that are shared across application fields and implementation domains. It needs to ensure that the detailed processes within each of the implementation domains can then use this information for their own purposes and can exchange this information as part of their role in the high-level business processes.

The gradual evolution and use of IDMP-related standards and terminologies across the landscape will be an important factor in future revisions of the IDMP logical model, as mentioned in section 4.1.3. The examples provided here serve as an indication of the directions in which further evolution may be expected.

4.2.1 Marketing Authorization and Pharmacotherapeutic Surveillance

The regulatory affairs have been at the core of the IDMP standard and remain so. In the portrayal of the landscape (see figure 1) the impact of regulatory affairs across the five implementation domains is indicated. A few examples may serve to illustrate this impact and the consequent requirements for the IDMP logical model.

a. In *Development and Production,* the identification of substances needs to enable access to all known possible side effects of and contraindications for such substance, in order to produce and update the product information for market authorization;

b. In *Regulation and Authorization,* the unique identification of substances needs to be linked directly to the substances recorded in the market authorisation, such that identification of problems with specific substances can be traced back directly to all authorised products in all countries;

c. In *Dissemination and Information,* the medicinal product needs to be linked to the pharmaceutical product and the substances it contains, in order to identify emergent side effects or contraindications linked to a particular substance and be able to propagate them to all medicinal products that contain this substance;

d. In *Prescription and Dispensing,* the values used for admissible use of the medication in the market authorisation need to be linked directly to the indication for which a medicinal product is being prescribed, in order to clearly identify off-label use of medication;

e. In *Utilization and Outcome Assessment,* the dosage as employed in both the product information and the prescription of the medicinal product needs to contribute to a proper calculation of a defined daily dose (DDD) for (a class of) medicinal products.

4.2.2 Effective Clinical Use

The aim is to extend the use of IDMP to clinical processes, through the implementation of IDMP related standards and terminologies. A few examples from the different domains may illustrate the specific requirements for the IDMP logical model, originating from clinical processes.

f. In *Development and Production,* a clear linkage between the product sold on the market and the pharmaceutical product it contains needs to be carefully maintained, to allow for safe substitution in jurisdictions where this is preferred and/or admissible;

g. In *Regulation and Authorization,* information on side effects and contraindications needs to be collected in such a way as to link directly to the decision support tools that are being employed by both patients and professionals to aid in medication safety;

h. In *Dissemination and Information,* both the pharmaceutical product identifiers and the relevant portions of the product information, as provided by the manufacturers and the regulators, needs to be traceable in the database and decision support rules, to allow for proper and timely maintenance of this information;

i. In *Prescription and Dispensing,* the identification used in prescription needs to be flexible, to allow for brand specific and generic prescription, and linked to the proper identifiers to allow safe and informed substitution during the dispensing process;

j. In *Utilization and Outcome Assessment,* the identification of adverse events on the basis of the use of medication, as identified on a patient's medication list, needs to be linked to the identification to be used for adverse event reporting (e.g. the ICSR required by the NCA).

4.2.3 Controlled Supply Chain

The third application field that crosses the boundaries of the individual implementation domains is the controlled supply chain of medicinal product packages. Also here we provide a few examples to illustrate the requirements for the IDMP logical model.

k. In *Development and Production,* there is a need for a globally unique identifier for the shipment of medication, which links directly to the medicinal products contained in the shipment;

l. In *Regulation and Authorization,* the identification of a specific batch or lot number in an individual case safety report is needed to aid in the identification of a possibly limited production error as the cause of the adverse event; recall of such a limited set of medicinal products may then be initiated;

m. In *Dissemination and Information,* support for reallocation of supplies across jurisdictions may be supported, using supply chain information based on packaged products and linking them to the (projected) needs for medication based on either medicinal or pharmaceutical product identifiers;

n. In *Prescription and Dispensing,* the substitution with different brands of the same product in times of shortage is enabled by a proper linkage between the different brands for the same product;

o. In *Utilization and Outcome Assessment,* the patient should be supported in case of a recall of a specific batch or lot of medication packages by either the manufacturer or the NCA; knowing which patients to alert would require detailed registration when dispensing medication.

5   Conclusion

As a follow-up to Work Package 1's first deliverable (Gap Analysis about Existing and New standards and Profiles), the "Requirements for a new ISO logical model" include the full life cycle of medicinal products, which is illustrated by the same five implementation domains as in the Gap Analysis.

A new ISO IDMP logical model has been recognised as a need after having observed that the IDMP standards include normative references to HL7 version 3 artefacts. In order to facilitate the adoption of HL7 FHIR and other implementation technologies, there is a need for a technology agnostic normative reference to an IDMP logical model.

One of the learnings fundamental to the present deliverable is that the needed IDMP logical model shall not be limited to the regulatory domain, but rather serve as a backbone for several specific logical models; in other words, an explicit logical model is needed for the guidance in the extension from the regulatory domain to clinical domains. Certainly, the ISO deliverable will address regulatory specificities and requirements, especially where they impact the full life cycle of medicinal products. More detailed logical models can be derived from (or linked to) the IDMP logical model to cater to the specific requirements within an individual domain or for an identified business process (e.g. market authorisation, prescription, or adverse event reporting).

These requirements further insist on the need to take into account the wealth of knowledge and artefacts that has been created in the first implementations of IDMP related standards and terminologies across the globe. Especially the FDA, EMA, and national competent authorities have invested considerably in the implementation of IDMP and related information systems. Some examples from EU countries have already been referenced in this document and we hope others will be made available to the ISO working group.

The reader is reminded that the present deliverable will be used primarily by the ISO standard developers appointed in ISO/TC 215, Working Group 6. Along the standard development process this document shall serve as a reference. It is expected that each UNICOM partner will provide specific help if and when questions may arise and, when appropriate, will engage directly in the ISO review of the draft standard in due time.

6 Overview of terms and concepts

6.1 Basic concepts

Drug

1. **FDA:** A substance recognized by an official pharmacopoeia or formulary. A substance intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease. A substance (other than food) intended to affect the structure or any function of the body

Substance

1. **Oxford dictionary**: a particular kind of matter with uniform properties.
2. **Oxford dictionary**: The real physical matter of which a person or thing consists and which has a tangible, solid presence.
3. **EN ISO 12238**: any matter of defined composition that has discrete existence, whose origin may be biological, mineral or chemical (§ 3.83)

IDMP

1. Identification of medicinal product (IDMP) is a suite of 5 ISO standards that defines the data elements and structure to uniquely and unambiguously identify medical product and substance (**from GS1 website)**

Medicinal product

1. **Article 1 (2) of European Council Directive 65/65/EEC** defines a medicinal product as follows: 'Any substance or combination of substances presented for treating or preventing disease in human beings or animals. Any substance or combination of substances which may be administered to human beings or animals with a view to making a medical diagnosis or to restoring, correcting or modifying physiological functions in human beings or in animals is likewise considered a medicinal product'.
2. **In IDMP**: Name of a (branded) product in a jurisdiction, characterized by modified substance, dosage form, strength and marketing authorisation holder (without specification of pack size) – (synonym in dm+d and SAM-2 : Actual Medicinal Product or AMP),

Packaged Medicinal Product

1. **In IDMP**: Name of a (branded) product in a jurisdiction, characterized by modified substance, dosage form, strength, marketing authorisation holder, and pack size (synonym in dm+d and SAM-2: Actual Medicinal Product Package or AMPP; in SNOMED CT: Real Packaged Clinical Drug)

Pharmaceutical product

1. **FDA definition of IDMP PhPID**: ISO 11616 Pharmaceutical Product Identification (PhPID) can be used to associate products with same or similar pharmaceutical composition. The PhPID is a unique identifier calculated by an algorithm based on substance identification (ISO 11238), dosage form (ISO 11239) and strengths with units of measurement (ISO 11240), to associate group of relevant medicinal product at specific levels.

6.2 Concepts in other drug models

Therapeutic Moiety (TM)

1. **Canadian Clinical Drug Data Set**: is the functional and clinically significant part of the active ingredient substance(s) present in a medicinal product (the TM class is an abstract representation of a medicinal product without reference to strength and dose form, focusing only on active ingredient substance(s)

International non-proprietary Name (INN):

1. **WHO:** term for description of therapeutic moiety

2. **WHO:** name for a group of medicinal products that contain the same therapeutic moiety or combination of moieties; also called the Virtual Therapeutic Moiety (VTM)

INN Modified

1. **From WHO:** Modified INN (INNM): In future, names for different salts or esters of the same active substance should differ only with regard to the inactive moiety of the molecule. *For example, oxacillin and ibufenac are INN and their salts are named oxacillin sodium and ibufenac sodium. The latter are called modified INN (INNM).*

Modified Substance

1. Substance with a therapeutic role, specified by salt/ester

Virtual Medicinal Product (VMP)

1. **In dm+d**: Group of medicinal products with the same modified substance, the same dosage form (at most granular level) and the same strength; *e.g. diclofenac sodium tabled with prolonged action 75 mg*
2. **In SAM-2**: Group of medicinal products with the same INN, the same dosage form (at the most granular level and standardized to EDQM) and the same strength (normalised if needed); *e.g. diclofenac tablet with prolonged action 75 mg*

VMP Group (synomym: INN prescription)

1. **In SAM-2**: Group of medicinal products with the same INN, the same high level dose form (aggregation to 20 classes, based on EDQM), and the same strength (normalized if needed); *e.g. diclofenac oral (prolonged action) 75mg*

Actual Medicinal Product (AMP)

1. Equivalent to the IDMP concept defined as Medicinal Product; *e.g. Voltaren tablet prolonged action Retard 75 mg*

Actual Medicinal Product Package (AMPP)

1. Equivalent to the IDMP concept defined as Packaged Medicinal Product; *e.g. Voltaren tablet prolonged use Retard 75 mg 30 tablets*

Note: the dm+d model also has VTM (group of medicinal products with the same modified substance), and ATM concepts (group of medicinal products marketed in one country under the same (brand)name)

6.3 Concepts and attributes (predicates) in SNOMED CT

Active Ingredient

the medicinal product attribute used at an abstract level to indicate a particular substance (descendant of 105590001 |Substance (substance)|) including those with the same moiety.

Precise Active Ingredient

the medicinal product attribute used to indicate a particular substance, not allowing for modified versions.

Modified Substance

in the SNOMED CT Substance Hierarchy, salts, hydrates, liposomal formulations, etc are considered to be modifications of the corresponding base substance.

Clinical Drug

an abstract representation of a Medicinal Product specifying the precise active ingredient, BoSS, strength, and manufactured dose form. This is equivalent to PhP 4 in IDMP 11616.

Real Packaged Clinical Drug

in the SNOMED CT Medicinal Product Concept Model National Extension this is a representation of a medicinal product as it is supplied in a package by a single organisation (manufacturer or supplier) in a single jurisdiction under a single name (which may be a trade or brand name) for placement into the supply chain.

role (766939001 |Plays role (attribute)|)

> can be used to indicate a therapeutic or other role, is an attribute applied to medicinal products.

modification (738774007 |Is modification of (attribute)|)

> is an attribute that may be present on substances.

Note: These two qualities are unconnected.

precisely

> the word 'precisely' is used in the context of a medicinal product's ingredient(s) to specify that exact substance.

only

> the Medicinal Product "containing only" (MP-only) concept is an abstract representation of the active ingredient(s) for a medicinal product. It means that the medicinal product must contain the active ingredient(s) specified (or a modification of the active ingredients) but not any other active ingredients.

7   Literature references

Handbook

Teoprey TJ, Lightstone SS, Nadeau T, Jagadish HV. Database Modeling and Design: Logical design (The Morgan Kauffmann Series in Data Mamagement Systems) 5th Edition, Morgan Kaufmann Publishers, 2011.

digital version at:

http://digilib.stmik-banjarbaru.ac.id/data.bc/9.%20Database/2011%20OK%20Database%20modeling%20and%20design%20%20logical%20design%205th%20ed.pdf

Further educational reading:

https://pdfslide.net/documents/database-modeling-and-design-logical-design.html

http://www.uml.org.cn/oobject/pdf/logical.pdf

https://en.wikipedia.org/wiki/Data_modeling#Conceptual,_logical_and_physical_schemas

Examples for drug databases from other countries:

The British dm+d

> https://www.nhsbsa.nhs.uk/sites/default/files/2020-04/dm%2Bd%20data%20model%2003.2020.pdf
>
> https://www.nhsbsa.nhs.uk/sites/default/files/2017-02/Data_Model_R2_v3.1_May_2015.pdf

The Belgian SAM

> https://www.ehealth.fgov.be/ehealthplatform/file/view/9db3ebe6668d219cc1484451318ef2a8?filename=sam2_-_conceptual_data_dossier_v2.1.pdf
>
> https://www.ehealth.fgov.be/ehealthplatform/file/view/703d60dfd0d0b7c8fc65d6db6b0a491a?filename=sam2_-_logical_data_dossier_v2.3.pdf
>
> https://www.ehealth.fgov.be/ehealthplatform/file/view/6607bf283941036549abe57902f15ecc?filename=sam2_-_physical_data_dossier_v2.3.pdf

The Dutch G-Standaard and its related Health and Care Information Model for Pharmaceutical Product

Related ISO-Standards

- Standards are listed following their number
- Hyperlinks point to their published abstract

    ISO/IEC Directives Part 2

    ISO/IEC 9075-1 - Information technology — Database languages — SQL — Part 1: Framework (SQL/Framework)

    ISO/IEC 11179-1 - Information technology — Metadata registries (MDR) — Part 1: Framework

    EN ISO 11615 – Health Informatics — Identification of medicinal products — Data elements and structures for the unique identification and exchange of regulated medicinal product information

    ISO/TS 13972 – Health Informatics – Detailed Clinical Models, characteristics and processes (under review

    ISO 15531-1 - Industrial automation systems and integration — Industrial manufacturing management data — Part 1: General overview

    ISO 17115 - Health informatics — Representation of categorial structures of terminology

    ISO/TS 18864 - Health informatics — Quality metrics for detailed clinical models

    ISO 19101-1 - Geographic information — Reference model — Part 1: Fundamentals

    ISO/IEC 19763-12 - Information technology — Metamodel framework for interoperability (MFI) — Part 12: Metamodel for information model registration

    CEN ISO/TS 20443 - Health informatics — Identification of medicinal products — Implementation guidelines for ISO 11615 data elements and structures for the unique identification and exchange of regulated medicinal product information

    ISO/TS 21089 - Health informatics — Trusted end-to-end information flows

    ISO/TS 21564 - Health Informatics — Terminology resource map quality measures

    ISO/IEC/IEEE 31320-2 - Information technology — Modeling Languages — Part 2: Syntax and Semantics for IDEF1X97