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Health informatics — Identification of medicinal products — Core principles for maintenance of identifiers and terms

Informatique de santé — Identification des médicaments — Principes essentiels pour la mise à jour des identifiants et des durées

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Foreword

ISO (the International Organization for Standardization) is a worldwide federation of national standards bodies (ISO member bodies). The work of preparing International Standards is normally carried out through ISO technical committees. Each member body interested in a subject for which a technical committee has been established has the right to be represented on that committee. International organizations, governmental and non-governmental, in liaison with ISO, also take part in the work. ISO collaborates closely with the International Electrotechnical Commission (IEC) on all matters of electrotechnical standardization.

The procedures used to develop this document and those intended for its further maintenance are described in the ISO/IEC Directives, Part 1. In particular, the different approval criteria needed for the different types of ISO documents should be noted. This document was drafted in accordance with the editorial rules of the ISO/IEC Directives, Part 2 (see www.iso.org/directives).

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. ISO shall not be held responsible for identifying any or all such patent rights. Details of any patent rights identified during the development of the document will be in the Introduction and/or on the ISO list of patent declarations received (see www.iso.org/patents).

Any trade name used in this document is information given for the convenience of users and does not constitute an endorsement.

For an explanation of the voluntary nature of standards, the meaning of ISO specific terms and expressions related to conformity assessment, as well as information about ISO's adherence to the World Trade Organization (WTO) principles in the Technical Barriers to Trade (TBT) see www.iso.org/iso/foreword.html.

This document was prepared by Technical Committee ISO/TC 215, *Health informatics*.

Any feedback or questions on this document should be directed to the user's national standards body. A complete listing of these bodies can be found at www.iso.org/members.html.

Introduction

This document describes the core operating principles and a proposed service delivery model for terminology maintenance services in support of five International Standards on the Identification of Medicinal Products (IDMP), i.e. ISO 11615, ISO 11616, ISO 11238, ISO 11239, ISO 11240. Collectively, the International Standards on IDMP provide the basis for data collection and information exchange about key medicinal product characteristics that support the unique and unambiguous identification of medicinal products for a variety of regulatory and commercial business objectives and use cases.

Since the International Standards on IDMP can be applied to a broad range of use cases, (e.g., regulatory product applications, product registration, creation of drug dictionaries, etc.), adherence to common coordination and maintenance principles is critical to help ensure consistent adoption, use and maintenance of the International Standards on IDMP.

Currently, many organizations serve as data owners or terminology service providers in several jurisdictions. These organizations maintain and distribute their own medicinal product terminology which does not fully correspond to terminology mapping and format criteria described in Technical Specifications on IDMP (i.e., ISO/TS 20443, ISO/TS 20451, ISO/TS 19844, ISO/TS 20440). The terminology maintenance service delivery model proposed in this document is adapted for IDMP based upon well-established IT service models which use a hybrid support approach comprised of centralized and decentralized services (also referred to as service components) for a comprehensive set of IT support services. These IT support models are often referred to as "federated enterprise architecture" models[20]. The success of the IDMP federated service delivery model proposed in this document will help provide a framework to support more collaboration and shared data governance among key IDMP stakeholders and is dependent upon several factors, including the following:

— Adherence to a set of core principles for each of the International Standards on IDMP;

— Adherence to the core principles described in this document;

— Strict enforcement of service level agreements between IDMP terminology service providers and their stakeholders to help address jurisdictional differences.

Since IDMP standards are in the process of adoption internationally, it is anticipated that this document will be revised to reflect real-world experience in how the information models, data elements and their associated terminologies are used, as well as to accommodate any potential gaps in mapping and governance for specific IDMP terminology domains (e.g., substance/specified substance, dosage form, route of administration).

This document leverages and complements several ISO and joint ISO/IEC specifications pertaining to support principles and processes that should be exhibited by developers of healthcare terminologies in support of international healthcare terminology standardization, information technology service management and the design and maintenance of quality systems. The applicable International Standards are ISO/IEC 20000-1:2018, ISO/IEC 20000-2:2012 and ISO/IEC 33002:2015.

The intended audience for this document includes the following:

— Organizations seeking an opportunity to support creation and/or dissemination of IDMP terminologies;

— Organizations interested in implementing or applying the International Standards on IDMP (e.g., technical format and/or scientific content) to their internal processes and systems in support of regulatory or healthcare-related business; and

— Global regulators, pharmaceutical/biopharmaceutical companies, Clinical Research Organizations (CROs) and universities/scientific institutes involved in the development, authorization and marketing of medicinal products.

Health informatics — Identification of medicinal products — Core principles for maintenance of identifiers and terms

1 Scope

The purpose of this document is to describe the core principles and proposed service delivery model for supporting implementation and ongoing maintenance of IDMP terminologies.

The information provided in this document can be used as evaluation and/or design criteria when considering current or future operations and service level agreements for systems and terminology support services in conformity with IDMP.

2 Normative references

There are no normative references in this document.

3 Terms and definitions

For the purposes of this document, the following terms and definitions apply.

ISO and IEC maintain terminological databases for use in standardization at the following addresses:

— ISO Online browsing platform: available at https://www.iso.org/obp

— IEC Electropedia: available at http://www.electropedia.org/

3.1
controlled vocabulary
finite list of values that represent the only allowed values for a data item

Note 1 to entry: These values can be codes, text, or numeric.

Note 2 to entry: It includes the use of a taxonomy to classify terms into parent/child or broad-to-narrow relationships. The terms within a taxonomy can be referred to as a sub-vocabulary.

Note 3 to entry: This definition is taken from Reference [21].

3.2
data governance
process focused on managing the quality, consistency, usability, security, and availability of information

Note 1 to entry: This process is closely linked to the notions of data ownership and stewardship.

Note 2 to entry: This definition is adapted from Reference [22].

3.3
data governance group
group of individuals (or a hierarchy of groups) typically representing a cross-section of stakeholder groups.

Note 1 to entry: Together, they define a set of rules for data governance in the form of policies, standards, requirements, guidelines, or data definitions.

Note 2 to entry: This definition is adapted from Reference [18].

3.4
data owner
organization that is in the position to obtain, create, and have significant control over the content, access and distribution of data

Note 1 to entry: This definition is adapted from Reference [18].

3.5
data steward
role within an organization responsible for ensuring that data-related work is performed according to policies and practices as established through *data governance* (3.2)

Note 1 to entry: This definition is adapted from Reference [18].

3.6
federated service delivery model
terminology maintenance support model whereby some services can be provided by a centralized regional authority and other services can be provided by public or private (decentralized) service providers.

3.7
maintenance organization
formal and recognized group or legal business entity involved in the direct or indirect provision of terminology services such as the creation, reconciliation, maintenance and distribution of IDMP controlled vocabularies

3.8
non-preferred term
term that has the equivalent meaning to the preferred term but its use is limited or it is not used

3.9
use case
description of a sequence of interactions between a user and a system (e.g., IT or business process component) used to help identify, clarify, and organize requirements to support a specific business goal

3.10
terminology maintenance services
standard operating procedures and processes related to the creation of new IDMP value sets (terms and identifiers), change management (maintenance) of *value sets* (3.11), and mapping and translations between value sets

3.11
value set
uniquely identifiable set of values consisting of concept representations drawn from one or more code systems, which can be resolved at a given point in time to an exact set of codes

4 Symbols and abbreviated terms

The following abbreviations are used in this document.

CDISC	Clinical Data Interchange Standards Consortium
CEN	European Committee for Standardization
FHIR	Fast Healthcare Interoperability Resources
HL7	Health Level Seven
IDMP	Identification of Medicinal Products

IT	Information Technology
SDO	Standards Development Organization
SMS	Service Management System
SNOMED CT	SNOMED Clinical Terminology
TC	Technical Committee

5 Maintenance of International Standards on IDMP — Leveraging existing relationships between global regulators and other standards development organizations

The proposed IDMP terminology maintenance model is adapted from several existing sources such as cooperative agreements between global regulators, e.g., bi-lateral agreements, International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH)[26] and SDOs, such as the ISO/CEN Vienna Agreement, or the Joint Initiative on SDO Global Health Informatics Standardization[27]. Key aspects of these agreements and collaborations include the following:

— Mutual agreement on goals, objectives, work plans and decision-making processes;

— Mutual agreement to harmonize standards to eliminate redundancy and duplication of effort; and

— Mutual agreement on all deliverables to meet broader aims to protect and promote public health globally.

It is recommended that organizations serving as data owners or service providers have well established processes in place and adopt the international IDMP terms and/or identifiers once they become available. In accordance with ISO/TS 20440:2016, Clause 4, a terminology mapping approach is recommended to address mapping challenges when a common or global terminology cannot be agreed upon, is precluded by regional requirements or when there are differences in granularity between high- and low-level terms. Refer to ISO/TS 20440 for more information about the mapping and reconciliation of regional terms.

6 IDMP terminology maintenance

6.1 Federated service delivery model

The proposed model for IDMP terminology maintenance is adapted using derived concepts from federated IT service delivery and change management process models[28]. In a federated service delivery model, some IT and terminology support services are provided by a central authority and others might be provided locally. Examples of central authorities include Regenstrief Institute[23], [Logical Observation Identifiers Names and Codes (LOINC)], SNOMED International[24], [SNOMED Clinical Terminology (SNOMED CT)] and the European Directorate for the Quality of Medicines & HealthCare[25], [EDQM (Standard Terms)]. Examples of local authorities include the US Food and Drug Administration (FDA), European Medicines Agency (EMA), Deutsches Arzneibuch (DAB) (German Pharmacopoeia) and the Korean Ministry of Food and Drug Safety. Consideration of this proposed maintenance model is based upon the intended purpose of the International Standards on IDMP, which is the consistent definition, representation and data exchange of medicinal product information internationally.

Federated service delivery models leverage disparate, seemingly different operational support groups that agree to a common set of operating principles in support of business drivers. Core operating principles are dependent upon continued progression and adoption of International Standards on IDMP, taking into account several key themes that IDMP maintenance organizations should adhere to, such as:

— All participants will work towards achieving the goal and purpose of the International Standards on IDMP;

— All stakeholders are key to the success of International Standards on IDMP; no single organization nor any individual segment of the industry can do it alone;

— Promote interoperability of IDMP information exchange based upon the existing Health Level Seven Version 3 messaging standards and other emerging technologies such as HL7's Fast Healthcare Interoperability Resources (FHIR) Specification;

— Coordination with other key stakeholders, such as ISO/TC 215 and HL7, to address identified issues with the underlying domain information models and standards for the purpose of creating and maintaining controlled terminologies for International Standards on IDMP;

— Provide guidance to stakeholders regarding access, implementation and training needs associated with the use of a specific maintenance organization's service;

— Commitment to support the need for IDMP terminology maintenance recommendations and business rules to be vendor neutral;

— Promote and encourage adoption of the International Standards on IDMP;

— Leverage and support trading partner relationships and not dictate relationships between trading partners;

— Establish and communicate methodology to measure success and evaluate market impact of their IDMP maintenance support activity.

A set of common operating principles should be established between the maintenance organization and key stakeholders, which should also apply to other maintenance organizations working in a common domain (e.g., route of administration or dosage form). A mutually agreed-upon set of common operating principles when applied to change management enables each of the various groups to operate in a similar fashion (where applicable) while enabling performance comparisons across the groups. The operation of the World-Wide-Web or Cloud Computing Services can be used to help further illustrate how a federated service delivery model works. Using these examples, these services rely upon the maintenance of core network and distributed local infrastructures (e.g., communication links [circuits], network servers, communications hub/switch) to operate and maintain services for millions of global stakeholders.

A federated change process builds upon a common set of change activities performed by independent maintenance organizations, while seeking synchronization of change-management activities to support global collaboration and consistent use of International Standards on IDMP. Adherence to a set of core principles facilitates a consistent approach for creating new and/or mapping of local terminologies in use. A common approach supports the need to create a global value set (terms and IDs) that can be adopted across multiple use cases thereby ensuring the integrity of the maintenance services for International Standards on IDMP. Standard change-management processes commonly refer to the following set of activities but are not limited to the following:

— Receiving requests for change;

— Categorization of changes;

— Authorization of changes;

— Producing change schedules;

— Planning/building/testing changes;

— Implementing changes;

— Reviewing the changes for success.

In a federated change-management model, the aforementioned activities are performed by the independent (decentralized) maintenance organizations and typically focus on change-request and change-build management. Although production acceptance and control (the functions of planning

and authorizing change releases into the production environment) still occur within the independent maintenance organizations, federated models add a layer of scheduling and production acceptance authorization for changes that have been identified by the impact analyses as potential risks to customer service levels.

6.2 Future IDMP data governance

To facilitate synchronization of activities across maintenance organizations, the establishment of a data governance group is suggested and should be comprised of members from stakeholder organizations seeking broader harmonization across regions. The role of the data governance group is to create a discussion and collaboration forum for organizations seeking to establish a harmonized terminology source in a specific IDMP domain or subject area, for example, Substance/Specified Substance. A data governance process will help ensure that the appropriate input from Subject Matter Experts (SMEs) and management representatives is obtained to help understand the requirements for IDMP data and its downstream uses. Effective data governance will also need ongoing contributions from data stewards. An IDMP data governance model will help to provide a framework for continued collaboration with data owners (e.g., regulators, biopharmaceutical companies) and determine a more formalized operating model, roadmap and process for cross-coordination between IDMP maintenance organizations. Since there are many jurisdictional systems already in use, implementation of International Standards on IDMP is expected to be managed incrementally over time and will vary across regions. As each region gains more experience with International Standards on IDMP, it is anticipated that these organizations might choose to retain and upgrade their existing systems or help develop new globally applicable reference sources through other external consortia or collaboration groups (e.g., a global pharmacopoeia cooperation group).

6.3 Change management

Key attributes for defining a successful federated service delivery model include the following:

— Leadership: Strong direction and support from all stakeholders;

— Culture: Trust and respect to ensure broad collaboration among stakeholders;

— Process: A roadmap that leads to the development of the federated model and provides feedback and check points to ensure objectives are met;

— Resources: Participation between central authority(-ies) and local/jurisdictional support organizations;

— Value: Aiming at supporting stakeholder objectives and effort within the change-management process;

— Education and change management: Communication is critical and should be part of any rollout program.

6.4 Relationships with data owners

Data owners are accountable and responsible for the accuracy of the information. Ownership implies power as well as control. The control of information includes not just the ability to access, create, modify, package, derive benefit from, sell or remove data, but also the right to assign these access privileges to others

Key stakeholders in the overall maintenance process include, but are not limited to global regulators and biopharmaceutical companies. For example, the maintenance process should be robust and flexible enough to support the regulatory use case. Key considerations for these data owners should support appropriate linkages between the pharma/biopharmaceuticals industry and the global regulator(s) responsible for approving the medicinal products in their jurisdiction or region. The urgency and frequency of required maintenance activity should be sufficient to support the regulatory process and ensure consistent understanding and meaning of individual terms across multiple jurisdictions.

In the context of the regulation of medicinal products used for human use, it is necessary to establish accepted controlled vocabularies that are used for specific concepts. It is anticipated that regulatory authorities might also cooperate with other jurisdictional authorities in order to establish and maintain harmonized terms that can be then promoted for global adoption. For example, holders of intellectual property associated with a medicinal product will not be required to disclose confidential or trade secret information to any entity other than directly to relevant regulatory authorities.

7 IDMP terminology maintenance core principles

The proposed maintenance core principles for International Standards on IDMP are designed to meet the broad spectrum of use cases for data sharing and information exchange between stakeholders. These principles should be used as evaluation criteria for determining an organization's ability to support International Standards on IDMP in accordance with the standards themselves and within the context of the proposed federated service delivery model. The core principles for IDMP terminology maintenance are as follows:

— Maintenance processes will be unique to the maintenance organization and applicable to the terminology to be supported. It is expected that these processes should include proportionate and appropriate evaluation procedures for change requests, including impact assessment of changes and notification of changes;

— There should be no changes to the associated content of controlled sub-vocabularies (terminologies) without the submission of a change request and discussion with stakeholders;

— All identifiers assigned to IDMP controlled vocabularies should be globally unique;

— Controlled vocabularies, identifiers, versions and whole vocabularies should never be deleted and instead designated as "retired" or "deprecated" and be traceable at every time point;

— Machine readable identifiers for supply chain purposes should remain unique and never be reused in accordance with ISO/TS 16791;

— Controlled vocabularies and identifiers should be maintained with backward compatibility consideration of any regional or retired concepts used to create or harmonize an internationally accepted value set;

— Requests for new terms and identifiers or term and identifier retirement will need to be processed within a reasonable period, and a decision communicated, including publication of the new, modified or retired term, within the time frame specified in agreed upon service level agreements;

— Requests for new terms and identifiers or term and identifier retirement should be supported with appropriate levels of information, details of which are to be specified in the approved service levels;

— The preferred means of processing change requests should be by means of electronic receipt and processing. It is anticipated that over time, this will be the only means of communication of change requests;

— There should be mechanisms in place to ensure that the consequent effects of a change in one of the controlled terminologies are processed in the other affected terminologies appropriately and in a timely manner;

— The terms and identifiers that are indispensable for the identification of medicinal products should, where appropriate, be added in both English and the local language, taking into consideration other official languages in which the standard is being implemented;

— Each of the controlled terminologies should be published in a form that is usable to stakeholders' systems and have robust security to protect data integrity. Electronic records rules might also apply. The release formats should be common to all of the IDMP controlled terminologies;

