



BSI Standards Publication

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

National foreword

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A list of organizations represented on this committee can be obtained on request to its committee manager.

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Technical Report

ISO/TR 14872

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
termes*

**Second edition
2025-12**



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Contents

Page

Foreword	iv
Introduction	v
1 Scope	1
2 Normative references	1
3 Terms and definitions	1
4 Abbreviated terms	2
5 Maintenance of International Standards on IDMP — description of existing relationships between regulators and other standards development organizations	2
6 IDMP terminology maintenance	3
6.1 IDMP maintenance organizations at global level	3
6.2 Core data within IDMP and data that is “derived”	3
7 Current maintenance processes	3
7.1 Generic description of governance and maintenance process	3
7.2 Governance and maintenance: substances and Global Pharmaceutical Product Identifier (PhPID)	4
7.3 Governance and maintenance: pharmaceutical dose forms	5
7.4 Governance and maintenance: units of measurement	5
7.5 Governance for SNOMED interactions with IDMP	6
7.6 Governance for MedDRA	7
7.7 Governance for Anatomical Therapeutic Chemical (ATC) classification system and Defined Daily Dose (DDD)	8
7.8 Governance for International Nonproprietary Names (INN)	9
7.9 Governance for GS1	10
8 IDMP core maintenance processes	11
8.1 General	11
8.2 General processes	11
8.3 Terminology processes	11
8.4 Unambiguity	12
9 International mapping and language translations	12
10 Integration of IDMP core with data sources that are considered “derived”	12
Bibliography	14

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).

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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*.

This second edition cancels and replaces the first edition (ISO/TR 14872:2019), which has been technically revised.

The main changes are as follows:

- the focus on describing the current (2025) implementation experiences and processes has been strengthened;
- references to a “federated service delivery model” have been removed, since this remains inspirational and does not correspond to the current practice;
- information about operating models (governance) of existing maintenance organizations impacting IDMP on a global level has been included.

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 presents a description of the current service delivery models for terminology and identifier maintenance services in support of five International Standards on the Identification of Medicinal Products (IDMP), i.e. ISO 11615 [\[1\]](#), ISO 11616 [\[2\]](#), ISO 11238 [\[3\]](#), ISO 11239 [\[4\]](#), ISO 11240 [\[5\]](#). 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 business objectives and use cases, with a global focus. The document includes descriptions of maintenance and governance processes for a number of organizations that are involved in the provision of core and derived data.

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 medicinal product dictionaries, etc.), description of common coordination and maintenance principles is critical to help ensure consistent adoption, use and maintenance of the International Standards associated with 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 necessarily fully correspond to terminology mapping and format criteria described in Technical Specifications on IDMP (i.e. ISO/TS 20443 [\[6\]](#), ISO/TS 20451 [\[7\]](#), ISO/TS 19844 [\[8\]](#), ISO/TS 20440 [\[9\]](#)). It is recognized that a structured and neutral description of current operating principles for terminology maintenance at global level not only facilitates a harmonized approach to IDMP implementation globally, but provides guidance for regional and local service providers to make use of these descriptions.

Since IDMP standards are in the process of adoption internationally, it is anticipated that this document will be periodically 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, translation 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, guiding principles and processes that are 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 [\[10\]](#), ISO/IEC 20000-2 [\[11\]](#) and ISO/IEC 33002 [\[12\]](#).

The intended audience for this document includes:

- organizations that have already created or are maintaining IDMP terminologies;
- 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 or scientific content, or both) to their internal processes and systems in support of regulatory or healthcare-related business;
- regulators, pharmaceutical/biopharmaceutical companies, clinical research organizations (CROs) and universities/scientific institutes involved in the development, authorization and marketing of medicinal products.

