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The Relationship Between SNOMED CT and IDMP to Facilitate Data Flow

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Introduction and Purpose

This document is written for the following audience:

SNOMED International members, healthcare providers, standards organisations, Clinical Decision Support system developers, Medical Product Dictionary managers, and others involved in pharmacovigilance.

The aim is to promote understanding of SNOMED CT Medicinal Product hierarchy and the relationship between it and the IDMP suite of standards. The development of the SNOMED CT Medicinal Product hierarchy has clear benefits to clinical delivery of care, and potential benefits to regulators and NCA's. The document aims to promote a clear understanding and to identify opportunities for future developments to assist implementation across all areas.

It gives a description of SNOMED CT, then discusses the harmony and synergies that exist between it and IDMP with reference to their different use cases, and as such, assumes a reasonable degree of understanding of the IDMP suite of standards (see <http://isotc215-wg6.team/about-idmp/> for more information).

This document has been produced through participation in the UNICOM project which has received funding from the European Union's Horizon 2020 research and innovation programme under grant agreement No. 875299. The implementation advice will be updated as further implementation experience is gathered from the community of practice. Thus it will be available from SNOMED International after the close of the UNICOM Project.

What is SNOMED CT?

SNOMED CT:

Is a multilingual clinical terminology that covers a broad scope.

- Is the most comprehensive, multilingual clinical healthcare terminology in the world
- Is a resource with comprehensive, scientifically validated clinical content
- Enables consistent representation of clinical content in electronic health records
- Is mapped to other international standards

- Is in use in more than eighty countries

The SNOMED CT clinical terminology:

- Enables clinicians to record data with enhanced accuracy and consistency.
- Is a dynamic product, growing and evolving, driven by the Community of Practice.
- Supports the development of comprehensive, high-quality clinical content in electronic health records.
- Provides a standardised way to represent clinical phrases captured by the clinician and enables automatic interpretation of these.
- Is built on a logical model that defines the way in which each type of SNOMED CT component and derivative is related and represented.

The core component types in SNOMED CT are:

- Concepts
 - Every concept represents a unique clinical meaning, which is referenced using a unique, persistent, numeric, and machine-readable SNOMED CT identifier. The identifier provides an unambiguous, unique reference to each concept and does not have any ascribed human interpretable meaning.
 - **E.g. 763158003 | Medicinal product (product) |**
- Descriptions
 - Two types of description are used to represent every concept – Fully Specified Name (FSN) and Synonym. The FSN represents a unique, unambiguous description of a concept's meaning. This is particularly useful when different concepts are referred to by the same commonly used word or phrase. Each concept can have only one FSN in each language or dialect.
 - **E.g. 16131008 | Product containing antivenom (product) | ; SYNONYM = Antivenom-containing product**
- Relationships
 - A relationship represents an association between two concepts. Relationships are used to logically define the meaning of a concept in a way that can be processed by a computer. A third concept, called a relationship type (or attribute), is used to represent the meaning of the association between the source and destination concepts. There are different types of relationships available within SNOMED CT.
 - **E.g. 127489000 | Has active ingredient (attribute) |**

Attributes and concept definitions in SNOMED CT

Attributes in SNOMED CT are used to define the properties or characteristics of concepts. These attributes are themselves concepts within SNOMED CT and are used to establish relationships between concepts. Each relationship consists of three parts: the source concept (or subject), the attribute (or predicate), and the target concept (or object). This structure allows for the precise definition of a concept in terms of its characteristics and its relationship to other concepts.

Example: Clinical Finding

- Concept: Acute appendicitis
- Attribute: Finding site

- Target Concept: Appendix structure

In this example, the relationship tells us that the "Finding site" of "Acute appendicitis" is the "Appendix structure". This relationship uses the attribute "Finding site" to link the clinical finding to a specific anatomical location, providing clear, structured information that can be understood and used across different systems and settings.

Creating Concept Definitions

Concept definitions in SNOMED CT are constructed using a combination of relationships. These definitions can include hierarchical relationships (e.g., parent-child relationships indicating subclassing or part-of relationships) and attribute relationships that specify the properties of the concept. By combining multiple relationships, SNOMED CT can represent complex medical concepts in a detailed and structured manner.

Example: Procedure

- Concept: Appendectomy
- Attribute 1: Method
- Target Concept 1: Excision
- Attribute 2: Procedure site - Direct
- Target Concept 2: Appendix structure

In this procedure example, the concept "Appendectomy" is defined through relationships that specify the "Method" of the procedure as "Excision" and the "Procedure site - Direct" as "Appendix structure". These relationships collectively define the appendectomy procedure in terms of what it involves (excision) and where it is performed (in the appendix), providing a clear, structured definition of the procedure.

By utilising relationships to represent attributes and create concept definitions, SNOMED CT facilitates the precise and consistent representation of medical information, supporting effective communication and interoperability in healthcare. This structured approach allows for detailed clinical documentation, decision support, and data analysis, contributing to improved patient care and outcomes.

SNOMED CT in practice

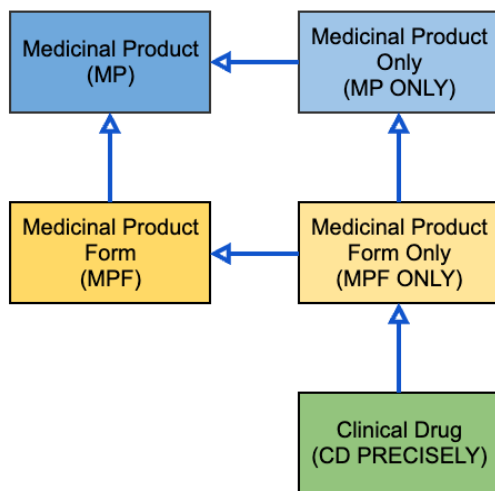
SNOMED CT is designed to provide unambiguous representation of clinical concepts for use in Electronic Health Records and to support interoperability by providing a terminology used in global communication standards, such as FHIR. SNOMED CT is designed and maintained as an ontology, which is supported by the use of an agreed concept model (data model). The model defines what attributes can be used to provide a computer-readable definition of a concept, which is then used to create the poly-hierarchies within the terminology. The model also provides a framework which allows for post coordination of clinical terms. This is where multiple concepts within SNOMED CT can be "joined together" to form a new concept. Which concepts can be joined are defined by the concept model, which provides details of semantic type, the attribute to be used and a value range for the attribute value. In the context of the drug model for example, dose form and active ingredient are authored attributes to clinical drug. Where possible concept hierarchies are aligned to agreed global

standards, for example the hierarchy of dose form is aligned to EDQM. In some cases the alignment is also supported by a published and updated mapping, as is the case for EDQM/SNOMED mapping table.

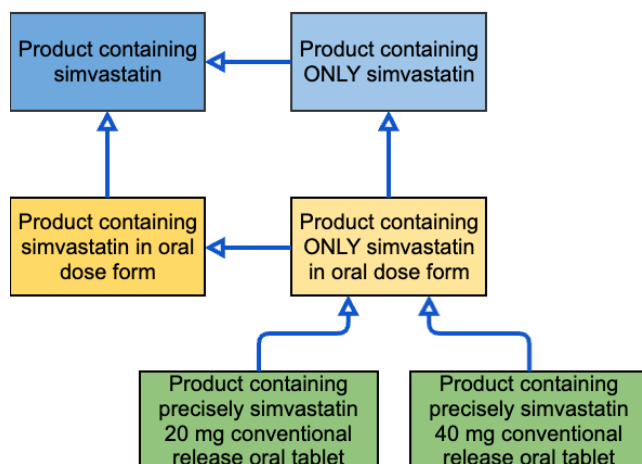
What is the SNOMED CT International Medicinal Product Model?

The SNOMED CT Medicinal Product hierarchy provides concepts to describe medicinal products at various levels of abstraction with international applicability and support for interoperability in patient care and health data analysis.

Medicinal products are described in the International Edition of SNOMED CT in five different levels of abstraction and arranged in a hierarchy.



Below, is an example of those classes populated in the International Edition with concepts representing commonly available clinical drugs:



- **Medicinal Product “containing”**

Examples:

108600003 |Product containing atorvastatin (medicinal product)|
409411009 |Product containing amlodipine and atorvastatin (medicinal product)|

- An abstract representation of a medicinal product based on the description of active ingredient substance(s) that it contains. It means that the medicinal product must contain the active ingredient(s) specified in the FSN but may also contain additional active ingredient(s).

- **Medicinal Product “containing only”**

Examples:

773455007 |Product containing only atorvastatin (medicinal product)|
773457004 |Product containing only amlodipine and atorvastatin (medicinal product)|

- An abstract representation of a medicinal product based on the description of active ingredient substance(s) that it contains. It means that the medicinal product must contain only the active ingredient(s) specified in the FSN.
- The substances included in the SNOMED CT are named in alignment with the International Nonproprietary Names (INN) denominations.

- **Medicinal Product Form “containing”**

Examples:

437876006 |Product containing paracetamol in oral dose form (medicinal product form)|
767783007 |Product containing codeine and paracetamol in oral dose form (medicinal product form)|

- An abstract representation of a medicinal product based on the description of active ingredient substance(s) that it contains and on the generalised intended site of use. It means that the medicinal product must contain the active ingredient(s) specified in the FSN but may also contain additional active ingredient(s).
- The medicinal forms are represented with concepts from the "736542009 |Pharmaceutical dose form (dose form)|" hierarchy. These concepts are included in SNOMED in close alignment with EDQM Standard Terms forms when possible, and a map between these SNOMED codes and EDQM codes is available: <https://confluence.ihtsdotools.org/pages/viewpage.action?pageId=154241637>

- **Medicinal Product Form “containing only”**

Examples:

780128004 |Product containing only paracetamol in oral dose form (medicinal product form)|
778848002 |Product containing only codeine and paracetamol in oral dose form (medicinal product form)|

- An abstract representation of a medicinal product based on the description of active ingredient substance(s) that it contains and on the generalised intended site of use. It means that the medicinal product must contain only the active ingredient(s) specified in the FSN.

- **Clinical Drug “containing precisely”**

Examples:

322236009 |Product containing precisely paracetamol 500 milligram/1 each conventional release oral tablet (clinical drug)|

765548006 |Product containing precisely doxazosin (as doxazosin mesylate) 4 milligram/1 each prolonged-release oral tablet (clinical drug)|

- An abstract representation of a medicinal product based on the description of the precise active ingredient, basis of strength substance (BoSS), strength, and manufactured dose form of a drug product. It implies that the drug product must contain only the precise active ingredient(s) specified in the FSN.
- In the strength representation, the units of measure are presented with concepts from the 767524001 |Unit of measure (qualifier value)| hierarchy. These are aligned with the conventions of the Unified Code for Units of Measure (UCUM) wherever possible.

The Medicinal Product “containing” and Medicinal Product Form “containing” concepts are helpful concepts for analysis, for historical recording, and for decision support, but are not helpful for the activities of the medication process such as prescribing, dispensing, and administration nor do they reflect the regulation of medicinal products. The Medicinal Product “only”, Medicinal Product Form “only”, and Clinical Drug “precisely” concepts are helpful to support the medication care process and to facilitate linkage to the medicinal product information flowing from IDMP implementation.

Within the International Edition of SNOMED CT, Medicinal Product concepts may be grouped based on the chemical structure, disposition (e.g., mechanism of action), and/or general therapeutic role of their active substances. Relationships to concepts representing each component of the FSN (e.g., active ingredient and pharmaceutical dose form) are included in the International Edition of SNOMED CT.

International vs. National Extensions of SNOMED CT


The SNOMED CT model specifies how these components can be managed in an implementation setting to meet a variety of primary and secondary uses.




SNOMED CT is designed to allow the International Edition to be enhanced by creating extensions that meet national or local requirements (e.g., a national extension). This extension mechanism allows SNOMED CT to be customised to address the terminology needs of a country or organisation that are not met by the International Edition, E.g., branded products and generic drugs. Concepts in the Medicinal Product hierarchy can be divided into two types.

- Internationally approved concepts and descriptions are those understood internationally, and described generically using internationally recognized components:
 - active ingredient
 - international nonproprietary names (INNs)
 - dose form
 - strength
- Local, jurisdictionally required concepts are those governed by regulations enforced in that jurisdiction and produced by authorization of a medicines regulatory authority and include proprietary components:
 - branded or trademarked names

- proprietary dose forms and pharmacopoeial dose forms eg. caplets
- additional characteristics: excipients (strawberry flavour, sugar-free); target population groups; indication for use
- packaging information: pack size, container description

Parents

▶  Product containing atorvastatin (medicinal product)

 Product containing only atorvastatin (medicinal product)  

SCTID: 773455007

773455007 | Product containing only atorvastatin (medicinal product)

|


en Product containing only atorvastatin (medicinal product)







en Atorvastatin only product

Count of base of active ingredient → 1

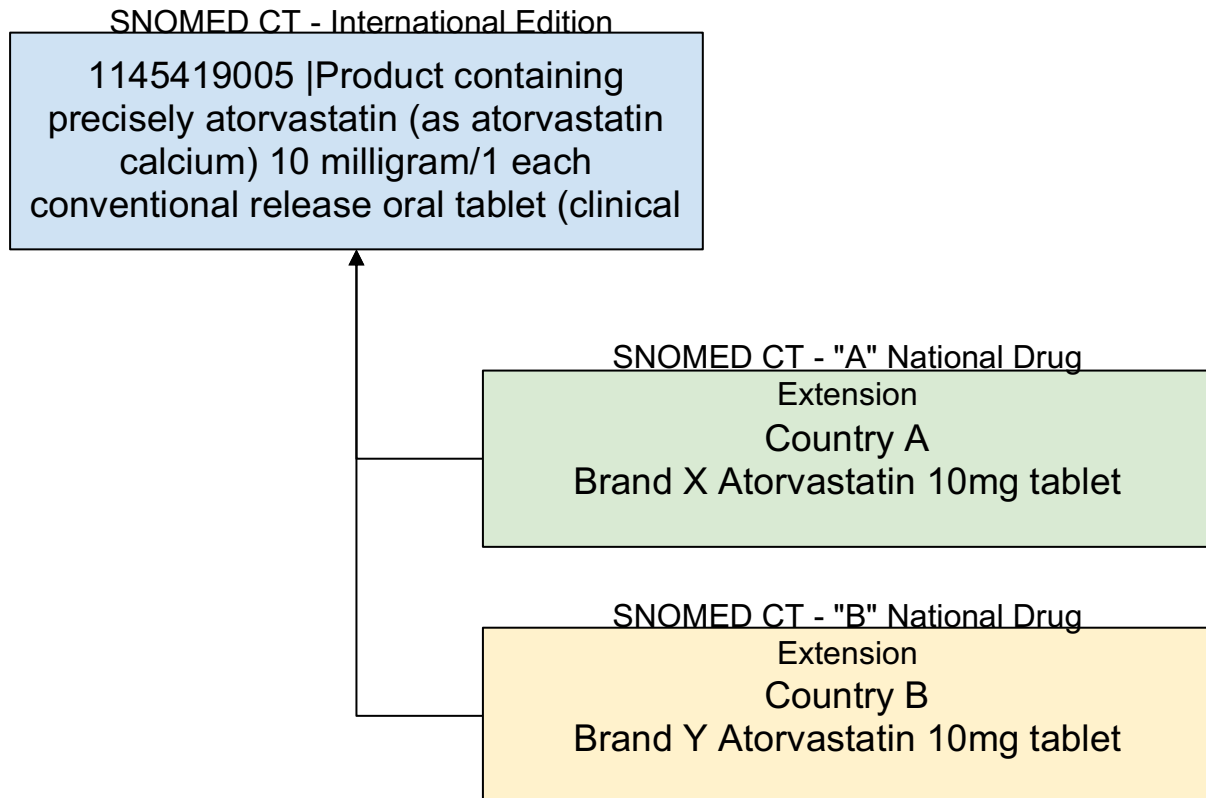
Has active ingredient → Atorvastatin

Children (1)

▼  Product containing only atorvastatin in oral dose form (medicinal product form)

-  Product containing precisely atorvastatin (as atorvastatin calcium) 10 milligram/1 each conventional release chewable tablet (clinical drug)
-  Product containing precisely atorvastatin (as atorvastatin calcium) 10 milligram/1 each conventional release oral tablet (clinical drug)
-  Product containing precisely atorvastatin (as atorvastatin calcium) 20 milligram/1 each conventional release chewable tablet (clinical drug)
-  Product containing precisely atorvastatin (as atorvastatin calcium) 20 milligram/1 each conventional release oral tablet (clinical drug)
-  Product containing precisely atorvastatin (as atorvastatin calcium) 40 milligram/1 each conventional release oral tablet (clinical drug)
-  Product containing precisely atorvastatin (as atorvastatin calcium) 80 milligram/1 each conventional release oral tablet (clinical drug)

The model in the International Edition of SNOMED CT provides support for National Extensions to describe the actual products authorised and marketed in their own jurisdiction and to author intermediate concepts as required by the local culture and practice of healthcare.



For further information on the SNOMED CT Medicinal Product content, please see the International Edition and National Medicinal Product Model specifications, available on Confluence at <https://confluence.ihtsdotools.org/display/IAP/Reference+Documentation++Drug+Model>

What is IDMP?

Identification of Medicinal Products is a set of five standards developed by the International Organisation for Standardization (ISO), regulators, and other stakeholders to provide trusted and accurate information to improve the medicinal product data exchange on a global level.

ISO 11615. Identification of medicinal products - Data elements and structures for the unique identification and exchange of regulated medicinal product information

The standard describes data elements and cardinalities for describing medicinal products on an international level, including complementary identifiers for authorised medicinal products (MPID) and medicinal product packages (PCID).

MPID consists of three segments reflecting the following information: 1) country of authorisation; 2) marketing authorisation holder identifier; 3) medicinal product.

PCID consists of 1) MPID segment, and 2) package description (pack size, container type and material) segment.

The data structure proposed in the standard is designed for regulatory use cases, and is therefore more granular than is typically needed in clinical practice. However, a smaller subset of IDMP data

model is relevant for any context where medicinal product data is captured and distributed. Different use cases might need a different subset of IDMP data elements.

The standard defines coded concepts in the data structure, but does not propose any specific code systems, and implementers are free to choose any controlled vocabulary that meets the IDMP requirements (see ISO 11238, ISO 11239, ISO 11240).

ISO 11616. Identification of medicinal products - Data elements and structures for the unique identification and exchange of regulated pharmaceutical product information

The standard describes data elements and cardinalities for describing pharmaceutical products. Pharmaceutical product is a medicinal product in its administrable form (i.e after reconstitution).

Pharmaceutical Product Identifier (PhPID) uniquely associates medical products with the same or similar pharmaceutical composition based on the following data elements: substance(s), strength(s) (units of measurement/presentation), reference strength(s), and dosage form.

PhPIDs act as a classification, using four different levels.

PhPID level	Active/specified substance	Administrable dose form	Strength / reference strength
PhPID Level 1	X		
PhPID Level 2	X		X
PhPID Level 3	X	X	
PhPID Level 4	X	X	X

One medicinal product can contain several pharmaceutical products (e.g. cream + tablets for vaginal use; contraceptive pills with different constitutions in one package).

As PhPID takes into account the administrable dose form, products with different authorised dose forms may carry identical PhPID set. For example, “Powder and solvent for solution” and “Powder for solution” would result in identical products at administration, therefore they would share the same PhPIDs.

ISO 11238. Identification of medicinal products - Data elements and structures for the unique identification and exchange of regulated information on substances

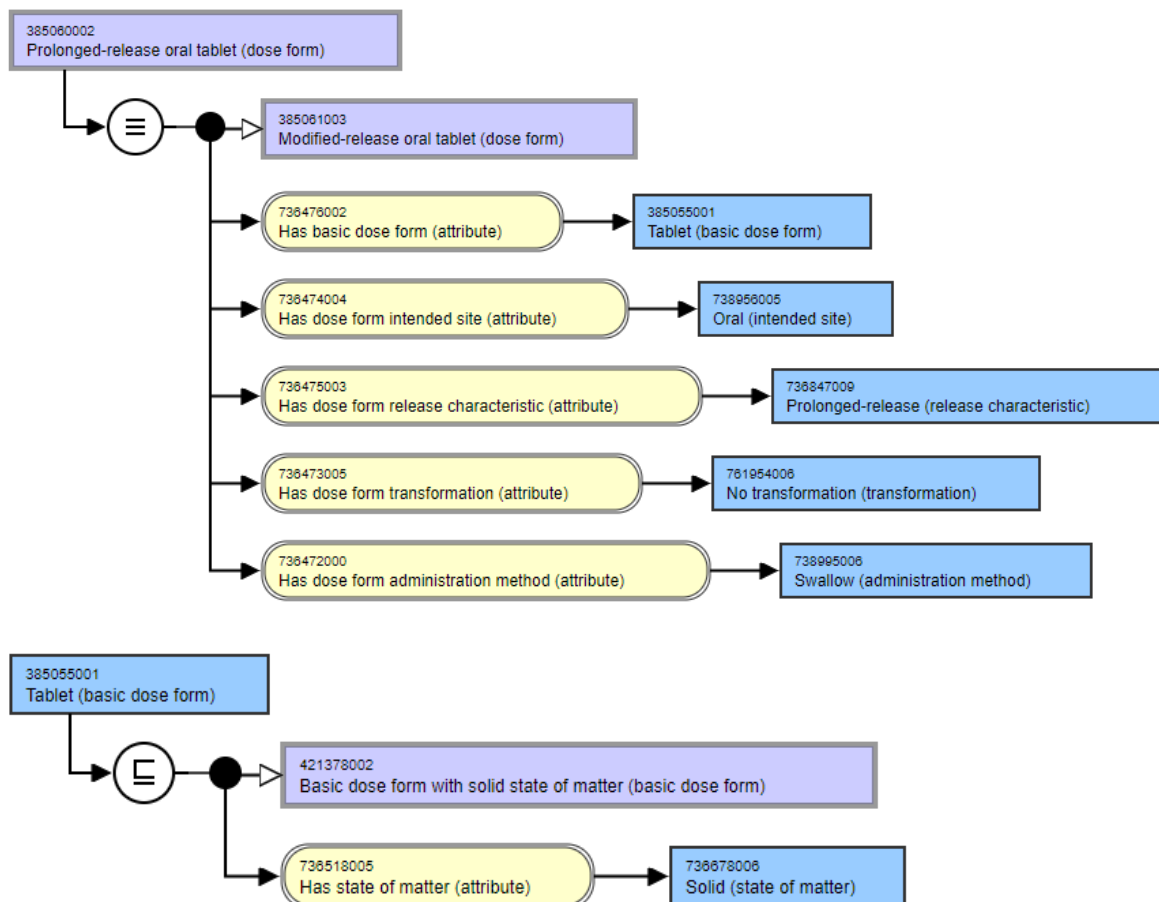
The standard facilitates assignment and maintenance of unique identifiers for all substances in medicinal products. The standard sets out the general rules for defining and distinguishing substances, and provides an information model for substances and specified substances to support the organisation and capturing of data.

The standard focuses on global identifiers for substances, but the information model includes substance codes, which allows the substances to be identified with different code systems.

ISO 11239. Identification of medicinal products - Data elements and structures for the unique identification and exchange of regulated information on pharmaceutical dose forms, units of presentation, routes of administration and packaging

The standard specifies data elements, structures and relationships between the data elements required for exchanging the medication data regarding pharmaceutical dose forms, units of presentation, routes of administration, and packaging (containers, closures, and administrative devices). The standard highlights the key features expected from the vocabularies used for the purpose: multilingual terms and definitions, concept versioning for traceable history, public availability without royalty fee. Also, rules for mapping new vocabularies to existing regional terms are provided.

The standard also provides more specific requirements for concepts and relationships describing dose forms. Every pharmaceutical dose form concept should be based on a basic dose form concept (inheriting state of matter attribute) and be attributed with the following four characteristics: release characteristics, transformation, administration method, intended site. This conceptual model has also been adopted in SNOMED CT:



According to the standard, pharmaceutical dose forms can be grouped to form a new concept class - combined pharmaceutical dose form (e.g powder and solvent for solution for injection). The pharmaceutical dose forms 'solvent for solution for injection' and 'powder for solution for injection' would be assigned to corresponding manufactured items, which after dissolution would result in the pharmaceutical product with administrable dose form 'solution for injection'. Combined pharmaceutical dose form is out of scope for SNOMED CT international release.

ISO 11240 Identification of medicinal products - Data elements and structures for the unique identification and exchange of units of measurement

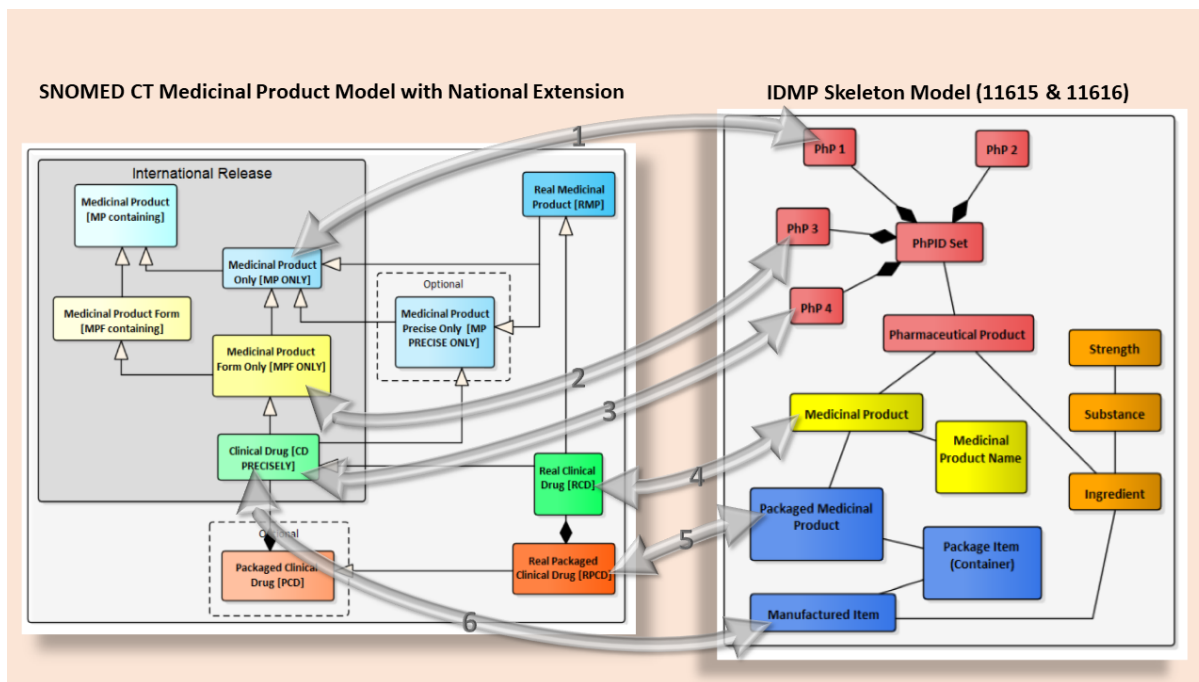
The standard sets out rules for representing units of measurement used in exchanging information about quantitative characteristics of medicinal products in human medicine. It ensures traceability to international metrological standards and provides guidelines for standardised, machine-readable documentation of product composition and strength. It defines requirements for coding units, structures for mapping between different unit vocabularies, and supports language translations.

The standard proposes UCUM as the code system for units of measurement (see ISO 21090 for the definition of datatype PQ). However, this applies mostly for data exchange between systems, and particular instances are allowed to use other, including locally defined, code systems for units as long as they are compatible with UCUM. The standard also includes an annex with a mapping table between SNOMED CT and UCUM concepts, demonstrating the translatability and compatibility of these code systems.

The Relationship between SNOMED CT and IDMP

SNOMED and IDMP models were originally designed to support different domains with differing use cases. However, as time has progressed and different levels of implementation have been achieved, the need to have closer links between regulation, supply chain, and clinical care has emerged more strongly, and some organizations are testing the use of IDMP at the point of care. Over time, experience and feedback will mean that changes in the SNOMED model and the IDMP model will emerge.

The diagram below shows how the classes of concepts in the medicinal product terminology present in SNOMED CT and classes to identify medicinal product concepts in the IDMP suite can be related to each other; the numbered relationship lines are given further detail in the table below. However, the semantic match of some elements is not exact or appropriate for all possible use cases; over time, feedback and usage will enable these relationships to be amended and updated based on implementation experience.



The table below provides further details of that diagram by comparing the classes of each medicinal product identification system together. Included is a comments column that further identifies any differences between the models. As implementation progresses, this table will be updated based on implementation experience.

Line in diagram	SNOMED CT		IDMP		Comments
	Class	Definition	Class	Definition	
No equivalence	Medicinal Product (Containing)	<p>An abstract representation of a medicinal product based on description of active ingredient substance(s) that it contains (regardless of any modification of those active ingredient substance(s)), but not exclusively limited by those substances, in that other substances may be present.</p> <p>Examples:</p> <ul style="list-style-type: none"> ● 108600003 Product containing atorvastatin (medicinal product) ● 409411009 Product containing amlodipine and atorvastatin (medicinal product) 	This "parent" concept acts both to scope the SCT domain and separate medicinal products from other products e.g. medical devices, foods and cosmetics.	<p>Not applicable</p> <p><i>The "Open world" view used in this SNOMED class does not correspond to any IDMP classes, although it could act as a higher level grouper for PhP1 concepts if use cases are identified.</i></p>	

1	Medicinal Product (Only)	<p>An abstract representation of a medicinal product based on a description of only and exclusively the active ingredient substance(s) that it contains but regardless of any modification of those active ingredient substances (s)</p> <p>Examples:</p> <ul style="list-style-type: none"> ● 773455007 Product containing only atorvastatin (medicinal product) ● 773457004 Product containing only amlodipine and atorvastatin (medicinal product) 	PhP Level 1 (from ISO 11616)	Active Substance(s) Reference Substance(s)	IDMP Class has additional attributes
N/A	Medicinal Product Form (Containing)	<p>An abstract representation of a medicinal product based on a description of active ingredients it contains, but not limited by that description, and on the (generalised) intended site of use for the product</p> <p>Examples:</p> <ul style="list-style-type: none"> ● 437876006 Product containing paracetamol in oral dose form (medicinal product form) ● 767783007 Product containing codeine and paracetamol in oral dose form (medicinal product form) 	No similar equivalent	Not applicable The "Open world" view used in SNOMED does not correspond to any concept currently in the IDMP suite of standards.	
2	Medicinal Product Form (Only)	<p>An abstract representation of a medicinal product based on a description of only and exclusively the active ingredient(s) it contains and on the (generalised) intended site of use for the product</p> <p>Examples:</p> <ul style="list-style-type: none"> ● 780128004 Product containing only 	PhP Level 3 (from ISO 11616)	Active Substance(s) + Administrable Dose Form	There is a difference between the manufactured Dose Form in SNOMED and the Administrable Dose Form in IDMP. And

		<p>paracetamol in oral dose form (medicinal product form) </p> <ul style="list-style-type: none"> 778848002 Product containing only codeine and paracetamol in oral dose form (medicinal product form) 			IDMP includes more attributes in the dose form definition.
N/A	No similar equivalent	Not required by the SNOMED use case	PhP Level 2 (from ISO 11616)	Active Substance(s) + Strength + Reference Strength	
3 (CD to PhP4) and 6 (CD to Manuf Item)	Clinical Drug	<p>An abstract representation of a medicinal product based on description of 1) its precise active ingredient substances only and explicitly, 2) the stated basis of strength substance(s) with strength, expressed as presentation strength with unit of presentation or as concentration strength as appropriate, and 3) with its manufactured dose form</p> <p>Examples:</p> <ul style="list-style-type: none"> 322236009 Product containing precisely paracetamol 500 milligram/1 each conventional release oral tablet (clinical drug) 765548006 Product containing precisely doxazosin (as doxazosin mesilate) 4 milligram/1 each prolonged-release oral tablet (clinical drug) 443620003 Product containing precisely aliskiren 300 milligrams and valsartan 320 milligram/1 each conventional release oral tablet (clinical drug) 322238005 Product containing precisely paracetamol 24 milligram/1 millilitre 	PhP Level 4 (from ISO 11616)) and /or Manufactured Item (not an identified class) (from ISO 11615)	<p>PhP4: Active Substance(s) + Strength + Reference Strength + Administrable Dose Form</p> <p>Manufactured Item: Qualitative and quantitative composition of a product as contained in the packaging of the Medicinal Product as put on the market or Investigational Medicinal Product as used in a clinical trial</p>	The clinical drug in SNOMED contains a Strength attribute, and the IDMP class contains an additional Reference Strength Attribute.

		conventional release oral solution (clinical drug)													
	Relationship between SNOMED Clinical Drug Attributes and IDMP Class Elements														
	<table border="1" style="width: 100%; border-collapse: collapse;"> <thead> <tr> <th style="width: 60%;">SNOMED Clinical Drug Attribute</th> <th>IDMP Class Element</th> </tr> </thead> <tbody> <tr> <td>Precise active Ingredient</td> <td>Active substance</td> </tr> <tr> <td>Manufactured dose form</td> <td>Administrable dose form</td> </tr> <tr> <td>Strength (Numerator & denominator values and units)</td> <td>Strength</td> </tr> <tr> <td style="text-align: center;">-</td> <td>Reference Strength</td> </tr> </tbody> </table>					SNOMED Clinical Drug Attribute	IDMP Class Element	Precise active Ingredient	Active substance	Manufactured dose form	Administrable dose form	Strength (Numerator & denominator values and units)	Strength	-	Reference Strength
SNOMED Clinical Drug Attribute	IDMP Class Element														
Precise active Ingredient	Active substance														
Manufactured dose form	Administrable dose form														
Strength (Numerator & denominator values and units)	Strength														
-	Reference Strength														
N/A	Real Medicinal Product [National Extension]	<p>The representation of a medicinal product marketed by a single organisation (supplier) in a single jurisdiction under a single name (which may be a trade or brand name) and which contains the same set of active ingredient substances, regardless of any modification of those active ingredient substances. It is a subtype of and real-world equivalent to the Medicinal Product Only (MP only) class in the International Edition of SNOMED CT</p> <p>Examples:</p> <ul style="list-style-type: none"> Inlyta product Pfizer Limited (real medicinal product) 	No similar equivalent												
4	Real Clinical Drug [National Extension]	<p>The representation of a medicinal product marketed by a single organisation (supplier) in a single jurisdiction under a single name (which may be a trade or brand name) and which contains the same set of precise active ingredient substances and strengths in a single manufactured dose form. It is a subtype of and real world equivalent to the</p>	Medicinal Product (MPID) (from ISO 11615)	Any pharmaceutical product or combination of pharmaceutical products that may be administered to human beings (or animals) for treating or preventing disease, with the aim/purpose of making a medical diagnosis or to restore, correct or modify physiological functions											

		<p>Clinical Drug (CD precisely) class in the International Edition of SNOMED CT</p> <p>Examples:</p> <ul style="list-style-type: none"> ● Inlyta 3 mg tablet Pfizer Limited (real clinical drug) 			
5	Real Packaged Clinical Drug [National Extension]	<p>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</p> <p>Examples:</p> <ul style="list-style-type: none"> ● Package containing 28 tablets Inlyta 3 mg tablet Pfizer Limited (real packaged clinical drug) 	Packaged Product (PCID) (from ISO 11615)	Medicinal Product in a container being part of a package, representing the entirety that has been packaged for sale or supply	

Summary

The concepts from ISO 11615 describing real authorised medicinal products (identified by MPIDs and PCIDs) correspond directly to concept classes in the SNOMED CT Medicinal Product National Extension model. This means that a trusted source of detailed medicinal product composition data and particularly of the definitional attributes used for concepts such as the Real Clinical Drug and Real Packaged Clinical Drug for each jurisdiction, which is consistent across all products, can flow directly to support the authoring of these concepts. This will be extremely valuable and should eliminate many of the uncertainties that currently plague medicinal product terminology for clinical use. For example: precise ingredient substance and basis of strength substance should be accurately available for all products, removing the ambiguities that can currently exist, which then adversely affect the accuracy of the description of product strength. Having this robust data provided by the regulatory agencies at the foundation of medicinal product terminology for patient care will mean that the creation of abstract classes will be accurate and manageable for machine processing rules.

It is for abstract concepts, such as Clinical Drugs, etc. that it is harder to be definitive about the relationship between classes of concepts in SNOMED CT because of the implementation uncertainties of IDMP, so they are placed in a relationship together in the drawing and the table tentatively only. For example, in some use cases, a SNOMED CT Clinical Drug could be linked to a PhP4 (ISO 11616) or to a Manufactured Item (ISO 11615). The Manufactured Item is not an identified concept in IDMP, so although it may match well with the Clinical Drug, it cannot be used on its own as a concept in accordance with the current IDMP model. The PhP4 uses an administrable dose form as one of its attributes, whereas the Manufactured Item uses the manufactured dose form. As noted above, the flexibility of the machine-processability of the model for medicinal products within SNOMED for the

development of additional levels of abstraction with minimal human effort means that further harmony and mapping could be developed should use cases show a requirement for this.

Both SNOMED CT and IDMP have valuable and complementary roles to play in describing medicinal products globally and nationally, and ideally, it should be possible to move consistently and safely between the two without loss of information. In the coming years, as various national regulatory agencies implement IDMP, and the SNOMED CT medicinal product model and National Extension model become more widely used, that complementary nature will provide ever higher quality medicinal product terminology for use in healthcare and regulatory processes such as pharmacovigilance and ultimately, therefore, should provide better quality pharmaceutical care for patients.

Implementation advice

Use cases for concurrent use of SNOMED CT and IDMP

1. National Medicinal Products SNOMED Extension maintenance:

- Countries implementing SNOMED CT need to create or adapt concepts in their national extensions to accurately represent the drugs available on their market. Real Clinical Drugs in SNOMED CT represent complex information including ingredients, strengths, dose forms, suppliers, and brand names. Additionally, a national extension may include detailed packaged drug information.
- The databases maintained by regulatory agencies, increasingly adopting the IDMP standard, serve as vital inputs for keeping these national extensions up to date. By understanding and aligning the IDMP classes with SNOMED classes, healthcare informatics professionals can automate the import and update processes for regulatory information into national SNOMED extensions. This alignment ensures that the national drug registries reflect the most current and comprehensive drug information, facilitating accurate drug identification, prescription, and administration within clinical systems.

2. Interoperability between clinical and supply chain systems:

- The use of SNOMED CT and IDMP standards together significantly enhances the interoperability between clinical systems (like EHRs) and supply chain systems within the pharmaceutical and healthcare sectors.
- Use Case: By employing both standards, healthcare providers and pharmaceutical companies can ensure that the information pertaining to medicinal products is consistent and accurate across all stages of the healthcare delivery process. For instance, a medication prescribed in a clinical setting (using SNOMED CT for clinical documentation) should be precisely matched to its equivalent in the supply chain system (identified using IDMP standards) for ordering and inventory management.

3. Interoperability between clinical and Pharmacovigilance and Safety Monitoring systems:

- The alignment between SNOMED CT and IDMP standards within Pharmacovigilance and Safety Monitoring systems brings about significant enhancements in the accuracy and efficiency of adverse event reporting and the overall management of drug safety data.


Approaches for Leveraging Regulatory Data to Maintain a SNOMED CT National Drugs Extension

National medication dictionaries, essential for the accurate and comprehensive cataloguing of pharmaceutical products, are updated through submissions from the pharmaceutical industry regarding new products. These submissions are structured using data formats that are compliant with IDMP standards. Following these submissions, regulatory agencies conduct the authorization process for these pharmaceutical products. Subsequently, they update and maintain national dictionaries, which serve as detailed repositories listing all currently available medications. This systematic approach ensures that healthcare providers and stakeholders have access to the latest, standardised information on medicinal products, facilitating better patient care and regulatory compliance.

In clinical environments, prescription systems leverage SNOMED CT to encode information about pharmaceutical products, thereby enhancing clinical data entry, supporting decision-making in clinical care, contributing to research, and powering analytics. National Digital Health programs maintain SNOMED extensions specific to their country to accurately represent the range of pharmaceutical products available within their territories.

The alignment of the SNOMED CT Medications model with the IDMP standards sets the stage for the harmonisation of these crucial healthcare resources. National medication dictionaries are key data inputs for developing National SNOMED Drug Extensions. Through this alignment, it becomes feasible to execute transformations that facilitate the upkeep of the SNOMED extensions. These updates can draw from the latest changes in National regulatory dictionaries, enabling their maintenance through automated or semi-automated processes. This integration ensures that the extensions remain current and reflect the most recent regulatory standards, thereby enhancing the accuracy and effectiveness of healthcare information systems.

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