

Logical model of the classification and identification of pharmaceutical and medicinal Products

0. Structure of this document

This document is divided into a number of distinct, but related sections.

- Overview of the proposed structures
- SECTION A – Substances and Ingredient Substances
- SECTION B – Pharmaceutical Products and Administered Pharmaceutical Products
- SECTION C – Medicinal Products

1. Overview of Proposed Structures

1.1. Introduction

This standard includes a 'logical model' for the pharmaceutical and medicinal products domain for a set of purposes including regulation and pharmacovigilance. The logical model may be used to create implementations which serve a variety of purposes. These implementations will generally modify the logical model so as to improve efficiency of processing, querying, communicating, etc.

Although this is a logical model and therefore to some extent separated from implementation issues, there remains a requirement that implementations are fit for purpose and that the model supports the user requirements.

There is an assumption presented within the user requirements that there shall be three major directories of entity containing and identifying:

- **medicinal products** – products which have, have been, or planned to be, made available by one or more manufacturers or suppliers,
- **pharmaceutical products** – products described at a 'generic' product level,
- **substances** – chemical or biological substances which are used as ingredients in pharmaceutical and medicinal products.

In order to accommodate the range of entities which need to be defined and identified there is a need to expand the number of key entry types by the introduction of additional levels.

1.2. Description of the structure of the logical model

1.2.1. Classes and their hierarchical relationships

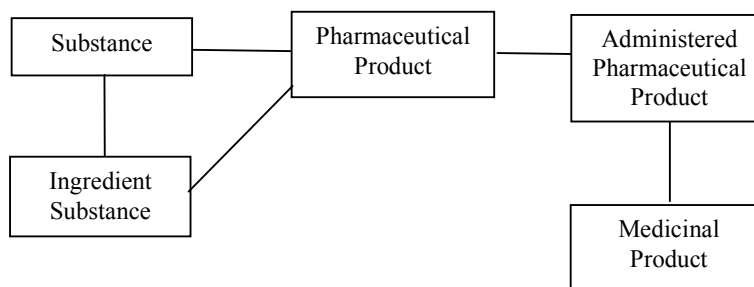


Figure 1. Overview of the logical model

1.2.2. Substance

A substance is any matter that has a discrete existence, irrespective of origin, which may be human, animal, vegetable, or chemical. Substances are the basic building blocks of medicinal products and will be described using a minimally sufficient number of data elements. A substance often describes an ‘active moiety’ within a pharmaceutical product

1.2.3. Ingredient Substance

A substance which has been in some manner changed through such processes as purification, complexing, deactivation, etc.

In the great majority of cases an ingredient substance is associated with a single substance but there are a few exceptions where the ingredient must refer to multiple substances.

1.2.4. Pharmaceutical Product

At this level we describe a pharmaceutical product at its most abstract. This will include the identity and quantities (generally the unit dose) of all clinically significant ingredients (generally the ‘active’ ingredients) and the dose form of the product. At this level we do not identify the route(s) of administration, excipients or any manufacturer information.

Certain entries at the Pharmaceutical Product level will not include what one would normally define as an ‘active ingredient’. For example there could be a Pharmaceutical Product entry for 5mL vial of water for injection.

1.2.5. Administered Pharmaceutical Product

A given Pharmaceutical Product will usually be associated with a number of Administered Pharmaceutical Products representing product types which are offered by different manufacturers or suppliers. At this level we include details of excipients and intended routes of administration.

1.2.6. Medicinal Product

At this level we have descriptions of the products which are, or are planned to be, made available and authorised by regulatory bodies. These descriptions may include pack information (e.g. Augmentin 375 mg tablets (21 tablet pack))

1.2.7. Devices

Although not shown within the overview models above, there will be a requirement to describe devices which are included in medicinal product packs. Examples:

- Estriol 0.01% cream 25mg with applicator,
- Optaflu-Suspension for injection in pre-filled syringe-Intramuscular use-pre-filled syringe (glass)-0.5 ml-10 pre-filled syringes.

SECTION A – Substances and Ingredient Substances

2. Substance

2.1. Introduction

Substances (drug substances) act ingredients or are modified and then act as ingredients in pharmaceutical and medicinal products. Substances are varied, ranging from simple chemical substances to complex biological substances.

Drug substances are described by a controlled vocabulary as provided by the prEN ISO 11238 - Health informatics – Identification of medicinal products – Structures and controlled vocabularies for drug substances.

In this vocabulary, drug substances are described at a relatively high level.

2.2. Substance and Substance Preparation Model

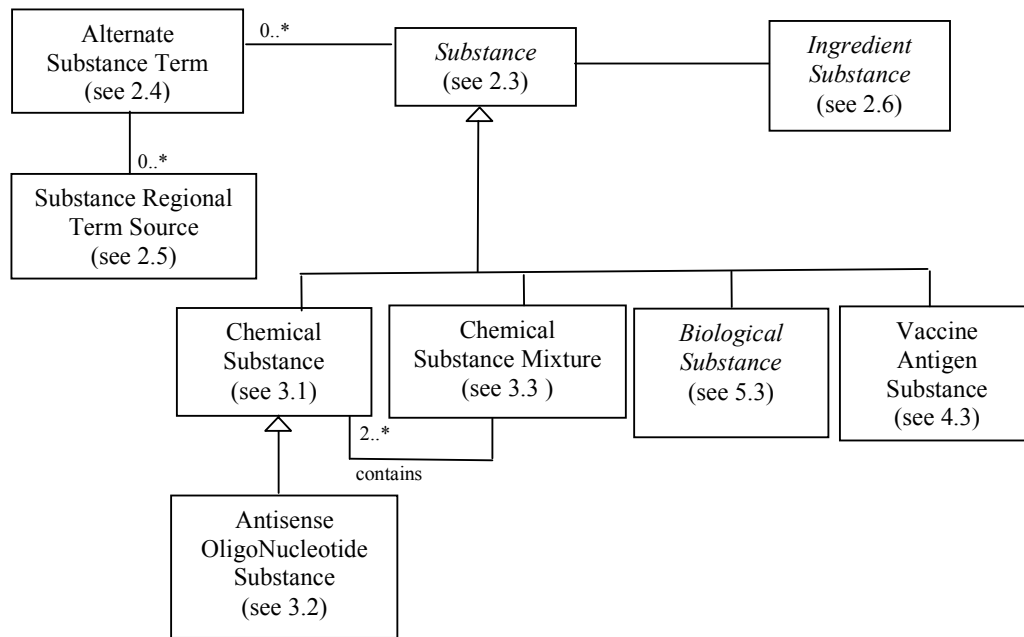


Figure 2. Substance Model

Note: Biological Substance is an abstract class which is further specialised.

2.3. Substance definition

Type: abstract class		
Information about a chemical element, chemical compound, naturally occurring material or their mixtures and solutions.		
Specializations		
A Substance shall always be specialized as a Chemical Substance, Chemical Substance Mixture, Biological Substance or Vaccine Antigen Substance		
Associations		
An instance of Substance may be associated with zero to many instances of Alternative Substance Term		
Attributes:		
substanceId	Type: UID	1
An identifier for this substance		
substanceName	Type: ST	1
A name that is associated with the substance		
Note: The type used here is string. An alternative is Entity Name (EN) which is preferred by HL7.		

2.4. Alternate Substance Term

Type: class		
Information about an alternative identifier and name for the substance		
Associations		
An instance of Alternative Substance Term is associated with one instance of Substance		
An instance of Alternative Substance Term may be associated with zero or more instances of Substance Regional Term Source		
Attributes:		
substanceId	Type: UID	1
An identifier for this substance		
IdSource	Type: UID	0 or 1
An identifier for the source of the alternative identifier. This OID may be specific to a version of the substance identification list		
Note: This attribute or the IdSourceName or both must be included		

IdSourceName	Type: ST	0 or 1
<p>The name of the source of the alternative identifier.</p> <p>Note: This attribute or the IdSource or both must be included</p>		
alternateId	Type: ST	1
<p>A string that provides the identifier for the substance.</p> <p>Example An InChI (IUPAC International Chemical Identifier) is a fixed length string of 25 characters capable of uniquely representing a chemical substance</p>		
alternateName	Type: ST	0 or 1
<p>The alternative name for the substance associated with the above identifier</p>		

2.5. Substance Regional Term Source

<p>Type: class</p> <p>Information about the a region where the alternative name and identifier is used.</p> <p>Associations An instance of Substance Regional Term Source is associated with one instance of Alternative Substance Term</p>		
<p>Attributes:</p>		
referenceCountry	Type: CV	1
<p>ISO country code referring to the country of origin of the regional term.</p> <p>The code should be represented using ISO 3166-1 alpha-2 which are two-letter codes representing countries and dependent territories.</p>		
languageCode	Type: CV	1
<p>indicates the language code of the Regional Term using ISO 639-1:2002 <i>Codes for the representation of names of languages -- Part 1</i></p>		

2.6. Ingredient Substance

Type: abstract class		
An Ingredient Substance is a substance which has additional properties or which has been prepared in a particular manner. The types of additional property generally depends upon the substance class, e.g. vaccine, herbal, etc.		
Attributes:		
ingredientSubstanceID	Type: UID	1
A unique identifier for the ingredient substance		
ingredientSubstanceName	Type: ST	1
A name by which the ingredient substance is designated		
ISSUE: Is there a need for regional names?		

3. Chemical Substances and Chemical Substance Mixtures

3.1. Chemical Substance

3.1.1. Introduction

Simple chemical substances will be primarily defined by two dimensional or even one-dimensional representations of the molecular structure.

Substances will be defined without regard to physical form (i.e. ice, liquid water, steam will all be defined as water). Physical of a substance can change depending on external conditions (pressure, temperature) and therefore is not considered an intrinsic property of a substance.

Crystalline and amorphous forms of a given substance will not be captured in the definition of a substance. The solid phase form of a substance is an important property that can influence pharmaceutical product performance but it is not a property that is intrinsic to a substance. This information should be captured at the product level.

Substances will be defined without regard to three dimensional structure. Rotamers or conformational isomers will not be assigned separate unique identifiers unless the conformational isomers are isolatable (e.g. substituted biphenyls). Three-dimensional structures can be difficult to determine and a single substance can have many potential 3-D structures that could exist in solution or in different crystal forms.

It often difficult to enumerate all the tautomeric forms that could exist for a given substance. It can also be difficult to determine the predominant tautomeric that exists in solution or in crystals. Therefore for most simple chemical substances different tautomeric forms will not be entered into the system as separate substances. Each chemical substance will be represented by a single tautomeric form. The choice of tautomeric form will be rule-based and not determined by predominant tautomeric form that may exist for a given substance (i.e. all aliphatic ketones will be defined as ketones and not enols). It may, however, be possible to map a substance to multiple tautomeric forms.

Substances will be defined without regard to grade or purity, although specific impurities or related substances may also be defined and assigned a unique identifier. Different grades or levels of purity of a chemical substance (e.g. water, distilled water, water for injection) will not be defined at the

substance level. Different pharmacopeias or regulatory authorities frequently have different limits on purity or specific impurities. The relationship between a substance and impurities should be captured at the product level since different manufacturers frequently will have different impurities.

The method of synthesis or processes that result in the formation of a simple chemical substances will not be described or indicated (e.g. glucagon produced by chemical synthesis, biotechnology processes or isolated from natural sources would be defined as the same substance).

Non-covalent interactions other than ionic interactions between ions and counterions and that of solvates will not be part of the definition of a substance. Liposomal and host guest complexes (e.g. cyclodextrin drug complexes) will be considered products and will not be defined at the substance level.

Stereoisomers (R, S, Z, E), racemic mixtures, different stoichiometric forms of salts and solvates of will be considered separate substances.

The model system must be capable of allowing incompletely defined substances where stereochemistry, stoichiometry or even complete connectivity is not known.

3.1.2. Chemical Substance Model

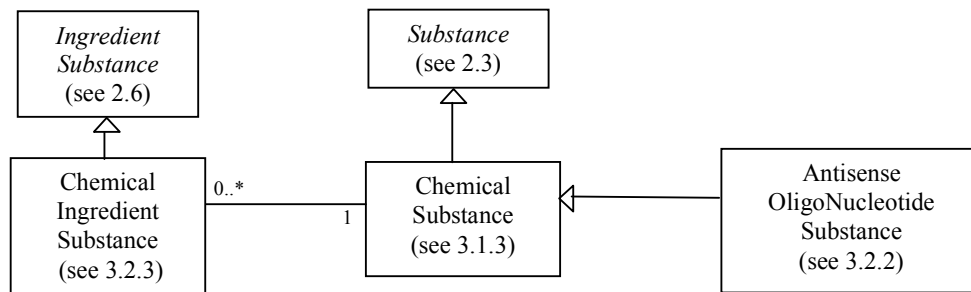


Figure 3. Chemical Substance Model

3.1.3. Chemical Substance Definition

Type: class		
Information about a type of substance that can be defined by a single molecular structure or a limited number of related chemical structures.		
Generalization		
An instance of Chemical Substance is always a specialization of an instance of Substance.		
Specialization		
An instance of Chemical Substance may be specialized as of an instance of Antisense OligoNucleotide Substance.		
Associations		
An instance of Chemical Substance may be associated with zero to many instances of Chemical Ingredient Substance		
Attributes:		
formula	Type: ST	0 or 1
An expression of the chemical or molecular formula of the chemical substance.		
Examples		
<ul style="list-style-type: none"> - hexane C₆H₁₄, - sodium chloride NaCl 		
ISSUE: Should this attribute be mandatory for chemical substances?		
molecularMass	Type: REAL	0 or 1
The mass of a molecule of the compound relative to the mass of a carbon atom taken as exactly 12.		
Note: In theory we can only refer to the molecular mass of a covalent compound since only covalent compounds are composed of molecules. For ionic substances such as sodium chloride, the molar mass should be entered		
ISSUE: Should this attribute be mandatory for chemical substances?		

numberOfMoieties	Type: INT	1
<p>Many substances are salts which separate (ionize) when dissolved. This attributes provides an indication of the number of moiety types</p> <p>EXAMPLE: Atenolol sulphate has 2 moieties: atenolol (the active moiety) and the sulphate ion</p>		
steriochemistry	Type: CV	0 or 1
<p>May be used to provide details of the relative spatial arrangement of atoms within chemical substance molecules</p> <p>Values: Absolute, Racemic, Relative, Unknown</p>		
structure	Type: ED	1
<p>Information about a structural representation of the chemical substance and the method used to create this representation</p> <p>Note: The ED data type provides a means of specifying the encoding type (e.g. Mol, Smiles, Inchi), the format of the representation (e.g. svg), and a string or graphic to hold the structural representation</p>		

3.2. Antisense OligoNucleotide Substance

3.2.1. Introduction

Antisense OligoNucleotide Substances are synthesized strands of nucleic acid (DNA, RNA or a chemical analogue) that will bind to the messenger RNA (mRNA) produced by a particular gene and inactivate it, effectively turning that gene "off".

3.2.2. Antisense OligoNucleotide Substance Definition

<p>Type: class Information about a type of Antisense OligoNucleotide Substance</p> <p>Generalization An instance of Antisense OligoNucleotide Substance is a specialization of an instance of Substance. Antisense OligoNucleotide Substance inherits all of the properties described for Chemical Substance but has additional property described below.</p> <p>NOTE: Details of how the Antisense OligoNucleotide Substance is prepared may be described using the structures presented in Biological Substance Preparation. This information is NOT deemed to be a part of the Antisense OligoNucleotide Substance itself since there will be wide variations. Antisense OligoNucleotide Substance Preparation details may be associated with a particular set of Medicinal Products.</p>		
Attributes:		
nucleotideSequence	Type: ST	1
<p>Refers to the succession of letters representing the nucleotides present in nucleic acid molecules. This sequence is read from 5' to 3'.</p>		

3.2.3. Chemical Ingredient Substance Definition

Type: class Information about a type of chemical substance which has been modified or has additional properties. Examples: <ul style="list-style-type: none">- substance has been purified- substance has a particular physical form (e.g. powdered, granulated, etc)		
Generalization An instance of Chemical Ingredient Substance is a specialization of an instance of Ingredient Substance from which it inherits the general properties of identification and naming		
Association An instance of Chemical Ingredient Substance is associated with one instance of Chemical Substance		
Attributes:		
descriptionOfModification	Type: ST	1
A textual description of the nature of the modification		
modificationCode	Type: CV	0 or 1
A code representing the type of modification		

3.3. Chemical Substance Mixture

3.3.1. Introduction

Where a mixture of substances are utilized as an ingredient in one or more pharmaceutical or medicinal product there is a requirement to record and identify it.

Generally, mixtures will contain related simple chemical substances (e.g.. Gentamicin would be entered as a mixture of Gentamicin C1, Gentamicin C2 and Gentamicin C1A).

There are essentially three types of mixtures allowed in the system;

- **“All of”** mixture where each component must be present in the substance,
- **“Any of”** mixture where any of the components can be present. An “Any of” mixture is used for mixtures in which one or more of the substances that make up the mixture may not be present.
- **“One of”** mixture where only one of the components of a mixture is present. A “One of” mixture is used for situations where only one several related substances can be present in a product.

The amount of different components (substances) in a mixture will not be captured at the substance level. This could vary depending on the manufacturer or method of synthesis, isolation or purification.

Mixtures will only be defined as substances when they are:

- isolated together from a natural source (e.g. fermentation broth, gentamicin), or
- are the result of a chemical synthesis (e.g. monoesterification of glycerol), or
- are necessary because of incomplete or ambiguous definition of a substance on a product label.

Example, a product label may list Lactic Acid, not DL-Lactic Acid (synthetic form) or L-Lactic Acid (natural derived form). This substance could be represented as a “One of” mixture of DL-Lactic Acid or L-Lactic Acid.

A mixture formed by combining two purified chemical substances together will be defined at the product level. Mixtures should only be created for closely related substances such as substances that are stereoisomers of each other.

Racemic or unknown stereoisomerism can be defined as single substance using an element to describe the state of knowledge regarding stereochemistry. This approach would minimize the number of mixtures that would have to be created. **Chemical Substance Model**

3.3.2. Chemical Substance Mixture Model

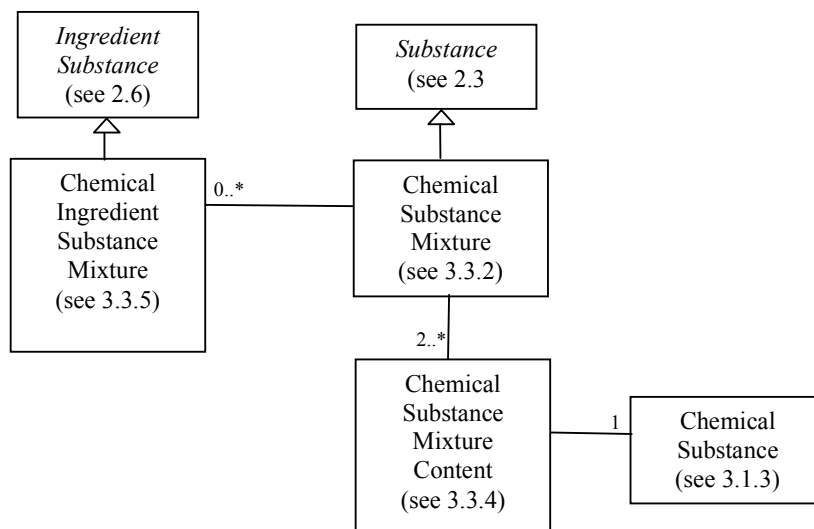


Figure 4. Chemical Substance Mixture Model

3.3.3. Chemical Substance Mixture Definition

Type: class		
Information about a mixture of chemical substances which together are utilized as an ingredient in one or more medicinal products.		
Generalization		
An instance of Chemical Substance Mixture is a specialization of an instance of Substance.		
Association		
An instance of Chemical Substance Mixture is associated with two or more instances of Chemical Substance		
An instance of Chemical Substance Mixture may be associated with zero to many instances of Chemical Ingredient Substance Mixture		
Attributes:		
mixtureType	Type: CV	1
Values:		
<ul style="list-style-type: none"> - AllOf - AnyOf - OneOf 		
numberOfSubstances	Type: INT	1
Number of chemical substance types within the mixture		

3.3.4. Chemical Substance Mixture Content

<p>Type: associative class A class may be created to denote the association between a mixture and its content.</p>		
Attributes:		
mixtureID	Type: UID	1
The identifier for the mixture held in the attribute SubstanceId		
substanceID	Type: UID	1
The identifier for a component chemical substance		

3.3.5. Chemical Ingredient Substance Mixture Definition

<p>Type: class Information about a type of chemical substance mixture which has been modified or has additional properties.</p> <p>Example: - substance mixture has been purified</p> <p>Generalization An instance of Chemical Ingredient Substance Mixture is a specialization of an instance of Ingredient Substance from which it inherits the general properties of identification and naming</p> <p>Association An instance of Chemical Ingredient Substance Mixture Ingredient is associated with one instance of Chemical Substance Mixture</p>		
Attributes:		
descriptionOfModification	Type: ST	1
A textual description of the nature of the modification		
modificationCode	Type: CV	0 or 1
A code representing the type of modification		

4. Vaccine Antigen Substance

4.1. Introduction

In general, vaccines are described in the product labelling in conformity with the pharmacopoeia monograph for vaccine antigens in a country or region. For non-pharmacopoeia vaccines they are normally described according to the formal Latin/Greek name and/or the disease being protected against. For bacteria and viruses, the strain description is taken into account. This refers also to the serotype or other appropriate sub-species, the antigen characterisation and identification of the designation as associated with the name of each antigen, if relevant. In addition, the adjuvants, the nature of any cellular system(s) used for production, and if relevant use of recombinant DNA technology (including the use of the expression 'produced in XXX cells <by recombinant DNA technology>') need to be captured. The production process of vaccines needs to be addressed at the level of the antigen state, taking into account the manufacturing methods, like inactivation and recombinant DNA technology.

An antigen is a substance that can provoke an immune response. Typically antigens are substances not usually found in the body

Vaccine antigens may be dead or inactivated organisms or purified products derived from them.

There are four types of traditional vaccines

- Vaccines containing killed microorganisms - these are previously virulent micro-organisms that have been killed with chemicals or heat. Examples are vaccines against flu, cholera, and hepatitis A.
- Vaccines containing live, attenuated virus microorganisms - these are live micro-organisms that have been cultivated under conditions that disable their virulent properties or which use closely-related but less dangerous organisms to produce a broad immune response. They typically provoke more durable immunological responses and are the preferred type for healthy adults. Examples include measles, rubella, and mumps.
- Toxoids - these are inactivated toxic compounds in cases where these (rather than the micro-organism itself) cause illness. Examples of toxoid-based vaccines include tetanus and diphtheria.
- Subunit - rather than introducing an inactivated or attenuated micro-organism to an immune system (which would constitute a "whole-agent" vaccine), a fragment of it can create an immune response.

A number of innovative vaccines are also in development and in use:

- Conjugate - certain bacteria have polysaccharide outer coats that are poorly immunogenic. By linking these outer coats to proteins (e.g. toxins), the immune system can be led to recognize the polysaccharide as if it were a protein antigen. This approach is used in the *Haemophilus influenzae* type B vaccine.
- Recombinant Vector - by combining the physiology of one micro-organism and the DNA of the other, immunity can be created against diseases that have complex infection processes
- DNA vaccination - in recent years a new type of vaccine, created from an infectious agent's DNA called *DNA vaccination*, has been developed.

Note that while most vaccines are created using inactivated or attenuated compounds from micro-organisms, synthetic vaccines are composed mainly or wholly of synthetic peptides, carbohydrates or antigens.

4.2. Vaccine Antigen Substance Model

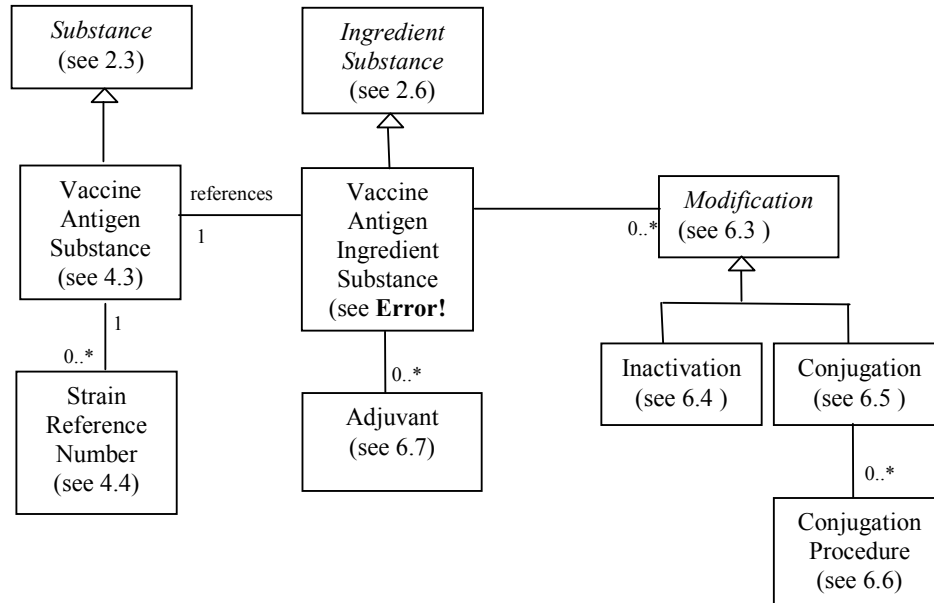


Figure 5. Vaccine Antigen Substance Model

4.3. Vaccine Antigen Substance Definition

Type: class		
Information about and identification of a vaccine antigen substance		
Generalization		
An instance of Vaccine Antigen Substance is a specialization of an instance of Substance.		
Associations		
An instance of Vaccine Antigen Substance may be associated with zero to many instances of Strain Reference Number		
An instance of Vaccine Antigen Substance may be associated with zero to many instances of Vaccine Antigen Ingredient Substance		
Attributes:		
infectiousAgentClass	Type: CV	1
Refers to the origin of organism being used in the particular type of vaccine for human use. There are 3 types of microorganisms as values possible as described in a vaccine controlled vocabulary		
parentOrganism	Type: CV	1
Refers to any microorganism (bacterium, virus or parasite) used for the elaboration of a drug substance in a vaccine		
Example: Influenza virus		

strain	Type: CV	1
Refers to a variant of a virus, bacterium or parasite Example: A/Vietnam/1194/2004		
subspecies	Type: CV	1
The rank immediately subordinated to a species Example: Vibrio cholerae Ogawa, classical biotype		
serovar	Type: CV	1
Refers to a group of microorganisms or viruses classified on the basis on the cell surface antigens Examples: - Vibrio cholerae Ogawa, classical biotype, serogroup 01 - A/H5N1.		
genotype	Type: CV	0 or 1
Refers to the classification based on the internally coded, inheritable information of any (micro) organism		
vaccineStrainReference	Type: CV	0 or 1
Refers to the strain reference used for the production of the vaccine and as numbered at collaborating centers Examples: X-157, CDC357, NIBRG-14).		
yearOfIsolation	Type: Year	0 or 1
The year when the parent organism has been isolated Example: Influenza virus New York strain, year of isolation 2004).		
geographicOrigin	Type: CV	0 or 1
The location of isolation of the parent organism Example: Bacillus of Calmette and Guérin, strain Tokyo 172.		
antigenType	Type: CV	1
Nature of the process used to create the antigen.		
antigenIdentification	Type: CV	1
Refers to a particular antigen used in the vaccines (e.g. Bordetella pertussis, filamentous haemagglutinin).		

4.4. Strain Reference Number

Type: class This class is used to provide details of the reference number(s) by which the strain is registered by competent authorities, e.g. American Type Culture Collection (ATCC)		
Associations An instance of Strain Reference Number is associated with one instance of Vaccine Antigen Substance		
Attributes:		
substanceID	Type: UID	1
Identifier for the antigen substance		
authority	Type: CV	1
Identifier and name of the competent registration authority		
referenceNumber	Type: ST	1
Classification established and maintained by the competent authority Example: American Type Culture Collection - Streptococcus pneumoniae ATCC 49619		

4.5. Vaccine Antigen Ingredient Substance

Type: class This class and its associated classes provide details of the identification and preparation of particular antigens. The details may be specific to a particular manufacturer.		
Generalisation An instance of Vaccine Antigen Ingredient Substance is a specialization of an instance of Ingredient Substance from which it inherits the general properties of identification and naming		
Associations An instance of Vaccine Antigen Ingredient Substance is associated with one instance of Vaccine Antigen Substance An instance of Vaccine Antigen Ingredient Substance may be associated with zero to many instances of Modification An instance of Vaccine Antigen Ingredient Substance may be associated with zero to many instances of Adjuvant		
Attributes:		
None		

5. Biological Substance

5.1. Introduction

Biological substances are very varied. The model presented below is the general model for biological substances and their preparation (designated as Modified Biological Substances).

5.2. Biological Substance Model

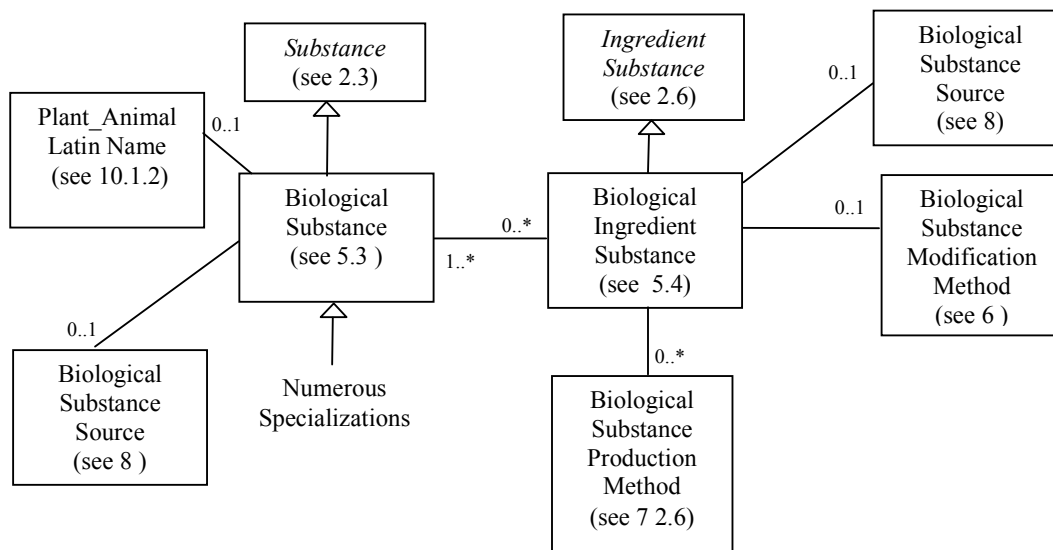


Figure 6. Biological Substance Model

5.3. Biological Substance definition

Type: class

Information about a biological substance

Generalization

An instance of Chemical Substance is always a specialization of an instance of Substance from which it inherits the identification and naming attributes.

Specialization

A Biological Substance shall always be specialized. Specializations include antigens, insulins, herbals, etc.

Association

An instance of Biological Substance may be associated with zero or one instance of Biological Substance Source

<p>Note: The source of the biological substance may be specified at the biological substance level or the biological ingredient substance level (or neither). The source shall NOT be defined in both places.</p> <p>An instance of Biological Substance may be associated with zero or one instance of Plant_Animal Naming Structure</p>		
Attribute:		
biologicalSubstanceDescription	Type: ST	0 or 1
A description of the substance		

5.4. Biological Ingredient Substance definition

<p>Type: class</p> <p>Information about a biological substance ingredient</p> <p>Generalization</p> <p>An instance of Chemical Substance is always a specialization of an instance of Ingredient Substance from which it inherits the identification and naming attributes.</p> <p>Associations</p> <p>An instance of Biological Ingredient Substance is associated with one to many instances of Biological Substance.</p> <p>Note: In virtually all situations an instance of Biological Ingredient Substance is associated with exactly ONE instance of Biological Substance. However, in the herbal medicines domain a number of herbal substances are treated together in order to produce a single biological Ingredient Substance</p> <p>An instance of Biological Ingredient Substance may be associated with zero to many instances of Biological Substance Production Method</p> <p>An instance of Biological Ingredient Substance may be associated with zero or one instance of Modification Method</p> <p>An instance of Biological Ingredient Substance may be associated with zero or one instance of Inactivation Method</p>		
Attribute:		
purificationMethod	Type: CV	0 or 1
<p>A coded description of the purification method</p> <p>Examples: filtration, chromatography</p> <p>Note: This attribute is only used where the biological substance is derived from blood or blood plasma</p>		

6. Biological Substance Modification Method

6.1. Biological Substance Modification Model

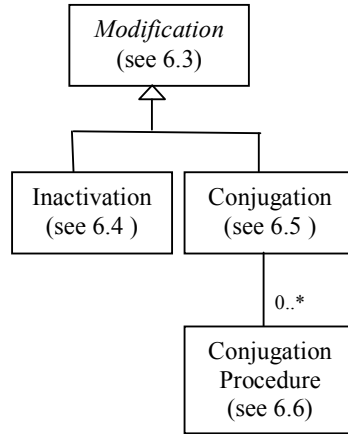


Figure 7. Biological Substance Modification

6.2. Biological Substance Modification definitions

6.3. Modification definition

Type: Abstract class
Specialization The class <i>Modification</i> is always specialized as <i>Inactivation</i> or <i>Conjugation</i>
Association An instance of <i>Modification</i> (specialized as <i>Inactivation</i> or <i>Conjugation</i>) is associated with one instance of <i>Vaccine Antigen Ingredient Substance</i> or one instance of <i>Biological Ingredient Substance</i>
Attributes:
NONE

6.4. Inactivation

Type: class
Holds information about the method used to inactivate the micro-organism when creating the biological ingredient substance

Generalization An instance of Inactivation is a specialization of an instance of Modification		
Attributes:		
inactivationMethod	Type: CV	1
Classification of the method used to deactivate the micro-organism. Examples: physical inactivation, chemical inactivation		
physicalInactivationAgent	Type: CV	0 or 1
If the Inactivation Method refers to 'Physical inactivation' and the Modification 'Inactivated', the values for the inactivation agents are as follows: <ul style="list-style-type: none"> ▪ Heat-inactivation ▪ Gamma irradiation 		
chemicalInactivationAgent	Type: CV	0 or 1
If the Inactivation Method refers to 'Chemical inactivation' and the Modification 'Inactivated', the values for the inactivation agents are as follows: <ul style="list-style-type: none"> ▪ Phenol ▪ Formaldehyde ▪ Glutaraldehyde ▪ Betapropiolactone 		

6.5. Conjugation

Type: class
Holds information about the method used to conjugate the antigen.
Note: A conjugate vaccine is created by covalently attaching a poor antigen to a carrier protein, thereby conferring the immunological attributes of the carrier on the attached antigen. This technique for the creation of an effective immunogen is most often applied to bacterial polysaccharides for the prevention of invasive bacterial disease.
Generalization An instance of Conjugation is a specialization of an instance of Modification
Association An instance of Conjugation may be associated with zero to many instances of Conjugation Procedure

Attributes:		
carrierProtein	Type: CV	1
<p>Name and identifier of Protein (Carrier Protein) used when the Modification is 'Conjugated'.</p> <p>The standard values are as follows:</p> <ul style="list-style-type: none"> ▪ Diphtheria toxoid ▪ Tetanus toxoid ▪ CRM 197 diphtheria protein ▪ Meningococcal group B outer membrane protein (OMP) 		
carrierProteinStrength	Type: RTO<PQ,PQ>	1
<p>Strength of the carrier protein</p>		
conjugationMethod	Type: CV	0 or 1
<p>The Conjugation Method (Coupling) that has been applied to the Antigen. The standard values for the coupling method should be specified when the Modification of the vaccine is 'Conjugated'.</p> <p>Values are taken from the controlled vocabulary</p>		

6.6. Conjugation Procedure

<p>Type: class</p> <p>Procedure that has been applied when the Modification of the vaccine is 'Conjugated', and the Conjugation Method is selected</p> <p>Association An instance of Conjugation Procedure is associated with one instance of Conjugation</p>		
Attributes:		
carrierProtein	Type: CV	1
<p>Name and identifier of Protein (Carrier Protein) used when the Modification is 'Conjugated'.</p> <p>The standard values are as follows:</p> <ul style="list-style-type: none"> ▪ Diphtheria toxoid ▪ Tetanus toxoid ▪ CRM 197 diphtheria protein ▪ Meningococcal group B outer membrane protein (OMP) 		

6.7. Adjuvant

Type: class

An agent that may stimulate the immune system and increase the response to a vaccine, without having any specific antigenic effect in itself. An immunologic adjuvant is defined as any substance that acts to accelerate, prolong, or enhance antigen-specific immune responses when used in combination with specific vaccine antigens.

Associations

An instance of Antigen is associated with one instance of Biological Ingredient Substance

Attributes:

adjuvantSubstance	Type: CV	1
Code and string specifying the adjuvant substance		
strength	Type: RTO<PQ,PQ>	1
The strength of the adjuvant		

7. Biological Substance Production Method

7.1. Introduction

This section describes the general methods utilized in producing the biological ingredient substance. These methods are described under the following headings:

- Recombinant Production
- Hybridoma Production

7.2. Model of Biological Substance Production Method

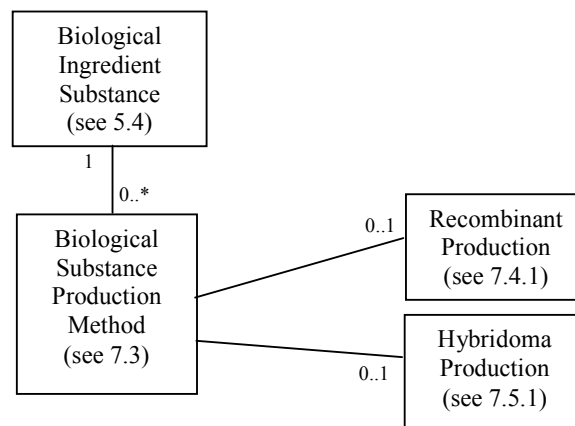


Figure 8. Model of Biological Substance Production Method

7.3. Biological Substance Production Method definition

Type: class

Information about the method of production of a biological ingredient substance

Associations

An instance of Biological Substance Production Method is associated with one instance of Biological Ingredient Substance.

Note: In virtually all situations an instance of Biological Ingredient Substance is associated with exactly ONE instance of Biological Substance. However, in the herbal medicines domain a number of herbal substances are treated together in order to produce a single biological Ingredient Substance.

An instance of Biological Substance Production Method is associated with zero or one instance of Recombinant Preparation

An instance of Biological Substance Production Method is associated with zero or one instance of Hybridoma Preparation

Attribute:
None

7.4. Recombinant Production

7.4.1. Recombinant Production definition

Type: class Information about the source and naming of a recombinant biological ingredient substance
Specialization: An instance of Recombinant Production is specialized according to the type of host
Attribute:
None

7.4.2. Recombinant Production model

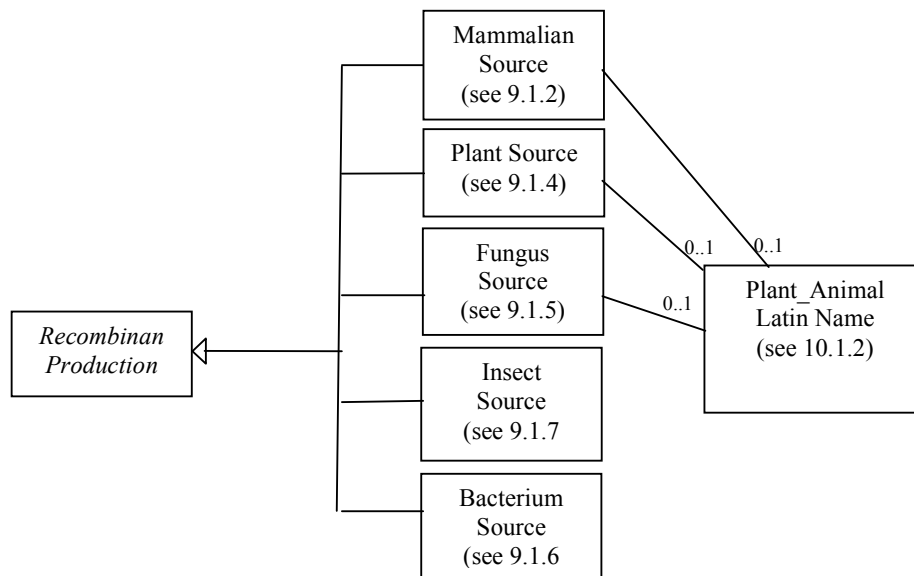


Figure 9. Model for Recombinant Production

7.5. Hybridoma Production

7.5.1. Hybridoma Production definition

Type: class Information about a hybridoma production process		
Generalization An instance of Hybridoma Production is a specialization of Biological Substance Production Method		
Attributes:		
hybridomaType	Type: CV	1
The type of hybridoma Example: mouse B lymphocyte		
monoclonalAntibodyType	Type: CV	0 or 1
The type of monoclonal antibody Example: Murine mAb		

7.5.2. Hybridoma Production model

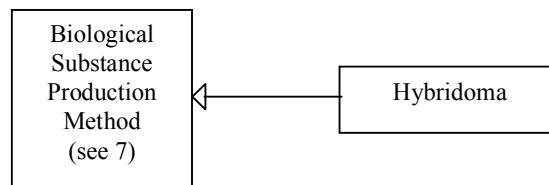


Figure 10. Model for Hybridoma Production

8. Biological Substance Source

8.1. Introduction

This class describes the source of the biological substance or biological ingredient substance. There are a number of variants to this general class,

- Biological Substance Source – universal
- Biological Substance Source – recombinant host
- Biological Substance Source – extractive
- Biological Substance Source – allergen extractive
- Biological Substance Source – immunogen origin

8.1.1. Biological Substance Source Class

Type: abstract class		
Information about a source of a biological substance source		
Specialization		
An instance of Biological Substance Source is always specialized as one of the following: Human Source, Animal Source, Mammalian Source, Plant Source, Fungus Source, Insect Source or Bacterium Source.		
Attributes:		
sourceType	Type: CV	1
The type of substance source, e.g. human source		
NOTE 1: In an HL7 implementation this will be held in the classCode which will be a sub-type of Entity		

8.2. Biological Substance Source model

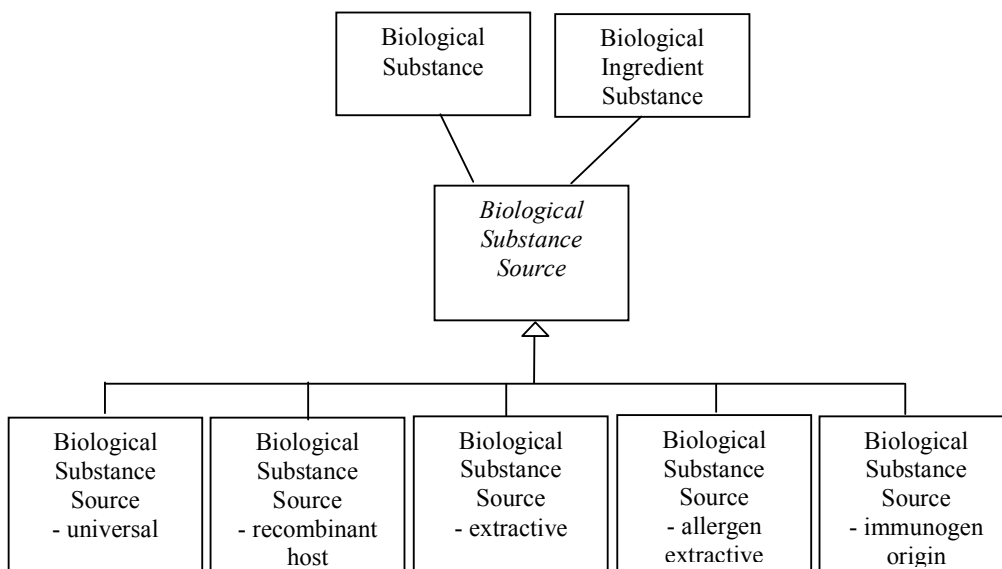


Figure 11. Biological Substance Source model

8.3. Biological Substance Source – Universal

8.3.1. Biological Substance Source – Universal model

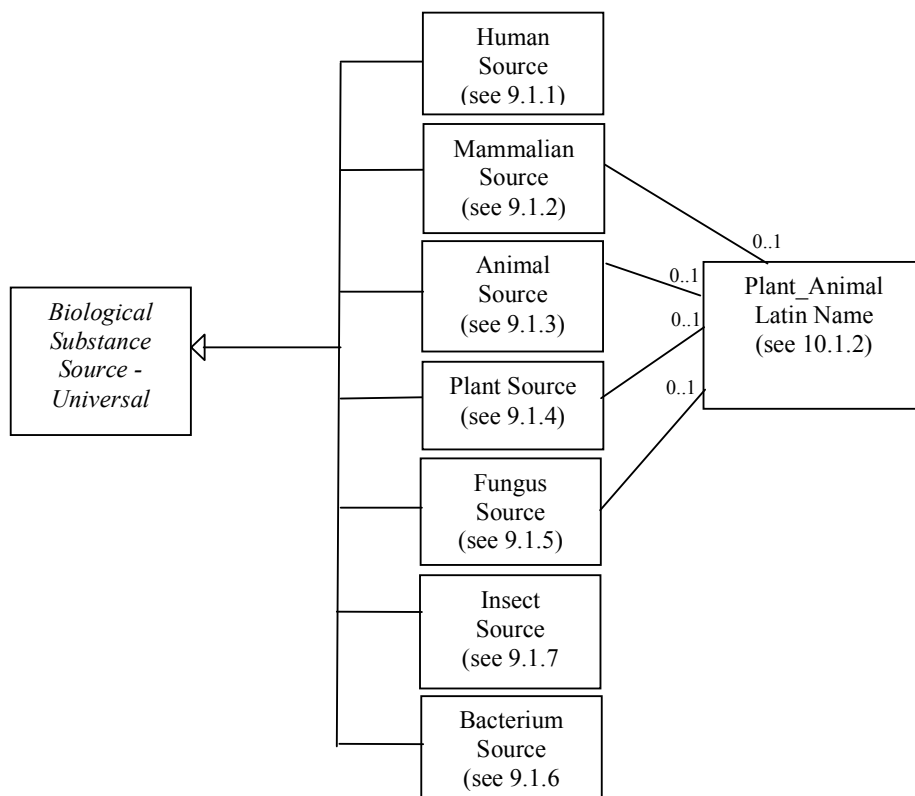


Figure 12. Biological Substance Source - universal

8.3.2. Biological Substance Source – Universal definition

Type: abstract class

Provides a means of describing the various possible types of the source of biological substances. These sources may be human, animal, mammal, plant, fungus, bacterium or insect

Specialisations

An instance of Biological Substance Source - Universal is specialized as an instance of one of the following:

- Human Source
- Mammalian Source
- Animal Source
- Plant Source
- Fungus Source
- Insect Source
- Bacterium Source

Attribute:
None

8.4. Biological Substance Source – Recombinant Host

8.4.1. Biological Substance Source – Recombinant Host model

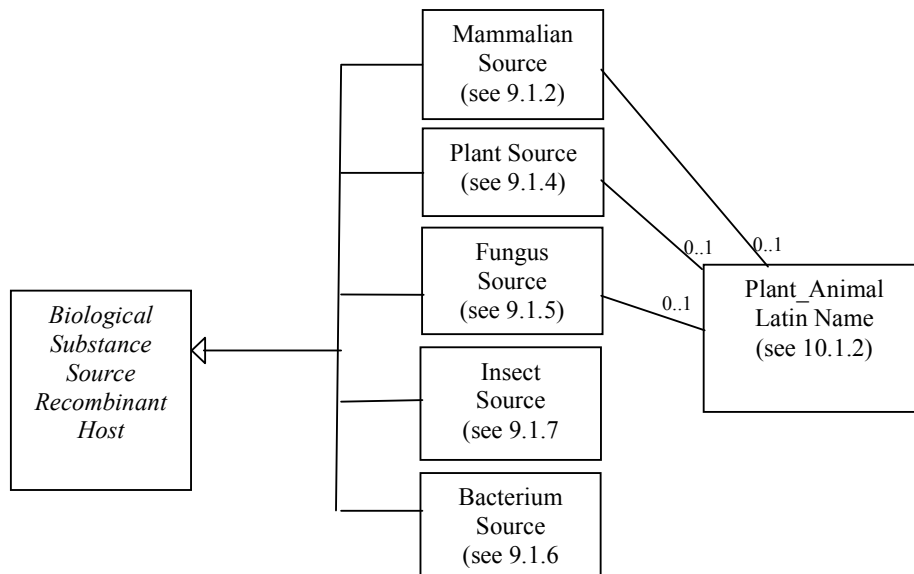


Figure 13. Biological Substance Source - Recombinant Host

8.4.2. Biological Substance Source – Recombinant Host definition

<p>Type: abstract class</p> <p>Provides a means of describing the various possible types of the host source for a preparation of a recombinant substance. insect</p> <p>Specialisations</p> <p>An instance of Biological Substance Source – Recombinant Host is specialized as an instance of one of the following:</p> <ul style="list-style-type: none"> - Mammalian Source - Plant Source - Fungus Source - Insect Source - Bacterium Source
Attribute:
None

8.5. Biological Substance Source – Extractive

8.5.1. Biological Substance Source – Extractive model

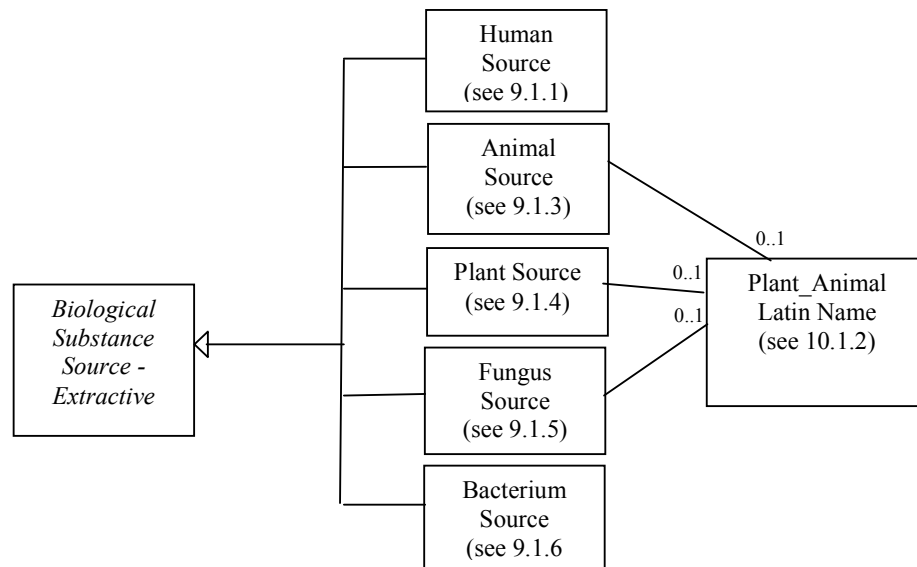


Figure 14. Biological Substance Source - Extractive

8.5.2. Biological Substance Source – Extractive definition

Type: abstract class

Provides a means of describing the various possible types of source from which a biological substance or biological substance ingredient is extracted.

Specialisations

An instance of Biological Substance Source – Extractive is specialized as an instance of one of the following:

- Human Source
- Animal Source
- Plant Source
- Fungus Source
- Bacterium Source

Attribute:

None

8.6. Biological Substance Source – Allergen Extractive

8.6.1. Biological Substance Source – Allergen Extractive model

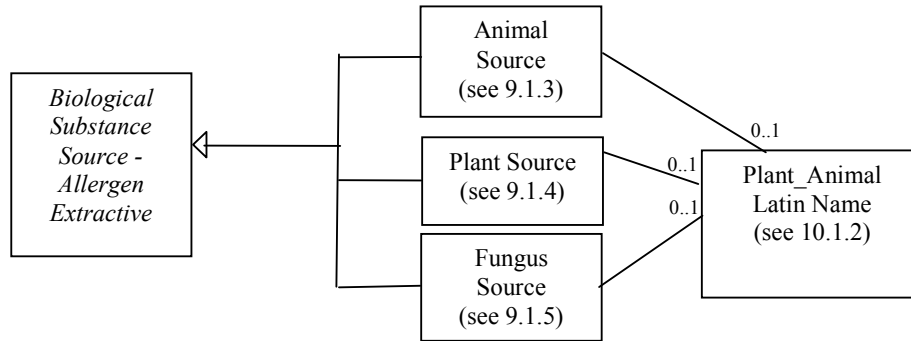


Figure 15. Biological Substance Source - Allergen Extractive

8.6.2. Biological Substance Source – Allergen Extractive definition

<p>Type: abstract class</p> <p>Provides a means of describing the various possible types of source from which an allergen biological substance or biological substance ingredient is extracted.</p> <p>Specialisations</p> <p>An instance of <i>Biological Substance Source – Allergen Extractive</i> is specialized as an instance of one of the following:</p> <ul style="list-style-type: none">- Animal Source- Plant Source- Fungus Source
<p>Attribute:</p>
<p>None</p>

8.7. Biological Substance Source – Immunogen Origin

8.7.1. Biological Substance Source – Immunogen Origin model

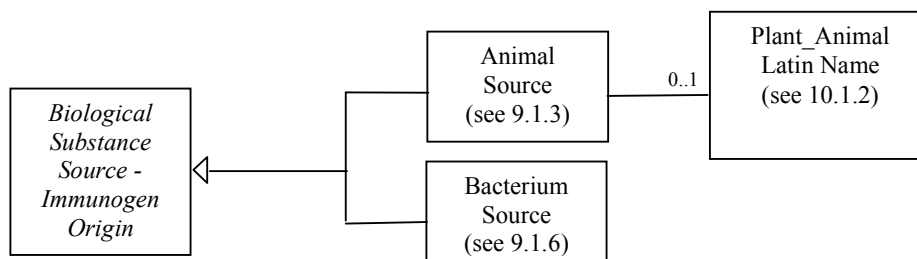


Figure 16. Biological Substance Source – Immunogen Origin

8.7.2. Biological Substance Source – Immunogen Origin definition

<p>Type: abstract class</p> <p>Provides a means of describing the various possible types of source from which a immunogen biological substance or biological substance ingredient is extracted.</p> <p>Specialisations</p> <p>An instance of Biological Substance Source – Immunogen Origin is specialized as an instance of one of the following:</p> <ul style="list-style-type: none"> - Animal Source - Bacterium Source
<p>Attribute:</p>
<p>None</p>

9. Biological Substance Source type definitions

9.1.1. Human Source

<p>Type: class</p> <p>Information about a source of a biological substance in which the starting material is of human origin.</p>			
<p>Attributes:</p>			
<table border="1"> <tr> <td>sourceMaterial</td> <td>Type: CV</td> <td>1</td> </tr> </table> <p>Refers to the material from which the biological drug substance is manufactured.</p> <p>Examples: plasma, blood, urine</p>	sourceMaterial	Type: CV	1
sourceMaterial	Type: CV	1	
<table border="1"> <tr> <td>plasmaExtractionMethod</td> <td>Type: CV</td> <td>0 or 1</td> </tr> </table> <p>Used only where the source material is plasma</p> <p>VALUES:</p> <p>1 = recovered - refers to plasma that is removed from whole blood</p> <p>2 = apheresis - refers to a blood collection process in which some part of the donation is returned to the donor</p>	plasmaExtractionMethod	Type: CV	0 or 1
plasmaExtractionMethod	Type: CV	0 or 1	
<table border="1"> <tr> <td>geographicDonorLocation</td> <td>Type: CV</td> <td>0 or 1</td> </tr> </table> <p>refers to the geographical origin of human donors of the source material.</p> <p>Use 3 ISO 3166 Country Codes</p>	geographicDonorLocation	Type: CV	0 or 1
geographicDonorLocation	Type: CV	0 or 1	

9.1.2. Mammalian Source

<p>Type: class</p> <p>Information about a source of a biological substance in which the starting material is of animal (non-human) origin.</p> <p>Association</p> <p>An instance of Mammalian Source may be associated with zero or one instance of Plant_Animal Latin Name</p>		
Attributes:		
animalLatinName	Type: CV	1
Refers to the formal name of the animal in Latin which has been published following the International Code of Zoological Nomenclature		
sourceMaterial	Type: CV	1
Refers to the material (part of animal) from which the biological drug substance is manufactured.		
Examples: plasma, blood, urine		
geographicDonorLocation	Type: CV	0 or 1
refers to the geographical origin of the mammal Use 3 ISO 3166 Country Codes		
transgenicFlag	Type: BL	1
Flag to indicate whether the mammal is transgenic		

9.1.3. Animal Source

<p>Type: class</p> <p>Information about a source of a biological substance in which the starting material is of animal (non-human) origin.</p> <p>Association</p> <p>An instance of Animal Source may be associated with zero or one instance of Plant_Animal Latin Name</p>		
Attributes:		
animalLatinName	Type: CV	1
Refers to the formal name of the animal in Latin which has been published following the International Code of Zoological Nomenclature		

sourceMaterial	Type: CV	1
Refers to the material (part of animal) from which the biological drug substance is manufactured. Examples: plasma, blood, urine, bee venom		
geographicDonorLocation	Type: CV	0 or 1
refers to the geographical origin of the animal Use 3 ISO 3166 Country Codes		

9.1.4. Plant Source

Type: class		
Information about a source of a biological substance in which the starting material is of plant origin.		
Association		
An instance of Plant Source may be associated with zero or one instance of Plant_Animal Latin Name		
Attributes:		
plantLatinName	Type: ST	1
Refers to the botanical name in Latin according to the binomial system (genus, species, variety and author).		
Plant Phyla/ Class	Type: CV	1
Taxonomic rank at the level below kingdom Example: tree, grass		
sourceMaterial	Type: CV	1
refers to the material (part of the plant) from which the drug substance is manufactured. Example: pollen		
transgenicFlag	Type: BL	1
Flag to indicate whether the plant is transgenic		

9.1.5. Fungus Source

Type: class		
Information about a source of a biological substance in which the starting material is of fungus origin.		
Association		
An instance of Fungus Source may be associated with zero or one instance of Plant_Animal Latin Name		

Attributes:		
fungusLatinName	Type: ST	1
Refers to the botanical name in Latin according to the binomial system (genus, species, variety and author).		

9.1.6. Bacterium Source

Type: class		
Information about a source of a biological substance in which the starting material is of bacterium origin.		
Attributes:		
bacteriumLatinName	Type: ST	1
Refers to latin name according to the binomial system (genus, species).		
strain	Type: CV	1
Refers to a variant of bacterium		
Example: Clostridium botulinum type A, type B or type E		
subspecies	Type: CV	0 or 1
This is to the rank immediately subordinated to a species		
Example: Vibrio cholerae Ogawa, classical biotype		
serovar	Type: CV	0 or 1
Refers to a group of microorganisms or viruses classified on the basis on the cell surface antigens		
genotype	Type: CV	0 or 1
Refers to the classification based on the internally coded, inheritable information of any (micro) organism		

9.1.7. Insect Source

Type: class		
Information about a source of a biological substance in which the starting material is of insect origin.		
Association		
An instance of Insect Source may be associated with zero or one instance of Plant_Animal Latin Name		
Attributes:		
callLine	Type: CV	1
Refers to a single cell type from insect origin and grown in a laboratory.		

10. Plant_Animal Latin Name

10.1. Introduction

Plant and animal substance names are described using the formal name of a plant/animal in Latin which has been published following the International Botanical Nomenclatural Code/International Code of Zoological Nomenclature. The formal name of a plant/animal may consist of 1, 2 or 3 components: Genus, Species and Infraspecies. Each component has two elements: the Latin name (its epithet) and the name of the author that published that name (e.g. *Tanacetum parthenium* Sch. Bip. (L.) var. *alpinum*). The Latin Plant/Animal Name (at Genus, Binomial, Species and Infraspecific level) needs to be presented as described below.

10.1.1. Plant_Animal Latin Name model

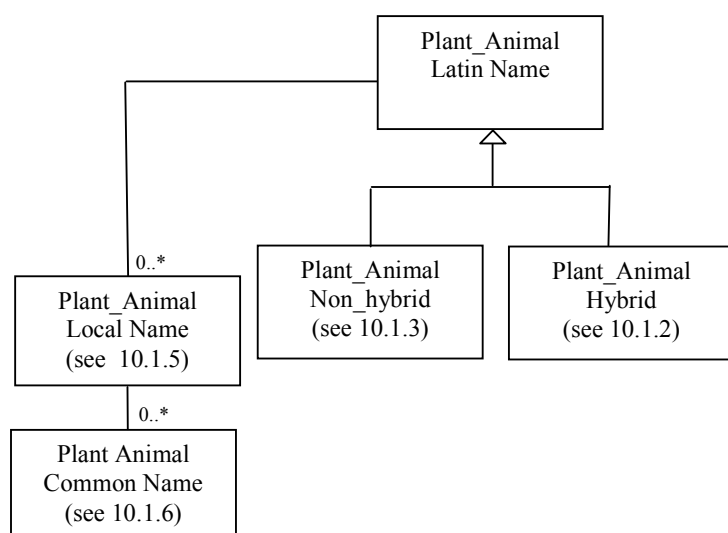


Figure 17. Plant_Animal Latin Names

10.1.2. Plant_Animal Latin Name definition

Type: class

Entry for a formal Latin name of a plant or animal

Specializations

An instance of Plant_Animal Latin Name is specialized as an instance of Plant_Animal Hybrid or an instance of Plant_Animal Non-hybrid

Associations

An instance of Plant_Animal Latin Name may be associated with zero to many instances of Plant_Animal Local Name

Attributes:		
nameID	Type: UID	1
A unique identifier for the Plant_Animal name entry		
genus	Type: ST	1
The genus of the plant/animal, being the Latin epithet of the genus of the plant/animal; it is present in names for genera, species and infraspecies. The Genus is always presented with an upper case letter according to the International Botanical Nomenclatural Code/International Code of Zoological Nomenclature (e.g. Tanacetum)		
genusCode	Type: CV	0 or 1
The genus as represented by a code value		
hierarchyLevel	Type: CV	1
A code used to describe the naming level of the plant or animal		
parent	Type: UID	0 or 1
A link to a parent term		

10.1.3. Plant_Animal Non-hybrid definition

Type: class		
Name elements for a plant or animal which is not a hybrid.		
Generalization		
An instance of Plant_Animal Non-hybrid is a specialization of Plant_Animal Latin Name		
Attributes:		
species	Type: ST	1
The Species of the plant/animal, being the Latin epithet of the species of the plant/animal; it is present in names for species and infraspecies. The Species will always start with a lower case letter according to the International Botanical Nomenclatural Code/International Code of Zoological Nomenclature (e.g. parthenium).		
speciesCode	Type: CV	0 or 1
The species as represented by a code value		
speciesPrimaryAuthor	Type: ST	1
The Species Primary Author, being the first author, who published the plant/animal name (of any rank) or subsequently reclassified the taxon placing it in a different Genus (e.g. Sch.Bip.).		
speciesParentheticalAuthor	Type: ST	0 or 1
The Species Parenthetical Author, being the first author, who published the plant/animal name (of any rank). Parenthetical authors are only required for names of taxa which have been subsequently reclassified in different Genera (e.g.: (L.)).		
infraspecificRank	Type: ST	0 or 1
The Genus of the plant, being the rank, at which the Latin plant/animal name was published: i.e. the subspecies, variety or forma. It is only indicated for infraspecific names (e.g. Subsp.,Var.).		

infraspecific	Type: ST	0 or 1
The Infraspecific, being the Latin epithet of the infraspecific category of the plant/animal; it is only applicable for infraspecific Latin names and starts with a lower case letter according to the International Botanical Nomenclatural Code/International Code of Zoological Nomenclature (e.g. alpinum).		
infraspecificPrimaryAuthor	Type: ST	0 or 1
The Infraspecific Primary Author, being the first author, who published the infraspecific plant/animal name (of any infraspecific rank) or subsequently reclassified the taxon placing it in a different infrasepcific rank (e.g. Baker).		
infraspecificParentheticalAuthor	Type: ST	0 or 1
The Infraspecific Parenthetical Author, being the first author, who published the infraspecific plant/animal name (of any rank). Parenthetical authors are only required for names of taxa which have been subsequently reclassified (e.g.: (L.)).		

10.1.4. Plant_Animal Hybrid definition

Type: class		
Name elements for a plant or animal which is a hybrid.		
Generalization		
An instance of Plant_Animal Hybrid is a specialization of Plant_Animal Latin Name		
Attributes:		
hybridType	Type: CV	1
A code representing the type of hybrid		
Values:		
<ul style="list-style-type: none"> - natural hybrid - man made hybrid - cultivar - un-named hybrid 		
naturalHybridName	Type: ST	0 or 1
String representation of the name of the natural hybrid		
manMadeHybridName	Type: ST	0 or 1
String representation of the name of the man-made hybrid		
cultivarName	Type: ST	0 or 1
String representation of the cultivar		
unNamedHybridName	Type: ST	0 or 1
String representation of the name of the un-named hybrid		

10.1.5. Plant_Animal Local Name

Type: class Name for a plant or animal which is used in a particular region or domain Association An instance of Plant_Animal Local Name is associated with one instance of Plant_Animal Latin Name An instance of Plant_Animal Local Name may be associated with zero to many instances of Plant_Animal Common Name		
Attributes:		
localBinominalName	Type: ST	1
The local name		
referenceCountry	Type: CV	1
Code representing the country where the local code is used		
acceptedName	Type: Boolean	1
Flag indicating the level of acceptance of the name		
citedName	Type: Boolean	1
Flag indicating whether the name has been sited		
referenceSource	Type: CV	0 or 1
Code representing the reference source of the name (if available)		

10.1.6. Plant_Animal Common Name

Type: class Name for a plant or animal which is in common use Association An instance of Plant_Animal Common Name is associated with one instance of Plant_Animal Local Name		
Attributes:		
commonName	Type: CV	1
Code representing the common name		
language	Type: CV	1
Code representing the language used in the display name for the common name		

SECTION B: Pharmaceutical Product and Administered Pharmaceutical Product

11. Pharmaceutical Product

11.1. Introduction

At the core of the categorization and nomenclature of medicinal products lies the concept of the pharmaceutical product. In this standard this concept is divided into two parts, each of which is considered separately, these are:

- Pharmaceutical Product. This is an abstract representation of the pharmaceutical product which has properties that are limited to:
 - o an identifier
 - o a name
 - o clinically significant ingredients (usually the 'active' ingredients), together with their strengths and/or quantities
 - o the dose form
 - o seasonal recommendation

- Administered Pharmaceutical Product. This is a concrete manifestation of the Pharmaceutical Product and includes details of excipients, routes of administration, and any associated administration device such as a (pre-filled) syringe. An Administered Pharmaceutical Product is generally associated with a particular manufacturer or supplier.

11.2. Model of Pharmaceutical Product

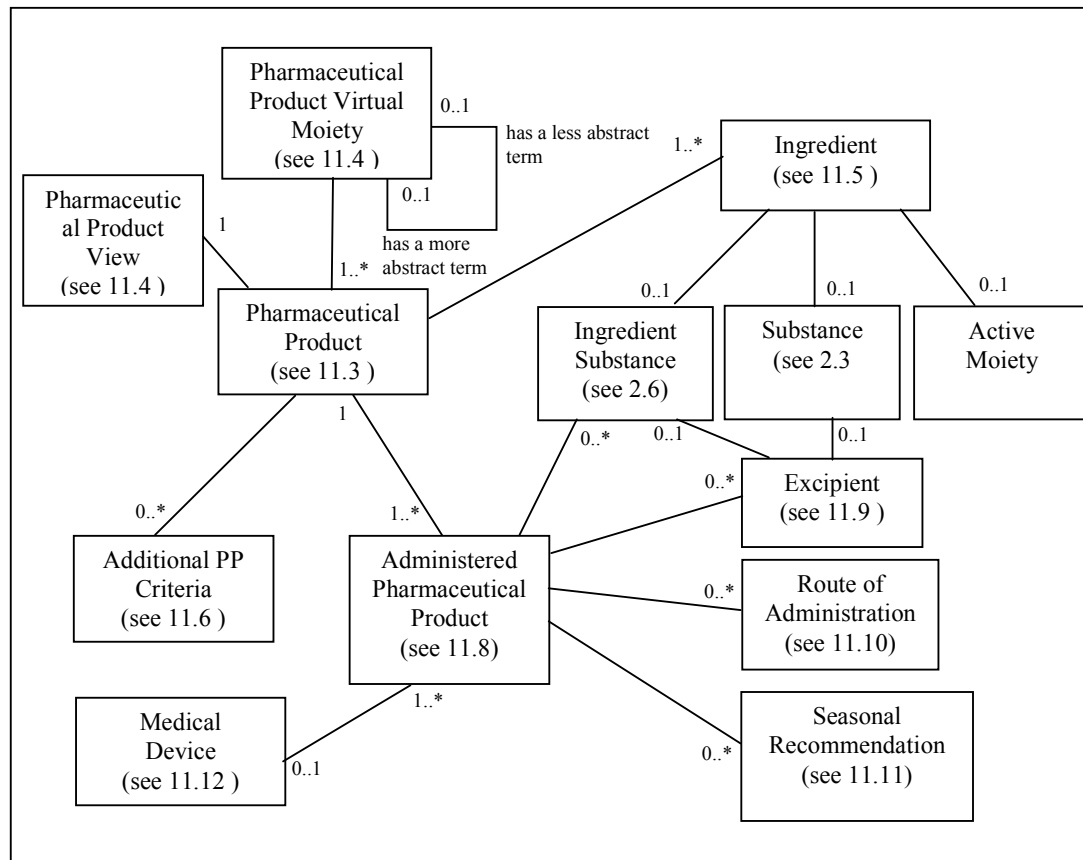


Figure 18. Pharmaceutical Product Data Model

11.3. Pharmaceutical Product

Type: class

Information about an abstract representation of a pharmaceutical product particularly in terms of clinically significant components, their amounts and strength and dose form.

Associations

An instance of Pharmaceutical Product is associated with one to many instances of Ingredient

An instance of Pharmaceutical Product is associated with one to many instances of Administered Pharmaceutical Product

An instance of Pharmaceutical Product may be associated with zero to many instances of Additional PhPID Criteria

An instance of Pharmaceutical Product is associated with one instance of Pharmaceutical Product View

Attributes:		
PhPID	Type: UID	1
A unique identifier for the abstract concept of the pharmaceutical product		
pharmaceuticalProductName	Type: ST	1
A name by which the abstract concept of the pharmaceutical product is designated ISSUE: Is one name sufficient or do we need multiple names in different languages/character sets? If multiple names required then this attribute needs to be removed and a class created.		
NameBasisCode	Type: CV	1
Basis or source of Pharmaceutical Product name expressed as a code value Example values: 1 Recommended International Non-proprietary Name – rINN 2 International Non-proprietary Name (Modified) – INN _M 3 United States Adopted Name – USAN 4 Other .		
doseForm	Type: CV	1
A code representing the dose form of the pharmaceutical product An agreed code set is required.		
unitDoseValue	Type: REAL	0 or 1
Amount of substance that is considered as a unit dose of the Pharmaceutical Product. This attribute carries the numeric part only (e.g. 2.5) : the subsequent attribute carries the type of unit of measure (e.g. mL).		
UOM_ID	Type: CV	0 or 1
Amount of substance that is considered as a unit dose of the Pharmaceutical Product. This attribute carries the type of <i>unit of measure</i> (e.g. mL): the preceding attribute carries numeric part (e.g. 2.5). NOTE: See Unit of Measure structure in Annex A)		
virtualMoiety	Type: UID	0 or 1
The identification of a pharmaceutical product virtual moiety which is related to this pharmaceutical product.		

11.4. Pharmaceutical Product Virtual Moiety

Type: class		
An abstract representation of a set of pharmaceutical products. This representation may be divorced from dose form or strength or both.		
Associations		
An instance of Pharmaceutical Product Virtual Moiety may be associated with one other instance of Pharmaceutical Product Virtual Moiety which provides a more abstract representation		
Co-Amoxiclav Suspension 125mg/31mg/5ml Sugar Free..... Co-Amoxiclav Suspension 125mg/31mg/5ml..... Co-Amoxiclav Suspension..... Co-Amoxiclav Paracetamol Oral Suspension Paediatric 120mg/5ml Sugar Free		
Attributes:		
PPVM_ID	Type: UID	1
A unique identifier for the abstract concept of the pharmaceutical product virtual moiety		
PPVM_parent	Type: UID	0..1
The identification of a more abstract virtual moiety		

11.5. Ingredient

Type: class		
Information about a clinically significant of an ingredient substance that is contained within the entity identified as a PhPID and the quantity, strength or unit dose that is involved.		
Associations		
An instance of Ingredient is associated with one instance of Pharmaceutical Product		
An instance of Ingredient is associated with zero or one instance of Substance		
An instance of Ingredient is associated with zero or one instance of Ingredient Substance		
An instance of Ingredient is associated with zero or one instance of Active Moiety		
Attributes:		
PhPID	Type: UID	1
The unique identifier for the abstract concept of the pharmaceutical product that contains the ingredient		
substance	Type: UID	0 or 1
The unique identifier for a substance that is contained in the Pharmaceutical Product and which acts as a clinically significant component (usually an active ingredient)		

SubstanceStrength	Type: RTO<PQ, PQ>	0 or 1												
<p>The strength or amount of the Substance which is used in creating the unit dose of the Pharmaceutical Product</p> <p>Note 1: The RTO<PQ, PQ> data type is described in ISO21090.</p>														
ingredientSubstance	Type: UID	0 or 1												
<p>The unique identifier for a substance that has been modified in a manner which leads it to be the basis of clinically significant pharmaceutical product than one which is based upon the generic substance type.</p>														
ingredientSubstanceStrength	Type: RTO<PQ, PQ>	0 or 1												
<p>The strength or amount of the Ingredient Substance which is used in creating the unit dose of the Pharmaceutical Product</p> <p>Note 1: The RTO<PQ, PQ> data type is described in ISO21090.</p>														
activeMoiety	Type: UID	0 or 1												
<p>It is sometimes essential to express the strengths or amounts of the ingredient in terms of an 'Active Moiety' rather than the actual substance or modified substance that is contained in the Pharmaceutical Product.</p> <p>Note: The Active Moiety is often an entry in the Substance file – but may not be the actual ingredient.</p> <p>Example: Pharmaceutical Product = Co-Amoxiclav 250/125 tablet</p> <p>This Pharmaceutical Product contains the substances Amoxicillin Trihydrate and Potassium clavulanate but their dose strengths are based upon the active moieties amoxicillin and clavulanic acid</p> <table border="1"> <thead> <tr> <th>Substance</th> <th>Strength</th> <th>Active Moiety</th> <th>Strength</th> </tr> </thead> <tbody> <tr> <td>Amoxicillin trihydrate</td> <td>287 mg</td> <td>Amoxicillin</td> <td>250 mg</td> </tr> <tr> <td>Potassium clavulanate</td> <td>149.6 mg</td> <td>clavulanic acid</td> <td>125 mg</td> </tr> </tbody> </table>			Substance	Strength	Active Moiety	Strength	Amoxicillin trihydrate	287 mg	Amoxicillin	250 mg	Potassium clavulanate	149.6 mg	clavulanic acid	125 mg
Substance	Strength	Active Moiety	Strength											
Amoxicillin trihydrate	287 mg	Amoxicillin	250 mg											
Potassium clavulanate	149.6 mg	clavulanic acid	125 mg											
moietyStrength	Type: RTO<PQ, PQ>	0 or 1												
<p>The strength or amount of the substance which is used in defining the strength of a component of a Pharmaceutical Product</p>														

11.6. Additional PhPID Criteria

<p>Type: class</p> <p>A criteria, expressed as a coded value which is pertinent to the clinical nature of the Pharmaceutical Product and its associated Pharmaceutical Products</p> <p>Examples:</p> <ul style="list-style-type: none"> - sugar-free - preservative-free

Association An instance of Additional PhPID Criteria is associated with one instance of Pharmaceutical Product		
Attributes:		
PhPID	Type: UID	1
The unique identifier for the abstract concept of the pharmaceutical product that contains the ingredient		
criteria	Type: CV	1
A code value which represents the criteria		

11.7. Pharmaceutical Product View

11.7.1. Introduction

This sub-section defines a set of views which provide different search and categorization options for the pharmaceutical product.

11.7.2. Pharmaceutical Product Moiety stratum

Type: class An abstract representation of a set of pharmaceutical products. This representation may be divorced from dose form or strength or both.		
Associations An instance of Pharmaceutical Product Moiety may be associated with one other instance of Pharmaceutical Product Moiety which provides a more abstract representation		
Attributes:		
PHPID_M	Type: UID	1
A unique identifier for the abstract concept of the pharmaceutical product moiety		
PHPID_M_L1	Type: ST	1
Concatenation of all the Moieties in the Pharmaceutical Product		
PHPID_M_L2	Type: ST	1
Concatenation of all the Moieties and strenght in the Pharmaceutical Product		
PHPID_M_L3	Type: ST	1
Concatenation of all the Moieties and Pharmaceutical Dose Forms in the Pharmaceutical Product		
PHPID_M_L4	Type: ST	1
Concatenation of all the Moieties, Pharmaceutical Dose Forms and strenght in the Pharmaceutical Product		

PHPID_M_L5	Type: ST	1
Concatenation of all the Moieties, Pharmaceutical Dose Forms, strength and Seasonal Recommendation in the Pharmaceutical Product is Administered Pharmaceutical Product Type = Vaccines		
PHPID_M_L6	Type: ST	1
Concatenation of all the Moieties, Pharmaceutical Dose Forms, strength and Medical Device in the Pharmaceutical Product is Administered Pharmaceutical Product Type = Advanced Therapies		

11.7.3. Pharmaceutical Product Substance Stratum

Type: class		
An abstract representation of the pharmaceutical product at substance level.		
Associations		
An instance of Pharmaceutical Product Substance may be associated with one other instance of Pharmaceutical Product Substance which provides a more abstract representation		
Attributes:		
PHPID_Sub	Type: UID	1
A unique identifier for the abstract concept of the pharmaceutical product moiety		
PHPID_Sub_L1	Type: ST	1
Concatenation of all the Substances in the Pharmaceutical Product		
PHPID_Sub_L2	Type: ST	1
Concatenation of all the Substances and strength in the Pharmaceutical Product		
PHPID_Sub_L3	Type: ST	1
Concatenation of all the Substances and Pharmaceutical Dose Forms in the Pharmaceutical Product		
PHPID_Sub_L4	Type: ST	1
Concatenation of all the Substances, Pharmaceutical Dose Forms and strength in the Pharmaceutical Product		
PHPID_Sub_L5	Type: ST	1
Concatenation of all the Substances, Pharmaceutical Dose Forms, strength and Seasonal Recommendation in the Pharmaceutical Product is Administered Pharmaceutical Product Type = Vaccines		
PHPID_Sub_L6	Type: ST	1
Concatenation of all the Substances, Pharmaceutical Dose Forms, strength and Medical Device in the Pharmaceutical Product is Administered Pharmaceutical Product Type = Advanced Therapies		

11.7.4. Pharmaceutical Product Ingredient Stratum

Type: class		
An abstract representation of the pharmaceutical product at ingredient level.		
Associations		
An instance of Pharmaceutical Product Ingredient may be associated with one other instance of Pharmaceutical Product Ingredient which provides a more abstract representation		
Attributes:		
PHPID_Ing	Type: UID	1
A unique identifier for the abstract concept of the pharmaceutical product Ingredient		
PHPID_Ing_L1	Type: ST	1
Concatenation of all the Ingredients in the Pharmaceutical Product		
PHPID_Ing_L2	Type: ST	1
Concatenation of all the Ingredients and strenght in the Pharmaceutical Product		
PHPID_Ing_L3	Type: ST	1
Concatenation of all the Ingredients and Pharmaceutical Dose Forms in the Pharmaceutical Product		
PHPID_Ing_L4	Type: ST	1
Concatenation of all the Ingredients, Pharmaceutical Dose Forms and strenght in the Pharmaceutical Product		
PHPID_Ing_L5	Type: ST	1
Concatenation of all the Ingredients, Pharmaceutical Dose Forms, strenght and Seasonal Recommendation in the Pharmaceutical Product is Administered Pharamceutical Product Type = Vaccines		
PHPID_Ing_L6	Type: ST	1
Concatenation of all the Ingredients, Pharmaceutical Dose Forms, strenght and Medical Device in the Pharmaceutical Product is Administered Pharamceutical Product Type = Advanced Therapies		

11.8. Administered Pharmaceutical Product

Type: class		
Information about a pharmaceutical product that has been created for supply as a medicinal product or as a part of a medicinal product.		
<p>Note 1: Generally an instance of administered pharmaceutical product will be associated with a particular manufacturer or supplier which will introduce a unique set of excipients. However, this will not always be true. For example, water for injection may be a general entry without reference to a particular supplier.</p> <p>Note 2: Each Pharmaceutical Product shall be associated with at least one instance of Administered Pharmaceutical Product, even where there are no additional associated information, i.e. no excipients, routes of administration, etc.</p>		
Associations		
An instance of Administered Pharmaceutical Product is associated with one instance of Pharmaceutical Product		
An instance of Administered Pharmaceutical Product is associated with zero or one instance of Medical Device.		
An instance of Administered Pharmaceutical Product is associated with zero to many instances of Excipient		
An instance of Administered Pharmaceutical Product is associated with zero to many instances of Route of Administration		
An instance of Administered Pharmaceutical Product is associated with zero or one instance of Drug Preparation Instructions		
An instance of Administered Pharmaceutical Product is associated with zero to many instances of Seasonal Recommendation		
Attributes:		
administeredPharmaceuticalProductID	Type: UID	1
A unique identifier for the administered pharmaceutical product		
PhPID	Type: UID	1
An identifier for the Pharmaceutical Product instance of which this is a manifestation		
manufacturerID	Type: UID	0 or 1
An identifier for the manufacturer/supplier that has made this pharmaceutical product available.		

11.9. Excipient

Type: class		
Details of a Substance or Modified Substance which acts as an excipient in a pharmaceutical product		
Associations		
An instance of Excipient is associated with one instance of Pharmaceutical Product		
An instance of Excipient is associated with zero or one instance of Substance		
An instance of Excipient is associated with zero or one instance of Modified Substance		
Attributes:		
pharmaceuticalProductID	Type: UID	1
An identifier for the pharmaceutical product that contains the excipient		
substance	Type: UID	0 or 1
An identifier for the substance that is acting as an excipient		
Note: Either an instance of Substance or Ingredient Substance shall be identified as the excipient		
ingredientSubstance	Type: UID	0 or 1
An identifier for the ingredient substance that is acting as an excipient		
Note: Either an instance of Substance or Ingredient Substance shall be identified as the excipient		
strength	Type: RTO<PQ, PQ>	0 or 1
The strength or amount of the Ingredient Substance which is used in creating the unit dose of the Pharmaceutical Product		
Note 1: The RTO<PQ, PQ> data type is described in ISO21090.		

11.10.Route of Administration

Type: class		
Details of a route of administration associated with the administered pharmaceutical product		
Associations		
An instance of Route of Administration is associated with one instance of Administered Pharmaceutical Product		
Attributes:		
administeredPharmaceuticalProductID	Type: UID	1
An identifier for the Administered Pharmaceutical Product associated with the route of administration		
route	Type: CV	1
A code representing the route of administration		

11.11. Seasonal Recommendation

Type: class Details of a seasonal recommendation associated with the Administered Pharmaceutical Product		
Associations An instance of Seasonal Recommendation is associated with one instance of Administered Pharmaceutical Product		
Attributes:		
pharmaceuticalProductID	Type: UID	1
An identifier for the administered pharmaceutical product associated with the seasonal recommendation		
recommendation	Type: CV	1
A code representing the seasonal recommendation		

11.12. Medical Device

Type: class Details of a device which is associated with the administered pharmaceutical product		
Note: These are devices that are crucially associated with the administration of the medicine, e.g. 0.5 mL glass syringe where the pharmaceutical product is a pre-filled syringe.		
Associations An instance of Seasonal Recommendation is associated with one instance of Administered Pharmaceutical Product		
Attributes:		
administeredPharmaceuticalProductID	Type: UID	1
An identifier for the administered pharmaceutical product associated with the medical device		
deviceType	Type: CV	1
A code representing the device type		

SECTION C: Medicinal Product

12. Medicinal Product

12.1. Introduction

In the context of the regulation and pharmacovigilance of medicinal products, and particularly for the purpose of uniquely identifying and characterising them, it is necessary to describe the medicinal products based on their key elements as regards the regulatory and administrative information and information related to the pharmaceutical product(s) such as the qualitative and quantitative composition, the pharmaceutical form, aspects related to the dosage and method of administration, the pharmaceutical particulars and packaging information including the nature and content of the container.

Regulatory and administrative information refers to:

- The name of the medicinal product as authorised in a region or a country
- The type of authorization procedure as applicable in a region or a country
- A special characterisation of the medicinal product in a region or a country e.g. orphan drug designation, paediatric use, biosimilar
- Information as regards the marketing authorization holder
- Information as regards the manufacturer
- The marketing authorization number(s)
- The date of first authorization of the medicinal product in a region or a country
- The date of variation of the authorization of the medicinal product in a region or country
- The date of renewal of a marketing authorization in a region or a country, where applicable
- The date of withdrawal of a marketing authorization in a region or a country, where applicable
- The date of marketing of a medicinal product in a region or a country
- The stop date of marketing a medicinal product in a region or a country
- The packaging information

12.2. Overview and description of the model design

A medicinal product may have two different statuses; it may be a product under trial by under the regime of different regulatory authorities or one which is authorised for marketing.

A medicinal product of either status shall contain one or more pharmaceutical products and possibly one or more devices.

A medicinal product shall be associated with one or more names. The naming will allow for structured naming based upon the elements (e.g. quantity) which are used in the construction of the name. The naming will allow for multiple languages and character sets.

An authorized medicinal product will be associated with one or more manufacturing Authorizations and through this to a manufacturing authorization holder.

An authorised medicinal product will be associated with one or more marketing Authorizations. Each authorization will be associated with one or more names that are authorized by the marketing authorization.

12.3. Model of Medicinal Product

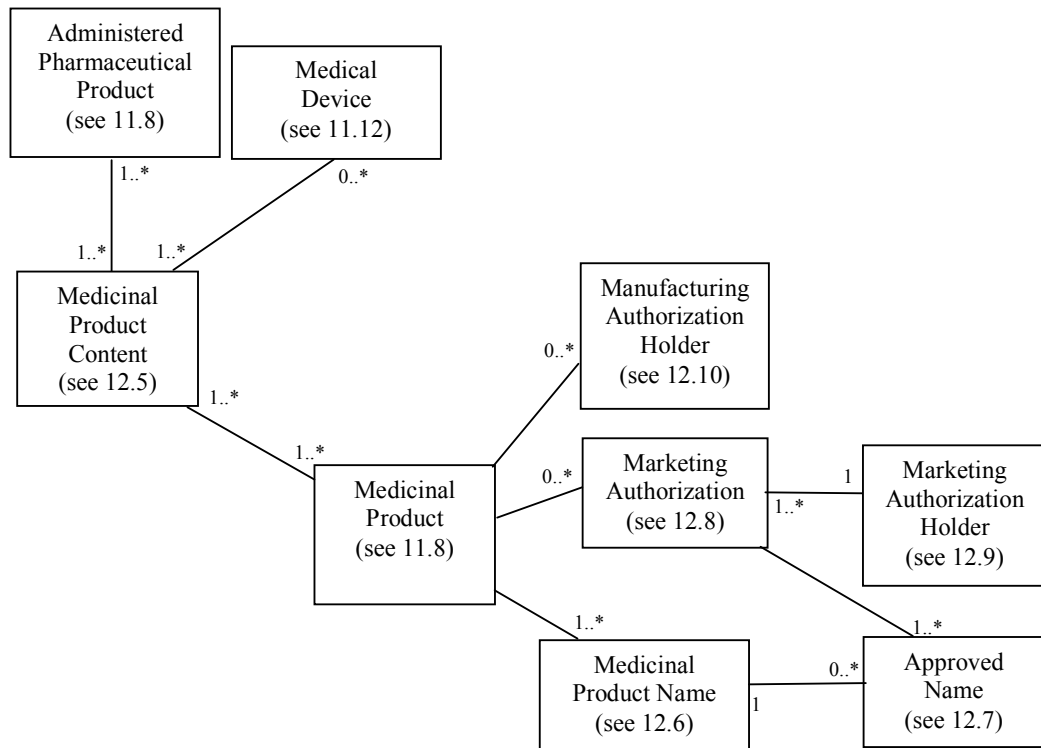


Figure 19. Medicinal Product Data Model

12.4. Medicinal Product

<p>Type: class</p> <p>Information about an authorized medicinal product that has been, or is being made available for use or which is undergoing trials</p> <p>Associations An instance of Medicinal Product is associated with one to many instances of Medicinal Product Content An instance of Medicinal Product is associated with one to many instances of Medicinal Product Name</p> <p>If the medicinal product has received authorization by one or more regulatory authorities the following associations are required, otherwise there are no such associations.</p> <p>An instance of an authorized Medicinal Product is associated with one to many instances of Marketing Authorization An instance of an authorized Medicinal Product is associated with one to many instances of Manufacturing Authorization Holder</p>		
Attributes:		
MPID	Type: UID	1
A unique identifier for the medicinal product		

12.5. Medicinal Product Content

<p>Type: class</p> <p>Details of a pharmaceutical product or actual device which is contained in an authorized medicinal product or trial medicinal product.</p> <p>Associations An instance of Medicinal Product Content is associated with one instance of Medicinal Product An instance of Medicinal Product Content is associated with zero or one instance of Administered Pharmaceutical Product An instance of Medicinal Product Content is associated with zero or one instance of Medical Device</p>		
Attributes:		
MedicinalProductID	Type: UID	1
A unique identifier for a medicinal product		
administeredPharmaceuticalProductID	Type: UID	0 or 1
An identifier for the administered pharmaceutical product that is contained in the medicinal product		
<p>Note: The instance shall include this attribute or the attribute for the medicalDeviceID</p>		

medicalDeviceID	Type: UID	0 or 1
An identifier for the medical device that is contained in the medicinal product		
Note: The instance shall include this attribute or the attribute for the pharmaceuticalProductID		
Quantity	Type: PQ	1
The number or quantity of the administered pharmaceutical product or device.		
Examples:		
<ul style="list-style-type: none"> - 28 tablets - 10 pre-filled syringes - 1 applicator 		

12.6. Medicinal Product Name

Type: class		
A long name and a short name associated with a medicinal product. In addition this class will utilize the ISO12090 Entity Name data type to facilitate the presentation of a structured representation of the name and the name elements.		
NOTE: This structure may be used to cover the requirements for both the medicinal product naming and the regional product naming.		
Associations		
An instance of Medicinal Product Name is associated with one instance of Medicinal Product		
Attributes:		
medicinalProductNameID	Type: UID	1
A unique identifier for the medicinal product name		
Note: The UID data type allows the designation by a regulatory authority which authorised the use of the name.		
MPID	Type: UID	1
A unique identifier for the medicinal product		

medicinalProductName	Type: ST	1
Full name of the medicinal product		
<p>NOTE: The naming of a medicinal product differs in regions and countries. There is no unique convention applied as regards the assignment of a medicinal product name. In general the medicinal product name can be either an invented name, a common or scientific name accompanied by a trade mark or the name of the marketing authorizationholder. Other descriptors e.g. strength, dosage form, target population and route of administration may be also part of the medicinal product name.</p> <p>It is important that the full and complete medicinal product name as approved by the regulator of the country or territory of authorization and as appearing on the package/labelling of the medicinal product, the container or the package insert needs to be described. It needs to be taken into account that in certain countries the medicinal product name may be reflected in more than one language taking into account the official languages of the country.</p>		
medicinalProductShortName	Type: ST	1
Shortened name of the medicinal product		
<p>NOTE: The medicinal product short name refers to the product name without the trademark or the name of the marketing authorization holder or any other descriptor reflected in the product name. This is needed, as in the spontaneous reporting environment health care professionals often only refer to the invented name or generic name of the medicinal product (e.g. PRODUCTX® 500mg solution for injection is often reported only as PRODUCTX which corresponds to the 'short name').</p>		
medicinalProductStructuredName	Type: EN	0..1
The name of the medicinal product utilizing the name elements used to construct the long name.		
language	Type: CV	1
Language used in medicinal product names using language code taken from ISO 639-3:2007 <i>Codes for the representation of names of languages -- Part 3: Alpha-3 code</i>		

12.7. Approved Name

Type: class		
A long and short name approved by a regulatory body that is associated with an authorised medicinal product.		
Associations		
An instance of Approved Name is associated with one instance of Marketing Authorization		
An instance of Approved Name is associated with one instance of Medicinal Product Name		
Attributes:		
marketingAuthorizationID	Type: UID	1
A unique identifier for the marketing authorizationfor the medicinal product		
medicinalProductNameID	Type: UID	1
A unique identifier for the medicinal product name		

12.8. Marketing Authorization

Type: class		
Details of a marketing authorization by a regulatory authority for a medicinal product		
Associations		
An instance of Marketing Authorization is associated with one instance of Medicinal Product		
An instance of Marketing Authorization is associated with one instance of Marketing AuthorizationHolder		
An instance of Marketing Authorization is associated with one or more instances of Authorized Name		
Attributes:		
medicinalProduct	Type: UID	1
A unique identifier for a medicinal product		
marketingAuthorizationHolder	Type: UID	1
A unique identifier for the marketing authorization holder		
marketingAuthorizationNumber	Type: UID	1
A unique identifier for the marketing authorization issued by the regulatory body		
marketingAuthorizationType	Type: CV	1
Code representing the type of authorization issued.		
Note: Requirement for list(s) of types		
marketingAuthorizationCountry	Type: CV	1
Code representing the country for which the authorization is issued		
The code should be represented using ISO 3166-1 alpha-2 which are two-letter codes representing countries and dependent territories.		
FirstMarketingAuthorizationDate	Type: TS	1
Date upon which the authorization first issued by this regulatory authority for this medicinal product		
marketingAuthorizationRenewalDate	Type: TS	0 or 1
Date upon which the authorization was renewed or (if in future), when renewal is due.		
marketingAuthorizationVariationDate	Type: TS	0 or 1
Date when there was the last variation to the authorization		
marketingAuthorizationWithdrawlDate	Type: TS	0 or 1
Date when authorization was withdrawn		
marketingStartDate	Type: TS	0 or 1
Date when marketing started under this authorization		

marketingEndDate	Type: TS	0 or 1
Date when marketing under this authorization ended		
language	Type: CV	1
Language associated with the authorization		
The language code shall be taken from ISO 639-3:2007 <i>Codes for the representation of names of languages -- Part 3: Alpha-3 code</i>		

12.9. Marketing AuthorizationHolder

Type: class		
Details of a marketing authorization holder for one or more medicinal products		
Associations		
An instance of Marketing Authorization Holder is associated with one or more instances of Marketing Authorization		
Attributes:		
marketingAuthorizationHolderID	Type: UID	1
A unique identifier for a marketing authorization holder		
marketingAuthorizationHolderName	Type: ST	1
Name of the marketing authorization holder		
marketingAuthorizationHolderCountry	Type: CV	1
Country of the marketing authorization holder		

12.10. Manufacturing Authorization Holder

Type: class		
Details of a marketing authorization by a regulatory authority for a medicinal product		
Associations		
An instance of Marketing Authorization is associated with one instance of Medicinal Product		
An instance of Marketing Authorization is associated with one instance of Marketing AuthorizationHolder		
An instance of Marketing Authorization is associated with one or more instances of Authorized Name		
Attributes:		
medicinalProduct	Type: UID	1
A unique identifier for a medicinal product		

manufacturingAuthorizationHolderID	Type: UID	1
A unique identifier for the manufacturing authorization holder		
manufacturingAuthorizationHolderName	Type: ST	1
Name of the manufacturing authorization holder		
address	Type: AD	1
Address of the manufacturing authorization holder using the ISO12090 data type AD (address)		
manufacturingAuthorizationDate	Type: TS	1
Date upon which the authorization for manufacture issued		
manufacturingAuthorizationAuthority	Type: CV	1
Identifier for the regulatory authority which issued the manufacturing authorization		

ANNEX (Informative) Data Types

A1 Introduction

The data types described in this annex are a sub-set of those defined in ISO21090 – Health Informatics – Harmonized data types for information interchange.

For the purposes of this standard the properties of the data types may be simplified, i.e. only a sub-set of the properties of each data type are generally required. This annex therefore presents a simplified definition of these data types.

The following data types are described

Symbol	Name
AD	Address
ADXP	Address Part
CV	Coded Value
ED	Encapsulated Data
EN	Entity Name
ENXP	Entity Name Part
INT	Integer
OID	ISO Object Identifier
PQ	Physical Quantity
REAL	Real
RTO	Ratio
ST	Character String
TS	Point in Time
UID	Unique Identifier

A2 Address

Short name AD

Description Mailing and home or office addresses. AD is primarily used to communicate data that will allow printing mail labels, or that will allow a person to physically visit that address.

Attributes	Type	Properties
part	Sequence<ADXP>	A sequence of address parts, such as street or post office Box, city, postal code, country, etc.

A3 Address Part

Short name ADXP

Description A character string that may have a type-tag signifying its role in the address. Typical parts that exist in about every address are street, house number, or post box, postal code, city, country but other roles may be defined regionally, nationally, or on an enterprise level. Addresses are usually broken up into lines, which may be indicated by special line-breaking delimiter elements (e.g., DEL). In addition to the string that represents the part, the part may also be encoded using the code property. The string content must always be provided whether the content is encoded or not

Attributes	Type	Properties
value	ST	The actual string value of the part.
code	ST	A code assigned to the part by some coding system, if appropriate
codeSystem	ST	The code system from which the code is taken. The choice of coding system depends on the part type. The type CNT (Country) is bound to the 3 letter codes defined in ISO 3166. The context of use may specify other bindings for other part types.
addressPartType	ST (see below)	Specifies whether an address part names the street, city, country, postal code, post box, etc.

AddressPartType Enumeration			
	AL	address line	An address line is for either an additional locator, a delivery address or a street address. An address generally has only a delivery address line or a street address line, but not both
	ADL	additional locator	This can be a unit designator, such as apartment number, suite number, or floor. There may be several unit designators in an address (e.g., "3rd floor, Appt. 342"). This can also be a designator pointing away from the location, rather than specifying a smaller location within some larger one (e.g., Dutch "t.o." means "opposite to" for house boats located across the street facing houses)
	UNID	unit identifier	The number or name of a specific unit contained within a building or complex, as assigned by that building or complex
	UNIT	unit designator	Indicates the type of specific unit contained within a building or complex. E.g. Apartment, Floor
	SAL	street address line	A full street address line, including building number details and the street name and type as appropriate
	BNR	building number	The number of a building, house or lot alongside the street. Also known as "primary street number". This does not number the street but rather the building
	BNN	building number numeric	The numeric portion of a building number
	BNS	building number suffix	Any alphabetic character, fraction or other text that may appear after the numeric portion of a building number
	CNT	country	Country
	CPA	county or parish	A sub-unit of a state or province. (49 of the United States of America use the term "county;" Louisiana uses the term "parish")
	CTY	municipality	The name of the city, town, village, or other community or delivery center
	DEL	delimiter	Delimiters are printed without framing white space.
	POB	post box	A numbered box located in a post station
	STA	state or province	A sub-unit of a country with limited sovereignty in a federally organized country
	ZIP	postal code	A postal code designating a region defined by the postal service

A4 Coded Value

General properties

Short name **CV**

Description Coded data, specifying only a code, code system, and the display name

Attributes	Type	Properties
codeValue	ST	The plain code symbol defined by the code system, or an expression in a syntax defined by the code system which describes the concept. Note: If a code is provided, it shall be an exact match to a plain code symbol or expression defined by the code system. If the code system defines a code or expression that includes whitespace, the code shall include the whitespace.
displayName	ST	A name or title for the code, under which the system shows the code value to its users.
codeSystem	UID	Specifies the code system that defines the code.
codeSystemName	ST	The common name of the coding system
codeSystem Version	ST	If applicable, a version descriptor defined specifically for the given code system.

A5 Encapsulated Data

General Properties

Short name **ED**

Description Data that is primarily intended for human interpretation or for further machine processing outside the scope of this International Standard. This includes unformatted or formatted written language, multimedia data, or structured information in as defined by a different standard (e.g., XML-signatures).

NOTE: Instead of the data itself, an EncapsulatedData type may contain only a reference to the location of the data.

Values Encapsulated data can be present in two forms, inline or by reference. Inline data is communicated or moved as part of the encapsulated data value, whereas by-reference data may reside at a different (remote) location. The data is the same whether it is located inline or remote.

Attributes	Type	Properties
data	bitstring	The actual data if supplied inline
mediaType	CV	Identifies the type of the encapsulated data and identifies a method to interpret or render the data.

charset	CV	Where applicable, specifies the character set and character encoding used. Otherwise Void Character sets are defined by Internet Assigned Numbers Authority (IANA).
language	CV	For character based information the language property specifies the human language of the text using ISO 639-1:2002 "Code for the representation of names of languages". Otherwise Void.
compression	CV	Indicates whether the raw byte data is compressed, and what compression algorithm was used. Void means no compression
reference	URL	URL reference to electronic information stored outside the record as a file, database entry etc, if supplied as a reference. The semantic value of an encapsulated DataValue is the same, regardless whether the data is present inline data or just by-reference. However, an encapsulated DataValue without inline data behaves differently, since any attempt to examine the data requires the data to be downloaded from the reference. An encapsulated DataValue may have both inline data and a reference. The reference must point to the same data as provided inline.
integrityCheck	bitstring	A short bitstring representing a cryptographically strong checksum over the binary data.
integrityCheck Algorithm	CV	Specifies the algorithm used to compute the <i>integrityCheck</i> value.
thumbnail	ED	An abbreviated rendition of the full data.

A6 Entity Name

Short name	EN
Description	A name for a 'thing'. In this standard the EN data type will be used to provide a structure for the systematic naming of medicinal and pharmaceutical product entries. An entity name may be as simple as a character string or may consist of several entity name parts.

Attributes	Type	Properties
part	Sequence<ENXP>	A sequence of entity name parts, such as dose form and strength, etc.

A7 Entity Name Part

Short name	ENXP
Description	A character string token representing a part of a name. May have a type code signifying the role of the part in the whole entity name, and qualifier codes for more detail about the name part type. In addition to the string that represents the part, the part may also be encoded using the code property. The string content must always be provided whether the content is encoded or not

Attributes	Type	Properties
value	ST	The actual string value of the part.
code	ST	A code assigned to the part by some coding system, if appropriate
codeSystem	ST	The code system from which the code is taken. The choice of coding system depends upon the part type.
entityNamePartType	ST – set of types to be defined	Specifies the type of entity name part.

A8 Integer

General Properties

Short name **INT**

Description Mathematical data type comprising the exact integral values.

Component

Attributes	Type	Properties
integerLiteral	ST	integer-literal = signed-number . signed-number = ["-"] number . number = digit-string An integer-literal denotes an integer value. If the negative-sign ("-") is not present, the value denoted is that of the digitstring interpreted as a decimal number. If the negative-sign is present, the value denoted is the negative of that value.

A9 ISO Object Identifier

General Properties

Short name **OID**

Description An ISO Object Identifier (OID) is a globally unique string consisting of numbers and dots (e.g., 2.16.840.1.113883.3.1). This string expresses a tree data structure, with the left-most number representing the root and the right-most number representing a leaf.

Declaration type OID specializes UID

Attributes	Type	Properties
OID-Literal	ST	OID-literal = string-literal, this being globally unique string identifier consisting of numbers and dots. NOTE 1: The OID data type specializes the UID type. Note that the OID-Literal restricts the UID-Literal to a particular format and does not constitute an additional attribute. NOTE 2: Each branch under the root corresponds to an assigning authority. Each of these assigning authorities may, in turn, designate its own set of assigning authorities that work under its auspices, and so on down the line. Eventually, one of these authorities assigns a unique (to it as an assigning authority) number that corresponds to a leaf node on the tree. The leaf may represent an assigning authority (in which case the

		OID identifies the authority), or an instance of an object. An assigning authority owns a namespace, consisting of its sub-tree.
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A10 Physical Quantity

General Properties

Short name **PQ**

Description A dimensioned quantity expressing the result of a measurement.

EXAMPLES : 20 mL blood, 15 minutes, 25.2 kg, 10 mmol/L

NOTE : Where the quantity is a ‘quantity of time’, this equates to a duration of time. For example, 25 minutes, 5 microseconds, etc. DURATION is also available for quantities of time expressed in customary units – days, hours, minutes etc.

Attributes	Type	Properties
value	REAL	The magnitude of the quantity measured in terms of the unit. NOTE: The type REAL provides the means of specifying the precision of the value.
unit	CV	The unit of measure specified in the Unified Code for Units of Measure (UCUM) [http://aurora.ig.iupui.edu/UCUM]. NOTE: Equality of physical quantities does not require the values and units to be equal independently. Value and unit is only how we represent physical quantities. For example, 1 m equals 100 cm. Although the units are different and the values are different, the physical quantities are equal! Therefore one should never expect a particular unit for a physical quantity but instead provide automated conversion between different comparable units.

A11 Ratio

General Properties

Short name **RTO**

Description A quantity constructed as the quotient of a numerator quantity divided by a denominator quantity.

Note 1: Common factors in the numerator and denominator are not automatically cancelled out. Ratios are different from rational numbers, i.e., in ratios common factors in the numerator and denominator never cancel out.

Note 2: The RTO data type supports titres (e.g., "1:128") and other quantities produced by laboratories that truly represent ratios.

Note 3: Should not be used to represent things like blood pressure which are often written using a ‘/’ character, giving the misleading impression that the item is a ratio, when in fact it is a structured value. E.g. visual acuity “6/24” is not a ratio.

EXAMPLE USES : Recording specified administration dosages (e.g. 5 mg / 100 ml), drug amounts based on body weight (e.g. 1 tablet / 10 kg), and titers (e.g. 1:128).

Attributes	Type	Properties
numerator	PQ	The quantity that is being divided in the ratio. The default is the integer number 1 (one.)
denominator	PQ	The quantity that divides the numerator in the ratio. The default is the integer number 1 (one.) The denominator must not be zero.
literal	ST	<p>A ratio literal form exists for all ratios where both numerator and denominators have literal forms. A ratio is simply the numerator literal a colon as separator followed by the denominator literal. When the colon and denominator are missing, the integer number 1 is assumed as the denominator.</p> <p>EXAMPLE: The rubella virus antibody titer value 1:64 could be represented using the literal "1:64".</p>

A12 Real

General Properties

Description Mathematical data type comprising the "real numbers". Specifically, each real data type designates a collection of mathematical real values which are known to certain applications to some finite precision and must be distinguishable to at least that precision in those applications..

Values The value space of the mathematical real type comprises all values which are the limits of convergent sequences of rational numbers. The value space of a computational real data type shall be a subset of the mathematical real type, characterized by two parametric values, *radix* and *factor*, which, taken together, describe the precision to which values of the data type are distinguishable.

Attributes	Type	Properties
realLiteral	ST	<p>real-literal = integer-literal ["*" scale-factor] .</p> <p>scale-factor = number "^" signed-number .</p> <p>A <i>real-literal</i> denotes a value of a real data type. The <i>integer-literal</i> is interpreted as a decimal integer value, and the <i>scalefactor</i>, if present, is interpreted as <i>number</i> raised to the power <i>signed-number</i>, where <i>number</i> and <i>signed-number</i> are expressed as decimal integers. If the <i>scale-factor</i> is not present, the value is that denoted by <i>integer-literal</i>. If the <i>scale-factor</i> is present, the value denoted is the rational value $\text{Multiply}(\text{integer-literal}, \text{scale-factor})$.</p> <p>NOTE 1: A real number is represented in decimal form with optional + or – sign, and optional decimal point, and optional exponential notation using a case insensitive “e” between the mantissa and the exponent. The number of significant digits must conform to the precision property. Alternative representations two-thousand are 2000, 2000., 2e3, 2.0e+3, +2.0e+3.</p> <p>NOTE 2: The literal form does not carry type information. For example, “2000” is a valid representation of both a real number and an integer number. No trailing decimal point is used to disambiguate from integer numbers.</p>

A13 Character String

General Properties

Short name **ST**

Description An indeterminate sequence of symbols of indeterminate length from a standard character set.

Attributes	Type	Properties
characterString	LIST<char>	A sequence of character of indeterminate length. Two variations of character string literals are defined, a token form and a quoted string. The token form consists only of the lower case and upper case Latin alphabet, the ten decimal digits and the underscore. The quoted string can contain any character between double-quotes. The double quotes prevent a character string from being interpreted as some other literal. The token form allows keywords and names to be parsed from the data type specification language.
charset	CV	[optional]. Specifies the character set and character encoding used. Character sets are defined by Internet Assigned Numbers Authority (IANA)
language	CV	[optional]. Specifies the language of the character string data.

A14 Point in time

General Properties

Short name **TS**

Description A quantity specifying a point on the axis of natural time. A point in time is most often represented as a calendar expression

Attributes	Type	Properties
value	ST	For the purposes of this standard there is a requirement for the representation of dates but not for time. A date-literal denoting a date value. The characterstring value represented by the string-literal shall conform to ISO 8601:2000, Representation of dates and times. Specifically, this International Standard recommends, but does not mandate a date notation of YYYYMMDD where YYYY is the year in the usual Gregorian calendar, MM is the month of the year between 01 (January) and 12 (December), and DD is the day of the month between 01 and 31. EXAMPLE: the fourth day of February in the year 1995 is written in the standard notation as 19950204. NOTE: The alternative notation of YYYY-MM-DD is allowed but not recommended.

A15 Unique Identifier

General Properties

Short name **UID**

Description A unique identifier string is a character string which identifies an object in a globally unique and timeless manner.

Attributes	Type	Properties
UID-Literal	ST	UID is to be a globally and timelessly unique identifier. NOTE: The allowable formats and values and procedures of this data type may be controlled by a Standards Development Organisation or through other data interchange regulatory body.