ISBT 128 STANDARD

Product Description Code Database

Version 7.1.1

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ICCBBA
PO Box 11309, San Bernardino, CA 92423-1309 USA

Telephone: +1.909.793.6516
E-mail: iccbba@iccbba.org

Fax: +1.909.793.6214
Website: http://www.isbt128.org

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Editor
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Technical Manager, ICCBBA

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Izabela Uhrynowska-Tyszkiewicz, MD, PhD	Poland

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1 Introduction

1.1 Purpose

The purpose of this document is to provide specifications and guidance for the use of the ISBT 128 Product Description Code Database. This database has been restructured to allow for better information management and more coding options.

1.2 Scope

This document describes the structure of the Product Description Code Database. It provides reference tables for the characteristics of each table comprising the database and describes the relationships between each of the database tables.

1.3 Intended Audience

The intended audience of this document is software developers and staff (management, information technology, quality, validation, and laboratory) at facilities using ISBT 128.

1.4 Normative References

ISBT 128 Standard Technical Specification

1.5 Other Reference

ICCBBA Website (www.isbt128.org)

1.6 Background

The ISBT 128 Product Description Code Database structure was extensively updated in 2015 to support the expanding scope of ISBT 128. The revised structure of the database may not affect all existing ISBT 128 software. Existing software that only utilizes the ISBT 128 Product Description code should not be affected. The Product Description codes themselves have not been redefined or restructured.

The product hierarchy has the following levels:

Category relates to the highest level of distinction and is related to the first one or two characters of the Product Description code as indicated in the ISBT 128 Technical Specification. The Category code is the means to group products under general headings such as blood, cellular therapy, tissues, etc.

The Subcategory is a new level which potentially allows a level of classification between the Category and Class. An example may be the Blood Components Category which could have in the future Subcategories of Red Blood Cells, Platelets, and Plasma.

The Class level is the highest level of description used in labeling. Examples of ISBT 128 Class names are Red Blood Cells; HPC, Cord Blood; Dermis; Cornea.

Below the Class level products are further described using Modifiers and/or Attributes.

The database design supports biovigilance and activity reporting by having hierarchical categorizations of product types and by providing associations of Attributes to those product types.

1.7 Changes in this Version

The following table indicates the changes between Version 7.1.0 and Version 7.1.1.

	Version 7.1.0 Chapter, Section, Table, or Figure	Version 7.1.1 Chapter, Section, Table, or Figure	Change	Rationale
1.	Tables 1, 3, 5, 7, 9, 11, 13, 15, 17, 19, 21	Tables 1, 3, 5, 7, 9, 11, 13, 15, 17, 19, 21	Revised the table names to incorporate “Field Definitions” within their names.	To provide a more appropriate naming convention to reflect their purpose.

2 Database Tables

Figure 1 shows the entities and relationships within the database. Entities are shown as boxes and represented in the database as tables. The arrows indicate the relationship between entities. The arrow ends indicate whether the relationship is one (single headed) or many (double headed). For example, in the figure below, a Category can map to many Subcategories. However, a Subcategory can map to only one Category.

Figure 1 Entity Relationship Diagram

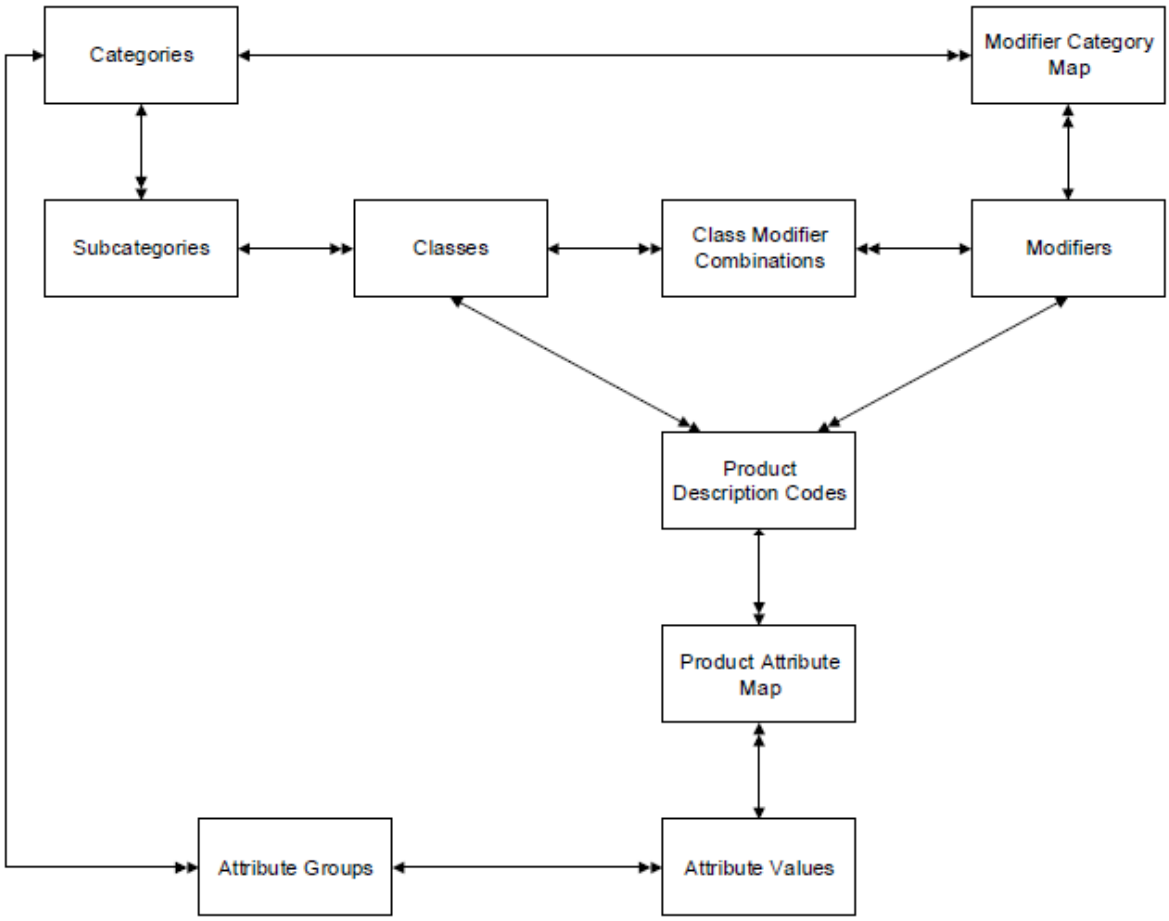
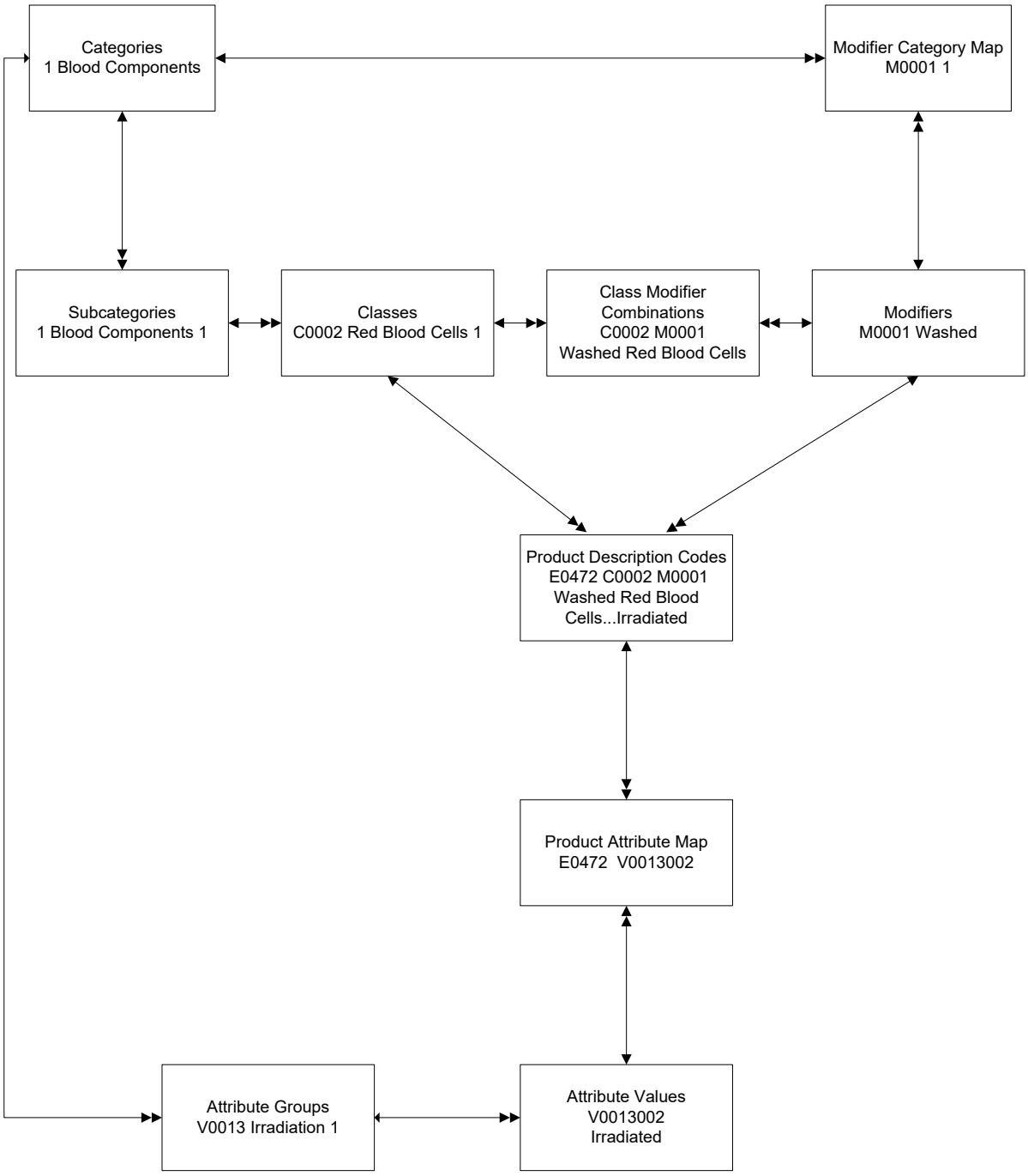


Figure 2 Entity Relationship Diagram Showing Example Instances



2.1 Categories Table

Categories define the highest level of categorization within the database and correspond to the fields of practice supported by ISBT 128: blood, cells, tissue, ocular tissue, reproductive tissue, organs, other blood products, and other therapies.

The Categories table lists product Categories and assigns each a unique Category number (Cat No). The Category number is used in other tables to associate values with a Category.

2.1.1 Structure

Table 1 Categories Table Field Definitions [RT047]

Field Name	Field Type	Field Size	Description of Information in this Field
Cat No	Number	n/a	Key field sequence number.
Category	Text	255	Text description of the Category.

Table 2 Example of Categories Table

Categories Table	
Cat No	**Category**
1	Blood Components
2	Cellular Therapy
3	Tissues
4	Other Blood Products
5	Ocular
6	Other Therapies
7	Organs
8	Reproductive
9	Fecal Microbiota
10	Regenerated Tissues

2.1.2 Related Tables

Table	Relationship to Categories Table
Subcategories	A foreign key (Category field) in the Subcategories table maps to the key field (Cat No) in the Categories table. Each Subcategory instance shall map to an instance in the Categories table.
Modifier Category Map	A foreign key (Category field) in the Modifier Category Map table maps to the key field (Cat No) in the Categories table. Each Modifier Category Map instance shall map to an instance in the Categories table.
Attribute Groups	A foreign key (Category field) of the Attribute Groups table maps to the key field (Cat No) in the Categories table. Each Attribute Group instance shall map to an instance in the Categories table.

2.2 Subcategories Table

Subcategories define the second level of categorization within the database. Each Subcategory is associated with one Category. However, a Category may have multiple Subcategories.

Use of Subcategories for products could support biovigilance efforts when an adverse event is found, or suspected, to be associated with a particular Subcategory of product.

This level of categorization has not been fully utilized at this stage but provides flexibility for the future.

2.2.1 Structure

Table 3 Subcategories Table Field Definitions [RT048]

Field Name	Field Type	Field Size	Description of Information in this Field
Subcat No	Number	n/a	Key field sequence number.
Subcategory	Text	255	Text description of the Subcategory.
Category	Number	n/a	Foreign key to the Categories table.

Table 4 Example of Subcategories Table

Subcategories Table		
Subcat No	**Subcategory**	**Category**
1	Blood Components	1
2	Cellular Therapy	2
3	Tissues	3
4	Other Blood Products	4
5	Ocular	5
6	Other Therapies	6
7	Organs	7
8	Reproductive	8
9	Fecal Microbiota	9
10	Regenerated Tissues	10

2.2.2 Related Tables

Table	Relationship to Subcategories Table
Classes	A foreign key (Subcategory) in the Classes table maps to a key field (Subcat No) in the Subcategories table. Each Classes instance shall map to an instance in the Subcategories table.

2.3 Classes Table

Classes are the third level of categorization of products in the database, and the highest level of description used in labeling. Examples of ISBT 128 Class names are Red Blood Cells; HPC, Cord Blood; Dermis; Cornea; Human Milk; Embryo; and Solvent Detergent Pooled Plasma. Classes support biovigilance efforts when an adverse event is found, or suspected, to be associated with a particular Class of product.

2.3.1 Structure

Table 5 Classes Table Field Definitions [RT049]

Field Name	Field Type	Field Size	Description of Information in this Field
ClassIdentifier	Text	5	Key field Class number Cxxxx.
ClassName	Text	100	Text description of Class.
StructuredName	Text	255	Structured description of Class. This field is not currently populated.
RETIREDATE	Text	11	Date on which the Class was retired. Format is DD MMM YYYY. The field is not populated for active codes.
Subcategory	Number	n/a	Foreign key to the Subcategories table.

Table 6 Example of Classes Table

Classes Table Excerpt				
ClassIdentifier	**ClassName**	**StructuredName**	**RETIRE DATE**	**Subcategory**
C0001	WHOLE BLOOD			1
C0002	RED BLOOD CELLS			1
C0003	FRESH FROZEN PLASMA			1
C0004	PLASMA			1
C0005	PLATELET-RICH PLASMA			1
C0006	PLATELETS			1
C0007	POOLED PLATELETS			1
C0008	CRYOPRECIPITATE			1
C0009	POOLED CRYOPRECIPITATE			1

Classes Table Excerpt				
ClassIdentifier	**ClassName**	**StructuredName**	**RETIRE DATE**	**Subcategory**
C0010	GRANULOCYTES			1
C0011	POOLED GRANULOCYTES			1
C0012	GRANULOCYTES-PLATELETS			1
C0013	LEUKOCYTES			1
C0014	POOLED PLASMA			1
C0015	PLATELET-RICH BUFFY COAT			1
C0016	POOLED PLATELET-RICH BUFFY COAT			1
C0017	LYMPHOCYTES		03 MAY 2010	1
C0018	MONOCYTES		03 MAY 2010	1
C0019	SERUM			1
C0020	POOLED SERUM			1
C0021	POOLED FRESH FROZEN PLASMA			1

2.3.2 Related Tables

Table	Relationship to Classes Table
Class Modifier Combinations	A foreign key (ClassIdentifier) in the Class Modifier Combinations table maps to a key field (ClassIdentifier) in the Classes table. Each Class Modifier Combinations instance shall map to an instance in the Classes table.
Product Description Codes	A foreign key (Class Identifier) in the Product Description Codes table maps to a key field (ClassIdentifier) in the Classes table. Each Product Description Codes instance shall map to an instance in the Classes table.

2.4 Modifiers Table

In some Categories of products, Modifiers are applied to Classes in order to provide the next step in describing a product. Examples are Frozen, Thawed, Washed, etc. Modifiers are not used with all Categories of products.

The Modifiers table lists Modifiers and assigns each a unique identifier (ModifierIdentifier). It allows assignment of a retirement date to a Modifier.

2.4.1 Structure

Table 7 Modifiers Table Field Definitions [RT050]

Field Name	Field Type	Field Size	Description of Information in this Field
ModifierIdentifier	Text	5	Key field Modifier number Mxxxx.
ModifierName	Text	255	Text description of Modifier.
RETIREDATE	Text	11	Date on which the Modifier was retired. Format is DD MMM YYYY. The field is not populated for active codes.

Table 8 Example of Modifiers Table

Modifiers Table Excerpt		
ModifierIdentifier	**ModifierName**	**RETIREDATE**
M0000		
M0001	Washed	
M0002	Frozen	
M0003	Frozen Rejuvenated	
M0004	Deglycerolized	
M0005	Deglycerolized Rejuvenated	

2.4.2 Related Tables

Table	Relationship to Modifiers Table
Class Modifier Combinations	A foreign key (ModifierIdentifier) in the Class Modifier Combinations table maps to a key field (ModifierIdentifier) in the Modifiers table. Each Class Modifier Combinations instance shall map to an instance in the Modifiers table.
Product Description Codes	A foreign key (Modifier Identifier) in the Product Description Codes table maps to a key field (ModifierIdentifier) in the Modifiers table. Each Product Description Codes instance shall map to an instance in the Modifiers table.

Table	Relationship to Modifiers Table
Modifier Category Map	A foreign key (Modifier) in the Modifier Category Map maps to a key field (ModifierIdentifier) in the Modifiers table. Each Modifier Category Map instance shall map to an instance in the Modifiers table.

2.5 Class Modifier Combinations Table

Each Class/Modifier combination is uniquely identified in this table. A Class/Modifier combination includes the combination of a Class with a null Modifier. Additionally, more than one modifier characteristic may be required to describe a product (e.g., Washed Apheresis RED BLOOD CELLS). In such cases, the combination is treated as a single Modifier (e.g., Washed Apheresis is treated as a single Modifier with its own ModifierIdentifier).

The Class Modifier Combinations table assigns each combination a ClassIdentifier and ModifierIdentifier.

2.5.1 Structure

Table 9 Class Modifier Combinations Table Field Definitions [RT051]

Field Name	Field Type	Field Size	Description of Information in this Field
ClassIdentifier	Text	5	Key field Class number Cxxxx. Foreign key to Classes table.
ModifierIdentifier	Text	5	Key field Modifier number Mxxxx. Foreign key to Modifiers table.
Name	Text	210	Text description of Class-Modifier combination.
RETIREDATE	Text	11	Date on which the Class-Modifier combination was retired. Format is DD MMM YYYY. The field is not populated for active codes.

Table 10 Example of Class Modifier Combinations table

Class Modifier Combinations Table Example			
ClassIdentifier	**ModifierIdentifier**	**Name**	**RETIREDATE**
C0004	M0000	PLASMA	
C0004	M0007	Apheresis PLASMA	
C0004	M0008	Thawed PLASMA	
C0004	M0009	Thawed Apheresis PLASMA	
C0004	M0010	Liquid PLASMA	
C0004	M0013	Liquid Apheresis PLASMA	

2.6 Attribute Groups Table

The Attribute Groups table contains an entry for each Attribute Group, assigns each a unique identifier (GroupIdentifier), and associates it with a Category. It allows the assignment of a retirement date to an Attribute Group.

2.6.1 Structure

Table 11 Attribute Groups Table Field Definitions [RT052]

Field Name	Field Type	Field Size	Description of Information in this Field
GroupIdentifier	Text	5	Key field, sequentially assigned group number in the format Vxxxx.
GroupName	Text	100	Text description of the Attribute Group.
RetireDate	Text	11	Date on which the Attribute Group was retired. Format is DD MMM YYYY. The field is not populated for active codes.
Category	Number	n/a	Foreign key to the Categories table.

Table 12 Example of Attribute Groups Table

Attribute Groups Table Excerpt			
GroupIdentifier	**GroupName**	**RetireDate**	**Category**
V0021	Method of Treatment		1
V0022	Hematocrit		1
V0023	Platelet Count	01 SEP 2009	1
V0024	Monitoring		1
V0025	Donor Exposure		1

2.6.2 Related Tables

Table	Relationship to Attribute Groups Table
Attribute Values	A foreign key (ATTRGRP) in the Attributes Values table maps to a key field (GroupIdentifier) in the Attribute Groups table. Each Attribute Values instance shall map to an instance in the Attribute Groups table.

2.7 Attribute Values Table

The Attribute Values table allows each Attribute to be associated with an Attribute Group. The Attribute Values table lists all Attribute variables, assigns each a unique Attribute formula (UNIQUE ATTRFORM), and associates it with the appropriate Attribute Group. The table indicates whether the Attribute is a core condition or if it is the default value for the group.

2.7.1 Structure

Table 13 Attribute Values Table Field Definitions [RT053]

Field Name	Field Type	Field Size	Description of Information in this Field
UNIQUE ATTRFORM	Text	8	Key field that uniquely identifies the Attribute Value as a combination of group and value.
ATTRGRP	Text	5	Foreign key to the Attribute Groups table.
Attribute Text	Text	50	Text description of the Attribute Value.
CORE CONDITION	Yes/No	n/a	A yes/no field that indicates if the value is a core condition value.
DEFAULT	Yes/No	n/a	A yes/no field that indicates if the value is the default value for the Attribute Group.
Retire Date	Text	11	Date on which the Attribute Value was retired. Format is DD MMM YYYY. The field is not populated for active codes.

Table 14 Examples of Attribute Values Table

Attribute Values Table Excerpt					
UNIQUE ATTRFORM	**ATTR GRP**	**Attribute Text**	**CORE CONDITION**	**DEFAULT**	**Retire Date**
V0001011	V0001	CP2D/450mL/refg	Yes	No	
V0001012	V0001	CP2D/500mL/refg	Yes	No	
V0001013	V0001	CP2D/XX/refg	Yes	No	
V0001014	V0001	CP2DA/450mL/refg	Yes	No	13 DEC 2011

2.7.2 Related Tables

Table	Relationship to Attribute Values Table
Product Attribute Map	A foreign key (attributevalue) in the Product Attribute Map table maps to a key field (UNIQUE ATTRFORM) in the Attribute Values table. Each Product Attribute Map instance shall map to an instance in the Attribute Values table.

2.8 Product Description Codes Table

The Product Description Codes table lists Product Descriptions and assigns each a unique code (PRODDESCRIPCODE) and a unique Product Formula. The Product Description code plays a critical role in product traceability and labeling.

2.8.1 Structure

Table 15 Product Description Codes Table Field Definitions [RT054]

Field Name	Field Type	Field Size	Description of Information in this Field
PRODDESCRIP CODE	Text	5	Key field that uniquely identifies the product.
Class Identifier	Text	5	Foreign key to the Classes table.
Modifier Identifier	Text	5	Foreign key to the Modifiers table.
PRODDESCRIP0	Text	254	Text description of the product including Modifier(s), Class, and Attribute Value(s).
CODEDATE	Text	11	Date the product was entered into the database. Format is DD MMM YYYY.
PRODDESCRIP1	Text	254	Blank field for use at the national level.
RETIREDATE	Text	11	Date on which the Product Description code was retired. Format is DD MMM YYYY. The field is not populated for active codes.
Product Formula	Text	255	Formula derived from Class, Modifier, and Attribute Value identifiers.

Table 16 Example of Product Description Codes Table

Product Description Codes Table Example							
PROD DESCRIP CODE	**Class Identifier**	**Modifier Identifier**	**PRODDESCRIP0**	**CODE DATE**	**PROD DESCRIP1**	**RETIRE DATE**	**Product Formula**
E2684	C0004	M0008	Thawed PLASMA| CPD/XX/refg	19 JUL 1996			C0004-M0008-V0001006
S1122	C0045	M0000	HPC, MARROW| NS/XX/<=-150C|10% DMSO|Cryopreserved	17 JUL 2007			C0045-M0000-V0002029-V0045003-V0050005
T0332	C0217	M0000	TENDON, GRACILIS |Frozen|Antibiotics	14 SEP 2012			C0217-M0000-V0061002-V0066007
X0004	C0285	M0000	SOLVENT DETERGENT POOLED PLASMA |NS/NS/<=-18C|AB	01 FEB 2008			C0285-M0000-V0003001-V0076005
V0003	C0279	M0000	CORNEA|Right |Hypothermic storage	10 AUG 2012			C0279-M0000-V0070003-V0071003
M0001	C0022	M0000	HUMAN MILK|<=-30C| Pasteurized| For nutritional use	14 SEP 2012			C0022-M0000-V0026003-V0027003-V0028003

2.8.2 Related Tables

Table	Relationship to Product Description Codes Table
Product Attribute Map	A foreign key (proddescripcode) in the Product Attribute Map table maps to a key field (PRODDESCRIPCODE) in the Product Description Codes table. Each Product Attribute Map instance shall map to an instance in the Product Description Codes table.

2.9 Version Table

The Version table identifies the version number of the product database and the date it was published.

Table 17 Version Table Field Definitions [RT028]

Field Name	Field Type	Field Size	Description of Information in this Field
Version Number	Text	50	The version number of the product database.
Date	Text	11	The date issued. The format is DD MMM YYYY.

Table 18 Example of Version Table

Version Table	
Version Number	**Date**
7.0.0	03 JAN 2017

3 Mapping Tables in the Database

Some of the database tables do not provide any additional data codes or formulas but are needed for creating associations (or maps) between tables.

3.1 Modifier Category Map Table

The Modifier Category Map table creates the association between Modifiers and their appropriate Categories. The association is created by mapping the Category number identifier to Modifier identifiers. The Modifier Category Map table has an entry for each Category-Modifier combination in use. The same Modifier can apply to multiple Categories. A single Category can also have multiple Modifiers.

3.1.1 Structure

Table 19 Modifier Category Map Table Field Definitions [RT055]

Field Name	Field Type	Field Size	Description of Information in this Field
Modifier	Text	5	Foreign key to the Modifiers table.
Category	Number	n/a	Foreign key to the Categories table.

Table 20 Example of Modifier Category Map Table

Modifier Category Map Table Example	
Modifier	**Category**
M0001	1
M0008	1
M0008	4
M0021	1
M0042	1

3.2 Product Attribute Map Table

The purpose of this table is to provide a mechanism for identifying any trends or commonalities in products of interest during biovigilance efforts. It contains a field for the Product Description code and a field for Attribute Values. This table lists and associates each Product Description code with pertinent Attribute Values.

3.2.1 Structure

Table 21 Product Attribute Map Table Field Definitions [RT056]

Field Name	Field Type	Field Size	Description of Information in this Field
proddescripcode	Text	5	Foreign key to the Product Description Codes table.
attributevalue	Text	8	Foreign key to the Attribute Values table.

Table 22 Example of Product Attribute Map Table

Product Attribute Map Table Example	
proddescripcode	**attributevalue**
E0002	V0001001
E0002	V0011002
S1379	V0002030
S1379	V0046002
S1379	V0051002
S1379	V0055006

