



2024 CDISC + TMF
EUROPE INTERCHANGE

BERLIN

24-25 APRIL: CONFERENCE & EXPO | 22, 23, 26 APRIL: TRAININGS

How to use WHODrug for Compliance with CM Domain in the CDISC SDTM standard

Marilina Castellano, Uppsala Monitoring Centre



Meet the Speaker

Marilina Castellano

Title: Product Manager

Organization: Uppsala Monitoring Centre (UMC)

Marilina is a pharmacist with a specialization in Pharmacovigilance and Regulatory Affairs. She joined UMC in 2016 and today in her role as Product Manager is responsible for the development of many applications and services in the WHODrug portfolio.



Disclaimer and Disclosures

- *The views and opinions expressed in this presentation are those of the author(s) and do not necessarily reflect the official policy or position of CDISC.*
- *The author has no real or apparent conflicts of interest to report.*



Agenda

1. Uppsala Monitoring Centre
2. Introducing WHODrug Global
3. CDISC and WHODrug Global

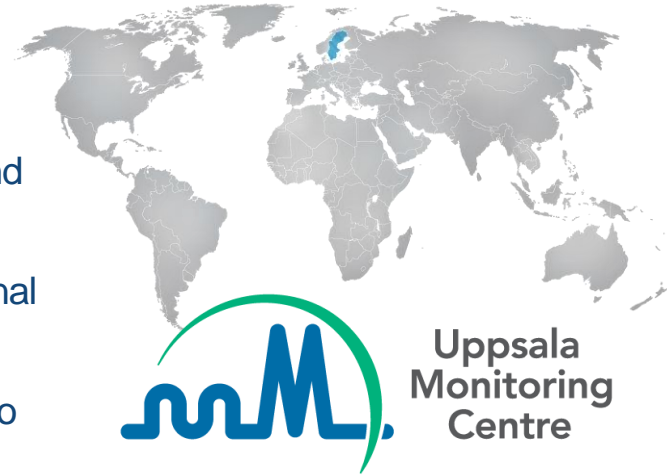


Uppsala Monitoring Centre

Have you heard of us?

Uppsala Monitoring Centre (UMC)

- Not-for-profit organisation, WHO Collaborating Centre
- Scientific, technical and operational support to WHO PIDM as the WHO Collaborating Centre for International Drug Monitoring
- Custodian of VigiBase, home of WHODrug Global, proposed maintenance organisation for ISO IDMP PhPID
- Conducts PV research, method development, signal detection and communication
- Provides education and training, IT solutions to strengthen National PV systems in the WHO PIDM
- Actively involved in global harmonisation efforts of ISO and ICH to support safer medicines



UMC and Global ISO IDMP



European Directorate
for the Quality
of Medicines
& HealthCare

Direction européenne
de la qualité
du médicament
& des soins de santé



Health
Canada



WHO Programme on International
Nonproprietary Names (INN)



IPRP
International Pharmaceutical
Regulators Programme



HL7
International



National Center
for Advancing
Translational Sciences



International Federation
of Pharmaceutical
Manufacturers & Associations



Agência Nacional
de Vigilância Sanitária

New formal collaboration between UMC and CDISC

The partnership seeks to improve the interoperability of CDISC standards and WHODrug Global for more effective sharing and use of medicinal product safety data.

A NEW COLLABORATION between two leading organisations in global medical data has been announced to bring greater efficiency and certainty to regulatory bodies, industry, and the healthcare community, ultimately aiming to improve patient safety worldwide.

Historically, lack of interoperability has been a significant stumbling block to the effective sharing and use of medicinal product safety data. The strategic partnership announced today takes aim at the problem, combining the expertise of the Clinical Data Interchange Standards Consortium (CDISC) in clinical data standards with that of Uppsala Monitoring Centre (UMC) as the developer of WHODrug Global, the world most widely used drug dictionary.

TOGETHER, CDISC AND UMC WILL WORK to strengthen interoperability between CDISC standards and WHODrug Global for the benefit of users, regulatory bodies, and the broader healthcare community.



Chris Decker, CEO and president of CDISC

"CDISC is excited to expand our long collaboration with Uppsala Monitoring Centre to support the global community in connecting WHODrug Global with CDISC's Study Data Tabulation Model."

<https://uppsalareports.org/articles/patient-safety-set-to-gain-from-new-partnership-between-cdisc-and-umc/>



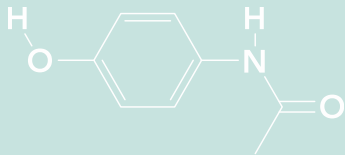


Introducing WHODrug Global

Types of medicines in WHODrug

>621 570 drug names from 171 countries

Conventional medicines



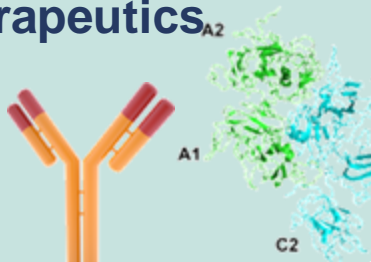
Vaccines



Herbal medicines



Biotherapeutics_{A2}



Traditional medicines



Anatomical Therapeutic Chemical (ATC) classification in WHODrug

- Maintained by WHO Collaborating Centre for Drug Statistics Methodology
- Used in WHODrug to classify medications according to their intended use
- All drugs in WHODrug are assigned at least one ATC code (preferably 4th level)
- Allows for aggregation of similar drugs



ATC: N05BC
Other Anxiolytics

ATC: N06AB
Selective serotonin
reuptake inhibitors



WHO Collaborating Centre for
Drug Statistics Methodology

WHODrug B3 & C3 formats

One
dictionary –
two formats

	Drug code	Drug name	Active ingredient(s)	ATC	Country of sale	Marketing authorisation holder	Pharmaceutical form	Strength	Medicinal Product ID
B3 format:	00599202029	Tradolan	Tramadol hydrochloride	N02AX, Other opioids					
C3 format:	00599202029	Tradolan	Tramadol hydrochloride	N02AX, Other opioids	Sweden	G.L. Pharma GmbH	COATED TABLETS, FILM	50 mg	2693211

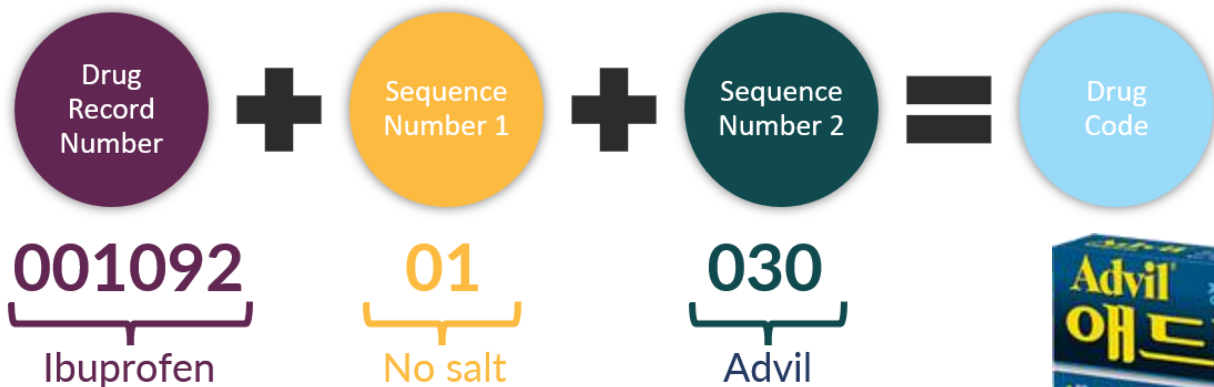
WHODrug Global Chinese

Drug code	Drug name	Active substance(s)	ATC	Country of sales	Marketing authorisation holder	Pharmaceutical form	Strength	Medicinal Product ID
00002701559	伯基	乙酰水杨酸	B01AC, 血小板凝固抑制剂, 不包括肝素类	中国	永信药品股份有限公司	胶囊, 肠溶	100 mg	1724492
00002701559	Bokey	Acetylsalicylic acid	B01AC, Platelet aggregation inhibitors excl. heparin	China	Yung shin	CAPSULES, ENTERIC-COATED	100 mg	1724492

WHODrug
Global
Chinese

WHODrug
Global

Drug code in WHODrug



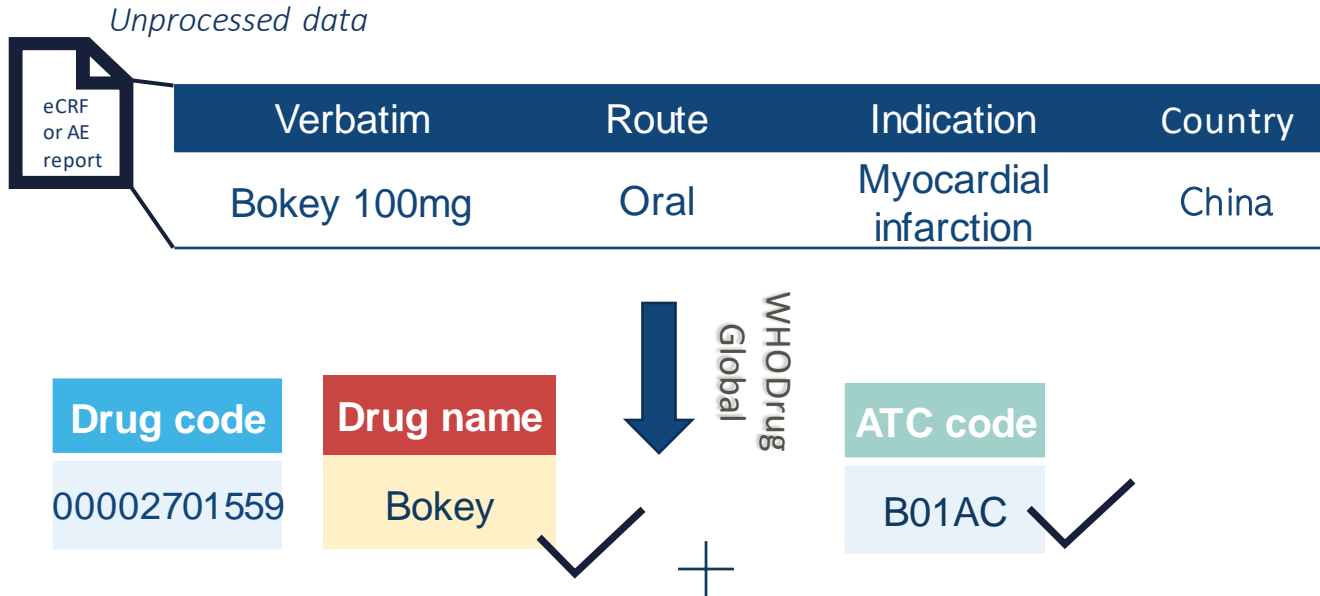
Drug code ends in **001** if Active substances



Preferred Name in WHODrug is always generic

- Preferred names (bases and variations) can be identified by the drug code with seq2=001
- Preferred base will have seq1=01 as well as seq2=001

Standardising drug information with medical coding...





CDISC and WHODrug Global

Meeting regulatory expectations with WHODrug

Japan, PMDA

PMDA Data Standards Catalog (2023-02-28) - Terminology Standards

Terminology Standard	Version(s)	Date Support Begins (YYYY-MM-DD)	Date Support Ends (YYYY-MM-DD)	Notes
CDISC Controlled Terminology	Between 2009-02-17 (inclusive) and 2011-06-10 (exclusive)	2016-10-01	2017-06-30	When using the version indicated in "Version(s)" column, consult PMDA at the consultation on data preparation of the submission of electronic study data.
CDISC Controlled Terminology	2011-06-10 or later	2016-10-01		
MedDRA	8.0 or later	2016-10-01		
WHODrug Global (since 2017 March)/ WHO Drug Dictionary Enhanced	2008.4 (2008-12-01) or later	2016-10-01		

FAQs on Electronic Study Data Submission³

Q4-7: In Section 4 (2) d of the notification on electronic study data, it states, that encoded information must also be included for data that can be encoded using "the WHODrug Global for drugs". Please explain the background of the need to use WHODrug Global, and give an example of how to store WHODrug Global data under the CM domain of SDTM.

A: In order to promote international standardization of clinical study data, and to allow cross-product analyses in the future, use of WHODrug Global is required for electronic study data submission. It is possible to use applicant-defined codes if no WHODrug Global equivalent codes are identified; in this case, it will be necessary to specify in the reviewer's guide which applicant defined codes have been assigned to which variables.

Table 4-7 presents examples of how to assign WHODrug Global codes to the CM domain of SDTM. It is also necessary to store WHODrug Global ATC codes wherever possible.

In cases where it is impossible to identify the single ATC code in WHODrug Global due to not collecting indication for use of the concomitant drug, please store not only single ATC code but also all ATC codes that correspond to the drug using the "Supplemental Qualifier special-purpose dataset".

Table 4-7 Relationship between CM Domain and WHODrug Global

Variable Name	Variable Label	WHODrug Global
CMDECOD	Standardized Medication Name	Generic name
CMCLAS	Medication Class	ATC text
CMCLASCD	Medication Class Code	ATC code

Data Standards Catalog²

U.S., FDA

FDA Data Standards Catalog⁵

FDA Data Standards Catalog v10.2 - Submission Data Terminologies													
For full description of column headings, see Instr. & Column Descriptions tab													
Use	Terminology	Organization(s)	Accepted Version(s)	FDA Center(s)	Date Support Begins	Date Support Ends	Date Requirement Begins [10]	Date Requirement Ends	Examples of Use	Statutory, Regulatory, or Guidance Authority Source	Statutory, Regulatory, or Guidance Authority Source	Information Sources	Information Sources
Medication	WHODrug Global	UMC	Current Version- B3 format	CDER, CBER	03/15/2018		03-15-2019		Use in SDTM CMDECOD and CMCLAS	Standardized Study Data		WHODrug Global	Study Data Technical Conformance Guide



WHODrug Global

Accepted Version(s)
Current Version- B3 format

Examples of Use
Use in SDTM CMDECOD and CMCLAS

6.4.2 WHODrug Global

6.4.2.1 General Considerations

World Health Organization (WHO) Drug Global⁵¹ is a dictionary maintained and updated by Uppsala Monitoring Centre. WHODrug Global contains unique product codes for identifying drug names and listing of medicinal product information, including active ingredients and therapeutic uses.

Typically, WHODrug Global is used to code concomitant medications. The variable --DECOD should be populated with the active substances from the WHODrug Global Dictionary, and --CLAS populated with the drug class.

When using WHODrug Global, --CLAS is recommended to be populated with the Anatomic Therapeutic Chemical (ATC) class most suitable per intended use, and the remainder of the ATC classes, if any, placed in SUPPCM. Alternately, the use of the SUPPCM or FACM domains to populate all ATC Classes associated with the --DECOD value is acceptable. ATC classes should be submitted at the fourth level or most specific available as defined within WHODrug Global.

Generally, studies included in a submission are conducted over many years and may have used different WHODrug Global versions to code concomitant medications. The expectation is the most current B3-format annual version of WHODrug Global at the time of study start will be used to code concomitant medications. There is no requirement to recode earlier studies to align with the WHODrug Global version of later studies.



China, NMPA - Guidelines for submission of clinical trial data⁹

原始数据库通常包含从病例报告表和外部文件中直接收集的原始数据，还可能包含极少量的衍生数据，如序号。原始数据库中的缺失数据不应进行填补。为满足数据递交的要求，直接收集的数据可能需要进行必要的标准化或编码，例如调整数据库中数据集名称/标签/结构、数据集中变量名称/标签，或在适用的情况下对变量值进行标准化编码，如监管活动医学词典（Medical Dictionary for Regulatory Activities, MedDRA）等。

递交数据库中至少以下内容应为中文：数据集标签和变量标签；在临床总结报告等文件中出现的不良事件名称、**合并用药名称**、病史名称。

Provisional translation:

In order to meet the data submission requirements, collected data may be required to be standardized or coded. At least the following content in the submitted database should be in Chinese: data set labels and variable labels; names of adverse events, names of concomitant drugs, and names of medical history appearing in clinical summary reports and other documents.

The provisional translation is unofficial and is provided solely to create a basic understanding.

CMDECOD

Retrieve by:

- Drug Code Seq 2 001
- Files:
DD(B3 format) or
MP(C3 format)



CMDECOD longer than 200 characters

SDTM Implementation Guide⁷

Table 1. Illustration of SDTM dataset where CMDECOD is longer than 200 characters.

USUBJID	CMSEQ	CMTRT	CMMODIFY	CMDECOD	CMCLAS	CMCLASCD
AB-21-01	1	Ascorbic acid;Biotin;Calcium;Carbohydrates nos; Chloride;Choline;Chromium;Colecalciferol; Copper;Cyanocobalamin;Docosahexaenoic acid; Fats nos;Folic acid;Fructooligosaccharides; Iodine;Iron;Magnesium;

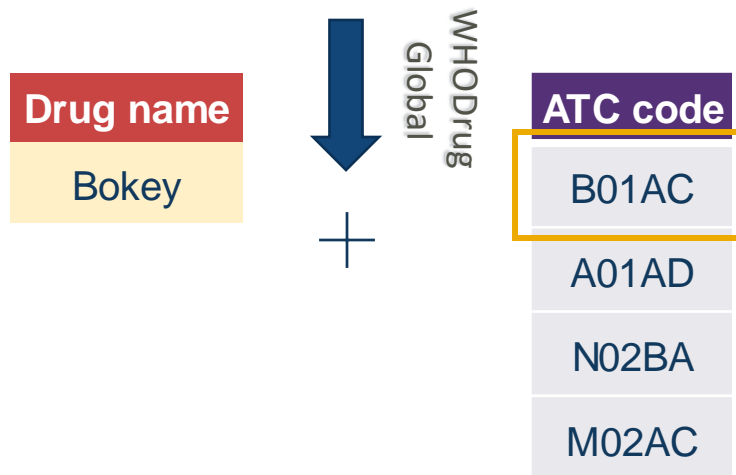
Table 2. Illustration of supplemental dataset for CM domain where CMDECOD is longer than 200 characters.

USUBJID	RDOMAIN	IDVAR	IDVARVAL	QNAM	QLABEL	QVAL
AB-21-01	CM	CMSEQ	1	CMDECOD1	Standardized Medication Name 1	Manganese;Nicotinic acid;Pantothenic acid;Phosphorus;Phytomenadione; Potassium;Proteins nos;Pyridoxine; Retinol;Riboflavin;Selenium;Sodium; Thiamine;Vitamin e nos;Zinc

CMCLAS, CMCLASCD – Multiple ATC codes

eCRF or AE report

Verbatim	Route	Indication	Country
Bokey 100mg	Oral	Myocardial infarction	China



CMCLAS, CMCLASCD – Multiple ATC codes

SDTM Implementation Guide⁷

USUBJID	CMSEQ	CMTRT	CMMODIFY	CMDECOD	CMCLAS	CMCLASCD
AB-21-01	1	Bokey 100 mg	Bokey	Acetylsalicylic acid	Platelet aggregation inhibitors excl. heparin	B01AC

USUBJID	RDOMAIN	IDVAR	IDVARVAL	QNAM	QLABEL	QVAL
AB-21-01	CM	CMSEQ	1	CMCLAS2	Medication Class 2	Other agents for local oral treatment
AB-21-01	CM	CMSEQ	1	CMCLSCD2	Medication Class Code 2	A01AD
AB-21-01	CM	CMSEQ	1	CMCLAS3	Medication Class 3	Preparations with salicylic acid derivates
AB-21-01	CM	CMSEQ	1	CMCLSCD3	Medication Class Code 3	M02AC
...

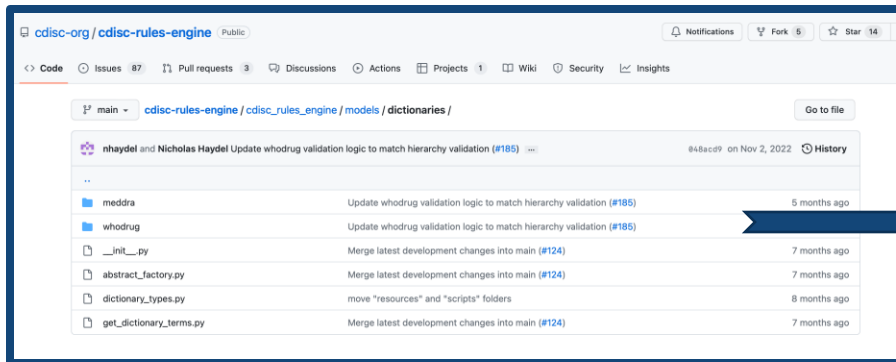
Validation/Conformance Rules

FDA Validation Rules v1.6, December 2022

FDA Validator Rule ID	Publisher	Publisher ID	FDA Validator Rule Message	FDA Validator Rule Description
SD1344	FDA	FDAB017	Value for --DECOD not found in WHODrug dictionary	Value for the Standardized Medication Name (--DECOD) variable must be populated using a Drug Name from the WHO Drug dictionary version specified in the define.xml.
SD1345	FDA	FDAB017	Value for --CLAS not found in WHODrug dictionary	Value for the Medication Class (--CLAS) variable must be populated using ATC Text from the WHO Drug dictionary version specified in the define.xml.
SD1346	FDA	FDAB017	Value for --CLASCD not found in WHODrug dictionary	Value for the Medication Class Code (--CLASCD) variable must be populated using ATC Code from the WHO Drug dictionary version specified in the define.xml.

CDISC CORE Rules Engine

WHODrug Global is included in CDISC's Rules Engine



```
1 from abc import abstractmethod
2 from cdisc_rules_engine.interfaces import DictionaryTermInterface
3
4 class BaseWhoDrugTerm(DictionaryTermInterface):
5
6     This class contains some common implementation
7     between all WhoDrug terms.
8     ...
9
10
11     def __init__(self, record_params: dict):
12         self.type: str = record_params["type"]
13         self.code: str = record_params["code"]
14
15     @classmethod
16     @abstractmethod
17     def from_txt_line(cls, line: str) -> "BaseWhoDrugTerm":
18         ...
```

(CDISC <https://github.com/cdisc-org/cdisc-rules-engine>)

Automated SDTM Compliant WHODrug coding output

WHODrug Global users can freely use
WHODrug KODA - AI/ML based drug coding engine

The screenshot displays the WHO Drug Koda interface. At the top, it shows the Uppsala Monitoring Centre logo and the title 'WHO Drug Koda'. Below the title, there are navigation tabs: Code, Review, Maintenance, Create Account, and Usage Statistics. On the right, it indicates 'Uploaded verbatim: 227,327' and 'Total of 42 rows'. The main table is divided into 'Reported' and 'Coded' sections. The 'Reported' section lists drug names, routes, indications, and countries. The 'Coded' section lists the drug name, ingredients, drug code, ATC code, coding path, and comments. Several rows are highlighted in yellow, indicating successful coding results.

Reported				Coded						
Verbatim	Route	Indication	Country	Id	Drug name	Ingredients	Drug code	ATC code	Coding path	Comments
Olanzapina/ Fluoxetina (Sym...					+ FLUOXETINE:OLANZAPINE	Fluoxetine;Olanzapine	12869401001	N06CA ¹	Lower certainty	
ERELSA TABLETS 50MG	Oral	VIRAEMIA			+ ERELSA	Elbasvir	08636901002	J05AP ¹	Identify form and...	
Ergenyl chrono	Transplacental	MATERNAL EXPOSURE TIMING UN...			+ ERGENYL CHRONO	Valproate sodium;Valp...	00228506012	N03AG ¹	Direct hit	
ERGOCALCIFEROL (VIT D2) 5...	Oral	VITAMIN D DEFICIENCY			+ ERGOCALCIFEROL	Ergocalciferol	00107901001	A11CC ¹	Lower certainty	
ERGOCALCIFEROL	Oral	ROUTINE HEALTH MAINTENANCE			+ ERGOCALCIFEROL	Ergocalciferol	00107901001	A11CC ¹	Direct hit	
Equate stool softener	Oral				+ EQUATE STOOL SOFTENER	Docusate sodium	00061602114	-	Direct hit	
Equetro	Unknown				+ EQUETRO	Carbamazepine	00052501262	-	Direct hit	
EQUINE THYMOCYTE IMMUN...	Intravenous (not other...	STEM CELL TRANSPLANT			+ EQUINE THYMOCYTE IMMUNE GLOBULIN	Antithymocyte immun...	00575403002	L04AA ¹	Direct hit	
AUGMENTIN	INTRAVENOUS	PREVENTION OF INFECTION DUE T...			+ AMOXICILLIN:CLAVULANIC ACID	Amoxicillin;Clavulanic ...	13759001001	J01CR ¹	Non-unique	
ZOFRAN	IV push	PRN FOR NAUSEA AND VOMITING			+ ZOFRAN [ONDANSETRON HYDROCHLORIDE]	Ondansetron hydrochl...	00955302002	A04AA ¹	Non-unique	
naphazoline (naphcon) 0.1%...	CONJUNCTIVAL	glaucoma			+ NAPHCN	Naphazoline hydrochl...	00419602009	S01GA	Identify ingredie...	
sodium fluoride (prevident 5...	DENTAL	dental caries			+ SODIUM FLUORIDE	Sodium fluoride	00168201001	A01AA	Lower certainty	
Acetylsalicylic acid	muscle	pain			+ ACETYLSALICYLIC ACID	Acetylsalicylic acid	00002701001	M02AC	Spelling suggesti...	
EPIDUBICIN HYDROCHLORI...	Intravenous drip	NON-HODGKIN'S LYM			+ EPIDUBICIN HYDROCHLORIDE	Epidubicin hydrochlori...	00699302001	L01DB ¹	Direct hit	
EPINEPHRINE/LIDOCAINE H...	Subcutaneous	ANAESTHESIA			+ EPINEPHRINE:LIDOCAINE HYDROCHLORIDE	Epinephrine;Lidocaine ...	13140406001	N01BB ¹	Identify ingredie...	

WHODrug Koda CDISC SDTM Compliant WHODrug coding output

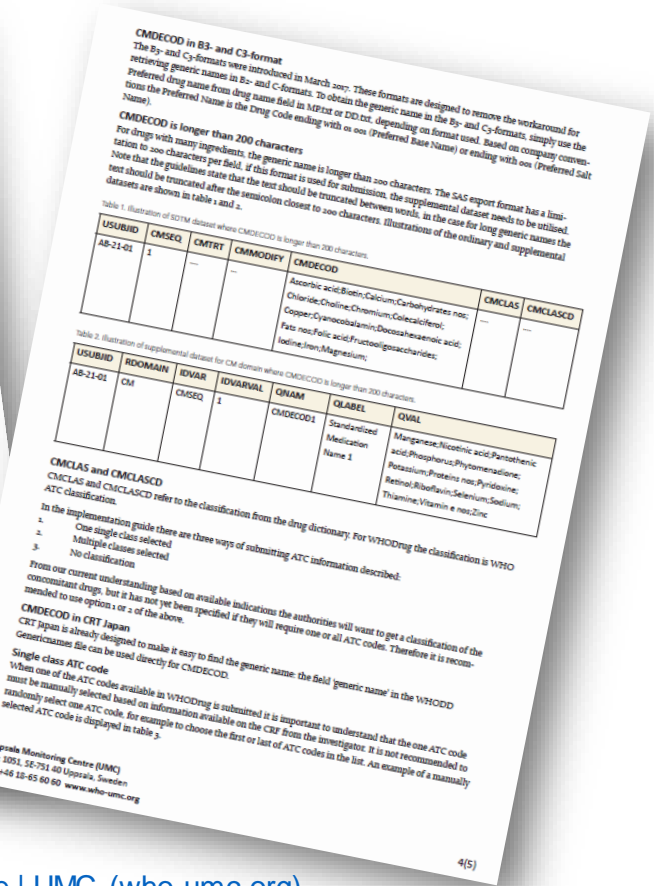
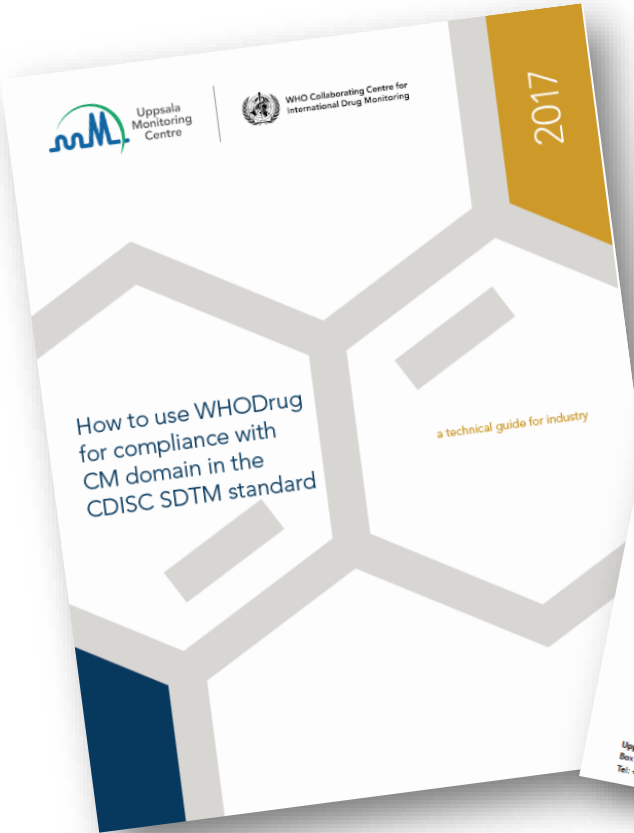
Updated testdata_export (6) Search Marilina Castellano

File Home Insert Page Layout Formulas Data

F1 Coded

CMCLAS, CMCLASCD **CMDECOD**

Coded	F	K	T	U	V	V		
Drug name	Drug code	ATC cod	ATC text	Preferred Drug name	Preferred Drug code	Preferred Base ATC codes	Available B3 format ATC texts	Coding path
4	AVEMEDIT	01707502031	N05CM Other hypnotics and sedatives	DEXMEDETOMIDINE HYDROCHLORIDE	707501001	N05CM	Other hypnotics and sedatives	Identify ingredients
5	ANESKET	00171202016	N01AX Other general anesthetics	KETAMINE HYDROCHLORIDE	171201001	N01AX	Other general anesthetics	Identify ingredients
6	LINZESS	06764201002	A06AX Other drugs for constipation	LINACLOTIDE	764201001	A06AX	Other drugs for constipation	Identify ingredients
8	TRADOL	00599202058	N02AX Other opioids	TRAMADOL HYDROCHLORIDE	599201001	N02AX	Other opioids	Identify ingredients
10	METAMIZOL SODICO	06276704235	N02BB Pyrazolones	METAMIZOLE SODIUM	276701001	N02BB	Pyrazolones	Direct hit
16	ATORVASTATINA [ATORVASTATIN]	01326101043	C10AA HMG CoA reductase inhibitors	ATORVASTATIN	326101001	C10AA	HMG CoA reductase inhibitors	Non-unique solved by
18	SALPIFAR	00020001ASX	N02BE Anilides	PARACETAMOL	020001001	N02BE	Anilides	Spelling suggestion
19	DYNASTAT	01400702003	M01AH Coxibs	PARECOXIB SODIUM	400701001	M01AH	Coxibs	Identify ingredients
20	PISAZOL	00599202873	N02AX Other opioids	TRAMADOL HYDROCHLORIDE	599201001	N02AX	Other opioids	Identify ingredients
21	CEFTRIAKONA [CEFTRIAKONE]	00672201067	J01DD Third-generation cephalosporins	CEFTRIAKONE	672201001	J01DD	Third-generation cephalosporins	Non-unique solved by
23	FUROSEMIDA [FUROSEMIDE]	00032601237	C03CA Sulfonamides, plain	FUROSEMIDE	032601001	C03CA	Sulfonamides, plain	Non-unique solved by
25	ERELSA	08636901002	J05AP Antivirals for treatment of HCV infection	ELBASVIR	636901001	J05AP	Antivirals for treatment of HCV infections	Identify form and strength
26	ERGENYL CHRONO	00228506012	N03AG Fatty acid derivatives	VALPROATE SODIUM;VALPROIC ACID	228501001	N03AG	Fatty acid derivatives	Direct hit
28	ERGOCALCIFEROL	00107901001	A11CC Vitamin D and analogues	ERGOCALCIFEROL	107901001	A11CC	Vitamin D and analogues	Direct hit
31	EQUINE THYMOCYTE IMMUNE GLOBULIN	00575403002	L04AA Selective immunosuppressants	ANTITHYMOCYTE IMMUNOGLOBULIN (HORSE)	575401001	L04AA	Selective immunosuppressants	Direct hit
32	AMOXICILIN;CLAVULANIC ACID	13759001001	J01CR Combinations of penicillins, incl. beta-lactamase inhibitors	AMOXICILIN;CLAVULANIC ACID	759001001	J01CR	Combinations of penicillins, incl. beta-lactamase inhibitors	Non-unique solved by
33	ZOFIRAN [ONDANSETRON HYDROCHLORIDE]	00955302002	A04AA Serotonin (5HT3) antagonists	ONDANSETRON HYDROCHLORIDE	955301001	A04AA	Serotonin (5HT3) antagonists	Non-unique solved by
34	NAPHCON	00419602009	S01GA Sympathomimetics used as decongestants	NAPHAZOLINE HYDROCHLORIDE	419601001	S01GA	Sympathomimetics used as decongestants	Identify ingredients
36	ACETYSALICYLIC ACID	00002701001	M02AC Preparations with salicylic acid derivatives	ACETYSALICYLIC ACID	002701001	M02AC	Salicylic acid and derivatives	Spelling suggestion
37	EPIRUBICIN HYDROCHLORIDE	06699302001	L01DB Anthracyclines and related substances	EPIRUBICIN HYDROCHLORIDE	699301001	L01DB	Anthracyclines and related substances	Direct hit
38	EPINEPHRINE;LIDOCAINE HYDROCHLORIDE	13140406001	N01BB Amides	EPINEPHRINE;LIDOCAINE HYDROCHLORIDE	140401001	N01BB	Amides	Identify ingredients
40	EPIRUBICIN HCL	06699302143	L01DB Anthracyclines and related substances	EPIRUBICIN HYDROCHLORIDE	699301001	L01DB	Anthracyclines and related substances	Direct hit
41	CLINDAMYCIN MIP [CLINDAMYCIN HYDROCHLORIDE]	00166002164	J01FF Lincosamides	CLINDAMYCIN HYDROCHLORIDE	166001001	J01FF	Lincosamides	Non-unique solved by
47	DICILLIN [DICLOXACILLIN SODIUM MONOHYDRATE]	00063302015	J01CF Beta-lactamase resistant penicillins	DICLOXACILLIN SODIUM MONOHYDRATE	063301001	J01CF	Beta-lactamase resistant penicillins	Non-unique solved by
48	AIRCORT [BECLOMETASONE DIPROPIONATE]	00212602337	C05AA Corticosteroids	BECLOMETASONE DIPROPIONATE	0212601001	R03BA	Corticosteroids	Non-unique solved by

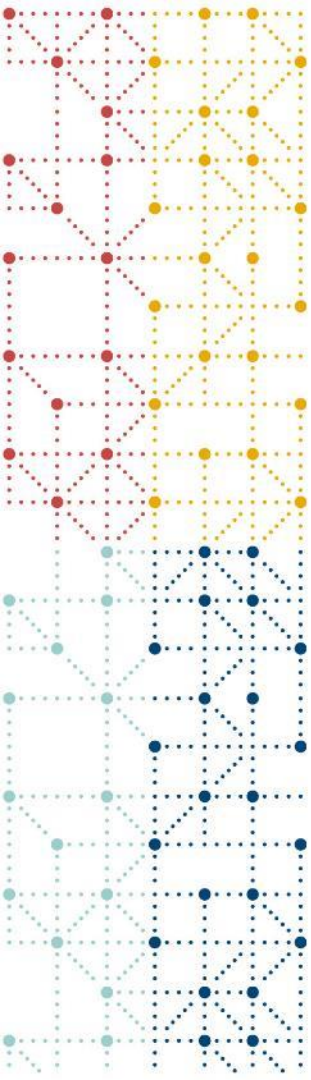


[Uppsala Monitoring Centre | UMC \(who-umc.org\)](http://Uppsala Monitoring Centre | UMC (who-umc.org))



References (as of 20240418)

- 1) [Notification on Handling of Submission of Electronic Study Data for New Drug Applications \(Provisional Translation\), PMDA](#) (translation as of Jun 2022)
- 2) [PMDA Data Standards Catalog, PMDA](#) (last updated Mar 2024)
- 3) [FAQs on Electronic Study Data Submission](#) (last updated April 2024)
- 4) [Notice in the Federal register, U.S FDA, Vol. 82, No. 204, October 24, 2017](#)
- 5) [Data Standards Catalog, U.S. FDA, v. 10.3](#) (last updated Apr 2024)
- 6) [Study Data Technical Conformance Guide, U.S. FDA, v. 5.7](#) (last updated Mar 2024)
- 7) [Study Data Tabulation Model Implementation Guide \(SDTMIG\), CDISC, v. 3.4](#) (last updated Nov 2021, *requires CDISC account for access*)
- 8) [FDA Validator Rules, U.S. FDA, v. 1.6](#) (last updated Dec 2022)
- 9) [Guidelines for submission of clinical trial data, NMPA](#) (last updated Jul 2020)



Thank You!

cdisc