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2023
KOREA
INTERCHANGE
SEOUL | 11-14 DECEMBER

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

Sohye Yoon, Uppsala Monitoring Centre

Meet the Speaker

Sohye Yoon

Title: Product Manager

Organization: Uppsala Monitoring Centre

Sohye Yoon is a Product manager at Uppsala Monitoring Centre. She has a bachelor's degree in Pharmacy from Ewha Women's University and a master's degree in Public Health Sciences from the Karolinska Institute. She joined UMC in 2018 as a Terminology Specialist and now works with the WHODrug Portfolio, which provides standardized drug information for clinical trials and pharmacovigilance.

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?

THALIDOMIDE AND CONGENITAL ABNORMALITIES

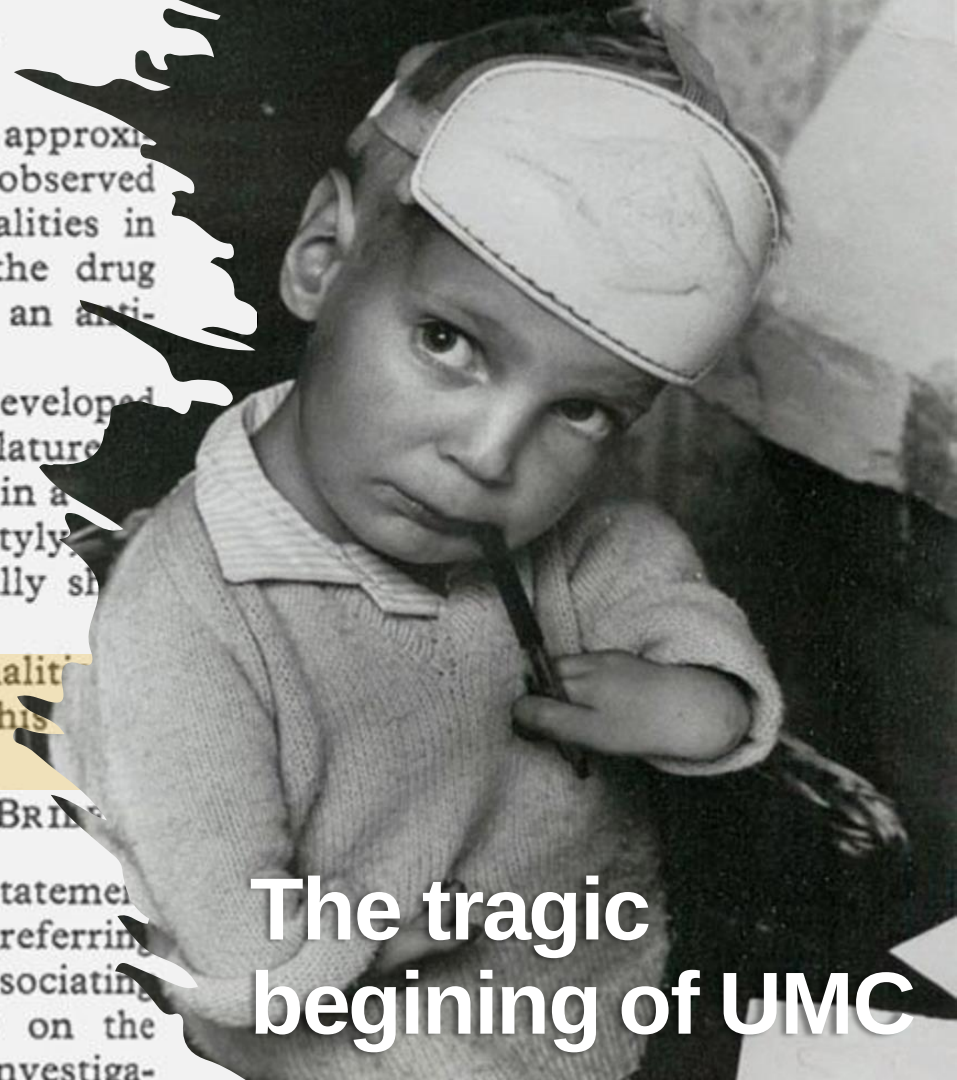
SIR,—Congenital abnormalities are present in approxi-mately 1·5% of babies. In recent months I have observed that the incidence of multiple severe abnormalities in babies delivered of women who were given the drug thalidomide (' Distaval ') during pregnancy, as an anti-emetic or as a sedative, to be almost 20%.

These abnormalities are present in structures develope from mesenchyme—i.e., the bones and musculature the gut. Bony development seems to be affected in a striking manner, resulting in polydactyly, syndactyly failure of development of long bones (abnormally sh femora and radii).

Have any of your readers seen similar abnormaliti babies delivered of women who have taken this during pregnancy?

Hurstville, New South Wales. W. G. McBRI

*** In our issue of Dec. 2 we included a statemen from the Distillers Company (Biochemicals) Ltd. referrin to " reports from two overseas sources possibly associatin thalidomide (' Distaval ') with harmful effects on the fœtus in early pregnancy ". Pending further investiga-



The tragic begining of UMC

Uppsala Monitoring Centre

- 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

WHO Programme of International Drug Monitoring

2023

156 Full members

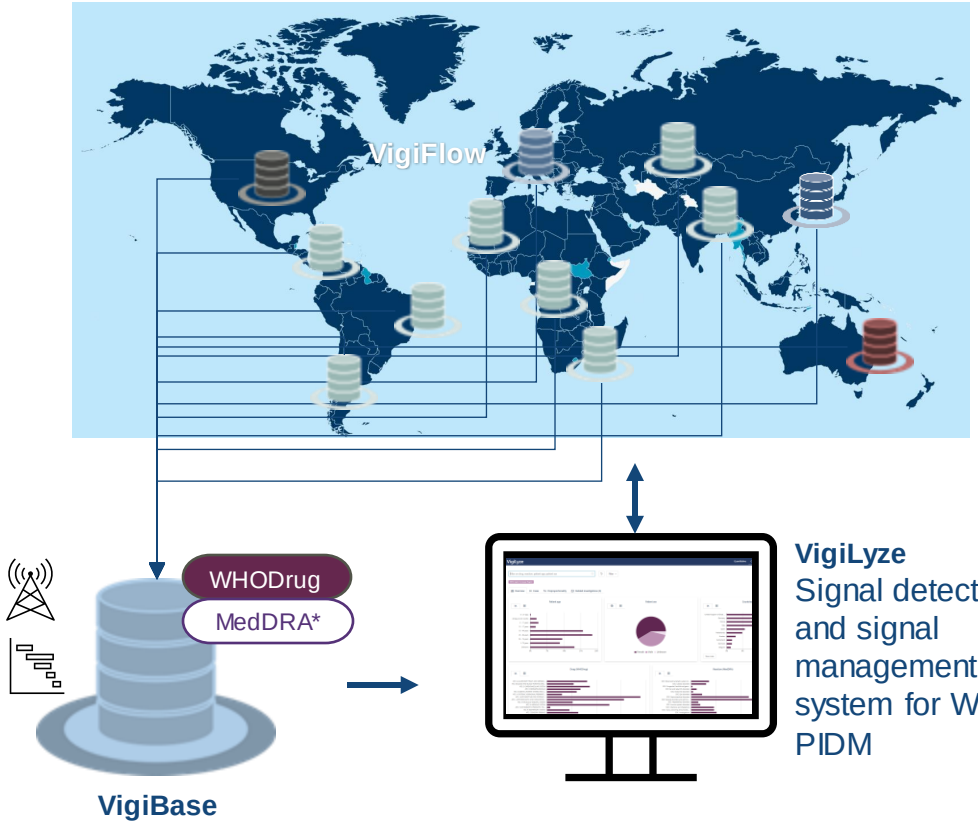
22 Associate members

Non-member

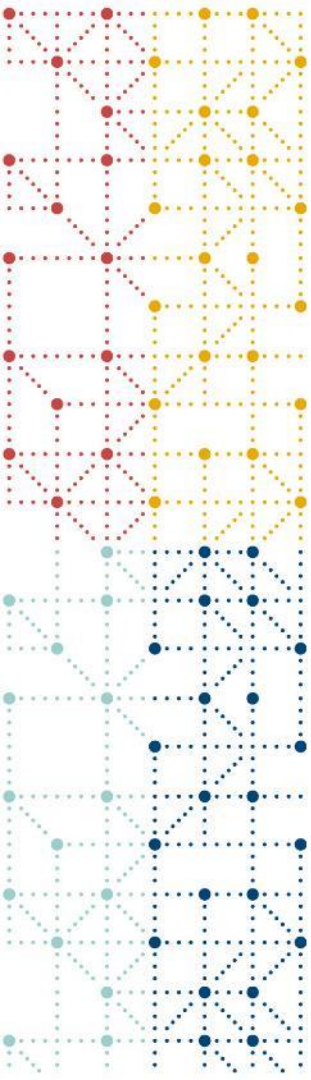
Covers > 99% of world population

VigiBase

- Global database of ADRs and AEFIs
- **>36 million cases globally collected** (7 mil. for vaccines) from 156 PIDM members
- Supports national analysis, regional collaborations and global referencing
- Complements statistical signal detection and method development
- Provides structured and coded data

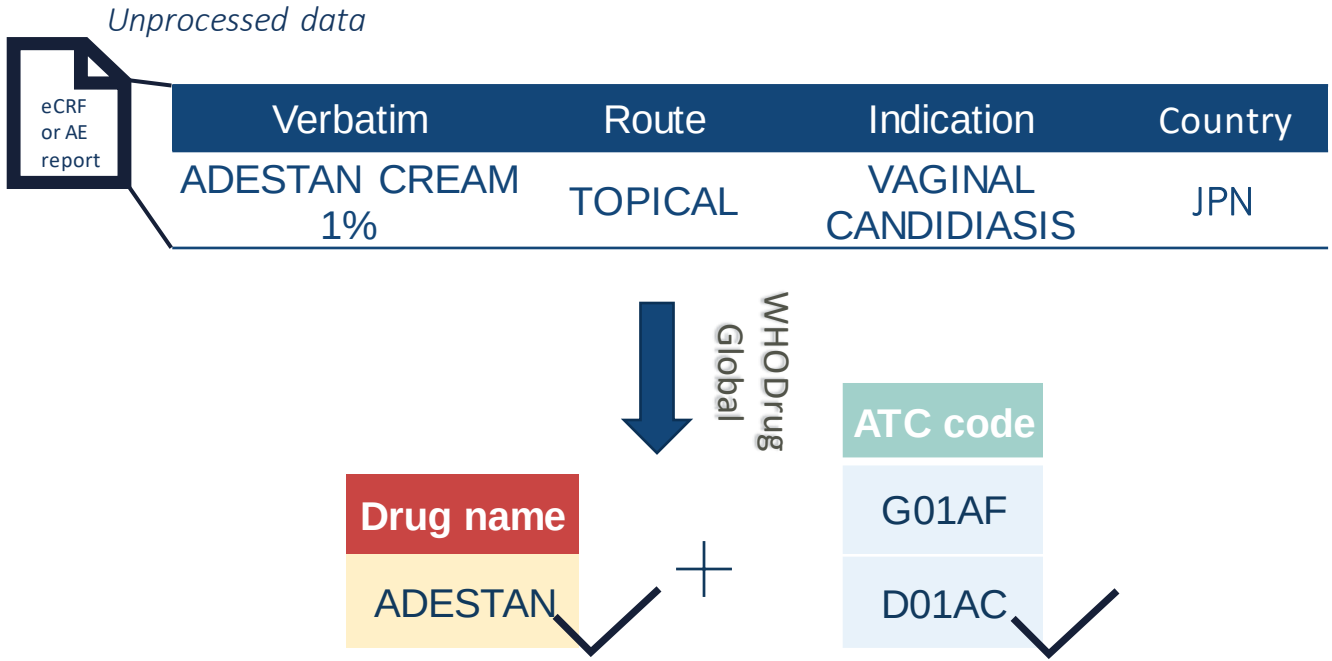


*__MedDRA__: Medical Dictionary for Regulatory Activities

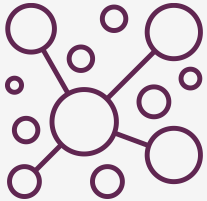


Introducing WHODrug Global

Standardizing drug information with medical coding…

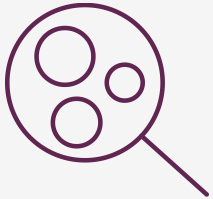


…allows for data aggregation and analysis…



Analysis on **different levels of precision**

Group by ATC based on the **labelled indication**



Group medicines with **similar properties**

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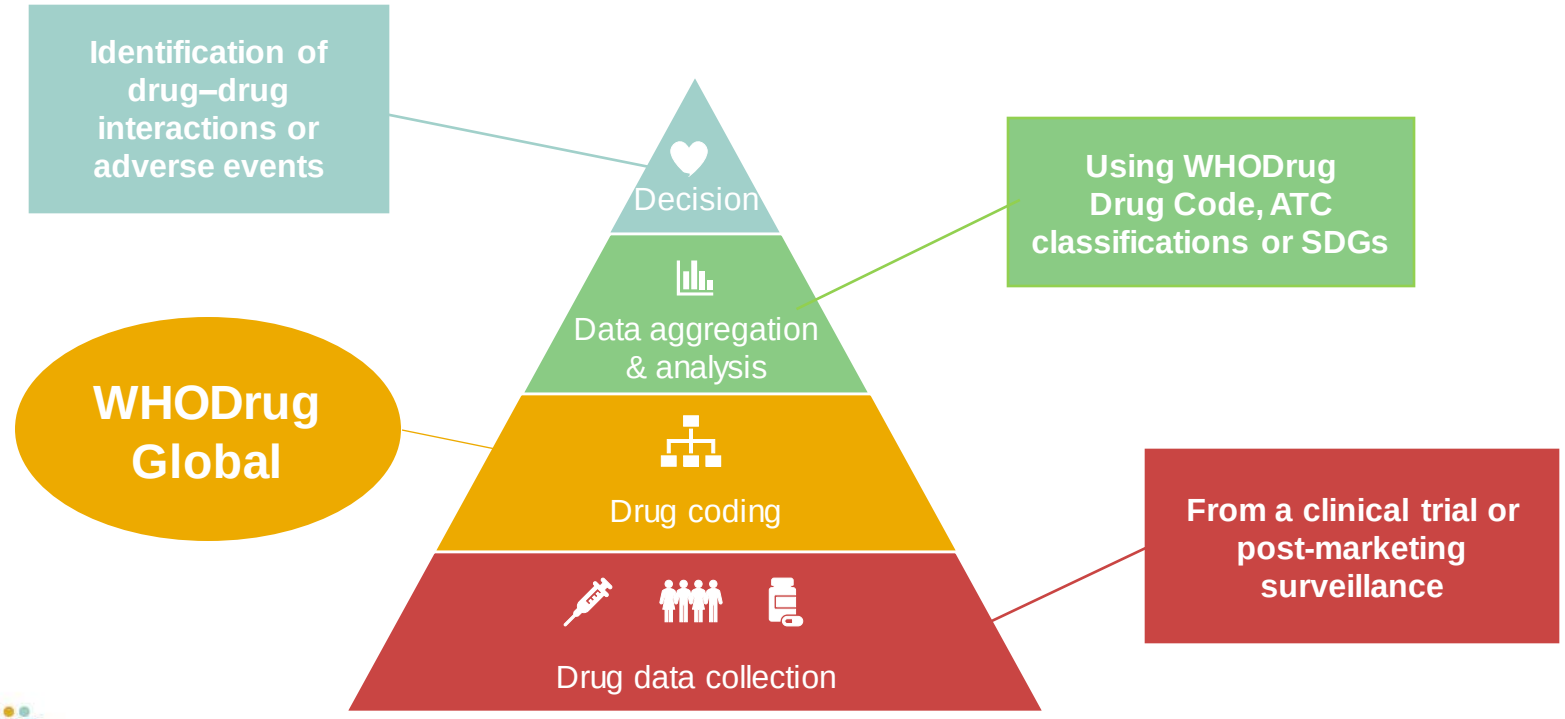
…and promotes safer use of medicines and vaccines!



Examples of use cases for WHODrug Global

- **Pre-marketing**
  - Coding of concomitant medications in clinical trials (via CDISC SDTM)
  - Use of WHODrug Global mandated by U.S. FDA and Japan's PMDA
- **Post-marketing**
  - ICSR Reporting in E2B(R3)
  - Patient reporting
  - National PV Surveillance Systems
  - Vaccine Surveillance

Who uses WHODrug Global?

- **Requested by industry and regulators**
  - Used by > 3000 industry organisations for identification and analysis of pre- and post-marketing safety data
  - Used by members of the WHO Programme for International Drug Monitoring

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WHODrug Global – Coverage

621 570 drug names from 171 countries

In the September 1, 2023 release of WHODrug Global

WHODrug Global dictionary includes:

- Continually updated information
- A hierarchical information structure
- Standardised and harmonized drug names
- Drug classifications
- Validated drug information
- Information in several languages

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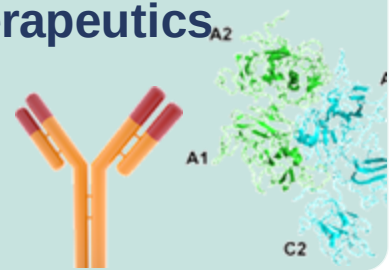
Types of medicines in WHODrug

Conventional medicines

Vaccines

Herbal medicines

Biotherapeutics



Traditional medicines

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Information in WHODrug

DRUG NAME

ACTIVE INGREDIENT

ATC CLASSIFICATION

DRUG CODE

COUNTRY OF SALE

MAH

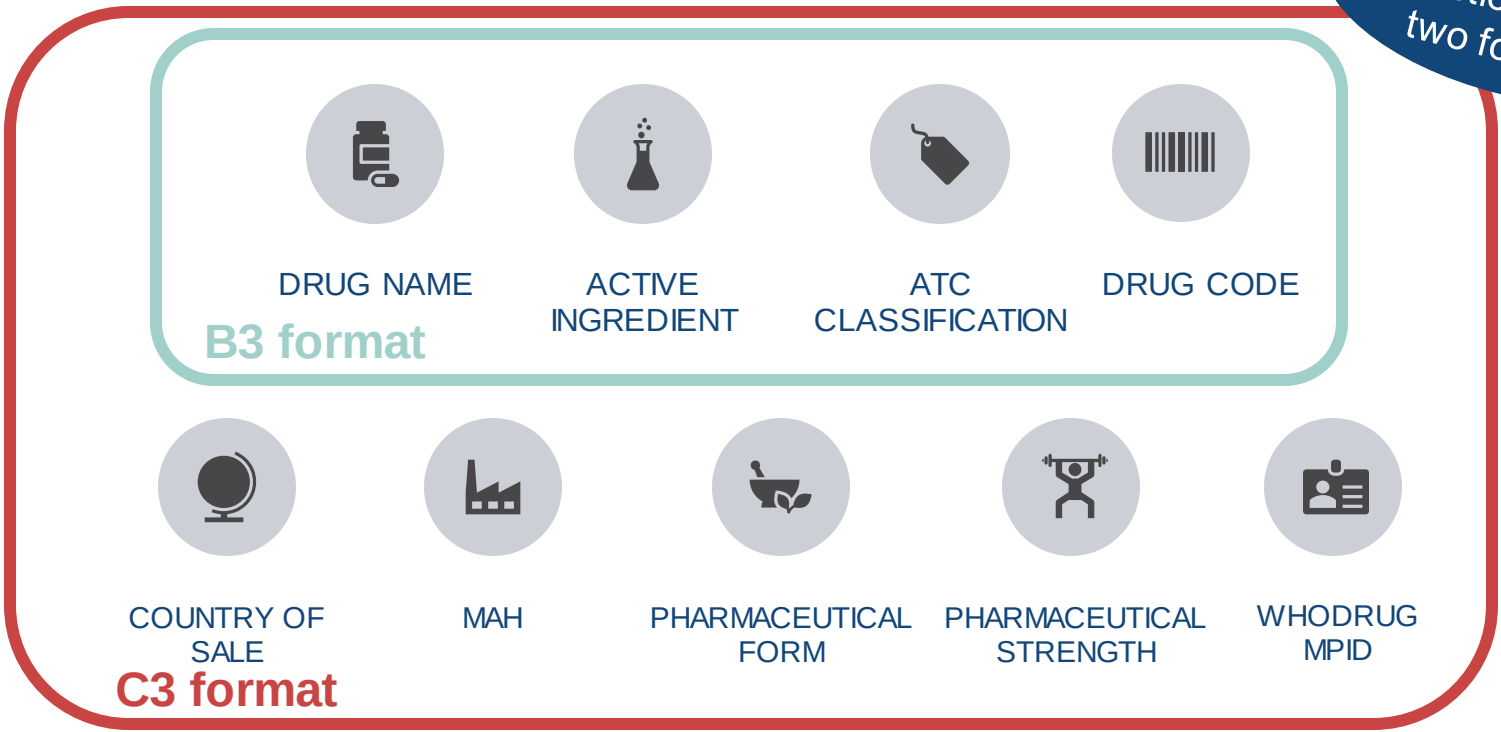
PHARMACEUTICAL FORM

PHARMACEUTICAL STRENGTH

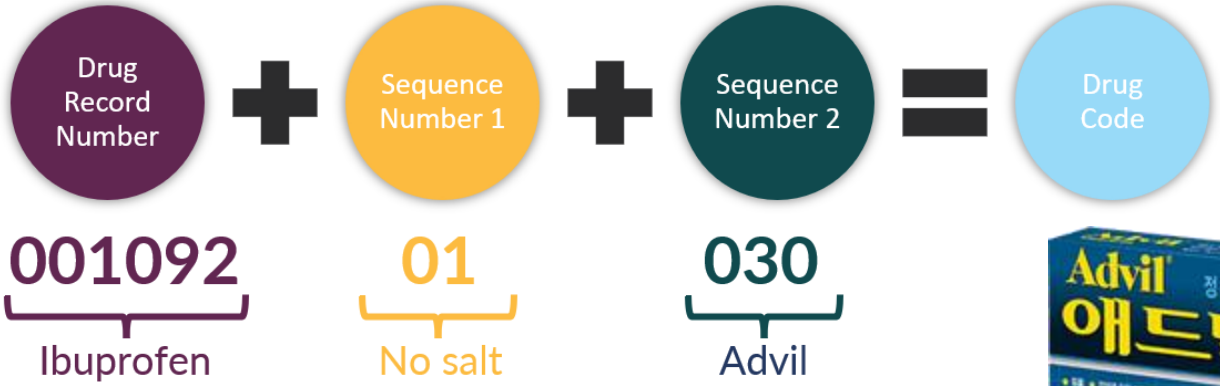
WHODRUG MPID

WHODrug Formats

One dictionary – two formats

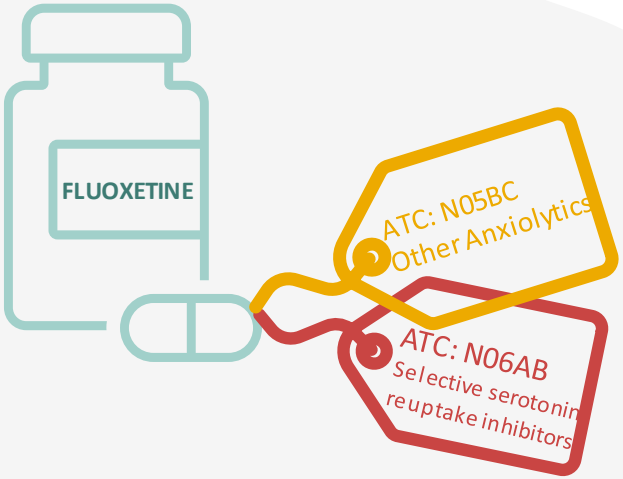


Drug code in WHODrug



ATC in WHODrug

- Used to classify medications according to their **intended use**
- All drugs in WHODrug are assigned at least one ATC code
- All records are preferably assigned ATC codes on the 4th level
- Allows for aggregation of similar drugs



WHODrug Global Chinese

- ✓ Drug names, active substance(s), ATC code text, country and pharmaceutical form are shown in Chinese for drugs approved in China
- ✓ All Chinese records have an equivalent English drug name in WHODrug Global connected by the drug code
- ✓ Simplifies coding and regulatory submission both inside and outside China

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

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CDISC and WHODrug Global

Meeting regulatory expectations with WHODrug

Regulatory expectations for WHODrug Global

- Regulatory expectations for the use WHODrug Global is present in several countries, as standardised medicinal product data enables safety analysis and identification of drug-related problems and the consequent development of safer medicines
  - Used in clinical trials to submit standardised drug information about concomitant medications in SDTM CDISC compliant data sets when submitting NDAs
  - Used to code drug information in ICSRs and AEFIs for post-marketing surveillance

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Japan, PMDA – Notification on Handling of Submission of Electronic Study Data for New Drug Applications [1]

エ　推奨される統制用語、辞書及び単位について
申請電子データを作成する際、CDISC において推奨される統制用語、事

d. Controlled terminology, dictionaries and units that are recommended

When preparing electronic study data, encoded information must also be included for data that can be encoded using the controlled terminology recommended by the CDISC, MedDRA for events, and WHODrug Global for drugs. The values are to be in SI units, in principle.

Please refer to the PMDA's website (https://www.pmda.go.jp/) for the list of acceptable codes.

象については MedDRA、薬剤については WHODrug Global を使用してコード化が可能なデータについては、コード化された情報も含めること。また、単位については SI 単位を使用することを原則とする。
使用可能なコードのリストについては、PMDA のウェブサイト（https://www.pmda.go.jp/）を参照すること。

Japan, PMDA – Data Standards Catalog[2]

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		

Japan, PMDA – FAQs on Electronic Study Data Submission[3]

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

U.S., FDA – Notice in the Federal Register[4]

Federal Register / Vol. 82, No. 204 / Tuesday, October 24, 2017 / Notices 49211

I. Background

On December 17, 2014, FDA published a final guidance for industry entitled "Providing Regulatory Submissions in Electronic Format—Standardized Study Data" (eStudy Data Guidance), posted on FDA's Study Data Standards Resources Web page at *https://www.fda.gov/forindustry/datastandards/studydatastandards/default.htm*. The eStudy Data Guidance implements the electronic submission requirements of section 745A(a) of the Federal Food, Drug, and Cosmetic Act for study data contained in NDAs, ANDAs, BLAs, and certain INDs to CBER or CDER by specifying the format for electronic submissions. The initial timetable for the implementation of electronic submission requirements for study data was December 17, 2016 (24 months after issuance of final guidance for NDAs, BLAs, ANDAs, and 36 months for INDs). The eStudy Data guidance states that a **Federal Register** notice will specify the transition date for all version updates (with the month and day for the transition date corresponding to March 15).

FDA currently supports the use of WHODG for the coding of concomitant medications in studies submitted to CBER or CDER in NDAs, ANDAs, BLAs, and certain INDs in the electronic common technical document format. Generally, the studies included in a submission are conducted over many years and may have used different WHODG versions to code concomitant medications. The expectation is that sponsors and applicants will use the most current B3-format annual version of WHODG at the time of study start. However, there is no requirement to recode earlier studies. The transition date for support of the most current B3-format annual version of WHODG is March 15, 2018. Although the use of the current B3-format annual version of WHODG is supported as of this **Federal Register** notice and sponsors or applicants are encouraged to begin using it, the use of the most current B3-format annual version will only be required in submissions for studies that start after March 15, 2019. The Catalog will list March 15, 2019, as the "date requirement begins." The Study Data Technical Conformance Guide provides addition information and recommendations on the coding of concomitant medications (*https://www.fda.gov/downloads/forindustry/*

be updated to list March 15, 2019, as the "date support ends." Studies that start after March 15, 2019, will be required to use the most current B3-format annual version of WHODG.

Dated: October 18, 2017.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2017–23029 Filed 10–23–17; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2011–N–0278]

Trand Doan Nguyen; Denial of Hearing; Final Debarment Order

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is denying Trang Doan Nguyen's (Nguyen's) request for a hearing and is issuing an order under the Federal Food, Drug, and Cosmetic Act (the FD&C Act) debarring Nguyen for 5 years from providing services in any capacity to a person that has an approved or pending drug product application. FDA bases this order on a finding that Nguyen was convicted of a misdemeanor under Federal law for conduct relating to the development or approval of a drug product or otherwise relating the regulation of a drug product under the FD&C Act and that the type of conduct underlying the conviction undermines the process for the regulation of drugs. In determining the appropriateness and period of Nguyen's debarment, FDA has considered the relevant factors listed in the FD&C Act. Nguyen has failed to file with the Agency information and analyses sufficient to create a basis for a hearing concerning this action.

DATES: The order is effective October 24, 2017.

ADDRESSES: Any application by Nguyen for special termination of debarment under section 306(d) of the FD&C Act (application) may be submitted as follows:

Electronic Submissions

• *Federal eRulemaking Portal:* *https://www.regulations.gov*. [illegible] the instructions for sub[illegible]

solely responsible for ensuring that your application does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your application, that information will be posted on *https://www.regulations.gov*.

• If you want to submit an application with confidential information that you do not wish to be made available to the public, submit the application as a written/paper submission and in the manner detailed (see "Written/Paper Submissions" and "Instructions").

Written/Paper Submissions

Submit written/paper submissions as follows:

• *Mail/Hand delivery/Courier (for written/paper submissions):* Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

• For a written/paper application submitted to the Dockets Management Staff, FDA will post your application, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in "Instructions."

Instructions: Your application must include the Docket No. FDA–2011–N–0278. An application will be placed in the docket and, unless submitted as "Confidential Submissions," publicly viewable at *https://www.regulations.gov* or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday.

• Confidential Submissions—To submit an application with confidential information that you do not wish to be made publicly available, submit your application only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states "THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION." The Agency will review this copy, including the claimed confidential information, in its consideration of your application. The second copy, which will have the claimed confidential information [illegible] redacted/blacked out, will be available [illegible] public viewing and posted on [illegible]

"The expectation is that sponsors and applicants will use the most current B3-format annual version of WHODG at the time of study start."

"…the use of the current B3-format annual version of WHODrug is supported as of this Federal Register notice and sponsors or applicants are encouraged to begin using it"

"…the use of the most current B3-format annual version will only be required in submissions for studies that start after March 15, 2019."

U.S., FDA – Data Standards Catalog[5]

FDA Data Standards Catalog v10.1 - 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] [11]	Date Requirement Ends	Examples of Use	Statutory, Regulatory, or Guidance Authority Sources	Statutory, Regulatory, or Guidance Authority Sources	Information Sources	Information Sources
Medication	WHODrug Global	UMC	Current Version-B3 format	CBER, CDER	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

Date Requirement Begins [10] [11]

03/15/2019

Examples of Use

Use in SDTM CMDECOD and CMCLAS

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U.S., FDA – Study Data Technical Conformance Guide[6]

6.4.2 WHODrug Global

6.4.2.1 General Considerations

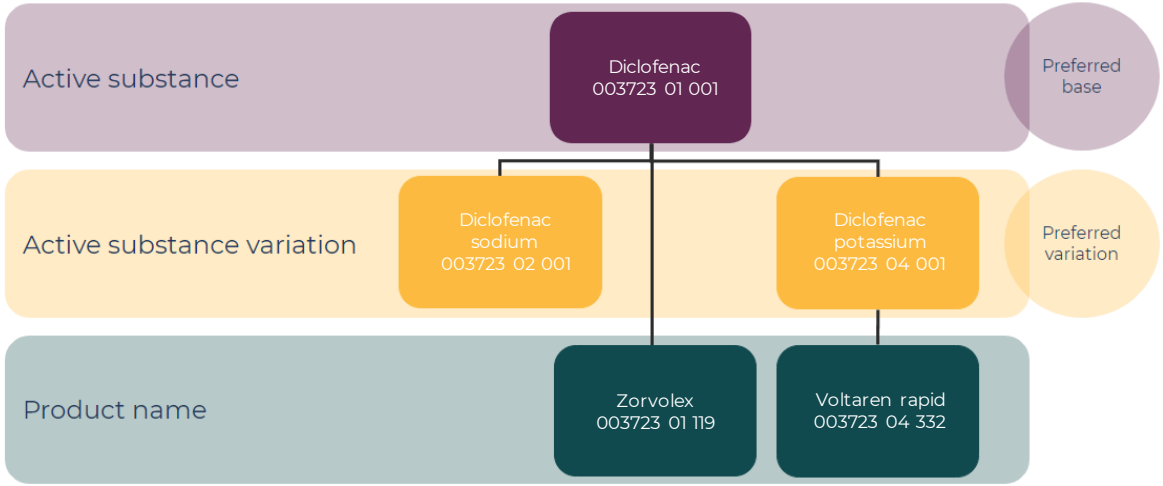
World Health Organization (WHO) Drug Global[61] is a dictionary maintained and updated by Uppsala Monitoring Centre. WHODrug Global contains unique product codes for identifying drug names and listing of medicinal product information, including active ingredients and therapeutic uses.

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.

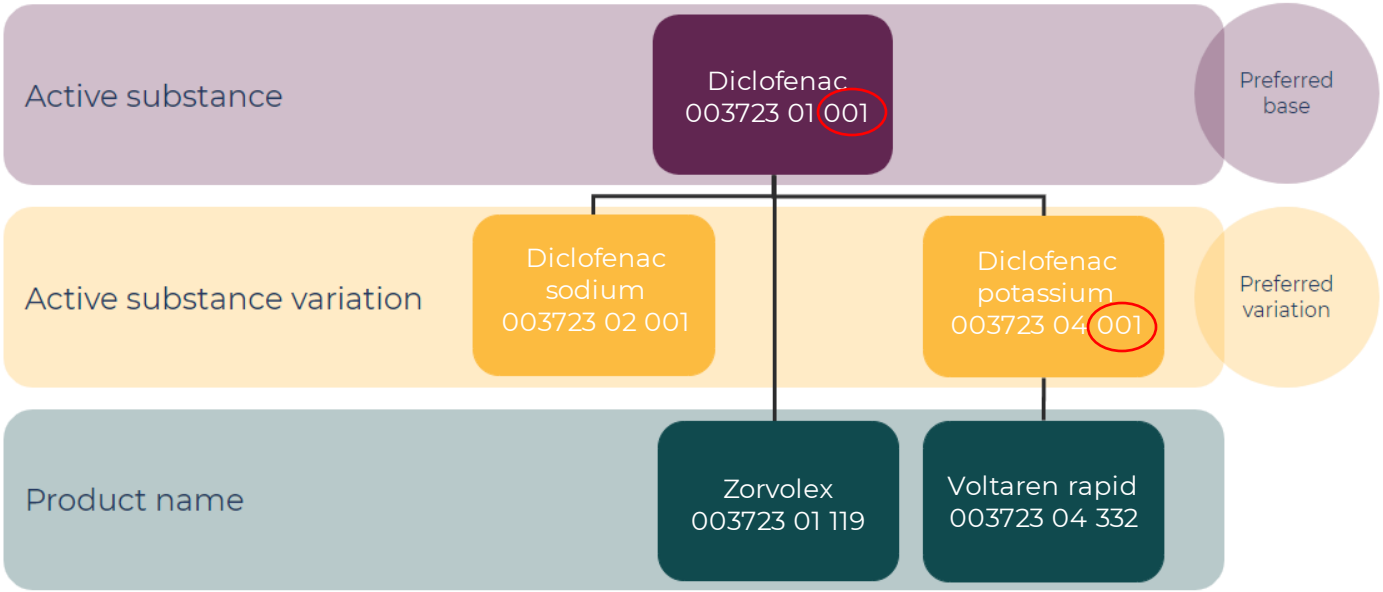
When using WHODrug Global, --CLAS is recommended to be populated with the Anatomic Therapeutic Chemical (ATC) class most suitable per intended use, and the remainder of the ATC classes, if any, placed in SUPPCM. Alternately, the use of the SUPPCM or FACM domains to populate all ATC Classes associated 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.

CMDECOD



- 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
- Can be retrieved from DD(B3 format) file or MP(C3 format) file


Active substance
Diclofenac
003723 01 001
Preferred base
Active substance variation
Diclofenac sodium
003723 02 001
Diclofenac potassium
003723 04 001
Preferred variation
Product name
Zorvolex
003723 01 119
Voltaren rapid
003723 04 332


Zorvolex
(diclofenac) capsules
18 mg
90 Capsules
IROKO


Voltaren
Rapid 12.5
PHARMACY MEDICINE
Voltaren
Rapid 12.5
Diclofenac potassium 12.5 mg
Back and Muscle Pain Relief
gsk
20 Tablets

CMDECOD longer than 200 characters

- For drugs with many ingredients, the generic name in WHODrug can be longer than 200 characters
- Supplemental dataset needs to be utilized in this scenario
- SDTMIG v. 3.4 states that the text **should be truncated between words** (4.5.3.2 Text Strings Greater than 200 Characters in Other Variables)
  - "Semicolons separate ingredients so text should be truncated after semicolon closest to 200 characters to improve readability"

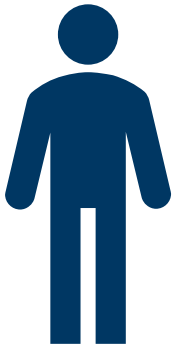
Table 1. Illustration of SDTM dataset where CMDECOD is longer than 200 characters.

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



+

Myocardial infarction

A01AD, Other agents for local oral treatment

B01AC, Platelet aggregation inhibitors excl. heparin

M02AC, Preparations with salicylic acid derivatives

N02BA, Salicylic acid and derivatives official

For example,

- EGTESTCD = "SPRTARRY", EGTEST = "Supraventricular Tachyarrhythmias", EGORRES = "ATRIAL FIBRILLATION"
- EGTESTCD = "SPRTARRY", EGTEST = "Supraventricular Tachyarrhythmias", EGORRES = "ATRIAL FLUTTER"

When a finding can have multiple results, the key structure for the findings dataset must be adequate to distinguish between the multiple results. See Section 4.1.9, Assigning Natural Keys in the Metadata.

4.2.8.3 Multiple Values for a Non-result Qualifier Variable

The SDTM permits 1 value for each qualifier variable per record. If multiple values exist (e.g., due to a "Check all that apply" instruction on a CRF), then the value for the qualifier variable should be "MULTIPLE" and SUPP-- should be used to store the individual responses. It is recommended that the SUPP-- QNAM value reference the corresponding standard domain variable with an appended number or letter. In some cases, the standard variable name will be shortened to meet the 8-character variable name requirement, or it may be clearer to append a meaningful character string as shown in the second Adverse Events (AE) example below, where the first 3 characters of the drug name are appended. Likewise, the QLABEL value should be similar to the standard label. The values stored in QVAL should be consistent with the controlled terminology associated with the standard variable. See Section 8.4, Relating Non-standard Variable Values to a Parent Domain, for additional guidance on maintaining appropriately unique QNAM values.

The following example includes selected variables from the ae.xpt and suppae.xpt datasets for a rash with locations on the face, neck, and chest.

ae.xpt

AETERM	AELOC
RASH	MULTIPLE

suppae.xpt

QNAM	QLABEL	QVAL
AELOC1	Location of the Reaction 1	FACE
AELOC2	Location of the Reaction 2	NECK
AELOC3	Location of the Reaction 3	CHEST

In some cases, values for QNAM and QLABEL more specific than these may be needed.

For example, a sponsor might conduct a study with 2 study drugs (e.g., open-label study of Abcicin + Xyzamin), and may require the investigator assess causality and describe action taken for each drug for the rash:

ae.xpt

AETERM	AEREL	AEACN
RASH	MULTIPLE	MULTIPLE

suppae.xpt

QNAM	QLABEL	QVAL
AERELABC	Causality of Abcicin	POSSIBLY RELATED
AERELXYZ	Causality of Xyzamin	UNLIKELY RELATED
AEACNABC	Action Taken with Abcicin	DOSE REDUCED
AEACNXYZ	Action Taken with Xyzamin	DOSE NOT CHANGED

In each of these examples, the use of SUPPAE should be documented in the Define-XML document and the annotated CRF. The controlled terminology used should be documented as part of value-level metadata.

If the sponsor has clearly documented that one response is of primary interest (e.g., in the CRF, protocol, or analysis plan), the standard domain variable may be populated with the primary response and SUPP-- may be used to store the secondary response(s).

For example, if Abcicin is designated as the primary study drug in the example above:

ae.xpt

AETERM	AEREL	AEACN
RASH	POSSIBLY RELATED	DOSE REDUCED

The SDTM permits one value for each Qualifier variable per record. If multiple values exist (e.g., due to a "Check all that apply" instruction on a CRF), then the value for the Qualifier variable should be "MULTIPLE" and SUPP-- should be used to store the individual responses.

If the sponsor has clearly documented that one response is of primary interest (e.g., in the CRF, protocol, or analysis plan), the standard domain variable may be populated with the primary response and SUPP-- may be used to store the secondary response(s).

USUBJID	CMSEQ	CMTRT	CMMODIFY	CMDECOD	CMCLAS	CMCLASCD
AB-21-01	1	Aspirin protect	Aspirin protect	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
…	…	…	…	…	…	…

U.S., FDA – Validator rules[8]

version 1.6, finalized December 2022

FDA Validator Rule ID	Publisher	Publisher ID	FDA Validator Rule Message	FDA Validator Rule Description	Domains
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.	CM
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.	CM
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.	CM

FDAB017	Controlled terms should use the exact term (case, spelling, and punctuation) used by the terminology maintenance organizations (e.g., MedDRA, CDISC controlled terminology).

China, NMPA - Guidelines for submission of clinical trial data[9]

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。

Provisional translation:

In order to meet the data submission requirements, collected data may be required to be standardized or coded

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

China, NMPA - Guidelines for submission of clinical trial data[9]

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:

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

WHODrug Global Chinese allows for retrieval of applicable drug information in Chinese language

Supporting data submission in dual languages

REPORTED TERM

VFEND

CODED DRUG NAME IN WHODRUG GLOBAL

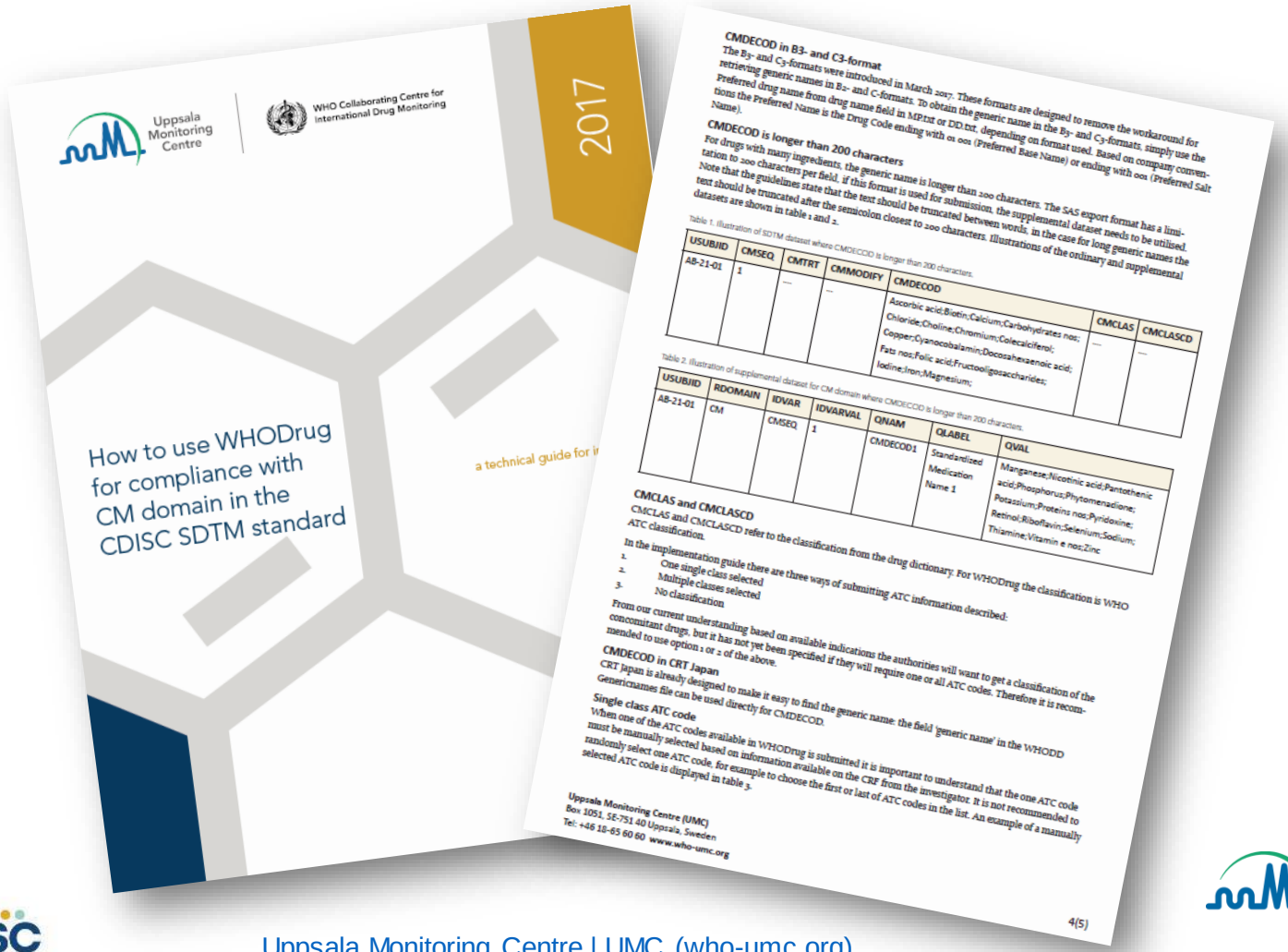
DRUG NAME	ACTIVE INGREDIENT	ATC CODE/TEXT	DRUG CODE
VFEND	Voriconazole	J02AC, Triazole derivatives	01510101002

DRUG NAME	ACTIVE INGREDIENT	ATC CODE/TEXT	DRUG CODE	DRUG NAME	ACTIVE INGREDIENT	ATC CODE/TEXT
威凡	伏立康唑	J02AC, 三唑衍生物	01510101002	VFEND	Voriconazole	J02AC, Triazole derivatives

SDTM compatible output in Chinese

SDTM compatible output in English

cdisc



cdisc

Uppsala Monitoring Centre

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

Thank You!

References

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 Feb 2023)
3) FAQs on Electronic Study Data Submission (as of Oct 2023)
4) Notice in the Federal register, U.S FDA, Vol. 82, No. 204,October 24, 2017
5) Data Standards Catalog, U.S. FDA, v. 10.1 (last updated Oct 2023)
6) Study Data Technical Conformance Guide, U.S. FDA, v. 5.5 (last updated Oct 2023)
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)