



WHODrug

-Lihua Liu, 06Dec2024



Meet the Speaker

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Lihua, Liu is a Principle Statistical programmers with 9+ years of experience in Pharmaceutical industry, currently, he is working for ICON to support the J&J Innovative Medicine FLEX program, to mainly support the Oncology Therapeutic Area projects. At the same time, he has also played a key leading role in NMPA eSub SME initiative, to driven the process and tool development of NMPA data package submission.



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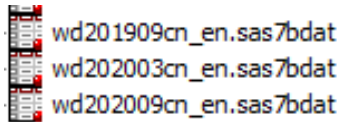
Agenda

- Background
- How to understand information stored in WHODrug
- Timeline of Dictionary formats
- Differences between B2/C formats & B3/C3 formats
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Background

- contains information about world-wide medicinal products intended for human use, their active substances, and relevant classifications and groupings
- used to structure and analyze clinical trial and post-marketing safety data
- updated by Uppsala Monitoring Centre (UMC) on a regular basis and released twice per year



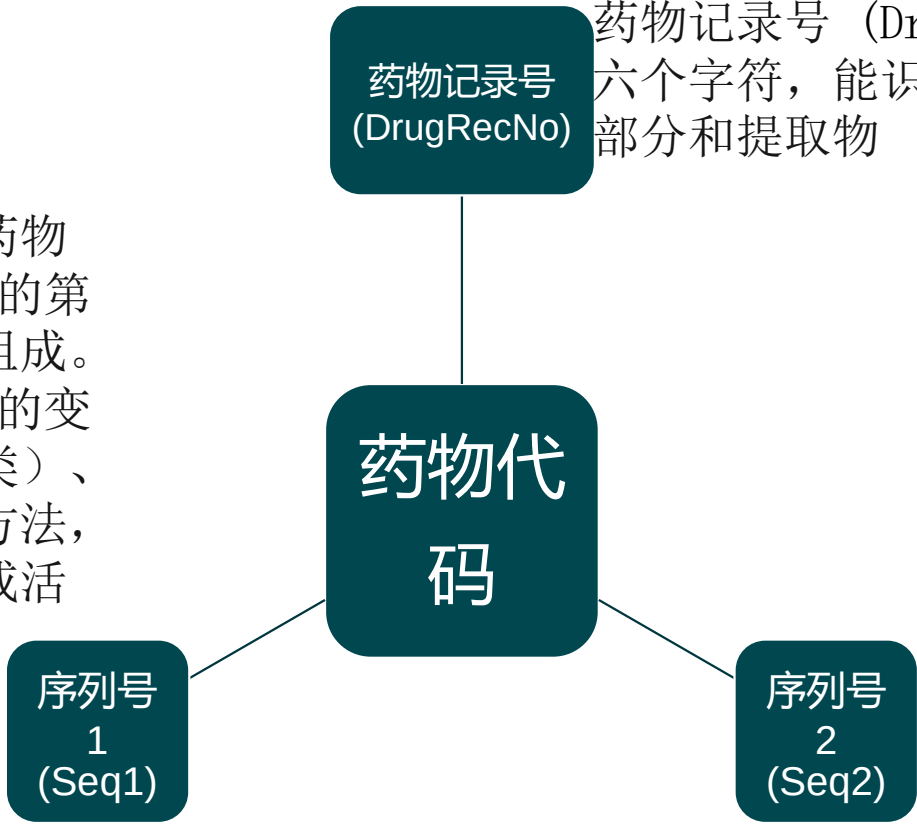
- the following types of data records are available in WHODrug:
 - Trade names
 - Active substances (bases and salt variations thereof)
 - Records representing defined groups of active substances and trade names (i.e. Umbrella Records).



How to understand information stored in WHODrug

药物代码 (Drug Code) - SUPPCM.CMTRDCD(non-standard)

序列号1 (Seq1) 是药物代码 (Drug Code) 的第二部分由两个字符组成。Seq1 用于标识不同的变体 (例如盐类和酯类)、植物的部分和提取方法, 从而定义活性物质或活性物质的组合



药物记录号 (DrugRecNo) 是药物代码的第一部分。它包括六个字符, 能识别活性部分, 不论是盐的形式还是植物的部分和提取物

序列号2 (Seq2) 是药物代码的第三部分, 由三个字符组成。Seq2 标识记录名称

首选名称 (Preferred Name) – CM.CMDECOD

- 对于所有的 WHODrug 记录, 首选名称始终都是活性物质的通用名称
- 特征: WHODrug 中 Seq2 (药物代码的最后三个字符)=001, Seq1不固定

DrugRecNo	Seq1	Seq2	药名	首选名称
000005	01	001	氨苄西林	是
000005	01	002	Ampicin	否
134314	01	001	氨苄西林; 氯唑西林	是
134314	01	003	Ampiclox	否

示例 5 首选和非首选名称。前两项记录含氨苄西林的基础形式, 后两项记录含氨苄西林和氯唑西林的基础形式。只有第一条和第三条记录为首选名称 (即具有 Seq2=001) 。

PREFNAME_CODE	PREFNAME_TERM_CN	TRADENAME_CODE	TRADENAME_TERM_CN
00000501001	氨苄西林	00000501001	氨苄西林
00000501001	氨苄西林	00000501002	AMPICIN [氨苄西林]
13431401001	氨苄西林:氯唑西林	13431401001	氨苄西林:氯唑西林
13431401001	氨苄西林:氯唑西林	13431401003	AMPICLOX [氨苄西林:氯唑西林]

首选基础形式名称 (Preferred Base Name)

- SUPPCM.CMBASPRF_(non-standard)

首选基础形式名称可用 Seq1=01 和 Seq2=001 来搜索 WHODrug 记录, 代表活性部分的确定名称

Relationship between trade name/Preferred Name/ Preferred Base Name



Preferred Base Name		Preferred Name		Trade Name	
CMBASPRF_CODE	CMBASPRF_CN	PREFNAME_CODE	PREFNAME_TERM_CN	TRADENAME_CODE	TRADENAME_TERM_CN
00000401001	苯海拉明	00000401001	苯海拉明	00000401022	THERAFILM
00000401001	苯海拉明	00000401001	苯海拉明	00000401023	DIFENIDRAMMINA
00000401001	苯海拉明	00000401001	苯海拉明	00000401024	DIPHENHYDRAMINUM
00000401001	苯海拉明	00000401001	苯海拉明	00000401025	DIFENHIDRAMINA [苯海拉明]
00000401001	苯海拉明	00000401001	苯海拉明	00000401026	RESTAMIN KOWA
00000401001	苯海拉明	00000401001	苯海拉明	00000401027	ANTI NAUSEANT
00000401001	苯海拉明	00000402001	盐酸苯海拉明	00000402001	盐酸苯海拉明
00000401001	苯海拉明	00000402001	盐酸苯海拉明	00000402002	BENADRYL [盐酸苯海拉明]
00000401001	苯海拉明	00000402001	盐酸苯海拉明	00000402003	INADRYL [盐酸苯海拉明]
00000401001	苯海拉明	00000402001	盐酸苯海拉明	00000402004	AMIDRYL
00000401001	苯海拉明	00000402001	盐酸苯海拉明	00000402005	CYMADRYL [盐酸苯海拉明]

ATC classification

- The Anatomical Therapeutic Chemical (ATC) classification system, 解剖-治疗-化学分类系统是药品层级分类系统，根据活性物质作用的器官或系统及其治疗作用、药理和化学特性进行分类。WHODrug 中整合了ATC 分类
- ATC levels:

ATC 代码	ATC 文本	
N	神经系统（第一级，解剖学大类）	第一级根据解剖学分14个大类
N02	镇痛药（第二级，治疗学亚组）	第二级根据药理/治疗特性对药物进行再分类
N02A	鸦片类（第三级，药理学亚组）	第三和第四级是继续根据化学、药理学和治疗学分类的亚组
N02AA	天然鸦片生物碱类（第四级，化学亚组）	
N02AA01	吗啡（第五级，化学物质）	第五级代表活性物质

ATC第五级分配不包含在 WHODrug 中，主要原因在于:ATC 第五级用于识别活性物质。由于并非所有的活性物质都被官方分配 ATC 代码, WHODrug 通常使用另一个方式唯一识别活性物质, 即药物代码

- WHODrug 词典中的所有记录被分配至少一个 ATC 代码，优选第四级 ATC 代码。如果由于任何原因，无法为 WHODrug 记录分配合适的第四级 ATC 代码，则会选择特定性降低的 ATC 代码分配（即第三级、第二级或第一级） -> this is how CM.CMCLASCD is based on



CMCLASCD	CMLVL1CD	CMLVL2CD	CMLVL3CD	CMLVL4CD
A16A	A	A16	A16A	
A02BX	A	A02	A02B	A02BX
V90	V	V90		



Timeline of Dictionary formats

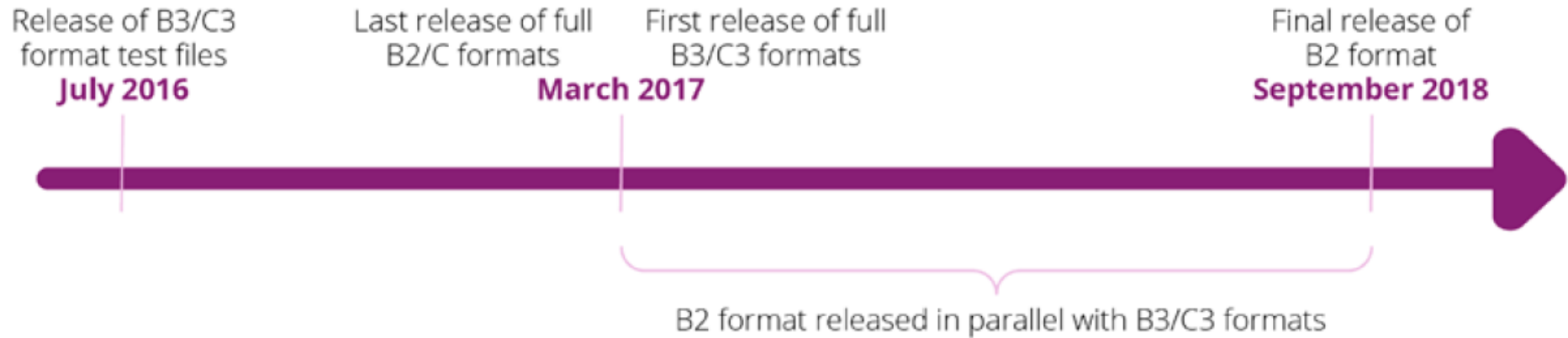


Figure 1. Timeline for the introduction of the B3/C3 formats.

B2-format files will be abandoned from March 2019 and onwards

B3-format of WHODrug Global will be required in FDA submissions for studies starting after March 15, 2019



Differences between B2/C formats & B3/C3 formats

What is B-formats, C-formats?

- The B-formats contains information about trade names, ingredients and ATC classification(s). The unique key is the alphanumeric Drug Code;
- The C-formats contains all the B-format information (including the Drug Code) but has in addition information regarding the countries in which the product is marketed, Marketing Authorisation Holders, pharmaceutical forms and strengths. The unique key is the alphanumeric Medicinal Product ID.

B3

Drug Code	Drug Name	Active Substance(s)	ATC
00764801074	Moveril	Thiocolchicoside	M03BX, Other centrally acting agents <i>official</i>

C3

Drug Code	Drug Name	Active Substance(s)	ATC	Country	Marketing Authorisation Holder	Pharmaceutical Form	Strength	Medicinal Product ID
00764801074	Moveril	Thiocolchicoside	M03BX, Other centrally acting agents <i>official</i>	Italy	Acarpia servicos farm	Ampoules, intramuscular	4 mg	1931652

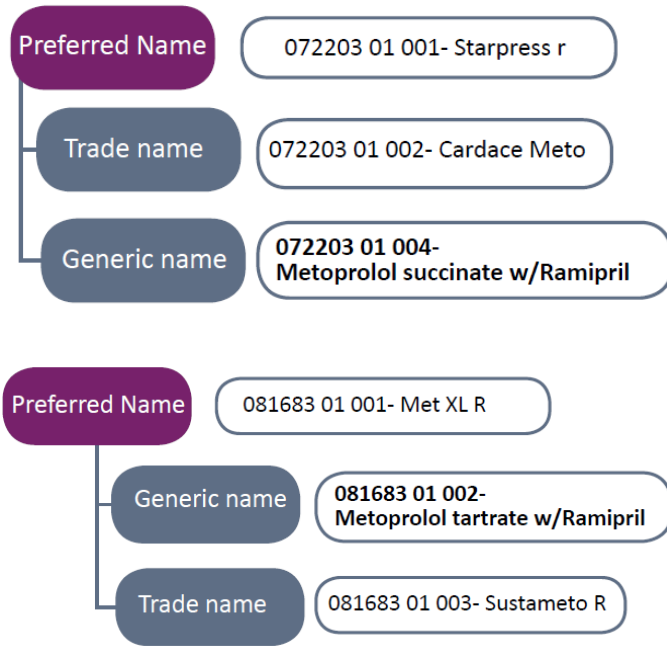
Example 1. The record Moveril in the B3-format and in the C3-format in WHODrug.

Differences between B2/C formats & B3/C3 formats

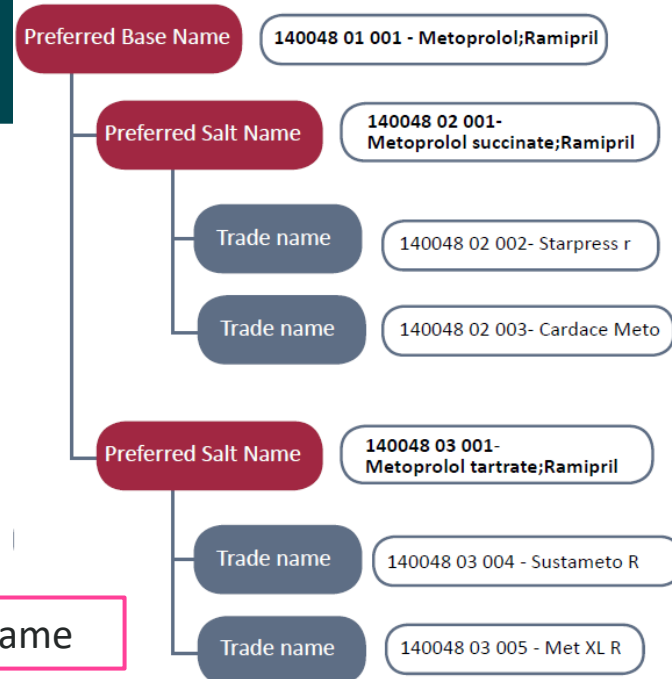
1. Multi-ingredient salt/base relationship

- **B2/C formats:** Different salt variations of a substance combination are located on separate Drug Record Numbers.
- **B3/C3 formats:** the relationship between salted and unsalted substances is applied for multi-ingredient records

B2/C formats



B3/C3 formats



PREFNAME	PREFNAM0	TRADENAM	TRADENA0
STARPRESS R	07220301	STARPRESS R	07220301001
STARPRESS R	07220301	CARDACE METO	07220301002

PREFNAME	PREFNAM0	TRADENAM	TRADENA0
MET XL R	08168301	SELO RAM	08168301005
MET XL R	08168301	METOPROLOL TARTRATE W/RAMIPRIL	08168301002
MET XL R	08168301	MET XL R	08168301001
MET XL R	08168301	PROLOMET R	08168301004

CMBASPRF_CODE	CMBASPRF_EN	PREFNAME_CODE	PREFNAME_TERM_EN	TRADENAME_CODE	TRADENAME_TERM_EN
14004801001	METOPROLOL;RAMIPRIL	14004801001	METOPROLOL;RAMIPRIL	14004801001	METOPROLOL;RAMIPRIL
14004801001	METOPROLOL;RAMIPRIL	14004801001	METOPROLOL;RAMIPRIL	14004801002	BBBEST R
14004801001	METOPROLOL;RAMIPRIL	14004802001	METOPROLOL SUCCINATE;RAMIPRIL	14004802001	METOPROLOL SUCCINATE;RAMIPRIL
14004801001	METOPROLOL;RAMIPRIL	14004802001	METOPROLOL SUCCINATE;RAMIPRIL	14004802002	STARPRESS R
14004801001	METOPROLOL;RAMIPRIL	14004802001	METOPROLOL SUCCINATE;RAMIPRIL	14004802003	CARDACE METO
14004801001	METOPROLOL;RAMIPRIL	14004802001	METOPROLOL SUCCINATE;RAMIPRIL	14004802004	BETAONE R
14004801001	METOPROLOL;RAMIPRIL	14004803001	METOPROLOL TARTRATE;RAMIPRIL	14004803001	METOPROLOL TARTRATE;RAMIPRIL
14004801001	METOPROLOL;RAMIPRIL	14004803001	METOPROLOL TARTRATE;RAMIPRIL	14004803002	SELO RAM
14004801001	METOPROLOL;RAMIPRIL	14004803001	METOPROLOL TARTRATE;RAMIPRIL	14004803003	PROLOMET R
14004801001	METOPROLOL;RAMIPRIL	14004803001	METOPROLOL TARTRATE;RAMIPRIL	14004803004	SUSTAMETO R
14004801001	METOPROLOL;RAMIPRIL	14004803001	METOPROLOL TARTRATE;RAMIPRIL	14004803005	MET XL R
14004801001	METOPROLOL;RAMIPRIL	14004803001	METOPROLOL TARTRATE;RAMIPRIL	14004803006	ACE REVELOL

Preferred Base Name

Preferred Salt Name

Trade name

2. Non-unique names

- **B2/C formats:** Non-unique names are made unique in the B2-format by the addition of /DRECNOSEQ1/ after the trade name.
- **B3/C3 formats:** To facilitate review, this is replaced by [INGREDIENT(S)] in the B3-format. If more than one ingredient they will be written in alphabetical order, separated by semicolons

Table 1. Non-unique names in the B2-format.

Drug Code	Drug name	Ingredients
00668101261	ZYFLOX /00668101/	Norfloxacin
00697202724	ZYFLOX /00697202/	Ciprofloxacin hydrochloride

Table 2. Non-unique names in the B3-format.

Drug Code	Drug name	Ingredients
00668101261	ZYFLOX [Norfloxacin]	Norfloxacin
00697202724	ZYFLOX [Ciprofloxacin hydrochloride]	Ciprofloxacin hydrochloride

Preferred Name

3. Multi-ingredient Generic Names

- **B2/C formats:** separated substance names in alphabetical order by **w/**
- **B3/C3 formats:** separated substance names in alphabetical order by **semicolon**

Table 3. Comparison of Generic Names in the B₂/C and B₃/C₃ formats.

Format	Generic Name
B ₂ /C	Glimepiride w/Metformin hydrochloride
B ₃ /C ₃	Glimepiride;Metformin hydrochloride

4. Field length

- **B2/C formats:** the generic record may show truncated generic names due to the character limitation of 45 in the B2-format and 80 in the C-format.
- **B3/C3 formats:** both these issues are resolved

	B2-format	B3-format
Field length 'drug name'	45	1500
Field length 'ATC text'	50	110

	C-format	C3-format
Field length 'drug name'	80	1500



Any questions?

