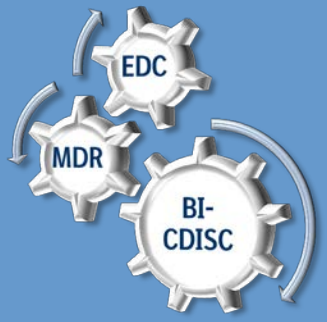
CDISC GS User Group Meeting
05 September 2017

WHO DD - New Format: B3 And Some Implications



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Topics

- WHODrug update to B3/C3 format: why and how
- Points to consider
- ATC and Ingredient Codes

Refresher B3 Format

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Why

- Ensure full compliance with CDISC without workarounds
  - Generic Drug Name can be populated (CDISC field CMDECOD)
  - Full ATC text can be populated (CDISC field CMCLAS)
- Structural Changes
  - Active Ingridients attached to Non-Unique Drug Names
  - Restructuring of salted drugs to unsalted generic combinations

How

	B2 Format	B3 Format
Field length ‚drug name‘	45	1500
Field length ‚ATC text‘	50	110
Non-unique Trade Names	Separated by adding /drug code/	Separated by adding [ingredients]
Preferred multi-ingredient names	Most often a trade name	Always a generic name

Refresher B3 Format

Refresher B3 Format

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- UMC offers support

UMC resources

- Change Analysis Tool (CAT)
- Webinars, live and recorded
- Documents (available on User Group Portal):
    1. *'WHODrug B3/C3 formats implementation guide'*
    2. *'How to use WHODrug for compliance with CM domain in the CDISC SDTM standard –technical guide for industry'*
- FAQ, continuously updated
- UMC consultancy for updating of synonym lists
- Individual support: drugdictionary@umc-products.com

Some Points to Consider

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- Until when will B2 format be maintained?
- Can we easily migrate or have other functions e.g. DM problems with the new format?
- What is needed to migrate studies in the PDB?
- Which migration tables (from/to versions) will be needed for PDB/PADS migration?

Some Points to Consider

- Different sceanrios needed for locked, ongoing, new studies
- Transition period required
- Technical capabilities of EDC system and Drug Safety DB
- Usage of MedDRA SOCs (investigations, procedures) in BI WHODrug dict!!! -> mapping tables
- B2-B3 relationship is n:1
  B2-B3 mapping tables needed to enable upgrade of PDBs and PADSs.
  Provide SDGs in B3 format
- No need to up-versioning individual studies but pooled analyses (ISS, ISE) have to be done in recent (as agreed with FDA) harmonised version

ATC and Ingredient Codes

- ATC Codes:
  - need for ATC5 in SDTM not clear
  - testing done for option 2, providing all ATC codes and all ATC code levels 1-4 as available
  - SUPPCM is increasing: around 4-5 times the number of observations than without ATC codes

CMCLAS and CMCLASCD

CMCLAS and CMCLASCD refer to the classification from the drug dictionary. For WHODrug the classification is WHO ATC classification.

In the implementation guide there are three ways of submitting ATC information described:

1. One single class selected
2. Multiple classes selected
3. No classification

- Ingredient Codes:
  Are these needed?