Questions and Answers from UMC webinar 'The new B3 format and how to use WHODrug for SDTM compliance '

If you think your question is missing, please contact drugdictionary@umc-products.com for assistance.

B3-format questions

Is there going to be a conversion table between current multi-ingredient codes and new ones? Will you provide us the tool to change the Drug code of B2 format to B3 format, like as CRT Japan?
The WHODrug Change Analysis Tool (CAT) will provide information on all changes and also show the new corresponding entry in B3-format. Therefore, the output from CAT can be used as a conversion/mapping table.

Will ATC level 5 be included in the new B3 format?
WHODrug ATC 5 will continue to be a separate product and it will be adjusted to be compatible with the B3-format drug codes.

Will there be any additional cost or change in license or subscription for B3/C3-formats?
There will be no change in cost, license or subscription, all users can choose to download and use B2-, B3- or C3-formats after March 2017. B2-format files will be abandoned from March 2019 an onwards.

Will the UMC continue to update the cross reference tool (IDF to WHODD) to which format B2/ B3 in the same time line as the overall implementation of the B37C3 format?
CRT Japan will be updated to map to the B3-format drug codes in line with the release plan for the B3-format.

Can you please confirm that PREF Name will be the same as current ingredients under B2?
Yes, the preferred name will be the same as the active ingredients for a specific trade name.

With the ATC code text, do you have any plans to indicate the" hierarchy" in the name? For example, there are several entries with the ATC name of corticosteroids.
The ATC hierarchy will not be reflected in the ATC text, only in the ATC code. However, we have seen suggestions to include the full hierarchy in the SDTM dataset and we are also looking into displaying the hierarchy in the new WHODrug Browser: *WHODrug Insight*.

Do you have a date in March for release of test files?
The test files will be released on March 1 2016; they will be available on the download area throughout the year.

Will the PTs with combination ingredient entries separated by semicolon be included as new WHODRUG entries or will just replace the previous names separated by W/?
All generic-marked entries will be changed to be separated with ; instead of w/. The drug code for almost of them will be changed since they are going to be grouped to the unsalted combination.

You mentioned changes to specific fields; will there be other changes to the files/ file structure provided for B3/C3?
All changes in the formats are discussed in the 'WHODrug B3-format implementation guide' available on the User Group Portal. There are four changes coming in the B3-format and two changes in the C3-format.

Format C3 will still utilize the Medicinal Product ID and not the Drug Code?
The database structure will still be the same in C3-format, it is only one field length and the logic for the hierarchy of the drug code for multi-ingredient drugs is changing.

Uppsala Monitoring Centre (UMC)
Box 1051, SE-751 40 Uppsala, Sweden
Tel: +46 18-65 60 60 **www.who-umc.org**

For companies that are not using WHODRUG currently but looking to implement it based on HA recommendations, is there a preferred format to use for implementation (B3 or C3)?
If a company does not have specific needs form the information in the C-formats we recommend to use the B3 format.

I think that B2 format and B3 format are not compatible because the structure of drug code in the dictionary. So, the transition from B2 to B3 is very time-consuming.
We acknowledge the transition will be time-consuming for some companies and we encourage you to utilize the UMC-resources offered. The UMC resources are described in the 'WHODrug B3/C3-formats implementation guide' available on the User Group Portal.

For the B2 format for non-unique names, why is there so much white space between the non-unique name and the slash encapsulated code fragment (e.g. ZYFLOX /00668101/)?
The reason for this is for computerised system to know where the appended information is located. In the B3-format this will be replaced by the square brackets and there will be one space between the trade name and the appended information.

Do you have an estimate of how many drug codes will change as the result of the new format?
Almost all drug codes for multi-ingredient drugs will be changed. Generally, a synonym or study list contains 20-25% multi-ingredients.

Will the ATC text field length of 110 characters eliminate the need for INA_LongText?
Yes, the INA-longtext will become the INA-file and an INA-shorttext file may be produced on request for some time.

For non-unique names in B3, where will the active ingredients be placed in the field, the last characters, or immediately following the Trade Name text?
The active ingredients will come directly after the trade name, with just one space between.

For the Multi-ingredient drugs will there be all new codes or description changes for existing codes?
Almost all multi-ingredient drugs will get a new drug code, description changes will occur where possible.

We're looking to update in 2018, will the 2017 B2 version get new entries during that year?
Yes, the B2-format will get new drugs and new ATC codes in all 2018, but no modifications on existing data will be made.

Will the ING LongText be part of the standard quarterly release?
The Ingredients_Longtext file is part of the standard release since March 1, 2012. In the B3-format package there will be no ingredients_longtext as it is no longer needed. But they will be release with the B2 files until B2-format is retired in March 2019.

Would there be a drastic change in drug codes of already existing drugs (i.e. 01726001001 drug code was assigned to INEGY earlier, now it will go to Ezetimibe;Simvastatin) or it's just an example?
The drug code for both INEGY and Ezetimibe;Simvastatin are likely to change in order to create the salt-base relationship for multi-ingredient drugs as well.

SDTM questions

In some of cases, the SUPPCM.QNAM do not longer than 8 character, it there any consideration of this?
In the SDTM implementation guide v3.2, section 4.1.5.3.2 there is guidance for how to do with QNAM longer than 8 characters: "In cases where the standard domain variable name is already 8 characters in length, sponsors should replace the last character with a digit when creating values for QNAM". For example, CMCLASCD should be changed to CMCLASC1 for the first value in QNAM when multiple ATC codes. We encourage all users of the SDTM standard to download a copy of the implementation guide from the CDISC home page (free of charge), as required by CDISC.

What data should we use as CMDECOD when we select the umbrella code as Drug code? Should I make CMDECOD to blank? Or should I store the label of that umbrella code? Can we select which way we take? (We need the Drug code when we do statistical analysis.)
We have not seen any specific requirements from authorities for how to report umbrella codes. UMC recommends to report the umbrella term in the CMDECOD field to avoid the CMDECOD to be blank.

When putting a value into QVAL, is it directly cut the CMDECOD? Or do we put meaningful cut off?
In the SDTM implementation guide v3.2, section 4.1.5.3.2 there is guidance for how to do with fields longer than 200 characters: "When splitting a text string into several records, the text should be split between words to improve readability". For CMDECOD this means to split the text after a semicolon. There is an example in the slide deck of the webinar.

Would the list of the multiple classcodes (i.e. ATC codes) sorted alphabetical or any other way?

We have not seen any guidance on this but it seems to make sense to sort them alphabetically.

Could you verify ATC should be in CMCLAS vs CMCLASCD as CMCLASCD is shows as the ATC code in the SDTM example from CDISC.
There was an error in the slides shown on the webinar and in the UC guide for how to use SDTM. It has been corrected in the slide deck and will be corrected in the guide. CMCLAS should contain the ATC text and CMCLASCD should contain the ATC code itself.

Is the recommendation to populate CMCLASCD with the most specific ATC code available (i.e. ATC4, or if ATC4 is not available then ATC3, etc…)
UMC recommends to report the ATC the most specific codes available, and to report on ATC level 4 where there is one.

In the current dictionary there are not generic entries in the longtext dataset for some drugs that start with a drugseq of 9, for example medical gases. What should be used for the generic name for these drugs.
Please find answer in question 21.

CAT and Browser questions

What format will be in the web-based browser?
The old web-based Browser will only display B2- and C-format, the new WHODrug Insight will display B2-, C-, B3, and C3-formats for applicable versions.

In my understanding, UMC uses sponsor's data for some analysis through CAT. I just wanted to make sure that you are using sponsor's data for safe and confidential manner.
UMC store data completely anonymous in CAT, we do not know which company uploaded which data, we cannot share any typedata outside of UMC. For CROs in need of more documentation on this, please ask UMC for assistance.

Size of files relates to processing time in CAT? Any recommendation to do this at a certain time slot to get quickest response, resp. don't use certain times due to daily/weekly/monthly admin tasks at the UMC server?
Larger files will take longer time and if many are analysing at the same time the analysis will take longer. But even if it takes longer no one should have to wait longer than one hour. CAT can be closed down while analysing, so a user can log out and get back later to retrieve the result without being active in the system.

When will the new browser be available? Or will the existing browser be updated?
The new WHODrug Insight will be available in spring 2015, companies with a World Wide Corporate License will get access to the system first and then it will be offered to all users.

Regulatory requirements questions

You said that regulatory authorities like to have some classification of ATC reported which infers a single selection of ATC. Actually from feedback I've seen (including at the WHODRUG UG meeting) the preference is to receive all possible ATC. I think this is something to clarify (if not in this webinar then later).
There is no official documentation from the authorities whether they would like one or all ATC codes, therefore we advice to continue as usual until further notice.

Sponsors must always include full generic text into SDTM datasets? Or are there any room for sponsors to decide to cut off 200+ characters?
Both PMDA and FDA have indicated they want all active substances reported, therefore we recommend using the supplemental dataset at all times if needed. This is likely to happen relatively seldom.

Is Japan requiring WHODrug for safety reporting?
PMDA in Japan is requiring the identification codes of the local IDF dictionary for safety reporting and WHODrug for concomitant medications in NDAs. UMC provides an add-on product that helps the conversion from WHODrug into IDF codes.

Will the FDA require all ATCs if multiple? What if company is using indication and route to select the ATC?
Please find answer in question 33.

Will you still keep umbrella entries - and are these acceptable to the regulators?
We will keep umbrella entries for situations when no more information can be found. We see authorities accepting umbrella entries with one exception: safety reporting to EMA. UMC is in dialogue with EMA regarding this but there is no news to share at this time.

Safety reporting questions

We use WHO-DD in a drug safety system, In the near future, our current pharmacovigilance system will be upgraded to comply with R3 and IDMP Standards. Please let me know if there are there any specific areas which need to validated due to the B3 / C3 changes, in other words would there be any impact on WHO-DD due to R3 and IDMP?
For the E2B R3 standard there is no need to validate due to B3, it will be easier to get the active ingredients to the

correct fields. For the safety system and the safety database there may need to be a validation process if the system or database does not support the number of characters in the B3-format. With regards to IDMP we are awaiting guidance from the authorities but we do not expect any major changes to the format. There may be additional information added that reflects the PhPID of the drug where available.

Uppsala Monitoring Centre (UMC)
Box 1051, SE-751 40 Uppsala, Sweden
Tel: +46 18-65 60 60 **www.who-umc.org**