Loading WHODrug Type C Format In TMS 4.5.

Decision Points and Considerations

September 2004

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Acknowledgements

Thanks to Thanks to the OCUG and TMS Focus Group for this opportunity to present this topic

Thanks to Kim Renjdrup and Andy Alasso for their comments and feedback about possible implementations of WHODrug Type C in TMS

Thanks to Daniel von Sydow and Malin Nord at the WHO Uppsala Monitoring Center for their comments into this topic

Many thanks to the OCUG Presentation committee and Lori Venable for their patience with the completion of these presentations.

Goals and Agenda

- Explain challenges to loading the WHO Drug Type C Format in TMS 4.5
- Identify the key decision points that must be addressed before loading
- Provide suggestions for possible loading and configuration options
- Provide suggestions on possible future enhancements and changes both to the WHODrug Type C format and TMS

Brief TMS Overview

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- TMS (Thesaurus Management System) is normally integrated with Oracle Clinical as well as other applications.
- During the Batch Validation process, the **Verbatim Terms** are compared to the dictionary data. The **Level** of the dictionary for which the Verbatim Term is compared is known as the **Classification Level**.
- If an exact match is found, then this matched term, and other associated data in the dictionary, is returned to Oracle Clinical

Brief TMS Overview

TMS defines an exact match as :

- Equivalent regardless of the case of the terms

and

- Equivalent regardless of the number of spaces between words of a multiple word term.

Brief TMS Overview

- The process of resolving Verbatim Terms (VT) which do not exactly match some term in a medical dictionary is commonly called "coding." In TMS terminology, this is called **Omission Management.**

- When a VT is assigned to a dictionary term, the term and its auxiliary data, also called **Level Details**, is returned to Oracle Clinical in the next Batch Validation.

- Other parts of the medical dictionary, known as Derivable Levels, can be returned to Oracle Clinical at the same time.

TMS Limitations

- TMS must have unique terms in the Classification Level of a dictionary.

- TMS can only return dictionary data back to Oracle Clinical if the data exists in a single derivable path. This means that for every term in the Classification Level of a Dictionary, TMS must have a single default term from any level higher than the classification level in order to return that data to Oracle Clinical.

Overview of WHODrug

- The WHODrug dictionaries are published by the Uppsala Monitoring Centre (UMC) on behalf of the World Health Organization (WHO).
- The WHODrug dictionary represents a collection of all manufactured drugs that have been reported to them.
- The WHODrug dictionary has had four major formats since 1968, with the current formats of Type B2 and Type C.

Overview of WHODrug

The WHODrug dictionary contains many levels including :

- Drug Names
- Anatomical Therapeutic Classifications (ATCs)
- Ingredients
- Source Codes
- Manufacturers

There are about 1200+ ATCs, there are currently more than 60,000 actual unique Drugs in the Type C format.

Differences in the WHODrug Type C Affecting TMS

- The Drug names themselves are **not** unique in Type C.
- ATC codes are now associated to every Drug Name in Type C
- A Pharmaceutical Product level, which contains the Pharmaceutical Form (PF), was introduced in Type C
- All ingredients and their amounts were introduced in Type C
- The Medicinal Product ID (MP ID), which represents 7 drug attributes, now uniquely identifies a drug (Drug Name, Name Specifier, Country, Manufacturer, All Ingredients w/ Strengths and Units, Pharmaceutical Form Drug Code (DrgRecNum+Seq1+Seq2))

WHODrug Loading Considerations

- Since the drug name is not unique in Type C, the drug name alone can not be loaded as the Classification level in TMS. Therefore, the drug names must be made unique somehow.

- In making drug names unique in Type C, the TMS built-in automatic matching would potentially be diminished. Some considerations have to be made for preserving TMS auto encoder efficiency.

Choices

Option 1: Use the Medicinal Product ID itself to make the Drug Names unique in the classification level

Option 2: Use the logical expansion of the Medicinal Product ID to make the Drug Names unique in the classification level and possibly populate a VTA Level with Drug Names only

- Drug Name
- Name Specifier
- Country
- Manufacturer
- All concatenated Ingredients with their Strengths and Units,
- Pharmaceutical Form
- Drug Code (DrgRecNum+Seq1+Seq2)

Choices (cont.)

Option 3: Add an additional level to store the Drug Names only as part of a Classification Group in the TMS WHODrug structure

Option 1 : Medicinal Product ID at Classification Level

Advantages

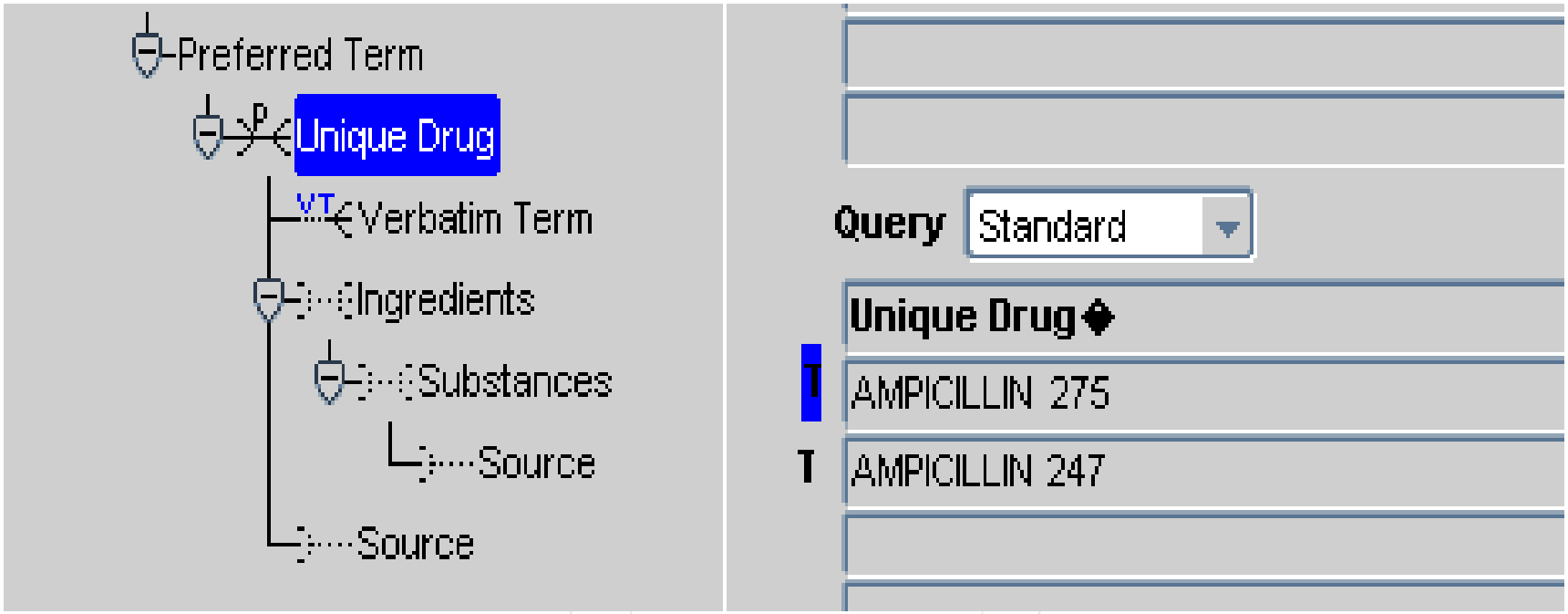
- Easy to load

Disadvantages

- Auto encoding would not be possible
- Coders would not have information needed to select correct VTA

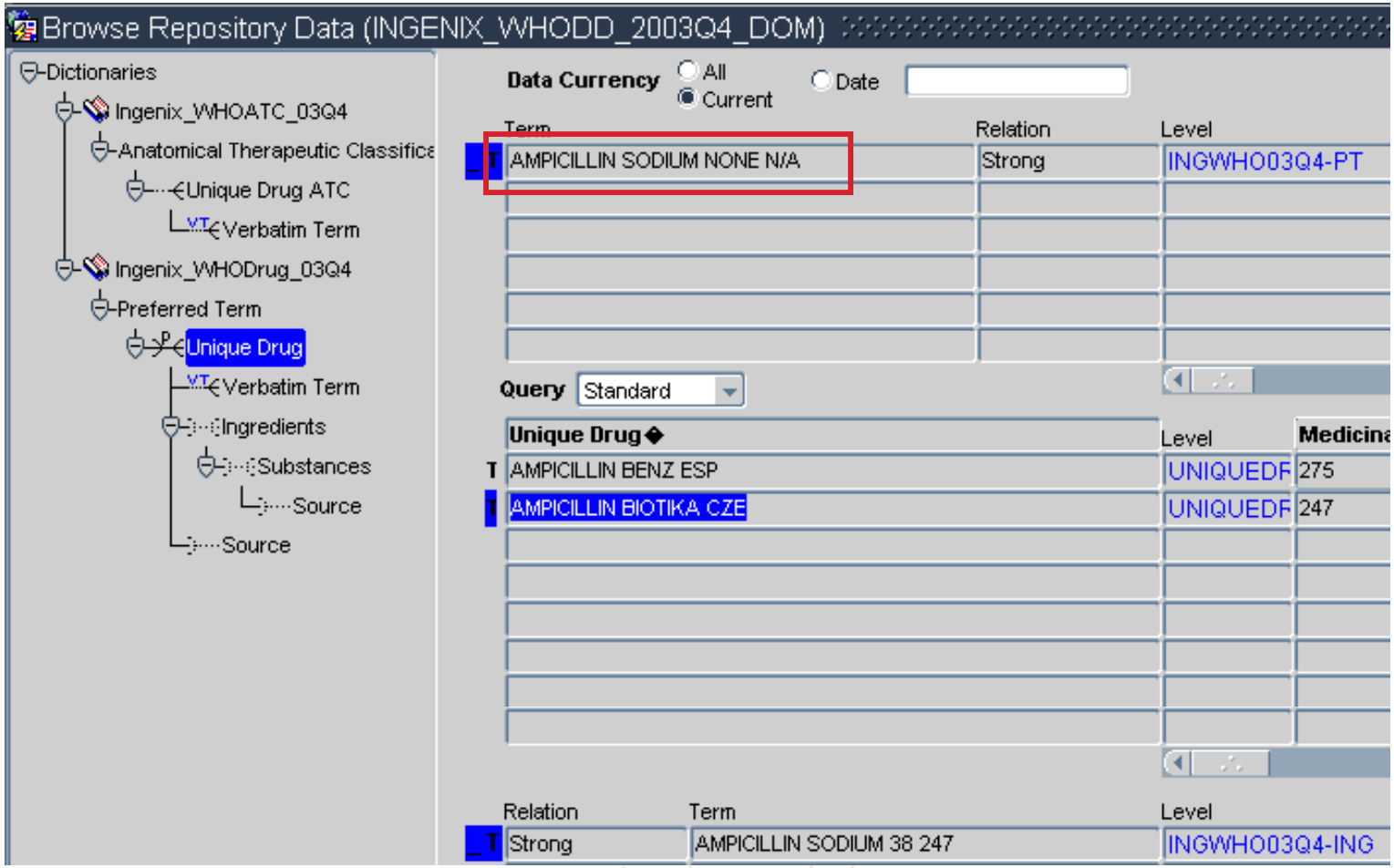
Some have suggested adding the MP_ID to only non-unique drug terms. This still leaves many terms (10,000+) which will not auto encode.

How it Looks to the Coder



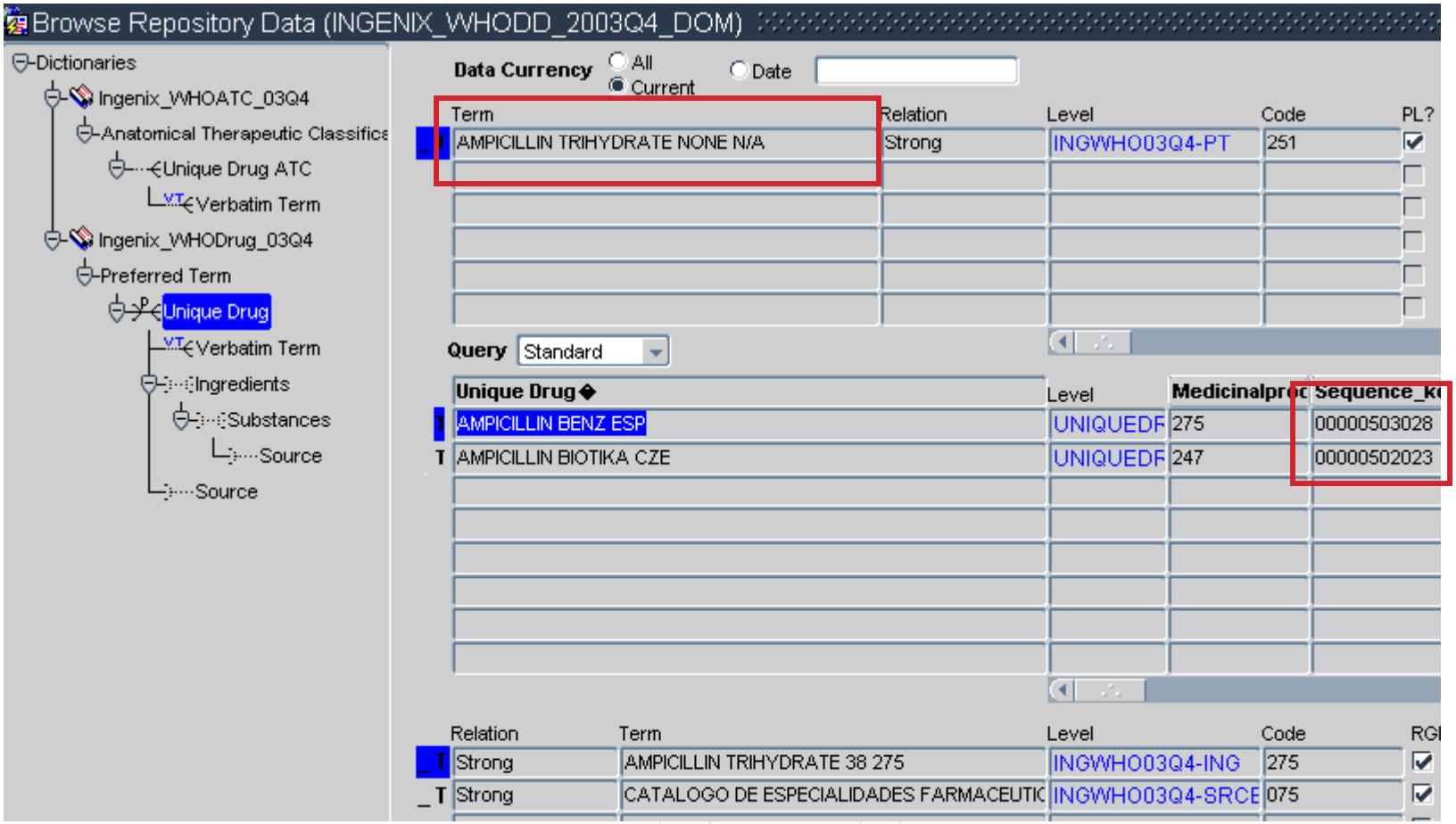
DrugName MP_ID

What it Really Means !



MP_ID 247 is Ampicillin Sodium

What it Really Means !



MP_ID 275 is Ampicillin Trihydrate.

Note the different Drug Codes

Option 2 : Use the Logical Expansion of the MP ID

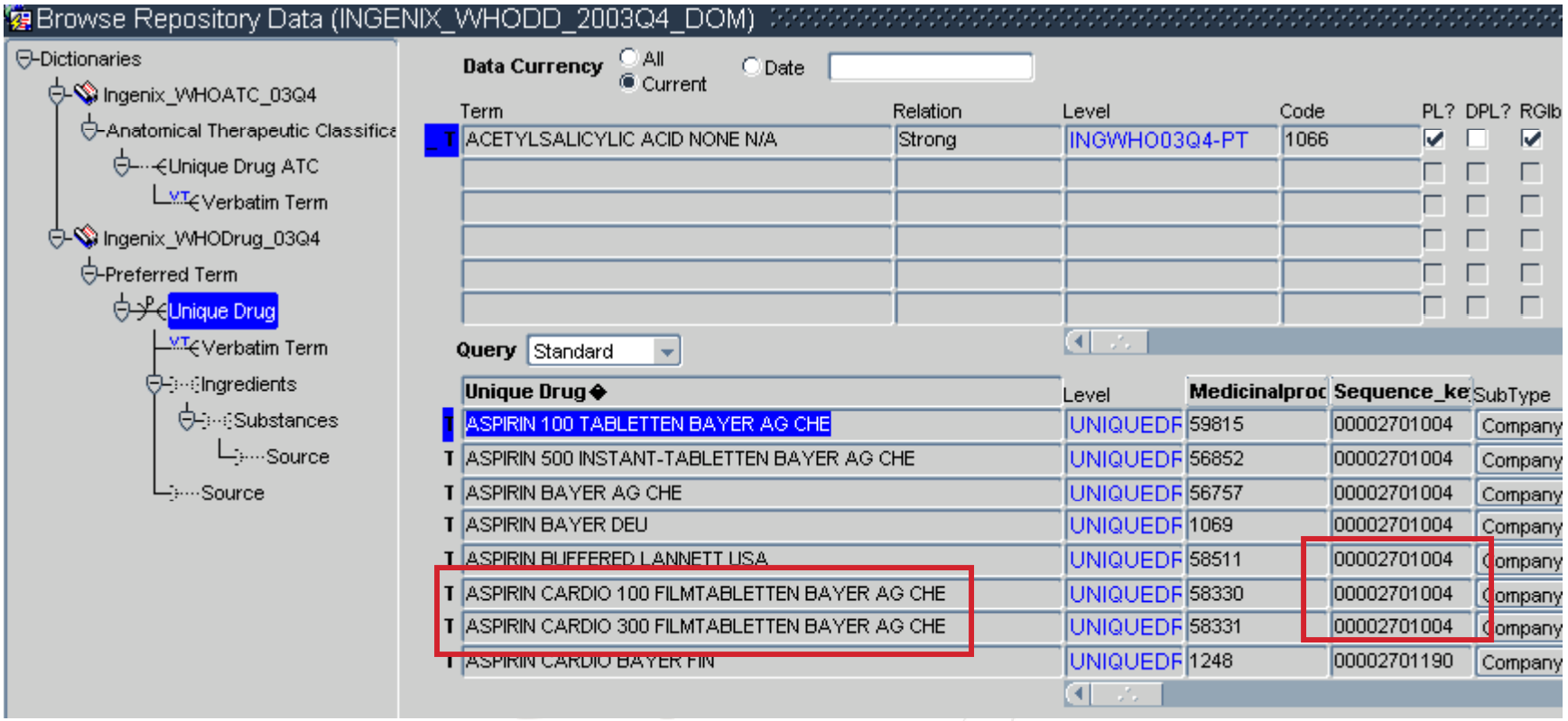
Advantages

- Information is available for coders to select appropriate VTA

Disadvantages

- Nothing auto encodes
- Load script is more complicated and takes longer
- Field length may require >CHAR 300

The Logical Expansion of the MP ID



Note the Aspirin Cardio includes the strength and form

Note the Drug Codes are the same

So Nothing Auto Encodes ? Ever ?

- Answer - Load Verbatim Term Assignments (VTAs)
- This also allows coders to use the filter buttons in TMS Omission Management to choose the VTA Level and only code on the Drug Names if desired
- Problem - Over 10,000 drug names are not unique.
-
- Do you have to manually code all 10,000+?
- Yes and No !

Yes - Manually Code All Duplicate Drug Names

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Advantages

- Control of the codes – you can select certain drugs from specific countries, or manufacturers, or ingredients, etc.
- You could reload same VTAs, once they are selected to new versions of the dictionary.

Yes - Manually Code All Duplicate Drug Names

Disadvantages

- As each version is released, you will need to repeat this exercise.
- How long will it take your team to code 10,000+ terms?
- Some of these terms you will never see in a study, but you will spend a lot of time on them initially.

No - Don't do it Manually

- Load only the Unique Drug Names as verbatim terms.
- Code the others as they are encountered as verbatim terms.

Advantages

- Over 40,000 will be able to have VTAs loaded
- You only spend time on those you need

No - Don't do it Manually

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Disadvantages

- You may give up consistency in decision making if this is done over time
- Many of the most common drugs encountered are in this group
- You need to repeat this with each new version of the dictionary

Alternative "No" - do it Systematically

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Advantages

- Same script can be used for each new version of the dictionary
- Logic can be applied that is consistent across all term choices
- The script will run faster than your team can do the work!

Decisions That Need to be Made

- How do you decide which drugs should have VTAs?
- We feel that all the drugs having the same DrgRecNum and Seq1 and can have a VTA selected.
- The same DrgRecNum and Seq 1 mean the drug is the same drug with the same Preferred term and the same ingredients.
- Further, WHODrug will continue to support the DrgRecNum and Seq numbers (see the document titled The New C Format: New Features that accompanies each version of the dictionary).

SS2

Slide 26

SS2 (can we reference a specific document from WHO-UMC here?)
Sunil Singh, 7/20/2004

Alternative "No" - do it Systematically

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Disadvantages

- Decisions still need to be made on the logic to be used
- Some terms will not have VTAs because the same drug name by different countries/manufacturers are really different drugs
- TMS loading Script development is complex and will take some time to run!
- This does not account for PF or strength.

Why not Assign Global VTAs to Drug Names with Multiple Drug Recnrs ?

In WHODrug Type, 4th Quarter 2003, there were about 775 cases where there were Drug Names with multiple Drug Record numbers, and therefore potentially different ingredients, Preferred Names, and ATCs.

There are many reasons why this has happened :

Reasons for Multiple Record Numbers

- A strategic decision by a manufacturer to change the active ingredients to improve the product over time, but keep the same Drug Name due to market share and brand recognition

- The lack of availability of some active ingredients in some countries or geographies, including cases where the raw materials are not available or are banned by a country for human use or import

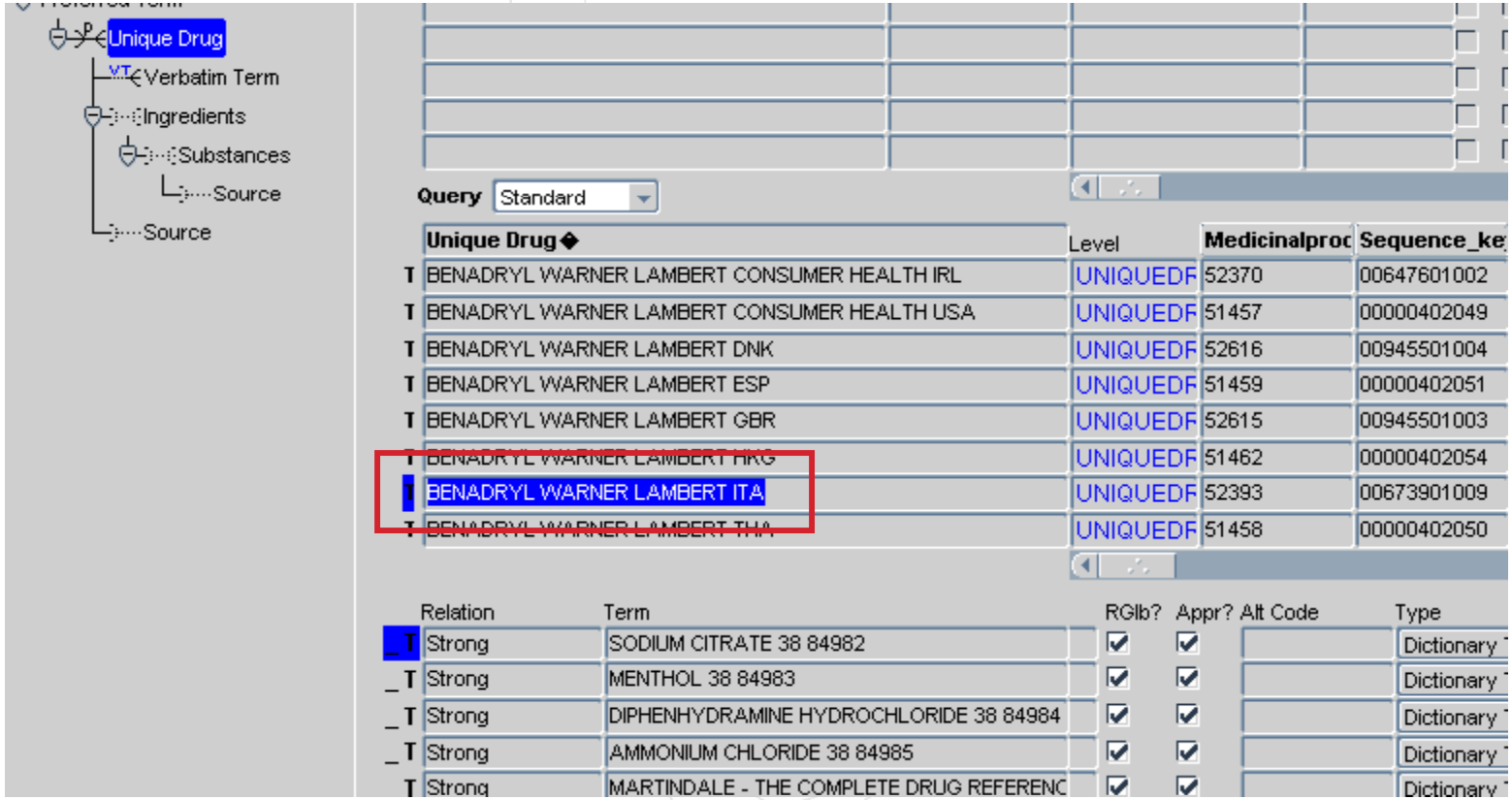
Reasons for Multiple Record Numbers

- The purchase or acquisition of one company or brand by another combined with a strategic decision to keep the same brand recognition and market share purposes, but to also change or improve the drug which might change the active ingredients

- The lack of enforcement of intellectual property rights or patents in some countries, where the same Drug Name is used illegally and manufactured with completely different ingredients. WHO-UMC is still obligated to report the creation and use of these drugs.

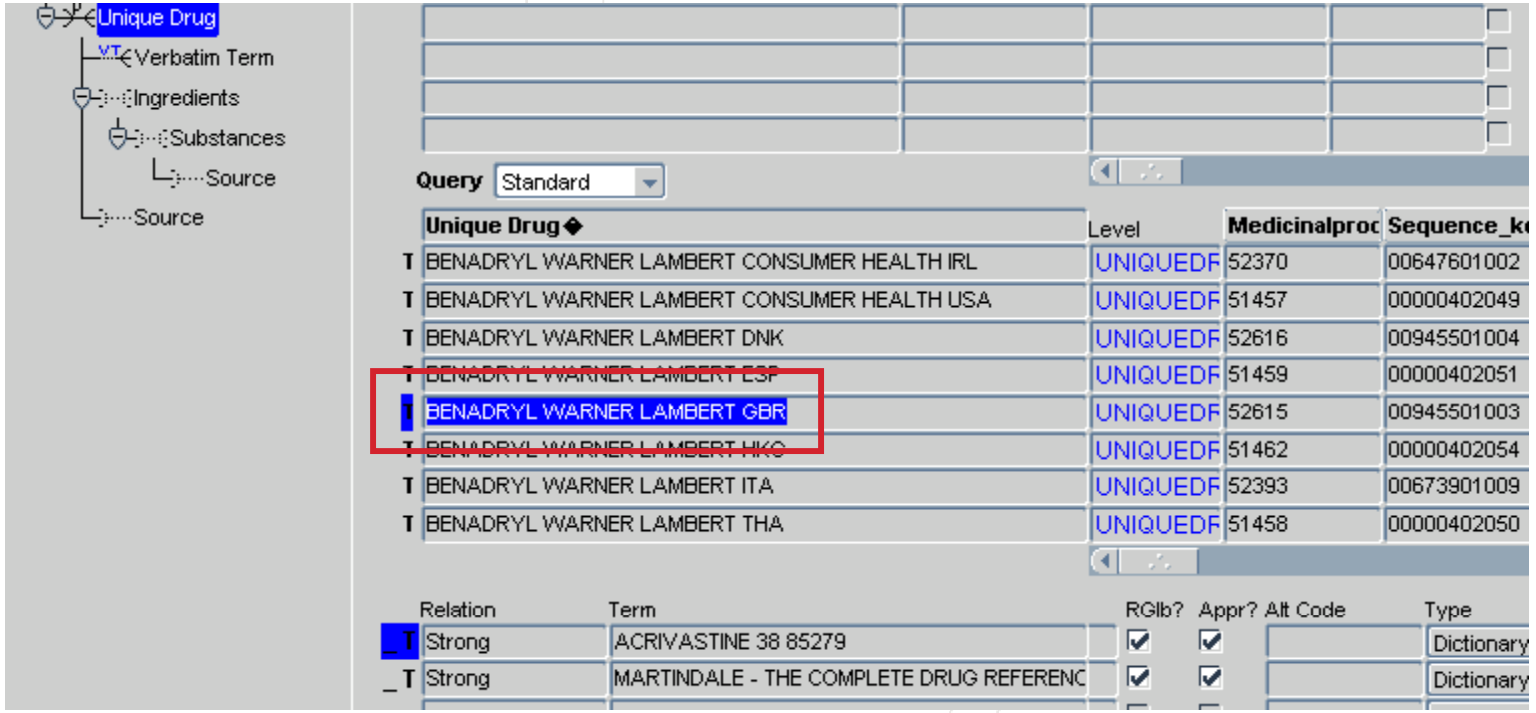
Example of Same Drug Name in Different Countries

Benadryl in Italy



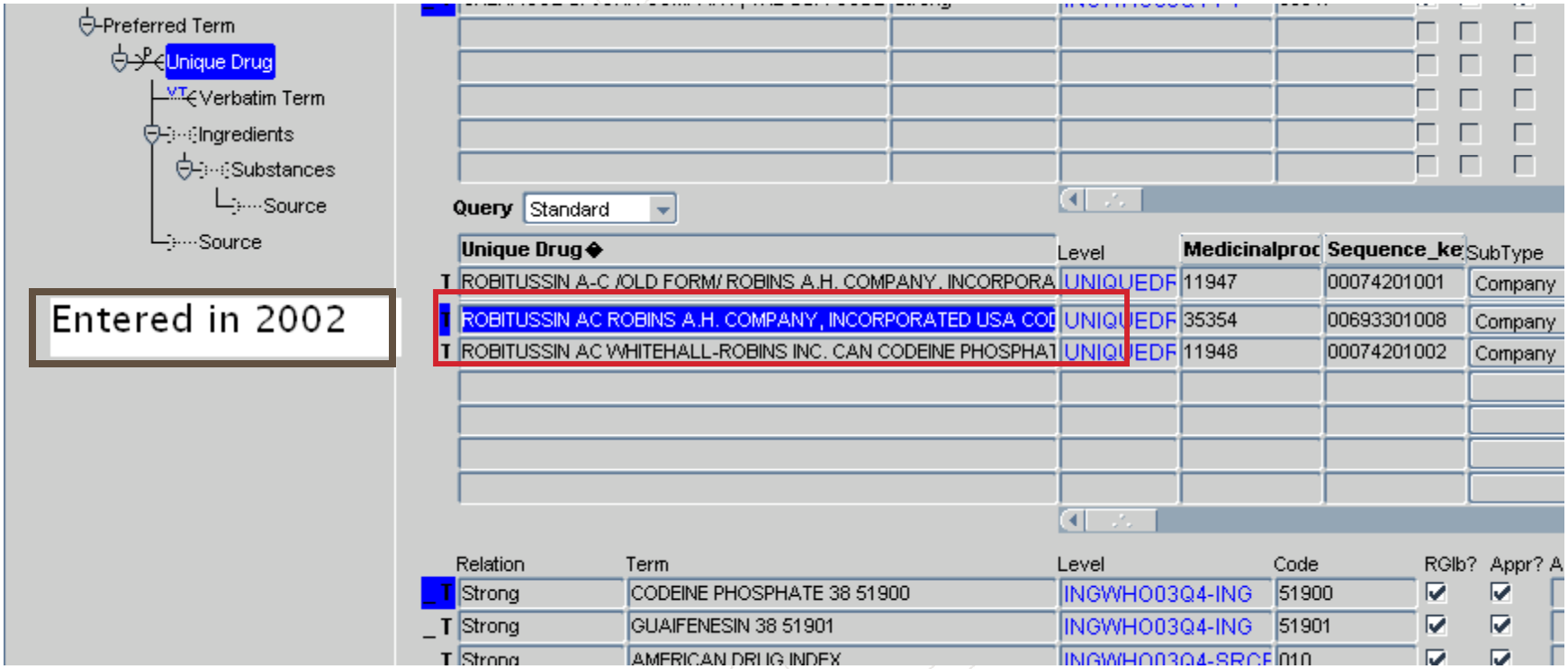
Example of Same Drug Name in Different Countries

Benadryl in the United Kingdom



Changes in the Drug

Robitussin AC



Changes in the Drug

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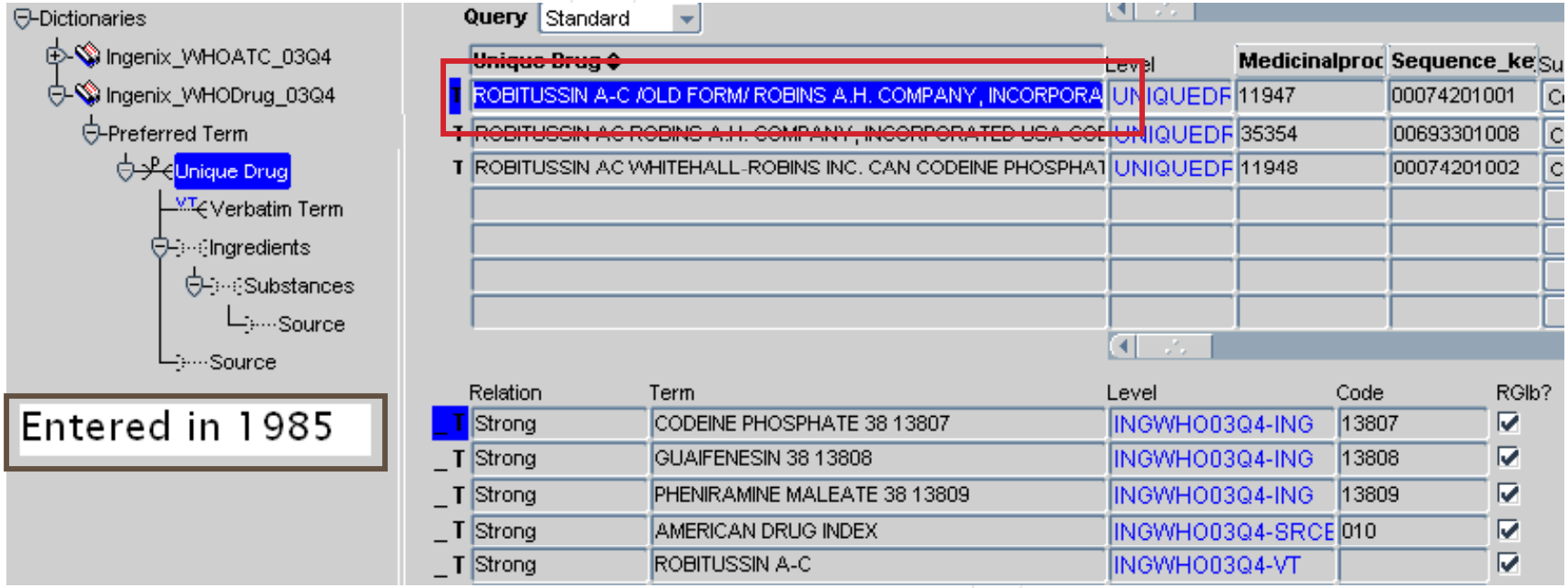
Robitussin AC



Default Algorithm for Preserving TMS Auto Coding WHODrug Type C

1. Where only one Medicinal Product ID exists for a specific Drug Name, then make this Drug Name a Verbatim Term.

2. Where multiple Medicinal Product IDs exist for a specific Drug Name, but only one Medicinal Product ID has Seq2='001' (i.e., a unique Preferred Term), then make this Drug Name a Verbatim Term.

3. Where multiple Medicinal Product IDs exist for a specific Drug Name, and multiple Medicinal Product IDs have Seq2='001' but only one Medicinal Product ID has COUNTRY='UNS' (i.e., the Country code is Unspecified), then make this Drug Name a Verbatim Term.

Default Algorithm For Preserving TMS Auto Coding WHODrug Type C

4. Where multiple Medicinal Product IDs exist for a specific Drug Name, and multiple MP IDs have Seq2='001' and multiple MP_IDs have COUNTRY='UNS' , then make the Drug Name of the lowest Medicinal Product ID the Verbatim Term

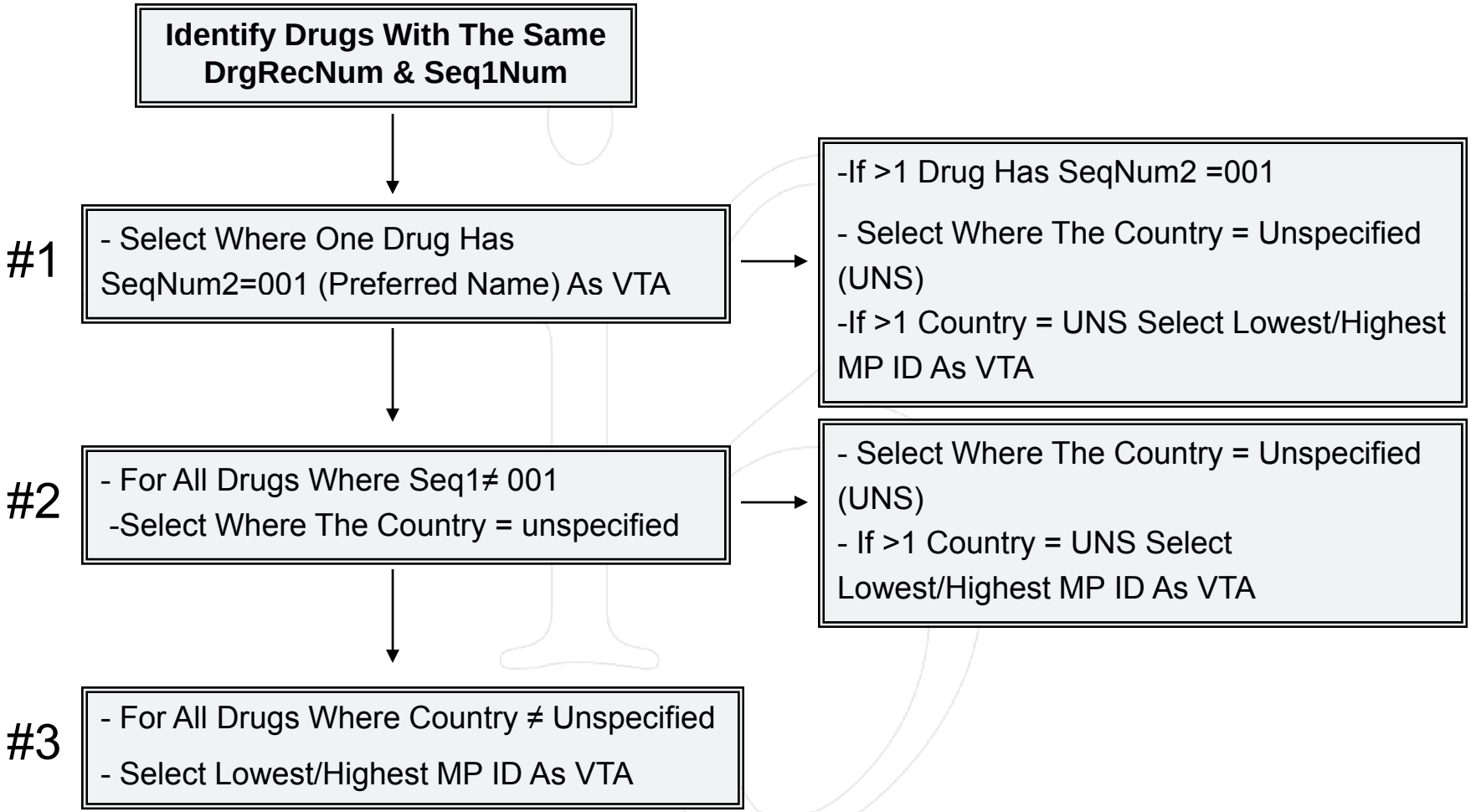
Note: If you use the Maximum MP_ID your VTAs will be altered in newer versions of the dictionary as MP_IDs are added.

Default Algorithm for Preserving TMS Auto Coding WHODrug Type C

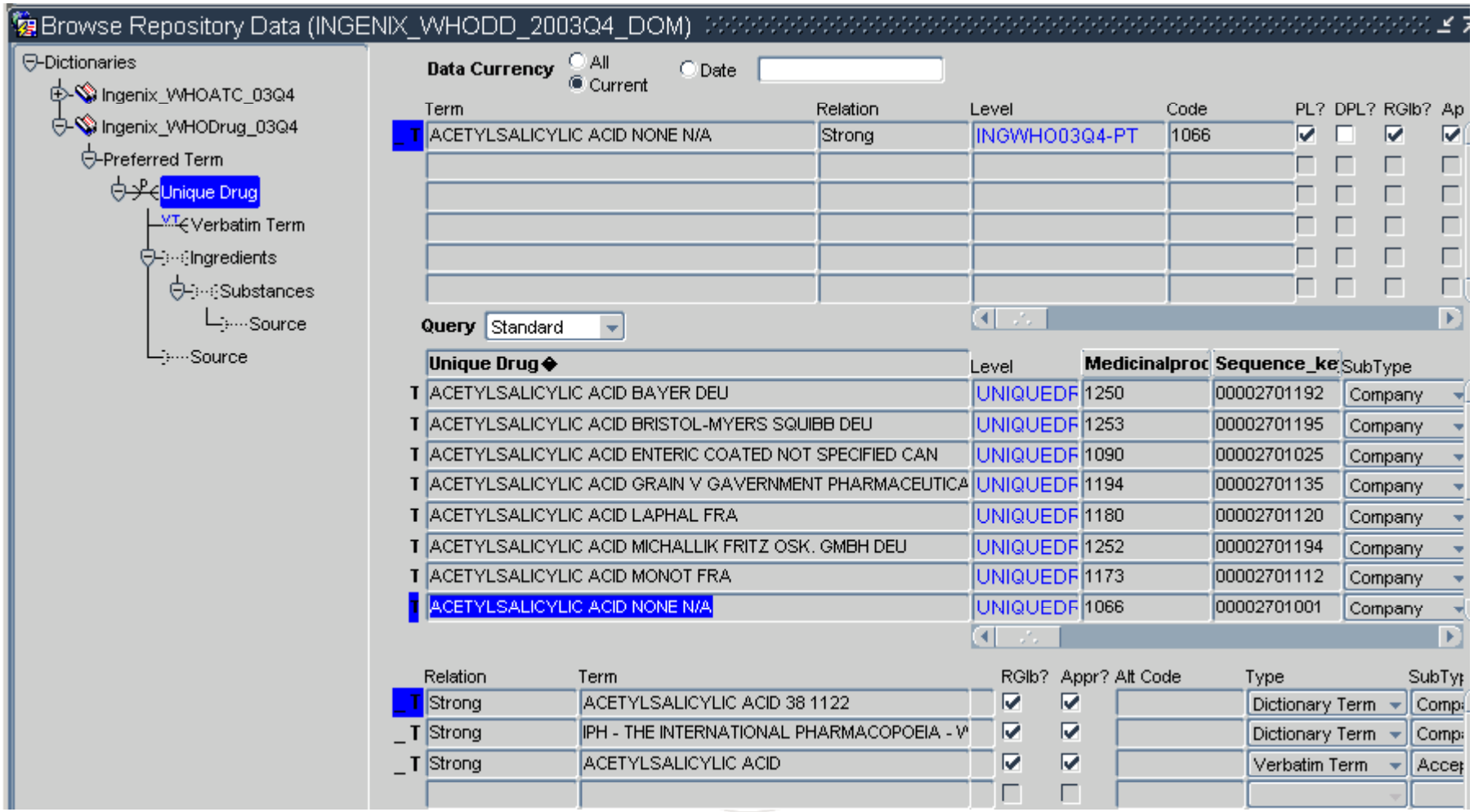
5. Where multiple Medicinal Product IDs exist for a specific Drug Name, and no Medicinal Product ID has Seq2='001' but only one Medicinal Product ID has COUNTRY='UNS' (i.e., the Country code is Unspecified), then make this Drug Name the Verbatim Term.

6. Where multiple Medicinal Product IDs exist for a specific Drug Name, and no Medicinal Product ID has Seq2='001' and no Medicinal Product ID has COUNTRY='UNS', then make the Drug Name with the lowest Medicinal Product ID the Verbatim Term.

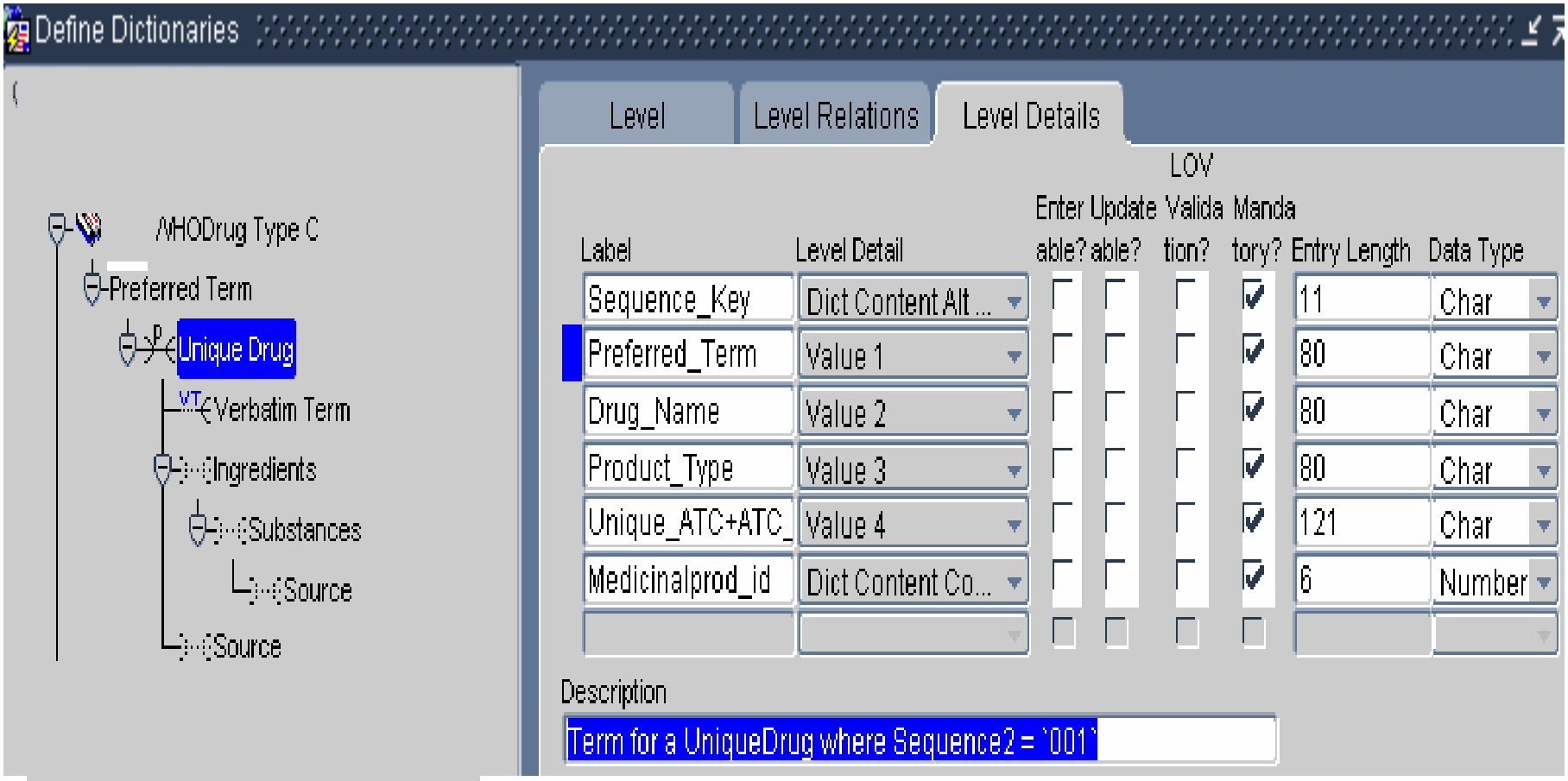
Decision Tree for Selecting VTA



View of TMS, Classification Level in WHODrug Type C



Derivable Level Details with Drug Name and Preferred Drug Name in WHODrug Type C



Want One More Option ?

Option 3: Creating a new level in TMS between Classification level and VT.

During the OPA 5.0 Enhancement meeting from 11-12 May 2004, Oracle OPA Development has suggested creating an intermediate level within the TMS dictionary itself to preserve auto coding.

Option 3 : New Level in TMS

Consider the possibilities…..

- Load Classification level with Drugname_MPID
  - This level is now unique and since your are not going to try to "code" anything to it, it does not need additional description
- For all drugs at the classification level, determine if there are multiple drug names and, for those, if they have the same or different DrgRecNum and SeqN 1
- If the Drug Name is unique, load it at the middle level intermediate

Option 3 : New Level in TMS

- If the Drug Name is not Unique, but all the DrgRecNum|SeqN1's are the same, verify that the PF, Strength and Ingredients are all the same and then choose one to DrugName_MPID to represent the rest and load that at the middle intermediate level.
- You can use the logic presented earlier or some other similar, reproducible logic for selecting which one will represent all these drugs that are the same.
- This would be a stored relation in the TMS dictionary structure

Option 3 : New Level in TMS

- Additionally, some other extensions of this option might make it more useful:
  - Where an entry is made the Intermediate Middle Level, also make a corresponding entry to a VTA level (combining aspects of Option 2)
  - All other non-unique drug names including multiple cases of the same drug name with different DrgRecNums| Seq1 can be loaded to the new mid-level with Drugname_PharmaceuticalForm_Strength_ Ingredients
  - This level will now give you the information your coders need to make decisions on the correct one to chose for coding.
  - A primary link could be considered between the Unique Drug classification level and the Intermediate Level.

Other Considerations of Option 3: Loading New Level

- Loading an additional dictionary level would require structural changes to the existing relations between the Unique Drug Names classification level and the intermediate Middle Level in order to change the default Drug Name/MP_ID, that is, the default coding behavior. These changes would be made through Maintain Repository Data, which can lead to other data-related mistakes or exposures of bugs which can be very difficult to repair.
- Some thinking from a validation perspective might be that the structure and data of a vendor dictionary should never be modified. In this context, modification of VTAs is not the same as modification of the WHO-UMC's dictionary data or dictionary structure

Dictionary Updates and Reducing Data Scope

- One consideration is whether or not all of the Drug data should be loaded. Why not parse all of the Drug Names only and simple load these Drug Names?
  - Not Loading the MP_ID or loss of the MP_ID will make updating this dictionary very difficult. This is because the default TMS APIs for updating the dictionary, TMS_LOAD_DICTIONARY.MigrateRelations and TMS_LOAD_DICTIONARY.MigrateTerms expect a unique DICT_CONTENT_CODE in the dictionary which comes from the vendor which can be compared with queries against the vendor source data to determine what DICT_CONTENT_CODEs to insert/update/delete.
  - Additionally, during the dictionary load process, it is not required to specify a DICT_CONTENT_CODE nor is uniqueness enforced! But during update calls using the TMS_LOAD_DICTIONARY API, it is a de facto expectation.

Dictionary Updates and Reducing Data Scope (2)

- This means not having the MP_ID for all of the WHODrug source data will make updating very difficult. Calls to TMS_USER_MT_DICTIONARY for updating, inserting and deleting terms will have to be made on a separate basis, without the benefit of the TMS migration APIs.
- Additionally, if only part of the drug data is loaded (a reduction in the data scope), it may be possible to make a validation argument that the dictionary loaded in TMS was not actually a representation of the WHO-UMCs WHODrug dictionary, but a customized dictionary which is a proprietary to a single organization, which may introduce some additional validation requirements.

Some Suggested TMS Enhancements

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- Not Requiring Classification Level to be Unique, but instead requiring the combination of the TERM_UPPER along with LEVEL_1 to be unique?
- Allowing configurable column lengths in TMS_DICT_CONTENTS for TERM and TERM_UPPER, so that customers which require a longer Term field (such as Option 2) can extend their classification content past 300 Characters?
- Create a TMS codelist which is default enables which requires dictionaries to be loaded with DICT_CONTENT_CODEs which are not null and unique?

Additional Discussions

1. Consider the slide for Aspirin - Should medications be coded to the level of detail available in the dictionary?

   >If so, how will you accomplish this?

2. Could a procedure be built into OC/TMS that allows for merging specified fields together and have THAT be the VTA that is classified in TMS?

3. Do your CRFs include all the needed information?

4. Will the information be used?

Questions / Contacts

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