

### Assigning Specific ATC Codes In TMS -

A New Approach Using A

Split WHO Drug Dictionary





#### Presented by

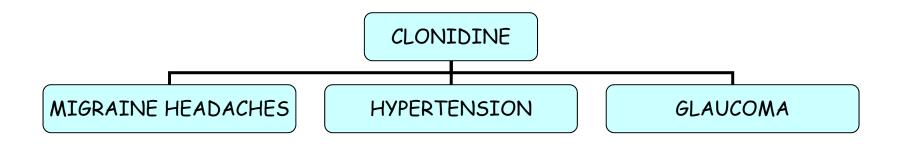
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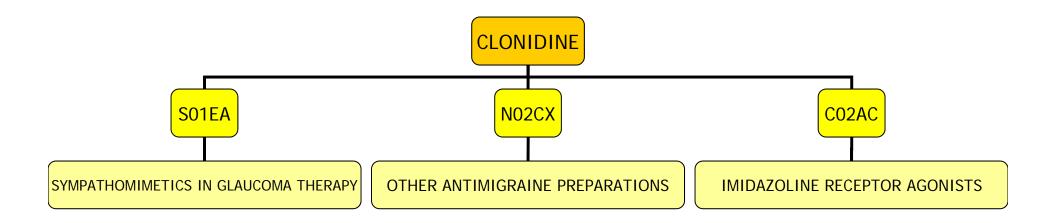


### **Drugs Have Multiple Uses**





## WHO Drug Dictionary Provides Multiple Classification Choices





## Assigning ATC Codes Choices Have Been

Choose ONE
 Classification
 That Is Primarily
 Used

Verbatim	Indication	ATC Code
Catapres-tts	Hypertensive	C02AC
Clonidine gtts	Glaucoma	C02AC
Catapressan	Migraines	C02AC



#### OR

Manually re-classify
Each Occurrence
of Each Term
Individually

Verbatim	Indication	ATC Code
Catapres-tts	Hypertensive	C02AC
Clonidine gtts	Glaucoma	S01EA
Catapressan	Migraines	N02CX

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#### OR

Allow ALL
 Choices To
 Be
 Included In
 Final SAS
 Data Sets
 Requiring
 Special
 SAS Code

Verbatim	Indication	ATC Code	
Catapres-tts	Hypertensive	C02AC	
Catapres-tts	Hypertensive	N02CX	
Catapres-tts	Hypertensive	S01EA	
Clonidine gtts	Glaucoma	C02AC	
Clonidine gtts	Glaucoma	N02CX	
Clonidine gtts	Glaucoma	S01EA	
Catapressan	Migraines	C02AC	
Catapressan	Migraines	N02CX	
Catapressan	Migraines	S01EA	



What If.....

You Could Choose
The Most
Appropriate
ATC Based On
The Indication

Verbatim	Indication	ATC Code	
Catapres-tts	Hypertensive	C02AC	
Clonidine gtts	Glaucoma	S01EA	
Catapressan	Migraines	N02CX	



### Today's Discussion

- Splitting Who Drug Into 2 Separate Dictionaries
- Study Set Up
- Processes For Using The Dictionaries
- Dictionary Structures And Loading Techniques



### Splitting The Dictionary Into Two Parts

WHO DRUG (Dictionary #1)

WHO ATC (Dictionary #2)



### Features Of Dictionary #1

 Verbatim Drugs Found In Dictionary #1 With One ATC Choice Are Fully Coded By That Dictionary

 Using Format C Of The WHO DD Associates Medicinal Products, Instead Of Only Preferred Names, Directly with ATC Codes, Allowing More Drugs To Have One Unique ATC Choice



## 💸 Ingenix Test WhoDrug

Preferred Term

<del>-<sup>M.T</sup>∈</del>Verbatim Term



Θ-∰Substances

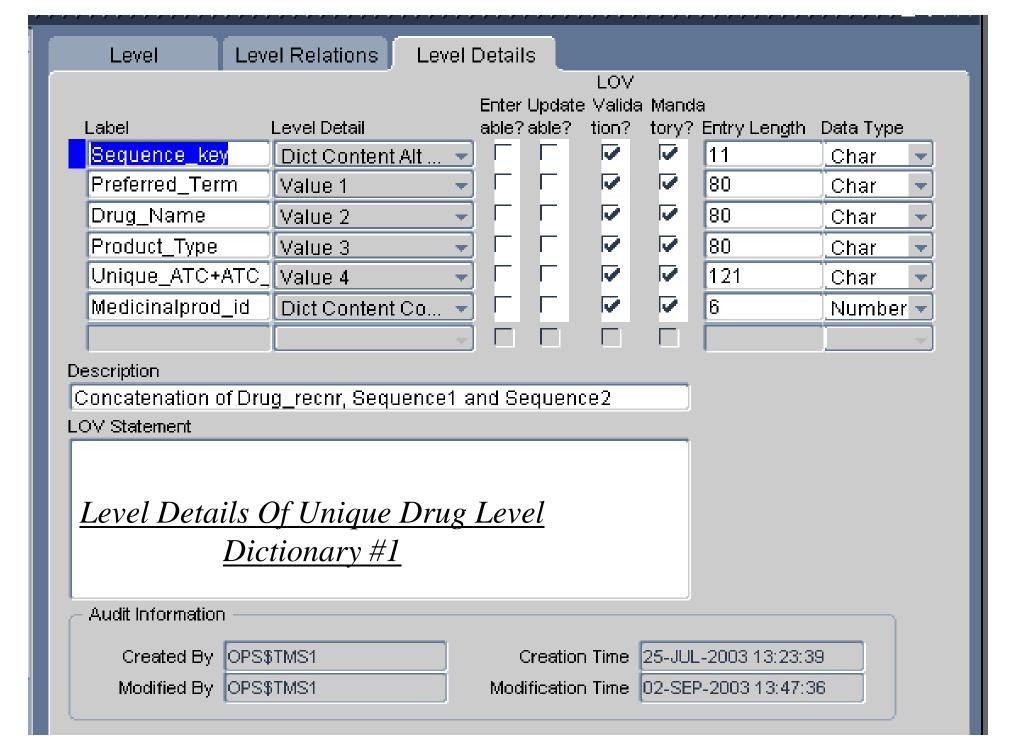
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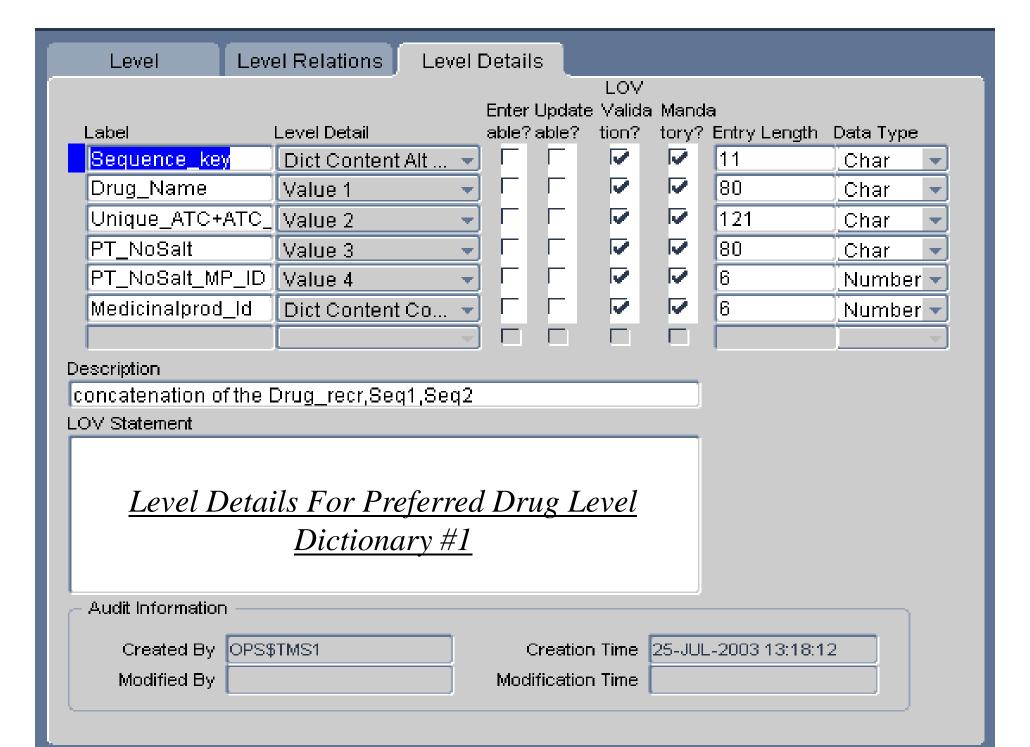
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### Contents Of Dictionary #1 (WHO Drug)

- ✓ Drug Name
- ✓ Preferred Name (Seq 1= 001)
- ✓ Unique Classification Term
- ✓ Drug Rec Num/Seq 1/ Seq 2
- ✓ Form
- ✓ Ingredients
- ✓ ATC Code||ATC Text, Where Only One Is Provided
- ✓ "Multiple" Where >1 Code Is Provided







### Contents Of Dictionary #2 (WHO ATC)

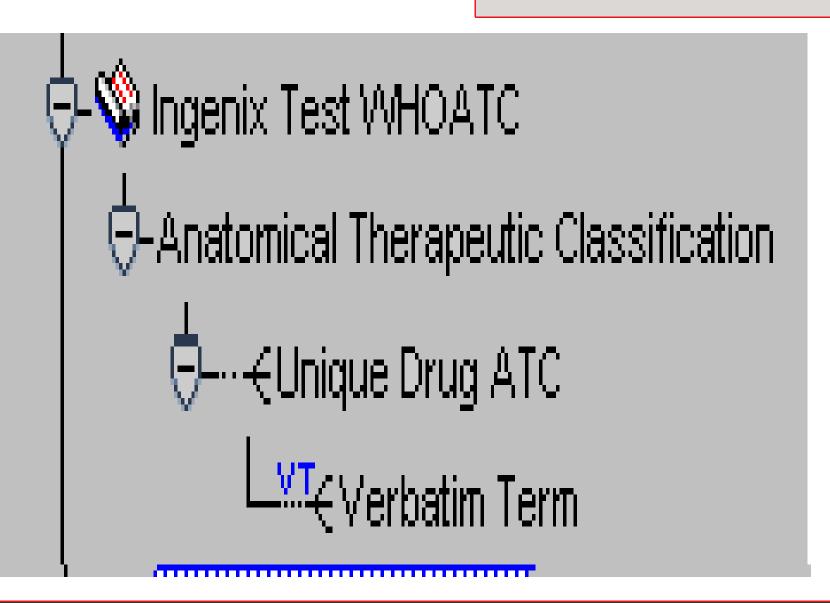
- $\sqrt{\text{Preferred Name (Seq 1= 001)}}$
- √ ATC Code
- √ ATC Text
- √ MP ID For Preferred Name
- √ ATC Level



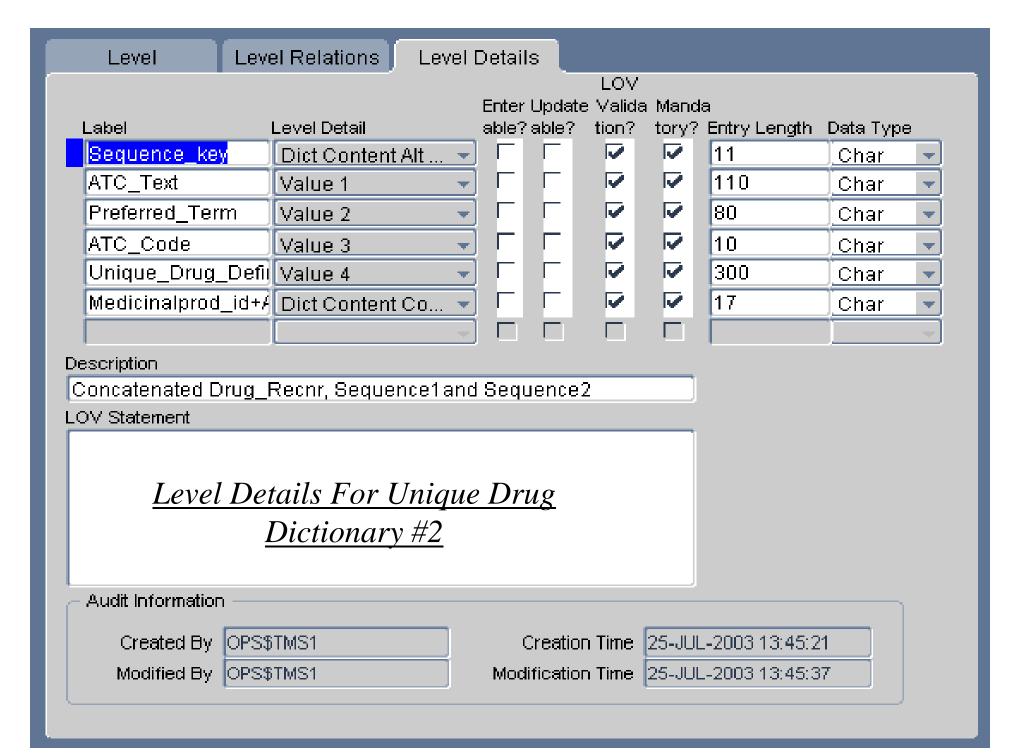
### Features Of Dictionary #2

- Verbatim Term = Derived Preferred Drug Name and the CRF Indication
- Fewer Terms Will Need To Be Classified Than If Drug Name and Indication Were Used As The New Verbatim
- Once A Verbatim Term (Derived Preferred Drug Name + CRF Indication) Is Classified, The Next Instance Of That Combination Will Auto Encode In Dictionary #2
- Previously, the user would need to reclassify this in HLC for each occurrence.

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Level	Level Relations	Level Details			
			LOV		
			pdate Valid		
Label	Level Detail	able?a			
Text	Value 1			110	Char
Level	Value 2	₩.		V 1	Number
ATC_Code	Dict Content	Co 🔻 🗆		<b>1</b> 0	Char
		<b>-</b>			
		<b>-</b>			
		□			-
		<del>-</del>			
Description				•	
2 SSSTIPLIST					
LOV Statement				·	
_	15 11 5		•		
<u>Leve</u>	el Details For 1	<u>Anatomical</u>	,		
There	meutic Classif	ication Lev	el.		
Therapeutic Classification Level					
	<u>Dictionary</u>	<i>7 #2</i>			
Audit Information	1				
Created Pu	ODERTME4		aation Tima	25-JUL-2003	13:40:38
Created By	OF3#119131			ZJ-JUL-ZUUJ	13.42.30
Modified By Modification Time					

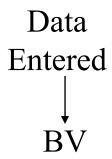
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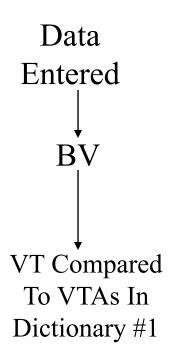
Data Entered



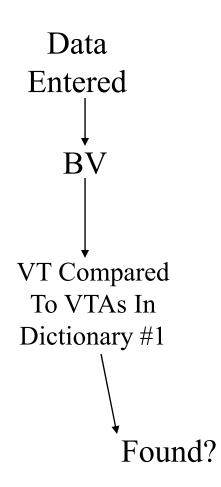




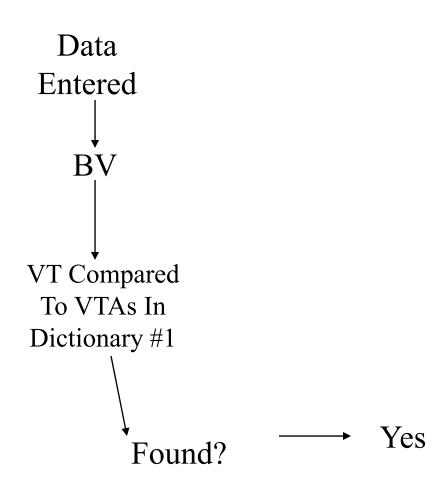




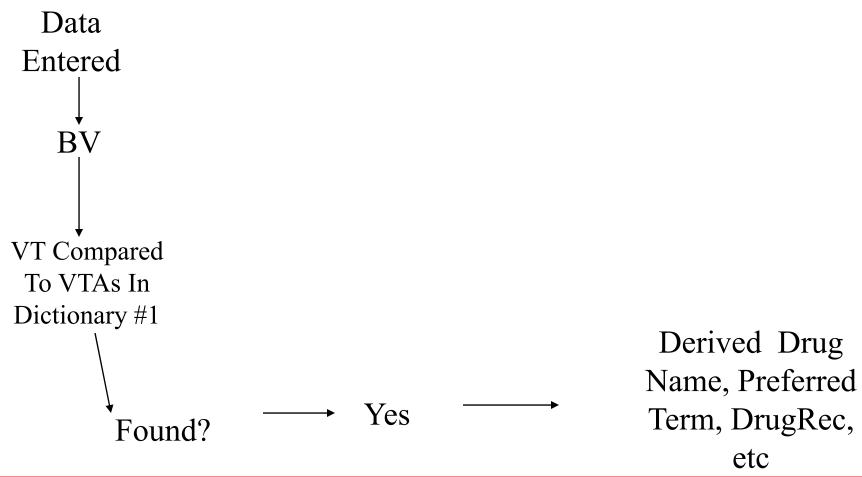




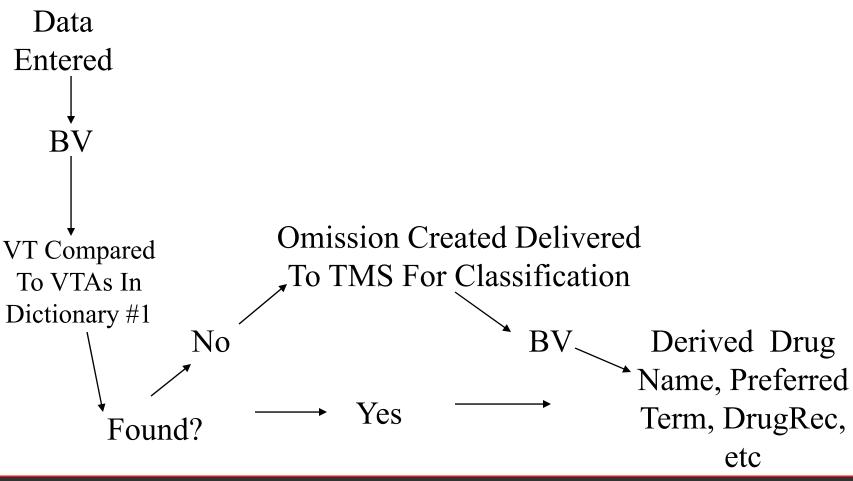






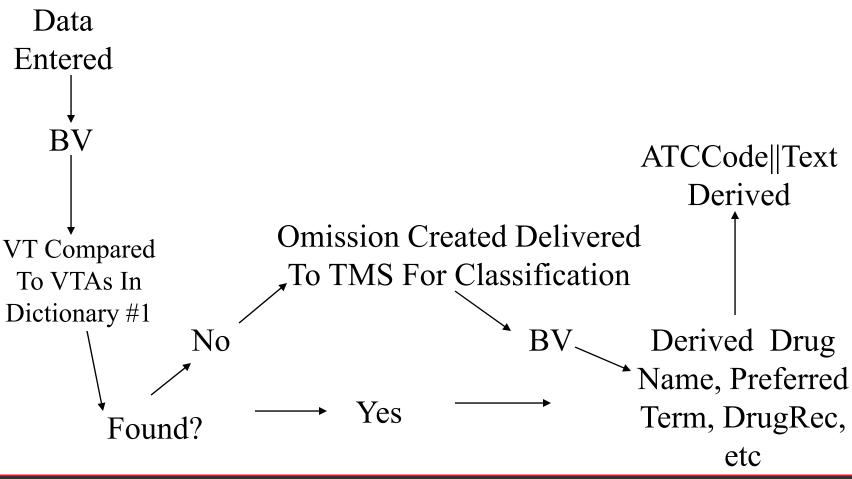








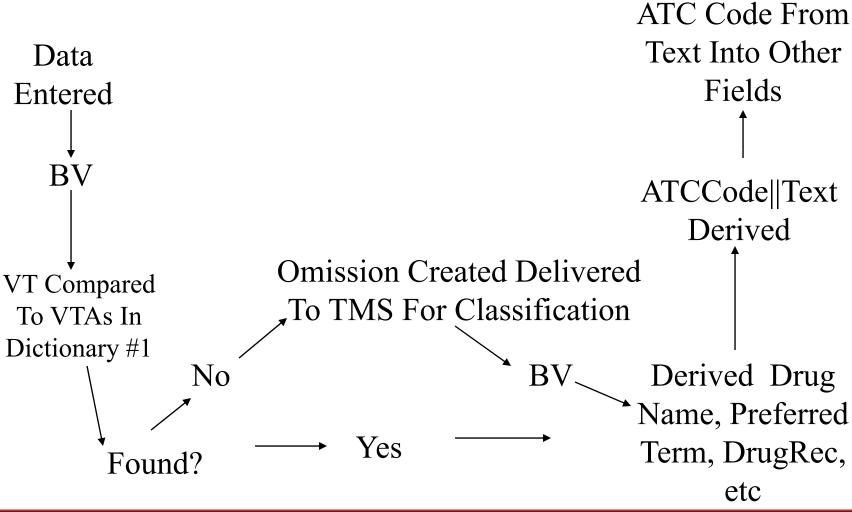






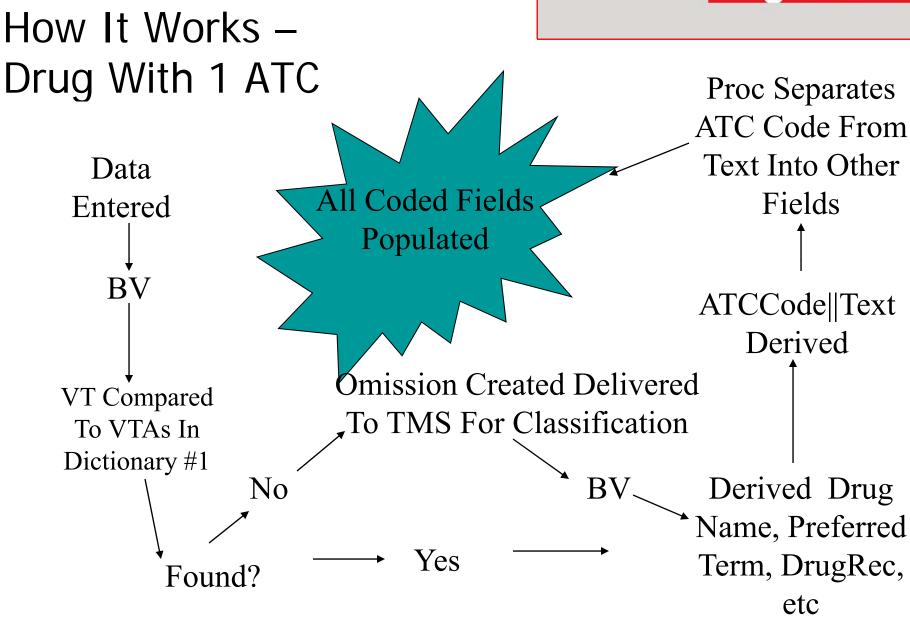
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**Proc Separates** 





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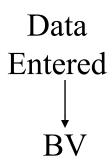




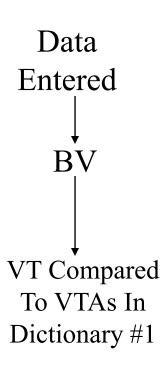


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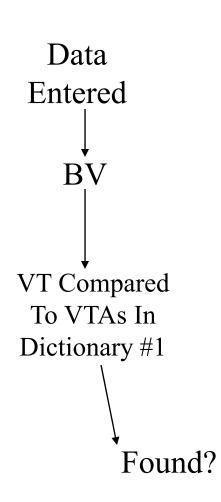




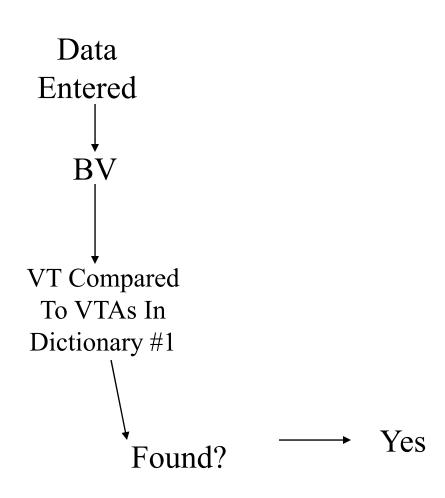
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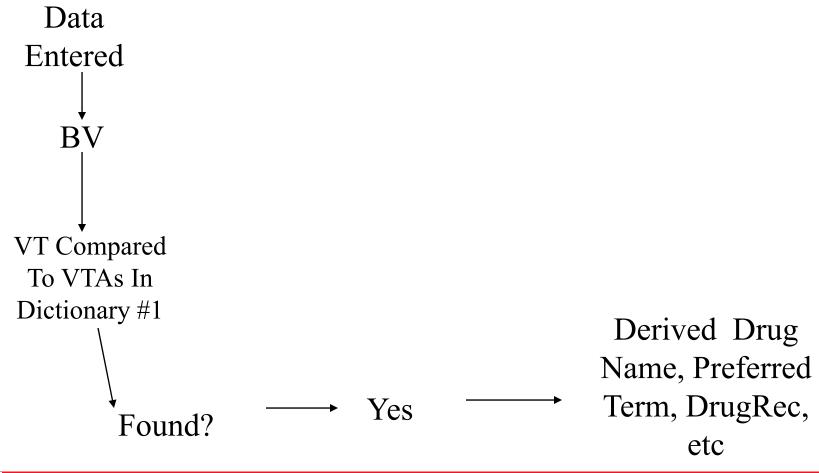


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# How It Works – Drug > 1 ATC

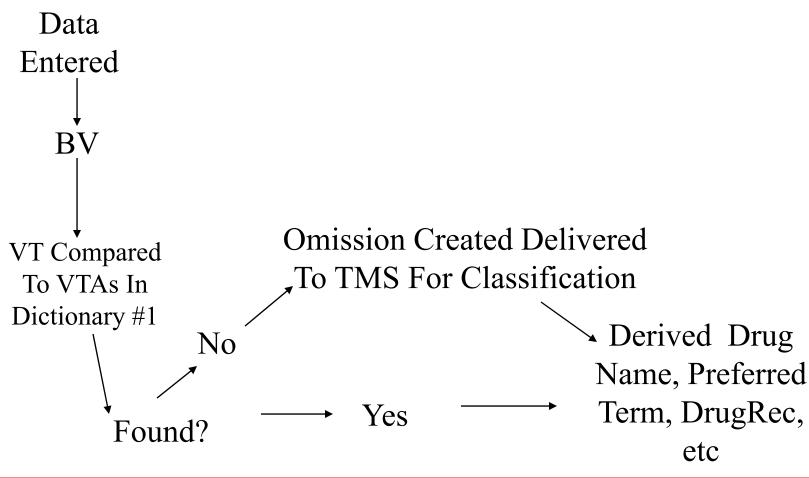
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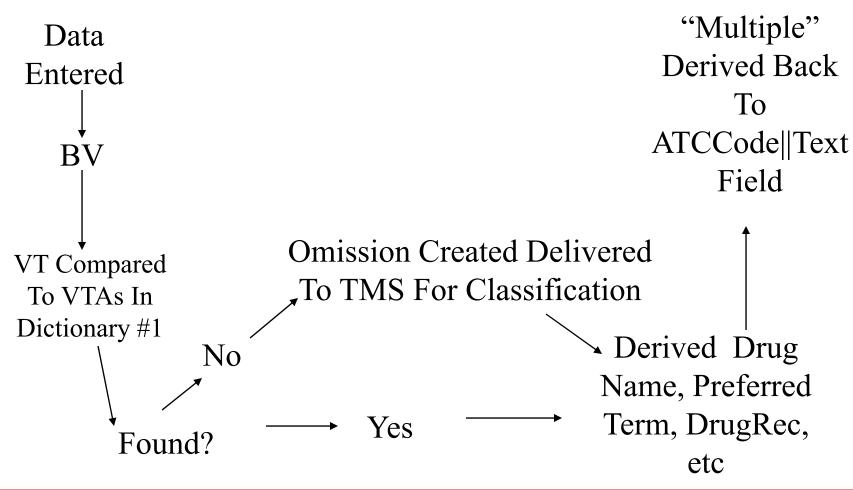
# How It Works – Drug > 1 ATC

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# How It Works – Drug > 1 ATC

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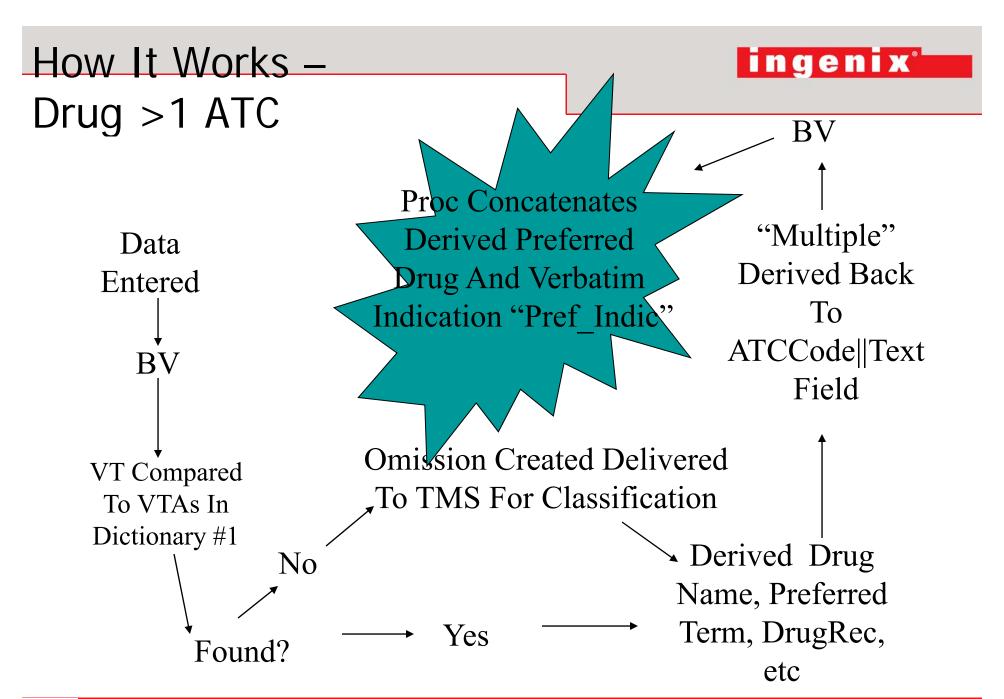


#### How It Works – ingenix° Drug > 1 ATC BV "Multiple" Data Derived Back Entered To ATCCode||Text BV Field **Omission Created Delivered** VT Compared To TMS For Classification To VTAs In Dictionary #1 ➤ Derived Drug No Name, Preferred Term, DrugRec, Yes

etc

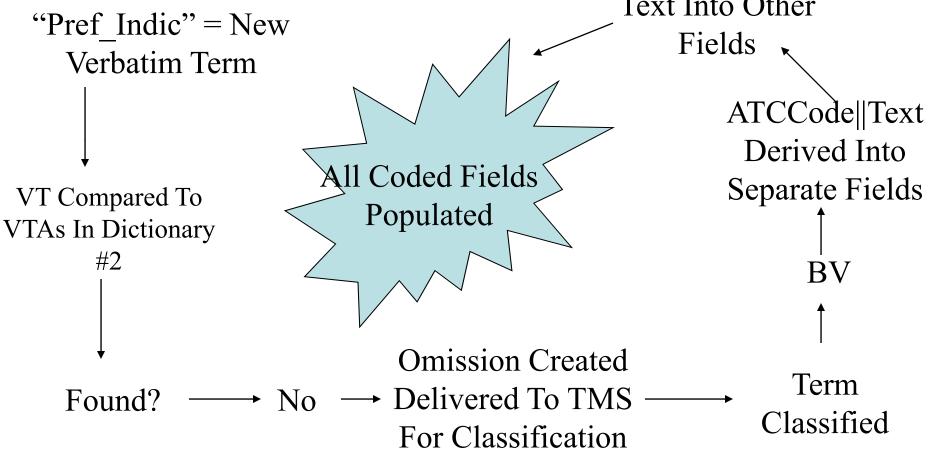


Found?



How It Works – Pref\_Indic Classified To ATC

Proc Separates
ATC Code From
Text Into Other





How It Works – Pref\_Indic Classified To ATC

"Pref\_Indic" = New Verbatim Term



How It Works – Pref\_Indic Classified To ATC

"Pref\_Indic" = New Verbatim Term

VT Compared To VTAs In Dictionary #2

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How It Works – Pref\_Indic Classified To ATC

"Pref Indic" = New Verbatim Term VT Compared To VTAs In Dictionary #2 Found?

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How It Works – Pref\_Indic Classified To ATC

"Pref Indic" = New Verbatim Term VT Compared To VTAs In Dictionary #2 Found? — No

How It Works – Pref\_Indic Classified To ATC

"Pref Indic" = New Verbatim Term VT Compared To VTAs In Dictionary #2 **Omission Created** → No → Delivered To TMS Found? For Classification

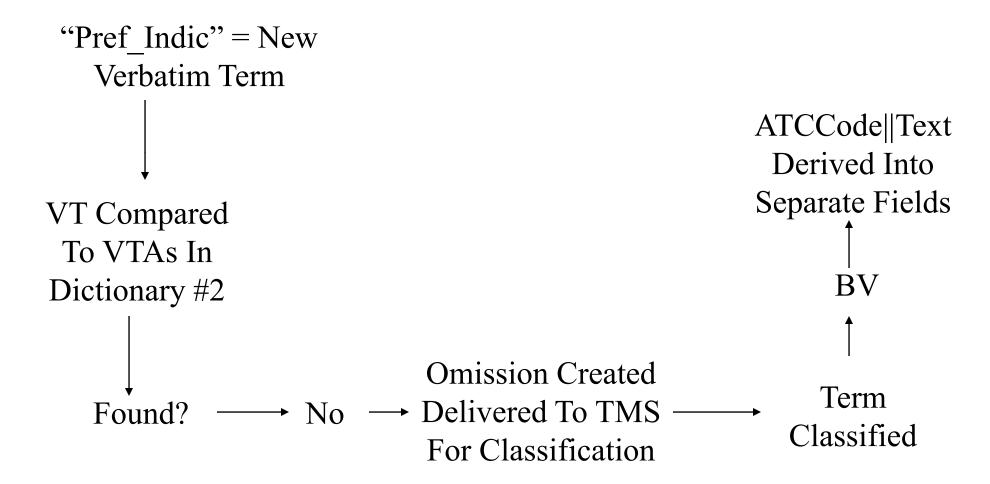
How It Works – Pref\_Indic Classified To ATC

"Pref Indic" = New Verbatim Term VT Compared To VTAs In Dictionary #2 **Omission Created** Term → No → Delivered To TMS Found? Classified For Classification

How It Works – Pref\_Indic Classified To ATC

"Pref Indic" = New Verbatim Term VT Compared To VTAs In BV Dictionary #2 **Omission Created** Term → No → Delivered To TMS Found? Classified For Classification

How It Works – Pref\_Indic Classified To ATC



Classified

How It Works – Proc Separates Pref\_Indic Classified To ATC ATC Code From Text Into Other "Pref Indic" = New Fields Verbatim Term ATCCode||Text **Derived Into** Separate Fields VT Compared To VTAs In BVDictionary #2 **Omission Created** Term Found? → Delivered To TMS

For Classification

How It Works – Proc Separates Pref\_Indic Classified To ATC ATC Code From Text Into Other "Pref Indic" = New Fields Verbatim Term ATCCode||Text **Derived Into** All Coded Fields Separate Fields VT Compared Populated To VTAs In BVDictionary #2 **Omission Created** Term Found? → Delivered To TMS Classified For Classification





# Study Set-Up

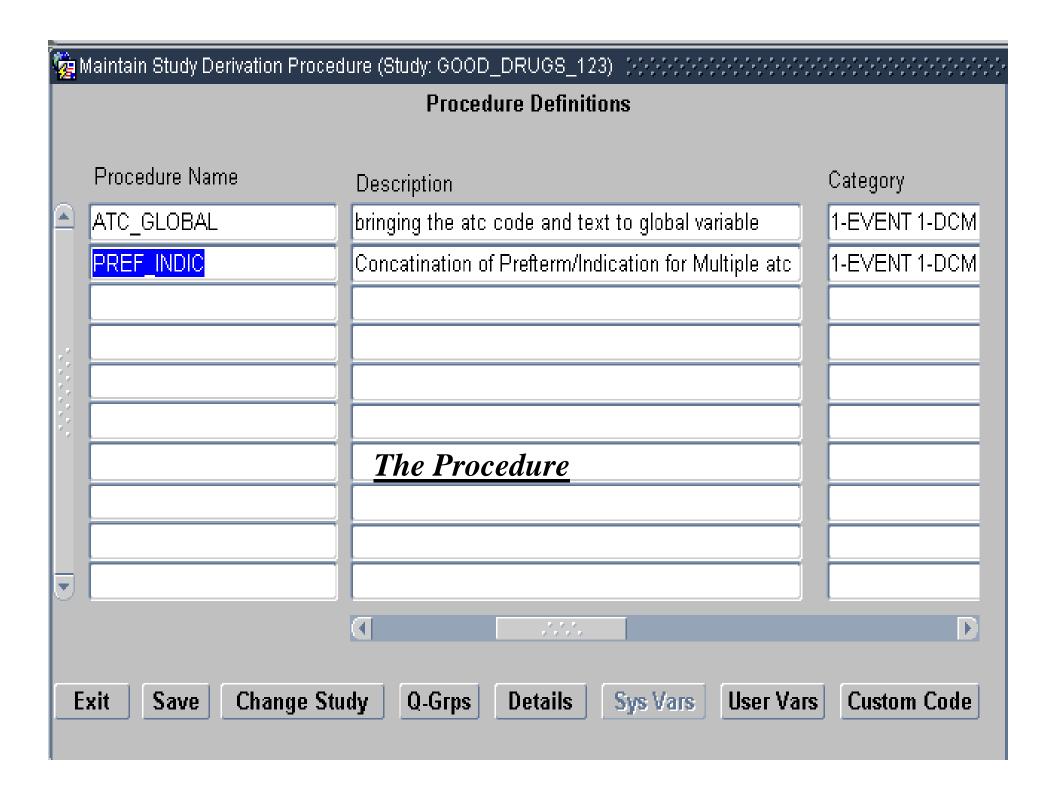
Both Dictionaries In Same Domain

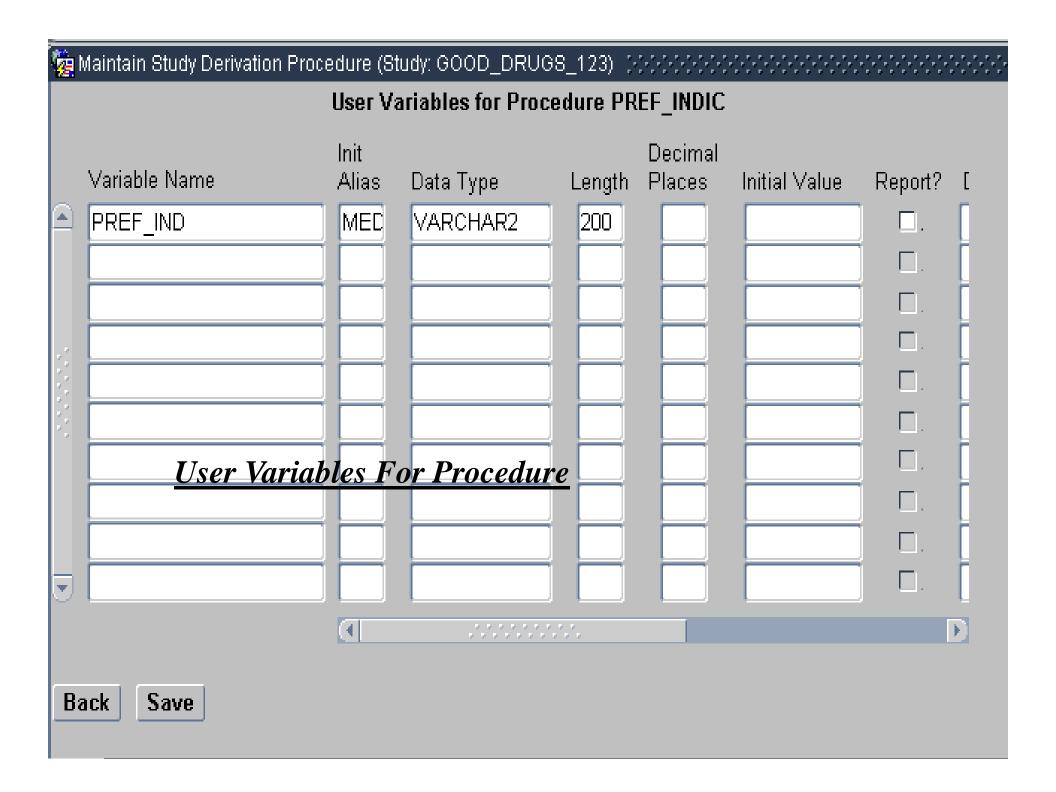
 Glib Has Questions For All Derivable Data Points From Each Dictionary



## Study Set Up

- A Procedure Concatenates The Derived Preferred Drug Name And Indication If The ATC Code="Multiple" In The WHO Drug
- A Procedure Derives ATC Code and Text To A Separate Field For Each







#### Custom Code for Procedure PREF\_INDIC

#### **Custom Code Location**



#### <u>Custom Code – Fields Concatenated</u>

```
PREF_IND :=";

if MED.ATCUNIQ = 'MULTIPLE|' then

PREF_IND := MED.PREFTERM||' '||MED.INDICATION;

end if;
```

Back

Save

#### 🍘 Maintain Study Derivation Procedure (Study: GOOD\_DRUGS\_123)

#### Custom Code for Procedure PREF INDIC

Custom Code Location

\* POST-DETAILS

Custom Code – Flag Reset To Create Omission

```
(resp tab(1).old derived value <> resp tab(1).new derived value
     or (resp_tab(1).old_derived_value is null and resp_tab(1).new_derived_value is not null).
     or (resp. tab(1), old_derived_value is not null and resp_tab(1), new_derived_value is null).
THEN
     update PATIENT_DM_TRACKING PDT
            set PDT.LOCAL_DATA_MODIFIED_FLAG = "Y"
            where PDT.PATIENT POSITION ID =
            RXCPDSTD.PATIENTS REC.PATIENT POSITION ID;
FND IF:
```

Back

Save

### Data Entered

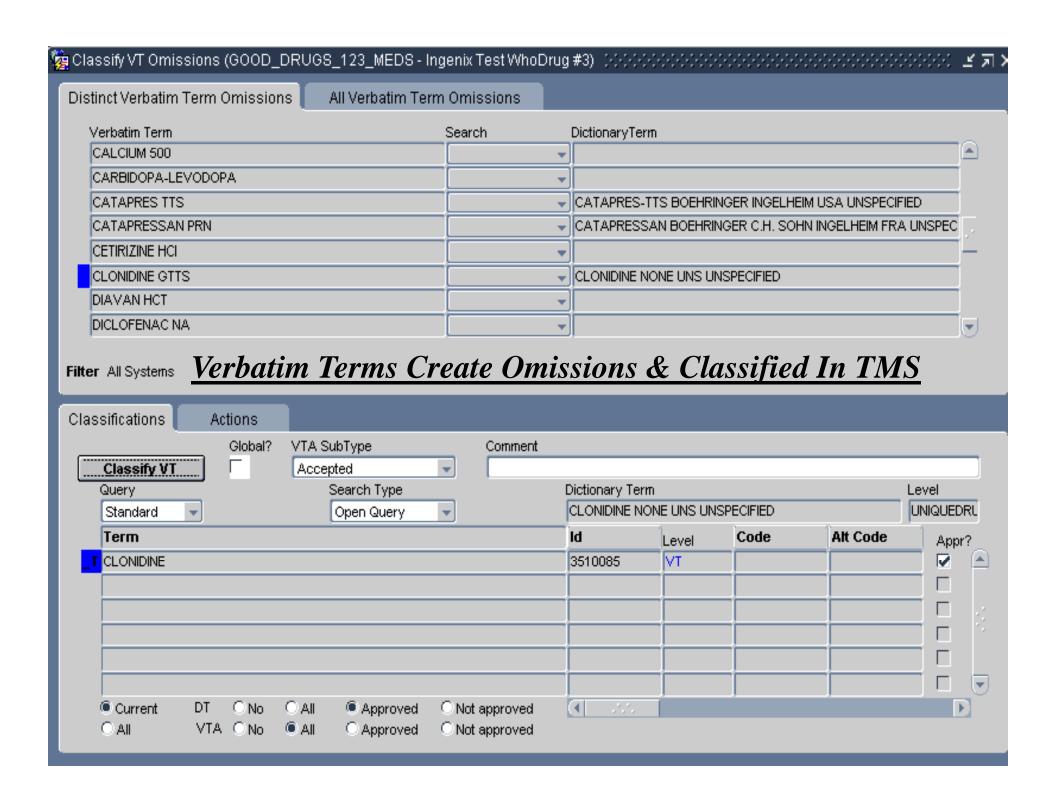
Drug Name	Indication	DRUGTERM	INGENIXDRGCD
VERAPAMIL	MIGRANES	VERAPAMIL	00014301001
ZOCOR	CHOLESTEROL	ZOCOR	00848101004
PAXIL	ANXIETY	PAXIL	00830802006
ESTROGEN	HRT		
GLUCOSAMINE	SUPPLEMENT	GLUCOSAMINE	00943601001
INDOCIN	GOUT	INDOCIN	00003801005
CATAPRES TTS	HYPERTENSIVE		
CATAPRESSAN PRN	MIGRAINES		
CLONIDINE GTTS	GLAUCOMA		
CATAPRES	HYPERTENSIVE		

### Catapres Auto Encodes

Drug Name	Indication	DRUGTERM	INGENIXDRGCD
VERAPAMIL	MIGRANES	VERAPAMIL	00014301001
ZOCOR	CHOLESTEROL	ZOCOR	00848101004
PAXIL	ANXIETY	PAXIL	00830802006
ESTROGEN	HRT		
GLUCOSAMINE	SUPPLEMENT	GLUCOSAMINE	00943601001
INDOCIN	GOUT	INDOCIN	00003801005
CATAPRES TTS	HYPERTENSIVE		
CATAPRESSAN PRN	MIGRAINES		
CLONIDINE GTTS	GLAUCOMA		
CATAPRES	HYPERTENSIVE	CATAPRES	00171101004

### The Rest Of The Fields Valued From Dictionary #1

DRUGTERM	INGENIXDRGCD	MP_ID	NO_SALT	PREFTERM	atx txt dict 2
VERAPAMIL	00014301001	3557	VERAPAMIL	VERAPAMIL	CO8DA PHEr
ZOCOR	00848101004	54039	SIMVASTATIN	SIMVASTATIN	C10AA HMG
PAXIL	00830802006	38405	PAROXETINE	PAROXETINE HYDRO	N06AB SELE
GLUCOSAMINE	00943601001	40716	GLUCOSAMINE	GLUCOSAMINE	M01 AX OTH
INDOCIN	00003801005	1685	INDOMETACIN	INDOMETACIN	MULTIPLE
CATAPRES	00171101004	17968	CLONIDINE	CLONIDINE	MULTIPLE



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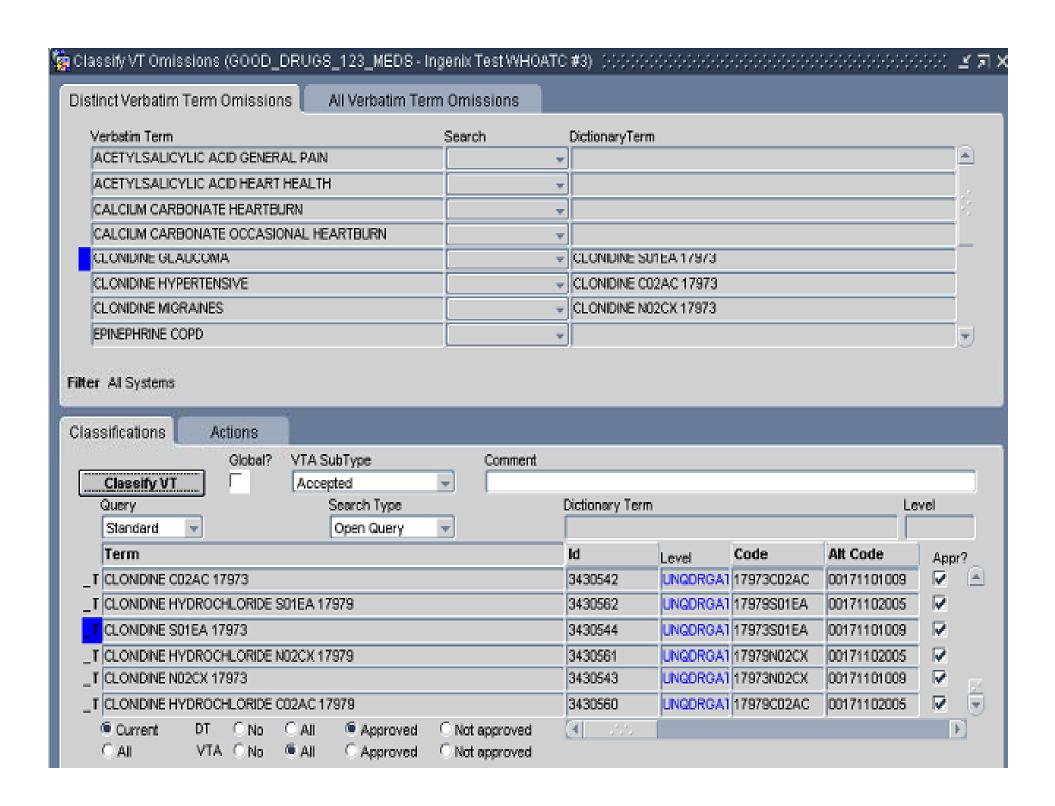
### After BV, Variables Derived From TMS

	NGENIXDRGCD N	MP_ID	NO_SALT	PREFTERM	atx txt dict 2
VERAPAMIL	00014301001	3557	VERAPAMIL	VERAPAMIL	CO8DAJPHENYLALKY
ZOCOR	00848101004	54039	SIMVASTATIN	SIMVASTATIN	C10AA HMG COA REE
PAXIL	00830802006	38405	PAROXETINE	PAROXETINE HYDRO	N06AB SELECTIVE SE
GLUCOSAMINE	00943601001	40716	GLUCOSAMINE	GLUCOSAMINE	M01 AX OTHER ANTIIN
INDOCIN	00003801005	1685	INDOMETACIN	INDOMETACIN	MULTIPLE
CATAPRES-TTS (	00171101010	17974	CLONIDINE	CLONIDINE	MULTIPLE
CATAPRESSAN	00171101006	17970	CLONIDINE	CLONIDINE	MULTIPLE
CLONIDINE	00171101001	17965	CLONIDINE	CLONIDINE	MULTIPLE
CATAPRES	00171101004	17968	CLONIDINE	CLONIDINE	MULTIPLE

### BV Run To Create New VT - Pref\_Indica



Page 1 of 1, Repeat 11 of 11. 🎊	***************************************	🌣 1 of 1, Repeat 11 of 11.	. >>>>>>>		
Drug Name	Indication	atx txt dict 2	ATCCD_GLOBAL	ATCTXT_GLOBAL	PREF_INDICA
VERAPAMIL	MIGRANES	C08DA PHENYLALKY	C08DA	PHENYLALKYLAMINE	
ZOCOR	CHOLESTEROL	C10AAJHMG COA REI	C10AA	HMG COA REDUCTAS	
PAXIL	ANXIETY	N06AB SELECTIVE SE	N06AB	SELECTIVE SEROTON	
ESTROGEN	HRT				
GLUCOSAMINE	SUPPLEMENT	M01 AX OTHER ANTIIN	M01AX	OTHER ANTIINFL./ANT	
INDOCIN	GOUT	MULTIPLE			INDOMETACIN GOUT
CATAPRES TTS	HYPERTENSIVE	MULTIPLE			CLONIDINE HYPERTEN
CATAPRESSAN PRN	MIGRAINES	MULTIPLE			CLONIDINE MIGRAINES
CLONIDINE GTTS	GLAUCOMA	MULTIPLE			CLONIDINE GLAUCOW
CATAPRES	HYPERTENSIVE	MULTIPLE			CLONIDINE HYPERTEN
,,,,,,,,,				W.	)



### ATC Codes & Text Are Returned To OC

Drug Name	Indication	ATCCD_GLOBAL	ATCCODE	ATC Level	ATCTXT
VERAPAMIL	MIGRANES	COBDA			
ZOCOR	CHOLESTEROL	C10AA			
PAXIL	ANXIETY	NOBAB			
ESTROGEN	HRT				
GLUCOSAMINE	SUPPLEMENT	M01AX			
INDOCIN	GOUT				
CATAPRES TTS	HYPERTENSIVE	C02AC	C02AC	4	MDAZOLNE RECE
CATAPRESSAN PRN	MIGRAINES	N02CX	N02CX	4	OTHER ANTIMIGRA
CLONIDINE GTTS	GLAUCOMA	S01EA	SOIEA	4	SYMPATHOMMETI
CATAPRES	HYPERTENSIVE	C02AC	C02AC	4	MDAZOLNE RECE



# Loading of Dictionary #1 (WHO Drug)

- The classification level of Unique Drug consists of a term with the logical expansion of the Medicinal Product ID from the MP table of the Type C (Vigibase) WHODrug Format
- A set of Global VTAs are loaded where the Drug Name from the MP table happens to be associated with only one Drug Name, Drug Record Number and Sequence 1
- A Primary Link is required only because there are few cases where the same occurrence of a Preferred Term exists with more than one Medicinal Product ID. It is not significant from a coding perspective.



SQL> desc whodrug_mp Name	Null?	Туре
MEDICINALPROD_ID DRUG_RECNR SEQUENCE1 SEQUENCE2 GENERIC DRUG_NAME NAME_SPECIFIER COUNTRY MANUFACTURER MA_HOLDER SOURCE_CODE SOURCE_COUNTRY SOURCE_YEAR PRODUCT_TYPE PRODUCT_GROUP DATE_ENTERED	NOT NULL NOT NULL NOT NULL	NUMBER(6) VARCHAR2(6) VARCHAR2(2) VARCHAR2(3) VARCHAR2(1) VARCHAR2(80) VARCHAR2(30) VARCHAR2(3) VARCHAR2(6) VARCHAR2(6) VARCHAR2(3)
DATE_CHANGED		DATE



# 💸 Ingenix Test WhoDrug



<del>-<sup>M.T</sup>∈</del>Verbatim Term

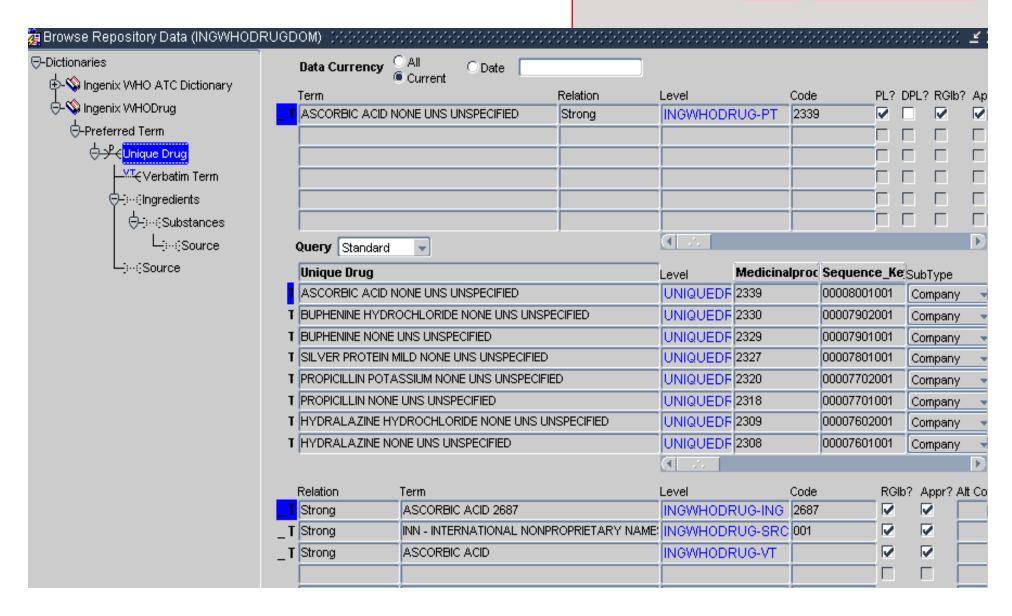


Θ-∰Substances

–⊱…Source

-⊱...Source

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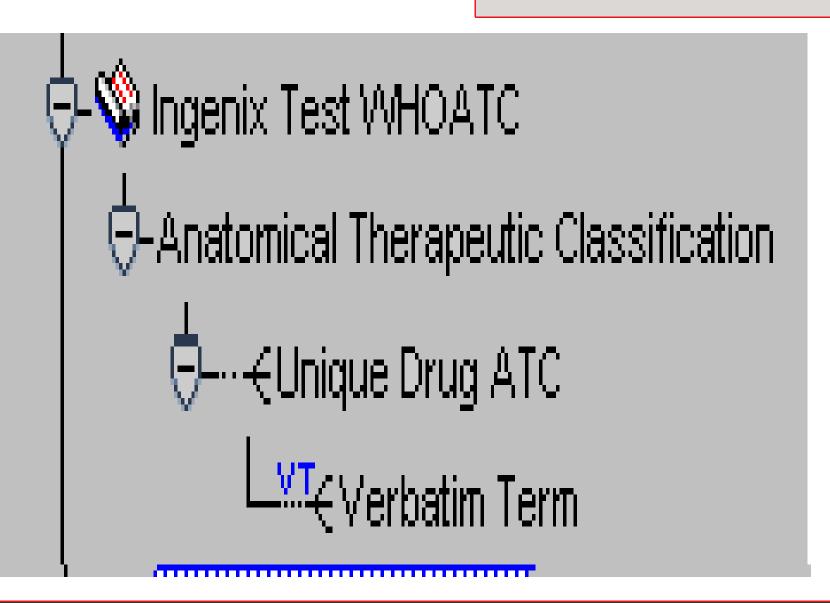




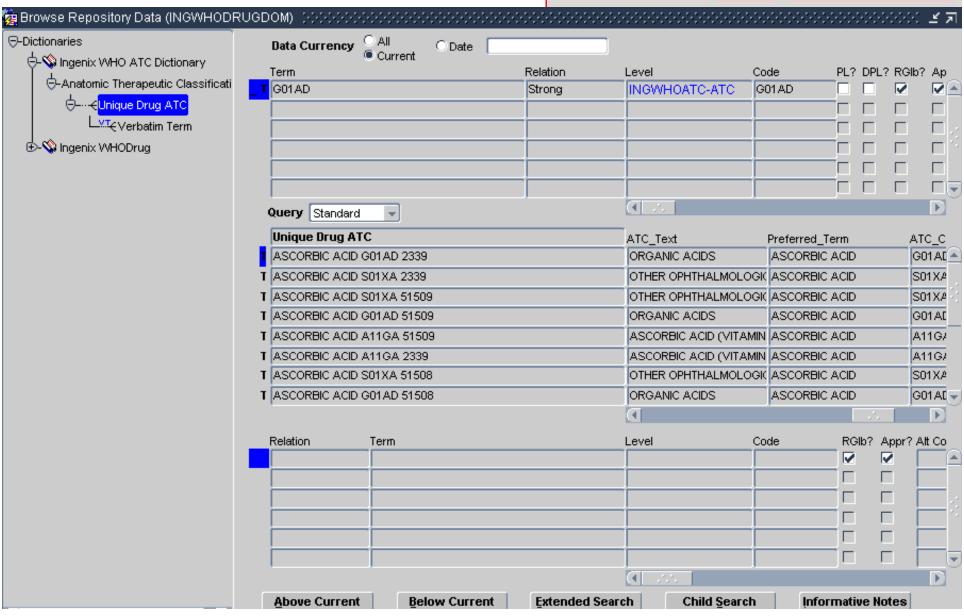
# Loading of Dictionary #2 (WHO ATC)

- The classification level of Drug Names with each possible ATC Code and the Medicinal Product ID
- The level detail contains the ATC Text, ATC Code, Preferred Name, and the logical expansion of the Medicinal Product ID separately
- The mandatory-ness to the ATC level can not be enforced since there are some ATCs which are not associated to any Drug Names

SQL> desc WHODRUG_THG Name	Null?	Туре	
THERAPGROUP_ID ATC_CODE CREATE_DATE OFFICIAL_ATC_CODE MEDICINALPROD_ID		NUMBER(6) VARCHAR2(10) VARCHAR2(8) VARCHAR2(1) NUMBER(6)	
SQL> desc WHODRUG_ATC Name	Nu11?	Туре	
ATC_CODE ATC_LEVEL TEXT	NOT NULL	VARCHAR2(10) NUMBER(1) VARCHAR2(110)	











### Conclusion

- This is one possible way to derive ATC codes from WHODrug, while in TMS, based on the indicated use
- Defining requirements for derived data from WHODrug should be the business driver for the implementation in TMS. A combination of multiple dictionary structure and derivation procedures achieved the requirements in this case.



### **Additional Questions?**

- Electronic copies will be posted on the OCUG Intranets Site and <u>www.ingenix.com</u> and <u>www.clinicalserver.com</u>
- Additional copies will be available at Ingenix Booth #10 in the Exhibit Hall, along with
  - Demo of RDC
  - Laptop Modem cables
- Additional copies will be available at DBMS Consulting's Booth #3 in the Exhibit Hall, along with
  - OPA 4.5 Architecture Posters
  - Flashlight giveaways