

Reusing Common TMS Dictionaries in  
an Integrated Oracle Clinical and  
Oracle AERS Environment:  
Leveraging One MedDRA and  
WHODrug Dictionary Load for Both  
CDM and PV Groups

Presented by Sunil G. Singh of DBMS Consulting



## *Acknowledgements*

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- Thanks to the audience members for attending.



## Goals

- Identify the advantages of having an integrated OC/TMS/AERS environment with one set of dictionaries.
- Identify the technical prerequisites of having an integrated OC/TMS/AERS environment with one set of dictionaries.
- Examine the business use prerequisites between Pharmacovigilance (PV) and Clinical Data Management (CDM) groups to make one set of TMS dictionary utilization possible.



## *Goals (2)*

- Examine possible periodic update paths for MedDRA and WHODrug in a common environment.
- Suggest possible integration friendly improvements in the AERS TMS dictionary structures.



## *Technical Prerequisites*

### OC/TMS/AERS environment integration:

- Common instances with UTF8 character set
  - Oracle Intermedia and Text Server installed
  - Oracle Portal installed
- Optionally integrated or separate Windows Middle Tiers



## *Technical Prerequisites (2)*

OC/TMS/AERS environment integration:

- Optional separate TMS repository instance (TMS 4.5.2) which is called by both separate OC and AERS environments
- This could potentially have impacts on processing time and is outside the scope of this current discussion.



## *Benefits of Integration*

<b>OC/TMS/AERS</b>	<b>Implied Benefits</b>
Maintaining a single production instance	Maintain, monitor & patch one instance Reduce amount of human administration effort
One backup and recovery plan	Reduce backup and DRP planning and resources
One load of TMS dictionaries	Reduce space utilization and possibly processing time of batch jobs
One set of MedDRA and WHOdrug dictionaries	Load and update one set of MedDRA and WHOdrug dictionaries



## *Prerequisites for Using the Same TMS Dictionaries*

OC/TMS/AERS environment integration:

- Agreement between all users on the structure of the WHODrug and MedDRA dictionary being the AERS default structure.
- Agreement between all users for a common update schedule of the same TMS WHODrug and MedDRA Dictionaries.





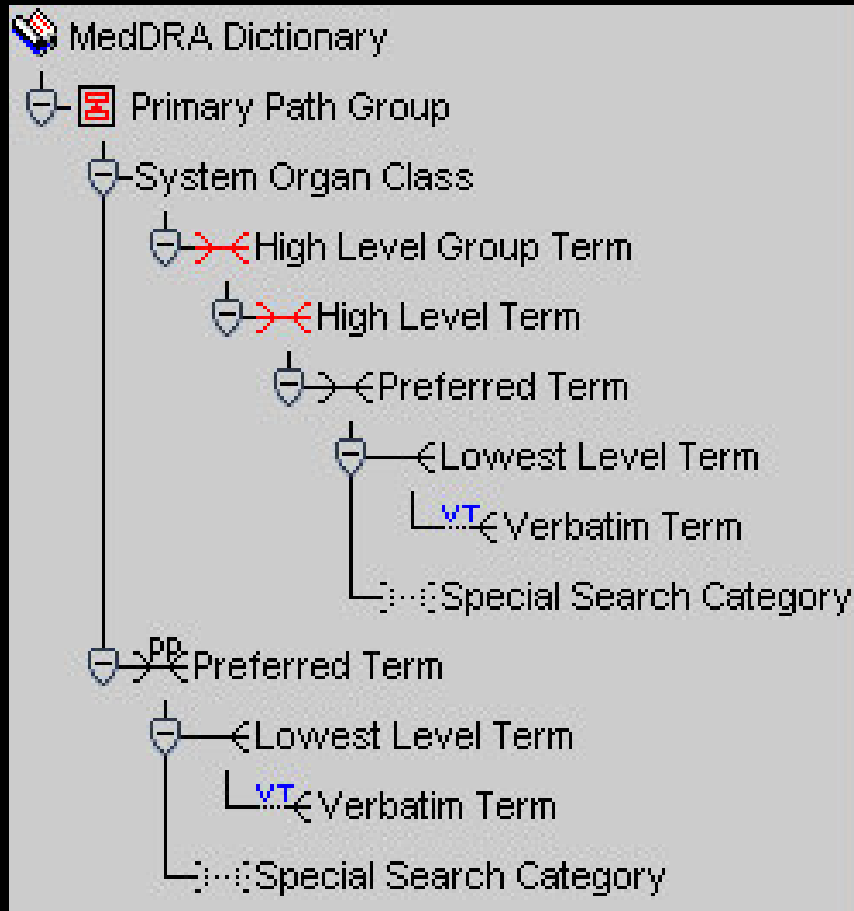
## *Prerequisites for Using the Same TMS Dictionaries (2)*

OC/TMS/AERS environment integration:

- Agreement on universal acceptance of coding between PV and CDM groups, or agreement on process changes to support separate coding through different TMS Dictionary Domains.
- Since Global VTAs can be used simultaneously with Domain VTAs, where the Domain VTAs take precedence over the Global VTAs, multiple sets of coding including Global VTAs are possible.



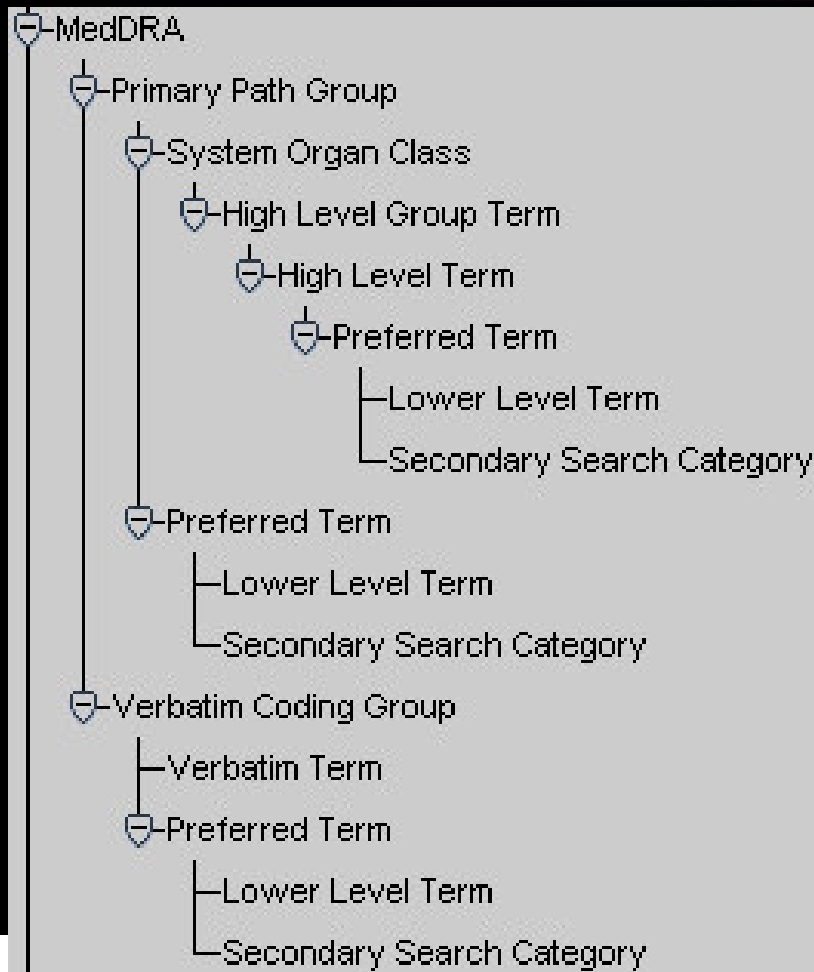
# Dictionary Structure: OC/TMS MedDRA



- Default OC/TMS MedDRA with Primary Path Dictionary
- Note only the LLT level is used for coding



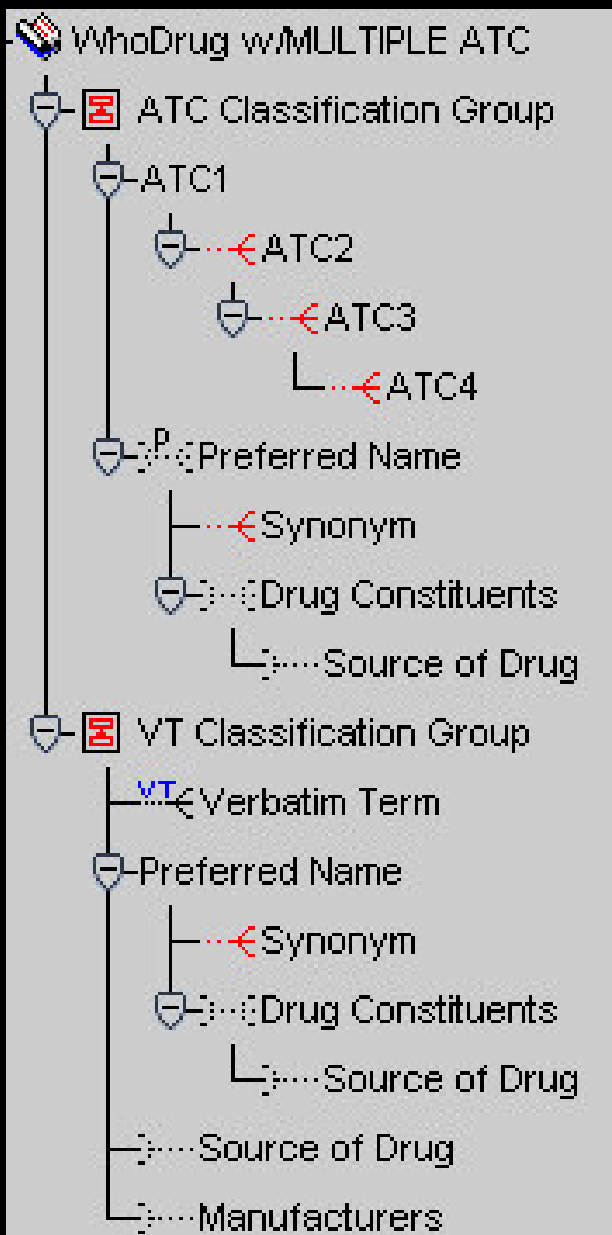
# Dictionary Structure: AERS/TMS MedDRA



- AERS/TMS MedDRA Dictionary
- Agreement between CDM and PV groups implies using a coding group of both LLT and PT



# Dictionary Structure: OC/TMS WHODrug

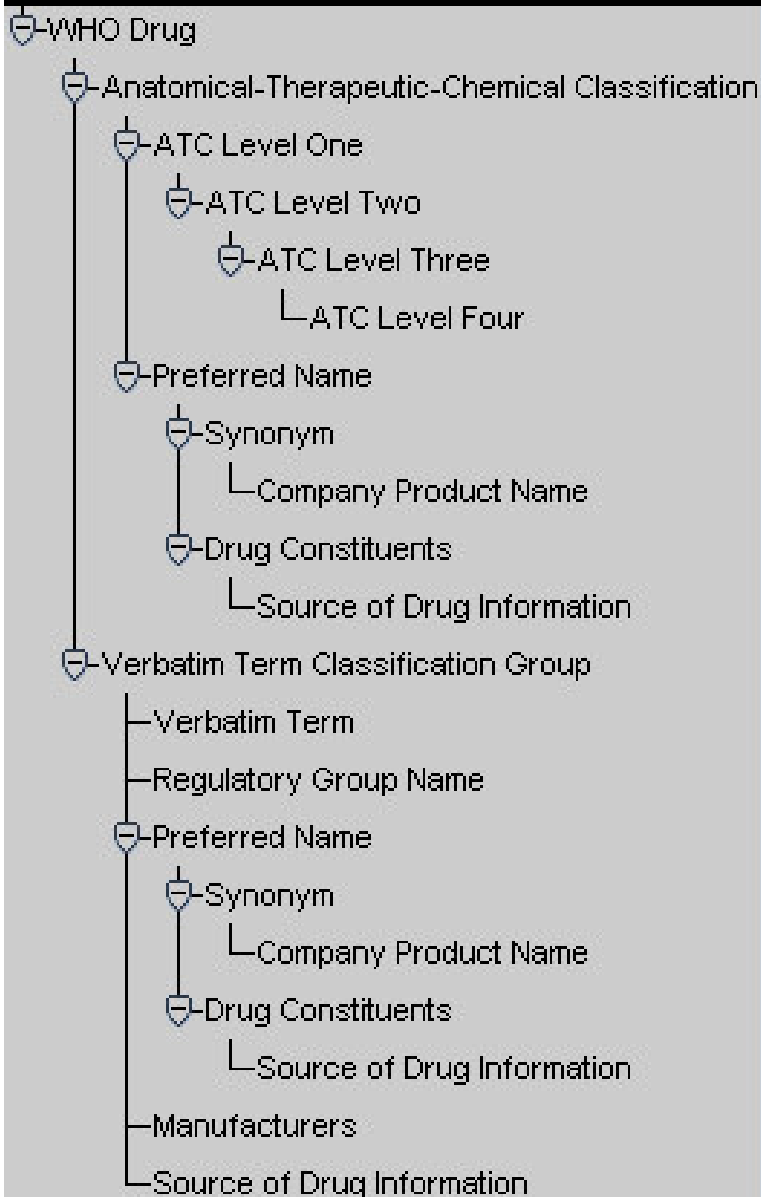


- OC/TMS WHODrug Dictionary
- Note that a Primary Link allows some type of derivation of ATCs



# Dictionary Structure: AERS/TMS WHODrug

- AERS/TMS WHODrug Dictionary
- Agreement between CDM and PV groups implies that no ATCs would be derived to OC



## Dictionary Structure: LLT Level

- Implications of Agreeing: OC/TMS MedDRA Classification Group at the LLT level

Classifications Actions

Global? VTA SubType Accepted Comment

**Classify VT**  Enter Notes? Search Type Open Query Dictionary Term

Query Standard

Term	Id	Level
<input checked="" type="checkbox"/> Aortic valve stenosis	222871	LLT
<input type="checkbox"/> Ectopia cordis	348161	LLT
<input type="checkbox"/> Ductus arteriosus stenosis fetal	343981	LLT
<input type="checkbox"/> Atresia biliary	231401	LLT
<input type="checkbox"/> Congenital tricuspid valve stenosis	312271	LLT
<input type="checkbox"/> Congenital pulmonary valve stenosis	311681	LLT

Current DT  No  All  Approved  Not approved  
 All VTA  No  All  Approved  Not approved



# Dictionary Structure: LLT and PT Levels

- Implications of Agreeing: AERS/TMS MedDRA Classification Group at the LLT and PT levels

Classifications Actions

**Classify VT**  Global?  VTA SubType  Comment

Query  Enter Notes?  Search Type  Dictionary Term

Term	Id	Level
_T Blood 1,25-dihydroxy vitamin D decreased	1348761	LLT
_T Blood 1,25-dihydroxy vitamin D increased	1348751	LLT
_T Blood 1,25-dihydroxycholecalciferol	1436831	PT
_T Blood 1,25-dihydroxycholecalciferol decreased	1372481	PT
_T Blood 1,25-dihydroxycholecalciferol increased	1372471	PT
<b>_T Blood 25-hydroxy vitamin D2</b>	1426261	LLT

Current    DT     No     All     Approved     Not approved  
 All    VTA     No     All     Approved     Not approved



# Dictionary Structure: MedDRA

## Derivation in OC

- Implications of Agreeing: OC/TMS all 5 MedDRA levels derivable

The screenshot displays a software interface for configuring MedDRA levels. On the left, a hierarchical tree shows levels 1 through 5, with 'Primary Path Group' circled in pink. The right panel, titled 'Relation Type: Level', shows configuration for a 'Parent' (Primary Path Group) and a 'Child' (Preferred Term). The 'Parent' configuration includes fields for Level Name, Short Name, Mandatory?, Many Cardinality?, Primary Link?, Primary Path Link?, and Derivable? (circled in pink). The 'Child' configuration includes fields for Level Name, Short Name, Mandatory?, and Many Cardinality?.

Field	Parent (Primary Path Group)	Child (Preferred Term)
Level Name	Primary Path Group	Preferred Term
Short Name	PPG	PT
Mandatory?	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
Many Cardinality?	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
Primary Link?	<input type="checkbox"/>	
Primary Path Link?	<input checked="" type="checkbox"/>	
Derivable?	<input checked="" type="checkbox"/>	





# Dictionary Structure: : MedDRA Derivation in AERS

- Implications of Agreeing: AERS/TMS all 5 MedDRA levels derivable

The screenshot displays a software interface for configuring dictionary relationships. On the left, a tree view shows the MedDRA hierarchy with levels 1 through 5. Level 1 is 'Primary Path Group', level 2 is 'System Organ Class', level 3 is 'High Level Group Term', level 4 is 'High Level Term', and level 5 is 'Preferred Term'. The 'Preferred Term' node is highlighted with a blue dashed box. On the right, a configuration form is shown for a 'Level' relationship. The 'Parent' side is configured with 'Level Name' as 'Primary Path Group', 'Short Name' as 'PPG', and 'Derivable?' checked. The 'Child' side is configured with 'Level Name' as 'Preferred Term', 'Short Name' as 'PT', and 'Derivable?' checked. The 'Derivable?' checkbox is circled in pink.



# Dictionary Structure: WHODrug ATC Derivation in OC

- Implications of Agreeing: OC/TMS WHODrug Type B2 dictionary has a Primary Link for deriving ATCs

The screenshot displays a software interface for configuring a dictionary structure. On the left, a tree view shows a hierarchy: ATC1 (Parent) -> ATC2 (Child) -> ATC3 (Child) -> ATC4 (Child). Below this, other nodes are listed: Preferred Name, Synonym, Drug Constituents, and Source of Drug. The 'Preferred Name' node is highlighted with a blue box. On the right, a configuration panel for the 'ATC Classification Group' is shown. The 'Parent' section has 'Level Name' set to 'ATC Classification Group' and 'Short Name' set to 'ATC'. The 'Child' section has 'Level Name' set to 'Preferred Name' and 'Short Name' set to 'PN'. Both sections have 'Mandatory?' unchecked and 'Many Cardinality?' checked. The 'Primary Link?' checkbox is checked, and the 'Derivable?' checkbox is also checked. The 'Relation Type' is set to 'Level'.



# Dictionary Structure: WHODrug No ATC Derivation in AERS

- Implications of Agreeing: AERS/TMS WHODrug Type B2 dictionary does NOT derive ATC codes.

The screenshot displays a software interface for dictionary configuration. On the left, a tree view shows the hierarchy: 'Anatomical-Therapeutic-Chemical Classification Group' (circled in pink), followed by 'ATC Level One', 'ATC Level Two', 'ATC Level Three', and 'ATC Level Four'. Below these are 'Preferred Name' (highlighted in blue), 'Synonym', and 'Company Product Name'. The main area is divided into 'Parent' and 'Child' configuration panels. The 'Parent' panel has fields for 'Level Name' (Anatomical-Therapeutic-Chemical, circled in pink), 'Short Name' (ATC), 'Mandatory?' (checkbox), 'Many Cardinality?' (checked), 'Primary Link?' (checkbox), 'Primary Path Link?' (checkbox), and 'Derivable?' (checkbox, circled in pink). The 'Child' panel has fields for 'Level Name' (Preferred Name), 'Short Name' (PN), 'Mandatory?' (checkbox), and 'Many Cardinality?' (checked).



# *Dictionary Structure: MedDRA*

## *Summary*

### Implication Summary:

- OC MedDRA users will code to LLT and PT levels if the AERS MedDRA dictionary is used. This is not so significant as all PTs are included in the LLT level of MedDRA, so the same coding would be available as in the case where LLT level only is used.



## *Dictionary Structure: WHODrug Summary*

### Implication Summary:

- OC WHODrug users will not derive ATC codes if the AERS WHODrug dictionary is used. This may be more significant if ATC codes are required in OC, but work-arounds could be used where views directly from TMS extract all possible ATCs to SAS.



## *Common Dictionary Updates*

Implications of agreement for common MedDRA and WHODrug updates:

- AERS can update as needed for MedDRA and WHODrug. Typically all versions of MedDRA are applied in AERS, while WHODrug is typically applied Quarterly or Semi-Annually or Annually depending on the company's subscription frequency.



## *Common Dictionary Updates: Virtual Dictionaries*

Implications of agreement for common MedDRA and WHODrug updates:

- Virtual Dictionaries are created by default in the AERS dictionary update process. Virtual dictionary domains (VDD) for OC can be created immediately after the AERS dictionary update process to accommodate existing studies. One VDD should be made for each TMS Domain related to OC in the base dictionary.



# *Common Dictionary Updates: Control Recoding*

Implications of agreement for common  
MedDRA and WHODrug updates:

- Recoding for both AERS and OC can be controlled by setting the Virtual Dictionary Domain to the existing OC Studies or AERS Cases.





## *Common Dictionary Updates: Impact Reports*

Implications of agreement for common MedDRA and WHODrug updates:

- Impact reports can continue to run as previously run from either copy-of-production environments, or from the TMS Predict tables. However, if the predict tables are used, the default AERS TMS Dictionary update scripts should be modified to have a SQL accept statement or pausing mechanism to allow time for running the impact reports.



## *Common Dictionary Updates: Summary*

Implications of agreement for common MedDRA and WHODrug updates:

- OC users will update MedDRA semi-annually; this is probably the same in both the OC/TMS and AERS/TMS environments.
- OC users will update WHODrug on the schedule require for AERS PV users, but Virtual Dictionary controls can prevent any unnecessary impact to coding.



## *TMS Domains*

Implications of agreement for common TMS Domains or creating separate TMS Domains for OC:

- All AERS Coding is stored in the TMS Domain "Latest". When coding is updated from AERS, the domain Latest is updated.
- OC should have separate Domains for Indication or Therapeutic Area, or by Sponsor as required.



## *TMS Domains: VTAs*

Implications of agreement for common TMS Domains or creating separate TMS Domains for OC:

- If Global VTAs can be used, then there should be a periodic review process for promotion of VTAs to Global VTAs if there is consistency in the OC and the AERS Latest domains.
- It is possible that some OC studies might also want to use the Latest domain if these studies would accept coding from AERS universally.



## *Improve Common Dictionaries*

Suggestions for improving potential AERS and OC common use of the same TMS dictionaries:

- Provide some loading configuration parameters in the AERS load of WHODrug to allow the possibility of derived ATCs.
- Provide some options for loading of MedDRA to control the classification level.



## *Improve Common Dictionaries (2)*

Suggestions for improving potential AERS and OC common use of the same TMS dictionaries:

- Provide an optional built-in pause or continuation before activation of updates to MedDRA and WHODrug from AERS. This would allow any impact reports for dictionary updating to run before TMS activation.



## *Overall Benefits*

- Reduction of initial loading time for MedDRA and WHODrug in TMS.
- Reduction in validation costs for updating MedDRA and WHODrug in TMS.
- Reduction in processing time for updating MedDRA and WHODrug in TMS.
- Facilitation of possible standardization of some coding terminology between CDM and PV groups.
- Administrative and maintenance cost reduction by making use of combined OC/TMS/AERS instances as well as common dictionaries.



## *Additional Questions ?*

- E-mail: [singh@clinicalserver.com](mailto:singh@clinicalserver.com)
- Call: US 001-860-983-5848
- Electronic copies will be posted on the OCUG Intranets Site and [www.clinicalserver.com](http://www.clinicalserver.com)

