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 Martin Marchetti at Nerviano Medical Science, whose input was invaluable for this presentation.
- 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 characterset
  - 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

OC/TMS/AERS	Implied Benefits
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:

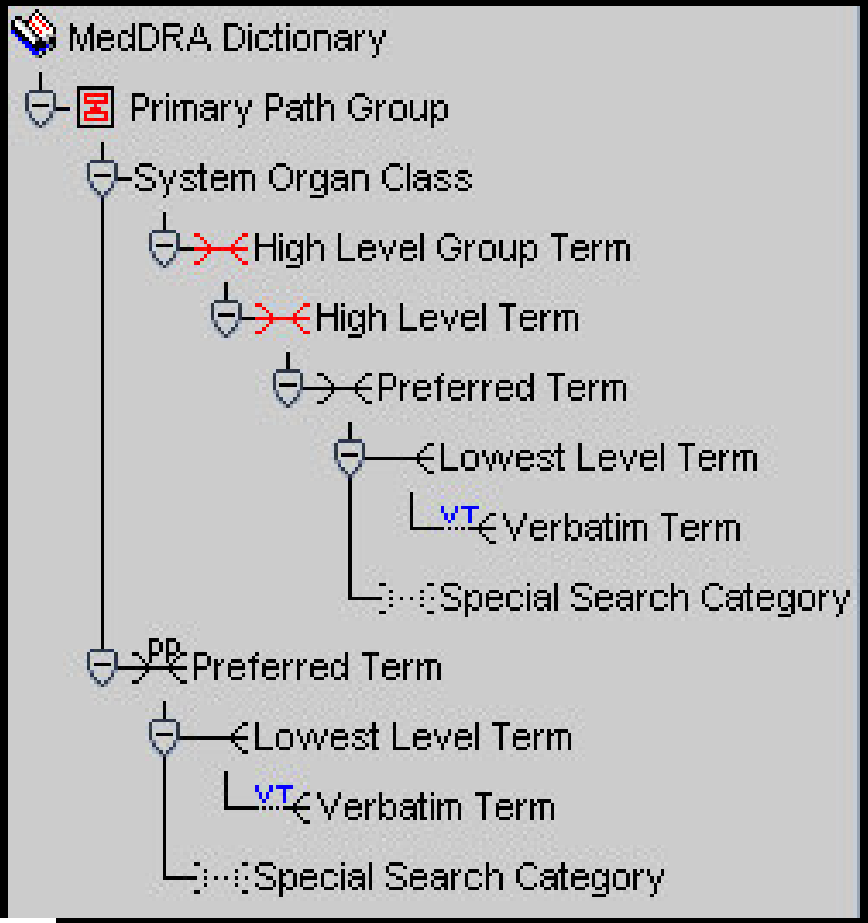
- Agreement between all users on the structure of the WHODrug and MedDRA dictionary being the AERS default structure.
- Agreement between all users for a common update schedule of the same TMS WHODrug and MedDRA Dictionaries.

Prerequisites for Using the Same TMS Dictionaries (2)

OC/TMS/AERS environment integration:

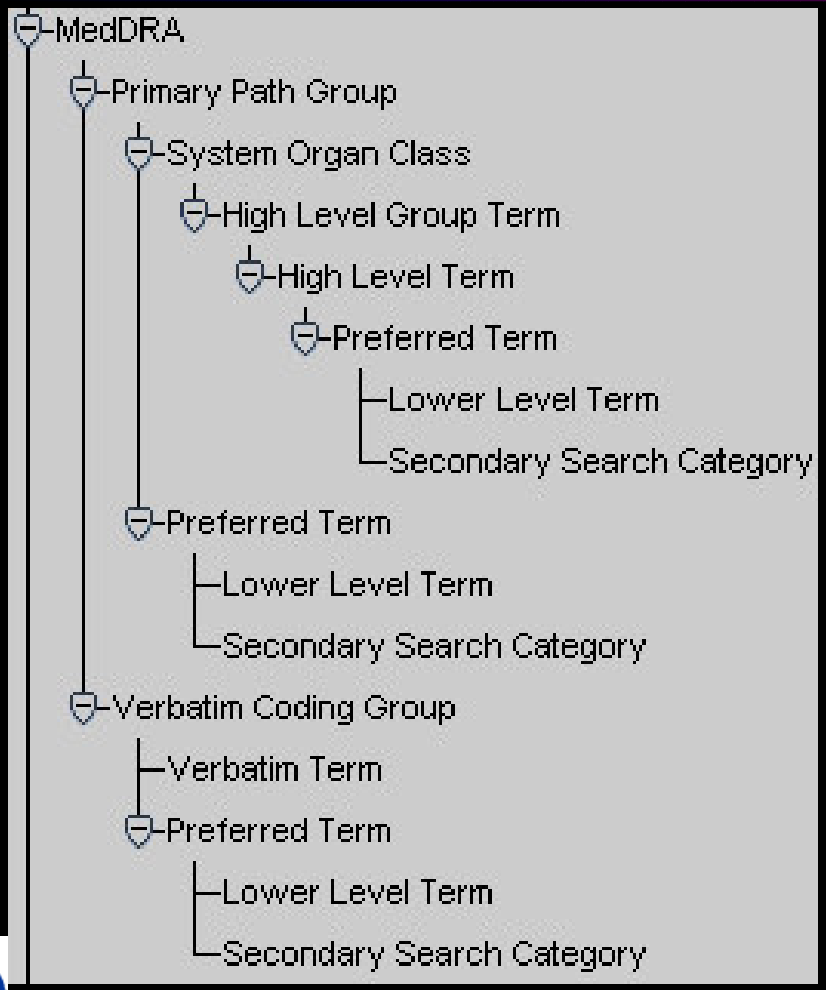
- Agreement on universal acceptance of coding between PV and CDM groups, or agreement on process changes to support separate coding though different TMS Dictionary Domains.
- Since Global VTAs can be used simultaneously with Domain VTAs, where the Domain VTAs take precedence over the Global VTAs, multiple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

Dictionary Structure: OC/TMS MedDRA

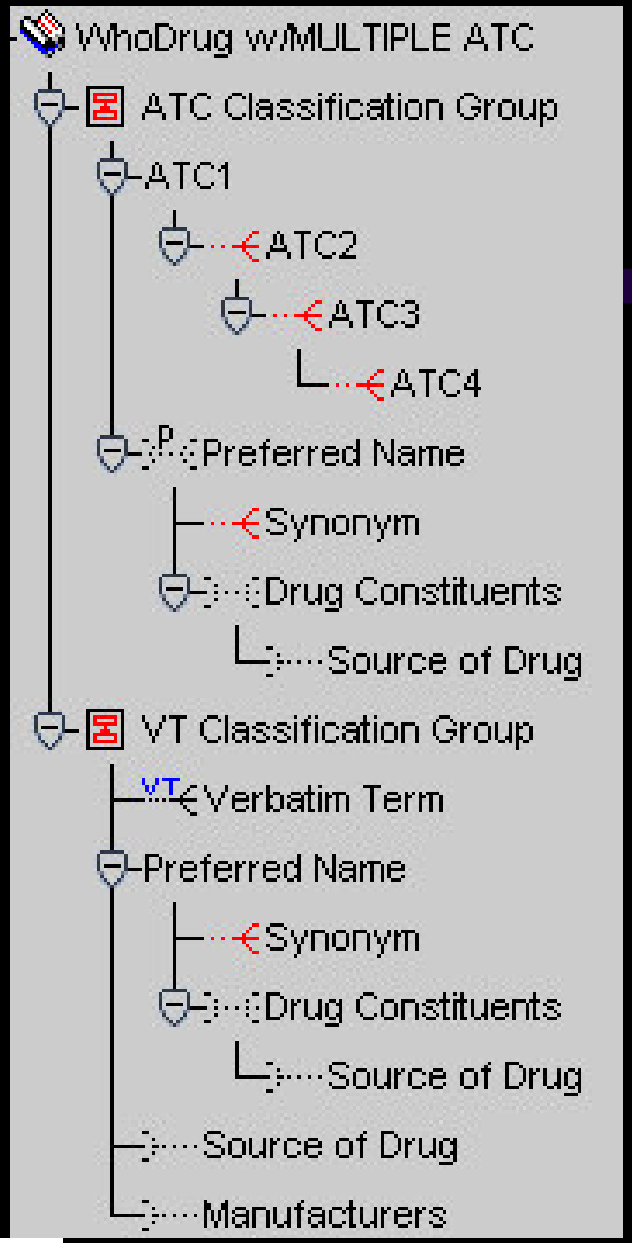


- Default OC/TMS MedDRA with Primary Path Dictionary
- Note only the LLT level is used for coding

Dictionary Structure: AERS/TMS MedDRA

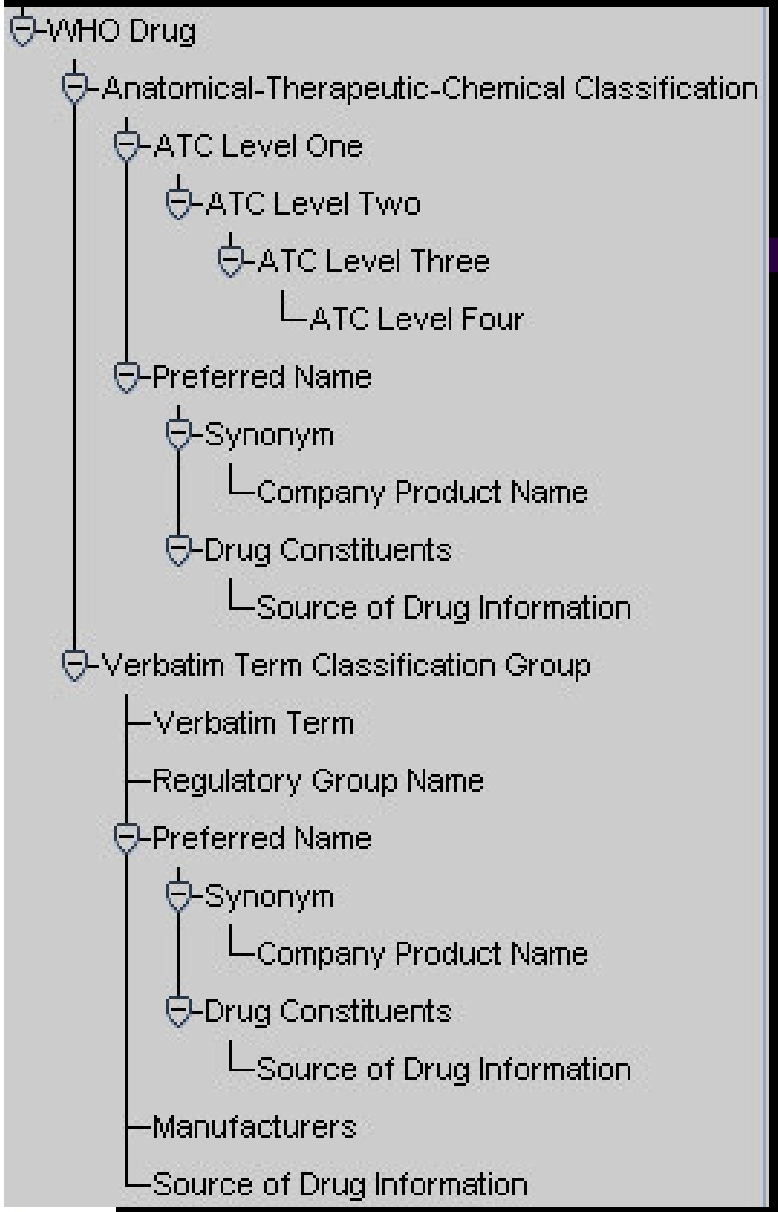


- AERS/TMS MedDRA Dictionary
- Agreement between CDM and PV groups implies using a coding group of both LLT and PT



Dictionary Structure: OC/TMS WHODrug

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

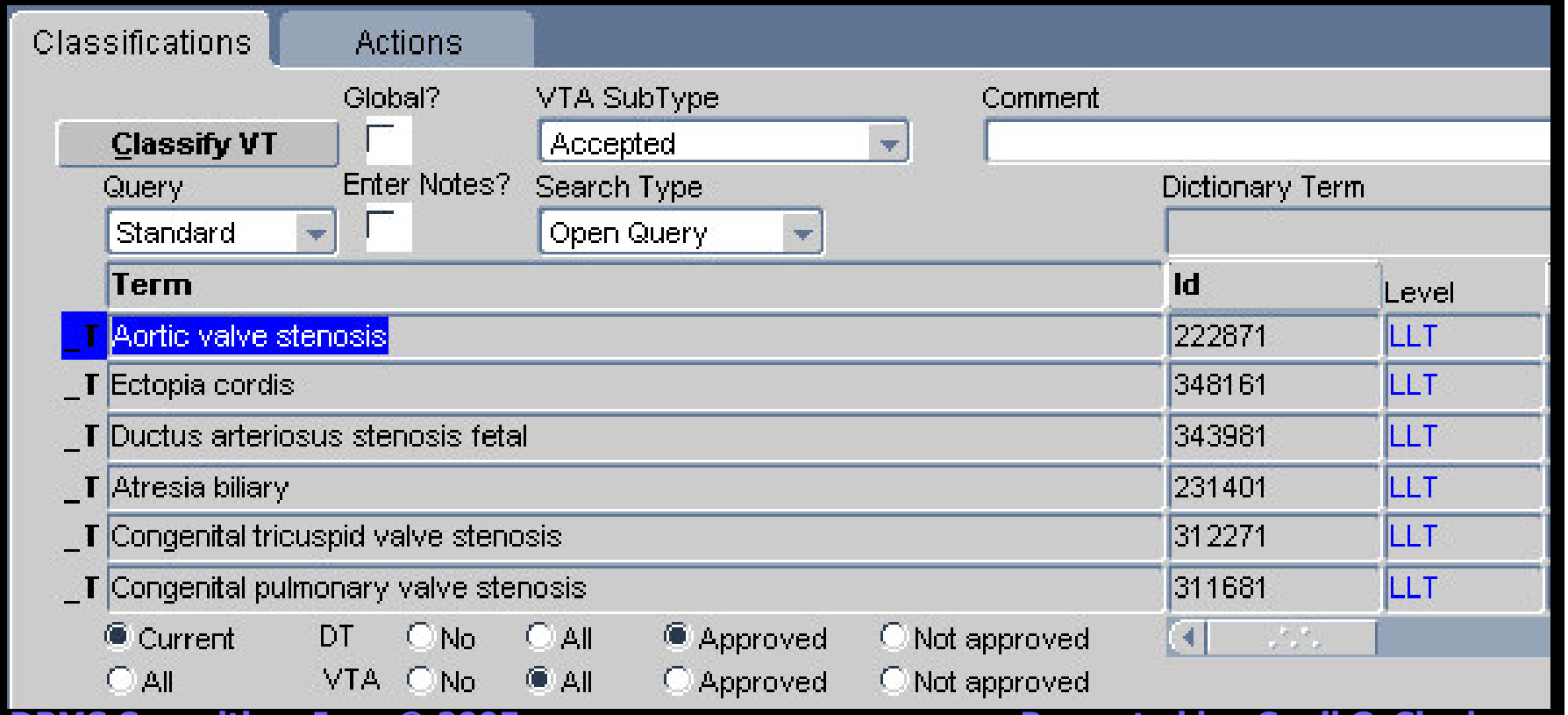


Dictionary Structure: AERS/TMS WHODrug

- 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



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: Accepted | Comment

Query: Standard | Enter Notes? | Search Type: Open Query | Dictionary Term

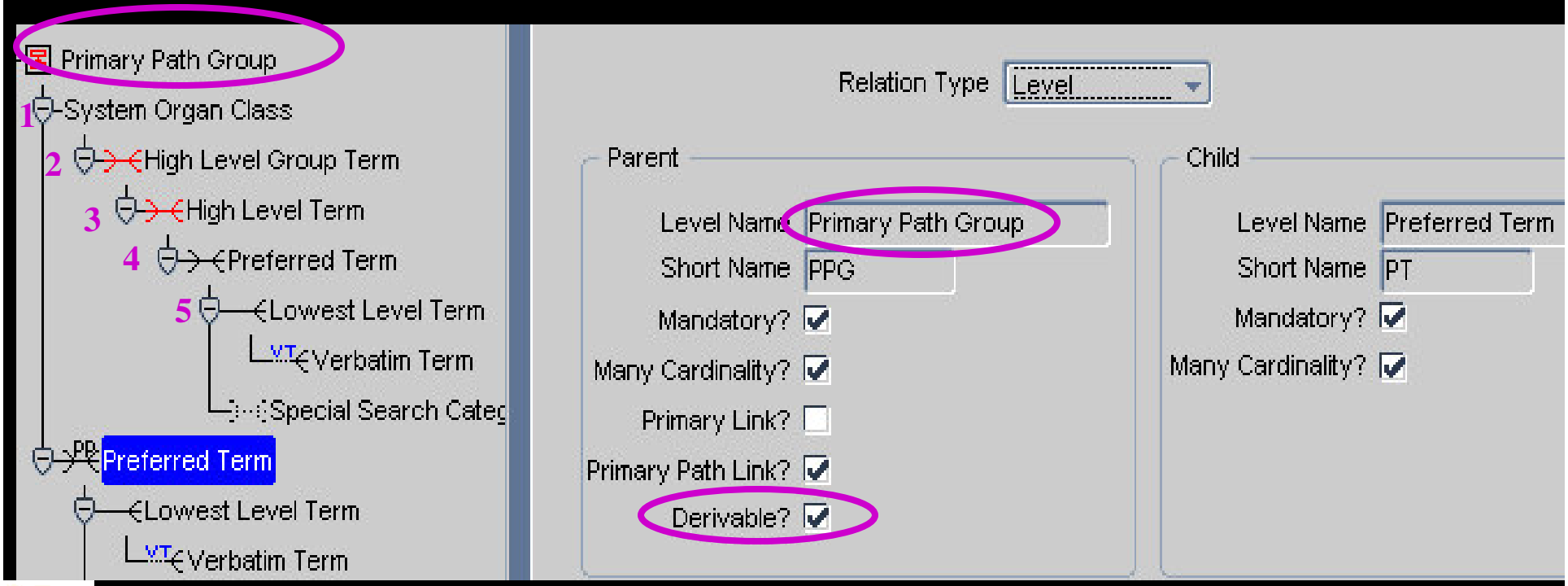
	Term	Id	Level
_T	Blood 1,25-dihydroxy vitamin D decreased	1348761	LLT
_T	Blood 1,25-dihydroxy vitamin D increased	1348751	LLT
_T	Blood 1,25-dihydroxycholecalciferol	1436831	PT
_T	Blood 1,25-dihydroxycholecalciferol decreased	1372481	PT
_T	Blood 1,25-dihydroxycholecalciferol increased	1372471	PT
_T	Blood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

Current / All | DT: No / All | Approved / Not approved

VTA: No / All | Approved / Not approved

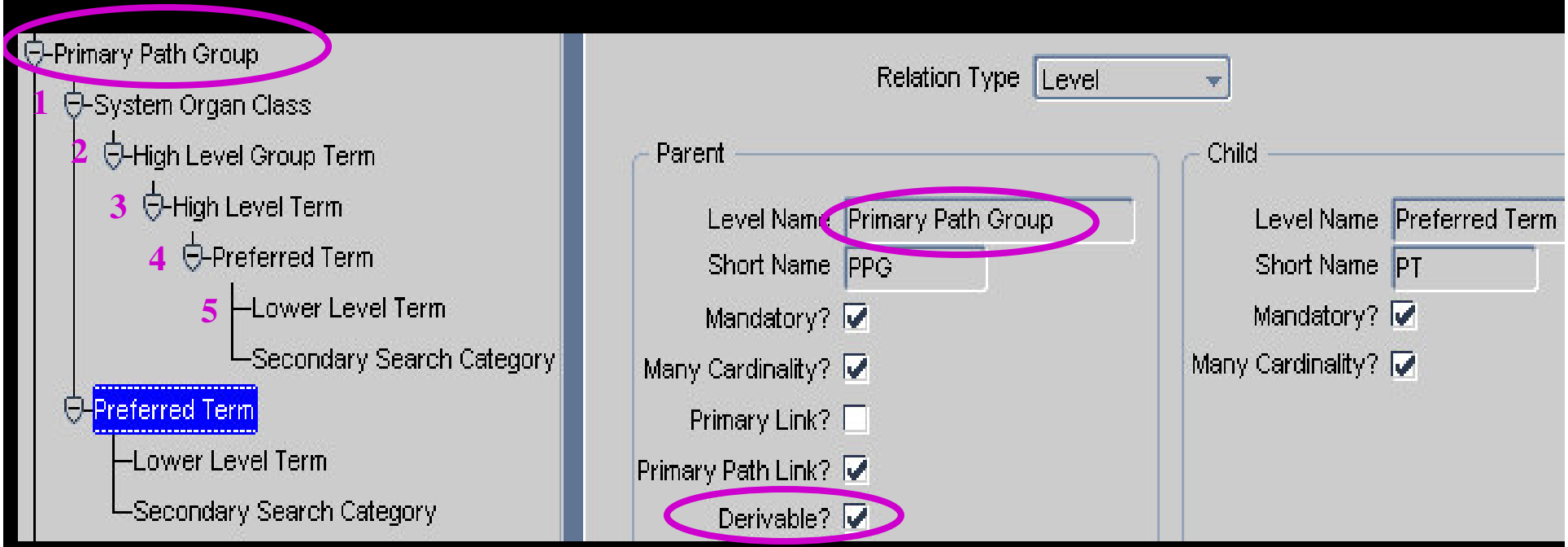
Dictionary Structure: MedDRA Derivation in OC

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



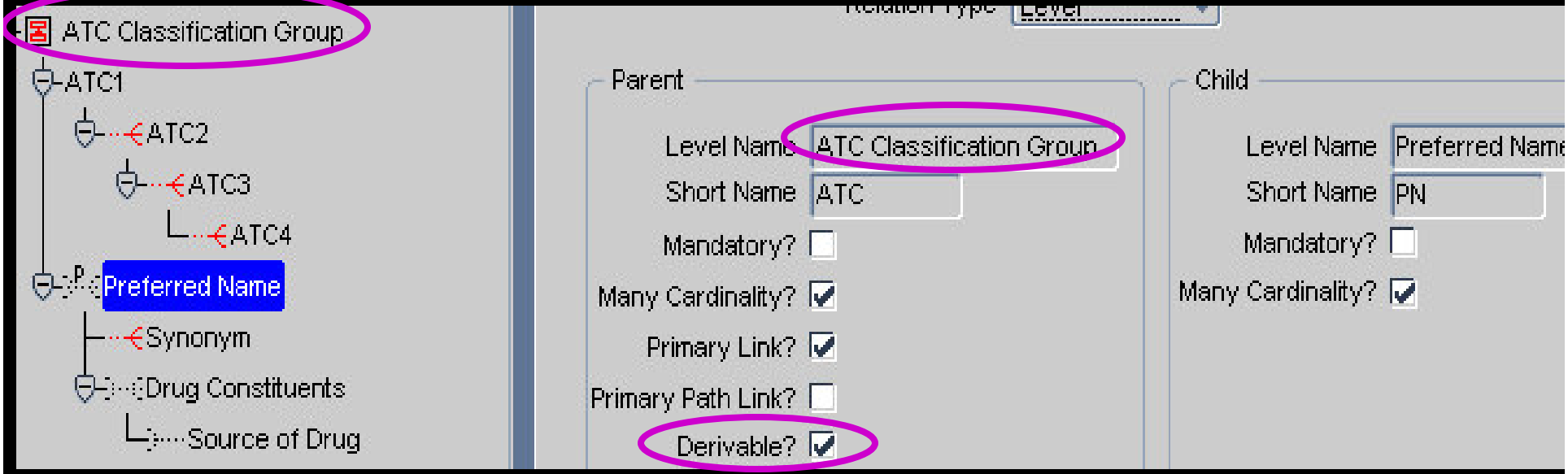
Dictionary Structure: : MedDRA Derivation in AERS

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



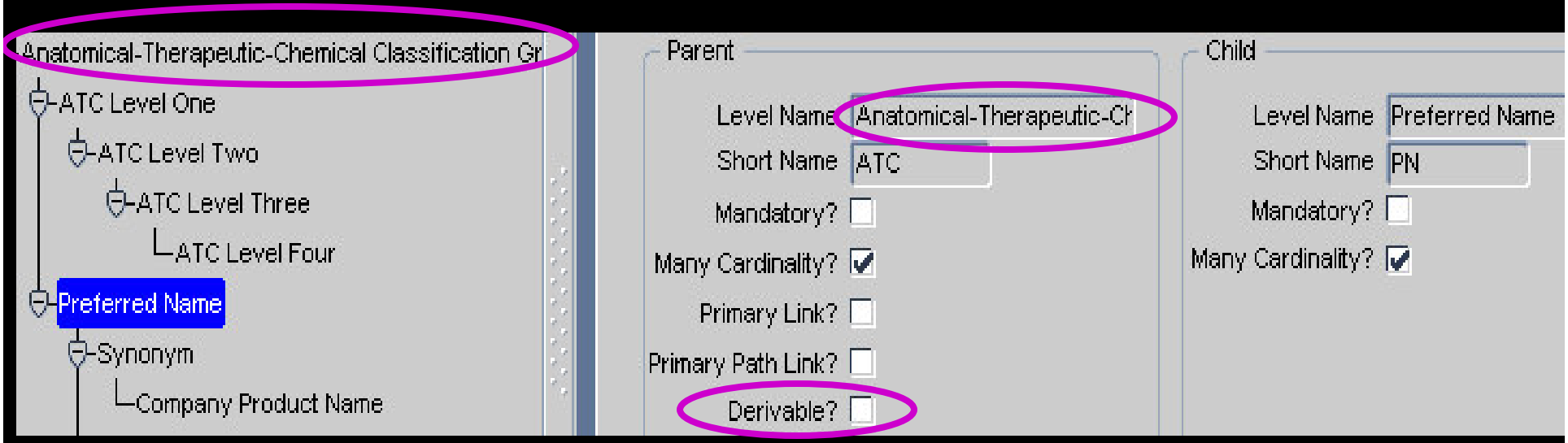
Dictionary Structure: WHODrug ATC Derivation in OC

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



Dictionary Structure: WHODrug No ATC Derivation in AERS

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



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 code s 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
- Call: US 001-860-983-5848
- Electronic copies will be posted on the OCUG Intranets Site and www.clinicalserver.com