Overview of changes to the WHODrug dictionary structure and loading into TMS.

Property of DBMS Consulting, Inc.

Daniel von Sydow / Sunil G. Singh

Introduction

- Daniel von-Sydow of WHO Uppsala Monitoring Centre
- Sunil G. Singh of DBMS Consulting, Inc.

Acknowledgements

- Thanks to OCUG for this and the TMS Focus group for this opportunity to speak.
- Thanks to the WHO-UMC for sending representation to the OCUG to share information about WHODrug.

Goals

- Provide an overview of potential upcoming changes to the WHODrug dictionary and possible implications of loading this updated structure into TMS
- These changes are preliminary, as well as there timescales. This presentation intends to raise issues to be resolved, but not necessarily solve all raised issues
- Daniel von-Sydow will address the changes in the WHODrug dictionary structure, while Sunil Singh will address the implications on loading into TMS.

Scope

- Limited to description of the changes and possible loading and maintenance implications
- The idea is to raise awareness about the structure changes and to send feedback to the WHO/UMC if there are concerns or serious issues.
- The intent of the WHO-UMC is to make improvements to the utilization of the WHODrug dictionary, and not disrupt the work of its users.

WHODrug Dictionary

- The Uppsala Monitoring Centre is launching a new output format for WHODrug
- Additional functionality for in-house use
- Additional features for WHODrug users

WHODrug changes

- New relationships for classification of products
- Additional information per product
- Herbal remedies
- New concepts: Medicinal product and Pharmaceutical Product

What's New? Classification of Products

- A product will be given the ATC code of its most common use.
- Facilitate analysis of therapeutic groups.
- Each product will still be given one Preferred Name.
- The new coding principles will be followed for new entries from 2002.

What's New? New Fields.

- Dosage form and Strength.
- Product Type. Medicinal/Herbal etc.
- Product Group. Same Company, Substance and ATC code. E.g. Losec/Prilosec.
- Market Authorization Holder. Company responsible for marketing.
- Country
- Date of last change

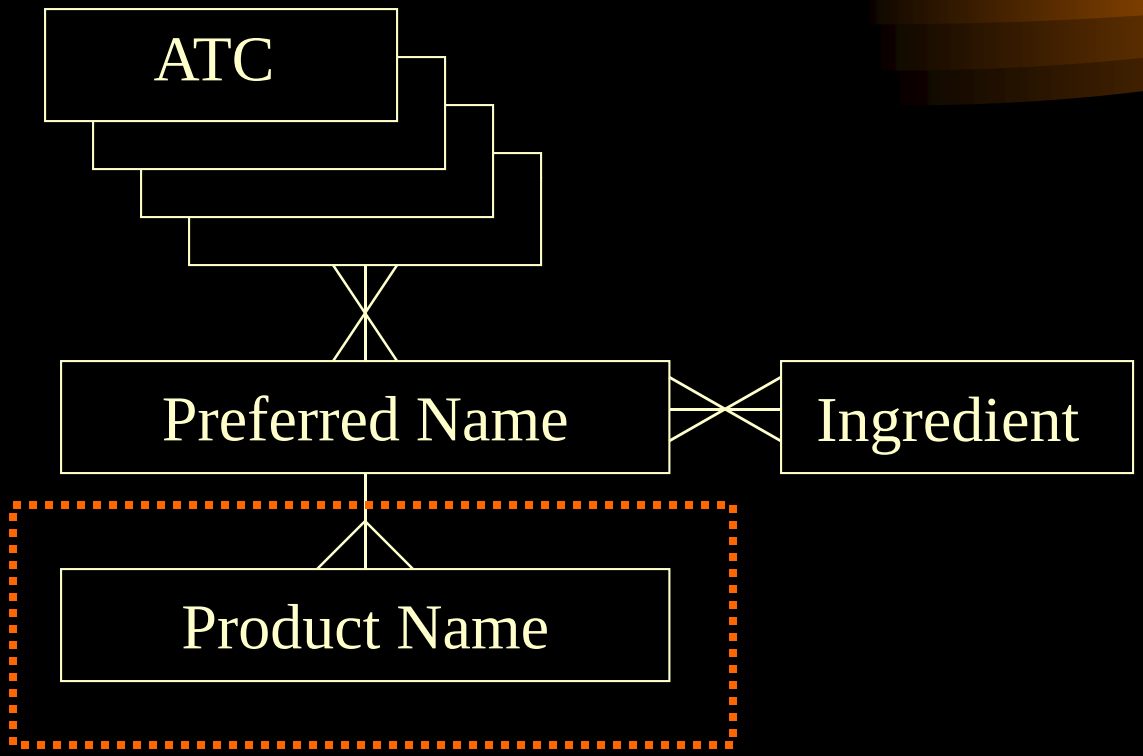
What's New? Herbal Remedies

- The UMC is collecting data on Herbal Remedies to allow ADR reporting.
- A new ATC classification has been developed for Herbal Remedies.

What's New? New concept: Pharmaceutical Product.

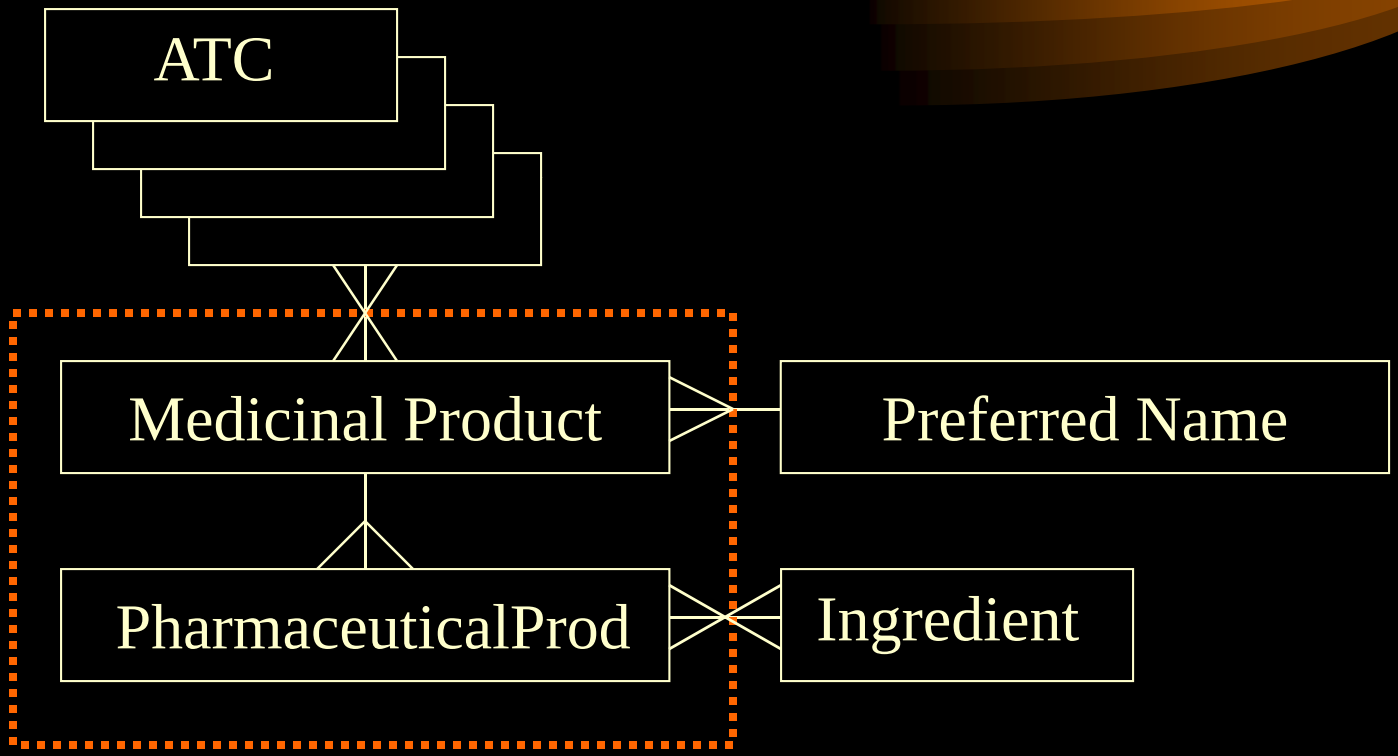
- It will be possible to have more than one composition (tablet, solution etc) per product.
- Examples: Oral Contraceptives, Predazone/Medrol.
- Future possibility to code ADRs on Pharmaceutical Product level.

WHO Drug Dictionary Current format



WHO Drug Dictionary

New format



When?

- All new products entered by the UMC are now coded using the new principles
- The new format will be available in flat file format from Q2 2002.
- The old format will be available in flat file format at least a year. Subject to user requirements.

TMS Loading scripts

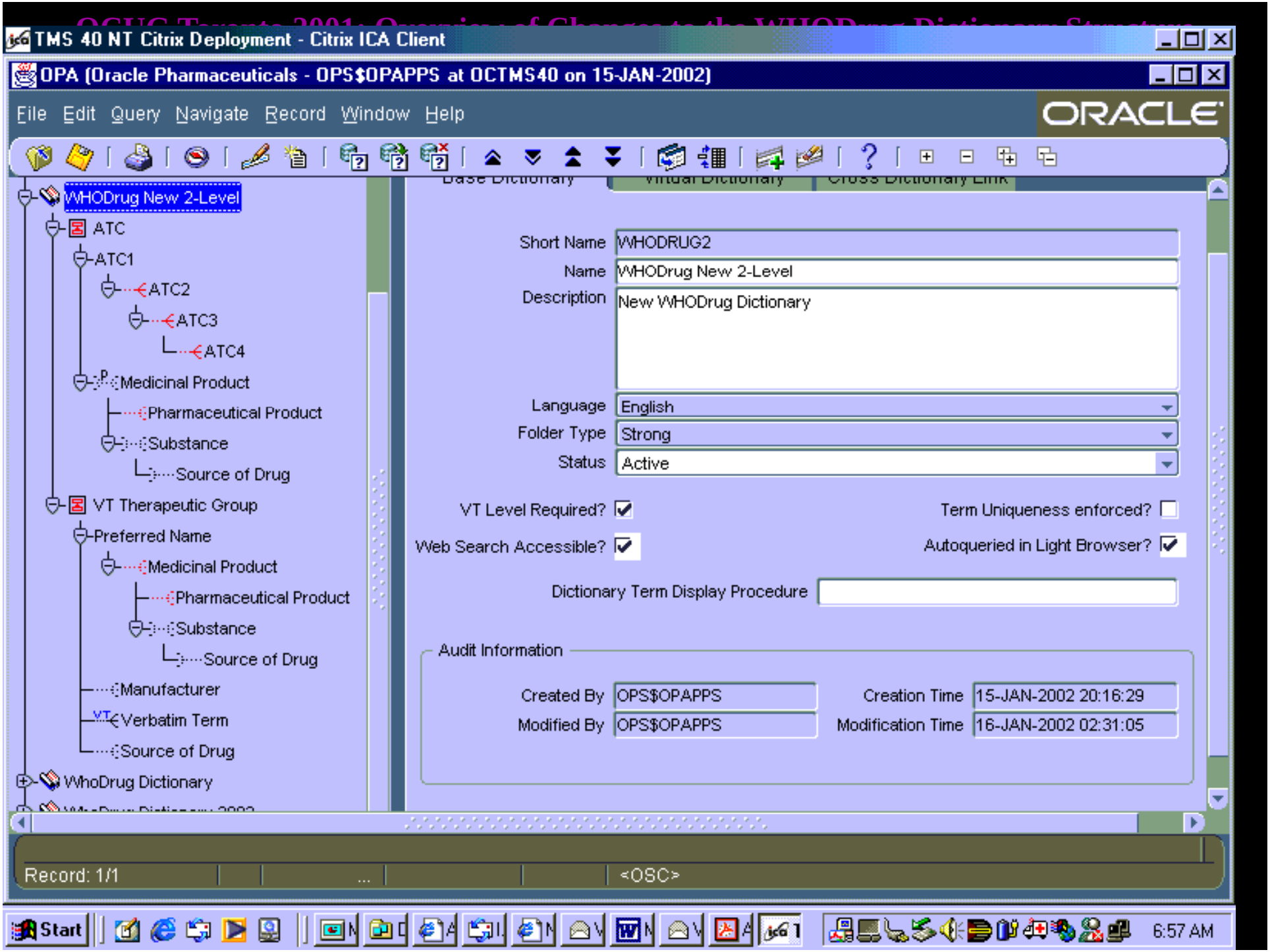
- The aim of UMC and DBMS Consulting is to provide both formats during the transitional period.
- It should be possible for DBMS Consulting to produce loading scripts in the old format even after the flat file format is discontinued.

Changes for TMS Dictionary Loading process

- SQL*Loader changes:
  - DD Flat file will be replaced with MP (Medicinal Products) and PP (Pharmaceutical Products) flat files.
  - A Separate Product Group Flat File and a Country code Flat File will need to be loaded.
  - Names of other files are changing such as:
    - BNA becomes SUN
    - INA becomes ATC

Changes for TMS Dictionary Loading process (2)

- Changes to Loading Logic:
  - Additional Classification Levels Medicinal Product and Pharmaceutical Product replace Synonym Level
  - Primary Link will be indicated (but not required) from Medicinal Product Level to ATC Group
  - Some other new level details loaded for MP and PP.
  - Some other new levels will be loaded which are not on the derivation path.


TMS 40 NT Citrix Deployment - Citrix ICA Client
OPA (Oracle Pharmaceuticals - OPS$OPAPPS at OCTMS40 on 15-JAN-2002)
File Edit Query Navigate Record Window Help
ORACLE
WHODrug New 2-Level
ATC
ATC1
ATC2
ATC3
ATC4
Medicinal Product
Pharmaceutical Product
Substance
Source of Drug
VT Therapeutic Group
Preferred Name
Medicinal Product
Pharmaceutical Product
Substance
Source of Drug
Manufacturer
Verbatim Term
Source of Drug
WhoDrug Dictionary
Base Dictionary
Virtual Dictionary
Cross Dictionary Link
Short Name WHODRUG2
Name WHODrug New 2-Level
Description New WHODrug Dictionary
Language English
Folder Type Strong
Status Active
VT Level Required?
Term Uniqueness enforced?
Web Search Accessible?
Autoqueried in Light Browser?
Dictionary Term Display Procedure
Audit Information
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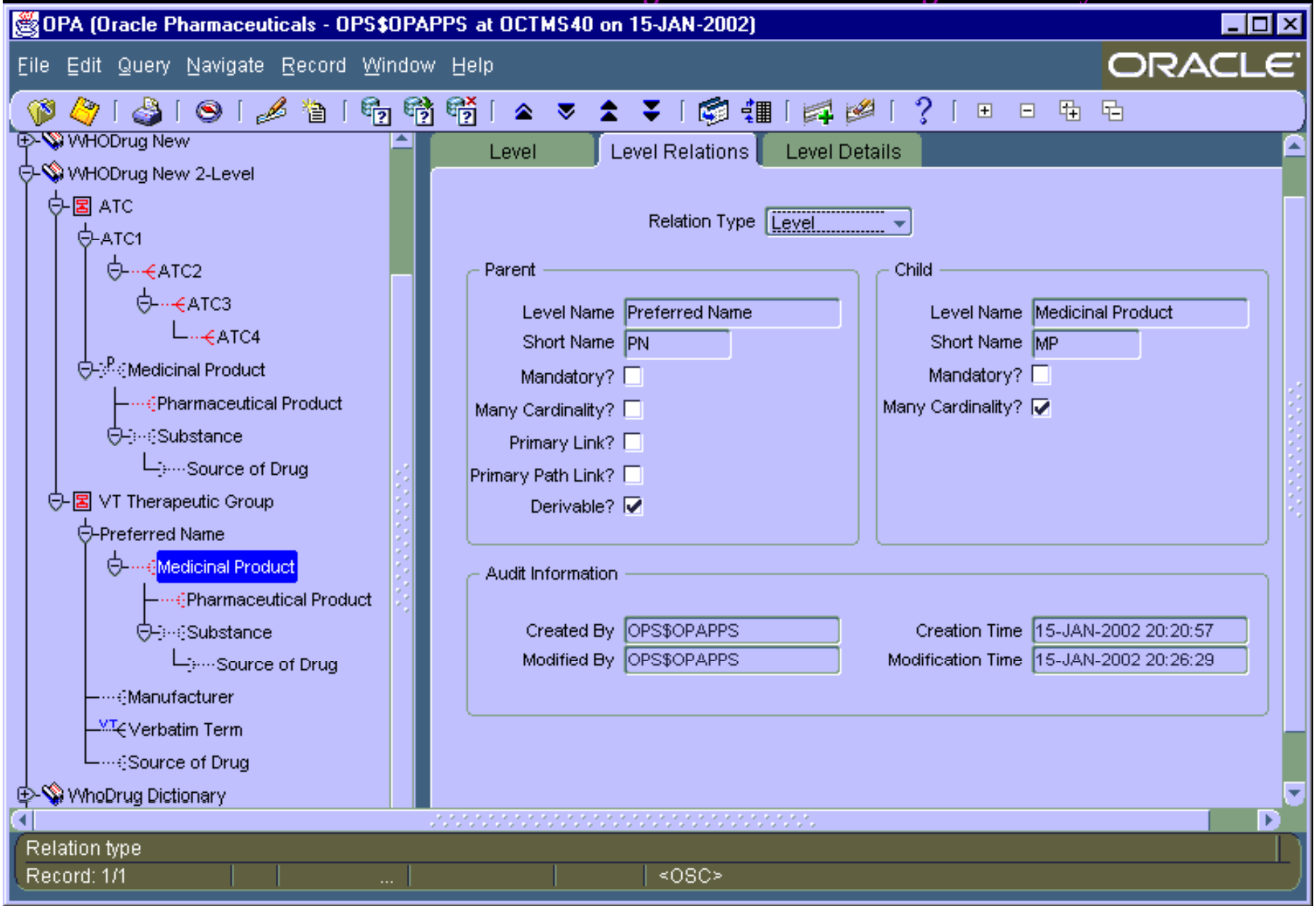
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Source of Drug
WhoDrug Dictionary
Level
Level Relations
Level Details
Relation Type Level
Parent
Level Name Preferred Name
Short Name PN
Mandatory?
Many Cardinality?
Primary Link?
Primary Path Link?
Derivable?
Child
Level Name Medicinal Product
Short Name MP
Mandatory?
Many Cardinality?
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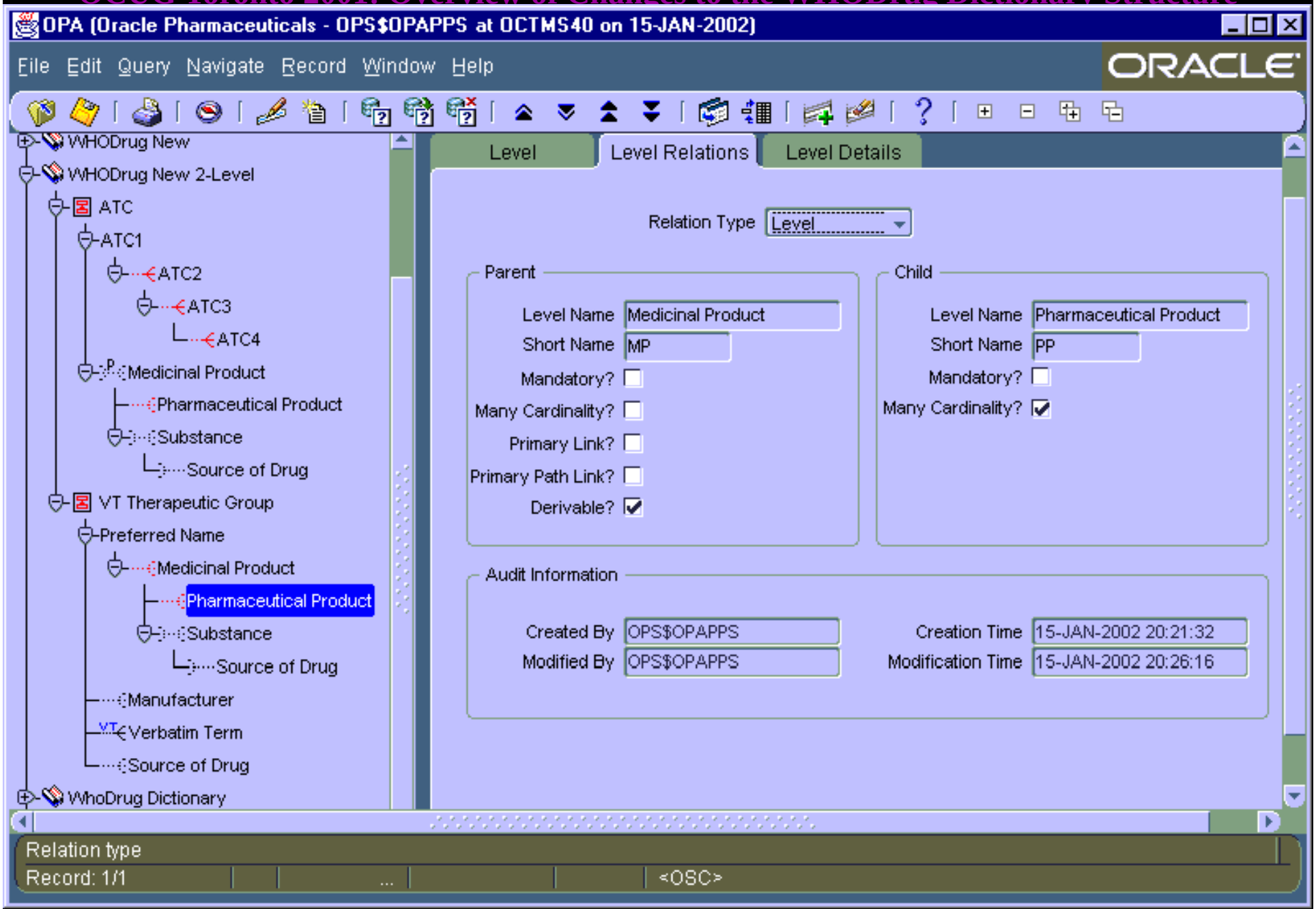
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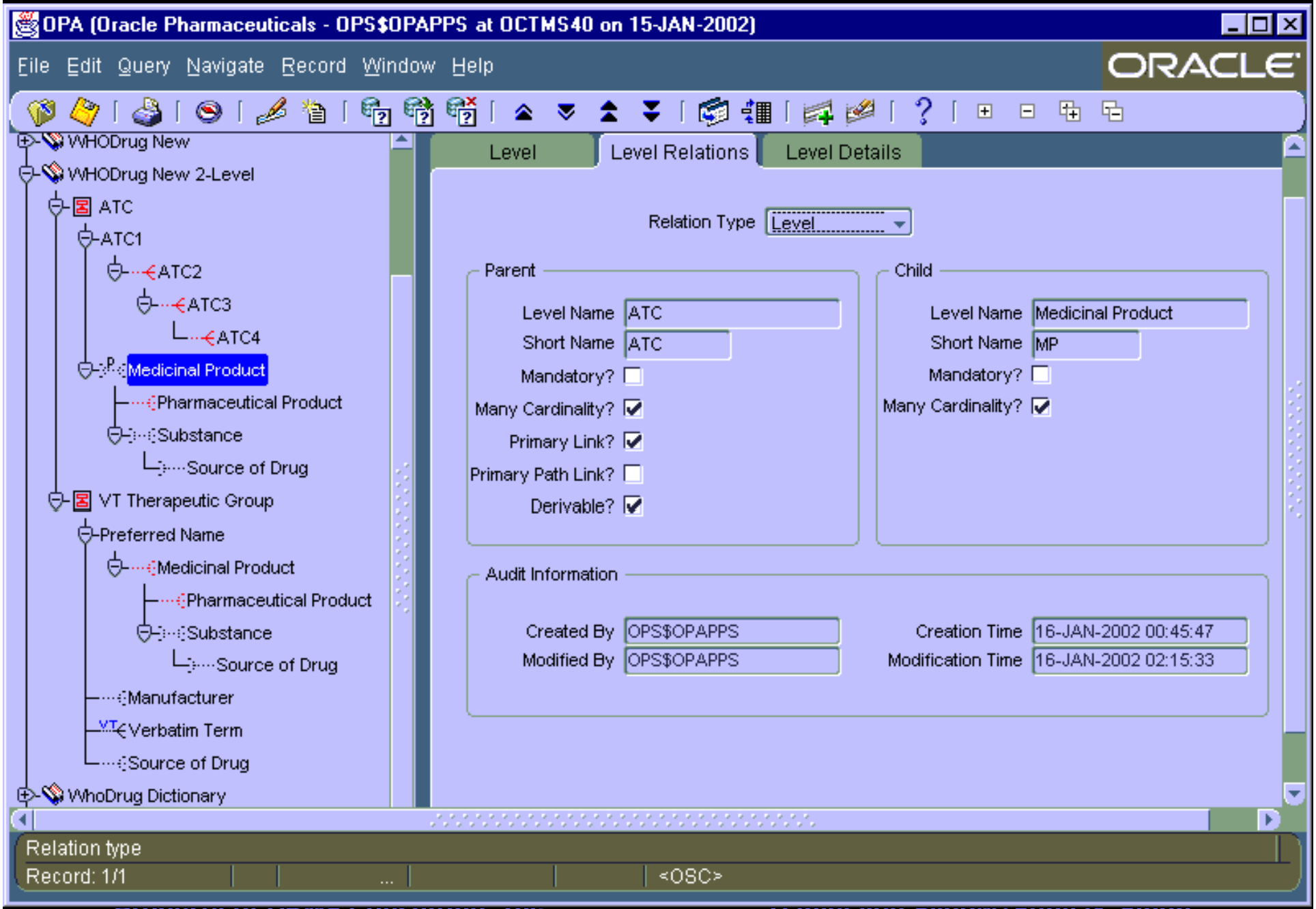
OCUG Toronto 2001: Overview of Changes to the WHODrug Dictionary Structure



Other considerations

- Only a small percentange of Medicinal Products will have Pharmaceutical Products associated with them.
- There will still be many cases where multiple ATC codes exist for a Medicinal Product. Relating ATCs to Medicinal Products may reduce the number of multiple ATCs, but will not create a 1-1 relationship.
- New additional fields and tables will not be populated for legacy drug entries before a recent time that has not been determined, probably 1-2 years.

Mapping Legacy WHODrug Structure to new Structure.

- Virtual dictionaries will not be able to map old WHODrug to new WHODrug Structure, since virtual dictionaries expect the same structure.
- Cross dictionary links and Named Relations are a possible way of mapping terms across the two dictionary versions, but this might be an arduous process. It may be possible to develop calls to TMS APIs to populate these named relations. This may also require that the new version be loaded in the same domain and Activation Group.

Mapping Legacy WHODrug Structure to new Structure (2)

- Loading scripts could instead be adjusted to mirror legacy WHODrug structure, and load into this same structure. This may be the supported long-term path for maintaining studies that require the existing WHODrug structure.

Conclusions

- Feedback is required regarding changes to WHODrug dictionary structures.
- There is flexibility in the nature of changes and timescales of deployments.
- A supportable path will be provided to migrate to this new structure or maintain the legacy structure until some undetermined point in the future.

Questions ?

- For more information about changes to WHODrug please contact Daniel.von-Sydow@who-umc.org
- For questions regarding the updated WHODrug within TMS, please contact singh@clinicalserver.com