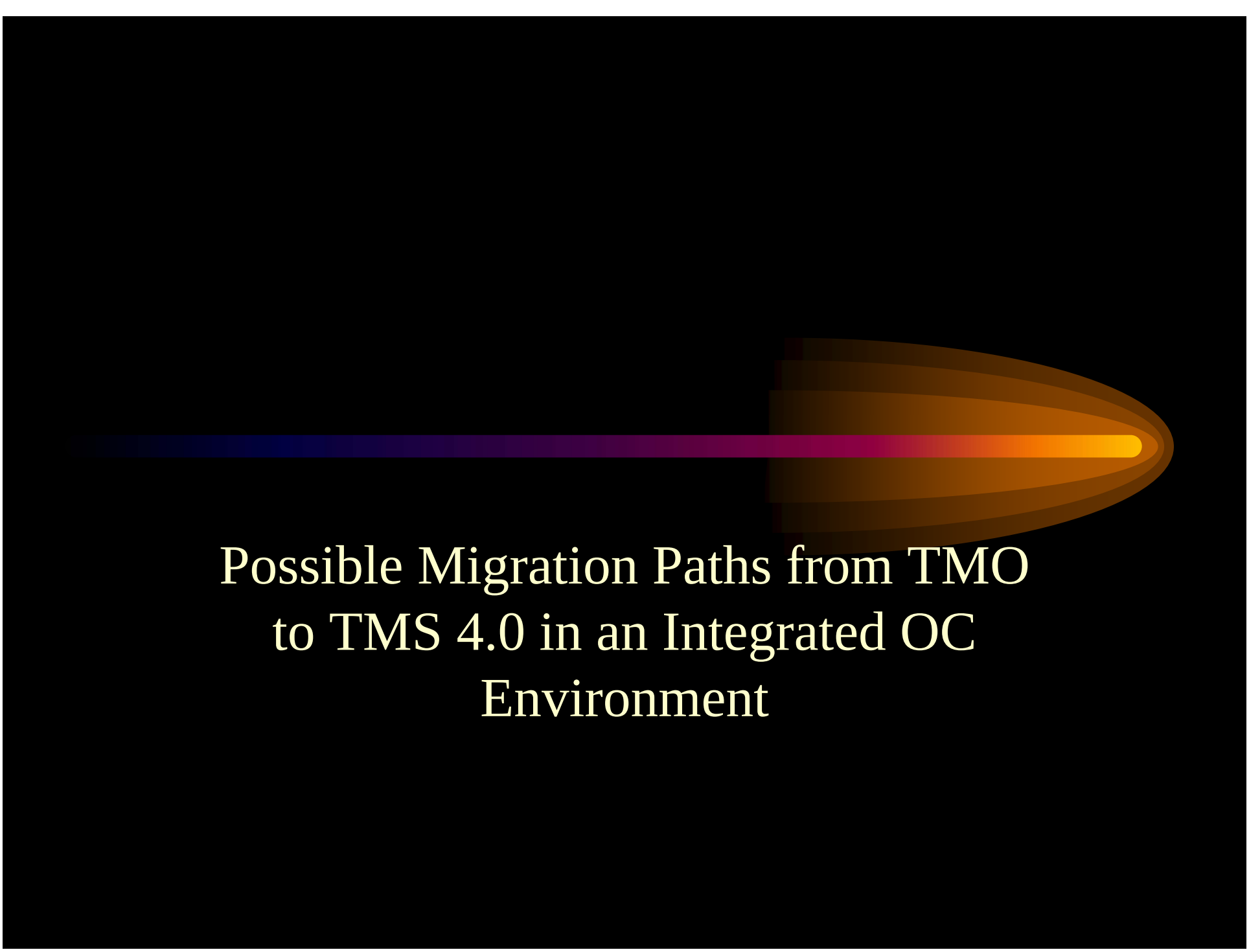
Possible Migration Paths from TMO
to TMS 4.0 in an Integrated OC
Environment

Introduction

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Goals

- Explore possible options for customers using TMO that wish to migrate to TMS 4.0 and OC 4.0 and examine advantages and disadvantages of each.
- Examine options of:
  - Stopping coding in TMO and perform coding of new studies in TMS.
  - Using a 2-step migration from TMO to TMS 3.2 and then from TMS 3.2 to TMS 4.0
  - Modifying TMO to TMS 3.2 migration scripts for direct migration to TMS 4.0

Scope

- High level discussion with some technical aspects.
- Not considering
  - Validation
  - Process modifications and changes to SOPs
  - Training issues that may arise from a TMO to TMS migration.

Stop coding in TMO and perform coding of new studies in TMS.

- Coding is halted in TMO. No existing studies associated with TMO will be re-associated with new dictionaries in TMS.
- Reload dictionaries (best for standard dictionaries) in TMS 4.0.x with PL/SQL Loading scripts that call the TMS APIs.

Stop coding in TMO and perform coding of new studies in TMS (2)

- Migrate the TMO PT Allocations to TMS VTAs.
  - This entails calling the TMS API tms_user_classification.CreateAcceptedVTA.
  - All arguments for this API can be derived from the new dictionary creation in TMS, except for the relevant Content Id, which must be matched from CDM_ACCEPTED_TERMS table to the TERM in the TMS_DICT_CONTENTS table.

Stop coding in TMO and perform coding of new studies in TMS (3)

- Associate only new studies with newly loaded TMS dictionaries.
- Derived coded data for existing studies coded with TMO can be examined using Data Entry -> Browse if the derived questions are made visible on the DCMs.

Advantages

- Very straightforward method of moving from TMO to TMS.
- If standard dictionaries are used (e.g. MedDRA), then very little development effort is required to load the new dictionaries, since these scripts are generally available.
- Relatively simple PL/SQL script can be written to call the tms_user_classification.CreateAcceptedVTA API.

Disadvantages

- Assumes that there are no existing studies that were coded in TMO that will continue to be coded in TMS.
- Does not migrate Company Terms, i.e. changes in the actual dictionary terms.
- Not applicable or realistic in most environments.

2-Step migration, TMO -> TMS 3.2 -> TMS 4.0.x

- Uses the migration scripts provided by Oracle, with modifications, to migrate from TMO to TMS 3.2 while retaining study associations.
- Environment is then upgraded from TMS 3.2 to TMS 4.0, using standard documented procedures.

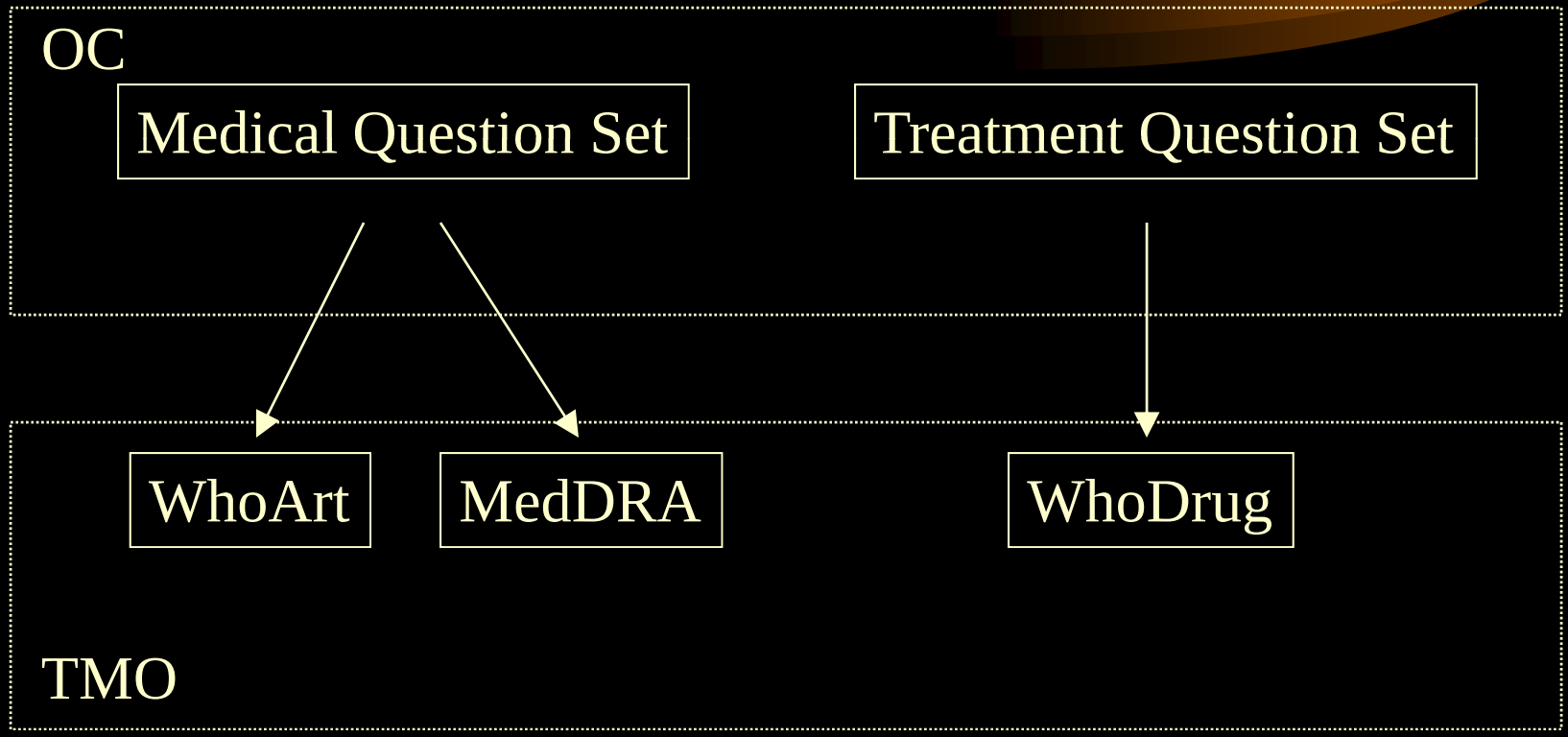
Process for TMO -> TMS 3.2 Migration

- Migrate Dictionary Definitions
- Migrate Domains
- Migrate Projects
- Migrate Question Sets
- Migrate Dictionaries and Dictionary Data
- Migrate VTAs

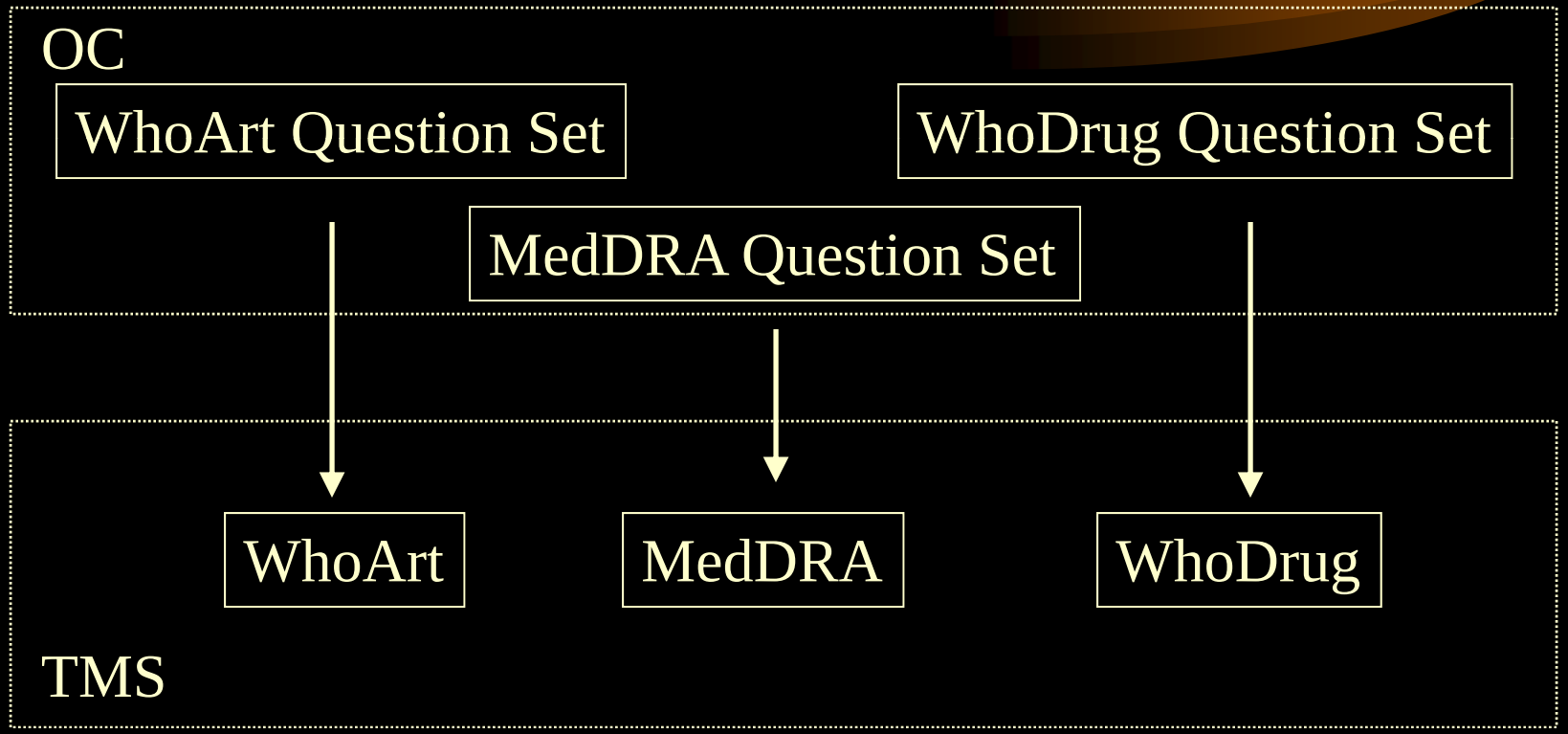
Process for TMO -> TMS 3.2 Migration (2)

- Each of the default scripts used in this process need to be modified to run correctly.
  - These changes are well-documented in “Migration from TMO to TMS in a Replicated Environment” from OCUG 2000 by Oracle Deutshland GmbH and Schwarz Pharma AG.
- However, other fundamental structural inconsistencies are possible due to the differences in the integration of TMO to OC and TMS to OC.

OC and TMO Integration



OC and TMS Integration



TMO, TMS and OC Integration Differences

- In a TMO and OC environment, **MORE THAN** one dictionary can be assigned to a Question Set.
- In a TMS and OC environment, only **ONE** dictionary can be assigned to a Question Set.
- If this multiple mapping of many dictionaries to one Question Set, the default script will be not be sufficient. There will be a shortage of Question Sets during the TMO to TMS migration.

A Strategy for Resolving TMO, TMS, OC Integration Differences

- For each dictionary that does not have a **UNIQUE** Question Set associated with it, add a new Question Set and Question Set Questions. Since only one dictionary can be associated with a Question Set for TMO -> TMS migration to be successful, allocate the “most complex” dictionary to the existing Question Set.
  - If a dictionary is sharing a Question Set that is used for frozen studies, this is a good candidate.

A Strategy for Resolving TMO, TMS, OC Integration Differences

- Create new Questions mapped to Question Set Questions created in previous step, such as Parent and Derived Questions.
- Update DCM Questions Table with new Question ID.
- Modify the script used for migrating TMO Question Sets, migratetmoquestionset.sql. Hard code the values of the new dictionary association with the new Question Set.
- Execute the default TMO to TMS 3.2 migration procedure.

Migration from TMS 3.2 to TMS 4.0

- Well known process that is supported by Oracle
- Several tables are rebuilt during the migration process, which may have an impact on the migration time
- Symmetric/Advanced replication must be quiesced.

Advantages

- Fully Supported migration path from TMO to TMS 4.0 if the default scripts are used.
- TMS 3.2 can be integrated with OC 3.1.1. This entire configuration can then be migrated to OC 4.0, providing a two-step migration to OC 4.0, potentially reducing downtime.

Disadvantages

- Several bugs exist in the default TMO to TMS 3.2 migration scripts which must be fixed.
- Potentially have to deal with the shared Question Set issue.
- An Interim 3.2 environment is required. For customers migrating directly to OC 4.0, this can be a severe resource constraint in terms of hardware, support and validation.

Direct Migration to TMS 4.0

- The process is the same as for migrating from TMO to TMS 3.2.
- All scripts in this process must be modified call the TMS 4.0.x APIs.
- This can be most effectively be done by examining each API call in the TMO -> TMS 3.2 migration scripts, and comparing these API calls to the TMS 4.0 Technical Reference Manual

List of API calls in the default TMO -> TMS 3.2 loading scripts

- This is the current list of TMS APIs that might change when updating the default TMO -> TMS 3.2 to TMS 4.0.x
  - `TMS_user_def_dictionary.InsertDict`
    `TMS_user_def_dictionary.InsertLevel`
    `TMS_user_def_dictionary.UpdateHier`
    `TMS_user_def_dictionary.InsertHier`
    `TMS_user_mt_dictionary.InsertContent`
    `TMS_user_mt_dictionary.InsertRelation`
    `TMS_user_def_dict_domain.InsertDefDictDomain`
    `TMS_def_Domains_m.InsertRow`

Advantages

- Direct migration does not require an interim TMS 3.2 environment. This can result in reduced migration and validation costs.
- An opportunity for an organization to develop a solid understanding of the TMS 4.0 API.

Disadvantages

- Oracle does not support this migration path. However, some sites have overcome this issue by extensive validation testing.
- The development and changes to the TMO -> TMS 3.2 PL/SQL scripts is an extensive process that requires skilled PL/SQL developers and testing.
- The same shared Question Set integration conflicts from migration of TMO to TMS 3.2 could potentially exist in a direct migration to TMS 4.0.x

Conclusions

- Several viable options for migration from TMO to TMS 4.0.
- Some potential TMO to OC and TMS to OC integration issues are possible which may require additional consideration by the business and technical groups.
- Direct migration from TMO to TMS 4.0 is possible, but requires extensive development and testing.

Useful and Referenced Sources

- TMS 3.2 Technical Reference Manual
- TMS 4.0 Technical Reference Manual (Part no. A82841.01)
- Instructions for Direct Migration from TMO to TMS (Metalink)
- Migrating to Oracle TMS, An Oracle White Paper, September 1999 (Metalink)
- Migration from TMO 3.1.1 to TMS 3.2 in a Replicated Environment: First Real Live Experiences, by Dr. Hauke Kindler, Oracle Deutschland GmbH et. al., presented at OCUG 2000 Orlando.


Questions ?