# Benefits of Coding in TMS with source data from OC RDC and InForm

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TMS Focus Group
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9:30am

# Acknowledgements


- Many thanks to the Oracle Health Sciences User Group and TMS Focus Group for this opportunity to present.
- Many thanks to Gert van't Hof for providing review and feedback for this presentation.

# Forward

- Companies using both RDC and the InForm EDC systems are looking for options to code verbatim terms from a centralized coding system.
- Examine a case study of solutions to code data in TMS for OC RDC trials, InForm trials and legacy trials.

# Agenda

- Achieve centralized coding with multiple external systems in TMS.
- Enforce secure and independent coding environments for each organization.
- Enable integration of separate source data:
  - OC and TMS Integration
  - CDR and TMS Integration
- Allow for independent coding practices, processes and workflow
- Share common processes, terminology and services.
- Conclude with a summary of benefits.

# Achieve Centralized Coding with TMS External Systems

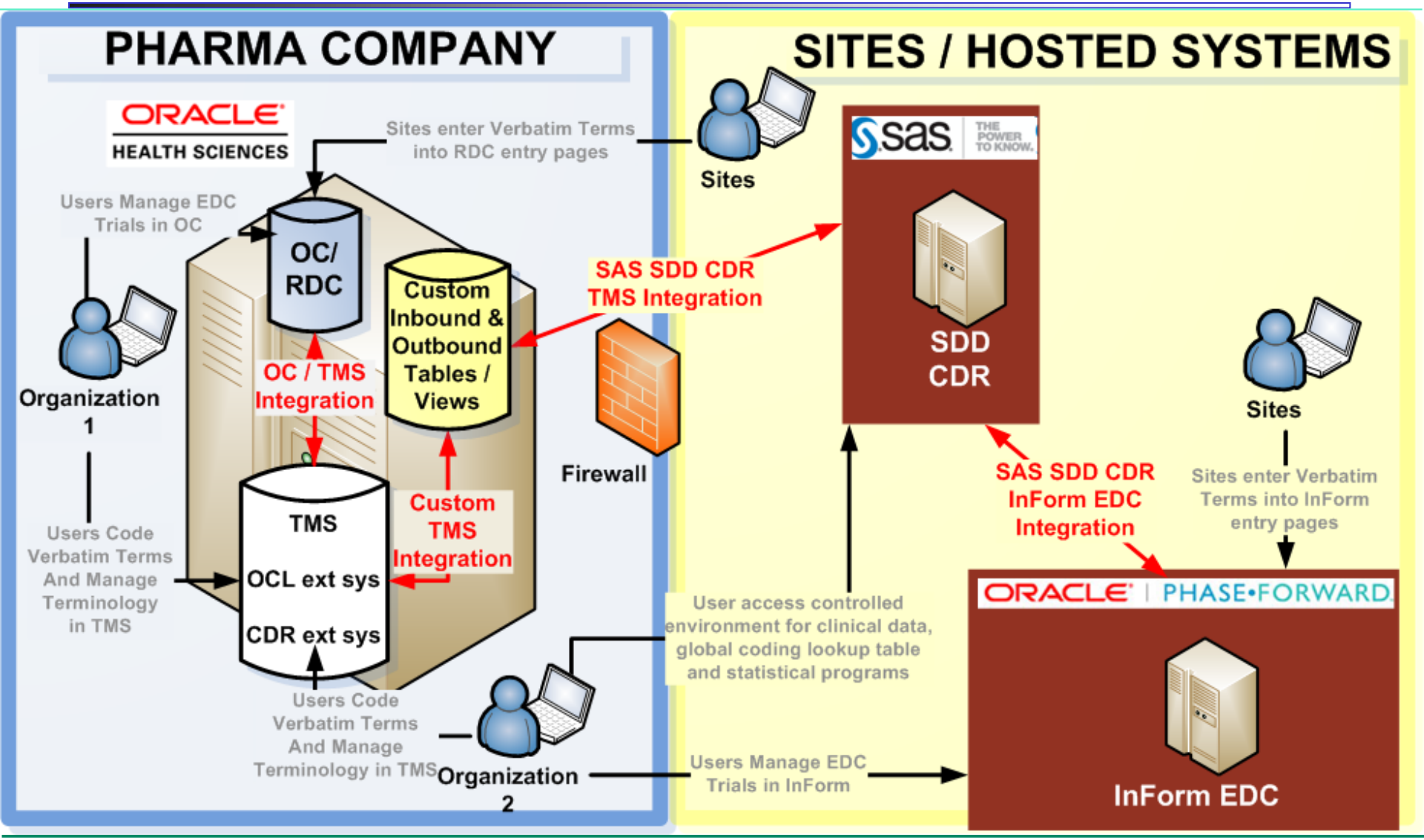
- Coder can classify verbatim terms in TMS from the Oracle Clinical external system for OC RDC trials and at the same time from a separate clinical data repository (SAS SDD CDR) external system for InForm and legacy trials.
- Benefits:
  - Share common dictionary terminologies that are maintained and supported centrally.
  - Support the system centrally.

# TMS Coding in Multiple External Systems

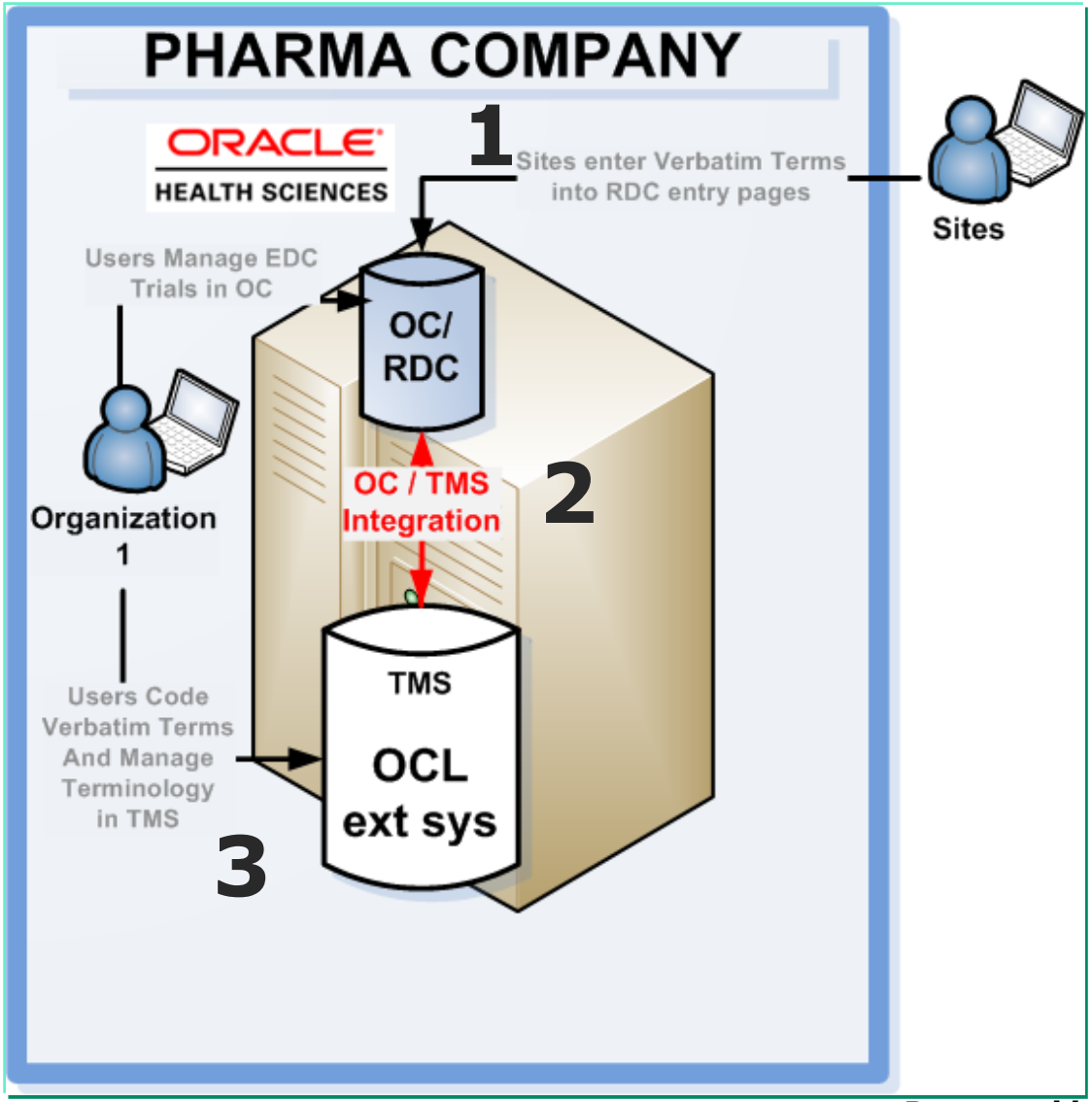
- Case Study – A Pharma Company has two organizations with separate coding environments in TMS.

| System/Integration | Organization 1 | Organization 2 |
|---|---|---|
| Coding System | TMS | TMS |
| TMS External System | OCL | CDR |
| EDC System | OC RDC | InForm, SAS SDD CDR for Legacy data |
| EDC / Coding Integrations | OC/TMS Integration | 1) InForm / SAS SDD CDR Integration |
| | | 2) SAS SDD CDR / TMS Integration |

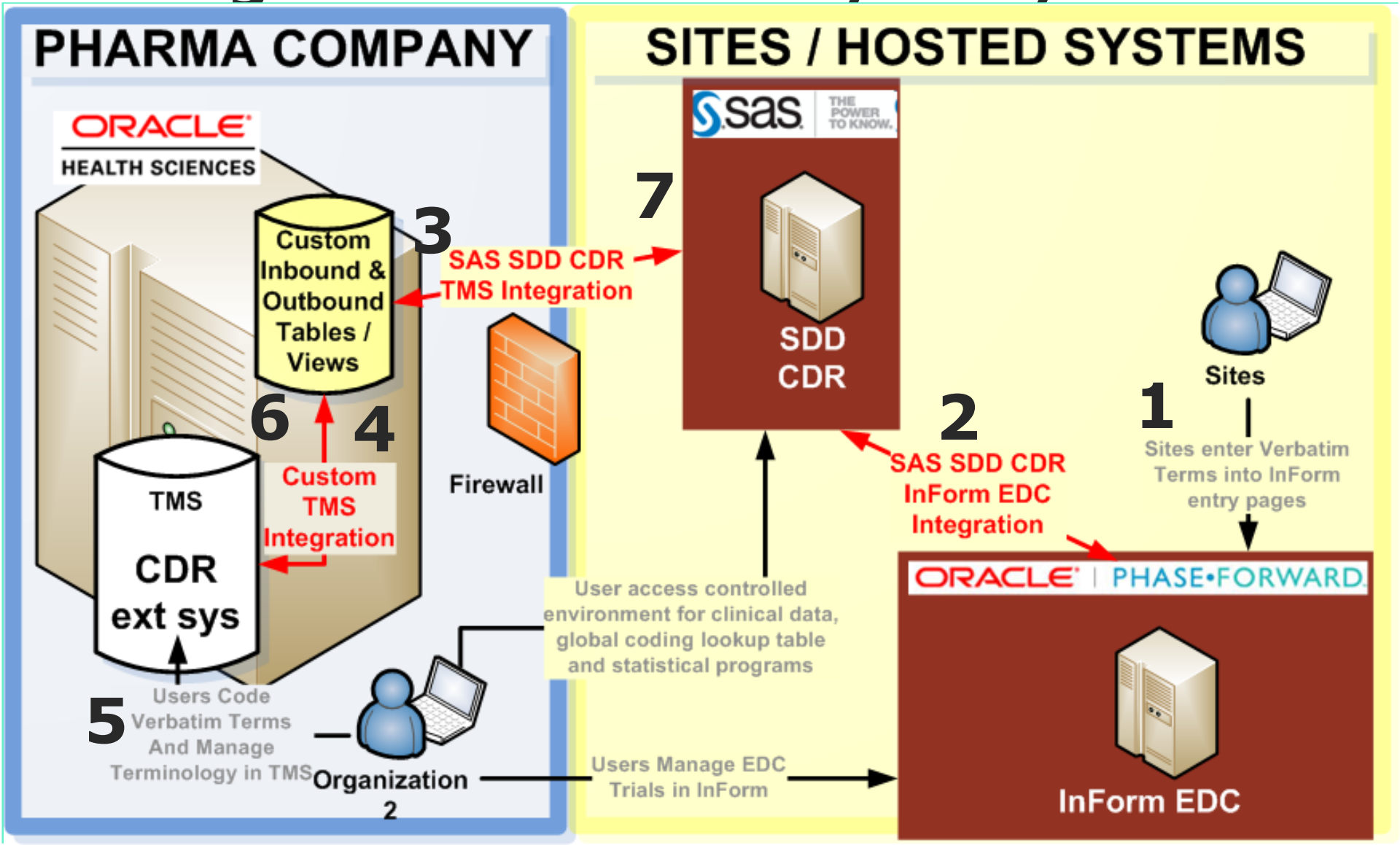
# Pharma Company Landscape for Two Independent Organizations



# Central Coding – Pharma Company Organization 1: OC/TMS

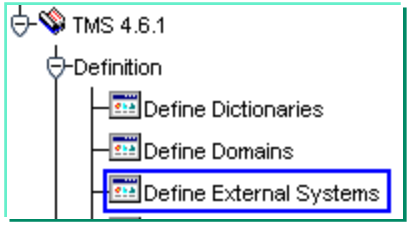


# Central Coding – Pharma Company Organization 2: EDC/CDR/TMS

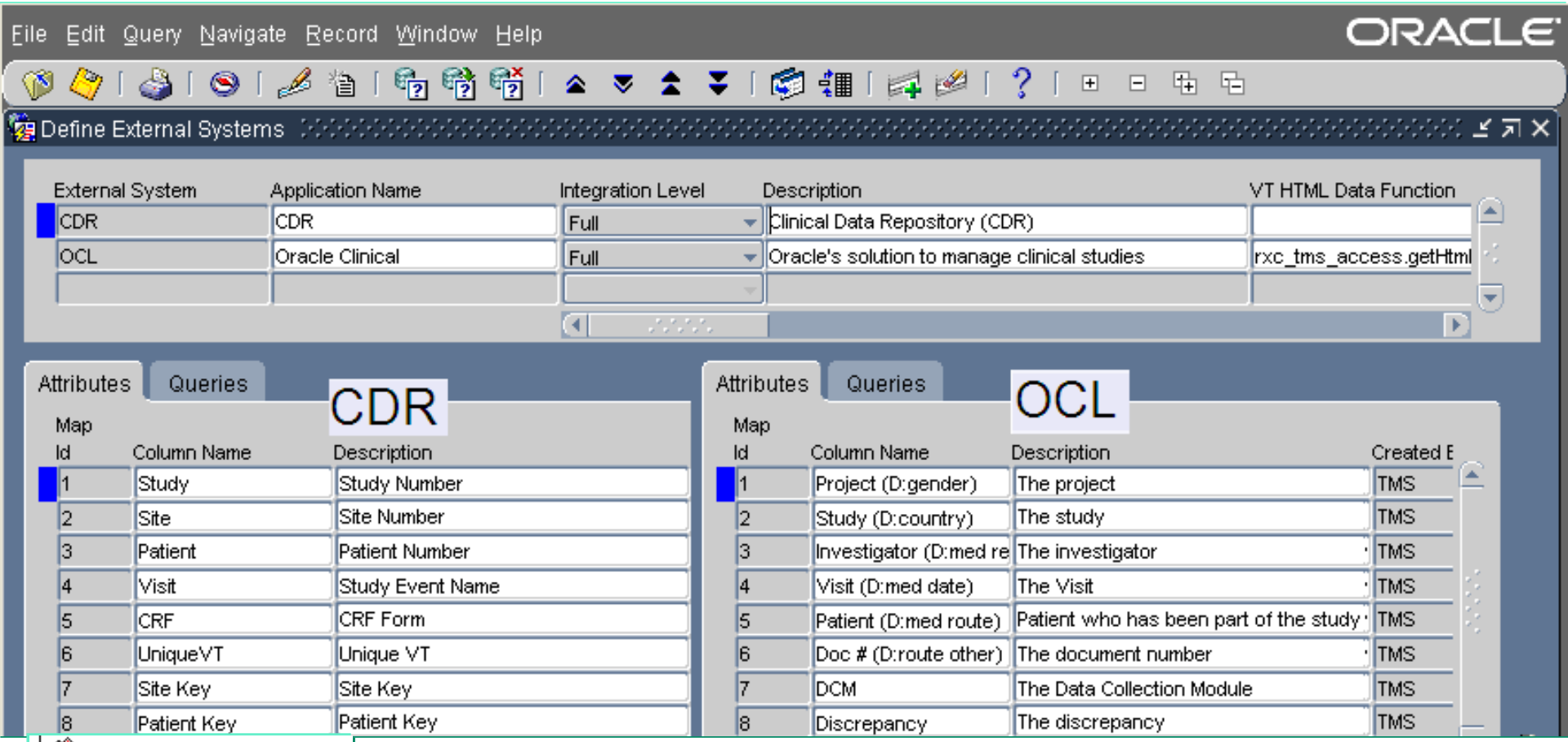


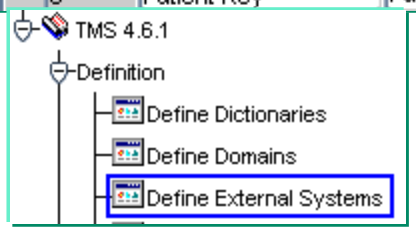
# Define Independent External Systems

- TMS allows for multiple external systems to operate side-by-side.
- Each external system can define up to eight different external values.
  - The Oracle Clinical (OCL) external systems has a standard set of eight external values.
  - Up to eight external values can be defined as needed for other non-OCL external systems.



# Case Study: Defining External Systems Eight External Values



# Requirement to Enforce Secure & Independent Coding Environments

- TMS allows you to create data access groups (DAGs) to control user access to data by selectively restricting or enabling the data that the users can access.
- Benefits:
  - Different organizations can code verbatim terms independently by allowing user access to data for the specific external system and dictionary/domain.
  - At the same time, an organization can secure coded data by restricting data access to users who are not authorized to use the external system or dictionary/domain.
  - Superusers who require access to operate across both organizations can be designated in TMS as Superusers.

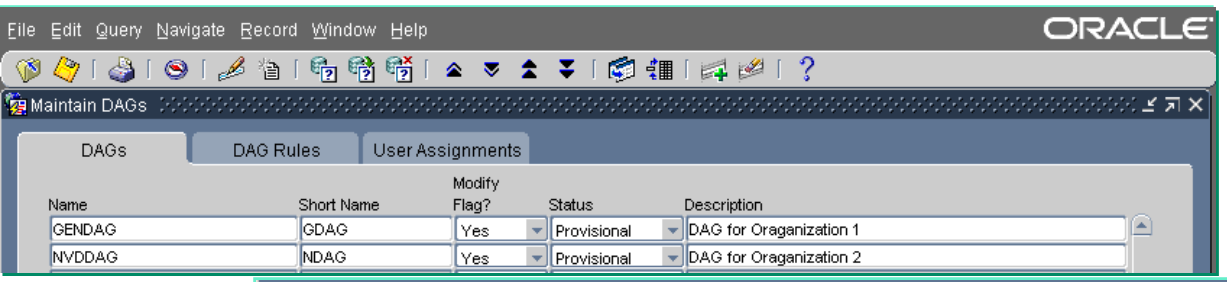
# Define DAGs

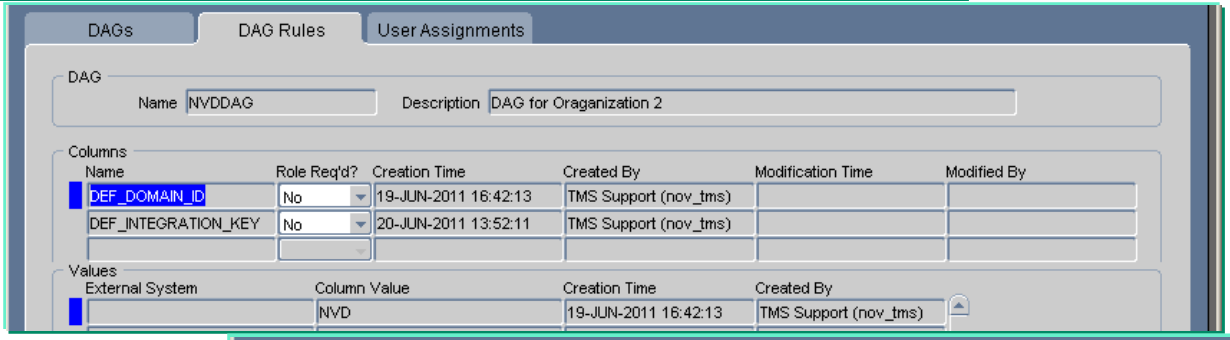
- Define the dictionary/domain combinations for which users in the group can see data.
- Define whether users in the group can make changes or only read data.
- Define whether users in the group can see data that originated in one or more specific external systems and from a particular project or study.

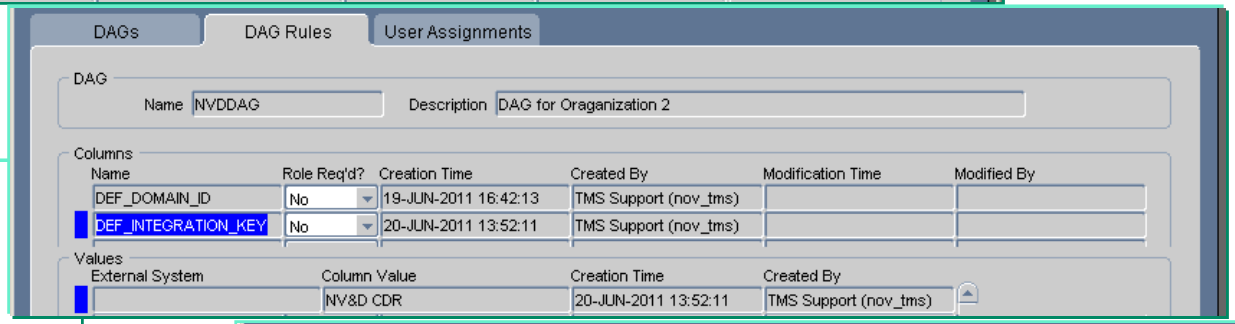
# DAGs Roles

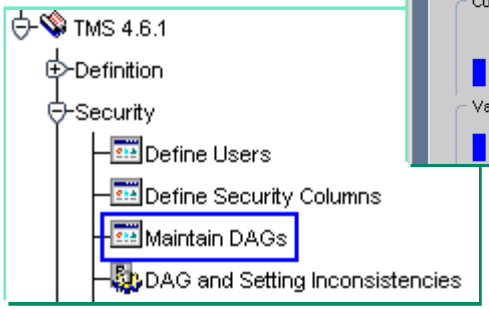
- Use DAG roles for the dictionary and domain columns to control operations users can perform there on the dictionary/domain data.
  - TMS_CLASSIFY
  - TMS_APPROVE
  - TMS_MAINTAIN
  - TMS_DUPG
  - TMS_RECLASSIFY
- Note: The user also requires the equivalent database role.

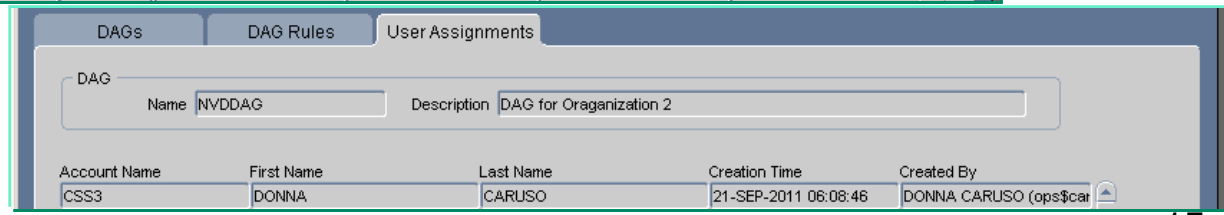
# Case Study: Defining DAGs by Domain & External System



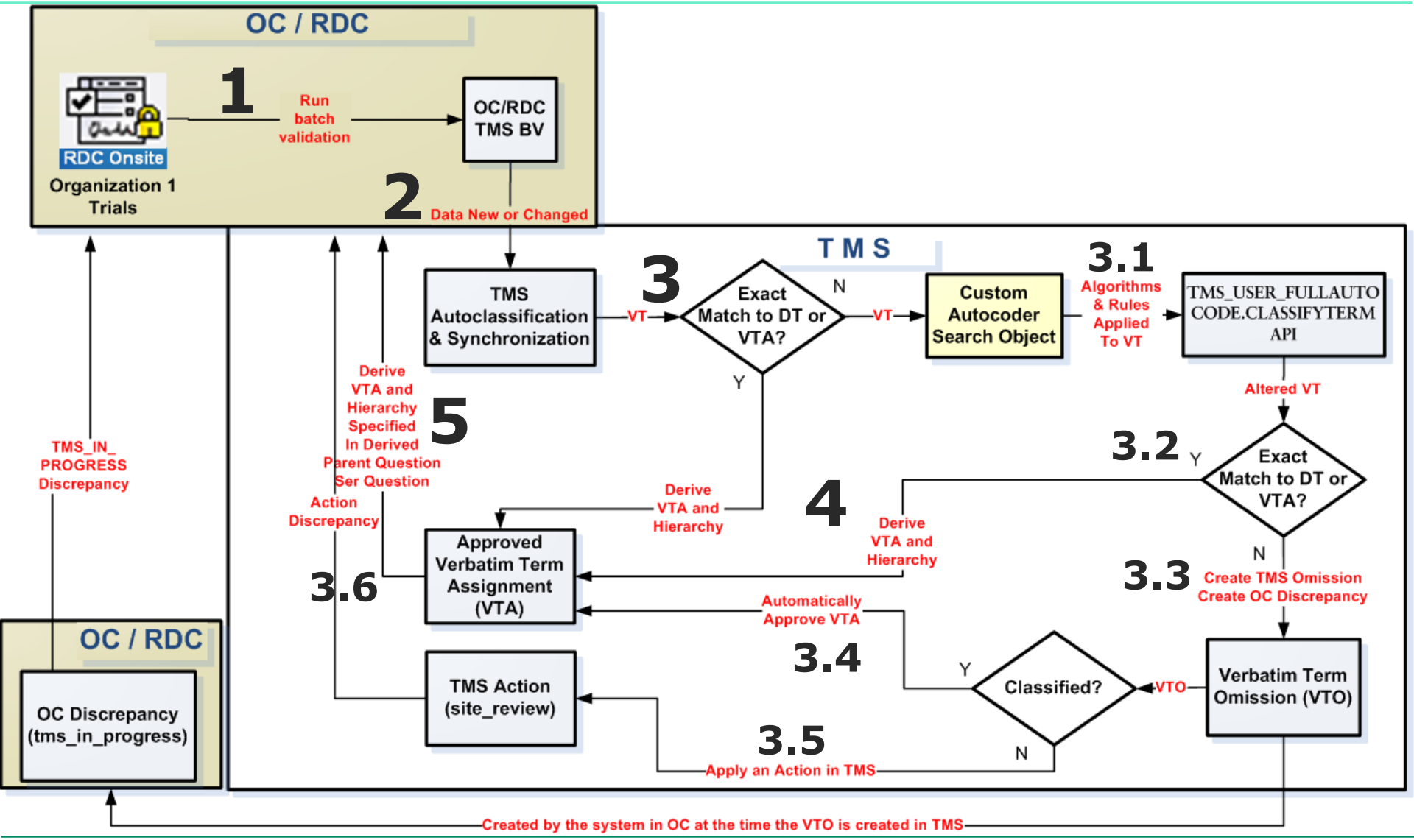
# External System Integration

- Each external system can independently integrate with TMS.
- Benefits:
  - OC and TMS Integration by the OC batch validation process.
  - CDR and TMS Integration by the custom TMS Integration Inbound and Outbound processes from SAS and from TMS.

# OC and TMS Integration

- Oracle Clinical Batch Validation runs on a single study, usually on a regular schedule such as nightly.
- Batch Validation finds data that is new or changed in OC and TMS since the last Batch Validation and sends the relevant data to the other system.
- Batch Validation runs TMS Autoclassification and Synchronization in TMS on new OC/RDC data, then the derived information, omissions, and actions associated with that same data are sent back to Oracle Clinical.

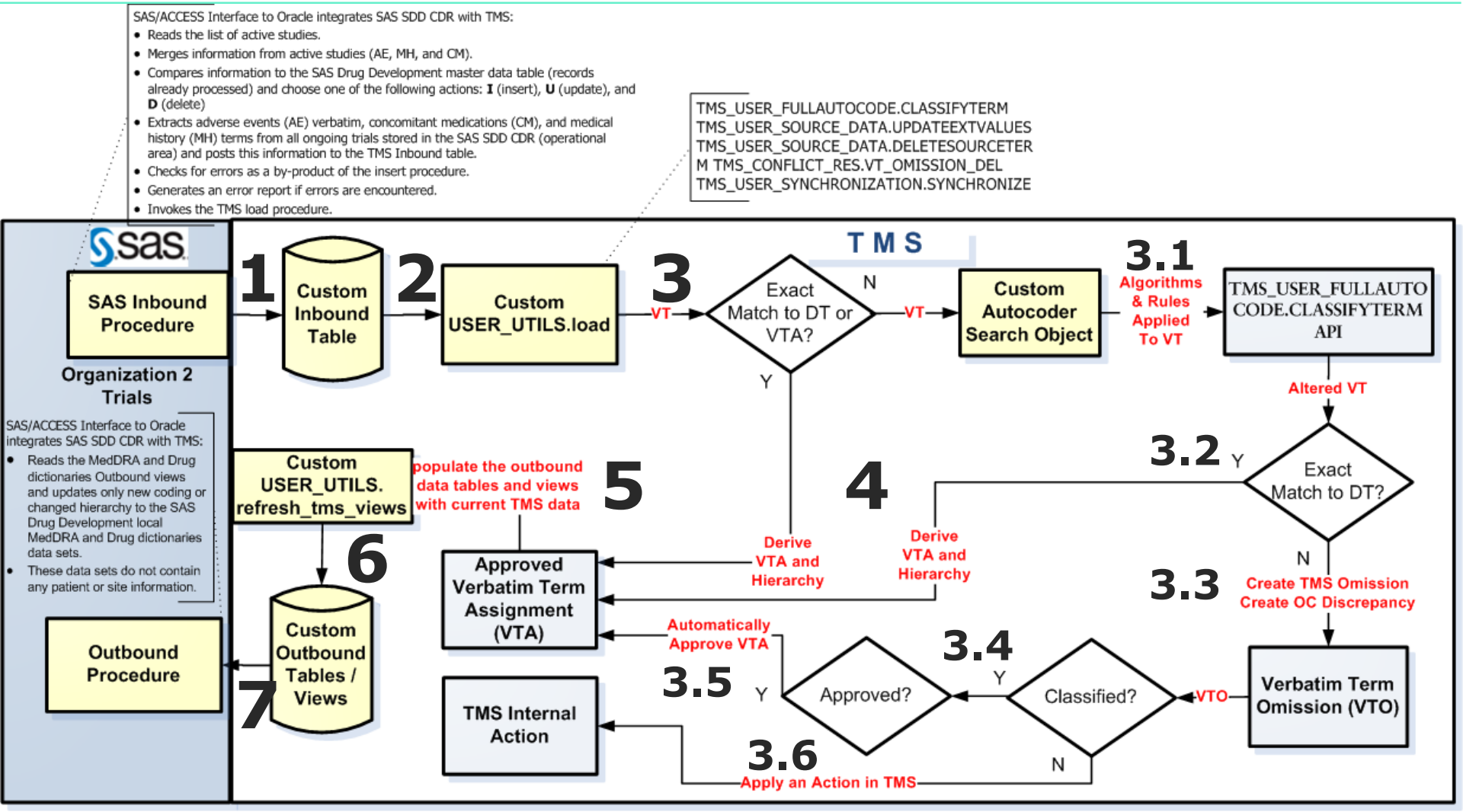
# Case Study: OC and TMS Integration Process Flow



# OC and CDR Integration

- The TMS load process runs every 30 minutes.
- Once a given record is processed within TMS, the record will be marked as processed and will not be processed again.
- To ensure that no other process tries to update the same record, the process first locks the records by the input criteria.
- Upon completion, the TMS load process updates the corresponding record within the inbound table to reflect the TMS processing status (processed_flag = Y, N, E for records that could not be processed in TMS due to missing or invalid data).

# Case Study: OC and CDR Integration Process Flow



# Independent Coding Practices, Processes and Workflow

- TMS enables different approval workflow by domain; one organization can automatically approve a VTA when it is classified while the other organization can enforce the manual approval process after classification.
- Coding in separate domains allows each organization to classify VTs independently based on their coding guidelines.
- Flexible custom search object definitions allows one organization to find autocoded matches to DTs and VTAs, while the other organization permits matches to DTs.

# Share Common Processes, Terminology and Services

- Common Processes:
  - TMS coding, approval, repository maintenance, and browsing.
  - Custom autocoder search object rules and algorithms to search the TMS repository to find matches for verbatim terms during the TMS_USER_FULLAUTOCODE.CLASSIFYTERM processing.
- Common Terminology:
  - The MedDRA and Drug dictionaries that are centrally versioned with common dictionary versioning and terminology maintenance processes. Each organization manages the VTAs within their specific domains.
- Centralized Support:
  - Support and maintain the system centrally.

# Conclusions: TMS Benefits in a Centralized Coding Environment

- Enables each external system and source data to independently integrate with TMS.
- Enforces secure data access and independent coding environments for each organization.
  - Different organizations can code verbatim terms independently.
  - An organization can secure coded data by restricting data access.
  - Superusers who require access to operate across both organizations can be designated in TMS as Superusers.
- Allows for different coding practices, processes and workflow.
- Shares common processes, terminology and services.

# Questions and Answers

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# Abstract


- Benefits of Coding in TMS with source data from OC RDC and InForm
- Presenter: Donna Caruso, DBMS Consulting
- Rating of Presentation: Intermediate
- Companies using both the Oracle Remote Data Capture (RDC) and the Oracle (Phase Forward) InForm electronic data capture systems are looking for options to code verbatim terms from a centralized coding system. A case study presents a solution to code data in the Thesaurus Management System (TMS) from the Oracle Clinical external system for OC RDC trials and from a separate clinical data repository (SAS SDD CDR) external system for InForm and legacy trials. This presentation will address considerations for coding in TMS with multiple external systems, maintaining independent and secure coding environments for each external system while sharing a common dictionary terminology that is maintained and supported centrally. Finally, a summary of benefits are discussed.

# Biography

Donna Caruso, Director, Project and Systems Release Management, DBMS Consulting, Inc.

- Donna has provided Global implementation expertise for the Oracle Health Sciences suite of applications for over 11 years. She specializes in project management, business and systems analysis, process engineering, systems validation, compliance and systems release management for the Pharmaceutical industry. She is an active leader in the OCUG community since 2000 as an OCUG Executive Co-Chair, TMS Co-Chair, DIS Co-Chair, Executive Committee member, and Joint Audit Team lead auditor for the Oracle Health Sciences applications. She is extremely grateful for the opportunity to make this presentation at the OHSUG 2011 Conference.