

ORACLE THESAURUS MANAGEMENT SYSTEM V4.6

THESAURUS MANAGEMENT SYSTEM

- Global centralized terminology management
- TMS classification engine supports mapping verbatim terminologies to standard terminologies
- Supports outsourcing verbatim term classification tasks
- Supports custom or vendor supplied dictionaries
- Supports dictionary versioning and access to previous versions
- HTML Browser provides enterprise-wide repository searching
- API-driven interface enables custom application integration
- Role-based security allows both data- and function-related access
- Workflow implementation facilitates control and reporting of user activities

Oracle Thesaurus Management System addresses the complexities associated with managing global thesauri. Designed to manage and classify free text captured during the drug development process, TMS meets the needs of multinational pharmaceutical, biotechnical and medical device companies, contract research organizations, academic institutions and regulatory authorities by providing a worldwide, scalable terminology repository. Within the Oracle OLS application suite, TMS provides terminology services for Oracle Clinical™, Oracle RDC™, Oracle AERS™ and Oracle Life Sciences Data Hub™.

Oracle TMS in the Drug Development Process

It is a well-established benchmark in the pharmaceutical industry that every day gained in accelerating product registration could be worth \$2-3 million in additional sales revenue. One of the most time-consuming tasks within the drug development process is classifying verbatim terms to permit deriving standard medical and drug terms for use in analysis from the free text originally captured.

The Oracle Thesaurus Management System (TMS) streamlines this critical and costly task by providing a centralized, globally available repository of dictionary terms and associated verbatim terms. Information in the repository is accessible through advanced searching and classification algorithms. TMS supports all dictionaries required by international regulatory authorities. Additionally, TMS can support and integrate with company/organization-specific dictionaries and legacy applications. The result is a global facility to standardize terminology use across dictionaries, computer applications, time, and organizations.

Comprehensive Thesaurus Implementation and Management

TMS has virtually no limitations on the number, organization, or use of dictionaries. Since many dictionaries exist for different types of information, their organization and defined hierarchies vary considerably. Specifically, Oracle TMS:

- Allows access to any number of dictionaries, including multiple versions of the same dictionary.
- Supports any number of levels of hierarchy.
- Supports custom, or commonly used dictionaries, such as MedDRA, MedDRA-

J, MedDRA SMQs, SNOMED, ICD9, WHO-ART, and WHO-Drug.

- Provides user-definable attributes for each term in a dictionary.
- Provides web-deployed browsing of an entire dictionary hierarchy.
- Permits searching for terms within a level, with the result showing related elements above and below.

Operations in a Globally Distributed Environment

Drug development in today's pharmaceutical enterprise is a global operation, and it is information technology that enables organizations to execute complex business processes throughout the global enterprise. As part of this technology, Oracle's Thesaurus Management System (TMS) meets the stringent requirements of global dictionary management with:

- A single, global TMS repository for flexible mapping of verbatim term assignments to any combination of dictionary terms — whether supplied by a vendor, or generated internally.
- The scalability and reliability of being built on Oracle's industry leading technology.
- The Oracle Symmetric Replication option is optionally available for high performance in globally distributed environments
 - When using replication, definition, loading, and maintenance from one master site; and classification from any site.
- Full web deployment to take advantage of the lower costs associated with centralized configuration management.
- Usage of bitmap indexes to improve performance.

Dictionary Versions and Version Control

Most vendor-supplied dictionaries are released with periodic updates. TMS permits these releases to be managed and controlled, permitting access to and use of earlier versions of the dictionaries through virtual dictionaries.

Versioning Verbatim Term Management

TMS provides an environment to assess the impact of dictionary versioning on verbatim terms linked to the dictionary. Reassignment of verbatim terms during dictionary versioning ensures continuity in the ongoing maintenance of an organization's verbatim term pool.

Point In Time (Virtual) Dictionaries

TMS permits users to create (instantiate) a dictionary such as MedDRA or WHO-Drug. This dictionary is considered the "base" dictionary, where the most recent dictionary data resides. A virtual dictionary is a base dictionary at a particular a point in time. The virtual dictionary inherits the dictionary structure rules of the base dictionary and any data active at the specified point in time. Such virtual dictionaries can be used for classification purposes.

Virtual dictionaries also provide functionality for:

- Periodic safety reporting across dictionary versions
- FDA audit reporting at the close of specific studies
- Reporting on classifications at given points in time

Dictionary-to-Dictionary Mapping

TMS 4.6 allows dictionary-to-dictionary relations (mappings), providing key support for the following functionalities:

- Translation Dictionaries: TMS supports multi-language coding by establishing different language dictionaries, with cross dictionary links to provide terminology equivalence.
- Dictionary Migration efforts: Cross dictionary links can support relationships between legacy dictionaries or company/organization dictionaries and vendor dictionaries.

HTML-Based Dictionary Browser

Designed for the analytic / read only user, the TMS 'lite' dictionary browser is an easy-to-use, HTML-based dictionary browser that allows users to browse and search any of the dictionaries loaded in TMS. The interface is generated from the TMS repository, and gives users the ability to navigate a dictionary hierarchy and to perform comprehensive searches with Oracle *interMedia* Text capabilities, such as soundex searches, stem searches, and thematic searches.

The HTML Browser enables searches based on MedDRA SMQs, for both terminology and patient data.

Advanced Searching and Autoclassification

Oracle TMS allows the development and integration of advanced algorithms to aid in coding and/or searching the thesaurus repository. Defined as TMS 'Search Objects,' these algorithms interface directly with TMS and can be used for:

- Autoclassification
- Candidate term identification
- Extended searching (searches across multiple levels of a dictionary)

TMS Search Objects can also be used to integrate user autoclassification and searching processes, as well as new, vendor-supplied autoclassification and searching processes. TMS Search Objects can utilize the *interMedia* option, containing ConText, which enables searches based on fuzzy logic, language stemming, and lexical search methods. Oracle Consulting offers an add-in product that assists organizations in defining and creating TMS Search Objects

API-Driven Architecture and Integration

To assist in classifying terms, many organizations have developed in-house applications implemented with standard and custom dictionaries. Upgrading to new environments, or loading new dictionaries such as MedDRA, can be difficult and

time-consuming. Oracle Thesaurus Management System has been designed with a set of application programming interfaces (APIs) to facilitate integration with legacy systems. With this API-driven system an enterprise can:

- Load terms into a dictionary.
- Test terms to insure conformity with dictionary definitions.
- Submit and classify verbatim terms using all of the TMS autoclassification functionality.
- Create customized searching algorithms using TMS Search Objects, and Oracle *interMedia*.
- Globally manage thesaurus omissions and, when integrated with Oracle Clinical, handle discrepancies globally via the batch validation process.
- Integrate third party autoclassification products such as TRW's AutoCode or Oracle Life Sciences Consulting's TMS Search Object Manager.

Workflow and Security

TMS allows groups from different departments within an organization to communicate electronically, and to electronically follow a coding workflow. TMS permits a bi-directional interaction between TMS and external systems.

Additionally, TMS supports communications within TMS, as TMS users are able to assign, reroute and otherwise manage tasks within TMS. This permits centralized coding teams to collaborate on coding,

Improved tracking and reporting facilitates management control of coding workflows.

TMS implements highly controllable and granular security controls through the establishment of Data Access Groups (DAGs). DAGs limit TMS users' access to dictionaries, domains, external integrations, subtypes of external integrations and assigned workflows.

Outsourcing Coding Support

TMS provides multiple avenues to outsource coding activity. TMS's enhanced security model combined with the enhanced web access features can permit external users to access only the appropriate coding environment. Alternatively, TMS permits the data exchange via Disconnected System Integration between a Sponsor and Vendor and allows the Sponsor to review, correct or accept the Vendor's classifications.

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