ORACLE HEALTH SCIENCES CENTRAL CODING

Designed to work with Oracle Health Sciences InForm GTM, Oracle Health Sciences Central Coding is a customizable, multilingual, Web-based coding and dictionary management application that automates the coding process.

Consistent and Accurate Coding and Dictionary Management

An important data component of every trial involves the input and management of a patient’s medical history, the medications prescribed, and the potential adverse events encountered. Collected as free text entries or “verbatim” in electronic case report forms (eCRFs), this information can vary dramatically from staff to staff and site to site. Sponsors and CROs need to streamline the process of transforming these verbatims into standard coded terms that are compliant with regulatory standards. Most importantly, the safety-related data needs to be standardized and available on a continual basis to minimize the risk to patient safety.

Easy-to-use, task-oriented interface provides status of terms and coding actions required.

Automated Coding Task Management

Oracle Health Sciences Central Coding streamlines the coding process, which can reduce errors and drive down expenses through advanced technology features such as fast and accurate auto-coding, customizable synonym and stop word lists, propagate functionality, and configurable workflow. With Oracle Health Sciences Central Coding, sponsors and CROs have a highly efficient way to review, resolve, and approve coded terms—all of which can happen simultaneously across staff, sites, studies, and locations.

Centrally Optimized Process Control

Because most sponsors and CROs employ a specialized team of professionals responsible for the coding activities of studies, a centralized collection and management approach is critical. Designed to connect to multiple studies, Oracle Health Sciences Central Coding acts as an independent collection and access point for all verbatims, and customizable flags and statuses enable users to tailor and optimize their workflow to assign, code and approve coded terms.

Coding-Centric Workflow

Oracle Health Sciences Central Coding provides powerful controls for coding, review, and approval of coded terms. Built-in automated workflow capabilities—such as auto-code, auto-approval of coded terms, auto-suggest, and review of coded terms—facilitate the process.
Using an inbox “to-do” methodology, Oracle Health Sciences Central Coding supports interactive and manual coding processes. The product’s configurable role and work management capabilities intelligently assign and route verbatim terms to the designated coders for coding, and to the designated reviewers for approval. Once terms are approved, they are automatically sent back to the Oracle Health Sciences InForm GTM EDC environment. As a result, coding can occur earlier in the study cycle, providing valuable data visibility.

**Oracle Health Sciences InForm GTM as the Source System**

Oracle Health Sciences Central Coding is tightly integrated with Oracle Health Sciences InForm GTM and is designed to complement its study management efficiencies. It automatically receives verbatims from Oracle Health Sciences InForm GTM studies and returns codes and terms to the EDC database, saving sponsors and CROs from costly integration services and time delays associated with a third-party coding solution.

This out-of-the-box integration with Oracle Health Sciences InForm GTM extends beyond the workflow capabilities between systems. For example, when additional context is needed to resolve a coding term, coders can review the information from within Oracle Health Sciences Central Coding. When more-detailed information or action is required, coders can initiate queries directly in Oracle Health Sciences Central Coding, propagate across all EDC trials running and receive status updates in Oracle Health Sciences InForm GTM.

**Advanced Dictionary Administration**

Adding to the complexity of the coding process is the need to manage multiple dictionaries and dictionary versions. Oracle Health Sciences Central Coding supports multilevel and multiaxial dictionaries in English and Japanese, including support for the industry-standard World Health Organization Drug Dictionary (WHO-DD), the Medical Dictionary for Regulatory Affairs (MedDRA and MedDRA/J), and JDrug, as well as many custom and proprietary dictionary formats used by sponsors and CROs. Most importantly, Oracle Health Sciences Central Coding helps users understand the differences between any version of MedDRA, MedDRA/J, WHO-DD, or JDrug; analyze the impact of those changes; and reconcile the differences in coded terms within the study.

**The Ownership Experience**

Staffed by professionals with extensive pharmaceutical, biotechnology, development, and IT experience, Oracle Health Sciences provides one of the most robust cloud applications service offerings in the industry that can scale to the demands of the smallest to the largest companies. Clients looking to bring applications directly into their enterprise can also leverage Oracle Health Sciences full range of mentoring programs, training offerings and implementation services to transfer knowledge in-house for additional flexibility.

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**HIGH-IMPACT FEATURES**

- High performance algorithm improves auto-code hit rates
- Configurable synonym lists can be applied across different studies, ensuring consistency and saving time
- Definable stop-word lists increases the speed and accuracy of autocoding
- Auto-query and query propagation functions reduce manual query efforts
- Intelligent code and propagate functions eliminate the need to manually code identical verbatims
- Impact analysis reports and reconciliation tools for updating coded terms within a study with a newer dictionary version
- Complete audit history provides a date and time stamp for all changes

**RELATED PRODUCTS**

- Oracle Health Sciences InForm GTM
- Oracle Health Sciences Clintrial