

#### **KEY FEATURES**

- Single, centralized data management environment
- Fully integrated, end-to-end data management solution for EDC, labs, and all data sources across your clinical trial
- Querying capability
- Manual and automated discrepancy reconciliation
- Metadata definition and loading
- Automated data loading
- Simple and complex mappings & transformations
- Ability to link in external PL/SQL or SAS programs
- Support for integrated and ad hoc reporting
- Fully integrated with InForm

#### **KEY BENEFITS**

- Accelerates study setup and conduct by delivering cleaner data to biostats faster
- Increases data quality with automated discrepancy reconciliation and data cleansing
- Provides better regulatory compliance with comprehensive security, audit trail, and two-way traceability across discrepancy lifecycle
- Offers more informed decision-making through pooling and analysis of clinical and non-clinical data
- Saves time and cost by reducing timeconsuming manual processes required to load, transform, and clean trial data

# ORACLE HEALTH SCIENCES DATA MANAGEMENT WORKBENCH

Oracle Health Sciences Data Management Workbench (DMW) offers the industry's only true end-to-end data management solution in a single environment. The software accelerates the speed and accuracy of clinical data integration, reconciliation, aggregation, and analysis by reducing timeconsuming manual processes required to load, transform, and clean trial data. You deliver cleaner, traceable data to biostats much more quickly – letting you make faster, more informed decisions to reduce cycle-times, improve control, and enable adaptive trials.

## Accelerate Study Setup and Conduct While Increasing Data Quality

Oracle Health Sciences Data Management Workbench provides faster audit query response, discrepancy reconciliation, and data cleansing, with fewer errors, so you can quickly deliver high-quality data to biostats for review.

- DMW lets you define, re-use, and automate mappings across multiple data sources, facilitating deep data cleansing to help reduce trial timelines and risk.
- Configurable and repeatable end-to-end data management workflows improves reuse of trial objects so you significantly improve user and investigator productivity and efficiency by reducing duplication of queries, increasing the timely receipt of queries, and decreasing the turnaround time needed to manage discrepancies.
- Comprehensive query management and data browsing capabilities reduce labor-intensive cleaning of data and increases the identification and resolution of cross-data source discrepancies, so you can provide higher-quality data faster.
- Lifecycle and library management simplifies creation of new studies leveraging existing components and streamlines the management of study components throughout the development lifecycle so you achieve greater efficiencies in study build and execution to reduce study cycle-times.
- Rich discrepancy reporting and non-technical ad hoc reporting and querying without impacting EDC performance at site or sponsor locations lets you quickly identify and resolve queries and discrepancies, reduce duplication of queries, and obtain queries faster to streamline medical monitoring and medical data review.
- DMW's intuitive user interface featuring role-based functionality and onscreen navigation as well as comprehensive inline help lets you reduce system training costs and data errors, increasing accuracy as well as user productivity.
- Controlled testing environment separates development, testing, and production environments for minimum impact, accelerating trial deployment and conduct while maintaining stringent checks and balances to help ensure optimum accuracy.



### INTEGRATED DATA FROM MULTIPLE SOURCES IN A SINGLE **ENVIRONMENT**

- InForm5.5 or 6.0
- PK/PD modeling
- Laboratory
- Safety/pharmacovigilance
- Contract research
- Drug supplies
- Trials management

## Reduce Clinical Trial Duration, Cost, and Risk

Oracle Health Sciences Data Management Workbench provides a true end-to-end data management solution to reduce manual processes to save time and cost, and increase traceability to help ensure compliance.

- DMW enables an efficient and automated end-to-end study workflow that streamlines trial design and build, data integration and cleanup, and Medical Data Review. You obtain more accurate and timely information to drive decision-making, letting you accelerate trial timelines, or identify and halt unproductive trials sooner.
- · Extensive use of automation throughout DMW minimizes manual processes and significantly reduces the need for custom programming to save time and cost.
- DMW gives you a single source of the truth for incorporation of industry standards for study conduct and analytics - such as CDISC SDTM - to speed trial setup, increase reusability, help ensure compliance, and respond quickly and effectively to audits.
- Data integration increases the level of standardization throughout the study process to provide a repeatable, reusable data format for discrepancy management and data pooling to resolve discrepancies faster and get to database lock sooner.
- Robust and scalable architecture built on Oracle's leading Oracle Life Sciences Data Hub • (LSH) clinical data warehousing platform optimized for maximum performance, scalability, and security lets you quickly deploy your trial regardless of the number of sites or locations and execute transformations faster, reducing trial duration.



## Streamline the Implementation of Industry and Organizational Standards

Oracle Health Sciences Data Management Workbench provides a true end-to-end data management solution in a single environment to provide better integration and facilitate the adoption of industry standards throughout the development lifecycle.

· DMW provides a comprehensive metadata management framework to drive standardization and re-use across your organization.



Sciences Data Management Workbench provides a "single source of the truth" for all stakeholders across the clinical data life cycle to speed trial cleansing, integration, and analysis.

- Facilitate incorporation of industry standards for study conduct and analytics such as CDISC SDTM, increase analytical capability and reusability, help ensure compliance, and respond quickly and effectively to audits.
- Data integration increases the level of standardization throughout the study process to provide a repeatable, reusable data format for discrepancy management and data pooling to resolve discrepancies faster and get to database lock sooner.
- Lifecycle and library management simplifies creation of new studies leveraging existing components and streamlines the management of study components throughout the development lifecycle so you achieve greater efficiencies in study build and execution to reduce study cycle-times.

## Future-Proof Your R&D Technology While Reducing Cost and Risk

- By combining the advanced data capture capabilities of InForm, the transformation and cleansing of DMW, with the automation of LSH, you can simplify your system landscape and reduce dependency on legacy systems saving time and reducing the cost of operating legacy environments and data centers.
- Oracle Health Sciences offers the industry's most comprehensive suite of best-of breed software solutions supporting early to late-phase development, safety and healthcare (secondary use) to help you deliver on the promise of personalized, value-based therapies.
- Oracle Health Sciences development and hosting resources are funded and managed by one
  of the world's largest technology companies so you minimize the risk of business
  disruption. While other companies struggle to support constantly changing industry
  requirements, Oracle provides the breadth and depth of resources to ensure continuity.

### Why Oracle Health Sciences

Backed by the resources of a Global 500 company, Oracle Health Sciences provides you with the industry's most comprehensive set of software solutions addressing every aspect of the health sciences value chain from discovery to care delivery. With thousands of professionals in offices throughout North America, EMEA, and Asia, Oracle Health Sciences offers unmatched resources to enable your organization's goals today and in the future.

## **Contact Us**

For more information about Oracle Health Sciences Data Management Workbench, visit oracle.com/healthsciences, e-mail healthsciences\_ww\_grp@oracle.com, or call +1.800.633.0643 to speak to an Oracle representative.

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DATA MANAGEMENT WORKBENCH

Data Management Workbench (DMW)

Oracle Life Sciences Data Hub (LSH)

· Open architecture integrates to other

visualization and analysis technologies

**TECHNICAL COMPONENTS** 

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## Hardware and Software, Engineered to Work Together



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