ORACLE HEALTH SCIENCES DATA MANAGEMENT WORKBENCH CLOUD SERVICE

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Oracle Health Sciences Data Management Workbench Cloud Service (DMW CS) offers the industry's only, true, end-to-end, data management solution in a single integrated environment. DMW CS accelerates the speed and accuracy of clinical data aggregation, reconciliation, transformation, and analysis. It enables these advances by reducing time-consuming, manual processes required to load, transform, and clean trial data. Data managers deliver cleaner, traceable data to biostats with greater speed, driving faster, more informed decisions to reduce cycle-times, improve control, and enable adaptive trials.

KEY FEATURES

- Single, centralized, data management environment
- Fully integrated, end-to-end, data management solution for EDC, labs, and all data sources across the clinical trial
- Querying capability
- Manual and automated discrepancy reconciliation
- Metadata definition and loading
- Automated data loading
- Simple and complex mappings and transformations
- Fully integrated with InForm

Accelerate Study Setup and Conduct, While Increasing Data Quality

DMW CS provides faster audit query response, discrepancy reconciliation, and data cleansing, with fewer errors. Deliver high-quality data to biostats for review.

- DMW CS defines, re-uses, and automates mappings across multiple data sources, facilitating deep data cleansing, as well as reducing trial timelines and risk.
- DMW CS provides configurable and repeatable, end-to-end, data management workflows for improved reuse of trial objects. These capabilities significantly improve productivity and efficiency for users and investigators, as well as reduce duplication of queries. This increases the timely receipt of queries, decreasing the turnaround time needed to manage discrepancies.
- Comprehensive query management and data browsing capabilities reduce labor-intensive cleaning of data. They also increase the identification and resolution of cross-data source discrepancies, providing higher-quality data faster.
- Lifecycle and library management simplify the creation of new studies leveraging reusable components. This also streamlines the end-to-end development lifecycle to achieve greater efficiencies in study build and execution, reducing study cycle-times.
- Rich discrepancy reporting, non-technical ad hoc reporting, and querying without impacting EDC performance at site or sponsor locations allow the quick identification and resolution of queries and discrepancies. These capabilities also reduce duplication of queries and provide queries faster for streamlined medical monitoring and medical data review.
- DMW CS's intuitive user interface, featuring role-based functionality, onscreen navigation, and comprehensive inline help, reduces system training costs, decreases data errors, increases accuracy, and enhances user productivity.
- A controlled testing environment separates development, testing and production environments to support regulatory controls. This accelerates trial deployment and conduct, while maintaining stringent checks and balances, ensuring quality and

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compliance.

Reduce Clinical Trial Duration, Cost, and Risk

DMW CS provides a true, end-to-end data management solution that reduces manual processes, saves time and cost, and increases traceability for ensured compliance.

- DMW CS enables an efficient and automated, end-to-end study workflow that streamlines trial design/build, data integration, data cleanup, and medical data review. Research teams obtain more accurate and timely information to drive decision-making, accelerate trial timelines, or identify and halt unproductive trials sooner.

- Extensive use of automation throughout DMW CS minimizes manual processes and significantly reduces the need for custom programming to save time and cost.

- DMW CS provides a single source of truth for incorporation of study conduct and analytics industry standards, such as CDISC SDTM. This speeds trial setup, increases reusability, helps ensure compliance, and enables quick, effective, audit responses.

- Data integration increases the level of standardization throughout the study process to provide a repeatable, reusable, data format for discrepancy management and data pooling. This allows resolution of discrepancies faster and getting to database lock sooner.

- A robust and scalable architecture optimized for maximum performance, scalability, and security enables quick trial deployment and faster transformations execution, reducing trial duration. This is regardless of the number of sites or locations.
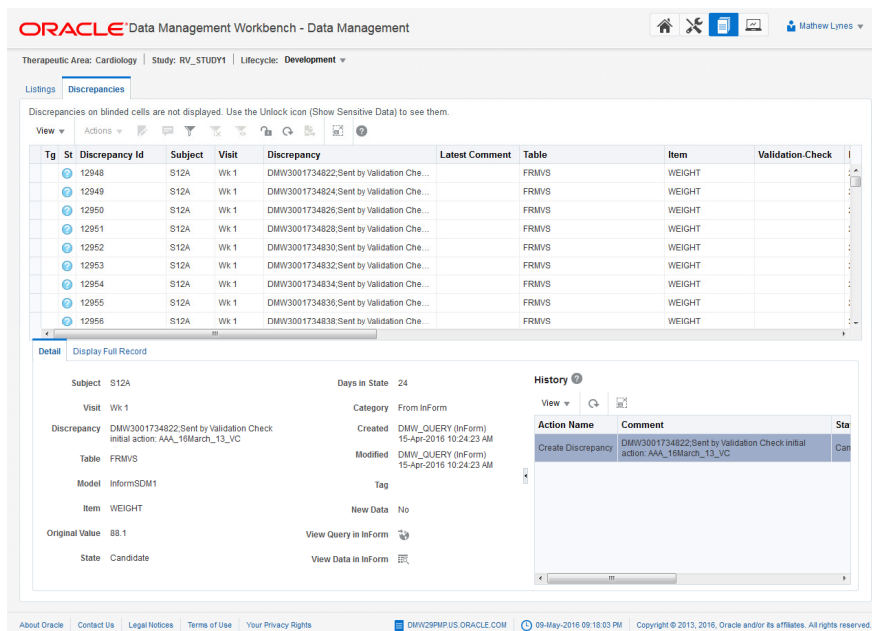
Oracle Health Sciences Data Management Workbench provides a "single source of the truth" for all stakeholders across the clinical data life cycle to speed trial cleansing, integration, and analysis.

Streamline the Implementation of Industry and Organizational Standards

DMW CS provides better integration and adoption of industry standards throughout the development lifecycle.

- DMW CS features a comprehensive, metadata management framework to drive standardization and re-use across the organization.
- Facilitating incorporation of industry standards for study conduct and analytics, such as CDISC SDTM, DMW CS increases analytical capability and reusability, helps ensure compliance, and enables quick, effective audit responses.
- The level of data integration standardization is increased throughout the study process. This provides for repeatable, reusable, business processes that include discrepancy management and data aggregating capabilities. These proficiencies enable quicker discrepancy resolution and faster database lock.
- The availability of lifecycle and library management capabilities simplifies the creation of new studies by leveraging reusable components. They also streamline study component management throughout the development lifecycle for greater study/build/execution efficiencies and reduced study cycle-times.

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

- By combining the advanced data capture capabilities of InForm with DMW CS, customers can simplify the clinical dataflow by eliminating legacy systems and complex integrations. These Oracle Health Sciences Data Management Workbench Cloud Service features, delivered through the cloud service, save time, while reducing the cost and risk 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), helping 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. These resources minimize business disruption risk. While other companies struggle to support constantly changing industry requirements, Oracle provides the breadth and depth of resources to ensure business continuity and value creation.

Why Oracle Health Sciences

Backed by the resources of a Global 500 company, Oracle Health Sciences offers the industry's most comprehensive suite of software solutions. These address 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.

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Integrated Cloud Applications & Platform Services

Oracle is committed to developing practices and products that help protect the environment