Oracle Health Sciences Central Designer streamlines the study development process for life sciences companies, letting you design, test, and deploy trials in as little as two weeks. The collaborative development environment enables you to leverage libraries and standards to rapidly transform complex protocols into a production-ready electronic data capture (EDC) study. The software enhances study design efficiency, reduces build time, improves data quality, and shortens trial delivery time.

Oracle Health Sciences Central Designer helps you build trials quickly and accurately:

- Powerful edit check and testing capabilities enable collaborative development. Rapidly transform complex protocols into a production-ready EDC study to save time and resources.
- A design environment with secure roles and rights allows multiple users to work on a single study without affecting each other’s changes, increasing speed and productivity.
- Templates and a Rules Development Wizard feature enable non-programmers to quickly and easily develop complex rules and edit checks helping to save time and focus technical resources on higher-value activities.
- Rich and robust library functionality facilitates sophisticated search and reuse of existing study design assets to help accelerate development time and ensure adherence to company standards.
- Detailed audit history reports let you track changes on any study or library object so you know who did what and when, increasing transparency and minimizing risk.
- Built-in task workflow management permits quick assessment of study development progress so you can easily keep the study design process on track.

Streamline and Extend Study Design Capabilities

Before a trial can go live, a trial sponsor must develop workflows, design and translate electronic case report forms (e-CRFs), define data items, and create edit checks. Final approval for a trial depends on the endorsement of many global stakeholders such as data managers, biostatisticians, and staff to ensure the design will satisfy their requirements. Oracle Health Sciences Central Designer enhances study design efficiency through component reuse, improves workflow through simultaneous global collaboration, and effectively applies standards in a global, multilingual environment.
Enhance Design Efficiency and Reuse Study Components

Oracle Health Sciences Central Designer simplifies the process of building studies through its flexible and intuitive interface and its ability to outline, define, and reuse study components and templates. Study designers can populate common study components such as frequently used visits, forms, and preferences, as well as include team members, libraries, and study deployment options.

Using Oracle Health Sciences Central Designer, teams can quickly design and review studies in an easy-to-view graphical layout.

Figures 1a and 1b. Users can quickly and easily assemble workflows for visits and the sequence of forms within a visit using the Oracle Health Sciences Central Designer Workspace Diagram Editor feature.
KEY FEATURES

• Create and reuse templates to populate common study components
• Access existing study components using advanced library search and retrieve capabilities
• Create and test rules using the step-by-step process in the Rules Development Wizard feature
• Build and run test cases prior to deployment
• Enable compliance with industry and company standards with library and data mapping capabilities
• Leverage the multiuser environment for easy and secure real-time access to study development from anywhere in the world
• Perform CRF design, rule development, library management, and translation all from one centralized system

The Oracle Health Sciences Central Designer architecture enables designers to search for any study component by name, category, or keyword — such as a specific form or all study objects related to a particular therapeutic area or study phase.

It further allows related study components such as form layouts, data items, code lists, and rules to be grouped together, which saves time by allowing designers to insert fully defined study components from a library into a study. The retrieved library component can then be changed within a study to meet specific study requirements without affecting the library copy.

Figure 2. Internal standards teams can run reports on study objects to determine how often library objects are being used and modified once they are incorporated into a study.

Simplify Rule Development

Using rules or edit checks within a design is vital to maintaining the overall quality of study data. Unfortunately, rule development can be time-consuming. Oracle Health Sciences Central Designer dramatically reduces the need to create and test rules repeatedly because rules are included when study objects are retrieved from a library. Users can then generate rule test cases and run them in the Oracle Health Sciences Central Designer environment before deployment.

Central Designer simplifies rule development with the Rules Development Wizard feature that walks the user step by step through the process of creating and testing a rule. The Rules Development Wizard enables nonprogrammers to develop range checks, constraints, and calculations at any level of the study design including the item, form, or visit level. Oracle Health Sciences Central Designer also makes it easier for programmers to develop more-complex rules by providing built-in functions within a Microsoft .NET language expression editor.
Apply Company and Industry Standards

Most life sciences companies today are driving toward incorporating industry standards recommended by the Clinical Data Interchange Standards Consortium (CDISC) and Health Level Seven (HL7) into their study designs to reduce submission time. To achieve this, Oracle Health Sciences Central Designer is CDISC Operational Data Model (ODM) certified, letting users import ODM 1.3 study metadata definitions into the Oracle Health Sciences Central Designer environment for reuse and assembly into studies or libraries.

Oracle Health Sciences Central Designer helps companies implement standards more efficiently and consistently through a role-based environment, allowing companies to establish exclusive rights to assigned users to create and manage study components within libraries. This group of librarians can develop study components that meet industry and company standards and then publish them for easy access by all study build teams.

Internal standards teams can run reports on study objects to determine how often library objects are being used and modified once they are incorporated into a study. By understanding usage, companies can continuously improve their libraries to reduce modifications and increase companywide adoption. In addition to standardizing study objects, Oracle Health Sciences Central Designer provides a way to create and apply various data views to existing data items. These reusable data mappings can be retrieved from a library and applied to items within a study to help define Study Data Tabulation Model (SDTM) industry-compliant data extracts from captured clinical data.
Improve Workflow and Simultaneous Global Collaboration

Oracle Health Sciences Central Designer is a multiuser, role-based solution that provides easy and secure real-time access to study designs under development from anywhere in the world. Companies can define and specify the roles and privileges for each user, while safeguarding against inadvertent or unauthorized changes. All assigned project tasks are conveniently listed every time a user logs on to the system — improving communication, streamlining the workflow processes, and providing teams with the flexibility to work together in parallel.

Figure 4. Selecting a task in Oracle Health Sciences Central Designer lets users directly access the focus area.

Manage a Single, Centralized Global Design Environment

With Oracle Health Sciences Central Designer, organizations can develop and manage all their studies from one central environment and deploy their studies to the Oracle Health Sciences InForm EDC platform. Users can import study design components from any CDISC ODM-compliant source from within the Oracle Health Sciences Central Designer environment and immediately reuse them as study objects in Central Designer.
Oracle Health Sciences Central Designer also allows users to harvest existing study components developed for Oracle Health Sciences InForm GTM. Oracle Health Sciences Central Designer provides one central and independent environment for building studies where design, rule development, library management, and translation all work from within one centralized system.

Oracle Health Sciences Central Designer is a multiuser, role-based environment.

The physical configuration of Oracle Health Sciences Central Designer requires a database server (Oracle Database 11g or 10g), an application server (Microsoft Windows Server 2008 or 2003), and one or more client computer.

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 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
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