

# ORACLE HEALTH SCIENCES CENTRAL DESIGNER

## KEY BENEFITS

### ENHANCE STUDY DESIGN EFFICIENCIES

- Quickly define and deploy multilanguage study workflows and components
- Easily reuse completed study components
- Simplify rules creation and testing via the “rules wizard”

### INCREASE REUSE AND THE APPLICATION OF STANDARDS

- Access approved library components using advanced search and retrieve capabilities
- Improve library management activities
- Define libraries using standards such as CDASH

### IMPROVE COMMUNICATION AND WORKFLOW

- Work concurrently with others by accessing the same study design simultaneously
- Streamline user workflow via team-assigned tasks

*Surpassing the capabilities of typical design tools by taking advantage of the latest technology as well as years of experience, Oracle Health Sciences Central Designer streamlines the study development process for life sciences companies. It enhances study design efficiency, reduces build time, improves data quality, and shortens trial delivery time. Oracle Health Sciences Central Designer is a centralized global design environment that will increase efficiency on even the most complex study.*

## 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 (eCRFs), define data items, and create edit checks. In addition, final approval for a trial depends on the endorsement of many global stakeholders, such as data managers, biostatisticians, and staff, to ensure that the design will satisfy their requirements. Oracle Health Sciences Central Designer helps enhance study design efficiency through component reuse; improve workflow through simultaneous global collaboration; and effectively apply 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 reuse study components. The product interface makes it easy to outline and define all the components of a study. Within the Oracle Health Sciences Central Designer environment, study designers can create and reuse study templates to 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 of any complexity in an easy-to-view graphical layout.

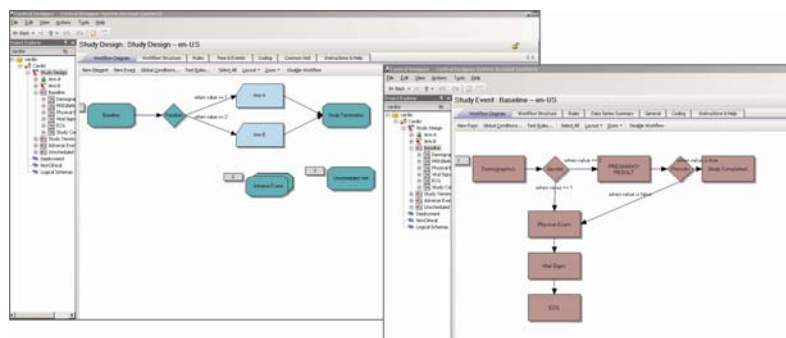


Figure 1. In this example, the study branches into two separate arms, where Arm 2 has a conditional follow-up element.

The Oracle Health Sciences Central Designer architecture enables designers to search for any study component by category or keyword, such as a “form,” “therapeutic area,” or

**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 Wizard interface
- Build and run test cases within the Oracle Health Sciences Central Designer solution 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 design, programming, data management, and translation all from one centralized system

“study phase.” It further allows related study components such as form layouts, data items, code lists, and rules to be grouped together. This advanced capability 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 as necessary within a study to meet the specific needs of the study without affecting the library copy.

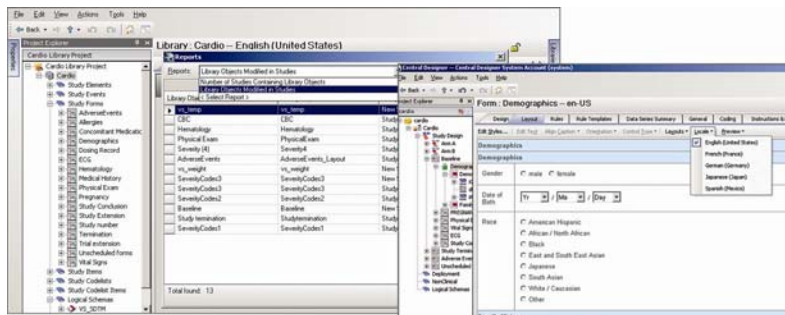


Figure 2. Internal standards teams can run reports on study objects to determine how often library objects are being used and modified once they are incorporated into a study.

**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. In most electronic data capture (EDC) environments, rules are developed in a language that requires the skill sets of a programmer, and the rule development process is performed after the designer has finished the layouts and defined the data items. With Oracle Health Sciences Central Designer, the need to create and test rules over and over is dramatically reduced 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.

Of course, new rules may need to be created. Oracle Health Sciences Central Designer has significantly simplified rule development by providing a “rules wizard” interface that walks the user step-by-step through the process of successfully creating a rule. The rules wizard is designed to enable 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, which can help reduce the amount of programming code by up to 75 percent when compared to a program using a Visual Basic development system.

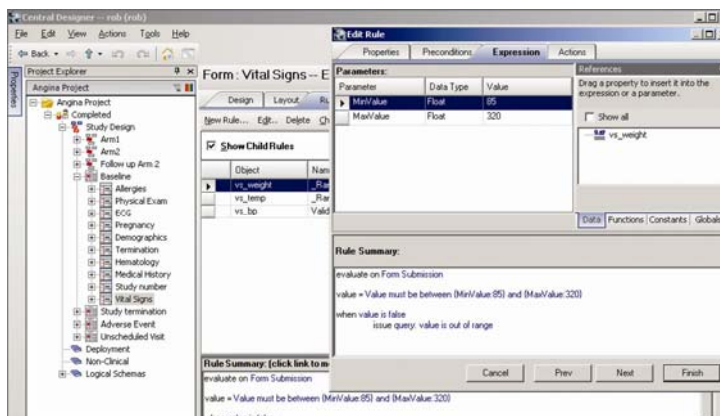


Figure 3. The Oracle Health Sciences Central Designer rules wizard interface walks users step-by-step through the process of successfully creating a rule.

## 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 can help 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 (logical schemas) can be retrieved from a library and applied to items within a study to define Study Data Tabulation Model (SDTM) industry-compliant data extracts from captured clinical data.

## Improve Workflow and Simultaneous Global Collaboration

In many organizations, the tasks associated with building a study are performed in a linear fashion due to limitations of most study design tools, which cannot effectively manage multiuser, multilanguage access. As a result, companies are forced to develop processes where one group must complete their task before the next group can start. 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 and streamlining the workflow processes. This unique and collaborative work style provides earlier access and visibility to designs and provides teams the flexibility to work together in parallel.

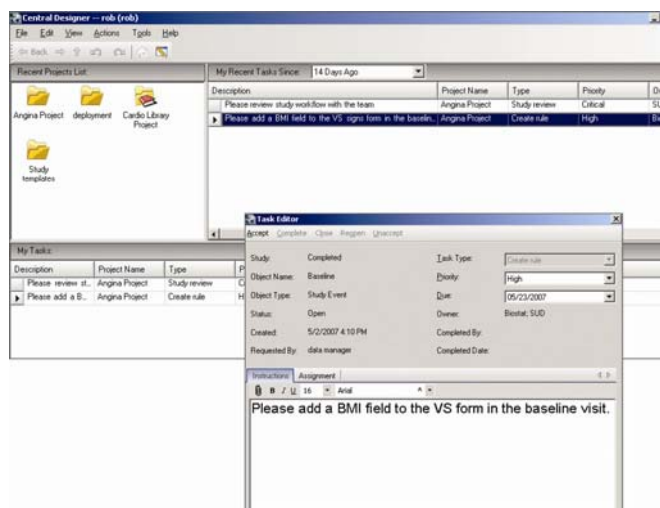


Figure 4. By selecting a task in Oracle Health Sciences Central Designer, users directly access the area to be worked on.

## 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 most complex studies. With Oracle Health Sciences, clients enjoy lifecycle project management, study design and implementation, site and user provisioning, out-of-the-box integrations, hosting and application management, user training, and 24x7 global support.

## RELATED PRODUCTS

- Oracle Health Sciences InForm GTM

## Manage a Single, Centralized Global Design Environment

With Oracle Health Sciences Central Designer, organizations can develop and manage all of their studies from one central environment and deploy their studies to the Oracle Health Sciences InForm EDC platform or to future potential deployment targets. Users can export or import study design components from any object data model-compliant source from within the Oracle Health Sciences Central Designer environment.

The Oracle Health Sciences Central Designer solution also allows users to harvest existing pieces of 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, programming, data management, and translation all work from within one centralized system.

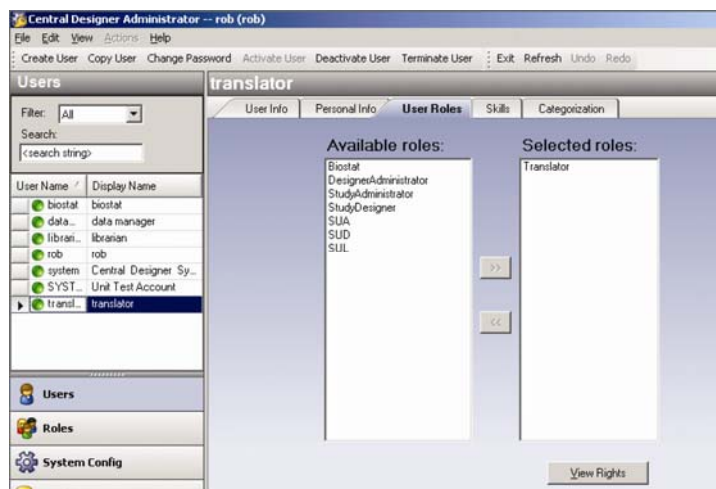


Figure 5. Oracle Health Sciences Central Designer is a multiuser, role-based environment.

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

## Contact Us

For more information about Oracle Health Sciences Central Designer, visit [oracle.com/healthsciences](http://oracle.com/healthsciences) or call +1.800.ORACLE1 to speak to an Oracle representative.



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