



Central Designer™

Central Designer lets you:

Enhance study design efficiencies

- Define study workflow and components quickly
- Easily reuse completed study components
- Simplify rules creation via new “Rules Wizard”

Increase reuse and the application of standards

- Use advanced search and retrieve capabilities to access approved library components including visits, form layouts, data items, codelists – and associated rules
- Improve library management
- Quickly define SDTM industry-compliant data extracts by using pre-defined data mappings/logical schemas

Improve communication and workflow

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

Reduce build time. Improve workflow. And increase efficiency on even the most complex study.

As the use of electronic data capture (EDC) for clinical studies becomes more prevalent, life sciences companies are re-examining how they implement this technology to maximize operational efficiencies. The process required to transform a protocol into a completely built EDC study is critical but also time-consuming.

For example, before a trial can go live, a trial sponsor must develop workflow, 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 the data managers, the biostatisticians and the sites that must ensure the design will satisfy their requirements.

Streamline and extend study design capabilities

Phase Forward has developed a next-generation study design environment called **Central Designer™** to help life sciences companies streamline their study development process. The new environment surpasses the capabilities of typical design tools by taking advantage of the latest technology and Phase Forward’s years of experience to enhance design efficiency and study component reuse, improve workflow and simultaneous global collaboration, and effectively apply standards. These enhancements are designed to enable you to reduce build time, improve data quality and shorten trial delivery time to the InForm™ ITM EDC platform.

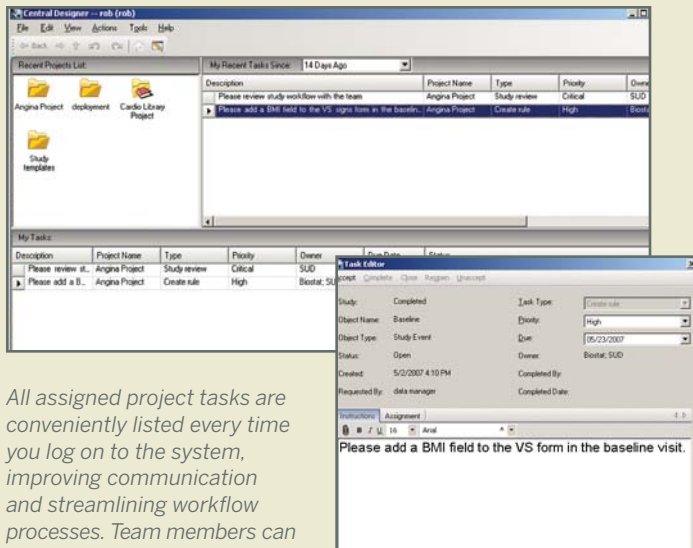
Enhance design efficiency and study component reuse

The Central Designer product simplifies the process of building studies through its flexible and intuitive interface and its ability to efficiently reuse study components. The product interface makes it easy to outline and define all the components of a study. Within the Central Designer environment, study designers can create and reuse study templates to populate common study components such as frequently used visits, forms and preferences, including team members, libraries and study deployment options.

Study templates can be accessed to quickly create the framework of even the most complex study. In addition to templates, the new object-based architecture within the Central Designer environment offers advanced search and retrieval capabilities to easily access existing study components from libraries.

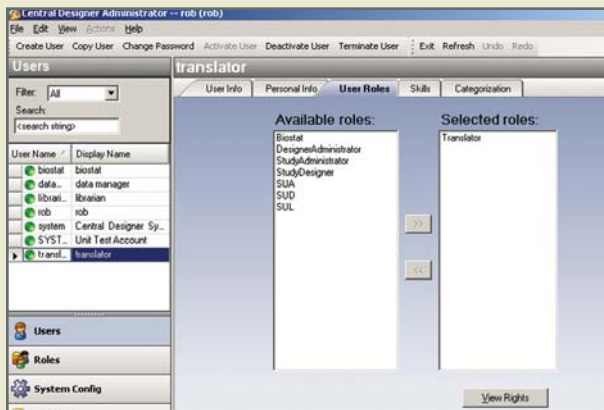
The Central Designer architecture enables designers to search for any study component by category or keyword such as a “form,” “therapeutic area” or “study phase” and further allows related study components such as form layouts, data items, codelists and rules to be grouped together. This advanced capability can save time by allowing designers to insert fully defined study components, such as a case report form containing rules and translations, from a library into a study. The retrieved library

Improve workflow



All assigned project tasks are conveniently listed every time you log on to the system, improving communication and streamlining workflow processes. Team members can collaborate simultaneously on project details or assign tasks to members on the team. By selecting a task in Central Designer, you directly access the area to be worked on.

Collaborate via centralized design environment



Central Designer is a multi-user, roles-based environment that allows companies to define and specify the roles and privileges for each user accessing the application while providing the functionality to safeguard against inadvertent or unauthorized changes.

component can then be changed as necessary within a study to meet the specific needs of the trial without affecting the library copy.

Simplify rule development

Using rules or edit checks within a design is vital to maintaining the overall data quality of your studies. Unfortunately, rule development can be a time-consuming exercise. In most EDC environments, rules are developed in a language that usually requires the skill sets of a programmer, and the rule development process is typically performed after the designer has finished the layouts and the data items have been defined. With Phase Forward's Central Designer product, the need to create rules over and over again is dramatically reduced because rules are included when study objects are retrieved from a library.

Of course, new rules may need to be created, and 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 non-programmers to develop range checks, constraints and calculations at any level of the study design including the item, form or visit level. Central Designer also makes it easier for programmers to develop more complex rules by providing built-in functions within a .NET language expression editor that can help reduce the amount of programming code by up to 75 percent when compared to Visual Basic Script.

Apply company and industry standards

Most life sciences companies today are rigorously driving towards incorporating industry standards recommended by CDISC and HL7 into their study designs to reduce submission time. In addition, the same companies are attempting to improve operational efficiencies by developing and implementing their own sets of internal standards. In order to meet these challenges, many design tools offer a basic level of library functionality to facilitate reuse. Not surprisingly, problems can soon arise as the quantity of unchecked and uncategorized components increases within these unsophisticated library structures.

To cope with these deficiencies, many individual designers rely on their own small set of trustworthy libraries to successfully build studies. Unfortunately, this individualized approach can reduce the overall efficiency of an enterprise and make it difficult to effectively implement standards across the organization.

The Central Designer product can help companies implement standards more efficiently and consistently through its new roles-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.

Also, 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 company-wide adoption. In addition to standardizing study objects, Central Designer also provides a way to create and apply various data views to your existing data items. These reusable data mappings (logical schemas) can be retrieved from a library and applied to items within a study to define SDTM industry-compliant data extracts from your captured clinical data.

Improve workflow and simultaneous global collaboration

In many organizations, the tasks associated with building a trial are performed in a linear fashion due to the inherent limitations of most study design tools that can't effectively manage multi-user access. As a result, companies are forced to develop processes where one group must complete their task before the next group can start. Central Designer is a multi-user, roles-based environment that provides easy and secure real-time access to study designs under development from anywhere in the world. This new environment allows companies to define and specify the roles and privileges for each user accessing the application while providing the functionality to safeguard against inadvertent or unauthorized changes. Study designers, database managers, programmers, study librarians, translators, IT professionals and biostatisticians can all collaborate simultaneously on project details or assign tasks to members on the team. A programmer or translator can be actively working in one area of a study while a designer is simultaneously working on another area of the same study. All assigned project tasks are conveniently listed every time you log 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 allows teams the flexibility to work together in parallel.

One centralized global design environment

With the Central Designer product, organizations can develop and manage all of their trials from one central environment and deploy their trials to Phase Forward's InForm™ EDC platform and future potential deployment targets. This new environment gives users the capability of exporting or importing study design components from any Object Data Model (ODM)-compliant source from within the Central Designer environment.

The Central Designer product also allows users to harvest existing pieces of study components developed for Phase Forward's InForm or Clintrial™ products. 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.

Central Designer™

Physical architecture

The physical configuration of the Central Designer software includes:

- A database server
- An application server
- One or more client computers

Each Central Designer application server runs on a Microsoft® Windows 2003 server.

The database server requires an Oracle 10g database.

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