

NetRegulus® NetRM™ Study Administrator Module

Web-based, comprehensive solutions for global Study and Quality management

NetRegulus NetRM Product Architecture

NetRegulus NetRM Software Solutions represent a revolutionary approach to regulatory data management. A series of Study and Quality modules sit atop a powerful relational database that leverages a single data model across all applications, for comprehensive data management, visibility and reporting. If desired, the Study and Quality modules can be used together, allowing organizations to continuously monitor and advance product quality and innovation in a single, integrated solution that spans the total product lifecycle.

NetRegulus NetRM Key Benefits

Global

Full language localization allows for complete presentation of the software interface in the user's preferred language, including double-byte characters for languages such as Japanese, Korean and Chinese.

Accessible

Authorized users can access and manage real-time Study and Quality data from any location in the world with a Web browser.

Powerful

NetRegulus NetRM Software is built on one of the most sophisticated architectures available today, allowing you to query and trend data across multiple data sets in ways not available in document-centric systems.

Intuitive

User interfaces and workflows are designed by life science professionals, enabling you to manage the most complicated tasks with a simple-to-use navigation scheme.

Configurable

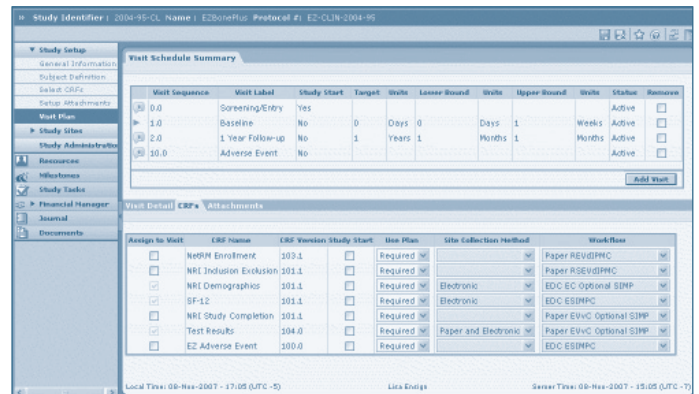
Modular architecture, configurable workflows, control of security zones, formatting to the field level, and user-controllable query tools let you design and adapt the system to your environment.

Cost-Effective

The use of standard software components lowers the initial cost of implementation and reduces training time. Plus, a centralized database allows master data, reports and other information to be reused without the need to reconfigure or revalidate the system each time a new study or module is added, lowering the total cost of ownership.

Trusted

NetRegulus solutions are used by some of the largest life sciences companies in the world. See why they trust PTC to help manage their mission-critical Study and Quality data.



The NetRegulus NetRM Study Administrator module allows you to rapidly create and configure studies and effectively oversee the study's conduct.

The Study Administrator Module

The Study Administrator module is one of four interrelated NetRegulus NetRM Study applications designed to facilitate the creation, data collection and reporting of electronic or paper clinical, postmarket surveillance, registry and other studies. The system is licensed per user rather than per study, which not only minimizes your software investment, but encourages trending across studies. The NetRegulus NetRM Study applications may be used alone or as part of the full NetRegulus NetRM suite of Study and Quality management solutions to provide a single view into the safety, manufacturing and performance trends covering the life of your products.

The Study Administrator module lets you rapidly create and configure studies, and then oversee the study's conduct. The configuration you perform in this module, including setting up the study visit plan and assigning workflows to CRFs and Attachments collected during the study, is used to create the rules and processes for enrolling subjects and entering and managing subject data. This module is also used to perform study and site trial management activities, such as setting up and monitoring milestones and financial information, and managing study security and workflows.

Study Administrator Module Features

- Set up new studies and sites quickly and easily using a guided menu
- Create study visit plans with treatment-specific visits, unscheduled visits, and visit-specific timing parameters
- Associate workflows with visit plan CRFs and Attachments, allowing the use of paper-based, EDC or a combination of processes within a study
- Track and monitor study and site tasks, milestones, resources and documents
- Create study and site budget “templates” and generate payment reports for subject CRFs and Attachments
- Record study, site and resource notes in an electronic journal
- Lock and unlock studies
- Administer study security access by study, site or user
- Utilize the powerful Work List to alert users when and where their involvement is needed
- Provide notifications and alerts of pending or overdue items
- Configure all field labels, tab labels, pull-down lists, menu items, and form text (warnings, errors, etc.) to match your own terminology
- Create data sets and graphs with an easy “point-and-click” interface that also allows users to save and reuse their report templates
- Set up “Watchdog” reports that are sent automatically by the system when an event or user-specified threshold is triggered
- Schedule and distribute reports via email – no need for recipients to log into the system
- Export report data to other commonly used tools for further analysis and/or processing

Other NetRegulus NetRM Modules

Study Data Manager

Conduct all aspects of data collection and management. Enroll study subjects, and manage and track subjects’ CRFs and attachments using dynamic workflow tasks configured to your business processes. Also, run reports of CRF data, within or across studies.

CRF Builder

Use a “drag-and-drop” interface to design forms used for paper or electronic studies. Create libraries of fields and field groups to rapidly create new CRFs. Embed intelligence for CRFs used in EDC studies. Use “wizards” to publish the forms and to create ad hoc pages for reporting of CRF data within or across studies.

CRF Administrator

Manage the company’s library of case report forms, and create and schedule automatic processes that validate data entered into one or more CRF fields against quality criteria you define.

Corrective and Preventive Actions (CAPA)

Initiate, evaluate, assign, monitor, review and approve corrective/preventive actions. Link multiple issues from various data sources to each action. Utilize sophisticated “Watchdog” technology to aid in effectiveness monitoring.

Complaints

Manage all activities related to customer complaints. Link complaints to existing actions, or create new corrective actions. Conduct regulatory reporting and other key activities related to risk management.

Nonconformance

Record, process, manage and track nonconformance reports, variances, deviations, exceptions and other quality events related to product manufacturing and processing.

Learn More

For more information on PTC’s NetRegulus NetRM Study and Quality modules, please visit www.ptc.com/go/netregulus.