

# NetRegulus® NetRM™ CRF 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

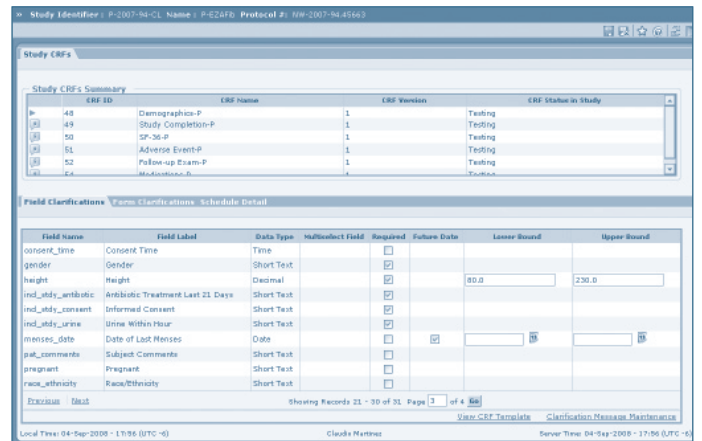
Modular architecture, configurable workflows, control of security zones, formatting to the field level, and user-controllable query tools let you design and adapt the system to your environment.

### 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 CRF Administrator module lets you manage the company's library of CRFs, and create and schedule data integrity checks.

## The CRF Administrator Module

The CRF 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 CRF Administrator module lets authorized users administer the library of case report forms (CRFs) built using the NetRegulus NetRM CRF Builder. Users can manage the form status, field label and verification information for the form, and create and schedule study-specific, automatic data integrity checks. This automatic data clarification process provides an essential time-savings measure that directly benefits paper-based studies and offers an important supplement to the "intelligent" forms that prevent many data inconsistencies that may occur in EDC studies. These automatic clarifications can check not only individual field entries – for example, missing values or entries above or below an expected range – but also entries across fields or forms, for example, the case of the 'pregnant male'.

## CRF Administrator Module Features

- Update field labels used for reporting
- Determine inclusion of fields used in paper-based, dual-data entry verification processes, allowing the system to skip the comparison of long text fields, if appropriate
- Tailor specific rules used to automatically sweep the study data to detect integrity issues, either for individual fields or for multiple fields within or across forms
- Schedule your data integrity checks to match the criticality and frequency of the data submitted on the CRF
- Specify whether the CRF will be deployed for data entry as a PDF or HTML file
- Record CRF notes in an electronic journal
- Configure all field labels, tab labels, pull-down lists, menu items, and form text (warnings, errors, etc.) to match your own terminology

## Other NetRegulus NetRM Modules

### Study Administrator

Rapidly create and configure electronic or paper clinical, postmarket surveillance, condition of approval, registry, and other types of studies. Oversee the study's progress, including tracking resources, study and site milestones, and financial payment information.

### 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](http://www.ptc.com/go/netregulus).