



Velos eIRB

Appropriate conduct and monitoring of a clinical study ensures early detection of complications, minimizes the chances of their occurrence or recurrence, and has a major impact on the credibility of the results.

Velos eResearch Product Line

Velos eResearch

- Account Management
- Study Setup
- Data Management
- Patient Management
- Reports & Ad-Hoc Queries

Velos eClinical

Velos eFinancials

Velos ePortal

Velos eIRB

Velos eSample

Velos eCardio

Velos eOncology

Velos eTools

Technology-based Services

Velos Grid Services

Velos Interface Engine

Contact Information

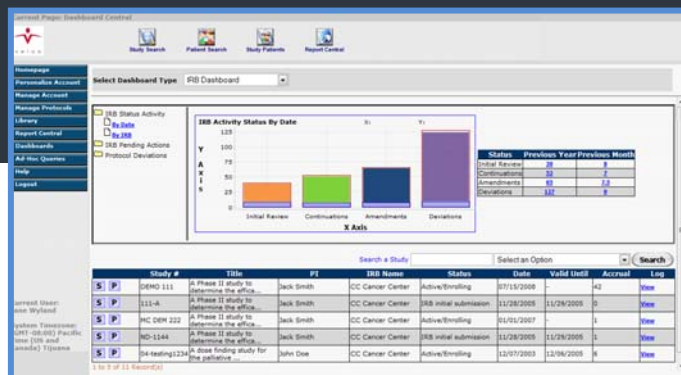
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Clinical research usually involves a variety of committee review processes such as those performed by Institutional Review Boards (IRBs), Protocol Review Committees, and General Clinical Research Centers (GCRCs). These committees are entrusted with the important job of reviewing, approving/declining and monitoring clinical trials at various stages in the clinical research process. Although such reviews have a common objective, the review process and workflow varies with the type and category of research, institution, and regulatory considerations. Like other areas of clinical research, the review process is one that can benefit from the use of information systems that are flexible enough to accommodate a variety of specialized needs, and have strong underlying technology for security, messaging and communications, form creation, and reporting.

Velos eIRB supports all aspects of clinical research administration including protocol design, version management, administrative schedules, and workflow and study status management. The capabilities are significantly augmented by the powerful built-in application management and form generator. This easy-to-use subsystem enables Velos system administrators to add administrative capabilities directly into Velos without having to rely on Velos or in-house programmers.

Velos eIRB strives to address the all-important balance between supporting institutional versus individual department and study needs. While extensive standard administrative capabilities are in place, customers also have virtually unlimited flexibility in what and how much information they choose to administer, where, and by whom. This combination of standard and customized administration capabilities enables some information to be maintained globally while other information can be controlled at individual department and study levels.



Centralization and Collaboration

Velos eIRB supports structured protocol management and enables users to maintain standard and study-specific protocol information. Velos users can build online protocols, track amendments and approvals, and share information with other select users. Customizable templates help create standardized protocols and informed consents, and enables rapid setup of new protocols. The system allows uploading and versioning of documents in a variety of file formats including Word, Excel, PDF, jpeg, etc. A powerful security infrastructure enables access control to select users and team members and specification of edit versus view rights. This security model, together with Velos' pure internet system platform, enable geographically dispersed reviewers to convene committee meetings far more efficiently than most current means of communication and review.

Administrative Workflows and Notifications

Individuals or groups monitoring trials perform numerous activities including careful reviews of the research protocol and plans for data and safety monitoring, evaluation of the progress of the study, assessment of data quality and participant risk versus benefit, performance of trial sites, and other factors that can affect study outcome; as well as making recommendations to the review boards and investigators concerning continuation or conclusion of the trial. Velos eIRB provides study administrators with an easy-to-use, flexible approach to configuring administrative schedules, site-specific workflows and notifications for their end-users, to aid them in achieving the above mentioned objectives. Alerts, notifications, and reminders can be configured throughout the schedule and set to trigger other events or to notify other team members of study activities or needs.

The advantage of research review automation is greatly increased when the system being used for the review process is closely integrated with the system being used for day-to-day study management activities.

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Configurable Forms and Reports

In addition to supporting site-specific workflows, the system also provides users with the tools and features to design and incorporate their own online forms. Forms such as Reviewer Comments forms, SAE reporting forms, Continuing Review Report forms, and others are easily designed to meet the site's specific needs. Incorporating both study administration (e.g. protocol documentation, the initial review process, study status tracking) and study execution (e.g. patient accrual, adverse event tracking, visit scheduling) in the same system creates a powerful platform that facilitates centralized up-to-the-minute reporting across studies and departments, and ensures timely access to critical information required for optimal monitoring of the entire research process.