

Velos eResearch FAQ's

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If you need assistance the following Contact Information is provided:

More info:
<http://med.miami.edu/orim>

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Office Hours:
Monday through Friday
8 am until 5 pm

Velos Basics

What is Velos eResearch? Velos eResearch is a web-based clinical research study management application. eResearch Supports Study Management. Velos helps with the following: Protocol Management, Patient Scheduling, Regulatory Reporting, Adverse Event Management and Reporting, Data Safety Monitoring, Budgets, Milestones, Invoices, Invoice Payment Receipts and Processing

Who can use Velos eResearch? UM Faculty and Staff involved with clinical research studies.

How do I get access? Contact us at Phone: (305) 243-2314/Fax: (305) 243-2053/E-mail: resinfo@med.miami.edu, for more instructions, or you can go to <http://www.med.miami.edu/orim/> and complete the Velos Access form under the Velos section.

Where do I get training? Velos team has weekly scheduled trainings sessions for Patient Management. Sign up using Ulearn (<http://ulearn.miami.edu>), class name is Velos Patient Management.

How do I start using Velos eResearch? Velos is being deployed by department/division for new and selected existing studies. For new studies PIs using the CRIS office will have easy access to use Velos as their study tracking tool.

Who can I call for support during week & work hours? Contact us at Phone: (305) 243-2314/Fax: (305) 243-2053/E-mail: resinfo@med.miami.edu

Who can I call for support on off hours and weekends? Contact us at Phone: (305) 243-2314/Fax: (305) 243-2053/E-mail: resinfo@med.miami.edu and we will contact you on the next business day.

Is eResearch intended to replace eProst? No, eProst is still the protocol authority. Velos is strictly used for Clinical Trials Management, not protocol management.

What is an Environment (i.e. training, production)? Velos has different environments to utilize during development. The Production environment is intended to be used with live studies, while the training environment is for testing out new studies as well as functionality.

Can I access Velos eResearch from home? Velos eResearch is a web-based clinical research study management application. Therefore, you only need internet access in order to use Velos eResearch.

My username and password are not working? What should I do? Try again. The log in credentials are case sensitive, but be sure to enter carefully in case of error. If issue persists you will need to use the Manage ID link under our login screen at <http://velos.miami.edu> or Contact resinfo@med.miami.edu for more help.

I forgot my username and password? you will need to use the Manage ID link under our login screen at <http://velos.miami.edu> or Contact resinfo@med.miami.edu for more help.

I forgot my e signature ? Contact us at Phone: (305) 243-2314/Fax: (305) 243-2053/E-mail: resinfo@med.miami.edu. We can reset your e-signature

Hardware and Software FAQ

Can I use a Mac? Yes, the Velos eResearch is compatible with both Macs and PCs.

What software do I need? Velos eResearch is a web-based system. An internet browser is the only software required (such as Internet Explorer, Safari, Firefox, etc).

Can I use Office 2007? Yes, especially if running reports and exporting data to excel or word.

Can I use VISTA? Yes, Velos eResearch may be used with Vista.



Our Objective:

To provide clinical researchers & study staff with user-friendly technology infrastructure for managing studies, tracking subjects, and facilitating analysis, while maintaining the privacy and safety of participants.

Study Management FAQ

Can I create and store my studies into eResearch? Yes, Velos eResearch is intended to store study information based from the eProst and Infoed study information. *Note: Infoed and eProst are data authorities, Velos has protocol information duplicated from Infoed and eProst.*

Can I create & customize my study calendar in eResearch? Yes, Velos eResearch is extremely customizable for each study calendar.

Can I create a budget in eResearch? Yes, Velos eResearch has the functionality of creating budgets customized for each study. Budgets can be created to document a general plan for Protocols dollar distribution, or be very specific to each Calendar used within a Protocol.

Can I run reports on the budget of each study for my department? Yes, Velos eResearch allows administration and staff that have access to the departments studies to create reports for the studies without viewing any patient information.

Can I use eResearch to track different amendments on my protocol? No, Velos eResearch is not a protocol tracking system. eProst is the appropriate system to track protocol changes.

What's a milestone? The Protocol Calendar is the framework on which the generation of patient schedules and subsequent workflow management is based. These functionalities can be executed only when a Protocol Calendar is associated to a study. This framework also ties into other features of the eResearch application, such as the Budget and Milestones.

What's an event? Events build the Calendar and each Event represents an activity that needs to occur, whether it is procedure, evaluation, medication log, labs, questionnaires, etc. Events are created in the **Event Library** and used to build future Calendars. Common attributes defined in the **Event Library** include the CPT Code, Research Cost and Standard of Care Costs.

Patient Management FAQ

Can I enroll a patient in eResearch? Yes, a patient can be enrolled into Velos eResearch. Although IDX system still needs to be utilized for scheduling patients. You may use the PLT (Patient Lookup Tool) to search for your patient in the clinical system and import the patient demographic information along with their associated medical record numbers.

Can I collect data for my patients on different data collection forms? Yes, case report forms can be inserted into each study and can be associated to either the patient or the study. The Form Designer allows users to design questionnaires, Case Report Forms (CRFs), regulatory forms and patient databases...basically anything that is needed to capture and compare data.

Can I track my consent in eResearch? The patients consent status can be tracked in Velos eResearch. Although the actual consent cannot be tracked in Velos eResearch.

Can I use eResearch for patient enrollment instead of IDX? No, IDX is handled separate from Velos eResearch, patients still need to be enrolled into IDX for their appointments.

Can I see if there's an adverse event for my study? Yes, Velos eResearch is intended to capture the adverse events and circulate emails to the PI's or designee for notification.

Can eResearch send me an email to remind me of incoming patients? Yes, notifications can be configured for many events that may be either related to study or patients management.

Administrative and Financial Management FAQ

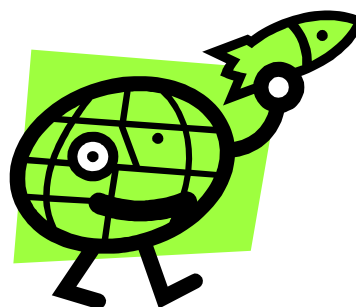
Can I see what studies are being conducted in my department? Yes, depending on the access rights and department access. The user will be able to see all of their studies.

Can I see what their status is with relation to budget and enrollment? Yes, depending on the access rights and department access. The user will be able to see study status, budget, and enrollment. The data will be in aggregate form for administrators and financial analysis.

Does eResearch generate an Invoice? Velos eResearch has the ability to generate an invoice.

Will eResearch be used for externally funded studies (i.e. Drug/Device companies or NIH)? Yes, depending on the study it can be customized. We can create calendars to track receivables' and payables.

Will eResearch be used for Department or Principle Investigator initiated studies? Yes, depending on the study it can be customized by creating case report forms as well as calendars.



Reports Management FAQ

Can I generate reports for my studies? It is a paradox in modern systems that users, who use the system to manage and operationalize complex information management and workflow tasks in their fields of expertise, are often unable to view the data in ways that are most immediately useful to them. The need for such views varies by user, by role, by institution, and by specialty in clinical research.

Can I export the data from the reports to excel or statistical software for analysis? Yes, the data can be exported into word or excel for any other type of analysis.

Can I create my own custom reports? Yes, they are called “ad-hoc reports” . An ad-hoc querying tool allows users to create reports based on any set of fields within any form that they design using the Form Designer in the Velos application. Areas where such reports occur are patient screening, eligibility management, and specific organizational workflows and forms. Once created, they are a part of each user’s report library.

Are there standard reports ? Velos eResearch has a rich library of reports that is “canned” and available to end-users. These are logically aligned along functional areas: Protocol, Patient, Budget, Adverse Event, and so on. Within these ‘built-in’ reports, each report allows users to: Extract using Parameters: such as protocol(s), dates, patients, sites etc.

Can I run reports on other departmental studies? No, reports can be run depending on the users rights. But typically the user can only run reports on the studies that they have access to.



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