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If you need assistance, the following Contact Information is provided:

Office of Research
1400 NW 10th Ave
Suite 1200
Miami, FL 33136

<http://www.med.miami.edu/orim/>

Office Hours:
Monday through Friday
8 am until 5 pm



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Velos Basics

What is Velos eResearch? Velos eResearch is a web-based clinical research study management application. Velos helps with the following: Protocol Management, Patient Scheduling, Regulatory Reporting, Adverse Event Management and Reporting, Data Safety Monitoring, Budgets, Milestones, Invoicing, 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 Request form.

Where do I get training? Velos team has bi-weekly scheduled trainings sessions for selected user roles, and can set up department- and/or study team—specific trainings upon request. Register for CBL and/or live classes in ULearn (<http://ulearn.miami.edu>—search for “Velos” to see all class listings).

How do I start using eResearch? Once a Velos Access Request form has been completed and submitted to the Office of Research Information Management team, and the user has been trained on the Velos eResearch system, an account will be set up granting the user access to the Velos eResearch system. If the user needs access to certain studies in the system, he/she should contact us at Phone: (305) 243-2314/Fax: (305) 243-2053/E-mail: resinfo@med.miami.edu, detailing the IRB number(s) to be added to the system.

How does a study get added to the Velos eResearch system? There are 3 ways the Office of Research gets notified to add a study to Velos eResearch: 1) IRB Protocol Application in eProst, section 1.17 (Will you use the University of Miami’s Velos eResearch system to track this study, its subjects, milestones, and/or related data collection?) is marked as YES; 2) CRIS negotiates a contract for the study; 3) Study team notifies a member of the Office of Research, requesting study setup in Velos eResearch.

Who can I call for support during business hours? Contact us at Phone: (305) 243-2314/Fax: (305) 243-2053/E-mail: resinfo@med.miami.edu, or on our website: <http://www.med.miami.edu/orim/>.

Who can I call for support during non-business hours, holidays and weekends? Contact us at <http://www.med.miami.edu/orim/> and we will contact you on the next business day.

Is Velos eResearch intended to replace eProst? No, eProst is still the protocol authority. Velos is strictly used as a tool 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. The training environment is also used to train our end-users and to familiarize them with navigating through the system.

Can I access Velos eResearch from home? Velos eResearch is a web-based clinical trial management system. Therefore, you only need internet access in order to use Velos eResearch. Velos eResearch can be accessed using the following browsers: Internet Explorer, Safari, and Firefox. However, be sure to disable all pop up blocking features prior to using it from any interface.

I had access to Velos but it doesn't let me login.

User accounts that have gone 90 days without being used will be deactivated. Users will be required to request reactivation via the Velos support team

My username and password are not working. What should I do? Since Velos eResearch uses the single sign-on feature that eProst, Infoed, Ulearn, MyUM, etc uses, you might need to try logging in again. Remember: log in credentials are case sensitive, so be sure to enter carefully in case of error. If the issue persists with other CAS applications, click on the links under "Your CaneID Account" or "Help Topics", and follow the instructions. If the issue only exists when accessing Velos eResearch, check your pop-up blocker features to make sure all are disabled. If issue persists, email resinfo@med.miami.edu or call 305-243-2314 for verification, as your account may have been deactivated.

I forgot my username and password. How do I reset it? In the Velos login screen, click on the "Forgot your CaneID or Password" link under "Help Topics", and follow the instructions.

Hardware and Software FAQ

Can I use a Mac (Apple PC)? 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 eReserach may be used with Vista.



Study Management FAQ

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

I cannot see my studies in Velos eResearch. How come? Only personnel on the approved eProst Protocol are supposed to be on the study team in Velos. If you do not see your study in Velos eResearch, contact resinfo@med.miami.edu for verification.

Velos eResearch does not show my current study status. Why not? Statures for some studies have been migrated into Velos eResearch from another system (eProst, PIPES), and may not be accurate to the current study status. If you notice a discrepancy, please contact resinfo@med.miami.edu, and we will be glad to assist you in updating your study's status in Velos eResearch.

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

Can I use Velos 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. Currently Velos tracks only those amendments that impact ICF or protocol so that users can take action if necessary for patient management purpose.

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



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What's an "event"? Events build the Calendar and each Event represents an activity that needs to occur within a study visit, 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.

I cannot view the documents when clicking on links within the details section (D button). Why does this happen? The issue is likely that you do not have access to that documentation within eProst. If issue persists, contact resinfo@med.miami.edu for verification and troubleshooting.

Patient Management FAQ

Can I enroll a patient in Velos eResearch? Yes, a patient can be enrolled into Velos eResearch. Nevertheless, the UChart system still needs to be utilized for scheduling patients for clinical visits.

If I use Velos eResearch, do I still have to submit a separate patient enrollment notification to the CRIS/CRRC office?

No. UM policy requires that you log your patient consents and any status change within 24 hours of occurrence. If you use Velos to comply with this, CRIS/CRRC is automatically notified.

If I use Velos eResearch, do I still have to submit a separate patient enrollment notification to the Jackson? Yes, you will still need to follow patient enrollment notification guidelines for Jackson studies, even if you are enrolling patients in Velos eResearch.

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. Please contact resinfo@med.miami.edu for assistance on creating CRFs for your Velos study, if you do not already have a data collection system in place.

Can I track my consent in Velos eResearch? The patients consent status can be tracked in Velos eResearch. However, the actual consent form (document) cannot be tracked in Velos eResearch.

Can I use Velos eResearch for patient enrollment instead of UChart and/or Cerner? No, UChart and/or Cerner is handled separately from Velos eResearch, and patients will still need to be enrolled into the UChart and/or Cerner systems..

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. You can enter adverse events for your patients in Velos eResearch. *NOTE: Adverse Events will still need to be reported to the IRB, in addition to documenting within the Velos eResearch system.*

Can Velos 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.

Can I enroll patients on different sites or facilities? Yes, Velos eResearch can enroll patients in multiple sites.

I cannot see some or all of my patients on my patient roster. How come? When users and/or studies are first set up in Velos, sometimes users do not have access to certain study sites for which their patients have been enrolled. This can be easily resolved. Please contact resinfo@med.miami.edu so that we may be able to resolve this issue for you.

Why is information missing or incorrect in Patient Demographics? UChart is the source data for most patients' demographic information in Velos eResearch. If you notice that some of your patients' demographic information is incomplete (gender, race, ethnicity, etc.), document the current patient information and contact patient registration for your facility and request an update. UChart will automatically update any inconsistencies occurring in Patient Demographics in Velos eResearch on a nightly basis.

Why do the patient study statuses in my Patient Roster show an incorrect current status? Unfortunately, the patient roster view presents "patient study status" as the status that was most recently entered for that patient, which may not necessarily be the "current" status. We have recently modified the Patient Status options to control which statuses are entered in which order. This will help eliminate any discrepancies that may occur regarding current status.



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Administrative & Financial Management FAQ

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

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.

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

Will Velos eResearch be used for externally funded studies (i.e. Drug/Device companies or NIH)? Yes, depending on the study it can be customized.

Will Velos eResearch be used for internally initiated studies? Yes, depending on the study it can be customized.

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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 organize 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. Velos eResearch has several report capabilities. Please contact res-info@med.miami.edu for assistance on generating reports for your studies.

Can I export the data from the reports to excel or statistical software for analysis? Yes, the data can be exported into word, excel, and any other format 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. The user can only run reports on the studies that they have access to.



UChart FAQ

What will happen to CaneCare? CaneCare is not going away. It will still be utilized and maintained as a supplemental application to support UChart.

Can you print from UChart and Velos? Yes you can print from both UChart and Velos.

How will the bill splitting process work and how is it different from today's process? The bill splitting process is going to be similar to the current process. With the exception that bills are linked to the patient encounter (appointment), so if the encounter is not associated with a study beforehand, then there will be the potential of incorrect billing. Hence the importance of linking the encounters appropriately ahead of time.

When would you use UChart before or after you consent a patient? You have to enroll the patient in the study through Velos, then you would use UChart to document the visit information. So you would use UChart after you ENROLL the patient via Velos.

Can you write research notes into the patients record and how can you retrieve them? Yes, you can create notes in the patient's record in UChart in the context of research. They can be retrieved by looking at the encounter where the note was entered, they can also be printed.

How is UChart going to help me be more compliant with my protocol? That is not the goal of UChart and UChart does not provide any type of scheduling tools yet. Therefore, this is not really applicable at this time. However, being able to see upcoming appointments for your patients and being responsible for scheduling their visits will improve processes in general.

How will the research monitor gain access to UChart, or how will we need to work with the Research Monitors so that they can confirm the data for the study? For now the research monitor will have to work with the research coordinator to review the patient charts in UChart.

How do we do audits on the patient records? It is to be assumed that UChart would run a list of patients that are associated to each specific study and then would have to look each patient up and review the charts using "ChartReview".

How do we link a patient to an encounter, and what happens if we don't link the patient to the encounter? As the appointment is being created, the research coordinator will see an area where all of the studies the patient is associated with are listed. At this point, the person doing the scheduling will associate the specific appointment with the study. If the appointment is not associated with a study, a warning message will display reminding the user that the patient is a research patient. It will in turn ask if the appointment should be associated to a study or not.

Is there a direct connection between UChart and Velos? Yes, there is a connection, but its partly automated. The goal is to be fully automated by the optimization phase (2011). Currently Velos receives the patient demographics realtime from UChart. However the association of the patient to the study in UChart from Velos is done in batch at a certain frequency and interval.



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