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# Velos eResearch (FAQ and Known Issues)

Statement

**Effective Date:** June 9, 2009

Known Issues

**Revision History**

Glossary

**Responsible Office:** Office of Research Information Management

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## Statement

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**Velos eResearch** the following section consists of a list of frequently asked questions and known issues. This document will be updated on a regular basis to keep our users fully updated on the status of the Velos eResearch system.

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## FAQ & Known Issues

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1. Can't see some or all of my patients on my study roster **P**
  - **Example:** I can see some of my patients on the patient roster for my study or studies but not all of them. In particular I can't see the ones in a certain enrolling site.
  - **Action:** This is not uncommon after we have migrated so many studies and teams begin using the system for the first time. Please contact support so we can fix the issue. It is a relatively simple correction, taking only a few minutes to resolve.
  
2. Can't view documents when clicking on links in **D**
  - **Example:** When I select the documents link on my study it takes me to eProst Login screen. After entering my eProst Login credentials the document doesn't appear.
  - **Action:** The issue is likely that you are not on the study team in eProst. The SCCC CRS team is actively working on amending the protocols in eProst to include the functional study team in Velos. If you experience this issue contact CRS support with the study's eProst number so that that they can resolve this.
  - **Action:** If your protocol was at WIRB or is currently handled at WIRB the eProst system may not have the documents so you will see these links as incomplete or missing. The SCCC CRS team is actively working on bringing your protocols back to the eProst system to correct

this situation. If you experience this issue contact CRS support so that that they can resolve this.

### 3. Report Central Canned Reports

- **Example:** When I run the Patient Dump report for a specific study in Velos, the Patient's Enrolling site is not coming out, but rather the patient's primary site. Also, I don't see the patient's date of birth on the report.
- **Action:** We are looking into all the canned reports and evaluating their content, in the following weeks we will be modifying some key canned reports to help in reporting.
- **Example:** When I run the Study Dump report I am only getting aggregate enrollment data but not any additional patient status numbers.
- **Action:** We are looking into all the canned reports and evaluating their content, in the following weeks we will be modifying some key canned reports to help in reporting

### 4. Race, Gender, and Ethnicity Accuracy

- **Example:** When I look at my patient's race, ethnicity or gender, it is either missing or incorrect.
- **Action:** We have been looking into this situation for a few months. IDX is the source data, as it is the central authority on the patient's demographic information. If you find that the information is not correct, document the correct patient information and contact patient registration for your facility and request an update.

### 5. Study Status Accuracy

- **Example:** The study status for my study is not correct, my study is currently active/enrolling and it says it is not active.
- **Action:** This is a simple correction that your CRS support team can update for you. Statuses were migrated from PIPES, but the Velos system default status may not have been assigned in some cases to correspond with the most correct PIPES status or the actual study status may have changed. If you actually click on the study status and go deeper into the status screen you will see that there are more statuses related to your study. CRS can set the correct default status as needed.
- **Example:** I don't see Study Completed Status.
- **Action:** Currently this status is not available from eProst, our data authority on the protocol approval. Once we receive this date we will update all studies with the appropriate Study Completed or Administratively Closed status along with their corresponding dates. This should be in a few weeks with our next eProst Patch.

### 6. Patient Status Roster Accuracy

- **Example:** The patient status within my patient roster is not accurate for my study
  - **Action:** If you actually check your patients status' within the patient status screen you will see that all of your patients status' are indeed there. The issue we are encountering is that the status showing on the browser is not the latest status. Velos is currently working on a solution that will correct this issue. If you need to know the status dates we recommend that temporarily you go to Reports Central and under patients do a "Patient Dump " report, which will provide all the information necessary.
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8. **Backup Coordinator or Study Team Member Can't See Needed Information**
- **Example:** I am the study team backup person and I don't see the studies.
  - **Action:** The CRS support team is putting the backup personnel in place for each protocol, however this takes time as they have to cross check the team with the eProst protocol to make sure they are synchronized. Only personnel on the approved eProst protocol are supposed to be on the study team in Velos.
9. **Adverse Event reporting**
- **Example:** Am I supposed to enter adverse events in Velos for my study patients?
  - **Answer:** You can enter adverse events for your patients in Velos. We are working on the AE form to change the required fields so that you can easily generate an AE/SAE summary to use for regulatory reporting. We will announce when this is available.
10. **If I use Velos, do I have to submit a separate patient enrollment notification to the CRIS/CRRC office?**
- **Answer:** 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. They will create an IDX case for your patient. If the patient screen fails or goes off study, CRIS/CRRC will close the case as well. **NOTE: Always make sure to enter an Informed Consent Signed status for your patient. This is the start date for your patient's case.**
11. **Who do I call if I have questions or need assistance?**
- **Answer:** Contact CRS for support. CRS will escalate to ORIM as needed.

- **CRS** – Clinical Research Support team from SCCC
- **IDX** - Clinical registration and billing system for UMHC/SCCC, UMMG, & ABLEH.
- **eProst** – UM’s protocol human subjects protocol submission, review, & version tracking system.
- **ORIM** – Office of Research Information Management team, supports the enterprise Velos eResearch implementation
- **PHI** – Protected Health Information – Patient information that is designated as protected by the University’s implementation of the Health Information Portability & Accountability Act.
- **PLT** – Patient Lookup Tool
- **IRB** – Institutional Review Board – Administered by the Human Subjects Research Organization and responsible for reviewing protocols to optimize patient safety.
- **CRIS/CRRC** – Clinical Research Initiation Services / Clinical Research Revenue Cycle – These teams are responsible for enabling the set up and tracking of 3<sup>rd</sup> party billing related to research. Reporting research patient status with 24 hours to CRRC is required by UM Policy.
- **MRN** – Medical Record Number – which is the patient’s clinical file that contains all the clinical data related to that patient. Along with billing information.
- **UMHC** – University of Miami Hospital Clinics
- **UMMG** – University of Miami Medical Group
- **JMH** – Jackson Memorial Hospital
- **ICF** – Informed Consent – this is the form