

Velos is a study management tool used to help investigators manage the set up and day-to-day activities of human research studies. At UT Southwestern, all research studies conducted on human subjects must be registered in Velos. Additionally, patients involved in the studies can be registered in Velos and enrolled in their respective studies within the system.

Once a study is approved by the IRB (Institutional Review Board) AND you have received performance site approval, you will begin screening and enrolling patients to your study in Velos. You should not enroll a patient to a performance site until performance site approval has been received for that site.

Velos will also associate patients with studies in Epic, and disassociate patients from studies in Epic, once certain criteria are met in Velos.

This tip sheet will guide you through the process of registering and enrolling patients to your studies. Velos requirements for Epic interface are noted throughout this document and are summarized on the **Velos Epic Integration – Velos Requirements for Epic Study Interface** document.

Refer to the [Velos Epic Integration – Velos Requirements for Epic Patient Interface](#) document for more information.

Step I: Log into Velos

1. Type this link in your web browser: <https://velos.swmed.edu>

2. Type your login ID in the **Username** field and password in the **Password** field.
3. Click **Login**.
4. To logout, click the **Logout** button.

Important Info & Tips

- You must enter your Username in all lowercase letters, but your password as you would normally enter it.
- The Velos default e-Signature is **1234**.
- You should allow for pop-ups from the Velos system in your internet browser.
- Fields required by Velos are marked with a (*); however, you should complete every field that applies to your study, even if the field does not have a (*).

Step 2: Verify Study Status

1. From the Summary page, click the **Study Status** tab.
2. Verify “**IRB – Approved**” study status has been received. *(This is an Epic interface requirement.)*
3. Verify performance site approval has been received for the site to which you will be enrolling patients. *(This is an Epic interface requirement.)*
4. Verify study status “**Study – Active/Enrolling**” has been added for each performance site to which you will be enrolling patients. *(This is an Epic interface requirement.)*

You are working on study: 26068

Summary | Site/Team | Protocol | **Study Status** | Forms | Milestones | Admin Schedule | Documents | Reports | Notifications

Once the “**Study-Active/Enrolling**” status has been added, the Patient Management icon will be present.

Search by Organization: All [v] Search

Current Status	Study Start Date	Study End Date	
IRB - Approved	05/07/2019		Change Dates

Study Status History: [ADD NEW STATUS](#)

Organization	Study Status	Status Valid From	Status Valid Until	Meeting Date	Notes	Delete
UT Southwestern Medical Center and Affiliates	IRB - Approved	05/07/2019	-	-	-	[X]
	IRB - Draft Study Created	04/30/2019	-	-	New study created in eIRB	[X]
	IRB - Submission Initiated	04/30/2019	-	-	-	[X]
	Study - Not Active	04/28/2019	-	-	-	[X]
Parkland Health and Hospital System	Study - Active/Enrolling	05/07/2019	-	-	-	[X]

Step 3: Add Active/Enrolling Status (if missing)

The “**Study – Active/Enrolling**” status should only be added to the site to which you are enrolling patients if the “**IRB – Approved**” study status has been received, performance site approval has been received for the site, and all other administrative statuses required for enrollment have been received.

Below is the process for adding the “**Study – Active/Enrolling**” study status if these requirements have been met.

1. From study Summary page, click the **Study Status** tab.

Personalize | Manage | Libraries | Reporting

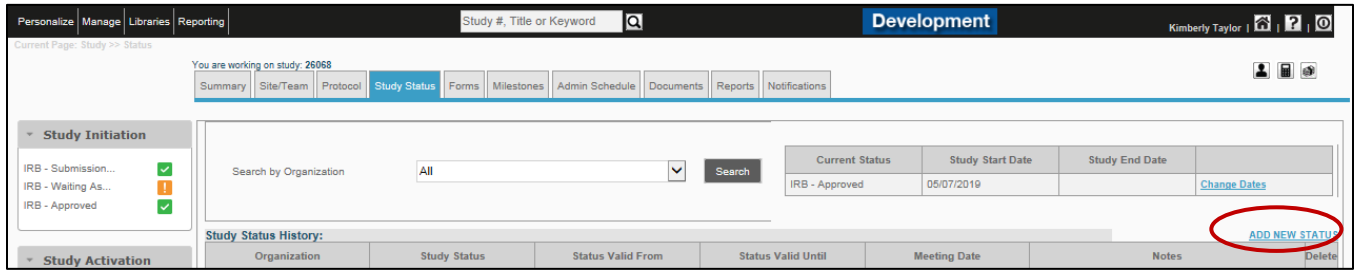
Study #, Title or Keyword [Q]

Current Page: Study >> Status

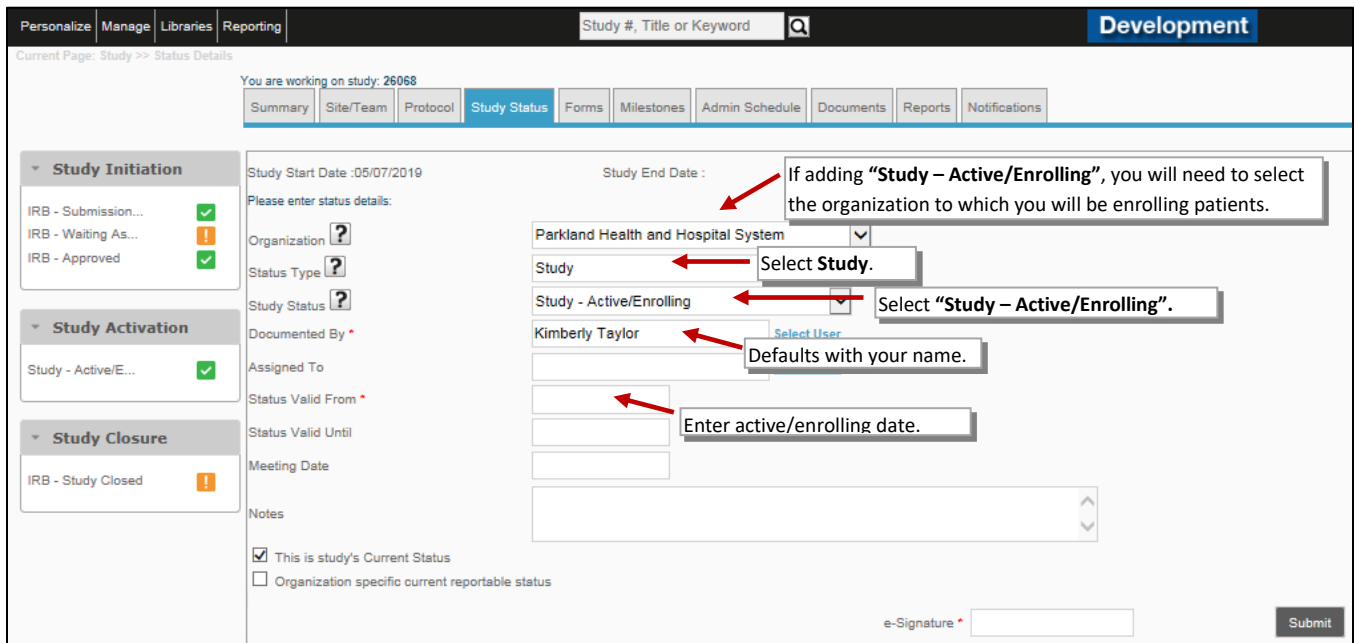
You are working on study: 26068

Summary | Site/Team | Protocol | **Study Status** | Forms | Milestones | Admin Schedule

2. Click the **Add New Status** link.



3. Verify or update required fields.



4. Enter your **e-Signature** and click **Submit**.

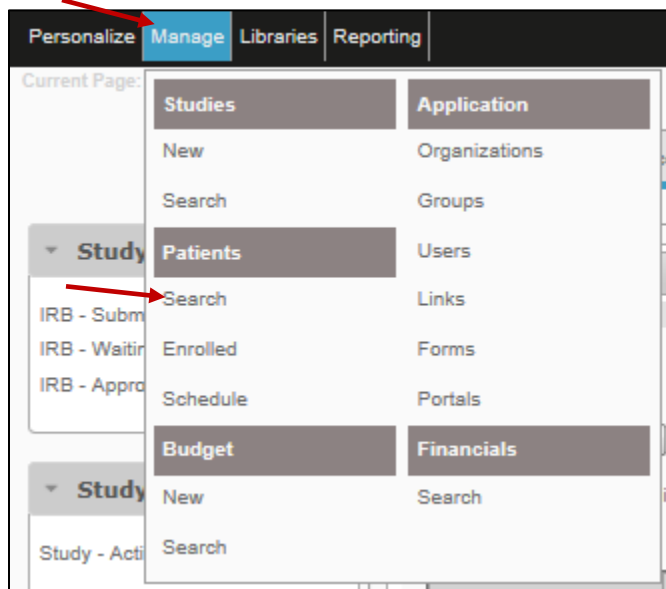
Important Info & Tips

- Before adding the "Study - Active/Enrolling" status for a site, verify that **ALL** administrative study approvals required for enrollment have been met and are shown on the Study Status tab (for example "IRB-Approved", "Performance Site Approved" for the site, "Coverage Analysis - PI Approved", etc. "IRB-Approved" and "Study - Active/Enrolling" are Epic interface requirements.)
- Parkland "Performance Site Approved" and Children's "Performance Site Approved" are required for interface with their respective Epic systems.

Step 4: Search for a Patient in Velos and Epic

(A) Search for Patient in Velos

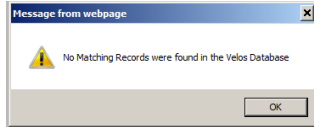
1. Point to the **Manage** link in the upper left portion of the screen, then click the **Search** link under **Patients**.



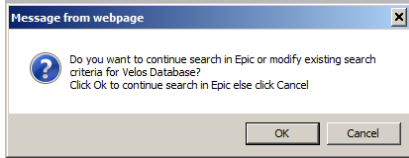
2. Enter the patient first name and last name in the corresponding Patient Name fields and click **Search**.

3. Review the results and verify data (such as MRN and Date of Birth). If the patient you were searching for is found, click on the Velos Patient ID link and proceed to **Step 6: Complete Demographics Tab**.

- If no patients matching the criteria are found in Velos, this message will appear. Click **OK**.



- The message below will appear. Click **OK** to search Epic and proceed to **(B)**.

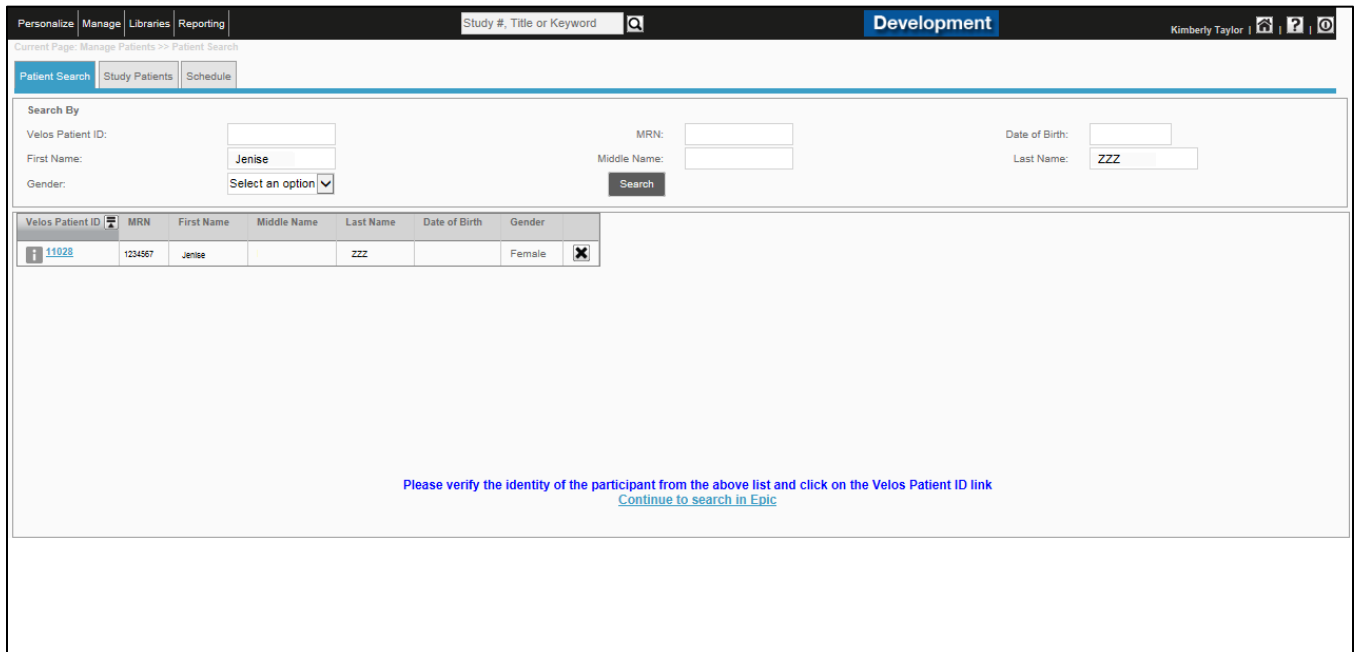


Important Info & Tips

- Search for patients by **First Name** and **Last Name**.
- Using other criteria may not locate the patient for which you are searching and **may result in a duplicate patient in Velos!**

(B) Search for Patient in Epic (if not found in Velos)

- Clicking **OK** under **Section (A), Number 5** will automatically search Epic using the criteria you entered. If sufficient information was not provided to search Epic, then you may need to re-enter the patient first name and last name again in the corresponding Patient Name fields and click **Search**.
- Review the results and verify data. If the patient you were searching for is found in Epic, click on the **Select** button and proceed to the **Patient Information Screen** section of this document.



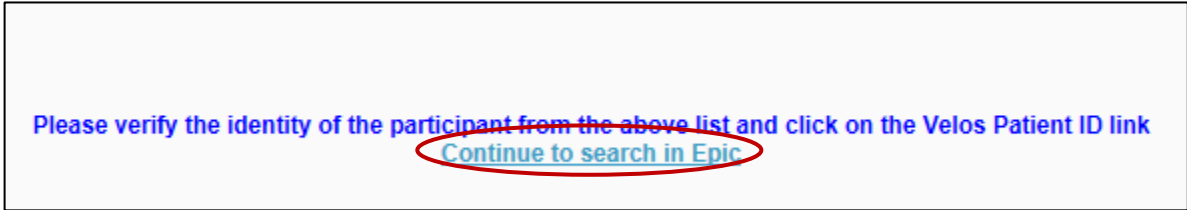
- If the search did not find the patient you were searching for, then proceed to **(C)** below.

(C) New Patient Process (Patient not found in Velos or Epic)

If the patient **WILL** be associated with a study record in Epic, **STOP HERE** and contact the Registration Clerk at the site the patient will be seen (UT Southwestern site, Parkland or Children’s) to have them added to Epic and generate an MRN. Once this step is complete, you will follow the process outlined above in (A) and (B) to search for the patient and you will locate them in the Epic search the same day.

- OR -

If the patient **WILL NOT** be associated with a study record in Epic, then click the **Click Here to Add New Patient** link at the bottom of the patient search screen and you will be directed to the Patient Information screen. (Proceed to **Section 5: Complete patient Information Screen** for the next steps.) **Use the Click Here to Add New Patient link with caution!**



Step 5: Complete Patient Information Screen

You will skip this step if the patient is found in the Velos search (Step 4 (A)) in the previous section.

1. Verify if information is correct on this screen, make changes if needed, complete required fields marked with a red asterisk as well as those required by your department.

2. Enter your **e-Signature** and click **Submit**.
3. You will be directed to the Demographics tab. Go to **Step 6: Complete Demographics Tab** below.

Step 6: Complete Demographics Tab

Personal Details Section

1. Verify if information is correct on this screen, make changes if needed, complete required fields marked with a red asterisk as well as those required by your department.
2. Enter your **e-Signature** and click **Submit**.

Patient Details

Patient ID: 78838
 Survival Status: Alive
 Death Date:

Personal Details

First Name: JENISE
 Middle Name:
 Last Name: ZZZ
 Date of Birth: 02/19/1970
 Gender: Female
 Marital Status: Select an option
 Country:
 Home Phone Number: 214-555-4446
 E-Mail:
 Ethnicity: Non-Hispanic/Latino
 Primary Race: White
 Additional Race: [Select Race](#)

Registration Details

Please save your changes before adding or modifying patient registration details.

The Patient is registered to the following Organization(s): [Register to a New Organization](#)

Organization	MRN	Registration Date	Provider	Group/Department	Access
UT Southwestern Medical Center and Affiliates	93502664	05/09/2019			Granted

Step 6: Complete Demographics Tab, *continued...*

Registration Details Section

In order for a patient to be associated with a study in the Epic system, the organization and Medical Record Number (MRN) must be listed here.

If the organizations and MRNs have not pulled in automatically, you can manually add them following the steps provided below. The steps provided in this section should be used to add SCCC if the study is cancer related.

(Note: Please enter MRNs accurately. If the MRNs in the Registration Details section do not match the MRNs in Epic, then the patients will not be flagged as research in Epic.)

1. Click the **Register to a New Organization** link.

Registration Details

Please save your changes before adding or modifying patient registration details

The Patient is registered to the following Organization(s):

Organization	MRN	Registration Date	Provider	Group/Department	Access
UT Southwestern Medical Center and Associates	93502664	05/09/2019			Granted
Other					

[Register to a New Organization](#)

2. Complete the required fields in the window.

Register Patient to an Organization

Organizations * Select the Organization.

MRN *

Specify groups/departments with access to edit this patient's groups will have this right Select

Registration Date

Provider Select User

If Other

Access to Patient Information for users of this organization Granted Revoked

Is the selected Organization patient's default Organization? Yes No

If changing patient's default facility Enter your e-Signature and click Submit. for the patient in any study will need to be updated manually (if required)

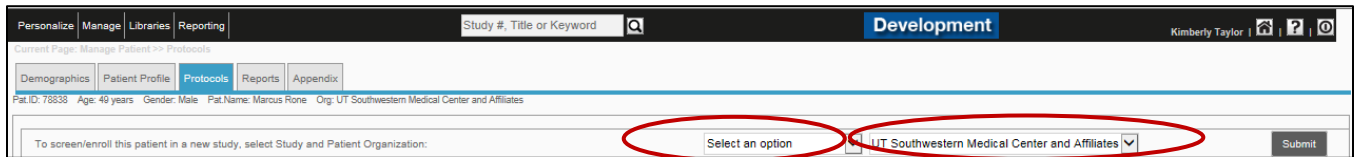
e-Signature * Submit

https://velosdev.swmed.edu/velos/jsp/updatePatientFacility.jsp

3. The window will close and you will proceed to the next section, **Protocols** tab.

Step 7 - Complete Protocols Tab

1. Click on the **Protocols** tab.
2. Select the Study Number from the first drop down.
(NOTE: The study must have the "Study - Active/Enrolling" status to be on the drop down list.)
3. Select **UT Southwestern Medical Center and Affiliates** from the second drop down list.
(NOTE: If the study is cancer related, then SCCC must be selected here, otherwise you will always select UT Southwestern.)



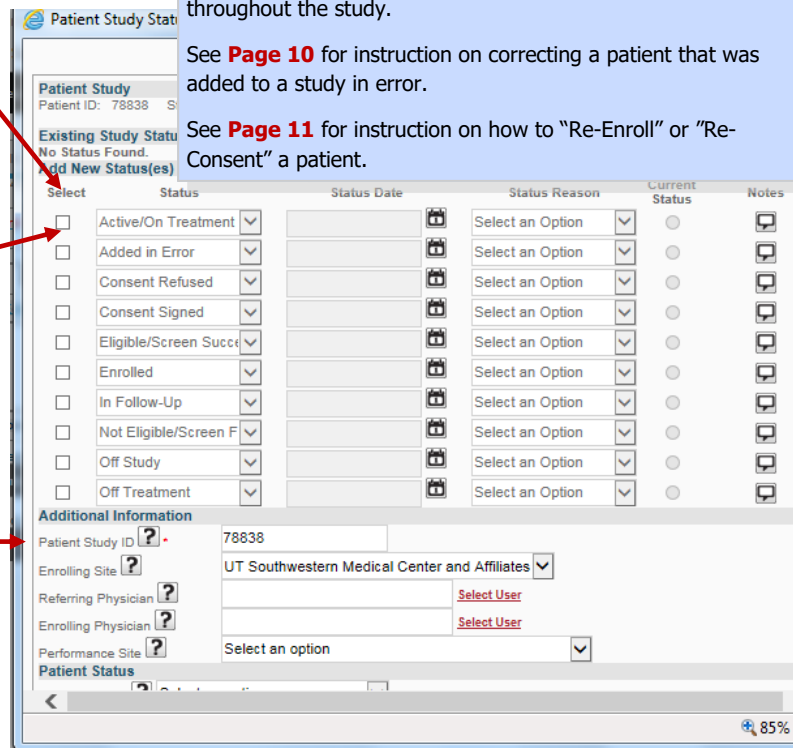
4. Click **Submit**. The Patient Status window will appear.

Step 8 - Add a Patient Status

1. Check the **Checkbox** beside the first status field to put a check in the box.
2. Click on the associated **Status** field and select the appropriate status.
3. Update the **Status Date** field if the appropriate date is not populated.
4. To add another status, check the checkbox under the next line and repeat the steps above.
5. Click the radio button beside the **Current Status**.
6. Update the additional information under the **Additional Information** and **Patient Status** sections, as appropriate, or required by your department.
7. Enter your **e-Signature** and click **Submit**.

Important Info & Tips


Be sure to update the statuses of your patient accordingly throughout the study.
See **Page 10** for instruction on correcting a patient that was added to a study in error.
See **Page 11** for instruction on how to "Re-Enroll" or "Re-Consent" a patient.

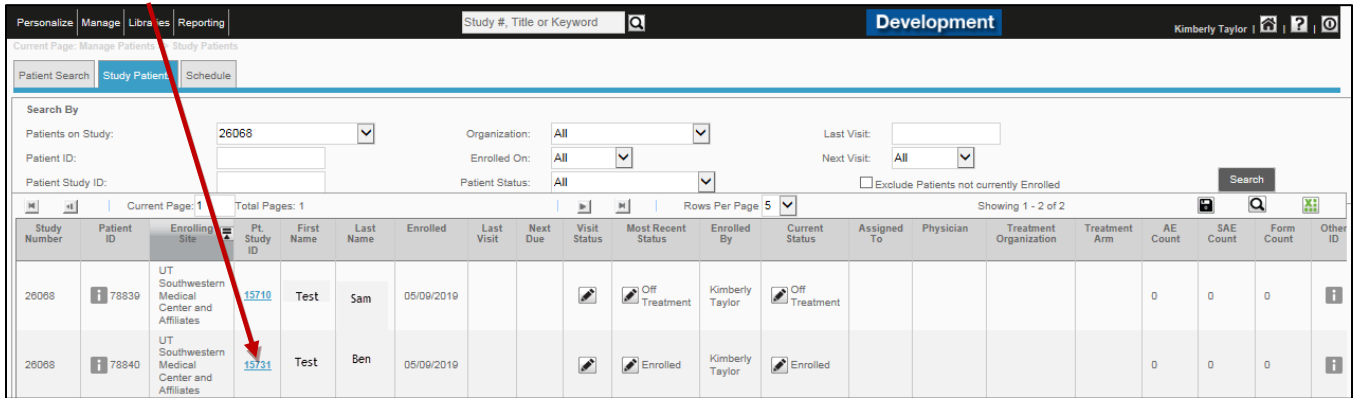


Important Info & Tips

- A patient is not considered to be "enrolled" in a study in Velos until the **Enrolled** status has been added to the patient. You will make sure all preliminary statuses have been met before adding the **Enrolled** status to the patient.
- The patient statuses of **Active/On Treatment**, **In Follow-Up**, **Lock Down**, **Off Study** and **Off Treatment** CANNOT be added until **Enrolled** has been added. (If adding these statuses at the same time as enrolled, be sure that **Enrolled** appears above them in the status window.)
- See the **Velos Epic Interface – Patient Statuses and Velos Requirements** document to see which patient status will trigger an interface with Epic.

How to Return to the Patient Status Window

1. Search for the study and click on  (Patient Management).
2. Click on the Pt Study ID link.



Personalize Manage Libraries Reporting Study #, Title or Keyword Search Development Kimberly Taylor

Current Page: Manage Patients >> Study Patients

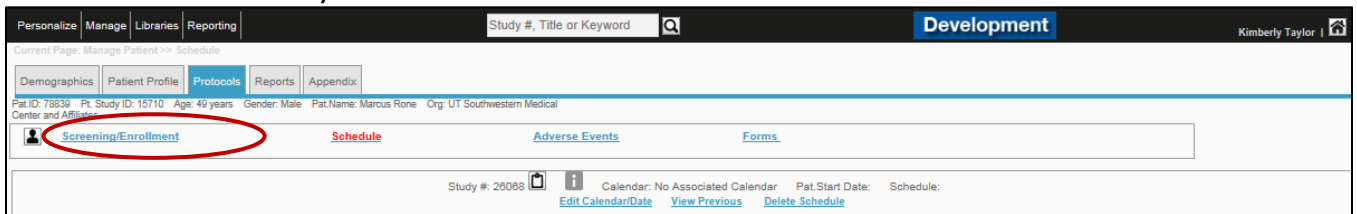
Patient Search Study Patient Schedule

Search By

Patients on Study: 26068 Organization: All Last Visit: Enrolled On: All Next Visit: All Patient Status: All Exclude Patients not currently Enrolled Search

Study Number	Patient ID	Enrolling Site	Pt Study ID	First Name	Last Name	Enrolled	Last Visit	Next Due	Visit Status	Most Recent Status	Enrolled By	Current Status	Assigned To	Physician	Treatment Organization	Treatment Arm	AE Count	SAE Count	Form Count	Other ID
26068	78839	UT Southwestern Medical Center and Affiliates	15710	Test	Sam	05/09/2019				Off Treatment	Kimberly Taylor	Off Treatment					0	0	0	
26068	78840	UT Southwestern Medical Center and Affiliates	15731	Test	Ben	05/09/2019				Enrolled	Kimberly Taylor	Enrolled					0	0	0	

3. Click on the SCREENING/ENROLLMENT link.



Personalize Manage Libraries Reporting Study #, Title or Keyword Search Development Kimberly Taylor

Current Page: Manage Patient >> Schedule

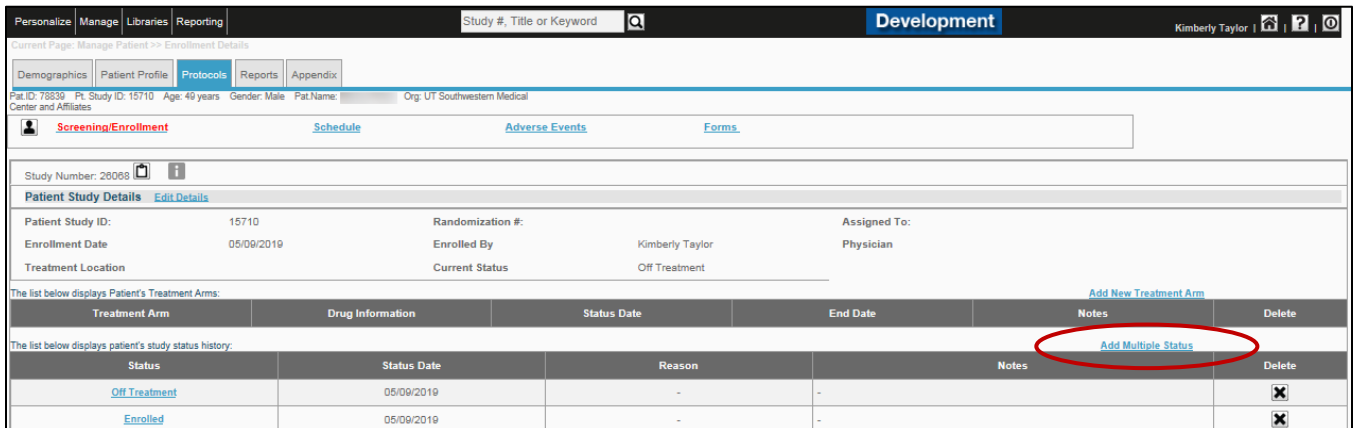
Demographics Patient Profile Protocols Reports Appendix

Pat ID: 78839 Pt Study ID: 15710 Age: 49 years Gender: Male Pat Name: Marcus Rone Org: UT Southwestern Medical Center and Affiliates

[Screening/Enrollment](#) Schedule Adverse Events Forms

Study #: 26068 Calendar: No Associated Calendar Pat Start Date: Schedule: Edit Calendar/Date View Previous Delete Schedule

4. The patient status screen below appears. To add additional statuses, you can click the **Add Multiple Status** link and follow the steps on the previous page under **Step 8: Adding a Patient Status**.



Personalize Manage Libraries Reporting Study #, Title or Keyword Search Development Kimberly Taylor

Current Page: Manage Patient >> Enrollment Details

Demographics Patient Profile Protocols Reports Appendix

Pat ID: 78839 Pt Study ID: 15710 Age: 49 years Gender: Male Pat Name: Marcus Rone Org: UT Southwestern Medical Center and Affiliates

[Screening/Enrollment](#) Schedule Adverse Events Forms

Study Number: 26068 Patient Study Details Edit Details

Patient Study ID: 15710 Randomization #: Assigned To: Enrollment Date: 05/09/2019 Enrolled By: Kimberly Taylor Physician: Treatment Location: Current Status: Off Treatment

The list below displays Patient's Treatment Arms:

Treatment Arm	Drug Information	Status Date	End Date	Notes	Delete

The list below displays patient's study status history:

Status	Status Date	Reason	Notes	Delete
Off Treatment	05/09/2019	-		
Enrolled	05/09/2019	-		

[Add Multiple Status](#)

Important Info & Tips

You can also access the patient status screen by searching for the patient following the steps below:

- Click on the **Patient Search** icon.
- Enter the first name, last name, or both, in the patient search fields.
- Click on the **Velos Patient ID** link.
- Click on the **Protocols** tab.
- Click on the **Study Number** link
- Click on the **SCREENING/ENROLLMENT** link.

Patient Added in Error

This section will guide you through the steps you should follow if a patient has been added to a study in error. **DO NOT DELETE the patient statuses already added to the patient.** If a study active flag was sent to Epic, removing these statuses will not correct the flag in Epic. Instead, add the “Added in Error” patient status as explained below.

1. Navigate to the Patient Status window (see previous section, if needed).
2. From the Patient Status window, click on the **Add Multiple Status** link.

Personalize Manage Libraries Reporting Study #, Title or Keyword Development Kimberly Taylor

Current Page: Manage Patient -> Enrollment Details

Demographics Patient Profile Protocols Reports Appendix

Pat ID: 75830 Pt. Study ID: 15710 Age: 49 years Gender: Male Pat Name: Org: UT Southwestern Medical Center and Affiliates

Screening/Enrollment Schedule Adverse Events Forms

Study Number: 26068

Patient Study Details Edit Details

Patient Study ID: 15710 Randomization #: Assigned To: Physician
 Enrollment Date: 05/09/2019 Enrolled By: Kimberly Taylor
 Treatment Location: Current Status: Off Treatment

The list below displays Patient's Treatment Arms:

Treatment Arm	Drug Information	Status Date	End Date	Notes	Delete

The list below displays patient's study status history:

Status	Status Date	Reason	Notes	Delete
Off Treatment	05/09/2019	-		✕
Enrolled	05/09/2019	-		✕

3. Click on the **Select** checkbox.
4. Click on the **Status** field and select “Added in Error” from the drop down list.
5. Click on the **Current Status** radio button.
6. Enter comments regarding the error in the **Notes** field.

Patient Study Status - Internet Explorer

Patient Study
 Patient ID: Study Number:

Existing Study Status(es) * Indicate Current Status

Status: Enrolled Status Date: 05/09/2019*

Add New Status(es)

Select	Status	Status Date	Status Reason	Current Status	Notes
<input checked="" type="checkbox"/>	Added in Error	05/09/2019	Select an Option	<input checked="" type="radio"/>	

7. Enter your **e-Signature** at the bottom of the window, then click **Submit**.
8. The status will push to Epic, and the “**Research: Inactive**” flag will be set in the respective Epic system(s).

Re-Enrolling a Patient to a Study

Sometimes a patient that is enrolled in a study will be taken off study for some reason, but then later will decide to participate on that study.

This section will guide you through the steps you should follow if you need to re-enroll a patient to a study. **DO NOT delete the patient statuses already added to the patient.**

1. From the Patient Status window, click on the **Add Multiple Status** link.

The screenshot shows the 'Patient Study Details' section of the Velos Patient Registration interface. The 'Add Multiple Status' link is circled in red. The interface includes a navigation bar with 'Personalize', 'Manage', 'Libraries', and 'Reporting'. The current page is 'Manage Patient >> Enrollment Details'. The patient profile shows 'Pt. Study ID: 15731', 'Age: 4 years', 'Gender: Female', and 'Pat. Name: Kimberly Taylor'. The 'Enrollment Date' is '05/09/2019'. The 'Current Status' is 'Enrolled'. The 'Add Multiple Status' link is located in the 'Notes' column of the 'Patient Study Status History' table.

Status	Status Date	Reason	Notes	Delete
Enrolled	05/09/2019	-	-	X

2. Click on the **Select** checkbox.
3. Click on the **Status** field and select “**Re-enrolled**” from the drop down list.
4. Click on the **Status Date** calendar icon to select the status date, if it is not already shown.
5. Click on the **Current Status** radio button.
6. Enter comments regarding the re-enrollment in the **Notes** field.

The screenshot shows the 'Add New Status(es)' form. Red arrows point to the 'Select' checkbox, the 'Status' dropdown menu (set to 'Re-enrolled'), the 'Status Date' calendar icon (set to '05/09/2019'), the 'Status Reason' dropdown menu (set to 'Select an Option'), the 'Current Status' radio button, and the 'Notes' text field. The form also displays 'Existing Study Status(es)' with 'Enrolled' and 'Status Date 05/09/2019*'. A note indicates '* Indicate Current Status'.

7. The “**Re-enrolled**” status will push to Epic, and the “**Research: Active**” flag will be set in the Epic system.

Re-Consenting a Patient to a Study

At some point you may need to re-consent a patient to a study. For example, if the patient has completed one treatment arm of the study and will need to sign another consent before starting a new treatment arm. In this instance, **DO NOT** add the “**Off Study**” status. Instead, follow the steps outlined above to add the “**Re-Consent**” status to the patient. Remember, **DO NOT** delete any existing patient statuses. (The “**Re-Consent**” status will not push an active flag to Epic. If a patient was taken off study, but needs to be on the study and re-consented, you will need to add the “**Re-enrolled**” status in order to trigger the “**Research: Active**” flag in Epic.)