Work Instruction Assigning Patients to a Study

Velos - eResearch v10.0





Version: 1.0, 02/16/2018

Revision History				
Version/Amendment #:	Version Date:	Description:	Completed By:	
Version 1.0	02/16/2018	Initial release	VPR CTO	

Documentation of Change History:

Version 1.0, 02/16/2018: VPR CTO initial release of version 10.0 work instructions;

PURPOSE

The purpose of this work instruction is to describe associating a patient to a study, associating a patient to a study calendar and managing patient status within Velos eResearch. For registering subjects in eResearch, please refer to the Patient Registration work instruction.

RESPONSIBILITY

The UT Health San Antonio Clinical Trials Office (CTO) and the Cancer Center CTO requires that the **Research Team (RT)** have the primary responsibility for management of patients on studies within Velos eResearch. These responsibilities include, but are not limited to: registering patients into eResearch, associating patients to the appropriate study, assigning patients to the correct study calendar, maintaining patient study schedules, managing patient status throughout course of study activity, managing patient visits and activities. These responsibilities apply to any member of the RT with patient responsibilities (Principal Investigator, Research Coordinator, Research Nurse, etc.).

ENTRY/PREREQUISITE CRITERIA

The following must occur prior to managing patients in eResearch:

- Study Registration study record created in eResearch
- Study Setup study build is complete, including calendars, forms, etc.
- Study Activation all approvals are in place and study is open for enrollment
- Study Calendars set to active
- Patient Registration patient record is either existing or has been created in eResearch
- Patient Management Access Rights user must have the appropriate access rights to manage patients in eResearch per study

REFERENCE DOCUMENTS

- Access to all Study Documents As needed to verify research subject consent and study status
- Complete Subject Study Record Subject Research Record Source Chart, as needed
- Subject Medical Record as needed

WORK INSTRUCTIONS

Role/Function	Description of Action
Research Team	1. Log into eResearch
Associate	 Click the MANAGE button from the toolbar and select SEARCH under the PATIENTS option
Patient to a Study – Patient Search	 3. Search for the Patient to be associated with the study by: Name – First, Middle, Last Date of birth Gender Velos Patient ID, (EPIC MRN) if known

Associate Patient to a Study – Patient Search (cont.)	4. Verify the Patient is the correct one to be associated with the study Patient Registration to register Patient in eResearch, then return to Step 3 above: Message from webpage × Click OK to Search the EPIC EMR OK Cancel
Research Team	 5. Click on the PATIENT ID link to select the appropriate patient Current Page1 Total Pages: 1 Rows Per Page ▼ PATIENT ID First Name Middle Name Last Name Date of Birth Gender 60894673 TEST VELOSONE 01/01/1980 Male 60894674 TEST VELOSTWO 01/01/1980 Female 1. Verify the Patient Demographic information Price PATIENT ID is the number assigned to the Patient registration record in the eResearch database. This is the EPIC MRN and is NOT the same as the Patient Study ID (assigned for the study). Never change the PATIENT ID field.
Associate Patient to a Study – Demographics Page	 Correct any information displayed in the Personal Details section, as necessary. Verify the Registration Details section Click on the Registration Details section link to add Facility ID (Patient MRN number) for any Organizations not already listed, as needed. This is important for patient billing. Register Patient for an Organization Frequent Facility 10 * University Health System Frequent Facility 10 * University Health System Frequent Facility 10 * University Health System Frequent Facility 10 * Select User Frequent Facility 10 * Select User Frequent Facility 10 * University Health System Frequent Facility 10 * Select User Frequent Facility 10 * Select User Frequent Facility 10 * Select User Frequent Select Machine of this organization Frequent information for uses to del this patients Granted © Granted © Grantation Frequent information for uses to the segantation of the segant of the segantation of the segantation of the segantation o

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Research Team Associate Patient to a Study – Protocols	 a. Select only the primary healthcare facilities from the Organizations* dropdown field (ex. University Health System, Methodist Healthcare System, etc.) b. Enter the Patient's MRN number in the Patient Facility ID* field (this is the organization's MRN which can differ from the Velos ID Number) c. You may omit the remaining fields. d. Enter your e-Signature and click the SUBMIT button 5. Verify the Other information section 6. Add a Note in Reason for Change (FDA Audit)* for all changes made to fields marked with the red asterisk. 7. Enter your e-Signature and click the SUBMIT button. Ш The Protocols tab shows other studies that Patient is/has been associated. 1. Select the Protocols tab Demographics Patient Profile Protocols Reports Appendix Pat.D: 60894673 Age: 37 years Gender: Male Pat.Name: TEST VELOSONE Org: UTHSCSA 2. If another study is listed and Patient Status shows that Patient is active on that study, verify if concurrent enrollment is allowed by either study. a. If concurrent enrollment is allowed by either study, the Patient should not be associated with the new study. b. If concurrent enrollment IS allowed by BOTH studies, then proceed to the next step. 3. To screen/enroll this patient in a new study, select Study and Patient
	Organization (if needed):

Refer to the following	screensh	ots for Addin	g/Managing	g Patient	Status	
L Strenin	p Enroliment	Schedule	Adverse Eventa	forma.		
Study Number: CTN Patient Study De	ts 17-0099 Test					
Patient Study ID: Enrollment Date	06460973	Randomizatio Enrolled By	en #:		Assigned To: Physician	
Treatment Locatio		Current Statu	a Consent Sig		ang provinsi	
The list below disclary the Treatm	ent Arm	Drug Information	Status Date	En	d Date	Add New Treatment Arm Notes Defete
The list below displays pa	dent's study status history					Add New Status
		🔶 Patient Study Status - Goog	gle Chrome		– 🗆 X	
		Secure https://uthscs	astag.veloseresearch.com/ve	los/jsp/patstudystatus	.jsp?patStudiesEnrolling	
		Patient ID: 06468973 Stu	dy Number. CTMS 17-0099 Test	t		
		Patient Study Status Status	Select an option	•		
		Reason Status Date *	Select an option	•		
		It is patient's current s	tatus in this study			
		Notes				
		Additional Information Patient Study ID *	06468973			
		Enrolling Site Assigned To	UTHSCSA	• Selec	ct.Uter	
		Physician Treatment Location	Select an option *		ct.User	
		Treating Organization	Select an option •			
		Disease Code Anatomic Site				
		Disease Type		Z ×		
		CONTRACTOR STORES	in option •			
		Evaluable Status Select a Unevaluable Status Select a				
		Patient Status Survival Status	Select an option	•		
		Date of Death Cause of Death	Select an option •			
		Specify Cause Death Related to Study				
		Reason of Death Related to S	Select an option study			
		e-Signature *	Submit	Submit and Add Another		
					-	
Research Team						
	1. Clicl	the Add Ne	<u>w Status</u> lin	ik		
	-	Study Status				
Manage	2. Fror	n the Patient	Study Stat	us form t	hat appears	s, select the appropriate first
Patient Status	stat	us from the s	tatus drop-	down fiel	d. Recomm	nended options are:
		0	dentified/R	eferred		
		o (Consent Sigr	ned		
		ο [Did not cons	sent		
		o F	Pre-Screen			
	₽ NOTE	: Some statu	uses do not	require a	"Reason" t	o be selected and as a result
						son" drop down menu. As
						iate option is available.
					an appropr	
	-	cify the appro				
		•				BOX should remain checked,
		as long a	s the status	being up	dated is the	e patient's current status.

Manage Patient Status	 b. Some status options have dynamic fields that appear when the status is selected. "Consent Signed" displays Informed Consent Details section which includes the Informed Consent Version Number used in consenting the patient Additional Details section Enter a study-specific Patient Study ID if it should not be the default. This number must remain unchanged throughout course of study. For Non-Cancer Studies - The remaining fields in this section may be left blank or completed if required for the study.
(cont.)	 Enrolling Site - If the enrollment site is different than UTHSCSA (e.g. STVHCS-VA), then select the appropriate Enrolling Site.
	P NOTE: Patient must first be registered to the corresponding Organization for the Enrollment Site to be available as a selection.
	 Assigned to - Select the personnel responsible for the patient Physician – Select the personnel responsible for the patient Treatment Location - Select if the patient is being treated as an inpatient or as an out patient Treating Organization – Specify which Primary Organization is treating the patient. Disease Code – Select the appropriate CTEP simplified disease code that matches the patient's specific disease. Anatomic Site - Select the appropriate NCI Disease site correlating to patient's primary diagnosis. Disease Type – Select the appropriate CTEP simplified disease code that matches the patient's specific disease.
	 Evaluable Status section Evaluable Status – Cancer-Related Studies Only. Leave blank for all other studies. a. Evaluable Flag – (Once information is known or Patient is off the study) specify if the data collected is evaluable or not. This allows for patients to safely be removed from the study while flagging the patient's data so it can be removed from submissions, if necessary. i. "No" – Select the Unevaluable Status ii. "Yes" – Select the Evaluable Status
	 b. Evaluable Status – Evaluable for Protocol, Evaluable for Toxicity Only, Not Applicable, Too Early. c. Unevaluable Status – Inadequate Testing, No Evidence of Disease, Not Treated, Patient Withdrew Consent, Protocol Violation.

Manage Patient Status	sta fol Ur (D 7. En D Ma patien	tient Status – Cancer-Related Studies Only. <i>Leave blank for all other</i> <i>udies</i> this allows for a more detailed Survival Status list for patients lowed for survival. Options include the following: Alive – Disease Status aknown, Alive – NED (no evidence of disease), Alive with Disease, Dead ate of Death must be entered), Lost to Follow-up and Alive. ter your e-Signature and click the SUBMIT button to update Patient Status anaging Patient Status – The Patient's status requires updates to track the t's progress throughout study participation as described below.
(cont.)	1.	Access the desired Study from the toolbar: Manage>> Studies >> Search or enter the study number in the "Search a Study" field and click the Search button.
		Search a Study Search
	2.	Once the study appears in search results, select the Patient Management icon I to access Patients associated to the study
	3.	Select the Pt. Study ID of desired Patient
	4.	Select the Screening/Enrollment link
	5.	Select the Add New Status link to open Patient Study Status window
	6.	Select the appropriate Status from the Status dropdown field. Refer to Appendix B for a complete list of Patient Study Statuses
		 NOTE: Some statuses affect other pages or features. Below is a list of such statuses and their actions Identified/Referred, Consent Signed – These statuses are typically the first patient statuses that may be added to the patient record in eResearch. When either status is added to the patient record, the Velos-Epic Research interface automatically applies a Start Date and links the patient to the study research account. Start Date is important for patient billing. Enrolled – includes patient in study accrual counts, and specifies patient has started treatment. Also some billing milestone rules require this status in order to properly trigger patient achievements in eResearch. Follow-up – used for long follow-up period. Off Study – patient has finished all study criteria. When this patient status is applied, the Velos-Epic Research interface automatically applies an End Date and changes the patient's

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Manage Patient Status (cont.)	 7. Some status select the apprication of the select the apprication of the selected. 8. Some status selected. • 	patient billing. options have a correspondent of the options have dynamic <u>Consent Signed</u> status of Details section to enter was signed. <u>Screening/Eligibility Vis</u> section to enter a scree user who completed the	an Enrollment Details section to
Example of multiple st	atuses associated to F	Patient for a Study:	
Fizito controzz Pr. study KD. THOAGEONT	Schedulo Ad	verse Events Forms.	
Sludy Number. CTMS 16-0147			
Patient Study ID: TRUGGE00 Enrollment Date 03/24/2017 Treatment Location Out Patient	7 Enrolled By	001 Off-Study	Assigned To: Physician Anond Prosed
The led below displays Patient's Treatment Jerrs. Treatment Arm	Drug Information	Status Dele	Add New Tractment Ann End Date Notes
The fiel below displays patient's study status history	Status Date	1	Add New Status Notes
Status	Constraint of the	Reason	
Disassociated with Study in EMR Off. Study	10/03/2017 09/15/2017	Reason Completed	Image: Part of the second se
Disasancialed with Study in EMR	10/03/2017		Image:
Desance international states in 1988 Off Story Associated and Story in 1989 Consult: Story in 1989 Consult: Story NOTE P: The Associate added automatically b status indicates the pa research account. The	ed with Study in EMF y the Velos-Epic Rese tient was successfully Disassociated with S	R and Disassociated wit arch Interface. The Ass associated to the stud	th Study in EMR patient statuses are sociated with Study in EMR patient y in Epic and linked to the study atus indicates that the patient is no
Descended with State to 1980 Off Story Associated with State to 1980 Consent Story The Association added automatically be status indicates the paresearch account. The longer on the study an Research Team	ed with Study in EMF y the Velos-Epic Rese tient was successfully Disassociated with S ad has been appropria	R and Disassociated wit arch Interface. The Ass v associated to the stud tudy in EMR patient sta tely updated to a Comp	th Study in EMR patient statuses are sociated with Study in EMR patient y in Epic and linked to the study atus indicates that the patient is no pleted status in Epic.
Descended at the State is 1000 Off. State Associated sets. State is 1000 Consent General Toxolid Added automatically bi status indicates the pa research account. The longer on the study an	ed with Study in EMF y the Velos-Epic Rese tient was successfully Disassociated with S d has been appropria	R and Disassociated wit arch Interface. The Ass associated to the stud tudy in EMR patient sta tely updated to a Comp	th Study in EMR patient statuses are sociated with Study in EMR patient y in Epic and linked to the study atus indicates that the patient is no pleted status in Epic.
Descended with State to 1980 Off Story Associated with State to 1980 Consent Story The Association added automatically be status indicates the paresearch account. The longer on the study an Research Team	ed with Study in EMF y the Velos-Epic Rese tient was successfully e Disassociated with S id has been appropria	R and Disassociated wit arch Interface. The Ass associated to the stud tudy in EMR patient sta tely updated to a Comp	th Study in EMR patient statuses are sociated with Study in EMR patient y in Epic and linked to the study atus indicates that the patient is no pleted status in Epic.
Descended with Static to 1000 Off Static Associated with Static total Consent Stated Consent Stated	ed with Study in EMF y the Velos-Epic Rese tient was successfully Disassociated with S id has been appropria	R and Disassociated wit arch Interface. The Ass associated to the stud tudy in EMR patient sta tely updated to a Comp	th Study in EMR patient statuses are sociated with Study in EMR patient y in Epic and linked to the study atus indicates that the patient is no oleted status in Epic.

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	3. Select Edit Calendar/Date to open Treatment Details window
	Current Page: Manage Patient >> Schedule
	Demographics Patient Profile Protocols Reports Appendix PaciD 60664720 PL Study ID: TV-1224 Age: 33 years Gender: Male Pat Name: TEST VELOS Org: UTHSCSA
	ScreeningEnrollment Schedule Adverse Events Forms
Associate Patient to a	Study #: <u>New 1234</u> Calendar: No Associated Calendar Pat Start Date: <u>Edit Calendar: Date</u> View Previous Delete Schedule This patient has not been assigned to a Study Calendar.
Study Calendar (cont.)	 Select desired Study Calendar from dropdown. *Only Active Calendars for the Study are listed. If you believe that the calendar options are incorrect or they are not available, please contact the appropriate CTO office, either VPR or Cancer Center.
	Treatment Details The following fields must be filled in order to generate a schedule for the patient and track events. Study Calendar CTMS 17-0099 TEST - Calendar Wis • Select the specific Study Calendar that the patient is assigned to for this study
	Patient Start Date Patient's schedule will be generated based on this start date. Calculate Schedule from the First Visit of the Calendar Template Calculate Schedule from a Visit other than the First Visit of the Calendar Template Select a Visit (Read Only)
	e-Signature * Submit
	5. Enter Patient Start Date – all Visit intervals and Event Visit windows are based on this date.
	6. Select the "Calculate Schedule from the First visit of the Calendar Template" radio button.
	7. Enter your e-Signature and click the SUBMIT button
	The Patient Study Calendar will populate with Suggested and Scheduled Visit Dates based on Study Schedule and Visit Windows.
Example of Schedule	page with a Patient Calendar:
Demographics Patient Profile Protocols	As Reports Appendix as Gender: Male PatName: TEST VELOS Org: UTHSCSA
Screening/Enrollment	Schedule Adverse Events Forms
	Study #: <u>New 1234</u> Calendar: New 1234 Patient Calendar Pat Start Date: 10/23/2014 Schedule: Current <u>Edit Calendar/Date</u> <u>View Previous</u> <u>Delete Schedule</u>
Select Schedule: New 1234 Patient Calend	
October 2014 Visit	Suggested Date Scheduled Date Visit Window 10/23/2014 10/23/2014
November 2014 Visit	Suggested Date Scheduled Date Visit Window
→ Visit 1	11/06/2014 11/06/2014 11/05/2014~11/07/2014
▶ Visit 2	11/08/2014 11/08/2014 11/06/2014~11/10/2014
Vist 3 - EOS	11/12/2014 11/12/2014 11/09/2014~11/15/2014

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EXIT CRITERIA

Upon completion of this work instruction, the Patient is associated to the study and has a study schedule assigned. Patient Management continues with Work Instruction Patient Visits.

APPENDIX A: VPR ROLES & RESPONSIBILITIES

RACI Chart		Research Team	
RACI Chart	Study Entry	Principal	Research
PATIENT MANAGEMENT	Team	Investigator	Team
-Assigning Patients to a Study			
-Associate Patients to a Study	С	A,R	R
-Manage Patient Status	С	A,R	R
-Associate Patient to a Study Calendar	С	A,R	R

R = Responsible party

A = Accountable party

C = consulting party

I = party to be kept informed

APPENDIX B: PATIENT STUDY STATUSES

P NOTE: Statuses used by other studies depend on the nature of the individual study. It is not expected that ALL patient study statuses listed be used by ALL studies. Select the most appropriate depending on the individual study.

Identified/Referred	Initial patient status for patients identified as potential candidates for the study
Did not Consent	Used for patients who are approached for study, but decide not to participate
Consent Signed	Used for Pre-Screen Consent or Screening Consent; enter date consent was signed
	Used for studies that include a pre-screening activity, or for Cancer studies that require
Pre-Screening	tumor testing
	Used for studies that include a pre-screening activity, or for Cancer studies that require
Pre-Screen Failure	tumor testing, when the patient is found to be ineligible for study
Screening/Eligibility	Used when patient is having screening procedures to determine eligibility
Screen Failure	Used when patient is found to be ineligible for the study
	Used if patient has a previous Pre-Screen failure or Screen Failure status and is being re-
Re-Screening	evaluated for study
	Used for patients to record date that active treatment begins, such as first day of
Enrolled	investigational drug
	"Off Study"; used when patient withdraws, or is withdrawn, from study after starting the
Withdrawn	investigational article or treatment
	Used for patients who have completed treatment as expected and are now in the follow-up
Follow-up	phase of study
	The Patient is no longer participating in the study; all research related interactions with the
Off-Study	patient are complete – TREATMENT AND FOLLOW-UP COMPLETED

END OF DOCUMENT