Q2. What is Velos and how do I navigate the system?

<u>Velos</u> is a clinical trial management system (CTMS) that allows users to initiate and track the progress of their clinical trial budget, coverage analysis, and documents.

First-time users are required to complete the <u>eResearch Access Request Form</u> to be granted access to systems such as Velos, eIRB, eGrants, eAgreements and Topaz. For information on which systems are connected and how they route to certain applications, please reference the <u>SPA Software and Web Applications Guide</u>.

Training courses offered via <u>Taleo Learn</u> in collaboration with IRSE Training include:

- Velos and eIRB Study Registration
- Velos Patient Registration

To access Velos, go to the Tools page on the UTSW website. Select Velos:



Log in using your UTSW username (lowercase only) and password:

wcg [®] Velos eResearch	Note: Only use lowercase
	letters as username. Typing capital letters will prevent login.
Technical Support v11.2.1 #948	

The Velos Homepage provides **Quick Links** to websites and guidance materials; for example, the Contracts and Agreements Pathfinder (CAP) for assistance with determining the contract type and which central office will assist with execution.

Personalize 👻 M	anage 👻 Libraries 👻 Reporting	g 🔽	Study #, Title or Keyword	م UTSouthwestern م	0 9 9
Current Page: Velos eRe	search >> Homepage				
Search A Study	Search a Study	Search	Advanced Search		Account Forms
Last Modified Stud	es				E
Quick Access	Study Number		Study Title	Stu	udy Status
Ê 🖩 🕨	10748		AREN03B2: Renal Tumors Classific	ation, B • • • IRE	3 - Continuing Review Approved
Ê 🖬 🖬	33640		NRG-GY019: A Randomized Phase	III, Two-A • • • IRE	3 - Mod Approved
Ê 🖬 🖬	43218		Identification of Trends in Physical A	ss ••• Stu	idy - Study Created in PHHS Velos
Ê 🖩 🖬	34123		The effects of low-dose analgesics	n ca ••• IRE	3 - Mod Approved
ê 🖩 🖬	41475		Prospective, single institutional stud	y •••• Stu	ıdy - Active/Enrolling
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			ClinicalTrials.gov Number is require	d Clin Ente	icalTrials.gov Number is required for billing. er in More Study Details
			Contracts and Agreements Pathfind	er (CAP) Con	Itracts and Agreements Pathfinder (CAP)
			eIRB	eIRI	В
			PeopleSoft Information Site	Peo	pleSoft Information Site
			Performance Site Review Form FAG	2 Free the l	quently asked questions to assist with filling out Performance Site Review Form
			Research Portal	Res	earch Portal
			Research Wizard	Res	earch Wizard
			UTSW Performance Site Review F/	IQ UTS Nov	W Performance Site Review FAQ (Updated ember 2020)
			Velos Glossary of Terms	Velo	s Glossary of Terms (Updated 1/1/2023)
			Velos Standard Reports Glossary	Des Octo	cription and sample of Velos Reports (Updated ober 2020)
			Velos Tip Sheets and Helpful Guide	s Stud Perf	dy, Patient Registraiton, Coverage Analysis, formance Site, etc.

Additionally, users may **Search a Study** by accessing the top navigation search option by study number, title, or keyword, or they may elect the **Advanced Search** option to filter using additional attributes. **NOTE:** users will need to deselect "**Exclude IRB- Study Closed Status**" if unable to locate the study.

Personalize 👻	Manage 🔻 Libraries 🔻 Repor	ting 🕶	Study #, Title or Keyword	٩	Medical Center
Current Page: Velos el	Research >> Homepage				
Search A Study	Search a Study	Search	Advanced Search		Account Forms
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Quick Access	Study Number		Study Title		Study Status
Ê 🖩 🖬	10748		AREN03B2: Renal Tumors	Classification, B • • •	IRB - Continuing Review Approved
Ê 🖬 🖬	33640		NRG-GY019: A Randomize	d Phase III, Two-A • • •	IRB - Mod Approved
Ê 🖬 🖬	43218		Identification of Trends in Pl	hysical Ass •••	Study - Study Created in PHHS Velos
Ê 🖬 🖬	34123		The effects of low-dose ana	lgesics on ca •••	IRB - Mod Approved
Ê 🖩 🖬	41475		Prospective, single institutio	nal study •••	Study - Active/Enrolling
My Links	1		Quick Links		Ø
			ClinicalTrials.gov Number is	required	ClinicalTrials.gov Number is required for billing. Enter in More Study Details
			Contracts and Agreements	Pathfinder (CAP)	Contracts and Agreements Pathfinder (CAP)
			eIRB		elRB
			PeopleSoft Information Site		PeopleSoft Information Site
			Performance Site Review F	orm FAQ	Frequently asked questions to assist with filling out the Performance Site Review Form
			Research Portal		Research Portal
			Research Wizard		Research Wizard
			UTSW Performance Site Re	eview FAQ	UTSW Performance Site Review FAQ (Updated November 2020)
			Velos Glossary of Terms		Velos Glossary of Terms (Updated 1/1/2023)
			Velos Standard Reports Glo	ossary	Description and sample of Velos Reports (Updated October 2020)
			Velos Tip Sheets and Helpf	ul Guides	Study, Patient Registraiton, Coverage Analysis, Performance Site, etc.

Within Advanced Search, users can search using the IRB ID (STU number) in the More Study Details field.

Personalize 👻 Manage 👻	Libraries 👻 Reporting 👻
Current Page: Manage Protocols >> S Search By	Search
Study #, Title or Keyword:	
Cancer-Related Study:	
Study Organizations:	
More Study Details:	STU-2023-0000
Status Type:	
Keyword:	

The most recently modified studies for which the user has access will display by **Quick Access** options, **Study Number, Study Title,** and **Study Status**. **Quick Access** links allow you to easily access **Study Administration**, **Budgets**, and **Financial Summary**.

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Curren	t Page: Velos eRe	search >> Homepage			
Sear	ch A Study	Search a Study	Search	Advanced Search	Account Forms
Last	Modified Stud	ies			
Quic	k Access	Study Number		Study Title	Study Status
Ē	E اا	10748		AREN03B2: Renal Tumors Classification, B • •	IRB - Continuing Review Approved
Ē	= 1.	33640		NRG-GY019: A Randomized Phase III, Two-A	IRB - Mod Approved
(= 1.	43218		Identification of Trends in Physical Ass	Study - Study Created in PHHS Velos
Ê	= 1.	34123		The effects of low-dose analgesics on ca	IRB - Mod Approved
Ē	⊞ ₁Ⅰ.	41475		Prospective, single institutional study	Study - Active/Enrolling
My Lir	nks	1		Quick Links	1
				ClinicalTrials.gov Number is required	ClinicalTrials.gov Number is required for billing. Enter in More Study Details
				Contracts and Agreements Pathfinder (CAP)	Contracts and Agreements Pathfinder (CAP)
				eIRB	eIRB
				PeopleSoft Information Site	PeopleSoft Information Site
				Performance Site Review Form FAQ	Frequently asked questions to assist with filling out the Performance Site Review Form
				Research Portal	Research Portal
				Research Wizard	Research Wizard
				UTSW Performance Site Review FAQ	UTSW Performance Site Review FAQ (Updated November 2020)
				Velos Glossary of Terms	Velos Glossary of Terms (Updated 1/1/2023)
				Velos Standard Reports Glossary	Description and sample of Velos Reports (Updated October 2020)
				Velos Tip Sheets and Helpful Guides	Study, Patient Registraiton, Coverage Analysis, Performance Site, etc.

The **Study Administration** view gives users the ability to see **Summary information**, **Site/Team information**, **Protocol information**, **Forms**, **Milestones**, **Documents**, **Action Schedule**, **Reports**, and **Notifications**. The left side of the screen allows users to view the current statuses of a study.

Personalize 🔫	Manage 👻	Libraries 🔻	Reporting 🔫			Study #, T	itle or Keyword		٩	UT Southwestern Medical Center	n 🕐 🗄	Ð
Current Page: Study :	>> Summary											
 Study Initia 	ation	You are v	working on study:									
		Summary	Site/Team Protocol	Study Status Forms	Milestones	Documents	Admin Schedule	Reports	Notifications			
IRB - Submis	\checkmark	_										
IRB - Waitin	1	Study Su	mmary									
into Approx		Study Inf	formation									
- Ohudu Aath	- the se	1										
 Study Activ 	ation	Study En	ntered By *			Select User			ncipal investigator was a m	najor author/initiator of this study?		
Study - Acti	~	Principal	I Investigator 🕐 🛛			Select User			RP Reportable			
		Primary F	Research Coordinator 🕐 *			Select User		U FD/	A Regulated Study 💟			
▼ Study Clos	ure											
	aro -		/IDE Information Available?									
IRB - Study		Study De	efinition									
		Study N	lumber (Velos ID)									
		Long St	udu Title 🕐 .									
		Long St	udy nue									
		Objective	e(s) ? •									
		Summar	ry 🕐									
									0			
		Study De	etails		Do you	want informati	on in this section to b	e available	to the public? O Yes	● No 💟		
L												

The **Site/Team** tab shows the primary roles that the study team play. Examples of roles are PI, Study Author, Finance Staff, and other personnel. You also can add or edit study team members.

Personalize - Manage - Libra	aries - Reporting -	Stud	y #, Title or Keyword	UT Southwes Medical C	tern 👌 🗇 🕀 Michel	lle Harris
Current Page: Study >> Team • Study Initiation	You : 42393 Sumt y Site/Team plocol Study	y Status Forms Milestones Documents Admin 1	Schedule Reports Notifications			
IRB - Submis V IRB - Waltin V IRB - Approv	Search by Organization	All	✓ Search	View Super Users with access to th	is Study	_
T Study Activation	Study Team			ADD NEW ORGANIZATION	ADD/EDIT STUDY TEAM M	EMBER
	Organization	User Name	Role	Access Rights	Status	Delete
Study - Act	UT Southwestern Medical Center and Af	hilates -	Principal Investigator		Active	• •
 Study Closure 		Kristen Hall	Study Author	8	Deactivate	• •
IRB - Study		► i Kristen Hall	Primary Research Coordinator	2	/ Active	⊙ ⊗
L		Kristen Hall	Other Study Personnel	E 9	Deactivate	⊙ ⊗
		► i James Caruso	Co-Investigator		/ Active	•9 (S
		► i James Caruso	Other Study Personnel		Deactivate	•9 (S
		Ferenzo Murray	Financial Staff - Edit Study/View Patient	E	Active	⊗ ⊗
	UTSW	Performance/Enrolling site	Local Sample Size: -		Track Study Status	8

The **Protocol** tab gives a calendar view of the billable protocol events. Click one of the items under **Calendar Name.**

Personalize 🗸 Manage 🚽	Libraries 🗸 Reporting 🗸	Study #, Title or Keyword	Q UTSouthwest Medical C	tern 👌 🕐 🤁 😁 Mary Baile	<i>y</i>
Current Page: Study >> Setup					
 Study Initiation 	You are working on study: 13222				🚢 🗐
otady mildadon	Summary Site/Tear Protocol udy Status Fo	rms Documents Admin Schedule Reports Notifica	tions		
IRB - Subm					
IRB - Wait	Church Distinguistics (Cattings				
IRB - Appr	Study Dictionaries/Settings				
	If no modifications have been specified, the default settings	will be applied.	VIEW/EDIT	DICTIONARIES AND SETTINGS	
 Study Activation 	Туре	Use			
	Adverse Event Dictionary	NCI v4.01			
Study - Ac	Patient Study ID Generation	manual			
	Study Treatment Arm				
✓ Study Closure	Treatment Arms currently associated with this study are:		ADD NEW		
IDB _ Stud	Treatment Arm	Description		Delet	Э
110-500	Control	-		\otimes	
	Intervention			\otimes	
	test 8.9	test 8.9		\otimes	
	Associated Calendars				
	Calcoders surrently associated with this study are:	UPDATE MULTIPLE SCHEDULES	COPY AN EXISTING CALENDAR	SELECT A CALENDAR FROM YOUR	LIBRARY
	Calendar Name	Refresh Description Notifications	Status Status Deta	ils Reports Delete	Save to Library
	10432-BUD test	CCAG Billing Grid-Mary Jo Cascardo	Offline for Editing Status Details	Schedule 😣	8
	10432-BUD test SA 1012021 test	CCAG Billing Grid-Mary Jo Cascardo	Work in Progress Status Details	; 💿 Schedule 😣	8

After selecting a **Calendar Name**, a **Calendar grid** will display specifics of a patient visit or test. To return to the **Summary Administration** view, click the back arrow at the top left of your screen.



Under the **Study Status** tab, users will add a new **Coverage Analysis Study Status**. **NOTE:** this status will trigger a Velos notification to the <u>clinicaltrials@utsouthwestern.edu</u> mailbox. This section also allows users to determine if anything further needs to be addressed.

Personalize 👻 Manage 👻	Libraries 👻 Reporting 👻		Study #, T	itle or Keyword	٩	UTSouthwestern Medical Center	
Current Page: Study >> Status							
 Study Initiation 	You are working on study:						
IRB - Submis	Summary Site/Team Protoco	Study Status Forms	Milestones Documents	Admin Schedule	Reports Notifications		
IRB - Waitin IRB - Approv	Search by Organization	All		Sauch	Current Status	Study Start Date Study End Date	
	Search by Organization	201		• Search	IRB - Continuing Review Approved	04/12/2006	Change Dates
 Study Activation 							
Study - Acti	Study Status History:						ADD NEW STAT
	Organization	Study Status	Status Valid From	Status Valid Unti	il Meeting Date	Notes	Delete
 Study Closure 	UT Southwestern Medical Center	and Affiliates					
IRB - Study		IRB - Continuing Review Approved	08/01/2022			Annual Update has been approved.	\otimes
		IRB - Continuing Review Approved	08/01/2022			Annual Update has been approved.	\otimes
		IRB - Mod Approved	04/11/2022			Modification has been approved.	\otimes
		IRB - Continuing Review Approved	11/08/2021			Annual Update has been approved.	\otimes
		IRB - Continuing Review Approved	11/08/2021			Annual Update has been approved.	\otimes
		IRB - Mod Approved	06/22/2021			Modification has been approved.	\otimes
		IRB - Mod Approved	06/17/2021			Modification has been approved.	\otimes
		IRB - Continuing Review Approved	11/12/2020			Annual Update has been approved.	\otimes
		IRB - Mod Approved	10/08/2020			Modification has been approved.	\otimes
		IRB - Mod Approved	10/06/2020			Modification has been approved	\otimes

The **Forms** tab allows users to complete several requests in the pick list, including **Coverage Analysis Modifications**.

Personalize 👻 Manage 👻	Libraries 👻 Reporting 👻		Study #, Title or Keyword	٩	Medical Center n 2	
My Profile My Links	You are working on study:					
New Trials	Summary Site/Team Protoco	ol Study Status Forms N	lilestones Documents Admin Schedule	Reports Notifications		
Settings Password/e-Sign	Jump to Form: Additional Sponsor Informatio	n 🗸	Go			
 Study Activation 	Section 1			0		
Study - Acti	Data Entry Date*					
	Additional Sponsor 1			Sponsor Look Up		
 Study Closure 	Additional Sponsor 2			Sponsor Look Up		
	Additional Sponsor 3			Sponsor Look Up		
IRB - Study	Additional Sponsor 4			Sponsor Look Up		
	Form Status*	Work In Progress 🗸	e-Signature *		s	ubmit

The **Documents** tab contains documents that are relative to the study, such as the protocol, informed consent, etc. Under the **Documents** tab users may click **Add Multiple New Documents** to upload draft contracts, draft budget, protocol, informed consent, and other regulatory documents.

Personalize 👻 Manage 👻	Libraries Reporting	,	Study #, Title or	r Keyword	۹	Medical Center	0 🕀 😌	
Current Page: Study >> Versions								
 Study Initiation 	You are working on stu	dy:						= 1 .
	Summary Site/Team	Protocol Study Status Forms	Milestone: Documents dr	min Schedule Reports No	otifications			
IRB - Submis								
IRB - Approv	Search By							
	Document # :	Category: Se	elect an option	Type:	Select an option	✓ St	atus: Select an option	~
 Study Activation 	Associated Docume	ents Listed Below		ADD NEW DOCUMENT	ADD MU	LTIPLE NEW DOCUMENTS		
Study - Acti	Document # ◊	Document Date ◊	Category ◊	 Type ◊	Section ◊	Appendix 0	Statu	s◊
		09/15/2022	Miscellaneous	Final	Sections (0)	Attachments (1)	Work i	in Progress 🖉 🕙
 Study Closure 		04/01/2022	Informed Consent	Follow Up	Sections (0)	Attachments (4)	Work i	in Progress 🥒 🕙
		04/01/2022	Protocol	Follow Up	Sections (0)	Attachments (5)	Work i	in Progress 🥒 🕙
IRB - Study		03/29/2019	Miscellaneous	Initial	Sections (0)	Attachments (1)	Work i	in Progress 🥒 🕙
		10/29/2021	Miscellaneous	Follow Up	Sections (0)	Attachments (8)	Work i	in Progress 🧪 🕙
	1	02/18/2008	-	Follow Up	Sections (0)	Attachments (1)	19	0
	1 to 6 of 6 Record(s)							

Within the **Admin Schedule** tab, users may associate and generate administrative calendars to a specific study to manage Administrative Calendar events. The main features of the **Admin Schedule** tab are the ability to select a calendar from your library to associate with a study or copy an existing calendar that pre-exists within the selected study.

Personalize 👻 Manage 👻	Libraries 👻 Reporting 👻	Study #, Title or Keyword	٩	UT Southwestern Medical Center	A () E		
Current Page: Study >> Admin Scheo	ule						
 Study Initiation 	You are working on study:				E		
	Summary Site/Team Protocol Study Status Forms Milesto	nes Documer Admin Schedule	ports Notifications				
IRB - Waitin	The administrative calendars linked to this study are:		COPY AN EXISTING C	ALENDAR	SELECT A CALENDAR FROM YOUR LIB	RARY	
 Study Activation 	Calendar Name Refresh D Notifications	escription	Calendar Status	Status Details	Reports	Delet	
	No Calendars Found					_	
Study - Acti	Schedule Displayed: No Active Calendars Schedule Start Date:						
 Study Closure 	Please select a calendar to proceed.						
IRB - Study							

Reports are initiated by study staff. The CA team builds out the CA based on what is submitted. This tool is used for billing compliance until the end of the study.

Personalize 👻 Manage 👻	Libraries 🔻 Reporting 👻	Study #, Title or Keyword	a UTSouthweste Medical Ce	ern 🔥 🕐 🗩		
Current Page: Study >> Reports					100000	
 Study Initiation 	You are working on study:				I	
IRB - Submis	Summary Site/Team Protocol Study Status Forms Mile:	stones Documents Admin Sched	Reports offications Available filters for this Report Type are:			
IRB - Approv	All Studies		Date Filter			
	Actively Enrolling Studies Report	0	All O Year O Month O Date Range			
 Study Activation 	O All Studies with Patient Count	0	[All]			
Study - Acti	O IRB Closed Studies	0				
	O Open Studies by Phase	0	Additional Filters:			
	O Protocol Tracking	0	Select Cancer-Non/Cancer Studies	[ALL]		
* Study Closure	O Research Funding Type	0	Select SCCC Performance Site	[ALL]		
IRB - Study	O Studies by Phase per Year	0	Colort only one Chudy			
	O Study Active/Enrolling Checklist		outer only one only			
	O Study Calendars Missing Coverage Type or Component ID	0	Select Organization	UT Southwestern Medical Ce		
	O Study Details	0	Select Study			
	O Study Team (Active Studies)	0	Select Org. Affiliated with Study	(ALL)		
	O Time to Activation Report	0	Select Specialty	[ALL]	1.1	
	O UT Southwestern ClinicalTrialsXpress Report	0	Select Study Status	[ALL]		
	Coverage Analysis		Select User	[ALL]		
	O Coverage Analysis DocuSign	0	Select at least one Study			
	O Study Calendar Report	0	Select Protocol Calendar (must select study first)	[ALL]		

Notifications: is populated by the study team.

Personalize 👻 Manage 👻 I	ibraries 🔻 Reporting 🕶	Study #, Title or Keyword	٩	UTSouthwestern Medical Center	n 🔿 Đ				
Current Page: Study >> Alerts and Notifications									
 Study Initiation 	You are working on study:								
IDD Submie	Summary Site/Team Protocol Study Status Forms Milestones	Documents Admin Schedule Reports	Notifications						
IRB - Waitin	Patient Calendar Notifications are not applicable to study Admin Calendars								
IRB - Approv	Adverse Event Notifications								
 Study Activation 			Send as E	mail					
	Send alert if Serious Adverse Event is reported				User Search				
Study - Acti	Send alert if death is reported as Adverse Event outcome				User Search				
 Study Closure 	Obudu Oslandar Oslavija Maliferativas								
	Study Calendar Specific Notifications								
IRB - Study	The list below displays the 'Active' Calendars associated with this study. Select the appropriate link to specify notifications for the study.								
	Phile Polandar								
	Study Calendar								

For more information about Velos Study Creation, Patient Registration, Velos/Epic Integrations, or Velos Gadgets, please reference the <u>Information Resources Velos webpage</u>.



Resources

IR Velos Overview Site

SPA Research Systems webpage

SPA Software and Web Applications Guide

SPA Clinical Research Review Study Webpage

Clinical Research Services Overview Taleo Module

Velos Login