

VelosCT Training Slides 2019

What is VelosCT?

- VelosCT is a Clinical Trial Management System (CTMS)
- VelosCT connects financial, administrative and clinical research activities to help manage studies
- Links study status, participant enrollment, calendars, budgets, and participant status to ensure compliant billing to Medicare/third party payers
- Other capabilities include budgeting, milestones, billing, protocol management, participant recruitment & management, query management, adverse event reporting, etc.


What does this mean for me?

- VelosCT will allow you to enter data and upload documents that the Clinical Trial Office (CTO) needs to initiate your studies internally
 - You can now initiate your IRB application in VelosCT (See VelosCT IRB Interface document)
- CTO will build study calendars with visits/events, coverage analysis, budget, and milestones for your study
- Once your study is active, you will be able to manage participants throughout the research process including, recruitment, enrollment, scheduling, visit/event tracking, data entry, notifications and monitoring
- All participants must be enrolled within 24 hours of the research visit, and associated to calendars with visits updated within 24-48 hours of when they occur.

What studies will you enter?

- **All New studies must include the submission of the [MCA/VelosCT Determination Checklist](#)**
- All studies managed by CTO will be entered in VelosCT. All studies that have hospital services will also be entered in VelosCT.
- This applies whether the study is managed by BMC or BU. If BMC infrastructure and/or clinical services are utilized, the study will need to be in VelosCT.
- In addition to studies, VelosCT will also be used to track legal documents (work with your assigned CTFA to enter these):
 - Confidential Disclosure agreements (CDAs)
 - Non-disclosure agreements (NDAs)

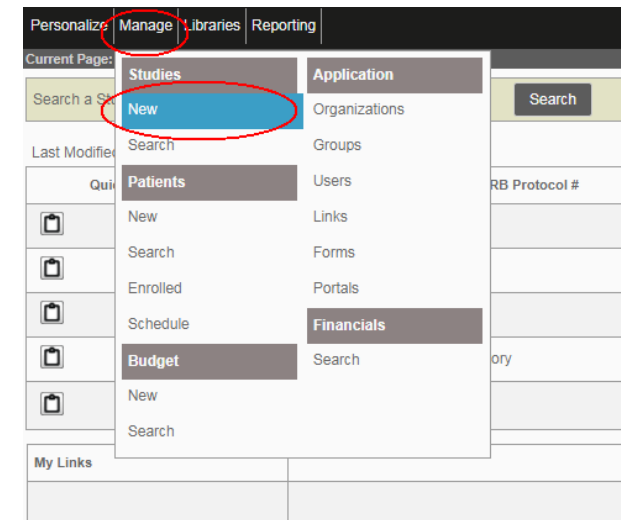
Login Information

- Make sure that you are in <https://bmc.velosresearch.com/velos/jsp/ereslogin.jsp> and not bmctest.velosresearch.com
 - Your VelosCT username and password will be the same as your BMC username and password
 - Email RBI@bmc.org for system access and user setup/permission questions.
- 
- For study specific questions you will always email your contact in the CTO
 - Full VelosCT Video Training is available on the Clinical Trial Office website at: <https://www.bmc.org/research-operations/clinical-trials#>

VelosCT Study Set Up

Entering a New Study

- Start by clicking Manage->Studies->New
- All fields with a * are mandatory and must be filled in to save your new study.
However, please fill as in much information as possible as multiple departments (CTO, Research Counsel, Revenue Integrity, RBI, etc.) will also be using this study record
- “Study entered by” will pre-populate with your name
- “IRB Protocol #” should be the IRB protocol number, if it is pending, enter “Pending plus an identifying study name”
- “Full Protocol Title” will be the full protocol title
- “Department” is not marked as mandatory but will determine your list for “Section/Division”, which is mandatory
- “Phase” is the final mandatory field



More Study Details

- Make sure to fill in all information that is pertinent to your study
- These fields are for BMC/BU specific information needed for proper analysis and account setup by the CTO

More Study Details

Sponsor Protocol / Grant Number:

Study Nickname

For study initiation, after completion of top portion of this screen, please upload Documents and add Study Team members prior to submitting *Study Initiation eForm*.

BUMC IRB Protocol# (from Interface)

Ceded Protocol# (from Interface)

CMS QCT?

Funder (If not same as Sponsor)

FDAAA registration required?

Study Initiated by Sponsor or PI?

FCOI PI Attestation Date:

Any Study Participant services occurring?
(specify applicable services below)

- Blood Tests (serum chemistries, etc.):
- Pathology Department services at BMC (histology, slide creation, etc.):
- Radiological assessments at BMC
- EKG Assessments at BMC
- Other Assessments at BMC:
 - If Other at BMC, list:
- Other Assessments, Non-BMC:
 - If Other, Non-BMC, list:

Sponsor expects to receive:

Participant Compensation:

- If simple, please explain; otherwise contact CTFA

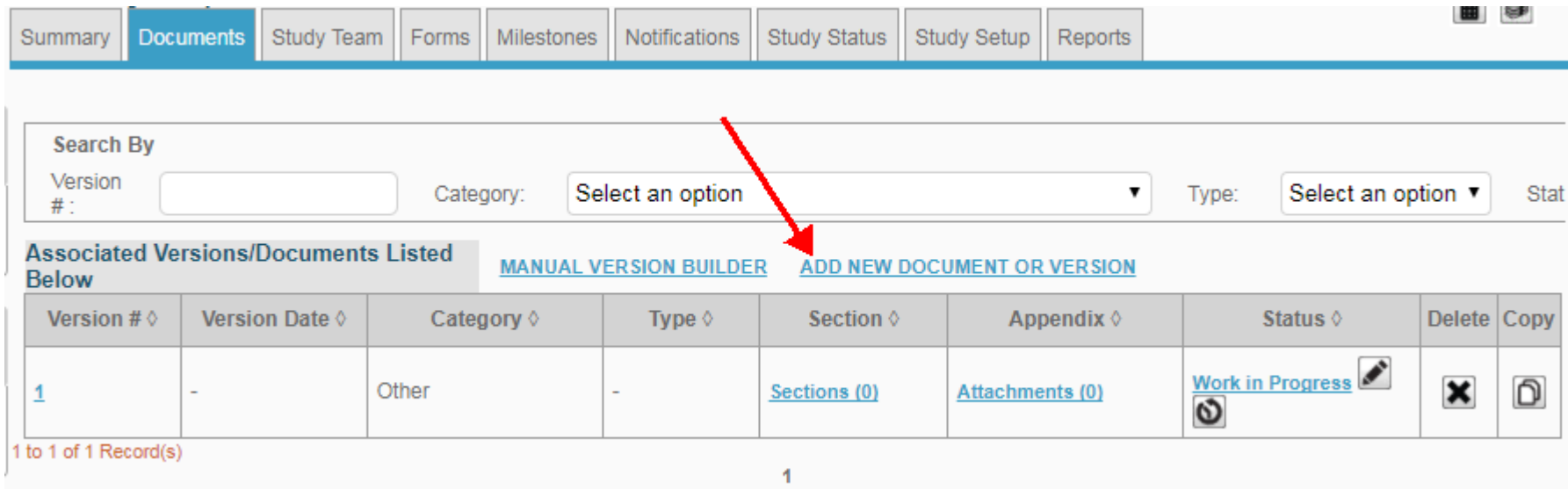
More Study Details

- Please note the reminder to complete the Study Initiation e-form
 - This e-form (see Forms tab) will notify CTO of your study submission in the system
- For BU studies, please also complete the following fields under the CTFA section:
 - Project Start Date
 - Project End Date
 - BU Internal Order IO# / SP#
- E-sign and submit

CTFA:	Douglas Finnegan 617-414-5651 douglas.finnegan@bmc.org ▼
Institution Managing Study Account (institution executing study agreement; If no agreement, funding account source):	BMC(Clinical Trial Office) ▼
Date Project Assigned to CTFA	<input type="text"/>
Prime Record?	Select an option ▼
Prime Title (for Lawson)	<input type="text"/>
Project Start Date	<input type="text"/>
Project End Date	<input type="text"/>
Admin ID [Go to SAM ->Address Book]	<input type="text"/>
Admin First Name	<input type="text"/>
Admin Last Name	<input type="text"/>
RFA (if account managed by Research Finance)	Select an option ▼
General Comments	<input type="text"/>
BU Internal Order IO # / SP #:	<input type="text"/>
BU SAP Grant Number:	<input type="text"/>
CFDA #	<input type="text"/>
Date CTO Approved for SAM/Lawson Setup	<input type="text"/>
CRA:	Select an option ▼
Active SDK Research Plan?	Select an option ▼
SDK Research Plan Name 1	<input type="text"/>
SDK Carrier Location 1	Select an option ▼
SDK Research Plan Name 2	<input type="text"/>
SDK Carrier Location 2	Select an option ▼
Business Analyst:	Select an option ▼
BMC Activity Number:	<input type="text"/>
BMC Accounting Unit:	<input type="text"/>
Migrated Account?	<input type="checkbox"/>
Date Notification Letter Sent	<input type="text"/>
REMINDER: For study initiation, please submit the Study Initiation eForm after uploading Documents and adding Study Team members.	<input checked="" type="checkbox"/>

Upload Documents

- The Documents tab is where you will upload all study related documents
 - Budget, Consent Form, Clinical Trial Agreement (CTA), Study protocol, FDA-related documents, etc.
- You can archive old versions of documents and upload new versions in their place at any time
- Disregard the Manual Version Builder link and the section column, this is only used if you were to create a document within VelosCT
- Click [ADD NEW DOCUMENT OR VERSION](#) link



The screenshot shows the 'Documents' tab selected in the top navigation bar. Below the navigation bar is a search section with fields for 'Version #', 'Category', and 'Type'. Below the search section is a table titled 'Associated Versions/Documents Listed Below'. The table has columns for Version #, Version Date, Category, Type, Section, Appendix, Status, Delete, and Copy. A red arrow points to the 'ADD NEW DOCUMENT OR VERSION' link located above the table. The table contains one record with Version # 1, Category Other, and Status Work in Progress.

Version #	Version Date	Category	Type	Section	Appendix	Status	Delete	Copy
1	-	Other	-	Sections (0)	Attachments (0)	Work in Progress	X	D

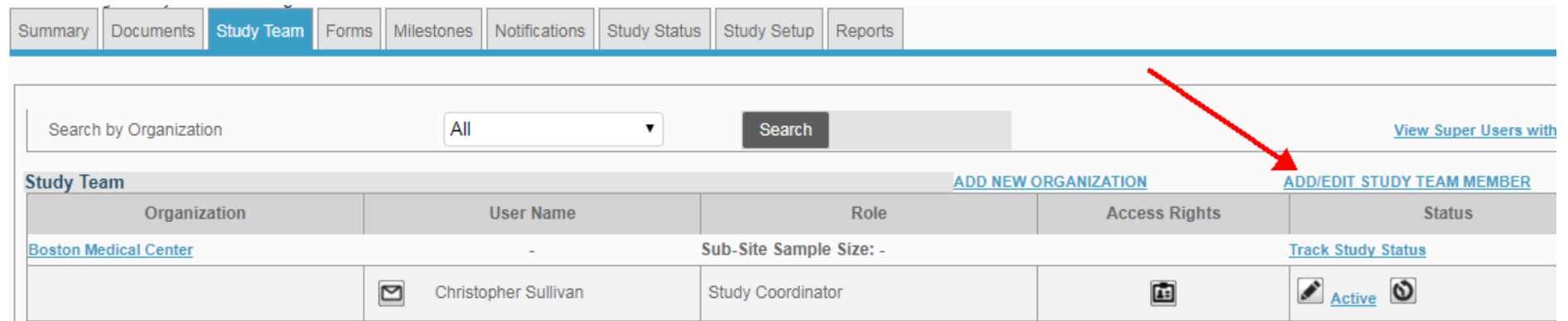
1 to 1 of 1 Record(s)

Upload Documents (cont'd)

- Mandatory fields include Version Number, Category, File (browse) and description
- E-sign and submit when you have uploaded your file and filled in the mandatory fields
- There will always be a Version 1 in category Other that exists with no document attached, feel free to delete this version after you have uploaded another document

Add Users to the Study Team

- Click on the Study Team tab within your study
- The study team will already include Study Creator (Study Entered by), the Principal Investigator (PI) and the Study Contact (Study Coordinator)
- If you need to add additional users that you want to have access to this study click on the [ADD/EDIT STUDY TEAM MEMBER](#) link



Summary Documents **Study Team** Forms Milestones Notifications Study Status Study Setup Reports

Search by Organization: All Search [View Super Users with](#)

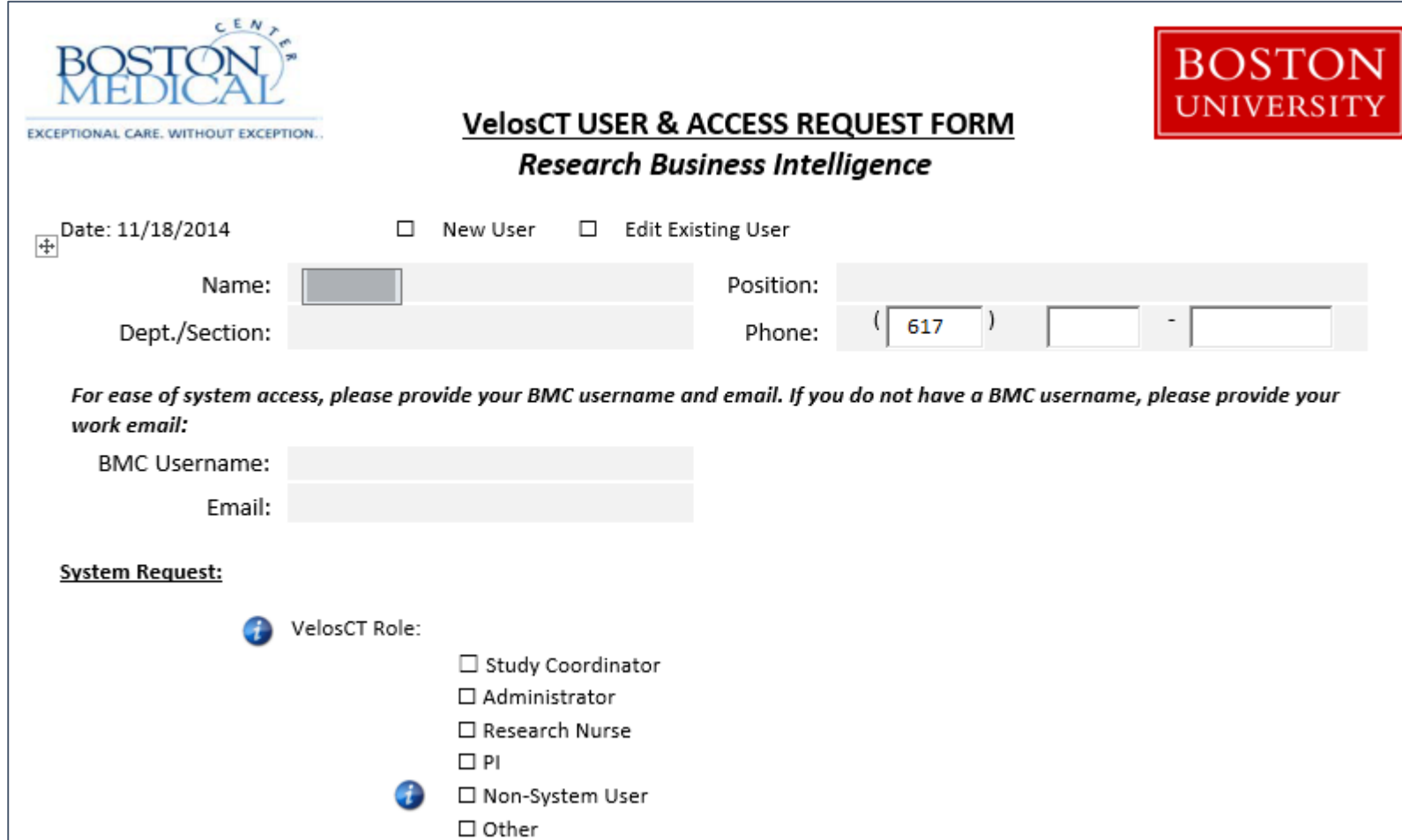
Study Team [ADD NEW ORGANIZATION](#) [ADD/EDIT STUDY TEAM MEMBER](#)

Organization	User Name	Role	Access Rights	Status
Boston Medical Center	-	Sub-Site Sample Size: -		Track Study Status
	Christopher Sullivan	Study Coordinator		Active

- You can search for current users by Name, Organization, Group or Job Type
- Once you find your user click the select box, assign them a role, e-sign and submit

Add Users to the Study Team

- If user does not exist please fill out the [New User Request Form](#), if your study team member will not be using the system, please use the add a non-system user form found on VelosCT forms tab



The screenshot shows the "VelosCT USER & ACCESS REQUEST FORM" for "Research Business Intelligence". The form includes a date field (11/18/2014), checkboxes for "New User" and "Edit Existing User", and input fields for Name, Position, Dept./Section, and Phone. A note asks for BMC username and email. The "System Request" section includes a "VelosCT Role" dropdown and checkboxes for Study Coordinator, Administrator, Research Nurse, PI, Non-System User, and Other.

BOSTON MEDICAL CENTER
EXCEPTIONAL CARE. WITHOUT EXCEPTION.

VELOSCT USER & ACCESS REQUEST FORM
Research Business Intelligence

BOSTON UNIVERSITY

Date: 11/18/2014 New User Edit Existing User

Name: Position:

Dept./Section: Phone: (617) -

For ease of system access, please provide your BMC username and email. If you do not have a BMC username, please provide your work email:

BMC Username:

Email:

System Request:

VelosCT Role:

- Study Coordinator
- Administrator
- Research Nurse
- PI
- Non-System User
- Other

Add Non System Users to the Study Team

- For study team members who will not be using VelosCT, but are members of Study Team (for example, PI), please use the add a non-system user form found on VelosCT forms tab. These non system users will be able to run reports on their studies through Lawson.

you are working on study: H-35669


Summary Documents Study Team **Forms** Milestones Notifications Study Status Study Setup Reports

Form Name: Add New Sponsor

Previous entries

- Add New Sponsor
- Add Sub-site (Organization) in VelosCT
- Amendment & Continuing Review Submission Form
- CTO Notes
- Invoice Contact Information
- Link VelosCT Study to INSPIR-II Protocol
- SDK Carrier Code Request (BU Managed Study only)
- Study Initiation eForm
- Study Team (Non-System User) Member Request**

No Records Found



Complete Study Initiation eForm

- Click on the forms tab to get to the available forms
- Choose Study Initiation eForm
- Click New and the form will appear

You are working on study: n-35669


Summary Documents Study Team **Forms** Milestones Notifications Study Status Study Setup Reports

Form Name: Add New Sponsor

Previous entries

- Add New Sponsor
- Add Sub-site (Organization) in VelosCT
- Amendment & Continuing Review Submission Form
- CTO Notes
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- Study Initiation eForm**
- Study Team (Non-System User) Member Request

No Records Found



Complete Study Initiation eForm

- Data entry date will default to today's date
- Enter any sub-site information that is applicable to your study
- You can enter CPT codes and procedures for your study if you have them, this information is helpful for your CTFA to complete their budgeting and analysis
- If you have additional information that does not fit on the form, please contact your CTFA directly
- Form status will be marked as completed and e-sign and submit, **this will send a notification to the CTO Inbox (CTO@bmc.org)**

VelosCT

Participant Enrollment and Visit Management

Brief Overview-CTO Responsibilities

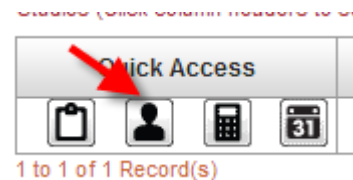
- Once Study team has created the shell, the CTO will be responsible for the Study Setup, which involves:
 - Medicare coverage analysis
 - Budget negotiation or provide pricing for clinical services
 - Informed consent form review of Cost and Injury language
 - Agreement execution and account setup
 - Final VelosCT calendar, budget, and invoice milestones setup
 - Final study setup in Epic for Epic-VelosCT interface – if necessary for research billing review

Training Overview-Patient Information

- Search for your existing study
- Search for participants to your study
- Add a Patient Study Status
- Update a Patient Schedule
- Add an Unscheduled Event
- Using the Schedule Tab
- Using the Enrolled Patient Tab

Search for an Existing Study

- Once the study calendar that the CTFA has created has been made Active and the Study Status is Active you can begin to add participants to the study
- Start by clicking Manage->Studies->Search
- You can search by the IRB protocol # or Study Title (using all or part of the title will work)
- If the study is Active/Enrolling you will see the Patient Icon under Quick Access on the left side of the screen
- You can click on the Icon to Search for participants to your study
- Within a study you can also click on the Study Setup tab to see a list of associated calendars, and click on the link of the calendar name
- Clicking on the Coverage Analysis tab will give you an exportable grid of the study calendar created by the CTO



Search for an Existing Study

Personalize | Manage | Libraries | Reporting | Study #, Title or Keyword | Sandy Lok | | |

Current Page: Velos eResearch >> Homepage

Search a Study [Advanced Search](#) Account Forms

Last Modified Studies

Quick Access	IRB Protocol #	Study Title	Study Status
	H-35673	Testing IRB Interface for automated INSP	Exempt
	ABC123	20170202 TEST IRB Protocol Initiation fo	Expired
	VelosTest16Aug	This is a velos Test Study to Test IRB I	Approved / Open - Full Board
	VelosCT MCA/Determination Inventory	New MCA Determinations Report formatted	Temporarily Inactive/ On-Hold
	H-12345	A Randomized, Double-Dummy	New IRB Protocol Application Requested via Interface

My Links	Quick Links
	- BMC Internal Website
	CITI Training
	ClinicalTrials.gov
	Country-specific clinical research regulatory info
	FDA

Search for Participants to a Study

- Please make sure your study calendar is active before searching for a new participant
- You should always use the search function as a look up to see if your study participant already has a record in VelosCT
- Best Practice to avoid duplication is to start on the Enrolled tab which will show you participants currently on your study. Please make sure to check here to see if your participant is already enrolled
- The Patient Search tab will allow you to search for existing participants in VelosCT
- If you find your participant, click on the Patient ID. This will bring you to the protocols tab where you select the study to enroll them on (click Submit to save)
- This will cause a Patient Study Status window to pop-up. Make sure to fill in all required fields (denoted with *). Patient Study ID will default to the VelosCT ID. Please update that field with your study specific ID number (if required by sponsor)
- E-sign and submit to be brought back to the Protocols tab
- Click on the [Schedule](#) link, then click [Edit Calendar/Date](#), associate the appropriate calendar, pick a start date and e-sign and submit
- You will now see your participant schedule on the Protocol Tab

First check enrolled tab to make sure they are not on study

Personalize | Manage | Libraries | Data Extraction

Current Page: Manage Patients => Study Patients

Training A | Home | Help | Logout

Patient Search | **Enrolled** | Schedule

Existing Patients on Study

Search By

Patients on Study: TrainingAA | Organization: All | Last Visit: |

VelosCT ID/Patient ID: | Enrolled: All | Next Visit: All |

Patient Study ID: | Patient Status: All | Exclude Patients not currently Enrolled | Search

Enter Screening/Enrollment details | [SELECT AN EXISTING PATIENT](#) | [ADD A NEW PATIENT](#)




Current Page: 1 | Total Pages: 2 | Rows Per Page: | Showing 1 - 13 of 20

Study Number	VelosCT 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	Physici
TrainingAA	VCT-39	Boston Medical Center	VCT-39	Harry	Jones	02/17/2016	Visit 3	02/19/2017		Enrolled	Etien Kroi	Enrolled		
TrainingAA	sponsor 333	Boston Medical Center	sponsor 222	AOFOURNEOOE	AMBITTWO	05/12/2015		05/04/2015		On-Intervention	Training A	On-Intervention		
TrainingAA	4000148	Boston Medical Center	4000148	SAMONE	TESTSAM	04/30/2015	Visit 0	05/01/2015		Enrolled	Training A	Enrolled		
TrainingAA	123456	Boston Medical Center	123456	BMC	Test	08/14/2015				Enrolled	Training A	Enrolled		
TrainingAA	4325447689	Boston Medical Center	sponsor 123	COFOURNEOOE	BRUCI			02/17/2016		Consented		Consented		

Go Patient Search tab and enter information to search

- VelosCT ID / Patient ID – can search by Medical Record Number (MRN)
- Patient Name – can search by last,first name

Personalize | Manage | Libraries | Data Extraction

Training A |  |  | 

Current Page: Manage Patients >> Patient Search

Patient Search | Enrolled | Schedule













Search By

VelosCT ID/Patient ID: Age: All Organization: All


Patient Name: Gender: Select an option Specialty: Select an option

Survival Status: Select an option Study: All Provider: **Search**

Current Page: 1 | Total Pages: 22 | Rows Per Page: | Showing 1 - 13 of 281

VelosCT ID	First Name	Last Name	Age	Gender	Patient Status	Other ID(s)	On a Study	Delete
 11122222	Test	Test	17 Years	Male	Alive		Yes (3)   FORM	
 1234			1 Years	Not Specified	Alive		Yes (1)   FORM	
 123456	BMC	Test	35 Years	Female	Alive		Yes (7)   FORM	


This shows all patients in VelosCT. If patient does not appear in search results, click “Continue to search in EMR”


Personalize | Manage | Libraries | Data Extraction Training A |  |  | 

Current Page: Manage Patients >> Patient Search



Patient Search | **Enrolled** | Schedule





Search By












VelosCT ID/Patient ID:  Age: Organization:

Patient Name:  Gender: Specialty:

Survival Status: Study: Provider:



 Current Page: Total Pages: 1



 Rows Per Page
Showing 1 - 5 of 5   

VelosCT ID	First Name	Last Name	Age	Gender	Patient Status	Other ID(s)	On a Study	Delete
 TrainingAAA	MICHELLE	SMITH	47 Years	Female	Alive		No   FORM	
 VCT-0000256	JOYCE	SMITH	52 Years	Female	Alive		No   FORM	
 VCT-0000257	CHRISTINE	SMITH	52 Years	Female	Alive		No   FORM	
 VCT-0000258	DELIA	SMITHDAVIS	66 Years	Female	Alive		Yes (1)   FORM	
 VCT-0000263	KALDA	SMITH	66 Years	Female	Alive		Yes (1)   FORM	

Select a study to add the participant to

Personalize | Manage | Libraries | Data Extraction

Training A |  |  | 

Current Page: Manage Patient >> Protocols

Demographics | **Protocols** | Reports | Appendix

VelosCT ID: VCT-0000256 Age: 52 years Gender: Female Pat.Name: JOYCE SMITH Org: Boston Medical Center

To screen/enroll this patient in a new study, select Study and Patient Organization:

This patient has been associated to the following studies:

IRB Protocol #	Study Title	Study Team Contact	Enrolled On	Last Visit	Done On	Next Visit	Patient Status
TrainingAA	Test Study for VelosCT user Training	Dean Robinson	-	-	-	-	 Consented  Forms

Patient Study Status Pop Up

VelosCT ID/Patient ID: VCT-0000256 IRB Protocol #: h1234

Patient Study Status

Status *

Reason

Status Date *

This is patient's current status in this study

Study Action Plan/Description

Informed Consent Details

Informed Consent Version Number

Additional Information

Patient Study ID *

Enrolling Site

Assigned To [Select User](#)

Physician [Select User](#)

Treatment Location

Treating Organization

Disease Code

Other Disease Code

Update a Patient Schedule

- Once a patient status is set to enrolled you are ready to update their schedule
- Under the Protocols tab, click the [Schedule](#) link
- You will see all the visits with a suggested date and a scheduled date pre-populated
- Clicking on the visit row will open it up for editing
- This is where you can edit the scheduled date and edit the visit
- There are four options to choose when you edit a date, choose the option that best fits your scenario
- Click on the [Edit Visit](#) link to edit the entire visit
- Select Done and click apply to all and all events in that visit will be marked as done

Select schedule link and edit calendar/date to associate a calendar

Personalize | Manage | Libraries | Data Extraction

Training A |  |  | 


Current Page: Manage Patient >> Schedule

Demographics | Protocols | Reports | Appendix

VelosCT ID: VCT-0000256 Pt. Study ID: VCT-0000256 Age: 52 years Gender: Female Pat.Name: JOYCE SMITH Org: Boston Medical Center

Patient is not yet 'Enrolled'.

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

Study #: [h1234](#)  Calendar: No Associated Calendar Pat.Start Date: Schedule:
[Edit Calendar/Date](#) | [View Previous](#) | [Delete Schedule](#)

This patient has not been assigned to a Study Calendar.

Associate a calendar and participant start date

*If this is a new participant starting at the first visit, select the first radio button

Treatment Details

If this is a new study or a new participant starting at the first visit of a study select the first radio button

The following fields must be filled in order to generate a schedule for the patient and track events.

Study Calendar

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](#)

Selected Visit

Valid e-Sign e-Signature *

Associate a calendar and participant start date – if this is an existing study and participant, select the next scheduled visit

Treatment Details

If this participant has already completed some visits, select the next visit for this participant from the drop down list.

The following fields must be filled in order to generate a schedule for the patient and track events.

Study Calendar
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

Selected Visit
[Read Only]

e-Signature *

Here you can edit multiple visits

Personalize | Manage | Libraries | Data Extraction

Training A | | |

Current Page: Manage Patient >> Schedule

Demographics | **Protocols** | Reports | Appendix

VelosCT ID: VCT-0000256 Pt. Study ID: Sponsor123 Age: 52 years Gender: Female Pat.Name: JOYCE SMITH Org: Boston Medical Center

Patient is not yet 'Enrolled'.

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

Study #: **TrainingAA** Calendar: 10.22.2014 Pat.Start Date: 02/17/2016 Schedule: **Current**

[Edit Calendar/Date](#) | [View Previous](#) | [Delete Schedule](#)

Select Schedule: 10.22.2014, 02/17/2016 Visit: All

[Edit Multiple Events](#)

click on grey to see events and dates and edit dates or check off events

February 2016 Visit	Suggested Date	Scheduled Date	Visit Window
▶ Visit 0	02/17/2016	02/17/2016	
▶ Visit 1	02/18/2016	02/18/2016	
August 2016 Visit	Suggested Date	Scheduled Date	Visit Window
▶ Visit 2	08/18/2016	08/18/2016	
February 2017 Visit	Suggested Date	Scheduled Date	Visit Window
▶ Visit 3	02/18/2017	02/18/2017	
▶ Visit 4	02/19/2017	02/19/2017	

Here you can edit visit – Do not add unscheduled visit, contact CTO

Personalize | Manage | Libraries | Data Extraction

Training A |  |  | 


Current Page: [Manage Patient >> Schedule](#)

Demographics | Protocols | Reports | Appendix

VelosCT ID: VCT-0000256 Pt. Study ID: Sponsor123 Age: 52 years Gender: Female Pat.Name: JOYCE SMITH Org: Boston Medical Center

Patient is not yet 'Enrolled'.

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

Study #: [TrainingAA](#)  Calendar: 10.22.2014 Pat.Start Date: 02/17/2016 Schedule: Current

[Edit Calendar/Date](#) | [View Previous](#) | [Delete Schedule](#)

Select Schedule: Visit: 

[Edit Multiple Events](#)

February 2016 Visit	Suggested Date	Scheduled Date	Visit Window
Visit 0	02/17/2016	02/17/2016	

[Edit Visit](#) [Add Unscheduled Event](#)

Suggested Date	Scheduled Date	Event Window	Event	Event Status	Linked Forms	Site of Service	Coverage Type ?	Additional Information
02/17/2016	02/17/2016	-	Informed Consent	Not done	No CRF	-	SP	
02/17/2016	02/17/2016	-	Demographics	Not done	No CRF	-	SP	
02/17/2016	02/17/2016	-	Medical History	Not done	No CRF	-	SP	
02/17/2016	02/17/2016	-	Prior and Concomitant Medications	Not done	No CRF	-	SP	
02/17/2016	02/17/2016	-	Physical Exam	Not done	No CRF	-	SOC	

Visit 1	Suggested Date	Scheduled Date	Visit Window
	02/18/2016	02/18/2016	

August 2016 Visit	Suggested Date	Scheduled Date	Visit Window
Visit 2	08/18/2016	08/18/2016	

Here you can check events as done for the visits

Edit Visit ✕

Visit Name: Visit 0

Status: Select an option ▼ Status Date: 02/17/2016 Apply To: All or Selected

	Edit	Status	Status Date*	Coverage Type ?	Reason for Change in Coverage Type
<input type="checkbox"/>	Informed Consent	Not done	<input type="text"/>	SP	<input type="text"/>
<input type="checkbox"/>	Demographics	Not done	<input type="text"/>	SP	<input type="text"/>
<input type="checkbox"/>	Medical History	Not done	<input type="text"/>	SP	<input type="text"/>
<input type="checkbox"/>	Prior and Concomitant Medications	Not done	<input type="text"/>	SP	<input type="text"/>
<input type="checkbox"/>	Physical Exam	Not done	<input type="text"/>	SOC	<input type="text"/>
<input type="checkbox"/>	Inguinal Node Exam	Not done	<input type="text"/>	SP	<input type="text"/>
<input type="checkbox"/>	CBC w/diff	Not done	<input type="text"/>	SOC	<input type="text"/>
<input type="checkbox"/>	Anal Cytology	Not done	<input type="text"/>	SOC	<input type="text"/>

Reason For Change (FDA Audit)

e-Signature*

Submit
Close

Add an Unscheduled Event

- Inside a patient schedule and in a visit, the CTO will have the option to add an unscheduled event
- If you need an event added that does not exist, please contact your CTFA and give them the required information. This includes: procedure name, CPT code, and price
- CTFA will let you know when event is added so that you can mark it as done appropriately

Patient Study Status

- When you add a new participant you must select a Patient Study Status
- Generally the initial status will be Consented, patient will need to be set to Enrolled status to update their schedule
- You can change the status as required by your team for tracking purposes
- You change the status by clicking on the edit icon under the Most Recent Status column for the patient row or by using the [Screening/Enrollment link](#) on the Protocols tab and then clicking the [Add New Status](#) link
- For a list of what each patient status means please see the appendix

Patient Study Status

Personalize | Manage | Libraries | Data Extraction

Current Page: Manage Patients => Study Patients

Training A | Home | Help | Logout

Patient Search: **Enrolled** | Schedule

Existing Patients on Study

Patient Study Status

Search By

Patients on Study: TrainingAA | Organization: All | Last Visit: |

VelosCT ID/Patient ID: | Enrolled: All | Next Visit: A |

Patient Study ID: | Patient Status: All | Exclude Patients not currently Enrolled | Search

Enter Screening/Enrollment details **SELECT AN EXISTING PATIENT** **ADD A NEW PATIENT**

Current Page: 1 | Total Pages: 2 | Rows Per Page: | Showing 1 - 13 of 20

Study Number	VelosCT 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
TrainingAA	VCT-39	Boston Medical Center	VCT-39	Harry	Jones	02/17/2016	Visit 3	02/19/2017		Enrolled	Etien Kroi	Enrolled		
TrainingAA	sponsor 333	Boston Medical Center	sponsor 222	AOFOURNEOOE	AMBITTWO	05/12/2015		05/04/2015		On-Intervention	Training A	On-Intervention		
TrainingAA	4000148	Boston Medical Center	4000148	SAMONE	TESTSAM	04/30/2015	Visit 0	05/01/2015		Enrolled	Training A	Enrolled		
TrainingAA	123456	Boston Medical Center	123456	BMC	Test	08/14/2015				Enrolled	Training A	Enrolled		
TrainingAA	4325447689	Boston Medical Center	sponsor 123	COFOURNEOOE	BRUCI			02/17/2016		Consented		Consented		

Using the Schedule Tab

- Start by clicking Manage->Patients->Schedule
- This will bring you to the Schedule tab within Patients
- This gives you a helpful view of all your participants currently on your studies with upcoming visits scheduled
- You can update patient status, visit status or click on the Pt. Study ID link to manage the patient schedule
- You can also export this list to excel using the excel icon to the far right of your screen



Using the Enrolled Patient Tab

- When you click on the patient icon you are brought to the enrolled tab
- This gives you a list of all patients associated with that particular study
- There are filter options on the top of the page that you may choose and then click search to see the results, for example you may want to see all patients who are currently in a particular status
- You can also customize the fields that show up on the header by right clicking on the header and checking or unchecking fields you do not need
- These results can also be exported to excel for report purposes

Roles and Responsibilities-Review

Study Team

- Enter all new studies, including study summary, more study details, study team and upload documents
- Fill out the study summary form, will trigger CTO that study is entered
- Maintain versions of documents
- Enter and track participant schedules, events and information
- Run reports as needed

Clinical Trial Office

- Update study status when appropriate
- Create study calendars, coverage analysis, budgets and milestones
- Invoice sponsors based on milestones
- Manage research billing review based on data in VelosCT
- Provide study team with support as needed

General Contact Info

Clinical Trial Office ([CTO](#))

Johanna Chesley – CTO Director

Michael Porreca – CTO Manager

Sandy Lok – Sr. Clinical Trial Financial Analyst

Minhao Yin – Sr. Clinical Trial Financial Analyst

Amruta Khedekar – Clinical Trial Financial Analyst

Simonia Belnavis – CTO Accountant

Fernanda Fortes – Clinical Trials Billing Coordinator

Bryant Shields – Billing Compliance Specialist

CTO Inbox – CTO@bmc.org (for all inquiries if unsure who to contact)

Research Business Intelligence ([RBI](#))

Christopher Sullivan – RBI Manager

Sheril Fnu – Research Data Analyst

Saloney Chhajer – Business Analyst

Michael Neuman – Data Analyst

RBI Inbox – RBI@bmc.org (for all inquiries if unsure who to contact)

**Please inform RBI of additional Study Team members within your department that require VelosCT training.*

Appendix

Study Status

- Active/Closed to Enrollment: In follow-up or data analysis
- Active/Enrolling: Ready to Enroll Patients
- Pending Activation: Activation requirements not yet met (IRB approval, contract execution, etc)
- Inactive/On Hold: Temporarily closed (Suspended, expired, etc)
- Closed: Completely closed through IRB

Patient Status

- Consented: Participant/Proxy signed consent form
- Ineligible: Participant successfully Screened but later determined to be ineligible for study
- Enrolled: Participant has been enrolled on study and schedule is ready to be updated
- Screen Failure: Participant Screened and determined ineligible for study
- On-Intervention: Active participant receiving research based treatment/tests
- Completed: Participant met “completed” requirements for study
- Expired: Participant passed away before completion of study
- In Follow-Up: Participant still active on research, not receiving study intervention
- Lost to Follow-Up: Eligible participant, unable to contact
- Terminated: Removed from study for reason other than completion, death or withdrawal
- Transferred Care to Another Institution: Active/Enrolled participant was transferred to another institution and is dis-enrolled from study at this site
- Withdrew Consent: After withdrawing, participant is now dis-enrolled from study

Role Definitions

- Principal Investigator: PI of study, access to study administration, patient management and forms
- Study Coordinator: Access to study administration, patient management and forms
- Study Creator: Individual who enters a study in, VelosCT access to study administration, patient management and forms
- Financial Administrator/Manager: Access to study administration, patient management and forms
- Study Co-Investigator, Study Assistant, Research Nurse, Technician, Regulatory Coordinator, Statistician, Data Manager: View only, or non-system user