



VelosCT Training Slides



What is VelosCT?

- VelosCT is a Clinical Trial Management System (CTMS)
- It will connect financial, administrative and clinical research activities
- The product links study status, participant enrollment, calendars, budgets, and participant status
 - These activities are required 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.
 - We want to invoice sponsors automatically and timely



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 enter the built-out study calendar with 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, associated to calendars and visits checked off in VelosCT within 2 business days of when they occur.



What studies will you enter?

- **All New studies must complete [MCA/VelosCT Determination Checklist](#) to determine if they require an MCA and entry into VelosCT.**
- All studies that have hospital services will be entered in VelosCT
- This includes all BMC studies and BU studies that have patient care associated with them utilizing BMC clinical resources, regardless of sponsor type (Corporate, Federal, Foundation..)
- If you know your study belongs in Velos, you do not need to do the MCA/VelosCT Determination form, you can just begin entering study directly in VelosCT.

MCA/VelosCT Determination Checklist

Protocol #:

Protocol Title:

Sponsor:

PI:

Entered By (if not PI):

Your E-mail:

Managing Institution:

Section I: Please indicate if your study falls into any of the following categories (check all that apply):

- Quality of Life (QOL) survey studies
- Retrospective (chart review) studies
- Outcomes research (e.g. clinical effectiveness of treatments to improve healthcare outcomes)
- Tissue/Specimen Collection-only studies
- Blood Draw studies [when BMC clinical infrastructure is not utilized AND the hospital billing system is not used for the bill of the blood draw]
- Observational studies (e.g. assess risk factors for disease development or progression, trends for clinical care and treatment in the absence of specific study-mandated interventions)
- Expanded Access/Compassionate Use/Emergency Use protocols
- Single Patient INDs
- Humanitarian Device Exemptions and Humanitarian Use Devices
- Not Applicable (this project will not utilize any BMC clinical infrastructure)

Section II: Please indicate on the following list if your study uses any BMC clinical services or infrastructure:

- Investigational Pharmacy Service (For study drug maintenance and dispensation. Follow IPS policy. No offsite study drug storage allowed.)
- Investigational Device (IDE) implants
- Infusion services
- Radiology (e.g. MRI, CT/PET/MUGA Scans)
- Pathology (e.g. Histology Slides)
- Lab Medicine (Processing or Providing Analysis of blood/tissue samples)
- Cardiology (e.g. EKGs)
- Ophthalmology (e.g. Retinal Exams)
- Performing Physical Exam in BMC clinical space
- Drawing Blood in BMC clinical space
- Other (please specify):
- I'm unsure how to answer. Please contact me.

Please indicate if you will be submitting charges through SDK and/or GE:

- Yes No

Note:

- If you placed an "X" in just the red boxes, the study will not require entry in VelosCT at this time.
- If you placed an "X" in any of the green boxes and indicate you will be entering charges in SDK and/or GE, please initiate the study entry in [VelosCT](#) (see VelosCT Training material and videos available online at <http://internal.bmc.org/grants/ClinicalTrials.html> for further guidance.) In addition, an SDK Research Carrier will be requested by the CTO.


Additional Information & Questions:

Once submitted, the request is automatically e-mailed to the BMC Clinical Trial Office (CTO@BMC.org). A Clinical Trial Financial Analyst will be in contact with you on next steps, as applicable.

Send Request To:

[Submit MCA/Velos Determination Checklist](#)

Login Information

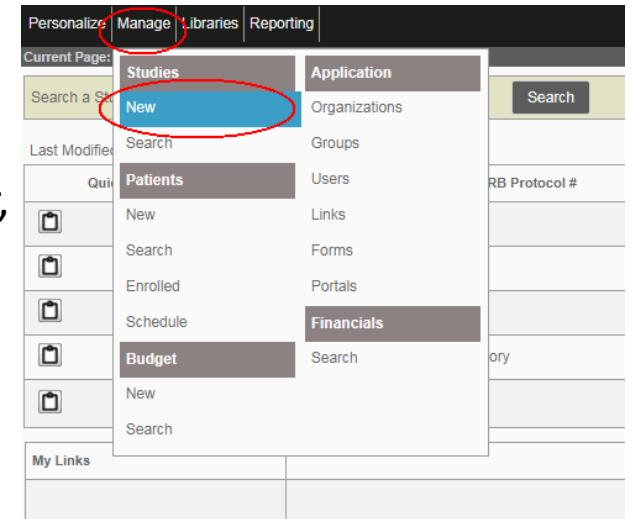
- Make sure that you are in <https://bmc.velosresearch.com/velos/jsp/ereslogin.jsp> and not bmctest.velosresearch.com
 - Your VelosCT username and password will be the same as your BMC username and password
 - Email RBI@bmc.org for system access and user setup/permission questions.
- 
- For study specific 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, 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 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

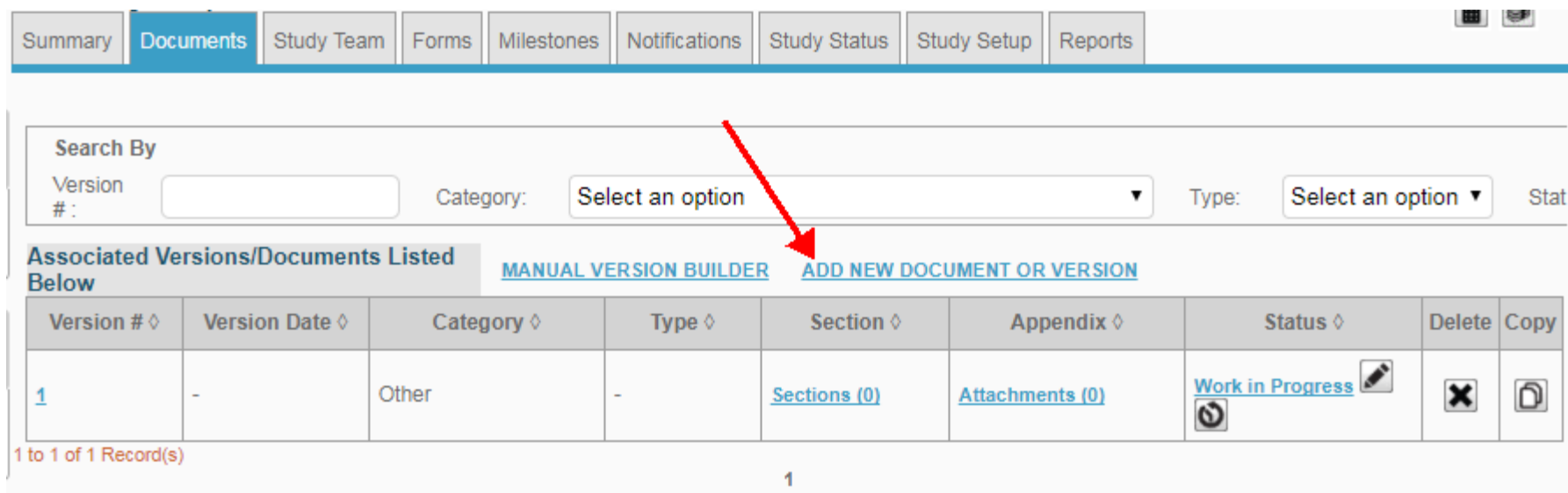
More Study Details

- Please note the reminder to complete the Study Initiation e-form
 - This e-form 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 displays the VelosCT interface with the 'Documents' tab selected. The navigation bar includes 'Summary', 'Documents', 'Study Team', 'Forms', 'Milestones', 'Notifications', 'Study Status', 'Study Setup', and 'Reports'. Below the navigation bar, there is a search section with 'Search By' options for 'Version #', 'Category', 'Type', and 'Stat'. The 'Associated Versions/Documents Listed Below' section contains two links: 'MANUAL VERSION BUILDER' and 'ADD NEW DOCUMENT OR VERSION'. A table below these links shows one record with the following details:

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

At the bottom of the table, it indicates '1 to 1 of 1 Record(s)' and a page number '1'. A red arrow points to the 'ADD NEW DOCUMENT OR VERSION' link.



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

BOSTON MEDICAL CENTER
EXCEPTIONAL CARE. WITHOUT EXCEPTION.

BOSTON UNIVERSITY

VelosCT USER & ACCESS REQUEST FORM
Research Business Intelligence

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

Name: Position:

Dept./Section: Phone: () -

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, 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 New

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**

Search

No Records Found



VelosCT

Participant Enrollment and Visit Management

Brief Overview-CTO Responsibilities

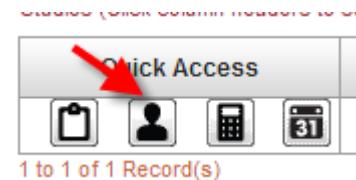
- Once Study team has created the shell, the CTO will be responsible for the Study Setup, which involves translating and building the study calendar, budget and milestones info into VelosCT from the documents the study team provides
- The first step is to associate a calendar with the study
- Calendars are saved as templates in VelosCT and can be associated with different studies and then modified for each particular study
- The calendar will be built to match the table of events in the protocol
- Once the calendar is associated the CTFA names it (define the calendar), imports events from the event library (select events) and enters the number of visits and the time points in which they will occur (manage visits)
- The Event Visit Grid will represent the events and visits that were defined, the CTFA can then select in which visits each event occurs
- The CTFA will also complete the coverage analysis and define the milestones
- The study team will have view only access to the study setup screens

Training Overview-Patient Information

- Search for your existing Study
- Add an existing participant to your Study
- Add a new participant to your Study
- 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 or Add participants to your study
- Within a study you can also click on the Study Setup tab to see a list of associated calendars, 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 |

Add an Existing Participant To a Study

- Please make sure your study calendar is active before entering 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, in the beginning there will not be any participant information but as participants get added to studies their demographics will be saved for future use
- 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 and click submit
- This will pop-up a Patient Study Status window, fill in all required fields. Patient Study ID will default to the Patient ID, please update that field with your study specific ID number (usually provided 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

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: 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 not here, go on to search 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 chose 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: Visit: 

[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 | | 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, 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 often or not as is 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
- Provide study team with support as needed

General Contact Info

Clinical Trial Office ([CTO](#))

[Kati Cini](#) – Associate Director, CTO

[Cara Martinoli](#) – Clinical Research Attorney

[Doug Finnegan](#) – Sr. Financial Analyst

[Sandy Lok](#) – Sr. Financial Analyst

[Michael Porreca](#) – Sr. Financial Analyst

[Roberto Cabrera](#) - Financial Analyst

Research Business Intelligence ([RBI](#))

[Christopher Sullivan](#) – Manager RBI

Fnu.Sheril@bmc.org – Research Data Analyst

RBI@bmc.org - General RBI Inbox

**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