

# VelosCT Basics Training Slides 2022

# 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 and status, calendars, and budgets to ensure compliant billing to Medicare/third party payers
- Other capabilities include budgeting, milestones, billing, protocol management, participant recruitment & management, reporting, etc.

# What does this mean for me?

- VelosCT will allow you to enter data and upload documents that the Clinical Trial Office (CTO) requires 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, visit/event tracking, data entry, 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 studies managed by CTO will be entered in VelosCT.
- All studies that have hospital services will also be entered in VelosCT. If BMC infrastructure and/or clinical services are utilized, the study will need to be in VelosCT.
- This applies to the study regardless of:
  - Funding source – Industry or Federal
  - Study management – BMC or BU
  - Study type – Clinical Trial, Grant, etc.

**Note: All New studies must include the submission of the [CTO Intake Form](#)**

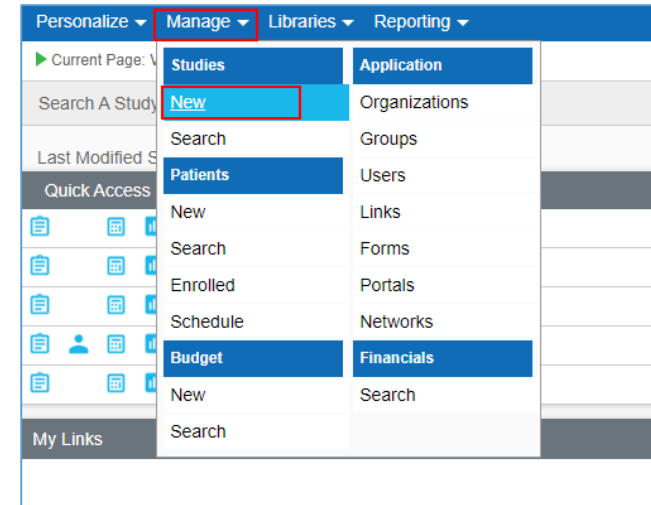
# Login Information

- To start the VelosCT Basics training, please continue watching the VelosCT training videos and log into the VelosCT test site at <https://bmctest.velosresearch.com/velos/jsp/ereslogin.jsp>
- Contact [CTO@bmc.org](mailto:CTO@bmc.org) to be assigned a training username and password to access the VelosCT test site, and test study to complete your training
- For study specific questions, please contact your department-assigned financial analyst (CTFA) or [CTO@bmc.org](mailto:CTO@bmc.org)
- VelosCT training materials, including the VelosCT User Access Request Form, are available on the Clinical Trial Office website at: <https://www.bmc.org/research-operations/clinical-trial-office>

# 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, RIS, etc.) will also use 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 the study protocol or nickname”
- “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?

Select an option ▼

Funder (If not same as Sponsor)

FDAAA registration required?

Select an option ▼

Study Initiated by Sponsor or PI?

Select an option ▼

FCOI PI Attestation Date:

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

Select an option ▼

- 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:

☐

☐

☐

No ▼

☐

☐

Sponsor expects to receive:

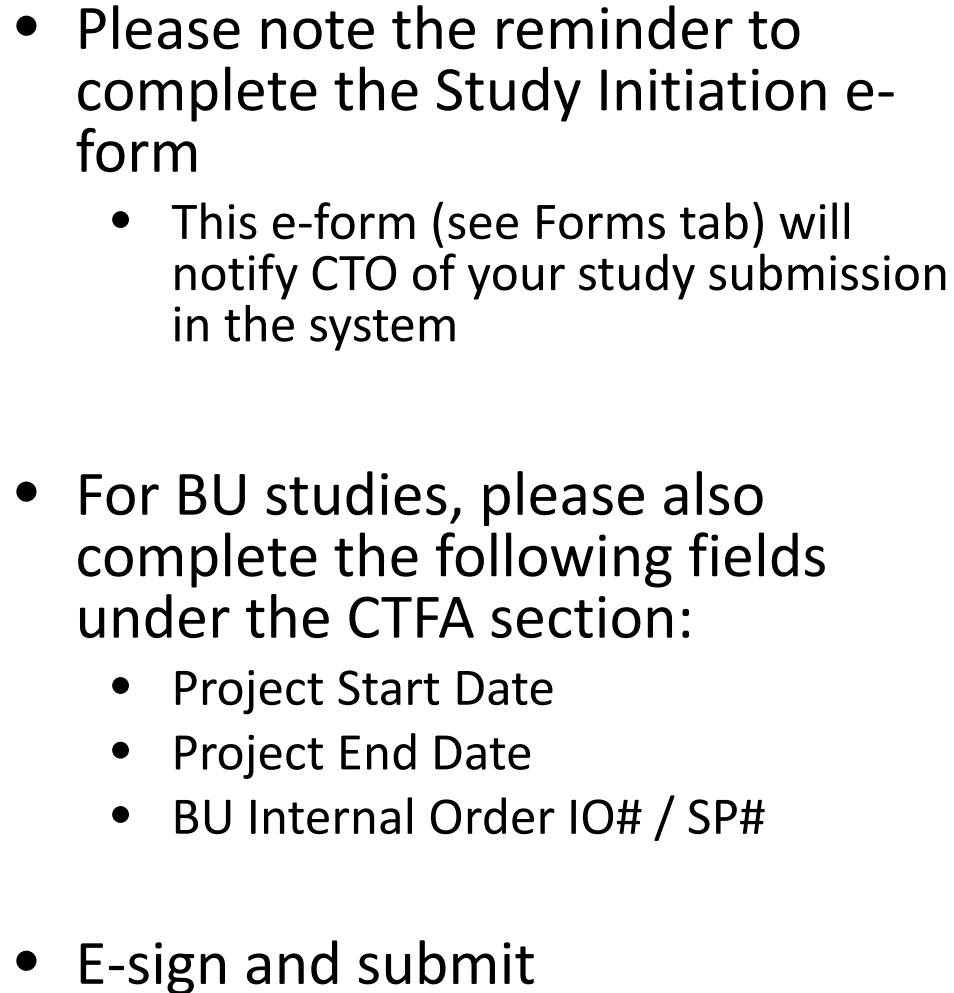
Select an option ▼

Participant Compensation:

☐

- If simple, please explain; otherwise contact CTFA



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# 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

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

Search By

Version #:  Category:  Type:  Status:

Associated Versions/Documents Listed Below

[ADD NEW VERSION](#) [ADD NEW VERSION/DOCUMENT](#)

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

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

Organization	User Name	Role	Access Rights	Status	Delete
Boston Medical Center	-	Local Sample Size: -		Track Study Status	
	Training L	Study Creator		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

  
EXCEPTIONAL CARE. WITHOUT EXCEPTION.

**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:

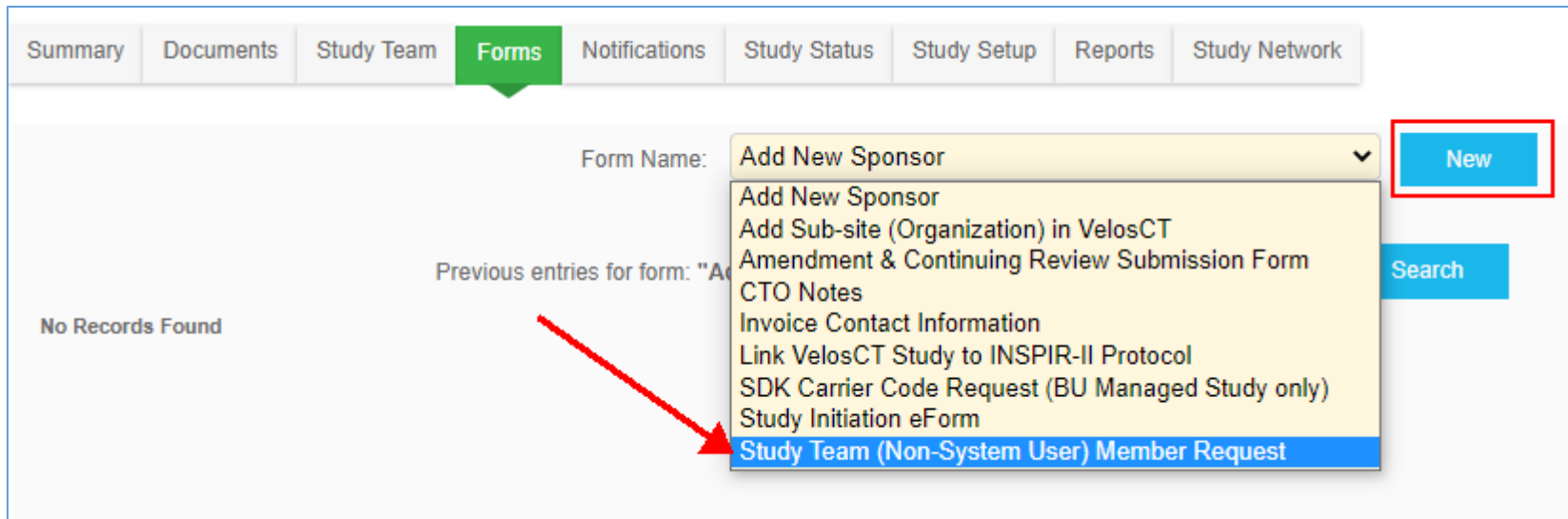
**System Request:**

 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 (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.



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

Form Name: Add New Sponsor

Previous entries for form: "A"

No Records Found

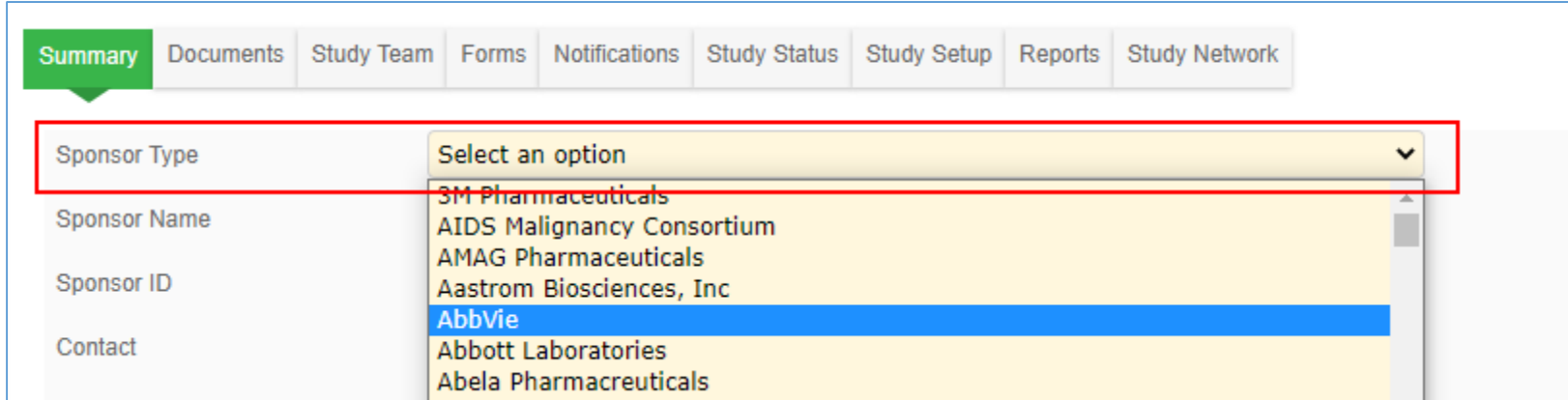
Study Team (Non-System User) Member Request

New

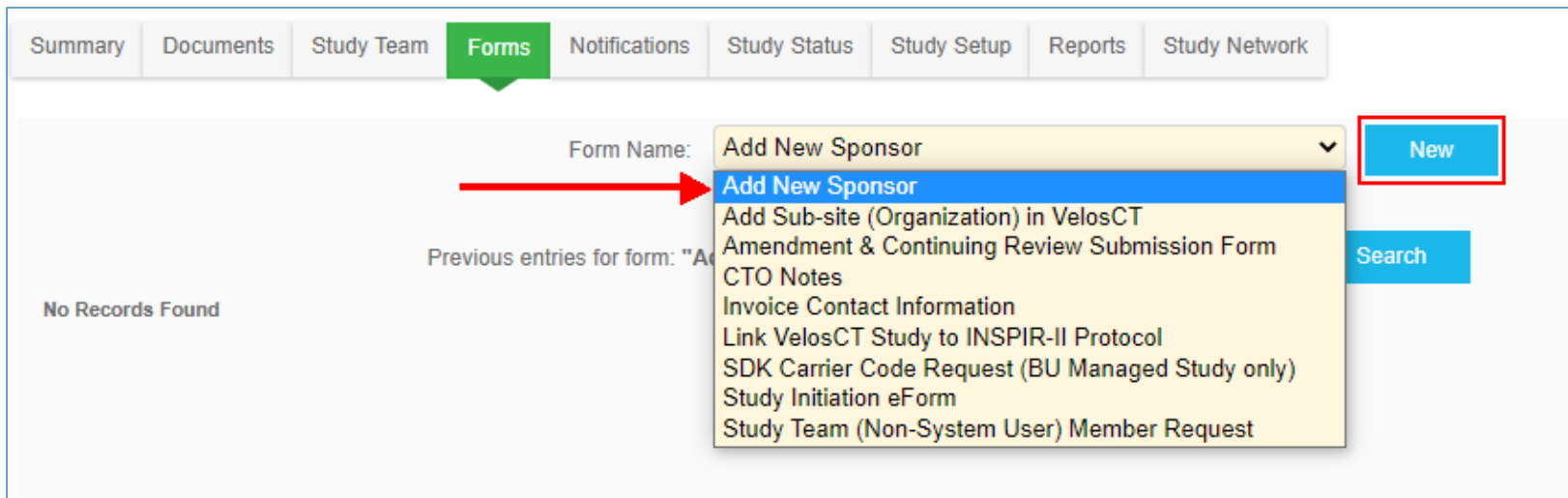
Search

# Add New Sponsor

- If the Sponsor's name is not available in the Summary tab, please complete the Add New Sponsor form.



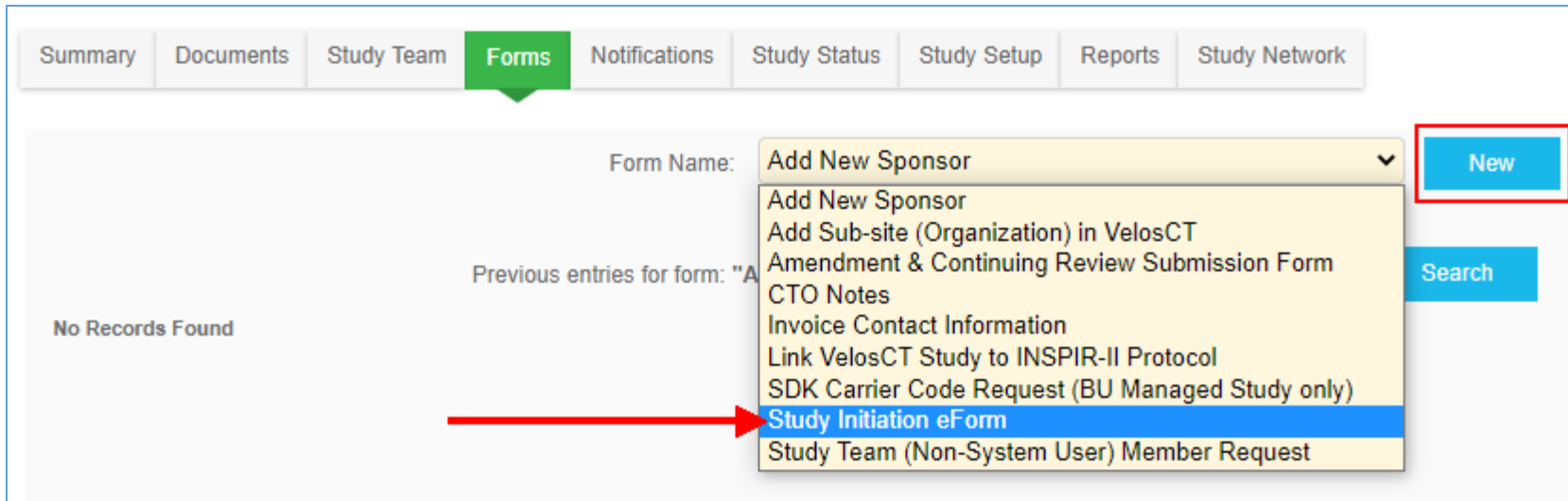
The screenshot shows the 'Summary' tab selected in the top navigation bar. Below the tabs, there is a form with the following fields: 'Sponsor Type', 'Sponsor Name', 'Sponsor ID', and 'Contact'. The 'Sponsor Type' dropdown menu is open, displaying a list of options: '3M Pharmaceuticals', 'AIDS Malignancy Consortium', 'AMAG Pharmaceuticals', 'Astrom Biosciences, Inc', 'AbbVie' (highlighted in blue), 'Abbott Laboratories', and 'Abela Pharmacreuticals'. A red rectangle highlights the 'Sponsor Type' dropdown and its list of options.



The screenshot shows the 'Forms' tab selected in the top navigation bar. Below the tabs, there is a form with the following fields: 'Form Name', 'Previous entries for form: "Add New Sponsor"', and 'No Records Found'. The 'Form Name' dropdown menu is open, displaying a list of options: 'Add New Sponsor' (highlighted in blue), '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', and 'Study Team (Non-System User) Member Request'. A red arrow points to the 'Add New Sponsor' option in the dropdown. To the right of the dropdown, there is a 'New' button (highlighted with a red rectangle) and a 'Search' button.

# 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



The screenshot displays the VelosCT interface for managing forms. At the top, a horizontal tab bar includes 'Summary', 'Documents', 'Study Team', 'Forms' (highlighted in green), 'Notifications', 'Study Status', 'Study Setup', 'Reports', and 'Study Network'. Below the tabs, the 'Form Name' dropdown menu is open, showing a list of available forms. A red arrow points to the 'Study Initiation eForm' option, which is highlighted in blue. To the right of the dropdown, a blue 'New' button is visible, outlined in red. Below the 'Form Name' dropdown, the text 'Previous entries for form: "A' is partially visible. On the left side of the main content area, the text 'No Records Found' is displayed. A blue 'Search' button is located to the right of the 'Form Name' dropdown.



# Complete Study Initiation eForm

- Data entry date will default to today's date
- Confirm that all required steps have been completed
- 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](mailto:CTO@bmc.org))**

# VelosCT

## Participant Enrollment and Visit Management

# Brief Overview-CTO Responsibilities

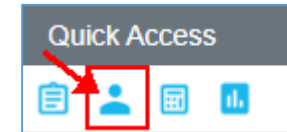
- Once Study team has created the shell, the CTO will be responsible for the Study Setup, which involves:
  - Medicare coverage analysis
  - Budget negotiation or provide pricing for clinical services
  - Informed consent form review of Cost and Injury language
  - Agreement execution and account setup
  - 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

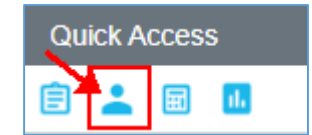
- Once the study calendar that the CTFA has created has been made Active and the Study Status is Active you can begin to add participants to the study
- Start by clicking Manage->Studies->Search
- You can search by the IRB protocol # or Study Title (using all or part of the title will work)
- If the 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



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# 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
Reporting

Study #, Title or Keyword

Current Page: Manage Patients >> Study Patients

Patient Search

Enrolled

Schedule

Search By

Patients on Study: TrainingLL
Organization:
Last Visit:

Patient ID:
Enrolled On:
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: 1


Rows Per Page
Showing 1 - 6 of 6

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
TrainingLL	VCT-0000086	Boston Medical Center	<a href="#">09854633311</a>	my	test					Consented		Consented
TrainingLL	456789	Boston Medical Center	<a href="#">Patient1</a>	Sick	Patient			08/26/2022		Consented		Consented


Existing patients on Study



## 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 name “last,first” format



Personalize ▾ Manage ▾ Libraries ▾ Reporting ▾

Study #, Title or Keyword 

Current Page: Manage Patients >> Patient Search

**Patient Search** Enrolled Schedule

**Search By**

Patient ID: 	<input type="text"/>	Age: <input type="text" value="All"/>	Organization: <input type="text" value="All"/>
Patient Name: 	<input type="text"/>	Gender: <input type="text" value="Select an option"/>	Specialty: <input type="text" value="Select an option"/>
Survival Status: <input type="text" value="Select an option"/>	Study: <input type="text" value="All"/>	Provider: <input type="text"/>	<input type="button" value="Search"/>

Please specify Search criteria to view a list of matching Patients

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

Personalize
Manage
Libraries
Reporting

Study #, Title or Keyword

Current Page: Manage Patients >> Patient Search

Patient Search

Enrolled

Schedule

Search By

Patient ID: ?

Age: All

Organization: All

Patient Name: ?

TEST

Gender: Select an option

Specialty: Select an option

Survival Status: Select an option

Study: All

Provider:

Search

Current Page: 1 Total Pages: 15

Rows Per Page 5


Showing 1 - 5 of 72





VelosCT ID	First Name	Last Name	Age	Gender	Patient Status	Other ID(s)	On a Study	Delete
<a href="#">11122222</a>	Test	Test	23 Years	Male	Alive		Yes (12)	
<a href="#">123456</a>	BMC	Test	42 Years	Female	Alive		Yes (17)	
<a href="#">123456789</a>	Test	Patient	24 Years	Female	Alive		Yes (7)	
<a href="#">4000148</a>	SAMONE	TESTSAM	36 Years	Male	Alive		Yes (4)	
<a href="#">4000175</a>	SAMONE2	TESTSAM2	36 Years	Male	Alive		Yes (7)	

Continue to search in EMR

# Select a study for the participant

Personalize ▾ Manage ▾ Libraries ▾ Reporting ▾

Study #, Title or Keyword 

▶ Current Page: Patient >> Protocols

Demographics

Patient Profile

Protocols

Reports

Appendix

Pat.ID: VCT-0000520 Age: 58 years Gender: Male Pat.Name: THREE TESTG Org: Boston Medical Center

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

Select an option ▾

Boston Medical Center ▾

Submit

No records found. This patient is either not 'Active' or not enrolled in any Study.

Make sure "Boston Medical Center" is selected here

The Patient Study Status window should pop up. If this window does not automatically pop up, click on the “Add New Status” link (right side)

Patient Study Status - Google Chrome

bmctest.velosresearch.com/velos/jsp/patstudystatus.jsp?patStudiesEnrollingOrg=&studyId=497&sta...

Patient ID: VCT-0000520
Study Number: TrainingAA

Patient Study Status

Status \*
Select an option

Reason
Select an option

Status Date \*

☒ This is patient's current status in this study

Notes

Additional Information

Patient Study ID \*
VCT-0000520

Enrolling Site

Assigned To
Select User

Physician
Select User

Treatment Location
Select an option

Treating Organization
Select an option

Disease Code

Anatomic Site

Registration process is incomplete and patient will not be linked to this study.

<a href="#">Add New Treatment Arm</a>		
End Date	Notes	Delete
<a href="#">Add New Status</a>		
Notes		Delete

# 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. For events that were not done or not required, mark the events as “**Not Required.**”

Click on the Schedule link and select Edit Calendar/Date to associate a calendar

Personalize ▾
Manage ▾
Libraries ▾
Reporting ▾
Study #, Title or Keyword

Current Page: Study Patient >> Schedule

Demographics
Patient Profile
**Protocols**
Reports
Appendix

Pat.ID: VCT-0000520   Pt. Study ID: VCT-0000520   Age: 56 years   Gender: Male   Pat.Name: THREE TESTG   Org: Boston Medical Center

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

Study #: TrainingAA
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.

## Select a Study Calendar and Participant Start Date

\*If this is a new participant starting at the first visit, select the first option

Patient Protocol Details - Google Chrome

bmctest.velosresearch.com/velos/jsp/patientprotocol.jsp?studyId=497&pkey=2922

Treatment Details

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

Study Calendar 10.22.2014 ▼  
Select the specific Study Calendar that the patient is assigned to for this study

Patient Start Date 08/30/2022  
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]

**Valid e-Sign** e-Signature \*

**If participant is starting at the first visit of the calendar, select first option**

# Select a Study Calendar and Participant Start Date

\*If this is an existing study and participant, select the next scheduled visit

Patient Protocol Details - Google Chrome

bmctest.velosresearch.com/velos/jsp/patientprotocol.jsp?studylo

**Treatment Details**

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

Study Calendar: 10.22.2014 ▼  
Select the specific Study Calendar that the patient is assigned to for this study

Patient Start Date: 08/30/2022  
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

Selected Visit: Select a Visit [Read Only]

**Valid e-Sign** e-Signature \* .... **Submit**

If participant has already completed visits prior to VelosCT, click "Select a Visit" and select the next visit from drop down list



After associating a calendar, you should now see the visits listed below

Personalize
Manage
Libraries
Reporting

Study #, Title or Keyword

Home
Help

Current Page: Study Patient >> Schedule

Demographics
Patient Profile
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Appendix

Pat.ID: VCT-0000520   Pt. Study ID: VCT-0000520   Age: 56 years   Gender: Male   Pat.Name: THREE TESTG   Org: Boston Medical Center

Screening/Enrollment
Schedule
Adverse Events
Attachments

Study #: TrainingAA
Calendar: 10.22.2014
Pat.Start Date: 08/30/2022

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

Select Schedule: 10.22.2014, 08/30/2022   Visit: All   Search

August 2022 Visit		Suggested Date	Scheduled Date	Visit Window
▶	Visit 0	08/30/2022	08/30/2022	
▶	Visit 1	08/31/2022	08/31/2022	

February 2023 Visit		Suggested Date	Scheduled Date	Visit Window
▶	Visit 2	02/28/2023	02/28/2023	

Click on visit to view events/dates and edit events/dates

# Click Edit Visit to edit the visit events/dates

\*If you need to add an unscheduled visit, **contact CTO**. Do not add the unscheduled visit yourself.

Demographics
Patient Profile
**Protocols**
Reports
Appendix

Pat.ID: VCT-0000520
Pl. Study ID: VCT-0000520
Age: 56 years
Gender: Male
Pat.Name: THREE TESTG
Org: Boston Medical Center

Screening/Enrollment
**Schedule**
Adverse Events
Attachments
Forms

Study #: TrainingAA
Calendar: 10.22.2014
Pat.Start Date: 08/30/2022
Schedule: Current

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

Select Schedule: 10.22.2014, 08/30/2022
Visit: All
Search
[Edit Multiple Events](#)

August 2022 Visit

Suggested Date	Scheduled Date	Visit Window
Visit 0	08/30/2022	08/30/2022

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

Suggested Date	Scheduled Date	Event Window	Event	Event Status	Linked Forms	Site of Service	Coverage Type	Additional Information
08/30/2022	08/30/2022	-	<a href="#">Informed Consent</a>	Not done	No CRF	-	SP	-
08/30/2022	08/30/2022	-	<a href="#">Demographics</a>	Not done	No CRF	-	SP	-
08/30/2022	08/30/2022	-	<a href="#">Medical History</a>	Not done	No CRF	-	SP	-

Here you can check events as done for the visits

\*If any events were not done or not required, select “Not Required” under the “Status” column

Edit Visit

Visit Name: Visit 0

Status

Select an option

Delayed

Incomplete

Completed Late

Done

Suspended

Not Required

Not done

To be rescheduled

Select an option

Status Date

08/30/2022

Performed By

Select an option

Apply To

All

Selected

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

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, coverage type, and price, if applicable
- 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
- Study teams must update the participant's status as required to ensure research billing compliance. Adding a new status will update the participant's status in VelosCT and Epic (hospital EMR).
- 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

Current Page: Manage Patients >> Study Patients

Patient Search **Enrolled** Schedule

Search By

Patients on Study: TrainingMM Organization: All Last Visit: Next Visit: All

Patient ID: Enrolled On: 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: 1 Rows Per Page 5 Showing 1 - 2 of 2

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
TrainingMM	4000175	Boston Medical Center	<a href="#">4000175</a>	SAMONE2	TESTSAM2	06/03/2022	Visit 0	06/03/2022		Enrolled	Training M
TrainingMM	VCT-0000086	Boston Medical Center	<a href="#">47890001254</a>	my	test	03/31/2022	Visit 0	03/31/2022		Enrolled	Bryant Shields

Existing participants on Study

Current Participant Study Status

# 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 initiation eform to notify 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

Minhao Yin – CTO Team Lead

Sandy Lok – Sr. Clinical Trial Financial Analyst

Amy Chung – Clinical Trial Financial Analyst

Amruta Khedekar – Clinical Trial Financial Analyst

Fernanda Fortes – Clinical Trials Billing Coordinator

Bryant Shields – Project Manager

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

*\*Please inform CTO if additional Study Team members within your department require*

*VelosCT training.*

## Research Information Systems ([RIS](#))

Christopher Sullivan – RIS Manager

Saloney Chhajed – Business Analyst

Michael Neuman – Data Analyst

Emily Davis – Application Analyst II

RIS Inbox – [RIS@bmc.org](mailto:RIS@bmc.org) (for all inquiries if unsure who to contact)

# 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