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: Clinical Trial Office

Submit MCA/Velos Determination Checklist

Login Information

- Make sure that you are in https://bmc.veloseresearch.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#

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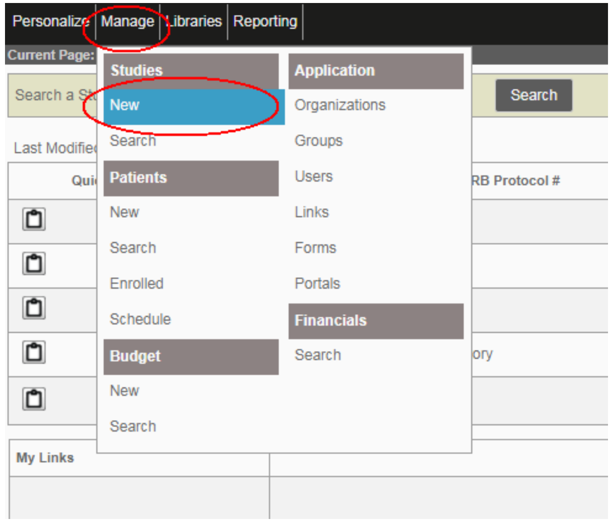
VelosCT
Study Set Up

Entering a New Study

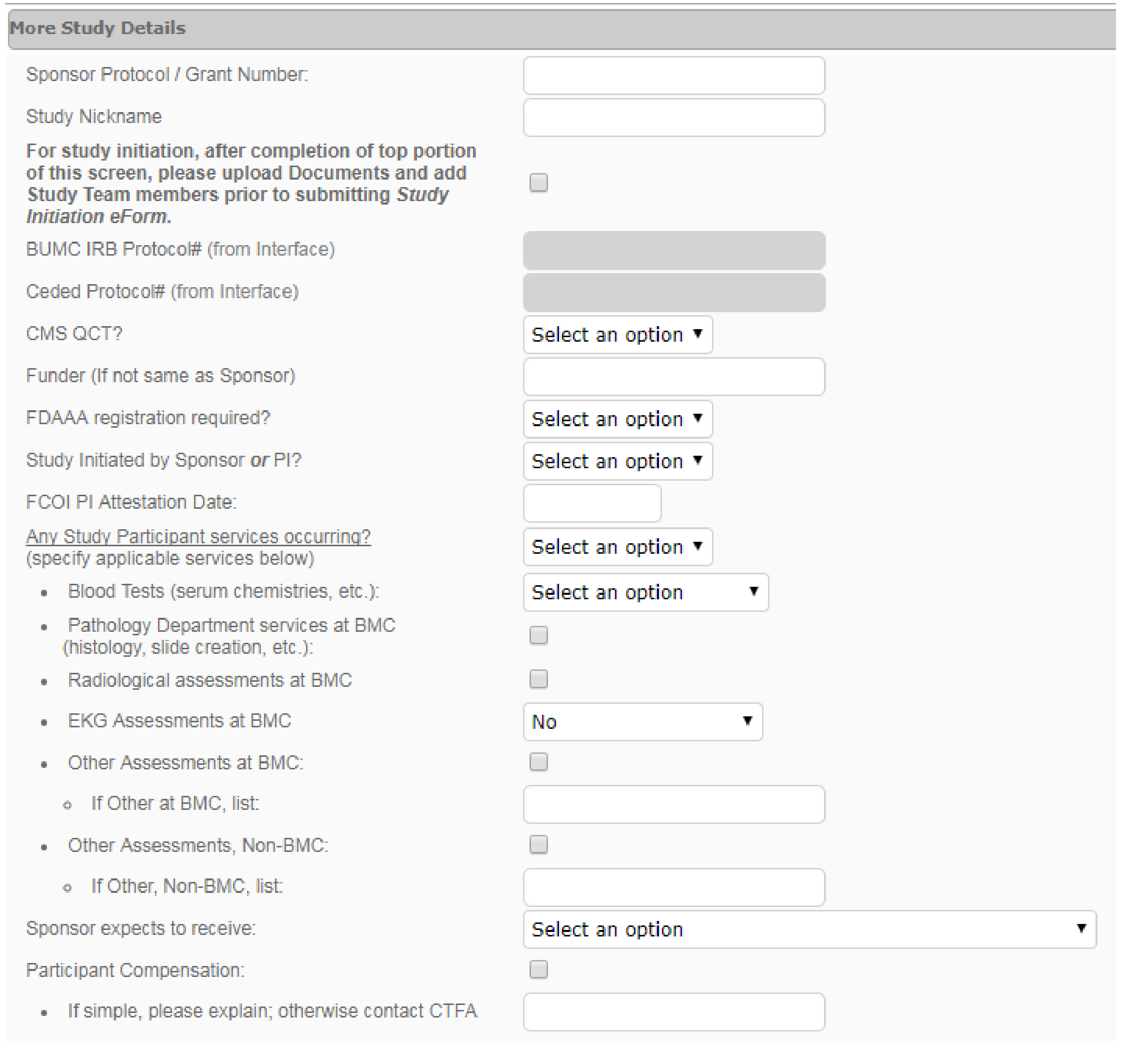


- Start by clicking Manage->Studies->New
- All fields with a * are mandatory and must be filled in to save your new study. However, please fill as in much information as possible as multiple departments (CTO, Revenue Integrity, RBI, etc.) will also be using this study record
- “Study entered by” will 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

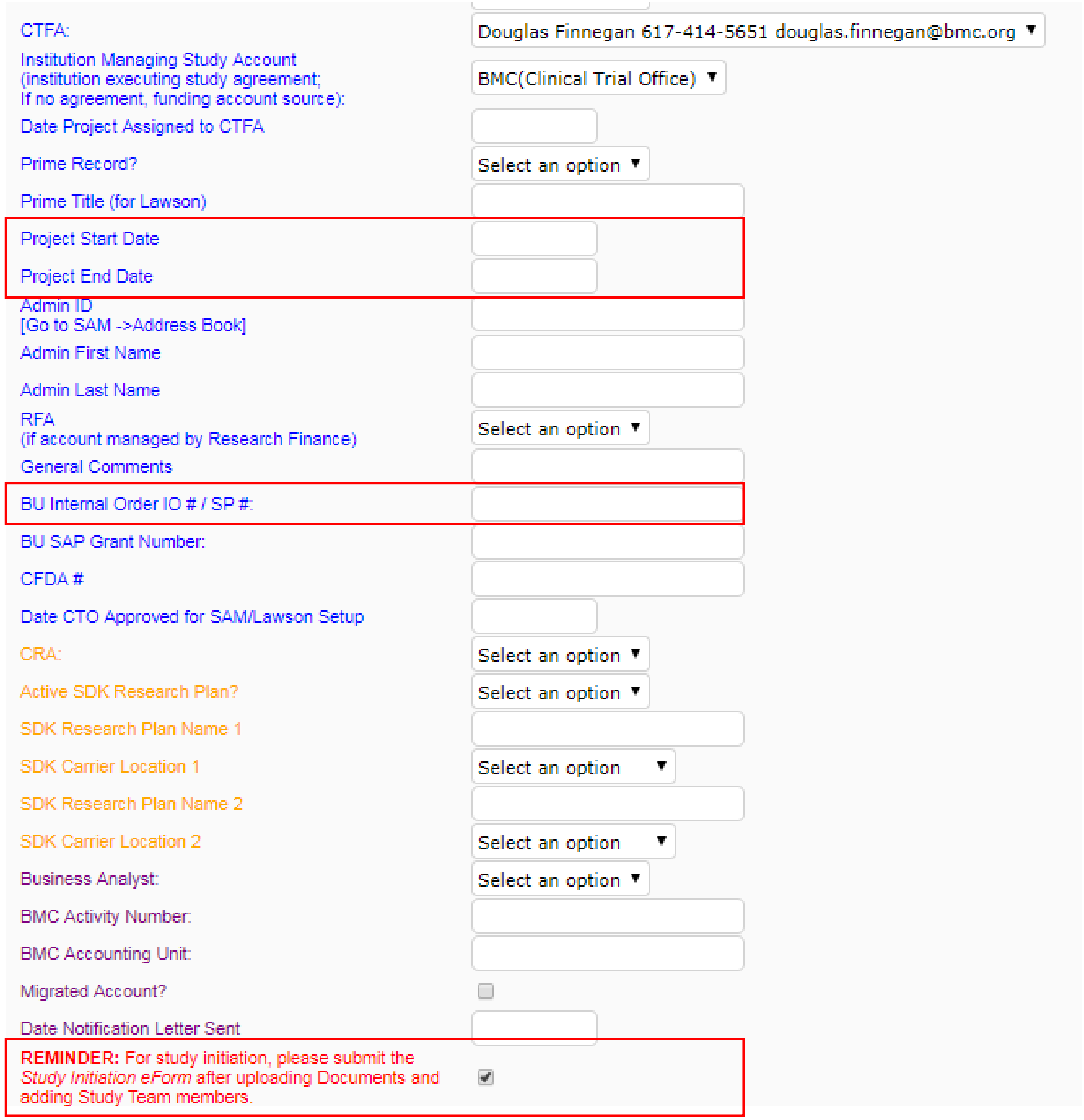
Sponsor Protocol / Grant Number:	
Study Nickname	
For study initiation, after completion of top portion of this screen, please upload Documents and add Study Team members prior to submitting *Study Initiation eForm*.	
BUMC IRB Protocol# (from Interface)	
Ceded Protocol# (from Interface)	
CMS QCT?	Select 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.):	Select an option
• Pathology Department services at BMC (histology, slide creation, etc.):	
• Radiological assessments at BMC	
• EKG Assessments at BMC	No
• Other Assessments at BMC:	
◦ If Other at BMC, list:	
• Other Assessments, Non-BMC:	
◦ If Other, Non-BMC, list:	
Sponsor expects to receive:	Select an option
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#

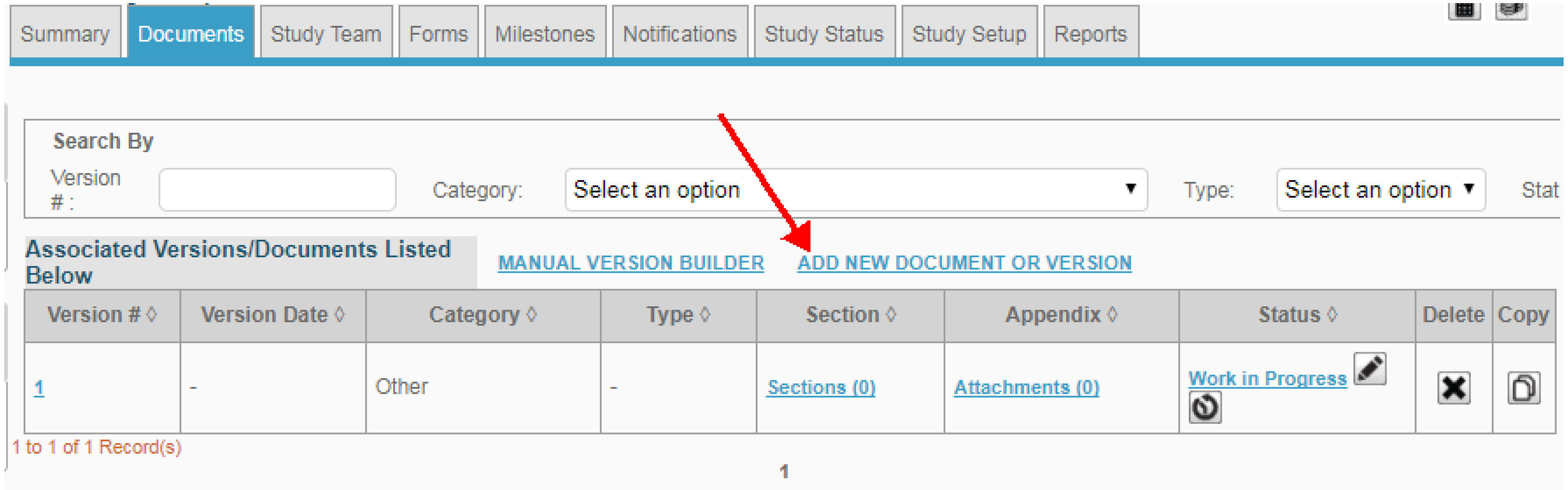
- E-sign and submit



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	
Prime Record?	Select an option
Prime Title (for Lawson)	
Project Start Date	
Project End Date	
Admin ID [Go to SAM ->Address Book]	
Admin First Name	
Admin Last Name	
RFA (if account managed by Research Finance)	Select an option
General Comments	
BU Internal Order IO # / SP #:	
BU SAP Grant Number:	
CFDA #	
Date CTO Approved for SAM/Lawson Setup	
CRA:	Select an option
Active SDK Research Plan?	Select an option
SDK Research Plan Name 1	
SDK Carrier Location 1	Select an option
SDK Research Plan Name 2	
SDK Carrier Location 2	Select an option
Business Analyst:	Select an option
BMC Activity Number:	
BMC Accounting Unit:	
Migrated Account?	
Date Notification Letter Sent	
REMINDER: For study initiation, please submit the *Study Initiation eForm* after uploading Documents and adding Study Team members.	

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



Upload Documents (cont'd)

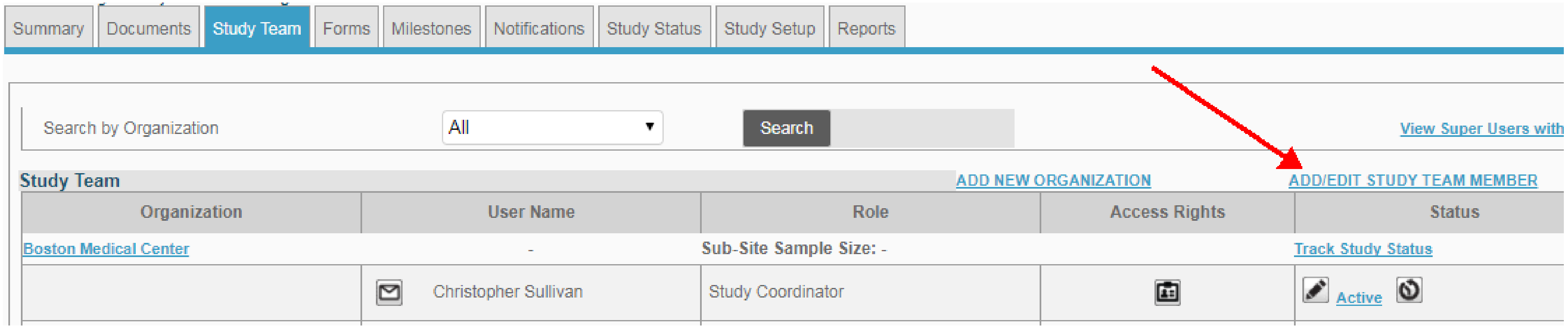
- Mandatory fields include Version Number, Category, File (browse) and description
- E-sign and submit when you have uploaded your file and filled in the mandatory fields
- There will always be a Version 1 in category Other that exists with no document attached, feel free to delete this version after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



•You can search for current users by Name, Organization, Group or Job Type

•Once you fins 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

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VelosCT USER & ACCESS REQUEST FORM

Research Business Intelligence

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:	

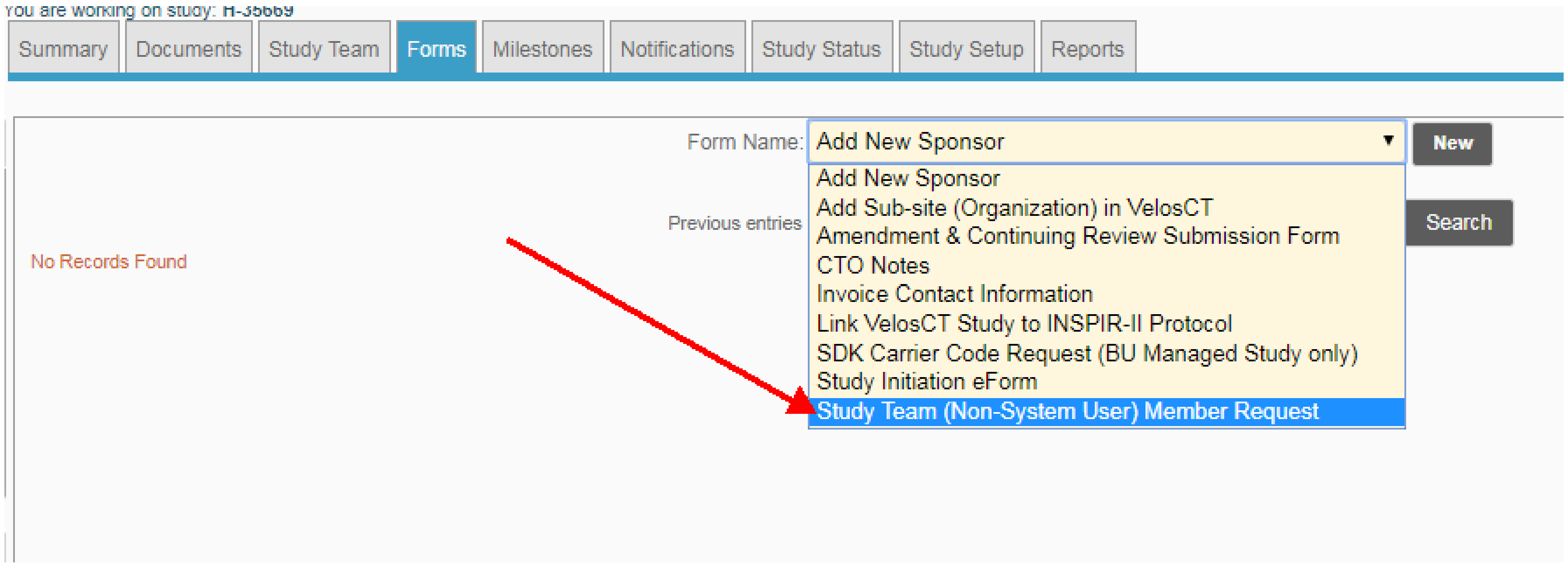
System Request:

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, 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.



VelosCT
Participant Enrollment and Visit Management

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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 compete the coverage analysis and define the milestones
- The study team will have view only access to the study setup screens

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Training Overview-Patient Information

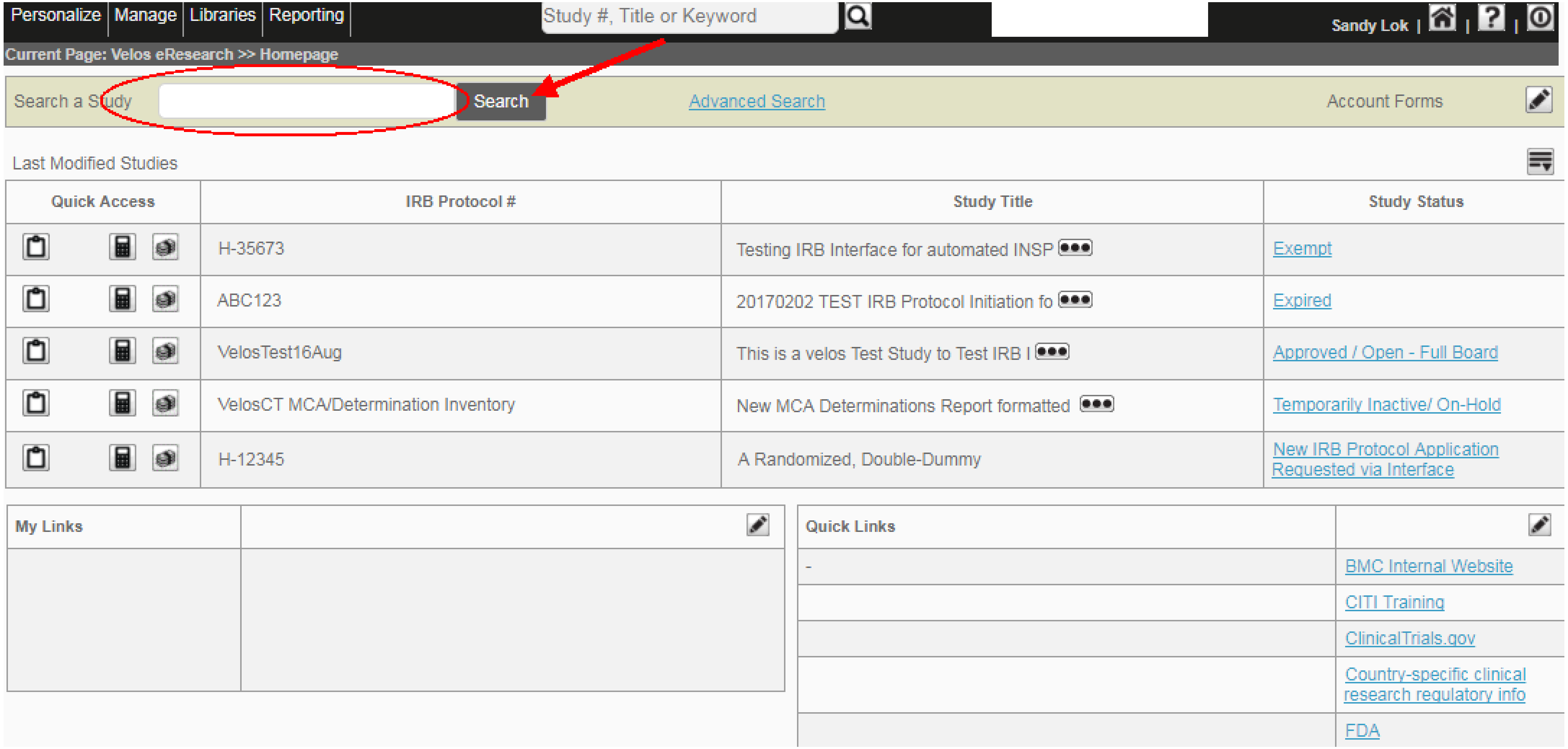
- Search for your existing Study
- Add an existing participant to your Study
- Add a new participant to your Study
- Patient Study Status
- Update a Patient Schedule
- Add an Unscheduled Event
- Using the Schedule Tab
- Using the Enrolled Patient Tab

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



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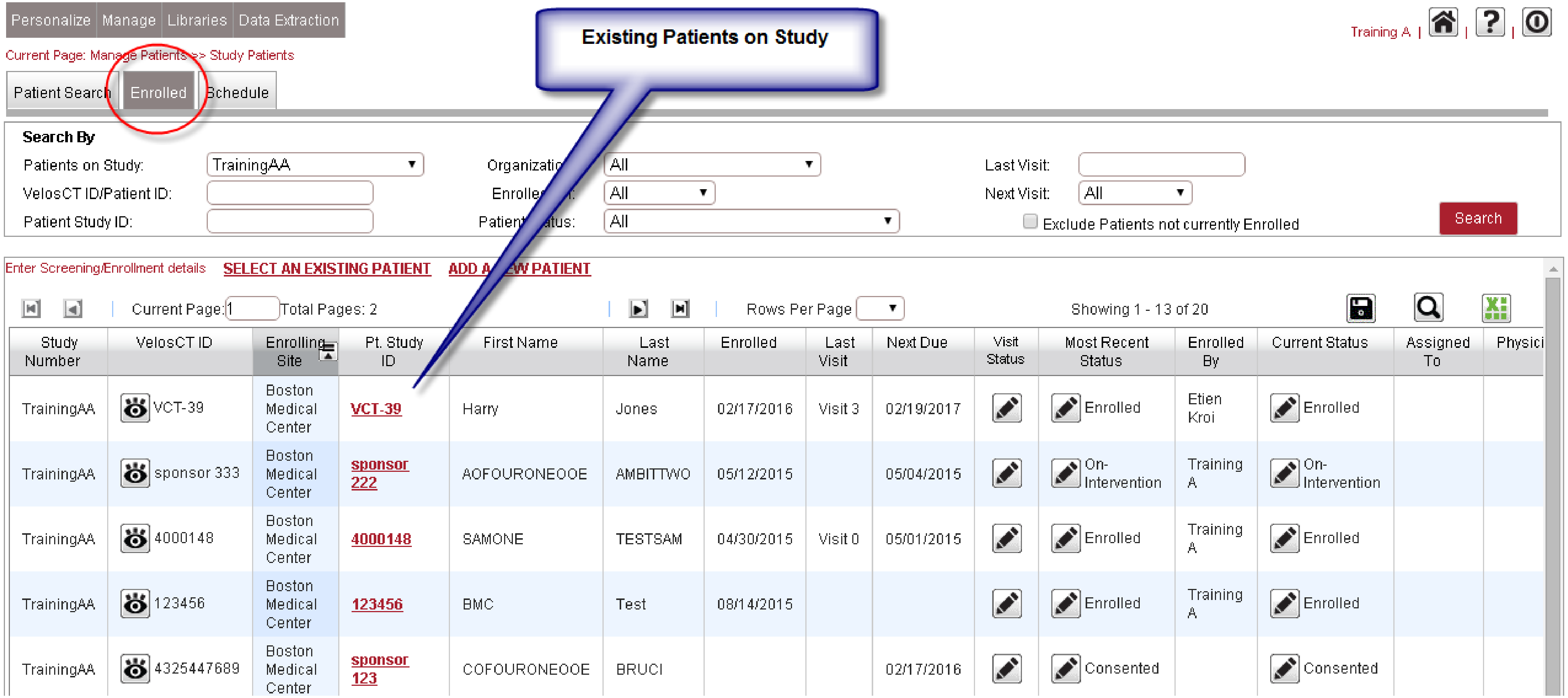
Add an Existing Participant To a Study

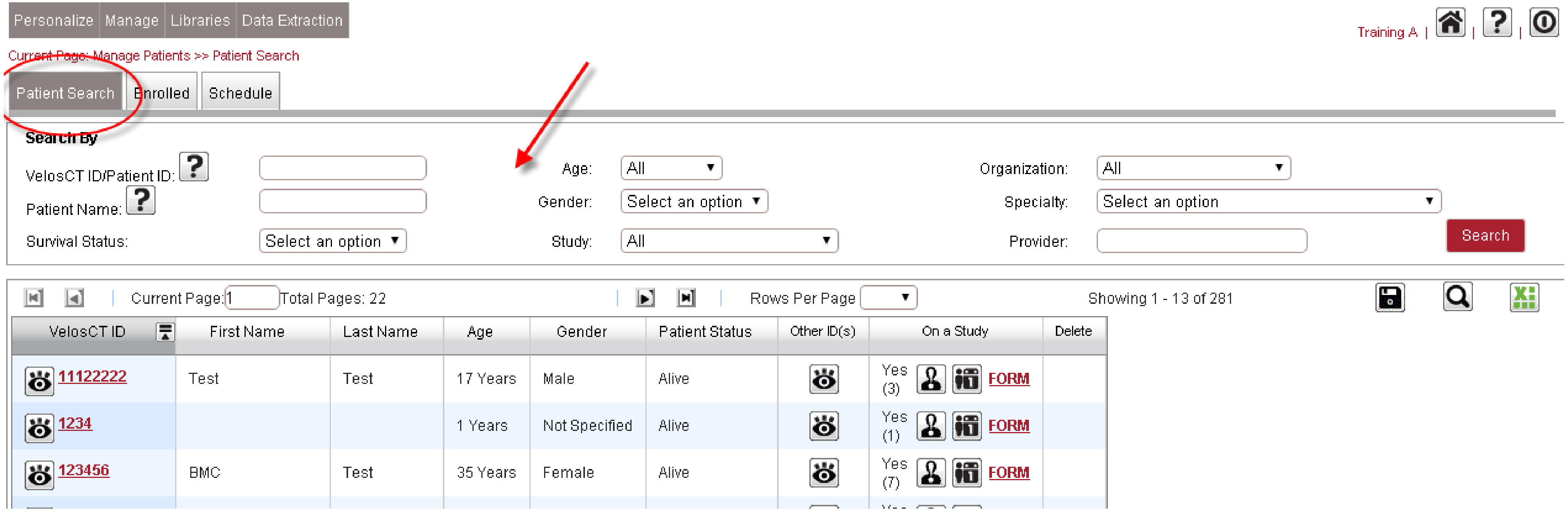
- Please make sure your study calendar is active before entering a new participant
- You should always use the search function as a look up to see if your study participant already has a record in VelosCT
- Best Practice to avoid duplication is to start on the Enrolled tab which will show you participants 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



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	AOFOURONEOOE	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	COFOURONEOOE	BRUCI			02/17/2016		Consented		Consented		

Go Patient Search tab and enter information to search



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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:

Patient Name: SMITH

Survival Status: Select an option

Age: All

Gender: Select an option

Study: All

Organization: All

Specialty: Select an option

Provider:

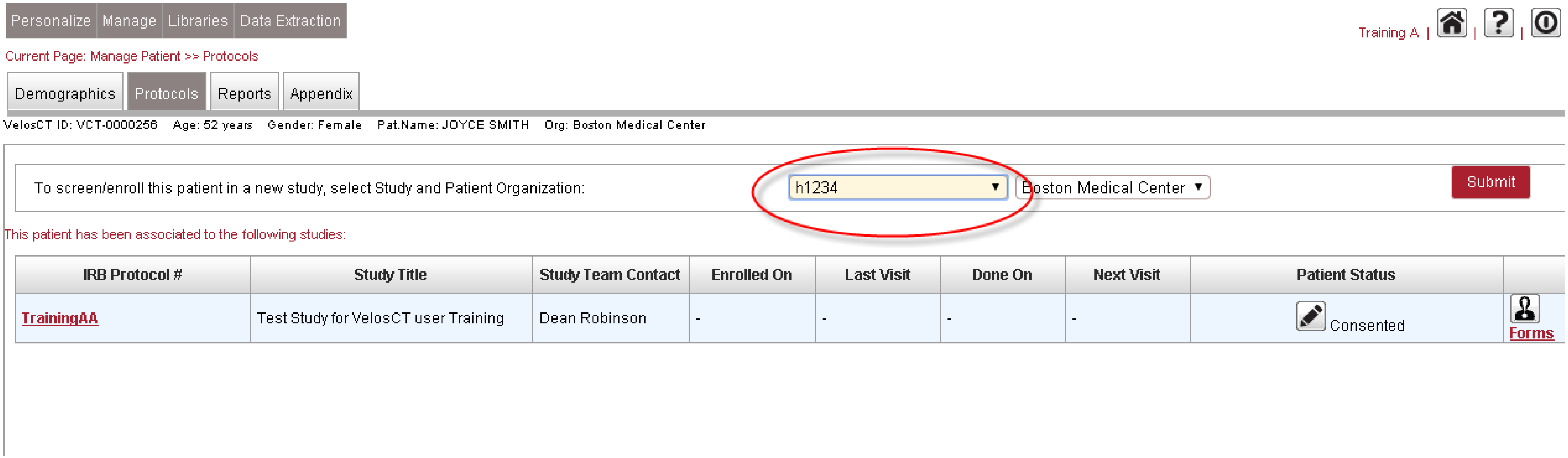
Search

Current Page: 1 Total Pages: 1 Rows Per Page Showing 1 - 5 of 5

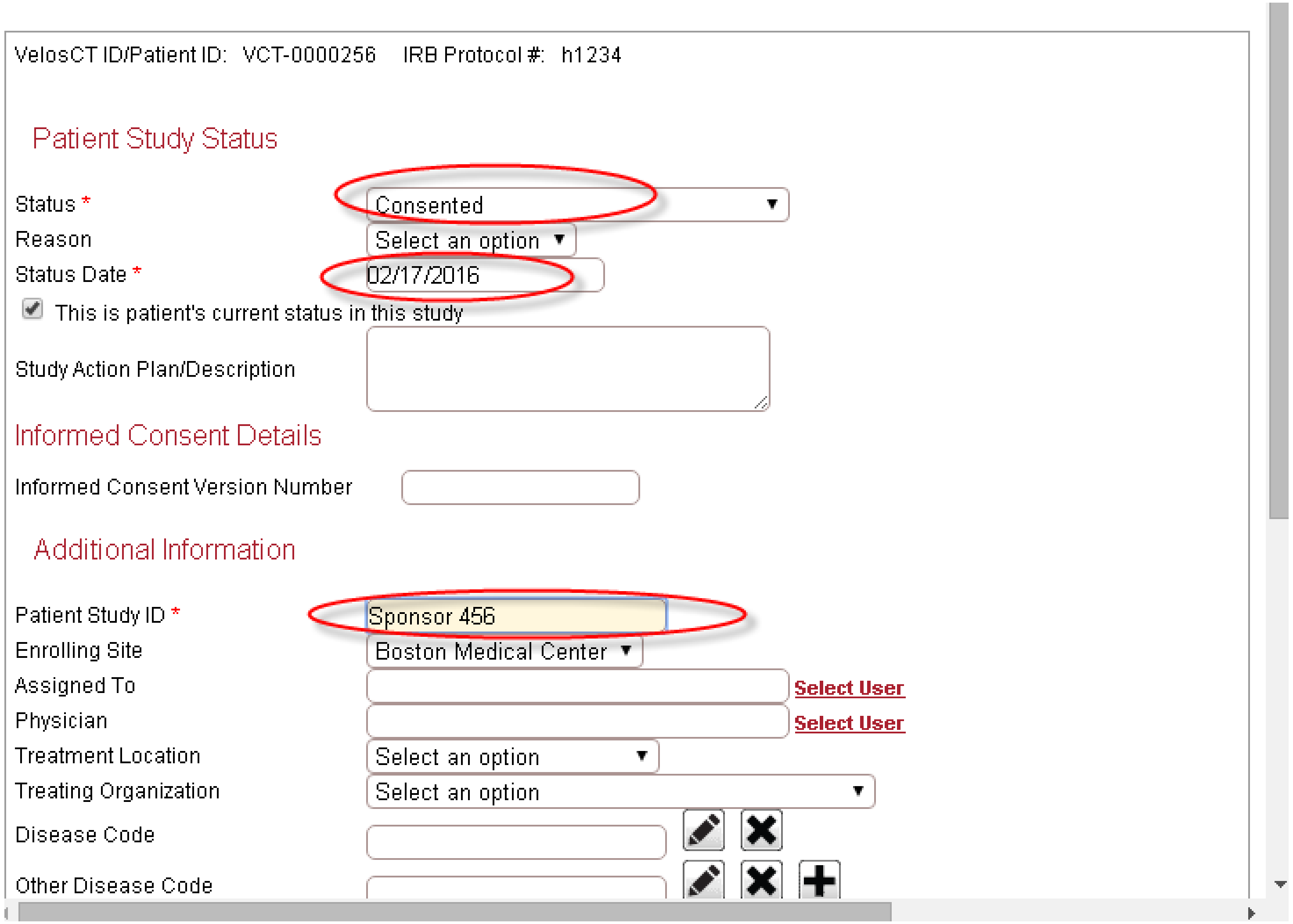
VelosCT ID	First Name	Last Name	Age	Gender	Patient Status	Other ID(s)	On a Study	Delete
TrainingAAA	MICHELLE	SMITH	47 Years	Female	Alive		No FORM	
VCT-0000256	JOYCE	SMITH	52 Years	Female	Alive		No FORM	
VCT-0000257	CHRISTINE	SMITH	52 Years	Female	Alive		No FORM	
VCT-0000258	DELIA	SMITHDAVIS	66 Years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

Continue to search in EMR

Select a study to add the participant to



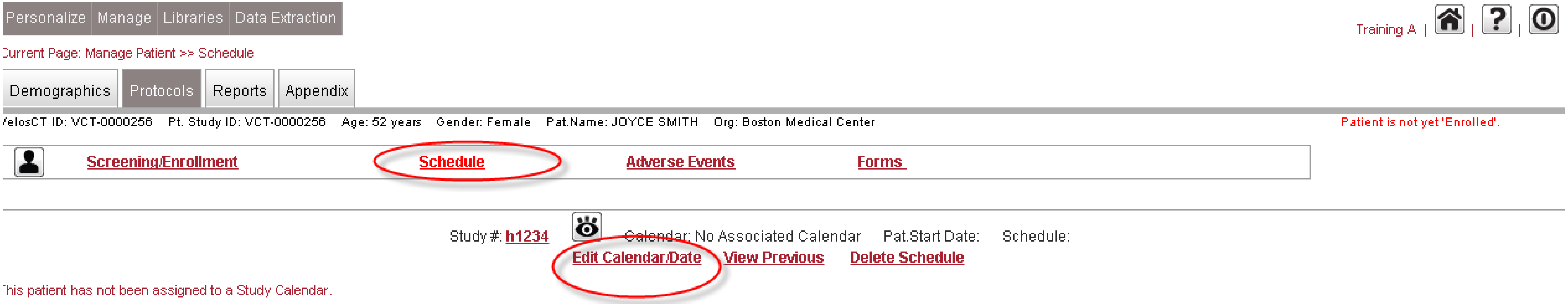
Patient Study Status Pop Up



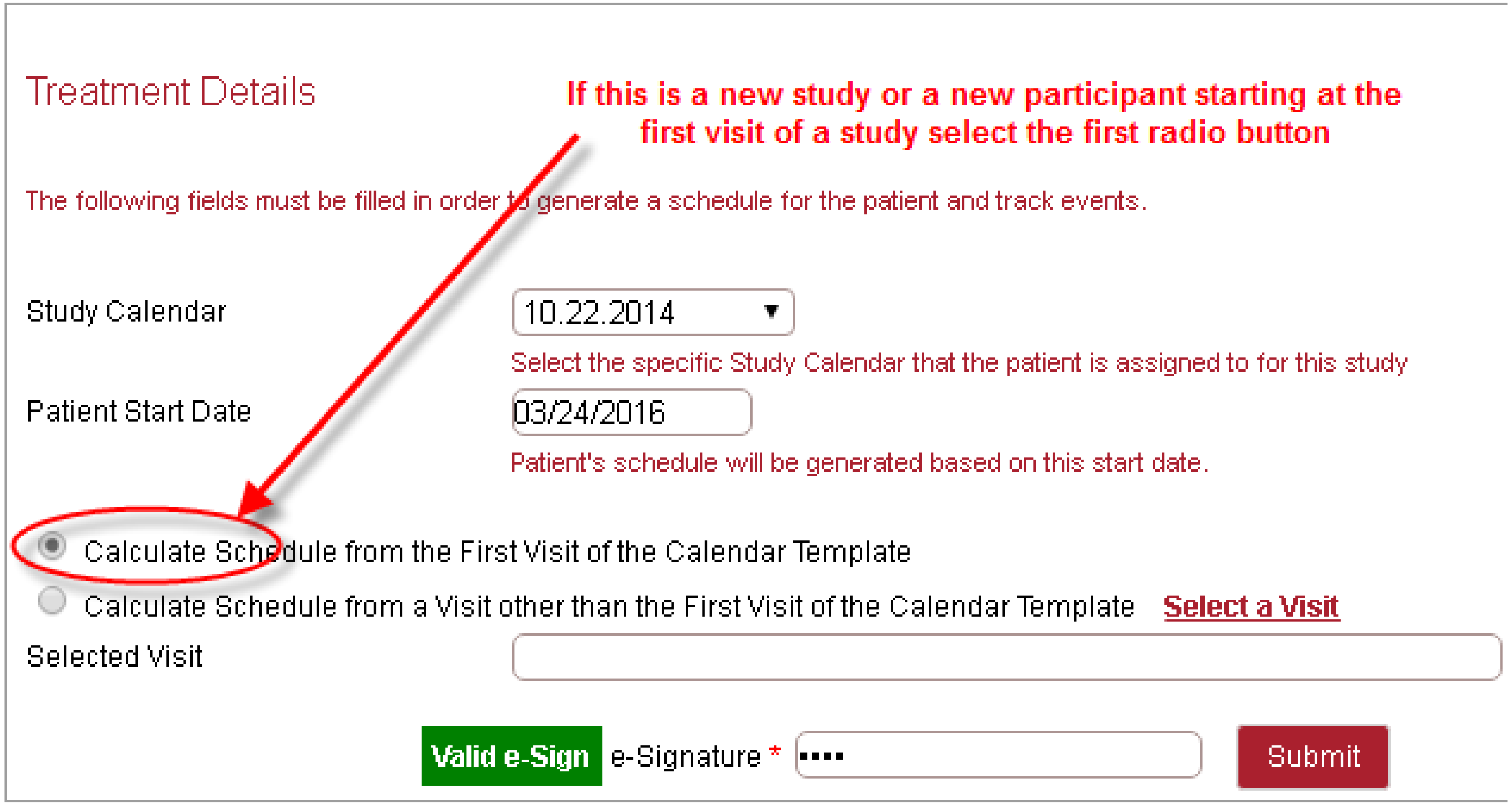
Update a Patient Schedule

- 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



Associate a calendar and participant start date
*If this is a new participant starting at the first visit, select the first radio button



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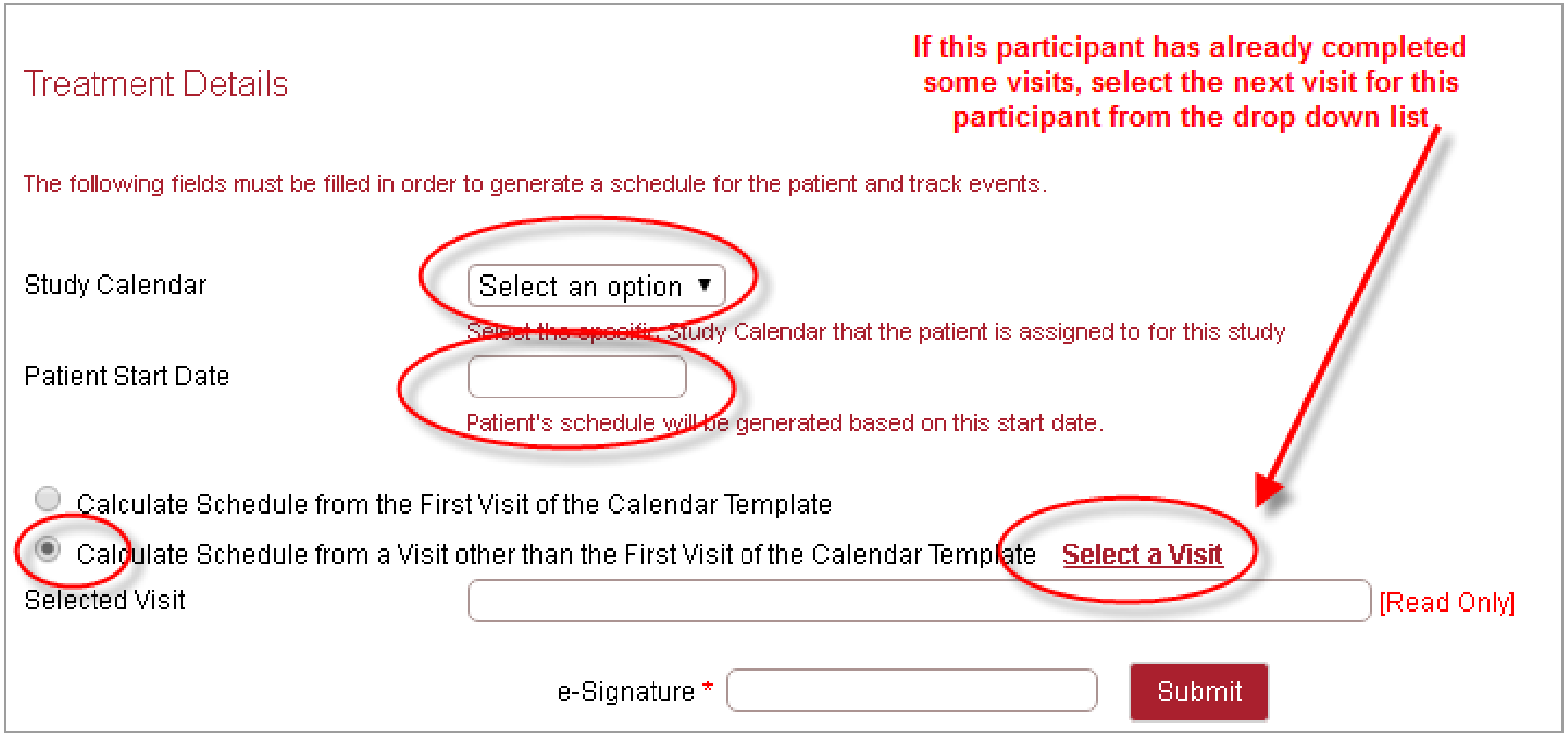
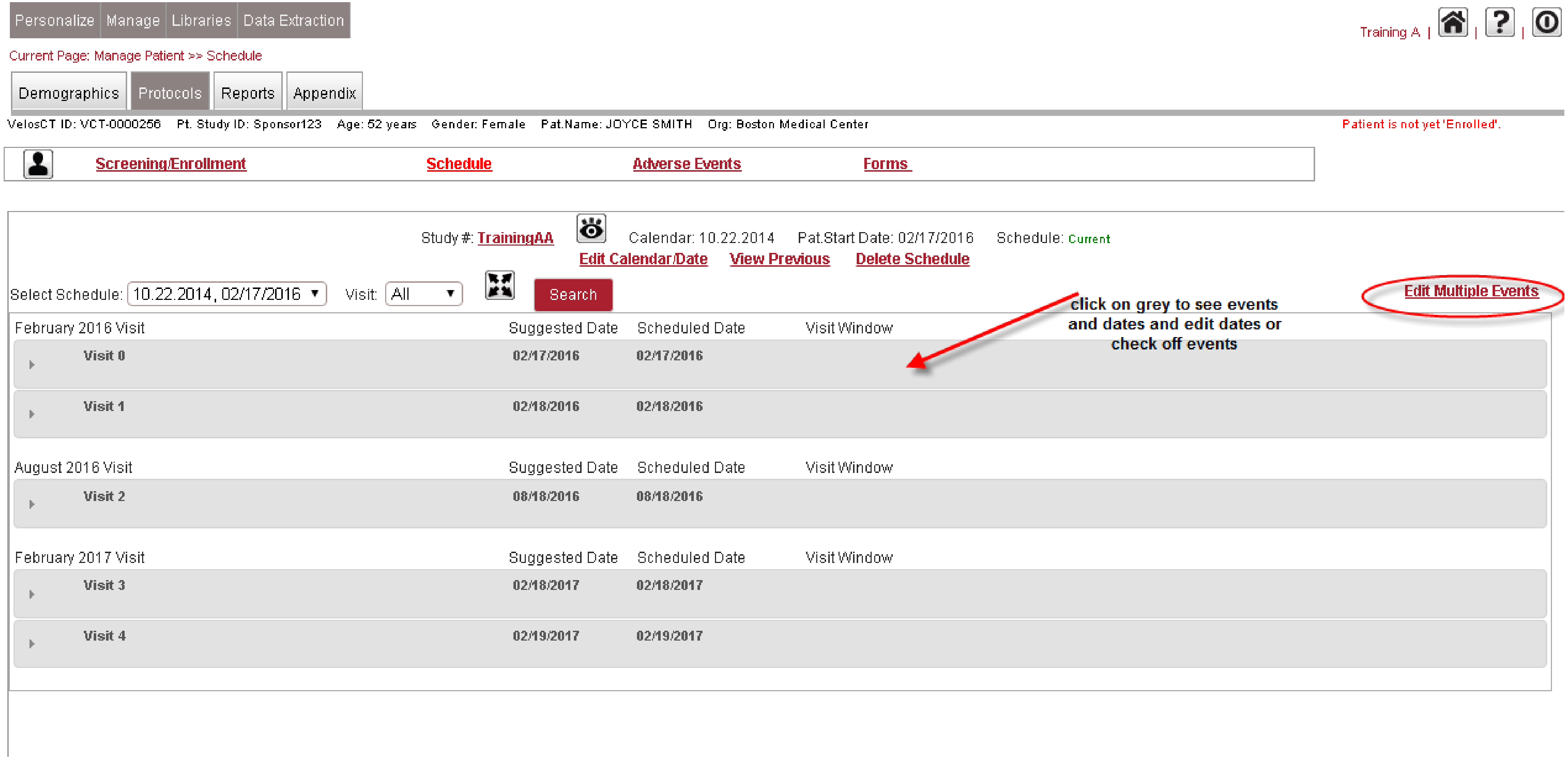
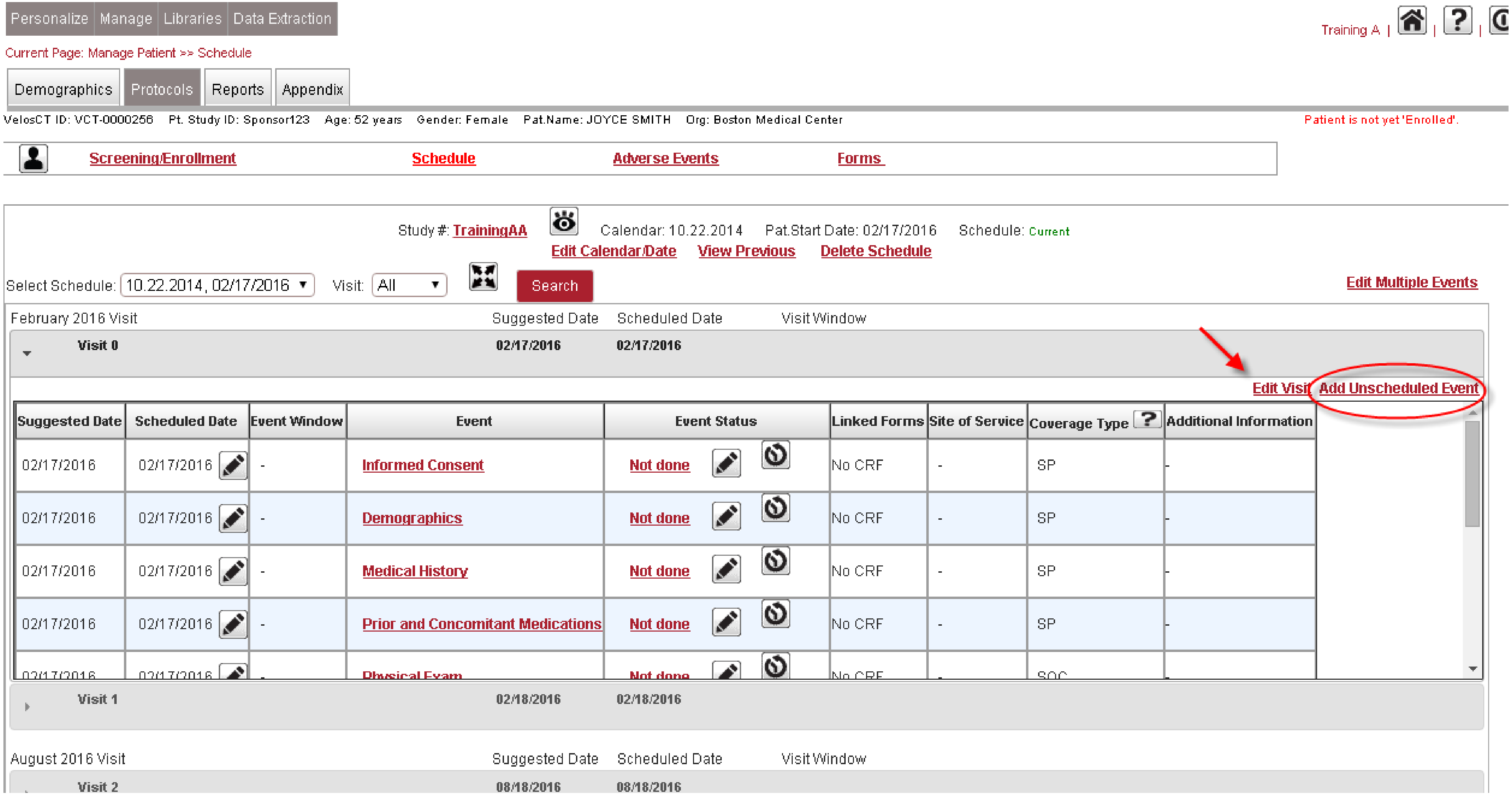
Associate a calendar and participant start date – if this is an existing study and participant, select the next scheduled visit



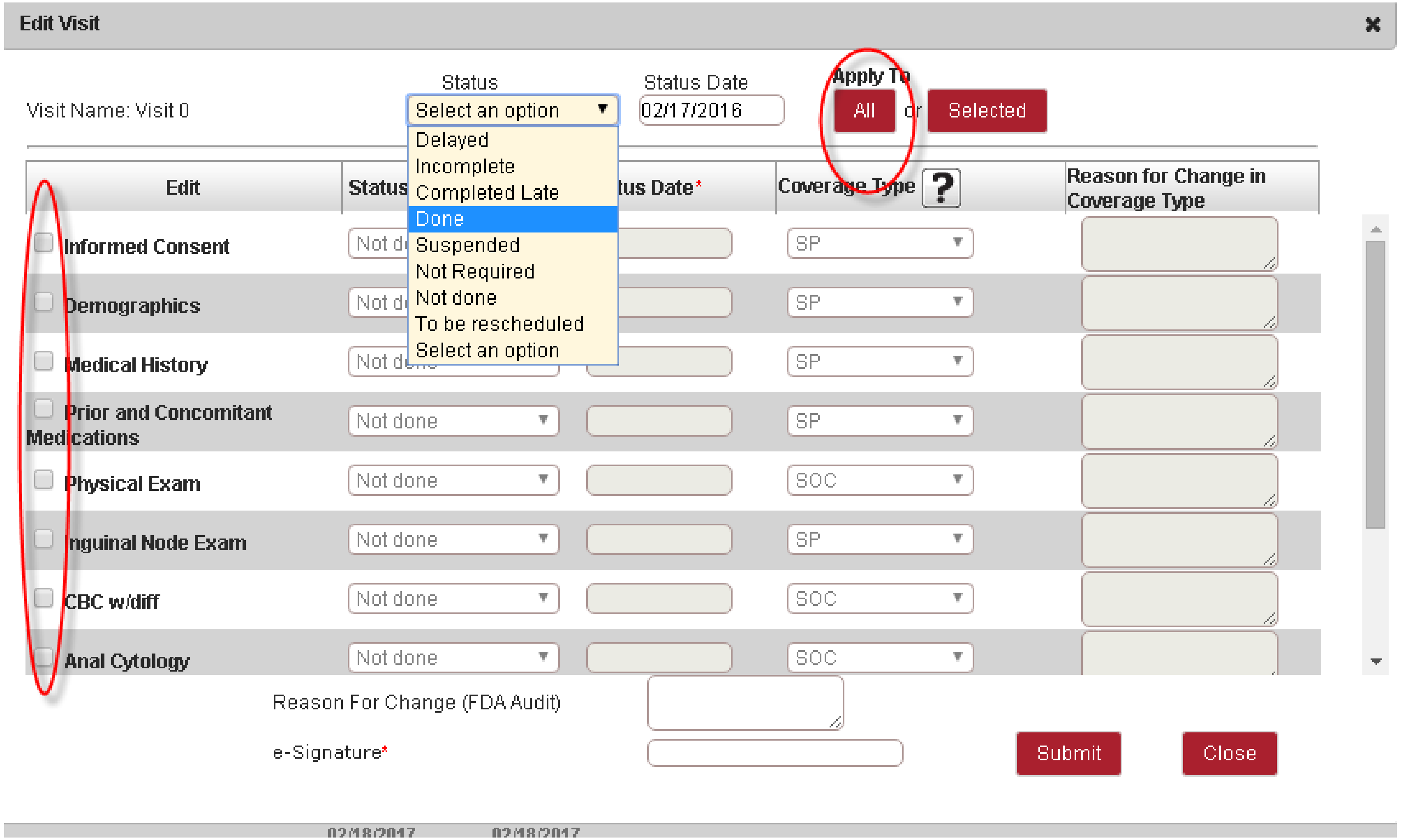
Here you can edit multiple visits



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



Here you can check events as done for the visits



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

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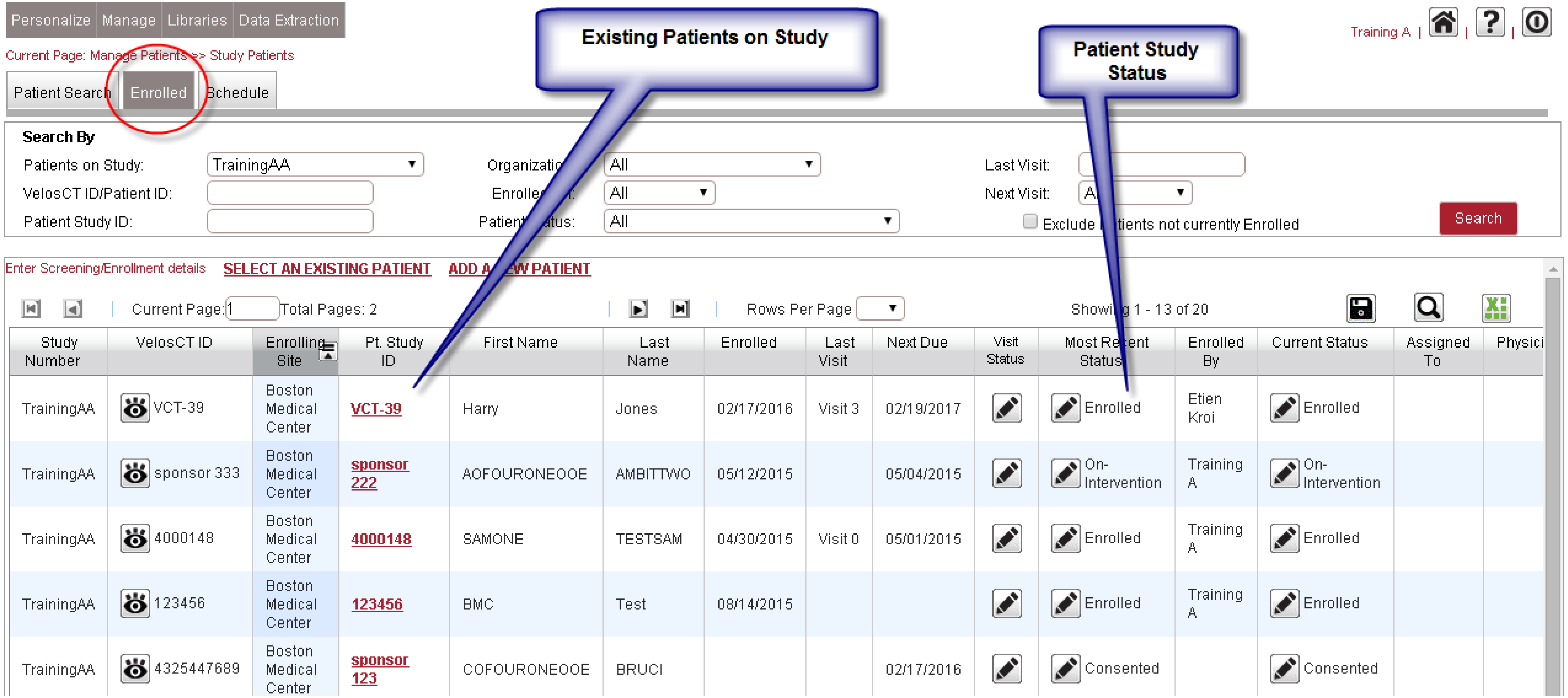
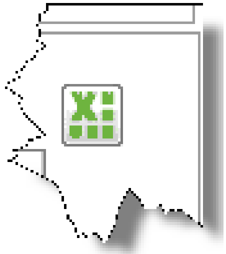
Patient Study Status



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	Clinical Trial Office
• 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	• 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