VelosCT Training

Fall 2014

Super Users-Training Team

Ashley Bourland

Allisson Dugan

Salli Fennessey

Dean Robinson

Jenna Sandler

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, patient enrollment, calendars, budgets, and patient status
- Other capabilities include budgeting, milestones, billing, protocol management, patient recruitment & management, query management, adverse event reporting, etc.

What does this mean for me?

- VelosCT will allow you to enter data and upload documents that the Clinical Trial Office (CTO) needs to initiate your studies internally
- 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 patients throughout the research process including, recruitment, registration, scheduling, visit/event tracking, data entry*, notifications and monitoring

*For Investigator-Initiated Studies

What studies will you enter?

- 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
- In Phase I we will be entering only new studies that will be reviewed through the CTO and current studies that are unenrolled
- In Phase II we will migrate already existing enrolled studies

Training Overview-Entering a new Study

- Get acquainted with VelosCT website
- Receive username and password
- Enter a new study via the Study Summary Tab
- More Study Details
- Upload Documents
- Add users to the Study Team
- Complete a Form
- Update Study Status

VelosCT website

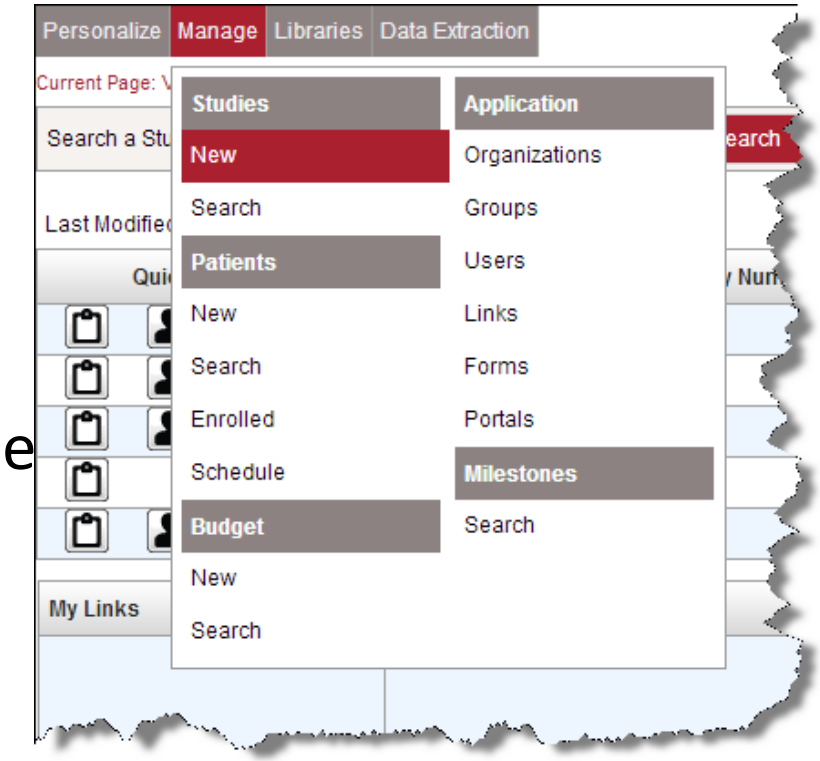
- The website we will be using today is: https://bmctest.veloseresearch.com
- This is the current test system
- Nothing entered today will be saved in the production system that will be used when we go live

Login Information

- For today you will receive a test username, they will be TrainingA, TrainingB, etc. The password will be Training1
- If you have a BMC network login, your username and password will be the same as your BMC username and password when the system goes live
- To send an email to internal system support, click on the envelope on the homepage or 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
- Please login to the system now

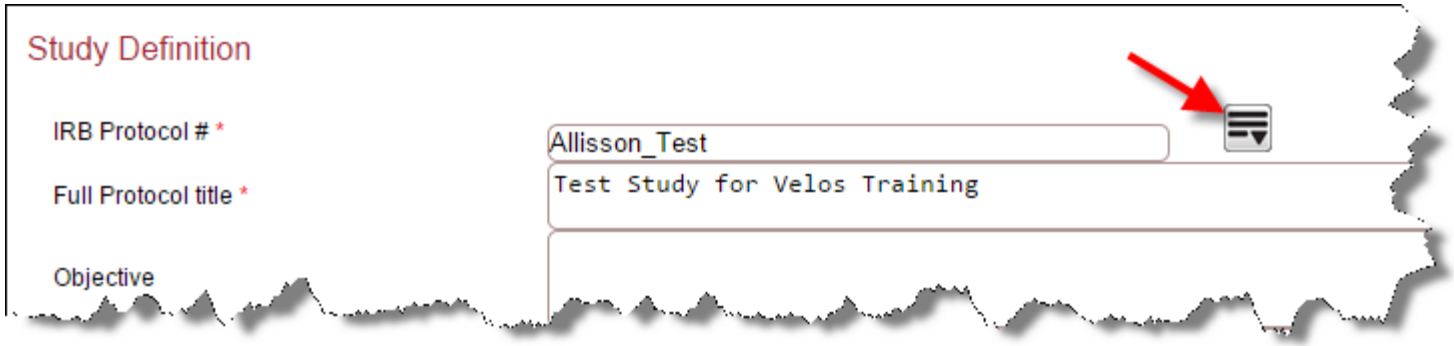
Entering a New Study

- Start by clicking Manage->Studies->New
- All fields with a * are mandatory and must be filled in to save your new study
- “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
- Type e-signature (temporary e-signature is 1234) and submit to save



More Study Details

- After you save your study summary basic information you can enter the more study details by clicking the icon next to IRB protocol #
- This will pop up a new window with BMC/BU specific information needed for proper analysis and account setup by the CTO
- Make sure to fill in all information that is pertinent to your study, there is a reminder to fill out the study setup related form
- Disregard the fields with blue writing
- E-sign and submit



Upload Documents

- The Documents tab is where you will upload all study related documents that you have
- These include: 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 Velos
- Click ADD NEW DOCUMENT OR VERSION link
- 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
- When you first go into the Documents tab there will 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 in the system by Name, Organization, Group or Job Type
- Once you have found your user click the select box, assign them a role, e-sign and submit
- If your user does not exist please fill out the New User Request Form (located on the CTO intranet-link in quick links on home page), if your study team member will not be using the system, please use the add a non-system user form

Complete Study Summary Form

- Click on the forms tab to get to the available forms
- Choose Study Summary Setup-Related Form
- Click new and the form will appear
- Data entry date will default to today's date
- Enter any sub-site information that is applicable to your study
- You can enter CPT codes and procedures for your study if you have them, this information is helpful for your CTFA to complete their budgeting and analysis
- If you have additional information that does not fit on the form, please contact your CTFA directly
- Form status will be marked as completed and e-sign and submit, this will send a notification to CTO

Checking/Updating the Study Status

- Study Status tab is where you can see the current status of your study
- CTO will be updating the CTO budget study status and the study team can view it at anytime without having to ask their financial analyst where they are in the process
- The study team will be responsible for updating the Study type Study Status
- Select the status type and then choose the appropriate study status for your study
- Your name will auto populate the Documented By field
- Enter the Status Valid From date, make sure the check box is checked if this is the current status
- For a list of what each study status means, please see the appendix

Brief Overview-CTO Responsibilities

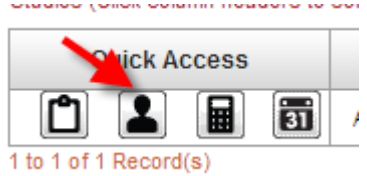
- The CTO will be responsible for the Study Setup, which involves translating and building the study calendar, budget and milestones info into VelosCT from the documents the study team provides
- The first step is to associate a calendar with the study
- Calendars are saved as templates in Velos and 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

Training Overview-Patient Information

- Search for your existing Study
- Add an existing patient to your Study
- Add a new patient 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 patients 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 patients to your study



- Within a study you can also click on the Study Stetup 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

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

Add a New Participant To a Study

- If you are unsuccessful in finding your participant after searching in Velos, you will need to enter a new patient
- Click Manage->Patients->New
- On the Patient Details screen the Patient ID (unique Velos ID) will be system-generated
- Enter Name, DOB and other demographics that you have, select a study and then e-sign and 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)
- Now click on the Demographics tab for this participant, here you can fill in additional information such as contact info, the facility ID is intended to be the MRN (if you have it) otherwise it will default to Patient ID
- Reason for change is required, please enter what information you updated on this screen
- E-sign and submit and then click on the Protocols tab, click on the study that you enrolled the participant on
- This brings you to 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

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

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

Add an Unscheduled Event

- Inside a patient schedule and in a visit, the CTO will have the option to add an unscheduled event
- The visit must be open and then you will get the Add Unscheduled Event link, click on the link
- 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

Using the Schedule Tab

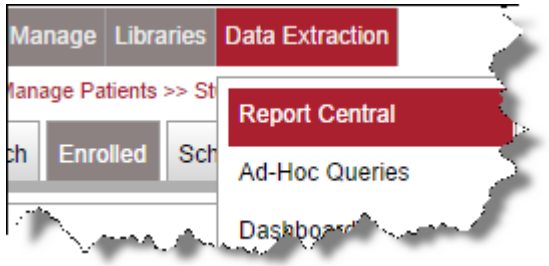
- Start by clicking Manage->Patients->Schedule
- This will bring you to the Schedule tab within Patients
- This gives you a helpful view of all your patients currently on your studies with upcoming visits scheduled
- You can update patient status, visit status or click on the Pt. Study ID link to manage 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

Running a Report

- Reports can be run be either clicking on the Reports tab within your study or by going to Data Extraction->Report Central
- You first select a report type, most likely Financial
- The Milestones Summary report will be helpful as it shows what was available to be invoiced, what has been invoiced, and what has been received



- Choose your report, then click the Select Study link and choose the study you would like to view, click the select button and then submit
- When you are back on the main screen, click Display and it will show you your report in a new window (you can export to excel or print)
- For a patient report, a good option is the Study Visit Calendar
- It works best if you select the month that you want to see a calendar of, select your study and display

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)

Selvin Ohene – Director CTO

Meghan Garland – Clinical Research Attorney

Allisson Dugan – Sr. Financial Analyst

Dean Robinson – Sr. Financial Analyst

Raymond Jaro – Research Accountant

Research Business Intelligence (RBI)

Garo Stone-DerHagopian – Director RBI

Christopher Sullivan – Business Analyst

Matthew Glynn – Business Analyst

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 velos, 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