



WebDCU™

User Manual

Data Coordination Unit
Medical University of South Carolina
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WebDCU™ General Overview

Several hundreds of clinical trials are being conducted at any one time in the United States. Investigators of these trials invest vast amounts of resources and energy into conducting these studies and often face daily challenges with data management and data quality control. The management, transfer and storage of data generated from these studies create several pitfalls to conducting successful clinical trials including lack of real-time data reporting, lack of resources for recording the data, endless amounts of paper and lack of document storage space.

The WebDCU™ system combines study tools required for this trial into one user-friendly system. Data is directly entered into the database via a secure internet connection at each clinical site. Pre-programmed logic checks allow for automatic notification of rule violations (i.e., out of range values, inclusion/exclusion criteria deviations, dates) which are displayed on the data entry screen for quick and efficient resolution at the site. This allows the clinical sites and principal investigators access to real time data.

NDMC Contact Information

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System Requirements

- Access to WebDCU™ requires a computer with high-speed internet access. (Please note that JavaScript must be enabled)
- As required by 21 CFR Part 11, any WebDCU™ user who leaves the workstation must log off the system. Additionally, automatic system protection (screen saver and password protection) must be enabled for SHORT periods of inactivity to protect against unauthorized data entry.

System Security and Password Protection

- Security of the database is dependent on maintaining individual password security.
- Each user is issued an individual password which is not to be shared with any other user. Recording of passwords which might expose them to viewing by others is strictly forbidden.
- Keep your password secure at all times. It is imperative that you do not share your user account information with others and that you keep your password secure at all times. The audit trail that is maintained in the study database is directly linked to your username. Sharing account information falsifies the audit trail and is contrary to Good Clinical Practice. If you feel the security of your password has been compromised, immediately change your password. To do so, click on [Toolbox] on the main menu page, then click 'Change Password' and follow the instructions.
- Due to security and technical issues, please refrain from using any auto-complete setting that store passwords.
- When a user is logged in to WebDCU™ but is inactive for 20 minutes, the screen will be blocked. To activate the screen, the user will need to correctly re-enter the password. If the password is entered correctly, the screen will be activated, and all data previously entered will be present. If the user fails to enter the username/password combination correctly 3 times, the user will be automatically logged out and all data will be lost. After 90 minutes of inactivity, the user will be logged off from the website and any unsaved data will be lost. Any activity which involves sending or receiving data to or from the website will

maintain an active connection. Scrolling through a report, reading or typing an extended narrative will not be detected as activity.

- To prevent loss of newly entered CRF data, the form should be saved before leaving the system inactive. Any data not saved will be lost if the system times out.

Logging in to WebDCU™

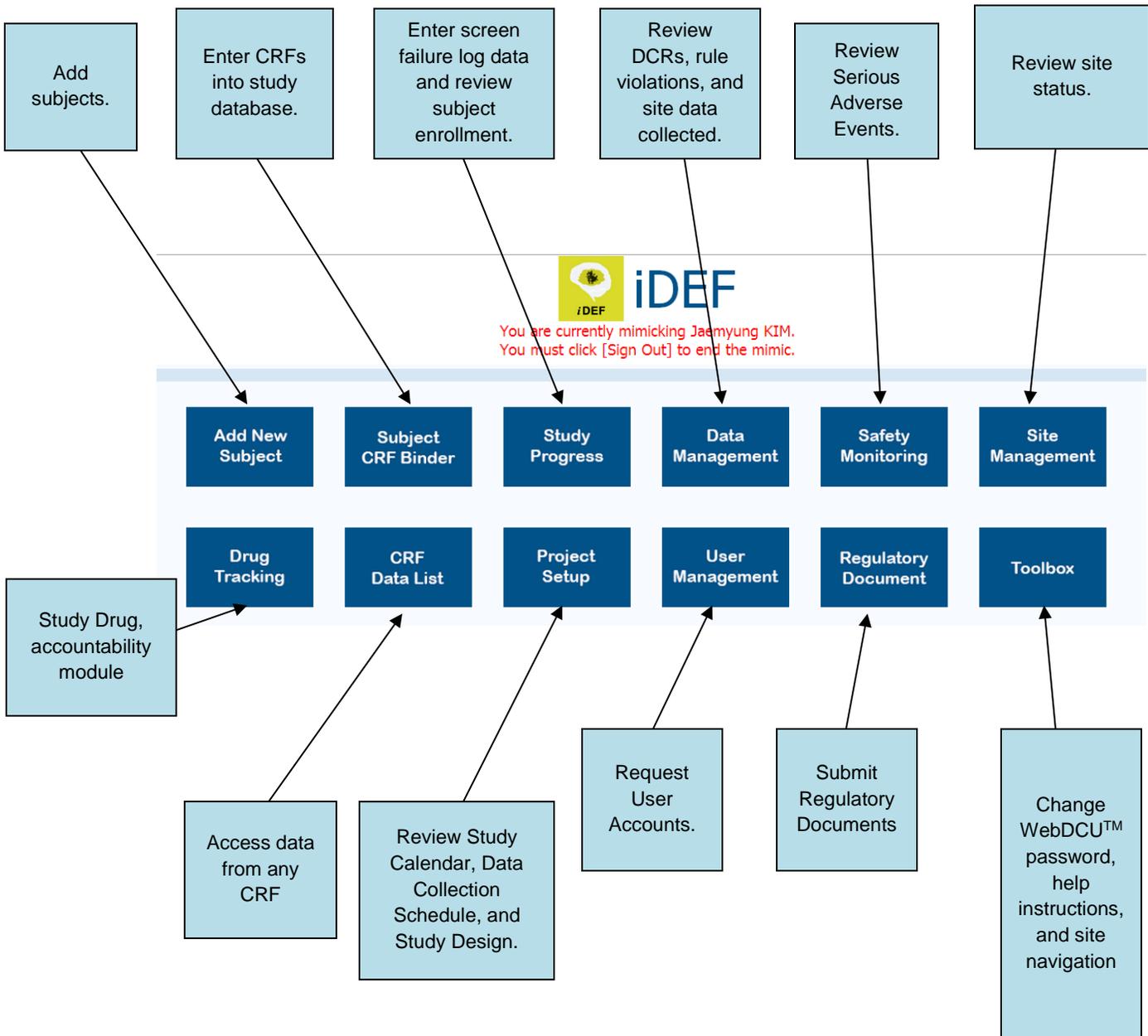
- Turn on your computer, click in your internet browser (Internet Explorer 7 or higher is recommended) and type <https://webdcu.musc.edu/login.asp> into the address bar at the top of the page.
- Type in your user name (email address) and your password and click 'Login'. If you have forgotten your password, click on the 'Forgot password?' link at the bottom of the main login screen to reset it. Once you are logged in, icons for all of the studies in which you are an active member will be displayed. Click the appropriate icon.
- The first time you log in you will automatically be directed to the 'Change password' page. Please note that your password must be 6-35 characters long and must only contain letters, numbers, and spaces. At least one upper case letter, one lower case letter and one number must be included.

Logging out of WebDCU™

- In order to protect the integrity of the trial data always log out prior to leaving your workstation. To log out, click on 'Sign Out' in the upper right hand corner of the main menu page or shut down the application by closing your internet browser.

Features on the Main Menu Page

Note: Icons that display on the homepage are specific to each user and the permissions that they are assigned. Therefore, the icons on the home page for each study team member may vary.



- **Add New Subject**
Allows you to add Subjects to the study database
- **Subject CRF Binder**
Allows you to add Visits to existing Subjects and enter or edit Case Report Form (CRF) data
- **Study Progress**
Allows you to view subject enrollment and enter monthly Screen Failure Logs.
- **Data Management**
Allows you to view data management information such as CRF, rule and DCR status
- **Safety Monitoring**
Allows medical safety monitor to review serious adverse events.
- **Site Management**
Allows you to review site status. Also contains payment module.
- **Drug Tracking**
Allows you to access drug accountability (for site pharmacist only)
- **CRF Data List**
This icon contains a separate icon for each CRF. Selecting an individual CRF icon, populates a list of the forms that have been entered specific to that CRF. The selection can be further refined by applying the filters available to each column.
- **Project Setup**
Allows you to review the Study Calendar, Data Collection Schedule, and Study Design. The PDFs of individual CRFs and visit study books are located under the Data Collection Schedule. These are accessed by clicking on the PDF icons.
- **User Management**
Allows you to request user accounts for study team members, view a listing of your study team members, and submit your site's Delegation of Authority (DOA) Log.
- **Regulatory Document**
Allows you to view and submit regulatory documents

- **Help & Toolbox**

Allows you to change your WebDCU™ password, and access help instructions and site navigation tools. This is also where you will find Project Documents. 'Project Documents' is where you will find documents that have trial-wide importance, such as the protocol, the Manual of Procedures (MOP) and the Data Collection Guidelines.

- **Project Management (Not Pictured)**

Where you will find CIRB minutes and a module for reporting Unanticipated Events to the CIRB

- **Data Monitoring (Not Pictured)**

Allows on site monitors to schedule monitoring visits and submit monitoring reports

- **Emergency Help (Not Pictured)**

Contains the number for the Emergency Randomization Hotline. Also contains the information for contacting Data Management support.

Obtaining a User Account and Defining Study Team Members

- In the WebDCU™ database, the User Account governs many of the functions available to study team members. Regardless of whether the study team member will need to gain access to the WebDCU™ database, each study team member must have a WebDCU™ User Account in order to track the required regulatory documents for that person.
- To start the process, a user account for the Primary Study Coordinator at each site will be created by the Data Manager, or designee, at the NDMC. An email notification will be sent from WebDCU™ with the user's account information.

Adding Study Team Member User Accounts (For Site Study Coordinators)

- To obtain a user account for the remainder of the study team, the Primary Study Coordinator should enter a study team member request.
- From the study's main menu page, the Primary Study Coordinator should click on [User Management], and then [Study Team Member Request]. Click on [Add New] in the upper right hand corner of the screen. Complete all information on the 'Study Team Member Request' page, and then click 'Save Record'.

- If the 'Study Team Member Request' was approved (see Request Process Status), a 'User Permission Request' may be added for this study team member and they may be added to the electronic DOA log.
 - If the 'Study Team Member Request' was NOT approved (see Request Process Status), contact your trial's Data Manager to get the issue resolved.
- To request a 'User Permission Request', return to the study's main menu page. Click on [User Management] and then [User Permission Request]. On the list record page, click on the blue number link to the left of the study team member name you are looking for.
 - Once on the 'User Permission Request' page, click on [Edit Record] in the top right hand corner of the screen. Select from the drop-down box in Question 8 what user group permissions this person should have. Click [Add New Row] if an additional user group needs to be added. All study team members should be added to the 'WebDCU User' group. When done, click [Save Record].
 - The NDMC Data Manager will review and approve the request or contact the site if they have any questions. Please note that only those assisting with study start-up and regulatory documents will be granted access prior to their site being released to enroll. All other team members will be granted access immediately prior to their site being released to enroll. All other team members added during the trial, will be granted access once they are on an approved site DOA.

Adding/Editing Study Team Members on Electronic DOA Log (for Site Regulatory Coordinators)

- From the study's main menu page, click on [User Management], and then [DOA Submission].
- Click on the blue number link to the left of your site name.
- Click [Edit Record] in the upper right hand corner.
 - **To add a site team member to the DOA log**, select their name from the 'Team Member' drop down box under section 6: Team Member Request and enter their start date on the study. Select the study team member's role(s) by selecting the appropriate radio button(s). Please

refer to the Study Role key at the bottom of the page. Next, select the radio buttons pertaining to the DOA responsibilities assigned to this study team member. Refer to the key at the bottom of the page.

- **To remove a site team member from the DOA log**, enter an end date next to their name under section 5: Active Team Members.
 - **To change the roles and/or responsibilities of a current site team member**, you will first need to enter an end date for their current roles and responsibilities under section 5: Active Team Members. Then, under section 6: Team Member Request, select their name and start date for the new roles and responsibilities. The start date and end date should match. Select appropriate roles and responsibilities based on the keys at the bottom of the page.
- If you need to leave the 'DOA Submission' page in the middle of completing the form, select "no" for Q7 "DOA Complete. Submit to Regulatory Document Manager for Review" then click on [Save Record]. This will save all changes you have made to the DOA log, but allows you to go back and finish editing the form prior to being reviewed by the Regulatory Document Manager.
 - Once all study team members have been added/edited along with their roles and responsibilities, select "yes" for Q7 "DOA Complete". Submit to Regulatory Document Manager for Review" then click on [Save Record]. The DOA will then be sent to the Regulatory Document Manager for review and approval. The regulatory document requirements for the newly added or edited study team members will not populate in the regulatory database until the DOA is approved.

Approving Electronic DOA Logs (for Regulatory Document Managers)

- From the study's main menu page, click on [User Management] and then [DOA Review].
- Click on the blue number link to the left of the site you would like to review.
- Once on the site's 'DOA Review' page, click [Edit Record] in the upper right hand corner of the page.
- Review all changes made to the DOA.

- If there are errors on the DOA, select “Rejected” for Q9: Review Status and enter the reason DOA is being rejected. Then click [Save Record]. An automated email will then be sent to the site alerting them the DOA has been rejected.
- If there are no errors on the DOA, select “Accepted” for Q9: Review Status. Then click [Save Record]. This approval will trigger the site’s regulatory document requirements to populate for the changes made to the DOA.

WebDCU™ GENERAL OPERATIONS GUIDE

The WebDCU™ data management system has a generic design. This means that the menu functions and database format will be similar throughout the system, even though the tables and questions may differ.

Adding a Record to a Table

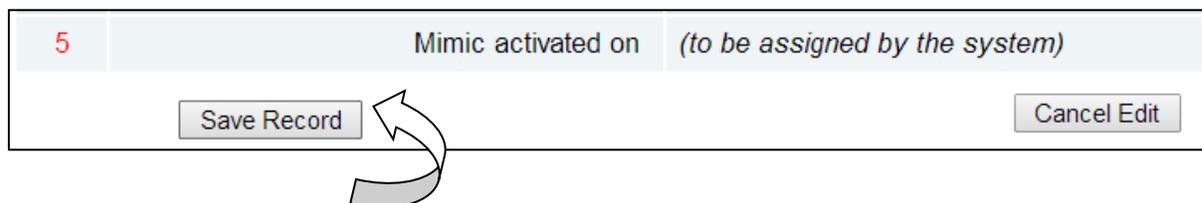
- From any List Record page, click the 'Add New' button located at the top right-hand corner of the table.



The screenshot shows a table with a header row and six data rows. Above the table is a 'Page Actions' dropdown menu and an 'Add New' button. A curved arrow points from the 'Add New' button to the table.

Spoke	Month	Year
University of Maryland Medical Center, Baltimore, MD	Jun	2010
University of Maryland Medical Center, Baltimore, MD	Jun	2010
University of Maryland Medical Center, Baltimore, MD	Jun	2010
Henry Ford Hospital, Detroit, MI	May	2010
Henry Ford Hospital, Detroit, MI	Jun	2010
Henry Ford Hospital, Detroit, MI	Jun	2010

- This will open the form. Questions numbered in red are required. Questions numbered in black are optional. After entering the required information, click the 'Save Record' button at the bottom of the page.



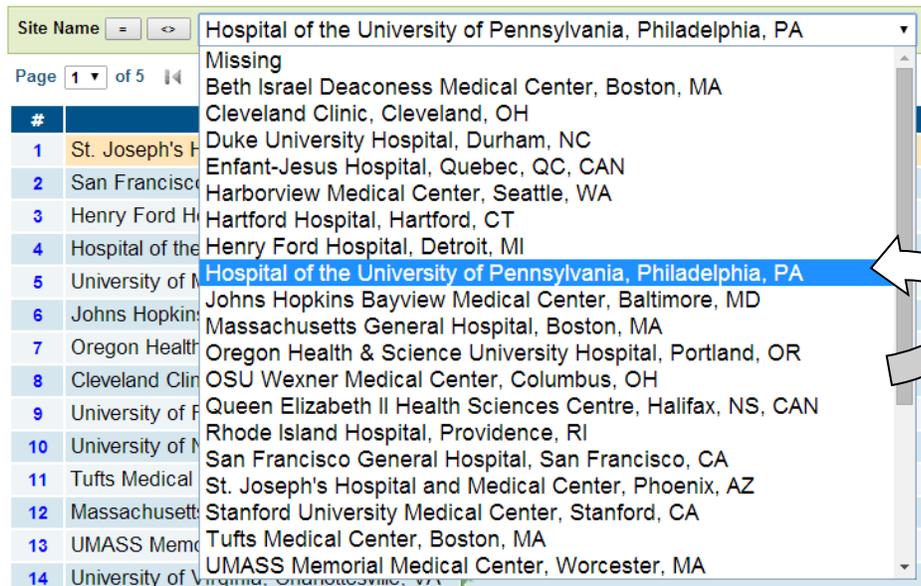
The screenshot shows a form with a red number '5' in a small box on the left. The text 'Mimic activated on' is followed by '(to be assigned by the system)'. At the bottom, there are two buttons: 'Save Record' and 'Cancel Edit'. A curved arrow points from the 'Save Record' button to the right.

5	Mimic activated on	(to be assigned by the system)
<input type="button" value="Save Record"/>		<input type="button" value="Cancel Edit"/>

- The browser will be forwarded to the List Record View page, which allows the user to view the information that was just entered. To return to the 'List Record' page, click the 'List Record' button in the top-right hand corner of the page.

Viewing/Sorting/Filtering Records

- The sorting and filtering features are available for all 'List Record' pages.
- To view additional details about a record, click the blue number link in the first column of the 'List Record' table.
- To sort any column in ascending order, click the column header once. To sort any column in descending order, click the column header twice. Clicking the header a third time will remove sorting order for that column. Please note that you can sort more than one column at a time.
- To filter records, select the criteria you want to filter by clicking on a value within any cell. When a cell is clicked, it will be highlighted in a light orange color. You may deselect a cell by clicking on it again or by clicking on another cell.
- The field that was selected will display in the upper left hand corner of the screen. You may make any changes to the selection by either typing in a different selection or making another choice from the drop down box. Then click the appropriate filter operator button (< >, =, like, etc.) to apply the filter. Different operators are provided based on the field type selected. The records will be filtered by the parameters selected.

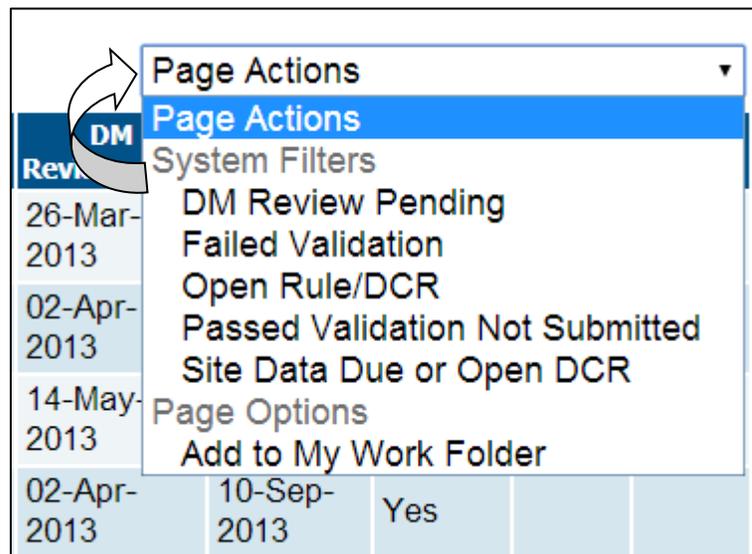


#	Site Name
1	St. Joseph's Hospital, Philadelphia, PA
2	San Francisco General Hospital, San Francisco, CA
3	Henry Ford Hospital, Detroit, MI
4	Hospital of the University of Pennsylvania, Philadelphia, PA
5	University of Michigan Medical Center, Ann Arbor, MI
6	Johns Hopkins Hospital, Baltimore, MD
7	Massachusetts General Hospital, Boston, MA
8	Oregon Health & Science University Hospital, Portland, OR
9	Cleveland Clinic, Cleveland, OH
10	OSU Wexner Medical Center, Columbus, OH
11	Queen Elizabeth II Health Sciences Centre, Halifax, NS, CAN
12	Rhode Island Hospital, Providence, RI
13	San Francisco General Hospital, San Francisco, CA
14	St. Joseph's Hospital and Medical Center, Phoenix, AZ
15	Stanford University Medical Center, Stanford, CA
16	Tufts Medical Center, Boston, MA
17	UMASS Memorial Medical Center, Worcester, MA
18	University of Virginia, Charlottesville, VA

- To remove a single filter, click on the **x** in the upper left hand corner of the screen adjacent to the filter you would like to remove. **Note:** This button will be viewable only when a filter has been applied.
- To remove the entire filter (after multiple filters have been applied), click on the **x** in the upper left hand corner of the screen. **Note:** This button will be viewable only when multiple filters have been applied.



- System Filters are provided to all users and are setup and maintained by the DCU. Each table will have specific system filters based on the records found in the table.
- The 'Page Actions' dropdown box is located in the upper right-hand corner of the table, just below the menu tabs. Click on the dropdown box and select the filter you wish to apply. The listing will then show only those records which meet the filter criteria.



Editing Records in a Table

- If a record needs to be updated or edited, click on the blue number link in the first column of the 'List Record' table.



#	Site	Month	Year
1	Beth Israel Deaconess Medical Center, Boston, MA	Feb	2013
2	Oregon Health & Science University Hospital, Portland, OR	Feb	2013
3	UMASS Memorial Medical Center, Worcester, MA	Feb	2013
4	Beth Israel Deaconess Medical Center, Boston, MA	Mar	2013

- This will open the Edit Record form. Click 'Edit Record' at the top right-hand corner of the screen. Edit the record as needed, then click 'Save Record' at the bottom of the table.
- To return to the List Record page, click the 'List Record' button in the top-right hand corner of the table.

REGULATORY DOCUMENTS

The Site Regulatory Coordinator will be able to submit regulatory documents through WebDCU™ based on the pre-specified regulatory document collection requirements. Regulatory documents are divided into two groups: “Site Documents”, such as IRB Approval, FWA, CAP/CLIA, and “People Documents”, such as CV and medical licenses.

In order for a regulatory document requirement to populate for a study team member, he/she must have an active WebDCU™ user account and be listed on their site’s electronic DOA log. Instructions for submitting your site’s DOA log can be found under ‘Obtaining a User Account and Defining Study Team Members’.

Viewing Status of Required Documents

- To view a listing of required documents, from the main menu page click on [Regulatory Document], and then [Site Reg Doc Status]. Select the site and expiry window you would like to review (it will always default to 60 days) and click [Apply].

Henry Ford Hospital, Detroit, MI		Expire Window (days): 60	Apply
Site Documents			
Site Status	Preparing		
CAP/CLIA Certification			
Delegation of Authority Log			
FDA Form 1572 - Statement of Investigator			
IRB Acknowledgement of Site Close-out			
IRB Approval of Site PI Change			
IRB Federal Wide Assurance			
IRB/REB Approval Protocol v3A (+ ICFs, HIPPAAs, and written information for the subject)			
IRB/REB Approval Protocol v4/1 (+ ICFs, HIPPAAs, and written information for the subject)			
Lab Normal Ranges			
Qualified Investigator Undertaking			
Research Ethics Board Attestation			
Signature Page - Protocol v4/1			
People Documents			
Person	Medical License	Curriculum Vitae	NIHSS Certification
Chandan MEHTA			
Lauren TACK			

- This will display a table view of the documents required to be collected at your site as well as the submission status of each document.



- If a regulatory document is accepted and will not expire within the expiry window, this will be indicated by a full green rectangle. If part of the rectangle is green, that indicates that the document will be expiring within the expiry window you set. If you mouse over the rectangle, a pop-up will indicate when the document expires.
- If a regulatory document has been expired for at least the expiry window you set, this will be indicated by a full red rectangle. If part of the rectangle is red, that indicates that the document expired within the expiry window you set. If you mouse over the rectangle, a pop-up will indicate when the document expired. To upload a new document, click on the  link and this will take you to [Reg Doc Submission].
- If a regulatory document is waived and therefore not required, this will be indicated by an empty green rectangle.
- If a regulatory document is missing or has not been submitted yet, this will be indicated by an empty red rectangle.

Submitting Regulatory Documents (for Site Regulatory Coordinators)

- From the main menu page, click on [Regulatory Document], and then [Site Reg Doc Submission] or [People Reg Doc Submission] depending on the type of regulatory document you will be submitting.
- This will take you to a 'List Record' page of all the regulatory documents at your site.
- Click on the 'Add New' or 'Edit' green arrow link adjacent to the document you would like to upload or edit.



#		Institution	Document
1	Add New 	William Beaumont Hospital, Royal Oak, MI	CAP/CLIA Certification

People Reg Doc Submission

	Data Value
Site	WebDCU Test Site 3, Charleston, SC
Team Member	GRIFFIN, Jessica
Document	GCP Training
Existing Documents	<input type="radio"/> ARCADIA-CSI: 10/01/2019 - 10/01/2022 accepted by Jessica GRIFFIN 
Waived	Please Select ▾
Reason waived	
Effective date	<input type="text"/> ▾ <input type="text"/>  (dd-mmm-yyyy) Complete
Expiration date	
File	Upload New File
Status	Pending
Reason for rejection	
Submitted by	(to be assigned by the system)
Submitted on	(to be assigned by the system)
Submit Notes	<input type="text"/>

Save Record

Cancel Edit

- If there are any existing documents available for selection, they will be listed under Q3 for 'Site Reg Doc Submission' and Q4 for 'People Reg Doc Submission'. To review an existing document, click on the blue file link. If there is an existing document you would like to use for regulatory document submission, select the radio button adjacent to that document.
- If there are no existing documents available or none that you would like to select, click on the 'Upload New File' link, browse for the document on your local computer, and then click 'upload file'. Please note: All regulatory files uploaded to WebDCU™ must be in PDF format. Word and picture files will be rejected.
- Enter the remaining required information on the submission form, and then click 'Save Record'. Required information will be indicated by a red question number. If you need assistance in completing the required fields (i.e. effective date, expiration date, etc.), refer to the trial-specific Regulatory Document Parameters document. This document can be found in WebDCU™ under [Toolbox]→[Project Documents].
- The document will then be in a pending status until the Trial Regulatory Document Manager verifies the information and approves/accepts the document.

Editing Rejected Documents (for Site Regulatory Coordinators)

- To edit a document that has been rejected, from the main menu page, click on [Regulatory Document], and then [Site Reg Doc Submission] or [People Reg Doc Submission]. Click the 'Edit' green arrow link adjacent to the record you would like to edit. Update the new file and/or information, and then click 'Save Record'.
- **Note:** All regulatory documents should be uploaded in PDF format.
- **File Upload Restrictions:** Only PDF files less than 3MB can be uploaded. If you are using Adobe Acrobat Professional, set your options to 'higher compression' (as opposed to 'higher quality'). If you are not using Adobe or experiencing difficulties with the file size limit, you may contact the appropriate DCU data manager.

Approving/Rejecting Documents (for Regulatory Document Managers)

- To review uploaded documents for approval/rejection, click on the [Regulatory Document] tab on the study-specific main menu page. Next, click on [Site Reg Doc Review] or [People Reg Doc Review], as appropriate. This will take you to a 'List Record' page of all submitted regulatory documents.
- To filter for the documents awaiting approval, select "Pending Docs" from the drop-down box in the upper right hand corner of the page. Click on the blue number link adjacent to the document you would like to review. This will take you to [Reg Doc Review].
- Click on the document link to review the document for accuracy. Select the 'Edit Record' button in the top right hand corner of the page. If the document is correct, select "Accepted". If the document is incorrect, select "Rejected" and enter a reason for rejection. If the effective date or expiration date has been incorrectly entered by the site, update the appropriate date to ensure it matches what is in the document. Next, click [Save Record]. The site will receive an automatic email notification if the document is rejected.

PROJECT DOCUMENTS

Locating Project Documents

- Study specific documents can be found by clicking on [Toolbox] on the home page and then clicking on [Project Documents]. To view or print a project document click on  icon next to the document. You may then print the document by selecting the appropriate print function from your browser toolbar.

Printing Study Books or Individual Worksheets

- Prior to enrolling a subject into the study you may wish to print the subject's study book. This is a collection of worksheets which defines the data that is required to be collected for the protocol.
- To print a complete study book for a subject, click on [Project Setup] on the home page and then click on [CRF Collection Schedule]. Click on the  icon adjacent to the name of the CRF to open the PDF file to print the individual CRF. To print the study book for a visit click on the  icon below the visit name. The PDF file can then be printed by selecting the appropriate print function from your browser toolbar. The most up-to-date CRFs and study books will always be in this location.
- **Note:** When new versions of the CRFs are published during the conduct of the study, you will be notified via e-mail and the revised worksheet and study book will be posted. Due to the possibility of frequent changes to these worksheets, it is recommended that you print only a few study books at a time. When a new worksheet version is posted it will be necessary for you to replace the out of date pages in any already printed study books.

Reporting Monthly Screen Failure Logs (for ARCADIA only)

Screen failure logs are posted on the 1st of every month. The previous month's screen failure log should be submitted in WebDCU™ by the 10th of the following month. If a log is not entered by this date, your site will receive an automatic email notification regarding the late Screen Failure Log email notification. Even if a site does not have any screen failures, the log must be submitted.

- To data enter the Screen Failure Log, click on [Study Progress] located on the home page. Then click on the [Screen Failure Log].
- Click the blue number link in the first column of the List Record table adjacent to the record that requires editing, click on 'Edit Record', enter the required information, and then click 'Save Record'.

WebDCU / DEF Andre THORNHILL Sign Out Help

Edit: Screen Failure Log

No.	Item Description	Data Value				
	Enter all patients, over the age of 18 years, who presented at your site with spontaneous ICH within 48 hours of onset, and were not randomized. Enter this data into WebDCUTM by the 10th day of the following month.					
1	Site	San Francisco General Hospital, San Francisco, CA				
2	Month	Nov				
3	Year	2013 (4 digits)				
4	Any screen failures to report?	<input type="radio"/> No <input type="radio"/> Yes				
5 Screen Failure						
No.	A. Screening day (dd)	B. Sex	C. Race	D. Ethnicity	E. Age (years)	F. Enter primary reason patient is not
5-1						
Add New Row						
7	General Comments					(150)

Last updated by System on 01-Nov-2013 4:00AM

Save Record Cancel Edit

Screen Failure Report (for all StrokeNet trials except ARCADIA)

- To print a copy of the Screen Failure Report worksheets, click on the [Toolbox] tab, and then click on [Project Documents].



- Click on the  icon adjacent to the Screen Failure Report to open the PDF file. The PDF file can be printed by selecting the appropriate print function from your browser toolbar.
- Screen failure reports should be submitted in WebDCU™ within 5 days of the screening date. If there are issues entering screen failures, please contact the appropriate Data Manager.
- To enter the Screen Failure Report, click on [Study Progress] tab, and then click on the [Screen Failure Report] button.



- Click [Add New] in the upper right corner of the page to initiate a new Screen Failure Report. Enter the required information and click on [Save Record] once finished.
- Users may add as many Screen Failure Reports as necessary. To update an existing report, click on the blue number link adjacent to the appropriate existing report and click [Edit Record]. Detailed instructions for completing

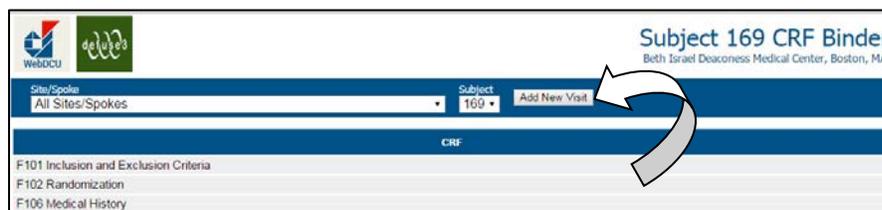
the Screen Failure Report can be found in the study-specific Data Collection Guidelines.

ENTERING DATA

Adding a Subject Visit

- Please note that you will only be able to view the CRFs for the visits which have been added for the subject. To move a subject into the next visit (and therefore make CRFs available for that visit) you will need to move your subject using the 'Add New Visit' button at the top of the Subject CRF Binder.
- The forms for that visit will be automatically posted in the [Subject CRF Binder] in the middle of your screen for that subject.

Note: Do not move a subject to a visit until that visit has actually occurred.



Entering/Viewing CRF Data

- From the home page, click [Subject CRF Binder]. Select the subject's site from the Site drop down box, if applicable. Now select the subject you would like to work on from the 'Subject' drop down box. The CRFs for that subject are posted on the Subject CRF Binder in the middle of the screen.
- Click on the appropriate icon for the CRF you would like to enter/view.

CRF	Baseline 20-Mar-2018	Randomization 21-Mar-2018
F101 Inclusion and Exclusion Criteria		
F102 Randomization		
F106 Medical History		

- The CRF will appear on screen. Enter the data, then click 'Save Record' located at the bottom left of the page.
- If required data is missing or contains formatting errors, you will receive a small pop up window in the middle of your screen listing your errors. You are required to fix the errors before you can save the form.
- After the data is saved, you will receive notification of any rule violations adjacent to the offending data.
- The different types of rule violations are listed below:
 - **Rejections** are signified by a red "R" preceding the violation number. These types of errors involve significant logical data errors. The only way to remove a rejection is to correct the data by editing the CRF.



Study Completed
 Consent withdrawn, specify
 Lost to follow-up
 Death
 Other, specify

R Q01 must be answered.

Q03	Consent withdrawn due to an adverse event	<input type="radio"/> No <input type="radio"/> Yes	 R Q03 must be answered.
-----	---	--	---

- **Protocol Violations and Warnings** are signified by a red "PV" or "W" respectively preceding the violation number. These types of rule violations are put in place to protect against typographical errors and to notify users of missing data or protocol violations.



No Yes Unknown

PV Q03 must be [Yes] or this is an eligibility violation.

- Protocol Violations and Warnings may be addressed in two ways.
 - If the data was incorrectly entered, the data may be edited. Click on 'Edit CRF' located at the top right hand corner of the screen. Edit the data as needed, enter the 'reason for change' at the bottom of the screen, and click on 'Save Record'.

OR

- If the entered data is correct as is and a protocol violation truly occurred, the site may dismiss the protocol violation (see Dismissing Protocol Violations or Warnings)

Dismissing Protocol Violations and Warnings

- To dismiss a warning or protocol violation, click on the  icon located below the red warning/protocol violation. Specify the reason you are dismissing, and click [confirm rule violation]. After this, the violation will be dismissed and you can submit the CRF.



WebDCU™ Rule Violation Confirmation

Rule Message: Q01 should be answered.

Response:

Confirm Rule Violation

Enrolling/Randomizing a Subject

- From the home page, click on 'Add New Subject', enter the required information, and then click 'Save Record'.
- This will generate a subject ID. Click on the  icon, at the bottom of the Subject Enrollment Form, to move to the [Subject CRF Binder]. Click on the 'Add New Visit' button to move the subject to the first visit and post the appropriate CRFs.
- Click on the CRF icon for each of the forms required to randomize the subject, enter the required information and then click 'Save Record' button. Once all eligibility criteria have been verified, click the 'Submit CRF' button.
- The computer will generate the randomization assignment and will display the treatment assignment for that subject on the screen. A screen shot of this form can be printed using the print function in the browser by selecting the appropriate print function from your browser toolbar.
- **Note:** For more detailed instructions of this process for each project, please refer to the Randomization Instructions located in Project Documents.

Treatment Unblinding Instructions (for study PIs)

Please note that this section will only apply to certain StrokeNet trials. Please refer to your Data Collection Guidelines to determine if this is applicable to your study.

Requests for unblinding will be received by the study PIs via the clinical hotline. Once a request to unblind is determined to be appropriate, the study PI who received the request should follow the steps below to unblind the subject's treatment assignment.

- Select the [Safety Monitoring] tab, and then select [Treatment Unblinding].
- Select the 'Add New' button located at the top right corner of the page.
- Complete the Treatment Unblinding form:

- Subject: select the subject to be unblinded from the dropdown list. To quickly find a subject ID, begin typing the number in the field.
 - Site: once the subject ID has been selected, you will be able to select the subject's enrolling site. While only one option will be available in this field, you will need to select the site from this dropdown field.
 - Requested by: indicate if unblinding was requested by the subject's treating physician or by a study team member.
 - Reason for unblinding: enter the reason for unblinding.
 - Notes: this field is optional and can be used to document any other relevant information about the unblinding.
- Once the Treatment Unblinding form is complete, select the 'Save Record' button at the bottom of the screen.
 - After saving, select the 'List Record' button at the top right of the page. On the List Record page, the subject's treatment assignment will be shown under the 'Treatment' column. Treatment assignment will display as one of the options available for your study.
 - Also on the 'List Record' page, the subject's gender and date of informed consent will be shown. This information is intended to be used to verify that unblinding has been requested for the correct subject before providing that information to the requestor.
 - Treatment assignment will be available in this view for pre-specified amount of time. After this time, the subject unblinding record will remain, but the 'Treatment' field will be blank.

Submitting CRF Data

- After the data has been saved, and is free of any rule violations (i.e. rejections, warnings, protocol violations), click on 'Submit CRF' at the bottom of the CRF. Note: Data is not complete until the user clicks on 'Submit CRF'.

Adding Additional CRFs

- Certain CRFs will be repeatable, such as Adverse Event forms, to allow multiple CRFs to be completed, when required.

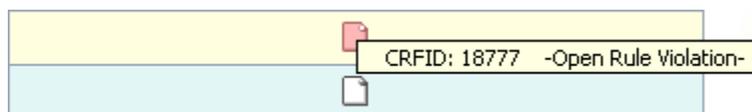
- To add an additional form, open a previously entered form of that type for that subject visit and click 'Add Repeat Form' in the header of the CRF. This will post an extra form on the CRF collection table for that visit.
- You must enter data on the added form and save it before you will be allowed to add another form.

Editing CRF Data

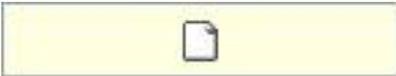
- To edit a CRF that has been saved, click on 'Edit CRF' located at the top right hand corner of the screen. Edit the data as needed, enter the 'reason for change' at the bottom of the screen, and click on 'Save Record'.

Interpreting the CRF Collection Table

- Each CRF is assigned a CRF ID number when it is posted. This number and the status of the CRF will appear while "hovering" with the mouse over the document icon in the Subject CRF Binder.



Icon	Description
	A CRF that has not yet been data entered
	A CRF that been data entered and has no violations or DCRs, but is not submitted
	A CRF with an open rule violation or DCR
	A submitted CRF that contains no clinical data

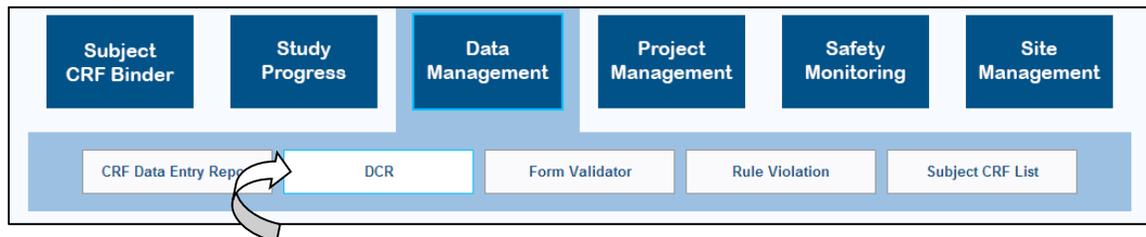
	A CRF with clinical data which has been submitted
	Yellow/Tan Cell background colors are used to indicate to the current user that a CRF needs attention.
	Blue Cell background color is used to indicate to the current user that a CRF does not need attention.

Responding to Data Clarification Requests (DCRs)

- DCRs will be generated by DCU Data Managers and Site Monitors, as needed. DCRs are signified by a red document icon on the Subject CRF Binder (see the figure below).

CRF	Baseline 08-Mar-2018	Randomization 12-Mar-2018
F101 Inclusion and Exclusion Criteria		
F102 Randomization		
F106 Medical History		

- To view open DCRs, click on [Data Management] on the home page then click on [DCR].



- Click on the green arrow in the CRF ID column for the query you want to review. This will take you to the CRF page that has been queried.
- The DCR will be posted at the bottom of the CRF page. Click on 'Add Response' next to the query and enter a response. Then click 'Save Response' at the bottom of the page.

Data Clarification Request				
DCR	Type	Status	Query	Action
5164	Monitor	Open	Please confirm the response to Q45. (Stephanie MONROE on 4/2/2013 3:54:42 PM)	Add Response

Data Clarification Request # 5164	
Query	Response
Please confirm the response to Q45.	Source documentation has been review and event head CT is present
	350 char.
	Save Response Cancel

- If the CRF requires editing, click 'Edit CRF' and correct the CRF data as needed. Then click 'Save Record' and then 'Submit CRF' at the bottom of the page.

Audit Trail Function

- The Audit Trail Function will display data points on a CRF which have been edited after submission.
- To use this feature, open the CRF, and click 'View Audit Trail'.

<div style="text-align: right;">Help</div> <div style="display: flex; justify-content: space-between; margin-top: 10px;"> Undo Accepted Create New DM DCR Edit CRF Delete CRF Data View Audit trail </div>	
Rule Status:	<input checked="" type="checkbox"/> DCR: Responded
Accept: 27-Sep-2013 20:31 System	Verify:
Data Value	

- The audit trail will be displayed in chronological order from left to right with changes highlighted in yellow.
- If no changes have been made to the form, the 'View Audit Trail' button will not be visible.

MONITORING MODULE

Monitoring Visit Planning (for Site Monitors)

- In preparation for a monitoring visit, from the main menu page, click on [Monitoring Visit Planner]. A list record view of the monitoring status of each enrolling site will appear on the screen. Click on the blue number link in the left hand column to view the details.
- To print the [Monitoring Visit Planner], click the green arrow icon  in the 'Printable Report' column. The report will contain the following information:
 - A. Site Contact Information
 - B. Active Site Team Members
 - C. Required Site Regulatory Documents
 - D. Screen Failure Log Summary
 - E. Site Enrollment and Retention Summary
 - F. Open Site Trial Operation Monitoring Issues
 - G. CRFs for Source Document Verification
 - H. Subjects to be Monitored



#	Site	Total Subjects Enrolled	Last Monitoring Visit	CRFs to be Monitored	Printable Report
<i>Total</i>		<i>50</i>	<i>17-Sep-2014</i>	<i>221</i>	
1	Beth Israel Deaconess Medical Center, Boston, MA	30	17-Sep-2014	142	R1 

- This report provides an overview of any issues at the site that need to be addressed as well as what will need to be monitored at the next visit.

Source Document Verification (for Site Monitors)

- To identify forms that require Source Document Verification (SDV), from the main menu page, click on [Project Setup], and then [CRF Collection Schedule]. Forms that require SDV are indicated with an 'M'. Refer to the Trial-specific Monitoring Plan to identify which data items on those forms require SDV.
- To identify forms that have not yet been source document verified, from the main menu page click on [Data Monitoring] and then [Monitor CRF Pending]. Click on the green arrow icon  next to the CRFID number to open the CRF. The “Q” number of items requiring source document verification will be highlighted in blue.

Q08	Ongoing or recent (within 2 weeks) hospitalization for gastrointestinal hemorrhage	
Q09	Ongoing or recent (within 1 week) hospitalization for acute pancreatitis	
Q31	Ongoing or recent (within 1 week) hospitalization for acute pancreatitis, or known ongoing biochemical or anatomic evidence of unresolved pancreatic injury	<input type="radio"/> No <input type="radio"/> Yes
Q10	Known chronic calcific pancreatitis	<input type="radio"/> No <input type="radio"/> Yes
Q11	Suspected pancreatic head malignancy	<input type="radio"/> No <input type="radio"/> Yes
Q12	Current ERCP performed on major papilla/ventral pancreatic duct in patient with pancreas divisum (no manipulation of minor papilla)	<input type="radio"/> No <input type="radio"/> Yes
Q13	Current ERCP for biliary stent removal or exchange without anticipated pancreatogram	<input type="radio"/> No <input type="radio"/> Yes
Q14	Prior biliary sphincterotomy, now scheduled for biliary therapy without anticipated pancreatogram	<input type="radio"/> No <input type="radio"/> Yes
Q15	Anticipated inability to follow protocol	<input type="radio"/> No <input type="radio"/> Yes
Q16	Absence of a rectum	<input type="radio"/> No <input type="radio"/> Yes
Inclusion Criteria		
<i>If Q23 is 0, then Q29 must be greater than or equal to 2, or this subject is not eligible.</i>		
Q17	Clinical suspicion or known sphincter of Oddi dysfunction (SOD)	<input type="radio"/> No <input type="radio"/> Yes <input type="radio"/> Unknown
Q18	History of post-ERCP pancreatitis (at least one episode)	<input type="radio"/> No <input type="radio"/> Yes <input type="radio"/> Unknown
Intra-Procedure		
Q19	Pancreatic sphincterotomy?	<input type="radio"/> No <input type="radio"/> Yes, needle-knife <input type="radio"/> Yes, traction <input type="radio"/> Unknown
Q20	Pre-cut (access) sphincterotomy?	<input type="radio"/> No <input type="radio"/> Yes, freehand <input type="radio"/> Yes, septotomy <input type="radio"/> Yes, over pancreatic stent

- Once a CRF passes monitor verification, the Site Monitor will document this by clicking on the [CRF passed verification] button at the top of the CRF page. Please note that you can only pass a CRF as verified after it has been submitted. If a form is accidentally marked as monitor verified, click the [Undo CRF Verified] button.

Creating and Closing Data Clarification Requests (DCRs) (for Site Monitors)

- To generate a DCR, open the CRF in need of review by clicking on the document icon of the Subject CRF Binder. Please note that you can only create DCRs for CRFs after they have been submitted.
- At the top of the page, click 'Create New Monitor DCR'. This will open the New Data Clarification Request screen at the bottom of the page.



<input type="button" value="Create New Monitor DCR"/> <input type="button" value="View Audit trail"/>		
iel VELEZ	Rule Status:	DCR:
	Accept:	Verify:

- Enter the required information and click 'Save Record'.

New Data Clarification Request

Query

Please confirm the response to Q45

1000 char.

- You may edit your query by clicking on 'Edit Query'. Please note that you will not be able to edit your query once a response is submitted by the site. To delete your query, click on 'Delete Query'.

Response	Action
	<input type="button" value="Add Response"/>
	<input type="button" value="Add Response"/>
	<input type="button" value="Edit Query"/>
	<input type="button" value="Delete Query"/>

- Once the site submits a response and resubmits the CRF, you will have the option of closing the DCR or generating a new query.
- If the data and response are satisfactory upon review, specify what action was taken by the site: If the site confirmed the accuracy of the data and no change was needed, select 'Data confirmed'. If the site corrected an error on the CRF, select 'Error corrected'. If the site added missing data or more information to

the CRF or if a new CRF was data entered in response to the DCR, select 'Missing item/CRF entered'. If the site was responding to a query based on a change that was made to the database by DCU, select 'Updated for DB Change'. You may then close the DCR by clicking 'Close DCR'.

- If the data and response are unsatisfactory, you should generate a new DCR by clicking 'New Query' and following the steps listed above.
- If the CRF data accurately reflects the source document, select the 'CRF Passed Verification' at the top of the CRF. **Note:** You can only pass a CRF as verified after it has been submitted by the site.

Monitoring Report Completion (for Site Monitors)

- After the required CRFs have been SDV'ed, from the main menu page, click on [Data Monitoring], and then [Monitor Visit]. Click on the 'Add New' button in the top right area to open the form for editing.

CRFs Verified	% CRFs Verified	CRFs Queried	Previous Visit Date	Monitoring Visit Report

- Select the site that was monitored, the name of the monitor, the start/stop dates of the monitoring visit, and the site study personnel that attended the monitoring visit. Then click 'Save Record'. Next, click 'Refresh Monitor Checklist' in the top right corner of the page. This will run the Central Auto checks in the "Site Trial Operation Monitoring Results" section and generate information about the site's performance.
- The results of all "Site Trial Operation Monitoring Results" are set to 'Pending'.
- Enter the required data. The Monitor should review each item in the checklist and enter the results as either 'passed' or 'failed' and indicate if any site actions are required for that particular item. **Note:** DO NOT click 'Refresh Monitoring Results' after changing the Central Monitoring results as this will overwrite the entry.
- Once complete, click 'Save Record' at the bottom of the screen. Next, contact your DCU Site Monitoring Manager to complete the process.

Responding to Site Actions Required per the Monitoring Report (for Site Study Coordinators)

- To respond to Monitor Site actions, from the main menu page, the site user should click on [Data Monitoring] and then click [Monitor Site Action Response]. To see a list of items needing a response, select the 'Site Response Required' filter from the [Page Actions] drop-down box in the upper right hand corner of the screen. Click on the blue number link in the left hand column of the record you want to open. Click on 'Edit Record' located at top right hand corner of the table, enter the required data, and then click 'Save Record'.

Closing Site Actions (for Site Monitors)

- To close Site Action items, the site monitor should click on [Data Monitoring] and then click [Monitor Site Action Review]. To see a list of items needing to be closed, select the 'Pending Site Action Review' filter from the [Page Actions] drop-down box in the upper right hand corner of the screen. Then filter for the appropriate site. Next, click on the blue number link in the left hand column of the record you want to open. If the site's response is satisfactory, select 'closed' for the site action status and then click [Save Record].

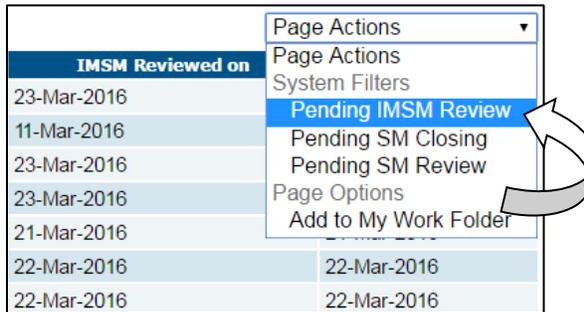
Monitoring Report Review (for Site PIs)

- To review the Monitoring Report, the Site PI should click [Data Monitoring] and then click [Monitor Visit Site View]. Click on the blue number link in the left hand column of the record you would like to open. Click on the PDF link to open the monitor visit report and review. Once reviewed, click 'Edit Record' at the top right hand corner of the screen, select "yes" for Q12: Monitor Report Reviewed by Site PI?, and then click 'Save Record'.

Medical Safety Monitoring (for Independent Medical Safety Monitors)

When an AE requires Medical Safety Monitoring review, the IMSM will receive an email notification that an event is pending review. To complete the review process, the IMSM will do the following:

- From the main menu page, click [Safety Monitoring] and then click [AE Review]. The submitted SAEs for all subjects will be posted on the List Record Table in the middle of the screen.
- To view records that require IMSM review, select the 'Pending IMSM Review' system query from the 'Page Actions' drop down box.



- Click on the green arrow link  adjacent to the Adverse Event record requiring review and review the record.

#	Hub	Site	Subject	CRF ID
1	Mass General	Beth Israel Deaconess Medical Center, Boston, MA	172	3425 

- Click on 'Add New MSM Review' at the bottom of the page. Enter responses regarding the relatedness, seriousness, and expectedness of the event and click 'Save' in the Action column. Please refer to the "Assessment of Safety" section of the ARCADIA protocol for study-specific definitions of seriousness, relatedness and expectedness.
- Once the IMSM completes the review steps, the SM will close the review.

cIRB AE Reports

- A cIRB Report is generated when the Medical Safety Monitor's review indicates that an event is Serious, Unexpected and Related.
- The cIRB manager will receive an email notification whenever a cIRB report is generated.
- To access cIRB reports, click [Safety Monitoring] on the main menu page and then click [cIRB AE Report].
- Click the blue number to the left of the record you would like to access. This will take you to the full report. This full report page can be printed as a PDF and sent to the cIRB.

- Please refer to the 'Safety Reporting' section of the ARCADIA Manual of Procedures for cIRB reporting requirements and timeframes.

SITE PAYMENTS

All tables in sections below are found in the study-specific database under the [Site Management] tab of the main menu page unless otherwise specified.

Identifying Payments Ready for Invoice/Payment (NCC Financial Manager and Site Financial Managers/Study Coordinators)

- The [Site Payment] table lists all payments, site-based or subject-based. The NCC financial manager will utilize this table to check whether payments are ready to be invoiced.
- Each payment condition check is listed on an individual basis in this table. For instance, you may filter by site or subject.
- To view sites or subjects eligible for payment, select 'Payment Ready, Not Invoiced' from the dropdown menu in the upper right corner of the page. All payment statuses of 'Ready' will be displayed.
- To view payments that have been invoiced but not paid, select 'Invoiced, Not Paid' from the dropdown menu in the upper right corner of the page. All payment statuses of 'Invoiced' will be displayed.
- You can also filter payment status by selecting a cell in that column. In the upper left corner of the page, select 'Ready' from the dropdown menu and filter as [=]. Other similar filters are available depending on the column selected.

Creating Invoices and Overview (NCC Financial Manager)

- The [Site Payment Summary] table provides a comprehensive listing of invoices at site level. This includes total number of payments invoiced, payments due, total amount due, as well as pending invoices.

- Click on the green arrow link in the 'Action' column to 'Create Invoice' when payment definitions have been met.
- Click on the blue number link adjacent to the record in order to view that specific site summary.
- Once on the 'Site Invoice' page, click [Edit Record] in upper right hand corner of screen
 - If Subaward number needs to be updated, access the [Site Purchase Order Info] table under the [Site Management] tab in the trial database.
 - If vendor information needs to be updated, access the [Subrecipient Vendor Information] table under the [Project Management] tab in the StrokeNet database.
 - If Principal Investigator and Coordinator information needs to be updated, access the [Site Purchase Order Info] table under the [Site Management] tab in the trial database.
- Click on [Edit Record] in the upper right corner of the page. Navigate to column F in the table and select whether to invoice by selecting the appropriate radio button. The invoice amount in column G defaults to a predetermined amount but is editable.
- If a payment definition is met but should not be paid at that time, select 'No' in the 'Invoice' column. If a payment definition is met but should not ever be paid, select 'Yes' in the 'Invoice' column and enter '0' in the 'Invoice Amount' column.
- If further edits are to be made, leave the form unlocked by selecting 'No' on line 16: Locked.
- If ready to create invoice, select 'Yes' for question 16: Locked?'. Then click [Save Record]. A printable invoice is then created and the form cannot be unlocked. Click on the green arrow link at the bottom of the page to view the printable invoice.

NOTE: Multiple site-based or subject-based payments may be invoiced together as long as they belong to the same site.

Marking an Invoice as Paid (NCC Financial Manager)

- Once a site invoice has been created and locked, a site invoice payment can be made. In the [Site Invoice Payment] table, click on the blue number link adjacent to the record in order to view that specific site invoice payment.
- Click on [Edit Record] in the upper right corner of the page.
- Select the method of payment (EFT or Check). If selecting EFT, enter the transfer date in the field below. If selecting Check, enter the check number and check issued date in the fields below.
- Save the record by clicking [Save] at the bottom of the page and the remaining fields will be automatically generated by WebDCU™.

Updating Site Purchase Order Information (NCC Financial Manager)

- The [Site Purchase Order Info] table provides purchase order information for each site, including PO number. This information should be updated by the Financial Manager if changes occur.
- In the [Site Purchase Order Info] table under the [Site Management] tab in the trial database, click on the blue number link adjacent to the site PO that needs to be updated.
- Click on [Edit Record] in the upper right corner of the page.
- Enter PO information as needed and save the record by clicking on [Save] at the bottom of the page.

Payment Definition (NCC Financial Managers)

- The [Payment Definition] table defines the payment amount and logic for each payment. Each payment is defined by name, type and a predetermined amount.
- These fields are for reference only and not editable by sites. If clarification is needed, contact the appropriate Data Manager at the NDMC.

SUBMITTING IMAGES/VIDEO THROUGH WEBDCU™

Aspera® is the platform in which the imaging will be uploaded into WebDCU. You will need to download this platform before you start enrolling and test the upload function to determine if further action is needed.

Transmission of images/ videos utilizing the secure IBM Aspera® web-based platform is the preferred method for submitting images and video data from your site to the DCU.

Sites not able to utilize the web-based Aspera® platform for any reason should follow the mailing protocol outlined at the end of this section.

Testing Aspera®

- Log in to WebDCU™, <https://webdcu.musc.edu/login.asp>, with your email address and password.
 - After logging in, click on your study's icon.
- Click [Site Management].
- Select [Aspera Upload Test]



- Click [Add New] in the top right hand corner of the page.

List: Aspera Upload Test

Help Add New

Test file upload	Imaging file uploaded by	Imaging file uploaded on	Upload success
ip	Jaemyung KIM	24-Jul-2019 11:11	Yes
ip	Jaemyung KIM	25-Jul-2019 10:21	Yes
ip	Jaemyung KIM	25-Jul-2019 10:24	Yes

is not valid to support any statistical analysis of study data. Unless noted, the Data Coordination Unit (DCU) assumes no responsibility for the use of this report. This report may contain protected health information covered by the Health Insurance Portability and Accountability Act (HIPAA). You are not the specific written consent of the person to whom it pertains. Anyone using this data specifically assumes responsibility for maintaining the confidentiality of the protected data.

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- Select the site you are testing in row 1 (See image below)
- Click on [Upload file (Aspera)], this will generate a pop up file upload window. Please follow the instructions below on the Aspera® installation and image upload process. For testing purposes, the file you should try to upload should be a zip file with a blank PDF.
- Answer the question in row 5, which asks if you were able to upload a file. If you were unable to upload a file, you can come back and repeat this process later.
- Save the record

No.	Item Description	Data Value
1	Site	Please Select
<p>Please follow below instruction to upload a test file using Aspera.</p> <ul style="list-style-type: none"> • Locate a file and compress (zip) the file. • Click 'Upload File (Aspera)'. Aspera client download will be prompted. Once installed, upload the zipped file and close the pop-up window. • If any error occurs, please report to DCU data manager with the error message (screen shot). • Save this form by clicking 'Save Record' button. 		
2	Test file upload <i>Zip file only</i>	
3	Imaging file uploaded by	<i>(to be assigned by the system)</i>
4	Imaging file uploaded on	<i>(to be assigned by the system)</i>
5	Upload started successfully	<input type="radio"/> No <input type="radio"/> Yes
GC	General comments	<input type="text"/> (250 char)

Test file upload:

Aspera® Installation and Uploading an Image

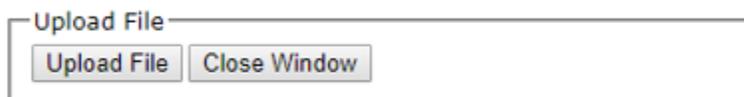
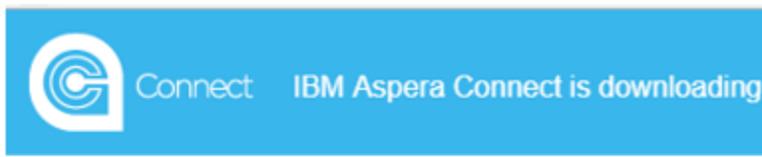
Please note, that the first time you click [Upload file (Aspera)] you will be required to install the IBM Aspera® client to your machine. Aspera® should only be downloaded once to a computer, multiple downloads of this program is not necessary.

- Click [Upload File (Aspera)], which will generate the pop up file upload window.
- Click [Download latest version]



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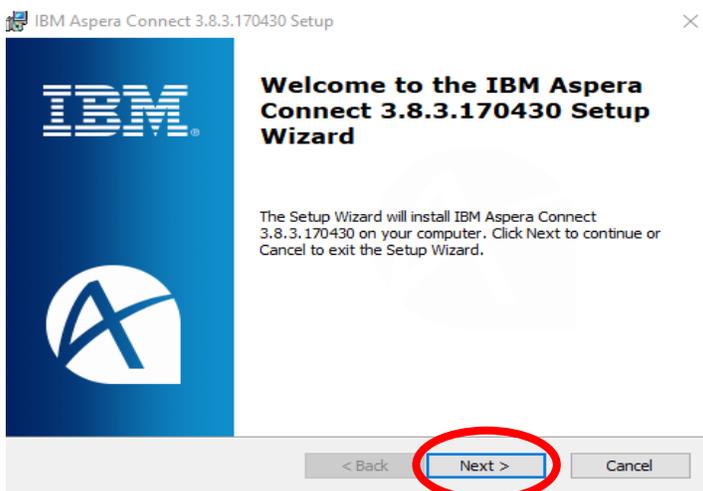
- Click the [IBMASperaConnect.msi] file in the bottom left hand corner of the page.



We

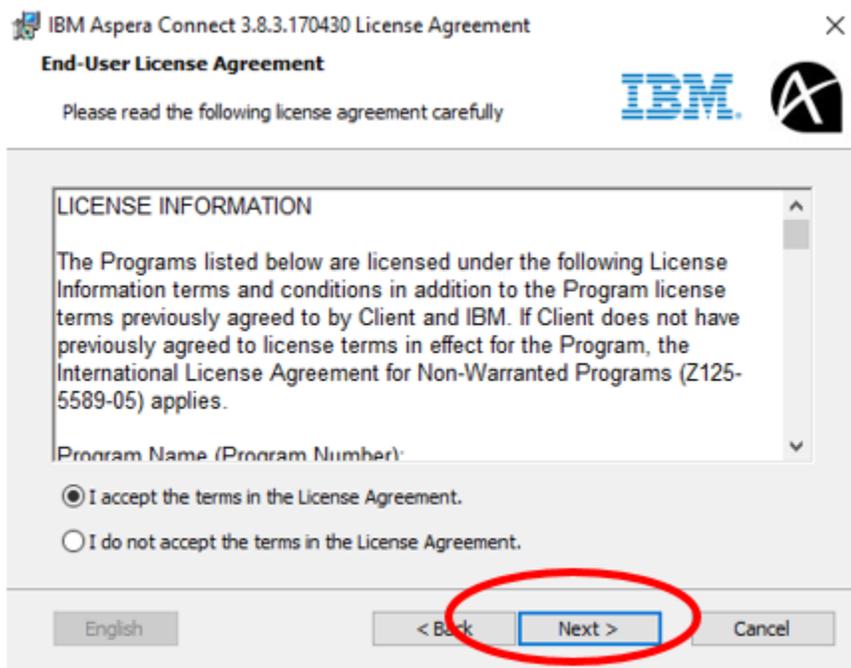


- The installation window should pop up if you completed the steps above.
 - Click [Next]

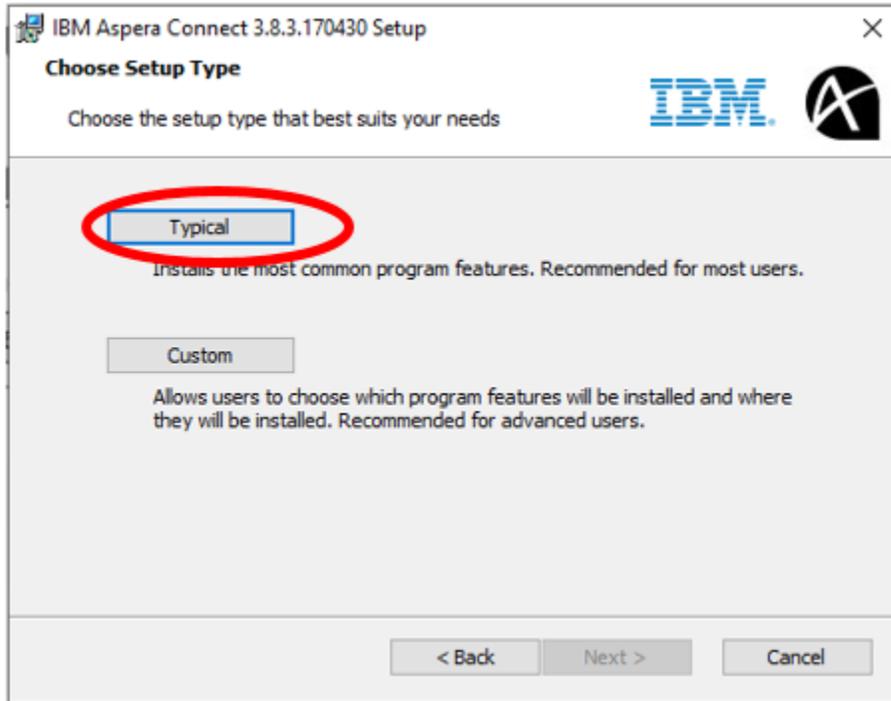


-
-

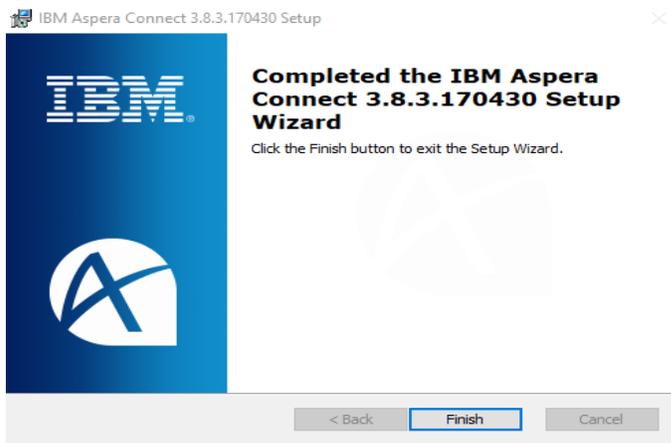
- Click [I accept the terms in the License Agreement] and click [Next]



- Click [Typical]



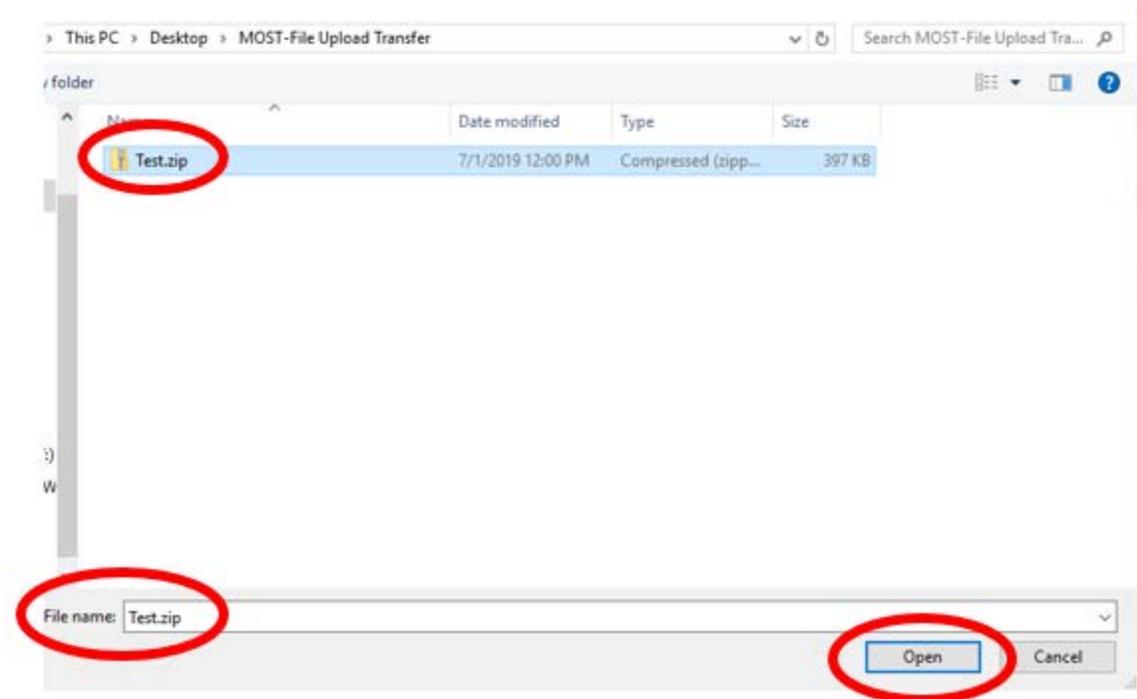
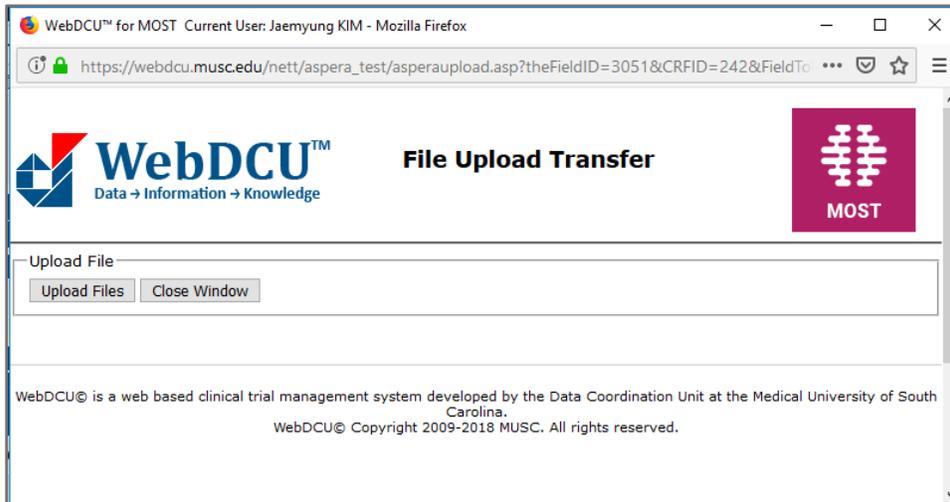
- Click [Install]. This will begin the installation process.
- Once the installation has finished, click [Finish]



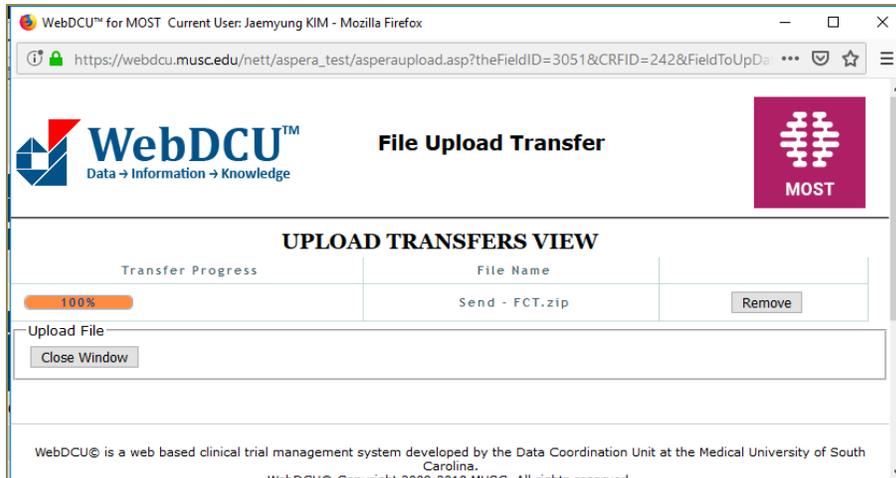
- Go back to the file upload window and click [Refresh]



- You will now be able to upload a file. Click [Upload file] (see image below), then a file selection window will open. Select the zipped image file on your computer and click [Open]. See the section below on how to create a Compressed Zip file.



- Once the upload process is initiated, the "Transfer Progress" will display. When done (i.e., Transfer Progress displays 100%), click [Close Window]. If you receive an error during this process, please reach out to the Data Manager for your study.



Create Compressed ZIP File/Folder in Windows or MAC OS

Copy/move all the image/ video files from the CD/DVD/USB thumb drive to your desktop (or other preferred location) and compress files into zip format.

- Windows OS
 - Simply select all of the files on the CD/DVD/USB thumb drive (Ctrl_A)
 - Open the context menu with a right-click and then click directly on “Send to” and “Compressed (zipped) folder” (see illustration below).

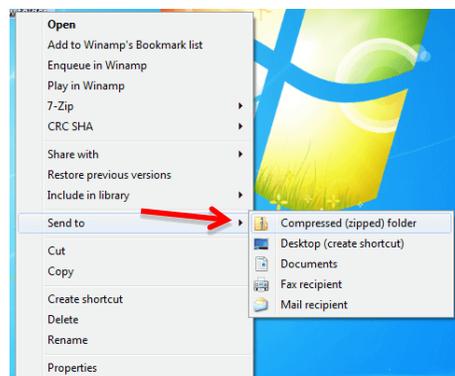


Image 1

- MAC OS
 - Locate the items to .zip in the Mac Finder (file system)
 - Right-click on the file or folder you want to zip
 - Select ‘Compress Items’
 - Find the newly created .zip archive in the same directory

- To rename it, press and hold (or right-click) the folder, select 'Rename,' and type the new name

The zip file should be deleted from the preferred saved location following confirmation that it was uploaded to IBM Aspera® Connect. This can be verified by selecting IBM Aspera® Connect on your toolbar (see Image 2 below) and confirming that the zip file has finished uploading. For example, as you can see from Image 3, this file is still being uploaded and thus should not be deleted from the desktop.



Image 2

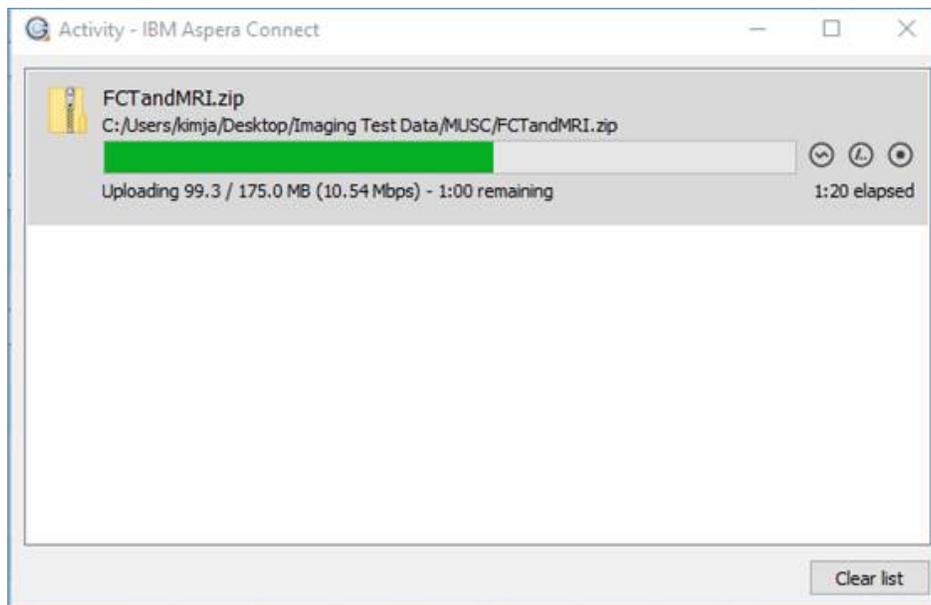


Image 3

Video Upload through Aspera® Platform

1. Log into WebDCU™, <https://webdcu.musc.edu/login.asp>, with your email address and password.
 - After logging in, “click on” WebDCU™ “Your Project” icon.
2. Click [Subject CRF Binder].

3. If several images/ videos were taken for one assessment, these must first be merged into one image/ video file. Select the subject whose zipped video file you wish to upload.
 - Click on the correlating CRF
4. Fill out the required data items on the case report form.
5. Uploading image/ video files through the Aspera® platform.
 - Click “Upload File (Aspera)” on the corresponding CRF which will generate the pop up file upload window.
 - The first time it is used, the Aspera® platform will have to be downloaded to the computer. To do so, select “Download latest version” in the first pop-up (see image 4) and then select “Typical” once the installation process starts (see image 5). Aspera® should only be downloaded once to a computer, multiple downloads of this program is not necessary.
 - If you are unable to download Aspera® for any reason, first please contact your site’s IT department to troubleshoot.
 - If your IT department is unable to resolve the issues with Aspera®, please contact one of individuals listed for data management support under the “Emergency Help” module in WebDCU™ for assistance.
 - If it is determined that you are restricted from downloading Aspera® due to site regulations, please follow the shipping protocol outlined under section 2.4 below.

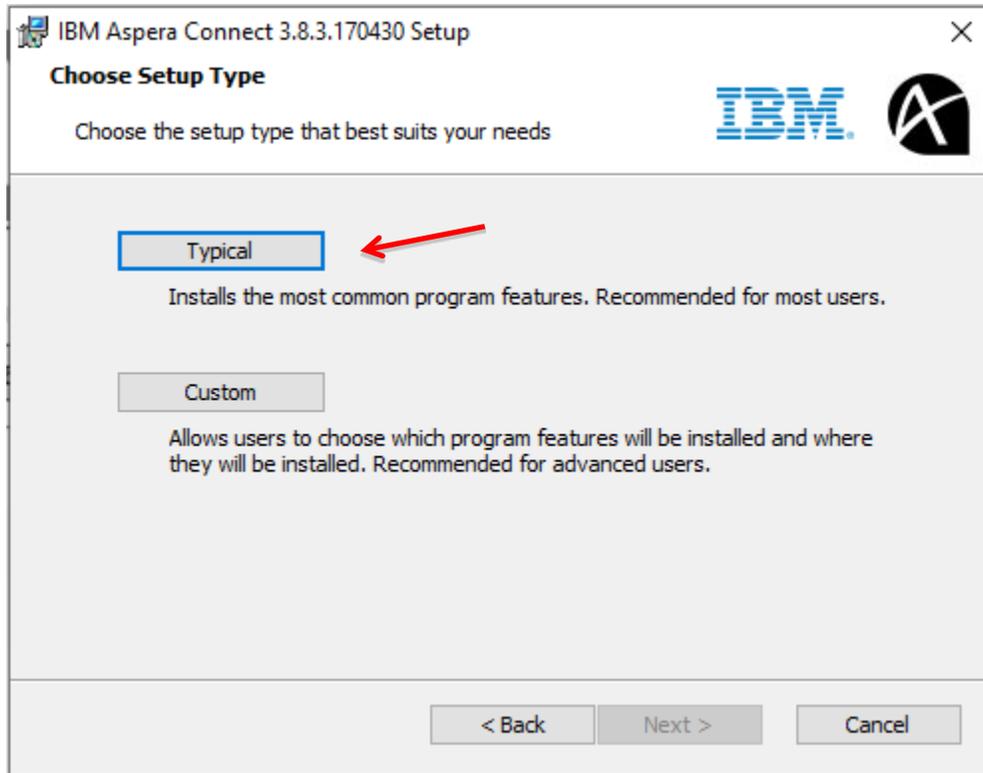


Image 4

- Click [Upload Files], then a file selection window will be opened.
- Select the subject's zipped video folder on the computer and click [Open].

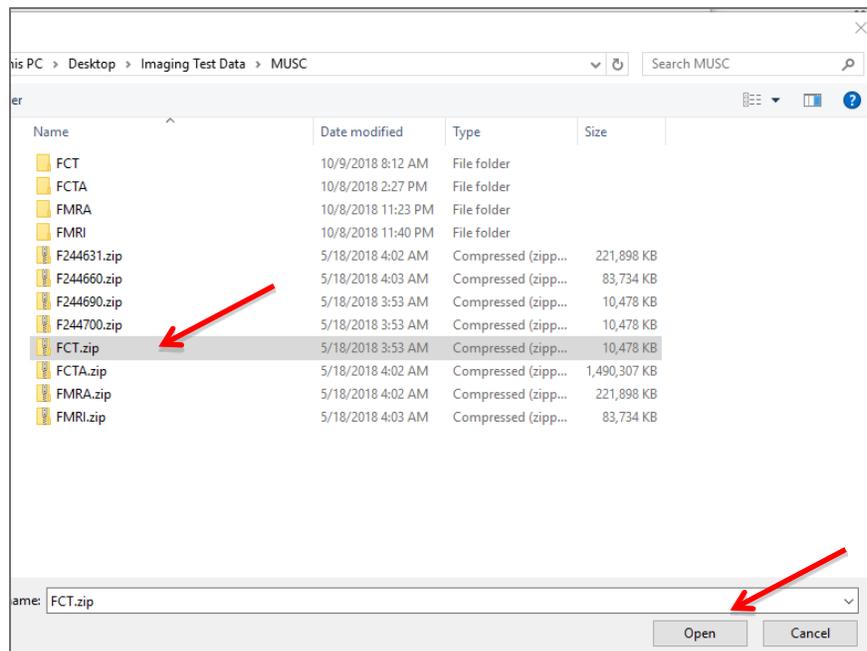


Image 5

- Once upload process is initiated, the “Transfer Progress” will display. When Done (i.e., Transfer Progress displays 100%), click [Close Window]

6. After final review of data on CRF, click [Submit CRF].

Shipping Protocol

If you are restricted from downloading Aspera® due to site regulations, you will need to mail the images/ videos via CD/DVD/USB thumb drive to the DCU.

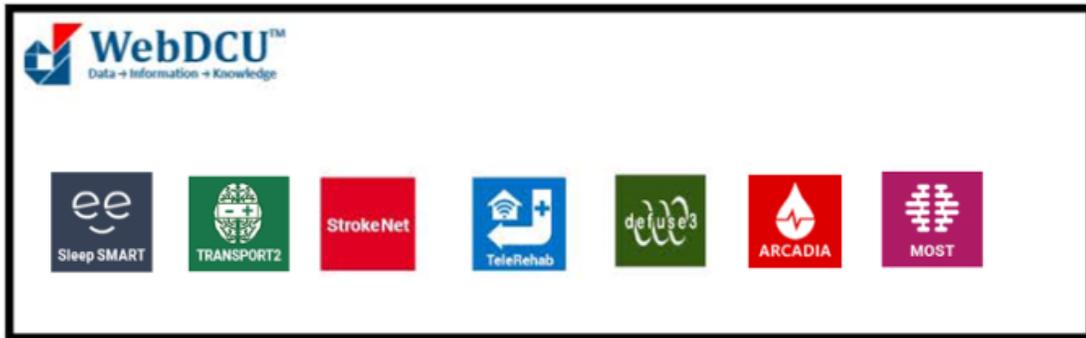
- A copy of all protocol required images/ videos should be sent via FedEx or imaging courier of your choice to the following address:

[Project Name] DCU Image/ Video Tech
Medical University of South Carolina
Department of Public Health Sciences
Data Coordination Unit
135 Cannon St., Suite 303
MSC 835
Charleston, SC – 29425-8350

- Sites are responsible for any costs associated with shipping images to the DCU

STUDY DATABASES

- The StrokeNet study databases contain interfaces for collecting and processing a study’s CRFs, medical safety monitoring, Community Consultation/Public Disclosure Summaries, and drug accountability (if applicable).
- Your WebDCU™ Project Selection page will contain icons for each study in which you have permissions. Click on a study icon to enter the study database. If you are within a study database, you can return to the WebDCU™ Project Selection page by clicking on the WebDCU™ icon located in the top, left corner.



STUDY SPECIFIC INFORMATION

ARCADIA Specifics

Drug Tracking for Central Pharmacy

Automatic Drug Requests

- The initial drug request (default of 6 kits) will be posted when site status is updated to “Ready to receive investigational product”. Site status will be manually updated by NDMC personnel when NCC Project Manager confirms site is regulatory ready.
- The WebDCU™ system will automatically post drug requests based on site inventory as study drug kits are dispensed to subjects.
- In both situations, an automatic email notification will be sent to the central pharmacy notifying them of the request.

Drug Packaging (for Central Pharmacy)

- To document the packaging of study drug bottles:
 - From the main menu page, click on [Drug Tracking] and then [Drug Bottle Packing].
 - Click [Add New] in the top right hand corner of the [Drug Bottle Packing] list record page.
 - Select the type of bottle being packed for Q1 and scan or data enter the barcode of the drug barrel being used in Q2.

- For Q3 select the number of bottles being packed. The maximum allowed per data entry is 10 bottles.
- For Q4 scan or data enter the bottle label barcodes for the bottles being packed, then click [Save Record].
- All bottles previously packed are listed in the [Packed Drug Bottles] table.

- To document the packaging of study drug kits:
 - From the main menu page, click on [Drug Tracking] and then [Drug Kit Assembling]
 - Click [Add New] in the top right hand corner of the [Drug Kit Assembling] list record page.
 - Select the type of kits being packaged
 - For each drug kit being packaged, scan or data enter the kit label barcode and both bottle label barcodes. All three barcodes should be entered on one line (i.e. for Drug Kit 1).
 - Once all kits are packed and barcodes entered, click [Save Record]
 - All kits previously packed are listed in the [Assembled Drug Kits] table.

Drug Shipping (for Central Pharmacy)

- To ship study drug, from the home page click [Drug Tracking] and then [Drug Shipping].

- To figure out which kit types have been requested for a particular site, use the 'Study Drug Requested to be Shipped' system filter located in the 'Page Actions' drop down menu. Select the record of the request that needs to be shipped by clicking on the blue number link in the left hand column.

- Click on 'Edit Record', enter the kit number being shipped, and then click 'Save Record'. A packing slip will then populate. The packing slip will not be final until all kits being shipped have been marked as shipped. When shipped to a site, an automated email notification is sent to a site primary pharmacist.

Drug Tracking (for Site Pharmacist or Designee)

Drug Receipt

When the central pharmacy ships study drug to a site, an automated email is sent to the site study pharmacist.

- Before a subject can be randomized, study drug must be documented as received in WebDCU™.

- To receive study drug, from the home page click [Drug Tracking] and then [Drug Receiving]. A List Record view of all study drug shipments that have been shipped to your site will appear. Note: Use the 'Study Drug to be Received' system filter located in the 'Page Actions' drop down menu to filter for the shipments that need to be received.
- Select the study drug kit that needs to be received by clicking on the blue number link in the left hand column. Click on 'Edit Record'; verify that the code on the kit matches the kit code listed in WebDCU, enter the 3-digit drug kit verification code for Q6, and then click 'Save Record'. If the kit codes do not match, contact the ARCADIA Data Manager. You will need to repeat this process for each kit received.

Drug Assignment and Dispensing

- Once a study drug kit has been received, you will be able to distribute that kit to a randomized subject.
- The site will be alerted of a study drug kit assignment once F512: Study Drug Kit Assignment has been data entered and submitted for a subject.
- When dispensing a study drug kit to a subject, the site pharmacist (or designee) will complete F513: Study Drug Kit Dispensing. The drug kit ID as well as the drug kit verification code will need to be entered in order to confirm the correct kit was dispensed.

Drug Damage

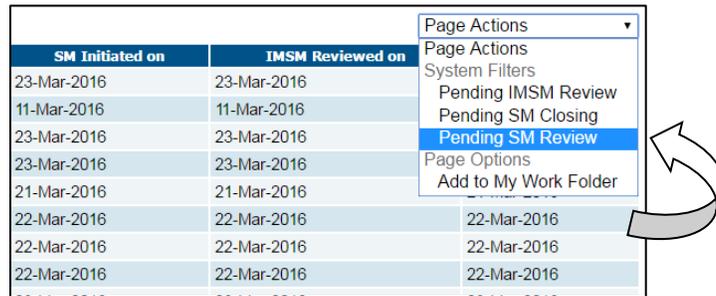
- If any study drug kits are damaged or unusable it must be reported in WebDCU. To report study drug kits as damaged, from the home page click [Drug Tracking] and then click [Drug Removing from Inventory]. Select the record of the kit that is damaged by clicking on the blue number link in the left hand column. Click on 'Edit Record', answer required questions, then 'Save Record'.

Medical Safety Monitoring and Adjudication (for Site Managers)

Site Manager Review Process

When an Adverse Event is reported by a site, the Site Manager will receive an email notification that an event is pending review. To complete the review process, the Site Manager will do the following:

- From the main menu page, click [Safety Monitoring] and then click [AE Review]. The submitted AEs for all subjects will be posted on the List Record Table in the middle of the screen.
- To view records that require Site Manager (SM) review, select the 'Pending SM Review' system query from the 'Page Actions' drop down box.



- Click on the green arrow link  adjacent to the Adverse Event record requiring review and review the record.



- If the event is incomplete or incorrect, the Site Manager may communicate changes that need to be made by submitting a Data Clarification Request (DCR). Click on the 'Create New DM DCR' button at the top of the eCRF page to submit a DCR.
- Click on 'Add New SM Review 1' at the bottom of the page. Indicate whether or not reporting to BMS is required and click 'Save' in the Action column. If 'Yes' is selected, a BMS reporting document will automatically be generated by the system. Please see the "BMS Reports" section below for instructions on how to access these reports.
- Click on 'Add New SM Review 2' at the bottom of the page. Indicate whether the BMS report has been submitted. This step will only appear if SM Review 1 is answered 'Yes'.

- Click on 'Add New SM Review 3' at the bottom of the page. Indicate whether MSM review and/or Adjudication is required for the event. Please refer to the 'Safety Reporting' section of the ARCADIA Manual of Procedures to determine if the event is an SAE (requiring MSM review). Refer to the Outcome Adjudication Core Appendix of the ARCADIA Manual of Procedures to determine if the event is a Primary or Secondary Endpoint (requiring Adjudication).
- If the AE requires review by the Medical Safety Monitor (MSM) and/or Adjudicators, an email notification will inform him/her of the required review. Once the MSM and/or Adjudicators complete their review steps, the SM will close the review
- If the MSM review finds that the event is Serious, Unexpected and Related, a cIRB reporting document will automatically be generated by the system. Please see the "cIRB AE Reports" section below for instructions on how to access these reports.
- To close the review, the SM will go back to the [AE Review] list records form (from the main menu page, click [Safety Monitoring] and then click [AE Review]). Then select the 'Pending SM Closing' system query from the 'Page Actions' drop down box. Click on the green arrow link  adjacent to the Adverse Event record that you would like to close. Click on 'Add New SM Closing' at the bottom of the page. Enter the required information and click 'Save' in the Action column.

BMS Reports

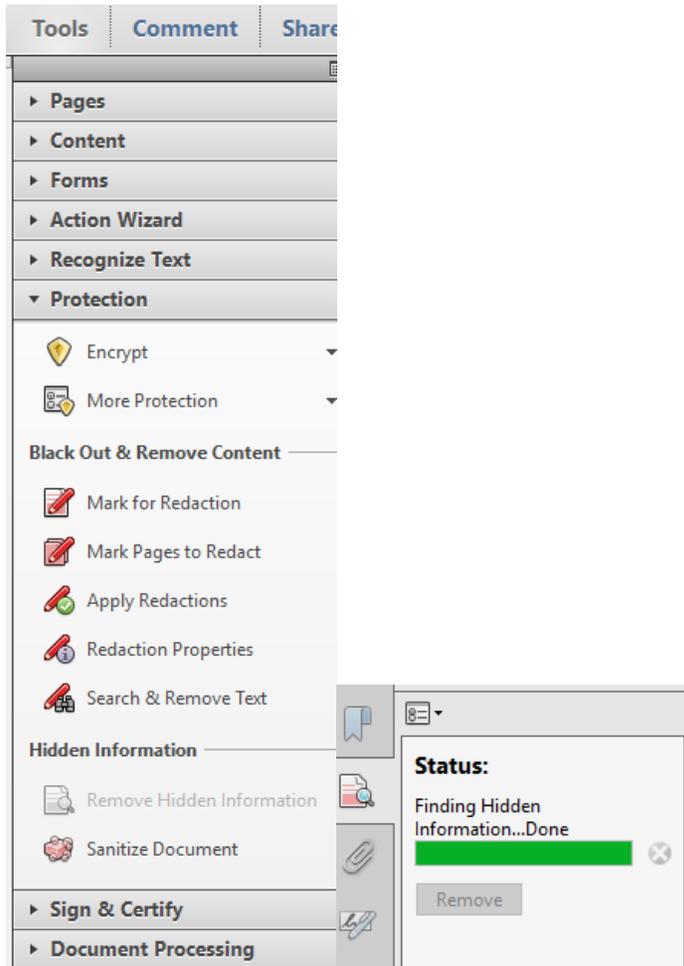
- A BMS Report is generated when the Site Manager answers "Yes" when completing 'SM Review 1' (indicating that BMS reporting is required).
- To access BMS reports, the SM will click [Safety Monitoring] on the main menu page and then click [BMS Protocol Number CV185-549].
- Click the blue number to the left of the record you would like to access. This will take you to the full report. This full report page can be printed as a PDF and sent to BMS.
- Please refer to the 'Safety Reporting' section of the ARCADIA Manual of Procedures for BMS reporting requirements and timeframes.

ECG redaction

- Prior to completing F501 and uploading the 12 lead ECG all subject PHI will need to be removed from the file. The file will need to be in the format of a PDF.
- To redact electronically use Adobe to remove PHI from file, click on the [Tools] tab then [Protection] then [Mark for Redaction]. After marking all PHI click [Apply

Redactions], a Status will appear on the left side, make sure and click [Remove] to remove any hidden data or Meta data.

- PHI can also be redacted from the ECG manually by marking through PHI completely with a marker or by covering with a black piece of paper. Ensure that whatever means used completely covers the information.
- Save file and then upload in WebDCU.

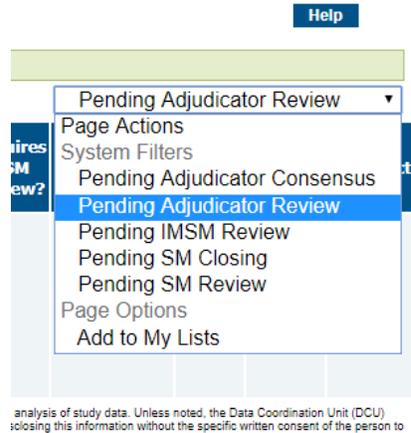


Adjudication (For Adjudicators)

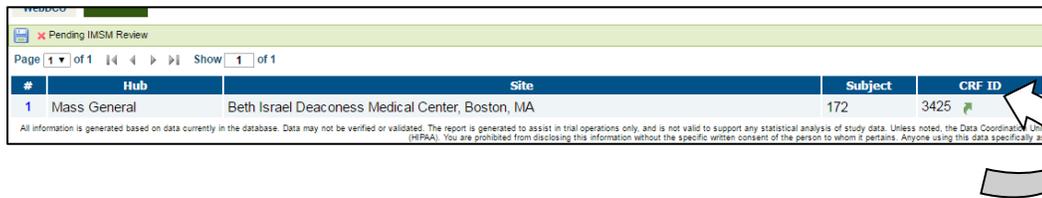
When an AE requires Adjudication, the Adjudicators will receive an email notification that an event is pending review. To complete the review process, the Adjudicators will do the following:

- From the main menu page, click [Safety Monitoring] and then click [AE Review]. The submitted AEs for all subjects will be posted on the List Record Table in the middle of the screen.

- To view records that require review from the Adjudicator, select the ‘Pending Adjudicator Review’ from the ‘Page Actions’ drop down box.



- Click on the green arrow link  adjacent to the Adverse Event record requiring review and review the record.



- Click on ‘Add New Adjudicator Review’ at the bottom of the page. Enter the required information and click ‘Save’ in the Action column.
- The adjudication process is complete when both adjudicators complete a review and consensus is achieved. If consensus is not initially achieved, both adjudicators will receive an automated email notification that additional review is required.
- To find records that require consensus review, select ‘Pending Adjudicator Consensus’ from the ‘Page Actions’ drop down box.
- Once the adjudicators reach consensus, one of the adjudicators will enter their final review by returning to the Adverse Event Record and clicking on ‘Add New Adjudicator Consensus.’ Enter the required information and click ‘Save’ in the Action column.
- Once the adjudicators complete the review steps, the SM will close the review.