



NIH SIREN
Emergency
Trials
Network

WebDCUTM User Manual

SIREN: **Strategies to Innovate Emergency Care Clinical Trials Network**

Data Coordination Unit
Medical University of South Carolina
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Version 6

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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.

Data Manager Contact Information

SIREN Database:

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HOBIT Database:

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Peyton Kline, peyton@muscd.edu, (843) 876-1105

C3PO Database:

Zeke Lowell, lowelle@muscd.edu, (843) 792-1453

System Requirements

- Access to WebDCU™ requires a computer with high-speed internet access. **NOTE:** 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 username and password which is not to be shared with any other user. Recording of passwords is strictly forbidden. Periodically, WebDCU™ users will be prompted to change their password to maintain greater security.
- 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 ICH 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.
- An acceptable password must be 8-35 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. If an invalid password was used, that account will be locked and can only be reactivated by request to the DCC Data Managers.
- 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 locked. 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 case report form (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 username (email address) and your password and click [Sign In]. If you have forgotten your password, click on the 'Forgot password?' link in blue 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. Enter your current or temporary password into the first box.

Enter the new password you have chosen into the 2 boxes below and click on [Save].

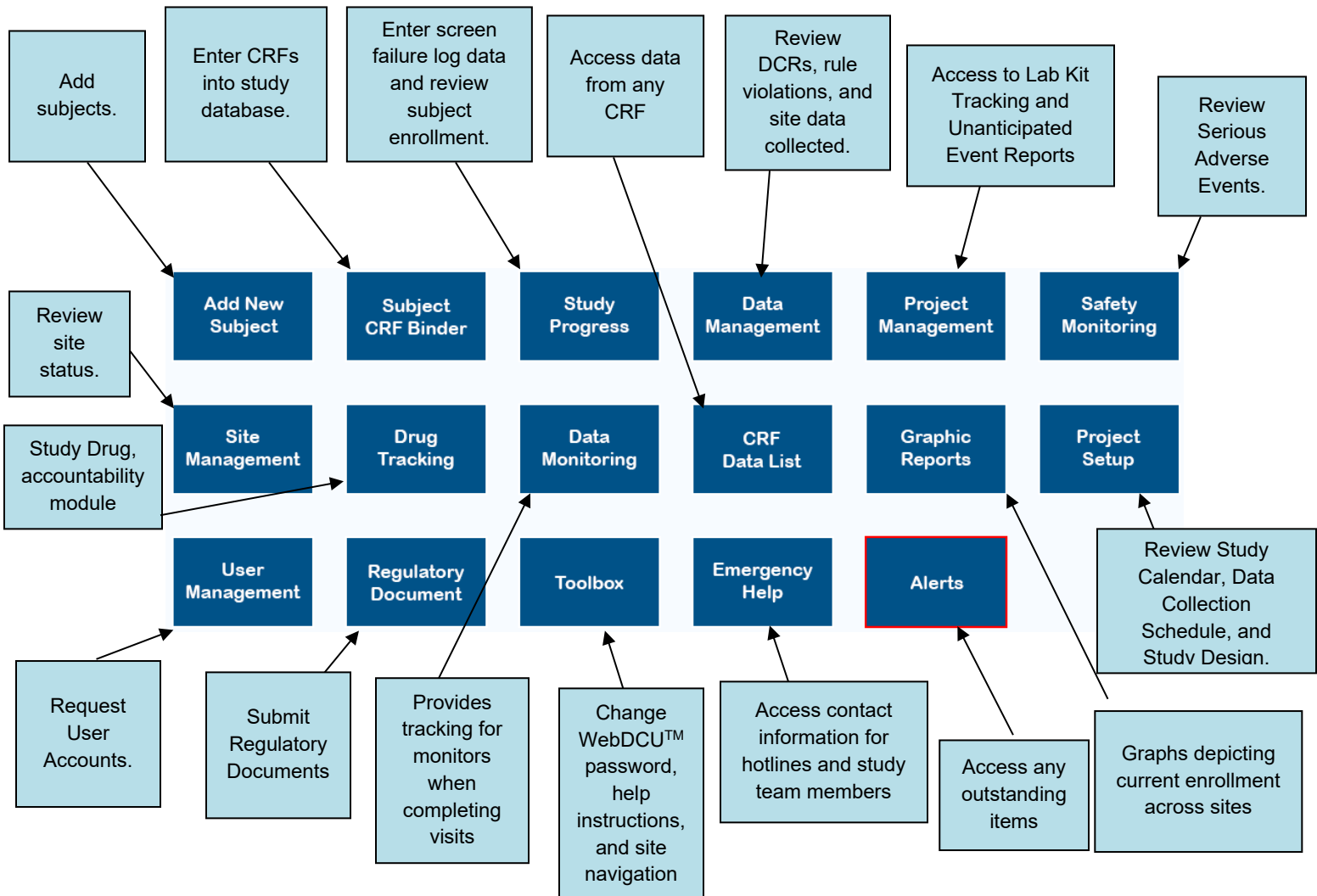
- The email address entered will be the person’s username. For that reason, email addresses cannot be edited after they are saved. To change an email address that has already been entered, contact the DCC Data Manager.

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 home page 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.



- There is an alternative expanded menu option for those who prefer it. This may be useful to new WebDCU™ users or to those who infrequently access the system.



Full Expanded Menu

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Full Menu for Teldon ALFORD

Teldon ALFORD Sign Out

Help

Add New Subject

Alerts

Emergency Help

Project Management

Project Event

Safety Monitoring

SAE Review

Subject CRF Binder

Graphic Reports

Randomized by Month

Randomized by Week

Cumulative Randomized by Month

Help & Toolbox

Project Documents

Help FAQs

Change Password

My Lists

Data Management

Subject CRF List

Rule Violation

DCR

Site CRF Data Entry Summary

Central IRB

Initial Site Submission

Initial Site Submission Review

Protocol Deviations/Exceptions/Violations

Unanticipated Problems

Modification Information

Changes to Sub-Investigator/Co-Investigator Information

Serious Adverse Events

Serious or Continuing Non-compliance

Data Monitoring

Monitoring Visit Planner

Monitor Visit

Monitor Query Summary by Form

Monitor Query Summary by Site

Monitor Site Action Response

Monitor Site Action Review

Monitor CRF Pending

Monitor Visit Site View

Monitor Visit Project PI Review

Site Management

Clinical Site

Site Status

Institution Group Member

Readiness Report

Site Payment Summary

Site Invoice

Site Invoice Payment

Site Payment

Payment Definition

Study Progress

Screen Failure Report

Subject Enrollment

Subject Visit

Study Calendar

Study Subject Status

Study Progress Summary

Site Enrollment Summary

Monthly Monitoring Log

Monthly Enrollment Summary

Project Setup

Data Dictionary

Code Item

Rule

Events

Email Recipients

Study Design

CRF Collection Schedule

Institution

Institution Group

Form Validator

Regulatory Document

Regulatory Document

Reg. Doc. Requirement

Site Reg. Doc. Summary

Site Reg. Doc. Status

Site Reg. Doc. Submission

Site Reg. Doc. Review

Site Reg. Doc. History

People Reg. Doc. Submission

People Reg. Doc. Review

People Reg. Doc. History

User Management

Study Team Member Request

User Permission Request

User Permission Review

DOA Review

Study Team Member

Site DOA Report

Site DOA List

User Group Member

User Permission

User Group Permission

User

User Mimic

User Group

CRF Data List

F101 Inclusion and Exclusion Criteria

F102 Randomization

F104 Adverse Event

F105 Laboratory Tests

F106 Medical History

F112 Concomitant Medications

F117 Vital Signs

F123 Hospital Discharge

F126 End of Study

F127 MedWatch

F138 Glasgow Coma Scale

F156 Glasgow Outcome Scale - Extended

F172 Surgical and Procedural Interventions

F172C Surgical and Procedural Interventions Child

F269 Abbreviated Injury Scale

F271 CT Scan

F272 CT Scan - Central Reader

F274 Pre-hospital Events

F275 Study Therapy

F286 Pupil Reactivity

F287 Therapy Intensity Level Scale

F501 Hourly Monitoring

F501C Hourly Monitoring Child

F502 Ventilatory Parameters

F502C Ventilatory Parameters Child

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- **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 CRF data
- **Study Progress**

Allows you to view subject enrollment, enrollment summaries, submit monthly Screen Failure Reports and update the Study Calendar

- **Data Management**

Allows you to view data management information such as CRF, rules 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.

- **Central IRB**

Allows initial site submission (site PSC) and review (CCC).

- **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

- **Toolbox**

Allows you to change your WebDCU™ password. Access help instructions, site navigation tools and project documents. [Project Documents] contains documents

that have trial-wide importance such as the Protocol, Manual of Procedures (MOP), Study Book and CRF Completion Guidelines.

- **Project Management**
Allows Data Managers to update Project Event table for tracking milestone goals. Contains Lab Kit Tracking module for shipping and receiving samples.
- **Data Monitoring**
Allows on site monitors to schedule monitoring visits and submit monitoring reports
- **Emergency Help**
Contains the number for the Emergency Randomization Hotline. Also contains the information for contacting Data Management support.
- **Alerts**
Allows you to access pending/rejected regulatory documents and any CRF alerts related to DCRs, rule violations and past due forms.

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 DCC. 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 DCC 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.

SIREN Database User Accounts

- Contact the DCC in order to activate permissions for user accounts requiring access to the SIREN database.
- The DCC will notify the user of their user name and temporary password once the account has been created. The username will always be the email address on record in the [User] table of the database. If an email address is changed in the database, the username is similarly changed.

NOTE: It is critical that Hub personnel immediately notify the DCC of personnel who are no longer working on SIREN and/or users whose permissions have changed, so that account access can be terminated and/or adjusted accordingly. Notification in advance is highly preferred.

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.

5 Active Team Members

No.	Team Member	Start Date	End Date	.R1	.R2	.R3	.R4	.R5	.R6	.A	.B	.C	.D	.E	.F	.G	.H	.I	.J
5-1	Kristina HILL	01-Jan-2015	02 Jan 2015	<input checked="" type="checkbox"/>						A									

Add new team members and make changes to existing team members.
If making a change to an existing team member, their current record must be terminated from above by entering an End Date.

6 Team Member Request

No.	Team Member	Start Date	End Date	.R1	.R2	.R3	.R4	.R5	.R6	.A	.B	.C	.D	.E	.F	.G	.H	.I	.J
6-1	Kristina HILL	02 Jan 2015		<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Add New Row

Study Roles	R1 - Principal Investigator R2 - Co-Investigator R3 - Primary Study Coordinator	R4 - Secondary Study Coordinator R5 - Regulatory Document Coordinator R6 - Pharmacists
DOA Responsibilities	A - Overall responsibility for the trial B - Internal NETT hub/spoke verification C - EFIC activities (CC/PD) D - Maintain regulatory compliance and WebDCU E - Ongoing clinical team training	F - Obtain informed consent G - Study drug accountability H - Blood draw accountability I - Complete CRFs/respond to queries J - Assess/Report AEs

7 DOA Request Approved No

10 Notes (250 char.)

Last updated by Kristina HILL on 28-Apr-2015 9:22AM

Save Record Cancel Edit

- 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 Project 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 Project 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 CCC Site Managers)

- From the study's main menu page, click on [User Management] and then [DOA Review].
 - The 'Page Actions' dropdown menu located in the upper right corner of the table, includes a "Pending review" filter. By selecting this filter, you will see all sites that have a DOA pending 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.

Page Actions ▾		
Add New		
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.

5	Mimic activated on	<i>(to be assigned by the system)</i>
<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.

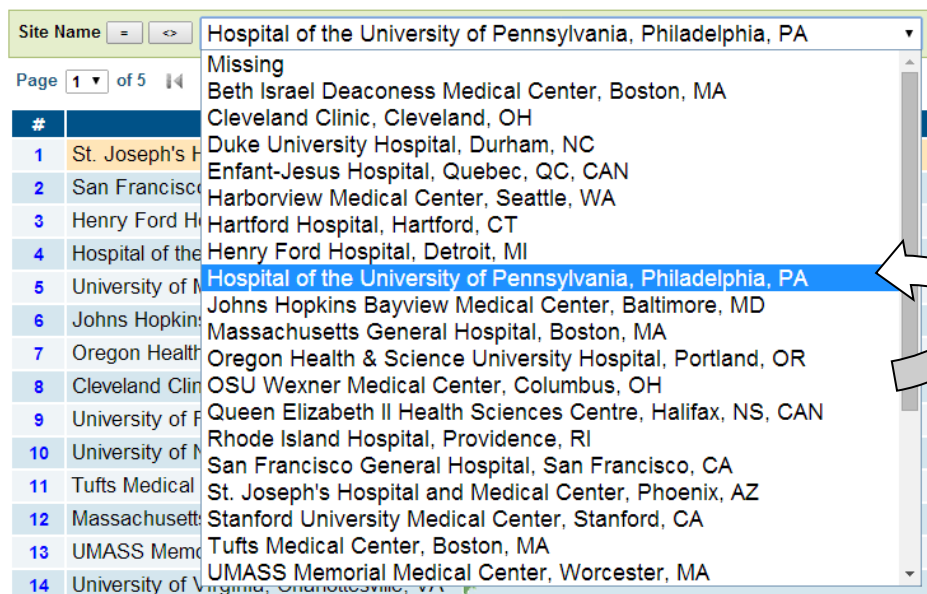
[Teldon ALFORD](#) [Sign Out](#) 

Data Value
B. Institution Limit

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.
NOTE: 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.
 - **Not null** (<>) parameter searches for fields which have a value, or where data is not missing from those fields.
 - **Equals** (=) parameter searches for values identical to the selected value. This can be used to identify null values easily by selecting [=] and leaving the adjacent text field empty.
 - **Greater than** (>) or **less than** (<) parameters search for values higher or lower than the selected value, respectively.
 - **Like** parameter searches for values similar to the value selected, or where fields contain part or whole of the selected value.



- To remove a single filter, click on the ✖ 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.

WebDCU HO₂BIT List: Site Status


Hub = Minnesota

Page 1 of 1 Show 3 of 3

#	Hub	Site Name	Status
1	Minnesota	Hennepin County Medical Center, Minneapolis, MN	Preparing - Low Priority
2	Minnesota	University of Iowa Hospitals & Clinics, Iowa City, IA	Preparing - High Priority
3	Minnesota	University of Nebraska Medical Center, Omaha, NE	Preparing - High Priority

All information is generated based on data currently in the database. Data may not be verified or validated. The report is generated to assist in trial operations only and is not valid to support any statistical analysis of study data. Unless noted, the Data Coordination Unit (DCU) assumes no responsibility for misappropriation of this information without the specific written consent of the person to whom it pertains. Anyone using this data specifically assumes responsibility for its use.

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- To remove the entire filter (after multiple filters have been applied), click on the  in the upper left hand corner of the screen. **Note:** This button will be viewable only when multiple filters have been applied.

Site Name = Hospital of the University of Pennsylvania, Philadelphia, PA Status = Ready to receive investigational product

Page 1 of 1 Show 1 of 1

#	Site Name
1	Hospital of the University of Pennsylvania, Philadelphia, PA

- System Filters are provided to all users and are setup and maintained by the DCC. 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.

Page Actions

- Page Actions
- System Filters
- DM Review Pending
- Failed Validation
- Open Rule/DCR
- Passed Validation Not Submitted
- Site Data Due or Open DCR
- Page Options
- Add to My Work Folder

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.

[My Lists] Bookmarks

- [My Lists] includes bookmarks that allow you to save the pages to which you need access on a regular basis. From the study-specific main menu page, click on [Toolbox] and then click on [My Lists]. To save a [My Lists] bookmark, click on the 'Page Actions' dropdown menu and select 'Add to My Lists' when you are on the page you would like to save.



SM last reviewed on	IQR last reviewed on	IMSM last reviewed on	
11-Dec-2015	31-Jan-2016	03-Feb-2016	
24-Mar-2016	31-Jan-2016	05-Feb-2016	
08-Jan-2016	31-Jan-2016	05-Feb-2016	
15-Jan-2016	31-Jan-2016	05-Feb-2016	
20-Jan-2016	31-Jan-2016	05-Feb-2016	
15-Jan-2016	31-Jan-2016	05-Feb-2016	08-Feb-2016
13-Jan-2016	31-Jan-2016	05-Feb-2016	10-Feb-2016
02-Feb-2016	02-Feb-2016	05-Feb-2016	10-Feb-2016

[Help](#)

Page Actions ▾


Page Actions

System Filters

- Pending IMSM Review
- Pending IQR Review
- Pending SM Closing
- Pending SM Review

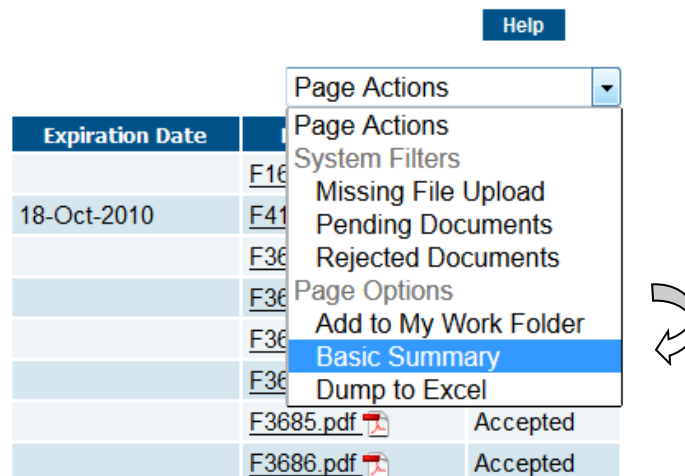
Page Options

- Add to My Lists

- You will be forwarded to the 'Edit Record' page for the [My Lists] table where you can name your query. Once finished, click on [Save Record].
- To return to the page you were working on, click on the link  icon.
- To edit or delete [My Lists] bookmarks go to [Toolbox] and click on [My Lists]. Click on the blue number link in the first column of the 'List Record' table adjacent to the record you would like to edit/delete. Click on [Edit Record] or [Delete Record] at the upper right corner of the page.
- You must confirm the deletion of any personal bookmark by entering the reason for deletion and your password, then click [Confirm Delete].

Basic Summary Tool

- The basic summary tool allows authorized users to summarize the data to which they have access.



- From any list record view, select 'Basic Summary' from the Page Actions drop down box located in the upper right corner of the table.
- To return to the page you were working on, click [Back] in the upper right corner of the summary report.

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, Federal Wide Assurance (FWA), CAP/CLIA, and etc.
- “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

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"/> <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"/>

- 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 Project Manager verifies the information and approves/accepts the document.

A few things to also note about the automatic transfer process for existing documents:

- o Documents will not be transferred if they are expired
- o Documents will only transfer if an existing document is allowed to be used for that requirement
- o Documents will not transfer if it is a site-specific or study-specific 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 DCC data manager.


Approving/Rejecting Documents (CCC Site Manager)

- 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 the study book for a visit click on the PDF 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.
- To print an individual worksheet, from the main menu page, click on the [Project Setup] tab, and then click on [CRF Collection Schedule]. Click on the  icon adjacent to the CRF name you would like to print. The PDF file can be printed by selecting the appropriate print function from your browser toolbar.

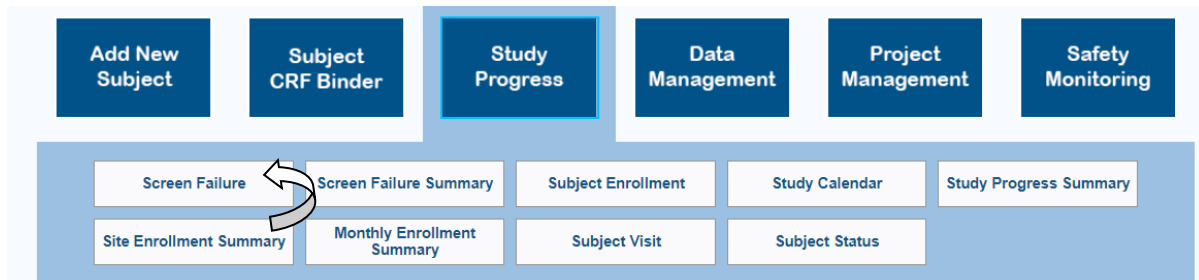
Note: When new versions of the CRFs are published during the conduct of the study, you will be notified via e-mail and the revised worksheet and study book will be posted. Due to the possibility of frequent changes to these worksheets, it is recommended that you print only a few study books at a time. 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.

Screen Failure

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



- Click on the  icon adjacent to the Screen Failure to open the PDF file. The PDF file can be printed by selecting the appropriate print function from your browser toolbar.
- Screen failures 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, click on [Study Progress] tab, and then click on the [Screen Failure] 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 & Deleting a Subject

From the main menu page, click on [Add New Subject]. If you only have permissions for one site, it will be populated automatically. If you have permissions for multiple sites, select the appropriate site from the dropdown list.

No.	Item Description	Data Value
Q01	Site	Please Select
Q02	Subject ID	
Q08	Date of informed consent	<input type="text"/> <input type="text"/> <input type="text"/> (dd-mm-yyyy)
Q09	Date of initiation of a definitive temperature control device	<input type="text"/> <input type="text"/> <input type="text"/> (dd-mm-yyyy)
P01	PRECICECAP enrollment anticipated	<input type="radio"/> No <input type="radio"/> Yes
Qc	General comments	<input type="text"/> (250 char)

Save Record Cancel Edit

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The subject will be assigned the next available subject ID number in the study database. To Remove a Subject ID please contact the Data Manager at the DCC.

Adding and Deleting a Subject Visit

- The first study visit will be posted automatically when a subject is added to WebDCU™.

CRF	Baseline 10/14/2016 (Initial Visit)
F138 Glasgow Coma Scale	<input type="checkbox"/>
F101 Inclusion and Exclusion Criteria	<input type="checkbox"/>
F106 Medical History	<input type="checkbox"/>
F274 Pre-hospital Events	<input type="checkbox"/>
F286 Pupil Reactivity	<input type="checkbox"/>
F117 Vital Signs	<input type="checkbox"/>
F105 Laboratory Tests	<input type="checkbox"/>
F271 CT Scan	<input type="checkbox"/>
F272 CT Scan Central Reader	<input type="checkbox"/>

The task completed in 0.1875 sec

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- To add a subsequent visit (and populate available CRFs for that particular visit), click on [Subject CRF Binder] of the study-specific main menu page. Select the subject you would like to work on from the 'Subject' drop-down menu. Click the 'Add New Visit' button, select the appropriate visit from the Next Visit

dropdown menu (if applicable), enter the visit date and click the 'Add Visit' button.

The screenshot shows the 'Subject 1006 CRF Binder' interface. At the top, there are navigation elements including 'WebDCU HO_SIT', 'Subject 1006', and 'Add New Visit'. Below this is a list of CRF forms on the left and a table on the right. A modal dialog box titled 'Add New Visit' is open, containing fields for 'Subject' (1006), 'Next Visit' (dropdown), and 'Date' (calendar). An 'Add Visit' button is at the bottom of the dialog. Red arrows highlight the 'Add Visit' button in the dialog and the 'Add New Visit' button in the top navigation bar.

- The forms for that visit will be posted in the CRF Collection Table for that subject.

NOTE: You should not move a subject to a visit until that visit has occurred. Failure to follow these instructions will result in incorrect and unnecessary late data reminders being sent to your hub.

- You can delete a visit (provided no CRFs for that visit have been data entered) by clicking on 'Delete Visit' in the header of the CRF Collection Table.

The screenshot shows the 'Subject 1006 CRF Binder' interface. At the top, there are navigation elements including 'WebDCU HO_SIT', 'Subject 1006', and 'Add New Visit'. Below this is a list of CRF forms on the left and a table on the right. The table has a header row with 'CRF' and 'Delete Visit'. A red arrow points to the 'Delete Visit' button in the header of the table.

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	<input checked="" type="checkbox"/>	
F102 Randomization		<input checked="" type="checkbox"/>
F106 Medical History	<input checked="" type="checkbox"/>	



- 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.

<input type="radio"/> Study Completed <input type="radio"/> Consent withdrawn, specify <input type="radio"/> Lost to follow-up <input type="radio"/> Death <input type="radio"/> 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.




- Protocol Violations and Warnings may be addressed in two ways.
 1. 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


2. 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.



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.

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].

Deleting CRFs

- To delete a CRF, open the form and click [Delete CRF Data] at the top right-hand corner of the page.
- A red message box will appear which asks for confirmation and acknowledgment that deletion is permanent. If this was done in error, click 'Cancel Deletion' at the bottom right of the message box.
- Enter a 'Reason for deletion' along with your WebDCU™ password and click 'Confirm Deletion' at the bottom left of the message box.

NOTE: CRFs that require extra processing such as randomization and AE/SAE forms may not be deleted using the process described above. To delete a form

that requires extra processing, please contact the DCC Data Managers assigned to your specific study with the following information:

Site:

Subject:

CRF ID:

Reason for deletion:

Adding Additional CRFs

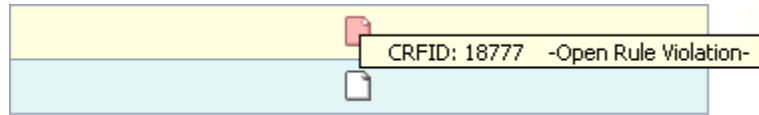
- Certain CRFs will be repeatable, such as Adverse Event forms, to allow multiple CRFs to be completed, when required. However, these additional forms are not automatically included on the CRF Collection Table.
- To add an additional form, open a previously entered form of that type for that subject 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 Binder

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

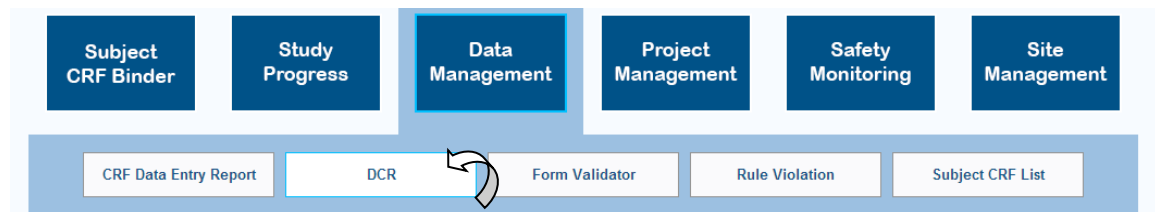
NOTE: The document icon will remain red until a data manager or monitor closes the DCR.

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

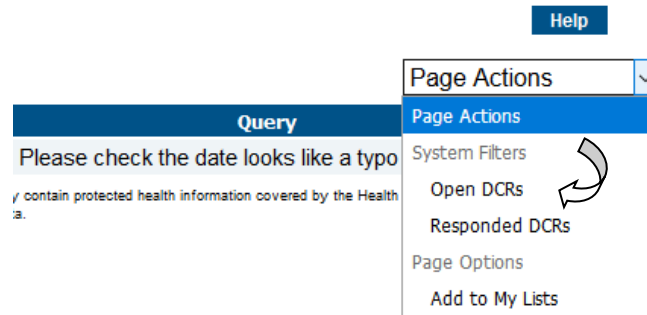
- To view open DCRs, click on the 'Alerts' tab on the main menu page.




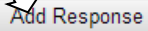
- You can also view open queries by using the DCR table located under the [Data Management] tab.



- To view forms with open queries, select the 'Open DCRs' system query from the 'Page Actions' drop-down menu.



- Click on the green arrow icon  under the 'CRF ID' column for the query to be reviewed. 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 'Add Response' next to the query and enter a response. Once finished, click 'Save Response' at the bottom of the page.

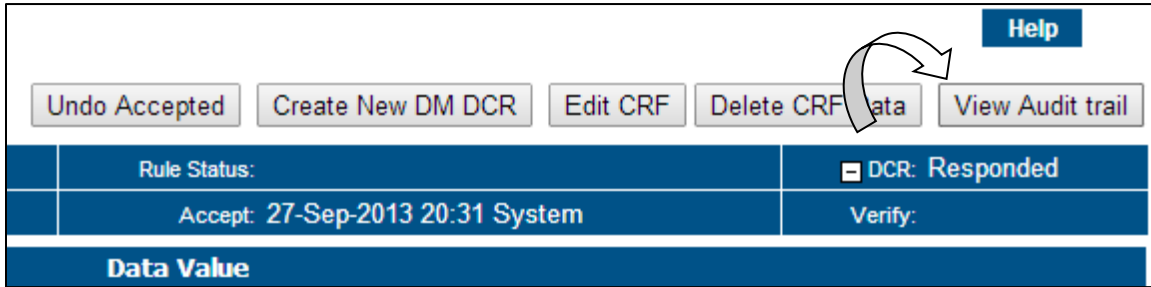
Data Clarification Request				
DCR	Type	Status	Query	Action
5164	Monitor	Open	Please confirm the response to Q45. (Stephanie MONROE on 4/2/2013 3:54:42 PM)	

Data Clarification Request # 5164	
Query	Response
Please confirm the response to Q45	<div style="border: 1px solid #ccc; padding: 5px;"> <p>Confirmed!</p> </div> <p style="text-align: right; font-size: small;">350 char.</p>
<input type="button" value="Save Response"/> <input type="button" value="Cancel"/>	

- If the form requires editing, click [Edit CRF] and correct the CRF data as needed. Once finished, click [Save Record] at the bottom of the page and then click [Submit CRF] at the top right-hand corner 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'.



- 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.

Study Calendar


- Once a subject has been added to the study database, the study calendar will be populated with target and actual visit dates. To view the study calendar, click on [Study Calendar] under the [Study Progress] tab of the main menu page.
- Actual visit dates are shown in green. Projected/target visit dates are shown in pink.

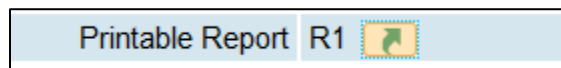
Sun	Mon	Tue	Wed	Thu	Fri	Sat
1073 - 1549 Day 1	1073 - 1549 Day 2	1073 - 1549 Day 3	1073 - 1549 Day 4	1073 - 1549 Day 5	1073 - 1549 Day 6	1073 - 1549 Day 7
1073 - 1548 Day 3	1073 - 1548 Day 4	1073 - 1548 Day 5	1073 - 1548 Day 6	1086 - 1546 Hospital Discharge	1226 - 1513 Day 30	1396 - 1552 Day 3
1073 - 1545 Day 5	1073 - 1545 Day 6	1073 - 1545 Day 7	1086 - 1546 Day 7	1086 - 1546 End of Study	1396 - 1552 Day 2	1590 - 1553 Day 1
1086 - 1546 Day 4	1086 - 1546 Day 5	1086 - 1546 Day 6	1753 - 1550 Day 3	1396 - 1552 Day 1	1502 - 1541 Hospital Discharge	1753 - 1550 Day 6
1396 - 1544 Day 5	1105 - 1542 Hospital Discharge	1514 - 1459 Day 90		1502 - 1507 Hospital Discharge	1753 - 1550 Day 5	1073 - 1549 Hospital Discharge
1396 - 1544 Hospital Discharge	1590 - 1510 Day 30	1514 - 1459 End of Study		1753 - 1550 Day 4		
1396 - 1543 Hospital Discharge	1753 - 1550 Day 1	1753 - 1550 Day 2		2200 - 1526 Day 30		
1396 - 1544 End of Study	1753 - 1551 Day 1	1073 - 1545 Hospital Discharge		1073 - 1548 Day 7		
1396 - 1543 End of Study		1753 - 1551 Day 2				
1502 - 1507 Day 30						
8	9	10	11	12	13	14
1396 - 1552 Day 4	1396 - 1552 Day 5	1396 - 1552 Day 6	1396 - 1552 Day 7	1635 - 1555 Day 1	1635 - 1555 Day 2	
1590 - 1553 Day 2	1590 - 1553 Day 3	1590 - 1553 Day 4	1396 - 1552 Hospital Discharge	1634 - 1531 Day 30		
1753 - 1550 Day 7			1396 - 1552 End of Study	1590 - 1553 Day 6		
1753 - 1550 Hospital Discharge			1514 - 1554 Day 1	1514 - 1554 Day 2		
			1590 - 1553 Day 5			
			1232 - 1530 Day 30			
15	16	17	18	19	20	21


- To filter the calendar for a particular subject, click on [Subject Progress] under the [Data Management] tab of the main menu page. To filter for the appropriate subject, select 'Subject Visit/Projected Subject Visits' from the 'Page Actions' dropdown menu at the top right-hand corner of the page.

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:
 - Site Contact Information
 - Active Site Team Members
 - Required Site Regulatory Documents
 - Screen Failure Log Summary
 - Site Enrollment and Retention Summary
 - Open Site Trial Operation Monitoring Issues
 - CRFs for Source Document Verification
 - Subjects to be Monitored




#	Site	Total Subjects Enrolled	Last Monitoring Visit	CRFs to be Monitored	Printable Report
	Total	50	17-Sep-2014	221	
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.

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	* No <input type="radio"/> Yes <input type="radio"/>
Q10	Known chronic calcific pancreatitis	* No <input type="radio"/> Yes <input type="radio"/>
Q11	Suspected pancreatic head malignancy	* No <input type="radio"/> Yes <input type="radio"/>
Q12	Current ERCP performed on major papilla/ventral pancreatic duct in patient with pancreas divisum (no manipulation of minor papilla)	* No <input type="radio"/> Yes <input type="radio"/>
Q13	Current ERCP for biliary stent removal or exchange without anticipated pancreatogram	* No <input type="radio"/> Yes <input type="radio"/>
Q14	Prior biliary sphincterotomy, now scheduled for biliary therapy without anticipated pancreatogram	* No <input type="radio"/> Yes <input type="radio"/>
Q15	Anticipated inability to follow protocol	* No <input type="radio"/> Yes <input type="radio"/>
Q16	Absence of a rectum	* No <input type="radio"/> Yes <input type="radio"/>
Inclusion Criteria If Q23 is 0, then Q29 must be greater than or equal to 2, or this subject is not eligible.		
Q17	Clinical suspicion or known sphincter of Oddi dysfunction (SOD)	* No <input type="radio"/> * Yes <input type="radio"/> Unknown <input type="radio"/>
Q18	History of post-ERCP pancreatitis (at least one episode)	* No <input type="radio"/> * Yes <input type="radio"/> Unknown <input type="radio"/>
Intra-Procedure		
Q19	Pancreatic sphincterotomy?	* No <input type="radio"/> <input type="radio"/> Yes, needle-knife <input type="radio"/> Yes, traction <input type="radio"/> Unknown
Q20	Pre-cut (access) sphincterotomy?	* No <input type="radio"/> <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:
 1. **Data confirmed.** If the site confirmed the accuracy of the data and no change was necessary, select 'Data confirmed'.

2. **Error corrected.** If the site corrected an error on the CRF, select 'Error corrected'.
 3. **Missing item/CRF entered.** If the site added missing data or more information to the form or if a new CRF was data entered in response to the DCR, select 'Missing item/CRF entered'.
 4. **Updated for DB change.** If the site was responding to a query based on a change that was made to the database by DCC, select 'Updated for DB Change'.
- 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.

List: Monitor Visit				
CRFs Verified	% CRFs Verified	CRFs Queried	Previous Visit Date	Monitoring Visit Report
Help				
Page Actions <input type="button" value="Add New"/>				

- 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].

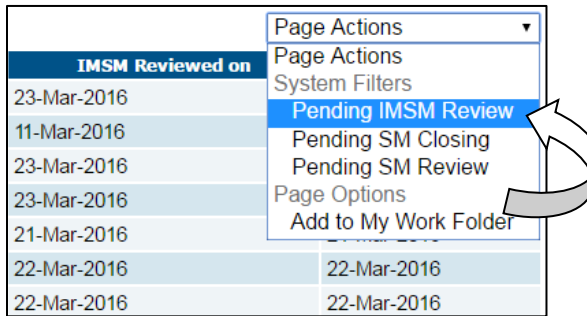
Monitoring Report Review (for Site PIs)


- 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 the 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.

A screenshot of a table with the following columns: #, Hub, Site, Subject, and CRF ID. The first row contains the values: 1, Mass General, Beth Israel Deaconess Medical Center, Boston, MA, 172, and 3425. A green arrow icon is located to the right of the CRF ID. Below the table, there is a disclaimer: "All information is generated based on data currently in the database. Data may not be verified or validated. The report is generated to assist in trial operations only, and is not valid to support any statistical analysis of study data. Unless noted, the Data Coordination Unit (DCU) is responsible for the accuracy of the information. You are prohibited from disclosing this information without the specific written consent of the person to whom it pertains. Anyone using this data specifically as..."

- 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.
- Once the IMSM completes the review steps, the SM will close the review.

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 (Financial Managers)

- The [Site Payment] table lists all payments, site-based or subject-based. The 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 (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.
- Quick reference for:
 - Hub - associated institution or university

- Site - hospital or medical center
 - Payments Invoiced, Payments Due, Total Amount Due
 - Pending Invoice - view an already created invoice
 - Draft Invoice - create a new invoice
- If PO number or vendor information need to be updated, access the [Project Site Payment] table under the [Network Management] main menu tab in the SIREN database. If you do not have the appropriate permissions, contact the appropriate Data Manager at the DCC.
 - In the [Site Invoice] table, click on the blue number link adjacent to the record in order to view that specific site invoice.
 - Payments from multiple subjects will appear in one table per site along with 'Date First Ready' and 'Current Status' - whether the payment is ready, invoiced or paid.
 - 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 (Financial Managers)

- 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 (Financial Managers)

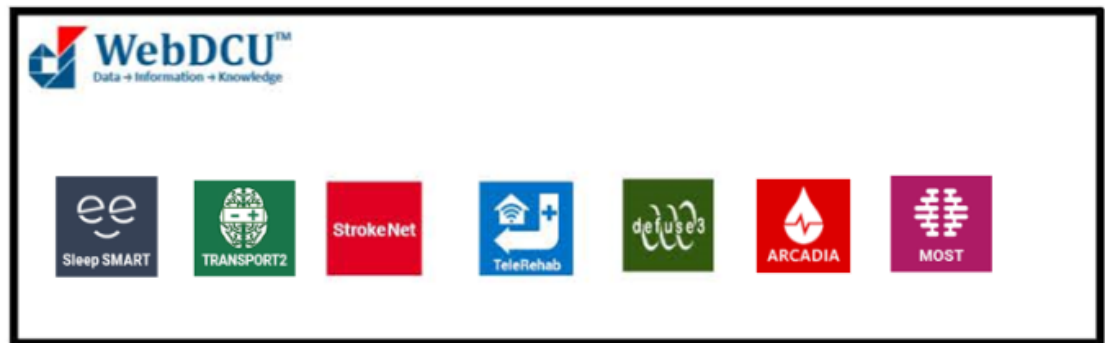
- Provides purchase order information for each site, including PO number and vendor information. This information should be updated by the Financial Manager if changes occur.
- In the [Project Site Payment] table under the [Network Management] main menu tab in SIREN, click on the blue number link adjacent 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 (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 CCC.

STUDY DATABASES

- The SIREN 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.



ASPERA IMAGE UPLOAD TO 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.

Testing the Aspera® Platform

1. Log into WebDCU™, <https://webdcu.musc.edu/login.asp>, with your email address and password.

o After logging in, “click on” WebDCU™ “HO₂BIT” icon.



2. Click [Site Management].



Randomized 30% (60 / 200) of recruitment target.

Add New Subject	Subject CRF Binder	Study Progress	Data Management	Project Management	Safety Monitoring
Site Management	Study Material Tracking	Central IRB	Data Monitoring	CRF Data List	Graphic Reports
Clinical Site	Site Status	BioHOBIT Site	Clinical Site Group Member	Readiness Report	
Site Payment Summary	Site Invoice	Site Invoice Payment	Site Payment	Payment Definition	
Site Address	Aspera File Upload Test	Aspera Upload Test Summary			

1. Click [Aspera File Upload Test]

Randomized 30% (60 / 200) of recruitment target.

Add New Subject

Subject CRF Binder

Study Progress

Data Management

Project Management

Safety Monitoring

Site Management

Study Material Tracking

Central IRB

Data Monitoring

CRF Data List

Graphic Reports

Clinical Site

Site Status

BioHOBIT Site

Clinical Site Group Member

Readiness Report

Site Payment Summary

Site Invoice

Site Invoice Payment

Site Payment

Payment Definition

Site Address

Aspera File Upload Test

Aspera Upload Test Summary

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

List: Aspera File Upload Test

loaded by	Test file upload	File uploaded on	File upload started successfully	File upload completed
	F1602.zip	19-Apr-2021 12:11	Yes	Yes
	F1625.zip	24-May-2021 09:36	Yes	Yes

Page Actions Add New

3. Fill in the selected site you are testing in row 1

No.	Item Description	Data Value
1	Site	Please Select
Please follow below instruction to upload a test file using Aspera. <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. 		
3	File uploaded by	(to be assigned by the system)
4	Test file upload	
4	File uploaded on	(to be assigned by the system)
5	File upload started successfully	<input type="radio"/> No <input type="radio"/> Yes <small>Answer 'Yes' only if the file upload process seems to start successfully. If not starting successfully, please try another attempt (total 3 attempts recommended) using different computers.</small>
GC	General comments	<input type="text" value=""/>

Save Record Cancel Edit

4. Click on [Upload File (Aspera)]. This will then generate a pop up file upload window. Please follow section 2.2 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.

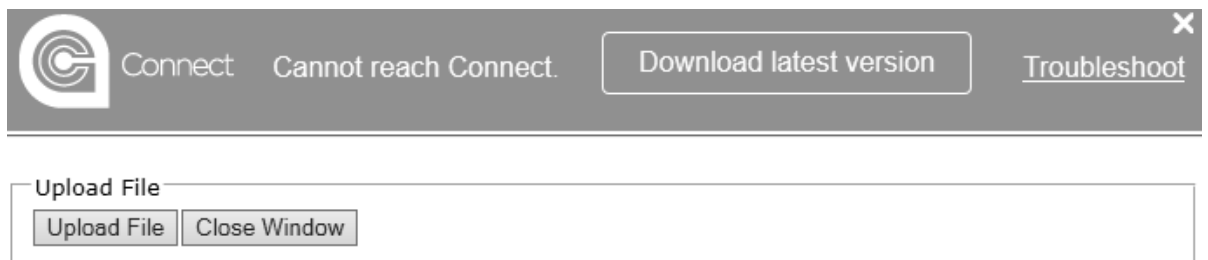
5. Answer the question in row 5, which asks if you were able to upload a file. If you were unable to upload a file, you can come back and repeat the process later.

6. Save the record

2.2 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.

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

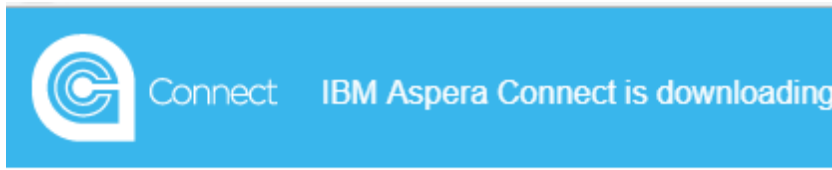


*** Please note, when you click on [Upload file (Aspera)] from step 6, you may see the below pop-up instead, asking you to 'Install Extension'. In this instance, please go ahead and install, following the prompts through to step 3. This is due to there being an updated version of Aspera that communicates differently with the current version of your internet browser. ***

WebDCU HO_BIT Edit: Aspera File Upload Test

No.	Item Description	Data Value
1	<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. 	Site: Please Select
2	Test file upload Zip file only	
3	WebDCU™ for MOST Current User: Laura ARNOLD - Microsoft Edge	(to be assigned by the system)
4	https://webdcu.musc.edu/nett/AsperaWeb/AsperaUpload.asp?thisFieldID=4481&thisCRFID=...	(to be assigned by the system)
5	<p>Required Steps</p> <p>To enable Aspera uploads and downloads, you need to install or upgrade to IBM Aspera Connect 3.9.8.</p> <p>Step 1: Install Extension</p> <p>Step 2: Download the App</p> <p>Step 3: Install Connect</p> <p>Already installed? Refresh / Troubleshoot</p>	<input type="radio"/> No <input type="radio"/> Yes <p>Error messages!</p> <p>id: Upload File (Aspera)</p> <p>IF57324.zip</p> <p>Cancel Edit</p>

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



Connect IBM Aspera Connect is downloading


Upload File

Upload File Close Window

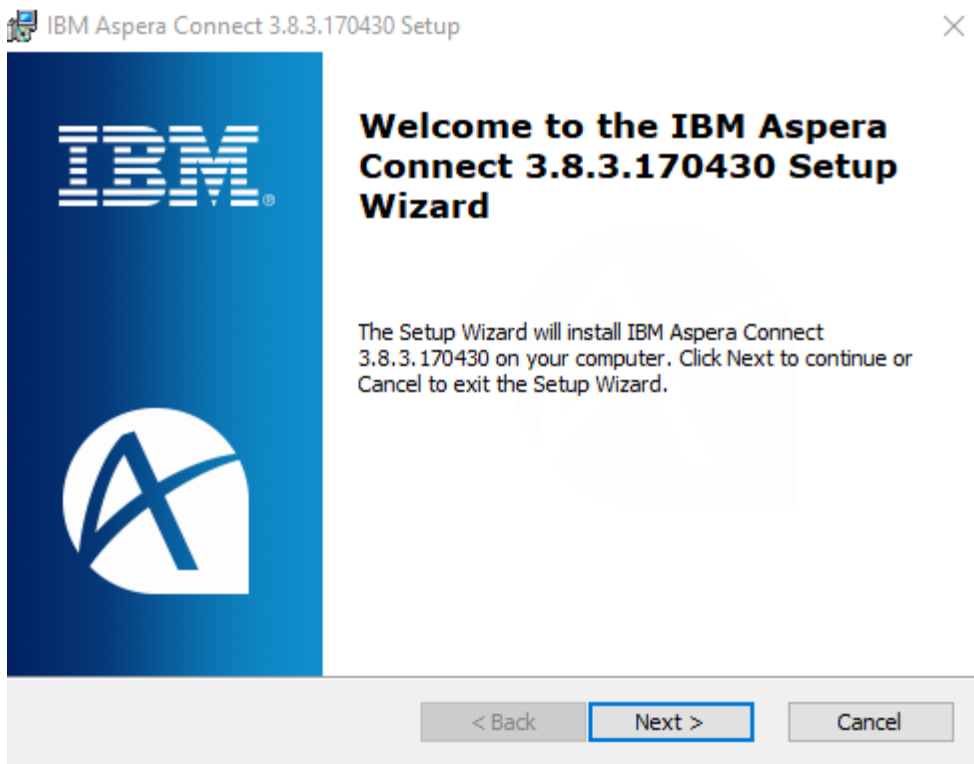
We

- The installation window should pop up if you completed the steps above.

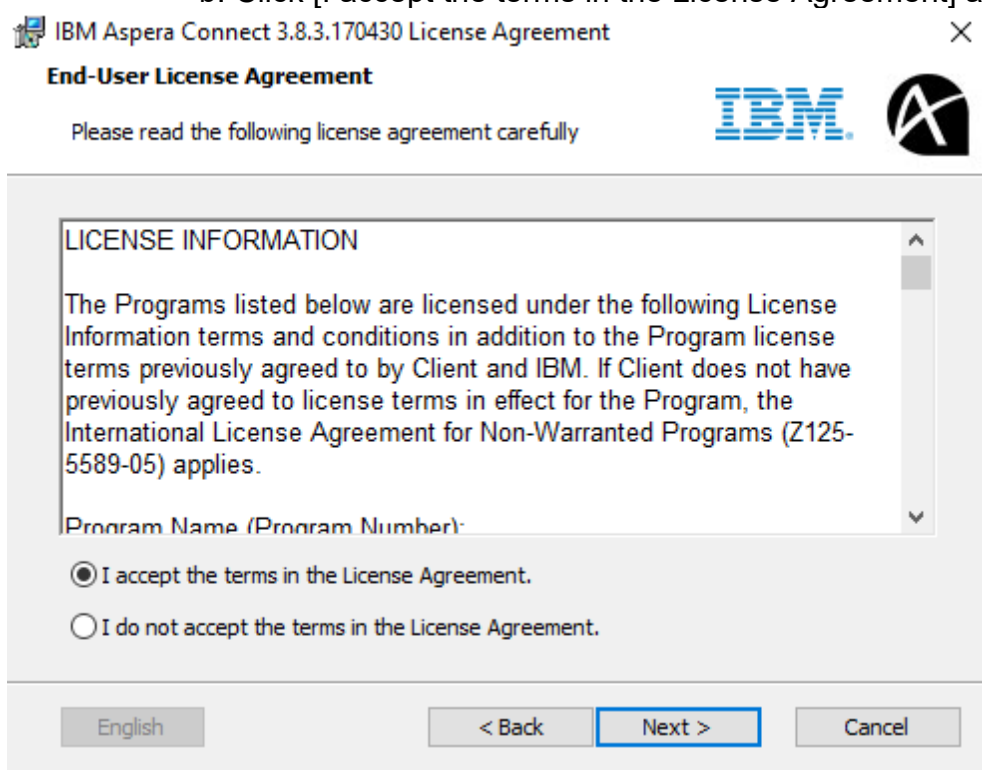
- Click [Next]



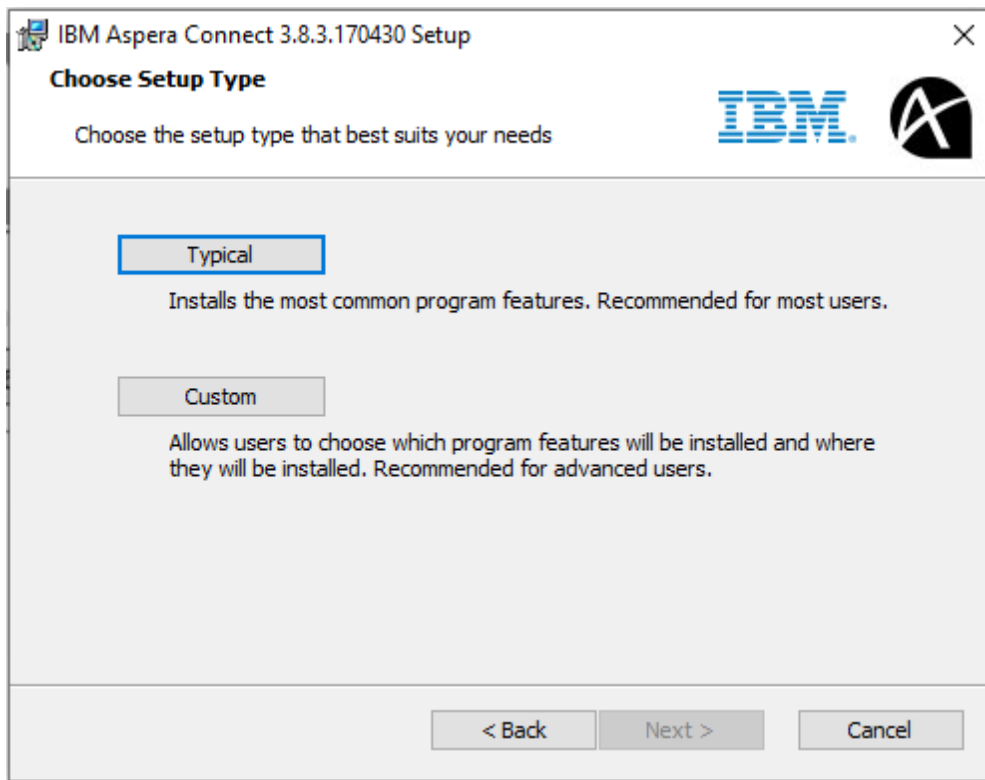
IBMASperaConnec....msi



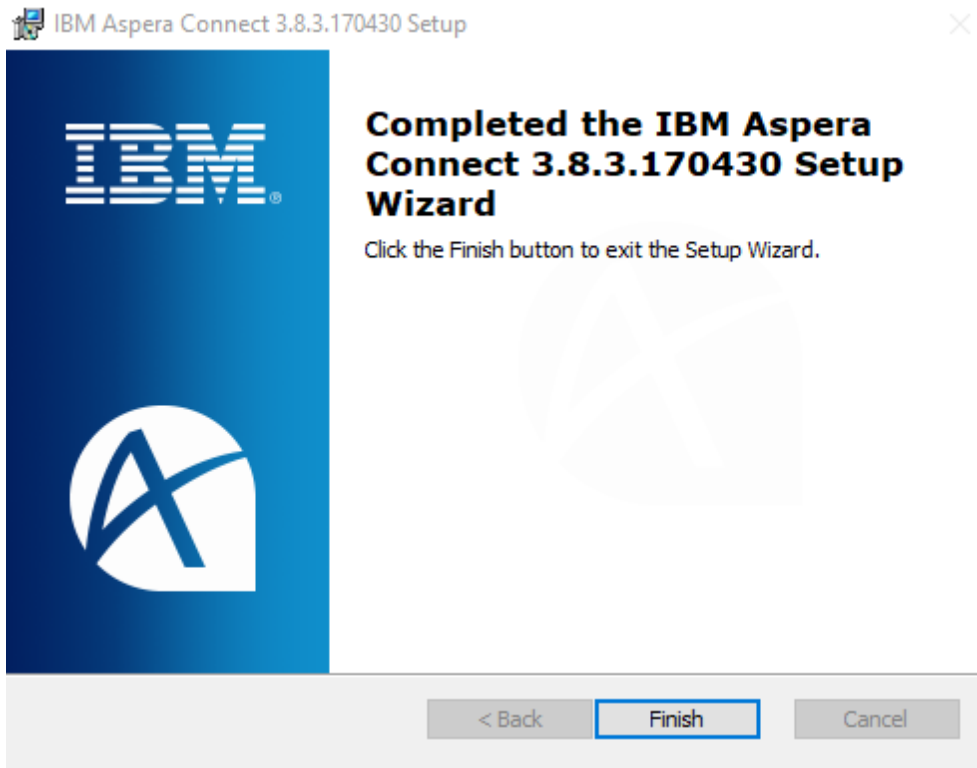
b. Click [I accept the terms in the License Agreement] and click [Next]



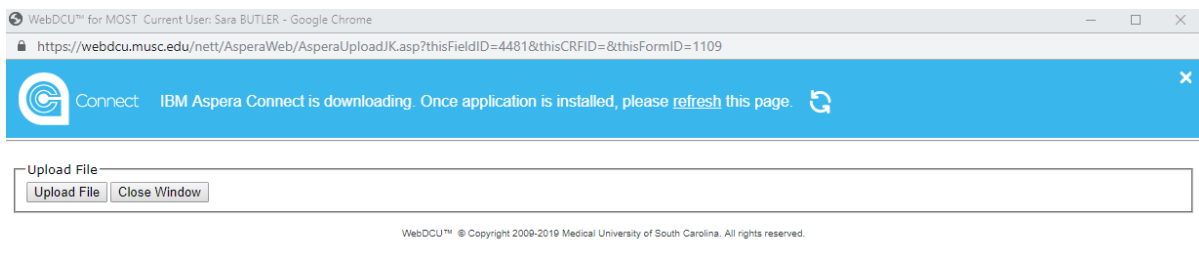
c. Click [Typical]



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

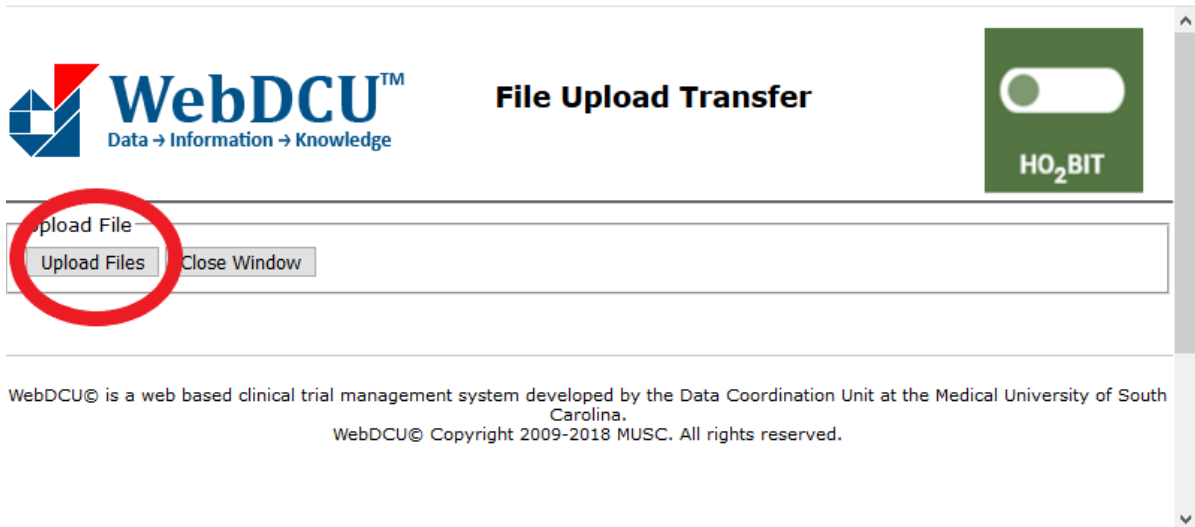


f. Go back to the file upload window and click [Refresh]



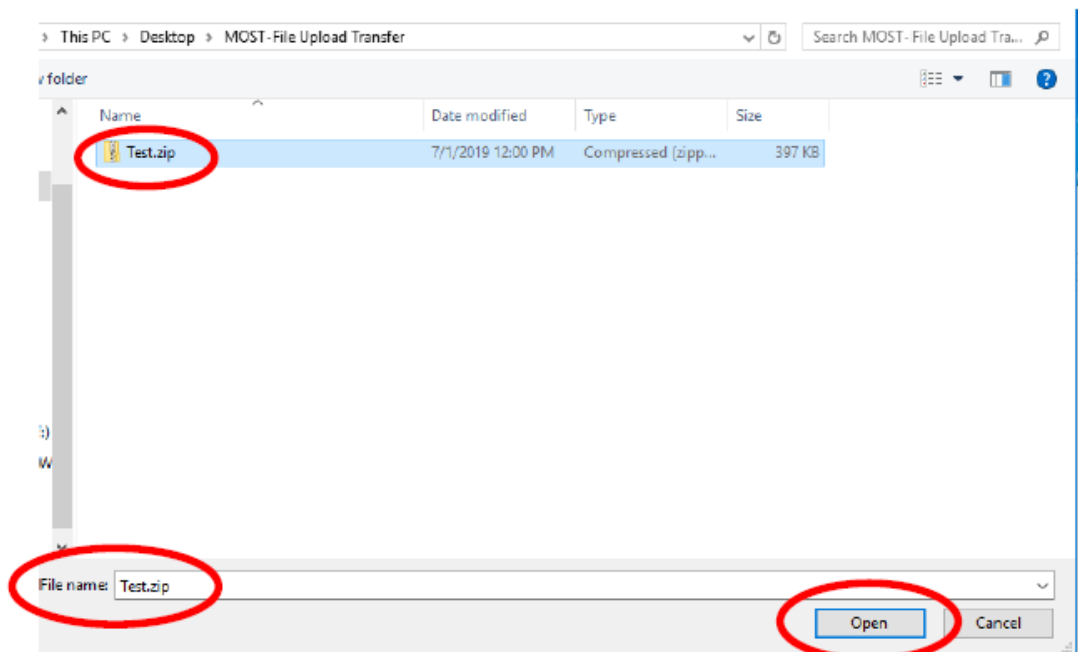
5. You will now be able to upload a file.

a. Click [Upload file]



b. then a file selection window will open. Select the zipped image file and your computer and click [Open]

Image 11



6. Once 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 management support with WebDCU.

The screenshot shows a web browser window with the URL https://webdcu.musc.edu/nett/aspera_test/asperaupload.asp?theFieldID=3051&CRFID=242&FieldToUpDa. The page header includes the WebDCU logo with the tagline "Data → Information → Knowledge" and the title "File Upload Transfer". A green toggle switch labeled "HO₂BIT" is visible in the top right corner.

UPLOAD TRANSFERS VIEW

Transfer Progress	File Name	
100%	Send - FCT.zip	Remove

Upload File

Close Window

WebDCU© is a web based clinical trial management system developed by the Data Coordination Unit at the Medical University of South Carolina.
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