UNIVERSITY OF

ROCHESTER

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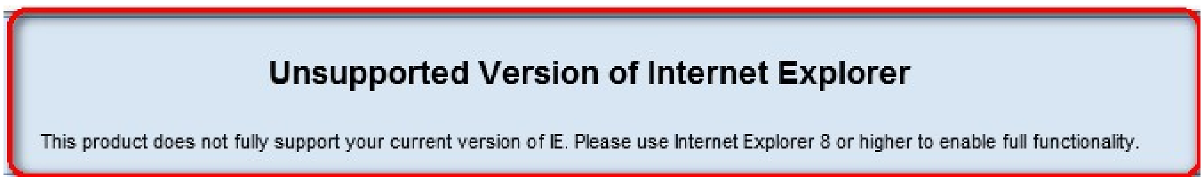
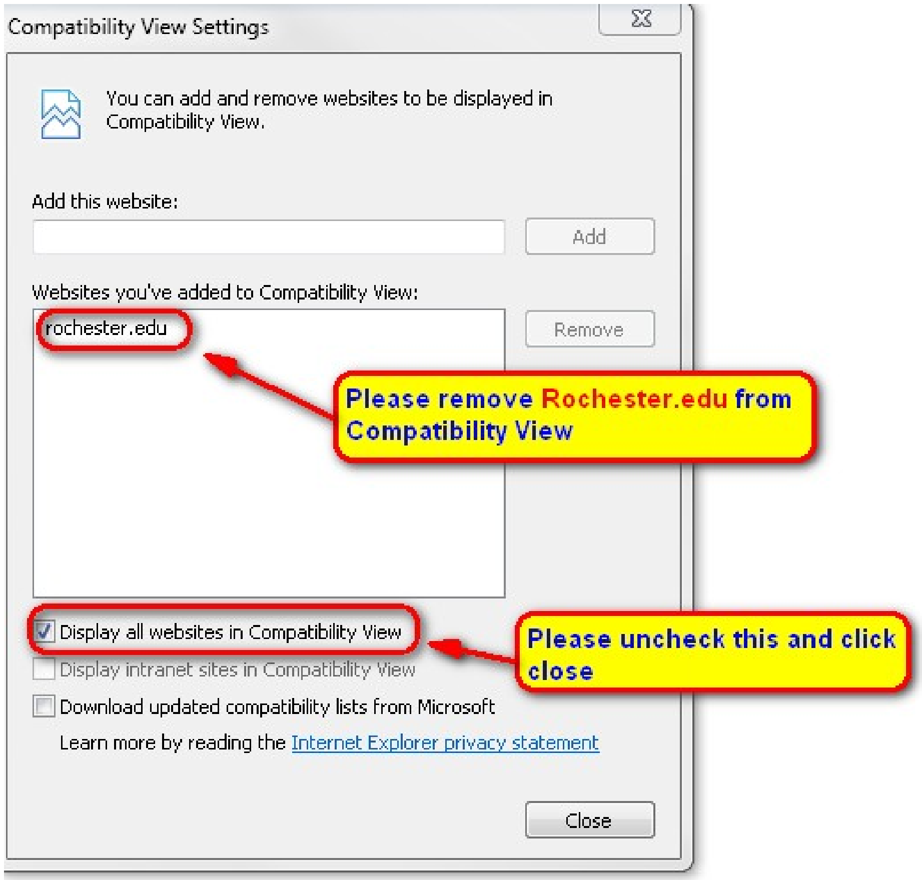
Most Common Questions

What to do if you get an error message' Unsupported Version of internet Explorer" as shown below when trying to connect to our eClinical site:



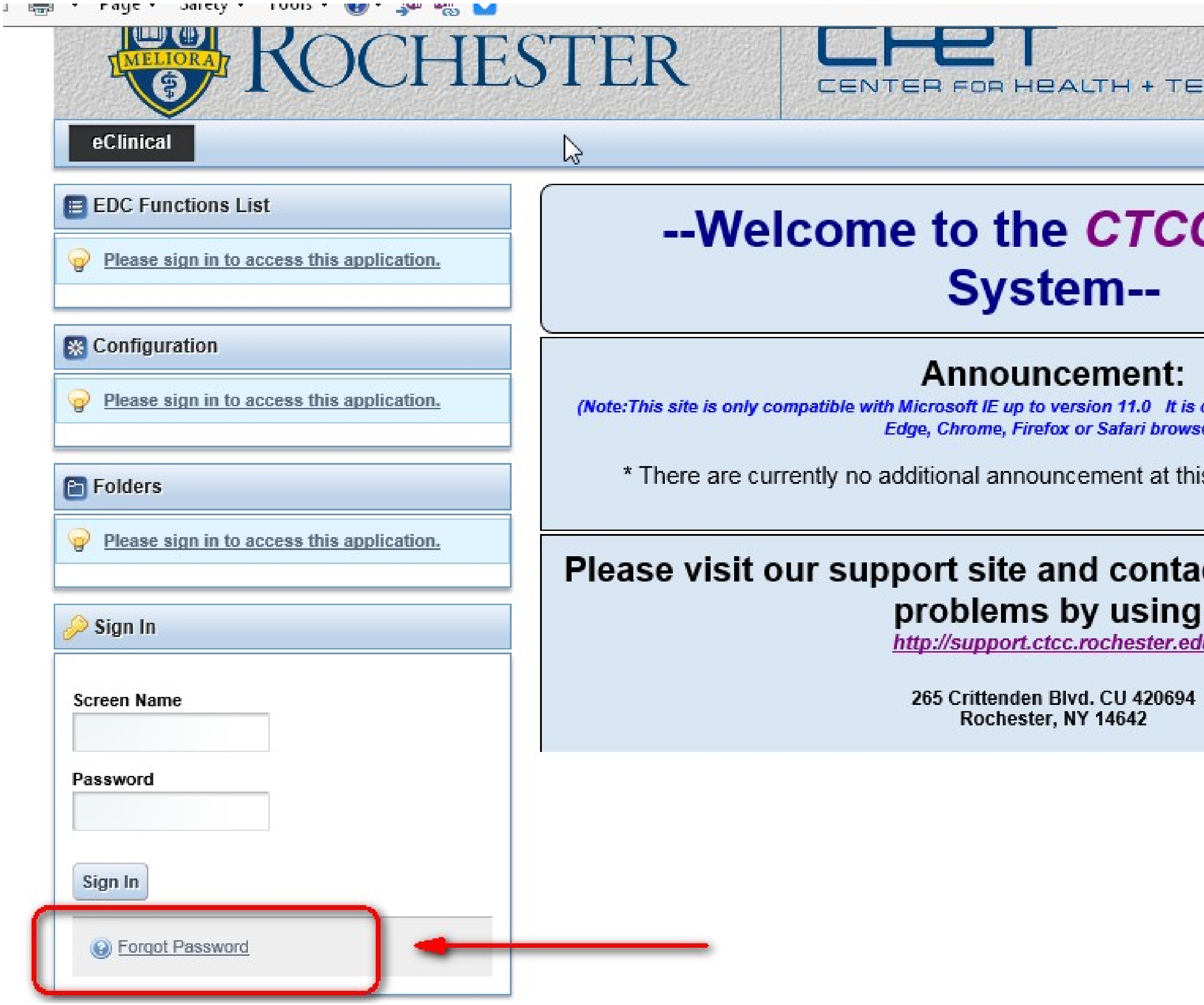
a) Click on tools/compatibility view settings to remove--> Rochester.edu and

Unchecks---> Display all websites in compatibility view as shown.



I forgot my password for eClinical. What do I do?

Please use forgot password link from the logon page as shown below to reset you password:



Note : Your password must satisfied the following rules:

Password minimum length must be eight (8) characters.
Password cannot start with a number.
Password maximum length is 30 characters.
Password cannot contain special characters.

*If you have failed at your login/password combination five (5) or more times, your account will be deactivated and you will need to call the support line (585-275-3893) to unlock it.

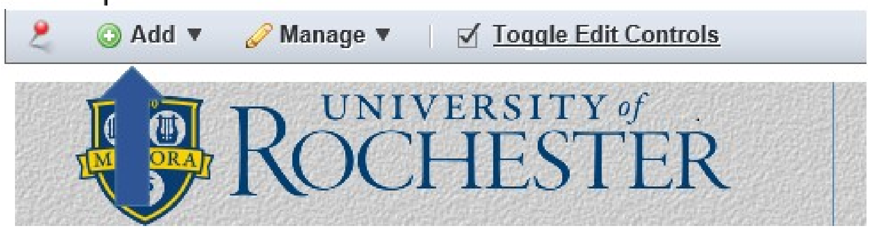
Why do I see screen flashing in the lower right corner of the system when I login and logout?

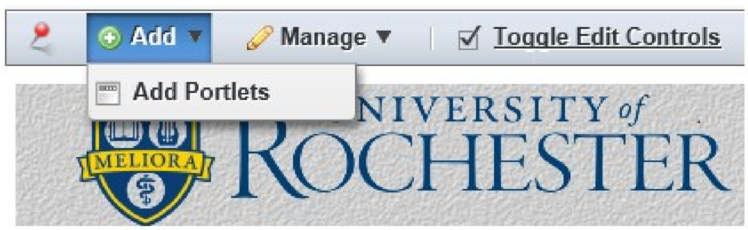
This is a normal part of the login/logout process. The portlets of our eClinical system are loading/closing which causes the rapid window flashing.

How to add portlet in portal 5.2:

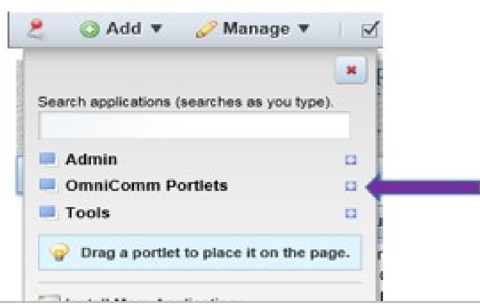
1) Logon to portal

2) Click Add portlets from the add menu as shown below

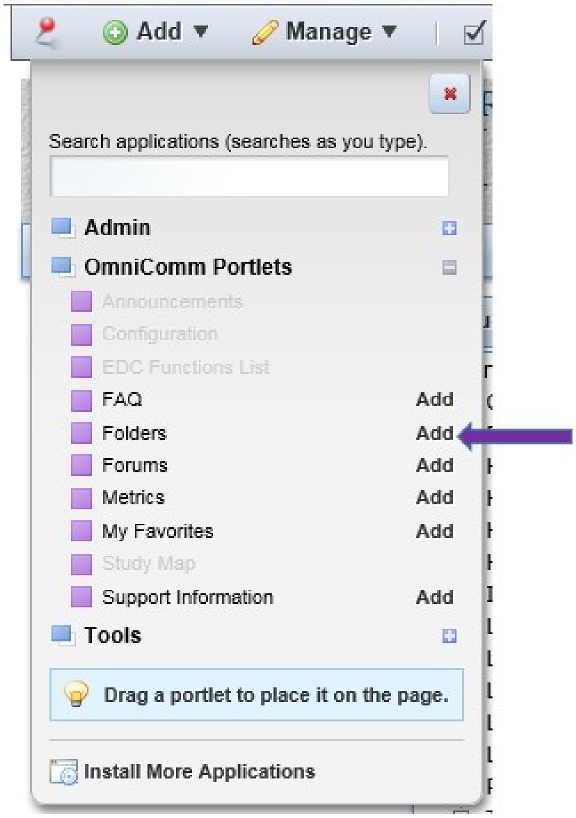


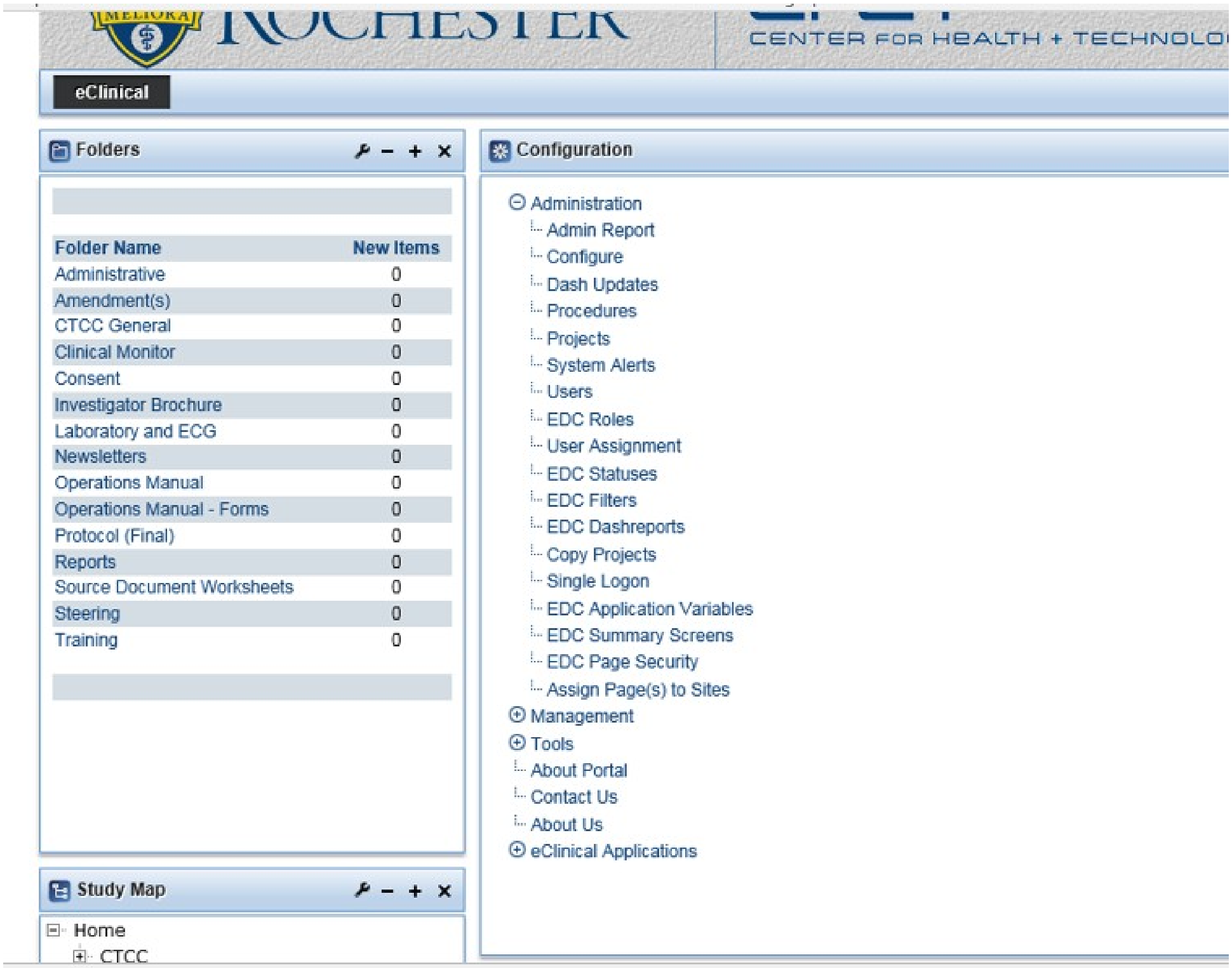


3) Click on the plus sign on the right hand side to expand and click Add



4) Pick the portlet from the drop down to add (ex: I pick FOLDER to add)

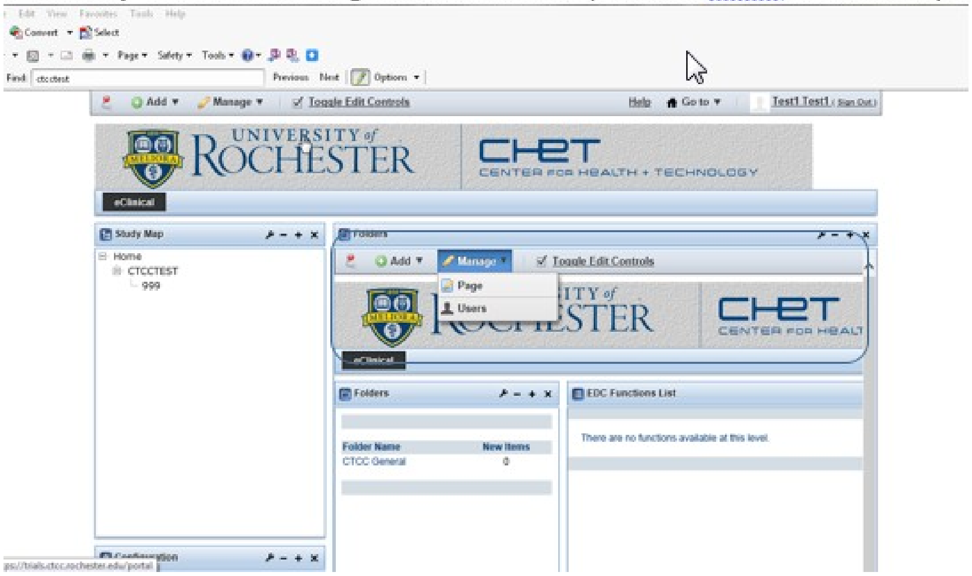



ROCHESTER
CENTER FOR HEALTH + TECHNOLO
eClinical
Folders
Configuration
Folder Name
New Items
Administrative 0
Amendment(s) 0
CTCC General 0
Clinical Monitor 0
Consent 0
Investigator Brochure 0
Laboratory and ECG 0
Newsletters 0
Operations Manual 0
Operations Manual - Forms 0
Protocol (Final) 0
Reports 0
Source Document Worksheets 0
Steering 0
Training 0
Administration
Admin Report
Configure
Dash Updates
Procedures
Projects
System Alerts
Users
EDC Roles
User Assignment
EDC Statuses
EDC Filters
EDC Dashreports
Copy Projects
Single Logon
EDC Application Variables
EDC Summary Screens
EDC Page Security
Assign Page(s) to Sites
Management
Tools
About Portal
Contact Us
About Us
eClinical Applications
Study Map
Home
CTCC

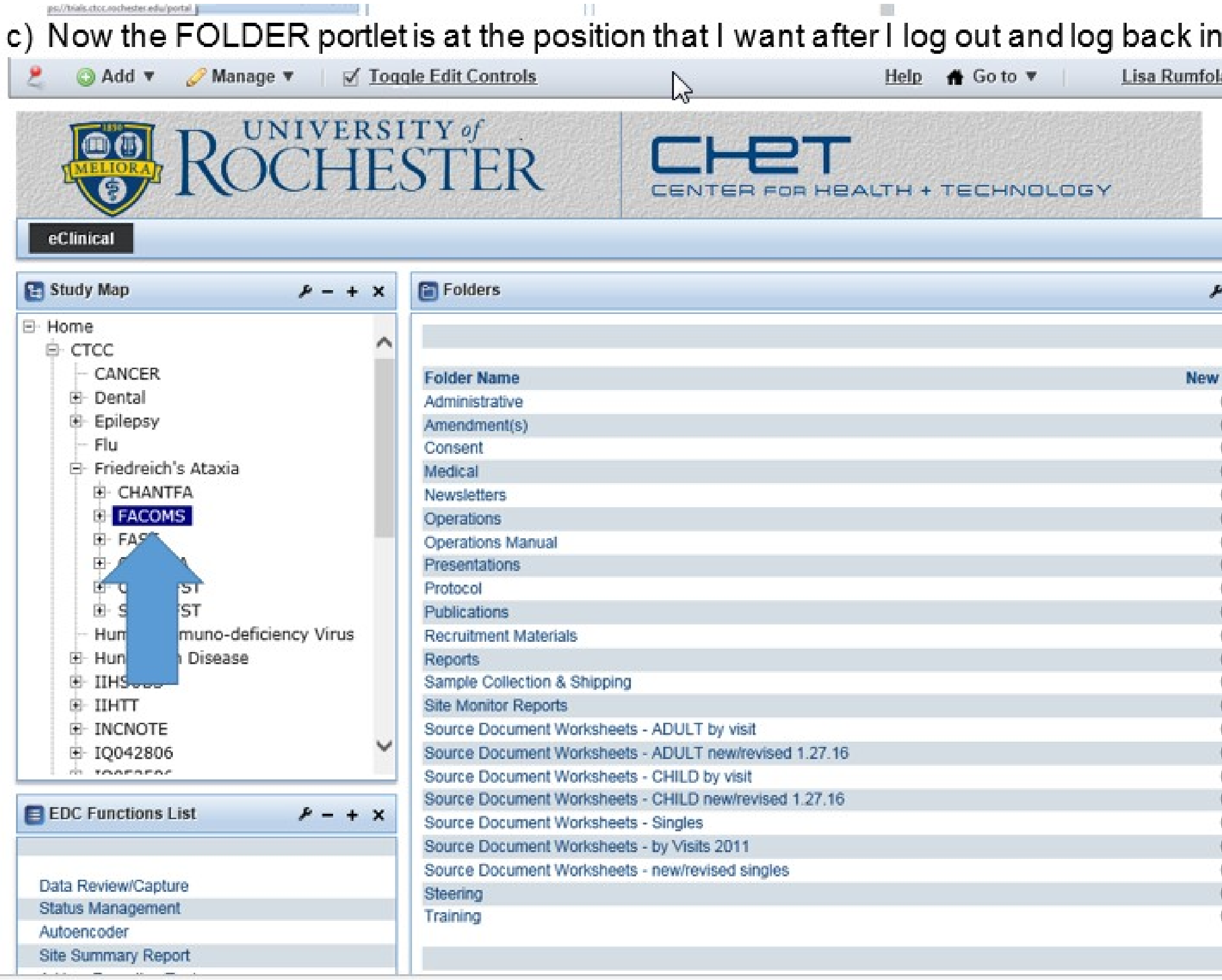
5) Now you can move the portlet around to where you want (For example, I want to mov

a) Left click on your mouse to hold down on the FOLDER portlet and move it to the po

b) You may see something like this below (Please don't be alarm, please logout and bac



c) Now the FOLDER portlet is at the position that I want after I log out and log back in



d) Click on Protocol in the Study Map and click on item in the folders portlet (e.g., Source
Click on item you and print

Folders

Go Back | Source Document Worksheets - Singles | Edit Mode

File Name	Description	Size (bytes)	Last Update	Versions
12 - Medications.pdf	FACOMS 12 - Medications	40391	10-SEP-2013	-
14 - 9HPT - NEW.pdf	FACOMS 14 - 9 Hole Peg Test	36924	10-SEP-2013	-
24 - Vital Signs.pdf	FACOMS 24 - Vital Signs	38710	10-SEP-2013	-
03 - Characteristics Form NEW.pdf	FACOMS 03 - Characteristics	113749	10-SEP-2013	-
06 - DNA Sample Collection Form NEW.pdf	FACOMS 06 - DNA Sample Collection Form	48868	10-SEP-2013	-
28 - EKG -- NEW.pdf	FACOMS 28 - EKG	133868	10-SEP-2013	-
50 - Subject site Transfer form.pdf	FACOMS 50 - Subject Site Transfer Form	42447	10-SEP-2013	-
52 - Conculsion of Study Part 1-10-08.pdf	FACOMS 52 - Study Conclusion Form	35633	10-SEP-2013	-
FACOMS SOA- Child.pdf	FACOMS Schedule of Activities - CHILD	14376	10-SEP-2013	-

Click on go back button to see regular view.

NOTE: Some studies that have several documents in the folders portlet and it may take a

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How come I don't see any links in my EDC Functions List Portlet and/or I cannot see any folders in my Folders portlet?

1. Be sure that you clicked your study in the Study Map portlet. Make sure you select the study and NOT the site number.
2. If you are not using Internet Explorer (i.e. you are using Firefox, Safari, Opera, etc.) your study will not be selected. You can tell if your study is selected by observing it highlighted in red in your Study Map portlet. If you are using Internet Explorer, be sure you are clicking on the Study Name itself, and not the plus/minus icon next to the study.
3. Once your study has been selected (and is highlighted) in red, you should be able to view links in your EDC Functions List and Folders portlets.
4. If you are still unable to see anything, and are positive you are using the correct browser, it may be a permissions issue. Please contact the support line at 585-275-3893 to try to troubleshoot any permission issues.

Where do I download the documentation for my study?

1. Click on the name of your study in the Study Map portlet.

2. Locate the Folders portlet.
3. If there are no documents in the folders, or if you think you have not been given the appropriate permissions, please call system support at 585-275-3893.

On resetting my password I get the error message:

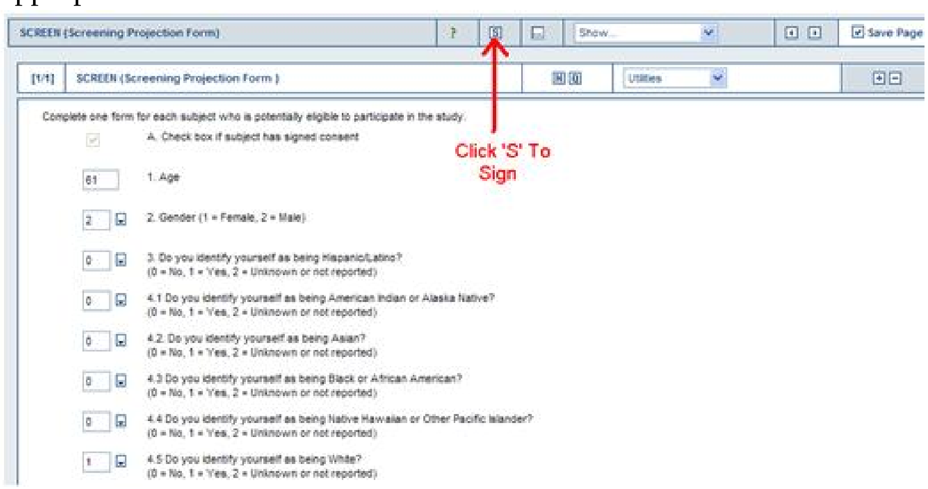
"xxx xxxx, your account with login xxxxx is not active. Please contact the administrator for more help." What should I do?

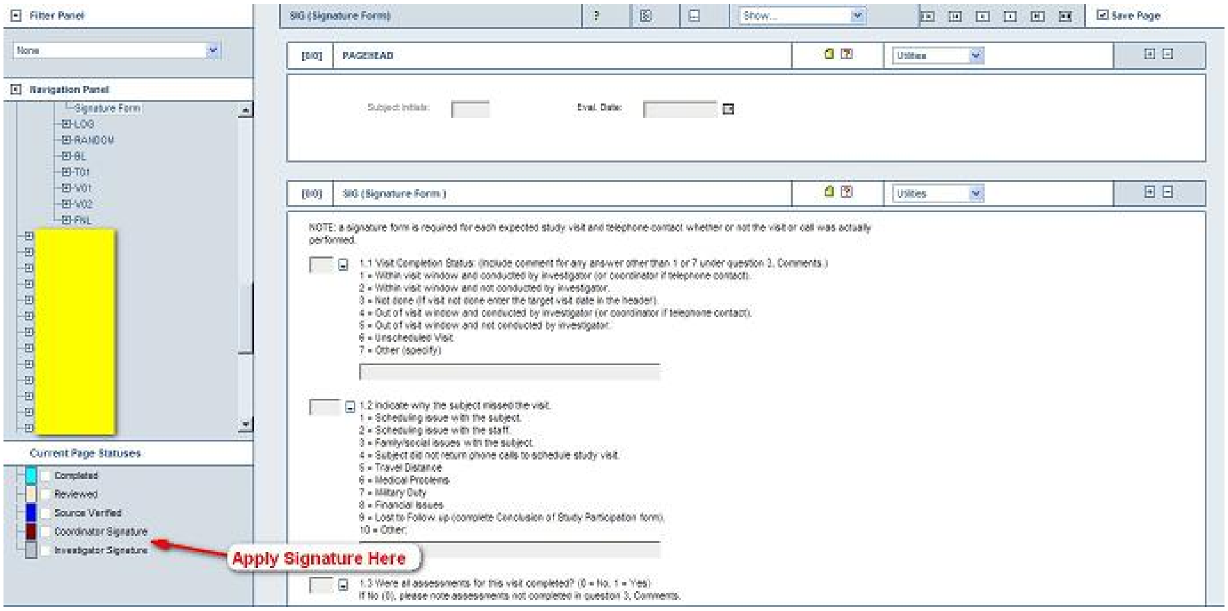
1. Your account has been deactivated becuase of a failed number of login attempts. Please call system support at 585-275-3893.
2. A system support person will verify your information and reactivate your account.
3. Once reactivated you can use the temp password issued to your email address to log back into the system.

How do I apply my electronic signature to a page in eClinical?

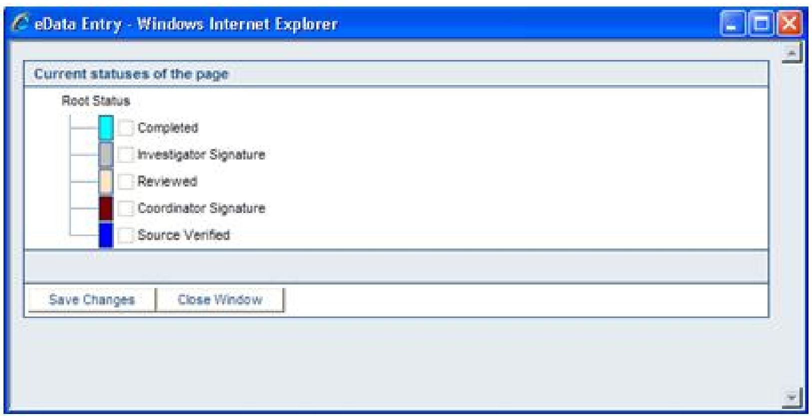
Please make sure you are in the Data Review/Capture (EDC) part of the system. For further reference, please see the Training Manual which can be found at the top of this page.

1. Be sure that the page has been completed and saved.
2. Single click the ‘S’ located near the top of the page. You can also click your appropriate status in the bottom left corner of the Window.





3. Click in the check box that corresponds with your role. (See below.)



4. Click Save Changes after you have checked the relevant box.
5. The system will require you to enter your password again.
6. You can verify that you have applied your signature at any time by clicking the ‘S’ button again. You can also look at the bottom left of your screen and see the same information there. You should see your name next to your role along with the time this document was signed.

Note: Any changes to the data on this page after it has been signed will remove the electronic signatures. It will have to be signed again.

I ran into problems while randomizing my patient. What should I do next?

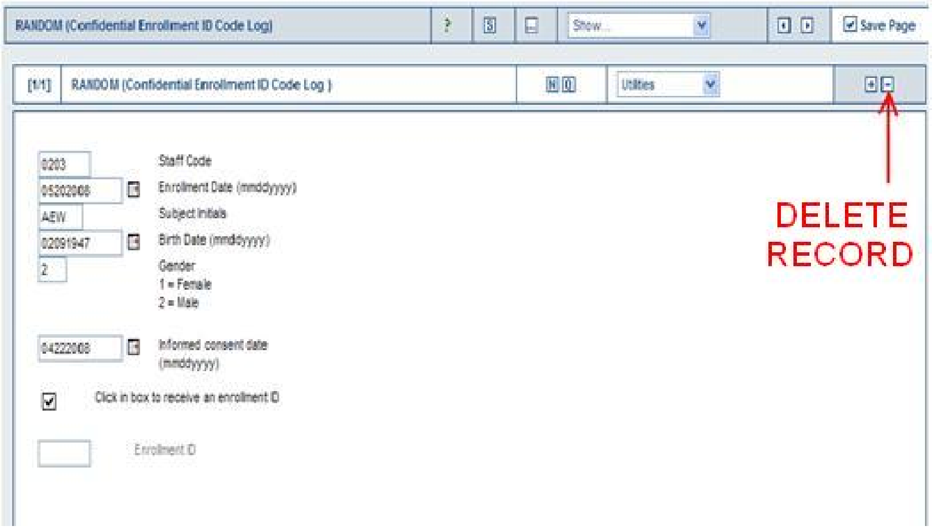
Please make sure you are in the Data Review/Capture (EDC) part of the system. For further reference, please see the Training Manual which can be found at the top of this page.

1. To randomize a subject, the Screening Demographics, Inclusion/Exclusion, and any specific assessments required per your protocol must be completed and saved. Please double-check that these pages have been properly filled out and saved for the subject.

2. Make sure that the information entered on the randomization page coincides with the information provided on the Screening Demographics and Inclusion/Exclusion pages (e.g. birthdates must match).

3. As you are filling out the information, be sure to use your Tab key to navigate through the fields.

4. If you keep getting an error when you are sure that you have filled it out correctly, you can delete the record by clicking the minus button. Proceed through the process of deleting the record. See image below for deleting a record.



5. If you have chosen to delete the record, and have previously saved the page, you will be prompted for a reason for change. If you have been prompted for a reason for change, please choose the response that best applies (usually data entry error).

6. If you deleted the record, hit the plus sign to add information to the page again. Please TAB through the fields while entering the data.

7. When all the information is filled out, you should be able to check the box labeled "Click in box to receive an enrollment ID."

8. Click once on the Save Page button. You should be able to view the enrollment ID for the patient.

9. If you have tried this process multiple times and are still unable to receive an enrollment ID, please call the system support line at 585-275-3893.

What are the most common pop-up blockers?

Other than the Ineternet Explorer default pop-up blocker, which is located under the tools menu in Internet Explorer, here is a list of common toolbars that also provide pop-up blocking functions. Note that the system will NOT perform correctly if pop-ups are being blocked.

Google Toolbar
YAHOO! Toolbar
AOL Toolbar
STOPzilla

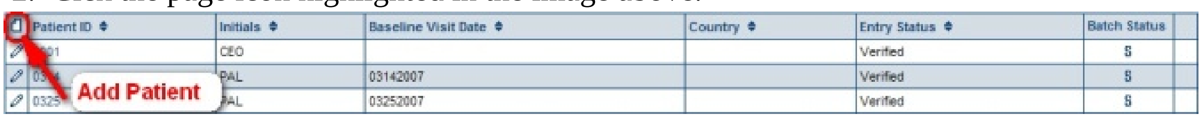
It is required that the pop-up blocking functionality of these toolbars is disabled. If the toolbar is not necessary, we recommend uninstalling the toolbar(s) in order to prevent any problems arising in the system.

Basic System Usage

How do I add a subject?

Please make sure you are in the Data Review/Capture (EDC) part of the system. For further reference, please see the Training Manual which can be found at the top of this page.

1. Navigate to your site level so you can see a list of all your subjects. To get to your site level, first select your protocol in the navigation panel to the left. You should then see your site number listed. Click on your site number. This is known as your site level and should show all subjects that have been entered at your site.
2. Cick the page icon highlighted in the image above.



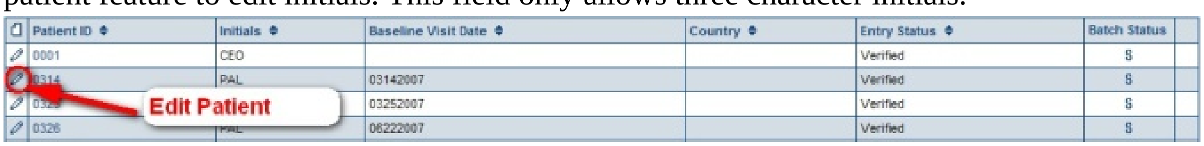
	Patient ID	Initials	Baseline Visit Date	Country	Entry Status	Batch Status
	[illegible]1	CEO			Verified	S
	03[illegible]	PAL	03142007		Verified	S
	0325	PAL	03252007		Verified	S

3. When creating the patient, be sure to enter the patient's initials. This field only allows three character initials.
4. If the patient has two initials, use a dash for the middle initial (i.e. P-W). If the patient has four initials, please use only the three that best apply.

How do I enter/update my subject's initials?

Please make sure you are in the Data Review/Capture (EDC) part of the system. For further reference, please see the Training Manual which can be found at the top of this page.

1. Navigate to your site level so you can see a list of all your subjects. To get to your site level, first select your protocol in the navigation panel to the left. You should then see your site number listed. Click on your site number. This is known as your site level and should show all subjects that have been entered at your site.
2. Click Edit Patient icon to edit your subject's initials. You should only use the edit patient feature to edit initials. This field only allows three character initials.



	Patient ID	Initials	Baseline Visit Date	Country	Entry Status	Batch Status
	0001	CEO			Verified	S
	0314	PAL	03142007		Verified	S
	03[illegible]	[illegible]	03252007		Verified	S
	0326	PAL	06222007		Verified	S

3. If the patient has two initials, use a dash for the middle initial (i.e. P-W). If the patient has four initials, please use only the three that best apply.

How do I add an unexpected event for my subject?

There are times when you may need to add an unexpected event. An example would be when a subject has a permanent withdrawal or unscheduled visit. Follow the steps below to add an unexpected event.

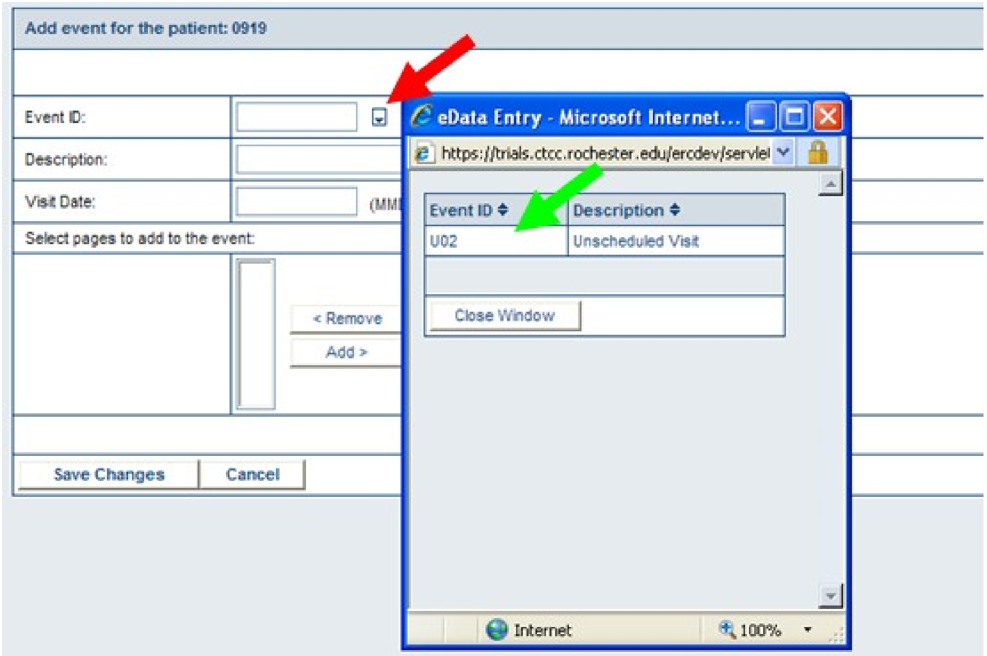
1. Select Subject

	Patient ID	Initials	Baseline Visit Date	Country	Entry Status	Batch Status	
	0119	SKB	01192007		Verified	S	
	0122	SKB	01222007		Verified	S	
	0123	SKB	01232007		Verified	S	
	0215	ABC	02152007		Verified	S	
	0220	CEO	11272006		Verified	S	
	0230	CEO	12132006		Verified	S	
	0245	LAR			No Data Entry	S	×
	0313	SKB	03132007		Verified	S	
	0330	CEO	11272006		Verified	S	
	0334	CEO	11282006		Verified	S	
	0345	CEO	11282006		Verified	S	
	0425	SKB	04272007		Verified	S	
	0427	SKB	04272007		Verified	S	
	0611	SKB	06102007		Verified	S	
	0612	SKB	06112007		Verified	S	
	0615	BSK	06152007		Verified	S	
	0620	SKB	06202007		Verified	S	
	0621	SKB	06212007		Verified	S	
	0710	LML	07102007		Verified	S	
	0711	SKB	07112007		Verified	S	
	0717	LML	07172007		Verified	S	
	0821	SKB	08212007		Verified	S	
	0912	SKB	09122007		Verified	S	
	0919	SKB	09192007		Verified	S	

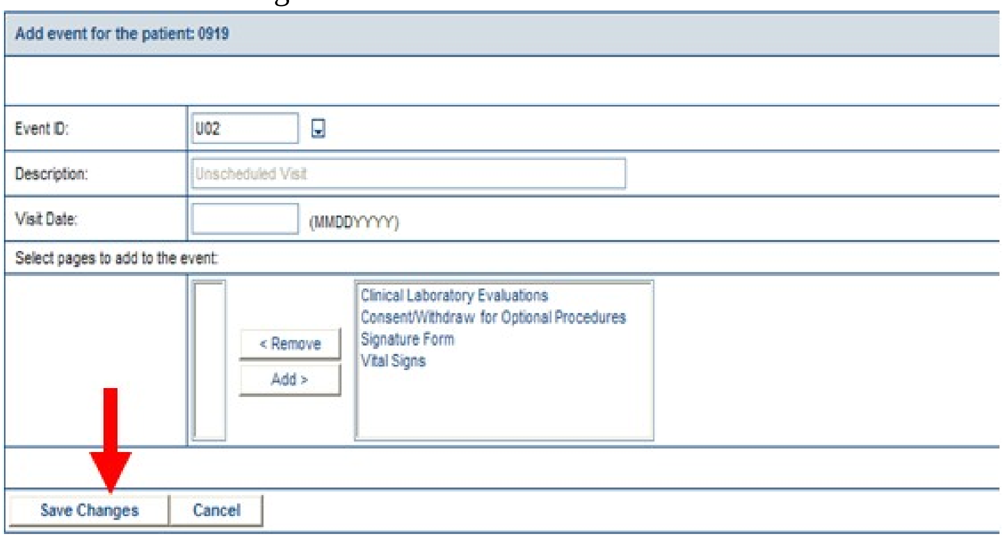
2. Click on "paper" icon

	Event ID	Description	Visit Date	Entry Status	Event Order	Batch Status	
	[illegible]	Pre Screen		Verified	1	S	
	SC	Screening		Verified	2	S	
	LOG	LOG		No Data Entry	3	S	
	RANDOM	Random		Verified	4	S	
	BL	Baseline		No Data Entry	5	S	
	V01	Visit 01 (Month 3)		No Data Entry	6	S	
	V02	Visit 02 (Month 6)		No Data Entry	7	S	
	V03	Visit 03 (Month 12)		No Data Entry	8	S	
	V04	Visit 04 (Month 18)		No Data Entry	9	S	
	V05	Visit 05 (Month 24)		No Data Entry	10	S	
	T01	Telephone Contact 01 (Month 30)		No Data Entry	11	S	
	V06	Visit 06 (Month 36)		No Data Entry	12	S	
	T02	Telephone Contact 02 (Month 42)		No Data Entry	13	S	
	V07	Visit 07 (Month 48)		No Data Entry	14	S	
	T03	Telephone Contact 03 (Month 54)		No Data Entry	15	S	
	V08	Visit 08 (Month 60)		No Data Entry	16	S	
	T04	Telephone Contact 04 (Month 66)		No Data Entry	17	S	
	V09	Visit 09 (Month 72)		No Data Entry	18	S	
	T05	Telephone Contact 05 (Month 78)		No Data Entry	19	S	
	V10	Visit 10 (Month 84)		No Data Entry	20	S	
	FNL	Final Visit		No Data Entry	21	S	
	CTCCONLY	CTCC Use Only		No Data Entry	22	S	

3. Click on drop down (red arrow)
4. Select Event to be added (green arrow)



5. Select Save Changes



NOTE: The Unexpected Event will be placed as the last event in the subject's schedule of events.

6. Click on appropriate event (U01, U02, PW, etc.) to enter data

	Event ID	Description	Visit Date	Entry Status	Event Order	Batch Status	
	PS	Pre Screen		Verified	1	S	
	SC	Screening		Verified	2	S	
	LOG	LOG		No Data Entry	3	S	
	RANDOM	Random		Verified	4	S	
	BL	Baseline		No Data Entry	5	S	
	V01	Visit 01 (Month 3)		No Data Entry	6	S	
	V02	Visit 02 (Month 6)		No Data Entry	7	S	
	V03	Visit 03 (Month 12)		No Data Entry	8	S	
	V04	Visit 04 (Month 18)		No Data Entry	9	S	
	V05	Visit 05 (Month 24)		No Data Entry	10	S	
	T01	Telephone Contact 01 (Month 30)		No Data Entry	11	S	
	V06	Visit 06 (Month 36)		No Data Entry	12	S	
	T02	Telephone Contact 02 (Month 42)		No Data Entry	13	S	
	V07	Visit 07 (Month 48)		No Data Entry	14	S	
	T03	Telephone Contact 03 (Month 54)		No Data Entry	15	S	
	V08	Visit 08 (Month 60)		No Data Entry	16	S	
	T04	Telephone Contact 04 (Month 66)		No Data Entry	17	S	
	V09	Visit 09 (Month 72)		No Data Entry	18	S	
	T05	Telephone Contact 05 (Month 78)		No Data Entry	19	S	
	V10	Visit 10 (Month 84)		No Data Entry	20	S	
	FNL	Final Visit		No Data Entry	21	S	
	CTCCONLY	CTCC Use Only		No Data Entry	22	S	
	U01	Unscheduled testing		No Data Entry	23	S	×
	U02	Unscheduled Visit		No Data Entry	24	S	×

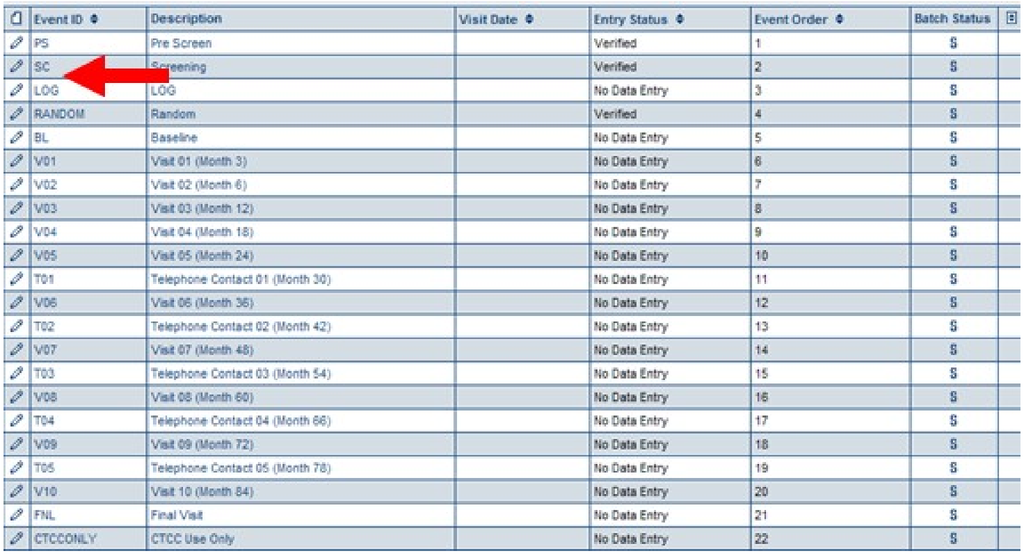
How do I add an unexpected page to an event for my subject?

NOTE: You can only add pages that do not currently exist as part of this event.

1. Select Subject

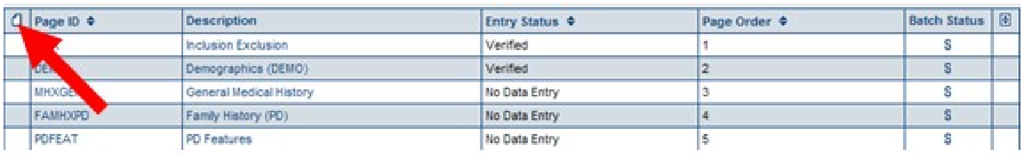
	Patient ID	Initials	Baseline Visit Date	Country	Entry Status	Batch Status	
	0119	SKB	01192007		Verified	S	
	0122	SKB	01222007		Verified	S	
	0123	SKB	01232007		Verified	S	
	0215	ABC	02152007		Verified	S	
	0220	CEO	11272006		Verified	S	
	0230	CEO	12132006		Verified	S	
	0245	LAR			No Data Entry	S	×
	0313	SKB	03132007		Verified	S	
	0330	CEO	11272006		Verified	S	
	0334	CEO	11282006		Verified	S	
	0345	CEO	11282006		Verified	S	
	0425	SKB	04272007		Verified	S	
	0427	SKB	04272007		Verified	S	
	0611	SKB	06102007		Verified	S	
	0612	SKB	06112007		Verified	S	
	0615	BSK	06152007		Verified	S	
	0620	SKB	06202007		Verified	S	
	0621	SKB	06212007		Verified	S	
	0710	LML	07102007		Verified	S	
	0711	SKB	07112007		Verified	S	
	0717	LML	07172007		Verified	S	
	0821	SKB	08212007		Verified	S	
	0912	SKB	09122007		Verified	S	
	0919	SKB	09192007		Verified	S	

2. Click on Event to which assessment should be added



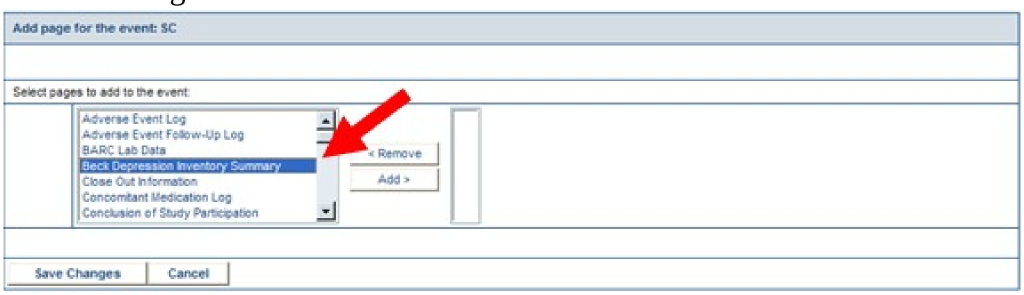
	Event ID	Description	Visit Date	Entry Status	Event Order	Batch Status	
	PS	Pre Screen		Verified	1	S	
	SC	Screening		Verified	2	S	
	LOG	LOG		No Data Entry	3	S	
	RANDOM	Random		Verified	4	S	
	BL	Baseline		No Data Entry	5	S	
	V01	Visit 01 (Month 3)		No Data Entry	6	S	
	V02	Visit 02 (Month 6)		No Data Entry	7	S	
	V03	Visit 03 (Month 12)		No Data Entry	8	S	
	V04	Visit 04 (Month 18)		No Data Entry	9	S	
	V05	Visit 05 (Month 24)		No Data Entry	10	S	
	T01	Telephone Contact 01 (Month 30)		No Data Entry	11	S	
	V06	Visit 06 (Month 36)		No Data Entry	12	S	
	T02	Telephone Contact 02 (Month 42)		No Data Entry	13	S	
	V07	Visit 07 (Month 48)		No Data Entry	14	S	
	T03	Telephone Contact 03 (Month 54)		No Data Entry	15	S	
	V08	Visit 08 (Month 60)		No Data Entry	16	S	
	T04	Telephone Contact 04 (Month 66)		No Data Entry	17	S	
	V09	Visit 09 (Month 72)		No Data Entry	18	S	
	T05	Telephone Contact 05 (Month 78)		No Data Entry	19	S	
	V10	Visit 10 (Month 84)		No Data Entry	20	S	
	FNL	Final Visit		No Data Entry	21	S	
	CTCCONLY	CTCC Use Only		No Data Entry	22	S	

3. Click on the "paper" icon



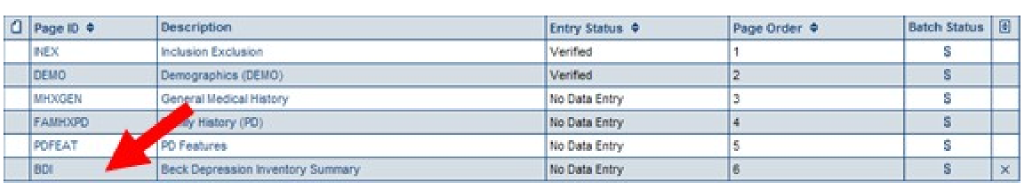
	Page ID	Description	Entry Status	Page Order	Batch Status	
		Inclusion Exclusion	Verified	1	S	
	DE	Demographics (DEMO)	Verified	2	S	
	MHXGE	General Medical History	No Data Entry	3	S	
	FAMHXPD	Family History (PD)	No Data Entry	4	S	
	PDFEAT	PD Features	No Data Entry	5	S	

4. Select Page to be added



5. Click Add (green arrow)
6. Click Save Changes (red arrow)

7. Click on Page

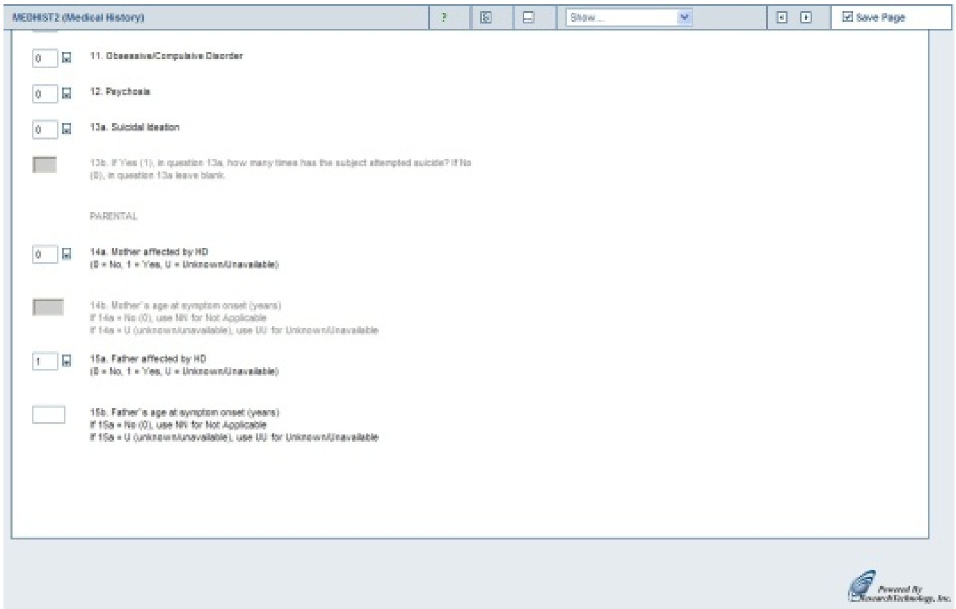


	Page ID	Description	Entry Status	Page Order	Batch Status	
	INEX	Inclusion Exclusion	Verified	1	S	
	DEMO	Demographics (DEMO)	Verified	2	S	
	MHXGEN	General Medical History	No Data Entry	3	S	
	FAMHXPD	y History (PD)	No Data Entry	4	S	
	PDFEAT	PD Features	No Data Entry	5	S	
	BDI	Beck Depression Inventory Summary	No Data Entry	6	S	×

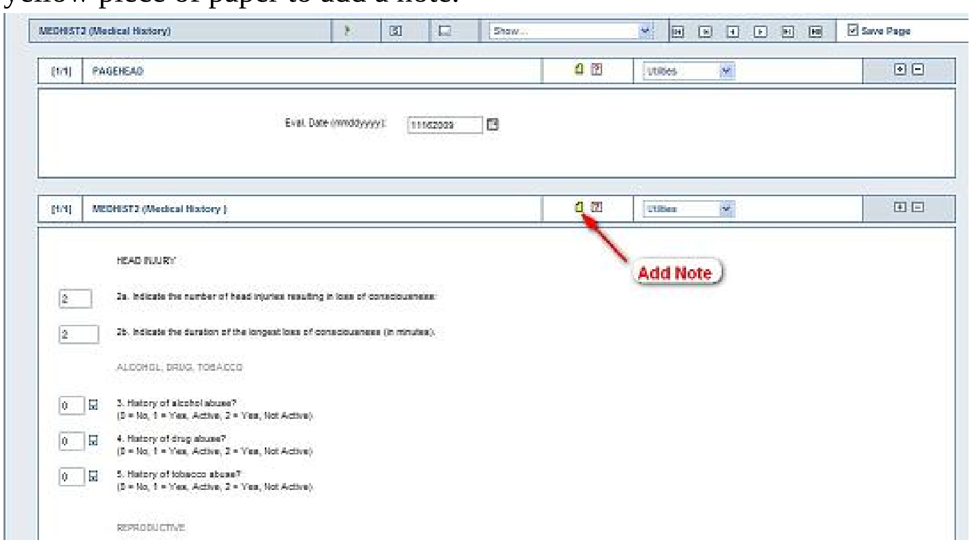
How do I add a note to a field on an eCRF page?

There are some cases where you will need to leave a note to clarify a data field. Below is an example that will walk you through adding a note when you cannot provide an appropriate value. Adding notes can only be done in the Data Review/Capture (EDC) portion of the system.

1. The father's age is unknown.



2. Put your cursor in the field to which you want to attach a note.
3. While the field is highlighted in yellow, scroll to the top of the page and click the yellow piece of paper to add a note.



4. Complete Type, Note Text, and Reason for Change and click Save.

Error Message Troubleshooting

Why am I seeing a red Page Lock message while trying to enter data?

The page lock could have resulted for a number of different reasons. A page lock is intended to prevent data entry by more than one person on the page at any given time. For example, if an investigator and coordinator are looking at the same page, the first person on the page will be able to enter/edit data, while the second person will receive a page lock with all fields being unenterable. If you have an on-site monitor reviewing your data, please ask the monitor to make sure he/she has selected "Review Mode On".

Why am I receiving a Page Lock message and I have checked that nobody else is on the page?

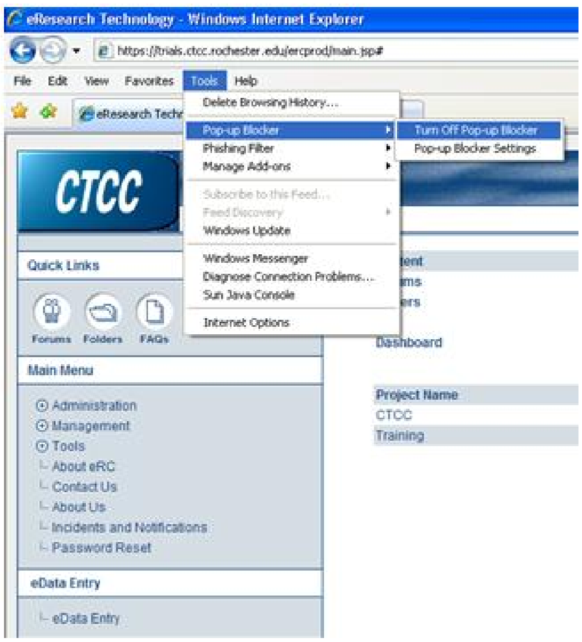
The page lock message can happen incorrectly when the system or Internet Explorer has previously locked up or crashed. A page lock status will automatically be removed after 60 minutes of inactivity in the system. If there is an immediate need to enter the data before the 60 minute timeout, please contact the system support line at 585-275-3893.

What should I do if I see a serious system error message?

This system error could have resulted from a double-click in the system such as when you were saving a page, adding and removing a page, or opening a page. The eClinical system is a single click system. One solution is to log out of eClinical, close down all windows in Internet Explorer, relaunch Internet Explorer, and login to the system again. If you receive a consistent error message while performing an action, please contact the system support line at 585-275-3893.

I click the Data Review/Capture Link. How come it tells me my session expired?

The eCliniacl system is only supported in Internet Explorer 6.0 or higher. Be sure you are not using Mozilla FireFox, MSN Explorer, or any other type of browser. If you are using Internet Explorer and are still experiencing the same problem, it is possible that a pop-up blocker is enabled on the computer. The eClinical system will not function properly if a pop-up blocker is turned on. To turn off the pop-up blocker in Internet Explorer 7.0, see the picture below. Also be sure there are not any secondary toolbars running that might block pop-ups such as the Google Toolbar, AOL Toolbar, or Yahoo! Toolbar. Please be sure that pop-up blocking is disabled for ALL toolbars that might be running. If you are having problems turning off your pop-up blocker, you should contact computer support services at your location to help you. Also see: What are the most common pop-up blockers under Most Common Questions.



Query Management

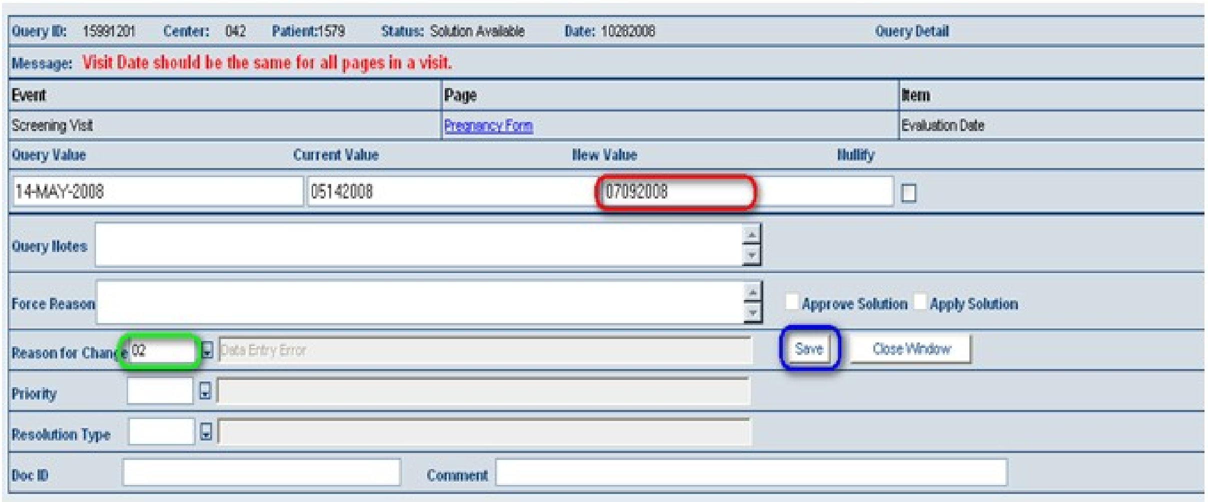
What do I do if my query does not turn white when I provide a response?

Unlike data entry on eCRF pages, in the query management application, it is important to use your mouse to navigate from field to field. If a query which you have responded to turns yellow with a status of solution available, you must perform the following steps to clear the query and update the eCRF page.

Using your mouse:

1. Click in the New Value Field (red)
2. Select Reason for Change (green)
3. Click on save (blue)

The query should turn from a status of solution available to solution provided (and turn from yellow to white).

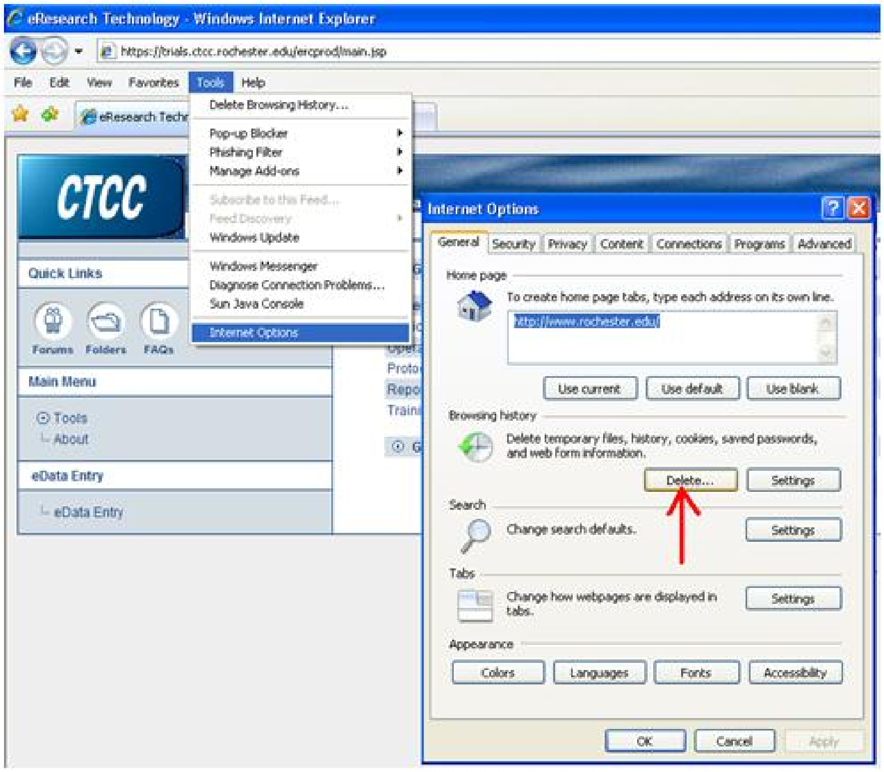


What do I do if the system tells me I have insufficient privileges when forcing a query closed?

This problem can be resolved by following these steps to clear your browser cache.

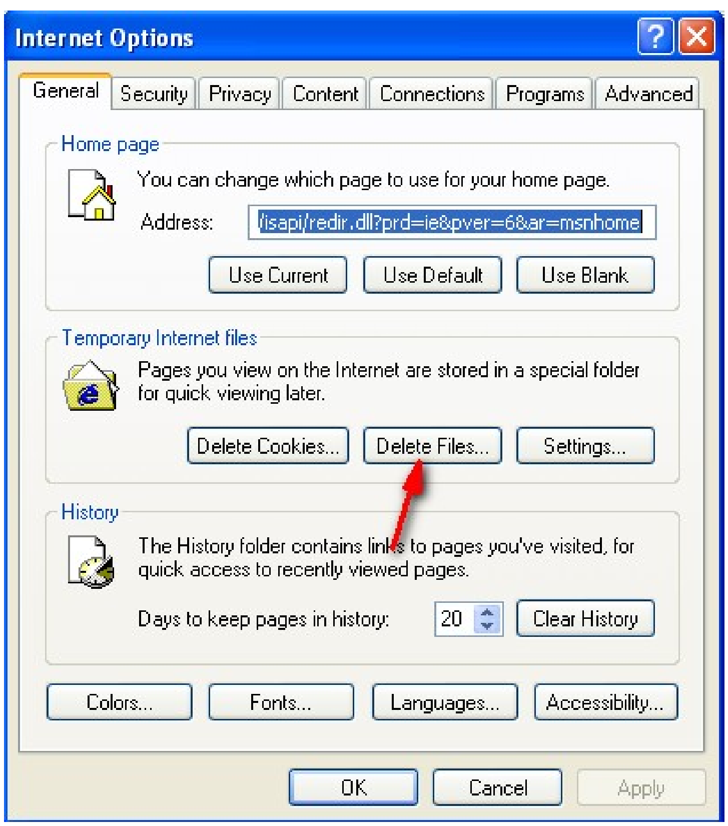
If you are using Internet Explorer 7.0:

1. Click Tools->Internet Options
2. Go to the General Tab
3. Click Delete Temporary Internet Files.

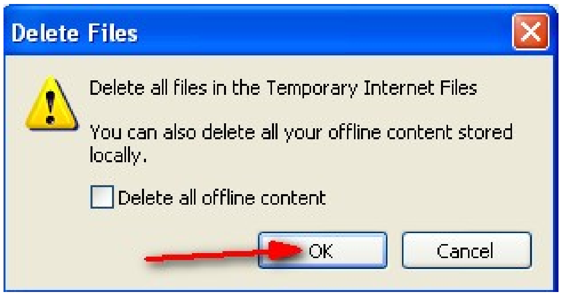


If you are using Internet Explorer 6.0:

1. Click Tools->Internet Options
2. Click Delete Files

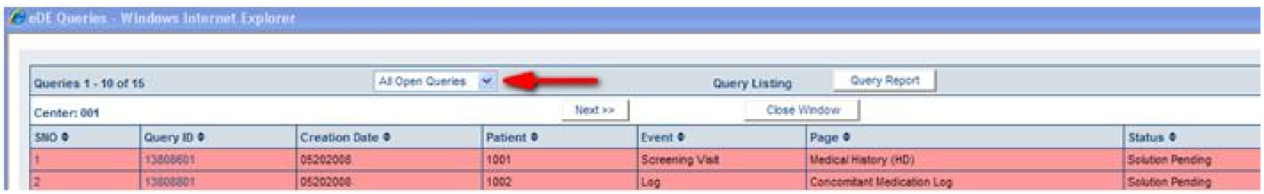


3. When prompted, click OK.



Why can't I see all of my open queries on the query management page?

1. Check the query filter box on the query management page. Make sure it says "All Open Queries."



2. Also, query management can only display ten queries at a time. If you have more than ten queries, you will neeed to hit the next button to view more.

How do I view which pages have data entered or queries associated with them?

In eData Entry (eDE), you will see a drop-down box of actions near the top. Site Summary will allow you to view all pages that have been filled out for all patients in the study along with the pages that have queries. The Query Management page allows you to view the queries that have been generated.