



OpenClinica User Manual

Participating Sites

Based on OpenClinica version 3.1

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About Openclinica

OpenClinica is an electronic data capture system. Data is entered by Research Nurses/Coordinators at participating sites via the internet.

OpenClinica studies can be accessed via the following website:

<https://webcrf.ncheer.unsw.edu.au/OpenClinica> for ETHOS study only

<https://webcrf.kirby.unsw.edu.au/OpenClinica> for all other studies

Always Save Your Work

OpenClinica will automatically not allow you to continue working after a period of inactivity therefore it is recommended that you save your work frequently. If no activity has occurred for 5 minutes any unsaved data will be lost.

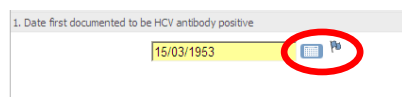
Going Back

It is recommended that you DO NOT use the 'back' button on your internet browser. To navigate back always click save and then use the OpenClinica menu (see navigating OpenClinica). If you do not wish to save your work simply click on the cancel or exit button in OpenClinica.

Entering Dates

OpenClinica allows you to manually type a date in or use an electronic calendar.

To use the electronic calendar, click on the calendar icon next to a date field.



A month by month calendar will appear showing the current month.

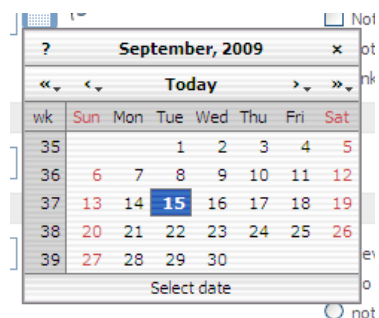
To select today simply click on 'Today' and the date field will be populated with today's date.

To navigate forward or backward by month click on '<' to go back and '>' to go forward.

To navigate forward or back by year click on '<<' to go back and '>>' to go forward.

To select the month from a drop down list click and hold '<' or '>'.

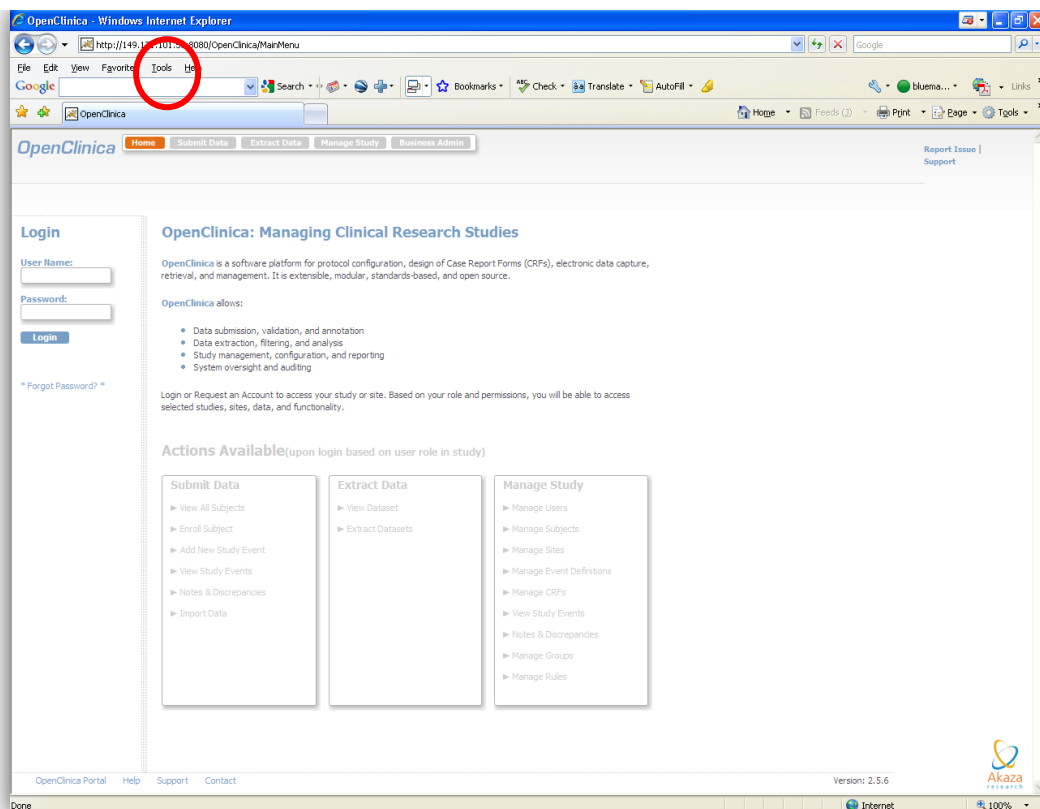
To select the year from a drop down list click and hold on '<<' or '>>'.



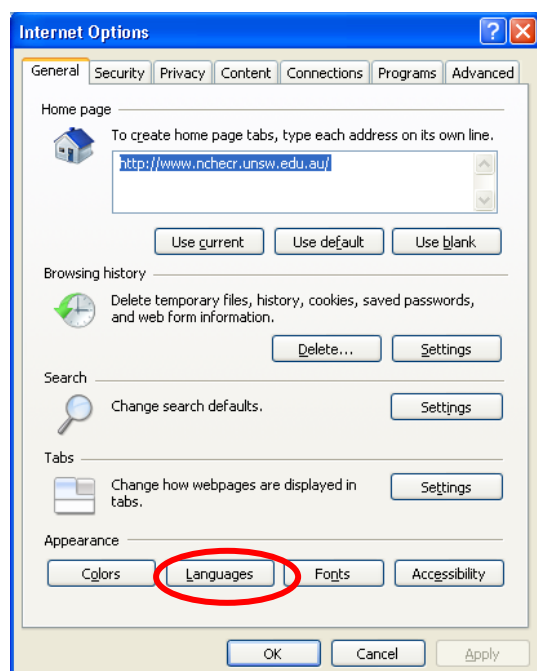
Setting your internet to Australian/European Date format

You must specifically set your internet browser if you want dates to appear in Australian/European format (dd/mm/yyyy). OpenClinica defaults to US date format. You only need to do this the first time you use OpenClinica on each computer that you use it.

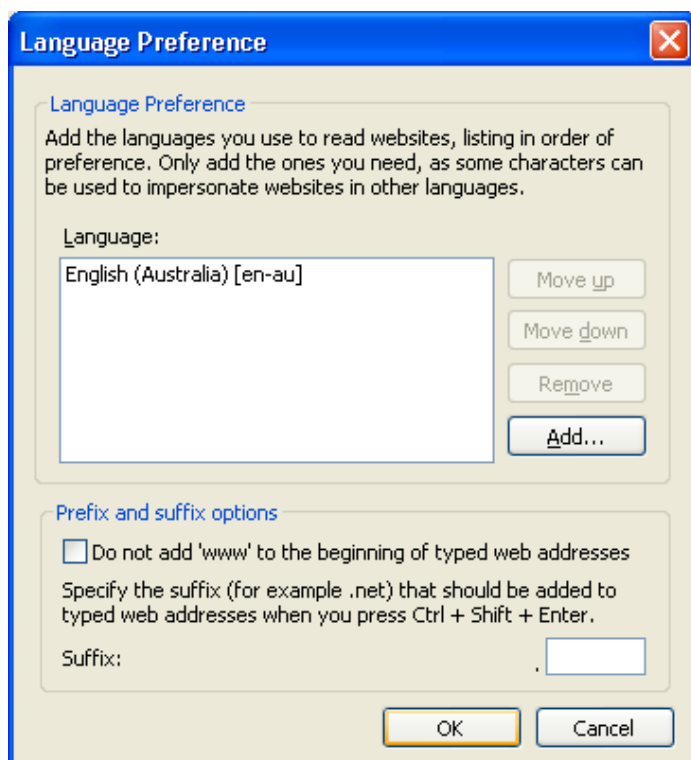
Open your internet browser and click on 'Tools' on the internet Toolbar.



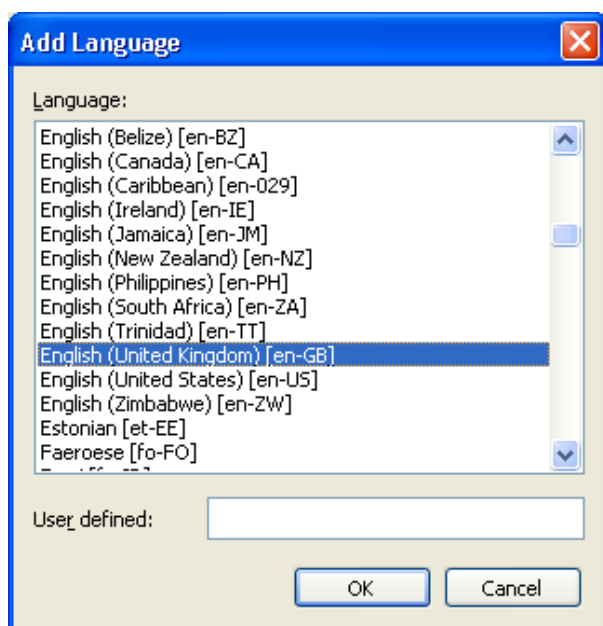
Select 'Internet Options' from the drop down menu.



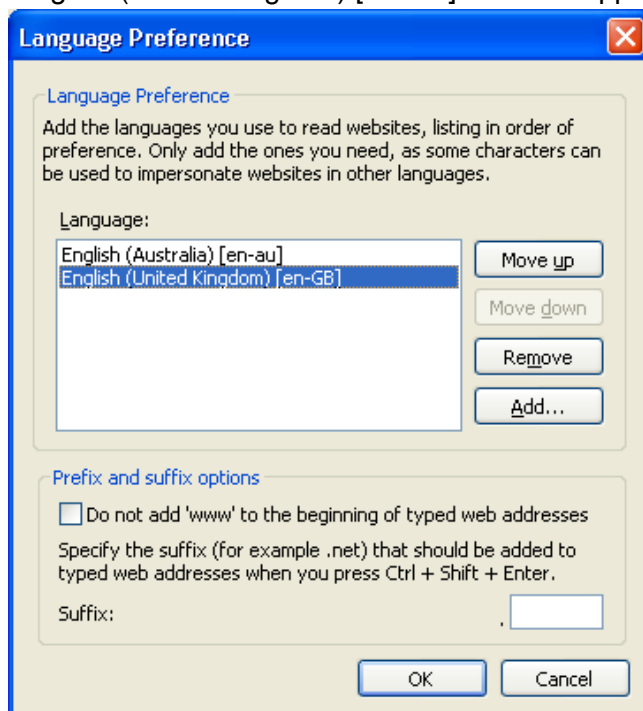
Click on Languages in the bottom left corner.



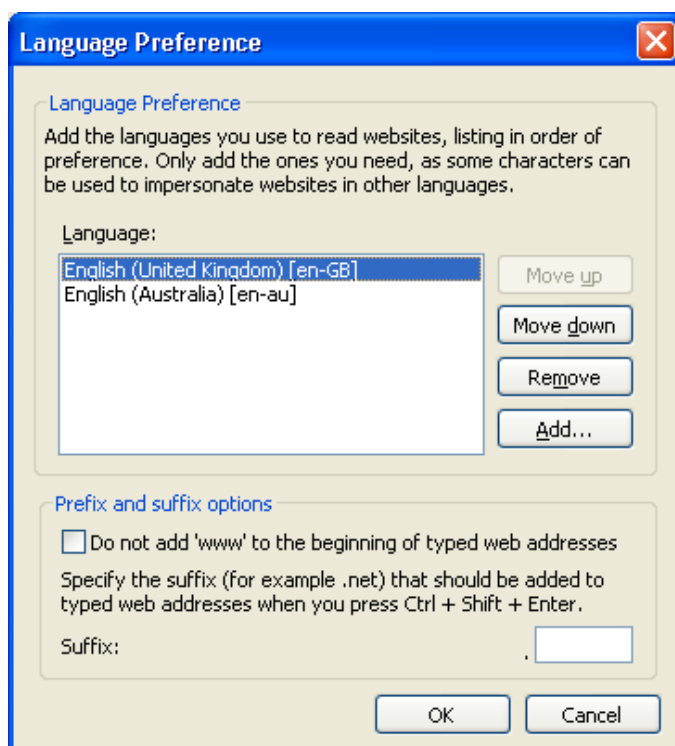
Click on 'Add' and select 'English (united Kingdom) [en-GB]' by scrolling through the list, selecting it and clicking on 'OK'.



'English (United Kingdom) [en-GB]' will now appear on your list of languages.



Highlight it and then click on 'Move up'. Repeat this process until it is at the top of the list.



Now click on OK and then OK again.

Dates will now appear in dd/mm/yyyy format in OpenClinica

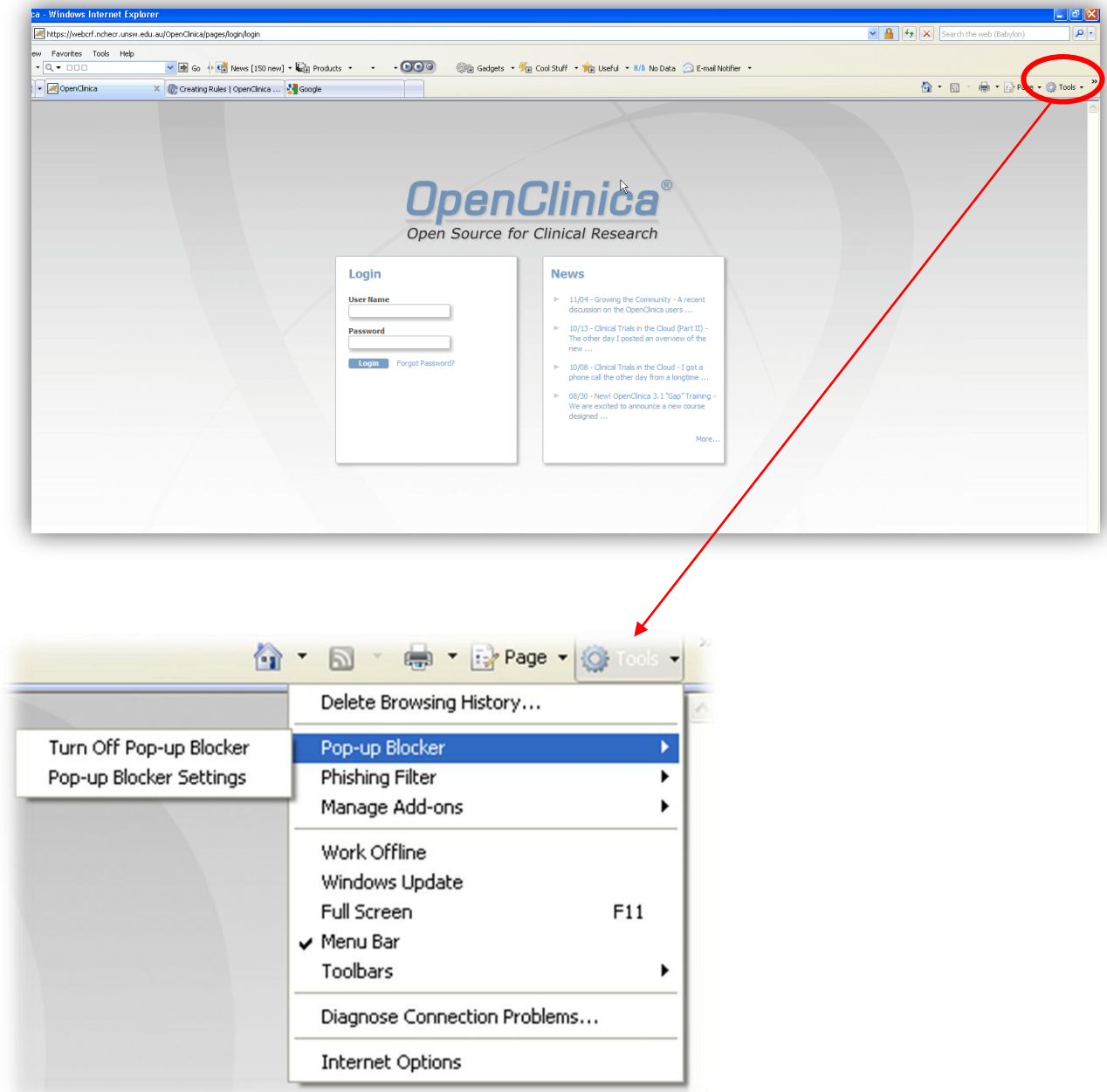
Allow Pop-ups

In order to see Notes and Discrepancies you must turn off the 'pop-up' blocker on your internet browser.

Open your internet browser and click on 'Tools' on the internet Toolbar

Click on the 'Pop-up Blocker'

Then Click on the 'Turn off Pop-up Blocker'



Logging in

Open the internet and go to the website

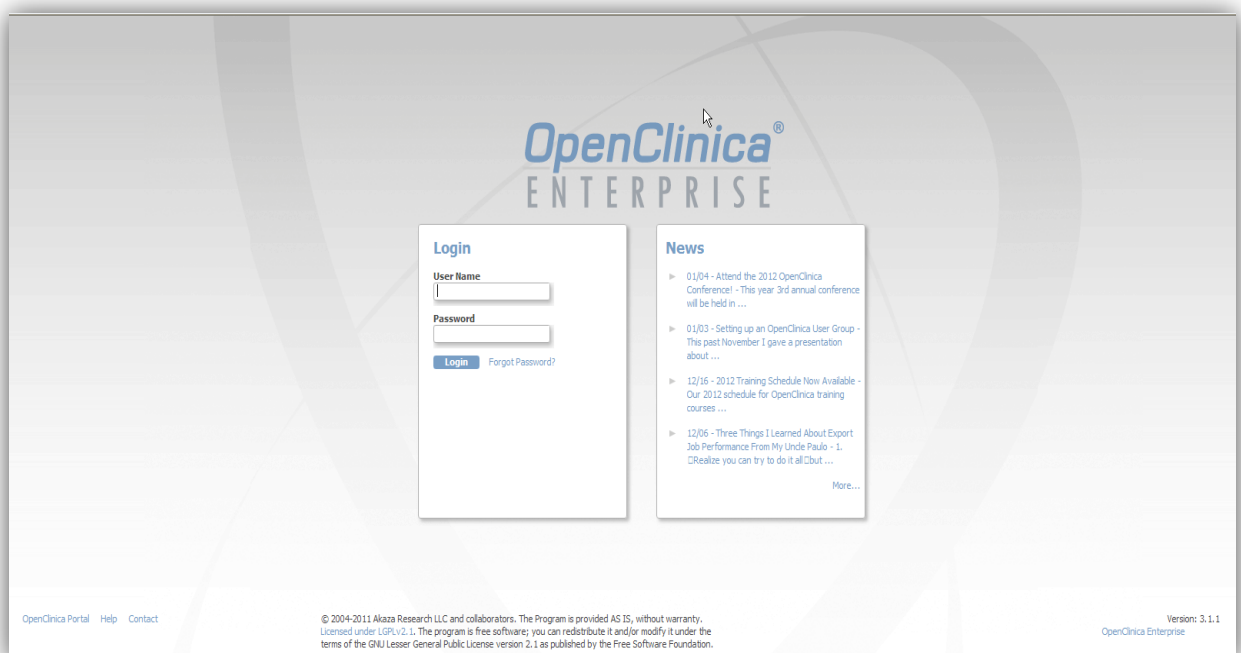
<https://webcrf.nchechr.unsw.edu.au/OpenClinica> for ETHOS study only

<https://webcrf.kirby.unsw.edu.au/OpenClinica> for all other studies

Enter your username and password.

When logging in for the first time the user will be asked to change their password. See 'Changing Password- First time user' for instructions.

Click 

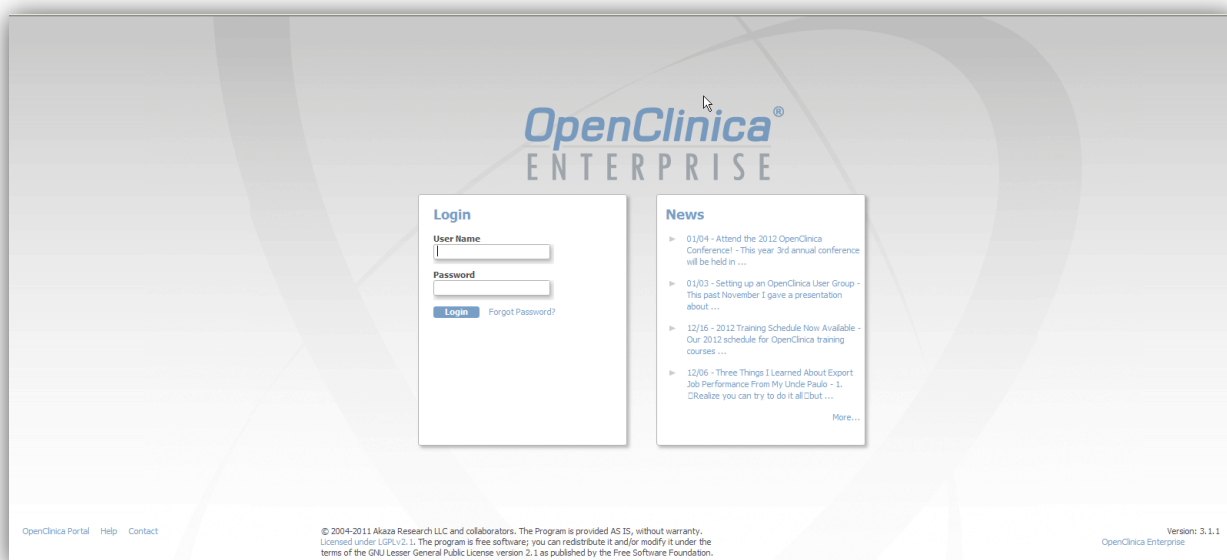


Changing Your Password – First time user

The first time you log into OpenClinica you will be required to change your password.

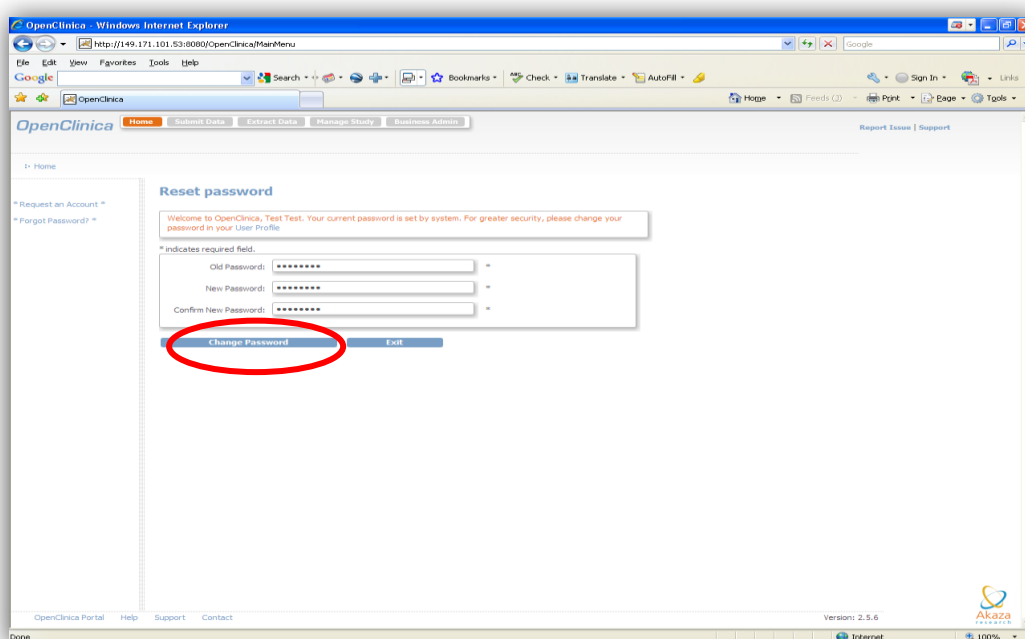
Your new password must consist of 8 or more characters. Both numbers and letters can be used.

Log in with the username and password given to you by your study coordinator at The Kirby Institute.



Enter 'old password', 'new password' and confirm 'new password'.

Then click 'change password'.



Changing Your Password

Once you have logged in you can change your password any time by clicking on 'Tasks' and selecting 'Update Profile'.

Enter your 'old password', 'new password' and confirm 'new password'.

Then click 'confirm profile changes'.

Your new password must consist of 8 or more characters. Both numbers and letters can be used.

The screenshot shows the OpenClinica 'Change User Profile' form. The browser window title is 'OpenClinica - Windows Internet Explorer'. The address bar shows 'http://149.171.101.53:8080/OpenClinica/UpdateProfile'. The form is titled 'Change User Profile' and includes a sidebar with navigation links like 'Alerts & Messages', 'Instructions', and 'Info'. The main form area contains the following fields:

- First Name: Test
- Last Name: Test
- Email: Test123@test.com
- Institutional Affiliation: TEST
- Default Active Study: St Vincents Hospital Sydney (dropdown)
- Password Challenge Question: City of Birth (dropdown)
- Password Challenge Answer: Sydney
- Old Password: [masked]
- New Password: [masked]
- Confirm New Password: [masked]
- Phone: 9385 0904

The 'Confirm Profile Changes' button is highlighted with a red circle. A 'Cancel' button is also visible. The footer of the page includes 'OpenClinica Portal', 'Help', 'Support', 'Contact', 'OpenClinica Enterprise', 'Version: 2.5.6', and the 'Akaza' logo.

If you forget your password

If at any time you forget your password contact your study coordinator at The Kirby Institute to have it reset.

Your study coordinator will assign you with a new password.

When you log in for the first time with this new password you will be asked to change it (see 'Changing your password – First time user').

Logging Out

To log out of OpenClinica click on the 'Log Out' link on the top right corner.

The screenshot displays the OpenClinica Enterprise web application interface. At the top right, the user's name 'shasri (Clinical Research Coordinator)' is shown next to a 'Log Out' link, which is circled in red. The interface includes a navigation bar with links like 'Home', 'Subject Matrix', 'Add Subject', 'Notes & Discrepancies', and 'Tasks'. A sidebar on the left contains sections for 'Alerts & Messages', 'Instructions', and 'Other Info'. The main content area shows a 'Welcome to ETHOS' message and a 'Subject Matrix' table. The table has columns for 'Study Subject ID', 'Resource Usage', 'Enrolment (Form 1)', 'Follow Up (Form 3)', 'Treatment (Form 4)', 'Lost to Follow Up (Form 5)', and 'Actions'. The table lists several subjects with their IDs and corresponding icons for each column. The 'Log Out' link is highlighted with a red circle.

OpenClinica[®] ENTERPRISE

ETHOS : Test Site 1 (ETH_001) | Change Study/Site

shasri (Clinical Research Coordinator) er **Log Out**

Home | Subject Matrix | Add Subject | Notes & Discrepancies | Tasks ▼

Report Issue | Support | Study Subject ID | Go

Alerts & Messages

Welcome to OpenClinica, Sharmila Siriragavan. You last logged in on 31-Jan-2012.

Instructions

If needed you may change the study/site or request access to a new study with a different role.

Other Info

Study: ETHOS

Site: Test Site 1

Start Date: N/A

End Date: N/A

PI: Greg Dore

Protocol Verification/IRB Approval Date:

Welcome to ETHOS

Notes & Discrepancies Assigned to Me: 0

Subject Matrix

15 Show More Select An Event Add New Subject

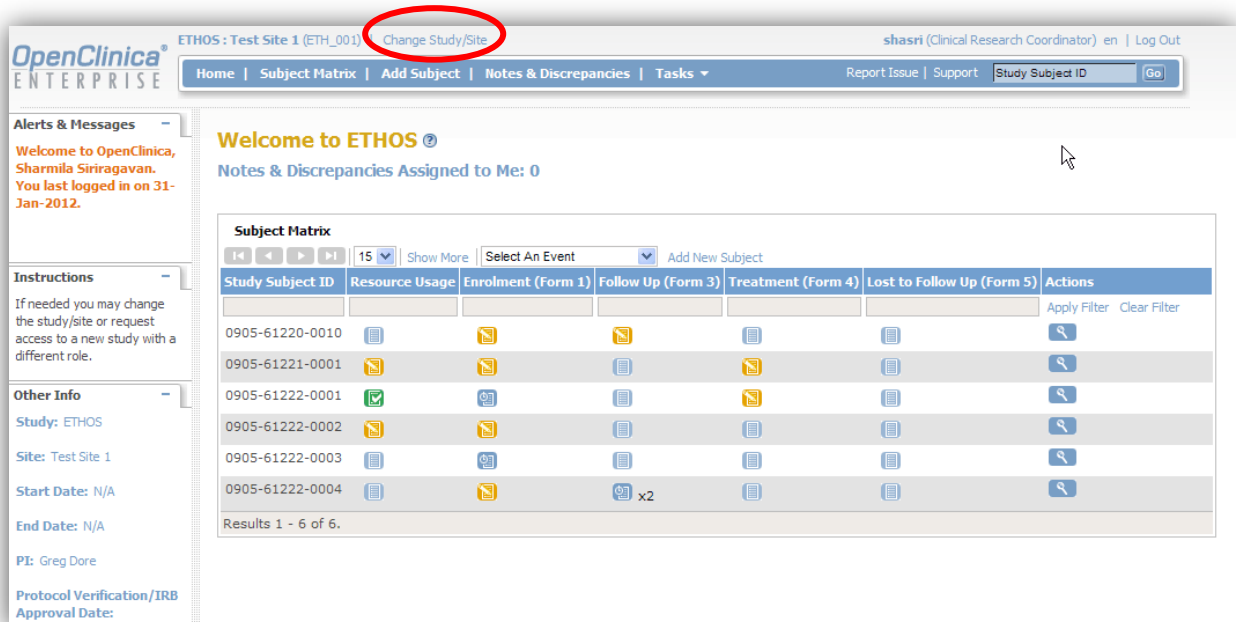
Study Subject ID	Resource Usage	Enrolment (Form 1)	Follow Up (Form 3)	Treatment (Form 4)	Lost to Follow Up (Form 5)	Actions
						Apply Filter Clear Filter
0905-61220-0010						
0905-61221-0001						
0905-61222-0001						
0905-61222-0002						
0905-61222-0003						
0905-61222-0004			x2			

Results 1 - 6 of 6.

Moving Between Studies

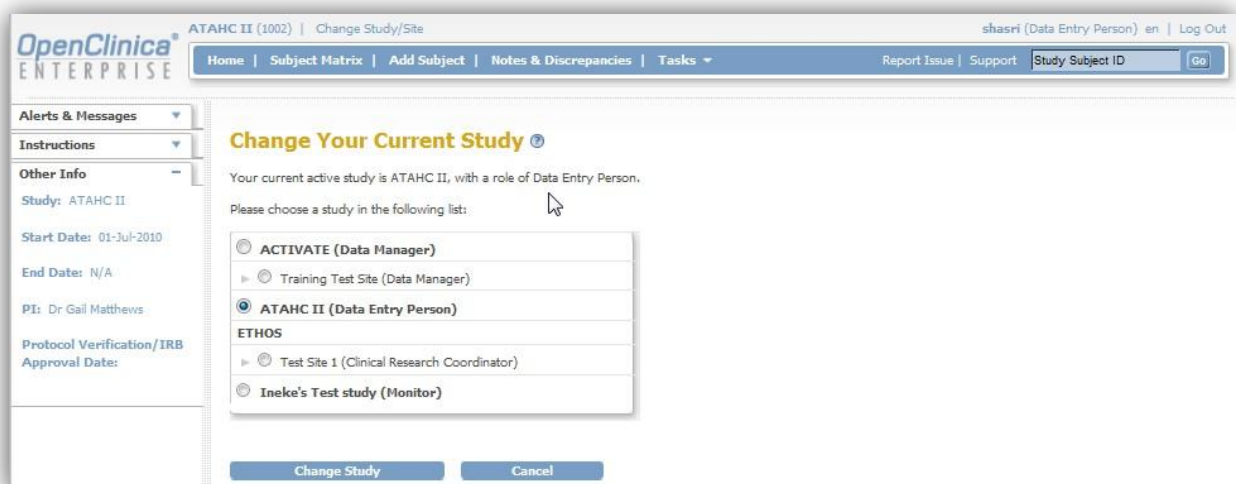
If you are using OpenClinica for more than one study at the Kirby Institute or at more than one site you can exit one study/site and start working on another without logging out.

Click on 'Change Study/Site' in the top left corner.



The screenshot shows the OpenClinica Enterprise interface for the 'ETHOS : Test Site 1 (ETH_001)' study. The 'Change Study/Site' button is highlighted in the top navigation bar. The main content area displays a 'Subject Matrix' table with columns for Study Subject ID, Resource Usage, Enrolment (Form 1), Follow Up (Form 3), Treatment (Form 4), Lost to Follow Up (Form 5), and Actions. The table lists several subjects, including 0905-61220-0010, 0905-61221-0001, 0905-61222-0001, 0905-61222-0002, 0905-61222-0003, and 0905-61222-0004. The left sidebar contains sections for Alerts & Messages, Instructions, and Other Info, including details about the study (ETHOS), site (Test Site 1), start date (N/A), end date (N/A), and PI (Greg Dore).

A list of studies and sites that you are involved with will be displayed.



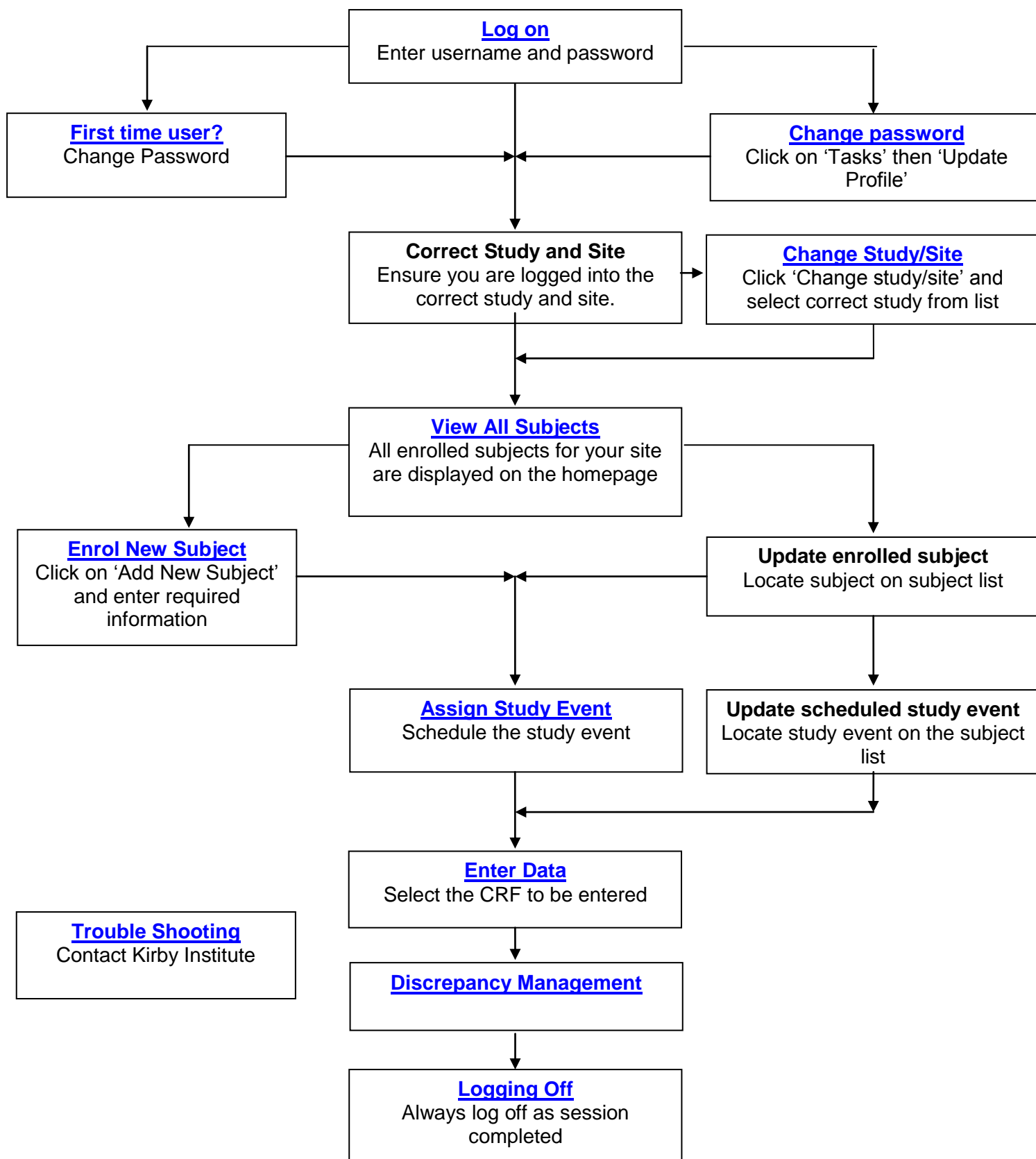
The screenshot shows the 'Change Your Current Study' dialog box in the OpenClinica Enterprise interface. The dialog box displays the current active study as 'ATAHC II' with a role of 'Data Entry Person'. It prompts the user to choose a study from the following list:

- ☐ ACTIVATE (Data Manager)
- ☐ Training Test Site (Data Manager)
- ☒ ATAHC II (Data Entry Person)
- ☐ ETHOS
- ☐ Test Site 1 (Clinical Research Coordinator)
- ☐ Ineke's Test study (Monitor)

At the bottom of the dialog box, there are two buttons: 'Change Study' and 'Cancel'.

Select the study/site you wish and click on 'Change Study' and then click 'Confirm'.

Data Entry Flow



Navigating OpenClinica – How to move through the system

OpenClinica has two ways of accessing its functions.

1. Clicking on the action you want in the navigation bar such as;
 1. Home – is the main page of the current site/study
 2. Subject matrix – is a table with event information for all subjects in the site/study
 3. Add Subject – allows to add a new subject to site/study
 4. Notes and Discrepancies – is a table with all the queries that arise when capturing, monitoring and cleaning the data
 5. Search box – allows to search a particular subject ID within the site/study

The screenshot displays the OpenClinica web application interface. At the top, the navigation bar includes links for Home, Subject Matrix, Add Subject, Notes & Discrepancies, and Tasks. A red arrow points from the 'Notes & Discrepancies' link in the navigation bar to the 'Notes & Discrepancies' section in the main content area. The main content area shows a table of 'Notes & Discrepancies Assigned to Me: 0'. The table has columns for Study Subject ID, Screening, E2, E4, E6, E8, E10, W2, W4, W6, W8, W10, W12, W14, W16, W18, W20, W22, W24, W26, W28, W30, W32, W34, W36, W38, W40, W42, W44, W46, W48, W50, W52, W54, W56, W58, W60, W62, W64, W66, W68, W70, W72, W74, W76, W78, W80, W82, W84, W86, W88, W90, W92, W94, W96, W98, W100, ETR, SVR12, SVR24, FU1, FU2, Drug Admin, Concom, AEs, Termination, Central Labs, and Actions. The table contains five rows of data, each representing a subject. The first row is for subject 1002-61402-01, the second for 1002-61402-02, the third for 1002-61402-03, the fourth for 1002-61402-04, and the fifth for 1002-61402-05. The table shows various event status icons (e.g., S, E, W) and a search box in the top right corner. The footer of the page includes copyright information and version details.

- OpenClinica**
Community Edition

ATAHC II : Training Site (TEST | 1002) | Change Study/Site shasri (Clinical Research Coordinator) en-gb | Log Out

Home | Subject Matrix | Add Subject | Notes & Discrepancies | Tasks ▼ Report Issue | Support Study Subject ID (10)

Welcome to ATACH II

Notes & Discrepancies Assigned to Me: 0

Submit Data
Subject Matrix Schedule Event
Add Subject View Events
Notes & Discrepancies Import Data
Other
Update Profile Log Out

[4] [←] [→] [15] Show More Select An Event Add New Subject	Study Subject ID	Screening	E2	E4	E6	F8	B8	BL	W2	W4	W6	W8	W12	W16	W20	W24	W28	W32	W36	W40	W44	W48	W72	W96	ETR	SVR12	SVR24	FU1	FU2	Drug Admin	Conmed	AEs	Termination	Central Labs	Actions
1002-61402-01	[S]																																		[S]
1002-61402-02	[C]																																		[S]
1002-61402-03																																			[S]
1002-61402-04	[S]																																		[S]
1002-61402-05	[S]																																		[S]

Results 1 - 5 of 5.

Instructions
If needed you may change the study/site or request access to a new study with a different role.

Other Info
Study: ATACH II
Site: Training Site
Start Date: N/A
End Date: N/A
PI: Barbara Young
Protocol Verification/IRB Approval Date:

OpenClinica Portal Help Contact

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Licensed under GPL v2.1. The program is free software: you can redistribute it and/or modify it under the terms of the GNU Lesser General Public License version 2.1 as published by the Free Software Foundation.

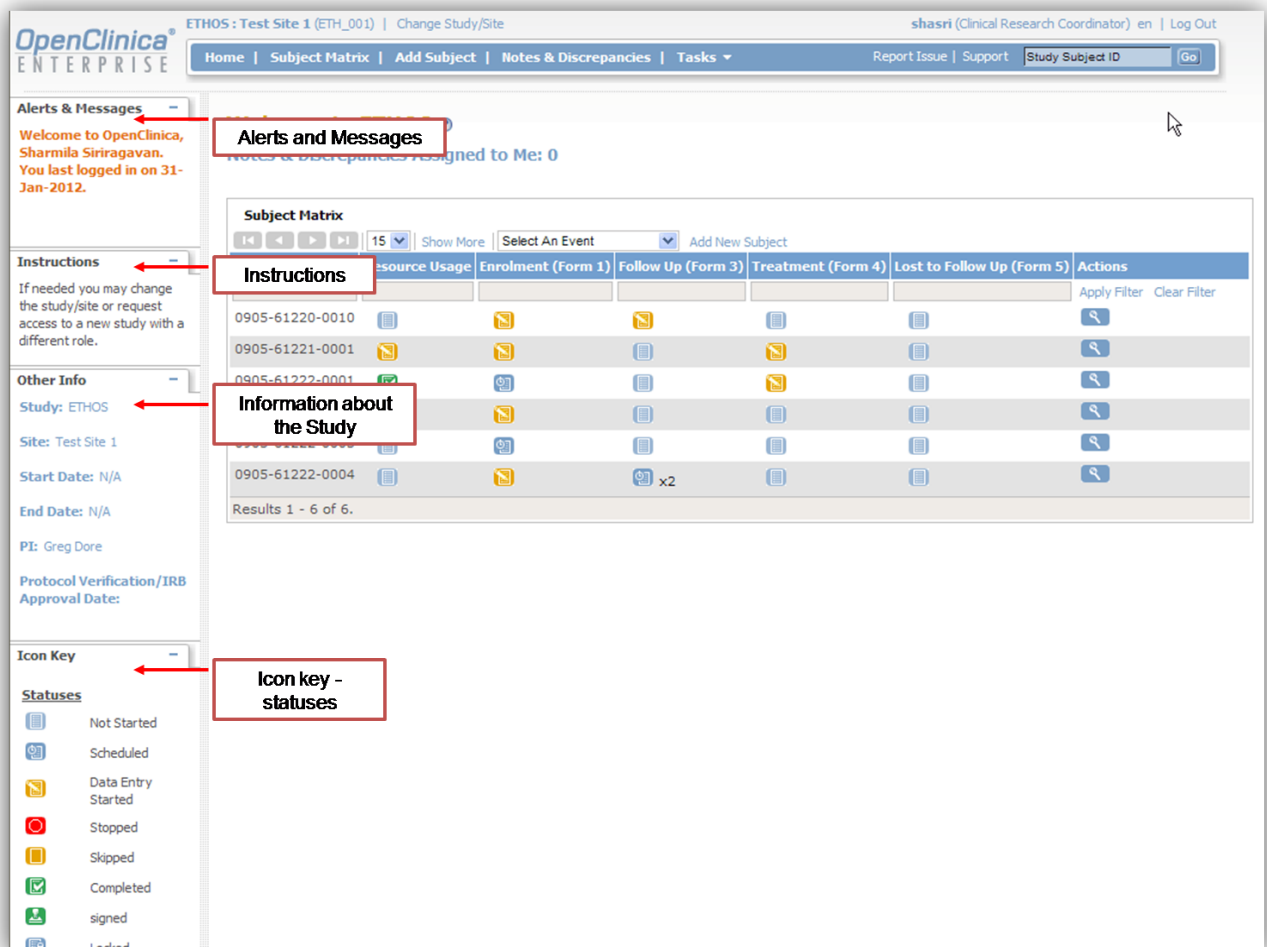
Version: 3.1-Community
OpenClinica Community

OpenClinica Home Page

OpenClinica Home page will have information panels on the left hand of the screen

Here will be contained:

- 1) Alerts and messages
- 2) Instructions on how to perform actions
- 3) Other Info – displays the information about the study and site
- 4) Icon key – an explanation of what the symbols used by OpenClinica mean



OpenClinica Enterprise ETHOS: Test Site 1 (ETH_001) | Change Study/Site shasri (Clinical Research Coordinator) en | Log Out

Home | Subject Matrix | Add Subject | Notes & Discrepancies | Tasks | Report Issue | Support | Study Subject ID | Go

Alerts & Messages
Welcome to OpenClinica, Sharmila Siriragavan. You last logged in on 31-Jan-2012.
Notes & Discrepancies Assigned to Me: 0

Instructions
If needed you may change the study/site or request access to a new study with a different role.

Other Info
Study: ETHOS
Site: Test Site 1
Start Date: N/A
End Date: N/A
PI: Greg Dore
Protocol Verification/IRB Approval Date:

Icon Key
Statuses
Not Started
Scheduled
Data Entry Started
Stopped
Skipped
Completed
signed
Locked

Subject Matrix
15 | Show More | Select An Event | Add New Subject

Resource Usage	Enrolment (Form 1)	Follow Up (Form 3)	Treatment (Form 4)	Lost to Follow Up (Form 5)	Actions
0905-61220-0010					Apply Filter Clear Filter
0905-61221-0001					
0905-61222-0001					
0905-61222-0004		x2			

Results 1 - 6 of 6.

The home page shows the Subject Matrix for the site.

The Subject Matrix is a table with the event/visit information for all of the subjects enrolled in the study at the site.

The home page will also display the name of study and the site, the data entry status for each patient enrolled and the number of notes & discrepancies for the site.

OpenClinica ENTERPRISE ETHOS : Test Site 1 (ETH_001) | Change Study/Site shasri (Clinical Research Coordinator) en | Log Out

Home | Subject Matrix | Add Subject | Notes & Discrepancies | Tasks | Report Issue | Support | Study Subject ID | Go

Welcome to ETHOS | Notes & Discrepancies Assigned to Me: 0

Subject Matrix

Study Subject ID	Resource Usage	Enrolment (Form 1)	Follow Up (Form 3)	Treatment (Form 4)	Lost to Follow Up (Form 5)	Actions
0905-61220-0010	[Icon]	[Icon]	[Icon]	[Icon]	[Icon]	[Icon]
0905-61221-0001	[Icon]	[Icon]	[Icon]	[Icon]	[Icon]	[Icon]
0905-61222-0001	[Icon]	[Icon]	[Icon]	[Icon]	[Icon]	[Icon]
0905-61222-0002	[Icon]	[Icon]	[Icon]	[Icon]	[Icon]	[Icon]
0905-61222-0003	[Icon]	[Icon]	[Icon]	[Icon]	[Icon]	[Icon]
0905-61222-0004	[Icon]	[Icon]	[Icon] x2	[Icon]	[Icon]	[Icon]

Results 1 - 6 of 6.

Icon Key

Statuses

- [Icon] Not Started
- [Icon] Scheduled
- [Icon] Data Entry Started
- [Icon] Stopped
- [Icon] Skipped
- [Icon] Completed
- [Icon] signed
- [Icon] Locked

OpenClinica Icons

OpenClinica uses different coloured icons to help you through data entry

	Administrative Editing		Initial Data Entry Completed
	Archive		Invalid
	Calendar		Locked
	Completed		New Version
	Create New		Not Started
	Delete		Print
	Discrepancy Note - Add		Reassign
	Discrepancy Note - Closed		Remove
	Discrepancy Note - New		Remove Role
	Discrepancy Note - Not Applicable		Restore
	Discrepancy Note - Resolution		Scheduled
Proposed			SDV
	Discrepancy Note - Updated		Set Role
	Double Data Entry		Sign
	Download		Skipped
	Edit		Started
	Enter Data		Stopped
	Export		Un-Archive
	Form contains changed/unsaved data		View
	Form has unchanged data		
	Help		

Navigating OpenClinica – Study and Site Details

Study and Site details appear in several places on the OpenClinica Homepage.

OpenClinica[®] ENTERPRISE ETHOS : Test Site 1 (ETH_001) [Change](#) **shasri (Clinical Research Coordinator)** en | [Log Out](#)

[Home](#) | [Subject Matrix](#) | [Add S](#) **Tasks** [Report Issue](#) | [Support](#) [Go](#)

Alerts & Messages
Welcome to OpenClinica, Sharmila Siriragavan. You last logged in on 31-Jan-2012.

Instructions
If needed you may change the study/site or request access to a new study with a different role.

Other Info
Study: ETHOS
Site: Test Site 1
Start Date: N/A
End Date: N/A
PI: Greg Dore
Protocol Verification/IRB Approval Date:

Icon Key
Statuses
 Not Started
 Scheduled
 Data Entry Started
 Stopped
 Skipped
 Completed
 signed
 Locked

Welcome to ETHOS
Notes & Discrepancies Assigned to Me: 0

Subject Matrix
15 [Show More](#) [Select An Event](#) [Add New Subject](#)

Study Subject ID	Resource Usage	Enrolment (Form 1)	Follow Up (Form 3)	Treatment (Form 4)	Lost to Follow Up (Form 5)	Actions
0905-61220-0010						Apply Filter Clear Filter
0905-61221-0001						Apply Filter Clear Filter
0905-61222-0001						Apply Filter Clear Filter
0905-61222-0002						Apply Filter Clear Filter
0905-61222-0003						Apply Filter Clear Filter
0905-61222-0004			x2			Apply Filter Clear Filter

Results 1 - 6 of 6.

View All Subjects

To view all the subjects either click on 'Home' or 'Subject Matrix' in the navigation bar.

OpenClinica ENTERPRISE ETHOS : Test Site 1 (ETH_001) | Change Study/Site shasri (Clinical Research Coordinator) en | Log Out

Home Subject Matrix Add Subject Notes & Discrepancies Tasks Report Issue Support Study Subject ID Go

Alerts & Messages
Welcome to OpenClinica, Sharmila Siriragavan. You last logged in on 31-Jan-2012.

Instructions
If needed you may change the study/site or request access to a new study with a different role.

Other Info
Study: ETHOS
Site: Test Site 1
Start Date: N/A
End Date: N/A
PI: Greg Dore
Protocol Verification/IRB Approval Date:





Welcome to ETHOS
Notes & Discrepancies Assigned to Me: 0

Subject Matrix

Study Subject ID	Resource Usage	Enrolment (Form 1)	Follow Up (Form 3)	Treatment (Form 4)	Lost to Follow Up (Form 5)	Actions
0905-61220-0010						
0905-61221-0001						
0905-61222-0001						
0905-61222-0002						
0905-61222-0003						
0905-61222-0004						

Results 1 - 6 of 6.

Subject: 0905-61221-0001
Event: Enrolment (Form 1)
Status: data entry started
Click for more options

The subject matrix indicates what stage data entry is up to. Each study event/visit will be listed and the icon will indicate the status of that event i.e. Scheduled , data entry not started , initial data entry started , data entry completed .

To view the status of a study event/visit for an individual patient place the cursor over the study event/visit for the patient you require and the status will be shown.

View Study Event/Visit

To view the details of an individual study event/visit for all subjects, select the desired study event/visit from the 'Select An Event' drop-down list, located above the column header. This action allows you to view the sections/CRFs within an individual study event/visit and their status.

The screenshot displays the OpenClinica Enterprise interface for the 'ETHOS: Test Site 1 (ETH_001)' study. The main area is titled 'Subject Matrix for Test Site 1'. Above the table, there is a 'Select An Event' dropdown menu currently set to 'Enrolment (Form 1)', which is circled in red. The table lists 11 study events, each with a subject ID, event status, event date, and columns for various form sections (Form1 Sections 1 to 7, DASS21 (v0905), MINI (v0905), Form1 Sections 9 to 13, and Form1 Section 14). Each row also includes an 'Actions' column with search and delete icons. The left sidebar contains navigation links for Alerts & Messages, Instructions, and Other Info. The top navigation bar includes links for Home, Subject Matrix, Add Subject, Notes & Discrepancies, Tasks, Report Issue, Support, and a search bar for Study Subject ID.

Study Subject ID	Event Status	Event Date	Form1 Sections 1 to 7	DASS21 (v0905)	MINI (v0905)	Form1 Sections 9 to 13	Form1 Section 14	Actions
0905-61202	[Icon]	17-Oct-2009	[Icon]	[Icon]	[Icon]	[Icon]	[Icon]	[Search] [X]
0905-61222-0003	[Icon]	19-Jan-2012	[Icon]	[Icon]	[Icon]	[Icon]	[Icon]	[Search] [X]
0905-61222-0010	[Icon]	10-Oct-2010	[Icon]	[Icon]	[Icon]	[Icon]	[Icon]	[Search] [X]
Test-1	[Icon]	03-Feb-2011	[Icon]	[Icon]	[Icon]	[Icon]	[Icon]	[Search] [X]
0905-61222-0004	[Icon]	19-Jan-2012	[Icon]	[Icon]	[Icon]	[Icon]	[Icon]	[Search] [X]
0905-61222-0022	[Icon]	03-Feb-2012	[Icon]	[Icon]	[Icon]	[Icon]	[Icon]	[Search] [X]
0905-61222-0002	[Icon]	19-Jan-2010	[Icon]	[Icon]	[Icon]	[Icon]	[Icon]	[Search] [X]
0905-61221-0001	[Icon]	17-Jan-2011	[Icon]	[Icon]	[Icon]	[Icon]	[Icon]	[Search] [X]
0905-61220-0010	[Icon]	10-Oct-2010	[Icon]	[Icon]	[Icon]	[Icon]	[Icon]	[Search] [X]
Test-2	[Icon]	04-Feb-2011	[Icon]	[Icon]	[Icon]	[Icon]	[Icon]	[Search] [X]
0905-61222-0001	[Icon]	19-Jan-2011	[Icon]	[Icon]	[Icon]	[Icon]	[Icon]	[Search] [X]

Results 1 - 11 of 11.

Exit

View One Subject

To view an individual subject's event/visit's CRFs click on the view icon in the actions column.

OpenClinica® ENTERPRISE ETHOS : Test Site 1 (ETH_001) | Change Study/Site shasri (Clinical Research Coordinator) en | Log Out

Home | Subject Matrix | Add Subject | Notes & Discrepancies | Tasks | Report Issue | Support | Study Subject ID | Go

Welcome to ETHOS
Notes & Discrepancies Assigned to Me: 0

Subject Matrix
15 | Show More | Select An Event | Add New Subject

Study Subject ID	Resource Usage	Enrolment (Form 1)	Follow Up (Form 3)	Treatment (Form 4)	Lost to Follow Up (Form 5)	Actions
0905-61220-0010	[Icon]	[Icon]	[Icon]	[Icon]	[Icon]	[View] [Edit] [Filter]
0905-61221-0001	[Icon]	[Icon]	[Icon]	[Icon]	[Icon]	[View] [Edit] [Filter]
0905-61222-0001	[Icon]	[Icon]	[Icon]	[Icon]	[Icon]	[View] [Edit] [Filter]
0905-61222-0002	[Icon]	[Icon]	[Icon]	[Icon]	[Icon]	[View] [Edit] [Filter]
0905-61222-0003	[Icon]	[Icon]	[Icon]	[Icon]	[Icon]	[View] [Edit] [Filter]
0905-61222-0004	[Icon]	[Icon]	[Icon]	[Icon]	[Icon]	[View] [Edit] [Filter]

Results 1 - 6 of 6.

Icon Key
Statuses
[Icon] Not Started
[Icon] Scheduled
[Icon] Data Entry Started
[Icon] Stopped
[Icon] Skipped
[Icon] Completed
[Icon] Signed
[Icon] Locked
[Icon] Invalid

All the event/visit CRFs will be displayed and their data entry status indicated by the icons.

OpenClinica® ENTERPRISE ETHOS : Test Site 1 (ETH_001) | Change Study/Site shasri (Clinical Research Coordinator) en | Log Out

Home | Subject Matrix | Add Subject | Notes & Discrepancies | Tasks | Report Issue | Support | Study Subject ID | Go

View Subject: 0905-61221-0001

Study Subject Record
Events

Page 1 of 1 | Find | Schedule New Event

Event (Occurrence Number)	Start Date	Location	Status	Actions	CRFs
Follow Up (Form 3) (1)	17-Feb-2012		data entry started	[View] [Edit]	Form 3 Sections 10 to 13 (2) Form 3 Section 14 (2) DASS21 (v0905) (1) MINI (v0905) (1) Form3 Sections 1 to 7 (1) 17-Feb-2012 (shasri)
Lost to Follow Up (Form 5)	17-Feb-2012		scheduled	[View] [Edit]	Form 5 Lost to follow up (1) 17-Feb-2012 (shasri)
Treatment (Form 4)	18-Jan-2012		data entry started	[View] [Edit]	Form 4 Section 3 (1) Form 4 Section 1 (1) Form 4 Section 2 (1) 18-Jan-2012 (shasri)
Enrolment (Form 1)	17-Jan-2011		data entry started	[View] [Edit]	Form1 Section 14 (2) Form1 Sections 1 to 7 (1) DASS21 (v0905) (1) MINI (v0905) (1) Form1 Sections 9 to 13 (3) 20-Jan-2012 (shasri) 17-Jan-2012 (shasri) 17-Jan-2012 (shasri) 18-Jan-2012 (shasri)
Resource Usage (1)	17-Jan-2011		data entry started	[View] [Edit]	Resource Usage Form (1) 17-Jan-2012 (shasri)

Icon Key
Statuses
[Icon] Not Started
[Icon] Scheduled
[Icon] Data Entry Started
[Icon] Stopped
[Icon] Skipped
[Icon] Completed
[Icon] Signed
[Icon] Locked
[Icon] Invalid

Actions
[View] View
[Edit] Edit

View All Icons

Add new subject

Once you enrol a subject at your site you must add them to OpenClinica before data entry can be started.

You can add a New Subject to a study in three different ways:

- 1) Click on 'Add Subject' in the navigation bar – this option allows for more than one subject to be added at a time for a study
- 2) Select 'Add Subject' from a Tasks list – this option allows for more than one subject to be added at a time for a study
- 3) Click on 'Add New Subject' in the Subject Matrix – this option allows only one subject to be added at a time for a study

The screenshot shows the OpenClinica Enterprise interface for the 'ETHOS : Test Site 1 (ETH_001)' study. The navigation bar at the top includes 'Home', 'Subject Matrix', 'Add Subject' (circled in red with a '1' callout), 'Notes & Discrepancies', and 'Tasks'. A dropdown menu for 'Add Subject' is open, showing options like 'Subject Matrix', 'Add Subject' (circled in red with a '2' callout), 'Notes & Discrepancies', and 'Other'. The 'Subject Matrix' table is visible below, with a 'Select An Event' dropdown showing 'Add New Subject' (circled in red with a '3' callout). The table has columns for 'Study Subject ID', 'Resource Usage', 'Enrolment (Form 1)', 'Follow Up (Form 3)', 'Treatment (Form 4)', 'Lost to Follow Up (Form 5)', and 'Actions'. The left sidebar contains 'Alerts & Messages', 'Instructions', and 'Other Info'.

Enter the following information:

- Study Subject ID – study number
The subject ID must be entered in the following format, including hyphens (unless specifically instructed to do otherwise by your Kirby Institute Study Coordinator):
Protocol number-Site number-Patient number (e.g. 0905-61222-10)*
- Secondary ID – if required by the study. This may be the subject's initials or other secondary subject identifier*
- Enrolment Date – date subject enrolled into the study
- Gender (if required)

The system will check to make sure the values are valid and that the subject does not already exist.



This is only possible if the subject ID number is entered in the correct format.

*Always refer to your project specific instructions for the format of the Study Subject ID and the Secondary ID

The screenshot shows the 'Test Site 1: Add Subject' form in the OpenClinica Enterprise interface. The top navigation bar includes the OpenClinica logo, the study name 'ETHOS: Test Site 1 (ETH_001)', and a 'Change Study/Site' link. The user 'shasri (Clinical Research Coordinator)' is logged in. The main menu has links for Home, Subject Matrix, Add Subject, Notes & Discrepancies, and Tasks. A search bar for 'Study Subject ID' is also present. The left sidebar contains sections for Alerts & Messages, Instructions, and Other Info, with details for the study (ETHOS), site (Test Site 1), start/end dates (N/A), PI (Greg Dore), and protocol verification/IRB approval date. The main form area is titled 'Test Site 1: Add Subject' and includes a note that an asterisk indicates a required field. The form contains input fields for 'Study Subject ID' (required), 'Secondary ID', 'Date of Enrollment for Study' (set to 02-Feb-2012), and a 'Sex' dropdown menu. Below the form are four buttons: 'Save and Assign Study Event', 'Save and Add Next Subject', 'Save and Finish', and 'Cancel'. A 'Workflow' section shows a sequence from 'Add New Subject' to 'Add Study Event'. The footer contains copyright information for Akaza Research LLC and the OpenClinica Enterprise version (3.1.1).

From here you can select one of four actions.

- 1) Save and assign study event – select this to schedule the subject's study visit
- 2) Save and add next subject – select this to enrol another subject
- 3) Save and finish – select this to exit the 'Add Subject' screen
- 4) Cancel – select this if you do not want to enrol the subject whose details you just entered.

Depending on which option you choose will determine which screen you are taken to next.

Adding New Study Event

Study Events are Study Visits or stand alone forms such as the Adverse Event and Drug Administration forms.

Once a subject has been added you must schedule study events before data entry can commence.

You can schedule a study visit in three ways.

- 1) Directly after enrolling the subject you can click on 'Save and assign study event' (see previous page)
- 2) Select 'Schedule Event' from the 'Tasks' menu
- 3) From the homepage locate the subject in the subject matrix. Then click on the study event you wish to schedule. Then click on 'Schedule'.

The screenshot displays the OpenClinica Enterprise interface for the study 'ETHOS: Test Site 1 (ETH_001)'. The user is 'shasri (Clinical Research Coordinator)'. The 'Add Subject' button in the top navigation bar is circled in red and labeled with a starburst '1'. The 'Tasks' dropdown menu is open, showing 'Schedule Event' circled in red and labeled with a starburst '2'. The 'Subject Matrix' table is visible, showing a list of subjects. The 'Schedule' button in the 'Actions' column for subject '0905-61222-0003' is circled in red and labeled with a starburst '3'.

Study Subject ID	Resource Usage	Enrolment (Form 1)	Follow Up (Form 3)	Treatment (Form 4)	Lost to Follow Up (Form 5)	Actions
0905-61220-0010						
0905-61221-0001						
0905-61222-0001						
0905-61222-0002						
0905-61222-0003						
0905-61222-0004						

OpenClinica ENTERPRISE

ETHOS : Test Site 1 (ETH_001) | Change Study/Site

shasri (Clinical Research Coordinator) en | Log Out

Home | Subject Matrix | Add Subject | Notes & Discrepancies | Tasks

Report Issue | Support | Study Subject ID | Go

Alerts & Messages

Instructions

Other Info

Study: ETHOS

Site: Test Site 1

Start Date: N/A

End Date: N/A

PI: Greg Dore

Protocol Verification/IRB Approval Date:

Schedule Study Event for

* indicates required field.

Study Subject ID: *

Study Event Definition: -Select- *

Start Date/Time: 02-Feb-2012 : (DD-MMM-YYYY HH:MM) *

End Date/Time: : (DD-MMM-YYYY HH:MM) *

Leave this field blank if the end date/time is not applicable.

Schedule Another Event: (optional)

Schedule Another Event: (optional)

Schedule Another Event: (optional)

Schedule Another Event: (optional)

Proceed to Enter Data | Cancel

OpenClinica Portal | Help | Contact

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Version: 3.1.1
OpenClinica Enterprise

If you have selected either option 1 or 3 then check you have selected the correct subject by double checking the displayed Study Subject ID in the field.

Check you have selected the correct study event to schedule. If not, choose the correct Study Event Definition from the drop down list.

Enter the 'Start Date'. The start date is the date of the visit for visit events or the date that you are scheduling the event for standalone forms i.e. the baseline visit date would be the start date for the baseline visit and the day you were scheduling the event would be the start date for standalone form such as the adverse event form.

Start time and the end date and time are not required. **Do not enter event start time or event end date and time.**

Then click **Proceed to Enter Data**.






FOR VISITS: START DATE = VISIT DATE

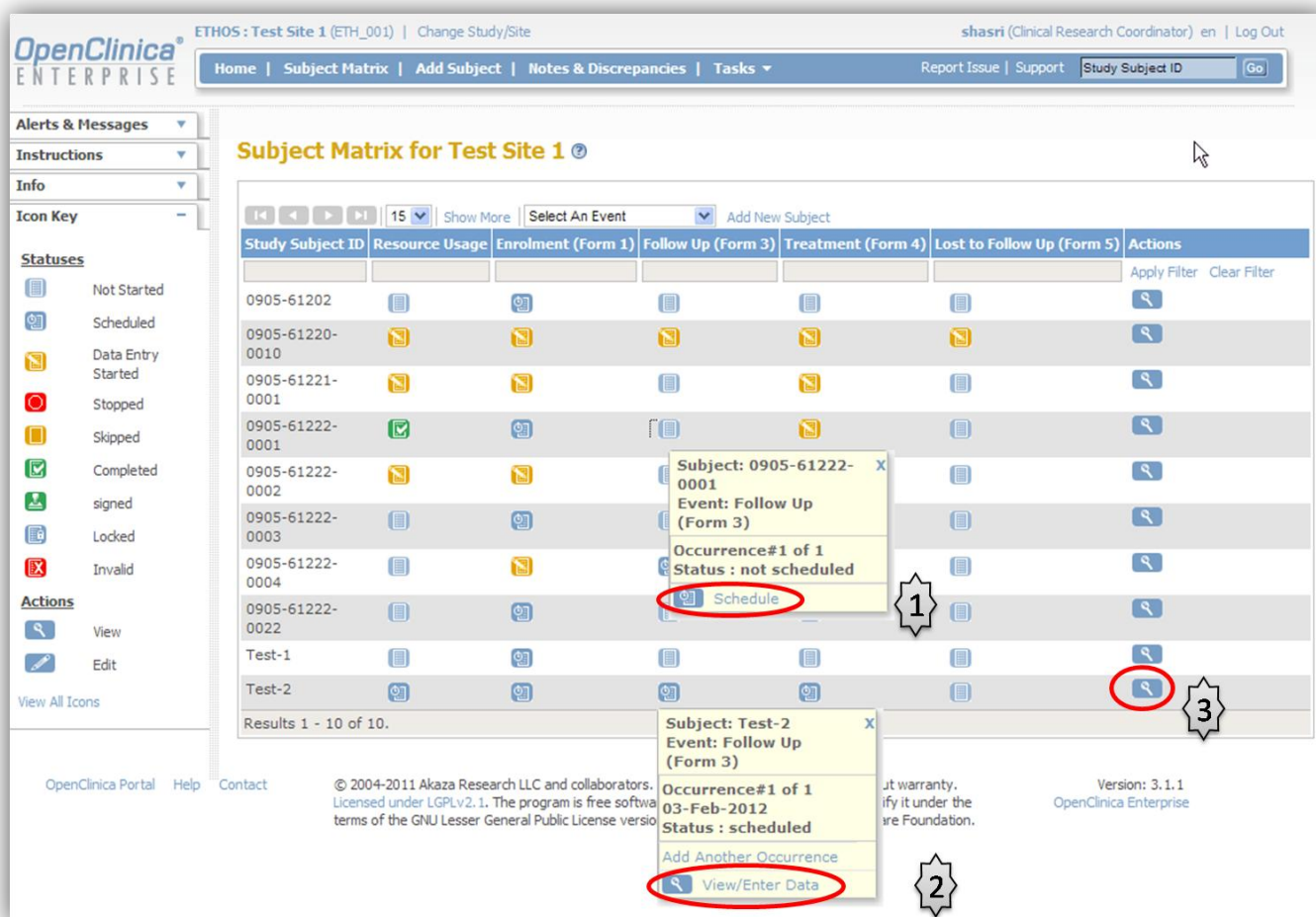
FOR STANDALONE FORMS: START DATE = DATE THE FORM IS BEING STARTED

Entering Data

You can only enter data once the Study Event/Visit has been scheduled (see 'Adding a New Study Event').

There are few different ways to open the CRF for entering data

- 1) Directly after scheduling an event/visit, click 'Proceed to Enter Data'
- 2) If the status of the event/visit that you wish to enter is 'Scheduled'  in the Subject Matrix, then place the cursor over the event icon and click View/Enter data.
- 3) If the status of the event/visit that you wish to enter is 'Scheduled'  in the Subject Matrix, then click 'View'  in the actions column. This action will display the 'Subject record page' then select the section of the CRF that you wish to enter.



OpenClinica ENTERPRISE ETHOS: Test Site 1 (ETH_001) | Change Study/Site shasri (Clinical Research Coordinator) en | Log Out

Home | Subject Matrix | Add Subject | Notes & Discrepancies | Tasks | Report Issue | Support | Study Subject ID | Go

Subject Matrix for Test Site 1

15 | Show More | Select An Event | Add New Subject

Study Subject ID	Resource Usage	Enrolment (Form 1)	Follow Up (Form 3)	Treatment (Form 4)	Lost to Follow Up (Form 5)	Actions
0905-61202						
0905-61220-0010						
0905-61221-0001						
0905-61222-0001						
0905-61222-0002						
0905-61222-0003						
0905-61222-0004						
0905-61222-0022						
Test-1						
Test-2						

Results 1 - 10 of 10.

Subject: 0905-61222-0001
Event: Follow Up (Form 3)
Occurrence#1 of 1
Status: not scheduled
Schedule

Subject: Test-2
Event: Follow Up (Form 3)
Occurrence#1 of 1
03-Feb-2012
Status: scheduled
Add Another Occurrence
View/Enter Data

OpenClinica Portal | Help | Contact | © 2004-2011 Akaza Research LLC and collaborators. Licensed under LGPLv2.1. The program is free software under the terms of the GNU Lesser General Public License version 2.1 or later. | Version: 3.1.1 OpenClinica Enterprise



Option 1 and Option 2 will **ONLY** display the 'Event information' followed by a table of all the relevant CRFs that make up the study event/visit.

OpenClinica ENTERPRISE ETH05 : Test Site 1 (ETH_001) | Change Study/Site shasri (Clinical Research Coordinator) en | Log Out

Home | Subject Matrix | Add Subject | Notes & Discrepancies | Tasks | Report Issue | Support | Study Subject ID | Go

Alerts & Messages
The study event with definition 'Enrolment (Form 1)' and subject 'Test-1' was created successfully.

Instructions
Info
















Study Events
Study Events: (1)
Enrolment (Form 1)
Status: scheduled
Form1 Sections 1 to 7
DASS21 (v0905)
MINI (v0905)
Form1 Sections 9 to 13
Form1 Section 14

Enter or Validate Data for CRFs in Enrolment (Form 1)

Edit Study Event

Study Subject ID	Test-1
Study Event	Enrolment (Form 1)
Location	N/A
Study Subject OID	SS_TEST1
Start Date	03-Feb-2011
End Date/Time	
Subject Event Status	scheduled
Last Updated by	0

CRFs in this Study Event:

CRF Name	Version	Status	Initial Data Entry	Double Data Entry	Actions
Form1 Sections 1 to 7	1				  
DASS21 (v0905)	1				  
MINI (v0905)	1				  
Form1 Sections 9 to 13	3				  
Form1 Section 14	2				  

[View this Subject's Record](#) [Exit](#)

Workflow

Study Event Overview → Data Entry → Mark Event CRF Complete

Then select the CRF section you want to start entering data on by clicking the 'Enter Data' icon next to the CRF section in the actions column.



Option number 3 will display all the events/visits CRFs that make up **ALL THE SCHEDULED, DATA ENTRY NOT STARTED, DATA ENTRY STARTED and COMPLETED** CRF sections of a selected subject

OpenClinica[®] ENTERPRISE

ETHOS : Test Site 1 (ETH_001) | Change Study/Site

shasri (Clinical Research Coordinator) en | Log Out

Home | Subject Matrix | Add Subject | Notes & Discrepancies | Tasks

Report Issue | Support | Study Subject ID | Go

Alerts & Messages

Instructions

Other Info

Study: ETHOS

Site: Test Site 1

Start Date: N/A

End Date: N/A

PI: Greg Dore

Protocol Verification/IRB Approval Date:

Icon Key

Statuses

- Not Started
- Scheduled
- Data Entry Started
- Stopped
- Skipped
- Completed
- signed
- Locked
- Invalid

View Subject: Test-2

Study Subject Record

Events

Page 1 of 1

Find

Schedule New Event

Event (Occurrence Number)	Start Date	Location	Status	Actions	CRFs (Name, Version, Status, Updated, Actions)																									
Follow Up (Form 3) (1)	03-Feb-2012		scheduled		<table><tr><td>Form3 Sections 1 to 7</td><td>1</td><td></td><td></td><td> </td></tr><tr><td>Form 3 Sections 10 to 13</td><td>2</td><td></td><td></td><td> </td></tr><tr><td>Form 3 Section 14</td><td>2</td><td></td><td></td><td> </td></tr><tr><td>DASS21 (v0905)</td><td>1</td><td></td><td></td><td> </td></tr><tr><td>MINI (v0905)</td><td>Followup</td><td></td><td></td><td> </td></tr></table>	Form3 Sections 1 to 7	1				Form 3 Sections 10 to 13	2				Form 3 Section 14	2				DASS21 (v0905)	1				MINI (v0905)	Followup			
Form3 Sections 1 to 7	1																													
Form 3 Sections 10 to 13	2																													
Form 3 Section 14	2																													
DASS21 (v0905)	1																													
MINI (v0905)	Followup																													
Treatment (Form 4)	05-Apr-2011		data entry started		<table><tr><td>Form 4 Section 2</td><td>1</td><td></td><td></td><td> </td></tr><tr><td>Form 4 Section 3</td><td>1</td><td></td><td></td><td> </td></tr><tr><td>Form 4 Section 1</td><td>1</td><td></td><td>17-Feb-2012 (shasri)</td><td> </td></tr></table>	Form 4 Section 2	1				Form 4 Section 3	1				Form 4 Section 1	1		17-Feb-2012 (shasri)											
Form 4 Section 2	1																													
Form 4 Section 3	1																													
Form 4 Section 1	1		17-Feb-2012 (shasri)																											
Enrolment (Form 1)	04-Feb-2011		scheduled		<table><tr><td>Form1 Sections 1 to 7</td><td>1</td><td></td><td></td><td> </td></tr><tr><td>DASS21 (v0905)</td><td>1</td><td></td><td></td><td> </td></tr><tr><td>MINI (v0905)</td><td>1</td><td></td><td></td><td> </td></tr><tr><td>Form1 Sections 9 to 13</td><td>3</td><td></td><td></td><td> </td></tr><tr><td>Form1 Section 14</td><td>2</td><td></td><td></td><td> </td></tr></table>	Form1 Sections 1 to 7	1				DASS21 (v0905)	1				MINI (v0905)	1				Form1 Sections 9 to 13	3				Form1 Section 14	2			
Form1 Sections 1 to 7	1																													
DASS21 (v0905)	1																													
MINI (v0905)	1																													
Form1 Sections 9 to 13	3																													
Form1 Section 14	2																													
Resource Usage (1)	03-Feb-2011		scheduled		<table><tr><td>Resource Usage Form</td><td>1</td><td></td><td></td><td> </td></tr></table>	Resource Usage Form	1																							
Resource Usage Form	1																													

Then select the CRF section you want to start entering data on by clicking the 'Enter Data' icon next to the CRF section in the actions column.

The data entry screen will now appear.

To move between data screens click on the tabs or select CRF section from the drop down list.

B1002_SCREENING 4 **1002-61202-10**

Jump tabs

Drop-down navigation menu

CRF Header Info

Eligibi...(0/11) Demogra...(0/5) Hepatit...(0/12)

-- Select to Jump --

Title: Section 1: Eligibility Checklist

Page: Save Exit

Date of screening visit

1. Inclusion Criteria

a) Male and female patients greater or equal to 16 years of age

-- Select One --

b) Recent hepatitis C infection with an estimated duration of Infection less than or equal to 18 months

-- Select One --

c) Adequate English to provide written, informed consent and to provide reliable responses to the study interview

-- Select One --

d) Provision of written, informed consent

-- Select One --

2. Exclusion Criteria

Is the Individual considered by the study investigators to be unlikely to participate in intensive follow-up and/or unwilling to provide extra blood samples?

-- Select One --

3. Eligibility Criteria

a) Has the patient met the eligibility criteria to enter the study?

-- Select One -- If No, patient is NOT ELIGIBLE please answer protocol exemption questions.

4. Early Acute Infection Substudy

Is the patient eligible to be enrolled in the early acute infection substudy?

-- Select One --

5. Data Linkage

Did the patient consent to data linkage?

-- Select One --

Return to top Save Exit

The CRF header will be collapsed by default.

You can view a CRF header information by clicking on the 'CRF Header Info' at the top left corner of the data entry screen.

B1002_SCREENING 4 **1002-61202-10**

▼ **CRF Header Info**

◀ **Eligibi...(0/11)** **Demogra...(0/5)** **Hepatit...(0/12)** ▶ -- Select to Jump -- ▼

Title: Section 1: Eligibility Checklist

Page: **Save** **Exit** 📄

Date of screening visit

📅 * 🚩

1. Inclusion Criteria

a) Male and female patients greater or equal to 16 years of age

-- Select One -- ▼ * 🚩

b) Recent hepatitis C infection with an estimated duration of Infection less than or equal to 18 months

-- Select One -- ▼ * 🚩

c) Adequate English to provide written, informed consent and to provide reliable responses to the study interview

-- Select One -- ▼ * 🚩

d) Provision of written, informed consent

-- Select One -- ▼ * 🚩

2. Exclusion Criteria

Is the Individual considered by the study investigators to be unlikely to participate in intensive follow-up and/or unwilling to provide extra blood samples?

-- Select One -- ▼ * 🚩

3. Eligibility Criteria

a) Has the patient met the eligibility criteria to enter the study?

-- Select One -- ▼ * 🚩 If No, patient is NOT ELIGIBLE please answer protocol exemption questions.

4. Early Acute Infection Substudy

Is the patient eligible to be enrolled in the early acute infection substudy?

-- Select One -- ▼ * 🚩

5. Data Linkage

Did the patient consent to data linkage?

-- Select One -- ▼ * 🚩

[Return to top](#) **Save** **Exit** 📄

Once expanded, you can collapse the information box by click on the 'CRF Header Info' again.

B1002_SCREENING 4
1002-61202-10

CRF Header Info
✖

Event: Screening (02/11/2011)	Sex: M
Study: ATACH II	Age At Enrollment: N/A
Site: N/A	Date of Birth:
Person ID:	

Discrepancy Notes on this CRF:

New	Updated	Resolution Proposed	Closed	Not Applicable
0	0	0	0	0

Eligibi...(0/11)
Demogra...(0/5)
Hepatit...(0/12)
▶ -- Select to Jump -- ▼

Title: Section 1: Eligibility Checklist

Page:
Save
Exit
📄

Date of screening visit

📅
*
🔒

1. Inclusion Criteria

a) Male and female patients greater or equal to 16 years of age

-- Select One --

*

🔒

b) Recent hepatitis C infection with an estimated duration of Infection less than or equal to 18 months

-- Select One --

*

🔒

c) Adequate English to provide written, informed consent and to provide reliable responses to the study interview

-- Select One --

*

🔒

d) Provision of written, informed consent

-- Select One --

*

🔒

2. Exclusion Criteria

While you are entering the data always have the 'CRF Header info' displayed to make sure that you are;

- Entering the data for the correct patient ID
- Entering the data for the correct event

When a user is entering data into a CRF no other user will be able to access that CRF. Once the user has exited the CRF other users may enter the CRF and enter data.

Enter Data as required.

Any data field marked with ‘*’ means that this data is required.

Screening 4 **1002-61202-10**

▼ CRF Header Info

There are issue(s) with your submission. The data has NOT been saved. See below for details.

- [Missing data in a required field.]

◀ Eligibi...(0/11) Demogra...(0/5) Hepatit...(0/12) ▶ -- Select to Jump --

Title: Section 1: Eligibility Checklist

Page: **Save** **Exit**

Date of screening visit

! [] *

1. Inclusion Criteria

a) Male and female patients greater or equal to 16 years of age

Yes *

b) Recent hepatitis C infection with an estimated duration of Infection less than or equal to 18 months

Yes *

c) Adequate English to provide written, informed consent and to provide reliable responses to the study interview

Yes *

d) Provision of written, informed consent

Yes *

2. Exclusion Criteria

Is the Individual considered by the study investigators to be unlikely to participate in intensive follow-up and/or unwilling to provide extra blood samples?

No *

3. Eligibility Criteria

a) Has the patient met the eligibility criteria to enter the study?

Yes * If No, patient is NOT ELIGIBLE please answer protocol exemption questions.

4. Early Acute Infection Substudy

Is the patient eligible to be enrolled in the early acute infection substudy?

Yes *

Always Save between screens by clicking on ‘Save’.

OpenClinica will only run the rules to check the data once ‘save’ has been pressed on the CRF page.

Data cleaning during data entry

Each study database in OpenClinica has been pre-programmed with validation rules to ensure that the data being entered is consistent with the protocol and study design, is logical, is consistent with data entered elsewhere in the database for that patient, is within expected ranges and is clinically and scientifically meaningful.

These data checks ensure that the data is as error-free as possible.

These pre-programmed validation rules are only triggered when 'SAVE' is pressed for that CRF page.

There is an order in which these rules will fire.

First OpenClinica will check for missing data on the CRF page. Then OpenClinica will check that the data entered is within the expected range. Finally OpenClinica will check that the data entered on that page is consistent with data entered on other pages, other CRFs and at other visits.

The screenshot shows the 'Eligibility Checklist' form in OpenClinica. The form has a title bar 'Title: Section 1: Eligibility Checklist' and a navigation bar with 'Eligibility (1/24)' and a dropdown menu '-- Select to Jump --'. The form contains several sections with input fields:

- Baseline Visit Date:** A text input field containing '10/10/2011'. To its right is a red arrow pointing to a red asterisk icon, indicating a validation failure.
- Study Arm:** A dropdown menu with the text 'Which arm will the patient be enrolled into?' and a '-- Select One --' button. To its right is a red arrow pointing to a red asterisk icon, indicating a validation failure.
- Estimated Date of Infection:** A text input field. To its right is a green asterisk icon, indicating a validation success.
- Treatment Regime:** A dropdown menu with a '-- Select One --' button. To its right is a red arrow pointing to a red asterisk icon, indicating a validation failure.

Two red boxes with text provide explanations for the asterisk icons:

- Field marked with '*' – if this field left blank or does not comply with expected values then a manual query has to be added to the field justifying the reason for blank field or failed validation rule before moving on to the next tab/section** (points to the red asterisks).
- Field without the '*' – if this field fails the validation check then the system will automatically generate a query that will need to be addressed at a later stage when the data becomes available** (points to the green asterisk).

Depending on the type of pre-programmed rule the data item has failed, OpenClinica will trigger one of two actions:

- 1) The site will be asked to amend the data item or justify the entry by adding a discrepancy note. See 'Notes and Discrepancies – Amend or Justify by adding a flag/note' for how to add a discrepancy note.
- 2) The site will be asked to amend the data item or press save to continue. A discrepancy note will be automatically generated by OpenClinica if the site chooses to press save rather than amend the data item. These discrepancies must be addressed at a later stage (see 'Discrepancy Management' for instructions on how to respond to these discrepancy notes after data entry).



A data field may have more than one validation rule associated with it. Please read the discrepancy note carefully as it will instruct you on how to proceed to the next tab/section of the CRF.

Annotations

Annotations are comments provided by the site to explain a data item. Annotations should not be used to explain data that has failed a validation check or is a blank field. These should only be used if required to explain data that has not failed a validation check and only if the explanation is needed to avoid future queries.

To enter an annotation click on the flag icon/discrepancy note next to the field that you wish to comment about.

The following screen will appear.

BL_VISIT: Add Discrepancy Note

"BL_VISIT" Properties:

Subject:	1002-61202-10	Event:	BL
Event Date:	03/11/2011	CRF:	G1002_BL_ELIG 1
Current Value:		More:	Data Dictionary

Add Note

Description:*

Detailed Note:

Type:*

Set to Status:*

Submit

When you click on the flag/discrepancy note during 'Data entry mode' the type of Discrepancy note will automatically be 'Annotation'

Only add an 'Annotation' note to explain the data.

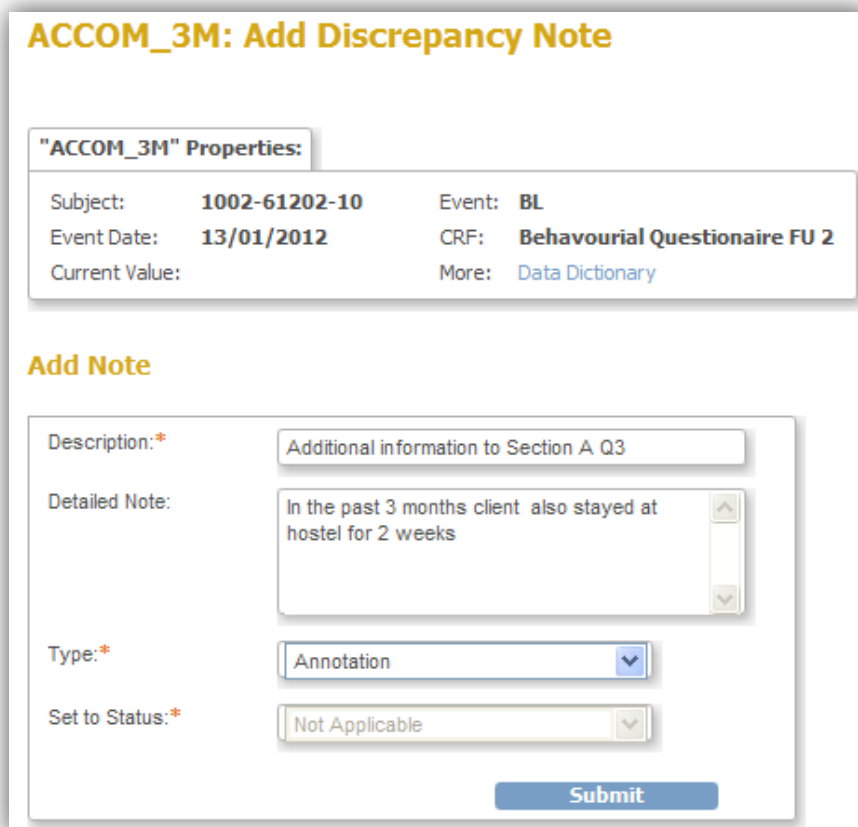


Do not enter actual data into an 'Annotation' note as this information will not be analysed and therefore the data would be missed.

Enter a description (e.g. Section name or number and Question name or number) into the 'Description' field.

Enter a detailed description of the additional information into the 'Detailed Note' field.

Then click 



ACCOM_3M: Add Discrepancy Note

"ACCOM_3M" Properties:

Subject:	1002-61202-10	Event:	BL
Event Date:	13/01/2012	CRF:	Behaviourial Questionnaire FU 2
Current Value:		More:	Data Dictionary

Add Note

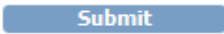
Description:*

Detailed Note:

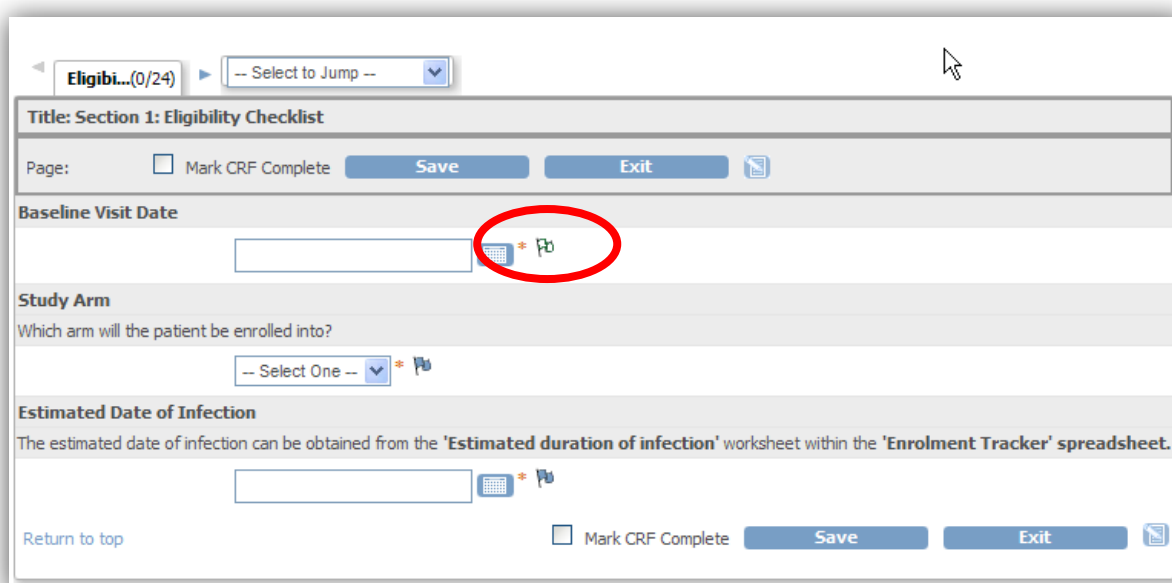
In the past 3 months client also stayed at hostel for 2 weeks

Type:*

Set to Status:*

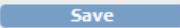
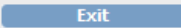



The flag icon will then change to white to indicate that additional information has been added to the field.





Eligibi...(0/24) -- Select to Jump --

Title: Section 1: Eligibility Checklist


Page: ☐ Mark CRF Complete   

Baseline Visit Date

 * 



Study Arm

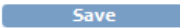
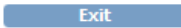

Which arm will the patient be enrolled into?

-- Select One -- * 

Estimated Date of Infection

The estimated date of infection can be obtained from the 'Estimated duration of infection' worksheet within the 'Enrolment Tracker' spreadsheet.

 * 

[Return to top](#) ☐ Mark CRF Complete   

Notes & Discrepancies Descriptions

A Discrepancy Note has four key components;

1. Description – enter the Section and Question number of which the note is being created. If the Section number or Question number is not available please use the name of the item.
2. Detailed note- enter the detailed issue about the particular item of the CRF
3. Type- site users must always use **'Failed Validation Check'**
4. Set to Status- site users must always use either **'New'** or **Resolution Proposed'**

Notes & Discrepancies – Amend or Justify by adding a flag/note

The site can choose to either amend the data into the field and press save or click on the flag icon next to the blank field and a discrepancy note will appear.

When adding a flag/discrepancy note site user can either:

1. Leave the Failed validation check status as **'New'** by only completing the 'Description' and 'Detailed note' about the field then click 'Submit'

HCV_QUAL: Add Discrepancy Note

"HCV_QUAL" Properties:

Subject:	1002-61202-10	Event:	BL
Event Date:	03/11/2011	CRF:	Visit
Current Value:		More:	Data Dictionary

Add Note

Description:*

Detailed Note:

Type:*

Set to Status:*

This flag will remain 'Red' until you address the discrepancy, update the data item in the eCRF (if possible) and change the status to 'Resolution Proposed'.

2. Propose a resolution by setting the status to '**Resolution Proposed**'. In this note you need to complete the 'Description' with the CRF section and question number and the details of the proposed resolution or an explanation into 'Detailed Note' section and then click 'Submit'.

The screenshot shows a web form titled "ACCOM_3M: Add Discrepancy Note". At the top, there is a section labeled "ACCOM_3M" Properties: containing a table with the following information:

Subject:	1002-61202-10	Event:	BL
Event Date:	21/11/2011	CRF:	Behaviourial Questionnaire FU 2
Current Value:		More:	Data Dictionary

Below this is the "Add Note" section. It contains four input fields and a "Submit" button:

- Description:***: A text box containing "Section A_ Question 4".
- Detailed Note:**: A text area containing "Participant stated that he lives at Hostel and Caravan. Please advice." with a vertical scrollbar on the right.
- Type:***: A dropdown menu with "Failed Validation Check" selected.
- Set to Status:***: A dropdown menu with "Resolution Proposed" selected.
- Submit**: A blue button at the bottom right of the form.

This flag will appear 'Green' and the Kirby Institute Data Manager will then review your proposed resolution and action.

If more information is required then the Kirby Institute Data Manager will change the status to 'Updated' (yellow flag). The Site Coordinator then needs to provide more details.

If the proposed resolution is sufficient to close the discrepancy note then the Kirby Institute Data Manager will change the status to 'Closed' and the Flag colour will change to 'Black'.

If the proposed resolution requires data to be entered into the CRF then the Kirby Institute Data Manager will enter the data into the CRF as provided in the Detailed Note by the site and change the status to 'Closed' and the Flag colour will change to 'Black'.

Eligibi...(0/24) -- Select to Jump --

Title: Section 1: Eligibility Checklist

Page: ☐ Mark CRF Complete [Save](#) [Exit](#)

Baseline Visit Date

Study Arm

Which arm will the patient be enrolled into?

-- Select One --

Estimated Date of Infection

The estimated date of infection can be obtained from the 'Estimated duration of infection'

[Return to top](#) ☐ Mark CRF Complete [Save](#) [Exit](#)

If you have **NOT** addressed the query i.e.; **NOT** proposed a resolution then the flag will turn from blue to red which means action will be required by the Site Coordinator at a later stage when the data becomes available

If you have addressed the query i.e.; proposed a resolution then the flag will turn from blue to green. Then the Kirby Institute Data Manager or Study Coordinator will review the green flags and 'update' if more information are required to close of the query (flag will turn from green to yellow). Or Close off the query (flag will turn from green to black)

Discrepancy Management

Types of Discrepancy notes

OpenClinica has an online discrepancy management system.

There are four different types of Notes and Discrepancies:

1. Annotations

Annotations are comments provided to explain a piece of data. These can be entered at any time by the site to provide an additional explanation for data entered. To do this click on the blue flag next to the data item to be commented on and enter the information into the discrepancy window. Click submit to continue.

2. Failed Validation Check

Failed Validation Checks are queries generated by the database because the data entered fails one of the programmed data checks or queries added by the data entry personnel because data is not available at the time of data entry.

3. Reason for change

Reason for change is an explanation justifying why a data item was changed after a CRF has been 'Marked as Complete'.

4. Query

Query is a question usually entered by the The Kirby Institute to query a particular data item.



When creating a Discrepancy Note the site user can only use note types **'Annotation'** or **'Failed Validation Check'**.

Status of Discrepancy notes

Each data item has a flag/discrepancy note and the colour of the flag indicates the status of the discrepancy note.

- ➡ Blue = none
- ➡ Red = new
- ➡ Yellow = updated
- ➡ Green = resolution proposed
- ➡ Black = closed / resolved
- ➡ White = Not Applicable



When creating a Discrepancy Note the site user can only set the status as '**New**' or '**Resolution Proposed**'

If any discrepancies are assigned to an individual site user then they will appear on the homepage when the user logs into OpenClinica.

Home

Subject Matrix

Add Subject

Notes & Discrepancies

Tasks

Report Issue

Support

Study Subject ID

Go

Welcome to ATAHC 11

Notes & Discrepancies Assigned to Me: 0

Subject Matrix

15

Show More

Select An Event

Add New Subject

Study Subject ID	Screening	E2	E4	E6	E8	BL	W2	W4	W6	W8	W12	W16	W20	W24	W28	W32	W36	W40	W44	W48	W72	W96	ETR	SVR12	SVR24	FU1	FU2	Drug Admin	Conmed	AEs	Termination	v1002_centralabs	Actions
1002-61202-10																																	
1007-61202-01																																	
adfasdfasdfsdf																																	
Barbara																																	
Ineke																																	
Marianne																																	
Sharmila																																	
SS2																																	

Results 1 - 8 of 8.

Navigating Notes and Discrepancy module

There are two different ways that you can access the Notes & Discrepancies module.

- 1) Click on 'Notes and Discrepancies' in the navigation bar
- 2) Select 'Notes and Discrepancies' from a Tasks list

The screenshot displays the OpenClinica Enterprise interface for the 'ETHOS : Test Site 1 (ETH_001)' study. The navigation bar at the top includes links for Home, Subject Matrix, Add Subject, and Notes & Discrepancies (highlighted with a red circle and callout '1'). A dropdown menu is open, showing options like Data, Subject Matrix, Add Subject, Notes & Discrepancies (highlighted with a red circle and callout '2'), Other, Update Profile, and Log Out. The main content area shows a 'Subject Matrix' table with columns for Study Subject ID, Resource Usage, Enrolment (Form 1), Follow Up (Form 3), Treatment (Form 4), Lost to Follow Up (Form 5), and Actions. The table lists several subjects with various icons indicating their status. The left sidebar contains 'Alerts & Messages', 'Instructions', and 'Other Info' sections.

Study Subject ID	Resource Usage	Enrolment (Form 1)	Follow Up (Form 3)	Treatment (Form 4)	Lost to Follow Up (Form 5)	Actions
0905-61220-0010	[Icon]	[Icon]	[Icon]	[Icon]	[Icon]	[Icon]
0905-61221-0001	[Icon]	[Icon]	[Icon]	[Icon]	[Icon]	[Icon]
0905-61222-0001	[Icon]	[Icon]	[Icon]	[Icon]	[Icon]	[Icon]
0905-61222-0002	[Icon]	[Icon]	[Icon]	[Icon]	[Icon]	[Icon]
0905-61222-0003	[Icon]	[Icon]	[Icon]	[Icon]	[Icon]	[Icon]
0905-61222-0004	[Icon]	[Icon]	[Icon] x2	[Icon]	[Icon]	[Icon]

The patients with discrepancies will be listed in the Notes and Discrepancies module. The flags indicate the status of the discrepancy and the study event with which it is associated.

You can view a summary of all the discrepancies by clicking on the "show summary statistics" at the left top corner of the list.

Home | Subject Matrix | Add Subject | Notes & Discrepancies | Tasks
Report Issue | Support | Study Subject ID | Go

Notes and Discrepancies

Hide summary statistics

	Query	Failed Validation Check	Reason for Change	Annotation	Total
New	--	373	--	--	373
Updated	--	--	--	--	--
Resolution Proposed	1	4	--	--	5
Closed	--	--	--	--	--
Not Applicable	--	--	--	9	9
Total	1	377	--	9	387

Study Subject ID	Type	Resolution Status	Site ID	Days Open	Days Since Updated	Event Name	CRF	Entity Name	Entity Value	Description	Assigned User	Actions
SS2	Failed Validation Check	New	VHCRP1002	34	34	Screening	J1002_Behavioural_QU	BHQ_DOB		SCR_BHQ_DOB2 Question 1: Yes was answered to this questionnaire being completed therefore please complete this question or press save and a discrepancy note will be logged.	()	Apply Filter Clear Filter
SS2	Failed Validation Check	New	VHCRP1002	30	30	Screening	B1002_SCREENING	HCV_QLDT	15/08/2011	SCR_HCV_QLDT3 HCV RNA qualitative date : date should not be prior to visit date. Please review and amend or press save and a discrepancy note will be logged.	()	

Sorting Notes and Discrepancies

From the Notes and Discrepancies list there are few filtering/sorting options which can be done:

Most commonly used options;

- Search by patient ID
 - o Type the patient ID that you wish to search into the grey shaded field under the 'Study Subject ID' and press 'Enter'. This action will display all the notes and discrepancies for that particular patient
- Filter by notes and discrepancies Type
 - o Place the mouse over the grey shaded area under 'Type' then left click to show the notes and discrepancy type then click on the desired type you wish to filter.



Sites only need to review **'Failed validation check'** and **'Query'** notes and discrepancies types.

- Filter by Resolution Status
 - o Place the mouse over the grey shaded area under 'Resolution Status' then left click to show the resolution status then click on the desired status you wish to filter.





Sites only need to review **Red (new)** and **Yellow (update)** flagged queries.

Other Options:

- Search by Days Open
 - Type the number of days that the discrepancy note has been open that you wish to search into the grey shaded field under the 'Days Open'. This action will display all the notes and discrepancies for the entered number of days opened.
- Search by Days since updated
 - Type the number of days that you wish to search into the grey shaded field under the 'Days Since Updated'. This action will display all the notes and discrepancy for the entered number of days updated.
- Search by Event name
 - Type the event name that you wish to search into the grey shaded field under the 'Event Name'. This action will display all the notes and discrepancy for that particular event name
- Search by CRF
 - Type the CRF that you wish to search into the grey shaded field under the 'CRF'. This action will display all the notes and discrepancy for that particular CRF
- Search by Assigned user
 - Type the user name that you wish to search into the grey shaded field under the 'Assigned User'. This action will display all the notes and discrepancies were assigned to that particular user

Viewing Notes and Discrepancies

Once you have filtered/sorted your notes and discrepancy list then you can either;






- View the discrepancy note
 - o By clicking on the  icon under action column. This action will ONLY display the discrepancy note without opening the CRF but will allow the user to update the thread from the "View".
- View the discrepancy note within the record
 - o By clicking on the  icon under action column. This action will not only display the discrepancy note but also navigate to the CRF page where the discrepancy was logged






ETHOS: Test Site 1 (ETH_001) | Change Study/Site shasri (Data Entry Person) en | Log Out










Home | Subject Matrix | Add Subject | Notes & Discrepancies | Tasks Report Issue | Support | Study Subject ID Go

Notes and Discrepancies

[Hide summary statistics](#)

	Query	Failed Validation Check	Reason for Change	Annotation	Total	
New		--	132	--	132	
Updated		--	2	--	2	
Resolution Proposed		--	99	--	99	
Closed		--	--	--	--	
Not Applicable		--	2	57	59	
Total	--	--	233	2	57	292

    15 [Show More](#) 

Study Subject ID	Type	Resolution Status	Site ID	Days Open	Days Since Updated	Event Name	CRF	Entity Name	Entity Value	Description	Assigned User	Actions
0905-61221-0001	Failed Validation Check	 New	ETH_001 0	33		Resource Usage	Resource Usage Form	RU_VISIT_REASON_6b		RUFS1Q3_6BPREVQU () Question 3: As 'Review of HCV treatment side effects' was ticked please answer 'Was a referral for side effects made?'		 
0905-61221-0001	Failed Validation Check	 Resolution Proposed	ETH_001 1	31		Resource Usage	Resource Usage Form	RU_VISIT_REASON_6a		RUFS1Q3_6APREVQU () Question 3: As 'Review of HCV treatment side effects' was ticked please answer 'Was medication for side effects prescribed?'		 
0905-61221-0001	Failed Validation Check	 New	ETH_001 0	33		Resource Usage	Resource Usage Form	RU_VISIT_REASON_4a		RUFS1Q3_4APREVQU () Question 3: As 'HCV related education/counselling and/or support' was		 



When selecting the Notes thru Notes and Discrepancies module will only allow the user to edit the NOTES only. It will **NOT allow the user to edit and save any changes in the actual field within the CRF.**

Responding to a query

Once a discrepancy has been created, the **Note Type** cannot be changed. The site user must respond to the discrepancy and propose a resolution by pressing 'Propose resolution'. The site's response will be added to the Note thread.



Please DO NOT select 'Update Note' when providing a resolution.

F1_DEMO_JJC_6M: Notes and Discrepancies

"F1_DEMO_JJC_6M" Properties:

Subject: 0905-61221-0001 Event: **Enrolment (Form 1)**
Event Date: 17-Jan-2011 CRF: **Form1 Sections 1 to 7**
Current Value: More: [Data Dictionary](#)
[Audit History](#)

Note Details

☐ **P905F1S2Q15YESNO Question 15: Qu 14 is yes therefore this field must be completed**

Last updated: 17-Jan-2012 by shasri
Assigned to: ()

ID: 15	Type: Failed Validation Check	Current Status: New	# of Notes: 1
P905F1S2Q15YESNO Question 15: Qu 14 is yes therefore this field must be completed		Status: New	17-Jan-2012 by shasri
		Update Note	Propose Resolution

[Begin New Thread](#)

Audit History

(No changes have been made to this data point since it was initially entered on 17-Jan-2012.)

Discrepancies can be responded to in two ways:

1) **Subject Matrix Module:**

Correct the data by changing it on the CRF and respond to the discrepancy by providing a description and detailed comment or reason for change

2) **Notes and Discrepancy Module:**

Respond to the discrepancy by providing a comment or clarification. This should only be done when the data entered is correct.



Selecting a note through the Notes and Discrepancies module, will only display the CRF in view mode NOT edit mode hence, the field item in the CRF cannot be updated and saved

Responding to the Notes and Discrepancies through the Subject Matrix Module

To change a data item as a result of a discrepancy you must not only enter the new data in the appropriate field but also enter the information into the Discrepancy Note and change the status of the note to 'Resolution Proposed'. See 'Entering Data'.

To respond to a note and edit and save the correct value in the CRF, first you must select the CRF section through the subject matrix module. Then click on the 'Enter data' icon.

OpenClinica[®] ENTERPRISE

ETHOS: Test Site 1 (ETH_001) | Change Study/Site

shasri (Clinical Research Coordinator) en | Log Out

Home | **Subject Matrix** | Add Subject | Notes & Discrepancies | Tasks

Report Issue | Support | Study Subject ID: [Go]

Alerts & Messages

Your data has been saved. You may continue entering/editing data now or return at a later time.

Instructions

Info

Study Events

Study Events: (4)

Resource Usage

Enrolment (Form 1)

Status: data entry started

DASS21 (v0905) 1

Form1 Sections 1 to 7 1

MINI (v0905) 1

Form1 Sections 9 to 13 3




















Form1 Section 14

Enter or Validate Data for CRFs in Enrolment (Form 1)

Edit Study Event

Study Subject ID	0905-61222-0001
Study Event	Enrolment (Form 1)
Location	N/A
Study Subject OID	SS_09056122_6999
Start Date	19-Jan-2011
End Date/Time	19-Jan-2011
Subject Event Status	data entry started
Last Updated by	shasri (19-Feb-2012)

CRFs in this Study Event:

CRF Name	Version	Status	Initial Data Entry	Double Data Entry	Actions
Form1 Section 14	2				  
DASS21 (v0905)	1		shasri	n/a	  
Form1 Sections 1 to 7	1		shasri	n/a	  
MINI (v0905)	1		shasri	n/a	  
Form1 Sections 9 to 13	3		shasri	n/a	  

View this Subject's Record | Exit

Once you have identified the CRF follow the instructions below;

- 1) Select the data item with the discrepancy note (RED or YELLOW flag)
- 2) View the notes to see the previous updates made by OpenClinica or by the Kirby Institute Data Manager or Study monitor.
- 3) Click 'Propose Resolution' and complete all the necessary fields as appropriate, then click on 'Submit' or 'Submit & Exit'
- 4) Change the CRF item as appropriately as instructed by the Data Manager or Study monitor or correct information as exactly on the subject's source documents.
- 5) Then press 'Save' in the CRF to update the changes.

[illegible]

Responding to Notes and Discrepancies through Notes and Discrepancies Module

To respond to the discrepancy note click on one of the options described above in the section 'Viewing Notes and Discrepancies' (View the discrepancy note or View the discrepancy note within the record).

NEW_NDLE: Notes and Discrepancies

"NEW_NDLE" Properties:

Subject:	Barbara	Event:	BL
Event Date:	28/10/2011	CRF:	I1002_Behavioural_FUQU
Current Value:	1	More:	Data Dictionary Audit History

Note Details

☐ **V_NEW_NDLE2 Question 8: Injected in the last month was not selected, however this field was completed. Please review and delete, amend or press save and a discrepancy note will be logged.**

Last updated: 31/10/2011 by byeung
Assigned to: ()

ID: 1169	Type: Failed Validation Check	Current Status: New	# of Notes: 1
V_NEW_NDLE2 Question 8: Injected in the last month was not selected, however this field was completed. Please review and delete, amend or press save and a discrepancy note will be logged.		Status: New	31/10/2011 by byeung

Update Note

Propose Resolution

[Begin New Thread](#)

Audit History

Audit Event	Date/Time of Server	User	Value Type	Old	New
Item data value updated	31/10/2011 15:58:13	byeung	NEW_NDLE		1
Item data status changed	31/10/2011 15:58:13	byeung	NEW_NDLE	available	unavailable

Then click on **Propose Resolution**

Also from the discrepancy note, the user can see the Audit history of the field.

PREG_DT: Notes and Discrepancies

"PREG_DT" Properties:

Subject: **Sharmila** Event: **BL**
Event Date: **30/09/2011** CRF: **Visit**
Current Value: **12/12/2012** More: [Data Dictionary](#)
[Audit History](#)

Note Details

☐ **LAB_PREG_DT Pregnancy test date: Date should not be in the future or greater than one week post visit date. Please review and amend or press save and a discrepancy note will be logged.**

Last updated: **05/10/2011** by shasri
Assigned to: **()**

ID: **806**

Type: **Failed Validation Check**

Current Status: **New**

of Notes: **1**

LAB_PREG_DT Pregnancy test date: Date should not be in the future or greater than one week post visit date. Please review and amend or press save and a discrepancy note will be logged.

Status: **New**

05/10/2011 by shasri

[Update Note](#)

[Propose Resolution](#)

Respond below to Update/Resolve/Close this Discrepancy Note:

[?](#) [X](#)

Description:*

Local Lab_Pregnancy test date

Detailed Note:

Date entered in error; correct date is 10/10/2010

Set to Status:*

Resolution Proposed

[Submit](#)

[Submit & Exit](#)

Enter the description (e.g. Section name or number and Question name or number) and detailed note (e.g. correct value or explanation for not providing the data) then click either 'submit' or 'submit & exit'.

Submit action will display the edited notes and discrepancies. Submit & Exit action will update and close the note and discrepancy.

Once the resolution has been proposed by the site the Kirby Institute Study Coordinator/ Data Manager will review the proposed resolution and if there is any additional information required will change it to 'updated'. If resolved it will be changed to 'Closed' by the Kirby Institute Data Manager.

Marking a CRF Complete

On the last page of each CRF will be a box labelled 'Mark CRF Complete. This box is used to indicate that data entry is complete and the data is ready for source verification by the Kirby Institute Study Coordinator/ or Study monitor. This box should only be checked upon instruction from the Kirby Institute.

Marking a CRF as signed

The Investigator at your site is the only person who can mark the CRF as being signed once he/she has reviewed the CRFs and believes them to be complete and accurate.

The CRFs should only be signed once all the information and discrepancies have been completed and The Kirby Institute Study Coordinator has advised your Investigator to do so.





Removing a Subject or Changing Subject Identifiers

Occasionally errors are made and in the event that you incorrectly enrol a subject you must contact your Kirby Institute Study Coordinator.

As a site research nurse you do not have access to remove subjects or change subjects enrolment details such as the subject identifier, gender, date of birth, enrolment date.

If you require any of these items changed you should open the Study subject record and add a discrepancy note to the appropriate field that requires change.

[Study Subject Record](#)

Study Subject ID	Sharmila	Person ID	
Secondary ID		Date of Birth	
OID	SS_SHARMILA	Sex	 Female
Status	available	Enrollment Date	 15/09/2010
Study Name	ATAHC II	Site Name	

[Audit Logs](#) | [Edit Record](#)

Date of Birth: Add Discrepancy Note

"Date of Birth" Properties:

Subject:	SS2	Event:	N/A
Event Date:	21/11/2011	CRF:	N/A
Current Value:		More:	N/A

Add Note

Description:*	<input type="text" value="Subject detail_DOB"/>
Detailed Note:	<div>DOB was entered in error; please change the DOB to 16/11/1980.</div>
Type:*	<div>Failed Validation Check</div>
Set to Status:*	<div>Resolution Proposed</div>

[Submit & Close](#)

Getting Help

You can get help from various places in OpenClinica.

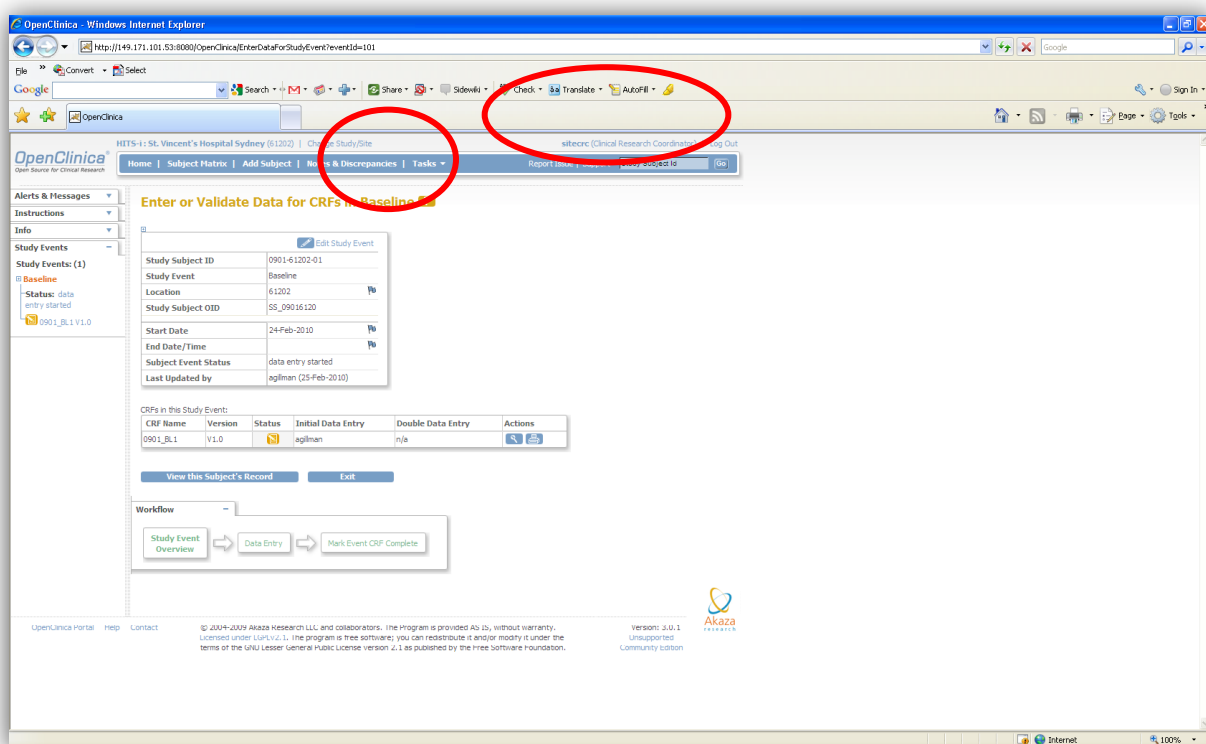
Many items in OpenClinica will have a '?' symbol next to them. Clicking on '?' will take you to the OpenClinica Online associated with that item.

Clicking on 'Report Issue' will allow you submit details of a problem to the software company

Clicking on 'Support' will take you to details of the software company's support packages.



For the fastest and most reliable support email your KIRBY INSTITUTE Study Coordinator/Data Manager with your question or problem



Internet Explorer (IE) Trouble shooting

If the site is using Internet Explorer version 8 (IE8) the compatibility view mode should be set and the "Automatically recover from page layout errors with Compatibility View" should be unchecked to prevent data being changed by IE during data entry where xml rules are running.

To do this, open IE8, From Tools menu-> Internet Options> Advanced> Browsing> uncheck "Automatically recover from page layout errors with Compatibility View."

