

OpenClinica: Data Manager Role

Introduction

- In the following document there is an overview of using OpenClinica as a Data Manager. This is a summary of the key points. It is derived from the OpenClinica User documentation and experience.
- The Openclinica User documentation can be obtained at: <https://docs.openclinica.com/3-1/>. There is also a *.pdf copy of the documentation on the study website. It is comprehensive and its encompasses the entire system not just its usage as a Data Manager.
- The summary is presented as a series of logical questions of Data Manager tasks that need to be done. These include:
 - How do I get a login?
 - How do I login?
 - How do I change my password?
 - How do I add a study subject?
 - How do I schedule an event?
 - How do I enter data?
 - Enter data: How do I supply contextual notes (Notes and Discrepancies)?
 - Enter data: How do I resolve data entry queries?
 - How do I complete a study subject?
 - How do I remove a study subject?
 - How do I provide feedback or notes issues with the database?
- We also cover study specific information.

How do I?

How do I get a login?

- To get a login, please contact the Study Coordinator, who will pass on your request.
- Please supply:
 - Your name
 - Your email address
 - Site

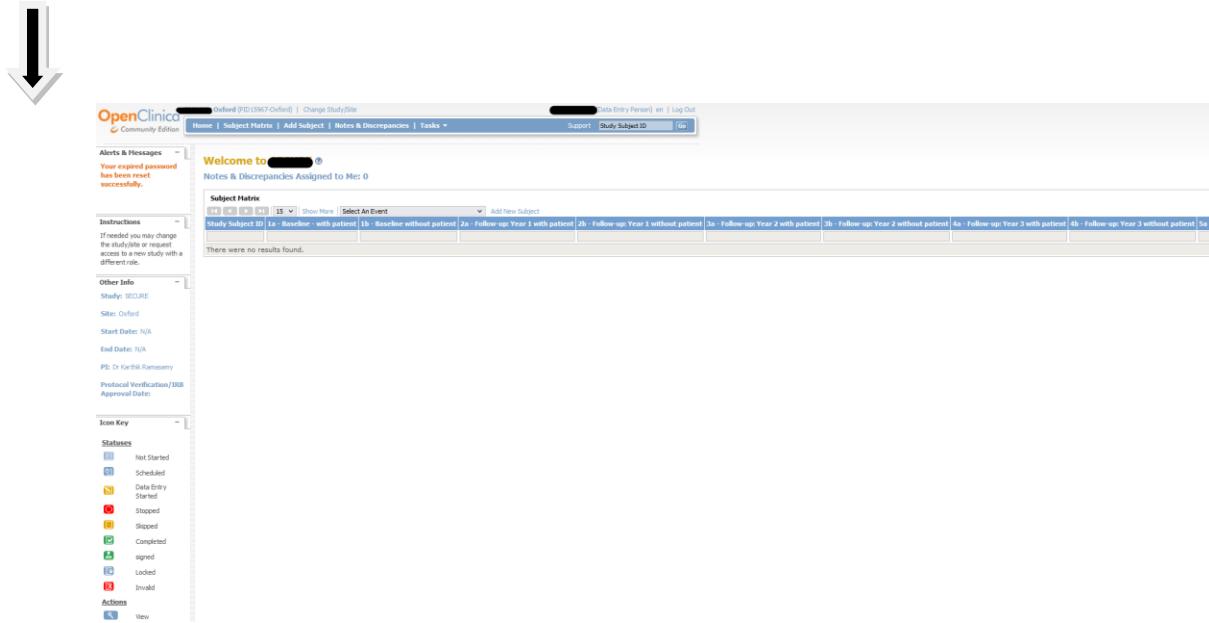
How do I login?

- Go to the login page: <https://study-url/prod>
- Enter your username as per the login details supplied

- Enter your password as per the login details supplied



OpenClinica Login Screen



OpenClinica Home Screen

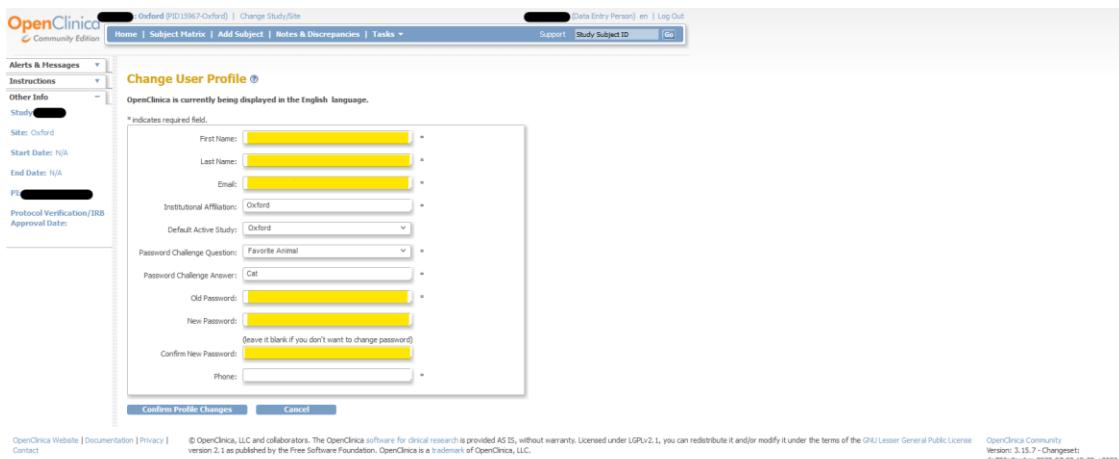
How do I change my password?

- Go to the Tasks menu, and hover over it and wait for the options to appear, then left-click on: **Update Profile** (highlighted in yellow)

OpenClinica Home Screen – hovering over Tasks

- In your case your First Name, Last Name, and Email will be pre-populated. Amend if desired.
- In:
 - Old Password: Enter current password
 - New Password: Enter your new password
 - Confirm New Password: Repeat your new password
 - **NB:** You may need to add a Phone entry. Feel free to add something nonsensical.





OpenClinica [REDACTED] Oxford (ID 1967-Oxford) | Change Study/Site [REDACTED] Data Entry Person [REDACTED] Log Out

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

Change User Profile

OpenClinica is currently being displayed in the English language.

* indicates required field.

First Name: [REDACTED]
Last Name: [REDACTED]
Email: [REDACTED]
Institutional Affiliation: Oxford
Default Active Study: Oxford
Password Challenge Question: Favorite Animal
Password Challenge Answer: Cat
Old Password: [REDACTED]
New Password: [REDACTED] (Leave it blank if you don't want to change password)
Confirm New Password: [REDACTED]
Phone: [REDACTED]

Confirm Profile Changes | Cancel

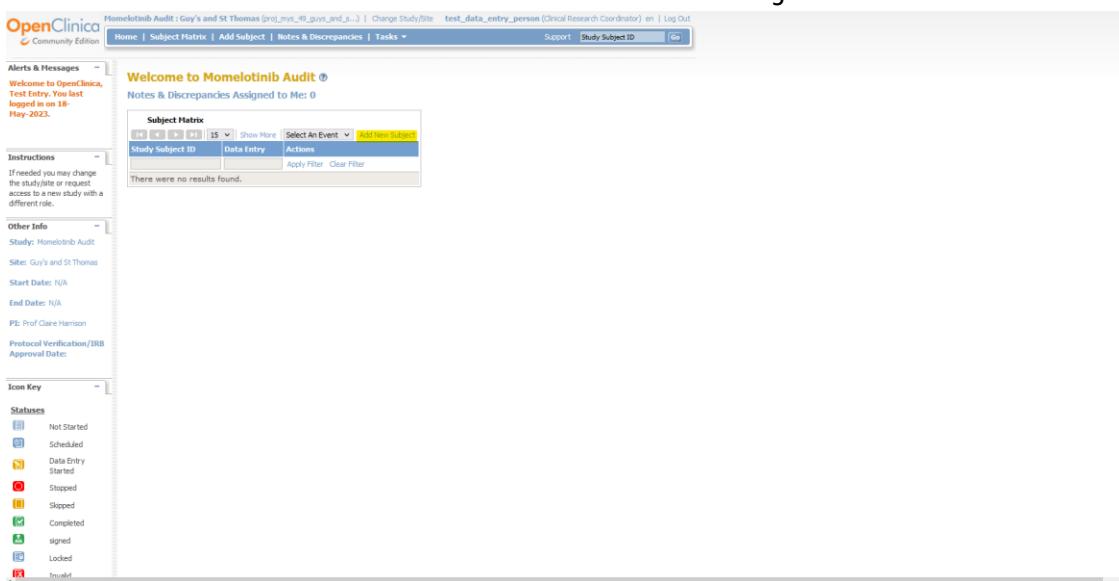
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Version: 3.15.7 - ChangeSet: de73c3efca 2020-07-09 18:28 +0000

OpenClinica Update Profile Page

How do I add a study subject?

- You can add a study subject in two ways:
- FIRST WAY:
 - From the Home Screen left-click on: Add New Subject



Homeotetinib Audit : Guy's and St Thomas [proj_mnt_49_guys_and_st_thomas] | Change Study/Site [REDACTED] test_data_entry_person (Clinical Research Coordinator) [REDACTED] Log Out

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

Welcome to Homeotetinib Audit

Notes & Discrepancies Assigned to Me: 0

Subject Matrix

Study Subject ID	Data Entry	Actions
		Add New Subject

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

Other Info

Study: Homeotetinib Audit
Site: Guy's and St Thomas
Start Date: N/A
End Date: N/A
PI: Prof Clare Harrison
Protocol Verification/IRB Approval Date:

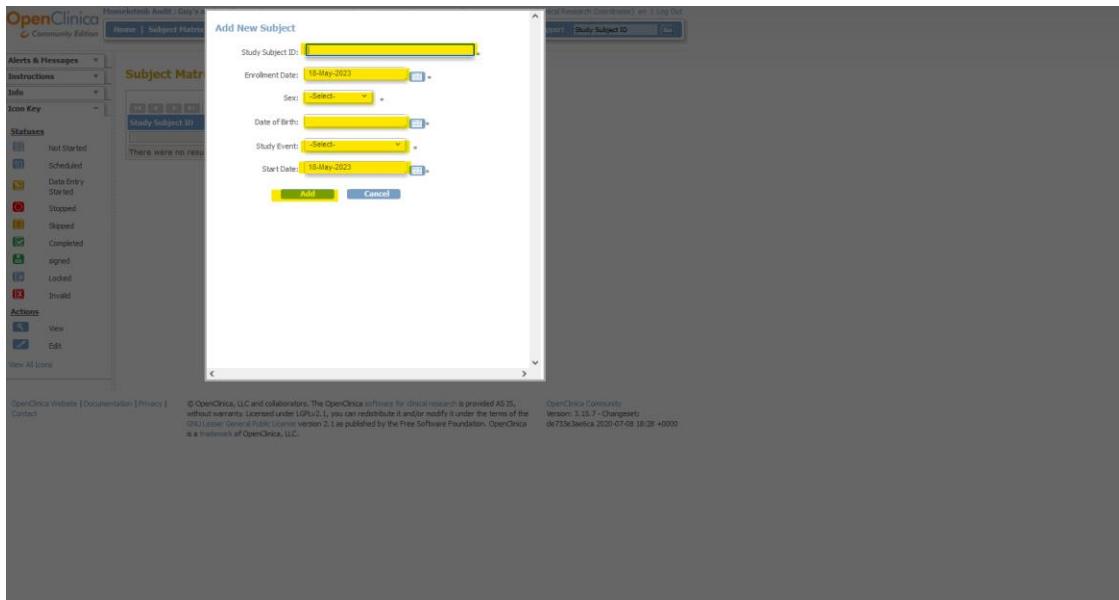
Icon Key

Statuses

- Not Started
- Scheduled
- Data Entry Started
- Stopped
- Skipped
- Completed
- Signed
- Locked
- In-Edit

OpenClinica Subject Matrix Screen

- Click on Add New Subject
- A modal (pop-up) will open (or should). Fill in the details and then click on Add:



OpenClinica Subject Matrix plus Add Subject Modal Screen

- **Study Subject Id:** How this is generated will be prescribed by the coordinating centre, but will generally have the form of a location code and sequential number. E.g. GST-001, GST-002, GST-003, ... GST-nnn
- **Enrolment Date:** The desired enrolment date. By convention this is the date of informed consent or (after informed consent) when the patient is added to the database.
- **Sex:** Add the participants biological sex. *In some cases this might be missing depending on how OpenClinica is configured.*
- **Date of Birth:** Add the participants date of birth. *In some cases this might be missing depending on how OpenClinica is configured.*
- **Study Event:** The study event you want to schedule, this by convention is the first or initial study event in the protocol if there are more than one.
- This will take you the events section of the subject record
 - Ensure that the latest version of the form has been scheduled
 - You can then begin entering data.
- This will lead you to the subject record for starting data entry

OpenClinica Subject Screen

- SECOND WAY:
 - Go to the Tasks menu, and hover over it and wait for the options to appear, then left-click on: Subject Matrix (highlighted in yellow) – this will work from wherever you are in OpenClinica

OpenClinica Notes and Discrepancies



- This will take you to the Subject Matrix, then click on the Add Subject button.



OpenClinica Subject Matrix

- A modal (pop-up) will open (or should). Fill in the details and then click on Add:

OpenClinica Home Screen plus Add Subject Modal Screen



- This will lead you to the subject record for starting data entry

OpenClinica
Community Edition

Homeolab Audit : Guy's and St Thomas (proj_myg_49_guys_and_st...) | Change Study/Site | test_data_entry_person (Clinical Research Coordinator) en | Log Out

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

Alerts & Messages

The Subject with unique identifier 'GST-TEST-003' was created successfully.

View Subject: GST-TEST-003

(1) Study Subject Record
(2) Events

Page 1 of 1

Schedule New Event

Event (Occurrence Number)	Start Date	Location	Status	Actions	CRFs (Name, Version, Status, Updated, Actions)																														
Data Entry	18-May-2023		scheduled		<table border="1"><tr><td>001-Characteristica</td><td>0.1</td><td></td><td></td><td></td></tr><tr><td>002-Comorbidities</td><td>0.1</td><td></td><td></td><td></td></tr><tr><td>003-Therapies-Pre-Momeolab</td><td>0.1</td><td></td><td></td><td></td></tr><tr><td>004-Homeolab-Treatment</td><td>0.1</td><td></td><td></td><td></td></tr><tr><td>005-Discontinuation</td><td>0.1</td><td></td><td></td><td></td></tr><tr><td>006-Last-Contact</td><td>0.1</td><td></td><td></td><td></td></tr></table>	001-Characteristica	0.1				002-Comorbidities	0.1				003-Therapies-Pre-Momeolab	0.1				004-Homeolab-Treatment	0.1				005-Discontinuation	0.1				006-Last-Contact	0.1			
001-Characteristica	0.1																																		
002-Comorbidities	0.1																																		
003-Therapies-Pre-Momeolab	0.1																																		
004-Homeolab-Treatment	0.1																																		
005-Discontinuation	0.1																																		
006-Last-Contact	0.1																																		

(3) Group
(4) Global Subject Record
(5) Subject Casebook

Go Back to Subject List

Icon Key

Statuses

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

Actions

- View
- Edit

[View All Icons](#)

OpenClinica Subject Screen

How do I schedule an event?

- Outside the registering the patient you can schedule an event two ways:
 1. Via the Subject Matrix

Via the Subject Matrix

OpenClinica Community Edition

Home | Subject Matrix | Add Subject | Notes & Discrepancies | Tasks | Support | Study Subject ID | Log Out

Alerts & Messages

Instructions

Info

Icon Key

Statuses

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

Actions

- View
- Edit

View All Icons

Change StudySite

Subject Matrix for Lincolnshire Clinical Research Facility

Show More | Select An Event | Add New Subject

Study Subject ID	Study Start / End	Baseline	3 Months	6 Months	9 Months	12 Months	18 Months	24 Months	30 Months	36 Months	42 Months	48 Months	54 Months	60 Months	Progression	Non-mandatory Imaging	Actions
009-TEST-1	15	15	15	15	15	15	15	15	15	15	15	15	15	15	15	15	15
009-TEST-2	15	15	15	15	15	15	15	15	15	15	15	15	15	15	15	15	15

Results 1 - 2 of 2.

OpenClinica Subject Matrix





OpenClinica Subject Matrix

OpenClinica Event Schedule



2-Medical-and-Examination 1.2 

009-TEST-2

CRF Header Info

Comorbidity (23) Comorbidity (21) Clinical (24)

Page: - Select to Jump -

No Comorbidities If there are no comorbidities then choose "Yes" otherwise leave

Myocardial Infarction: 

Congestive Heart: 

Failure: 

Hypertension: 

Peripheral Vascular Disease: 

Stroke / TIA: 

Dementia: 

Chronic Obstructive Pulmonary Disease: 

Connective Tissue Disease: 

Peptic Ulcer Disease: 

Liver Disease Mid: 

Diabetes Mellitus: 

Hemiplegia: 

Moderate to Severe Chronic Kidney Disease: 

Diabetes - end organ damage: 

Any Malignancy: 

Leukaemia: 

Lymphoma: 

OpenClinica eCRF

2. Via the Subject Record

- The Subject Record is accessed by clicking on the Study Subject ID link

OpenClinica Community Edition

Change Study/Site Data Entry Person: en | Log Out

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

Alerts & Messages  Instructions  Info  Icon Key 

Not Started  Scheduled  Data Entry Started  Skipped  Completed signed  Locked  Invalid  Actions  View  Edit 

View All Icons

Subject Matrix for Lincolnshire Clinical Research Facility 

Study Subject ID: 009-TEST-1 | Study Start / End: Baseline | 3 Months | 6 Months | 9 Months | 12 Months | 18 Months | 24 Months | 30 Months | 36 Months | 42 Months | 48 Months | 54 Months | 60 Months | Progression | Non-mandatory Imaging | Actions

009-TEST-1                                <img alt="Icon" data-bbox="7268 541 72

OpenClinica Community Edition

Change Study Site Data Entry Person: en | Log Out

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

View Subject: 009-TEST-1

0 Study Subject Record
0 Events

Page 1 of 1 Find Schedule New Event

Event (Occurrence Number)	Start Date	Location	Status	Actions	CRFs (Name, Version, Status, Updated, Actions)
Study Start / End	09-Jun-2023		scheduled	<input checked="" type="checkbox"/>	1-Study-Beginning-and-End 1.3 <input type="button" value="View"/> <input type="button" value="Edit"/> <input type="button" value="Delete"/>

0 Group
0 Global Subject Record
0 Subject Casebook

Go Back to Subject List

Icon Key

Statuses

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

Actions

-
-

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OpenClinica Subject



- Ensure the version is set to the latest and then click on the data entry button

OpenClinica Community Edition

Change Study Site Data Entry Person: en | Log Out

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

View Subject: 009-TEST-1

0 Study Subject Record
0 Events

Page 1 of 1 Find Schedule New Event

Event (Occurrence Number)	Start Date	Location	Status	Actions	CRFs (Name, Version, Status, Updated, Actions)
Study Start / End	09-Jun-2023		scheduled	<input checked="" type="checkbox"/>	1-Study-Beginning-and-End 1.3 <input type="button" value="View"/> <input type="button" value="Edit"/> <input type="button" value="Delete"/>

0 Group
0 Global Subject Record
0 Subject Casebook

Go Back to Subject List

Icon Key

Statuses

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

Actions

-
-

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OpenClinica Subject



2-Medical-and-Examination 1.2 

009-TEST-2

CRF Header Info

Comorbidity (0/23) Comorbidity (0/1) Clinical (0/4) - Select to Jump -

Title: Comorbidities

Instructions: If you have other comorbidities you wish to record outside this form then please use the next tab

Page: 

No Comorbidities If there are no comorbidities then choose "Yes" otherwise leave

Myocardial Infarction: 

Congestive Heart: 

Failure: 

Hypertension: 

Peripheral Vascular Disease: 

Stroke / TIA: 

Dementia: 

Chronic Obstructive Pulmonary Disease: 

Connective Tissue Disease: 

Peptic Ulcer Disease: 

Liver Disease Milrin: 

Diabetes Mellitus: 

Hemiplegia: 

Moderate to Severe Chronic Kidney Disease: 

Diabetes - end organ damage: 

Any Malignancy: 

Leukaemia: 

Lymphoma: 

OpenClinica eCRF

How do I enter data?

- Fill in the form like any other web-form.
- Ensure you save the form (you will be prompted)

001-Characteristics-v0-2 0.2 

GST-TEST-003

CRF Header Info

Blood (0/7) Physical (0/4) Genetics (0/0) - Select to Jump -

Title: Physical

Page: 

Spleen at dx: 

Symptoms: 

PB Blasts at dx: 

Transfusion dependent at dx: 

at dx: 



OpenClinica eCRF



- You cannot save the form if you have not provided compulsory data. You *can* save without providing the data if a relevant discrepancy note is generated. Click on the relevant flag (highlighted in yellow)

001-Characteristics-v0-2 0.2

GST-TEST-003

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

- [Missing data in a required field.]
- [Missing data in a required field.]

Physical (0/4)

Title: Physical

Page: Save Exit

Spleen at dx: [] 10 (cm)

Symptoms: Please enter * 10

PB Blasts at dx: [] 10 (%)

Transfusion dependent at dx: * 10

Return to top Save Exit

OpenClinica eCRF plus Discrepancy Note



- Ensure you add the description and any pertinent extra information and then submit.

characteristics_diagnosis_physical_spleen_at_dx: Add Discrepancy Note

characteristics_diagnosis_physical_spleen_at_dx Properties

Subject: GST-TEST-003 Event: Data Entry

Event Date: 18-May-2023 CRF: 001-Characteristics-v0-2 0.2

Current Value: None Data Dictionary

Add Note

Description: * No data

Detailed Note: [Missing data in a required field.]

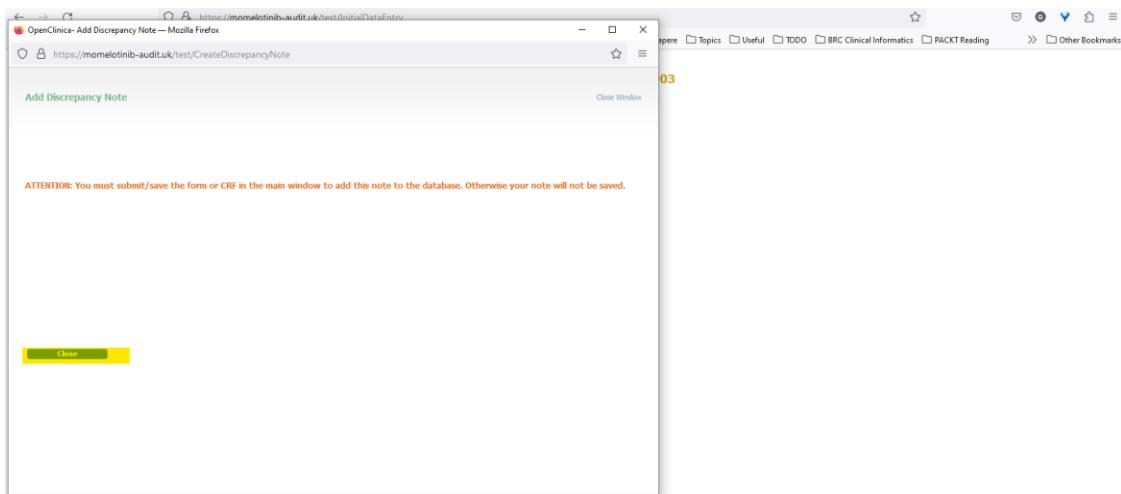
Type: * Failed Validation Check

Set to Status: * New

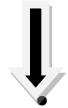
Save

OpenClinica eCRF plus Discrepancy Note





OpenClinica eCRF plus Discrepancy Modal



You can now save.

001-Characteristics-v0-2 0.2

GST-TEST-003

▼ 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.]
• [Missing data in a required field.]

Physical (0/4)

Title: Physical

Page:

Spleen at dx: cm

Symptoms: Please enter %

PB Blasts at dx: %

Transfusion dependent %
at dx:

OpenClinica eCRF

Enter data: How do I supply contextual notes (Notes and Discrepancies)?

- The system is the same as for addressing compulsory data fields, but instead of the system forcing you to click the flag, you click it optionally and then fill in the relevant details.
- Essentially the same as above.
- The following shows adding a comment.

001-Characteristics-v0-2 0.2

GST-TEST-003

CRF Header Info

Physical (2/4) Genetics (0/3) NGS (0/1) Select to Jump

Title: Genetics

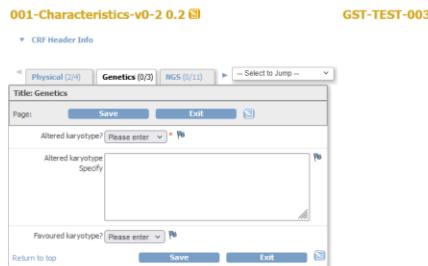
Page: Save Exit

Altered karyotype? Please enter * 10

Altered karyotype
Specify

Preferred karyotype? Please enter * 10

Return to top Save Exit



OpenClinica eCRF



001-Characteristics-v0-2 0.2 ⓘ

GST-TEST-003

▼ CRF Header Info

Physical (2/4) Genetics (0/2) NGS (0/1) > Select to Jump

Title: Genetics

Page: Save Exit

Altered karyotype? Please enter ⓘ

Altered karyotype
Specify

Flavoured karyotype? Please enter ⓘ

Return to top Save Exit

OpenClinica eCRF



OpenClinica- Add Discrepancy Note — Mozilla Firefox

characteristics_diagnosis_genetics_altered_karyotype: Add Discrepancy Note

"characteristics_diagnosis_genetics_altered_karyotype" Properties

Subject: GST-TEST-003 Event: Data Entry

Event Date: 18-May-2023 CRF: 001-Characteristics-v0-2 0.2

Current Value: More: Data Dictionary

Add Note

Description: ⓘ

Detailed Note:

Type: ⓘ Annotation

Set to Status: ⓘ Not Applicable

Submit

OpenClinica eCRF



OpenClinica- Add Discrepancy Note — Mozilla Firefox

characteristics_diagnosis_genetics_altered_karyotype: Add Discrepancy Note

"characteristics_diagnosis_genetics_altered_karyotype" Properties

Subject: GST-TEST-003 Event: Data Entry

Event Date: 18-May-2023 CRF: 001-Characteristics-v0-2.0.2

Current Value: More: Data Dictionary

Add Note

Description:

Detailed Note:

Type:

Set to Status:

Submit

OpenClinica eCRF



OpenClinica- Add Discrepancy Note — Mozilla Firefox

characteristics_diagnosis_genetics_altered_karyotype: Add Discrepancy Note

"characteristics_diagnosis_genetics_altered_karyotype" Properties

Subject: GST-TEST-003 Event: Data Entry

Event Date: 18-May-2023 CRF: 001-Characteristics-v0-2.0.2

Current Value: More: Data Dictionary

Add Note

Description:

Detailed Note:

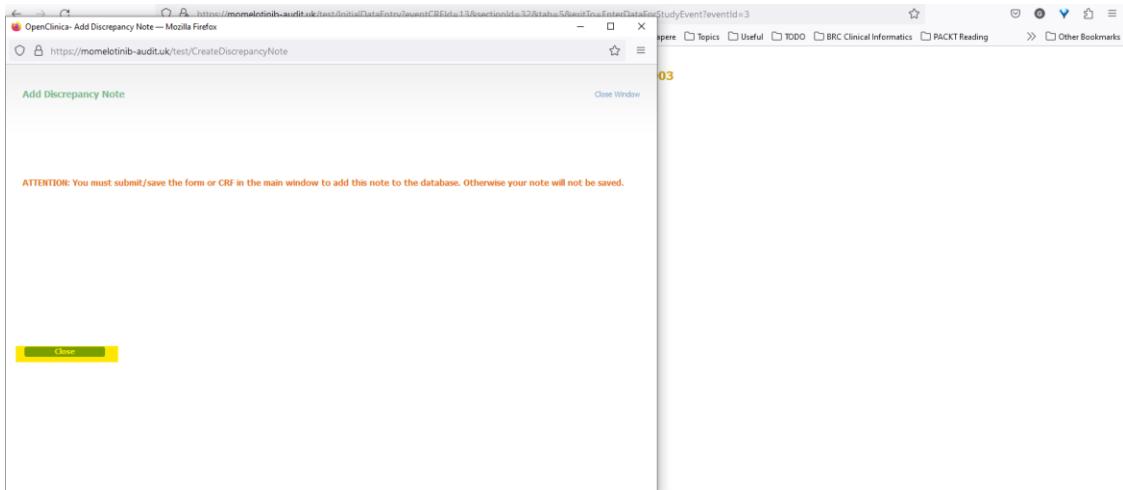
Type:

Set to Status:

Submit

OpenClinica eCRF





OpenClinica eCRF



OpenClinica eCRF

Enter data: How do I resolve data entry queries?

- The resolution of data entry queries happens via a separate role. You don't have to resolve notes or comments.

How do I complete a study subject?

- Complete all the tabs of the eCRFs and then select 'Mark CRF Complete'
- **Please ensure that ALL the data and discrepancies have been addressed because this locks the form and it is not straight-forward to unlock it again.**

How do I remove a study subject?

- This user role cannot delete study subjects. To remove a study subject either contact the coordinating study centre or ask someone in your team who have the permission to remove the subject.

How do I provide feedback or notes issues with the database?

Study Specific Instructions

- No study specific instructions.