

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

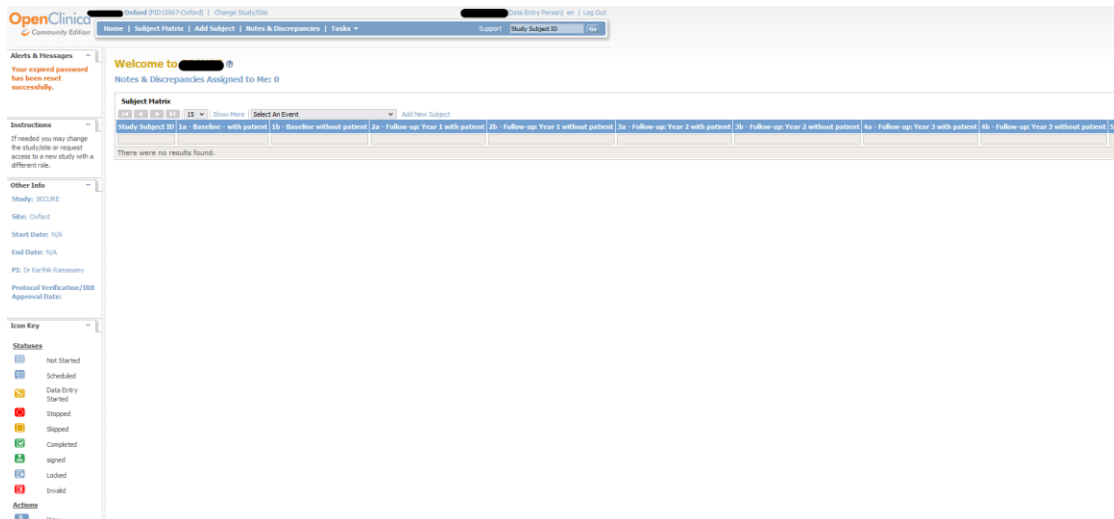
How do I login?

- 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



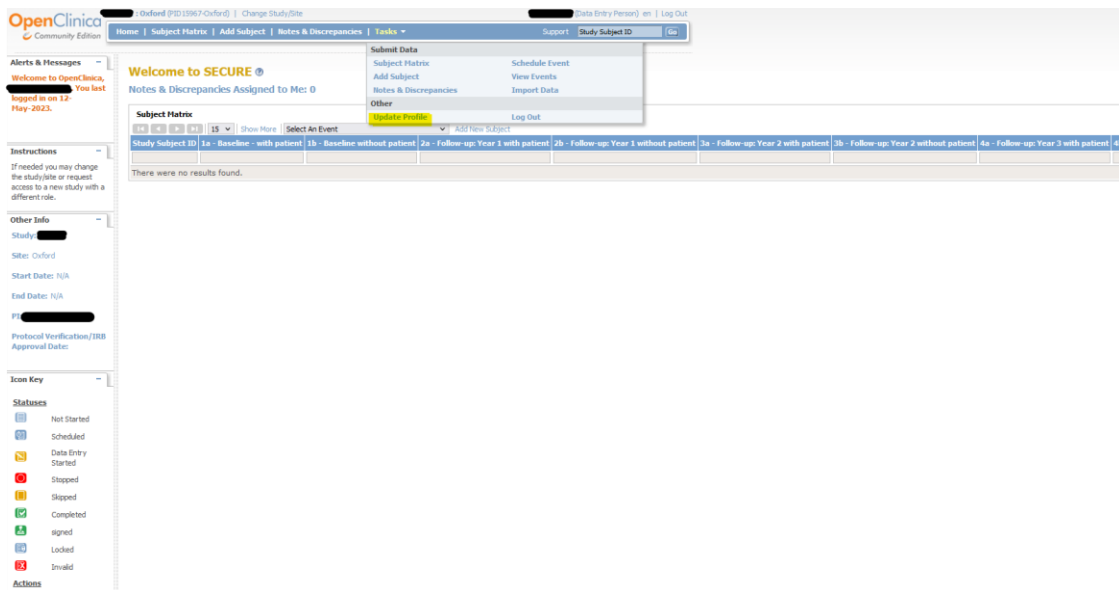
OpenClinica Login Screen



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 Community Edition

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

Alerts & Messages

Instructions

Other Info

Study: [Redacted]

Site: Oxford

Start Date: N/A

End Date: N/A

PI: [Redacted]

Protocol Verification/IRB Approval Date:

Change User Profile

OpenClinica is currently being displayed in the English language.

* indicates required field.

First Name:

Last Name:

Email:

Institutional Affiliation:

Default Active Study:

Password Challenge Question:

Password Challenge Answer:

Old Password:

New Password:

Confirm New Password:

Phone:

Confirm Profile Changes Cancel

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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

OpenClinica Community Edition

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

Alerts & Messages

Welcome to OpenClinica, Test Entry. You last logged in on 18 May 2023.

Instructions

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

Other Info

Study: Mometotinib 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

Completed

signed

Locked

Invalid

Welcome to Mometotinib Audit

Notes & Discrepancies Assigned to Me: 0

Subject Matrix

Study Subject ID Data Entry Actions

There were no results found.



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 Community Edition

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.

Instructions

Other Info

Study: Homedrb Audit

Site: Guy's and St Thomas

Study Subject ID: GST-TEST-003

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

Invalid

Actions

View

Edit

View All Icons

View Subject: GST-TEST-003

Study Subject Record

Events

Page 1 of 1

Event (Occurrence Number) | Start Date | Location | Status | Actions | CRFs (Name, Version, Status, Updated, Actions)

Event (Occurrence Number)	Start Date	Location	Status	Actions	CRFs (Name, Version, Status, Updated, Actions)
Data Entry	18-May-2023		Scheduled		001-Characteristics 0.1 002-Consent/Identities 0.1 003-Therapies-Pre-Homedrb 0.1 004-Homedrb-Treatment 0.1 005-Discontinuation 0.1 006-Last-Contact 0.1

Group: Global Subject Record

Subject Cardbook

Go Back to Subject List

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 Community Edition

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

Alerts & Messages

The table lists discrepancy notes that have been created for a given study/site and by default displays the oldest items first. Sort or filter using the column headers. To view or update the note, please select the "View" or "New within record" action icons.

Instructions

Other Info

Study: Homedrb Audit

Site: Guy's and St Thomas

Start Date: N/A

End Date: N/A

PI: Prof Clare Harrison

Protocol Verification/IRB Approval Date:

Submit Data

Subject Matrix

Add Subject

Notes & Discrepancies

Other

Update Profile

Log Out

Workflow

Manage Study

Notes and Discrepancies

There were no results found.

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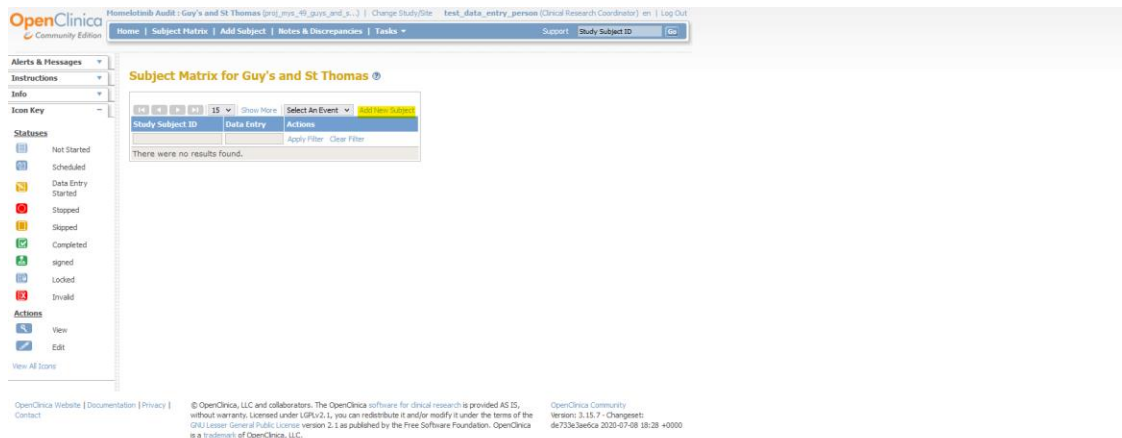
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OpenClinica Notes and Discrepancies



- 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 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

OpenClinica Subject Matrix



OpenClinica Community Edition

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

Study Subject ID: [Search] Go

Alerts & Messages

Instructions

Info

Icon Key

Not Started

Scheduled

Data Entry Started

Stopped

Skipped

Completed

Signed

Locked

Invalid

Actions

View

Edit

View All Icons

Subject Matrix for Lincolnshire Clinical Research Facility

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																	Apply Filter Clear Filter
009-TEST-2																	

Results 1 - 2 of 2.

Subject: 009-TEST-2 X
Event: Baseline
Status: not scheduled

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OpenClinica Subject Matrix

OpenClinica Community Edition

Change Study/Site

Study Subject ID: [Search] Go

Alerts & Messages

Instructions

Other Info

Study: C03N05

Site: Lincolnshire Clinical Research Facility

Start Date: 13-Jan-2022

End Date: N/A

PI: Charlotte Kallmeyer

Protocol Verification/IRB Approval Date:

Schedule Study Event for 009-TEST-2

* indicates required field.

Study Subject ID: 009-TEST-2

Study Event Definition: Baseline (Non-repeating)

Start Date/Time: 09-Jun-2023

End Date/Time:

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

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OpenClinica Event Schedule

CRF Header Info

Comorb..._0020 Comorb..._001 Clinica..._004 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: Save Exit

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

Myocardial Infarction Select No

Congestive Heart Failure Select No

Hypertension Select No

Peripheral Vascular Disease Select No

Stroke / TIA Select No

Dementia Select No

Chronic Obstructive Pulmonary Disease Select No

Connective Tissue Disease Select No

Peptic Ulcer Disease Select No

Liver Disease HMI Select No

Diabetes Mellitus Select No

Hemiplegia Select No

Moderate to Severe Chronic Kidney Disease Select No

Diabetes - end organ damage Select No

Any Malignancy Select No

Leukaemia Select No

Lymphoma Select No

OpenClinica eCRF

2. Via the Subject Record

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

OpenClinica Community Edition

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

Support Study Subject ID Go

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

Subject Matrix for Lincolnshire Clinical Research Facility

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

009-TEST-2

Results 1 - 2 of 2.

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OpenClinica Subject Matrix



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

Other Info

Study: COSMOS

Site: Lincolnshire Clinical Research Facility

Start Date: 13-Jan-2022

End Date: N/A

PI: Charlotte Kallmeyer

Protocol Verification/IRB Approval Date:

Icon Key

Statuses

Not Started

Scheduled

Data Entry Started

Stopped

Skipped

Completed

signed

Locked

Invalid

Actions

View

Edit

View All Icons

View Subject: 009-TEST-1

Study Subject Record

Events

Page 1 of 1

Event (Occurrence Number)	Start Date	Location	Status	Actions: CRFs (Name, Version, Status, Updated, Actions)
Study Start / End	09-Jun-2023		scheduled	1-Study-Beginning-and-End 1.3 v [View] [Edit] [Delete]

Group

Global Subject Record

Subject Casebook

Go Back to Subject List

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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

Alerts & Messages

Instructions

Other Info

Study: COSMOS

Site: Lincolnshire Clinical Research Facility

Start Date: 13-Jan-2022

End Date: N/A

PI: Charlotte Kallmeyer

Protocol Verification/IRB Approval Date:

Icon Key

Statuses

Not Started

Scheduled

Data Entry Started

Stopped

Skipped

Completed

signed

Locked

Invalid

Actions

View

Edit

View All Icons

View Subject: 009-TEST-1

Study Subject Record

Events

Page 1 of 1

Event (Occurrence Number)	Start Date	Location	Status	Actions: CRFs (Name, Version, Status, Updated, Actions)
Study Start / End	09-Jun-2023		scheduled	1-Study-Beginning-and-End 1.3 v [View] [Edit] [Delete]

Group

Global Subject Record

Subject Casebook

Go Back to Subject List

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OpenClinica Subject



CRF Header Info

Comorb... (2/25) Comorb... (2/1) Clinica... (2/4) 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: Save Exit

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

Myocardial Infarction No

Congestive Heart Failure No

Hypertension No

Peripheral Vascular Disease No

Stroke / TIA No

Dementia No

Chronic Obstructive Pulmonary Disease No

Connective Tissue Disease No

Peptic Ulcer Disease No

Liver Disease Mild No

Diabetes Mellitus No

Hemiplegia No

Moderate to Severe Chronic Kidney Disease No

Diabetes - end organ damage No

Any Malignancy No

Leukaemia No

Lymphoma No

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)

CRF Header Info

Blood (2/7) Physical (2/4) Genetics (2/3) Select to Jump

Title: Physical

Page: Save Exit

Spleen at doc No (m)

Symptoms No

PS (Blasts at doc No (%))

Transfusion dependent No at doc

Return to top: Save Exit

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)

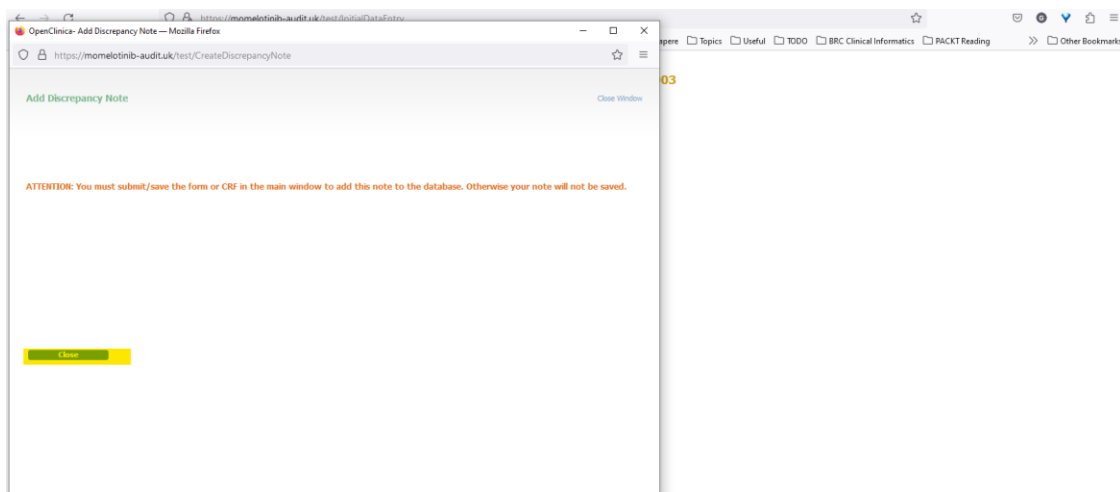
OpenClinica eCRF plus Discrepancy Note



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

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.]


Blood (2/7) **Physical (2/4)** Genetics (2/3) → Select to Jump →


Title: Physical


Page: Save Exit 

Spleen at div: ! ! (s) 

Symptoms: Please enter ▼ No 

PB Starts at div: ! ! (s) 

Transfusion dependent: Please enter ▼ No 

Return to top Save Exit 

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)**  -- Select to Jump --

Title: Genetics

Page: 

Altered karyotype? 

Altered karyotype Specify 

Paired karyotype? 




OpenClinica eCRF





001-Characteristics-v0-2 0.2  GST-TEST-003


CRF Header Info


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


Title: Genetics

Page: 

Altered karyotype? 

Altered karyotype Specify 

Favoured karyotype? 



OpenClinica eCRF



OpenClinica- Add Discrepancy Note — Mozilla Firefox

https://momelotinib-audit.uk/test/CreateDiscrepancyNote?isGroup=-1&eventCRFid=13&subjectid=3&itemid=199&groupLabel=3sec

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:

OpenClinica eCRF



OpenClinica - Add Discrepancy Note - Mozilla Firefox

https://momelotnib-audit.uk/test/initialDataEntry/subjectCRFId=13§ionId=32&tab=5&eventTrs=EnterDataForStudyEvent?eventId=3

characteristics_diagnosis_genetics_altered_karyotype: Add Discrepancy Note

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: *

Annotation

Failed Validation Check

Annotation

Reason for Change

OpenClinica eCRF



OpenClinica - Add Discrepancy Note - Mozilla Firefox

https://momelotnib-audit.uk/test/initialDataEntry/subjectCRFId=13§ionId=32&tab=5&eventTrs=EnterDataForStudyEvent?eventId=3

characteristics_diagnosis_genetics_altered_karyotype: Add Discrepancy Note

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: *

Annotation

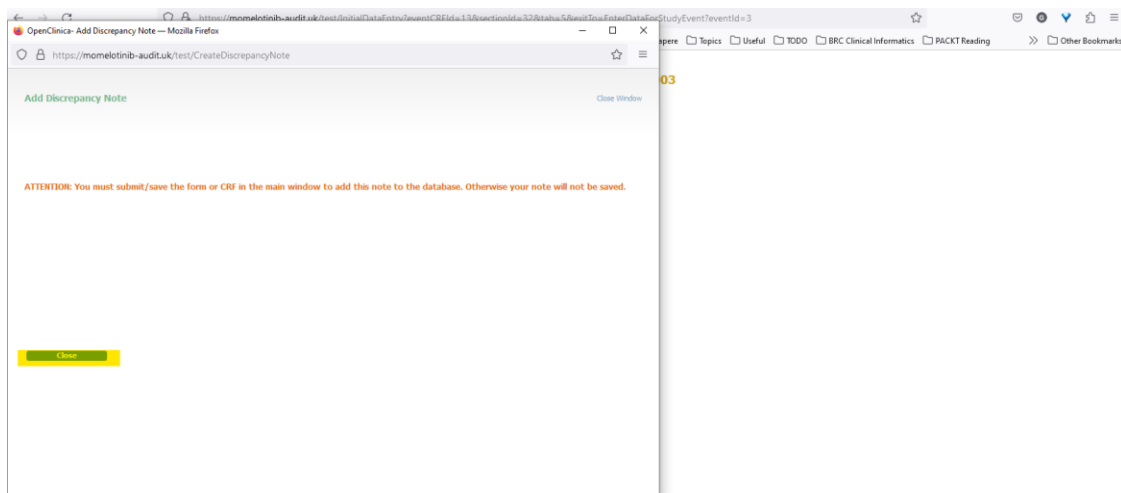
Failed Validation Check

Annotation

Reason for Change


OpenClinica eCRF





OpenClinica eCRF



001-Characteristics-v0-2 0.2  GST-TEST-003

CRF Header Info





Physical (1/4) **Genetics (0/3)**  Select to Jump --


Table: Genetics

Page: 

Altered karyotype?  RB

Altered karyotype Specify

Revised karyotype? 



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.