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QUARTZ LUNG

eCRF Completion Guidelines

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Prospective, randomised, multicentre trial of first line systemic treatment and radiotherapy in stage IV non-small cell lung cancer.

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Role	Name	Signature	Date
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For general enquiries or access issues relating to Medidata Rave, please contact a Southampton Clinical Trials Unit representative via email at: tourist-quartzlung@soton.ac.uk or by telephone on 02381 205154.

For technical problems (e.g. password resets), please contact the appropriate Medidata help desk via the email or telephone numbers given below:-

Medidata RAVE EDC Helpdesk Details			
Software Supplier	Medidata	**Software Name**	Medidata RAVE EDC
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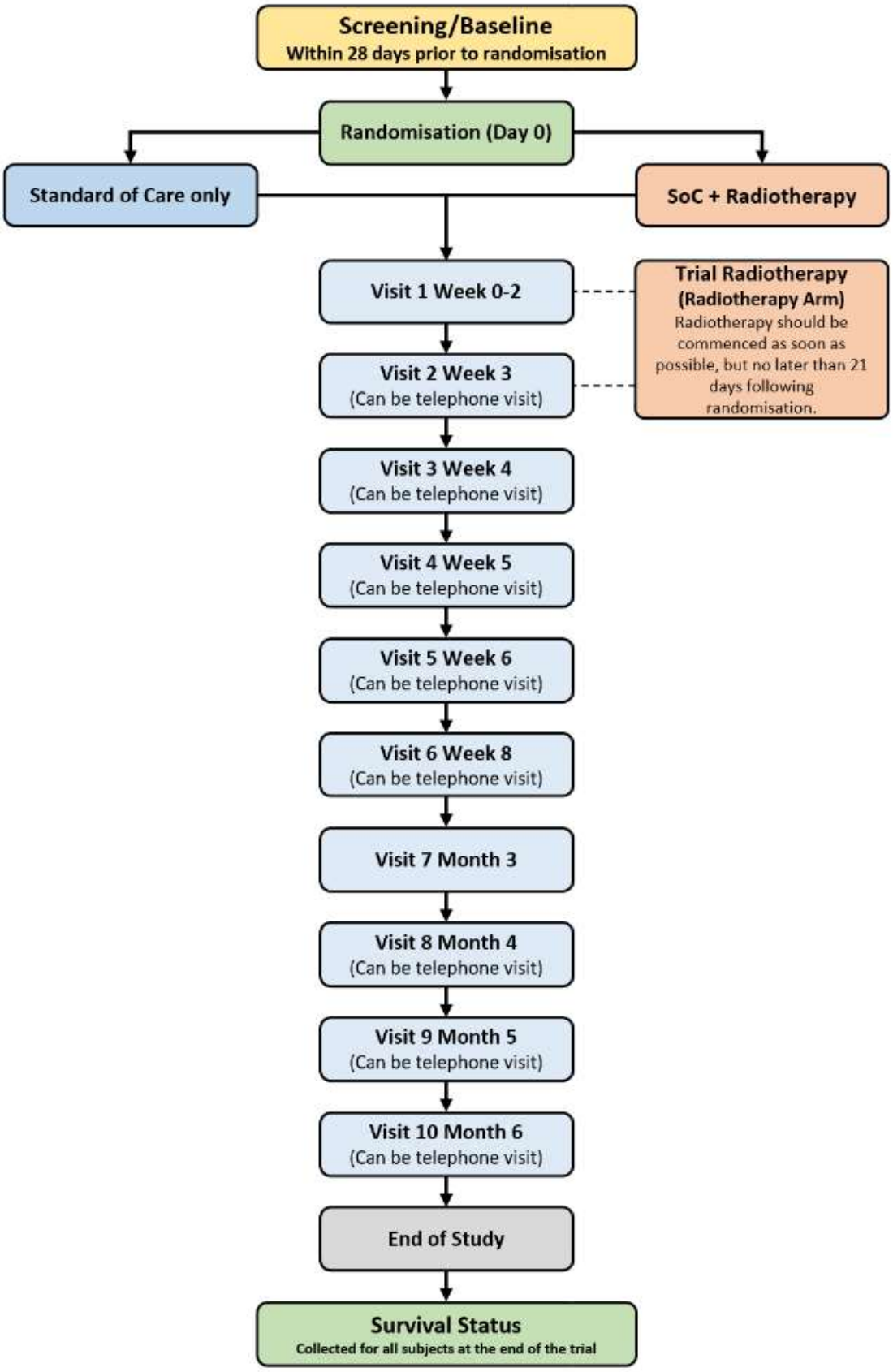
1. OVERVIEW OF TRIAL VISITS



2. QUARTZ LUNG SPECIFIC FORMS

Not all forms available within the database have been explained here, only those which have specific data requirements or a high likelihood of non-conformant data.

Please note that except for unknown concomitant medication start dates and previous treatment dates, exact dates for all other data items should be entered.

Dates should be entered in the format DD MMM YYYY unless specified otherwise. If the day and month are not known, enter UN and UNK, e.g. 'UN UNK 2013'. Unknown years should be entered in the format '0001'.

When an assessment/procedure is recorded as being **'Not Done'** a reason is requested. The reason(s) for it not being done e.g. 'Subject refused' should be supplied, rather than a duplicated statement 'not done'.

Help boxes are denoted by the icon. These support data entry by indicating what data format certain data items should be in or they provide guidance on how to complete log lines where applicable. To view the help text, click on the icon.

Forms can be accessed using the overview panel in the centre of the subject screen or via the folder/form visit pane on the left-hand side of the subject screen.

At each visit, please ensure the Adverse Event form and the Concomitant Medications form are updated as applicable.

Randomisation

Patients should not be added to the RAVE until they have completed Screening and Baseline and are ready to be randomised.

Randomisation takes place on ALEA after the patient has been deemed eligible following the screening assessments specified in the protocol.

Screening eligibility data should be completed on RAVE within 5 days of Randomisation, in order for eligibility checks to be completed.

Medical History

Medical History should include any significant pre-existing medical conditions or events which began or occurred before consenting to the trial.

Adverse Events

When entering Adverse Events (AE) on the Adverse Events form, please use the correct CTCAE v5.0 term and avoid using "Other" unless there is no other appropriate CTCAE term. A change in grade for an AE must be added on a new logline; typically the previous grade AE will have an end date the day before the new AE starts.

Where adverse event start dates are unknown, every reasonable avenue should be explored to investigate the correct start date. As a last resort, the previous visit date or the first day of the month should be stated, depending on which is closest to the actual start date.

Concomitant Medications

When entering Concomitant Medications (CM), please avoid selecting "Other" as an answer to questions unless there is no other option that applies.

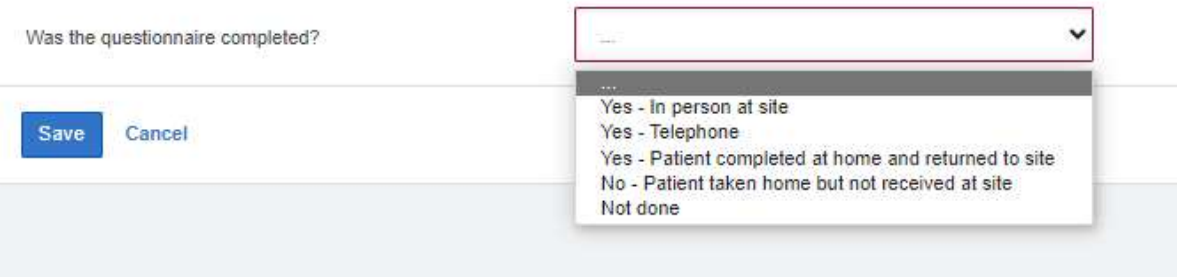
An example:
We find a CM has been added and the reason has been provided as "Other". In the comments box it is written "Patient has nausea". This is incorrect because Nausea should be listed as an AE or MH condition, so Data Manager (DM) raises a query. The Clinical Research Coordinator (CRC) should determine if the Nausea is related to an AE or MH condition, check if it has been previously added to the database and add if necessary. Next, the reason can be changed from "Other" to the appropriate choice.

LB Chemistry

Results for LB Chemistry are only required if there are abnormal and clinically significant results, otherwise just answer if the sample was collected and date of sample collection. Clinically significant results must also be raised as a new Adverse Event.

Trial Visits

For visits where questionnaires are required, the following answers are available to "Was the questionnaire completed?":

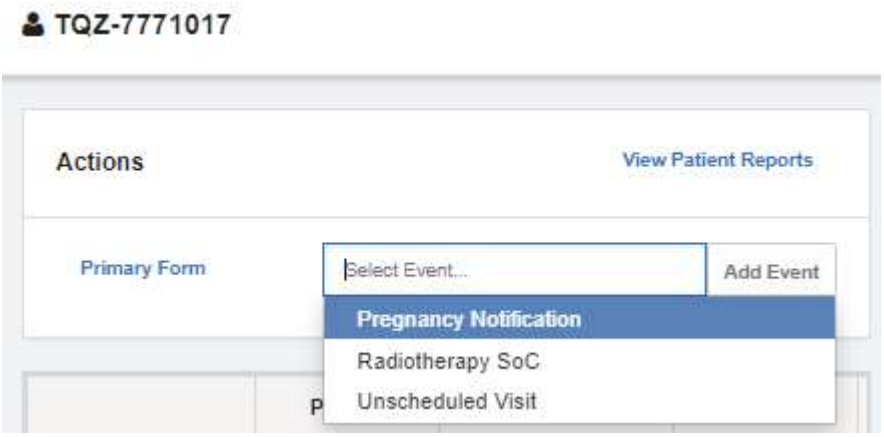


If the questionnaire was taken home by the patient, please update this answer when it is returned.

If you are collecting data over the phone for one of the visits, please transcribe the results from the patient to a paper record first and not directly into the RAVE database. It is site team's responsibility to ensure that patients who take questionnaires home return them at the next visit!

Add Event Function

If additional visit folders are required, the Add Event function can be used. You can select any of the below folders on the dropdown list.



Pregnancy notification should be added when the patient has been confirmed pregnant during the trial (this does not include the partners of patients who are not on the trial).

Radiotherapy SoC should be added if the patient has any radiotherapy as standard of care during the trial.

The Radiotherapy SoC form should be added for:

- Any radiotherapy treatment for Control Arm patients.
- Any additional radiotherapy treatment for Radiotherapy Arm patients which is not prescribed by the trial protocol.

Unscheduled Visit should be added for additional scans and visits that may take place.

For Unscheduled Visits you must select the tests which were completed at the visit by checking the checkboxes, but no additional forms will appear for entry as results are not required to be entered.

3. GENERAL INSTRUCTIONS

Once logged on via www.imedidata.com using your unique username and password, you will be directed to the Rave EDC home page where you will have access to the QUARTZ LUNG study once all pre-requisite e-learning has been completed.

3.1 Data Entry Timelines

Task	Timelines Recommended
Data Entry by site	10 business days given to sites to enter data from visit due date
Entry of eligibility data	5 business days given to sites to enter data from randomisation date
Entry of data 4 weeks prior to a scheduled DMEC/TMG/TSC	5 business days given to sites to enter data from visit due date
Queries responded to by site for eligibility and safety data	5 business days given to sites to respond to Paper or Database Queries from date sent/created

3.2 Navigation

Once you click into the QUARTZ LUNG study you will see the Subject list for your site. The navigation bar at the top of the screen allows you to navigate between different studies (if you have access to more than one).

3.3 Icon Keys

Icon keys will appear at site, subject, form and question level. A table of common icons is shown below.

Some Icons can be used to show the current status of an entry (e.g. the "Complete" icon) or show that corrective action is required on an entry (e.g. the "Query Open" icon), or to use as an "Action" button to make entries (e.g. the "Edit" icon)

Importance (1 = Highest, 10 = Least)	Icon	Description
1		Open Query
2		Answered Query
3		Read Only Opened Query
4		Non-Conformant Data
5		Requires Review
6		Requires Translation
7		Requires Verification
9		Overdue
10		Requires Coding

11		Requires Signature
12		Entered
13		Entering
14		Unsubmitted Form
15		Requires Data Freeze
16		Requires Data Lock
17		Data entry complete Locked

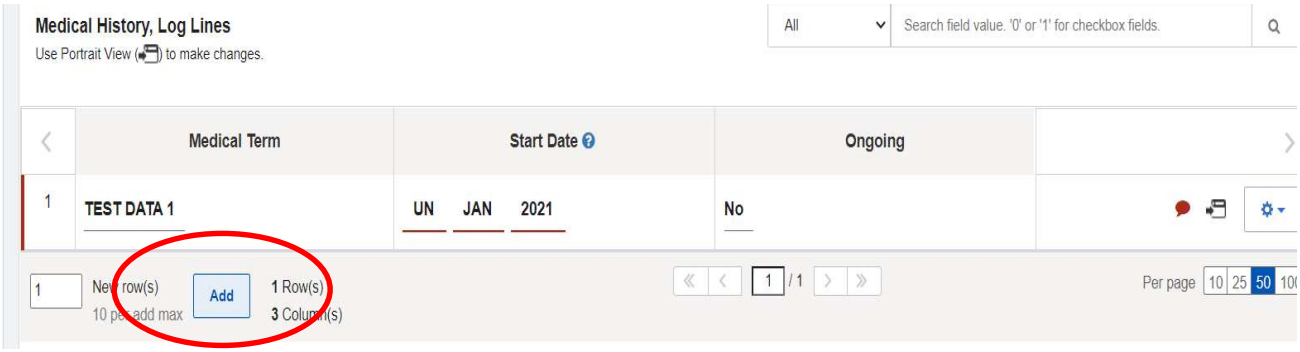
Important Note: Only some of these icon keys will be visible depending on your role.

3.4 Log Forms

The log form allows users to add additional entries to a single form. Each entry is a log line. By default, log forms display 20 log lines per page. This can be changed in the 'My Profile' section of Medidata. Log lines can be added, inactivated, and reactivated as described below.

<u>Addition of a New Log Line</u>

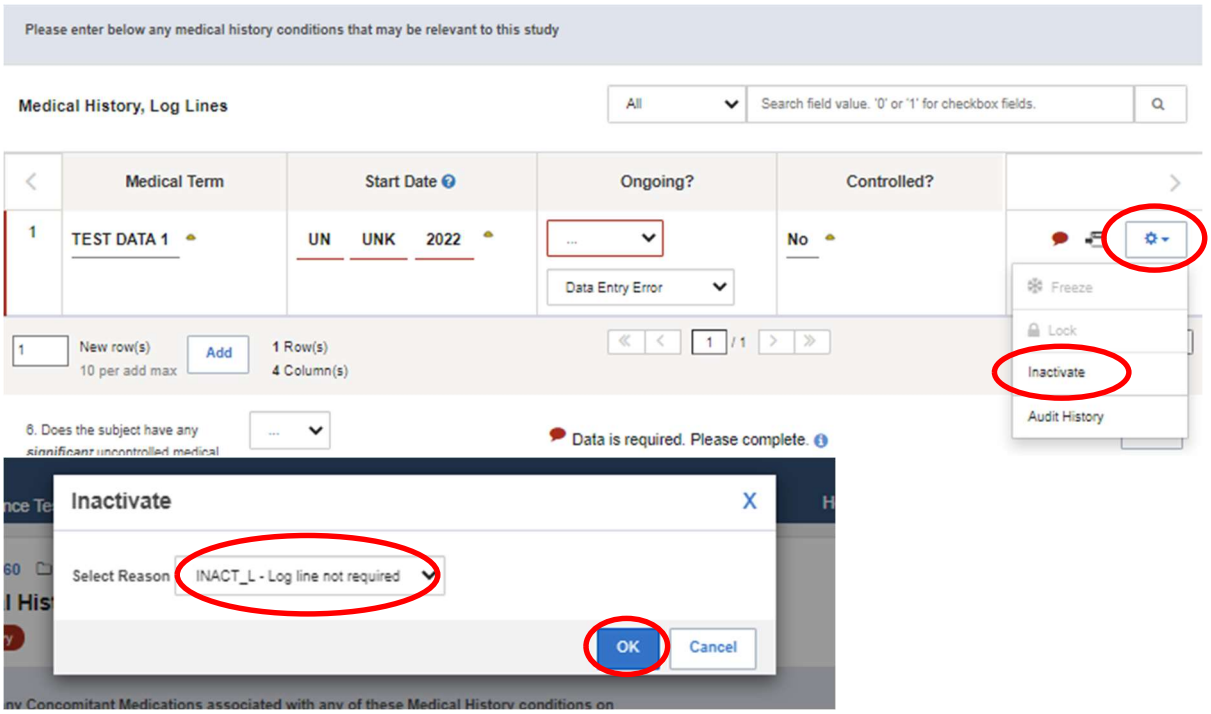
To add additional log lines within a log form, click on 'Add' (repeat process to add multiple records) or by changing the number in the 'New row(s) field to add multiple lines and then click on 'Add'.



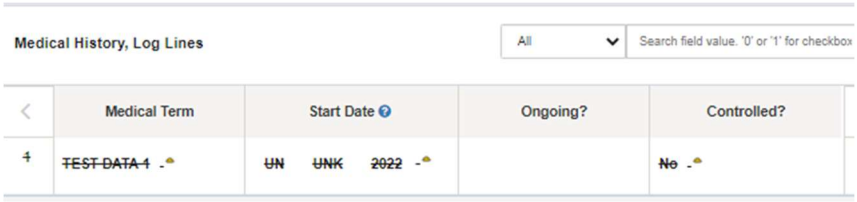
Inactivate/Activate Records

Records in a log form or an add entry table can be inactivated. This will not delete data or remove it from the form. It will always remain visible but will appear scored through.

To do this, select 'Inactivate' from the actions button (the cog wheel) on the right of the log line.



Select the reason for inactivating and click 'OK.' The record will appear scored through as below:

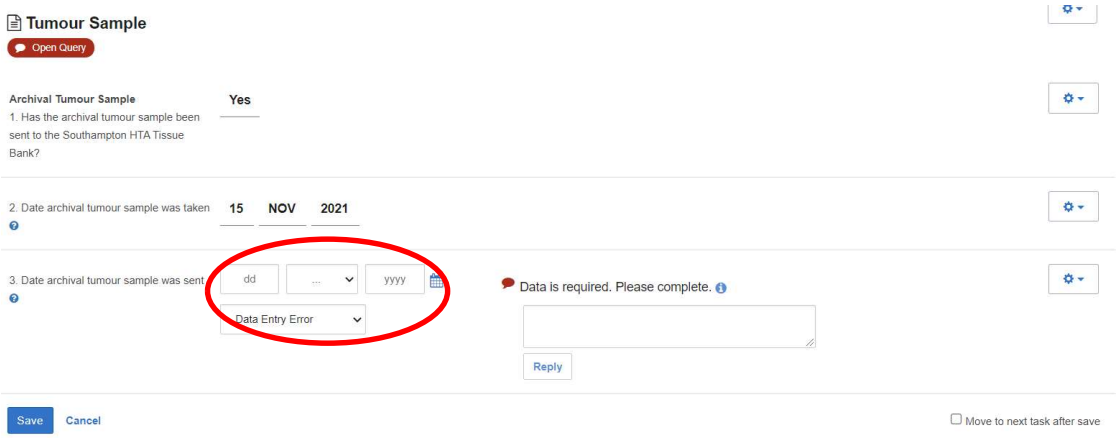


To reactivate a log line, select 'Reactivate' from the same cog wheel icon, enter the reason, and select 'OK.'

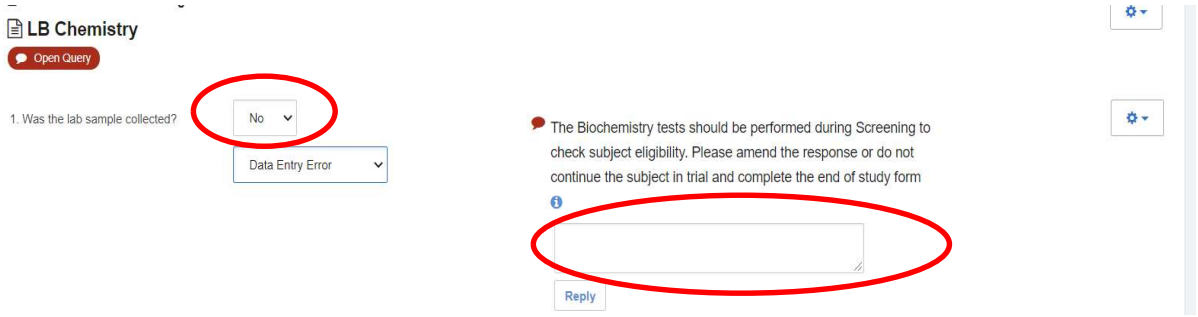
3.5 Answering Queries

You can respond to queries in two ways:

1. Modify the data in the data entry field and click save. No additional response is required.



2. Include an additional response in the user response field. Once an answer is entered click the 'Reply' button underneath the response field and this will then appear below the query.

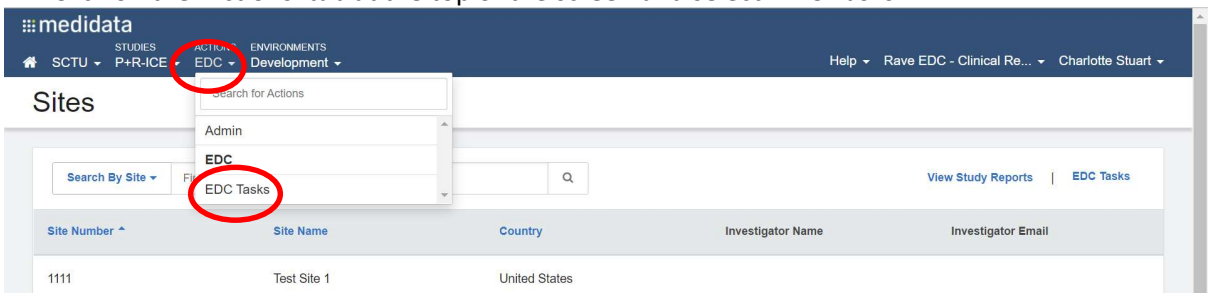


3.6 Task Summary

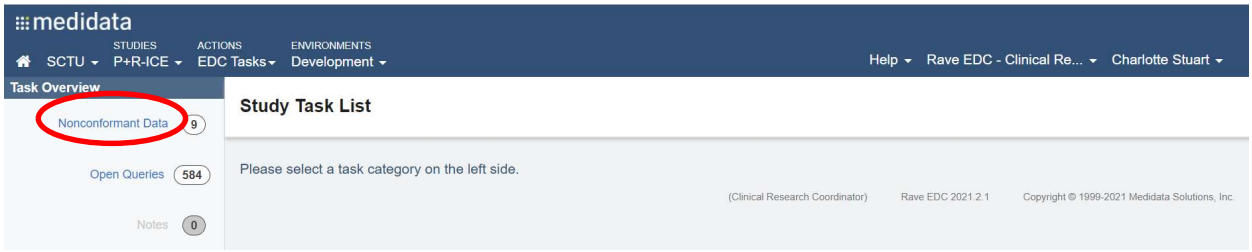
After entering data, it is a good idea to go into the "Task Summary" to see if any "Open Queries" can be resolved. The "Task Summary" can be accessed in two ways:

1. Via the actions tab at the top of the screen.
2. Via the patient overview page

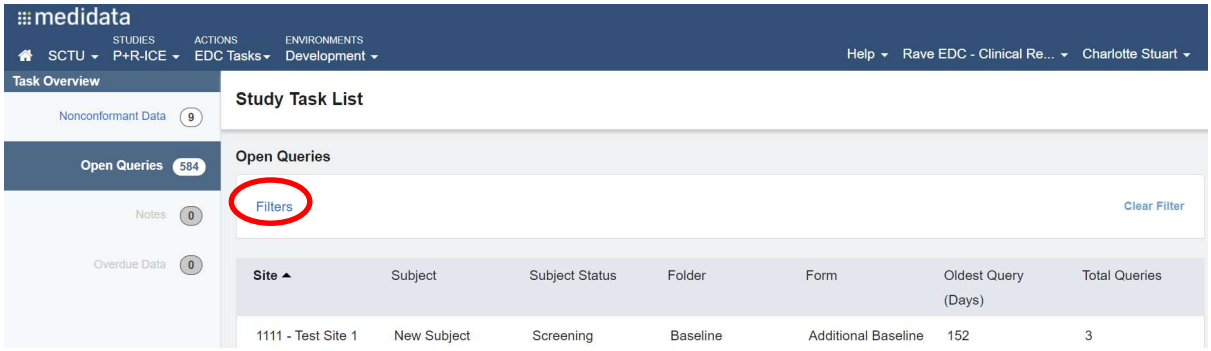
1. Click on the 'Actions' tab at the top of the screen and select 'EDC Tasks'



You will then be able to see the options on the left to select tasks such as 'Nonconformant data' By clicking on this you will be able to see all the non-conformant data at your site.



These results can be narrowed down by patient, form, visit, etc by clicking on the 'Filters' button and selecting the result you want to look at.



2. On the individual patient overview form, you will be able to see what actions need to be taken for the patient record you are viewing. The three circled examples below would show that this patient has not had their Physical Examination form entered at Cycle 2, that there are open queries on the LB Chemistry form at the Screening visit and that the LB Chemistry form at Cycle 1 has only partially been completed.

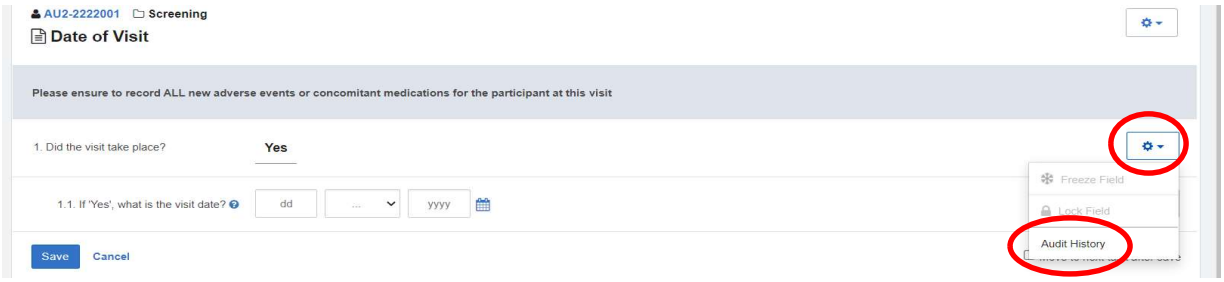
3.7 Changing Previously Entered and Saved Data

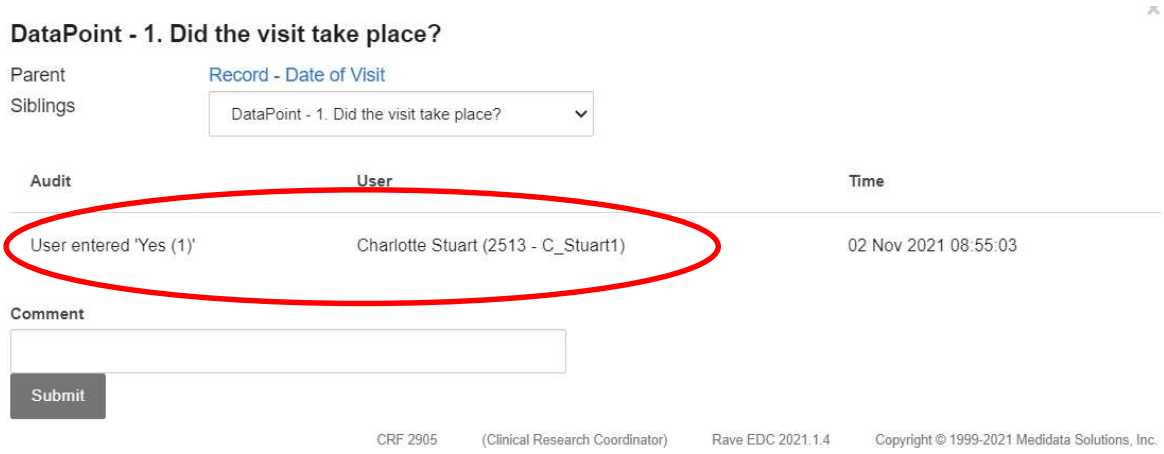
In case of data entry error or new data becoming available, it is possible to change entered and saved data by simply clicking into the field you wish to edit.

Important Note: Please do not record any subject-identifiable information in the eCRF pages, item comments or query responses, as it will be permanently stored in the audit trail. Please refer to a person's role or group if necessary, e.g. Research Nurse, Investigator, Clinical Research Coordinator etc.

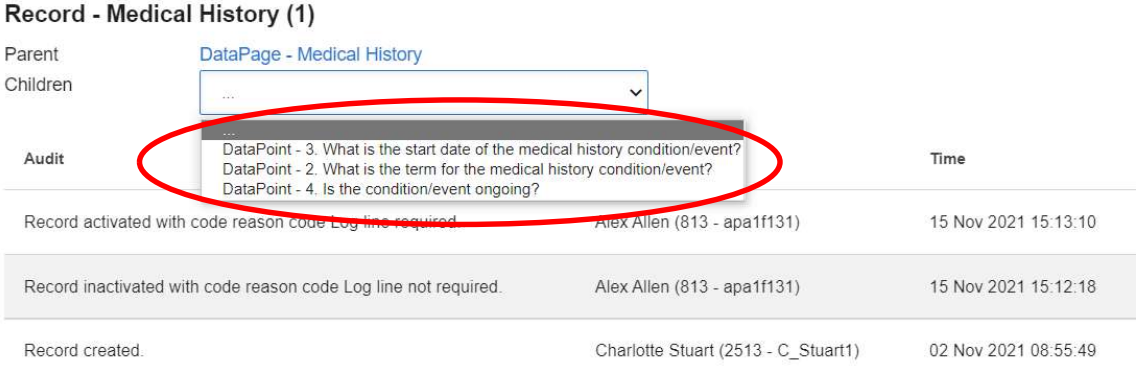
3.8 Audit History

The Audit history page can be utilised to see previous responses to queries, who entered or amended data and to add comments. To access the Audit history, click on the actions button (the cog wheel) on the right of the data point and click on 'Audit History' and you will see how the data point has changed, along with any queries/query responses and when these changes were made.





While on the Audit trail page there is sometimes a choice of data points, so ensure the correct one is selected from the drop-down list before entering the comments e.g.:



4. DATA ENTRY GUIDELINES

The following table contains guidance on entering data that will be coded, such as adverse events. This will help to reduce queries raised during the coding process.

All entered terms must be terms from the CTCAE v5.0 only.

Guidance on data entered by sites that will be coded – *Adverse Events, Concomitant Medications, Medical History, End of Study forms*		
Coding Guidance	**Issue**	**Example (if applicable)**
A	Avoid using '/' as the terms used will often not be considered synonymous in the coding dictionary	'Shivering/shaking' are two terms
B	Only enter a single term	Fever and chills are two different medical concepts so cannot be coded as one individual event
C	Avoid 'describing' an event	'Patient attended visit with a runny nose, cough, aching limbs and sore throat.' This contains four different medical events and each should be entered separately
D	Avoid uncommon acronyms or acronyms that could mean different things in different contexts	'PE' for pulmonary embolism or pleural effusion, or pre-eclampsia for example
E	Surgery in medical history can contain two separate events	'Surgery on foot due to broken foot' contains two events, 'Broken foot' and 'Foot surgery'
F	Queries raised by the coder are an open dialogue and sites should respond accordingly	An example of the coding query where another term is suggested: *'Would >>AE TERM<< accurately reflect the adverse event as entered in this field?'* If the other suggested term is not correct, sites can respond to this with 'no' and provide further information that may help with finding an appropriate medical term. Clinician decision should be sought
H	Clarify any potentially ambiguous term. Ensure it matches CTCAE v5.0	'Canal stenosis' could be 'ear canal' or 'spinal canal'. 'Cold' could refer to a common cold or feeling cold

5. eCRF SIGN-OFF

Once all required data has been entered and cleaned for a subject, the eCRF is ready for sign-off. SCTU will advise when this should take place and provide instructions at the same time.

6. DOCUMENT HISTORY

Version number	Effective date	Summary of changes	Author
V1	21/05/2024	New Document	Oliver Edwards
V2	17/09/2024	Updated Randomisation section.	Oliver Edwards