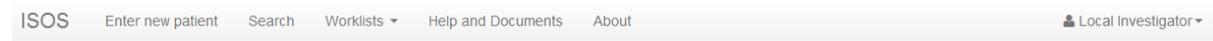


ISOS Database User Guide

Local Investigators

The majority of users will be classified as Local Investigators, this is effectively the 'Data Entry' role. When you log on you will be presented with the menu below. Any recent news items will appear below the welcome message.



Welcome to the ISOS Data Entry website
This site will open for data entry presently.

From left to right –

'Enter new patient' – This is where you click to start entering a new CRF

'Search' – This will allow you to search for a previously entered CRF using the ISOS ID

'Worklists' – This will provide lists of entered CRFs for quick reference

'Help and Documents' – Access to help documents (such as this file)

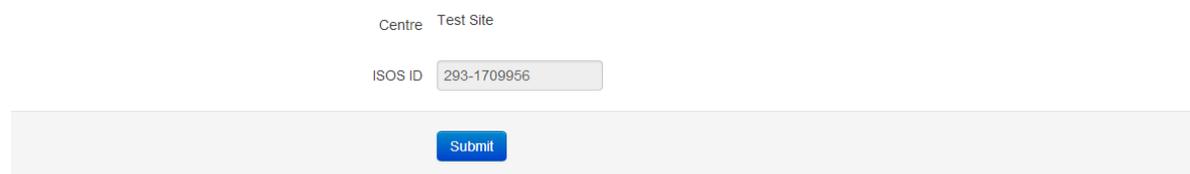
'About' – A few words about the project and security

'User menu' – Your name as entered in the system will appear here and you will have the option to update your details and log out of the system

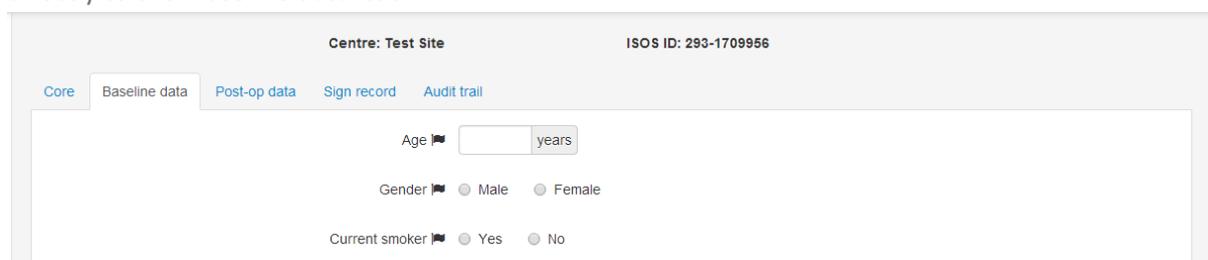
Enter new patient

On clicking on the Enter new Patient option you will be presented with a screen similar to that below, the 10 digit ISOS ID will have been automatically generated from your site ID and an integer chosen and checked to ensure it is unique to that patient. Ensure that your site is showing correctly and that you record the ISOS ID on your paper CRF.

Please confirm your centre and record the ISOS ID on your paper CRF before submitting:



Once you have done that, then click Submit to start entering data for your patient, you will move directly to the 'Baseline data' tab.

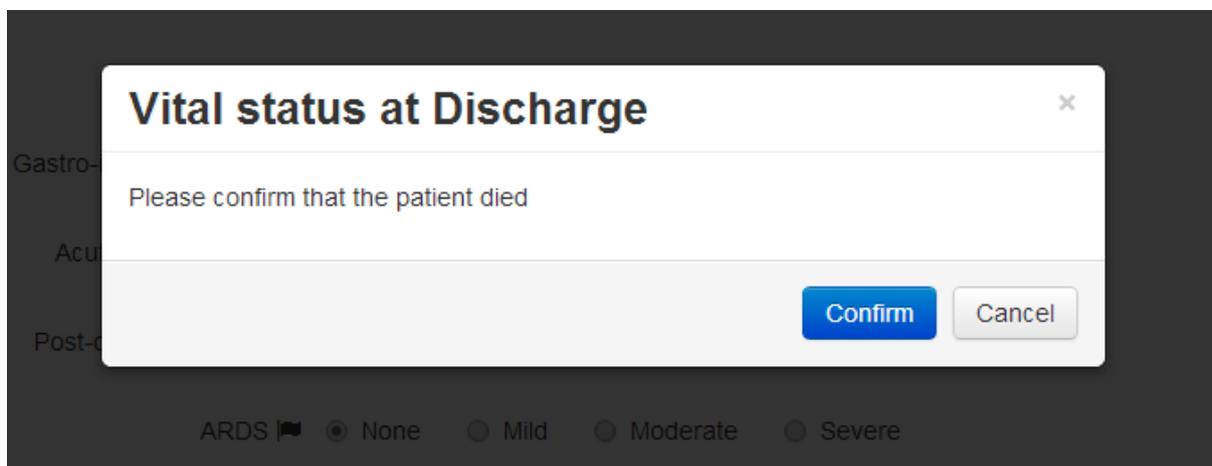


You can use the 'Tab' key to move between data fields, the left and right arrows to select radio buttons and the space key to check checkboxes; or you can do all the above with the mouse if you prefer.

The Post-op data tab contains most of the data entry points regarding complications, in order to ease data entry we have included a button to mark all the complications to 'None', clicking this will enter these values, though they can be changed manually.

Click here if there were no post-op complications

This page also includes the 30-day survival data point, as this is such an important datum you will be asked to confirm if you enter that the patient died.



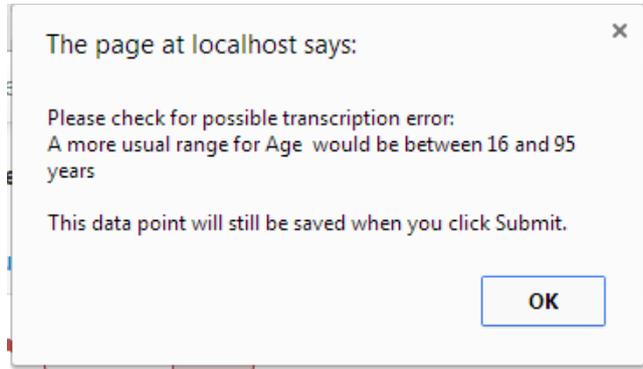
Once you have completed transferring data from the CRF to the database you will have to mark the record as complete, this will move the record to the Local Co-ordinators worklist of records that require signing off. This page will also flag incomplete areas of the record as well as providing a final reminder of the ISOS ID. Once you have marked the record as complete you will no longer be able to edit it, though it may be unlocked by a Local Co-ordinator.

A screenshot of the "Sign record" page in the application. The page has a navigation bar with tabs for "Core", "Baseline data", "Post-op data", "Sign record", and "Audit trail". A green notification banner at the top says "Don't forget to write the ISOS ID on your paper case record form. You may need to come back and check your data." Below this, a green box displays "The ISOS ID for this record is 293-1709956". A blue box indicates "The following pages are incomplete -" with a list: "Baseline data" and "Post-op data". There is a text input field with the label "If required add text in here to explain any omissions or errors". Below the input field are radio buttons for "Mark record as complete?" with options "Yes" and "No". A blue "Submit" button is at the bottom.

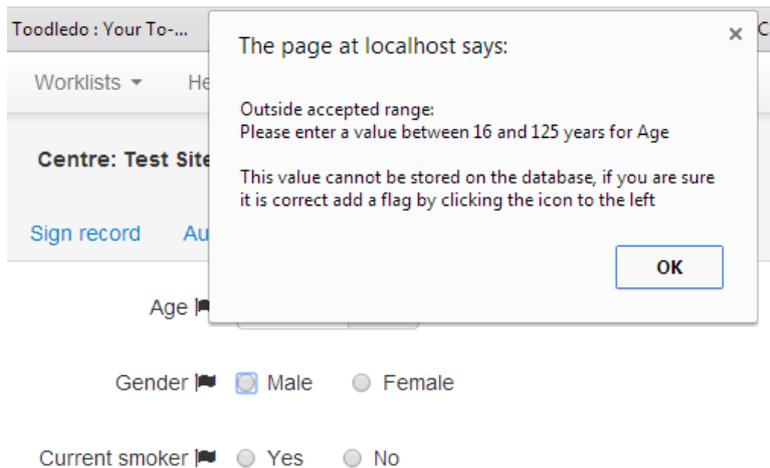
Error messages and flags

As you enter data it will be checked against the validation limits we have set within the database and pop-up errors may warn you of potential errors.

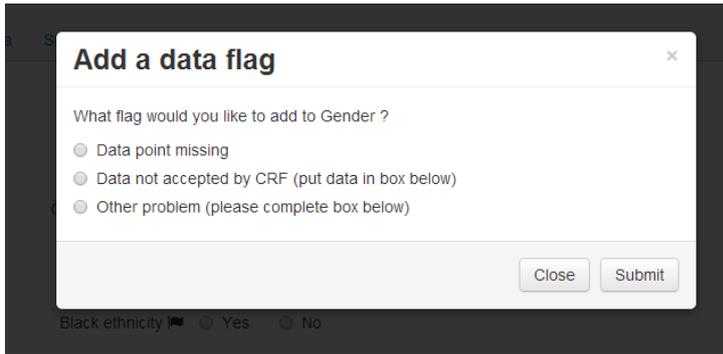
The error below warns that a value is out of the range we would expect, but is still a value which can be stored in the database, for instance a white cell count of over $150 \times 10^9/L$ would be unusual but possible.



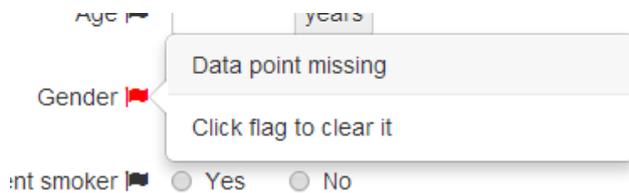
Whereas the error below indicates that the value cannot even be stored on the database, if you are absolutely sure that this is a valid result, then it directs you to click on the flag to the left of the value and enter it in there as an exception



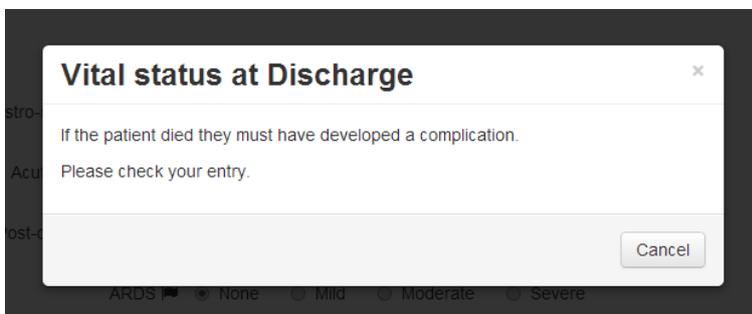
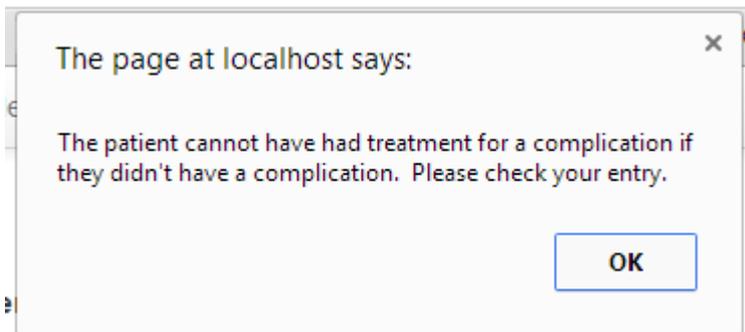
If you click on the flag you will be presented with the below menu where you can mark a data point as missing, enter a value that the database cannot accept otherwise or record another problem with that data point.



If you complete this form then the flag will show up in red on the main data entry form and you will be unable to enter a value in the associated form control. If you mouse over the flag you will see the flag value you have entered and if you click on the flag you can clear it (if a data point that was missing becomes available for instance).



On the post-op data page you may try to enter a death or a treatment for a post-op complication without recording a post-op complication in the radio buttons above, if you do this you will get one of the below error messages.



Country specific CRFs

Some participating countries have supplemental CRFs, these will appear on the data tabs between post-op data and signing off the patient, the UK tabs are shown below as an example.



Audit trail

This tab will show all the changes made to the record, who made those changes and when. We record all changes to all records entered onto the database for data security reasons.

Search

This tab will allow you to enter the full 10 digit ISOS ID (including the hyphen) to directly search for a CRF entered in your centre.

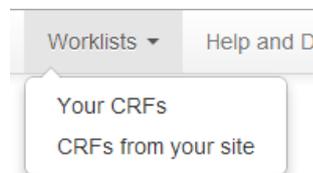
Enter the full ISOS ID of the patient you'd like to search for

ISOS ID (ddd-ddddddd)

On entering the ID and hitting Submit you will be taken to the CRF (assuming it exists).

Worklists

On clicking on this tab a dropdown menu will appear, giving you the choice of a list of the CRFs you have entered, or all CRFs from your site.



On selecting one of these options you will be taken to a table, with a list of CRFs, you can open a CRF by clicking on the radio button to the left of the record and clicking on select at the bottom right of the table. Note that you can change the number of records that appear on any one page with the dropdown at the top left of the table.

Your CRFs

Click on any heading to sort by that field.

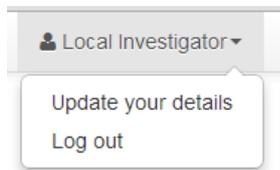
10 records per page Search:

ISOS ID	Centre	Completed?	Signed?	Select
293-4121101	Test Site	No	No	<input type="radio"/>
293-8887909	Test Site	No	No	<input type="radio"/>
293-2638819	Test Site	No	No	<input type="radio"/>
293	Test Site	No	No	<input type="radio"/>
293-1709956	Test Site	Yes	No	<input type="radio"/>
293-2451133	Test Site	Yes	No	<input type="radio"/>

Showing 1 to 6 of 6 entries ← Previous 1 Next →

User Menu

From this you will have two options in a dropdown, to edit your details (to do so you will have to provide your current password) and change your password, or to log out.

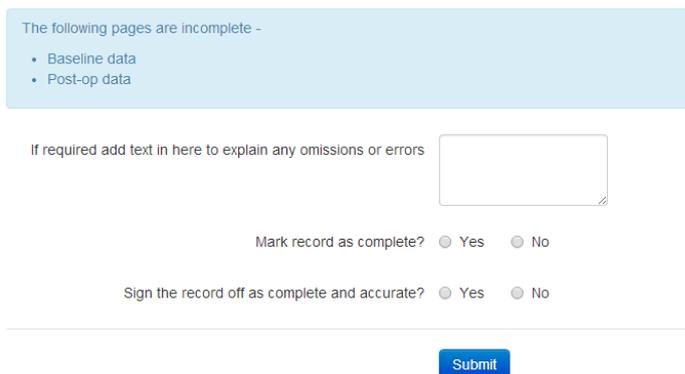


Local Co-ordinators

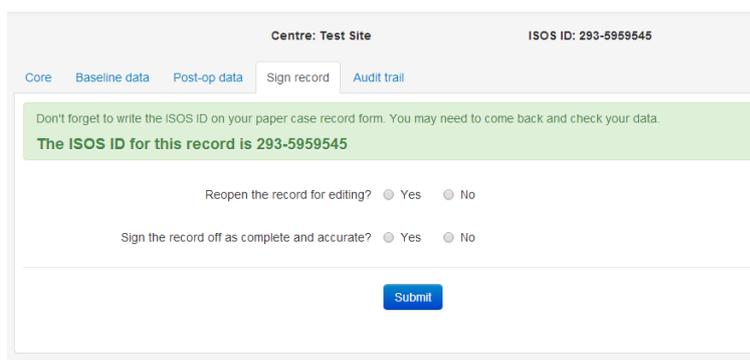
Each site will have at least one local co-ordinator, this may be the local primary investigator or their authorised deputy. They have responsibility for confirming the registration of their Local Investigators as well as signing off CRFs as being complete and correct. Once the site has completed data entry the Local Co-ordinator will be responsible for confirming the data set is complete and then they will be able to download their local data in a spreadsheet.

Signing off CRFs

If you enter a CRF under your login you will be presented with a slightly different sign patient page

A screenshot of a web form for signing off a CRF. At the top, a light blue box says 'The following pages are incomplete -' followed by a bulleted list: 'Baseline data' and 'Post-op data'. Below this is a text area with the prompt 'If required add text in here to explain any omissions or errors' and an empty text box. Underneath are two radio button questions: 'Mark record as complete?' with 'Yes' and 'No' options, and 'Sign the record off as complete and accurate?' with 'Yes' and 'No' options. At the bottom is a blue 'Submit' button.

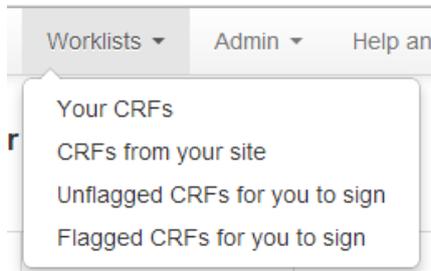
As well as marking the record as complete you can also sign the record off as being complete and accurate, if the record is signed off it is also marked as complete. If someone has previously marked the record as complete then you would be presented with the option to reopen the record for editing, or to sign it off as shown below.

A screenshot of a web form for signing off a CRF. At the top, it says 'Centre: Test Site' and 'ISOS ID: 293-5959545'. Below this are tabs for 'Core', 'Baseline data', 'Post-op data', 'Sign record', and 'Audit trail'. A green box contains the text: 'Don't forget to write the ISOS ID on your paper case record form. You may need to come back and check your data. The ISOS ID for this record is 293-5959545'. Below this are two radio button questions: 'Reopen the record for editing?' with 'Yes' and 'No' options, and 'Sign the record off as complete and accurate?' with 'Yes' and 'No' options. At the bottom is a blue 'Submit' button.

Once the record has been signed off as complete it can be reopened by the Local Co-ordinators from the sign record tab, but we would recommend that you are absolutely sure before signing it off in the first place.

Worklists

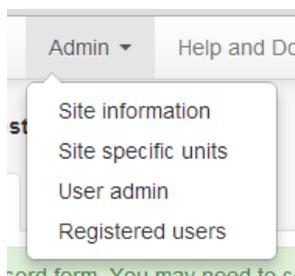
To assist the Local Co-ordinators with this task they have two additional Worklists



The Unflagged CRFs for you to sign worklist will give you a list of CRFs that the database thinks are complete and that haven't had any data points flagged as being in error or missing, one selecting a record from this list you will go directly to the Sign record tab to speed up the process. The Flagged CRFs worklist conversely is those records which are marked as complete by the Local Investigators, but have data missing or data points flagged; as these records likely need further review on selecting them you will be taken to the Baseline data tab.

Admin menu

In order to assist with your administrative role the following options are available on the Admin menu



Site information

We require some basic information about your site, this is entered in the Site information page, until this is done you will get a gentle reminder on logging on as below.

Please go to Admin -> Site Information and complete the one-time hospital information form there.

Site specific units

If you wish to change the default units your site uses for either haemoglobin or creatinine, that option is available here. All data is stored on the database in UK units, so although we recommend you don't change this value multiple times, it will not endanger the validity of the data if you did so.

User admin

You have the ability to confirm the registration of your Local Investigators, this screen is where you do that. If there are no users waiting to be verified it will be reflected on the screen, otherwise you

will get a list as below, you can verify more than one user at once by checking the checkboxes by their names.

User administration

Select users to verify for data entry access

Name	Email	Centre	Select
Reallfinal Check	russ.hewson+4@gmail.com	Test Site	<input type="checkbox"/>

Registered users

Finally you have the ability to alter the registration details for users at your site, the main reason you will want to do this is to promote a further Local Co-ordinator. If you wish to do this you select a user from the table as shown below and click the button marked 'Edit'.

Please select a user to edit their details -

10 records per page Search:

Name	Centre	Country	Privilege	Select
Local Admin	Test Site	Shangri-La	Local Co-ordinator	<input type="radio"/>
Local Investigator	Test Site	Shangri-La	Local Investigator	<input type="radio"/>
Reallfinal Check	Test Site	Shangri-La	Awaiting approval	<input type="radio"/>
wdaew awdada	Test Site	Shangri-La	Awaiting admin approval	<input type="radio"/>

Showing 1 to 4 of 4 entries

Sign off page

Once you have completed data entry and all CRFs have been signed, an option will become available from the Admin menu to sign off the dataset and close your site for data entry. Once this is done your local data set will become available.