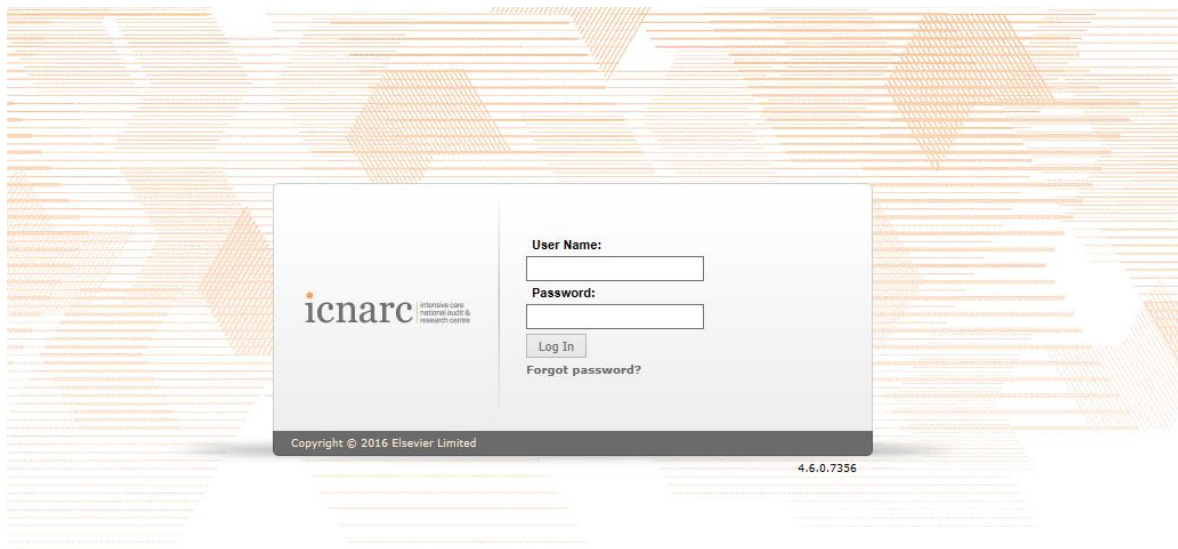


MACRO User guide

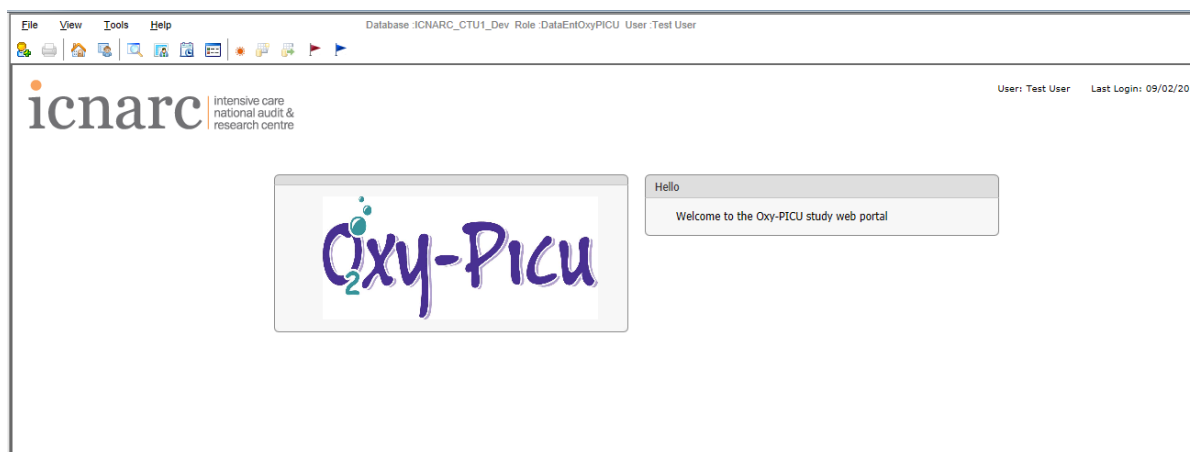
Logging in

To log in to the MACRO web portal, use the following URL: <https://ctu.icnarc.org/macro/>

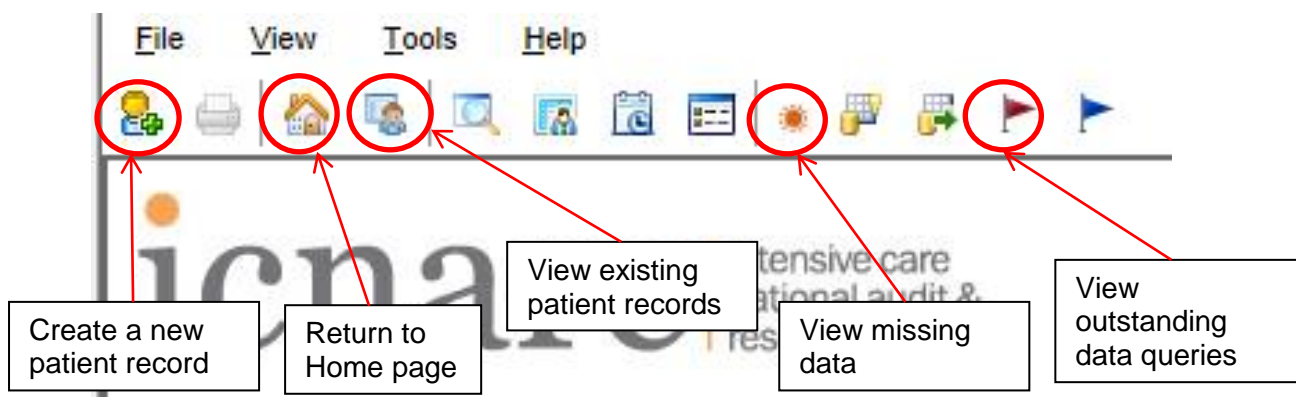
This will open a new page in a pop-up window, so ensure the pop-up blocker is switched off. The login screen will then appear.



Once you have logged in, you will start at the home page for the study you have access to.

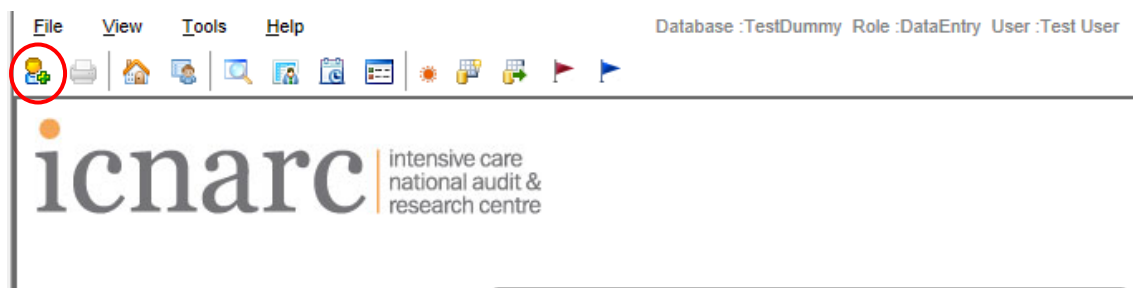


Navigating the home page

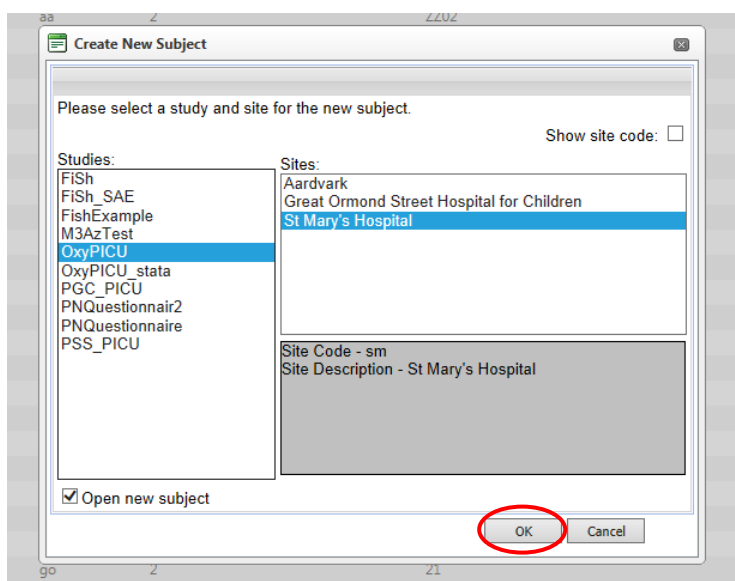


Creating a new record

You can add a new patient record by clicking on the 'Create a new study subject' icon (see below).

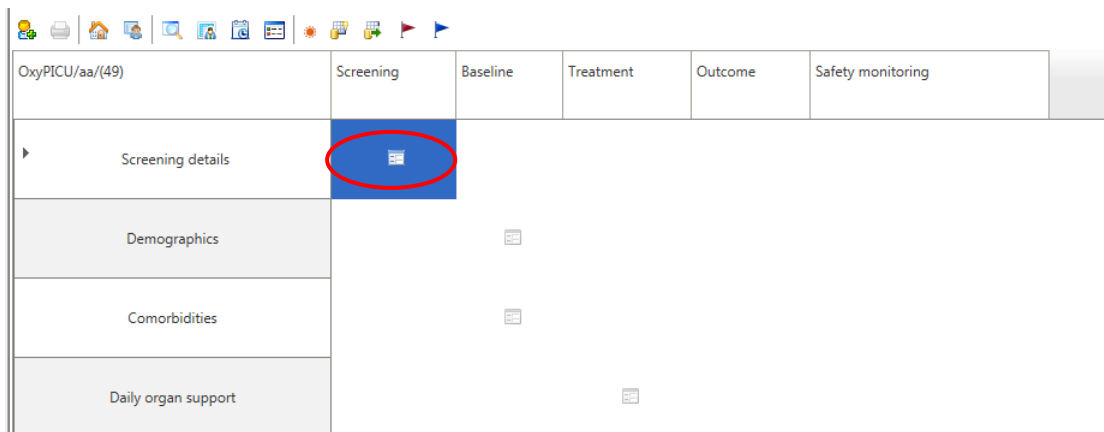


After clicking on the 'Create a new study subject' icon, a pop-up box will appear allowing you to select the study and site for which you wish to create a new patient record. Once you have chosen the correct study and site, press 'OK' to create the record.

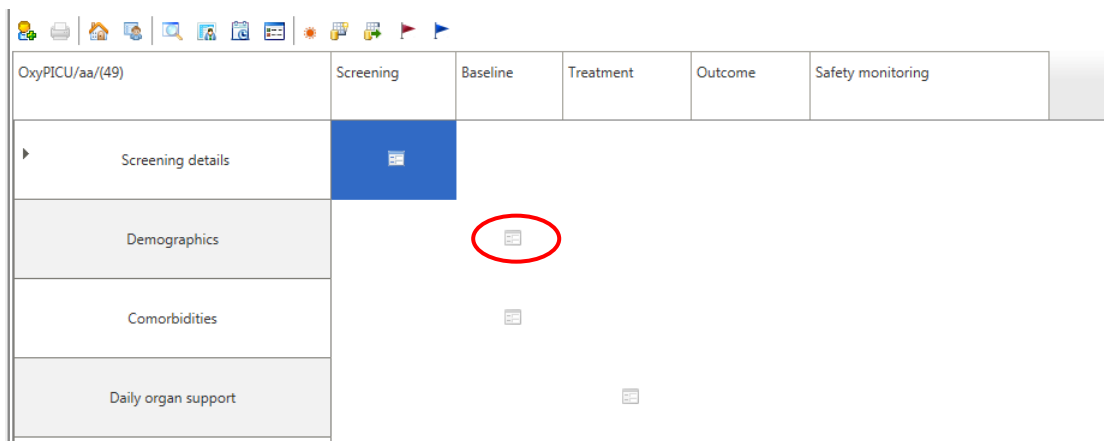


Editing a record

After creating a new record you will see the summary screen (below), which shows all of the pages within the record. You can navigate to a specific page by double clicking on the page icon.



Some later pages cannot be completed until an earlier page has been completed. If this is the case, the page icon will be greyed out and you will be unable to open it.



When a page is opened, the field which is currently selected will be highlighted yellow, and data can be entered in this field.

The screenshot shows the 'Screening details' page. The 'Oxy-Picu' logo is visible in the top right corner. The 'Trial number' field is highlighted in yellow and circled in red, indicating it is the currently selected field for data entry. Below the 'Trial number' field, there is a question: 'Does the patient fulfil all inclusion criteria' with two radio button options: 'Yes' and 'No'.

If the wrong option button is selected in error, the selection can be cleared by right clicking on the option button and selecting 'Clear'.

The screenshot shows a form with several fields. A context menu is open over the 'Yes' radio button for the question 'Does the patient fulfil all inclusion criteria'. The menu items are: View Question Information..., View Audit Trail..., View Warning..., View Inform Message..., Comments, Notes, DCRs, SDV Mark, Change Status, and Clear. The 'Clear' option is circled in red. Other fields include 'Does the patient fulfil any exclusion criteria', 'Treatment allocation' (88-92% selected), 'Date/Time of first face-to-face contact' (01/01/20...), 'Date/Time of randomisation' (01/01/2017 09:00), and 'Days post randomisation' (31/01/2017).

If a required field is missing, the missing icon will appear next to it.

The screenshot shows a form with four fields: 'Lactate (mmol/l)', 'Source', 'SpO2 (%)', and 'Systolic blood pressure (mmHg)'. Each field has a missing icon (a sun with rays) next to it. The 'SpO2 (%)' field's missing icon is circled in red.

If data are marked as 'Not Recorded' in the Case Report Form (CRF) or are missing, right click on the missing icon next to the field and select 'Not Available' from the 'Change Status' option in the drop down menu.

The screenshot shows a form with several fields. A context menu is open over the missing icon next to the 'SpO2 (%)' field. The menu items are: View Question Information..., View Audit Trail..., View Warning..., View Inform Message..., Comments, Notes, DCRs, SDV Mark, Change Status, and Clear. The 'Change Status' option is circled in red, and its sub-menu is open, showing 'Missing' and 'Not Available' options. Other fields include 'Source', 'Lactate (mmol/l)', 'Systolic blood pressure (mmHg)', 'Mechanical respiratory support', and 'pH reaction'.

Once data are entered in the correct format a green tick will appear next to the data.


Trial number ✓

Does the patient fulfil all inclusion criteria Yes No ✓

Does the patient fulfil any exclusion criteria Yes No ✓

Once all data have been entered, you can move on to the next page in a record by selecting the save and move on to next page icon at the bottom of the page.

Days post randomisation ✓




If a page repeats e.g. the observations page, you will be asked if you want to open a new cycle of the eForm. If you choose 'Yes', you will navigate to a new version of the same page. If you choose 'No', you will navigate to the next part of the form.

Would you like to open a new cycle of this eForm?

To return to the summary screen, you can save and close the record using the save and close icon. This will take you back to the summary screen for that record.

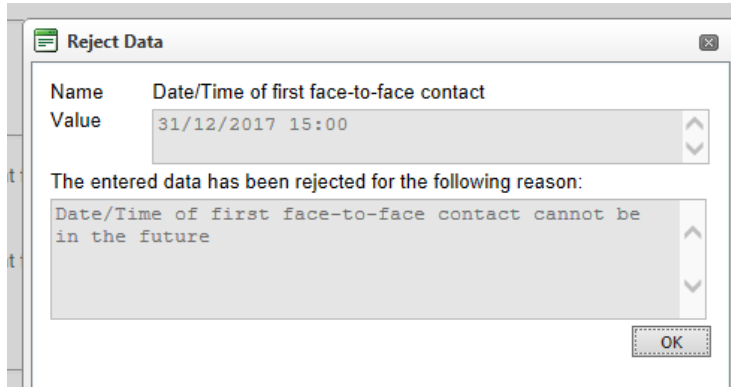
File View Tools Help Database : ICNARC_CTU1_Dev Role : DataEntOxyPICU User : Te



Visit: Screening eForm: Screening details ✓

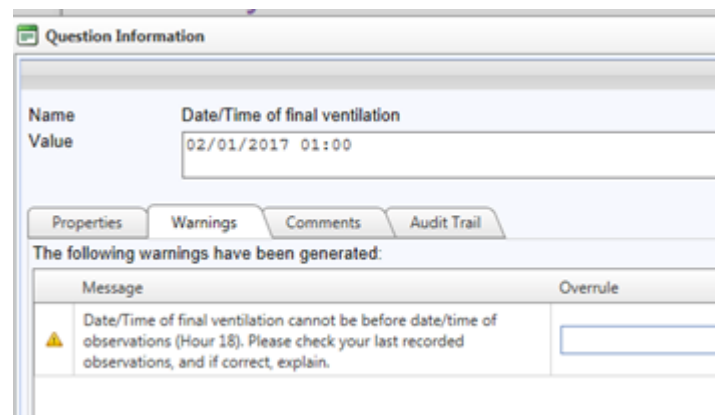
Unusual or incorrect data

Some data are not possible e.g. dates in the future, and will be rejected. These cannot be saved in the record and the data must be changed.



Some data are possible but unusual, so will generate a warning icon (below - left) and a warning message (below – right).

Type of intervention	<input checked="" type="radio"/> IV <input type="radio"/> NIV <input type="radio"/> HFHO <input type="radio"/> NR
Ventilator settings	
Flow rate (l/kg/min)	<input type="text"/>
Pressure (cmH2O)	<input type="text"/>
Mean airway pressure (cmH2O)	<input type="text"/>
Observations	
SpO2 (%)	<input type="text"/>




If unusual data are correct, they can be confirmed by entering an explanation in the 'Override' section.

The screenshot shows a software interface titled "Question Information". It contains a form with the following fields:

- Name:** Date/Time of final ventilation
- Value:** 02/01/2017 01:00

Below the form are four tabs: "Properties", "Warnings", "Comments", and "Audit Trail". The "Warnings" tab is active, displaying the message: "The following warnings have been generated:"


Message	Override
 Date/Time of final ventilation cannot be before date/time of observations (Hour 18). Please check your last recorded observations, and if correct, explain.	<input type="text" value="Observations taken earlier than recorded time"/>


A red oval highlights the "Override" dropdown menu in the warning row.

Once unusual data have been confirmed, the warning icon will be replaced with a confirmed warning icon.

End of ventilation

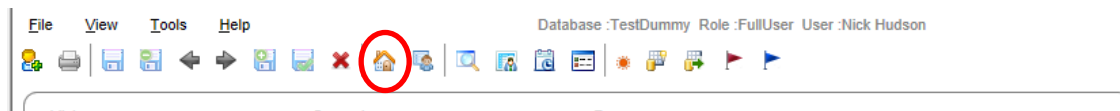
Last ventilation during current PICU stay

Date/Time of final ventilation **02/01/2017 01:00**  (dd/mm/yyyy hh:mm)

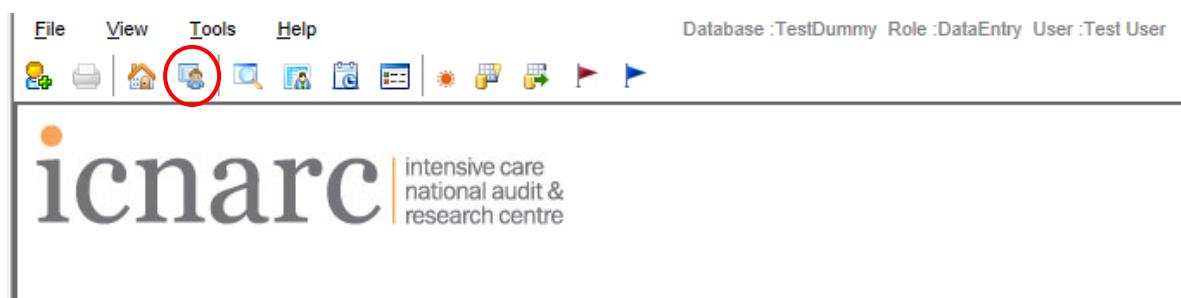
Reason for end of ventilation 

Reviewing existing patients

To return to the home page at any time, you can click on the home page icon at the top of the page.



From the home page you can review existing patients by clicking on the 'Open the Subject List page' icon.



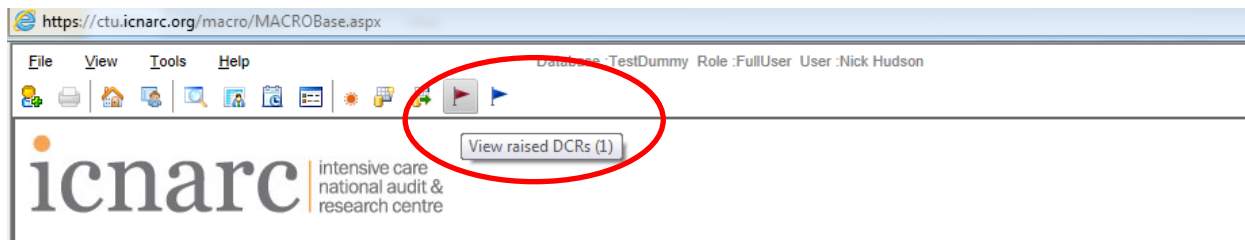
Selecting this will bring up a list of all patients who have already have records in the database. You can go into a specific record by double clicking on that row. This will bring you to the overall record for that patient.

Please note that the Subject Label refers to the patient's Trial Number

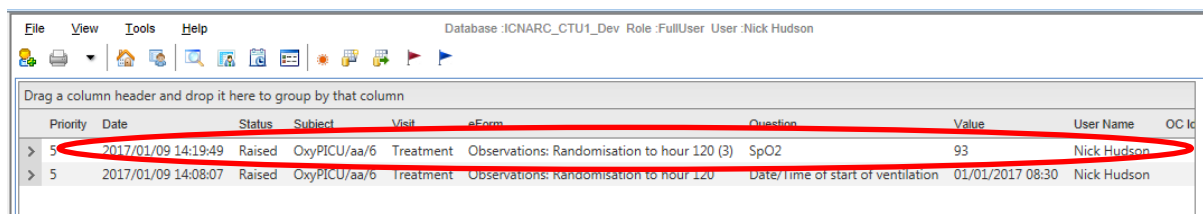
Status	Study	Site	Subject ID	Subject Label	Last Modified
*	OxyPICU	aa	20	4	2017/01/05 17:00:40
*	OxyPICU	aa	21	5	2017/01/06 15:20:31
*▶	OxyPICU	aa	22	6	2017/01/09 15:07:37
*	OxyPICU	aa	23	7	2017/01/13 15:16:42
*	OxyPICU	aa	24	8	2017/01/16 10:06:43
⚠	OxyPICU	aa	25	9	2017/01/18 11:59:21
*	OxyPICU	aa	26	10	2017/01/19 16:09:35
*	OxyPICU	aa	27	10	2017/01/20 11:32:13
*	OxyPICU	aa	28	11	2017/01/25 16:50:51
*	OxyPICU	aa	29	12	2017/01/23 11:46:57

Data validation

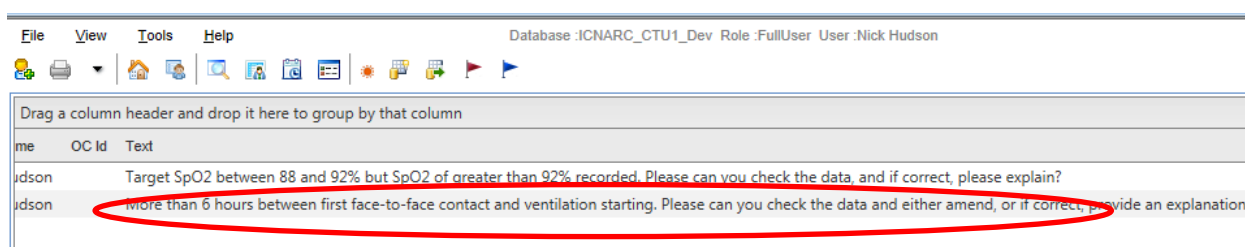
Unusual data which are confirmed to be correct will be reviewed by the team at ICNARC. If they have any questions or need any further clarification, they will raise a Data Clarification Request (DCR). You can check for any DCRs through the home page.



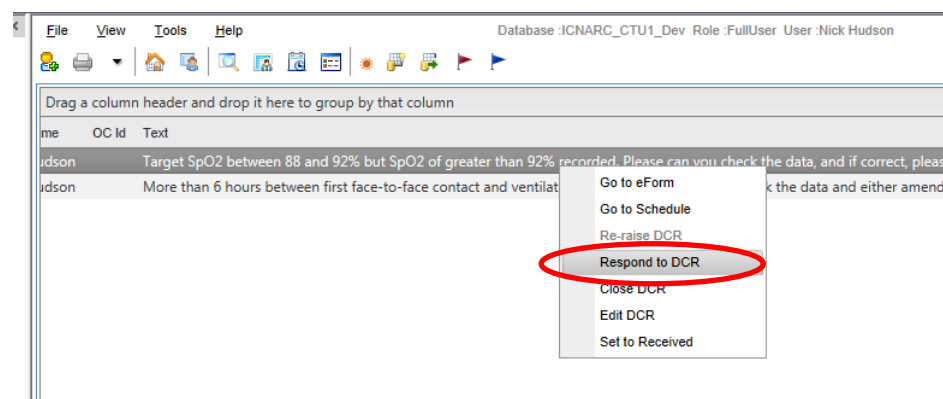
Clicking on the red flag will take you through to the DCR itself. This will tell you which record and which question the check relates to.



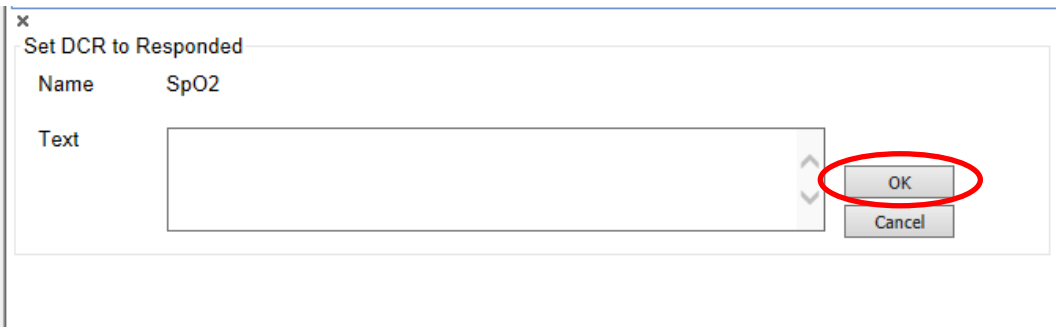
There will also be an explanation from the team at ICNARC as to why the DCR has been raised.



You can respond to a DCR by right-clicking on the DCR and selecting the 'Respond to DCR' option from the drop-down options.



An explanation can be entered in the text field and sent back to the ICNARC team by clicking 'OK'.



The image shows a dialog box with a title bar containing a close button (x) and the text "Set DCR to Responded". Inside the dialog, there is a label "Name" followed by the text "SpO2". Below this is a label "Text" followed by a large, empty text input field. To the right of the text field are two buttons: "OK" and "Cancel". The "OK" button is circled in red.