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# Standard Operating Procedure (SOP) 008

## Macro User Guide

### Scope

To describe the process for entering data required in the Case Report Forms on to MACRO for the PICnIC Feasibility Study.

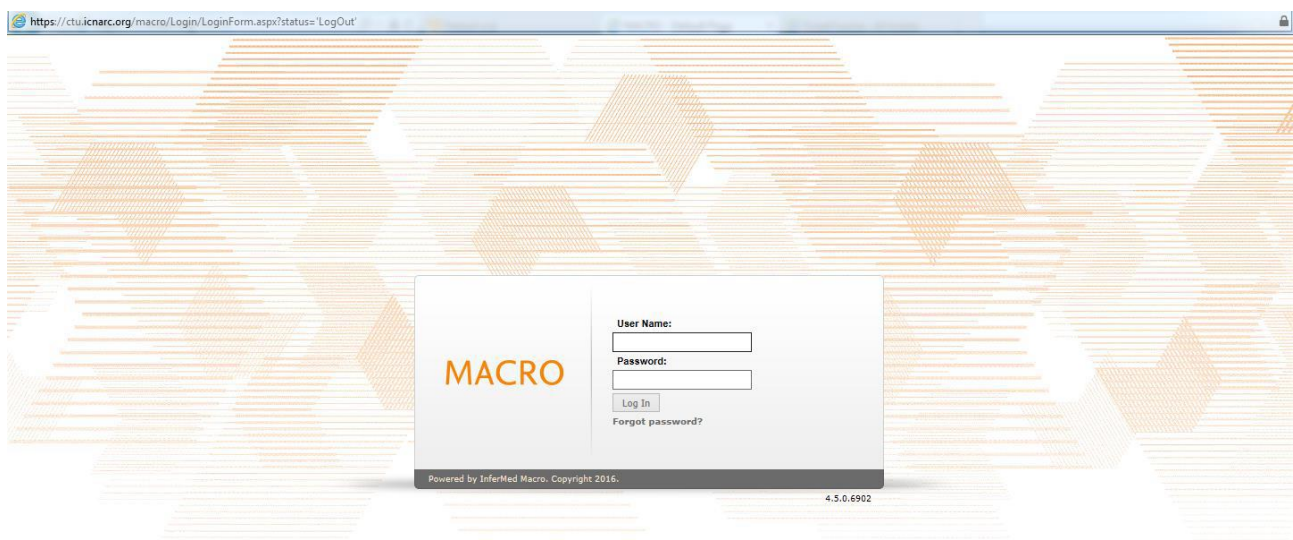
### Creating an account

To request an account, first ensure you have been delegated the relevant permissions on the Delegation Log (Section 12: Site Staff Information, of the ISF) and that this has been sent to the ICNARC CTU. Then, email picnic@icnarc.org to request an account be set up. Once the account is set up, the trial team will be in contact with the relevant log in details.

### Logging in

To log in to MACRO, use the following URL: <https://ctu.icnarc.org/macro/>. We recommend Google Chrome for best performance.

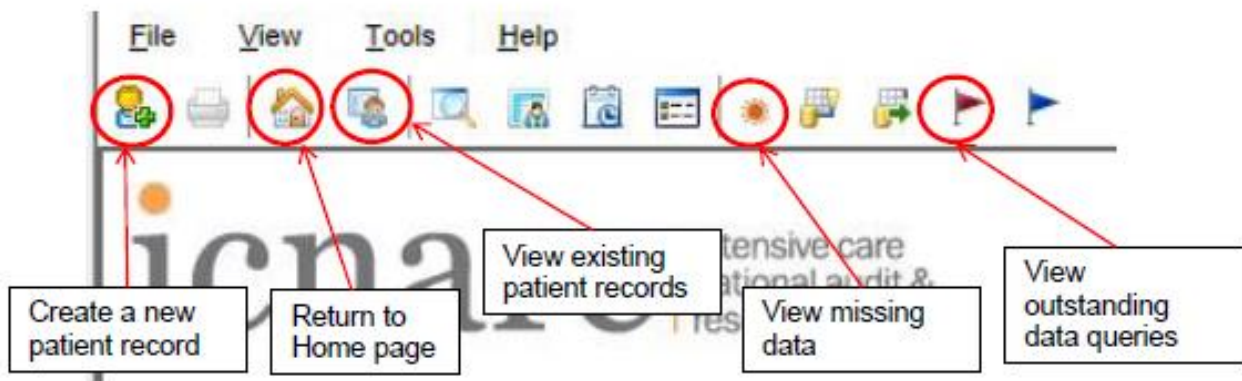
This will open a new page in a pop-up window, so ensure the pop-up blocker is switched off. The login screen will then appear.



Once you have logged in, you will start at the home page for the PICnIC Study.



## Navigating the home page

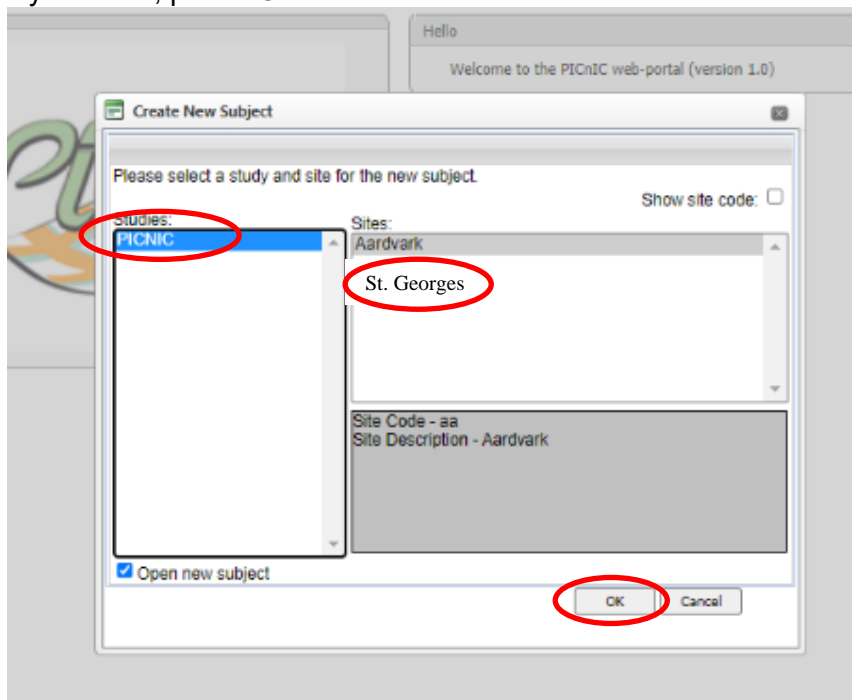


## Creating a new record

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.



This will bring you to a landing page where you will need to select the appropriate period the patient is being entered in to.



Study number/Surveillance number



This number should be based on the next available number on the Study Number or Ecology Surveillance Number lists (e.g. Ecology Surveillance number will have EXXXX and Trial number will be XXXX).

Which part of the trial is the child participating in?

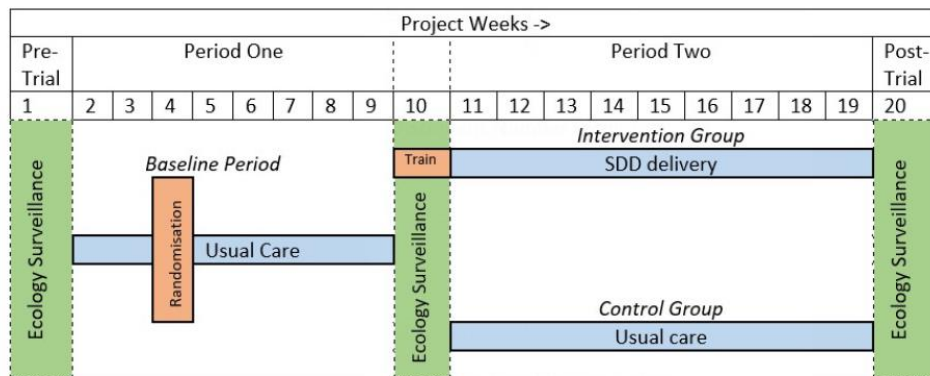
- ☐ Ecology
- ☐ Usual Care
- ☐ Intervention

Ecology Surveillance Periods should be used at all sites on week 1, 10 and 20. They are for all patients admitted to the PICU during these time periods only, regardless of ventilation status. The Ecology Surveillance number should be taken from the 'PICnIC Ecology Surveillance Number List' EXXXX in Section 6: Screening and Enrolment, of the ISF. (Further details can be found on SOP 003\_Patient screening and enrolment).

Usual Care should be selected for all sites during Period One (weeks 2-9) and then again for sites randomised to usual care during Period Two (weeks 11-19).

Intervention should be selected for sites randomised to receive SDD intervention during Period Two (weeks 11-19).

The Study Number for the usual care and intervention groups should be taken from the 'PICnIC Study Number List' in Section 6: Screening and Enrolment, of the ISF. (Further details can be found on SOP 003\_Patient screening and enrolment).



Week 11 shall be treated as a transition period

After selecting the group the patient is enrolled in, you will see the summary screen (below), which shows all of the pages within the patient 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 complete. If this is the case the page icon will be greyed out and you will be unable to open it. There will also be some pages that are greyed out because they are not relevant to the group the patient is enrolled in.

File

View

Tools

Help

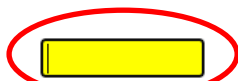
Database :ICNARC\_CTU1\_Dev Role :FullUser User :Alanna Brown

PICNIC/aa/(158)	Site Landing Page	Ecology Weeks	Screening/Baseline	Surveillance	Outcome	Treatment	Antibiotics	Discharg
<div>▶</div> <div>Site Landing Page</div>								
Ecology Surveillance (Part 1)								
Ecology Surveillance (Part 2)								
Admission								
Weekly Surveillance								
Outcomes- HCAI and Microbiology results								
Outcomes (Additional Pages, Microbiology results)								
SDD Administration								

## Entering data

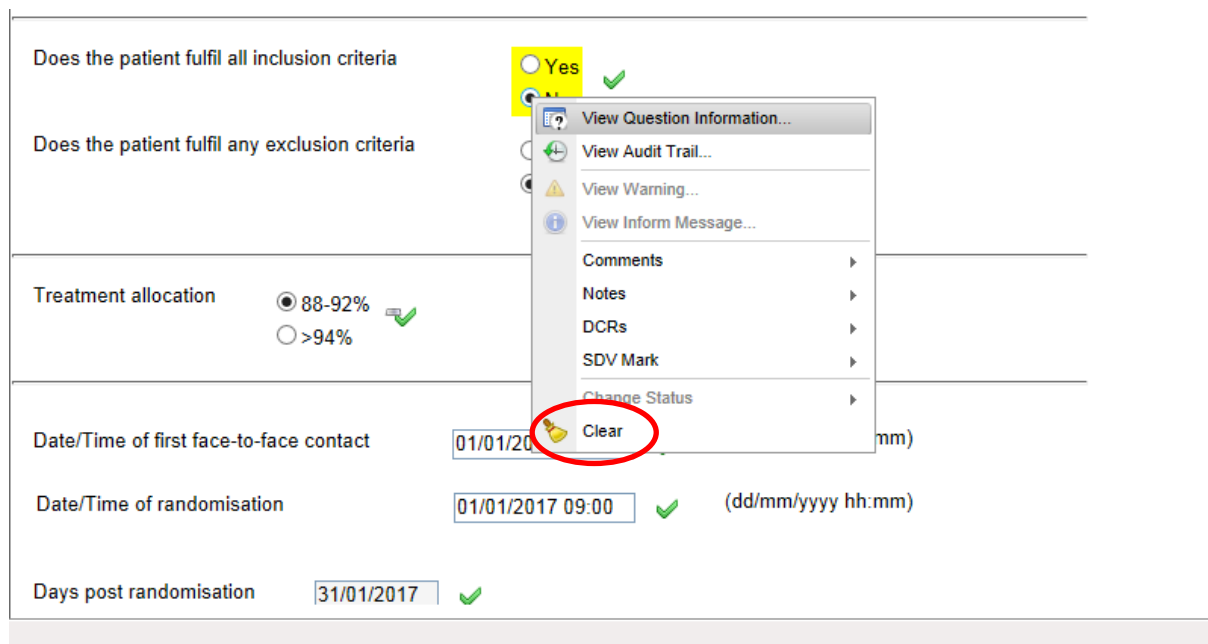
When a page is opened, the field which is currently selected will be highlighted yellow, and data can be entered in this field.

Study number/Surveillance number



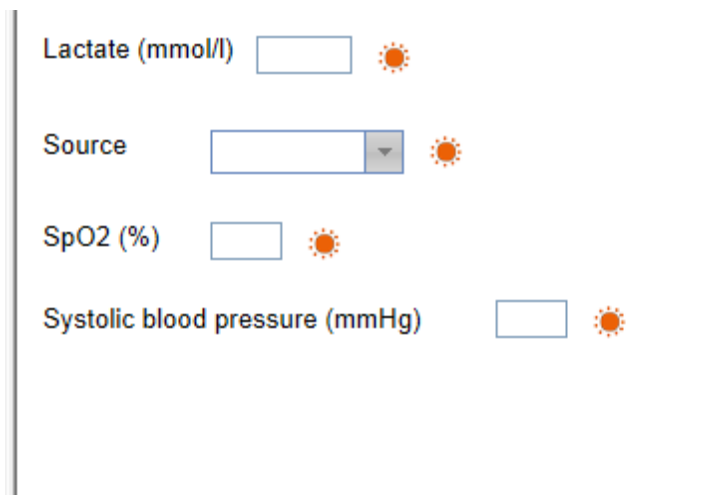
uld be based on the next available number on the Study Nur

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 data entry 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 options 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. (This may only appear once the form is saved)



The screenshot shows a data entry form with several fields. The 'Lactate (mmol/l)' field is empty and has a missing icon (a red sun) next to it. The 'Source' field is empty and has a missing icon next to it. The 'SpO2 (%)' field is empty and has a missing icon next to it. The 'Systolic blood pressure (mmHg)' field is empty and has a missing icon next to it.

If data are marked as '*not recorded*' or '*unknown*' on the Case Report Form (CRF), right click on the missing icon next to the field and select 'Not Available' from the 'Change Status' option in the drop-down menu. Also please add a reason in 'comments' if available.

Source [ ] [ ] [ ]

Lactate (mmol/l) [ ] [ ]

Source [ ] [ ] [ ]

SpO2 (%) [ ] [ ]

Systolic blood pressure (mmHg) [ ] [ ]

Mechanical respiratory support ☐ No ☐ Yes ☐ No

AP ☐ Yes ☐ No

pill reaction ☐ Both fixed ☐ Other reac ☐ Unknown

Change Status ▸

Missing

Not Available

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

Trial number 019 [ ]

Does the patient fulfil all inclusion criteria ☐ Yes ☒ No

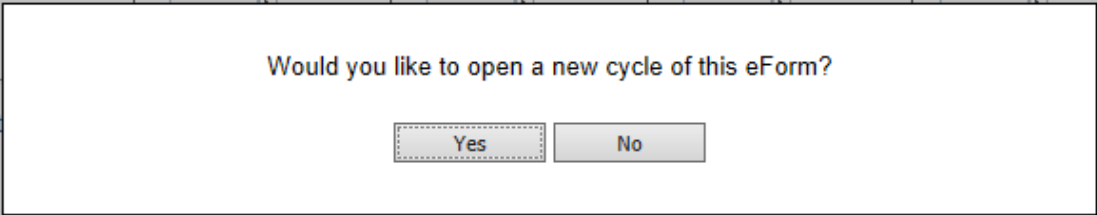
Does the patient fulfil any exclusion criteria ☐ Yes ☒ No

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 31/01/2017 [ ]



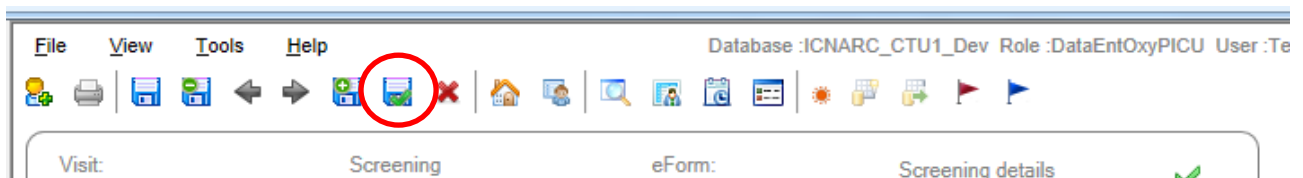
If a page repeats e.g weekly surveillance, you will be asked if you want to open a new cycle of the eForm. If you choose 'Yes', you will navigate to a new version of the same page. If you choose 'No', you will navigate to the next CRF page in the patient record.



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

Yes No

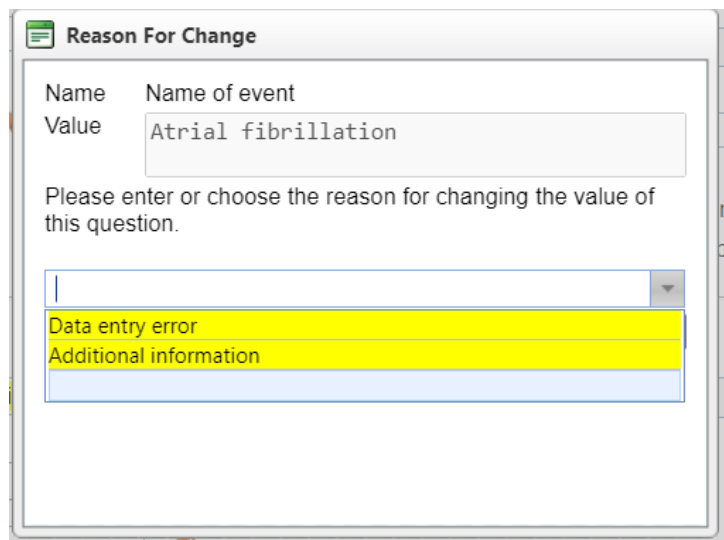
To return to the summary screen, you can save and close the record using the save and close icon. This will take you back to the summary screen for that record.



File View Tools Help Database :ICNARC\_CTU1\_Dev Role :DataEntOxyPICU User :Te

Visit: Screening eForm: Screening details

If an answer is amended after being saved, you will be prompted to provide a Reason For Change. This can be selected from a list, or a reason written in the text field.



Reason For Change

Name Name of event

Value Atrial fibrillation

Please enter or choose the reason for changing the value of this question.

Data entry error

Additional information

## Unusual or incorrect data

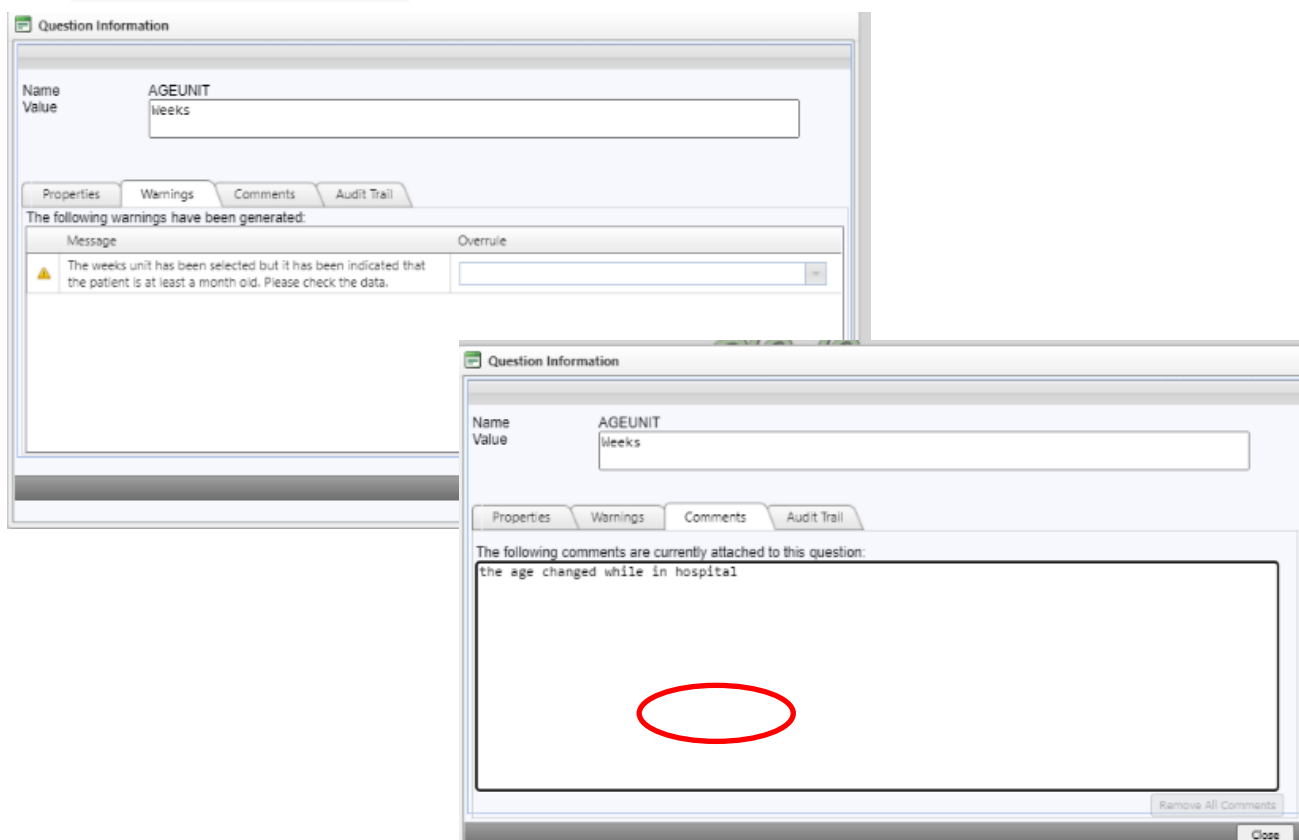
### Rejected Data

If some data are not possible (e.g. dates in the future), this will be rejected which will be displayed by a pop up. These cannot be saved in the record and the data must be changed.



### Warnings

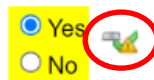
Some data are possible but unusual, so will generate a warning icon and a warning message. If unusual data are correct, please confirm by explaining in a comment. The comments will be reviewed, and if deemed acceptable by the trial team the warning will be overruled.





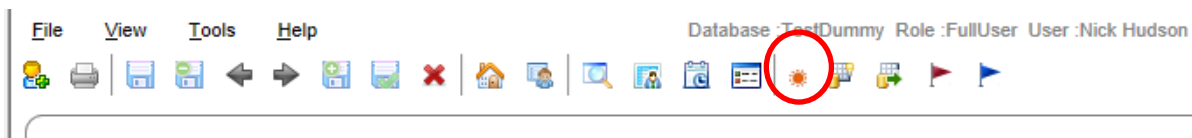
Once the warning has been overruled, the warning icon will be replaced with a confirmed warning icon.

**Mechanically  
Ventilated**



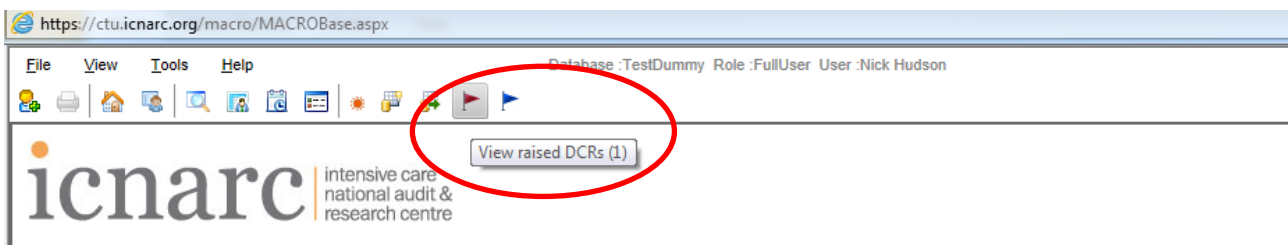
## Missing data

You can find a list containing all missing data for your site by pressing this button. Missing fields should be completed later, once these data are available.



## Data Clarification Requests

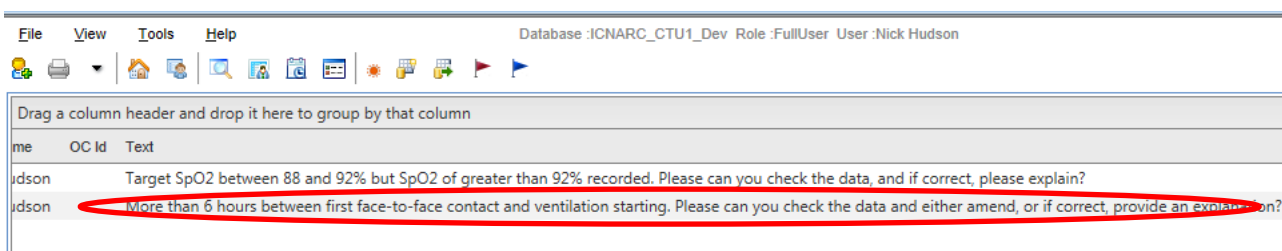
Unusual data which are confirmed to be correct will be reviewed by the team at ICNARC. If they have any questions or need any further clarification, they will raise a Data Clarification Request (DCR). You can check for any DCRs through the home page.



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.

Drag a column header and drop it here to group by that column								
Priority	Date	Status	Subject	Visit	eForm	Question	Value	User Name
5	2017/01/09 14:19:49	Raised	OxyPICU/aa/6	Treatment	Observations: Randomisation to hour 120 (3)	SpO2	93	Nick Hudson
> 5	2017/01/09 14:08:07	Raised	OxyPICU/aa/6	Treatment	Observations: Randomisation to hour 120	Date/Time of start of ventilation	01/01/2017 08:30	Nick Hudson

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

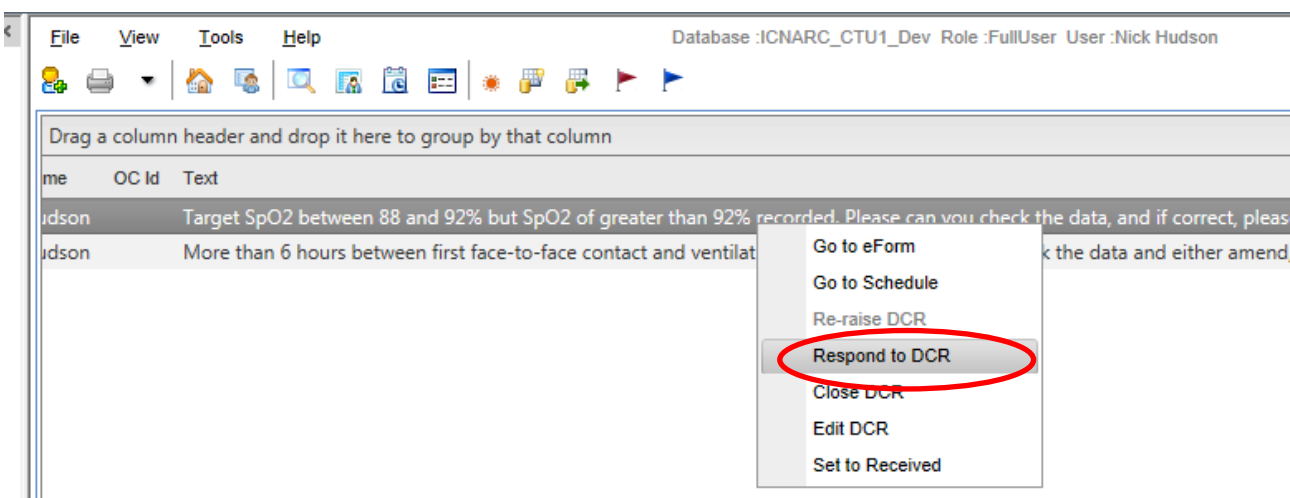


Database :ICNARC\_CTU1\_Dev Role :FullUser User :Nick Hudson

Drag a column header and drop it here to group by that column

me	OC Id	Text
udson		Target SpO2 between 88 and 92% but SpO2 of greater than 92% recorded. Please can you check the data, and if correct, please explain?
udson		More than 6 hours between first face-to-face contact and ventilation starting. Please can you check the data and either amend, or if correct, provide an explanation?

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



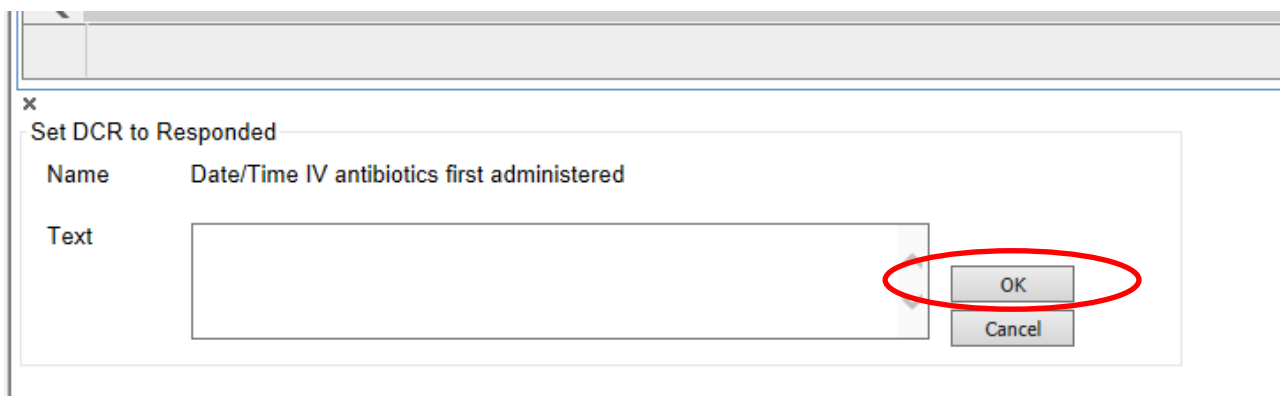
Database :ICNARC\_CTU1\_Dev Role :FullUser User :Nick Hudson

Drag a column header and drop it here to group by that column

me	OC Id	Text
udson		Target SpO2 between 88 and 92% but SpO2 of greater than 92% recorded. Please can you check the data, and if correct, please explain?
udson		More than 6 hours between first face-to-face contact and ventilation starting. Please can you check the data and either amend, or if correct, provide an explanation?

- Go to eForm
- Go to Schedule
- Re-raise DCR
- Respond to DCR**
- Close DCR
- Edit DCR
- Set to Received

An explanation can be entered in the text field and sent back to the ICNARC team by clicking 'OK'. The explanations will be reviewed by the trial team and if acceptable the DCR will be closed.



Set DCR to Responded

Name Date/Time IV antibiotics first administered

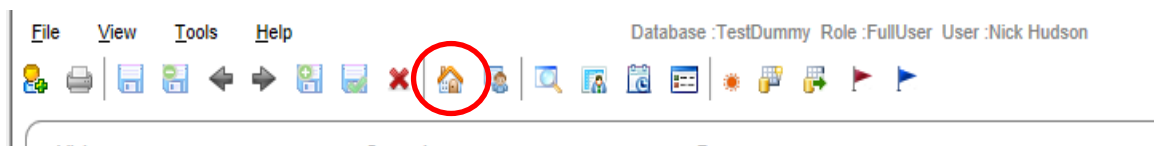
Text

OK

Cancel

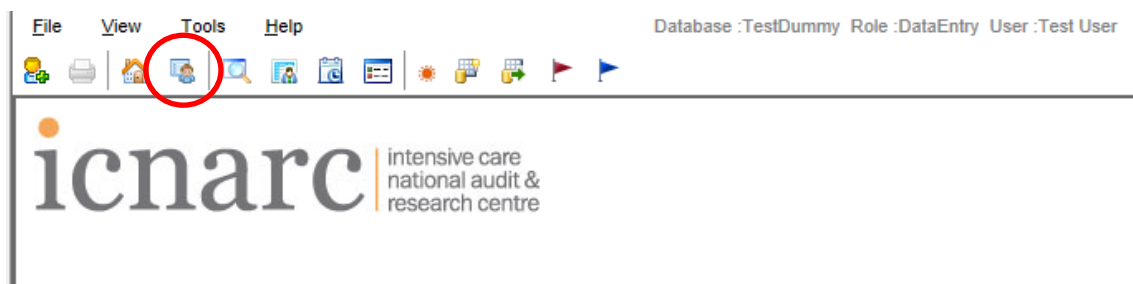
## Reviewing existing patients

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 using one of two methods.

- 1) Clicking on the 'Open the Subject List page' icon.

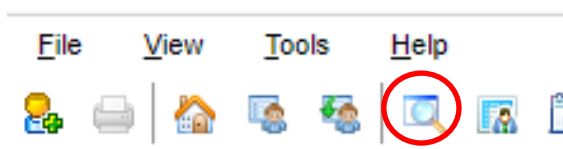


Selecting this will bring up a list of all patients who have already have records in the database. You can go into a specific record by double clicking on that row. This will bring you to the overall record for that patient.

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

Status	Study	Site	Subject ID	Subject Label	Last Modified
	All Studies	ap			
▲	PICNIC	ap	1	1505	2021/05/13 17:54:45 (GMT+1:00)
▲	PICNIC	ap	2	E7777	2021/05/10 17:35:18 (GMT+1:00)
▲	PICNIC	ap	3	E1001	2021/05/13 14:37:41 (GMT+1:00)

- 2) Using the search panel allows for a more accurate search for a specific study number.



Ensure the search is set to 'Subject' and 'Label' and enter the study number in subject field.

**Search**

Subject ▼

**General**

Study: OxyPICU\_RCT ▼

Site: All Sites ▼

Subject Group: All Subject Groups ▼

Subject:

☐ ID ☒ **Label**

## Guidance on eForms

Please see SOP 007\_Guidance for completion of Case Report Forms for guidance on the data points to be collected for the study. The below information will assist on completing certain sections of eForms on Macro.

Each eForm asks you to input the study number. This will help ensure the correct details are being recorded for the correct patient. A rejection will occur if you enter incorrect details to allow you to double check you are entering the correct patient details.

Study number

**Reject Data**

Name: Study number (weekly surveillance)

Value: 8958

The entered data has been rejected for the following reason:

The study or surveillance number entered in this form is different than the one in the landing page. Please review

OK

## Microbiology results

A positive microbiology result, where the sample has antimicrobial resistance present, is recorded on the eForm in the following way:

- Ensure 'yes' is selected for the question 'present'
- You can enter more than one organism if required

Sample result

Gram Negative Bacteria

Present? Organism

1. ☒ Yes ☐ No

Antimicrobial resistance present?

☒ Yes ☐ No

☒ A ☐ B ☐ C ☒ D ☐ E



Gram Negative Bacteria  
 A: Co-amoxiclav  
 B: Piperacillin-tazobactam  
 C: Ceftriaxone  
 D: Ceftazidime  
 E: Gentamicin  
 F: Amikacin  
 G: Ciprofloxacin  
 H: Ertapenem  
 I: Meropenem  
 J: ESBL  
 K: AmpC  
 L: Carbapenemases  
 M: Other, please specify

Gram Positive Bacteria

Present? Organism

1. ☒ Yes ☐ No

Antimicrobial resistance present?

☐ Yes ☐ No

☐ N ☐ O ☐ P ☐ Q ☐ R



Gram Positive Bacteria  
 N: Vancomycin  
 O: Penicillin  
 P: Flucloxacillin  
 Q: Gentamicin  
 R: Linezolid  
 S: Other, please specify

Virology

Present? Organism

1. ☐ Yes ☐ No

Antimicrobial resistance present?

☐ Yes ☐ No

If yes, specify

Fungal

Present? Organism

1. ☐ Yes ☐ No

Antimicrobial resistance present?

☐ Yes ☐ No

☐ T ☐ U ☐ V ☐ W



Fungal  
 T: Fluconazole  
 U: Amphotericin B  
 V: Echinocandin  
 W: Other, please specify

If antimicrobial resistance is present in:

- Gram Negative bacteria organism
- Gram Positive bacteria organism
- Fungal organism

Use the antibiotic / resistance marker key to select the corresponding radio button. Multiple may be selected for each specified organism.

## SDD Administration and Deviation

The administration of all SDD treatment should be recorded on the eForm, please ensure that all 4 doses for each day have data entered.

- Start with completing information for day 1 dose 1 (this should be the same date as becoming eligible): the time SDD was given, mechanical ventilation status, confirming oral paste was given and specifying the amount of gastric suspension (ml).

**SDD Administration**

SDD treatment should start within 6hrs of being identified as eligible and continue for a maximum of 30 days (treatment period) or until patient is extubated/no longer mechanically ventilated.

Study Number

**SDD suspension dosing**

0-4 years	5-12 years	≥13 years
2.5 ml	5 ml	10 ml

Dosing (4 per day, every 6 hours while intubated)

Day  ☒   
 ☒   
(ddmm/yyyy)

	Time dose given (24 hrs)	Mechanically Ventilated	Oral paste given (1 syringe)	Gastric suspension given (ml)
Dose 1	<input type="text" value="12:30"/> <input checked="" type="checkbox"/> <input type="radio"/> Not given <input checked="" type="checkbox"/>	<input checked="" type="radio"/> Yes <input checked="" type="checkbox"/> <input type="radio"/> No <input checked="" type="checkbox"/>	<input type="radio"/> Yes <input checked="" type="checkbox"/> <input type="radio"/> No <input checked="" type="checkbox"/>	<input type="text" value=""/> <input checked="" type="checkbox"/>
Dose 2	<input type="text" value=""/> <input checked="" type="checkbox"/> <input type="radio"/> Not given <input checked="" type="checkbox"/>	<input checked="" type="radio"/> Yes <input checked="" type="checkbox"/> <input type="radio"/> No <input checked="" type="checkbox"/>	<input type="radio"/> Yes <input checked="" type="checkbox"/> <input type="radio"/> No <input checked="" type="checkbox"/>	<input type="text" value=""/> <input checked="" type="checkbox"/>
Dose 3	<input type="text" value=""/> <input checked="" type="checkbox"/> <input type="radio"/> Not given <input checked="" type="checkbox"/>	<input type="radio"/> Yes <input checked="" type="checkbox"/> <input type="radio"/> No <input checked="" type="checkbox"/>	<input type="radio"/> Yes <input checked="" type="checkbox"/> <input type="radio"/> No <input checked="" type="checkbox"/>	<input type="text" value=""/> <input checked="" type="checkbox"/>
Dose 4	<input type="text" value=""/> <input checked="" type="checkbox"/> <input type="radio"/> Not given <input checked="" type="checkbox"/>	<input type="radio"/> Yes <input checked="" type="checkbox"/> <input type="radio"/> No <input checked="" type="checkbox"/>	<input type="radio"/> Yes <input checked="" type="checkbox"/> <input type="radio"/> No <input checked="" type="checkbox"/>	<input type="text" value=""/> <input checked="" type="checkbox"/>

- It will likely be the case that on the first and last day of SDD treatment, not all 4 doses will be given due to timing of patients becoming eligible. Please ensure that 'not given' is selected for the doses that are not relevant.
- If for any reason a dose was not given, please select 'not given' and indicate if the patient was mechanically ventilated at this time.
- When relevant, please ensure gastric suspension dosing is recorded using the dosing guide. If none is given, please enter '0' ml.

If the patient becomes eligible near the end of the day and does not receive their first dose until the following day, mark all doses on day 1 as not given. Report the first administered dose on day 2. (Please see example below).

File View Tools Help Database: SCHARC\_CTU1\_Dev Role: DataEntryCHC User: Ailanna Brown

**SDD suspension dosing**

0-4 years	5-12 years	≥13 years
2.5 ml	5 ml	10 ml

Dosing (4 per day, every 6 hours while intubated)

Day  ☒   
 ☒   
(ddmm/yyyy)

	Time dose given (24 hrs)	Mechanically Ventilated	Oral paste given (1 syringe)	Gastric suspension given (ml)
Dose 1	<input type="text" value=""/> <input checked="" type="checkbox"/> <input checked="" type="radio"/> Not given <input checked="" type="checkbox"/>	<input type="radio"/> Yes <input checked="" type="checkbox"/> <input checked="" type="radio"/> No <input checked="" type="checkbox"/>	<input type="radio"/> Yes <input checked="" type="checkbox"/> <input type="radio"/> No <input checked="" type="checkbox"/>	<input type="text" value=""/> <input checked="" type="checkbox"/>
Dose 2	<input type="text" value=""/> <input checked="" type="checkbox"/> <input checked="" type="radio"/> Not given <input checked="" type="checkbox"/>	<input type="radio"/> Yes <input checked="" type="checkbox"/> <input checked="" type="radio"/> No <input checked="" type="checkbox"/>	<input type="radio"/> Yes <input checked="" type="checkbox"/> <input type="radio"/> No <input checked="" type="checkbox"/>	<input type="text" value=""/> <input checked="" type="checkbox"/>
Dose 3	<input type="text" value=""/> <input checked="" type="checkbox"/> <input checked="" type="radio"/> Not given <input checked="" type="checkbox"/>	<input type="radio"/> Yes <input checked="" type="checkbox"/> <input checked="" type="radio"/> No <input checked="" type="checkbox"/>	<input type="radio"/> Yes <input checked="" type="checkbox"/> <input type="radio"/> No <input checked="" type="checkbox"/>	<input type="text" value=""/> <input checked="" type="checkbox"/>
Dose 4	<input type="text" value=""/> <input checked="" type="checkbox"/> <input checked="" type="radio"/> Not given <input checked="" type="checkbox"/>	<input type="radio"/> Yes <input checked="" type="checkbox"/> <input checked="" type="radio"/> No <input checked="" type="checkbox"/>	<input type="radio"/> Yes <input checked="" type="checkbox"/> <input type="radio"/> No <input checked="" type="checkbox"/>	<input type="text" value=""/> <input checked="" type="checkbox"/>

Dosing (4 per day, every 6 hours while intubated)

Day  ☒   
 ☒   
(ddmm/yyyy)

	Time dose given (24 hrs)	Mechanically Ventilated	Oral paste given (1 syringe)	Gastric suspension given (ml)
Dose 1	<input type="text" value="00:30"/> <input checked="" type="checkbox"/> <input type="radio"/> Not given <input checked="" type="checkbox"/>	<input checked="" type="radio"/> Yes <input checked="" type="checkbox"/> <input type="radio"/> No <input checked="" type="checkbox"/>	<input checked="" type="radio"/> Yes <input checked="" type="checkbox"/> <input type="radio"/> No <input checked="" type="checkbox"/>	<input type="text" value="2.5"/> <input checked="" type="checkbox"/>
Dose 2	<input type="text" value=""/> <input checked="" type="checkbox"/> <input type="radio"/> Not given <input checked="" type="checkbox"/>	<input type="radio"/> Yes <input checked="" type="checkbox"/> <input type="radio"/> No <input checked="" type="checkbox"/>	<input type="radio"/> Yes <input checked="" type="checkbox"/> <input type="radio"/> No <input checked="" type="checkbox"/>	<input type="text" value=""/> <input checked="" type="checkbox"/>

If one or both SDD treatments were not given AND the patient was mechanically ventilated, then please complete the SDD administration deviation section on the eForm.

- Ensure the 'study date' and 'time dose due' matches the deviation on the SDD Administration part of the eForm

**SDD Administration Deviation**

Enter SDD administration deviations relating to the administration days on this eForm  
Only to be completed if one or both SDD treatments were not given AND patient was mechanically ventilated.

Study Number

Study date  ✓

Time dose due  ✓

**Oral Paste Syringe** ☐ N/A ✓

☐ Not in PICU ☐ Nil by mouth ☐ Dose missed ☐ Unable to administer via prescribed route ☐ Omitted on clinician's instruction ☐ SDD not available ☐ Other (specify)

**Gastric Suspension** ☒ N/A ✓

☐ Not in PICU ☐ Nil by mouth ☐ Dose missed ☐ Unable to administer via prescribed route ☐ Omitted on clinician's instruction ☐ SDD not available ☐ Other (specify)

- Specify the reason that the oral paste / gastric suspension was not given. If one was given but not the other, please select N/A for the treatment that did not deviate

## Antibiotic Use

Antibiotic use should be recorded from index admission up to 30 days. The start date of antibiotics can be before PICU admission if they were continued whilst on PICU. If the patient was still on antibiotics at PICU discharge or at 30 days post enrolment 'NA' can be selected which will blank out end date and the reason of end of course.

**Antibiotic**

Antibiotic name  ✓ Use generic name.

Initial prescribed dose  ✓  ✓

Date/time start of course  ✓

Date of end of course  ☒ N/A Still on antibiotics at PICU discharge / 30 days post enrolment ✓

Reason for end of course  If other, specify:

## Safety Monitoring

eForms regarding safety will only be available for all patients in Period Two. For those on Usual Care, only NG tube blockage will be available for completion.

**Adverse events (specified)**

'If the adverse events specified did not occur then record severity as 0'  
Start date and time should be recorded as dd/mm/yyyy hh:mm

- The severity of each specified Adverse events must be reported. If not experienced, answer 'none'.
- If the event occurred multiple times, you will be able to record this on the eForm

Event	Severity	Start date/time	Related
Ng tube blockage	1. Mild	04/04/2021 12:00	Probably
Choking on paste	1. None		
Allergic reaction to SDD	1. Mild 2. Moderate	05/04/2021 14:00	Definitely

## SAE Reporting Form

For each event that meets the criteria, the completed CRF should be uploaded via the top of the eForm within 24 hours or becoming aware of the event. Following this, the eForm should also be completed.

### Serious Adverse Event Reporting Form

**Serious adverse event form**

1.

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SAE ID

**Patient details**

Study number

Treating Clinician