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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.

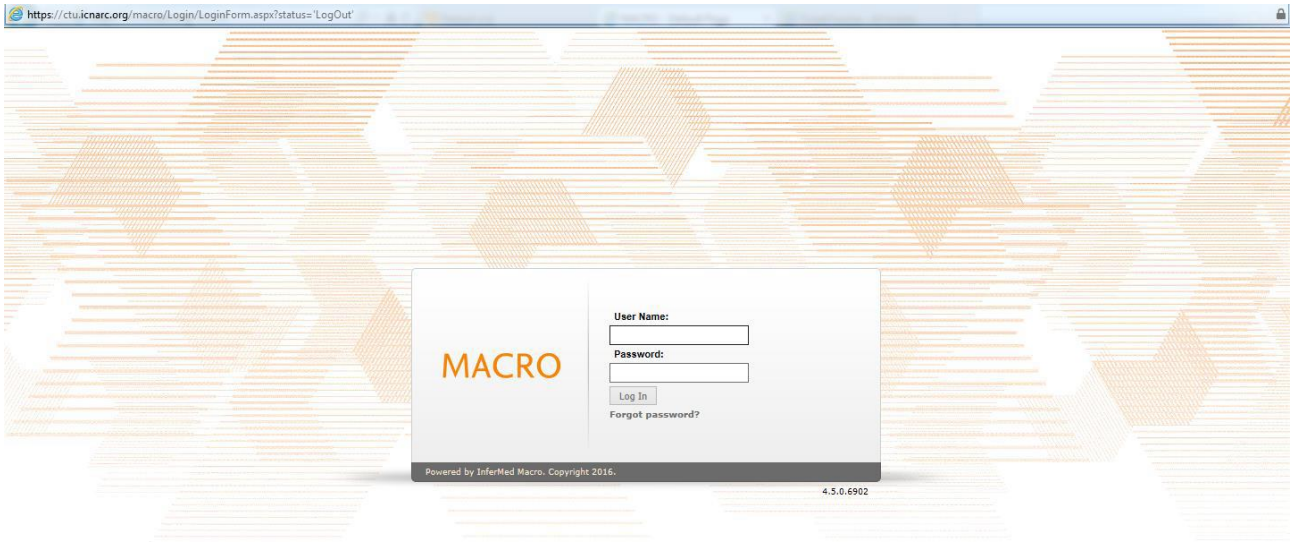
Creating an account

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

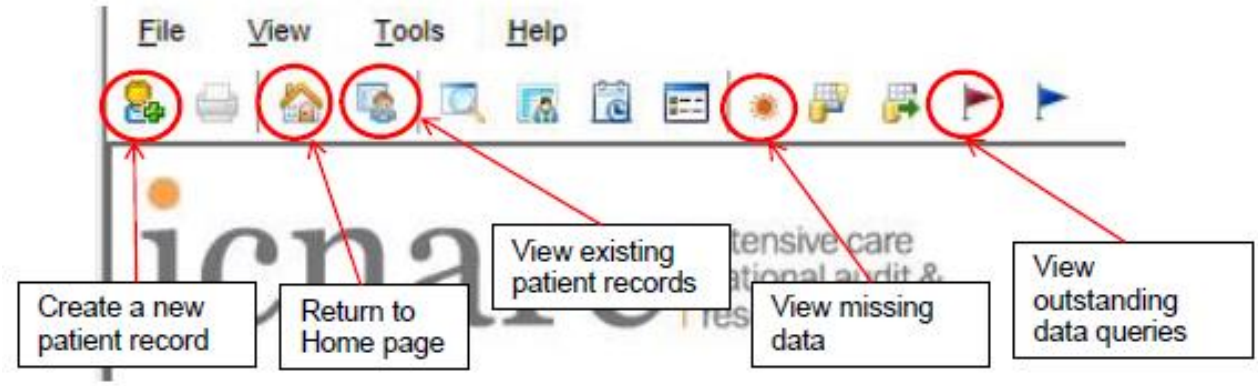
To log in to MACRO, use the following URL: https://ctu.icnarc.org/macro/. We recommend Google Chrome for best performance.

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.



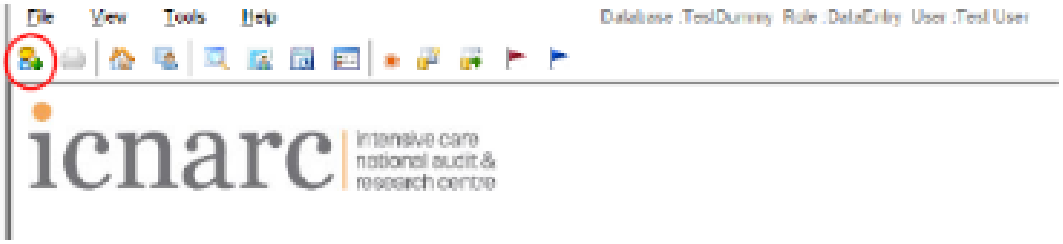
Once you have logged in, you will start at the home page for the PICnIC Study.

Navigating the home page

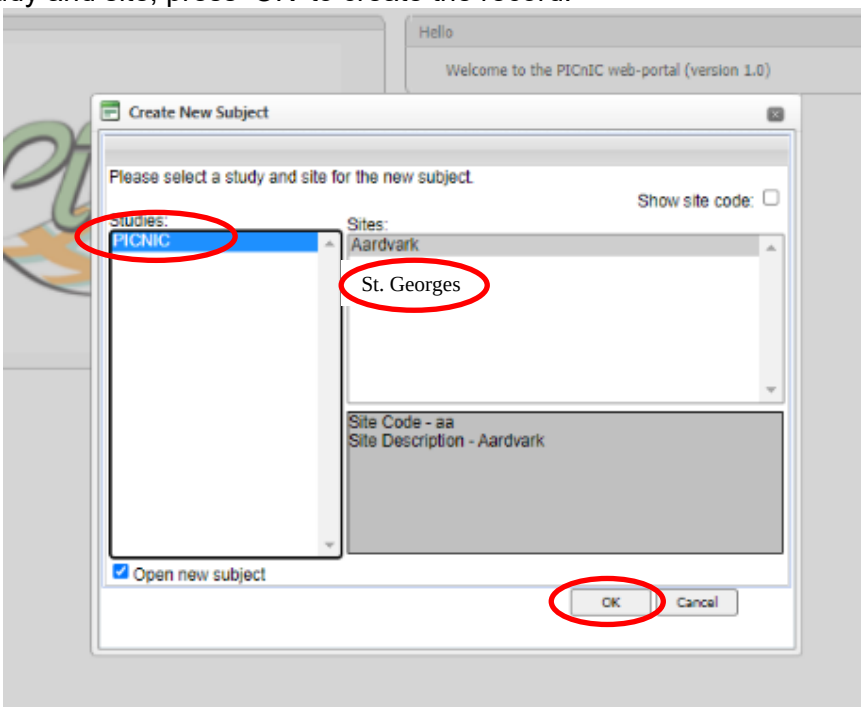


Creating a new record

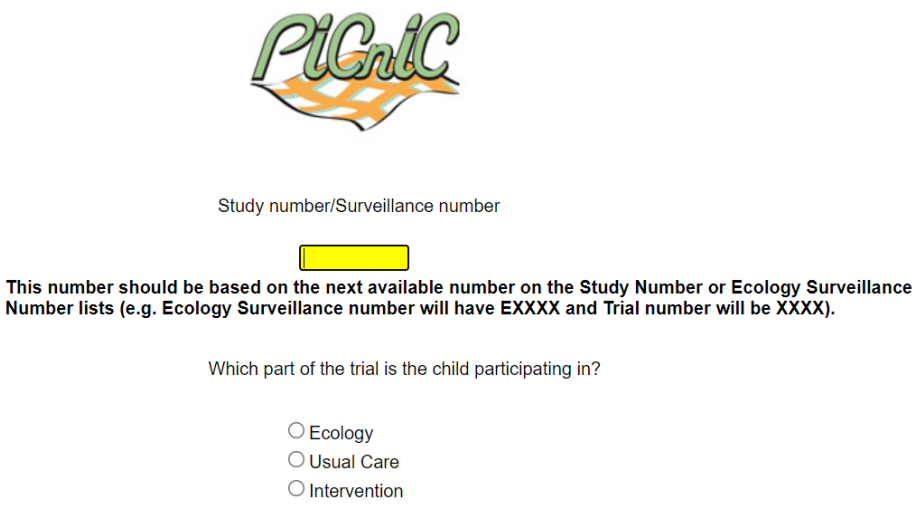
You can add a new patient record by clicking on the 'Create a new study subject' icon (see below).



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.

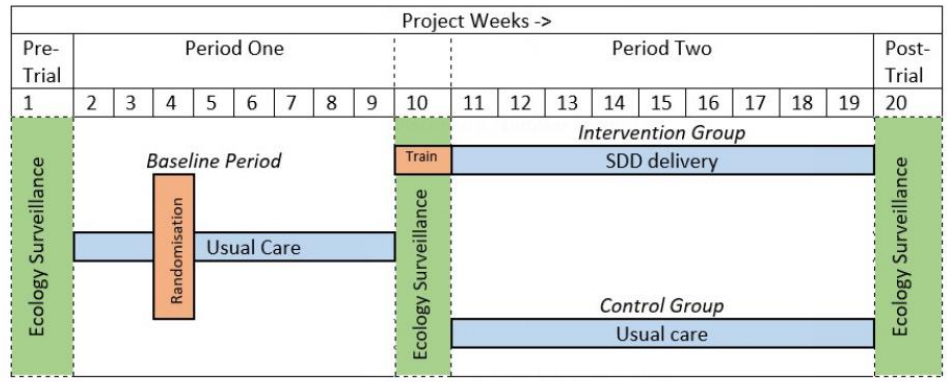


Ecology Surveillance Periods should be used at all sites on week 1, 10 and 20. They are for all patients admitted to the PICU during these time periods only, regardless of ventilation status. The Ecology Surveillance number should be taken from the ‘PICnIC Ecology Surveillance Number List’ EXXXX in Section 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).

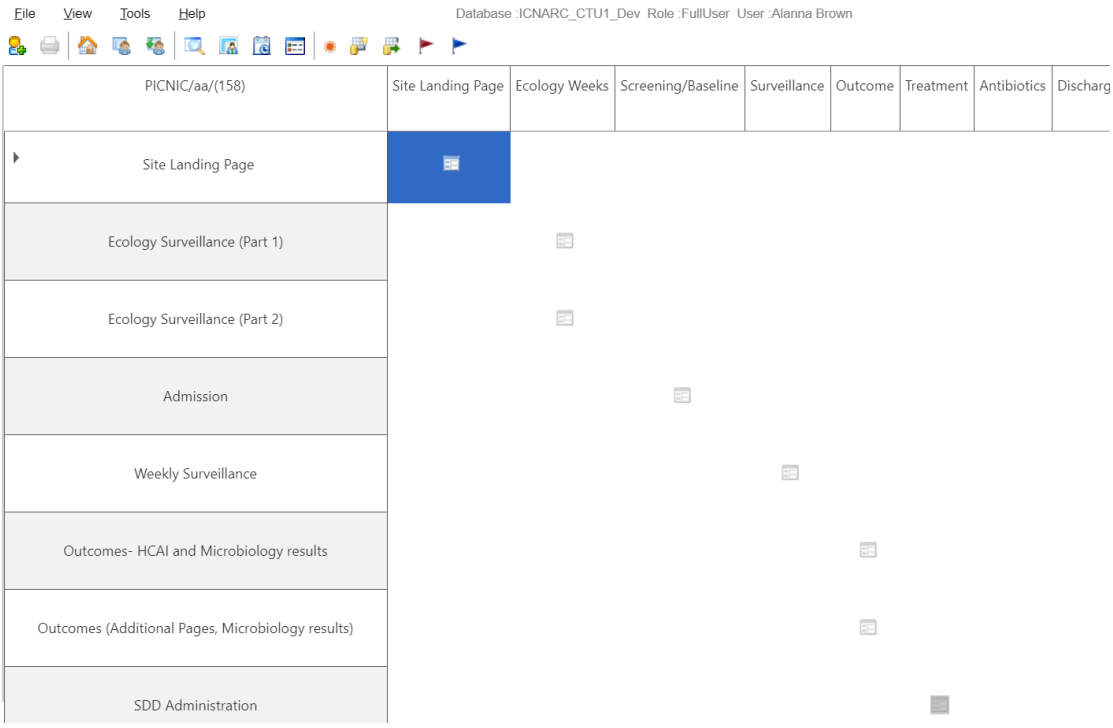
Intervention should be selected for sites randomised to receive SDD intervention during Period Two (weeks 11-19).

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).

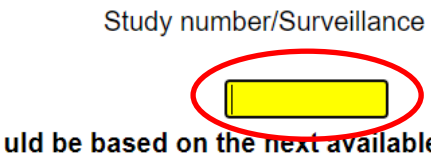


Week 11 shall be treated as a transition period

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.

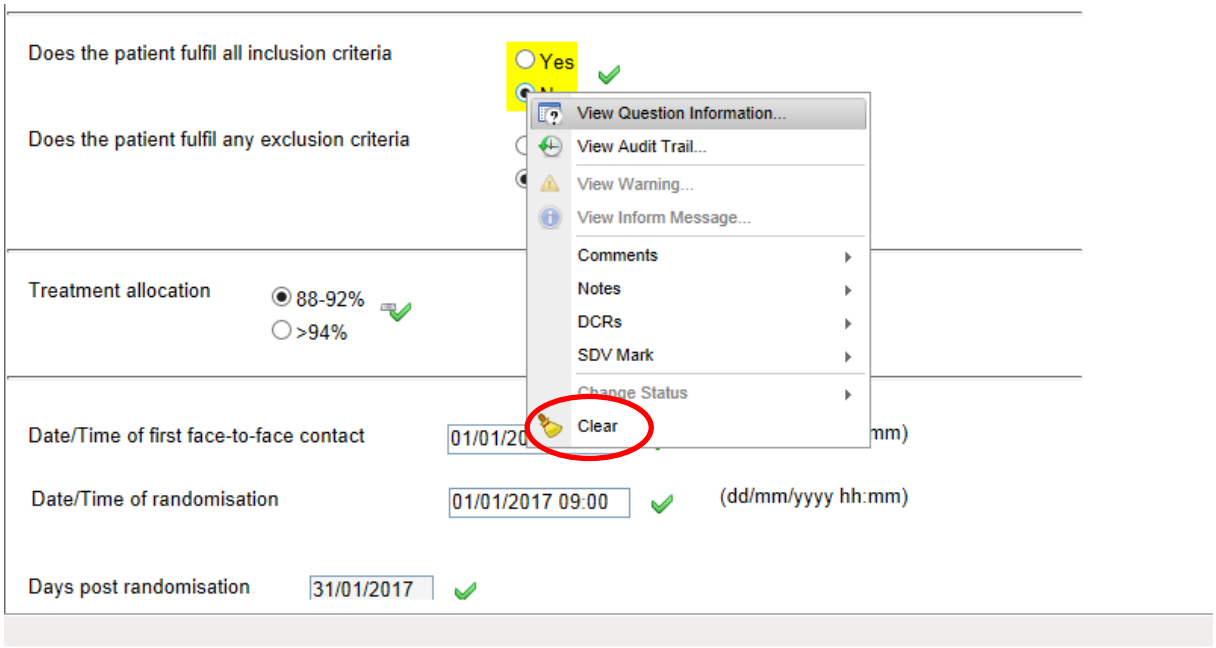


When a page is opened, the field which is currently selected will be highlighted yellow, and data can be entered in this field.

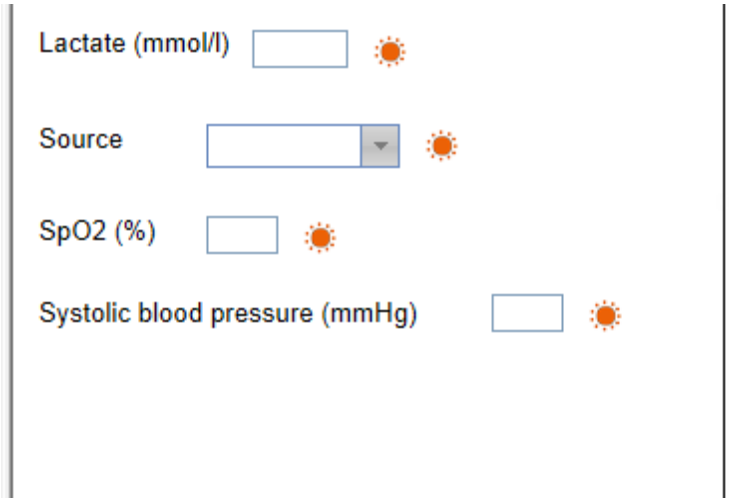


uld be based on the next available number on the Study Nur

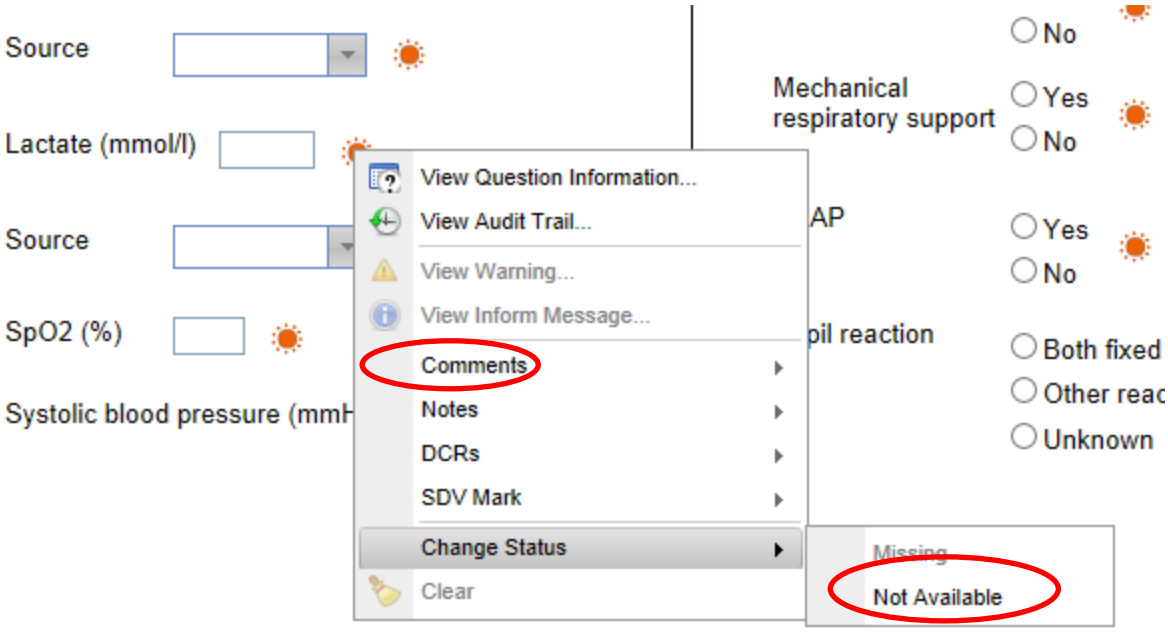
If the wrong option button is selected in error, the selection can be cleared by right clicking on the option button and selecting clear.



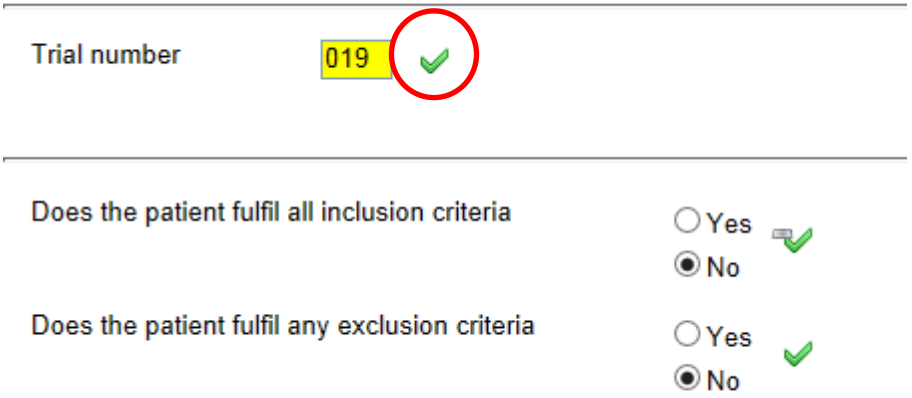
If a required field is missing, the missing icon will appear next to it. (This may only appear once the form is saved)



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.

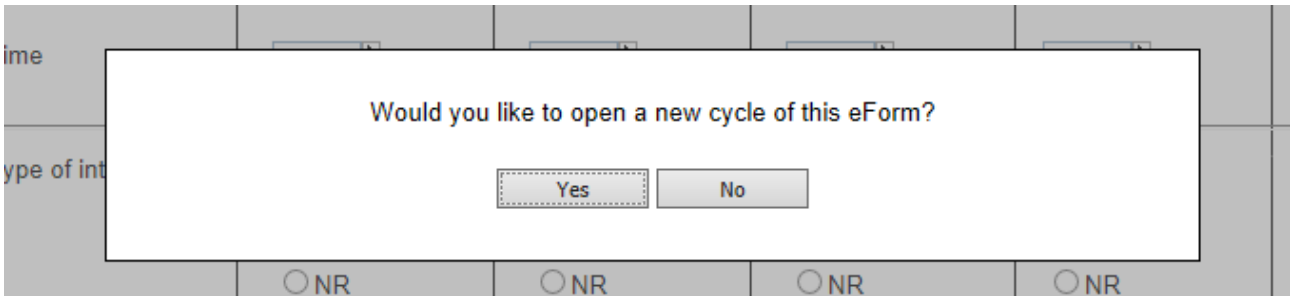


Once data are entered in the correct format a green tick will appear next to the data.

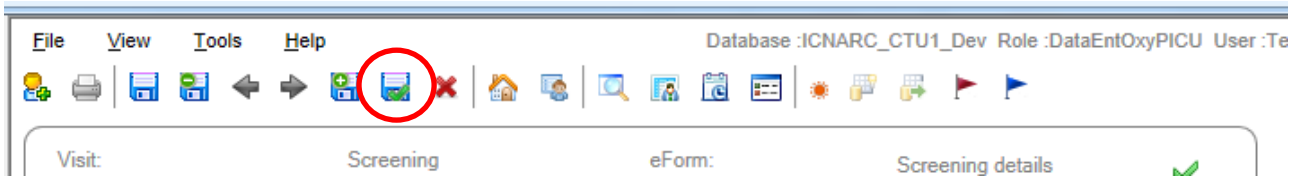


Once all data have been entered, you can move on to the next page in a record by selecting the save and move on to next page icon at the bottom of the page.

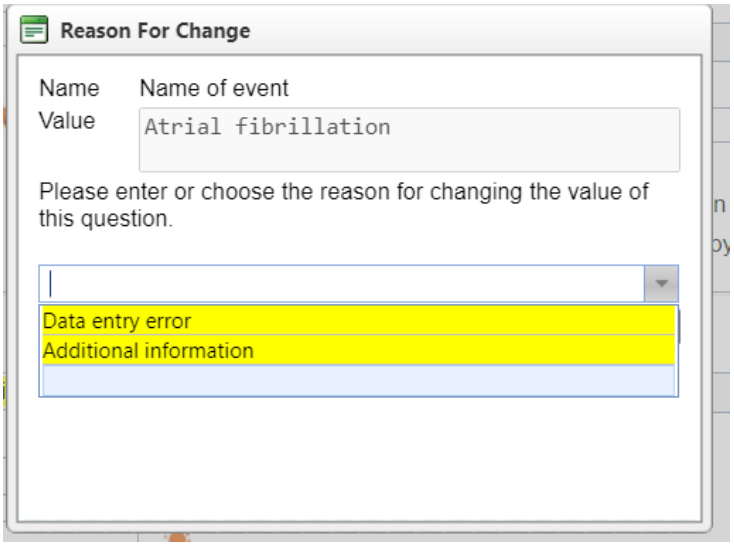
If a page repeats e.g weekly surveillance, you will be asked if you want to open a new cycle of the eForm. If you choose ‘Yes’, you will navigate to a new version of the same page. If you choose ‘No’, you will navigate to the next CRF page in the patient record.



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.



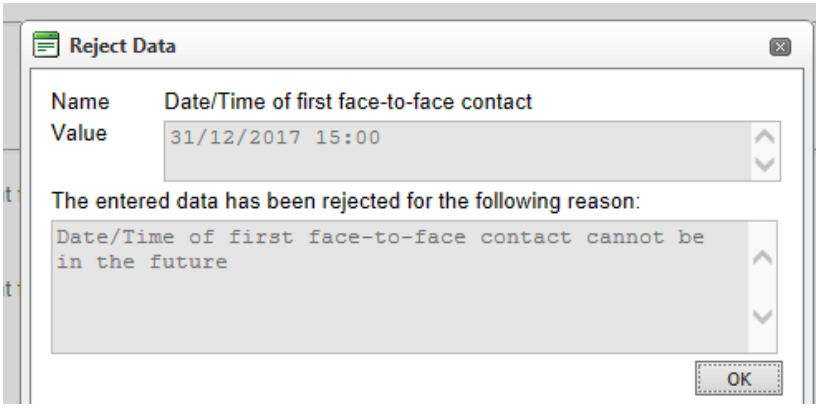
If an answer is amended after being saved, you will be prompted to provide a Reason For Change. This can be selected from a list, or a reason written in the text field.



Unusual or incorrect data

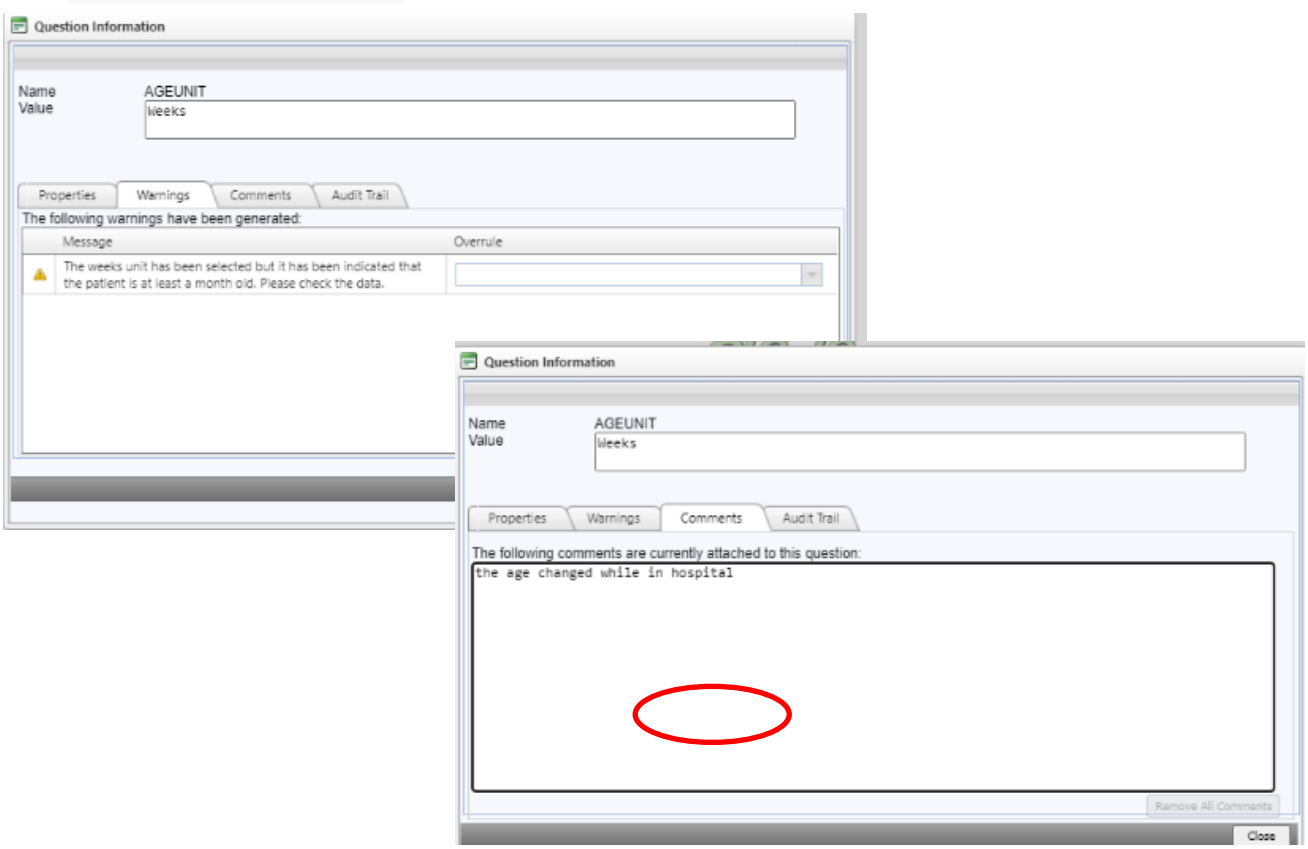
Rejected Data

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.

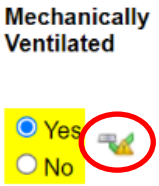


Warnings

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.

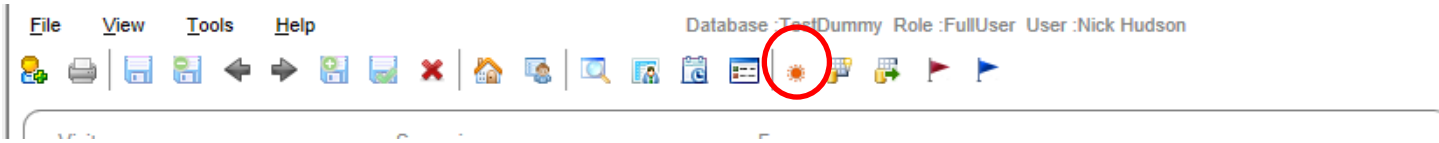


Once the warning has been overruled, the warning icon will be replaced with a confirmed warning icon.



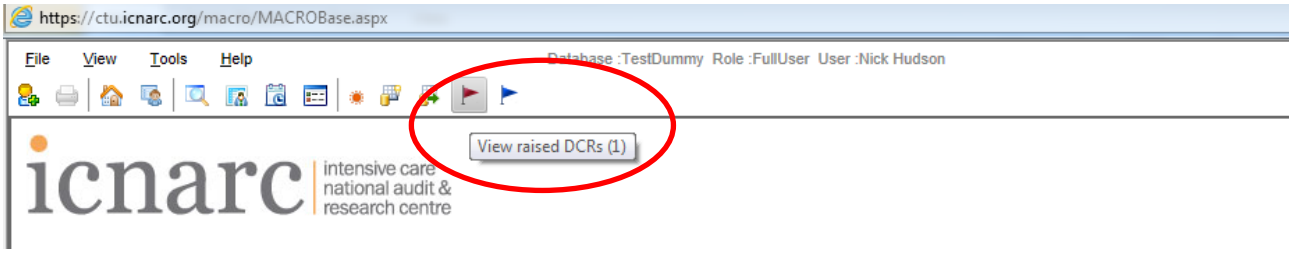
Missing data

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.

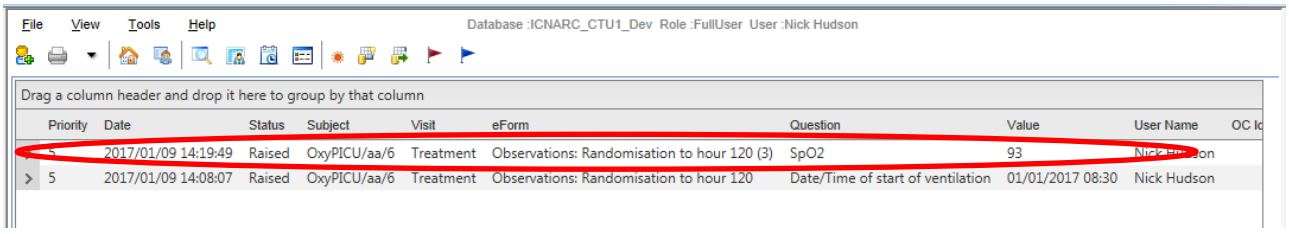


Data Clarification Requests

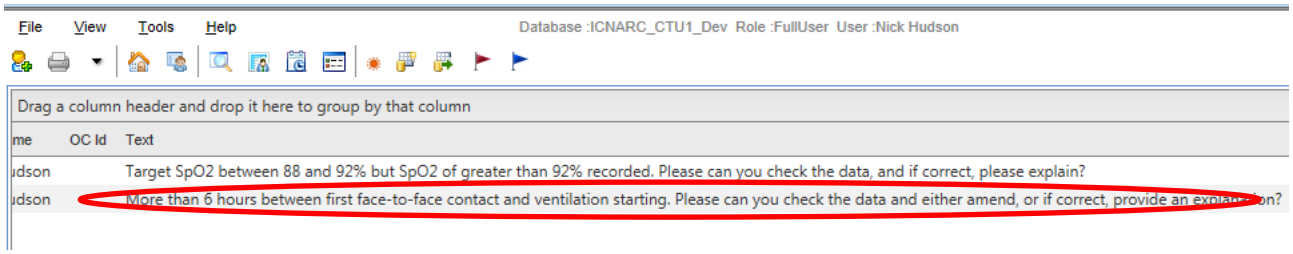
Unusual data which are confirmed to be correct will be reviewed by the team at ICNARC. If they have any questions or need any further clarification, they will raise a Data Clarification Request (DCR). You can check for any DCRs through the home page.



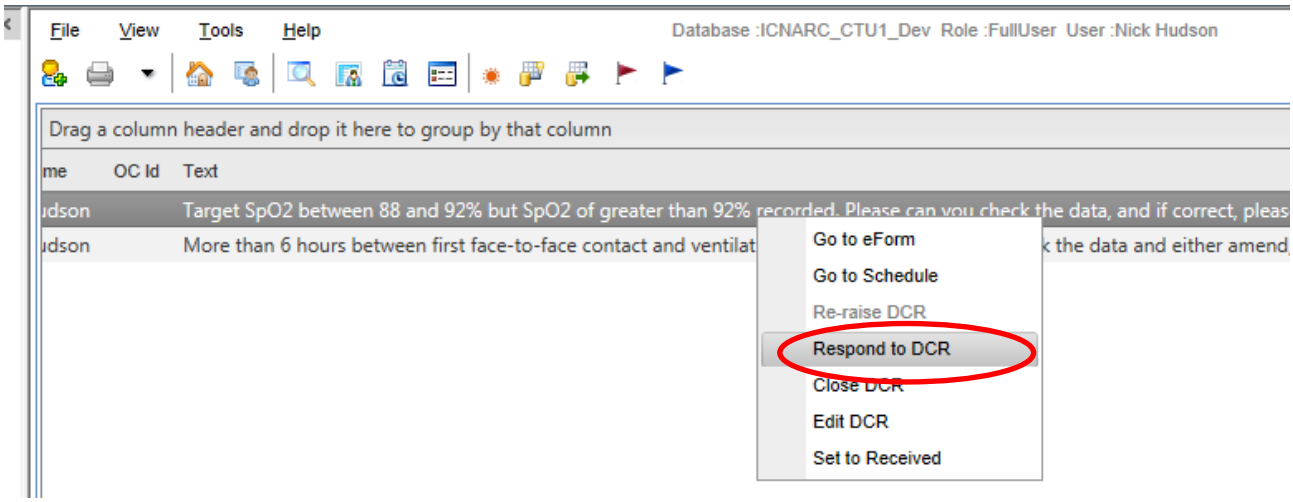
Clicking on the red flag will take you through to the DCR itself. This will tell you which record and which question the check relates to.



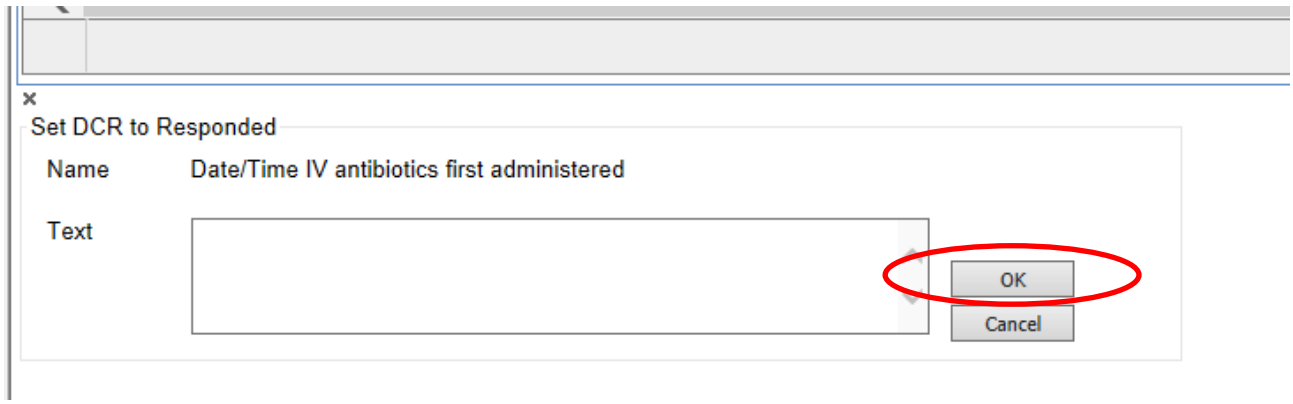
There will also be an explanation from the team at ICNARC as to why the DCR has been raised.



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

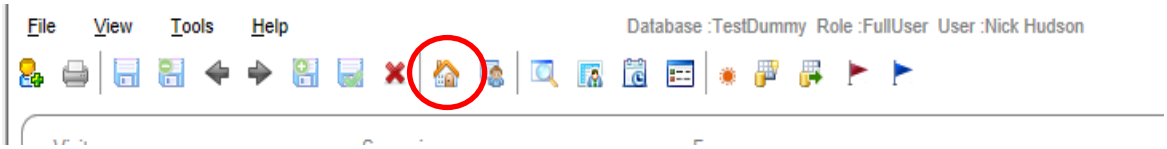


An explanation can be entered in the text field and sent back to the ICNARC team by clicking 'OK'. The explanations will be reviewed by the trial team and if acceptable the DCR will be closed.



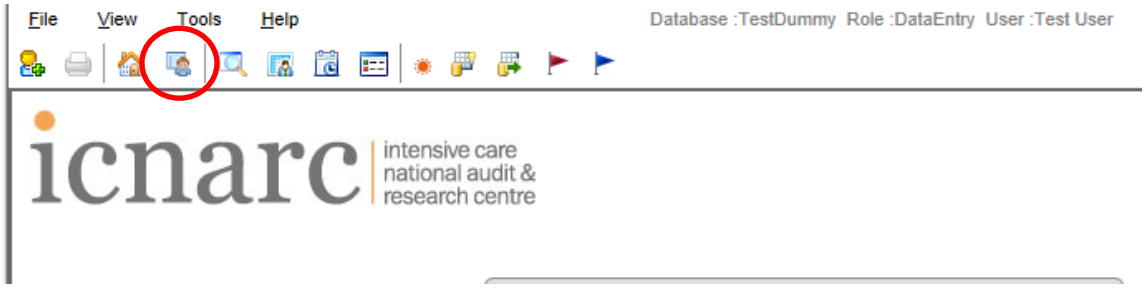
Reviewing existing patients

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



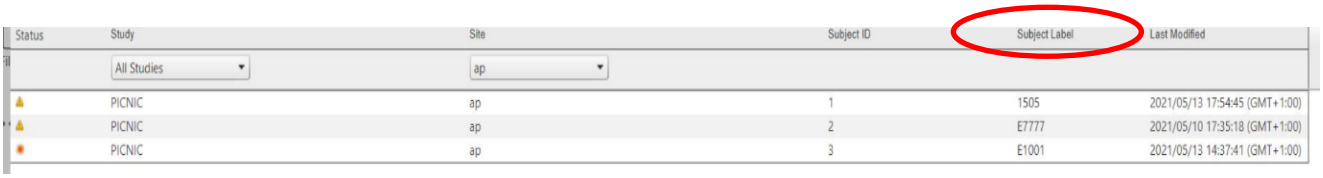
From the home page you can review existing patients using one of two methods.

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

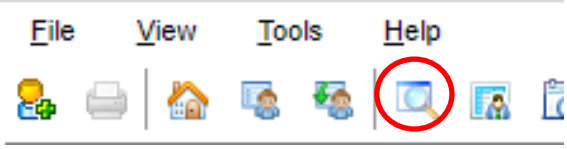


Selecting this will bring up a list of all patients who have already have records in the database. You can go into a specific record by double clicking on that row. This will bring you to the overall record for that patient.

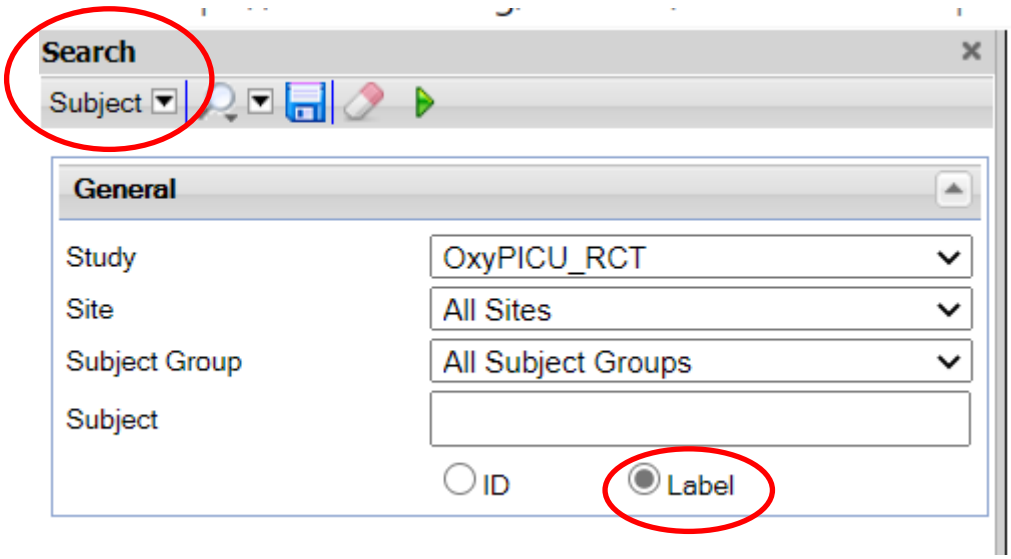
Please note that the Subject Label refers to the patient's Study Number



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



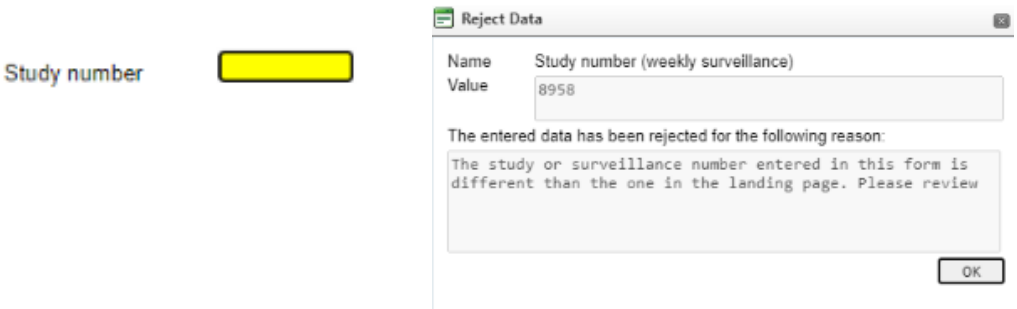
Ensure the search is set to 'Subject' and 'Label' and enter the study number in subject field.



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.

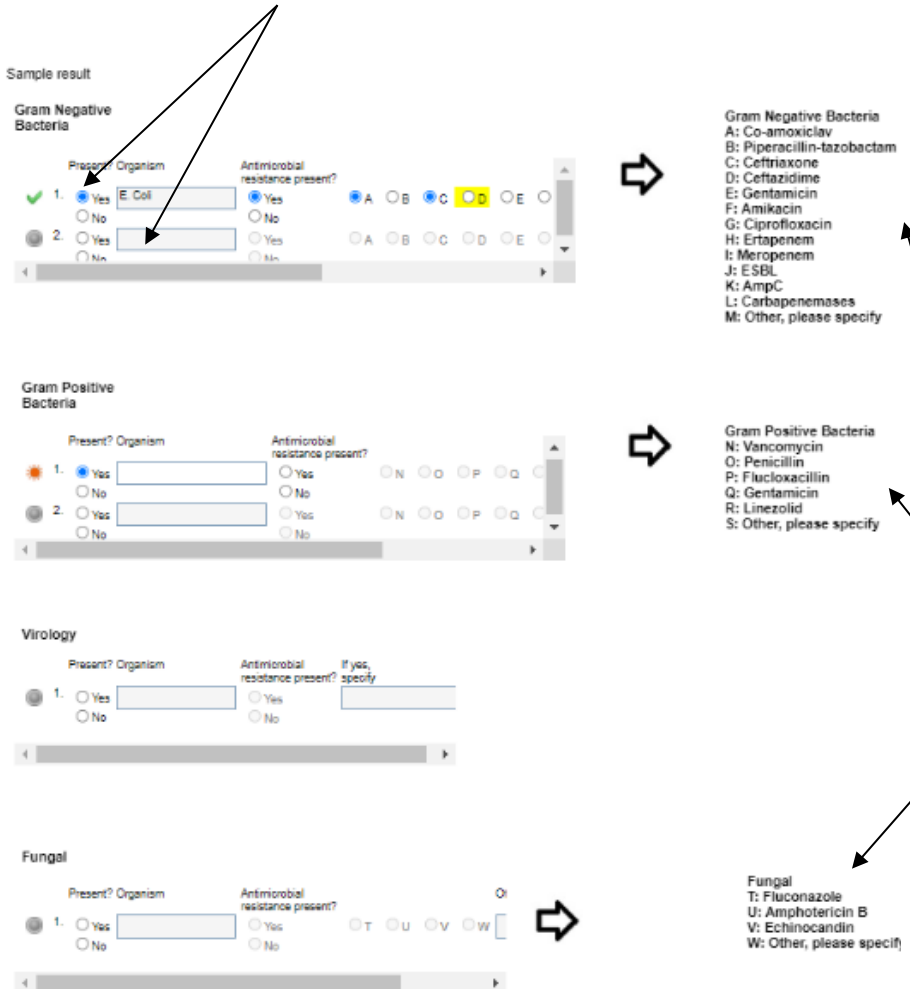
Each eForm asks you to input the study number. This will help ensure the correct details are being recorded for the correct patient. A rejection will occur if you enter incorrect details to allow you to double check you are entering the correct patient details.



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



If antimicrobial resistance is present in:

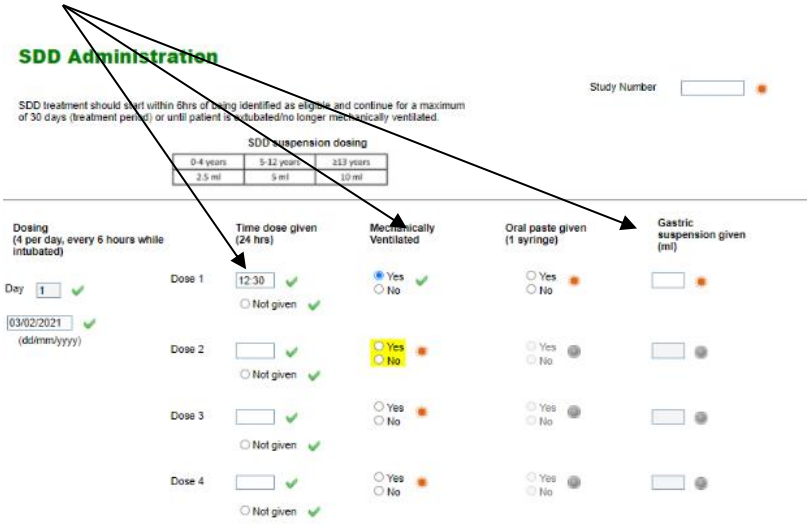
-Gram Negative bacteria organism
-Gram Positive bacteria organism
-Fungal organism

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).

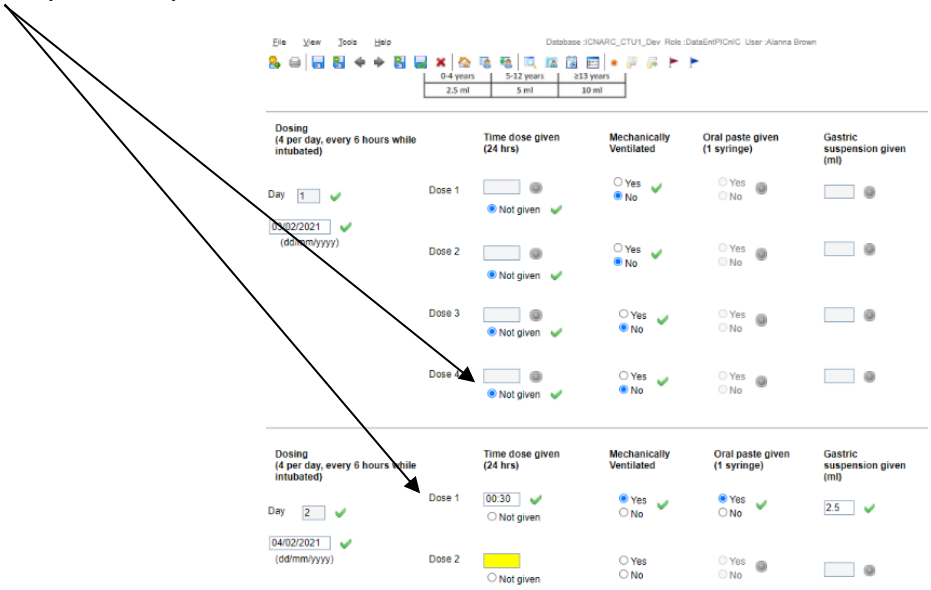


- It will likely be the case that on the first and last day of SDD treatment, not all 4 doses will be given due to timing of patients becoming eligible. Please ensure that 'not given' is selected for the doses that are not relevant.

- If for any reason a dose was not given, please select 'not given' and indicate if the patient was mechanically ventilated at this time.

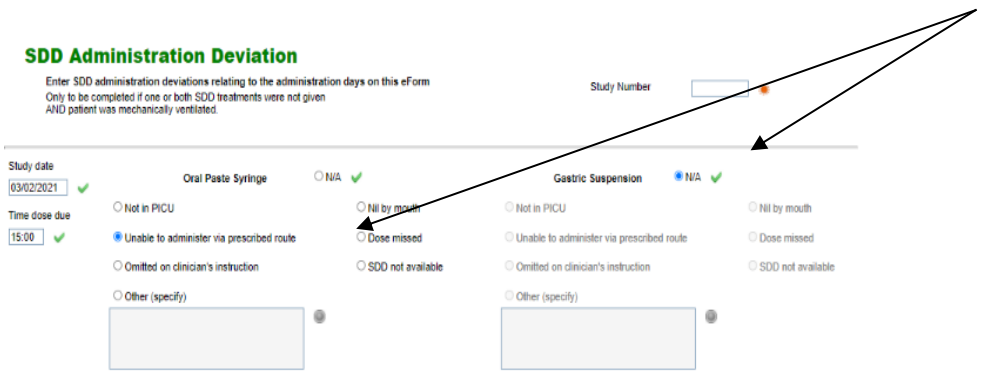
- When relevant, please ensure gastric suspension dosing is recorded using the dosing guide. If none is given, please enter '0' ml.

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).



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.

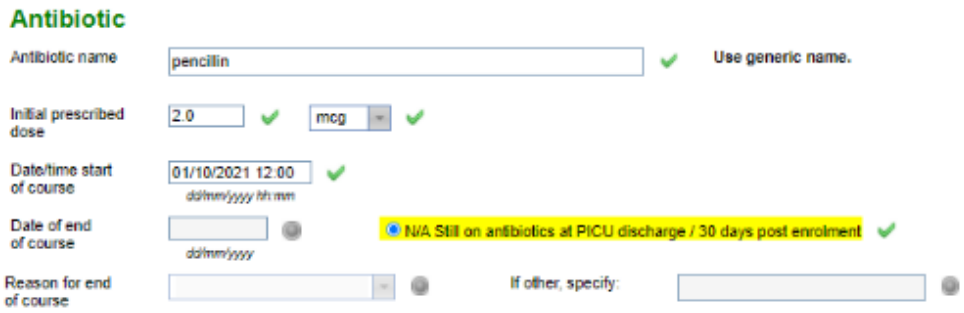
- Ensure the ‘study date’ and ‘time dose due’ matches the deviation on the SDD Administration part of the eForm



- 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

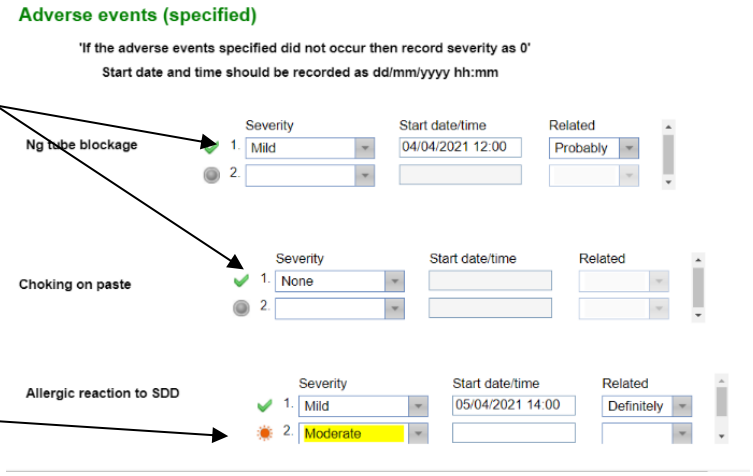
Antibiotic use should be recorded from index admission up to 30 days. The start date of antibiotics can be before PICU admission if they were continued whilst on PICU. If the patient was still on antibiotics at PICU discharge or at 30 days post enrolment ‘NA’ can be selected which will blank out end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



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.

- 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

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.