CliRes Database Instructions

The following sections are included in these instructions:

1 SIGNING UP

1.1 Registering for access

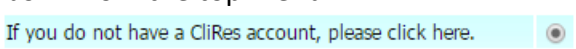
All staff who require access to the CliRes data system must register for a unique username and password. There are 3 types of access requests:

- Registering a username for a new site which does not already have a site number (see 1.2)
- Registering as a new user for an existing site which already has a site number (see 1.4)
- Registering as a new user for an existing site which already has a site number, but you would like to have an additional site number for the same site (this is not optimal, but accepted if, for example, different wards want to have separate site numbers) (see 1.5)

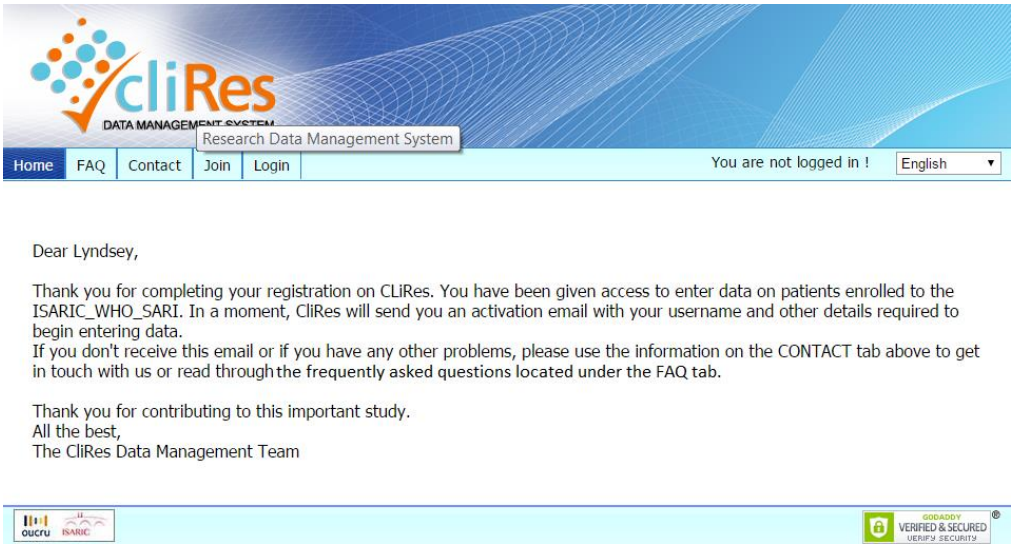
1.2 Registering a username for a new site that does not already have a site number

All new sites must register on the SARI, CliRes EDC system. The first person to register a new site will be assigned as the Site Owner. This person will have the responsibility to approve all additional users for this site. When another person registers for database access under the same site, an email will be sent to the Site Owner for approval (see 1.3 & 1.4). Therefore, the person who will be responsible for access to site data entry is the person who should register first.

To register, the person who will be the Site Owner should:

- Enter the following web address www.CliResdms.org
- Select 'Join' from the top menu.
- Select 

- Complete all fields.
- Select 'Next' (at the bottom of the page).
- A webpage with the following message will be displayed:



You will then receive an email with information on your username and password. It will also include the terms and conditions of database use. Upon acceptance of these terms, your access will be activated.

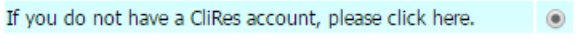
1.3 Site numbers & network numbers

- A site number will be allocated following registration of a new site.
- Confirmation of these numbers will be sent via email to the first person who registers a new site and becomes the Site Owner.
- The Site Owner will be assigned administrative rights and will need to approve additional CliRes users for their site.
- Registration of a new site will include the selection of the primary research network to which the site is affiliated (if any). Each network will have a code to help identify participants from this network within the dataset. It is important to note the **network code will not be visible on the CliRes database** and this number does not need to be documented on any of the patient CRFs. This number **will be included in the data extractions only**.

1.4 Registering as a new user for an existing site which already has a site number

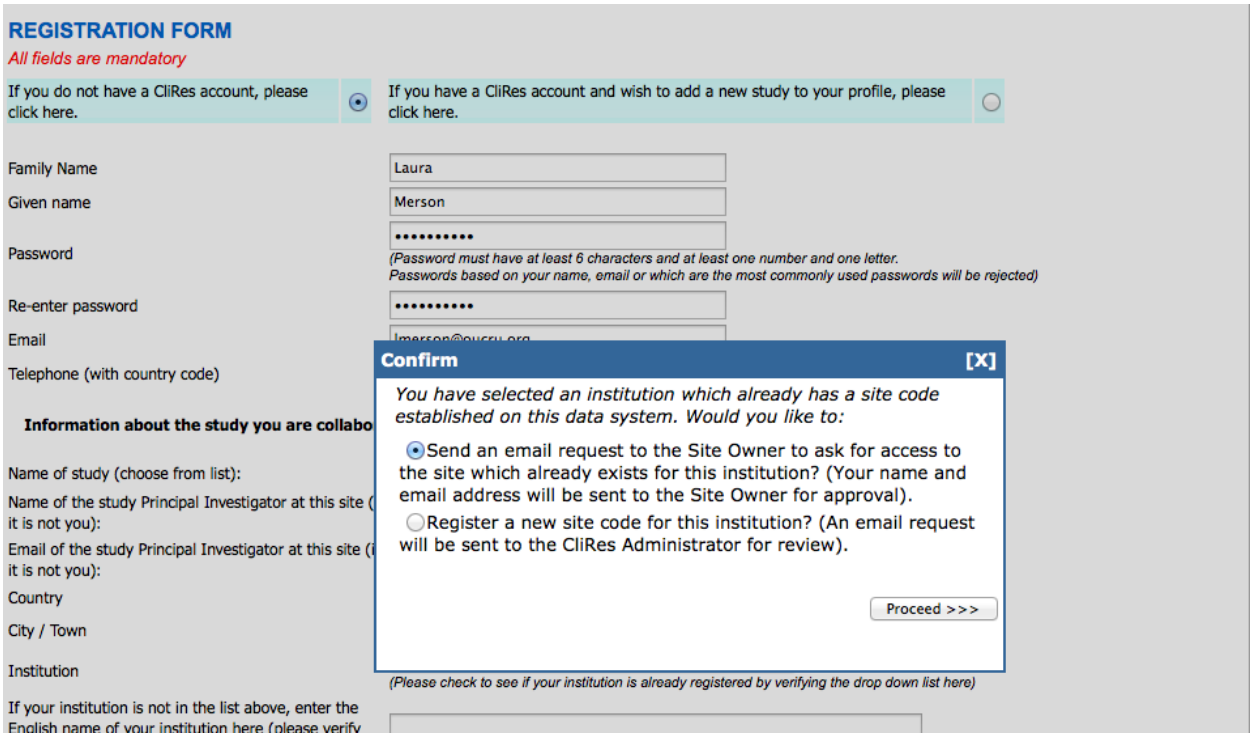
All individuals must have a unique username. If your site has already been registered by the Site Owner, you can register to be a user for that site. When you do, an email will be sent to the Site Owner with a link to approve your access.

To register, the user should:

- Enter the following web address www.CliResdms.org
- Select 'Join' from the top menu.
- Select 

- Complete all fields including the selection of the existing site.
- Select 'Next' (at the bottom of the page).

The following message will appear:

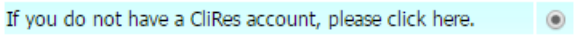


You should choose the first (top) option. An email will be sent to the Site Owner for approval. You will be notified by email if your request is approved. If it is approved, the notification email will include information on your username and password. It will also include the terms and conditions of database use. Upon acceptance of these terms, your access will be activated.

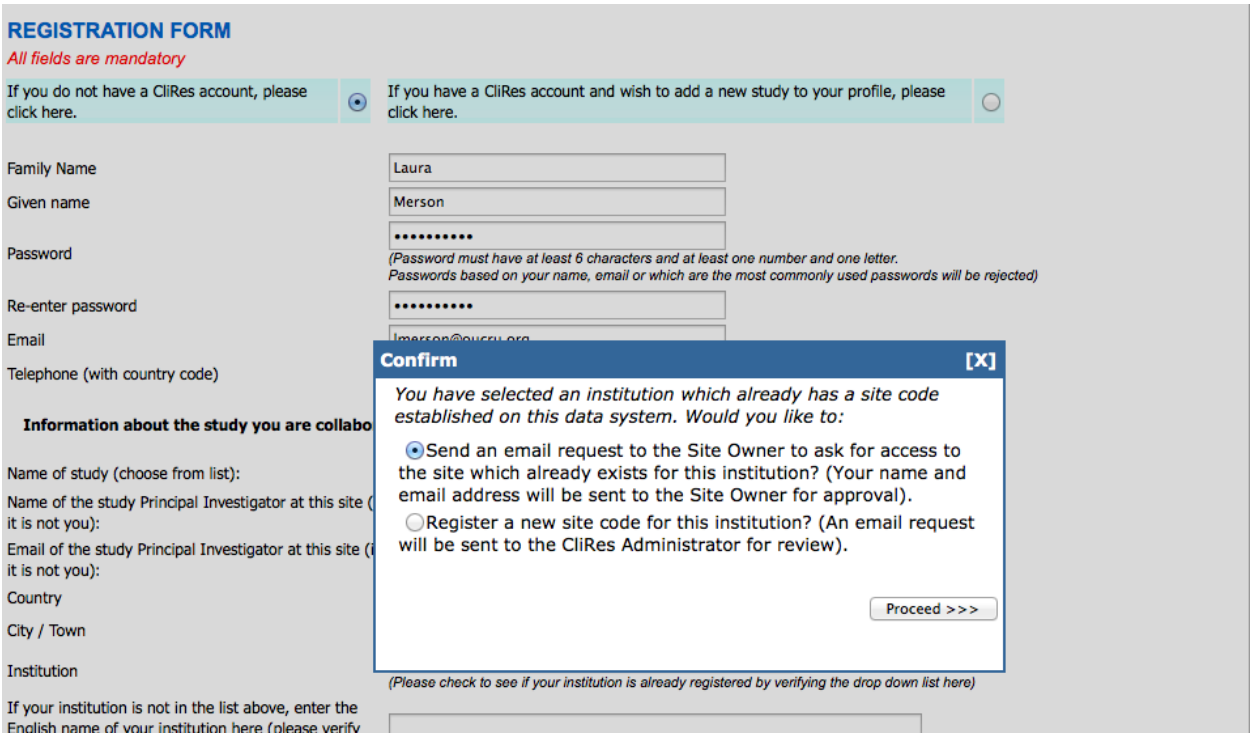
1.5 Registering as a new user for an existing site, but you would like to have a different site number for this same site

Our preference is to have one site number per site, but we understand that sometimes different wards or departments within a single site may wish to separate their datasets. If this is true, the first person who registers for this new site number will become the Site Owner of the new site. All other users will need to register for access to the site dataset as above (see 1.4).

To register, the person who will be the Site Owner should:

- Enter the following web address www.CliResdms.org
- Select 'Join' from the top menu.
- Select 

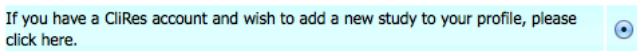
- Complete all fields including the selection of the existing site.
- Select 'Next' (at the bottom of the page).
- A webpage with the following message will be displayed:



You should choose the second (bottom) option. An email will be sent to the Database Administrator for approval. You will be notified by email if your request is approved. If it is approved, the notification email will include information on your new site number, username and password. It will also include the terms and conditions of database use. Upon acceptance of these terms, your access will be activated.

1.6 Adding sites or datasets/studies to your permission

If you already have a username and password which has been approved for a certain site, you can add permission to access an additional site or an additional dataset/study (Ebola, Viral haemorrhagic fever, etc) by updating your permissions. To do so:

- Enter the following web address www.CliResdms.org
- Select 'Join' from the top menu.
- Select 

- Complete all fields including the selection of the new site or new dataset.
- Select 'Next' (at the bottom of the page).

Your request will be sent to the Site Owner for approval. If the Site Owner clicks the email link to approve your request, you will receive notification of approval via email. The notification will require you to accept the terms and conditions of access for the database. Upon acceptance, your access will be updated to include the new site or dataset/study.

1.7 CliRes database training and testing

- We suggest that someone familiar with this user guide and the database provide training for other team members to ensure understanding and consistency of use.
- All sites can enter test patients to familiarise themselves with the database design and CRF layout. To do so, enrol a patient with site code 000 (e.g. participant number 000-

0123). This is a universal test code that can accommodate fake data without risk to the true dataset. It is a good idea for all staff to practice using the database before hand using this site code to generate participant numbers.

1.8 Laboratory Reference Ranges

- **All sites must provide** a copy of their laboratory **haematology and biochemistry reference ranges when collecting samples** to the Data Manager. Please email a copy to data@iddo.org along with your site number.

2 SELECTING MODULES / TIERS

2.1 SARI CRF

- The CRF for SARI is the same CRF for the Clinical Characterisation Protocol for Severe Emerging Infections (CCP) and for the SPRINT_SARI short term incidence study. This is comprised of four main CRFs – the INCLUSION CRITERIA CRF, the RAPID CRF, the CORE CRF and the DAILY CRF. There are also SUPPLEMENTAL CRFs, which include optional modules and extra space on the paper forms for information that does not fit on the printed sheets.
- The sites will decide which combinations of CRFs to complete based on the options below.

Tier	**CRFs to be completed for each eligible patient**
Tier 0	INCLUSION CRF + RAPID CRF
Tier 1	INCLUSION CRF + CORE CRF + DAILY CRF* *DAILY CRF should be completed on the **first day of hospital admission AND the first day of ICU admission** (if applicable) (note: these could be the same day)
Tier 2	INCLUSION CRF + CORE CRF + DAILY CRF** **DAILY CRF should be completed on the **first and second days of hospital admission AND the first and second days of ICU admission** (if applicable) (note: these could overlap)
Tier 3	SAME AS TIER 2 + EPIDEMIOLOGY CRF

2.2 Selection of Tier & selection of CRFs

Before you begin data entry, you must select the Tier that your site will use. This will automatically program your site database with the corresponding CRFs. All persons who have been given permission to access a site will be able to change the selected Tier. To select your Tier:

a) Login to CliRes.
b) Select **MODULE SELECTION** from the database menu (on the left hand side).

c) Select the applicable tick box next to the chosen **FORM ID/CRFs**.
d) Click on save settings (at bottom of page).

Note that the Tier or modules chosen for your site can be changed at anytime. Changing the Tier/modules will result in the appearance (or disappearance) of the corresponding CRFs on your site's dataset. This function only hides the CRFs, it does not delete or remove any information which has been entered onto them.

E.g. for SPRINT SARI: If a site moves from Tier 2 to Tier 0 during the study, the CORE and DAILY CRFs will no longer appear on the data entry or data view options – but they are still saved in the database.

E.g. for other datasets: If you include a module at the start of data collection, then later de-select it from the list on MODULE SELECTION you will no longer see the CRF listed in the participant CRF data entry or data view pages – but they are still saved on the database.

All data that has been entered for a site, regardless of the selected Tier/module, can be extracted by the Site Owner via the DATA EXTRACTION function (see section 5 below). If you wish to view individual patient CRFs within the data entry or data view functions, you must have selected the Tier/module which corresponds to those CRFs being active and visible.

3 ENROLLING PARTICIPANTS

3.1 Creating new subjects on the database

A number for each participant (PIN) must be enrolled to the database before data can be entered for that participant. To do this:

a) Login to CliRes.
b) Select 'ENROLL NEW CODES' from the database menu (on the left hand side).
c) Enter the PIN XXX-YYYY
d) Click on 'Enrol'.
e) The new PIN should then appear at the top of the patient enrolment list.

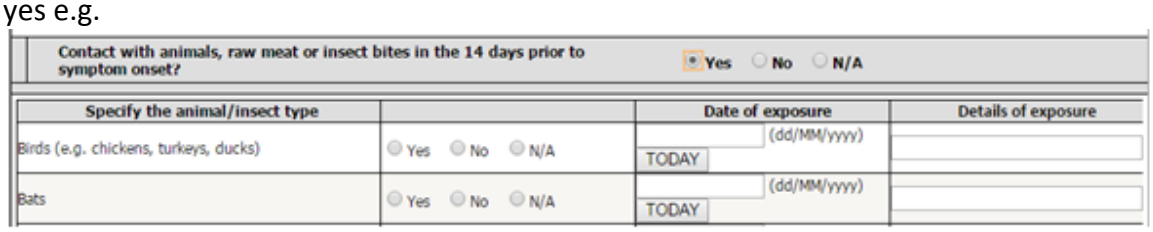
3.2 Patient Identification Number (PIN)

- Participant identification numbers consist of a 3-digit site code and a unique participant number. They will be in the format of XXX-YYYY where XXX is the site code and YYYY is the unique sequential number assigned to that individual.
- You were assigned a site code for your site when you registered for your username to access the database. The site codes that you have access to will be listed on the ENROLL NEW CODES page.
- Unique participant numbers should be assigned by the site and may include letters and/or numbers in any combination with up to 4 characters (XXX-YYYY) E.g. 000-A001. We suggest that your site defines the number of characters to be used in PINs and keeps this consistent for all PINs. This will avoid confusion of assigning two patients as 020-001 and 020-0001 (for example).
- Should a site wish to recruit patients from different wards, or where it is otherwise too difficult to implement sequential number order. It is acceptable to assign patient numbers in blocks and include alphabetical characters e.g. Ward X will assign numbers from 0001 or A001 and Ward Y 0002 or B002 onwards.

4 Entering data

4.1 CliRes e-CRF visit schedule

The electronic Clinical Record From (eCRF) visit schedule for each patient consists of a tree with the relevant eCRF forms available (as branches from the tree). Some Days e.g. Day 2 will only appear when the required forms for the previous visit e.g. Day 1 have been started. In some cases supplementary core eCRFs become available when the relevant question is answered as yes e.g.



4.2 Data entry

All users are assigned a data entry and modifications role can enter and change data values in the CliRes database. All data entry must be done online via the CliRes webpage. To do this:

a) Login to CliRes www.CliResdms.org
b) Select DATA ENTRY from the database menu (on the left hand side).
c) Enter the PIN XXX-YYYY and click on search.
d) Click on the relevant form type within the CliRes database.
e) Enter data as per original source document using the keyboard.
f) Click on 'Save'.

4.3 Data Entry Rules

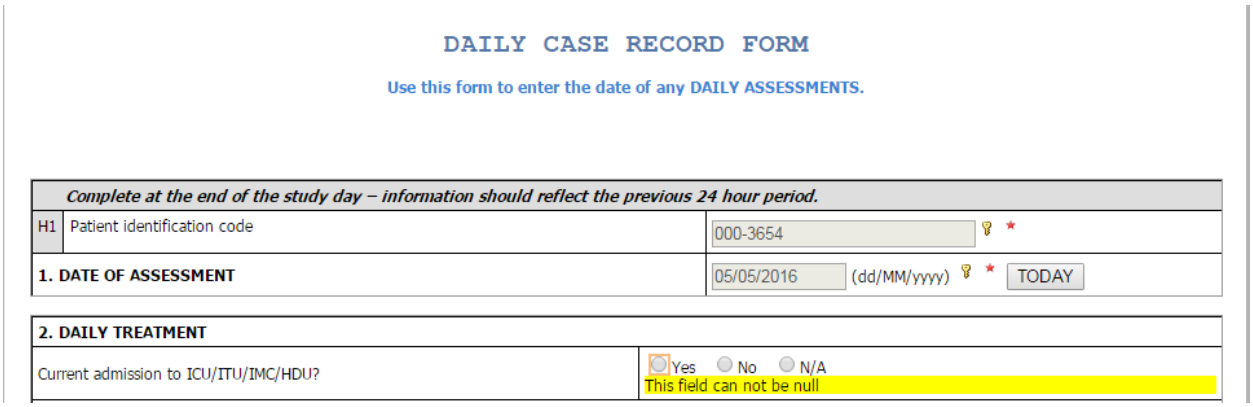
The following rules must be adhered to when entering data:

Abbreviated text or summaries

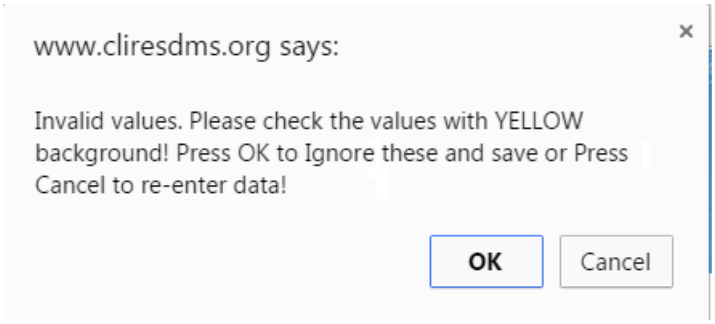
No abbreviations or summaries of text data will be permitted, and any ambiguous abbreviations/wording provided by site will be queried.

Mandatory CRF fields

Mandatory CRF fields are highlighted in yellow with the following warning message:



The field will remain yellow until the required data has been entered or when saving the CRF the following warning message will be displayed and users should complete the following:

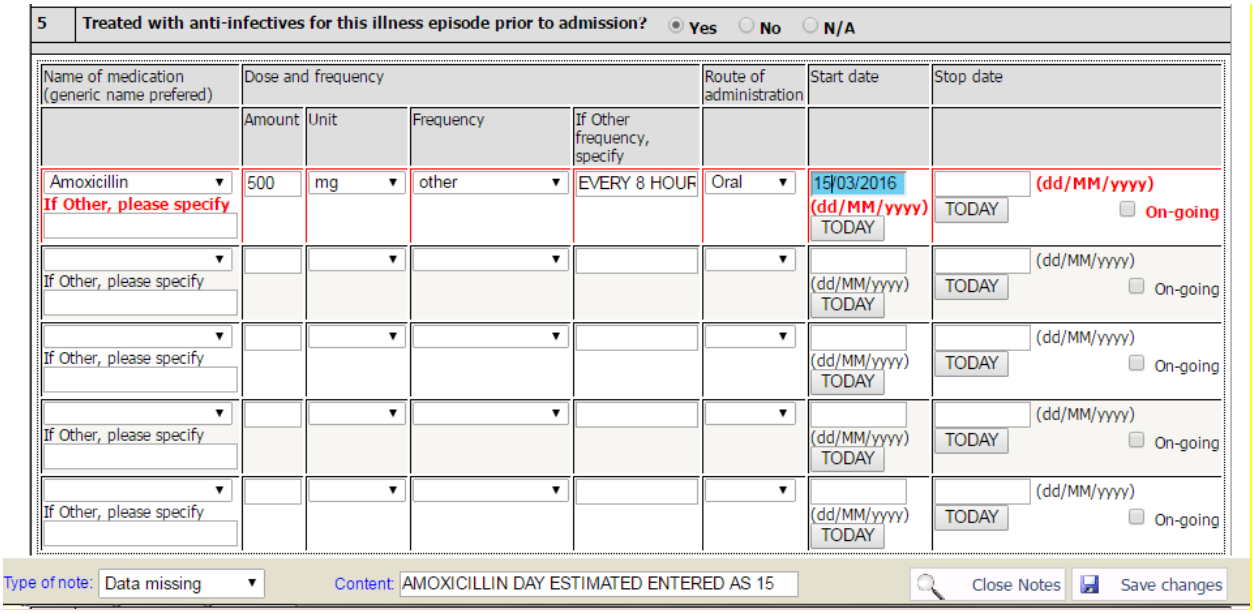


a) If data are unobtainable /missing click on 'OK' and continue to save the form with fields empty.

b) Click on 'Cancel' and go back and review empty fields and add data.

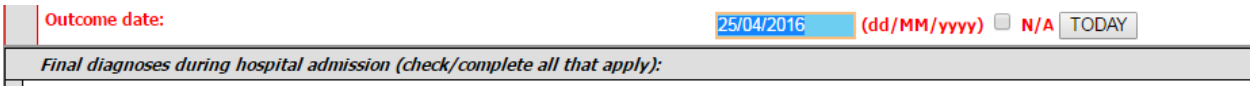
Entering partial dates

- Missing or unknown day will be entered as 15 and a database note (database note function - located at the bottom of the CRF web page) added confirming that it is estimated.
- Missing months or years must be queried.

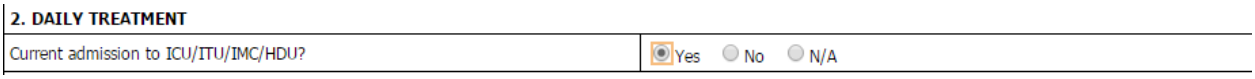


Deleting incorrect dates or times

If you enter a date or time incorrectly e.g. MM/DD/YYYY instead of the accepted database format DD/MM/YYYY. Place the cursor to the right of the incorrect digit and press 'Backspace'.



De selecting tick boxes

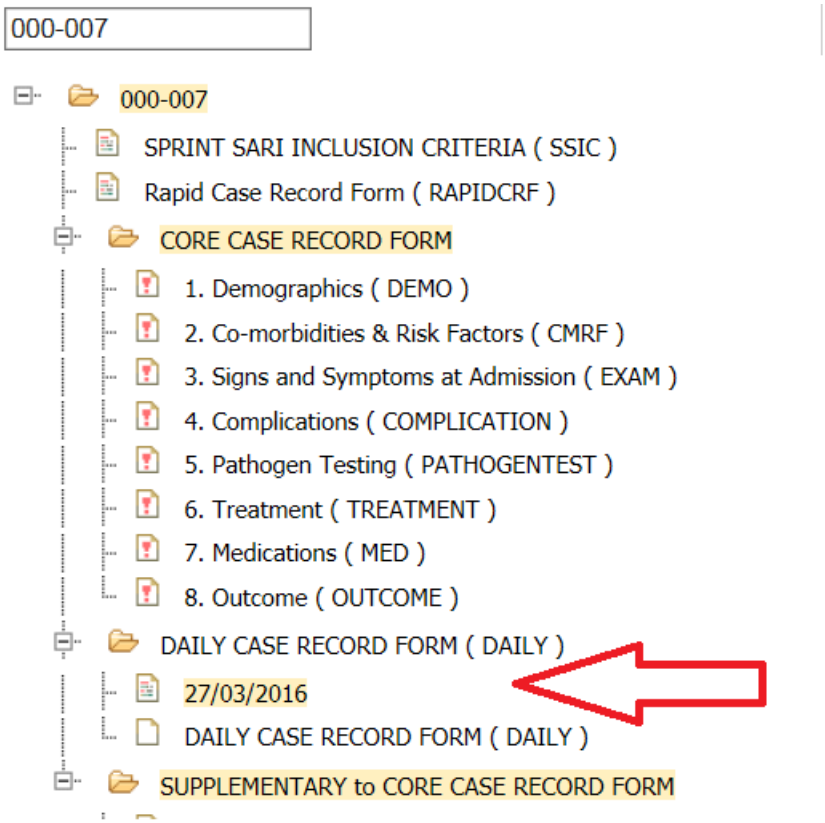


To de select check boxes or radio buttons place the cursor on the selected radio button or tick box and double click.

Populating new eCRFs

All eCRFs for each Day must be completed before the eCRFs for the next Study Day will appear (Figure **1**).

Figure 1. Clinres showing all forms for dummy patient 000-007 Daily CRF for day 1 27/03/2016 have been completed and hence next set of Daily CRF form becomes available.



Mistakenly opening eCRFs which do not require data entry

If you mistakenly go into a CRF which does not require data entry, scroll to the bottom of the web page and click on 'Cancel'.

Missing eCRFs and data fields

If a CRF and/or data item are deemed missing (e.g. unable to obtain the information, the visit/test was not done or if a patient has not attended their visit) the associated eCRF and/or fields should be completed as follows.

Missing CRF/visit:

a) If applicable only confirm the date of assessment.
b) Leave the field(s) blank, please do not select the N/A or unknown tick boxes.
c) Save the eCRF(s).

Missing data field

a) Leave the field(s) blank, please do not select the N/A or unknown tick boxes.
b) Save the eCRF(s).

Entering lab values

Specified laboratory or vital sign values must be given within certain ranges. ClinRes will alert the user if a value is not within the specified range with the following warning message:

If the given value given is correct, click on 'OK' to save the CRF and ignore the warning message. Or if the value is incorrect click on 'Cancel' to go back and amend the value then save the CRF.

Entering concomitant medications

All concomitant medications (immunosuppressants, anti infectives and corticosteroids) should be entered using their **generic name**. The generic name, is the official name given to the active ingredient of the medicine. Whilst a brand name, is the trade name given by the manufacturer for the medicine. For example, **ibuprofen is the generic name** for the active ingredient of a medicine used to treat pain. Some companies will sell ibuprofen as branded versions, such as Nurofen and Headex.

All concomitant medication needs to include where possible information on the following: dose, units, frequency, route of administration, duration- weeks, days or N/A and start and end

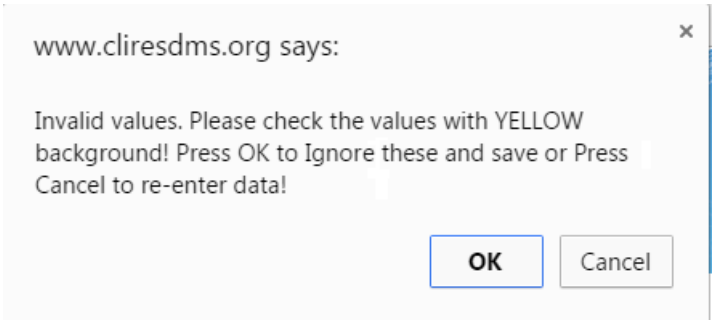
The following CRF sections should document the following:

Core CRF - Section 2: should document **all ADMISSION** IMMUNOSUPPRESSANTS AND ANTI-INFECTIVES: Any anti-invectives (antibiotics, antibacterials, antifungals and antivirals) the patient was treated with for this illness episode prior to their admission.

Core CRF – Section 7: should document all ANTI INFECTIVES AND CORTICOSTEROIDS: Any anti infectivies (antibiotics and anti-virials) **administered during hospitalization and at discharge.**

Overruling database warnings

All database warnings may be over ruled. Upon saving the CRF the following warning message will be displayed:



a) If data are unobtainable /missing click on 'OK' and continue to save the form with fields empty.

b) Click on 'Cancel' and go back and review empty fields and add data

Incorrect patient numbers and associated data

Should you enter a patient number incorrectly, please complete the following steps:

a) Re-enter the correct patient number in ENROLL NEW CODES.
b) Re-enter any associated data under the correct patient number.
c) Please inform the team of the incorrect patient number on the database by emailing data@iddo.org along with your site number.

4.4 Suggestions for additional database modifications

Should you note that an additional database modification is required. For example, an option is not listed on the drop down menu and you would like it to be added. Please notify the SARI Database Manager and, if appropriate, a request will be launched with the database programmer to complete the modification.

4.5 Checking data entry

All data entered in the database needs to be checked against the original source document by another member of the trial team who did complete data entry.

Data verification staff will check data carefully between the CRFs and electronic database and ensure data are verified for:

1) **Completeness:** Data are recorded fully on CRFs and database. The latest CRF version has been used. The necessary data are recorded in the appropriate sections.
2) **Accuracy:** Data that is recorded on the CRFs must be clear and entered correctly into electronic database.
3) **Logic:** Data must be logical, e.g. the birthday must be before the study enrolment date; or the second hospitalization date must be after the first date; etc. All data limits or standards must be satisfied, e.g. lab results must be within the acceptable ranges or be clearly explained.

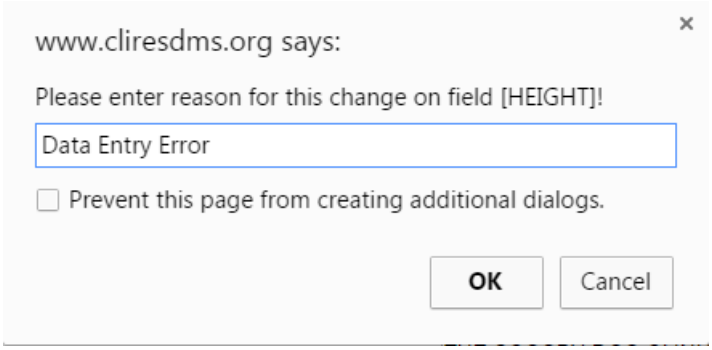
Data commonly found to be discrepant include: time (date, time), wrong data field input, incorrect lab results, and missing data.

4.6 Verification Process

This verification process will require internet access and should be done daily. The simplest way to complete the verification process is whilst in logged in Data Entry Role. To do this:

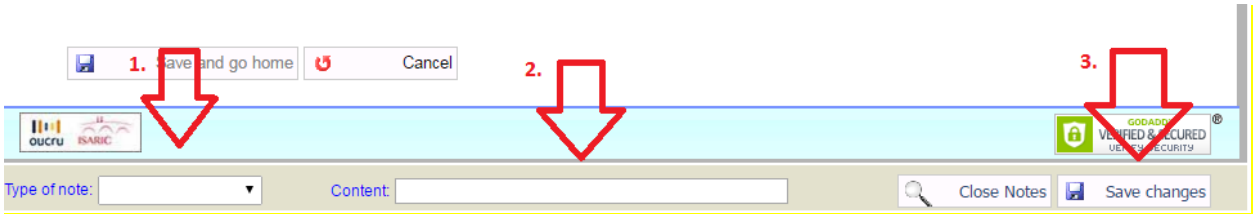
a) Login into Clinres.
b) Select Data Entry from the database menu (on the left hand side).
c) Click on the relevant subject.
d) Select relevant day (if applicable) and eCRF.
e) Visually audit the on-screen data, referring to the original source document.
f) If data are clearly incomplete, inaccurate or illogical amend the data (using appropriate ICH GCP signature and date annotation for corrections made to the paper CRF).

g) Confirm reason for change e.g. Data Entry Error on the database and click on OK.



h) Initial and date the top of the paper CRF page to confirm it has been checked e.g. Checked LAC 20Dec2015.

i) More complex data queries which require further investigation should be recorded in the database notes section located at the bottom of the CRF page. Using the following three step process:

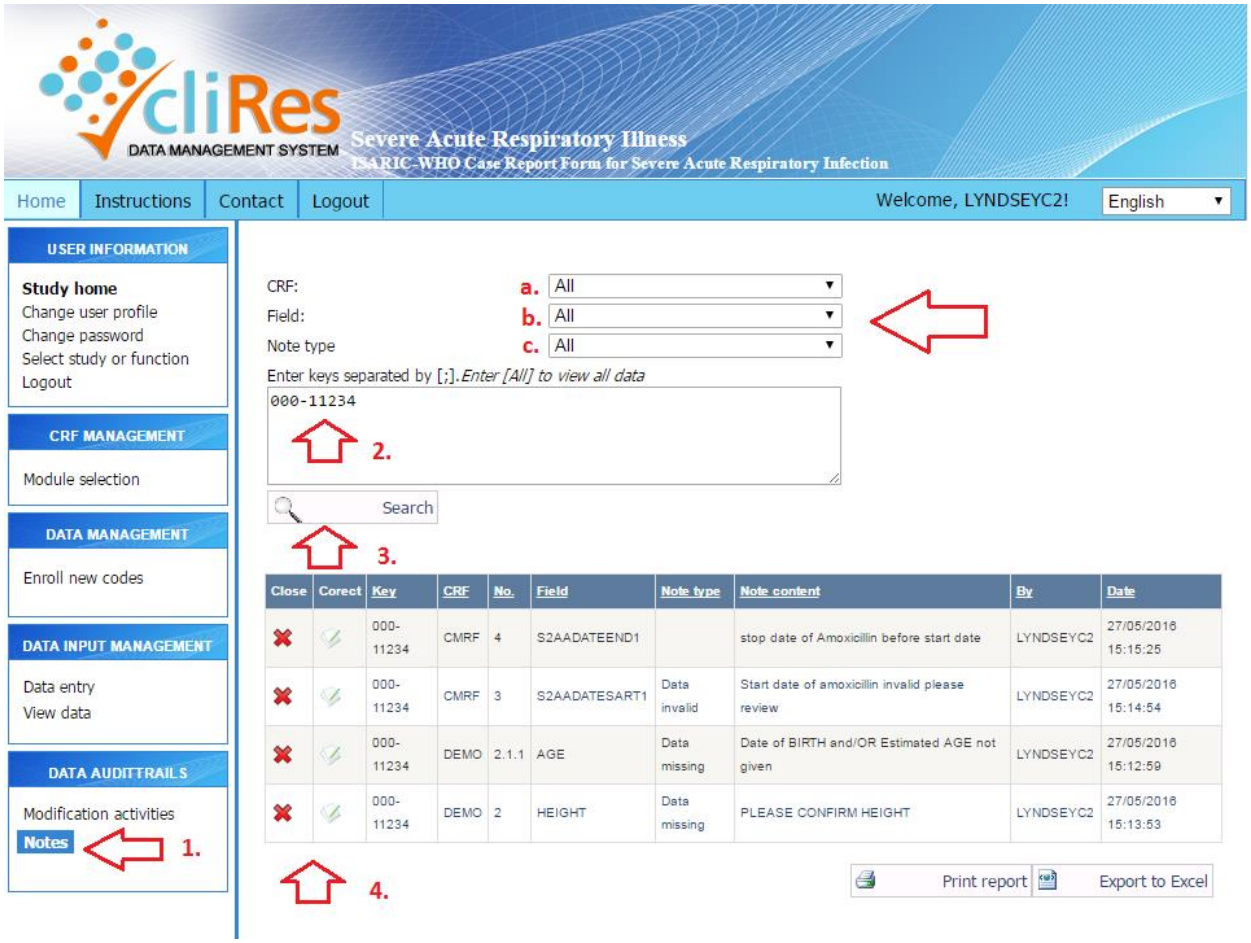


1. Confirm the type of note – Out of range, Data Missing, Data Unclear, Data Invalid.
2. Confirm content - add details about the data entry error.
3. Click on 'Save changes'.

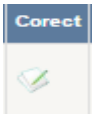
5 Reviewing notes/queries

On a weekly basis complete the following:

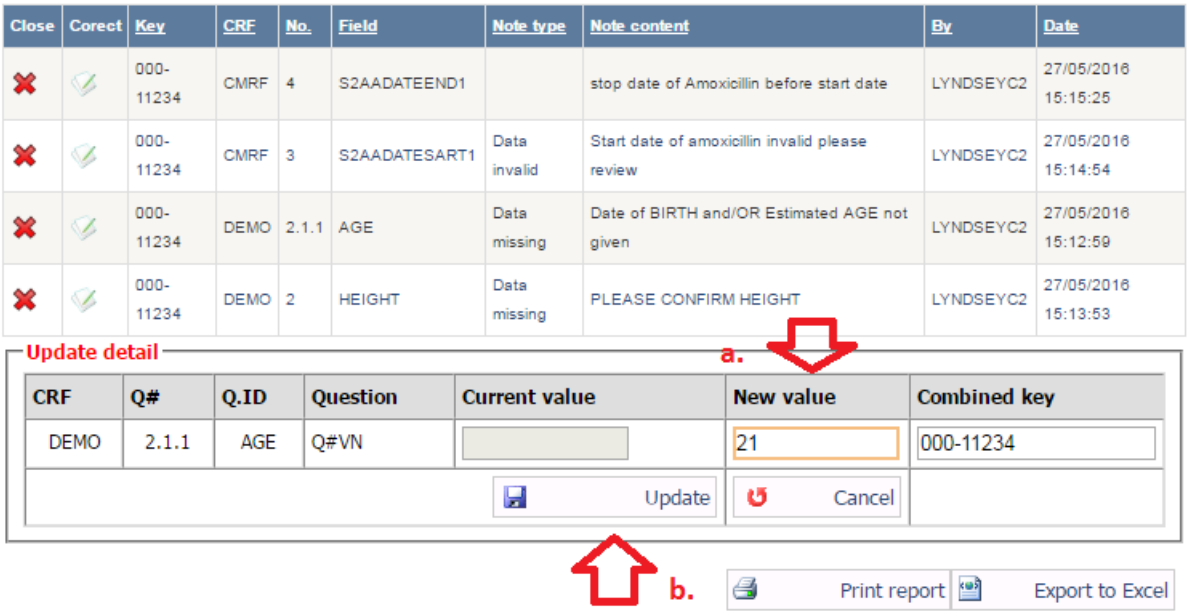
1. From the menu on the left side select 'Notes'.
    a) Select ALL for 'CRF'.
    b) Select ALL for 'Field'.
    c) Select ALL for 'Note Type'.
2. Enter the Patient Identification Number (PIN).
3. Click on 'Search'.



5.1 Correcting notes/queries

To correct the note select the pencil icon 

(4.) and the following screen will appear:



a) Enter the new value.
b) Click on 'Update'.

The database updates the field and the note is automatically removed from the list.

5.2 Closing notes/queries

If the note/query cannot be resolved (the information is unknown/unobtainable), close the note by clicking on 

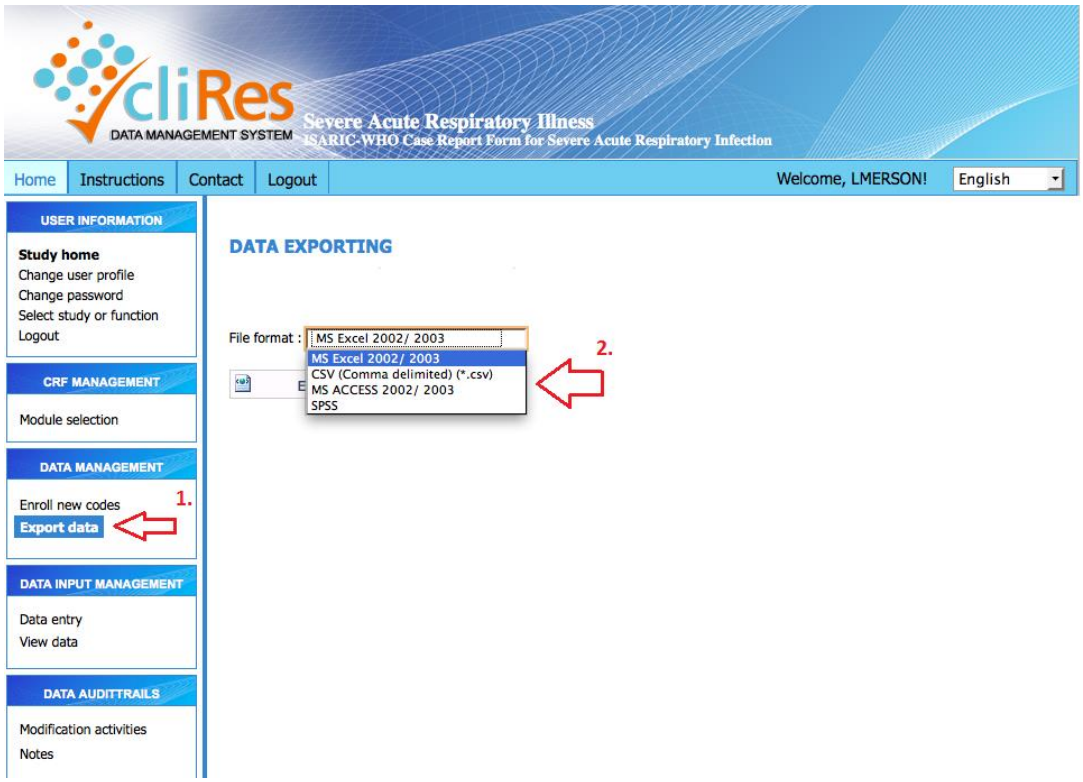
(4).

6 Exporting data

Only Site Owners will be assigned the data export function.

To extract your site(s) data complete the following:

1. Select ‘Export data’ from the menu on the left hand side.
2. From the file format drop menu select the extraction format e.g. CSV etc.



3. Click on ‘Export’ and automatic download of the file should begin.

Should you require further assistance with any of the database functions please email data@iddo.org