# Place in Site Master File #9

## Instructions for the AID-ICU trial - eCRF

**The screening and randomisation procedure is described in the trial document 'Instruction for screening and randomisation'.**

**Log on**

Go to www.cric.nu/aid-icu

Here you will find links to the data entry system (OpenClinica), the Medication Dispensing System and the trial documents.

Click the 'Screen, randomise and enter data'-link.


Enter your email and personal password. If you have not received your login, please send an email to aid-icu@cric.nu


If your browser presents a warning about a certificate from an untrusted source, please accept the connection and – if possible – install the certificate on your computer. The certificate is required to encrypt the connection between your computer and the server.

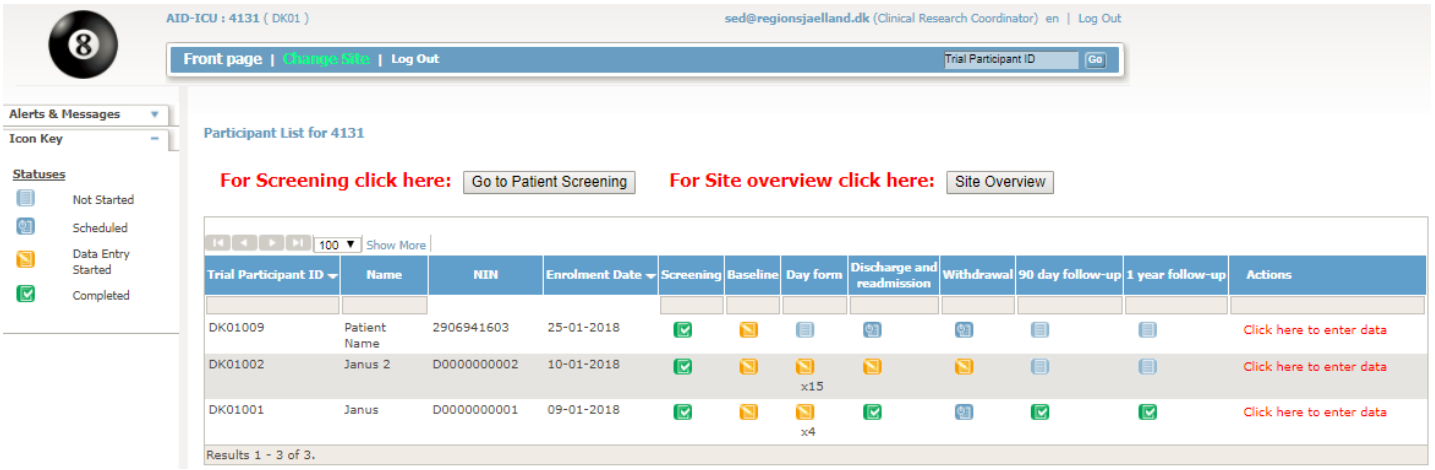
We recommend using an updated browser when entering data into this eCRF

# A quick tour through the eCRF

## Participant list

After login you will see the participant list

*(following screen shots taken from a demo version of the AID-ICU eCRF)*




Each trial participant has one row. In the first three columns you will find

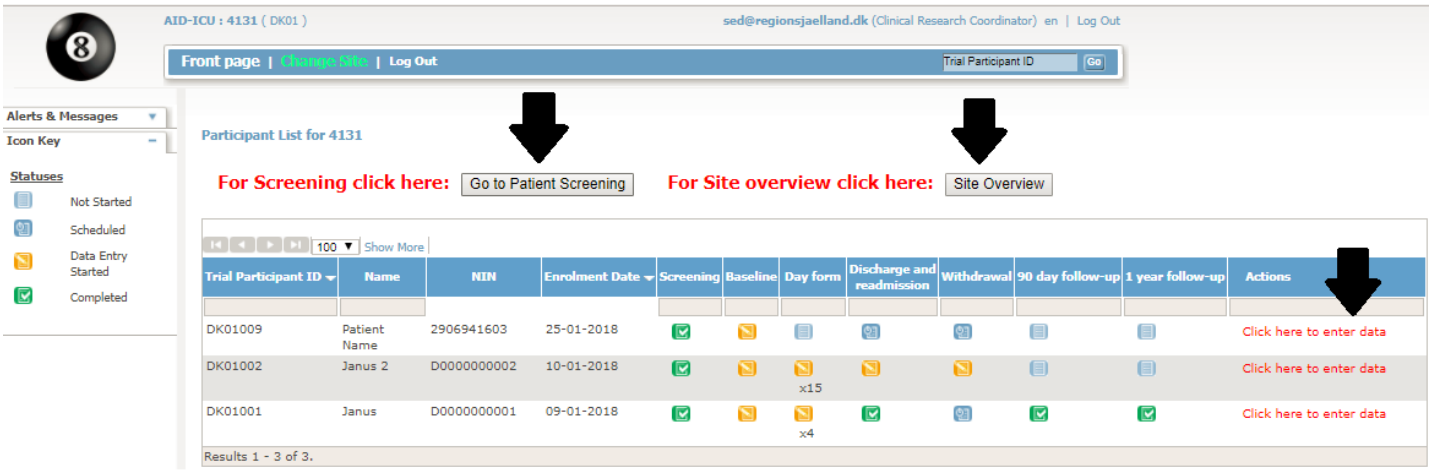
- Trial participant ID – an automatically generated identifier number. Write this ID in your screening log and use it when communication with the coordinating centre.
- Name of the patient (as written in the screening procedure)
- National identification number (as described in the instruction for screening and randomisation)
- Enrolment date

The next columns show the different trial events (i.e. screening, baseline, day forms etc.).

New day forms will be generated daily (to a maximum of 90 days). The colour of the icon in the column with 'Day forms' will switch to green when <u>all</u> generated day forms have been completed. When a new form is generated the icon will turn yellow again until all day forms have been completed. To see which day forms are incomplete, either click the 'Click here to enter data' or go to the site overview (see next page).

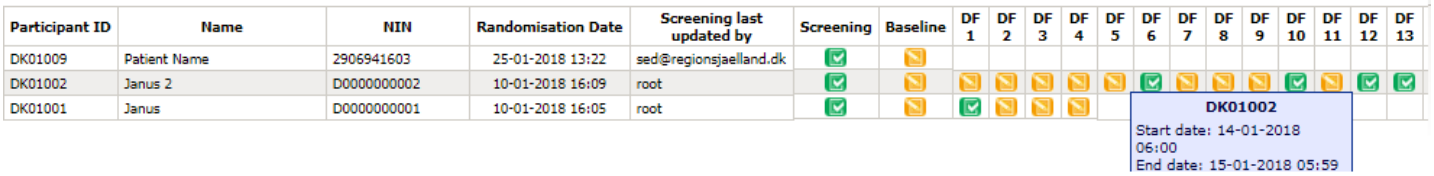
From the front page (participant list) you can proceed to:

- Screening procedure (patient screening)
- Site overview
- Participant details (data entry)




## Site overview

In the upper right corner, you will find the Site Overview button. Clicking this give you a quick overview of your enrolled patients.




Hovering the  will display the start and end date of the day form.

Click the  to enter the incomplete form.

If icons are missing, the forms have not yet been generated.

**Data entry – general information**

After randomisation the following forms will be available:

- Baseline form
- Day form (1 for each day the patient is in the ICU to a maximum of 90 days)
- Discharge and readmission form (to be completed at discharge or death and in case of readmission)
- Withdrawal form (to be completed if the patient is withdrawn from the trial because of SUSAR or withdrawal of consent)
- 90-day follow-up form (becomes active 90 days after randomisation) if the patient dies in the ICU and the discharge from is completed, the follow-up form will automatically be completed.
- 1-year follow-up form (becomes active one year after randomisation)

To enter the above listed forms, go to participant details by clicking 'Click here to enter data' in the right side.

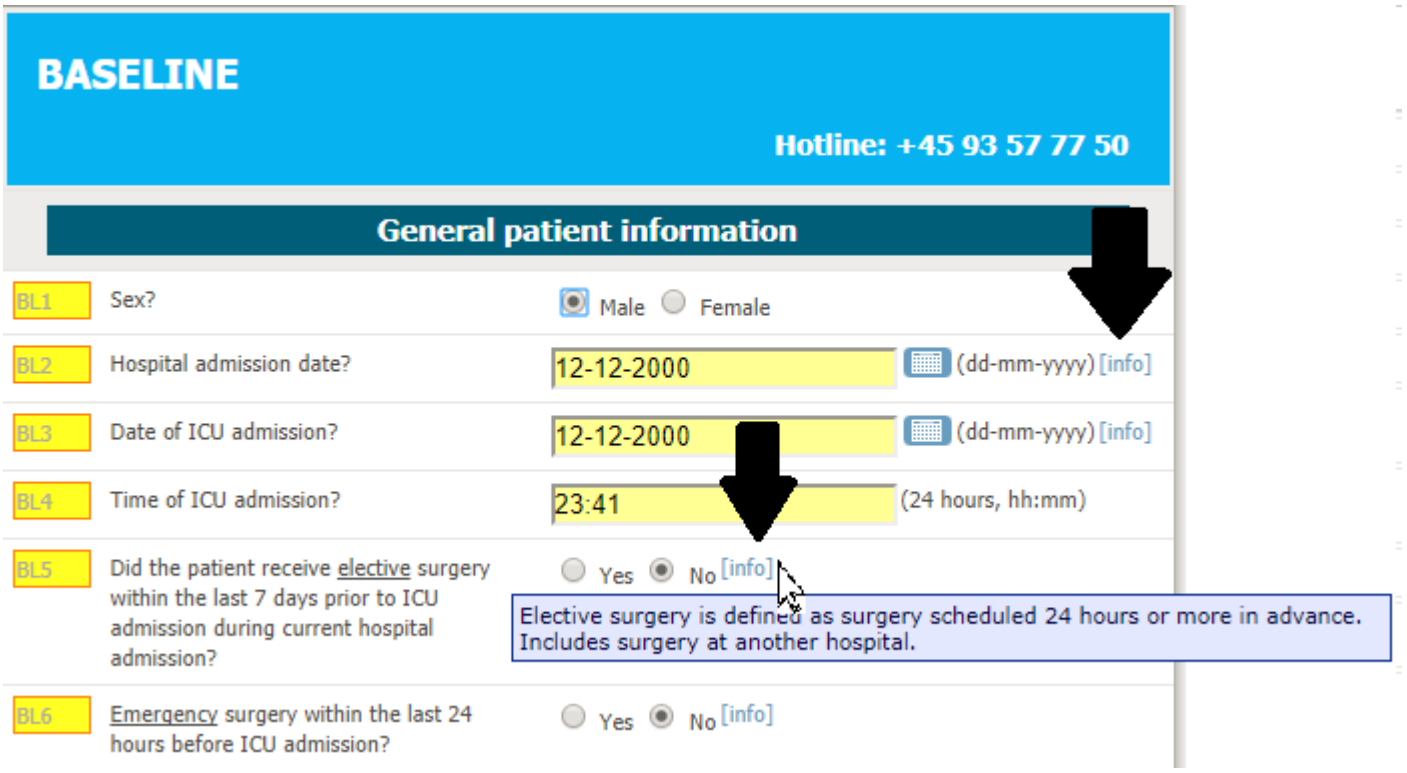
After entering the page of a participant, you can either

- Enter or edit data. If you want to edit data in an already submitted form, click '**Administrative edit**'.
- View data (read only)

| Event (Occurrence Number) | Start Date | End Date | CRFs (Status, Updated, Actions) | |
|---|---|---|---|---|
| 1 year follow-up | 10-01-2019 16:05 | 10-01-2019 16:05 | Administrative edit | Click here to view data (read only) |
| Day form (4) | 13-01-2018 06:00 | 14-01-2018 05:59 | Click here to enter data | Click here to view data (read only) |
| 90 day follow-up | 13-01-2018 12:30 | 13-01-2018 12:30 | Administrative edit | Click here to view data (read only) |
| Day form (3) | 12-01-2018 06:00 | 13-01-2018 05:59 | Click here to enter data | Click here to view data (read only) |
| Day form (2) | 11-01-2018 06:00 | 12-01-2018 05:59 | Click here to enter data | Click here to view data (read only) |
| Day form (1) | 10-01-2018 16:05 | 11-01-2018 05:59 | Administrative edit | Click here to view data (read only) |
| Screening | 09-01-2018 14:19 | 10-01-2018 16:05 | Administrative edit | Click here to view data (read only) |
| Baseline | 10-01-2018 16:05 | | Click here to enter data | Click here to view data (read only) |
| Discharge and readmission | 14-01-2018 12:00 | | Click here to enter data | Click here to view data (read only) |
| Withdrawal | 10-01-2018 16:05 | | Click here to enter data | Click here to view data (read only) |

**In the forms**

Questions and uncertainties may be answered by hovering the cursor over the [info] next to each question in the eCRF. A blue box will appear as shown on the screen shot below. This information should be read carefully and followed stringently.

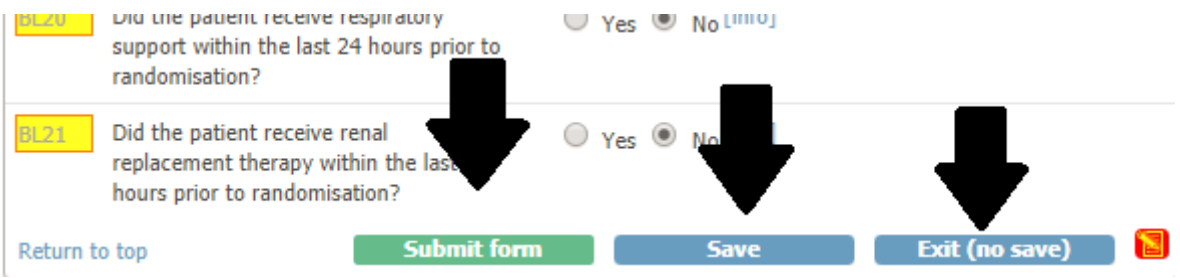



Date format is always **dd-mm-yyyy.** You can use the calendar by clicking on the  or you can enter the date directly.

Time format is 24 hours (**hh:mm**)

At the bottom of each form you will have the opportunity to:

- **Submit form**. This will only appear as an option once the form is complete
- **Save**. This will be an option when data has been entered
- **Exit (no save).** Use this if you entered the form and want to leave without entering data.



The icons at the patient list and in the overview will turn green when a complete form has been submitted (using the Submit form-button). If complete and only saved (using the Save-button), the icon will continue to be yellow .

**Participant Details**

**DK01009**
**NIN: 2906941603**
**Name: Patient Name**

Find

| Event (Occurrence Number) | Start Date | End Date | CRFs (Status, Updated, Actions) | | | |
|---|---|---|---|---|---|---|
| Screening | 25-01-2018 12:21 | 25-01-2018 13:22 | | Administrative edit | Click here to view data (read only) | 25-01-2018 (sed@regionsjaelland.dk) |
| Baseline | 25-01-2018 13:22 | | | Click here to enter data | Click here to view data (read only) | () |
| Day form (1) | 25-01-2018 12:00 | | | Click here to enter data | Click here to view data (read only) | 25-01-2018 (root) |
| Discharge and readmission | 25-01-2018 13:22 | | | Click here to enter data | Click here to view data (read only) | |
| Withdrawal | 25-01-2018 13:22 | | | Click here to enter data | Click here to view data (read only) | |

# Specific forms in the eCRF

### Baseline form

This is the most comprehensive form. It will take around 10 minutes to complete.

Please pay attention to the following:

- "Hospital admission date" and "Date of ICU admission": if the patient has been transferred from another ICU/hospital, please enter date and time of the first admission.
- When filling in the baseline form, all data should represent the condition at the time of randomisation, relevant periods before randomisation are specified within the questions or [info].

### Day form

All days are defined as from 06:00 to 06:00, 24h time, local time zone. The first day form will be available on the first morning after randomisation at 06:00 (i.e. the day after randomisation). The last day is from 06:00 until discharge or death. Hence, in most cases the first and last day will not be 24 hours. Hereafter a day form is generated once a day at 06:00 to a maximum of 90.

If a day form does not turn green when complete, please make sure the form has been submitted and not only saved.

### Discharge and readmission

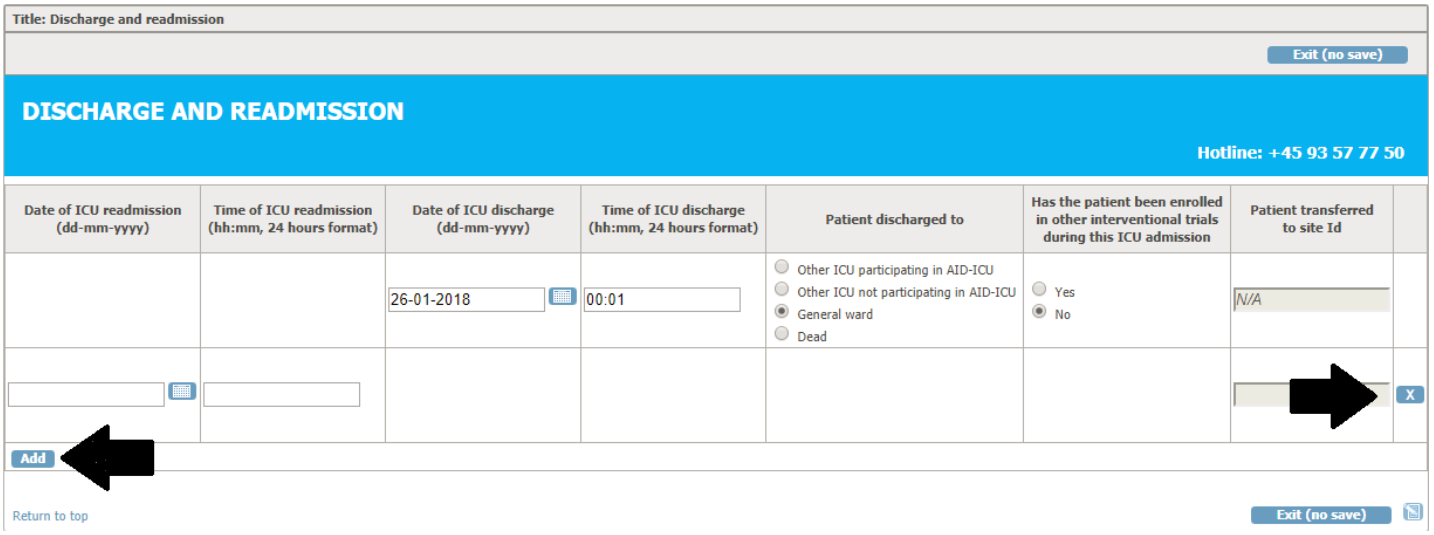
The discharge and readmission form is used to both discharge and readmit the patient (available several times). Hence, this form will only turn green if the patient is registered dead in the ICU.

If a patient dies within the ICU, discharge the patient in the system by completing the discharge form.

Entering the patient as discharged using this form will stop the generation of day forms and remove already generated day forms after the discharge date. Therefore, it may be advantageous to fill in the discharge form before active day forms.

If the patient is readmitted to the ICU, go to the discharge and readmission form again and click Add. This will generate a new row. Please complete date and time of readmission.

If an unnecessary row is generated, you must delete it by clicking 'X' in the right side (see next page).




After filling in the readmission row of the discharge and readmission form, day forms will again be generated.

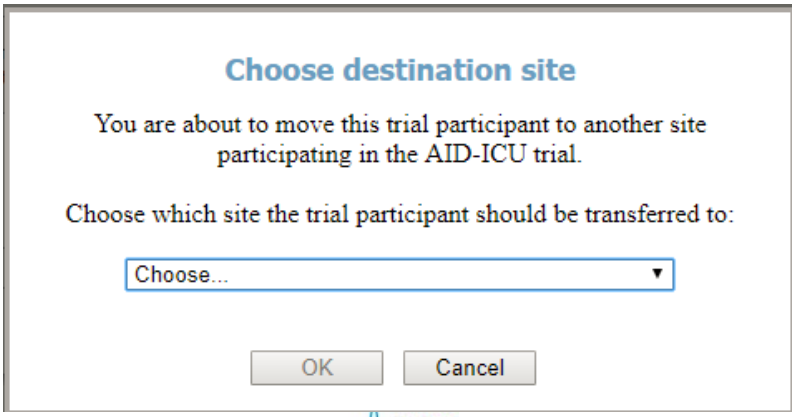
**Patients transferred from/to another ICU**

ICUs **not** participating in the AID-ICU trial:

- If a patient is transferred **to your** ICU from an ICU not participating in AID-ICU, please screen the patient for inclusion in AID-ICU throughout the visit.
- If a patient is transferred **from your** ICU to an ICU not participating in AID-ICU, the patient will be regarded as discharged from the ICU. Please complete the discharge form. 90-day and 1-year follow-up still needs to be completed.

ICUs participating in the AID-ICU trial:

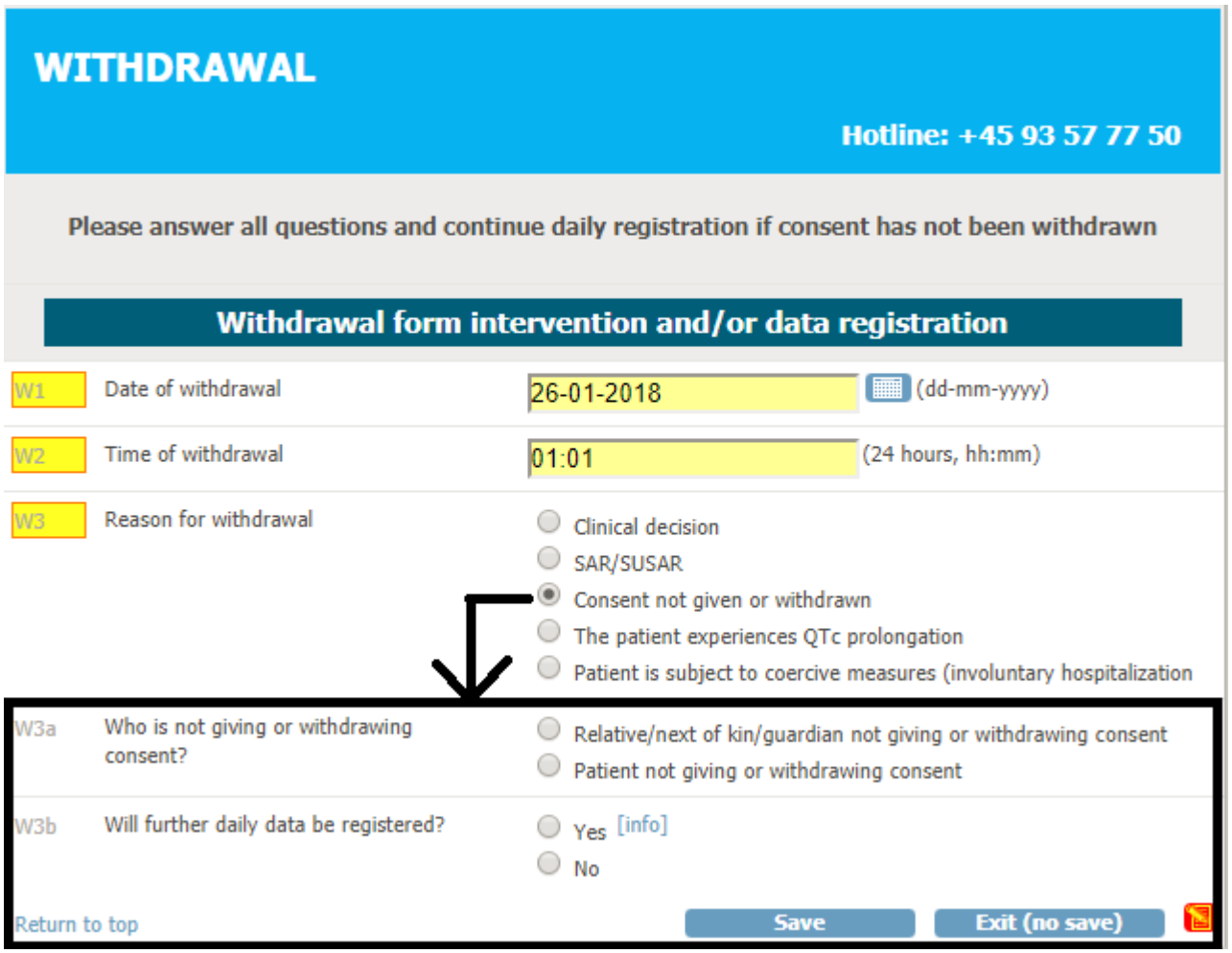
- If a patient is transferred **to your** ICU and has not been transferred in the eCRF, please contact the transferring site (or coordinating centre) as soon as possible.
- If a patient is transferred **from your** ICU to a participating ICU, complete the discharge form and choose the centre from the list (see below). In the eCRF system, the patient will be transferred to a 'transfer site' which is accessible by both departments. **Please inform the receiving ICU that the patient is enrolled in the AID-ICU trial**.



**Withdrawal**

The patient can be withdrawn from the trial for the following reasons:

1. At the choice of the treating clinician in conjunction with the coordinating investigator.
2. SAR/SUSAR
3. Consent not given or withdrawn
4. QTc prolongation
5. The patient is subject to involuntary hospitalisation (coercive measure).




Please fill in the withdrawal form. Note that the two last questions will only appear if 'Consent not given or withdrawn' is chosen, as shown above. If the patient accept continued data registration, please obtain consent to this on the consent form.

**Follow-up**

90 days and one year after randomisation, the relevant follow-up forms will be activated respectively. Please fill in these forms when available. These two forms should take a fairly short time to fill in.

If the patient dies within the ICU and this is registered in the discharge form, date of death will automatically be filled in and thus follow-up forms will appear green  and will not have to be filled in.

If the patient is registered dead in the 90-day follow-up form, the one-year follow-up form will likewise be filled in automatically.