

Please use the CRF/randomization tool: reduse.spinnakersoftware.com

Training

For training purposes, we have created a test site named VUL-TESTSITE. Patients added to this site will not be included in the trial.

IMPORTANT: Please only use this site for training purposes and **DO NOT** add real patients to this site. If you randomize a real patient to this site, we will not be able to transfer them to your site and they will **not be included in the trial**.

Randomization

Patients can be randomized using a general site user account, or using a personal account. To randomize a patient:

1. Log in to the CRF/randomization tool using either a general site user account or your personal account if you have one. For information about how to get an account, please see the separate file “randomization-CRF access instructions”
2. When you log in, you will be prompted to select your site if you have access to more than one site. Make sure you select the correct site. If you are adding a real patient, please check that you **DO NOT** select the training site (VUL-TESTSITE). To change sites, you must log out and log back in and select the new site.
3. Click on “Add Patient”
4. Answer all of the questions in the three modules (Patient details, Inclusion/exclusion, and Consent/Randomisation). If the patient fulfils all inclusion and no exclusion criteria, they will be randomized to the trial.
5. If the identifying information entered matches another patient who was already randomized then you will receive an alert and that patient will not be randomized again. Ensure the patient receives the same treatment to which they were randomized initially.
6. Please print the randomization result page and add it to the patient ledger.

Patient summary page

1. The patient summary page can be accessed by clicking on the patient ID number in the list of patients. This page contains the following functions, described in more detail below:
 - a. Edit patient
 - b. Transfer patient
 - c. SUSAC
 - d. Protocol deviation

Edit patient

1. If information that was collected during randomization needs to be updated, this can be done using the Edit patient button. You must be logged in to an Investigator account to edit a patient’s information.

Transfer patient

1. If a patient is transferred to another ICU, please use the “Transfer patient” button on the patient summary page. You must be logged in to an Investigator account to transfer a patient.
2. Indicate the location to which the patient was transferred, or whether they were transferred to a non-REDUSE ICU.
3. Transferred patients will be indicated in the patient list with a letter T next to the patient number. The T will be red if the patient was transferred to another REDUSE ICU, grey if the patient was transferred to a non-REDUSE ICU, and green if the patient was transferred TO your ICU from another site.
7. For patients who are transferred to your site, ensure the patient receives the same treatment to which they were randomized initially. To check what treatment the patient should receive, click on “randomization” in the left menu (only available for investigator accounts)

Protocol deviations and SUSAC

1. Protocol deviations and SUSAC can be added using either a general site user account or your personal account. In the top right-hand corner of the patient summary page, you can find the protocol deviation and SUSAC forms.
2. To create an event, click on the correct form type and fill in and save the form. There is no limit to the number of each type of form. Add one form per event.
3. SUSACs will be signed off by the principal investigator after they are added.
4. Ensure that all SUSACs are followed up until they are resolved and that a final SUSAC report is added.

Data entry - general

4. Log in to the CRF/randomization tool using an investigator’s personal account or a follow-up assessor/coordinator account. Data can only be added to most of the CRF forms using these personal accounts. The general site user account **will not work**. For information about how to get an account, please see the separate file “randomization-CRF access instructions”. Instructions for specific forms are found below.
5. When logging in, select the correct site if applicable. If you are adding data for a real patient, please check that you **DO NOT** select the training site (VUL-TESTSITE).
6. CRF data entry forms can be found by clicking on the “patients” in the top menu. You can use the search function to find a specific patient number if needed.
7. Empty data entry forms are indicated with a red X. Completed forms are indicated with a green checkmark. Incomplete forms are indicated with a yellow question mark. Not required forms will be indicated in grey.
8. Click on the form that you want to work with to open the form and add information.
9. A form can be saved at any time by adding the form or updating the form (button at the bottom of the page). If any required fields are missing or out of range, the form will not be saved until those fields are corrected. Look for the red “X” with a message at the affected questions.
10. A general comments field is now available at the top of each form. Use this field to document any clarifications to the added data.
11. Special considerations for certain forms are detailed in the next sections.

Origin of sepsis

1. Origin of sepsis data can only be added using an Investigator account. The general site user account **will not work**.
2. In the first question, select all suspected infection foci that are applicable to the patient. Additional detailed questions will appear for all selected infection foci. Answer all questions that appear.
3. The form will be marked as complete when all of the questions in the relevant sections are answered.

Discharge

1. Discharge data can only be added using an Investigator account. The general site user account **will not work**.
2. Please indicate when the patient was discharged from the ICU. If the patient was readmitted, please indicate this in the ICU readmission section. You can add up to 5 ICU readmissions.
3. Information about discharges and readmission will pre-fill the daily data forms with the days that the patient was not in the ICU. If the patient is discharged from ICU prior to day 5, we recommend filling in the discharge form before filling in the daily forms.
4. If the patient's status is "deceased" at any discharge, please fill in the date of death on a separate form (see Death below)
5. Complications that were recorded on the daily forms do not need to be recorded again on the discharge form. Add only complications that occur outside of the first six ICU days.

Daily data

1. Daily data can only be added using an Investigator account. The general site user account **will not work**.
2. It is **strongly recommended** to fill out the discharge form before filling out daily forms. If the discharge form is filled out, the ICU admission status will be pre-filled on the daily forms. Non-ICU days will be marked with a red X and these forms will not need to be filled in.
3. For newly randomized patients, only one daily data form will be available (day 1). New daily data forms will appear for each day following randomization. Forms for days 1-5 are more detailed and forms for days 6-90/discharge are less detailed. Since any ICU readmissions within 90 days will need to be documented, forms will continue to appear until day 90 or until the patient dies or has active intensive care withdrawn, whichever comes sooner. After the ICU discharge date, forms will need to be marked manually as not in ICU.
6. In each daily form, you will first be asked whether the patient is in the ICU that day. When you select "yes", the daily form questions will appear.

Death

1. Death data can only be added using an Investigator, Follow Up Investigator, or Follow Up Coordinator account. The general site user account **will not work**.
2. Please add the date and time of death if it occurs at any time during the study period, until the final (12 month) follow-up.

Consent

1. Consent data can only be added using an Investigator account. The general site user account **will not work**.
2. If consent is obtained from the patient, the “consent withdrawal” section will appear. This section is not required, only fill this section in if consent was withdrawn.

90-day and 6- and 12-month follow-up

1. Follow-up data can only be added by Follow Up Investigator and Follow Up Coordinator accounts. The general site user account and ordinary investigator accounts **will not work**.

Bugs and feedback

If something isn't working as it should, you can either email jane.fisher@advansci-research.com, or you can use the feedback button found on the far right side of each page to send a bug report ticket directly to the developers.