Manual for the AID-ICU study – screening and data generation for eCRF paper version.

The screening and data generation is described in this study document.

AID-ICU study hotline +45 35 45 69 49

or

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Please do not hesitate to call or write.

Introduction

There are 7 documents for this study

- 1 – AID-ICU SCREENING
- 2 – AID-ICU GENERAL PATIENT INFORMATIN
- 3 – AID-ICU SAPS II
- 4 – AID-ICU DAYFORM
- 5 – AID-ICU DISCHARGE AND READMISSION
- 6 – AID-ICU WITHDRAWAL
- 7 - AID-ICU FOLLOW UP 90 DAY

1 – AID-ICU SCREENING

Each patient over 18 years acutely admitted to your ICU during the two weeks of inception is eligible for the AID-ICU and needs a participant Identification Number (ID). This participant ID is generated automatically in the database when you start to screen a patient.

For your paper CRF you need to make a participant ID manually, please do as followed:

A participant ID contains:
Country identification number, site identification number, participant identification number

e.g. DK01001 for the first patient screened at site 01 in Denmark. The next patient screened will get DK01002

Please find your country information below. Please see the site user template for site ID or contact the hotline.

Country	Code	Site	Patient id
Denmark	DK	01-99	001-999
Sweden	SW	01-99	001-999
Norway	NO	01-99	001-999
Finland	FI	01-99	001-999
Netherland	NL	01-99	001-999
Switzerland	SD	01-99	001-999
Germany	DD	01-99	001-999
United Kingdom	GB	01-99	001-999
Italy	IT	01-99	001-999
France	FR	01-99	001-999
Belgium	BE	01-99	001-999
Spain	ES	01-99	001-999
Canada	CD	01-99	001-999
Brazil	BA	01-99	001-999

Tip.

If you start your participant number at 001 and consecutively give the next number in line when you include patients, this will give you the same participant ID, when you enter data into the database.

If the patient is excluded please save the data for entry, we need the participants ID and reason for exclusion.

The participant ID goes in the top right corner of EVERY sheet.

2 – AID-ICU GENERAL PATIENT INFORMATIN

Start the form by filling in the participant ID.

This form takes between 10 – 15 minutes to complete.

Please pay attention to the following:

"Date and time of ICU and hospital admission": If the patient has been transferred from another ICU/hospital please enter data and time of **the first admission**.

3 – AID-ICU SAPS II

Start the form by filling in the participant ID.

When entering values for SAPS II scores please report the most deranged values obtained within the first 24 hours of ICU admission. If values are missing within the first 24 ours, please use the value of the next ICU day.

4 – AID-ICU DAYFORM

Start the form by filling in the participant ID.

The first day form starts, when the day starts in your department e.g. 6 AM (decided by the local investigator). The last day is from start of a day (e.g. 6 AM) until discharge/death. Hence, in most cases the first and last day will not be 24 hours. Hereafter a day form needs to be filled in once a day with a maximum of 90 days.

Please state the day number within the study at every day form and the date. This to ensure continuity.

5 – AID-ICU DISCHARGE AND READMISSION

Start the form by filling in the participant ID.

The discharge/readmission form is used to discharge and readmit the patient.

If a patient dies in the ICU, the study period ends here, then fill in the "7 - AID-ICU FOLLOW UP 90 DAY" form. This information will help the system (when you enter data into the AID-ICU database) to calculate the length of stay in ICU and hospital.

If a patient is readmitted to the ICU, fill in the readmission date and time, and start a new day form. It is necessary to follow all included patient that is readmitted within the 90 days follow up period.

If a patient has been discharged from the hospital and readmitted to an ICU participating in AID-ICU data registration has to be continued from this day.

Patients transferred from/to other ICUs.

ICUs participating in AID-ICU:
If a patient is transferred from your ICU to an ICU participating in AID-ICU, complete the discharge form and send it with the patient to the new ICU. Remember to make agreement with the site investigator so that data collection continues.

ICUs **not** participating in AID-ICU:
If a patient is transferred to your ICU please screen the patient for inclusion in AID-ICU.
If you transfer a patient to another ICU **not** participating in AID-ICU the patient will be regarded discharged from ICU. Please complete the discharge form. Follow-up still has to be completed at day 90.

6 – AID-ICU WITHDRAWAL

The patient can be withdrawn from the study if consent is not given or is withdrawn. Please check with your national coordinator if you need consent for participation in your country.

If consent is not given or withdrawn, please fill in the withdrawal form.

Please check with your national coordinator if you need to withdraw all data or just discontinue.

7 - AID-ICU FOLLOW UP 90 DAY

Start the form by filling in the participant ID.

Ninety days after admission to the ICU the follow-up form needs to be filled in. The only questions in this form are vital status and length of stay in ICU and hospital.