

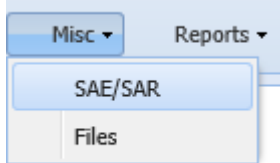
# User manual SAE/SAR (11june2018)

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### 1. Find the menu SAE/SAR

Misc -> SAE/SAR

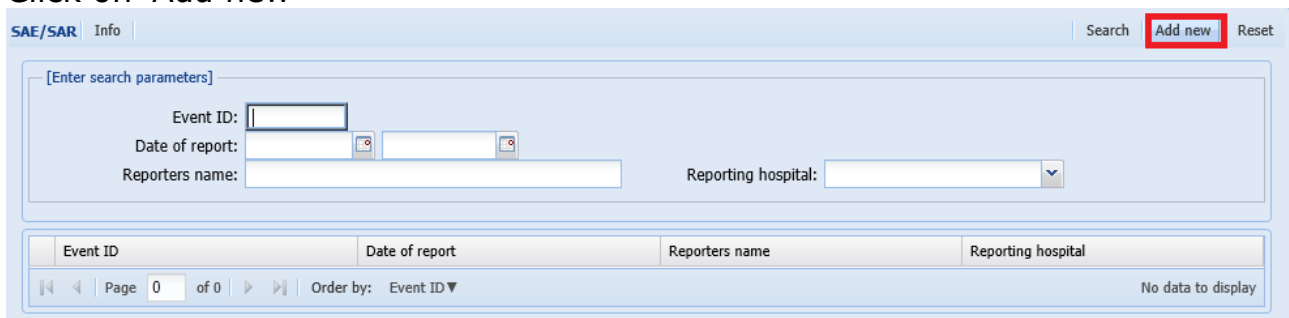


### 2. Find an existing SAE/SAR registration

When you enter the menu 'SAE/SAR' you get a variety of possibilities for entering search parameters. The system brings forward all events, however if you wish to limit the number search on one parameter or combine more parameters.

### 3. Register a new SAE/SAR

Click on 'Add new'



## 4. Event and Description

Start entering information.

SAE/SAR Info Back Save Reset Preview report Send report

Event ID:

**Event** Description Donation Recipient

**Is the event/reaction you are about to report:**

Unexpected or unforeseen and unwanted or undesired?

If not, please do not report!

If you are in doubt, you can see definitions and examples [here](#)

Where did the event occur?:

Baseline data: 0: Within SCTP

Date for SAE/SAR: 1: Outside SCTP - (Organs imported to SCTP)

Date of report:  Time:  User of last change:

To select from predefined lists in grids, click in the box a list of value will appear. In the 'Specify' box next to each selected value it is possible to make a free text comment.

SAE/SAR Info Back Save Reset Preview report Send report

Event ID: 1

Event Description Donation Recipient

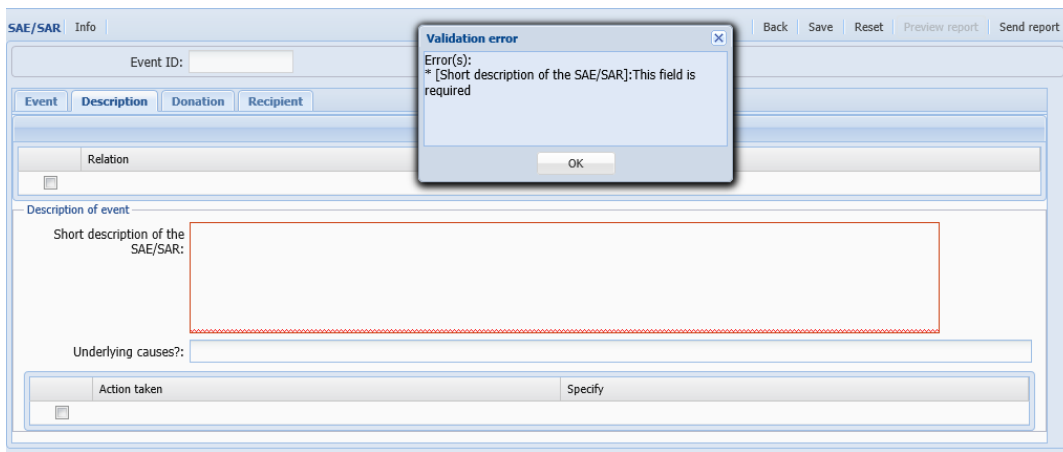
The SAE/SAR related to

Relation	Specify
<input checked="" type="checkbox"/> <input type="text"/>	<input type="text"/>
<input type="checkbox"/> 1: Organ (anatomy, function)	
<input type="checkbox"/> 2: Equipment (technical issues and errors)	
<input type="checkbox"/> 3: Routines, procedures, operation (human factors and errors)	
<input type="checkbox"/> 4: Transmission of an infection	
<input type="checkbox"/> 5: Transmission of a malignancy	
<input type="checkbox"/> 6: Transmission of a disease/disorder	
<input type="checkbox"/> 7: Other	

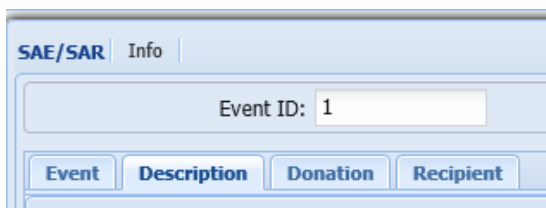
Underlying causes?:

Action taken	Specify
<input type="checkbox"/>	<input type="text"/>

Most of the fields in 'Event' and 'Description' tabs are mandatory to fill in. If you try and save and data is lacking you will get a warning.



Fill in the missing information and save data then you will get an Event ID



## 5. Donation *or* Recipient

Information should only be registered **either** in 'Donation' or 'Recipient' tab. By selecting '0: Donation' or '1: Recipient', only the correct tab will appear.

Register information in 'Donation' tab if the SAE/SAR in any way is **related to a donor**

- One or more recipients are affected by deceased donor organ transplantation
- Living donor

Register information in 'Recipient' tab if the SAE/SAR is related to one recipient and has **nothing to do with an organ donor**

SAE/SAR reaction	
Action taken	Specify
<input checked="" type="checkbox"/> 2: Direct contact with recipient centers affected by the SAE	Telephone contact and fax of the pathology report
<input type="checkbox"/>	

Has the SAE/SAR occurred in relation to/affecting organ **donation**?

Please select donation, if the event/reaction has occurred due to the organ donor, one or more recipients are affected or if the event is related to a living donor

**OR**

Has the SAE/SAR occurred in relation to/affecting only one **recipient**?

Please select recipient, if only one recipient is affected, and the incident is not related to the organ donor

Incident related to:  x v

0: DONATION

1: RECIPIENT

## 5.1 More about the donation tab (event related/connected to organ donor)

Click in the donor field to bring forward a pop-up to select the donor involved

The screenshot shows the 'SAE/SAR' application interface, specifically the 'Donation' tab. At the top, there is a header with 'SAE/SAR Info' and navigation buttons: 'Back', 'Save', 'Reset', 'Preview report', and 'Send report'. Below the header, the 'Event ID' is set to '1'. The main content area has tabs for 'Event', 'Description', 'Donation', and 'Recipient', with 'Donation' being the active tab. A heading asks, 'Has the SAE occurred in relation to/affecting organ donation?' followed by a sub-heading: 'Please fill in info in this tab, if the event/reaction has occurred due to the organ donor, one or more recipients are affected or if the event is related to a living donor'. Below this is a table with two columns: 'Occurrence' and 'Specify'. The first row has a checked checkbox under 'Occurrence' with the value '3: Allocation' and the text 'The kidney got stuck in custom' under 'Specify'. A green instruction reads: 'After selecting donor, please save to get list of recipients'. Below this is a 'Donor:' field with a red arrow pointing to it. At the bottom, there are two tables. The first table has columns: 'Scandianumber', 'Involved in incident', 'Treatment type', and 'Tx center code'. The second table has columns: 'Involved in incident', 'Organ type', and 'Exported to'.

To find the donor press search or enter one or more search parameters to limit the number of donors.

The screenshot shows the 'Registered donors' search interface. At the top, there is a header with 'Registered donors Info' and a 'Search' button (highlighted with a red box) and a 'Reset' button. Below the header, there is a search area with the text '[Enter search parameters]'. It contains several input fields: 'Donor number' with the value '47', 'Country' with a dropdown menu, 'Name' with a text input field, 'Date of donation' with two date pickers, and 'Proc center' with a dropdown menu. Below the search area is a table with columns: 'Donor number', 'Country', and 'Proc center'. The first row has the values '47', 'S: Sweden', and 'UP: Uppsala'. At the bottom, there is a pagination control showing 'Page 1 of 1' and 'Order by: Donor number'. The text 'Displaying 1 - 1 of 1' is also visible.

Click on the specific donor and data will be transferred.

## After selecting the donor – save data to get list of recipients

SAE/SAR Info Back **Save** Reset Preview report Send report

Event ID: 1

**Event Description Donation Recipient**

**Has the SAE occurred in relation to/affecting organ donation?**  
Please fill in info in this tab, if the event/reaction has occurred due to the organ donor, one or more recipients are affected or if the event is related to a living donor

Occurrence	Specify
<input checked="" type="checkbox"/> 3: Allocation	The kidney got stuck in custom
<input type="checkbox"/>	

**After selecting donor, please save to get list of recipients**

Donor: 47: Firstname: , Donor country code: S, Donor type: DECEASED

Scandianumber	Involved in incident	Treatment type	Tx center code
→ 13814			UP: Uppsala
→ 8004			ST: Stockholm

Involved in incident	Organ type	Exported to
→	PA	B: Belgium

The list will contain recipients (top) related to the selected donor and organs exported (bottom) out of Scandiatransplant.

To register if the recipient was involved in the incident and to update information on the recipient, please click on the line with recipient information

SAE/SAR Info Back Save Reset Preview report Send report

Event ID: 1

**Event Description Donation Recipient**

**Has the SAE occurred in relation to/affecting organ donation?**  
Please fill in info in this tab, if the event/reaction has occurred due to the organ donor, one or more recipients are affected or if the event is related to a living donor

Occurrence	Specify
<input checked="" type="checkbox"/> 3: Allocation	The kidney got stuck in custom
<input type="checkbox"/>	

**After selecting donor, please save to get list of recipients**

Donor: 93925: Firstname: , Donor country code: DK, Donor type: DECEASED

Scandianumber	Involved in incident	Treatment type	Tx center code
→ 197988		LI	CP: København

Involved in incident	Organ type	Exported to

Then a new window will open up, if you register that the recipient was not involved, no further information is needed, however if the recipient was involved more data entry is needed.

If the recipient belongs to another center than the reporter, the recipient center can update the information by entering the original SAE/SAR event and update the information through the 'Donation tab'.

**Recipient information** Info Back Save Reset

Scandianumber: 197988 Involved in incident: Y: Yes

First name: First name: L. Last name: Surname: N.

Treatment type: LI ABO: 0

Country code: DK Tx center code: CP: København

Short description:

Underlying causes?:

**Action taken recip**

Action taken	Specify
<input type="checkbox"/>	

Clinical consequences of the SAR:

Clinical outcome of the SAR:

## 5.2 More about the recipient tab (event is not related to an organ donor)

Click in the recipient field to bring forward a pop-up to select the recipient involved.

To find the recipient press search or enter one or more search parameters to limit the number of recipients.

**SAE/SAR** Info Back Save Reset Preview report Send report

Event ID: 3

**Event Description Donation Recipient**

**Has the SAE occurred in relation to/affecting only one recipient?**

Please fill in info in this tab, if only one recipient is affected, and the incident is not related to the organ donor

Occurence	Specify
<input checked="" type="checkbox"/> 1: Transplantation	Organ dropped on the floor
<input type="checkbox"/>	

Recipient:

Affected organ(s)

Pancreas:  Intest:  Heart:

**Registered recipients** Info Search Reset

[Enter search parameters]

SCANDIANUMBER:  Country:

First name:  Last name:

Date of birth:  Tx center:

SCANDIANUMBER	Country	Tx center
Page 0 of 0		

No data to display

Select the recipient involved and data will be transferred, add additional information.

SAE/SAR Info Back Save Reset Preview report Send report

Event ID: 3

**Recipient**

**Has the SAE occurred in relation to/affecting only one recipient?**

Please fill in info in this tab, if only one recipient is affected, and the incident is not related to the organ donor

Occurrence	Specify
<input checked="" type="checkbox"/> 1: Transplantation	Organ dropped on the floor
<input type="checkbox"/>	

Recipient: 910107:

Affected organ(s)

Pancreas: <input type="checkbox"/>	Islets: <input type="checkbox"/>	Heart: <input checked="" type="checkbox"/>
Right lung: <input type="checkbox"/>	Left lung: <input type="checkbox"/>	Double lung: <input type="checkbox"/>
Large bowel: <input type="checkbox"/>	Stomach: <input type="checkbox"/>	Spleen: <input type="checkbox"/>
Right kidney: <input type="checkbox"/>	Left kidney: <input type="checkbox"/>	
Whole liver: <input type="checkbox"/>	Split liver: <input type="checkbox"/>	
Small intestine: <input type="checkbox"/>		

Clinical consequences of the SAR: 3: Moderate

Clinical outcome of the SAR: 5: Unknown

## 6. Sending report – acute

When you are done with the initial data registration and you need to inform the involved transplant centers within ScandiTransplant **acute** you can preview and send the report.

Using the 'Send report' function will notify all coordinators on the involved centers with a SMS and an email and the competent authority with email.

SAE/SAR Info Back Save Reset Preview report Send report

Event ID: 3

**Recipient**

**Is the event/reaction you are about to report:**

Unexpected or unforeseen and unwanted or undesired?

If not, please do not report!

If you are in doubt, you can see definitions and examples [here](#)

Where did the event occur?: 0: Within SCTP

Baseline data

Date for SAE/SAR: 06-Dec-2017 Time: 09:00

Date of report: 19-Dec-2017 Time: 10:58

User of last change: IDW

## 7. Sending report – not acute

Each day at 10 O'clock CET reports changed and created within the last 24 hours will automatically be included in an email to all coordinators and competent authorities.

So, if you don't need to send out an acute message, the sending of reports will be handled automatically by YASWA.