



## Place in Site Master File #9

### Instructions for the SUP-ICU trial - eCRF

The screening and randomisation procedure is described in the trial document 'Manual for the SUP-ICU trial – screening and randomisation'.

#### Log on

Please go to <http://www.sup-icu.com>.


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

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An international critical care research programme

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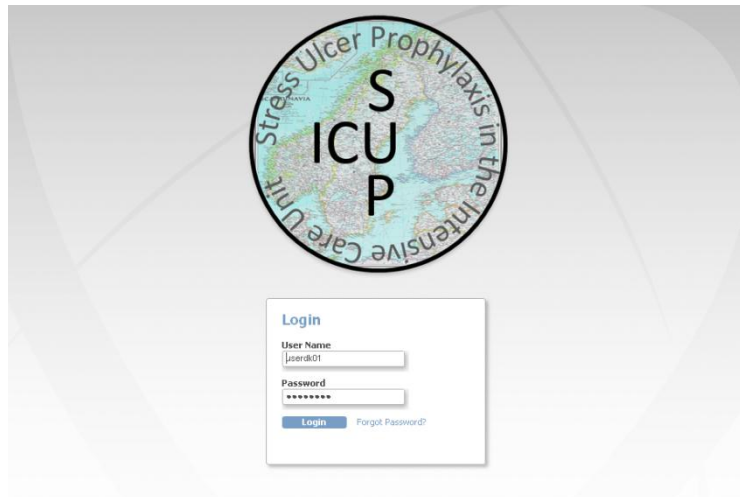
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**SUP-ICU trial (not yet recruiting)**

 <p><b>Screen, randomise, and enter data</b> Do you want to screen, randomise or enter data? → Click here</p>	 <p><b>Trial medication</b> Do you want to dispense trial medication? → Click here</p>	 <p><b>Trial documents</b> Protocol, trial procedures, Site Master File etc. → Click here</p>
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Click the 'Screen, randomise and enter data' link.

If you have not received your login, please send an email to [contact@sup-icu.com](mailto:contact@sup-icu.com)



If your browser presents a warning about a certificate from an un-trusted 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 avoiding the use of internet explorer as browser when using this eCRF.

# A quick tour through the eCRF

## Participant list

After login in you will see the participant list.

(Screen shots below is from a demo version of the SUP-ICU eCRF)

Trial Participant ID	Name	Enrolment Date	Screening	Baseline	Day Form	Discharge and readmission	Withdrawal	Follow-Up	Actions
AU01001	Christian Petersen	2015-10-23	✓	📄	📄 x3	📄	📄	📄	<a href="#">Click here to enter data</a>
AU01002	[Name unknown]	2015-10-26	✓	✓	📄 x3	📄	📄	📄	<a href="#">Click here to enter data</a>
AU01003	Lisa Thomsen	2015-10-26	✓	📄	📄 x3	📄	📄	📄	<a href="#">Click here to enter data</a>
AU01004	John Thomas	2015-10-29	✓	📄	📄	📄	📄	📄	<a href="#">Click here to enter data</a>
AU01005	Emma Jackson	2015-10-29	✓	📄	📄	📄	📄	📄	<a href="#">Click here to enter data</a>

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 communicating with the coordinating centre.
- National identification number (as described in the instruction for screening and randomisation)
- Name of the patient (as written in the screening procedure)
- Enrolment date

The next columns show the different trial events. The colours of the icons indicate the status of the event

- 📄 = not started, data entry not possible (day forms, follow-up form)
- 📄 = the form is scheduled. In this state data entry is possible if necessary (discharge/withdrawal)
- 📄 = data entry possible/started but incomplete
- ✓ = completed
- 📄 = data has been entered, but not saved (appears when filling out forms in the eCRF)

New forms will be generated daily (maximum of 90 days). The colour of the icon in the column with day forms will turn green when all generated daily forms have been completed. When a new form is generated it will turn back to yellow until all forms have been completed. To see which day forms are incomplete you have to click on the participant (further information are provided below).

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

1. Screening procedure
2. Site overview
3. Participant details (data entry)

Participant List for Canberra, Australia

For Screening click here: [Go to Patient Screening](#) For Site overview click here: [Site Overview](#)

Trial Participant ID	Name	Enrolment Date	Screening	Baseline	Day Form	Discharge and readmission	Withdrawal	Follow-Up	Actions
AU01001	Christian Petersen	2015-10-23	✓	📄	📄 x3	📄	📄	📄	<a href="#">Click here to enter data</a>
AU01002	[Name unknown]	2015-10-26	✓	📄	📄 x3	📄	📄	📄	<a href="#">Click here to enter data</a>
AU01003	Lisa Thomsen	2015-10-26	✓	📄	📄 x3	📄	📄	📄	<a href="#">Click here to enter data</a>
AU01004	John Thomas	2015-10-29	✓	📄	📄	📄	📄	📄	<a href="#">Click here to enter data</a>
AU01005	Emma Jackson	2015-10-29	✓	📄	📄	📄	📄	📄	<a href="#">Click here to enter data</a>

Results 1 - 5 of 5.

## Site overview

In the upper right corner (see screen shot above) you will find the 'Site overview' button.

Clicking this button will give you a quick overview of your enrolled patients.

### Site Overview

AU01 ▾ [Click here to get back to Front page](#)

- Click "Participant ID" or "Name" to highlight row
- Hover on Form status symbol to see start date and end date
- Click Form status symbol to enter form data

Participant ID	Name	Screening	Baseline	DF 1	DF 2	DF 3	DF 4	DF 5	DF 6	DF 7	DF 8	DF 9	DF 10	DF 11	DF 12	DF 13	DF 14	DF 15	DF 16	DF 17
AU01001	Christian Petersen	✓	📄	📄	📄	📄														
AU01002	[Name unknown]	✓	📄	📄	📄	📄														
<b>AU01003</b>	<b>Lisa Thomsen</b>	✓	📄	📄	📄	📄														
AU01004	John Thomas	✓	📄	📄	📄															
AU01005	Emma Jackson	✓	📄	📄	📄															

Point at 📄 (without clicking) to see start and end date of the form.

Click the participant ID to highlight the row (green).

Click 📄 to enter the incomplete form.

If icons are missing the forms have not yet been generated. If the patient has been discharged and readmitted, day forms during the period out of ICU will be empty and should not be completed.

## Data entry – general information

After randomisation the following forms will be available:

- Baseline form
- Day form (1 per day when the patient is in the ICU with a maximum of 90 days)
- Discharge form (to be completed at discharge or death).
- Withdrawal form (to be completed if the patient is withdrawn from the trial because of clinical indication or withdrawal of consent)
- Follow-up form (becomes active 90 days after randomisation). If the patient dies in the ICU and the discharge form is completed, the follow-up form will automatically be completed

To enter the forms (participant details) click the link 'Click here to enter data'

Participant List for Canberra, Australia

For Screening click here: [Go to Patient Screening](#)

For Site overview click here: [Site Overview](#)

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Trial Participant ID	Name	Enrolment Date	Screening	Baseline	Day Form	Discharge and readmission	Withdrawal	Follow-Up	Actions
AU01001	Christian Petersen	2015-10-23			x3				<a href="#">Click here to enter data</a>
AU01002	[Name unknown]	2015-10-26			x3				<a href="#">Click here to enter data</a>
AU01003	Lisa Thomsen	2015-10-26			x3				<a href="#">Click here to enter data</a>
AU01004	John Thomas	2015-10-29							<a href="#">Click here to enter data</a>
AU01005	Emma Jackson	2015-10-29							<a href="#">Click here to enter data</a>

Results 1 - 5 of 5.

All generated forms will now be available. You have the opportunity to

1. enter or edit data. If you want to edit data in a submitted form click 'Administrative edit'.
2. view data (read only)

Front page | Log Out Trial Participant ID  Go

### Participant Details

**DK01002**  
**NIN: D1205681245**  
**Name: Michael Thomsom**

Find

Event (Occurrence Number)	Start Date	End Date	CRFs (Status, Updated, Actions)
Screening	16-11-2015 08:42	16-11-2015 09:17	16-11-2015 (userdk01) <b>Administrative edit</b> <a href="#">Click here to view data (read only)</a>
Baseline	16-11-2015 09:17		<a href="#">Click here to enter data</a> <a href="#">Click here to view data (read only)</a>
Discharge and readmission	16-11-2015 09:17		<a href="#">Click here to enter data</a> <a href="#">Click here to view data (read only)</a>
Withdrawal	16-11-2015 09:17		<a href="#">Click here to enter data</a> <a href="#">Click here to view data (read only)</a>

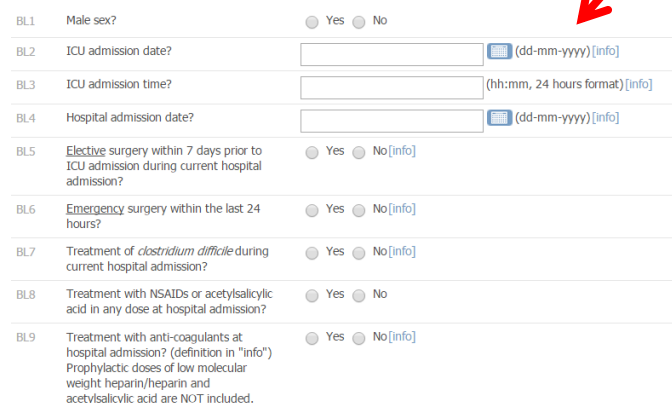
## In the forms:

Click on 'info' to see explanations and further information.

**Please read this information carefully!**

Date format is always **dd-mm-yyyy**. You can use the Calendar or enter the date directly

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



BL1 Male sex?  Yes  No

BL2 ICU admission date?  (dd-mm-yyyy) [info]

BL3 ICU admission time?  (hh:mm, 24 hours format) [info]

BL4 Hospital admission date?  (dd-mm-yyyy) [info]

BL5 Elective surgery within 7 days prior to ICU admission during current hospital admission?  Yes  No [info]

BL6 Emergency surgery within the last 24 hours?  Yes  No [info]

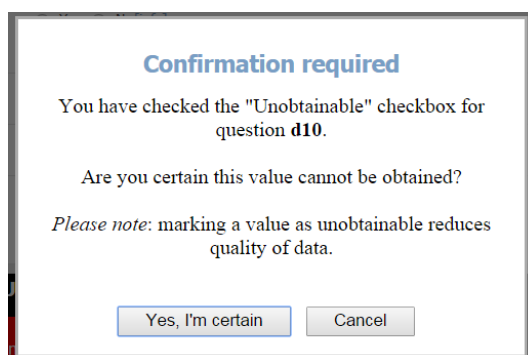
BL7 Treatment of *clostridium difficile* during current hospital admission?  Yes  No [info]

BL8 Treatment with NSAIDs or acetylsalicylic acid in any dose at hospital admission?  Yes  No

BL9 Treatment with anti-coagulants at hospital admission? (definition in "info") Prophylactic doses of low molecular weight heparin/heparin and acetylsalicylic acid are NOT included.  Yes  No [info]

When answering some of the questions you will have the opportunity to check an 'unobtainable' box.

Missing data will reduce the quality of data and we kindly ask you to confirm that the information requested is unobtainable before checking this box.



**Confirmation required**


You have checked the "Unobtainable" checkbox for question **d10**.

Are you certain this value cannot be obtained?

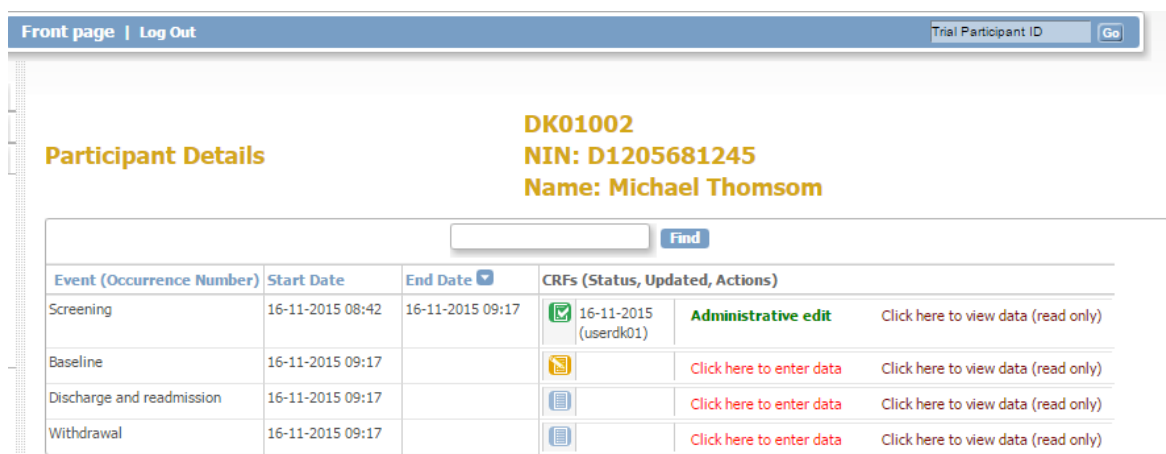
*Please note: marking a value as unobtainable reduces quality of data.*

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

- **Exit (no save)**. Use this bottom if you entered the form without changing data
- **Save**. This will only be an option when data has been entered
- **Submit form**. This will only be an option when the form is complete

Icons at the patient list and in the overview will turn green  when a complete form has been **submitted**.





If complete and only **saved**, the icon will be still be yellow .



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**Participant Details**

**DK01002**  
**NIN: D1205681245**  
**Name: Michael Thomsom**

Event (Occurrence Number)	Start Date	End Date	CRFs (Status, Updated, Actions)
Screening	16-11-2015 08:42	16-11-2015 09:17	 16-11-2015 (userdk01) <b>Administrative edit</b> <a href="#">Click here to view data (read only)</a>
Baseline	16-11-2015 09:17		 <a href="#">Click here to enter data</a> <a href="#">Click here to view data (read only)</a>
Discharge and readmission	16-11-2015 09:17		 <a href="#">Click here to enter data</a> <a href="#">Click here to view data (read only)</a>
Withdrawal	16-11-2015 09:17		 <a href="#">Click here to enter data</a> <a href="#">Click here to view data (read only)</a>

## Specific forms in the eCRF

### Baseline form

This is the most comprehensive form and will take 15-20 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 date and time of the first admission
- When entering values for SAPS and SOFA scores please report the most deranged values obtained 24 hours prior to randomisation. If bilirubin, creatinine and carbamid (urea) is unavailable from 24 hours prior to randomisation, write the first value from the first 24 hours in ICU.
- PaO<sub>2</sub> and FiO<sub>2</sub>: please report the corresponding values of the lowest ratio obtained

### Day form

The first day form will be available 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 is generated once a day at the same time with a maximum of 90 days. The first day form will be available the day after randomisation.

If GI bleeding is observed additional questions have to be answered.

Every day serious adverse reactions (SARs) have to be recorded as part of the day form (7 questions).

To be considered a SAR the event has to be related to the trial medication!

If a SAR occurs please report the SAR to the coordinating centre within 24 hours (see the trial document ‘Instruction SAR/SUSAR’).

If a day form does not turn green despite it is complete, please make sure the form has been submitted (and not just saved).

### Discharge/readmission

The discharge/readmission form is used to 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 in the ICU, discharge the patient in the system by completing the discharge form.

Completing this form will stop the generation of day forms and remove the patient from the list of active participants in the Medication dispensing system.

TIP: If you enter data retrospectively and the patient has been discharged or is dead it may be advantageous to complete the discharge form before day forms, as the system will remove irrelevant day forms.

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

If an unnecessary row by accident is generated you have to delete it by clicking 'X' in the right side.

DISCHARGE AND READMISSION FORM						
Date of ICU readmission (dd-mm-yyyy)	Time of ICU readmission (hh:mm, 24 hours format)	Date of ICU discharge (dd-mm-yyyy)	Time of ICU discharge (hh:mm, 24 hours format)	Patient discharged to	Has the patient been enrolled in other interventional trials during this ICU admission	
		06-10-2015	15:00	<input checked="" type="radio"/> General Ward <input type="radio"/> ICU participating in SUP-ICU trial <input type="radio"/> ICU not participating in SUP-ICU trial <input type="radio"/> Dead	<input type="radio"/> Yes <input checked="" type="radio"/> No	
				<input type="radio"/> General Ward <input type="radio"/> ICU participating in SUP-ICU trial <input type="radio"/> ICU not participating in SUP-ICU trial <input type="radio"/> Dead	<input type="radio"/> Yes <input type="radio"/> No	X

After completing the discharge/readmission form, day forms will again be generated and the patient will be active in the Medication dispensing system for allocation of trial medication.

If PPI or H2RA has been prescribed in the ward, please consider the indication:

- If there is a clinical indication to continue PPI/H2RA, please complete the withdrawal form (see below).
- If the clinical decision is to discontinue PPI/H2RA at ICU admission, please continue trial medication.

If the withdrawal form is completed the patient will not be active in the Medication dispensing system. Please continue daily data collection.

### Patients transferred from/to other ICUs

#### ICUs not participating in SUP-ICU:

If a patient is transferred to your ICU please screen the patient for inclusion in SUP-ICU.

If you transfer a patient to another ICU **not** participating in SUP-ICU the patient will be regarded discharged from ICU. Please complete the discharge form. Follow-up still has to be completed at day 90.

#### ICUs participating in SUP-ICU:

If a patient is transferred from your ICU to an ICU participating in SUP-ICU, complete the discharge form and choose the centre at the list. In the electronic system, the patient will be transferred to a 'transferral site' accessible by you and the receiving department. Please complete all forms as soon as possible. Hereafter



the patient will be transferred to the receiving department. **Please inform the receiving department that the patient is enrolled in SUP-ICU.**

If a patient is transferred to your ICU and has not been transferred in the electronic system, please contact the coordinating centre soon as possible.

## Withdrawal

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

1. Indication for treatment with open label PPI/H2RA
2. Clinical decision other than the above mentioned
3. SAR/SUSAR
4. Consent not given or withdrawn

Please complete the withdrawal form.

The daily allocation of trial medication will be stopped in the Medication dispensing system. Remember to discontinue the medication in the patient chart. Please continue completing day forms unless consent to do this has been withdrawn.

Will only be shown if 'Consent not given or withdrawn' has been marked in W3

**WITHDRAWAL FORM**

**WITHDRAWAL FROM INTERVENTION AND/OR DATA REGISTRATION**

W1 Date of withdrawal?  (dd-mm-yyyy)

W2 Time of withdrawal? (24 hours)  (hh:mm)

W3 Reason for withdrawal?

- Indication for treatment with open label PPI/H2RA
- Clinical decision other than the above
- SAR/SUSAR
- Consent not given or withdrawn

W4a Who is not giving or withdrawing consent?

- Relative/next of kin/guardian not giving or withdrawing consent
- Patient not giving or withdrawing consent

W4b Will further daily data be registered?

- Yes
- No

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## Follow-up

Ninety days after randomisation the follow-up form will be activated. The only questions in this form are vital status and date of death.

If the patient dies in the ICU and this is marked in the discharge form, the follow-up form will automatically be completed.

**Follow-Up** ✓

DK01002  
NIN: D1205681245  
Name: Michael Thomsson

CRF Header Info

**Follow-up** (4/4)

Title: Follow-up

Instructions:

**FOLLOW-UP FORM**

f0 Date of follow-up  Calculated as 90 days after randomisation

f1 Is the patient dead?  Yes  No

f2 Date of death?  (dd-mm-yyyy)

f3 Time of death?  (hh:mm, 24 hours format)

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