



Place in Site Master File #9a

Instructions for the HOT-COVID trial - eCRF

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

Log on

Please go to <http://www.cric.nu/hot-covid>.

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



Handling Oxygenation Targets in COVID-19

Hotline: **+45 21 18 25 43**



Screen, randomise, and enter data



Trial documents

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

If you have not received your login, please send an email to hot-covid@cric.nu



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 version 8 or older 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 HOT-COVID eCRF)

Participant List for Danish test site

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

Participant ID	Name	NIN	Enrolment Date	Screening	Baseline	Day form	Discharge and readmission	Withdrawal	90 days follow-up	1 year follow-up	Consent form	Actions
DK01013	<Name not defined>	<NIN not defined>	14-08-2020									Click here to enter data
DK01012	John Doe	D1111111111	14-08-2020									Click here to enter data
DK01011	Dr. Jones	D1122334455	06-08-2020									Click here to enter data
DK01010	DDD DDDD	D1212121212	03-08-2020									Click here to enter data
DK01009	Test03	D1122553311	03-08-2020									Click here to enter data
DK01008	Janus 6	D0000000006	16-07-2020									Click here to enter data
DK01007	Janus 5	D0000000005	16-07-2020									Click here to enter data
DK01006	Janus 4	D0000000004	15-07-2020									Click here to enter data
DK01005	Janus 3	D0000000003	15-07-2020									Click here to enter data
DK01004	Janus 2	D0000000002	15-07-2020									Click here to enter data
DK01003	<Name not defined>	<NIN not defined>	15-07-2020									Click here to enter data

Results 1 - 11 of 11.

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.
- 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. 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)

1
2

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

Participant ID	Name	NIN	Enrolment Date	Screening	Baseline	Day Form	Discharge and randomisation	Withdrawal	90 days follow up	1 year follow up	Consent form	Actions
DK01013	<Name not defined>	<NIN not defined>	14-08-2020									Click here to enter data
DK01012	John Doe	D1111111111	14-08-2020									Click here to enter data
DK01011	Dr. Jones	D1122334455	06-08-2020									Click here to enter data
DK01010	DDD DDDD	D1212121212	03-08-2020									Click here to enter data
DK01009	Test03	D1122553311	03-08-2020									Click here to enter data
DK01008	Janus 6	D0000000006	16-07-2020									Click here to enter data
DK01007	Janus 5	D0000000005	16-07-2020									Click here to enter data
DK01006	Janus 4	D0000000004	15-07-2020									Click here to enter data
DK01005	Janus 3	D0000000003	15-07-2020									Click here to enter data
DK01004	Janus 2	D0000000002	15-07-2020									Click here to enter data
DK01003	<Name not defined>	<NIN not defined>	15-07-2020									Click here to enter data

3

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

DK01 [Click here to get back to Front page.](#) [Click here to scroll to Exclusions](#)

- 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	NIN	Randomisation Date	Screening last updated by	Screening	Baseline	DF 1	DF 2	DF 3	DF 4	DF 5
DK01012	John Doe	D1111111111	14-08-2020 13:35	tlk@rn.dk							
DK01011	Dr. Jones	D1122334455	06-08-2020 15:15	tlk@rn.dk							
DK01010	DDD DDDD	D1212121212	03-08-2020 10:26	tlk@rn.dk							
DK01009	Test03	D1122553311	03-08-2020 10:15	tlk@rn.dk							
DK01008	Janus 6	D0000000006	16-07-2020 13:25	root							
DK01007	Janus 5	D0000000005	16-07-2020 13:11	root							
DK01006	Janus 4	D0000000004	15-07-2020 13:18	root							
DK01005	Janus 3	D0000000003	15-07-2020 12:48	root							
DK01004	Janus 2	D0000000002	15-07-2020 12:44	root							

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.

CRIC • Blegdamsvej 9, 7812 • 2100 Copenhagen Ø • +45 35 45 71 67 • contact@cric.nu • www.cric.nu

If icons are missing the forms have not yet been generated. If the patient has been discharged and readmitted, Daily 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 SUSAR or withdrawal of consent)
- 90 days follow-up (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
- 1 year follow-up (becomes active one year after randomisation).

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

Participant ID	Name	NIN	Enrolment Date	Screening	Baseline	Day form	Discharge and readmission	Withdrawal	90 days follow-up	1 year follow-up	Consent form	Actions
DK01013	<Name not defined>	<NIN not defined>	14-08-2020									Click here to enter data
DK01012	John Doe	D1111111111	14-08-2020									Click here to enter data
DK01011	Dr. Jones	D1122334455	06-08-2020			x2						Click here to enter data
DK01010	DDD DDDD	D1212121212	03-08-2020			x11						Click here to enter data
DK01009	Test03	D1122553311	03-08-2020			x11						Click here to enter data
DK01008	Janus 6	D0000000006	16-07-2020			x19						Click here to enter data
DK01007	Janus 5	D0000000005	16-07-2020			x29						Click here to enter data

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)

ID: DK01012
NIN: D111111111
Name: John Doe

Participant Details

Event (Occurrence Number)	Start Date	End Date	CRFs (Status, Updated, Actions)
Baseline	14-08-2020 13:35		Click here to enter data Click here to view data (read only) <i>[No manual data entry yet]</i>
Discharge and readmission	14-08-2020 13:35		Click here to enter data Click here to view data (read only)
Withdrawal	14-08-2020 13:35		Click here to enter data Click here to view data (read only)
Consent form	14-08-2020 13:35		Click here to enter data Click here to view data (read only)
Screening	14-08-2020 13:32	14-08-2020 13:35	Administrative edit Click here to view data (read only) 14-08-2020 (tlk@rn.dk)

1

2

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**



When answering some of the questions you will have the opportunity to check an 'Not Available' 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.

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 .

Participant Details

ID: DK01012
NIN: D111111111
Name: John Doe

Event (Occurrence Number)	Start Date 	End Date	CRFs (Status, Updated, Actions)		
Baseline	14-08-2020 13:35		 Click here to enter data	Click here to view data (read only)	<i>[No manual data entry yet]</i>
Discharge and readmission	14-08-2020 13:35		 Click here to enter data	Click here to view data (read only)	
Withdrawal	14-08-2020 13:35		 Click here to enter data	Click here to view data (read only)	
Consent form	14-08-2020 13:35		 Click here to enter data	Click here to view data (read only)	
Screening	14-08-2020 13:32	14-08-2020 13:35	 Administrative edit	Click here to view data (read only)	14-08-2020 (tlk@rn.dk)

Specific forms in the eCRF

Baseline form

This is the most comprehensive form and will take 20-30 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
- 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. 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 with a maximum of 90 days. The first day form will be available the day after randomisation.

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

Completing this form will stop the generation of day forms.

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 Daily 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 of readmission.

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

Dischar...(8/14)

Title: Discharge and readmission

Exit (no save)

DISCHARGE AND READMISSION FORM

Support: mail or +45 1234 5678

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 [info]	Has the patient been enrolled in other interventional trials during this ICU admission	Patient transferred to site Id
		11-08-2020	10:00	<input checked="" type="radio"/> General Ward <input type="radio"/> ICU participating in HOT-COVID trial <input type="radio"/> ICU not participating in HOT-COVID trial <input type="radio"/> Home (including nursing homes and similar) <input type="radio"/> Dead	<input type="radio"/> Yes <input checked="" type="radio"/> No	N/A
13-08-2020	11:45					DK01
				<input type="radio"/> General Ward <input type="radio"/> ICU participating in HOT-COVID trial <input type="radio"/> ICU not participating in HOT-COVID trial <input type="radio"/> Home (including nursing homes and similar) <input type="radio"/> Dead	<input type="radio"/> Yes <input type="radio"/> No	

Add

Return to top

Exit (no save)

After completing the discharge/readmission form, day forms will again be generated.

Patients transferred from/to other ICUs

ICUs not participating in HOT-COVID:

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

If you transfer a patient to another ICU **not** participating in HOT-COVID the patient will be regarded discharged from ICU. Please complete the discharge form. Ninety days follow-up and one year follow-up still have to be completed.

ICUs participating in HOT-COVID:

If a patient is transferred from your ICU to an ICU participating in HOT-COVID, complete the discharge form and choose the centre in 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 the HOT-COVID trial.**

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. SUSAR
2. Consent not given or withdrawn

Please complete the withdrawal form.

CRIC • Blegdamsvej 9, 7812 • 2100 Copenhagen Ø • +45 35 45 71 67 • contact@cric.nu • www.cric.nu

Please continue completing Daily forms unless consent to do this has been withdrawn.

Title: Withdrawal

Instructions:

[Exit \(no save\)](#)

WITHDRAWAL FORM
 Support: [mail](#) or +45 1234 5678

Withdrawal from intervention and/or data registration

W1	Date of withdrawal?	<input type="text"/>	(dd-mm-yyyy)
W2	Time of withdrawal? (24 hours)	<input type="text"/>	(hh:mm)
W3	Reason for withdrawal?	<input type="radio"/> SUSAR [info] <input checked="" type="radio"/> Consent not given or withdrawn	
W3a	Who is not giving or withdrawing consent?	<input type="radio"/> Relative/next of kin/guardian not giving or withdrawing consent <input type="radio"/> Patient not giving or withdrawing consent	
W3b	Will further daily data be registered?	<input type="radio"/> Yes [info] <input type="radio"/> No	

[Return to top](#)
[Exit \(no save\)](#)

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

Follow-up

Ninety days and one year after randomisation, the relevant follow-up forms will be activated respectively, please fulfil these.

If the patient dies within the ICU and this is marked in the discharge form, date of death will automatically be fulfilled in the 90 days and one-year follow-up forms. However, the form still has to be fulfilled, as other questions need answering.

If the patient dies within the ICU and this is marked in the discharge form, the one-year follow-up form will automatically be completed and will thus not appear.

For patients discharged to "ICU not participating in HOT-COVID" information on days with life support in the non-trial ICU (respiratory support, renal replacement therapy and circulatory support) need to be entered. Please provide consecutive intervals (start and end dates) for relevant supportive therapies. Use the add button if more intervals are needed.

Days with life support

F3	Circulatory support (infusion of vasopressor/inotropes) in an ICU not participating in HOT-COVID?	<input checked="" type="radio"/> Yes [info] <input type="radio"/> No	
----	--	---	--

"Add" new row for each episode.

Within 90 days from randomisation.
 If treatment interval exceeds 90-days follow-up date enter the date of 90-days follow-up.

	F3a Start date		F3b End date
	<input type="text" value="07-06-2020"/> (dd-mm-yyyy)		<input type="text" value="13-06-2020"/> (dd-mm-yyyy)

Add