Place in Site Master File #9a

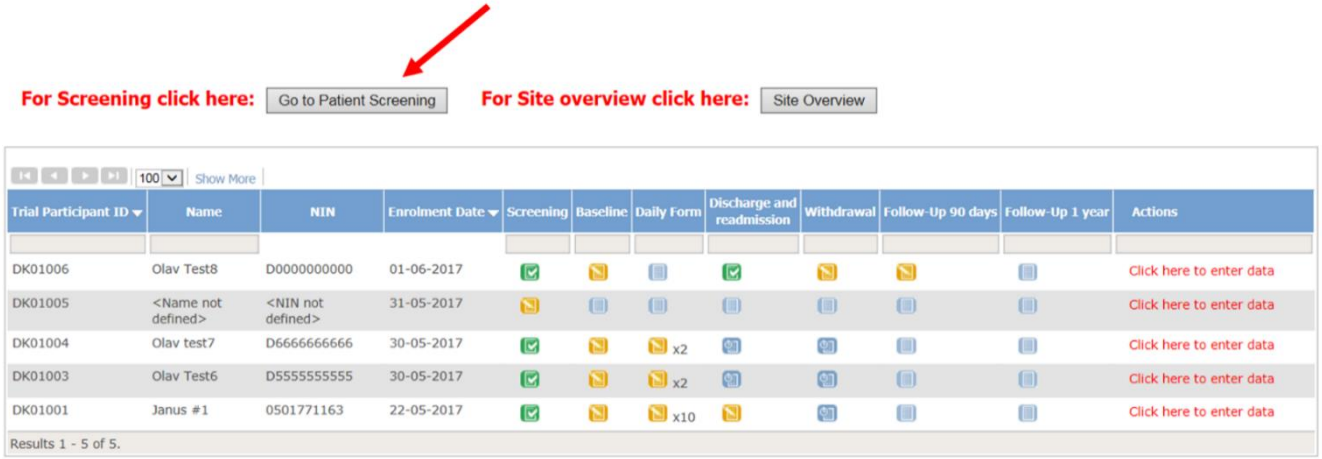
Instruction for the HOT-COVID trial – screening and randomisation

Please screen all adults meeting the inclusion criteria (admitted acutely to the ICU, receiving oxygen supplementation above the defined criteria, are expected to receive oxygen supplementation within the ICU for at least 24 hours, have an intra-arterial catheter AND are SARS-CoV-2 positive) to assess their eligibility for inclusion in HOT-COVID. A screening log is maintained to monitor patient recruitment at each site and will enable a description of the patient population from which eligible patients have been enrolled. All patients will be allocated a site specific 'Trial participant ID' when initiating the screening procedure.

1. Go to www.cric.nu/hot-covid
   Click the eCRF link to 'Screen, randomise and enter data'

2. Login to the eCRF with your personal login. If you have not received your login, please send an e-mail to hot-covid@cric.nu, or use the HOT-COVID hotline +45 2118 2543

3. Click the 'Go to patient screening' button



4. A national identification number (NIN) is needed to help identifying the patient

<u>Danish sites:</u>

- Enter the CPR number in Danish participants
- If a fictive CPR number has been constructed **use the letter D** as a prefix to override the check of a valid CPR number

<u>In all other countries, NIN has to be constructed</u>

NIN is a unique number identifying the patient and will be checked by the system to make sure the same patient is not randomised more than once. The NIN consists of:

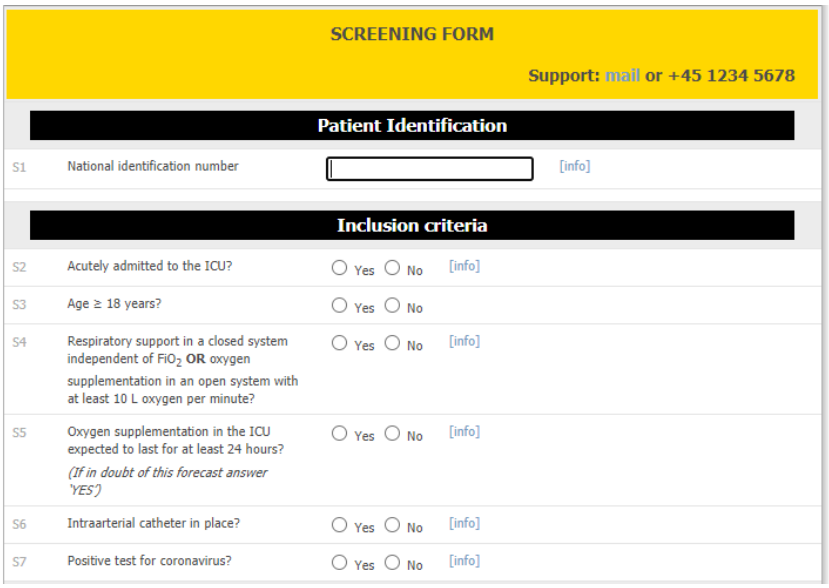
- Date of birth (ddmmyy) (for Switzerland 0101+year)
- A site identifier (automatically generated)
- A serial number. Enter 01

If a warning appears (see below), please check that the patient has not previously been enrolled

WARNINGS: two types of warnings are possible:

Red warning: The NIN is completely identical with a previously constructed NIN. If it is NOT the same patient, **please change the serial number to 02**

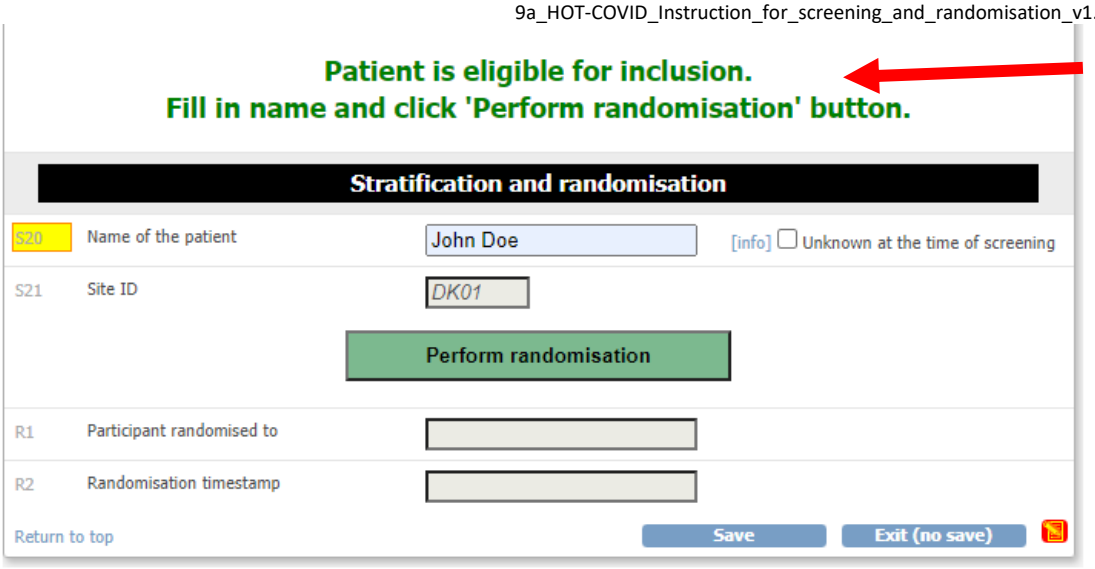
Yellow warning: The NIN is partly identical to a previously constructed NIN. If the name of the patient does not appear on the list shown, please press '**accept**' and continue



5. Complete the screening form

Note that fertile women (defined as age <50 years) have to have a negative pregnancy test before screening and that consent according to national regulations **always** has to be obtained

When the form is complete the text in the randomisation window will change to either green (eligible) or red (not eligible)



6. Make sure all answers are correct.

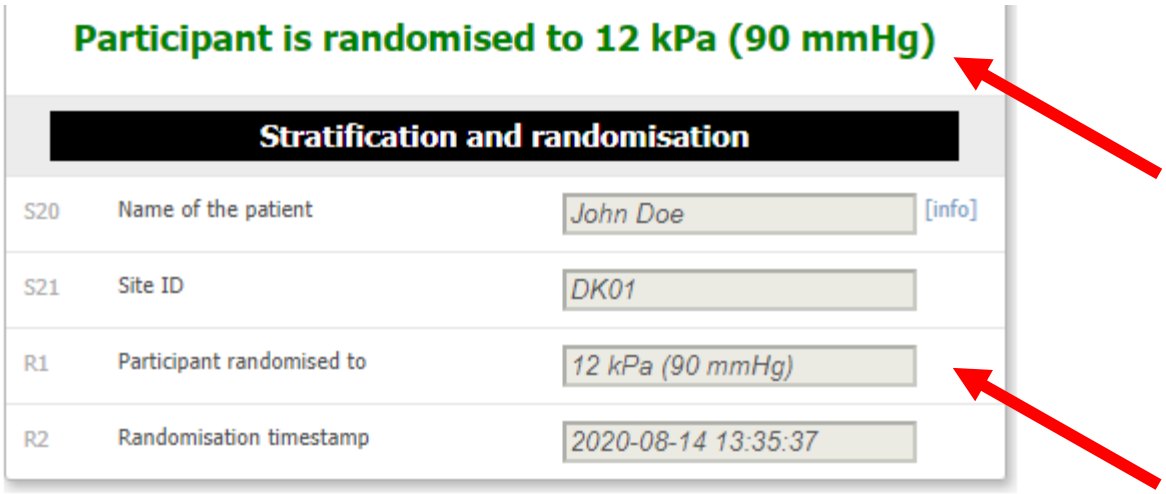
If the patient is eligible for randomisation enter the name of the patient (Switzerland: initials only). If unknown the name and correct birthdate can be added later on during the trial. This will help you identify the patient when entering data

7. When the form is complete *'Perform randomisation'* will be active. Click the button

The patient has now been randomised and the allocated oxygenation target will be highlighted

You can save/find the allocated oxygenation target by

- printing the message
- opening the email send to the email account used when signing up
- opening the screening form. The oxygenation target will be visible in the randomisation window



8. Adjust the FiO_2 to achieve the allocated oxygenation target

    - Prescribe the allocated oxygenation target in the patient's ICU chart
    - Write a note in the patient's medical journal stating inclusion of the patient in the HOT-ICU trial as well as the allocated oxygenation target

The allocated oxygenation target should be upheld throughout the duration of the ICU stay, including readmissions up until maximally 90 days after randomisation