SCREENING — Hotline: 3545 0606

Welcome to the CLASSIC screening procedure

#	Question	Answer	Info	Validation and limits	Further comments for data manager
	Patient identification				
S1	National identification number	_____	**For Danish sites:** CPR number (10 digits without dash). If the patient has a fictive CPR number, please use the letter D as a prefix, e.g. **D**1002550JH0 (D followed by 10 characters). If an unknown patient is identified, you have the option to change the fictive CPR number to the correct CPR number. **For non-Danish sites:** The national identification number is some identification string which may consist of both numbers and letters. The system uses this identification to check if this patient has previously been screened in CLASSIC.	Required for DK sites	Denmark: RED WARNING A participant with identical CPR number has previously been enrolled in the CLASSIC trial and cannot be randomised again. If the participant was enrolled at your department, please readmit the patient in the system. If not please contact the coordinating centre for transferal of the patient in the system. contact classic@cric.nu or +45 3545 0606 WARNING if CPR is invalid Format of CPR is not correct. It should be 10 digits long. If a fictive CPR is entered, please use the prefix 'D' (capital D) followed by 10 characters. See 'info'. Other countries: RED WARNING: (validating on enrolled patients only)

					The trial participant below with the same national identification number (NIN) has previously been enrolled in the CLASSIC trial. If the trial participant below is not identical to the one you are trying to screen, please increase the serial number by 1 (e.g. change 01 to 02). If the trial participant has been enrolled previously, please readmit the patient in the system. For further information please contact classic@cric.nu or +45 3545 0606 YELLOW WARNING: (Validating on enrolled patients in the same country with the same birthday) The trial participants listed below are potentially identical with the one you are trying to screen. Please check the list below. If the trial participant you are trying to screen is NOT identical to any of the participants below, please press accept to continue. If the patient has been enrolled previously, please readmit the patient in the system. For further information please contact classic@cric.nu or +45 3545 0606

					Warning if NIN of an excluded patient is entered again: A patient with the same NIN has previously been excluded. If you want to screen the patient again, please press accept. For further information please contact classic@cric.nu or +45 3545 0606
Inclusion criteria					
S2	Is the patient ≥ 18 years old?	☐ YES ☐ NO		Required	
S3	Is the patient admitted to or planned to be admitted to the ICU?	☐ YES ☐ NO	Patients from other locations in the hospital (e.g. emergency departments, general wards or the recovery room) may be enrolled if the patient for clinical reasons is planned to be admitted to the ICU. High-dependency, step-up or step-down beds are considered as being part of the trial site ICU if staff trained in the protocol looks after the patients in these beds.	Required	
S4	Does the patient have septic shock **according to the Sepsis-3 criteria**?	☐ YES ☐ NO	O Suspected or confirmed site of infection or positive blood culture AND O Ongoing infusion of vasopressor/inotrope agent	Required	

			(norepinephrine, epinephrine, phenylephrine, vasopressin analogues, angiotensin, dopamine, dobutamin, milrinone or levosemindan) to maintain a mean arterial blood pressure of 65 mmHg or above AND O Lactate of 2 mmol/L or above in any plasma sample performed within the last 3-hours		
S5	Has the patient received at least 1 L of IV fluid (crystalloids, colloids or blood products) in the last 24-hours prior to screening?	☐ YES ☐ NO	We will count all crystalloids (any saline, $NaHCO_3^-$, Ringer's and Plasmalyte™ solutions) colloids (albumin 4, 5 or 20%, gelatine, hydroxyethyl starch and dextran solutions) and blood products (units or red cells, plasma or platelets) the participant has received according to the source data within the last 24-hours independent of location (in- or pre-hospital). Intraosseous fluid will be counted as IV.	Required	
Exclusion criteria **Please ensure that the patient does not fulfil any criteria below at ICU admission**					
S6	Has the patient had septic shock for more than 12 hours at the time of screening?	☐ YES ☐ NO	Septic shock according to the Sepsis-3 criteria (definition given in inclusion criteria) for more than 12 hours at the time of screening	Required	

S7	Does the patient have **life-threatening** bleeding?	☐ YES ☐ NO	Life threatening clinical bleeding needing transfusion of blood products as defined by the clinicians	Required	
S8	Does the patient have acute burn injury of more than 10% of the body surface area?	☐ YES ☐ NO	Burn injury leading to the present ICU admission. Patients with burn injury who are readmitted to the ICU or were initially care for in a general ward and admitted to the ICU for infection may be included. The latest documented estimate of the burn area will be used as these may be down-graded after the initial assessments.	Required	
S9	Is the patient pregnant?	☐ YES ☐ NO	Women with known pregnancy based on clinical examination, the history or a human chorionic gonadotropin (hCG) test.	Required	
S10	Consent unobtainable according to national regulations?	☐ YES ☐ NO	YES, if the clinician or investigator is unable to obtain necessary consent before or after inclusion of the patient according to the national regulations.	Required	

If YES to S2-S5 and NO to S6-S10:

Trial participant is eligible for inclusion in the CLASSIC Trial.
Fill in name, and then click the 'Perform randomisation' button.

If YES to S2-S5 and YES to one or more of S6-S10:

The patient fulfils one or more exclusion criteria.
Thus, this patient cannot be randomised in the CLASSIC trial.
If this is correct, click 'Submit' button to exclude the patient.

If NO to one or more of S2-S5

The inclusion criteria are not fulfilled.
Thus, the patient cannot be randomised in the CLASSIC trial.
If this is correct, click 'Submit' button to exclude the patient.

If YES to all inclusion criteria and NO to all exclusion criteria, the patient can be included in the CLASSIC trial					
Stratification variables					
S14	Site				Automatically generated
S15	Metastatic cancer or hematological malignancy?	☐ YES ☐ NO	Metastatic cancer: proven metastasis by surgery, CT scan or any other method Haematological malignancy includes any of the following: O Leukaemia: Acute lymphoblastic leukaemia (ALL), acute myelogenous leukaemia (AML), chronic myelogenous leukaemia (CML), chronic lymphocytic leukaemia (CLL). O Lymphoma: Hodgkin's disease, and Non-Hodgkin		

			lymphoma (e.g. small lymphocytic lymphoma (SLL), diffuse large B-cell lymphoma, follicular lymphoma and mantle cell lymphoma) O Hairy cell leukaemia (HCL), marginal zone lymphoma, Burkitt's lymphoma, post-transplant lymphoproliferative disorder (PTLD), T-cell prolymphocytic leukaemia (T-PLL), B-cell prolymphocytic leukaemia (B-PLL), Waldenström's macroglobulinemia and other NK- or T-cell lymphomas O Multiple myeloma/plasma cell myeloma		

Info box

Randomisation complete

NIN: xxxxxxxxxx
Name: xxx
Participant ID: DKxxxxx

Participant randomised to:
xxxxx [conservative group/ liberal group]