BASELINE FORM

Hotline: 3545 0606

The registration below is based on information from the first day in the ICU.

#	Question	Answer	Unit	Info	Validation and limits decimals	Further comments for data manager
BL1	Sex?	☐ Male ☐ Female		Genotypic sex of the patient	Single select Required	
BL2	Hospital admission date?	|__|__|-|__|__|-|__|__|__|__|	dd-mm-yyyy	The date of admission to the first hospital the patient was admitted to during the current hospital admission	Required	Date must be prior to randomisation
BL3	ICU admission date?	|__|__|-|__|__|-|__|__|__|__|	dd-mm-yyyy	The date of admission to the first ICU or high-dependency or step-up/step-down bed the patient was admitted to during the current hospital admission	Required	Can not be before hospital admission date. Can be after randomisation date, but give warning if ICU admission date is after randomisation date "ICU admission date is after randomisation date - are you sure this is the correct?" → yes to proceed.
BL4	ICU admission time?	|__|__|-|__|__|	24 hours, hh:mm	The time of admission to the first ICU or high-dependency	Required	Can be after ransomisation

				or step-up/step-down bed the patient was admitted to during the current hospital admission		time, but give warning if admission time is after randomisation time (same date) "ICU admission time is after randomisation time - are you sure this is the correct?" → yes to proceed.
BL5	From where was the patient admitted?	☐ Emergency department or directly from the pre-hospital setting Hospital ward ☐ Operating or recovery room. Another ICU.		☐ Accident/Emergency/Casualty/Acute department in the same or another hospital or direct admission to the ICU by an ambulance service or similar. ☐ Any location in the same or another hospital not covered in the other 3 categories. ☐ Including surgical	Single select required	

				theatre, endoscopy and angiography suite and any recovery facilities observing patients following invasive procedures. ☐ either within the same or another hospital		
BL6	Focus of infection (documented or suspected):	☐ Pulmonary. ☐ Gastrointestinal ☐ Urinary tract ☐ Skin or soft tissue ☐ Other		e.g. pneumonia, or empyema e.g. primary, secondary or tertiary peritonitis, abscess, cholangitis, cholecystitis, or invasive diarrhoeal disease e.g. urinary tract infection, or pyelonephritis e.g. cellulitis, phlegmon, erysipelas, or fasciitis	Single-select required	

				Other infectious focus documented or suspected including meningitis, endocarditis, osteomyelitis, arthritis and bacteraemia If several foci are suspected, choose the suspected main focus		
Co-morbidities prior to ICU admission						
BL7	History of ischemic heart disease or heart failure?	☐ YES ☐ NO		Previous myocardial infarction, invasive intervention for coronary artery disease, stable or unstable angina, NYHA class 3 or 4 or measured	Single-select required	

				LVEF < 40%.		
BL8	History of chronic hypertension?	☐ YES ☐ NO		Treatment at time of hospital admission with any antihypertensive agent e.g. diuretics, adrenergic receptor antagonists (alpha/beta/alpha+beta blockers), alpha-2 receptor agonists, calcium channel blockers, ACE-inhibitors, ANG-II receptor antagonists, aldosterone antagonists.	Single-select required	
BL9	Chronic renal replacement therapy?	☐ YES ☐ NO		Use of renal replacement therapy at least once a week e.g. chronic haemodialysis, haemofiltration or peritoneal dialysis. Must have been present in the past medical history prior to ICU admission.	Single-select required	

Blood values, interventions and vital parameters Add randomization date and time						
BL10	Participant weight:	|__|__|__|	kg	Measured or estimated	Required Minimum 30kg maximum 300kg	
BL11	Highest plasma lactate value in the last 3 hours prior to randomisation:	Select unit: mmol/L ☐ |__|__| , |__| mg/dL ☐ |__| , |__|__|	mmol/L or mg/dL	**If no lactate values available for the last 3 hours use the latest available.**	Required Limits 0.0-25.0 mmol/L 1 decimal Cannot be unobtainable	Data entry only possible when a unit has been selected (single select only) and only in the field corresponding to selected unit. System will automatically convert between units (To convert from mg/dL, multiply with 0.111). The value of both units will be visible, but only the selected unit can be corrected. Both values will be transcribed to database. WARNING if p-lactate<2mmol/

						L: ”Are you sure this is the correct value? P-lactate ≥2mmol/L is an inclusion criterion!” → yes to accept. ➔ Email to coordinating investigator if WARNING has been accepted
BL12	Highest dose of noradrenaline in the last 3 hours prior to randomisation:	|__| , |__ |__|	µg/kg/min	Highest infusion rate in µg/kg/min Infusion for at least 1h. Bolus not included.	Required Limits 0.0-2.00 2 decimals	WARNING: If BL12 = 0 : “Are you sure this is correct? Ongoing infusion of vasopressor/inotropic agent is an inclusion criteria.” → yes to accept . No e-mail.
BL13	Infused volume of IV fluids in the last 24 hours prior to	|__|__|__|__|	mL	Defined as all crystalloids (any saline, NaHCO3-, Ringer’s and Plasmalyte™	Required Lower limit 0.	WARNING if BL13<1000mL: ”Are you sure

	randomisation:			solutions), colloids (albumin 4, 5 or 20%, gelatine, hydroxyethyl starch and dextran solutions) and blood products (units of red cells, plasma or platelets) the participant has received within the last 24-hours independent of location (in- or pre-hospital). Intraosseous fluid will be counted as IV.	Negative values can not be accepted. No upper limit, but if value ≥ 9999mL give warning: "Are you sure this is the correct amount of fluid?" – YES to proceed No decimals	this is the correct value? At least 1000mL IV fluid in the last 24 hours prior to randomisation is an inclusion criterion!" → yes to accept. Email to coordinating investigator if WARNING has been accepted
BL14	Use of systemic (IV, IM or oral/per GI tube) corticosteroids in the last 24 hours prior to randomisation	☐ yes ☐ no		Including any dose of hydrocortisone, methylprednisolone, dexamethasone or prednisolone	Single-select required	
BL15	Highest plasma creatinine value in the last 24 hours prior to randomisation:	Select unit: µmol/L ☐ |__|__|__| mg/dL ☐ |__|__|__|__|__|	µmol/L or mg/dl		Required Limits 40-999 (µmol/L) No decimals	Data entry only possible when a unit has been selected (single select only) and only in the field corresponding to selected unit. System will automatically convert between units (To convert

						from mg/dL multiply with 88.4). The value of both units will be visible, but only the selected unit can be corrected. Both values will be transcribed to database.
BL16	Use of <u>acute</u> renal replacement therapy in the last <u>3 days</u> prior to randomisation:	☐ YES ☐ NO		Any form of renal replacement therapy (e.g. dialysis, hemofiltration or hemo-diafiltration) at any rate in the last 72 hours, which has been initiated during the current hospitalisation (including any stay in another hospital immediately prior that in the site)	Single-select required	
BL17	Use of <u>any form of</u> renal replacement therapy within the last <u>24 hours</u> prior to randomisation:	☐ YES ☐ NO		Any form of acute or chronic intermittent or continuous renal replacement therapy (including days between intermittent dialysis) within the last 24 hours prior to randomisation.	Single-select Required	WARNING + required change: if BL 17 = yes and BL16=no. ”If the patient received <u>acute</u> renal replacement therapy within 24hrs, please also answer ‘yes’ to question

						BL16 'Use of acute renal replacement therapy in the last 3 days prior to randomisation'" WARNING: If BL16=yes and BL17=no: "Are you sure the patient did not receive renal replacement therapy within 24 hrs? You have answered 'yes' in question BL16. - → Accept if correct
BL18	Habitual plasma creatinine value prior to current hospitalisation: estimated or measured.	Select unit: µmol/L ☐ |__|__|__| mg/dL ☐ |__|__|__|__|__| Select: Measured: ☐ Estimated: ☐	µmol/L or mg/dL	Use any sample prior to current hospital admission. If there are no values recorded in the source data, please estimate habitual creatinine and mark as estimated	Required Limits 40-999 No decimals	Can NOT be "unobtainable" Data entry only possible when a unit has been selected (single select only) and only in the field corresponding to selected unit. System will automatically convert

						between units. The value of both units will be visible, but only the selected unit can be corrected. Both values will be transcribed to database. Add warning if BL17 > BL15: "Are you sure the habitual creatinine value is higher than the highest value within the last 24 hours?"
SMS-ICU (Simplified Mortality Score for the Intensive Care Unit) Add randomisation date and time						
BL19	Lowest systolic blood pressure within the last 24 hours prior to randomisation?	|__|__|__|	mmHg	In case of cardiac arrest within the 24 hour period type the value 0	Do not allow decimals Required Limits 30-150mmHg No decimals	
BL20	Did the patient receive respiratory support within the last 24 hours prior to randomisation?	☐ YES ☐ NO		Invasive or non-invasive mechanical ventilation including continuous mask CPAP or CPAP via tracheostomy within the last 24 hours prior to	Single-select Required	

				randomisation. Intermittent CPAP is NOT considered as respiratory support.		
BL21	Did the patient receive acute surgery during current hospital admission?	☐ YES ☐ NO		Surgery during current hospital admission that was added to the operating room schedule	Single-select required	