# Place in Site Master File #2

## Case report form

### Screening form:

| NAME | QUESTION | ANSWER | INFO BOX | Note+limit in eCRF |
|---|---|---|---|---|
| | | **PATIENT IDENTIFICATION** | | |
| S1 | National identification number | I__I__I__I__I__I__I-I__I__I__I__I | **Denmark:**<br>CPR nummer.<br>If the patient has a fictive CPR number please use the letter D as a prefix, e.g D100255-0jh0<br><br>If an unknown patient is identified you have the option to change the fictive CPR number to the correct CPR number.<br><br>**Switzerland:**<br>The national identification number will consist of 0101 + site id + 01<br><br>Site id is system generated<br><br>**Other countries:**<br>The national identification number will consist of date of birth + site id + 01<br><br>Site id is system generated | **Denmark:**<br>RED WARNING<br>A participant with identical CPR number has previously been enrolled in the SUP-ICU trial and cannot be randomised again.<br>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.<br><br>contact@sup-icu.com or +45 3545 7450<br><br>WARNING if CPR is invalid<br>Format of CPR is not correct. It should be 10 digits long.<br>If a fictive CPR is entered, please use the **prefix 'D'** (capital D) followed by 10 characters. See 'info'.<br><br>**Other countries:**<br>RED WARNING:<br>(validating on enrolled patients only)<br><br>The trial participant below with the same national identification number (NIN) has previously been enrolled in the SUP-ICU 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).<br>If the trial participant has been enrolled previously, please readmit the patient in the system.<br><br>For further information please contact contact@sup-icu.com or +45 3545 7450<br><br>YELLOW WARNING:<br>(Validating on enrolled patients in the **same country** with the **same birthday**)<br><br>The trial participants listed below are potentially identical with the one you are trying to screen.<br>Please check the list below.<br>If the trial participant you are trying to screen is NOT identical to any of the participants below, please **press accept** to continue.<br>If the patient has been enrolled previously, please readmit the patient in the system.<br><br>For further information please contact contact@sup-icu.com or +45 3545 7450<br><br>Warning if NIN of an excluded patient is entered again:<br><br>A patient with the same NIN has previously been excluded. If you want to screen the patient again, please press accept.<br><br>For further information please contact contact@sup-icu.com or +45 3545 7450 |

| | | | | |
|---|---|---|---|---|
| | | **INCLUSION CRITERIA** | | |
| S2 | Was the patient acutely admitted to the ICU? | Yes No | Acute admission: a non-planned ICU admission.<br>It does NOT include:<br>1) planned recovery after surgery or similar planned admission<br>2) admission to semi intensive care, intermediate intensive care or similar bed. | |
| S3 | Age ≥ 18 years? | Yes No | | |
| S4 | Systolic blood pressure < 90 mmHg or mean arterial pressure < 70 mmHg? | Yes No | | |
| S5 | Ongoing continuous treatment with vasopressors or inotropes (any of the following: noradrenaline, phenylephrine, vasopressin, terlipressin, dopamine dobutamine, adrenaline, milrinone or levosimendan) | Yes No | | |
| S6 | Lactate > 4 mmol/l | Yes No | | |
| S7 | Renal replacement therapy (acute or chronic intermittent or continuous renal replacement therapy) | Yes No | | |
| S8 | Invasive mechanical ventilation which is expected to last > 24 hours. If in doubt of the forecast answer 'YES'. | Yes No | | |
| S9 | Acute coagulopathy documented within the last 24 hours (definition in INFO) | Yes No | Platelets < 50 x $10^9$/l or INR > 1.5 or PT > 20 seconds | |
| S10 | History of coagulopathy within 6 months prior to | Yes No | Platelets < 50 x $10^9$/l or INR > 1.5 or PT > 20 seconds | |

| | | | | |
|---|---|---|---|---|
| | hospital admission. (definition in INFO) | | | |
| S11 | History of chronic liver disease? | Yes No | Portal hypertension, cirrhosis proven by biopsy, computed tomography (CT) scan or ultrasound, history of variceal bleeding or hepatic encephalopathy in the past medical history | |
| S12 | Ongoing treatment with anti-coagulants (definition in INFO)<br><br>Prophylactic doses of low molecular weight heparin/heparin and acetylsalicylic acid are NOT included | Yes No | Anticoagulant drugs includes:<br>• Dipyridamole<br>• Vitamin K antagonists<br>• ADP-receptor inhibitors<br>• Therapeutic doses of low molecular weight heparin<br>• New oral anticoagulant drugs<br>• Intravenous direct thrombin (II) inhibitors<br>• Similar drugs | |
| **EXCLUSION CRITERIA** | | | | |
| S13 | Contraindications to proton pump inhibitor? | Yes No | Including intolerance of PPI and treatment with atazanavir (HIV medication) | |
| S14 | Ongoing treatment with proton pump inhibitor or histamine-2-receptor antagonist on a daily basis? | Yes No | If PPI/H2RA is discontinued in ICU answer NO.<br><br>If PPI/H2RA is continued in ICU answer YES. | |
| S15 | GI bleeding of any origin during current hospital admission? | Yes No | | |
| S16 | Peptic ulcer confirmed by endoscopy or other method during current hospital admission? | Yes No | | |
| S17 | Withdrawal from active therapy or brain death? | Yes No | | |
| S18 | Organ transplant during current hospital admission? | Yes No | | |
| S19 | Known pregnancy? | Yes No | In fertile women a negative urine-hCG or plasma-hCG is needed | |
| S20 | Consent according to national regulations not obtainable? | Yes No | | |
| **STRATIFICATION VARIABLES** | | | | |

| | | | | |
|---|---|---|---|---|
| S21 | Name of the patient<br><br>**Switzerland**<br>Patient initials | _____ | Will be shown in the medication dispensing system.<br>If the trial participant is unknown, please click the 'unknown at admission' check box. | |
| S22 | Haematological malignancy? | Yes No | Includes any of the following:<br>• leukemia: Acute lymphoblastic leukemia (ALL), acute myelogenous leukemia (AML), chronic myelogenous leukemia (CML), chronic lymphocytic leukemia (CLL)<br>• lymphoma: Hodgkin's disease, Non-Hodgkin lymphoma (e.g. small lymphocytic lymphoma (SLL), diffuse large B-cell lymphoma (DLBCL), follicular lymphoma (FL), mantle cell lymphoma (MCL), hairy cell leukemia (HCL), marginal zone lymphoma (MZL), Burkitt's lymphoma (BL), post-transplant lymphoproliferative disorder (PTLD), T-cell prolymphocytic leukemia (T-PLL), B-cell prolymphocytic leukemia (B-PLL), Waldenström's macroglobulinemia, other NK- or T-cell lymphomas<br>• Multiple myeloma/plasma cell myeloma | |
| s23 | Site | | Automatically generated in the eCRF | |
| s24 | Vial identifier number | | Automatically generated in the eCRF | |
| s25 | Randomisation time stamp | | Automatically generated in the eCRF | |

Date:

Name of person completing the form:

Signature:

## Baseline form

| NAME | QUESTION | ANSWER | INFO | Note+limit in eCRF |
|---|---|---|---|---|
| GENERAL INFORMATION | | | | |
| BL1 | Male sex | Yes No | | |
| BL2 | ICU admission date | I__I__I-I__I__I-I__I__I__I__I<br><br>Format: dd-mm-yyyy | If the patient was transferred directly from another ICU, please write the date of admission to the first ICU | Date and time before randomisation |
| BL3 | ICU admission time | I__I__I:I__I__I<br><br>Format: hh:mm (24 hours format) | If the patient was transferred directly from another ICU, please write the time of admission to the first ICU | Date and time before randomisation |
| BL4 | Hospital admission date | I__I__I-I__I__I-I__I__I__I__I<br><br>Format: dd-mm-yyyy | If the patient was transferred from another hospital, report the date of admission to the first hospital. | Date more than 30 days prior to ICU admission has to be accepted |
| BL5 | Elective surgery within 7 days prior to ICU admission during current hospital admission? | Yes No | Surgery scheduled 24 hours or more in advance. Includes surgery at another hospital. | |
| BL6 | Emergency surgery within the last 24 hours? | Yes No | Surgery added to the operating room plan 24 hours or less prior to surgery. Includes surgery at another hospital. | |
| BL7 | Treatment of *clostridium difficile* during current hospital admission? | Yes No | Treatment includes: Vancomycin (enteral), Metronidazole (enteral or intravenous) or Fidaxomicin (enteral) | |
| BL8 | Treatment with NSAIDs or acetylsalicylic acid in any dose at hospital admission? | Yes No | | |
| BL9 | Treatment with anti-coagulants at hospital admission? | Yes No | **Includes**<br>• Vitamin K antagonists (e.g. Warfarin)<br>• Dipyridamole (e.g. | |

| | | | | |
|---|---|---|---|---|
| | (definition in INFO)<br><br>Prophylactic doses of low molecular weight heparin/heparin and acetylsalicylic acid are NOT included | | Persantine)<br>• ADP-receptor inhibitors (e.g. Clopidogrel, Prasugrel, Ticagrelor)<br>• Therapeutic doses of low molecular weight heparin<br>• New oral anticoagulant (factor IIa and Xa inhibitors, e.g Dabigatran, Apixaban, Xarelto)<br>• Intravenous direct thrombin (II) inhibitors (e.g. Bivalirudin)<br>• Similar drugs | |
| BL10 | Intravenous thrombolysis within the previous 3 days? | Yes No | | |
| **CO-MORBIDITIES**<br>**The registration below is based on information from the patient's files**<br>**PLEASE READ THE INFO BOXES!** | | | | |
| BL11 | Chronic lung disease? | Yes No | Chronic obstructive pulmonary disease (COPD), asthma or other chronic lung disease or treatment with any relevant drug indicating this at admission to hospital | |
| BL12 | Previous myocardial infarction? | Yes No | | |
| BL13 | Chronic heart failure (NYHA III-IV)? | Yes No | New York Heart Association Functional Class (NYHA) III-IV. NYHA III: The patient has marked limitations in physical activity due to symptoms (fatigue, palpitation or dyspnoea) even during less than ordinary activity (walking short distances 20-100 m. or walking up stairs to 1st floor). The patient is only comfortable at rest. NYHA class IV: The patient is not able to carry out any physical activity (without discomfort (fatigue, palpitation or dyspnoea)). Symptoms are present even at rest and the patient is mostly bedbound | |
| BL14 | Chronic renal replacement therapy within the last year prior to hospital admission? | Yes No | | |
| BL15 | Treatment with at | | For a 70 kg person this equals 21 mg | |

| | | | | |
|---|---|---|---|---|
| | least 0.3 mg/kg/dayof prednisolone equivalent for at least 1 month in the 6 months prior to ICU admission? | Yes No | per day for at least one month in the 6 months prior to ICU admission | |
| BL16 | Metastatic cancer? | Yes No | Proven metastasis by surgery, CT scan or any other method | |
| BL17 | AIDS? | Yes No | HIV positive patients with one or more HIV defining diseases such as pneumocystis jerovechii pneumonia, Kaposi's sarcoma, Lymphoma, tuberculosis or toxoplasma infection | |
| SAPS 2 (Simplified Acute Physiology 2) Score and SOFA (Sequential Organ Failure Assessment) Score<br>The registration below is based on values obtained in the 24 hours prior to randomisation.<br>Please select the most deranged values (from general ward, ICU or other) | | | | |
| BL18 | Lowest Glasgow coma score in the 24 hours prior to randomisation. (If sedated, use last score before sedation? If unknown write 15) (Info for instruction) | I__I__I | If not scored in the last 24 hours, use the last available GCS-score. Glasgow Coma Score is the sum of points (range 3-15) given for the following categories: eyes, verbal response, and motor response.<br>**EYE**S: 1 point: Does not open eyes. 2 points: Opens eyes in response to painful stimuli. 3 points: Opens eyes in response to voice. 4 points: Opens eyes spontaneously<br>**VERBAL:** 1 point: Makes no sounds. 2 points: Incomprehensible sounds. 3 points: Utters inappropriate words. 4 points: Confused, disorientated. 5 points: Oriented, converses normally.<br>**MOTOR:** 1 point: Makes no movements. 2 points: Extension to painful stimuli. 3 points: Abnormal flexion to painful stimuli 4 points: Flexion / withdrawal to painful stimuli. 5 points: Localizes painful stimuli. 6 points: Obeys commands. | Limit: 3-15<br>Values outside range cannot be accepted |
| BL19 | Was the core temperature ≥ 39°C (102.2 Fahrenheit) in the 24 hours prior to randomisation? | Yes No | Core temperature: rectal, urinary bladder, central line, or tympanic. If oral, inguinal or axillary temperatures are used, add 0.5°C to measured value | |
| BL20 | Urinary output in the 24 hours prior to randomisation? If urine volume is measured for a short period MULTIPLY TO GET TOTAL OUTPUT IN 24 HOURS! (ml) | I__I__I__I__I | | Limit: 0-8000<br>No decimals |
| BL21 | Lowest systolic | | | Limit: 70-150 |

| | | | | |
|---|---|---|---|---|
| | arterial pressure in the 24 hours prior to randomisation? (mmHg) | I__I__I__I | | No decimals |
| BL22 | Highest systolic arterial pressure in the 24 hours prior to randomisation? (mmHg) | I__I__I__I | | Limit: 70-150<br>No decimals |
| BL23 | Lowest mean arterial pressure (MAP) in the 24 hours prior to randomisation? (mmHg) | I__I__I__I | If mean arterial pressure (MAP) is not calculated by monitoring equipment, use the manual sphygmomanometer recording of systolic (SBP) and diastolic blood pressure (DBP) to obtain MAP using this equation MAP = (DBP x 2 + SBP) /3 | Limit 45-150<br>No decimals |
| BL24 | Lowest heart rate in the 24 hours prior to randomisation? | I__I__I__I | If the patient has an atrial arrhythmia, measure the ventricular response rate (R waves) only to record the heart rate. | Limit 40-200<br>No decimals |
| BL25 | Highest heart rate in the 24 hours prior to randomisation? (beats/min) | I__I__I__I | If the patient has an atrial arrhythmia, measure the ventricular response rate (R waves) only to record the heart rate. | Limit 40-200<br>No decimals |
| BL26 | Highest dose of noradrenaline (norepinephrine) in the 24 hours prior to randomisation? (µg/kg/min) | I__I__I__I__I | Administration of the drug for at least 1 hour. Otherwise write 0.<br><br>Does not include boli. | Limit: 0-2.00<br>0,1 or 2 decimals |
| BL27 | Highest dose of adrenaline in the 24 hours prior to randomisation? (µg/kg/min) | I__I__I__I | Administration of the drug for at least 1 hour. Otherwise write 0.<br><br>Does not include boli. | Limit: 0-0.50<br>0,1 or 2 decimals. |
| BL28 | Highest dose of dopamine in the 24 hours prior to randomisation? (µg/kg/min) | I__I__I__I | Administration of the drug for at least 1 hour. Otherwise write 0.<br><br>Does not include boli. | Limit: 0-10.0<br>0,1 or 2 decimals |
| BL29 | Did the patient receive dobutamine, vasopressin, phenylephrine, milrinone or levosimendan in the 24 hours prior to randomisation? | Yes No | | |

| | | | | |
|---|---|---|---|---|
| BL30 | Lowest p-sodium (p-natrium) in the 24 hours prior to randomisation? (mmol/l) | I__I__I__I | | Limit: 100-160<br>No decimals<br>cannot be higher than B31 |
| BL31 | Highest p-sodium (p-natrium) in the 24 hours prior to randomisation? (mmol/l) | I__I__I__I | | Limit: 100-160<br>No decimals<br>cannot be lower than B30 |
| BL32 | Lowest p-potassium (p-kalium) in the 24 hours prior to randomisation? (mmol/l) | I__I__I | | Limit: 2.0-6.0<br>0 or 1 decimal.<br>Cannot be higher than B33 |
| BL33 | Highest p-potassium (p-kalium) in the 24 hours prior to randomisation? (mmol/l) | I__I__I | | Limit: 2.0-6.0<br>0 or 1 decimal.<br>Cannot be lower than B32 |
| BL34 | Lowest white blood cell count in the 24 hours prior to randomisation? ($10^9$ /l) | I__I__I__I | To convert from $mm^3$ divide with 1000<br><br>If the lab returns a value of e.g. "<0.1", please report "0.1". | Limit: 0.1-400<br>0 or 1 decimal.<br>Cannot be higher than B35 |
| BL35 | Highest white blood cell count in the 24 hours prior to randomisation? ($10^9$ /l) | I__I__I__I | To convert from $mm^3$ divide with 1000<br><br>If the lab returns a value of e.g. "<0.1", please report "0.1". | Limit: 0.1-400<br>0 or 1 decimal.<br>Cannot be higher than B34 |
| BL36 | Lowest platelet count? ($10^9$/l) | I__I__I__I | To convert from $mm^3$ divide with 1000<br><br>If the lab returns a value of e.g. < 3, please report 3 | Limit: 3-800<br>No decimals |
| BL37 | Highest bilirubin in the 24 hours prior to randomisation? (µmol/l)<br>If no value is obtained, write the first value from the first 24 hours in ICU. | I__I__I__I | To convert from mg/dl multiply with 17.1 | Limit: 5-300<br>No decimals |
| BL38 | Highest creatinine in the 24 hours prior to | I__I__I__I__I | To convert from mg/dl multiply with 88.4 | Limit: 40-1000<br>No decimals |

| | | | | |
|---|---|---|---|---|
| | randomisation ? (µmol/l)<br>If no value is obtained, write the first value from the first 24 hours in ICU. | | | |
| BL39 | Highest carbamid (urea) in the 24 hours prior to randomisation? (mmol/l).<br>If no value is obtained, write the first value from the first 24 hours in ICU. | I__I__I__I | To convert from mg/dl multiply with 0.05 | Limit: 2-40<br>0 or 1 decimal |
| BL40 | Lowest s-bicarbonate ($HCO3^-$) in the 24 hours prior to randomisation? (mmol/l) | I__I__I__I | mmol/l = mEq/l | Limit: 5-40<br>0 or 1 decimal |
| Enter values for **the lowest PaO2/FiO2-ratio** in the 24 hours prior to randomisation.<br>**Do not enter the ratio itself!**<br>**Please report the corresponding PaO2 and FiO2** | | | | |
| BL41 | PaO2 (kPa) | I__I__I__I | To convert from mmHg: multiply by 0.133<br><br>For calculation of FiO2 use the list below:<br><br>Nasal catheter: flow of oxygen and corresponding FiO2<br>0 L: 21 %<br>1 L: 27 %<br>2 L: 33 %<br>3 L: 37 %<br>4 L: 40 %<br>5 L: 44 %<br>6 L: 48 %<br><br>Hudson mask: flow of oxygen / air flow and corresponding FiO2<br>0 L: 21 %<br>3 / 12 L: 29 %<br>7,5 / 7,5 L: 41 %<br>10 / 5 L: 48 %<br>15 / 0 L: 59 %<br><br>High flow oxygen via nasal cannula: flow of oxygen and corresponding FiO2<br>10 L: 62 %<br>15 L: 82 %<br>20 L: 90 %<br>30 L: 95 %<br><br>Please report the corresponding PaO2 and FiO2 that give the lowest ratio. | Limit: 5-40<br>0 or 1 decimal |
| BL42 | FiO2 (%) | I__I__I__I | | Limit 21-100<br>Values outside range cannot be accepted.<br>0 or 1 decimal |

| | | | | |
|---|---|---|---|---|
| | | | For calculation of FiO2 use the list below:<br><br>No oxygen treatment: 21 %<br><br>Nasal catheter: flow of oxygen and corresponding FiO2<br>0 L: 21 %<br>2 L: 33 %<br>4 L: 40 %<br>6 L: 48 %<br><br>Hudson mask: flow of oxygen / air flow and corresponding FiO2<br>0 / 15 L: 21 %<br>3 / 12 L: 29 %<br>7,5 / 7,5 L: 41 %<br>10 / 5 L: 48 %<br>15 / 0 L: 59 %<br><br>Example 1:<br>1 patient has 2 corresponding measurements of FiO2 and PaO2.<br><br>#1: PaO2 in the arterial blood gas was 8 kPa. The patient had a Hudson mask with 15 L oxygen flow. The corresponding FiO2 was 59% (see above). Thus, the PaO2/FiO2 was 8/0,59 = 13,6 kPa.<br><br>#2: PaO2 in the arterial blood gas was 9 kPa. The patient had a nasal catheter with 6 l oxygen flow. The corresponding FiO2 was 48% (see above). Thus, the PaO2/FiO2 was 9/0,36 = 18,8 kPa.<br><br>Measurement number 1 gives the lowest ratio and must be reported. | |
| BL43 | Respiratory support (invasive or non-invasive ventilation including continuous mask CPAP or CPAP via a tracheotomy) in the 24 hours prior to randomisation? | Yes No | Intermittent CPAP is NOT considered mechanical ventilation | |

Date:

Name of person completing the form:

Signature:

## Day form

| NAME | QUESTION | ANSWER | INFO | NOTE+LIMIT |
|---|---|---|---|---|
| GENERAL INFORMATION | | | | |
| D1 | Was the trial medication delivered to the patient on this day? | Yes No | | |
| D2 | Treatment with open-label proton pump inhibitor or histamine-2-receptor antagonist on this day?<br><br>**IF YES:**<br>Reason for treatment with PPI/H2RA (choose one only):<br><br>a) Clinical indication for treatment with PPI/H2RA because of GI bleeding, verified ulcer/varices/gastritis or as part of a bowel rest regimen?<br><br>b) Prophylaxis/treatment for other reasons than described above? (is considered a protocol violation) | Yes No<br><br>Yes No<br><br>Yes No | Use of PPI/H2RA as stress ulcer prophylaxis and treatment without an obvious indication is considered a protocol violation | If 'YES' answer a and b<br><br>Either a OR b has to be answered 'YES'.<br><br>Only 'YES' in either a or b.<br><br>If 'YES' in a:<br>Warning!<br>PLEASE **DISCONTINUE** TRIAL INTERVENTION AND COMPLETE WITHDRAWAL FORM<br><br>If 'YES' in b:<br>Warning!<br>PLEASE **CONTINUE** TRIAL INTERVENTION AND DISCONTINUE OPEN-LABEL THERAPY |
| D3 | Respiratory support (invasive or non-invasive ventilation including continuous mask CPAP or CPAP via a tracheotomy) on this day? | Yes No | Intermittent CPAP is NOT considered mechanical ventilation | |
| D4 | Continuous treatment with vasopressor and/or inotrope | Yes No | Continuous treatment with norepinephrine, epinephrine, dobutamine, dopamine, vasopressin, levosimendan, phenylephrine or milrinone at any time during the day | |
| D5 | Renal replacement therapy on this day? (including days between intermittent renal replacement therapy) | Yes No | Any type of acute and chronic renal replacement therapy is included (e.g. dialysis) | |
| D6 | Onset of pneumonia on this day? PLEASE READ criteria for pneumonia in INFO! | Yes No | Two or more serial chest radiographs with at least one of the following (one radiograph is sufficient for patients with no underlying pulmonary or cardiac | |

| | | | | |
|---|---|---|---|---|
| | | | disease):<br><br>1. new or progressive *and* persistent infiltrate<br>2. consolidation<br>3. cavitation<br><br>AND at least one of the following:<br><br>1. fever (>38°C) with no other recognised cause<br>2. leucopaenia (white cell count < 4 x 109/l) or leucocytosis (white cell count >12 x 109/l)<br><br>AND at least two of the following<br><br>1. new onset of purulent sputum or change in character of sputum, or increased respiratory secretions or increased suctioning requirements<br>2. new onset or worsening cough, or dyspnoea, or tachypnoea<br>3. rales or bronchial breath sounds<br>4. worsening gas exchange (hypoxaemia, increased oxygen requirement, increased ventilator demand) | |
| D7 | Treatment for suspected or documented clostridium difficile enteritis on this day? Definition of treatment in info. | Yes No | Treatment includes Vancomycin (enteral), Metronidazole (enteral or intravenous) and Fidaxomicin (enteral) | |
| D8 | Acute myocardial ischemia on this day?<br>PLEASE READ criteria for acute myocardial ischemia in INFO! | Yes No | **- ST-elevation myocardial infarction**<br>**OR**<br>**- Non-ST elevation myocardial infarction**<br>**OR**<br>**- Unstable angina pectoris**<br><br>according to the criteria in the clinical setting in question (e.g. elevated biomarkers, ischemic signs on ECG and clinical presentation) | |

| | | | | |
|---|---|---|---|---|
| | | | **AND**<br><br>the patient receiving treatment as a consequence of this (reperfusion strategies (PCI/thrombolysis) or initiation/increased antithrombotic treatment) | |
| D9 | Enteral feeding and/or oral nutritional intake on this day? | Yes No | | |
| D10 | Number of units of red blood cells transfused during this day? | I__I__I | | Limit: 0-15<br>No decimals |
| BLEEDING FORM | | | | |
| B1 | Did the patient have hematemesis, coffee ground emesis, melena, haematochezia or bloody nasogastric aspirate on this day? | Yes No | | If 'YES' in B1 B2-B7 have to be answered.<br>Otherwise proceed to SAR1-SAR7 |
| B2 | Did the patient have spontaneous drop of systolic, diastolic or, mean arterial pressure of **20 mmHg** or more within 24 hours after the bleeding episode and in absence of other causes? | Yes No | | |
| B3 | Was vasopressor initiated or increased by 20% or more within 24 hours after the bleeding episode and in absence of other causes? | Yes No | Vasopressors include: noradrenaline, adrenaline, dopamine, vasopressin or terlipressin | |
| B4 | Did the haemoglobin decrease by at least 2 g/dl (1.24 mmol/l) within 24 hours after the bleeding episode and in absence of other causes? | Yes No | | |
| B5 | Did the patient receive 2 units of packed red blood cells or more within 24 hours after the bleeding episode and in absence of other causes? | Yes No | | |
| B6 | Was the origin of the bleeding confirmed? | Yes No | | If 'YES' mark <u>at least one</u> option below |

| | | | | |
|---|---|---|---|---|
| | IF YES:<br>Gastric or duodenal ulcer?<br>Gastritis?<br>Bleeding oesophageal Varices?<br>Other? | Yes No<br>Yes No<br>Yes No<br>Yes No<br>Yes No | | |
| B7 | Was endoscopy, open/laparoscopic surgery or coiling performed?<br><br>**IF YES:** | Yes No | | If 'YES' mark <u>at least one</u> option below |
| | Endoscopy?<br>Open/laparoscopic surgery?<br>Coiling? | Yes No<br>Yes No<br>Yes No | | |
| | SERIOUS ADVERSE REACTIONS<br>PLEASE READ THE INFO.<br>If the patient experiences a SAR the trial intervention has to be stopped and the coordinating centre has to be contacted at contact@sup-icu.com or +45 3545 7450 within 24 hours. .<br>Please complete withdrawal form, continue daily registration and complete follow-up. | | | |
| SAR1 | Anaphylactic reaction related to the intervention on this day? | Yes No | Urticaria **<u>and</u>** at least one of the following<br>• Worsened circulation (>20% decrease in blood pressure or >20% increase in vasopressor dose)<br>• Increased airway resistance (>20% increase in the peak pressure on the ventilation)<br>• Clinical stridor or bronchospasm<br>• Subsequent treatment with bronchodilators | WARNING if YES<br>Remember to discontinue the trial medication, complete the withdrawal form contact the coordinating centre within 24 hours at contact@sup-icu.com or +45 3545 7450 |
| SAR2 | Agranulocytosis related to the intervention on this day? | Yes No | Any new, acute and severe drop in granulocytes to < 0.5 x $10^9$/l requiring active monitoring or treatment | WARNING if YES<br>Remember to discontinue the trial medication, complete the withdrawal form contact the coordinating centre within 24 hours at contact@sup-icu.com or +45 3545 7450 |
| SAR3 | Pancytopenia related to the intervention on this day? | Yes No | Any new, severe drop in red blood cells, white blood cells <u>and</u> platelets requiring active | WARNING if YES<br>Remember to discontinue the trial medication, |

| | | | | |
|---|---|---|---|---|
| | | | monitoring or treatment | complete the withdrawal form contact the coordinating centre within 24 hours at contact@sup-icu.com or +45 3545 7450 |
| SAR4 | Acute hepatic failure related to the intervention on this day? | Yes No | Severe and progressing hepatic failure as judged by the treating doctor or the investigator | WARNING if YES Remember to discontinue the trial medication, complete the withdrawal form contact the coordinating centre within 24 hours at contact@sup-icu.com or +45 3545 7450 |
| SAR5 | Steven-Johnson syndrome or toxic epidermal necrolysis related to the intervention on this day? | Yes No | Severe dermatological reactions with a skin biopsy confirming the diagnosis | WARNING if YES Remember to discontinue the trial medication, complete the withdrawal form contact the coordinating centre within 24 hours at contact@sup-icu.com or +45 3545 7450 |
| SAR6 | Interstitial nephritis related to the intervention on this day? | Yes No | Nephritis affecting the interstitium of the kidneys surrounding the tubules with a kidney biopsy confirming the diagnosis | WARNING if YES Remember to discontinue the trial medication, complete the withdrawal form contact the coordinating centre within 24 hours at contact@sup-icu.com or +45 3545 7450 |
| SAR7 | Angioedema (Quincke's oedema) related to the intervention on this day? | Yes No | A vascular reaction involving the deep dermis, subcutaneous or submucosal tissues, resulting in a characteristic localized oedema. | WARNING if YES Remember to discontinue the trial medication, complete the withdrawal form contact the coordinating centre within 24 hours at contact@sup-icu.com or +45 3545 7450 |

Date:
Name of person completing the form:
Signature:

## Discharge and readmission form

| NAME | QUESTION | ANSWER |
|---|---|---|
| | **DISCHARGE** | |
| DI1 | Date of ICU discharge (dd-mm-yyyy) | I__I__I-I__I__I-<br>I__I__I__I__I |
| DI2 | Time of ICU discharge (24 hours (hh:mm)) | I__I__I:I__I__I |
| DI3 | Patient discharge to (**choose one only)**<br>General ward<br>ICU participating in the SUP-ICU trial<br>ICU not participating in the SUP-ICU trial<br>Dead | <br>Yes No<br>Yes No<br>Yes No<br>Yes No |
| DI4 | Has the patient been enrolled in other interventional trials during this ICU admission? | Yes No |
| | READMISSION | |
| DI5 | Date of ICU readmission (dd-mm-yyyy) | I__I__I-I__I__I-<br>I__I__I__I__I |
| DI6 | Time of ICU readmission (24 hours (hh:mm)) | I__I__I:I__I__I |

Date:

Name of person completing the form:

Signature:

## Withdrawal form

**PLEASE ANSWER ALL QUESTIONS AND CONTINUE DAILY REGISTRATION IF CONSENT HAS NOT BEEN WITHDRAWN**

| NAME | QUESTION | ANSWER | INFO | NOTE+LIMIT |
|---|---|---|---|---|
| | **WITHDRAWAL FROM INTERVENTION AND/OR DATA REGISTRATION** | | | |
| W1 | Date of withdrawal (dd-mm-yyyy) | I__I__I-I__I__I-I__I__I__I__I | | |
| W2 | Time of withdrawal (24 hours (hh:mm)) | I__I__I:I__I__I | | |
| W3 | Reason for withdrawal (mark <u>one</u> answer):<br><br>a) Indication for treatment with open label PPI/H2RA<br>b) Clinical decision other than the above<br>c) SAR/SUSAR<br>d)Consent not given or withdrawn | <br><br>Yes No<br>Yes No<br>Yes No<br>Yes No<br>Yes No | | |
| W4a | Who is not giving or withdrawing consent?<br><br>Relative/next of kin/guardian not giving or withdrawing consent<br><br>Patient not giving or withdrawing consent | <br><br>Yes No<br><br>Yes No | | Only to be answered if YES in W3 |
| W4b | Will further daily data be registered? | Yes No | 'NO' is only an option if consent has been withdrawn | Only to be answered if YES in W3 |

Date:

Name of person completing the form:

Signature:

## Follow-up form

| NAME | QUESTION | ANSWER |
|---|---|---|
| F1 | Was the patient dead at date for follow-up? | Yes No |
| F2 | If 'YES': Date of death (dd-mm-yyyy) | I__I__I-I__I__I-I__I__I__I__I |

Date:

Name of person completing the form:

Signature: