

CLIF Consortium

Protocol of the CLIF Acute-oN-ChrONic LIver Failure in Cirrhosis (CANONIC) Core Study

Case Report Form (Final)

Center: _____

Investigator: _____

Investigator's Signature:

The highlighted information is essential for data analyses and it should be available. Please, make sure it is collected.

Study Calendar and Data Collection Schedule

Study Calendar and Data Collection Schedule

Study Parameters	Hospital Admission	Liver Unit Admission	Inclusion Data (@)	Screening data	Onset of e.h. organ failure(*)	Day 1 (**)	Day 2 (**)	Day 3-7 (**)	Day 8-14 (**)	Day 15-21 (**)	Day 22-28 (**)	28-day Follow-up	3-month Follow-up	6-month Follow-up	1-year Follow-up
Visit date	XXX	XXX	XXX	XXX	XXX	XXX	XXX	XXX	XXX	XXX	XXX	XXX	XXX	XXX	XXX
Inclusion/Exclusion Criteria				XXX											
Informed consents				XXX											
Background Assessment	XXX														
Prior Course of Disease	XXX														
First Extra-Hepatic Organ Failure					XXX										
Enrollment in Other Studies		XXX	XXX		XXX	XXX	XXX	XXX	XXX	XXX	XXX				
Precipitating Events Prior to Hospital Admission	XXX														
Precipitating Events		XXX	XXX		XXX										
Previous Treatments	XXX														
Treatments Administered		XXX	XXX		XXX	XXX	XXX	XXX	XXX	XXX	XXX				
Clinical Data at Hospital Adm.	XXX														
Admission data		XXX													
Clinical Features		XXX	XXX		XXX	XXX	XXX	XXX	XXX	XXX	XXX				
Exploratory data	XXX	XXX	XXX		XXX	XXX	XXX	XXX	XXX	XXX	XXX				
Laboratory data	XXX	XXX	XXX		XXX	XXX	XXX	XXX	XXX	XXX	XXX				
Microbiological data	XXX	XXX	XXX		XXX	XXX	XXX	XXX	XXX	XXX	XXX				
Scores		XXX	XXX		XXX	XXX	XXX	XXX	XXX	XXX	XXX				
Place and Clinical Course of Patient at the End of the Visit			XXX			XXX	XXX	XXX	XXX	XXX	XXX				
Sample collection (**)							XXX (#)	XXX	XXX		XXX				
Vital status during the follow-up												XXX	XXX	XXX	XXX

(*) Group #3 patients only.

(**) Groups #1, #2 and #4 patients, only.

(@) To be filled in only when the patient has been admitted to the Liver Unit and some relevant event has occurred before study inclusion or when the patient has been enrolled in the study without being admitted to the Liver Unit.

(#) SampleS to be taken on Day 1 or Day 2 after patient’s inclusion. These will be the only samples collected for patients in Group #3.

SUMMARY OF PATIENT'S INFORMATION.

Patient's Identification Number*: _____

* Patient's Identification Number = Center Code (2 digits) + Patient Id (3 digits).
The Patient's Id number is automatically assigned by the data entry application.

Screening:

Date: ____ / ____ / ____

Hospital Admission:

Date: ____ / ____ / ____

Time (24h): ____:____

Admission to the Liver Unit:

Date: ____ / ____ / ____

Time (24h): ____:____

Study Inclusion:

Date: ____ / ____ / ____

Time (24h): ____:____

Onset of first extra-hepatic organ failure (Group #3 patients):

Date: ____ / ____ / ____

Time (24h): ____:____

PATIENT'S SCREENING DATA**Inclusion Criteria**

- CIRRHOTIC PATIENT ADMITTED TO THE HOSPITAL FOR MORE THAN ONE DAY TO TREAT A COMPLICATION OF LIVER DISEASE? YES / NO

Exclusion Criteria

- Is the patient pregnant ? YES / NO
- Is the patient younger than 18 year-old ? YES / NO
- Has the patient an acute or subacute liver failure without underlying cirrhosis ? YES / NO
- Is the patient admitted for more than one day for scheduled procedures (e.g., band ligation, transjugular intrahepatic porto-systemic shunting) ? YES / NO
- Is she/he an outpatient with cirrhosis and refractory ascites, hospitalized for more than 1 day for a scheduled large-volume paracentesis ? YES / NO
- Is she/he a patient with cirrhosis who developed decompensation following partial hepatectomy ? YES / NO
- Has the patient a hepatocellular carcinoma outside Milan criteria ? YES / NO
- Has the patient any previously known severe extra-hepatic diseases (e.g., chronic renal failure requiring hemodialysis, severe heart disease; severe chronic pulmonary disease, psychiatric disorders) ? YES / NO
- Is the patient taking immunosuppressive drugs other than corticosteroids at dose for severe alcoholic hepatitis ? YES / NO
- Is she/he a HIV patient ? YES / NO
- Is she/he a patient who cannot provide prior informed consent and is there any documented evidence that the patient has no legal surrogate decision maker and it appears unlikely that the patient will regain consciousness or sufficient ability to provide delayed informed consent ? YES / NO
- Are physician and team not committed to intensive care if needed ? YES / NO

Informed Consents**F1. CONSENT FORM FOR PROSPECTIVE COLLECTION OF MEDICAL INFORMATION/DATA:**

- Informed Consent: SIGNED / NOT SIGNED
- If signed: Date of signature __ / __ / __

F2. SAMPLE CONSENT FOR RESEARCH INVOLVING BLOOD DRAW:

- Informed Consent: SIGNED / NOT SIGNED
- If signed: Date of signature __ / __ / __

F3. SAMPLE CONSENT FOR RESEARCH ON LEFTOVER LIVER-BIOPSY SPECIMENS:

- Informed Consent: SIGNED / NOT SIGNED
- If signed: Date of signature __ / __ / __

F.4. SURROGATE CONSENT TO TAKE PART IN A RESEARCH STUDY:

- Informed Consent: SIGNED / NOT SIGNED
- If signed: Date of signature __ / __ / __

F.5. CONSENT TO TAKE PART IN A RESEARCH STUDY FOR INDIVIDUALS ENROLLED UNDER PRIOR SURROGATE CONSENT:

- Informed Consent: SIGNED / NOT SIGNED
- If signed: Date of signature __ / __ / __

F.6. GENETIC TESTING:

- Informed Consent: SIGNED / NOT SIGNED
- If signed: Date of signature __ / __ / __

- IS PATIENT INCLUDED IN THE STUDY? (Yes / No / No data)**• If patient is NOT INCLUDED: Reason for patient's exclusion:**

- No data /**
- Inclusion/Exclusion criteria NOT fulfilled /**
- Physician's denial /**
- Patient's refusal /**
- Other (specify _____)**

• If patient is INCLUDED: Patient's allocation group at inclusion:

- Group 1: Patient with an extra-hepatic organ failure at the moment of inclusion /**
- Group 2: "Control" patient with no extra-hepatic organ failure at the moment of study inclusion and included immediately after a "Group 1" patient /**
- Group 3: Patient with no extra-hepatic organ failure at the moment of study inclusion and not allocated to Group 2.**

Patients in Group #3 will switch to Group #4 if an extra-hepatic organ failure occurs during hospital follow-up.

• For patients assigned to Group 1:

- Type of extra-hepatic organ failure detected:**
 - **Renal failure (Yes / No / No data). If yes:**
 - **Moment of Onset:**
 - **No data /**
 - **Prior to hospitalization /**
 - **At hospital admission /**
 - **Between hospital admission and study inclusion**
 - **Date of extra-hepatic organ failure: ___ / ___ / _____**
 - **Cerebral failure (Yes / No / No data). If yes:**
 - **Moment of Onset:**
 - **No data /**
 - **Prior to hospitalization /**
 - **At hospital admission /**
 - **Between hospital admission and study inclusion**
 - **Date of extra-hepatic organ failure: ___ / ___ / _____**

- **Respiratory failure (Yes / No / No data). If yes:**
 - **Moment of Onset:**
 - **No data /**
 - **Prior to hospitalization /**
 - **At hospital admission /**
 - **Between hospital admission and study inclusion**
 - **Date extra-hepatic organ failure: __ / __ / ____**

- **Cardiac failure (Yes / No / No data). If yes:**
 - **Moment of Onset:**
 - **No data /**
 - **Prior to hospitalization /**
 - **At hospital admission /**
 - **Between hospital admission and study inclusion**
 - **Date of extra-hepatic organ failure: __ / __ / ____**

- **Coagulation (Yes / No / No data). If yes:**
 - **Moment of Onset:**
 - **No data /**
 - **Prior to hospitalization /**
 - **At hospital admission /**
 - **Between hospital admission and study inclusion**
 - **Date of extra-hepatic organ failure: __ / __ / ____**

PATIENT'S DATA AT HOSPITAL ADMISSION**Background Assessment**

- Age (years) _____
- Sex (male / female)
- Ethnic group (No data / Caucasian / Black / Asian / Other [specify _____])
- Patient on the waiting list of liver transplantation (Yes / No / No data)
If yes, date of inclusion ___ / ___ / _____
- Cause of cirrhosis:
 - Alcohol (Yes / No / No data)
 - NAFLD (Yes / No / No data)
 - HCV (Yes / No / No data)
 - HBV (Yes / No / No data)
 - PBC (Yes / No / No data)
 - Cryptogenic (Yes / No / No data)
 - Other (Yes / No / No data); If yes, specify _____
- Other previous disease (Yes / No / No data). If yes:
 - Arterial hypertension (Yes / No / No data)
 - Coronary artery disease (Yes / No / No data)
 - Congestive heart failure (Yes / No / No data)
 - Neurologic disease (Yes / No / No data); If yes,
Specify _____
 - Chronic obstructive pulmonary disease (Yes / No / No data)
 - Diabetes requiring treatment (Yes / No / No data). If yes:
 - Hypoglycemiants drugs (Yes / No / No data)
 - Insulin (Yes / No / No data)
 - Chronic renal failure (Yes / No / No data). If yes:
 - Patient on renal replacement therapy? (Yes / No / No data)
 - Other (Yes / No / No data); If yes:
Specify _____

Prior Course of Disease

- Any previous decompensation (Yes / No / No data)? If yes:

- Time since 1st decompensation:

- No data
- ≤ 1 week
- > 1 week - 1 month
- > 1-3 months
- > 3 months -1 year
- > 1-2 years
- > 2 years

- Type of decompensation(s) (All decompensations presented):

- Ascites (Yes / No / No data). If yes: Number: No data / 0 / 1 / 2 / 3 / >3
- Encephalopathy (Yes / No / No data). If yes: Number: No data / 0 / 1 / 2 / 3 / >3
- GI-bleeding (Yes / No / No data). If yes: Number: No data / 0 / 1 / 2 / 3 / >3
- Spontaneous bacterial peritonitis (SBP) (Yes / No / No data).
If yes: Number: No data / 0 / 1 / 2 / 3 / >3
- Others (Yes / No / No data).
If yes: Specify _____

- Hospitalization within the previous three months (Yes / No / No data)

If yes:

- Number of hospital admissions (No data / 1 / 2 / 3 / >3)

- Cause(s) of admission:

In case of repeated causes for different hospitalizations, enter details of the worst cause.

- Ascites (Yes / No / No data); If yes,

Type: No data / Mild to Moderate / Large - Tense.

- Encephalopathy (Yes / No / No data); If yes:

Stage: West Haven Score (No data / 1 / 2 / 3 / 4)

- Bacterial infection (Yes / No / No data). If yes:
 - Type of infection:
 - SBP (Yes / No / No data)
 - Pneumonia (Yes / No / No data)
 - Urinary tract infection (UTI) (Yes / No / No data)
 - Skin infection (Yes / No / No data)
 - Unproved suspected infection (Yes / No / No data)
 - Other (Yes / No / No data); If yes, specify _____
 - Sepsis (Yes / No / No data). If yes:
Sepsis category: No data / Sepsis Only / Severe sepsis / Septic shock
- Gastrointestinal bleeding (Yes / No / No data). If yes:
 - Etiology:
 - Variceal bleeding (Yes / No / No data)
 - Peptic ulcer lesion (Yes / No / No data)
 - Portal hypertension non-variceal bleeding (Yes / No / No data)
 - Other causes (Yes / No / No data); If yes, specify _____
 - Unknown (Yes / No / No data)
- HRS (Yes / No / No data). If yes: Type: No data / I / II.
- Surgery (Yes / No / No data). If yes: Specify _____.
- Other (Yes / No / No data). If yes: Specify _____.
- Any ICU Admission? (Yes / No / No data)

Precipitating Event(s) Prior to Hospital Admission
(within the previous 3 months prior to hospitalization)

• Any precipitating event within the previous 3 months? Yes / No / No data. If yes:

• Type of events:

○ Bacterial infection (Yes / No / No data). If yes:

▪ Type of infection:

- SBP (Yes / No / No data)
- Pneumonia (Yes / No / No data)
- Urinary tract infection (UTI) (Yes / No / No data)
- Skin infection (Yes / No / No data)
- Unproved suspected infection (Yes / No / No data)
- Other (Yes / No / No data); If yes, specify _____

▪ Sepsis (Yes / No / No data). If yes:

- Sepsis category: No data / Sepsis Only / Severe sepsis / Septic shock

▪ Time from onset of the last infection (days) _____

▪ Site of acquisition: No data / Community / Hospital

▪ Resolution of the last infection (Yes / No / No data)

○ Gastrointestinal bleeding (Yes / No / No data). If yes:

▪ Etiology:

- Variceal bleeding (Yes / No / No data)
- Peptic ulcer lesion (Yes / No / No data)
- Portal hypertension non-variceal bleeding (Yes / No / No data)
- Other causes (Yes / No / No data) If yes, specify _____
- Unknown (Yes / No / No data)

▪ GI-bleeding complicated by hypovolemic shock? (Yes / No / No data)

▪ Time from onset of the last hemorrhage (days, if days < 1, enter 1) _____

▪ Resolution (Yes / No / No data)

- Significant alcohol consumption (≥ 40 g per day for a minimum of 6 months and within the 3 months prior to study enrollment).
(Yes / No / No data)
- Acute alcoholic hepatitis (based on liver biopsy) (Yes / No / No data); If yes:
 - Time from onset to present hospitalization (days) _____
- TIPS (Yes / No / No data). If yes:
 - Time from insertion to present hospitalization (days) _____
- Surgery (Yes / No / No data). If yes:
 - Time to present hospital admission (days) _____
 - Type of surgery, specify _____
- Therapeutic paracentesis (Yes / No / No data). If yes:
 - Number of therapeutic paracentesis _____
 - Time from last therapeutic paracentesis to present hospitalization (days) ____
 - Volume of last therapeutic paracentesis (L) _____
 - Use of albumin (Yes / No / No data) If yes:
Dose for last therapeutic paracentesis (g) _____
- Acute hepatitis (Yes / No / No data). If yes:
 - Etiology:
 - No data /
 - Viral (specify _____) /
 - Toxic (specify _____) /
 - Other (specify _____) /
 - Unknown
 - Time from onset to present hospitalization (days) _____
- Other precipitating events (Yes / No / No data); If yes:
 - Specify _____
 - Time from onset to present hospitalization (days) _____

Previous treatments administered (within the last 3 months)

- β -blockers (Yes / No / No data); If yes:
 - Type: No data / Propranolol / Nadolol / Carvedilol
(Aproximate Average Dose Received, mg/day _____
Number of days on treatment _____)
- Corticoids (Yes / No / No data); If yes:
 - Type: No data / Prednisone / Prednisolone / Methylprednisolone / Hydrocortisone
(Aproximate Average Dose Received, mg/day _____
Number of days on treatment _____)
- Diuretics (Yes / No / No data). If yes:
 - Spironolactone (Yes / No / No data); If yes:
Aproximate Average Dose Received, mg/day _____
Number of days on treatment _____
 - Canrenoate (Yes / No / No data); If yes:
Aproximate Average Dose Received, mg/day _____
Number of days on treatment _____
 - Furosemide (Yes / No / No data); If yes:
Aproximate Average Dose Received, mg/day _____
Number of days on treatment _____
 - Hydrochlorotiazide (Yes / No / No data); If yes:
Aproximate Average Dose Received, mg/day _____
Number of days on treatment _____
 - Amiloride (Yes / No / No data); If yes:
Aproximate Average Dose Received, mg/day _____
Number of days on treatment _____
 - Other (Yes / No / No data); If yes:
Specify _____
Aproximate Average Dose Received, mg/day _____
Number of days on treatment _____
- Prophylaxis for spontaneous bacterial peritonitis (Yes / No / No data). If yes:
 - Type: No data / Primary / Secondary
 - Drugs: No data / Quinolones / Other-Specify _____

- Antibiotics (Yes / No / No data). If yes:

Antibiotic: _____	Aproximate Average Dose Received _____	Units _____
Antibiotic: _____	Aproximate Average Dose Received _____	Units _____
Antibiotic: _____	Aproximate Average Dose Received _____	Units _____
Antibiotic: _____	Aproximate Average Dose Received _____	Units _____
Antibiotic: _____	Aproximate Average Dose Received _____	Units _____
Antibiotic: _____	Aproximate Average Dose Received _____	Units _____

- Proton pump inhibitors (Yes / No / No data). If yes:

- Type: No data / Omeprazole / Pantoprazole / Lansoprazole / Rabeprazole / Esomeprazole
- Aproximate Average Dose Received, mg/day _____
- Number of days on treatment _____

- Therapy for viral Hepatitis (Yes / No / No data). If yes:

- Type:

- Pegylated interferon α 2a (Yes / No / No data); If yes:
Aproximate Average Dose Received ($\mu\text{g}/\text{week}$) _____

- Pegylated interferon α 2b (Yes / No / No data); If yes:
Aproximate Average Dose Received ($\mu\text{g}/\text{Kg}/\text{week}$) _____

- Ribavirin (Yes / No / No data); If yes:
Aproximate Average Dose Received (mg/day) _____

- Lamivudine (Yes / No / No data); If yes:
Aproximate Average Dose Received (mg/day) _____

- Adefovir (Yes / No / No data); If yes:
Aproximate Average Dose Received (mg/day) _____

- Entecavir (Yes / No / No data); If yes:
Aproximate Average Dose Received (mg/day) _____

- Tenofovir (Yes / No / No data); If yes:
Aproximate Average Dose Received (mg/day) _____

- Telbivudine (Yes / No / No data); If yes:
Aproximate Average Dose Received (mg/day) _____

- Other (Yes / No / No data); If yes:
Specify: _____
Aproximate Average Dose Received (mg/day) _____

- Transjugular intrahepatic portosystemic shunting (TIPS) (Yes / No / No data); If yes:
Time from TIPS insertion to hospitalization (days) _____
- Terlipressin (Yes / No / No data). If yes:
 - Indication:
 - Hepatorenal syndrome (Yes / No / No data).
 - Gastrointestinal bleeding (Yes / No / No data).
 - Systemic hemodynamic support (Yes / No / No data).
 - Aproximate Average Dose Received (mg/day) _____
 - Number of days on treatment _____
- Band ligation (Yes / No / No data)
- Sclerotherapy of varices (Yes / No / No data)
- Lactulose (Yes / No / No data) If yes:
 - Aproximate Average Dose Received (g/day) _____
 - Number of days on treatment _____
- Rifaximin (Yes / No / No data) If yes:
 - Aproximate Average Dose Received (mg/day) _____
 - Number of days on treatment _____
- Others (Yes / No / No data) If yes, specify _____

Clinical Data at Hospital Admission

- Site of admission : No data / ICU / Regular Ward
- Cause(s) of admission (all clinical features should be indicated):
 - Ascites (Yes / No / No data); If yes:
 - Type: No data / Mild to Moderate / Large - Tense
 - Encephalopathy (Yes / No / No data); If yes:
 - Stage: West Haven Score (No data / 1 / 2 / 3 / 4)
 - Bacterial infection (Yes / No / No data). If yes:
 - Type of infection:
 - SBP (Yes / No / No data)
 - Pneumonia (Yes / No / No data)
 - Urinary tract infection (UTI) (Yes / No / No data)
 - Skin infection (Yes / No / No data)
 - Unproved suspected infection (Yes / No / No data)
 - Other (Yes / No / No data); If yes, specify _____
 - Sepsis (Yes / No / No data), If yes:
 - Sepsis category: No data / Sepsis Only / Severe sepsis / Septic shock
 - Time from onset of the infection (days) _____
 - Site of acquisition: No data / Community / Hospital
 - Gastrointestinal bleeding (Yes / No / No data); If yes:
 - Etiology:
 - Variceal bleeding (Yes / No / No data)
 - Peptic ulcer lesion (Yes / No / No data)
 - Portal hypertension non-variceal bleeding (Yes / No / No data)
 - Other causes (Yes / No / No data); If yes, specify _____
 - Unknown (Yes / No / No data)
 - GI-bleeding complicated by hypovolemic shock? (Yes / No / No data)
 - Time from onset to present hospital admission (days)_____
 - Resolution (Yes / No / No data);
 - Renal failure (Yes / No / No data); If yes:
 - Renal failure type: No data / HRS type I / HRS type II / Pre-renal / Other (Specify _____) / Unknown / Still undetermined
 - Other causes (Specify _____).

Exploratory data at Hospital Admission

- Body weight (Kg) _____

- Arterial pressure:
Systolic Blood Pressure (mmHg) _____
Diastolic Blood Pressure (mmHg) _____
The mean arterial pressure (MAP) will be calculated by the data-entry application.

- Heart rate (beats/min) _____

- Axillary temperature (°C) _____

- Respiratory rate (breaths/min) _____

- Supplemental oxygen (Yes / No / No data);
 - If No: FiO₂ will take the value "21%".
 - If Yes: Delivery device (Choose one of the following):
 - No data;
 - Nasal catheter; If chosen: Flow (liters of O₂ / min): 1 / 2 / 3 / 4 / 5 / 6+
 - Face mask with reservoir; If chosen: Flow (liters of O₂ / min): 6 / 7 / 8 / 9 / 10+
 - Venturi mask; If chosen: Flow (liters of O₂ / min): 4 / 8 / 12+

- SpO₂ (%) _____
The SpO₂ / FiO₂ ratio will be calculated by the data-entry application.

- Urine volume (mL/h) _____

- Chest X-ray (Normal / Abnormal / No data); If Abnormal:
Specify _____

Laboratory data at Hospital Admission

- Hematocrit _____ (%)
- Hemoglobin level _____ (g/dL) / _____ (g/L)
- White Blood Cells count _____ (x 10⁹ cells/L) / _____ (x cells/mm³)
- % immature neutrophils (bands) _____ (%)
- Platelet count _____ (x 10³/μL) / _____ (x 10⁹/L)
- Total serum bilirubin _____ (mg/dL) / _____ (μmol/L)
- Serum albumin _____ (g/dL) / _____ (g/L)
- Control prothrombin time _____ (sec)
- Prothrombin time _____ (sec)
- % of Control _____ (%)
- INR _____
- Activated partial-thromboplastin time ratio _____
- ALT _____ (U/L) / _____ (μkat/L)
- AST _____ (U/L) / _____ (μkat/L)
- AP _____ (U/L) / _____ (μkat/L)
- GGT _____ (U/L)
- Blood glucose _____ (mg/dL) / _____ (mmol/L)
- When needed:
 - Supplemental oxygen (Yes / No / No data);
 - If No: FiO₂ will take the value "21%".
 - If Yes: Delivery device (Choose one of the following):
 - No data;
 - Nasal catheter; If chosen: Flow (liters of O₂ / min): 1 / 2 / 3 / 4 / 5 / 6+
 - Face mask with reservoir; If chosen: Flow (liters of O₂ / min): 6 / 7 / 8 / 9 / 10+
 - Venturi mask; If chosen: Flow (liters of O₂ / min): 4 / 8 / 12+
 - PaO₂ _____ (mmHg) / _____ (kPa)
 - Arterial pH _____
 - PaCO₂ _____ (mmHg) / _____ (kPa)
 - Serum bicarbonate _____ (mEq/L) / _____ (mmol/L)
 - Serum lactate _____ (mg/dL) / _____ (mmol/L)

The PaO₂ / FiO₂ ratio will be calculated by the data-entry application.
- Plasma C-reactive protein _____ (mg/L)
- Serum creatinine _____ (mg/dL) / _____ (μmol/L)
- Blood urea nitrogen _____ (mg/dL) / _____ (mmol/L)
- Serum sodium _____ (mEq/L) / _____ (mmol/L)
- Serum potassium _____ (mEq/L) / _____ (mmol/L)
- Urine sodium concentration _____ (mEq/L) / _____ (mmol/L)
- Urine creatinine concentration _____ (mg/dL) / _____ (μmol/L)
- Proteinuria (dipstick test: No data / Absent / Trace / 1+ / 2+ / 3+ / 4+)
- Hematuria: Yes / No / No data (If yes, cells / HPF: No data / <10 / 11-20 / 21-50 / >50)
- Ascitic fluid total protein concentration _____ (g/dL) / _____ (g/L)
- Ascitic fluid neutrophil count _____ (Cells/mL)

Microbiological data at Hospital Admission (only in patients with infections)

- Culture done (sample taken):
 - Ascitic fluid (Yes / No / No data); If yes:
- Result: No data / Positive / Negative
 - If positive, isolated organism:
 - Gram positive (Yes / No / No data). If yes:
 - *Enterococcus faecalis* (Yes / No / No data).
If yes: Multiresistent Yes / No / No data
 - *Staphylococcus aureus* (Yes / No / No data).
If yes: Multiresistent Yes / No / No data
 - *Streptococcus pneumoniae* (Yes / No / No data).
If yes: Multiresistent Yes / No / No data
 - *Staphylococcus epidermidis* (Yes / No / No data).
If yes: Multiresistent Yes / No / No data
 - *Streptococcus viridans* (Yes / No / No data).
If yes: Multiresistent Yes / No / No data
 - Other (Yes / No / No data) (If yes, Specify _____).
If yes: Multiresistent Yes / No / No data
 - Gram negative (Yes / No / No data). If yes:
 - *Escherichia coli* (Yes / No / No data).
If yes: Multiresistent Yes / No / No data
 - *Pseudomonas aeruginosa* (Yes / No / No data).
If yes: Multiresistent Yes / No / No data
 - *Klebsiella pneumoniae* (Yes / No / No data).
If yes: Multiresistent Yes / No / No data
 - *Enterobacter spp* (Yes / No / No data).
If yes: Multiresistent Yes / No / No data
 - *Proteus mirabilis* (Yes / No / No data).
If yes: Multiresistent Yes / No / No data
 - Other (Yes / No / No data) (If yes, Specify _____).
If yes: Multiresistent Yes / No / No data
 - Polimicrobial (Yes / No / No data)
 - Fungus (Yes / No / No data)
 - Other (Yes / No / No data) (If yes, specify _____).

- Blood (Yes / No / No data); If yes:
 - Result: No data / Positive / Negative
 - If positive, isolated organism:
 - Gram positive (Yes / No / No data). If yes:
 - *Enterococcus faecalis* (Yes / No / No data).
If yes: Multiresistent Yes / No / No data
 - *Staphylococcus aureus* (Yes / No / No data).
If yes: Multiresistent Yes / No / No data
 - *Streptococcus pneumoniae* (Yes / No / No data).
If yes: Multiresistent Yes / No / No data
 - *Staphylococcus epidermidis* (Yes / No / No data).
If yes: Multiresistent Yes / No / No data
 - *Streptococcus viridans* (Yes / No / No data).
If yes: Multiresistent Yes / No / No data
 - Other (Yes / No / No data) (If yes, Specify _____).
 - If yes: Multiresistent Yes / No / No data
 - Gram negative (Yes / No / No data). If yes:
 - *Escherichia coli* (Yes / No / No data).
If yes: Multiresistent Yes / No / No data
 - *Pseudomonas aeruginosa* (Yes / No / No data).
If yes: Multiresistent Yes / No / No data
 - *Klebsiella pneumoniae* (Yes / No / No data).
If yes: Multiresistent Yes / No / No data
 - *Enterobacter spp* (Yes / No / No data).
If yes: Multiresistent Yes / No / No data
 - *Proteus mirabilis* (Yes / No / No data).
If yes: Multiresistent Yes / No / No data
 - Other (Yes / No / No data) (If yes, Specify _____).
 - If yes: Multiresistent Yes / No / No data
 - Polimicrobial (Yes / No / No data)
 - Fungus (Yes / No / No data)
 - Other (Yes / No / No data) (If yes, specify _____).

- Urine (Yes / No / No data); If yes:
 - Result: No data / Positive / Negative
 - If positive, isolated organism:
 - Gram positive (Yes / No / No data). If yes:
 - *Enterococcus faecalis* (Yes / No / No data).
If yes: Multiresistent Yes / No / No data
 - *Staphylococcus aureus* (Yes / No / No data).
If yes: Multiresistent Yes / No / No data
 - *Streptococcus pneumoniae* (Yes / No / No data).
If yes: Multiresistent Yes / No / No data
 - *Staphylococcus epidermidis* (Yes / No / No data).
If yes: Multiresistent Yes / No / No data
 - *Streptococcus viridans* (Yes / No / No data).
If yes: Multiresistent Yes / No / No data
 - Other (Yes / No / No data) (If yes, Specify _____).
 - If yes: Multiresistent Yes / No / No data
 - Gram negative (Yes / No / No data). If yes:
 - *Escherichia coli* (Yes / No / No data).
If yes: Multiresistent Yes / No / No data
 - *Pseudomonas aeruginosa* (Yes / No / No data).
If yes: Multiresistent Yes / No / No data
 - *Klebsiella pneumoniae* (Yes / No / No data).
If yes: Multiresistent Yes / No / No data
 - *Enterobacter spp* (Yes / No / No data).
If yes: Multiresistent Yes / No / No data
 - *Proteus mirabilis* (Yes / No / No data).
If yes: Multiresistent Yes / No / No data
 - Other (Yes / No / No data) (If yes, Specify _____).
 - If yes: Multiresistent Yes / No / No data
 - Polimicrobial (Yes / No / No data)
 - Fungus (Yes / No / No data)
 - Other (Yes / No / No data) (If yes, specify _____).

- Pleural fluid (Yes / No / No data); If yes:
 - Result: No data / Positive / Negative
 - If positive, isolated organism:
 - Gram positive (Yes / No / No data). If yes:
 - *Enterococcus faecalis* (Yes / No / No data).
If yes: Multiresistent Yes / No / No data
 - *Staphylococcus aureus* (Yes / No / No data).
If yes: Multiresistent Yes / No / No data
 - *Streptococcus pneumoniae* (Yes / No / No data).
If yes: Multiresistent Yes / No / No data
 - *Staphylococcus epidermidis* (Yes / No / No data).
If yes: Multiresistent Yes / No / No data
 - *Streptococcus viridans* (Yes / No / No data).
If yes: Multiresistent Yes / No / No data
 - Other (Yes / No / No data) (If yes, Specify _____).
 - If yes: Multiresistent Yes / No / No data
 - Gram negative (Yes / No / No data). If yes:
 - *Escherichia coli* (Yes / No / No data).
If yes: Multiresistent Yes / No / No data
 - *Pseudomonas aeruginosa* (Yes / No / No data).
If yes: Multiresistent Yes / No / No data
 - *Klebsiella pneumoniae* (Yes / No / No data).
If yes: Multiresistent Yes / No / No data
 - *Enterobacter spp* (Yes / No / No data).
If yes: Multiresistent Yes / No / No data
 - *Proteus mirabilis* (Yes / No / No data).
If yes: Multiresistent Yes / No / No data
 - Other (Yes / No / No data) (If yes, Specify _____).
 - If yes: Multiresistent Yes / No / No data
 - Polimicrobial (Yes / No / No data)
 - Fungus (Yes / No / No data)
 - Other (Yes / No / No data) (If yes, specify _____).

- Other (Yes / No / No data); If yes:
 - Specify: _____
 - Result: No data / Positive / Negative
 - If positive, isolated organism:
 - Gram positive (Yes / No / No data). If yes:
 - *Enterococcus faecalis* (Yes / No / No data).
If yes: Multiresistent Yes / No / No data
 - *Staphylococcus aureus* (Yes / No / No data).
If yes: Multiresistent Yes / No / No data
 - *Streptococcus pneumoniae* (Yes / No / No data).
If yes: Multiresistent Yes / No / No data
 - *Staphylococcus epidermidis* (Yes / No / No data).
If yes: Multiresistent Yes / No / No data
 - *Streptococcus viridans* (Yes / No / No data).
If yes: Multiresistent Yes / No / No data
 - Other (Yes / No / No data) (If yes, Specify _____).
 - If yes: Multiresistent Yes / No / No data
 - Gram negative (Yes / No / No data). If yes:
 - *Escherichia coli* (Yes / No / No data).
If yes: Multiresistent Yes / No / No data
 - *Pseudomonas aeruginosa* (Yes / No / No data).
If yes: Multiresistent Yes / No / No data
 - *Klebsiella pneumoniae* (Yes / No / No data).
If yes: Multiresistent Yes / No / No data
 - *Enterobacter spp* (Yes / No / No data).
If yes: Multiresistent Yes / No / No data
 - *Proteus mirabilis* (Yes / No / No data).
If yes: Multiresistent Yes / No / No data
 - Other (Yes / No / No data) (If yes, Specify _____).
 - If yes: Multiresistent Yes / No / No data
- Polimicrobial (Yes / No / No data)
- Fungus (Yes / No / No data)
- Other (Yes / No / No data) (If yes, specify _____).

PATIENT'S ADMISSION TO THE LIVER UNIT

Enrollment in Other Prophylactic or Therapeutic Studies (prior to Admission to the Liver Unit)

- Is the patient already included in a prophylactic or therapeutic study at the time of admission Yes / No / No data)? If yes:
 - Type of study:
 - No data
 - / Prophylactic
 - / Therapeutic
 - / Non randomized
 - / Randomized placebo-controlled
 - / Randomized comparative
 - Study treatment (specify _____)
 - Control treatment (specify _____)
 - Does the patient continue in the study after admission (Yes / No / No data)?

Precipitating Events since Hospitalization

- Bacterial infection (Yes / No / No data). If yes:
 - Timeframe of infection (choose one of the following):
 - No data /
 - New Infection /
 - Type of infection:
 - SBP (Yes / No / No data)
 - Pneumonia (Yes / No / No data)
 - Urinary tract infection (UTI) (Yes / No / No data)
 - Skin infection (Yes / No / No data)
 - Unproved suspected infection (Yes / No / No data)
 - Other (Yes / No / No data); If yes, specify: _____
 - Sepsis (Yes / No / No data). If yes:
 - Sepsis category: No data / Sepsis Only / Severe sepsis / Septic shock
 - Time from infection to Liver Unit admission (days) _____
 - Site of acquisition: No data / Community / Hospital

- Infection under antibiotic treatment /
 - Therapeutic Response (Yes / No / No data)
 - Resolution of Infection (Yes / No / No data)
- Superinfection /
 - Type of infection:
 - SBP (Yes / No / No data)
 - Pneumonia (Yes / No / No data)
 - Urinary tract infection (UTI) (Yes / No / No data)
 - Skin infection (Yes / No / No data)
 - Unproved suspected infection (Yes / No / No data)
 - Other (Yes / No / No data); If yes, specify _____
 - Sepsis (Yes / No / No data). If yes:
Sepsis category: No data / Sepsis Only / Severe sepsis / Septic shock
 - Time from infection to Liver Unit admission (days) _____
 - Site of acquisition: No data / Community / Hospital
- Gastrointestinal bleeding (Yes / No / No data). If yes:
 - Etiology:
 - Variceal bleeding (Yes / No / No data)
 - Peptic ulcer lesion (Yes / No / No data)
 - Portal hypertension non-variceal bleeding (Yes / No / No data)
 - Other causes (Yes / No / No data); If yes, specify _____
 - Unknown (Yes / No / No data)
 - GI-bleeding complicated by hypovolemic shock? (Yes / No / No data)
 - Time from onset of the last hemorrhage (days, if days<1, enter 1) _____
 - Resolution (Yes /No / No data);
- TIPS (Yes / No / No data). If yes:
 - Time to Liver Unit admission (days) _____
- Surgery (Yes / No / No data); If yes:
 - Time to Liver Unit admission (days) _____
 - Type of surgery (specify _____)

- Therapeutic paracentesis (Yes / No / No data). If yes:
 - Number of therapeutic paracentesis _____
 - Time from the last paracentesis to Liver Unit admission (days) _____
 - Volume of last therapeutic paracentesis (L) _____
 - Use of albumin (Yes / No / No data) If yes:
Dose for last therapeutic paracentesis (g) _____
- Acute hepatitis (Yes / No / No data). If yes
 - Etiology:
 - No data
 - Viral (specify _____) /
 - Toxic (specify _____) /
 - Other (specify _____) /
 - Unknown
 - Time to Liver Unit admission (days) _____
- Other precipitating events (Yes / No / No data); If yes:
 - Specify: _____
 - Time to Liver Unit admission (days) _____

Treatments Administered since Hospitalization

Has the patient received any treatment between hospitalization and admission to the Liver Unit? (Yes / No / No data). If yes, specify:

- Treatment for ascites (Yes / No / No data). If yes:
 - Paracentesis (Yes / No / No data). If yes
 - Total volume removed (L) _____
 - Total dose of Albumin dose (g) _____
 - Diuretics (Yes/No/ No data). If yes:
 - Spironolactone (Yes / No / No data); If yes:
Dose (mg/day) _____
 - Canrenoate (Yes / No / No data); If yes:
Dose (mg/day) _____
 - Furosemide (Yes / No / No data); If yes:
Dose (mg/day) _____
 - Hydrochlorotiazide (Yes / No / No data); If yes:
Dose (mg/day) _____
 - Amiloride (Yes / No / No data); If yes:
Dose (mg/day) _____
 - Others (Yes / No / No data); If yes:
Specify _____
Dose (mg/day) _____

- Treatment for encephalopathy (Yes / No / No data). If yes:
 - Lactulose (Yes / No / No data); If yes, dose (g/day) _____
 - Rifaximin (Yes / No / No data); If yes, dose (mg/day) _____
 - Neomycin (Yes / No / No data); If yes, dose (mg/day) _____
 - Metronidazole (Yes / No / No data); If yes, dose (mg/day) _____
 - Others (Yes / No / No data); If yes:
Specify _____
Dose (mg/day) _____

- Treatment for GI-Bleeding (Yes / No / No data): If yes
 - Pharmacological treatment (Yes / No / No data). If yes:
 - Somatostatin (Yes / No / No data); If yes, dose (µg/h) _____
 - Terlipressin (Yes / No / No data); If yes, dose(mg/day) _____
 - Others (Yes / No / No data); If yes, specify _____
 - Endoscopic Therapy (Yes / No / No data). If yes:
 - Band ligation (Yes / No / No data)
 - Sclerotherapy of varices (Yes / No / No data)
 - Haemostasis of peptic lesion (Yes / No / No data)
 - TIPS (Yes / No / No data)
 - Others (Yes / No / No data); If yes, specify _____

- Treatment for infection (Yes / No / No data).
 If yes, choose one of the following:
 - Antibiotics alone:

Antibiotic 1 _____	; Dose: _____	Unit: _____
Antibiotic 2 _____	; Dose: _____	Unit: _____
Antibiotic 3 _____	; Dose: _____	Unit: _____
Antibiotic 4 _____	; Dose: _____	Unit: _____
Antibiotic 5 _____	; Dose: _____	Unit: _____

..... /
 - Antibiotics with albumin:

Albumin dose (g/day) _____

Antibiotic 1 _____	; Dose: _____	Unit: _____
Antibiotic 2 _____	; Dose: _____	Unit: _____
Antibiotic 3 _____	; Dose: _____	Unit: _____
Antibiotic 4 _____	; Dose: _____	Unit: _____
Antibiotic 5 _____	; Dose: _____	Unit: _____

..... /
 - No data

- Fluid therapy (Yes / No / No data). If yes:
 - Type:
 - Cristalloid (Yes / No / No data).
If Yes: Specify _____ / Average Volume (L/day) _____
 - Colloid (Yes / No / No data).
If Yes: Type _____ / Average Volume (L/day) _____
 - Albumin (Yes / No / No data).
If Yes:
 - Concentration (%): No data / 5 / 20 / 25
 - Average Volume (mL/day): _____
 - Indication:
 - Spontaneous bacterial peritonitis (Yes / No / No data)
 - Hepatorenal syndrome (Yes / No / No data)
 - Volume Replacement (Yes / No / No data)
 - Hepathic encephalopathy (Yes / No / No data)
 - Bleeding (Yes / No / No data)
 - Others (Yes / No / No data); If yes, specify _____

- Transfusion (Yes / No / No data). If yes
 - Red Blood cells (Yes / No / No data) If Yes: Blood units _____
 - Fresh frozen plasma (Yes / No / No data) If Yes: Units _____
 - Platelets (Yes / No / No data) If Yes: Volume (mL) _____
 - Crioprecipitate (Yes / No / No data) If Yes: Volume (mL) _____

- Vasoactive drugs (Yes / No / No data). If yes:
 - Indication: No data / Hepatorenal Syndrome / Sitemic Hemodinamic Support
 - Drug:
 - Terlipressin (Yes / No / No data); If yes, dose (mg/day) _____
 - Noradrenaline (Yes / No / No data); If yes, dose ($\mu\text{g}/\text{Kg}/\text{min}$) _____
 - Midodrine (Yes / No / No data); If yes, dose (mg/day) _____
 - Dopamine (Yes / No / No data); If yes, dose ($\mu\text{g}/\text{Kg}/\text{min}$) _____
 - Others (Yes / No / No data). If yes, specify _____

- Surgery (Yes / No / No data), If yes, specify _____

- Corticoids (Yes / No / No data). If yes:
 - No data / Prednisone / Prednisolone / Methylprednisolone / Hydrocortisone (dose, mg/day) _____

- Prophylaxis of bacterial infection (Yes / No / No data) If yes:
 - Type: No data / Primary / Secondary
 - Drugs: No data / Quinolones / Other-specify _____

- Prophylaxis of gastrointestinal bleeding (Yes / No / No data). If yes:
 - Type: No data / Primary / Secondary
 - Specify: No data / Propranolol / Nadolol / Carvedilol (dose, mg/day) _____

- Mechanical ventilation (Yes / No / No data); If yes:
 - Tidal volume (mL) _____
 - PEEP (cm H₂O) _____
 - FiO₂ (%) _____
 - PaO₂ _____ (mmHg) / _____ (kPa)
The PaO₂ / FiO₂ ratio will be calculated by the data-entry application.

- Renal replacement therapy (Yes / No / No data)

- Other (Yes / No / No data); If yes: specify _____

Admission Data (to the Liver Unit or equivalent service)

- Type of admission:
 - Through emergency department (Yes / No / No data); If yes:
 - From home (Yes / No / No data)
 - From skilled nursing facility (Yes / No / No data)
 - From another hospital (Yes / No / No data)
 - Transfer from another department of the same hospital (Yes / No / No data)
 - Transfer from another hospital (Yes / No / No data)
 - Directly from home (Yes / No / No data)

Clinical Features at Admission to the Liver Unit

- Ascites (Yes / No / No data); If yes:
 - Type: No data / Mild to Moderate / Large - Tense
- Encephalopathy (Yes / No / No data); If yes:
 - Stage: West Haven score (No data / 1 / 2 / 3 / 4).
- Renal failure (Yes / No / No data); If yes:
 - Renal failure type:
No data / HRS type I / HRS type II / Pre-renal / Other (specify _____) /
Unknown / Still undetermined
- Others (Yes / No / No data); If yes, specify _____

Exploratory data at Admission to the Liver Unit

- Body weight (Kg) _____

- Arterial pressure:

Systolic Blood Pressure (mmHg) _____

Diastolic Blood Pressure (mmHg) _____

The mean arterial pressure (MAP) will be calculated by the data-entry application.

- Heart rate (beats/min) _____

- Axillary temperature (°C) _____

- Respiratory rate (breaths/min) _____

- Supplemental oxygen (Yes / No / No data);

- If No: FiO₂ will take the value "21%".

- If Yes: Delivery device (Choose one of the following):

- No data;

- Nasal catheter; If chosen: Flow (liters of O₂ / min): 1 / 2 / 3 / 4 / 5 / 6+

- Face mask with reservoir; If chosen: Flow (liters of O₂ / min): 6 / 7 / 8 / 9 / 10+

- Venturi mask; If chosen: Flow (liters of O₂ / min): 4 / 8 / 12+

- SpO₂ (%) _____

The SpO₂ / FiO₂ ratio will be calculated by the data-entry application.

- Urine volume (mL/h) _____

- Chest X-ray (Normal / Abnormal / No data); If Abnormal:

Specify _____

- Abdominal ultrasonography (it must be performed prior to study inclusion):

- Suspected hepatocellular carcinoma (Yes / No / No data); If yes:

- Classification according to BCLC criteria: No data / A / B / C / D)

- Kidneys (normal, abnormal / No data); If Abnormal:

- Specify: _____ ? _____

Laboratory data at Admission to the Liver Unit

- Hematocrit _____ (%)
- Hemoglobin level _____ (g/dL) / _____ (g/L)
- White Blood Cells count _____ (x 10⁹ cells/L) / _____ (x cells/mm³)
- % immature neutrophils (bands) _____ (%)
- Platelet count _____ (x 10³/μL) / _____ (x 10⁹/L)
- Total serum bilirubin _____ (mg/dL) / _____ (μmol/L)
- Serum albumin _____ (g/dL) / _____ (g/L)
- Control prothrombin time _____ (sec)
- Prothrombin time _____ (sec)
- % of Control _____ (%)
- INR _____
- Activated partial-thromboplastin time ratio _____
- ALT _____ (U/L) / _____ (μkat/L)
- AST _____ (U/L) / _____ (μkat/L)
- AP _____ (U/L) / _____ (μkat/L)
- GGT _____ (U/L)
- Blood glucose _____ (mg/dL) / _____ (mmol/L)
- When needed:
 - Supplemental oxygen (Yes / No / No data);
 - If No: FiO₂ will take the value "21%".
 - If Yes: Delivery device (Choose one of the following):
 - No data;
 - Nasal catheter; If chosen: Flow (liters of O₂ / min): 1 / 2 / 3 / 4 / 5 / 6+
 - Face mask with reservoir; If chosen: Flow (liters of O₂ / min): 6 / 7 / 8 / 9 / 10+
 - Venturi mask; If chosen: Flow (liters of O₂ / min): 4 / 8 / 12+
 - PaO₂ _____ (mmHg) / _____ (kPa)
 - Arterial pH _____
 - PaCO₂ _____ (mmHg) / _____ (kPa)
 - Serum bicarbonate _____ (mEq/L) / _____ (mmol/L)
 - Serum lactate _____ (mg/dL) / _____ (mmol/L)

The PaO₂ / FiO₂ ratio will be calculated by the data-entry application.
- Plasma C-reactive protein _____ (mg/L)
- Serum creatinine _____ (mg/dL) / _____ (μmol/L)
- Blood urea nitrogen _____ (mg/dL) / _____ (mmol/L)
- Serum sodium _____ (mEq/L) / _____ (mmol/L)
- Serum potassium _____ (mEq/L) / _____ (mmol/L)
- Urine sodium concentration _____ (mEq/L) / _____ (mmol/L)
- Urine creatinine concentration _____ (mg/dL) / _____ (μmol/L)
- Proteinuria (dipstick test: No data / Absent / Trace / 1+ / 2+ / 3+ / 4+)
- Hematuria: Yes / No / No data (If yes, cells / HPF: No data / <10 / 11-20 / 21-50 / >50)
- Ascitic fluid total protein concentration _____ (g/dL) / _____ (g/L)
- Ascitic fluid neutrophil count _____ (Cells/mL)

Microbiological Data at Admission to the Liver Unit (only in patients with infections)

- Culture done (sample taken):
 - Ascitic fluid (Yes / No / No data); If yes:
 - Result: No data / Positive / Negative
 - If positive, isolated organism:
 - Gram positive (Yes / No / No data). If yes:
 - *Enterococcus faecalis* (Yes / No / No data).
If yes: Multiresistant Yes / No / No data
 - *Staphylococcus aureus* (Yes / No / No data).
If yes: Multiresistant Yes / No / No data
 - *Streptococcus pneumoniae* (Yes / No / No data).
If yes: Multiresistant Yes / No / No data
 - *Staphylococcus epidermidis* (Yes / No / No data).
If yes: Multiresistant Yes / No / No data
 - *Streptococcus viridans* (Yes / No / No data).
If yes: Multiresistant Yes / No / No data
 - Other (Yes / No / No data) (If yes, Specify _____).
 - If yes: Multiresistant Yes / No / No data
 - Gram negative (Yes / No / No data). If yes:
 - *Escherichia coli* (Yes / No / No data).
If yes: Multiresistant Yes / No / No data
 - *Pseudomonas aeruginosa* (Yes / No / No data).
If yes: Multiresistant Yes / No / No data
 - *Klebsiella pneumoniae* (Yes / No / No data).
If yes: Multiresistant Yes / No / No data
 - *Enterobacter spp* (Yes / No / No data).
If yes: Multiresistant Yes / No / No data
 - *Proteus mirabilis* (Yes / No / No data).
If yes: Multiresistant Yes / No / No data
 - Other (Yes / No / No data) (If yes, Specify _____).
 - If yes: Multiresistant Yes / No / No data
 - Polimicrobial (Yes / No / No data)
 - Fungus (Yes / No / No data)
 - Other (Yes / No / No data) (If yes, specify _____).

- Blood (Yes / No / No data); If yes:
 - Result: No data / Positive / Negative
 - If positive, isolated organism:
 - Gram positive (Yes / No / No data). If yes:
 - *Enterococcus faecalis* (Yes / No / No data).
If yes: Multiresistent Yes / No / No data
 - *Staphylococcus aureus* (Yes / No / No data).
If yes: Multiresistent Yes / No / No data
 - *Streptococcus pneumoniae* (Yes / No / No data).
If yes: Multiresistent Yes / No / No data
 - *Staphylococcus epidermidis* (Yes / No / No data).
If yes: Multiresistent Yes / No / No data
 - *Streptococcus viridans* (Yes / No / No data).
If yes: Multiresistent Yes / No / No data
 - Other (Yes / No / No data) (If yes, Specify _____).
If yes: Multiresistent Yes / No / No data
 - Gram negative (Yes / No / No data). If yes:
 - *Escherichia coli* (Yes / No / No data).
If yes: Multiresistent Yes / No / No data
 - *Pseudomonas aeruginosa* (Yes / No / No data).
If yes: Multiresistent Yes / No / No data
 - *Klebsiella pneumoniae* (Yes / No / No data).
If yes: Multiresistent Yes / No / No data
 - *Enterobacter spp* (Yes / No / No data).
If yes: Multiresistent Yes / No / No data
 - *Proteus mirabilis* (Yes / No / No data).
If yes: Multiresistent Yes / No / No data
 - Other (Yes / No / No data) (If yes, Specify _____).
If yes: Multiresistent Yes / No / No data
 - Polimicrobial (Yes / No / No data)
 - Fungus (Yes / No / No data)
 - Other (Yes / No / No data) (If yes, specify _____).

- Urine (Yes / No / No data); If yes:
 - Result: No data / Positive / Negative
 - If positive, isolated organism:
 - Gram positive (Yes / No / No data). If yes:
 - *Enterococcus faecalis* (Yes / No / No data).
If yes: Multiresistent Yes / No / No data
 - *Staphylococcus aureus* (Yes / No / No data).
If yes: Multiresistent Yes / No / No data
 - *Streptococcus pneumoniae* (Yes / No / No data).
If yes: Multiresistent Yes / No / No data
 - *Staphylococcus epidermidis* (Yes / No / No data).
If yes: Multiresistent Yes / No / No data
 - *Streptococcus viridans* (Yes / No / No data).
If yes: Multiresistent Yes / No / No data
 - Other (Yes / No / No data) (If yes, Specify _____).
If yes: Multiresistent Yes / No / No data
 - Gram negative (Yes / No / No data). If yes:
 - *Escherichia coli* (Yes / No / No data).
If yes: Multiresistent Yes / No / No data
 - *Pseudomonas aeruginosa* (Yes / No / No data).
If yes: Multiresistent Yes / No / No data
 - *Klebsiella pneumoniae* (Yes / No / No data).
If yes: Multiresistent Yes / No / No data
 - *Enterobacter spp* (Yes / No / No data).
If yes: Multiresistent Yes / No / No data
 - *Proteus mirabilis* (Yes / No / No data).
If yes: Multiresistent Yes / No / No data
 - Other (Yes / No / No data) (If yes, Specify _____).
If yes: Multiresistent Yes / No / No data
 - Polimicrobial (Yes / No / No data)
 - Fungus (Yes / No / No data)
 - Other (Yes / No / No data) (If yes, specify _____).

- Pleural fluid (Yes / No / No data) If yes:
 - Result: No data / Positive / Negative
 - If positive, isolated organism:
 - Gram positive (Yes / No / No data). If yes:
 - *Enterococcus faecalis* (Yes / No / No data).
If yes: Multiresistent Yes / No / No data
 - *Staphylococcus aureus* (Yes / No / No data).
If yes: Multiresistent Yes / No / No data
 - *Streptococcus pneumoniae* (Yes / No / No data).
If yes: Multiresistent Yes / No / No data
 - *Staphylococcus epidermidis* (Yes / No / No data).
If yes: Multiresistent Yes / No / No data
 - *Streptococcus viridans* (Yes / No / No data).
If yes: Multiresistent Yes / No / No data
 - Other (Yes / No / No data) (If yes, Specify _____).
If yes: Multiresistent Yes / No / No data
 - Gram negative (Yes / No / No data). If yes:
 - *Escherichia coli* (Yes / No / No data).
If yes: Multiresistent Yes / No / No data
 - *Pseudomonas aeruginosa* (Yes / No / No data).
If yes: Multiresistent Yes / No / No data
 - *Klebsiella pneumoniae* (Yes / No / No data).
If yes: Multiresistent Yes / No / No data
 - *Enterobacter spp* (Yes / No / No data).
If yes: Multiresistent Yes / No / No data
 - *Proteus mirabilis* (Yes / No / No data).
If yes: Multiresistent Yes / No / No data
 - Other (Yes / No / No data) (If yes, Specify _____).
If yes: Multiresistent Yes / No / No data
 - Polimicrobial (Yes / No / No data)
 - Fungus (Yes / No / No data)
 - Other (Yes / No / No data) (If yes, specify _____).

- Other (Yes / No / No data); If yes:
 - Specify: _____
 - Result: No data / Positive / Negative
 - If positive, isolated organism:
 - Gram positive (Yes / No / No data). If yes:
 - *Enterococcus faecalis* (Yes / No / No data).
If yes: Multiresistant Yes / No / No data
 - *Staphylococcus aureus* (Yes / No / No data).
If yes: Multiresistant Yes / No / No data
 - *Streptococcus pneumoniae* (Yes / No / No data).
If yes: Multiresistant Yes / No / No data
 - *Staphylococcus epidermidis* (Yes / No / No data).
If yes: Multiresistant Yes / No / No data
 - *Streptococcus viridans* (Yes / No / No data).
If yes: Multiresistant Yes / No / No data
 - Other (Yes / No / No data) (If yes, Specify _____).
 - If yes: Multiresistant Yes / No / No data
 - Gram negative (Yes / No / No data). If yes:
 - *Escherichia coli* (Yes / No / No data).
If yes: Multiresistant Yes / No / No data
 - *Pseudomonas aeruginosa* (Yes / No / No data).
If yes: Multiresistant Yes / No / No data
 - *Klebsiella pneumoniae* (Yes / No / No data).
If yes: Multiresistant Yes / No / No data
 - *Enterobacter spp* (Yes / No / No data).
If yes: Multiresistant Yes / No / No data
 - *Proteus mirabilis* (Yes / No / No data).
If yes: Multiresistant Yes / No / No data
 - Other (Yes / No / No data) (If yes, Specify _____).
 - If yes: Multiresistant Yes / No / No data
 - Polimicrobial (Yes / No / No data)
 - Fungus (Yes / No / No data)
 - Other (Yes / No / No data) (If yes, specify _____).

Scores

All scores except APACHE II will be derived from data introduced in the data-entry application. Additional information for Lille and Cardiovascular SOFA-Subscore is required:

Lille's score information:

- Does the patient suffer from alcoholic hepatitis? (Yes / No / No data) If yes:

The Lille score can be calculated only if the patient has been under corticosteroid treatment for at least 7 days:

- Is it applicable to this visit? (Yes / No / No data) If yes:

The following parameters at Days 0 and 7 of treatment are required

- Bilirubin at day 0 ($\mu\text{mol/L}$) _____
- Bilirubin at day 7 ($\mu\text{mol/L}$) _____
- Creatinine at day 0 ($\mu\text{mol/L}$) _____

In patients who have received albumin infusions, use the last available albumin value before the infusion of albumin occurred. If albumin infusions are not received, enter 0.

- Albumin at day 0 (g/L) _____
- Patient's prothrombin time at day 0 (sec) _____

SOFA Subscores:

- **Cardiovascular Subscore information:**

- Dopamine (Yes / No / No data); If yes: Dose ($\mu\text{g/Kg/min}$) _____
- Dobutamine (Yes / No / No data)
- Terlipressin for Systemic Hemodynamic Support (Yes / No / No data)
- Epinephrine (Yes / No / No data); If yes: Dose ($\mu\text{g/Kg/min}$) _____
- Norepinephrine (Yes / No / No data); If yes: Dose ($\mu\text{g/Kg/min}$) _____

APACHE II score information:

- Has the patient been admitted to the ICU unit? (Yes / No / No data)
- Does the patient have arterial samples? (Yes / No / No data)

If at least one of the previous answers is YES please fill in:

- APACHE II _____

PATIENT'S DATA AT STUDY INCLUSION

(This section should be filled in only when the patient has been admitted to the Liver Unit and some relevant event has occurred before study inclusion or when the patient has been enrolled in the study without being admitted to the Liver Unit)

Has the patient been admitted to the Liver Unit (Yes/No/No data); If yes:

Has any relevant event occurred between the Liver Unit Admission and the Study Inclusion (Yes / No / No data)? If Yes:

Enrollment in Other Prophylactic or Therapeutic Studies (between Liver Unit admission and study inclusion).

• Has the patient been included in a prophylactic or therapeutic study during this period (Yes / No / No data)?

▪ If yes:

• Type of study:

No data

/ Prophylactic

/ Therapeutic

/ Non randomized

/ Randomized placebo-controlled

/ Randomized comparative

• Study treatment (specify _____)

• Control treatment (specify _____)

• Does the patient continue in the study after this period (Yes / No / No data)?

Precipitating Event(s) since Admission to the Liver Unit

- Bacterial infection (Yes / No / No data). If yes:
 - Timeframe of infection (choose one of the following):
 - No data /
 - New Infection /
 - Type of infection:
 - SBP (Yes / No / No data)
 - Pneumonia (Yes / No / No data)
 - Urinary tract infection (UTI) (Yes / No / No data)
 - Skin infection (Yes / No / No data)
 - Unproved suspected infection (Yes / No / No data)
 - Other (Yes / No / No data); If yes, specify _____
 - Sepsis (Yes / No / No data). If yes:
Sepsis category: No data / Sepsis Only / Severe sepsis / Septic shock
 - Time from infection to study inclusion (days) _____
 - Site of acquisition: No data / Community / Hospital
 - Infection under antibiotic treatment /
 - Therapeutic Response (Yes / No / No data)
 - Resolution of Infection (Yes / No / No data)
 - Superinfection /
 - Type of infection:
 - SBP (Yes / No / No data)
 - Pneumonia (Yes / No / No data)
 - Urinary tract infection (UTI) (Yes / No / No data)
 - Skin infection (Yes / No / No data)
 - Unproved suspected infection (Yes / No / No data)
 - Other (Yes / No / No data); If yes, specify _____
 - Sepsis (Yes / No / No data). If yes:
Sepsis category: No data / Sepsis Only / Severe sepsis / Septic shock
 - Time from infection to study inclusion (days) _____
 - Site of acquisition: No data / Community / Hospital

- Gastrointestinal bleeding (Yes / No / No data);
 - Etiology:
 - Variceal bleeding (Yes / No / No data)
 - Peptic ulcer lesion (Yes / No / No data)
 - Portal hypertension non-variceal bleeding (Yes / No / No data)
 - Other causes (Yes / No / No data); If yes, specify _____
 - Unknown (Yes / No / No data)
 - GI-bleeding complicated by hypovolemic shock? (Yes / No / No data)
 - Time from onset of the last hemorrhage (days, if days < 1, enter 1) _____
 - Resolution (Yes / No / No data);
- TIPS (Yes / No / No data). If yes:
 - Time to study inclusion (days) _____
- Surgery (Yes / No / No data). If yes:
 - Time to study inclusion (days) _____
 - Type of surgery, specify _____
- Therapeutic paracentesis (Yes / No / No data). If yes:
 - Number of therapeutic paracentesis _____
 - Time from the last paracentesis to study inclusion (days) _____
 - Volume of last therapeutic paracentesis (L) _____
 - Use of albumin (Yes / No / No data); If yes:
Dose for last therapeutic paracentesis (g) _____
- Acute hepatitis (Yes / No / No data). If yes:
 - Etiology:
 - No data /
 - Viral (specify _____) /
 - Toxic (specify _____) /
 - Other (specify _____) /
 - Unknown
 - Time to study inclusion (days) _____
- Other precipitating events (Yes / No / No data); If yes:
 - Specify: _____
 - Time to study inclusion (days) _____

Treatments Administered since Admission to the Liver Unit

Has the patient received any treatment between the admission to the Liver Unit and study inclusion? (Yes / No / No data). If yes, specify:

- Treatment for ascites (Yes / No / No data). If yes:
 - Paracentesis (Yes / No / No data). If yes
 - Total volume removed (L) _____
 - Total dose of Albumin dose (g) _____
 - Diuretics (Yes/No/ No data). If yes:
 - Spironolactone (Yes / No / No data); If yes:
 - Dose (mg/day) _____
 - Canrenoate (Yes / No / No data); If yes:
 - Dose (mg/day) _____
 - Furosemide (Yes / No / No data); If yes:
 - Dose (mg/day) _____
 - Hydroclorotiazide (Yes / No / No data); If yes:
 - Dose (mg/day) _____
 - Amiloride (Yes / No / No data); If yes:
 - Dose (mg/day) _____
 - Others (Yes / No / No data); If yes:
 - Specify _____
 - Dose (mg/day) _____
- Treatment for encephalopathy (Yes / No / No data). If yes:
 - Lactulose (Yes / No / No data); If yes, dose (g/day) _____
 - Rifaximin (Yes / No / No data); If yes, dose (mg/day) _____
 - Neomycin (Yes / No / No data); If yes, dose (mg/day) _____
 - Metronidazole (Yes / No / No data); If yes, dose (mg/day) _____
 - Others (Yes / No / No data); If yes:
 - Specify _____
 - Dose (mg/day) _____

- Treatment for GI-Bleeding (Yes / No / No data): If yes
 - Pharmacological treatment (Yes / No / No data). If yes:
 - Somatostatin (Yes / No / No data); If yes, dose ($\mu\text{g/h}$) _____
 - Terlipressin (Yes / No / No data); If yes, dose(mg/day) _____
 - Others (Yes / No / No data); If yes, specify _____
 - Endoscopic Therapy (Yes / No / No data). If yes:
 - Band ligation (Yes / No / No data)
 - Sclerotherapy of varices (Yes / No / No data)
 - Haemostasis of peptic lesion (Yes / No / No data)
 - TIPS (Yes / No / No data)
 - Others (Yes / No / No data); If yes, specify _____

- Treatment for infection (Yes / No / No data).

If yes, choose one of the following:

- Antibiotics alone:

Antibiotic 1 _____; Dose: _____ Unit: _____

Antibiotic 2 _____; Dose: _____ Unit: _____

Antibiotic 3 _____; Dose: _____ Unit: _____

Antibiotic 4 _____; Dose: _____ Unit: _____

Antibiotic 5 _____; Dose: _____ Unit: _____

.....
 /

- Antibiotics with albumin:

Albumin dose (g/day) _____

Antibiotic 1 _____; Dose: _____ Unit: _____

Antibiotic 2 _____; Dose: _____ Unit: _____

Antibiotic 3 _____; Dose: _____ Unit: _____

Antibiotic 4 _____; Dose: _____ Unit: _____

Antibiotic 5 _____; Dose: _____ Unit: _____

.....
 /

- No data

- Fluid therapy (Yes / No / No data). If yes:
 - Type:
 - Cristalloid (Yes / No / No data).
If Yes: Specify _____ / Average Volume (L/day) _____
 - Colloid (Yes / No / No data).
If Yes: Type _____ / Average Volume (L/day) _____
 - Albumin (Yes / No / No data).
If Yes:
 - Concentration (%): No data / 5 / 20 / 25
 - Average Volume (mL/day): _____
 - Indication:
 - Spontaneous bacterial peritonitis (Yes / No / No data)
 - Hepatorenal syndrome (Yes / No / No data)
 - Volume Replacement (Yes / No / No data)
 - Hepathic encephalopathy (Yes / No / No data)
 - Bleeding (Yes / No / No data)
 - Others (Yes / No / No data); If yes, specify _____
- Transfusion (Yes / No / No data). If yes
 - Red Blood cells (Yes / No / No data) If Yes: Blood units _____
 - Fresh frozen plasma (Yes / No / No data) If Yes: Units _____
 - Platelets (Yes / No / No data) If Yes: Volume (mL) _____
 - Crioprecipitate (Yes / No / No data) If Yes: Volume (mL) _____
- Vasoactive drugs (Yes / No / No data). If yes:
 - Indication: No data / Hepatorenal Syndrome / Sitemic Hemodinamic Support
 - Drug:
 - Terlipressin (Yes / No / No data); If yes, dose (mg/day) _____
 - Noradrenaline (Yes / No / No data); If yes, dose ($\mu\text{g}/\text{Kg}/\text{min}$) _____
 - Midodrine (Yes / No / No data); If yes, dose (mg/day) _____
 - Dopamine (Yes / No / No data); If yes, dose ($\mu\text{g}/\text{Kg}/\text{min}$) _____
 - Others (Yes / No / No data). If yes, specify _____
- Surgery (Yes / No / No data), If yes, specify _____

- Corticoids (Yes / No / No data). If yes:
 - No data / Prednisone / Prednisolone / Methylprednisolone / Hydrocortisone (dose, mg/day) _____

- Prophylaxis of bacterial infection (Yes / No / No data) If yes:
 - Type: No data / Primary / Secondary
 - Drugs: No data / Quinolones / Other-specify _____

- Prophylaxis of gastrointestinal bleeding (Yes / No / No data). If yes:
 - Type: No data / Primary / Secondary
 - Specify: No data / Propranolol / Nadolol / Carvedilol (dose, mg/day) _____

- Mechanical ventilation (Yes / No / No data); If yes:
 - Tidal volume (mL) _____
 - PEEP (cm H2O) _____
 - FiO2 (%) _____
 - PaO2 _____ (mmHg) / _____ (kPa)
The PaO₂ / FiO₂ ratio will be calculated by the data-entry application.

- Renal replacement therapy (Yes / No / No data)

- Other (Yes / No / No data); If yes: specify _____

Clinical Features at Study Inclusion

- Ascites (Yes / No / No data); If yes,
 - Type: No data / Mild to Moderate / Large-Tense
- Encephalopathy (Yes / No / No data); If yes:
 - Stage: West Haven score: No data / 1 / 2 / 3 / 4
- Renal failure (Yes / No / No data); If yes:
 - Renal failure type:
 No data / HRS type I / HRS type II / Pre-renal / Other (specify _____) /
 Unknown / Still undetermined
- Others (Yes / No / No data); If yes, specify _____

Exploratory data at Study Inclusion

- Body weight (Kg) _____

- Arterial pressure:

Systolic Blood Pressure (mmHg) _____

Diastolic Blood Pressure (mmHg) _____

The mean arterial pressure (MAP) will be calculated by the data-entry application.

- Heart rate (beats/min) _____

- Axillary temperature ($^{\circ}$ C) _____

- Respiratory rate (breaths/min) _____

- Supplemental oxygen (Yes / No / No data);

- If No: FiO₂ will take the value "21%".

- If Yes: Delivery device (Choose one of the following):

- No data;

- Nasal catheter; If chosen: Flow (liters of O₂ / min): 1 / 2 / 3 / 4 / 5 / 6+

- Face mask with reservoir; If chosen: Flow (liters of O₂ / min): 6 / 7 / 8 / 9 / 10+

- Venturi mask; If chosen: Flow (liters of O₂ / min): 4 / 8 / 12+

- SpO₂ (%) _____

The SpO₂ / FiO₂ ratio will be calculated by the data-entry application.

- Urine volume (mL/h) _____

- Chest X-ray (Normal / Abnormal / No data); If Abnormal:

Specify _____

Laboratory Data at Study Inclusion

- Hematocrit _____ (%)
- Hemoglobin level _____ (g/dL) / _____ (g/L)
- White Blood Cells count _____ (x 10⁹ cells/L) / _____ (x cells/mm³)
- % immature neutrophils (bands) _____ (%)
- Platelet count _____ (x 10³/μL) / _____ (x 10⁹/L)
- Total serum bilirubin _____ (mg/dL) / _____ (μmol/L)
- Serum albumin _____ (g/dL) / _____ (g/L)
- Control prothrombin time _____ (sec)
- Prothrombin time _____ (sec)
- % of Control _____ (%)
- **INR**
- Activated partial-thromboplastin time ratio _____
- ALT _____ (U/L) / _____ (μkat/L)
- AST _____ (U/L) / _____ (μkat/L)
- AP _____ (U/L) / _____ (μkat/L)
- GGT _____ (U/L)
- Blood glucose _____ (mg/dL) / _____ (mmol/L)
- When needed:
 - Supplemental oxygen (Yes / No / No data);
 - If No: FiO₂ will take the value "21%".
 - If Yes: Delivery device (Choose one of the following):
 - No data;
 - Nasal catheter; If chosen: Flow (liters of O₂ / min): 1 / 2 / 3 / 4 / 5 / 6+
 - Face mask with reservoir; If chosen: Flow (liters of O₂ / min): 6 / 7 / 8 / 9 / 10+
 - Venturi mask; If chosen: Flow (liters of O₂ / min): 4 / 8 / 12+
 - PaO₂ _____ (mmHg) / _____ (kPa)
 - Arterial pH _____
 - PaCO₂ _____ (mmHg) / _____ (kPa)
 - Serum bicarbonate _____ (mEq/L) / _____ (mmol/L)
 - Serum lactate _____ (mg/dL) / _____ (mmol/L)

The PaO₂ / FiO₂ ratio will be calculated by the data-entry application.
- Plasma C-reactive protein _____ (mg/L)
- Serum creatinine _____ (mg/dL) / _____ (μmol/L)
- Blood urea nitrogen _____ (mg/dL) / _____ (mmol/L)
- Serum sodium _____ (mEq/L) / _____ (mmol/L)
- Serum potassium _____ (mEq/L) / _____ (mmol/L)
- Urine sodium concentration _____ (mEq/L) / _____ (mmol/L)
- Urine creatinine concentration _____ (mg/dL) / _____ (μmol/L)
- Proteinuria (dipstick test: No data / Absent / Trace / 1+ / 2+ / 3+ / 4+)
- Hematuria: Yes / No / No data (If yes, cells / HPF: No data / <10 / 11-20 / 21-50 / >50)
- Ascitic fluid total protein concentration _____ (g/dL) / _____ (g/L)
- Ascitic fluid neutrophil count _____ (Cells/mL)

Microbiological Data at Study Inclusion (only in patients with infections)

- Culture done (sample taken):
 - Ascitic fluid (Yes / No / No data); If yes:
 - Result: No data / Positive / Negative
 - If positive, isolated organism:
 - Gram positive (Yes / No / No data). If yes:
 - *Enterococcus faecalis* (Yes / No / No data).
If yes: Multiresistent Yes / No / No data
 - *Staphylococcus aureus* (Yes / No / No data).
If yes: Multiresistent Yes / No / No data
 - *Streptococcus pneumoniae* (Yes / No / No data).
If yes: Multiresistent Yes / No / No data
 - *Staphylococcus epidermidis* (Yes / No / No data).
If yes: Multiresistent Yes / No / No data
 - *Streptococcus viridans* (Yes / No / No data).
If yes: Multiresistent Yes / No / No data
 - Other (Yes / No / No data) (If yes, Specify _____).
 - If yes: Multiresistent Yes / No / No data
 - Gram negative (Yes / No / No data). If yes:
 - *Escherichia coli* (Yes / No / No data).
If yes: Multiresistent Yes / No / No data
 - *Pseudomonas aeruginosa* (Yes / No / No data).
If yes: Multiresistent Yes / No / No data
 - *Klebsiella pneumoniae* (Yes / No / No data).
If yes: Multiresistent Yes / No / No data
 - *Enterobacter spp* (Yes / No / No data).
If yes: Multiresistent Yes / No / No data
 - *Proteus mirabilis* (Yes / No / No data).
If yes: Multiresistent Yes / No / No data
 - Other (Yes / No / No data) (If yes, Specify _____).
 - If yes: Multiresistent Yes / No / No data
 - Polimicrobial (Yes / No / No data)
 - Fungus (Yes / No / No data)
 - Other (Yes / No / No data) (If yes, specify _____).

- Blood (Yes / No / No data); If yes:
 - Result: No data / Positive / Negative
 - If positive, isolated organism:
 - Gram positive (Yes / No / No data). If yes:
 - *Enterococcus faecalis* (Yes / No / No data).
If yes: Multiresistant Yes / No / No data
 - *Staphylococcus aureus* (Yes / No / No data).
If yes: Multiresistant Yes / No / No data
 - *Streptococcus pneumoniae* (Yes / No / No data).
If yes: Multiresistant Yes / No / No data
 - *Staphylococcus epidermidis* (Yes / No / No data).
If yes: Multiresistant Yes / No / No data
 - *Streptococcus viridans* (Yes / No / No data).
If yes: Multiresistant Yes / No / No data
 - Other (Yes / No / No data) (If yes, Specify _____).
 - If yes: Multiresistant Yes / No / No data
 - Gram negative (Yes / No / No data). If yes:
 - *Escherichia coli* (Yes / No / No data).
If yes: Multiresistant Yes / No / No data
 - *Pseudomonas aeruginosa* (Yes / No / No data).
If yes: Multiresistant Yes / No / No data
 - *Klebsiella pneumoniae* (Yes / No / No data).
If yes: Multiresistant Yes / No / No data
 - *Enterobacter spp* (Yes / No / No data).
If yes: Multiresistant Yes / No / No data
 - *Proteus mirabilis* (Yes / No / No data).
If yes: Multiresistant Yes / No / No data
 - Other (Yes / No / No data) (If yes, Specify _____).
 - If yes: Multiresistant Yes / No / No data
 - Polimicrobial (Yes / No / No data)
 - Fungus (Yes / No / No data)
 - Other (Yes / No / No data) (If yes, specify _____).

- Urine (Yes / No / No data); If yes:
 - Result: No data / Positive / Negative
 - If positive, isolated organism:
 - Gram positive (Yes / No / No data). If yes:
 - *Enterococcus faecalis* (Yes / No / No data).
If yes: Multiresistent Yes / No / No data
 - *Staphylococcus aureus* (Yes / No / No data).
If yes: Multiresistent Yes / No / No data
 - *Streptococcus pneumoniae* (Yes / No / No data).
If yes: Multiresistent Yes / No / No data
 - *Staphylococcus epidermidis* (Yes / No / No data).
If yes: Multiresistent Yes / No / No data
 - *Streptococcus viridans* (Yes / No / No data).
If yes: Multiresistent Yes / No / No data
 - Other (Yes / No / No data) (If yes, Specify _____).
 - If yes: Multiresistent Yes / No / No data
 - Gram negative (Yes / No / No data). If yes:
 - *Escherichia coli* (Yes / No / No data).
If yes: Multiresistent Yes / No / No data
 - *Pseudomonas aeruginosa* (Yes / No / No data).
If yes: Multiresistent Yes / No / No data
 - *Klebsiella pneumoniae* (Yes / No / No data).
If yes: Multiresistent Yes / No / No data
 - *Enterobacter spp* (Yes / No / No data).
If yes: Multiresistent Yes / No / No data
 - *Proteus mirabilis* (Yes / No / No data).
If yes: Multiresistent Yes / No / No data
 - Other (Yes / No / No data) (If yes, Specify _____).
 - If yes: Multiresistent Yes / No / No data
 - Polimicrobial (Yes / No / No data)
 - Fungus (Yes / No / No data)
 - Other (Yes / No / No data) (If yes, specify _____).

- Pleural fluid (Yes / No / No data); If yes:
 - Result: No data / Positive / Negative
 - If positive, isolated organism:
 - Gram positive (Yes / No / No data). If yes:
 - *Enterococcus faecalis* (Yes / No / No data).
If yes: Multiresistant Yes / No / No data
 - *Staphylococcus aureus* (Yes / No / No data).
If yes: Multiresistant Yes / No / No data
 - *Streptococcus pneumoniae* (Yes / No / No data).
If yes: Multiresistant Yes / No / No data
 - *Staphylococcus epidermidis* (Yes / No / No data).
If yes: Multiresistant Yes / No / No data
 - *Streptococcus viridans* (Yes / No / No data).
If yes: Multiresistant Yes / No / No data
 - Other (Yes / No / No data) (If yes, Specify _____).
 - If yes: Multiresistant Yes / No / No data
 - Gram negative (Yes / No / No data). If yes:
 - *Escherichia coli* (Yes / No / No data).
If yes: Multiresistant Yes / No / No data
 - *Pseudomonas aeruginosa* (Yes / No / No data).
If yes: Multiresistant Yes / No / No data
 - *Klebsiella pneumoniae* (Yes / No / No data).
If yes: Multiresistant Yes / No / No data
 - *Enterobacter spp* (Yes / No / No data).
If yes: Multiresistant Yes / No / No data
 - *Proteus mirabilis* (Yes / No / No data).
If yes: Multiresistant Yes / No / No data
 - Other (Yes / No / No data) (If yes, Specify _____).
 - If yes: Multiresistant Yes / No / No data
 - Polimicrobial (Yes / No / No data)
 - Fungus (Yes / No / No data)
 - Other (Yes / No / No data) (If yes, specify _____).

- Other (Yes / No / No data); If yes:
 - Specify: _____
 - Result: No data / Positive / Negative
 - If positive, isolated organism:
 - Gram positive (Yes / No / No data). If yes:
 - *Enterococcus faecalis* (Yes / No / No data).
If yes: Multiresistent Yes / No / No data
 - *Staphylococcus aureus* (Yes / No / No data).
If yes: Multiresistent Yes / No / No data
 - *Streptococcus pneumoniae* (Yes / No / No data).
If yes: Multiresistent Yes / No / No data
 - *Staphylococcus epidermidis* (Yes / No / No data).
If yes: Multiresistent Yes / No / No data
 - *Streptococcus viridans* (Yes / No / No data).
If yes: Multiresistent Yes / No / No data
 - Other (Yes / No / No data) (If yes, Specify _____).
 - If yes: Multiresistent Yes / No / No data
 - Gram negative (Yes / No / No data). If yes:
 - *Escherichia coli* (Yes / No / No data).
If yes: Multiresistent Yes / No / No data
 - *Pseudomonas aeruginosa* (Yes / No / No data).
If yes: Multiresistent Yes / No / No data
 - *Klebsiella pneumoniae* (Yes / No / No data).
If yes: Multiresistent Yes / No / No data
 - *Enterobacter spp* (Yes / No / No data).
If yes: Multiresistent Yes / No / No data
 - *Proteus mirabilis* (Yes / No / No data).
If yes: Multiresistent Yes / No / No data
 - Other (Yes / No / No data) (If yes, Specify _____).
 - If yes: Multiresistent Yes / No / No data
 - Polimicrobial (Yes / No / No data)
 - Fungus (Yes / No / No data)
 - Other (Yes / No / No data) (If yes, specify _____).

Scores

All scores except APACHE II will be derived from data introduced in the data-entry application.
Additional information for Lille and Cardiovascular SOFA-Subscore is required:

Lille's score information:

- Does the patient suffer from alcoholic hepatitis? (Yes / No / No data) If yes:

The Lille score can be calculated only if the patient has been under corticosteroid treatment for at least 7 days:

- Is it applicable to this visit? (Yes / No / No data) If yes:

The following parameters at Days 0 and 7 of treatment are required

- Bilirubin at day 0 ($\mu\text{mol/L}$) _____
- Bilirubin at day 7 ($\mu\text{mol/L}$) _____
- Creatinine at day 0 ($\mu\text{mol/L}$) _____

In patients who have received albumin infusions, use the last available albumin value before the infusion of albumin occurred. If albumin infusions are not received, enter 0.

- Albumin at day 0 (g/L) _____
- Patient's prothrombin time at day 0 (sec) _____

SOFA Subscores:

- **Cardiovascular Subscore information:**

- Dopamine (Yes / No / No data); If yes: Dose ($\mu\text{g/Kg/min}$) _____
- Dobutamine (Yes / No / No data)
- Terlipressin for Systemic Hemodynamic Support (Yes / No / No data)
- Epinephrine (Yes / No / No data); If yes: Dose ($\mu\text{g/Kg/min}$) _____
- Norepinephrine (Yes / No / No data); If yes: Dose ($\mu\text{g/Kg/min}$) _____

APACHE II score information:

- Has the patient been admitted to the ICU unit? (Yes / No / No data)
- Does the patient have arterial samples? (Yes / No / No data)

If at least one of the previous answers is YES please fill in:

- APACHE II _____

Place of Patient at the End of the Visit

- ICU (Yes / No / No data)
- Ward (Yes / No / No data)

ONSET OF THE FIRST EXTRA-HEPATIC ORGAN FAILURE
(Group #3 patients, only)

First extra-hepatic organ failure data

Patients in Group #3 will switch to Group #4 if an extra-hepatic organ failure occurs during hospital follow-up.

- First extra-hepatic organ failure detected (Yes / No / No data). If yes:
 - Renal failure (Yes / No / No data). If yes:
 - Site where extra-hepatic organ failure was detected: No data / General ward / ICU
 - Date of onset: __ / __ / ____
 - Cerebral failure (Yes / No / No data). If yes:
 - Site where extra-hepatic organ failure was detected: No data / General ward / ICU
 - Date of onset: __ / __ / ____
 - Respiratory failure (Yes / No / No data). If yes:
 - Site where extra-hepatic organ failure was detected: No data / General ward / ICU
 - Date of onset: __ / __ / ____
 - Cardiac failure (Yes / No / No data). If yes:
 - Site where extra-hepatic organ failure was detected: No data / General ward / ICU
 - Date of onset: __ / __ / ____
 - Coagulation (Yes / No / No data). If yes:
 - Site where extra-hepatic organ failure was detected: No data / General ward / ICU
 - Date of onset: __ / __ / ____

Enrollment in Other Prophylactic or Therapeutic Studies between study inclusion and the onset of first extra-hepatic organ failure

- Has the patient been included in a prophylactic or therapeutic study during this period (Yes / No / No data).
 - If yes:
 - Type of study:
 - No data
 - / Prophylactic
 - / Therapeutic
 - / Non randomized
 - / Randomized placebo-controlled
 - / Randomized comparative
 - Study treatment (specify _____)
 - Control treatment (specify _____)
 - Does the patient continue in the study after the onset of the organ failure (Yes / No / No data)?

Clinical features at the onset of first extra-hepatic organ failure

- Ascites (Yes / No / No data); If yes:
 - Type: No data / Mild to Moderate / Large - Tense
- Encephalopathy (Yes / No / No data); If yes:
 - Stage: West Haven score: No data / 1 / 2 / 3 / 4
- Renal failure (Yes / No / No data); If yes:
 - Renal failure type:
 - No data / HRS type I / HRS type II / Pre-renal / Other (specify _____) /
 - Unknown / Still undetermined
- Others (Yes / No / No data); If yes, specify _____

Precipitating event(s) between study inclusion and the onset of the first extrahepatic organ failure

- Bacterial infection (Yes / No / No data). If yes:
 - Timeframe of infection (choose one of the following):
 - No data /
 - New Infection /
 - Type of infection:
 - SBP (Yes / No / No data)
 - Pneumonia (Yes / No / No data)
 - Urinary tract infection (UTI) (Yes / No / No data)
 - Skin infection (Yes / No / No data)
 - Unproved suspected infection (Yes / No / No data)
 - Other (Yes / No / No data); If yes, specify _____
 - Sepsis (Yes / No / No data). If yes:
Sepsis category: No data / Sepsis Only / Severe sepsis / Septic shock
 - Time from infection (days) _____
 - Site of acquisition: No data / Community / Hospital
 - Infection under antibiotic treatment /
 - Therapeutic Response (Yes / No / No data)
 - Resolution of Infection (Yes / No / No data)
 - Superinfection /
 - Type of infection:
 - SBP (Yes / No / No data)
 - Pneumonia (Yes / No / No data)
 - Urinary tract infection (UTI) (Yes / No / No data)
 - Skin infection (Yes / No / No data)
 - Unproved suspected infection (Yes / No / No data)
 - Other (Yes / No / No data); If yes, specify _____
 - Sepsis (Yes / No / No data). If yes:
Sepsis category: No data / Sepsis Only / Severe sepsis / Septic shock
 - Time from infection (days) _____
 - Site of acquisition: No data / Community / Hospital

- Gastrointestinal bleeding (Yes / No / No data);
 - Etiology:
 - Variceal bleeding (Yes / No / No data)
 - Peptic ulcer lesion (Yes / No / No data)
 - Portal hypertension non-variceal bleeding (Yes / No / No data)
 - Other causes (Yes / No / No data); If yes, specify _____
 - Unknown (Yes / No / No data)
 - GI-bleeding complicated by hypovolemic shock? (Yes / No / No data)
 - Time from onset of the last hemorrhage (days, if days < 1, enter 1) _____
 - Resolution (Yes / No / No data);
- TIPS (Yes / No / No data). If yes:
 - Time to extrahepatic organ failure (days) _____
- Surgery (Yes / No / No data):
 - Time to extrahepatic organ failure (days) _____
 - Type of surgery (specify _____)
- Therapeutic paracentesis (Yes / No / No data). If yes:
 - Number of therapeutic paracentesis _____
 - Time from last paracentesis to extrahepatic organ failure (days) _____
 - Volume of last therapeutic paracentesis (L) _____
 - Use of albumin (Yes / No / No data); If yes:
 - Dose for last therapeutic paracentesis (g) _____
- Acute hepatitis (Yes / No / No data). If yes:
 - Etiology:
 - Etiology:
 - No data /
 - Viral (specify _____) /
 - Toxic (specify _____) /
 - Other (specify _____) /
 - Unknown
 - Time to extrahepatic organ failure (days) _____
- Other precipitating events (Yes / No / No data); If yes:
 - Specify: _____
 - Time to extrahepatic organ failure (days) _____

Exploratory data at the onset of first extra-hepatic organ failure

- Body weight (Kg) _____

- Arterial pressure:

Systolic Blood Pressure (mmHg) _____

Diastolic Blood Pressure (mmHg) _____

The mean arterial pressure (MAP) will be calculated by the data-entry application.

- Heart rate (beats/min) _____

- Axillary temperature (°C) _____

- Respiratory rate (breaths/min) _____

- Supplemental oxygen (Yes / No / No data);

- If No: FiO₂ will take the value "21%".

- If Yes: Delivery device (Choose one of the following):

- No data;

- Nasal catheter; If chosen: Flow (liters of O₂ / min): 1 / 2 / 3 / 4 / 5 / 6+

- Face mask with reservoir; If chosen: Flow (liters of O₂ / min): 6 / 7 / 8 / 9 / 10+

- Venturi mask; If chosen: Flow (liters of O₂ / min): 4 / 8 / 12+

- SpO₂ (%) _____

The SpO₂ / FiO₂ ratio will be calculated by the data-entry application.

- Urine volume (mL/h) _____

- Chest X-ray (Normal / Abnormal / No data); If Abnormal:

Specify _____

Laboratory data at the onset of first extra-hepatic organ failure

- Hematocrit _____ (%)
- Hemoglobin level _____ (g/dL) / _____ (g/L)
- White Blood Cells count _____ (x 10⁹ cells/L) / _____ (x cells/mm³)
- % immature neutrophils (bands) _____ (%)
- Platelet count _____ (x 10³/μL) / _____ (x 10⁹/L)
- Total serum bilirubin _____ (mg/dL) / _____ (μmol/L)
- Serum albumin _____ (g/dL) / _____ (g/L)
- Control prothrombin time _____ (sec)
- Prothrombin time _____ (sec)
- % of Control _____ (%)
- INR _____
- Activated partial-thromboplastin time ratio _____
- ALT _____ (U/L) / _____ (μkat/L)
- AST _____ (U/L) / _____ (μkat/L)
- AP _____ (U/L) / _____ (μkat/L)
- GGT _____ (U/L)
- Blood glucose _____ (mg/dL) / _____ (mmol/L)
- When needed:
 - Supplemental oxygen (Yes / No / No data);
 - If No: FiO₂ will take the value "21%".
 - If Yes: Delivery device (Choose one of the following):
 - No data;
 - Nasal catheter; If chosen: Flow (liters of O₂ / min): 1 / 2 / 3 / 4 / 5 / 6+
 - Face mask with reservoir; If chosen: Flow (liters of O₂ / min): 6 / 7 / 8 / 9 / 10+
 - Venturi mask; If chosen: Flow (liters of O₂ / min): 4 / 8 / 12+
 - PaO₂ _____ (mmHg) / _____ (kPa)
 - Arterial pH _____
 - PaCO₂ _____ (mmHg) / _____ (kPa)
 - Serum bicarbonate _____ (mEq/L) / _____ (mmol/L)
 - Serum lactate _____ (mg/dL) / _____ (mmol/L)

The PaO₂ / FiO₂ ratio will be calculated by the data-entry application.
- Plasma C-reactive protein _____ (mg/L)
- Serum creatinine _____ (mg/dL) / _____ (μmol/L)
- Blood urea nitrogen _____ (mg/dL) / _____ (mmol/L)
- Serum sodium _____ (mEq/L) / _____ (mmol/L)
- Serum potassium _____ (mEq/L) / _____ (mmol/L)
- Urine sodium concentration _____ (mEq/L) / _____ (mmol/L)
- Urine creatinine concentration _____ (mg/dL) / _____ (μmol/L)
- Proteinuria (dipstick test: No data / Absent / Trace / 1+ / 2+ / 3+ / 4+)
- Hematuria: Yes / No / No data (If yes, cells / HPF: No data / <10 / 11-20 / 21-50 / >50)
- Ascitic fluid total protein concentration _____ (g/dL) / _____ (g/L)
- Ascitic fluid neutrophil count _____ (Cells/mL)

Microbiological data at the onset of first extra-hepatic organ failure (only in patients with infections)

- Culture done (sample taken):
 - Ascitic fluid (Yes / No / No data); If yes:
 - Result: No data / Positive / Negative
 - If positive, isolated organism:
 - Gram positive (Yes / No / No data). If yes:
 - *Enterococcus faecalis* (Yes / No / No data).
If yes: Multiresistent Yes / No / No data
 - *Staphylococcus aureus* (Yes / No / No data).
If yes: Multiresistent Yes / No / No data
 - *Streptococcus pneumoniae* (Yes / No / No data).
If yes: Multiresistent Yes / No / No data
 - *Staphylococcus epidermidis* (Yes / No / No data).
If yes: Multiresistent Yes / No / No data
 - *Streptococcus viridans* (Yes / No / No data).
If yes: Multiresistent Yes / No / No data
 - Other (Yes / No / No data) (If yes, Specify _____).
 - If yes: Multiresistent Yes / No / No data
 - Gram negative (Yes / No / No data). If yes:
 - *Escherichia coli* (Yes / No / No data).
If yes: Multiresistent Yes / No / No data
 - *Pseudomonas aeruginosa* (Yes / No / No data).
If yes: Multiresistent Yes / No / No data
 - *Klebsiella pneumoniae* (Yes / No / No data).
If yes: Multiresistent Yes / No / No data
 - *Enterobacter spp* (Yes / No / No data).
If yes: Multiresistent Yes / No / No data
 - *Proteus mirabilis* (Yes / No / No data).
If yes: Multiresistent Yes / No / No data
 - Other (Yes / No / No data) (If yes, Specify _____).
 - If yes: Multiresistent Yes / No / No data
- Polimicrobial (Yes / No / No data)
- Fungus (Yes / No / No data)
- Other (Yes / No / No data) (If yes, specify _____).

- Blood (Yes / No / No data); If yes:
 - Result: No data / Positive / Negative
 - If positive, isolated organism:
 - Gram positive (Yes / No / No data). If yes:
 - *Enterococcus faecalis* (Yes / No / No data).
If yes: Multiresistent Yes / No / No data
 - *Staphylococcus aureus* (Yes / No / No data).
If yes: Multiresistent Yes / No / No data
 - *Streptococcus pneumoniae* (Yes / No / No data).
If yes: Multiresistent Yes / No / No data
 - *Staphylococcus epidermidis* (Yes / No / No data).
If yes: Multiresistent Yes / No / No data
 - *Streptococcus viridans* (Yes / No / No data).
If yes: Multiresistent Yes / No / No data
 - Other (Yes / No / No data) (If yes, Specify _____).
 - If yes: Multiresistent Yes / No / No data
 - Gram negative (Yes / No / No data). If yes:
 - *Escherichia coli* (Yes / No / No data).
If yes: Multiresistent Yes / No / No data
 - *Pseudomonas aeruginosa* (Yes / No / No data).
If yes: Multiresistent Yes / No / No data
 - *Klebsiella pneumoniae* (Yes / No / No data).
If yes: Multiresistent Yes / No / No data
 - *Enterobacter spp* (Yes / No / No data).
If yes: Multiresistent Yes / No / No data
 - *Proteus mirabilis* (Yes / No / No data).
If yes: Multiresistent Yes / No / No data
 - Other (Yes / No / No data) (If yes, Specify _____).
 - If yes: Multiresistent Yes / No / No data
 - Polimicrobial (Yes / No / No data)
 - Fungus (Yes / No / No data)
 - Other (Yes / No / No data) (If yes, specify _____).

- Urine (Yes / No / No data); If yes:
 - Result: No data / Positive / Negative
 - If positive, isolated organism:
 - Gram positive (Yes / No / No data). If yes:
 - *Enterococcus faecalis* (Yes / No / No data).
If yes: Multiresistent Yes / No / No data
 - *Staphylococcus aureus* (Yes / No / No data).
If yes: Multiresistent Yes / No / No data
 - *Streptococcus pneumoniae* (Yes / No / No data).
If yes: Multiresistent Yes / No / No data
 - *Staphylococcus epidermidis* (Yes / No / No data).
If yes: Multiresistent Yes / No / No data
 - *Streptococcus viridans* (Yes / No / No data).
If yes: Multiresistent Yes / No / No data
 - Other (Yes / No / No data) (If yes, Specify _____).
 - If yes: Multiresistent Yes / No / No data
 - Gram negative (Yes / No / No data). If yes:
 - *Escherichia coli* (Yes / No / No data).
If yes: Multiresistent Yes / No / No data
 - *Pseudomonas aeruginosa* (Yes / No / No data).
If yes: Multiresistent Yes / No / No data
 - *Klebsiella pneumoniae* (Yes / No / No data).
If yes: Multiresistent Yes / No / No data
 - *Enterobacter spp* (Yes / No / No data).
If yes: Multiresistent Yes / No / No data
 - *Proteus mirabilis* (Yes / No / No data).
If yes: Multiresistent Yes / No / No data
 - Other (Yes / No / No data) (If yes, Specify _____).
 - If yes: Multiresistent Yes / No / No data
 - Polimicrobial (Yes / No / No data)
 - Fungus (Yes / No / No data)
 - Other (Yes / No / No data) (If yes, specify _____).

- Pleural fluid (Yes / No / No data); If yes:
 - Result: No data / Positive / Negative
 - If positive, isolated organism:
 - Gram positive (Yes / No / No data). If yes:
 - *Enterococcus faecalis* (Yes / No / No data).
If yes: Multiresistent Yes / No / No data
 - *Staphylococcus aureus* (Yes / No / No data).
If yes: Multiresistent Yes / No / No data
 - *Streptococcus pneumoniae* (Yes / No / No data).
If yes: Multiresistent Yes / No / No data
 - *Staphylococcus epidermidis* (Yes / No / No data).
If yes: Multiresistent Yes / No / No data
 - *Streptococcus viridans* (Yes / No / No data).
If yes: Multiresistent Yes / No / No data
 - Other (Yes / No / No data) (If yes, Specify _____).
 - If yes: Multiresistent Yes / No / No data
 - Gram negative (Yes / No / No data). If yes:
 - *Escherichia coli* (Yes / No / No data).
If yes: Multiresistent Yes / No / No data
 - *Pseudomonas aeruginosa* (Yes / No / No data).
If yes: Multiresistent Yes / No / No data
 - *Klebsiella pneumoniae* (Yes / No / No data).
If yes: Multiresistent Yes / No / No data
 - *Enterobacter spp* (Yes / No / No data).
If yes: Multiresistent Yes / No / No data
 - *Proteus mirabilis* (Yes / No / No data).
If yes: Multiresistent Yes / No / No data
 - Other (Yes / No / No data) (If yes, Specify _____).
 - If yes: Multiresistent Yes / No / No data
 - Polimicrobial (Yes / No / No data)
 - Fungus (Yes / No / No data)
 - Other (Yes / No / No data) (If yes, specify _____).

- Other (Yes / No / No data); If yes:
 - Specify _____
 - Result: No data / Positive / Negative
 - If positive, isolated organism:
 - Gram positive (Yes / No / No data). If yes:
 - *Enterococcus faecalis* (Yes / No / No data).
If yes: Multiresistent Yes / No / No data
 - *Staphylococcus aureus* (Yes / No / No data).
If yes: Multiresistent Yes / No / No data
 - *Streptococcus pneumoniae* (Yes / No / No data).
If yes: Multiresistent Yes / No / No data
 - *Staphylococcus epidermidis* (Yes / No / No data).
If yes: Multiresistent Yes / No / No data
 - *Streptococcus viridans* (Yes / No / No data).
If yes: Multiresistent Yes / No / No data
 - Other (Yes / No / No data) (If yes, Specify _____).
 - If yes: Multiresistent Yes / No / No data
 - Gram negative (Yes / No / No data). If yes:
 - *Escherichia coli* (Yes / No / No data).
If yes: Multiresistent Yes / No / No data
 - *Pseudomonas aeruginosa* (Yes / No / No data).
If yes: Multiresistent Yes / No / No data
 - *Klebsiella pneumoniae* (Yes / No / No data).
If yes: Multiresistent Yes / No / No data
 - *Enterobacter spp* (Yes / No / No data).
If yes: Multiresistent Yes / No / No data
 - *Proteus mirabilis* (Yes / No / No data).
If yes: Multiresistent Yes / No / No data
 - Other (Yes / No / No data) (If yes, Specify _____).
 - If yes: Multiresistent Yes / No / No data
 - Polimicrobial (Yes / No / No data)
 - Fungus (Yes / No / No data)
 - Other (Yes / No / No data) (If yes, specify _____).

Treatments administered between study inclusion and the onset of first extra-hepatic organ failure

Has the patient received any treatment between the study inclusion and the onset of first extra-hepatic organ failure? (Yes / No / No data). If yes, specify:

- Treatment for ascites (Yes / No / No data). If yes:
 - Paracentesis (Yes / No / No data). If yes
 - Total volume removed (L) _____
 - Total dose of Albumin dose (g) _____
 - Diuretics (Yes/No/ No data). If yes:
 - Spironolactone (Yes / No / No data); If yes:
Dose (mg/day) _____
 - Canrenoate (Yes / No / No data); If yes:
Dose (mg/day) _____
 - Furosemide (Yes / No / No data); If yes:
Dose (mg/day) _____
 - Hydroclorotiazide (Yes / No / No data); If yes:
Dose (mg/day) _____
 - Amiloride (Yes / No / No data); If yes:
Dose (mg/day) _____
 - Others (Yes / No / No data); If yes:
Specify _____
Dose (mg/day) _____

- Treatment for encephalopathy (Yes / No / No data). If yes:
 - Lactulose (Yes / No / No data); If yes, dose (g/day) _____
 - Rifaximin (Yes / No / No data); If yes, dose (mg/day) _____
 - Neomycin (Yes / No / No data); If yes, dose (mg/day) _____
 - Metronidazole (Yes / No / No data); If yes, dose (mg/day) _____
 - Others (Yes / No / No data); If yes:
Specify _____
Dose (mg/day) _____

- Treatment for GI-Bleeding (Yes / No / No data): If yes
 - Pharmacological treatment (Yes / No / No data). If yes:
 - Somatostatin (Yes / No / No data); If yes, dose (µg/h) _____
 - Terlipressin (Yes / No / No data); If yes, dose(mg/day) _____
 - Others (Yes / No / No data); If yes, specify _____
 - Endoscopic Therapy (Yes / No / No data). If yes:
 - Band ligation (Yes / No / No data)
 - Sclerotherapy of varices (Yes / No / No data)
 - Haemostasis of peptic lesion (Yes / No / No data)
 - TIPS (Yes / No / No data)
 - Others (Yes / No / No data); If yes, specify _____

- Treatment for infection (Yes / No / No data).
 If yes, choose one of the following:
 - Antibiotics alone:

Antibiotic 1 _____	; Dose: _____	Unit: _____
Antibiotic 2 _____	; Dose: _____	Unit: _____
Antibiotic 3 _____	; Dose: _____	Unit: _____
Antibiotic 4 _____	; Dose: _____	Unit: _____
Antibiotic 5 _____	; Dose: _____	Unit: _____

..... /
 - Antibiotics with albumin:

Albumin dose (g/day) _____

Antibiotic 1 _____	; Dose: _____	Unit: _____
Antibiotic 2 _____	; Dose: _____	Unit: _____
Antibiotic 3 _____	; Dose: _____	Unit: _____
Antibiotic 4 _____	; Dose: _____	Unit: _____
Antibiotic 5 _____	; Dose: _____	Unit: _____

..... /
 - No data

- Fluid therapy (Yes / No / No data). If yes:
 - Type:
 - Cristalloid (Yes / No / No data).
If Yes: Specify _____ / Average Volume (L/day) _____
 - Colloid (Yes / No / No data).
If Yes: Type _____ / Average Volume (L/day) _____
 - Albumin (Yes / No / No data).
If Yes:
 - Concentration (%): No data / 5 / 20 / 25
 - Average Volume (mL/day): _____
 - Indication:
 - Spontaneous bacterial peritonitis (Yes / No / No data)
 - Hepatorenal syndrome (Yes / No / No data)
 - Volume Replacement (Yes / No / No data)
 - Hepathic encephalopathy (Yes / No / No data)
 - Bleeding (Yes / No / No data)
 - Others (Yes / No / No data); If yes, specify _____

- Transfusion (Yes / No / No data). If yes
 - Red Blood cells (Yes / No / No data) If Yes: Blood units _____
 - Fresh frozen plasma (Yes / No / No data) If Yes: Units _____
 - Platelets (Yes / No / No data) If Yes: Volume (mL) _____
 - Crioprecipitate (Yes / No / No data) If Yes: Volume (mL) _____

- Vasoactive drugs (Yes / No / No data). If yes:
 - Indication: No data / Hepatorenal Syndrome / Sitemic Hemodinamic Support
 - Drug:
 - Terlipressin (Yes / No / No data); If yes, dose (mg/day) _____
 - Noradrenaline (Yes / No / No data); If yes, dose (µg/Kg/min) _____
 - Midodrine (Yes / No / No data); If yes, dose (mg/day) _____
 - Dopamine (Yes / No / No data); If yes, dose (µg/Kg/min) _____
 - Others (Yes / No / No data). If yes, specify _____

- Surgery (Yes / No / No data), If yes, specify _____

- Corticoids (Yes / No / No data). If yes:
 - No data / Prednisone / Prednisolone / Methylprednisolone / Hydrocortisone (dose, mg/day) _____

- Prophylaxis of bacterial infection (Yes / No / No data) If yes:
 - Type: No data / Primary / Secondary
 - Drugs: No data / Quinolones / Other-specify _____

- Prophylaxis of gastrointestinal bleeding (Yes / No / No data). If yes:
 - Type: No data / Primary / Secondary
 - Specify: No data / Propranolol / Nadolol / Carvedilol (dose, mg/day) _____

- Mechanical ventilation (Yes / No / No data); If yes:
 - Tidal volume (mL) _____
 - PEEP (cm H₂O) _____
 - FiO₂ (%) _____
 - PaO₂ _____ (mmHg) / _____ (kPa)
The PaO₂ / FiO₂ ratio will be calculated by the data-entry application.

- Renal replacement therapy (Yes / No / No data)

- Other (Yes / No / No data); If yes: specify _____

Scores

All scores except APACHE II will be derived from data introduced in the data-entry application.
Additional information for Lille and Cardiovascular SOFA-Subscore is required:

Lille's score information:

- Does the patient suffer from alcoholic hepatitis? (Yes / No / No data) If yes:

The Lille score can be calculated only if the patient has been under corticosteroid treatment for at least 7 days:

- Is it applicable to this visit? (Yes / No / No data) If yes:

The following parameters at Days 0 and 7 of treatment are required

- Bilirubin at day 0 (µmol/L) _____
- Bilirubin at day 7 (µmol/L) _____
- Creatinine at day 0 (µmol/L) _____

In patients who have received albumin infusions, use the last available albumin value before the infusion of albumin occurred. If albumin infusions are not received, enter 0.

- Albumin at day 0 (g/L) _____
- Patient's prothrombin time at day 0 (sec) _____

SOFA Subscores:

- **Cardiovascular Subscore information:**

- Dopamine (Yes / No / No data); If yes: Dose (µg/Kg/min) _____
- Dobutamine (Yes / No / No data)
- Terlipressin for Systemic Hemodynamic Support (Yes / No / No data)
- Epinephrine (Yes / No / No data); If yes: Dose (µg/Kg/min) _____
- Norepinephrine (Yes / No / No data); If yes: Dose (µg/Kg/min) _____

APACHE II score information:

- Has the patient been admitted to the ICU unit? (Yes / No / No data)
- Does the patient have arterial samples? (Yes / No / No data)

If at least one of the previous answers is YES please fill in:

- APACHE II _____

DAY 1

**(after study inclusion and during hospitalization for patients in Groups #1 and #2;
after the onset of 1st extra-hepatic organ failure and during hospitalization for
Group #4)**

Day 1 Date: ____ / ____ / ____

Time (24h): ____:____

Enrollment in other Prophylactic or Therapeutic Studies within this period

• Has the patient been included in a prophylactic or therapeutic study during this period (Yes / No / No data).

▪ If yes:

• Type of study:

No data

/ Prophylactic

/ Therapeutic

/ Non randomized

/ Randomized placebo-controlled

/ Randomized comparative

• Study treatment (specify _____)

• Control treatment (specify _____)

• Does the patient continue in the study after this period
(Yes / No / No data)?

Clinical features during the period

- Ascites (Yes / No / No data); If yes,
 - Type: No data / Mild to Moderate / Large - Tense
- Encephalopathy (Yes / No / No data); If yes:
 - Stage: West Haven score: No data / 1 / 2 / 3 / 4
- Renal failure (Yes / No / No data); If yes:
 - Renal failure type:
 - No data / HRS type I / HRS type II / Pre-renal / Other (specify _____) / Unknown / Still undetermined
- Bacterial infection (Yes / No / No data). If yes:
 - Timeframe of infection (choose one of the following):
 - No data /
 - New Infection /
 - Type of infection:
 - SBP (Yes / No / No data)
 - Pneumonia (Yes / No / No data)
 - Urinary tract infection (UTI) (Yes / No / No data)
 - Skin infection (Yes / No / No data)
 - Unproved suspected infection (Yes / No / No data)
 - Other (Yes / No / No data); If yes, specify _____
 - Sepsis (Yes / No / No data). If yes:
 - Sepsis category: No data / Sepsis Only / Severe sepsis / Septic shock
 - Time from infection (days) _____
 - Site of acquisition: No data / Community / Hospital
 - Infection under antibiotic treatment /
 - Therapeutic Response (Yes / No / No data)
 - Resolution of Infection (Yes / No / No data)

- Superinfection /
 - Type of infection:
 - SBP (Yes / No / No data)
 - Pneumonia (Yes / No / No data)
 - Urinary tract infection (UTI) (Yes / No / No data)
 - Skin infection (Yes / No / No data)
 - Unproved suspected infection (Yes / No / No data)
 - Other (Yes / No / No data); If yes, specify _____
 - Sepsis (Yes / No / No data). If yes:
Sepsis category: No data / Sepsis Only / Severe sepsis / Septic shock
 - Time from infection (days) _____
 - Site of acquisition: No data / Community / Hospital
- Gastrointestinal bleeding (Yes / No / No data);
 - Etiology:
 - Variceal bleeding (Yes / No / No data)
 - Peptic ulcer lesion (Yes / No / No data)
 - Portal hypertension non-variceal bleeding (Yes / No / No data)
 - Other causes (Yes / No / No data); If yes, specify _____
 - Unknown (Yes / No / No data)
 - GI-bleeding complicated by hypovolemic shock? (Yes / No / No data)
 - Resolution (Yes / No / No data);
- Others (Yes / No / No data), If yes, specify _____

Exploratory data

- Body weight (Kg) _____

- Arterial pressure:

Systolic Blood Pressure (mmHg) _____

Diastolic Blood Pressure (mmHg) _____

The mean arterial pressure (MAP) will be calculated by the data-entry application.

- Heart rate (beats/min) _____

- Axillary temperature (°C) _____

- Respiratory rate (breaths/min) _____

- Supplemental oxygen (Yes / No / No data);

- If No: FiO₂ will take the value "21%".

- If Yes: Delivery device (Choose one of the following):

- No data;

- Nasal catheter; If chosen: Flow (liters of O₂ / min): 1 / 2 / 3 / 4 / 5 / 6+

- Face mask with reservoir; If chosen: Flow (liters of O₂ / min): 6 / 7 / 8 / 9 / 10+

- Venturi mask; If chosen: Flow (liters of O₂ / min): 4 / 8 / 12+

- SpO₂ (%) _____

The SpO₂ / FiO₂ ratio will be calculated by the data-entry application.

- Urine volume (mL/h) _____

- Chest X-ray (Normal / Abnormal / No data); If Abnormal:

Specify _____

Laboratory data

- Hematocrit _____ (%)
- Hemoglobin level _____ (g/dL) / _____ (g/L)
- White Blood Cells count _____ (x 10⁹ cells/L) / _____ (x cells/mm³)
- % immature neutrophils (bands) _____ (%)
- Platelet count _____ (x 10³/μL) / _____ (x 10⁹/L)
- Total serum bilirubin _____ (mg/dL) / _____ (μmol/L)
- Serum albumin _____ (g/dL) / _____ (g/L)
- Control prothrombin time _____ (sec)
- Prothrombin time _____ (sec)
- % of Control _____ (%)
- INR _____
- Activated partial-thromboplastin time ratio _____
- ALT _____ (U/L) / _____ (μkat/L)
- AST _____ (U/L) / _____ (μkat/L)
- AP _____ (U/L) / _____ (μkat/L)
- GGT _____ (U/L)
- Blood glucose _____ (mg/dL) / _____ (mmol/L)
- When needed:
 - Supplemental oxygen (Yes / No / No data);
 - If No: FiO₂ will take the value "21%".
 - If Yes: Delivery device (Choose one of the following):
 - No data;
 - Nasal catheter; If chosen: Flow (liters of O₂ / min): 1 / 2 / 3 / 4 / 5 / 6+
 - Face mask with reservoir; If chosen: Flow (liters of O₂ / min): 6 / 7 / 8 / 9 / 10+
 - Venturi mask; If chosen: Flow (liters of O₂ / min): 4 / 8 / 12+
 - PaO₂ _____ (mmHg) / _____ (kPa)
 - Arterial pH _____
 - PaCO₂ _____ (mmHg) / _____ (kPa)
 - Serum bicarbonate _____ (mEq/L) / _____ (mmol/L)
 - Serum lactate _____ (mg/dL) / _____ (mmol/L)

The PaO₂ / FiO₂ ratio will be calculated by the data-entry application.
- Plasma C-reactive protein _____ (mg/L)
- Serum creatinine _____ (mg/dL) / _____ (μmol/L)
- Blood urea nitrogen _____ (mg/dL) / _____ (mmol/L)
- Serum sodium _____ (mEq/L) / _____ (mmol/L)
- Serum potassium _____ (mEq/L) / _____ (mmol/L)
- Urine sodium concentration _____ (mEq/L) / _____ (mmol/L)
- Urine creatinine concentration _____ (mg/dL) / _____ (μmol/L)
- Proteinuria (dipstick test: No data / Absent / Trace, 1+, 2+, 3+, 4+)
- Hematuria: Yes / No / No data (If yes, cells / HPF: No data / <10 / 11-20 / 21-50 / >50)
- Ascitic fluid total protein concentration _____ (g/dL) / _____ (g/L)
- Ascitic fluid neutrophil count _____ (Cells/mL)

Microbiological data (only in patients with infections)

- Culture done (sample taken):
 - Ascitic fluid (Yes / No / No data); If yes:
 - Result: No data / Positive / Negative
 - If positive, isolated organism:
 - Gram positive (Yes / No / No data). If yes:
 - *Enterococcus faecalis* (Yes / No / No data).
If yes: Multiresistent Yes / No / No data
 - *Staphylococcus aureus* (Yes / No / No data).
If yes: Multiresistent Yes / No / No data
 - *Streptococcus pneumoniae* (Yes / No / No data).
If yes: Multiresistent Yes / No / No data
 - *Staphylococcus epidermidis* (Yes / No / No data).
If yes: Multiresistent Yes / No / No data
 - *Streptococcus viridans* (Yes / No / No data).
If yes: Multiresistent Yes / No / No data
 - Other (Yes / No / No data) (If yes, Specify _____).
 - If yes: Multiresistent Yes / No / No data
 - Gram negative (Yes / No / No data). If yes:
 - *Escherichia coli* (Yes / No / No data).
If yes: Multiresistent Yes / No / No data
 - *Pseudomonas aeruginosa* (Yes / No / No data).
If yes: Multiresistent Yes / No / No data
 - *Klebsiella pneumoniae* (Yes / No / No data).
If yes: Multiresistent Yes / No / No data
 - *Enterobacter spp* (Yes / No / No data).
If yes: Multiresistent Yes / No / No data
 - *Proteus mirabilis* (Yes / No / No data).
If yes: Multiresistent Yes / No / No data
 - Other (Yes / No / No data) (If yes, Specify _____).
 - If yes: Multiresistent Yes / No / No data
- Polimicrobial (Yes / No / No data)
- Fungus (Yes / No / No data)
- Other (Yes / No / No data) (If yes, specify _____).

- Blood (Yes / No / No data); If yes:
 - Result: No data / Positive / Negative
 - If positive, isolated organism:
 - Gram positive (Yes / No / No data). If yes:
 - *Enterococcus faecalis* (Yes / No / No data).
If yes: Multiresistant Yes / No / No data
 - *Staphylococcus aureus* (Yes / No / No data).
If yes: Multiresistant Yes / No / No data
 - *Streptococcus pneumoniae* (Yes / No / No data).
If yes: Multiresistant Yes / No / No data
 - *Staphylococcus epidermidis* (Yes / No / No data).
If yes: Multiresistant Yes / No / No data
 - *Streptococcus viridans* (Yes / No / No data).
If yes: Multiresistant Yes / No / No data
 - Other (Yes / No / No data) (If yes, Specify _____).
 - If yes: Multiresistant Yes / No / No data
 - Gram negative (Yes / No / No data). If yes:
 - *Escherichia coli* (Yes / No / No data).
If yes: Multiresistant Yes / No / No data
 - *Pseudomonas aeruginosa* (Yes / No / No data).
If yes: Multiresistant Yes / No / No data
 - *Klebsiella pneumoniae* (Yes / No / No data).
If yes: Multiresistant Yes / No / No data
 - *Enterobacter spp* (Yes / No / No data).
If yes: Multiresistant Yes / No / No data
 - *Proteus mirabilis* (Yes / No / No data).
If yes: Multiresistant Yes / No / No data
 - Other (Yes / No / No data) (If yes, Specify _____).
 - If yes: Multiresistant Yes / No / No data
 - Polimicrobial (Yes / No / No data)
 - Fungus (Yes / No / No data)
 - Other (Yes / No / No data) (If yes, specify _____).

- Urine (Yes / No / No data); If yes:
 - Result: No data / Positive / Negative
 - If positive, isolated organism:
 - Gram positive (Yes / No / No data). If yes:
 - *Enterococcus faecalis* (Yes / No / No data).
If yes: Multiresistant Yes / No / No data
 - *Staphylococcus aureus* (Yes / No / No data).
If yes: Multiresistant Yes / No / No data
 - *Streptococcus pneumoniae* (Yes / No / No data).
If yes: Multiresistant Yes / No / No data
 - *Staphylococcus epidermidis* (Yes / No / No data).
If yes: Multiresistant Yes / No / No data
 - *Streptococcus viridans* (Yes / No / No data).
If yes: Multiresistant Yes / No / No data
 - Other (Yes / No / No data) (If yes, Specify _____).
 - If yes: Multiresistant Yes / No / No data
 - Gram negative (Yes / No / No data). If yes:
 - *Escherichia coli* (Yes / No / No data).
If yes: Multiresistant Yes / No / No data
 - *Pseudomonas aeruginosa* (Yes / No / No data).
If yes: Multiresistant Yes / No / No data
 - *Klebsiella pneumoniae* (Yes / No / No data).
If yes: Multiresistant Yes / No / No data
 - *Enterobacter spp* (Yes / No / No data).
If yes: Multiresistant Yes / No / No data
 - *Proteus mirabilis* (Yes / No / No data).
If yes: Multiresistant Yes / No / No data
 - Other (Yes / No / No data) (If yes, Specify _____).
 - If yes: Multiresistant Yes / No / No data
 - Polimicrobial (Yes / No / No data)
 - Fungus (Yes / No / No data)
 - Other (Yes / No / No data) (If yes, specify _____).

- Pleural fluid (Yes / No / No data); If yes:
 - Result: No data / Positive / Negative
 - If positive, isolated organism:
 - Gram positive (Yes / No / No data). If yes:
 - *Enterococcus faecalis* (Yes / No / No data).
If yes: Multiresistant Yes / No / No data
 - *Staphylococcus aureus* (Yes / No / No data).
If yes: Multiresistant Yes / No / No data
 - *Streptococcus pneumoniae* (Yes / No / No data).
If yes: Multiresistant Yes / No / No data
 - *Staphylococcus epidermidis* (Yes / No / No data).
If yes: Multiresistant Yes / No / No data
 - *Streptococcus viridans* (Yes / No / No data).
If yes: Multiresistant Yes / No / No data
 - Other (Yes / No / No data) (If yes, Specify _____).
 - If yes: Multiresistant Yes / No / No data
 - Gram negative (Yes / No / No data). If yes:
 - *Escherichia coli* (Yes / No / No data).
If yes: Multiresistant Yes / No / No data
 - *Pseudomonas aeruginosa* (Yes / No / No data).
If yes: Multiresistant Yes / No / No data
 - *Klebsiella pneumoniae* (Yes / No / No data).
If yes: Multiresistant Yes / No / No data
 - *Enterobacter spp* (Yes / No / No data).
If yes: Multiresistant Yes / No / No data
 - *Proteus mirabilis* (Yes / No / No data).
If yes: Multiresistant Yes / No / No data
 - Other (Yes / No / No data) (If yes, Specify _____).
 - If yes: Multiresistant Yes / No / No data
 - Polimicrobial (Yes / No / No data)
 - Fungus (Yes / No / No data)
 - Other (Yes / No / No data) (If yes, specify _____).

- Other (Yes / No / No data); If yes:
 - Specify: _____
 - Result: No data / Positive / Negative
 - If positive, isolated organism:
 - Gram positive (Yes / No / No data). If yes:
 - *Enterococcus faecalis* (Yes / No / No data).
If yes: Multiresistent Yes / No / No data
 - *Staphylococcus aureus* (Yes / No / No data).
If yes: Multiresistent Yes / No / No data
 - *Streptococcus pneumoniae* (Yes / No / No data).
If yes: Multiresistent Yes / No / No data
 - *Staphylococcus epidermidis* (Yes / No / No data).
If yes: Multiresistent Yes / No / No data
 - *Streptococcus viridans* (Yes / No / No data).
If yes: Multiresistent Yes / No / No data
 - Other (Yes / No / No data) (If yes, Specify _____).
 - If yes: Multiresistent Yes / No / No data
 - Gram negative (Yes / No / No data). If yes:
 - *Escherichia coli* (Yes / No / No data).
If yes: Multiresistent Yes / No / No data
 - *Pseudomonas aeruginosa* (Yes / No / No data).
If yes: Multiresistent Yes / No / No data
 - *Klebsiella pneumoniae* (Yes / No / No data).
If yes: Multiresistent Yes / No / No data
 - *Enterobacter spp* (Yes / No / No data).
If yes: Multiresistent Yes / No / No data
 - *Proteus mirabilis* (Yes / No / No data).
If yes: Multiresistent Yes / No / No data
 - Other (Yes / No / No data) (If yes, Specify _____).
 - If yes: Multiresistent Yes / No / No data
- Polimicrobial (Yes / No / No data)
- Fungus (Yes / No / No data)
- Other (Yes / No / No data) (If yes, specify _____).

Treatments administered within the period

Has the patient received any treatment during this period? (Yes / No / No data).

If yes, specify:

- Treatment for ascites (Yes / No / No data). If yes:
 - Paracentesis (Yes / No / No data). If yes
 - Total volume removed (L) _____
 - Total dose of Albumin dose (g) _____
 - Diuretics (Yes/No/ No data). If yes:
 - Spironolactone (Yes / No / No data); If yes:
Dose (mg/day) _____
 - Canrenoate (Yes / No / No data); If yes:
Dose (mg/day) _____
 - Furosemide (Yes / No / No data); If yes:
Dose (mg/day) _____
 - Hydrochlorotiazide (Yes / No / No data); If yes:
Dose (mg/day) _____
 - Amiloride (Yes / No / No data); If yes:
Dose (mg/day) _____
 - Others (Yes / No / No data); If yes:
Specify _____
Dose (mg/day) _____

- Treatment for encephalopathy (Yes / No / No data). If yes:
 - Lactulose (Yes / No / No data); If yes, dose (g/day) _____
 - Rifaximin (Yes / No / No data); If yes, dose (mg/day) _____
 - Neomycin (Yes / No / No data); If yes, dose (mg/day) _____
 - Metronidazole (Yes / No / No data); If yes, dose (mg/day) _____
 - Others (Yes / No / No data); If yes:
Specify _____
Dose (mg/day) _____

- Treatment for GI-Bleeding (Yes / No / No data): If yes
 - Pharmacological treatment (Yes / No / No data). If yes:
 - Somatostatin (Yes / No / No data); If yes, dose ($\mu\text{g/h}$) _____
 - Terlipressin (Yes / No / No data); If yes, dose(mg/day) _____
 - Others (Yes / No / No data); If yes, specify _____
 - Endoscopic Therapy (Yes / No / No data). If yes:
 - Band ligation (Yes / No / No data)
 - Sclerotherapy of varices (Yes / No / No data)
 - Haemostasis of peptic lesion (Yes / No / No data)
 - TIPS (Yes / No / No data)
 - Others (Yes / No / No data); If yes, specify _____

- Treatment for infection (Yes / No / No data).

If yes, choose one of the following:

- Antibiotics alone:

Antibiotic 1 _____; Dose: _____ Unit: _____

Antibiotic 2 _____; Dose: _____ Unit: _____

Antibiotic 3 _____; Dose: _____ Unit: _____

Antibiotic 4 _____; Dose: _____ Unit: _____

Antibiotic 5 _____; Dose: _____ Unit: _____

.....
 /

- Antibiotics with albumin:

Albumin dose (g/day) _____

Antibiotic 1 _____; Dose: _____ Unit: _____

Antibiotic 2 _____; Dose: _____ Unit: _____

Antibiotic 3 _____; Dose: _____ Unit: _____

Antibiotic 4 _____; Dose: _____ Unit: _____

Antibiotic 5 _____; Dose: _____ Unit: _____

.....
 /

- No data

- Fluid therapy (Yes / No / No data). If yes:
 - Type:
 - Cristalloid (Yes / No / No data).
If Yes: Specify _____ / Average Volume (L/day) _____
 - Colloid (Yes / No / No data).
If Yes: Type _____ / Average Volume (L/day) _____
 - Albumin (Yes / No / No data).
If Yes:
 - Concentration (%): No data / 5 / 20 / 25
 - Average Volume (mL/day): _____
 - Indication:
 - Spontaneous bacterial peritonitis (Yes / No / No data)
 - Hepatorenal syndrome (Yes / No / No data)
 - Volume Replacement (Yes / No / No data)
 - Hepatic encephalopathy (Yes / No / No data)
 - Bleeding (Yes / No / No data)
 - Others (Yes / No / No data); If yes, specify _____

- Transfusion (Yes / No / No data). If yes
 - Red Blood cells (Yes / No / No data) If Yes: Blood units _____
 - Fresh frozen plasma (Yes / No / No data) If Yes: Units _____
 - Platelets (Yes / No / No data) If Yes: Volume (mL) _____
 - Crioprecipitate (Yes / No / No data) If Yes: Volume (mL) _____

- Vasoactive drugs (Yes / No / No data). If yes:
 - Indication: No data / Hepatorenal Syndrome / Systemic Hemodynamic Support
 - Drug:
 - Terlipressin (Yes / No / No data); If yes, dose (mg/day) _____
 - Noradrenaline (Yes / No / No data); If yes, dose ($\mu\text{g}/\text{Kg}/\text{min}$) _____
 - Midodrine (Yes / No / No data); If yes, dose (mg/day) _____
 - Dopamine (Yes / No / No data); If yes, dose ($\mu\text{g}/\text{Kg}/\text{min}$) _____
 - Others (Yes / No / No data). If yes, specify _____

- Surgery (Yes / No / No data), If yes, specify _____

- Corticoids (Yes / No / No data). If yes:
 - No data / Prednisone / Prednisolone / Methylprednisolone / Hydrocortisone (dose, mg/day) _____

- Prophylaxis of bacterial infection (Yes / No / No data) If yes:
 - Type: No data / Primary / Secondary
 - Drugs: No data / Quinolones / Other-specify _____

- Prophylaxis of gastrointestinal bleeding (Yes / No / No data). If yes:
 - Type: No data / Primary / Secondary
 - Specify: No data / Propranolol / Nadolol / Carvedilol (dose, mg/day) _____

- Mechanical ventilation (Yes / No / No data); If yes:
 - Tidal volume (mL) _____
 - PEEP (cm H₂O) _____
 - FiO₂ (%) _____
 - PaO₂ _____ (mmHg) / _____ (kPa)
The PaO₂ / FiO₂ ratio will be calculated by the data-entry application.

- Renal replacement therapy (Yes / No / No data)

- Other (Yes / No / No data); If yes: specify _____

Scores

All scores except APACHE II will be derived from data introduced in the data-entry application. Additional information for Lille and Cardiovascular SOFA-Subscore is required:

Lille's score information:

- Does the patient suffer from alcoholic hepatitis? (Yes / No / No data) If yes:

The Lille score can be calculated only if the patient has been under corticosteroid treatment for at least 7 days:

- Is it applicable to this visit? (Yes / No / No data) If yes:

The following parameters at Days 0 and 7 of treatment are required

- Bilirubin at day 0 ($\mu\text{mol/L}$) _____
- Bilirubin at day 7 ($\mu\text{mol/L}$) _____
- Creatinine at day 0 ($\mu\text{mol/L}$) _____

In patients who have received albumin infusions, use the last available albumin value before the infusion of albumin occurred. If albumin infusions are not received, enter 0.

- Albumin at day 0 (g/L) _____
- Patient's prothrombin time at day 0 (sec) _____

SOFA Subscores:

- **Cardiovascular Subscore information:**

- Dopamine (Yes / No / No data); If yes: Dose ($\mu\text{g/Kg/min}$) _____
- Dobutamine (Yes / No / No data)
- Terlipressin for Systemic Hemodynamic Support (Yes / No / No data)
- Epinephrine (Yes / No / No data); If yes: Dose ($\mu\text{g/Kg/min}$) _____
- Norepinephrine (Yes / No / No data); If yes: Dose ($\mu\text{g/Kg/min}$) _____

APACHE II score information:

- Has the patient been admitted to the ICU unit? (Yes / No / No data)
- Does the patient have arterial samples? (Yes / No / No data)

If at least one of the previous answers is YES please fill in:

- APACHE II _____

Place and clinical course of patient at the end of the period

- ICU (Yes / No / No data). If yes:
 - Number of days in the ICU _____
- Ward (Yes / No / No data)
- Discharged (Yes / No / No data); If yes: Date ____ / ____ / _____
- Discharged and re-admitted (Yes / No / No data); If yes: Date ____ / ____ / _____
- **Alive / Dead / No data**
 - If Dead:
 - **Date of exitus ____ / ____ / _____**
 - Causes of death:
 - Hepatocellular carcinoma (Yes / No / No data)
 - Hypovolemic shock (Yes / No / No data)
 - Septic shock (Yes / No / No data)
 - Multiorgan failure in the absence of hypovolemic or septic shock (Yes / No / No data). If yes:
 - Organ failures:
 - Hepatic (Yes / No / No data)
 - Renal (Yes / No / No data)
 - Cerebral (Yes / No / No data)
 - Respiratory (Yes / No / No data)
 - Cardiac (Yes / No / No data)
 - Coagulation (Yes / No / No data).
 - Multiorgan failure after recovering from hypovolemic shock (Yes / No / No data). If yes:
 - Organ failures:
 - Hepatic (Yes / No / No data)
 - Renal (Yes / No / No data)
 - Cerebral (Yes / No / No data)
 - Respiratory (Yes / No / No data)
 - Cardiac (Yes / No / No data)
 - Coagulation (Yes / No / No data).
 - Multiorgan failure after recovering from septic shock (Yes / No / No data). If yes:
 - Organ failures:
 - Hepatic (Yes / No / No data)
 - Renal (Yes / No / No data)
 - Cerebral (Yes / No / No data)
 - Respiratory (Yes / No / No data)
 - Cardiac (Yes / No / No data)
 - Coagulation (Yes / No / No data).
 - Other (Yes / No / No data); If yes, specify _____
 - Unknown (Yes / No / No data)

- If Alive:
 - Patient transplanted (Yes / No / No data); If yes: Date ____ / ____ / ____
 - Patient's evolution:
 - No data
 - Cured (complete resolution of all specific complications)
 - Better (partial resolution of all specific complications or complete resolution of some complications)
 - Stable (complications not resolved)
 - Worse (worsening of all complications or development of new ones)

Biological samples scheduled for this visit

- Were **plasma** samples taken? (Yes / No / No data). If yes: Date ____ / ____ / ____.
- Were **blood** samples taken? (Yes / No / No data). If yes: Date ____ / ____ / ____.
- Were **urine** samples taken? (Yes / No / No data). If yes: Date ____ / ____ / ____.
- Were **ascitis fluid** samples taken? (Yes / No / No data). If yes: Date ____ / ____ / ____.
- Was **liver biopsy** performed? (Yes / No / No data). If yes: Date ____ / ____ / ____.

For patient Groups #1, #2 and #4, samples can be taken at Day 1 or alternatively at 2.

For patient Group #3, samples will be taken only at Day 1 or alternatively at Day 2.

SAMPLES COLLECTION DATA FOR DAY 1 OR 2 SHOULD BE ENTERED IN DAY 2 WINDOW INTO THE DATA-ENTRY APPLICATION.

DAY 2

**(after study inclusion and during hospitalization for patients in Groups #1 and #2;
after the onset of 1st extra-hepatic organ failure and during hospitalization for
Group #4)**

Day 2 Date: ____ / ____ / ____

Time (24h): ____ : ____

Enrollment in Other Prophylactic or Therapeutic Studies within this period

• Has the patient been included in a prophylactic or therapeutic study during this period (Yes / No / No data).

▪ If yes:

• Type of study:

No data

/ Prophylactic

/ Therapeutic

/ Non randomized

/ Randomized placebo-controlled

/ Randomized comparative

• Study treatment (specify _____)

• Control treatment (specify _____)

• Does the patient continue in the study after this period
(Yes / No / No data)?

Clinical features during the period

- Ascites (Yes / No / No data); If yes,
 - Type: No data / Mild to Moderate / Large - Tense
- Encephalopathy (Yes / No / No data); If yes:
 - Stage: West Haven score: No data / 1 / 2 / 3 / 4
- Renal failure (Yes / No / No data); If yes:
 - Renal failure type:
 - No data / HRS type I / HRS type II / Pre-renal / Other (specify _____) / Unknown / Still undetermined
- Bacterial infection (Yes / No / No data). If yes:
 - Timeframe of infection (choose one of the following):
 - No data /
 - New Infection /
 - Type of infection:
 - SBP (Yes / No / No data)
 - Pneumonia (Yes / No / No data)
 - Urinary tract infection (UTI) (Yes / No / No data)
 - Skin infection (Yes / No / No data)
 - Unproved suspected infection (Yes / No / No data)
 - Other (Yes / No / No data); If yes, specify _____
 - Sepsis (Yes / No / No data). If yes:
 - Sepsis category: No data / Sepsis Only / Severe sepsis / Septic shock
 - Time from infection (days) _____
 - Site of acquisition: No data / Community / Hospital
 - Infection under antibiotic treatment /
 - Therapeutic Response (Yes / No / No data)
 - Resolution of Infection (Yes / No / No data)

- Superinfection /
 - Type of infection:
 - SBP (Yes / No / No data)
 - Pneumonia (Yes / No / No data)
 - Urinary tract infection (UTI) (Yes / No / No data)
 - Skin infection (Yes / No / No data)
 - Unproved suspected infection (Yes / No / No data)
 - Other (Yes / No / No data); If yes, specify _____
 - Sepsis (Yes / No / No data). If yes:
 - Sepsis category: No data / Sepsis Only / Severe sepsis / Septic shock
 - Time from infection (days) _____
 - Site of acquisition: No data / Community / Hospital
- Gastrointestinal bleeding (Yes / No / No data);
 - Etiology:
 - Variceal bleeding (Yes / No / No data)
 - Peptic ulcer lesion (Yes / No / No data)
 - Portal hypertension non-variceal bleeding (Yes / No / No data)
 - Other causes (Yes / No / No data); If yes, specify _____
 - Unknown (Yes / No / No data)
 - GI-bleeding complicated by hypovolemic shock? (Yes / No / No data)
 - Resolution (Yes / No / No data);
- Others (Yes / No / No data), If yes, specify _____

Exploratory data

- Body weight (Kg) _____

- Arterial pressure:

Systolic Blood Pressure (mmHg) _____

Diastolic Blood Pressure (mmHg) _____

The mean arterial pressure (MAP) will be calculated by the data-entry application.

- Heart rate (beats/min) _____

- Axillary temperature ($^{\circ}\text{C}$) _____

- Respiratory rate (breaths/min) _____

- Supplemental oxygen (Yes / No / No data);

- If No: FiO_2 will take the value "21%".

- If Yes: Delivery device (Choose one of the following):

- No data;

- Nasal catheter; If chosen: Flow (liters of O_2 / min): 1 / 2 / 3 / 4 / 5 / 6+

- Face mask with reservoir; If chosen: Flow (liters of O_2 / min): 6 / 7 / 8 / 9 / 10+

- Venturi mask; If chosen: Flow (liters of O_2 / min): 4 / 8 / 12+

- SpO_2 (%) _____

The SpO_2 / FiO_2 ratio will be calculated by the data-entry application.

- Urine volume (mL/h) _____

- Chest X-ray (Normal / Abnormal / No data); If Abnormal:

Specify _____

Laboratory data

- Hematocrit _____ (%)
- Hemoglobin level _____ (g/dL) / _____ (g/L)
- White Blood Cells count _____ (x 10⁹ cells/L) / _____ (x cells/mm³)
- % immature neutrophils (bands) _____ (%)
- Platelet count _____ (x 10³/μL) / _____ (x 10⁹/L)
- Total serum bilirubin _____ (mg/dL) / _____ (μmol/L)
- Serum albumin _____ (g/dL) / _____ (g/L)
- Control prothrombin time _____ (sec)
- Prothrombin time _____ (sec)
- % of Control _____ (%)
- **INR**
- Activated partial-thromboplastin time ratio _____
- ALT _____ (U/L) / _____ (μkat/L)
- AST _____ (U/L) / _____ (μkat/L)
- AP _____ (U/L) / _____ (μkat/L)
- GGT _____ (U/L)
- Blood glucose _____ (mg/dL) / _____ (mmol/L)
- When needed:
 - Supplemental oxygen (Yes / No / No data);
 - If No: FiO₂ will take the value "21%".
 - If Yes: Delivery device (Choose one of the following):
 - No data;
 - Nasal catheter; If chosen: Flow (liters of O₂ / min): 1 / 2 / 3 / 4 / 5 / 6+
 - Face mask with reservoir; If chosen: Flow (liters of O₂ / min): 6 / 7 / 8 / 9 / 10+
 - Venturi mask; If chosen: Flow (liters of O₂ / min): 4 / 8 / 12+
 - PaO₂ _____ (mmHg) / _____ (kPa)
 - Arterial pH _____
 - PaCO₂ _____ (mmHg) / _____ (kPa)
 - Serum bicarbonate _____ (mEq/L) / _____ (mmol/L)
 - Serum lactate _____ (mg/dL) / _____ (mmol/L)

The PaO₂ / FiO₂ ratio will be calculated by the data-entry application.
- Plasma C-reactive protein _____ (mg/L)
- Serum creatinine _____ (mg/dL) / _____ (μmol/L)
- Blood urea nitrogen _____ (mg/dL) / _____ (mmol/L)
- Serum sodium _____ (mEq/L) / _____ (mmol/L)
- Serum potassium _____ (mEq/L) / _____ (mmol/L)
- Urine sodium concentration _____ (mEq/L) / _____ (mmol/L)
- Urine creatinine concentration _____ (mg/dL) / _____ (μmol/L)
- Proteinuria (dipstick test: No data / Absent / Trace / 1+ / 2+ / 3+ / 4+)
- Hematuria: Yes / No / No data (If yes, cells / HPF: No data / <10 / 11-20 / 21-50 / >50)
- Ascitic fluid total protein concentration _____ (g/dL) / _____ (g/L)
- Ascitic fluid neutrophil count _____ (Cells/mL)

Microbiological data (only in patients with infections)

- Culture done (sample taken):
 - Ascitic fluid (Yes / No / No data); If yes:
 - Result: No data / Positive / Negative
 - If positive, isolated organism:
 - Gram positive (Yes / No / No data). If yes:
 - *Enterococcus faecalis* (Yes / No / No data).
If yes: Multiresistent Yes / No / No data
 - *Staphylococcus aureus* (Yes / No / No data).
If yes: Multiresistent Yes / No / No data
 - *Streptococcus pneumoniae* (Yes / No / No data).
If yes: Multiresistent Yes / No / No data
 - *Staphylococcus epidermidis* (Yes / No / No data).
If yes: Multiresistent Yes / No / No data
 - *Streptococcus viridans* (Yes / No / No data).
If yes: Multiresistent Yes / No / No data
 - Other (Yes / No / No data) (If yes, Specify _____).
 - If yes: Multiresistent Yes / No / No data
 - Gram negative (Yes / No / No data). If yes:
 - *Escherichia coli* (Yes / No / No data).
If yes: Multiresistent Yes / No / No data
 - *Pseudomonas aeruginosa* (Yes / No / No data).
If yes: Multiresistent Yes / No / No data
 - *Klebsiella pneumoniae* (Yes / No / No data).
If yes: Multiresistent Yes / No / No data
 - *Enterobacter spp* (Yes / No / No data).
If yes: Multiresistent Yes / No / No data
 - *Proteus mirabilis* (Yes / No / No data).
If yes: Multiresistent Yes / No / No data
 - Other (Yes / No / No data) (If yes, Specify _____).
 - If yes: Multiresistent Yes / No / No data
- Polimicrobial (Yes / No / No data)
- Fungus (Yes / No / No data)
- Other (Yes / No / No data) (If yes, specify _____).

- Blood (Yes / No / No data); If yes:
 - Result: No data / Positive / Negative
 - If positive, isolated organism:
 - Gram positive (Yes / No / No data). If yes:
 - *Enterococcus faecalis* (Yes / No / No data).
If yes: Multiresistent Yes / No / No data
 - *Staphylococcus aureus* (Yes / No / No data).
If yes: Multiresistent Yes / No / No data
 - *Streptococcus pneumoniae* (Yes / No / No data).
If yes: Multiresistent Yes / No / No data
 - *Staphylococcus epidermidis* (Yes / No / No data).
If yes: Multiresistent Yes / No / No data
 - *Streptococcus viridans* (Yes / No / No data).
If yes: Multiresistent Yes / No / No data
 - Other (Yes / No / No data) (If yes, Specify _____).
 - If yes: Multiresistent Yes / No / No data
 - Gram negative (Yes / No / No data). If yes:
 - *Escherichia coli* (Yes / No / No data).
If yes: Multiresistent Yes / No / No data
 - *Pseudomonas aeruginosa* (Yes / No / No data).
If yes: Multiresistent Yes / No / No data
 - *Klebsiella pneumoniae* (Yes / No / No data).
If yes: Multiresistent Yes / No / No data
 - *Enterobacter spp* (Yes / No / No data).
If yes: Multiresistent Yes / No / No data
 - *Proteus mirabilis* (Yes / No / No data).
If yes: Multiresistent Yes / No / No data
 - Other (Yes / No / No data) (If yes, Specify _____).
 - If yes: Multiresistent Yes / No / No data
- Polimicrobial (Yes / No / No data)
- Fungus (Yes / No / No data)
- Other (Yes / No / No data) (If yes, specify _____).

- Urine (Yes / No / No data); If yes:
 - Result: No data / Positive / Negative
 - If positive, isolated organism:
 - Gram positive (Yes / No / No data). If yes:
 - *Enterococcus faecalis* (Yes / No / No data).
If yes: Multiresistant Yes / No / No data
 - *Staphylococcus aureus* (Yes / No / No data).
If yes: Multiresistant Yes / No / No data
 - *Streptococcus pneumoniae* (Yes / No / No data).
If yes: Multiresistant Yes / No / No data
 - *Staphylococcus epidermidis* (Yes / No / No data).
If yes: Multiresistant Yes / No / No data
 - *Streptococcus viridans* (Yes / No / No data).
If yes: Multiresistant Yes / No / No data
 - Other (Yes / No / No data) (If yes, Specify _____).
 - If yes: Multiresistant Yes / No / No data
 - Gram negative (Yes / No / No data). If yes:
 - *Escherichia coli* (Yes / No / No data).
If yes: Multiresistant Yes / No / No data
 - *Pseudomonas aeruginosa* (Yes / No / No data).
If yes: Multiresistant Yes / No / No data
 - *Klebsiella pneumoniae* (Yes / No / No data).
If yes: Multiresistant Yes / No / No data
 - *Enterobacter spp* (Yes / No / No data).
If yes: Multiresistant Yes / No / No data
 - *Proteus mirabilis* (Yes / No / No data).
If yes: Multiresistant Yes / No / No data
 - Other (Yes / No / No data) (If yes, Specify _____).
 - If yes: Multiresistant Yes / No / No data
 - Polimicrobial (Yes / No / No data)
 - Fungus (Yes / No / No data)
 - Other (Yes / No / No data) (If yes, specify _____).

- Pleural fluid (Yes / No / No data); If yes:
 - Result: No data / Positive / Negative
 - If positive, isolated organism:
 - Gram positive (Yes / No / No data). If yes:
 - *Enterococcus faecalis* (Yes / No / No data).
If yes: Multiresistant Yes / No / No data
 - *Staphylococcus aureus* (Yes / No / No data).
If yes: Multiresistant Yes / No / No data
 - *Streptococcus pneumoniae* (Yes / No / No data).
If yes: Multiresistant Yes / No / No data
 - *Staphylococcus epidermidis* (Yes / No / No data).
If yes: Multiresistant Yes / No / No data
 - *Streptococcus viridans* (Yes / No / No data).
If yes: Multiresistant Yes / No / No data
 - Other (Yes / No / No data) (If yes, Specify _____).
 - If yes: Multiresistant Yes / No / No data
 - Gram negative (Yes / No / No data). If yes:
 - *Escherichia coli* (Yes / No / No data).
If yes: Multiresistant Yes / No / No data
 - *Pseudomonas aeruginosa* (Yes / No / No data).
If yes: Multiresistant Yes / No / No data
 - *Klebsiella pneumoniae* (Yes / No / No data).
If yes: Multiresistant Yes / No / No data
 - *Enterobacter spp* (Yes / No / No data).
If yes: Multiresistant Yes / No / No data
 - *Proteus mirabilis* (Yes / No / No data).
If yes: Multiresistant Yes / No / No data
 - Other (Yes / No / No data) (If yes, Specify _____).
 - If yes: Multiresistant Yes / No / No data
 - Polimicrobial (Yes / No / No data)
 - Fungus (Yes / No / No data)
 - Other (Yes / No / No data) (If yes, specify _____).

- Other (Yes / No / No data); If yes:
 - Specify: _____
 - Result: No data / Positive / Negative
 - If positive, isolated organism:
 - Gram positive (Yes / No / No data). If yes:
 - *Enterococcus faecalis* (Yes / No / No data).
If yes: Multiresistent Yes / No / No data
 - *Staphylococcus aureus* (Yes / No / No data).
If yes: Multiresistent Yes / No / No data
 - *Streptococcus pneumoniae* (Yes / No / No data).
If yes: Multiresistent Yes / No / No data
 - *Staphylococcus epidermidis* (Yes / No / No data).
If yes: Multiresistent Yes / No / No data
 - *Streptococcus viridans* (Yes / No / No data).
If yes: Multiresistent Yes / No / No data
 - Other (Yes / No / No data) (If yes, Specify _____).
 - If yes: Multiresistent Yes / No / No data
 - Gram negative (Yes / No / No data). If yes:
 - *Escherichia coli* (Yes / No / No data).
If yes: Multiresistent Yes / No / No data
 - *Pseudomonas aeruginosa* (Yes / No / No data).
If yes: Multiresistent Yes / No / No data
 - *Klebsiella pneumoniae* (Yes / No / No data).
If yes: Multiresistent Yes / No / No data
 - *Enterobacter spp* (Yes / No / No data).
If yes: Multiresistent Yes / No / No data
 - *Proteus mirabilis* (Yes / No / No data).
If yes: Multiresistent Yes / No / No data
 - Other (Yes / No / No data) (If yes, Specify _____).
 - If yes: Multiresistent Yes / No / No data
- Polimicrobial (Yes / No / No data)
- Fungus (Yes / No / No data)
- Other (Yes / No / No data) (If yes, specify _____).

Treatments administered within the period

Has the patient received any treatment during this period? (Yes / No / No data).

If yes, specify:

- Treatment for ascites (Yes / No / No data). If yes:
 - Paracentesis (Yes / No / No data). If yes
 - Total volume removed (L) _____
 - Total dose of Albumin dose (g) _____
 - Diuretics (Yes/No/ No data). If yes:
 - Spironolactone (Yes / No / No data); If yes:
 - Dose (mg/day) _____
 - Canrenoate (Yes / No / No data); If yes:
 - Dose (mg/day) _____
 - Furosemide (Yes / No / No data); If yes:
 - Dose (mg/day) _____
 - Hydrochlorotiazide (Yes / No / No data); If yes:
 - Dose (mg/day) _____
 - Amiloride (Yes / No / No data); If yes:
 - Dose (mg/day) _____
 - Others (Yes / No / No data); If yes:
 - Specify _____
 - Dose (mg/day) _____

- Treatment for encephalopathy (Yes / No / No data). If yes:
 - Lactulose (Yes / No / No data); If yes, dose (g/day) _____
 - Rifaximin (Yes / No / No data); If yes, dose (mg/day) _____
 - Neomycin (Yes / No / No data); If yes, dose (mg/day) _____
 - Metronidazole (Yes / No / No data); If yes, dose (mg/day) _____
 - Others (Yes / No / No data); If yes:
 - Specify _____
 - Dose (mg/day) _____

- Treatment for GI-Bleeding (Yes / No / No data): If yes
 - Pharmacological treatment (Yes / No / No data). If yes:
 - Somatostatin (Yes / No / No data); If yes, dose ($\mu\text{g/h}$) _____
 - Terlipressin (Yes / No / No data); If yes, dose(mg/day) _____
 - Others (Yes / No / No data); If yes, specify _____
 - Endoscopic Therapy (Yes / No / No data). If yes:
 - Band ligation (Yes / No / No data)
 - Sclerotherapy of varices (Yes / No / No data)
 - Haemostasis of peptic lesion (Yes / No / No data)
 - TIPS (Yes / No / No data)
 - Others (Yes / No / No data); If yes, specify _____

- Treatment for infection (Yes / No / No data).

If yes, choose one of the following:

- Antibiotics alone:

Antibiotic 1 _____; Dose: _____ Unit: _____

Antibiotic 2 _____; Dose: _____ Unit: _____

Antibiotic 3 _____; Dose: _____ Unit: _____

Antibiotic 4 _____; Dose: _____ Unit: _____

Antibiotic 5 _____; Dose: _____ Unit: _____

.....
 /

- Antibiotics with albumin:

Albumin dose (g/day) _____

Antibiotic 1 _____; Dose: _____ Unit: _____

Antibiotic 2 _____; Dose: _____ Unit: _____

Antibiotic 3 _____; Dose: _____ Unit: _____

Antibiotic 4 _____; Dose: _____ Unit: _____

Antibiotic 5 _____; Dose: _____ Unit: _____

.....
 /

- No data

- Fluid therapy (Yes / No / No data). If yes:
 - Type:
 - Cristalloid (Yes / No / No data).
If Yes: Specify _____ / Average Volume (L/day) _____
 - Colloid (Yes / No / No data).
If Yes: Type _____ / Average Volume (L/day) _____
 - Albumin (Yes / No / No data).
If Yes:
 - Concentration (%): No data / 5 / 20 / 25
 - Average Volume (mL/day): _____
 - Indication:
 - Spontaneous bacterial peritonitis (Yes / No / No data)
 - Hepatorenal syndrome (Yes / No / No data)
 - Volume Replacement (Yes / No / No data)
 - Hepathic encephalopathy (Yes / No / No data)
 - Bleeding (Yes / No / No data)
 - Others (Yes / No / No data); If yes, specify _____

- Transfusion (Yes / No / No data). If yes
 - Red Blood cells (Yes / No / No data) If Yes: Blood units _____
 - Fresh frozen plasma (Yes / No / No data) If Yes: Units _____
 - Platelets (Yes / No / No data) If Yes: Volume (mL) _____
 - Crioprecipitate (Yes / No / No data) If Yes: Volume (mL) _____

- Vasoactive drugs (Yes / No / No data). If yes:
 - Indication: No data / Hepatorenal Syndrome / Sitemic Hemodinamic Support
 - Drug:
 - Terlipressin (Yes / No / No data); If yes, dose (mg/day) _____
 - Noradrenaline (Yes / No / No data); If yes, dose ($\mu\text{g}/\text{Kg}/\text{min}$) _____
 - Midodrine (Yes / No / No data); If yes, dose (mg/day) _____
 - Dopamine (Yes / No / No data); If yes, dose ($\mu\text{g}/\text{Kg}/\text{min}$) _____
 - Others (Yes / No / No data). If yes, specify _____

- Surgery (Yes / No / No data), If yes, specify _____

- Corticoids (Yes / No / No data). If yes:
 - No data / Prednisone / Prednisolone / Methylprednisolone / Hydrocortisone (dose, mg/day) _____

- Prophylaxis of bacterial infection (Yes / No / No data) If yes:
 - Type: No data / Primary / Secondary
 - Drugs: No data / Quinolones / Other-specify _____

- Prophylaxis of gastrointestinal bleeding (Yes / No / No data). If yes:
 - Type: No data / Primary / Secondary
 - Specify: No data / Propranolol / Nadolol / Carvedilol (dose, mg/day) _____

- Mechanical ventilation (Yes / No / No data); If yes:
 - Tidal volume (mL) _____
 - PEEP (cm H₂O) _____
 - FiO₂ (%) _____
 - PaO₂ _____ (mmHg) / _____ (kPa)
The PaO₂ / FiO₂ ratio will be calculated by the data-entry application.

- Renal replacement therapy (Yes / No / No data)

- Other (Yes / No / No data); If yes: specify _____

Scores

All scores except APACHE II will be derived from data introduced in the data-entry application. Additional information for Lille and Cardiovascular SOFA-Subscore is required:

Lille's score information:

- Does the patient suffer from alcoholic hepatitis? (Yes / No / No data) If yes:

The Lille score can be calculated only if the patient has been under corticosteroid treatment for at least 7 days:

- Is it applicable to this visit? (Yes / No / No data) If yes:

The following parameters at Days 0 and 7 of treatment are required

- Bilirubin at day 0 ($\mu\text{mol/L}$) _____
- Bilirubin at day 7 ($\mu\text{mol/L}$) _____
- Creatinine at day 0 ($\mu\text{mol/L}$) _____

In patients who have received albumin infusions, use the last available albumin value before the infusion of albumin occurred. If albumin infusions are not received, enter 0.

- Albumin at day 0 (g/L) _____
- Patient's prothrombin time at day 0 (sec) _____

SOFA Subscores:

- **Cardiovascular Subscore information:**

- Dopamine (Yes / No / No data); If yes: Dose ($\mu\text{g/Kg/min}$) _____
- Dobutamine (Yes / No / No data)
- Terlipressin for Systemic Hemodynamic Support (Yes / No / No data)
- Epinephrine (Yes / No / No data); If yes: Dose ($\mu\text{g/Kg/min}$) _____
- Norepinephrine (Yes / No / No data); If yes: Dose ($\mu\text{g/Kg/min}$) _____

APACHE II score information:

- Has the patient been admitted to the ICU unit? (Yes / No / No data)
- Does the patient have arterial samples? (Yes / No / No data)

If at least one of the previous answers is YES please fill in:

- APACHE II _____

Place and clinical course of patient at the end of the period

- ICU (Yes / No / No data). If yes:
 - Number of days in the ICU _____
- Ward (Yes / No / No data)
- Discharged (Yes / No / No data); If yes: Date ____ / ____ / _____
- Discharged and re-admitted (Yes / No / No data); If yes: Date ____ / ____ / _____
- **Alive / Dead / No data**
 - If Dead:
 - **Date of exitus ____ / ____ / _____**
 - Causes of death:
 - Hepatocellular carcinoma (Yes / No / No data)
 - Hypovolemic shock (Yes / No / No data)
 - Septic shock (Yes / No / No data)
 - Multiorgan failure in the absence of hypovolemic or septic shock (Yes / No / No data). If yes:
 - Organ failures:
 - Hepatic (Yes / No / No data)
 - Renal (Yes / No / No data)
 - Cerebral (Yes / No / No data)
 - Respiratory (Yes / No / No data)
 - Cardiac (Yes / No / No data)
 - Coagulation (Yes / No / No data).
 - Multiorgan failure after recovering from hypovolemic shock (Yes / No / No data). If yes:
 - Organ failures:
 - Hepatic (Yes / No / No data)
 - Renal (Yes / No / No data)
 - Cerebral (Yes / No / No data)
 - Respiratory (Yes / No / No data)
 - Cardiac (Yes / No / No data)
 - Coagulation (Yes / No / No data).
 - Multiorgan failure after recovering from septic shock (Yes / No / No data). If yes:
 - Organ failures:
 - Hepatic (Yes / No / No data)
 - Renal (Yes / No / No data)
 - Cerebral (Yes / No / No data)
 - Respiratory (Yes / No / No data)
 - Cardiac (Yes / No / No data)
 - Coagulation (Yes / No / No data).
 - Other (Yes / No / No data); If yes, specify _____
 - Unknown (Yes / No / No data)

- If Alive:
 - Patient transplanted (Yes / No / No data); If yes: Date ____ / ____ / ____
 - Patient's evolution:
 - No data
 - Cured (complete resolution of all specific complications)
 - Better (partial resolution of all specific complications or complete resolution of some complications)
 - Stable (complications not resolved)
 - Worse (worsening of all complications or development of new ones)

Biological samples scheduled for this visit

- Were **plasma** samples taken? (Yes / No / No data). If yes: Date ____ / ____ / ____.
- Were **blood** samples taken? (Yes / No / No data). If yes: Date ____ / ____ / ____.
- Were **urine** samples taken? (Yes / No / No data). If yes: Date ____ / ____ / ____.
- Were **ascitis fluid** samples taken? (Yes / No / No data). If yes: Date ____ / ____ / ____.
- Was **liver biopsy** performed? (Yes / No / No data). If yes: Date ____ / ____ / ____.

For patient Groups #1, #2 and #4, samples can be taken at Day 1 or alternatively at 2.

For patient Group #3, samples will be taken only at Day 1 or alternatively at Day 2.

SAMPLES COLLECTION DATA FOR DAY 1 OR 2 SHOULD BE ENTERED IN DAY 2 WINDOW INTO THE DATA-ENTRY APPLICATION.

PERIOD 3 - 7

**(after study inclusion and during hospitalization for patients in Groups #1 and #2;
after the onset of 1st extra-hepatic organ failure and during hospitalization for
Group #4)**

Period 3-7 Date: ____ / ____ / ____

(Unless the patient has been discharged before, please choose the last day of the period).

Time (24h): ____:____

Enrollment in Other Prophylactic or Therapeutic Studies within this period

• Has the patient been included in a prophylactic or therapeutic study during this period (Yes / No / No data).

▪ If yes:

• Type of study:

No data

/ Prophylactic

/ Therapeutic

/ Non randomized

/ Randomized placebo-controlled

/ Randomized comparative

• Study treatment (specify _____)

• Control treatment (specify _____)

• Does the patient continue in the study after this period
(Yes / No / No data)?

Clinical features during the period

- Ascites (Yes / No / No data); If yes,
 - Type: No data / Mild to Moderate / Large - Tense
- Encephalopathy (Yes / No / No data); If yes:
 - Stage: West Haven score: No data / 1 / 2 / 3 / 4
- Renal failure (Yes / No / No data); If yes:
 - Renal failure type:
 - No data / HRS type I / HRS type II / Pre-renal / Other (specify _____) / Unknown / Still undetermined
- Bacterial infection (Yes / No / No data). If yes:
 - Timeframe of infection (choose one of the following):
 - No data /
 - New Infection /
 - Type of infection:
 - SBP (Yes / No / No data)
 - Pneumonia (Yes / No / No data)
 - Urinary tract infection (UTI) (Yes / No / No data)
 - Skin infection (Yes / No / No data)
 - Unproved suspected infection (Yes / No / No data)
 - Other (Yes / No / No data); If yes, specify _____
 - Sepsis (Yes / No / No data). If yes:
 - Sepsis category: No data / Sepsis Only / Severe sepsis / Septic shock
 - Time from infection (days) _____
 - Site of acquisition: No data / Community / Hospital
 - Infection under antibiotic treatment /
 - Therapeutic Response (Yes / No / No data)
 - Resolution of Infection (Yes / No / No data)

- Superinfection /
 - Type of infection:
 - SBP (Yes / No / No data)
 - Pneumonia (Yes / No / No data)
 - Urinary tract infection (UTI) (Yes / No / No data)
 - Skin infection (Yes / No / No data)
 - Unproved suspected infection (Yes / No / No data)
 - Other (Yes / No / No data); If yes, specify _____
 - Sepsis (Yes / No / No data). If yes:
Sepsis category: No data / Sepsis Only / Severe sepsis / Septic shock
 - Time from infection (days) _____
 - Site of acquisition: No data / Community / Hospital
- Gastrointestinal bleeding (Yes / No / No data);
 - Etiology:
 - Variceal bleeding (Yes / No / No data)
 - Peptic ulcer lesion (Yes / No / No data)
 - Portal hypertension non-variceal bleeding (Yes / No / No data)
 - Other causes (Yes / No / No data); If yes, specify _____
 - Unknown (Yes / No / No data)
 - GI-bleeding complicated by hypovolemic shock? (Yes / No / No data)
 - Time from onset to present study visit (days, if days < 1, enter 1) _____
 - Resolution (Yes / No / No data);
- Others (Yes / No / No data), If yes, specify _____

Exploratory data

For repeated values in the same visit (period), the last available value of each variable will be taken.

- Body weight (Kg) _____

- Arterial pressure:

Systolic Blood Pressure (mmHg) _____

Diastolic Blood Pressure (mmHg) _____

The mean arterial pressure (MAP) will be calculated by the data-entry application.

- Heart rate (beats/min) _____

- Axillary temperature (°C) _____

- Respiratory rate (breaths/min) _____

- Supplemental oxygen (Yes / No / No data);

- If No: FiO₂ will take the value "21%".

- If Yes: Delivery device (Choose one of the following):

- No data;

- Nasal catheter; If chosen: Flow (liters of O₂ / min): 1 / 2 / 3 / 4 / 5 / 6+

- Face mask with reservoir; If chosen: Flow (liters of O₂ / min): 6 / 7 / 8 / 9 / 10+

- Venturi mask; If chosen: Flow (liters of O₂ / min): 4 / 8 / 12+

- SpO₂ (%) _____

The SpO₂ / FiO₂ ratio will be calculated by the data-entry application.

- Urine volume (mL/h) _____

- Chest X-ray (Normal / Abnormal / No data); If Abnormal:

Specify _____

Laboratory data (For repeated values in the same period, the last available value of each variable will be taken).

- Hematocrit _____ (%)
- Hemoglobin level _____ (g/dL) / _____ (g/L)
- White Blood Cells count _____ (x 10⁹ cells/L) / _____ (x cells/mm³)
- % immature neutrophils (bands) _____ (%)
- Platelet count _____ (x 10³/μL) / _____ (x 10⁹/L)
- Total serum bilirubin _____ (mg/dL) / _____ (μmol/L)
- Serum albumin _____ (g/dL) / _____ (g/L)
- Control prothrombin time _____ (sec)
- Prothrombin time _____ (sec)
- % of Control _____ (%)
- INR _____
- Activated partial-thromboplastin time ratio _____
- ALT _____ (U/L) / _____ (μkat/L)
- AST _____ (U/L) / _____ (μkat/L)
- AP _____ (U/L) / _____ (μkat/L)
- GGT _____ (U/L)
- Blood glucose _____ (mg/dL) / _____ (mmol/L)
- When needed:
 - Supplemental oxygen (Yes / No / No data);
 - If No: FiO₂ will take the value "21%".
 - If Yes: Delivery device (Choose one of the following):
 - No data;
 - Nasal catheter; If chosen: Flow (liters of O₂ / min): 1 / 2 / 3 / 4 / 5 / 6+
 - Face mask with reservoir; If chosen: Flow (liters of O₂ / min): 6 / 7 / 8 / 9 / 10+
 - Venturi mask; If chosen: Flow (liters of O₂ / min): 4 / 8 / 12+
 - PaO₂ _____ (mmHg) / _____ (kPa)
 - Arterial pH _____
 - PaCO₂ _____ (mmHg) / _____ (kPa)
 - Serum bicarbonate _____ (mEq/L) / _____ (mmol/L)
 - Serum lactate _____ (mg/dL) / _____ (mmol/L)

The PaO₂ / FiO₂ ratio will be calculated by the data-entry application.
- Plasma C-reactive protein _____ (mg/L)
- Serum creatinine _____ (mg/dL) / _____ (μmol/L)
- Blood urea nitrogen _____ (mg/dL) / _____ (mmol/L)
- Serum sodium _____ (mEq/L) / _____ (mmol/L)
- Serum potassium _____ (mEq/L) / _____ (mmol/L)
- Urine sodium concentration _____ (mEq/L) / _____ (mmol/L)
- Urine creatinine concentration _____ (mg/dL) / _____ (μmol/L)
- Proteinuria (dipstick test: No data / Absent / Trace / 1+ / 2+ / 3+ / 4+)
- Hematuria: Yes / No / No data (If yes, cells / HPF: No data / <10 / 11-20 / 21-50 / >50)
- Ascitic fluid total protein concentration _____ (g/dL) / _____ (g/L)
- Ascitic fluid neutrophil count _____ (Cells/mL)

Microbiological data (only in patients with infections)

- Culture done (sample taken):
 - Ascitic fluid (Yes / No / No data); If yes:
 - Result: No data / Positive / Negative
 - If positive, isolated organism:
 - Gram positive (Yes / No / No data). If yes:
 - *Enterococcus faecalis* (Yes / No / No data).
If yes: Multiresistent Yes / No / No data
 - *Staphylococcus aureus* (Yes / No / No data).
If yes: Multiresistent Yes / No / No data
 - *Streptococcus pneumoniae* (Yes / No / No data).
If yes: Multiresistent Yes / No / No data
 - *Staphylococcus epidermidis* (Yes / No / No data).
If yes: Multiresistent Yes / No / No data
 - *Streptococcus viridans* (Yes / No / No data).
If yes: Multiresistent Yes / No / No data
 - Other (Yes / No / No data) (If yes, Specify _____).
 - If yes: Multiresistent Yes / No / No data
 - Gram negative (Yes / No / No data). If yes:
 - *Escherichia coli* (Yes / No / No data).
If yes: Multiresistent Yes / No / No data
 - *Pseudomonas aeruginosa* (Yes / No / No data).
If yes: Multiresistent Yes / No / No data
 - *Klebsiella pneumoniae* (Yes / No / No data).
If yes: Multiresistent Yes / No / No data
 - *Enterobacter spp* (Yes / No / No data).
If yes: Multiresistent Yes / No / No data
 - *Proteus mirabilis* (Yes / No / No data).
If yes: Multiresistent Yes / No / No data
 - Other (Yes / No / No data) (If yes, Specify _____).
 - If yes: Multiresistent Yes / No / No data
- Polimicrobial (Yes / No / No data)
- Fungus (Yes / No / No data)
- Other (Yes / No / No data) (If yes, specify _____).

- Blood (Yes / No / No data); If yes:
 - Result: No data / Positive / Negative
 - If positive, isolated organism:
 - Gram positive (Yes / No / No data). If yes:
 - *Enterococcus faecalis* (Yes / No / No data).
If yes: Multiresistent Yes / No / No data
 - *Staphylococcus aureus* (Yes / No / No data).
If yes: Multiresistent Yes / No / No data
 - *Streptococcus pneumoniae* (Yes / No / No data).
If yes: Multiresistent Yes / No / No data
 - *Staphylococcus epidermidis* (Yes / No / No data).
If yes: Multiresistent Yes / No / No data
 - *Streptococcus viridans* (Yes / No / No data).
If yes: Multiresistent Yes / No / No data
 - Other (Yes / No / No data) (If yes, Specify _____).
 - If yes: Multiresistent Yes / No / No data
 - Gram negative (Yes / No / No data). If yes:
 - *Escherichia coli* (Yes / No / No data).
If yes: Multiresistent Yes / No / No data
 - *Pseudomonas aeruginosa* (Yes / No / No data).
If yes: Multiresistent Yes / No / No data
 - *Klebsiella pneumoniae* (Yes / No / No data).
If yes: Multiresistent Yes / No / No data
 - *Enterobacter spp* (Yes / No / No data).
If yes: Multiresistent Yes / No / No data
 - *Proteus mirabilis* (Yes / No / No data).
If yes: Multiresistent Yes / No / No data
 - Other (Yes / No / No data) (If yes, Specify _____).
 - If yes: Multiresistent Yes / No / No data
 - Polimicrobial (Yes / No / No data)
 - Fungus (Yes / No / No data)
 - Other (Yes / No / No data) (If yes, specify _____).

- Urine (Yes / No / No data); If yes:
 - Result: No data / Positive / Negative
 - If positive, isolated organism:
 - Gram positive (Yes / No / No data). If yes:
 - *Enterococcus faecalis* (Yes / No / No data).
If yes: Multiresistent Yes / No / No data
 - *Staphylococcus aureus* (Yes / No / No data).
If yes: Multiresistent Yes / No / No data
 - *Streptococcus pneumoniae* (Yes / No / No data).
If yes: Multiresistent Yes / No / No data
 - *Staphylococcus epidermidis* (Yes / No / No data).
If yes: Multiresistent Yes / No / No data
 - *Streptococcus viridans* (Yes / No / No data).
If yes: Multiresistent Yes / No / No data
 - Other (Yes / No / No data) (If yes, Specify _____).
 - If yes: Multiresistent Yes / No / No data
 - Gram negative (Yes / No / No data). If yes:
 - *Escherichia coli* (Yes / No / No data).
If yes: Multiresistent Yes / No / No data
 - *Pseudomonas aeruginosa* (Yes / No / No data).
If yes: Multiresistent Yes / No / No data
 - *Klebsiella pneumoniae* (Yes / No / No data).
If yes: Multiresistent Yes / No / No data
 - *Enterobacter spp* (Yes / No / No data).
If yes: Multiresistent Yes / No / No data
 - *Proteus mirabilis* (Yes / No / No data).
If yes: Multiresistent Yes / No / No data
 - Other (Yes / No / No data) (If yes, Specify _____).
 - If yes: Multiresistent Yes / No / No data
 - Polimicrobial (Yes / No / No data)
 - Fungus (Yes / No / No data)
 - Other (Yes / No / No data) (If yes, specify _____).

- Pleural fluid (Yes / No / No data); If yes:
 - Result: No data / Positive / Negative
 - If positive, isolated organism:
 - Gram positive (Yes / No / No data). If yes:
 - *Enterococcus faecalis* (Yes / No / No data).
If yes: Multiresistent Yes / No / No data
 - *Staphylococcus aureus* (Yes / No / No data).
If yes: Multiresistent Yes / No / No data
 - *Streptococcus pneumoniae* (Yes / No / No data).
If yes: Multiresistent Yes / No / No data
 - *Staphylococcus epidermidis* (Yes / No / No data).
If yes: Multiresistent Yes / No / No data
 - *Streptococcus viridans* (Yes / No / No data).
If yes: Multiresistent Yes / No / No data
 - Other (Yes / No / No data) (If yes, Specify _____).
 - If yes: Multiresistent Yes / No / No data
 - Gram negative (Yes / No / No data). If yes:
 - *Escherichia coli* (Yes / No / No data).
If yes: Multiresistent Yes / No / No data
 - *Pseudomonas aeruginosa* (Yes / No / No data).
If yes: Multiresistent Yes / No / No data
 - *Klebsiella pneumoniae* (Yes / No / No data).
If yes: Multiresistent Yes / No / No data
 - *Enterobacter spp* (Yes / No / No data).
If yes: Multiresistent Yes / No / No data
 - *Proteus mirabilis* (Yes / No / No data).
If yes: Multiresistent Yes / No / No data
 - Other (Yes / No / No data) (If yes, Specify _____).
 - If yes: Multiresistent Yes / No / No data
 - Polimicrobial (Yes / No / No data)
 - Fungus (Yes / No / No data)
 - Other (Yes / No / No data) (If yes, specify _____).

- Other (Yes / No / No data); If yes:
 - Specify: _____
 - If yes, Result: No data / Positive / Negative
 - If positive, isolated organism:
 - Gram positive (Yes / No / No data). If yes:
 - *Enterococcus faecalis* (Yes / No / No data).
If yes: Multiresistent Yes / No / No data
 - *Staphylococcus aureus* (Yes / No / No data).
If yes: Multiresistent Yes / No / No data
 - *Streptococcus pneumoniae* (Yes / No / No data).
If yes: Multiresistent Yes / No / No data
 - *Staphylococcus epidermidis* (Yes / No / No data).
If yes: Multiresistent Yes / No / No data
 - *Streptococcus viridans* (Yes / No / No data).
If yes: Multiresistent Yes / No / No data
 - Other (Yes / No / No data) (If yes, Specify _____).
 - If yes: Multiresistent Yes / No / No data
 - Gram negative (Yes / No / No data). If yes:
 - *Escherichia coli* (Yes / No / No data).
If yes: Multiresistent Yes / No / No data
 - *Pseudomonas aeruginosa* (Yes / No / No data).
If yes: Multiresistent Yes / No / No data
 - *Klebsiella pneumoniae* (Yes / No / No data).
If yes: Multiresistent Yes / No / No data
 - *Enterobacter spp* (Yes / No / No data).
If yes: Multiresistent Yes / No / No data
 - *Proteus mirabilis* (Yes / No / No data).
If yes: Multiresistent Yes / No / No data
 - Other (Yes / No / No data) (If yes, Specify _____).
 - If yes: Multiresistent Yes / No / No data
- Polimicrobial (Yes / No / No data)
- Fungus (Yes / No / No data)
- Other (Yes / No / No data) (If yes, specify _____).

Treatments administered within the period

Has the patient received any treatment during this period? (Yes / No / No data).

If yes, specify:

- Treatment for ascites (Yes / No / No data). If yes:
 - Paracentesis (Yes / No / No data). If yes
 - Total volume removed (L) _____
 - Total dose of Albumin dose (g) _____
 - Diuretics (Yes/No/ No data). If yes:
 - Spironolactone (Yes / No / No data); If yes:
Dose (mg/day) _____
 - Canrenoate (Yes / No / No data); If yes:
Dose (mg/day) _____
 - Furosemide (Yes / No / No data); If yes:
Dose (mg/day) _____
 - Hydrochlorotiazide (Yes / No / No data); If yes:
Dose (mg/day) _____
 - Amiloride (Yes / No / No data); If yes:
Dose (mg/day) _____
 - Others (Yes / No / No data); If yes:
Specify _____
Dose (mg/day) _____

- Treatment for encephalopathy (Yes / No / No data). If yes:
 - Lactulose (Yes / No / No data); If yes, dose (g/day) _____
 - Rifaximin (Yes / No / No data); If yes, dose (mg/day) _____
 - Neomycin (Yes / No / No data); If yes, dose (mg/day) _____
 - Metronidazole (Yes / No / No data); If yes, dose (mg/day) _____
 - Others (Yes / No / No data); If yes:
Specify _____
Dose (mg/day) _____

- Treatment for GI-Bleeding (Yes / No / No data): If yes
 - Pharmacological treatment (Yes / No / No data). If yes:
 - Somatostatin (Yes / No / No data); If yes, dose ($\mu\text{g/h}$) _____
 - Terlipressin (Yes / No / No data); If yes, dose(mg/day) _____
 - Others (Yes / No / No data); If yes, specify _____
 - Endoscopic Therapy (Yes / No / No data). If yes:
 - Band ligation (Yes / No / No data)
 - Sclerotherapy of varices (Yes / No / No data)
 - Haemostasis of peptic lesion (Yes / No / No data)
 - TIPS (Yes / No / No data)
 - Others (Yes / No / No data); If yes, specify _____

- Treatment for infection (Yes / No / No data).

If yes, choose one of the following:

- Antibiotics alone:

Antibiotic 1 _____; Dose: _____ Unit: _____

Antibiotic 2 _____; Dose: _____ Unit: _____

Antibiotic 3 _____; Dose: _____ Unit: _____

Antibiotic 4 _____; Dose: _____ Unit: _____

Antibiotic 5 _____; Dose: _____ Unit: _____

.....
 /

- Antibiotics with albumin:

Albumin dose (g/day) _____

Antibiotic 1 _____; Dose: _____ Unit: _____

Antibiotic 2 _____; Dose: _____ Unit: _____

Antibiotic 3 _____; Dose: _____ Unit: _____

Antibiotic 4 _____; Dose: _____ Unit: _____

Antibiotic 5 _____; Dose: _____ Unit: _____

.....
 /

- No data

- Fluid therapy (Yes / No / No data). If yes:
 - Type:
 - Cristalloid (Yes / No / No data).
If Yes: Specify _____ / Average Volume (L/day) _____
 - Colloid (Yes / No / No data).
If Yes: Type _____ / Average Volume (L/day) _____
 - Albumin (Yes / No / No data).
If Yes:
 - Concentration (%): No data / 5 / 20 / 25
 - Average Volume (mL/day): _____
 - Indication:
 - Spontaneous bacterial peritonitis (Yes / No / No data)
 - Hepatorenal syndrome (Yes / No / No data)
 - Volume Replacement (Yes / No / No data)
 - Hepathic encephalopathy (Yes / No / No data)
 - Bleeding (Yes / No / No data)
 - Others (Yes / No / No data); If yes, specify _____
- Transfusion (Yes / No / No data). If yes
 - Red Blood cells (Yes / No / No data) If Yes: Blood units _____
 - Fresh frozen plasma (Yes / No / No data) If Yes: Units _____
 - Platelets (Yes / No / No data) If Yes: Volume (mL) _____
 - Crioprecipitate (Yes / No / No data) If Yes: Volume (mL) _____
- Vasoactive drugs (Yes / No / No data). If yes:
 - Indication: No data / Hepatorenal Syndrome / Sitemic Hemodinamic Support
 - Drug:
 - Terlipressin (Yes / No / No data); If yes, dose (mg/day) _____
 - Noradrenaline (Yes / No / No data); If yes, dose ($\mu\text{g}/\text{Kg}/\text{min}$) _____
 - Midodrine (Yes / No / No data); If yes, dose (mg/day) _____
 - Dopamine (Yes / No / No data); If yes, dose ($\mu\text{g}/\text{Kg}/\text{min}$) _____
 - Others (Yes / No / No data). If yes, specify _____

- Surgery (Yes / No / No data), If yes, specify _____

- Corticoids (Yes / No / No data). If yes:
 - No data / Prednisone / Prednisolone / Methylprednisolone / Hydrocortisone (dose, mg/day) _____

- Prophylaxis of bacterial infection (Yes / No / No data) If yes:
 - Type: No data / Primary / Secondary
 - Drugs: No data / Quinolones / Other-specify _____

- Prophylaxis of gastrointestinal bleeding (Yes / No / No data). If yes:
 - Type: No data / Primary / Secondary
 - Specify: No data / Propranolol / Nadolol / Carvedilol (dose, mg/day) _____

- Mechanical ventilation (Yes / No / No data); If yes:
 - Tidal volume (mL) _____
 - PEEP (cm H₂O) _____
 - FiO₂ (%) _____
 - PaO₂ _____ (mmHg) / _____ (kPa)
The PaO₂ / FiO₂ ratio will be calculated by the data-entry application.

- Renal replacement therapy (Yes / No / No data)

- Other (Yes / No / No data); If yes: specify _____

Scores

All scores except APACHE II will be derived from data introduced in the data-entry application.

Additional information for Lille and Cardiovascular SOFA-Subscore is required:

Lille's score information:

- Does the patient suffer from alcoholic hepatitis? (Yes / No / No data) If yes:

The Lille score can be calculated only if the patient has been under corticosteroid treatment for at least 7 days:

- Is it applicable to this visit? (Yes / No / No data) If yes:

The following parameters at Days 0 and 7 of treatment are required

- Bilirubin at day 0 ($\mu\text{mol/L}$) _____
- Bilirubin at day 7 ($\mu\text{mol/L}$) _____
- Creatinine at day 0 ($\mu\text{mol/L}$) _____

In patients who have received albumin infusions, use the last available albumin value before the infusion of albumin occurred. If albumin infusions are not received, enter 0.

- Albumin at day 0 (g/L) _____
- Patient's prothrombin time at day 0 (sec) _____

SOFA Subscores:

- **Cardiovascular Subscore information:**

- Dopamine (Yes / No / No data); If yes: Dose ($\mu\text{g/Kg/min}$) _____
- Dobutamine (Yes / No / No data)
- Terlipressin for Systemic Hemodynamic Support (Yes / No / No data)
- Epinephrine (Yes / No / No data); If yes: Dose ($\mu\text{g/Kg/min}$) _____
- Norepinephrine (Yes / No / No data); If yes: Dose ($\mu\text{g/Kg/min}$) _____

APACHE II score information:

- Has the patient been admitted to the ICU unit? (Yes / No / No data)
- Does the patient have arterial samples? (Yes / No / No data)

If at least one of the previous answers is YES please fill in:

- APACHE II _____

Place and clinical course of patient at the end of the period

- ICU (Yes / No / No data). If yes:
 - Number of days in the ICU _____
- Ward (Yes / No / No data)
- Discharged (Yes / No / No data); If yes: Date ____ / ____ / ____
- Discharged and re-admitted (Yes / No / No data); If yes: Date ____ / ____ / ____
- **Alive / Dead / No data**
 - If Dead:
 - **Date of exitus ____ / ____ / ____**
 - Causes of death:
 - Hepatocellular carcinoma (Yes / No / No data)
 - Hypovolemic shock (Yes / No / No data)
 - Septic shock (Yes / No / No data)
 - Multiorgan failure in the absence of hypovolemic or septic shock (Yes / No / No data). If yes:
 - Organ failures:
 - Hepatic (Yes / No / No data)
 - Renal (Yes / No / No data)
 - Cerebral (Yes / No / No data)
 - Respiratory (Yes / No / No data)
 - Cardiac (Yes / No / No data)
 - Coagulation (Yes / No / No data).
 - Multiorgan failure after recovering from hypovolemic shock (Yes / No / No data). If yes:
 - Organ failures:
 - Hepatic (Yes / No / No data)
 - Renal (Yes / No / No data)
 - Cerebral (Yes / No / No data)
 - Respiratory (Yes / No / No data)
 - Cardiac (Yes / No / No data)
 - Coagulation (Yes / No / No data).
 - Multiorgan failure after recovering from septic shock (Yes / No / No data). If yes:
 - Organ failures:
 - Hepatic (Yes / No / No data)
 - Renal (Yes / No / No data)
 - Cerebral (Yes / No / No data)
 - Respiratory (Yes / No / No data)
 - Cardiac (Yes / No / No data)
 - Coagulation (Yes / No / No data).
 - Other (Yes / No / No data); If yes, specify _____
 - Unknown (Yes / No / No data)

- If Alive:
 - Patient transplanted (Yes / No / No data); If yes: Date ____ / ____ / ____.
 - Patient's evolution:
 - No data
 - Cured (complete resolution of all specific complications)
 - Better (partial resolution of all specific complications or complete resolution of some complications)
 - Stable (complications not resolved)
 - Worse (worsening of all complications or development of new ones)

Biological samples scheduled for this visit

- Were **plasma** samples taken? (Yes / No / No data). If yes: Date ____ / ____ / ____.
- Were **blood** samples taken? (Yes / No / No data). If yes: Date ____ / ____ / ____.
- Were **urine** samples taken? (Yes / No / No data). If yes: Date ____ / ____ / ____.
- Were **ascitis fluid** samples taken? (Yes / No / No data). If yes: Date ____ / ____ / ____.
- Was **liver biopsy** performed? (Yes / No / No data). If yes: Date ____ / ____ / ____.

For patient Group #3, samples will be taken only at Day 1 or alternatively at Day 2. They should not be collected in this period.

PERIOD 8 - 14

**(after study inclusion and during hospitalization for patients in Groups #1 and #2;
after the onset of 1st extra-hepatic organ failure and during hospitalization for
Group #4)**

Period 8 - 14 Date: ____ / ____ / ____

(Unless the patient has been discharged before, please choose the last day of the period).

Time (24h): ____ : ____

Enrollment in Other Prophylactic or Therapeutic Studies within this period

• Has the patient been included in a prophylactic or therapeutic study during this period (Yes / No / No data).

▪ If yes:

• Type of study:

No data

/ Prophylactic

/ Therapeutic

/ Non randomized

/ Randomized placebo-controlled

/ Randomized comparative

• Study treatment (specify _____)

• Control treatment (specify _____)

• Does the patient continue in the study after this period
(Yes / No / No data)?

Clinical features during the period

- Ascites (Yes / No / No data); If yes,
 - Type: No data / Mild to Moderate / Large - Tense
- Encephalopathy (Yes / No / No data); If yes:
 - Stage: West Haven score: No data / 1 / 2 / 3 / 4
- Renal failure (Yes / No / No data); If yes:
 - Renal failure type:
 - No data / HRS type I / HRS type II / Pre-renal / Other (specify _____) /
 - Unknown / Still undetermined
- Bacterial infection (Yes / No / No data). If yes:
 - Timeframe of infection (choose one of the following):
 - No data /
 - New Infection /
 - Type of infection:
 - SBP (Yes / No / No data)
 - Pneumonia (Yes / No / No data)
 - Urinary tract infection (UTI) (Yes / No / No data)
 - Skin infection (Yes / No / No data)
 - Unproved suspected infection (Yes / No / No data)
 - Other (Yes / No / No data); If yes, specify _____
 - Sepsis (Yes / No / No data). If yes:
 - Sepsis category: No data / Sepsis Only / Severe sepsis / Septic shock
 - Time from infection (days) _____
 - Site of acquisition: No data / Community / Hospital
 - Infection under antibiotic treatment /
 - Therapeutic Response (Yes / No / No data)
 - Resolution of Infection (Yes / No / No data)

- Superinfection /
 - Type of infection:
 - SBP (Yes / No / No data)
 - Pneumonia (Yes / No / No data)
 - Urinary tract infection (UTI) (Yes / No / No data)
 - Skin infection (Yes / No / No data)
 - Unproved suspected infection (Yes / No / No data)
 - Other (Yes / No / No data); If yes, specify _____
 - Sepsis (Yes / No / No data). If yes:
Sepsis category: No data / Sepsis Only / Severe sepsis / Septic shock
 - Time from infection (days) _____
 - Site of acquisition: No data / Community / Hospital
- Gastrointestinal bleeding (Yes / No / No data);
 - Etiology:
 - Variceal bleeding (Yes / No / No data)
 - Peptic ulcer lesion (Yes / No / No data)
 - Portal hypertension non-variceal bleeding (Yes / No / No data)
 - Other causes (Yes / No / No data); If yes, specify _____
 - Unknown (Yes / No / No data)
 - GI-bleeding complicated by hypovolemic shock? (Yes / No / No data)
 - Time from onset to present study visit (days, if days < 1, enter 1) _____
 - Resolution (Yes / No / No data);
- Others (Yes / No / No data), If yes, specify _____

Exploratory data

For repeated values in the same visit (period), the last available value of each variable will be taken.

- Body weight (Kg) _____

- Arterial pressure:

Systolic Blood Pressure (mmHg) _____

Diastolic Blood Pressure (mmHg) _____

The mean arterial pressure (MAP) will be calculated by the data-entry application.

- Heart rate (beats/min) _____

- Axillary temperature (°C) _____

- Respiratory rate (breaths/min) _____

- Supplemental oxygen (Yes / No / No data);

- If No: FiO₂ will take the value "21%".

- If Yes: Delivery device (Choose one of the following):

- No data;

- Nasal catheter; If chosen: Flow (liters of O₂ / min): 1 / 2 / 3 / 4 / 5 / 6+

- Face mask with reservoir; If chosen: Flow (liters of O₂ / min): 6 / 7 / 8 / 9 / 10+

- Venturi mask; If chosen: Flow (liters of O₂ / min): 4 / 8 / 12+

- SpO₂ (%) _____

The SpO₂ / FiO₂ ratio will be calculated by the data-entry application.

- Urine volume (mL/h) _____

- Chest X-ray (Normal / Abnormal / No data); If Abnormal:

Specify _____

Laboratory data (For repeated values in the same period, the last available value of each variable will be taken).

- Hematocrit _____ (%)
- Hemoglobin level _____ (g/dL) / _____ (g/L)
- White Blood Cells count _____ (x 10⁹ cells/L) / _____ (x cells/mm³)
- % immature neutrophils (bands) _____ (%)
- Platelet count _____ (x 10³/μL) / _____ (x 10⁹/L)
- Total serum bilirubin _____ (mg/dL) / _____ (μmol/L)
- Serum albumin _____ (g/dL) / _____ (g/L)
- Control prothrombin time _____ (sec)
- Prothrombin time _____ (sec)
- % of Control _____ (%)
- **INR**
- Activated partial-thromboplastin time ratio _____
- ALT _____ (U/L) / _____ (μkat/L)
- AST _____ (U/L) / _____ (μkat/L)
- AP _____ (U/L) / _____ (μkat/L)
- GGT _____ (U/L)
- Blood glucose _____ (mg/dL) / _____ (mmol/L)
- When needed:
 - Supplemental oxygen (Yes / No / No data);
 - If No: FiO₂ will take the value "21%".
 - If Yes: Delivery device (Choose one of the following):
 - No data;
 - Nasal catheter; If chosen: Flow (liters of O₂ / min): 1 / 2 / 3 / 4 / 5 / 6+
 - Face mask with reservoir; If chosen: Flow (liters of O₂ / min): 6 / 7 / 8 / 9 / 10+
 - Venturi mask; If chosen: Flow (liters of O₂ / min): 4 / 8 / 12+
 - PaO₂ _____ (mmHg) / _____ (kPa)
 - Arterial pH _____
 - PaCO₂ _____ (mmHg) / _____ (kPa)
 - Serum bicarbonate _____ (mEq/L) / _____ (mmol/L)
 - Serum lactate _____ (mg/dL) / _____ (mmol/L)

The PaO₂ / FiO₂ ratio will be calculated by the data-entry application.
- Plasma C-reactive protein _____ (mg/L)
- Serum creatinine _____ (mg/dL) / _____ (μmol/L)
- Blood urea nitrogen _____ (mg/dL) / _____ (mmol/L)
- Serum sodium _____ (mEq/L) / _____ (mmol/L)
- Serum potassium _____ (mEq/L) / _____ (mmol/L)
- Urine sodium concentration _____ (mEq/L) / _____ (mmol/L)
- Urine creatinine concentration _____ (mg/dL) / _____ (μmol/L)
- Proteinuria (dipstick test: No data / Absent / Trace / 1+ / 2+ / 3+ / 4+)
- Hematuria: Yes / No / No data (If yes, cells / HPF: No data / <10 / 11-20 / 21-50 / >50)
- Ascitic fluid total protein concentration _____ (g/dL) / _____ (g/L)
- Ascitic fluid neutrophil count _____ (Cells/mL)

Microbiological data (only in patients with infections)

- Culture done (sample taken):
 - Ascitic fluid (Yes / No / No data); If yes:
 - Result: No data / Positive / Negative
 - If positive, isolated organism:
 - Gram positive (Yes / No / No data). If yes:
 - *Enterococcus faecalis* (Yes / No / No data).
If yes: Multiresistent Yes / No / No data
 - *Staphylococcus aureus* (Yes / No / No data).
If yes: Multiresistent Yes / No / No data
 - *Streptococcus pneumoniae* (Yes / No / No data).
If yes: Multiresistent Yes / No / No data
 - *Staphylococcus epidermidis* (Yes / No / No data).
If yes: Multiresistent Yes / No / No data
 - *Streptococcus viridans* (Yes / No / No data).
If yes: Multiresistent Yes / No / No data
 - Other (Yes / No / No data) (If yes, Specify _____).
 - If yes: Multiresistent Yes / No / No data
 - Gram negative (Yes / No / No data). If yes:
 - *Escherichia coli* (Yes / No / No data).
If yes: Multiresistent Yes / No / No data
 - *Pseudomonas aeruginosa* (Yes / No / No data).
If yes: Multiresistent Yes / No / No data
 - *Klebsiella pneumoniae* (Yes / No / No data).
If yes: Multiresistent Yes / No / No data
 - *Enterobacter spp* (Yes / No / No data).
If yes: Multiresistent Yes / No / No data
 - *Proteus mirabilis* (Yes / No / No data).
If yes: Multiresistent Yes / No / No data
 - Other (Yes / No / No data) (If yes, Specify _____).
 - If yes: Multiresistent Yes / No / No data
 - Polimicrobial (Yes / No / No data)
 - Fungus (Yes / No / No data)
 - Other (Yes / No / No data) (If yes, specify _____).

- Blood (Yes / No / No data); If yes:
 - Result: No data / Positive / Negative
 - If positive, isolated organism:
 - Gram positive (Yes / No / No data). If yes:
 - *Enterococcus faecalis* (Yes / No / No data).
If yes: Multiresistent Yes / No / No data
 - *Staphylococcus aureus* (Yes / No / No data).
If yes: Multiresistent Yes / No / No data
 - *Streptococcus pneumoniae* (Yes / No / No data).
If yes: Multiresistent Yes / No / No data
 - *Staphylococcus epidermidis* (Yes / No / No data).
If yes: Multiresistent Yes / No / No data
 - *Streptococcus viridans* (Yes / No / No data).
If yes: Multiresistent Yes / No / No data
 - Other (Yes / No / No data) (If yes, Specify _____).
 - If yes: Multiresistent Yes / No / No data
 - Gram negative (Yes / No / No data). If yes:
 - *Escherichia coli* (Yes / No / No data).
If yes: Multiresistent Yes / No / No data
 - *Pseudomonas aeruginosa* (Yes / No / No data).
If yes: Multiresistent Yes / No / No data
 - *Klebsiella pneumoniae* (Yes / No / No data).
If yes: Multiresistent Yes / No / No data
 - *Enterobacter spp* (Yes / No / No data).
If yes: Multiresistent Yes / No / No data
 - *Proteus mirabilis* (Yes / No / No data).
If yes: Multiresistent Yes / No / No data
 - Other (Yes / No / No data) (If yes, Specify _____).
 - If yes: Multiresistent Yes / No / No data
 - Polimicrobial (Yes / No / No data)
 - Fungus (Yes / No / No data)
 - Other (Yes / No / No data) (If yes, specify _____).

- Urine (Yes / No / No data); If yes:
 - Result: No data / Positive / Negative
 - If positive, isolated organism:
 - Gram positive (Yes / No / No data). If yes:
 - *Enterococcus faecalis* (Yes / No / No data).
If yes: Multiresistent Yes / No / No data
 - *Staphylococcus aureus* (Yes / No / No data).
If yes: Multiresistent Yes / No / No data
 - *Streptococcus pneumoniae* (Yes / No / No data).
If yes: Multiresistent Yes / No / No data
 - *Staphylococcus epidermidis* (Yes / No / No data).
If yes: Multiresistent Yes / No / No data
 - *Streptococcus viridans* (Yes / No / No data).
If yes: Multiresistent Yes / No / No data
 - Other (Yes / No / No data) (If yes, Specify _____).
 - If yes: Multiresistent Yes / No / No data
 - Gram negative (Yes / No / No data). If yes:
 - *Escherichia coli* (Yes / No / No data).
If yes: Multiresistent Yes / No / No data
 - *Pseudomonas aeruginosa* (Yes / No / No data).
If yes: Multiresistent Yes / No / No data
 - *Klebsiella pneumoniae* (Yes / No / No data).
If yes: Multiresistent Yes / No / No data
 - *Enterobacter spp* (Yes / No / No data).
If yes: Multiresistent Yes / No / No data
 - *Proteus mirabilis* (Yes / No / No data).
If yes: Multiresistent Yes / No / No data
 - Other (Yes / No / No data) (If yes, Specify _____).
 - If yes: Multiresistent Yes / No / No data
 - Polimicrobial (Yes / No / No data)
 - Fungus (Yes / No / No data)
 - Other (Yes / No / No data) (If yes, specify _____).

- Pleural fluid (Yes / No / No data); If yes:
 - Result: No data / Positive / Negative
 - If positive, isolated organism:
 - Gram positive (Yes / No / No data). If yes:
 - *Enterococcus faecalis* (Yes / No / No data).
If yes: Multiresistent Yes / No / No data
 - *Staphylococcus aureus* (Yes / No / No data).
If yes: Multiresistent Yes / No / No data
 - *Streptococcus pneumoniae* (Yes / No / No data).
If yes: Multiresistent Yes / No / No data
 - *Staphylococcus epidermidis* (Yes / No / No data).
If yes: Multiresistent Yes / No / No data
 - *Streptococcus viridans* (Yes / No / No data).
If yes: Multiresistent Yes / No / No data
 - Other (Yes / No / No data) (If yes, Specify _____).
 - If yes: Multiresistent Yes / No / No data
 - Gram negative (Yes / No / No data). If yes:
 - *Escherichia coli* (Yes / No / No data).
If yes: Multiresistent Yes / No / No data
 - *Pseudomonas aeruginosa* (Yes / No / No data).
If yes: Multiresistent Yes / No / No data
 - *Klebsiella pneumoniae* (Yes / No / No data).
If yes: Multiresistent Yes / No / No data
 - *Enterobacter spp* (Yes / No / No data).
If yes: Multiresistent Yes / No / No data
 - *Proteus mirabilis* (Yes / No / No data).
If yes: Multiresistent Yes / No / No data
 - Other (Yes / No / No data) (If yes, Specify _____).
 - If yes: Multiresistent Yes / No / No data
 - Polimicrobial (Yes / No / No data)
 - Fungus (Yes / No / No data)
 - Other (Yes / No / No data) (If yes, specify _____).

- Other (Yes / No / No data); If yes:
 - Specify: _____
 - Result: No data / Positive / Negative
 - If positive, isolated organism:
 - Gram positive (Yes / No / No data). If yes:
 - *Enterococcus faecalis* (Yes / No / No data).
If yes: Multiresistent Yes / No / No data
 - *Staphylococcus aureus* (Yes / No / No data).
If yes: Multiresistent Yes / No / No data
 - *Streptococcus pneumoniae* (Yes / No / No data).
If yes: Multiresistent Yes / No / No data
 - *Staphylococcus epidermidis* (Yes / No / No data).
If yes: Multiresistent Yes / No / No data
 - *Streptococcus viridans* (Yes / No / No data).
If yes: Multiresistent Yes / No / No data
 - Other (Yes / No / No data) (If yes, Specify _____).
 - If yes: Multiresistent Yes / No / No data
 - Gram negative (Yes / No / No data). If yes:
 - *Escherichia coli* (Yes / No / No data).
If yes: Multiresistent Yes / No / No data
 - *Pseudomonas aeruginosa* (Yes / No / No data).
If yes: Multiresistent Yes / No / No data
 - *Klebsiella pneumoniae* (Yes / No / No data).
If yes: Multiresistent Yes / No / No data
 - *Enterobacter spp* (Yes / No / No data).
If yes: Multiresistent Yes / No / No data
 - *Proteus mirabilis* (Yes / No / No data).
If yes: Multiresistent Yes / No / No data
 - Other (Yes / No / No data) (If yes, Specify _____).
 - If yes: Multiresistent Yes / No / No data
 - Polimicrobial (Yes / No / No data)
 - Fungus (Yes / No / No data)
 - Other (Yes / No / No data) (If yes, specify _____).

Treatments administered within the period

Has the patient received any treatment during this period? (Yes / No / No data).

If yes, specify:

- Treatment for ascites (Yes / No / No data). If yes:
 - Paracentesis (Yes / No / No data). If yes
 - Total volume removed (L) _____
 - Total dose of Albumin dose (g) _____
 - Diuretics (Yes/No/ No data). If yes:
 - Spironolactone (Yes / No / No data); If yes:
 - Dose (mg/day) _____
 - Canrenoate (Yes / No / No data); If yes:
 - Dose (mg/day) _____
 - Furosemide (Yes / No / No data); If yes:
 - Dose (mg/day) _____
 - Hydrochlorotiazide (Yes / No / No data); If yes:
 - Dose (mg/day) _____
 - Amiloride (Yes / No / No data); If yes:
 - Dose (mg/day) _____
 - Others (Yes / No / No data); If yes:
 - Specify _____
 - Dose (mg/day) _____

- Treatment for encephalopathy (Yes / No / No data). If yes:
 - Lactulose (Yes / No / No data); If yes, dose (g/day) _____
 - Rifaximin (Yes / No / No data); If yes, dose (mg/day) _____
 - Neomycin (Yes / No / No data); If yes, dose (mg/day) _____
 - Metronidazole (Yes / No / No data); If yes, dose (mg/day) _____
 - Others (Yes / No / No data); If yes:
 - Specify _____
 - Dose (mg/day) _____

- Treatment for GI-Bleeding (Yes / No / No data): If yes
 - Pharmacological treatment (Yes / No / No data). If yes:
 - Somatostatin (Yes / No / No data); If yes, dose ($\mu\text{g/h}$) _____
 - Terlipressin (Yes / No / No data); If yes, dose(mg/day) _____
 - Others (Yes / No / No data); If yes, specify _____
 - Endoscopic Therapy (Yes / No / No data). If yes:
 - Band ligation (Yes / No / No data)
 - Sclerotherapy of varices (Yes / No / No data)
 - Haemostasis of peptic lesion (Yes / No / No data)
 - TIPS (Yes / No / No data)
 - Others (Yes / No / No data); If yes, specify _____

- Treatment for infection (Yes / No / No data).

If yes, choose one of the following:

- Antibiotics alone:

Antibiotic 1 _____; Dose: _____ Unit: _____

Antibiotic 2 _____; Dose: _____ Unit: _____

Antibiotic 3 _____; Dose: _____ Unit: _____

Antibiotic 4 _____; Dose: _____ Unit: _____

Antibiotic 5 _____; Dose: _____ Unit: _____

.....
 /

- Antibiotics with albumin:

Albumin dose (g/day) _____

Antibiotic 1 _____; Dose: _____ Unit: _____

Antibiotic 2 _____; Dose: _____ Unit: _____

Antibiotic 3 _____; Dose: _____ Unit: _____

Antibiotic 4 _____; Dose: _____ Unit: _____

Antibiotic 5 _____; Dose: _____ Unit: _____

.....
 /

- No data

- Fluid therapy (Yes / No / No data). If yes:
 - Type:
 - Cristalloid (Yes / No / No data).
If Yes: Specify _____ / Average Volume (L/day) _____
 - Colloid (Yes / No / No data).
If Yes: Type _____ / Average Volume (L/day) _____
 - Albumin (Yes / No / No data).
If Yes:
 - Concentration (%): No data / 5 / 20 / 25
 - Average Volume (mL/day): _____
 - Indication:
 - Spontaneous bacterial peritonitis (Yes / No / No data)
 - Hepatorenal syndrome (Yes / No / No data)
 - Volume Replacement (Yes / No / No data)
 - Hepathic encephalopathy (Yes / No / No data)
 - Bleeding (Yes / No / No data)
 - Others (Yes / No / No data); If yes, specify _____

- Transfusion (Yes / No / No data). If yes
 - Red Blood cells (Yes / No / No data) If Yes: Blood units _____
 - Fresh frozen plasma (Yes / No / No data) If Yes: Units _____
 - Platelets (Yes / No / No data) If Yes: Volume (mL) _____
 - Crioprecipitate (Yes / No / No data) If Yes: Volume (mL) _____

- Vasoactive drugs (Yes / No / No data). If yes:
 - Indication: No data / Hepatorenal Syndrome / Sitemic Hemodinamic Support
 - Drug:
 - Terlipressin (Yes / No / No data); If yes, dose (mg/day) _____
 - Noradrenaline (Yes / No / No data); If yes, dose ($\mu\text{g}/\text{Kg}/\text{min}$) _____
 - Midodrine (Yes / No / No data); If yes, dose (mg/day) _____
 - Dopamine (Yes / No / No data); If yes, dose ($\mu\text{g}/\text{Kg}/\text{min}$) _____
 - Others (Yes / No / No data). If yes, specify _____

- Surgery (Yes / No / No data), If yes, specify _____

- Corticoids (Yes / No / No data). If yes:
 - No data / Prednisone / Prednisolone / Methylprednisolone / Hydrocortisone (dose, mg/day) _____

- Prophylaxis of bacterial infection (Yes / No / No data) If yes:
 - Type: No data / Primary / Secondary
 - Drugs: No data / Quinolones / Other-specify _____

- Prophylaxis of gastrointestinal bleeding (Yes / No / No data). If yes:
 - Type: No data / Primary / Secondary
 - Specify: No data / Propranolol / Nadolol / Carvedilol (dose, mg/day) _____

- Mechanical ventilation (Yes / No / No data); If yes:
 - Tidal volume (mL) _____
 - PEEP (cm H₂O) _____
 - FiO₂ (%) _____
 - PaO₂ _____ (mmHg) / _____ (kPa)
The PaO₂ / FiO₂ ratio will be calculated by the data-entry application.

- Renal replacement therapy (Yes / No / No data)

- Other (Yes / No / No data); If yes: specify _____

Scores

All scores except APACHE II will be derived from data introduced in the data-entry application.
Additional information for Lille and Cardiovascular SOFA-Subscore is required:

Lille's score information:

- Does the patient suffer from alcoholic hepatitis? (Yes / No / No data) If yes:

The Lille score can be calculated only if the patient has been under corticosteroid treatment for at least 7 days:

- Is it applicable to this visit? (Yes / No / No data) If yes:

The following parameters at Days 0 and 7 of treatment are required

- Bilirubin at day 0 ($\mu\text{mol/L}$) _____
- Bilirubin at day 7 ($\mu\text{mol/L}$) _____
- Creatinine at day 0 ($\mu\text{mol/L}$) _____

In patients who have received albumin infusions, use the last available albumin value before the infusion of albumin occurred. If albumin infusions are not received, enter 0.

- Albumin at day 0 (g/L) _____
- Patient's prothrombin time at day 0 (sec) _____

SOFA Subscores:

- **Cardiovascular Subscore information:**

- Dopamine (Yes / No / No data); If yes: Dose ($\mu\text{g/Kg/min}$) _____
- Dobutamine (Yes / No / No data)
- Terlipressin for Systemic Hemodynamic Support (Yes / No / No data)
- Epinephrine (Yes / No / No data); If yes: Dose ($\mu\text{g/Kg/min}$) _____
- Norepinephrine (Yes / No / No data); If yes: Dose ($\mu\text{g/Kg/min}$) _____

APACHE II score information:

- Has the patient been admitted to the ICU unit? (Yes / No / No data)
- Does the patient have arterial samples? (Yes / No / No data)

If at least one of the previous answers is YES please fill in:

- APACHE II _____

Place and clinical course of patient at the end of the period

- ICU (Yes / No / No data). If yes:
 - Number of days in the ICU _____
- Ward (Yes / No / No data)
- Discharged (Yes / No / No data); If yes: Date ____ / ____ / _____
- Discharged and re-admitted (Yes / No / No data); If yes: Date ____ / ____ / _____
- **Alive / Dead / No data**
 - If Dead:
 - **Date of exitus ____ / ____ / _____**
 - Causes of death:
 - Hepatocellular carcinoma (Yes / No / No data)
 - Hypovolemic shock (Yes / No / No data)
 - Septic shock (Yes / No / No data)
 - Multiorgan failure in the absence of hypovolemic or septic shock (Yes / No / No data). If yes:
 - Organ failures:
 - Hepatic (Yes / No / No data)
 - Renal (Yes / No / No data)
 - Cerebral (Yes / No / No data)
 - Respiratory (Yes / No / No data)
 - Cardiac (Yes / No / No data)
 - Coagulation (Yes / No / No data).
 - Multiorgan failure after recovering from hypovolemic shock (Yes / No / No data). If yes:
 - Organ failures:
 - Hepatic (Yes / No / No data)
 - Renal (Yes / No / No data)
 - Cerebral (Yes / No / No data)
 - Respiratory (Yes / No / No data)
 - Cardiac (Yes / No / No data)
 - Coagulation (Yes / No / No data).
 - Multiorgan failure after recovering from septic shock (Yes / No / No data). If yes:
 - Organ failures:
 - Hepatic (Yes / No / No data)
 - Renal (Yes / No / No data)
 - Cerebral (Yes / No / No data)
 - Respiratory (Yes / No / No data)
 - Cardiac (Yes / No / No data)
 - Coagulation (Yes / No / No data).
 - Other (Yes / No / No data); If yes, specify _____
 - Unknown (Yes / No / No data)

- If Alive:
 - Patient transplanted (Yes / No / No data); If yes: Date ____ / ____ / ____
 - Patient's evolution:
 - No data
 - Cured (complete resolution of all specific complications)
 - Better (partial resolution of all specific complications or complete resolution of some complications)
 - Stable (complications not resolved)
 - Worse (worsening of all complications or development of new ones)

Biological samples scheduled for this visit

- Were **plasma** samples taken? (Yes / No / No data). If yes: Date ____ / ____ / ____.
- Were **blood** samples taken? (Yes / No / No data). If yes: Date ____ / ____ / ____.
- Were **urine** samples taken? (Yes / No / No data). If yes: Date ____ / ____ / ____.
- Were **ascitis fluid** samples taken? (Yes / No / No data). If yes: Date ____ / ____ / ____.
- Was **liver biopsy** performed? (Yes / No / No data). If yes: Date ____ / ____ / ____.

For patient Group #3, samples will be taken only at Day 1 or alternatively at Day 2. They should not be collected in this period.

PERIOD 15 - 21

**(after study inclusion and during hospitalization for patients in Groups #1 and #2;
after the onset of 1st extra-hepatic organ failure and during hospitalization for
Group #4)**

Period 15 – 21 Date: ____ / ____ / ____

(Unless the patient has been discharged before, please choose the last day of the period).

Time (24h): ____ : ____

Enrollment in Other Prophylactic or Therapeutic Studies within this period

• Has the patient been included in a prophylactic or therapeutic study during this period (Yes / No / No data).

▪ If yes:

• Type of study:

No data

/ Prophylactic

/ Therapeutic

/ Non randomized

/ Randomized placebo-controlled

/ Randomized comparative

• Study treatment (specify _____)

• Control treatment (specify _____)

• Does the patient continue in the study after this period
(Yes / No / No data)?

Clinical features during the period

- Ascites (Yes / No / No data); If yes,
 - Type: No data / Mild to Moderate / Large - Tense
- Encephalopathy (Yes / No / No data); If yes:
 - Stage: West Haven score: No data / 1 / 2 / 3 / 4
- Renal failure (Yes / No / No data); If yes:
 - Renal failure type:
 - No data / HRS type I / HRS type II / Pre-renal / Other (specify _____) / Unknown / Still undetermined
- Bacterial infection (Yes / No / No data). If yes:
 - Timeframe of infection (choose one of the following):
 - No data /
 - New Infection /
 - Type of infection:
 - SBP (Yes / No / No data)
 - Pneumonia (Yes / No / No data)
 - Urinary tract infection (UTI) (Yes / No / No data)
 - Skin infection (Yes / No / No data)
 - Unproved suspected infection (Yes / No / No data)
 - Other (Yes / No / No data); If yes, specify _____
 - Sepsis (Yes / No / No data). If yes:
 - Sepsis category: No data / Sepsis Only / Severe sepsis / Septic shock
 - Time from infection (days) _____
 - Site of acquisition: No data / Community / Hospital
 - Infection under antibiotic treatment /
 - Therapeutic Response (Yes / No / No data)
 - Resolution of Infection (Yes / No / No data)

- Superinfection /
 - Type of infection:
 - SBP (Yes / No / No data)
 - Pneumonia (Yes / No / No data)
 - Urinary tract infection (UTI) (Yes / No / No data)
 - Skin infection (Yes / No / No data)
 - Unproved suspected infection (Yes / No / No data)
 - Other (Yes / No / No data); If yes, specify _____
 - Sepsis (Yes / No / No data). If yes:
Sepsis category: No data / Sepsis Only / Severe sepsis / Septic shock
 - Time from infection (days) _____
 - Site of acquisition: No data / Community / Hospital
- Gastrointestinal bleeding (Yes / No / No data);
 - Etiology:
 - Variceal bleeding (Yes / No / No data)
 - Peptic ulcer lesion (Yes / No / No data)
 - Portal hypertension non-variceal bleeding (Yes / No / No data)
 - Other causes (Yes / No / No data); If yes, specify _____
 - Unknown (Yes / No / No data)
 - GI-bleeding complicated by hypovolemic shock? (Yes / No / No data)
 - Time from onset to present study visit (days, if days < 1, enter 1) _____
 - Resolution (Yes / No / No data);
- Others (Yes / No / No data), If yes, specify _____

Exploratory data

For repeated values in the same visit (period), the last available value of each variable will be taken.

- Body weight (Kg) _____

- Arterial pressure:

Systolic Blood Pressure (mmHg) _____

Diastolic Blood Pressure (mmHg) _____

The mean arterial pressure (MAP) will be calculated by the data-entry application.

- Heart rate (beats/min) _____

- Axillary temperature (°C) _____

- Respiratory rate (breaths/min) _____

- Supplemental oxygen (Yes / No / No data);

- If No: FiO₂ will take the value "21%".

- If Yes: Delivery device (Choose one of the following):

- No data;

- Nasal catheter; If chosen: Flow (liters of O₂ / min): 1 / 2 / 3 / 4 / 5 / 6+

- Face mask with reservoir; If chosen: Flow (liters of O₂ / min): 6 / 7 / 8 / 9 / 10+

- Venturi mask; If chosen: Flow (liters of O₂ / min): 4 / 8 / 12+

- SpO₂ (%) _____

The SpO₂ / FiO₂ ratio will be calculated by the data-entry application.

- Urine volume (mL/h) _____

- Chest X-ray (Normal / Abnormal / No data); If Abnormal:

Specify _____

Laboratory data (For repeated values in the same period, the last available value of each variable will be taken).

- Hematocrit _____ (%)
- Hemoglobin level _____ (g/dL) / _____ (g/L)
- White Blood Cells count _____ (x 10⁹ cells/L) / _____ (x cells/mm³)
- % immature neutrophils (bands) _____ (%)
- Platelet count _____ (x 10³/μL) / _____ (x 10⁹/L)
- Total serum bilirubin _____ (mg/dL) / _____ (μmol/L)
- Serum albumin _____ (g/dL) / _____ (g/L)
- Control prothrombin time _____ (sec)
- Prothrombin time _____ (sec)
- % of Control _____ (%)
- **INR**
- Activated partial-thromboplastin time ratio _____
- ALT _____ (U/L) / _____ (μkat/L)
- AST _____ (U/L) / _____ (μkat/L)
- AP _____ (U/L) / _____ (μkat/L)
- GGT _____ (U/L)
- Blood glucose _____ (mg/dL) / _____ (mmol/L)
- When needed:
 - Supplemental oxygen (Yes / No / No data);
 - If No: FiO₂ will take the value "21%".
 - If Yes: Delivery device (Choose one of the following):
 - No data;
 - Nasal catheter; If chosen: Flow (liters of O₂ / min): 1 / 2 / 3 / 4 / 5 / 6+
 - Face mask with reservoir; If chosen: Flow (liters of O₂ / min): 6 / 7 / 8 / 9 / 10+
 - Venturi mask; If chosen: Flow (liters of O₂ / min): 4 / 8 / 12+
 - PaO₂ _____ (mmHg) / _____ (kPa)
 - Arterial pH _____
 - PaCO₂ _____ (mmHg) / _____ (kPa)
 - Serum bicarbonate _____ (mEq/L) / _____ (mmol/L)
 - Serum lactate _____ (mg/dL) / _____ (mmol/L)

The PaO₂ / FiO₂ ratio will be calculated by the data-entry application.
- Plasma C-reactive protein _____ (mg/L)
- Serum creatinine _____ (mg/dL) / _____ (μmol/L)
- Blood urea nitrogen _____ (mg/dL) / _____ (mmol/L)
- Serum sodium _____ (mEq/L) / _____ (mmol/L)
- Serum potassium _____ (mEq/L) / _____ (mmol/L)
- Urine sodium concentration _____ (mEq/L) / _____ (mmol/L)
- Urine creatinine concentration _____ (mg/dL) / _____ (μmol/L)
- Proteinuria (dipstick test: No data / Absent / Trace / 1 / 2+ / 3+ / 4+)
- Hematuria: Yes / No / No data (If yes, cells / HPF: No data / <10 / 11-20 / 21-50 / >50)
- Ascitic fluid total protein concentration _____ (g/dL) / _____ (g/L)
- Ascitic fluid neutrophil count _____ (Cells/mL)

Microbiological data (only in patients with infections)

- Culture done (sample taken):
 - Ascitic fluid (Yes / No / No data); If yes:
 - Result: No data / Positive / Negative
 - If positive, isolated organism:
 - Gram positive (Yes / No / No data). If yes:
 - *Enterococcus faecalis* (Yes / No / No data).
If yes: Multiresistent Yes / No / No data
 - *Staphylococcus aureus* (Yes / No / No data).
If yes: Multiresistent Yes / No / No data
 - *Streptococcus pneumoniae* (Yes / No / No data).
If yes: Multiresistent Yes / No / No data
 - *Staphylococcus epidermidis* (Yes / No / No data).
If yes: Multiresistent Yes / No / No data
 - *Streptococcus viridans* (Yes / No / No data).
If yes: Multiresistent Yes / No / No data
 - Other (Yes / No / No data) (If yes, Specify _____).
 - If yes: Multiresistent Yes / No / No data
 - Gram negative (Yes / No / No data). If yes:
 - *Escherichia coli* (Yes / No / No data).
If yes: Multiresistent Yes / No / No data
 - *Pseudomonas aeruginosa* (Yes / No / No data).
If yes: Multiresistent Yes / No / No data
 - *Klebsiella pneumoniae* (Yes / No / No data).
If yes: Multiresistent Yes / No / No data
 - *Enterobacter spp* (Yes / No / No data).
If yes: Multiresistent Yes / No / No data
 - *Proteus mirabilis* (Yes / No / No data).
If yes: Multiresistent Yes / No / No data
 - Other (Yes / No / No data) (If yes, Specify _____).
 - If yes: Multiresistent Yes / No / No data
 - Polimicrobial (Yes / No / No data)
 - Fungus (Yes / No / No data)
 - Other (Yes / No / No data) (If yes, specify _____).

- Blood (Yes / No / No data); If yes:
 - Result: No data / Positive / Negative
 - If positive, isolated organism:
 - Gram positive (Yes / No / No data). If yes:
 - *Enterococcus faecalis* (Yes / No / No data).
If yes: Multiresistent Yes / No / No data
 - *Staphylococcus aureus* (Yes / No / No data).
If yes: Multiresistent Yes / No / No data
 - *Streptococcus pneumoniae* (Yes / No / No data).
If yes: Multiresistent Yes / No / No data
 - *Staphylococcus epidermidis* (Yes / No / No data).
If yes: Multiresistent Yes / No / No data
 - *Streptococcus viridans* (Yes / No / No data).
If yes: Multiresistent Yes / No / No data
 - Other (Yes / No / No data) (If yes, Specify _____).
 - If yes: Multiresistent Yes / No / No data
 - Gram negative (Yes / No / No data). If yes:
 - *Escherichia coli* (Yes / No / No data).
If yes: Multiresistent Yes / No / No data
 - *Pseudomonas aeruginosa* (Yes / No / No data).
If yes: Multiresistent Yes / No / No data
 - *Klebsiella pneumoniae* (Yes / No / No data).
If yes: Multiresistent Yes / No / No data
 - *Enterobacter spp* (Yes / No / No data).
If yes: Multiresistent Yes / No / No data
 - *Proteus mirabilis* (Yes / No / No data).
If yes: Multiresistent Yes / No / No data
 - Other (Yes / No / No data) (If yes, Specify _____).
 - If yes: Multiresistent Yes / No / No data
 - Polimicrobial (Yes / No / No data)
 - Fungus (Yes / No / No data)
 - Other (Yes / No / No data) (If yes, specify _____).

- Urine (Yes / No / No data); If yes:
 - Result: No data / Positive / Negative
 - If positive, isolated organism:
 - Gram positive (Yes / No / No data). If yes:
 - *Enterococcus faecalis* (Yes / No / No data).
If yes: Multiresistent Yes / No / No data
 - *Staphylococcus aureus* (Yes / No / No data).
If yes: Multiresistent Yes / No / No data
 - *Streptococcus pneumoniae* (Yes / No / No data).
If yes: Multiresistent Yes / No / No data
 - *Staphylococcus epidermidis* (Yes / No / No data).
If yes: Multiresistent Yes / No / No data
 - *Streptococcus viridans* (Yes / No / No data).
If yes: Multiresistent Yes / No / No data
 - Other (Yes / No / No data) (If yes, Specify _____).
 - If yes: Multiresistent Yes / No / No data
 - Gram negative (Yes / No / No data). If yes:
 - *Escherichia coli* (Yes / No / No data).
If yes: Multiresistent Yes / No / No data
 - *Pseudomonas aeruginosa* (Yes / No / No data).
If yes: Multiresistent Yes / No / No data
 - *Klebsiella pneumoniae* (Yes / No / No data).
If yes: Multiresistent Yes / No / No data
 - *Enterobacter spp* (Yes / No / No data).
If yes: Multiresistent Yes / No / No data
 - *Proteus mirabilis* (Yes / No / No data).
If yes: Multiresistent Yes / No / No data
 - Other (Yes / No / No data) (If yes, Specify _____).
 - If yes: Multiresistent Yes / No / No data
 - Polimicrobial (Yes / No / No data)
 - Fungus (Yes / No / No data)
 - Other (Yes / No / No data) (If yes, specify _____).

- Pleural fluid (Yes / No / No data); If yes:
 - Result: No data / Positive / Negative
 - If positive, isolated organism:
 - Gram positive (Yes / No / No data). If yes:
 - *Enterococcus faecalis* (Yes / No / No data).
If yes: Multiresistent Yes / No / No data
 - *Staphylococcus aureus* (Yes / No / No data).
If yes: Multiresistent Yes / No / No data
 - *Streptococcus pneumoniae* (Yes / No / No data).
If yes: Multiresistent Yes / No / No data
 - *Staphylococcus epidermidis* (Yes / No / No data).
If yes: Multiresistent Yes / No / No data
 - *Streptococcus viridans* (Yes / No / No data).
If yes: Multiresistent Yes / No / No data
 - Other (Yes / No / No data) (If yes, Specify _____).
 - If yes: Multiresistent Yes / No / No data
 - Gram negative (Yes / No / No data). If yes:
 - *Escherichia coli* (Yes / No / No data).
If yes: Multiresistent Yes / No / No data
 - *Pseudomonas aeruginosa* (Yes / No / No data).
If yes: Multiresistent Yes / No / No data
 - *Klebsiella pneumoniae* (Yes / No / No data).
If yes: Multiresistent Yes / No / No data
 - *Enterobacter spp* (Yes / No / No data).
If yes: Multiresistent Yes / No / No data
 - *Proteus mirabilis* (Yes / No / No data).
If yes: Multiresistent Yes / No / No data
 - Other (Yes / No / No data) (If yes, Specify _____).
 - If yes: Multiresistent Yes / No / No data
 - Polimicrobial (Yes / No / No data)
 - Fungus (Yes / No / No data)
 - Other (Yes / No / No data) (If yes, specify _____).

- Other (Yes / No / No data); If yes:
 - Specify: _____
 - Result: No data / Positive / Negative
 - If positive, isolated organism:
 - Gram positive (Yes / No / No data). If yes:
 - *Enterococcus faecalis* (Yes / No / No data).
If yes: Multiresistent Yes / No / No data
 - *Staphylococcus aureus* (Yes / No / No data).
If yes: Multiresistent Yes / No / No data
 - *Streptococcus pneumoniae* (Yes / No / No data).
If yes: Multiresistent Yes / No / No data
 - *Staphylococcus epidermidis* (Yes / No / No data).
If yes: Multiresistent Yes / No / No data
 - *Streptococcus viridans* (Yes / No / No data).
If yes: Multiresistent Yes / No / No data
 - Other (Yes / No / No data) (If yes, Specify _____).
 - If yes: Multiresistent Yes / No / No data
 - Gram negative (Yes / No / No data). If yes:
 - *Escherichia coli* (Yes / No / No data).
If yes: Multiresistent Yes / No / No data
 - *Pseudomonas aeruginosa* (Yes / No / No data).
If yes: Multiresistent Yes / No / No data
 - *Klebsiella pneumoniae* (Yes / No / No data).
If yes: Multiresistent Yes / No / No data
 - *Enterobacter spp* (Yes / No / No data).
If yes: Multiresistent Yes / No / No data
 - *Proteus mirabilis* (Yes / No / No data).
If yes: Multiresistent Yes / No / No data
 - Other (Yes / No / No data) (If yes, Specify _____).
 - If yes: Multiresistent Yes / No / No data
 - Polimicrobial (Yes / No / No data)
 - Fungus (Yes / No / No data)
 - Other (Yes / No / No data) (If yes, specify _____).

Treatments administered within the period

Has the patient received any treatment during this period? (Yes / No / No data).

If yes, specify:

- Treatment for ascites (Yes / No / No data). If yes:
 - Paracentesis (Yes / No / No data). If yes
 - Total volume removed (L) _____
 - Total dose of Albumin dose (g) _____
 - Diuretics (Yes/No/ No data). If yes:
 - Spironolactone (Yes / No / No data); If yes:
 - Dose (mg/day) _____
 - Canrenoate (Yes / No / No data); If yes:
 - Dose (mg/day) _____
 - Furosemide (Yes / No / No data); If yes:
 - Dose (mg/day) _____
 - Hydrochlorotiazide (Yes / No / No data); If yes:
 - Dose (mg/day) _____
 - Amiloride (Yes / No / No data); If yes:
 - Dose (mg/day) _____
 - Others (Yes / No / No data); If yes:
 - Specify _____
 - Dose (mg/day) _____
- Treatment for encephalopathy (Yes / No / No data). If yes:
 - Lactulose (Yes / No / No data); If yes, dose (g/day) _____
 - Rifaximin (Yes / No / No data); If yes, dose (mg/day) _____
 - Neomycin (Yes / No / No data); If yes, dose (mg/day) _____
 - Metronidazole (Yes / No / No data); If yes, dose (mg/day) _____
 - Others (Yes / No / No data); If yes:
 - Specify _____
 - Dose (mg/day) _____

- Treatment for GI-Bleeding (Yes / No / No data): If yes
 - Pharmacological treatment (Yes / No / No data). If yes:
 - Somatostatin (Yes / No / No data); If yes, dose ($\mu\text{g/h}$) _____
 - Terlipressin (Yes / No / No data); If yes, dose(mg/day) _____
 - Others (Yes / No / No data); If yes, specify _____
 - Endoscopic Therapy (Yes / No / No data). If yes:
 - Band ligation (Yes / No / No data)
 - Sclerotherapy of varices (Yes / No / No data)
 - Haemostasis of peptic lesion (Yes / No / No data)
 - TIPS (Yes / No / No data)
 - Others (Yes / No / No data); If yes, specify _____

- Treatment for infection (Yes / No / No data).

If yes, choose one of the following:

- Antibiotics alone:

Antibiotic 1 _____; Dose: _____ Unit: _____

Antibiotic 2 _____; Dose: _____ Unit: _____

Antibiotic 3 _____; Dose: _____ Unit: _____

Antibiotic 4 _____; Dose: _____ Unit: _____

Antibiotic 5 _____; Dose: _____ Unit: _____

.....
 /

- Antibiotics with albumin:

Albumin dose (g/day) _____

Antibiotic 1 _____; Dose: _____ Unit: _____

Antibiotic 2 _____; Dose: _____ Unit: _____

Antibiotic 3 _____; Dose: _____ Unit: _____

Antibiotic 4 _____; Dose: _____ Unit: _____

Antibiotic 5 _____; Dose: _____ Unit: _____

.....
 /

- No data

- Fluid therapy (Yes / No / No data). If yes:
 - Type:
 - Cristalloid (Yes / No / No data).
If Yes: Specify _____ / Average Volume (L/day) _____
 - Colloid (Yes / No / No data).
If Yes: Type _____ / Average Volume (L/day) _____
 - Albumin (Yes / No / No data).
If Yes:
 - Concentration (%): No data / 5 / 20 / 25
 - Average Volume (mL/day): _____
 - Indication:
 - Spontaneous bacterial peritonitis (Yes / No / No data)
 - Hepatorenal syndrome (Yes / No / No data)
 - Volume Replacement (Yes / No / No data)
 - Hepathic encephalopathy (Yes / No / No data)
 - Bleeding (Yes / No / No data)
 - Others (Yes / No / No data); If yes, specify _____

- Transfusion (Yes / No / No data). If yes
 - Red Blood cells (Yes / No / No data) If Yes: Blood units _____
 - Fresh frozen plasma (Yes / No / No data) If Yes: Units _____
 - Platelets (Yes / No / No data) If Yes: Volume (mL) _____
 - Crioprecipitate (Yes / No / No data) If Yes: Volume (mL) _____

- Vasoactive drugs (Yes / No / No data). If yes:
 - Indication: No data / Hepatorenal Syndrome / Sitemic Hemodinamic Support
 - Drug:
 - Terlipressin (Yes / No / No data); If yes, dose (mg/day) _____
 - Noradrenaline (Yes / No / No data); If yes, dose ($\mu\text{g}/\text{Kg}/\text{min}$) _____
 - Midodrine (Yes / No / No data); If yes, dose (mg/day) _____
 - Dopamine (Yes / No / No data); If yes, dose ($\mu\text{g}/\text{Kg}/\text{min}$) _____
 - Others (Yes / No / No data). If yes, specify _____

- Surgery (Yes / No / No data), If yes, specify _____

- Corticoids (Yes / No / No data). If yes:
 - No data / Prednisone / Prednisolone / Methylprednisolone / Hydrocortisone (dose, mg/day) _____

- Prophylaxis of bacterial infection (Yes / No / No data) If yes:
 - Type: No data / Primary / Secondary
 - Drugs: No data / Quinolones / Other-specify _____

- Prophylaxis of gastrointestinal bleeding (Yes / No / No data). If yes:
 - Type: No data / Primary / Secondary
 - Specify: No data / Propranolol / Nadolol / Carvedilol (dose, mg/day) _____

- Mechanical ventilation (Yes / No / No data); If yes:
 - Tidal volume (mL) _____
 - PEEP (cm H₂O) _____
 - FiO₂ (%) _____
 - PaO₂ _____ (mmHg) / _____ (kPa)
The PaO₂ / FiO₂ ratio will be calculated by the data-entry application.

- Renal replacement therapy (Yes / No / No data)

- Other (Yes / No / No data); If yes: specify _____

Scores

All scores except APACHE II will be derived from data introduced in the data-entry application.
Additional information for Lille and Cardiovascular SOFA-Subscore is required:

Lille's score information:

- Does the patient suffer from alcoholic hepatitis? (Yes / No / No data) If yes:

The Lille score can be calculated only if the patient has been under corticosteroid treatment for at least 7 days:

- Is it applicable to this visit? (Yes / No / No data) If yes:

The following parameters at Days 0 and 7 of treatment are required

- Bilirubin at day 0 ($\mu\text{mol/L}$) _____
- Bilirubin at day 7 ($\mu\text{mol/L}$) _____
- Creatinine at day 0 ($\mu\text{mol/L}$) _____

In patients who have received albumin infusions, use the last available albumin value before the infusion of albumin occurred. If albumin infusions are not received, enter 0.

- Albumin at day 0 (g/L) _____
- Patient's prothrombin time at day 0 (sec) _____

SOFA Subscores:

- **Cardiovascular Subscore information:**

- Dopamine (Yes / No / No data); If yes: Dose ($\mu\text{g/Kg/min}$) _____
- Dobutamine (Yes / No / No data)
- Terlipressin for Systemic Hemodynamic Support (Yes / No / No data)
- Epinephrine (Yes / No / No data); If yes: Dose ($\mu\text{g/Kg/min}$) _____
- Norepinephrine (Yes / No / No data); If yes: Dose ($\mu\text{g/Kg/min}$) _____

APACHE II score information:

- Has the patient been admitted to the ICU unit? (Yes / No / No data)
- Does the patient have arterial samples? (Yes / No / No data)

If at least one of the previous answers is YES please fill in:

- APACHE II _____

Place and clinical course of patient at the end of the period

- ICU (Yes / No / No data). If yes:
 - Number of days in the ICU _____
- Ward (Yes / No / No data)
- Discharged (Yes / No / No data); If yes: Date ____ / ____ / _____
- Discharged and re-admitted (Yes / No / No data); If yes: Date ____ / ____ / _____
- **Alive / Dead / No data**
 - If Dead:
 - **Date of exitus ____ / ____ / _____**
 - Causes of death:
 - Hepatocellular carcinoma (Yes / No / No data)
 - Hypovolemic shock (Yes / No / No data)
 - Septic shock (Yes / No / No data)
 - Multiorgan failure in the absence of hypovolemic or septic shock (Yes / No / No data). If yes:
 - Organ failures:
 - Hepatic (Yes / No / No data)
 - Renal (Yes / No / No data)
 - Cerebral (Yes / No / No data)
 - Respiratory (Yes / No / No data)
 - Cardiac (Yes / No / No data)
 - Coagulation (Yes / No / No data).
 - Multiorgan failure after recovering from hypovolemic shock (Yes / No / No data). If yes:
 - Organ failures:
 - Hepatic (Yes / No / No data)
 - Renal (Yes / No / No data)
 - Cerebral (Yes / No / No data)
 - Respiratory (Yes / No / No data)
 - Cardiac (Yes / No / No data)
 - Coagulation (Yes / No / No data).
 - Multiorgan failure after recovering from septic shock (Yes / No / No data). If yes:
 - Organ failures:
 - Hepatic (Yes / No / No data)
 - Renal (Yes / No / No data)
 - Cerebral (Yes / No / No data)
 - Respiratory (Yes / No / No data)
 - Cardiac (Yes / No / No data)
 - Coagulation (Yes / No / No data).
 - Other (Yes / No / No data); If yes, specify _____
 - Unknown (Yes / No / No data)

○ If Alive:

- Patient transplanted (Yes / No / No data); If yes: Date ____ / ____ / ____
- Patient's evolution:
 - No data
 - Cured (complete resolution of all specific complications)
 - Better (partial resolution of all specific complications or complete resolution of some complications)
 - Stable (complications not resolved)
 - Worse (worsening of all complications or development of new ones)

PERIOD 22 - 28

**(after study inclusion and during hospitalization for patients in Groups #1 and #2;
after the onset of 1st extra-hepatic organ failure and during hospitalization for
Group #4)**

Period 22 - 28 Date: ____ / ____ / ____

(Unless the patient has been discharged before, please choose the last day of the period).

Time (24h): ____ : ____

Enrollment in Other Prophylactic or Therapeutic Studies within this period

• Has the patient been included in a prophylactic or therapeutic study during this period (Yes / No / No data).

▪ If yes:

• Type of study:

No data

/ Prophylactic

/ Therapeutic

/ Non randomized

/ Randomized placebo-controlled

/ Randomized comparative

• Study treatment (specify _____)

• Control treatment (specify _____)

• Does the patient continue in the study after this period
(Yes / No / No data)?

Clinical features during the period

- Ascites (Yes / No / No data); If yes,
 - Type: No data / Mild to Moderate / Large - Tense
- Encephalopathy (Yes / No / No data); If yes:
 - Stage: West Haven score: No data / 1 / 2 / 3 / 4
- Renal failure (Yes / No / No data); If yes:
 - Renal failure type:
 - No data / HRS type I / HRS type II / Pre-renal / Other (specify _____) / Unknown / Still undetermined
- Bacterial infection (Yes / No / No data). If yes:
 - Timeframe of infection (choose one of the following):
 - No data /
 - New Infection /
 - Type of infection:
 - SBP (Yes / No / No data)
 - Pneumonia (Yes / No / No data)
 - Urinary tract infection (UTI) (Yes / No / No data)
 - Skin infection (Yes / No / No data)
 - Unproved suspected infection (Yes / No / No data)
 - Other (Yes / No / No data); If yes, specify _____
 - Sepsis (Yes / No / No data). If yes:
 - Sepsis category: No data / Sepsis Only / Severe sepsis / Septic shock
 - Time from infection (days) _____
 - Site of acquisition: No data / Community / Hospital
 - Infection under antibiotic treatment /
 - Therapeutic Response (Yes / No / No data)
 - Resolution of Infection (Yes / No / No data)

- Superinfection /
 - Type of infection:
 - SBP (Yes / No / No data)
 - Pneumonia (Yes / No / No data)
 - Urinary tract infection (UTI) (Yes / No / No data)
 - Skin infection (Yes / No / No data)
 - Unproved suspected infection (Yes / No / No data)
 - Other (Yes / No / No data); If yes, specify _____
 - Sepsis (Yes / No / No data). If yes:
Sepsis category: No data / Sepsis Only / Severe sepsis / Septic shock
 - Time from infection (days) _____
 - Site of acquisition: No data / Community / Hospital
- Gastrointestinal bleeding (Yes / No / No data);
 - Etiology:
 - Variceal bleeding (Yes / No / No data)
 - Peptic ulcer lesion (Yes / No / No data)
 - Portal hypertension non-variceal bleeding (Yes / No / No data)
 - Other causes (Yes / No / No data); If yes, specify _____
 - Unknown (Yes / No / No data)
 - GI-bleeding complicated by hypovolemic shock? (Yes / No / No data)
 - Time from onset to present study visit (days, if days < 1, enter 1) _____
 - Resolution (Yes / No / No data);
- Others (Yes / No / No data), If yes, specify _____

Exploratory data

For repeated values in the same visit (period), the last available value of each variable will be taken.

- Body weight (Kg) _____

- Arterial pressure:

Systolic Blood Pressure (mmHg) _____

Diastolic Blood Pressure (mmHg) _____

The mean arterial pressure (MAP) will be calculated by the data-entry application.

- Heart rate (beats/min) _____

- Axillary temperature (°C) _____

- Respiratory rate (breaths/min) _____

- Supplemental oxygen (Yes / No / No data);

- If No: FiO₂ will take the value "21%".

- If Yes: Delivery device (Choose one of the following):

- No data;

- Nasal catheter; If chosen: Flow (liters of O₂ / min): 1 / 2 / 3 / 4 / 5 / 6+

- Face mask with reservoir; If chosen: Flow (liters of O₂ / min): 6 / 7 / 8 / 9 / 10+

- Venturi mask; If chosen: Flow (liters of O₂ / min): 4 / 8 / 12+

- SpO₂ (%) _____

The SpO₂ / FiO₂ ratio will be calculated by the data-entry application.

- Urine volume (mL/h) _____

- Chest X-ray (Normal / Abnormal / No data); If Abnormal:

Specify _____

Laboratory data (For repeated values in the same period, the last available value of each variable will be taken).

- Hematocrit _____ (%)
- Hemoglobin level _____ (g/dL) / _____ (g/L)
- White Blood Cells count _____ (x 10⁹ cells/L) / _____ (x cells/mm³)
- % immature neutrophils (bands) _____ (%)
- Platelet count _____ (x 10³/μL) / _____ (x 10⁹/L)
- Total serum bilirubin _____ (mg/dL) / _____ (μmol/L)
- Serum albumin _____ (g/dL) / _____ (g/L)
- Control prothrombin time _____ (sec)
- Prothrombin time _____ (sec)
- % of Control _____ (%)
- **INR**
- Activated partial-thromboplastin time ratio _____
- ALT _____ (U/L) / _____ (μkat/L)
- AST _____ (U/L) / _____ (μkat/L)
- AP _____ (U/L) / _____ (μkat/L)
- GGT _____ (U/L)
- Blood glucose _____ (mg/dL) / _____ (mmol/L)
- When needed:
 - Supplemental oxygen (Yes / No / No data);
 - If No: FiO₂ will take the value "21%".
 - If Yes: Delivery device (Choose one of the following):
 - No data;
 - Nasal catheter; If chosen: Flow (liters of O₂ / min): 1 / 2 / 3 / 4 / 5 / 6+
 - Face mask with reservoir; If chosen: Flow (liters of O₂ / min): 6 / 7 / 8 / 9 / 10+
 - Venturi mask; If chosen: Flow (liters of O₂ / min): 4 / 8 / 12+
 - PaO₂ _____ (mmHg) / _____ (kPa)
 - Arterial pH _____
 - PaCO₂ _____ (mmHg) / _____ (kPa)
 - Serum bicarbonate _____ (mEq/L) / _____ (mmol/L)
 - Serum lactate _____ (mg/dL) / _____ (mmol/L)

The PaO₂ / FiO₂ ratio will be calculated by the data-entry application.
- Plasma C-reactive protein _____ (mg/L)
- Serum creatinine _____ (mg/dL) / _____ (μmol/L)
- Blood urea nitrogen _____ (mg/dL) / _____ (mmol/L)
- Serum sodium _____ (mEq/L) / _____ (mmol/L)
- Serum potassium _____ (mEq/L) / _____ (mmol/L)
- Urine sodium concentration _____ (mEq/L) / _____ (mmol/L)
- Urine creatinine concentration _____ (mg/dL) / _____ (μmol/L)
- Proteinuria (dipstick test: No data / Absent / Trace / 1+ / 2+ / 3+ / 4+)
- Hematuria: Yes / No / No data (If yes, cells / HPF: No data / <10 / 11-20 / 21-50 / >50)
- Ascitic fluid total protein concentration _____ (g/dL) / _____ (g/L)
- Ascitic fluid neutrophil count _____ (Cells/mL)

Microbiological data (only in patients with infections)

- Culture done (sample taken):
 - Ascitic fluid (Yes / No / No data); If yes:
 - Result: No data / Positive / Negative
 - If positive, isolated organism:
 - Gram positive (Yes / No / No data). If yes:
 - *Enterococcus faecalis* (Yes / No / No data).
If yes: Multiresistent Yes / No / No data
 - *Staphylococcus aureus* (Yes / No / No data).
If yes: Multiresistent Yes / No / No data
 - *Streptococcus pneumoniae* (Yes / No / No data).
If yes: Multiresistent Yes / No / No data
 - *Staphylococcus epidermidis* (Yes / No / No data).
If yes: Multiresistent Yes / No / No data
 - *Streptococcus viridans* (Yes / No / No data).
If yes: Multiresistent Yes / No / No data
 - Other (Yes / No / No data) (If yes, Specify _____).
 - If yes: Multiresistent Yes / No / No data
 - Gram negative (Yes / No / No data). If yes:
 - *Escherichia coli* (Yes / No / No data).
If yes: Multiresistent Yes / No / No data
 - *Pseudomonas aeruginosa* (Yes / No / No data).
If yes: Multiresistent Yes / No / No data
 - *Klebsiella pneumoniae* (Yes / No / No data).
If yes: Multiresistent Yes / No / No data
 - *Enterobacter spp* (Yes / No / No data).
If yes: Multiresistent Yes / No / No data
 - *Proteus mirabilis* (Yes / No / No data).
If yes: Multiresistent Yes / No / No data
 - Other (Yes / No / No data) (If yes, Specify _____).
 - If yes: Multiresistent Yes / No / No data
- Polimicrobial (Yes / No / No data)
- Fungus (Yes / No / No data)
- Other (Yes / No / No data) (If yes, specify _____).

- Blood (Yes / No / No data); If yes:
 - If yes, Result: No data / Positive / Negative
 - If positive, isolated organism:
 - Gram positive (Yes / No / No data). If yes:
 - *Enterococcus faecalis* (Yes / No / No data).
If yes: Multiresistent Yes / No / No data
 - *Staphylococcus aureus* (Yes / No / No data).
If yes: Multiresistent Yes / No / No data
 - *Streptococcus pneumoniae* (Yes / No / No data).
If yes: Multiresistent Yes / No / No data
 - *Staphylococcus epidermidis* (Yes / No / No data).
If yes: Multiresistent Yes / No / No data
 - *Streptococcus viridans* (Yes / No / No data).
If yes: Multiresistent Yes / No / No data
 - Other (Yes / No / No data) (If yes, Specify _____).
 - If yes: Multiresistent Yes / No / No data
 - Gram negative (Yes / No / No data). If yes:
 - *Escherichia coli* (Yes / No / No data).
If yes: Multiresistent Yes / No / No data
 - *Pseudomonas aeruginosa* (Yes / No / No data).
If yes: Multiresistent Yes / No / No data
 - *Klebsiella pneumoniae* (Yes / No / No data).
If yes: Multiresistent Yes / No / No data
 - *Enterobacter spp* (Yes / No / No data).
If yes: Multiresistent Yes / No / No data
 - *Proteus mirabilis* (Yes / No / No data).
If yes: Multiresistent Yes / No / No data
 - Other (Yes / No / No data) (If yes, Specify _____).
 - If yes: Multiresistent Yes / No / No data
 - Polimicrobial (Yes / No / No data)
 - Fungus (Yes / No / No data)
 - Other (Yes / No / No data) (If yes, specify _____).

- Urine (Yes / No / No data); If yes:
 - Result: No data / Positive / Negative
 - If positive, isolated organism:
 - Gram positive (Yes / No / No data). If yes:
 - *Enterococcus faecalis* (Yes / No / No data).
If yes: Multiresistent Yes / No / No data
 - *Staphylococcus aureus* (Yes / No / No data).
If yes: Multiresistent Yes / No / No data
 - *Streptococcus pneumoniae* (Yes / No / No data).
If yes: Multiresistent Yes / No / No data
 - *Staphylococcus epidermidis* (Yes / No / No data).
If yes: Multiresistent Yes / No / No data
 - *Streptococcus viridans* (Yes / No / No data).
If yes: Multiresistent Yes / No / No data
 - Other (Yes / No / No data) (If yes, Specify _____).
 - If yes: Multiresistent Yes / No / No data
 - Gram negative (Yes / No / No data). If yes:
 - *Escherichia coli* (Yes / No / No data).
If yes: Multiresistent Yes / No / No data
 - *Pseudomonas aeruginosa* (Yes / No / No data).
If yes: Multiresistent Yes / No / No data
 - *Klebsiella pneumoniae* (Yes / No / No data).
If yes: Multiresistent Yes / No / No data
 - *Enterobacter spp* (Yes / No / No data).
If yes: Multiresistent Yes / No / No data
 - *Proteus mirabilis* (Yes / No / No data).
If yes: Multiresistent Yes / No / No data
 - Other (Yes / No / No data) (If yes, Specify _____).
 - If yes: Multiresistent Yes / No / No data
 - Polimicrobial (Yes / No / No data)
 - Fungus (Yes / No / No data)
 - Other (Yes / No / No data) (If yes, specify _____).

- Pleural fluid (Yes / No / No data); If yes:
 - Result: No data / Positive / Negative
 - If positive, isolated organism:
 - Gram positive (Yes / No / No data). If yes:
 - *Enterococcus faecalis* (Yes / No / No data).
If yes: Multiresistant Yes / No / No data
 - *Staphylococcus aureus* (Yes / No / No data).
If yes: Multiresistant Yes / No / No data
 - *Streptococcus pneumoniae* (Yes / No / No data).
If yes: Multiresistant Yes / No / No data
 - *Staphylococcus epidermidis* (Yes / No / No data).
If yes: Multiresistant Yes / No / No data
 - *Streptococcus viridans* (Yes / No / No data).
If yes: Multiresistant Yes / No / No data
 - Other (Yes / No / No data) (If yes, Specify _____).
 - If yes: Multiresistant Yes / No / No data
 - Gram negative (Yes / No / No data). If yes:
 - *Escherichia coli* (Yes / No / No data).
If yes: Multiresistant Yes / No / No data
 - *Pseudomonas aeruginosa* (Yes / No / No data).
If yes: Multiresistant Yes / No / No data
 - *Klebsiella pneumoniae* (Yes / No / No data).
If yes: Multiresistant Yes / No / No data
 - *Enterobacter spp* (Yes / No / No data).
If yes: Multiresistant Yes / No / No data
 - *Proteus mirabilis* (Yes / No / No data).
If yes: Multiresistant Yes / No / No data
 - Other (Yes / No / No data) (If yes, Specify _____).
 - If yes: Multiresistant Yes / No / No data
 - Polimicrobial (Yes / No / No data)
 - Fungus (Yes / No / No data)
 - Other (Yes / No / No data) (If yes, specify _____).

- Other (Yes / No / No data): If yes:
 - Specify: _____
 - Result: No data / Positive / Negative
 - If positive, isolated organism:
 - Gram positive (Yes / No / No data). If yes:
 - *Enterococcus faecalis* (Yes / No / No data).
If yes: Multiresistent Yes / No / No data
 - *Staphylococcus aureus* (Yes / No / No data).
If yes: Multiresistent Yes / No / No data
 - *Streptococcus pneumoniae* (Yes / No / No data).
If yes: Multiresistent Yes / No / No data
 - *Staphylococcus epidermidis* (Yes / No / No data).
If yes: Multiresistent Yes / No / No data
 - *Streptococcus viridans* (Yes / No / No data).
If yes: Multiresistent Yes / No / No data
 - Other (Yes / No / No data) (If yes, Specify _____).
 - If yes: Multiresistent Yes / No / No data
 - Gram negative (Yes / No / No data). If yes:
 - *Escherichia coli* (Yes / No / No data).
If yes: Multiresistent Yes / No / No data
 - *Pseudomonas aeruginosa* (Yes / No / No data).
If yes: Multiresistent Yes / No / No data
 - *Klebsiella pneumoniae* (Yes / No / No data).
If yes: Multiresistent Yes / No / No data
 - *Enterobacter spp* (Yes / No / No data).
If yes: Multiresistent Yes / No / No data
 - *Proteus mirabilis* (Yes / No / No data).
If yes: Multiresistent Yes / No / No data
 - Other (Yes / No / No data) (If yes, Specify _____).
 - If yes: Multiresistent Yes / No / No data
- Polimicrobial (Yes / No / No data)
- Fungus (Yes / No / No data)
- Other (Yes / No / No data) (If yes, specify _____).

Treatments administered within the period

Has the patient received any treatment during this period? (Yes / No / No data).

If yes, specify:

- Treatment for ascites (Yes / No / No data). If yes:
 - Paracentesis (Yes / No / No data). If yes
 - Total volume removed (L) _____
 - Total dose of Albumin dose (g) _____
 - Diuretics (Yes/No/ No data). If yes:
 - Spironolactone (Yes / No / No data); If yes:
 - Dose (mg/day) _____
 - Canrenoate (Yes / No / No data); If yes:
 - Dose (mg/day) _____
 - Furosemide (Yes / No / No data); If yes:
 - Dose (mg/day) _____
 - Hydrochlorotiazide (Yes / No / No data); If yes:
 - Dose (mg/day) _____
 - Amiloride (Yes / No / No data); If yes:
 - Dose (mg/day) _____
 - Others (Yes / No / No data); If yes:
 - Specify _____
 - Dose (mg/day) _____

- Treatment for encephalopathy (Yes / No / No data). If yes:
 - Lactulose (Yes / No / No data); If yes, dose (g/day) _____
 - Rifaximin (Yes / No / No data); If yes, dose (mg/day) _____
 - Neomycin (Yes / No / No data); If yes, dose (mg/day) _____
 - Metronidazole (Yes / No / No data); If yes, dose (mg/day) _____
 - Others (Yes / No / No data); If yes:
 - Specify _____
 - Dose (mg/day) _____

- Treatment for GI-Bleeding (Yes / No / No data): If yes
 - Pharmacological treatment (Yes / No / No data). If yes:
 - Somatostatin (Yes / No / No data); If yes, dose ($\mu\text{g/h}$) _____
 - Terlipressin (Yes / No / No data); If yes, dose(mg/day) _____
 - Others (Yes / No / No data); If yes, specify _____
 - Endoscopic Therapy (Yes / No / No data). If yes:
 - Band ligation (Yes / No / No data)
 - Sclerotherapy of varices (Yes / No / No data)
 - Haemostasis of peptic lesion (Yes / No / No data)
 - TIPS (Yes / No / No data)
 - Others (Yes / No / No data); If yes, specify _____

- Treatment for infection (Yes / No / No data).

If yes, choose one of the following:

- Antibiotics alone:

Antibiotic 1 _____; Dose: _____ Unit: _____

Antibiotic 2 _____; Dose: _____ Unit: _____

Antibiotic 3 _____; Dose: _____ Unit: _____

Antibiotic 4 _____; Dose: _____ Unit: _____

Antibiotic 5 _____; Dose: _____ Unit: _____

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- Antibiotics with albumin:

Albumin dose (g/day) _____

Antibiotic 1 _____; Dose: _____ Unit: _____

Antibiotic 2 _____; Dose: _____ Unit: _____

Antibiotic 3 _____; Dose: _____ Unit: _____

Antibiotic 4 _____; Dose: _____ Unit: _____

Antibiotic 5 _____; Dose: _____ Unit: _____

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- No data

- Fluid therapy (Yes / No / No data). If yes:
 - Type:
 - Cristalloid (Yes / No / No data).
If Yes: Specify _____ / Average Volume (L/day) _____
 - Colloid (Yes / No / No data).
If Yes: Type _____ / Average Volume (L/day) _____
 - Albumin (Yes / No / No data).
If Yes:
 - Concentration (%): No data / 5 / 20 / 25
 - Average Volume (mL/day): _____
 - Indication:
 - Spontaneous bacterial peritonitis (Yes / No / No data)
 - Hepatorenal syndrome (Yes / No / No data)
 - Volume Replacement (Yes / No / No data)
 - Hepathic encephalopathy (Yes / No / No data)
 - Bleeding (Yes / No / No data)
 - Others (Yes / No / No data); If yes, specify _____
- Transfusion (Yes / No / No data). If yes
 - Red Blood cells (Yes / No / No data) If Yes: Blood units _____
 - Fresh frozen plasma (Yes / No / No data) If Yes: Units _____
 - Platelets (Yes / No / No data) If Yes: Volume (mL) _____
 - Crioprecipitate (Yes / No / No data) If Yes: Volume (mL) _____
- Vasoactive drugs (Yes / No / No data). If yes:
 - Indication: No data / Hepatorenal Syndrome / Sitemic Hemodinamic Support
 - Drug:
 - Terlipressin (Yes / No / No data); If yes, dose (mg/day) _____
 - Noradrenaline (Yes / No / No data); If yes, dose ($\mu\text{g}/\text{Kg}/\text{min}$) _____
 - Midodrine (Yes / No / No data); If yes, dose (mg/day) _____
 - Dopamine (Yes / No / No data); If yes, dose ($\mu\text{g}/\text{Kg}/\text{min}$) _____
 - Others (Yes / No / No data). If yes, specify _____

- Surgery (Yes / No / No data), If yes, specify _____

- Corticoids (Yes / No / No data). If yes:
 - No data / Prednisone / Prednisolone / Methylprednisolone / Hydrocortisone (dose, mg/day) _____

- Prophylaxis of bacterial infection (Yes / No / No data) If yes:
 - Type: No data / Primary / Secondary
 - Drugs: No data / Quinolones / Other-specify _____

- Prophylaxis of gastrointestinal bleeding (Yes / No / No data). If yes:
 - Type: No data / Primary / Secondary
 - Specify: No data / Propranolol / Nadolol / Carvedilol (dose, mg/day) _____

- Mechanical ventilation (Yes / No / No data); If yes:
 - Tidal volume (mL) _____
 - PEEP (cm H2O) _____
 - FiO₂ (%) _____
 - PaO₂ _____ (mmHg) / _____ (kPa)
The PaO₂ / FiO₂ ratio will be calculated by the data-entry application.

- Renal replacement therapy (Yes / No / No data)

- Other (Yes / No / No data); If yes: specify _____

Scores

All scores except APACHE II will be derived from data introduced in the data-entry application. Additional information for Lille and Cardiovascular SOFA-Subscore is required:

Lille's score information:

- Does the patient suffer from alcoholic hepatitis? (Yes / No / No data) If yes:

The Lille score can be calculated only if the patient has been under corticosteroid treatment for at least 7 days:

- Is it applicable to this visit? (Yes / No / No data) If yes:

The following parameters at Days 0 and 7 of treatment are required

- Bilirubin at day 0 ($\mu\text{mol/L}$) _____
- Bilirubin at day 7 ($\mu\text{mol/L}$) _____
- Creatinine at day 0 ($\mu\text{mol/L}$) _____

In patients who have received albumin infusions, use the last available albumin value before the infusion of albumin occurred. If albumin infusions are not received, enter 0.

- Albumin at day 0 (g/L) _____
- Patient's prothrombin time at day 0 (sec) _____

SOFA Subscores:

- **Cardiovascular Subscore information:**

- Dopamine (Yes / No / No data); If yes: Dose ($\mu\text{g/Kg/min}$) _____
- Dobutamine (Yes / No / No data)
- Terlipressin for Systemic Hemodynamic Support (Yes / No / No data)
- Epinephrine (Yes / No / No data); If yes: Dose ($\mu\text{g/Kg/min}$) _____
- Norepinephrine (Yes / No / No data); If yes: Dose ($\mu\text{g/Kg/min}$) _____

APACHE II score information:

- Has the patient been admitted to the ICU unit? (Yes / No / No data)
- Does the patient have arterial samples? (Yes / No / No data)

If at least one of the previous answers is YES please fill in:

- APACHE II _____

Place and clinical course of patient at the end of the period

- ICU (Yes / No / No data). If yes:
 - Number of days in the ICU _____
- Ward (Yes / No / No data)
- Discharged (Yes / No / No data); If yes: Date ____ / ____ / _____
- Discharged and re-admitted (Yes / No / No data); If yes: Date ____ / ____ / _____
- **Alive / Dead / No data**
 - If Dead:
 - **Date of exitus ____ / ____ / _____**
 - Causes of death:
 - Hepatocellular carcinoma (Yes / No / No data)
 - Hypovolemic shock (Yes / No / No data)
 - Septic shock (Yes / No / No data)
 - Multiorgan failure in the absence of hypovolemic or septic shock (Yes / No / No data). If yes:
 - Organ failures:
 - Hepatic (Yes / No / No data)
 - Renal (Yes / No / No data)
 - Cerebral (Yes / No / No data)
 - Respiratory (Yes / No / No data)
 - Cardiac (Yes / No / No data)
 - Coagulation (Yes / No / No data).
 - Multiorgan failure after recovering from hypovolemic shock (Yes / No / No data). If yes:
 - Organ failures:
 - Hepatic (Yes / No / No data)
 - Renal (Yes / No / No data)
 - Cerebral (Yes / No / No data)
 - Respiratory (Yes / No / No data)
 - Cardiac (Yes / No / No data)
 - Coagulation (Yes / No / No data).
 - Multiorgan failure after recovering from septic shock (Yes / No / No data). If yes:
 - Organ failures:
 - Hepatic (Yes / No / No data)
 - Renal (Yes / No / No data)
 - Cerebral (Yes / No / No data)
 - Respiratory (Yes / No / No data)
 - Cardiac (Yes / No / No data)
 - Coagulation (Yes / No / No data).
 - Other (Yes / No / No data); If yes, specify _____
 - Unknown (Yes / No / No data)

- If Alive:
 - Patient transplanted (Yes / No / No data); If yes: Date ____ / ____ / ____
 - Patient's evolution:
 - No data
 - Cured (complete resolution of all specific complications)
 - Better (partial resolution of all specific complications or complete resolution of some complications)
 - Stable (complications not resolved)
 - Worse (worsening of all complications or development of new ones)

Biological samples scheduled for this visit

- Were **plasma** samples taken? (Yes / No / No data). If yes: Date ____ / ____ / ____.
- Were **blood** samples taken? (Yes / No / No data). If yes: Date ____ / ____ / ____.
- Were **urine** samples taken? (Yes / No / No data). If yes: Date ____ / ____ / ____.
- Were **ascitis fluid** samples taken? (Yes / No / No data). If yes: Date ____ / ____ / ____.
- Was **liver biopsy** performed? (Yes / No / No data). If yes: Date ____ / ____ / ____.

For patient Group #3, samples will be taken only at Day 1 or alternatively at Day 2. They should not be collected in this period.

28-DAYS FOLLOW-UP (ALL PATIENTS)**Vital status during the follow-up (Information can be obtained by phone call)**

- Follow-up date __ / ____ / _____
- Patient's vital status: Alive / Dead / No data
 - If patient's dead:
 - Date of exitus __ / ____ / _____
 - Causes of death:
 - Hepatocellular carcinoma (Yes / No / No data)
 - Hypovolemic shock (Yes / No / No data)
 - Septic shock (Yes / No / No data)
 - Multiorgan failure in the absence of hypovolemic or septic shock (Yes/No/No data). If yes:
 - Organ failures:
 - Hepatic (Yes / No / No data)
 - Renal (Yes / No / No data)
 - Cerebral (Yes / No / No data)
 - Respiratory (Yes / No / No data)
 - Cardiac (Yes / No / No data)
 - Coagulation (Yes / No / No data).
 - Multiorgan failure after recovering from hypovolemic shock (Yes / No / No data). If yes:
 - Organ failures:
 - Hepatic (Yes / No / No data)
 - Renal (Yes / No / No data)
 - Cerebral (Yes / No / No data)
 - Respiratory (Yes / No / No data)
 - Cardiac (Yes / No / No data)
 - Coagulation (Yes / No / No data).
 - Multiorgan failure after recovering from septic shock (Yes / No / No data). If yes:
 - Organ failures:
 - Hepatic (Yes / No / No data)
 - Renal (Yes / No / No data)
 - Cerebral (Yes / No / No data)
 - Respiratory (Yes / No / No data)
 - Cardiac (Yes / No / No data)
 - Coagulation (Yes / No / No data).
 - Other (Yes / No / No data); If yes, specify _____
 - Unknown (Yes / No / No data)
 - If patient's alive:
 - Patient transplanted (Yes / No / No data); If yes: Date __ / ____ / _____

3-MONTHS FOLLOW-UP (ALL PATIENTS)**Vital status during the follow-up (Information can be obtained by phone call)**

- Follow-up date __ / ____ / _____
- Patient's vital status: Alive / Dead / No data
 - If patient's dead:
 - Date of exitus __ / ____ / _____
 - Causes of death:
 - Hepatocellular carcinoma (Yes / No / No data)
 - Hypovolemic shock (Yes / No / No data)
 - Septic shock (Yes / No / No data)
 - Multiorgan failure in the absence of hypovolemic or septic shock (Yes/No/No data). If yes:
 - Organ failures:
 - Hepatic (Yes / No / No data)
 - Renal (Yes / No / No data)
 - Cerebral (Yes / No / No data)
 - Respiratory (Yes / No / No data)
 - Cardiac (Yes / No / No data)
 - Coagulation (Yes / No / No data).
 - Multiorgan failure after recovering from hypovolemic shock (Yes / No / No data). If yes:
 - Organ failures:
 - Hepatic (Yes / No / No data)
 - Renal (Yes / No / No data)
 - Cerebral (Yes / No / No data)
 - Respiratory (Yes / No / No data)
 - Cardiac (Yes / No / No data)
 - Coagulation (Yes / No / No data).
 - Multiorgan failure after recovering from septic shock (Yes / No / No data). If yes:
 - Organ failures:
 - Hepatic (Yes / No / No data)
 - Renal (Yes / No / No data)
 - Cerebral (Yes / No / No data)
 - Respiratory (Yes / No / No data)
 - Cardiac (Yes / No / No data)
 - Coagulation (Yes / No / No data).
 - Other (Yes / No / No data); If yes, specify _____
 - Unknown (Yes / No / No data)
 - If patient's alive:
 - Patient transplanted (Yes / No / No data); If yes: Date __ / ____ / _____

6-MONTHS FOLLOW-UP (ALL PATIENTS)**Vital status during the follow-up (Information can be obtained by phone call)**

- Follow-up date __ / ____ / _____
- Patient's vital status: Alive / Dead / No data
 - If patient's dead:
 - Date of exitus __ / ____ / _____
 - Causes of death:
 - Hepatocellular carcinoma (Yes / No / No data)
 - Hypovolemic shock (Yes / No / No data)
 - Septic shock (Yes / No / No data)
 - Multiorgan failure in the absence of hypovolemic or septic shock (Yes/No/No data). If yes:
 - Organ failures:
 - Hepatic (Yes / No / No data)
 - Renal (Yes / No / No data)
 - Cerebral (Yes / No / No data)
 - Respiratory (Yes / No / No data)
 - Cardiac (Yes / No / No data)
 - Coagulation (Yes / No / No data).
 - Multiorgan failure after recovering from hypovolemic shock (Yes / No / No data). If yes:
 - Organ failures:
 - Hepatic (Yes / No / No data)
 - Renal (Yes / No / No data)
 - Cerebral (Yes / No / No data)
 - Respiratory (Yes / No / No data)
 - Cardiac (Yes / No / No data)
 - Coagulation (Yes / No / No data).
 - Multiorgan failure after recovering from septic shock (Yes / No / No data). If yes:
 - Organ failures:
 - Hepatic (Yes / No / No data)
 - Renal (Yes / No / No data)
 - Cerebral (Yes / No / No data)
 - Respiratory (Yes / No / No data)
 - Cardiac (Yes / No / No data)
 - Coagulation (Yes / No / No data).
 - Other (Yes / No / No data); If yes, specify _____
 - Unknown (Yes / No / No data)
 - If patient's alive:
 - Patient transplanted (Yes / No / No data); If yes: Date __ / ____ / _____

1-YEAR FOLLOW-UP (ALL PATIENTS)**Vital status during the follow-up (Information can be obtained by phone call)**

- Follow-up date __ / ____ / _____
- Patient's vital status: Alive / Dead / No data
 - If patient's dead:
 - Date of exitus __ / ____ / _____
 - Causes of death:
 - Hepatocellular carcinoma (Yes / No / No data)
 - Hypovolemic shock (Yes / No / No data)
 - Septic shock (Yes / No / No data)
 - Multiorgan failure in the absence of hypovolemic or septic shock (Yes/No/No data). If yes:
 - Organ failures:
 - Hepatic (Yes / No / No data)
 - Renal (Yes / No / No data)
 - Cerebral (Yes / No / No data)
 - Respiratory (Yes / No / No data)
 - Cardiac (Yes / No / No data)
 - Coagulation (Yes / No / No data).
 - Multiorgan failure after recovering from hypovolemic shock (Yes / No / No data). If yes:
 - Organ failures:
 - Hepatic (Yes / No / No data)
 - Renal (Yes / No / No data)
 - Cerebral (Yes / No / No data)
 - Respiratory (Yes / No / No data)
 - Cardiac (Yes / No / No data)
 - Coagulation (Yes / No / No data).
 - Multiorgan failure after recovering from septic shock (Yes / No / No data). If yes:
 - Organ failures:
 - Hepatic (Yes / No / No data)
 - Renal (Yes / No / No data)
 - Cerebral (Yes / No / No data)
 - Respiratory (Yes / No / No data)
 - Cardiac (Yes / No / No data)
 - Coagulation (Yes / No / No data).
 - Other (Yes / No / No data); If yes, specify _____
 - Unknown (Yes / No / No data)
 - If patient's alive:
 - Patient transplanted (Yes / No / No data); If yes: Date __ / ____ / _____

Notes:

Notes for Summary of Patient's Information

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Notes for Patient's Screening data

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Notes for Patient's Data at Hospital Admission

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Notes for Patient's Admission to the Liver Unit

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Notes for Patient's Data at Study Inclusion

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Notes for Onset of the First Extra-Hepatic Organ Failure (Group #3 patients only)

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Notes for Day 1 Visit (Groups #1 and #2 and Group #4 after the onset of 1st extra-hepatic organ failure during hospitalization)

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Notes for Day 2 Visit (Groups #1 and #2 and Group #4 after the onset of 1st extra-hepatic organ failure during hospitalization)

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Notes for Period 3-7 days Visit (Groups #1 and #2 and Group #4 after the onset of 1st extra-hepatic organ failure during hospitalization)

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Notes for Period 8-14 days Visit (Groups #1 and #2 and Group #4 after the onset of 1st extra-hepatic organ failure during hospitalization)

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Notes for Period 15-21 days Visit (Groups #1 and #2 and Group #4 after the onset of 1st extra-hepatic organ failure during hospitalization)

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Notes for Period 22-28 days Visit (Groups #1 and #2 and Group #4 after the onset of 1st extra-hepatic organ failure during hospitalization)

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Notes for 28-days Follow-up

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Notes for 3-months Follow-up

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Notes for 6-months Follow-up

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Notes for 1-year Follow-up

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