DAY FORM

Hotline: + 45 4829 6773

Day number: |__|__| **Date |__|__| - |__|__| - |__|__|__|__|**

#	Question	Answer	Unit	Info	Validation and limits	Further comments for data manager
Fluids and trial drug						
D1	Cumulated fluid balance on this day	|__|__|__|__|__|mL		All fluid input and output in mL cumulated over 24 hours. This includes all types of IV fluids, blood products, medicines, nutrition products AND oral fluids, nutrition products, and medicine. Daily output as urine, drainage, perspiration, aspirates, stools, bleeding.) The first and last day or in case of referral of the patient to another GODIF ICU the day may be shorter than 24 hours. The fluid balance must be documented with a prefix of + or – in front of the XXXX ml The first and the last day in this study might have a span for less than 24 hours.	Required	Skal både kunne være et positivt og et negativt tal. -5000 - +30.000 Præfix nødvendigt Når D1 er < + 1000 ml så skal D7
D2	Urinary output on this day?	|__|__|__|__|__|mL		24 hours output. Measured at the same time every day. The first and last day or in case of referral of the patient to another GODIF ICU the day may be shorter than 24 hours. If the patient did not have any urinary output on this day type “0”. The first and the last day in this study might have a span for less than 24 hours.	Required	

D3	Measured weight in kg on this day	_____ kg	With one decimal	Required	
D4	Cumulative dose of trial drug on this day.	_____ mL	Cumulative dose of trial drug measured at the same time every day. The first and last day or in case of referral of the patient to another GODIF ICU the day may be shorter than 24 hours. An ICU day will often start at 6:00 am or 8:00 am and last 24 hours. This is the same timeframe where the fluid balance is measured. It must be registered according the ICU day definitions at your site.	Required	Hvis der skrives 0 mL, så skal en ny boks åbnes. Hvor der skal stå: why did the patient not receive trial medication? Følgende afkrydsningsbokse: Patient meets pausing criteria, escape RRT, withdrawal from the study, other - describe
D4a	Reason for pausing trial drug:	☐ Neutral fluid balance (-750 to +750 ml) ☐ Escape renal replacement therapy ☐ withdrawal from the study ☐ Other			If other is chosen, go to D4b
D4b	Describe other reason for pausing trial drug	_____			
D5	Plasma concentration of creatinine on this day	Select unit: µmol/L ☐ |__|__|__| mg/dL ☐ |__|__|__|__|	If several measures of creatinine use highest value.	Required Limits 30-999 No decimals	Data entry only possible when a unit has been selected (single select only) and only in the field

		Not available ☐		If value > 999 µmol/L or <30 µmol/L give warning: "Are you sure this is the correct value" – YES to proceed	corresponding to selected unit. System will automatically convert between units (To convert from mg/dL multiply with 88.4). The value of both units will be visible, but only the selected unit can be corrected. Both values will be transcribed to database. WARNING if 'unobtainable': "Are you sure there are no measured creatinine on this day? → "Yes, I'm certain" /" No, take me back" to proceed"
D6	Indication for a new estimate of fluid balance?	☐ YES ☐ NO	In case of clinical evidence of **significant** fluid overload or dehydration when the cumulative fluid balance is close to neutral according to fluid chart, the clinician can revise the estimate for neutral fluid balance. **In case the clinician sets a new fluid balance. This will be the new target for fluid removal in this study and MUST be documented in the patient file and MUST**	Required	Hvis der sættes kryds i YES. Så skal der være to bokse mere: Dehydration og clinical fluid overload. Herefter efterfølgende bokse under **dehydration**: weight lower than

			be used as a new estimate for cumulative fluid balance		habitual weight, other. (choose one) Under **clinical fluid overload** skal der være følgende valgmuligheder: periferal oedema, weight higher than habitual weight, other. (Choose one). Der skal til sidst komme et felt op til det nye estimat for væskebalancen. Hvis YES, så skal D6a åbne op
Reasons for new estimate of fluid balance					
D6a	Significant clinical fluid overload	☐ YES ☐ NO		Required if D6 is YES	Hvis YES skal D6a1 og D6b åbne op. Hvis NO i D6a1+D6b skal D6c åbne op.
D6a1	Peripheral oedemas	☐ YES ☐ NO		Required if D6a is YES	
D6b	Weight higher than habitual weight	☐ YES ☐ NO		Required if D6 is YES	
D6c	Explain with the patient is significant overhydrated which is not due to oedemas or weight gain.	_____			

D6d	Dehydration	☐ YES ☐ NO		Required if D6 is NO	Hvis YES så skal D6d1 og 2 åbne op.
D6d1	Weight lower than habitual weight	☐ YES ☐ NO		Required if D6b is YES	Ved NO i D6b1+2 skal D6d3 åbnes
D6d2	Clinical signs of dehydration with low blood pressure and reduced skin turgor.	☐ YES ☐ NO		Required if D6b is YES	Ved NO i D6d1+2 skal D6d3 åbnes
D6d3	Explain why the patient is dehydrated which is not due to weight loss or clinical signs of dehydration	_____		Required if NO i D6d1 og 2	
D6e	New estimate of fluid balance	_____ ml	Must be documented with a prefix of + or – in front of the new estimate.	Required if D6 is YES	Her skal der kunne skrives et tal der både er positivt og negativt, hvorfor præfix med +/- er nødvendig. -5000 til + 20.000 ml (ref. ramme)
Major protocol violations on this day					
MPV1	Participants withdrawing or withdrawn from the allocated intervention despite having fluid overload. This includes patients discontinued from the trial by the choice of the patient or the clinician for other reasons than SAR/SAEs or SUSARs.	☐ YES ☐ NO		Required	
MPV2	Discontinuation of goal directed fluid removal for 2 days before a neutral cumulative fluid balance has been achieved?	☐ YES ☐ NO	Trial drug paused or not titrated to effect according to protocol/algorithm	Required	

MPV3	Continuation of administration of trial drug for 2 days despite fulfilling pausing criteria resulting in a negative cumulative fluid balance (< - 750 ml)?	☐ YES ☐ NO	This does not include maintenance dose of trial drug to maintain a neutral fluid balance	Required	
MPV4	Is extra furosemide administered without the presence of escape indications?	☐ YES ☐ NO	Furosemide not dosed as escape medicine or as habitual furosemide. Escape indication for open-label furosemide are: Hyperkalaemia (p-K > 6 mmol/l), respiratory failure (P/F-ratio < 26 kPa (200 mmHg)) and pulmonary oedema if treating physician has a suspicion of respiratory deterioration is due to fluid overload. Reason for escape doses must be described in the medical record. The maximum dose of furosemide per 24 hours is 1500 mg and must not be exceeded.	Required	
MPV5	Administration of other diuretics outside this protocol?	☐ YES ☐ NO	Other diuretics the patient is not normally treated with before admittance to the hospital. This does not include thiazides administered to treat hypernatraemia.	Required	
MVP6	Initiation of renal replacement therapy (RRT) without the presence of RRT escape indications?	☐ YES ☐ NO	The escape indications for RRT: Hyperkalaemia (p-K > 6 mmol/l) OR respiratory failure (P/F-ratio < 26 kPa (200 mmHg)) and pulmonary oedema if treating physician has a suspicion of respiratory deterioration is due to fluid overload OR severe metabolic acidosis attributable to AKI (pH < 7.20 and SBE < -10 mmol/L) OR persistent AKI > 72 h (defined as: oliguria/anuria or s-creatinine has not declined to 50% from peak value).	Required	

Co-interventions					
D7	Did the patient receive infusion of vasopressors or inotropes on this day?	☐ YES ☐ NO	Vasopressor/inotrope agents: norepinephrine, epinephrine, phenylephrine, vasopressin analogues, angiotensin, dopamine, dobutamine, milrinone or levosimendan.	Required	
D8	Did the patient receive mechanical ventilation on this day?	☐ YES ☐ NO	Invasive or non-invasive mechanical ventilation as the use of positive pressure ventilation using a ventilator. CPAP alone is NOT mechanical ventilation	Required	
D9	Use of escape renal replacement therapy on this day?	☐ YES ☐ NO	Any form of renal replacement therapy (e.g. dialysis, hemofiltration or hemodiafiltration) at any rate on this day.	Required	Hvis YES, så skal nedenstående 4 felter åbnes op.
D9a	Was the reason hyperkalaemia (p-K > 6 mmol/l)?	☐ YES ☐ NO		Required if D15 is YES	
D9b	Was the reason respiratory failure (P/F-ratio < 26 kPa (200 mmHg)) and pulmonary oedema due to fluid overload?	☐ YES ☐ NO		Required if D15 is YES	
D9c	Was the reason severe metabolic acidosis attributable to AKI (pH < 7.20 and SBE < -10 mmol/L)	☐ YES ☐ NO		Required if D15 is YES	
D9d	Was the reason persistent AKI > 72 h (defined as: oliguria/anuria or s-creatinine has not declined to 50% from peak value)?	☐ YES ☐ NO		Required if D15 is YES	

D10	Use of escape open-label furosemide on this day?	☐ YES ☐ NO	open label furosemide can only be used in case of: Hyperkalaemia (p-K > 6 mmol/l) or respiratory failure (P/F-ratio < 26 kPa (200 mmHg)) and pulmonary oedema if treating physician has a suspicion of respiratory deterioration is due to fluid overload Escape doses must be described in the medical record. The maximum dose of furosemide per 24 hours is 1500 mg and must not be exceeded.	Required	Ved YES – da skal der komme et felt op med total dose of open-label furosemide _____mg
D10a	Total dose of open-label furosemide on this day?	_____ mg		Required if YES in D15	
D11	Use of resuscitation algorithm on this day?	☐ YES ☐ NO	Situation with severe hypoperfusion or severe circulatory impairment: lactate ≥ 4 mmol/l, MAP < 50 mmHg (+/- vasopressor/inotrope), mottling beyond edge of kneecap (mottling score > 2).	Required	
Serious adverse events **If the patient experiences a SAE the coordinating center must be informed by email within 24 hours.** **Mail: godif@cric.dk or by telephone +45 4829 6773**					
SAE1	Did the patient have cerebral ischemia on this day?	☐ YES ☐ NO	Defined as any form of cerebral ischemia on a CT- OR MRI scan on this day?	Required	

SAE2	Did the patient have acute myocardial ischemia on this day?	☐ YES ☐ NO	Defined as participant with acute myocardial infarction (ST-elevation myocardial infarction or non-ST elevation myocardial infarction) or unstable angina pectoris according to the criteria in the clinical setting in question (e.g. elevated biomarkers, ischemic signs on ECG and clinical presentation) AND the participant received treatment as a consequence of this (reperfusion strategies (PCI/thrombolysis) OR initiation/increased antithrombotic treatment).	Required	
SAE3	Did the patient have intestinal ischemia on this day?	☐ YES ☐ NO	Defined as ischemia verified by endoscopy OR open surgery on this day?	Required	
SAE4	Did the patient have limb ischemia on this day?	☐ YES ☐ NO	Defined as clinical signs AND need of open/percutaneous vascular intervention, amputation OR initiation/increased antithrombotic treatment on this day?	Required	

SAE5	Did the patient develop a new episode for acute kidney injury stage 3 on this day? (see link for definition)	☐ YES ☐ NO	AKI modified KDIGO stage 3: A 3 times increase in baseline p-creatinine or increase in p-creatinine to ≥ 354 µmol/L or use of renal replacement therapy (any form) because of renal failure.	Required	Dette felt skal være utilgængeligt på dayform 1 eller forklaring i infobox om at AKI grad 3 ikke er en SAE når man kommer ind I studiet med tilstanden
SAE6	Did the patient experience atrial fibrillation for the first time?	☐ YES ☐ NO	New onset atrial fibrillation. The patient has never had atrial fibrillation before.	Required	Hvis der svares YES til dette felt, så skal det efterfølgende blive inaktivt, da man ikke kan have new onset atrial fibrillation mere end en gang.
Serious Adverse Reactions If the patient experiences a SAR, the coordinating center must be contacted by e-mail godif@cric.nu or phone +45 4829 6773 within 24 hours.					
SAR1	Anaphylactic reaction on this day?	☐ YES ☐ NO	Urticaria **and** at least one of the following: - Worsened circulation (> 20% decrease in blood pressure or > 20% increase in vasopressor dose) - Increased airway resistance (>20% increase in the peak pressure on the ventilation) - Clinical stridor or bronchospasm - Subsequent treatment with bronchodilators	Required	WARNING if YES Remember to contact the coordinating centre without undue delay at godif@cric.nu or +45 4829 6773

SAR2	General tonic-clonic seizures on this day?	☐ YES ☐ NO	Stiffening and/or jerking movements of all 4 extremities in a patient who becomes or is unconscious in the ICU after randomisation	Required	WARNING if YES Remember to contact the coordinating centre without undue delay at godif@cric.nu or +45 4829 6773
SAR3	Severe electrolyte disturbance of p-K < 2.5 mmol/L, p-Na < 120 mmol/L, p-Cl < 90 mmol/L on this day?	☐ YES ☐ NO	On any plasma sample, including point-of-care testing, done in the ICU after randomisation and start of trial drug.	Required	WARNING if YES Remember to contact the coordinating centre without undue delay at godif@cric.nu or +45 4829 6773
SAR4	Agranulocytosis on this day?	☐ YES ☐ NO	Agranulocytosis is defined as any new drop in granulocytes to < 0.5 x 10^9/L	Required	WARNING if YES Remember to contact the coordinating centre without undue delay at godif@cric.nu or +45 4829 6773
SAR5	Aplastic anaemia on this day?	☐ YES ☐ NO	defined as a syndrome of bone marrow failure characterized by peripheral pancytopenia and morrow hypoplasia. Drop in haemoglobin < 5.0 mmol/L, neutrophil leucocytes < 0.5 x 10^9/L, thrombocytes < 20 x 10^9/L, reticulocytes < 1 %.	Required	WARNING if YES Remember to contact the coordinating centre without undue delay at godif@cric.nu or +45 4829 6773
SAR6	Pancreatitis on this day?	☐ YES ☐ NO	Diagnosed after randomisation and start of trial drug.	Required	WARNING if YES Remember to contact the coordinating centre without undue delay at godif@cric.nu or +45 4829 6773

SAR7	Circulatory collapse leading to cardiac arrest on this day?	☐ YES ☐ NO		Required	WARNING if YES Remember to contact the coordinating centre without undue delay at godif@cric.nu or +45 4829 6773
SAR8	Steven Johnsons syndrome on this day?	☐ YES ☐ NO		Required	WARNING if YES Remember to contact the coordinating centre without undue delay at godif@cric.nu or +45 4829 6773
SAR9	Toxic epidermal necrolysis on this day?	☐ YES ☐ NO		Required	WARNING if YES Remember to contact the coordinating centre without undue delay at godif@cric.nu or +45 4829 6773
SAR10	Hearing impairment/loss on this day?	☐ YES ☐ NO	The patient complaining of hearing impairment (not former known).	Required	WARNING if YES Remember to contact the coordinating centre without undue delay at godif@cric.nu or +45 4829 6773