OUTCOME FORM

CRASH-19

PLEASE COMPLETE AT DEATH, DISCHARGE OR DAY 28 WHICHEVER COMES FIRST

1. HOSPITAL NAME, ID

2. PATIENT RANDOMISATION NUMBER

3. OUTCOME

3.1 DEATH IN HOSPITAL

a) Date of death			b) Time of death (24hr)	
DAY (DD)	MONTH (MM)	YEAR (YYYY)	HOUR (HH)	MIN (MM)

c) Primary Cause of death *(tick one option)*

- ☐ Respiratory failure incl. ARDS
- ☐ Congestive cardiac failure
- ☐ Myocardial Infarction
- ☐ Sepsis
- ☐ Multi organ failure
- ☐ Other, describe here (only one) _____

3.2 PATIENT ALIVE *(Select one and provide date)*

a) Still in this hospital now *(28 days after randomisation)* – Date

DAY (DD)	MONTH (MM)	YEAR (YYYY)

b) Transferred to another hospital – Date of discharge

DAY (DD)	MONTH (MM)	YEAR (YYYY)

c) Discharged home – Date of discharge

DAY (DD)	MONTH (MM)	YEAR (YYYY)

3.3 Ability to self-care at discharge versus before illness *(circle one):*

SAME AS BEFORE ILLNESS	WORSE	BETTER

4. MANAGEMENT

a) Admitted to ICU	YES	NO	Needed, not available
i) If yes, days in ICU (if none, write '0')			
b) Ventilatory support	YES	NO	Needed, not available
i) Mechanical ventilation	YES	NO	Needed, not available
ii) CPAP/BIPAP	YES	NO	Needed, not available
c) Corticosteroids	YES	NO	
d) Antimalarial	YES	NO	
e) Antiviral	YES	NO	
f) Antibiotics	YES	NO	
g) Vasopressor/inotrope	YES	NO	

5. TRIAL TREATMENT GIVEN

If standard care only, skip to Q6			Total number of days
a) Aspirin 150 mg	YES	NO	
b) Losartan 100 mg	YES	NO	
c) Losartan <100 mg	YES	NO	
d) Simvastatin 80 mg	YES	NO	

6. COMPLICATIONS

a) Myocardial infarction	YES	NO
b) Congestive cardiac failure	YES	NO
c) Severe cardiac arrhythmia	YES	NO
d) Myocarditis	YES	NO
e) Respiratory failure including ARDS	YES	NO
f) Viral pneumonitis	YES	NO
g) Acute renal failure	YES	NO
h) Sepsis	YES	NO
i) Stroke	YES	NO
j) Gastrointestinal bleeding	YES	NO

7. PERSON COMPLETING FORM

a) Name	first/last name		
b) Job title			
c) Signature			
d) Date	DAY (DD)	MONTH (MM)	YEAR (YYYY)

OUTCOME FORM

CRASH-19

OUTCOME CRF COMPLETION GUIDANCE

Q no.	
	To avoid infection transmission from the use of paper, outcome data can be entered **directly** into the trial database at https://ctu-redcap.lshtm.ac.uk/. Please ensure that **all** outcome data is contained in the patient's medical records.
OUTCOME	
3.1	• Do not enter multiple causes of death, please use clinical judgement to determine **one primary** cause.
MANAGEMENT	
4	• Only report management that occurred/was given after randomisation.
4.ai	• Include any days/ part days spent in High Dependency Unit. Part days count as '1'.
TRIAL TREATMENTS GIVEN	
5	• If the patient received aspirin or simvastatin, only record the number of days the **full** dose was given. • If the patient did not receive the allocated treatment or the full dose was not given, use the database notes to explain why.
COMPLICATIONS - Before answering 'YES', please ensure that the complication fulfils the definition given below:	
6	• If the patient experienced a complication not listed, and it is suspected to be related to the trial drug, please consider if it should be reported as a Serious Adverse Reaction.
6.a	• **Myocardial infarction:** Detection of rise and/or fall of cardiac biomarker values (preferably troponin) with at least one value above the 99th percentile of the upper reference limit **and** with at least one of the following: ➢ Symptoms of ischaemia ➢ ECG abnormalities: new or presumably new significant ST-T changes or new left bundle branch block or pathological Q waves ➢ Imaging evidence of new loss of viable myocardium, or new regional wall motion abnormality ➢ Identification of an intracoronary thrombus by angiography or autopsy ➢ Cardiac death with symptoms suggestive of myocardial ischaemia ➢ Stent thrombosis associated with MI when detected by coronary angiography or autopsy in the setting of myocardial ischaemia and with a rise and/or fall of cardiac biomarker values with at least one value above the 99th percentile URL
6.b	• **Congestive cardiac failure:** A clinical diagnosis of heart failure may include the following symptoms: unusual breathlessness on light exertion, recurrent breathlessness when lying flat, fluid retention, jugular venous distension, pulmonary oedema on physical exam or chest x-ray presumed due to cardiac dysfunction.
6.c	• **Severe cardiac arrhythmia:** Any arrhythmia that causes symptoms.
6.d	• **Myocarditis:** Established using histological, immunological or immunohistochemical criteria.
6.e	• **Respiratory failure incl. ARDS:** Arterial oxygen tension (PaO_2) of <8.0 kPa (60 mmHg) and or an arterial carbon dioxide tension ($PaCO_2$) of >6.0 kPa (45 mmHg).
6.f	• **Viral pneumonitis:** Abnormal Chest X ray or CT findings consistent with COVID-19 infection.
6.g	• **Acute renal failure:** 1) Increase in serum creatinine ≥0.3 mg/dL (≥26.5 µmol/L) within 48 hours; **or** 2) Increase in serum creatinine ≥1.5 times baseline, which is known or presumed to have occurred within the prior 7 days; **or** 3) Urine volume <0.5 mL/kg/h for 6 hours.
6.h	• **Sepsis:** The diagnosis of sepsis is based on the presence of both: 1) Infection **and** 2) A systemic inflammatory response syndrome (SIRS). SIRS requires two or more of the following: ➢ Temperature <36 °C or >38 °C ➢ Respiratory rate >20 breaths/min ➢ Heart rate >90 beats/min ➢ White blood cell count <$4x10^9$/L (<4000/mm³) or >$12x10^9$/L (>12,000/mm³)
6.i	• **Stroke:** Defined as 'a new focal neurological deficit with signs and symptoms lasting more than 24 hours'.
6.j	• **Gastrointestinal bleeding:** Any significant upper or lower GI bleeding. The diagnosis of significant bleeding is clinical but may include patients with hypotension, tachycardia, or those likely to need transfusion, urgent endoscopy or surgery.
PERSON COMPLETING THE FORM	
7.a	• Please use the first and last name that is used on the trial team members log.
7.c	• Signature of the person completing the paper form if applicable – this is confirmation that the data is accurate and, valid and that all outcome data is contained in the patient's medical records

IF a paper form is used, please ensure you:

- Write clearly and legibly throughout, using CAPITAL LETTERS and using permanent black or blue ink pen.
- Where multiple choices are given, circle the correct answer.
- Insert dates using the format **DD/MM/YYYY** e.g. if 23 February 2018, record as 23/02/2018.
- Indicate all times using 24-hour clock in format of **hours:minutes** e.g. if 2:45 pm, record as 14:45.
- If the time is midnight, record this as 00:00 the following day e.g. midnight on 23/02/2018 is 24/02/2018 at 00:00.

Upload the data to the database within 24 hours of completion.