STOP-COVID19 Superiority Trial Of Protease inhibition in COVID-19

PARTICIPANT ID*				

Site ID followed by participant number, no dashes

INITIALS		

STOP-COVID19 Worksheet

1. Screening - Informed Consent

Question	Answers
Date of Screening (dd-mm-yyyy)	
Consent provided by (tick one)	○ Participant ○ Personal legal representative ○ Professional legal representative
Date of consent (dd-mm-yyyy)	

2. Screening - Demographics

Question	Answers
Age (years)	
Sex at birth	○ Male ○ Female
Ethnicity (tick one)	○ English / Welsh / Scottish / Northern Irish / British ○ Irish ○ Gypsy or Irish Traveller ○ Any other White background ○ White and Black Caribbean ○ White and Black African ○ White and Asian ○ Any other Mixed / Multiple ethnic background ○ Indian ○ Pakistani ○ Bangladeshi ○ Chinese ○ Any other Asian background ○ African ○ Caribbean ○ Any other Black / African / Caribbean background ○ Arab ○ Any other ethnic group ○ Unknown
If "Any other ethnic group" - specify	

Living status	○ Own home (on own or with others) ○ Sheltered housing ○ Care home (nursing or residential) ○ Prison ○ Other
If other, specify	

3. Screening - SARS-CoV-2 Test

Question	Answers
Approximate day of onset of COVID-19 symptoms (dd-mm-yyyy)	
Date of hospital admission (dd-mm-yyyy)	
Positive SARS CoV-2 PCR test?	○ YES ○ NO
If yes: Date of positive PCR test (dd-mm-yyyy)	
Sample type (tick one)	○ Nasal/NP swab ○ Throat swab ○ Combined nasal/NP + throat swab ○ Lower respiratory tract specimen ○ Unknown

4. Screening - Co-Morbidities

Question	Answers
Chronic Neutropenia *If 'YES': '**The participant is not eligible to take part in the trial if absolute neutrophil count less than 1.0 x 109 cells per L, please check absolute neutrophil count result (within 72 hours of randomisation).**.*	○ YES ○ NO
Chronic cardiac disease, including congenital heart disease (not hypertension)	○ YES ○ NO
Hypertension	○ YES ○ NO
COPD	○ YES ○ NO
Chronic pulmonary disease (not COPD or asthma)	○ YES ○ NO
Asthma (physician diagnosed)	○ YES ○ NO
Chronic kidney disease (eGFR less than 44 ml/min, on dialysis or previous transplant) **The participant is not eligible to take part in the trial if eGFR is less than 30 ml/min, please check eGFR result (within 72 hours of randomisation).**	○ YES ○ NO
Moderate or severe liver disease (cirrhosis with portal hypertension) **The participant is not eligible to take part in the trial if alanine aminotransferase (ALT) and/or aspartate aminotransferase (AST) greater than 5 times the upper limit of normal, please check ALT and AST result (within 72 hours of randomisation).**	○ YES ○ NO

Mild liver disease	○ YES ○ NO
Chronic neurological disorder	○ YES ○ NO
Malignant neoplasm	○ YES ○ NO
Chronic hematologic disease	○ YES ○ NO
AIDS / HIV	○ YES ○ NO
Obesity (as defined by clinical staff)	○ YES ○ NO
Diabetes with complications	○ YES ○ NO
Diabetes without complications	○ YES ○ NO
Rheumatologic disorder	○ YES ○ NO
Dementia	○ YES ○ NO
Malnutrition	○ YES ○ NO
Smoking	○ Yes ○ Never smoked ○ Former smoker ○ Unknown
Other relevant risk factor	○ YES ○ NO
If YES, specify other risk factors	

5. Screening - Signs and Symptoms on Admission

Question	Answers
Admission signs and symptoms (observed/reported at admission and associated with this episode of acute illness)	
History of fever	○ YES ○ NO
Cough with sputum production	○ YES ○ NO
Cough with bloody sputum/haemoptysis	○ YES ○ NO
Sore throat	○ YES ○ NO
Runny nose (Rhinorrhoea)	○ YES ○ NO
Ear pain	○ YES ○ NO
Wheezing	○ YES ○ NO
Chest pain	○ YES ○ NO
Muscle aches (Myalgia)	○ YES ○ NO
Joint pain (Arthralgia)	○ YES ○ NO
Fatigue / Malaise	○ YES ○ NO
Shortness of breath (Dyspnea)	○ YES ○ NO
Lower chest wall indrawing	○ YES ○ NO
Headache	○ YES ○ NO
Altered consciousness/confusion	○ YES ○ NO

Seizures	○ YES ○ NO
Abdominal pain	○ YES ○ NO
Vomiting / Nausea	○ YES ○ NO
Diarrhoea	○ YES ○ NO
Conjunctivitis	○ YES ○ NO
Skin rash	○ YES ○ NO
Skin ulcers	○ YES ○ NO
Lymphadenopathy	○ YES ○ NO
Bleeding (Haemorrhage) If YES, specify site(s):	○ YES ○ NO [ ]
Lost or changed sense of smell	○ YES ○ NO
Other signs or symptoms: If YES, specify	○ YES ○ NO [ ]

6. Screening - Clinical Assessments

Question	*Answers*
Vital signs Please record the most recent values for Screening/Randomisation.	
Pulse	____ bpm
Blood Pressure systolic	____ mmHg
Blood Pressure diastolic	____ mmHg
Tympanic temperature	____ °C
SpO2	____ %
SpO2 measured on	○ Air ○ Oxygen ○ N/A
If SpO2 measured on oxygen, please provide amount of oxygen received?	____
Oxygen unit	○ L ○ %
Has a **CT scan** been performed for clinical reasons since admission?	○ YES ○ NO
If Yes: ***Date of CT scan***	____ ____ ____ *(dd-mm-yyyy)*
CT scan result	

7. Screening - Clinical Status and NEWS

Question	Answers
Clinical status on 7 point scale Record the worst score for the day so far.	○ 1. Not hospitalized, no limitations on activities ○ 2. Not hospitalized, limitation on activities ○ 3. Hospitalized, not requiring supplemental oxygen ○ 4. Hospitalized, requiring supplemental oxygen ○ 5. Hospitalized, on non-invasive ventilation or high flow oxygen devices ○ 6. Hospitalized, on invasive mechanical ventilation or ECMO (Extracorporeal membrane oxygenation) ○ 7. Death
NEWS Record most recent score for the day, from 0-20 points	

Please record Concomitant Medications information

Is the participant co-enrolled in another trial?	○ YES ○ NO
If 'YES': Trials	☐ RECOVERY ☐ RECOVERY RS ☐ REMAP CAP ☐ ACCORD ☐ Other
Other trials, specify	

Has the participant received any of the following medications (trial setting or clinical care)?
Please tick other for adding additional trial medications.

- ☐ Lopinavir-Ritonavir
- ☐ Low-dose Dexamethasone
- ☐ Hydroxychloroquine
- ☐ Azithromycin
- ☐ Tocilizumab
- ☐ Remdesivir
- ☐ Other trial drugs

If Other trial drugs, specify

Other Concomitant Medications
(not already recorded above)

Antiviral agents

Antiviral agent?

- ○ YES
- ○ NO

If YES:

- ☐ Ribavirin
- ☐ Interferon beta
- ☐ Neuraminidase inhibitor
- ☐ Other

Other antiviral agents,- specify

Antibiotics

Antibiotic?

- ○ YES
- ○ NO

If YES, Rifampicin?

- ○ YES
- ○ NO

The participant is not eligible to take part in the trial if on Rifampicin. If already randomised, either the trial drug or Rifampicin must be stopped.

Corticosteroid

Corticosteroid?

- ○ YES
- ○ NO

If YES, Route:

- ☐ Oral
- ☐ Intravenous
- ☐ Inhaled

If YES, please provide type and dose:

Antifungal agents

Antifungal agents?

'The participant is not eligible to take part in the trial if on Itraconazole or Ketoconazole'

- ☐ None
- ☐ Itraconazole (Exclusion criteria)
- ☐ Ketoconazole (Exclusion criteria)
- ☐ Other

If Other, please specify

If the participant commenced any of the following medications the participant is not eligible to take part in the trial. Please select as appropriate.(continued on next page)

Diltiazem

- ○ YES
- ○ NO

Verapamil

- ○ YES
- ○ NO

Phenytoin

- ○ YES
- ○ NO

Protease or integrase inhibitors
- ○ YES
- ○ NO

Non-nucleoside reverse transcription inhibitors
- ○ YES
- ○ NO

8. Screening - ECG

Question	Answers
ECG done?	○ YES ○ NO
If 'ECG done'', ECG result	○ Normal result ○ Abnormal result, not clinically significant ○ Abnormal result, clinically significant
Is it appropriate for the participant to continue in the trial?	○ YES ○ NO

9. Screening - Samples

Question	Answers
If participant is female: Pregnancy test performed?	○ Yes ○ No ○ N/A
If pregnancy test performed: Pregnancy test result *If Positive: Without a negative pregnancy test result, the participant is not eligible to take part in the trial.*	○ Positive ○ Negative
If Pregnancy test was NOT performed: Is the participant either permanently sterilized or post-menopausal? *If NO: A pregnancy test MUST be completed before randomisation in the trial.*	○ YES ○ NO

Screening - Blood Results

Question	***Answers***
Date of blood sample (dd-mm-yyyy) Blood sample results up to 72 hours prior to randomisation are acceptable.	
Sodium	mmol/L
Potassium	mmol/L
Creatinine	umol/L
Urea	mmol/L
eGFR *If the eGFR is less than 30 the participant is not eligible for the trial.*	ml/min

Albumin g/L

Bilirubin umol/L

AST (Aspartate Aminotransferase) U/L

AST value should be between 0 and 225 U/L. If the AST value is out with this range, the participant is not eligible for the trial.

ALT (Alanine Aminotransferase) U/L

ALT value should be between 0 and 275 U/L. If the ALT value is out with this range, the participant is not eligible for the trial.

Haemoglobin

Haemoglobin Unit

- g/L
- g/dL

White blood cell count x10^9/L

Neutrophil count x10^9/L

If the neutrophil value is less than 1 x10^9/L, the participant is not eligible for the trial.

Eosinophil count x10^9/L

Platelets x10^9/L

Lymphocyte count x10^9/L

STOP-COVID19 Superiority Trial Of Protease inhibition in COVID-19

PARTICIPANT ID				

INITIALS		

10. Randomisation

Question	Answers
Screening and Randomisation on the same day?	◯ YES ◯ NO
If NO: Date of randomisation (dd-mm-yyyy) Randomisation must be within 24 hours of screening.	

***If NO*:**

Please add an AE report if the participant has experienced any AEs since consent.

STOP-COVID19 Superiority Trial Of Protease inhibition in COVID-19

PARTICIPANT ID				

INITIALS		

11. Randomisation - AEs and Conmeds

Question	Answers
Please record Concomitant Medications information only if randomisation is on a different day to screening	
Is the participant co-enrolled in another trial?	○ YES ○ NO
If 'YES': Trials	☐ RECOVERY ☐ RECOVERY RS ☐ REMAP CAP ☐ ACCORD ☐ Other
Other trials, specify	
Has the participant received any of the following medications (trial setting or clinical care)? Please tick other for adding additional trial medications.	☐ Lopinavir-Ritonavir ☐ Low-dose Dexamethasone ☐ Hydroxychloroquine ☐ Azithromycin ☐ Tocilizumab ☐ Remdesivir ☐ Other trial drugs
If Other trial drugs, specify	

STOP-COVID19 Superiority Trial Of Protease inhibition in COVID-19

PARTICIPANT ID				

INITIALS		

STOP-COVID19 Superiority Trial Of Protease inhibition in COVID-19

PARTICIPANT ID				

INITIALS		

Other Concomitant Medications
(other than any recorded above)

Antiviral agents

Antiviral agent?

- ○ YES
- ○ NO

If YES:

- ☐ Ribavirin
- ☐ Interferon beta
- ☐ Neuraminidase inhibitor
- ☐ Other

Other antiviral agents,- specify

Antibiotics

Antibiotic?

- ○ YES
- ○ NO

If YES, Rifampicin?

- ○ YES
- ○ NO

The participant is not eligible to take part in the trial if on Rifampicin. If already randomised, either the trial drug or Rifampicin must be stopped.

Corticosteroid

Corticosteroid?

- ○ YES
- ○ NO

If YES, Route:

- ☐ Oral
- ☐ Intravenous
- ☐ Inhaled

If YES, please provide type and dose:

STOP-COVID19 Superiority Trial Of Protease inhibition in COVID-19

PARTICIPANT ID				

INITIALS		

Antifungal agents

Antifungal agents?

'The participant is not eligible to take part in the trial if on Itraconazole or Ketoconazole '

- ☐ None
- ☐ Itraconazole (Exclusion criteria)
- ☐ Ketoconazole (Exclusion criteria)
- ☐ Other

If Other, please specify

If the participant commenced any of the following medications the participant is not eligible to take part in the trial. Please select as appropriate.(continued on next page)

Diltiazem

- ○ YES
- ○ NO

Verapamil

- ○ YES
- ○ NO

Phenytoin

- ○ YES
- ○ NO

STOP-COVID19 Superiority Trial Of Protease inhibition in COVID-19

PARTICIPANT ID				

INITIALS		

Protease or integrase inhibitors
- ○ YES
- ○ NO

Non-nucleoside reverse transcription inhibitors
- ○ YES
- ○ NO

STOP-COVID19 Superiority Trial Of Protease inhibition in COVID-19

PARTICIPANT ID				

INITIALS		

12. Randomisation – Clinical Assessment

Only complete Section 12 if randomisation is on different day from screening

Vital Signs

Question	**Answers**
Please record the most recent values for Screening/Randomisation.	
Pulse	..... bpm
Blood Pressure systolic	..... mmHg
Blood Pressure diastolic	..... mmHg
Tympanic temperature	..... °C
SpO2	..... %
SpO2 measured on	○ Air ○ Oxygen ○ N/A
If Oxygen: what was the amount of oxygen received?	.....
Unit of oxygen	○ L ○ %

STOP-COVID19 Superiority Trial Of Protease inhibition in COVID-19

PARTICIPANT ID				

INITIALS		

Question	Answers
Has a CT scan been performed for clinical reasons since admission?	○ YES ○ NO
If 'YES': Has CT scan been previously recorded in eCRF?	○ YES ○ NO
If NO: *Date of CT scan*	____ ____ ____ *(dd-mm-yyyy)*
. CT scan result	
Has the participant had a positive SARS CoV-2 PCR test since admission?	○ YES ○ NO
If YES: *Date of positive result*	____ ____ ____ *(dd-mm-yyyy)*

STOP-COVID19 Superiority Trial Of Protease inhibition in COVID-19

PARTICIPANT ID				

INITIALS		

13. Randomisation – Clinical Status and NEWS

Only complete Section 13 if randomisation is on different day from screening

Question	Answers
Clinical status on 7 point scale Record the worst score for the day so far.	○ 1. Not hospitalized, no limitations on activities ○ 2. Not hospitalized, limitation on activities ○ 3. Hospitalized, not requiring supplemental oxygen ○ 4. Hospitalized, requiring supplemental oxygen ○ 5. Hospitalized, on non-invasive ventilation or high flow oxygen devices ○ 6. Hospitalized, on invasive mechanical ventilation or ECMO (Extracorporeal membrane oxygenation) ○ 7. Death
NEWS Record most recent score for the day, from 0-20 points	

STOP-COVID19 Superiority Trial Of Protease inhibition in COVID-19

PARTICIPANT ID				

INITIALS		

14. Randomisation - Inclusion Criteria

Number	Question	Answers
1.	Male or female	○ YES ○ NO
2.	Greater than or equal to 16 years of age	○ YES ○ NO
3.	SARS-CoV-2 infection (clinically suspected[+] or laboratory confirmed[*]) (tick all that apply).	☐ Clinically suspected ☐ Laboratory confirmed

*Laboratory-confirmed: SARS-CoV-2 infection as determined by polymerase chain reaction (PCR), or other commercial or public health assay in any specimen < 96 hours prior to randomization.
[+]Clinically suspected: in general, SARS-CoV-2 infection should be suspected when a patient presents with (i) typical symptoms (e.g. influenza-like illness with fever and muscle pain, or respiratory illness with cough and shortness of breath); and (ii) compatible chest X-ray findings (consolidation or ground-glass shadowing); and (iii) alternative causes have been considered unlikely or excluded (e.g. heart failure, influenza). However, the diagnosis remains a clinical one based on the opinion of the managing doctor

4.	Admitted to hospital as in-patient less than 96 hours prior to randomisation^	○ YES ○ NO

^Where a patient has been admitted to hospital for a non COVID-19 reason and develops COVID-19 symptoms whilst an in-patient, randomisation may occur up to 96 hours from onset of symptoms.

5. Illness of any duration, and at least one of the following (tick all that apply)

- ☐ Radiographic infiltrates by imaging (e.g. chest x-ray, computed tomography (CT scan)
- ☐ Evidence of rales/crackles on physical examination
- ☐ Peripheral capillary oxygen saturation (SpO2) less than or equal to 94% on room air prior to randomisation
- ☐ Requiring supplemental oxygen
- ☐ Lymphocyte count less than 1 x 10^9 cells per litre (L)

6.	Participant (or legally authorised representative) has provided written informed consent	○ YES ○ NO
7.	Able to take oral medication	○ YES ○ NO
8.	Participant (or legally authorised representative) understands and agrees to comply with planned trial procedures. '	○ YES ○ NO

STOP-COVID19 Superiority Trial Of Protease inhibition in COVID-19

PARTICIPANT ID				

INITIALS		

15. Randomisation - Exclusion Criteria

Number	Question	Answers
1.	Alanine aminotransferase (ALT) and/or aspartate aminotransferase (AST) greater than 5 times the upper limit of normal, result within 72 hours of randomisation (the result closest to randomisation should be used if several results are available)	◯ YES ◯ NO
2.	History of severe liver disease '	◯ YES ◯ NO
3.	Stage 4 severe chronic kidney disease or requiring dialysis (i.e. eGFR < 30 ml/min), result within 72 hours of randomisation (the result closest to randomisation should be used if several results are available)	◯ YES ◯ NO
4.	Absolute neutrophil count less than 1.0 x 10^9 cells per L within 72 hours of randomisation (the result closest to randomisation should be used if several results are available)	◯ YES ◯ NO
5.	Current treatment with potent Cyp3A4 inducers/inhibitors (e.g. Itraconazole, Ketoconazole, Diltiazem, Verapamil, Phenytoin or Rifampicin)	◯ YES ◯ NO
6.	HIV treatments – current treatment with protease/ inhibitors or non-nucleoside reverse transcriptase inhibhibitors *The Liverpool HIV checker (https://www.hiv-druginteractions.org/checker) should be used to check for any HIV drug interactions. Simvastatin could be used as a surrogate for Brensocatib as it metabolised similarly by CYP 3A4 pathway.	◯ YES ◯ NO
7.	Pregnant or breast feeding	◯ YES ◯ NO

STOP-COVID19 Superiority Trial Of Protease inhibition in COVID-19

PARTICIPANT ID				

INITIALS		

8.	Anticipated transfer to another hospital which is not a trial site within 24 hours	◯ YES ◯ NO
9.	Allergy to Brensocatib	◯ YES ◯ NO
10.	Use of any investigational drug within five times of the elimination half-life after the last trial dose or within 30 days, whichever is longer.	◯ YES ◯ NO

Co-enrolment into COVID-19 CTIMPs will be described in individual agreements between STOP-COVID19 and other trials.

Co-enrolment into COVID-19 non-CTIMP intervention trials will be allowed.

Co-enrolment to other non-COVID-19 Clinical Trials of Investigational Medicinal Product (CTIMPs) will not be allowed.

Enrolment in observational trials or studies will be allowed.

Women of child-bearing potential must be willing to have pregnancy testing prior to trial entry.

16. Randomisation - Eligibility Checks

	Question	**Answers**
	Eligibility must be checked prior to randomisation by a doctor delegated this task in the Delegation Log. Ensure this is documented in the medical notes and/or eCRF prior to randomisation.	
	Were all INCLUSION and EXCLUSION criteria met?	◯ YES ◯ NO
	Is the participant eligible to take part in the trial?	◯ YES ◯ NO
	Was eligibility reviewed by a doctor within 24 hours of date of screening?	◯ YES ◯ NO
	Was eligibility signed off by a doctor within 24 hours prior to randomisation?	◯ YES ◯ NO

Signature of delegated doctor:

Date:

STOP-COVID19 Superiority Trial Of Protease inhibition in COVID-19

PARTICIPANT ID				

INITIALS		

17. Randomisation - Randomisation

Question	Answers
Has the participant been randomised?	○ YES ○ NO
Date of first dose (dd-mm-yyyy)	

18. Randomisation - Samples Tayside and Sheffield Only

Question	Answers
Research blood sample taken?	○ YES ○ NO
TAYSIDE ONLY	
Sputum sample for storage available?	○ YES ○ NO

STOP-COVID19 Superiority Trial Of Protease inhibition in COVID-19

PARTICIPANT ID				

INITIALS		

19. Daily Data Collection while in Hospital

Please complete a 'Daily Data Collection' Report for every day the participant spends in hospital (except days 3, 5, 8, 11, 15, 29). The report is at the end of the CRF.

STOP-COVID19 Superiority Trial Of Protease inhibition in COVID-19

PARTICIPANT ID				

INITIALS		

20. Day 3

Question	Answers
Date (dd-mm-yyyy)	
Data collection via telephone call?	○ YES ○ NO
***If YES**: Date of discharge*	*(dd-mm-yyyy)*
Has the participant had a positive SARS CoV-2 PCR test since admission?	○ YES ○ NO
***If YES:** Date of positive result*	*(dd-mm-yyyy)*

21. Day 3 - AEs

Please add an AE report if participant experienced an AE since last day of data collection.

22. Day 3 - Clinical Status

Question	Answers
Clinical status on 7 point scale To be collected retrospectively, worst score for whole day.	○ 1. Not hospitalized, no limitations on activities ○ 2. Not hospitalized, limitation on activities ○ 3. Hospitalized, not requiring supplemental oxygen ○ 4. Hospitalized, requiring supplemental oxygen ○ 5. Hospitalized, on non-invasive ventilation or high flow oxygen devices ○ 6. Hospitalized, on invasive mechanical ventilation or ECMO (Extracorporeal membrane oxygenation) ○ 7. Death

*** Day 3 - This section is NOT required for telephone calls ***

NEWS

Record score closest to 8am for the day, from 0-20 points

Has a CT scan been performed for clinical reasons since admission?

- ○ YES
- ○ NO

If YES: *Has CT scan been previously recorded in eCRF?*

- ○ YES
- ○ NO

If NO: *Date of CT scan* *(dd-mm-yyyy)*

CT scan result

Was the participant discharged?

- ○ YES
- ○ NO

*** Day 3 - Blood section is NOT required for telephone calls ***

Question	*Answers*
Date of blood test	(dd-mm-yyyy)
Sodium	mmol/L
Potassium	mmol/L
Creatinine	umol/L
Urea	mmol/L
eGFR	ml/min
Albumin	g/L
Bilirubin	umol/L
AST (Aspartate Aminotransferase)	U/L'
ALT (Alanine Aminotransferase)	U/L
Haemoglobin	
Haemoglobin Unit	☐ g/L ☐ g/dL
White blood cell count	x10^9/L
Neutrophil count *If the neutrophil value is less than 1 x10^9/L, please complete the discontinuation of trial medication form.'*	x10^9/L
Eosinophil count	x10^9/L
Platelets	x10^9/L
Lymphocyte count	x10^9/L

DAY 3

PARTICIPANT ID				

INITIALS		

23. Day 5

Question	Answers
Date (dd-mm-yyyy)	
Data collection via telephone call?	○ YES ○ NO
***If YES**: Date of discharge*	*(dd-mm-yyyy)*
Has the participant had a positive SARS CoV-2 PCR test since admission?	○ YES ○ NO
***If YES:** Date of positive result*	*(dd-mm-yyyy)*

24. Day 5 - AEs

Please add an AE report if participant experienced an AE since last day of data collection.

25. Day 5 - Clinical Status

Question	Answers
Clinical status on 7 point scale To be collected retrospectively, worst score for whole day.	○ 1. Not hospitalized, no limitations on activities ○ 2. Not hospitalized, limitation on activities ○ 3. Hospitalized, not requiring supplemental oxygen ○ 4. Hospitalized, requiring supplemental oxygen ○ 5. Hospitalized, on non-invasive ventilation or high flow oxygen devices ○ 6. Hospitalized, on invasive mechanical ventilation or ECMO (Extracorporeal membrane oxygenation) ○ 7. Death

STOP-COVID19 Superiority Trial Of Protease inhibition in COVID-19

PARTICIPANT ID				

INITIALS	

*** Day 5 - This section is NOT required for telephone calls ***

NEWS

Record score closest to 8am for the day, from 0-20 points

Has a CT scan been performed for clinical reasons since admission?

- ○ YES
- ○ NO

If YES: *Has CT scan been previously recorded in eCRF?*

- ○ YES
- ○ NO

If NO: *Date of CT scan* *(dd-mm-yyyy)*

CT scan result

Was the participant discharged?

- ○ YES
- ○ NO

STOP-COVID19 Superiority Trial Of Protease inhibition in COVID-19

PARTICIPANT ID				

INITIALS	

*** Day 5 - Blood section is NOT required for telephone calls ***

Question	*Answers*
Date of blood test	(dd-mm-yyyy)
Sodium	mmol/L
Potassium	mmol/L
Creatinine	umol/L
Urea	mmol/L
eGFR	ml/min
Albumin	g/L
Bilirubin	umol/L
AST (Aspartate Aminotransferase)	U/L'
ALT (Alanine Aminotransferase)	U/L
Haemoglobin	
Haemoglobin Unit	☐ g/L ☐ g/dL
White blood cell count	x10^9/L
Neutrophil count *If the neutrophil value is less than 1 x10^9/L, please complete the discontinuation of trial medication form.'*	x10^9/L
Eosinophil count	x10^9/L
Platelets	x10^9/L
Lymphocyte count	x10^9/L

STOP-COVID19 Superiority Trial Of Protease inhibition in COVID-19

PARTICIPANT ID				

INITIALS		

26. Day 8

Question	Answers
Date (dd-mm-yyyy)	
Data collection via telephone call?	○ YES ○ NO
***If YES**: Date of discharge*	*(dd-mm-yyyy)*
Has the participant had a positive SARS CoV-2 PCR test since admission?	○ YES ○ NO
***If YES:** Date of positive result*	*(dd-mm-yyyy)*

STOP-COVID19 Superiority Trial Of Protease inhibition in COVID-19

PARTICIPANT ID				

INITIALS		

27. Day 8 – AEs and Con meds

Please add an AE report if participant experienced an AE since last day of data collection.

Please record Concomitant Medications information

Is the participant co-enrolled in another trial?

- ○ YES
- ○ NO

If 'YES':
Trials

- ☐ RECOVERY
- ☐ RECOVERY RS
- ☐ REMAP CAP
- ☐ ACCORD
- ☐ Other

Other trials, specify

Has the participant received any of the following medications (trial setting or clinical care)?
Please tick other for adding additional trial medications.

- ☐ Lopinavir-Ritonavir
- ☐ Low-dose Dexamethasone
- ☐ Hydroxychloroquine
- ☐ Azithromycin
- ☐ Tocilizumab
- ☐ Remdesivir
- ☐ Other trial drugs

If Other trial drugs, specify

Other Concomitant Medications

Antiviral agents

Antiviral agent?

- ○ YES
- ○ NO

If YES:

- ☐ Ribavirin
- ☐ Interferon beta
- ☐ Neuraminidase inhibitor
- ☐ Other

Other antiviral agents,- specify

Antibiotics

Antibiotic?

- ○ YES
- ○ NO

If YES, Rifampicin?

- ○ YES
- ○ NO

The participant is not eligible to take part in the trial if on Rifampicin. If already randomised, either the trial drug or Rifampicin must be stopped.

Corticosteroid

Corticosteroid?

- ○ YES
- ○ NO

If YES, Route:

- ☐ Oral
- ☐ Intravenous
- ☐ Inhaled

If YES, please provide type and dose:

STOP-COVID19 | Superiority Trial Of Protease inhibition in COVID-19

PARTICIPANT ID				

INITIALS		

Antifungal agents

Antifungal agents?

'The participant is not eligible to take part in the trial if on Itraconazole or Ketoconazole. If already randomised, either the trial drug or Itraconazole/Ketoconazole must be stopped.'

- ☐ None
- ☐ Itraconazole (Exclusion criteria)
- ☐ Ketoconazole (Exclusion criteria)
- ☐ Other

If Other, please specify

If the participant commenced any of the following medications the participant is not eligible to take part in the trial. If already randomised, either the trial drug or following medications must be stopped. Please select as appropriate. (continued on next page)

Diltiazem

- ○ YES
- ○ NO

Verapamil

- ○ YES
- ○ NO

Phenytoin

- ○ YES
- ○ NO

STOP-COVID19 Superiority Trial Of Protease inhibition in COVID-19

PARTICIPANT ID				

INITIALS		

Protease or integrase inhibitors
- ○ YES
- ○ NO

Non-nucleoside reverse transcription inhibitors
- ○ YES
- ○ NO

STOP-COVID19 Superiority Trial Of Protease inhibition in COVID-19

PARTICIPANT ID				

INITIALS		

28. Day 8 – Clinical Assessment –

*** NOT required for telephone calls ***

Vital Signs

Question	Answers
For follow-up, please record results closest to 8am.	
Pulse	bpm
Blood Pressure systolic	mmHg
Blood Pressure diastolic	mmHg
Tympanic temperature	°C
SpO2	%
SpO2 measured on	○ Air ○ Oxygen ○ N/A
If Oxygen: what was the amount of oxygen received?	
Unit of oxygen	○ L ○ %

29. Day 8 – Clinical Status

Question	Answers
Clinical status on 7 point scale To be collected retrospectively, worst score for whole day.	○ 1. Not hospitalized, no limitations on activities ○ 2. Not hospitalized, limitation on activities ○ 3. Hospitalized, not requiring supplemental oxygen ○ 4. Hospitalized, requiring supplemental oxygen ○ 5. Hospitalized, on non-invasive ventilation or high flow oxygen devices ○ 6. Hospitalized, on invasive mechanical ventilation or ECMO (Extracorporeal membrane oxygenation) ○ 7. Death

STOP-COVID19 | Superiority Trial Of Protease inhibition in COVID-19

PARTICIPANT ID				

INITIALS		

*** Day 8 - This section is NOT required for telephone calls ***

NEWS

Record score closest to 8am for the day, from 0-20 points

Has a CT scan been performed for clinical reasons since admission?

- ○ YES
- ○ NO

If YES: *Has CT scan been previously recorded in eCRF?*

- ○ YES
- ○ NO

If NO: *Date of CT scan* *(dd-mm-yyyy)*

CT scan result

Was the participant discharged?

- ○ YES
- ○ NO

STOP-COVID19 | Superiority Trial Of Protease inhibition in COVID-19

PARTICIPANT ID				

INITIALS	

*** Day 8 - Blood section is NOT required for telephone calls ***

Question	*Answers*
Date of blood test	(dd-mm-yyyy)
Sodium	mmol/L
Potassium	mmol/L
Creatinine	umol/L
Urea	mmol/L
eGFR	ml/min
Albumin	g/L
Bilirubin	umol/L
AST (Aspartate Aminotransferase)	U/L'
ALT (Alanine Aminotransferase)	U/L
Haemoglobin	
Haemoglobin Unit	☐ g/L ☐ g/dL
White blood cell count	x10^9/L
Neutrophil count *If the neutrophil value is less than 1 x10^9/L, please complete the discontinuation of trial medication form.'*	x10^9/L
Eosinophil count	x10^9/L
Platelets	x10^9/L
Lymphocyte count	x10^9/L

STOP-COVID19 Superiority Trial Of Protease inhibition in COVID-19

PARTICIPANT ID				

INITIALS		

30. Day 8 – Samples Tayside and Sheffield Only

*** NOT required for telephone calls ***

Research blood sample taken?

- ○ YES
- ○ NO

TAYSIDE ONLY

Sputum sample for storage if available?

- ○ YES
- ○ NO

Endotracheal aspirate sample for storage if available

- ○ YES
- ○ NO

STOP-COVID19 Superiority Trial Of Protease inhibition in COVID-19

PARTICIPANT ID				

INITIALS		

31. Day 11

Question	Answers
Date (dd-mm-yyyy)	
Data collection via telephone call?	○ YES ○ NO
***If YES**: Date of discharge*	*(dd-mm-yyyy)*
Has the participant had a positive SARS CoV-2 PCR test since admission?	○ YES ○ NO
***If YES:** Date of positive result*	*(dd-mm-yyyy*

32. Day 11 – AEs

Please add an AE report if participant experienced an AE since last day of data collection.

33. Day 11 – Clinical Status

Question	Answers
Clinical status on 7 point scale To be collected retrospectively, worst score for whole day.	○ 1. Not hospitalized, no limitations on activities ○ 2. Not hospitalized, limitation on activities ○ 3. Hospitalized, not requiring supplemental oxygen ○ 4. Hospitalized, requiring supplemental oxygen ○ 5. Hospitalized, on non-invasive ventilation or high flow oxygen devices ○ 6. Hospitalized, on invasive mechanical ventilation or ECMO (Extracorporeal membrane oxygenation) ○ 7. Death

STOP-COVID19 Superiority Trial Of Protease inhibition in COVID-19

PARTICIPANT ID				

INITIALS		

*** Day 11 - This section is NOT required for telephone calls ***

NEWS

Record score closest to 8am for the day, from 0-20 points

Has a CT scan been performed for clinical reasons since admission?

- ○ YES
- ○ NO

If YES: *Has CT scan been previously recorded in eCRF?*

- ○ YES
- ○ NO

If NO: *Date of CT scan*

(dd-mm-yyyy)

CT scan result

Was the participant discharged?

- ○ YES
- ○ NO

STOP-COVID19 Superiority Trial Of Protease inhibition in COVID-19

PARTICIPANT ID				

INITIALS		

*** Day 11- Blood section is NOT required for telephone calls ***

Question	*Answers*
Date of blood test	(dd-mm-yyyy)
Sodium	mmol/L
Potassium	mmol/L
Creatinine	umol/L
Urea	mmol/L
eGFR	ml/min
Albumin	g/L
Bilirubin	umol/L
AST (Aspartate Aminotransferase)	U/L'
ALT (Alanine Aminotransferase)	U/L
Haemoglobin	
Haemoglobin Unit	☐ g/L ☐ g/dL
White blood cell count	x10^9/L
Neutrophil count *If the neutrophil value is less than 1 x10^9/L, please complete the discontinuation of trial medication form.*	x10^9/L
Eosinophil count	x10^9/L
Platelets	x10^9/L
Lymphocyte count	x10^9/L

STOP-COVID19 Superiority Trial Of Protease inhibition in COVID-19

PARTICIPANT ID				

INITIALS		

STOP-COVID19 Superiority Trial Of Protease inhibition in COVID-19

PARTICIPANT ID				

INITIALS		

34. Day 15

Question	Answers
Date (dd-mm-yyyy)	
Data collection via telephone call?	○ YES ○ NO
***If YES**: Date of discharge*	*(dd-mm-yyyy)*
Has the participant had a positive SARS CoV-2 PCR test since admission?	○ YES ○ NO
***If YES:** Date of positive result*	*(dd-mm-yyyy)*

STOP-COVID19 | Superiority Trial Of Protease inhibition in COVID-19

PARTICIPANT ID				

INITIALS		

35 Day 15 – AEs and Conmeds

Please add an AE report if participant experienced an AE since last day of data collection.

Please record Concomitant Medications information

Is the participant co-enrolled in another trial?

- ○ YES
- ○ NO

If 'YES':
Trials

- ☐ RECOVERY
- ☐ RECOVERY RS
- ☐ REMAP CAP
- ☐ ACCORD
- ☐ Other

Other trials, specify

Has the participant received any of the following medications (trial setting or clinical care)?
Please tick other for adding additional trial medications.

- ☐ Lopinavir-Ritonavir
- ☐ Low-dose Dexamethasone
- ☐ Hydroxychloroquine
- ☐ Azithromycin
- ☐ Tocilizumab
- ☐ Remdesivir
- ☐ Other trial drugs

If Other trial drugs, specify

STOP-COVID19 | Superiority Trial Of Protease inhibition in COVID-19

PARTICIPANT ID				

INITIALS		

Other Concomitant Medications

Antiviral agents

Antiviral agent?

- ○ YES
- ○ NO

If YES:

- ☐ Ribavirin
- ☐ Interferon beta
- ☐ Neuraminidase inhibitor
- ☐ Other

Other antiviral agents,- specify

Antibiotics

Antibiotic?

- ○ YES
- ○ NO

If YES, Rifampicin?

- ○ YES
- ○ NO

The participant is not eligible to take part in the trial if on Rifampicin. If already randomised, either the trial drug or Rifampicin must be stopped.

Corticosteroid

Corticosteroid?

- ○ YES
- ○ NO

If YES, Route:

- ☐ Oral
- ☐ Intravenous
- ☐ Inhaled

If YES, please provide type and dose:

STOP-COVID19 Superiority Trial Of Protease inhibition in COVID-19

PARTICIPANT ID				

INITIALS		

Antifungal agents

Antifungal agents?

'The participant is not eligible to take part in the trial if on Itraconazole or Ketoconazole. If already randomised, either the trial drug or Itraconazole/Ketoconazole must be stopped.'

- ☐ None
- ☐ Itraconazole (Exclusion criteria)
- ☐ Ketoconazole (Exclusion criteria)
- ☐ Other

If Other, please specify

If the participant commenced any of the following medications the participant is not eligible to take part in the trial. If already randomised, either the trial drug or following medications must be must be stopped. Please select as appropriate.(continued on next page)

Diltiazem

- ○ YES
- ○ NO

Verapamil'

- ○ YES
- ○ NO

Phenytoin

- ○ YES
- ○ NO

STOP-COVID19 Superiority Trial Of Protease inhibition in COVID-19

PARTICIPANT ID				

INITIALS		

Protease or integrase inhibitors
- ○ YES
- ○ NO

Non-nucleoside reverse transcription inhibitors
- ○ YES
- ○ NO

STOP-COVID19 Superiority Trial Of Protease inhibition in COVID-19

PARTICIPANT ID				

INITIALS		

36. Day 15 – Clinical Assessment

Question	Answers
Vital Signs	
Pulse	bpm
Blood Pressure systolic	mmHg
Blood Pressure diastolic	mmHg
Tympanic temperature	°C
SpO2	%
SpO2 measured on	☐ Air ☐ Oxygen ☐ N/A
If SpO2 measured on oxygen, please provide amount of oxygen received?	
Oxygen unit	○ L ○ %

37. Day 15 – Clinical Status

Question	Answers
Clinical status on 7 point scale To be collected retrospectively, worst score for whole day.	○ 1. Not hospitalized, no limitations on activities ○ 2. Not hospitalized, limitation on activities ○ 3. Hospitalized, not requiring supplemental oxygen ○ 4. Hospitalized, requiring supplemental oxygen ○ 5. Hospitalized, on non-invasive ventilation or high flow oxygen devices ○ 6. Hospitalized, on invasive mechanical ventilation or ECMO (Extracorporeal membrane oxygenation) ○ 7. Death

STOP-COVID19 Superiority Trial Of Protease inhibition in COVID-19

PARTICIPANT ID				

INITIALS		

*** Day 15 - This section is NOT required for telephone calls ***

NEWS

Record score closest to 8am for the day, from 0-20 points

Has a CT scan been performed for clinical reasons since admission?

- ○ YES
- ○ NO

If YES: *Has CT scan been previously recorded in eCRF?*

- ○ YES
- ○ NO

If NO: *Date of CT scan*

(dd-mm-yyyy)

CT scan result

Was the participant discharged?

- ○ YES
- ○ NO

STOP-COVID19 | Superiority Trial Of Protease inhibition in COVID-19

PARTICIPANT ID				

INITIALS		

*** Day 15 - Blood section is NOT required for telephone calls ***

Question	*Answers*
Date of blood test	(dd) (mm) (yyyy) *(dd-mm-yyyy)*
Sodium	mmol/L
Potassium	mmol/L
Creatinine	umol/L
Urea	mmol/L
eGFR	ml/min
Albumin	g/L
Bilirubin	umol/L
AST (Aspartate Aminotransferase)	U/L'
ALT (Alanine Aminotransferase)	U/L
Haemoglobin	
Haemoglobin Unit	☐ g/L ☐ g/dL
White blood cell count	x10^9/L
Neutrophil count *If the neutrophil value is less than 1 x10^9/L, please complete the discontinuation of trial medication form.'*	x10^9/L
Eosinophil count	x10^9/L
Platelets	x10^9/L
Lymphocyte count	x10^9/L

STOP-COVID19 Superiority Trial Of Protease inhibition in COVID-19

PARTICIPANT ID				

INITIALS		

38. Day 15 – Samples Tayside and Sheffield Only

*** NOT required for telephone calls ***

Question	Answers
Research blood sample taken?	○ YES ○ NO

TAYSIDE ONLY

Sputum sample for storage if available?	○ YES ○ NO
Endotracheal aspirate sample for storage if available	○ YES ○ NO
Nasal swab for SARS CoV-2 PCR	○ YES ○ NO

STOP-COVID19 Superiority Trial Of Protease inhibition in COVID-19

PARTICIPANT ID				

INITIALS		

39. Day 29

Question	Answers
Date (dd-mm-yyyy)	
Data collection via telephone call?	○ YES ○ NO
***If YES**: Date of discharge*	*(dd-mm-yyyy)*
Has the participant had a positive SARS CoV-2 PCR test since admission?	○ YES ○ NO
***If YES:** Date of positive result*	*(dd-mm-yyyy)*

STOP-COVID19 | Superiority Trial Of Protease inhibition in COVID-19

PARTICIPANT ID				

INITIALS		

40. Day 29 – AEs and Conmeds

Please add an AE report if participant experienced an AE since last day of data collection.

Please record Concomitant Medications information

Is the participant co-enrolled in another trial?

- ○ YES
- ○ NO

If 'YES':
Trials

- ☐ RECOVERY
- ☐ RECOVERY RS
- ☐ REMAP CAP
- ☐ ACCORD
- ☐ Other

Other trials, specify

Has the participant received any of the following medications (trial setting or clinical care)?
Please tick other for adding additional trial medications.

- ☐ Lopinavir-Ritonavir
- ☐ Low-dose Dexamethasone
- ☐ Hydroxychloroquine
- ☐ Azithromycin
- ☐ Tocilizumab
- ☐ Remdesivir
- ☐ Other trial drugs

If Other trial drugs, specify

Other Concomitant Medications

Antiviral agents

Antiviral agent?

- ○ YES
- ○ NO

If YES:

- ☐ Ribavirin
- ☐ Interferon beta
- ☐ Neuraminidase inhibitor
- ☐ Other

Other antiviral agents,- specify

Antibiotics

Antibiotic?

- ○ YES
- ○ NO

If YES, Rifampicin?

- ○ YES
- ○ NO

The participant is not eligible to take part in the trial if on Rifampicin. If already randomised, either the trial drug or Rifampicin must be stopped.

Corticosteroid

Corticosteroid?

- ○ YES
- ○ NO

If YES, Route:

- ☐ Oral
- ☐ Intravenous
- ☐ Inhaled

If YES, please provide type and dose:

STOP-COVID19 | Superiority Trial Of Protease inhibition in COVID-19

PARTICIPANT ID				

INITIALS		

Antifungal agents

Antifungal agents?

'The participant is not eligible to take part in the trial if on Itraconazole or Ketoconazole. If already randomised, either the trial drug or Itraconazole/Ketoconazole must be stopped.'

- ☐ None
- ☐ Itraconazole (Exclusion criteria)
- ☐ Ketoconazole (Exclusion criteria)
- ☐ Other

If Other, please specify

If the participant commenced any of the following medications the participant is not eligible to take part in the trial. If already randomised, either the trial drug or following medications must be must be stopped. Please select as appropriate. (continued on next page)

Diltiazem

- ○ YES
- ○ NO

Verapamil'

- ○ YES
- ○ NO

Phenytoin

- ○
- ○

STOP-COVID19 Superiority Trial Of Protease inhibition in COVID-19

PARTICIPANT ID				

INITIALS		

YES NO

Protease or integrase inhibitors ○ YES ○ NO

Non-nucleoside reverse transcription inhibitors ○ YES ○ NO

41. Day 29 – EQ-5D

EQ-5D questionnaire completed? ○ YES ○ NO

STOP-COVID19 Superiority Trial Of Protease inhibition in COVID-19

PARTICIPANT ID				

INITIALS		

42. Day 29 – Clinical Assessment

*** NOT required for telephone calls ***

Vital Signs

Question	Answers
For follow-up, please record results closest to 8am.	
Pulse	..... bpm
Blood Pressure systolic	..... mmHg
Blood Pressure diastolic	..... mmHg
Tympanic temperature	..... °C
SpO2	..... %
SpO2 measured on	◯ Air ◯ Oxygen ◯ N/A
If Oxygen*: what was the amount of oxygen received?*	.....
Unit of oxygen	◯ L ◯ %

43. Day 29 – Clinical Status

Question	Answers
Clinical status on 7 point scale To be collected retrospectively, worst score for whole day.	◯ 1. Not hospitalized, no limitations on activities ◯ 2. Not hospitalized, limitation on activities ◯ 3. Hospitalized, not requiring supplemental oxygen ◯ 4. Hospitalized, requiring supplemental oxygen ◯ 5. Hospitalized, on non-invasive ventilation or high flow oxygen devices ◯ 6. Hospitalized, on invasive mechanical ventilation or ECMO (Extracorporeal membrane oxygenation) ◯ 7. Death

STOP-COVID19 Superiority Trial Of Protease inhibition in COVID-19

PARTICIPANT ID				

INITIALS		

*** Day 29 - This section is NOT required for telephone calls ***

NEWS

Record score closest to 8am for the day, from 0-20 points

Has a CT scan been performed for clinical reasons since admission?

- ○ YES
- ○ NO

If YES: *Has CT scan been previously recorded in eCRF?*

- ○ YES
- ○ NO

If NO: *Date of CT scan* *(dd-mm-yyyy)*

CT scan result

Was the participant discharged?

- ○ YES
- ○ NO

If 'YES': *Date of discharge* *(dd-mm-yyyy)*

STOP-COVID19 Superiority Trial Of Protease inhibition in COVID-19

PARTICIPANT ID				

INITIALS		

*** Day 29 - Blood section is NOT required for telephone calls ***

Question	*Answers*
Date of blood test	(dd-mm-yyyy)
Sodium	mmol/L
Potassium	mmol/L
Creatinine	umol/L
Urea	mmol/L
eGFR	ml/min
Albumin	g/L
Bilirubin	umol/L
AST (Aspartate Aminotransferase)	U/L′
ALT (Alanine Aminotransferase)	U/L
Haemoglobin	
Haemoglobin Unit	☐ g/L ☐ g/dL
White blood cell count	x10^9/L
Neutrophil count *If the neutrophil value is less than 1 x10^9/L, please complete the discontinuation of trial medication form.'*	x10^9/L
Eosinophil count	x10^9/L
Platelets	x10^9/L
Lymphocyte count	x10^9/L

STOP-COVID19 Superiority Trial Of Protease inhibition in COVID-19

PARTICIPANT ID				

INITIALS		

44. Day 29 - Samples Tayside and Sheffield Only

*** NOT required for telephone calls ***

Question	Answers
Research blood sample taken?	○ YES ○ NO
TAYSIDE ONLY	
Sputum sample for storage if available?	○ YES ○ NO
Endotracheal aspirate sample for storage if available	○ YES ○ NO
Nasal swab for SARS CoV-2 PCR	○ YES ○ NO

STOP-COVID19 Superiority Trial Of Protease inhibition in COVID-19

PARTICIPANT ID				

INITIALS		

45. Completion of Trial/Early Withdrawal

Question	Answers
Completion of Trial/Early Withdrawal	
Was the participant randomised?	○ YES ○ NO
Did the participant complete the trial (reach Day 29)?	○ YES ○ NO
Date last trial medication taken? (dd-mm-yyyy)	
Number of tablets remaining?	
Date of completion/withdrawal (dd-mm-yyyy)	*(dd-mm-yyyy)*

If participant did not complete the trial, what was the main reason (tick one only)

Reason

- ○ Commenced restricted medications
- ○ Advice from GP/other healthcare professional
- ○ Adverse Event
- ○ Participant's choice
- ○ Pregnancy
- ○ On advice of investigator
- ○ Lost to follow-up
- ○ Died
- ○ Other

Details

COMPLETION OF TRIAL

PARTICIPANT ID				

INITIALS		

STOP-COVID19 | Superiority Trial Of Protease inhibition in COVID-19

PARTICIPANT ID				

INITIALS		

Discontinuation of Trial Medication Form

Question	Answers
Permanent Discontinuation of Trial Medication	
Instructions: Where a participant is withdrawing completely from the trial, do not complete this form but complete the Completion of Trial Form. The discontinuation of trial medication form should only be completed when participants are permanently stopping the trial medication but are continuing in the trial. When participants stop trial medication they should be encouraged to continue with the trial visits and the trial wherever possible.	
What date was the last dose taken? (dd-mm-yyyy)	
Reason for stopping of study medication (main reason only)	
Reason	○ Allergic reaction to trial drug ○ Absolute neutrophil count less than 1.0 x 10^9 per L ○ Advice from GP/other healthcare professional ○ Persistent adverse effects which are determined to be severe, persistent, treatment-related and not responsive to treatment ○ Other Adverse event ○ Participant's choice ○ Pregnancy ○ On advice of investigator ○ Other
Number of tablets remaining	

STOP-COVID19 Superiority Trial Of Protease inhibition in COVID-19

PARTICIPANT ID				

INITIALS		

STOP-COVID19 Superiority Trial Of Protease inhibition in COVID-19

PARTICIPANT ID				

INITIALS		

Unscheduled Assessment in the event of an AE

Complete one of these forms when PI decides an unscheduled assessment is required. Not all AEs will require an unscheduled assessment.

Question	Answers
Date: (dd-mm-yyyy)	

Unscheduled Assessment - AEs and Conmeds

Please add an AE report if participant experienced an AE since last day of data collection.

Please record Concomitant Medications information

Is the participant co-enrolled in another trial?	○ YES ○ NO
If 'YES': Trials	☐ RECOVERY ☐ RECOVERY RS ☐ REMAP CAP ☐ ACCORD ☐ Other
Other trials, specify	
Has the participant received any of the following medications (trial setting or clinical care)? Please tick other for adding additional trial medications.	☐ Lopinavir-Ritonavir ☐ Low-dose Dexamethasone ☐ Hydroxychloroquine ☐ Azithromycin ☐ Tocilizumab ☐ Remdesivir ☐ Other trial drugs

If Other trial drugs, specify

Other Concomitant Medications

Antiviral agents

Antiviral agent?

- ○ YES
- ○ NO

If YES:

- ☐ Ribavirin
- ☐ Interferon beta
- ☐ Neuraminidase inhibitor
- ☐ Other

Other antiviral agents,- specify

Antibiotics

Antibiotic?

- ○ YES
- ○ NO

If YES, Rifampicin?

- ○ YES
- ○ NO

The participant is not eligible to take part in the trial if on Rifampicin. If already randomised, either the trial drug or Rifampicin must be stopped.

Corticosteroid

Corticosteroid?

- ○ YES
- ○ NO

If YES, Route:

- ☐ Oral
- ☐ Intravenous
- ☐ Inhaled

If YES, please provide type and dose:

Antifungal agents

Antifungal agents?

'The participant is not eligible to take part in the trial if on Itraconazole or Ketoconazole. If already randomised, either the trial drug or Itraconazole/Ketoconazole must be stopped.'

- ☐ None
- ☐ Itraconazole (Exclusion criteria)
- ☐ Ketoconazole (Exclusion criteria)
- ☐ Other

If Other, please specify

If the participant commenced any of the following medications the participant is not eligible to take part in the trial. If already randomised, either the trial drug or following medications must be must be stopped. Please select as appropriate. (continued on next page)

Diltiazem

- ○ YES
- ○ NO

Verapamil

- ○ YES
- ○ NO

Phenytoin

- ○
- ○

STOP-COVID19 | Superiority Trial Of Protease inhibition in COVID-19

PARTICIPANT ID				

INITIALS		

YES NO

Protease or integrase inhibitors
- ○ YES
- ○ NO

Non-nucleoside reverse transcription inhibitors
- ○ YES
- ○ NO

STOP-COVID19 Superiority Trial Of Protease inhibition in COVID-19

PARTICIPANT ID				

INITIALS		

Unscheduled Assessment - Vital Signs

Question	Answers
For follow-up, please record results closest to 8am.	
Pulse	..... bpm
Blood Pressure systolic	..... mmHg
Blood Pressure diastolic	..... mmHg
Tympanic temperature	..... °C
SpO2	..... %
SpO2 measured on	○ Air ○ Oxygen ○ N/A
If Oxygen*: what was the amount of oxygen received?*	.....
Unit of oxygen	○ L ○ %

Unscheduled Assessment - Clinical Status

Question	Answers
Clinical status on 7 point scale To be collected retrospectively, worst score for whole day.	○ 1. Not hospitalized, no limitations on activities ○ 2. Not hospitalized, limitation on activities ○ 3. Hospitalized, not requiring supplemental oxygen ○ 4. Hospitalized, requiring supplemental oxygen ○ 5. Hospitalized, on non-invasive ventilation or high flow oxygen devices ○ 6. Hospitalized, on invasive mechanical ventilation or ECMO (Extracorporeal membrane oxygenation) ○ 7. Death

Has a CT scan been performed for clinical reasons since admission?

○ YES
○ NO

If YES: *Has CT scan been previously recorded in eCRF?*

○ YES
○ NO

If NO: *Date of CT scan* _____ _____ _____ *(dd-mm-yyyy)*

CT scan result

Was the participant discharged?

○ YES
○ NO

If 'YES': *Date of discharge* _____ _____ _____ *(dd-mm-yyyy)*

Unscheduled Assessment - Samples Tayside and Sheffield Only

Question	Answers
Research blood sample taken?	◯ YES ◯ NO

Adverse Events

Complete one of these forms for each adverse event

Question	Answers
AEs & SAEs must be followed up until recovered/recovered with sequelae/death or for 30 days after participant's day 29, whichever happens first. If still ongoing at last day of data collection contact participant 30 days after last trial involvement and update AE log if required. **SUSARs** must be followed up until resolved.	
Description of adverse event Where possible, **give diagnosis**. If diagnosis is not known, give sign or symptom. Update if diagnosis is determined.	
Onset date Onset date should be in one of the following formats: DD-MM- YYYY or NK-MM-YYYY	
Date reported to Investigator (dd-mm-yyyy)	
Severity	○ 1. Mild ○ 2. Moderate ○ 3. Severe
Relationship to Trial Drug	○ 1. None ○ 2. Possible ○ 3. Probable ○ 4. Definite
Is this an SAE?	○ YES ○ NO
If YES, has an SAE form been completed? If no, a SAE form must be completed within 24 hours of SAE being reported	○ YES ○ NO
Signature of PI or delegated doctor	
Date of signature: (dd-mm-yyyy)	

Action taken
Please select all appropriate actions taken.

- ☐ 1. None
- ☐ 2. Hospitalisation
- ☐ 3. IMP temporarily stopped
- ☐ 4. IMP permanently stopped
- ☐ 5. Con Meds commenced
- ☐ 6. Other (specify)

If Other, action taken:

Outcome

- ○ 1. Recovered
- ○ 2. Recovered with sequelae
- ○ 3. Recovering
- ○ 4. Not recovered
- ○ 5. Unknown
- ○ 6. Fatal

Enter date recovered/date of death/date of last contact
If the outcome of the AE is recovered, recovered with sequelae, not recovered or fatal then please enter date resolved or date of death

If the outcome is recovering or unknown then please enter the date of last contact AND mark as not recovered

Date resolved, date of death or date of last contact should be in the one of the following formats: DD-MM-YYYY or NK-MM-YYYY

STOP-COVID19 | Superiority Trial Of Protease inhibition in COVID-19

PARTICIPANT ID				

INITIALS		

Daily Data Collection While in Hospital

Complete one of these forms on each day the participant is in hospital (print as required)

	Question	***Answers***
	Date	☐☐ ☐☐ ☐☐☐☐ *(dd-mm-yyyy)*
	Day of Data Collection	☐☐
	Clinical Status To be collected retrospectively, worst score for whole day.	○ 1. Not hospitalized, no limitations on activities ○ 2. Not hospitalized, limitation on activities ○ 3. Hospitalized, not requiring supplemental oxygen ○ 4. Hospitalized, requiring supplemental oxygen ○ 5. Hospitalized, on non-invasive ventilation or high flow oxygen devices ○ 6. Hospitalized, on invasive mechanical ventilation or ECMO (Extracorporeal membrane oxygenation) ○ 7. Death
	NEWS score Closest result to 8am to be used.	☐☐ 0-20 points

STOP-COVID19 | Superiority Trial Of Protease inhibition in COVID-19

PARTICIPANT ID				

INITIALS		

Was a CT scan performed for clinical reasons since admission? ○ Yes ○ No ○ Unknown

If YES: Has CT scan been previously recorded in eCRF? ○ YES ○ NO

If NO*: Date of CT scan (dd-mm-yyyy)* | | |

CT scan results

Was the participant discharged? ○ YES ○ NO