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STAR-COVID19 Worksheet

1. Baseline - Informed Consent

1.1	Date of Consent	☐☐ ☐☐ ☐☐☐☐ *(dd-mm-yyyy)*
1.2	Consent provided by	◯ Participant ◯ Personal legal representative ◯ Professional legal representative

2. Baseline - Demographics

2.1	Age	☐☐☐ years
2.2	Sex at birth	◯ Male ◯ Female
2.3	Ethnicity	◯ 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

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2.3.1	*If 'Ethnicity' is equal to 'Any other ethnic group', please provide details*	
2.4	Living status	◯ Own home (on own or with others) ◯ Sheltered housing ◯ Care home (nursing or residential) ◯ Prison ◯ Other
2.4.1	*If 'Living status' is equal to 'Other', please provide details:*	

3. Baseline - Hospital Admission

3.1	Approximate day of onset of Pneumonia symptoms	*(dd-mm-yyyy)*
3.2	Date of hospital admission	*(dd-mm-yyyy)*
3.3	Date of chest X-ray or CT Scan	*(dd-mm-yyyy)*
3.4	New radiographic infiltrates observable? *If NO: 'The participant is not eligible to take part in the trial.'*	◯ YES ◯ NO
3.4.1	If YES: Bilateral radiographic infiltrates observable?	◯ YES ◯ NO
3.5	Causative pneumonia pathogen identified?	◯ YES ◯ NO
3.5.1	*If 'Causative pneumonia pathogen identified?' is equal to 'YES', specify the source*	◯ BAL ◯ Blood ◯ Sputum ◯ Nasal / NP Swab ◯ Oropharyngeal Swab ◯ Combined naso/oropharyngeal swab ◯ Other

3.5.1.1	***If Source is equal to 'Other', please provide details***	

3.6	**Please record Novel Coronavirus (nCoV) test details on page 23**	

4. Baseline - Focused Medical History

4.1	Chronic Neutropenia	◯ YES ◯ NO
4.2	Chronic cardiac disease, including congenital heart disease (not hypertension)	◯ YES ◯ NO
4.3	Hypertension	◯ YES ◯ NO
4.4	COPD	◯ YES ◯ NO
4.5	Chronic pulmonary disease (not COPD or asthma)	◯ YES ◯ NO
4.6	Asthma (physician diagnosed)	◯ YES ◯ NO
4.7	Chronic kidney disease (defined as 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
4.8	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) is greater than 5 times the upper limit of normal. Please check ALT and AST result (within 72 hours of randomisation).**	◯ YES ◯ NO

4.9	Mild liver disease	○ YES ○ NO
4.10	Chronic neurological disorder	○ YES ○ NO
4.11	Malignant neoplasm	○ YES ○ NO
4.12	Chronic hematologic disease	○ YES ○ NO
4.13	AIDS / HIV	○ YES ○ NO
4.14	Obesity (as defined by clinical staff)	○ YES ○ NO
4.15	Diabetes with complications	○ YES ○ NO
4.16	Diabetes without complications	○ YES ○ NO
4.17	Rheumatologic disorder	○ YES ○ NO
4.18	Dementia	○ YES ○ NO
4.19	Malnutrition	○ YES ○ NO
4.20	Smoking	○ Yes ○ Never smoked ○ Former smoker ○ Unknown
4.21	Other relevant risk factor	○ YES ○ NO
4.21.1	*If 'Other relevant risk factor' is equal to 'YES', provide details:*	

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5. Baseline - Signs and Symptoms on Admission

	Admission signs and symptoms (observed/reported at admission and associated with this episode of acute illness)	
5.1	History of fever	◯ YES ◯ NO
5.2	Cough without sputum production	◯ YES ◯ NO
5.3	Cough with sputum production	◯ YES ◯ NO
5.4	Cough with bloody sputum/haemoptysis	◯ YES ◯ NO
5.5	Sore throat	◯ YES ◯ NO
5.6	Runny nose (Rhinorrhoea)	◯ YES ◯ NO
5.7	Ear pain	◯ YES ◯ NO
5.8	Wheezing	◯ YES ◯ NO
5.9	Chest pain	◯ YES ◯ NO
5.10	Muscle aches (Myalgia)	◯ YES ◯ NO
5.11	Joint pain (Arthralgia)	◯ YES ◯ NO
5.12	Fatigue / Malaise	◯ YES ◯ NO
5.13	Shortness of breath (Dyspnea)	◯ YES ◯ NO
5.14	Lower chest wall indrawing	◯ YES ◯ NO

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5.15	Headache	○ YES ○ NO
5.16	Altered consciousness/confusion	○ YES ○ NO
5.17	Seizures	○ YES ○ NO
5.18	Abdominal pain	○ YES ○ NO
5.19	Vomiting / Nausea	○ YES ○ NO
5.20	Diarrhoea	○ YES ○ NO
5.21	Conjunctivitis	○ YES ○ NO
5.22	Skin rash	○ YES ○ NO
5.23	Skin ulcers	○ YES ○ NO
5.24	Lymphadenopathy	○ YES ○ NO
5.25	Bleeding (Haemorrhage)	○ YES ○ NO
5.25.1	*If 'Bleeding (Haemorrhage)' is equal to 'YES' specify sites(s):*	
5.26	Lost or changed sense of smell	○ YES ○ NO

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5.27	Other signs or symptoms	○ YES ○ NO
5.27.1	***If 'Other signs or symptoms' is equal to 'YES', please specify***	

6. Baseline - Clinical Assessments

Step Vital Signs - Baseline

	Please record the most recent values for Randomisation. For follow-up, please record results closest to 8am.	
1	Pulse	bpm
2	Blood Pressure systolic	mmHg
3	Blood Pressure diastolic	mmHg
4	Tympanic temperature	°C
5	Respiratory rate	breaths per minute
6	SpO2	%
7	SpO2 measured on	○ Air ○ Oxygen
7.1	*If 'SpO2 measured on Oxygen, please record the* amount of oxygen received?	
7.2	If 'SpO2 measured on' is equal to 'Oxygen' *please record the Unit:*	○ L ○ %

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7. Baseline - Clinical Status and NEWS

7.1	Clinical status on 7- point scale *If 1. Not hospitalized, no limitations on activities* *2. Not hospitalized, limitation on activities* *6. Hospitalized, on invasive mechanical ventilation or ECMO (Extracorporeal membrane oxygenation)* *7. Death* *Participant is not eligible to take part in the trial.*	◯ 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
7.2	NEWS Record most recent score for the day	..... 0-20 points

8. Baseline - Samples

Number	Question	Answers
8.1	*If participant is female, answer this question:* Pregnancy test performed	◯ YES ◯ NO ◯ N/A
8.1.1	*If 'Pregnancy test was not performed' answer this question:* Is the participant either permanently sterilized or post-menopausal?	◯ YES ◯ NO
8.1.2	*If a pregnancy test was performed record* Pregnancy test result ***Without a negative pregnancy test result, the participant is not eligible to take part in the trial.***	◯ Positive ◯ Negative
8.2	Please record Blood samples in Baseline Blood form.	

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9. Baseline - CURB65 score

CURB-65 score calculated using the worst values obtained on admission or in the 24 hours prior to randomisation.
Use the CURB65 calculator on https://www.mdcalc.com/curb-65-score-pneumonia-severity

9.1	**C=Confusion** (Abbreviated Mental Test Score obtained on admission or in the 24 hours prior to randomisation)	○ 0 ○ 1 ○ 2 ○ 3 ○ 4 ○ 5 ○ 6 ○ 7 ○ 8 ○ 9 ○ 10 ○ Clinically diagnosed delirium
9.2	**U=Urea** (as recorded in Baseline Bloods Report)	
9.3	**R=Respiratory rate** (as recorded in Baseline Vital Signs Report)	
9.4	**B=Blood Pressure - Systolic** (as recorded in Baseline Vital Signs Report)	
9.5	**B=Blood Pressure - Diastolic** (as recorded in Baseline Vital Signs Report)	
9.6	**Age** (as recorded in Baseline Demographics)	

Total CURB65 score

If the participant has a score of 0 and no bilateral radiographic infiltrates were visible on the chest X-ray or CT scan (max 48 hours after hospital admission), the participant is not eligible.

10. Baseline - ConMeds

Please record each ConMed belonging to the following drug classes:

Antiviral or COVID-19 targeted agents,

Antibiotics,

Corticosteroids,

Other treatments administered for COVID-19 including experimental or compassionate use and any

Other medication.

NOTE: add 1 report per ConMed on Castor

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11. Baseline - Inclusion Criteria

If any of the Inclusion criteria are answered NO, the participant is not eligible to take part in the trial.

11.1	18 years of age or older	◯ YES ◯ NO
11.2	Community acquired pneumonia (defined as a new radiographic infiltrate on chest x-ray or CT scan in a patient presenting with respiratory symptoms both of which are clinically evident less than 48 hours after hospitalisation). **At least 1 criteria needs to be ticked, otherwise the participant is not eligible to take part in the trial**	☐ X-ray ☐ CT Scan
11.3	Tested for suspected SARS-CoV-2 infection via RT-PCR or another approved laboratory method*	◯ YES ◯ NO
11.4	Increased risk of mortality on admission (defined by CURB65 score greater than or equal to 1 or the presence of bilateral radiographic infiltrates)	◯ YES ◯ NO
11.5	Treatment can be commenced within 96 hours of hospital admission	◯ YES ◯ NO
11.6	Requires hospitalisation but NOT requiring mechanical ventilation at randomisation	◯ YES ◯ NO
11.7	Participant (or legally authorised representative) provides written informed consent	◯ YES ◯ NO
11.8	Able to take oral medication at randomisation	◯ YES ◯ NO
11.9	Participant (or legally authorised representative) understands and agrees to comply with planned trial procedures.	◯ YES ◯ NO

* For the avoidance of doubt, this trial permits inclusion of patients presenting with acute respiratory infections whether or not the test for SARS-CoV-2 is positive. Patients can be randomised to the study while awaiting the results of the test for SARS-CoV-2.

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12. Baseline - Exclusion Criteria

If any of the Exclusion criteria are answered YES, the participant is not eligible to take part in the trial.

12.1	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
12.2	Stage 4 severe chronic kidney disease or requiring dialysis (i.e. eGFR less than 30), result within 72 hours of randomisation (the result closest to randomisation should be used if several results are available)	◯ YES ◯ NO
12.3	Pregnant or breast feeding	◯ YES ◯ NO
12.4	Anticipated transfer to another hospital which is not a trial site within 24 hours	◯ YES ◯ NO
12.5	Hospital-acquired pneumonia (defined as onset of respiratory illness more than 48 hours after admission to hospital)	◯ YES ◯ NO
12.6	Allergy to SFX-01	◯ YES ◯ NO
12.7	Patients in whom active treatment is not considered appropriate.	◯ YES ◯ NO
12.8	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

Women of childbearing potential (WOCBP) must be willing to have pregnancy testing prior to trial entry and agree to use approved contraception throughout the trial.

Enrolment in observational trials will not be an exclusion to participation.

Co-enrolment in another CTIMP is not acceptable.

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13. Baseline - Eligibility Checks

Eligibility must be checked prior to randomisation by a doctor delegated this task in the Delegation Log

13.1	Is the participant eligible to take part in the trial? (Were all INCL/EXCL criteria met?)	○ YES ○ NO
13.2	Was eligibility signed off by a delegated doctor prior to randomisation?	○ YES ○ NO
13.2.1	Doctor's Name	
13.2.2	Date of signature	*(dd-mm-yyyy)*

14. Baseline - Randomisation

14.1	Has the participant been randomised?	○ YES ○ NO
14.1.1	*Date of Randomisation*	*(dd-mm-yyyy)*
14.1.2	*Date of First Dose* ***Treatment should commence within 96 hours of hospital admission, otherwise the participant is ineligible.***	*(dd-mm-yyyy)*

15. Baseline - Sample Sites Only

15.1	**Sample Sites Only -** *Research blood sample taken for Neutrophil test?*	○ YES ○ NO
15.2	**Sample Sites Only -** *Research blood sample taken for Nrf2 pathway?*	○ YES ○ NO
15.3	***Sample Sites Only -*** *Measurement of interleukin-6, interleukin-1 beta and TNF-alpha in blood?*	○ YES ○ NO

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16. In Hospital: Daily Data Collection

Please add a "In Hospital: Daily Data Collection" Report for each day the participant was hospitalized (except outcome days 3, 5, 8, 11, 15, 29)

17. Day 3 - Day 3

17.1	Date	☐☐ ☐☐ ☐☐☐☐ *(dd-mm-yyyy)*
17.2	Data collection via telephone call?	◯ YES ◯ NO
17.3	****Only required for discharged participants**** Was the participant discharged on the day?	◯ YES ◯ NO -> ☐☐ ☐☐ ☐☐☐☐ (dd-mm-yyyy)

18. Day 3 - AEs and ConMeds

Please add/update AE and/or ConMeds report if the participant has experienced any AEs, or had any changes to ConMeds since the last day of data collection.

19. Day 3 - Clinical Status

***** only required if participant in hospital *****

19.1	SpO2	☐☐☐ %
19.2	*SpO2 measured on*	◯ Air ◯ Oxygen
19.2.1	*If 'SpO2 measured on Oxygen', please record amount of oxygen received*	☐☐
19.2.2	*If 'SpO2 measured on Oxygen', please record Unit* question:	◯ L ◯ %

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19.3	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

***** only required if participant in hospital **'***

19.4 *NEWS – (Record score closest to 8am for the day.)* ..... *0-20 points*

***** only required if participant in hospital **'***

19.5 *Please record Bloods for Day 3 in Day 3 Blood Report.*

19.6 *Please record any positive SARS-CoV-2 Test in the SARS-CoV-2 form*

20. Day 5 - Day 5

20.1	Date	.... *(dd-mm-yyyy)*
20.2	Data collection via telephone call?	○ YES ○ NO
20.3	****Only required for discharged participants**** Was the participant discharged on the day?	○ YES ○ NO -> .... (dd-mm-yyyy)

21. Day 5 - AEs and ConMeds

Please add/update AE and/or ConMeds report if the participant has experienced any AEs, or had any changes to ConMeds since last day of data collection.

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22. Day 5 - Clinical Status

***** only required if participant in hospital **'***

22.1	SpO2	%
22.2	*SpO2 measured on*	◯ Air ◯ Oxygen
22.2.1	*If 'SpO2 measured on Oxygen', please record amount of oxygen received*	
22.2.2	*If 'SpO2 measured on Oxygen', please record Unit* question:	◯ L ◯ %

22.3	Clinical status on 7 point scale To be collected retrospectively, Worst value 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

***** only required if participant in hospital **'***

22.4	*NEWS – (Record score closest to 8am for the day.)*	*0-20 points*

***** only required if participant in hospital **'***

22.5	*Please record Bloods for Day 5 in Bloods Report.*
22.6	Please record any new positive SARS-CoV-2 Test in the SARS-CoV-2 form

23. Day 8 - Day 8

23.1	Date	☐☐ ☐☐ ☐☐☐☐ *(dd-mm-yyyy)*
23.2	Data collection via telephone call?	◯ YES ◯ NO
23.3	****Only required for discharged participants**** Was the participant discharged on the day?	◯ YES ◯ NO -> ☐☐ ☐☐ ☐☐☐☐ (dd-mm-yyyy)

24. Day 8 - AEs and ConMeds

Please add/update AE and/or ConMeds report if the participant has experienced any AEs, or had any changes to ConMeds since last day of data collection.

25. Day 8 - Clinical Status

***** only required if participant in hospital **'***

25.1	SpO2	☐☐☐ %
25.2	*SpO2 measured on*	◯ Air ◯ Oxygen
25.2.1	*If 'SpO2 measured on Oxygen', please record amount of oxygen received*	☐☐☐
25.2.2	*If 'SpO2 measured on Oxygen', please record Unit* question:	◯ L ◯ %
25.3	Clinical status on 7 point scale To be collected retrospectively, Worst value 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

**** only required if participant in hospital *****

25.4 *NEWS – (Record score closest to 8am for the day.)* ..... *0-20 points*

**** only required if participant in hospital *****

25.5 *Please record Bloods for Day 8 in Bloods Report.*

25.6 Please record any new positive SARS-CoV-2 Test in the SARS-CoV-2 form

26. Day 8 - Sample Sites Only

26.1 *Sample Sites Only* - Research blood sample taken for Neutrophil test?
- ◯ YES
- ◯ NO

26.2 *Sample Sites Only* - Measurement of interleukin-6, interleukin-1 beta and TNF-alpha in blood?
- ◯ YES
- ◯ NO

27. Day 11 - Day 11

27.1 Date .... *(dd-mm-yyyy)*

27.2 Data collection via telephone call?
- ◯ YES
- ◯ NO

27.3 ****Only required for discharged participants****
Was the participant discharged on the day?
- ◯ YES
- ◯ NO -> .... (dd-mm-yyyy)

28. Day 11 - AEs and ConMeds

Please add/update AE and/or ConMeds report if the participant has experienced any AEs, or had any changes to ConMeds since last day of data collection.

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29. Day 11 - Clinical Status

***** only required if participant in hospital **'***

29.1 SpO2 _____ %

29.2 SpO2 measured on

- ◯ Air
- ◯ Oxygen

29.2.1 If 'SpO2 measured on Oxygen', please record amount of oxygen received _____

29.2.2 *If 'SpO2 measured on Oxygen', please record Unit* question:

- ◯ L
- ◯ %

29.3 Clinical status on 7 point scale
To be collected retrospectively,
Worst value 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

***** only required if participant in hospital **'***

29.4 NEWS – (Record score closest to 8am for the day.) _____ *0-20 points*

***** only required if participant in hospital **'***

29.5 Please record Bloods for Day 11 in Bloods Report.

29.6 Please record any new positive SARS-CoV-2 Test in the SARS-CoV-2 form.

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30. Day 15 - Day 15

30.1	Date	☐☐ ☐☐ ☐☐☐☐ *(dd-mm-yyyy)*
30.2	Data collection via telephone call?	◯ YES ◯ NO
30.3	****Only required for discharged participants**** Was the participant discharged on the day?	◯ YES ◯ NO -> ☐☐ ☐☐ ☐☐☐☐ (dd-mm-yyyy)

31. Day 15 - AEs and ConMeds

Please add/update AE and/or ConMeds report if the participant has experienced any AEs, or had any changes to ConMeds since last day of data collection.

32. Day 15 - Clinical Status

***** only required if participant in hospital **'***

32.1	SpO2	☐ %
32.2	*SpO2 measured on*	◯ Air ◯ Oxygen
32.2.1	*If 'SpO2 measured on Oxygen', please record amount of oxygen received*	☐
32.2.2	*If 'SpO2 measured on Oxygen', please record Unit* question:	◯ L ◯ %
32.3	Clinical status on 7 point scale To be collected retrospectively, Worst value 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

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***** only required if participant in hospital **'***

32.4 *NEWS – (Record score closest to 8am for the day.)* ..... *0-20 points*

***** only required if participant in hospital **'***

32.5 *Please record Bloods for Day 15 in Bloods Report.*

32.6 Please record any new positive SARS-CoV-2 Test in the SARS-CoV-2 form

33. Day 15 - Sample Sites Only

33.1 *Sample Sites Only* - Research blood sample taken for Neutrophil test?

- ◯ YES
- ◯ NO

33.2 *Sample Sites Only* - Research blood sample taken for Nrf2 pathway?

- ◯ YES
- ◯ NO

33.3 *Sample Sites 33.3 Only - Measurement of interleukin-6,* interleukin-1 beta and TNF-alpha in blood

- ◯ YES
- ◯ NO

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34. Day 29 - Day 29

34.1	Date	☐☐ ☐☐ ☐☐☐☐ *(dd-mm-yyyy)*
34.2	Data collection via telephone call?	◯ YES ◯ NO
34.3	****Only required for discharged participants**** Was the participant discharged on the day?	◯ YES ◯ NO -> ☐☐ ☐☐ ☐☐☐☐ (dd-mm-yyyy)

35. Day 29 - AEs and ConMeds

Please add/update AE and/or ConMeds report if the participant has experienced any AEs, or had any changes to ConMeds since last day of data collection.

36. Day 29 - Clinical Status

***** only required if participant in hospital **'***

36.1	SpO2	☐☐☐ %
36.2	*SpO2 measured on*	◯ Air ◯ Oxygen
36.2.1	*If 'SpO2 measured on Oxygen', please record amount of oxygen received*	☐☐
36.2.2	*If 'SpO2 measured on Oxygen', please record Unit* question:	◯ L ◯ %
36.3	Clinical status on 7 point scale To be collected retrospectively, Worst value 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

***** only required if participant in hospital **'***

36.3.1	*NEWS – (Record score closest to 8am for the day.)*	☐☐ *(0-20 points)*

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Bloods

	Baseline	Day 3	Day 15
Date of blood sample	DD-MM-YYYY	DD-MM-YYYY	DD-MM-YYYY
U&Es and/or LFTs done on this date?	◯ **YES** ◯ **NO**	◯ **YES** ◯ **NO**	◯ **YES** ◯ **NO**
Sodium (mmol/L)			
Potassium (mmol/L)			
Creatinine (µmol/L)			
Urea (mmol/L)			
eGFR (ml/min)		*not required*	
AST (U/L)			
ALT (U/L)			
Albumin (g/L)			
Bilirubin (µmol/L)			
Was Full Blood Count done on this date?	◯ **YES** ◯ **NO**	◯ **YES** ◯ **NO**	◯ **YES** ◯ **NO**
Haemoglobin (g/L) or Haemoglobin (g/dL)			
White blood cell count($x10^9$/L)			
Neutrophil count ($x10^9$/L)		*not required*	
Eosinophil count ($x10^9$/L)		*not required*	
Platelets ($x10^9$/L)			
Lymphocyte count ($x10^9$/L)		*not required*	

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SARS-CoV-2 Test(s)

Add details for Baseline SARS-CoV-2 test.
Add a line for each additional positive SARS-CoV-2 test.

	Date of nCoV test	**Sample type**	**Novel Coronavirus (nCoV) test result**
Baseline (required)	DD-MM-YYYY	◯ BAL ◯ Blood ◯ Sputum ◯ Nasal / NP Swab ◯ Oropharyngeal Swab ◯ *Combined naso/oropharyngeal swab* ◯ *Other (specify)*	◯ Positive ◯ Negative ◯ Inconclusive
	DD-MM-YYYY	◯ BAL ◯ Blood ◯ Sputum ◯ Nasal / NP Swab ◯ Oropharyngeal Swab ◯ *Combined naso/oropharyngeal swab* ◯ *Other (specify)*	◯ Positive ◯ Negative ◯ Inconclusive
	DD-MM-YYYY	◯ BAL ◯ Blood ◯ Sputum ◯ Nasal / NP Swab ◯ Oropharyngeal Swab ◯ *Combined naso/oropharyngeal swab* ◯ *Other (specify)*	◯ Positive ◯ Negative ◯ Inconclusive
	DD-MM-YYYY	◯ BAL ◯ Blood ◯ Sputum ◯ Nasal / NP Swab ◯ Oropharyngeal Swab ◯ *Combined naso/oropharyngeal swab* ◯ *Other (specify)*	◯ Positive ◯ Negative ◯ Inconclusive

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Discontinuation of Trial Medication'

	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.	
1	What date was the last dose taken?	☐☐ ☐☐ ☐☐☐☐ *(dd-mm-yyyy)*
Reason for stopping study medication (main reason only)		
2	Reason for stopping study medication (main reason only)	○ Allergic reaction to trial drug ○ 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
2.1	If Other, provide Details	
3	Number of tablets remaining (0-14)	

PARTICIPANT ID				

INITIALS		

37. Completion of Trial/Early Withdrawal - Completion of Trial/Early Withdrawal

	Completion of Trial/Early Withdrawal	
37.1	Was the participant randomised?	◯ YES ◯ NO
37.1.1	If 'YES', did the participant complete the trial (reach Day 29)?	◯ YES ◯ NO
37.1.2.1	*'Date last trial medication taken?'*	*(dd-mm-yyyy)*
37.1.2.2	*Number of tablets remaining?*	
37.1.1.1	*Date of completion/withdrawal?*	*(dd-mm-yyyy)*

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

37.2	Reason *If Pregnancy, a 'Pregnancy Notification Form must be completed.'*	◯ Advice from GP/other healthcare professional ◯ Adverse Event ◯ Participant's choice ◯ Pregnancy ◯ On advice of investigator ◯ Lost to follow-up ◯ Died ◯ Other
37.2.1	*If Other , provide Details*	

To be electronically verified by the PI once participant has completed the trial.

I have reviewed this CRF and confirm that, to the best of my knowledge, it accurately reflects the trial information obtained for this participant. All entries were made either by myself or by a person under my supervision who has signed the Delegation and Signature Log.

PARTICIPANT ID				

INITIALS		

In Hospital: Daily Data Collection'

1	Date *Warning shown if field's value is larger than NOW: 'Date cannot be in the future'*	☐☐☐ *(dd-mm-yyyy)*
2	Day of Data Collection	☐
3	SpO2	☐ %
4	*SpO2 measured on*	◯ Air ◯ Oxygen
4.1	*If 'SpO2 measured on Oxygen', please record amount of oxygen received*	☐
4.2	*If 'SpO2 measured on Oxygen', please record Unit* question:	◯ L ◯ %
5	Clinical status on 7 point scale To be collected retrospectively, Worst value 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
6	*NEWS – (Record score closest to 8am for the day.)*	☐ *0-20 points*
7	***Please add/update AE and/or ConMeds report if the participant has experienced any AEs, or had any changes to ConMeds since last day of data collection.***	
8	Was the participant discharged on the day?	◯ YES ◯ NO

PARTICIPANT ID				

INITIALS		

Report 'Unscheduled Assessment in the event of an AE'

1	Date of Assessment	☐☐ ☐☐ ☐☐☐☐ *(dd-mm-yyyy)*
2	***Please add/update AE and/or ConMeds report if the participant has experienced any AEs, or had any changes to ConMeds since last day of data collection.***	
Vital Signs	***Please record the most recent values for Randomisation. For follow-up, please record results closest to 8am.***	
3	Pulse	☐ bpm
4	Blood Pressure systolic	☐ mmHg
5	Blood Pressure diastolic	☐ mmHg
6	Tympanic temperature	☐ °C
7	SpO2	☐ %
8	SpO2 measured on	◯ Air ◯ Oxygen
	If 'SpO2 measured on Oxygen, please record the amount of oxygen received?	☐
	If 'SpO2 measured on' is equal to 'Oxygen' *please record the Unit:*	◯ L ◯ %
9	Clinical status on 7 point scale To be collected retrospectively, Worst value 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
10	Was the participant discharged on the day?	◯ YES ◯ NO

PARTICIPANT ID				

INITIALS		

Concomitant Medications

				For Corticosteroids only	***For Corticosteroids and* "Other treatments administered for COVID19 including experimental or compassionate use " only**
Class	***Name of drug (generic)***	***Date commenced***	***Ongoing at end of study or End Date***	***Route***	***Maximum daily dose & unit***
1 – Antiviral or COVID-19 targeted agent *2 – Antibiotic* *3 – Corticosteroid* *4 – Other treatments administered for COVID-19 including experimental or compassionate use* *5 – Other (specify)*		*DD-MM-YYYY* *NK-MM-YYYY* *NK-NK-YYYY* *NK*	*DD-MM-YYYY*	*1 - Oral* *2 - Intravenous (IV)* *3 - Inhaled* *4 - Subcutaneous* *5 - Other (specify)* *6 - Unknown*	
		DD – MM - YYYY	○ *Ongoing* *or* *DD – MM - YYYY*		
		DD – MM - YYYY	○ *Ongoing* *or* *DD – MM - YYYY*		
		DD – MM - YYYY	○ *Ongoing* *or* *DD – MM - YYYY*		
		DD – MM - YYYY	○ *Ongoing* *or* *DD – MM - YYYY*		

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INITIALS		

Adverse Events

***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, then contact participant 30 days after last trial involvement and update AE log if required. **SUSARs** must be followed up until resolved.*

	For new infections only									
Description of Adverse Event	***Name of new infection and Method of Diagnosis***	***Onset date***	***Date reported to investigator***	***Severity***	***Relation-ship to Trial Drug***	***Is this an SAE?***	***Action taken***	***Outcome***	***Date Recovered / Date of death / Date of last contact***	***PI or delegated doctor signature and date of review***
Where possible, give diagnosis. If diagnosis is not known, give sign or symptom. Update if diagnosis is determined.	*1 – BAL 2 – Blood 3 – Sputum 4 – Nasal / NP Swab 5 – Oropharyngeal Swab 6 – Combined naso/oropharyngeal swab 7 – Other (specify)*	*DD-MM-YYYY*	*DD-MM-YYYY*	*1 – Mild 2 – Moderate 3 - Severe*	*1 - None 2 - Possible 3 - Probable 4 - Definite*	*If Yes,an SAE form must be completed within 24 hours of SAE being reported.*	*1 – None 2 – Hospitalisation 3 – IMP temporary stopped 4 – IMP permanently stopped 5 – Con Meds commenced 6 – Other (specify)*	*1 – Recovered 2 – Recovered with sequelae 3 – Recovering 4 – Not recovered 5 – Unknown 6 - Fatal*	*DD-MM-YYYY*	
		DD – MM - YYYY	*DD – MM - YYYY*			○ *YES* ○ *NO*			*DD – MM - YYYY*	*DD – MM - YYYY*
		DD – MM - YYYY	*DD – MM - YYYY*			○ *YES* ○ *NO*			*DD – MM - YYYY*	*DD – MM - YYYY*
		DD – MM - YYYY	*DD – MM - YYYY*			○ *YES* ○ *NO*			*DD – MM - YYYY*	*DD – MM - YYYY*