Inclusion/Exclusion

GenOMICC participant IDs are found inside each specimen kit.

GenOMICC ID number _____

Please ensure that the ID Number is correct and is in the format 'GCC' followed by exactly 5 digits before saving this page

Inclusion Criteria

Is the patient critically ill (need for continuous monitoring/mechanical ventilation)? ○ Yes ○ No

Does the patient have a primary diagnosis that meets the entry criteria?
(e.g. COVID-19, Influenza, Pneumonia, Emerging infections, Burns, Vaping/CAR T-cell reactions, need for ECLS, Cellulitis, Reaction to Vaccination) See https://genomicc.org/countries/uk/entry/ ○ Yes ○ No

Patients can be recruited once they become well again – please update this section as at date patient first met eligibility.

Is the pt co-enrolled in any other clinical trials/studies? ○ Yes ○ No

Please compete the details for all studies that this participant is currently involved with.

Name of the study _____

Participant ID for the study _____

Name of the study _____

Participant ID for the study _____

Name of the study _____

Participant ID for the study _____

This warning will only appear if the patient has not received continuous monitoring (as selected above). Disregard for vaccine reactions or unexplained hepatitis in children

THIS PATIENT MAY NOT BE ELIGIBLE FOR THE STUDY

This patient will only be eligible for the study if they are being recruited within the Outbreaks or exposures of public health interest cohort (see https://genomicc.org/countries/uk/entry/).

Patients from the groups specified in this cohort may be recruited even if they are not admitted to critical care.

Consent

Consent version used
(not all versions are available/valid at all sites)

◯ 4.0

We are now using Version 4 consent documents.

Consent/assent was provided by

◯ patient
◯ next-of-kin
◯ consultant
◯ other

Date of consent

_____

Initials of person recording consent

_____

Note - If consent was initially gained from a Next of Kin or a consultee in the first instance, please follow up consent directly with the patient if they regain capacity.

A new consent page can be added to reflect direct patient consent and the new date of consent.

If a patient does not regain capacity, then they remain in the study with NOK / Consultee consent.

Sampling Details

How was this participant recruited?

The following fields are dependent on the choices made in this section – we have shown all the choices based on retrospective recruitment.

- ○ Prospective Recruitment (Patient is currently in ICU)
- ○ Patient attended for follow-up appointment after discharge and was recruited by face-to-face discussion
- ○ Retrospective Recruitment (Participant was contacted at home retrospectively after discharge)

Confirm sample has been taken using GenOMICC sample kit, boxed and sent for posting

- ☐

Which option has the participant chosen for providing a sample?

- ○ By Third-party Research Nurse visit (Blood)
- ○ At Hospital Out-patient appointment (Blood)
- ○ By Self-administered saliva kit (Saliva)

Please confirm that a sample collection box containing a correctly labelled Saliva collection kit, along with a Participant Information Sheet and copy of consent form has been packaged for posting to the participant

- ☐

Has the participant been informed that contact details (name, address, phone number, e-mail) will be passed to the Third Party blood sampling service?

- ○ Yes ○ No

Has the participant consented to receive SMS messages from the Third Party blood sampling service as part of the process of arranging and carrying out the appointment?

- ○ Yes ○ No

Participant Preferred Title

- ○ Miss
- ○ Mrs
- ○ Ms
- ○ Mx
- ○ Mr
- ○ Dr
- ○ Professor

Participant First Name

_____

Participant Last Name

_____

Address Line 1

_____

Address Line 2

_____

Address Line 3

_____

City

_____

County

_____

Country

_____

Postcode

_____

Contact Phone number(s). If entering multiple numbers, please separate them with commas.

_____

Contact email

_____

Please confirm that a sample collection kit box ☐ containing a correctly labelled EDTA tube, along with a Patient Information Sheet and copy of consent form has been packaged for posting to the participant

_____

Data At Recruitment

National Audit Database ID number i.e. ICNARC number, SICSAG number or equivalent

_____

NHS or CHI number

Please enter 10 zeros if there is no NHS/CHI number '0000000000'

_____

Patient name

_____

Date of birth (DD-MM-YYYY using hyphens to separate)	_____
Date the patient first met the inclusion criteria (DD-MM-YYYY using hyphens to separate) Date of admission to ICU (Day 1)	_____ (Date of admission to ICU (Day 1))

Diagnosis

Primary diagnosis	○ Confirmed COVID-19 ○ Suspected COVID-19 ○ Suspected reaction to vaccination ○ Suspected reaction to therapy ○ Unexplained hepatitis in children ○ Confirmed Infection with influenza virus ○ Suspected influenza virus ○ Acute pneumonia complicating confirmed infection with influenza virus ○ Confirmed or suspected current or recent infection with an emerging infection ○ Dengue ○ Soft tissue infections causing systemic sepsis ○ Full thickness burns covering > 20% of body surface area ○ Confirmed infection with respiratory syncytial virus ○ Primary pneumonia with radiographic changes at presentation to critical care ○ Pancreatitis of any aetiology ○ Reaction to CAR T-cell therapy ○ ECLS ○ Vaping-associated lung injury ○ Other emerging critical care syndrome
Confirmed suspected or emerging infection	○ HPAI (Highly pathogenic avian influenza) ○ MERS (Middle East Respiratory Syndrome) ○ SARS (Severe Acute Respiratory Syndrome) ○ Ebola ○ Zika virus ○ other
Other confirmed/suspected emerging infection	_____
Percentage of body area with full thickness burns	_____

Highest known transaminase (AST or ALT) assay result reported for this patient on or prior to the date of recruitment.

_____

Vaccine reaction

- ◯ Cerebral venous sinus thromobosis
- ◯ Deep vein thrombosis/pulmonary embolism
- ◯ Other thrombotic events, with or without thrombocytopaenia
- ◯ Neuroinflammatory disorders
- ◯ Anaphylaxis
- ◯ Vasculitis
- ◯ Other potentially life-threatening suspected complications of vaccine

Additional details relating to primary diagnosis (e.g. suspected syndrome, vaccine type, therapy type, symptoms etc.)

_____

Is the patient receiving invasive ventilation? ◯ Yes ◯ No

Did the patient have functionally-limiting comorbidity before this illness?
(such as heart failure, chronic obstructive pulmonary disease (COPD), or reduced exercise tolerance of any cause)? ◯ Yes ◯ No

Answering yes here does not exclude a patient.

Did the patient have significant immunosuppression before this illness?
(such as cancer chemotherapy or acquired immune deficiency syndrome)? ◯ Yes ◯ No

Answering yes here does not exclude a patient.

Do you think this patient's illness is unusual*? ◯ Yes ◯ No

* answer yes if you think, in your own opinion, that this patient's illness is unusually severe, or has unusual or unexplained clinical features. Imagine if you had 2 or 3 similar patients at the same time would you consider the possibility of a new illness or outbreak?

Demography

Age (Years)

This is the age when first met the inclusion (as noted above) – not age at recruitment

_____

(If including months use decimal point and number of months, e.g. 0.3 for 3 months, 1.11 for 1 yr 11 months)

Sex ◯ Male ◯ Female

Postcode

_____

(Please provide the first half of the postcode)

Confirmed COVID-19
No additional microbiology results are required. Please complete the 60 day follow up page

Unexplained hepatitis in children
No additional microbiology results are required. Please complete the 60 day follow up page

Presumed Primary infection

Presumed primary infection causing critical illness (if applicable)

- ◯ Not applicable
- ◯ SARS-CoV-2 (COVID-19)
- ◯ Acinetobacter Baumanii.
- ◯ Chlamydia pneumoniae.
- ◯ Clostridium (other)
- ◯ Dengue
- ◯ Escherichia Coli
- ◯ Enterococci
- ◯ Influenza A.
- ◯ Influenza B.
- ◯ Klebsiella pneumoniae.
- ◯ Legionella pneumophila.
- ◯ Mycoplasma pneumoniae.
- ◯ Parainfluenza species.
- ◯ Respiratory syncitial virus.
- ◯ Staphylococcus aureus
- ◯ Staphylococci (other)
- ◯ Streptococcus pneumoniae
- ◯ Group A Streptococcus / Streptococcus pyogenes
- ◯ Streptococci (other)
- ◯ Other

Presumed Primary Infection: Other - please specify

_____

_____

Blood culture

Only record samples taken within the first 3 calendar days from admission to ICU (day 0)

Blood culture sample: Organism detected

- ☐ Staph. Aureus
- ☐ Strep. Pneumoniae
- ☐ Chlamydia pneumoniae
- ☐ Mycoplasma pneumoniae
- ☐ Klebsiella pneumoniae
- ☐ Acinetobacter Baumanii
- ☐ Other

Other - please specify

_____

Date sample taken

_____

Simply leave microbiology pages blank if there is nothing to report and mark the page as complete.

Serology

Only record samples taken within the first 3 calendar days from admission to ICU (day 0)

Serology sample: Organism detected

- ☐ SARS-CoV-2(COVID-19)
- ☐ Dengue
- ☐ Other

Other - please specify

_____

Date sample taken

_____

Urinary antigen test

Only record samples taken within the first 3 calendar days from admission to ICU (day 0)

Urinary antigen sample: Organism detected

- ☐ Legionella pneumophila.
- ☐ Streptococcus pneumoniae.
- ☐ Other

Other - please specify

_____

Date sample taken

_____

Throat/nose swab

Only record samples taken within the first 3 calendar days from admission to ICU (day 0)

Throat/nose swab sample: Organism detected	☐ Influenza A ☐ Influenza B ☐ Respiratory syncitial virus ☐ Parainfluenza species ☐ SARS-CoV-2(COVID-19) ☐ Mycoplasma pneumoniae ☐ Chlamydia pneumoniae ☐ Other
Other - please specify	_____
Date sample taken	_____

Tracheal aspirate

Only record samples taken within the first 3 calendar days from admission to ICU (day 0)

Tracheal aspirate sample: Organism detected	☐ SARS-CoV-2(COVID-19) ☐ Staph. Aureus ☐ Strep. Pneumoniae ☐ Klebsiella pneumoniae ☐ Other
Other - please specify	_____
Date sample taken	_____

Urine Culture

Only record samples taken within the first 3 calendar days from admission to ICU (day 0)

Urine culture sample: Organism detected

- ☐ E. Coli
- ☐ Enterococci
- ☐ Staph. Aureus
- ☐ Klebsiella pneumoniae
- ☐ Strep. Pneumoniae
- ☐ Other

Other - please specify _____

Date sample taken _____

Fluid from infected collection

Only record samples taken within the first 3 calendar days from admission to ICU (day 0)

Fluid from infected collection sample: Organism detected

- ☐ Staph. Aureus
- ☐ Other

Other - please specify _____

Date sample taken _____

Wound swab

Only record samples taken within the first 3 calendar days from admission to ICU (day 0)

Wound swab sample: Organism detected

- ☐ Staph. Aureus
- ☐ Staphylococci (other)
- ☐ Streptococci (Group A)
- ☐ Streptococci (other)
- ☐ Clostridium (other)
- ☐ Other

Other - please specify _____

Date sample taken _____

mini-BAL

Only record samples taken within the first 7 calendar days from admission to ICU (day 0)

mini-BAL sample 1: Organism detected

- ☐ SARS-CoV-2(COVID-19)
- ☐ Staph. Aureus
- ☐ Strep. Pneumoniae
- ☐ Klebsiella pneumoniae
- ☐ Other

Other - please specify

_____

Date sample taken

_____

BAL

Only record samples taken within the first 7 calendar days from admission to ICU (day 0)

BAL sample: Organism detected

- ☐ SARS-CoV-2(COVID-19)
- ☐ Staph. Aureus
- ☐ Strep. Pneumoniae
- ☐ Klebsiella pneumoniae
- ☐ Other

Other - please specify

_____

Date sample taken

_____

Cerebrospinal Fluid

Only record samples taken within the first 7 calendar days from admission to ICU (day 0)

CSF: Organism detected

- ☐ Neisseria meningitidis
- ☐ Strep. Pneumoniae
- ☐ Haemophilus influenzae
- ☐ Klebsiella pneumoniae
- ☐ Streptococci (other)
- ☐ Listeria monocytogenes
- ☐ Other

Other - please specify

_____

Date sample taken

_____

CSF non-culture diagnostics

Only record samples taken within the first 7 calendar days from admission to ICU (day 0)

CSF non-culture diagnostics: Organisms detected

- ☐ Herpes simplex virus
- ☐ Herpes virus (other)
- ☐ Entrerovirus
- ☐ Crytptococcus
- ☐ Mycobacterium tuberculosis
- ☐ SARS-CoV-2(COVID-19)
- ☐ Other

Other - please specify

_____

Date sample taken

_____

Follow Up 60 Days

Change the field label to read "Date of 60 day follow up (DD-MM-YYYY using hyphens to separate)

60 days from date patient first met criteria

_____

60 day checker

_____

Alive at 60 days ○ Yes ○ No

Date of death (DD-MM-YYYY using hyphens to separate)

_____

Participant Change of Status

Date of Change of Status	_____
Who is withdrawing the participant from the trial?	◯ Participant ◯ PI or clinical delegate ◯ Carer/Guardian
Name of individual withdrawing patient	_____
Withdrawal status	◯ Partial Withdrawal ◯ Full Withdrawal
Reason for withdrawal	◯ Participant declined to give reason ◯ Other

Partial Withdrawal

Data WILL continue to be updated and used for research, but no further contact will be made with the participant

Total Withdrawal

- no further contact will be made with the participant;
- data will not be updated from health records;
- data will not be removed from research that is underway or has already been done, and an audit record will be maintained to confirm participation.

Please don't hesitate to contact us with any questions you may have.

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