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 (requires continuous monitoring, mechanical ventilation or organ support)? ◯ Yes ◯ No

Does the patient have a primary diagnosis that meets the entry criteria?
(Any suspected or confirmed infection, any non-infectious syndromes such as pancreatitis or burns, or other rarer conditions)
See https://genomicc.org/countries/uk/entry/ ◯ Yes ◯ No

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

Exclusion criteria

Has the patient ever received a bone marrow transplant? ◯ Yes ◯ No

Co-enrolment

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 PATIENT IS NOT ELIGIBLE FOR THE STUDY

This warning will appear if 'yes' has been selected to the exclusion criteria or if 'no' has been selected to 'Is the patient critically ill'.

THIS PATIENT MAY NOT BE ELIGIBLE FOR THE STUDY

This warning will appear if the patient has not received continuous monitoring (as selected above). Disregard for outbreaks or exposures of public health interest cohort.

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)

- ○ 5

We are now using version 5 consent documents.

Consent/assent was provided by

- ○ Patient
- ○ Next-of-kin
- ○ Personal consultee [E,W,NI]
- ○ Nominated (professional) consultee [E,W,NI]
- ○ Welfare guardian/attorney [S]

Date of consent _____

Initials of person recording consent _____

Note - if consent was obtained from a next of kin or consultee in the first instance, please follow up consent directly with the patient if they regain capacity.

If a patient will never regain capacity or be able to consent directly, please email the GenOMICC study team to inform them.

If direct patient consent is obtained, please add a new consent page to reflect this and record the new date of consent.

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

Sampling Details

How was this participant recruited?

The following fields are dependent on the choices made in this section - if 'prospective recruitment' is selected, the below fields will appear.

- ◯ Prospective Recruitment (Patient is currently in ICU or still in hospital)
- ◯ 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)

Is this participant part of the ACUTE sub-study?

ACUTE is a sub-study initally recruiting at a limited number of sites. Contact GenOMICC study team if you would like more details.

◯ Yes ◯ No

The ACUTE sub-study is a pilot running at a limited number of sites. Please only select 'yes' if your site is already taking part in the ACUTE sub-study.

Confirm sample for DNA extraction (and additional samples if this is an ACUTE patient) has/have been taken using GenOMICC sample kit, boxed and sent for posting

☐

If 'retrospective recruitment' is selected the below fields will appear.

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)

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

If 'By Third-party Research Nurse visit' is selected as the sampling option, the below fields will appear.

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	☐
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	☐ **If 'By Self-administered saliva kit' is selected as the sampling option, this field will appear.**

Data At Recruitment

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

NHS or CHI number

If no NHS/CHI number is available, please enter 10 zeros '00000000000'

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 0)

(Date of admission to ICU (Day 0))

Primary Diagnosis

Primary diagnosis for admission to critical care (confirmed or suspected)

- ◯ Acute hepatitis (unexplained) in children
- ◯ Acute hepatitis associated with gene therapy
- ◯ Acute pneumonia complicating confirmed infection with influenza virus
- ◯ Appendicitis
- ◯ CAR T-cell reactions
- ◯ Cholecystitis
- ◯ COVID-19
- ◯ COVID-19 MISC (Multisystem inflammatory syndrome temporally associated with COVID-19)
- ◯ Cytokine storm secondary to therapy
- ◯ ECLS
- ◯ Encephalitis
- ◯ Endocarditis
- ◯ Full thickness burns covering > 20% of body surface area
- ◯ Haemophagocytic syndrome
- ◯ Heat stroke
- ◯ Influenza
- ◯ Meningitis
- ◯ Pancreatitis of any aetiology
- ◯ Peritonitis
- ◯ Pneumonia with radiographic changes at presentation to critical care
- ◯ Pyelonephritis
- ◯ Radiation poisoning
- ◯ Reaction to vaccination
- ◯ RSV (respiratory syncytial virus) infection
- ◯ Soft tissue infections causing systemic sepsis
- ◯ Stevens-Johnson Syndrome/Toxic Epidermal Necrolysis
- ◯ Still disease
- ◯ Urinary tract infection
- ◯ Any emerging critical care syndrome not listed above
- ◯ Any primary infection not listed above
- ◯ Any reaction to therapy not listed above

Confirmed suspected or emerging infection

If 'Any primary infection not listed above' is selected, these fields will appear.

- ◯ HPAI (Highly pathogenic avian influenza)
- ◯ MERS (Middle East Respiratory Syndrome)
- ◯ SARS (Severe Acute Respiratory Syndrome)
- ◯ Ebola
- ◯ Zika virus
- ◯ Dengue
- ◯ Mpox virus
- ◯ Marburg virus
- ◯ Lassa fever virus
- ◯ Crimean-Congo Haemorrhagic Fever orthonairovirus
- ◯ Hendra henipavirus
- ◯ Nipah henipavirus
- ◯ Variola virus (minor or major)
- ◯ Bacillus anthracis
- ◯ Coxiella burnetti
- ◯ Rickettsia spp
- ◯ Yersinia pestis
- ◯ West Nile fever virus
- ◯ Yellow fever virus
- ◯ Rift Valley fever virus
- ◯ other

HAZARD - Group 3 pathogens

Please follow all local Health & Safety protocols and contact the GenOMICC Team for further details before shipping this sample

If 'Any primary infection not listed above' is selected, this warning will appear.

Percentage of body area with full thickness burns

_____

If 'Full thickness burns' is selected, this field will appear.

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

_____

If 'Acute hepatitis (unexplained) in children' is selected, this field will appear.

Vaccine reaction

If 'Reaction to vaccination' is selected, these fields will appear.

- ◯ Cerebral venous sinus thromobosis
- ◯ Deep vein thrombosis/pulmonary embolism
- ◯ Other thrombotic events, with or without thrombocytopaenia
- ◯ Neuroinflammatory disorders including Guillian-Barre syndome
- ◯ 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.)

_____

If 'Any emerging critical care syndrome not listed above' or 'Any reaction to therapy not listed above' is selected, this field will appear.

Has the patient received invasive ventilation for their current eligible condition?

◯ Yes ◯ No

Answering no here does not exclude a patient.

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*?

* 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?

◯ Yes ◯ No

Demography

Age (Years) at the time when the patient first met the inclusion criteria

_____

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

Please record the patients age at the time they met the inclusion criteria here - not their age at the time of recruitment.

Sex at birth

◯ Male ◯ Female

Postcode

(Please provide the first half of the postcode)

_____

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 _____

Note - the following pages cover day 3 and day 7 microbiology results.

All day 3 and day 7 microbiology results are required for all conditions where available (including for patients recruited with Covid).

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

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 _____

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

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

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
Reason for withdrawal	◯ Participant declined to give reason ◯ Other
Withdrawal status	◯ Partial Withdrawal ◯ Full Withdrawal

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.

Email us on - genomicc@roslin.ed.ac.uk

Telephone - 0300 365 7660