

# GenOMICC

## The GenOMICC Study

### Genetics of Mortality in Critical Care

Completion guide for REDCap data entry

Updated: May 2026



THE UNIVERSITY of EDINBURGH  
Baillie Gifford Pandemic Science Hub



# REDCap – electronic case report form

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- REDCap is the electronic database we use to collect clinical data.
- We call each record an 'electronic case report form' or 'eCRF' for short.
- We link each eCRF to a participant sample, so it is essential that samples are labelled with a GCC\_ID that matches their eCRF entry.
- We will let you know each month if we have any data queries relating to your eCRFs.



# Getting Started

- GenOMICC REDCap access can be requested by emailing the study team [genomicc@roslin.ed.ac.uk](mailto:genomicc@roslin.ed.ac.uk) and providing your:
  - name
  - email address - (must be an NHS email)
  - site (hospital) name
- Each site has its own REDCap data entry group and participant ID stickers. If data is being added across more than one site within your Trust, please let us know and we will set up additional REDCap accounts for you.
- Log-on details will be emailed directly to all new users.

Before adding a new record to REDCap, read through this guide to see how eCRFs are created and completed

# Entering the patient ID

- The GenOMICC ID for each patient is the barcode number on the pre-printed stickers found inside each specimen kit.
- The ID number should always be entered into the eCRF exactly as it is shown on the label 'GCCxxxxx'.
- This is GCC (uppercase) followed by 5 digits. Please don't add in spaces or hyphens.
- If you do make a mistake entering the patient GCC\_ID, please continue to enter the data and then let us know what the correct number should be. We can correct this for you without the need to add a new record.



It is important that the GCC\_ID entered on the eCRF matches the sample GCC\_ID.

# Creating or editing a record

**Project Home and Design**

- Project Home
- Codebook
- Project status: **Development**

**Data Collection**

- Record Status Dashboard
- Add / Edit Records** (highlighted)
- GenOMICC ID number **GCC67892**

**Applications**

- Calendar
- Data Exports, Reports, and Stats
- Field Comment Log

**Reports**

- 1) Crosshouse
- 2) consent form

**Help & Information**

- Help & FAQ
- Video Tutorials
- Suggest a New Feature
- Contact REDCap administrator

The grid below displays the form-by-form progress of data entered for the currently selected record. You may click on the colored status icons to access that form/event.

**Legend for status icons:**

- Incomplete (red circle)
- Incomplete (no data saved) (grey circle)
- Unverified (yellow circle)
- Complete (green circle)
- Many statuses (all same) (red, yellow, green circles)
- Many statuses (mixed) (blue circle)

**NEW** GenOMICC ID number **GCC67892**  
Arm 1: Main study

Data Collection Instrument	Recruitment	Micro results first 3 days	Micro results first 7 days	Follow up 60 days	Participant change of status
Inclusion/Exclusion	<input type="radio"/>				
Consent	<input type="radio"/>				
Sampling Details	<input type="radio"/>				
Data At Recruitment	<input type="radio"/>				
Presumed Primary infection		<input type="radio"/>			
Blood culture		<input type="radio"/>			
Serology		<input type="radio"/>			
Urinary antigen test		<input type="radio"/>			
Throat/nose swab		<input type="radio"/>			
Tracheal aspirate		<input type="radio"/>			
Urine Culture		<input type="radio"/>			
Fluid from infected collection		<input type="radio"/>			
Wound swab		<input type="radio"/>			
mini-BAL			<input type="radio"/>		
BAL			<input type="radio"/>		
Cerebrospinal Fluid			<input type="radio"/>		
CSF non-culture diagnostics			<input type="radio"/>		
Follow Up 60 Days				<input type="radio"/>	
Participant Change of Status					<input type="radio"/>

Click 'Add/Edit Records' to create a new record or alter an existing one.

A box will pop up where a new (or existing) GCC\_ID can be added.

Always add patient records into Arm 1: Main study.

The GCC\_ID used to create the eCRF should match the sample ID for each patient.

Move through each page remembering to save.

# Inclusion/Exclusion

## Inclusion/Exclusion

Data Access Group: [No Assignment] ?

Editing existing GenOMICC ID number GCC12345.

Event: Recruitment (Arm 1: Main study)

GenOMICC ID number

GCC12345

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

reset

\* must provide value

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)

Yes  No

reset

See <https://genomicc.org/countries/uk/entry/>

\* must provide value

### Exclusion criteria

Has the patient ever received a bone marrow transplant?

Yes  No

reset

\* must provide value

Is the pt co-enrolled in any other clinical trials/studies?

Yes  No

reset

\* must provide value

### Form Status

Complete?

Complete

This should always be yes. Although, the patient does not need to be undergoing the monitoring at the actual time of recruitment. Once a patient is eligible for GenOMICC, they remain so for the rest of their lives.

There is only one exclusion to recruitment and that's if a patient has had a bone marrow transplant.


If the patient is enrolled in other studies, select 'yes' – new fields will appear where we ask for the name of the study and ID number.

# Consent

## Consent

Current instance: 1 - 01-10-2022, v3.5, Next-of-kin

Data Access Group: [No Assignment]

 Editing existing GenOMICC ID number **GCC12345**. (Instance #1)

**Event: Recruitment (Arm 1: Main study)**

<b>GenOMICC ID number</b>	GCC12345
<b>Consent version used</b> (not all versions are available/valid at all sites) <small>* must provide value</small>	<span>5</span>
<b>Consent/assent was provided by</b> <small>* must provide value</small>	<span>Patient</span>
<b>Date of consent</b> <small>* must provide value</small>	<span>12-12-2024</span> <span>Today</span> D-M-Y
<b>Initials of person recording consent</b> <small>* must provide value</small>	<span>FG</span>

**Form Status**

<b>Complete?</b>	<span>Complete</span>
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Save & Exit Form Save & Stay - Cancel -

Select the correct version of the consent form from the dropdown menu – circled here in red.

Please add a new consent page, version, and date each time consent status has been updated.

A patient may be included in the study with consent from a relative or consultee (if they are unable to consent for themselves), then provide direct consent once they have regained capacity.

# Sampling details

## Sampling Details

Data Access Group: [No Assignment] ?

Editing existing GenOMICC ID number **GCC12345**.

**Event: Recruitment (Arm 1: Main study)**

**GenOMICC ID number** GCC12345

**How was this participant recruited?**  
*\* must provide value*

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?**  
*\* must provide value*

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

Yes  No

**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**  
*\* must provide value*

**Form Status**

**Complete?**

Different pop-up boxes will will automatically appear, depending on the option selected for how the patient was recruited.

The ACUTE sub-study is only happening at a small number of sites, so in most cases the answer here is no. We have separate ACUTE guidance for the completion of REDCap.

Always confirm that samples have been taken and posted in the data field (as circled in red)

<p><b>Which option has the participant chosen for providing a sample?</b></p> <p>* must provide value</p>	<p><input checked="" type="radio"/> By Third-party Research Nurse visit (Blood)</p> <p><input type="radio"/> At Hospital Out-patient appointment (Blood)</p> <p><input type="radio"/> By Self-administered saliva kit (Saliva )</p>
<p><b>Has the participant been informed that contact details (name, address, phone number, e-mail) will be passed to the Third Party blood sampling service?</b></p> <p>* must provide value</p>	<p><input type="radio"/> Yes <input type="radio"/> No</p>
<p><b>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?</b></p> <p>* must provide value</p>	<p><input type="radio"/> Yes <input type="radio"/> No</p>
<p><b>Participant Preferred Title</b></p> <p>* must provide value</p>	<p><input type="text"/></p>
<p><b>Participant First Name</b></p> <p>* must provide value</p>	<p><input type="text"/></p>
<p><b>Participant Last Name</b></p> <p>* must provide value</p>	<p><input type="text"/></p>
<p><b>Address Line 1</b></p> <p>* must provide value</p>	<p><input type="text"/></p>
<p><b>Contact Phone number(s). If entering multiple numbers, please separate them with commas.</b></p> <p>* must provide value</p>	<p><input type="text"/></p>
<p><b>Contact email</b></p>	<p><input type="text"/></p>
<p><b>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</b></p> <p>* must provide value</p>	<p><input checked="" type="checkbox"/></p>

## Retrospective recruitment only

A series of data fields will appear for completion, if the 'third-party research nurse visit' sampling option has been selected.

The patient must be informed their personal information will be passed onto Inuvi, the third-party research organisation, for the purposes of arranging the sampling appointment. (We will delete the participant's contact information after the sampling appointment has taken place).

We will automatically collect this information each day from REDCap and send it to Inuvi where they will contact the patient directly to arrange an appointment. Nurses at site do not need to do anything except ensure that a sample kit has been promptly dispatched with the correct postage.

Please check the box circled in red to confirm the kit has been sent to the patient. It is important the kit is sent without delay as it will be required by the Inuvi nurse attending the patient for sampling.

# Data at recruitment



## Data At Recruitment

Data Access Group: [No Assignment] ?

Editing existing GenOMICC ID number **GCC12345**.

**Event: Recruitment (Arm 1: Main study)**

**GenOMICC ID number** GCC12345

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

**NHS or CHI number**   
\* must provide value

**Patient name**   
\* must provide value

**Date of birth (DD-MM-YYYY using hyphens to separate)**   D-M-Y  
\* must provide value

**Date the patient first met the inclusion criteria (DD-MM-YYYY using hyphens to separate)**   D-M-Y

**Date of admission to ICU (Day 0)**   D-M-Y  
Date of admission to ICU (Day 0)  
\* must provide value

**Primary Diagnosis**

- 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

The ICNARC or SICSAG number is not a compulsory field, so please leave this blank if there is no number available.

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

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There is a long list of diagnoses to choose from.

Depending on which diagnosis is selected, other dropdown choices may appear, such as an ALT results box for hepatitis patients.

# Data at recruitment continued..



<b>Has the patient received invasive ventilation for their current eligible condition?</b> <small>* must provide value</small>	<input checked="" type="radio"/> Yes <input type="radio"/> No	reset
<b>Did the patient have functionally-limiting comorbidity before this illness?</b> (such as heart failure, chronic obstructive pulmonary disease (COPD), or reduced exercise tolerance of any cause)? <small>* must provide value</small>	<input checked="" type="radio"/> Yes <input type="radio"/> No	reset
<b>Did the patient have significant immunosuppression before this illness?</b> (such as cancer chemotherapy or acquired immune deficiency syndrome)? <small>* must provide value</small>	<input type="radio"/> Yes <input checked="" type="radio"/> No	reset
<b>Do you think this patient's illness is unusual*?</b>  <small>* 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?</small> <small>* must provide value</small>	<input type="radio"/> Yes <input checked="" type="radio"/> No	reset
<b>Demography</b>		
<b>Age (Years) at the time when the patient first met the inclusion criteria</b> <small>* must provide value</small>	<input type="text" value="64"/> <small>If including months use decimal point and number of months, e.g. 0.3 for 3 months, 1.11 for 1 yr 11 months</small>	
<b>Sex at birth</b> <small>* must provide value</small>	<input checked="" type="radio"/> Male <input type="radio"/> Female	reset
<b>Postcode</b> <b>(Please provide the first half of the postcode)</b> <small>* must provide value</small>	<input type="text" value="AB12"/> <small>0 characters remaining</small>	

The additional fields here give us some information on the severity of the patient's illness.

We also use this information to understand more about how well the patient was before they became eligible for GenOMICC.

We require age in years and months, as at the date the patient was eligible for the study (date of admission to ICU).

Please only enter the first half of the postcode on this page. If there is no postcode available, please simply add **XX99** (such as in the event of an overseas participant).

# Blood culture

**Blood culture**

Assign record to a Data Access Group? -- select a group --

Adding new GenOMICC ID number **GCC67892**. (Instance #1)

Event: **Micro results first 3 days (Arm 1: Main study)**

GenOMICC ID number: GCC67892

**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
- Klebsiella pneumoniae
- Acinetobacter Baumannii
- Other

Date sample taken:  Today D-M-Y

Form Status

Complete? Incomplete

Save & Exit Form Save & ...

- Cancel -

If a patient is admitted on a Monday (Day 0), then Thursday is Day 3 (i.e. third calendar day after admission – Tuesday is Day 1 after admission, Wednesday is Day 2 etc.). Any tests run on Monday, Tuesday, Wednesday, or Thursday can and should be entered in these sections.

If any lab tests show a result not listed, select 'other'. Another field will pop up for you to enter the details. If the result showed no growth or no specific organism, then leave the fields blank but mark the page as 'complete' so that we know the tests have been considered.

The same guidance applies to all microbiology pages (not shown in this guide) and include; **Serology, Urinary Antigen Test, Throat/Nose Swab, Tracheal Aspirate, Urine Culture, Fluid from Infected Collection and Wound Swab.**

# Mini-BAL

**mini-BAL**

Assign record to a Data Access Group? -- select a group --

Adding new GenOMICC ID number **GCC67892**. (Instance #1)


Event: **Micro results first 7 days (Arm 1: Main study)**

GenOMICC ID number GCC67892

**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

Date sample taken   Today D-M-Y

Form Status

Complete? Incomplete

Save & Exit Form Save & ...

- Cancel -

The following test results may be included if taken within 7 days of admission to ICU (day 0).

The same guidance applies to all the 7-day test result pages (not shown on this guide) if known and include: **BAL, Cerebrospinal Fluid (CSF) and CSF Non-Culture Diagnostics.**

# Follow-up at 60 days



## Follow Up 60 Days

Data Access Group: [No Assignment] ?

Editing existing GenOMICC ID number **GCC12345**.

**Event: Follow up 60 days (Arm 1: Main study)**

**GenOMICC ID number** GCC12345

**Date of 60 day follow up (DD-MM-YYYY using hyphens to separate)**  
**\*60 days from date patient first met criteria\***  
\* must provide value

D-M-Y

**60 day checker**  
 [View equation](#)

**Alive at 60 days**  
\* must provide value  
 Yes  No [reset](#)

**Form Status**

**Complete?**  ▾

▾

Please ensure at least 60 days have passed since Day 0 (admission to ICU when patient first became eligible) before this check is completed. (It does not matter if the check is carried out after 60 days).

We'll send a reminder if the follow up is not completed, after 60 days have passed.

This information can be obtained by checking electronic hospital records or the participant may be contacted at home if required.

# Participant change of status



## Participant Change of Status

Data Access Group: [No Assignment] ?

Editing existing GenOMICC ID number **GCC12345**.

**Event: Participant change of status (Arm 1: Main study)**

**GenOMICC ID number** GCC12345

**Date of Change of Status**   D-M-Y

**Who is withdrawing the participant from the trial?**  
 Participant  
 PI or clinical delegate  
 Carer/Guardian reset

**Reason for withdrawal**  
 Participant declined to give reason  
 Other reset

**Withdrawal status**  
 Partial Withdrawal  
 Full Withdrawal reset

**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.

Update status to '**Partial Withdrawal**' if a participant wishes to remain in the study but receive no future contact.

Update status to '**Full Withdrawal**' if the participant withdraws consent and no longer wishes to take part. Please also let the GenOMICC team know so we can destroy the DNA sample.

The participant change of status page is **ONLY** for patients who have withdrawn consent **or** do not wish to be contacted again in the future.


This page should not be updated to record any deaths – participants who subsequently die can remain in the study.

Anyone who fully withdraws will not be included in further research, but they can't be removed from research that has already taken place.



# Record Active Status

## Record Active Status

Data Access Group: [No Assignment] ?

 Editing existing GenOMICC ID number **GCC12345**.

Event: **Participant change of status (Arm 1: Main study)**

GenOMICC ID number	GCC12345
Confirm if this Record is Inactive	<input checked="" type="checkbox"/> Mark this record as inactive
Date of Inactivation	<input type="text" value="12-05-2026"/>  Today D-M-Y
Reason for Inactivation	<input type="text" value=""/> 
Form Status	
Complete?	

- Ineligible participant
- Participant enrolled twice in error
- Sample collection not completed
- Sample not available - logistical issue
- Sample not available - technical issue
- Cancel -

- This new page was introduced in May 2026.
- We can use this to inactivate records for participants who are unable to proceed in fully taking part due to sampling issues or some other technical reason, whilst still retaining an audit trail of their consent.
- Please correspond with the GenOMICC study team to discuss each participant on a case-by-case basis, where updating this page may be appropriate.

# Thank-you

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Please don't hesitate to contact us with any issues or questions

**E: [genomicc@roslin.ed.ac.uk](mailto:genomicc@roslin.ed.ac.uk)**

**T: 0300 365 7660**

It is helpful to us if your hospital name can be in the subject heading of any emails.

