



The GenOMICC Study

Genetics of Mortality in Critical Care

Completion guide for REDCap data entry

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THE UNIVERSITY of EDINBURGH
Baillie Gifford Pandemic Science Hub



REDCap – electronic case report form

- 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 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
- View data collection status of all records
- Add / Edit Records**
- Create new records or edit/view existing ones
- GenOMICC ID number **GCC67892**
[Select other record](#)

Applications

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

Reports

- Search Organize Edit
- 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
- Incomplete (no data saved) ?
- Unverified
- Complete
- Many statuses (all same)
- Many statuses (mixed)

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)

GenOMICC ID number	GCC12345
Consent version used (not all versions are available/valid at all sites) <small>* must provide value</small>	5
Consent/assent was provided by <small>* must provide value</small>	Patient
Date of consent <small>* must provide value</small>	12-12-2024 Today D-M-Y
Initials of person recording consent <small>* must provide value</small>	FG
Form Status	
Complete?	Complete
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?
ACUTE is a sub-study initially recruiting at a limited number of sites. Contact GenOMICC study team if you would like more details.
** must provide value*

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)

Which option has the participant chosen for providing a sample? <small>* must provide value</small>	<input checked="" type="radio"/> By Third-party Research Nurse visit (Blood) <input type="radio"/> At Hospital Out-patient appointment (Blood) <input type="radio"/> 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? <small>* must provide value</small>	<input type="radio"/> Yes <input type="radio"/> 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? <small>* must provide value</small>	<input type="radio"/> Yes <input type="radio"/> No
Participant Preferred Title <small>* must provide value</small>	<input type="text"/>
Participant First Name <small>* must provide value</small>	<input type="text"/>
Participant Last Name <small>* must provide value</small>	<input type="text"/>
Address Line 1 <small>* must provide value</small>	<input type="text"/>
Contact Phone number(s). If entering multiple numbers, please separate them with commas. <small>* must provide value</small>	<input type="text"/>
Contact email	<input type="text"/>
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 <small>* must provide value</small>	<input checked="" type="checkbox"/>

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.

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..



Has the patient received invasive ventilation for their current eligible condition? <small>* must provide value</small>	<input checked="" type="radio"/> Yes <input type="radio"/> No	reset
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)? <small>* must provide value</small>	<input checked="" type="radio"/> Yes <input type="radio"/> No	reset
Did the patient have significant immunosuppression before this illness? (such as cancer chemotherapy or acquired immune deficiency syndrome)? <small>* must provide value</small>	<input type="radio"/> Yes <input checked="" type="radio"/> No	reset
Do you think this patient's illness is unusual*? <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
Demography		
Age (Years) at the time when the patient first met the inclusion criteria <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>	
Sex at birth <small>* must provide value</small>	<input checked="" type="radio"/> Male <input type="radio"/> Female	reset
Postcode (Please provide the first half of the postcode) <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	<input type="text" value="12-12-2024"/> <input type="button" value="Today"/> D-M-Y
Who is withdrawing the participant from the trial?	<input checked="" type="radio"/> Participant <input type="radio"/> PI or clinical delegate <input type="radio"/> Carer/Guardian
Reason for withdrawal	<input checked="" type="radio"/> Participant declined to give reason <input type="radio"/> Other
Withdrawal status	<input type="radio"/> Partial Withdrawal <input checked="" type="radio"/> 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.

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 no longer wishes to participate in the study. Please also let the GenOMICC team know so we can destroy the patient's 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.

We will ensure anyone who fully withdraws is not included in further research however, they can't be removed from research that has already taken place.

Participant change of status

- The withdrawal section on the 'participant change of status page' does not need to be completed following death – deceased patients remain in the study.
- We may ask you to fully withdraw an eCRF if we have no sample for a patient – this means we are not trying to reconcile records with samples where there is no possibility of receiving one.

Thank-you



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

E: 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.

