

# GenOMICC

## The GenOMICC Study

### Genetics of Mortality in Critical Care

Site guide for REDCap data entry

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THE UNIVERSITY  
of EDINBURGH



Biotechnology and  
Biological Sciences  
Research Council

# 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](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 attempting to add a record, users should make sure they understand how the eCRF is completed by working through this guide.



# CREATING OR EDITING A RECORD

The screenshot shows the GenOMICC web interface. The 'Add / Edit Records' button is highlighted with a red box. The interface includes sections for Project Home and Design, Data Collection, Applications, Reports, and Help & Information.

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.

The GenOMICC ID for each patient is the barcode number on the pre-printed stickers found inside each specimen kit – the GCC\_ID used to create the eCRF should match the sample ID for each patient.

Always add patient records into Arm 1: Main study.

# ADDING THE GCC\_ID



The GenOMICC patient 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 on the eCRF matches the sample GCC\_ID identically - we match data and samples using these numbers.



# 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 (need for continuous monitoring/mechanical ventilation)?**  Yes  No  
\* must provide value

**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/>  
\* must provide value

**Is the pt co-enrolled in any other clinical trials/studies?**  Yes  No  
\* must provide value

**Form Status**

**Complete?**

The patient does not need to be undergoing monitoring at the time of recruitment – once a patient is eligible for GenOMICC, they remain so for the rest of their lives.

Some categories such as unusual events or outbreaks do not require continuous monitoring to be eligible. In these cases, select 'no' and proceed.


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 – 01-10-2020, v2.4, 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>2.4</span> ▾
<b>Consent/assent was provided by</b> <small>* must provide value</small>	<span>next-of-kin</span> ▾
<b>Date of consent</b> <small>* must provide value</small>	<span>01-10-2020</span>  <span>Today</span> D-M-Y
<b>Initials of person recording consent</b> <small>* must provide value</small>	<span>JM</span>
<b>Form Status</b>	
<b>Complete?</b>	<span>Complete</span> ▾

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, then provide consent themselves once they have regained capacity.

# SAMPLING DETAILS

**Sampling Details**

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

Adding new GenOMICC ID number **GCC67892**.

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

**GenOMICC ID number** GCC67892

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

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)

**Which option has the participant chosen for providing a sample?**  
\* must provide value

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?**  
\* must provide value

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?**  
\* must provide value

Yes  No

**Participant Preferred Title**  
\* must provide value

**Participant First Name**  
\* must provide value

**Participant Last Name**  
\* must provide value

**Address Line 1**  
\* must provide value

**Address Line 2**

**Address Line 3**

Further fields will automatically appear, depending on the option selected for how the patient was recruited.

## 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.
- Please ask the patient if they wish to receive SMS appointment reminders.



# SAMPLING DETAILS CONTINUED

<b>City</b> <small>* must provide value</small>	<input type="text"/>
<b>County</b> <small>* must provide value</small>	<input type="text"/>
<b>Country</b> <small>* must provide value</small>	<input type="text"/>
<b>Postcode</b> <small>* must provide value</small>	<input type="text"/>
<b>Contact Phone number(s). If entering multiple numbers, please separate them with commas.</b> <small>* must provide value</small>	<input type="text"/>
<b>Contact email</b>	<input type="text"/>
<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> <small>* must provide value</small>	<input type="checkbox"/>
<b>Form Status</b>	
<b>Complete?</b>	<input type="text" value="Incomplete"/>
<input type="button" value="Save &amp; Exit Form"/> <input type="button" value="Save &amp; ..."/>	
<input type="button" value="- Cancel -"/>	

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.

**Retrospectively recruited patients using third-party sampling:** 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.

We will delete the patient's personal information after the sampling appointment has taken place.

# DATA AT RECRUITMENT



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 1)**   D-M-Y  
\* must provide value

**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 diagnosis**   
\* must provide value

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.

If the primary diagnosis is confirmed Covid-19 or unexplained hepatitis, then no other microbiology results are required.

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

# DATA AT RECRUITMENT CONTINUED



**Is the patient receiving invasive ventilation?**  
\* must provide value  Yes  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)?**  
\* must provide value  Yes  No reset

**Did the patient have significant immunosuppression before this illness? (such as cancer chemotherapy or acquired immune deficiency syndrome)?**  
\* must provide value  Yes  No reset

**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?  
\* must provide value  Yes  No reset

**Demography**

**Age (Years)**  
\* must provide value   
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**  
\* must provide value  Male  Female reset

**Postcode**  
(Please provide the first half of the postcode)  
\* must provide value   
0 characters remaining

**Form Status**

**Complete?**  
 reset

Save & Exit Form Save & Stay

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**

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    D-M-Y

Form Status

Complete?

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

Assign record to a Data Access Group?

Adding new GenOMICC ID number **GCC67892**.

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

GenOMICC ID number

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\*

\* must provide value

D-M-Y

60 day checker

Alive at 60 days

\* must provide value

Yes  No

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 reminders 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**

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

Adding new GenOMICC ID number **GCC56789**.

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

GenOMICC ID number: GCC56789

Date of Change of Status:  Today 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.**

Form Status

Complete?  Incomplete

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

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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. This does not affect your accrual.





# 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.

