The GenOMICC Study

Genetics of Mortality in Critical Care

Site guide for REDCap data entry

Date Created: September 2022

ROSLIN

THE UNIVERSITY of EDINBURGH

UKRI 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 and providing your:

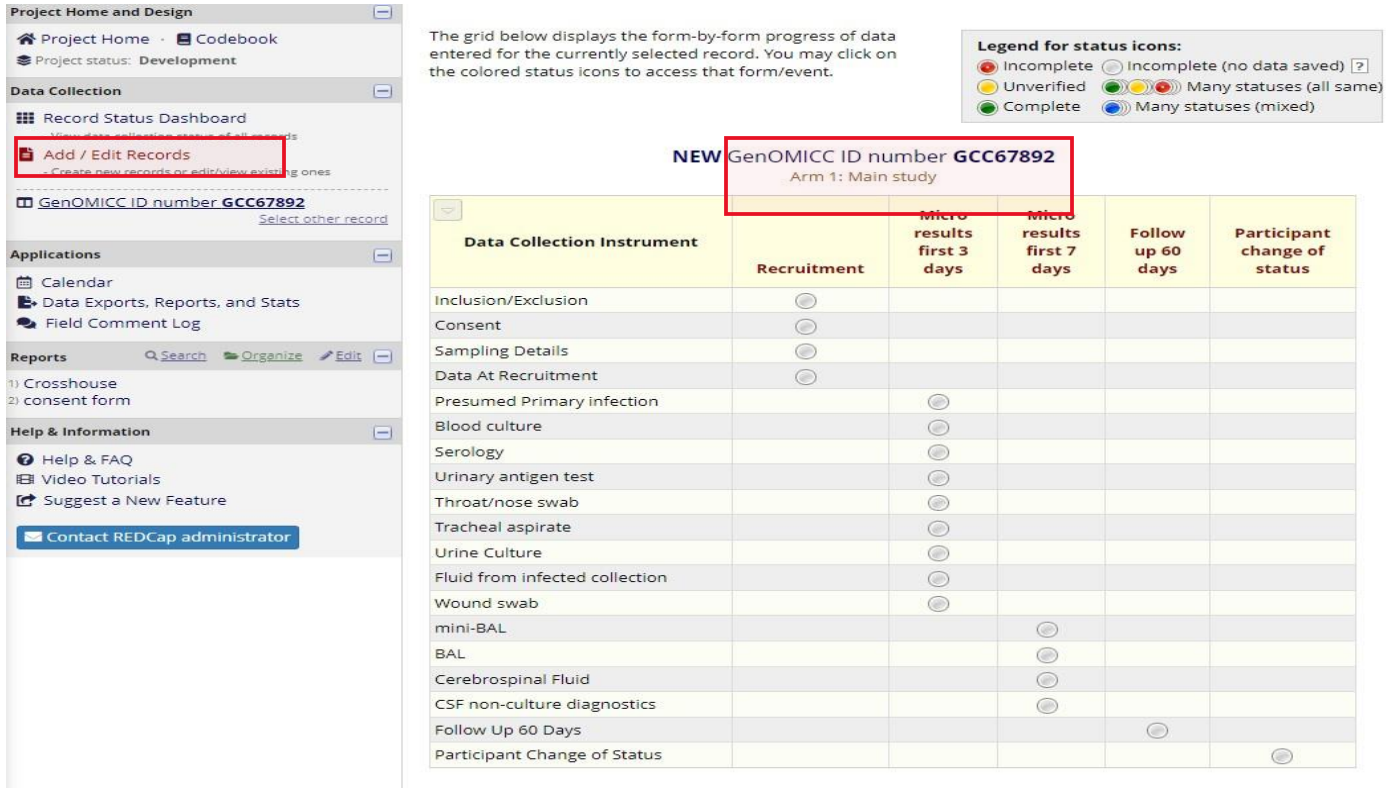
- name
- email address - (must be an NHS email)
- site (hospital) name

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



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

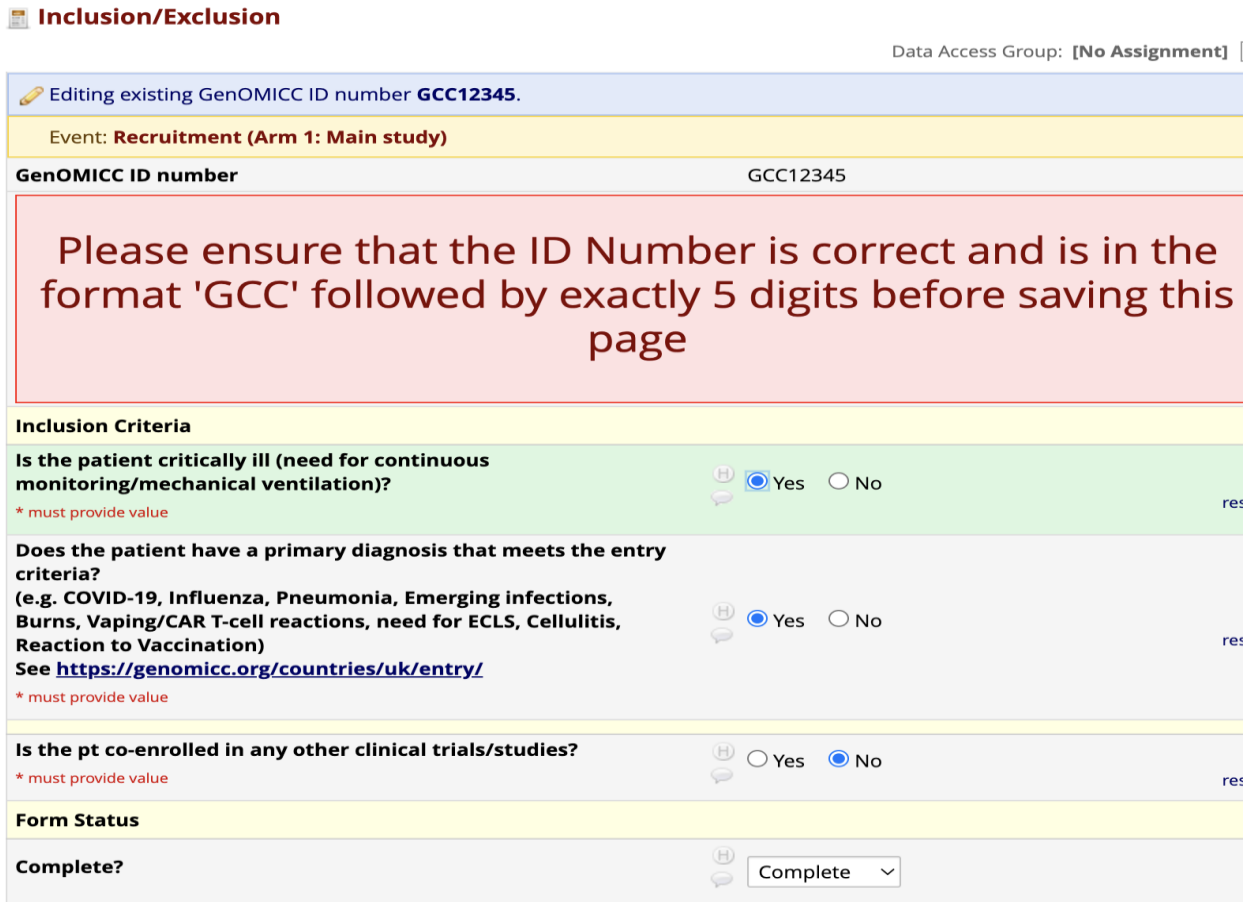
The GenOMICC patient ID number should always be entered into the eCRF exactly as it is shown on the label 'GCCxxxxx'.

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

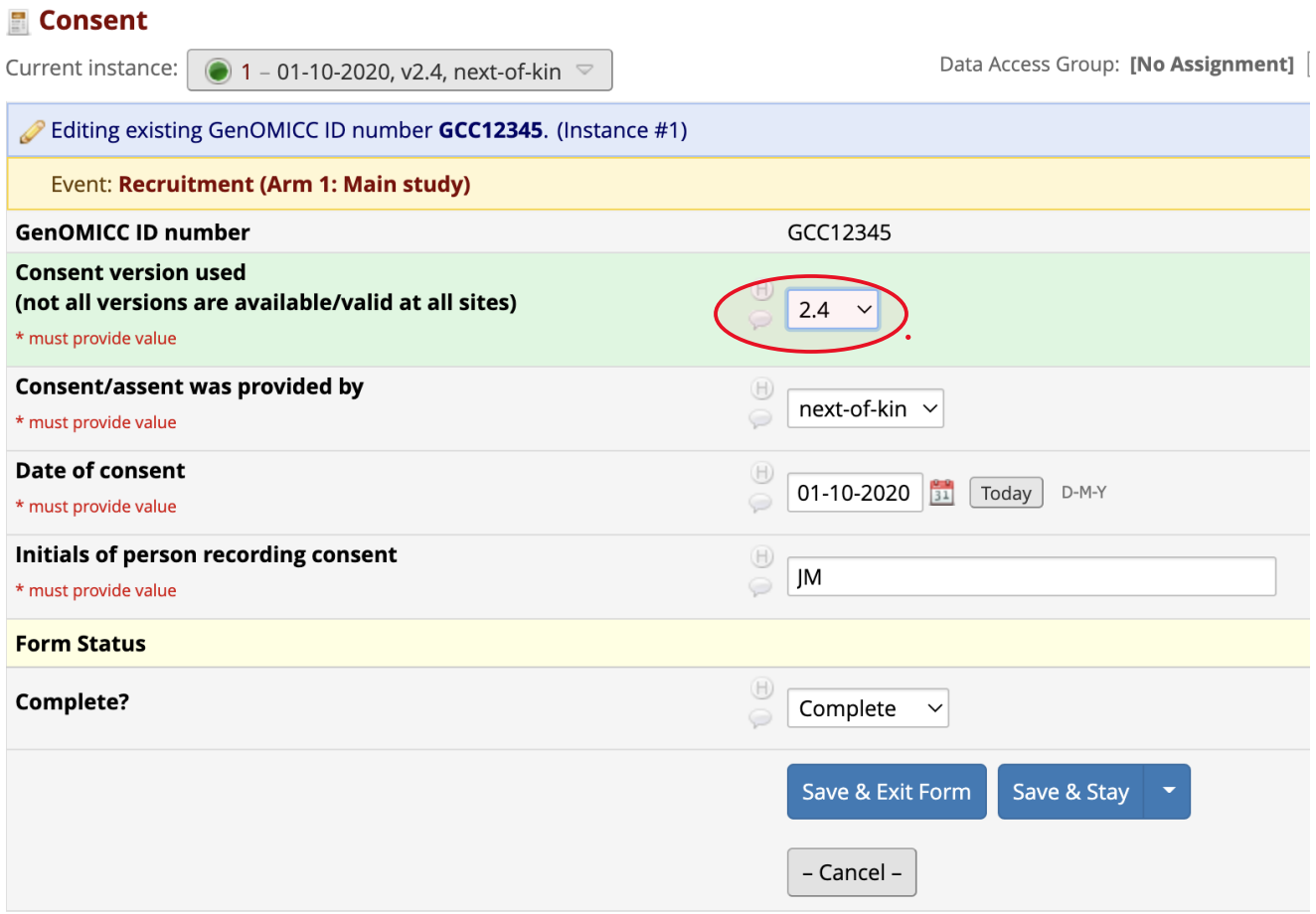


The patient does not need to be undergoing monitoring at the time of recruitment – once a patient is eligible for GenOMICC, they remain so for the rest of their lives.

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

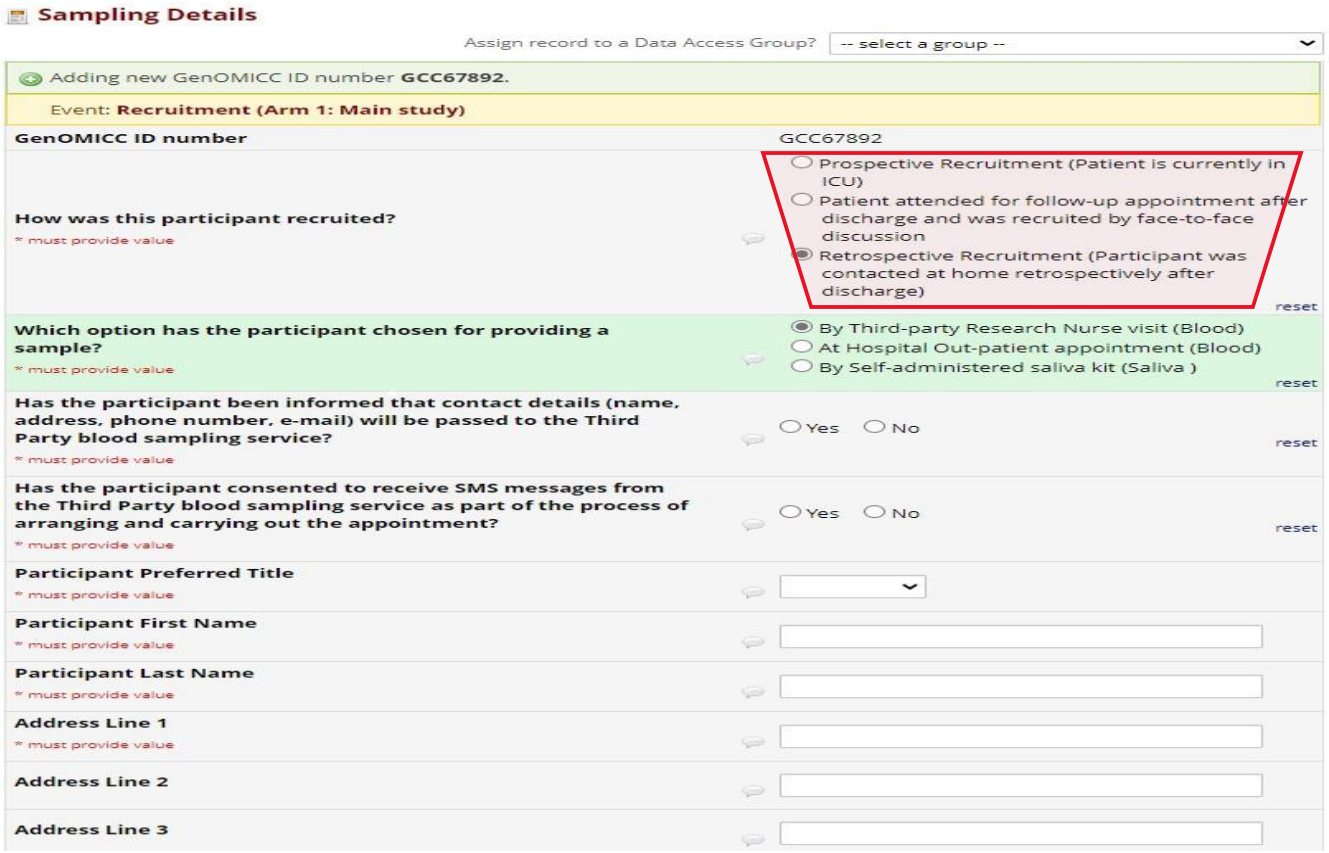


Select the correct version of the consent form from the dropdown menu – circled here in red.

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

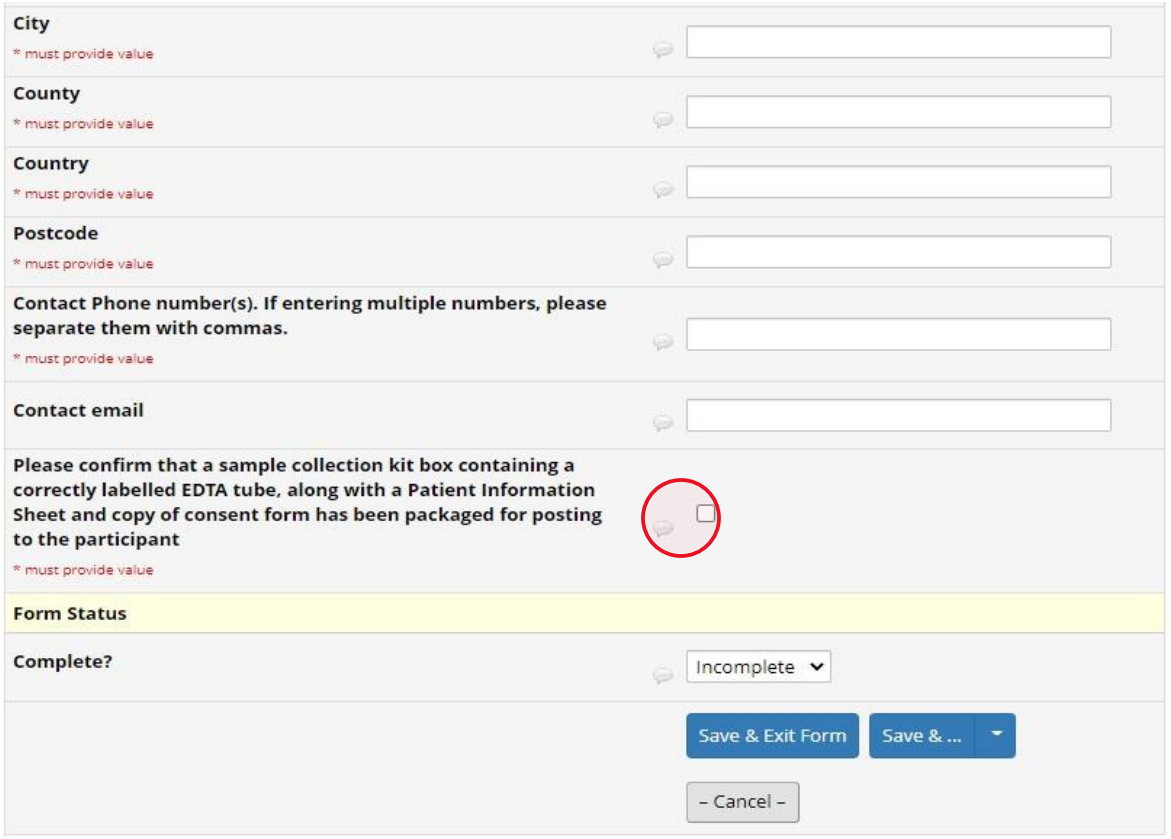


Further fields will automatically appear, depending on the option selected for how the patient was recruited.

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

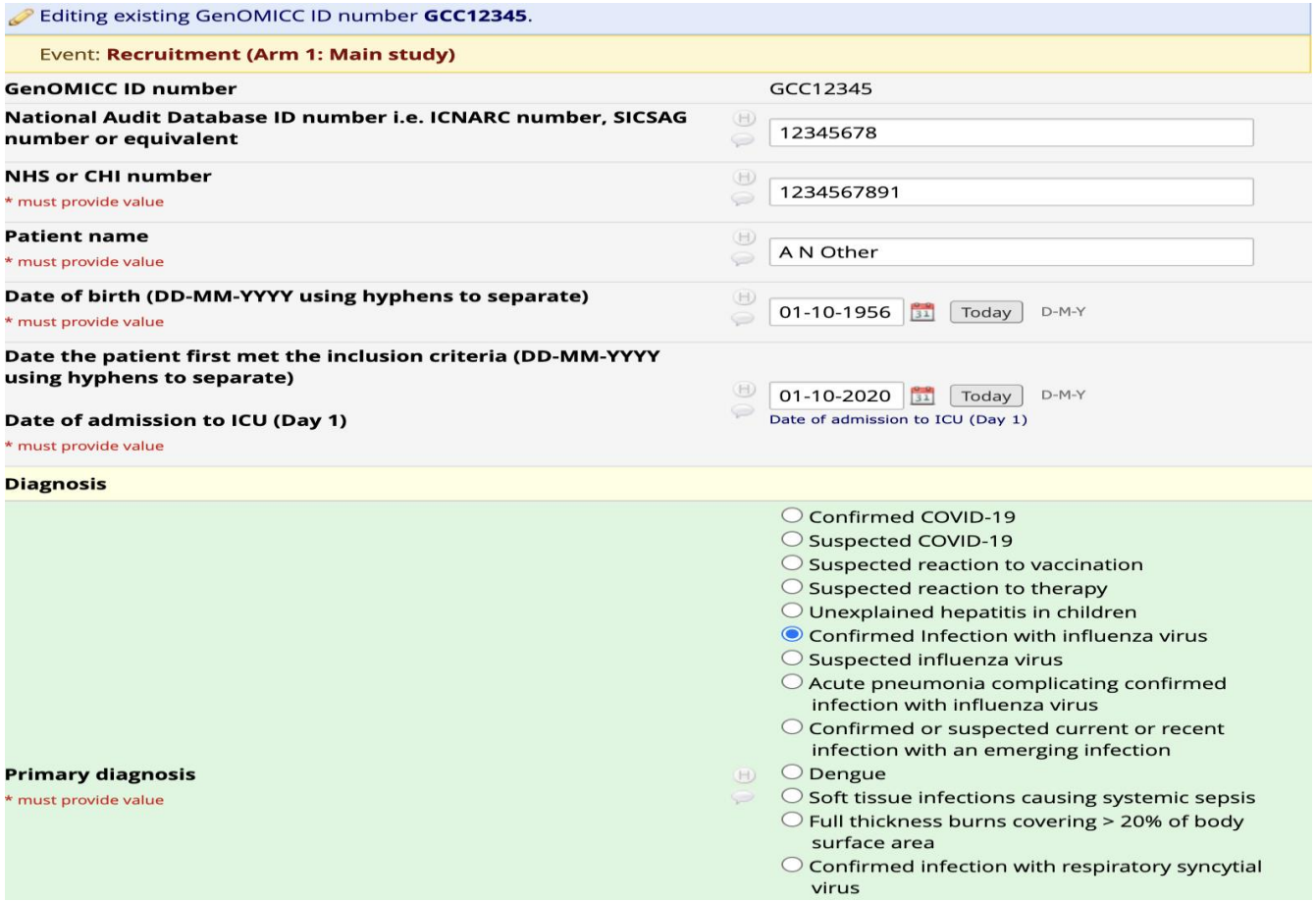


Please check the box circled in red to confirm the kit has been sent to the patient. It is important the kit is sent without delay as it will be required by the Inuvi nurse attending the patient for sampling.

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	12345678
NHS or CHI number * must provide value	1234567891
Patient name * must provide value	A N Other
Date of birth (DD-MM-YYYY using hyphens to separate) * must provide value	01-10-1956 Today D-M-Y
Date the patient first met the inclusion criteria (DD-MM-YYYY using hyphens to separate)	01-10-2020 Today D-M-Y
Date of admission to ICU (Day 1) * must provide value	Date of admission to ICU (Day 1)
Diagnosis	
Primary diagnosis * must provide value	○ 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

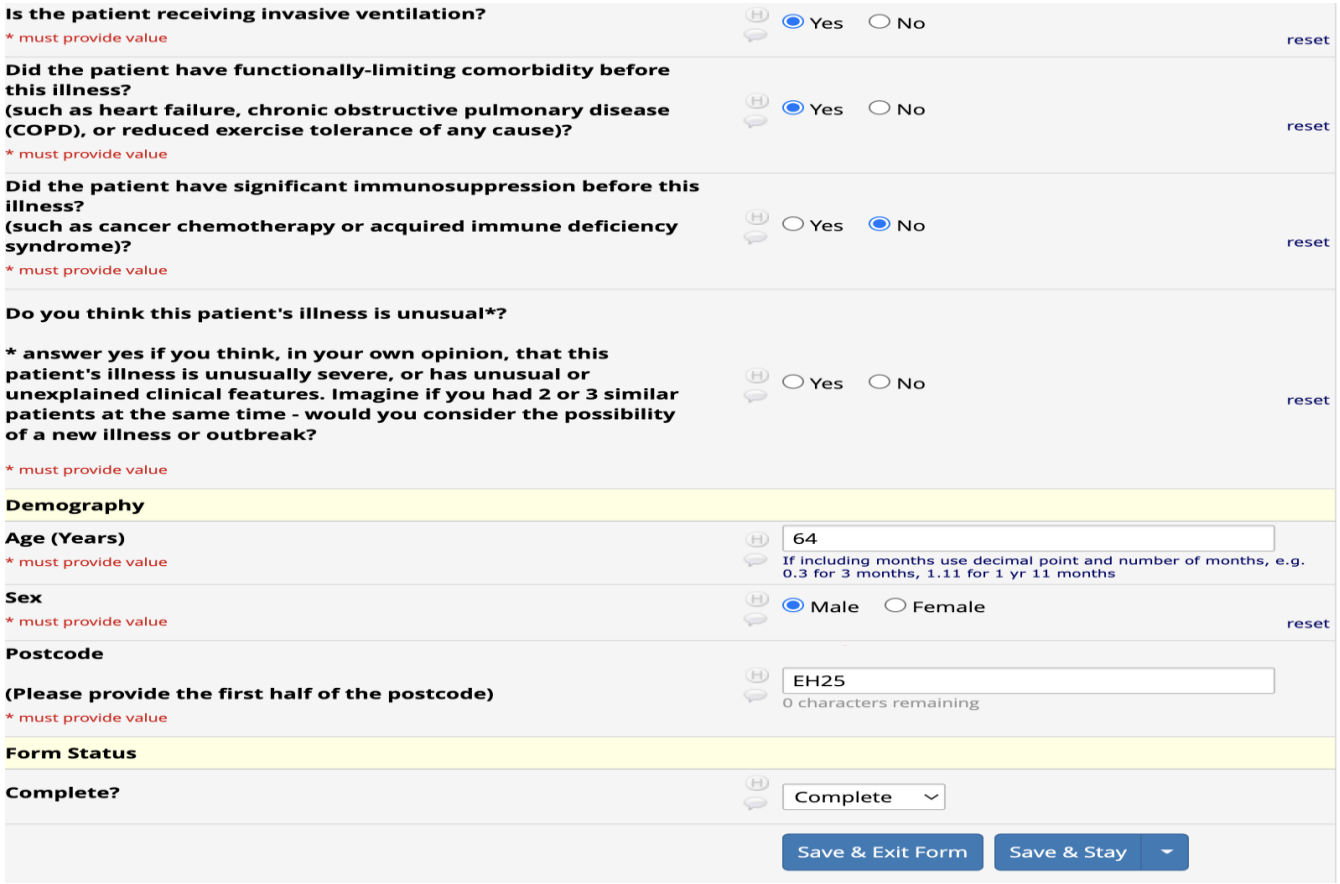
The ICNARC or SICSAG number is not a compulsory field, so please leave this blank if there is no number available.

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	64 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	EH25 0 characters remaining
Form Status	
Complete?	Complete

Save & Exit Form | Save & Stay

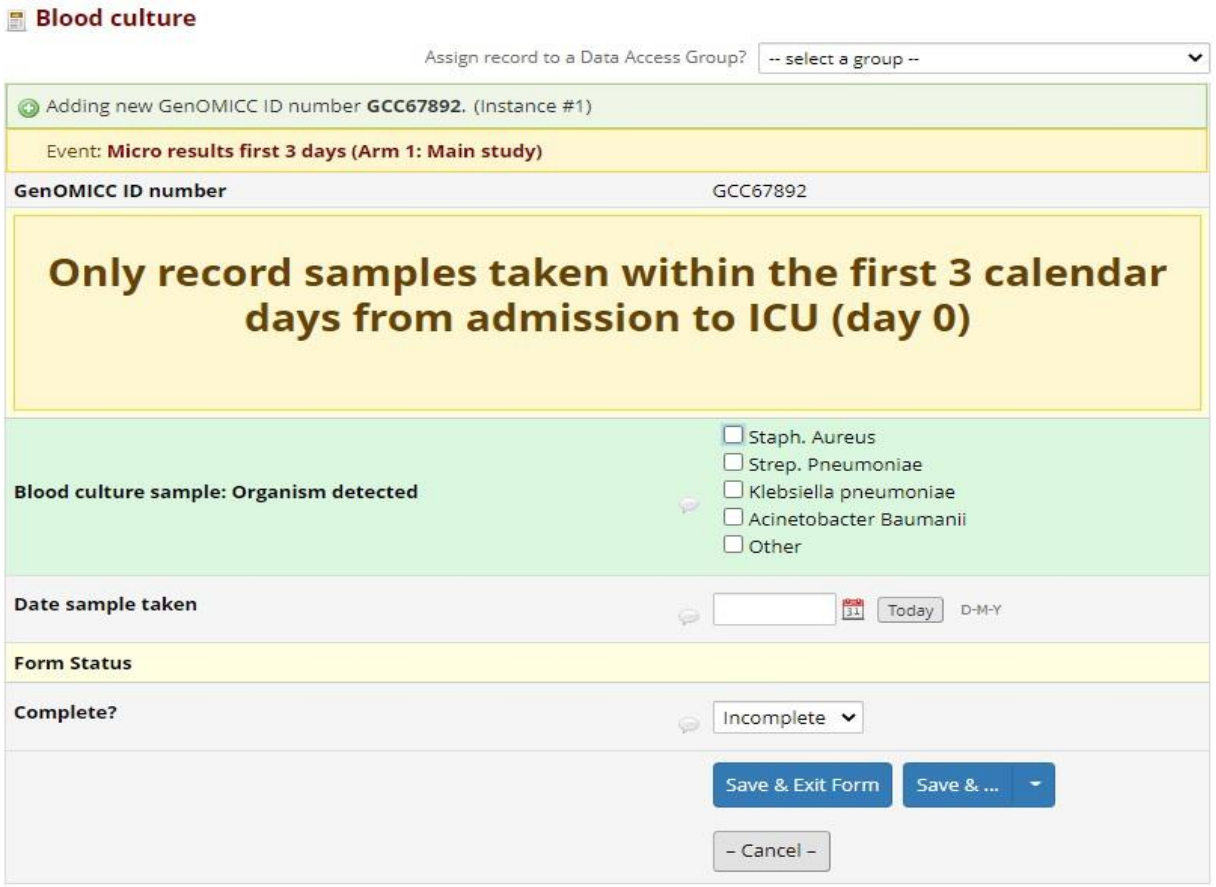
The additional fields here give us some information on the severity of the patient's illness.

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

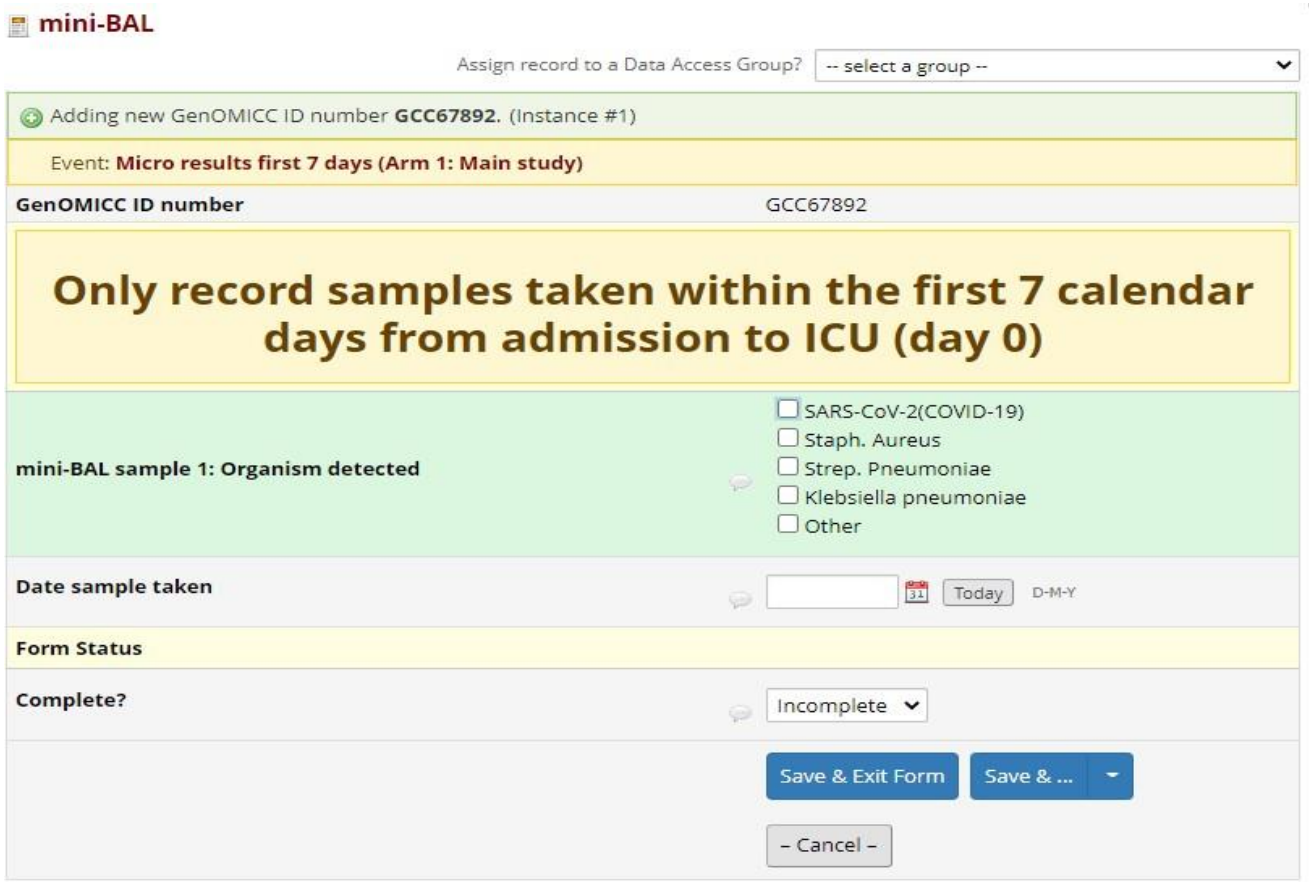


If a patient is admitted on a Monday (Day 0), then Thursday is Day 3 (i.e. third calendar day after admission – Tuesday is Day 1 after admission, Wednesday is Day 2 etc.). Any tests run on Monday, Tuesday, Wednesday, or Thursday can and should be entered in these sections.

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.

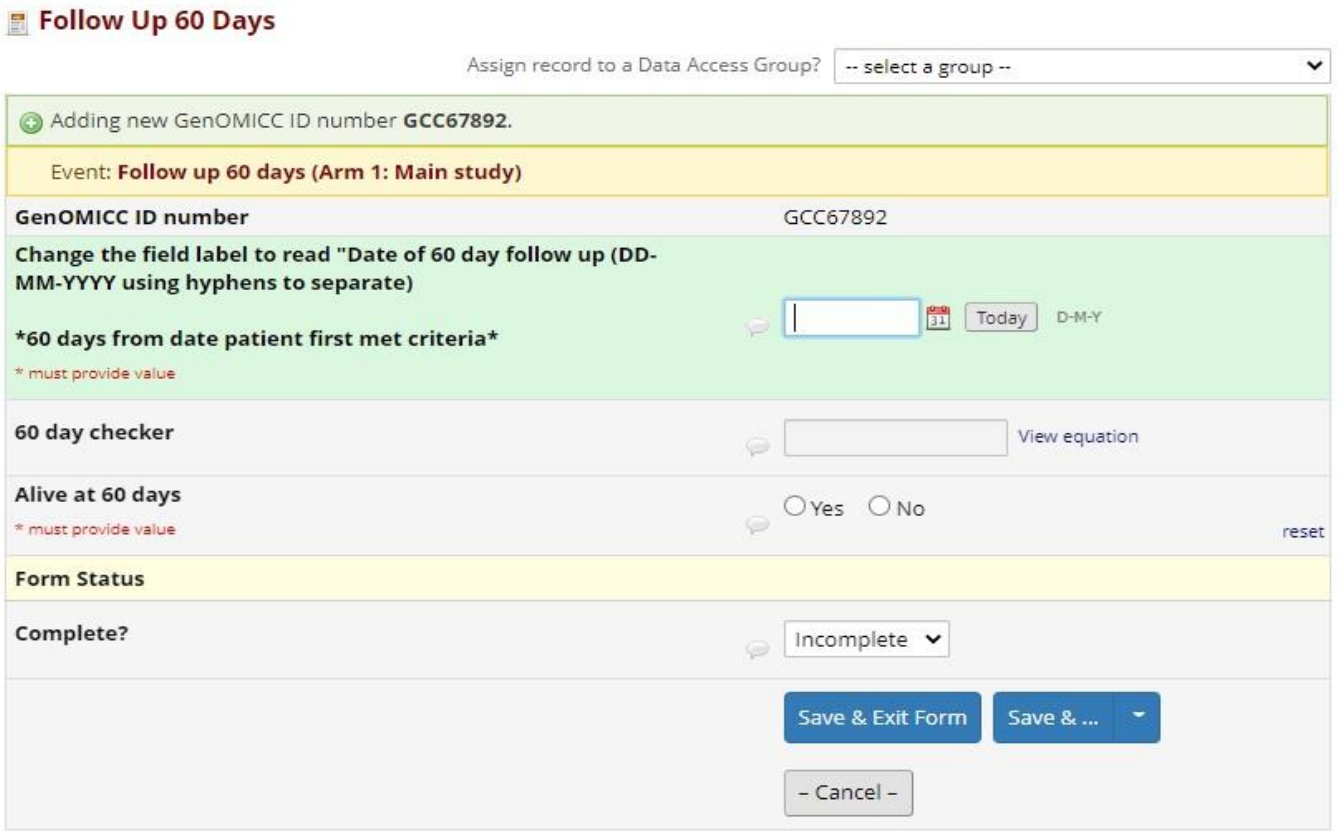
MINI-BAL



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

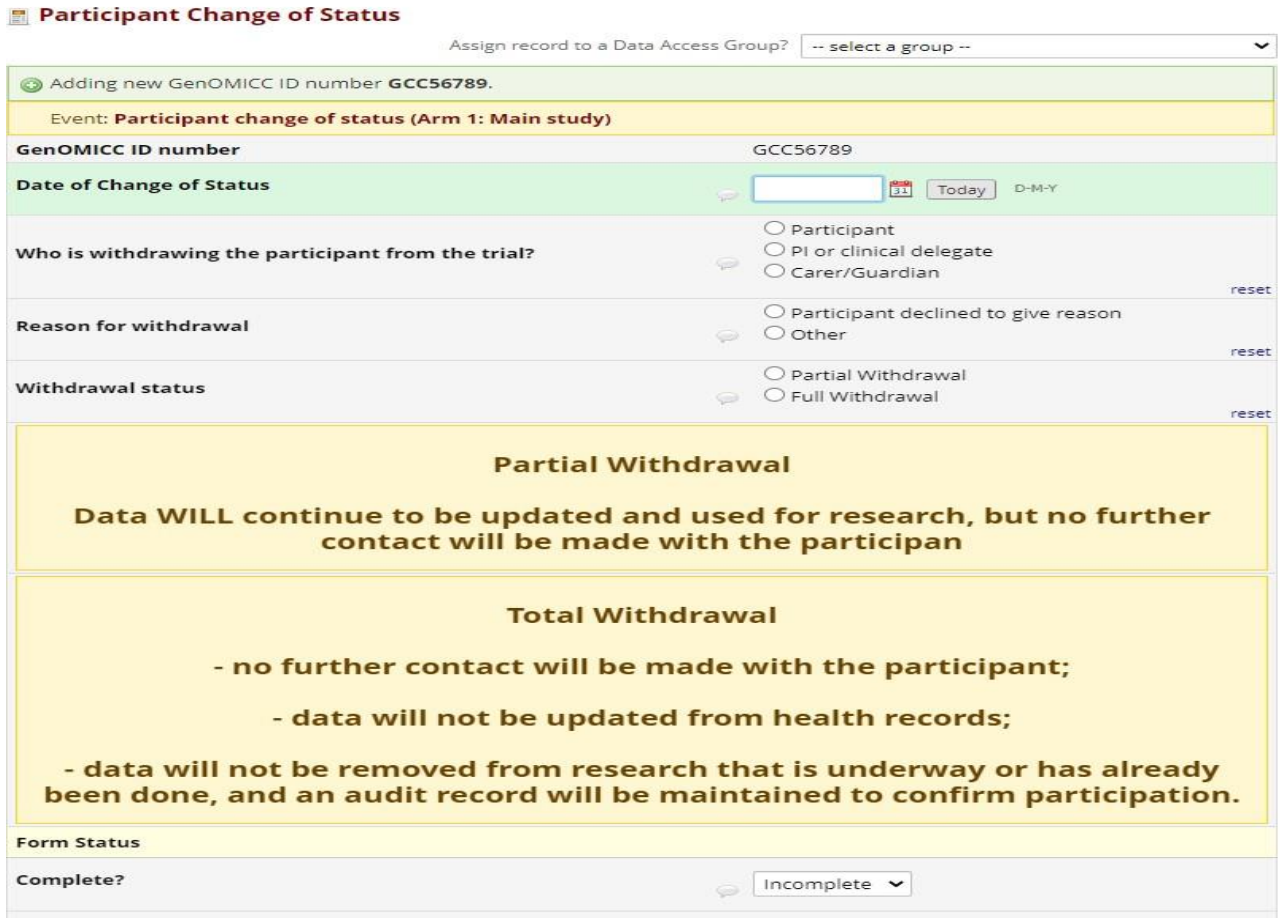


Please ensure at least 60 days have passed since Day 0 (admission to ICU when patient first became eligible) before this check is completed. It does not matter if the check is carried out after 60 days.

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



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. This does not affect your accrual.

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.