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

ROSLIN

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.

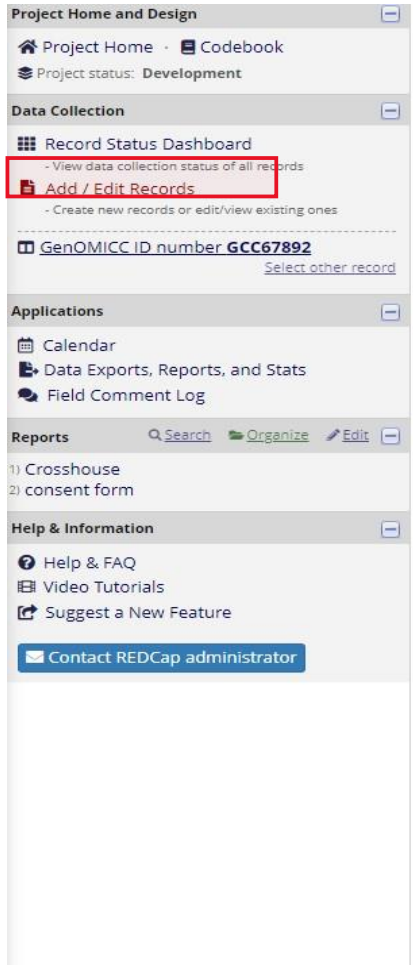
Before adding a new record to REDCap, read through this guide to see how eCRFs are created and completed

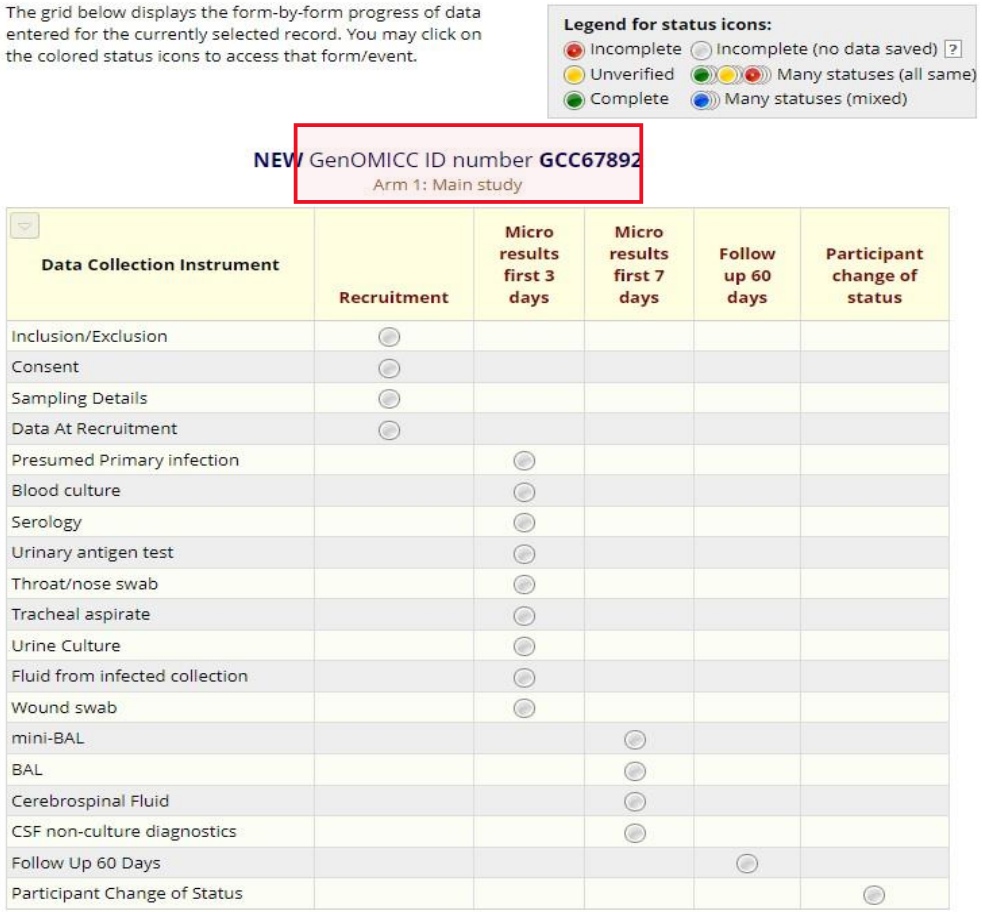
Entering the patient ID

- 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





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

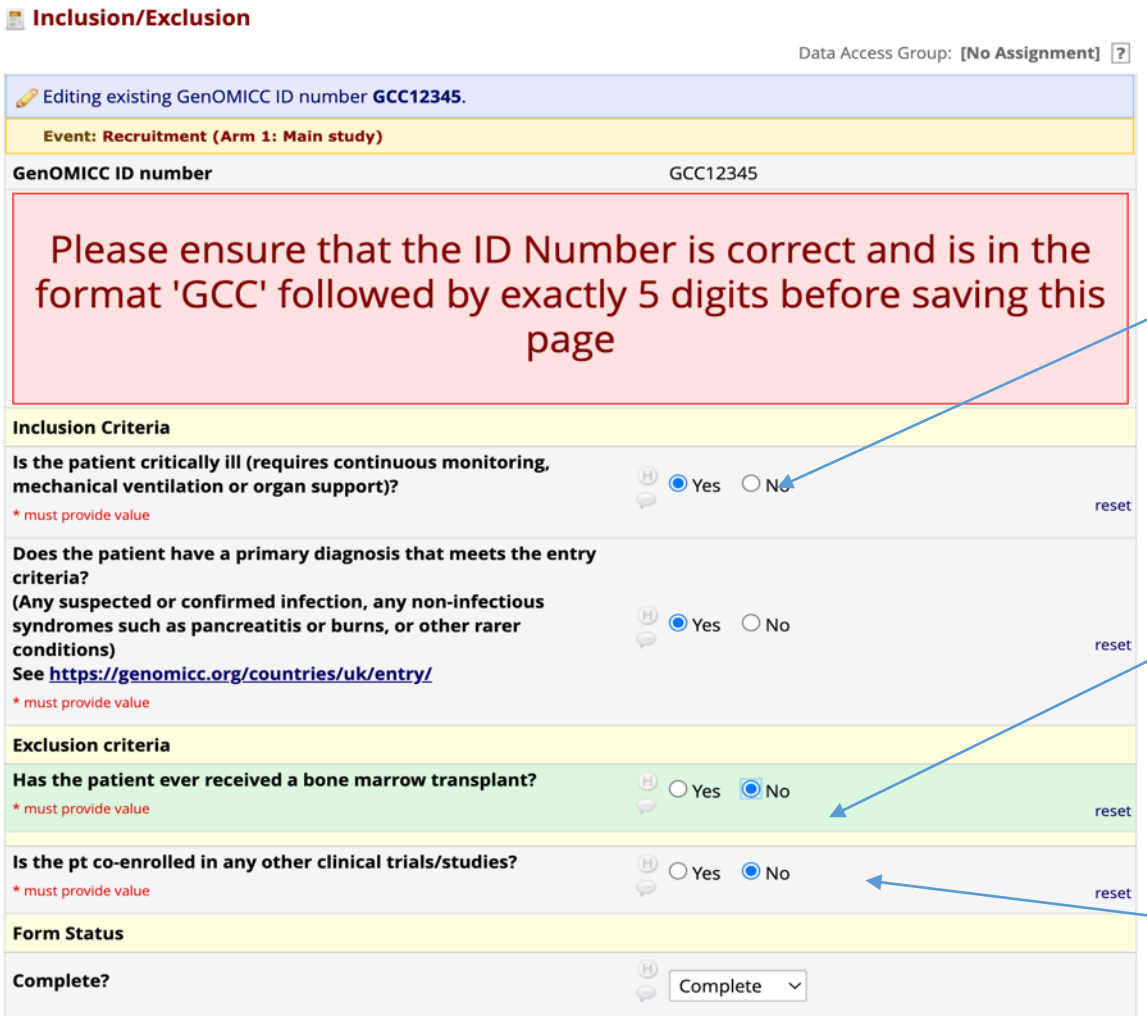
A box will pop up where a new (or existing) GCC_ID can be added.

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

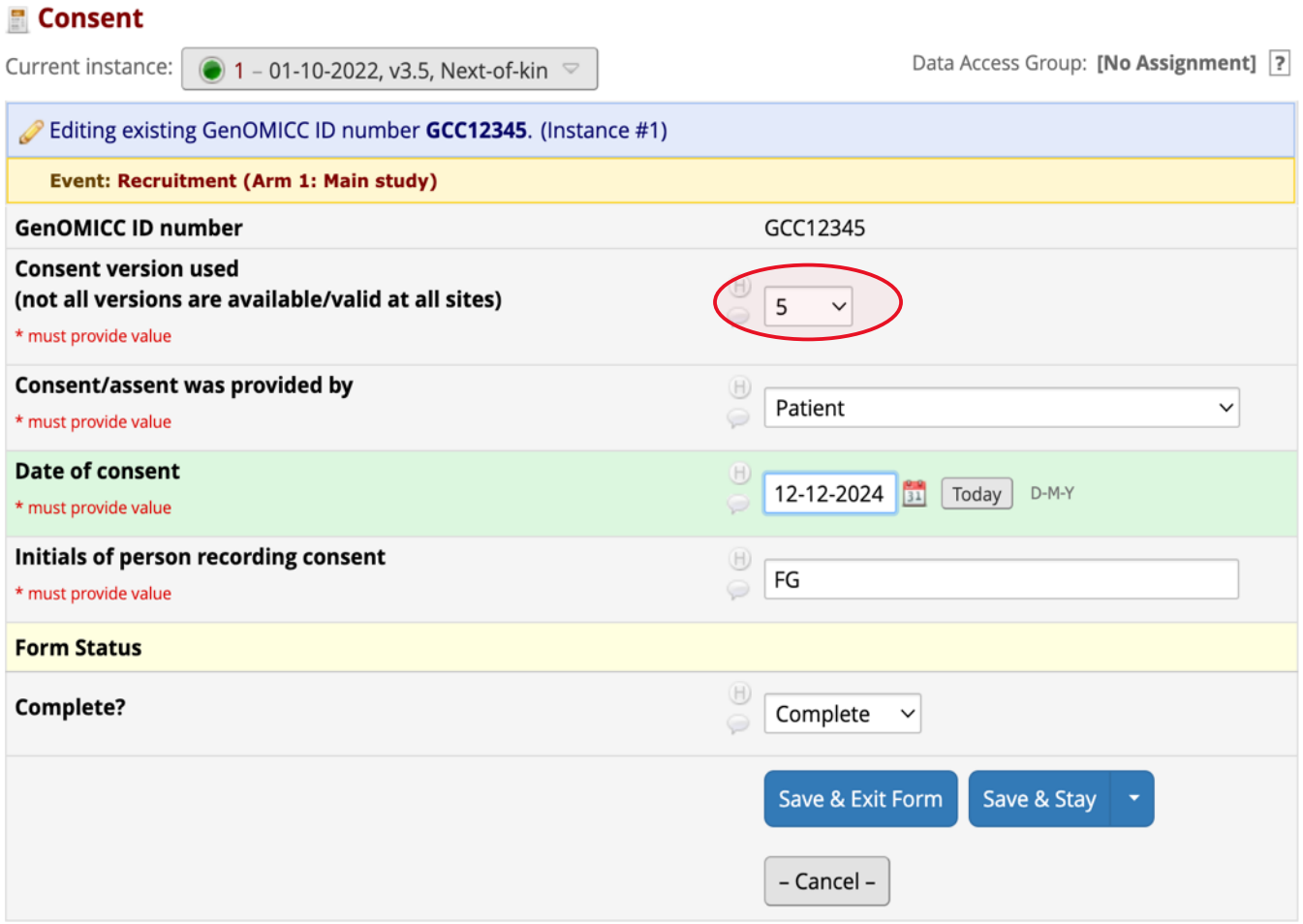


This should always be yes. Although, the patient does not need to be undergoing the monitoring at the actual time of recruitment. Once a patient is eligible for GenOMICC, they remain so for the rest of their lives.

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

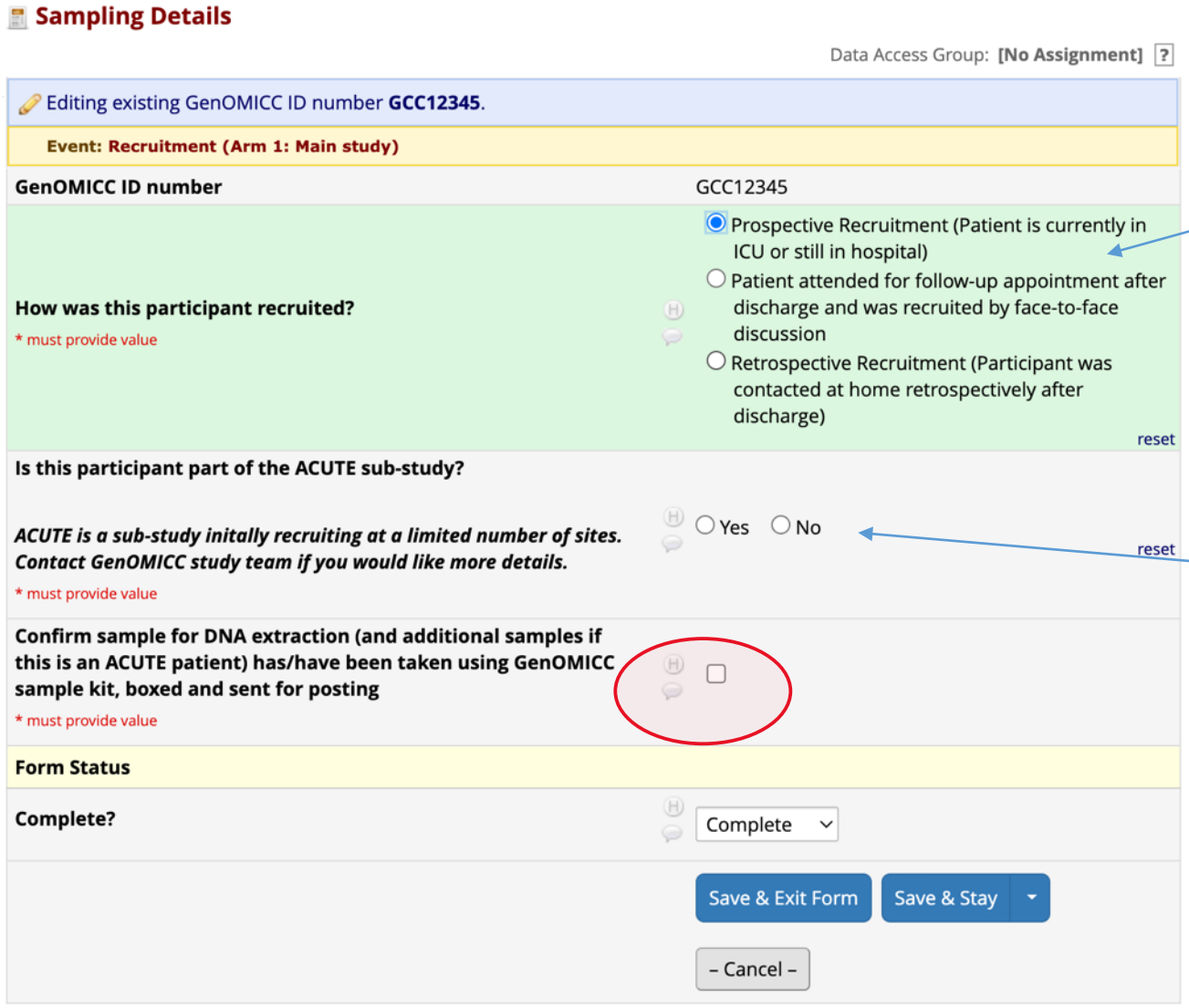


Select the correct version of the consent form from the dropdown menu – circled here in red.

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.

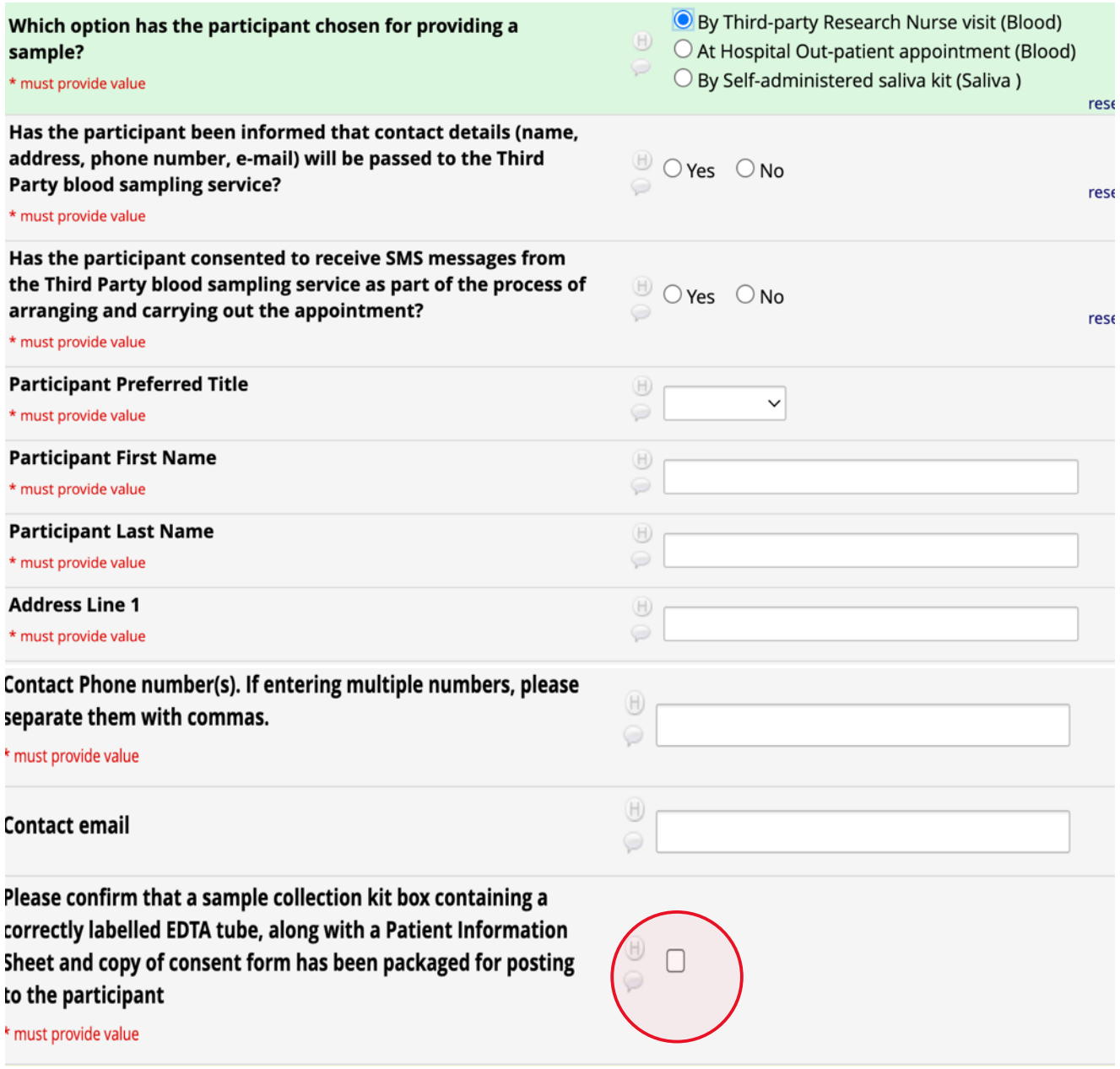
Sampling details



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)



Retrospective recruitment only

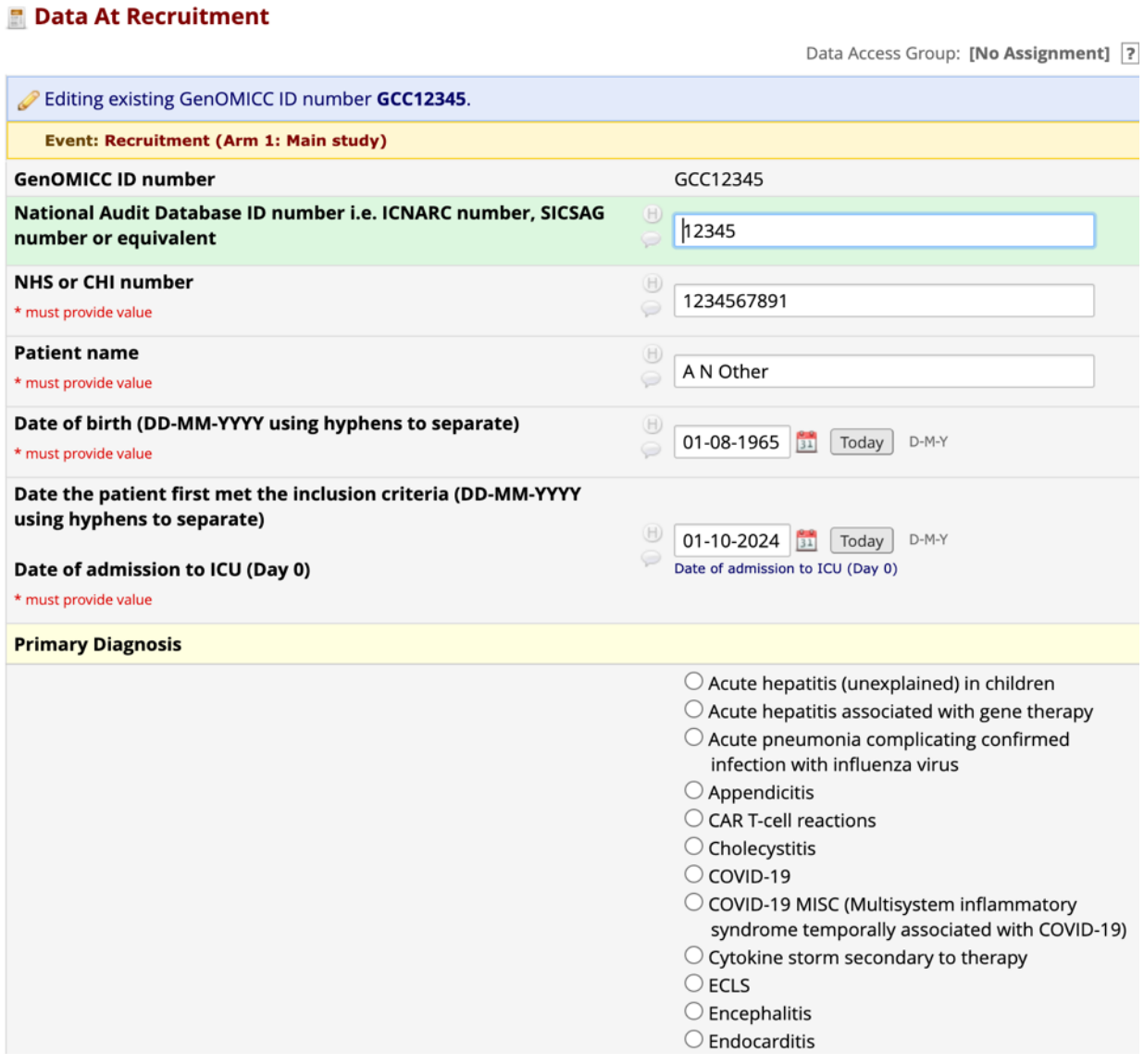
A series of data fields will appear for completion, if the 'third-party research nurse visit' sampling option has been selected.

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	12345
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	01-08-1965 Today D-M-Y
Date the patient first met the inclusion criteria (DD-MM-YYYY using hyphens to separate)	01-10-2024 Today D-M-Y
Date of admission to ICU (Day 0) * must provide value	Date of admission to ICU (Day 0)

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

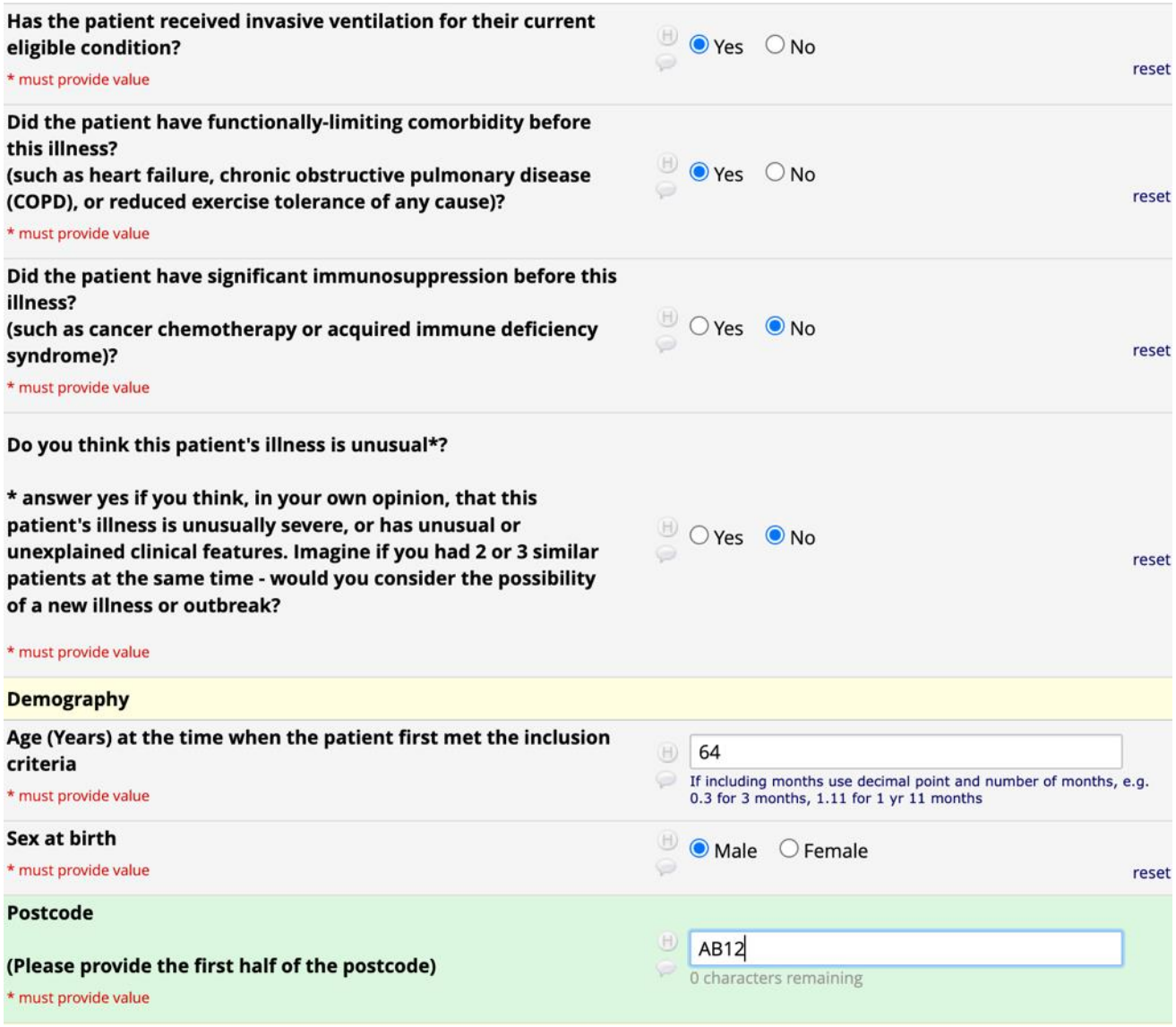
The ICNARC or SICSAG number is not a compulsory field, so please leave this blank if there is no number available.

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? * 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) at the time when the patient first met the inclusion criteria * 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 at birth * must provide value	◉ Male ○ Female reset
Postcode (Please provide the first half of the postcode) * must provide value	AB12 0 characters remaining

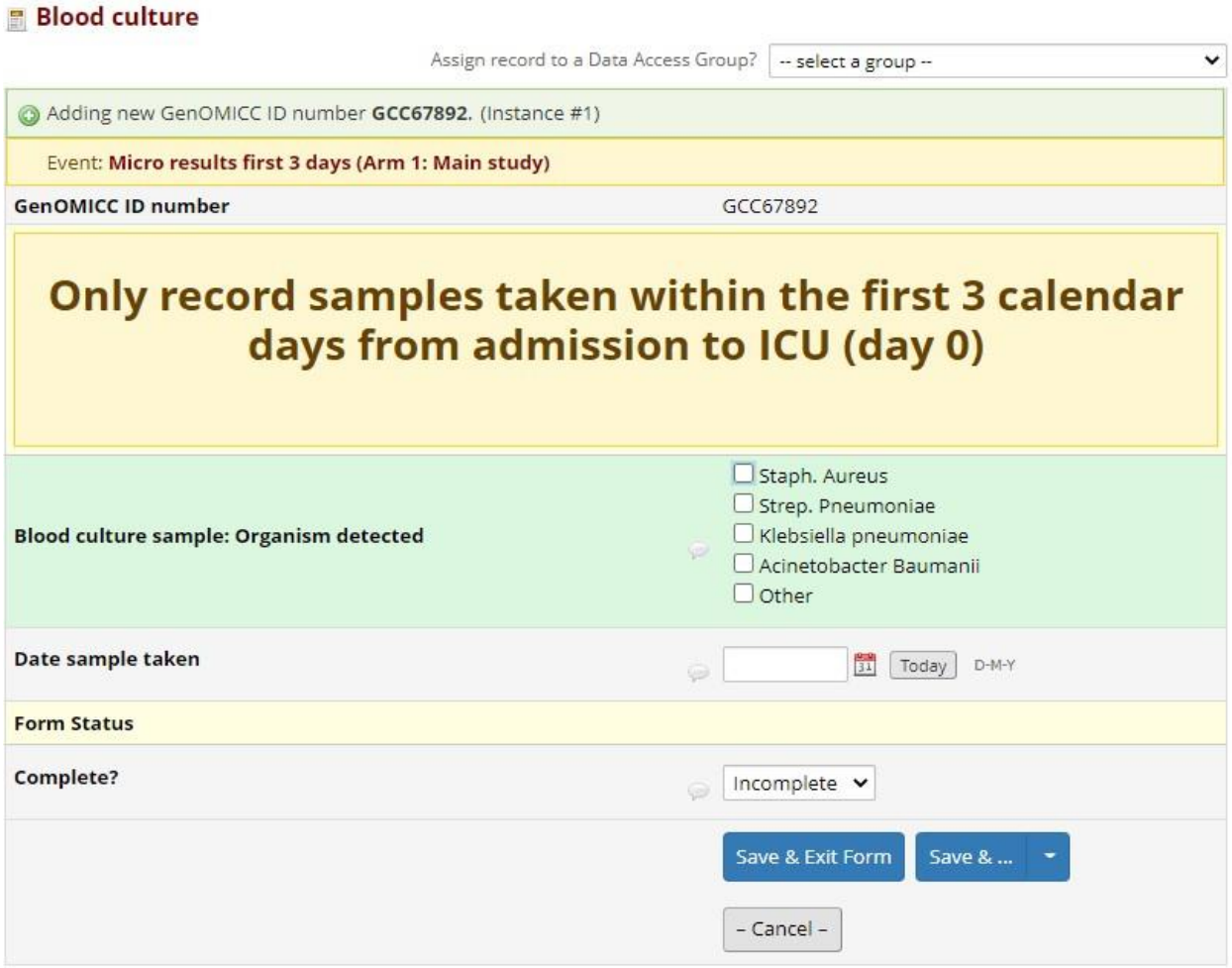
The additional fields here give us some information on the severity of the patient's illness.

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

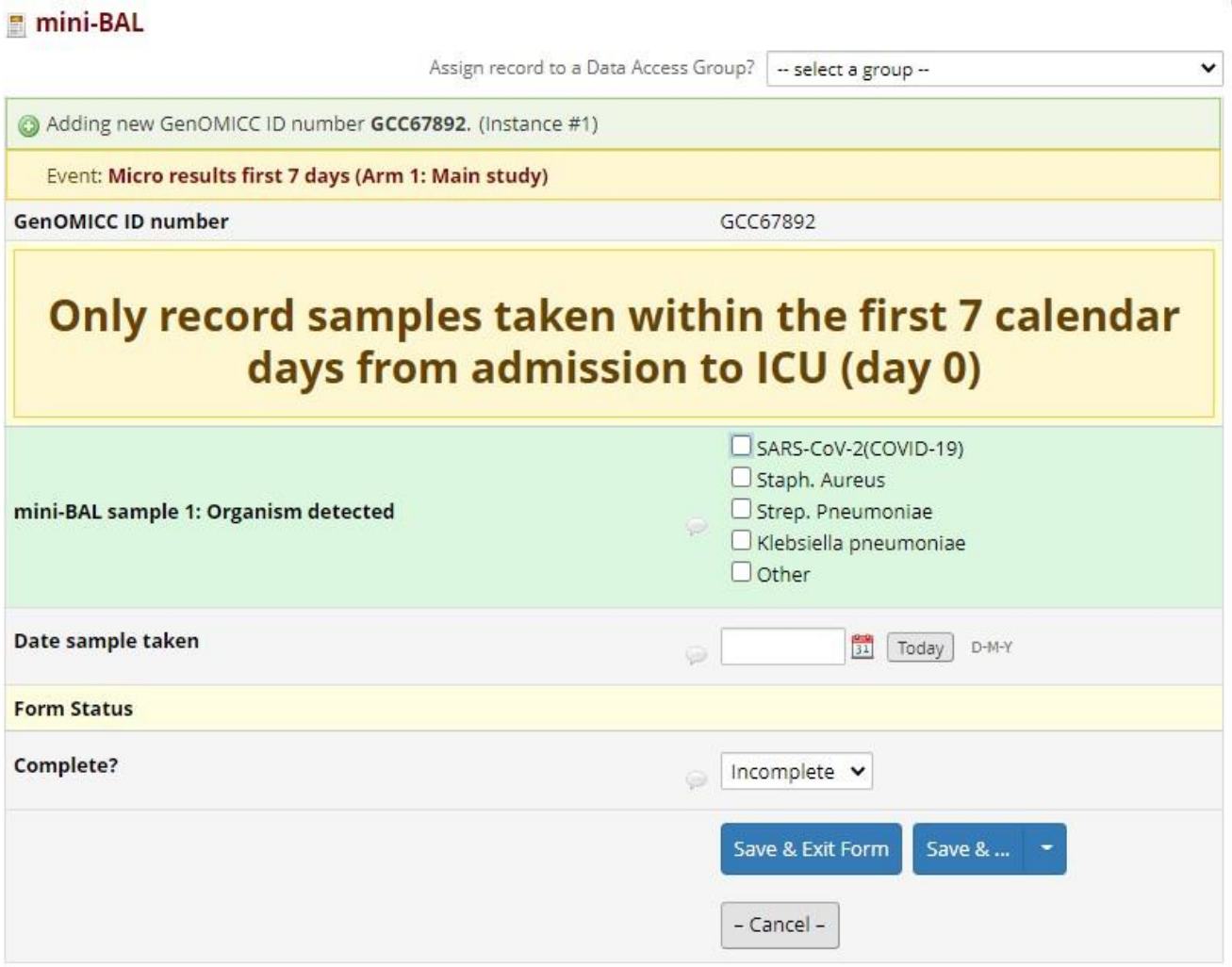


If a patient is admitted on a Monday (Day 0), then Thursday is Day 3 (i.e. third calendar day after admission – Tuesday is Day 1 after admission, Wednesday is Day 2 etc.). Any tests run on Monday, Tuesday, Wednesday, or Thursday can and should be entered in these sections.

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.**

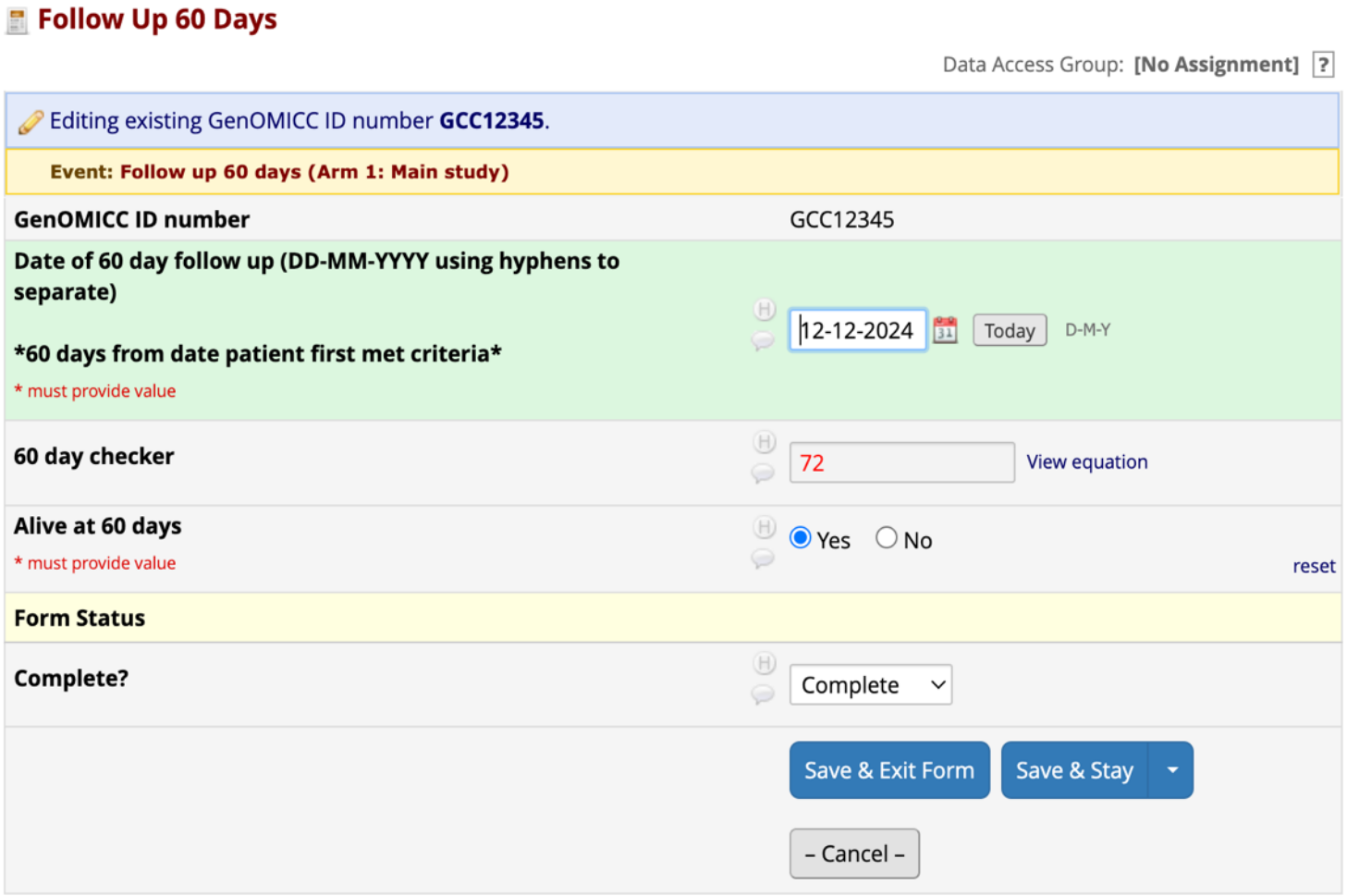
Mini-BAL



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

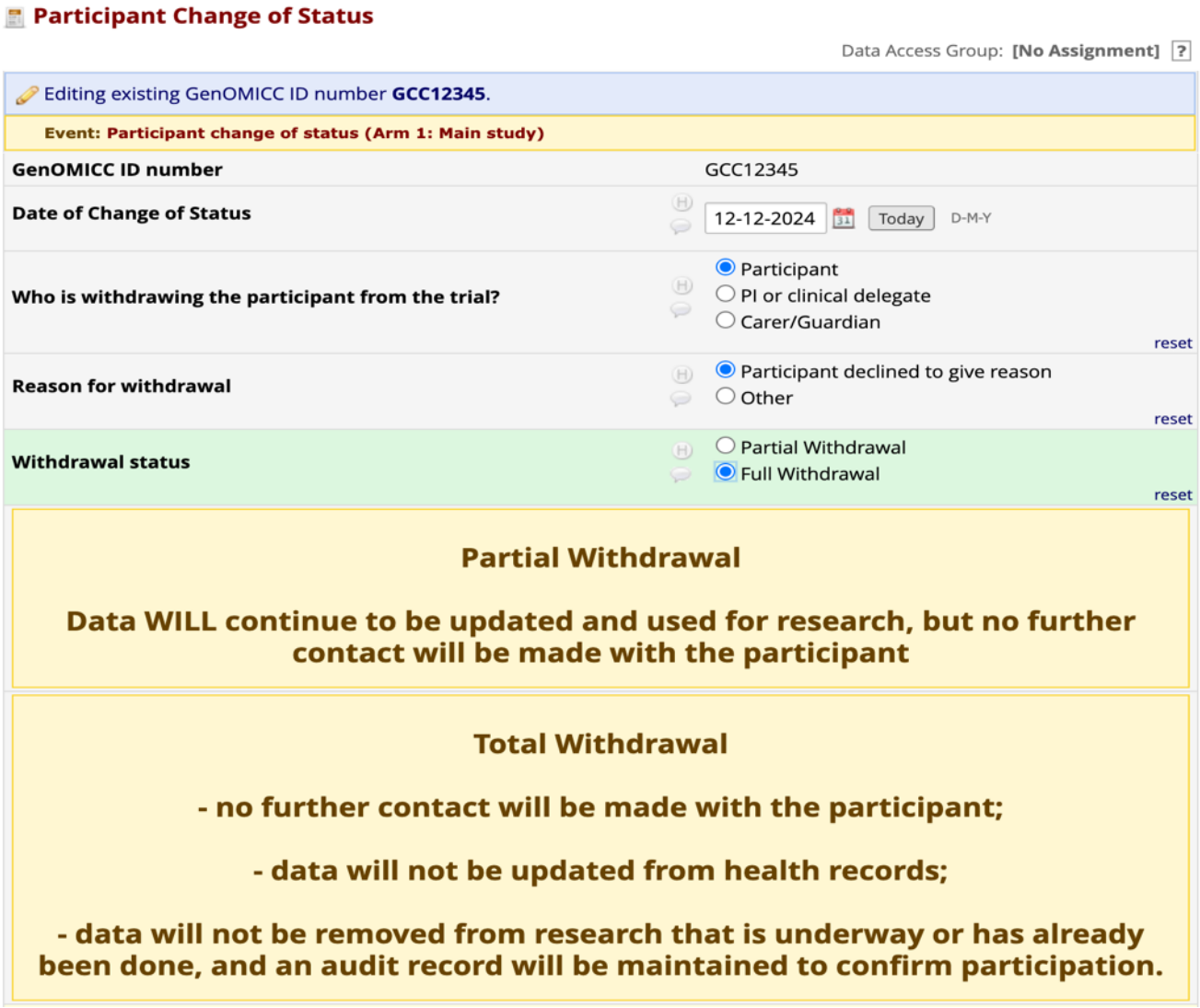


Please ensure at least 60 days have passed since Day 0 (admission to ICU when patient first became eligible) before this check is completed. (It does not matter if the check is carried out after 60 days).

We'll send 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



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

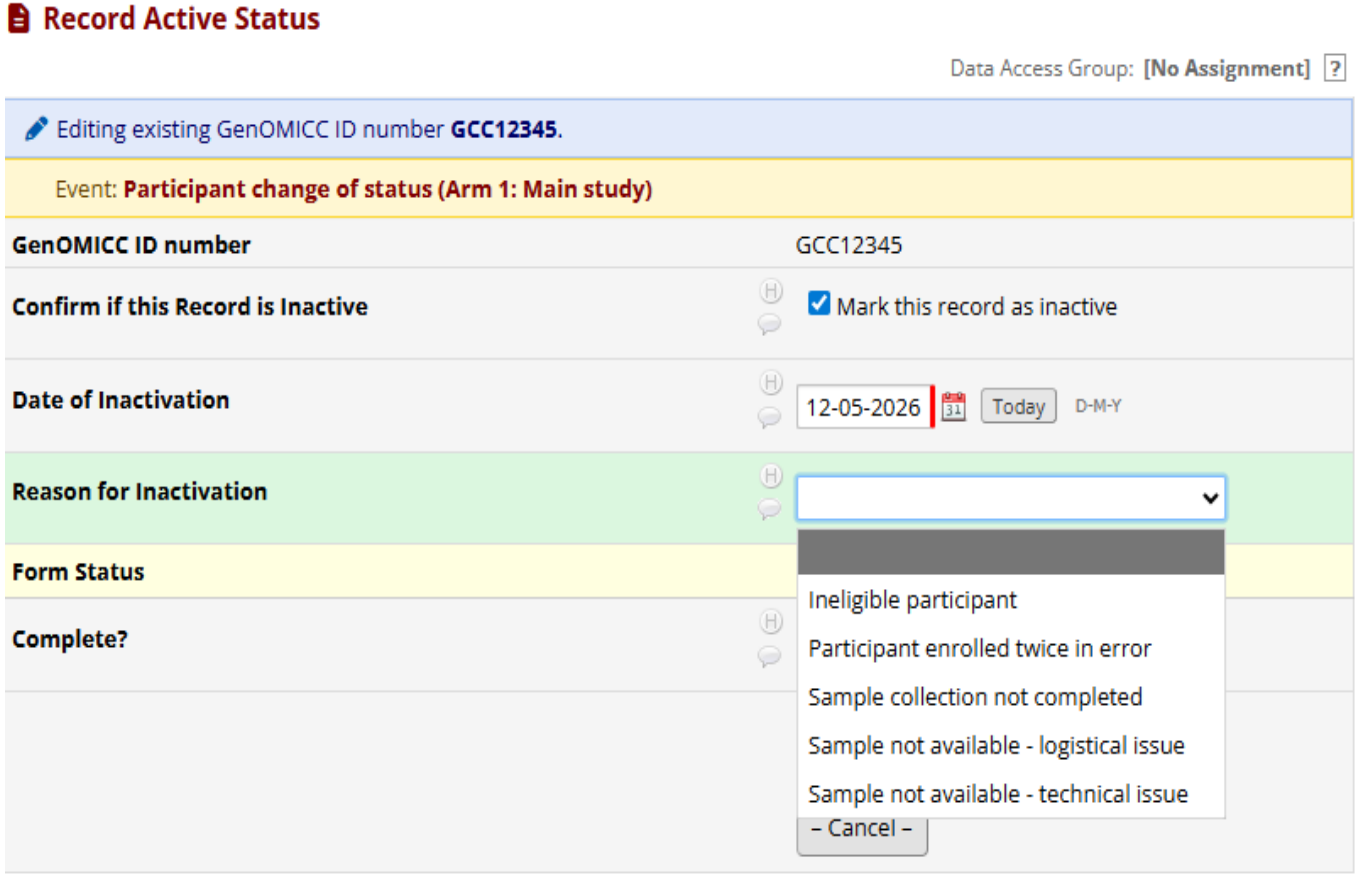
Update status to '**Full Withdrawal**' if the participant withdraws consent and no longer wishes to take part. Please also let the GenOMICC team know so we can destroy the DNA sample.

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



- 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

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.