

REDCap completion guide for preterm birth <32 weeks postmenstrual age

The REDCap pages noted below should be completed for all records created for the preterm birth < 32 weeks postmenstrual age group.

(Microbiology pages are not required to be completed for this cohort and can be left blank).

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 checked="" type="radio"/>				
Consent	<input checked="" type="radio"/> +				
Sampling Details	<input checked="" type="radio"/>				
Data At Recruitment	<input checked="" type="radio"/>				
Follow Up 60 Days				<input checked="" type="radio"/>	

Inclusion/Exclusion page

GenOMICC ID number: GCC44555

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

Other Studies

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

Form Status

Complete? reset

Consent

GenOMICC ID number: GCC44555

Consent version used (not all versions are available/valid at all sites) reset
* must provide value

Consent/assent was provided by reset
* must provide value

Date of consent Today reset
* must provide value

Initials of person recording consent reset
* must provide value

Form Status

Complete? reset

Sampling details

GenOMICC ID number	GCC44555
How was this participant recruited? <small>* must provide value</small>	<input type="radio"/> Prospective Recruitment (Patient is currently in ICU or still in hospital) <input type="radio"/> Patient attended for follow-up appointment after discharge and was recruited by face-to-face discussion <input type="radio"/> Retrospective Recruitment (Participant was contacted at home retrospectively after discharge)
Form Status	
Complete?	Incomplete
<input type="button" value="Save & Exit Form"/> <input type="button" value="Save & Go To Next Form"/> <input type="button" value="- Cancel -"/>	

Data at Recruitment

GenOMICC ID number	GCC44555
National Audit Database ID number i.e. ICNARC number, SICSAG number or equivalent	<input type="text"/>
NHS or CHI number <small>* must provide value</small>	<input type="text"/>
Patient name <small>* must provide value</small>	<input type="text"/>
Date of birth (DD-MM-YYYY using hyphens to separate) <small>* must provide value</small>	<input type="text"/> <input type="button" value="Today"/> D-M-Y
Date the patient first met the inclusion criteria (DD-MM-YYYY using hyphens to separate)	<input type="text"/> <input type="button" value="Today"/> D-M-Y
Date of admission to ICU (Day 0) <small>* must provide value</small>	<input type="text"/> <input type="button" value="Today"/> Date of admission to ICU (Day 0)

Primary Diagnosis	
Primary diagnosis for admission to critical care (confirmed or suspected) <small>* must provide value</small>	<input type="radio"/> Acute hepatitis (unexplained) in children <input type="radio"/> Acute hepatitis associated with gene therapy <input type="radio"/> Acute pneumonia complicating confirmed infection with influenza virus <input type="radio"/> Appendicitis <input type="radio"/> CAR T-cell reactions <input type="radio"/> Cholecystitis <input type="radio"/> COVID-19 <input type="radio"/> COVID-19 MISC (Multisystem inflammatory syndrome temporally associated with COVID-19) <input type="radio"/> Cytokine storm secondary to therapy <input type="radio"/> ECLS <input type="radio"/> Encephalitis <input type="radio"/> Endocarditis <input type="radio"/> Full thickness burns covering > 20% of body surface area <input type="radio"/> Haemophagocytic syndrome <input type="radio"/> Heat stroke <input checked="" type="radio"/> Influenza <input type="radio"/> Meningitis <input type="radio"/> Pancreatitis of any aetiology <input type="radio"/> Peritonitis <input type="radio"/> Pneumonia with radiographic changes at presentation to critical care <input checked="" type="radio"/> Preterm birth < 32 weeks postmenstrual age <input type="radio"/> Pyelonephritis <input type="radio"/> Radiation poisoning <input type="radio"/> Reaction to vaccination <input type="radio"/> RSV (respiratory syncytial virus) infection <input type="radio"/> Soft tissue infections causing systemic sepsis <input type="radio"/> Stevens-Johnson Syndrome/Toxic Epidermal Necrolysis <input type="radio"/> Still disease <input type="radio"/> Urinary tract infection <input type="radio"/> Any emerging critical care syndrome not listed above <input type="radio"/> Any primary infection not listed above <input type="radio"/> Any reaction to therapy not listed above

When Preterm birth < 32 weeks postmenstrual age is selected as the Primary Diagnosis, the following fields will appear:

Estimate Gestational Age at birth (weeks)	<input type="text"/>
Estimated Gestational Age at birth (days)	<input type="text"/>
Birth weight (g)	<input type="text"/>
Has the patient received invasive ventilation for their current eligible condition? <small>* must provide value</small>	<input type="radio"/> Yes <input type="radio"/> No reset
Demography	
Sex at birth <small>* must provide value</small>	<input type="radio"/> Male <input type="radio"/> Female reset
Postcode <small>(Please provide the first half of the postcode)</small> <small>* must provide value</small>	<input type="text"/> 4 characters remaining
Form Status	
Complete?	Complete <input type="button" value="v"/>
<input type="button" value="Save & Exit Form"/> <input type="button" value="Save & Stay"/> <input type="button" value="- Cancel -"/>	

Follow up page

The final page requiring completion is the follow up page:

Follow Up 60 Days				<input checked="" type="radio"/>	
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The 60-day follow up is our usual follow-up period but in the case of preterm babies it is 36 weeks. Unfortunately, we can't change the name of this banner on REDCap, so please do treat this as your 36 week follow up page.

Editing existing GenOMICC ID number GCC44555	
Event: Follow up 60 days (Arm 1: Main study)	
GenOMICC ID number	GCC44555
Date of follow up / outcome (DD-MM-YYYY using hyphens to separate) <small>* must provide value</small>	<input type="text" value="06-01-2026"/> <input type="button" value="Today"/> D-M-Y
36 weeks PMA	
Estimated 36 weeks PMA date	<input type="text" value="28-12-2025"/> <input type="button" value="View equation"/>
Alive at target follow up / outcome date <small>* must provide value</small>	<input checked="" type="radio"/> Yes <input type="radio"/> No reset
What respiratory support was the patient receiving at the 36 weeks PMA date (either in hospital or elsewhere)?	<input type="radio"/> No support <input type="radio"/> Nasal cannulae (< 2l per min) <input type="radio"/> High flow nasal cannulae (> 2l per min) <input type="radio"/> CPAP <input type="radio"/> NIPPV <input type="radio"/> Invasive PPV reset
Form Status	
Complete?	Complete <input type="button" value="v"/>
<input type="button" value="Save & Exit Form"/> <input type="button" value="Save & Stay"/> <input type="button" value="- Cancel -"/>	

Participant change of status page

This page is *only* used to withdraw participants from the study where consent has been withdrawn. Please always notify the GenOMICC team in these instances.

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	12-12-2024 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 reset
Reason for withdrawal	<input checked="" type="radio"/> Participant declined to give reason <input type="radio"/> Other reset
Withdrawal status	<input type="radio"/> Partial Withdrawal <input checked="" type="radio"/> 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.

Record Active Status page

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.

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=""/> <ul style="list-style-type: none">Ineligible participantParticipant enrolled twice in errorSample collection not completedSample not available - logistical issueSample not available - technical issue- Cancel -
Form Status	
Complete?	