



CLARITY

CLARITY REDCap Guide

Contents

Setting up your REDCap Account	3
Step 1: REDCap account creation email	3
Step 2: Accessing the CLARITY data project	4
Step 3: Adding a new patient record on REDCap	5
Step 4: Filling form 1	6
Step 5: Filling patient details	7
Step 6: Saving progress on REDCap	8
Step 7: Completion of form on REDCap and going to the next form	9
Step 8: Viewing patient records	11
Important and helpful tips for data collection (Please read!)	13
1. Contents of each form	13
2. Storage of data and patient records	17
FAQ	19

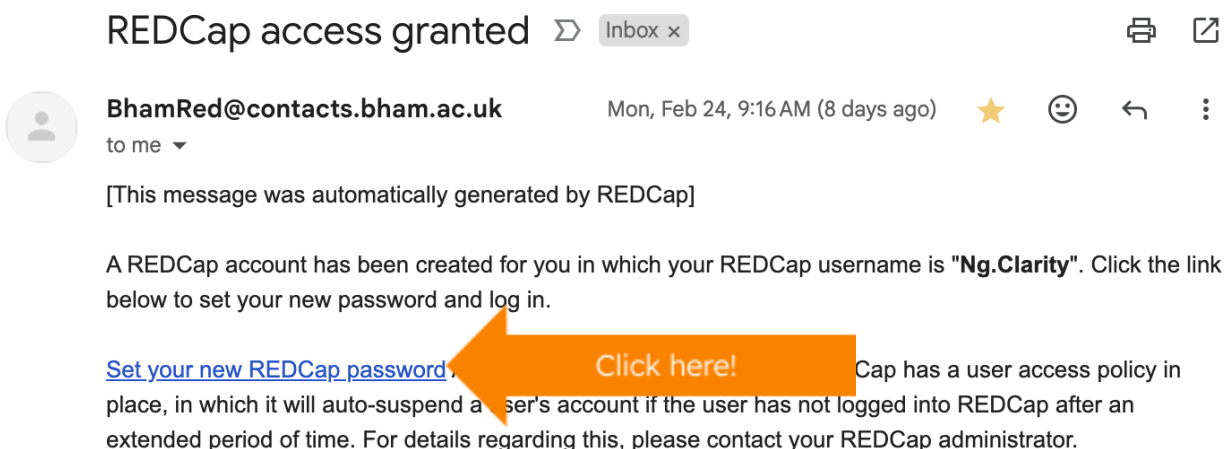
Setting up your REDCap Account

Step 1: REDCap account creation email

You will receive your REDCap login details via an email titled "REDCap Access Granted." Please check your inbox as well as your junk/spam folder, as it may have been filtered there.

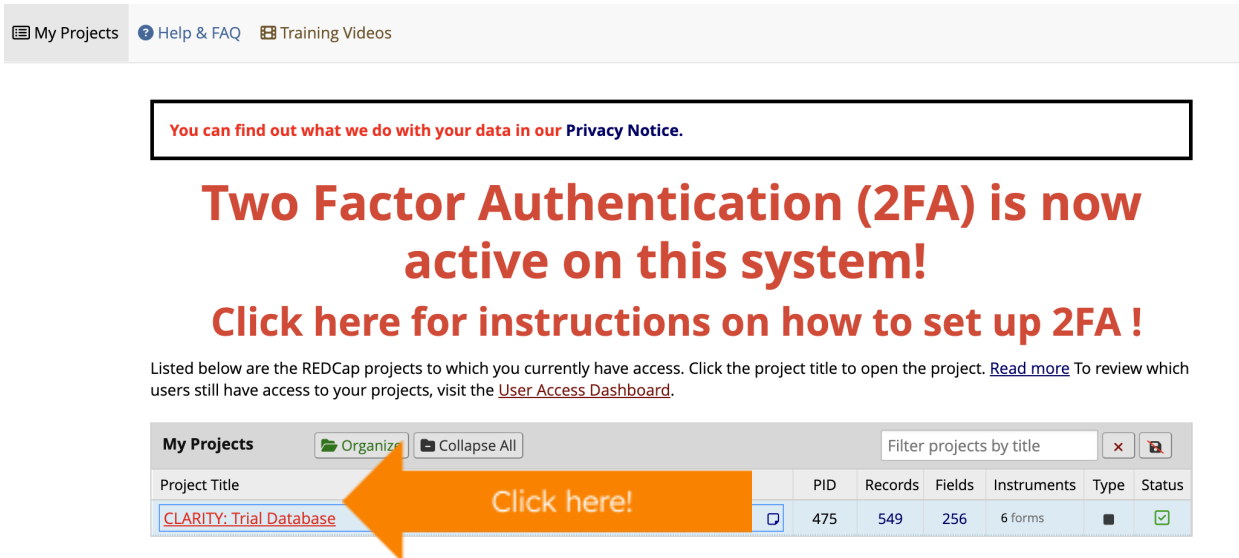
This email will include your username and a link to set up your new password. To access it, click on "Set your new REDCap password."

Important: This is the only way to create your REDCap account. Be sure to keep this email safe!



Step 2: Accessing the CLARITY data project

Once you have set your password and your account is created, login to REDCap through the same website (<https://bistc.redcap.bham.ac.uk/>) Your home page should look like the image below:



The screenshot shows the REDCap home page. At the top, there is a navigation bar with links for 'My Projects', 'Help & FAQ', and 'Training Videos'. Below this, a message box states: 'You can find out what we do with your data in our [Privacy Notice](#).' A large red banner in the center reads: 'Two Factor Authentication (2FA) is now active on this system! Click here for instructions on how to set up 2FA !'. Below the banner, a text block says: 'Listed below are the REDCap projects to which you currently have access. Click the project title to open the project. [Read more](#) To review which users still have access to your projects, visit the [User Access Dashboard](#).' The 'My Projects' section features a table with columns: Project Title, PID, Records, Fields, Instruments, Type, and Status. The first row is 'CLARITY: Trial Database' with PID 475, 549 records, 256 fields, 6 forms, and a status of 'Active' (indicated by a green checkmark). A large orange arrow points to the 'CLARITY: Trial Database' project title.

Project Title	PID	Records	Fields	Instruments	Type	Status
CLARITY: Trial Database	475	549	256	6 forms		Active

Click on “CLARITY: Trial Database” to access the project

Note: After logging in, please make sure to set up your password recovery question, which will allow you to use the 'Forgot your password?' link on the login page without the need to contact the REDCap Administrator. You will be prompted to set your recovery question on the My Projects page, but you can also set it on your 'My Profile' page under 'Login-related options'.

Step 4: Filling form 1

Click on the status circle to begin filling in the details.

There will be 6 forms for you to complete. Forms 2 to 5 will only appear once you have completed form 1.

Important note for 30-day follow-up and preventing duplicates:

Please record each patient's **REDCap ID and hospital number (or other identifier) in a local database** to enable you to find their medical records based on their REDCap ID in the future and complete the 30-day follow-up. More information on this can be found under the **Storage of data and patient records section**.

The screenshot shows the REDCap interface for the 'CLARITY: Trial Database' (PID 475). The left sidebar contains navigation links for Project Home and Design, Data Collection, Applications, and Help & Information. The main content area displays the 'Record Home Page' for a new record, 'NEW Record ID 25981-1'. A table lists the data collection instruments and their status:

Data Collection Instrument	Status
Form 1: Patient characteristics	
Form 6: Record management	

A large orange arrow points to the status icon for Form 1, with the text 'Click here!' and a large orange circle containing the number '1'.

Legend for status icons:

- Incomplete (Red circle with white dot)
- Incomplete (no data saved) (Gray circle with white dot)
- Unverified (Yellow circle with white dot)
- Complete (Green circle with white dot)

Step 5: Filling patient details

Begin filling the form on REDCap. Do NOT enter data if your centre does not have R&D approval.

CLARITY: Trial Database PID 475

Actions: [Download PDF of instrument\(s\)](#) [Video: Basic data entry](#)

[Save & Exit Form](#)
[Save & ...](#)
[- Cancel -](#)

Form 1: Patient characteristics

Adding new Record ID 25981-1.

Record ID25981-1

Patient Inclusion

Confirm patient eligibility

Does this patient meet the following criteria?

Include patients:

- Aged 16 to 39
- Right iliac fossa pain
- Under the care of the general surgery team

Exclude patients:

- Previous appendicectomy
- Current pregnancy
- Under the care of another specialty (i.e. urology or medicine)

And your centre has R&D and caldicott approval to upload these data

☒ Yes
☐ No

reset

Age in years at presentation or admission

Patients under 16 and over 39 are not eligible for inclusion in CLARITY

☒ 16 to 20 years
☐ 21 to 30 years
☐ 31 to 39 years

reset

* must provide value

Years (whole years at the time of presentation or admission)

Step

Patient characteristics

Enter patient characteristics on initial presentation or admission, these may be

Step 6: Saving progress on REDCap

If you would like to stop and save your progress, you can click on “Save and Exit form” or the other Save options available.

Comorbidities / long-term health conditions
* must provide value

- ☐ Normal
- ☐ Stroke
- ☐ Coronary artery disease
- ☐ Heart failure
- ☐ Peripheral arterial or vascular disease
- ☐ Heart valve disorders
- ☐ Arrhythmia
- ☐ Venous thromboembolic disease/Pulmonary embolism
- ☐ Hypertension
- ☐ Diabetes mellitus
- ☐ Chronic obstructive pulmonary disease
- ☐ Asthma
- ☐ Transient ischaemic attack
- ☐ Solid organ cancers
- ☐ Haematological cancers (i.e. leukaemia or lymphoma)
- ☐ Metastatic cancers
- ☐ Dementia
- ☐ Depression
- ☐ Bipolar disorder
- ☐ Peptic ulcer disease
- ☐ HIV/AIDS
- ☐ Osteoarthritis
- ☐ Chronic liver disease
- ☐ Inflammatory bowel disease
- ☐ Chronic kidney disease

Form Status

Complete? Incomplete

Save & Exit Form **Save & ...** **- Cancel -**

Click here!

Click here!

Save & Exit Form **Save & ...** **- Cancel -**

Save & Stay
Save & Go To Next Form
Save & Exit Record
Save & Go To Next Record

Step 7: Completion of form on REDCap and going to the next form

Once you have completed the form on REDCap, you can mark it as complete. If you want to exit the form, you can click “Save and Exit Form”. If you would like to continue to fill forms 2 to 6, please click on “Save and Go to Next Form”. **Before doing any of this, please double check to ensure that all forms are complete before you mark it as complete.**

Comorbidities / long-term health conditions
* must provide value

- ☐ None
- ☐ Stroke
- ☐ Coronary artery disease
- ☐ Heart failure
- ☐ Peripheral arterial or vascular disease
- ☐ Heart valve disorders
- ☐ Arrhythmia
- ☐ Venous thromboembolic disease/Pulmonary embolism
- ☐ Hypertension
- ☐ Diabetes mellitus
- ☐ Chronic obstructive pulmonary disease
- ☐ Asthma
- ☐ Transient ischaemic attack
- ☐ Solid organ cancers
- ☐ Haematological cancers (i.e. leukaemia or lymphoma)
- ☐ Metastatic cancers
- ☐ Dementia
- ☐ Depression
- ☐ Bipolar disorder
- ☐ Peptic ulcer disease
- ☐ HIV/AIDS
- ☐ Osteoarthritis
- ☐ Chronic liver disease
- ☐ Inflammatory bowel disease
- ☐ Chronic kidney disease

Form Status

Complete? Click here! Incomplete ▾

Save & Exit Form Save & ... ▾

- Cancel -

Comorbidities / long-term health conditions

* must provide value

☐ Peripheral arterial or vascular disease
☐ Heart valve disorders
☐ Arrhythmia
☐ Venous thromboembolic disease/Pulmonary embolism
☐ Hypertension
☐ Diabetes mellitus
☐ Chronic obstructive pulmonary disease
☐ Asthma
☐ Transient ischaemic attack
☐ Solid organ cancers
☐ Haematological cancers (i.e, leukaemia or lymphoma)
☐ Metastatic cancers
☐ Dementia
☐ Depression
☐ Bipolar disorder
☐ Peptic ulcer disease
☐ HIV/AIDS
☐ Osteoarthritis
☐ Chronic liver disease
☐ Inflammatory bowel disease
☐ Chronic kidney disease

Save & Exit Form

Save & ...

- Cancel -

Form Status

Complete?

Complete

Save & Exit Form

Save & ...

Click here!

Save & Stay

Save & Go To Next Form

Save & Exit Record

Save & Go To Next Record

Step 8: Viewing patient records

To view all the patient records, click on “Record Status Dashboard”.

REDCap
Logged in as ng.clarity | Log out
My Projects
Contact REDCap administrator

Project Home and Design
Project Home · Codebook
Project status: **Production**

Data Collection — gb_TM6_test
Record Status Dashboard
Add / Edit Records
Show data collection instruments
Form 1: Patient characteristics
Form 2: Initial investigations and treatment
Form 3: CLARITY and ambulatory care
Form 4: Clinical management
Form 5: 30-day patient outcomes
Form 6: Record management

Applications
Alerts & Notifications
Calendar
Data Quality and Resolve Issues

Help & Information
Help & FAQ
Video Tutorials
Suggest a New Feature
Contact REDCap administrator

CLARITY: Trial Database PID 475

Actions: Download PDF of instrument(s) Video: Basic data entry

Form 1: Patient characteristics
You may view an existing record/response by selecting it from one of the drop-down lists below. The records are separated into each drop-down list according to their status for this particular data collection instrument. To create a new record/response, click the button below.

Total records: 550 / In group: 1

-- select record --
Complete Records (1) -- select record --
Add new record

Show Unverified Records above

Data Search
Choose a field to search (excludes multiple choice fields) All fields
Search query
Begin typing to search the project data, then click an item in the list to navigate to that record.

Upon complete of form 1 and marking it as complete, the patient record now will have a green circle on form 1. Please fill all the forms by the end of collection.

REDCap
Logged in as ng.clarity | Log out
My Projects
Contact REDCap administrator

Project Home and Design
Project Home · Codebook
Project status: **Production**

Data Collection — gb_TM6_test
Record Status Dashboard
Add / Edit Records
Show data collection instruments

Applications
Alerts & Notifications
Calendar
Data Quality and Resolve Issues

Help & Information
Help & FAQ
Video Tutorials
Suggest a New Feature
Contact REDCap administrator

CLARITY: Trial Database PID 475 Page speed was boosted using Rap

Record Status Dashboard (all records)
Displayed below is a table listing all existing records/responses and their status for every data collection instrument (and if longitudinal, for every event). You may click any of the colored buttons in the table to open a new tab/window in your browser to view that record on that particular data collection instrument. Please note that if your form-level user privileges are restricted for certain data collection instruments, you will only be able to view those instruments, and if you belong to a Data Access Group, you will only be able to view records that belong to your group.

Dashboard displayed: [Default dashboard] v
Displaying record Page 1 of 1: "25981-1" through "25981-1" v of 1 records

+ Add new record

Displaying: Instrument status only | Lock status only | All status types

Record ID	Form 1: Patient characteristics	Form 2: Initial investigations and treatment	Form 3: CLARITY and ambulatory care	Form 4: Clinical management	Form 5: 30-day patient outcomes	Form 6: Record management
25981-1	●	●	●	●	●	●

Important and helpful tips for data collection (Please read!)

1. Contents of each form

Before filling each form for each patient, please have a look at the top of each form for instructions on what to do. We have also outlined how each form should be filled below. If you are still unsure, please reach out to the relevant WhatsApp group or email us at CLARITY-study@contacts.bham.ac.uk for clarification.

Form 1 - patient characteristics

This form involves adding details such as patient age, sex, BMI, past surgical history, and comorbidities, among other characteristics. It must be completed before filling out the other forms.

Form 1: Patient characteristics

Editing existing Record ID 25981-1.

Record ID 25981-1

Confirm patient eligibility

Does this patient meet the following criteria?

Include patients:

- Aged 16 to 39
- Right iliac fossa pain
- Under the care of the general surgery team

Exclude patients:

- Previous appendicectomy
- Current pregnancy
- Under the care of another specialty (i.e. urology or medicine)

And your centre has R&D and caldicott approval to upload these data

☒ Yes
☐ No

reset

Age in years at presentation or admission

Patients under 16 and over 39 are not eligible for inclusion in CLARITY

* must provide value

☒ 16 to 20 years
☐ 21 to 30 years
☐ 31 to 39 years

Years (whole years at the time of presentation or admission) reset

Step 1

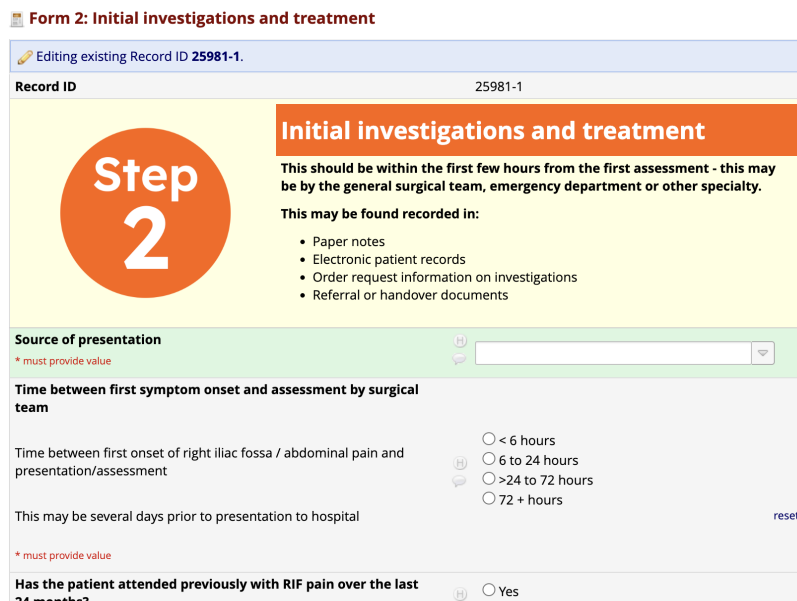
Patient characteristics

Enter patient characteristics on initial presentation or admission, these may be found recorded in:

- Paper notes

Form 2 - any initial investigations and treatment the patient received

This needs to be filled within the first few hours from the first assessment. Important information to obtain includes time between symptom onset and assessment, any RIF pain, the time the patient was assessed, and the grade of the person reviewing the patient at assessment, among other things.



Form 2: Initial investigations and treatment

Editing existing Record ID 25981-1.

Record ID 25981-1

Step 2

Initial investigations and treatment

This should be within the first few hours from the first assessment - this may be by the general surgical team, emergency department or other specialty.

This may be found recorded in:

- Paper notes
- Electronic patient records
- Order request information on investigations
- Referral or handover documents

Source of presentation
* must provide value

Time between first symptom onset and assessment by surgical team

Time between first onset of right iliac fossa / abdominal pain and presentation/assessment

This may be several days prior to presentation to hospital

* must provide value

Has the patient attended previously with RIF pain over the last 24 months?

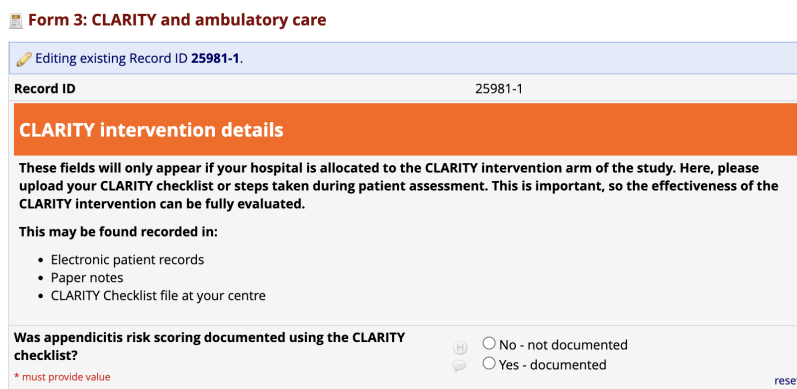
☐ < 6 hours
☐ 6 to 24 hours
☐ >24 to 72 hours
☐ 72 + hours

☐ Yes

reset

Form 3 - upload the steps you followed based on the CLARITY checklist

This will only appear if your site has been allocated to the intervention arm of the trial. Please fill in all the details of the checklist, and if the patient had any outpatient or ambulatory follow-up.



Form 3: CLARITY and ambulatory care

Editing existing Record ID 25981-1.

Record ID 25981-1

CLARITY intervention details

These fields will only appear if your hospital is allocated to the CLARITY intervention arm of the study. Here, please upload your CLARITY checklist or steps taken during patient assessment. This is important, so the effectiveness of the CLARITY intervention can be fully evaluated.

This may be found recorded in:

- Electronic patient records
- Paper notes
- CLARITY Checklist file at your centre

Was appendicitis risk scoring documented using the CLARITY checklist?
* must provide value

☐ No - not documented
☐ Yes - documented

reset

Form 4 - clinical management of the patient

Only complete this form once the patient received an operation or at 30 days after initial admission or assessment! This section is important as we will need to know if the patient received any operation within the 30-day period.

Step 4

Clinical management and surgery

This refers to any intervention for any condition underlying the clinical presentation during the admission.

This may be found recorded in:

- Paper notes
- Electronic patient records
- Operation notes
- Prescription charts

Did the patient receive an operation within 30 days of admission / assessment?
For any indication - not just appendicitis

☐ Yes
☐ No

* must provide value [reset](#)

Was non-operative management attempted?

☐ No - initial decision for operative management
☐ Yes - nonoperative management initially attempted but then failed
☐ Yes - nonoperative management successful

Within 30 days of presentation [reset](#)

When was the patient discharged

☐ < 24 hours
☐ 24 to 48 hours
☐ >48 to 72 hours
☐ 72+ hours
☐ N/A patient was not admitted to hospital

* must provide value [reset](#)

Form Status

Form 5 - 30-day outcomes

Importantly, any patient re-attendance (missed appendicitis, ongoing symptoms or post-op complications) should be captured here (under the form description section). Outcomes include death within 30 days, critical care admission and any readmission within the 30 days. Fill this form:

- **IF** the patient experienced any of the mentioned outcomes
- **OR** after 30 days from admission or assessment!



30-Day patient outcomes

Within 30 days of presentation, with day of presentation taken as day 0. If an outcome occurs outside this timeframe, record it as if it had not happened.

This may be found recorded in:

- Paper notes
- Electronic patient records
- Order requests or results
- Discharge and clinic letters

Underlying final diagnosis causing symptoms on presentation

* must provide value

Mortality, length of stay, critical care, readmission and reintervention

Did the patient die within 30 days of discharge/assessment in hospital?

* must provide value

☐ No - Alive
 ☐ Yes - Died out of hospital
 ☐ Yes - Died in hospital

[reset](#)

Critical care admission (including intensive care and high dependency units)

* must provide value

☐ No
 ☐ Yes, planned admission from theatre
 ☐ Yes, unplanned admission from theatre
 ☐ Yes, unplanned admission from ward

[reset](#)

30-day reoperation or reintervention for any cause (tick all that apply)

* must provide value

☐ No
 ☐ Yes - return to theatre
 ☐ Yes - endoscopic reintervention
 ☐ Yes - interventional radiology reintervention

2. Storage of data and patient records

To ensure accurate data collection and prevent duplicate entries in the CLARITY trial, we strongly advise each site to maintain a secure local database of patients and their assigned REDCap numbers. This helps in tracking enrolled patients, avoiding data duplication, and ensuring robust follow-up.

Here are some examples of how you can maintain the **local database**:

1. **Secure hospital computer system** – A dedicated, password-protected Excel spreadsheet or database stored on a hospital-approved network drive, accessible only to authorised staff.
2. **Paper records** – A printed list kept in a locked office or research office, accessible only to the study team.

Each method must comply with **local hospital data governance policies** and **General Data Protection Regulation (GDPR)** standards where applicable.

To ensure patient confidentiality and compliance with the data security policies, follow these best practices:

1. **Access Control**: Only authorised members of the CLARITY research team should have access to the database. Use password-protected files, encrypted hospital databases, or secure filing systems for paper records.
2. **Regular Updates & Maintenance**: Ensure data is updated promptly after patient inclusion or follow-up. Outdated records should be reviewed and securely deleted per hospital policy.
3. **Anonymisation**: Never store patient names or personal identifiers. If initials or hospital numbers are used, ensure they are stored separately from patient outcomes.
4. **Data Transfer & Sharing**: Avoid emailing spreadsheets or sending data via unsecured channels. If team members need access, use a hospital-approved secure drive or internal research portal.

5. Retention & Deletion Policies: Once the trial is complete, patient records must be securely destroyed following local policies and GDPR guidelines. Hospitals may have mandatory retention periods for research data—ensure compliance with these policies.

Preventing Duplication & Errors

- Before entering a new patient on REDCap, cross-check their details against the local database.
- If a patient re-presents to the hospital within the study period, update their existing record rather than creating a new entry.
- If an error or duplicate entry occurs, flag it for review immediately

FAQ

1) What do I do if I (or someone on my team) do not have REDCap access?

Contact your site coordinator as soon as possible and they will get that issued for you quickly.

2) Will the centre not be included if 95% data is not complete?

For centre eligibility, the patients that are included need to have 95% data completeness. If there are any issues with this, please get in touch with your site coordinator as soon as possible so we can best support you for data inclusion.

3) Can we use printed case report forms (CRFs)?

Yes, you can, but paper CRFs should NOT leave the hospital grounds. They should be kept in a safe place in the hospital in accordance with the research ethics rules of your site (typically this is a secure locked cupboard only accessible to yourselves). For example, some sites require paper CRF storage for up to 18 months. Collaborators are encouraged to input data directly into REDCap where possible.

4) What should I do if I there is a mistake with the data?

You can go back and edit the entry if it is still within the data collection period. If the mistake is noticed after the data lock, please contact your site coordinator immediately.

5) Can I delete a record in REDCap?

Deleting records is typically restricted to administrators. If you need to remove a record, contact your site coordinator.

6) What should we do when a patient self-discharges?

If a patient self-discharges during their initial hospital attendance, it is important to ensure that their data remains complete and that follow-up is attempted where possible. Fill in the CRF as much as possible. Once the patient is entered into the CLARITY database, ensure their unique REDCap number is retained to prevent duplicate entries if they re-present.

7) What is non-operative management of appendicitis?

Non-operative management of appendicitis refers to the treatment of appendicitis without surgical intervention in patients who meet the inclusion criteria. This includes individuals aged 16 to 39 years (inclusive) who present to the hospital with right iliac fossa pain and are assessed by the general surgery team. Eligible patients may be in any hospital setting including the emergency department, surgical admissions unit, and paediatrics ward.