CLARITY REDCap Guide

Contents

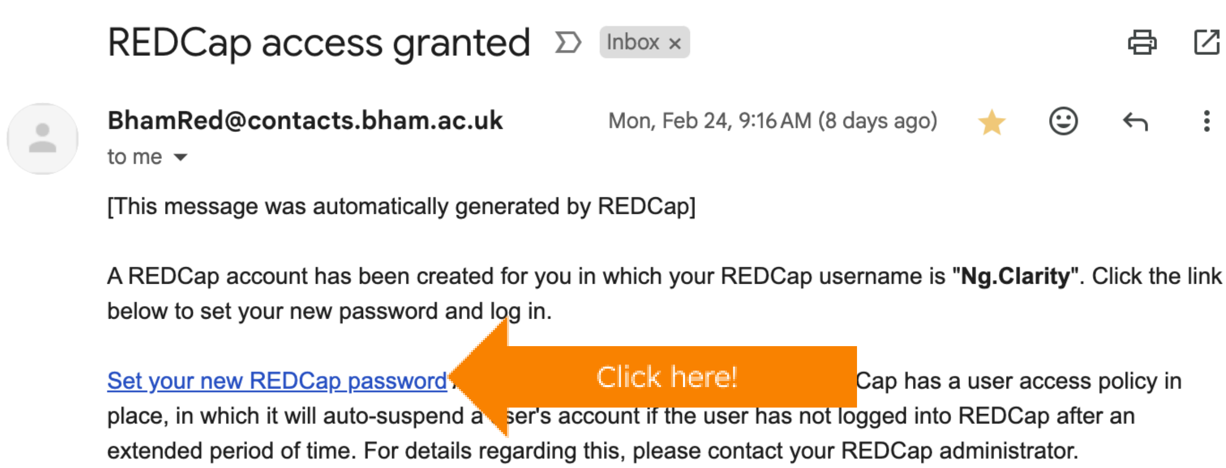
Setting up your REDCap Account

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:

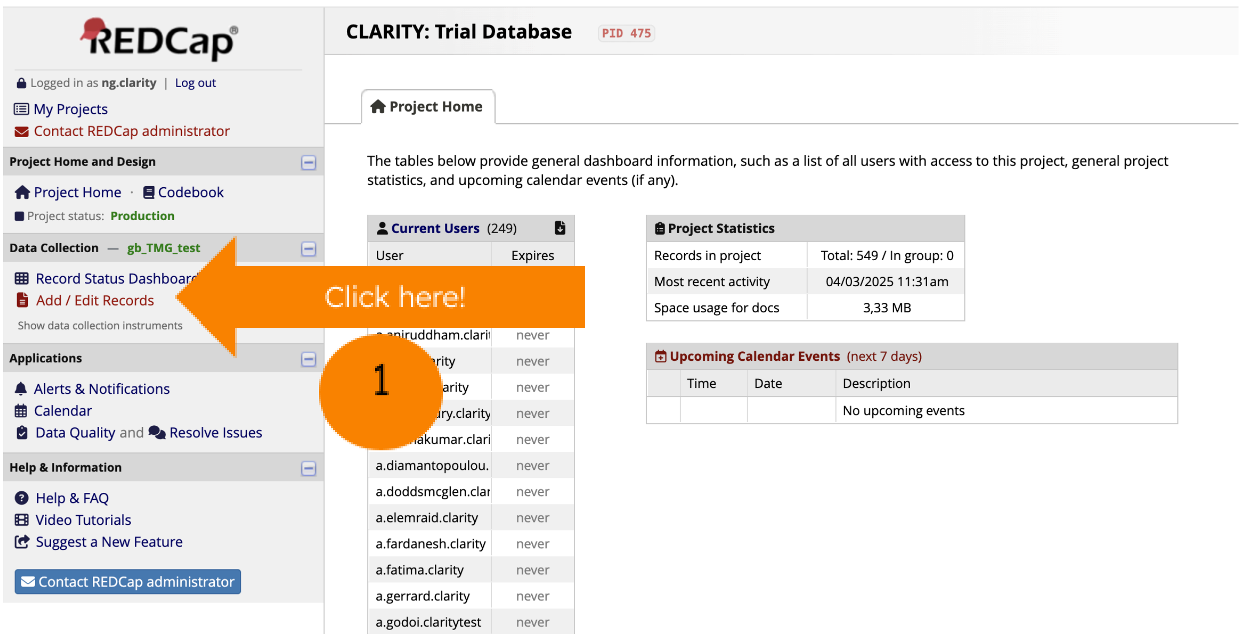
Click on “CLARITY: Trial Database” to access the project

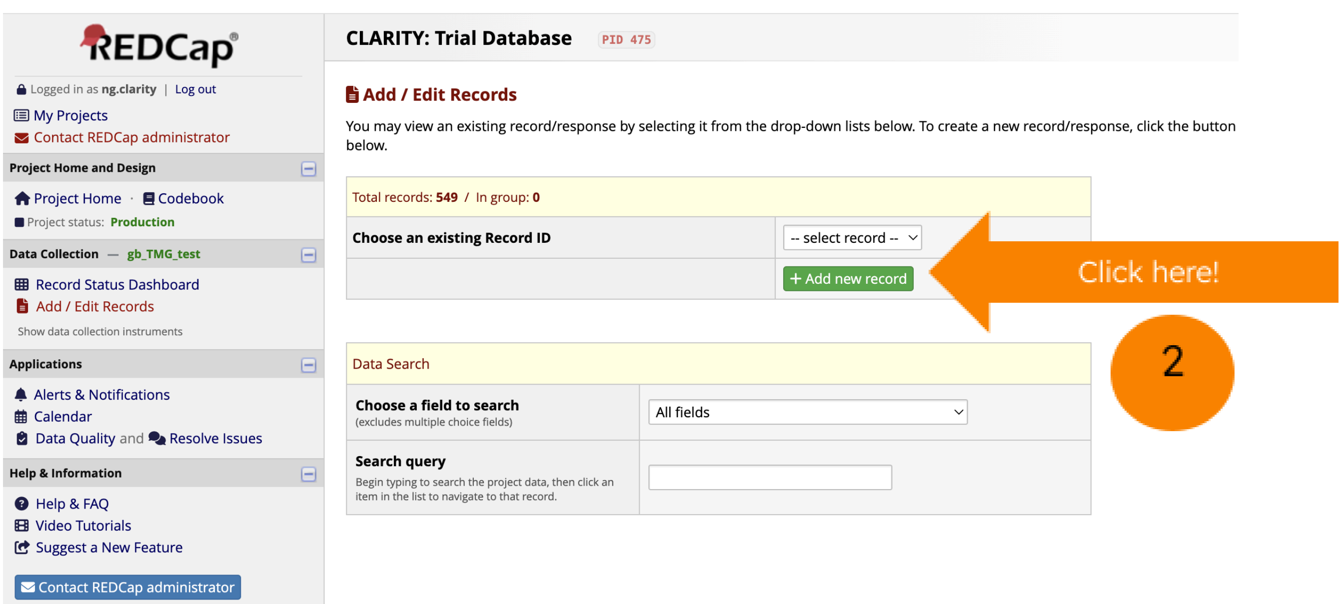
Note: After logging in, please make sure to set up your password recovery question, which will allow you to use the 'Forgot your password?' link on the login page without the need to contact the REDCap Administrator. You will be prompted to set your recovery question on the My Projects page, but you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

Step 3: Adding a new patient record on REDCap

Before adding a new patient **please check if this patient has not already been included** by looking in the local database or patient's notes. More information on this under **Storage of data and patient records section**.

To add a patient record, click on "Add/Edit Records" and then "Add new record"





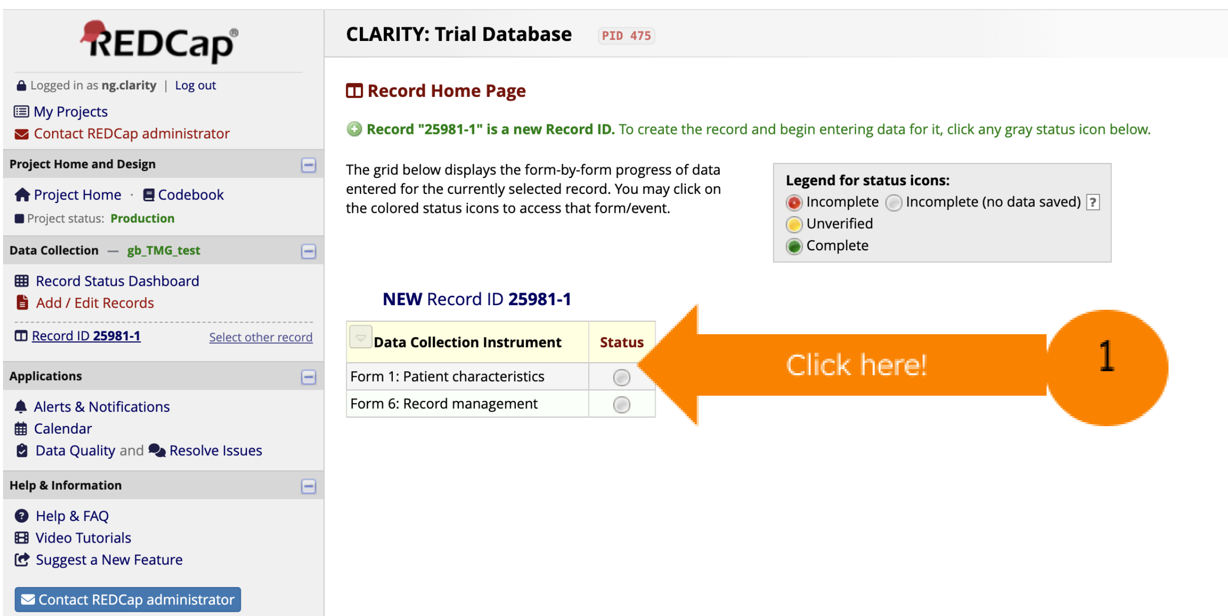
Step 4: Filling form 1

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.**

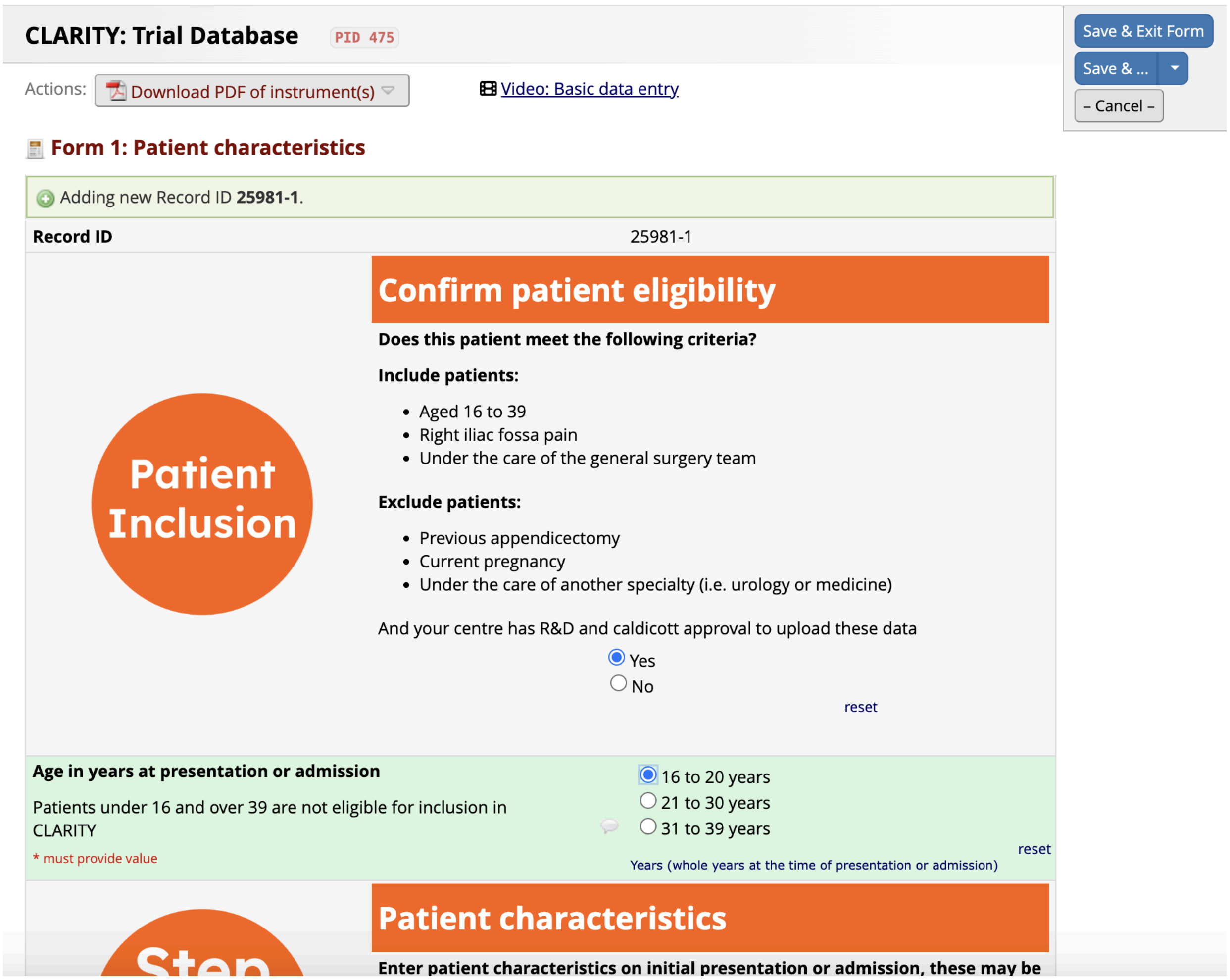
Important note for 30-day follow-up and preventing duplicates:

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**.



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

Save & Exit Form

Save & ...

– Cancel –

Actions: Download PDF of instrument(s)

Video: Basic data entry

Form 1: Patient characteristics

Adding new 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

reset

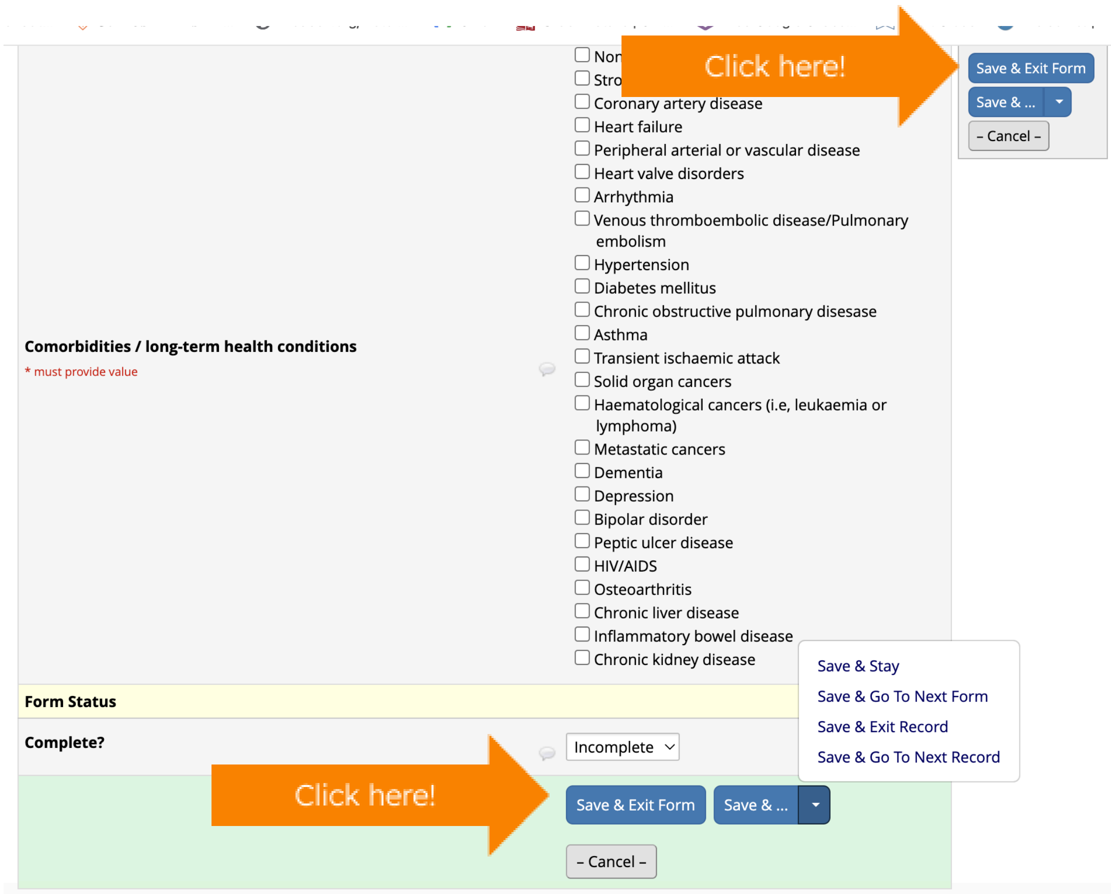
Years (whole years at the time of presentation or admission)

Patient characteristics

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

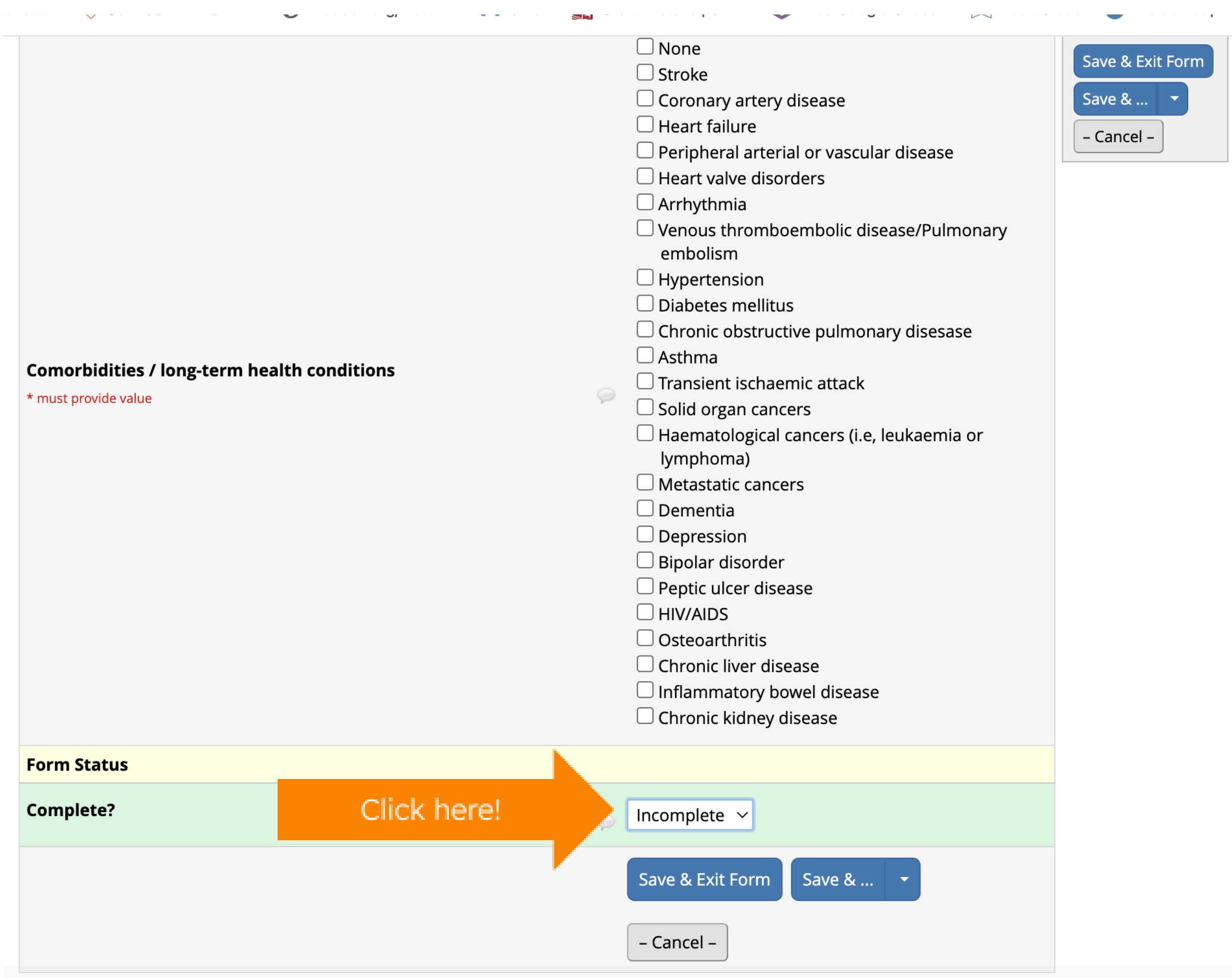
Step 6: Saving progress on REDCap

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



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.**


Save & Exit Form
Save & ...
– Cancel –

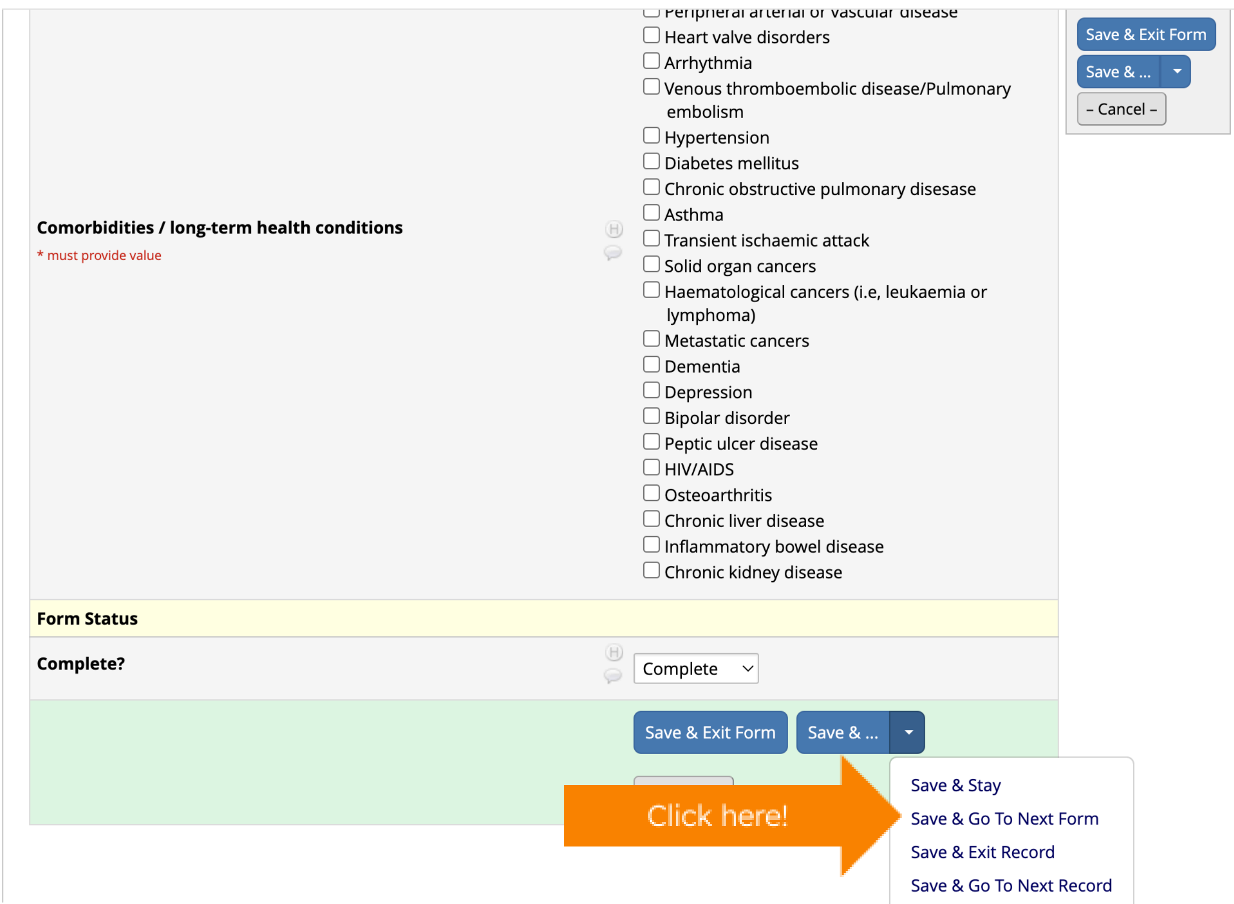
Comorbidities / long-term health conditions
* must provide value

- ☐ 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

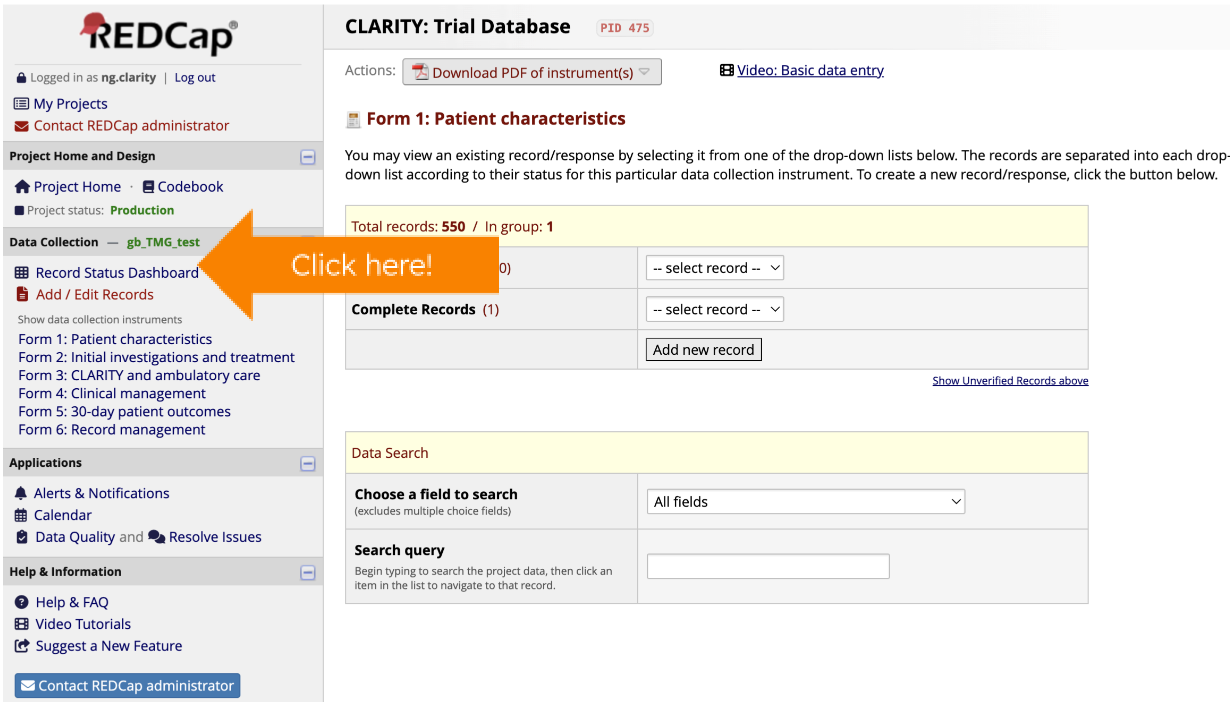
Complete? Click here! Incomplete

Save & Exit Form
Save & ...
– Cancel –

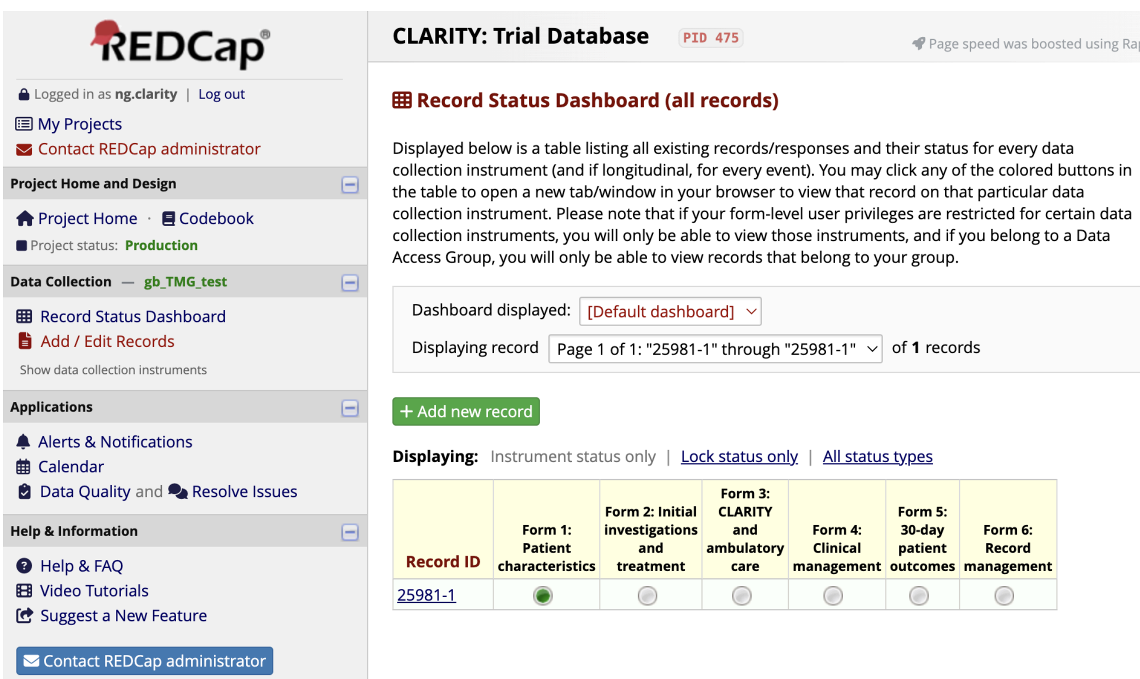

Peripheral arterial or vascular disease
Heart valve disorders
Arrhythmia
Venous thromboembolic disease/Pulmonary embolism
Hypertension
Diabetes mellitus
Chronic obstructive pulmonary disesase
Asthma
Transient ischaemic attack
Solid organ cancers
Haematological cancers (i.e, leukaemia or lymphoma)
Metastatic cancers
Dementia
Depression
Bipolar disorder
Peptic ulcer disease
HIV/AIDS
Osteoarthritis
Chronic liver disease
Inflammatory bowel disease
Chronic kidney disease
Comorbidities / long-term health conditions
* must provide value
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”.



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.**



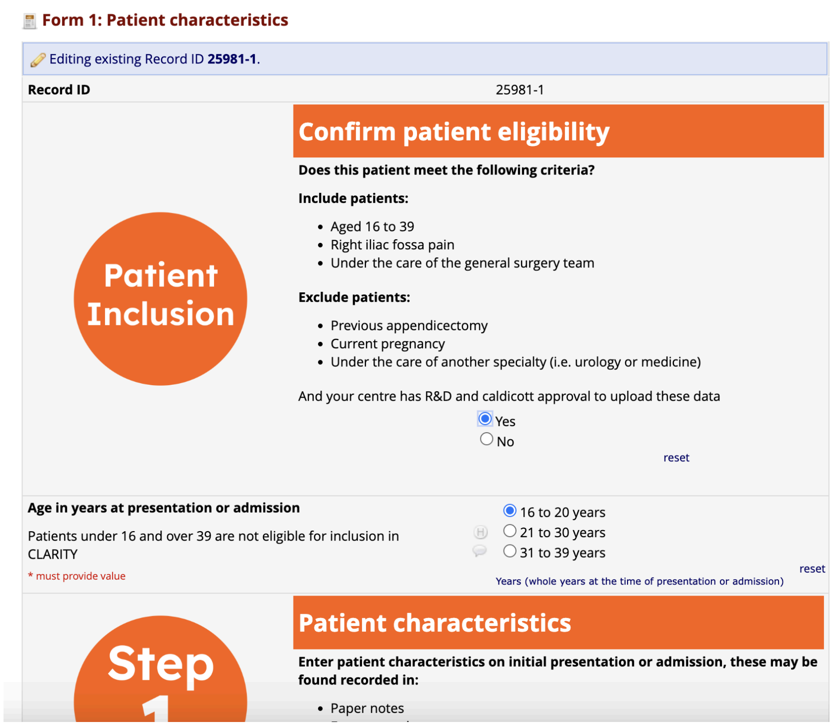
Important and helpful tips for data collection (Please read!)

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.

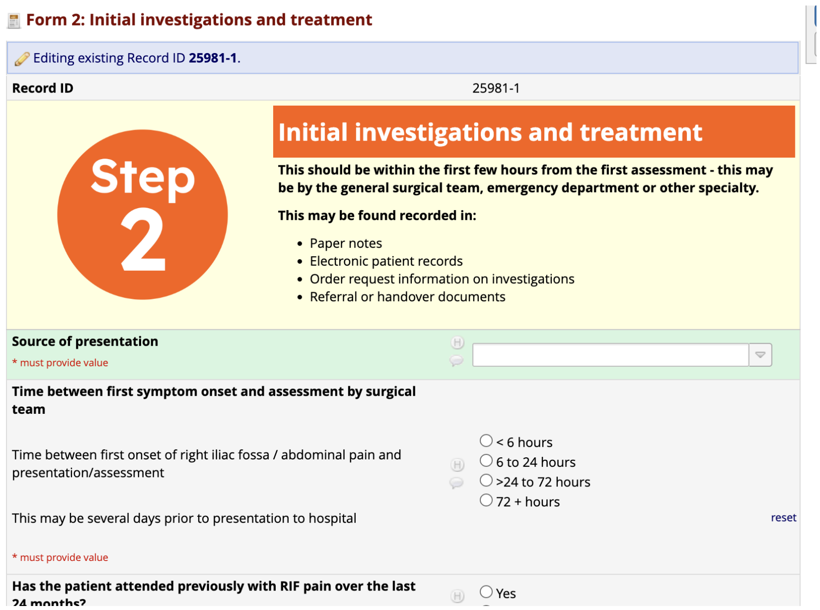
Form 1 - patient characteristics

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 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

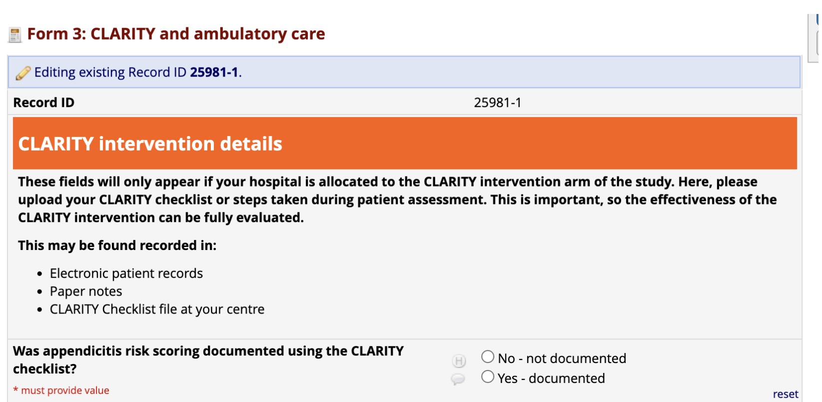
* must provide value

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

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

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:

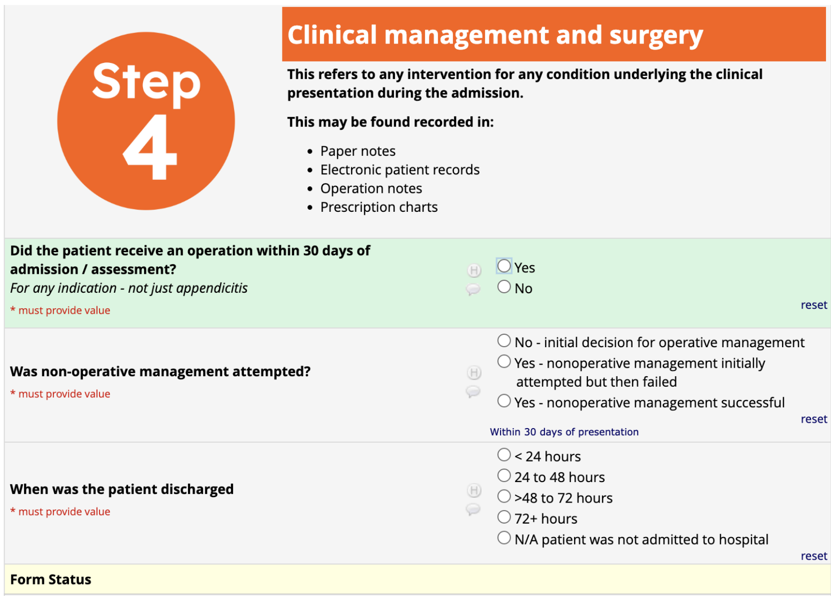
- Electronic patient records
- Paper notes
- CLARITY Checklist file at your centre

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
* must provide value

- Yes
- No

reset

Was non-operative management attempted?
* must provide value

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

reset

Within 30 days of presentation

When was the patient discharged
* must provide value

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

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!**

Final Step

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.