



POET Study: Guide to using REDCap for Data Collection

This guide is to be read and used in conjunction with the study protocol

Project Hub: <https://www.stratacollaboration.com/poet>

Study Protocol: https://www.stratacollaboration.com/files/uqd/f0f5c1_ec8342663acc4e359a5894485c0fe4eb.pdf

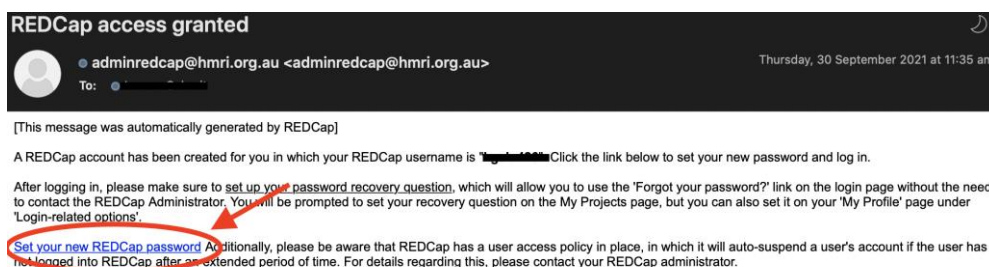
Updated: 16 April 2024

Contents

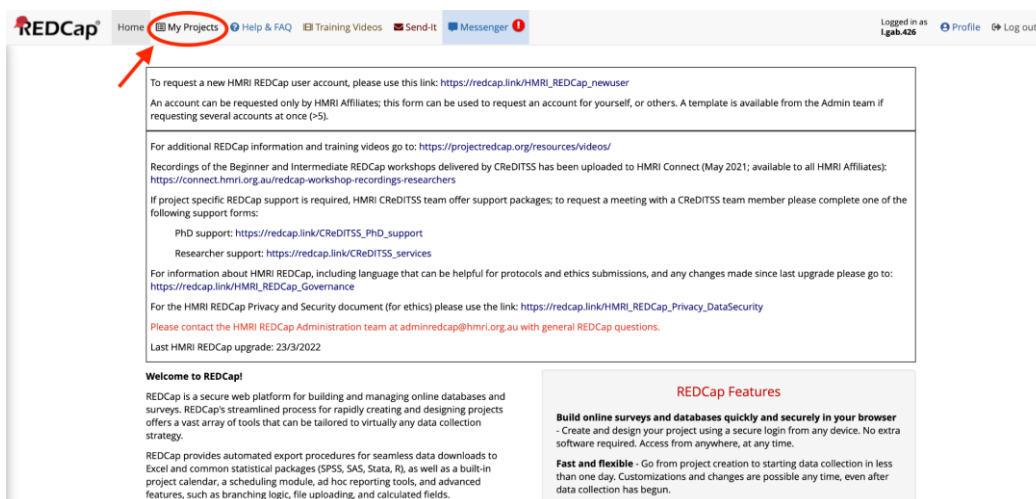
SECTION 1: GETTING STARTED	2
SECTION 2: ENTERING DATA FOR NEW PATIENTS	4
SECTION 3: ENTERING DATA FOR PRE-EXISTING PATIENTS.....	7
SECTION 4: DATA COMPLETENESS	8
SECTION 5: WHERE MIGHT I FIND THE CLINICAL DATA	9
SECTION 6: LOGISTICS FAQs	9
SECTION 7: STUDY SPECIFIC FAQs.....	10

SECTION 1: GETTING STARTED

1. All registered collaborators will receive an email granting access to the REDCap system. Follow the instructions on the email and contact your Local Lead if you have not received this at the start of the project.



2. Click on the email link to login for the first time. You will be prompted to change your password. Follow the instructions to set up a new password.
 - NOTE: your password should be kept secure. Never share your login details with others.
3. Completing the password reset will lead you to the Project Homepage. All subsequent logins will lead you to this page. From this screen select **My Projects**.



4. Select 'POET Data Collection' under my projects.

- This will lead you to the POET study homepage. This page will allow you to perform data entry and data export.

The screenshot shows the POET study homepage. The left sidebar contains navigation links for 'My Projects', 'REDCap Messenger', 'Project Home and Design', 'Data Collection', and 'Applications'. The top navigation bar includes 'Project Home', 'Project Setup', 'Other Functionality', and 'Project Revision History'. The main content area displays a 'Current Users (22)' table, a 'Project Statistics' table, and an 'Upcoming Calendar Events' section.

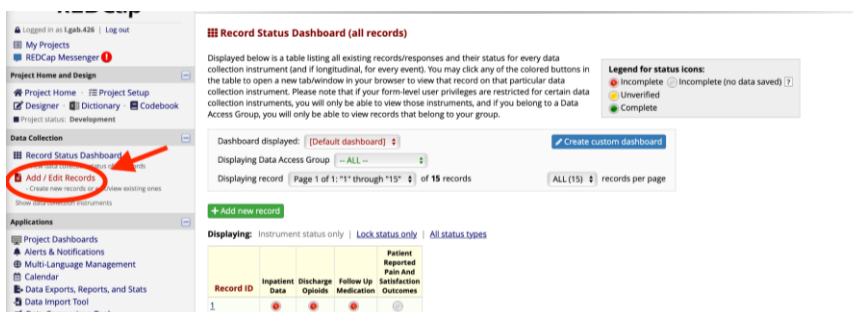
User	Expires
	never
	never
	never
	never
	never
	never
	never
	never
	never
	never
	never
	never
	never
	never
	never
	never
	never
	never
	never
	never
	never

Records in project	15
Most recent activity	21/03/2022 3:17pm
Space usage for docs	2.09 MB

Time	Date	Description
		No upcoming events

SECTION 2: ENTERING DATA FOR NEW PATIENTS

1. Every patient will require **one** record in REDCap each.
2. To create a new record, click 'Add/Edit Records' under the heading 'Data Collection' on the left-hand side of the Project Homepage.



3. Select '+Add new record' for each new patient at your centre. A REDCap study ID will be automatically generated and displayed as the **Record ID**.

OPERAS Data Collection PID: 2966

Add / Edit Records

You may view an existing record/response by selecting it from the drop-down lists below. To create a new record/response, click the button below.

NOTICE: This project is currently in Development status. Real data should NOT be entered until the project has been moved to Production status.

Total records: 15

Choose an existing Record ID:

+ Add new record

Data Search

Choose a field to search (excludes multiple choice fields):

Search query

Begin typing to search the project data, then click an item in the list to navigate to that record.

4. **IMPORTANT:** You cannot record your NHI in REDCap.

Your site will receive a list of potentially eligible patients to screen and mark for inclusion or exclusion.

Each record should have their '**patient ID**' rather than NHI entered on REDCap and their study inclusion status completed.

Patient ID	NHI	Date of index scope	Type	Date of diagnosis	Cancer site	District
lakes_lower_1			Colonoscopy		Colon -ascending colon	Lakes

5. After clicking 'Add new record' you will be taken to the first data collection page. Use this form to enter the patient data you have collected for the study.

PLEASE READ PRIOR TO DATA COLLECTION:

To ensure accuracy, all excluded cases must be done so rigourously.

1. Ensure correct pathology diagnosis dates and type of cancer

Check relevant **pathology/histology reports** based on the date given in your Excel sheet.

If the date on the Excel sheet is incorrect, please enter the **correct** date based on local pathology

2. Ensure it meets the definition for a PCCRC/PEUGIC






The definition of PCCRC/PEUGIC is purely a '**time based definition**'. I.e. a cancer is diagnosed within 6 to 48 months after an index endoscopy, without any other relevant endoscopies in the intervening time.

These cases should included in data collection, **regardless of**:

- Whether the lesion was seen or not at index endoscopy
- Whether or not the cancer was avoidable/unavoidable
- If other districts were involved

Some cases may be synchronous lesions. I.e. cancer is diagnosed at index endoscopy, but another **synchronous** cancer in a different segment was not diagnosed. These cases should also be **included** in data collection

6. All patients that are sent to centres must be marked for inclusion or excluded even if patients are excluded, reason for exclusion must be recorded

Variable: exclusion Branching logic: [inclusion] = '0'

Why were they excluded?

* must provide value

☐ Aged under 18
☐ Not diagnosed between Jan 2008 - Dec 2022
☐ Non-primary GI malignancy
☐ Histological subtype is part of exclusion criteria
☐ Malignancy was diagnosed on the previous scope in the relevant area
☐ No scope of relevant area within 6 to 48 month period prior to diagnosis
☐ Other (please specify)

7. You may save the data on the form at any time by clicking the buttons at the bottom of each data collection form.
- 'Save and stay' saves the record as it is.
 - 'Save & exit record' saves the record and returns the user to the 'Add/Edit Records' homepage.
 - 'Save & go to next form' saves the record and takes the user to the next page in the form.

8. If you save a form with incomplete data, you will be prompted that required fields are missing.
- If you click 'okay' you will return to your incomplete form.
 - If you click 'ignore and leave record' you will return to the 'Add/Edit Records' homepage
 - If you click 'ignore and go to next form' you will be taken to the next page in the record.

Save your progress at frequent intervals on REDCap as REDCap does not automatically save any entered data.

SECTION 3: ENTERING DATA FOR PRE-EXISTING PATIENTS

1. If you'd like to return to a patient at a later date to complete their forms, you can access their record from the 'Add/Edit Records' home page. Using your local cross-reference of hospital IDs and REDCap IDs, you can look up a patient by their REDCap ID in the 'choose an existing Record ID' section or 'search query' section.

Add / Edit Records

You may view an existing record/response by selecting it from the drop-down lists below. To create a new record/response, click the button below.

NOTICE: This project is currently in Development status. **Real data should NOT be entered** until the project has been moved to Production status.

Total records: **16**

Choose an existing Record ID

-- select record --

+ Add new record

Data Search

Choose a field to search
(excludes multiple choice items)

All fields

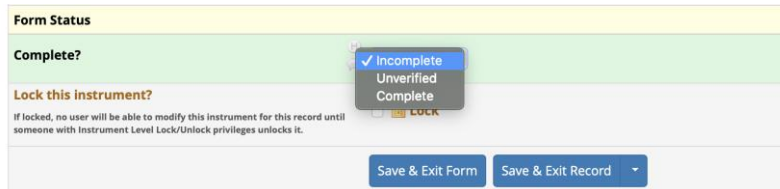
Search query
Begin typing to search the project data, then click an item in the list to navigate to that record.

Save your progress at frequent intervals on REDCap as REDCap does not automatically save any entered data.

SECTION 4: DATA COMPLETENESS

Please complete all fields that appear on each REDCap record.

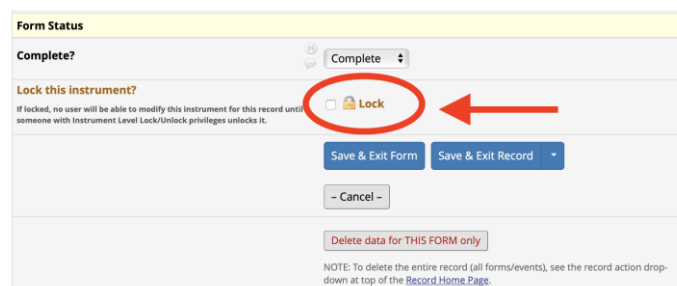
1. When a record is complete (i.e. all possible fields have been completed) you can mark the form as complete by changing the form status field from incomplete to complete..



The screenshot shows the 'Form Status' section of a REDCap record. The 'Complete?' dropdown menu is open, showing three options: 'Incomplete' (selected with a checkmark), 'Unverified', and 'Complete'. Below the dropdown, there is a 'Lock this instrument?' section with a 'LOCK' button. At the bottom, there are 'Save & Exit Form' and 'Save & Exit Record' buttons.

REDCap allows you to mark a form as complete even though your data fields are not filled up. Please ensure that all your data fields are complete before marking it as 'complete'.

2. When a record is complete (i.e. all pages are complete in the data collection form for that record are complete), the record may be 'locked'. This indicates to the POET Data Analysis Team that the data from that patient is final and accurate. To lock data, click 'Lock Record' on the relevant Data collection form.



The screenshot shows the 'Form Status' section of a REDCap record. The 'Complete?' dropdown menu is set to 'Complete'. Below it, the 'Lock this instrument?' section has a 'Lock' button highlighted with a red circle and a red arrow pointing to it. Below the 'Lock' button, there are 'Save & Exit Form', 'Save & Exit Record', and 'Cancel' buttons. At the bottom, there is a 'Delete data for THIS FORM only' button and a note: 'NOTE: To delete the entire record (all forms/events), see the record action drop-down at top of the Record Home Page.'

SECTION 5: WHERE MIGHT I FIND THE CLINICAL DATA

Patient demographics

Should be relatively straightforward for age, ethnicity, etc

Cancer characteristics

It is crucial that **formal pathology reports** are reviewed for this study.

Ministry of Health NZ Cancer Registry coding can be inaccurate (this is the data that we send to local centres), therefore manual verification of tumour histology, location, and grade based on local pathology reports is needed.

This may be in clinic letters, or pathology reports under the laboratory section of your online clinical portal

Endoscopy details

This information will be on endoscopy reports in clinical notes.

In the second half of the 2010s, many centres in NZ shifted to 'Provation' for reporting of scopes. This resulted in more standardised reporting. Prior to this, reporting was more variable and dependent on local programs. Collect what is available.

If you have any technical questions or things you are not sure of please either contact your local lead or the study team at poet.ca.study@gmail.com

SECTION 6: LOGISTICS FAQs

What is the link to the REDCap database?

Link to REDCap: <https://redcap-cmh.hanz.health.nz/index.php?action=myprojects>

How do I get a REDCap login and password?

An REDCap login and password will be emailed to you after your hospital lead completes mini-team registration and emails Aotearoa Clinical Trials. The subject of the email is 'REDCap access granted'.

Who do I contact if I am having problems accessing or using REDCap?

Please contact your local hospital lead in the first instance. If they are unable to assist you, contact the POET study team at poet.ca.study@gmail.com

SECTION 7: STUDY SPECIFIC FAQs

If you have a question about patient inclusion or patient clinical details, please read the protocol. If this has not answered it please contact the study team

My patient had an index colonoscopy then 1 year later was diagnosed with gastric cancer. They did not have a prior gastroscopy within the 6 to 48 month period, only colonoscopies. Should they be included?

No. This patient did not have an index colonoscopy of the relevant area.

My patient had a lesion seen on prior endoscopy and malignancy was suspected but not confirmed by biopsy. A management plan was made after this. Should this be included?

Yes, it is important to what proportion of these cases are due to delays in diagnosis/treatment. This could be classified as a World Endoscopy Organisation Class C lesion (lesion not resected) – potentially avoidable.

My patient had a colonoscopy prior to their diagnosis of cancer and a lesion endoscopically resected. The lesion wasn't missed but they developed a cancer 1 year later. Should I still collect data on this case?

Yes, it is important to know if these were avoidable or unavoidable PCCRC/PEUGIC cases. This could be classified as a World Endoscopy Organisation Class D lesion (incompletely resected).

My patient had lesions seen on prior endoscopy which weren't excised, and a subsequent procedure for excisions was booked for them which happened 7 months later. On subsequent endoscopy, a malignant lesion was found. Should I still collect data on this case as lesions were seen on the prior scope?

Yes, it is important to know if these were avoidable or unavoidable PCCRC/PEUGIC cases. This would potentially be classified as a World Endoscopy Organisation Class C lesion (lesion not resected) – potentially avoidable.

My patient had a lesion seen on prior endoscopy, but they weren't fit for surgery, so no follow up was scheduled. They later developed a cancer. Should I collect data on this case?

Yes, it is important to know if these were avoidable or unavoidable PCCRC/PEUGIC cases.

A cancer was diagnosed on the index endoscopy, but they developed another synchronous cancer in a different segment of the GI tract, should this patient be included?

Yes, data on synchronous cancers is important and data should be collected on the synchronous cancer which was not seen on index endoscopy.

My patient did not have a lesion detected on index endoscopy, but they had one at their scheduled follow up 3.5 years later and it was decided this was a 'new' cancer. Should this be included?

Yes, it is important to what proportion of these cases are likely true new interval cancers.

The patient had high grade dysplasia in their Barrett's oesophagus on index scope, they had cancer detected on their scheduled follow up 1 year later. Should this be included?

Yes, data should be collected on these patients.

My patient moved districts and was diagnosed with cancer somewhere else. I cannot see this data. Should I include them?

Yes they should be marked for inclusion. Please contact the study team about these cases.

What constitutes adequate photo documentation in this study?

If you have any doubts about the quality of photo documentation, please email the study team. Deidentified photos may be reviewed later.