



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/ugd/f0f5c1_ec8342663acc4e359a5894485c0fe4eb.pdf

Updated: 16 April 2024



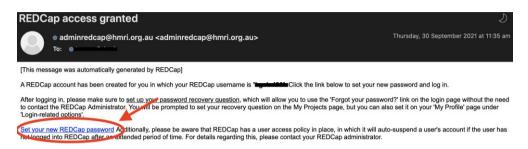
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SECTION 1: GETTING STARTED

 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.
- 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.*

REDCap	Home	My Projects @ Help & FAQ I Training Videos Send-It Messenger		Logged in as I.gab.426	• Profile	🕪 Log out
		To request a new HMBI REDCap user account, please use this link: https://redcap.link/HM An account can be requested only by HMRI Affiliates; this form can be used to request an requesting several accounts at once (~5). For additional REDCap information and training videos go to: https://projectredcap.org/re Recordings of the Beginner and Intermediate REDCap workshops delivered by CReDITSS I	account for yourself, or others. A template is available from the Admin team sources/videos/			
		https://connect.html.org.au/redcap-workshop-recordings-researchers If project specific REDCap support is required, HMRI CREDITSS team offer support packages; to request a meeting with a CREDITSS team member please complete one of the following support forms: PhD support: https://redcap.link/CREDITSS_PhD_support Researcher support: https://redcap.link/CREDITSS_services For information about HMRI REDCap, including language that can be helpful for protocols and ethics submissions, and any changes made since last upgrade please go to: https://redcap.link/HMRI_REDCap_Governance For the HMRI REDCap_Forway and Security document (for ethics) please use the link: https://redcap.link/HMRI_REDCap_Privacy_DataSecurity Please contact the HMRI REDCap Administration team at adminredcap@hmri.org.au with general REDCap questions. Last HMRI REDCap upgrade: 3/24/2022				
		Welcome to REDCap! REDCap is a secure web platform for building and managing online databases and surveys. REDCap's streamlined process for rapidly creating and designing projects offers a vast array of tools that can be tailored to vitrually any data callection strategy. REDCap provides automated export procedures for samiless data downloads to Excel and common statistical packages (SPSS, SAS, SRat, R), as well as a built-in project calendar, as branching logic, file uploading, and calculated fields.	REDCap Features Build online survey and databases quickly and securely in your bro - Create and design your projed uning a secure login from any device. No software required. Access from anywhere, at any time. Fast and flexible - Go from project creation to starting data collection in than one day. Customizations and changes are possible any time, even a data collection has begun.	extra less		

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



5. This will lead you to the POET study homepage. This page will <u>allow</u> you to perform data entry and data export.

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🗣 Field Comment Log
E File Repository never
L User Rights and III DAGs Amage Locking/E-signatures
Customize & Manage Locking/E-signatures Data Quality never



- 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.

Logged in as Lgab.426 Log out My Projects REDCap Messenger	Record Status Dashboard (all records) Displayed below is a table listing all existing records/responses and their status for every data				
Project Home and Design	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				
	the table to open a new tablewindow in your browser to view that record on that particular data collection instruments, you will only be able to view hobie instruments, and if you being to a Data Access Croix, you will only be able to view records that being to your group.				
Data Collection	Dashboard displayed: [Default dashboard]				
Record Status Dashboard read status Dashboard read status trans of an and read status trans of an and read status transition of an and read status transition of an and read status transitions of an and and read status transitions	Desphaying record (Page 1 of 1:*** through *15* \$) of 13 records ALL(15) \$ records per page \$ 4066 new record				
Applications 😑					
🕎 Project Dashboards	Displaying: Instrument status only Lock status only All status types				
Alerts & Notifications Multi-Language Management Calendar Language Advised Ad	Record ID Base Opide Mediation Outcome				
Data Import Tool Data Comparison Tool					

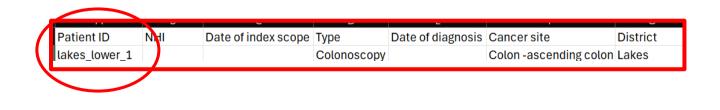
3. Select '+Add new record' for each new patient at your centre. A REDCap study ID will be automatically generated and displayed as the *Record ID*.

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 buttor 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 - select record - 💠			
	+ Add new record		
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.			

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

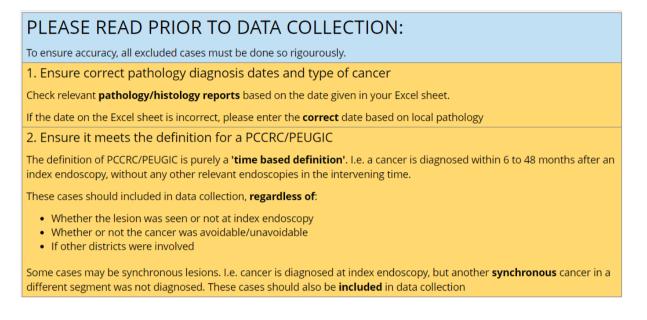
Your site will receive a list of potentially eligible patients to screen and mark for inclusion or exclusion.

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





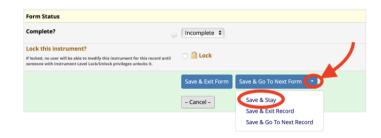
5. After clicking 'Add new record' you will be taken to the first data collection page. Use this form to enter the patient data you have collected for the study.



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



- 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.

Modif	fy instrument 🛛 🔀 Download PDF of instrument(s) 🕙 🛛 🖽 <u>Video: Basic data en</u>	iry.
nt D	NOTE: Some fields are required!	×
xistin	Your data was successfully saved, but you did not provide a value for some fields that require a value. Please enter a value for the fields on this page that are listed below.	No A:
	Provide a value for • Data collection period • Date of Birth • Gender	d Hom
mog	• Ethnic group	
ion alue	ASA physical status	- 10
h	This is often found in the Anaesthetics report.	
alue	Does the patient have the following measurements recorded? BMI category	
value	Underlying co-morbidities (select all that apply) Any relative or absolute contraindications to opioid use? (select all that apply) Any relative or absolute contraindications to NSAID use? (select all that apply) Smoking status Vaoing status	
p	Alcohol consumption (standard drinks/week)	
alue	Surgical procedure • Indication for surgery	- 10
l sta	Urgency Complications during inpatient stay (Clavien-Dindo grade)	
ouna	Date of admission Date of procedure	g the p
value	• Date of discharge • Referral to Acute Pain Service for difficulty managing pain?	Syster s-class
tien nts i	Okay Ignore and leave record Ignore and go to next form	1
alue		-

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

 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				
ou may view an existing record/responselow.	e by selecting it from the	drop-down lists below. To	create a new record/resp	oonse, click the butto
NOTICE: This project is currently i project has been moved to Production		Real data should NOT b	be entered until the	
Total records: 16		\frown		
Choose an existing Record ID		select record 🗘		
Data Search				
Choose a field to search (excludes matche choice neits)	All fields		¢	
Search query Begin typing to search the project data, then click a item in the list to navigate to that record.	n			

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



SECTION 4: DATA COMPLETENESS

Please complete <u>all</u> 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..

Complete?	
	/ incomplete
Lock this instrument? If locked, no user will be able to modify this instrument for this record until	Complete
someone with Instrument Level Lock/Unlock privileges unlocks it.	

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.

Form Status	
Complete?	Complete 🛟
Lock this instrument? If locked, no user will be able to modify this instrument for this record until someone with Instrument Level Lock/Unlock privileges unlocks it.	
	Save & Exit Form Save & Exit Record -
	– Cancel –
	Delete data for THIS FORM only
	NOTE: To delete the entire record (all forms/events), see the record action drop- down at top of the <u>Record Home Page</u> .



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 <u>histology</u>, <u>location</u>, <u>and grade</u> based on local pathology reports is needed.

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

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 <u>poet.ca.study@gmail.com</u>



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 <u>not confirmed by biopsy</u>. 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 <u>endoscopically resected</u>. 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 <u>subsequent procedure for excisions was booked for them</u> 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 <u>different</u> 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.