

REDCap User Guide 3

Entering Patient Data on REDCap

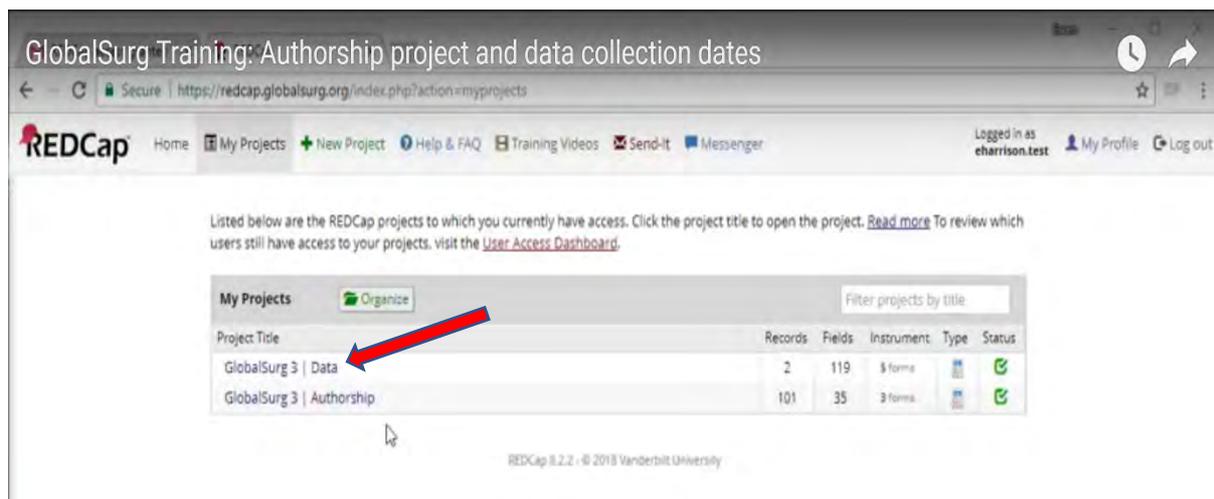
GlobalSurg Training

Entering patient data on REDCap



Prerequisite:

We also use REDCap to collect patient data, and that is done within the “Data” project.



GlobalSurg Training: Authorship project and data collection dates

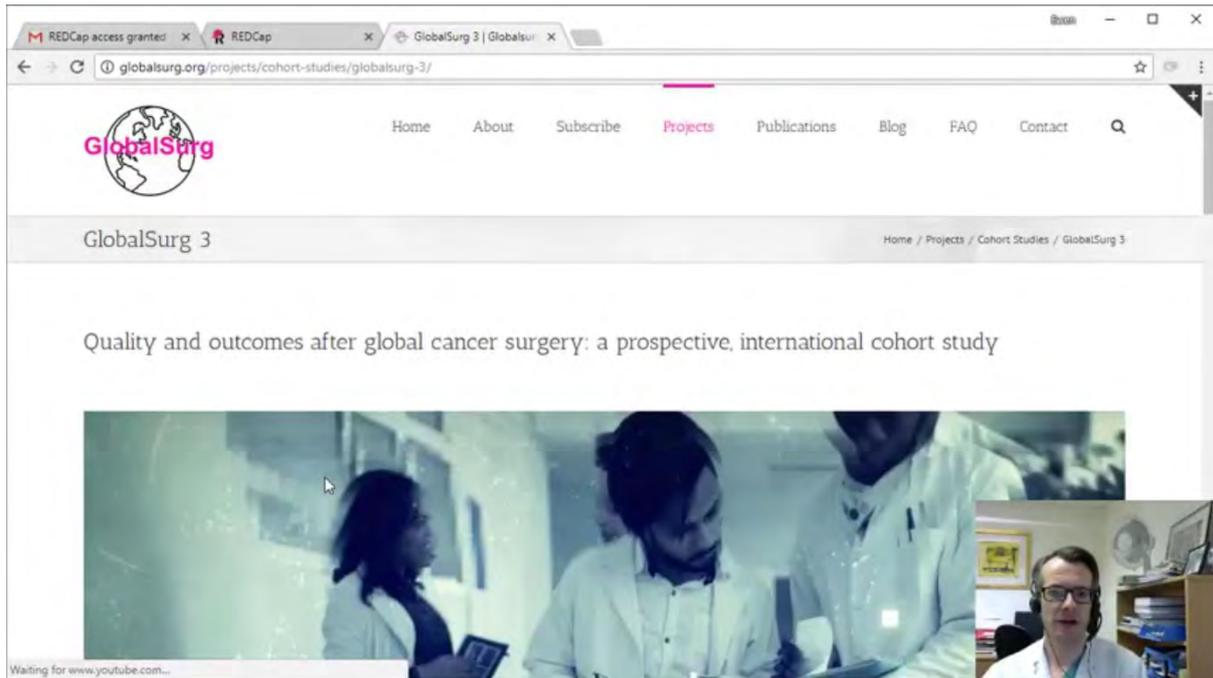
Secure | <https://redcap.globalsurg.org/index.php?action=myprojects>

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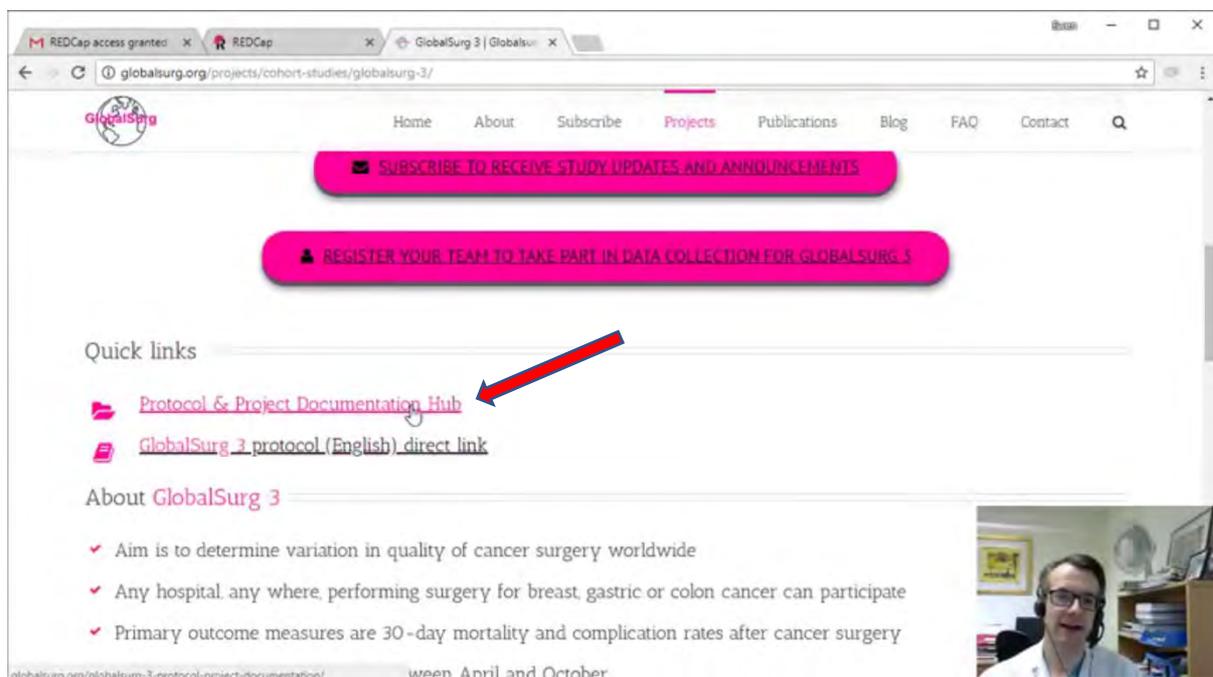
Listed below are the REDCap projects to which you currently have access. Click the project title to open the project. [Read more](#) To review which users still have access to your projects, visit the [User Access Dashboard](#).

Project Title	Records	Fields	Instrument	Type	Status
GlobalSurg 3 Data	2	119	3 forms		
GlobalSurg 3 Authorship	101	35	3 forms		

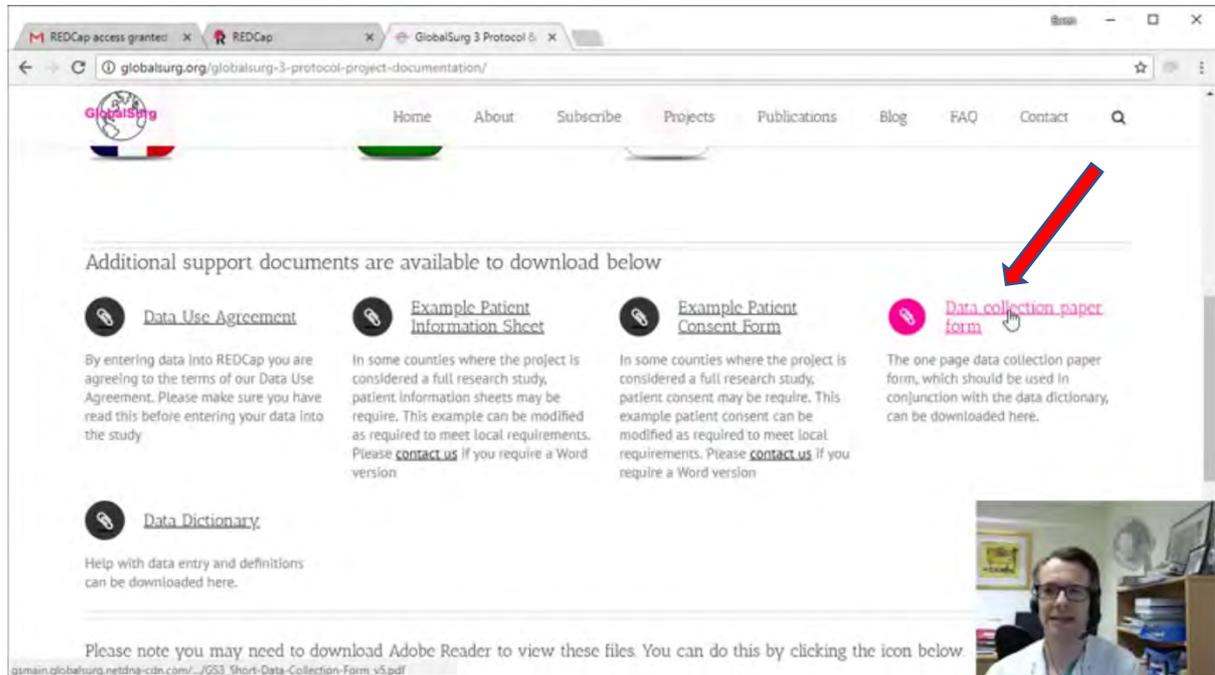
REDCap 8.2.2 - © 2018 Vanderbilt University



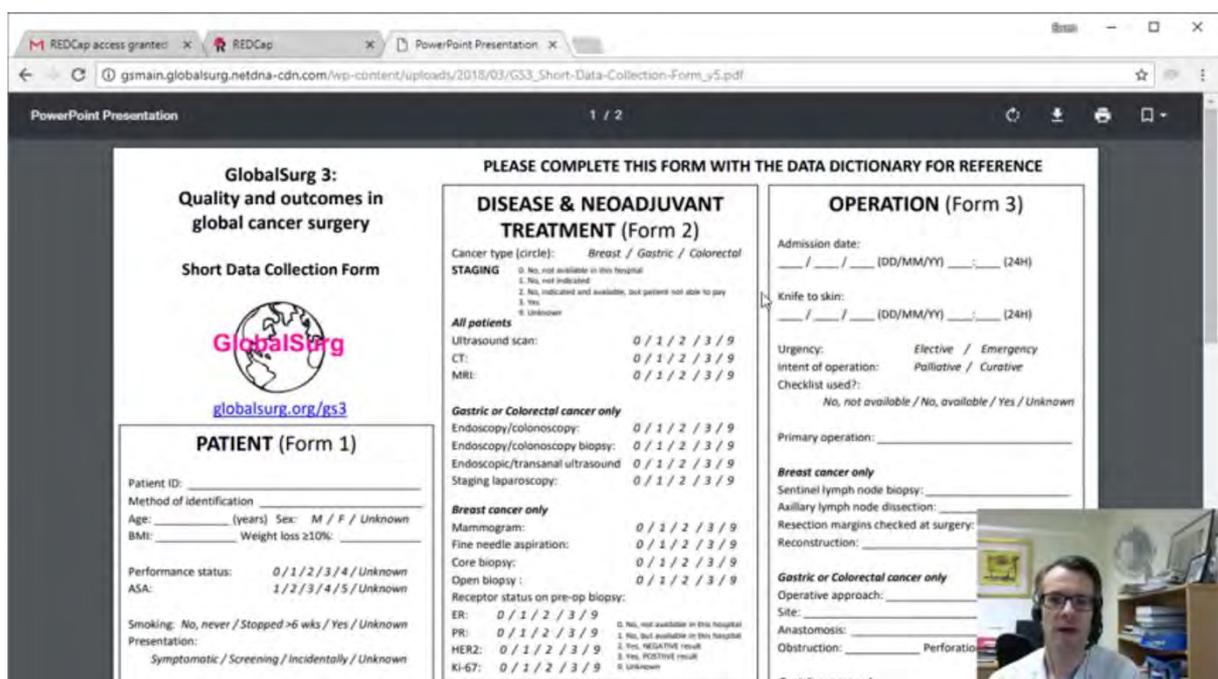
2. Before commencing data collection, please visit the “Protocol & Project Documentation Hub” on www.globalSurg.org



- This has the protocol in different languages, and the support documents – “Data Use Agreement”, “Example Patient Information Sheet”, “Example Patient Consent Form”, “Data Collection Paper Form” and the “Data Dictionary” further down the page. Click on the “Data collection paper form”, which is what we are particularly interested in:

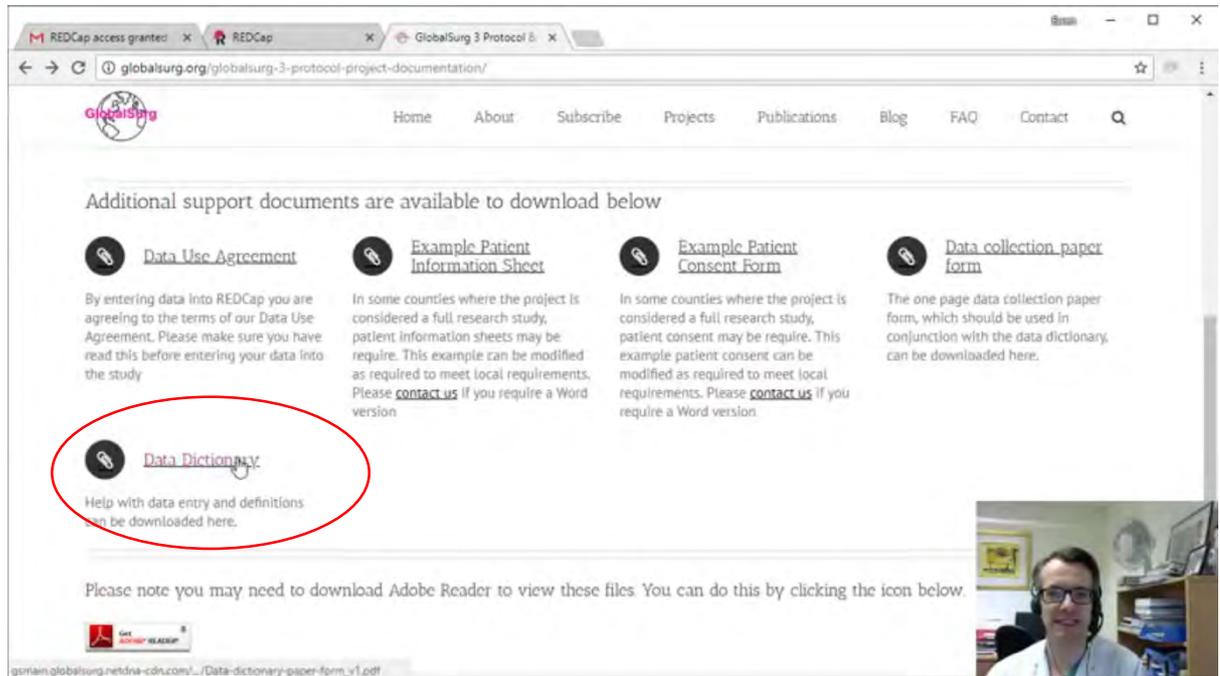


- Click on the “Data collection paper form” link, and this will open up the data collection paper form (pictured below). This is a two-sided form which you can use if you prefer to collect patient data on paper, before transferring to REDCap.

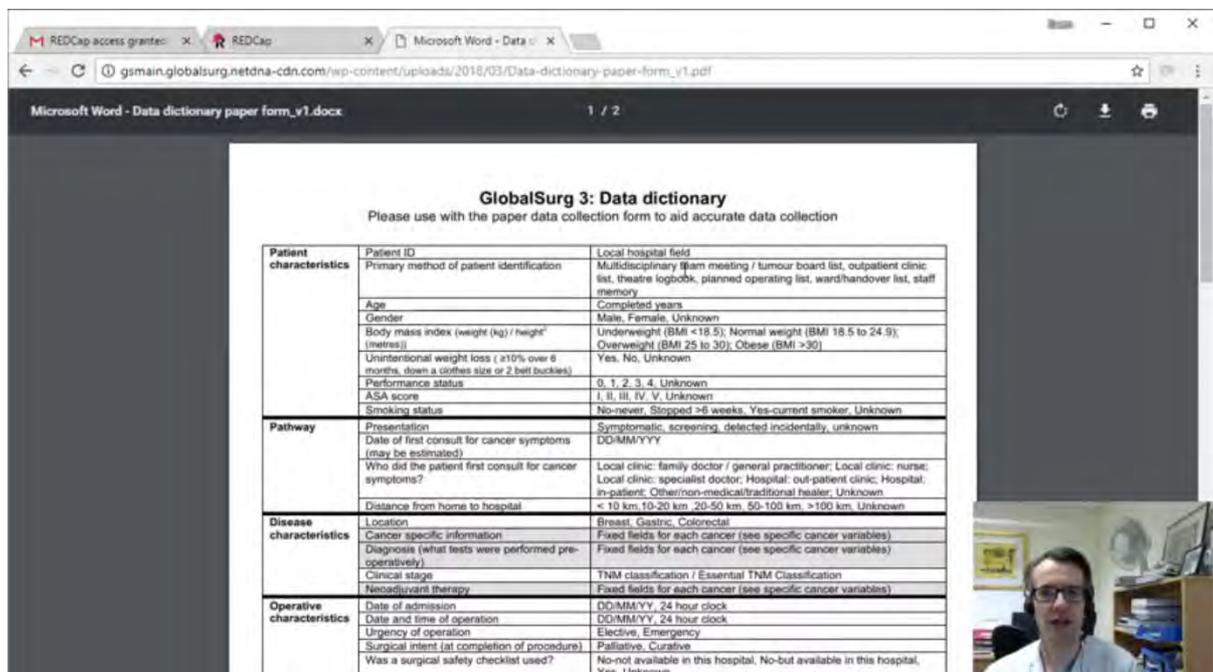


The screenshot shows a PowerPoint presentation of the 'Data Collection Paper Form'. The form is divided into three main sections: 'PATIENT (Form 1)', 'DISEASE & NEOADJUVANT TREATMENT (Form 2)', and 'OPERATION (Form 3)'. The 'PATIENT (Form 1)' section includes fields for Patient ID, Method of identification, Age, Sex, BMI, Weight loss, Performance status, ASA, Smoking, and Presentation. The 'DISEASE & NEOADJUVANT TREATMENT (Form 2)' section includes fields for Cancer type, STAGING, All patients (Ultrasound scan, CT, MRI), Gastric or Colorectal cancer only (Endoscopy/colonoscopy, Endoscopic/transanal ultrasound, Staging laparoscopy), Breast cancer only (Mammogram, Fine needle aspiration, Core biopsy, Open biopsy), and Receptor status on pre-op biopsy (ER, PR, HER2, Ki-67). The 'OPERATION (Form 3)' section includes fields for Admission date, Knife to skin, Urgency, Intent of operation, Checklist used, Primary operation, Breast cancer only (Sentinel lymph node biopsy, Axillary lymph node dissection, Resection margins checked at surgery, Reconstruction), Gastric or Colorectal cancer only (Operative approach, Site, Anastomosis, Obstruction), and Gastric cancer only.

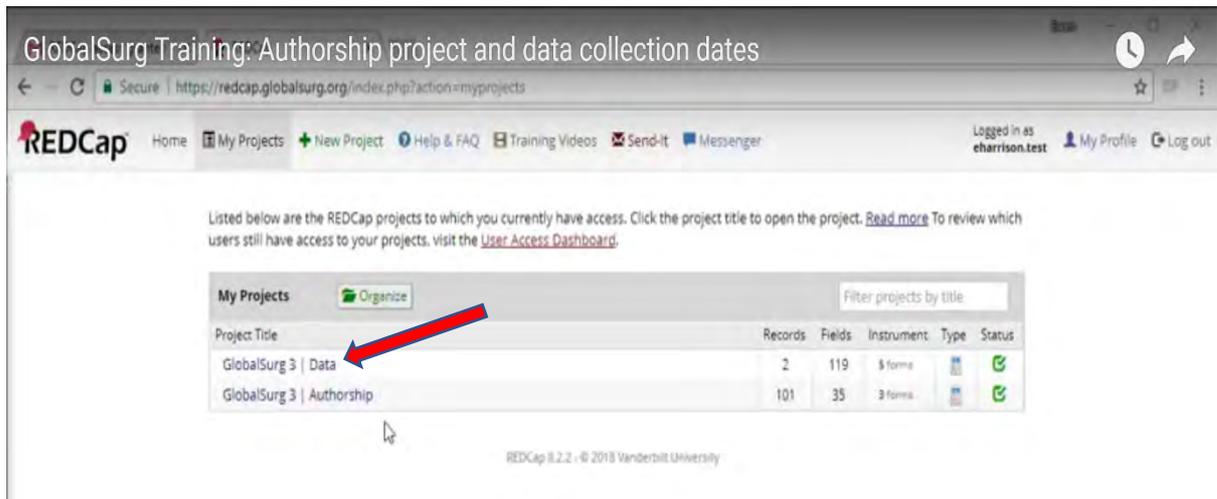
- The “Data collection paper form” should be used in combination with the “Data Dictionary”.



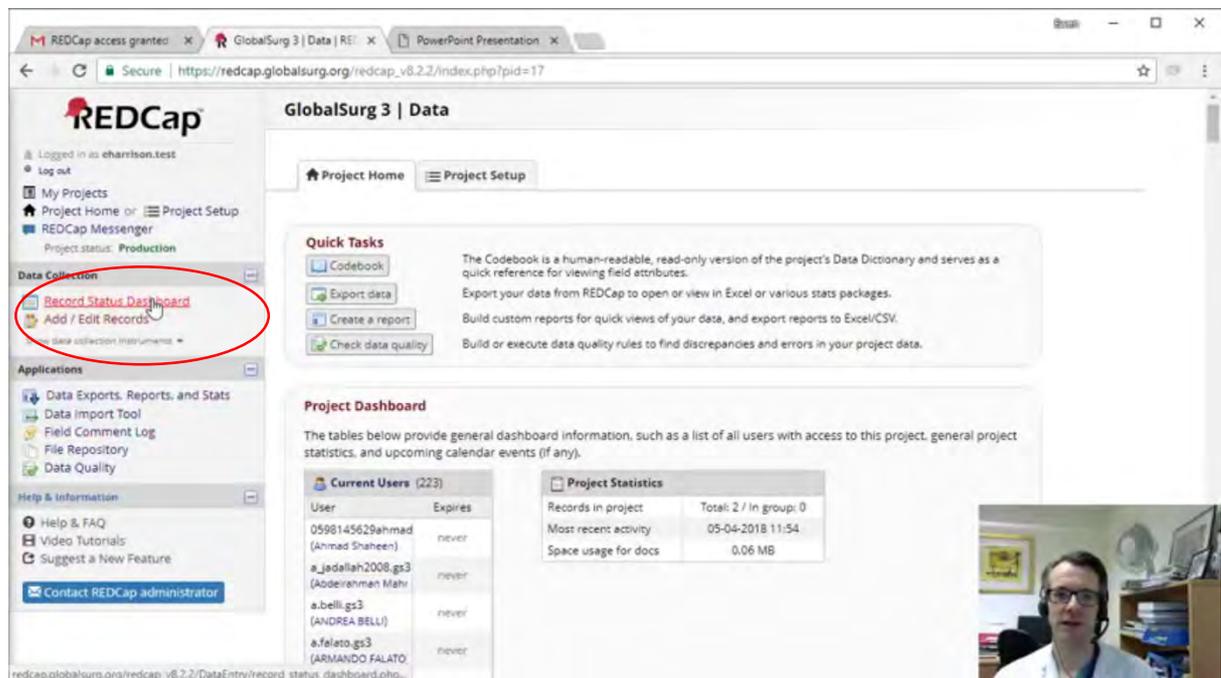
The Data Dictionary is a two-sided document that only needs to print out once. This provides a description of all the variables required. These two should be used in combination to ensure that the correct data is recorded.



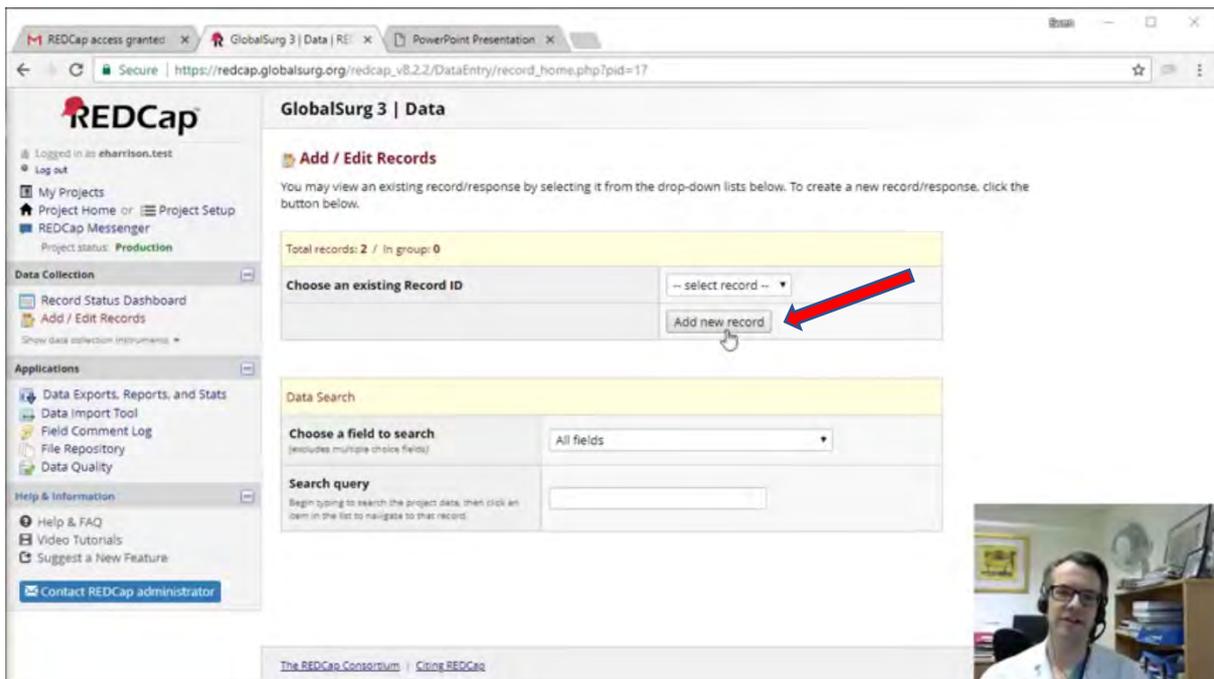
6. Go back to REDCap and click on the “Data” Project:



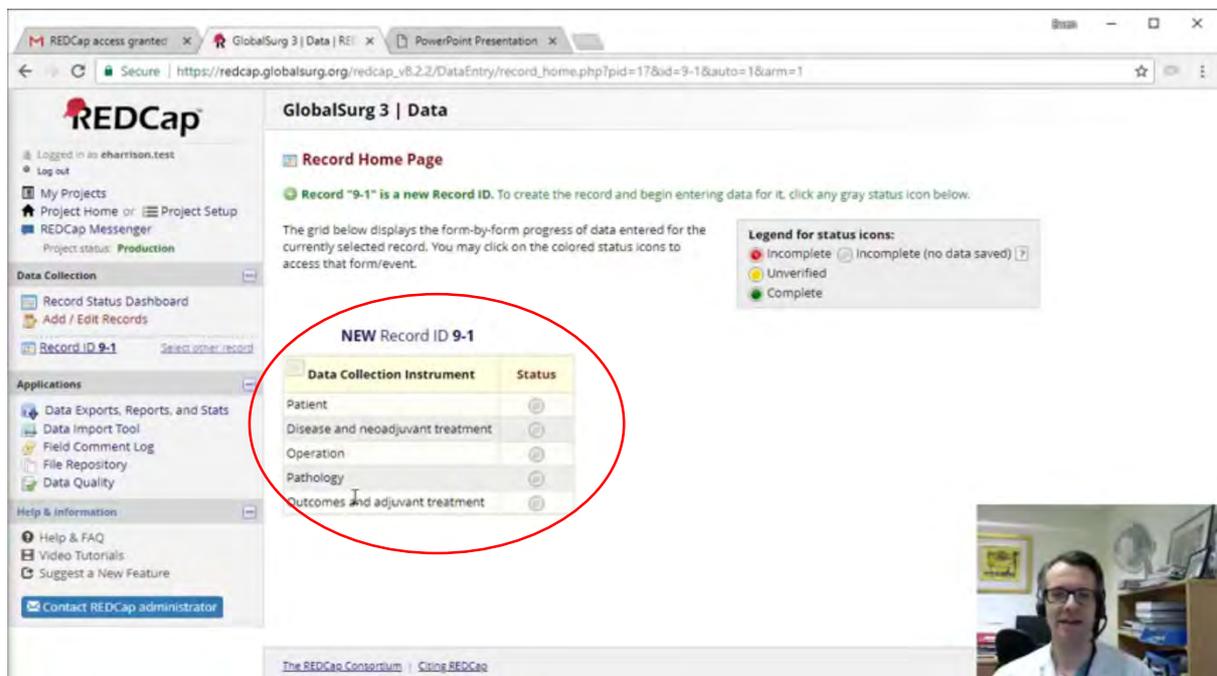
7. This will open the project Homepage, and the links required are on the left-hand side (circled in the picture below). If we click on the “Record Status Dashboard”, there will be no records there, because none have been collected yet.



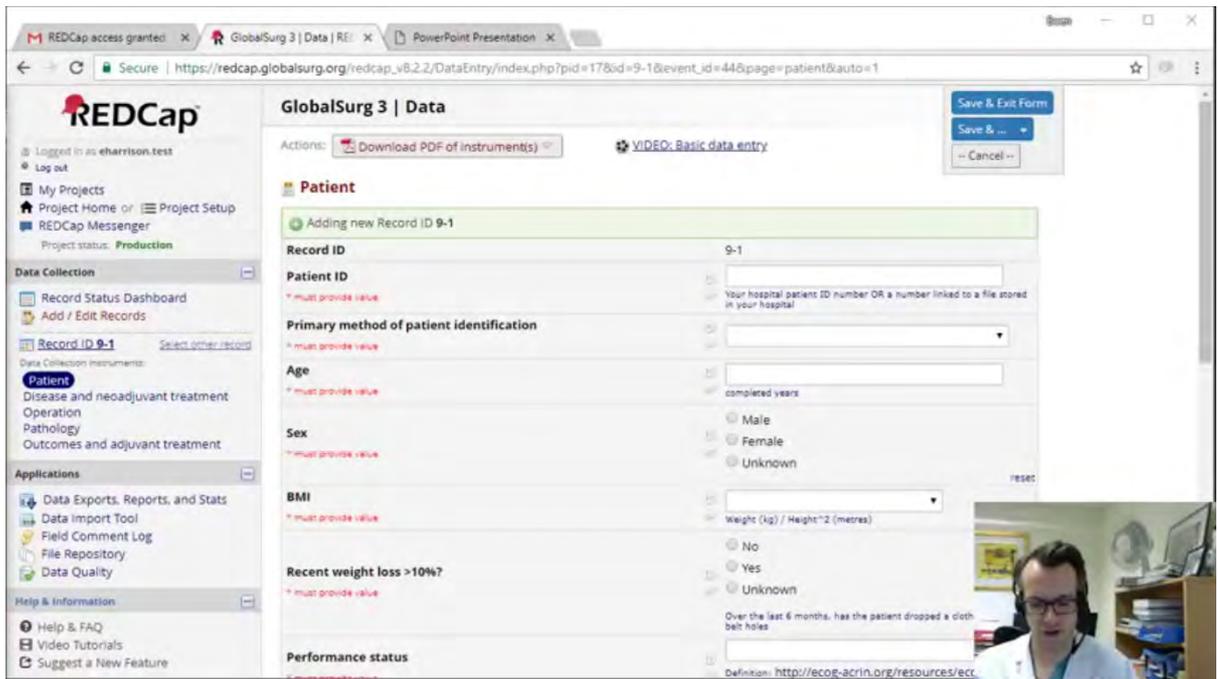
8. To add the first record, click “Add/Edit Records” (shown in the circle in the picture above). This opens the “Add/Edit records” page. To add the record, click on the “Add new record” button, shown in the next picture.



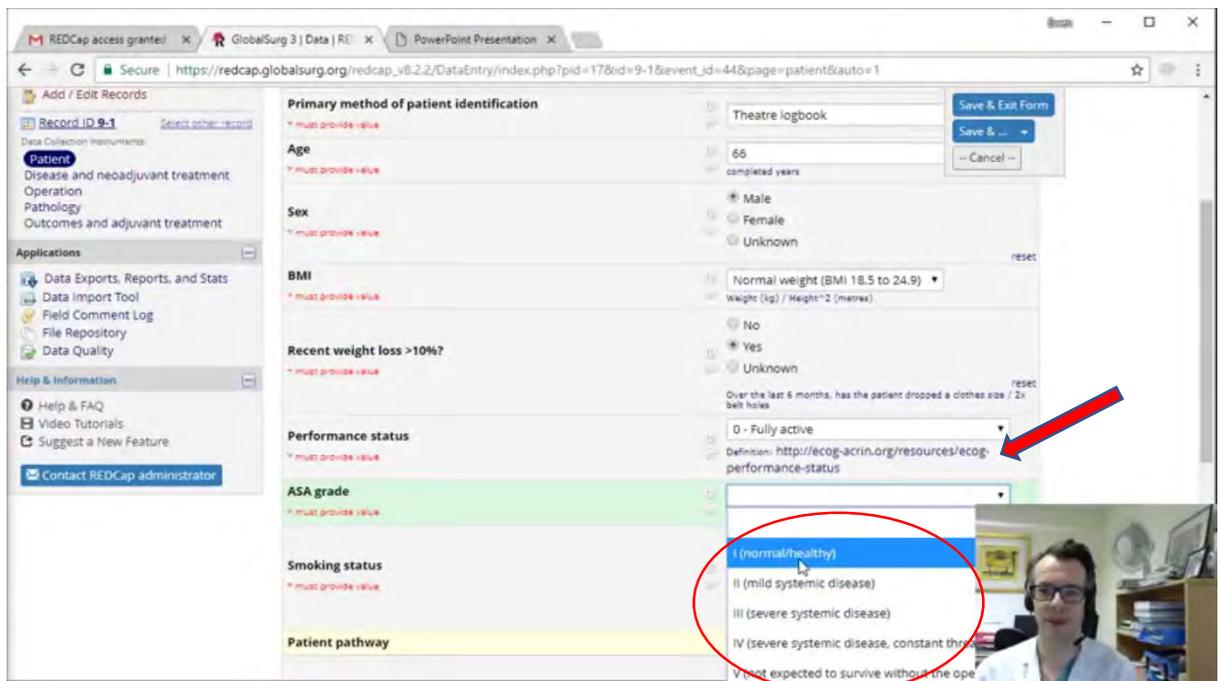
- This will open the “Record Home Page” shown below, which shows the five data collection instruments (Patient, Disease and Neoadjuvant treatment, Operation, Pathology and Outcomes and Adjuvant Treatment) that should be completed.



10. Click on the first one, “Patient” and enter the details from the paper data collection form in the fields.



The screenshot shows the REDCap interface for 'GlobalSurg 3 | Data'. The 'Patient' section is active, showing a form for adding a new record (ID 9-1). Fields include Record ID (9-1), Patient ID, Primary method of patient identification, Age, Sex (Male, Female, Unknown), BMI, Recent weight loss >10% (No, Yes, Unknown), and Performance status. A video call window is visible in the bottom right corner.

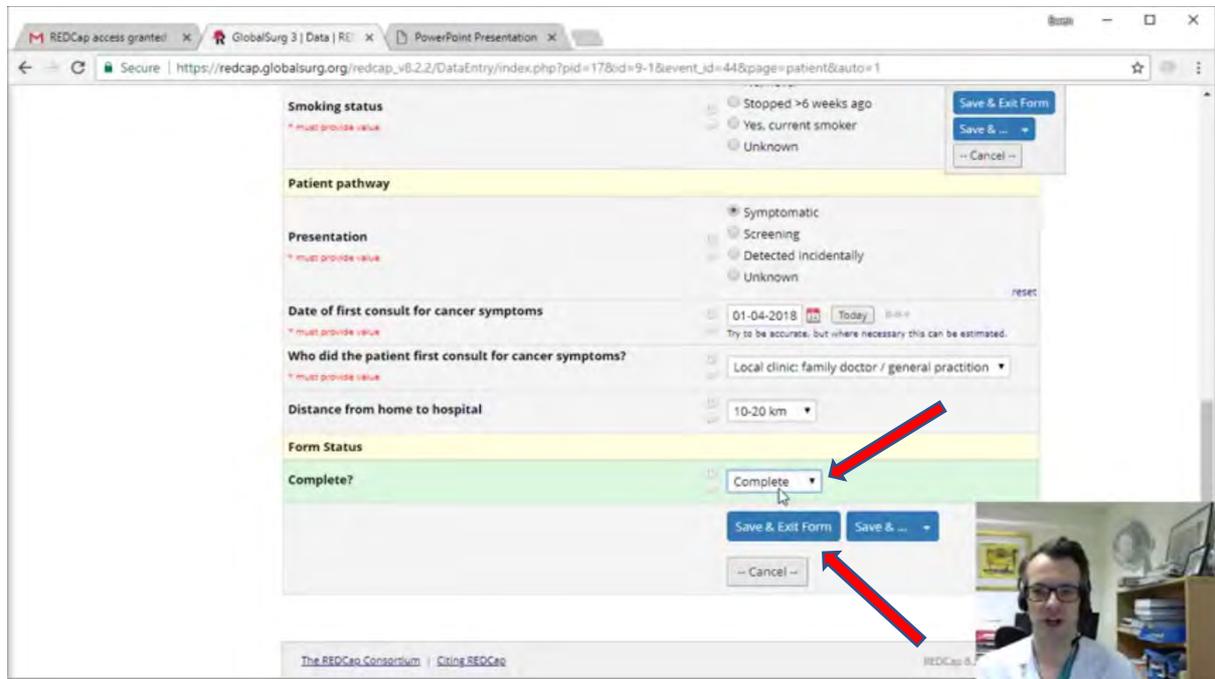


This screenshot shows the 'Performance status' dropdown menu expanded. The options are: I (normal/healthy), II (mild systemic disease), III (severe systemic disease), and IV (severe systemic disease, constant threat to life). A red arrow points to the definition link for Performance status: <http://ecog-acrin.org/resources/ecog-performance-status>.

- The “Performance status” is often used in cancer studies, and its definition can be found at the link under the option box, indicated by the arrow above.
- The American Society of Anaesthesiology (ASA) is used here, and patients should be identified on the scales from I-V, especially by the anaesthetists.

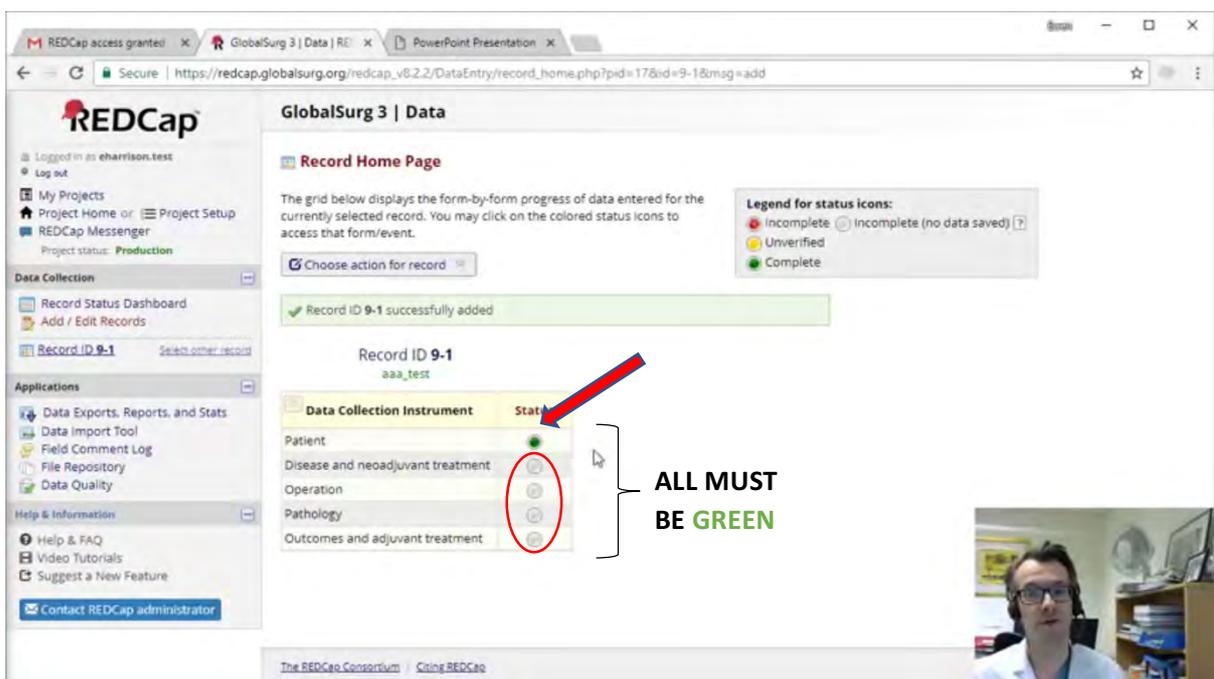
NOTE:- Please make efforts to provide data in all fields, and avoid selecting the ‘unknown’ option if at all possible.

11. Once all the data in that form is filled in, set the “Form Status” to “Complete”, and then click on “Save & Exit Form” to save data and exit the form.

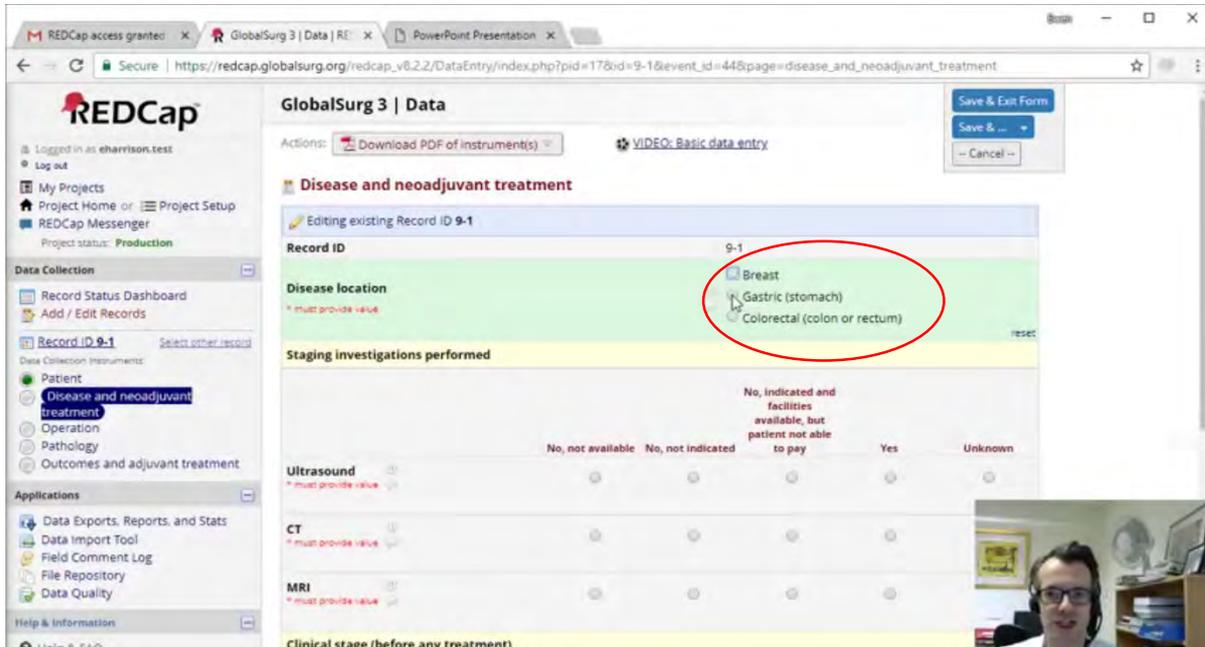


12. When the form closes, it will return to the “Record Home Page”, and you should see that the dot beside the “Patient” Data Collection Instrument has turned “Green”. It is imperative that for each of your patients, all five dots are green.

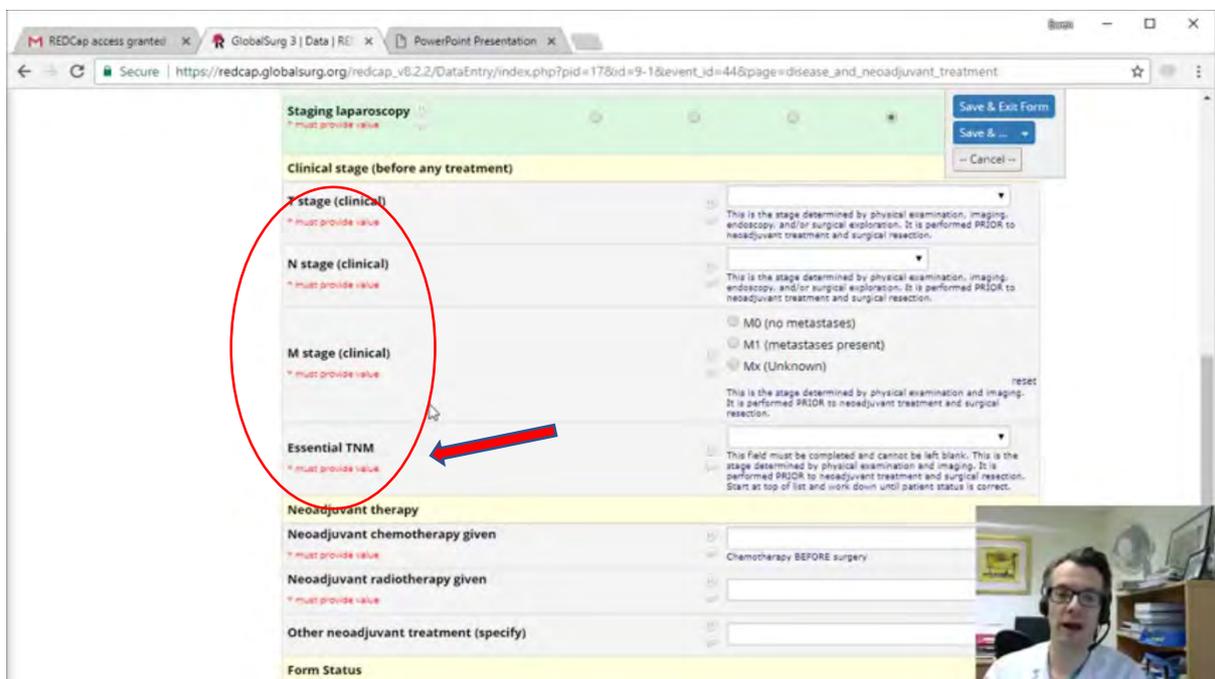
If the dots are not green, the patient is not included. If the patient is not included, then you run the risk of not fulfilling the requirements of the study, and this may affect your authorship.



13. Moving on to the next form, “Disease and neoadjuvant treatment”, you cannot fill in any of the other forms, unless you select which cancer the patient has – Gastric, Breast or Colorectal. This is because the rest of the questions depend on this choice.

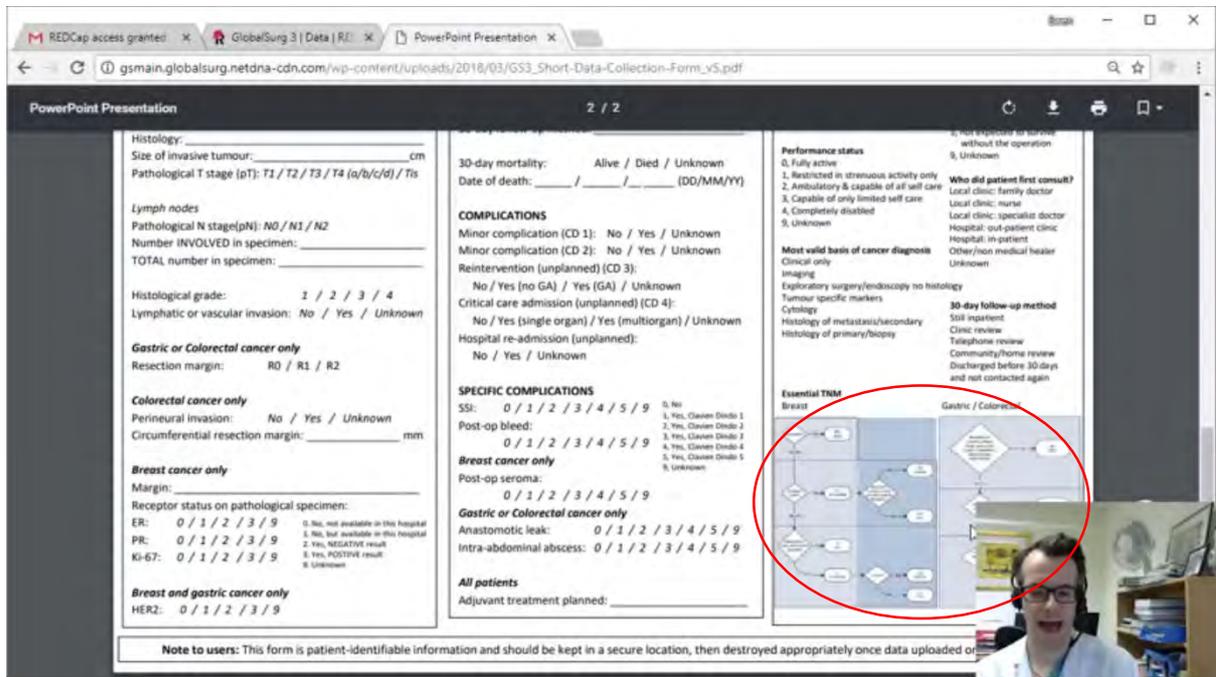


14. The clinical stage is the stage before any treatment is performed, and that includes neoadjuvant chemotherapy and other treatments. It is made up of T, N and M.



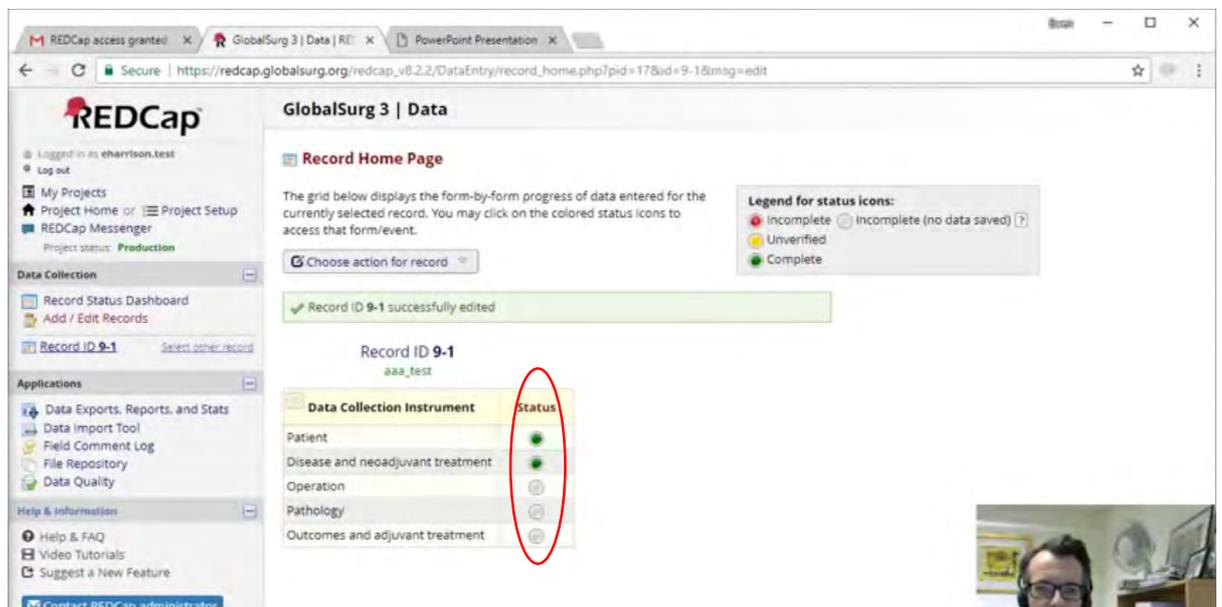
a. “Essential TNM is really important. Back on the paper “data collection form”, on the back, bottom right hand corner are the flow diagrams which explain

the Essential TNM. It is a way of determining stage without necessarily having all the details of a formal T,N and M.



The screenshot shows a REDCap form with multiple sections for data entry. A red circle highlights the 'Essential TNM' section, which contains a flowchart for determining cancer stage. The flowchart starts with 'Performance status' (0-5) and 'Who did patient first consult?' (Local clinic, Hospital, etc.). It branches based on 'Most valid basis of cancer diagnosis' (Clinical only, imaging, etc.) and '30-day follow-up method' (Still inpatient, Clinic review, etc.). The flowchart leads to 'Essential TNM' categories for Breast, Gastric/Colorectal, and All patients.

15. Once all the fields are completed, click on “complete” on the form, and then “Save and Exit”. You will be taken back to the “Record Home Page”, and will see a second “green” dot.



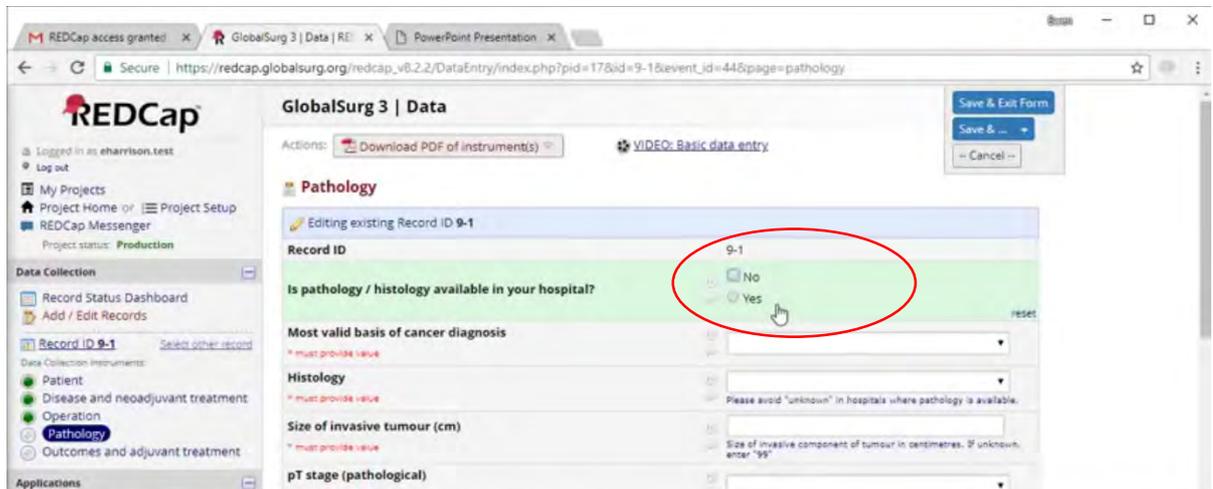
The screenshot shows the REDCap Record Home Page for record ID 9-1. A table displays the status of various data collection instruments. The 'Operation' instrument has a green dot, indicating it is complete. A red circle highlights the green dot for the 'Operation' instrument.

Data Collection Instrument	Status
Patient	Unverified
Disease and neoadjuvant treatment	Complete
Operation	Complete
Pathology	Unverified
Outcomes and adjuvant treatment	Unverified

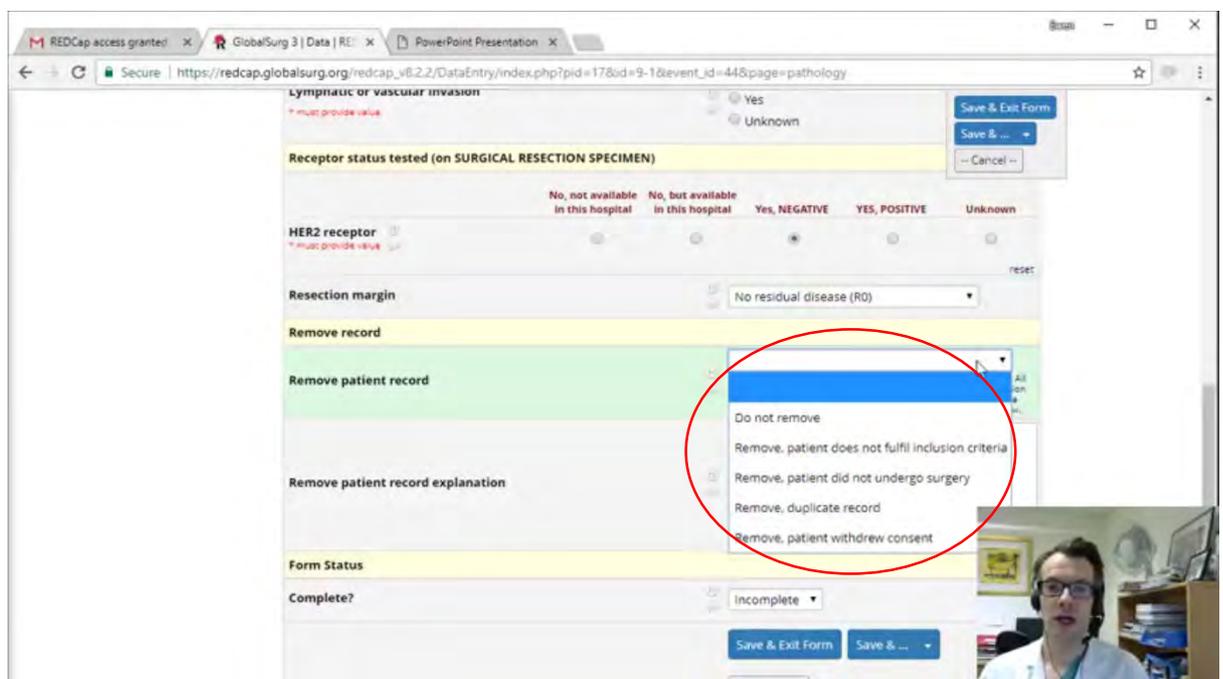
16. Complete the “Operation” form as well and set the form “complete”, and “Save & Exit”, for a third “green” dot.

17. For the next form, “Pathology”, you will normally get the details of the pathology from the pathology form issued from your pathology department. If you do not have

a pathology or histology department in your hospital, select “No” at the top of the form. For now, we will be grateful if you could go through the form and just answer the questions even if you do not have histology.

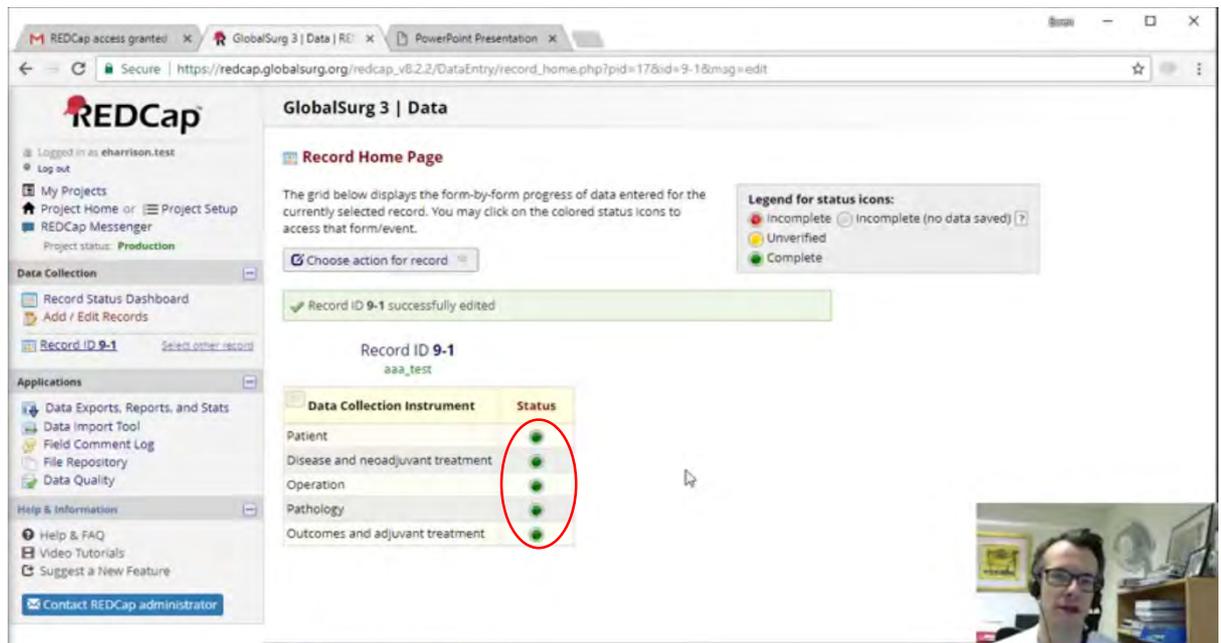


- Further down the “Pathology” form is the “Remove record” section. We have disabled the patient removal step for data governance purposes. If a patient had been entered in error, you can request at the bottom of this form for the records to be removed. This will be fully audited. You should select the reason why the patient is to be removed and include free text in the “Remove patient record explanation” box, explaining the reason.



- Set the form to “complete”, “Save & Exit” for the fourth “green” dot on the “Record home page”.

20. When you have filled in and set all form to “complete”, your “Record Home Page” for that patient should have all five “green dots”.



Where to Get Help

If you need help, there are several places to get it. For REDCap help, this can be found in the left-hand side menus (shown with the arrow in the picture below), if it is something that cannot be helped by that, then contact your fellow collaborators or hospital lead. If they do not know, then contact your national lead, and if they do not know, contact enquiry@globalsurg.org.

