

REDCap User Guide 5

Validation

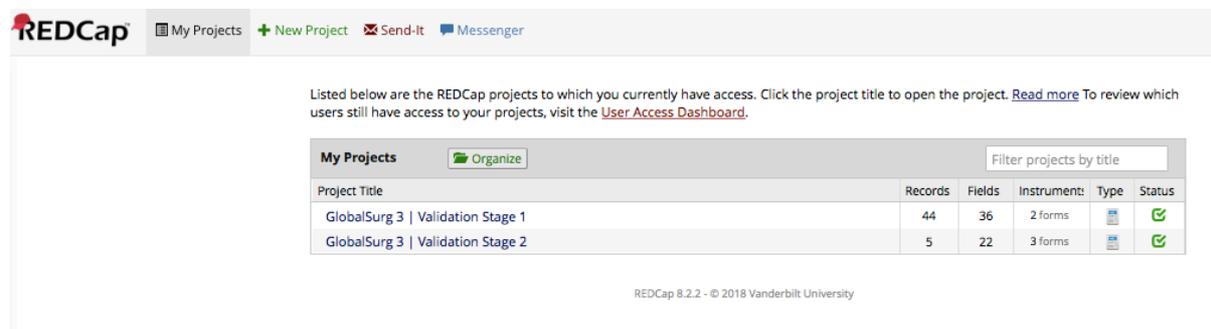


Validation Stage 1

Prerequisite: you must have [registered](#) to act as a data validator for GlobalSurg 3 and have been issued with a REDCap validators account for the study. This guide should be used in conjunction with the GlobalSurg 3 study protocol and validation guides which can accessed [here](#)

When you log into REDCap, you will see projects called 'Validation Stage 1' and 'Validation Stage 2' on the My Projects page.

Validation Stage 1 and *Validation Stage 2* contain the data collection forms to be completed. **Please note that both parts must be completed.**



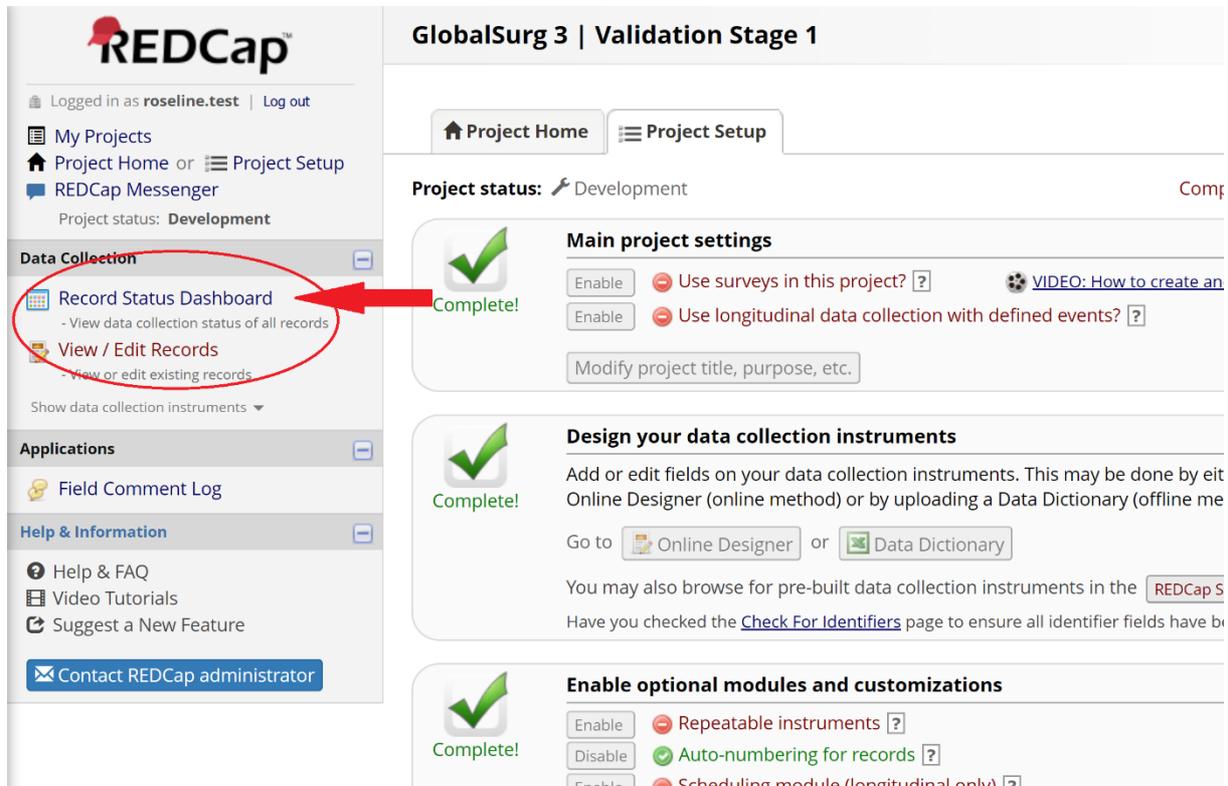
REDCap My Projects + New Project Send-It Messenger

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 Validation Stage 1	44	36	2 forms		
GlobalSurg 3 Validation Stage 2	5	22	3 forms		

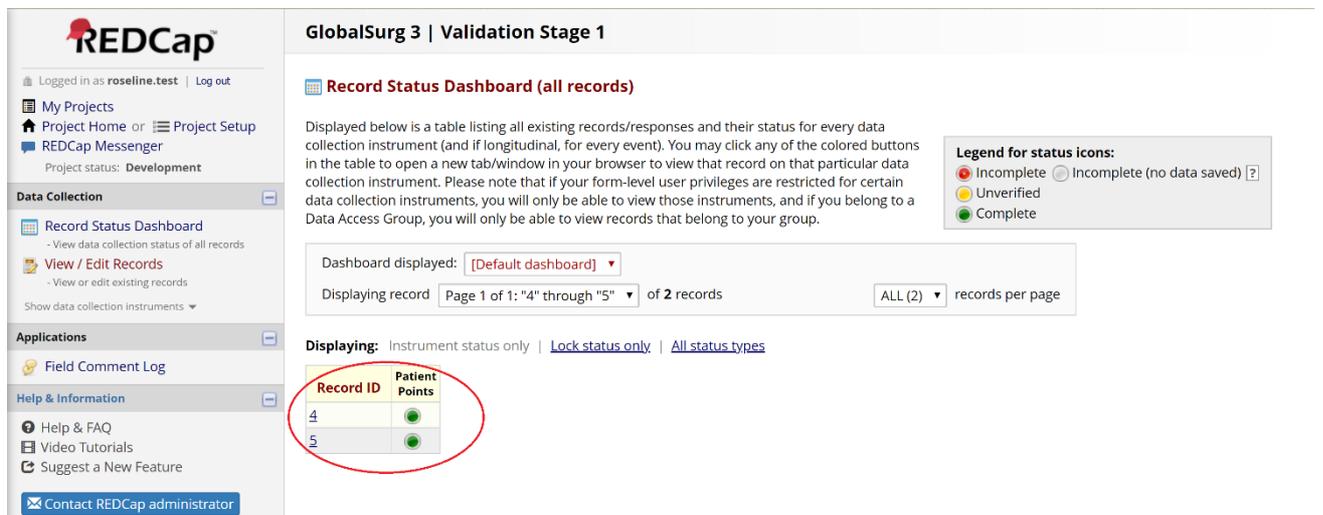
REDCap 8.2.2 - © 2018 Vanderbilt University

1. Select 'Validation Stage 1' and navigate to the Record Status Dashboard as shown



The screenshot shows the REDCap interface for 'GlobalSurg 3 | Validation Stage 1'. The left sidebar contains a 'Data Collection' section where 'Record Status Dashboard' is circled in red. A red arrow points from this menu item to the main content area. The main content area shows the 'Record Status Dashboard' with three sections: 'Main project settings', 'Design your data collection instruments', and 'Enable optional modules and customizations'. Each section has a green checkmark and the word 'Complete!'.

2. The patients to be validated will be displayed on the dashboard as shown below. To access each patient, click on the green dot beside the record ID. The example shown here has only 2 patients but the number will vary depending on each hospital.



The screenshot shows the 'Record Status Dashboard (all records)' in REDCap. It includes a legend for status icons: Incomplete (red dot), Incomplete (no data saved) (grey dot), Unverified (yellow dot), and Complete (green dot). Below the legend is a table with two columns: 'Record ID' and 'Patient Points'. The table contains two rows of data, both with green dots in the 'Patient Points' column. A red circle highlights the table.

Record ID	Patient Points
4	●
5	●

3. The primary data entered for the patient to be validated will be shown - it is greyed out as the primary data is read-only and cannot be modified. See the example on the next page.

Please find the corresponding patient in your hospital records system/theatre log books and compare the primary data shown with that in the hospital records.

Please then answer the questions on the form (example shown on the next page).

Please note: the available options will automatically update depending on your answers to the questions:

'Are you able to find this patient?'

'Do any of the provided data values appear incorrect?'

If you find some of the primary data does not match that of the hospital records, there will be an opportunity on the form to indicate this, and to enter the values you believe to be correct (as shown in the hospital records).

Example forms from REDCap are shown from the next page.

REDCap

GlobalSurg 3 | Validation Stage 1

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

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

Patient Points

Editing existing Record ID 4

Record ID 4

Identifying patients for validation

You will be validating patients at: Edinburgh Royal Infirmary
Your data collection period to validate starts on: 2018-09-02
Your data collection period to validate ends on: 2018-09-29

Below are a series of data values for your centre in the GlobalSurg 3 study. Please use these values to identify patients in your theatre logbooks, notes or similar hospital records.

If you do not believe one or more of the data values to be accurate, please use the option provided to give the correct value.

Hospital/ GlobalSurg Identifier

Age

Gender

Date admitted

Date of operation

Cancer type Breast
 Gastric (stomach)
 Colorectal (colon or rectum)

Primary operation

Are you able to find this patient? Yes
 No
* must provide value [reset](#)

Do any of the provided data values appear incorrect? Yes
 No
* must provide value [reset](#)

Validation variables

Please complete the following data values for the patient

Can you find whether the operation was performed as an elective or emergency procedure? Yes
 No
* must provide value [reset](#)

Can you find whether the operation is palliative or curative? Yes
 No
* must provide value [reset](#)

Can you find information on 30-day surgical re-intervention (Clavien-Dindo grade 3 or above)? Yes
 No
* must provide value [reset](#)

30-day surgical re-intervention required Yes
 No
* must provide value [reset](#)

Can you find information on 30-day mortality? Yes
 No
* must provide value [reset](#)

Can you find a post-operative pathology report for this patient? Yes
 No
 Pathology not available in this hospital
* must provide value [reset](#)

Can you find post-operative pathology information on T and N stage for this patient? Yes
 No
* must provide value [reset](#)

If you had any difficulties performing this task
comment here: Please state here if you think the cancer type is incorrect

Information relating to your hospital and the period to be validated will be shown here – this should help you identify patients in your hospital records

The primary data entered for the patient will be shown here – this cannot be modified

Please compare this information with that found in the hospital records for the patient

Please answer Yes or No to these questions. You must provide a value

The questions in this section will automatically update depending on your answers to the Yes/No questions above

This example shows the questions you will see if the patient can be found and the primary data is correct

REDCap
GlobalSurg 3 | Validation Stage 1

Logged in as **katie.test** | [Logout](#)

My Projects
Project Home or [Project Setup](#)
REDCap Messenger
Project status:
Development

Data Collection

Record Status Dashboard
- View data collection status of all records

View / Edit Records
- View or edit existing records

Record ID 5
Select other record
Data Collection Instruments:
Patient Points

Applications
Field Comment Log

Help & Information
Help & FAQ
Video Tutorials
Suggest a New Feature

Contact REDCap administrators

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

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

Patient Points

[Editing existing Record ID 5](#)

Record ID 5

Identifying patients for validation

You will be validating patients at: Edinburgh Royal Infirmary
Your data collection period to validate starts on: 2018-09-02
Your data collection period to validate ends on: 2018-09-29

Below are a series of data values for your centre in the GlobalSurg 3 study. Please use these values to identify patients in your theatre logbooks, notes or similar hospital records.

If you do not believe one or more of the data values to be accurate, please use the option provided to give the correct value.

Hospital/ GlobalSurg Identifier

Age

Gender

Date admitted

Date of operation

Cancer type
 Breast
 Gastric (stomach)
 Colorectal (colon or rectum)

Primary operation

Are you able to find this patient? Yes
 No
* must provide value [reset](#)

Do any of the provided data values appear incorrect? Yes
 No
* must provide value [reset](#)

Which data values appear incorrect? (select all that apply)
* must provide value

Age
 Gender
 Date admitted
 Date of operation
 Primary operation
Select all that apply

What do you think is the correct value?

Corrected age (in completed years)
* must provide value

Corrected gender
* must provide value Male
 Female [reset](#)

If the primary data appears incorrect compared to the hospital records, select Yes here

A menu will appear to allow you to indicate which data is incorrect

For each data variable you indicate is incorrect, a new field will automatically appear to allow you to enter the values you believe to be correct (those shown in the hospital records). In this example, the fields for 'corrected age' and 'corrected gender' are shown because 'age' and 'gender' were selected as the data values that are incorrect

- Once you have answered all the questions on the form, set the it to 'Complete', click 'Save and Exit' and return to the Records Status Dashboard to repeat for **each patient** to be validated at your hospital

Set the form to complete, Save & Exit

This concludes **Validation Stage 1**.

Please now return to the My Projects tab and select **Validation Stage 2**

Validation Stage 2

During data collection for GlobalSurg 3, the primary data collection team should have entered **every eligible patient** during the 4-week data collection period.

If during the validation process, you identify any patients that should have been included but have been missed by the primary data collection team, this should be indicated in the 'Validation Stage 2' project. Please note: Validation stage 2 should be completed even if no missing patients are identified.

- From the My Projects tab select 'Validation stage 2' and navigate to the 'Records Status Dashboard'

Information on the name of your hospital is shown here

2. Click on the grey dot under the 'Missing patients' heading

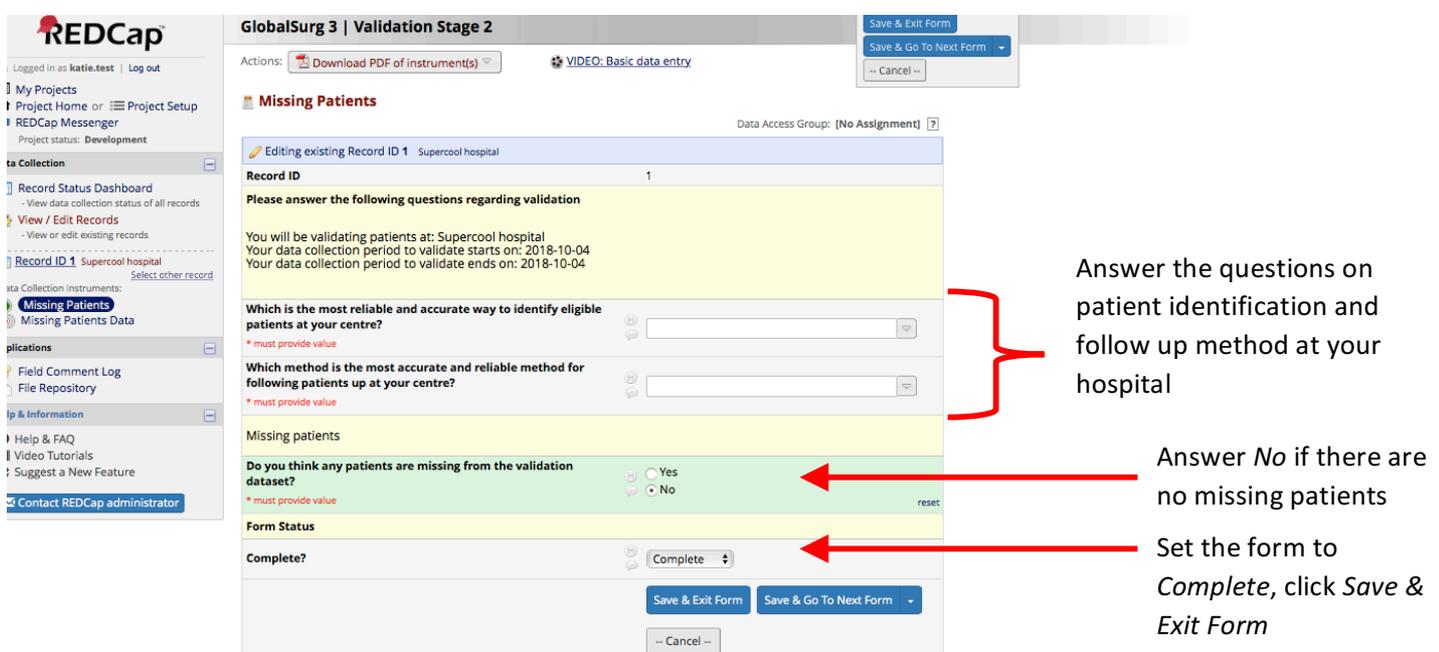
2.1 If no missing patients are identified

If all the eligible patients during the 4-week data collection period at your hospital have been identified and entered by the primary data collection team, please complete the sections related to the methods of patient identification and follow-up at your hospital.

Answer 'No' to the question 'Do you think any patients are missing from the validation dataset?'

Set the form to *Complete*, click *Save & Exit form*.

The validation process is now complete



Answer the questions on patient identification and follow up method at your hospital

Answer *No* if there are no missing patients

Set the form to *Complete*, click *Save & Exit Form*

2.2 If you identify missing patients

If you find patients in the hospital records that are not in the primary data you have been sent to validate, but that you believe should be included in the study, please answer 'Yes' to the question 'Do you think any patients are missing from the validation dataset?' and enter the number of missed patients in the box below.

Set the form to *Complete*, then click *Save & Go to Next Form*

The next form to open will give you the opportunity to enter the details of the missing patient.

Enter the patient details and then set the form to *Complete*.

If there is only 1 missing patient, or you are entering the final missing patient click *Save & Exit form*. If you need to add further missing patient(s), click *Save and Go To Next Instance*. Repeat this until you have entered a form for each missing patient

GlobalSurg 3 | Validation Stage 2

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

Missing Patients Data

Current instance: 1 -- 56, Female, Gastric (stomach), Emergency, Dead, Yes Data Access Group: [No Assignment]

Editing existing Record ID 1 Supercool hospital

Record ID 1

Leave this part of the form blank if there are no missing patients

Please provide the following information for each patient you believe are missing from the validation cohort

Enter information on each missing patient in turn using the "SAVE AND ADD A NEW INSTANCE" button at the bottom of this page until all patients are entered

Age (in completed years)
* must provide value

Gender
* must provide value Male Female [reset](#)

Cancer type
* must provide value

Urgency of the operation
* must provide value Elective Emergency [reset](#)

30-day mortality
* must provide value Alive Dead [reset](#)

Are there more missing patient values to add?
* must provide value Yes No [reset](#)
If yes, please add this patient by selecting the "SAVE AND ADD NEW INSTANCE" at the button of this page

Form Status

Complete?

[Save & Exit Form](#) [Save & Go To Next Form](#)

[-- Cancel --](#)

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

Enter the details of the missing patient

Click *Save & Go To Next Instance* if you need to add another missing patient

You can also add missing patients directly from the Records Status Dashboard by clicking on the '+' symbol or the '+ Add new' button as indicated below

GlobalSurg 3 | Validation Stage 2

Record Home Page

The grid below displays the form-by-form progress of data entered for the currently selected record. You may click on the colored status icons to access that form/event.

Choose action for record ▾

Record ID 1 Supercool hospital

Data Collection Instrument	Status
Missing Patients	
Missing Patients Data	 +
Admin	

Repeating Instruments

Missing Patients Data

1	 56, Female, Gastric (stomach), Emergency, Dead, Yes
2	 78, Male, Colorectal (colon or rectum), Emergency, Alive, No
3	 56, Male, Breast, Elective, Dead, Yes

+ Add new

Once you have added all the missing the patients, the validation exercise at your hospital is complete.

If you have any questions or need any help, please contact
enquiry@globalsurg.org

Thank you for taking part in the GlobalSurg 3 Validation Exercise!