



GLOBALSURG 3 VALIDATION USER GUIDE

A multicentre evaluation of research processes to validate a worldwide study

Validation for GlobalSurg 3 will provide important information on data collection and confidence intervals during result analysis. This information is essential to demonstrate the dataset is of high quality and therefore enable publication of the study in a high-impact medical journal.

The purpose of the validation exercise is to **observe** the primary dataset only. The original data will **not** be corrected, updated or modified in any way.

The validation exercise will not be used to exclude any collaborators or centres that have entered complete patient datasets from the study or any subsequent publications. Its purpose is to quantify the inherent uncertainty in data collection, not to exclude collaborators or remove data.

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Introduction

GlobalSurg 3 is a multicentre international study determining quality and outcomes in global cancer surgery for breast, gastric and colorectal cancer. Any hospital performing surgery for breast, gastric, or colorectal cancer anywhere in the world is eligible to take part. Across centres worldwide, mini-teams of up to 3 collaborators will collect data for a four-week period between April and October 2018, with a 30 day follow up.

Validating data is important in ensuring that the results obtained for the study are of high quality. The aim is to achieve this by assessing the methods used for patient identification, data collection and patient follow up. The process itself will involve three parts:

- A. Patient identification and follow up
- B. Independent Validation
- C. National Lead and Hub Country Interviews

Timeline:

Month	Study Period	Part A	Part B	Part C	
April					
May					
June					
July					
August					
September					
October					
November					
December					
January					
February					

April - November 2018

Patient identification and follow-up information will be completed by each mini-team in the form of questions built into the data collection form

Validator Registration begins September 18th 2018

National Leads, assisted by Hospital Leads where relevant, will help to recruit Independent Validators (one per centre). Data collection periods will be confirmed with local collaborators via the Data Completion form in the REDCap Authorship project prior to validation. Validator recruitment and registration progress can be viewed at <https://argoshare.is.ed.ac.uk/validation/> for each centre.

October 2018 - February 2019

Once the mini-team has completed the final data sign-off, Independent Validators will verify total number of eligible cases and data quality for one randomly selected 4-week data collection period.

November 2018 - February 2019

GlobalSurg 3 Steering Committee to conduct National Lead and Hub country interviews exploring data collection and validation in resource-limited settings via Skype or Telephone

Part A: Patient identification and follow-up information (completed by primary data collection mini-team)

During data collection, mini-teams will have already entered into REDCap the methods used to identify and perform 30-day follow-up for each patient. This will provide initial information to inform the data validation process.

Part B: Independent Validators

One Independent Validator at each participating centre will be recruited. The Validator should:

- 1) Be a senior medical student or doctor
- 2) Be independent of the mini-team collecting data
- 3) Have access to logbooks from all eligible theatres (or whichever form of patient identification is used at the centre)
- 4) Read the GlobalSurg 3 study protocol and complete associated training modules

Validation process

Each participating centre requires a single validator. Collaborators can check whether a validator is registered at their hospital via this link:

<https://argoshare.is.ed.ac.uk/validation/>

Once a Validator has been identified, they will be asked to register on REDCap.

Following Validator registration, a data collection period for the centre will be selected at random by the GlobalSurg committee.

The Validator will then be issued with a REDCap account which will give them access to selected patient variables at their centre over the specified data collection period. They will not have access to *all* the patient data entered by the data collection mini-team at their centre.

Validators will have 30 days to complete patient validation on REDCap. All patients entered during the 4-week data collection period will be validated, but this does not include all variables, only a subset:

Validation: Stage 1

Below are selected data values from your centre in the GlobalSurg 3 study. Please use these values to identify each patient in your theatre logbook, notes or similar hospital records.

Specified data values (basic patient dataset)

Hospital / GlobalSurg identifier

Age

Gender

Date admitted

Date of primary operation

Cancer type

Primary operation

Questions on basic patient dataset

Are you able to find this patient? (Yes/No)

Are any of the data values incorrect? (Yes/No)

For those that are incorrect, please provide what you believe to be the correct value

Validation points

For this section please refer to your centre's records using the information above to identify the patient. Please fill out each field below with the details you believe are correct.

Can you find if the operation was performed as an elective or emergency procedure?

(Yes/No)

Urgency of operation (*Elective/Emergency*)

Can find whether the operation is palliative or curative? (Yes/No)

Type of operation (*Palliative/Curative*)

Can you find information on 30-day surgical re-intervention (Clavien-Dindo grade 3 or above)? (Yes/No)

30-day surgical re-intervention required (Yes/No)

Can you find information on 30-day mortality? (Yes/No)

30-day mortality (*Alive/Dead*)

Can you find a post-operative pathology report for this patient?

(Yes/No/*Pathology not available in this hospital*)

Can you find information on post-operative T and N stage for this patient?

(Yes/No)

Please select the post-operative T and N stage



Did you come across any difficulties performing this task? (*free text*)

Validation: Stage 2

How many patients do you think are missing? (*provide number; state zero if you are satisfied no cases are missing*)

Please provide the following information for each missing patient:

Age

Sex

Cancer type (*Breast/Gastric/Colorectal*)

Emergency/elective operation

30-day mortality (*Alive/Dead/Unknown*)

This will be piloted in one centre before wider dissemination

Part C: National lead and Hub Country Interviews

The GlobalSurg 3 Steering Committee will conduct National Lead and Hub country interviews exploring the barriers and facilitators to data collection and validation in resource-limited settings via Skype or Telephone.